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Pesticide residues in food

**Joint FAO/WHO Meeting
on Pesticide Residues**



Pesticide Residues in Food 2022

Joint FAO/WHO Meeting on Pesticide Residues

Sponsored jointly by FAO and WHO Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group, Rome, Italy 13 to 22 September 2022

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R, residue and analytical aspects; T, toxicological evaluation

* New compound

** Evaluated within the periodic review programme of the Codex Committee on Pesticide Residues

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**2022 Joint FAO/WHO Meeting on Pesticide Residues
13–22 September 2022 (FAO pre-meeting 8–12 Sep)
Rome, Italy**

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Abbreviations

AChE	acetylcholinesterase
AD	administered dose
ADI	acceptable daily intake
ADME	absorption, distribution, metabolism, excretion
AGF	aspirated grain fractions
ALP	alkaline phosphatase
ALT	alanine transaminase
AR	administered radioactivity
ARfD	acute reference dose
as	as received
AST	aspartate transaminase
AUC, AUC _{0-∞}	area under the concentration–time curve
BBCH	Biologische Bundesanstalt, Bundessortenamt und Chemische Industrie
BMD	benchmark dose
bw	body weight
CAC	Codex Alimentarius Commission
CAR/PXR	constitutive androstane receptor/pregnane X receptor
CAS	Chemical Abstracts Service
CCPR	Codex Committee on Pesticide Residues
cGAP	critical GAP
ChE	cholinesterase
C _{max}	maximum concentration
DAA	days after application
DAFT	days after first treatment
DALA	days after last application
DAT	days after treatment
DM	dry matter
DNA	deoxyribonucleic acid
DT ₅₀	time required for 50 % dissipation of the initial concentration
dw	dry weight
EFSA	European Food Safety Authority
eq	equivalent(s)

ESI	electrospray ionization
FAO	Food and Agriculture Organization of the United Nations
GABA _A	γ-aminobutyric acid, type A
GAP	good agricultural practice
GC-ECD	gas chromatography–electron capture detector
GC-MS	gas chromatography–mass spectrometry
GC-NPD	nitrogen-phosphorus detectors
GD	gestation day
GECDE	global estimate of chronic dietary exposure
GEMS	Global Environment Monitoring System–Food Contamination Monitoring and Assessment Programme
GGTP	γ-glutamyl transpeptidase/transferase
GI	gastrointestinal tract
GLP	good laboratory practice
HBGV	health-based guidance values
Hb	haemoglobin
HCB	hexchlorobenzene
HPLC	high performance liquid chromatography
HPRT	hypoxanthine–guanine phosphoribosyl transferase
HR	highest residue level in the edible portion of a commodity
HR-P	highest residue level in a processed commodity
Ht	haematocrit
IC ₅₀	half-maximal inhibitory concentration
IEDI	International Estimated Daily Intake
ILV	independent laboratory validation
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JECFA	Joint FAO/WHO Expert Committee on Food Additives
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LC ₅₀	median lethal concentration
LC-MS/MS	liquid chromatography-tandem mass spectrometry
LD ₅₀	median lethal dose
LLNA	local lymph node assay
LOAEL	lowest-observed-adverse-effect level

LOD	limit of detection
LOQ	limit of quantification
LP	large portion
mADI	microbiological ADI
mARfD	microbiological ARfD
MOA	mode of action
MRL	maximum residue limit
NIS	sodium/iodide symporter
NOAEC	no-observed-adverse-effect concentration
NOAEL	no-observed-adverse-effect level
NTE	neuropathy target esterase
OECD	Organisation for Economic Co-operation and Development
PBI	plant-back interval
PF	processing factor
PHI	pre-harvest interval
PND	postnatal day
Po	post-harvest
POD	point of departure
ppm	parts per million
PXR	pregnane X receptor
QuEChERS	quick, easy, cheap, effective, rugged and safe
QSAR	quantitative structure–activity relationship
RAC	raw agricultural commodity
RBC	red blood cell
RSD	relative standard deviation
RTI	re-treatment interval
SC	suspension concentrate
SCE	sister chromatid exchange
SD	standard deviation
SDHI	succinate dehydrogenase inhibitor
SPE	solid phase extraction
STMR	supervised trials median residue
STMR-P	supervised trials median residue in a processed commodity
$T_{1/2}$	half-life

T3	triiodothyronine
T4	thyroxine
THF	tetrahydrofuran
TLC	thin layer chromatography
T _{max}	time to reach maximum concentration
TPO	thyroid peroxidase
TRR	total radioactive residues
TSH	thyroid stimulating hormone
TTC	threshold of toxicological concern
UDP-GT	uridine diphosphate glucuronosyltransferase
US	United States of America
v/v	volume for volume
WHO	World Health Organization
w/v	weight for volume
w/w	weight for weight

Use of JMPR reports and evaluations by registration authorities

Most of the summaries and evaluations contained in this report are based on unpublished proprietary data provided for use by JMPR in making its assessments. A registration authority should not grant a registration on the basis of an evaluation unless it has first received authorization for such use from the owner of the data provided for the JMPR review or has received the data on which the summaries are based, either from the owner of the data or from a second party that has obtained permission from the owner of the data for this purpose.

1. Introduction

A Joint Meeting of the Food and Agriculture Organization of the United Nations (FAO) Panel of Experts on Pesticide Residues in Food and the Environment and the World Health Organization (WHO) Core Assessment Group on Pesticide Residues (JMPR) was held at FAO Head-quarters, Rome (Italy), from 13 to 22 September 2022. FAO Panel Members met in preparatory sessions from 8 to 12 September.

The Meeting was opened by Dr Jingyuan Xia, Director, Plant Production and Protection Division (NSP), FAO. On behalf of FAO and WHO, Dr Xia welcomed and thanked the participants for providing their expertise and for devoting significant time and effort to the work of the JMPR, noting that this was the first physical JMPR meeting since 2019 due to the impact of the COVID-19 pandemic, with 45 participants from 15 countries.

Dr Xia highlighted food safety is fundamental to healthy and sustainable food systems. The establishment of pesticide residue standards is a key and critical element in the global effort to improve food safety and agricultural development in the world. The unique role of the JMPRs work in establishing internationally acceptable MRLs for pesticide residues in food and feed which acted as global benchmarks in trade facilitation, as well as providing authoritative assessments, important in consumer protection. Dr Xia then outlined how the JMPRs efforts aligned with the Divisions strategic objectives of ensuring food security and nutrition; enhancing food quality and safety; supporting farmers' livelihoods; protecting the environment and biodiversity; and facilitating safe trade and economic growth. As the establishment of global standards were a key and critical element in the global efforts to improve food safety and agricultural development in the world.

Dr Xia also took the opportunity to express his and called on the meeting participants to express their appreciation to Madam YongZhen Yang, retiring FAO JMPR Secretariat, for her dedicated commitment and outstanding contribution in fulfilling the secretariat role over the past 16 years.

Dr Soren Madsen, WHO JMPR Secretariat, took the opportunity to thank the FAO for giving priority to JMPR to allow the meeting to occur at FAO headquarters.

During the meeting, the FAO Panel of Experts was responsible for reviewing residue and analytical aspects of the pesticides under consideration, including data on their metabolism, fate in the environment and use patterns, and for estimating the maximum levels of residues that might occur as a result of use of the pesticides according to good agricultural practice (GAP). Maximum residue levels and supervised trials median residue (STMR) values were estimated for commodities of animal origin. The WHO Core Assessment Group was responsible for reviewing toxicological and related data in order to establish acceptable daily intakes (ADIs) and acute reference doses (ARfDs), where necessary.

The Meeting evaluated 34 pesticides, including seven new compounds and four compounds that were re-evaluated within the periodic review programme of the CCPR, for toxicity or residues, or both.

The Meeting established ADIs and ARfDs, estimated maximum residue levels and recommended them for use by CCPR, and estimated STMR and highest residue (HR) levels as a basis for estimating dietary intake.

The Meeting also estimated the dietary exposures (both short-term and long-term) of the pesticides reviewed and, on this basis, performed a dietary risk assessment in relation to the relevant ADI and where necessary ARfD. Cases in which ADIs or ARfDs may be exceeded were clearly indicated in order to facilitate the decision-making process by CCPR.

The Meeting considered a number of current issues related to the risk assessment of chemicals, the evaluation of pesticide residues and the procedures used to recommend maximum residue levels.

2. General consideration items

2.1 Requirements for data on the impact of residues on the human intestinal microbiome

For almost 20 years the Joint FAO/WHO Expert Committee on Food Additives (JECFA) has been assessing residues of veterinary drugs for their possible impact on the human microbiome, specifically for two end-points of concern: disruption of the bacterial colonization barrier and increase in bacterial resistance. To facilitate these assessments, guidance from International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products, VICH GL36(R), was adopted by the sixty-sixth meeting of the JECFA Committee, for food-producing animal drugs. Essentially VICH GL36(R) comprises a stepwise approach to determine if a microbiological acceptable daily intake (mADI) would be necessary, based on an evaluation of whether product residues reaching the human colon are microbiologically active. It entails answering three questions to determine the need for establishing a mADI. First, determine if the product residues, and/or its metabolites, are microbiologically active against representatives of the human intestinal microbiota. Second, determine whether the product residues enter the human colon. Third, examine whether the residues entering the human colon remain microbiologically active. If the answer to any of these questions is “no”, then there is no need to calculate a mADI, and the assessment does not need to be completed. However, if a mADI needs to be calculated, the two end-points of concern for human health must be considered. The guidance also discusses test systems to address these toxicological end-points of concern, taking into consideration the complexity of the human intestinal microbiome. More recently, JECFA has adapted this approach to assess the acute effects of veterinary drug residues to establish a mARfD, as necessary.

Whilst the initial focus of JECFA was on antibiotics, it is now recognized that other drugs can have detrimental effects regarding these end-points of concern, and the Committee now systematically assesses the possible need for a mADI and mARfD for all drugs. Over the last decade evidence has accumulated that a wide range of compounds can affect the human microbiome, including pesticides. Hence, JMPR needs to consider how it will address this concern. A good starting point would be VICH GL36(R), and its provisions may well be sufficient for this purpose.

At present, the assessment considers only bacteria, yet the intestinal microbiome also includes, fungi, archaea, protozoa, and viruses, all of which play an important role in human health. Thus, consideration needs to be given to whether, and if so how, the impact of residues on some/all of the other components of the human intestinal microbiome should be addressed, particularly in the case of fungicides. Also, consideration should be given to extending the assessment of possible impact of residues on the human microbiome to beyond the two existing end-points of concern discussed above.

The Meeting recommended that the joint secretariat convene a microbiome expert working group to consider the above points with a view to developing draft guidance for discussion and eventual adoption by JMPR.

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2.2 ***Non-linear kinetics (KMD)***

Following the recommendation of JMPR 2019 and 2021, the electronic working group on the assessment and interpretation of non-linear dispositional kinetics was established. The purpose of the electronic working group was to develop guidance on the assessment and interpretation of non-linear dispositional kinetics. The electronic working group is proposing to focus on five key areas:

- a) kinetic non-linearity associated with systemic absorption;
- b) kinetic non-linearity associated with distribution to a keystone target organ (tissue or cell);
- c) kinetic non-linearity associated with elimination;
- d) kinetic non-linearity associated with metabolism to the keystone ultimate toxicant(s);
- e) guidance on the extrapolation of non-linear kinetic findings in animals to human health risk assessment in the JMPR context.

Development of the guidance would be enhanced by the consideration of relevant case studies. Therefore JMPR invites industry and others to submit for consideration, draft case studies (with their supporting data) in the five areas of focus.

2.3 ***Interpretation and follow-up of positive results in in-vitro gene mutation assays***

Information on genotoxicity is a key component in hazard/risk assessment of all chemical agents used for anthropic use, including pesticides. Many regulatory agencies and advisory bodies have made recommendations on strategies for genotoxicity testing and assessment (for example EFSA, 2011; WHO, 2020). The majority of testing strategies recommend the use of a basic test battery comprising two or more in vitro tests to cover the three main mutagenicity end-points: gene mutation, clastogenicity (structural chromosome aberrations) and aneugenicity (changes in the number of chromosomes). In addition they recommend an in vivo test as a follow-up to assess whether any genotoxic potential observed in vitro is expressed in vivo. The choice of an in vivo study is not established by default but rather should reflect the positive end-point observed in vitro.

In the case of follow-up for positive in vitro gene mutation tests either in bacteria and/or mammalian cells (HPRT, XPRT and *tk* loci) the most appropriate in vivo assays would be the in vivo transgenic rodent somatic and germ cell gene mutation assays (for example the Muta™ mouse or Big Blue® mouse and rat assays), as the intent is to determine whether the findings of in vitro gene mutation is replicated by in vivo gene mutation (that is, whether they are biologically relevant to the in vitro results). The in vivo alkaline comet assay could be an acceptable alternative to confirm positive in vitro gene mutation results in general. Although it does not directly detect gene mutations the in vivo alkaline comet assay is sensitive to DNA lesions that may ultimately result in gene mutation. However, for bacterial gene mutation caused by non-DNA reactive gene mutagens (for instance intercalating agents likely to be detected only by tester strains such as TA 1537 used in the Ames test) the in vivo alkaline comet assay is not appropriate and the transgenic rodent somatic and germ cell gene mutation assays are the recommended test.

In the case of a positive in vitro chromosomal aberration assay or in vitro micronucleus assay the recommended follow-up is the in vivo micronucleus assay.

In the absence of such follow-up information it is not possible to discount the relevance of the positive in vitro results.

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2.4 A risk-based decision tree approach for the safety evaluation of residues of pesticides, veterinary drugs, food additives and contaminants

The Joint FAO/WHO Meeting on Pesticide Residues (JMPR) and Joint FAO/WHO Expert Committee on Food additives (JECFA) are sometimes variously asked for advice on substances for which the establishment of health-based guidance values (HBGVs) and/or recommendation of maximum residue limits (MRLs) is not appropriate, for example when there is an incomplete data package. Such substances may be legacy compounds for which there is still a niche use, compounds with no commercial sponsor but supported by a member state, compounds with no authorized use but which cause contamination of food because of environmental persistence, or the misuse or abuse of authorized compounds. Occasionally, the conclusion may be that a substance is a genotoxic carcinogen. Some of these considerations are more relevant to some committees than to others. In the absence of HBGVs and/or MRLs, approaches are needed to enable the committees to give meaningful advice to risk managers on such compounds. JECFA has developed such approaches for contaminants, but for authorized substances there is no agreed solution.

In the early 2000s, a number of activities were undertaken to discuss possible approaches to these situations with regard to veterinary drugs, including a Joint FAO/WHO "Technical workshop on residues of veterinary drugs without ADI/MRL", convened in Bangkok in 2004, and an FAO/RIVM/WHO workshop: "Updating the principles and methods of risk assessment: maximum residue levels (MRLs) for pesticides and veterinary drugs", held in Bilthoven, The Netherlands in 2005. Subsequently this led to the publication of EHC 240, *Principles and methods for the risk assessment of chemicals in food*, in 2009. The Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF) considered a report of a working group on residues of veterinary drugs without ADI/MRL at their Sixteenth Session, in Cancun, Mexico, 2006.

This issue was raised at the Sixty-sixth JECFA meeting (2006), together with a number of related activities. The Committee concluded that there was need for an overarching approach, and recommended that the JECFA Secretariat convene a working group to develop a decision-tree for the evaluation of veterinary drugs. This led to the development of a decision tree approach for the safety evaluation of residues of veterinary drugs, which was discussed at the seventieth meeting of JECFA (2008). The scheme was endorsed by the Committee and a number of revisions suggested. The scheme was revised accordingly and provided under the title "A risk-based decision tree approach for the safety evaluation of veterinary drugs" to CCRVDF for its Eighteenth Session (2009), as a work-in-progress. CCRVDF agreed with the proposed general principles and supported further work on the approach.

The scheme was discussed at the Seventy-fifth meeting of JECFA (2011) and a number of follow-up actions recommended. However, these were not taken up immediately, due to resource limitations. The Seventy-eighth meeting of JECFA (2013) reiterated the recommendations, which included the establishment of an e-Working group to develop guidance for establishing ARfDs for residues of veterinary drugs. This was done, and such guidance has been developed and adopted by JECFA. Since then, approaches for the establishment of a microbiological ARfD have been developed and guidance adopted by JECFA.

A number of other recommendations to further develop the decision tree were made by the Seventy-fifth meeting of JECFA (2013), which included undertaking work on preliminary risk assessment, and on the feasibility of using a threshold of toxicological concern (TTC) approach for residues of veterinary drugs. These were not followed up. A number of sections in the draft document note that extensive further work was required. These included characterization of exposure and management of risk. Since then, much work has been undertaken on exposure assessment, but consideration has yet to be given to how this might be integrated into the decision tree. Guidance on some parts of the scheme was developed, but has yet to be adopted by JECFA, such as on the identification of strengths and weaknesses in the risk assessment (uncertainties and sensitivity analysis).

The 2022 meeting of JECFA discussed the decision tree and concluded that there was a continuing need for such an approach. It was agreed that the approach should be finalized and published as guidance for JECFA. There was a need to develop some aspects further, for instance to include some additional aspects and there may be others that can be omitted. The Committee noted that the scheme was essentially generic and should be applicable to additional committees that provide advice to the Codex Alimentarius on food safety, such as JMPR. Thus JECFA recommended that the joint secretariat, together with other secretariats as appropriate, convene an electronic working group comprising experts from the three committees under JECFA, JMPR, and in exposure assessment, to further develop the decision-tree approach, with a view to its finalization in 2023 or 2024.

The present JMPR discussed the decision tree and agreed that in principle it would be of value to their work. It would provide an opportunity to integrate issues, such as the microbiological assessment of pesticide residues and less-than-lifetime exposure, into the work of JMPR. The Meeting endorsed the recommendation that a cross-committee electronic working group be convened, to further develop the decision-tree approach with a view to generalizing this to the work of JECFA and JMPR.

A diagrammatic outline of the current decision tree approach is shown below.

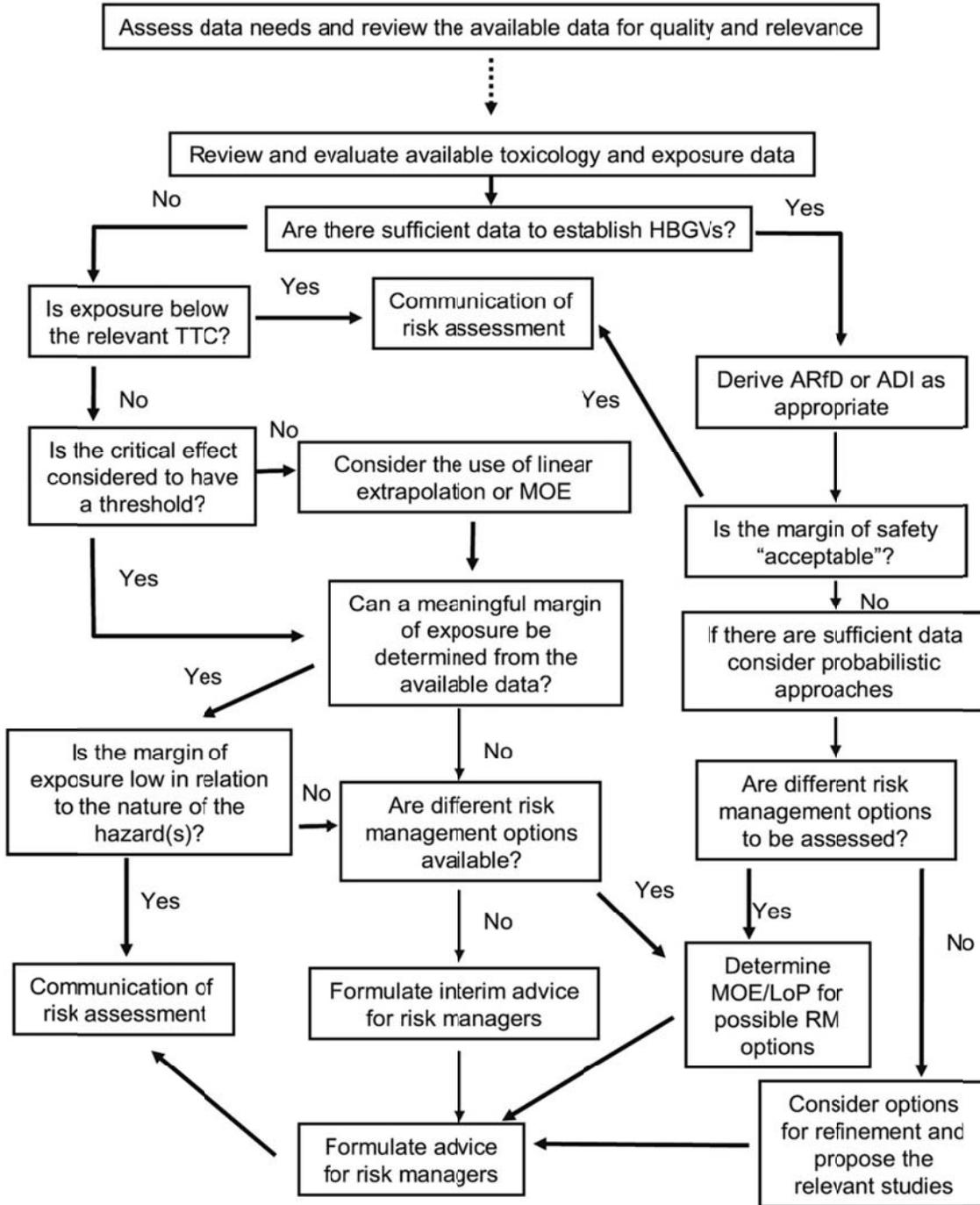


Figure 2.4.1 Decision tree approach in the risk assessment of residues of veterinary drugs

2.5 Unnecessary use of in vitro animal studies

The Meeting noted that a number of the submissions it received had included in vivo studies, which were either duplicates of existing studies or were addressing end-points where validated in vitro alternatives were available.

The Meeting believes that in the interests of animal welfare:

- sponsors should not duplicate existing in vivo studies;
- where validated non-animal alternative tests exist, these should be utilized;
- if using alternative testing strategies, where OECD (or equivalent) guidance exists this should be followed.

If an in vivo study which is covered by the above descriptions identifies adverse effects it should be provided to JMPR for consideration.

2.6 Establishment of MRLs for pesticides for okra

The current Meeting received request by Fifty-second Session of the CCPR regarding the establishment of MRLs for pesticides for okra. Specifically, advice on the following three option was sought in combination with the submission of monitoring data on chilli pepper and okra, as well as supervised field trial data on these crops. The following options were outlined in the CCPR Report 52 (158):

Option 1: Include a footnote to the current Subgroup 12B reading: Only data from chili pepper can be used to set a CXL; or

Option 2: Create a separate Subgroup 12D Okra with chili pepper as the representative commodity;

Option 3: Create a separate Subgroup 12D Okra (including martynia and roselle) with okra as the representative commodity.

In context of the options, the Meeting first considered the data provided and added new information to its database used in 2018, following the methodology described in the respective JMPR Report.

Monitoring data on chilli peppers and okra

The Meeting received monitoring data from the European Union, India (based on data from 2012-2019; additional data from 2017-2021 was only provided as summary information) and Singapore on okra in combination with data from chilli pepper from Singapore. A simple analysis on the data was conducted, showing that the Overall data populations (based on all quantified results without stratification according to the different analytes or years of sampling) were significantly different ($p < 0.05$). For monitoring data from Singapore, which was the only source of data both on chilli peppers and okra, weak statistical similarity was observed ($p = 0.064$), but no similarity was identified between chilli pepper data from Singapore and okra data from India or the European Union.

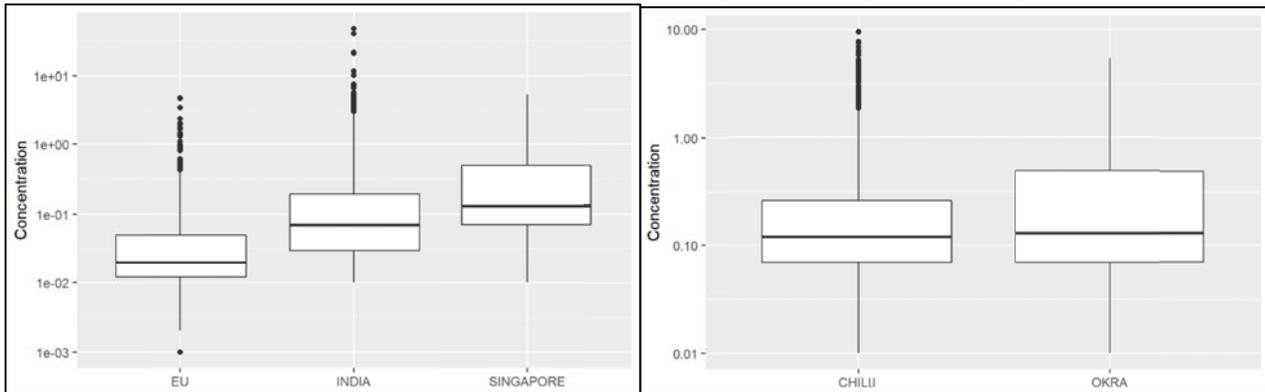


Figure 2.6.1 Comparison of residues (mg/kg) in okra from different regions

Figure 2.6.2 Comparison of residues (mg/kg) in chili pepper and okra from Singapore

The Meeting noted that the use of monitoring data is of very limited use to draw conclusions regarding similarity of residues in crops for extrapolation of maximum residue levels. The underlying treatment regimes and GAP conditions are unknown and it remains open if similarities in the data are indeed based on comparable use pattern/residue concentration relationships or coincidence following application of different amounts of pesticide in the field. In addition, monitoring data address the residue population for products on the market. Quality control systems often involve mechanisms to ensure national/supranational MRL compliance of consignments before marketing by analysis of residues. Since local MRLs for okra have normally been established in CODEX Member countries based on their national regulatory practices (e.g. by extrapolation, being member in a commodity group or default MRL systems), the underlying residue distribution described by monitoring data is expected to be truncated at established MRL levels compared to unbiased data from supervised field trials.

In summary, the Meeting concluded that monitoring data does not give sufficient information on the underlying relationship between application of a pesticide and the resulting residue levels to support extrapolation of MRLs. In addition, comparison of datasets, especially regarding upper limit residue concentrations relevant for MRL setting, is flawed. Identification of representative commodities for group recommendations should be based on supervised field trials, ideally conducted under side-by-side conditions to minimise variability in the data.

Field trial data on pepper (bell, chilli) and okra

The Meeting received field trial information from Thailand on the use of pesticides on Bell pepper, chilli peppers and/or okra. In addition, Crop Life International sent summarized residue data on okra from India involving treatment with cypermethrin in the 1979–1981. Further field trial data were provided by IAEA involving application of two compounds to one plot in Uganda.

A study conducted in Australia with supervised field trial results for Bell-peppers (“Capsicum”), chili peppers and okra treated according to the same use pattern (3 × 0.028 kg alpha-cypermethrin/ha, 7 day RTI, sampling: -1, 0, 1 and 3 or 4 days) was also made available to the Meeting. In some trials, double rate (2×) applications were applied in parallel plots. Residues found are shown below.

Table 2.6.1 Alpha-cypermethrin residues found following three applications to peppers, chili peppers and okra (Trial S16-07411-07)

Crop, Trial ID	Residues in mg/kg			
	-1 DAT	0 DAT	1 DAT	3 or 4 DAT
Bell pepper	< 0.01 (0.005)	0.011	0.025	0.011
Bell pepper	0.11	0.12	0.098	0.094
Bell pepper 2x rate	0.094	0.25	0.17	0.21
Chili pepper	0.014	0.057	0.05	0.036
Chili pepper 2x rate	0.056	0.21	0.1	0.056
Chili pepper	0.033	0.045	0.034	0.025
Bell pepper	0.098	0.21	0.18	0.087
Bell pepper, 2x rate	0.22	0.61	0.56	0.29
Okra,	0.012	0.011	0.011	< 0.01 (0.009)

The Meeting noted that only one trial was conducted on okra, not allowing robust comparison of potential residues to chilli pepper, but is added to the database of information previously reported by the JMPR, according the procedure described in the 2018 JMPR Report.

From Thailand, a use pattern in okra (undefined number of sprayings, undefined intervals, 0.084 kg ai/ha per application, PHI: 5 days) and supervised field trials for cypermethrin were provided (4 × 0.084 kg ai/ha, 7 days RTI, Sampling 0 to 20 DALA). Without information on the local practice regarding number of sprayings and their interval, the Meeting could not conclude on the GAP compliance of the supervised field trials. Residues in okra at the PHI were: 0.01, 0.02, 0.05, 0.18 and 0.20 mg/kg.

The information on okra provided by CropLife International on okra in India involved data from four sites with three sub-plots each (except one trial with two sub-plots only). Cypermethrin was applied as foliar spray with two applications involving 25 to 100 g ai/ha and plot per treatment. Samples were collected either after 7 or 14/15 days. However, the Meeting noted that no GAP information from India is available allowing selection of proper analytical results. In addition, no samples were collected at day zero, which would ease comparison with residues directly after treatment in other crops to identify morphological differences or similarities. Overall, the information was not added to the database of information previously reported by the JMPR, according the procedure described in the 2018 JMPR Report.

The trial in Uganda was performed on okra (Onen, Goeffrey; 9-September-2022, no report number) following a use pattern of 0.175+0.088 kg ai/ha (single dose) and 0.35+0.18 kg ai/ha (double dose) for tebuconazole and trifloxystrobin, respectively, in two foliar spraying, 7 day RTI, with sampling intervals ranging from immediately after harvest to 20 DALA. In total, three replicates were conducted for each experiment. Residues in okra fruits found are shown below.

Table 2.6.2 Residues of tebuconazole and trifloxystrobin following one or two applications

Replicate, Analyte	Residues in mg/kg							
	0 DAT	1 DAT	3 DAT	5 DAT	7 DAT	10 DAT	15 DAT	20 DAT
2 × 0.175 + 0.088 kg ai/ha (tebuconazole and trifloxystrobin, respectively), 7 day RTI, foliar spray								
Rep.1, Tebuconazole	0.64	0.49	0.27	0.026	< 0.01	0.07	< 0.01	< 0.01
Rep.2, Tebuconazole	0.56	0.44	0.38	0.21	0.14	< 0.01	< 0.01	< 0.01
Rep.3, Tebuconazole	1.12	0.65	0.3	0.36	0.29	< 0.01	< 0.01	< 0.01
Rep.1, Trifloxystrobin	0.29	0.06	0.02	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01
Rep.2, Trifloxystrobin	0.15	0.12	0.04	0.02	0.014	< 0.01	< 0.01	< 0.01
Rep.3, Trifloxystrobin	0.31	0.11	0.043	0.03	< 0.01	< 0.01	< 0.01	< 0.01
2 × 0.35 + 0.18 kg ai/ha (tebuconazole and trifloxystrobin, respectively), 7 day RTI, foliar spray								
Rep.1, Tebuconazole	1.48	0.42	0.39	0.074	0.07	0.08	< 0.01	< 0.01

Replicate, Analyte	Residues in mg/kg							
	0 DAT	1 DAT	3 DAT	5 DAT	7 DAT	10 DAT	15 DAT	20 DAT
Rep.2, Tebuconazole	1.02	0.72	0.87	0.53	0.46	0.17	0.03	0.03
Rep.3, Tebuconazole	1.2	0.92	0.98	0.42	0.25	0.03	< 0.01	< 0.01
Rep.1, Trifloxystrobin	0.08	0.07	0.06	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01
Rep.2, Trifloxystrobin	0.24	0.12	0.1	0.04	0.04	< 0.01	< 0.01	< 0.01
Rep.3, Trifloxystrobin	0.35	0.19	0.18	0.1	0.04	< 0.01	< 0.01	< 0.01

Since previous analysis by 2018 JMPR involved comparison of normalized residues at day 0 to identify potential similarities or differences between crops based on morphology—not to address the variability between different fields—the Meeting decided to consider each residue value reported immediately after harvest as an independent trial. The values were added to the database of information previously reported by the JMPR, according to the procedure described in the 2018 JMPR Report.

Additional information sourced from the public literature

Information is available on residues in okra following treatment with pesticides in the public literature. Respective studies are cited below with a brief summary of use conditions and reported residue concentrations for okra at day zero. This information was also added to the database of information previously reported by the JMPR, according to the procedure described in the 2018 JMPR Report.

Khan *et al.*, (2021) reported results following the application of cypermethrin in two supervised field trials on okra conducted in Pakistan. The active substance was sprayed at rates of 0.06 kg ai/ha. Residues in okra (day 0) were 2.19 and 1.55 mg/kg.

Kavitha *et al.*, (2021) reported results of cypermethrin and spiromesifen foliar applications to okra, grown in India, at rates of 0.05 kg ai/ha or 0.125 kg ai/ha, respectively. Residues in okra (day 0) were 0.276 mg/kg for cypermethrin and 2.401 mg/kg for spiromesifen.

Ratnamma *et al.*, (2021) reported the results of two trials in which acetamiprid was applied at single (10 g ai/ha) or double foliar spray rates (20 g ai/ha) to okra cultivated in India. Residues in okra (day 0) were 2.034 and 4.044 mg/kg.

In a single trial, ethion was applied to okra as a single foliar spray at 469 g ai/ha. Residues in okra (day 0) were 8.02 mg/kg (Rao *et al.*, 2022).

Ratnamma *et al.*, (2022) reported the results of two trials, where thiamethoxam was applied at single (25 g ai/ha) or double foliar spray rates (50 g ai/ha) to okra cultivated in India. Residues in okra (day 0) were 1.541 and 3.117 mg/kg.

Updated analysis of initial residues (normalized to application rate 1 kg ai/ha) for Fruiting vegetables, other than Cucurbits from the 2018 JMPR Report

After adding additional residue information on okra from the studies presented above to the database used by the 2018 JMPR, a new plot of residues normalized to 1 kg ai/ha was generated:

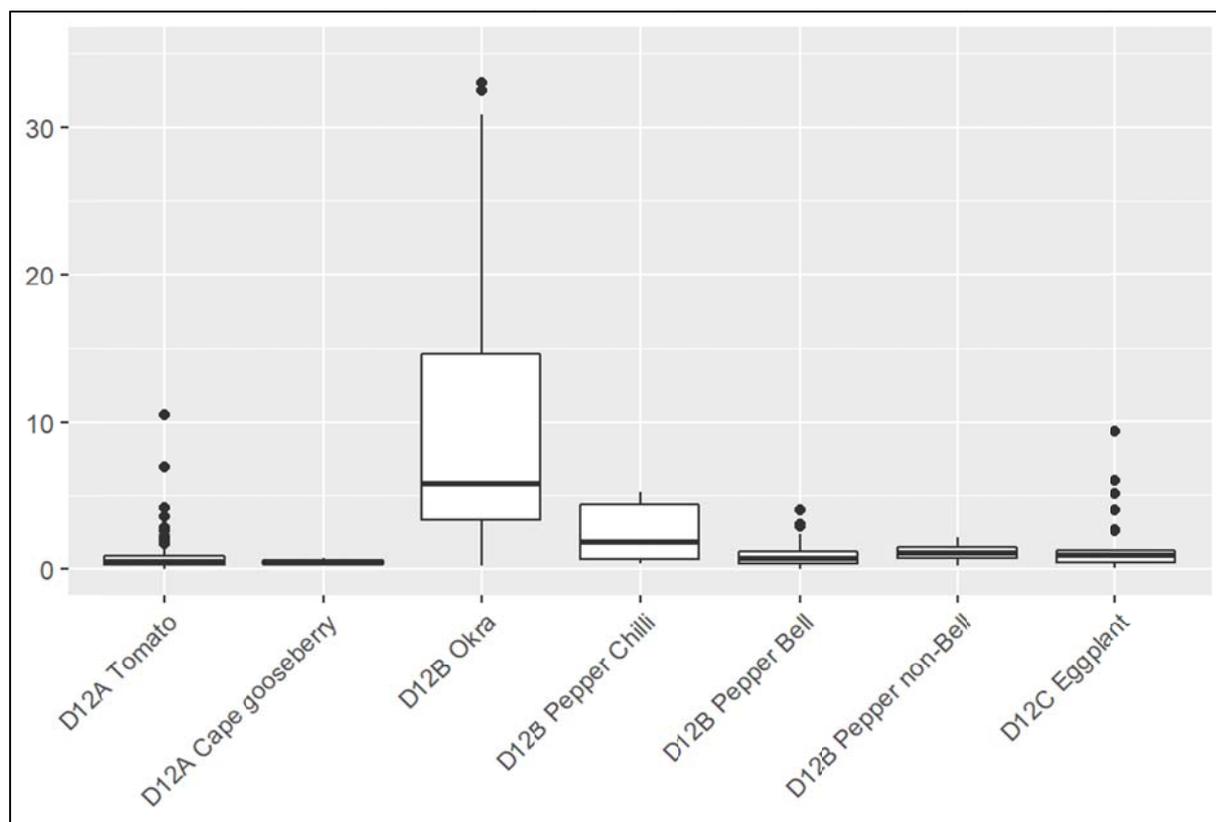


Figure 2.6.3 Box-Plot for normalized residues in fruiting vegetables for day 0 residues

Based on the new analysis, the Meeting confirms its conclusion from 2018 that residues in okra differ significantly from those in chilli peppers (Kruskal-Wallis-test, $p=0.002$).

Conclusion

The Meeting concluded that based on the newly provided data, no scientific evidence was identified supporting correlation of residue data in chilli pepper and okra following treatment according to the same use pattern and refers back to its recommendations for (sub) group maximum residue levels for Fruiting vegetables, other than Cucurbits outlined in the 2018 JMPR Report (2.9). Consequently, both Option 1 and Option 2 lack a robust data basis to support the proposed grouping or extrapolation.

Regarding Option 3, introduction of a specific sub-group 12D Okra (including martynia and roselle) with okra as the representative commodity would result in appropriate MRL estimates. However, difficulties in the data generation for a minor crop are acknowledged by the Meeting.

Future analysis of residues for okra, chilli pepper and related sub-groups should be based on comparable use patterns with corresponding field trials instead of monitoring data. Ideally, residues should be analysed directly after the last application ("day zero") in these studies to minimize the variability due to plant growth and/or environmental influences.

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2.8 Enhancing operational procedures of JMPR to reduce the backlog

The Meeting noted the discussions at the Fifty-second Session of the Codex Committee on Pesticide Residues (CCPR) on opportunities for enhancing the operational procedures of the FAO/WHO Joint Meeting on Pesticide Residues (JMPR) and CCPR to reduce the backlog of evaluations and meet the future demands of establishing Codex maximum residue limits (MRLs) for pesticides, as well as establishing an electronic working group to progress the discussions.

Discussions at the current JMPR meeting identified two possible areas of opportunity for increased efficiencies. Actions could usefully be taken by the sponsors of compounds, particularly in relation to improvements in the submission of information for assessments. Also, some potential efficiencies may be achieved within the workflow, evaluation, and consideration processes within JMPR. These proposals will require further consideration and will be brought forward as appropriate to the e-working group.

2.9 OECD Update to the Guidance on Residue Definitions

The Meeting was provided a draft of the OECD Guidance Document on Residue Definitions and a brief overview of the approaches to be proposed. The OECD subgroup working on this project includes many JMPR experts from both FAO and WHO panels.

The Meeting appreciated the opportunity to preview the work being done by the OECD and will consider the procedures and processes, in whole or in part, once the document has been finalized and published by the OECD.

Further, the Meeting noted that while there were many JMPR experts involved in the project, they were, with one exception, participating as representatives of their national regulatory agencies. The Meeting encouraged the JMPR Secretariats to work with the OECD Residue Chemistry Expert Group to ensure specific JMPR expert representation on future OECD projects working in areas of interest to the JMPR.

2.10 Information on residues in rotational crops following use on paddy rice

The Meeting noted that according to the current edition of the FAO Manual on “Submission and evaluation of pesticide residues data for the estimation of maximum residue levels in food and feed” (FAO, 2016, 3rd Edition),¹ information on rotational crops following treatment in paddy rice are not required.

The present Meeting reconsidered this position, taking into account information on the agricultural practice for paddy rice cultivation and International Harmonised Guidelines (OECD TG504; *OECD Guidelines for the Testing of Chemicals, Residues in Rotational Crops (Limited Field Studies)*), indicating potential crop rotation for this crop. Therefore, uptake of soil residues by follow-on crops needs to be considered in estimating maximum residue levels, STMR and HR values. It was decided that the information given in the FAO Manual from 2016 does not reflect current agricultural practice and considers data on rotational crops (confined rotational crop information, conditional information on field rotational crop studies) as necessary to support uses on paddy rice. The FAO Manual will be amended for the next revision accordingly.

2.11 Common pyrazole metabolites

The Meeting noted that a number of pesticides under consideration at the current meeting had common pyrazole metabolites, which were identified by different company code numbers. The toxicological data available on these pyrazole metabolites varied across the dossiers and this resulted in different conclusions being reached for the same pyrazole metabolite. The Meeting only identified this issue at the last minute and was unable to resolve it within the available time. The Meeting proposed to consider this at the 2023 meeting of JMPR and invites sponsors to present information to support this activity.

¹ <http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/jmpr/jmpr-docs/en/>

3. Responses to specific concerns raised by the Codex Committee on Pesticide Residues (CCPR)

3.1 Chlorothalonil (081)(R)

The United Kingdom submitted a concern form at the Fifty-second CCPR stating that the exposure estimated for the high temperature hydrolysis product R613636 from cranberry exceeded the threshold of toxicological concern for Cramer class III, that the overall chronic exposure to R613636 from all commodities had not been addressed, and that the acute exposure to R613636 from cranberry had not been addressed.

The 2019 Extra Meeting agreed that R613636 could be assessed using the TTC approach as a Cramer Class III compound (1.5 µg/kg per day). As the consumption data within the IEDI model used to assess long-term dietary exposure does not allow specifically for assessment of sterilised foods, the Meeting decided to apply the factor of 0.23 (representing the percentage of TRR recovered as R613636 in simulated hydrolysis studies) to the maximum IEDI of 9.33 µg/kg bw for chlorothalonil to assess exposure to R613636. The estimated exposure was 2.37 µg/kg bw. While this estimate is greater than the threshold of 1.5 µg/kg per day, the Meeting noted that the estimate assumes that all foods are sterilised, and that it is very unlikely that all foods would be subjected to such high-temperature (120 °C) treatment. The 2019 Extra Meeting concluded that long-term exposure to R613636 was unlikely to present a public health concern.

The 2021 JMPR did not have information specific to residues of R613636 in processed cranberry commodities and made a preliminary evaluation of the overall chronic and acute exposures. The 2021 Meeting concluded that there were no public health concerns.

Responses to specific concerns

The current Meeting received processing studies on barley, wheat grain, cabbages, common beans with pod (*Phaseolus vulgaris*) and tomato that include analysis for R613636.

From cabbage (chlorothalonil in RAC: 34 mg/kg), boiled cabbages were prepared, and the levels of R613636 in boiled cabbages (four trials) and cooking water (1 trial) were < 0.01 mg/kg.

From tomatoes (chlorothalonil in RAC: 9.6 mg/kg), pasteurised tomato juice and dry pomace as a by-product (four trials), tomato puree (four trials) and canned tomatoes (four trials) were prepared, with levels of R613636 < 0.01 mg/kg in all commodities.

From common beans (chlorothalonil in RAC: 6.7 mg/kg), canned beans (four trials) and boiled beans (four trials) were prepared, with R613636 < 0.01 mg/kg in all commodities.

Two studies were available for barley. In the first study, malt (three trials), beer (four trials), pot barley and abrasion dust as a by-product (four trials) were prepared from barley (chlorothalonil in grain: 0.24 mg/kg), with residues of R613636 < 0.01 mg/kg in all commodities. In the second study, malt, beer and pot barley were prepared from barley (chlorothalonil in grain: 0.39 mg/kg and 0.21 mg/kg) with R613636 residues < 0.01 mg/kg in all commodities.

From wheat (chlorothalonil in grain: 0.02 mg/kg and 0.01 mg/kg), bran, flour, wholemeal flour, wholemeal bread and wheat germ were prepared. R613636 was < 0.01 mg/kg except one sample of wheat germ (0.02 mg/kg).

In summary, the residues of R613636 in various processed commodities, some of which were subject to high temperature treatment, were 0.02 mg/kg or lower. As a conservative assumption that

STMR and HR of R613636 were assumed to be 0.02 mg/kg in all commodities previously evaluated by the JMPR (including raw commodities).

The Meeting considered R613636 could be assessed using the threshold of toxicological concern for a Cramer Class III compound of 1.5 µg/kg bw/day. The estimated exposure based on above-mentioned assumption, resulted in the maximum long-term exposure of 0.52 µg/kg bw/day. The estimated exposures are below the threshold of toxicological concern for Cramer Class III compounds. The Meeting concluded that R613636 were unlikely to present a dietary exposure concern from the uses considered by the JMPR.

For acute dietary exposure, the Meeting considered R613636 could be assessed using the threshold of the Cramer class III TTC of 1.5 µg/kg bw/day for chronic exposure as a conservative approach. The estimated exposure based on above-mentioned assumption, resulted in the maximum short-term exposure of 0.15 µg/kg bw/day. The estimated exposures are below the threshold of toxicological concern for Cramer Class III compounds. The Meeting concluded that R613636 were unlikely to present a dietary exposure concern from the uses on cranberry.

Therefore, the Meeting reconfirmed the conclusion that exposure to R613636 from the uses of chlorothalonil is not expected to be a safety concern.

3.2 Terbufos (167) (T)

Both the JMPR and Canadian assessments agree on the NOAEL of 0.15 mg/kg body weight (bw) for the acute neurotoxicity study used in the derivation of the ARfD. The key difference between the Canadian and JMPR assessments is that the Canadian assessment applied an extra 10-fold safety factor (above the default factor of 100-fold) based on what is described as a steep dose response.

The 2003 JMPR monograph describes the effects in the study. At 0.15 mg/kg bw there were no adverse effects reported. At 0.3 mg/kg bw there was no significant inhibition of erythrocyte or brain acetylcholinesterase activity but three (out of 10) males and one (out of 10) females had miosis (constricted pupils). At 0.9 mg/kg bw (six times the NOAEL) marked effects including tremors were seen. The effects were fully reversible, seen on day one but not at the next observation period on day 8.

As only some animals (4/20) at the LOAEL of 0.3 mg/kg bw showed any evidence of an adverse effect (a mild effect) and there were no adverse effects at the NOAEL of 0.15 mg/kg bw, the scientific basis behind the extra 10-fold factor used in the Canadian evaluation is unclear. With a clear threshold at the NOAEL and minimal adverse effects at the LOAEL JMPR would normally apply the default 100-fold safety factor.

On the available evidence the JMPR does not see a reason to review the ARfD and ADI for terbufos ahead of its scheduled periodic review.

4. Dietary exposure assessment for pesticide residues in food

Benzpyrimoxan, diazinon, isoflucypram methidathion, pyridate and quintozene were considered for toxicology and residues by the current JMPR, but as no residue recommendations were made, dietary risk assessments were not conducted for these compounds.

4.1 Chronic dietary exposure

Chronic dietary exposure estimates using the 17 GEMS/Food Cluster diets

At the current Meeting, an international estimated daily intake (IEDI) was calculated for each compound for which an acceptable daily intake (ADI) was established. The IEDI was calculated by multiplying the median concentrations of residues by the average daily per capita consumption of treated commodities. The concentrations were supervised trials median residues (STMRs) and/or supervised trials median residues in a processed commodity (STMR-Ps).

The per capita food consumption amounts were estimated using the 17 Global Environment Monitoring System–Food Contamination Monitoring and Assessment Programme (GEMS/Food) cluster diets. A detailed description of the method is included in the Environmental Health Criteria 240 (EHC 240) monograph.²

These IEDIs were expressed as a percentage of the maximum ADI for a 55 kg or 60 kg person, depending on the region covered by each cluster diet (Table 4.1). The spreadsheet application is available at <https://www.who.int/data/gho/samples/food-cluster-diets>. The estimation made for metalaxyl/metalaxyl-M in pineapple did not affect the assessment made by the 2021 JMPR. The detailed calculations of the chronic (long-term) dietary exposure assessments are given in Annex 3. The IEDI did not exceed the maximum ADI for any of the 28 compounds evaluated (includes one metabolite).

Table 4.1 Summary of chronic (long-term) dietary exposure assessments (IEDI) using the 17 Cluster diets

CCPR code	Compound name	ADI (mg/kg bw)	Range of IEDI, as percent of the maximum ADI
312	Afidopyropen	0–0.08	0–4
229	Azoxystrobin	0–0.2	10–20
261	Benzovindiflupyr	0–0.05	0–2
178	Bifenthrin	0.01	10–40
326	Broflanilide	0–0.02	0–1
15	Chlormequat ^a	0–0.05	1–20
230	Chlorantraniliprole	0–2	0–1
224	Difenoconazole	0–0.01	10–80
027	Dimethoate	0–0.001	10–100
055	Omethoate ^b	0–0.0004	

² FAO/WHO (2009). Principles and methods for the risk assessment of chemicals in food. A joint publication of the Food and Agriculture Organization of the United Nations and the World Health Organization. Geneva: World Health Organization (Environmental Health Criteria 240; <http://www.who.int/foodsafety/publications/chemical-food/en/>).

Dietary exposure assessment

CCPR code	Compound name	ADI (mg/kg bw)	Range of IEDI, as percent of the maximum ADI
247	Emamectin benzoate	0–0.0005	2–20
208	Famoxadone	0–0.006	1–20
297	Fenazaquin	0–0.05	0–2
327	Fluazaindolizine	0–0.3	0–1
328	Fluindapyr	0–0.04	0–1
211	Fludioxonil	0–0.4	1–6
285	Flupyradifurone	0–0.08	6–20
248	Flutriafol	0–0.01	9–30
216	Indoxacarb	0–0.01	2–20
329	Inpyrfluxam	0–0.06	0–5
050/105	Mancozeb/dithiocarbamates ^c ETU ^d	0–0.03 0.004	5–50
231	Mandipropamid	0–0.2	1–8
320	Mefentrifluconazole	0–0.04	6–40
287	Quinclorac	0–0.4	0–1
294	Spiromesifen	0–0.03	3–20
252	Sulfoxaflor	0–0.05	1–7
324	Tetraniliprole	0–2	0–0
317	Triflumuron	0–0.008	0–4
	4-trifluoromethoxyaniline	0–0.02	0–0

Notes:

ADI: acceptable daily intake; bw: body weight; CCPR: Codex Committee on Pesticide Residues; IEDI: international estimated daily intake.

^a Assessed as chlormequat cation.

^b Metabolite of dimethoate considered under the parent compound.

^c Group ADI (or in any combination) for ethylene-bis-dithiocarbamates (EBDCs: mancozeb, maneb, metiram and zineb).

^d Main metabolite of EBDC, considered under mancozeb.

Chronic dietary exposure estimates using WHO Chronic Individual Food Consumption–summary statistics (CIFOCOss) database

In a continuation of the trial exercise, food consumption data from national dietary surveys were used as the basis for estimating mean and high consumer chronic dietary exposure to pesticide residues for the general population and different age/sex groups. The global estimate of chronic dietary exposure (GECDE) model, developed by JECFA (veterinary drugs) in 2011,³ was used for estimating potential high consumer dietary exposure to pesticide residues for population subgroups of toxicological concern, such as women of childbearing age, infants, toddlers and young children. The GECDE model is based on summary statistics derived from individual food consumption data from representative national surveys and takes account of consumption of one commodity at a high level (for consumers of that commodity only) plus consumption of the remaining commodities at a population mean level. This model is intended to be used when raw individual dietary records are not available for use in risk assessments, which is often the case for evaluations undertaken by JMPR i.e. the GECDE serves as a proxy for deriving a high percentile dietary exposure value from a distribution of dietary exposures obtained by using the raw data.

Food consumption data suitable for use in the GECDE model are available in the WHO Chronic Individual Food Consumption–summary statistics (CIFOCOss) database, which contains individual and summary food consumption data derived from national surveys that have two or more records per survey participant. For use in chronic dietary exposure assessments, results for each individual are averaged over the number of days of the survey prior to deriving population statistics. For many countries, different population subgroups are surveyed separately over different time periods and may use different approaches. In these cases it is not possible to estimate dietary exposure for the population as a whole.

In the mean and high consumer chronic dietary exposure estimates (GECDE), the STMR residue levels were assigned to each food with a maximum residue level recommendation for the pesticide. In some cases, dilution factors were required to correct the STMR for the raw commodity (e.g. tea leaves) to a level relevant to the food reported as consumed in the dietary survey (e.g. tea beverage) and processing factors were applied where relevant.

In order not to underestimate the exposure, when multiple ingredients of a composite food reported in CIFOCOss could have been associated with a residue, the highest single residue per ingredient was taken into account and assigned to the full composite food. In certain cases this approach was considered too conservative and proportions were introduced to reduce the overestimation. This is the case of 'Soft drink with fruit' assumed to contain up to 25 percent of fruits, 'Soft drink without fruit' up to 10 percent of sugar, "Pasta" and "Bakery products" up to 50 percent of cereals. Coffee and infusions, follow-on and infant formula and porridges reconstituted were assumed to contain up to 90 percent, 20 percent and 50 percent of water (or milk), respectively. A range of other complex composite foods the main ingredient was assumed to account up to 30 percent.

The results are summarized in Table 4.2. Similar to the IEDI results (Table 4.1), the mean chronic dietary exposure did not exceed the maximum ADI, except for five compounds: difenoconazole (up to 260 percent), dimethoate (up to 230 percent), flutriafol (up to 130 percent), indoxacarb (up to 140 percent) and mancozeb (up to 210 percent), mainly for children and adolescents, and/or infant and toddlers populations.

³ FAO/WHO (2012). Joint FAO/WHO Expert Meeting on Dietary Exposure Assessment Methodologies for Residues of Veterinary Drugs. Final Report including Report of Stakeholder Meeting. Geneva: World Health Organization (http://www.fao.org/fileadmin/user_upload/agns/pdf/jecfa/Dietary_Exposure_Assessment_Methodologies_for_Residues_of_Veterinary_Drugs.pdf).

As expected, chronic dietary exposure estimates for the high consumer were higher than the IEDI (Table 4.1) and the mean chronic dietary exposure, exceeding the maximum ADI for eleven compounds evaluated for at least one population group: azoxystrobin (up to 120 percent), bifenthrin (up to 150 percent), difenoconazole (up to 530 percent), dimethoate (up to 790 percent), emamectin benzoate (up to 410 percent), famoxadone (up to 190 percent), flutriafol (up to 360 percent), indoxacarb (up to 360 percent), mancozeb (up to 600 percent), mefentrifluconazole (up to 310 percent) and spiromesifen (up to 150 percent).

Table 4.2 Chronic dietary exposure estimates using WHO Chronic Individual Food Consumption–summary statistics (CIFOCOs)

Pesticide	ADI (mg/kg bw)	Population group ^a	Range of dietary exposures across national dietary surveys, as percent of maximum ADI ^b	
			Mean	High
Afidopyropen	0–0.08	All	0–8	1–50
		All adults	0–4	0–27
		Adults, female	0–5	0–24
		Children & adolescents	0–13	0–56
		Infants & toddlers	1–10	2–45
Azoxystrobin	0–0.2	All	2–34	4–99
		All adults	0–23	0–53
		Adults, female	0–23	0–53
		Children & adolescents	1–46	1–120
		Infants & toddlers	4–41	7–79
Benzovindiflupyr	0–0.05	All	0–4	1–17
		All adults	0–2	0–11
		Adults, female	0–2	0–10
		Children & adolescents	0–5	0–19
		Infants & toddlers	0–7	1–21
Bifenthrin	0.01	All	7–68	13–140
		All adults	0–40	0–86
		Adults, female	0–42	0–95
		Children & adolescents	2–81	2–140
		Infants & toddlers	14–85	39–150
Broflanilide	0–0.02	All	0–3	0–12
		All adults	0–3	0–8
		Adults, female	0–3	0–8
		Children & adolescents	0–4	0–15
		Infants & toddlers	0–4	0–17
Chlormequat	0–0.05	All	0–8	1–54
		All adults	0–6	0–34
		Adults, female	0–15	0–36
		Children & adolescents	1–10	1–51
		Infants & toddlers	1–14	3–70

Pesticide	ADI (mg/kg bw)	Population group ^a	Range of dietary exposures across national dietary surveys, as percent of maximum ADI ^b	
			Mean	High
Chlorantraniliprole	0–2	All	0–2	0–7
		All adults	0–1	0–3
		Adults, female	0–1	0–3
		Children & adolescents	0–3	0–8
		Infants & toddlers	0–2	0–6
Difenoconazole	0–0.01	All	7–240	14–530
		All adults	0–140	0–320
		Adults, female	0–140	0–250
		Children & adolescents	13–260	13–520
		Infants & toddlers	45–260	96–520
Dimethoate ^c	0–0.001	All	11–160	35–750
		All adults	5–69	5–420
		Adults, female	2–68	2–420
		Children & adolescents	0–190	0–750
		Infants & toddlers	30–230	35–790
Emamectin benzoate	0–0.0005	All	0–20	1–170
		All adults	0–16	0–150
		Adults, female	0–17	0–150
		Children & adolescents	0–27	0–410
		Infants & toddlers	3–24	7–120
Famoxadone	0–0.006	All	1–26	5–190
		All adults	1–16	1–100
		Adults, female	1–16	1–79
		Children & adolescents	0–51	0–160
		Infants & toddlers	3–61	10–190
Fenazaquin	0–0.05	All	0–8	0–40
		All adults	0–3	0–21
		Adults, female	0–4	0–9
		Children & adolescents	0–10	0–24
		Infants & toddlers	0–7	1–23
Fluazaindolizine	0–0.3	All	0–2	0–7
		All adults	0–1	0–3
		Adults, female	0–1	0–3
		Children & adolescents	0–4	0–8
		Infants & toddlers	0–2	0–4
Fluindapyr	0–0.04	All	0–27	1–93
		All adults	0–18	0–48
		Adults, female	0–18	0–48

Dietary exposure assessment

Pesticide	ADI (mg/kg bw)	Population group ^a	Range of dietary exposures across national dietary surveys, as percent of maximum ADI ^b	
			Mean	High
		Children & adolescents Infants & toddlers	0-36 0-4	0-100 0-26
Fludioxonil	0-0.4	All All adults Adults, female Children & adolescents Infants & toddlers	0-15 0-7 0-7 0-24 0-15	2-77 0-34 0-34 0-95 3-49
Flupyradifurone	0-0.08	All All adults Adults, female Children & adolescents Infants & toddlers	1-12 0-9 0-9 0-17 2-10	4-36 0-19 0-21 0-45 2-39
Flutriafol	0-0.01	All All adults Adults, female Children & adolescents Infants & toddlers	6-98 0-69 0-69 0-130 13-73	29-290 1-150 1-170 0-360 18-280
Indoxacarb	0-0.01	All All adults Adults, female Children & adolescents Infants & toddlers	1-79 1-58 1-61 0-110 10-140	2-180 1-140 1-110 0-290 14-360
Inpyrfluxam	0-0.06	All All adults Adults, female Children & adolescents Infants & toddlers	0-5 0-3 0-3 0-8 0-12	0-28 0-10 0-10 0-25 0-35
Mancozeb	0-0.03	All All adults Adults, female Children & adolescents Infants & toddlers	9-140 2-110 2-100 11-210 21-140	64-510 2-300 2-200 11-460 32-600
Mandipropamid	0-0.2	All All adults Adults, female Children & adolescents Infants & toddlers	0-13 0-6 0-9 0-20 0-16	0-54 0-25 0-24 0-59 0-48
Mefentrifluconazole	0-0.04	All	4-57	8-280

Pesticide	ADI (mg/kg bw)	Population group ^a	Range of dietary exposures across national dietary surveys, as percent of maximum ADI ^b	
			Mean	High
		All adults	0-41	0-160
		Adults, female	0-43	0-180
		Children & adolescents	2-84	2-310
		Infants & toddlers	11-80	18-250
Quinclorac	0-0.4	All	0-4	0-11
		All adults	0-3	0-7
		Adults, female	0-3	0-7
		Children & adolescents	0-7	0-13
		Infants & toddlers	0-4	0-14
Spiromesifen	0-0.03	All	0-37	1-140
		All adults	0-14	1-63
		Adults, female	0-22	1-60
		Children & adolescents	0-57	0-150
		Infants & toddlers	1-54	3-120
Sulfoxaflor	0-0.05	All	1-18	5-54
		All adults	1-10	2-25
		Adults, female	1-11	1-25
		Children & adolescents	0-23	0-56
		Infants & toddlers	3-23	8-66
Tetraniliprole	0-2	All	0-1	0-3
		All adults	0	0-2
		Adults, female	0	0-2
		Children & adolescents	0-1	0-4
		Infants & toddlers	0-1	0-3
Triflumuron	0-0.008	All	0-6	1-47
		All adults	0-6	0-20
		Adults, female	0-6	0-30
		Children & adolescents	1-7	1-39
		Infants & toddlers	1-6	1-55
4-trifluoromethoxyaniline ^d	0-0.02	All	0-1	0-14
		All adults	0	0-2
		Adults, female	0	0-2
		Children & adolescents	0-1	0-11
		Infants & toddlers	0-1	0-17

Notes:

ADI: acceptable daily intake; bw: body weight; CIFOCSs: Chronic Individual Food Consumption database–summary statistics. (<https://apps.who.int/fooscollab/Download/DownloadConso>)

^a The most recent national surveys for each country were sourced from the FAO/WHO CIFOCSs database for 40 countries: whole population, 16 surveys; adults, 33 surveys; adult women, 39 surveys; children and adolescents (aged 3–17 years), 27 surveys; infants (aged 0–11 months) and toddlers (aged 1–3 years), 20 surveys.

^b For each national survey in the CIFOCC database, for a specified age group, a high percentile dietary exposure was first calculated for each commodity based on an assigned supervised trials median residue (STMR) and a highest reliable percentile (HRP) food consumption: if there were more than 180 consumers of a commodity, a 97.5th percentile dietary exposure for consumers only was derived; if there were more than 60 but fewer than 181 consumers, a 95th percentile dietary exposure was derived; if there were more than 30 but fewer than 61 consumers, a 90th percentile dietary exposure was derived; and if there were more than 10 but fewer than 31 consumers, a median dietary exposure was derived. If there were fewer than 11 consumers, only the mean dietary exposure for the whole population was derived for that Codex commodity code. The high dietary exposure estimate is the highest of these commodity-specific estimate and the population mean dietary exposure estimate for all other commodities. The mean dietary exposure estimates apply the population mean food consumption for all relevant commodities.

^c Includes omethoate, the metabolite of dimethoate.

^d Metabolite of triflumuron.

4.2 Acute dietary exposure

The current or previous Meetings agreed that acute reference dose (ARfD) for azoxystrobin, isoflucypram, broflanilide, chlorantraniliprole, fludioxonil, isoflucypram, mandipropamid, spiromesifen, tetraniliprole, triflumuron were unnecessary. An ARfD for mancozeb has not yet been considered by the Meeting. Therefore, for these compounds, acute dietary exposure assessment was not conducted.

At the current Meeting, an international estimate of short-term intakes was calculated for compounds for which an ARfD was established. For each relevant food commodity, the highest expected residue (highest residue in the edible portion of a commodity (HR) or highest residue in a processed commodity (HR-P) and the highest large portion (LP) data for the general population (all ages) and children (6 years and under) were used for the calculation of the international estimate of short-term intakes. The LP data are derived from national dietary survey data by WHO. For bulked and blended commodities, the STMR or STMR-P is used as the residue level in the international estimate of short-term intakes calculation. A description of the method is included in EHC 240. The spreadsheet application is available at https://cdn.who.int/media/docs/default-source/food-safety/gems-food/iesti_calculation21_data-overview.xlsx.

The international estimate of short-term intakes results are expressed as a percentage of the ARfD, which are shown in Table 4.3. The commodities and source of consumption data used when the ARfD was exceeded were also included. The detailed calculations of acute dietary exposure are given in Annex 4.

Table 4.3 Summary of acute dietary exposure assessments (international estimate of short-term intakes)

CCPR code	Compound name	ARfD (mg/kg bw)	Maximum percent of ARfD
312	Afidopyropen	0.3/0.2 ^a	0–2
261	Benzovindiflupyr	0.1	0–10
178	Bifenthrin	0.01	0–310 250 apple (Children 1–6 yrs, China) 310 pear (Children < 6 yrs, Canada) 260 peach (Children 1–6 yrs, Japan) 110 apricot (Children 2–4 yrs, Germany) 210 nectarine (Children 2–6 yrs, Netherlands)
15	Chlormequat	0.05	0–60
224	Difenoconazole	0.3	0–3

CCPR code	Compound name	ARfD (mg/kg bw)	Maximum percent of ARfD
027	Dimethoate Omethoate ^b	0.02 0.002	0–120 120 orange (Children 1–6 yrs, Australia)
247	Emamectin benzoate	0.02	0–70
208	Famoxadone	0.6	0–20
297	Fenazaquin	0.1	0–60
327	Fluazaindolizine	1	0–9
328	Fluindapyr	0.6	0–1
285	Flupyradifurone	0.2	0–8
248	Flutriafol	0.05	0–70
216	Indoxacarb	0.1	0–20
329	Inpyrfluxam	0.3	0–40
138	Metalaxyl ^c	0.5	0–1
320	Mefentrifluconazole	0.3	0–370 110 Kale (Children 2–4 yrs, Germany) 130 Endive, raw (Children 2–6 yrs, Netherlands) 140 Endive, total (Children 2–6 yrs, Netherlands) 140 Amaranth leaves (Toddlers, Belgium) 140 Lettuce, head (Children 2–6 yrs, Netherlands) 140 Lettuce, leaf, raw (Children 2–6 yrs, Netherlands) 140 Cos lettuce (Children 2–6 yrs, Netherlands) 140 Chicory leaves (Toddlers, Belgium) 140 Chrysanthemums, Edible leaved (Toddlers, Belgium) 140 Spinach, total (Toddlers, Belgium) 200 Mustard greens, raw (Children 1–6 yrs, China) 240 Endive, cooked/boiled (Toddlers, Netherlands) 240 Chinese cabbage (Children 1–6 yrs, China) 370 Leaf lettuce, total (Children 1–6 yrs, China)
252	Sulfoxaflor	0.3	0–2
	4-trifluoromethoxyaniline ^d	0.02	0–1
287	Quinclorac	2	0–0

Notes:

ARfD: acute reference dose; bw: body weight; CCPR: Codex Committee on Pesticide Residues; international estimate of short-term Intake.

^a For women of childbearing age.

^b The assessment includes the metabolite omethoate.

^c The assessment covers use of metalaxyl and metalaxyl-M.

^d Metabolite of triflumuron.

Possible refinement when the international estimate of short-term intakes exceeds the ARfD***Bifenthrin***

The Meeting concluded that the estimated acute dietary exposure to residues of bifenthrin for the consumption of apple, pear, peach, apricot and nectarine by children may present a public health concern. As no alternative GAP data were available to the Meeting to estimate lower HR values for these commodities, no refinement of the acute dietary exposure estimates was possible. International estimate of short-term intakes can be refined if alternative GAP data become available in the future.

The ARfD of 0.01 mg/kg bw established by the 2009 JMPR was derived from a threshold dose of 1.3 mg/kg bw in the acute study in rats (single dose), which was supported by the NOAEL of 1 mg/kg bw in a developmental toxicity study in rats. As the studies were considered adequate and in the case of the acute study the LOAEL is less than 3 times the NOAEL, it is unlikely that the ARfD can be refined significantly.

Dimethoate

The Meeting concluded that the estimated acute dietary exposure to residues of dimethoate for the consumption of oranges by children may present a public health concern. As no alternative GAP data were available to the Meeting to estimate a lower HR value for this commodity, no refinement of the acute dietary exposure estimates was possible. International estimate of short-term intakes can be refined if alternative GAP data become available in the future.

The ARfD of 0.02 mg/kg bw established for dimethoate in 2019 on the basis of an overall NOAEL of 2 mg/kg bw in an acute neurotoxicity study based on inhibition of erythrocyte acetylcholinesterase activity and a special study in pre-weaning females and in young adult females. At the present Meeting, a ARfD of 0.002 mg/kg bw was established for the first time for omethoate, the main metabolite of dimethoate, which was considered under the parent compound assessment. As the studies were considered adequate, and the basis of the ARfD for omethoate was a benchmark dose analysis of an acute study of cholinesterase inhibition, it is unlikely that the ARfD can be refined.

Mefentrifluconazole

The Meeting concluded that the estimated acute dietary exposure to residues of mefentrifluconazole for the consumption of various leafy vegetables (amaranth leaves, chicory leaves, edible leaved chrysanthemums, endive, lettuce, Chinese cabbage, kale and mustard greens) by children and/or toddlers may present a public health concern. As no alternative GAP data were available to the Meeting to estimate lower HR values for these commodities, no refinement of the acute dietary exposure estimates was possible. International estimate of short-term intakes can be refined if alternative GAP data become available in the future.

The ARfD of 0.3 mg/kg bw established by the 2021 JMPR was based on the NOAEL of 25 mg/kg bw per day for maternal and developmental toxicity in a rabbit study. As the study was considered adequate and clinical signs were seen after only a few doses at 50 mg/kg bw per day in another study in rabbits, it is unlikely that the ARfD can be refined significantly.

5 Evaluation of data for acceptable daily intake and acute reference dose for humans, maximum residue levels and supervised trials median residue values

5.1 Afidopyropen (312)

TOXICOLOGY

Following the 2019 JMPR evaluation of afidopyropen a request for consideration of additional maximum residue limits (MRLs) was made by the Codex Committee on Pesticide Residues (CCPR). A 28-day oral study in rats and a repeat-dose oral study in pregnant rabbits were provided by the sponsor in an attempt to identify points of inflection in the dose-metabolism curve for afidopyropen. As these studies would have had no effect on the health-based guidance values (HBGVs), they were not reviewed by this Meeting. They should be provided for the periodic review of afidopyropen.

There was no information available in the public domain, and no experimental data were provided which addressed the possible impact of afidopyropen residues on the human intestinal microbiome.

A toxicological monograph was not prepared.

RESIDUE AND ANALYTICAL ASPECTS

Afidopyropen is an insecticide developed for control of piercing and sucking insects. Afidopyropen disrupts the gating of TRPV (Transient Receptor Potential Vanilloid) channel complexes in chordotonal stretch receptor organs of insects. This disrupts feeding and other behaviour in target insects leading to death by starvation.

Afidopyropen was first evaluated by the 2019 JMPR when an ADI of 0–0.08 mg/kg bw was established. The Meeting also established an ARfD of 0.2 mg/kg bw for women in childbearing age and an ARfD of 0.3 mg/kg for the general population. In addition, it was concluded that the metabolites M440I007 and CPCA are likely to be of similar toxicity to its parent. The 2021 JMPR reconsidered the wording of the residue definition. The residue definitions are:

Definition of the residue for compliance with the MRL for plant and animal commodities: *afidopyropen*

Definition of the residue for dietary risk assessment for plant commodities: *sum of afidopyropen + dimer of [(3R,6R,6aR,12S,12bR)-3-[(cyclopropanecarbonyl)oxy]-6,12-dihydroxy-4,6a,12b-trimethyl-11-oxo-9-(pyridin-3-yl)-1,3,4,4a,5,6,6a,12,12a,12b-decahydro-2H,11H-naphtho[2,1-b]pyrano[3,4-e]pyran-4-yl]methyl rac-cyclopropanecarboxylate (M007).*

Definition of the residue for dietary risk assessment for animal commodities, except liver: *afidopyropen + M001 + CPCA and its carnitine conjugate, expressed as afidopyropen.*

Definition of the residue for dietary risk assessment for liver: *afidopyropen + M001 + M017 + CPCA and its carnitine conjugate, expressed as afidopyropen.*

The residue is not fat-soluble.

At the Fifty-first Session of the CCPR (2019), afidopyropen was scheduled for toxicology and residue evaluation by the 2022 JMPR.

The Meeting received information from the manufacturer on aerobic soil metabolism, use patterns and residues resulting from supervised trials on strawberries, sorghum and alfalfa/clover.

Environmental fate in soil

The Meeting received information on environmental fate in soil.

Aerobic soil metabolism

The aerobic metabolism and degradation in soil was tested on four soil types from the United States of America, including silt loam, loamy sand and sandy loam soils. Pyranone-6-¹⁴C-afidopyropen was applied at approximately 0.2 mg/kg and soil samples were incubated for up to 120 days at 20 °C with 50 percent maximum water holding capacity. Major degradation products exceeding 10 percent of the applied radioactivity were M057 (max. 25.7 percent AR after 29 days) and M003 (max. 11.8 percent after 5 days). Modelled DT₅₀ and DT₉₀ values for parent afidopyropen were 9.5–14 days and 82–268 days, respectively, following Gustafson-Holden model kinetics (FOMC). The major metabolites followed single 1st order kinetics with estimated DT₅₀/DT₉₀ values of 17.5–23.8/58–79 days for M003 and 7.7–39/26–132 days for M057.

The current Meeting noted that both the metabolic pattern following aerobic soil degradation observed in the newly provided study and the estimated half-life times are similar to the conclusion drawn by the 2019 Meeting. The Meeting confirms its previous conclusion, that afidopyropen and its soil metabolites are not persistent in soil.

Methods of analysis

The current Meeting did not receive additional analytical methods for afidopyropen. All supervised field trials were analysed with analytical methods already evaluated and described by the 2019 Meeting.

Stability of pesticide residues in stored analytical samples

The current Meeting did not receive additional information on the storage stability of afidopyropen and its metabolite M007.

The 2019 Meeting evaluated the storage stability of these analytes and concluded that they are stable for at least 24 months in all plant commodity categories. Field trial samples were analysed within this interval.

Results of supervised residue trials on crops

The Meeting received information on use patterns and supervised residue trials for strawberries, sorghum, alfalfa and clover from the United States.

Strawberries

Afidopyropen is registered in the United States for the use on strawberries with a maximum GAP involving two foliar spraying of 0.05 kg ai/ha each (7 day retreatment interval (RTI)) and a PHI of 0 days. The maximum rate is 0.1 kg ai/ha per crop and a maximum of 0.3 kg ai/ha and year.

Supervised field trials conducted in Canada and the United States on strawberries were provided approximating the cGAP both with two additional initial treatments at ~ 0.01 kg ai/ha at 7 day RTI (treatment regime: 0.01 kg ai/ha + 0.01 kg ai/ha + 0.05 kg ai/ha + 0.05 kg ai/ha, total crop rate: 0.12 kg ai/ha). The Meeting concluded that the two first treatments in addition to the cGAP do not affect residue concentrations at harvest.

Residues of afidopyropen in strawberries were (n=5): 0.0326, 0.0356, 0.0439, 0.0475, 0.06 mg/kg.

Residues of afidopyropen plus M007 in strawberries were (n=5): 0.0426, 0.0456, 0.0539, 0.0575, 0.07 mg/kg. Highest residues in a single sample were 0.0778 mg/kg.

The Meeting estimated a maximum residue level of 0.15 mg/kg for afidopyropen and STMR and HR values of 0.0539 mg/kg and 0.0778 mg/kg, respectively, for afidopyropen plus M007 in strawberries.

Sorghum

Afidopyropen is registered in the United States for the use on sorghum with a maximum GAP involving two foliar spraying of 0.02 kg ai/ha each (14 day RTI) and a PHI of 14 days for grain. The maximum rate is 0.044 kg ai/ha per year.

Supervised field trials conducted in the United States on sorghum were provided approximating the cGAP.

Residues of afidopyropen in sorghum grain were (n=12): < 0.01(3), 0.01, 0.016, 0.019, 0.034, 0.041, 0.042, 0.067, 0.071, 0.104 mg/kg.

Residues of afidopyropen plus M007 in sorghum grain were (n=12): < 0.02(3), 0.02, 0.026, 0.029, 0.044, 0.051, 0.052, 0.077, 0.081, 0.114 mg/kg.

The Meeting estimated a maximum residue level of 0.2 mg/kg for afidopyropen and an STMR value of 0.0365 mg/kg for afidopyropen plus M007 in sorghum grain.

Alfalfa forage

Afidopyropen is registered in the United States for the use on non-grass animal feed crops with a maximum GAP involving two foliar spraying of 0.022 kg ai/ha followed by 0.036 kg ai/ha (7 day RTI) and a PHI of 0 days for forage. The maximum rate is 0.058 kg ai/ha per year.

Supervised field trials conducted in the United States on alfalfa were provided approximating the cGAP.

Residues of afidopyropen plus M007 in alfalfa forage were (n=9): 0.783, 0.999, 1.08, 1.13, 1.19, 1.24, 2.07, 2.31, 2.45 mg/kg (as received).

The Meeting estimated a median residue level of 1.19 mg/kg and highest residue level of 2.45 mg/kg for afidopyropen plus M007 in alfalfa forage (as received).

Clover forage

Afidopyropen is registered in the United States for the use on non-grass animal feed crops with a maximum GAP involving two foliar spraying of 0.022 kg ai/ha followed by 0.036 kg ai/ha (7 day RTI) and a PHI of 0 days for forage. The maximum rate is 0.058 kg ai/ha per year.

Supervised field trials conducted in the United States on clover were provided approximating the cGAP.

Residues of afidopyropen plus M007 in clover forage were (n=9): 0.601, 0.662, 0.926, 1.01, 1.39, 1.68, 2.09, 2.22, 2.59 mg/kg (as received).

The Meeting estimated a median residue level of 1.39 mg/kg and highest residue level of 2.59 mg/kg for afidopyropen plus M007 in clover forage (as received).

Grass forage

Afidopyropen is registered in the United States for the use on grass animal feed crops with a maximum GAP involving two foliar spraying of 0.022 kg ai/ha followed by 0.036 kg ai/ha (7 day RTI) and a PHI of 0 days for forage. The maximum rate is 0.058 kg ai/ha per year.

Supervised field trials conducted in the United States on grass were provided approximating the cGAP.

Residues of afidopyropen plus M007 in grass forage were (n=12): 0.805, 1.09, 1.36, 1.36, 1.48, 1.92, 2.04, 2.1, 2.19, 2.82, 3.2 and 4.12 mg/kg (as received).

The Meeting estimated a median residue level of 1.98 mg/kg and highest residue level of 4.12 mg/kg for afidopyropen plus M007 in grass forage (as received).

Sorghum forage

Afidopyropen is registered in the United States for the use on sorghum with a maximum GAP involving two foliar spraying of 0.02 kg ai/ha each (14 day RTI) and a PHI of 7 days for forage. The maximum rate is 0.044 kg ai/ha per year.

Supervised field trials conducted in the United States on sorghum were provided approximating the cGAP.

Residues of afidopyropen plus M007 in sorghum forage were (n=12): 0.0225, 0.0275, 0.037, 0.0375, 0.039, 0.0485, 0.0515, 0.06, 0.063, 0.103, 0.25 and 0.255 mg/kg (as received).

The Meeting estimated a median residue level of 0.05 mg/kg and highest residue level of 0.255 mg/kg for afidopyropen plus M007 in sorghum forage (as received).

Alfalfa fodder

Afidopyropen is registered in the United States for the use on non-grass animal feed crops with a maximum GAP involving two foliar spraying of 0.022 kg ai/ha followed by 0.036 kg ai/ha (7 day RTI) and a PHI of 0 days for cutting. The maximum rate is 0.058 kg ai/ha per year.

Supervised field trials conducted in the United States on alfalfa were provided approximating the cGAP. Alfalfa was cut according to GAP treatment and left in the field to dry until commercial dryness.

Residues of afidopyropen in alfalfa hay were (n=9): 0.362, 1.32, 1.35, 1.83, 2.71, 2.8, 2.91, 3.12 and 4.19 mg/kg (fresh).

Residues of afidopyropen plus M007 in alfalfa hay were (n=9): 0.382, 1.81, 1.81, 3.10, 4.13, 4.76, 5.13, 5.29 and 5.46 mg/kg (as received).

The Meeting estimated a maximum residue level of 8 mg/kg (dry matter, based on 89 percent dry-weight) for afidopyropen and a median and highest residue for afidopyropen plus M007 in alfalfa fodder (as received) of 4.13 mg/kg and 5.46 mg/kg, respectively.

Clover fodder

Afidopyropen is registered in the United States for the use on non-grass animal feed crops with a maximum GAP involving two foliar spraying of 0.022 kg ai/ha followed by 0.036 kg ai/ha (7 day RTI) and a PHI of 0 days for cutting. The maximum rate is 0.058 kg ai/ha per year.

Supervised field trials conducted in the United States on clover were provided approximating the cGAP. Clover was cut according to GAP treatment and left in the field to dry until commercial dryness.

Residues of afidopyropen in clover hay were (n=9): 1.24, 1.47, 1.59, 2.43, 2.5, 2.64, 3.95, 4.28 and 5.93 mg/kg (fresh).

Residues of afidopyropen plus M007 in clover hay were (n=9): 1.92, 2.23, 2.26, 3.23, 3.50, 3.58, 4.37, 4.42 and 8.55 mg/kg (as received).

The Meeting estimated a maximum residue level of 10 mg/kg (dry matter, based on 89 percent dry-weight) for afidopyropen and a median and highest residue for afidopyropen plus M007 in clover fodder (as received) of 3.5 mg/kg and 8.55 mg/kg, respectively.

Grass hay

Afidopyropen is registered in the United States for the use on grass animal feed crops with a maximum GAP involving two foliar spraying of 0.022 kg ai/ha followed by 0.036 kg ai/ha (7 day RTI) and a PHI of 0 days for cutting. The maximum rate is 0.058 kg ai/ha per year.

Supervised field trials conducted in the United States on grass were provided approximating the cGAP. Grass was cut according to GAP treatment and left in the field to dry until commercial dryness.

Residues of afidopyropen in grass hay were (n=12): 2.39, 2.59, 2.77, 3.15, 3.27, 3.48, 4.12, 4.46, 4.64, 4.82, 5.76 and 8.38 mg/kg (DM based).

Residues of afidopyropen plus M007 in grass hay were (n=12): 3.36, 3.69, 3.83, 4.53, 5.24, 5.85, 6.79, 7.06, 7.13, 8.9, 14.0 and 14.9 mg/kg (DM based).

The Meeting estimated a maximum residue level of 15 mg/kg (dry-matter, trial specific dry-weight basis) for afidopyropen and a median and highest residue for afidopyropen plus M007 in grass hay (dry-matter) of 6.32 mg/kg and 14.9 mg/kg, respectively.

Sorghum stover

Afidopyropen is registered in the United States for the use on sorghum with a maximum GAP involving two foliar spraying of 0.02 kg ai/ha each (14 day RTI) and a PHI of 14 days for stover. The maximum rate is 0.044 kg ai/ha per year.

Supervised field trials conducted in the United States on sorghum were provided approximating the cGAP.

Residues of afidopyropen in sorghum stover were (n=12): 0.0105, 0.011, 0.0155, 0.0155, 0.0205, 0.0305, 0.048, 0.0505, 0.081, 0.085, 0.119, 0.14 mg/kg (fresh).

Residues of afidopyropen plus M007 in sorghum stover were (n=12): 0.0205, 0.021, 0.0255, 0.0255, 0.0305, 0.0405, 0.0605, 0.0635, 0.091, 0.098, 0.134 and 0.155 mg/kg (as received).

The Meeting estimated a maximum residue level of 0.3 mg/kg (dry matter, based on 88 percent dry-weight) for afidopyropen and a median and highest residue for afidopyropen plus M007 in sorghum stover (as received) of 0.0505 mg/kg and 0.155 mg/kg, respectively.

Residues in animal commodities

Farm animal feeding studies

The 2019 Meeting evaluated farm animal feeding studies with afidopyropen on lactating cows and laying hens.

In the following tables, residues in bovine tissues and milk and in poultry tissues and eggs according to the residue definitions for MRL setting (afidopyropen) and for exposure estimation

(afidopyropen + M001 + CPCA and its carnitine conjugate, expressed as afidopyropen for animal commodities except liver and afidopyropen + M001 + M017 + CPCA and its carnitine conjugate, expressed as afidopyropen for liver) are summarized.

Table 5.1.1 Overview of mean and highest residue levels observed in the dietary feeding study with lactating cows

	1.54 ppm		4.61 ppm		15.3 ppm	
	parent	Total ^a	parent	Total ^a	parent	Total ^a
Liver	0.017 (0.019)	0.15 (0.15)	0.046 (0.056)	0.18 (0.19)	0.19 (0.20)	0.36 (0.37)
Kidney	< 0.01 (< 0.01)	< 0.13 (< 0.13)	< 0.01 (< 0.01)	< 0.13 (< 0.13)	< 0.01 (< 0.01)	< 0.13 (< 0.13)
Muscle	< 0.01 (< 0.01)	< 0.13 (< 0.13)	< 0.01 (< 0.01)	0.15 (0.17)	< 0.01 (< 0.01)	0.29 (0.29)
Fat	< 0.01 (< 0.01)	< 0.13 (< 0.13)	< 0.01 (< 0.01)	< 0.13 (< 0.13)	< 0.01 (< 0.01)	< 0.13 (< 0.13)
Milk	< 0.001 (< 0.001)	< 0.013 (< 0.013)	< 0.001 (< 0.001)	0.016 (0.020)	< 0.001 (< 0.001)	0.035 (0.044)

Notes:

^a Total residues include parent+M001+CPCA-carnitine, corrected for their respective molecular weights in g/mol (parent = 593.67, M001 = 457.52, CPCA-carnitine =265.74). In liver residue levels of parent were corrected for M017 using a correction factor of 1.2.

Source: FAO and WHO. 2020. *Pesticide residues in food 2019 - Report 2019 - Joint FAO/WHO Meeting on Pesticide Residues*. Rome.

Table 5.1.2 Overview of mean (and highest) residue levels observed in the dietary feeding study with laying hens

	0.20 ppm		0.62 ppm		2.0 ppm	
	parent	Total ^a	parent	Total ^a	parent	Total ^a
Liver	0.010 (0.011)	0.14 (0.15)	0.025 (0.027)	0.16 (0.17)	0.085 (0.095)	0.24 (0.28)
Muscle	< 0.01 (< 0.01)	< 0.13 (< 0.13)	< 0.01 (< 0.01)	< 0.13 (< 0.13)	0.011 (0.012)	0.14 (0.13)
Fat	< 0.01 (< 0.01)	< 0.13 (< 0.13)	0.011 (0.012)	0.14 (0.14)	0.036 (0.042)	0.16 (0.17)
Eggs	< 0.01 (< 0.01)	< 0.13 (< 0.13)	0.011 (0.018) ^b	0.14 (0.14)	0.026 (0.036)	0.15 (0.16)

Notes:

^a Total residues include parent+ M001+CPCA-carnitine (+ M017 in liver) corrected for molecular weight differences in g/mol (parent = 593.67, M001 = 457.52, M017 = 609.7; CPCA-carnitine =265.74).

^b Results from day 28 and 32 only.

Source: FAO and WHO. 2020. *Pesticide residues in food 2019 - Report 2019 - Joint FAO/WHO Meeting on Pesticide Residues*. Rome.

Farm animal dietary burden

Dietary burdens were calculated for beef cattle, dairy cattle, broilers and laying poultry based on feed items evaluated by the JMPR in 2019 and the current recommendations. The dietary burdens, estimated using the most recent version of the OECD livestock dietary burden calculator diets are presented in

Annex 6 and summarized below. As Australia does not allow the importation of fodders due to biosecurity concerns, forage and fodder commodities were excluded from the dietary burden calculation for Australia.

Table 5.1.3 Estimated maximum and mean dietary burdens of farm animals (sum of afidopyropen and M007)

	Animal dietary burden: sum of afidopyropen and M007, ppm of dry matter diet							
	United States-Canada		European Union		Australia ^{/a}		Japan	
	max	mean	max	mean	max	mean	max	mean
Beef cattle	3.8	1.7	17.5	8.7	0.09	0.09	6.67	3.1
Dairy cattle	9.4	4.53	18.2 ❶	9.0 ❷	0.082	0.082	12.2	5.8
Broilers	0.04	0.04	0.036	0.036	0.035	0.035	0.035	0.035
Layers	0.037	0.037	1.2 ❸	0.54 ❹	0.035	0.035	0.03	0.03

Notes:

^{a/} Excluding forage/fodder due to import restrictions.

❶ Highest maximum beef or dairy cattle dietary burden suitable for HR estimates for mammalian tissues and milk.

❷ Highest mean beef or dairy cattle dietary burden suitable for STMR estimates for mammalian tissues and milk.

❸ Highest maximum poultry dietary burden suitable for HR estimates for poultry tissues and eggs.

❹ Highest mean poultry dietary burden suitable for STMR estimates for poultry tissues and eggs.

Animal commodity maximum residue levels

Cattle

The calculations used to estimate maximum residue levels, STMR and HR values for cattle matrices are shown below. For cattle, the maximum dietary burden of 18.2 ppm represents 119 percent of the highest dose administered in the provided feeding study, which is at the upper end of acceptable under dosing for the estimation of residues in animal commodities.

Table 5.1.4 Anticipated residues of afidopyropen in cattle commodities

	Feed Level (ppm) for milk residues	Total residues (mg eq/kg) in milk	Feed Level (ppm) for tissue residues	Total residues (mg eq/kg)			
				Muscle	Liver	Kidney	Fat
HR Determination (beef or dairy cattle) - Parent + M001 + CPCA-carnitine + M017 (liver only)							
Feeding Study	15.3	0.035	15.3	0.29	0.38	< 0.13	< 0.13
Dietary burden and estimate of highest residue	18.2	0.042	18.2	0.34	0.45	< 0.15	< 0.15
STMR Determination (beef or dairy cattle) - Parent + M001 + CPCA-carnitine + M017 (liver only)							
Feeding Study	4.61	0.016	4.61	0.15	0.18	< 0.13	< 0.13
	15.3	0.035	15.3	0.29	0.36	< 0.13	< 0.13
Dietary burden and estimate of median residue	9.0	0.024	9.0	0.21	0.25	< 0.13	< 0.13
MRL Determination (beef or dairy cattle) - Parent							
Feeding Study	15.3	< 0.001	15.3	< 0.01	0.20	< 0.01	< 0.01
Dietary burden and estimate of highest residue	18.2	< 0.001	18.2	< 0.01	0.24	< 0.01	< 0.01

The Meeting confirms its previous recommendation on maximum residue levels of 0.001(*) mg/kg in milk, 0.3 mg/kg in edible offal (based on liver), 0.01(*) mg/kg in meat (mammalian except marine mammals) and 0.01(*) mg/kg in mammalian fats.

For estimating dietary exposure, calculated HR values are: 0.45 mg/kg for edible offal (based on liver), 0.34 mg/kg for muscle, and 0.15 mg/kg for kidney and fat and 0.042 mg/kg in milk. Calculated STMRs are: 0.25 mg/kg edible offal (based on liver), 0.21 mg/kg for muscle, 0.13 mg/kg for kidney and fat, and 0.024 mg/kg for milk.

Poultry

The calculations used to estimate maximum residue levels, STMR and HR values for poultry matrices are shown below.

Table 5.1.5 Anticipated residues of afidopyropen in poultry commodities

	Feed Level (ppm) for egg residues	Total residues (mg eq/kg) in egg	Feed Level (ppm) for tissue residues	Total residues (mg eq/kg)		
				Muscle	Liver	Fat
HR Determination (poultry broiler or layer) - Parent + M001+ CPCA-carnitine + M017 (liver only)						
Feeding Study	0.62	0.14	0.62	< 0.13	0.17	0.14
	2.0	0.16	2.0	0.14	0.28	0.17
Dietary burden and estimate of highest residue	1.2	0.149	1:2	0.134	0.22	0.16
STMR Determination (poultry broiler or layer)–Parent + M001+ CPCA-carnitine + M017 (liver only)						
Feeding Study	0.20	< 0.13	0.20	< 0.13	0.14	< 0.13
	0.62	0.14	0.62	< 0.13	0.16	0.14
Dietary burden and estimate of median residue	0.54	0.138	0.54	< 0.13	0.156	0.138
MRL Estimation (poultry broiler of layer)–Parent only						
Feeding Study	0.62	0.018	0.62	< 0.01	0.011	< 0.01
	2.0	0.036	2.0	< 0.01	0.027	0.012
Dietary burden and estimate of highest residue	1.2	0.027	1.2	< 0.01	0.019	0.011

The Meeting confirms its previous recommendation on a maximum residue level of 0.01(*) mg/kg in poultry meat (muscle).

The Meeting estimated maximum residue levels of 0.015 mg/kg in poultry fat, 0.02 mg/kg in poultry edible offal and 0.03 mg/kg in eggs to replace its previous recommendation.

For estimating dietary exposure calculated HR values are: 0.22 mg/kg for poultry edible offal (based on liver), 0.134 mg/kg for muscle, 0.16 mg/kg for fat and 0.149 mg/kg for eggs. Calculated STMRs are: 0.156 mg/kg for liver and poultry edible offal (based on liver), 0.13 mg/kg for muscle, 0.138 mg/kg for fat and 0.138 mg/kg for eggs.

RECOMMENDATIONS

On the basis of the data from supervised trials, the Meeting concluded that the residue levels listed in Annex 1 are suitable for establishing maximum residue limits and for IEDI and international estimate of short-term intakes assessment.

Definition of the residue for compliance with the MRL for plant and animal commodities: *afidopyropen*

Definition of the residue for dietary risk assessment for plant commodities: *sum of afidopyropen + dimer of [(3R,6R,6aR,12S,12bR)-3-[(cyclopropanecarbonyl)oxy]-6,12-dihydroxy-4,6a,12b-trimethyl-11-oxo-9-(pyridin-3-yl)-1,3,4,4a,5,6,6a,12,12a,12b-decahydro-2H,11H-naphtho[2,1-b]pyrano[3,4-e]pyran-4-yl]methyl rac-cyclopropanecarboxylate (M007).*

Definition of the residue for dietary risk assessment for animal commodities, except liver: *afidopyropen + M001 + CPCA and its carnitine conjugate, expressed as afidopyropen.*

Definition of the residue for dietary risk assessment for liver: *afidopyropen + M001 + M017 + CPCA and its carnitine conjugate, expressed as afidopyropen.*

The residue is not fat-soluble.

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The ADI for afidopyropen is 0–0.08 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for afidopyropen were estimated for the 17 GEMS/Food Consumption Cluster Diets using the STMR or STMR-P values estimated by the JMPR. The results are shown in Annex 3 of the 2022 JMPR Report.

The IEDIs ranged from 0–4 percent of the maximum ADI. The Meeting concluded that long-term dietary exposure to residues of afidopyropen from uses considered by the JMPR is unlikely to present a public health concern.

Acute dietary exposure

The ARfD for afidopyropen is 0.2 mg/kg bw for women of childbearing age and 0.3 mg/kg bw for adults and children. The International Estimate of Short Term Intakes (international estimate of short-term intakes) for afidopyropen were calculated for the food commodities and their processed commodities for which HRs/HR-Ps or STMRs/STMR-Ps were estimated by the present Meeting and for which consumption data were available. The results are shown in Annex 4 of the 2022 JMPR Report.

The international estimate of short-term Intake were 0–1 percent of the ARfD for women of childbearing age and 0–2 percent of the ARfD for children and 0–1 percent of the ARfD for adults. The Meeting concluded that acute dietary exposure to residues of afidopyropen from uses considered by the present Meeting is unlikely to present a public health concern.

5.2 Azoxystrobin (229)

TOXICOLOGY

Following the JMPR 2008 evaluation of azoxystrobin, a request for consideration of additional maximum residue limits (MRLs) was made by the Codex Committee on Pesticide Residues (CCPR). Two sets of acute toxicity, irritation and sensitization studies were provided for azoxystrobin by the sponsor. The studies provided did not affect the azoxystrobin dietary risk assessment, and so were not reviewed by this Meeting. They should be provided for the periodic review of azoxystrobin.

A review of the literature available in the public domain revealed information available regarding the potential effects of azoxystrobin on the human intestinal microbiome. This information, in addition to any data on this topic produced by the sponsor, should be considered during any further toxicological re-evaluation of azoxystrobin.

A toxicological monograph was not prepared.

RESIDUE AND ANALYTICAL ASPECTS

Azoxystrobin was first evaluated for toxicology and residues by the JMPR in 2008. It was evaluated for residues by the JMPR in 2011, 2012, 2013, 2017 and 2019. An ADI of 0–0.02 mg/kg bw was established and an ARfD was considered unnecessary.

The residue definition for compliance with the MRL and for dietary risk assessment for plant and animal commodities is parent azoxystrobin. The residue is fat soluble.

Azoxystrobin was scheduled at the Fifty-first Session of the CCPR for the evaluation of additional MRLs in 2021 and rescheduled to the 2022 JMPR. The current Meeting received additional analytical methods, storage stability data, GAP information and residue trial data from uses on mango, papaya, sugar beet, and sugar beet processed commodities.

Methods of analysis

Residue analytical method RAM 305/03 was used for the analysis of azoxystrobin in the supervised residue trials on mango, papaya, sugar beet, and the processing study on sugar beet. Method RAM 305 was previously validated as version RAM 305/01 in a wide range of crops and crop types by the 2008 JMPR. Method RAM 305/03 is procedurally the same as the version RAM 01 and validation data evaluated for RAM 305/01 are applicable to RAM 305/03.

Recoveries and percent RSDs for RAM 305/03 were within the acceptable range (70–120 percent). The LOQ is 0.01 mg/kg for all versions of the method and all plant commodities tested.

The Meeting concluded that RAM 305/03 was sufficiently validated and is suitable to measure azoxystrobin in mango peel and flesh, papaya peel and flesh, and sugar beet and its processed commodities.

Stability of pesticides residues in stored analytical samples

In 2008, the JMPR evaluated data on the stability of azoxystrobin in plant and animal commodities stored frozen at ≤ -18 °C. The 2008 Meeting concluded that residues of azoxystrobin were stable for at least 24 months in high water and high starch commodities.

The Meeting concluded that the storage stability data are adequate to support the storage durations in studies provided to the current Meeting.

Results of supervised residue trials on crops

Mango

The cGAP for azoxystrobin on mango from Brazil is four foliar-directed applications at 120 g ai/ha with a 7-day PHI and 14-day re-treatment interval (RTI), followed by a post-harvest dip or spray application at 120 g ai/hL.

In independent trials matching the cGAP for foliar + post-harvest dip applications, residues of azoxystrobin in whole fruit were (n=4): 1.67, 1.93, 2.11, and 2.67 mg/kg.

In independent trials matching the cGAP for foliar + post-harvest spray applications, residues of azoxystrobin in whole fruit were (n=4): 1.66, 2.16, 2.31, and 2.54 mg/kg.

The Meeting considered the foliar + post-harvest dip and foliar + post-harvest spray applications independent and agreed to combine the data sets to estimate a maximum residue level.

Residues of azoxystrobin in mangos (whole fruit) from trials approximating the cGAP were (n=8): 1.66, 1.67, 1.93, 2.11, 2.16, 2.31, 2.54, and 2.67 mg/kg.

The Meeting estimated a maximum residue level (based on the mean + 4 SD) of 4 mg/kg (Po) for azoxystrobin in mangoes and withdrew its previous recommendation.

Residues in mango flesh from trials approximating cGAP were (n=8): 0.02 (4), 0.05, 0.06 (2), and 0.07 mg/kg.

The Meeting estimated an STMR of 0.035 mg/kg for mango flesh.

Papaya

The cGAP for azoxystrobin on papaya from Brazil is four foliar-directed applications at 100 g ai/ha with a 3 day PHI and 14 day re-treatment interval (RTI), followed by a post-harvest dip or spray application at 120 g ai/hL.

In independent trials matching the cGAP for foliar + post-harvest dip applications, residues of azoxystrobin were (n=4): 1.12, 1.13, 1.22, and 2.40 mg/kg.

In independent trials matching the cGAP for foliar + post-harvest spray applications, residues of azoxystrobin were (n=4): 0.93, 1.31, 1.33, and 1.50 mg/kg.

The Meeting considered the foliar + post-harvest dip and foliar + post-harvest spray applications independent and agreed to combine the data sets to estimate a maximum residue level.

Residues of azoxystrobin in mangos (whole fruit) from trials approximating the cGAP were (n=8): 0.93, 1.12, 1.13, 1.22, 1.31, 1.33, 1.50, and 2.40 mg/kg.

The Meeting estimated a maximum residue level (based on mean + 4 SD) of 4 mg/kg (Po) for azoxystrobin in papaya to replace its previous recommendation.

Residues in papaya flesh from trials approximating the cGAP were (n=8): 0.01, 0.05 (2), 0.10 (2), 0.12, 0.13, and 0.17 mg/kg.

The Meeting estimated an STMR of 0.10 mg/kg for papaya flesh.

Sugar beet

The critical GAP in the United States consists of one post-harvest application at a rate of 4.7 g ai/tonne roots.

In independent trials matching the cGAP, residues of azoxystrobin in sugar beet roots were (n=6): 0.73, 1.1, 1.3, 1.4, 2.0, 2.4 mg/kg.

The Meeting estimated a maximum residue level (based on mean + 4 SD) of 4 mg/kg (Po) and an STMR of 1.35 mg/kg for azoxystrobin in sugar beets. Furthermore, the Meeting withdrew its previous recommendation of 1 mg/kg for azoxystrobin in root and tuber vegetables except potato and recommended a new maximum residue level of 1 mg/kg for azoxystrobin in root and tuber vegetables except potato and sugar beet.

Fate of residues during processing

Processing factors and residue estimates for sugar beet processed commodities are summarized below.

Table 5.2.1 Processing factors and residue estimates for azoxystrobin

Raw commodity	STMR	Processed commodity	Processing Factors	STMR-P/ Median-P
Sugar beet root	1.35	Molasses	0.20	0.27
		Refined sugar	0.017	0.023
		Dried pulp	0.47	0.635
		Ensiled pulp	0.12	0.162

The Meeting estimated the STMR-Ps/median-Ps listed in Table 5.2.1 for use in dietary risk assessment and estimation of animal dietary burdens.

Residues in animal commodities

Dietary burdens were calculated for beef cattle, dairy cattle, broilers and laying poultry based on feed items evaluated by the JMPR. The dietary burdens, estimated using the 2018 OECD Feed diets listed in Appendix XIV Electronic attachments to the 2016 Edition of the FAO Manual, are presented in Annex 6.

Of the commodities evaluated by the current Meeting, only sugar beet molasses, dried pulp, and ensiled pulp need consideration with respect to livestock diets.

Table 5.2.2 shows the dietary burdens calculated by the 2013 JMPR and the current Meeting.

Table 5.2.2 Estimated maximum and mean dietary burdens of farm animals

	Livestock dietary burden, azoxystrobin, ppm of dry matter diet (2013/2022)							
	Japan		United States- Canada		European Union		Australia	
	Max	Mean	Max	Mean	Max	Mean	Max	Mean
Beef cattle	0.96/6.9	0.96/1.8	17/25	12/16	61/63	25/26	72/83 ^①	51/51 ^③
Dairy cattle	16/19	3.0/3.5	30/45	12/14	74/81 ^②	29/31 ^④	46/51	20/22
Poultry–broiler	1.4/1.4	1.4/1.4	1.7/1.7	1.7/1.7	2.2/5.7	1.9/5.0	1.7/1.7	1.7/1.7
Poultry–layer	1.4/1.4	1.4/1.4	1.7/1.7	1.7/1.7	21/25 ^⑤	9.5/12 ^⑥	1.7/1.7	1.7/1.7

Notes:

- ① Highest maximum beef or dairy cattle burden suitable for MRL estimates for mammalian tissues.
- ② Highest maximum dairy cattle burden suitable for MRL estimates for milk.
- ③ Highest mean beef or dairy cattle burden suitable for STMR estimates for mammalian tissues.
- ④ Highest mean dairy cattle burden suitable for STMR estimates for milk.

- ⑤ Highest maximum poultry broiler or layer burden suitable for MRL estimates for poultry eggs and tissues.
- ⑥ Highest mean poultry broiler or layer burden suitable for STMR estimates for poultry eggs and tissues.

The Meeting noted that the new estimations did not result in a significant change of the dietary burdens of farm animals. Based on the minor change in livestock dietary burden, the Meeting did not recalculate residues in animal commodities or revise its recommendations for maximum residue levels.

RECOMMENDATIONS

On the basis of the data from supervised trials, the Meeting concluded that the residue levels listed in Annex 1 are suitable for establishing maximum residue limits and for IEDI and international estimate of short-term Intake assessment.

Definition of the residue for compliance with the MRL and for dietary risk assessment for plant and animal commodities: *azoxystrobin*.

The residue is fat-soluble.

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The ADI for azoxystrobin is 0–0.2 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for azoxystrobin were estimated for the 17 GEMS/Food Consumption Cluster Diets using the STMR or STMR-P values estimated by the previous and present JMPR. The results are shown in Annex 3 of the 2022 JMPR Report. The IEDIs ranged 3–20 percent of the maximum ADI.

The Meeting concluded that the long-term intake of residues of azoxystrobin from uses considered by the JMPR is unlikely to present a public health concern.

Acute dietary exposure

The 2008 Meeting determined that the establishment of an acute reference dose is unnecessary for azoxystrobin. The Meeting concluded that the acute dietary exposure to residues of azoxystrobin, from uses considered by the present Meeting, is unlikely to present a public health concern.

5.3 Benzovindiflupyr (261)

TOXICOLOGY

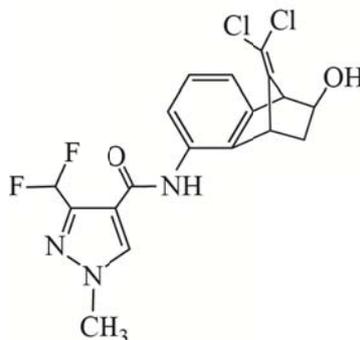
Benzovindiflupyr is the approved International Organization for Standardization (ISO) name for *N*-[11-(dichloromethylidene)-3-tricyclo[6.2.1.0^{2,7}]undeca-2(7),3,5-trienyl]-3-(difluoromethyl)-1-methylpyrazole-4-carboxamide (IUPAC) for which the Chemical Abstracts Service number is 1072957-71-1. Benzovindiflupyr (SYN545192) is a broad-spectrum foliar fungicide of the pyrazole chemical class. Technical benzovindiflupyr consists of the enantiomers SYN546526 and SYN546527, at a ratio of 1:1. Both enantiomers are fungicidally active. Benzovindiflupyr is a succinate dehydrogenase inhibitor and thus inhibits the citric acid cycle in fungi.

Benzovindiflupyr was previously evaluated by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) in 2013. That meeting established an acceptable daily intake (ADI) of 0–0.05 mg/kg body weight (bw) based on an increased incidence of minimal hepatocellular pigmentation and reduced body weight gain in a two-year study in rats. An acute reference dose (ARfD) of 0.1 mg/kg bw was also established based on a NOAEL of 10 mg/kg bw for decreased motor activity at one hour following oral gavage dosing in an acute neurotoxicity study in rats.

The compound was reviewed by the present meeting following a request from the Codex Committee on Pesticide Residues (CCPR) for additional maximum residue levels (MRLs), for which additional information on some of the metabolites was provided. All provided studies were compliant with good laboratory practice (GLP) unless otherwise stated, and were conducted in accordance with current test guideline requirements.

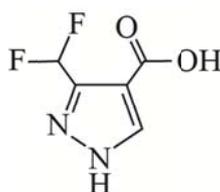
Toxicological data on metabolites and/or degradates

SYN546039 (CSCD695908)



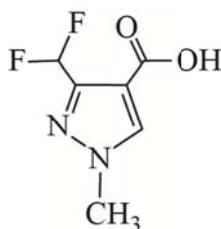
Based on the JMPR 2013 evaluation the present Meeting concluded that SYN546039 is at least 10-fold less toxic than its parent molecule.

SYN545720 (CSCD465008, R958945)



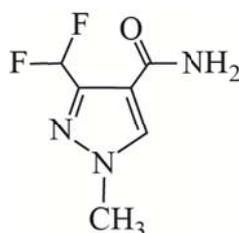
Metabolite SYN545720 was assessed at JMPR 2013. Based on the JMPR 2013 evaluation the present Meeting concluded that SYN545720 is not toxicologically relevant.

NOA449410 (CA4312; also sedaxane metabolite CSAA798670, R648993 and fluxapyroxad metabolite M700F001)



For the current meeting several studies were provided that have been previously evaluated by JMPR for other compounds: the metabolite is common to benzovindiflupyr, fluxapyroxad (JMPR 2012) and pydiflumetofen (JMPR 2018). Based on the JMPR 2012 and 2018 evaluations the present Meeting concluded that NOA449410 is not toxicologically relevant.

SYN508272 (CSCC210616; R423363; Reg. No. 5621781; Metabolite of BAS 700 F)



For the current meeting several studies were provided that have been previously evaluated by JMPR for other compounds: SYN508272 is also a metabolite of pydiflumetofen (JMPR 2018). Based on read-across from the pydiflumetofen evaluation, SYN508272 is unlikely to be carcinogenic, a reproductive and developmental toxicant or a neurotoxicant. Overall, the Meeting concluded that the toxicological properties of SYN508272 resemble those of benzovindiflupyr. Accordingly, human exposure to SYN508272 should be adequately covered by the health-based guidance values (HBGVs) of the parent benzovindiflupyr.

Toxicological evaluation

The Meeting concluded that NOA449410 and SYN545720 are not toxicologically relevant. Metabolite SYN508272 should be adequately covered by the ADI of 0–0.05 mg/kg bw and the ARfD of 0.1 mg/kg bw established for the parent, benzovindiflupyr. Metabolite SYN546039 is at least 10-fold less toxic than benzovindiflupyr.

A toxicological monograph addendum was prepared.

Summary

	Value	Study	Safety factor
ADI ^a	0–0.05 mg/kg bw ^b	Two-year toxicity study (rat)	100
ARfD ^a	0.1 mg/kg bw ^b	Acute neurotoxicity study (rat)	100

Notes:

^a From JMPR 2013.

^b Applies to benzovindiflupyr and SYN508272.

RESIDUE AND ANALYTICAL ASPECTS

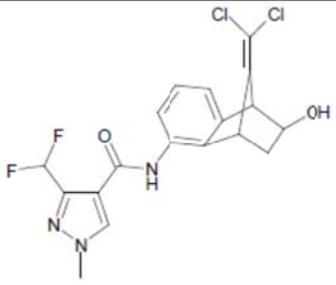
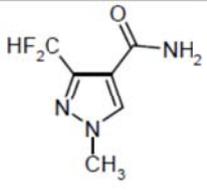
Benzovindiflupyr is a broad-spectrum fungicide first evaluated by JMPR in 2013 for Toxicology and in 2014 for Residues. The compound was re-evaluated in 2016, 2018 and 2019 for additional uses.

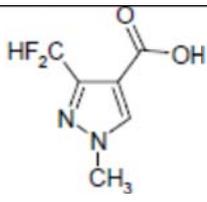
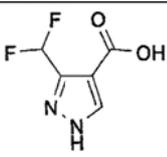
An ADI of 0–0.05 mg/kg bw and an ARfD of 0.1 mg/kg bw were established by the 2013 JMPR. The 2014 JMPR Meeting recommended the residue definition for plant and animal commodities (for compliance with MRLs and for estimation of dietary intake) as: benzovindiflupyr. The residue is fat soluble.

Benzovindiflupyr was scheduled at the Fifty-first Session of the CCPR for evaluation of additional uses by the 2021 JMPR and rescheduled for evaluation by the 2022 JMPR. The Meeting received additional information from the manufacturer on the toxicity of metabolites, method of residue analysis, use patterns, supervised residue trials (blueberries, dried ginseng, sugar beets and maize) and processing studies on sugar beets.

Chemical Names

Table 5.3.1 Metabolites referred to in this appraisal

Code	Structural formula, short name, IUPAC name	JMPR 2014 conclusions
SYN 546039	 <p>hydroxy-benzovindiflupyr CSCD695908 IUPAC: N-[(1RS,2RS,4SR)-9-(dichloromethylene)-2-hydroxy-1,2,3,4-tetrahydro-1,4-methanonaphthalen-5-yl]-3-(difluoromethyl)-1-methyl-1H-pyrazole-4-carboxamide</p>	<p>JMPR 2014: Found in rat goat (milk, liver, kidney, muscle, fat) hen (eggs, liver, muscle, skin with fat)</p> <p>tomato fruit wheat forage/hay/straw wheat grains soya bean forage/hay soya bean seeds</p> <p>rotational crops: lettuce leaves, turnip roots/leaves, wheat forage/hay/straw</p>
SYN 508272	 <p>pyrazole amide CSCC210616 IUPAC: 3-difluoromethyl-1-methyl-1H-pyrazole-4-carboxylic acid amide</p>	<p>JMPR 2014: Found in goat (milk, liver, kidney, muscle, fat) hen (eggs, liver, muscle, skin with fat)</p> <p>wheat hay/straw wheat grains soya bean forage soya bean hay</p> <p>rotational crops: turnip leaves, wheat forage/hay/straw</p> <p>photolysis in water</p> <p>common metabolite with other pyrazole fungicides like bixafen,</p>

Code	Structural formula, short name, IUPAC name	JMPR 2014 conclusions
		fluindapyr, fluxapyroxad, inpyrfluxam, isopyrazam and sedaxane
NOA 449410	 <p>pyrazole acid CSAA798670 IUPAC: 3-difluoromethyl-1-methyl-1H-pyrazole-4-carboxylic acid</p>	<p>JMPR 2014: Found in:</p> <ul style="list-style-type: none"> tomato fruit wheat hay/straw wheat grains soya bean forage/hay soya bean seeds <p>rotational crops: lettuce leaves, turnip roots/leaves, wheat forage/hay/straw</p> <p>photolysis in water</p> <p>(not detected in goat and hen commodities)</p> <p>common metabolite with other pyrazole fungicides like bixafen, fluxapyroxad, inpyrfluxam, isopyrazam and sedaxane</p>
SYN 545720	 <p>N-desmethylpyrazole-acid CSCD465008 or R958945, IUPAC: 3-difluoromethyl-1H-pyrazole-4-carboxylic acid CAS nr 151734-02-0</p>	<p>JMPR 2014: Found in</p> <ul style="list-style-type: none"> tomato fruit soya bean forage/hay soya bean seeds <p>rotational crops: lettuce leaves, turnip roots/leaves, wheat forage/hay/straw</p> <p>(not detected in rat, goat and hen commodities)</p> <p>(not found in photolysis in water)</p> <p>common metabolite with other pyrazole fungicides like bixafen, fluxapyroxad, inpyrfluxam, isopyrazam and sedaxane</p>

Methods of analysis

The Meeting received additional validation information for benzovindiflupyr and SYN 546039 in blueberries, dried ginseng roots, sugar beet commodities and maize commodities for analytical methods already considered by the JMPR in 2014. The Meeting concluded that the presented (modified) methods were sufficiently validated and are suitable to quantify benzovindiflupyr and SYN 546039 (including conjugates) in plant commodities.

Stability of pesticide residues in stored analytical samples

The Meeting agreed that the demonstrated storage stability on various representative plant commodities evaluated by the JMPR 2014 covered the residue sample storage intervals used in the field trials and processing studies considered by the current Meeting.

Residue definition

The Meeting received additional toxicological information on hydroxy-benzovindiflupyr (SYN 546039) and the three cleavage products: pyrazole amide (SYN 508272), pyrazole acid (NOA 449410) and N-desmethyl pyrazole acid (SYN 545720). The three cleavage products are common to other pyrazole fungicides like bixafen, fluindapyr, fluxapyroxad, inpyrfluxam, isopyrazam and sedaxane. The 2014 JMPR concluded that these metabolites were not relevant for the residue definition, because the residue levels were low and/or because the toxicity was much lower than parent.

The current Meeting concluded that the three cleavage products (pyrazole amide, pyrazole acid and N-desmethyl pyrazole acid) are not covered by the health based guidance values of benzovindiflupyr and should be assessed by TTC (Cramer class III).

Hydroxy-benzovindiflupyr (SYN 546039 including conjugates) was found at significant levels in the metabolism studies on legume forage/fodder (9.2–12 percent TRR, 0.34–1.6 mg/kg eq), moderate levels in cereal hay/straw (0.5–3.6 percent TRR, 0.032–0.23 mg/kg eq) and low levels in fruit crops, cereal grains/forage and seeds of pulses/oilseed (0.1–2.1 percent TRR, < 0.01 mg/kg eq).

Actual levels of hydroxy-benzovindiflupyr (including conjugates) in field trials conducted at cGAP were 0.92–3.5 mg/kg in legume hay, 0.15–0.71 mg/kg in legume forage, 0.040–1.2 mg/kg in cereal hay/straw, < 0.01–0.32 mg/kg in cereal forage and 0.018–0.19 mg/kg in grapes. Hydroxy-benzovindiflupyr (including conjugates) levels in other crops were low: < 0.01 mg/kg in pome fruit, bulb onions, dry beans, soya beans, potatoes, sweet corn, sugar cane, rape seed, peanuts, and < 0.01–0.035 mg/kg in fruiting vegetables, dry peas, cereal grains and coffee beans.

Hydroxy-benzovindiflupyr (including conjugates) was found in the livestock metabolism studies evaluated by the 2014 JMPR: mammalian muscle, fat and milk (22 percent–39 percent TRR, < 0.01–0.035 mg/kg eq); mammalian edible offal (22–50 percent TRR, 0.040–0.65 mg/kg eq); and eggs (12–22 percent TRR; 0.014–0.015 mg/kg eq). It was found at low levels in poultry tissues (1.3–5.2 percent TRR, < 0.01 mg/kg eq).

Actual levels of hydroxy-benzovindiflupyr (including conjugates) in feeding studies on lactating cows at the maximum dietary burden were < 0.01 mg/kg in milk and muscle, 0.019 mg/kg in fat and 0.037 mg/kg in mammalian offal. No feeding studies on poultry were available. Based on the metabolism studies, actual levels of hydroxy-benzovindiflupyr (including conjugates) in poultry tissues and eggs are expected to be < 0.01 mg/kg at the maximum dietary burden. The current Meeting concluded that this metabolite is 10 times less toxic than parent.

Because the contribution of hydroxybenzovindiflupyr to the overall dietary risk is low (4.5 percent relative exposure increase), the Meeting confirmed that hydroxy-benzovindiflupyr should not be included in the residue definition for dietary risk assessment for either plant or animal commodities.

The Meeting therefore confirmed its definition of the residue for compliance with the MRL and dietary risk assessment for plant and animal commodities as: benzovindiflupyr.

Results of supervised residue trials on crops

Supervised trials were available for the use of benzovindiflupyr on blueberries, ginseng, sugar beets and maize. Product labels were available from the United States.

Blueberries

Benzovindiflupyr is registered in the United States as a foliar spray on lowbush blueberries with a critical GAP (cGAP) application rate of 2×0.076 kg ai/ha, a retreatment interval (RTI) of 10 days and a PHI of 1 day.

Because the United States label registered lowbush blueberries only, the Meeting decided that the supervised trials on highbush blueberries could not be matched to this cGAP. Five supervised trials on lowbush blueberries from the United States performed at an application rate of 2×0.074 – 0.076 kg ai/ha with an RTI of 10 days and a PHI of 1 day, approximated this cGAP. Residues of benzovindiflupyr in lowbush blueberries were: 0.48, 0.51, 0.65, 0.69, 0.87 mg/kg (n=5).

The Meeting considered five trials sufficient for the minor crop blueberries and estimated a maximum residue level of 2 mg/kg, a HR of 0.98 mg/kg (individual highest residue) and an STMR of 0.65 mg/kg for benzovindiflupyr in blueberries (FB0020). The recommendation refers to blueberries, as the Codex Classification does not distinguish between lowbush and highbush blueberries (both have code FB0020).

Dried ginseng roots

Benzovindiflupyr is registered in the United States on ginseng with a cGAP rate of 4×0.076 kg ai/ha, an RTI of 14 days and a PHI of 15 days.

Four supervised trials on ginseng from the United States performed at 4×0.073 – 0.080 kg ai/ha with an RTI of 13–15 days and a PHI of 15 days approximated this cGAP. Fresh ginseng roots from these trials were dried for 6–8 days until an estimated dry matter content of 70–90 percent was reached. Residues of benzovindiflupyr in dried ginseng roots were: 0.034, 0.068, 0.094, 0.14 mg/kg (n=4), as received.

According to the Codex Classification, ginseng should comply with Codex Standard 295R-2009. This regional standard has been replaced by Codex Standard 321-2015. Codex Standard 321-2015 stipulates that dried ginseng roots should contain no more moisture than 14.0 percent (i.e. have a dry matter content of at least 86.0 percent). The actual dry matter content of the individual dried ginseng root samples from the supervised field trials were not reported, but were estimated at 70 percent–90 percent in the study report.

The Meeting concluded that residues in ginseng roots with an estimated dry matter content of 70–90 percent were not affected by more than 25 percent ($100 \text{ percent} \times (86-70) / 86 = 18.6 \text{ percent}$). The Meeting considered four trials sufficient for the minor crop ginseng roots and estimated a maximum residue level of 0.3 mg/kg, a HR of 0.16 mg/kg (highest individual) and an STMR of 0.081 mg/kg for benzovindiflupyr in dried ginseng roots (DV 0604 and DT 0604).

Sugar beet roots

Benzovindiflupyr is registered in the United States on sugar beets with two different GAPs:

- A) a single in-furrow or banded soil application at 0.075 kg ai/ha at the 2–8 leaf-stage, followed by a foliar application at 0.075 kg ai/ha up to BBCH 31;

- B) two foliar applications at 2×0.075 kg ai/ha with an RTI of 5 days and the last application applied up to BBCH 31.

The Meeting considered the two foliar applications (GAP B) as cGAP. Because all the supervised trials provided to the Meeting were conducted with the combined soil and foliar treatment (GAP A) with a longer RTI of 25–46 days between the soil and subsequent foliar application, none of the trials matched the cGAP. The Meeting decided that the trials were not suitable to derive maximum residue levels.

Maize grains

Benzovindiflupyr is registered in Canada on maize (field corn, popcorn, sweet corn, specialties) with a cGAP of 2×0.075 kg ai/ha, an RTI of 7 days and a PHI of 7 days. None of the trials provided to the present or previous JMPR Meetings matched with this GAP.

Benzovindiflupyr is registered in the United States on maize (field corn) and popcorn with a cGAP rate of 2×0.051 kg ai/ha, a retreatment interval (RTI) of 14 days and a PHI of 7 days.

Seven supervised trials on maize from the United States performed at 2×0.050 – 0.053 kg ai/ha with an RTI of 13–15 days and a PHI of 6–7 days approximated this cGAP. Residues of benzovindiflupyr in maize grains were: < 0.01 (6), 0.016 mg/kg (n=7).

The Meeting estimated a maximum residue level of 0.02 mg/kg and an STMR of 0.01 mg/kg for benzovindiflupyr in maize (GC 0645). The Meeting decided to extrapolate this MRL to popcorn (GC 0656).

Residues in animal feeds

Maize forage

Benzovindiflupyr is registered in Canada on maize (field corn, popcorn, sweet corn, specialties) with a cGAP of 2×0.075 kg ai/ha, an RTI of 7 days and a PHI of 7 days. None of the trials provided to the present or previous JMPRs matched with this GAP.

Benzovindiflupyr is registered in the United States on maize (field corn) and popcorn with a cGAP rate of 2×0.051 kg ai/ha, a retreatment interval (RTI) of 14 days and a PHI of 7 days.

Trials provided as maize forage (whole plant) that could possibly be matched to the US GAP, were harvested at BBCH 85–89. The Meeting considered these samples not representative for green forage plants, as the plants already lost moisture and thus may have concentrated their residues. The Meeting decided not to derive median and highest residues for maize forage.

Maize stover

Benzovindiflupyr is registered in Canada on maize (field corn, popcorn, sweet corn, specialties) with a cGAP of 2×0.075 kg ai/ha, a retreatment interval (RTI) of 7 days and a PHI of 7 days. None of the trials provided to the present or previous JMPRs matched with this GAP.

Benzovindiflupyr is registered in the United States on maize (field corn) and popcorn with a cGAP rate of 2×0.051 kg ai/ha, an RTI of 14 days and a PHI of 7 days.

Seven supervised trials on maize stover (remaining plant) from the United States performed at 2×0.050 – 0.053 kg ai/ha with an RTI of 13–15 days and a PHI of 6–7 days approximated this cGAP. Residues of benzovindiflupyr in maize stover were: 0.86, 1.2, 1.3, 1.6, 1.7, 2.3, 2.9 mg/kg (n=7) on an as received basis (assuming a dry matter content of 83 percent derived from the OECD 2018 feed calculator), corresponding to 1.0, 1.5, 1.6, 1.9, 2.0, 2.8, 3.5 mg/kg (n=7) on dry weight basis

The Meeting estimated a maximum residue level of 7 mg/kg, as dry weight and a median residue of 1.6 mg/kg and a highest residue of 2.9 mg/kg as received for maize stover. The Meeting decided to extrapolate these residues to popcorn stover.

Sugar beet leaves and tops

Benzovindiflupyr is registered in the United States on sugar beets with two different GAPs:

- A) a single in-furrow or banded soil application at 0.075 kg ai/ha at the 2–8 leaf-stage, followed by a foliar application at 0.075 kg ai/ha up to BBCH 31.
- B) two foliar applications at 2× 0.075 kg ai/ha with an RTI of 5 days and the last application applied up to BBCH 31.

The Meeting considered the two foliar applications (GAP B) as cGAP. Because all the supervised trials provided to the Meeting were conducted with the combined soil and foliar treatment (GAP A) with a longer RTI of 25–46 days between the soil and subsequent foliar application, none of the trials matched the cGAP. The Meeting decided that the trials were not suitable to derive maximum residue levels.

Fate of residues during processing

The Meeting received new information on the fate of benzovindiflupyr residues during processing in sugar beet roots. Furthermore, median and highest residues could be derived for maize processed commodities, based on the processing data evaluated by the JMPR 2016.

Table 5.3.2 Estimation of processing factors for commodities considered at this and previous Meetings

Raw commodity (STMR/HR)	Processed commodity	Individual processing factors	Mean or best estimate processing factor	STMR-P = STMR-RAC × PF (mg/kg)	HR-P = HR-RAC × PF (mg/kg)
Maize grains (0.01 mg/kg)	Maize meal (JMPR 2016)	< 0.25	< 0.25 (n=1)	0.0025	
	Maize flour (JMPR 2016)	0.25	0.25 (n=1)	0.0025	
	Maize grits (JMPR 2016)	< 0.25	< 0.25 (n=1)	0.0025	
	Maize refined oil (wet processing) (JMPR 2016)	0.50	0.50 (n=1)	0.0050	
	Maize starch (JMPR 2016)	< 0.25	< 0.25 (n=1)	0.0025	
	Maize gluten (JMPR 2016)	0.75	0.75 (n=1)	0.0075	
	Maize bran (JMPR 2016)	0.50	0.50 (n=1)	0.0050	
	Maize milled by-product (JMPR 2016)	< 0.25	< 0.25 (n=1)	0.0025	

Residues in animal commodities

Dietary burdens were calculated for beef cattle, dairy cattle, broilers and laying poultry based on feed items evaluated by the current and previous JMPRs and including maize grains and maize stover. The dietary burdens, estimated using the 2018 update of the OECD feed calculator, are presented in Annex 6 of the 2022 JMPR Report and summarized below.

Table 5.3.3 Estimated maximum and mean dietary burdens of farm animals

	Animal dietary burden: benzovindiflupyr, ppm of dry matter diet							
	United States-Canada		European Union		Australia ^{/a}		Japan	
	max	mean	max	mean	max	mean	max	mean
Beef cattle	3.035	1.269	6.894	2.559	14.80 ^①	4.200 ^③	0.661	0.466
Dairy cattle	8.093	3.012	7.519	3.029	14.33 ^②	4.065 ^④	3.520	1.830
Poultry-broiler	0.196	0.196	0.270	0.270	0.065	0.065	0.047	0.047
Poultry-layer	0.194	0.194	2.154 ^⑤	0.894 ^⑥	0.065	0.065	0.039	0.039

Notes:

- ① Highest maximum beef or dairy cattle dietary burden suitable for MRL estimates for mammalian tissues.
- ② Highest maximum dairy cattle dietary burden suitable for MRL estimates for mammalian milk.
- ③ Highest mean beef or dairy cattle dietary burden suitable for STMR estimates for mammalian tissues.
- ④ Highest mean dairy cattle dietary burden suitable for STMR estimates for milk.
- ⑤ Highest maximum poultry dietary burden suitable for MRL estimates for poultry tissues and eggs.
- ⑥ Highest mean poultry dietary burden suitable for STMR estimates for poultry tissues and eggs.

The 2019 JMPR estimated a mean/maximum dietary burden of 5.145/14.80 ppm for beef cattle, 5.145/14.33 ppm for dairy cattle and 0.857/2.075 ppm for layer poultry. The Meeting noted that the contribution of maize grain and maize stover increased the mean dietary burdens for poultry by less than 10 percent. The Meeting therefore confirmed its previous recommendations for maximum residue levels in animal products.

Residue values for exposure calculations

The 2022 JMPR re-evaluated the study reports provided to previous Meetings in order to obtain field trial information for N-desmethyl pyrazole acid (SYN 545720) and Hydroxy-benzovindiflupyr (SYN 546039) (see Table below). Parent residue values were corrected where necessary (see Table below). Correct parent residue values were used in the dietary burden calculations, IEDI, international estimate of short-term intakes and GECDE estimations conducted by the 2022 JMPR.

Table 5.3.4 Corrected previously residue values

Commodity	Compound	Selected residues (mg/kg)
Group of Pome fruit	Parent (corrected values in bold)	0.020, 0.022, 0.026 , 0.031, 0.038, 0.039, 0.040 , 0.041, 0.042, 0.044, 0.048, 0.057 , 0.058 , 0.060 , 0.062, 0.066 , 0.067, 0.069, 0.074, 0.086 , 0.096, 0.10, 0.16 mg/kg (n=23) with HR of 0.17 mg/kg (individual highest residue) and an STMR of 0.057 mg/kg
	SYN 546039 including conjugates	< 0.01 (23) mg/kg (n=23) with HR of 0.01 mg/kg and STMR of 0.01 mg/kg
Grapes	Parent (corrected values in bold)	0.089 , 0.10, 0.11, 0.15, 0.16 , 0.16, 0.23 , 0.36 , 0.39, 0.40 , 0.47, 0.55, 0.76 mg/kg (n=13) with HR of 0.81 mg/kg (highest individual) and an STMR of 0.23 mg/kg
	SYN 546039 including conjugates	0.018, 0.020, 0.022 (2), 0.032, 0.039, 0.041 , 0.056, 0.056, 0.10, 0.078, 0.081, 0.19 mg/kg (n=13) with HR of 0.22 mg/kg (highest individual) and an STMR of 0.041 mg/kg – (residues are often higher at higher PHI)
Subgroup of Bulb onions	Parent	JMPR 2019: < 0.01 (5), 0.011, 0.012 and 0.015 mg/kg (n=8) with an HR of 0.015 mg/kg and an STMR of 0.01 mg/kg
	SYN 546039 including conjugates	< 0.01 (8) mg/kg (n=8) with an HR of 0.01 mg/kg and an STMR of 0.01 mg/kg
Group of Cucurbits	Parent	JMPR 2016: < 0.01 (2), 0.010, 0.013, 0.017, 0.018, 0.022 (2), 0.023 , 0.026, 0.033, 0.049, 0.050, 0.052, 0.053, 0.12 and 0.14 mg/kg (n=17) with HR of 0.16 mg/kg (highest individual residue) and an STMR of 0.023 mg/kg based

Commodity	Compound	Selected residues (mg/kg)
		on combined data from cucumbers, summer squash and melons
	SYN 546039 including conjugates	< <u>0.01</u> (14), 0.014, 0.014, 0.018 (n=17) mg/kg with an HR of 0.018 mg/kg and an STMR of 0.01 mg/kg
Group of Fruiting vegetables, other than Cucurbits	Parent (corrected values in bold)	< 0.01, 0.040, 0.040, 0.044, 0.053, 0.054, 0.060, 0.060 , 0.061, <u>0.085, 0.093</u> , 0.10, 0.11, 0.14, 0.20, 0.35, 0.36, 0.38, 0.43, 0.62 mg/kg (n=20) with an HR of 0.72 mg/kg (highest individual) and an STMR of 0.089 mg/kg
	SYN 546039 including conjugates	< <u>0.01</u> (19), 0.016 mg/kg with an HR of 0.016 mg/kg and an STMR of 0.01 mg/kg
Subgroup of dry beans (excl soya beans)	Parent (corrected values in bold)	< 0.01 (5), 0.010, 0.010 , 0.011, 0.016, 0.020, 0.044, 0.044 , 0.078 mg/kg (n=13) with an STMR of 0.010 mg/kg
	SYN 546039 including conjugates	< 0.01 (13) mg/kg with an STMR of 0.01 mg/kg
	SYN 545720	< 0.01 (13) mg/kg with an STMR of 0.01 mg/kg
Dry soya beans	Parent (corrected values in bold)	< <u>0.01</u> (15), 0.011 , 0.012, 0.018, 0.064 mg/kg (n=19) with an STMR of 0.01 mg/kg
	SYN 546039 including conjugates	< <u>0.01</u> (19) mg/kg with an STMR of 0.01 mg/kg
	SYN 545720	< <u>0.01</u> (19) mg/kg with an STMR of 0.01 mg/kg
Subgroup of dry peas	Parent (corrected values in bold)	< 0.01 (4), < 0.01, 0.014, 0.024 , 0.033, 0.054 , 0.11 mg/kg (n=10) with an STMR of 0.012 mg/kg
	SYN 546039 including conjugates	< <u>0.01</u> (9), 0.025 mg/kg (n=10) with an STMR of 0.01 mg/kg
	SYN 545720	< 0.01 (9), 0.020 mg/kg (n=10) with an STMR of 0.01 mg/kg
Potatoes	Parent (corrected values in bold)	< <u>0.01</u> (8), 0.010, 0.013, 0.014, 0.015 mg/kg (n=12) with an HR of 0.018 mg/kg (highest individual) and an STMR of 0.01 mg/kg
	SYN 546039 including conjugates	< 0.01 (12) mg/kg (n=12) with an HR of 0.01 mg/kg and an STMR of 0.01 mg/kg
Wheat, rye and triticale	Parent (corrected values in bold)	< 0.01 (8), 0.011, 0.012 (2), 0.014 , 0.017, 0.020, <u>0.021, 0.025</u> (2), 0.026 (2), 0.027, 0.030 , 0.032, 0.034, 0.040 , 0.041, 0.042, 0.046, 0.059, 0.066, 0.073 mg/kg (n=30) with an STMR of 0.023 mg/kg
	SYN 546039 including conjugates	< <u>0.01</u> (29), 0.011 mg/kg (n=30) with an STMR of 0.01 mg/kg
Barley and oats	Parent (corrected values in bold)	0.014, 0.029, 0.061, 0.078, 0.15, 0.21 , 0.26, 0.32, 0.42, 0.54, 0.59 mg/kg (n=11) with an STMR of 0.21 mg/kg
	SYN 546039 including conjugates	< <u>0.01</u> (9), 0.025, 0.035 mg/kg (n=11) with an STMR of 0.01 mg/kg
Sweetcorn on the cob (with husks removed)	Parent	JMPR 2016: < <u>0.01</u> (15) mg/kg with an HR of 0.01 mg/kg and an STMR of 0.01 mg/kg based on trials in the US
	SYN 546039 including conjugates	< <u>0.01</u> (15) mg/kg (n=15) with an HR of 0.01 mg/kg and an STMR of 0.01 mg/kg
Sugar cane canes (and tops)	Parent (corrected values in bold)	0.013, 0.030 , 0.062, <u>0.068, 0.070</u> , 0.12 , 0.14, 0.21 mg/kg (n=8) with an HR of 0.25 mg/kg (highest individual) and an STMR of 0.069 mg/kg
	SYN 546039 including conjugates	< 0.01 (8) mg/kg (n=8) with an HR of 0.01 mg/kg and an STMR of 0.01 mg/kg
Rapeseed, seed	Parent	JMPR 2016: < 0.01 (2), 0.011, 0.019, <u>0.023</u> , 0.031, 0.045, 0.062 and 0.10 mg/kg (n=9) with an STMR of 0.023 mg/kg based on trials in Canada
	SYN 546039 including conjugates	< <u>0.01</u> (9) mg/kg (n=9) with an STMR of 0.01 mg/kg
	SYN 545720	< <u>0.01</u> (9) mg/kg (n=9) with an STMR of 0.01 mg/kg
Peanuts, nutmeat	Parent	JMPR 2016 < <u>0.01</u> (4), 0.020 (2) mg/kg (n=6) with an STMR of 0.01 mg/kg based on trials in Brazil
	SYN 546039 including conjugates	< 0.01 (6) mg/kg (n=6) with an STMR of 0.01 mg/kg
	SYN 545720	< 0.01 (6) mg/kg (n=6) with an STMR of 0.01 mg/kg

Commodity	Compound	Selected residues (mg/kg)
Coffee beans, green	Parent	JMPR 2016: < 0.01 (3), 0.020 (2), and 0.070 mg/kg (n=6) with an STMR of 0.015 mg/kg based on trials in Brazil
	SYN 546039 including conjugates	< 0.01, < 0.01, < 0.01, < 0.01, < 0.01, 0.020 mg/kg (n=6) with an STMR of 0.01 mg/kg
	SYN 545720	< 0.01 (6) mg/kg (n=6) with an STMR of 0.01 mg/kg
Legume forage (excl peanuts and soya bean)	Parent (corrected values in bold)	0.28, 0.29, 0.43 , 0.61 , 0.93 mg/kg (n=5) with a highest residue of 0.97 mg/kg (highest individual) and a median residue of 0.43 mg/kg (as received)
	SYN 546039 including conjugates	0.15, 0.21, <u>0.34</u> , 0.58, 0.71 mg/kg (n=5) with a highest residue of 0.77 mg/kg (highest individual) and a median residue of 0.34 mg/kg (as received) Note: different sample choice compared to parent
Legume hay (excl peanuts, soya bean)	Parent (corrected values in bold)	1.1 , 1.8, <u>2.2</u> , 3.1, 3.6 mg/kg (n=5) with a highest residue of 3.9 mg/kg (highest individual) and a median residue of 2.2 mg/kg (as received)
	SYN 546039 including conjugates	0.92, 1.1, <u>1.1</u> , 3.0, 3.5 mg/kg (n=5) with a highest residue of 4.4 mg/kg (highest individual) and a median residue of 1.1 mg/kg (as received). Note: different sample choice compared to parent
Peanut hay	Parent (corrected values in bold)	unscaled: 0.43, 1.8, 2.7, 2.8, 2.8 , 2.8 , <u>3.0</u> , 3.7, 6.2 , 7.0, 7.2 , 7.6 , 9.0 mg/kg (n=13) with a highest residue of 10 mg/kg (highest individual) and a median residue of 3.0 mg/kg (as received) scaled (x0.75): highest individual residue of 7.5 mg/kg and median residue of 2.25 mg/kg (as received)
	SYN 546039 including conjugates	unscaled: 0.031, 0.12, 0.14, 0.21, 0.26, 0.26, <u>0.30</u> , 0.34, 0.31, 0.44, 0.66, 0.71, 1.3 mg/kg (n=13) with a highest residue of 1.8 mg/kg (highest individual) and a median residue of 0.30 mg/kg (as received). scaled (x0.75): highest individual residue of 1.35 mg/kg and median residue of 0.225 mg/kg (as received).
Wheat, barley, oat, rye, triticale forage	Parent (corrected values in bold)	< 0.01, 0.38, 0.40, 0.45, 0.48, 0.55, 0.56, 0.62, 0.66, 0.71, 0.73, 0.74, 0.82, 0.90, 0.94, 1.0 , 1.1 , 1.2, 1.2, 1.2, 1.3, 1.3, 1.4, 1.4, 1.4, 1.8, 1.8, 1.8, 1.9, 2.0, 2.2, 3.4 mg/kg (n=32) with a highest residue of 3.7 mg/kg (highest individual) and a median residue of 1.05 mg/kg (as received)
	SYN 546039 including conjugates	< 0.01, 0.022, 0.024, 0.043, 0.045, 0.058, 0.064, 0.077, 0.082, 0.084, 0.086, 0.086, 0.087, 0.088, 0.093, <u>0.095</u> , <u>0.10</u> , 0.10, 0.10, 0.11, 0.11, 0.11, 0.15, 0.15, 0.16, 0.16, 0.16, 0.16, 0.16, 0.18, 0.31, 0.32 mg/kg (n=32) with a highest residue of 0.38 mg/kg (highest individual) and median residue 0.0975 mg/kg (as received)
Wheat, barley, oat, rye, triticale hay and straw	Parent (corrected values in bold)	0.54, 0.72, 0.78, 1.0 , 1.4 , 1.5, 1.6, 1.6, 1.6 , 1.6 , 1.8 , 2.0 , 2.0 , 2.2, 2.2, 2.3, 2.4 , 2.5, 2.6, 2.6 , 2.8 , 2.9, <u>3.4</u> , 3.8, 3.8 , 3.9, 4.0, 4.0, 4.1, 4.7, 5.2, 5.2, 5.4, 5.5 , 6.0, 6.1, 6.2, 6.6, 6.9, 7.1, 7.2, 7.8 , 8.5, 8.6, 12 mg/kg (n=45) with a highest residue of 12 mg/kg and a median residue of 3.4 mg/kg (as received)
	SYN 546039 including conjugates	0.040, 0.061, 0.068, 0.070, 0.084, 0.085, 0.10, 0.12, 0.13, 0.14, 0.14, 0.15, 0.15, 0.15, 0.16, 0.16, 0.18, 0.18, 0.19, 0.20, 0.20, 0.21, <u>0.21</u> , 0.22, 0.24, 0.25, 0.25, 0.26, 0.28, 0.28, 0.30, 0.32, 0.33, 0.40, 0.40, 0.40, 0.41, 0.41, 0.42, 0.42, 0.46, 0.53, 0.65, 0.68, 1.2 mg/kg (n=45) with a highest residue of 1.3 mg/kg (highest individual) and a median residue of 0.21 mg/kg (as received)
Mammals	Parent	STMR: muscle < 0.01, fat 0.010, edible offal 0.012, milk < 0.01 HR: muscle < 0.01, fat 0.019, edible offal 0.064,
	SYN 546039 including conjugates	STMR: muscle < 0.01, fat 0.010, edible offal 0.012, milk < 0.01 HR: muscle < 0.01, fat 0.019, edible offal 0.037,
Poultry	Parent	STMR: muscle < 0.01, fat < 0.01, edible offal < 0.01, eggs < 0.01 HR: muscle < 0.01, fat < 0.01, edible offal < 0.01, eggs < 0.01
	SYN 546039 including conjugates	STMR: muscle < 0.01, fat < 0.01, edible offal < 0.01, eggs < 0.01 HR: muscle < 0.01, fat < 0.01, edible offal < 0.01, eggs < 0.01

Notes:

Parent corrected: after re-evaluation of the 2016 JMPR study reports, some parent values were corrected. Bold values in the 2016 JMPR parent data and current parent data indicate which values were corrected.

Source: Adapted from FAO and WHO 2017. Pesticide residues in food 2016–Report 2016–Joint FAO/WHO Meeting on Pesticide Residues. FAO Plant Production and Protection Paper, 229. Rome.

RECOMMENDATIONS

On the basis of the data obtained from supervised trials, the Meeting concluded that the residue levels listed in Annex 1 are suitable for establishing maximum residue limits and for IEDI, international estimate of short-term intakes and GECDE assessments.

Definition of the residue for compliance with the MRL and dietary risk assessment for plant and animal commodities: *benzovindiflupyr*

The residue is fat-soluble.

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The ADI for benzovindiflupyr is 0–0.05 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for benzovindiflupyr were estimated for the 17 GEMS/Food Consumption Cluster Diets using the STMR or STMR-P values estimated by the 2022 and previous JMPRs. The results are shown in Annex 3 of the 2022 JMPR Report.

The IEDIs ranged from 0.27–1.9 percent of the maximum ADI. The Meeting concluded that long-term dietary exposure to residues of benzovindiflupyr from uses considered by the 2022 and previous JMPRs is unlikely to present a public health concern.

Acute dietary exposure

The ARfD for benzovindiflupyr is 0.1 mg/kg bw. The International Estimate of Short Term Intakes (international estimate of short-term intake) for benzovindiflupyr were calculated for the food commodities and their processed commodities for which HRs/HR-Ps or STMRs/STMR-Ps were estimated by the present Meeting and for which consumption data were available. The results are shown in Annex 4 of the 2020 JMPR Report.

The international estimate of short-term intake varied from 0–10 percent of the ARfD for children and 0–9 percent of the ARfD for the general population. The Meeting concluded that acute dietary exposure to residues of benzovindiflupyr from uses considered by the present Meeting is unlikely to present a public health concern.

Threshold of toxicological concern (TTC) consideration for metabolites

The three cleavage products (pyrazole amide, pyrazole acid and N-desmethyl pyrazole acid) are common to other pyrazole fungicides like bixafen, fluindapyr, fluxapyroxad, inpyrfluxam, isopyrazam and sedaxane. In the absence of overall information on the uses of all active substances and considering the lack of a specific health-based guidance value, the Meeting decided there was insufficient information to perform a combined risk assessment for residues resulting from use with all active substances leading to formation of these three cleavage products. The Meeting concluded that the three cleavage products (pyrazole

amide, pyrazole acid and N-desmethyl pyrazole acid) could be assessed using the TTC approach (Cramer Class III threshold of 1.5 µg/kg bw per day) and that the exposure should be based on the anticipated residues following use of each active substance, separately.

Pyrazole amide (SYN 508272) and pyrazole acid (NOA 449410) were detected at low levels in food crops (<1 percent TRR, < 0.01 mg/kg eq), and animal commodities (<5 percent TRR, < 0.01 mg/kg eq) in the metabolism studies evaluated by the 2014 JMPR.

N-desmethyl pyrazole acid (SYN 545720, including conjugates) was present at moderate levels in the metabolism studies on seeds of pulses/oilseeds (47 percent TRR, 0.047 mg/kg eq, ratio 47/15 to parent) evaluated by the 2014 JMPR. It was detected at low levels in fruit crops (0.1 percent TRR, < 0.001 mg/kg eq, ratio 0.2/91 to parent). It was not detected in cereals grains or animal commodities.

Actual levels of N-desmethyl pyrazole acid (including conjugates) in field trials conducted at cGAP were < 0.01–0.020 mg/kg in dry pea seeds and < 0.01 mg/kg in dry beans, dry soya bean seeds, rape seeds, peanut nutmeat and green coffee beans.

Based on the benzovindiflupyr uses evaluated by the 2022 and previous JMPRs and the ratios to parent derived from metabolism studies, the Meeting estimated the following dietary exposures:

- Pyrazole amide (SYN 508272): 0.0003–0.0026 µg/kg bw per day (IEDI)
- Pyrazole acid (NOA 449410): 0.0008–0.0045 µg/kg bw per day (IEDI)
- N-desmethyl pyrazole acid (SYN 545720) 0.0075–0.0399 µg/kg bw per day (IEDI). This last estimate could be refined to 0.0052–0.0248 µg/kg bw per day using the field trial information for SYN545720 for pulses, oilseeds and coffee beans (see Annex below).

The Meeting concluded that the estimated dietary exposure to residues of pyrazole amide, pyrazole acid and N-desmethyl pyrazole acid from benzovindiflupyr uses considered by the 2022 and previous JMPRs is below the TTC for Cramer Class III compounds and is unlikely to present a public health concern. Should further benzovindiflupyr uses be considered in the future, these conclusions may need to be re-evaluated.

5.4 Benzpyrimoxan (325)

TOXICOLOGY

Benzpyrimoxan is the ISO-approved common name for 5-(1,3-dioxan-2-yl)-4-[4-(trifluoromethyl)benzyloxy]pyrimidine (IUPAC), Chemical Abstracts Service number 1449021-97-9. Benzpyrimoxan is a new insecticide having biological activity towards rice plant hoppers (Hemiptera: Delphacidae). Benzpyrimoxan displays strong activity towards the nymphal stages of rice plant hoppers, but lacks activity towards the adults.

Benzpyrimoxan has not previously been evaluated by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) and was reviewed by the present Meeting at the request of the Codex Committee on Pesticide Residues (CCPR). All critical studies were performed according to national or international test guidelines and contained statements of compliance with good laboratory practice (GLP) unless otherwise specified. No information was identified in the public domain from a search of the PubMed, Google Scholar and Web of Science databases, not surprisingly for such a new chemical with an unknown pesticidal mode of action (MOA).

Biochemical aspects

The absorption, distribution, metabolism, excretion and toxicokinetic properties of benzpyrimoxan have been investigated in the rat using two different radiolabelled test materials (on the phenyl and pyrimidinyl rings) administered orally. A study in bile duct-cannulated rats with the two labels was also available. In addition an *in vitro* comparative metabolism study was provided.

Following oral administration of ¹⁴C-labelled benzpyrimoxan as a single low dose of 1 mg/kg body weight (bw) to rats, the compound was rapidly and extensively absorbed. In bile duct-cannulated rats, oral absorption was approximately 76–83 percent (mean 80 percent) of administered radioactivity (AR) at the low dose of 1 mg/kg bw based on the sum of radioactivity excreted in bile (29–46 percent AR) and urine (36–48 percent AR), and residual radioactivity in the gastrointestinal (GI) tract and liver (0.1 percent AR) by 72 hours after dosing. At the high single dose of 100 mg/kg bw, absorption was only slightly slower and less. At the low dose, radioactivity in blood and plasma reached maximum concentrations (T_{max}) at 1–9 hours post dose, then rapidly decreased in a biphasic pattern. At the high dose, the area under the curve (AUC) was approximately 50–80 times higher (that is, slightly less than dose-proportional) when compared to the low dose, and the T_{max} was in the range of 6–12 hours post dosing.

No significant sex-related, dose-related or label-related differences were noted in the distribution profile of benzpyrimoxan. At around the T_{max} the highest level of radioactivity was found in the GI contents, followed by the liver, plasma, GI tract itself, kidneys and adrenals. By 24 hours post dose, radioactivity concentrations in all organs and tissues had significantly decreased and by 168 hours post dose were nearly negligible, suggesting that no organs or tissues specifically retained benzpyrimoxan and/or its metabolites.

The absorbed radioactivity was rapidly excreted via urine, faeces and expired air. Radioactivity in expired air was confirmed as ¹⁴C carbon dioxide. At the low dose, radioactivity in urine, faeces and expired air accounted for 39–65 percent, 33–44 percent and 6 percent AR respectively by 168 hours post dosing. Almost all the radioactivity excreted in faeces resulted from biliary excretion. At the high dose, radioactivity in urine, faeces and expired air accounted for 36–45 percent, 54–58 percent and 2.4 percent AR respectively by 168 hours post dosing. These data indicate that at the high dose of 100 mg/kg bw more radioactivity was eliminated via faeces, possibly resulting from unabsorbed material.

Benzpyrimoxan was extensively metabolized, with up to nine metabolites identified in plasma, 15 in urine and six in bile. Unchanged parent compound was detected only in faeces, in small amounts (0.19–0.39 percent AR) at the low dose but at much higher levels (24–29 percent AR) with the high dose. Neither sex nor dose level had any significant impact on metabolism. Metabolite DH-05 was the only major metabolite in urine, accounting for 14–28 percent of administered dose (AD) at the low dose, whilst the DH-02 conjugates were the only major metabolites in bile, accounting for 13–14 percent AD at the low dose. In plasma, at the low dose, DH-01 was a major metabolite, accounting for 79–85 percent of the total radioactive residue (TRR) in this matrix at six hours post dosing (around the T_{max}). At the high dose, DH-01 and DH-101 were significant metabolites, accounting for 21–32 percent and 23–30 percent respectively of the plasma TRR at nine hours post dosing (around the T_{max}).

Overall, no significant differences between phenyl-labelled and pyrimidine-labelled benzpyrimoxan were seen in the absorption, distribution, metabolism, excretion or toxicokinetic profiles of rats.

In an *in vitro* comparative metabolism study with rat, mouse, dog and human liver microsomes, the main metabolites detected in all species were DH-01, DH-02, DH-05, DH-22 and DH-101. There were no qualitative differences between species in metabolite profiles and no significant unique human metabolite was detected.

Toxicological data

The acute oral median lethal dose (LD_{50}) of benzpyrimoxan in rats was greater than 2000 mg/kg bw and the dermal LD_{50} in rats was greater than 2000 mg/kg bw. The inhalation median lethal concentration (four-hour LC_{50}) of a benzpyrimoxan aerosol in rats was greater than 3.9 mg/L, the maximum attainable concentration. Benzpyrimoxan was a very slight irritant to rabbit skin. It was non-irritant in an *in vitro* eye irritation test and slightly irritant to the rabbit eye *in vivo*. Benzpyrimoxan was sensitizing to skin in a Guinea pig maximization test when tested at concentrations up to 50 percent in olive oil, but was negative in a local lymph node assay (LLNA) at up to 10 percent in acetone/olive oil.

The short-term toxicity of benzpyrimoxan was investigated by the dietary route in studies with mice, rats and dogs. The main target organs of toxicity in all species were the liver and the haematological system, with associated effects on spleen and/or bone marrow. In addition, effects on the kidney and urinary bladder, due to the deposition of crystals, with ensuing obstructive nephropathy were noted in mice and rats. Mice appeared the least sensitive species to the toxicity of benzpyrimoxan, with rats and dogs showing similar sensitivity.

The effects on the urinary system caused by benzpyrimoxan in rats and mice, but not in dogs were considered unlikely to be relevant to humans. A mechanistic study showed that the different responses observed in rodents and dogs appeared to be due to differences in the critical concentration at which the main constituent of the crystals (metabolite DH-05) crystallises in the glomerular filtrate when it is concentrated. The effect was not due to species differences in the formation of DH-05, as this metabolite was formed *in vitro* not only in rats and mice, but also in dogs and humans. Rather the cause lay in a number of species differences in urinary concentration rates and urine composition.

In the subsequent 90-day dietary study in mice, benzpyrimoxan was administered at concentrations of 0, 400, 2000 or 4000 (males)/6000 (females) ppm (equal to 0, 56, 282 and 523 mg/kg bw per day for males, 0, 66, 327 and 971 mg/kg bw per day for females). The NOAEL was 400 ppm (equal to 56 mg/kg bw per day) based on liver (hypertrophy) and spleen (extramedullary haemopoiesis) histopathological changes associated with changes in organ weights and/or

haematological and clinical chemistry findings (increased alanine and aspartate aminotransferase [ALT and AST] activities) at the LOAEL of 2000 ppm (equal to 282 mg/kg bw per day).

In a 90-day dietary study in rats, benzpyrimoxan was administered at concentrations of 0, 100, 300, 1000 or 3000 ppm (equal to 0, 6.26, 18.7, 64.2 and 194 mg/kg bw per day for males, 0, 7.41, 22.2, 78.1 and 227 mg/kg bw per day for females). The NOAEL was 300 ppm (equal to 18.7 mg/kg bw per day) based on clinical chemistry (increased plasma γ -glutamyl transpeptidase [GGTP] and total cholesterol in females and increased AST in males) and increased liver weight at the LOAEL of 1000 ppm (equal to 64.2 mg/kg bw per day).

In a 90-day dietary study in dogs, benzpyrimoxan was administered at concentrations of 0, 500, 2500 or 10 000 ppm, (equal to 0, 17, 79 and 302 mg/kg bw per day for males, 0, 16, 81 and 246 mg/kg bw per day for females). The NOAEL was 500 ppm (equal to 16 mg/kg bw per day) based on liver toxicity (increased weight, hypertrophy and increased levels of ALP, total cholesterol, triglycerides and phospholipids) and bone marrow histopathology (hypocellularity of femoral bone marrow in females) at the LOAEL of 2500 ppm (equal to 79 mg/kg bw per day).

In a one-year dietary study in dogs, benzpyrimoxan was administered at concentrations of 0, 100, 500 or 2500 ppm (equal to 0, 2.9, 14.6 and 71 mg/kg bw per day for males, 0, 2.7, 14.3 and 67 mg/kg bw per day for females). The NOAEL was 500 ppm (equal to 14.3 mg/kg bw per day) based on increased platelet count in both sexes, liver toxicity (increased relative weight in both sexes), hepatocyte brown pigmentation (lipofuscin) in both sexes, hypertrophy in males, increased levels of total cholesterol, triglycerides and phospholipids in males and increased levels of ALP in females, at the LOAEL of 2500 ppm (equal to 67 mg/kg bw per day).

The overall NOAEL for the dog was 500 ppm (equal to 16 mg/kg bw per day) on the basis of the 90-day and one-year study, with an overall LOAEL of 2500 ppm (equal to 67 mg/kg bw per day).

In a carcinogenicity dietary study in mice, benzpyrimoxan was administered at concentrations of 0, 80, 400 or 2000 (males)/1500 (females) ppm, (equal to 0, 7.7, 40 and 195 mg/kg bw per day for males, 0, 8.9, 44 and 163 mg/kg bw per day for females). The carcinogenicity NOAEL was 1500 ppm (equal to 163 mg/kg bw per day), the highest dose tested. The NOAEL for chronic toxicity was 400 ppm (equal to 40 mg/kg bw per day) based on decreased body weight gain, gall bladder calculi and liver effects in both sexes at the LOAEL of 1500 ppm (equal to 163 mg/kg bw per day).

In a chronic toxicity/carcinogenicity study in rats, benzpyrimoxan was administered in the diet for one year (chronic toxicity group) or two years (carcinogenicity group), at dose levels of 0, 60, 300 or 1500 ppm (equal to 0, 2.3, 12 and 59 mg/kg bw per day for males, 0, 2.9, 15 and 78 mg/kg bw per day for females in the chronic phase: in the carcinogenicity phase this was 0, 2.7, 14 and 69 mg/kg bw per day for males, 0, 3.6, 17.5 and 90 mg/kg bw per day for females). The carcinogenicity NOAEL was 1500 ppm (equal to 69 mg/kg bw per day), the highest dose tested. The top dose caused significant toxicity. The NOAEL for chronic toxicity was 300 ppm (equal to 14 mg/kg bw per day) based on decreased body weights and body weight gains, changes in some haematological and clinical chemistry parameters, and increased weights of liver with associated histopathological changes at the LOAEL of 1500 ppm (equal to 69 mg/kg bw per day).

The Meeting concluded that benzpyrimoxan is not carcinogenic in mice or rats.

The genotoxic potential of benzpyrimoxan was investigated in an adequate range of in vitro and in vivo tests. No evidence indicating induction of gene mutation or structural chromosomal aberrations was found. Benzpyrimoxan induced polyploidy in vitro in Chinese hamster lungs cells at precipitating concentrations following short-term exposure but not after long-term treatment, where the likelihood of

such an effect is much greater. Therefore, the finding was considered a chance observation. Benzpyrimoxan was negative in vivo in a bone marrow micronucleus study.

The Meeting concluded that benzpyrimoxan is unlikely to be genotoxic.

In view of the lack of carcinogenicity in mice and rats and the fact that the compound is unlikely to be genotoxic, the Meeting concluded that benzpyrimoxan is unlikely to pose a carcinogenic risk to humans.

In a two-generation reproduction toxicity study, benzpyrimoxan was given in the diet to rats at concentrations of 0, 60, 300 or 2000 ppm (equal to 0, 2.5, 12 and 85 mg/kg bw per day for males, 0, 4.7, 24 and 156 mg/kg bw per day for females). The NOAEL for parental toxicity was 300 ppm (equal to 12 mg/kg bw per day), based on effects on body weight, body weight gain, feed consumption and toxicity to the liver and thyroid at the LOAEL of 2000 ppm (equal to 85 mg/kg bw per day). The NOAEL for reproductive toxicity was 300 ppm (equal to 12 mg/kg bw per day) based on a slight reduction in the gestation index (number of females with live pups/number of pregnant females) for the F1 generation and increased post-implantation loss in both generations at a LOAEL of 2000 ppm (equal to 85 mg/kg bw per day). The NOAEL for offspring toxicity was also 300 ppm (equal to 12 mg/kg bw per day) based on reduced pup body weight and reduced viability on lactation days 0, 4 and 14 at the LOAEL of 2000 ppm (equal to 85 mg/kg bw per day).

In a rat prenatal developmental toxicity study, benzpyrimoxan was administered by gavage from gestation day (GD) 6–19 at 0, 10, 50 or 250 mg/kg bw per day. The NOAEL for maternal toxicity was 50 mg/kg bw per day based on effects on body weight, body weight gains, feed consumption and placental weight at 250 mg/kg bw per day. The NOAEL for embryo/fetal toxicity was 250 mg/kg bw per day, the highest dose tested.

In a rabbit prenatal developmental toxicity study, benzpyrimoxan was administered by gavage from GDs 6 to 27 at 0, 3, 10 or 30 mg/kg bw per day. The NOAEL for maternal toxicity was 10 mg/kg bw per day based on effects on body weight, body weight gains, food consumption, gravid uterine weight and abortions at 30 mg/kg bw per day. The NOAEL for embryo/fetal toxicity was 10 mg/kg bw per day, based on reduced fetal weight at 30 mg/kg bw per day. It is noted that fetal effects were most likely secondary, unspecific consequence of maternal toxicity.

The Meeting concluded that benzpyrimoxan is not teratogenic.

In an acute neurotoxicity study benzpyrimoxan was administered to rats by single gavage dose at 0, 500, 1000 or 2000 mg/kg bw. The NOAEL for acute neurotoxicity and general toxicity was 2000 mg/kg bw, the highest dose tested. No specific neurotoxicity study with repeated administration was available but functional neurological examinations in the 90-day rat study and histopathological examination of the brain, spinal cord and sciatic nerve in short-term and long-term studies in rats and mice showed no evidence of neurotoxicity.

The Meeting concluded that benzpyrimoxan is not neurotoxic.

No specific immunotoxicity study was available, but no concern was identified from the available studies. The Meeting concluded that benzpyrimoxan is unlikely to be immunotoxic.

Toxicological data on metabolites and/or degradates

The metabolites found in crops and livestock, and/or after high temperature hydrolysis, were DH-01, DH-02, DH-02-glucuronide, DH-03, DH-04, DH-05, DH-06, DH-06-glucuronide, DH-07, DH-08, DH-101, DH-102 and DH-402.

Metabolites DH-01, DH-02, DH-05 and DH-101 are major rat metabolites and hence considered covered by the parent.

Metabolite DH-02-glucuronide is easily cleaved in the human gastrointestinal tract to release the aglycone, DH-02. The aglycone is considered a major rat metabolite and hence, covered by the parent. Therefore DH-02-glucuronide is also covered by parent.

Metabolite DH-402: based on the levels found in the rat and by read-across from the major rat metabolite DH-101, DH-402 is considered covered by parent.

Metabolites DH-03, DH-06, DH-07 and DH-102 are either not present in the rat or are not major rat metabolites. However, genotoxicity QSAR analysis, limited genotoxicity experimental data (Ames test for DH-102) and genotoxicity read-across evaluation indicated that they are unlikely to be genotoxic. Therefore, if a dietary risk assessment were to be required for DH-03, DH-06, DH-07 or DH-102, the TTC Cramer class III value of 1.5 µg/kg bw per day should be used.

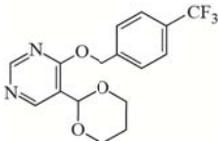
Metabolite DH-06-glucuronide is easily cleaved in the human gastrointestinal tract to release the aglycone DH-06. Since the aglycone is unlikely to be genotoxic, in the absence of further information it has been assigned the TTC Cramer class III value. Therefore, DH-06 glucuronide is also assigned the TTC Cramer class III value of 1.5 µg/kg bw per day.

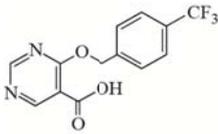
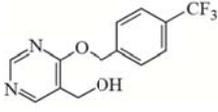
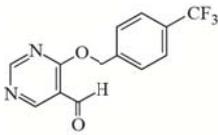
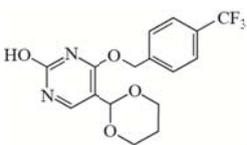
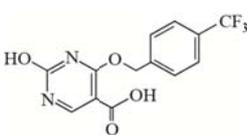
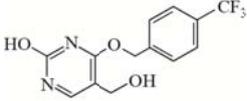
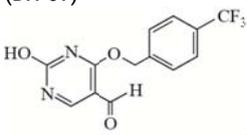
Metabolite DH-04 has been tested in genotoxicity and general toxicity studies. Metabolite DH-04 was negative in an Ames test and an in vitro micronucleus assay, was of low acute oral toxicity with an LD₅₀ of greater than 2000 mg/kg bw in rats, but caused appreciable toxicity in a dietary 90-day study in rats where a NOAEL of 19.6 mg/kg bw per day was identified based on the occurrence of considerable adverse effects at the LOAEL of 65.2 mg/kg bw per day. A comparison of these results with those obtained in the equivalent 90-day rat study performed with the parent substance indicate that DH-04 is approximately three times more toxic than benzpyrimoxan.

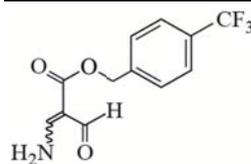
Metabolite DH-08; no information was available for this metabolite, therefore if a dietary risk assessment were to be required the genotoxicity TTC value of 0.0025 µg/kg bw per day should be used.

The table below provides an overall summary overview of the toxicological characterization of these metabolites.

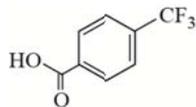
Summary of benzpyrimoxan and its metabolites

Compound, code and structure	Rat ADME			Reference value for dietary risk assessment
	Toxicity covered by toxicological properties of parent compound (content in rat biofluids >10 percent of absorbed dose)?	Genotoxicity assessment (data, QSAR, read-across)	General toxicity	
Benzpyrimoxan (NNI-1501) 	N/A	Unlikely to be genotoxic (data)	Full data-set	ADI: 0.1 mg/kg bw per day
NNI-1501-acid, (DH-01)	Yes	Unlikely to be genotoxic as covered by parent	Covered parent	by Parent ADI

	(high levels in plasma)			
NNI-1501-CH ₂ OH (DH-02) and its glucuronide	Yes (high levels in plasma)	Unlikely to be genotoxic as covered by parent	Covered by parent	Parent ADI
				
NNI-1501-aldehyde (DH-03)	No (not found in rat)	Unlikely to be genotoxic (QSAR and RA)	No information	TTC Cramer class III value: 1.5 µg/kg bw per day
				
NNI-1501-2-OH (DH-04)	No (not found in rat)	Unlikely to be genotoxic (data)	Three times more toxic than parent based on 90-day study	Approximately three times more toxic than parent
				
NNI-1501-acid-2-OH (DH-05)	Yes (high levels in urine)	Unlikely to be genotoxic as covered by parent	Covered by parent	Parent ADI
				
NNI-1501-CH ₂ OH-2-OH (DH-06) and its glucuronide	No (low levels in rat)	Unlikely to be genotoxic (QSAR and RA)	No information	TTC Cramer class III value: 1.5 µg mg/kg bw per day
				
NNI-1501-aldehyde-2-OH (DH-07)	No (not found in rat)	Unlikely to be genotoxic (QSAR and RA)	No information	TTC Cramer class III value: 1.5 µg/kg bw per day
				
NNI-1501-enamine-aldehyde, (DH-08)	No (not found in rat)	No information available	No information available	TTC for genotoxicity: 0.0025 µg/kg bw per day

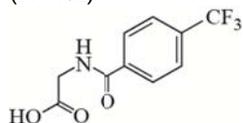


NNI-1501-benzoic acid Yes Unlikely to be genotoxic Covered by Parent ADI
(DH-101) (high levels in plasma) as covered by parent parent



NNI-1501-benzyl alcohol No Unlikely to be genotoxic No information TTC Cramer class
(DH-102) (not found in rat or at very (Ames + QSAR) available III value:
low levels) 1.5 µg/kg bw per
day

NNI-1501-benzoyl glycine Yes (high levels in urine and Unlikely to be genotoxic Covered by Parent ADI
(DH-402) kidneys + similar to major as covered by parent parent rat metabolite DH-101)



Notes:

QSAR: Quantitative structure–activity relationship.

RA: Read-across.

Microbiological data

There was no information available in the public domain and no experimental data were provided that addressed the possible impact of benzpyrimoxan residues on the human intestinal microbiome.

Human data

No information was available from the sponsor since benzpyrimoxan is a new compound. A literature search provided no information.

The Meeting concluded that the existing database on benzpyrimoxan was adequate to characterize the potential hazards to the general population, including fetuses, infants and children.

Toxicological evaluation

The Meeting established an ADI for benzpyrimoxan of 0–0.1 mg/kg bw based on the NOAEL of 10 mg/kg bw per day from the rabbit developmental study. A safety factor of 100 was applied. The rabbit NOAEL is supported by the NOAEL of 12 mg/kg bw per day for parental, offspring and reproductive toxicity in the two-generation rat study, the chronic NOAEL of 14 mg/kg bw per day from the rat two-year study, and the NOAEL of 14.3 mg/kg bw per day from the one-year dog study.

The parent compound's ADI applies also to DH-01, DH-05 and DH-04 (multiplied by three).

The Meeting concluded that it was not necessary to establish an acute reference dose (ARfD) for benzpyrimoxan in view of its low acute oral toxicity and the absence of developmental toxicity, neurotoxicity or any other toxicological effects that would be likely to be elicited by a single dose.

A toxicological monograph was prepared.

Levels relevant to risk assessment of benzpyrimoxan

Species	Study	Effect	NOAEL	LOAEL
Mouse	78-week study of carcinogenicity ^a	Toxicity	400 ppm, equal to 40 mg/kg bw per day	1500 ppm, equal to 163 mg/kg bw per day
		Carcinogenicity	1500 ppm, equal to 163 mg/kg bw per day ^c	
Rat	Acute neurotoxicity study ^b	Neurotoxicity	2000 mg/kg bw ^c	
		General toxicity	2000 mg/kg bw ^c	
	Two-year studies of toxicity and carcinogenicity ^a	Toxicity	300 ppm, equal to 14 mg/kg bw per day	1500 ppm, equal to 69 mg/kg bw per day
		Carcinogenicity	1500 ppm, equal to 69 mg/kg bw per day ^c	
	Two-generation study of reproductive toxicity ^a	Reproductive toxicity	300 ppm, equal to 12 mg/kg bw per day	2000 ppm, equal to 85 mg/kg bw per day
		Parental toxicity	300 ppm, equal to 12 mg/kg bw per day	2000 ppm, equal to 85 mg/kg bw per day
		Offspring toxicity	300 ppm, equal to 12 mg/kg bw per day	2000 ppm, equal to 85 mg/kg bw per day
	Developmental toxicity study ^b	Maternal toxicity	50 mg/kg bw per day	250 mg/kg bw per day
	Embryo/fetal toxicity	250 mg/kg bw per day ^c		
Rabbit	Developmental toxicity study ^b	Maternal toxicity	10 mg/kg bw per day	30 mg/kg bw per day
		Embryo/fetal toxicity	10 mg/kg bw per day	30 mg/kg bw per day
Dog	13-week and one-year studies of toxicity ^d	Toxicity	500 ppm, equal to 16 mg/kg bw per day	2500 ppm, equal to 67 mg/kg bw per day
Metabolite DH-04				
Rat	13-week study of toxicity ^a	Toxicity	300 ppm, equal to 19.6 mg/kg bw per day	1000 ppm, equal to 65.2 mg/kg bw per day

Notes:

^a Dietary administration.

^b Gavage administration.

^c Highest dose tested.

^d Two or more studies combined.

Acceptable daily intake (ADI) applies to benzpyrimoxan, DH-01, DH-05 and DH-04 (multiplied by 3)

0–0.1 mg/kg bw

Acute reference dose (ARfD)

Not necessary

Information that would be useful for the continued evaluation of the compound

Results from epidemiological, occupational health and other such observational studies of human exposure.

Critical end-points for setting guidance values for exposure to benzpyrimoxan***Absorption, distribution, excretion and metabolism in mammals***

Rate and extent of oral absorption	Rapid and extensive; 80 percent at 1 mg/kg bw
Dermal absorption	No data
Distribution	Wide; highest concentrations in liver, plasma, GI tract, kidney and adrenals
Potential for accumulation	No evidence of accumulation
Rate and extent of excretion	Rapid and nearly complete by 72 hours post dose via bile and urine
Metabolism in animals	Extensively metabolized
Toxicologically significant compounds in animals and plants	Parent, DH-01, DH-04 and DH-05

Acute toxicity

Rat, LD ₅₀ , oral	>2000 mg/kg bw
Rat, LD ₅₀ , dermal	>2000 mg/kg bw
Rat, LC ₅₀ , inhalation	>3.9 mg/L
Rabbit, dermal irritation	Mildly irritating
Rabbit, ocular irritation	Mildly irritating
Guinea pig, dermal sensitization	Sensitizing (Magnussen & Kligmann)

Short-term studies of toxicity

Target/critical effect	Liver weight and histopathology with associated clinical chemistry
Lowest relevant oral NOAEL	16 mg/kg bw per day (dog)
Lowest relevant dermal NOAEL	200 mg/kg bw per day (rat)
Lowest relevant inhalation NOAEC	0.1 mg/L (rat)

Long-term studies of toxicity and carcinogenicity

Target/critical effect	Decreased body weight, body weight gain, feed consumption, haematology and liver toxicity
Lowest relevant NOAEL	14 mg/kg bw per day (rat)
Carcinogenicity	Not carcinogenic

Genotoxicity

Unlikely to be genotoxic

Reproductive toxicity	
Target/critical effect	Parental: decreases in body weight, body weight gain and feed consumption; toxicity to liver and thyroid Offspring: decreased pup body weight, low viability index days 0, 4 and 14 Reproductive: decreased gestation index in F1 generation and increased post implantation loss in F1 and F2
Lowest relevant parental NOAEL	12 mg/kg bw per day (rat)
Lowest relevant offspring NOAEL	12 mg/kg bw per day (rat)
Lowest relevant reproductive NOAEL	12 mg/kg bw per day (rat)
Developmental toxicity	
Target/critical effect	Maternal: decreased body weight, body weight gain, feed consumption and gravid uterine weight, two abortions Embryo/fetal: reduced fetal weight
Lowest relevant maternal NOAEL	10 mg/kg bw per day (rabbit)
Lowest relevant embryo/fetal NOAEL	10 mg/kg bw per day (rabbit)
Neurotoxicity	
Acute neurotoxicity NOAEL	>2000 mg/kg bw, highest dose tested (rat).
Subchronic neurotoxicity NOAEL	No evidence from routine studies
Developmental neurotoxicity NOAEL	No data
Other toxicological studies	
Immunotoxicity	No evidence from routine studies
Studies on toxicologically relevant metabolites	
Metabolite DH-04	Acute oral LD ₅₀ : >2000 mg/kg bw (rat) 90-day NOAEL: 19.6 mg/kg bw per day (rat) Not genotoxic (Ames, micronucleus in vitro)
Microbiological data	No information available
Human data	No clinical cases or poisoning incidents have been recorded

Summary

	Value	Study	Safety factor
ADI	0–0.1 mg/kg bw a	Rabbit developmental study	100
ARfD	Unnecessary		

Notes:

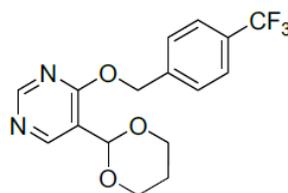
^a ADI applies to benzpyrimoxan, DH-01, DH-05 and DH-04 (multiplied by 3).

RESIDUE AND ANALYTICAL ASPECTS

Benzpyrimoxan is an insecticide (insect growth regulator) having biological activity to rice plant hopper larvae (Hemiptera: Delphacidae). Benzpyrimoxan has high activity against nymphal stages of rice plant hoppers without any adulticidal activity. It is registered for the control of sap sucking insects on rice.

At the Fifty-first Session of the CCPR (2019), it was scheduled for the evaluation as a new compound in 2020 and rescheduled to the 2022 JMPR. The Meeting received information on identity, physical and chemical properties, animal and plant metabolism, rotational crop study, environmental fate, analytical methods, GAP information, storage stability, processing, supervised residue trials and farm animal feeding study.

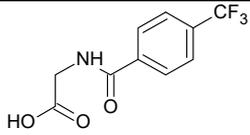
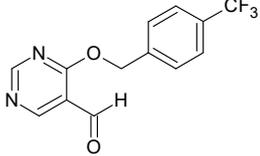
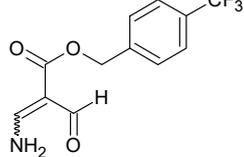
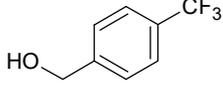
The IUPAC name for benzpyrimoxan is 5-(1,3-dioxan-2-yl)-4-[4-(trifluoromethyl)benzyloxy]pyrimidine.



The following abbreviations are used for the major metabolites discussed in Table 5.4.1 below.

Table 5.4.1 Metabolites and their codes referred to in the appraisal

Code	Name and Matrix	Structure
Benzpyrimoxan-2-OH DH-04	5-(1,3-dioxan-2-yl)-4-[[4-(trifluoromethyl)phenyl] methoxy]pyrimidin-2-ol Rice, Soil	
Benzpyrimoxan-acid-2-OH DH-05	2-hydroxy-4-[[4-(trifluoromethyl)phenyl] methoxy]pyrimidine-5-carboxylic acid Goat, Hen	
Benzpyrimoxan-CH ₂ OH DH-02	(4-[[4-(trifluoromethyl)phenyl] methoxy]pyrimidin-5-yl)methanol Goat, Hen	
Benzpyrimoxan-CH ₂ OH-2-OH DH-06	5-(hydroxymethyl)-4-[[4-(trifluoromethyl)phenyl] methoxy]pyrimidin-2-ol Goat, Hen	
Benzpyrimoxan-acid DH-01	4-[[4-(trifluoromethyl)phenyl] methoxy]pyrimidine-5-carboxylic acid Goat	

Code	Name and Matrix	Structure
Benzpyrimoxan-benzoyl-glycine DH-402	N-[4-(trifluoromethyl)benzoyl]glycine Goat	
Benzpyrimoxan-aldehyde DH-03	4-[[4-(trifluoromethyl)phenyl] methoxy]pyrimidine-5-carbaldehyde High temperature hydrolysis	
Benzpyrimoxan-enamine-aldehyde DH-08	[4-(trifluoromethyl)phenyl] methyl (2E)-3-amino-2-formylprop-2-enoate High temperature hydrolysis	
4-TFMPM DH-102	[4-(trifluoromethyl)phenyl] methanol High temperature hydrolysis	

Physical and chemical properties

Benzpyrimoxan is not volatile. It has a higher solubility in organic solvents (up to 178 g/L in dichloromethane) in comparison to water (5 mg/L). The octanol/water partition coefficient $\log P_{ow}$ of 3.4 for benzpyrimoxan suggests a potential to partition into fat. Benzpyrimoxan is hydrolytically stable under natural and basic conditions while it is considered to be moderately persistent under acidic conditions (pH 4), with DT_{50} value at 25 °C of about 50 days. It is stable to photolysis.

METABOLISM

Plant metabolism

The Meeting received plant metabolism studies for after foliar application on paddy rice with benzpyrimoxan labelled at [Phenyl- $U-^{14}C$] and [Pyrimidinyl-4(6)- ^{14}C].

[^{14}C]-benzpyrimoxan was applied to rice grown pots under paddy conditions in a greenhouse at a rate of 0.20 kg ai/ha (1× GAP). In one experiment, the plant was sprayed three times at 7 day intervals, at heading stage (BBCH 55) and milk stage (BBCH 61–65 and 73–75). In a second experiment, the plant was sprayed twice with an interval of 7 days, at heading stage (BBCH 55) and milk stage (BBCH 61–65), with the third application at BBCH 87–89, 4 weeks after the second application. Samples were taken at 7 days after treatment (DAT). Samples of panicle, foliage and root were collected at milk stage. At ripe stage, panicle, straw and root were collected and then panicle was separated into grain and hulls after 14 days of air drying.

Total radioactive residues (TRR) in panicle and foliage at milk stage were 1.2–1.4 and 1.8–2.4 mg eq/kg, respectively. The TRRs in hull and straw at ripe stage were 2.8–4.7 and 3.3–3.7 mg eq/kg, respectively. Relatively small amounts of radioactive residues were detected in grain (0.10–0.25 mg eq/kg) and root (0.05–0.09 mg eq/kg). At least 77 percent TRR of [Pyrimidinyl-4(6)- ^{14}C] label were recovered from the samples in the surface rinse with acetonitrile (15–49 percent TRR), acetonitrile/water (45–86 percent TRR) and acetonitrile/0.1 mol/L HCl (1.4–9.4 percent TRR) in all the

plant parts at both stages. The post-extraction solids (PES) of all samples were characterized by enzyme, and acidic or alkaline hydrolyses, which released an additional 2–19 percent TRR.

Benzpyrimoxan was the predominant residue in all samples at milk and ripe stages, at levels of 0.05–0.14 mg/kg (48–57 percent TRR) in grain, 1.7–2.8 mg/kg (60–61 percent TRR) in hull and 1.6–1.9 mg/kg (48–51 percent TRR) in straw. Benzpyrimoxan-2-OH (DH-04) was the major metabolite in all samples at both stages, at 0.02–0.04 mg eq/kg (15–17 percent TRR) in grain, 0.14–0.24 mg eq/kg (5.0–5.1 percent TRR) in hull and 0.34–0.39 mg eq/kg (9.3–12 percent TRR) in straw.

Minor (< 10 percent TRR) metabolites were also detected. Benzpyrimoxan-CH₂OH (DH-02) conjugate was identified in hulls (3.1–3.8 percent TRR; 0.11–0.15 mg eq/kg) and straw (2.6–4.4 percent TRR, 0.09–0.16 mg eq/kg). Benzpyrimoxan-acid-2-OH (DH-05) (free and conjugated) was identified in hulls (1.1–1.7 percent TRR, 0.05 mg eq/kg) and straw (4.4–4.8 percent TRR, 0.15–0.18 mg eq/kg). Benzpyrimoxan-CH₂OH-2-OH (DH-06) (free and conjugated) was found in hulls (1.2 percent TRR, 0.03 mg eq/kg) and straw (3.4–3.5 percent TRR, 0.11–0.13 mg eq/kg).

Conclusions

Parent benzpyrimoxan is the main residue in rice. The potential metabolic pathway in rice is hydroxylation of a pyrimidine ring to benzpyrimoxan-2-OH (DH-04), followed by hydrolysis of an acetal moiety to form a hydroxymethyl moiety and carboxylic acid moiety.

Animal metabolism

The Meeting received animal metabolism studies on rats, lactating goats and laying hens where animals were dosed with [¹⁴C]-benzpyrimoxan. The metabolism and distribution of benzpyrimoxan in farm animals were investigated using the [Phenyl-U-¹⁴C] and the [Pyrimidinyl-4(6)-¹⁴C]-benzpyrimoxan.

Rats

The metabolism of benzpyrimoxan in rats was reviewed in the framework of the toxicological evaluation by the WHO Core Assessment Group of the 2022 JMPR.

Lactating goats

Lactating goats received daily oral dosing of [¹⁴C]-benzpyrimoxan for 5 consecutive days at 14 ppm in the diet for [Phenyl-U-¹⁴C]-benzpyrimoxan and at 15 ppm in the diet for [Pyrimidinyl-4(6)-¹⁴C]-benzpyrimoxan. The goats were sacrificed 6 hours after the last dose for the phenyl label and 8 hours after the last dose for the pyrimidinyl label.

TRR were highest in the liver (0.22–0.69 mg eq/kg) and kidney (0.18–0.25 mg eq/kg), followed by muscle (0.008–0.010 mg eq/kg) and fat (0.008–0.015 mg eq/kg). The concentration of radioactivity in the milk reached a plateau of 0.052–0.095 mg eq/kg by day 3–5.

Liver and kidney were extracted with acetonitrile/water and acetonitrile, fat with hexane/acetone and acetone and milk (Day 5) with acetonitrile and acetonitrile/water. Liver, kidney and milk were further extracted with acetonitrile/0.1 mol/L HCl. Muscle was not analysed due to low concentration (< 0.01 mg eq/kg). Most of radioactive residues (78–93 percent TRR) in milk and tissues were extracted (neutral solvent: 57–93 percent TRR, ACN/HCl: < 1.2–3.8 percent TRR).

Benzpyrimoxan was not detected in any sample except in liver (2.3 percent TRR, 0.014 mg/kg). Benzpyrimoxan-acid-2-OH (DH-05) was found as a predominant metabolite in kidney (40–47 percent TRR, 0.074–0.11 mg eq/kg) and milk (59–86 percent TRR, 0.048–0.062 mg eq/kg) and as a major metabolite in liver (6.4–11 percent TRR, 0.025–0.039 mg eq/kg).

Benzpyrimoxan-CH₂OH (DH-02) (free and conjugated) was found as a major metabolite in liver (3.1–22 percent TRR, 0.019–0.051 mg eq/kg) and kidney (5.9–16 percent TRR, 0.011–0.039 mg eq/kg). Benzpyrimoxan-CH₂OH-2-OH (DH-06) (free and conjugated) was the major metabolite in liver (4.8–15 percent TRR, 0.029–0.036 mg eq/kg) and benzpyrimoxan-acid (DH-01) in kidney (16–20 percent TRR, 0.038 mg eq/kg).

Benzpyrimoxan-2-OH (DH-04) was identified as a minor metabolite in liver (2.6–3.1 percent TRR, 0.006–0.019 mg eq/kg) and benzpyrimoxan-benzoyl-glycine (DH-402) in kidney (7.9 percent TRR, 0.019 mg eq/kg).

Laying hens

Laying hens received daily oral dosing for 7 consecutive days of [Phenyl-U-¹⁴C]-benzpyrimoxan at a rate equivalent to 11 ppm in the diet and of [Pyrimidinyl-4(6)-¹⁴C]-benzpyrimoxan at 13 ppm. The hens were sacrificed 6 hours after the last dose.

TRRs in tissues were highest in liver (0.066–0.19 mg eq/kg) and subcutaneous fat (0.065–0.18 mg eq/kg), followed by abdominal fat (0.042–0.063 mg eq/kg) and leg and breast muscle (0.003–0.014 mg eq/kg). Residue levels in egg white reached a plateau of 0.006–0.009 mg eq/kg by days 4–7 and those in egg yolk reached a plateau of 0.13–0.20 mg eq/kg by day 5–7.

Liver, muscle and egg were extracted with acetonitrile/water and acetonitrile, and fat with hexane/acetone and acetone. Liver, muscle and egg were further extracted with acetonitrile/0.1 mol/L HCl. Good extractability was achieved for fat samples (95–96 percent TRR). Over 50 percent TRR was extracted from liver and muscle samples (neutral solvent: 54–79 percent TRR, ACN/HCl: 1.7–2.2 percent TRR), and 34–73 percent TRR from eggs (neutral solvent: 31–67 percent TRR, ACN/HCl: 2.9–6.7 percent TRR).

Benzpyrimoxan was the predominant component in muscle (43 percent TRR, 0.006 mg/kg) and fat (71 percent TRR, 0.043–0.089 mg/kg), a minor residue in eggs (5.7–13 percent TRR, 0.002–0.004 mg/kg) and was not detected in liver.

DH-05 was identified as a major metabolite in liver (20–28 percent TRR, 0.012–0.050 mg eq/kg). DH-02 was a major metabolite in liver (6.1–22 percent TRR, 0.011–0.013 mg eq/kg), fat (9.8–14 percent TRR, 0.006–0.018 mg eq/kg) and was identified as a major metabolite in muscle (14 percent TRR) and egg (13–27 percent TRR), but at levels below 0.01 mg eq/kg. DH-06 was found as a minor component in liver (3.3 percent TRR, 0.002–0.006 mg eq/kg). No other metabolites were identified.

Conclusions

Parent benzpyrimoxan is the minor residue or no residue in animal commodities except hen muscle and fat. The major metabolites of benzpyrimoxan in farm animals are formed by hydrolysis of the acetal moiety to form a hydroxymethyl moiety (DH-02 and DH-06) and its resulting carboxylic acid moiety (DH-01 and DH-05), followed by conjugation to glucuronides. Hydroxylation of a pyrimidine ring are also observed.

Environmental fate

The Meeting received aerobic soil (paddy and upland) metabolism, aqueous hydrolysis and aqueous photolysis studies for benzpyrimoxan.

In the aerobic paddy soil metabolism study conducted in a vessel with phenyl and pyrimidinyl radiolabelled benzpyrimoxan, benzpyrimoxan was degraded in paddy soil very gradually with a DT₅₀ of > 1

year at 25 °C. Benzpyrimoxan was detected with 73–95 percent AR during 180 days incubation period. Several identified and unknown degradates were detected, however, none of which accounted for more than 10 percent of AR throughout the study period for both radiolabels.

In the aerobic upland soil metabolism study conducted in a vessel with phenyl and pyrimidinyl radiolabelled benzpyrimoxan, benzpyrimoxan was gradually degraded in upland soil with a DT₅₀ of 124 days at 25 °C. Benzpyrimoxan was detected as the major component with 33 percent AR after 180 days incubation. Several identified degradants were detected but accounted for less than 10 percent of AR and did not accumulate

In conclusion, benzpyrimoxan was gradually degraded in soil, and the breakdown products also moderately degraded to form unextracted residue and CO₂. Benzpyrimoxan is persistent in soil.

In the aqueous hydrolysis study, benzpyrimoxan was hydrolytically stable at pH 7 and 9 at 50 °C but decomposed at pH 4 with a DT₅₀ of 50–51 days at 25 °C. The hydrolysis product was benzpyrimoxan-enamine aldehyde (DH-08) with maximum amounts of 13 percent AR. Several identified and unknown hydrolysis products accounted for less than 10 percent of AR. Hydrolysis is unlikely to be a major route of environmental degradation.

In the aqueous photolysis study, benzpyrimoxan was photolytically stable at 25 °C for 25 days. Photolysis in water is unlikely to be a major route of environmental degradation.

Rotational crop metabolism

No rotational crop studies were provided to the Meeting.

The Meeting noted that residue of benzpyrimoxan may be taken up by follow-on and rotational crops since this compound is persistent in soil,

The Meeting considered that information on the agricultural practice for paddy rice cultivation and International Harmonised Guidelines (OECD TG504) indicated potential crop rotation for paddy rice.

The Meeting could not conclude on the residues related to benzpyrimoxan in rotational crops.

Methods of analysis

The Meeting received information on analytical methods for benzpyrimoxan and its metabolites in plant and animal matrices.

Plant matrices

In the method for determination of benzpyrimoxan and benzpyrimoxan-2-OH (DH-04) in rice matrices (grain, husked rice, polished rice, cooked rice, bran and straw), samples were extracted with acetonitrile/water and acetonitrile/0.1 mol/L HCl (After SPE clean-up, residues were determined by LC-MS/MS. The method was validated with an LOQ of 0.01 mg/kg for each analyte.

A QuEChERS method was also validated for benzpyrimoxan and DH-04 in husked rice with an LOQ of 0.01 mg/kg for each analyte.

The Meeting concluded that the presented methods were sufficiently validated and are suitable to measure benzpyrimoxan and DH-04 in rice commodities.

Animal matrices

In the method for determination of benzpyrimoxan, benzpyrimoxan-acid (DH-01), benzpyrimoxan-CH₂OH (DH-02), benzpyrimoxan-2-OH (DH-04), benzpyrimoxan-acid-2-OH (DH-05) and benzpyrimoxan-CH₂OH-2-OH (DH-06), cow tissues (muscle, liver, kidney) and cream samples were extracted with acetonitrile/water

and cleaned up by SPE. Fat samples were extracted with hexane/acetone and acetonitrile/water, the hexane layer extracted with acetonitrile followed by SPE clean-up. Milk and skin milk samples were centrifuged and provided to SPE. An aliquot of each sample was treated with β -glucuronidase. The residues were determined by LC-MS/MS.

The method recoveries of DH-01 in liver were < 70 percent due its conversion to DH-05, although the sum of DH-01 and DH-05 recovery was within the acceptable range.

In the method for the analysis of benzpyrimoxan, DH-02 and DH-05 in hen commodities, egg, muscle and liver samples were extracted twice with acetonitrile/water and purified by SPE. Fat samples were extracted with hexane/acetone and acetonitrile/water, the lower layer collected, the hexane layer extracted with acetonitrile and the hydro-organic layer combined. The extract was cleaned up by SPE. The residues were analysed by LC-MS/MS at a LOQ of 0.01 mg/kg

The Meeting concluded that the presented methods were sufficiently validated at a LOQ of 0.01 mg/kg and are suitable to measure benzpyrimoxan, DH-01 (except liver), DH-02 (free and conjugated), DH-04, DH-05 and DH-06 (free and conjugated) in animal commodities. DH-4 and DH-06 (free and conjugated) were not validated in hen commodities.

Stability of pesticide residues in stored analytical samples

The Meeting received information on storage stability of benzpyrimoxan and benzpyrimoxan-2-OH (DH-04) in rice grain (paddy rice), brown rice and straw fortified at 0.5 mg/kg and stored at -20 °C.

Benzpyrimoxan and DH-04 were stable for at least 2.5 months in rice grain, husked rice and straw, which covered the residue sample storage intervals used in the field trials considered by the current Meeting.

The Meeting received information on storage stability of benzpyrimoxan, DH-01, DH-02, DH-04, DH-05 and/or DH-06 in animal commodities fortified at 0.1 mg/kg and stored at -20 °C.

Benzpyrimoxan, DH-04 and DH-06 were stable for at least 3 months in milk, muscle and liver, at least 2.5 months in fat, and at least 1 month in kidney, DH-05 was stable for at least 1 month in milk, muscle, liver, kidney, fat and egg and DH-02 was stable for at least 3 months in muscle and liver, for at least 2.5 months in fat, and for at least 1 month in kidney and egg.

The Meeting noted that DH-01 was unstable in liver, kidney and fat, quantitatively degrading to DH-05 within 1 month of frozen storage. DH-01 was stable for at least 3 months in muscle.

Definition of the residue

Plant commodities

In plant metabolism studies on benzpyrimoxan in rice, benzpyrimoxan (48–61 percent TRR) was a major component in all rice commodities (grains, hull and straw). DH-04 (5.0–17 percent TRR) was identified at 0.02–0.39 mg eq/kg in all rice commodities. DH-02 conjugate, DH-05 (free and conjugated), DH-06 (free and conjugated) were detected at > 0.01 mg eq/kg and not greater than 4.5 percent TRR in feed commodities (panicle, foliage, hull and straw).

The Meeting decided that the suitable analyte for enforcement purposes is parent benzpyrimoxan in rice commodities.

In deciding which compounds should be included in the residue definition for dietary risk assessment, the Meeting considered the toxicological properties of the candidate DH-04 (benzpyrimoxan-2-OH). The Meeting agreed that DH-04 was approximately 3 times more toxic than parent.

The Meeting decided that the suitable analytes for dietary risk assessment are benzpyrimoxan and benzpyrimoxan-2-OH.

Animal commodities

In animal metabolism studies, benzpyrimoxan was the predominant component in hen muscle (43 percent TRR, 0.006 mg eq/kg) and hen fat (71 percent TRR, 0.043–0.089 mg eq/kg), but the minor residue in goat liver (2.3 percent TRR, 0.014 mg/kg) and eggs (5.7–13 percent TRR, 0.002–0.004 mg/kg), and not detected in hen liver, goat kidney, goat muscle, goat fat and milk.

Benzpyrimoxan-acid-2-OH (DH-05) was the predominant component of the residue in goat kidney (40–47 percent TRR) and milk (59–86 percent TRR), and the major residue in liver (goat: 6.4–11 percent TRR, hen: 20–28 percent TRR).

Benzpyrimoxan-acid (DH-01) was only found in goat kidney (16–20 percent TRR) and it may be converted to DH-05 in liver, kidney and fat during storage and/or analysis. The Meeting considered that interconversion of DH-01 to DH-05 may have occurred in the matrices due to the storage interval between sampling and extraction of 24–50 days in animal metabolism studies.

The Meeting decided that the suitable analytes for enforcement purposes are parent benzpyrimoxan, DH-01 and DH-05 in animal commodities.

The metabolism and feeding studies for ruminant show that total residues of benzpyrimoxan, DH-01 and DH-05 in skim milk are 1.5 times higher than in cream. Laying hen metabolism study shows that total residues in fat are higher than in muscle, but the ratio does not show a clear fat solubility.

The Meeting considered the residues of benzpyrimoxan not to be fat-soluble.

In deciding which compounds should be included in the residue definition for dietary risk assessment, the Meeting considered the likely occurrence of the compound and the toxicological properties of the candidates DH-01, DH-02 (free and conjugated), DH-05 and DH-06 (free and conjugated).

DH-02 (free and conjugated) was a major metabolite in only goat liver (3.1–22 percent TRR, 0.019–0.051 mg eq/kg) and kidney (5.9–16 percent TRR, 0.011–0.039 mg eq/kg) and DH-06 (free and conjugated) only in goat liver (4.8–15 percent TRR, 0.029–0.036 mg eq/kg).

Since liver and kidney contributes little to the total dietary exposure and an ARfD for benzpyrimoxan was not considered necessary, the Meeting concluded that these metabolites should not be included in the residue definition for dietary risk assessment.

The Meeting concluded that the toxicities of DH-01 (benzpyrimoxan-acid) and DH-05 (benzpyrimoxan-acid-2-OH) were covered by the health-based guidance values for parent compound.

The Meeting decided to define the residue for dietary risk assessment for animal commodities as the sum of benzpyrimoxan, benzpyrimoxan-acid and benzpyrimoxan-acid-2-OH, expressed as benzpyrimoxan.

The Meeting recommended the following residue definitions for benzpyrimoxan:

Definition of the residue for compliance with the MRL for rice commodities: *Benzpyrimoxan*

Definition of the residue for dietary risk assessment for rice commodities: *Sum of benzpyrimoxan and 3 × benzpyrimoxan-2-OH, expressed as benzpyrimoxan*

Definition of the residue for compliance with the MRL and dietary risk assessment for animal commodities: *Sum of benzpyrimoxan, benzpyrimoxan-acid and benzpyrimoxan-acid-2-OH, expressed as benzpyrimoxan*

The Meeting considers the residue not to be fat-soluble.

Results of supervised residue trials on crops

Supervised trials were available for the use of benzpyrimoxan on rice.

Product labels were available from Japan.

Total residues for estimation of dietary exposure from food commodities are calculated by summing up the concentrations of benzpyrimoxan and 3 × benzpyrimoxan-2-OH (expressed as benzpyrimoxan equivalents), because benzpyrimoxan-2-OH is three times higher toxicity than parent benzpyrimoxan. The method of calculation is illustrated below.

Example of the method for calculation of total residues (mg/kg) for dietary exposure

Benzpyrimoxan	Benzpyrimoxan-2-OH (DH-04)	Total
< 0.01	< 0.01 × 3	< 0.04
< 0.01	0.025 × 3	0.085

For the purpose to calculating the livestock animal dietary burden, no factor of 3 is applied to the residue levels of the metabolite. Total residues are benzpyrimoxan + benzpyrimoxan-2-OH, expressed as benzpyrimoxan.

As no studies on residues in follow-on and rotational crops were provided to the Meeting, no estimations for maximum residue levels, STMR and median residues levels in annual crops sown/planted after rice cultivation could be made. The supervised residue trials with direct application and studies on rotational crops will be evaluated together at a future meeting when all results will be available.

Rice

The critical GAP for rice in Japan allows three spray applications of 0.01 kg ai/hL with a PHI of 7 days. Data were available from supervised trials on rice in Japan matching Japanese GAP.

Benzpyrimoxan residues in rice grain with husk were (n=5): 1.2, 1.6, 1.9, 2.0 and 3.4 mg/kg.

Total residues in rice grain were (n=5): 1.7, 2.8, 3.7, 3.9 and 5.6 mg/kg.

For the purposes to calculate the livestock animal dietary burden residues (benzpyrimoxan plus DH-04, expressed as benzpyrimoxan) in rice grain were (n=5): 1.4, 2.0, 2.5, 2.6 and 4.1 mg/kg.

As indicated no recommendation could be made for rice. Benzpyrimoxan residues in husked rice were (n=8): 0.06, 0.10, 0.20, 0.30, 0.32, 0.33, 0.44 and 0.46 mg/kg.

Total residues in husked rice were (n=8): 0.15, 0.19, 0.41, 0.72, 0.74, 0.75, 0.79 and 0.89 mg/kg.

As indicated no recommendation could be made for rice, husked.

Residues in animal feeds

Rice, hay and/or straw

The critical GAP for straw of rice in Japan allows three spray applications of 0.01 kg ai/hL with a PHI of 7 days. Data were available from supervised trials on rice in Japan matching the GAP.

Benzpyrimoxan residues in rice straw were (n=8): 4.2, 4.7, 5.6, 5.8, 7.2, 7.8, 8.1 and 9.0 mg/kg on dry weight basis.

Total residues (benzpyrimoxan plus DH-04, expressed as benzpyrimoxan) in rice straw were (n=8): 5.5, 6.2, 6.8, 7.2, 9.0, 9.7, 10 and 11 mg/kg on dry weight basis.

No recommendation could be made for rice straw until the contribution of residues from direct application as well as uptake through the soil can be assessed.

Fate of residues during processing

High temperature hydrolysis

The hydrolysis of [¹⁴C]-benzpyrimoxan was studied in sterile buffered solutions of pH 4, 5 and 6. [Phenyl-U-¹⁴C] and [Pyrimidinyl-4(6)-¹⁴C]-benzpyrimoxan were incubated at 1.0 mg/L in aqueous buffered solutions to simulate common processing practices (pasteurization, baking/boiling and sterilisation).

At pH 4, 5 and 6 with heating, the predominant residue was parent benzpyrimoxan (92–100 percent AR). Some minor degradation products (benzpyrimoxan-aldehyde (DH-03), benzpyrimoxan-enamine-aldehyde (DH-08) and benzpyrimoxan-benzyl alcohol (DH-102)) were identified with up to 7.4 percent AR.

Benzpyrimoxan residue is stable during processing and no DH-04 residue is expected.

Residues in processed commodities

The Meeting received information on the fate of total residues of benzpyrimoxan and benzpyrimoxan-2-OH (DH-04) during processing in rice, husked. Calculated processing factors are summarized in the following table.

Table 5.4.2 Processing factors for rice, husked and STMR-P values

Raw commodity	Processed commodity	Calculated processing factor [#] (best estimate)
Rice, husked = Brown rice	Bran	8.6, 9.5 (9.1)
	Polished rice	0.41, 0.43 (0.42)
	Cooked polished rice	0.068, 0.095 (0.082)

Notes:

[#] Each value represents a separate study. The factor is the ratio of the residue in processed commodity divided by the residue in the RAC.

Residues in animal commodities

Farm animal feeding studies

The Meeting received a lactating dairy cow and a laying hen feeding studies, which provided information on likely residues resulting in animal commodities, milk and eggs from benzpyrimoxan in the animal diet.

Lactating dairy cows

Holstein dairy cows were dosed with benzpyrimoxan for 28 days at the equivalent of 8, 24 and 80 ppm in the diet. Residues of benzpyrimoxan, and benzpyrimoxan-acid-2-OH (DH-05) in milk, and residues of benzpyrimoxan, benzpyrimoxan-acid (DH-01) and DH-05 in tissues (liver, kidney, muscle and fat) were determined.

For whole milk, no benzpyrimoxan residue was detected at all feeding levels. DH-05 residue was detected at all feeding level and achieved a plateau concentration of 0.012–0.034 mg/kg at the 8 ppm (1 ×) feeding level after 3 days of dosing.

For liver, residues of benzpyrimoxan and DH-05 were detected at all feeding levels (benzpyrimoxan: < 0.01–0.15 mg/kg, DH-05: 0.011–0.25 mg/kg). No residue of DH-01 was found at any feeding level.

For kidney, benzpyrimoxan residues were found at the 80 ppm feeding level (1 cow: 0.031 mg/kg). DH-01 residue was detected with < 0.01–0.032 mg/kg at the 24 and 80 ppm feeding levels. DH-05 residue was detected with 0.032–0.30 mg/kg at all feeding levels.

For fat, benzpyrimoxan residue was detected with < 0.01–0.031 mg/kg at the 80 ppm feeding level. DH-05 residue was detected with < 0.01–0.18 mg/kg at all feeding levels. No DH-01 residue was found at any feeding level.

For muscle, no residues (< 0.01 mg/kg) were found at any feeding level.

Laying hens

Laying hens were dosed with benzpyrimoxan for 29 days at the equivalent of 3, 9 and 30 ppm in the diet. Residues of benzpyrimoxan and DH-05 were determined in eggs, liver, muscle and fat.

For eggs, DH-05 residue was found (< 0.01–0.011 mg/kg) at the 30 ppm feeding level. Benzpyrimoxan residue was below the LOQ (< 0.01 mg/kg) at any feeding level.

For liver, DH-05 residue was detected with < 0.01–0.067 mg/kg at all feeding levels. No benzpyrimoxan residue was found at any feeding level.

For fat, benzpyrimoxan residue was detected with 0.012–0.015 mg/kg at the 30 ppm feeding level. No DH-05 residue was found at any feeding level.

For muscle, no residues (< 0.01 mg/kg) were found at any feeding level.

Farm animal dietary burden

The Meeting noted that the studies on residues in follow-on and rotational crops were not provide to the Meeting, and decided not to estimate maximum residue levels and STMRs on annual crops that may lead to animal feeds. The estimations will be made in the future when the studies are available.

RECOMMENDATIONS

Definition of the residue for compliance with the MRL for plant commodities: *Benzpyrimoxan*

Definition of the residue for dietary risk assessment for plant commodities: *Sum of benzpyrimoxan and benzpyrimoxan-2-OH, expressed as benzpyrimoxan*

Definition of the residue for compliance with the MRL and dietary risk assessment for animal commodities: *Sum of benzpyrimoxan, benzpyrimoxan-acid and benzpyrimoxan-acid-2-OH, expressed as benzpyrimoxan*

The residue is not fat-soluble.

FUTURE WORK OR INFORMATION*Desirable information:*

- Submission of existing soil dissipation studies.
- Information on residues in rotational crops (confined rotational crop study and/or field residue trials on rotational crops)

DIETARY RISK ASSESSMENT

The Meeting could not make any recommendations for residue levels in crops since information on the residues in follow-on and rotational crops was not provided to the Meeting. Furthermore, no dietary exposure assessment was conducted.

5.5 Bifenthrin (178)

RESIDUE AND ANALYTICAL ASPECTS

Bifenthrin is a pyrethroid insecticide and miticide. It was first evaluated for residues and toxicology by the JMPR in 1992. Bifenthrin was evaluated under the periodic review programme in 2009 (T) and 2010 (R), and subsequently evaluated in 2015 and 2019 for additional MRLs.

An ADI of 0–0.01 mg/kg bw and an ARfD of 0.01 mg/kg bw were established by the 2009 JMPR. The definition of the residue for compliance with the MRL and for dietary risk assessment for animal and plant commodities is *bifenthrin* (sum of isomers). The residue is fat-soluble.

Bifenthrin was scheduled at the Fifty-first Session of the CCPR for the evaluation of additional uses by the 2021 Extra JMPR and was re-scheduled to the 2022 JMPR.

The current Meeting received information on new GAPs and supervised residue trials for apple, peach, avocado, pomegranate, pepper (bell, non-bell), melon, spinach, and peanut, as well as processing studies on apple and peanut.

Methods of analysis

The Methods used in residue trials were similar to or slight modifications to the method evaluated by previous Meetings. In general, the data generation methods considered by this Meeting involved extraction with acetone and cleaning-up with SPE. Final determination was achieved using GC-ECD or GC-MSD. The methods were considered suitable for analysis of bifenthrin in trials.

Stability of pesticide residues in stored analytical samples

The 2010 and 2015 JMPR evaluated the stability of bifenthrin in analytical samples stored under frozen conditions and concluded that bifenthrin is stable for at least 18 months in high acid, 49 months in high water, 36 months in high oil and high starch, and 15 months in high protein commodities under frozen conditions. The maximum frozen storage intervals in the supervised trials provided to the current Meeting were shorter than the storage intervals indicated above.

Results of supervised residue trials on crops

The Meeting received information on supervised trials of bifenthrin on apple, peach, avocado, pomegranate, melon, peppers (sweet and chili), spinach and peanut.

Pome fruit, except Japanese persimmon

Apple

The GAP for bifenthrin is in the United States for the US pome fruit group, consisting of foliar applications at 0.224 kg ai/ha with re-treatment intervals (RTIs) of not less 30 days and a PHI of 14 days, no more than 3 applications and a total application rate not more than 0.56 kg ai/ha per year with no more 0.51 kg ai/ha applied after petal fall (BBCH 69). Given the annual rate limitation, the cGAP is an initial application at 0.112 kg ai/ha followed by 2 applications, each at 0.224 kg ai/ha.

In independent trials approximating the cGAP but with retreatment intervals of 20 rather than 30 days, residues of bifenthrin in fruits were (n=8): 0.10, 0.11, 0.13, 0.19, 0.20, 0.24, 0.29, and 0.42 mg/kg.

Noting that the residue decline studies on apple and peach showed no significant changes in concentration between 7 and 21 days after the final application, the Meeting agreed that the difference in retreatment intervals between the trials and the cGAP would not affect residues by more than 25 percent and agreed to use the data from the trials to estimate a maximum residue level.

The Meeting estimated a maximum residue level of 0.7 mg/kg, an STMR of 0.195 mg/kg and an HR of 0.45 mg/kg (highest individual result) for bifenthrin in apple. Noting that the registration is for the US pome fruit group, which does not include Japanese persimmon, the Meeting agreed to extrapolate the estimates for apple to the group of pome fruit, except persimmon, Japanese.

The Meeting noted that acute dietary exposure assessment for apple and pear exceeded the ARfD of 0.01 mg/kg bw (*apple: 250 percent for children in China; pear: 310 percent for children in Canada*). No alternative GAP was available.

Peach

The critical GAP for bifenthrin is in United States for the US Peach subgroup 12-12B, consisting of foliar applications at 0.22 kg ai/ha with RTI of not less 30 days and a PHI of 14 days, no more than 3 application and the total application rate less than 0.56 kg ai/ha per year with no more 0.51 kg ai/ha applied after petal fall (BBCH 69). Given the annual rate limitation, the cGAP is an initial application at 0.12 kg ai/ha followed by 2 applications, each at 0.22 kg ai/ha.

In independent trials approximating the cGAP, residues of bifenthrin in fruit without stone were (n=11): 0.12, 0.12, 0.17, 0.20(2), 0.22, 0.24, 0.26, 0.30, 0.38 and 0.41 mg/kg.

Noting that the residue decline studies on apple and peach showed no significant changes in concentration between 7 and 21 days after the final application, the Meeting agreed that the difference in retreatment intervals between the trials and the cGAP would not affect residues by more than 25 percent. Furthermore, the 2017 JMPR concluded that for stone fruit, based on the weight of the stone relative to the whole fruit, residues measured in fruit without stones would overestimate whole-fruit residues by about 10 percent and that correcting for this factor would lead to the same maximum residue level estimation. Therefore, the Meeting agreed to use the data from the trials to estimate a maximum residue level.

The Meeting estimated a maximum residue level of 0.8 mg/kg, an STMR of 0.22 mg/kg and an HR of 0.49 mg/kg (highest individual result) for bifenthrin in peach and agreed to extrapolate to the subgroup of peaches.

The Meeting noted that acute dietary exposure assessment showed that residues in peach, apricot, and nectarine exceeded the ARfD of 0.01 mg/kg bw (*peach: 230 percent for children in Japan; apricot: 110 percent for children in Germany; nectarine: 210 percent for children in Netherlands*). No alternative GAP was available.

Avocado

The critical GAP for bifenthrin on avocado in the United States is a foliar applications at 0.062 kg ai/ha with an RTI of not less 14 days and a PHI of 1 day, no more than 5 applications.

Five independent trials were conducted on avocado in the United States with 5 foliar applications at rates of 0.081–0.091 kg ai/ha, and RTIs of 13–17 days, the total application rates of 0.40–0.44 kg

ai/ha and a PHI of 1 day. The residues of bifenthrin in fruits (without stone) were (n=5): 0.076, 0.08, 0.11, 0.26 and 0.30 mg/kg. The scaled residues using the scaling factors of 0.73–0.77 (last application rate in trial/GAP) were (n=5): 0.056, 0.058, 0.089, 0.20 and 0.22 mg/kg.

Based on the scaled residue data, the Meeting estimated a maximum residue level of 0.5 mg/kg (assuming the pit constitutes 15 percent of the whole fruit weight), an STMR of 0.089 mg/kg and an HR of 0.23 mg/kg (highest individual result) for bifenthrin in avocado.

Pomegranate

The critical GAP for bifenthrin on pomegranate in the United States is foliar applications at 0.22 kg ai/ha with RTI of not less 14 days and a PHI of 14 days, no more than 3 application and the total application rate less than 0.56 kg ai/ha per year. Given the annual rate limitation, the cGAP is an initial application at 0.12 kg ai/ha followed by 2 applications, each at 0.22 kg ai/ha.

In independent trials matching the cGAP, residues of bifenthrin in pomegranate were (n=4): 0.11, 0.16, 0.17 and 0.18 mg/kg.

The Meeting estimated a maximum residue level of 0.5 mg/kg, a STMR of 0.165 mg/kg and an HR of 0.22 mg/kg (highest individual result) for bifenthrin in pomegranate.

Melon (cantaloupe)

The critical GAP for bifenthrin on melon in the United States is 3 foliar applications at 0.11 kg ai/ha at RTI of not less 7 days and a PHI of 3 days, with no more than two applications after bloom.

In independent trials matching the cGAP, residues of bifenthrin in fruits were (n=4): < 0.1(2), 0.11 and 0.12 mg/kg.

The Meeting agreed that four trials were insufficient to make a recommendation for melon.

Peppers

The critical GAP for bifenthrin in the United States is for the US crop group covering use on peppers and eggplant and consists of 2 foliar applications at 0.11 kg ai/ha with RTI of not less 7 days and a PHI of 7 days, no more than 2 applications.

Five independent trials on pepper, sweet were conducted in the United States approximating the GAP. The residues of bifenthrin in fruits were (n=5): < 0.055, 0.06, 0.10, 0.14 and 0.17mg/kg.

Seven independent trials on pepper, chilli were conducted in the United States approximating the GAP. The residues of bifenthrin in fruits were (n=7): < 0.05, 0.08, 0.10, 0.14, 0.15, 0.18 and 0.29 mg/kg.

The ranked order of the combined bifenthrin residues in sweet pepper and pepper, chilli were (n=12): < 0.05, < 0.055, 0.06, 0.08, 0.10(2), 0.14(2), 0.15, 0.17, 0.18, and 0.29 mg/kg.

The Meeting noted that the provided trials were previously evaluated by the 2010 JMPR under a registered use on peppers and that the current registration is for peppers and eggplant. The Meeting estimated a maximum residue level of 0.4 mg/kg, an STMR of 0.12 mg/kg, and an HR of 0.31 mg/kg (from a single sample) for bifenthrin in the Subgroup of peppers (except okra, martynia and roselle) to replace its previous recommendation. The Meeting agreed to extrapolate those estimates to the Subgroup of eggplants.

For estimating residues in dried chili peppers, the Meeting used the data from chili peppers and a default processing factor of 7. On that basis, the Meeting estimated a maximum residue level of 4 mg/kg an STMR of 0.98 mg/kg, and an HR of 2.2 mg/kg for bifenthrin in chili pepper, dried to replace its previous recommendation of 5 mg/kg.

Spinach

The critical GAP for bifenthrin on spinach in the United States is 4 foliar applications at 0.11 kg ai/ha at RTI of not less 7 days and a PHI of 40 days.

In independent trials on spinach approximating the cGAP, residues of bifenthrin in spinach were (n=4): 0.05 (2) and 0.15 mg/kg (2).

The Meeting agreed that four trials were insufficient to make a recommendation for spinach.

Peanut

The critical GAP for bifenthrin on peanut in the United States is five foliar applications at 0.11 kg ai/ha with RTI of not less 14 days and a PHI of 14 days.

In four trials involving one soil application (0.28 kg ai/ha) and one foliar application (0.28 kg ai/ha), with harvest 3–17 DALA, the residues of bifenthrin in nutmeat were (n=4): < 0.05 (4) mg/kg.

In four trials with 5 foliar applications at 0.11 kg ai/ha, with RTIs between last two sprays of 9–35-days and harvest 0–8 DALA, residues of bifenthrin in nutmeat were (n=4) < 0.05 (4) mg/kg.

In a trial to obtain samples for processing studies, 3 foliar applications were made at 0.34 kg ai/ha, and RTIs of 11–47 days, with harvest 13 DALA, the bifenthrin residue in nutmeat was < 0.05 mg/kg.

None of the available trials matched the cGAP. Noting the residues from all trials, including the trials with exaggerated rates, were < 0.05 mg/kg, the Meeting agreed to estimate a maximum residue level of 0.05(*) and an STMR of 0.05 mg/kg for bifenthrin in peanut.

Residues in animal feeds

Peanut vine, hay and hull

The only GAP provided for peanuts was from the United States. There is a label restriction in the United States which excludes the feeding of green immature plants and peanut hay to livestock. The Meeting did not make new estimates for residues in animal commodities and confirmed its previous recommendation.

Fate of residues during processing

The Meeting received processing studies for apple and peanut.

Estimated processing factors for apple considered at this Meeting are summarized below.

Table 5.5.1 Processing factors for estimation of STMR

RAC	Processed commodity	Median or best estimate processing factor	STMR-P = STMR _{RAC} × PF (mg/kg)
Apple (STMR = 0.2 mg/kg)	Juice	< 0.048	0.0096
	Wet pomace	2.5	0.5

For peanut, four nutmeat samples were obtained from a trial with three applications of bifenthrin at 0.336 kg ai/ha. Residues in all samples of nutmeat and meal were < 0.05 mg/kg. In oil, bifenthrin residues were < 0.05 mg/kg in three samples and 0.05 mg/kg in one sample. A processing factor for oil could not be calculated due to the non-quantifiable residue in the nutmeat.

Noting that the dosing in the trial was at a 1.8× rate and that when scaled to a cGAP rate the expected residues in meal and refined oil would be < 0.05 mg/kg, the Meeting agreed to estimate the median-P for meal at 0.05 mg/kg and the STMR-P for refined oil at 0.05 mg/kg.

Farm animal dietary burden

Dietary burdens were calculated for beef cattle, dairy cattle, broilers and laying poultry based on feed items evaluated by the JMPR. The dietary burdens, estimated using the 2018 OECD Feed diets listed in Appendix XIV Electronic attachments to the 2016 Edition of the FAO Manual, are presented in Annex 6.

The maximum total dietary burdens calculated in 2019 were 8.3 ppm (beef cattle), 7.4 ppm (dairy cattle), 0.59 ppm (poultry broiler) and 2.0 ppm (poultry layer). The only animal feed evaluated by the current Meeting is apple pomace. Maximum total dietary burdens calculated by the current Meeting using the OECD diets were unchanged or slightly less than those derived by the 2019 Meeting. The Meeting therefore confirmed its previous recommendations for residue levels in animal products.

RECOMMENDATIONS

On the basis of the data obtained from supervised trials, the Meeting concluded that the residue levels listed in Annex 1 are suitable for establishing maximum residue limits and for IEDI and international estimate of short-term intakes assessments.

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The ADI for bifenthrin is 0–0.01 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for bifenthrin were estimated for the 17 GEMS/Food Consumption Cluster Diets using the STMR or STMR-P values estimated by the JMPR. The results are shown in Annex 3 of the 2022 JMPR Report. The IEDIs ranged from 10–40 percent of maximum ADI of 0.01 mg/kg bw. The Meeting concluded that the long-term dietary exposure to residues of bifenthrin from uses considered by the current Meeting is unlikely to present a public health concern.

Acute dietary exposure

The ARfD for bifenthrin is 0.01 mg/kg bw, the International Estimate of Short-Term Intakes (international estimate of short-term intake) was calculated for food commodities and their processed commodities for

which HRs/HR-Ps or STMRs/STMR-Ps were estimated by the present Meeting and for which consumption data were available. The results are shown in Annex 4 of the 2022 JMPR report.

The international estimate of short-term intakes were less than 100 percent of the ARfD, except for apple (up to 230 percent for children in China), pear (up to 310 percent for children in Canada), peach (up to 260 percent for children in Japan), apricot (up to 110 percent for children in Germany), and nectarine (up to 210 percent for children in Netherlands). The Meeting concluded that acute dietary exposure to residues of bifenthrin may present a public health concern for those commodities.

5.6 Broflanilide (326)

TOXICOLOGY

Broflanilide is the common name approved by International Organization for Standardization (ISO) for *N*-[2-bromo-4-(perfluoropropan-2-yl)-6-(trifluoromethyl)phenyl]-2-fluoro-3-(*N*-methylbenzamido) benzamide (IUPAC), with the Chemical Abstracts Service number 1207727-04-5.

It is a meta-diamide pro-insecticide that exerts its pesticidal mode of action (MOA) by binding to an inter-subunit allosteric ionotropic site on the insect γ -aminobutyric acid (GABA) receptor, resulting in a blocking of inhibitory neurotransmission.

Broflanilide has not previously been evaluated by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) and was reviewed by the present meeting at the request of the Codex Committee on Pesticide Residues (CCPR).

All critical studies contained statements of compliance with good laboratory practice (GLP) and were conducted in accordance with relevant national or international test guidelines, unless otherwise specified. No additional information from a literature search was identified that complemented the toxicological information provided for the current assessment.

Biochemical aspects

In disposition studies, intact and cannulated rats were administered [^{14}C]broflanilide labelled at either the phenyl (B label) or benzamide ring (C label). Both cannulated and intact rats were administered single oral doses of 5 mg/kg body weight (B or C label), or of 500 mg/kg body weight (C label only). Intact rats only were repeat-dosed at 5 mg/kg body weight (bw) with B label for up to 14 days. The oral absorption, calculated in bile duct-cannulated rats as the sum of the percentages of dose recovered in bile, urine, liver and carcass, was 14–23 percent of the administered dose (AD) following the single low dose, and 2 percent of AD at the single high dose.

Following oral doses, radioactivity was widely distributed. The total radioactivity retained in tissues accounted for less than 2 percent of AD following a single low dose, 0.1 percent of AD following a single high dose, and 4 percent or less of AD after repeated doses. Irrespective of dose or label position, the highest concentrations were measured in fat (1.8–3.0 percent AD from repeated dosing). There was no notable sex difference in the distribution or concentration of radioactivity.

There were no significant sex differences in either the rates or routes of excretion. After single oral doses excretion was rapid with more than 92 percent (urine, faeces and cage wash) of the AD excreted at 48 hours. The major route of excretion was through the faeces, accounting in general for more than 90 percent of AD independent of dose level or exposure period. In bile duct-cannulated rats, excreted radioactivity (bile, urine, faeces and cage wash) was greater than 85 percent of AD at 48 hours following a single low (B and C) or high dose (C label). There were no major differences in the patterns of excretion between sexes.

In toxicokinetic studies designed to assess absorption or bioavailability saturation effects after a single oral exposure, rats were administered [*B-ring*- ^{14}C]broflanilide or [*C-ring*- ^{14}C]broflanilide at doses ranging from 5 to 500 mg/kg bw. In general there were no significant differences in the toxicokinetic profile between males and females. Peak concentration (C_{max}) for plasma and area under the concentration–time curve (AUC) values broadly increased with increasing dose between 20 and 100 mg/kg bw, while at doses above 100 mg/kg bw the increases were not dose-proportional: values

increased approximately three-fold against an expected five-fold increase. In general, the time to reach C_{\max} (T_{\max}) and the terminal half-life ($t_{1/2}$) were longer in animals given B-labelled broflanilide. Following consecutive daily oral low doses the C_{\max} and $AUC_{(0-t)}$ values were approximately three-fold higher than those after a single low dose, with no substantial sex differences. The T_{\max} values after repeated dosing were comparable to those after a single low dose.

After single or repeated low doses, unchanged broflanilide was the major radioactive component in faecal extracts, accounting for 52–77 percent of AD in intact or bile duct-cannulated rats, and for 88–94 percent of AD after a single high dose to intact or cannulated rats. In faecal samples from single or repeated low-dose rats, six metabolites were identified. Among these, metabolite S(PFP-OH)8007, (M8) and DM-8007 (M11) accounted for a maximum of approximately 2 percent and 5 percent of AD, respectively. Other metabolites accounted for a maximum of 4 percent of AD each. In the urine the major metabolite was hippuric acid which accounted for 6–11 percent of AD (C label) at the low dose in intact or bile duct-cannulated rats, and 0.7–0.8 percent at the high dose in intact rats. In bile samples, seven metabolites were identified, accounting for a maximum of 3 percent of AD each. The most abundant components in plasma, liver, kidney and fat were metabolite DM-8007 which accounted for 8–58 percent of total radioactivity (low dose and high dose), metabolite DC-DM-8007 which accounted for up to 17 percent of total radioactivity, and metabolite S(PFP-OH)8007 which accounted for up to 13 percent of total radioactivity (low dose).

In an *in vitro* study with human, rat and mouse hepatocytes, metabolism of broflanilide was extensive. Biodegradation in mice and rats was slightly faster than in humans. No human-specific metabolites of broflanilide were identified. In an identical study performed with metabolite DM-8007, the concentration of metabolite DM-8007 remained largely unchanged in human hepatocytes, while its biodegradation was apparent with mouse hepatocytes. No human-specific metabolites of DM-8007 were identified.

Toxicological data

The acute oral median lethal dose (LD_{50}) in rats was greater than 5000 mg/kg bw, the dermal LD_{50} was greater than 5000 mg/kg bw and the acute inhalation lethal median concentration (LC_{50}) was greater than 2.20 mg/L. Broflanilide was not irritating to the skin or eyes of rabbits. Broflanilide was not a skin sensitizer in mouse or Guinea pig.

In all species, the most common effects were increased adrenal gland weight and/or ovarian weight correlating with an increased incidence of vacuolation in the adrenal gland cortex and ovary interstitial cells, with rat being the most sensitive species.

In a 90-day toxicity study in mice in which broflanilide was administered at dietary concentrations of 0, 200, 1500 or 7000 ppm (equal to 0, 26.3, 199 and 955 mg/kg bw per day for males, 0, 32.3, 230 and 1148 mg/kg bw per day for females) the NOAEL was 1500 ppm (equal to 230 mg/kg bw per day) based on effects on the adrenal glands (increased adrenal weight and increased incidence of minimal cortical vacuolation) in females at 7000 ppm (equal to 1148 mg/kg bw per day).

In a 90-day toxicity study in rats in which broflanilide was administered at dietary concentrations of 0, 500, 1500, 5000 or 15 000 ppm (equal to 0, 35, 104, 345 and 1109 mg/kg bw per day for males, 0, 41, 126, 418 and 1239 mg/kg bw per day for females) no NOAEL could be identified due to effects on adrenal glands (increased weights correlated with increased vacuolation in both sexes and hypertrophy in females in the adrenal cortex), ovaries (increased incidence of vacuolation in interstitial cells) at 500 ppm (equal to 35 mg/kg bw per day), the lowest dose tested.

In a non-GLP and non-guideline complementary 90-day study in rats, aimed at specifically investigating broflanilide's target organ toxicity (in the adrenal gland and ovary), broflanilide was administered at dietary concentrations of 0 or 30 ppm (equal to 0 and 2.0 mg/kg bw per day for males, 0 and 2.2 mg/kg bw per day for females). The NOAEL was 30 ppm (equal to 2.0 mg/kg bw per day), the only dose tested.

In a 28-day and a 90-day toxicity study on dogs in which broflanilide was administered by capsule at dose levels of 0, 100, 300 or 1000 mg/kg bw per day, the NOAEL was 1000 mg/kg bw per day, the highest dose tested.

In a one-year toxicity study on dogs in which broflanilide was administered by capsule at dose levels of 0, 100, 300 or 1000 mg/kg bw per day, no NOAEL could be identified due to reduced body weight in females, increased adrenal weight and adrenal gland enlargement in males, cortical cell hypertrophy in males, and vacuolation of the zona fasciculata of the adrenal gland in females at 100 mg/kg bw per day, the lowest dose tested.

In a carcinogenicity study in mice, broflanilide was administered at dietary concentrations of 0, 200, 1500 or 7000 ppm (equal to 0, 21, 157 and 745 mg/kg bw per day for males, 0, 22, 172 and 820 mg/kg bw per day for females). The NOAEL was 1500 ppm (equal to 157 mg/kg bw per day) based on pale and abnormal teeth in both sexes, increased absolute and relative adrenal weights, enlarged adrenal, marginally increased incidence of haematopoiesis, cortical vacuolation, corticomedullary vacuolation and inflammatory cell foci in the adrenal gland in females, slightly increased ovarian cysts, and a slight increase in cystic tubules in the kidneys of males, at 7000 ppm (equal to 745 mg/kg bw per day). No treatment-related increases in tumour incidence were observed in this study.

In a two-year toxicity and carcinogenicity study in rats, broflanilide was administered at dietary concentrations of 0, 100, 300, 1500 or 15 000 ppm (equivalent to 0, 4.5, 14, 70 and 709 mg/kg bw per day for males, 0, 5.9, 19, 95 and 953 mg/kg bw per day for females). Satellite animals were given broflanilide at doses of 0, 30, 100, 300, 1500 or 15 000 ppm (equivalent to 0, 1.7, 5.7, 16, 84 and 822 mg/kg bw per day for males, 0, 2.1, 7.2, 20, 104 and 1128 mg/kg bw per day for females) for 12 months. No NOAEL could be identified for females due to an increased incidence of ovarian vacuolation at 100 ppm (equal to 5.9 mg/kg bw per day), the lowest dose tested, after 24 months of treatment. The NOAEL for carcinogenicity was 300 ppm (equal to 19 mg/kg bw per day) based on increased incidence of ovarian tumours of sex cord stromal origin and uterus adenocarcinomas at 1500 ppm (equal to 95 mg/kg bw per day). A treatment-related increase in the incidence of Leydig cell adenomas was observed at the highest dose of 15 000 ppm (equal to 953 mg/kg bw per day).

The Meeting concluded that broflanilide is not carcinogenic in mice but is carcinogenic in rats.

Broflanilide was tested for genotoxicity in an adequate range of in vitro and in vivo assays. No evidence of genotoxicity was found.

The Meeting concluded that broflanilide is unlikely to be genotoxic.

In view of the lack of genotoxicity, the absence of carcinogenicity in mice and the fact that tumours were only observed at moderate to high dose levels in rats, the Meeting concluded that broflanilide is unlikely to pose a carcinogenic risk to humans from the diet.

In a two-generation reproductive toxicity study in rats, broflanilide was administered at dietary concentrations of 0, 30, 100, 300, 1500 or 15 000 ppm (equal to 0, 2.3, 7.5, 22.6, 112 and 1147 mg/kg bw/day for males, 0, 2.3, 7.5, 22.8, 111 and 1153 mg/kg bw per day for females). The NOAEL for parental toxicity was 30 ppm (equal to 2.3 mg/kg bw per day), based on increased adrenal weights and vacuolation of the adrenal cortex in males and females of the F0 and F1 generations, and ovary interstitial

glands vacuolation in females of the F0 generation at 100 ppm (equal to 7.5 mg/kg bw per day). The NOAEL for reproductive toxicity was 15 000 ppm (equal to 1147 mg/kg bw per day), the highest dose tested. The NOAEL for offspring toxicity was 300 ppm (equal to 22.6 mg/kg bw per day) based on decreased body weights of pups at 1500 ppm (equal to 112 mg/kg bw per day).

In a prenatal developmental toxicity study in rats, broflanilide was administered by gavage at dose levels of 0, 100, 300 or 1000 mg/kg bw per day, from gestation day (GD) 6 until GD 19. The NOAEL for maternal toxicity was 1000 mg/kg bw per day, the highest dose tested. The NOAEL for embryo/fetal toxicity was 1000 mg/kg bw per day, the highest dose tested.

In a prenatal developmental toxicity study in rabbits, broflanilide was administered by gavage at dose levels of 0, 100, 300 or 1000 mg/kg bw per day, from GDs 6 to 28. The NOAEL for maternal toxicity was 1000 mg/kg bw per day, the highest dose tested. The NOAEL for embryo/fetal toxicity was 1000 mg/kg bw per day, the highest dose tested.

The Meeting concluded that broflanilide is not teratogenic.

In an acute neurotoxicity study in rats, broflanilide was administered by gavage at dose levels of 0, 200, 600 or 2000 mg/kg bw. The NOAEL for both systemic toxicity and neurotoxicity was 2000 mg/kg bw, the highest dose tested. In a 90-day neurotoxicity study in rats, broflanilide was administered at dietary concentrations of 0, 1 500, 5000 or 15 000 ppm (equal to 0, 99, 320 and 1041 mg/kg bw per day for males, 0, 118, 423 and 1137 mg/kg bw per day for females). The NOAEL for both systemic toxicity and neurotoxicity was 15 000 ppm (equal to 1041 mg/kg bw per day), the highest dose tested.

The Meeting concluded that broflanilide is not neurotoxic.

In a 28-day immunotoxicity study in rats, broflanilide was administered at dietary concentrations of 0, 1200, 4000 or 12 000 ppm (equal to 0, 104, 344, and 1020 mg/kg bw per day). The NOAEL for systemic toxicity and immunotoxicity was 12 000 ppm (equal to 1020 mg/kg bw per day), the highest dose tested.

The Meeting concluded that broflanilide is not immunotoxic.

In a number of in vitro assays broflanilide and its metabolite DM-8007 (M11) did not bind to rat or human estrogen receptors, rat androgen receptors, nor did they transactivate androgen/estrogen receptors.

A number of in vitro and in vivo investigative studies were conducted to explore several possible MOAs for the vacuolation seen in the adrenal cortex and ovary, and for Leydig cell, ovary and uterus tumours in the rat. No MOA was established unequivocally for any of these effects and therefore their human relevance could not be discounted.

Toxicological data on metabolites and/or degradates

Metabolite DM-8007 (M11)

Metabolite DM-8007 is a rat (less than 5 percent of AD in faeces; approximately 50 percent of total radioactivity in plasma, liver and kidney), livestock and plant metabolite. Exposure in the rat was demonstrated in several toxicological studies.

The acute oral LD₅₀ of DM-8007 was greater than 2000 mg/kg bw.

Metabolite DM-8007 was tested in a gene mutation assay in bacteria. There was no evidence of mutagenicity.

In a 28-day toxicity study in rats, metabolite DM-8007 was administered at dietary concentrations of 0, 300, 1000 or 3000 ppm (equal to 0, 33, 85 and 278 mg/kg bw per day for males, 0, 31, 94 or 378 mg/kg bw per day for females). The NOAEL was 3000 ppm (equal to 278 mg/kg bw per day), the highest dose tested.

In a 90-day toxicity study in rats, metabolite DM-8007 (purity 99.7 percent) was administered at dietary concentrations of 0, 125, 500 or 3000 ppm (equal to 0, 7.8, 31 and 190 mg/kg bw per day for males, 0, 8.8, 36 or 215 mg/kg bw per day for females). The NOAEL was 3000 ppm (equal to 190 mg/kg bw per day), the highest dose tested.

Based on the results of experimental studies and the structural similarity to broflanilide, the Meeting concluded that metabolite DM-8007 is not of greater toxicity than broflanilide and would be covered by the health-based guidance values for the parent.

Metabolite DC-DM-8007

Metabolite DC-DM-8007 is a metabolite in rats (less than 3 percent of its hydroxylated and conjugated forms in faeces or bile), poultry (laying hens) and ruminants (lactating goats).

The acute oral LD₅₀ of metabolite DC-DM-8007 was greater than 2000 mg/kg bw.

Metabolite DC-DM-8007 was tested in a gene mutation assay in bacteria. There was no evidence of mutagenicity.

In a 28-day toxicity study in rats, metabolite DC-DM-8007 was administered at dietary concentrations of 0, 100, 500 or 1500 ppm (equal to 0, 11, 47 and 156 mg/kg bw per day in males, 0, 12, 44 or 145 mg/kg bw/day in females). No NOAEL could be identified due to increased extramedullary haematopoiesis in the spleen, reticulocyte counts in both sexes and increased spleen weights in females at 100 ppm (equal to 11 mg/kg bw per day), the lowest dose tested.

In a 90-day toxicity study in rats, metabolite DC-DM-8007 was administered at dietary concentrations of 0, 30, 75 or 750 ppm (equal to 0, 1.9, 5.3 and 54 mg/kg bw per day in males, 0, 2.2, 5.7 and 56 mg/kg bw per day in females). The NOAEL was 30 ppm (equal to 2.2 mg/kg bw per day) based on decreased red blood cells, haematocrit, haemoglobin, increased reticulocytes and extramedullary haematopoiesis in the spleen, and increased spleen weights in females, at 75 ppm (equal to 5.7 mg/kg bw per day).

The Meeting concluded that metabolite DC-DM-8007 has similar NOAELs to the parent compound. The reference values of the parent apply also to this metabolite.

Metabolite S(PFP-OH)-8007, (M8)

Metabolite S(PFP-OH)-8007 is a rat metabolite (less than 3 percent of the AD in faeces; up to 13 percent of total radioactivity in plasma, liver, kidney and fat) and minor plant metabolite (cabbage, tomato, Japanese radish, soya bean, rice and tea).

The acute oral LD₅₀ of metabolite S(PFP-OH)-8007 was greater than 2000 mg/kg bw.

Metabolite S(PFP-OH)-8007 was tested in a gene mutation assay in bacteria. There was no evidence of mutagenicity.

In a 28-day toxicity study in rats, metabolite S(PFP-OH)-8007 was administered at dietary concentrations of 0, 300, 1000 or 3000 ppm (equal to 0, 26, 81 and 243 mg/kg bw per day for males, 0, 30, 109 and 265 mg/kg bw per day for females). The NOAEL was 300 ppm (equal to 26 mg/kg bw per day)

based on increased adrenal weights and increased vacuolation in the adrenals of both sexes and increased vacuolation in the interstitial glands of the ovary at 1000 ppm (equal to 81 mg/kg bw per day).

In a 90-day toxicity study in rats, metabolite S(PFP-OH)-8007 was administered at dietary concentrations of 0, 125, 500 or 3000 ppm (equivalent to 0, 8.3, 32, 193 mg/kg bw per day for males, 0, 9.1, 37 and 219 mg/kg bw per day for females). No NOAEL could be identified due to increased adrenal weights and increased vacuolation in the adrenals of both sexes, and increased ovary weight and vacuolation in interstitial glands of the ovary at 125 ppm (equal to 8.3 mg/kg bw per day) the lowest dose tested.

Metabolite S(PFP-OH)-8007 has a similar toxicity profile to broflanilide. After 90 days of dosing, the LOAEL of metabolite S(PFP-OH)-8007 (8.3 mg/kg bw per day) was lower than that of broflanilide (35 mg/kg bw per day). Considering the dose levels used and the severity of the effects, the Meeting concluded that metabolite S(PFP-OH)-8007 toxicity is greater than the parent compound by a factor of three.

Metabolite hippuric acid

Hippuric acid (2-benzamidoacetic acid) is a major metabolite in rats (up to 11 percent of AD in urine) and livestock (lactating goats).

Hippuric acid is commonly found at milligram per litre levels in human urine. The Meeting concluded that it is of no toxicological concern from the use of broflanilide.

Metabolites B-Oxam and B-Urea

Metabolites B-Oxam and B-Urea are found in rotational crops. These metabolites were predicted to be negative for genotoxic effects (Ames end-point) by QSAR analysis. It was concluded that metabolites B-Oxam and B-Urea are unlikely to possess mutagenic potential. The Meeting concluded that the TTC approach should be applied using Cramer class III, 1.5 µg/kg bw per day.

Metabolites DC-DM-(A4-OH)-8007 and DC-DM-(A6-OH)-8007 (free and conjugate)

Free and conjugated forms of metabolites DC-DM-(A4-OH)-8007 and DC-DM-(A6-OH)-8007 are livestock metabolites (liver and kidney).

No specific toxicological data were available. The Meeting noted that metabolites DC-DM-(A4-OH)-8007 and DC-DM-(A6-OH)-8007 are structurally similar to the rat intermediate metabolite DC-DM-(A-OH)-8007 (M9B) (present at greater than 2 percent of AD in faeces), a hydroxylated form of metabolite DC-DM-8007, for which toxicity data are available.

The Meeting concluded that the toxicity of free and conjugated metabolites DC-DM-(A4-OH)-8007 and DC-DM-(A6-OH)-8007 is not greater than that of the parent compound. The reference values of the parent apply to these metabolites.

Metabolite DM-(C2-OH)-8007 (free and conjugate)

Free and conjugated metabolite DM-(C2-OH)-8007 are livestock metabolites (liver and kidney).

No specific toxicological data were available. The Meeting noted that metabolite DM-(C2-OH)-8007 is structurally similar to the rat intermediate metabolite DM-(C4-OH)-8007, (C) (present at up to 15 percent of total radioactivity in plasma, liver and kidney), a hydroxylated form of metabolite DM-8007 for which toxicity data are available and exposure in rats was demonstrated in several toxicological studies.

The Meeting concluded that toxicity of the free and conjugated metabolite DM-(C2-OH)-8007 is not greater than that of the parent compound. The reference values of the parent apply to these metabolites.

Microbiological data

There was no information available in the public domain and no experimental data were provided that addressed the possible impact of broflanilide residues on the human intestinal microbiome.

Human data

No information was provided on the health of workers involved in the manufacture or use of broflanilide. No information on accidental or intentional poisoning in humans was available.

The Meeting concluded that the existing database on broflanilide was adequate to characterize the potential hazards to the general population, including fetuses, infants and children.

Toxicological evaluation

The Meeting established an acceptable daily intake (ADI) for broflanilide of 0–0.02 mg/kg bw, based on the LOAEL of 5.9 mg/kg bw per day in the two-year toxicity and carcinogenicity study in rats, and using a safety factor of 100 for intra- and interspecies differences and an additional safety factor of three for using a LOAEL as the point of departure (POD). This ADI is supported by the 90-day rat study NOAEL of 2.0 mg/kg bw per day, and the two-generation reproductive study parental NOAEL of 2.3 mg/kg bw per day. The upper bound of this ADI provides a margin of at least 4750 relative to the LOAEL for tumours. It is considered adequately protective of effects observed at the LOAEL of 100 mg/kg bw per day in the one-year dog study.

The Meeting concluded that it was not necessary to establish an ARfD for broflanilide in view of its low acute oral toxicity and the absence of developmental toxicity and any other toxicological effects that would be likely to be elicited by a single dose.

A toxicological monograph was prepared.

Levels relevant to risk assessment of broflanilide

Species	Study	Effect	NOAEL	LOAEL
Mouse	78-week study of toxicity and carcinogenicity ^a	Toxicity	1500 ppm, equal to 157 mg/kg bw/day	7000 ppm, equal to 745 mg/kg bw/day
		Carcinogenicity	7000 ppm, equal to 745 mg/kg bw/day ^c	-
Rat	Acute neurotoxicity study ^b	Neurotoxicity	2000 mg/kg bw/day ^c	-
	Two-year studies of toxicity and carcinogenicity ^{a,d}	Toxicity	-	100 ppm, equal to 5.9 mg/kg bw/day ^e
		Carcinogenicity	300 ppm, equal to 19 mg/kg bw/day	1500 ppm, equal to 95 mg/kg bw/day
	Two-generation study of reproductive toxicity ^a	Reproductive toxicity	15 000 ppm, equal to 1147 mg/kg bw/day ^c	-
		Parental toxicity	30 ppm, equal to 2.3 mg/kg bw/day	100 ppm, equal to 7.5 mg/kg bw/day
Offspring toxicity		300 ppm, equal to	1500 ppm, equal to	

Species	Study	Effect	NOAEL	LOAEL
			23 mg/kg bw/day	111 mg/kg bw/day
	Developmental toxicity study ^b	Maternal toxicity	1000 mg/kg bw/day ^c	-
		Embryo/fetal toxicity	1000 mg/kg bw/day ^c	-
Rabbit	Developmental toxicity study ^b	Maternal toxicity	1000 mg/kg bw/day ^c	-
		Embryo and fetal toxicity	1000 mg/kg bw/day ^c	-
Dog	13-week toxicity ^f	Toxicity	1000 mg/kg bw/day ^c	-
	One-year studies of toxicity ^f	Toxicity	-	100 mg/kg bw/day ^e
Metabolite DM-8007 (M11)				
Rat	Four-week study of toxicity ^a	Toxicity	3000 ppm, equal to 278 mg/kg bw/day ^c	-
	13-week toxicity ^a	Toxicity	3000 ppm, equal to 190 mg/kg bw/day ^c	-

Notes:^a Dietary administration.^b Gavage administration.^c Highest dose tested.^d Two or more studies combined.^e Lowest dose tested.^f Capsule administration.

Acceptable daily intake (ADI), applies to broflanilide and DM-8007, expressed as broflanilide

0–0.02 mg/kg bw

Acute reference dose (ARfD)

Unnecessary

Information that would be useful for the continued evaluation of the compound

Results from epidemiological, occupational health and other such observational studies of human exposure

Critical end-points for setting guidance values for exposure to broflanilide

Absorption, distribution, excretion and metabolism in mammals

Rate and extent of oral absorption	Rapid, T_{max} 1–2 hours; 14–23 percent of AD
Distribution	Wide; highest concentrations in fat
Potential for accumulation	No evidence of accumulation
Rate and extent of excretion	>88 percent of AD excreted within 48 hours, complete by 168 hours; major route via faeces

Metabolism in animals	Extensive, via hydroxylation or demethylation, and hydroxylation followed by conjugation
Toxicologically significant compounds in animals and plants	Broflanilide, DM-8007
Acute toxicity	
Rat, LD ₅₀ , oral	>5000 mg/kg bw
Rat, LD ₅₀ , dermal	>5000 mg/kg bw
Rat, LC ₅₀ , inhalation	>2.2 mg/L
Rabbit, dermal irritation	Not irritating
Rabbit, ocular irritation	Not irritating
Mouse and Guinea pig, dermal sensitization	Not sensitizing (LLNA, Magnussen & Kligmann)
Short-term studies of toxicity	
Target/critical effect	Adrenal gland and ovary vacuolation (mouse, rat, dog)
Lowest relevant oral NOAEL	2 mg/kg bw per day (rat)
Lowest relevant dermal NOAEL	1000 mg/kg bw per day, highest dose tested (rat)
Lowest relevant inhalation NOAEC	0.031 mg/L (rat)
Long-term studies of toxicity and carcinogenicity	
Target/critical effect	Ovary weight and vacuolization (rat)
Lowest relevant NOAEL	No NOAEL identified; LOAEL 5.9 mg/kg bw per day (rat), the lowest dose tested
Carcinogenicity	Not carcinogenic in mice; increase in Leydig cell adenomas, uterus adenocarcinomas and benign tumours of sex cord stromal origin in the ovary in rats ^a
Genotoxicity	
Unlikely to be genotoxic	
Reproductive toxicity	
Target/critical effect	Adrenal weight and vacuolization, ovary weight and vacuolization/decrease in pup weights (rat)
Lowest relevant parental NOAEL	2.3 mg/kg bw per day (rat)
Lowest relevant offspring NOAEL	22.6 mg/kg bw per day (rat)
Lowest relevant reproductive NOAEL	1147 mg/kg bw per day, the highest dose tested (rat)
Developmental toxicity	
Target/critical effect	No effects
Lowest relevant maternal NOAEL	1000 mg/kg bw per day, the highest dose tested (rat, rabbit)
Lowest relevant embryo/fetal NOAEL	1000 mg/kg bw per day, the highest dose tested (rat, rabbit)
Neurotoxicity	
Acute neurotoxicity NOAEL	>2000 mg/kg bw, highest dose tested (rat)
Subchronic neurotoxicity NOAEL	1041 mg/kg bw per day, highest dose tested (rat)
Developmental neurotoxicity NOAEL	No data
Other toxicological studies	
Immunotoxicity	>1020 mg/kg bw per day, highest dose tested (rat)
Studies on toxicologically relevant metabolites	

Metabolite DM-8007	Acute oral LD ₅₀ : >2000 mg/kg bw (rat) 28-day NOAEL: 278 mg/kg bw per day, the highest dose tested (rat) 90-day NOAEL: 190 mg/kg bw per day, the highest dose tested (rat) Not genotoxic (Ames)
Microbiological data	No data available
Human data	No clinical cases or poisoning incidents have been recorded

Notes:

^a Unlikely to pose a carcinogenic risk to humans via exposure from the diet.

Summary

	Value	Study	Safety factor
ADI	0–0.02 mg/kg bw ^a	Two-year study of toxicity and carcinogenicity (rat)	300 (100 for intra- and interspecies variation and three for using the LOAEL as the POD)
ARfD	Not necessary		

Notes:

^a Applies to broflanilide and DM-8007, expressed as broflanilide.

RESIDUE AND ANALYTICAL ASPECTS

Broflanilide is a meta-diamide insecticide for the control of chewing-insect pests. It is the precursor to its active form desmethyl broflanilide, which acts by binding to the GABA receptor, resulting in a block of inhibitory neurotransmission and death of target insects. At the Fifty-first Session of the CCPR, broflanilide was scheduled for evaluation as a new compound in 2020 and rescheduled to the 2022 JMPR.

The Meeting received information on identity, physicochemical properties, metabolism (plant, confined rotational crops and animals), environmental fate, field rotational crops, methods of residue analysis, freezer storage stability, registered use patterns, supervised residue trials, fate of residues in processing, and livestock feeding studies.

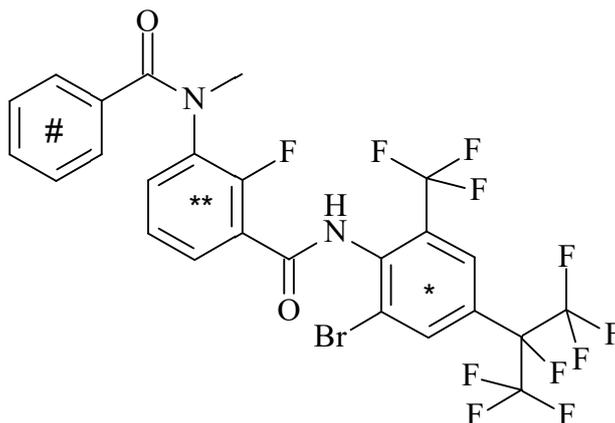


Figure 5.6.1 Chemical structure of broflanilide

Notes:

IUPAC name: *N*-[2-bromo-4-(perfluoropropan-2-yl)-6-(trifluoromethyl)phenyl]-2-fluoro-3-(*N*-methylbenzamido)benzamide. The molecular weight of parent is 663.3 g/mol). * B-ring; # C-ring; ** A-ring.

Table 5.6.1 Overview of metabolites and codes referred to in the appraisal

Code Names	Chemical Names (IUPAC)	Structure
DM-8007, MLP-8473 (Reg. No 5856361)	3-benzamido- <i>N</i> -[2-bromo-4-(perfluoropropan-2-yl)-6-(trifluoromethyl)phenyl]-2-fluorobenzamide	<p>Molar mass: 649.3 g/mol</p>
S(PFP-OH)- 8007 (Reg. No 5959598)	<i>N</i> -[2-bromo-4-(1,1,1,3,3,3-hexafluoro-2-hydroxypropan-2-yl)-6-(trifluoromethyl)phenyl]-2-fluoro-3-(<i>N</i> -methylbenzamido)benzamide	<p>Molar mass: 661.3 g/mol</p>
DC-DM-8007 Reg.No. 5936906	3-amino- <i>N</i> -[2-bromo-4-(perfluoropropan-2-yl)-6-(trifluoromethyl)phenyl]-2-fluorobenzamide	<p>Molecular mass: 545.1 g/mol</p>
DC-DM-(A4- OH)-8007 KAK-1606-146	3-amino- <i>N</i> -[2-bromo-4-(perfluoropropan-2-yl)-6-(trifluoromethyl)phenyl]-2-fluoro-6-hydroxybenzamide	

Code Names	Chemical Names (IUPAC)	Structure
DC-DM-(A6-OH)-8007 267-022-015-2	3-amino- <i>N</i> -[2-bromo-4-(perfluoropropan-2-yl)-6-(trifluoromethyl)phenyl]-2-fluoro-4-hydroxybenzamide	
DM-(C2-OH)-8007 267-014-033-4	<i>N</i> -2-bromo-4-(perfluoropropan-2-yl)-6-(trifluoromethyl)phenyl-3-(2-hydroxybenzamido)benzamide	
B-urea (Reg. No 6065386)	[2-bromo-4-(perfluoropropan-2-yl)-6-(trifluoromethyl)phenyl]urea	 Molar mass: 451.1 g/mol
B-oxam-acid (Reg. No 6066332)	<i>N</i> -[2-bromo-4-(perfluoropropan-2-yl)-6-(trifluoromethyl)phenyl]oxamic acid	 Molar mass: 480.1 g/mol
Hippuric acid	<i>N</i> -benzoylglycine	
H-U27B (and related but not fully elucidated H-U27C)	Hydroxyl cysteine conjugate of DM-8007	

Physical and chemical properties

Parent broflanilide and metabolites DM-8007, S(PFP-OH)-8007 and DC-DM-8007 have low solubility in water, but at least broflanilide has a good solubility in organic solvent. The $\log P_{OW}$ at 20 or 25 °C and at pH of 4, 7 and 10 ranges between 3.8–5.9 for these compounds, suggesting that the parent and metabolites have the potential to partition into fat. Parent broflanilide was shown to be hydrolytically stable at pH 4, 7 and 9. Broflanilide was not prone to photodegradation in water pH 7 (DT_{50} : 69–89 days), but showed slow degradation at pH 5 (DT_{50} : 14–20 days) and moderately fast degradation at pH 9 (DT_{50} : 3–6 days). The vapour pressure indicates that broflanilide is not volatile.

METABOLISM

Plant metabolism

The metabolic fate in plants was investigated following application of [B-ring- $U-^{14}C$]- and [C-ring- $U-^{14}C$]-labelled broflanilide (Figure 5.6.1) to cabbage, tomato, Japanese radish, soya bean, rice, wheat and tea.

Cabbage

Cabbages grown outdoors received two foliar applications of [B-ring-U-¹⁴C]- and [C-ring-U-¹⁴C]-labelled broflanilide at nominal rates of 0.025 kg ai/ha each at immature stage (BBCH 45) and 7 days later (BBCH 46). Immature cabbage (BBCH 46) was harvested 6 days after application 1, while mature cabbage (BBCH 49) was harvested 21 days after application 2.

TRRs were highest in cabbage (inner and outer leaves) taken at 6 DAT1 ranging between 0.304–0.352 mg eq/kg. In cabbage (inner and outer leaves) taken at 21 DAT2, about half of the previous TRR for the B-ring was found, while levels for the C-ring remained the same.

The outer leaves received a surface rinse with acetonitrile before homogenization, which released 55–66 percent of the TRR. Homogenized samples of the rinsed outer leaves and the inner leaves were subjected to extraction with acetonitrile (twice) and acetonitrile:water (1+1, v/v) (once). Extracted radioactivity was similar for both labels ranging between 92–95 percent TRR, while the PES accounted for 6–8 percent TRR.

Parent broflanilide was the major identified residue in immature and mature cabbage (inner and outer leaves) accounting for 66–84 percent TRR (0.10–0.25 mg/kg). Additionally, two minor metabolites were identified, namely S(PFP-OH)-8007 and DM-8007 accounting for 3.8–7.6 percent TRR (0.01–0.012 mg eq/kg) and 2.9–7.9 percent TRR (0.009–0.021 mg eq/kg), respectively. The unextracted residue was not further characterized

Tomato

Tomato grown outdoors received two foliar applications of [B-ring-U-¹⁴C]- and [C-ring-U-¹⁴C]-labelled broflanilide at nominal rates of 0.025 kg ai/ha each. The first application occurred at the pre-bud stage (approx. BBCH 49–50) and the second application 83 days later at the beginning ripening stage (approximately BBCH 79–81). Immature tomatoes and leaves (BBCH 75) were harvested 71 days after application 1, while mature tomatoes and leaves (approximately BBCH 88) were harvested 10 days after application 2.

TRR was very low or non-detected in tomato leaves and immature fruits from harvest 1. In samples from harvest 2, radioactivity was highest in leaves, ranging between 0.904–1.596 mg eq/kg while in tomato fruits, levels were significantly lower at 0.01 mg eq/kg. Samples of tomato leaves and fruits received a surface rinse with acetonitrile before homogenization, which released 70–80 percent TRR.

Portions of the tomato leaves from harvest 2 were subjected to extraction with acetonitrile (twice) and acetonitrile:water (1+1, v/v) (once). Extracted radioactivity was similar for both labels ranging between 96–99 percent TRR in tomato leaves and 70–80 percent TRR in tomato fruit. The PES in tomato fruit accounted for 20–30 percent TRR, but was < 0.003 mg eq/kg in absolute concentration and not further analysed.

Parent broflanilide was the major identified residue, accounting for 87–89 percent TRR (0.76–1.3 mg/kg) in tomato leaves and 60–68 percent TRR (0.006–0.007 mg eq/kg) in tomato fruit. Additionally, metabolites S(PFP-OH)-8007 and DM-8007 were identified in tomato leaves and fruit at minor levels accounting for 3.0–3.4 percent TRR (0.0003–0.051 mg eq/kg) and 3.4–4.0 percent TRR (0.0004–0.060 mg eq/kg), respectively.

Japanese radish

Japanese radish grown indoors received two applications of [B-ring-U-¹⁴C]- and [C-ring-U-¹⁴C]-labelled broflanilide. The first treatment was applied to the soil at a rate of 0.4 kg ai/ha immediately after seeding,

and a second treatment was applied foliar 41 days later at a rate of 0.225 kg ai/ha, 29 days before the final harvest. Plants (leaves and root) were collected at three sampling points: 40DAT1 (intermediate harvest-1), 14DAT2 (intermediate harvest-2) and 29DAT2 (final harvest).

TRRs were highest in radish leaves ranging between 3.6–4.4 mg eq/kg for the 14DAT2 and 29 DAT2 sampling time points. In radish roots, the TRR was at least two orders in magnitude lower, ranging between 0.0036–0.0119 mg eq/kg.

Radish leaves were surface-rinsed with acetonitrile (except the intermediate harvest-1) and the root was further separated into peel and flesh. All samples were homogenized by blending with dry ice. Portions of the samples were subjected to extraction with acetonitrile:water (8+2, v/v) (twice) and acetonitrile:0.1M HCl (8+2, v/v) (once).

The extracted radioactivity in radish leaves ranged between 95–99 percent TRR, except for leaves from intermediate harvest 1 for the C-ring label (70 percent TRR). In these samples the radioactivity in the PES accounted for 30 percent TRR, but was < 0.0021 mg eq/kg in absolute concentration. In radish roots, the sum of the radioactivity found in peel and flesh extracts accounted for 54–96 percent TRR, while 4.3–47 percent TRR remained in the PES. However, absolute concentrations in the PES were throughout < 0.0056 mg eq/kg.

Parent broflanilide was the major identified residue in radish leaves, accounting for 77–82 percent TRR (2.8–3.6 mg/kg). Additionally, metabolites S(PFP-OH)-8007 and DM-8007 were identified at minor levels, accounting for 1.7–2.9 percent TRR (0.067–0.12 mg eq/kg) and 2.5–3.3 percent TRR (0.11–0.13 mg eq/kg), respectively. Residues in roots were not further investigated.

Soya bean

Soya bean grown outdoors received two foliar applications of [B-ring-U-¹⁴C]- and [C-ring-U-¹⁴C]-labelled broflanilide at nominal rates of 0.025 kg ai/ha each. The first application occurred at bud formation (approx. BBCH 49–51) and the second application 77 days later at the beginning of the pod and seed ripening stage (approx. BBCH 79–81). Soya bean forage and hay samples were harvested at 21DAT1 (BBCH 69) and 35DAT1 (BBCH 74), respectively. The mature soya bean seeds were harvested at 12DAT2.

Similar TRR levels were found for both labels, with the highest levels in soya bean forage ranging between 0.460–0.433 mg eq/kg. In soya bean seeds, the detected radioactivity was < 0.01 mg eq/kg for both labels and was not further analysed.

Portions of soya bean forage and hay were subjected to extraction with acetonitrile (twice) and acetonitrile:water (1+1, v/v) (once). The extracted radioactivity was similar for both labels ranging between 92–93 percent TRR in soya bean forage and 89–91 percent TRR in soya bean hay.

Parent broflanilide was the major identified residue, accounting for 75–76 percent TRR (0.32–0.34 mg/kg) in soya bean forage and 67–71 percent TRR (0.19 mg eq/kg) in soya bean hay. Additionally, metabolites S(PFP-OH)-8007 and DM-8007 were identified in soya bean forage and hay at minor levels accounting for 3.8–5.6 percent TRR (0.010–0.021 mg eq/kg) and 5.1–8.3 percent TRR (0.022–0.023 mg eq/kg), respectively.

Rice

Rice grown indoors received two applications of [B-ring-U-¹⁴C]- and [C-ring-U-¹⁴C]-labelled broflanilide. The first treatment was applied to the flooding water at a rate of 0.3 kg ai/ha immediately after seed transplantation, followed by a foliar application at a rate of 0.15 kg ai/ha 73 days later. The rice plants

were collected at 13DAT2 (intermediate harvest: foliage) and at 32DAT2 (the final harvest: husked rice, hulls, straw and root).

The TRR (sum of foliage surface rinse, extracts and PES) was generally similar for both labels, with the highest levels found in rice hulls and straw at 5.5–6.8 mg eq/kg and 4.2–4.9 mg eq/kg, respectively. In husked rice, levels were at least one order in magnitude lower at 0.021 mg eq/kg for the B-ring label and 0.11 mg eq/kg for the C-ring label.

Only the foliage from the intermediate harvest was surface-rinsed with acetonitrile. Portions of the foliage, husked rice, straw and hulls were subjected to extraction with acetonitrile:water (8+2, v/v) (twice), followed by SPE fractionation of the extracts.

The extracted radioactivity from rice forage, husked rice, hulls and straw ranged between 85–98 percent TRR, except for husked rice for the C-ring label (18 percent TRR). In this sample the radioactivity in the PES accounted for 82 percent TRR. Further characterization of the PES using acid/enzyme treatments showed that 21 percent TRR accounted for the starch fraction and 7.2 percent TRR for the protein fraction. Since the absolute measured radioactivity in the extracts was similar for both labels, it was assumed that the higher radioactivity in the PES from C-ring label was due to incorporation of $^{14}\text{CO}_2$ into the plant matrix.

Parent broflanilide was the major identified residue, accounting for 84–87 percent TRR (1.0–1.6 mg/kg) in rice foliage, 83–90 percent TRR (4.6–8.1 mg/kg) in hulls and 85–87 percent TRR (3.6–4.1 mg/kg) in straw. In husked rice, although the relative amounts of parent broflanilide differed between the two labels, accounting for 64 percent TRR using the B-ring label and 13 percent TRR using the C-ring label, the radioactive residue levels were similar (0.013–0.014 mg eq/kg). Additionally, metabolites S(PFP-OH)-8007 and DM-8007 were identified in all matrices accounting for 1.0–8.5 percent TRR (0.002–0.28 mg eq/kg) and 0.8–5.4 percent TRR (0.001–0.26 mg eq/kg), respectively.

Wheat

Wheat grown indoors received seed treatment of [B-ring- ^{14}C]-labelled broflanilide applied at 10 g ai/100 kg seeds, corresponding to actual application rate of 0.022 kg ai/ha. Immature wheat plants (wheat forage) were collected at growth stage BBCH 39 (77 DAT), and half of the forage was allowed to dry for 8 days at room temperature to produce wheat hay. Mature wheat plants were harvested at growth stage BBCH 89 (154 DAT) and were separated into straw and grains.

TRR levels in wheat matrices were generally low, with the highest level measured in wheat straw at 0.029 mg eq/kg, while the TRR in wheat grain was up to 0.011 mg eq/kg.

Portions of wheat straw and grains were subjected to extraction with acetonitrile:water (1+1, v/v) (twice), followed by acetonitrile (once). The straw extracts were further partitioned with ethyl acetate, followed by fractionation using SPE. The PES of wheat straw and grains were characterized by enzyme solubilization using macerozyme, tyrosinase and amylase.

Extractability with solvents was higher in straw (79 percent TRR) compared to grains (29 percent TRR). Further characterization of the PES released additionally 6.7 percent TRR from wheat straw and 24 percent TRR from wheat grain. No individual components could be identified in either matrix. In wheat straw, one unknown component accounted for 14 percent TRR, but the level was < 0.01 mg eq/kg.

Tea grown outdoors received two foliar applications of [B-ring- ^{14}C]- and [C-ring- ^{14}C]-labelled broflanilide at nominal rates of 0.1 kg ai/ha each with a RTI of 14 days. Tea leaves were harvested at 7 days after the second application (7DAT2) and 14DAT2.

The TRR was generally similar for both labels and harvest times, ranging between 15–20 mg eq/kg. Tea leaves were surface-rinsed with acetonitrile followed by extraction with acetonitrile (twice) and acetonitrile:water (1+1, v/v) (once). The extracted radioactivity from tea leaves ranged between 99.3–99.6 percent TRR, with over 97 percent radioactive being removed by the acetonitrile rinse.

Parent broflanilide was the major identified residue, accounting for 96–97 percent TRR (14–19 mg/kg). Additionally, metabolites S(PFP-OH)-8007 and DM-8007 were identified at minor levels of 1.0–1.4 percent TRR (0.14–0.27 mg eq/kg) and up to 1.0 percent TRR (0.20 mg eq/kg), respectively.

Summary of plant metabolism

In all plant metabolism studies, broflanilide was degraded into DM-8007 via demethylation or into S(PFP-OH)-8007 via oxidative defluorination (substitution of fluorine with hydroxy group). Parent broflanilide was the major identified component in all matrices, while both metabolites were detected at minor levels.

Animal metabolism

The Meeting received studies on the metabolism of broflanilide in laboratory animals, lactating goats and laying hens. The evaluation of the metabolism studies in laboratory animals was carried out by the WHO Core Assessment Group.

Lactating goats

In lactating goats, the metabolic fate of broflanilide was investigated using [B-ring-U-¹⁴C]- and [C-ring-U-¹⁴C]-labelled broflanilide. The compound was administered orally once daily (after morning milking) for 10 consecutive days at 19 ppm (0.62 mg/kg bw day) and 20 ppm (0.73 mg/kg bw) for the B-ring and C-ring label, respectively.

The majority of the radioactivity was found in faeces, at 51–75 percent of the applied radioactivity (AR). In urine, 24 percent AR was found in the C-ring treatment, while only 0.7 percent AR was found in the B-ring treatment. In edible tissues, the highest TRRs were found in fats (omental, subcutaneous and renal), ranging from 2.6–3.4 mg eq/kg for both labels and in liver, ranging from 0.46 mg eq/kg (C-ring) to 2.2 mg eq/kg (B-ring). In muscle and kidney, TRRs were lower for both labels, ranging between 0.22–0.37 mg eq/kg and 0.25–0.27 mg eq/kg, respectively.

In whole milk, the radioactive residues ranged between 0.12–0.43 mg eq/kg for both labels. Residue levels reached a plateau after approximately 6 days and 2 days for the B-ring and C-ring labels, respectively. In milk fat, residues were ~2 orders in magnitude higher compared to skim milk for both labels, reaching up to 4.1 mg eq/kg.

Samples of flank and loin muscles, liver and kidney were extracted twice with acetonitrile/water (1+1, v/v) and once with acetonitrile. Skim milk was extracted twice with acetone:water (1+1, v/v) and once with acetone. Fats and milk fat were extracted twice with acetone/hexane (1+4, v/v) and once with acetone. Solvent extraction released at least 88 percent TRR from most matrices, except for liver (42–68 percent TRR, both labels) and kidney (76 percent TRR, B-ring label).

The PES from liver (B and C-ring labels) and kidney (B-ring label only) were further characterized by enzyme solubilization using protease and lipase, followed by incubations with 1 mol/L HCl and 1 mol/L NaOH, which released additionally 16–59 percent TRR. The extracts and solubilizates were also treated with β -glucuronidase in order to cleave conjugates to their respective aglycons.

Parent broflanilide was only detected as a minor residue in muscle, kidney and liver, accounting for 0.5–6.7 percent TRR (0.005–0.022 mg/kg). A major identified metabolite using both labels was DM-

8007 in muscle, milk, fats, liver (only C-label) and kidney, accounting for 21.3–99.9 percent TRR (0.01–3.4 mg eq/kg). In the B-label treated goat only, metabolite DC-DM-8007 was detected at major proportions in muscle, milk, fats, liver and kidney, ranging from 29–67 percent TRR (0.017–2.3 mg eq/kg), while in the C-label only, hippuric acid was detected in skim milk, liver and kidney at 19–69 percent TRR (0.018–0.13 mg/kg). Also, hydroxylated and conjugated DC-DM-(A4-OH)-8007, DC-DM-(A6-OH)-8007 and DM-(C2-OH)-8007 were identified in liver, accounting for up to 15 percent TRR (0.32 mg eq/kg), 11 percent TRR (0.24 mg eq/kg) and 17 percent TRR (0.078 mg eq/kg), respectively, and in kidney (B-label only), accounting for less than 10 percent TRR (0.007 to 0.019 mg eq/kg).

Laying hens

In laying hens, the metabolic fate of broflanilide was investigated using [B-ring-U-¹⁴C]- and [C-ring-U-¹⁴C]-labelled broflanilide. The compound was administered orally once daily for 14 consecutive days to 10 laying hens per label, at 14 ppm (0.86 mg/kg bw day) and 15 ppm (0.84 mg/kg bw) for the B- and C-label, respectively. Eggs and excreta samples were collected twice daily, at approximately 12 hour intervals. Samples of breast muscle, thigh (leg) muscle, abdominal and subcutaneous fat, liver and the entire gastrointestinal tract were collected after sacrifice, which occurred 6 hr after the last dose.

The majority of the radioactivity was found in excreta at 56–65 percent AR. In edible tissues radioactivity was highest in fat at 15–19 mg eq/kg, followed by egg yolk at 3.4–3.6 mg eq/kg and liver at 1.8–2.6 mg eq/kg. Incorporation of radioactivity into egg whites reached steady state within 3–4 days, while no plateau was reached in egg yolks.

Egg white, egg yolk, and muscle samples were extracted twice with acetonitrile/water (1+1, v/v) and then once with acetonitrile. Fat samples were extracted twice with acetone/hexane (1:4, v:v) then once with acetone. Liver samples were initially extracted three times with acetonitrile:water (1:1, v:v) and then once with acetonitrile. Extraction with solvents released at least 89 percent TRR from all matrices, except for liver where 65–72 percent TRR were released. The PES of hen liver from both radiolabels were further characterized by enzyme solubilization using protease and lipase, followed by incubations with 1 mol/L HCl and 1 mol/L NaOH, which released additionally 29–36 percent TRR.

Parent broflanilide was only tentatively identified (TLC analysis) in egg white from the B-label at 2.1 percent TRR (0.0004 mg/kg). The predominant identified residue for both labels was metabolite DM-8007 in all matrices, accounting for 57100 percent TRR (0.013–19 mg eq/kg). As a minor metabolite only occurring with the B-label, DC-DM-8007 was detected in all matrices, accounting for up to 3 percent TRR (0.55 mg eq/kg) in subcutaneous fat. In egg white, DC-DM-8007 accounted for 16 percent TRR, but residues were low (0.003 mg eq/kg). H-U27B (B-label), a hydroxyl cysteine conjugate of DM-8007 and the similar, but structurally not fully elucidated compound H-U27C (C-label) were identified in liver only, accounting for 5.3 percent TRR (0.131 mg eq/kg) and 3.3 percent TRR (0.061 mg eq/kg), respectively.

Summary of livestock metabolism

Generally, the transfer of radioactivity into animal food and feed matrices was low. The metabolism in lactating goats and laying hens is similar, starting with N-demethylation of parent broflanilide to form the main metabolite DM-8007, which is either hydroxylated and conjugated, or cleaved to DC-DM-8007 (identified using the B-label) and hippuric acid (identified using the C-label), via the intermediate benzoic acid. DC-DM-8007 is subsequently hydroxylated, followed by conjugation.

Environmental fate in soil

The Meeting received studies on aerobic soil degradation, soil photolysis, confined rotational crop metabolism and field rotational crops.

In two aerobic soil degradation studies performed with fresh soil under laboratory conditions, ¹⁴C-labelled broflanilide (A-ring, B-ring, or C-ring), was very persistent with estimated half-lives in various soils ranging between 288 to 1000 days. Identified metabolites were DM-8007 (up to 4.9 percent AR), S(PFP-OH)-8007 (up to 1.2 percent AR) and DC-DM-8007 (up to 2.3 percent AR). On the contrary, in a soil dissipation study under field conditions, broflanilide and metabolite DM-8007 were not, or only moderately persistent with estimated half-lives, ranging from 3.3 to 18 days and from 8 to 91 days, respectively. Therefore, the Meeting concluded that broflanilide does not have the potential to accumulate in soil.

Half-life of ¹⁴C-labelled broflanilide for soil photolysis was estimated (single 1st order kinetics) to 389 US solar days, or 347 OECD solar days. The only identified metabolite was DM-8007 at up to 4.2 percent AR. The Meeting concluded that photolysis does not represent a significant degradation pathway for broflanilide.

A confined rotational crop metabolism study was conducted with [A-ring-U-¹⁴C]- and [B-ring-U-¹⁴C]-labelled broflanilide, each applied at a rate of 0.15 kg ai/ha to a sandy loam soil. After plant-back intervals (PBIs) of 30, 120 and 270 days, the nature and level of radioactive residues were investigated in lettuce, radish and wheat.

Radioactivity for both labels in all matrices was comparable, with consistently higher levels found for the B-ring label. TRR levels were highest in wheat hay and straw for all PBIs, ranging between 0.014–0.067 mg/eq kg and 0.022–0.075 mg eq/kg, respectively, with the tendency to be higher at later PBIs.

Crop matrices with TRRs ≥ 0.01 mg/kg were extracted two times with acetonitrile/water (8:2, v/v), followed by one time with acetonitrile. Extractabilities ranged between 71–92 percent in radish foliage, 77–94 percent TRR in lettuce (immature and mature), 88–92 percent in wheat forage, 36–70 percent TRR in wheat hay, 58–77 percent TRR in straw and 22–84 percent TRR in grain. The highest radioactivity remaining in the PES was found in wheat straw from the treatment with B-labelled broflanilide (0.025 mg eq/kg), but no further characterization was performed.

In food matrices, parent broflanilide was identified in lettuce (immature and mature) at 19.6–46.6 percent TRR (0.002–0.008 mg/kg) at 120 and 270 day PBI and in radish leaves at 2.8–18.1 percent TRR (< 0.001–0.002 mg/kg) for the 270 day PBI only. In feed matrices, parent broflanilide was identified as a minor component in wheat forage, hay and straw, accounting for 4.3–16.7 percent TRR (0.001–0.004 mg/kg) in all PBIs.

Metabolite DM-8007 was a minor residue in wheat hay and straw and in radish leaves ranging between 1.5–3.7 percent TRR (< 0.001–0.002 mg eq/kg) at 30 and 270 day PBIs.

For the B-label only, an additional identified metabolite was B-urea, accounting for 9.7–30.2 percent TRR (0.004–0.010 mg eq/kg) in wheat forage, hay and straw in all PBIs, for 31.9 percent TRR (0.004 mg eq/kg) for the 270 day PBI only in radish leaves, for 26.6–34.5 percent TRR (0.003–0.005 mg eq/kg) at 120 and 270 day PBIs in immature lettuce and for 35.6 percent TRR (0.004 mg eq/kg) for the 270 day PBI only in mature lettuce. Once again for the B-label only, metabolite B-oxam-acid was identified in wheat forage, hay and straw, accounting for 5.4–35.6 percent TRR (0.001–0.024 mg eq/kg) and in radish leaves, accounting for 14.9 percent TRR (0.002 mg eq/kg) for the 270 day PBI only

In two field rotational crop trials, conducted during the 2016/17 growing seasons in the United States, broflanilide was applied once to bare soil at 0.05 kg ai/ha. Wheat, lettuce and radish were planted 30, 60, 90 and 360 DAT and sampled at normal crop maturity.

Residues of broflanilide as well as metabolites S(PFP-OH)-8007, DM-8007, B-oxam-acid and B-urea were < LOQ (0.01 mg eq/kg), with the exception of parent broflanilide in lettuce planted at 30 days PBI (0.013 mg/kg).

Summary of environmental fate in soil

The Meeting concluded that residues of broflanilide are not very persistent under field conditions and does not have the potential to accumulate in soil. From rotational crop studies, the Meeting concluded that significant carry-over of broflanilide residues in succeeding crops is unlikely.

Methods of analysis

The Meeting received analytical methods for the determination of broflanilide and metabolites S(PFP-OH)-8007, DM-8007, B-urea and B-oxamic acid in plant matrices and for broflanilide and metabolites DC-DM-8007 and DM-8007 in animal matrices.

For matrices of plant origin, a method for all analytes based on QuEChERS employed extraction with acetonitrile/water + buffer salts, followed by clean-up using dispersive solid phase extraction (dSPE) with PSA (optional for B-urea and B-oxamic acid). All analytes were determined by LC-MS/MS with an LOQ of 0.001 for broflanilide and metabolites S(PFP-OH)-8007 and DM-8007, and 0.01 mg/kg for B-urea and B-oxamic acid. Two additional methods employed extraction with acetonitrile or acetonitrile/water, followed by clean-up using liquid-liquid extraction and/or SPE. Final determination was done by LC-MS/MS, GC-ECD or HPLC-UV with LOQs ranging between 0.01–0.1 mg/kg.

For animal matrices, the method employed extraction with acetonitrile, followed by acetonitrile/water for milk, egg, liver, kidney and muscle. Samples of fat were extracted with acetone/hexane, followed by acetone. Liver, kidney and muscle were further partitioned with a salt solution (MgSO₄; NaCl; sodium citrate sesquihydrate and sodium citrate dehydrate), followed by clean-up with PSA. Final determination for all analytes was accomplished by LC-MS/MS with an LOQ of 0.001 mg/kg for milk and 0.01 mg/kg for all other matrices.

The Meeting concluded that suitable methods are available to measure residues of broflanilide and metabolites S(PFP-OH)-8007, DM-8007, B-urea and B-oxamic acid in plant matrices as well as broflanilide and metabolites DC-DM-8007 and DM-8007 in animal matrices.

Stability of pesticide residues in stored analytical samples

The Meeting received information on the storage stability of broflanilide and its metabolites S(PFPOH)-8007, DM-8007, B-oxam-acid and B-urea in a variety of plant matrices stored under frozen conditions. Samples were fortified at levels ranging from 0.01 to 0.5 mg/kg.

Residues of broflanilide and metabolite DM-8007 were stable in high acid matrices (grapes), high protein matrices (kidney beans), high water matrices (lettuce), high starch matrices (potato) and high oil matrices (soya bean seed) for at least 24 months.

Residues of metabolite S(PFP-OH)-8007 were stable for at least 25 months in high acid matrices (grapes) and high oil matrices (soya bean seed), for at least 28 months in high protein matrices (kidney beans) and high water matrices (lettuce), and for at least 24 months in high starch matrices (potato).

Residues of B-oxam-acid and B-urea were stable in high acid matrices (grapes), high protein matrices (kidney beans), high water matrices (lettuce), high starch matrices (wheat grain) and high oil matrices (soya bean seed) for at least 16 months.

All samples from field trials were analysed within the tested storage stability time.

For animal matrices, the Meeting received information on the storage stability of broflanilide and its metabolites DM-8007 and DC-DM-8007 in muscle, liver, kidney, milk and fat stored at -20 °C. Samples were fortified at 0.01 mg/kg.

Residues of broflanilide and metabolite DM-8007 were stable in all tested matrices for at least 2 months. Metabolite DC-DM-8007 was not stable in muscle and kidney, but stable up to one month in liver and at least 2 months in milk and fat. Samples were analysed within this time frame, except for the analysis of DC-DM-8007 in muscle (maximum storage 28 days) as well as in kidney and liver (maximum storage 36 days).

Definition of the residue

In food commodities from plant metabolism studies conducted on cabbage, Japanese radish, tomato, soya bean, rice and tea, the predominant residue was parent broflanilide, accounting for 66–84 percent TRR in cabbage, 77–82 percent TRR in Japanese radish leaves, 60–68 percent TRR in tomato fruit, 13–64 percent TRR in husked rice and 96–97 percent TRR in tea. In studies with wheat (seed treatment) and in Japanese radish root, TRR levels were too low for identification. In feed matrices, residues of broflanilide accounted for 75–76 percent TRR in soya bean forage, 67–71 percent TRR in soya bean hay, 83–90 percent TRR in rice hulls and 85–87 percent TRR in rice straw.

The Meeting concluded that parent broflanilide is a major residue in plants and is a suitable marker compound for compliance with MRLs.

Analytical methods are available for monitoring broflanilide in all plant matrices.

On deciding which compounds should be included in the residue definition for risk assessment, the Meeting considered the likely occurrence of the compounds and the toxicological properties of the metabolites S(PFP-OH)-8007 and DM-8007.

The Meeting concluded that S(PFP-OH)-8007 is covered by the health based guidance value of broflanilide, but is toxicologically 3 times more potent. In plant metabolism studies, S(PFP-OH)-8007 was identified as a minor metabolite (< 10 percent TRR), with levels between 3 and 33 times lower than parent. The metabolite was analysed in various food and feed commodities from supervised field trials and residues above LOQ were detected occasionally, but always at least one order in magnitude lower compared to parent. Taking into account its higher potency, its contribution to the overall dietary exposure was still insignificant compared to parent residues (+0.1 percent relative), due to the low concentrations found in treated commodities.

Metabolite DM-8007 was identified in plant metabolism studies as a minor metabolite (< 10 percent TRR), with levels between 8 to 2500 times lower than the parent. Additionally, the metabolite was analysed in various food and feed commodities from supervised field trials and residues above the LOQ were only detected occasionally, but always at least one order in magnitude lower, compared to parent. The Meeting concluded that metabolite DM-8007 is of no greater toxicity than parent broflanilide and is covered by the toxicological reference values of the parent.

The Meeting noted that broflanilide represents the major part of the residues in plant commodities, sufficiently addressing the overall potential dietary exposure from plant commodities and agreed to set the definition of the residue for dietary risk assessment for plant commodities as parent broflanilide.

In animal metabolism studies performed with lactating goats and laying hens, the predominant metabolic pathway is N-demethylation of parent broflanilide to form DM-8007. Its subsequent cleavage results in DC-DM-8007 (identified using the B-label) and hippuric acid (identified using the C-label), via the

intermediate benzoic acid. Depending on the label and tissue, some percentages may appear higher/lower than truly present due to the selective radiodetection.

Parent broflanilide was only detected as a minor residue in muscle, kidney and liver from lactating goats (0.5–6.7 percent TRR) and tentatively in egg white (2.1 percent TRR). In a cow feeding study, residues of broflanilide were detected in milk from the 10 ppm feeding level (approximately 7 times higher than the maximum dietary burden) at up to 0.0018 mg/kg and in cream from the 1.5 ppm (approximate maximum dietary burden) and the 10 ppm feeding levels at up to 0.016 mg/kg. In all other tissues broflanilide was not detected. The Meeting noted that broflanilide is not a suitable marker for the residue definition for compliance with the MRL for animal commodities alone.

The predominant identified residue in metabolism studies was metabolite DM-8007, accounting for 21–100 percent TRR (0.01–3.4 mg eq/kg) in lactating goat matrices and for 57–100 percent TRR (0.013–19 mg eq/kg) in laying hen matrices. In a cow feeding study, residues of DM-8007 were detected in milk (up to 0.12 mg/kg), cream (up to 1.3 mg/kg), fats (up to 0.79 mg/kg), liver (up to 0.078 mg/kg) and in muscle and kidney (up to 0.08 mg/kg). In matrices from laying hens, residues of DM-8007 were found in eggs, liver and fat at up to 0.023 mg/kg, 0.021 mg/kg and 0.15 mg/kg, respectively.

Hence, the Meeting decided to include parent broflanilide and metabolite DM-8007 into the residue definition for compliance with MRLs.

Analytical methods are available for measuring broflanilide and DM-8007 in animal matrices.

In muscle and fat tissues of all animals investigated, residue concentrations of the sum of broflanilide and DM-8007 were 8–60 times higher in fat compared to muscle. Similarly, levels were approximately 200–300 times higher in milk fat compared to skim milk and approximately 400 times higher in egg yolk compared to egg white. The log P_{ow} of DM-8007 is 5.8 in pH 7 buffer solution. The Meeting concluded that residues according to the residue definition are fat-soluble.

On deciding which compounds should be additionally included in the residue definition for risk assessment, the Meeting considered the likely occurrence and toxicological properties for the candidates DC-DM-8007 and hippuric acid as well as the hydroxylated and conjugated metabolites DC-DM-(A4-OH)-8007, DC-DM-(A6-OH)-8007 and DM-(C2-OH)-8007.

In goat metabolism study (20 ppm dose level), DC-DM-8007 was detected in muscle, milk, fats and kidney at similar proportions as DM-8007 (13–67 percent TRR), but higher proportion in liver. In laying hens (15 ppm dose level), DC-DM-8007 occurred mostly at minor proportions in all matrices (0.8–3.0 percent TRR), with the exception of egg white (16 percent TRR). In the cow feeding study, DC-DM-8007 residues above LOQ were only occasionally found at the 1.5 and 10 ppm feeding levels in milk (up to 0.0015 mg/kg) and in cream (up to 0.015 mg/kg), but levels were at least one order in magnitude lower compared to DM-8007. In all cow tissues, as well as in any matrices from a laying hen feeding study, DC-DM-8007 was < LOQ. The Meeting concluded that DC-DM-8007 does not significantly contribute to the dietary exposure and is covered by the toxicological reference value of the parent.

In goat metabolism study, hippuric acid accounted for 19–69 percent TRR in skim milk, liver and kidney. Compared to DM-8007, the residue levels were similar (kidney, liver) or higher (~3 fold in skim milk), but the metabolite was not analysed in the livestock feeding studies. In rat metabolism studies hippuric acid was found in urine at levels of 11 percent AD and is commonly found in mg or g/l concentrations in human urine. Hippuric acid is of no toxicological concern. Hence, the Meeting decided to not include hippuric acid into the residue definition for dietary risk assessment for animal commodities.

In addition, the hydroxylated and conjugated metabolites DC-DM-(A4-OH)-8007, DC-DM-(A6-OH)-8007 and DM-(C2-OH)-8007 were identified in liver and kidney from goats (15, 11 and 17 percent TRR, respectively), at lower or similar levels or higher relative to DM-8007. However, they were not detected in muscle, milk and fat. The Meeting concluded that these metabolites do not significantly contribute to dietary exposure and are covered by the toxicological reference values of the parent.

The Meeting decided to include broflanilide and metabolite DM-8007 in the residue definition for dietary exposure purposes for animal commodities

Definition of the residue for compliance with the MRL and for dietary risk assessment for plant commodities: *Broflanilide*

Definition of the residue for compliance with the MRL and for dietary risk assessment for animal commodities: *Sum of broflanilide plus 3-benzamido-N-[2-bromo-4-(perfluoropropan-2-yl)-6-(trifluoromethyl)phenyl]-2-fluorobenzamide (DM-8007), expressed as broflanilide.*

The residue is fat-soluble.

Results of supervised residue trials on crops

Supervised trials were available for the use of broflanilide on green onion (Welsh onion), leek, cabbage, Chinese cabbage, tomatoes, radish, Japanese radish, turnip, potato, wheat, barley, maize and coffee. No trials according to GAP were provided on turnip.

Green onions, Subgroup of

The critical GAP for green onions in Japan allows three foliar applications of broflanilide at 2.5 g ai /hL with a PHI of 1 day.

Field trials with green onion in Japan were performed according to the GAP (± 25 percent). The ranked order of broflanilide residues was (n=3): 0.38, 0.46, 1.32 mg/kg.

Field trials with leek in Japan were performed according to the GAP (± 25 percent). The ranked order of residues was (n=3): 0.10, 0.20, 0.22 mg/kg.

The Meeting noted that residues in green onion and leek belong to different populations and could not be combined.

The Meeting concluded that the number of trials is insufficient to estimate maximum residue levels for broflanilide in green onions and leek.

Cabbages, Head and Chinese cabbage, (type Pe-tsai)

The critical GAP for cabbage and Chinese cabbage in Japan allows three foliar applications of broflanilide at 2.5 g ai /hL, and PHI of 14 days. No trials were provided matching this GAP.

A GAP for cabbage and Chinese cabbage in China allows a maximum of one foliar application of broflanilide at 24 g ai/ha and PHI of 5 days.

A total of 12 field trials conducted with cabbage in China were provided. In trials conducted at 33.8 g ai/ha, broflanilide residues were (n=6): < 0.01, 0.03, 0.11, 0.12, 0.16 and 0.42 mg/kg. In trials conducted at 45 g ai/ha, residues were (n=6): 0.12, 0.31, 0.33, 0.48 and 1.6 (2) mg/kg.

The proportionality approach was used in both datasets, and scaling factors of 0.71 or 0.53 were applied, giving residues in ranked order (n=12): < 0.01, 0.02, 0.06, 0.08, 0.09, 0.11, 0.17 (2), 0.26, 0.30 and 0.84 (2) mg/kg.

In field trials conducted with Chinese cabbage (n=4) in China at 45 g ai/hg, the ranked order of residues was (n=4): 0.39, 0.41, 0.99, 1.8 mg/kg. By applying the scaling factor of 0.53, residues were: 0.21, 0.22, 0.53 and 0.95 mg/kg.

The Meeting recognized that the residue population from trials on cabbage and Chinese cabbage were not significantly different according to the Kruskal-Wallis H-test and decided to combine the data sets. The ranked order of residues for estimating maximum residue levels and dietary risk assessment was (n=16): < 0.01, 0.02, 0.06, 0.08, 0.09, 0.11, 0.17 (2), 0.21, 0.22, 0.26, 0.30, 0.53, 0.84(2) and 0.95 mg/kg.

The Meeting estimated a maximum residue level of 2 mg/kg and an STMR of 0.19 mg/kg for broflanilide in Head cabbage and Chinese cabbage, (type Pe-tsai).

For animal feed, the Meeting estimated a highest residue of 0.95 mg/kg and median residue of 0.19 mg/kg for broflanilide in cabbage.

Tomato (including cherry tomato)

The critical GAP for tomato in the Republic of Korea allows two foliar applications of broflanilide at 2.5 g ai/hL with a RTI of 7 days and a PHI of 2 days. Information on the spray volume was not provided.

A total of 20 field trials conducted with tomato in the United States were performed with 2× 25 g ai/ha (translating into a spray concentration of 8.8–13 g ai/hL) with a RTI of 7 days and harvest after 1 DALA.

The Meeting noted that the proportionality principle could not be applied to trials as the resultant scaling factors are outside the acceptable range (not lower than 0.3).

Hence, the Meeting concluded that no maximum residue level could be estimated for broflanilide in tomato.

Radish, Japanese

The critical GAP for Japanese radish in Japan allows three foliar applications of broflanilide at 2.5 g ai/hL with a PHI of 1 day.

Field trials with Japanese radish in Japan were performed according to the GAP (±25 percent). The ranked order of broflanilide residues in radish roots were (n=6): < 0.01(6) mg/kg.

The Meeting estimated a maximum residue level of 0.01(*) mg/kg and an STMR of 0.01 mg/kg for broflanilide in radish, Japanese.

Tuberous and corm vegetables, Subgroup of

The critical GAP for subgroup of tuberous and corm vegetables in the United States allows one in-furrow soil application of broflanilide at 50 g ai/ha and the PHI covered by conditions of use.

Field trials conducted with potato from Canada and the United States were performed according to GAP (±25 percent). The ranked order of broflanilide residues was (n=20): < 0.001(5), 0.0012(2), 0.0015(2), 0.0017, 0.0018, 0.0021, 0.0023, 0.0026, 0.0029, 0.0046, 0.0049(2), 0.015, 0.034 mg/kg.

The Meeting estimated a maximum residue level of 0.04 mg/kg and an STMR of 0.00175 mg/kg for broflanilide in the subgroup of tuberous and corm vegetables.

For animal feed, the Meeting estimated a highest residue of 0.034 mg/kg and median residue of 0.00175 mg/kg for broflanilide in potato culls.

Cereal grains, Group of (except rice)

The critical GAP for cereals (barley, oat, wheat, triticale, rye, millet, sorghum, amaranth, buckwheat, cañihua, chia, cram-cram, huauzontle, quinoa, spelt) in the United States allows for seed treatment with broflanilide at a concentration of 50 g ai/t seeds. The critical GAP for maize, including sweet corn in the United States allows one in-furrow soil application of broflanilide at 50 g ai/ha and the PHI covered by conditions of use.

The Meeting considered that both treatments are similar, as they are both soil treatments. In addition, the results of a seed treatment metabolism study performed with wheat at 100 g ai/ton seeds demonstrated that uptake of radioactivity through the roots into the plant is very limited (TRR maximum of 0.011 mg ai/kg). Therefore, the Meeting decided to consider all data sets for wheat, barley and maize to explore a potential group recommendation.

Field trials with wheat were conducted in Canada and the United States at an exaggerated rate of 100 g ai/ton of seed, giving broflanilide residues of < 0.001 (25) mg/kg.

Field trials with barley were conducted in Canada and the United States at an exaggerated rate of 100 g ai/ton of seed, giving broflanilide residues of < 0.001 (16) mg/kg.

In field trials with maize conducted in Canada and the United States according to the GAP, broflanilide residues were < 0.001 (20) mg/kg.

In field trials with sweet corn conducted in the United States following GAP treatment (± 25 percent), broflanilide residues were < 0.001 (12), mg/kg.

The Meeting noted that for the overdosed seed treatment trials in wheat and barley, as well as for the in-furrow treatment of maize all residues were <LOQ.

Hence, the Meeting estimated a maximum residue level of 0.001(*) mg/kg for broflanilide for the group of cereals grains, except rice.

The Meeting also estimated an STMR of 0 mg/kg for the group of cereals grains, except rice and sweet corns, and an STMR of 0.001 mg/kg for sweet corns.

Coffee beans, green

The critical GAP for coffee in Colombia allows two foliar applications of broflanilide at 18 g ai/ha with a RTI of 30 days and a PHI of 45 days.

In field trials conducted with coffee in Brazil and Colombia following GAP (± 25 percent), the ranked order of broflanilide residues was (n=9): < 0.001(2), 0.0015, 0.0016, 0.0023, 0.0034, 0.0037, 0.0039, 0.005 mg/kg.

The Meeting estimated a maximum residue level of 0.01 mg/kg, and a STMR of 0.0023 mg/kg for broflanilide in coffee beans, green.

Residues in animal feeds*Wheat forage*

The critical GAP for wheat in Canada and the United States allows for seed treatment with broflanilide at a concentration of 50 g ai/t seeds with no livestock feeding restrictions.

Field trials were conducted with wheat in Canada and the United States at an exaggerated rate of 100 g ai/ton of seed. The ranked order of residues in wheat forage was (n=25): < 0.001 (24), 0.0011 mg/kg.

The Meeting noted that trials were overdosed and decided to set 0.001 mg/kg (as received) as highest and median residue for broflanilide in wheat forage.

Maize forage

The critical GAP for maize in the United States allows one in-furrow soil application of broflanilide at 50 g ai/ha and the PHI covered by conditions of use.

In field trials conducted with maize in Canada and the United States, broflanilide residues in maize forage following GAP (± 25) were $< 0.001(25)$ mg/kg, as received.

The Meeting estimated a highest and median residue of 0.001 mg/kg (as received) for broflanilide in maize forage.

Cereal grains (including pseudocereals) feed products with low water (<20 percent) content (hay, straw), Subgroup of (except rice)

The critical GAP for wheat and barley in the United States allows for seed treatment with broflanilide at 50 g ai/t seeds with no livestock feeding restrictions. The critical GAP for maize in the United States allows one in-furrow soil application of broflanilide at 50 g ai/ha and the PHI covered by conditions of use. As discussed previously, the Meeting considered that both treatments are similar.

Field trials were conducted with wheat and barley in Canada and the United States at an exaggerated rate of 100 g ai/ton of seed. The ranked order of residues for wheat hay was (n=25): $< 0.001(24)$, 0.0012 mg/kg and for barley hay was (n=16): $< 0.001(14)$, 0.0018, 0.0032 mg/kg, as received.

The Meeting decided to combine the data sets for wheat and barley hay as they were considered similar and apply proportionality principle to the residues from the overdosed trials. Therefore, a scaling factor of 0.5 was applied to residues $>LOQ$, resulting in a total residue population of (n=41): 0.0006, 0.0009, $\leq 0.001(38)$, 0.0016 mg/kg, as received.

The ranked order of residues for wheat straw was (n=25): $< 0.001(23)$, 0.001(2) mg/kg and for barley straw was (n=16): $< 0.001(16)$ mg/kg, as received.

The Meeting decided to combine the data sets for wheat and barley straw and apply the scaling factor of 0.5, resulting in a total residue population of (n=41): 0.0005(2), $< 0.001(39)$, mg/kg, as received.

The ranked order of residues in maize stover following GAP treatment (± 25) was (n=25): $< 0.001(25)$ mg/kg as received.

Based on the more critical hay data, the Meeting estimated a highest residue of 0.0016 mg/kg (as received), a median residue of 0.001 mg/kg (as received) and a maximum residue level of 0.01 mg/kg (dw, based on 88 percent DM content) for the subgroup of cereal grains (including pseudocereals) feed products with low water (<20 percent) content (hay, straw), except rice feed products.

Fate of residues during processing

The Meeting received information on the hydrolysis of [B-ring- $U-^{14}C$]- and [C-ring- $U-^{14}C$]-labelled broflanilide, simulating typical processing conditions (90 °C, pH 4, 20 minutes to simulate pasteurization, 100 °C, pH 5, 60 minutes to simulate boiling, baking and brewing and 120 °C, pH 6, 20 minutes to simulate sterilisation). No significant hydrolysis of broflanilide was observed at the conditions studied.

The Meeting concluded that broflanilide is stable under the conditions of pasteurization, boiling, baking and brewing, as well as sterilisation.

The fate of broflanilide residues has been examined simulating household and commercial processing of potato, maize, wheat and coffee, and the results are shown in Table 5.6.2.

Table 5.6.2 Estimated processing factors for maximum residue and dietary exposure of processed commodities according to the residue definition broflanilide

Crop	Residue (mg/kg) in RAC		Processed commodity	Individual PF	Median or best estimate PF	Residue (mg/kg) in processed commodity	
	MRL	STMR				MRL-P	STMR-P
Potato	0.04	0.0018	Starch	< 0.06, < 0.19, 0.27	< 0.19	-	0.0003
			Process waste	0.12, < 0.19, 0.69	< 0.19	-	0.0003
			Dried pulp	0.55, 1.2, 2.3	1.2	-	0.0022
Maize	0.001	0	Bran	1.4	1.4	0.002	0
			Dry milling flour	2.1	2.1	0.002	0
			Germ	0.74, 1.2	0.99	-	0
			Gluten	1.6	1.6	-	0
			Gluten feed meal	6.77	6.77	-	0
			Milled by-products	6.29	6.29	-	0
			RBD oil	0.35, 0.81	0.28	-	0
			Starch	< 0.16	< 0.16	-	0
Wheat	0.001	0	Flour	0.30, 0.44, 0.54	0.44	-	0
			Gluten	0.80, 4.14, 4.97	4.1	-	0
			Milled by-products	6.8, 8.3, 12.2	8.3	-	0
			Starch	0.02, 0.02, 0.04	0.02	-	0
			Germ	1.14, 1.75, 2.77	1.75	0.002	0
			Whole grain bread	0.45, 0.63, 0.78	0.63	-	0
Coffee	0.01	0.0023	Instant coffee	< 0.09, < 0.14, < 0.26	< 0.09	-	0.0002
			Roasted and ground coffee beans	0.38, 0.82, 2.36	0.82	-	0.0019

Residues in animal commodities

Farm animal feeding studies

The Meeting received feeding studies with broflanilide on lactating cows and laying hens.

The study with lactating cows was conducted at treatment rates of 0.015, 0.15, 1.5 and 10 ppm. Residues of parent broflanilide were only detected in milk from the 10 ppm group at up to 0.0018 mg/kg and in cream from the 1.5 and 10 ppm groups at up to 0.016 mg/kg.

Residues of metabolite DM-8007 above LOQ were detected in milk from the 0.15 ppm, 1.5 ppm and 10 ppm groups at up to 0.12 mg/kg and in cream from in all groups at up to 1.3 mg/kg. Metabolite DM-8007 was also detected above LOQ in fats from all groups at up to 0.79 mg/kg, in liver from the 1.5 and 10 ppm groups at up to 0.078 mg/kg and in muscle and kidney from the 10 ppm group at up to 0.08 mg/kg.

The study with laying hens was conducted at treatment rates of 0.02, 0.10 and 0.50 ppm. In eggs and tissues, residues of broflanilide and metabolite DC-DM-8007 were consistently below LOQ for all dose levels.

Residues of metabolite DM-8007 above LOQ were only found in eggs and liver from the 0.5 ppm group at up to 0.023 and 0.021 mg/kg, respectively, as well as in fat from all groups at up to 0.15 mg/kg.

Estimated maximum and mean dietary burdens of livestock and animal commodities maximum residue levels

Dietary burden calculations for beef cattle, dairy cattle, broilers and laying poultry are presented in Annex 6. The calculations were made according to the livestock diets from United States-Canada, European Union, Australia and Japan in the OECD Table (Annex 6 of the 2006 JMPR Report). The summary results are shown in Table 5.6.3.

Table 5.6.3 Estimated livestock dietary burden for broflanilide, ppm of dry matter diet

	United States-Canada		European Union		Australia		Japan	
	Max.	Mean	Max.	Mean	Max.	Mean	Max.	Mean
Beef cattle	0.052	0.004	1.3	0.26	0.021	0.004	-	-
Dairy cattle	0.019	0.0026	1.3 ^①	0.26 ^②	0.02	0.004	0.001	0.001
Poultry-broiler	-	-	0.018	0.001	-	-	-	-
Poultry-layer	-	-	0.33 ^③	0.065 ^④	-	-	-	-

Notes:

- ① Highest maximum beef or dairy cattle burden suitable for MRL estimates for mammalian meat and milk.
- ② Highest mean beef or dairy cattle burden suitable for STMR estimates for mammalian meat and milk.
- ③ Highest maximum broiler or laying hen burden suitable for MRL estimates for poultry products and eggs.
- ④ Highest mean broiler or laying hen burden suitable for STMR estimates for poultry products and eggs.

Animal commodities maximum residue levels

For beef and dairy cattle, a maximum and mean dietary burden of 1.3 ppm and 0.26 ppm were estimated, respectively.

For maximum residue level estimation, the maximum dietary burden of 1.3 ppm was evaluated by interpolating between the 0.15 and 1.5 ppm dosing levels of the lactating cow feeding study (Table 5.6.4).

Table 5.6.4 Maximum residue level estimation of broflanilide in cattle commodities

Maximum residue level beef or dairy cattle	Feed level (ppm)	Sum of broflanilide + DM-8007 in milk (mg/kg)	Sum of broflanilide + DM-8007 in cream (mg/kg)	Sum of broflanilide + DM-8007 (mg/kg)			
				Liver	Kidney	Muscle	Fat
Feeding study	0.15	0.003 ^a	0.021 ^a	< 0.02	< 0.02	< 0.02	0.026
	1.5	0.012 ^a	0.153 ^a	0.023	0.02	< 0.02	0.17
Dietary burden and highest residue	1.3	0.011	0.13	0.023	0.02	< 0.02	0.15

Notes:

^a Mean at plateau level.

For the STMR estimation, the mean dietary burden of 0.26 ppm was evaluated by interpolating between the 0.15 and 1.5 ppm dosing levels of the lactating cow feeding study (Table 5.6.5).

Table 5.6.5 STMR estimation of broflanilide in cattle commodities

STMR beef or dairy cattle	Feed level (ppm)	Sum of broflanilide + DM-8007 in milk (mg/kg)	Sum of broflanilide + DM-8007 in cream (mg/kg)	Sum of broflanilide + DM-8007 (mg/kg)			
				Liver	Kidney	Muscle	Fat
Feeding study	0.15	0.003 ^a	0.021 ^a	< 0.02	< 0.02	< 0.02	0.024

STMR beef or dairy cattle	Feed level (ppm)	Sum of broflanilide + DM-8007 in milk (mg/kg)	Sum of broflanilide + DM-8007 in cream (mg/kg)	Sum of broflanilide + DM-8007 (mg/kg)			
				Liver	Kidney	Muscle	Fat
	1.5	0.012 ^a	0.153 ^a	0.02	< 0.02	< 0.02	0.13
Dietary burden and mean residue	0.26	0.004	0.032	0.02	< 0.02	< 0.02	0.033

Notes:

^a Mean at plateau level.

The Meeting estimated a maximum residue level for milks at 0.015 mg/kg, milk (fat) at 0.4 mg/kg (assuming 40 percent fat content in cream), edible offal (mammalian) at 0.03 mg/kg and 0.15 mg/kg for meat from mammals (fat) and mammalian fats.

The Meeting estimated STMR values of 0.004 mg/kg in milks, 0.08 mg/kg in milk (fat) (assuming 40 percent fat content in cream), 0.02 mg/kg in edible offal (mammalian), 0.02 mg/kg in muscle from mammals and 0.033 mg/kg in mammalian fats.

For broiler and laying poultry, a maximum and mean dietary burden of 0.33 ppm and 0.065 ppm were estimated, respectively. For maximum residue level estimation, the maximum dietary burden of 0.33 ppm was evaluated by interpolating between the 0.1 and 0.5 ppm dosing levels of the laying hen feeding study (Table 5.6.6).

Table 5.6.6 Maximum residue level estimation of broflanilide in poultry commodities

Maximum residue level broiler or layer poultry	Feed level (ppm)	Sum of broflanilide + DM-8007 in eggs (mg/kg)	Sum of broflanilide + DM-8007 (mg/kg)		
			Liver	Muscle	Fat
Feeding study	0.1	< 0.02	< 0.02	< 0.02	0.049
	0.5	0.033	0.031	< 0.02	0.16
Dietary burden and highest residues	0.33	0.027	0.026	< 0.02	0.113

For the STMR estimation, the mean dietary burden of 0.065 ppm was evaluated by interpolating between the 0.02 and 0.1 ppm dosing levels of the laying hen feeding study (Table 5.6.7).

Table 5.6.7 STMR estimation of broflanilide in poultry commodities

STMR broiler or layer poultry	Feed level (ppm)	Sum of broflanilide + DM-8007 in eggs (mg/kg)	Sum of broflanilide + DM-8007 (mg/kg)		
			Liver	Muscle	Fat
Feeding study	0.02	< 0.02	< 0.02	< 0.02	0.020
	0.1	< 0.02	< 0.02	< 0.02	0.044
Dietary burden and mean residues	0.065	< 0.02	< 0.02	< 0.02	0.034

The Meeting recommended a maximum residue level of 0.03 mg/kg for eggs, 0.03 mg/kg for poultry edible offal, 0.02(*) mg/kg for poultry meat and 0.15 mg/kg for poultry fats.

The Meeting estimated an STMR value of 0.02 mg/kg in eggs, poultry edible offal and poultry muscle as well as 0.034 mg/kg for poultry fats.

RECOMMENDATIONS

On the basis of the data obtained from supervised trials, the Meeting concluded that the residue levels listed in Annex 1 are suitable for establishing maximum residue limits and for IEDI.

Definition of the residue for compliance with the MRL and dietary risk assessment for plant commodities: *Broflanilide*

Definition of the residue for compliance with the MRL and dietary risk assessment for animal commodities: *Sum of broflanilide plus 3-benzamido-N-[2-bromo-4-(perfluoropropan-2-yl)-6-(trifluoromethyl)phenyl]-2-fluorobenzamide (DM-8007), expressed as broflanilide*

The residue is fat-soluble.

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The ADI for broflanilide is 0–0.02 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for broflanilide were estimated for the 17 GEMS/Food Consumption Cluster Diets using the STMR or STMR-P values estimated by the JMPR. The results are shown in Annex 3 of the 2019 JMPR Report.

The IEDIs ranged from 0–1 percent of the maximum ADI. The Meeting concluded that long-term dietary exposure to residues of broflanilide from uses considered by the JMPR is unlikely to present a public health concern.

Acute dietary exposure

The Meeting determined that establishment of an acute reference dose is unnecessary for broflanilide and concluded that the acute exposure of residues of broflanilide from uses considered by the Meeting is unlikely to present a public health concern.

5.7 Chlorantraniliprole (230)

RESIDUE AND ANALYTICAL ASPECTS

Chlorantraniliprole was first evaluated for residues and toxicological aspects by the 2008 JMPR. The 2008 JMPR established an ADI for chlorantraniliprole of 0–2 mg/kg bw and concluded that an ARfD was not necessary.

The 2008 JMPR also established the definition of residue as follows:

Definition of the residue for both compliance with MRL and estimation of dietary intake for plant and animal commodities: *chlorantraniliprole*

The residue is fat soluble.

It was evaluated for additional uses by JMPR in 2010, 2013, 2014 and 2016. At the Fifty-second Session of the CCPR (2021), chlorantraniliprole was listed for consideration of additional uses by the 2022 JMPR.

The current Meeting received new information on method of analysis, storage studies, use patterns, supervised residue trials and processing studies on avocado and tea.

Methods of analysis

The Meeting noted that the analytical method for avocado had been evaluated by the 2008 JMPR.

The Meeting received information on a new analytical method for chlorantraniliprole in tea.

Chlorantraniliprole was extracted from tea leaves (dry) with acetonitrile/water (8:2, v/v), cleaned-up and analysed with LC-MS/MS. Tea infusion, prepared by soaking tea leaves in boiling water and filtered, was cleaned-up and then analysed with the same method. Recovery data supported an LOQ of 0.01 mg/kg. The Meeting agreed that the method is suitable for analysing chlorantraniliprole in dried tea leaves and tea infusion.

Stability of pesticides in stored analytical samples

Stability studies of chlorantraniliprole in tea leaves (dry) were available. The Meeting concluded that chlorantraniliprole in tea leaves stored at ≤ 20 °C was stable for at least 4 months. All the residue samples were analysed within this period. Concurrent recoveries for tea leaves in the field trial samples were 73–116 percent.

Results of supervised residue trials on crops

Avocado

The critical GAP for avocado in the United States is two foliar applications at 0.112 kg ai/ha with a minimum interval of 10 days and PHI of 1 day.

In trials matching the GAP, residues of chlorantraniliprole in avocados were (n=5): 0.043, 0.063, 0.083, 0.094 and 0.16 mg/kg.

The Meeting estimated a maximum residue level of 0.3 mg/kg and an STMR value of 0.083 mg/kg for avocado.

Tea, green, black (black, fermented and dried)

The critical GAP for tea in Japan is one foliar application of chlorantraniliprole (5 g ai/hL) before each pick with a PHI of 3 days.

The Meeting noted that the typical interval between picks is 30 days. According to the decline study, 0.3–9.6 percent of the DAT3 residue remained 18 days. The Meeting considered that the residue carry-over from previous treatments would be insignificant and agreed that the trials approximated the cGAP in Japan.

In trials approximating the GAP, residues of chlorantraniliprole in tea leaves (dry) were (n=10): 19 (2), 22, 23, 24, 25, 28 (2), 29 and 32 mg/kg.

The Meeting estimated a maximum residue level of 80 mg/kg and an STMR of 24.5 mg/kg.

Fate of residues during processing*Tea infusion*

The Meeting received residue data for chlorantraniliprole in tea infusions.

Residues of chlorantraniliprole in tea infusion, prepared from the tea leaves in trials conducted in 2020 and 2021, were (n=8): 0.14, 0.16, 0.18, 0.20 (2), 0.22 (2) and 0.23 mg/kg.

The Meeting estimated an STMR value of 0.20 mg/kg in tea infusion.

RECOMMENDATIONS

On the basis of the data from supervised trials the Meeting concluded that the residue levels listed in Annex 1 are suitable for establishing maximum residue limits and for IEDI and international estimate of short-term intake assessment.

Definition of the residue for compliance with MRL and for estimation of dietary risk assessment for plant and animal commodities: *chlorantraniliprole*.

The residue is fat-soluble.

DIETARY RISK ASSESSMENT***Long-term dietary exposure***

The ADI for chlorantraniliprole is 0–2 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for chlorantraniliprole were estimated for the 17 GEMS/Food Consumption Cluster Diets using the STMR or STMR-P values estimated by the current and earlier JMPR. The results are shown in Annex 3 of the 2022 JMPR Report.

The IEDIs ranged from 0–1 percent of the maximum ADI for chlorantraniliprole. The Meeting concluded that long-term dietary exposure to residues of chlorantraniliprole from uses considered by the JMPR is unlikely to present a public health concern.

Acute dietary exposure

The ARfD for chlorantraniliprole is not necessary. The Meeting concluded that acute dietary exposure to residues of chlorantraniliprole from uses considered by the present Meeting is unlikely to present a public health concern.

5.8 Chlormequat (015)

RESIDUE AND ANALYTICAL ASPECTS

Chlormequat is a plant growth regulator and usually formulated as the chloride salt. It acts primarily by reducing cell elongation, as well as by lowering the rate of cell division and by inhibiting the synthesis of gibberellins. Chlormequat was evaluated by the Meeting in 1970, 1972, 1994 (T, R), 1997 (R), 1999 (T, for ARfD), 2000 (R) and 2017 (T, R, periodic re-evaluation).

The 2017 Meeting reaffirmed the ADI of 0–0.05 mg/kg bw (established in 1997) and ARfD of 0.05 mg/kg bw (established in 1999). The 2017 Meeting confirmed residue definitions as follows:

The residue definition (for compliance with the MRL and dietary risk assessment) in plant and animal commodities: chlormequat cation.

The residue is not fat soluble.

The Forty-third Session of the Codex Alimentarius Commission (2020) approved the new work proposals including the priority list of pesticides for evaluation by the current Meeting. The priority list included chlormequat for evaluation of uses on barley and wheat.

The current Meeting received new information on: GAP in Canada, analytical methods, supervised residue trials and processing studies, for wheat and barley.

Analytical methods

The 2017 Meeting evaluated two LC-MS/MS methods and one GC method for plant commodities, and a LC-MS/MS method and an ion chromatography method for animal commodities for determining chlormequat chloride.

The current Meeting received information on a new LC-MS/MS method (M01-011), which was similar to the LC-MS/MS method (CEN/TC 275/WG 4N) provided to the 2017 JMPR, for determining chlormequat chloride in the supervised residue trials and processing studies. In this method, a homogenized samples of wheat or barley matrices (grain, leafy parts and processed commodities) were fortified with a known concentration of chlormequat-D4 chloride as internal standard. Residues of chlormequat/internal standard were extracted from the fortified sample with methanol/water (2:1, v/v). An aliquot of extract was then filtered for determination of chlormequat chloride by LC-MS/MS.

At the fortification levels of 0.01 and 0.1 mg/kg in grain, straw, hay, forage and processed commodities of wheat and barley, the mean recoveries were 90–110 percent and the RSD values were < 13 percent. The validated LOQ was 0.01 mg/kg for chlormequat chloride in these matrices.

Stability of pesticide residues in stored analytical samples

The 2017 Meeting evaluated the stability data on chlormequat chloride in cereal matrices (grain, straw and processed matrices) stored at approximately -18 or -20°C. The proved stable periods cover the sample storage intervals in the residue trials.

Results of supervised residue trials on crops

The Meeting received supervised trial data for chlormequat on wheat and barley conducted in Canada and the United States in 2015–2016.

*Cereal grains**Wheat*

The 2017 JMPR evaluated supervised trials conducted in France, Germany and Italy on winter, spring and durum wheat against the critical GAP in Argentina (one foliar application at the maximum rate of 2.025 kg ai/ha during BBCH 21–31) and estimated the maximum residue level of 2 mg/kg and STMR of 0.58 mg/kg for wheat.

The GAP of Argentina as shown above is valid at the time of this evaluation and is more critical than GAP of Canada for wheat (one foliar application at a maximum rate of 1.12 kg ai/ha, up to GS 39).

The current Meeting received information on supervised residue trials conducted in Canada (5) and the United States (17) on spring and winter wheat. In the US trials, grains were harvested with hulls intact while the definition of the subgroup covering wheat states “without husks”. The processing study using the wheat grains obtained in the trials conducted in the United States showed that the residues in pre-processing grain and in the grains at harvest were similar with the best estimate of processing factor of 1.0. Therefore, the Meeting decided to use the data on residues in grains with husk from these US trials for evaluation.

As in each trial in Canada and the United States, a single application made at GS 32 or 39 at rates of 1.0–1.1 kg ai/ha while the GAP in Argentina allows a maximum rate of 2.025 kg ai/ha, the Meeting decided to use the proportionality principle for estimating a maximum residue level and an STMR. Scaled residues were calculated using the formula below.

Scaled residue (mg/kg) = (residue in the trial, mg/kg) × 2.025 (kg ai/ha) / (rate used in the trial, kg ai/ha).

After each scaled residue value, the residue found in each trial and respective application rate are indicated in a pair of parentheses, e.g., (residue value in mg/kg, application rate in kg ai/ha).

Residues of chlormequat cation in spring wheat grain in the trials in Canada and the United States with the application at GS 32 approximating the GAP in Argentina with scaling were in rank order (n=14): 0.52 (0.29, 1.119), 0.60 (0.31, 1.050), 0.92 (0.50, 1.105), 0.93 (0.53, 1.090), 1.2 (0.65, 1.102), 1.5 (0.86, 1.132), 1.8 (1.0, 1.110), 1.9 (1.01, 1.092), 2.2 (1.2, 1.090), 2.5 (1.4, 1.130), 2.6 (1.44, 1.124), 3.4 (1.85, 1.102), 3.4 (1.94, 1.149) and 5.3 (1.44, 1.124) mg/kg.

Residues of chlormequat cation in winter wheat grain in the trials in Canada and the United States with the application at GS 39 approximating the GAP in Argentina with scaling were in rank order (n=9): 0.47 (0.26, 1.114), 0.77 (0.43, 1.127), 0.94 (0.52, 1.119), 0.99 (0.54, 0.102), 0.99 (0.54, 0.102), 1.4 (0.78, 1.140), 1.5 (0.85, 1.142), 2.3 (1.26, 1.102) and 2.8 (1.54, 1.132) mg/kg.

As the application timing in the trials on spring wheat was GS 32 and on winter wheat was GS 39 while the GAP in Argentina specifies BBCH 31, influence of the application timing (GS 32 vs GS 39) on the residues were tested by Mann-Whitney test, which indicates that there is no significant difference between the two residue populations. The Meeting decided to combine the data from the two different application timing to derive a maximum residue level and STMR.

Combined residue populations of chloride cation from the independent trials (one trial used for comparison above was not independent) in Canada and the United States on spring and winter wheat were in rank order (n=22): 0.47, 0.52, 0.59, 0.77, 0.91, 0.92, 0.94, 0.99, 0.99, 1.2, 1.5, 1.5, 1.8, 1.9, 2.2, 2.3, 2.5, 2.6, 2.8, 3.4, 3.4 and 5.3 mg/kg.

The residue population from the trials in Canada and the United States would lead to a higher estimates of maximum residue level and STMR. Based on the residue population from the north American trials, the Meeting estimated a maximum residue level of 7 mg/kg and an STMR of 1.5 mg/kg for wheat.

International estimate of short-term Intake calculation for wheat grain and its processed products resulted in a maximum of 110 percent of ARfD for children (consumption of wheat flakes; the processing factor of 0.8 estimated by the 2017 JMPR for the processing of oat its flakes was used). The Meeting therefore used an alternative GAP approach for estimating maximum residue level and STMR, and decided to evaluate the trial data against the GAP of Canada for wheat.

The combined residues of chlormequat cation in wheat grain from the trials matching the GAP in Canada were in rank order (n=22): 0.26, 0.29, 0.31, 0.43, 0.50, 0.50, 0.52, 0.54, 0.54, 0.65, 0.85, 0.86, 1.0, 1.0, 1.2, 1.3, 1.4, 1.4, 1.5, 1.9, 1.9 and 2.9 mg/kg.

The Meeting estimated a maximum residue level of 4 mg/kg for wheat to replace the previous recommendation of 2 mg/kg. The Meeting estimated an STMR of 0.855 mg/kg.

Barley

The 2017 JMPR evaluated supervised trials conducted in France, Germany and Spain on barley with the application timing at BBCH 32–37 against the critical GAP in the United Kingdom (one foliar application at the maximum rate of 1.65 kg ai/ha during BBCH 25–30) and estimated a maximum residue level of 2 mg/kg and STMR of 0.37 mg/kg for barley.

The current critical GAP was from the United Kingdom for barley which allows one foliar application at the maximum rate of 1.50 kg ai/ha up to and including GS 32. This GAP is similar to GAP in Canada (one foliar application at the maximum rate of 1.43 kg ai/kg up to GS 39).

The current Meeting received information on supervised residue trials conducted in Canada (10) and the United States (10) on barley in 2016 with a single application at GS 32 at rates 1.36–1.50 kg ai/ha.

Residues of chlormequat cation in barley grains in the independent trials conducted in Canada and the United States approximating GAP in the United Kingdom were in rank order (n=10): 0.12, 0.54, 1.0, 1.0, 1.5, 1.5, 1.6, 2.6, 3.3 and 3.9 mg/kg.

The Meeting estimated a maximum residue level of 7 mg/kg and an STMR of 1.5 mg/kg for barley.

International estimate of short-term intake calculation for barley grain and its processed products resulted in a maximum of 110 percent of ARfD for children (consumption of barley flakes; the processing factor of 0.8 estimated by the 2017 JMPR for the processing of oat its flakes was used). The Meeting looked for an alternative GAP that would lead to a smaller estimate of maximum residue level and STMR. GAP of Canada for wheat is similar to GAP of the United Kingdom and it would lead to the same maximum residue level. There was insufficient information available on the validity of GAP contained in the use pattern table of the Evaluation of the 2017 JMPR, the Meeting decided to maintain the previous recommendation of 2 mg/kg (STMR 0.37 mg/kg) until information becomes available on valid GAPs for barley in countries which allow lower application rates than the GAP used by this Meeting to enable the alternative GAP approach.

Residues in animal feeds

Barley forage

The 2017 JMPR received data on barley forage taken after one application of chlormequat at BBCH 32 or 37 in the trials conducted in Europe. However, as feeding cereal grain forage was not common in Europe unless specified on the label, the data were not evaluated.

The critical GAP is in the United Kingdom for barley allows one foliar application up to and including GS 32 at the maximum rate of 1.50 kg ai/ha. Neither the United Kingdom label nor the Canadian label contains restrictions regarding grazing or cutting for feed. Generally, forage can be used for grazing or cutting for feed 2 to 3 weeks after the application of pesticides.

In the trials conducted on barley in Canada and the United States and provided to the current Meeting, barley forage samples were not taken or analysed. The Meeting therefore evaluated the European trials against the critical GAP in the United Kingdom.

Residues of chlormequat cation in forage taken 14 to 21 days after the application in the European trials approximating GAP in Canada were in rank order:

Application at BBCH 37 (n=3): 2.9, 3.6 and 12 mg/kg; and

Application at BBCH 32 (n=4): 1.9, 3.3, 3.7 and 6.7 mg/kg.

Mann-Whitney U-test indicates that these two populations were not significantly different. The Meeting combined the residue populations to estimate a median residue and highest residue.

The combined residues of chlormequat cation in barley forage were in rank order (n=7): 1.9, 2.9, 3.3, 3.6, 3.7, 6.7 and 12 mg/kg.

The Meeting estimated a median residue of 3.6 mg/kg (as received) and highest residue of 12 mg/kg (as received) for barley forage.

Wheat forage

The 2017 JMPR evaluated supervised trials conducted in France, Germany and Italy against the critical GAP in Argentina (one foliar application at the maximum rate of 2.025 kg ai/ha during BBCH 21–31) and estimated a median residue of 8.7 mg/kg and highest residue of 25 mg/kg for wheat forage (as received).

The current Meeting received information on residues of chlormequat cation in wheat forage, samples of which were taken at around GS 30 after one application at GS 12–30 at rates of 0.48–0.64 kg ai/ha, much lower rates than in the critical GAP in Argentina. As residues of chlormequat cation at 14–21 DAT were in a range of 0.85–12 mg/kg, the Meeting concluded that the median and highest residues recommended by the 2017 JMPR cover the residues found in wheat forage from the trials in Canada and the United States.

Barley, hay and/or straw

The 2017 JMPR evaluated supervised trials conducted in Europe on barley against the critical GAP in the United Kingdom (one foliar application at the maximum rate of 1.65 kg ai/ha during BBCH 25–30; since expired) and estimated a maximum residue level of 50 mg/kg (dw), and a median residue of 4.15 mg/kg (as received) and highest residue of 30 mg/kg for barley straw and fodder, dry.

Residues of chlormequat cation in barley hay in the trials conducted in the United States approximating the GAP in the United Kingdom were in rank order (n=10): 5.4, 14, 18, 19, 33, 36, 39, 46, 48 and 60 mg/kg (as received), or 6.1, 15, 20, 22, 38, 41, 53, 54, and 68 mg/kg (dw).

Residues of chlormequat cation in barley straw in the trials conducted in the United States approximating the GAP in the United Kingdom were in rank order (n=10): 2.4, 3.8, 4.5, 5.9, 6.7, 9.8, 14, 16, 17, and 30 mg/kg (as received) or 2.8, 4.3, 5.1, 6.7, 7.6, 11, 15, 18, 19 and 34 mg/kg (dw).

The residue population of hay from the United States trials would lead to a higher maximum residue level, and median and highest residue than the residue population of straw and those estimated by the 2017 JMPR based on the European trials. Using the residue population of hay from the United States trials, the Meeting estimated a maximum residue level of 150 mg/kg (dw) for barley hay and/or straw and withdrew the previous recommendation for barley straw and fodder, dry of 50 mg/kg, dw. The Meeting also estimated a median residue and highest residue of 34.5 mg/kg and 73 mg/kg (as received) for barley hay and 8.25 mg/kg and 32 mg/kg (as received) for barley straw.

Wheat hay and/or straw

The 2017 JMPR evaluated residue trials on wheat conducted in Europe against the critical GAP in Argentina and estimated a maximum residue level of 80 mg/kg (dw), median residue of 13 mg/kg (as received) and highest residue of 55 mg/kg for wheat straw and fodder, dry.

Residues of chlormequat cation in wheat hay from the trials in Canada and the United States approximating the GAP in Argentina after scaling were in rank order (including one pair of not-independent trials for comparison of application timing):

Application at GS 39 (n=9): 28 (15.6, 1.114), 28 (15.6, 1.114), 34 (18.3, 1.102), 34 (18.6, 1.119), 42 (23.5, 1.127), 67 (36.5, 1.102), 70 (39.5, 1.142), 74 (41.6, 1.132) and 80 (43.4, 1.102) mg/kg; and

Application at GS 32 (n=14): 0.64 (0.36, 1.13), 6.9 (3.73, 1.105), 7.4 (4, 1.090), 21 (11.2, 1.119), 30 (16.7, 1.132), 37 (20, 1.102), 41 (21, 1.050), 43 (23.9, 1.119), 55 (29.5, 1.092), 59 (32.7, 1.124), 62 (33.6, 1.102), 63 (36, 1.149), 64 (35, 1.111) and 111 (0, 1.090) mg/kg.

Mann-Whitney U-test indicates that these two data populations are not significantly different.

The combined data set from independent trials in Canada and the United States were in rank order (n=22): 0.64, 6.9, 7.4, 21, 28, 30, 34, 34, 37, 41, 42, 43, 55, 59, 62, 63, 64, 67, 70, 74, 80 and 111 mg/kg (as received) or 0.73, 7.8, 8.4, 23, 32, 34, 38, 38, 42, 46, 48, 49, 62, 67, 70, 73, 72, 76, 80, 85, 91 and 127 mg/kg (dw).

Residues of chlormequat cation in wheat straw from the trials in Canada and the United States approximating GAP in Argentina after scaling were:

Application at GS 39 (n=9): 3.8 (2.09, 1.127), 14 (7.44, 1.114), 16 (9.07, 1.119), 17 (9.42, 1.142), 20 (11.0, 1.132), 21 (11.3, 1.102), 22 (11.9, 1.102), 32 (18, 1.140) and 40 (21.5, 1.102) mg/kg

Application at GS 32 (n=14): 7.4 (4.0, 1.090), 10 (5.4, 1.050), 15 (7.93, 1.105), 17 (9.46, 1.132), 18 (9.76, 1.119), 20 (11, 1.130), 23 (12.6, 1.102), 23 (12.6, 1.102), 24 (13.7, 1.149), 35 (19.6, 1.124), 36 (19.9, 1.119), 37 (20.1, 1.102), 45 (24, 1.109) and 55 (30, 1.110) mg/kg,

Mann-Whitney U-test indicates that these two populations are not significantly different. The Meeting decided to combine these datasets.

The combined data set from independent trials in Canada and the United States were in rank order (n=22): 3.8, 7.4, 10, 14, 15, 16, 17, 17, 18, 20, 20, 21, 22, 23, 23, 24, 35, 36, 37, 40, 45 and 55 mg/kg (as received) or 4.3, 8.4, 11, 16, 17, 18, 19, 19, 20, 23, 23, 24, 25, 26, 26, 27, 40, 41, 42, 45, 51 and 62 mg/kg. (dw).

The residue population of hay from trials conducted in Canada and the United States would lead to a higher maximum residue level than that from the residue population in straw from the trials and the previous recommendation made in 2017 based on straw. Using the data population of residues in hay, the Meeting estimated a maximum residue level of 200 mg/kg (dw) for wheat hay and/or straw. The previous recommendation on wheat straw or fodder, dry (80 mg/kg, dw) was withdrawn. The Meeting estimated a median residue and highest residue of 42.5 and 117 mg/kg (as received) for wheat hay and 20.5 and 55 mg/kg (as received) for wheat straw.

Since barley hay/straw and wheat hay/straw are not distinguishable in trade, the Meeting agreed that the higher maximum residue level of wheat of 200 mg/kg should also apply to barley hay and/or straw.

Fate of residues during processing

Processing

The Meeting received information on processing of wheat to bran, flour, middlings, shorts, germ and aspirated grain fractions; and of barley to bran, pearled barley and flour. For the processing studies, samples of wheat and barley grains were obtained from the supervised trials with the applications at the critical GAP rate and its 2-fold rate, and chlormequat cation was analysed. Processing factors of wheat to its processed commodities and barley to its processed commodities are summarized below together with the processing factors derived by the 2017 JMPR for additional processed commodities. Using the best estimates of processing factors and the STMR values for wheat and barley, the STMR-P values were calculated for processed commodities of wheat and barley. For estimation of acute dietary exposure from flakes of wheat and barley, the Meeting used the processing factor of 0.80 for the processing of oat to its flakes estimated by the 2017 JMPR.

Processing factors of chlormequat for wheat to its processed commodities and barley to its processed commodities are shown below.

Table 5.8.1 Calculated STMR-Ps for processed food and feed commodities

Commodity (Food/feed)	N	Processing factor		STMR/ STMR-P/ Median
		Individual	Best estimate	
Wheat grain at harvest	4	-	-	0.855
Bran	4+6	1.15, 1.16, 2.22, 2.38 2.5, 2.8, 2.9, 3.1, 3.4, 4.6	2.65	2.3
Flour	4+5	0.086, 0.089, 0.113, 0.115 0.19, 0.28, 0.29, 0.30, 0.41	0.19	0.16
Germ	4	4.34, 4.81, 5.36, 6.21	5.1	4.3
Wholemeal ^a	6	0.86, 0.91, 1.0, 1.0, 1.1, 1.4	1.0	0.855
Wholemeal bread	6	0.49, 0.51, 0.53, 0.55, 0.63, 0.79	0.54	0.46
Barley grain at harvest	4	-	-	0.37
Bran	4	0.884, 0.914, 0.937, 1.02	0.93	0.34
Pearled barley	4+5	0.180, 0.213, 0.224, 0.315 0.06, 0.8, 0.9, 1.0, 1.0	0.32	0.12
Flour	4	0.159, 0.163, 0.189, 0.229	0.18	0.066
Malt	5	0.69, 0.9, 0.9, 0.9, 1.0	0.9	0.33
Beer	5	0.015, 0.1, 0.2, 0.2, 0.2	0.2	0.074
Wheat grain at harvest	4	-	-	0.855
Middlings	4	0.33, 0.34, 0.73, 0.84	0.54	0.46
Shorts	4	0.47, 0.48, 1.6, 1.8	1.0	0.89
AGF	2	7.67, 8.48	8.1	6.9

Commodity (Food/feed)	N	Processing factor		STMR/ STMR-P/ Median
		Individual	Best estimate	
Barley grain at harvest	4	-	-	0.37
Spent grain	4	0.01, 0.02, 0.02, 0.03	0.02	0.007

Notes:

NB: Values in italics were from the 2017 JMPR.

^a The processing factors calculated separately for wheat wholemeal flour and wholemeal in the 2017 JMPR Report were combined under wheat "wholemeal".

Based on the processing factors and maximum residue level of wheat grain of 4 mg/kg, the Meeting estimated maximum residue levels for wheat bran (unprocessed) at 10 mg/kg, replacing the previous recommendation of 7 mg/kg, and for wheat germ at 20 mg/kg.

Residues in animal commodities*Livestock dietary burden*

Dietary burden calculations for cattle and poultry are provided below. The dietary burdens were estimated using the OECD diets listed in Appendix IX of the 2016 edition of the FAO Manual.

Table 5.8.2 Estimated maximum and mean dietary burdens of farm animals

Animal dietary burden: chlormequat, ppm of dry matter diet								
	United States-Canada		European Union		Australia		Japan	
	max	Mean	max	Mean	max	Mean	Max	Mean
Beef cattle	22.4	9.72	32.6	12.9	133.0	48.3	3.22	3.22
Dairy cattle	28.5	11.5	32.6	12.9	99.8	38.8	3.05	2.78
Poultry broiler	3.17	3.17	2.00	2.00	1.92	1.92	0.34	0.34
Poultry layer	3.17	3.17	15.3	6.83	1.88	1.88	1.47	1.47

The calculated highest maximum dietary burden was 133.0 ppm (chlormequat cation) based on the Australian diet, which is more than 30 percent higher than the highest dose rate in the cattle feeding study. Therefore, it was not possible to estimate residues in mammalian commodities at the highest maximum burden.

Chlormequat was registered in Australia and, according to the current product labels, approved for use on wheat with one application at a maximum rate of 0.758 kg ai/ha from Z 25 to Z 31, but not for other cereal grains. Grazing and cutting for stock feed are not allowed before 21 days after the application. Most of forage and hay data and all of straw data used for estimating median and highest residue were from the samples taken at 20 days or later after application in the trials. Taking into consideration the registration of chlormequat for wheat in Australia, no importation of hay or straw into Australia, and that the application timing in the GAP in Australia is comparable to the GAP of Argentina, the Meeting decided to apply the proportionality principle to the median and highest residue values of wheat feed items for re-calculating the maximum and mean dietary burden based on the Australian diet.

Based on the maximum rate of 2.025 kg ai/ha in Argentinian GAP for wheat and that of 0.758 kg ai/ha in the Australian GAP for wheat, the median and highest residue in wheat derived feed were scaled for the purpose of calculating dietary burdens based on the Australian diet. The scaled median and highest residues were: 15.9 and 28.8 mg/kg in wheat hay, 7.67 and 20.6 mg/kg for wheat straw, and 3.26 and 9.36 mg/kg for wheat forage.

After recalculation using adjusted median and highest residue for wheat and removing forage, hay and straw derived from other cereal grains, animal dietary burdens based on the Australian diet, together with other diets, were as follows.

Table 5.8.3 Recalculated maximum and mean dietary burdens of chlormequat (for adjustment for the Australian diet)

	Livestock dietary burden, chlormequat, ppm of dry matter diet							
	United States-Canada		European Union		Australia		Japan	
	Max	Mean	max	Mean	max	Mean	Max	Mean
Beef cattle	22.4	9.72	32.6	12.9	37.4 ^①	18.1 ^②	3.22	3.22
Dairy cattle	28.5	11.5	32.6 ^③	12.9 ^④	26.0	12.3	3.05	2.78
Poultry broiler	3.17	3.17	2.00	2.00	3.10	3.10	0.34	0.34
Poultry layer	3.17	3.17	15.3 ^⑤	6.83 ^⑥	2.99	2.99	1.47	1.47

Notes:

- ① Highest maximum dietary burden for beef cattle suitable for estimation of maximum residue levels for mammalian meat, fat and offal.
- ② Highest mean dietary burden for beef cattle suitable for estimation of STMRs for mammalian meat, fat and offal.
- ③ Highest maximum dietary burden for dairy cattle suitable for estimation of maximum residue level for milks.
- ④ Highest mean dietary burden for dairy cattle suitable for estimation of STMRs for milks.
- ⑤ Highest maximum dietary burden for broiler and layer suitable for estimation of maximum residue levels for poultry meat, fat, offal, and eggs.
- ⑥ Highest mean dietary burden for broiler and layer suitable for estimation of STMRs for poultry meat, fat, offal and eggs.

Animal commodity maximum residue levels.

Mammals

The highest maximum dietary burden of chlormequat cation for dairy cattle was 32.6 ppm and the highest mean dietary burden was 12.9 ppm.

Table 5.8.4 Residues found in milk

	Feed level (ppm, cation)	Residue in milk (mg/kg as the cation)
MRL		
Feeding study	28	0.15
	93	0.26
Dietary burden (max) & highest residue	32.6	0.16
STMR		
Feeding study	28	0.15
Dietary burden (mean)	12.9	0.069

The Meeting estimated a maximum residue level of 0.2 mg/kg for milks to replace the previous recommendation of 0.3 mg/kg, and an STMR of 0.069 mg/kg for milks.

The highest maximum dietary burden of chlormequat cation for beef cattle was 37.4 ppm and the highest mean dietary burden was 18.1 ppm.

Table 5.8.5 Residues in tissues from cattle dosed with chlormequat in the diet

	Feed level (ppm, cation)	Residues (mg/kg, as chlormequat cation)			
		Meat	Fat	Liver	Kidney
MRL					
Feeding study	28	0.085	0.040	0.078	0.36

	Feed level (ppm, cation)	Residues (mg/kg, as chlormequat cation)			
		Meat	Fat	Liver	Kidney
	93	0.085 ^a	0.078	0.39	0.82
Dietary burden, HR	37.4	0.085	0.043	0.11	0.40
STMR					
Feeding study	28	< 0.04	< 0.04	0.062	0.31
Dietary burden, STMR	18.1	< 0.04	< 0.04	0.036	0.20

Notes:

^a This value is from the dose level of 28 ppm as the cation. A higher highest residue was observed among the cows fed at this level than those fed 93 ppm as the cation.

The Meeting estimated maximum residues level of 0.2 mg/kg for meat from mammals other than marine mammals, confirming the previous recommendation, and an STMR and an HR of 0.04 and 0.085 mg/kg, respectively.

The Meeting estimated a maximum residue level of 0.1 mg/kg for mammalian fat, confirming the previous recommendation, and an STMR and an HR of 0.04 and 0.043 mg/kg, respectively.

Based on the residue data for kidney, higher than those for liver, the Meeting estimated a maximum residue level of 0.5 mg/kg for edible offal, mammalian, replacing the previous recommendation of 1 mg/kg. The Meeting estimated an STMR and an HR of 0.036 and 0.11 mg/kg for liver, and 0.20 and 0.40 mg/kg for kidney, respectively.

Poultry

The highest maximum dietary burden of chlormequat cation for poultry was 15.3 ppm and the highest mean dietary burden was 6.83 ppm. No residues of chlormequat cation above the LOQ (0.05 mg/kg as chlormequat chloride) were found at the highest feeding level of 46.5 ppm (as the cation) in meat or fat. Therefore, the Meeting estimated maximum residue levels of 0.04(*) mg/kg for poultry meat and fat confirming the previous recommendations. The Meeting estimated STMR and HR for meat and fat of 0.04 mg/kg.

Table 5.8.6 Residues in eggs and tissues from poultry dosed with chlormequat in the diet

	Feed level (ppm, cation)	Residues in liver (mg/kg, cation)	Residues in eggs (mg/kg, cation)
MRL			
Feeding study	14.0	0.078	0.093
	46.5	0.26	0.12
Dietary burden, HR	15.3	0.085	0.094
STMR			
Feeding study	4.65	0.04	< 0.04
	14	0.054	0.078
Dietary burden, STMR	6.83	0.043	0.049

The Meeting estimated a maximum residue level of 0.2 mg/kg for poultry edible offal, replacing the previous recommendation, and an STMR and an HR of 0.043 and 0.085 mg/kg respectively. The Meeting also estimated a maximum residue level of 0.2 mg/kg for eggs, replacing the previous recommendation, and an STMR and an HR of 0.049 and 0.094 mg/kg respectively.

RECOMMENDATIONS

On the basis of the data from supervised trials, the Meeting concluded that the residue levels listed in Annex 1 are suitable for establishing maximum residue limits and for IEDI and international estimate of short-term intake assessments.

Definition of the residue (for compliance with the MRL and dietary exposure assessment) in plant and animal commodities: *chlormequat cation*.

The residue is not fat soluble.

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The International Estimated Daily Intakes (IEDIs) of chlormequat cation were calculated for the 17 GEMS/Food cluster diets using STMRs/STMR-Ps estimated by the current Meeting. The results are shown in Annex 3 of the 2022 Report.

The ADI for chlormequat chloride is 0–0.05 mg/kg bw/day (or 0–0.0388 mg/kg bw/day expressed as chlormequat cation). The calculated IEDIs for chlormequat cation were 1–20 percent of the maximum ADI for chlormequat expressed as cation. The Meeting concluded that the long-term dietary exposure to residues of chlormequat cation, when chlormequat chloride is used in accordance with GAPs that have been considered by JMPR, are unlikely to pose a public health concern.

Acute dietary exposure

The International Estimated Short-Term Intakes (international estimate of short-term intakes) of chlormequat cation were calculated for food commodities using HRs/HR-Ps or STMRs/STMR-Ps estimated by the current Meeting. The results are shown in Annex 4 to the 2022 Report.

The ARfD for chlormequat chloride is 0.05 mg/kg bw (or 0.0388 mg/kg bw expressed as chlormequat cation).

The calculated international estimate of short-term intakes for chlormequat ranged from 0–60 percent of the ARfD for children, and 0–30 percent for the general population. The Meeting concluded that the acute dietary exposure to residues of chlormequat cation, when chlormequat chloride is used in accordance with GAPs that have been considered by JMPR, are unlikely.

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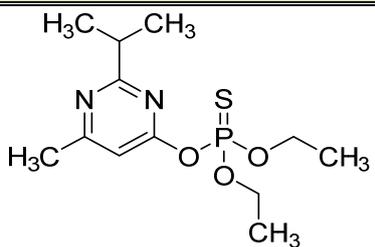
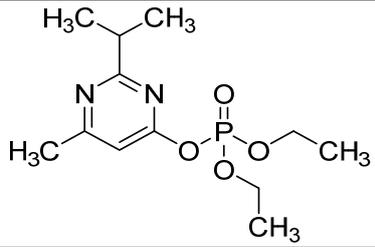
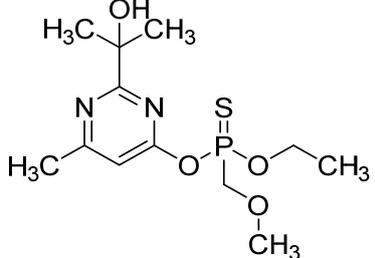
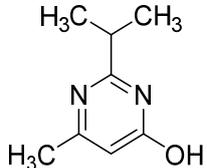
RESIDUE AND ANALYTICAL ASPECTS

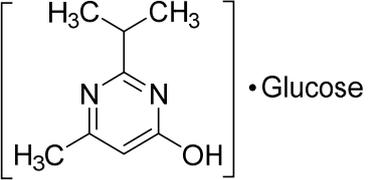
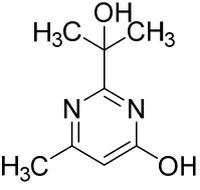
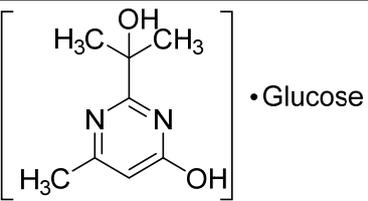
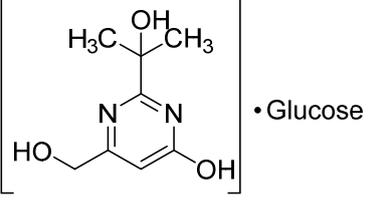
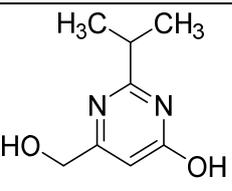
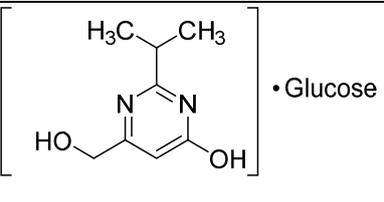
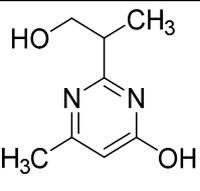
Diazinon is a contact organophosphorus insecticide with a wide range of insecticidal activity. It is effective against sucking, chewing and boring insects, including soil-living insects. Diazinon has been evaluated on numerous occasions by the JMPR commencing in 1963. The Most recent periodic review was in 1993. Following public health concerns identified by the International Agency for Research on Cancer (IARC), the JMPR in 2016 evaluated all previously considered toxicological data in addition to new studies. The 2016 JMPR recommended an ADI of 0–0.003 mg/kg bw and an ARfD of 0.03 mg/kg bw. Diazinon was scheduled at the Fifty-first Session of the CCPR (2019) for Periodic Review for residues by the 2020 JMPR and re-scheduled for the 2022 JMPR.

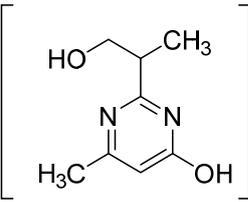
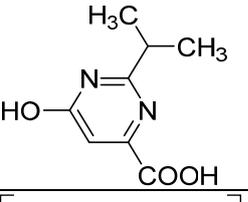
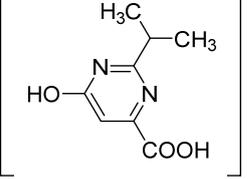
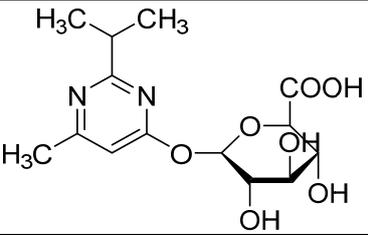
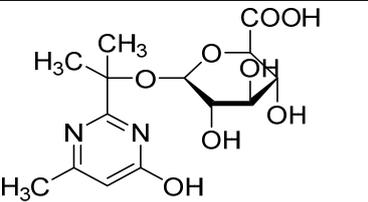
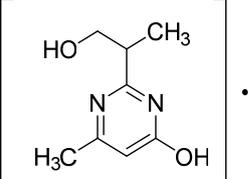
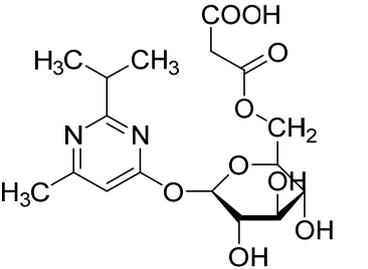
The Meeting received information from the manufacturer on physical and chemical properties, animal and plant metabolism, rotational crop studies, environmental fate in soil, analytical methods, storage stability, use patterns, supervised residue trials, processing studies and livestock feeding studies.

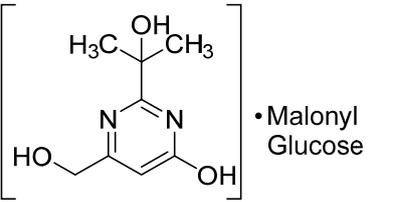
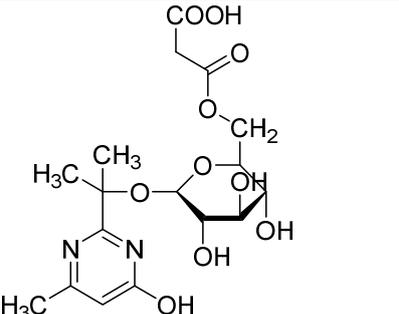
In this document, the common names, chemical structures and chemical names of the metabolites are shown below.

Table 5.9.1 Summary information on compounds referred to in the appraisal

Name/Code	Chemical name	Chemical structure	Occurrence in metabolism studies
Diazinon	<i>O,O</i> -diethyl- <i>O</i> -(2-isopropyl-6-methyl-4-pyrimidinyl)-phosphorothioate		Apple Beans Sweet corn Lettuce Potatoes Goat Hen Rotated spring wheat
G-24576 (diazoxon)	<i>O,O</i> -diethyl- <i>O</i> -(2-isopropyl-6-methyl-4-pyrimidinyl) phosphate		Goat Hen
CGA-14128 (hydroxydiazinon)	<i>O,O</i> -diethyl- <i>O</i> -(2-[2-hydroxy-2-isopropyl]-6-methyl-4-pyrimidinyl)phosphorothioate		Goat Hen
G-27550 B ₁	6-methyl-2-(1-methyl-ethyl)-4-pyrimidinol		Apple Beans Sweet corn Lettuce Potatoes

Name/Code	Chemical name	Chemical structure	Occurrence in metabolism studies
			Goat Hen Rotated Spring wheat
Glucose conjugate of G-27550	6-methyl-2-(1-methyl-ethyl)-4-pyrimidinol glucose conjugate		Bean, vines only
GS-31144 C	2-(2-hydroxyisopropyl)-6-methyl-4-pyrimidinol		Apple Beans Sweet corn Lettuce Potatoes Goat Hen Rotated spring wheat
Glucose conjugate of GS-31144 E ₂	2-(2-hydroxyisopropyl)-6-methyl-4-pyrimidinol glucose conjugate		Apple Beans Sweet corn Lettuce Potatoes
Two glucose conjugates of trihydroxy pyrimidinyl moiety† G and H	2-(2-hydroxyisopropyl)-6-hydroxymethyl-4-pyrimidinol glucose conjugate		Apple Beans Sweet corn Lettuce Potatoes Rotated spring wheat
JAK-III-57 D	2-(1-methylethyl)-6-hydroxymethyl-4-pyrimidinol		Apple Beans Sweet corn Lettuce Potatoes Rotated spring wheat
Glucose conjugate of JAK-III-57 F ₂	2-(1-methylethyl)-6-hydroxymethyl-4-pyrimidinol glucose conjugate		Apple Beans Sweet corn Lettuce Potatoes Rotated spring wheat
CL-XIX-29 E ₁ (also referred to as M3 in some studies)	2-(1-hydroxypropan-2-yl)-6-methyl-4-pyrimidinol		Apple Beans Sweet corn Lettuce Potatoes Hen Rotated spring wheat

Name/Code	Chemical name	Chemical structure	Occurrence in metabolism studies
Glucose conjugate of CL-XIX-29 F1	2-(1-hydroxypropan-2-yl)-6-methyl-4-pyrimidinol glucose conjugate	 <p>• Glucose</p>	Apple Beans Sweet corn Lettuce Potatoes Rotated spring wheat
JAK-IV-23	2-isopropyl-6-oxo-1,6-dihydropyrimidine-4-carboxylic acid		Beans
Glucose conjugate of JAK-IV-23	2-isopropyl-6-oxo-1,6-dihydropyrimidine-4-carboxylic acid glucose conjugate	 <p>• Glucose</p>	Beans
Glucuronic acid conjugates of G-27550	6-methyl-2-(1-methyl-ethyl)-4-pyrimidinol glucuronic acid conjugate		Hen
Glucuronic acid conjugates of GS-31144	2-(2-hydroxyisopropyl)-6-methyl-4-pyrimidinol glucuronic acid conjugate		Hen
Glucuronic acid conjugates of CL-XIX-29	2-(1-hydroxypropan-2-yl)-6-methyl-4-pyrimidinol malonyl glucuronic acid conjugate	 <p>• Glucuronic acid</p>	Hen
A conjugate of G-27550 ^s (postulated to be a malonyl glucose conjugate)	6-methyl-2-(1-methyl-ethyl)-4-pyrimidinol malonyl glucose conjugate		Beans Lettuce

Name/Code	Chemical name	Chemical structure	Occurrence in metabolism studies
A conjugate of JAK-III-57 [§] (postulated to be a malonyl glucose conjugate)	2-(1-methylethyl)-6-hydroxymethyl-4-pyrimidinol malonyl glucose conjugate		Beans Lettuce
A conjugate of GS-31144 [§] (postulated to be a malonyl glucose conjugate)	2-(2-hydroxyisopropyl)-6-methyl-4-pyrimidinol malonyl glucose conjugate		Beans Lettuce

Notes:

† The structure of the two metabolites G and H were not fully elucidated. The mass spectral analysis did not confirm the positions of the hydroxyl groups. The metabolites were susceptible to hydrolysis with β -glucosidase but no identification work was undertaken on the aglycone.

§ The identity of the conjugates were not established. The aglycones released from enzymatic or acid hydrolysis were confirmed.

With respect to the physical and chemical properties that may impact residues in crops, diazinon is regarded as moderately volatile, it has a higher solubility in organic solvents, compared to its solubility in water, and the partition coefficient (3.3–3.8) indicates its potential to sequester in fat.

Plant metabolism

Plant metabolism data, conducted via pre-emergence/soil directed applications followed by foliar applications, were provided for apple, beans with pods, sweet corn, lettuce and potatoes. In all the studies, the extraction procedure resulted in fractions that contained identified metabolites that were not individually quantified.

Apple

Apples, grown outdoors, were treated with [¹⁴C]-pyrimidine-diazinon three times. The first application was at a rate of 3.36 kg ai/ha applied in the early tight cluster stage (approximately BBCH 55); this application was split between a soil application (3.024 kg ai/ha) and a foliar application to a single branch (0.336 kg ai/ha). The second and third applications were foliar applications at a rate of 10.09 kg ai/ha, made to the same branch when the apples were present, 104 days and 133 days after the first application.

Mature apples were harvested 14 days after the last treatment. Foliage samples were also collected. The foliage, pulp and peel were analysed. The TRR in leaves, peel, pulp and whole apple were 51.1 mg eq/kg, 3.44 mg eq/kg, 0.126 mg eq/kg and 1.29 mg eq/kg respectively. Solvent extractabilities, methanol: water (9: 1), ranged from 89.7 percent of the TRR for peel to 91.9 percent of the TRR for leaves.

The major residue identified in leaves, peel and whole apple was diazinon (22.3 mg/kg, 43.7 percent TRR for leaves, 2.5 mg/kg, 73.3 percent TRR for peel and 0.89 mg/kg, 69 percent TRR for whole apple). Metabolite G-27550 was found at 11.9 percent TRR (0.4 mg eq/kg) in peel, at 5.9 percent TRR (3 mg eq/kg) in leaves and at 14.7 percent TRR (0.19 mg/kg) in whole apple.

In the pulp the major residue was G-27550 (60.7 percent TRR, 0.08 mg eq/kg). Diazinon was found at a level of 16.1 percent TRR (0.02 mg/kg).

Glucose conjugates of GS-31144, CL-XIX-29, JAK-111-57 and of the trihydroxy pyrimidyl moiety were identified. For peel, pulp and whole apple the individual levels of these metabolites were not reported.

The PES accounted for 8.1 percent TRR (4.1 mg eq/kg) in leaves, 10.4 percent TRR (0.4 mg eq/kg) in peel, 9 percent TRR (0.01 mg eq/kg) in pulp and 11.6 percent TRR (0.15 mg eq/kg) in whole apple. The TRR identified was 72 percent TRR for leaves, 89 percent TRR for peel, 86 percent TRR for pulp and 87 percent TRR for whole apple.

Beans with pods

Beans with pods, grown outdoors, were treated with [¹⁴C]-pyrimidine-diazinon three times. A pre-emergence application was made at a rate of 4.48 kg ai/ha applied 1 day after sowing. Two foliar applications were made at a rate of 1.4 kg ai/ha. The first foliar application was made 34 days after the pre-emergence application and the 2nd foliar application was made 15 days later.

Samples of beans with pods and vines were taken 14 days after the last application, which was stated to represent crop maturity. Immature crop fractions were also sampled: vines were taken 3 days before the first foliar application, 31 DAFT (days after first treatment), and vines with beans were taken 7 days after the first foliar application (41 DAFT). The growth stages of the various crop fractions sampled and analysed were not stated.

The TRR in beans with pods harvested 14 DALA, was 0.456 mg eq/kg. The solvent extractability, methanol: water (9:1), was 76 percent TRR. Diazinon was found at a level of 2.1 percent TRR (0.01 mg/kg). The predominant residue was G-27550 at 26.7 percent TRR (0.12 mg eq/kg). The metabolite JAK-111-57 (4.4 percent TRR, 0.02 mg eq/kg) was also identified. The metabolite CL-XIX-29 and glucose conjugates of GS-31144, CL-XIX-29, JAK-111-57 and of the trihydroxy pyrimidyl moiety were also identified. However, the individual levels were not reported. The TRR identified in beans with pods was 53 percent TRR. The PES accounted for 24 percent TRR (0.109 mg eq/kg).

The TRR in the vines with beans, harvested 41 DAFT, was 4.45 mg eq/kg. The identification and characterization of the TRR was unsuccessful.

The TRR in vines was 0.425 mg eq/kg and 3.53 mg eq/kg for vines harvested 32 DAFT and 14 DALA respectively. Solvent extraction was undertaken with methanol: water (9:1) and was 54 percent TRR for the vines harvested 32 DAFT. The solvent extractability was higher for the vines harvested 14 DALA at 82 percent TRR. Diazinon was not identified in either of the vine samples. In vines, harvested 32 DAFT, the highest contribution to the TRR was 17.3 percent TRR (0.07 mg eq/kg) which was attributed to a mixture of two glucose conjugates of the trihydroxy pyrimidyl moiety and an unknown metabolite. The metabolites CL-XIX-29 and a glucose conjugate of GS-31144 accounted for 15.5 percent TRR (0.07 mg eq/kg), with the individual levels not reported. In the vines harvested 14 DALA, the highest contribution to the TRR (27.5 percent TRR, 0.97 mg eq/kg) was attributed to a mixture of CL-XIX-29 and a glucose conjugate of GS-31144. An unknown metabolite occurred at a level of 19.5 percent TRR (0.69 mg eq/kg). Glucose conjugates of GS-31144 and CL-XIX-29 were identified and together accounted

for 12.5 percent TRR (0.44 mg eq/kg), with the individual levels not stated. The TRR identified in the vines was 58 percent TRR. The PES accounted for 18 percent TRR (0.639 mg eq/kg).

In a supplementary study, retained samples of beans with pods and vines harvested 14 DALA were re-extracted after 69 months of storage. The TRR and solvent extractability (methanol: water (9:1)) for the beans with pods was 0.509 mg eq/kg and 75 percent TRR. This was comparable to the earlier extractions for which the TRR was 0.456 mg eq/kg and the solvent extractability was 76 percent TRR. For the vines the TRR and the solvent extractability was 3.76 mg eq/kg and 78 percent TRR respectively which was comparable to the earlier extraction for which the TRR was 3.53 mg eq/kg and the solvent extractability was 82 percent TRR.

For both beans with pods and vines the extracted residue was partitioned with ethyl acetate and only the aqueous fraction was subjected to further analysis. In beans with pods, the highest contribution to the TRR was 20.3 percent TRR (0.103 mg eq/kg) which was found to contain JAK-IV-23, glucose conjugates of the trihydroxy pyrimidinyl moiety and unidentified conjugates of G-27550, JAK-III-57 and GS-31144. In vines, this fraction accounted for 17.4 percent TRR (0.652 mg eq/kg). The individual levels of the metabolites were not reported for either beans with pods or vines. In vines the highest contribution to the TRR was 27 percent TRR (1.013 mg eq/kg) which was found to contain CL-XIX-29 and a glucose conjugate of GS-31133, with the individual levels not being specified. Free G-27550, GS-31144 and JAK-III-59 were also identified in both beans with pods and vines.

The PES, from the beans with pods, from the supplementary study were subject to further extraction with methanol: water (9:1), 1 percent NaCl, cellulase hydrolysis and protease hydrolysis. The extraction procedures individually released 2.1–8.5 percent TRR (0.011–0.044 mg eq/kg), leaving 6.4 percent TRR (0.033 mg eq/kg) in the final post-extraction solids. In the released radioactivity, diazinon, G-27550 and GS-31144 were identified along with a number of unidentified polar fractions, with the individual levels of the analytes not specified

Sweet corn

Sweet corn, grown in a greenhouse, was treated with [¹⁴C]-pyrimidine-diazinon three times. The first application was made pre-emergence, on the day of sowing, at a rate of 4.48 kg ai/ha. The second and third applications were foliar applications at a rate of 3.5 kg ai/ha applied 50 and 74 DAFT. Samples of various sweet corn fractions were taken 2 days prior to the last application (72 DAFT) and 14 DALA.

The TRR in the crop fractions sampled 72 DAFT were 2.070 mg eq/kg, 0.087 mg eq/kg and 0.810 mg eq/kg for forage, ears and stalks respectively. The solvent extractabilities (methanol: water (9:1)) were 69 percent TRR for forage, 59 percent TRR for ears and 20 percent TRR for stalks.

The TRR in cob and grain harvested 14 DALA were 0.250 mg eq/kg and 0.453 mg eq/kg respectively. Solvent extraction was undertaken with methanol: water (9:1) and was 47.5 percent TRR, for the cob, and 26.4 percent TRR for the grain.

Following solvent extraction, the residue was partitioned with ethyl acetate. Although the majority of the TRR was shown to be aqueous soluble, only the organo-soluble fractions of forage (72 DAFT), stalks (72 DAFT), cobs and grain were subject to further analysis. For forage (14 DALA) both the organo-soluble and aqueous fractions were analysed.

In grain, diazinon was not identified. The metabolites G-27550, GS-31144 and JAK-111-57 were identified at levels of < 1 percent TRR (< 0.004 mg eq/kg). Two unknown metabolites at 0.1 percent TRR (0.0005 mg eq/kg) were also found in the grain. A total of 1.1 percent TRR (0.005 mg eq/kg) was identified in grain. The PES accounted for 74 percent TRR (0.33 mg eq/kg). Subsequent treatment of the

PES with amyloglucosidase released around 60 percent TRR (0.28 mg eq/kg) which was found to be highly polar in nature and likely to comprise of a complex mixture of sugar conjugates. The identities of the aglycone were not established.

In the stalks, harvested 72 DAFT, the predominant residue identified was G-27550 (7.7 percent TRR, 0.0624 mg eq/kg). The metabolites GS-31144 (1.3 percent TRR, 0.01 mg eq/kg) and JAK-111-57 (1.1 percent TRR, 0.009 mg eq/kg) were also identified. Two unknown metabolites were found at levels of 0.6 percent TRR (0.005 mg eq/kg) and 1.5 percent TRR (0.0122 mg eq/kg). Diazinon was not identified. A total of 10 percent TRR (0.0819 mg eq/kg) was identified. The PES accounted for 80 percent TRR (0.646 mg eq/kg).

In the forage samples harvested 72 DAFT, diazinon was identified at a level of 0.5 percent TRR (0.01 mg/kg). The predominant residue was G-27550 (7 percent TRR, 0.145 mg eq/kg). The metabolites GS-31144 (0.7 percent TRR, 0.0145 mg eq/kg) and JAK-111-57 (1.3 percent TRR, 0.0269 mg eq/kg) were also identified. Two unknown metabolites occurred at levels of < 1 percent TRR (< 0.026 mg eq/kg). The TRR identified was 9.5 percent TRR (0.2 mg eq/kg). The PES accounted for 31 percent TRR (0.64 mg eq/kg).

In sweet corn forage (14 DALA), the predominant residue was G27550 (14.5 percent TRR, 0.56 mg eq/kg). Conjugates of CL-XIX-29, JAK-111-57 and of the trihydroxy pyrimidinyl moiety accounted for 12.4 percent TRR (0.48 mg eq/kg), with the individual levels not specified. Unknown metabolite was found at 11.8 percent TRR (0.46 mg eq/kg). Approximately 41 percent TRR (1.6 mg eq/kg) was identified. The PES accounted for 25.5 percent TRR (0.992 mg eq/kg).

Lettuce

Lettuce, grown outdoors, was treated with [¹⁴C]-pyrimidine-diazinon three times. The first application was made pre-emergence at a rate of 4.48 kg ai/ha. The second and third applications were foliar applications at a rate of 1.4 kg ai/ha applied at 7 days intervals. Immature leaves were harvested prior to the last application (0 DALA). Mature leaves were harvested 14 DALA.

The TRR were 1.885 mg eq/kg and 0.656 mg eq/kg for immature and mature lettuce respectively. Solvent extraction was undertaken using methanol: water (9:1, v/v). The solvent extractabilities were 87.2 percent of the TRR and 78.4 percent of the TRR for immature and mature lettuce respectively.

For immature lettuce, 47 percent TRR was found to be aqueous soluble and 40 percent TRR was found to be organosoluble. Only the organosoluble residue was subjected to further analysis. The main components identified in the organosoluble fraction from immature lettuce were G-27550 (18.9 percent TRR, 0.36 mg eq/kg) and diazinon (18.6 percent TRR, 0.35 mg/kg). The PES, remaining after solvent extraction, was 12.8 percent TRR (0.241 mg eq/kg).

For mature lettuce both the organosoluble and aqueous soluble extracts were subject to further identification/characterization. The extracts were also treated with β -glucosidase to confirm the presence of the conjugates identified. The main metabolites identified were G-27550 (17.5 percent TRR, 0.12 mg eq/kg), diazinon (11.8 percent TRR, 0.08 mg/kg) and GS-31144 (11.7 percent TRR, 0.08 mg eq/kg). An unknown metabolite accounted for 12.7 percent TRR (0.08 mg eq/kg). Glucose conjugates of GS-31144, CL-XIX-29, JAK-111-57 as well as free CL-XIX-29 were also identified, with the individual levels not being specified. Two glucose conjugates of the trihydroxy pyrimidinyl moiety were also identified. In total 63.5 percent of the TRR was identified. Following solvent extraction, the PES for mature lettuce accounted for 21.6 percent TRR (0.142 mg eq/kg).

In a supplementary study, retained samples of immature and mature lettuce, after 69 months of storage, were re-extracted with methanol: water (9: 1) followed by partitioning with ethyl acetate. The resulting aqueous phase was subjected to further analysis.

For immature lettuce the TRR and the solvent extractability were 2.2 mg eq/kg and 82 percent TRR. This compared to the original extraction for which the TRR was 1.9 mg eq/kg and 87 percent TRR. For mature lettuce the TRR was 0.75 mg eq/kg and the solvent extractability was 72 percent TRR. This was also comparable to the original extraction for which the TRR and solvent extractability was 0.66 mg eq/kg and 78 percent TRR respectively.

For immature lettuce, the main fraction accounted for 11.7 percent TRR (0.255 mg eq/kg). This fraction contained G-27550 and an unknown metabolite, with the individual levels not stated. The metabolite G-27550 was also identified separately at a level of 8 percent TRR (0.175 mg eq/kg). The metabolites GS-31144 (5.7 percent TRR, 0.124 mg eq/kg) and glucose conjugates of GS-31144 (1.2 percent TRR, 0.027 mg eq/kg), CL-XIX-29/ JAK-III-57 (3.6 percent TRR, 0.079 mg eq/kg) and of the trihydroxy pyrimidinyl moiety (2.5 percent TRR, 0.054 mg eq/kg). Enzymatic and acid hydrolysis released G-27550 and GS-31144 as well as three unidentified metabolites. These accounted for 8.5 percent TRR (0.185 mg eq/kg) with the individual levels not specified. A further conjugate of G-27550 accounted for 3 percent TRR (0.064 mg eq/kg).

In mature lettuce, the main fraction accounted for 16.7 percent TRR (0.125 mg eq/kg). This fraction contained conjugates of G-27550, GS-31144 and three unknown metabolites. The individual levels were not specified. The metabolites G-27550/unknown (4.7 percent TRR, 0.035 mg/ eq/kg), G-27550 (3.2 percent TRR, 0.024 mg/eq/kg), GS-31144 (7.8 percent TRR, 0.059 mg eq/kg) and JAK-III-57 (1.3 percent TRR, 0.01 mg eq/kg). Glucose conjugates of GS-31144 (3.6 percent TRR, 0.027 mg eq/kg), CL-XIX-29/ JAK-III-57 (10.1 percent TRR, 0.076 mg eq/kg) and of the trihydroxy pyrimidinyl moiety (4 percent TRR, 0.03 mg eq/kg) were also identified.

The PES, from the mature lettuce from the supplementary study were subject to further extraction with methanol: water (9:1), 1 percent NaCl, cellulase hydrolysis and protease hydrolysis. In the released radioactivity, low levels of diazinon, G-27550 and GS-31144 were identified along with a number of unidentified polar fractions, for which the number and levels of metabolites was not stated.

The PES accounted for approximately 80 percent TRR for tubers harvested -1 and 15 DALA (0.057 mg eq/kg for -1 DALA and 0.23 mg eq/kg for 15 DALA). Treatment of the PES from the tubers harvested 15 DALA with amyloglucosidase solubilized around 33 percent TRR. The identity of the solubilized radioactivity was not confirmed. Acid hydrolysis of the PES released around 72 percent TRR with 11.5 percent TRR identified as G-27550.

The TRR for foliage were 0.059 mg eq/kg and 1.930 mg eq/kg at -1 and 15 DALA respectively. The solvent extractabilities using methanol: water (9:1) were 32 percent TRR and 81.5 percent TRR for foliage harvested -1 DALA and 15 DALA respectively. Further characterization and identification was only undertaken on the foliage samples from 15 DALA. Diazinon was found in the potato foliage at 14.2 percent TRR (0.27 mg/kg). The highest contribution to the radioactivity, accounting for 20.8 percent TRR (0.4 mg eq/kg) was a glucose conjugate of JAK-111-57 and CL-XIX-29, with the individual levels not specified. A glucose conjugate of the trihydroxy pyrimidinyl moiety accounted for 14.1 percent TRR (0.27 mg eq/kg). Free CL-XIX-29 and a glucose conjugate of GS-31144 accounted for 11.5 percent TRR (0.22 mg eq/kg), with the individual levels not stated. The Total radioactivity identified was 68 percent TRR (1.31 mg eq/kg). The PES were 18.5 percent TRR (0.357 mg eq/kg).

Summary and conclusion of metabolism in crops

The metabolism of diazinon has been investigated in apples, beans with pods, sweet corn, lettuce and potatoes. All studies were undertaken with the application of [¹⁴C]-pyrimidine-diazinon three times. The first application was either a pre-emergence application or a soil directed application followed by two foliar applications.

The Meeting noted that the time period over which the studies were conducted (15 months for apple, 21 and 68 months for beans with pods, 18 months for sweetcorn, 19 months and 69 months for lettuce and 16 months for potatoes) was longer than would be standard. HPLC profiles of crop fractions of lettuce and beans with pods extracted after 19 months of storage and extracted after 69 months of storage were comparable. The Meeting noted that stability data from fortified samples showed that G-24576 was unstable in a range of plant commodities and therefore the Meeting concluded that in the absence of data to support the storage interval from harvest to extraction, the plant metabolism data could not be relied on for an assessment of the residue definitions for risk assessment.

The data indicate that the metabolism in all 5 crops is qualitatively similar and proceeds with cleavage of the ester bond of diazinon leading to the loss of the diethylthiophosphate moiety and the formation of G-27550. Oxidation of the isopropyl moiety of G-27550 leads to the formation of GS-31144 and CL-XIX-29 while oxidation of the methyl moiety on the pyrimidine ring of G-27550 leads to the formation of JAK-III-57. Glucose conjugates of G-27550 and of the hydroxypyrimidine metabolites were identified.

However, the lower solvent extractability for beans with pods, sweet corn, lettuce and potatoes compared to apples indicates potential qualitative and quantitative differences in the metabolism. The radioactivity remaining in the PES, after solvent extraction, was high for beans with pods, sweet corns, lettuce and potatoes and subsequent analysis did not fully establish the identity of the released radioactivity but toxicological relevant metabolites were released such as diazinon, G-27550 and GS-31144.

The level of identification in beans with pods, sweet corn, lettuce and potatoes was low. For the crop fractions relevant to human consumption the level of identification was 24 percent TRR (0.109 mg eq/kg) for beans with pods, 1.1 percent TRR (0.005 mg eq/kg) for grain, 40 percent TRR (0.75 mg eq/kg) for immature lettuce leaves, 63.5 percent TRR (0.42 mg eq/kg) for mature lettuce leaves and 11.5 percent TRR (0.03 mg eq/kg) for potato tubers.

For apples, the radioactivity identified was 86 percent TRR (0.112 mg eq/kg) for pulp, 87 percent TRR (1.12 mg eq/kg) for whole apples and 89 percent TRR (3.01 mg eq/kg) for peel. The PES, following methanol: water extraction (9:1) accounted for 12 percent TRR (0.15 mg eq/kg) in whole apple.

For the plant metabolites identified, G-27550, GS-31144 and CL-XIX-29 were also identified in the rat.

Environmental fate

The Meeting received information on the environmental fate and behaviour of diazinon, including hydrolytic stability, aqueous photolysis, photochemical degradation in soil, and aerobic soil degradation studies.

Aqueous hydrolysis

Hydrolysis of diazinon was rapid at pH 5 (DT₅₀ of 0.15 days at 70 °C and 12 days at 25 °C) and significantly slower under neutral conditions (DT₅₀ of 0.4 days at 70 °C and 138 days at 25 °C) and basic conditions (0.2 days at 70 °C and 77 days at 25 °C).

Hydrolysis of diazinon also increased with temperature. The main degradation product identified was G-27550. At pH 5 and 25 °C, after 21 days diazinon accounted for 29 percent AR and G-27550 accounted for 67 percent AR.

The Meeting concluded that hydrolysis could be a significant degradation pathway under environmental conditions.

Aqueous photolysis

The photolysis of diazinon in aqueous solutions was investigated in two studies. Diazinon was found to be stable in deionised water at 20–25 °C when exposed to artificial light for 12 days. In a buffer solution at pH 7, temperatures 12–49 °C, diazinon was found to degrade when exposed to natural sunlight over 30 days. Only metabolite G-27550 was identified. The DT₅₀ values calculated from the second study were 23 and 26 days.

The Meeting concluded that the degradation of diazinon, as a result of aqueous photolysis, was slow and was therefore unlikely to be a significant pathway under environmental conditions.

Soil photolysis

The photodegradation of diazinon in soil was investigated in two studies.

The DT₅₀ for diazinon ranged from 17.3 to 37.4 hours under sunlight, while the DT₅₀ values for diazinon in the dark control samples ranged from 15–39 days. The DT₅₀, calculated from study 1 only, for artificial light was 5.5 days.

The only degradation products identified were G-27550 and GS-31144. G-27550 accounted for up to 43 percent, 24 percent and 18 percent AR in artificially irradiated, natural sunlight and dark control samples, respectively after the exposure period. GS-31144 accounted for up to 3 percent AR after 21 hours of natural sunlight but was not found in the dark or artificial sunlight samples.

There were four unknown compounds which individually exceeded 10 percent of the AR at several time points.

The Meeting concluded that soil photolysis is a route of degradation for diazinon.

Aerobic soil degradation

Soil degradation studies were conducted in three soil types at application rates ranging from 1.2 to 10 mg ai/kg dw of soil. After 76 days of incubation at 20 °C in the dark, diazinon ranged from 1.8–9.1 percent AR. The main degradation products identified were GS-31144 and G-27550. G-27550 accounted for 48.1–65.8 percent AR after 76 days of incubation.

The mineralization of diazinon into CO₂ accounted for up to a maximum 9.9 percent AR. Extractability from all samples declined with time, with 62.2–73 percent AR extracted at day 76.

The DT₅₀ values calculated for diazinon were 8 days, 23 days and 9.9 days for sandy loam, loamy sand and clay loam soils respectively. The DT₅₀ values calculated for G-27550 were 124 days, 131 days and 124 days for sandy loam, loamy sand and clay loam soils respectively

The Meeting concluded that under aerobic conditions diazinon was non-persistent in soil and that G-27550 was persistent in soil.

Residues in succeeding or rotational crops

Confined rotational crop studies

The Meeting received two confined rotational crop studies.

In the first confined rotational crop study a primary crop of maize was treated with [¹⁴C]-pyrimidine-diazinon three times. The first application was made at a rate of 4.48 kg ai/ha (pre-emergence) followed by two foliar applications at a rate of 3.5 kg ai/ha (BBCH 30–39). The two foliar applications were made 50 and 74 days after sowing of the primary crop

Rotational crops of wheat, lettuce, sugar beet and soya bean were planted after harvest of the primary maize crop, which was 98 days after the last foliar application.

The TRR in immature lettuce and mature lettuce were 0.072 mg eq/kg and 0.039 mg eq/kg respectively. The solvent extractability for the mature lettuce using methanol: water (9:1, v/v) was 72 percent TRR. No further characterization/ identification of the residue was undertaken for the lettuce samples.

For sugar beet roots the TRR were 0.048 mg eq/kg and 0.016 mg eq/kg for immature roots and mature roots respectively. The TRR in the leaves were 0.061 mg eq/kg, 0.040 mg eq/kg and 0.16 mg eq/kg for 25 percent mature leaves, immature leaves and mature leaves respectively. Solvent extraction was only undertaken for the 50 percent mature leaves with 91 percent TRR extracted with methanol: water (9:1, v/v). No further characterization/ identification of the residue was undertaken for the sugar beet samples.

In the mature soya beans, the TRR was 0.19 mg eq/kg. The solvent extractability with methanol: water (9:1, v/v) was 16 percent TRR. For the mature pods, the TRR was 0.23 mg eq/kg and the solvent extractability with methanol: water (9:1, v/v) was 43 percent TRR. The TRR determined in the stalks were 0.12 mg eq/kg, 0.16 mg eq/kg and 0.19 mg eq/kg for 25 percent mature stalks, 50 percent mature stalks and 50 percent mature stalks respectively. The solvent extractability with methanol: water (9:1, v/v) ranged from 63–72 percent TRR. No further characterization/ identification of the extracted residue and unextracted residue was undertaken for the soya bean samples.

In wheat grain, the TRR was 0.24 mg eq/kg and the solvent extractability with methanol: water (9:1, v/v) was 11.6 percent TRR. In the extracted residue, a glucose conjugate of the trihydroxy pyrimidinyl moiety (0.8 percent TRR, 0.002 mg eq/kg), GS-31144 (0.4 percent TRR, < 0.001 mg eq/kg) and an unknown metabolite with G-27750 (0.8 percent TRR, 0.002 mg eq/kg) were identified.

For wheat hulls, stalks and foliage the TRR range from 0.14 mg eq/kg (foliage) to 0.62 mg eq/kg (wheat hulls). Solvent extractabilities with methanol water (9:1, v/v) ranged from 58 percent TRR (wheat hulls) to 70 percent TRR (stalks). In the extracted residue from these crop fractions a glucose conjugate of the trihydroxy pyrimidinyl moiety (0.012–0.055 mg eq/kg), CL-XIX-29 (0.004–0.023 mg eq/kg), JAK-111-57 (0.004–0.08 mg eq/kg), CL-XIX-29 with a glucose conjugate of JAK-III-57 (0.008 mg eq/kg) and GS-31144 (0.008–0.029 mg eq/kg) were identified at various levels. An unknown metabolite quantified with G-27750 was also identified (0.03–0.085 mg eq/kg). Diazinon was only found in the stalks at 0.045 mg/kg.

The TRR identified was 1.2 percent TRR (0.002 mg eq/kg) for wheat grain, 19 percent TRR (0.094 mg eq/kg) for wheat hulls, 21 percent TRR (0.133 mg eq/kg) for mature stalks and 24 percent TRR

(0.033 mg eq/kg) for 25 percent mature foliage. No further analysis of the unextracted residue was undertaken.

A second study focused on the uptake of residues in rotational crops with no identification of the radioactive residues undertaken. Primary crops of lettuce, beans with pods and potatoes were all treated with [¹⁴C]-pyrimidine-diazinon at a rate of 4.48 kg ai/ha, applied pre-emergence, one day after sowing of the primary crop, followed by two foliar applications at 1.4 kg ai/ha. The foliar applications were made at intervals of 34 days and 41 days for lettuce, 34 days and 49 days for beans with pods, and 75 days and 82 days for potatoes, after the pre-emergence application. Rotational crops of wheat, lettuce, soya beans and sugar beet were planted 90 to 327 DALA after harvest of the primary crop.

The TRR in wheat grain, immature wheat stalks, immature and mature lettuce, and sugar beet roots and leaves were < 0.01 mg eq/kg. Residues above 0.01 mg/kg were obtained in mature wheat stalks (0.012 mg eq/kg), wheat hulls (0.011 mg eq/kg) and wheat full grazing leaves (0.014 mg eq/kg). Residues above 0.01 mg eq/kg were also obtained in various soya bean fractions; mature beans (0.015 mg eq/kg), mature pods (0.012 mg eq/kg), 0.011 mg eq/kg (50 percent mature stalks) and 0.027 mg eq/kg (mature stalks).

Solvent extraction was undertaken for a limited number of crop fractions using methanol: water (9:1, v/v). The solvent extractabilities were low and ranged from 16 percent TRR (mature soya beans) to 61 percent TRR (50 percent mature soya bean stalks).

Summary and conclusion of metabolism in rotational crops

The Meeting noted that the rotational crops did not investigate shorter PBI of 30 days and the rotational crops were planted after the harvest of treated primary crops, rather than being planted after applications to the bare soil. Although significant crop interception will have occurred for the foliar applications and the intervals (34–75 days) between the pre-emergence and first foliar application may have further reduced the total amount of residue available in the soil, residues above 0.01 mg/kg were identified in rotational crops. Based on the use patterns provided to the current Meeting residues above 0.01 mg/kg are expected in rotational crops. However, the identity of the residues in rotational crops has not been confirmed.

Owing to the limited information on the identity of the metabolites in rotated crops, the Meeting decided a comparison of the primary and rotational crop metabolism was not possible. The data available for wheat, indicates that the metabolite G-27550 is likely to be significant in rotational crops.

Field rotational crop study

A field rotational crop study was conducted using lettuce, turnips and wheat planted 30, 60 and 180 days after the last application to a primary crop. Primary crops of lettuce, squash, melons and tomatoes were treated with one pre-emergence application at 4.48 kg ai/ha followed by five foliar applications at 0.56 kg ai/ha and then harvested before planting of the rotational crops. The foliar applications to the primary crop were made at various growth stages and therefore the intervals between the applications and the amount of crop interception varied.

Residues of diazinon, G-24576 and CGA-14128 were < 0.01 mg/kg in all rotational crop samples from all plant back periods. The Meeting decided that a conclusion on the residue levels in rotational crops could not be drawn as the relevant residues for rotational crops could not be confirmed from the metabolism studies, noting that metabolite G-27550, which based on the available information may be significant in rotational crops, had not been included in the trials. The storage stability data on fortified samples showed that G-24576 rapidly degraded in a range of plant commodities and therefore the

reported results of < 0.01 mg/kg for this metabolite in rotational crops could not be relied on as the samples were stored for up to 15 months prior to analysis.

Animal metabolism

The meeting received information on metabolism of diazinon in ruminants (lactating goat) and poultry (laying hens).

Rat

Metabolism studies on laboratory animals including rats were reviewed in the framework of the toxicological evaluation by the WHO core Assessment Group of the 2016 JMPR.

Lactating goat

Two goats were orally dosed, by capsule, with [¹⁴C]-pyrimidine-diazinon at a rate of 109–114 ppm for four consecutive days. Goats were slaughtered 24 hours after the last dose. The majority (72–77 percent) of the administered dose was excreted in urine (64 percent) and faeces (9–12 percent). The total radioactivity excreted in milk was 0.31 percent AD.

The TRR in milk over the 4 days ranged from 0.45–0.469 mg eq/kg, for animal 1 and 0.33 mg eq/kg–0.46 mg eq/kg for animal 2. A plateau was reached after 2 to 3 days. The solvent extractability for milk, using acetonitrile: water (1:1, v/v), was 91 percent TRR (0.627 mg eq/kg). The predominant residues were GS-31144 (37.3 percent TRR, 0.256 mg eq/kg) and G-27550 (39.3 percent TRR, 0.270 mg eq/kg). A total of 77 percent TRR was identified and 9 percent TRR (0.06 mg eq/kg) remained in the PES.

For liver the TRR was 1.57 mg eq/kg. The solvent extractability with methanol: water (9:1, v/v) was 79 percent TRR (1.24 mg eq/kg). The predominant metabolites identified were GS-31144 (19 percent TRR, 0.298 mg eq/kg) and G-27550 (19.2 percent TRR, 0.301 mg eq/kg). A total of 39 percent TRR was identified. The PES accounted for 21 percent TRR (0.33 mg eq/kg) and was not subject to any further analysis.

In kidney the TRR was 3.0 mg eq/kg. Solvent extraction with methanol: water (9:1 v/v) released 94 percent TRR (2.84 mg eq/kg). The predominant metabolites identified were GS-31144 (31 percent TRR, 0.92 mg eq/kg) and G-27550 (19.8 percent TRR, 0.60 mg eq/kg). A total of 52 percent TRR was identified. The PES accounted for 6 percent TRR (0.18 mg eq/kg).

The TRR determined in fat was around 0.36 mg eq/kg. Around 95 percent TRR was extracted with methanol: water (9:1, v/v). The predominant residue was diazinon (maximum 68 percent TRR, 0.25 mg/kg). The metabolite CGA-14128 accounted for around 12.8 percent TRR (0.047 mg eq/kg). The metabolites GS-31144, G-27550 and G-24576 were also identified. The total radioactivity identified exceeded 95 percent TRR for fat.

The TRR determined in muscle was around 0.40 mg eq/kg. Methanol: water (9:1, v/v) extracted ≥ 95 percent TRR. The predominant residues were GS-31144 (maximum 40 percent TRR, 0.18 mg eq/kg) and G-27550 (maximum 35 percent TRR, 0.16 mg eq/kg). Over 76 percent TRR was identified in muscle and the PES was ≤ 5 percent TRR (0.02 mg eq/kg).

The solvent extracts from the tissue samples were subject to acid hydrolysis (6 M HCl at 85°C, left overnight). Increased levels of GS-31144, G27550, G-24576 and CGA-14128 indicate the potential presence of conjugates of these metabolites. The liver and kidney solvent extracts were also treated with β-glucuronidase (incubated at 37 °C, left overnight). No details were reported but increased levels of the

metabolites GS-31144 and G-27550 were observed indicating the potential presence of glucuronic conjugates of these metabolites.

Laying hens

Laying hens were orally dosed, by capsule, with [¹⁴C]-pyrimidine-diazinon at a rate of 25 ppm for seven consecutive days. Hens were slaughtered 24 hours after the last dose. The majority (79 percent) of the administered dose was excreted. The total radioactivity found in eggs was 0.3 percent of the administered dose. For tissues the total radioactivity, taken 24 hours after the last dose, accounted for 0.09 percent of the administered dose.

The TRR in egg yolk and egg white were 0.065 mg eq/kg and 0.066 mg eq/kg respectively. Solvent extractability with methanol: water (9,1, v/v) was 67 percent TRR (0.043 mg eq/kg) for egg yolk and 98 percent TRR (0.065 mg eq/kg) for egg white. The predominant residues identified were a mixture of glucuronic conjugates of G-27550, GS-31144 and CL-XIX-29 and CL-XIX-29 (25 percent TRR, 0.016 mg eq/kg in yolk and 41 percent TRR, 0.027 mg eq/kg in egg white). The metabolite G-31144 accounted for 19 percent TRR (0.012 mg eq/kg) in yolk and 33 percent TRR (0.022 mg eq/kg in egg white) and G-27550 accounted for 11 percent TRR (0.007 mg eq/kg) in yolk and 9.4 percent TRR (0.006 mg eq/kg) in egg white. For egg yolks 33 percent TRR (0.022 mg eq/kg) remained in the PES and a total of 63 percent TRR (0.04 mg eq/kg) was identified. For egg whites, 2 percent TRR (0.001 mg eq/kg) remained in the PES and 98 percent TRR (0.065 mg eq/kg) was identified.

In liver, the TRR was 0.11 mg eq/kg and 63 percent of the TRR was extracted with methanol: water (9:1, v/v). The predominant residue, accounting for 47 percent TRR (0.052 mg eq/kg) was a mixture of glucuronic acid conjugates of G-27550, GS-31144 and CL-XIX-29. The levels of the individual metabolites were not determined. The PES, following solvent extraction, accounted for 37 percent TRR (0.041 mg eq/kg). Following treatment with protease diazinon, CGA-14128, G-24576, G-27550, GS-31144 and CL-XIX-29 were identified. For liver, 63 percent TRR (0.69 mg eq/kg) was identified.

For kidney, the TRR was 0.15 mg eq/kg. The solvent extractability using methanol: water (9:1,v/v) was 76 percent TRR (0.11 mg eq/kg). The predominant residue (56 percent TRR, 0.083 mg eq/kg) was a mixture of glucuronic conjugates of G-27550, GS-31144, CL-XIX-29 with the individual levels not being reported. The PES accounted for 24 percent TRR and 76 percent TRR (0.11 mg eq/kg) was identified.

In muscle, the TRR was 0.025 mg eq/kg and 64 percent TRR (0.016 mg eq/kg) was extracted with methanol: water (9: 1, v/v). Glucuronic acid conjugates of G-27550, GS-31144, CL-XIX-29 and CL-XIX-29 accounted for 22 percent TRR (0.006 mg eq/kg) in the organosoluble fraction. Glucuronic acid conjugates of G-27550, GS-31144, G-27550, GS-31144 and CL-XIX-29 also accounted for a further 31 percent TRR (0.008 mg eq/kg) in the aqueous soluble fraction. In all cases, the individual levels of the metabolites were not reported. After solvent extraction, 36 percent TRR (0.009 mg eq/kg) remained in the PES. For muscle, 64 percent of the TRR (0.016 mg eq/kg) was identified.

The TRR in skin with fat and peritoneal fat were low at 0.018 mg eq/kg and 0.01 mg eq/kg respectively. The solvent extractability with methanol water (9:1, v/v) was 46 percent TRR (0.008 mg eq/kg) and 31 percent TRR (0.003 mg eq/kg) for skin with fat and peritoneal fat respectively. The PES were ≤ 0.01 mg eq/kg. No metabolites > 10 percent TRR or > 0.01 mg eq/kg were identified.

Treatment of the PES from eggs and tissues with protease released between 21 percent TRR (egg yolk) and 69 percent TRR (Peritoneal fat). Further analysis was only undertaken for the liver samples. It was reported that residues of diazinon, CGA-14128, G-24576, G-27550, GS-31144 and CL-XIX-29 were found, with the individual levels not specified.

Summary and conclusion of metabolism in livestock

The Meeting concluded that, in all species investigated (goats, hens and rats), the total administered radioactivity was predominantly eliminated in excreta. The data indicate that the metabolic profile was qualitatively similar in all three species and proceeds with cleavage of the ester bond of diazinon leading to the loss of the diethyl thiophosphate moiety and the formation of G-27550. Oxidation of the isopropyl moiety of diazinon leads to the formation of CGA-14128 while replacement of sulphur in the diethyl thiophosphate group of diazinon with oxygen leads to the formation of G-24576. Oxidation of the isopropyl moiety of G-27550 leads to the formation of GS-31144. Oxidation of the isopropyl moiety also leads to the formation of CL-XIX-29 (hens and rats only).

For poultry, based on the low levels of radioactivity observed in eggs and tissues, the Meeting decided the extractability and level of identification was sufficient. However, the predominant residues in eggs, liver, kidney and muscle were glucuronic acid conjugates of various aglycones for which the individual levels were not specified. In goat liver the PES was high and the level of identification in both liver and kidney was low (< 52 percent TRR). Owing to these deficiencies a quantitative consideration of the data for the assessment of the residue definitions for livestock was not possible.

The metabolite G-24576 (diazoxon) was identified in all tissues, milk and eggs. The Meeting noted that the storage stability data conducted with fortified samples, evaluated by the 1999 JMPR, demonstrated that G-24576 rapidly degrades in milk and tissues (except fat) within 0–4 months. As samples were stored for up to 5 months in the lactating goat study and up to 12 months in the poultry study the levels reported for this metabolite in the various animal matrices cannot be relied on. The Meeting considered that this metabolite is more toxic than diazinon.

Methods of analysis

The Meeting received information on analytical methods for diazinon in plant and animal matrices.

The Meeting received the description and validation data for the analysis of diazinon in pineapple. Residues were extracted with acetonitrile: water (9:1, v/v) with final determination by LC-MS/MS. The method was successfully validated with an LOQ of 0.01 mg/kg. This method was also successfully validated by an independent laboratory, demonstrating good reproducibility.

The Meeting also received the description and validation data for the analysis of diazinon, G-24576 and CGA-14128 in a range of plant commodities. Residues were extracted with acetone: water (9:1, v/v) followed by extraction with petroleum ether: dichloromethane: water (5:5:1, v/v/v) with final determination by GC-FPD. The Meeting noted that the individual recoveries were not available for each fortification level and for some commodities the mean recoveries were (up to 128 percent. However, the Meeting decided the method was suitable for the determination of diazinon, G-24576 and CGA-14128 in crops of a high water content, crops of a high acid content, crops of a high oil content, crops of a high starch content, crude and refined corn oil. The LOQ validated was 0.01 mg/kg for all three analytes. For hops the method was validated with an LOQ of 0.01 mg/kg for diazinon and CGA-14128. The Meeting decided that the method was not validated for the determination of G-24576 in hops owing to the low mean recovery of 54 percent.

For animal matrices, the Meeting received the description and validation data for the determination of diazinon in muscle, fat, liver, milks and egg. Residues were extracted from animal matrices, except fat, with acetone: water (9:1, v/v) followed by extraction with petroleum ether: dichloromethane: water (5:5:1, v/v/v). For fat, residues were extracted with acetonitrile. Final determination was by GC-FPD or GC-NPD (diazinon only). The Meeting noted that the individual recoveries were not available and the mean

recoveries for some commodities ranged from 68–125 percent. However, the Meeting decided the method was suitable for the determination of diazinon, G-24576 and CGA-14128 in animal commodities (muscle, fat, liver, milk and eggs) with an LOQ of 0.01 mg/kg for the GC-FPD method. Diazinon could also be determined in muscle, fat, liver, milk and eggs with an LOQ of 0.005 mg/kg for the GC-NPD method.

The Meeting was unable to conclude on the acceptability of method REM 4/81, used in the storage stability studies for animal matrices, as no validation data were provided.

The extraction efficiency was not investigated for any of the analytical methods. The meeting noted that the plant and animal metabolism data involved extraction with methanol: water (except milk which used acetonitrile: water) whereas the analytical methods used acetonitrile: water or acetone: water followed by petroleum ether: dichloromethane: water. Based on the high solubility of diazinon in a range of organic solvents the Meeting concluded that the methods are acceptable for the extraction of incurred residues of diazinon in plants and animals.

Stability of pesticide residues in stored analytical samples

The Meeting received freezer storage stability data for diazinon, CGA-14128, G-27550 and G-24576 in various homogenized plant matrices.

Diazinon was stable in pineapple pulp (high acid) and peel at ≤ -18 °C for at least 3 months of storage. Diazinon, CGA-14128 and G-27550 were stable in strawberries (high acid) at ≤ -20 °C for at least 56 days of storage. G-24576 was found to rapidly decline in strawberries, when stored at ≤ -20 °C, with a recovery of < 9 percent at the first time point of 1 month of storage. The strawberry samples, fortified with G-24576 only, were found to contain residues of G-27550, indicating that G-24576 may degrade to G-27550.

The Meeting also received storage stability data for diazinon, G-24576 and CGA-1412 in maize (high starch), tomato (high water), potato (high starch), apple (high water), strawberry (high acid), lettuce (high water) and various processed fractions.

The Meeting concluded that G-24576 was stable in refined corn oil for at least 26 month of storage at ≤ -12 °C. Significant degradation was observed in all other commodities.

For diazinon and CGA-14128 the data showed different rates of decline in the various commodities. The Meeting concluded on the following storage stability intervals, see Table 5.9.2 below.

Table 5.9.2 Storage stability of diazinon and CGA-14128 in different plant matrices

Matrices	Crop	Storage interval demonstrated (months) at ≤ -12 °C	
		Diazinon	CGA-14128
High water	Tomato	26	Up to 6
	Apple	Up to 26	Not stable
	Lettuce	26	26
High acid	Strawberries	2	2
	Pineapples	3	No data
High starch	Maize	26	26
	Potato	26	26
High oil	Soya beans	27	27
Processed commodities	Refined corn oil	27	27
	Tomato paste	16	4
	Sugar beet molasses	16	4

The Meeting agreed that the demonstrated storage stability covered the storage intervals for diazinon in the field trials for apple and pineapple. The Meeting also agreed that the data were sufficient to support the storage interval for the rotational crop field trial samples (lettuce, wheat and turnips).

For animal commodities, the Meeting decided that the data indicated that diazinon is stable in muscle, liver, kidney and fat for at least 8 months of freezer storage. However, the Meeting was unable to conclude on the acceptability of the data as no validation data were provided for the analytical method used to quantify residues.

The Meeting noted that the 1999 JMPR evaluated storage stability data for diazinon, CGA-14128 and G-24576 for milk and tissues in an interim study. This study was not provided to the current Meeting. Diazinon and CGA-14128 were stable in milk and tissues for 9 months of storage when stored at ≤ -18 °C. G-24576 was stable in fat for 9 months of storage at ≤ -18 °C. However, in milk and muscle degradation of G-24576 was observed at the first time point of 4 months. For liver, G-24576 was found to have degraded in the time zero sample.

The Meeting concluded that the demonstrated storage stability for diazinon and CGA-14128 in animal commodities covered the storage interval in the feeding studies. The data do not support the storage interval in the feeding studies for G-24576.

Definition of the residue

Plant commodities

The nature of the diazinon residue was investigated in apple, bean with pods, sweet corn, lettuce and potatoes following one pre-emergence or soil directed application and two foliar applications. In the metabolism studies, the storage intervals between harvest and extraction were not supported, the individual levels of the metabolites were not always quantified in the extracted residues, the level of identification was low and the residue remaining in the PES was high and therefore the data is of limited value for a comparison of the metabolism for the assessment of the residue definition for risk assessment for plants.

The Meeting noted that diazinon was identified in various crop fractions in the metabolism studies and was found at levels above 0.01 mg/kg in the residue trials provided to the Meeting for apples, pears, pineapples and cabbage. The Meeting considered that diazinon was a suitable marker for the enforcement of MRLs. Suitable analytical methods are available to analyse diazinon in plants.

The nature of the residue on processing has not been investigated. The environmental hydrolysis studies included information on the effects of pH and temperature and indicate that diazinon is susceptible to hydrolysis and this is likely to be more prominent at higher temperatures. The potential for degradation products to be formed in processed commodities, particularly G-27550 cannot be excluded. Therefore, the Meeting could not confirm if diazinon would be a suitable marker for the enforcement of MRLs for processed commodities.

As a result of concerns relating to the lack of suitable quantitative information on the individual levels of metabolites in plants, a conclusion was unable to be reached on a residue definition for dietary risk assessment.

Animal commodities

The nature of the diazinon residue was investigated in lactating goats and laying hens following oral administration of the test substance. Owing to the low level of identification in some tissues, the lack of

suitable quantitative information on the individual levels of metabolites and the storage stability, the Meeting decided not to use the animal metabolism studies to establish residue definitions for livestock.

The Meeting recommended the following residue definitions for diazinon:

Definition of the residue for compliance with MRLs for plants: *Diazinon*

As for risk assessment, the Meeting was unable to reach a conclusion on a residue definition for plant commodities.

The Meeting was unable to conclude on the residue definition for compliance with MRLs and for risk assessment for animal commodities.

Results of supervised residue trials on crops

Supervised trials were available for apple, pears, pineapple, cabbage and wheat.

As a conclusion could not be reached on the residue definition for risk assessment, the Meeting withdrew all previous recommendations for maximum residue levels for diazinon, including the spice MRLs.

Pome fruits

The critical GAP for apples, pears and quince is for Chile which is 3 applications of 0.07 kg ai/hL applied at 15 day intervals with a PHI of 21 days.

Apple

A total of three independent trials conducted in the United States at 0.053 kg ai/hl–0.087 kg ai/hl, with a RTI of 14-15 days and a PHI of 21 days matched the GAP. Where replicate trials at different application rates were conducted at the trial site and both application regimes matched the GAP, the trial giving the highest residue was selected.

Residues of diazinon in independent trials approximating the critical GAP were (n= 3): 0.02, 0.04 (2) mg/kg.

Pears

A total of two independent trials conducted in the United States at 0.078 kg ai/hl, with a RTI of 14-15 days and a PHI of 21 days matched the GAP.

The Meeting agreed to apply the proportionality principle to two trials conducted at 0.18 kg ai/hl, noting that as residues were < 0.01 mg/kg a scaling factor was not required.

Residues of diazinon in independent trials approximating the critical GAP were (n= 4): < 0.01 (3) and 0.06 mg/kg.

As the median residues of diazinon for apples and pears are within a 5-fold range, the Meeting decided to make a recommendation for apples, pears and quince on the basis of the combined data sets for apples and pears.

Residues of diazinon on the basis of the combined data set were (n= 7): < 0.01 (3), 0.02, 0.04 (2) and 0.06 mg/kg

The Meeting estimated a maximum residue level of 0.15 mg/kg for apples, pears and quince.

*Assorted tropical and sub-tropical fruits–inedible peel**Pineapples*

The critical GAP is for the United States which is 2 applications of 1.12 kg ai/ha with retreatment intervals of 28 days and a PHI of 7 days.

As no trials matched the GAP the Meeting did not estimate a maximum residue level.

Cabbage, Head

The critical GAP is for Costa Rica which is 3 applications of 0.75 kg ai/ha with a retreatment interval of 8 days and a PHI of 10 days.

As no trials matched the GAP the Meeting did not estimate a maximum residue level.

Wheat

The critical GAP is for the Russian Federation which is 1 application of 1.08 kg ai/ha and a PHI of 60 days.

As no trials matched the GAP the Meeting did not estimate a maximum residue level.

Residues in animal feeds*Wheat straw*

The critical GAP is for the Russian Federation which is 1 application of 1.08 kg ai/ha and a PHI of 60 days.

As no trials matched the GAP the Meeting did not estimate residue levels for use in the estimation of livestock dietary burdens.

Fate of residues during processing*High temperature hydrolysis*

No information on the nature of the residue on processing was received by the Meeting. Based on the environmental hydrolysis study, that included the effects of temperature and pH, the Meeting concluded that diazinon is likely to be susceptible to hydrolysis and this is likely to be more prominent at higher temperatures. The formation of hydrolysis products such as G-27550 could not be excluded in processed foods.

Processing

The Meeting received information on the processing of apples and pears. Residues of diazinon, G-24576 and CGA-14128 were determined in the RAC and processed fractions. No details on the processing conditions employed were available.

Residues of G-24576 and CGA-14128 were all < 0.01 mg/kg. Residues of diazinon were also < 0.01 mg/kg in the RAC for pears. The Meeting decided that the storage interval of 9 months was supported for diazinon and CGA-14128. However, G-24576 would not be stable over the storage interval. No information about the level of the metabolite G-27550 was available.

The Meeting did not estimate processing factors, STMR-P and HR-P as a conclusion could not be reached on the residue definitions for processed commodities.

Residues in animal commodities**Farm animal feeding studies**

Farm animal feeding studies in lactating cattle and laying hens were provided to the Meeting.

Lactating cattle

Groups of three lactating cows were fed diazinon in the diet once daily at a dose rate of 41, 124 and 414 ppm for 28–30 consecutive days. One animal served as a control.

Milk samples were taken twice daily and combined for each individual animal. Residues of CGA 14128 and G-24576 were < 0.01 mg/kg in all milk samples. At a feeding rate of 124 ppm, diazinon in milk was ≤ 0.01 mg/kg. At a feeding rate of 414 ppm, the highest residue of diazinon was 0.08 mg/kg at 7 days. A plateau was reached in milk after 3 days and the mean residue over the plateau period was 0.03 mg/kg.

Tissue samples were collected at sacrifice which occurred within 24 hours of the last dose. The metabolite G-24576 was not found in any tissue samples. However, the storage stability data demonstrated that G-24576 would be unstable in all tissue samples, apart from fat, and therefore no conclusions can be drawn from the levels reported. The storage data evaluated by the 1999 JMPR indicated that diazinon and GCA 14128 would be stable over the 5 months of storage, but this study was not available to the current Meeting. The mean and highest residues in tissue samples are summarized below.

Table 5.9.3 Mean and highest residues of diazinon and GCA 14128 found in animal tissues

Tissue	Residue level at day 28, day 29 and day 30 (mg/kg)								
	41 ppm			121 ppm			414 ppm		
	Diazinon	G-24576	CGA-14128	Diazinon	G-24576	CGA-14128	Diazinon	G-24576†	CGA-14128
Liver									
HR	< 0.01	< 0.01	< 0.01	0.02	< 0.01	< 0.01	0.06	< 0.01	< 0.01
Mean	< 0.01	< 0.01	< 0.01	0.01	< 0.01	< 0.01	0.03	< 0.01	< 0.01
Kidney									
HR	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01	0.01	< 0.01	< 0.01
Mean	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01	0.01	< 0.01	< 0.01
Fat									
HR	0.04	< 0.01	< 0.01	0.10	< 0.01	< 0.01	0.84	< 0.01	0.06
Mean	0.03	< 0.01	< 0.01	0.08	< 0.01	< 0.01	0.56	< 0.01	0.05
Muscle									
HR	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01	0.02	< 0.01	< 0.01
Mean	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01	0.01	< 0.01	< 0.01

Notes:

† G-24576 was found to be unstable in all animal commodities except fat.

Laying hens

Three groups of 15 hens were fed diazinon in the diet once daily at a dose rate of 0.5, 1.5 and 5 ppm for 28 consecutive days. A further 15 hens served as control animals.

Egg samples were taken daily. Tissue samples were taken at sacrifice which occurred 19–23 hours after the last dose.

Residues of diazinon, G-24576 and GCA 14128 were < 0.01 mg/kg in all samples. However, the Meeting noted that G-24576 would not be stable in the samples over the storage interval prior to analysis.

Farm animal dietary burden

As the Meeting was unable to estimate STMRs and HRs for plants, the dietary burdens of livestock could not be estimated.

Animal commodity maximum residue levels

As the dietary burdens of livestock could not be estimated, the Meeting was unable to estimate maximum residue levels for animal commodities.

RECOMMENDATIONS

The residue definition for compliance with the MRL for plant is: *diazinon*.

The Meeting was unable to conclude on a residue definition for risk assessment for plants.

The Meeting was unable to conclude on a residue definition for compliance with MRLs and for risk assessment for animal commodities.

DIETARY RISK ASSESSMENT

As the Meeting was unable to recommend residue definitions for risk assessment for plants and animal commodities, long-term and acute dietary exposure assessments could not be conducted.

5.10 Difenoconazole (224)

RESIDUE AND ANALYTICAL ASPECTS

Difenoconazole was evaluated for the first time by the JMPR 2007 when an acceptable daily intake (ADI) of 0–0.01 mg/kg bw and an acute reference dose (ARfD) of 0.3 mg/kg bw were established. In 2007, 2010, 2013, 2015, and 2017 the JMPR evaluated the compound for residues and recommended a number of maximum residue levels.

The definition of the residue for compliance with MRL and for dietary risk assessment for plant commodities is parent *difenoconazole*, while for animal commodities it is defined as *sum of difenoconazole and 1-[2-chloro-4-(4-chloro-phenoxy)-phenyl]-2-(1,2,4-triazol)-1-yl-ethanol (CGA205375), expressed as difenoconazole*. The residue is fat-soluble.

Difenoconazole was scheduled at the Fifty-second Session of the CCPR for the evaluation of additional MRLs in 2022 JMPR. The current Meeting received additional analytical methods, storage stability data, GAP information and residue trial data from uses on goji berries, pencil yams, ginger, and tea as well as their processed commodities.

Methods of analysis

The Meeting received additional information on analytical methods for difenoconazole in goji berry, pencil yam, ginger, and tea commodities.

For all provided analytical methods, residues of difenoconazole were extracted with acetonitrile/water (1/1, v/v), cleaned up by SPE, and analysed by HPLC-MS/MS.

Recoveries and percent RSDs were within the acceptable range. The LOQ was 0.01 mg/kg for all commodities tested.

The Meeting concluded that the presented methods were sufficiently validated and are suitable to measure difenoconazole in plant commodities.

Stability of pesticides residues in stored analytical samples

The current Meeting received additional information on freezer storage stability of difenoconazole in goji berry, dried goji berry, pencil yam, dried pencil yam, ginger, dried ginger, fresh tea leaves, green tea, and black tea.

Residues of difenoconazole were stable for at least 12 months in fresh and dried goji berry, 14 months in fresh and dried pencil yam, 12 months in fresh ginger, hot-dried ginger, and freeze-dried ginger, and 12 months in fresh tea leaves, green tea, and black tea when stored frozen at ≤ -18 °C.

The Meeting concluded that the storage stability data were sufficiently validated and are adequate to support the storage durations in the studies provided to the current Meeting.

Results of supervised residue trials on crops

Goji berry

The use of difenoconazole on goji berry is registered in the People's Republic of China for foliar spray applications. The Meeting determined that the Critical GAP consists of three treatments with a re-treatment interval (RTI) of 7 days at a target application concentration of 0.010 kg ai/hL with a PHI of 5 days.

In independent trials matching the cGAP, residues of difenoconazole in goji berries were (n=4): 0.24, 0.59, 0.70, and 2.2 mg/kg.

The Meeting estimated a maximum residue level of 5 mg/kg, an STMR of 0.65 mg/kg, and an HR of 2.4 mg/kg (from a single sample) for difenoconazole in goji berry.

Meeting withdrew its previous recommendation of 0.6 mg/kg for difenoconazole in fruiting vegetables other than cucurbits except dried chili pepper and recommended a new maximum residue level of 0.6 mg/kg in Fruiting vegetables, other than Cucurbits except dried chili pepper and goji berry.

Pencil Yam

The use of difenoconazole on pencil yam is registered in China for foliar spray applications. The Meeting determined that the Critical GAP consists of three treatments (RTI=7 days) at a target application rate of 0.080 kg ai/ha with a PHI of 60 days.

In independent trials matching the cGAP, residues of difenoconazole in pencil yams were (n=4): < 0.01 (3) and 0.010 mg/kg.

The Meeting estimated a maximum residue level of 0.02 mg/kg, an STMR of 0.010 mg/kg, and an HR of 0.010 mg/kg for difenoconazole in pencil yam.

Ginger

The use of difenoconazole on ginger is registered in China for foliar spray applications. The Meeting determined that the Critical GAP consists of three treatments (RTI=7 days) at a target application rate of 0.11 kg ai/ha with a PHI of 14 days.

In independent trials matching the cGAP, residues of difenoconazole in ginger were (n=8): < 0.01 (4), 0.033, 0.038, 0.062, and 0.10 mg/kg.

The Meeting estimated a maximum residue level of 0.2 mg/kg, an STMR of 0.022 mg/kg, and an HR of 0.10 mg/kg for difenoconazole in fresh ginger.

Tea

The Meeting received a GAP for tea from China consisting of three treatments (RTI=7 days) at a target application concentration of 0.010 kg ai/hL with a PHI of 14 days.

In independent trials matching the GAP, residues of difenoconazole in green tea (dry) were (n=8): 0.019, 0.060, 0.20, 0.35, 0.62, 0.77, 2.4, and 4.2 mg/kg.

Residues in black tea (fermented and dry) derived from the green tea (dry) samples were (n=8): 0.023, 0.061, 0.22, 0.26, 0.32, 0.39, 1.7, and 4.5 mg/kg.

The 2021 Extra Meeting recommended a maximum residue level of 20 mg/kg and an STMR of 4.85 mg/kg for residues of difenoconazole in tea, green, black (black fermented and dried). The current Meeting confirmed its previous recommendation, which accommodates the residues listed above.

Fate of residues during processing

The Meeting received new information on the fate of difenoconazole residues during processing in goji berry, pencil yam, and ginger.

Table 5.10.1 Estimated processing factors for the commodities considered at this Meeting

RAC	Processed Commodity	Processing Factor	Median Processing Factor	STMR RAC (mg/kg)	HR RAC (mg/kg)	STMR-P (mg/kg)	HR-P (mg/kg)
Goji berry	Dried goji berry	1.3, 1.5, 1.6, 1.7, 1.8, 1.9, 2.0, 2.5(2), 2.6, 3.1, 4.2, 5.0, 11, 26, 28	2.5	0.65	2.4	1.6	5.5
Pencil Yam	Dried Pencil Yam	2.3, 3.4	2.9	0.010	0.010	0.029	0.029
Ginger	Hot Dried ^a	3.2, 3.4, 4.6, 5.1(2), 5.7, 6.7, 7.0, 7.5, 7.6, 7.8, 8.0	6.0	0.022	-	0.13	-

Notes:

^a Hot dried ginger processing factors are higher than freeze dried ginger processing factors. Dried ginger was ground to a powder prior to analysis.

Using the estimated maximum residue level of 5 mg/kg for goji berry and applying the processing factor of 2.5, the Meeting estimated a maximum residue level of 15 mg/kg for difenoconazole in goji berry, dried.

Using the estimated maximum residue level of 0.02 mg/kg for pencil yam and applying the processing factor of 2.9, the Meeting estimated a maximum residue level of 0.07 mg/kg for difenoconazole in pencil yam, dried.

Using the estimated maximum residue level of 0.2 mg/kg for ginger and applying the processing factor of 6.0, the Meeting estimated a maximum residue level of 1.5 mg/kg for difenoconazole in ginger, dried.

Residues in animal commodities*Estimated maximum and mean dietary burdens of livestock and animal commodities maximum residue levels*

No animal feeds are associated with the uses considered by the current Meeting. The Meeting confirmed its previous recommendations.

RECOMMENDATIONS

On the basis of the data from supervised trials, the Meeting concluded that the residue levels listed in Annex 1 are suitable for establishing maximum residue limits and for IEDI and international estimate of short-term intake assessment.

Definition of the residue for compliance with the MRL and for dietary risk assessment for plant commodities: *difenoconazole*.

Definition of the residue for compliance with the MRL and for dietary risk assessment for animal commodities: *sum of difenoconazole and 1-[2-chloro-4-(4-chloro-phenoxy)-phenyl]-2-(1,2,4-triazol)-1-yl-ethanol*, expressed as *difenoconazole*.

The residue is fat-soluble.

DIETARY RISK ASSESSMENT***Long-term dietary exposure***

The ADI for difenoconazole is 0–0.01 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for difenoconazole were estimated for the 17 GEMS/Food Consumption Cluster Diets using the STMR or STMR-P values estimated by the previous and present JMPR. The results are shown in Annex 3 of the 2022 JMPR Report. The IEDIs ranged 10–80 percent of the maximum ADI.

The Meeting concluded that the long-term dietary exposure to residues of difenoconazole from uses considered by the JMPR is unlikely to present a public health concern.

Acute dietary exposure

The 2007 JMPR established an ARfD of 0.3 mg/kg bw. The International Estimate of Short-Term Intakes (international estimate of short-term Intake) for difenoconazole were calculated for the food commodities for which STMRs or HRs were estimated by the present Meeting and for which consumption data were available. The results are shown in Annex 4 of the 2022 JMPR Report. The international estimate of short-term intake varied from 0–3 percent of the ARfD for children and 0 percent for the general population.

The Meeting concluded that the acute dietary exposure to residues of difenoconazole from other uses that have been considered by the present Meeting is unlikely to present a public health concern.

5.11 Dimethoate (027)/Omethoate (055) (addendum)

TOXICOLOGY

Dimethoate is the ISO-approved common name for *O,O*-dimethyl-S-((methylcarbamoyl)methyl) phosphorodithioate-2-dimethoxyphosphinothiylsulfanyl-*N*-methylacetamide (IUPAC), with the Chemical Abstract Service number 60-51-5. Dimethoate is an organophosphate insecticide, having contact and systemic action, against a broad range of insects in agriculture and also used for the control of the housefly. It acts by inhibiting acetylcholinesterase (AChE).

The Joint FAO/WHO Meeting on Pesticide Residues (JMPR) evaluated dimethoate for toxicological effects in 1963, 1965, 1967, 1984, 1987, 1996, 2003 and 2019. The 2019 Meeting established an acceptable daily intake (ADI) of 0–0.001 mg/kg body weight (bw) and an acute reference dose (ARfD) of 0.02 mg/kg bw. Omethoate (also known as dimethoxon), the oxygen analogue metabolite of dimethoate, appears to be the substance active against insects and mammals.

While considering the metabolites of dimethoate the Meeting noted the conclusion of the 1996 JMPR:

“Omethoate has been extensively investigated for mutagenicity in vitro and in vivo. The Meeting concluded that it has clear mutagenic potential but that the weight of the evidence observed in vivo was negative; however, the positive result obtained in the mouse spot test could not be completely disregarded.”

At JMPR 1996 the ADI for omethoate was withdrawn. Although a number of new studies focused on the inhibition of AChE by omethoate, no new genotoxicity studies were provided to the 2019 Meeting. Hence, the 2019 Meeting was unable to complete the assessment of omethoate with respect to its mutagenic potential, and consequently, the assessment of dimethoate. The present Meeting continued the evaluation of omethoate on the basis of data provided in 2019, new data on the genotoxicity of omethoate and new data on other metabolites of dimethoate.

Biochemical aspects of omethoate

In the rat, omethoate was rapidly and more than 98 percent absorbed and rapidly excreted largely unchanged (85–96 percent) via the urine. The pattern of excretion and metabolism was similar for oral and intravenous dosing. Retention within organs and tissues after 48 hours was very low.

The main metabolic pathway of omethoate in the rat consisted of hydrolysis of the thiophosphoric acid structure to yield the desmethylated metabolite, or the sulfur-containing side chain, which is then *S*-methylated, followed by sulfoxidation to form the sulfinyl metabolite. The main radioactive compound in urine was the parent omethoate, and the major metabolites were *N*-methyl-2-(methylsulfonyl)-acetamide and *O*-desmethyl-omethoate.

Toxicological data for omethoate

The median lethal dose (LD₅₀) in rats was 22–28 mg/kg bw via the oral route, via the dermal route 145–232 mg/kg bw, and the median lethal concentration (LC₅₀) was 0.287 mg/L air by inhalation.

In both short- and long-term studies the main toxic effect in all tested species was the inhibition of AChE and consequent clinical signs. Clinical signs generally occurred at doses higher than those causing critical (greater than 20 percent) inhibition of erythrocyte and/or brain AChE.

In four short-term studies in rats, the overall NOAEL was 0.08 mg/kg bw per day based on inhibition of erythrocyte AChE, with an overall LOAEL of 0.16 mg/kg bw per day. There were two 28-day

studies, the first employing dietary concentrations of 0, 0.2, 0.4, 0.8, 1.6 or 8 ppm (equivalent to 0, 0.02, 0.04, 0.08, 0.16 and 0.8 mg/kg bw per day), the second, range-finding, study using dietary concentrations of 0, 2.5 or 15 ppm (equal to 0, 0.23 and 1.24 mg/kg bw per day for males, 0, 0.26 and 1.40 mg/kg bw per day for females). A 90-day dietary toxicity study employed concentrations of 0, 0.5, 1, 2 or 4 ppm (equal to 0, 0.04, 0.08, 0.17 and 0.34 mg/kg bw per day for males, 0, 0.05, 0.10, 0.19 and 0.36 mg/kg bw per day for females). In addition, a 32-week drinking water toxicity study administering concentrations of 0, 0.1 or 0.3 ppm (equal to 0, 0.0093 or 0.0271 mg/kg bw per day for males, and 0, 0.0109 or 0.0322 mg/kg bw per day for females) was taken into account by the Meeting.

In two 90-day studies, dogs were administered omethoate in the diet at 0, 0.4, 0.8 or 1.6 ppm (equal to 0, 0.016, 0.032 and 0.063 mg/kg bw per day for males, 0, 0.17, 0.034 and 0.069 mg/kg bw per day for females), or 0 or 0.0125 mg/kg bw per day by gavage. A one-year gavage study of omethoate in dogs employed doses of 0, 0.025, 0.125 or 0.625 mg/kg bw per day. From these the Meeting identified an overall NOAEL for oral toxicity of 0.063 mg/kg bw per day based on inhibition of erythrocyte and brain AChE, with an overall LOAEL of 0.125 mg/kg bw per day.

In a 24-month chronic toxicity/carcinogenicity study in mice treated with omethoate in drinking water at concentrations of 0, 0.5, 4 or 32 ppm (equal to 0, 0.10, 0.82 and 6.48 mg/kg bw per day for males, 0, 0.11, 0.80 and 6.61 mg/kg bw per day for females), the NOAEL for toxicity could not be identified due to an inhibition of erythrocyte AChE activity slightly above the threshold value of 20 percent at the lowest dose tested. The NOAEL for carcinogenicity in mice was 32 ppm (equal to 6.48 mg/kg bw per day), the highest dose tested.

In a 24-month combined chronic toxicity/carcinogenicity study in rats, omethoate was administered through drinking water at concentrations of 0, 0.5, 4 or 32 ppm (equal to 0, 0.04, 0.30 and 2.92 mg/kg bw for males, 0, 0.05, 0.44 and 3.93 mg/kg bw per day for females). The NOAEL for toxicity was 0.5 ppm (equal to 0.04 mg/kg bw per day) based on inhibition of AChE activities at the LOAEL of 4 ppm (equal to 0.30 mg/kg bw per day). The NOAEL for carcinogenicity was 32 ppm (equal to 2.92 mg/kg bw per day), the highest dose tested.

The Meeting concluded that omethoate is not carcinogenic in mice or rats.

Omethoate was tested for genotoxicity in an adequate range of *in vitro* and *in vivo* assays. It gave a positive/equivocal response in a number of *in vitro* tests, including a bacterial reverse mutation assay, sister chromatid exchange (SCE), forward mutation assay in mammalian cells (HPRT test) and unscheduled DNA synthesis in mammalian cells. Positive responses were only obtained at either high or severely cytotoxic concentrations and with no clear dose-dependency. Omethoate gave negative responses *in vivo* in the micronucleus, SCE and unscheduled DNA synthesis tests.

In studies previously evaluated by the Meeting, positive findings in a somatic cell assay *in vivo* were noted for the mouse spot test, indicating a potential for omethoate to induce point mutations *in vivo*. However, the Meeting noted that the doses used were well above those causing AChE inhibition.

A combination of two newly provided, more recent *in vivo* studies (comet and combined comet/micronucleus assay) showed that neither strand breaks nor chromosomal damage occurred at noncytotoxic doses of omethoate.

The Meeting concluded that omethoate is unlikely to be genotoxic *in vivo*.

In view of the lack of genotoxicity *in vivo* and the absence of carcinogenicity in mice and rats, the Meeting concluded that omethoate is unlikely to pose a carcinogenic risk to humans at levels occurring in the diet.

In a two-generation reproduction study in rats, omethoate was administered via drinking water at doses of 0, 0.5, 3.0 or 18 ppm (equal to 0, 0.08, 0.57 and 3.16 mg/kg bw per day for males, 0, 0.12, 0.72 and 4.35 mg/kg bw per day for females). The NOAEL for parental toxicity was 0.5 ppm (equal to 0.08 mg/kg bw per day) based on inhibition of AChE activity at 3 ppm (equal to 0.57 mg/kg bw per day). The NOAEL for reproductive toxicity was 3 ppm (equal to 0.57 mg/kg bw per day) based on reduced fertility and impairment of reproductive performance in the parental generation females at 18 ppm (equal to 3.16 mg/kg bw per day). The NOAEL for offspring toxicity was 3 ppm (equal to 0.57 mg/kg bw per day) based on depressed body weights, retarded body weight gains, and inhibition of brain AChE in pups at 18 ppm (equal to 3.16 mg/kg bw per day).

In a developmental study employing doses of 0, 0.3, 1.0 or 3.0 mg/kg bw per day of omethoate administered by gavage to pregnant rats from GDs 6 to 15, the NOAEL for both maternal and developmental toxicity was 1.0 mg/kg bw per day based on tremors, depressed food consumption, reduction in body weight gain and mortality in dams, depression in placental weights and a reduction in the mean fetal weight in the highest dose group of 3.0 mg/kg bw per day.

In a developmental toxicity study in rabbits, omethoate was administered by gavage at doses of 0, 0.2, 1.0 or 5.0 mg/kg bw per day. The NOAEL for both maternal and developmental toxicity was 0.2 mg/kg bw per day based on inhibition of erythrocyte and brain AChE and increased malformations (arthrogryposis, epignathus, which were probably secondary to AChE inhibition) at 1 mg/kg bw per day.

In another developmental toxicity study in rabbits, omethoate was administered at doses of 0, 0.20, 1.0 or 4.0 mg/kg bw per day. The maternal NOAEL was 0.20 mg/kg bw per day based on reduction in red blood cell (RBC) AChE activity at 1.0 mg/kg bw per day. The developmental NOAEL was 1.0 mg/kg bw per day based on reductions in gravid uterine weights, fetal body weights and delayed skeletal ossification occurring at 4.0 mg/kg bw per day.

The Meeting concluded that omethoate is not teratogenic at doses that do not substantially inhibit cholinesterase.

In an acute neurotoxicity study in the rat, with administration of omethoate by gavage at dose levels of 0, 0.2, 0.25, 0.35 or 5 mg/kg bw the NOAEL was 0.25 mg/kg bw, based on changes in respiration, impairment of co-ordination, effects on pupil reflex and inhibition of brain AChE activity at 0.35 mg/kg bw.

In a delayed polyneuropathy study in hens gavaged with a single dose of 140 mg/kg bw of omethoate there was no behavioural or histopathological evidence of delayed neurotoxicity. There was no measurement of cholinesterase activity or neuropathy target esterase (NTE) inhibition as would be expected in a more recent study. However, enzyme studies with human and hen autopsy tissue suggested that omethoate does not cause delayed neuropathy in humans. No inhibition of NTE was found in humans or hens at four times the LD₅₀.

The Meeting concluded that omethoate is neurotoxic but does not cause delayed polyneuropathy.

A comparative cholinesterase assay in neonatal pups and adult rats after acute oral dosing with omethoate at 0.1, 0.3, 0.6 or 0.9 mg/kg bw did not show significant differences in AChE inhibition due to age or sex. A point of departure (POD) was determined at 0.2 mg/kg bw (BMD₂₀, rounded to one significant figure) for inhibition of erythrocyte AChE in pups, as the erythrocyte enzyme was slightly more sensitive than the brain enzyme.

Toxicological data on metabolites other than omethoate

Apart from omethoate, a number of plant metabolites and animal metabolites have been identified, including:

- O-desmethyl-N-desmethyl omethoate (Met XXIII)
- O-desmethyl-isodimethoate (Met XII)
- Desmethyldimethoate (Met X)
- O-desmethyl-omethoate (Met XI)
- O-desmethyl-omethoate carboxylic acid (Met XX)
- O,O-dimethyl phosphonic acid (Met XVII), and
- dimethoate carboxylic acid (Met III).

Newly provided ChE studies and reproduction screening studies were conducted on dimethoate plant metabolites Met III, Met X, Met XI, Met XII, Met XX and Met XXIII. These studies showed that the metabolites possessed a very low potency for AChE inhibition.

New genotoxicity studies were provided for in vitro gene mutation in bacterial and mammalian cells and micronucleus induction in human lymphocytes: with the exception of Met III all studies were negative. With Met III positive results were seen for in vitro mammalian cell gene mutation and micronucleus tests, but results were negative in appropriate follow-up in vivo studies.

The Meeting concluded that these metabolites were of no toxicological relevance compared to dimethoate.

QSAR analysis for *O,O*-dimethyl phosphonic acid (XVII) did not give any genotoxicity alert. Hence TTC Cramer class III (0.0015 mg/kg bw per day) should be applied to this metabolite as it does not contain a structure consistent with an AChE inhibitor.

O-desmethyl-isodimethoate and O-desmethyl-omethoate carboxylic acid

Metabolites *O*-desmethyl-*iso*-dimethoate and *O*-desmethyl-omethoate carboxylic acid are weaker AChE inhibitors than dimethoate and can be considered covered by the ADI and ARfD for dimethoate.

Microbiological data

There was not sufficient information available in the public domain and no experimental data were provided to enable assessment of the possible impact of dimethoate residues on the human intestinal microbiome.

Human data

There was no information on the effect of omethoate on humans.

The Meeting concluded that the existing database on omethoate was adequate to characterize the potential hazards to the general population, including fetuses, infants and children.

Toxicological evaluation

The Meeting established an ADI of 0–0.0004 mg/kg bw for omethoate, separate to that for dimethoate, on the basis of a NOAEL of 0.04 mg/kg bw per day for inhibition of AChE activities in a two-year dietary toxicity/carcinogenicity study in rat. A safety factor of 100 was applied. This value is considered sufficiently protective for the slight AChE inhibition observed in red blood cells in the two-year dietary study in mice at 0.5 ppm (equal to 0.1 mg/kg bw per day).

The Meeting established an ARfD for omethoate of 0.002 mg/kg bw, separate to that for dimethoate, on the basis of the BMD₂₀ of 0.2 mg/kg bw from an acute comparative cholinesterase assay for red blood cell and brain AChE inhibition in adult rats and pups. A safety factor of 100 was applied.

The ADI and ARfD for omethoate are 2.5-fold and 10-fold respectively lower than those established for dimethoate.

A toxicological monograph addendum was prepared.

Levels of relevant to risk assessment for omethoate

Species	Study	Effect	NOAEL	LOAEL
Mouse	Two-year study on toxicity and carcinogenicity ^f	Toxicity	-	0.5 ppm equal to 0.10 mg/kg bw/day ^e
		Carcinogenicity	32 ppm equal to 6.48 mg/kg bw/day ^c	-
Rat	Two 28-day, one 90-day dietary and one 32-week drinking water studies of toxicity ^{a,b}	Toxicity	0.08 mg/kg bw/day	0.16 mg/kg bw/day
	Two-year study on toxicity and carcinogenicity ^f	Toxicity	0.5 ppm equal to 0.04 mg/kg bw/day ^e	4 ppm equal to 0.30 mg/kg bw/day
		Carcinogenicity	32 ppm equal to 2.92 mg/kg bw/day ^c	-
	Two-generation study of reproductive toxicity ^f	Reproductive toxicity	3 ppm equal to 0.57 mg/kg bw/day	18 ppm equal to 3.16 mg/kg bw/day
		Parental toxicity	0.5 ppm equal to 0.08 mg/kg bw/day	3 ppm equal to 0.57 mg/kg bw/day
		Offspring toxicity	3 ppm equal to 0.57 mg/kg bw/day	18 ppm equal to 3.16 mg/kg bw/day
	Developmental Toxicity study ^d	Maternal toxicity	1 mg/kg bw/day	3 mg/kg bw/day
		Embryo/fetal toxicity	1 mg/kg bw/day	3 mg/kg/day
	Acute neurotoxicity study		0.25 mg/kg bw	0.35 mg/kg bw
Acute comparative cholinesterase assay		ChE inhibition, pups and adults	0.2 mg/kg bw (POD from BMD analysis) ^g	-
Rabbit	Developmental toxicity study ^{d,b}	Maternal toxicity	0.2 mg/kg bw per day	1 mg/kg bw per day
		Embryo/fetal toxicity	0.2 mg/kg bw/day	1 mg/kg bw/day
Dog	90-day gavage, 90-day dietary and one-year gavage study ^{a,d,b}	Toxicity	0.063 mg/kg bw/day	0.125 mg/kg bw/day

Notes:

^a Dietary administration.

^b Two or more studies combined.

^c Highest dose tested.

^d Gavage administration.

^e Lowest dose tested.

^f Administration through drinking water.

^g Methodology described in the monograph.

Acceptable daily intake (ADI) applies to omethoate

0–0.0004 mg/kg bw

Acute reference dose (ARfD) applies to omethoate

0.002 mg/kg bw

Information that would be useful for the continued evaluation of the compound

Results from further epidemiological, occupational health and other such observational studies of human exposure.

Critical end-points for setting guidance values for exposure for omethoate

Absorption, distribution, excretion and metabolism in mammals

Rate and extent of oral absorption	Rapidly and completely absorbed (≥98 percent)
Dermal absorption	No data
Distribution	Widely distributed
Potential for accumulation	None
Rate and extent of excretion	Excretion is rapid; >80 percent of the dose excreted in urine within 24 hours
Metabolism in animals	Limited
Toxicologically significant compounds in animals and plants	Omethoate

Acute toxicity

Rat, LD ₅₀ , oral	22–28 mg/kg bw
Rat, LD ₅₀ , dermal	145–232 mg/kg bw
Rat, LC ₅₀ , inhalation	0.287 mg/L

Short-term studies of toxicity

Target/critical effect	Inhibition of Acetyl Cholinesterase
Lowest relevant oral NOAEL	0.063 mg/kg bw per day (dog)
Lowest relevant dermal NOAEL	2.5 mg/kg bw per day (rabbit)

Long-term studies of toxicity and carcinogenicity

Target/critical effect	Inhibition of RBC AChE and brain AChE (rat, mouse)
Lowest relevant NOAEL	0.04 mg/kg bw per day (rat)
Carcinogenicity	Not carcinogenic in mice or rats

Genotoxicity

Unlikely to be genotoxic in vivo

Reproductive toxicity

Target/critical effect	Reduced fertility and impairment of reproductive performances
Lowest relevant parental NOAEL	0.08 mg/kg bw per day (rat)
Lowest relevant offspring NOAEL	0.57 mg/kg bw per day (rat)

Lowest relevant reproductive NOAEL	0.57 mg/kg bw per day (rat)
Developmental toxicity	
Target/critical effect	Increase in malformations (arthrogryposis, epignathus), probably secondary to AChE inhibition (rabbit)
Lowest relevant maternal NOAEL	0.2 mg/kg bw per day (rabbit)
Lowest relevant embryo/fetal NOAEL	0.2 mg/kg bw per day (rabbit)
Neurotoxicity	
Acute neurotoxicity NOAEL	0.25 mg/kg bw (rat)
Acute comparative cholinesterase assay, BMD ₂₀	0.2 mg/kg bw (rat)

Summary

	Value	Study	Safety factor
ADI	0–0.0004 mg/kg bw	Two-year chronic toxicity and carcinogenicity studies (rat)	100
ARfD	0.002 mg/kg bw	Acute comparative cholinesterase assay (rat)	100

RESIDUE AND ANALYTICAL ASPECTS

Dimethoate is an organophosphate insecticide which acts through acetylcholinesterase inhibition. It has been evaluated on numerous occasions by the JMPR since 1963, with the last periodic review conducted in 1996 (toxicology) and 1998 (residues), a subsequent evaluation for toxicology and residues in 2003 to establish an acute reference dose and further evaluations for additional uses in 2006 and 2008.

Dimethoate was scheduled by the Fiftieth Session of the CCPR (2018) for periodic review and the 2019 JMPR considered information supplied by the sponsor on identity, physicochemical properties, metabolism and environmental fate, methods of residue analysis, freezer storage stability, registered use patterns, supervised residue trials, fate of residues in processing, and animal feeding studies, together with additional supervised residue trial data supplied by Australia for mandarin, oranges, avocados, mangoes, capsicum and pulses, and by Thailand for yard-long bean.

The 2019 JMPR established a revised ADI of 0–0.001 mg/kg bw and reaffirmed the ARfD of 0.02 mg/kg bw for dimethoate, but was unable to complete the assessment of omethoate, a metabolite of dimethoate and also used as a pesticide, with respect to its mutagenic potential.

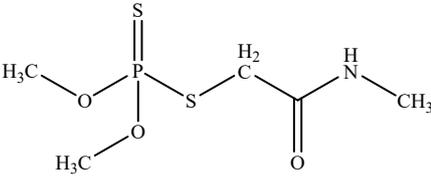
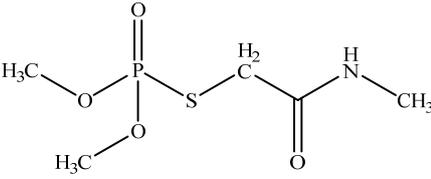
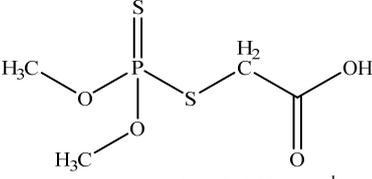
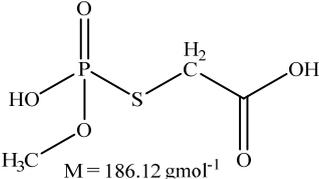
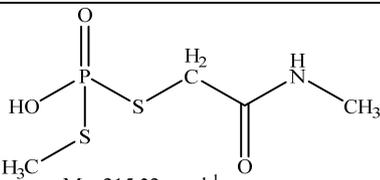
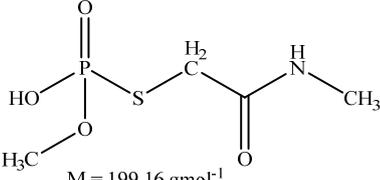
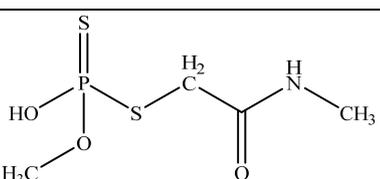
The 2019 JMPR also recommended a residue definition of dimethoate and omethoate (measured and reported separately) for MRL-compliance in plant and animal commodities and concluded that the residue is not fat-soluble.

However, the Meeting was unable to recommend residue definitions for dietary risk assessment because of concerns relating to the genotoxicity of omethoate and other related metabolites.

Evaluation of the metabolism studies in rats was carried out by the WHO Core Assessment Group in 2019 and a further assessment of omethoate and its metabolites was conducted by the current Meeting. Residue components observed in the dimethoate rat metabolism study were dimethoate, omethoate, dimethoate carboxylic acid, dimethyl dithiophosphate, dimethyl thiophosphate, and dimethyl phosphate.

The previously-provided residue information evaluated by the 2019 JMPR was re-evaluated in light of this new toxicological information and new information on current dimethoate GAP.

Table 5.11.1 Major metabolites discussed in this appraisal

Component name	Structure	Origin
Dimethoate		Parent compound
Omethoate (XI)		Potato, olives, wheat, rat, goat, hen
Dimethoate carboxylic acid (III)		Potato, olives, wheat, rat, goat, hen
O-desmethyl omethoate carboxylic acid (XX)		Potato, wheat
O-desmethyl isodimethoate (XII)		Potato, olives, wheat
O-desmethyl omethoate (XI)		Potato, olives, wheat
Desmethyl dimethoate (X)		Potato, hydrolysis, soil (minor component)

Component name	Structure	Origin
O-desmethyl N-desmethyl omethoate (XXIII)		Potato, olives, wheat

Residue definition

Plant commodities

For MRL-compliance, based on the metabolism studies and field trials, the 2019 JMPR concluded that dimethoate and omethoate were good marker compounds particularly for shorter pre-harvest intervals, and in directly treated commodities such as leafy vegetables and fruits and noted that suitable validated methods were available for dimethoate and omethoate in an extensive range of plant commodities.

The 2019 JMPR further noted that in residue trials for some commodities, for example cherries and olives, omethoate was present at higher levels than dimethoate, particularly around harvest. Therefore, inclusion of both dimethoate and omethoate in the definition for compliance with MRLs was warranted and since omethoate is itself a pesticide, it should therefore be measured separately from dimethoate.

The 2019 JMPR considered that a suitable residue definition for compliance with MRLs in plant commodities was *dimethoate and omethoate, measured and reported separately*.

The 2019 JMPR also considered that dimethoate and omethoate were expected to have similar bioavailability to livestock, and determined that the *sum of dimethoate and omethoate* would be used to estimate median and highest residues in feed commodities for estimation of livestock dietary burden.

For dietary exposure assessment, the 2019 JMPR reviewed metabolism studies in olives, potatoes and wheat, supervised field trials where a number of these metabolites were analysed and a number of older studies containing summarized metabolism data on lemons, sugar beet, maize, cotton, peas, potatoes and beans.

The 2019 JMPR concluded that in the olive, wheat and potato studies, the major components of the residue in matrices treated directly with dimethoate at shorter sampling intervals (0–14 days) were dimethoate and omethoate.

In matrices to which residues are translocated, and at longer intervals after application, the metabolite pattern is different and dimethoate and omethoate are present at lower levels and the major residues are metabolites O-desmethyl N-desmethyl omethoate (XXIII), O-desmethyl isodimethoate (XII), O-desmethyl omethoate carboxylic acid (XX) and O-desmethyl omethoate (XI).

In a number of residue trials in wheat, olives and sugar beet, dimethoate, omethoate and six metabolites were analysed. No residues of any of the components were found above 0.01 mg/kg in wheat grain, and in sugar beet roots all components other than desmethyl dimethoate (X) were also below the LOQ. In olives, dimethoate and omethoate were the most significant residue components, with dimethoate carboxylic acid (III) found in olive flesh (0.02 mg/kg) and desmethyl dimethoate (X) found in sugar beet roots (0.03 mg/kg).

The current Meeting, in deciding which metabolites should be included in the residue definition for plant commodities, considered the likely occurrence and toxicological relevance of the compounds present at more than 10 percent of total identified residues in the metabolism studies.

Compounds considered were omethoate, O-desmethyl-N-desmethyl omethoate, O-desmethyl-isodimethoate, desmethyl dimethoate, O-desmethyl omethoate carboxylic acid, O-desmethyl-omethoate and O,O-dimethyl phosphonic acid.

The Meeting noted that O-desmethyl-N-desmethyl omethoate, O-desmethyl-isodimethoate, desmethyl dimethoate, O-desmethyl omethoate carboxylic acid, O-desmethyl-omethoate and O,O-dimethyl phosphonic acid were of no toxicological relevance and these metabolites were not discussed further.

Omethoate was a significant residue in most directly treated plant matrices, both in the plant metabolism studies and supervised field trials, and present in some processed olive and orange commodities. It was also found in the rat metabolism study, has a lower ADI (0.0004 mg/kg bw/day) and a lower ARfD (0.002 mg/kg bw) than dimethoate. The Meeting considered that omethoate should be included in the residue definition.

Based on the above, the current Meeting considered that for dietary intake risk assessment for plant commodities, the residue definition should be: *Dimethoate plus 2.5× omethoate, expressed as dimethoate for long-term dietary exposure and dimethoate plus 10× omethoate for acute dietary exposure.*

Animal commodities

Based on the goat and laying hen metabolism studies, the 2019 JMPR concluded that the major component of the residue was incorporated into phosphorylated natural products. Dimethoate residues were not detected in any matrix, indicating rapid metabolism.

Omethoate residues were found in cattle liver (0.12 mg eq/kg), poultry liver (0.081 mg eq/kg) and egg white (0.004 mg eq/kg).

Residues of dimethoate carboxylic acid (III) made up 16 percent TRR (0.13 mg eq/kg) in poultry liver, 2.5 percent TRR (0.031 mg eq/kg) in goat liver, 8.3 percent TRR (0.019 mg eq/kg) in goats milk and 3.9 percent TRR (0.005 mg eq/kg) in egg white.

In the lactating cattle feeding study, no residues of dimethoate were found above the LOQ in milk, muscle, liver, or kidney, while low levels of omethoate were detected in milk, kidney, and muscle for the highest dose group, in liver for the highest and second highest dose groups, while low levels of dimethoate were detected in fat at all doses, without any clear correlation between dose and residue level. Omethoate was detected in fat at higher dose levels.

In the laying hen feeding study, no residues of dimethoate or omethoate were detected in tissues or eggs at any dose level.

The 2019 JMPR considered that a suitable residue definition for compliance with MRLs in animal commodities was *dimethoate and omethoate, measured and reported separately* and that residues of dimethoate and omethoate are not fat-soluble.

For dietary exposure assessment, in deciding which metabolites should be included in the residue definition for animal commodities, the current Meeting noted that the only metabolites found in animal commodities were considered omethoate and dimethoate carboxylic acid. The Meeting noted that dimethoate carboxylic acid was of no toxicological relevance and decided it need not be included in the residue definition.

Omethoate was found in at low levels in cattle milk (< 0.02 mg/kg) and most cattle tissues (< 0.005 mg/kg) but in the goat and poultry metabolism studies, was only found in goat liver (9.8 percent

TRR, 0.12 mg eq/kg), poultry liver (16 percent TRR, 0.081 mg eq/kg) and egg white (3.9 percent TRR, 0.005 mg eq/kg).

It was also found in the rat metabolism study and is more toxic than dimethoate. The Meeting considered that omethoate should be included in the residue definition for risk assessment.

Based on the above, the current Meeting considered that for dietary intake risk assessment for animal commodities, the residue definition should be: *Dimethoate plus 2.5× omethoate, expressed as dimethoate for long-term dietary exposure and dimethoate plus 10× omethoate for acute dietary exposure.*

Results of supervised residue trials on crops

The 2019 JMPR evaluated supervised trials on the use of dimethoate on mandarins, oranges, cherries, olives, avocados, mangoes, bulb onions, brassica vegetables, melons, sweet peppers, tomatoes, leaf lettuce, legume vegetables, pulses, root and tuber vegetables, barley, wheat and rape seed.

Product labels provided to the 2019 Meeting were from Australia, Brazil, Thailand, United States and a number of European Union member states. The current Meeting noted that since 2019, all European Union dimethoate authorizations have been withdrawn and that of the proposed MRLs recommended by the 2019 JMPR, only those for citrus, avocados, tomatoes, dried beans, rape seed (Australian GAPs) and yard-long beans (Thailand GAP) were still valid. New GAP information was provided for Brussels sprouts (Canada) and a new GAP was identified for wheat.

For acute dietary exposure estimation, the highest individual total residue values from the trials have been used to derive the highest residues.

The residue trial tables include values for the sum of dimethoate and omethoate for use in the livestock dietary burden calculation where applicable.

Where residues were reported below the LOQ, the following conventions were adopted for summing residues (using an LOQ of 0.01 mg/kg as an example):

Table 5.11.2 Convention adopted for summing of residues

Dimethoate (mg/kg)	Omethoate (mg/kg)	Sum of dimethoate and omethoate (mg/kg)
0.30	0.04	0.34
0.30	< 0.01	0.31
< 0.01	< 0.01	< 0.02

For dietary intake estimation it is necessary to account for the residues of both dimethoate and omethoate. In order to estimate STMR and HR values for use in the dietary intake calculations, the relative toxicity of the two compounds must be taken into account. Since dimethoate and omethoate share a common toxicological mode of action, in line with the approach taken by previous Meetings, the toxicologically significant residues were estimated by adding the dimethoate and omethoate residues after scaling the omethoate residues to dimethoate toxicity equivalents - based on the ratio of the dimethoate to omethoate maximum ADIs for STMR estimation and acute RfDs for HR estimation.

For long-term dietary exposure estimation, toxic equivalent residues (mg teq/kg) = dimethoate + 2.5×omethoate.

For acute dietary exposure estimation, toxic equivalent residues (mg teq/kg) = dimethoate + 10×omethoate.

Where residues were reported as < 0.01 mg/kg, a value of 0.01 mg/kg was used when calculating total residues for dietary exposure estimation.

Citrus fruit

The 2019 JMPR concluded that the critical GAP for citrus fruit was in Australia, a post-harvest dip or flood application of 0.04 kg ai/100 L (40 ppm), with no withholding period required.

In mandarin trials supporting this GAP, dimethoate residues in whole fruit were: 0.58, 0.70, 0.71 and 0.82 mg/kg (n=4) and omethoate residues were: < 0.01 (4) mg/kg (n=4).

In orange trials supporting this GAP, dimethoate residues in whole fruit were: 0.51, 0.59, 0.60, 0.63, 0.66 and 0.67 mg/kg (n=6) and omethoate residues were: 0.003 (3), 0.004 (2) and 0.005 mg/kg (n=6).

The 2019 Meeting also agreed to combine the residue data sets for oranges and mandarins to estimate maximum residue levels for the subgroups of mandarins and oranges and noted that these levels would accommodate the foliar application GAPs in Australia and Brazil.

The combined mandarin and orange (whole fruit) dataset for dimethoate was: 0.51, 0.58, 0.59, 0.60, 0.63, 0.65, 0.67, 0.70, 0.71, and 0.82 mg/kg (n=10).

The combined mandarin and orange (whole fruit) dataset for omethoate was: 0.003 (3), 0.004 (2), 0.005, and < 0.01 (4) mg/kg (n=10).

The Meeting confirmed the 2019 JMPR estimated maximum residue levels of 2 mg/kg for dimethoate and 0.02 mg/kg for omethoate in the subgroup of mandarins and the subgroup of oranges.

Residues for livestock dietary burden estimation (sum of dimethoate and omethoate) in citrus (whole fruit) were: 0.51, 0.59 (2), 0.6, 0.63, 0.66, 0.675, 0.71, 0.72 and 0.83 mg/kg (n=10). The median residue was 0.645 mg/kg.

Mandarin

For dietary exposure estimation, in the Australian trials matching the critical GAP, dimethoate residues in mandarin flesh were: 0.014, 0.056, 0.056 and 0.076 mg/kg (n=4) with a highest value of 0.089 mg/kg and omethoate residues were: < 0.01 (4) mg/kg (n=4).

For assessing long-term dietary exposure, the toxic equivalent residues in mandarin flesh (dimethoate + 2.5× omethoate residues) were: 0.039, 0.081 0.081 and 0.1 mg teq/kg.

For assessing acute dietary exposure, the toxic equivalent residues in mandarin flesh were: 0.11, 0.16, 0.16 and 0.18 mg teq/kg and the highest individual value was 0.19 mg teq/kg.

The Meeting estimated an STMR_{chronic} of 0.081 mg teq/kg, an HR of 0.19 mg teq/kg and a STMR_(acute) residue of 0.16 mg teq/kg for dimethoate in the subgroup of mandarins.

Orange

For dietary exposure estimation, in the Australian trials matching the critical GAP, dimethoate residues in orange flesh were: 0.19, 0.26, 0.275, 0.34, 0.37 and 0.38 mg/kg (n=6) and omethoate residues were: 0.001 (2), 0.002 (3) and 0.003 mg/kg (n=6).

For assessing long-term dietary exposure, the toxic equivalent residues in orange flesh were: 0.19, 0.265, 0.28, 0.345, 0.38 and 0.385 mg teq/kg.

For assessing acute dietary exposure from residues in oranges, the toxic equivalent residues in flesh were: 0.2, 0.28, 0.285, 0.36, 0.4 and 0.4 mg teq/kg.

The Meeting estimated an STMR_{chronic} of 0.31 mg teq/kg, an HR of 0.4 mg teq/kg and a STMR_(acute) residue of 0.32 mg teq/kg for dimethoate in the subgroup of oranges.

The Meeting noted that an acute dietary exposure assessment showed that residues in the *subgroup of oranges exceed the ARfD of 0.02 mg/kg bw, at 120 percent for peeled oranges for Australian children*. No alternative GAP was available.

Avocados

The 2019 JMPR concluded that the critical GAP for avocados was in Australia, for dilute foliar applications of 0.03 kg ai/100 L as required (with a 7-day PHI) followed by a 1-minute post-harvest dip using 0.04 kg ai/100 L, with no withholding period.

In avocado trials supporting this GAP, dimethoate residues in (whole fruit) were: 0.41, 0.44, 0.71, and 0.75 mg/kg (n=4) and omethoate residues were: 0.016, 0.025, 0.042, and 0.067 mg/kg (n=4).

The Meeting confirmed the 2019 JMPR estimated maximum residue level of 2 mg/kg for dimethoate and 0.15 mg/kg for omethoate in avocado.

For dietary exposure estimation, in the Australian trials matching the critical GAP, dimethoate residues in flesh were: 0.062, 0.062, 0.11 and 0.17 mg/kg (n=4) and omethoate residues were: < 0.01, < 0.01, 0.01 and 0.032 mg/kg (n=4).

For assessing long-term dietary exposure from residues in avocados, the toxic equivalent residues in flesh were: 0.087, 0.087, 0.135 and 0.25 mg teq/kg.

For assessing acute dietary exposure from residues in avocados, the toxic equivalent residues in flesh were: 0.16, 0.16, 0.21 and 0.49 mg teq/kg.

The Meeting estimated an STMR_{chronic} of 0.11 mg teq/kg, an HR of 0.49 mg teq/kg and a STMR_(acute) residue of 0.37 mg teq/kg for dimethoate in avocados.

Brussels sprouts

The 2019 JMPR estimated a maximum residue level for Brussels sprouts based on the GAP in the Czech Republic. As this GAP no longer exists, the current Meeting re-evaluated the available data based on a newly provided Canadian GAP.

The critical GAP in Canada for Brussels sprouts is for 2 foliar applications of 0.48 kg ai/ha, with a 7-day minimum retreatment interval and a PHI of 21 days.

In trials matching this GAP, but with a lower application rate (0.24–0.25 kg ai/ha) dimethoate residues in Brussels sprouts were: < 0.01 (3), 0.01, 0.02,(3) and 0.03 (2) mg/kg (n=9) and omethoate residues were: < 0.01 (8) and 0.01 mg/kg (n=9).

When proportionally adjusted to the Canadian application rate (scaling factor of 1.9), dimethoate residues were: < 0.019 (3), 0.019, 0.038 (3) and 0.058 (2) mg/kg (n=9) and omethoate residues were: < 0.019 (8) and 0.019 mg/kg (n=9).

The current Meeting estimated a maximum residue level of 0.1 mg/kg for dimethoate and 0.03 mg/kg for omethoate in Brussels sprouts, to replace the 2019 JMPR estimations.

For assessing long-term dietary exposure from residues in Brussels sprouts, the toxic equivalent residues were: < 0.067 (3), 0.067, 0.086 (3) and 0.11 (2) mg teq/kg (n=9).

For assessing acute dietary exposure from residues in Brussels sprouts, the toxic equivalent residues were: < 0.21 (3), 0.21, 0.23 (3) and 0.25 (2) mg teq/kg (n=9).

The Meeting estimated an $STMR_{\text{chronic}}$ of 0.086 mg teq/kg, an HR of 0.25 mg teq/kg and a $STMR_{\text{(acute)}}$ residue of 0.23 mg teq/kg for dimethoate in Brussels sprouts.

Tomato

The 2019 JMPR concluded that the critical GAP for tomatoes was in Australia, for 2 × 0.3 kg ai/ha foliar applications with a minimum 14-day retreatment interval and a 21-day PHI. Scaled dimethoate residues in trials from Europe supporting this GAP were: < 0.005 mg/kg (n=8) and omethoate residues were: < 0.005 (6), 0.005 and 0.005 mg/kg (n=8).

The Meeting confirmed the 2019 JMPR estimated maximum residue level of 0.01(*) mg/kg for dimethoate and 0.01 mg/kg for omethoate in tomato.

Residues for livestock dietary burden estimation (sum of dimethoate and omethoate) in tomato were: < 0.01 (6) and 0.01 (2) mg/kg (n=8). The median residue was 0.01 mg/kg.

For assessing long-term dietary exposure from residues in tomatoes, the toxic equivalent residues were: < 0.0175 (6) and 0.0175 (2) mg teq/kg.

For assessing acute dietary exposure from residues in tomatoes, the toxic equivalent residues were: < 0.055 (6) and 0.055 (2) mg teq/kg.

The Meeting estimated an $STMR_{\text{chronic}}$ of 0.0175 mg teq/kg, an HR of 0.055 mg teq/kg and a $STMR_{\text{(acute)}}$ residue of 0.055 mg teq/kg for dimethoate in tomatoes.

Yard-long bean (pods)

The 2019 JMPR concluded that the critical GAP for yard-long beans was in Thailand, for 4 × 0.6 kg ai/ha foliar applications with a 7-day PHI.

Dimethoate residues in trials in supporting this GAP were: < 0.05 (5) and 0.05 mg/kg (n=6) and omethoate residues were: < 0.05 (6) mg/kg (n=6).

The Meeting confirmed the 2019 JMPR estimated maximum residue level of 0.07 mg/kg for dimethoate and 0.05 mg/kg for omethoate in yard long bean.

For assessing long-term dietary exposure from residues in yard-long bean, the toxic equivalent residues were: < 0.175 (5) and 0.175 mg teq/kg.

For assessing acute dietary exposure from residues in yard-long bean, the toxic equivalent residues were: < 0.55 (5) and 0.55 mg teq/kg.

The Meeting estimated an $STMR_{\text{chronic}}$ of 0.175 mg teq/kg, an HR of 0.55 mg teq/kg and a $STMR_{\text{(acute)}}$ residue of 0.55 mg teq/kg for dimethoate in yard-long bean.

Beans (dry)

The 2019 JMPR concluded that the critical GAP for dry beans (except soya beans) was in Australia, for foliar applications of 0.32 kg ai/ha, with a minimum 14-day retreatment interval and a 14 day PHI for both grazing and harvest.

Dimethoate residues in dry beans from trials supporting this GAP were: < 0.05 (4), 0.066, and 0.4 mg/kg (n=6) and omethoate residues were: < 0.05 (5), and 0.064 mg/kg (n=6).

Residues for livestock dietary burden estimation (sum of dimethoate and omethoate) in dry beans were: < 0.10 (4), 0.12, and 0.46 mg/kg (n=6). The median residue was 0.1 mg/kg.

The Meeting estimated a maximum residue level of 0.7 mg/kg for dimethoate and 0.08 mg/kg for omethoate in the subgroup of dry beans (except soya bean) to replace the previous estimation for the subgroup of dry beans.

For assessing long-term dietary exposure from residues in dry beans, the toxic equivalent residues were: < 0.175 (4), 0.19 and 0.56 mg teq/kg.

For assessing acute dietary exposure from residues in dry beans, the toxic equivalent residues were: < 0.55 (4), 0.57 and 1.0 mg teq/kg.

The Meeting estimated an $STMR_{\text{chronic}}$ of 0.175 mg teq/kg and a $STMR_{\text{(acute)}}$ residue of 0.38 mg/kg for dimethoate in dry beans (subgroup) except soya bean.

Wheat

The 2019 JMPR estimated a maximum residue level for wheat based on the GAP in the Czech Republic. As this GAP no longer exists, the current Meeting re-evaluated the available data based on the current GAP in the United States.

The critical GAP in the United States for wheat is for a single foliar application of 0.56 kg ai/ha, with a 35-day PHI and a 14-day grazing interval.

In trials matching this GAP, but at a lower application rate of 0.2–0.21 kg ai/ha, dimethoate residues in wheat grain were: < 0.001 (9), 0.002 (2), 0.005, < 0.01 (5) and 0.01 mg/kg (n=18) and omethoate residues were: < 0.0012 (12) and < 0.01 (6) mg/kg (n=18).

When proportionally adjusted to the US application rate (scaling factor of 2.66), dimethoate residues were: < 0.0027 (9), 0.0053 (2), 0.013, < 0.027 (5) and 0.027 mg/kg (n=18) and omethoate residues were: < 0.0027 (12) and < 0.027 (6) mg/kg (n=18).

Scaled residues for livestock dietary burden estimation (sum of dimethoate and omethoate) in wheat were: < 0.0053 (9), < 0.008 (2), < 0.016 and < 0.053 (6) mg/kg (n=18). The median residue was 0.008 mg/kg.

The Meeting estimated a maximum residue level of 0.06 mg/kg for dimethoate and 0.03 mg/kg for omethoate in wheat to replace the 2019 JMPR estimations.

For assessing long-term dietary exposure from wheat, the toxic equivalent residues were: < 0.0093 (9), 0.012 (2), 0.02, < 0.093 (5) and 0.09 mg teq/kg (n=18).

For assessing acute dietary exposure from wheat, the toxic equivalent residues were: < 0.029 (9), 0.032 (2), 0.04, < 0.29 (5) and 0.29 mg teq/kg (n=18).

The Meeting estimated an $STMR_{\text{chronic}}$ of 0.011 mg teq/kg and a $STMR_{\text{(acute)}}$ residue of 0.032 mg/kg for dimethoate in wheat.

Rape seed (canola)

The 2019 JMPR concluded that the critical GAP for rape seed (canola) was in Australia, for a single foliar application of 0.14 kg ai/ha, with a 7 day PHI for both grazing and harvest.

In rape seed trials supporting this GAP, dimethoate residues were: < 0.02, 0.02, 0.026, 0.027, 0.028, 0.051, 0.066 and 0.084 mg/kg (n=8) and omethoate residues were: < 0.02 (7) and 0.02 mg/kg (n=8).

The Meeting confirmed the 2019 JMPR estimated maximum residue level of 0.15 mg/kg for dimethoate and 0.03 mg/kg for omethoate in rape seed.

For assessing long-term dietary exposure from rape seed, the toxic equivalent residues were: < 0.07, 0.07, 0.076, 0.077, 0.078, 0.1, 0.12 and 0.13 mg teq/kg (n=8).

For assessing acute dietary exposure from rape seed, the toxic equivalent residues were: < 0.22, 0.22, 0.23 (3), 0.25, 0.27 and 0.28 mg teq/kg.

The Meeting estimated an $STMR_{\text{chronic}}$ of 0.0775 mg teq/kg and a $STMR_{\text{acute}}$ residue of 0.23 mg/kg for dimethoate in rape seed.

Residues in animal feeds

Bean forage

The 2019 JMPR concluded that in the Australian residue trials on dry beans, the data for forage did not match GAP, as samples were only collected at intervals of 0 and 7 days after application and no median or highest residues could be estimated for bean forage.

Wheat forage

The current Meeting reviewed the available data on wheat forage (whole plants) in light of the United States GAP and the 14-day pre-grazing interval. In trials matching this GAP, but at a lower application rate of 0.2–0.21 kg ai/ha, total residues (sum of dimethoate and omethoate) were: < 0.02, 0.03, 0.03, 0.05, 0.08, 0.28, 0.29, 0.44, 0.61, 0.75, 1.5 and 1.65 mg/kg as received (n=12).

When proportionally adjusted to the United States application rate (scaling factor of 2.66), total residues in wheat forage (for livestock dietary burden estimation) were: < 0.053, 0.08, 0.08, 0.13, 0.21, 0.75, 0.77, 1.2, 1.6, 2.0, 4.0 and 4.4 mg/kg as received (n=12).

The Meeting estimated a median total residue of 0.76 mg/kg fw and a highest total residue of 4.4 mg/kg fw for the sum of omethoate and dimethoate in wheat forage (for livestock dietary burden estimation).

Wheat straw

The 2019 JMPR estimated a maximum residue level for wheat straw and fodder, dry based on the GAP in the Czech Republic. As this GAP no longer exists, the current Meeting re-evaluated the available data based on the GAP in United States.

The critical GAP in United States for wheat is for a single foliar application of 0.56 kg ai/ha, with a 35-day PHI and a 14-day grazing interval.

In trials matching this GAP, but at a lower application rate of 0.2–0.21 kg ai/ha, residues of dimethoate in wheat straw were: < 0.01 (8), 0.01 (2), 0.05 (3), 0.08, 0.19, 0.68, 0.76 and 0.83 mg/kg as received (n=18).

When proportionally adjusted to the United States application rate (scaling factor of 2.66), dimethoate residues in straw were: < 0.027 (8), 0.027 (2), 0.13 (3), 0.21, 0.51, 1.8, 2.0 and 2.2 mg/kg as received (n=18).

After adjustment for dry weight using the default dry matter content of 88 percent from the OECD livestock feed table, dry weight residues in straw were: < 0.03 (8), 0.03 (2), 0.15 (3), 0.24, 0.58, 2.1, 2.3 and 2.5 mg/kg dry weight.

In these trials, residues of omethoate were: < 0.01 (13), 0.01, 0.02, 0.05 (2) and 0.074 mg/kg as received (n=18).

When proportionally adjusted to the US application rate (scaling factor of 2.66), omethoate residues in straw were: < 0.027 (13), 0.027, 0.053, 0.13 (2) and 0.2 mg/kg as received (n=18).

After adjustment for dry weight using the default dry matter content of 88 percent from the OECD livestock feed table, dry weight residues in straw were: < 0.03 (13), 0.03, 0.06, 0.15 (2) and 0.22 mg/kg dry weight.

The Meeting estimated a maximum residue level of 4 mg/kg (dw) for dimethoate and 0.3 mg/kg (dw) for omethoate in wheat straw and/or hay to replace the 2019 JMPR estimations.

For estimation of the livestock dietary burden, total (sum of dimethoate and omethoate) residues in straw were: < 0.02 (8), 0.02 (2), 0.06 (3), 0.09, 0.24, 0.7, 0.81 and 0.9 mg/kg (as received) (n=18).

When proportionally adjusted to the US application rate (scaling factor of 2.66), total residues in straw were: < 0.053 (8), 0.053 (2), 0.16 (3), 0.24, 0.64, 1.9, 2.2 and 2.4 mg/kg as received (n=18). The median total residue was 0.053 mg/kg (0.06 mg/kg dry weight) and the highest total residue was 2.4 mg/kg (2.7 mg/kg dry weight).

Fate of residues during processing

The 2019 JMPR evaluated an hydrolysis study (simulating high temperature processing conditions) and concluded that both dimethoate and omethoate were hydrolysed to their desmethyl metabolites under simulated baking/boiling/brewing conditions (28/36 percent AR) and after sterilisation (60/63 percent) respectively and that no conversion from dimethoate to omethoate was observed under any of the conditions.

Residues in processed commodities

Processing factors were calculated by the 2019 JMPR for dimethoate and omethoate (for maximum residue level estimation, for calculating livestock dietary burdens and for risk assessment).

Table 5.11.3 Processing factors for citrus and cereal commodities

Processed commodity	Dimethoate	Omethoate
ORANGE		
Juice	0.14	0.20
Dry pulp	2.1	1.6
Molasses	5.8	5.9
Orange oil	0.20	< 0.07
WHEAT		
Wholemeal flour	0.66	0.5
White flour	0.21	0.5
Bran	4.4	3.5
Wheat germ	2.9	2.0

Maximum residue levels in processed commodities

Where residues concentrated in the processed food commodities, maximum residue levels were estimated using the estimated maximum residue levels for the raw commodities and applying the calculated mean processing factors.

Table 5.11.4 Estimated dimethoate and omethoate maximum residue levels for processed commodities.

Commodity	Processing factors ^a		Maximum Residue Level (mg/kg)	
	Dimethoate	Omethoate	Dimethoate	Omethoate
Orange			MRL= 2.0	0.02
Orange dried pulp	2.1	1.6	4.2	0.032
Wheat			MRL= 0.06	0.03
Wheat bran	4.4	3.5	0.26	0.105
Wheat germ	2.9	2.0	0.17	0.06

Notes:

^a The ratio of the residues in the processed item divided by the residue in the Raw Agricultural Commodity.

The Meeting estimated a maximum residue level of 5 mg/kg for dimethoate and 0.04 mg/kg for omethoate in citrus pulp, dry to replace the previous estimations.

The Meeting estimated a maximum residue level of 0.3 mg/kg for dimethoate and 0.15 mg/kg for omethoate in wheat bran to replace the previous estimations.

The Meeting estimated a maximum residue level of 0.2 mg/kg for dimethoate and 0.06 mg/kg for omethoate in wheat germ to replace the previous estimations.

Residues in processed food commodities

For estimating dietary exposure from toxic equivalent residues in processed food commodities, the Meeting applied the processing factors for dimethoate and omethoate to the levels of dimethoate and omethoate in the individual trials then scaled the individual omethoate residues for "potency" (based on the ratio of the dimethoate to omethoate HBGVs) and summed the resulting values from each trial to obtain a data set of toxic equivalent residues for estimating STMR-P and HR-P values.

Table 5.11.5 Calculated dimethoate toxic equivalent residue STMR-Ps, STMR_{acute} and HR-Ps for processed food commodities

RAC	Processing factors ^a		Residues (mg/kg) ^b		Toxic equivalent residues ^c (mg teq/kg)	
	Dimethoate	Omethoate	Dimethoate Median-P	Omethoate Median-P	STMR-P _{chronic}	STMR-P _{acute}
Orange	median=0.615	median=0.0035				
Juice	0.14	0.2	0.086	0.0007	0.088	0.093
Oil	0.2	0.07	0.12	0.000245	0.12	0.13
Molasses	5.8	5.9	3.6	0.021	3.6	3.8
Wheat grain	median=0.004	median=0.0027				
Wheat bran	4.4	3.5	0.018	0.009	0.041	0.11
Wheat germ	2.9	2.0	0.012	0.0053	0.025	0.065
Wholemeal flour	0.66	0.5	0.0026	0.0013	0.006	0.016
White flour	0.21	0.5	0.00084	0.0013	0.0042	0.014

Notes:

^a The ratios of the residue in the processed item divided by the residue in the Raw Agricultural Commodity.

^b Sum of calculated [dimethoate+10×omethoate] residues in the processed commodity.

^c Sum of calculated [dimethoate+2.5×omethoate] residues in the processed commodity.

Residues in processed feed commodities

For estimating residues in processed feed commodities, the Meeting applied the processing factors for dimethoate and omethoate to the levels of dimethoate and omethoate in the individual trials and summed the resulting values to obtain a data set of total residues for estimating median-P and highest-P values.

Table 5.11.6 Calculated median-Ps for total residues (dimethoate+omethoate) in processed feed commodities

RAC	Processing factors ^a		Total residues (mg/kg)		
	Dimethoate	Omethoate	Dimethoate ^b	Omethoate ^b	Median-P
Orange + mandarin (whole fruit)	0.645	0.0045			
Citrus pulp, dry	2.1	1.6	1.35	0.0072	1.36

Notes:

^a The ratios of the residue in the processed item divided by the residue in the Raw Agricultural Commodity.

^b Each value is the sum of calculated [dimethoate+omethoate] residues in the processed commodity.

Residues in animal commodities**Farm animal dietary burden**

Farm animal feeding studies in lactating cattle and laying hens were evaluated by the 2019 JMPR. In the lactating cow study, no residues of dimethoate were found above the LOQ (0.001 mg/kg) in milk, muscle, liver or kidney from any dose group ((1, 3.4, 10 and 33 ppm in the diet).

Low levels of omethoate were measured in milk and cattle tissues from the 33 ppm dose group and in cattle liver from the 10 ppm dose group. No residues of omethoate were found above the LOQ (0.001 mg/kg) in any of the egg or tissue samples from any dose group.

For fat, there were some low level residues of dimethoate and to a lesser extent of omethoate, without a consistent relationship between dose and residue level. The depuration data showed that clearance was rapid, with no detections above the LOQ.

Table 5.11.7 Residues of dimethoate and omethoate in milk and tissues from lactating cows dosed with the equivalent of 1, 3.4, 10.1 or 33.2 ppm dimethoate daily for 28 days

Matrix	Dose (ppm)	Dimethoate residues (mg/kg)			Omethoate residues (mg/kg)		
		Values ^a	mean	Max ^b	Values ^a	mean	Max ^b
Milk (28d)	3.4	< 0.001 (3)	< 0.001	< 0.001	< 0.001 (3)	< 0.001	< 0.001
	10.1	< 0.001 (3)	< 0.001	< 0.001	< 0.001 (3)	< 0.001	< 0.001
	33.2	< 0.001 (3)	< 0.001	< 0.001	0.0188, 0.001465, 0.0054, 0.0125, 0.013, 0.01355	0.011	0.0189
Muscle	3.4	< 0.001 (9)	< 0.001	< 0.001	< 0.001 (9)	< 0.001	< 0.001
	33.2	< 0.001 (9)	< 0.001	< 0.001	Loin: 0.00495, 0.0021, < 0.001 Flank: 0.005, 0.002, < 0.001 Round: 0.00485, 0.00195, < 0.001	0.0025	0.0051
Liver	3.4	< 0.001 (3)	< 0.001	< 0.001	< 0.001 (3)	< 0.001	< 0.001
	10.1	< 0.001 (3)	< 0.001	< 0.001	0.0018, 0.00135, 0.00105	0.0014	0.0018
	33.2	< 0.001 (3)	< 0.001	< 0.001	0.004, 0.0056, 0.0039	0.00455	0.0059
Kidney	3.4	< 0.001 (3)	< 0.001	< 0.001	< 0.001 (3)	< 0.001	< 0.001
	10.1	< 0.001 (3)	< 0.001	< 0.001	< 0.001 (3)	< 0.001	< 0.001
	33.2	< 0.001 (3)	< 0.001	< 0.001	0.0047, < 0.001, < 0.001	0.0019	0.0047

Matrix	Dose (ppm)	Dimethoate residues (mg/kg)			Omethoate residues (mg/kg)		
		Values ^a	mean	Max ^b	Values ^a	mean	Max ^b
Fat	1.0	O: 0.0023, < 0.001, < 0.001 P: 0.0269, 0.0046, < 0.001 S: 0.00255, < 0.001, < 0.001	0.0014 ⁽³⁾	0.0026 ⁽³⁾	O: < 0.001 (3) P: < 0.001 (3) S: < 0.001 (3)	< 0.001	< 0.001
	3.4	O: 0.00255, < 0.001, < 0.001 P: 0.0014, < 0.001, < 0.001 S: 0.0019, 0.00185, < 0.001	0.0014	0.0026	O: < 0.001 (3) P: < 0.001 (3) S: < 0.001 (3)	< 0.001	< 0.001
	10.1	O: 0.0175, < 0.001, < 0.001 P: 0.00275, < 0.001, < 0.001 S: 0.0099, < 0.001, < 0.001	0.00125 ⁽³⁾	0.0028 ⁽³⁾	O: < 0.001 (3) P: < 0.001 (3) S: < 0.001 (3)	< 0.001	< 0.001
	33.2	O: 0.0054, 0.0016, < 0.001 P: 0.004, 0.0019, < 0.001 S: 0.0019, < 0.001, < 0.001	0.002	0.0055	O: 0.00125, < 0.001, < 0.001 P: 0.00215, < 0.001, < 0.001 S: 0.004, < 0.001, < 0.001	0.001	0.004

Notes:

P = perirenal, S = subcutaneous, O = omental.

^a Mean values from duplicate analyses.

^b Highest individual result.

In the laying hen study, the 2019 JMPR reported that no residues of dimethoate or omethoate were found above the LOQ in any of the egg or tissue samples from animals in any dose group (0.15, 0.4, 1.2 and 4 ppm in the diet).

Livestock dietary burden

Dietary burden calculations for cattle and poultry are provided below. The dietary burdens were estimated using the 2018 OECD Feed diets listed in Appendix XIV Electronic attachments to the 2016 edition of the FAO Manual.

Table 5.11.8 Summary of livestock dietary burden (ppm dimethoate+omethoate)

	United States-Canada		European Union		Australia		Japan	
	Max	Mean	Max	Mean	Max	Mean	Max	Mean
Beef cattle	0.42	0.16	3.6	0.71	17.6 ^①	3.0 ^②	0.0022	0.0022
Dairy cattle	3.7	0.76	3.8	0.93	11.0 ^③	2.3 ^④	0.0009	0.0009
Broiler hens	0.007	0.01	0.029	0.029	0.082	0.082	0.0009	0.0009
Laying hens	0.007	0.0067	1.8 ^⑤	0.33 ^⑥	0.082	0.082	-	-

Notes:

① Highest maximum dietary burden for beef cattle suitable for estimation of MRLs for mammalian meat and offal.

② Highest mean dietary burden for beef cattle suitable for estimation of STMRs for mammalian meat and offal.

③ Highest maximum dietary burden for dairy cattle suitable for estimation of MRLs for milk.

④ Highest mean dietary burden for dairy cattle suitable for estimation of STMRs for milk.

⑤ Highest maximum dietary burden for broiler and layer poultry suitable for estimation of MRLs for poultry meat, offal and eggs.

⑥ Highest mean dietary burden for broiler and layer poultry suitable for estimation of STMRs for poultry meat, offal and eggs.

Animal commodity maximum residue levels**Cattle**

For estimating maximum residue levels in mammalian commodities, the maximum dietary burden for beef cattle was 17.6 ppm and for dairy cattle was 11 ppm. Mean dietary burdens were 3.0 ppm for beef cattle and 2.3 ppm for dairy cattle.

For dimethoate, the Meeting noted that in the cattle feeding study, residues of dimethoate were all < 0.001 mg/kg in milk, muscle, liver and kidney from animals in all dose groups (up to 33 ppm, about 2–3 times the maximum dietary burdens), and the Meeting estimated maximum residue levels of 0.001(*) mg/kg for dimethoate in mammalian meat, edible offal mammalian and milks.

For mammalian fat, there was no clear relationship between the administered dose and measured residues of dimethoate in fat. As a conservative estimate, the Meeting agreed to use the highest residue found in the feeding study (0.027 mg/kg) and the overall mean residue (0.003 mg/kg) to estimate a maximum residue level and assess dietary exposure.

The Meeting estimated a maximum residue level of 0.03 mg/kg for dimethoate in mammalian fat

Since dimethoate residues in muscle, liver, kidney and milk were all < 0.001 mg/kg in all dose groups (up to 33 ppm, about 2–3 times the maximum dietary burdens), the Meeting estimated dimethoate STMRs and HRs of 0 mg/kg for mammalian meat, liver, kidney and milk and for mammalian fat, the Meeting estimated an HR of 0.027 mg/kg and an STMR of 0.003 mg/kg.

For omethoate, the Meeting agreed to interpolate the results from the 10.1 ppm and 33.2 ppm feed levels to estimate maximum residue levels and HRs in tissues (at a maximum dietary burden of 17.6 ppm) and in milk (at a maximum dietary burden of 11 ppm) and median residues were extrapolated from the 3.4 ppm feed level.

Table 5.11.9 Omethoate highest and median residues in mammalian commodities

	Feed level (ppm) for milk	Residues (m/kg) in milk	Feed level (ppm) for tissues	Residues (mg/kg) in			
				Muscle	Liver	Kidney	Fat
HR and MRL (beef or dairy cattle)							
Feeding study	10.1 33.2	< 0.001 0.011	10.1 33.2	< 0.001 ^a 0.0051	< 0.001 0.0059	< 0.001 0.0047	- -
Dietary burden and highest residue	11	0.0014	17.6	0.003	0.0031	0.0022	0.027 ^b
Median residue (beef or dairy cattle)							
Feeding study	3.4	< 0.001	3.4	< 0.001	< 0.001	< 0.001	-
Dietary burden and highest residue	2.3	< 0.001	3.0	< 0.001	< 0.001	< 0.001	0.003 ^b

Notes:

^a Residue is in muscle from animals in the 3.4 ppm dose group.

^b The highest and overall mean values from all dose groups in the feeding study.

Highest residues of omethoate were 0.0014 mg/kg in milk, 0.0031 mg/kg in liver, 0.0022 mg/kg in kidney, 0.003 mg/kg in muscle and 0.002 mg/kg in fat.

The Meeting estimated maximum residue levels of 0.0015 mg/kg for omethoate in milk, 0.005 mg/kg in mammalian meat and edible offal (based on residues in liver) and 0.003 mg/kg in mammalian fat.

The Meeting estimated median omethoate residues of 0 mg/kg in kidney and fat (based on residues < 0.001 mg/kg in dose groups 3-fold higher than the mean dietary burden) and 0.001 mg/kg in milk, muscle and liver.

For assessing long-term dietary exposure from animal commodities, the toxic equivalent median_{chronic} residues were 0.0025 mg teq/kg for milk, liver and mammalian meat, 0.003 mg teq/kg for mammalian fat and 0 mg teq/kg for kidney.

For assessing acute dietary exposure from animal commodities, the toxic equivalent highest residues were 0.03 mg teq/kg for mammalian meat, 0.031 mg teq/kg for liver, 0.022 mg teq/kg for kidney and 0.047 mg teq/kg for mammalian fat and the toxic equivalent median residue for milk is 0.01 mg/kg.

Poultry

The maximum dietary burden for poultry for both meat and egg production was 1.8 ppm, while the highest mean dietary burden was 0.33 ppm.

In a poultry feeding study, when hens were fed dimethoate daily for 28 days at 0.15, 0.4, 1.2 or 4 ppm in the diet, the JMPR 2019 reported that no residues of dimethoate or omethoate were found above the LOQ (0.001 mg/kg) in any of the egg or tissue samples from any dose group.

The Meeting therefore estimated maximum residue levels of 0.001(*) mg/kg, HRs and STMRs of 0 mg/kg for both dimethoate and omethoate in poultry meat, poultry fats, poultry, edible offal of, and eggs.

RECOMMENDATIONS

On the basis of the data obtained from supervised trials, the Meeting concluded that the residue levels listed in Annex 1 are suitable for establishing maximum residue limits and for IEDI and international estimate of short-term Intake assessments.

Definition of the residue for compliance with the MRL for plant and animal commodities: *Dimethoate and omethoate (measured and reported separately)*

Definition of the residue for dietary risk assessment for plant and animal commodities: Sum of dimethoate plus 2.5× omethoate for long-term dietary exposure and the sum of dimethoate plus 10× omethoate for acute dietary exposure.

The residue is not fat-soluble.

DIETARY RISK ASSESSMENT

The Meeting considered how to best approach the dietary risk assessment of mixed residues of dimethoate and omethoate and decided that an appropriately conservative approach would be to sum the dimethoate and omethoate residues after first scaling the omethoate residues to account for the differences in toxicity. The relevant factors for chronic and short-term intake were derived from the ratios of the dimethoate and omethoate maximum ADI and acute RfD values and are 2.5 and 10 respectively. Dietary intake estimates for the combined adjusted residues were compared with the dimethoate maximum ADI and ARfD.

Long-term dietary exposure

The ADI for dimethoate is 0–0.001 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for dimethoate (including omethoate) were estimated for the 17 GEMS/Food Consumption Cluster Diets using the STMR or STMR-P values estimated by the JMPR. The results are shown in Annex 3 of the 2022 JMPR Report.

The IEDIs ranged from 10–100 percent of the maximum ADI. The Meeting concluded that long-term dietary exposure to residues of dimethoate (including omethoate) from uses considered by the JMPR is unlikely to present a public health concern.

Acute dietary exposure

The ARfD for dimethoate is 0.02 mg/kg bw. The International Estimate of Short Term Intakes (international estimate of short-term intakes) for dimethoate (including omethoate) were calculated for the food commodities and their processed commodities for which HRs/HR-Ps or STMRs/STMR-Ps were estimated by the present Meeting and for which consumption data were available. The results are shown in Annex 4 of the 2022 JMPR Report.

The international estimate of short-term intake varied from 0–120 percent of the ARfD for children and 0–70 percent of the ARfD for the general population. The Meeting concluded that acute dietary exposure to residues of dimethoate (including omethoate) from uses considered by the present Meeting is unlikely to present a public health concern except for **oranges (120 percent for Australian children)**.

5.12 Emamectin benzoate (247)

RESIDUE AND ANALYTICAL ASPECTS

Emamectin benzoate is a foliar insecticide derivative of abamectin, which is isolated from fermentation of *Streptomyces avermitilis*, a naturally occurring soil actinomycete. It acts by stimulating the release of γ -aminobutyric acid, an inhibitory neurotransmitter, thus causing insect paralysis within hours of ingestion, and subsequent insect death 2–4 days later. It is also registered for use as a veterinary drug in the treatment of sea lice infestations in salmon and trout in several countries.

Emamectin benzoate was considered for the first time for toxicology and residues by the 2011 JMPR and for new uses by the 2014 JMPR. An ADI of 0–0.0005 mg/kg bw and ARfD of 0.02 mg/kg bw were established.

The Definition of the residue for compliance with the MRL and for the estimation of the dietary exposure for plant and animal commodities: *emamectin B1a benzoate*.

The residue is not fat soluble.

The Meeting received new information on analytical methodology, storage stability and additional supervised residues trials on basil, chives, coffee, flowerhead brassica vegetables, leafy vegetables (including brassica leafy vegetables), soya bean and tea.

Methods of analysis

The Meeting received description and validation data for QuEChERS analytical methods for determination of emamectin B1a benzoate and emamectin B1b benzoate in plant and animal commodities for enforcement as well as a QuEChERS method for determination of emamectin B1a benzoate, emamectin B1b benzoate, and its metabolites 8,9-ZMa, AB1a, MFB1a, and FAB1a in plant commodities. New description and validation data was also received for method RAM 465 in plant commodities.

Method RAM 465/01 was evaluated by the 2011 JMPR and is considered sufficiently validated for emamectin B1a benzoate, emamectin B1b benzoate and the avermectin-like metabolites 8,9-ZMa, AB1a, MFB1a, and FAB1a in high water, high starch, high acid, and high oil matrices. New validation data was provided for RAM 465/02 demonstrating the modified method is valid for determination of emamectin B1a benzoate, emamectin B1b benzoate and the avermectin-like metabolites 8,9-ZMa, AB1a, MFB1a, and FAB1a in coffee commodities (green beans, roasted and instant coffee), grapes, potatoes and tomatoes. The LOQ for this method is 0.001 mg/kg for each matrix and analyte.

Method GRM004.06A involves acetonitrile extraction with QuEChERS salts and final determination by HPLC with triple quadrupole mass spectrometric detection (LC-MS/MS). The method was sufficiently validated for emamectin B1a benzoate, emamectin B1b benzoate and the avermectin-like metabolites 8,9-ZMa, AB1a, MFB1a, and FAB1a in apricots, broad beans (dry), cotton, lettuces, melons, oranges, tobacco (dry leaves), walnuts, wheat (grain) and zucchinis. The LOQ was 0.001 mg/kg for each matrix and analyte.

QuEChERS multi-residues methods for enforcement were validated for the determination of parent emamectin benzoate (B1a and B1b) in both plant (EN 15662:2009-2) and animal (DIN EN 15662:2018) commodities. Both methods involve extraction in acetonitrile/water with QuEChERS salts followed by SPE clean-up, dilution, and quantification by HPLC with triple quadrupole mass spectrometric detection (LC/MS-MS, positive ion spray). The plant commodity method was validated in broad beans (dry), lettuces, oranges, tea, tobacco, walnuts and wheat grain. The animal commodity method was

validated in muscle (cattle), liver (cattle), kidney (cattle), fat (cattle) and eggs. The LOQ was 0.001 mg/kg for each matrix and analyte.

The Meeting concluded that methods RAM465/02 and GRM004.06A are suitable analytical methods to measure emamectin B1a benzoate, emamectin B1b benzoate and the avermectin-like metabolites 8,9-ZMa, AB1a, MFB1a, and FAB1a for plant commodities and that QuEChERS multi-residues methods are now available for analysis of emamectin B1a benzoate and emamectin B1b benzoate in both plant and animal commodities.

Stability of pesticide residues in stored analytical samples

The 2011 JMPR found that emamectin B1a benzoate and emamectin B1b benzoate were stable when stored at -20 °C or lower for at least 27 months (804 days) in plant commodities with high water content (tomatoes and green beans with pods), at least 18 months (545 days) in plant commodities with high starch content (potatoes), and at least 9 months in plant commodities with high oil content (cottonseed), and special plant commodities (cotton gin trash) and recommended that storage stability information on a high acid commodity would be desirable.

A storage stability study on a high acid commodity (orange) was provided to the current Meeting demonstrating residues of emamectin benzoate and its metabolites are stable for up to 24 months in whole orange when stored deep frozen.

In storage stability studies conducted concurrently with the supervised residues trials residues of emamectin benzoate and its metabolites were observed to be stable for at least 56 months in fresh basil and 52 months in dried chives, at least 3 months in dried tea leaves and at least 9 months in Chinese broccoli when stored frozen. These durations generally covered the longest period of storage for all samples obtained from supervised residue trials with only minor exceptions for dried chives (56 months stored, demonstrated stability 52 months) and soya beans (10 months stored, demonstrated stability of 9 months in high oil matrices). The Meeting considered any potential losses would be minor and the data for dried chives and soya beans remains valid.

Results of supervised residue trials on crops

The Meeting received supervised residue trials for emamectin benzoate on basil, chives, coffee, broccoli, cauliflower, Chinese broccoli, lettuce leaf, mustard greens, spinach and tea.

Chives

In the United States, the critical GAP for herbs (including chives) is three foliar applications of emamectin benzoate at up to 16.8 g ai/ha (maximum 50.4 g ai/ha per year) with a retreatment interval of 7 days and a harvest withholding period of 7 days.

The Meeting noted the cGAP for chives is for three applications whilst six applications were applied in the trials. Given the rapid decline of emamectin B1a benzoate and the RTI of 7 days it was concluded that the earlier applications would not contribute significantly to the final residue and the trials were considered suitable for maximum residue level estimation.

In independent trials approximating the critical GAP, residues of emamectin B1a benzoate in fresh chive leaves were (n=4): < 0.001, 0.001 (2) and 0.005 mg/kg (n=4).

The Meeting estimated a maximum residue level of 0.01 mg/kg, an STMR of 0.001 mg/kg and an HR of 0.006 (from a single sample) mg/kg for emamectin B1a benzoate in chives.

Flowerhead brassicas

In Italy, the critical GAP for broccoli and cauliflower is a maximum three foliar applications at 14.2 g ai/ha with a minimum retreatment interval of 7 days and a harvest withholding period of 3 days.

Broccoli

In the independent trials approximating cGAP in Italy, residues of emamectin B1a benzoate in broccoli at 3 DALA were (n=5): < 0.001, 0.001, 0.002, 0.002, and 0.004 mg/kg.

Cauliflower

In the independent trials approximating cGAP in Italy, residues of emamectin B1a benzoate in cauliflower were (n=12): < 0.001 (9) and 0.001 (3) mg/kg.

For the Italian GAP, the five trials on broccoli were considered sufficient to make a recommendation for broccoli individually. Based on the dataset for cauliflower the maximum residue level would be 0.002 mg/kg with an STMR at 0.001 mg/kg and a HR at 0.001 mg/kg.

The Meeting agreed to estimate the maximum residue level for the subgroup of Flowerhead brassicas based on the dataset for broccoli. The Meeting estimated a maximum residue level of 0.007 mg/kg, an STMR of 0.002 mg/kg and an HR of 0.004 mg/kg for emamectin B1a benzoate in Flowerhead brassicas, subgroup of.

Spinach

In the United States, the critical GAP for leafy vegetables (including spinach) is six foliar applications of emamectin benzoate at 16.8 g ai/ha (maximum of 101 g ai/ha per season) with a retreatment interval of 7 days and a harvest withholding period of 7 days.

In the independent trials approximating cGAP in the United States, residues of emamectin B1a benzoate in spinach were (n=6): < 0.005 (2), 0.006 (2), 0.007 and 0.024 mg/kg.

The Meeting estimated a maximum residue level of 0.05 mg/kg, an STMR of 0.006 mg/kg and an HR of 0.036 (from a single sample) mg/kg for emamectin B1a benzoate in spinach.

*Brassica leafy vegetables**Chinese broccoli*

In Thailand, the GAP for Chinese broccoli is two foliar applications of emamectin benzoate at 14.4 g ai/ha with a retreatment interval of 7 days and a harvest withholding period of 3 days.

In the independent trials matching cGAP in Thailand, residues of emamectin B1a benzoate in Chinese broccoli were (n=6): < 0.005 (5) and 0.12 mg/kg. The HR was 0.14 mg/kg (from a single sample).

Mustard greens

In the United States, the critical GAP for brassica leafy vegetables is six foliar applications of emamectin benzoate at 16.8 g ai/ha (maximum of 101 g ai/ha per season) with a retreatment interval of 7 days and a harvest withholding period of 14 days.

In the independent trials matching cGAP in the United States, residues of emamectin B1a benzoate in mustard greens were (n=6): < 0.005 (2), 0.008, 0.011, 0.014 and 0.108 mg/kg (STMR = 0.01 mg/kg).

The Meeting noted that Mustard greens are a representative crop for the subgroup and concluded the dataset for mustard greens was sufficient for estimation of a maximum residue level for the subgroup of brassica leafy vegetables.

The Meeting estimated a maximum residues level of 0.2 mg/kg, an STMR of 0.01 mg/kg and a HR of 0.219 (from a single sample) mg/kg for the subgroup of brassica leafy vegetables. This maximum residue level will also cover the expected residues of emamectin benzoate for the Thailand GAP for Chinese broccoli.

Soya bean (dry)

In the United States, the critical GAP for soya beans is three foliar applications of emamectin benzoate at 16.8 g ai/ha (maximum of 50.4 g ai/ha per year) with a retreatment interval of 7 days and a harvest withholding period of 28 days.

In the independent trials matching cGAP in the United States residues of emamectin B1a benzoate in soya beans (dry) were (n=19): < 0.001 (19) mg/kg.

The Meeting estimated a maximum residue level of 0.001(*) mg/kg for soya beans (dry). The Meeting noted that residues of emamectin B1a benzoate were also < 0.001 mg/kg (LOQ) following application at 5× rate and concluded an STMR of 0 mg/kg for soya beans (dry) was appropriate.

Basil

In the United States, the critical GAP for herbs is three foliar applications of emamectin benzoate at up to 16.8 g ai/ha (maximum of 50.4 g ai/ha per year) with a retreatment interval of 7 days and a harvest withholding period of 7 days.

The Meeting noted that the cGAP for basil is for three applications whilst six applications were applied in the trials. Given the rapid decline of emamectin B1a benzoate and the RTI of 7 days it was concluded that the earlier applications would not contribute significantly to the final residue and the trials were considered suitable for maximum residue level estimation.

In independent trials approximating the critical GAP, residues of emamectin B1a benzoate in fresh basil leaves and stems were (n=4): 0.001, 0.004, 0.005, and 0.028 mg/kg.

The Meeting estimated a maximum residue level of 0.06 mg/kg, an STMR of 0.0045 mg/kg and an HR of 0.032 (from a single sample) mg/kg for emamectin B1a benzoate in basil leaves.

Tea

In Japan, the critical GAP for tea is one foliar application of emamectin benzoate at 1000-fold dilution (1 g ai/100L) applied at 7 days before plucking.

In the independent trials matching cGAP in Japan, residues of emamectin B1a benzoate in dried green tea leaves were (n=8): 0.003, 0.004, 0.007, 0.008, 0.010, 0.011, 0.022 and 0.066 mg/kg.

The Meeting estimated a maximum residue level of 0.1 mg/kg and an STMR of 0.009 mg/kg for emamectin B1a benzoate in Tea, Black, Green dried and fermented.

Fate of residues during processing

The fate of emamectin benzoate residues during processing of raw agricultural commodities was investigated in basil, chives, tea and soya beans.

The studies showed that emamectin B1a benzoate concentrated in dried basil (PF=6.4) and dried chives (PF=5.0) but did not concentrate in tea infusions (PF=0.002). Emamectin B1a benzoate was also observed to concentrate in soya bean aspirated grain fractions with finite results of 0.005 and 0.021 mg/kg observed however no finite residues were observed in the RAC therefore a processing factor cannot be estimated. The Meeting noted residues in the soya bean aspirated grain fractions at 5× cGAP and agreed that expected residues at cGAP would be low and not contribute significantly to the livestock dietary burdens.

Table 5.12.1 Processing factors, STMR-Ps and HR-Ps for emamectin B1a benzoate, used for dietary risk assessment and MRL estimation

Raw commodity	Processed commodity	Processing factor	STMR-P = STMR _{RAC} × PF (mg/kg)	HR-P = HR _{RAC} × PF (mg/kg)	MRL _{RAC} × PF (mg/kg)	Recommended MRL (mg/kg)
Basil	Dried basil	6.4	0.0045 × 6.4 = 0.029	0.032 × 6.4 = 0.205	0.06 × 6.4 = 0.4	0.4
Chives	Dried chives	5.0	0.001 × 5.0 = 0.005	0.005 × 5.0 = 0.025	0.01 × 5.0 = 0.05	0.05
Tea	Tea infusion	0.002	0.009 × 0.002 = 0.000018	-	-	-

Based on the estimated maximum residue level of 0.06 mg/kg, the HR and STMR in basil at 0.032 mg/kg and 0.0045 mg/kg respectively, and the processing factor (6.4) for dried basil, the Meeting estimated a maximum residue level in dried basil (DH 0722) of 0.4 mg/kg (HR-P = 0.205 mg/kg, STMR-P = 0.029 mg/kg).

Based on the estimated maximum residue level of 0.01 mg/kg, the HR and STMR in chives at 0.005 mg/kg and 0.001 mg/kg respectively, and the processing factor (5.0) for dried chives, the Meeting estimated a maximum residue level in dried chives (DH 0727) of 0.05 mg/kg (HR-P = 0.025 mg/kg, STMR-P = 0.005 mg/kg).

Residues in animal commodities

Cattle

Based on the uses considered, kale and turnip tops (brassica leafy vegetables subgroup), soya bean seed and soya bean aspirated grain fractions may be part of the diet. It is noted that the soya bean GAP does not allow grazing or cutting for stock feed.

Estimation of livestock dietary burden

Dietary burdens were calculated for beef cattle and dairy cattle based on feed items presented above. The dietary burdens estimated using the most recent version of the OECD livestock dietary burden calculator diets are presented in Annex 6 and summarized below.

Table 5.12.2 Estimated maximum and mean dietary burdens of cattle (emamectin B1a benzoate)

	Animal dietary burden: emamectin B1a benzoate, ppm of dry matter diet							
	United States-Canada		European Union		Australia		Japan	
	max	mean	max	Mean	max	mean	max	mean
Beef cattle	0.0002#	0.0002#	0.2262 ^①	0.0302 ^②	0.1734#	0.0276#	-	-
Dairy cattle	0.1153	0.0155	0.2025 ^②	0.0232	0.1948#	0.0248 ^① #	-	-

Notes:

- ① Highest maximum beef or dairy cattle dietary burden suitable for MRL estimates for mammalian tissues.
- ② Highest maximum dairy cattle dietary burden suitable for MRL estimates for mammalian milk.

- ③ Highest mean beef or dairy cattle dietary burden suitable for STMR estimates for mammalian tissues.
- ④ Highest mean dairy cattle dietary burden suitable for STMR estimates for milk.

The use of emamectin in Australia for brassica leafy vegetables and root and tuber vegetables prohibits the grazing, waste crop or produce for stock food being fed to livestock therefore kale leaves and turnip tops have not been included in the dietary burden calculations for Australia.

The maximum dietary burdens for beef cattle and dairy cattle are estimated to be 0.2302 ppm in the feed DW and 0.2051 ppm in the feed DW respectively.

Poultry

From all uses of emamectin benzoate considered by the JMPR, soya bean seed is the only significant feed item consumed by poultry. Given finite residues are not observed in soya bean seed the poultry burden is expected to be insignificant.

Animal commodity maximum residue levels

Cattle

A ruminant feeding study was evaluated by the 2011 JMPR. Lactating Holstein-Friesian cows were dosed daily with emamectin benzoate at 0, 0.03, 0.09 and 0.30 mg/kg dry matter in feed for 28 consecutive days. As noted by the 2011 JMPR, the analytical method could not discriminate between emamectin B1a benzoate and 8,9-ZMa, therefore residues are the sum of both. Since metabolism studies showed that 8,9-ZMa is not formed in livestock, values reported represent the mean and highest residues of emamectin B1a benzoate only. Maximum emamectin B1a benzoate residues at the highest dose were 0.12 mg/kg in liver, 0.042 mg/kg in kidney, 0.015 mg/kg in fat and 0.0061 mg/kg in muscle. Mean residues of emamectin B1a benzoate at the highest dose were 0.097 mg/kg in liver, 0.037 mg/kg in kidney, 0.013 mg/kg in fat, 0.0058 mg/kg in muscle and 0.0032 mg/kg in milk.

The calculations used to estimate highest total residues for use in estimating maximum residue levels, STMR and HR values are shown below.

For maximum residue level estimation, the high residues in the tissues and milk were calculated by interpolating the maximum dietary burden (0.19 ppm) between the relevant feeding levels (0.09 and 0.30 ppm) from the dairy cow feeding study and using the highest tissue concentrations from individual animals within those feeding groups and using the mean milk concentration from those feeding groups.

The STMR values for the tissues and milk were calculated by interpolating the mean dietary burden (0.018 ppm) between the relevant feeding levels (0 and 0.03 ppm) from the dairy cow feeding study and using the mean tissue and milk concentrations from those feeding groups.

Table 5.12.3 Residues of emamectin B1a benzoate in animal commodities

	Feed Level (ppm) for milk residues	Emamectin B1a benzoate residues (mg/kg) in milk	Feed Level (ppm) for tissue residues	Emamectin B1a benzoate (mg/kg)			
				Muscle	Liver	Kidney	Fat
HR Determination (beef or dairy cattle)							
Feeding Study	0.09	0.008	0.09	0.0020	0.029	0.013	0.0066
	0.30	0.0032	0.30	0.0061	0.12	0.042	0.015
Dietary burden and estimate of highest residue	0.2025	0.0021	0.2262	0.0046	0.088	0.032	0.012

	Feed Level (ppm) for milk residues	Emamectin B1a benzoate residues (mg/kg) in milk	Feed Level (ppm) for tissue residues	Emamectin B1a benzoate (mg/kg)			
				Muscle	Liver	Kidney	Fat
STMR Determination (beef or dairy cattle)							
Feeding Study	0 0.03	0 < 0.0005	0 0.03	0 < 0.002	0 0.0086	0 0.0037	0 0.0021
Dietary burden and estimate of highest residue	0.0248	< 0.0005	0.0302	< 0.002	0.0071	0.0031	< 0.002

The Meeting estimated a maximum residue level for emamectin B1a benzoate of 0.003 mg/kg in milks, 0.005 mg/kg in meat from mammals other than marine mammals, 0.1 mg/kg in mammalian offal to replace the previous recommendations for milks, meat and offal and confirmed the previous recommendation of 0.02 mg/kg in mammalian fat. The residue in animal commodities is not considered fat soluble.

RECOMMENDATIONS

On the basis of the data from supervised trials the Meeting concluded that the residue levels listed in Annex 1 are suitable for establishing maximum residue limits.

Definition of the residue for compliance with the MRL and for dietary risk assessment for plant and animal commodities: *emamectin B1a benzoate*. *The Meeting considers the residue not fat soluble*.

Summary of recommendations are presented below.

DIETARY RISK ASSESSMENT

Emamectin benzoate is also registered for use as a veterinary drug in salmon and trout in several countries with Joint FAO/WHO Expert Committee on Food Additives (JECFA) recommending maximum residues levels for muscle and fillet (muscle + skin) at 0.1 mg/kg. The median residue (0.037 mg/kg) and MRL level reported by JECFA Meeting 78 (2013) have been used for dietary exposure estimations.

Long-term dietary exposure

The International Estimated Daily Intake (IEDI) for emamectin B1a benzoate was calculated for the food commodities for which STMRs were estimated and for which consumption data were available.

The International Estimated Daily Intakes of emamectin B1a benzoate for the 17 GEMS/Food cluster diets, based on estimated STMRs were 2–20 percent of the maximum ADI of 0.0005 mg/kg bw.

The Meeting concluded that the long-term dietary exposure to residues of emamectin B1a benzoate from uses that have been considered by the JMPR is unlikely to present a public health concern.

Acute dietary exposure

The ARfD for emamectin B1a benzoate is 0.02 mg/kg bw. The International Estimate of Short Term Intakes (international estimate of short-term intakes) for emamectin B1a benzoate were calculated for the food commodities and their processed commodities for which HRs/HR-Ps or STMRs/STMR-Ps were estimated by the present Meeting and for which consumption data were available. The international

estimate of short-term intake varied from 0–70 percent of the ARfD for children and 0–60 percent for the general population.

The Meeting concluded that acute dietary exposure to residues of emamectin B1a benzoate from uses considered by the present Meeting is unlikely to present a public health concern.

5.13 Famoxadone (208)

RESIDUE AND ANALYTICAL ASPECTS

Famoxadone (ISO common name) is an oxazolidinedione fungicide belonging to the quinol inhibitor family, which inhibits mitochondrial respiration of fungi. It was evaluated for the first time by JMPR 2003, which established an acceptable daily intake (ADI) of 0–0.006 mg/kg bw and an acute reference dose (ARfD) of 0.6 mg/kg bw. Famoxadone was scheduled at the Fifty-first Session of the CCPR for the evaluation of additional MRLs in 2021 and rescheduled to the 2022 JMPR.

The definition of the residue for compliance with MRLs and for dietary assessment is famoxadone. The residue is fat-soluble.

The current Meeting received information on analytical methods and supervised residue trials to support new MRLs in cane berries, bulb vegetables, cucurbit vegetables, fruiting vegetables, and hops.

Methods of analysis

The Meeting received method validation and concurrent recovery data for use of Method AMR 2801-93 (reviewed by 2003 JMPR) and Method AMR 3705-95 RV2. All methods were demonstrated to have adequate performance for recovery of famoxadone, with an LOQ of 0.02 mg/kg in most commodities tested; exceptions are winter barley and wheat forage (0.1 mg/kg) and dried hops cones (0.05 mg/kg).

Stability of pesticide residues in stored analytical samples

Concurrent storage stability data were provided for cane berry, cucumber, bulb onion, green onion, and hops (dried cones). Residues of famoxadone were stable in the tested commodities for at least the tested storage durations:

- Cane berry: at least 216 days (7 months);
- Cucumber: at least 313 days (10.3 months);
- Bulb onion: at least 873 days (28.7 months);
- Green onion: at least 796 days (26.2 months), and
- Hops (dried cones): at least 252 days (8.3 months).

Results of supervised residue trials on crops

The Meeting received data from supervised residue trials and GAP information on cane berries; bulb and green onion; cucumber, cantaloupe, and summer squash; tomatoes and peppers, and hops. In addition, the meeting received residue decline data for forage of winter barley and winter wheat to supplement data supplied to the 2003 Meeting and to provide support for other high-water commodities for which residue decline data were not available.

Cane berries

The GAP for cane berries is from the United States. The label allows multiple applications at a maximum rate of 0.175 kg ai/ha, on a 5-day interval, with a 0-day PHI. The maximum number of applications is not specified. Based on the listed annual limit of 1.26 kg ai/ha, the application pattern for the cGAP is one application at 0.035 kg ai/ha followed by 7 applications at 0.175 kg ai/ha.

Field trials in the United States were conducted with 6 applications on generally a 7-day interval (generally ranging from 6 to 8 days with one trial having one application done at a 12-day interval) at a

rate of approximately 0.21 kg ai/ha, with harvest 0 DALA. The Meeting agreed that an application 35 days before harvest would not contribute significantly to residues and that the difference in retreatment interval between the cGAP and the trials for one application would not affect residue levels by more than 25 percent. Therefore, the Meeting agreed that the field trials for cane berries are suitable for estimating residues.

Residues of famoxadone in cane berries from independent trials approximating the critical GAP were (n=7): 0.44, 0.83, 1.0, 1.1, 2.0, 2.6, and 6.0 mg/kg.

Noting that the registered use corresponds to the Codex Subgroup of Cane berries (FB 2005), the Meeting estimated a maximum residue level of 10 mg/kg for famoxadone in the Subgroup of cane berries, an STMR of 1.1 mg/kg, and an HR of 6.6 mg/kg (from a single sample).

Bulb vegetables

The GAP for bulb vegetables is from the United States and consists of multiple applications each at 0.175 kg ai/ha, on a 5-day interval, with a 3-day PHI. A maximum number of applications is not specified. Based on the maximum rate per crop cycle of 1.47 kg ai/ha, the application pattern for the cGAP is one application at 0.07 kg ai/ha followed by 8 applications at 0.175 kg ai/ha.

Onion, bulb

Field trials in the United States were conducted with 6 or 7 applications on generally a 6-day interval (ranging from 4 to 8 days) at a rate of approximately 0.19 kg ai/ha, with harvest 2–3 DALA. The Meeting agreed that the initial applications from the cGAP would not likely contribute significantly to residues at harvest and that the trials were suitable for estimating residues.

From independent trials approximating the critical GAP, residues of famoxadone in bulb onion were (n=7): < 0.02 (4), 0.06, 0.078, and 0.22 mg/kg.

The Meeting estimated a maximum residue level of 0.4 mg/kg, an STMR of 0.02 mg/kg, and an HR of 0.23 mg/kg (from a single sample) for famoxadone in the subgroup of bulb onion.

Onion, green

Field trials in the United States were conducted with 7 applications on generally a 6-day interval (ranging from 4 to 6 days) at a rate of approximately 0.19 kg ai/ha, with harvest 3 or 4 DALA. The Meeting agreed that the initial applications from the cGAP would not likely contribute significantly to residues at harvest and that the trials were suitable for estimating residues.

From independent trials approximating the critical GAP, residues of famoxadone in green onion were (n=4): 1.4, 3.8, 4.4, and 15 mg/kg.

The Meeting agreed that four trials was insufficient for estimating residues in green onions.

Fruiting vegetables, Cucurbits

The 2003 JMPR recommended maximum residue level for famoxadone in cucumber and summer squash, each at 0.2 mg/kg based on a GAP from Italy. The current Meeting received a more critical GAP from the United States consisting of 4 applications each at 0.175 kg ai/ha, on a 5-day interval, with a 3-day PHI. The new GAP applies to the Crop Group of Fruiting vegetables, Cucurbits.

Field trials in the United States were conducted in cucumber, summer squash, and melon with 7 applications on generally a 5-day interval (ranging from 4–8 days) at approximate rates of either 0.14 or 0.21 kg ai/ha in side-by-side trials, with harvest 3 DALA. Residue-decline data for cucurbit vegetables

were insufficient to provide a robust estimation of half-life. The Meeting agreed that for cucumber and summer squash, the first three applications from the field trials would not lead to significant residues at harvest due to significant growth dilution and that the trials for those crops are suitable for making recommendations. As both 0.14 and 0.21 kg ai/ha fall within 25 percent of the cGAP application rate of 0.175 kg ai/ha, the Meeting chose whichever result from the side-by-side trials was greater when making its residue estimates. For melons, fruit development is slower than for cucumber and squashes, and the Meeting agreed that contributions to residues at harvest from the first few applications could not be excluded; therefore, the trials in melons did not reflect the cGAP.

Fruiting vegetables, Cucurbits–Cucumbers and Summer Squashes, Subgroup of

Cucumber

Residues of famoxadone in cucumber from independent trials were (n=6): < 0.02, 0.048, 0.054, 0.064, 0.12, and 0.16 mg/kg.

Summer squash

Residues of famoxadone in summer squash from independent trials were (n=5): 0.028, 0.064, 0.17, 0.22, and 0.26 mg/kg.

The Meeting noted that the recommended representative commodities for the subgroup of cucumber and summer squashes are cucumber and summer squash and that the median residues from cucumber and summer squash trials are within five-fold. The residue populations are different (Mann-Whitney H test). Based on the dataset from summer squash, the Meeting estimated a maximum residue level of 0.6 mg/kg, an STMR of 0.17 mg/kg, and an HR of 0.37 mg/kg (from a single sample) to make a recommendation for the Subgroup of Fruiting vegetables, cucurbits–cucumbers and summer squashes and withdrew its previous separate recommendations for cucumber and summer squash.

Tomatoes

The GAP for tomato is from the United States and consists of multiple applications each at 0.14 kg ai/ha, on a 5-day interval, with a 3-day PHI. A maximum number of applications is not specified. Based on the listed limit of 1.26 kg ai/ha per crop cycle, the application pattern for the cGAP is 9 applications at 0.14 kg ai/ha. The 2003 Meeting recommended a maximum residue level of 2 mg/kg in tomato based on registered uses in Greece (up to 8 applications at 0.11 kg/ha, 3-day PHI).

Field trials in the United States were conducted with 6 applications, each at 0.21 kg ai/ha, generally on a 5-day retreatment interval (ranging from 4–6 days), with harvest 3 DALA. The Meeting agreed that the first three applications from the field trials would not lead to significant residues at harvest due to significant growth dilution and that the trials are suitable for estimating residues.

Residues of famoxadone in tomatoes from independent trials conducted at an exaggerated rate were (n=17): 0.14 (2), 0.15 (2), 0.17 (2), 0.23, 0.24, 0.30, 0.33, 0.40, 0.42, 0.50, 0.62, 0.68, and 0.71 mg/kg.

After scaling (factor = 0.67), residues were (n=17): 0.093 (2), 0.10 (2), 0.11 (2), 0.15, 0.16, 0.20, 0.22, 0.24, 0.27, 0.28, 0.33, 0.41, 0.45, and 0.47 mg/kg.

The Meeting noted that these residues are accommodated by the 2003 recommendation and confirmed its previous recommendation of a maximum residue level of 2 mg/kg, and STMR of 0.1 mg/kg and an HR of 1.1 mg/kg for famoxadone in tomato.

Peppers

The GAP for peppers is from the United States and consists of multiple applications each at 0.175 kg ai/ha, on a 5-day interval, with a 3-day PHI. A maximum number of applications is not specified. Based on the listed limit of 1.26 kg ai/ha per crop cycle, the application pattern for the cGAP is one application at 0.035 kg ai/ha followed by 7 applications at 0.175 kg ai/ha.

Field trials in the United States were conducted with 6 applications on generally a 5-day interval (ranging from 4–7 days) at a rate of 0.21 kg ai/ha, with harvest 3 DALA. The Meeting agreed that an application 35 days before harvest would not contribute significantly to residues at harvest and that the trials are suitable for estimating residues of famoxadone in peppers.

Residues of famoxadone in bell and *chili* peppers from independent trials approximating the critical GAP were (n=11): 0.078, 0.16, 0.20, 0.34, 0.36, 0.47, 0.51, 0.60, 0.63, 0.68, and 3.6 mg/kg.

The Meeting noted that the registration allows for use on bell and chili peppers, but not on other members of the Subgroup of peppers. The Meeting estimated a maximum residue level of 5 mg/kg, an STMR of 0.47 mg/kg, and an HR of 3.7 mg/kg (from a single sample) for famoxadone in each of peppers, sweet (including pimento or pimienta) and peppers, chili.

For dried chili peppers, the Meeting used the default factor of 10 to estimate a maximum residue level of 50 mg/kg for famoxadone in peppers chili, dried, an STMR of 4.7 mg/kg, and an HR of 37 mg/kg.

Hops

The critical GAP for hops is from the United States and consists of six applications each at 0.14 kg ai/ha, on a 6-day interval, with a 7-day PHI.

Residues of famoxadone in hops (dried cones) from independent trials approximating the critical GAP but at a 2× rate were (n=5): 14, 15, 26, 42, and 46 mg/kg. After scaling to an application rate of 0.14 kg ai/ha, residues were (n=5): 7.0, 7.5, 13, 21, and 23 mg/kg.

The Meeting estimated a maximum residue level of 50 mg/kg and an STMR of 13 mg/kg for hops (dry).

Fate of residues during processing

No new data on fate of residues during processing were provided to the Meeting. The 2003 Meeting evaluated the effects of processing on residues in tomato commodities. The current Meeting confirmed its previous recommendations with respect to tomato RAC, and by extension, processed tomato commodities.

Residues in animal commodities

The recommendations made by the current Meeting did not include animal feed items; therefore, the Meeting confirmed its previous recommendations for residues in animal commodities.

RECOMMENDATIONS

On the basis of the data obtained from supervised trials, the Meeting concluded that the residue levels listed in Annex 1 are suitable for establishing maximum residue limits and for IEDI and international estimate of short-term intakes assessments.

Definition of the residue for compliance with the MRL and dietary risk assessment for plant and animal commodities: *famoxadone*.

The residue is fat-soluble.

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The ADI for famoxadone is 0–0.006 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for famoxadone were estimated for the 17 GEMS/Food Consumption Cluster Diets using the STMR or STMR-P values estimated by the JMPR. The results are shown in Annex 3 of the 2022 JMPR Report.

The IEDIs ranged from 1–20 percent of the maximum ADI. The Meeting concluded that long-term dietary exposure to residues of famoxadone from uses considered by the JMPR is unlikely to present a public health concern.

Acute dietary exposure

The ARfD for famoxadone is 0.6 mg/kg bw. The International Estimate of Short-Term Intakes (international estimate of short-term intakes) for famoxadone were calculated for the food commodities and their processed commodities for which HRs/HR-Ps or STMRs/STMR-Ps were estimated by the present Meeting and for which consumption data were available. The results are shown in Annex 4 of the 2022 JMPR Report.

The international estimate of short-term intake varied from 0–20 percent of the ARfD for children and 0–9 percent of the ARfD for the general population. The Meeting concluded that acute dietary exposure to residues of famoxadone from uses considered by the present Meeting is unlikely to present a public health concern.

5.14 Fenazaquin (297)

RESIDUE AND ANALYTICAL ASPECTS

Fenazaquin is a quinazoline insecticide/acaricide. It was first evaluated by JMPR in 2017 for toxicology and residues. Subsequently, additional uses were evaluated by the 2019 Extra JMPR Meeting.

The 2017 JMPR established an ADI of 0–0.05 mg/kg bw and an ARfD of 0.1 mg/kg bw, applying to fenazaquin, tertiarybutylphenylethanol (TBPE), 4-hydroxyquinazoline and 2-hydroxy-fenazaquin acid. Residue definition for plant commodities is fenazaquin for compliance with the MRL and for dietary risk assessment. For animal commodities, the residue definition is the sum of fenazaquin and 2-hydroxy-fenazaquin acid for compliance with the MRL and the sum of fenazaquin, 2-hydroxy-fenazaquin acid, and tautomeric forms of 4-hydroxyquinazoline for dietary risk assessment. The residue is fat-soluble.

Fenazaquin was scheduled at the Fifty Second Session of the CCPR for evaluation of additional uses by the 2022 JMPR. The Meeting received information on residue trials (avocado, berries, citrus fruits, pome fruits, stone fruits, fruiting vegetables, beans and peas, and mint), processing and storage stability. In addition, a confined rotational crop study and a new analytical method were provided.

Confined rotational crop study

A confined rotational crop study with [¹⁴C-phenyl] and [¹⁴C-quinazoline] fenazaquin was conducted using lettuce, radish and wheat at 30, 120, and 365 day plant back intervals. Radiolabelled fenazaquin was applied to the bare soil at a rate of 550–556 g/ha. Total radioactive residues from the two labels were in similar levels, and gradually declined with increasing PBIs in the food commodities. The total radioactive residues were 0.004–0.055 mg eq/kg in immature lettuce, 0.008–0.067 mg eq/kg in mature lettuce, 0.008–0.104 mg eq/kg in radish roots, 0.007–0.030 mg eq/kg in radish tops, 0.009–0.129 mg eq/kg in wheat forage, 0.013–0.189 mg eq/kg in wheat hay, 0.025–0.243 mg eq/kg in wheat straw and 0.010–0.069 eq/kg in wheat grain.

Extractability of residues using organic solvents was 58.8–61.1 percent TRR in immature lettuce, 51.2–63.9 percent TRR in mature lettuce, 72.7–80.6 percent TRR in radish roots, 61.9–85.7 percent TRR in radish tops, 65.7–91.4 percent TRR in wheat forage, 49.6–69.6 percent TRR in wheat hay, 47.2–72.4 percent TRR in wheat straw and 28.6–49.3 percent TRR in wheat grain.

Only in 30-day PBI radish roots, parent fenazaquin was found at a greater level than 10 percent TRR or 0.01 mg/kg, representing 28.6–29.0 percent TRR (0.026–0.031 mg/kg). In all tested rotational crops except for wheat grain, metabolite 4-hydroxyquinazoline was detected, but did not exceed the level of 13.8 percent TRR or 0.012 mg eq/kg. The other identified metabolites were also found in the crops, but at low levels of below 4.5 percent TRR or 0.004 mg eq/kg, in addition, many minor components present at very low levels below 0.016 mg eq/kg were found, except for two components in wheat hay (0.023 mg eq/kg and 0.035 mg eq/kg) and one component in wheat straw (0.064 mg eq/kg).

The Meeting concluded that type and amount of residues in rotational crops would not impact on the current residue definition for plant commodities, and that significant residues are not expected in leafy vegetable, root and tuber vegetable or cereals grown as rotational crops.

Environmental fate

The 2017 JMPR concluded that fenazaquin is moderately persistent in soil under field conditions (DT₅₀ values ranging from 26–114 days) and that the photolysis of fenazaquin in soil, under sunlight conditions, was an important degradation pathway (soil surface DT₅₀ of 15 days).

Methods of analysis

Analysis of fenazaquin residue was conducted using analytical methods evaluated and considered suitable by previous JMPRs. The recovery test results from the studies provided to the current Meeting were acceptable and the LOQs of fenazaquin were 0.01 mg/kg. In some storage stability tests, a new method employing QuEChERS and LC-MS/MS was used. The Meeting considered this method was sufficiently validated with LOQ of 0.01 mg/kg in apple, tomato, grape, peach and orange matrices.

Stability of pesticide residues in stored analytical samples

The Meeting received storage stability studies for fenazaquin in high water commodities (apple, cucumber, melon, peach, tomato) and high acid commodities (grape, orange). The results demonstrated that residues of fenazaquin were stable for at least 12 or 13 months in the stored frozen matrices, respectively.

In the previous JMPR, the Meeting considered fenazaquin residues are stable when stored frozen for up to 3.5 months for high starch commodity (maize grain) and at least 17 months for high oil commodity (almond nutmeat). For high protein commodities, the information was not available to the Meeting.

The frozen sample storage intervals in the field trials were all within the acceptable storage stability periods.

Results of supervised residue trials on crops

The US GAP provided to the Meeting permits a single foliar application of 0.538 kg ai/ha (0.538 kg ai/ha/year) fenazaquin on all registered crops. All residue trials provided to this Meeting were conducted with a single foliar application in the United States.

Citrus fruits

The US GAP (1×0.538 kg ai/ha, 7-day PHI) covers the commodities in the Codex citrus fruits group and residue trials on lemon, orange and grapefruit matched this GAP.

Orange

In whole oranges, residues were (n= 10 from independent trials): 0.08, 0.09, 0.11, 0.11, 0.12, 0.13, 0.15, 0.15, 0.19 and 0.23 mg/kg. In flesh, residues of fenazaquin were not detected, all < 0.01 mg/kg (n=10).

The Meeting estimated a maximum residue level of 0.4 mg/kg, an STMR of 0.01 mg/kg and an HR of 0.01 mg/kg for the Subgroup of oranges, sweet, sour. The median (whole fruit) residue was 0.125 mg/kg.

Lemon

In whole lemons, residues were (n=5): 0.02, 0.04, 0.08, 0.11 and 0.12 mg/kg. In flesh, residues of fenazaquin were not detected, all < 0.01 mg/kg (n=5).

The Meeting estimated a maximum residue level of 0.3 mg/kg, an STMR of 0.01 mg/kg and an HR of 0.01 mg/kg for the Subgroup of lemons and limes. For kumquat, the Meeting estimated an STMR of 0.08 mg/kg and an HR of 0.12 mg/kg for whole fruit. The median (whole fruit) residue is 0.08 mg/kg.

Grapefruit

In whole grapefruits, residues were (n=5 from independent trials): 0.03, 0.04, 0.07, 0.11 and 0.14 mg/kg. In flesh, residues of fenazaquin were not detected, all < 0.01 mg/kg (n=5)

The Meeting estimated a maximum residue level of 0.3 mg/kg, an STMR of 0.01 mg/kg and an HR of 0.01 mg/kg for the Subgroup of pummelo and grapefruits. The median (whole fruit) residue is 0.07 mg/kg.

Mandarin

For the Subgroup of mandarins, the Meeting agreed to extrapolate the residue data set for lemons to estimate a maximum residue level.

The Meeting estimated a maximum residue level of 0.3 mg/kg, an STMR of 0.01 mg/kg and an HR of 0.01 mg/kg for the Subgroup of mandarins. The median (whole fruit) residue is 0.08 mg/kg.

Pome fruits

The US GAP (1×0.538 kg ai/ha, 7-day PHI) covers the commodities in the Codex pome fruit group except Japanese persimmon and residue trials on apple and pear matched this GAP.

In apple, residues were (n=11 from independent trials): < 0.01, 0.02, 0.03, 0.04, 0.05, 0.08, 0.09, 0.11, 0.12, 0.13, and 0.15 mg/kg with the highest analytical value of 0.18 mg/kg.

In pear, residues were (n=5 from independent trials): 0.12, 0.14, 0.15, 0.23 and 0.28 mg/kg with highest analytical value of 0.29 mg/kg.

The median residues in the datasets for apple and pear are within a 5-fold difference, however, the Mann-Whitney test showed that the residues were not from the same population. For pears, with higher residues, only five trial results were available, and the Meeting considered that 5 trials were not enough to support a pome fruit group maximum residue level.

For apples, the Meeting estimated a maximum residue level of 0.3 mg/kg, an STMR of 0.08 mg/kg and an HR of 0.18 mg/kg.

For pears, the Meeting agreed there were insufficient trials to estimate a maximum residue level.

Stone fruits

The US GAP (1×0.538 kg ai/ha, 3-day PHI) covers the commodities in the Codex stone fruits group and residue trials on cherries, plums and peaches matched this GAP, although residues were measured in fruit without stones.

The 2017 JMPR concluded that for stone fruit, residues measured in fruit without stones would overestimate whole-fruit residues by about 10 percent and that correcting for this factor would lead to the same maximum residue level estimation.

The median residues in the datasets for cherries, plums and peaches are within a 5-fold difference, however, the Kruskal-Wallis test showed that these data sets were not from the same population. Therefore, the Meeting decided to estimate separate recommendations for the subgroups.

Cherries

In cherries (without stones), residues were (n=5 from independent trials): 0.26, 0.47, 0.56, 0.84 and 0.91 mg/kg with highest analytical value of 0.97 mg/kg.

The Meeting agreed there were insufficient trials on cherries to estimate a maximum residue level.

Peaches (including Nectarine and Apricots), Subgroup of

In peaches (without stones), residues were (n=9): 0.20, 0.21, 0.24, 0.26, 0.38, 0.41, 0.44, 0.65 and 0.89 mg/kg with highest analytical value of 1.2 mg/kg.

The Meeting estimated a maximum residue level of 1.5 mg/kg, an STMR of 0.38 mg/kg and an HR of 1.2 mg/kg for the Subgroup of Peaches (including Nectarine and Apricots).

Plums

In plums (without stones), residues were (n=6): < 0.01, 0.016, 0.11, 0.18, 0.18 and 0.24 mg/kg with highest analytical value of 0.25 mg/kg

The Meeting estimated a maximum residue level of 0.5 mg/kg, an STMR of 0.145 mg/kg and an HR of 0.25 mg/kg for the Subgroup of plums.

Cane berries, Subgroup of

The US GAP (1×0.538 kg ai/ha, 7-day PHI) covers the commodities in the Codex cane berries subgroup and in residue trials on raspberries matching this GAP (PHI 7 days), residues were (n=5): 0.18, 0.18, 0.18, 0.24 and 0.36 mg/kg with highest analytical value of 0.41 mg/kg.

The Meeting estimated a maximum residue level of 0.7 mg/kg, an STMR of 0.18 mg/kg and an HR of 0.41 mg/kg for the Subgroup of cane berries.

Bush berries, Subgroup of

The US GAP (1×0.538 kg ai/ha, 7-day PHI) covers the commodities in the Codex bush berries subgroup and in residue trials on blueberries matching this GAP (PHI 7 days), residues were (n=6): 0.17, 0.23, 0.23, 0.24, 0.31 and 0.41 mg/kg with highest analytical value of 0.42 mg/kg.

The Meeting estimated a maximum residue level of 0.8 mg/kg, an STMR of 0.235 mg/kg and an HR of 0.42 mg/kg for the Subgroup of bush berries.

Small fruit vine climbing, Subgroup of

The US GAP (1×0.538 kg ai/ha, 7-day PHI) covers the commodities in the Codex small fruit vine climbing subgroup and in residue trials on grapes matching this GAP (PHI 7 days), residues were (n=12): 0.05, 0.05, 0.07, 0.10, 0.18, 0.18, 0.20, 0.22, 0.28, 0.32, 0.32 and 0.33 mg/kg with highest analytical value of 0.40 mg/kg.

The Meeting estimated a maximum residue level of 0.7 mg/kg, an STMR of 0.19 mg/kg and an HR of 0.4 mg/kg for the Subgroup of small fruit vine climbing.

Low growing berries, Subgroup of

The US GAP (1×0.538 kg ai/ha, 3-day PHI) covers the commodities in the Codex low growing berries subgroup and in residue trials on strawberries matching this GAP, residues were (n=8): 0.078, 0.35, 0.41, 0.46, 0.52, 0.56, 0.65 and 1.2 mg/kg with highest analytical value of 1.2 mg/kg

The Meeting estimated a maximum residue level of 2 mg/kg, an STMR of 0.49 mg/kg and an HR of 1.2 mg/kg for the Subgroup of low growing berries.

Avocado

The US GAP for avocado is 1×0.538 kg ai/ha, 7-day PHI and in residue trials matching this GAP, residues in avocados (without stones) were (n=5): 0.032, 0.037, 0.045, 0.049 and 0.082 mg/kg. In avocado flesh, residues were (n=5): < 0.01 (4) and 0.01 mg/kg.

Based on information available from other avocado residue studies, stones do not make up more than 15 percent of the whole fruit weight and the Meeting concluded that correcting the reported residues to express them on a whole fruit basis would lead to the same maximum residue level estimation.

The Meeting estimated a maximum residue level of 0.15 mg/kg, an STMR of 0.01 mg/kg and an HR of 0.01 mg/kg for avocado.

Fruiting vegetables, Cucurbits

The US GAP (1×0.538 kg ai/ha, 3-day PHI) covers the commodities in the Codex fruiting vegetables, Cucurbits and residue trials on cucumber, summer squash and melons matched the GAP.

In cucumber, residues were (n=6): 0.03, 0.04, 0.05, 0.06, 0.07 and 0.17 mg/kg

In Summer squash, residues were (n=5): 0.04, 0.06, 0.08, 0.08 and 0.13 mg/kg

In melons, residues were (n=6): 0.02, 0.05, 0.05, 0.07, 0.09 and 0.15 mg/kg

The median residues in the datasets for cucumber, summer squash and melons are within a 5-fold difference and the Kruskal-Wallis test showed that the residues were not from different populations. Therefore, the Meeting decided to estimate recommendations for the Group of Fruiting vegetables, Cucurbits.

The combined residues were (n=17): 0.02, 0.03, 0.04, 0.04, 0.05, 0.05, 0.05, 0.06, 0.06, 0.07, 0.07, 0.08, 0.08, 0.09, 0.13, 0.15 and 0.17 mg/kg with highest analytical value of 0.19 mg/kg.

The Meeting estimated a maximum residue level of 0.3 mg/kg, an STMR of 0.06 mg/kg and an HR of 0.19 mg/kg for the Group of Fruiting vegetables, Cucurbits.

Tomatoes, Subgroup of

The US GAP (1×0.538 kg ai/ha, 3-day PHI) covers the commodities in the Codex subgroup of tomatoes (PHI, 3 days) and in residue trials on tomatoes, residues were (n=11 from independent trials): 0.029, 0.029, 0.037, 0.038, 0.046, 0.052, 0.058, 0.061, 0.065, 0.071 and 0.19 mg/kg with highest analytical value of 0.19 mg/kg.

The Meeting estimated a maximum residue level of 0.3 mg/kg, an STMR of 0.052 mg/kg and an HR of 0.19 mg/kg for the Subgroup of tomatoes.

Peppers, Subgroup of

The US GAP (1×0.538 kg ai/ha, 3-day PHI) covers the commodities in the Codex subgroup of peppers and in residue trials matching this GAP, residues in sweet peppers (6) and *chili peppers* (3) were (n=9): 0.018, 0.054, 0.056, 0.056, 0.079, 0.082, 0.12, 0.12 and 0.19 mg/kg with highest analytical value of 0.22 mg/kg.

The Meeting estimated a maximum residue level of 0.3 mg/kg, an STMR of 0.079 mg/kg and an HR of 0.22 mg/kg for the Subgroup of peppers (except *martynia*, okra and roselle).

For dried chili peppers, the Meeting applied the default concentration factor of 10 to the data set for fresh peppers and estimated a maximum residue level of 3 mg/kg, an STMR of 0.79 mg/kg and an HR of 2.2 mg/kg for dried chili pepper.

Eggplant, Subgroup of

The US GAP (1×0.538 kg ai/ha, 3-day PHI) covers the commodities in the Codex subgroup of eggplants and in line with the 2018 JMPR recommendation that residue data on tomatoes or peppers (whichever is higher) could be extrapolated to eggplants, the Meeting agreed to extrapolate the data for peppers to estimate a maximum residue level of 0.3 mg/kg, an STMR of 0.079 mg/kg and an HR of 0.22 mg/kg for the Subgroup of eggplants

Legume vegetables, Group of

The US GAP (1×0.538 kg ai/ha, 7-day PHI) covers all commodities in the Codex legume vegetables group (except underground beans and peas) and residue trials on snap beans with pods, snap peas with pods, lima beans without pods and garden pea without pods matched this GAP.

Plant metabolism studies previously evaluated by the JMPR covered fruit (apple, orange, grape) and cereals (maize). As plant metabolism studies covering pulses and oilseeds or a third crop from a group different to fruits or cereal grains were not available, the Meeting could not estimate dietary intake of residues in legume vegetables.

Beans and peas with pods, Subgroup of

In snap beans with pods, residues were (n=6): 0.09, 0.094, 0.099, 0.1, 0.17 and 0.18 mg/kg and in snap peas with pods, residues were (n=3): 0.041, 0.1 and 0.13 mg/kg.

The Meeting agreed to combine the data for beans and peas with pods for mutual support to estimate subgroup maximum residue levels.

The combined data set for snap beans and snap peas is (n=9): 0.041, 0.09, 0.094, 0.099, 0.1, 0.1, 0.13, 0.17 and 0.18 mg/kg

The Meeting estimated but did not recommend a maximum residue level of 0.4 mg/kg for the Subgroups of beans with pods and peas with pods because a dietary intake assessment could not be completed.

Beans and peas without pods, Subgroup of

In lima beans without pods, residues were (n=5): < 0.01 (4) and 0.017 mg/kg and in garden peas without pods, residues were (n=5): < 0.01 (5).

The Meeting agreed to combine the data for beans and peas without pods for mutual support to estimate subgroup maximum residue levels.

The Meeting estimated but did not recommend a maximum residue level of 0.02 mg/kg for the Subgroups of beans with pods and peas without pods because a dietary intake assessment could not be completed.

Pulses, Group of

The US GAP (1×0.538 kg ai/ha, 7-day PHI) covers all commodities in the Codex dry beans and dry peas subgroups and residue trials on pinto bean (dry) and Australian winter pea (dry) matched this GAP.

Plant metabolism studies previously evaluated by the JMPR covered fruit (apple, orange, grape) and cereals (maize). As plant metabolism studies covering pulses and oilseeds or a third crop from a group different to fruits or cereal grains were not available, the Meeting could not estimate dietary intake of residues in pulses.

Dry beans, Subgroup of

In pinto bean (dry), residues were (n=9): < 0.01, < 0.01, 0.014, 0.016, 0.018, 0.028, 0.033, 0.088 and 0.17 mg/kg in Australian winter pea (dry), residues were (n=5): < 0.01, 0.011, 0.013, 0.014 and 0.052 mg/kg.

The median residues in the datasets for are within a 5-fold difference and the Kruskal-Wallis test showed that the residues were from the same population. Therefore, the Meeting decided to estimate subgroup maximum residue levels.

The combined data set is (n=14): < 0.01, < 0.01, < 0.01, 0.011, 0.013, 0.014, 0.014, 0.016, 0.018, 0.028, 0.033, 0.052, 0.088 and 0.17 mg/kg.

The Meeting estimated but did not recommend a maximum residue levels of 0.3 mg/kg for the Subgroup of dry beans (except soya bean) and the Subgroup of dry peas because a dietary intake assessment could not be completed.

Mints

In residue trials on mint matching the US GAP for peppermint and spearmint (1×0.538 kg ai/ha, 7-day PHI), residues in mint (fresh) were (n=5): 0.57, 0.64, 0.93, 1.6 and 5.3 mg/kg with highest analytical value of 5.5 mg/kg.

Plant metabolism studies previously evaluated by the JMPR covered fruit (apple, orange, grape) and cereals (maize). As plant metabolism studies covering leafy commodities or a third crop from a group different to fruits or cereal grains were not available, the Meeting could not evaluate the residue data on mints.

Residues in animal feeds

Pea vines and hays

In the residue trials on peas matching the US GAP (PHI, 7 days), residues in pea vines were (n=5): 0.26, 1.5, 1.7, 1.8 and 3.8 mg/kg with highest analytical value of 4.5 mg/kg and in pea hay, residues were (n=5): 0.78, 5.3, 6.8, 9.5 and 22 mg/kg with highest analytical value of 23 mg/kg

As no recommendations for legume vegetable food commodities were made (because no metabolism study was available for leafy commodities), the Meeting did not estimate animal feed intake from residues in pea vines or hay.

Fate of residues during processing

The Meeting received information on the fate of fenazaquin during processing of on orange, plum, grapes, tomato and mint. In the mint oil processing study, residue data for fresh mint was not reported. Therefore, the Meeting could not estimate a processing factor for mint oil.

Processing factors were calculated for fenazaquin (for maximum residue level estimation and for calculating livestock dietary burdens) and for total residues (for risk assessment).

Where residues concentrated in the processed food commodities, maximum residue levels were estimated using the estimated maximum residue levels for the raw commodities and applying the calculated best estimate processing factors.

Table 5.14.1 Estimated maximum residue levels for processed commodities

Commodity	Processing factors		Fenazaquin
	Calculated Processing Factors #	Best Estimate	Maximum Residue Level (mg/kg)
Orange			MRL=0.4
Citrus oil	78.7	78.7	32
Grapes			MRL=0.7
Dried grapes	2.2, 2.2, 2.9	2.2	1.5
Plums			MRL=0.5
Dried prunes	4.8	4.8	2.4

Notes:

The ratio of the residues in the processed item divided by the residue in the Raw Agricultural Commodity.

The Meeting estimated a maximum residue level of 40 mg/kg for citrus oil.

The Meeting estimated a maximum residue level of 1.5 mg/kg for dried grapes.

The Meeting estimated a maximum residue level of 3 mg/kg for dried prunes.

For processed food and feed commodities, STMR-Ps, median-Ps and HR-Ps (where relevant) were calculated using the STMRs or median residues for the raw commodities and applying the calculated best estimate processing factors.

Table 5.14.2 Calculated STMR-Ps and HR-Ps for processed food and feed commodities

RAC	Processing factors		Fenazaquin residue (mg/kg)	
	Calculated Processing factors #	Best Estimate	STMR-P	HR-P
Lemon			Median=0.08	
Lemons and lime (subgroup), juice	0.01 (orange)	0.01	0.0008	-
Orange			Median=0.125	
Oranges (subgroup), juice	0.01 (orange)	0.01	0.00125	-
Citrus oil	78.7 (orange)	78.7	9.84	
Citrus pulp, dry	0.18 (orange)		Median=0.15 0.027	
Grapefruit			Median=0.0.07	-
Pummelo and grapefruit (subgroup), juice	0.01 (orange)	0.01	0.0007	-
Mandarins			Median=0.0.08	-
Mandarin (subgroup), juice	0.01 (orange)	0.01	0.0008	-
Grapes			STMR=0.19	HR=0.4
Red wine	< 0.02, < 0.02, < 0.03	< 0.02	0.0038	
Grape juice	0.13, 0.14, 0.36	0.14	0.027	
Dried grapes	2.2, 2.2, 2.9	2.2	0.42	0.88
Plums			STMR=0.145	HR=0.25
Dried prunes	4.8	4.8	0.7	1.2
Tomato			STMR=0.052	
Paste	0.9	0.9	0.047	-
Puree	0.41	0.41	0.021	

Notes:

The ratios of the residue in the processed item divided by the residue in the Raw Agricultural Commodity.

Residues in animal commodities

Farm animal feeding studies

The 2019 JMPR evaluated a 28-day dairy cow feeding study where animals were dosed with 12.5 ppm, 37.5 ppm or 125 ppm fenazaquin by capsule. Milk samples were taken daily, milk and cream samples were taken from the Day-25 collection and analysed for fenazaquin. Liver, muscle, kidney and fat samples were taken about 8 hours after the last dose and analysed for fenazaquin and 2-OH fenazaquin acid.

Residues of fenazaquin in milk plateaued after 3 days and in tissues were highest in fat and lower in liver and kidney and in muscle were <LOQ at the highest dose. Similarly, residues of 2-OH fenazaquin acid were <LOQ in muscle. The highest levels of 2-OH fenazaquin acid were found in liver, with lesser amounts in kidney.

Table 5.14.3 Residues in milk and tissues from cattle dosed for 28 days with fenazaquin in the diet

Tissue	Dose level, ppm	Residues, mg eq/kg ^a									
		Fenazaquin		2-OH fenazaquin acid		4-OH quinazoline ^b		Fenazaquin + 2-OH fenazaquin acid		Fenazaquin + 2-OH fenazaquin acid + 4-OH quinazoline	
		max	mean	max	mean	max	mean	max	mean	max	mean
Liver	12.5	Not analysed		0.017	0.014	0.018	0.011	0.027	0.024	0.045	0.039
	37.5	< 0.01	< 0.01	0.052	0.049	0.039	0.037	0.062	0.059	0.1	0.096
	125	0.059	0.033	0.15	0.13	0.12	0.094	0.21	0.16	0.33	0.25
Kidney	12.5	Not analysed		0.009	0.009	< 0.002	< 0.002	< 0.019	< 0.019	< 0.021	< 0.021
	37.5	< 0.01	< 0.01	0.027	0.024	0.018	0.018	0.037	0.034	0.055	0.052
	125	0.022	0.013	0.061	0.056	0.018	0.014	0.074	0.071	0.092	0.089
Muscle	12.5	Not analysed		< 0.009	< 0.009	Assumed 0		< 0.019	< 0.019	< 0.019	< 0.019
	37.5	Not analysed		< 0.009	< 0.009	Assumed 0		< 0.019	< 0.019	< 0.019	< 0.019
	125	< 0.01	< 0.01	< 0.009	< 0.009	Assumed 0		< 0.019	< 0.019	< 0.019	< 0.019
Fat ^c	12.5	0.056	0.045	Not analysed		Assumed 0		0.056	0.045	0.056	0.045
	37.5	0.12	0.11	Not analysed		Assumed 0		0.12	0.11	0.12	0.11
	125	0.42	0.31	Not analysed		Assumed 0		0.42	0.31	0.42	0.31
Milk	37.5	< 0.01	< 0.01	< 0.0025 ^d	< 0.0025 ^d	< 0.015	< 0.015	< 0.00125	< 0.0125	< 0.0275	< 0.0275
	125	0.046	0.031	0.0115 ^d	0.00775 ^d	0.069	0.0465	0.0575	< 0.0125	0.13	< 0.0175

Notes:

^a For fenazaquin and 2-OH fenazaquin acid reported as not analysed or <LOQ mg/kg, residues were assumed to be 0.01 mg/kg and combined residues are listed as <combined fenazaquin-equivalent LOQs only when all residues were reported as < 0.01 mg/kg.

^b Calculated from 2-OH fenazaquin acid by a factor of 0.75 (liver) or 0.25 (milk) from the goat metabolism study evaluated by the 2017 JMPR. Residues in fat were assumed to be zero.

^c Perirenal fat (highest concentrations).

^d For milk, residues calculated from fenazaquin by a factor of 0.25 (for 2-OH fenazaquin acid) or 1.5 (for 4-quinazoline).

Farm animal dietary burden

The 2019 JMPR estimated maximum and mean dietary burdens of 0.133 ppm in cattle (arising from consumption of almond hulls). For the additional uses considered by the current Meeting, citrus pulp, dry, tomato pomace and apple pomace are relevant for farm animal dietary burden calculation (cattle only).

The Meeting considered that residues of 2-hydroxy-fenazaquin acid and 4-hydroxyquinoline detectable in those feeds would have little effect on levels of dietary burdens and estimated dietary burdens based on only fenazaquin residues.

Table 5.14.4 Estimated maximum and mean dietary burdens of farm animals

	Animal dietary burden: fenazaquin ppm, of dry matter diet							
	United States-Canada		European Union		Australia		Japan	
	Max	Mean	Max	Mean	Max	Mean	Max	Mean
Beef cattle	0.002	0.0025	0.04	0.04	0.18 ^①	0.18 ^②	-	-
Dairy cattle	0.15	0.15	0.022	0.022	0.17 ^③	0.17 ^④	-	-

Notes:

- ① Highest maximum beef or dairy cattle dietary burden suitable for MRL estimates for mammalian tissues.
- ② Highest mean beef or dairy cattle dietary burden suitable for STMR estimates for mammalian tissues.
- ③ Highest maximum dairy cattle dietary burden suitable for MRL estimates for mammalian milk.
- ④ Highest mean dairy cattle dietary burden suitable for STMR estimates for mammalian milk.

For dietary risk assessment, the Meeting estimated residues using the approach adopted by the 2019 Extra JMPR, using conversion factors calculated from the metabolism study to estimate unmeasured residues of 2-OH fenazaquin acid (0.25×fenazaquin) and 4-OH quinazoline (1.5×fenazaquin) in milk and unmeasured residues of 4-OH quinazoline in liver (0.75×2-OH-fenazaquin acid) and kidney (0.25×2-OH-fenazaquin acid).

Table 5.14.5 Maximum residue level, STMR and HR in mammalian animal commodities

	Feed level (ppm) for milk	Residues (mg eq/kg) in milk	Feed level (ppm) for tissues	Residues (mg eq/kg) in			
				Muscle	Liver	Kidney	Fat
MRL (beef or dairy cattle) based on fenazaquin+2-OH fenazaquin acid							
Feeding study	37.5	< 0.0125	12.5	< 0.019	0.027	< 0.019	0.056
Dietary burden and highest residue	0.17	< 0.000057	0.18	< 0.00027	0.00039	< 0.00027	0.0008
STMR (beef or dairy cattle) based on fenazaquin+2-OH fenazaquin acid+4-OH quinazoline							
Feeding study	37.5	< 0.0275	12.5	< 0.019	0.039	< 0.021	0.045
Dietary burden and highest residue	0.17	< 0.00013	0.18	< 0.00027	0.00056	< 0.0003	0.00065
HR (beef or dairy cattle) based on fenazaquin+2-OH fenazaquin acid+4-OH quinazoline							
Feeding study	37.5	< 0.0275	12.5	< 0.019	0.045	< 0.019	0.056
Dietary burden and highest residue	0.18	< 0.00013	0.18	< 0.00027	0.00065	< 0.0003	0.00081

Based on the anticipated residues, the Meeting estimated maximum residue levels of 0.02 (*) mg/kg for milks; milk fats; meat (from mammals other than marine mammals; as fat); edible offal (mammalian) and mammalian fats (except milk fats).

The Meeting estimated STMRs of 0 mg/kg for milks and meat (from mammals other than marine mammals) and 0.00065 mg/kg for mammalian fats (except milk fats).

The Meeting estimated HRs of 0 mg/kg for meat (from mammals other than marine mammals) and 0.00081 mg/kg for mammalian fats (except milk fats).

For mammalian edible offal, the Meeting estimated an STMR of 0.00056 mg/kg and a HR of 0.00065 mg/kg (based on residues in liver).

For poultry, since none of the feed items were applicable, the Meeting did not estimate maximum residue levels for eggs or poultry commodities.

RECOMMENDATIONS

On the basis of the data obtained from supervised trials, the Meeting concluded that residue levels listed in Annex 1 are suitable for establishing maximum residue limits and for IEDI and international estimate of short-term intakes assessment.

Definition of the residue for compliance with the MRL and for dietary risk assessment for plant commodities: *Fenazaquin*.

Definition of the residue for compliance with the MRL for animal commodities: *Sum of fenazaquin and 2-hydroxy-fenazaquin acid, expressed as fenazaquin equivalents*.

Definition of the residue for dietary risk assessment for animal commodities: *Sum of fenazaquin, and 2-hydroxy-fenazaquin acid and tautomeric forms of 4-hydroxyquinazoline, expressed as fenazaquin equivalents*.

The residue is fat-soluble.

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The ADI for fenazaquin is 0–0.05 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for fenazaquin were estimated for the 17 GEMS/Food Consumption Cluster Diets using the STMR or STMR-P values estimated by the JMPR. The results are shown in Annex 3 of the 2022 JMPR Report.

The IEDIs ranged from 0–2 percent of the maximum ADI. The Meeting concluded that long-term dietary exposure to residues of fenazaquin from uses considered by the JMPR is unlikely to present a public health concern.

Acute dietary exposure

The ARfD for fenazaquin is 0.1 mg/kg bw. The International Estimate of Short Term Intakes (international estimate of short-term intakes) for fenazaquin were calculated for the food commodities and their processed commodities for which HRs/HR-Ps or STMRs/STMR-Ps were estimated by the present Meeting and for which consumption data were available. The results are shown in Annex 4 of the 2022 JMPR Report.

The international estimate of short-term intake varied from 0–60 percent of the ARfD for children and 0–20 percent of the ARfD for the general population. The Meeting concluded that acute dietary exposure to residues of fenazaquin from uses considered by the present Meeting is unlikely to present a public health concern.

5.15 Fluazaindolizine (327)

TOXICOLOGY

Fluazaindolizine is the ISO-approved common name for 8-chloro-*N*-[(2-chloro-5-methoxyphenyl)sulfonyl]-6-(trifluoromethyl)-imidazol[1,2-*a*]pyridine-2-carboxamide (IUPAC), Chemical Abstracts Service number 1254304-22-7. This compound is a sulfonamide of the imidazopyridine class. The substance is a nematicide for application in various crops including cucumbers, tomatoes and carrots. Its mode of action (MOA) in target organisms has not been sufficiently elucidated as yet.

Fluazaindolizine has not previously been evaluated by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) and was reviewed by the present Meeting at the request of the Codex Committee on Pesticide Residues (CCPR). All critical studies contained statements of compliance with good laboratory practice (GLP) and were conducted in accordance with current test guidelines, unless otherwise specified. Additional information that would complement the toxicological studies is scarce from public scientific literature, as is to be expected for such a new compound.

Biochemical aspects

Fluazaindolizine was subject to extensive investigations of its toxicokinetic behaviour and metabolism in the rat and to a much lesser extent in other species and in vitro. For the absorption, distribution, metabolism and excretion (ADME) studies in rats and mice, the test substance was ¹⁴C-radiolabelled in the imidazopyridine moiety or in the phenyl ring.

Following oral administration of a single low dose of 10 mg/kg body weight (bw) to rats, rapid absorption was observed, the time to reach maximum concentration (T_{max}) being 0.25–0.625 hours after administration: this was slower (T_{max} at 3–6 hours) after a single high dose of 200 mg/kg bw. Based on urinary and biliary excretion, an oral absorption of 52–60 percent was estimated for the low dose whereas absorption of the high dose was slightly lower at 45–50 percent. The applied radioactivity was widely distributed throughout the body but total organ and tissue residues after seven days accounted for less than 0.5 percent of the applied dose, irrespective of dose or repeated administration of unlabelled compound. Highest concentrations were consistently found in plasma, followed by liver and kidneys. There was no evidence of accumulation.

Elimination was virtually complete after seven days with the major part of radioactivity excreted within the first 24 hours. At the low dose, elimination via urine and faeces was more or less equal, accounting for 41–54 percent for the two routes in the different groups and experiments. Repeated low dose administration did not alter this pattern. Excretion via bile was variable, ranging from 5–18 percent in the various groups, Excretion via exhalation was negligible.

Metabolism in the rat was limited and the major part of the administered dose (AD) excreted chemically unchanged. However several metabolites were identified resulting from *O*-demethylation, hydroxylation of the phenyl ring, and hydrolysis of the amide bond. A few metabolites were further conjugated. The only metabolite excreted in appreciable quantities was IN-QEK31. This metabolite amounted to 8–10 percent of AD in urine and bile when combined.

In the mouse, elimination was similar in rapidity to that seen in the rat and virtually complete, but faecal elimination was by far the predominant route. Biliary excretion was not investigated in the mouse. Similar to the rat, metabolism was limited and metabolic pathways and resulting metabolites were the same in both species.

A qualitatively similar metabolism to that seen in vivo was confirmed by a comparative in vitro study in which hepatocytes of mouse, rat, rabbit, dog and human origin were used. In all these species, metabolism was similar even though the most rapid biotransformation took place in human cells with dog liver cells showing the lowest metabolic rate. Again, unchanged parent was the most abundant analyte. Metabolites were the same as in vivo but there were quantitative differences between species. No unique human metabolite was found.

Analysis of blood samples obtained from routine toxicological studies of different duration (14 days to approximately one year) revealed an increase in plasma concentrations of fluazaindolizine with dose. This increase, however, was partly sublinear suggesting a saturation of absorption at doses above 44 mg/kg bw per day (300 ppm) in mice and greater than 29 mg/kg bw per day (500 ppm) in female rats, but the effect was not seen in male rats or in dogs. The same metabolites as in the ADME studies were found in plasma but at very much lower amounts than the parent which was consistently the predominant compound.

Toxicological data

The acute oral median lethal dose (LD₅₀) of fluazaindolizine in rats ranged from 940 to 1248 mg/kg bw for different batches.

Dermal LD₅₀ values of greater than 2000 mg/kg bw or even greater than 5000 mg/kg bw were reported. Inhalation median lethal concentrations (LC₅₀) of greater than 5.3 mg/L, and greater than 5.8 mg/L were reported.

The compound was either not, or only marginally, irritating to the skin or to the eyes of rabbits. Studies for skin sensitization revealed contradictory results depending on the batch tested. The current technical fluazaindolizine was not sensitizing, though some older batches showed evidence of sensitizing potential.

In repeat dose studies target organs were the kidney in rodents and the liver in dogs.

In a 90-day study in mice, dietary doses of 0, 200, 1000, 3000 or 7000 ppm (equal to 0, 44, 146, 444 and 1101 mg/kg bw per day for males, 0, 50, 157, 511 and 1177 mg/kg bw per day for females) were administered. The NOAEL was 1000 ppm (equal to 146 mg/kg bw per day), based on histopathological findings in the gall bladder and kidneys in both sexes at 3000 ppm (equal to 444 mg/kg bw per day).

In a combined 90-day study of general toxicity and neurotoxicity (see also below) in rats, fluazaindolizine was fed at dietary doses of 0, 500, 1500, 3000 or 6000 ppm (equal to 0, 28, 84, 166 and 348 mg/kg bw per day for males, 0, 31, 97, 189 and 376 mg/kg bw per day for females). The NOAEL was 1500 ppm (equal to 84 mg/kg bw per day) based on histopathological findings in the kidney at 3000 ppm (equal to 166 mg/kg bw per day).

In a 90-day toxicity feeding study in dogs, the initial dose levels were 0, 125, 500, 1500 or 4000 ppm. The maximum dose was reduced because of lower food intake, first to 3000 ppm and then, because of one female animal's death, to 2500 ppm. The corresponding mean daily intakes were approximately 5.5, 20, 59 and 68 mg/kg bw for males, and for females 5.1, 21, 61, and 93 mg/kg bw. The NOAEL was 500 ppm (equal to 20 mg/kg bw per day) based on mild histopathological and clinical chemistry findings of liver toxicity, and a lower body weight gain in males at 1500 ppm (equal to 59 mg/kg bw per day).

In a one-year study in dogs, doses of 0, 125, 500, 1000 or 2000 ppm (equal to 0, 4.4, 20, 36 and 66 mg/kg bw per day for males, 0, 4.6, 17, 37 and 70 mg/kg bw per day for females) were applied. The NOAEL of 1000 ppm (equal to 36 mg/kg bw per day) was based on transient body weight losses, lower

food consumption and food efficiency in both sexes as well as on mild anaemia and one death in females at 2000 ppm (equal to 66 mg/kg bw per day).

The overall NOAEL in dogs was 36 mg/kg bw per day with a LOAEL of 59 mg/kg bw per day.

In an 18-month carcinogenicity study in mice, fluazaindolizine was administered at dietary doses of 0, 100, 300, 1000 or 3000 ppm (equal to 0, 15, 43, 142 and 427 mg/kg bw per day for males, 0, 17, 54, 177, and 525 mg/kg bw per day for females). The NOAEL was 1000 ppm (equal to 142 mg/kg bw per day), based on increased incidences of amyloidosis in numerous organs in males and females at 3000 ppm (equal to 427 mg/kg bw per day). The NOAEL for carcinogenicity was 3000 ppm (equal to 427 mg/kg bw per day), the highest dose tested.

In a combined chronic toxicity and carcinogenicity study in rats, fluazaindolizine was administered over 12 or 24 months. Over 12 months the nominal concentrations were 0, 150, 500, 1500 or 4500 ppm (equal to 0, 6.5, 25, 76 and 241 mg/kg bw per day for males, 0, 6.8, 27, 78 or 254 mg/kg bw per day for females). The NOAEL for long-term toxicity was 1500 ppm (equal to 76 mg/kg bw per day) based on histopathological findings and a few gross lesions of the kidneys in both sexes, an increase in relative kidney weight in females and marginal urinalysis findings in males at 4500 ppm (equal to 241 mg/kg bw per day). The NOAEL for carcinogenicity was 4500 ppm (equal to 241 mg/kg bw per day), the highest dose tested.

The meeting concluded that fluazaindolizine is not carcinogenic in mice or rats.

Fluazaindolizine was tested for genotoxicity in an adequate range of studies in vitro and in vivo. The in vitro studies for gene mutation in bacteria and mammalian cells were all negative. Various batches of fluazaindolizine were tested. By contrast, the compound proved positive for chromosome aberrations in peripheral human lymphocytes. However, when the same (and also other) batches of fluazaindolizine were tested in the in vivo micronucleus assay in mice with examination either of bone marrow cells or peripheral reticulocytes, the results from these studies were consistently negative.

The Meeting concluded that fluazaindolizine is unlikely to be genotoxic in vivo.

In view of the lack of in vivo genotoxicity and the absence of carcinogenicity in mice and rats, the Meeting concluded that fluazaindolizine is unlikely to pose a carcinogenic risk to humans.

In a two-generation study, fluazaindolizine was administered to rats at dietary concentrations of 0, 150, 500, 1500 or 4500 ppm. During certain study intervals, namely the lactation periods in F0 and F1 females and up to postnatal day (PND) 42 for the F1 offspring, these dietary doses were reduced to 90, 300, 900 or 2700 ppm to adjust for increased food consumption and compound intake. The overall mean daily intakes in the parental generation were lowest in males during the premating phase and were calculated as 0, 9, 30, 88 and 265 mg/kg bw. The parental NOAEL was 1500/900 ppm (equal to 88 mg/kg bw per day) based on lower body weight gain and reduced food consumption, gross and histopathological lesions in the kidneys and the urinary tract, supported by urinalysis findings at 4500 ppm (equal to 265 mg/kg bw per day). The reproductive NOAEL was the highest dose tested, 4500/2700 ppm (equal to 265 mg/kg bw per day). Since microscopic lesions in the kidney and urinary bladder were observed in weanlings at the two upper dose levels, an offspring NOAEL of 500/300 ppm (equal to 30 mg/kg bw per day) was identified.

In a developmental study in rats, fluazaindolizine was administered by oral gavage from GD 6 to GD 20 at dose levels of 0, 35, 100, 200 or 400 mg/kg bw per day. The maternal NOAEL was 200 mg/kg bw per day based on lower food consumption throughout the treatment period and initial body weight losses followed by lower body weight gain for the rest of the study at 400 mg/kg bw per day. The developmental NOAEL was 200 mg/kg bw per day based on lower mean fetal weight at 400 mg/kg bw per day.

In a developmental study in rabbits, fluazaindolizine was administered by oral gavage at doses of 0, 10, 30 or 120 mg/kg bw per day from days 7–28 of presumed gestation. The maternal NOAEL was 30 mg/kg bw per day, based on poor condition in a number of does at 120 mg/kg bw per day that was characterized by lower food intake, a decrease in body weight gain and transient body weight losses, followed by abortion or premature killing for humane reasons. There was histopathological evidence of nephrotoxicity and liver toxicity, along with haemorrhages in the stomach and urinary tract. In the absence of any adverse effects the NOAEL for developmental toxicity was 120 mg/kg bw per day, the highest dose tested.

The Meeting concluded that fluazaindolizine is not teratogenic.

In an acute neurotoxicity study in rats, doses of 0, 30, 125, 450 or 1750 mg/kg bw were administered by oral gavage. The systemic NOAEL in this study was 125 mg/kg bw based on effects on body weight and feed consumption, lower body temperature on day of dosing and a transient decrease in motor activity at 450 mg/kg bw per day. The NOAEL for acute neurotoxicity was 1750 mg/kg bw, the highest dose tested.

In a combined general toxicity and neurotoxicity study over 90 days (see above) no evidence of neurotoxicity was observed up to 6000 ppm (equal to 348 mg/kg bw per day), the highest dose tested.

The Meeting concluded that fluazaindolizine is not neurotoxic.

In a four-week dietary immunotoxicity study, fluazaindolizine was fed to male rats at dietary concentrations of 0, 500, 1500 or 5500 ppm (equal to 35.5, 106 and 393 mg/kg bw per day). The NOAEL for immunotoxicity was 5500 ppm (equal to 393 mg/kg bw per day), the highest dose tested.

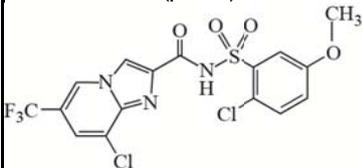
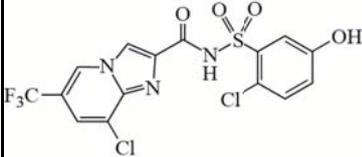
The Meeting concluded that fluazaindolizine is not immunotoxic.

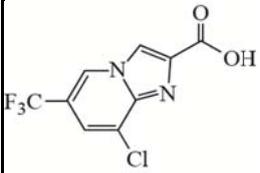
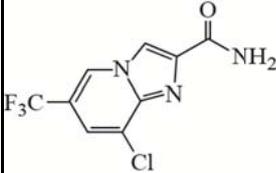
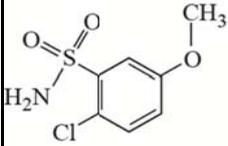
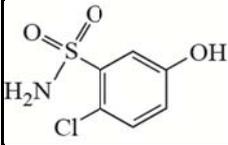
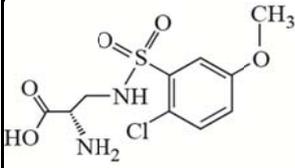
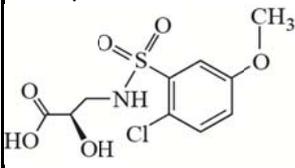
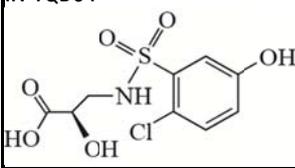
A small number of mechanistic studies were performed to investigate the potential effects of fluazaindolizine on the endocrine system even though no such evidence was obtained in the many routine toxicological studies carried out. These studies were not informative for risk assessment.

Toxicological data on metabolites and/or degradates

A number of plant and animal metabolites were examined for various toxicological end-points.

Overview of toxicological characterization of plant/livestock metabolites of fluazaindolizine (parent compound included for comparison)

Compound, codes and structure	Major rat metabolite (≥ 10 percent of AD)?	Genotoxicity assessment	General toxicity	Conclusion on toxicological reference values
Fluazaindolizine (parent) 	Parent	Not genotoxic in vivo	Full dataset	ADI: 0.3 mg/kg bw ARfD: 1.0 mg/kg bw
IN-REG72 	No; Minor rat and food animal metabolite	Not genotoxic (studies in vitro and in vivo)	No data, but covered by parent (structural similarity)	Covered by parent ADI and ARfD

Compound, codes and structure	Major rat metabolite (≥ 10 percent of AD)?	Genotoxicity assessment	General toxicity	Conclusion on toxicological reference values
IN-QEK31 	Yes; (up to 8–10 percent in urine and bile if combined); Food animal, crop, soil and water metabolite	Not genotoxic in vivo (studies)	Comprehensive data set; not more toxic than parent	Covered by parent ADI and ARfD
IN-RYC33 	No; Animal (hen) metabolite	No data; negative QSAR prediction (OASIS, ISS)	No data, but covered by IN-QEK31 (structural similarity) and consequently by parent	Covered by parent ADI and ARfD
IN-F4106 	No; Rat and food animal, soil and water metabolite; Also process intermediate in manufacture of parent	Not genotoxic in vivo (studies)	Comprehensive data set, not more toxic than parent	Covered by parent ADI and ARfD
IN-A5760 	No; Rat and food animal, crop, water and soil metabolite	Not genotoxic in vivo (studies)	No data, but covered by IN-F4106 (structural similarity and further biotransformation) and consequently by parent	Covered by parent ADI and ARfD
IN-QZY47 	No; Rodent intermediate but not present intact in detectable quantities; crop metabolite	Not genotoxic (in vitro data)	Limited database suggesting lower toxicity than parent	Covered by parent ADI and ARfD
IN-TMQ01 	No; Rat intermediate but not present intact in detectable quantities; crop metabolite	Not genotoxic (in vitro data)	Limited database suggesting lower toxicity than parent	Covered by parent ADI and ARfD
IN-TQD54 	No; Crop metabolite	Not genotoxic (in vitro data)	Low acute oral toxicity in the rat; no further data	TTC for non-genotoxic compounds (Cramer class III) should be used (1.5 $\mu\text{g}/\text{kg}$ bw/day)
IN-UJV12	No; Crop metabolite	Unlikely to be genotoxic (studies)	Low acute oral toxicity in the rat; no further data	TTC for non-genotoxic compounds (Cramer class III) should be (1.5 $\mu\text{g}/\text{kg}$ bw/day)

Compound, codes and structure	Major rat metabolite (≥ 10 percent of AD)?	Genotoxicity assessment	General toxicity	Conclusion on toxicological reference values

Notes:

AD Administered dose.

ADI Acceptable daily intake.

ARfD Acute reference dose.

TTC Threshold of toxicological concern.

Microbiological data

There was no information available in the public domain, and no experimental data were provided which addressed the possible impact of fluazaindolizine residues on the human intestinal microbiome.

Human data

From health observations in manufacturing personnel, no adverse effects had been reported. No information on poisoning incidents was available.

The Meeting concluded that the existing database on fluazaindolizine was adequate to characterize the potential hazards to the general population, including fetuses, infants and children.

Toxicological evaluation

The Meeting established an ADI of 0–0.3 mg/kg bw for fluazaindolizine based on the NOAEL of 30 mg/kg bw per day for maternal toxicity in the developmental toxicity study in rabbits, and offspring toxicity in the two-generation study in rats and using a safety factor of 100. The ADI is supported by the NOAEL of 36 mg/kg bw per day from the one-year study in dogs.

The Meeting established an ARfD of 1.0 mg/kg bw for fluazaindolizine from the NOAEL of 125 mg/kg for systemic toxicity in the acute neurotoxicity study in rats and using a safety factor of 100.

A toxicological monograph was prepared.

Levels relevant to risk assessment of fluazaindolizine

Species	Study	Effect	NOAEL	LOAEL
Mouse	78-week study of toxicity and carcinogenicity ^a	Toxicity	1000 ppm, equal to 142 mg/kg bw per day	3000 ppm, equal to 427 mg/kg bw per day
		Carcinogenicity	3000 ppm, equal to 427 mg/kg bw per day ^c	-
Rat	Acute neurotoxicity study ^b	Systemic toxicity	125 mg/kg bw	450 mg/kg bw per day
	Two-year study of toxicity and carcinogenicity ^a	Toxicity	1500 ppm, equal to 76 mg/kg bw per day	4500 ppm, equal to 241 mg/kg bw per day
		Carcinogenicity	4500 ppm, equal to	-

Species	Study	Effect	NOAEL	LOAEL
			241 mg/kg bw per day ^c	
	Two-generation study of reproductive toxicity ^a	Reproductive toxicity	4500/2700 ppm equal to 265 mg/kg bw per day ^c	-
		Parental toxicity	1500/900 ppm equal to 88 mg/kg bw per day	4500/2700 ppm equal to 265 mg/kg bw per day
		Offspring toxicity	500/300 ppm equal to 30 mg/kg bw per day	1500/900 ppm equal to 88 mg/kg bw per day
	Developmental toxicity study ^b	Maternal toxicity	200 mg/kg bw per day	400 mg/kg bw per day
		Embryo/fetal toxicity	200 mg/kg bw per day	400 mg/kg bw per day
Rabbit	Developmental toxicity study ^b	Maternal toxicity	30 mg/kg bw per day	120 mg/kg bw per day
		Embryo/fetal toxicity	120 mg/kg bw per day ^c	-
Dog	90-day and one-year studies ^{a, d}	Toxicity	1000 ppm, equal to 36 mg/kg bw per day	1500 ppm, equal to 59 mg/kg bw per day

^a Dietary administration.

^b Gavage administration.

^c Highest dose tested.

^d Two studies combined.

Acceptable daily intake (ADI), applies to fluazaindolizine, IN-QEK31, IN-REG72, IN-QZY47, IN-TMQ01, IN-F4106, IN-A5760 and IN-RYC33

0–0.3 mg/kg bw

Acute reference dose (ARfD), applies to fluazaindolizine, IN-QEK31, IN-REG72, IN-QZY47, IN-TMQ01, IN-F4106, IN-A5760 and IN-RYC33

1.0 mg/kg bw

Information that would be useful for the continued evaluation of the compound

Results from epidemiological, occupational health and other such observational studies of human exposure.

Critical end-points for setting guidance values for exposure to fluazaindolizine

Absorption, distribution, excretion and metabolism in mammals

Rate and extent of oral absorption	Rapid (T_{max} 0.25–0.625 h at low dose of 10 mg/kg bw); Absorption 52–60 percent at low dose, 45–50 percent at high dose of 200 mg/kg bw
Dermal absorption	No data
Distribution	Widely distributed, highest residues in plasma and liver; Much of non-absorbed portion found in GIT and contents
Potential for accumulation	No evidence of accumulation
Rate and extent of excretion	Nearly complete within 7 days; mostly excreted within 24 h

Metabolism in animals	Limited; at least 7 metabolites present in small amounts; Mainly hydroxylation of the phenyl ring, <i>O</i> -methylation and cleavage of amide bond, sometimes followed by conjugations
Toxicologically significant compounds in animals and plants	Fluazaindolizine, IN-QEK31, IN-REG72, IN-QZY47, IN-TMQ01, IN-F4106, IN-A5760, IN-RCY33
Acute toxicity	
Rat, LD ₅₀ , oral	940 mg/kg bw
Rat, LD ₅₀ , dermal	>5000 mg/kg bw
Rat, LC ₅₀ , inhalation	>5.8 mg/L
Rabbit, dermal irritation	Not irritating
Rabbit, ocular irritation	Not irritating
Dermal sensitization	Not sensitizing (M&K test, LLNA) when batches from current manufacturing process were tested
Short-term studies of toxicity	
Target/critical effect	Body weight, feed consumption, anaemia, mortality, liver (dog); kidney (rat, mouse); gall bladder, (mouse)
Lowest relevant oral NOAEL	36 mg/kg bw per day (dog)
Lowest relevant dermal NOAEL	1000 mg/kg bw per day (rat)
Lowest relevant inhalation NOAEC	No data
Long-term studies of toxicity and carcinogenicity	
Target/critical effect	Amyloidosis (mouse); nephrotoxicity (rat)
Lowest relevant NOAEL	76 mg/kg bw per day (rat)
Carcinogenicity	Not carcinogenic in mice or rats
Genotoxicity	
	Unlikely to be genotoxic in vivo
Reproductive toxicity	
Target/critical effect	Food consumption and body weight (parental); microscopic lesions in kidney and urinary bladder (parental and offspring)
Lowest relevant parental NOAEL	88 mg/kg bw per day (rat)
Lowest relevant offspring NOAEL	30 mg/kg bw per day (rat)
Lowest relevant reproductive NOAEL	265 mg/kg bw per day, highest dose tested (rat)
Developmental toxicity	
Target/critical effect	Body weight gain and food intake (rat) Reduced food intake and body weight, abortions and mortality (rabbit) Reduced fetal weight (rat)
Lowest relevant maternal NOAEL	30 mg/kg bw per day (rabbit)
Lowest relevant embryo/fetal NOAEL	200 mg/kg bw per day (rat), 120 mg/kg bw per day, highest dose tested (rabbit)
Neurotoxicity	
Acute neurotoxicity NOAEL	125 mg/kg bw, for systemic toxicity (rat) 1750 mg/kg bw, highest dose tested, for neurotoxicity (rat)
Subchronic neurotoxicity NOAEL	348 mg/kg bw per day, the highest dose tested (rat)
Developmental neurotoxicity NOAEL	No data

Other toxicological studies	
Immunotoxicity	393 mg/kg bw per day, the highest dose tested (rat)
Studies on toxicologically relevant metabolites	
IN-QEK31	Not genotoxic in vivo, toxicity similar to parent compound (experimental studies on acute, short-term, reproductive and developmental toxicity)
IN-REG72	Not genotoxic in vitro or in vivo
IN-F4106	Not genotoxic in vivo, toxicity similar to parent compound (experimental studies on acute, short-term, reproductive and developmental toxicity)
IN-A5760	Not genotoxic in vivo
IN-QZY47	Not genotoxic (in vitro data), very low acute oral toxicity, short-term toxicity less severe than with parent
IN-TMQ01	Not genotoxic (in vitro data), very low acute oral toxicity, no effects in short-term toxicity studies up to 847 mg/kg bw per day (less toxic than parent)
IN-TQD54	Not genotoxic (in vitro data), very low acute oral toxicity
IN-UJV12	Unlikely to be genotoxic
Microbiological data	No data available
Human data	Not available for this new compound; no evidence of health effects in manufacturing plant personnel

Summary

	Value	Study	Safety factor
ADI ^a	0–0.3 mg/kg bw	Developmental study in rabbits and two-generation study in rats, supported by one-year study in dogs	100
ARfD ^a	1.0 mg/kg bw	Acute neurotoxicity (rat)	100

Notes:

^a Applies to fluazaindolizine and the following metabolites: IN-QEK31, IN-REG72, IN-QZY47, IN-TMQ01, IN-F4106, IN-A5760, and IN-RYC33.

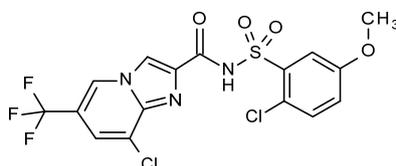
RESIDUE AND ANALYTICAL ASPECTS

Fluazaindolizine is a new selective nematicide for the control of plant parasitic nematodes. At the Fifty-first Session of the CCPR, it was scheduled for evaluation as a new compound in 2021, then rescheduled to the 2022 JMPR.

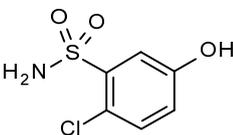
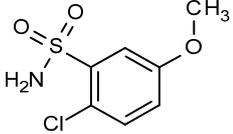
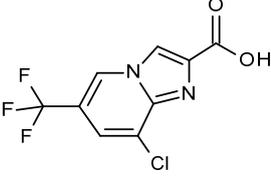
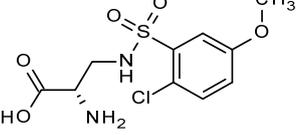
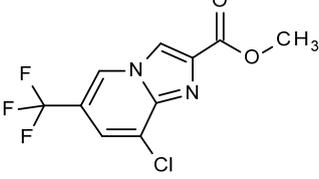
Fluazaindolizine is used for annual crops (e.g., fruiting vegetables, cucurbits, root vegetables, row crops) and certain perennial crops (e.g., citrus, tree nuts and stone fruits). Application methods include drip, drench, in furrow spray with or without soil incorporation either before or at planting, with the option for follow-up in crop treatment.

The Meeting received information on the metabolism of fluazaindolizine and a number of its metabolites in lactating goats and laying hens, the metabolism of fluazaindolizine in tomato, carrot, potato, soya bean and sugarcane and follow crops, methods of residue analysis, freezer storage stability, GAP information, supervised residue trials on a range of crops as well as livestock feeding studies (lactating cow).

Fluazaindolizine



The following abbreviations are used for the major metabolites discussed below:

Code Names, MW	Chemical Name	Chemical Structure
IN-A5760	2-chloro-5-hydroxybenzenesulfonamide	
IN-F4106	2-chloro-5-methoxybenzenesulfonamide	
IN-QEK31	8-chloro-6-(trifluoromethyl)imidazo[1,2-a]pyridine-2-carboxylic acid	
IN-QZY47	3-[[[(2-chloro-5-methoxyphenyl)sulfonyl]amino]-L-alanine	
IN-R2W56 IN-QEK31 methyl ester	8-chloro-6-(trifluoromethyl)imidazo[1,2-a]pyridine-2-carboxylic acid methyl ester	

Code Names, MW	Chemical Name	Chemical Structure
IN-R3Z85 IN-A5760 glucose conjugate	2-chloro-5-(β -D-glucopyranosyloxy)benzenesul-fonamide	
IN-REG72	8-chloro-N-[(2-chloro-5-hydroxyphenyl)sulfonyl]-6-(trifluoromethyl)imidazo[1,2-a]pyridine-2-carboxamide	
IN-RSU03 (racemate) IN-TMQ01 (R-enantiomer)	3-[[[(2-chloro-5-methoxyphenyl)sulfonyl]amino]-2-hydroxypropanoic acid	
IN-RYC33	8-chloro-6-(trifluoromethyl)imidazo[1,2-a]pyridine-2-carboxamide	
IN-TUT81 IN-QZY47 malonyl conjugate	N-(carboxyacetyl)-3-[[[(2-chloro-5-methoxyphenyl)sulfonyl]-amino]-L-alanine	
IN-UGA20 IN-QEK31 glucose conjugate	β -D-glucopyranose 1-[8-chloro-6-(trifluoromethyl)imidazo[1,2-a]pyridine-2-carboxylate]	
IN-UHD13 IN-QEK31 inositol conjugate	[(2S,3R,5S,6S)-2,3,4,5,6-pentahydroxycyclohexyl]1-[8-chloro-6-(trifluoromethyl)imidazo[1,2-a]pyridine-2-carboxylate]	
IN-UJV12 (S-enantiomer)	3-[[[(2-chloro-5-hydroxyphenyl)sulfonyl]amino]-L-alanine	

Code Names, MW	Chemical Name	Chemical Structure
IN-UJU44 QEK31 malic acid conjugate	2-[[[8-chloro-6-(trifluoromethyl)imidazo[1,2-a]pyridin-2-yl]carbonyl]oxy]butanedioic acid	
IN-UNS90 (racemate) IN-TQD54 (R-enantiomer)	3-[[[(2-chloro-5-hydroxyphenyl)sulfonyl]amino]-2-hydroxypropanoic acid	
IN-VM862	3-chloro-5-(trifluoromethyl)pyridin-2-amine	
IN-WUK12 Glutamic acid conjugate of IN QEK31	N-[[[8-chloro-6-(trifluoromethyl)imidazo[1,2-a]pyridine-2-yl]carbonyl]-L-glutamic acid	
IN-A5760 glucuronide conjugate	2-chloro-5-(β-L-glucopyranuronosyloxy)benzenesulfonamide	
IN-A5760 sulfate conjugate	2-chloro-5-(sulfooxy)benzenesulfonamide	
IN-REG72 glucose conjugate	8-chloro-N-[(2-chloro-5-(β-D-glucopyranosyl)phenyl)sulfonyl]-6-(trifluoromethyl)imidazo[1,2-a]pyridine-2-carboxamide	
IN-RSU03 glucose conjugate	3-[[[(2-chloro-5-methoxyphenyl)sulfonyl]amino]-(2R)-(β-D-glucopyranosyloxy)propanoic acid	

Code Names, MW	Chemical Name	Chemical Structure
IN-RSU03 malonyl conjugate	(2R)-[[[6-O-(2-carboxyacetyl)-β-D-glucopyranosyl]oxy]-3-[[2-chloro-5-methoxyphenyl)sulfonyl]amino]-propanoic acid	
IN-UNS90 glucose conjugate	3-[[[2-chloro-5-hydroxyphenyl)sulfonyl]amino]-(2R)-(β-D-glucopyranosyloxy)-propanoic acid	
IN-UNS90 phenolic glucose conjugate	3-[[[2-chloro-5-(β-D-glucopyranosyloxy)phenyl)sulfonyl]amino]-(2R)-hydroxypropanoic acid	
IN-QEK31 glycerol glucuronide	imidazo[1,2-a]pyridine-2-carboxylic acid, 8-chloro-6-(trifluoromethyl)-, 3-(hexopyranuronosyloxy)-2-hydroxypropyl ester	
Acetylated IN-QZY47 IN-QZY47 acetyl conjugate	N-acetyl-3-[[[2-chloro-5-methoxyphenyl)sulfonyl]amino]-L-alanine	
IN-A5760 glutathione conjugate		

Based on the information on physical and chemical properties, fluazaindolizine is not volatile and is not lipid soluble, with a $\log P_{ow}$ of around -0.16. Fluazaindolizine is hydrolytically stable at environmental pH and aqueous photolysis is likely to be a major degradation pathway of fluazaindolizine in the environment.

METABOLISM

The Meeting received studies on the metabolism of fluazaindolizine in plants, laboratory animals as well as lactating goats and laying hens. Metabolism studies for the metabolites IN-QEK31, IN-QZY47 and IN-

TMQ01 in lactating goat and IN-QEK31 in laying hen were also made available to the Meeting. The studies on laboratory animals were evaluated by the WHO Core Assessment Group.

Plant metabolism

Fluazaindolizine is typically applied to the soil pre- or at planting with additional soil directed applications during crop growth.

Plant metabolism studies with ^{14}C -fluazaindolizine following soil application were conducted on crops representative of fruiting vegetables (tomato), root and tuber vegetables (carrot, potato), cereals/grasses (sugarcane) and oilseeds (soya beans). Fluazaindolizine was applied either as [phenyl- ^{14}C (U)]fluazaindolizine or [imidazo[1,2-a]pyridine-5,8a- ^{14}C]fluazaindolizine. In all experiments, selected extracts were hydrolysed with acid or enzymes to release exocons from their conjugates.

Where conducted in the metabolism studies, chiral analysis confirmed compounds measured in the studies using the racemic standards IN-UNS90 and IN-RSU03 were always present in the R-forms, designated IN-TQD54 and IN-TMQ01, respectively. It is assumed these compounds are always present in their R-enantiomeric forms.

The pattern of metabolites formed in primary and rotated crops is similar with hydrolysis of fluazaindolizine at the amide bond to form IN-F4106 and IN-QEK31 and subsequent formation of conjugates, typically with sugars. The demethylated form of fluazaindolizine is also hydrolysed at the amide bond, forming IN-A5760 and IN-QEK31 which may undergo conjugation.

In the following descriptions of the metabolism studies, the components are grouped into those "related to" various compounds. Here "related to" for IN-REG72, IN-A5760, IN-F4106, IN-UJV12, IN-TQD54, IN-TMQ01 and IN-QZY47 includes conjugates while for IN-QEK31 it includes conjugates as well as IN-R2W56 and IN-RYC33.

Soil treatments

Tomato

The metabolic fate of ^{14}C -fluazaindolizine in tomato plants maintained in a greenhouse was examined following planting seedlings into soil treated by soil drench with a SC-formulation at 1.5 kg ai/ha with a subsequent soil directed application at 0.5 kg ai/ha 30 days later. Samples of foliage and fruit were collected 30 to 62 days after the second application.

Total radioactive residues (TRR) were higher in leaves (0.44–5.7 mg eq/kg) than in fruit (0.029–0.079 mg eq/kg).

The extractability of ^{14}C with methanol:water (7:3) was good at 92–98 percent TRR for fruit and 80–94 percent TRR for foliage.

Parent fluazaindolizine was only detected at low levels in tomato fruit (≤ 0.9 percent TRR). The major components of ^{14}C identified in fruit from the [Ph- ^{14}C]-experiment were those related to IN-A5760 (37–50 percent TRR), those related to IN-RSU03 (19–24 percent TRR), and those related to IN-TQD54 (2.5–13 percent TRR). The major components of ^{14}C identified in fruit from the [IP-5,8a- ^{14}C]-experiment were those related to IN-QEK31 (53–72 percent TRR). Other components observed with either label were IN-REG72 (0.7–0.8 percent TRR), and IN-F4106 (3–8 percent TRR).

In foliage, fluazaindolizine parent accounted for ≤ 3.7 percent TRR. The major component metabolites from the [Ph- ^{14}C]-experiment were those related to IN-RSU03 (51–57 percent TRR), while in the [IP-5,8a- ^{14}C]-experiment the major components were those related to IN-QEK31 (34–50 percent TRR).

Other components observed with either label were those related to IN-A5760 (10–14 percent TRR), those related to IN-QZY47 (9–10 percent TRR), those related to IN-TQD54 (8–9 percent TRR), IN-REG72 (0.9–3 percent TRR), and IN-F4106 (4–6 percent TRR).

Soya beans

Soya bean seeds were sown into soil treated with a drench application of an SC formulation of ^{14}C -fluazaindolizine at 1 kg ai/ha. Forage was collected 48 days after sowing, fodder (hay) at 75 days and grain at maturity at 112 days.

TRRs were highest in hay (0.66 mg eq/kg) and forage (0.44 mg eq/kg) and lowest in seeds (0.27 mg eq/kg) for the $[\text{Ph-}^{14}\text{C}]$ -experiment and highest in seeds (2.0 mg eq/kg) and lowest in hay (1.0 mg eq/kg) and forage (0.76 mg eq/kg) for the $[\text{IP-5,8a-}^{14}\text{C}]$ -experiment. The extractability of ^{14}C with methanol/water was good for forage (> 90 percent TRR), hay (> 87 percent TRR) and seeds (> 78 percent TRR). A further 7.0–2 percent TRR was released with additional treatments.

In forage from the $[\text{Ph-}^{14}\text{C}]$ -experiment, fluazaindolizine accounted for 7.2 percent TRR in extracts (7.0 percent TRR in methanol:water; 0.2 percent TRR with further treatments). The principal component of the ^{14}C were related to IN-QZY47 (64.2 percent TRR). Other metabolites included IN-F4106 (11 percent TRR), IN-REG72 (0.7 percent TRR) and IN-RSU03 (IN-TMQ01, 1 percent TRR). A polar metabolite accounting for 4.2 percent TRR was tentatively assigned as a conjugate of IN-UJV12. Multiple unidentified metabolites accounted for a total of 17.6 percent TRR, not exceeding 2.6 percent TRR individually (≤ 0.011 mg eq/kg).

In forage from the $[\text{IP-5,8a-}^{14}\text{C}]$ -experiment, fluazaindolizine accounted for 6.9 percent TRR (0.053 mg/kg). The major component of ^{14}C was compounds related to IN-QEK31 (75 percent TRR). Minor metabolites included IN-REG72 (1.4 percent TRR) and one tentatively identified as IN-VM862 (0.6 percent TRR). Multiple unidentified metabolites were also detected; all ≤ 2.0 percent TRR (≤ 0.015 mg eq/kg).

In hay from the $[\text{Ph-}^{14}\text{C}]$ -experiment, fluazaindolizine accounted for 6.1 percent TRR. The principal residue was those related to IN-QZY47 (64.8 percent TRR) those related to IN-F4106 (18 percent TRR), IN-REG72 (1.2 percent TRR), and IN-RSU03 (IN-TMQ01 1.2 percent TRR). A polar metabolite accounted for 2.4 percent TRR and was tentatively assigned as a conjugate of IN-UJV12. Multiple unidentified metabolites were also detected; all ≤ 3.4 percent TRR, ≤ 0.022 mg eq/kg.

In hay from the $[\text{IP-5,8a-}^{14}\text{C}]$ -experiment, fluazaindolizine accounted for 4.8 percent TRR. The major residue component was compounds related to IN-QEK31 (69.6 percent TRR). IN-REG72 (0.9 percent TRR) was identified at low levels.

The principal residue identified in seed in the $[\text{Ph-}^{14}\text{C}]$ -experiment was parent fluazaindolizine (47 percent TRR) with compounds related to IN-F4106 (54 percent TRR), those related to IN-QZY47 (15 percent TRR), those related to IN-A5760 (6 percent TRR) and IN-REG72 (9.4 percent TRR). Multiple unidentified metabolites were detected; none > 1.3 percent TRR.

In seed from the $[\text{IP-5,8a-}^{14}\text{C}]$ -experiment, parent fluazaindolizine accounted for 8.3 percent TRR (0.167 mg/kg). Compounds related to IN-QEK31 accounting for 95 percent TRR. IN-REG72 was present at 1.2 percent TRR.

Carrot

Carrot seeds were sown into treated sandy loam soil about one hour after a soil drench application with an SC formulation of ^{14}C -fluazaindolizine at a nominal application rate of 1.5 kg ai/ha. A further application was 30 days later at a nominal application rate of 0.5 kg ai/ha. Samples of foliage (30DAA1;

BBCH 42), immature root and foliage sample (43DAA2, BBCH 45) and root and foliage sample at crop maturity (63DAA2, BBCH 49) were collected.

Extractability of ^{14}C using methanol:water was good for roots (86–93 percent TRR) and for foliage (67–87 percent TRR). Additional extraction using acetonitrile:water at 50 °C with sonication, released a further 4.2–7.3 percent TRR while sequential treatment with enzyme, HCl and NaOH released a further 5.2–10.4 percent TRR.

In foliage from the [Ph- ^{14}C]-experiment, fluazaindolizine accounted for 20.9 percent TRR, (0.926 mg/kg) decreasing as days after application increased. The principal components were compounds related to IN-RSU03 (32–68 percent TRR), those related to IN-QZY47 (6.5–16 percent TRR). Other identified components were those related to IN-TQD54 (1.4–3.1 percent TRR), IN-F4106 (0.3–4.2 percent TRR) and IN-REG72 (0.4–1.3 percent TRR).

In foliage from the [IP-5,8a- ^{14}C]-experiment, fluazaindolizine accounted for 40.6 percent TRR at 30DAA1 decreasing to 13.4 percent TRR in the mature foliage. The components identified were those related to IN-QEK31 (21–45 percent TRR). Other identified metabolites were free and conjugated IN-REG72 (2.9–5.4 percent TRR), and IN-VM862 (0.3 percent TRR).

In roots from the [Ph- ^{14}C]-experiment, fluazaindolizine accounted for 1.7–8.4 percent. The principal residues were those related to IN-RSU03 (51–63 percent TRR) and those related to IN-QZY47 (20–27 percent TRR). Other identified metabolites were those related to IN-TQD54 (3.6–3.7 percent TRR). Multiple unidentified metabolites were also detected accounting for an aggregate total of 2.4–4.9 percent TRR, but none exceeded 2.6 percent TRR individually (≤ 0.003 mg eq/kg).

In roots from the [IP-5,8a- ^{14}C] experiment fluazaindolizine accounted for 12–13 percent TRR, and the main residue were those related to IN-QEK31 (62–68 percent TRR). A volatile metabolite was also detected in the mature carrot root extracts and accounted for 3.8 percent TRR. Multiple unidentified metabolites were detected accounting for an aggregate total of 1.4–6.1 percent TRR, not exceeded ≤ 3.4 percent TRR (≤ 0.002 mg eq/kg).

Potato

Seed potatoes were sown into treated sandy loam soil about 2 hours prior to a soil drench application with [^{14}C]-fluazaindolizine, at a nominal application rate of 1.0 kg ai/ha and maintained in a glasshouse. A further application at 1.0 kg ai/ha was made to the same plots 30 days after the initial application. Foliage samples were collected at 15DAA2 and tuber and foliage at 35DAA2 (immature) and at 70DAA2 (mature).

Extractability of ^{14}C in tubers using methanol:water was good (> 75 percent TRR). Further treatments released an additional 11–15 percent TRR. Extractability of ^{14}C in foliage using methanol:water was also good (> 73 percent TRR).

In tubers from the [Ph- ^{14}C]-experiment, fluazaindolizine accounted for 6.8 percent TRR, (0.006 mg/kg) in early tubers but was not detected in mature tubers. The principal residue was compounds related to IN-QZY47 (21–23 percent TRR), those related to IN-TQD54 (10–20 percent TRR), and those related to IN-RSU03 (8–12 percent TRR). Other identified metabolites were those related to IN-F4106 (6–6.6 percent TRR), those related to IN-A5760 (3.4–3.9 percent TRR), IN-REG72 (0.4 percent TRR) and those related to IN-UJV12 (1.4–6.3 percent TRR).

In tubers from the [IP-5,8a- ^{14}C]-experiment, fluazaindolizine was accounted for 9.3 percent TRR, (0.004 mg/kg) in early tubers and was not detected in mature tubers. The major residue was compounds related to IN-QEK31 (64–69 percent TRR). Multiple unidentified metabolites were also detected

accounting for an aggregate total of 3.6–8.2 percent TRR in each sample but each individually was ≤ 1.7 percent TRR (≤ 0.001 mg eq/kg).

In foliage from the [Ph-¹⁴C]-experiment, fluazaindolizine was present in low quantities (0.2 percent TRR; 0.010 mg/kg). The principal residues were compounds related to IN-RSU03 (12 percent TRR), those related to IN-QZY47 (16 percent TRR), those related to IN-TQD54 (14 percent TRR), and those related to IN-A5760 (12 percent TRR). Other identified metabolites were IN-F4106 (4.2 percent TRR), and those related to UJV12 (5.2 percent TRR).

In foliage from the [IP-5,8a-¹⁴C]-experiment, fluazaindolizine accounted for 1.9 percent TRR, (0.015 mg/kg) with IN-REG72 (0.7 percent TRR). The principal residue was compounds related to IN-QEK31 (27–50 percent TRR). Multiple unidentified metabolites were also detected accounting for an aggregate total of 37.7 percent TRR but each individually was ≤ 3.5 percent TRR (≤ 0.027 mg eq/kg).

Sugarcane

Mature sugar cane sets (cv. NC0310) at the 2–3 leaf stage (BBCH 12) were transplanted into soil and within 2 hours of transplant, the soil was treated with [¹⁴C]-fluazaindolizine applied as soil drench at a nominal rate of 1.0 kg ai/ha. Samples were taken at BBCH 32, (51 DAA) and whole plants above soil level at maturity at BBCH 39 (231 DAA).

The extractability of ¹⁴C with methanol/water was (> 69 percent TRR) for foliage and (> 80 percent TRR) for mature cane. The major residue identified in [Ph-¹⁴C] experiment sugarcane foliage was compounds related to IN-RSU03 (IN-TMQ01, 44–54 percent TRR), those related to IN-TQD54 (22–27 percent TRR) and those related to IN-A5760 (3.8–7.4 percent TRR). Multiple unidentified metabolites accounted for a total of 6.6–7.1 percent TRR, but individually none was > 2.3 percent TRR (0.004 mg eq/kg). Parent fluazaindolizine was not detected.

The principal residue in the [IP-5-8a-¹⁴C] experiment sugarcane foliage was compounds related to IN-QEK31 (28–46 percent TRR). IN-REG72 and its glucose conjugate were also detected at low levels (≤ 4.6 percent TRR, ≤ 0.004 mg eq/kg). Multiple unidentified metabolites were detected accounting for a total of 25.5–36.7 percent TRR but individually none were > 6.2 percent TRR (0.007 mg eq/kg). Parent fluazaindolizine was not detected.

The principal residue identified in [Ph-¹⁴C] mature sugarcane was compounds related to IN-RSU03 (26 percent TRR), those related to IN-A5760 (23 percent TRR), those related to IN-TQD54 (12 percent TRR), those related to IN-QZY47 (4.9 percent TRR) and those related to IN-UJV12 (8.6 percent TRR). Multiple unidentified metabolites accounted for a total of 19.0 percent TRR (< 0.005 mg eq/kg), but individually none was > 7.0 percent TRR (0.001 mg eq/kg). Parent fluazaindolizine was not detected.

The principal residue identified in [IP-5-8a-¹⁴C] mature sugarcane was compounds related to IN-QEK31 (65 percent TRR). The glucose conjugate of IN-REG72 was also detected at low levels (3.9 percent TRR). Multiple unidentified metabolites were also detected accounting for an aggregate total of 19.5 percent TRR, but individually none > 3.1 percent TRR (0.002 mg eq/kg). Parent fluazaindolizine was not detected.

Rotational crop metabolism

The residue profile in follow crops grown in soil treated with fluazaindolizine is expected to be similar to that of primary crops as in both, plants are exposed following application to the soil.

Confined rotational crop studies

In the confined rotational crop study conducted in a glasshouse, bare sandy loam soil was treated with ^{14}C -fluazaindolizine at the equivalent of ≈ 1.95 kg ai/ha ($0.9\times$ maximum seasonal rate) and spinach, radish and spring wheat were sown 30, 120 and 300 days after soil application (plant-back interval, PBI). Fluazaindolizine, IN-F4106, and IN-QEK31 were the major residues extracted from soil.

In general, ^{14}C residues in rotated crops were lower with longer PBIs apart from wheat commodities from the [IP-5,8a- ^{14}C]-experiment soil application, where TRR levels in the various commodities at the 30- and 300-day PBIs were comparable

The majority of residues were readily extracted across all commodities using a methanol:water mixture (70:30, v/v). In cases where residues were more extensively incorporated into the crop matrix, such as wheat straw or grain samples, additional enzymatic and acid treatments allowed for recovery of > 90 percent TRR.

Spinach

Extractability of ^{14}C in spinach using methanol:water was good (> 81 percent TRR). In the [Ph- ^{14}C]-experiment, fluazaindolizine was found at all PBIs (0.4–14.1 percent TRR, ≤ 0.091 mg/kg) decreasing in later samples. The principal residue was compounds related to IN-QZY47 (42–76 percent TRR). Other identified metabolites were IN-REG72 (free and conjugated, 0.3–5.3 percent TRR), those related to IN-RSU03 (1.8–9.2 percent TRR), those related to IN-TQD54 (0.5–8.2 percent TRR), those related to IN-A5760 (1.1–7.1 percent TRR), those related to IN-UJV12 (0.5–3.1 percent TRR), and those related to IN-F4106 (0.5–21 percent TRR). Multiple unidentified metabolites were also detected accounting for an aggregate total of 6.6–14.2 percent TRR in each sample but each individually was ≤ 2.8 percent TRR (≤ 0.013 mg eq/kg).

In the [IP-5,8a- ^{14}C] experiment, fluazaindolizine was identified in all spinach samples (2.9–29.0 percent TRR, ≤ 0.114 mg/kg) decreasing in concentration in later samples. The principal residue was compounds related to IN-QEK31 (48–72 percent TRR). Other identified metabolites were the IN-REG72 (free and conjugated, 1.4–11.6 percent TRR). Multiple unidentified metabolites accounted for an aggregate of 10.7–29.4 percent TRR, but each individually was ≤ 5.3 percent TRR (≤ 0.011 mg eq/kg).

Radish

Extractability of ^{14}C in radish foliage using methanol:water was good (> 84 percent TRR). In the [Ph- ^{14}C] experiment, fluazaindolizine was identified in radish foliage at all PBIs (0.2–11.8 percent TRR, ≤ 0.039 mg/kg) decreasing in later samples. The principal residue was compounds related to IN-QZY47 (31–37 percent TRR), those related to IN-RSU03 (14–36 percent TRR), those related to IN-TQD54 (12–22 percent TRR), those related to IN-A5760 (5.2–6.2 percent TRR), those related to IN-UJV12 (0.8–1.6 percent TRR), those related to IN-F4106 (1.2–20 percent TRR), and IN-REG72 (free and conjugated 0.2–2.9 percent TRR).

In the [IP-5,8a- ^{14}C] experiment, fluazaindolizine was found in all samples (1.0–6.8 percent TRR, ≤ 0.036 mg/kg) decreasing in concentrations at later PBIs. The major residue identified was compounds related to IN-QEK31 (65–75 percent TRR) together with IN-REG72 (free and conjugated ≤ 2.7 percent TRR).

In the [Ph- ^{14}C]-experiment, fluazaindolizine was identified in radish roots at all PBIs (1.7–12.2 percent TRR, ≤ 0.047 mg/kg) decreasing in later samples. The principal residue identified was compounds related to IN-QZY47 (37–40 percent TRR), those related to IN-RSU03 (20–37 percent TRR), those related to IN-TQD54, (6.1–7.6 percent TRR), those related to IN-A5760 (1.1–6.6 percent TRR), those

related to IN-F4106 (1.6–16.3 percent TRR), those related to In-UJV12 (2.5 percent TRR), and IN-REG72 (free and conjugated, 0.6–5.9 percent TRR).

In the [IP-5,8a-¹⁴C]-experiment, fluazaindolizine was found in all samples (6.3–17.3 percent TRR, \leq 0.048 mg/kg) decreasing in concentration in later samples. The principal residue identified was compounds related to IN-QEK31 (36–89 percent TRR). Other identified metabolites were IN-REG72 (free and conjugated 7.0–9.3 percent TRR).

Wheat

Extractability of ¹⁴C in forage using methanol:water was good (>83 percent TRR). In the [Ph-¹⁴C]-experiment, fluazaindolizine was only identified in wheat forage at small quantities at 30-day PBI (0.7 percent TRR, 0.009 mg/kg) and it was not found in later PBIs. The principal residue identified was compounds related to IN-TQD54 (53–67 percent TRR), those related to IN-RSU03 (11–16 percent TRR), those related to IN-QZY47 (4.1–4.7 percent TRR), those related to IN-A5760 (3.3–4.1 percent TRR), and those related to IN-F4106 (1.3–2.2 percent TRR). Other identified metabolites were IN-REG72 (free and conjugated, 1.3–1.7 percent TRR).

In the [IP-5,8a-¹⁴C]-experiment, fluazaindolizine was identified in forage at all PBIs (0.6–3.9 percent TRR, \leq 0.016 mg/kg), decreasing in later samples. The major residue identified was compounds related to IN-QEK31 (43–76 percent TRR), IN-REG72 (free and conjugated \leq 2.8 percent TRR).

Extractability of ¹⁴C in hay using methanol:water was good (>76 percent TRR). In the [Ph-¹⁴C]-experiment, fluazaindolizine was only identified in small quantities in wheat hay at the 30-day PBI (0.5 percent TRR, 0.008 mg/kg) and not in later samples. The major residue was compounds related to IN-TQD54 (46–54 percent TRR), those related to IN-RSU03 (11–17 percent TRR), those related to IN-A5760 (3.9–5.4 percent TRR), those related to IN-QZY47 (1.5–2.3 percent TRR), and those related to IN-F4106 (2.2–2.7 percent TRR). Other identified metabolites were IN-REG72 (free and conjugated 1.4–2.7 percent TRR). Chiral HPLC analysis conducted on the isolated IN-RSU03 demonstrated that only the *R*-enantiomer, IN-TMQ01, was present.

In the [IP-5,8a-¹⁴C]-experiment, fluazaindolizine was identified in hay only in the 30- and 120-day PBIs, at low concentrations (0.7–1.4 percent TRR, \leq 0.016 mg/kg). The principal residues identified were compounds related to IN-QEK31 (32–71 percent TRR), with IN-REG72 (free and conjugated \leq 8.0 percent TRR, \leq 0.091 mg/kg).

Extractability of ¹⁴C in straw using methanol:water was good for the [Ph-¹⁴C]-experiment (> 72 percent TRR) and poor for the [IP-5,8a-¹⁴C] experiment (< 65 percent TRR). Further treatments of [IP-5,8a-¹⁴C]-experiment straw samples released an additional 27.7–38.9 percent TRR with terminal residues remaining in solids accounting for \leq 8.3 percent TRR.

In the [Ph-¹⁴C]-experiment, fluazaindolizine was only identified in wheat straw in small quantities at the 30-day PBI (0.7 percent TRR, 0.041 mg/kg) and was not found in later PBIs. The principal residue identified in straw was compounds related to IN-TQD54 (37–43 percent TRR), those related to IN-RSU03 (15–17 percent TRR), those related to IN-A5760 (3.8–7.3 percent TRR), and those related to IN-F4106 (2.7–3.3 percent TRR). Other identified metabolites were IN-REG72 (free and conjugated 0.9–3.2 percent TRR) and IN-UJV12 (< 0.1–0.5 percent TRR).

In the [IP-5,8a-¹⁴C]-experiment, fluazaindolizine was found in straw only in the 30- and 120-day PBIs (1.4–4.3 percent TRR, \leq 0.153 mg/kg). The principal residue was compounds related to IN-QEK31 (26–40 percent TRR) together with IN-REG72 (free and conjugated 0.2–7.2 percent TRR).

Extractability of ^{14}C in grain using methanol:water was poor for the [Ph- ^{14}C]- (16–34 percent TRR) and [IP-5,8a- ^{14}C]-experiments (54–63 percent TRR). Selected samples were subjected to further treatments which released an additional 63–84 percent TRR for the [Ph- ^{14}C]- 300 DAA grain sample with terminal residues remaining in solids accounting for 2.8 percent TRR and an additional 36–46 percent TRR released for the [IP-5,8a- ^{14}C] sample with terminal residues remaining in solids accounting for 0.7 percent TRR.

In grain from the [Ph- ^{14}C]-experiment, it was not possible to obtain accurate profiles from the 120- and 300-day PBI samples due to the large quantity of endogenous materials and large volumes of sample extract required to release the ^{14}C residue. The profiles obtained demonstrated that the residue was comprised of multiple metabolites although it was not possible to accurately determine their identity. The majority of the ^{14}C residues were released by enzyme and/or acidic extractions which may alter the nature of the residue in the extraction process.

In the [Ph- ^{14}C]-experiment, fluazaindolizine was found in grain at the 30-day PBI (3.3 percent TRR, 0.003 mg/kg). The major residue identified was IN-A5760 (3.5–6.1 percent TRR, 0.002–0.005 mg eq/kg). Other identified metabolites were compounds related to IN-TQD54 (4.4 percent TRR), those related to IN-RSU03 (0.9–8.4 percent TRR), and IN-F4106 (\leq 3.3 percent TRR) and those related to IN-QZY47 (\leq 2.3 percent TRR). IN-REG72 was tentatively observed in the 300DAA grain at 7.9 percent TRR.

In the [IP-5,8a- ^{14}C]-experiment, fluazaindolizine was not found in the grain samples. The principal residue identified in grain was compounds related to IN-QEK31 (69–76 percent TRR) with a glucose conjugate of IN-REG72 (\leq 2.6 percent TRR, \leq 0.040 mg eq/kg).

In conclusion, the metabolism of fluazaindolizine and various metabolites taken up from the soil (such as major metabolites IN-F4106 and IN-QEK31) was consistent across all crops with differences mainly in the degree and complexity of conjugation that occurs in the various crops. The major metabolic route in primary and rotated crops was the hydrolysis of fluazaindolizine at the amide bond, resulting in IN-F4106 and IN-QEK31. Fluazaindolizine was also *O*-demethylated to form IN-REG72, which also was hydrolysed to IN-A5760 and IN-QEK31. A less prominent pathway was hydrolysis of fluazaindolizine at the sulfonamide bond, resulting in IN-RYC33 or the further degradation of IN-QEK31 to IN-VM862. Several conjugates were also formed, typically with various sugars

In summary, the metabolism of fluazaindolizine and various metabolites taken up from the soil (such as major metabolites IN-F4106 and IN-QEK31) was consistent across all crops with differences mainly in the degree and complexity of conjugation that occurs in the various crops. The major metabolic route in primary and rotated crops was the hydrolysis of fluazaindolizine at the amide bond, resulting in IN-F4106 and IN-QEK31. Fluazaindolizine was also *O*-demethylated to form IN-REG72, which also was hydrolysed to IN-A5760 and IN-QEK31. A less prominent pathway was hydrolysis of fluazaindolizine at the sulfonamide bond, resulting in IN-RYC33 or the further degradation of IN-QEK31 to IN-VM862. Several conjugates were also formed, typically with various sugars. A summary of residue components (as percent TRR) detected in metabolism and crop rotation studies expressed in terms of groups of related compounds is shown below.

Table 5.15.1 Residue profiles for fluazaindolizine and metabolites in different plant matrices

Component	percent TRR								
	Fluazaindolizine	IN-REG72	IN-F4106	IN-A5760	IN-QEK31	IN-QZY47	IN-TQD54	IN-RSU03	IN-UJV12
Tomato fruit	< 0.9	< 0.8	3-8	35-50	53-72		2.5-13	19-24	

Component	percent TRR								
	Fluazaindolizine	IN-REG72	IN-F4106	IN-A5760	IN-QEK31	IN-QZY47	IN-TQD54	IN-RSU03	IN-UJV12
Tomato foliage	<3.7	0.9-3	4-6	10-14	34-50	9-10	8-9	51-57	
Soya forage	7.2	0.7-1.4	11		75	64		1	
Soya hay	6.1	0.9-1.2	18		70	65		1.2	2.4
Soya seed	8-47	1-9	54	6	95	15			
Carrot tops	21-41	0.4-5	0.3-4		21-45	6-16	1-3	32-68	
Carrot root	1.7-13				62-68	20-27	4	51-63	
Potato tuber	0-9	0.4	6-7	3-4	64-69	21-23	10-20	8-12	1-6
Potato foliage	0.2-1.9	0.7	4	12	27-50	16	14	12	5
Sugarcane foliage		4.6		4-7	28-46		22-27	44-54	
Sugarcane		3.9		23	65	5	12	26	9
Spinach	0.4-29	0.3-12	0.5-21	1-7	48-72	42-76	0.5-8	2-9	0.5-3
Radish foliage	0.2-12	0.2-3	1-20	5-6	65-75	31-37	12-22	14-36	1-2
Radish root	2-17	0.6-9	2-16	1-7	36-89	37-40	6-8	20-37	2
Wheat forage	0.6-4	1.3-2.8	1-2	3-4	43-76	4-5	53-67	11-16	
Wheat hay	0.5-1.4	1.4-8	2-3	4-5	32-71	2	46-54	11-17	
Wheat straw	0.7-4.3	0.9-7	3	4-7	26-40		37-43	15-17	0.5
Wheat grain	3	8		4-6	69-76	2	4	1-8	

Animal metabolism

The Meeting received animal metabolism studies on rats, lactating goats and laying hens dosed with fluazaindolizine and separate studies following dosing with IN-QEK31 (lactating goats, laying hens) and IN-QZY47 and IN-TMQ01 (lactating goats). Lactating goats and laying hens were dosed with [Ph-¹⁴C(U)]-fluazaindolizine and [imidazo-(1,2- α)-pyridine-2-¹⁴C]-fluazaindolizine.

Rats

Metabolism of fluazaindolizine in rats was evaluated by the WHO Core Assessment Group of the 2021 JMPR. Metabolites identified in rats included: IN-REG72, IN-UHD20, IN-UHD21, IN-F4106, IN-QEK31, IN-A5760 and sulfate or glucuronide conjugates of IN-A5760.

On dosing of laboratory animals with IN-F4106, IN-A5760 and conjugates were identified. Following dosing with IN-QZY47, acetylated IN-QZY47 was the predominant metabolite and following dosing with IN-TMQ01, IN-F4106 and IN-TQD54 were identified.

Lactating goats

Lactating goats were orally dosed by gavage once daily for seven consecutive days with ¹⁴C-fluazaindolizine at doses equivalent to 12 ppm in the diet and sacrificed within 6 hours of the last dose. Milk samples were collected daily.

By 6 hours after the last dose, the majority of the ¹⁴C was recovered in faeces (51–52 percent of the administered dose (AD)) and urine (21–33 percent AD). Milk accounted for < 0.1 to 0.1 percent AD while tissues accounted for 0.8–0.9 percent AD. The material balance was 97–108 percent AD.

Residues in milk reached a plateau by 5 days of dosing.

TRR levels in edible tissues from the [Ph-¹⁴C]/[IP-2-¹⁴C]-fluazaindolizine dosed goats were 0.223/0.275 mg eq/kg in liver, 0.358/0.357 mg eq/kg in kidney, 0.011/0.010 mg eq/kg in muscle, 0.015/0.008 mg eq/kg in omental fat, 0.028/0.014 mg eq/kg in renal fat and 0.024/0.013 mg eq/kg in subcutaneous fat. Radioactive residues did not selectively partition into skim milk or cream or into the various fat types.

Extractability from tissues with acetonitrile:0.1 M ammonium formate, pH 7 (9:1) was good for liver, kidney, muscle and fat (> 85 percent TRR) and Day 4–6 milk (> 96.9 percent TRR). Digestion of liver PES with protease released additional residues, with overall ≥ 96 percent TRR extracted.

In the [Ph-¹⁴C] experiment, fluazaindolizine accounted for 17.5–84.6 percent TRR in tissues and milk. The phenyl-derived metabolites included IN-A5760 (maximum 4.1 percent TRR), IN-F4106 (maximum 38.4 percent TRR) and IN-REG72 (maximum 7.0 percent TRR). Several minor unidentified metabolites were also detected, none of which individually were greater than 7.3 percent TRR, which combined accounted for 5.5–12.8 percent TRR in milk and tissues.

In the [IP-2-¹⁴C] experiment, fluazaindolizine accounted for 25.0–83.2 percent TRR in tissues and milk. The imidazopyridine-derived metabolites included IN-QEK31 (maximum 42.8 percent TRR), IN-REG72 (maximum 11.6 percent TRR) and IN-R2W56 (maximum 0.6 percent TRR). Several minor unidentified metabolites were also detected, none of which individually were greater than 4.0 percent TRR, which combined accounted for 4.0–8.3 percent TRR in milk and tissues.

Laying hens

The metabolism of ¹⁴C-fluazaindolizine was studied in laying hens. Hens were dosed orally *via* capsules, once a day for a total of 14 days, with ¹⁴C-fluazaindolizine at doses equivalent to 13 ppm in the diet. Hens were sacrificed 6 hours after the final dose.

The recovery of the administered dose was 94.6 percent for [Ph-¹⁴C]-fluazaindolizine and 93.5 percent for the [IP-2-¹⁴C]-fluazaindolizine. For both [¹⁴C]-labels, 92.9–94 percent AD was recovered from the excreta and cage wash < 0.1 percent AD was recovered in eggs, muscle and fat with 0.6 percent AD recovered in liver.

TRR levels in edible tissues were 0.732/0.701 mg eq/kg in liver, 0.043/0.047 mg eq/kg in muscle and 0.020/0.027 mg eq/kg in abdominal fat from the [Ph-¹⁴C]/[IP-2-¹⁴C]-fluazaindolizine dosed hens. Radioactivity plateaued in whole eggs within 10 days at 0.017 mg eq/kg in the [Ph-¹⁴C]-fluazaindolizine and within 8 days at *ca.* 0.018 mg eq/kg in the [IP-2-¹⁴C]-fluazaindolizine.

Extractability of eggs, liver, muscle, and fat with acetonitrile/buffer was > 87.3 percent TRR. Most of radioactive residues (82.4–98.0 percent TRR) was identified and/or characterized in liver and eggs from the [Ph-¹⁴C]-fluazaindolizine dosed hens. Fluazaindolizine was a major residue, accounting for 67.5–96.5 percent TRR in liver and eggs, at levels of 0.013 mg/kg in eggs, 0.680 mg/kg in liver, 0.041 mg/kg in muscle and 0.014 mg/kg in fat. IN-F4106 (maximum 5.7 percent TRR) and IN-REG72 (maximum 1.1 percent TRR) were also detected. Several minor unidentified metabolites were also detected, none of which individually were greater than 11.3 percent TRR, which combined accounted for 0.9–11.3 percent TRR in eggs and tissues.

The majority of radioactive residues (73.1–97.9 percent TRR) was identified and/or characterized in tissues and eggs from the [IP-2-¹⁴C]-fluazaindolizine dosed hens. Fluazaindolizine was a major residue, accounting for 66.2–97.1 percent TRR, levels of 0.012 mg/kg in eggs, 0.639 mg/kg in liver, 0.046 mg/kg in muscle and 0.018 mg/kg in fat. In eggs and tissues, IN-QEK31 (maximum 4.9 percent TRR), IN-REG72

(maximum 1.1 percent TRR), IN-RYC33 (maximum 11.0 percent TRR) and IN-R2W56 (maximum 1.9 percent TRR) were detected. An unidentified metabolite was detected in abdominal fat which accounted for 2.5 percent TRR (0.001 mg/kg).

In summary, the major residue in tissues, milk and eggs following dosing with fluazaindolizine is the parent compound.

Metabolism of IN-QEK31

A lactating goat received repeated oral administration of [IP-2-¹⁴C]-IN-QEK31 by gelatine capsule once daily on five consecutive days at a dose level equivalent to 12.5 ppm in the feed. Animals were euthanized approximately 6 hours after the last dose.

The majority of the ¹⁴C was recovered in urine (57 percent AD) and faeces (14 percent AD). Milk accounted for 2.1 percent AD while tissues for < 0.1 percent AD. Residues in milk reached a plateau by 1 to 4 days of dosing.

TRR in edible tissues were 0.035 mg eq/kg in liver, 0.282 in kidney, < 0.001 in muscle, 0.005 in omental fat, 0.046 in renal fat and 0.002 mg eq/kg in subcutaneous fat.

Extractability of milk and tissues with acetonitrile:(100 mM ammonium formate) (9:1) was good with > 90 percent TRR released, the exception being liver for which (79.7 percent TRR). Extraction of the bound liver residues with more polar and acidic extraction methods did not release any further radioactivity; however, PES were low (0.007 mg eq/kg).

Unchanged IN-QEK31 accounted for 74.3–95.4 percent TRR in tissues and milk. A single metabolite was present at greater than 10 percent TRR which was identified as IN-R2W56 and detected only in renal fat. Several minor unidentified metabolites were also detected, none of which individually were greater than 5.0 percent TRR, which combined accounted for 6.2 percent TRR in milk and tissues.

Hens were dosed orally *via* capsule with [IP-2-¹⁴C]-IN-QEK31 once a day for 14 days, at a dose equivalent to 10 ppm in the diet and sacrificed 6 hours after the final dose.

IN-QEK31 was rapidly eliminated from hens into the excreta (approximately 93.2 percent of the dose). Edible tissues and eggs contained negligible amounts of radioactivity (< 0.1 percent) of the administered total dose. Radioactivity in whole eggs reached plateau within 5 days post first dose (*ca.* 0.005 mg/kg).

TRR were 0.014 mg eq/kg in liver and 0.002 mg eq/kg in abdominal fat and < 0.001 mg eq/kg in muscle. Most of the radioactive residues (\geq 71.1 percent TRR) were extracted with acetonitrile:(100 mM ammonium formate). Unchanged IN-QEK31 accounted for 71 percent TRR in liver. As TRR in egg, muscle and fat samples were very low (< 0.01 mg eq/kg), metabolite profiling was not conducted.

In summary, the major residue in tissues, milk and eggs following dosing with IN-QEK31 is IN-QEK31.

Metabolism of IN-QZY47

The metabolism of [Phenyl-¹⁴C(U)]-IN-QZY47 was investigated in a lactating goat following repeated oral administration by gelatin capsule once daily for five consecutive days at a dose level equivalent to 20 ppm in the feed. Animals were euthanized approximately 6 hours after the last dose

The majority of the ¹⁴C was recovered in urine (75 percent AD) and faeces (7.2 percent AD). Milk accounted for 20.2 percent AD while tissues for < 0.1 percent AD. Residues in milk reached a plateau by 1 to 4 days of dosing.

TRR were 0.344 mg eq/kg in liver, 0.824 mg eq/kg in kidney, 0.057 mg eq/kg in muscle, 0.034 mg eq/kg in omental fat, 0.044 mg eq/kg in renal fat and 0.050 mg eq/kg in subcutaneous fat. There was no selective partitioning of residues (less than 2-fold) in the milk fractions.

Extractability of milk and tissues with acetonitrile:(100 mM ammonium formate) (9:1, v/v) was good (> 81 percent TRR). The majority of radioactive residues (74.6–98.6 percent TRR) were identified and/or characterized. In milk and tissues, metabolites included IN-F4106 (maximum 81.4 percent TRR), IN-A5760 (maximum 11.4 percent TRR) and IN-A5760 conjugates (maximum 41.0 percent TRR). IN-QZY47 was detected in milk (5.3 percent TRR) but not in tissues. Several minor unidentified metabolites were also detected, none of which individually were greater than 8.3 percent TRR or 0.017 mg eq/kg

Metabolism of IN-TMQ01

The metabolism of [Phenyl-¹⁴C(U)]-IN-TMQ01 was investigated in a lactating goat following oral administration by gelatin capsule, once daily for five consecutive days at a dose level equivalent to 11 ppm in the feed. Animals were euthanized approximately 6 hours after the last dose.

Most of the residues were recovered in faeces (44 percent AD) and urine (34 percent AD). Milk and tissues accounted each for < 0.1 percent AD. Residues in milk reached a plateau by 1 to 4 days of dosing.

In milk and tissues containing residues greater than 0.01 mg eq/kg, the radioactive residues (from 66.1 percent for liver to 100.0 percent TRR for muscle and fat) were extracted with acetonitrile: 100 mM ammonium formate. Digestion with protease released the remaining radioactive residues in liver.

The majority of radioactive residues (66.1–100 percent TRR) were identified and/or characterized. Unchanged IN-TMQ01 accounted for 42.7–86.7 percent TRR in tissues. IN-F4106 accounted for 1.0–43.6 percent TRR in tissues and essentially all of the residue in milk (97.5 percent TRR; 0.007 mg eq/kg). Several minor unidentified metabolites were also detected, none of which individually exceeded 4.8 percent TRR, with the exception of muscle and subcutaneous fat in which a single unknown component accounted for 13.7–22.7 percent TRR. However, these unknowns only equated to a low concentration of ≤ 0.001 mg eq/kg.

Environmental fate

The Meeting received aqueous and soil photolysis, aqueous hydrolysis and aerobic soil studies for fluazaindolizine.

Fluazaindolizine and metabolites (IN-F4106, IN-QEK31) are stable to hydrolysis (aqueous and soil) at environmental pH, however aqueous photolysis is fast and may be a significant route of degradation with DT_{50} values ≤ 1.6 days for fluazaindolizine.

Fluazaindolizine does not undergo significant photolytic degradation on moist soil when exposed to artificial sunlight (DT_{50} 138 days). Soil metabolite IN-QEK31 degrades readily on moist soil surface in the presence of light while IN-F4106 was stable.

In laboratory aerobic soil degradation studies on fluazaindolizine the major soil degradates were IN-F4106, IN-QEK31 and IN-VM862. The laboratory DT_{50} values for fluazaindolizine in different soils were 3.4–241 days (geometric mean 28.1 days). DT_{50} were 177–461 days (geometric mean 216 days) for IN-F4106, 57.2–182 days (geometric mean 89 days) for IN-QEK31, 347–452 days for aerobic soil degradation and 42–57 days overall dissipation including volatilization for IN-VM862, 28.4–117 days (geometric mean 58 days) for IN-REG72 and 3.7–88.6 days (geometric mean 27 days) for IN-A5760.

In field dissipation studies, the DT_{50} values for fluazaindolizine degradation ranged from 5.0 to 171 days (geometric mean of 28.1 days), indicating non-persistence. Soil metabolites show limited potential to accumulate following application on consecutive years, with the exception of IN-F4106 which may accumulate.

Field rotational crop studies

The persistence in soil and potential uptake of fluazaindolizine and degradates by plants was further evaluated in field studies at locations in the European Union and the United States.

Fluazaindolizine (SC formulation) was applied to bare ground at 1×1.25 kg ai/ha, 2×1.25 kg ai/ha (total 2.5 kg ai/ha), 4×0.82 kg ai/ha applications (total 3.3 kg ai/ha) or 4×1.12 kg ai/ha applications (total 4.48 kg). Three PBIs were targeted at each site, 7–30, 60–270 and 270–365 days.

Fluazaindolizine residues were observed at levels above the LOQ (0.01 mg/kg) in a variety of crops: up to 0.018 mg/kg in leafy vegetables (radish tops), 0.023 mg/kg in broccoli, 0.039 mg/kg in celery, 0.023 mg/kg in root crops (radish roots), immature pea seed 0.18 mg/kg, pulses 1.5 mg/kg (pea seed), rape seed 0.022 mg/kg, forages 0.035 mg/kg (soya bean), and fodders 0.8 mg/kg (pea hay).

Compounds hydrolysed by acid to IN-A5760, IN-F4106, IN-QEK31, IN-QZY47, IN-TMQ01, IN-UJV12, IN-TQD54 were observed in all commodities and generally at levels greater than parent fluazaindolizine with residues up to 2.3 mg/kg (pea hay) for IN-A5760, 1.3 mg/kg (pea ay) for IN-F4106, 1.3 mg/kg (pea mature seed) for IN-QEK31, 9.2 mg/kg (pea hay) for IN-QZY47, 3.7 mg/kg (carrot tops) for IN-TMQ01, 1.4 mg/kg (pea hay) for IN-UJV12 and 0.62 mg/kg (corn stover) for IN-TQD54.

In summary, at the maximum use pattern considered by the Meeting, soil application at up to 2.24 kg ai/ha, residues of fluazaindolizine and metabolites are expected in rotated crops. Residues associated with follow crops will be assessed in the section on supervised trials.

Methods of analysis

The Meeting received information on analytical methods for fluazaindolizine and components of interest in plant and animal matrices.

The methods for plants involve two parts. Part 1 is analysis without hydrolysis (fluazaindolizine and free IN-F4106, IN-QEK31, IN-QZY47, IN-R2W56, IN-REG72, IN-TEQ01, IN-RYC33) and part 2 with hydrolysis of compounds to IN-A5760, IN-F4106, IN-QEK31, IN-QZY47, IN-TMQ01, IN-UJV12, IN-TQD54. Hydrolysis of fluazaindolizine and IN-REG72 results in cleavage of the amide bond and formation of IN-F4106 plus IN-QEK31 and IN-A5760 plus IN-QEK31 respectively, as shown in the Figure 5.15.1 below.

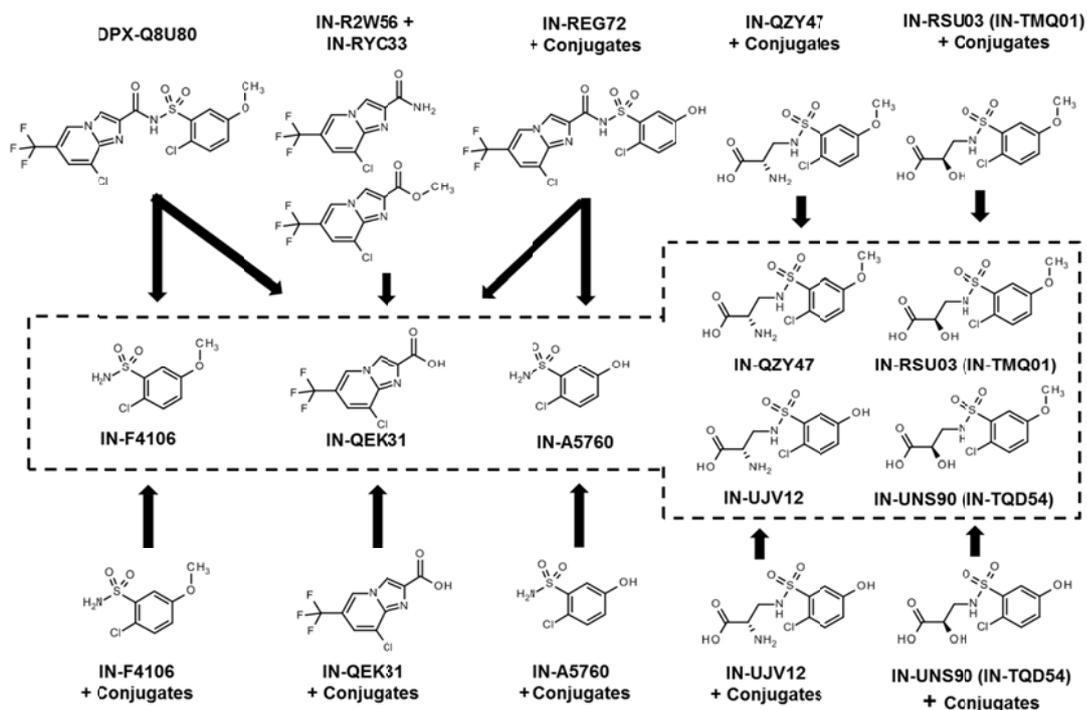


Figure 5.15.1 Metabolites of fluazaindolizine (DPX-Q8U80) determined in the analytical methods

Residues are reported in terms of the analytes but may be converted to parent equivalents using molecular weight conversion factors: 2.26 for IN-A5760, 2.11 for IN-F4106, 1.77 for IN-QEK31, 1.52 for IN-QZY47, 1.51 for IN-TMQ01, 1.59 for IN-UJV12 and 1.58 for IN-TQD54.

In methods for plants, fluazaindolizine and its metabolites (free IN-F4106, IN-QEK31, IN-QZY47, IN-R2W56, IN-REG72, IN-TEQ01, IN-RYC33) are extracted using methanol:water. For oily crops the extract is partitioned against hexane, and the hexane discarded. The final determination is by LC-MS/MS, with validated LOQs typically of 0.01 mg/kg for each compound. This method is used to measure parent fluazaindolizine residues.

To measure compounds hydrolysed to IN-A5760, IN-F4106, IN-QEK31, IN-QZY47, IN-TMQ01, IN-UJV12, IN-TQD54, a separate aliquot of the methanol:water extract is hydrolysed with concentrated HCl (1.2–2 M HCl, 80 °C overnight), followed by clean-up on a SAX SPE column and analysis by LC-MS/MS. The LOQs for plant commodities are typically 0.01 mg/kg for each compound. In the hydrolysis step, exocons are released from their conjugates, fluazaindolizine is converted to IN-F4106 and IN-QEK31, IN-REG72 to IN-A5760 and IN-QEK31 and IN-RYC33 to IN-QEK31.

In the method for animal commodities residues of fluazaindolizine and metabolites (free IN-A5760, IN-F4106, IN-REG72, IN-QEK31, IN-R2W56 and IN-RYC33) are extracted with acetonitrile:water followed by clean-up on strong cation exchange and strong anion exchange columns and analysis by LC-MS/MS. The validated LOQ is 0.01 mg/kg for tissues and milk for the individual compounds.

The Meeting concluded that the presented methods were sufficiently validated and are suitable to measure fluazaindolizine and metabolites in plant and animal commodities.

The multi-residue method, DFG S19 is not suitable for analysis of fluazaindolizine, IN-QEK31, IN-QZY47, IN-TMQ01, IN-UJV12, and IN-TQD54 in crops, but is considered valid for the determination of residues of IN-F4106, IN-A5760, and IN-RYC33 in tomato, soya bean and grapefruit (but not wheat straw).

The multi-residue method, DFG S19 is not suitable for analysis of fluazaindolizine, IN-REG72 and IN-QEK31 in animal commodities but is considered valid for the determination of residues of IN-F4106, IN-A5760, and IN-RYC33 in milk, egg, bovine meat, fat, and liver.

Stability of pesticide residues in stored analytical samples

The Meeting received information on storage stability of fluazaindolizine and metabolites (IN-A5760, IN-F4106, IN-QEK31, IN-QZY47, IN-R2W56, IN-REG72, IN-RYC33, IN-TMQ01, IN-UJV12, IN-TQD54) in raw/processed plant commodities.

Fluazaindolizine and metabolites are stable on frozen storage in a high-acid commodity (orange at least 24 months), high-water commodity (tomato at least 34 months), high-oil (soya bean seed at least 33 months), and high-starch (wheat grain at least 24 months), high-protein commodities (dry pea seed at least 24 months), dry crop commodities (field corn stover at least 24 months, pea hay at least 23 months).

The demonstrated stability intervals on frozen storage generally encompass the duration of storage in the residue trials evaluated by the Meeting.

Fluazaindolizine and metabolites (IN-A5760, IN-F4106, IN-QEK31, IN-R2W56, IN-REG72, IN-RYC33) are stable on frozen storage in milk for at least 6.8 months, in muscle for at least 6.7 months, in fat for at least 8.5 months and for analytes other than IN-R2W56 in kidney for at least 8.3 months. IN-R2W56 was stable in kidney for 7 days but not in a sample stored for 250 days. Fluazaindolizine, IN-QEK31 and IN-R2W56 were stable in liver for at least 0.77 months (23 days), IN-RYC33 for 0.47 months (14 days) and IN-REG72, IN-F4106 and IN-A5760 for 0.23 months (7 days).

Most of the samples in the livestock feeding study were analysed within 14 days.

Definition of the residue

Plant commodities

The metabolism of fluazaindolizine was similar in the primary treated crops (tomato, carrot, potato, sugarcane, soya bean) and in rotational crops (spinach, radish, wheat).

Parent fluazaindolizine was a minor component of the residue, detected in all crops, but often at low levels, ranging from ≤ 0.9 percent TRR in tomato fruit to ≤ 12 percent TRR in mature carrot. Levels were higher in soya bean seed (up to 46 percent TRR) and carrot foliage (up to 41 percent TRR). The main components of the ^{14}C residues were free and conjugated IN-RSU03, IN-TQD54, IN-QZY47, IN-A5760, IN-F4106 and IN-QEK31

In the $[\text{Ph-}^{14}\text{C}]$ -experiments the sum of IN-RSU03 and its conjugates accounted for; tomato fruit ≤ 24 percent TRR, tomato foliage 49–57 percent TRR, carrot root ≤ 63 percent TRR, carrot foliage ≤ 68 percent TRR, potato tuber/foliage ≤ 12 percent TRR and in sugarcane foliage/cane ≤ 54 percent TRR, the sum of IN-TQD54 and its conjugates accounted for; tomato fruit ≤ 13 percent TRR, potato tuber/foliage ≤ 20 percent TRR, sugarcane foliage/cane ≤ 32 percent TRR, the sum of IN-QZY47 and its conjugates accounted for; tomato foliage ≤ 10 percent TRR, soya bean forage/hay ≤ 62 percent TRR, carrot root ≤ 27 percent TRR, carrot foliage ≤ 16 percent TRR, potato tuber/foliage ≤ 23 percent TRR, the sum of IN-A5760 and its conjugates accounted for; tomato fruit ≤ 50 percent TRR, tomato foliage ≤ 14 percent TRR, potato tuber 12 percent TRR, sugarcane ≤ 23 percent TRR, the sum of IN-F4106 and its conjugates accounted for; soya bean forage/hay ≤ 17.8 percent TRR, soya bean seed 53.5 percent TRR.

In the [IP-5,8a-¹⁴C]-experiments the sum of IN-QEK31 and its conjugates accounted for; tomato fruit 53–72 percent TRR, tomato foliage ≤ 50 percent TRR, soya bean forage/hay/seed ≤ 95 percent TRR, carrot root ≤ 66 percent TRR, carrot foliage ≤ 45 percent TRR, potato tubers ≤ 69 percent TRR, potato foliage ≤ 50 percent TRR, sugarcane foliage/cane ≤ 65 percent TRR.

In studies on rotational crops, also reflecting uptake from soil, residues were detected at levels above the LOQ for a number of compounds and residues may occur in rotational (follow) crops. The compounds were fluazaindolizine as well as free and sometimes conjugated forms of the metabolites IN-REG72, IN-RSU03, IN-QZY47, IN-TQD54, INA5760, IN-F4106, IN-UJV12, IN-R3Z85 for the [Ph-¹⁴C]-experiments and free and conjugated forms of IN-REG72, IN-RYC33, IN-UJU44, IN-R2W56, IN-QEK31, IN-UGA20 for the [IP-5,8a-¹⁴C]-experiments.

Parent fluazaindolizine was detected at low levels or <LOD in rotated crops (wheat forage/hay/straw ≤ 0.7 percent TRR, spinach ≤ 29 percent TRR, radish foliage/roots ≤ 17 percent TRR).

In the [Ph-¹⁴C]-experiments the sum of IN-RSU03 and its conjugates accounted for; wheat forage/hay/straw ≤ 17 percent TRR, radish foliage/roots ≤ 37 percent TRR, the sum of IN-TQD54 and its conjugates accounted for; wheat forage/hay/straw ≤ 67 percent TRR, radish foliage ≤ 22 percent TRR, the sum of IN-QZY47 and its conjugates accounted for; spinach ≤ 76 percent TRR, radish foliage/roots ≤ 40 percent TRR, the sum of IN-F4106 and its conjugates accounted for; spinach ≤ 27 percent TRR, radish roots ≤ 16 percent TRR.

In the [IP-5,8a-¹⁴C]-experiments the sum of IN-QEK31 and its conjugates accounted for; wheat forage/hay/straw ≤ 71 percent TRR, wheat grain ≤ 76 percent TRR, spinach ≤ 72 percent TRR, radish foliage ≤ 75 percent TRR, radish root ≤ 89 percent TRR. IN-UGA20 was also a significant metabolite (wheat hay ≤ 17 percent TRR, radish roots ≤ 14 percent TRR).

Supervised field trials monitored fluazaindolizine, as well as compounds hydrolysed with acid to IN-A5760, IN-F4106, IN-QEK31, IN-QZY47, IN-TMQ01, IN-UJV12, and IN-TQD54 with residues of all analytes detected.

As fluazaindolizine occurs in most crops that have detectable residues and provides a pragmatic option as analysis of other compounds involves an intensive hydrolysis step, the Meeting decided the residue definition for compliance with MRLs in plants should be fluazaindolizine.

In deciding which compounds should be included in the residue definition for risk assessment for plant commodities the Meeting considered the likely occurrence of the compounds and the toxicological properties of the candidates. Compounds considered were fluazaindolizine, IN-REG72, IN-A5760, IN-F4106, IN-QEK31, IN-QZY47, IN-RYC33, IN-TMQ01, IN-UJV12, and IN-TQD54 and their conjugates.

Based on toxicological properties the following compounds are assumed to be covered by the fluazaindolizine HBGVs: fluazaindolizine, and free and conjugated forms of IN-REG72, IN-A5760, IN-F4106, IN-QEK31, IN-QZY47, IN-RYC33 and IN-TMQ01.

Each of the compounds is variously the predominant or a significant residue in primary and rotated crops. The Meeting agreed that the residue definition for dietary risk assessment for plant commodities should account for residues of fluazaindolizine, and free and conjugated forms of the following compounds: IN-REG72, IN-QEK31, IN-A5760, IN-F4106, IN-QZY47, IN-RYC33, and IN-TMQ01.

It is noted the analytical method utilising acid hydrolysis converts conjugates to their free form and also hydrolyses fluazaindolizine to IN-QEK31 and IN-F4106, IN-REG72 to IN-QEK31 and IN-A5760 and converts IN-RYC33 to IN-QEK31. To avoid double counting when expressing all residues in terms of fluazaindolizine, the Meeting considered the maximum of the sum of IN-A5760, IN-F4106, IN-QZY47 and

IN-TMQ01 or IN-QEK31 measured after hydrolysis to provide the best measure of the compounds included in the residue definition.

For example, for hydrolysis products containing the imidazopyridine ring

- IN-A5760 when expressed in parent equivalents would account for IN-A5760 and its conjugates as well as IN-REG72 and its conjugates and IN-QEK31,
- IN-F4106 would account for IN-F4106 and its conjugates as well as fluazaindolizine and IN-QEK31,
- IN-QZY47 would account for IN-QZY47 and its conjugates and IN-QEK31 and
- IN-TMQ01 for IN-TMQ01 and its conjugates and IN-QEK31.

For the hydrolysis products containing the phenyl ring,

- IN-QEK31, when expressed in parent equivalents accounts for IN-A5760, IN-F4106, IN-QZY47, IN-TMQ01, and fluazaindolizine, IN-REG72 as well as IN-RYC33 and IN-R2W56.

To implement the residue definition for dietary risk assessment for plant commodities the maximum concentration of the sum of compounds containing the imidazopyridine ring and hydrolysed using acid to IN-A5760, IN-F4106, IN-QZY47 and IN-TMQ01 (expressed as fluazaindolizine) or the compounds containing the phenyl ring and hydrolysed to IN-QEK31 (expressed as fluazaindolizine) should be used.

Insufficient toxicological data was available for IN-TDQ54 and IN-UJV12 and the Meeting considered they could be assessed using the threshold of toxicological concern (TTC) approach Cramer class III (1.5 µg/kg bw/day).

Animal commodities

Livestock will be exposed to residues in feed, both from treated and rotated crops.

The metabolism of fluazaindolizine in lactating goats and laying hens was qualitatively similar. Fluazaindolizine was a major component of the ¹⁴C residue in both the lactating goat and laying hen metabolism studies (goat: muscle > 62 percent TRR, fat > 67 percent TRR, kidney > 65 percent TRR, liver > 18 percent TRR, milk > 72 percent TRR; hen: egg > 76 percent TRR, fat > 66 percent TRR, liver > 91 percent TRR). The predominant metabolite was IN-F4106 (goat: muscle 26 percent TRR, fat 7 percent TRR, kidney 7 percent TRR, liver 39 percent TRR; hen: egg 6 percent TRR, fat 4 percent TRR, liver 3 percent TRR) together with small amounts of IN-A5760 (goat: muscle 3.4 percent TRR, liver 4.8 percent TRR, kidney 0.8 percent TRR), IN-REG72 (goat: liver 12 percent TRR, kidney 3.3 percent TRR, fat 5 percent TRR, milk 5 percent TRR; hen: liver 1.1 percent TRR) and IN-RYC33 (hen: egg 11 percent TRR, fat 2.5 percent TRR, liver 0.7 percent TRR).

In studies on the metabolism of IN-QEK31, limited metabolism occurred with IN-QEK31 the major component of the ¹⁴C residue (goat: fat 74 percent TRR, liver 69 percent TRR, kidney 94 percent TRR, milk 95 percent TRR; hen: liver 71 percent TRR).

In a study on the metabolism on IN-QZY47, only low levels of IN-QZY47 were detected in milk (3.1 percent TRR) with no residues detected in tissues. The predominant residue in tissues was IN-F4106 (milk 23 percent TRR, liver 41 percent TRR, kidney 15 percent TRR, muscle 81 percent TRR, fat > 60 percent TRR) with lower levels of IN-A5760 (milk 2.3 percent TRR, liver 10 percent TRR, kidney 5.3 percent TRR, fat 5 percent TRR).

In a metabolism study on IN-TMQ01 in a lactating goat, IN-TMQ01 was the predominant ¹⁴C residue in liver (48 percent TRR), kidney (87 percent TRR), muscle (43 percent TRR) and fat (50 percent TRR) with IN-F4106 the predominant ¹⁴C residue in milk (98 percent TRR) and muscle (44 percent TRR).

Fluazaindolizine is present in milk, eggs and all tissues in the lactating goat and most tissues in laying hen metabolism studies and would be suitable for monitoring compliance.

Methods are available for the determination of fluazaindolizine and IN-A5760, IN-F4106, IN-REG72, IN-QEK31, IN-R2W56 and IN-RYC33 in tissues, milk and eggs.

The Meeting agreed the residue for compliance monitoring for tissues, milk and eggs should be fluazaindolizine.

In deciding which compounds should be included in the residue definition for risk assessment, the Meeting considered the likely occurrence of the compounds and the toxicological properties of the candidates. The compounds fluazaindolizine, IN-A5760, IN-F4106, IN-REG72, IN-QEK31, IN-QZY47, IN-RYC33, and IN-TMQ01 are considered to be covered by the HBGV for fluazaindolizine.

The predominant residues livestock are exposed to are IN-A5760, IN-F4106, IN-QEK31, IN-QZY47 and IN-TMQ01 at similar levels and these compounds, together with fluazaindolizine will comprise the majority of residues. The metabolism study with IN-QZY47 suggests no residues of IN-QZY47 are expected in tissues, and only very low residues in milk. Residues of IN-QZY47 in poultry commodities are also expected to be insignificant. IN-REG72 and IN-RYC33 are only found at low levels in livestock feed items and the Meeting considered IN-REG72 and IN-RYC33 would not be found at significant levels in livestock tissues, milk, or eggs. When expressed in terms of fluazaindolizine, IN-QEK31 residues are accounted for by the sum of IN-A5760, IN-F4106 and IN-TMQ01 and noting that metabolism and feeding studies with IN-QEK31 suggest only low residues are expected, the Meeting agreed it was not necessary to include IN-QZY47, IN-REG72 or IN-QEK31 in the residue definition for risk assessment.

The Meeting agreed the residue definition for risk assessment for animal commodities should be the sum of fluazaindolizine, IN-A5760, IN-F4106, and IN-TMQ01 (expressed as fluazaindolizine).

Consideration of metabolites using TTC approach

The Meeting also considered that IN-TDQ54 and IN-UJV12, metabolites relevant for livestock dietary burden, could be assessed using the threshold of toxicological concern for Cramer Class III compounds of 1.5 µg/kg bw per day.

The Meeting recommended the following residue definitions for fluazaindolizine.

Definition of the residue for compliance with MRL for plant and animal commodities: *fluazaindolizine*.

Definition of the residue for dietary risk assessment for plant commodities:

fluazaindolizine, and free and conjugated forms of the following compounds: 2-chloro-5-hydroxybenzenesulfonamide (IN-A5760), 2-chloro-5-methoxybenzenesulfonamide (IN-F4106), 8-chloro-6-(trifluoromethyl)imidazo[1,2-a]pyridine-2-carboxylic acid (IN-QEK31), 3-[[[(2-chloro-5-methoxyphenyl)sulfonyl]amino]-L-alanine (IN-QZY47), 8-chloro-N-[(2-chloro-5-hydroxyphenyl)sulfonyl]-6-(trifluoromethyl)imidazo[1,2-a]pyridine-2-carboxamide (IN-REG72), 8-chloro-6-(trifluoromethyl)imidazo[1,2-a]pyridine-2-carboxamide (IN-RYC33) and 3-[[[(2-chloro-5-methoxyphenyl)sulfonyl]amino]-(2R)-hydroxypropanoic acid (IN-TMQ01) (expressed as fluazaindolizine). This can be implemented by taking the maximum of the sum of compounds containing the imidazopyridine ring and hydrolysed using acid to IN-A5760, IN-F4106, IN-QZY47 and IN-TMQ01 (expressed as fluazaindolizine) OR compounds containing the

phenyl ring and hydrolysed to 8-chloro-6-(trifluoromethyl)imidazo[1,2-a]pyridine-2-carboxylic acid (IN-QEK31) (expressed as fluazaindolizine).

Definition of the residue for dietary risk assessment for animal commodities:

Sum of fluazaindolizine, 2-chloro-5-hydroxybenzenesulfonamide (IN-A5760), 2-chloro-5-methoxybenzenesulfonamide (IN-F4106), and 3-[[[(2-chloro-5-methoxyphenyl)sulfonyl]amino]-(2R)-hydroxypropanoic acid (IN-TMQ01) (expressed as fluazaindolizine).

In deciding whether the residue for compliance is regarded as fat-soluble, the Meeting noted mean residues at the highest dose level (20.3 ppm) in the lactating cow study according to the compliance residue definition were 0.0066 mg/kg in muscle and 0.034 mg/kg in fat while residues in milk were similar in milk fat compared to whole milk (day-14 whole milk 0.061 mg/kg, cream 0.065 mg/kg, skim milk 0.07 mg/kg). In the laying hen metabolism study, residues of fluazaindolizine were 0.041 mg/kg in muscle and 0.0135 mg/kg in skin+fat.

The Meeting considers overall the residue for compliance is not fat-soluble.

To estimate livestock dietary burdens, the Meeting noted residues of fluazaindolizine, IN-A5760, IN-F4106 and IN-TMQ01 in feeds are required. In addition, IN-QZY47 is transformed into IN-F4106 and IN-A5760 in livestock and residue levels in feed are also required for IN-QZY47.

Results of supervised residue trials on crops

Supervised trials were available for the use of fluazaindolizine on a range of crops with product labels available from Australia and Canada.

The residue concentrations in the evaluation tables are expressed in terms of the individual compounds and not as fluazaindolizine equivalents.

In evaluating the crop residue data, a range of values are required to be derived. Estimates are made for residues of:

- fluazaindolizine for estimation of maximum residue levels and livestock dietary burden
- Maximum of $2.26 \times \text{IN-A5760} + 2.11 \times \text{IN-F4106} + 1.52 \times \text{IN-QZY47} + 1.51 \times \text{IN-TMQ01}$ or $1.77 \times \text{IN-QEK31}$ for estimation of STMR and HR values
- $\text{IN-F4106} + 1.068 \times \text{IN-A5760}$ for estimation of livestock dietary burden
- IN-QZY47 for estimation of livestock dietary burden
- IN-TMQ01 for estimation of livestock dietary burden
- Inputs required for compounds being assessed using the TTC approach
- IN-UJV12 for estimation of livestock dietary burden and median and highest values
- IN-TDQ54 for estimation of livestock dietary burden and median and highest values

In calculating sums, residues present at < 0.01 mg/kg are assumed present at 0.01 mg/kg.

Analyte	Residue (mg/kg)	Factor to convert to fluazaindolizine equivalents	Converted residue (mg/kg)
IN-A5760	0.01	2.26	0.0226
IN-F4106	0.05	2.11	0.1055
IN-QZY47	0.01	1.52	0.0152
IN-TMQ01	0.01	1.51	0.0151
Sum			0.1584

Fruiting vegetables, cucurbits (cucumber, melon, squash)

In Canada, cGAP for cucurbits consists of four soil applications at pre-plant or broadcast followed by soil incorporation/chemigation at 0.56–2.24 kg ai/ha and at 14-day intervals with a PHI of 1 day with a maximum application of 2.24 kg ai/ha/year.

The Meeting received supervised residue trials on cucumber and summer squash conducted in Canada and the United States.

In nine trials on cucumber approximating cGAP residues: < 0.01 (4), 0.0105, 0.012, 0.0155, 0.0535, 0.0755 mg/kg for fluazaindolizine.

In nine trials approximating cGAP residues in squash were: < 0.01 (6), 0.011, 0.0455, 0.089 mg/kg for fluazaindolizine.

The Meeting noted that residues in cucumber and summer squash are similar, confirmed by a Mann-Whitney U test, and decided to combine the data sets for mutual support. The combined data is: < 0.01 (10), 0.0105, 0.011, 0.012, 0.0155, 0.0455, 0.0535, 0.0755, 0.089 mg/kg.

Total residues for dietary risk assessment are 0.0740 (4), 0.0755, 0.0763, 0.0808, 0.0909, 0.1078, 0.1105, 0.1261, 0.1310, 0.1331, 0.1416, 0.1648, 0.1720, 0.2729, 0.3674 mg/kg.

The Meeting estimated a maximum residue level of 0.15 mg/kg, an STMR of 0.1092 mg/kg and an HR of 0.3674 for fluazaindolizine in the fruiting vegetable cucurbit subgroup of cucumbers and summer squashes.

Residues of IN-UJV12 in cucumber and squash were: < 0.01 (11), 0.0105, 0.0105, 0.0135, 0.0155, 0.0165, 0.0165, 0.0205 mg/kg.

Residues for the TTC approach in cucumber and squash were: < 0.01 (18) mg/kg.

IN-UJV2; < 0.01 (11), 0.0105 (2), 0.0135, 0.0155, 0.0165 (2), 0.0205 mg/kg, with a median of 0.01 mg/kg and a highest residue of 0.0205 mg/kg

IN-TQD54: < 0.01 (18) mg/kg, with a median and highest residue of 0.01 mg/kg

In 10 trials conducted in melon conducted in Canada and the United States approximating cGAP residues in whole melons were: < 0.01 (5), 0.011, 0.012, 0.012, 0.041, 0.056 mg/kg for fluazaindolizine, maximum individual analytical result 0.089 mg/kg.

Total residues for dietary risk assessment in melon pulp were: 0.0740, 0.0763, 0.0900, 0.0960, 0.1340, 0.1355, 0.1835, 0.2144, 0.3380, 0.3937 mg/kg.

The Meeting estimated a maximum residue level of 0.1 mg/kg (OECD calculator estimate 0.07 mg/kg but highest individual value was 0.089 mg/kg) for fluazaindolizine in Melons, pumpkins and winter squash, subgroup of.

The Meeting also estimated an STMR of 0.1348 mg/kg and an HR of 0.3937 mg/kg for melon pulp.

Residues for the TTC approach were:

IN-UJV12: < 0.01 (9), 0.0125 mg/kg, with a median of 0.01 mg/kg and a highest residue of 0.0125 mg/kg.

IN-TQD54: < 0.01 (9), 0.0105 mg/kg, with a median of 0.01 mg/kg and a highest residue of 0.0105 mg/kg.

Fruiting vegetables, other than cucurbits (tomato, peppers including chili)

In Canada cGAP for fruiting vegetables is for three soil applications at pre-plant or broadcast followed by soil incorporation or chemigation at 0.56–2.24 kg ai/ha and at 14-day intervals with a PHI of 1 day with a maximum application of 2.24 kg ai/ha/year.

In 17 trials approximating cGAP on tomato conducted in Canada and the United States, residues of fluazaindolizine were: < 0.01 (15), 0.025, 0.0665 (highest of 0.11) mg/kg.

Total residues in tomato for dietary risk assessment were (n=17) were: 0.0740 (8), 0.0748, 0.0751, 0.0751, 0.0797, 0.0808, 0.0842, 0.0967, 0.1204, 0.9630 mg/kg.

The Meeting estimated a maximum residue level of 0.15 mg/kg (OECD calculator estimate 0.07 mg/kg but highest individual value was 0.11 mg/kg), an STMR of 0.0748 mg/kg and an HR of 0.9630 mg/kg for fluazaindolizine in tomato.

The Meeting agreed to extrapolate the results for tomato to eggplant and estimated a maximum residue level of 0.15 mg/kg, an STMR of 0.0748 mg/kg and an HR of 0.9630 mg/kg for fluazaindolizine in eggplant.

For livestock dietary burden, residues in tomato were (n=17):

[IN-F4106+1.068×IN-A5760]: 0.0207 (10), 0.0212 (2), 0.0234, 0.0239, 0.0255, 0.0427, 0.3385 mg/kg, with a median of 0.0207 mg/kg

IN-QZY47: < 0.01 (15), 0.0125, 0.058 mg/kg, with a median of 0.01 mg/kg

IN-TMQ01: < 0.01 (13), 0.0105, 0.0135, 0.025, 0.14 mg/kg, with a median of 0.01 mg/kg.

For the TTC approach, residues in tomatoes were (n=17):

IN-UJV12: < 0.01 (17) mg/kg, with median and highest residues of 0.01 mg/kg.

IN-TQD54: < 0.01 (15), 0.011, 0.061 mg/kg, with a median of 0.01 mg/kg and a highest residue of 0.061 mg/kg

In 13 trials on pepper, including chili peppers, conducted in Canada and the United States approximating cGAP, residues of fluazaindolizine were: < 0.01 (12), 0.0265 mg/kg.

Total residues in peppers for dietary risk assessment were: 0.0740 (9), 0.0755, 0.0909, 0.1209, 0.3102 mg/kg.

The Meeting estimated a maximum residue level of 0.03 mg/kg, an STMR of 0.0740 mg/kg and an HR of 0.3102 mg/kg for fluazaindolizine in peppers.

Residues in peppers for the TTC approach were (n=13)

IN-UJV12: < 0.01 (13) mg/kg, with a median and a highest residue of 0.01 mg/kg

IN-TQD54: < 0.01 (11), 0.0205, 0.0375 mg/kg, with a median of 0.01 mg/kg and a highest residue of 0.0375 mg/kg

Using a default concentration factor of 10, the Meeting estimated a maximum residue level of 0.3 mg/kg, a STMR of 0.74 mg/kg and a HR of 3.102 mg/kg for fluazaindolizine in dried chili pepper.

*Root and tuber vegetables**Carrot*

In Canada cGAP for carrot is for two soil applications, pre-plant or broadcast followed by soil incorporation or chemigation at 0.56–2.24 kg ai/ha and at 14-day intervals with a PHI of 65 days with a maximum application of 2.24 kg ai/ha/year.

In 11 trials on carrots conducted in Canada and the United States approximating cGAP, residues in carrots were: < 0.01 (6), 0.02, 0.0235, 0.04, 0.0995, 0.265 mg/kg for fluazaindolizine.

Total residues for dietary risk assessment were: 0.0740, 0.0740, 0.1034, 0.1271, 0.1329, 0.1485, 0.1503, 0.4375, 0.5862, 0.7679, 1.973 mg/kg.

The Meeting estimated a maximum residue level of 0.4 mg/kg, a STMR of 0.1485 mg/kg and an HR of 1.973 mg/kg for fluazaindolizine in carrots.

For livestock dietary burden, residues in carrot were (n=11):

[IN-F4106+1.068×IN-A5760]: 0.0207 (6), 0.0232, 0.0287, 0.0332, 0.0737, 0.1489 mg/kg, with a median of 0.0297 mg/kg and a highest residue of 0.1489 mg/kg

IN-QZY47: < 0.01 (3), 0.014, 0.0205, 0.031, 0.0335, 0.089, 0.1095, 0.115, 0.5 mg/kg, with a median of 0.031 and a highest residue of 0.5 mg/kg

IN-TMQ01: < 0.01 (2), 0.012, 0.024, 0.0245, 0.045, 0.0535, 0.0765, 0.24, 0.39, 0.595 mg/kg, with a median of 0.01 mg/kg and a highest residue of 0.595 mg/kg

For the TTC approach, residues in carrot were (n=11):

IN-UJV12: ≤ 0.01 (11) mg/kg, with a median and a highest residue of 0.01 mg/kg

IN-TQD54: < 0.01 (8), 0.025, 0.042, 0.049 mg/kg, with a median of 0.01 mg/kg and a highest residue of 0.049 mg/kg.

Tuberous and corm vegetables

In Canada cGAP for tuberous and corm vegetables is for two soil applications at pre-plant or broadcast followed by soil incorporation or chemigation at 0.56–2.24 kg ai/ha and at 14-day intervals with a PHI of 40 days with a maximum application of 2.24 kg ai/ha/year.

In 19 trials on potatoes conducted in Canada and the United States approximating cGAP, residues in were: < 0.01 (4), 0.012, 0.014, 0.0165, 0.0165, 0.021, 0.028, 0.0305, 0.031, 0.0415, 0.0435, 0.0465, 0.0515, 0.068, 0.1075, 0.16 mg/kg for fluazaindolizine.

Total residues for dietary risk assessment were: 0.0740 (3), 0.0751, 0.0983, 0.1014, 0.1057, 0.1095, 0.1182, 0.1231, 0.1558, 0.1816, 0.2089, 0.2272, 0.2515, 0.2856, 0.3709, 0.4116, 0.7356 mg/kg.

The Meeting estimated a maximum residue level of 0.2 mg/kg, a STMR of 0.1231 mg/kg and an HR of 0.7356 mg/kg for fluazaindolizine in tuberous and corm vegetables.

For livestock dietary burden, residues in potatoes were (n=19):

[IN-F4106+1.068×IN-A5760]: 0.0207 (4), 0.0212, 0.0247, 0.0302, 0.0317, 0.0322, 0.0337 (2), 0.0357, 0.0372, 0.0419, 0.0437, 0.0452, 0.0570, 0.0717, 0.1127 mg/kg, with a median of 0.0337 mg/kg and a highest residue of 0.1127 mg/kg.

IN-QZY47: < 0.01 (9), 0.011, 0.012, 0.015, 0.02, 0.022, 0.024, 0.038, 0.0425, 0.0455, 0.072 mg/kg, with a median of 0.011 mg/kg and a highest residue of 0.072 mg/kg.

IN-TMQ01: < 0.01 (8), 0.0115, 0.0205, 0.024, 0.031, 0.0425, 0.046, 0.0475, 0.12, 0.17, 0.19, 0.335 mg/kg, with a median of 0.0205 mg/kg and a highest residue of 0.335 mg/kg.

For the TTC approach, residues were:

IN-UJV12: < 0.01 (15), 0.011, 0.0115, 0.012, 0.016 mg/kg, with a median of 0.01 mg/kg and a highest residue of 0.016 mg/kg.

IN-TQD54: < 0.01 (11), 0.0105, 0.0115, 0.0235, 0.0305, 0.031, 0.034, 0.044, 0.0865 mg/kg, with a median of 0.01 mg/kg and a highest residue of 0.0865 mg/kg.

Residues in rotational crops

Fluazaindolizine and metabolites are moderately persistent to persistent in the environment and may contribute to residues in follow/rotational crops through uptake from soil.

In assessing the potential uptake of residues, the Meeting considered the maximal season rate to be 2.24 kg ai/ha as detailed for all crops on the Canadian label. Application rates relevant for plateau concentrations in soil for the various compounds of interest can be calculated using the compound aerobic soil degradation DT_{50} (median) values for the various compounds of interest. Geometric mean DT_{50} value of 28.1 days for fluazaindolizine, 89 days for IN-QEK31, 293 days for IN-F4106 and 27 days for IN-A5760. For compounds not formed in soil, the concentration for fluazaindolizine is used (IN-QZY47, IN-TMQ01, IN-UJV12 and IN-TQD54). The estimated application rate for plateau residues in soil for fluazaindolizine, IN-A5760 and IN-QEK31 is 2.24 kg ai/ha, for IN-F4106 3.87 kg ai/ha.

Field rotational crop studies were used to derive estimates of residues in various commodities if the field were treated at the maximal seasonal rate. In combining residues from different trials to derive the various inputs required, individual analyte residues were scaled to the maximum seasonal rate.

The commodity groups studied in the field crop rotational studies were:

Fruit (strawberry)

Fruiting vegetables (tomato)

Leafy vegetables/Brassicac (lettuce, spinach, radish tops, turnip tops, broccoli, Swiss chard)

Root and tuber - tops (carrot tops, radish tops, turnip tops)

Root and tuber (carrots, radish, turnip)

Cereals (corn/maize, sorghum, wheat)–forage, straw or stover, hay, grain

Oilseeds/pulses (rape, beans, peas, soya beans)–forage, hay, grain

Bulb and stem vegetable (celery)

For each trial location/year, the highest residue from the PBIs that were longer than the PBI on the Canada label were used: 0 days for carrots, 14 days for root vegetables, except sugar beets (except carrot roots), leaves of root and tuber vegetables, bulb vegetables, leafy vegetables, brassica head and stem vegetable, legume vegetables, succulent or dried, foliage of legume vegetables, low growing berries, cereal grain, forage, fodder, and straw of cereal grains, grass forage, fodder, and hay, oilseeds, stalk, stem, and leaf petioles, and 365 days for all other crops.

Table 5.15.2 Example of scaled residues (mg/kg) in radish tops in one trial conducted at 4.67 kg ai/ha (68 days PBI) and residues scaled

kg ai/ha	PBI (days)	Fluazaindolizine	IN-A5760	IN-F4106	IN-QZY47	IN-TMQ01	IN-UJV12	IN-TQD54
4.67	68	0.01	0.038	0.0115	0.16	0.35	0.0305	0.245
Scaling factor		2.24/4.67	2.24/4.67	3.87/4.67	2.24/4.67	2.24/4.67	2.24/4.67	2.24/4.67
Scaled residues		0.0048	0.0182	0.0095	0.0767	0.1679	0.0146	0.1175

The sum of IN-F4106+1.068×IN-A5760 was 0.0289 mg/kg (expressed as IN-F4106).

When there were multiple crops within a rotational crop category, for example leafy vegetables, where residue data were available for lettuce, spinach, radish tops, turnip tops and Swiss chard, the highest of the STMR/median residues and HR/highest residues for the individual crops were selected for the STMR/median and HR/highest residue for the crop grouping.

Strawberry (Canada PBI 14 days, n=9)

Residues of fluazaindolizine: < 0.005 (4), < 0.0051 (5) mg/kg.

Total residues for dietary risk assessment were: 0.0446, 0.0455, 0.0459, 0.0494, 0.0530, 0.0585, 0.0637, 0.0996, 0.1416 mg/kg.

The Meeting estimated a maximum residue level of 0.015 mg/kg for strawberries, an STMR of 0.0530 mg/kg and an HR of 0.1416 mg/kg.

For the TTC approach, residues in strawberry were (n=11):

Residues of IN-UJV12 were: 0.0050 (4), 0.0051 (5) mg/kg, with a median of 0.005 mg/kg and a highest residue of 0.0051 mg/kg.

Residues of IN-TQD54 were: 0.0050 (4), 0.0051 (4), 0.0084 mg/kg, with a median of 0.0051 mg/kg and a highest residue of 0.0084 mg/kg.

Tomato (Canada PBI not relevant, n=10)

Residues of fluazaindolizine: 0.0050 (6), 0.0051, 0.0051, 0.0052, 0.0052 mg/kg.

Total residues for dietary risk assessment were: 0.0445, 0.0451, 0.0455, 0.0464, 0.0467, 0.0475, 0.0526, 0.0526, 0.0706, 0.1889 mg/kg.

Residues in tomatoes for livestock dietary burden were (n=10):

[IN-F4106+1.068×IN-A5760]: 0.0139, 0.0141, 0.0142, 0.0145, 0.0146, 0.0150, 0.0155, 0.0166, 0.0216, 0.0379 mg/kg

IN-QZY47: 0.0050 (6), 0.0051 (2), 0.0052 (2) mg/kg

IN-TMQ01: 0.0050 (2), 0.0051, 0.0052 (2), 0.0058, 0.0065, 0.0082, 0.0114, 0.0669 mg/kg,

Residues for the TTC approach were:

IN-UJV12: 0.0050 (6), 0.0051 (2), 0.0052 (2) mg/kg

IN-TQD54: 0.0050 (4), 0.0051, 0.0052 (2), 0.0070, 0.0105, 0.0249 mg/kg

Residues arising from rotational crops are lower than the ones found in treated tomatoes, peppers and eggplant and the Meeting confirms its previous estimations based on trials conducted with the primary crops.

*Brassica vegetables (except Brassica leafy vegetables)**Broccoli (Canada PBI 14 days, n=10)*

Residues of fluazaindolizine: 0.0050 (4), 0.0051 (3), 0.0056, 0.0069, 0.0072 mg/kg.

Total residues for dietary intake assessment were: 0.0443, 0.0446, 0.0450, 0.0451, 0.0460, 0.0467, 0.0487, 0.0514, 0.0564, 0.0705 mg/kg.

The Meeting estimated a maximum residue level of 0.02 mg/kg, an STMR of 0.04335 mg/kg and a HR of 0.0705 mg/kg for fluazaindolizine in the Group 010 Brassica vegetables (except Brassica leafy vegetables).

Residues for the TTC approach were:

IN-UJV12: 0.0050 (6), 0.0051 (4) mg/kg, with a median of 0.0050 mg/kg and a highest residue of 0.0051 mg/kg.

IN-TQD54: 0.0050 (6), 0.0051 (4) mg/kg, with a median of 0.0050 mg/kg and a highest residue of 0.0051 mg/kg.

*Leafy vegetables (including Brassica leafy vegetables)**Spinach (Canada PBI 14 days, n=2)*

Residues of fluazaindolizine in spinach: 0.0143, 0.0178 mg/kg.

Total residues for dietary risk assessment: 0.4982, 0.6035 mg/kg.

Residues for the TTC approach were:

IN-UJV12: 0.0129, 0.0187 mg/kg.

IN-TQD54: 0.0089, 0.0179 mg/kg.

Radish tops (Canada PBI 14 days, n=6)

Residues of fluazaindolizine in radish tops were: 0.0048, 0.0050, 0.0178, 0.0179 (3) mg/kg.

Total residues for dietary risk assessment: 0.1656, 0.3259, 0.3444, 0.4315, 0.6248, 1.275 mg/kg.

Residues for livestock dietary burden:

[IN-F4106+1.068×IN-A5760]: 0.0290, 0.0296, 0.0501, 0.0589, 0.0630, 0.0954 mg/kg.

IN-QZY47: 0.0251, 0.0548, 0.0767, 0.0824, 0.1742, 0.2276 mg/kg.

IN-TMQ01: 0.0179, 0.0645, 0.1472, 0.1502, 0.1679, 0.4819 mg/kg.

Residues for the TTC approach were:

IN-UJV12: 0.0146, 0.0179, 0.0179, 0.0182, 0.0320, 0.0602 mg/kg.

IN-TQD54: 0.0179, 0.0842, 0.1175, 0.1333, 0.1493, 0.6782 mg/kg.

Turnip tops (Canada PBI 14 days, n=5)

Residues of fluazaindolizine in turnip tops were: 0.005, 0.0051, 0.0051, 0.0051, 0.0051 mg/kg.

Total residues for dietary risk assessment : 0.0503, 0.0642, 0.0890, 0.1043, 0.1122 mg/kg.

Residues for livestock dietary burden:

[IN-F4106+1.068×IN-A5760]: 0.0141, 0.0142, 0.0142, 0.0143, 0.0165 mg/kg.

IN-QZY47: 0.0086, 0.0173, 0.0333, 0.0339, 0.0426 mg/kg.

IN-TMQ01: 0.0051, 0.0051, 0.0051, 0.0117, 0.0124 mg/kg.

Residues for the TTC approach were:

IN-UJV12: 0.0051, 0.0051, 0.0051, 0.0051, 0.0084 mg/kg.

IN-TQD54: 0.0051, 0.0051, 0.0051, 0.0112, 0.0144 mg/kg.

Carrot tops (Canada PBI 0 days, n=3)

Residues of fluazaindolizine in carrot tops: 0.0050, 0.0050, 0.0060 mg/kg.

Total residues for dietary risk assessment : 0.2177, 0.5851, 2.857 mg/kg.

Residues for the TTC approach were:

IN-UJV12: 0.0050 (3) mg/kg.

IN-TQD54: 0.0050, 0.0100, 0.0609 mg/kg.

Swiss chard (Canada PBI 14 days, n=5):

Residues of fluazaindolizine in Swiss chard: 0.0049, 0.0050, 0.0051, 0.0051, 0.0077mg/kg.

Total residues for dietary risk assessment: 0.0452, 0.0456, 0.0460, 0.0697, 0.1007 mg/kg.

Residues for the TTC approach were:

IN-UJV12: 0.0050, 0.0050, 0.0051, 0.0051, 0.0069 mg/kg.

IN-TQD54: 0.0049, 0.0050, 0.0050, 0.0051, 0.0051 mg/kg.

Lettuce (Canada PBI 14 days, n=13)

Residues of fluazaindolizine in lettuce: 0.0049 (3), 0.0050 (3), 0.0051 (3), 0.0061, 0.0178, 0.0179 (2) mg/kg.

Total residues for dietary risk assessment: 0.0458, 0.0536, 0.0647, 0.0716, 0.0773, 0.1134, 0.1579, 0.1601 (2), 0.1663, 0.1700, 0.1828, 1.388 mg/kg.

IN-UJV12: 0.0049, 0.0049, 0.0049, 0.0050, 0.0050, 0.0050, 0.0051, 0.0051, 0.0051, 0.0051, 0.0178, 0.0179, 0.0179 mg/kg.

IN-TQD54: 0.0049, 0.0049, 0.0049, 0.0050, 0.0050, 0.0050, 0.0051, 0.0051, 0.0051, 0.0051, 0.0178, 0.0179, 0.0179 mg/kg.

Of the leafy vegetable datasets available (spinach, lettuce, Swiss chard, carrot tops, radish tops and turnip tops) with five or more residue trials on rotational crops, radish tops had the highest fluazaindolizine residues, while residues of the other analytes of interest were sometimes highest in lettuce. The Meeting agreed to use the radish tops data to estimate a maximum residue level for leafy vegetables and the highest of the radish and lettuce data to estimate STMR and HR, respectively.

The Meeting estimated a maximum residue level of 0.04 mg/kg, an STMR of 0.3880 mg/kg (radish) and a HR of 1.388 mg/kg (lettuce) for fluazaindolizine in Group of Leafy vegetables (including Brassica leafy vegetables).

For livestock dietary burden, the Meeting estimated based on radish tops data:

[IN-F4106+1.068×IN-A5760]: median and highest residues of 0.0501 and 0.0954 mg/kg, respectively

IN-QZY47: median and highest residues of 0.07955 and 0.2276 mg/kg, respectively.

IN-TMQ01: median and highest residues for 0.1472) and 0.4819 mg/kg, respectively

For TTC the approach, also based on radish top data,

IN-UJV12: median and highest residues of 0.0182 and 0.0602 mg/kg, respectively

IN-TQD54: median and highest residues of 0.1175 and 0.6782 mg/kg, respectively

Legume vegetables, Group of

Soya bean immature seed = seed+pod (Canada PBI 14 days, n=7)

Residues of fluazaindolizine: 0.0050, 0.0050, 0.0050, 0.0050, 0.0051, 0.0178, 0.0178 mg/kg.

Total residues for dietary risk assessment: 0.0449, 0.0451, 0.0456, 0.0470, 0.1228, 0.1589, 0.1589 mg/kg.

Residues for the TTC approach were:

IN-UJV12: 0.0050 (4), 0.0051, 0.0178, 0.0178 mg/kg.

IN-TQD54: 0.0050 (4), 0.0051, 0.0178, 0.0178 mg/kg.

Pea immature, seed plus pod (Canada PBI 14 days, n=6)

Residues of fluazaindolizine were: 0.0049 (2), 0.0050, 0.0051, 0.0072, 0.0090 mg/kg.

Total residues for dietary risk assessment: 0.0442, 0.0453, 0.0681, 0.0737, 0.1021, 0.1420 mg/kg.

Residues for the TTC approach were:

IN-UJV12: 0.0049, 0.0050, 0.0051, 0.0062, 0.0066, 0.0094 mg/kg.

IN-TQD54: 0.0049, 0.0049, 0.0050, 0.0050, 0.0050, 0.0051 mg/kg.

Bean immature seed (Canada PBI 14 days, n=2)

Residues of fluazaindolizine were: 0.0179 (2) mg/kg.

Total residues for dietary risk assessment were: 0.1601 (2) mg/kg.

Residues for the TTC approach were:

IN-UJV12: 0.0179 (2) mg/kg.

IN-TQD54: 0.0179 (2) mg/kg.

The Meeting agreed to use the highest of the soya bean and pea data (both seed with pods) to estimate STMR and HR values.

The Meeting estimated a maximum residue level of 0.04 mg/kg, an STMR of 0.0709 mg/kg (pea) and an HR of 0.1589 (soya) mg/kg for fluazaindolizine in Group 014 Legume vegetables [immature seed with pod].

For TTC approach, the Meeting estimated:

IN-UJV12: median and highest residues of 0.00565 (pea) and 0.0178 (soya) mg/kg, respectively.

IN-TQD54: median and highest residues of 0.0050 (soya) and 0.0178 (soya) mg/kg, respectively.

Pulses, Group of

Soya bean seed (dry), Subgroup of (Canada PBI 14 days, n=7)

Residues of fluazaindolizine: 0.0050 (3), 0.0051, 0.0073, 0.0178, 0.0178 mg/kg.

Total residues for dietary risk assessment were: 0.0456, 0.0463, 0.0507, 0.0593, 0.1589, 0.1589, 0.1974 mg/kg.

Residues for livestock dietary burden were:

IN-F4106+1.068×IN-A5760: 0.0139, 0.0140, 0.0140, 0.0141, 0.0143, 0.0497, 0.0497 mg/kg.

IN-QZY47: 0.0050, 0.0050, 0.0050, 0.0051, 0.0053, 0.0178, 0.0178 mg/kg.

IN-TMQ01: 0.0050, 0.0050, 0.0050, 0.0050, 0.0051, 0.0178, 0.0178 mg/kg.

Residues for the TTC approach were:

IN-UJV12: 0.0050, 0.0050, 0.0050, 0.0050, 0.0051, 0.0178, 0.0178 mg/kg.

IN-TQD54: 0.0050, 0.0050, 0.0050, 0.0050, 0.0051, 0.0178, 0.0178 mg/kg.

Pea seed (dry), Subgroup of (Canada PBI 14 days, n=11)

Residues of fluazaindolizine: 0.0049, 0.0050, 0.0051, 0.0072, 0.0073, 0.0094, 0.0148, 0.0220, 0.0264, 0.0343, 0.0565 mg/kg.

Total residues for dietary risk assessment: 0.0464, 0.0503, 0.0631, 0.0646, 0.0656 (2), 0.1141, 0.1150, 0.2716, 0.2738, 1.2392 mg/kg.

Residues for livestock dietary burden:

[IN-F4106+1.068×IN-A5760]: 0.0138, 0.0141, 0.0142, 0.0169, 0.0198, 0.0202, 0.0205 (2), 0.0462, 0.0659, 0.3567 mg/kg.

IN-QZY47: 0.0064, 0.0071, 0.0072, 0.0073 (2), 0.0084, 0.0473, 0.0505, 0.0821, 0.1110, 0.2960 mg/kg.

IN-TMQ01: 0.0049 (2), 0.0050 (3), 0.0051, 0.0071, 0.0072, 0.0073 (2), 0.0235 mg/kg.

Residues for the TTC approach were:

IN-UJV12: 0.0049, 0.0051, 0.0071, 0.0072, 0.0073 (2), 0.0123, 0.0126, 0.0222, 0.0261, 0.0740 mg/kg.

IN-TQD54: 0.0049 (2), 0.0050 (3), 0.0051, 0.0071, 0.0072, 0.0073 (2), 0.0101 mg/kg.

Bean seed (dry), Subgroup of (Canada PBI 14 days, n=2)

Residues of fluazaindolizine: 0.0179 (2) mg/kg.

Total residues for dietary risk assessment: 0.1601 (2) mg/kg.

Residues for livestock dietary burden:

[IN-F4106+1.068×IN-A5760]: 0.0501 (2) mg/kg.

IN-QZY47: 0.0179 (2) mg/kg.

IN-TMQ01: 0.0179 (2) mg/kg.

Residues for the TTC approach were:

IN-UJV12: 0.0179 (2) mg/kg.

IN-TQD54: 0.0179 (2) mg/kg.

Residues were highest in peas dry and the Meeting agreed to use the dry pea dataset to make the estimations.

The Meeting estimated a maximum residue level of 0.09 mg/kg and an STMR of 0.0656 mg/kg for fluazaindolizine in Group 015 Pulses.

For livestock dietary burden, the Meeting estimated median residues of 0.0202 mg/kg for [IN-F4106+1.068×IN-A5760], 0.0084 mg/kg for IN-QZY47 and 0.0051 mg/kg for IN-TMQ01.

For TTC approach, the Meeting estimated a median residue of 0.0073 mg/kg for IN-UJV12 and of 0.0051 mg/kg for IN-TQD54.

Root and tuber vegetables

Carrot roots (Canada PBI 0 days, n=3)

Residues of fluazaindolizine were: 0.0050 (3) mg/kg.

Total residues for dietary risk assessment : 0.0449, 0.1096, 0.2055 mg/kg.

Residues for livestock dietary burden:

[IN-F4106+1.068×IN-A5760]: 0.0139 (3) mg/kg.

IN-TMQ01: 0.0052, 0.0403, 0.0998 mg/kg.

Residues for the TTC approach were:

IN-UJV12: 0.0050 (3) mg/kg.

IN-TQD54: 0.0050 (2), 0.0060 mg/kg.

Radish root (Canada PBI 14 days, n=6)

Residues of fluazaindolizine were: 0.0048, 0.0072, 0.0178, 0.0179 (3) mg/kg.

Total residues for dietary risk assessment: 0.1583, 0.1628, 0.1662, 0.2472, 0.3127, 0.9322 mg/kg.

Residues for the TTC approach were:

IN-UJV12: 0.0050, 0.0050, 0.0178, 0.0179, 0.0179, 0.0245 mg/kg.

IN-TQD54: 0.0070, 0.0152, 0.0178, 0.0179, 0.0215, 0.2008 mg/kg.

Turnip roots (Canada PBI 14 days, n=5)

Residues of fluazaindolizine were: 0.0050, 0.0051, 0.0077, 0.0091, 0.0106 mg/kg.

Total residues for dietary risk assessment: 0.0539, 0.0610, 0.0650, 0.0799, 0.1090 mg/kg.

Residues for livestock dietary burden

[IN-F4106+1.068×IN-A5760]: 0.0140, 0.0141, 0.0142 (2), 0.0143 mg/kg.

IN-QZY47: 0.0107, 0.0159, 0.0179, 0.0279, 0.0470 mg/kg.

IN-TMQ01: 0.0050, 0.0051 (4) mg/kg.

Residues for the TTC approach were:

IN-UJV12: 0.0050, 0.0051 (4) mg/kg.

IN-TQD54: 0.0050, 0.0051 (4) mg/kg.

Radish and turnip roots had the highest fluazaindolizine residues of the root and tuber vegetable datasets available.

Based on radish data, the Meeting estimated a maximum residue level of 0.04 mg/kg, an STMR of 0.1935 mg/kg and a HR of 0.9322 mg/kg for fluazaindolizine in Group 16 root vegetables (except carrot)

For livestock dietary burden, the Meeting estimated, based on turnip data:

[IN-F4106+1.068×IN-A5760]: median and highest residues of 0.0142 and 0.0143 mg/kg, respectively.

IN-QZY47: median and highest residues of 0.0179 and 0.0470 mg/kg, respectively.

IN-TMQ01: median and highest residues of 0.0051 and 0.0051 mg/kg, respectively.

For TTC approach, the Meeting estimated based on radish data:

IN-UJV12: median and highest residues of 0.0178 and 0.0245 mg/kg, respectively.

IN-TQD54: median and highest residues of 0.0178 and 0.2008 (radish) mg/kg, respectively.

Stalk and stem vegetables

Celery (Canada PBI 14 days, n=5):

Residues of fluazaindolizine were: 0.0050, 0.0051, 0.0087, 0.0091, 0.0197 mg/kg.

Total residues for dietary risk assessment: 0.0458, 0.0666, 0.0674, 0.1595, 0.8281 mg/kg.

The Meeting estimated a maximum residue level of 0.04 mg/kg, an STMR of 0.0674 mg/kg and a HR of 0.8281 mg/kg for fluazaindolizine in Group 17 Stalk and stem vegetables.

The Meeting agreed to extrapolate the conclusions to bulb vegetables and estimated a maximum residue level of 0.04 mg/kg, an STMR and HR of 0.0674 and 0.8281 mg/kg, respectively for Bulb vegetables.

For the TTC approach the Meeting also estimated:

IN-UJV12: 0.0050, 0.0051 (2), 0.0052, 0.0088 mg/kg, median of 0.0051 mg/kg and highest residues of 0.0088 mg/kg.

IN-TQD54: 0.0050, 0.0051 (2), 0.0052, 0.0121 mg/kg, median of 0.0051 mg/kg and highest residues of 0.0121 mg/kg.

Cereal grains, Group of

Field corn grain (Canada PBI 14 days, n=10)

Residues of fluazaindolizine were: 0.0050 (5), 0.0067 (4), 0.0068 mg/kg.

Total residues for dietary risk assessment: 0.0457, 0.0477, 0.0497, 0.0596, 0.0599, 0.0601 (2), 0.0607, 0.0654, 0.1015 mg/kg.

Residues for livestock dietary burden

[IN-F4106+1.068×IN-A5760]: 0.0139 (3), 0.0140, 0.0141, 0.0186, 0.0187, 0.0188 (2), 0.0190 mg/kg.

IN-QZY47: 0.0050 (3), 0.0052, 0.0063, 0.0067 (4), 0.0068, mg/kg.

IN-TMQ01: 0.0050, 0.0057, 0.0067 (4), 0.0068, 0.0086, 0.0117, 0.0181 mg/kg.

Residues for the TTC approach were:

IN-UJV12: 0.0050 (5), 0.0067 (4), 0.0068 mg/kg.

IN-TQD54: 0.0050 (3), 0.0067 (4), 0.0068, 0.0077, 0.0098 mg/kg.

Sorghum grain (Canada PBI 14 days, n=1)

Residues of fluazaindolizine were: 0.0178 mg/kg.

Total residues for dietary risk assessment: 0.1589 mg/kg.

Residues for livestock dietary burden

[IN-F4106+1.068×IN-A5760]: 0.0497 mg/kg.

IN-QZY47: 0.0178 mg/kg.

IN-TMQ01: 0.0178 mg/kg.

Residues for the TTC approach were.

IN-UJV12: 0.0178 mg/kg.

IN-TQD54: 0.0178 mg/kg.

Wheat grain (Canada PBI 14 days, n=13)

Residues of fluazaindolizine were: 0.0050 (4), 0.0051, 0.0070, 0.0072, 0.0073, 0.0073, 0.0076, 0.0178, 0.0179, 0.0179 mg/kg.

Total residues for dietary risk assessment: 0.0445, 0.0478, 0.0622, 0.0642, 0.0652, 0.0674, 0.0676, 0.1025, 0.1060, 0.1601 (2), 0.2517, 0.6799 mg/kg.

Residues for livestock dietary burden

[IN-F4106+1.068×IN-A5760]: 0.0139, 0.0140, 0.0141, 0.0143, 0.0194, 0.0201, 0.0204, 0.0205, 0.0212, 0.0480, 0.0497, 0.0501 (2) mg/kg.

IN-QZY47: 0.0050 (3), 0.0051, 0.0064, 0.0070, 0.0072, 0.0073 (2), 0.0076, 0.0178, 0.0179 (2) mg/kg.

IN-TMQ01: 0.0050 (3), 0.0051, 0.0070, 0.0072, 0.0073 (2), 0.0076, 0.0178, 0.0179 (2), 0.3766 mg/kg.

Residues for the TTC approach were:

IN-UJV12: 0.0050 (4), 0.0051, 0.0070, 0.0072, 0.0073, 0.0073, 0.0076, 0.0178, 0.0179, 0.0179 mg/kg.

IN-TQD54: 0.0050 (3), 0.0051, 0.0070, 0.0072, 0.0073, 0.0073, 0.0076, 0.0164, 0.0178, 0.0179, 0.0179 mg/kg.

Sweet corn (Canada PBI 14 days, n=10) Field corn, immature

Residues of fluazaindolizine were: 0.0050 (5), 0.0067 (4), 0.0068 mg/kg.

Total residues for dietary risk assessment: 0.0446 (2), 0.0450, 0.0465, 0.0540, 0.0596, 0.0599, 0.0601, 0.0607, 0.1401 mg/kg.

Residues for livestock dietary burden

[IN-F4106+1.068×IN-A5760]: 0.0139 (3), 0.0140, 0.0141, 0.0186, 0.0187, 0.0188, 0.0190, 0.0351 mg/kg.

IN-TMQ01: 0.0050 (3), 0.0062, 0.0067 (3), 0.0068, 0.0070, 0.0370 mg/kg.

Residues for the TTC approach were:

IN-UJV12: 0.0050 (5), 0.0067 (4), 0.0068 mg/kg.

IN-TQD54: 0.0050 (5), 0.0067 (3), 0.0068, 0.0471 mg/kg.

As there was only one trial on sorghum, the Meeting considered the wheat data to make the estimations for cereal grains

The Meeting estimated a maximum residue level of 0.03 mg/kg, and an STMR of 0.0676 mg/kg, for fluazaindolizine in Group 20 Cereal Grains

For livestock dietary burden, the Meeting estimated median residues of 0.0204 mg/kg for [IN-F4106+1.068×IN-A5760], of 0.0072 mg/kg for IN-QZY47 and of 0.0073 mg/kg for IN-TMQ01.

For TTC approach, the Meeting estimated median residues for IN-UJV12 of 0.0072 mg/kg and of 0.0073 mg/kg for IN-TQD54.

Oilseeds, Group of

Rape seed (Canada PBI 14 days, n=5)

Residues of fluazaindolizine were: 0.0071, 0.0072, 0.0073, 0.0073, 0.0075 mg/kg.

Total residues for dietary risk assessment: 0.0631, 0.0642, 0.0656 (2), 0.0669 mg/kg.

Residues for livestock dietary burden.

[IN-F4106+1.068×IN-A5760]: 0.0198, 0.0201, 0.0205 (2), 0.0209 mg/kg.

IN-QZY47: 0.0071, 0.0072, 0.0073 (2), 0.0075 mg/kg.

IN-TMQ01: 0.0071, 0.0072, 0.0073 (2), 0.0075 mg/kg.

Residues for the TTC approach were:

IN-UJV12: 0.0071, 0.0072, 0.0073, 0.0073, 0.0075 mg/kg.

IN-TQD54: 0.0071, 0.0072, 0.0073, 0.0073, 0.0075 mg/kg.

Soya bean seed (dry) (Canada PBI 14 days, n=7)

Residues of fluazaindolizine were: 0.0050, 0.0050, 0.0050, 0.0051, 0.0073, 0.0178, 0.0178 mg/kg.

Total residues for dietary intake assessment: 0.0456, 0.0463, 0.0507, 0.0593, 0.1589 (2), 0.1974 mg/kg.

Residues for livestock dietary burden

[IN-F4106+1.068×IN-A5760]: 0.0139, 0.0140 (2), 0.0141, 0.0143, 0.0497 (2) mg/kg.

IN-QZY47: 0.0050 (3) 0.0051, 0.0053, 0.0178 (2) mg/kg.

IN-TMQ01: 0.0050 (4), 0.0051 0.0178 (2) mg/kg.

Residues for the TTC approach were.

IN-UJV12: 0.0050, 0.0050, 0.0050, 0.0050, 0.0051, 0.0178, 0.0178 mg/kg.

IN-TQD54: 0.0050, 0.0050, 0.0050, 0.0050, 0.0051, 0.0178, 0.0178 mg/kg.

Highest residues in soya bean, max of analytes for others

The Meeting estimated a maximum residue level of 0.04 mg/kg (based on soya beans) and an STMR of 0.0656 mg/kg (based on rape seed) for Oilseeds

For the TTC approach, the Meeting estimated, also based on rape seed data, median residues of 0.0073 mg/kg for IN-UJV12 and IN-TQD54.

Residues in animal feeds

All residues in forages and fodders discussed below were reported on an as received basis.

Legume forages

Bean vines (Canada PBI 14 days, n=2)

Fluazaindolizine: 0.0179, 0.0179 mg/kg.

[IN-F4106+1.068×IN-A5760]: 0.0501 (2) mg/kg.

IN-QZY47: 0.3136, 2.150 mg/kg.

IN-TMQ01: 0.0179 (2) mg/kg.

Residues for the TTC approach were:

IN-UJV12: 0.0179, 0.0466 mg/kg.

IN-TQD54: 0.0179 (2) mg/kg.

Soya bean forage (Canada PBI 14 days, n=7)

Fluazaindolizine: 0.0050 (2), 0.0073, 0.0107, 0.0110, 0.0178 (2) mg/kg.

[IN-F4106+1.068×IN-A5760]: 0.0140, 0.0141, 0.0150, 0.0214, 0.0362, 0.0497 (2) mg/kg.

IN-QZY47: 0.0505, 0.0629, 0.0904, 0.1062, 0.1536, 0.1950, 0.3391 mg/kg.

IN-TMQ01: 0.0050 (4), 0.0051, 0.0178 (2) mg/kg.

Residues for the TTC approach were:

IN-UJV12: 0.0078, 0.0114, 0.0146, 0.0178, 0.0265, 0.0455, 0.0651 mg/kg.

IN-TQD54: 0.0050 (4), 0.0051, 0.0178, 0.0178 mg/kg.

Pea forage (Canada PBI 14 days, n=5)

Fluazaindolizine: 0.0067, 0.0071, 0.0072, 0.0073 (2) mg/kg.

IN-F4106+1.068×IN-A5760: 0.0198, 0.0202, 0.0205, 0.0205, 0.0509 mg/kg.

IN-QZY47: 0.0133, 0.0155, 0.0241, 0.0264, 0.0464 mg/kg.

IN-TMQ01: 0.0067, 0.0071, 0.0072, 0.0073 (2) mg/kg.

Residues for the TTC approach were:

IN-UJV12: 0.0071, 0.0072, 0.0073, 0.0073, 0.0094 mg/kg.

IN-TQD54: 0.0067, 0.0071, 0.0072, 0.0073, 0.0073 mg/kg.

Pea vines (Canada PBI 14 days, n=11)

Fluazaindolizine: 0.0049 (2), 0.0050, 0.0051, 0.0067, 0.0071, 0.0072, 0.0073 (2), 0.0076, 0.0105 mg/kg.

IN-F4106+1.068×IN-A5760: 0.0198, 0.0202, 0.0205 (2), 0.0217, 0.0228, 0.0263, 0.0616, 0.0777, 0.1140, 0.1156 mg/kg.

IN-QZY47: 0.0071, 0.0072, 0.0110, 0.0175, 0.0191, 0.0597, 0.0717, 0.1280, 0.1337, 0.2663, 0.3034 mg/kg.

IN-TMQ01: 0.0049 (2), 0.0050 (2), 0.0051, 0.0053, 0.0067, 0.0071, 0.0072, 0.0073 (2) mg/kg.

Residues for the TTC approach were:

IN-UJV12: 0.0067, 0.0071, 0.0072 (2), 0.0073 (2), 0.0092, 0.0262, 0.0318, 0.0488, 0.0641 mg/kg.

IN-TQD54: 0.0049 (2), 0.0050 (3), 0.0051, 0.0067, 0.0071, 0.0072, 0.0073 (2) mg/kg.

Based on soya bean forage data, the Meeting estimated a median and highest residue of 0.0107 and 0.0178 mg/kg respectively, for fluazaindolizine in Legume forages (bean, cowpea, crown vetch, Lespedeza, pea, peanut, soya bean, trefoil and vetch).

The Meeting also estimated based on soya bean or pea data:

[IN-F4106+IN-A5760]: median of 0.0214 mg/kg (soya bean) and highest residue of 0.0509 mg/kg (pea)

IN-QZY47: median and highest residues of 0.1062 and 0.3391 mg/kg, respectively, based on soya bean

IN-TMQ01: median of 0.0072 mg/kg (pea) and highest residue of 0.0178 mg/kg (soya bean)

For TTC approach

IN-UJV12: median of 0.0178 mg/kg and highest residues of 0.0651 mg/kg, based on soya bean

IN-TQD54: median of 0.0072 mg/kg (pea) and highest residues of 0.0178 mg/kg (soya bean)

*Subgroup of Products of legume feeds with low water (<20 percent) content (hay)**Bean hay (Canada PBI 14 days, n=2)*

Fluazaindolizine residues were: 0.0179, 0.0305 mg/kg.

IN-F4106+1.068×IN-A5760: 0.0501, 0.1073 mg/kg.

IN-TMQ01: 0.0179, 0.0179 mg/kg.

Residues for the TTC approach were:

IN-UJV12: 0.0323, 0.1971 mg/kg.

IN-TQD54: 0.0179, 0.0179 mg/kg.

Soya bean hay (Canada PBI 14 days, n=7)

Fluazaindolizine residues were: 0.0050, 0.0123, 0.0178, 0.0274, 0.0283, 0.0355, 0.0619 mg/kg.

IN-F4106+1.068×IN-A5760: 0.0156, 0.0539, 0.0571, 0.0660, 0.0733, 0.1047, 0.1889 mg/kg.

IN-QZY47: 0.1867, 0.2064, 0.2950, 0.3296, 0.3415, 0.4206, 1.0709 mg/kg.

IN-TMQ01: 0.0050, 0.0051, 0.0063, 0.0109, 0.0178, 0.0178, 0.1150 mg/kg.

Residues for the TTC approach were:

IN-UJV12: 0.0259, 0.0467, 0.0497, 0.0669, 0.0700, 0.0748, 0.1383 mg/kg.

IN-TQD54: 0.0050, 0.0050, 0.0051, 0.0052, 0.0178, 0.0178, 0.0200 mg/kg.

Pea hay (Canada PBI 14 days, n=11)

Fluazaindolizine residues were: 0.0049, 0.0051, 0.0073, 0.0118, 0.0182, 0.0188, 0.0194, 0.0318, 0.0491, 0.0548, 0.0848 mg/kg.

IN-F4106+1.068×IN-A5760: 0.0202, 0.0205, 0.0229, 0.0612, 0.1678, 0.1687, 0.1922, 0.1968, 0.3336, 0.4945, 0.8342 mg/kg.

IN-QZY47: 0.0072, 0.0078, 0.0279, 0.0296, 0.1144, 0.3012, 0.4005, 0.5121, 0.5662, 1.4933, 1.6035 mg/kg.

IN-TMQ01: 0.0049, 0.0051, 0.0071, 0.0072, 0.0073, 0.0073, 0.0110, 0.0114, 0.0116, 0.0118, 0.0305 mg/kg.

Residues for the TTC approach were:

IN-UJV12: 0.0071, 0.0072, 0.0073, 0.0073, 0.0303, 0.0462, 0.0710, 0.1438, 0.1452, 0.3478, 0.3559 mg/kg.

IN-TQD54: 0.0049, 0.0051, 0.0057, 0.0059, 0.0061, 0.0067, 0.0070, 0.0071, 0.0072, 0.0073, 0.0073 mg/kg.

Residues were highest in pea hay and soya bean hay.

Based on pea hay data, the Meeting estimated a maximum residue level of 0.17 mg/kg (dry weight basis) (assumed 88 percent dry matter) for fluazaindolizine in Subgroup of Products of legume feeds with low water (<20 percent) content (hay).

The Meeting also estimated, on a fresh weight basis:

Fluazaindolizine: median and highest residue of 0.0274 (soya bean) and 0.0848 (pea) mg/kg, respectively.

[IN-F4106+1.068×IN-A5760]: median and highest residues of 0.1687 and 0.8342 mg/kg, based on pea.

IN-QZY47: median and highest residues of 0.3296 (soya bean) and 1.6035 (pea) mg/kg,

IN-TMQ01: median and highest residues for of 0.0109 and 0.1150 mg/kg, based on soya bean

For the TTC approach

IN-UJV12: median and highest residues of 0.0669 (soya bean) and 0.3559 (pea) mg/kg

IN-TQD54: median and highest residues for of 0.0067 (pea) and 0.0200 (soya bean) mg/kg.

Cereal forages

Field corn forage (Canada PBI 14 days, n=10)

Residues of fluazaindolizine: 0.0050 (5), 0.0067 (4), 0.0068 mg/kg.

IN-F4106+1.068×IN-A5760: 0.0141, 0.0165, 0.0190, 0.0193, 0.0201, 0.0361, 0.0441, 0.0768, 0.0881, 0.0974 mg/kg.

IN-QZY47: 0.0050, 0.0060, 0.0065, 0.0068, 0.0086, 0.0095, 0.0127, 0.0148, 0.0166, 0.0254 mg/kg.

IN-TMQ01: 0.0081, 0.0287, 0.0300, 0.0359, 0.0574, 0.0738, 0.0773, 0.0778, 0.1003, 0.1144 mg/kg.

Residues for the TTC approach were:

IN-UJV12: 0.0050, 0.0050, 0.0050, 0.0057, 0.0067, 0.0067, 0.0067, 0.0067, 0.0068, 0.0107 mg/kg.

IN-TQD54: 0.0109, 0.0131, 0.0165, 0.0219, 0.0292, 0.0417, 0.0728, 0.1345, 0.1538, 0.1878 mg/kg.

Sorghum forage (Canada PBI 14 days, n=2)

Fluazaindolizine residues were: 0.0089, 0.0178 mg/kg.

IN-F4106+1.068×IN-A5760: 0.0445, 0.0497 mg/kg.

IN-QZY47: 0.0222, 0.0509 mg/kg.

IN-TMQ01: 0.1671, 0.4507 mg/kg.

Residues for the TTC approach were:

IN-UJV12: 0.0089, 0.0178 mg/kg.

IN-TQD54: 0.0187, 0.0402 mg/kg.

Wheat forage (Canada PBI 14 days, n=13)

Fluazaindolizine residues were: 0.0050 (3), 0.0051, 0.0067, 0.0070, 0.0072, 0.0073 (3), 0.0076, 0.0178, 0.0179 (2) mg/kg.

IN-F4106+1.068×IN-A5760: 0.0139, 0.0161, 0.0194, 0.0201, 0.0214, 0.0251, 0.0270, 0.0358, 0.0470, 0.0479, 0.0525, 0.0633, 0.0654 mg/kg.

IN-QZY47: 0.0050, 0.0050, 0.0054, 0.0070, 0.0072, 0.0073, 0.0073, 0.0076, 0.0076, 0.0149, 0.0178, 0.0179, 0.0179 mg/kg.

IN-TMQ01: 0.0070, 0.0072, 0.0159, 0.0188, 0.0233, 0.0298, 0.0309, 0.0330, 0.0349, 0.0534, 0.0747, 0.0931, 0.1611 mg/kg.

Residues for the TTC approach were:

IN-UJV12: 0.0050, 0.0050, 0.0050, 0.0050, 0.0051, 0.0070, 0.0072, 0.0073, 0.0073, 0.0076, 0.0178, 0.0179, 0.0179 mg/kg.

IN-TQD54: 0.0264, 0.0316, 0.0398, 0.0525, 0.0673, 0.0698, 0.1120, 0.1167, 0.1434, 0.1435, 0.1720, 0.2153, 0.4361 mg/kg.

Based on wheat data, the Meeting estimated a median and highest residue of 0.0072 and 0.0179 mg/kg, respectively for fluazaindolizine in cereal forages,

The Meeting also estimated (all on a fresh weight basis):

[IN-F4106+1.068×IN-A5760]: median and highest residues 0.0281 and 0.0974 mg/kg, respectively, based on maize

IN-QZY47: median and highest residues of 0.00905 and 0.0254 mg/kg, respectively, based on maize.

IN-TMQ01: median and highest residues of 0.0656 (maize) and 0.1611 (wheat) mg/kg, respectively.

Residues for the TTC approach were:

IN-UJV12: median and highest residues of 0.0072 and 0.0179 mg/kg, respectively, based on wheat

IN-TQD54: median and highest residues of 0.1120 and 0.4361 mg/kg, based on wheat.

Cereal grains (including pseudocereals) feed products with low water (<20 percent) content (hay and/or straw)

Field corn stover (Canada PBI 14 days, n=10)

Fluazaindolizine residues were: 0.0050 (5), 0.0067 (4), 0.0068 mg/kg.

IN-F4106+1.068×IN-A5760: 0.0219, 0.0418, 0.0544, 0.0669, 0.0676, 0.0744, 0.0751, 0.0815, 0.1422, 0.2650 mg/kg.

IN-QZY47: 0.0050, 0.0064, 0.0067, 0.0067, 0.0067, 0.0068, 0.0093, 0.0102, 0.0102, 0.0113 mg/kg.

IN-TMQ01: 0.0112, 0.0629, 0.0738, 0.0933, 0.1023, 0.1110, 0.1204, 0.1607, 0.1646, 0.2067 mg/kg.

Residues for the TTC approach were:

IN-UJV12: 0.0055, 0.0067, 0.0067, 0.0067, 0.0067, 0.0068, 0.0087, 0.0108, 0.0158, 0.0384 mg/kg.

IN-TQD54: 0.0165, 0.0307, 0.0649, 0.0698, 0.0765, 0.0800, 0.0804, 0.0869, 0.1073, 0.2200 mg/kg.

Sorghum straw (Canada PBI 14 days, n=2)

Fluazaindolizine residues were: 0.0089, 0.0178 mg/kg.

IN-F4106+1.068×IN-A5760: 0.0462, 0.0592 mg/kg.

IN-QZY47: 0.0347, 0.0571 mg/kg.

IN-TMQ01: 0.3289, 0.6336 mg/kg.

Residues for the TTC approach were:

IN-UJV12: 0.0089, 0.0178 mg/kg.

IN-TQD54: 0.0453, 0.0754 mg/kg.

Wheat hay (Canada PBI 14 days, n=13)

Fluazaindolizine residues were: 0.0050 (3), 0.0051, 0.0055, 0.0070, 0.0072, 0.0073 (2), 0.0076, 0.0178, 0.0179 (2) mg/kg.

IN-F4106+1.068×IN-A5760: 0.0236, 0.0253, 0.0254, 0.0272, 0.0276, 0.0443, 0.0521, 0.0547, 0.0564, 0.0776, 0.0962, 0.1628, 0.2905 mg/kg.

IN-QZY47: 0.0050, 0.0050, 0.0056, 0.0070, 0.0072, 0.0073, 0.0073, 0.0076, 0.0178, 0.0179, 0.0179, 0.0201, 0.0315 mg/kg.

IN-TMQ01: 0.0070, 0.0094, 0.0172, 0.0222, 0.0357, 0.0428, 0.0485, 0.0735, 0.1447, 0.2044, 0.2150, 0.3196, 0.3469 mg/kg.

Residues for the TTC approach were:

IN-UJV12: 0.0050 (2), 0.0051, 0.0055, 0.0067, 0.0070, 0.0072, 0.0073, 0.0074, 0.0076, 0.0178, 0.0179 (2) mg/kg.

IN-TQD54: 0.0577, 0.0613, 0.0796, 0.0850, 0.1031, 0.1171, 0.1459, 0.1996, 0.2995, 0.4659, 0.6117, 0.6899, 0.8673 mg/kg.

Wheat straw (Canada PBI 14 days, n=13)

Fluazaindolizine residues found were: 0.0050(3), 0.0051, 0.0072, 0.0073, 0.0073, 0.0076, 0.0179 (2), 0.0258, 0.0313, 0.0553 mg/kg.

IN-F4106+1.068×IN-A5760: 0.0203, 0.0289, 0.0399, 0.0611, 0.0831, 0.0851, 0.1328, 0.1556, 0.1565, 0.1601, 0.2557, 0.4667, 0.5487 mg/kg.

IN-QZY47: 0.0050, 0.0050, 0.0070, 0.0072, 0.0073, 0.0073, 0.0076, 0.0144, 0.0159, 0.0178, 0.0179, 0.0179, 0.0224 mg/kg.

IN-TMQ01: 0.0165, 0.0356, 0.0495, 0.0500, 0.0682, 0.0949, 0.0986, 0.1025, 0.1820, 0.2061, 0.2467, 0.4956, 0.6133 mg/kg.

Residues for the TTC approach were:

IN-UJV12: 0.0050, 0.0050, 0.0050, 0.0050, 0.0051, 0.0070, 0.0073, 0.0073, 0.0076, 0.0136, 0.0178, 0.0179, 0.0179 mg/kg.

IN-TQD54: 0.0488, 0.0650, 0.0672, 0.1211, 0.1233, 0.1735, 0.2204, 0.2269, 0.2688, 0.2991, 0.3027, 0.4622, 0.7526 mg/kg.

The number of residue trials on sorghum was too few to allow estimation of median and highest residues for sorghum fodder. Of the crops with sufficient trials, residues were highest in maize and wheat fodders.

Based on wheat data, the Meeting estimated a maximum residue level of 0.09 mg/kg (dry weight basis) (assumed 88 percent dry matter) for fluazaindolizine in cereal straw and fodder dry,

The Meeting also estimated, based on a fresh weight basis:

Fluazaindolizine: median and highest residues of 0.0073 and 0.0553 mg/kg respectively, based on wheat.

[IN-F4106+1.068×IN-A5760]: median and highest residues of 0.1328 and 0.5487 mg/kg, respectively, based on wheat.

IN-QZY47: median and highest residues of 0.0076 and 0.0315 mg/kg, respectively, based on wheat.

IN-TMQ01: median and highest residues of 0.1067 (maize) and 0.6133 (wheat) mg/kg, respectively.

Residues for the TTC approach were:

IN-UJV12: median and highest residues of 0.0073 (wheat) and 0.0384 (maize) mg/kg, respectively.

IN-TQD54: median and highest residues of 0.2204 and 0.8673 mg/kg, respectively, based on wheat.

Rape seed, forage (Canada PBI 14 days, n=5)

Fluazaindolizine residues found were: 0.0071, 0.0072, 0.0073, 0.0073, 0.0075 mg/kg.

IN-F4106+1.068×IN-A5760: 0.0198, 0.0201, 0.0205, 0.0205, 0.0209 mg/kg.

IN-QZY47: 0.0071, 0.0072, 0.0110, 0.0231, 0.0462 mg/kg.

IN-TMQ01: 0.0071, 0.0072, 0.0073, 0.0073, 0.0079 mg/kg.

Residues for the TTC approach:

IN-UJV12: 0.0071, 0.0072, 0.0073, 0.0073, 0.0075 mg/kg.

IN-TQD54: 0.0071, 0.0072, 0.0081, 0.0130, 0.0319 mg/kg.

Based on rape forage data, the Meeting estimated for oilseed forages, all on a fresh weight basis:

Fluazaindolizine: median and highest residue of 0.0073 (and 0.0075 mg/kg respectively).

[IN-F4106+1.068×IN-A5760]: median and highest residues of 0.0205 and 0.0209 mg/kg, respectively.

IN-QZY47: median and highest residues of 0.0110 and 0.0462 mg/kg, respectively.

IN-TMQ01: median and highest residues of 0.0073 and 0.0079 mg/kg, respectively.

Residues for the TTC approach:

IN-UJV12: median and highest residues of 0.0073 and 0.0075 mg/kg, respectively.

IN-TQD54 and median and highest residues of 0.0081 and 0.0319 mg/kg, respectively.

Rape seed, hay and/or straw (Canada PBI 14 days, n=5)

Fluazaindolizine residues found were: 0.0073, 0.0073, 0.0075, 0.0170, 0.0251 mg/kg.

IN-F4106+1.068×IN-A5760: 0.0245, 0.0270, 0.0442, 0.0455, 0.2330 mg/kg.

IN-QZY47: 0.0073, 0.0129, 0.0181, 0.0219, 0.0777 mg/kg.

IN-TMQ01: 0.0072, 0.0073, 0.0073, 0.0190, 0.0210 mg/kg.

Residues for the TTC approach:

IN-UJV12: 0.0072, 0.0073, 0.0088, 0.0094, 0.0608 mg/kg.

IN-TQD54: 0.0266, 0.0731, 0.1018, 0.1084, 0.2968 mg/kg.

The Meeting estimated a maximum residue level of 0.05 mg/kg (dry weight basis) for Rape seed, hay, and/or straw

Fate of residues during processing

The Meeting received information on the fate of fluazaindolizine residues during conditions simulating commercial processing.

Fluazaindolizine was not degraded and is hydrolytically stable under conditions simulating pasteurization (pH 4, 90 °C, 20 minutes), baking/brewing/boiling (pH 5, 100 °C, 60 minutes) and sterilisation (pH 6, 120 °C, 20 minutes).

Information on the fate of residues during processing was made available to the Meeting for maize, potatoes, soya beans, strawberries, tomatoes, and wheat. In some cases residues for individual compounds were <LOQ and processing factors could not be calculated. In these cases residues are assumed to be zero.

Processing factors (PF) are estimated by dividing the residues of analyte in processed commodity by the sum of potential source residues in the raw commodity, expressed in terms of analyte.

Table 5.15.3 summarizes the processing factors for fluazaindolizine. Residues concentrated (PF > 1) on processing for dried tomato, tomato wet pomace, tomato paste and soya bean meal.

Table 5.15.3 Processing factors and median and highest residue values for fluazaindolizine used for estimation of maximum residue levels including livestock dietary burdens

Processed commodity	Raw commodity [median residue]	Raw commodity [highest residue]	Individual processing factors	Median or best estimate processing factor	Median residue-P (mg/kg)	Highest residue-P (mg/kg)
Tomato dried	0.01	0.0665	1.8 4.9	3.35	0.0335	0.2228
Tomato canned			0 0.22	0.11	0.0011	
Tomato juice			0 0.53	0.265	0.0026	
Tomato wet pomace			1 2.4	1.7	0.017	
Tomato paste			1.2 1.3	1.25	0.0125	
Tomato purée			0.53 0.8	0.665	0.0066	
Potato , flakes/granules	0.028	0.16	0 0.07	0.035	0.001	
Potato crisps			0.03 0.18	0.105	0.0029	
French fries peeled			0 0.04	0.02	0.0006	
French fries unpeeled			0.08 0.91	0.495	0.01386	
Potato boiled unpeeled			0.07 0.15	0.11	0.00308	0.0176
Potato boiled peeled			0 0.02	0.01	0.00028	0.0016
Potato microwaved unpeeled			0.4 1.3	0.85	0.0238	0.1615
Soya bean meal (mechanically extracted)	0.0051		1.3 1.3 1.6	1.3	0.0066	
Soya bean meal (solvent extracted)			1.3 1.4 1.4	1.4	0.0071	
Soya bean hulls			0.9 0.9 1.7	0.9	0.0046	
Soya bean refined oil			0 0 0	0	0	

Using the estimated maximum residue level of 0.15 mg/kg for tomatoes and applying the processing factor of 3.35 for dried tomato, the Meeting estimated a maximum residue level of 0.5 mg/kg for tomato dried.

Inputs for estimation of dietary exposure are required for processed commodities. Table 5.15.4 summarizes estimated STMR-P and HR-P values, calculated using information on the concentration of the relevant compounds on processing also summarized in the series of tables on processing that follow. The STMR-P and HR-P values were calculated as $2.26 \times \text{IN-A5760} + 2.11 \times \text{IN-F4106} + 1.52 \times \text{IN-QZY47} + 1.51 \times \text{IN-TMQ01}$.

Table 5.15.4 STMR-P and HR-P values

Processed commodity	STMR-P (mg/kg)	HR-P (mg/kg)
Strawberry juice	0.0142	0.0734
Strawberry canned	0.0081	0.0419
Strawberry jam	0.0040	0.0210
Strawberry frozen fruit	0.0121	0.0629
Strawberry, dried	0.0830	0.4297
Tomato dried	0.4624	6.6960
Tomato canned	0.0711	0.9389
Tomato juice	0.0590	0.8314
Tomato paste	0.2476	3.5309
Tomato purée	0.1268	1.8056
Potato, flakes/granules	0.0956	1.0275
Potato crisps	0.0673	0.6757
French fries peeled	0.0319	0.3213
French fries unpeeled	0.1215	1.0607
Potatoes boiled unpeeled	0.0560	0.6538
Potatoes boiled peeled	0.0343	0.3695
Potatoes baked microwaved unpeeled	0.1661	1.3600
Soya bean refined oil	0	
Maize starch	0	
Maize grits	0.0144	
Maize flour	0.0366	
Maize refined oil	0	
Wheat bran	0	
Wheat flour	0	
Wheat germ	0	

Table 5.15.5 Processing factors and median and highest residue values for $[\text{IN-F4106} + 1.068 \times \text{IN-A5760}]$, used as inputs to calculate total residues (Table 5.15.4) and for estimation of livestock dietary

Processed commodity	Raw commodity [median residue]	Raw commodity [highest residue]	Individual processing factors	Median or best estimate processing factor	Median residue-P (mg/kg)	Highest residue-P (mg/kg)
Tomato dried	0.0207	0.3385	4.6 7.5 14	7.5	0.1552	2.539
Tomato canned			0.7 0.9 1.1	0.9	0.0186	
Tomato juice			0.6 0.9 1.9	0.9	0.0186	
Tomato wet pomace			1.1 1.1 1.2	1.1	0.0228	
Tomato paste			2.6 3.9 5.7	3.9	0.0807	
Tomato purée			1.2 2.0 2.4	2	0.0414	
Potato, flakes/granules	0.0337	0.1127	0 0.1 0.6	0.1	0.0034	
Potato crisps			0.08 0.3 0.5	0.3	0.0101	
French fries peeled			0 0.04 0.2	0.04	0.0013	

Processed commodity	Raw commodity [median residue]	Raw commodity [highest residue]	Individual processing factors	Median or best estimate processing factor	Median residue-P (mg/kg)	Highest residue-P (mg/kg)
French fries unpeeled			0.2 0.7 1.0	0.7	0.0236	
Potato boiled unpeeled			0.06 0.07 0.2	0.07	0.0024	0.0079
Potato boiled peeled			0 0.03 0.08	0.03	0.0010	0.0034
Potato microwaved unpeeled			0.4 1.2 1.4	1.2	0.0404	0.135
Soya bean meal (mechanically extracted)	0.0593		1.2 1.4 1.5	1.4	0.083	
Soya bean meal (solvent extracted)			1.5 1.6 1.6	1.6	0.095	
Soya bean hulls			0.8 0.9 1.5	0.9	0.053	
Soya bean refined oil			0 0	0	0	
Maize starch	0.0164		0 0	0	0	
Maize grits			0 0	0	0	
Maize flour			0 2	0.1	0.00164	
Maize meal			0 1.7	0.85	0.0139	
Maize refined oil			0 0	0	0	

Table 5.15.6 Processing factors and median and highest residue values for IN-QZY47, used as inputs to calculate total residues (Table 5.15.4) and for estimation of livestock dietary burdens

Processed commodity	Raw commodity [median residue]	Raw commodity [highest residue]	Individual processing factors	Median or best estimate processing factor	Median residue-P (mg/kg)	Highest residue-P (mg/kg)
Tomato dried	0.01	0.058	4.4	4.4	0.044	0.2552
Tomato canned			1.2	1.2	0.012	
Tomato juice			0.7	0.7	0.007	
Tomato wet pomace			0.7	0.7	0.007	
Tomato paste			2.7	2.7	0.027	
Tomato purée			1.4	1.4	0.014	
Potato , flakes/granules	0.011	0.072	1.7 3.7	2.7	0.0297	
Potato crisps			0.6 1.2	0.9	0.0099	
French fries peeled			0.8 1.2	1	0.011	
French fries unpeeled			1.2 2.1	1.7	0.0187	
Potato boiled unpeeled			1.1 1.2	1.2	0.0132	0.0864
Potato boiled peeled			1.0 1.1	1	0.011	0.072
Potato microwaved unpeeled	1.4 1.6	1.5	0.0165	0.108		
Soya bean meal (mechanically extracted)	0.0051		1.5 1.6	1.6	0.00816	
Soya bean meal (solvent extracted)			1.3 1.7	1.5	0.00765	
Soya bean hulls			1.8 1.9	1.8	0.00918	
Soya bean refined oil			0 0	0	0	
Maize starch	0.00675		0 0	0	0	
Maize grits			0.7 1.0	0.85	0.0057375	
Maize flour			1.3 1.6	1.45	0.0097875	

Processed commodity	Raw commodity [median residue]	Raw commodity [highest residue]	Individual processing factors	Median or best estimate processing factor	Median residue-P (mg/kg)	Highest residue-P (mg/kg)
Maize meal			1.5 1.6	1.55	0.0104625	
Maize refined oil			0 0	0	0	

Table 5.15.7 Processing factors and median and highest residue values for IN-TMQ01, used as inputs to calculate total residues (Table 5.15.4) and for estimation of livestock dietary burdens

Processed commodity	Raw commodity [median residue]	Raw commodity [highest residue]	Individual processing factors	Median or best estimate processing factor	Median residue-P (mg/kg)	Highest residue-P (mg/kg)
Strawberry juice	0.0123	0.0694	0.5 0.7 0.8	0.7	0.00861	
Strawberry canned			0.3 0.4 0.4	0.4	0.00492	
Strawberry jam			0.2 0.2 0.2	0.2	0.00246	
Strawberry frozen fruit			0.6 0.6 0.7	0.6	0.00738	0.0416
Strawberry dried			3.8 4.1 5.4	4.1	0.05043	0.2845
Tomato dried	0.01	0.14	4.5	4.5	0.045	0.63
Tomato canned			0.9	0.9	0.009	
Tomato juice			0.6	0.6	0.006	
Tomato wet pomace			0.8	0.8	0.008	
Tomato paste			2.4	2.4	0.024	
Tomato purée			1.2	1.2	0.012	
Potato , flakes/granules	0.0205	0.335	1.0 1.7	1.4	0.0287	
Potato crisps			0.6 1.3	1	0.0205	
French fries peeled			0.3 0.6	0.4	0.0082	
French fries unpeeled			0.8 2.0	1.4	0.0287	
Potato boiled unpeeled			0.8 1.2	1	0.0205	0.335
Potato boiled peeled			0.4 0.6	0.5	0.0102	0.168
Potato microwaved unpeeled			1.7 1.8	1.8	0.0369	0.603
Maize starch	0.00675		0 0 0	0	0	
Maize grits			0.4 0.5 0.7	0.5	0.0034	
Maize flour			0.8 1.4 1.7	1.4	0.0094	
Maize meal			1.1 1.4 1.7	1.4	0.00943	
Maize refined oil			0 0 0	0	0	

Median and highest residue values have been estimated for two compounds for which the Meeting decided to utilise the TTC approach.

Table 5.15.8 Processing factors and median and highest residue of IN-UJV12

Processed commodity	Raw commodity [median residue]	Raw commodity [highest residue]	Individual processing factors	Median or best estimate processing factor	Median residue-P (mg/kg)	Highest residue-P (mg/kg)
Tomato dried	0.01	0.01	4.7	4.7	0.047	0.047
Tomato canned			1.2	1.2	0.012	
Tomato juice			0.7	0.7	0.007	
Tomato wet pomace			0.8	0.8	0.008	
Tomato paste			2.8	2.8	0.028	

Processed commodity	Raw commodity [median residue]	Raw commodity [highest residue]	Individual processing factors	Median or best estimate processing factor	Median residue-P (mg/kg)	Highest residue-P (mg/kg)
Tomato purée			1.3	1.3	0.013	
Potato , flakes/granules	0.01	0.016	1.5 3.1	2.3	0.023	
Potato crisps			0.5 1.3	0.9	0.009	
French fries peeled			0.6 1.1	0.8	0.008	
French fries unpeeled			0.8 2.0	1.4	0.014	
Potato boiled unpeeled			1.3 1.4	1.4	0.014	0.0224
Potato boiled peeled			0.7 1.1	0.9	0.014	0.0224
Potato microwaved unpeeled			1.5 1.8	1.6	0.016	0.0256
Maize starch	0.00585		0 0	0	0	
Maize grits			0 0.5	0.2	0.0012	
Maize flour			0 1.3	0.6	0.0035	
Maize meal			1 1.5	1.2	0.0070	
Maize refined oil			0 0	0	0	

Table 5.15.9 Processing factors and median and highest residues of IN-TQD54

Processed commodity	Raw commodity [median residue]	Raw commodity [highest residue]	Individual processing factors	Median or best estimate processing factor	Median residue-P (mg/kg)	Highest residue-P (mg/kg)
Strawberry juice	0.0051	0.0084	0.8 0.9	0.8	0.0041	
Strawberry canned			0 0.5	0.2	0.0010	
Strawberry jam			0 0	0	0	
Strawberry frozen fruit			0 0.5	0.2	0.0010	0.0017
Strawberry, dried			3.3 3.8	3.6	0.0184	0.0302
Tomato dried	0.01	0.061	3.5	3.5	0.035	0.2135
Tomato canned			1.1	1.1	0.011	
Tomato juice			0.6	0.6	0.006	
Tomato wet pomace			0.8	0.8	0.008	
Tomato paste			2.3	2.3	0.023	
Tomato purée			1.2	1.2	0.012	
Potato , flakes/granules	0.01	0.0865	1.2 2.2	1.7	0.017	
Potato crisps			0.6 1.3	1	0.01	
French fries peeled			0.4 0.7	0.6	0.006	
French fries unpeeled			0.8 2.1	1.5	0.015	
Potato boiled unpeeled			1.0 1.2	1.1	0.011	0.0952
Potato boiled peeled			0.7 0.8	0.8	0.008	0.0692
Potato microwaved unpeeled			1.5 1.8	1.6	0.016	0.1384
Soya bean meal (mechanically extracted)	0.0050		0 0 0	0	0	
Soya bean meal (solvent extracted)			0 0 0	0	0	
Soya bean hulls			0 0 0.09	0	0	
Soya bean refined oil			0 0 0	0	0	
Maize starch	0.0067		0 0 0	0	0	

Processed commodity	Raw commodity [median residue]	Raw commodity [highest residue]	Individual processing factors	Median or best estimate processing factor	Median residue-P (mg/kg)	Highest residue-P (mg/kg)
Maize grits			0.15 0.2 0.2	0.2	0.00134	
Maize flour			0.3 0.6 1.0	0.6	0.00402	
Maize meal			0 0.4 0.9	0.4	0.00268	
Maize refined oil			0 0 0	0	0	

Residues in animal commodities

The dietary risk assessment definition for animal commodities includes fluazaindolizine, IN-A5760, IN-F4106 and IN-TMQ01.

Farm animal feeding studies

The Meeting received a study on the transfer of fluazaindolizine to cow tissues and milk. Dairy cows were oral dosed once daily with fluazaindolizine at the equivalent of 2.3, 6.7 and 20.3 ppm in the feed for 28 days, with sacrifice 22–24 hours after the last dose.

Residues of fluazaindolizine in milk were <LOQ for the 2.3 ppm dose group, with the exception of one day-24 sample with residues of 0.01 mg/kg; however, fluazaindolizine in milk was quantifiable (≥ 0.01 mg/kg) in milk from the 6.7 and 20.3 ppm dose groups.

Fluazaindolizine residues in milk plateaued by day three, with average residues of 0.020 and 0.066 mg/kg, respectively, for the 6.7- and 20.3-ppm dose groups (milk samples from day 3 to day 28). Fluazaindolizine residues in skim milk and cream were generally similar to or slightly lower than residue levels in whole milk.

Mean fluazaindolizine residues were 0.020 mg/kg in milk, < 0.01 mg/kg in muscle, 0.020 mg/kg in fat, 0.021 mg/kg in liver and 0.091 mg/kg in kidney for the 6.7 ppm dose group. Maximum fluazaindolizine residues were < 0.01 mg/kg in muscle, 0.022 mg/kg in fat, 0.023 mg/kg in liver and 0.096 mg/kg in kidney for the 6.7 ppm dose group. Mean residues in tissues showed a linear relationship with dose. Once dosing stopped, residues declined with a DT_{50} of < 0.5 days.

Residues of IN-REG72, IN-F4106, IN-A5760, IN-RYC33, and IN-R2W56 were not detected (< 0.003 mg/kg) in whole milk, skim milk, cream, and tissue samples, with the exception of IN-F4106 in cows dosed with fluazaindolizine 6.7 ppm dose group < 0.01 mg/kg kidney, 20.3 ppm dose group < 0.01 mg/kg liver; 0.01 mg/kg kidney. IN-QEK31 was ≤ 0.01 mg/kg in all samples of milk, skim milk and cream.

In another study, lactating cows were dosed orally once daily with IN-QEK31 for 28 days at the equivalent of 19.5 ppm in the feed. IN-QEK31 was detected at above 0.01 mg/kg (LOQ) in milk and tissues. Residues in milk appeared to reach a plateau at 3 days of dosing. Mean IN-QEK31 residues were 0.203 mg/kg in milk, < 0.01 mg/kg in muscle, < 0.01 mg/kg in fat, 0.013 mg/kg in liver and 0.13 mg/kg in kidney. Maximum IN-QEK31 residues were < 0.01 mg/kg in muscle, < 0.01 mg/kg in fat, 0.016 mg/kg in liver and 0.19 mg/kg in kidney. Once dosing stopped, residues declined with a DT_{50} of < 1.2 days.

IN-A5760 and IN-F4106 residues in tissues and milk may arise from feeding IN-A5760 and IN-F4106, from feeding IN-QZY47 or from feeding IN-TMQ01. Metabolism studies are available to allow estimation of the contribution from the various sources. IN-TMQ01 residues arise from the feeding of IN-TMQ01.

Farm animal dietary burden

Inputs for the livestock dietary burdens were obtained from primary treated crops (carrot culls, tomato pomace, potato culls) and from residues in rotational crops (cereal and legume forages, cereal and legume fodders, cereal grain and pulse seeds, oilseed fodder, kale, cabbage leaves, turnip roots and by-products from processing).

Dietary burdens were calculated for beef cattle, dairy cattle, broilers and laying poultry based on feed items evaluated by the JMPR by the current Meeting. The dietary burdens, estimated using the most recent version of the OECD livestock dietary burden calculator, are presented in Annex 6 and summarized below.

Separate feeding studies were carried out in lactating cattle with fluazaindolizine and IN-QEK31 to determine residues. Metabolism studies in lactating goats were available for IN-QEK31, IN-QZY47, IN-TMQ01. For laying hens, metabolism studies were available for fluazaindolizine and IN-QEK31. The livestock dietary burdens were calculated separately for components required for dietary risk assessment:

- Fluazaindolizine;
- the sum of $IN-F4106 + 1.068 \times IN-A5760$
- IN-QZY47;
- IN-TMQ01;

In addition, livestock burdens were calculated for compounds being assessed using the TTC approach:

- IN-UJV12;
- IN-TQD54.

Inputs for the livestock dietary burdens were obtained from primary treated crops (carrot culls, tomato pomace, potato culls) and from residues in rotational crops (cereal and legume forages, cereal and legume fodders, cereal grain and pulse seeds, oilseed fodder, kale, cabbage leaves, turnip roots).

Residues in animal commodities from the fluazaindolizine transfer studies with lactating cows and laying hens were used in estimating maximum residue levels.

Table 5.15.10 Estimated maximum and mean dietary burdens of farm animals (fluazaindolizine)

	Animal dietary burden: fluazaindolizine, ppm of dry matter diet							
	United States-Canada		European Union		Australia		Japan	
	Max	Mean	Max	Mean	Max	Mean	Max	Mean
Beef cattle	0.27	0.05	0.57	0.11	0.38	0.10	0.04	0.01
Dairy cattle	0.32	0.06	0.57 ^① ^②	0.10	0.35	0.11 ^③ ^④	0.07	0.02
Broilers	0.01	0.002	0.23	0.02	0.01	0.01	0.01	-
Layers	0.01	0.002	0.28 ^⑤	0.04 ^⑥	0.01	0.01	0.01	-

Notes:

- ① Highest maximum beef or dairy cattle dietary burden suitable for HR estimates for mammalian tissues.
- ② Highest maximum dairy cattle dietary burden suitable for HR estimates for mammalian milk.
- ③ Highest mean beef or dairy cattle dietary burden suitable for STMR estimates for mammalian tissues.
- ④ Highest mean dairy cattle dietary burden suitable for STMR estimates for milk.
- ⑤ Highest maximum poultry dietary burden suitable for HR estimates for poultry tissues and eggs.
- ⑥ Highest mean poultry dietary burden suitable for STMR estimates for poultry tissues and eggs.

Additionally, metabolism studies with the various compounds were used to estimate the source of these compounds to the residues for dietary risk assessment.

Table 5.15.11 Estimated maximum and mean dietary burdens of farm animals (sum of IN-F4106+1.068×IN-A5760)

	Animal dietary burden: sum of IN-F4106+1.068×IN-A5760, ppm of dry matter diet							
	United States-Canada		European Union		Australia		Japan	
	Max	Mean	Max	Mean	Max	Mean	Max	Mean
Beef cattle	0.43	0.12	0.85	0.21	0.99 ❶	0.20	0.36	0.09
Dairy cattle	0.83	0.18	0.86	0.21	0.98 ❷	0.25 ❸ ❹	0.69	0.16
Broilers	0.02	0.02	0.15	0.04	0.02	0.02	0.02	0.02
Layers	0.02	0.02	0.32 ❺	0.10 ❻	0.02	0.02	0.02	0.02

Notes:

- ❶ Highest maximum beef or dairy cattle dietary burden suitable for HR estimates for mammalian tissues.
- ❷ Highest maximum dairy cattle dietary burden suitable for HR estimates for mammalian milk.
- ❸ Highest mean beef or dairy cattle dietary burden suitable for STMR estimates for mammalian tissues.
- ❹ Highest mean dairy cattle dietary burden suitable for STMR estimates for milk.
- ❺ Highest maximum poultry dietary burden suitable for HR estimates for poultry tissues and eggs.
- ❻ Highest mean poultry dietary burden suitable for STMR estimates for poultry tissues and eggs.

Table 5.15.12 Estimated maximum and mean dietary burdens of farm animals (IN-QZY47)

	Animal dietary burden: IN-QEK31, ppm of dry matter diet							
	United States-Canada		European Union		Australia		Japan	
	Max	Mean	Max	Mean	Max	Mean	Max	Mean
Beef cattle	0.40	0.08	2.8	0.57	4.7 ❶	0.95 ❷	0.2	0.04
Dairy cattle	1.9	0.39	2.9	0.50	3.8 ❸	0.84 ❹	0.50	0.11
Broilers	0.01	0.001	0.42	0.03	0.01	0.01	0.01	-
Layers	0.01	0.001	1.16 ❺	0.19 ❻	0.01	0.01	0.01	-

Notes:

- ❶ Highest maximum beef or dairy cattle dietary burden suitable for HR estimates for mammalian tissues.
- ❷ Highest maximum dairy cattle dietary burden suitable for HR estimates for mammalian milk.
- ❸ Highest mean beef or dairy cattle dietary burden suitable for STMR estimates for mammalian tissues.
- ❹ Highest mean dairy cattle dietary burden suitable for STMR estimates for milk.
- ❺ Highest maximum poultry dietary burden suitable for HR estimates for poultry tissues and eggs.
- ❻ Highest mean poultry dietary burden suitable for STMR estimates for poultry tissues and eggs.

Table 5.15.13 Estimated maximum and mean dietary burdens of farm animals (IN-TMQ01)

	Animal dietary burden: IN-TMQ01, ppm of dry matter diet							
	United States-Canada		European Union		Australia		Japan	
	Max	Mean	Max	Mean	Max	Mean	Max	Mean
Beef cattle	0.64	0.06	2.2 ❶	0.47 ❷	1.7	0.45	0.30	0.06
Dairy cattle	1.40	0.31	2.0 ❸	0.42	2.00	0.56 ❹	0.63	0.16
Broilers	0.01	0.01	0.50	0.04	0.01	0.01	0.01	0.01
Layers	0.01	0.01	0.78 ❺	0.12 ❻	0.01	0.01	0.01	0.01

Notes:

- ❶ Highest maximum beef or dairy cattle dietary burden suitable for HR estimates for mammalian tissues.
- ❷ Highest maximum dairy cattle dietary burden suitable for HR estimates for mammalian milk.
- ❸ Highest mean beef or dairy cattle dietary burden suitable for STMR estimates for mammalian tissues.
- ❹ Highest mean dairy cattle dietary burden suitable for STMR estimates for milk.
- ❺ Highest maximum poultry dietary burden suitable for HR estimates for poultry tissues and eggs.
- ❻ Highest mean poultry dietary burden suitable for STMR estimates for poultry tissues and eggs.

Livestock dietary burdens have been estimated for two compounds for which the Meeting decided to utilise the TTC approach.

Table 5.15.14 Estimated maximum and mean dietary burdens of farm animals (IN-UJV12)

	Animal dietary burden: IN-UJV12, ppm of dry matter diet							
	United States-Canada		European Union		Australia		Japan	
	Max	Mean	Max	Mean	Max	Mean	Max	Mean
Beef cattle	0.11	0.05	0.51	0.13	1.02❶	0.19❷	0.06	0.01
Dairy cattle	0.35	0.08	0.48	0.13	0.82❷	0.17❸	0.14	0.03
Broilers	0.01	-	0.02	0.01	0.01	-	0.01	-
Layers	0.01	-	0.19❸	0.05❹	0.01	-	-	-

Notes:

- ❶ Highest maximum beef or dairy cattle dietary burden suitable for HR estimates for mammalian tissues.
- ❷ Highest maximum dairy cattle dietary burden suitable for HR estimates for mammalian milk.
- ❸ Highest mean beef or dairy cattle dietary burden suitable for STMR estimates for mammalian tissues.
- ❹ Highest mean dairy cattle dietary burden suitable for STMR estimates for milk.
- ❺ Highest maximum poultry dietary burden suitable for HR estimates for poultry tissues and eggs.
- ❻ Highest mean poultry dietary burden suitable for STMR estimates for poultry tissues and eggs.

Table 5.15.15 Estimated maximum and mean dietary burdens of farm animals (IN-TQD54)

	Animal dietary burden: IN-TQD54, ppm of dry matter diet							
	United States-Canada		European Union		Australia		Japan	
	Max	Mean	Max	Mean	Max	Mean	Max	Mean
Beef cattle	0.21	0.07	2.34❶	0.50❷	2.16	0.45	0.44	0.11
Dairy cattle	1.52	0.33	2.02❷	0.44❸	2.85	0.58	1.15	0.29
Broilers	0.01	-	0.05	0.01	0.005	0.004	0.006	0.004
Layers	0.007	0.001	0.46❸	0.10❹	0.005	0.004	0.007	0.004

Notes:

- ❶ Highest maximum beef or dairy cattle dietary burden suitable for HR estimates for mammalian tissues and milk.
- ❷ Highest mean beef or dairy cattle dietary burden suitable for STMR estimates for mammalian tissues and milk.
- ❸ Highest maximum poultry dietary burden suitable for HR estimates for poultry tissues and eggs.
- ❹ Highest mean poultry dietary burden suitable for STMR estimates for poultry tissues and eggs.
- ❺ Highest maximum poultry dietary burden suitable for HR estimates for poultry tissues and eggs.
- ❻ Highest mean poultry dietary burden suitable for STMR estimates for poultry tissues and eggs.

Animal commodity maximum residue levels**Cattle**

The calculations used to estimate highest residues for use in estimating maximum residue levels, STMR and HR values are shown below.

Table 5.15.16 Animal commodity residues for cattle

	Feed Level (ppm) for milk residues	Fluazaindolizine residues (mg/kg) in milk	Feed Level (ppm) for tissue residues	Fluazaindolizine residues (mg/kg)			
				Muscle	Liver	Kidney	Fat
Highest residue for maximum residue level estimation (beef or dairy cattle)							
Feeding Study	6.7	0.0199	6.7	< 0.01	0.0233	0.0957	0.0217
Dietary burden and estimate of highest residue	0.57	0.0017	0.57	0.00085	0.0020	0.0081	0.0018
Median Determination (beef or dairy cattle)							
Feeding Study	6.7	0.0199	6.7	< 0.01	0.0223	0.0912	0.0195
Dietary burden and estimate of median residue	0.11	0.00033	0.11	0.00016	0.00037	0.0015	0.00032

Table 5.15.17 Residues of IN-F4106+1.068×IN-A5760 from feeding IN-F4106+1.068×IN-A5760

	Feed Level (ppm) for milk residues	IN-F4106+1.068×IN-A5760 (mg eq/kg) in milk	Feed Level (ppm) for tissue residues	IN-F4106+1.068×IN-A5760 residues (mg/kg)			
				Muscle	Liver	Kidney	Fat
Highest Determination (beef or dairy cattle)							
Metabolism Study	7.61*		7.61*	0.03319	0.2054	0.5764	0.0336
Dietary burden and estimate of highest residue	0.98		0.99	0.0043 (+0.00013 +0.0147)	0.0267 (+0.00029 +0.0911)	0.0750 (+0.00032 +0.2556)	0.0044 (+0.00005 +0.0149)
Median Determination (beef or dairy cattle)							
Metabolism Study	7.61*	0.00794	7.61*	0.03319	0.2054	0.5764	0.0336
Dietary burden and estimate of median residue	0.32	0.00033 (+0.00037 +0.00063)	0.32	0.0011 (+0.00005 +0.0030)	0.0067 (+0.00012 +0.0184)	0.0189 (+0.00013 +0.0517)	0.0011 (+0.00002 +0.0030)

Notes:

*= IN-QZY47 metabolism dose in terms of IN-F4106.

*Additional IN-F4106 is produced from IN-TMQ01 and IN-QZY47, the figures in brackets are the contribution from livestock exposure to IN-TMQ01 and to IN-QZY47. Residues of IN-F4106+1.068×IN-A5760 are the sum of the three sources.

Table 5.15.18 Residues of IN-F4106+1.068×IN-A5760 from feeding TMQ01

	Feed Level (ppm) for milk residues	IN-F4106+1.068×IN-A5760 (mg/kg) in milk	Feed Level (ppm) for tissue residues	IN-F4106+1.068×IN-A5760 (mg/kg)			
				Muscle	Liver	Kidney	Fat
Highest Determination (beef or dairy cattle)							
Metabolism Study	10.9		10.9	0.000624	0.001443	0.001574	0.00023
Dietary burden and estimate of highest	2.0		2.2	0.00013	0.00029	0.00032	0.00005

	Feed Level (ppm) for milk residues	IN-F4106+1.068×IN-A5760 (mg/kg) in milk	Feed Level (ppm) for tissue residues	IN-F4106+1.068×IN-A5760 (mg/kg)			
				Muscle	Liver	Kidney	Fat
residue							
Median Determination (beef or dairy cattle)							
Metabolism Study	10.9	0.004885	10.9	0.000624	0.001443	0.001574	0.00023
Dietary burden and estimate of median residue	0.56	0.00025	0.56	0.00003	0.00007	0.00008	0.00001

Table 5.15.19 Residues of IN-F4106+1.068×IN-A5760 from feeding IN-QZY47

	Feed Level (ppm) for milk residues	IN-F4106+1.068×IN-A5760 (mg/kg) in milk	Feed Level (ppm) for tissue residues	IN-F4106+1.068×IN-A5760 (mg/kg)			
				Muscle	Liver	Kidney	Fat
Highest Determination (beef or dairy cattle)							
Metabolism Study	10.6		10.6	0.0332	0.2054	0.5764	0.0336
Dietary burden and estimate of highest residue	3.8		4.7	0.0147	0.0911	0.2556	0.0149
Median Determination (beef or dairy cattle)							
Metabolism Study	10.6	0.0079	10.6	0.0332	0.2054	0.5764	0.0336
Dietary burden and estimate of median residue	0.84	0.00063	0.95	0.0030	0.0184	0.0517	0.0030

A metabolism study with IN-TMQ01 in a lactating goat was used to estimate residues of IN-TMQ01.

Table 5.15.20 Residues of IN-TMQ01

	Feed Level (ppm) for milk residues	IN-TMQ01 (mg/kg) in milk	Feed Level (ppm) for tissue residues	IN-TMQ01 (mg/kg)			
				Muscle	Liver	Kidney	Fat
Highest Determination (beef or dairy cattle)							
Metabolism Study	10.9		10.9	0.000854	0.009996	0.19074	0.001485
Dietary burden and estimate of highest residue	2.0		2.0	0.00016	0.0018	0.0350	0.00027
Median Determination (beef or dairy cattle)							
Metabolism Study	10.9	< 0.001	10.9	0.000854	0.009996	0.19074	0.001485
Dietary burden and estimate of median residue	0.57	0.00008	0.57	0.00004	0.00052	0.0100	0.00008

The Meeting estimated a maximum residue level of 0.01(*) mg/kg in milks, meat (mammalian except marine mammals) and mammalian fat (except milk fat) and of 0.01 mg/kg in edible offal.

Based on total residues (fluazaindolizine + $[2.11 \times (\text{IN-F4106} + 1.068 \times \text{IN-A5760})] + 1.51 \times \text{IN-TMQ01}$), the Meeting estimated STMRs of 0.0096 mg/kg in meat (mammalian except marine mammals),

of 0.0092 mg/kg in mammalian fat, of 0.1657 in mammalian offal (based on liver) and of 0.0029 mg/kg in milk.

The Meeting estimated HRs of 0.0415 mg/kg in meat (mammalian except marine mammals), 0.0431 mg/kg in mammalian fat and 0.7592 mg/kg in mammalian offal (based on kidney).

Residues of the fluazaindolizine were similar in milk fat compared to whole milk. Using this information, the Meeting estimated a maximum residue level of 0.01(*) mg/kg for milk fat and an STMR value of 0.0033 mg/kg.

Median and highest residue values have been estimated for IN-UJV12 and IN-TQD54, for which the Meeting decided to apply the TTC approach. Extrapolation of residues in the IN-QZY47 metabolism study with a lactating goat were used to estimate residues of IN-UJV12 and of IN-TQD54

Table 5.15.21 Residues of IN-UJV12

	Feed Level (ppm) for milk residues	IN-UJV12 (mg/kg) in milk	Feed Level (ppm) for tissue residues	IN-UJV12 (mg/kg)			
				Muscle	Liver	Kidney	Fat
Highest Determination (beef or dairy cattle)							
Metabolism Study	10.1*		10.1*	< 0.001	< 0.001	< 0.001	< 0.001
Dietary burden and estimate of highest residue	0.82		1.02	0.0001	0.0001	0.0001	0.0001
Median Determination (beef or dairy cattle)							
Metabolism Study	10.1*	0.000488	10.1*	< 0.001	< 0.001	< 0.001	< 0.001
Dietary burden and estimate of median residue	0.17	0.000008	0.19	0.00002	0.00002	0.00002	0.00002

Notes:

*=Expressed IN-QZY47 metabolism dose in terms of IN-UJV12.

Extrapolation of residues in the IN-QZY47 metabolism study with a lactating goat was used to estimate residues of IN-TQD54.

Table 5.15.22 Residues of IN-TQD54

	Feed Level (ppm) for milk residues	IN-TQD54 (mg/kg) in milk	Feed Level (ppm) for tissue residues	IN-TQD54 (mg/kg)			
				Muscle	Liver	Kidney	Fat
Highest Determination (beef or dairy cattle)							
Metabolism Study	10.15*		10.15*	< 0.001	< 0.001	< 0.001	< 0.001
Dietary burden and estimate of highest residue	2.85		2.85	0.00028	0.00028	0.00028	0.00028
Median Determination (beef or dairy cattle)							
Metabolism Study	10.15*	0.000488	10.15*	< 0.001	< 0.001	< 0.001	< 0.001
Dietary burden and estimate of median residue	0.58	0.00003	0.58	0.00006	0.00006	0.00006	0.00006

Notes:

*=Expressed IN-QZY47 metabolism dose in terms of IN-TQD54.

Poultry

The calculations used to estimate maximum residue levels, as well as total residues for use in estimating STMR and HR values are shown below.

Table 5.15.23 Residues of fluazaindolizine

	Feed Level (ppm) for egg residues	Fluazaindolizine residues (mg/kg) in eggs	Feed Level (ppm) for tissue residues	Fluazaindolizine residues (mg/kg)			
				Muscle	Liver	Kidney	Fat
Highest residue for maximum residue level estimation (broilers or layers)							
Metabolism Study	13.1	0.013056	13.1	0.041495	0.032		0.0135
Dietary burden and estimate of highest residue	0.28	0.000279	0.28	0.000887	0.0146		0.00029
Median Determination (broilers or layers)							
Feeding Study	13.1	0.013056	13.1	0.041495	0.032		0.0135
Dietary burden and estimate of median residue	0.04	0.00004	0.04	0.00013	0.0021		0.00004

Extrapolation of TRRs in the fluazaindolizine metabolism study with laying hens was used to estimate residues of [IN-F4106 + 1.068×IN-A5760]. The dose level and TRR in the fluazaindolizine metabolism study were converted to IN-F4106 equivalents.

Table 5.15.24 Residues of IN-F4106+1.068×IN-A5760

	Feed Level (ppm) for egg residues	IN-F4106+1.068×IN-A5760 (mg/kg) in eggs	Feed Level (ppm) for tissue residues	IN-F4106+1.068×IN-A5760 residues (mg/kg)			
				Muscle	Liver	Kidney	Fat
Highest Determination (broilers or layers)							
Metabolism Study	6.2*	0.008048	6.2*	0.020356	0.346529		0.009468
Dietary burden and estimate of highest residue	0.32	0.0004	0.32	0.0011	0.0179		0.0005
Median Determination (broilers or layers)							
Metabolism Study	6.2*	0.008048	6.2*	0.020356	0.346529		0.009468
Dietary burden and estimate of median residue	0.1	0.00013	0.1	0.00033	0.00559		0.00015

Notes:

* Dose in the fluazaindolizine metabolism study expressed in IN-F4106 equivalents.

Extrapolation of TRRs in the fluazaindolizine metabolism study with laying hens was used to estimate residues of IN-TMQ01.

Table 5.15.25 Residues of IN-TMQ01

	Feed Level (ppm) for egg residues	IN-TMQ01 (mg/kg) in eggs	Feed Level (ppm) for tissue residues	IN-TMQ01 (mg/kg)			
				Muscle	Liver	Kidney	Fat
Highest Determination (broilers or layers)							
Metabolism Study	8.67	0.0112	8.67	0.0284	0.484		0.0132
Dietary burden and	0.78	0.001	0.78	0.00256	0.0436		0.0012

	Feed Level (ppm) for egg residues	IN-TMQ01 (mg/kg) in eggs	Feed Level (ppm) for tissue residues	IN-TMQ01 (mg/kg)			
				Muscle	Liver	Kidney	Fat
estimate of highest residue							
Median Determination (broilers or layers)							
Metabolism Study	8.67	0.0112	8.67	0.0284	0.484		0.0132
Dietary burden and estimate of median residue	0.12	0.00016	0.12	0.00039	0.0067		0.00018

The Meeting estimated maximum residue levels of 0.01(*) mg/kg for eggs poultry meat and poultry fat 0.01(*) mg/kg and of 0.02 mg/kg for poultry edible offal (liver).

STMR and HR values were estimated based on total residues (fluazaindolizine + [2.11×(IN-F4106+1.068×IN-A5760)] + 1.51×IN-TMQ01).

The Meeting estimated STMRs of 0.0014 mg/kg for poultry meat, of 0.00063 mg/kg for poultry fat, of 0.035 mg/kg poultry edible offal (liver) and of 0.0006 mg/kg in eggs.

The Meeting estimated HRs of 0.0071 mg/kg for poultry meat, of 0.0032 mg/kg for poultry fat, of 0.1182 mg/kg for poultry edible offal (liver) and of 0.00263 mg/kg for eggs.

Median and highest residue values have been estimated for IN-UJV12 and IN-TQD54, for which the Meeting decided to apply the TTC approach. Extrapolation of TRRs in the fluazaindolizine metabolism study with laying hens was used to estimate the residues.

Table 5.15.26 Residues of IN-UJV12

	Feed Level (ppm) for egg residues	IN-UJV12 (mg/kg) in eggs	Feed Level (ppm) for tissue residues	IN-UJV12 (mg/kg)			
				Muscle	Liver	Kidney	Fat
Highest Determination (broilers or layers)							
Metabolism Study	8.24	0.0107	8.25	0.0271	0.4607		0.0126
Dietary burden and estimate of highest residue	0.19	0.00025	0.19	0.00062	0.0106		0.00029
Median Determination (broilers or layers)							
Metabolism Study	8.24	0.0107	8.25	0.0271	0.4607		0.0126
Dietary burden and estimate of median residue	0.05	0.00006	0.05	0.00016	0.0028		0.00007

Extrapolation of TRRs in the fluazaindolizine metabolism study with laying hens was used to estimate residues of IN-TQD54. The dose level and TRR were converted to IN-TQD54 equivalents.

Table 5.15.27 Residues of IN-TQD54

	Feed Level (ppm) for egg residues	IN-TQD54 (mg/kg) in eggs	Feed Level (ppm) for tissue residues	IN-TQD54 (mg/kg)			
				Muscle	Liver	Kidney	Fat
Highest Determination (broilers or layers)							
Metabolism Study	8.27	0.0107	8.27	0.0272	0.4623		0.0126

	Feed Level (ppm) for egg residues	IN-TQD54 (mg/kg) in eggs	Feed Level (ppm) for tissue residues	IN-TQD54 (mg/kg)			
				Muscle	Liver	Kidney	Fat
Dietary burden and estimate of highest residue	0.46	0.00060	0.46	0.0015	0.026		0.00070
Median Determination (broilers or layers)							
Metabolism Study	8.27	0.0107	8.27	0.0272	0.4623		0.0126
Dietary burden and estimate of median residue	0.10	0.00013	0.10	0.00033	0.0056		0.00015

RECOMMENDATIONS

On the basis of the data obtained from supervised trials, the Meeting concluded that the residue levels listed in Annex 1 are suitable for establishing maximum residue limits and for IEDI and international estimate of short-term intakes assessment.

Definition of the residue for compliance with the MRL for plant and animal commodities: *fluazaindolizine*.

Definition of the residue for dietary risk assessment for plant commodities:

fluazaindolizine, and free and conjugated forms of the following compounds: 2-chloro-5-hydroxybenzenesulfonamide (IN-A5760), 2-chloro-5-methoxybenzenesulfonamide (IN-F4106), 8-chloro-6-(trifluoromethyl)imidazo[1,2-a]pyridine-2-carboxylic acid (IN-QEK31), 3-[[2-chloro-5-methoxyphenyl)sulfonyl]amino]-L-alanine (IN-QZY47), 8-chloro-N-[(2-chloro-5-hydroxyphenyl)sulfonyl]-6-(trifluoromethyl)imidazo[1,2-a]pyridine-2-carboxamide (IN-REG72), 8-chloro-6-(trifluoromethyl)imidazo[1,2-a]pyridine-2-carboxamide (IN-RYC33) and 3-[[2-chloro-5-methoxyphenyl)sulfonyl]amino]-(2R)-hydroxypropanoic acid (IN-TMQ01) (expressed as *fluazaindolizine*). This can be implemented by taking the maximum of the sum of compounds containing the imidazopyridine ring and hydrolysed using acid to IN-A5760, IN-F4106, IN-QZY47 and IN-TMQ01 (expressed as *fluazaindolizine*) OR compounds containing the phenyl ring and hydrolysed to 8-chloro-6-(trifluoromethyl)imidazo[1,2-a]pyridine-2-carboxylic acid (IN-QEK31) (expressed as *fluazaindolizine*).

Definition of the residue for dietary risk assessment for animal commodities: the sum of *fluazaindolizine*, 2-chloro-5-hydroxybenzenesulfonamide (IN-A5760), 2-chloro-5-methoxybenzenesulfonamide (IN-F4106), and 3-[[2-chloro-5-methoxyphenyl)sulfonyl]amino]-(2R)-hydroxypropanoic acid (IN-TMQ01) (expressed as *fluazaindolizine*).

The residue is not fat-soluble.

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The ADI for *fluazaindolizine* is 0–0.3 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for *fluazaindolizine* were estimated for the 17 GEMS/Food Consumption Cluster Diets using the STMR or STMR-P values estimated by the JMPR. The results are shown in Annex 3 of the 2022 JMPR Report.

The IEDIs ranged from 0–1 percent of the maximum ADI. The Meeting concluded that the long-

term dietary exposure to residues of fluazaindolizine from uses considered by the Meeting is unlikely to present a public health concern.

Acute dietary exposure

The ARfD for fluazaindolizine is 1 mg/kg bw. The International Estimate of Short-Term Intakes (international estimate of short-term intakes) for fluazaindolizine were calculated for the food commodities and their processed commodities for which HRs/HR-Ps or STMRs/STMR-Ps were estimated by the present Meeting and for which consumption data were available. The results are shown in Annex 4 of the 2022 JMPR Report.

The international estimate of short-term intake varied from 0–9 percent of the ARfD for children and 0–5 percent of the ARfD for the general population. The Meeting concluded that acute dietary exposure to residues of fluazaindolizine from uses considered by the present Meeting is unlikely to present a public health concern.

Threshold of toxicological concern (TTC) consideration for metabolites

The Meeting agreed that metabolites IN-UJV12 and IN-TDQ54 could be assessed using the TTC approach (Cramer Class III threshold of 1.5 µg/kg bw per day).

The current Meeting estimated dietary exposures of 0.14–0.30 µg/kg bw per day for IN-UJV12 and of 0.15–0.44 µg/kg bw per day for IN-TQD54.

The Meeting concluded that the estimated dietary exposures to residues of IN-UJV12 and IN-TQD54 from uses considered by the JMPR are below the TTC for Cramer Class III compounds and are unlikely to present a public health concern. Should further uses be considered in the future, these conclusions may need to be re-evaluated.

5.16 Fludioxonil (211)

TOXICOLOGY

Fludioxonil is the International Organization for Standardization (ISO)-approved name for 4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1H-pyrrole-3-carbonitrile (IUPAC) for which the Chemical Abstracts Service number is 131341-86-1. Fludioxonil is a non-systemic, broad-spectrum fungicide with a long residual activity. It is a member of the phenylpyrrole group of substances. While originally developed as a seed storage protectant, fludioxonil is also used as a post-harvest, shelf-life extending treatment for fruit. Fludioxonil, being fat soluble, is absorbed into the outer wax layer of the plant and seeds resulting in mycelial growth inhibition and spore rupture. Within fungal cells, fludioxonil interferes with cell intracellular osmolality

Fludioxonil was first evaluated by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) in 2004, which established an acceptable daily intake (ADI) of 0–0.4 mg/kg body weight (bw) based on hepatotoxicity and reduced body weight gain at the next highest dose, in a two-year study in rats. An acute reference dose (ARfD) was considered unnecessary.

Fludioxonil was reviewed by the present Meeting following a request by the Codex Committee on Pesticide Residues (CCPR) for consideration of additional maximum residue levels (MRLs) and new information was supplied on metabolites. All provided studies were compliant with good laboratory practice (GLP) unless otherwise stated and were generally conducted in accordance with current test guideline requirements. As these studies would have had no effect on the health-based guidance values (HBGVs), they were not reviewed by this Meeting, and should be provided for the periodic review of fludioxonil.

Toxicological data on metabolites and/or degradates

CGA 192155

Metabolite CGA 192155 is a plant and animal metabolite that is not found in rats. The acute oral median lethal dose (LD₅₀) of CGA 192155 in rats is greater than 2000 mg/kg bw.

In a 28-day repeated dietary oral exposure study, rats were treated with CGA 192155 at 0, 1000, 5000 or 15 000 ppm (equal to 0, 78, 382 and 1147 mg/kg bw per day for males, 0, 80, 389 and 1065 mg/kg bw per day for females). The NOAEL was 5000 ppm (equal to 382 mg/kg bw per day) based on reductions in body weight and body weight gain (correlated with reduced food consumption) at 15 000 ppm (equal to 1065 mg/kg bw per day).

In a 13-week repeated dietary oral exposure study, rats were treated with CGA 192155 at 0, 100, 1000 or 7000 ppm (equal to 0, 5.9, 57.5 and 415 mg/kg bw per day for males, 0, 6.7, 66.2 and 461 mg/kg bw per day for females). The NOAEL was 1000 ppm (equal to 57.5 mg/kg bw per day) based on reductions in body weight and body weight gain (correlated with small reductions in food consumption) at 7000 ppm (equal to 415 mg/kg bw per day).

Metabolite CGA 192155 did not induce bacterial reverse mutations, nor did CGA 192155 induce mutations in mammalian cells in vitro. It did induce chromosomal aberrations in vitro but was negative in an in vivo micronucleus test.

In view of these studies the Meeting concluded that CGA 192155 was unlikely to be genotoxic in vivo.

Overall, the Meeting concluded that the toxicological properties of CGA 192155 resemble those of fludioxonil. Accordingly, human exposure to CGA 192155 should be covered by HBGVs for fludioxonil.

CGA 227731

This compound is a plant metabolite not found in rats. CGA 227731 is unlikely to be genotoxic based on findings in bacterial reverse mutation assays, an in vitro micronucleus assay, an in vivo comet assay and a transgenic rat somatic and germ cell gene mutation assay. No other toxicological data were available on this metabolite. Accordingly, the Meeting concluded that the Cramer class III threshold of toxicological concern (TTC) of 1.5 µg/kg bw per day should apply to CGA 227731.

CGA 265378

This compound is an animal metabolite not found in rats. No repeat-dose toxicity data was provided or available for CGA 265378. JMPR (2004) has previously concluded that metabolite CGA 265378 is unlikely to be genotoxic. Accordingly, the Meeting concluded that the Cramer class III TTC of 1.5 µg/kg bw per day should apply to CGA 227731.

CGA 308103

This compound is a plant metabolite not found in rats. No repeat-dose toxicity data were provided or available for CGA 308103. Metabolite CGA 308103 is unlikely to be genotoxic. Accordingly, the Meeting concluded that the Cramer class III TTC of 1.5 µg/kg bw per day should apply to CGA 308103.

CGA 308565/SYN 51879 tautomeric pair

The CGA 308565/SYN 51879 tautomeric pair are plant metabolites not found in rats. No repeat-dose toxicity data were provided or available for CGA 308565/SYN 51879. Metabolite CGA 308565/SYN 518579 is unlikely to be genotoxic. Accordingly, the Meeting concluded that the Cramer class III TTC of 1.5 µg/kg bw per day should apply to the CGA 308565/SYN 51879 tautomeric pair.

CGA 339833

This compound is a plant metabolite not found in rats. The acute oral LD₅₀ of CGA 339833 in rats is greater than 2000 mg/kg bw. In a 90-day dietary toxicity study, rats were treated with CGA 339833 at 0, 10, 100, 800, 2500 or 7000 ppm (equal to 0, 0.7, 7.1, 58, 190 and 510 mg/kg bw per day for males, 0, 0.9, 8.7, 67, 210 and 600 mg/kg bw per day for females). The NOAEL for CGA 339833 was 800 ppm (equal to 58 mg/kg bw per day) based on increased relative liver weight correlating with hepatocellular hypertrophy, increased relative kidney weight correlating with urinary tubular casts in males, and minimal to slight olfactory epithelial atrophy at 2500 ppm (equal to 190 mg/kg bw per day).

Overall, the Meeting concluded that the toxicological properties of CGA 339833 resemble those of fludioxonil. Accordingly, human exposure to CGA 339833 should be covered by the HBGVs for fludioxonil.

SYN 551031 (N-lactic acid conjugate of fludioxonil)

This compound is a plant metabolite not found in rats. Metabolite SYN 551031 did not induce bacterial reverse mutations, was genotoxic in an in vitro micronucleus test, but was not genotoxic in an in vivo micronucleus test. Based on weight of evidence the Meeting concluded that SYN 551031 is unlikely to be genotoxic in vivo. The Meeting concluded that the toxicological potency of SYN 551031 (an N-lactic acid conjugate of fludioxonil) is likely to be less than or equal to that of fludioxonil, given the structure and physicochemical properties of the compound. Overall the Meeting concluded that the toxicity of SYN 551031 should be covered by HBGVs for fludioxonil.

Toxicological evaluation

The 2004 Meeting established an ADI of 0–0.4 mg/kg bw for fludioxonil based on a NOAEL of 40 mg/kg bw per day in the two-year combined carcinogenicity and toxicity study in rats and using a safety factor of 100. The current meeting concluded that the parent ADI applies also to CGA 192155, CGA 339833 and SYN 551031.

The 2004 Meeting concluded that an ARfD for fludioxonil was not necessary and this conclusion applies to all of the metabolites assessed by the present Meeting.

A toxicological addendum was prepared.

Levels relevant to risk assessment of fludioxonil metabolites

Species	Study	Effect	NOAEL	LOAEL
CGA 192155				
Rat	28-day study of toxicity ^a	Toxicity	5000 ppm, equal to 382 mg/kg bw/day	15 000 ppm, equal to 1065 mg/kg bw/day
	13-week study of toxicity ^a	Toxicity	1000 ppm, equal to 57.5 mg/kg bw/day	7000 ppm, equal to 414.7 mg/kg bw/day
CGA 339833				
Rat	90-day study of toxicity ^a	Toxicity	800 ppm, equal to 58 mg/kg bw/day	2500 ppm, equal to 190 mg/kg bw/day

^a Dietary administration.

Acceptable daily intake (ADI)*

0–0.4 mg/kg bw

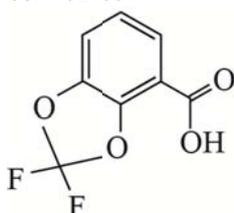
* Established by JMPR 2004. Applies to sum of fludioxonil, CGA 192155, CGA 339833 and SYN 551031

Acute reference dose (ARfD)

Unnecessary

Critical end-points for setting guidance values for exposure to fludioxonil metabolites**Studies on toxicologically relevant metabolites**

CGA 192155



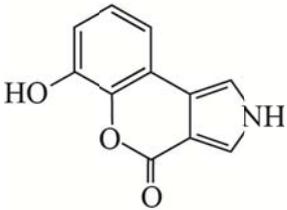
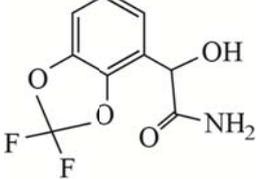
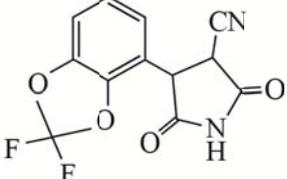
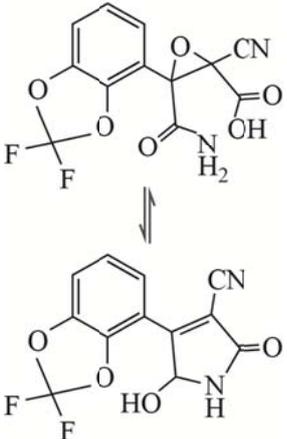
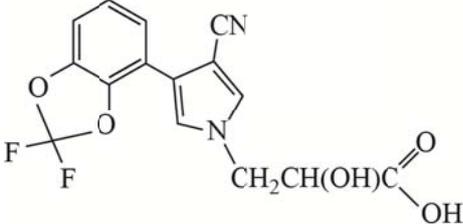
Acute oral LD₅₀: >2000 mg/kg bw (rat)

28-day NOAEL: 382 mg/kg bw per day (rat)

13-week NOAEL: 57.5 mg/kg bw per day (rat)

Not genotoxic:

negative Ames, negative forward mutation in mammalian cells, positive in vitro chromosomal aberration, negative in vivo micronucleus test

Studies on toxicologically relevant metabolites	
CGA 227731 	Not genotoxic: positive Ames in <i>S. typhimurium</i> strain TA1537; negative in other strains and species, negative in vitro micronucleus, negative in vivo comet assay, negative in vivo transgenic rat gene mutation assay
CGA 265378 ^a 	Acute oral LD ₅₀ : >2000 mg/kg bw (rat) Not genotoxic: negative Ames, negative forward mutation in mammalian cells, positive in vitro chromosomal aberration, negative in vivo micronucleus
CGA 308103 ^a 	Acute oral LD ₅₀ : > 1000 < 2000 mg/kg bw (rat) Not genotoxic: negative Ames, negative in vitro micronucleus
CGA 308565 	Acute oral LD ₅₀ : >2000 mg/kg bw (rat) Not genotoxic: negative Ames, positive in vitro micronucleus, negative in vivo micronucleus
CGA 339833/SYN 51879 ^a 	Acute oral LD ₅₀ : >2000 mg/kg bw (rat) 90-day NOAEL: 58 mg/kg bw per day Not genotoxic: negative Ames, negative forward mutation in vitro, positive in vitro chromosomal aberration, negative in vivo micronucleus
SYN 551031 	Not genotoxic: negative Ames, positive forward mutation in vitro, negative in vivo micronucleus Toxicological potency less than, or equal to that of fludioxonil

Notes:

^a Evaluated by JMPR in 2004.

RESIDUE AND ANALYTICAL ASPECTS

Fludioxonil is a phenylpyrrole fungicide that was first evaluated for toxicology and residues by the JMPR in 2004. The Meeting derived an ADI of 0–0.4 mg/kg bw, decided that an ARfD is unnecessary and concluded that the residue definition for compliance with the MRL and for dietary risk assessment in plant commodities is *fludioxonil* and the residue definition for compliance with the MRL and for dietary risk assessment in animal commodities is the *sum of fludioxonil and its benzopyrrole metabolites, determined as 2, 2-difluorobenzo[1,1]dioxole-4-carboxylic acid and expressed as fludioxonil*. The residue is fat-soluble.

Fludioxonil was listed at the Fifty-second Session of the CCPR for the evaluation of additional MRLs by the 2022 JMPR for banana, mango, papaya, beans and peas with pods, pulses, sugar beets, and tree nuts.

Additionally, new toxicology data (metabolism and toxicokinetics, genotoxicity, neurotoxicity, immunotoxicity and phototoxicity) for fludioxonil as well as genotoxicity studies for several of its metabolites were provided to the current Meeting for follow up evaluation to the 2004 JMPR. As a result of the evaluation of these new data, the current Meeting agreed that exposure risks from the metabolites CGA 192155, SYN 551031, and CGA 339833 would be covered by the health-based guidance values (HBGVs) of the parent; while the exposure risks from the metabolites CGA 227731, CGA 308565/SYN 518579, CGA 265378, and CGA 308103 should be assessed using the Threshold of Toxicological Concern (TTC) approach.

Methods of analysis

Methods REM 133.06 and AG-597B, which were previously evaluated by the 2004, 2006, and 2012 JMPR, were used for the analysis of fludioxonil in banana, mango, papaya, beans with pods, pulses, sugar beets, and tree nuts. The Meeting received additional method validation and concurrent recovery data and both methods were demonstrated to have adequate performance for recovery of fludioxonil with an LOQ of 0.01 mg/kg in all matrices. Mean recoveries were within the acceptable range of 70–120 percent with RSDs of ≤ 20 percent.

The Meeting concluded that for the commodities considered by the Meeting, the methods used in the new residue trials were sufficiently validated and suitable to measure fludioxonil in plant commodities.

Stability of pesticide residues in stored analytical samples

The stability of fludioxonil residues in samples on frozen storage was evaluated by the 2004 and 2010 JMPR for a range of commodities. Although storage stability data are not available for any high protein content commodity, collectively the existing stability data for fludioxonil are acceptable to support the storage duration of samples in the trials considered by the current Meeting. Samples in the trials were stored frozen for periods less than the period of stability demonstrated in studies supplied to the 2004 and 2010 JMPR and were satisfactory.

Definition of the residue

The current Meeting considered the toxicological properties of the metabolites CGA 192155, SYN 551031, and CGA 339833 and concluded that they are covered by the HBGV for fludioxonil. When establishing the residues definition for dietary risk assessment, the Meeting considered their potential contribution to the

dietary risk under the assumption them being covered by the parent HBGV and decided that CGA 192155, SYN 551031, and CGA 339833 would not be included.

The Meeting confirms its previous recommendation on the residue definition for fludioxonil.

Results of supervised residue trials on crops

The Meeting received information on supervised field trials on banana, mango, papaya, fresh beans with pods, dry edible beans, dry peas, sugar beets, almonds, and pecans.

Banana

The critical GAP for bananas is from Columbia and is comprised of a single post-harvest spray application at 20 g ai/hL.

The Meeting received supervised residue trials conducted in Ecuador matching the critical GAP.

For estimation of maximum residue levels, residue levels of fludioxonil in bananas (whole fruit) ranked order were (n = 6): 0.58, 0.76, 0.82, 0.93, 1.1, and 1.2 mg/kg.

Residues in the edible portion (banana pulp) for dietary risk assessment in ranked order were (n = 6): < 0.01 (2), < 0.011, 0.014, 0.015, and 0.021 mg/kg.

The Meeting estimated an STMR value of 0.013 mg/kg (based on the pulp) and a maximum residue level (based on the mean + 4×SD, whole fruit) of 2 mg/kg (Po) for banana.

Mango

Mangoes were previously evaluated by the 2012 JMPR where a maximum residue level of 2 mg/kg and a STMR of 0.02 mg/kg were estimated based on the GAP from South Africa, comprising a single post-harvest hot dip application at 52 °C at a maximum rate of 34.5 g ai/hL.

The Meeting received a new critical GAP for mangoes from Brazil comprising a single post-harvest spray or dip application at 120 g ai/hL.

Supervised residue trials were provided to the Meeting that were conducted in Brazil matching the new critical GAP.

For estimation of maximum residue levels, residue levels of fludioxonil in mangoes (whole fruit, dip application) ranked order were (n = 4): 3.7 (2), 3.9, and 5.0 mg/kg.

Residues in the edible portion (mango pulp, dip application) for dietary risk assessment in ranked order were (n = 4): 0.01, 0.02, 0.04, and 0.05 mg/kg.

For estimation of maximum residue levels, residue levels of fludioxonil in mangoes (whole fruit, spray application) ranked order were (n = 4): 4.4, 4.5 (2), and 5.0 mg/kg.

Residues in the edible portion (mango pulp, spray application) for dietary risk assessment in ranked order were (n = 4): < 0.01, 0.03, 0.04, and 0.06 mg/kg.

The Meeting noted that both treatments were applied at the same concentration (i.e. application rate) and considered the trials to be independent according to GAP.

Fludioxonil residues in mangoes (whole fruit, dip and spray applications) in ranked order were (n=8): 3.7 (2), 3.9, 4.4, 4.5 (2), and 5.0 (2) mg/kg.

Fludioxonil residues in mango pulp (dip and spray applications) in ranked order were (n = 8): < 0.01, 0.01, 0.02, 0.03, 0.04 (2), 0.05, and 0.06 mg/kg.

The Meeting estimated an STMR value of 0.04 mg/kg (based on the pulp) and a maximum residue level (based on the mean + 4×SD, whole fruit) of 7 mg/kg (Po) for mango. The latter replaces its previous recommended maximum residue level of 2 mg/kg for mango.

Papaya

The critical GAP for papayas is from Brazil and is comprised of a single post-harvest spray or dip application at 120 g ai/hL.

The Meeting received supervised residue trials conducted in Brazil matching the critical GAP.

For estimation of maximum residue levels, residue levels of fludioxonil in papayas (whole fruit, dip application) ranked order were (n = 4): 1.2, 1.5, 2.3, and 3.2 mg/kg.

Residues in the edible portion (papaya pulp, dip application) for dietary risk assessment in ranked order were (n = 4): 0.03, 0.06, 0.10, and 0.15 mg/kg.

For estimation of maximum residue levels, residue levels of fludioxonil in papayas (whole fruit, spray application) ranked order were (n = 4): 1.5, 1.7, 2.1, and 2.7 mg/kg.

Residues in the edible portion (papaya pulp, spray application) for dietary risk assessment in ranked order were (n = 4): 0.15 (2) and 0.16 (2) mg/kg.

The Meeting noted that both treatments were applied at the same concentration (i.e. application rate) which resulted in comparable residue levels in/on the fruit and decided to combine both datasets.

Fludioxonil residues in papayas (whole fruit, dip and spray applications) in ranked order were (n=8): 1.2, 1.5 (2), 1.7, 2.1, 2.3, 2.7, and 3.2 mg/kg.

Fludioxonil residues in papaya pulp (dip and spray applications) in ranked order were (n = 8): 0.03, 0.06, 0.10, 0.15 (3), and 0.16 mg/kg.

The Meeting estimated an STMR value of 0.15 mg/kg (based on the pulp) and a maximum residue level (based on the mean + 4×SD, whole fruit) of 5 mg/kg (Po) for papaya.

Legume vegetables, Group of

Beans with pods, Subgroup of and Subgroup of peas with pods

Beans with pods were previously evaluated by the 2013 JMPR where a maximum residue level of 0.6 mg/kg and a STMR of 0.02 mg/kg were estimated in Snap bean (young pods) and Beans, except broad bean and soya bean based on the GAP from the United States for snap beans (common beans) of 4 foliar applications × 250 g ai/ha, 7-day RTI, and 7-day PHI.

Peas with pods were previously evaluated by the 2004 JMPR where a maximum residue level of 0.3 mg/kg and a STMR of 0.04 mg/kg were estimated in Peas (pods and succulent=immature seeds) based residue data for beans with pods and the GAP from France for legume (pod and seed) of 250 g ai/ha, number of applications not specified, and a 14-day PHI.

Labels were provided from Canada on succulent beans (3 foliar applications × 250 g ai/ha, 7-day RTI, and 7-day PHI) and from Latvia on fresh beans and peas with pods (3 foliar applications × 250 g ai/ha, 10-day RTI, and 14-day PHI). Based on the shorter RTI and PHI the Meeting decided that the GAP from Canada is the critical GAP.

The Meeting received three supervised residue trials conducted in Bulgaria, France and Italy approximating the Canadian GAP which is insufficient to support a recommendation. The Meeting agreed

to consider the GAP from Latvia. The Meeting received eight supervised residue trials conducted in Bulgaria, Southern France, Greece, Italy and Spain matching the Latvian GAP.

Fludioxonil residues in beans green with pods in ranked order were (n = 8): < 0.01, 0.01, 0.03, 0.05, 0.06, 0.07, 0.13, and 0.48 mg/kg.

The Meeting estimated a maximum residue level of 0.8 mg/kg and an STMR value of 0.055 mg/kg for the subgroup of beans with pods, except soya bean (succulent seeds in pods). The Meeting withdrew its previous recommendations of a maximum residue level 0.6 mg/kg for beans (*Phaseolus* spp.) immature pods and succulent seeds) and a maximum residue level of 0.6 m/kg for snap beans (young pods).

Residue trials for peas with pods were not available to the Meeting. Noting that beans with pods (*Phaseolus* spp.) is a representative crop for the subgroup of peas with pods, the Meeting decided to extrapolate its recommendation for the subgroup of beans with pods and estimated a maximum residue level of 0.8 mg/kg and an STMR value of 0.055 mg/kg for the subgroup of peas with pods. The Meeting withdrew its previous recommendation of a maximum residue level 0.3 mg/kg for peas (pods and succulent=immature seeds).

Pulses, Group of

Dry beans, Subgroup of (except soya beans)

Dry beans were previously evaluated by the 2013 JMPR where a maximum residue level of 0.5 mg/kg and a STMR of 0.04 mg/kg were estimated based on the GAP from the United States for dried beans (except cowpeas) of 4 foliar applications × 245 g ai/ha, 7-day RTI, and 7-day PHI.

The Meeting received a new GAP for dried shelled bean (except soya bean) from Canada consisting of 3 foliar applications × 244 g ai/ha, 7-day RTI, and 7-day PHI.

The Meeting received supervised residue trials for dry beans conducted in Canada matching the Canadian GAP. The Meeting also reassessed American dry bean residue data from the 2013 JMPR where 4 foliar applications were made at a rate of 245 g ai/ha, 6 to 8-day RTI and 5 to 8-day PHI. Residue decline data for dry peas indicate a half-life of fludioxonil of approximately 7.2 days. Based on the half-life, the Meeting decided that a first application (28 days before harvest) would not contribute significantly to residues at harvest. Therefore the Meeting determined that the dry bean trials from the 2013 JMPR sufficiently approximate the GAP from Canada and are suitable for making a recommendation.

Fludioxonil residues in dry beans in ranked order were (n = 13): < 0.01, < 0.011, 0.018, 0.02 (2), 0.023, 0.029, 0.04 (2), 0.06 (2), 0.12, and 0.23 mg/kg.

The Meeting estimated a maximum residue level of 0.3 mg/kg and an STMR value of 0.029 mg/kg for the subgroup of dry beans (except soya beans). The Meeting withdrew its previous recommendation of a maximum residue level 0.5 mg/kg for beans (dry).

Dry peas, Subgroup of

Dry peas were previously evaluated by the 2004 JMPR where a maximum residue level of 0.07 mg/kg and a STMR of 0.02 mg/kg were estimated based on the GAP from Austria and Spain for pulse, dry seed of 2 foliar applications × 250 g ai/ha and a 14-day PHI. Lentils and chick-peas were previously evaluated by the 2018 JMPR where a maximum residue level of 0.3 mg/kg and an STMR value of 0.11 mg/kg were estimated based on the GAP from Canada of 3 foliar applications × 244 g ai/ha, 7-day RTI, and 7-day PHI.

The Meeting received a new critical GAP for dried peas from Canada consisting of 3 foliar applications at 244 g ai/ha, 7-day RTI, and 7-day PHI.

The Meeting received the same supervised residue trials for dry peas conducted in Canada that were assessed by the 2018 JMPR for lentils and chick-peas, matching the Canadian GAP for dry peas.

Fludioxonil residues in dry peas in ranked order were (n = 7): 0.018, 0.046 (2), 0.11 (2), 0.13, and 0.17 mg/kg.

The Meeting estimated a maximum residue level of 0.3 mg/kg and an STMR value of 0.11 mg/kg for the subgroup of dry peas. The Meeting withdrew its previous recommendations of maximum residue levels of 0.07 mg/kg for peas (dry), 0.3 mg/kg for chick-pea (dry), and 0.3 mg/kg for lentil (dry).

Sugar beet

The critical GAP for sugar beets is from the United States and is comprised of a single post-harvest spray application at 4.5 g ai/1000 kg of roots.

The Meeting received supervised residue trials conducted in the United States matching the critical GAP.

Fludioxonil residues in sugar beet roots in ranked order were (n = 6): 0.64, 0.90, 0.96, 1.2, 1.7, and 1.9 mg/kg.

The Meeting estimated a maximum residue level (based on the mean + 4×SD) of 4 mg/kg (Po) and an STMR value of 1.1 mg/kg for sugar beet.

Tree nuts, Group of

Pistachios were previously evaluated by the 2004 JMPR where a maximum residue level of 0.2 mg/kg and a STMR of 0.05 mg/kg were estimated based on the GAP from the United States of 4 foliar applications × 250 g ai/ha and a 7-day PHI.

The Meeting received a GAP from the United States for numerous tree nuts consisting of 4 foliar applications at a rate of 247 g ai/ha/application, with a 14-day RTI, and a 14-day PHI. For pistachios, the GAP assessed by the 2004 JMPR remains the critical GAP for this commodity.

The Meeting received supervised residue trials for almonds and pecans conducted in the United States matching the US GAP for tree nuts.

Fludioxonil residues in almond nutmeat in ranked order were (n = 5): ≤0.01 (3), 0.018, and 0.15 mg/kg.

Fludioxonil residues in pecan nutmeat in ranked order were (n = 5): < 0.01 (5) mg/kg.

Since residues of fludioxonil were higher in almonds than in pecans, the Meeting agreed to use the almond dataset for the estimation of maximum residue levels and dietary risk assessment for tree nut commodities.

The Meeting estimated a maximum residue level of 0.3 mg/kg and an STMR value of 0.01 mg/kg for the group of tree nuts (except Canarium nut, Chilean hazelnut, and Pistachios).

Residues in animal feeds**Bean forage**

Labels were provided for registrations in Canada on succulent beans (3 foliar applications × 250 g ai/ha, 7-day RTI, and 7-day PHI) and in Latvia on fresh beans with pods (3 foliar applications × 250 g ai/ha, 10-day RTI, and 14-day PHI). Based on the shorter RTI and PHI the Meeting decided that the GAP from Canada is the critical GAP.

The Meeting received three supervised residue trials conducted in Bulgaria, France, and Italy approximating the Canadian GAP which is insufficient to support a recommendation. The Meeting agreed to consider the GAP from Latvia.

The Meeting received eight supervised residue trials conducted in Bulgaria, Greece, Italy, France, and Spain matching the Latvian GAP.

Fludioxonil residues in beans, remaining plant, in ranked order were (n = 8): 0.40, 0.50, 2.3, 3.3, 4.2, 5.1, 7.8, and 11 mg/kg.

The Meeting estimated a highest residue of 11 mg/kg and a median value of 3.75 mg/kg for bean forage (as received).

Almond hulls

The critical GAP for almonds is from the United States consisting of 4 foliar applications at a rate of 247 g ai/ha, with a 14-day RTI, and 14-day PHI.

The Meeting received supervised residue trials for almonds conducted in the United States matching the GAP of the United States.

Fludioxonil residues in almond hulls in ranked order were (n = 5): 1.1, 1.7, 1.8, 3.3, and 7.6 mg/kg.

The Meeting estimated a maximum residue level of 20 mg/kg (dw) and a median value of 1.8 mg/kg for almond hulls (as received).

Fate of residues in processing

Processing data on sugar beet roots and almond nutmeat were provided. All data relevant for an estimation of maximum residue levels in processed commodities or for dietary exposure calculations are summarized in the following Table.

Table 5.16.1 Processing factors and residue estimates for fludioxonil

Raw commodity	Residue in RAC, mg/kg		Processed commodity	Processing Factors	Residue in processed commodity, mg/kg	
	Max	STMR		Fludioxonil [best estimate]	MRL	STMR-P
Sugar beet roots	4	1.1	Refined sugar	0.10	--	0.11
			Molasses	0.56	--	0.62
			Ensiled pulp	0.62	--	0.68
			Dried pulp	1.3	--	1.4
Almond nutmeat	0.2	0.01	Roasted almonds	0.80	--	0.008
			Almond oil	1.5	0.3	0.015

Residues in animal commodities

Farm animal feeding studies

Farm animal feeding studies are reported in the evaluations of the 2004 JMPR (lactating dairy cow), 2013 JMPR (laying hen), and 2018 JMPR (lactating dairy cow).

Farm animal dietary burden

The Meeting has added feed items (bean forage and almond hulls) and their associated residues to the dietary burden calculations used by the 2018 Meeting. Dietary burden calculations are provided in Annex 6; the dietary burden estimates are summarized below.

Table 5.16.2 Estimated maximum and mean dietary burdens of farm animals

Animal	Dietary burden estimates, ppm							
	Canada-US		European Union		Australia		Japan	
	Maximum	Mean	Maximum	Mean	Maximum	Mean	Maximum	Mean
Beef cattle	11	8.7	22	12	23	10	0.10	0.10
Dairy cattle	3.9	3.2	26	12 ^②	38 ^①	9.9	0.65	0.65
Broiler poultry	0.04	0.04	1.5	0.79	0.03	0.03	0.02	0.02
Laying hen	0.04	0.04	1.9 ^③	0.87 ^④	0.03	0.03	0.02	0.02

Notes:

- ① Highest maximum beef or dairy cattle dietary burden suitable for MRL estimates for mammalian tissues and milk.
- ② Highest mean beef or dairy cattle dietary burden suitable for STMR estimates for mammalian tissues and milk.
- ③ Highest maximum poultry dietary burden suitable for MRL estimates for poultry tissues and eggs.
- ④ Highest mean poultry dietary burden suitable for STMR estimates for poultry tissues and eggs.

Animal commodity maximum residue levels

Cattle

For beef and dairy cattle, the Meeting estimated a maximum dietary burden of 38 ppm and a mean dietary burden of 12 ppm. The burdens calculated by the current meeting are substantially greater than those used by the 2018 meeting (23 ppm and 6.4 ppm, respectively). Based on the new dietary burden and the results of the dairy cattle feeding studies evaluated by the 2018 JMPR, the calculations used to estimate highest total residues for use in estimating maximum residue levels and STMR values in mammalian commodities are shown below.

Table 5.16.3 Maximum residue level and STMR in mammalian commodities

Fludioxonil feeding study	Feed level (ppm) for milk residues	Total Residues (mg/kg) in milk ^a	Feed level (ppm) for tissue residues	Total Residues ^a (mg/kg)			
				Muscle	Liver	Kidney	Fat
MRL beef or dairy cattle							
Feeding study ^b	20	0.030	20	< 0.01	0.079	0.082	0.011
	100	0.15	100	0.012	0.35	0.29	0.033
Dietary burden and high residue	38	0.06	38	0.011	0.14	0.129	0.016
STMR beef or dairy cattle							
Feeding study ^b	20 ^b	0.026	20	< 0.01	0.055	0.062	0.01
Dietary burden and residue estimate	12	0.016	12	0.006	0.033	0.037	0.006

Notes:

^a Total residues = fludioxonil and its benzopyrrole metabolites, determined as 2,2-difluorobenzo[1,1]dioxole-4-carboxylic acid and expressed as fludioxonil.

^b Although the dairy cattle feeding study evaluated by the 2004 JMPR was conducted at a feeding level of 5.5 ppm, no quantifiable residues were observed in any matrices, as such it was decided to extrapolate from the feeding study evaluated by the 2018 JMPR where quantifiable residues were observed at a 20 ppm feeding level.

The Meeting confirmed its previous recommendation of a maximum residue level of 0.02 mg/kg for meat, based on fat (from mammals other than marine mammals) and mammalian fats (except milk fats).

The Meeting recommended a maximum residue level for milks at 0.07 mg/kg and edible offal (mammalian) at 0.15 mg/kg. The Meeting estimated STMRs of 0.006 mg/kg for muscle, 0.006 mg/kg for mammalian fat, 0.037 mg/kg for edible offal (mammalian), and 0.016 mg/kg in milks. These recommendations are intended to replace previous recommendations for these ruminant matrices.

Poultry

For poultry, the Meeting estimated a maximum dietary burden of 1.9 ppm and a mean dietary burden of 0.87 ppm which are the same as the dietary burdens estimated by the 2018 JMPR.

The Meeting therefore confirmed its previous recommendations.

RECOMMENDATION

On the basis of the data obtained from supervised residue trials the Meeting concluded that the residue levels listed in Annex 1 are suitable for establishing maximum residue limits and for IEDI assessment.

Definition of the residue for compliance with the MRL and for dietary risk assessment for plant commodities: *fludioxonil*.

Definition of the residue for compliance with the MRL and for dietary risk assessment for animal commodities: *sum of fludioxonil and its benzopyrrole metabolites, determined as 2,2-difluorobenzo[1,3]dioxole-4-carboxylic acid and expressed as fludioxonil*.

The residue is fat-soluble.

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The International Estimated Daily Intakes (IEDIs) of fludioxonil were calculated for the 17 GEMS/Food cluster diets using STMRs and STMR-Ps estimated by the JMPR in 2004, 2006, 2010, 2012, 2013, 2018 and current Meeting. The results are shown in Annex 3.

The ADI is 0–0.4 mg/kg bw and the calculated IEDIs were 1–6 percent of the maximum ADI. The Meeting concluded that the long-term intake of residues of fludioxonil from the uses considered by the JMPR is unlikely to present a public health concern

Acute dietary exposure

The 2004 JMPR decided that an ARfD for fludioxonil was unnecessary. The Meeting therefore concluded that the acute dietary exposure to residues of fludioxonil resulting from uses that have been considered by the JMPR is unlikely to present a public health concern.

Metabolites covered by the health-based guidance value (HBGV)

The Meeting concluded that metabolites CGA 192155, SYN 551031, and CGA 339833 are covered by the HBGV.

Residues of CGA 192155, SYN 551031, and CGA 339833 were not measured in any of the supervised field trials assessed by any of the previous Meetings or by the current Meeting. The Meeting estimated the dietary exposure to combined residues of fludioxonil, CGA 192155, SYN 551031, and CGA 339833 by applying conversion factors (based on the ratio of combined residues of fludioxonil, CGA 192155, SYN 551031, and CGA 339833 against residues of the parent) to the fludioxonil STMRs for those crops in which combined residue levels of these metabolites were significant when compared against the parent (i.e. ≥ 10 percent of the parent). The Meeting concluded that metabolites CGA 192155, SYN 551031, and CGA 339833 do not contribute significantly to the dietary exposure from fludioxonil (i.e., calculated IEDIs remained in the range of 1–6 percent of the HBGV) and are unlikely to present a public health concern.

Threshold of toxicological concern (TTC) consideration for metabolites***CGA 227731***

The metabolite CGA 227731 could be assessed using the TTC approach (Cramer Class III threshold of 1.5 $\mu\text{g}/\text{kg}$ bw per day).

Residues of CGA 227731 were not measured in any of the supervised field trials assessed by any of the previous Meetings or by the current Meeting but were observed in the soya bean seed treatment metabolism study and accounted for 1.9 percent of the TRR in forage (0.002 mg/kg) and 1.5 percent of the TRR in hay (< 0.001 mg/kg). Residues of CGA 227731 were also observed in rotational wheat matrices accounting for 10.7 percent of the TRR in forage (0.006 mg/kg) and up to 22 percent of the TRR in straw (0.016 mg/kg). Residues of CGA 227731 were not found in any of the foliar metabolism studies conducted in plants (grapes, tomatoes, peaches, green onions, or head lettuce); seed treatment metabolism studies in potatoes, rice, wheat, or cotton; or in rotational lettuce, sugar beets, mustard greens, or turnips (2004 JMPR).

The Meeting concluded that no quantifiable residues of CGA 227731 are expected in soya bean forage and hay or rotational wheat forage, but that low concentrations of CGA 227731 might be expected in wheat straw grown in rotation with fludioxonil-treated crops.

Given that metabolite CGA 227731 was only present at insignificant levels in animal feed commodities, the Meeting agreed that dietary exposure to residues of CGA 227731 is expected to be below the TTC for Cramer Class III compounds of 1.5 $\mu\text{g}/\text{kg}$ bw per day and is unlikely to present a public health concern. Should further uses be considered in the future, these conclusions may need to be re-evaluated.

CGA 308565/SYN 518579 tautomeric pair, CGA 265378 and CGA 308103

The CGA 308565/SYN 518579 tautomeric pair, CGA 265378 and CGA 308103 could be assessed using the TTC approach (Cramer Class III threshold of 1.5 $\mu\text{g}/\text{kg}$ bw per day).

Residues of all components were not measured in any of the supervised field trials assessed by any of the previous Meetings or by the current Meeting. Based on metabolism studies previously evaluated by the 2004 JMPR, conversion factors to fludioxonil STMRs based on the ratio of each metabolite to parent were estimated. For post-harvest uses and seed treatment uses, generally no residues of the metabolites were expected.

The Meeting estimated a dietary exposures to:

- CGA 308565/SYN 518579 metabolites of 0.0956 µg/kg bw/day;
- CGA 265378 of 0.236 µg/kg bw/day; and,
- CGA 308103 of 0.198 µg/kg bw/day.

The Meeting concluded that the estimated dietary exposure to residues of CGA 308565/SYN 518579 tautomeric pair, CGA 265378 and CGA 308103 from uses considered by the JMPR is below the TTC for Cramer Class III compounds and is unlikely to present a public health concern. Should further uses be considered in the future, these conclusions may need to be re-evaluated.

5.17 Fluindapyr (328)

TOXICOLOGY

Fluindapyr is the International Organization for Standardization-approved name for 3-(difluoromethyl)-*N*-(7-fluoro-1,1,3-trimethyl-2,3-dihydro-1*H*-inden-4-yl)-1-methyl-1*H*-pyrazole-4-carboxamide (IUPAC), with Chemical Abstracts Service number 1383809-87-7.

Fluindapyr is a systemic fungicide belonging to the chemical class of pyrazole-4-carboxamides and to the group of succinate dehydrogenase inhibitors (SDHI). It possesses protective, curative and eradicator properties, and has broad-spectrum activity against a wide range of fungal diseases in plants.

Fluindapyr is a racemic mixture containing two enantiomers *R* and *S* in the ratio 1:1. Fluindapyr has not previously been evaluated by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) and was reviewed by the present Meeting at the request of the Codex Committee on Pesticide Residues (CCPR).

All critical studies contained statements of compliance with good laboratory practice (GLP) and were conducted in accordance with current test guidelines unless otherwise specified. No additional information from a literature search was identified that complemented the toxicological information submitted for the current assessment.

Biochemical aspects

When labelled fluindapyr is administered orally to rats, radioactivity is rapidly absorbed, with a time to maximum concentration (T_{max}) of three hours. After single and repeated oral administration of 50 mg/kg body weight (bw) per day, the oral absorption was about 70–80 percent.

After a single oral dose of 1000 mg/kg bw maximum concentration (C_{max}) values for radioactivity were approximately 3–4 times higher than after a single oral 50 mg/kg bw dose and the area under the concentration–time curve (AUC) values was approximately 8–12 times higher, confirming that the extent of systemic exposure increased less than in direct proportion to dose. There was no accumulation of radioactive material in the analysed tissues. After repeated doses of unlabelled compound at 50 mg/kg bw followed by a single labelled dose, the highest levels of radioactivity at T_{max} were found in the liver.

The elimination of radioactivity was rapid with most of the radioactivity excreted in the first 24 hours after administration. Less than 0.2 percent of the radioactive dose was recovered from the carcass at 168 hours. The majority of radioactivity was excreted via bile (c 60 percent), with 10–20 percent of the administered radioactivity appearing in the urine of bile duct-cannulated animals. Higher levels of urinary excretion (c 30 percent) occurred in non-cannulated rats, indicating some degree of enterohepatic recirculation. The overall mean radioactivity recovered in excreta accounted for over 90 percent of the dose. The excretion profile was similar in male and female rats.

Fluindapyr was extensively metabolized, primarily through *N*-demethylation, oxidation of methyl groups to hydroxymethyl and further to carboxylic acids. Unchanged fluindapyr was not excreted via urine. The main metabolite found in the urine was 1-carboxy-*N*-desmethyl-fluindapyr at up to 10 percent of administered dose (AD). Biliary excretion was lower in females than males. The main biliary metabolites were 1-carboxy-*N*-desmethyl-fluindapyr (11 percent in males, 3.9 percent in females) and 1-OH-methyl-fluindapyr (20 percent in males, 8 percent in females).

Toxicological data

The acute oral median lethal dose (LD₅₀) for fluindapyr was greater than 2000 mg/kg bw and the dermal LD₅₀ was greater than 2000 mg/kg bw. The inhalation median lethal concentration (LC₅₀) for fluindapyr

was greater than 5.19 mg/L. Fluindapyr was not irritating to the skin or eyes of rabbits, and was shown to be sensitizing, in a local lymph node assay (LLNA) test in mice. Fluindapyr was not phototoxic.

In repeat-dose toxicity studies on mice, rats and dogs, the main effects were on body weight, and liver (increased weight and hepatocellular hypertrophy), with changes in clinical chemistry parameters.

In a 90-day dietary toxicity study in mice, fluindapyr was administered at dietary concentrations of 0, 300, 1000 or 3000 ppm (equal to 0, 51, 162 and 529 mg/kg bw per day for males, 0, 81, 274 and 799 mg/kg bw per day for females). The NOAEL was 3000 ppm (equal to 529 mg/kg bw per day), the highest dose tested.

In a 90-day dietary toxicity study in rats, fluindapyr was administered at dietary concentrations of 0, 100, 450 or 2000/6000 ppm (equal to 0, 6, 24 and 330 mg/kg bw per day for males, 0, 7, 30 and 139 mg/kg bw per day for females). The NOAEL was 2000/(6000) ppm (equal to 139 mg/kg bw per day), the highest dose tested.

In a 90-day oral toxicity study in dogs, fluindapyr was administered in gelatine capsules at dose levels of 0, 10, 40 or 200 mg/kg bw per day. The NOAEL was 10 mg/kg bw per day based on bile duct hyperplasia at 40 mg/kg bw per day.

In a one-year, oral toxicity study in dogs, fluindapyr was administered by capsule at dose levels of 0, 4, 8, 40 or 100 mg/kg bw per day for males and 0, 2, 4, 8 or 40 mg/kg bw per day for females. The NOAEL was 4 mg/kg bw per day based on hyperplasia of the bile duct at 8 mg/kg bw per day.

In an 18-month carcinogenicity study in mice, fluindapyr was administered at dietary concentrations of 0, 100, 500 or 3000 ppm (equal to 0, 14, 67 and 412 mg/kg bw per day for males, 0, 18, 84 and 538 mg/kg bw per day for females). The NOAEL for toxicity was 500 ppm (equal to 67 mg/kg bw per day) based on hepatotoxicity (increased weights, hypertrophy, necrosis and higher incidences of pigmented macrophages) at 3000 ppm (equal to 412 mg/kg bw per day). The NOAEL for carcinogenicity was 3000 ppm (equal to 412 mg/kg bw per day), the highest dose tested.

In a 104-week combined chronic toxicity and carcinogenicity study in rats, fluindapyr was administered in the diet at concentrations of 0, 100, 400 or 1600 ppm (equal to 0, 4, 17 and 67 mg/kg bw per day for males, 0, 5, 21 and 83 mg/kg bw per day for females), and additionally 4800 ppm (equal to 202 mg/kg bw per day) for males only. The NOAEL for toxicity and carcinogenicity was 100 ppm (equal to 5 mg/kg bw per day) based on increases in mammary gland adenocarcinomas in females at 400 ppm (equal to 21 mg/kg bw per day).

The Meeting concluded that fluindapyr is carcinogenic in female rats but not in mice or male rats.

Fluindapyr was tested for genotoxicity in an adequate range of in vitro and in vivo assays. No evidence of genotoxicity was found.

The Meeting concluded that fluindapyr is unlikely to be genotoxic.

In view of the lack of genotoxicity and the absence of carcinogenicity in mice and male rats, and the fact that the carcinogenicity in female rats exhibits a threshold, the Meeting concluded that fluindapyr is unlikely to pose a carcinogenic risk to humans at levels occurring due to exposure from the diet.

In a two-generation reproductive toxicity study in rats, fluindapyr was administered at dietary concentrations of 0, 100, 400 or 1600/3200 ppm (equal to 0, 4.8, 19.6, and 161 mg/kg bw per day for males, 0, 6.7, 26, and 201 mg/kg bw per day for females). The NOAEL for parental toxicity was 400 ppm (equal to 19.6 mg/kg bw per day) based on thyroid follicular cell hypertrophy at 3200 ppm (equal to 161 mg/kg bw per day). The reproductive NOAEL was 400 ppm (equal to 26 mg/kg bw per day) based on the effects on female reproductive organs associated with changes in the oestrous cycle observed at

3200 ppm (equal to 201 mg/kg bw per day). The offspring NOAEL was 400 ppm (equal to 28.1 mg/kg bw per day), based on reduced body weights at 3200 ppm, (equal to 161 mg/kg bw per day).

In a developmental toxicity study in rats, fluindapyr was administered by gavage at dose levels of 0, 60, 300 or 1000 mg/kg bw per day from gestation day (GD) 6-20. The maternal NOAEL was 300 mg/kg bw per day based on reductions in body weight and body weight gain at 1000 mg/kg bw per day. The embryo/fetal NOAEL was 1000 mg/kg bw per day, the highest dose tested.

In a developmental toxicity study in rabbits, fluindapyr was administered by gavage at dose levels of 0, 50, 250 or 750 mg/kg bw per day from GD 6–27. The maternal NOAEL was 250 mg/kg bw per day based on decreased food consumption and body weight gain at 750 mg/kg bw per day. The embryo/fetal NOAEL was 750 mg/kg bw per day, the highest dose tested.

The Meeting concluded that fluindapyr is not teratogenic.

In an acute neurotoxicity study in rats, fluindapyr was administered by gavage at doses of 0, 125, 500 or 2000 mg/kg bw and in a follow-up at 0, 15, 30 or 60 mg/kg bw. The NOAEL for systemic toxicity was 60 mg/kg bw based on reduced motor and locomotor activity in females at 125 mg/kg bw. The NOAEL for neurotoxicity was 2000 mg/kg bw, the highest dose tested.

In a 90-day neurotoxicity study in rats, fluindapyr was administered at dietary concentrations of 0, 200, 600 or 5000 (males)/2000(females) ppm (equal to 0, 12, 34 and 296 mg/kg bw per day for males, 0, 13, 39 and 123 mg/kg bw per day for females). The systemic NOAEL was 600 ppm (equal to 39 mg/kg bw per day) based on reductions in body weight gain and food consumption at 2000 ppm (equal to 123 mg/kg bw per day). The NOAEL for repeat-dose neurotoxicity was 2000 ppm (equal to 123 mg/kg bw per day), the highest dose tested.

The Meeting concluded that fluindapyr is not neurotoxic.

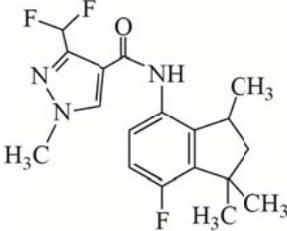
No immunotoxicity data had been provided. There was no evidence of immunotoxicity from the standard toxicity studies.

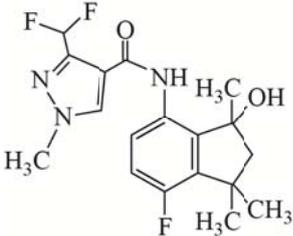
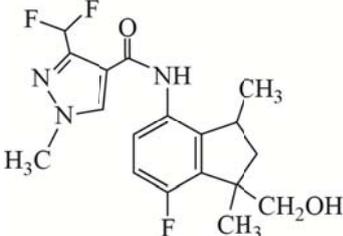
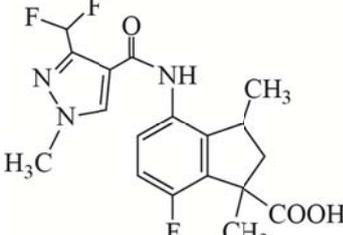
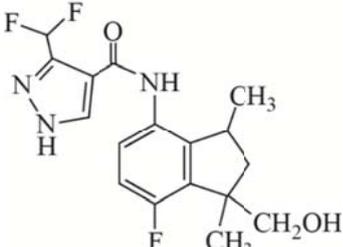
The Meeting concluded that fluindapyr is unlikely to be immunotoxic.

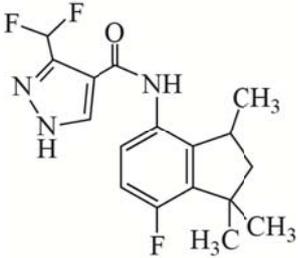
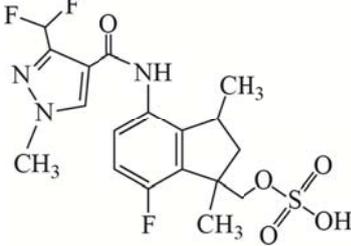
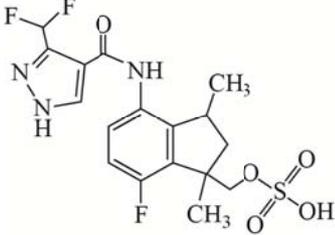
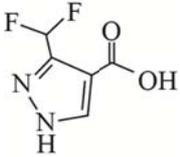
Toxicological data on metabolites and/or degradates

The plant metabolites 3-OH-fluindapyr, 1-OH-met-fluindapyr, 1-*cis*-COOH-fluindapyr, 1-*trans*-COOH-fluindapyr, 1-OH-met-*N*-desmethyl-fluindapyr, *N*-desmethyl-fluindapyr, 1-SO₄-met-fluindapyr, 1-SO₄-desmethyl-fluindapyr and *N*-desmethylpyrazole carboxylate were assessed.

Summary overview of toxicological characterization of plant/livestock metabolites

Compound, codes and structure	Rat ADME (>10 percent of AD)	Genotoxicity assessment (data, QSAR, read-across)	General toxicity	Conclusion
Fluindapyr 		Full data set Negative	Full data set	
3-OH-fluindapyr	Minor metabolite Structure very	Unlikely to be genotoxic (Ames, mammalian cell	LD ₅₀ : 2000 mg/kg bw	Covered by parent

Compound, codes and structure	Rat ADME (>10 percent of AD)	Genotoxicity assessment (data, QSAR, read-across)	General toxicity	Conclusion
	similar to parent	gene mutation and cytogenetic study using human lymphocytes)		ADI/ARfD due to similarity of structure
1-OH-met-fluindapyr 	Present at >10 percent in bile	QSAR—no alerts for genotoxicity		Covered by parent ADI/ARfD as it is a major rat metabolite
1-COOH-fluindapyr (cis & trans) 	Structure very similar to parent	Unlikely to be genotoxic based on data. trans Gene mutation in vitro (bacterial and mammalian cells); in vitro micronucleus cis Gene mutation in vitro (bacterial and mammalian cells); in vitro micronucleus, and in vivo micronucleus	trans Acute oral LD ₅₀ : >2000 mg/kg bw (rat) 28-day NOAEL: 614 mg/kg bw per day (rat) cis Acute oral LD ₅₀ : >2000 mg/kg bw (rat) 28-day NOAEL: 651mg/kg bw per day (rat)	Covered by parent ADI/ARfD due to similarity of structure
1-OH-met-<i>N</i>-desmethyl-fluindapyr 	Present at >10 percent in bile	No data	No data	Covered by parent ADI/ARfD as it is a major rat metabolite.
<i>N</i>-desmethyl-fluindapyr	Structure very similar to parent and 1-OH-met- <i>N</i> -desmethyl which is a major metabolite in bile	QSAR—no alerts for genotoxicity	No data	Covered by parent ADI/ARfD due to similarity of structure to parent and a major rat

Compound, codes and structure	Rat ADME (>10 percent of AD)	Genotoxicity assessment (data, QSAR, read-across)	General toxicity	Conclusion
				metabolite
1-SO ₄ -met-fluindapyr 	Not present in rat Conjugate of 1-OH-methyl-fluindapyr which is a major rat metabolite.	QSAR–no alerts for genotoxicity.	No data	Covered by parent ADI/ARfD as it is a conjugate of a major rat metabolite
1-SO ₄ -desmethyl-fluindapyr 	Not present in rat. Conjugate of 1-OH-met- <i>N</i> -desmethyl fluindapyr which is a major rat metabolite	QSAR–no alerts for genotoxicity.	No data	Covered by parent ADI/ARfD as it is a conjugate of a major rat metabolite
<i>N</i> -desmethyl-pyrazole carboxylate 	Not a rat metabolite	QSAR–no alerts for genotoxicity	No data	TTC–Cramer class III, 1.5 µg/kg bw per day

Microbiological data

There was no information available in the public domain and no experimental data were submitted which addressed the possible impact of fluindapyr residues on the human intestinal microbiome.

Human data

The sponsor had not received any reports of disease or adverse health effects attributable to exposure associated with the handling, testing or the manufacture of fluindapyr and/or formulations.

No information on accidental or intentional poisoning in humans is available.

The Meeting concluded that the existing database on fluindapyr was adequate to characterize the potential hazards to the general population, including fetuses, infants and children.

Toxicological evaluation

The Meeting established an ADI of 0–0.04 mg/kg bw, based on the NOAEL of 4 mg/kg bw per day in the one-year oral toxicity study in dogs, supported by the two-year rat combined toxicity and carcinogenicity

study and using a safety factor of 100. The margin between the upper bound ADI and the LOAEL for tumours in rats is 525 times.

The Meeting established an ARfD of 0.6 mg/kg bw on the basis of the NOAEL of 60 mg/kg bw, in the acute neurotoxicity study in rats and using a safety factor of 100.

A toxicological monograph was prepared.

Levels relevant to risk assessment of fluindapyr

Species	Study	Effect	NOAEL	LOAEL
Mouse	78-week study of toxicity and carcinogenicity ^a	Toxicity	500 ppm, equal to 67 mg/kg bw/day	3000 ppm, equal to 412 mg/kg bw/day
		Carcinogenicity	3000 ppm, equal to 412 mg/kg bw/day ^c	-
Rat	Acute neurotoxicity study ^b	Systemic toxicity	60 mg/kg bw	125 mg/kg bw
		Neurotoxicity	2000 mg/kg bw ^c	-
	Two-year study of toxicity and carcinogenicity ^a	Toxicity	100 ppm, equal to 5 mg/kg bw/day	400 ppm, equal to 21 mg/kg bw/day
		Carcinogenicity	100 ppm, equal to 5 mg/kg bw/day	400 ppm, equal to 21 mg/kg bw/day
	Two-generation study of reproductive toxicity ^a	Reproductive toxicity	400 ppm, equal to 26 mg/kg bw/day	3200 ppm, equal to 201 mg/kg bw/day
		Parental toxicity	400 ppm, equal to 19.6 mg/kg bw/day ^c	3200 ppm, equal to 161 mg/kg bw/day
		Offspring toxicity	400 ppm, equal to 19.6 mg/kg bw/day ^c	3200 ppm, equal to 161 mg/kg bw/day ^c
	Developmental toxicity study ^b	Maternal toxicity	300 mg/kg bw/day	1000 mg/kg bw/day
Embryo/fetal toxicity		1000 mg/kg bw/day ^c	-	
Rabbit	Developmental toxicity study ^b	Maternal toxicity	250 mg/kg bw/day	750 mg/kg bw/day ^d
		Embryo/fetal toxicity	750 mg/kg bw/day ^c	-
Dog	One-year study of toxicity ^e	Toxicity	4 mg/kg bw/day	8 mg/kg bw/day

Notes:

^a Dietary administration.

^b Gavage administration.

^c Highest dose tested.

^d Lowest dose tested.

^e Capsule administration.

Acceptable daily intake (ADI)*

0–0.04 mg/kg bw

Acute reference dose (ARfD)*

0.6 mg/kg

*Applies to fluindapyr, 3-OH-fluindapyr, 1-OH-met-fluindapyr, cis/trans 1-COOH-fluindapyr, 1-OH-met-N-desmethyl-fluindapyr, N-desmethyl-fluindapyr, 1-SO₄-met-fluindapyr and 1-SO₄-desmethyl-fluindapyr.

Information that would be useful for the continued evaluation of the compound

Results from epidemiological, occupational health and other such observational studies of human exposure.

Critical end-points for setting guidance values for exposure to fluindapyr

Absorption, distribution, excretion and metabolism in mammals

Rate and extent of oral absorption	Rapidly absorbed; (T_{\max} 3 h), oral absorption is >70 percent (rat)
Dermal absorption	No data
Distribution	Wide; highest concentrations in liver
Potential for accumulation	No evidence of accumulation
Rate and extent of excretion	Rapid and nearly complete via urine and faeces; 80 percent within 24 hours
Metabolism in animals	Extensively metabolized mainly through <i>N</i> -demethylation, oxidation of methyl groups to hydroxymethyl and further to carboxylic acid
Toxicologically significant compounds in animals and plants	Fluindapyr (parent); 3-OH-fluindapyr, 1-OH-met-fluindapyr, <i>cis/trans</i> 1-COOH-fluindapyr, <i>N</i> -desmethyl-fluindapyr, 1-OH-met- <i>N</i> -desmethyl-fluindapyr, 1-SO ₄ -met-fluindapyr, 1-SO ₄ -desmethyl-fluindapyr, <i>N</i> -desmethyl-pyrazole carboxylate

Acute toxicity

Rat, LD ₅₀ , oral	>2000 mg/kg bw
Rat, LD ₅₀ , dermal	>2000 mg/kg bw
Rat, LC ₅₀ , inhalation	>5.19 mg/L
Rabbit, dermal irritation	Not irritating
Rabbit, ocular irritation	Not irritating
Mouse, dermal sensitization	Sensitizing (LLNA)

Short-term studies of toxicity

Target/critical effect	Body weight, and liver; increased weight, clinical chemistry, bile duct hypertrophy (dog)
Lowest relevant oral NOAEL	4 mg/kg bw per day (dog)

Long-term studies of toxicity and carcinogenicity

Target/critical effect	Mammary tumours (rat) Liver (mouse)
Lowest relevant NOAEL	5 mg/kg bw per day (rat)
Carcinogenicity	Mammary tumours in female rats ^a

Genotoxicity Unlikely to be genotoxic

Reproductive toxicity	
Target/critical effect	Lower body weight (pup and parent), thyroid toxicity, altered estrous cycling
Lowest relevant parental NOAEL	19.6 mg/kg bw per day (rat)
Lowest relevant offspring NOAEL	19.6 mg/kg bw per day (rat)
Lowest relevant reproductive NOAEL	26 mg/kg bw per day (rat)
Developmental toxicity	
Target/critical effect	Reduction in body weight and body weight gain
Lowest relevant maternal NOAEL	250 mg/kg bw per day (rabbit)
Lowest relevant embryo/fetal NOAEL	750 mg/kg bw per day (rabbit)
Neurotoxicity	
Acute neurotoxicity NOAEL	60 mg/kg bw, (systemic toxicity, rat) 2000 mg/kg bw, the highest dose tested (neurotoxicity, rat)
Subchronic neurotoxicity NOAEL	123 mg/kg bw per day, the highest dose tested (rat)
Developmental neurotoxicity NOAEL	No data
Other toxicological studies	
Immunotoxicity	No evidence from routine studies
Studies on toxicologically relevant metabolites	
3-hydroxy-fluindapyr	Acute oral LD ₅₀ : >2000 mg/kg bw (rat) Unlikely to be genotoxic
1-trans-COOH-fluindapyr	Acute oral LD ₅₀ : >2000 mg/kg bw (rat) 28-day NOAEL: 614mg/kg bw per day (rat) Unlikely to be genotoxic
1-cis-COOH-fluindapyr	Acute oral LD ₅₀ : >2000 mg/kg bw (rat) 28-day NOAEL: 651mg/kg bw per day (rat) Unlikely to be genotoxic
Microbiological data	No data available
Human data	No clinical cases or poisoning incidents have been recorded

Notes:

^a Unlikely to pose a carcinogenic risk to humans via exposure from the diet.

Summary

	Value	Study	Safety factor
ADI	0–0.04 mg/kg bw ^a	One-year dog study supported by a two-year rat study.	100
ARfD	0.6 mg/kg bw	Acute neurotoxicity study	100

Notes:

^a Applies to fluindapyr and 3-OH- fluindapyr, 1-OH-met-fluindapyr, *cis/trans* 1-COOH-fluindapyr, 1-OH-met-*N*-desmethyl-fluindapyr, *N*-desmethyl-fluindapyr, 1-SO₄-met-fluindapyr and 1-SO₄-desmethyl-fluindapyr.

RESIDUE AND ANALYTICAL ASPECTS

Fluindapyr (ISO common name) is a broad spectrum fungicide, which belongs to the succinate dehydrogenase inhibitors (SDHI) class of compounds. The mode of action is inhibition of the energy production process in pathogenic fungi.

Fluindapyr was scheduled at the Fifty-first Session of the CCPR for evaluation as a new compound by the 2021 JMPR and rescheduled for evaluation by the 2022 JMPR. The Meeting received information on identity, physical chemical properties, plant and animal metabolism, soil degradation, residue analysis, storage stability, use patterns, residues resulting from supervised trials on wheat, sorghum, maize, rice, almonds and pecan nuts, fate of residues during processing, and livestock feeding studies.

The IUPAC name for fluindapyr is 3-(difluoromethyl)-N-(7-fluoro-1,1,3-trimethyl-2,3-dihydro-1H-inden-4-yl)-1-methyl-1H-pyrazole-4-carboxamide.

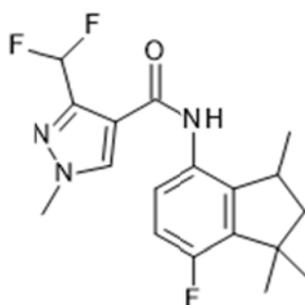
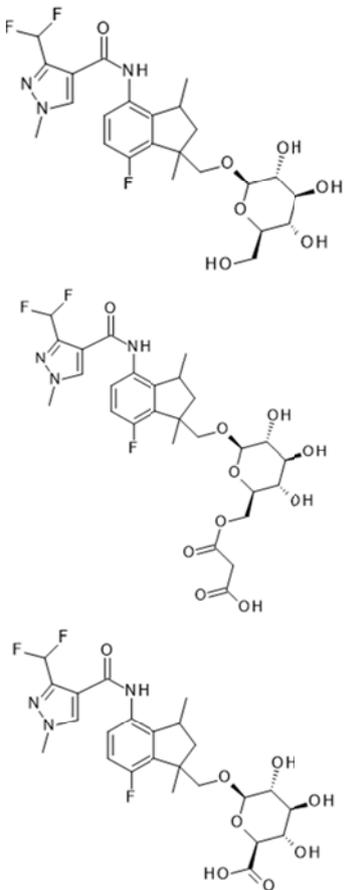
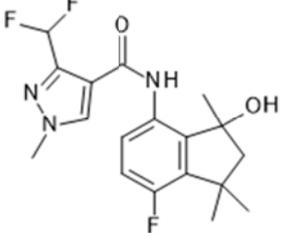
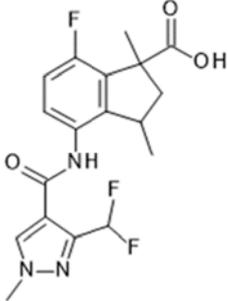
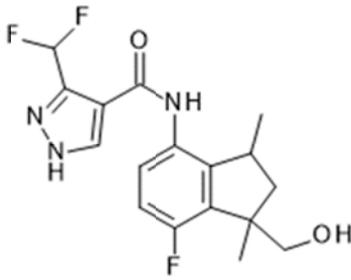
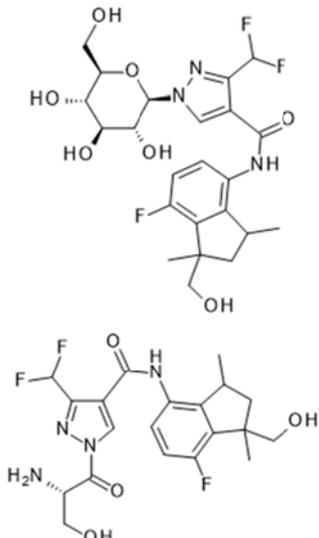
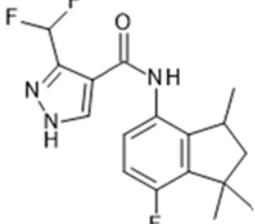
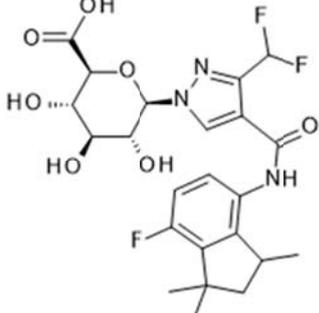
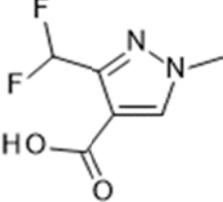


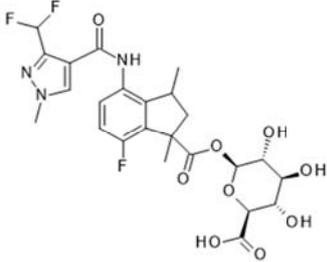
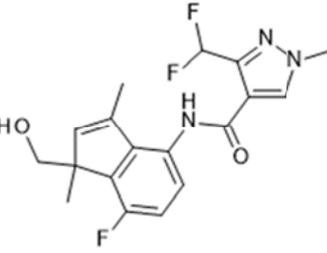
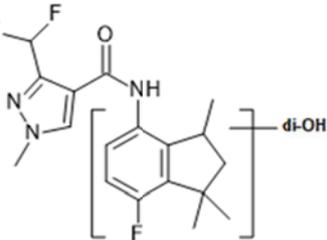
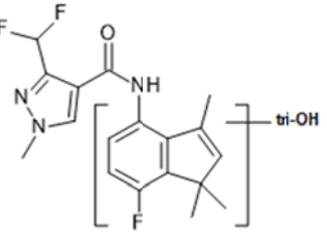
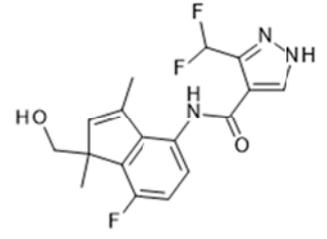
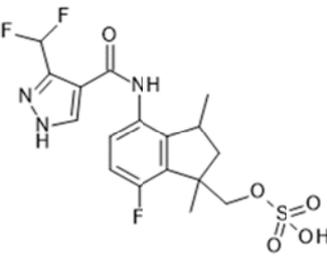
Table 5.17.1 Abbreviations used for relevant compounds referred to in the appraisal

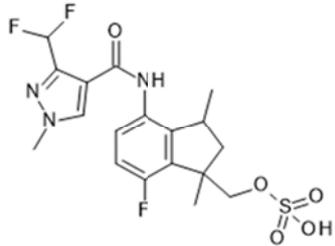
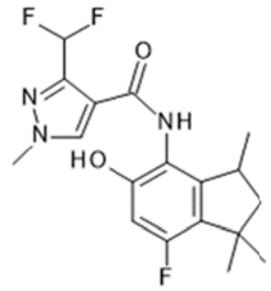
Code	Name and Matrix	Structure
1-OH-Met-fluindapyr (Code: 510153) 1-Hydroxymethyl- fluindapyr 1-OH-Met-F M24, M26 in animal studies	3-(difluoromethyl)-N-[7-fluoro-1-(hydroxymethyl)-1,3-dimethyl-2,3-dihydro-1H-inden-4-yl]-1-methyl-1H-pyrazole-4-carboxamide MW = 367 g/mol Found in: goat (various tissues), hen (all tissues), rat, primary crops (grape, sugar beet, wheat, rice) and rotational (carrot, lettuce, wheat) crops	

Code	Name and Matrix	Structure
<p>1-OH-Met-fluindapyr-Glu 1-Hydroxymethyl-fluindapyr glucoside (plant) 1-Hydroxymethyl-fluindapyr gluc-mal (plant) 1-Hydroxymethyl-fluindapyr glucuronide (animals) M13, M15 in animal studies</p>	<p>3-(difluoromethyl)-N-(7-fluoro-1-(hydroxymethyl)-1,3-dimethyl-2,3-dihydro-1H-inden-4-yl)-1-methyl-1H-pyrazole-4-carboxamide gluc MW-Glu= 529 g/mol MW-Glu-Mal = 615 g/mol MW-Glucuronide = 544 g/mol Found in: goat liver, primary crops (grapes fruit and leaves), wheat (forage, hay, straw), soya bean (forage and hay)</p>	
<p>3-OH-fluindapyr (Code:510152) 3-Hydroxy-fluindapyr M34 in animal studies</p>	<p>3-(difluoromethyl)-N-(7-fluoro-3-hydroxy-1,1,3-trimethyl-2,3-dihydro-1H-inden-4-yl)-1-methyl-1H-pyrazole-4-carboxamide MW = 367 g/mol Found in: some goat tissues, primary crops (grape fruit and leaves, wheat matrices, rice, and limited in sugar beet and rice) and rotational crops</p>	
<p>1-COOH-fluindapyr (Code: 510216) 1-Carboxy-fluindapyr M23, M25 in animal studies Diastereoisomer ratio = 1.72:1</p>	<p>4-(3-(difluoromethyl)-1-methyl-1H-pyrazole-4-carboxamido)-7-fluoro-1,3-dimethyl-2,3-dihydro-1H-indene-1-carboxylic acid MW = 381 g/mol Found in: goat liver and kidney and hen liver and muscle and rat metabolite. Limited amounts in primary crops (sugar beet roots and rice grain and straw) and rotational crops</p>	

Code	Name and Matrix	Structure
1-OH-Met-N-DesMet-fluindapyr (Code: 510215) 1-Hydroxymethyl-N-Desmethyl-fluindapyr M18, M19 in animal studies Diastereoisomer ratio = 2.2:1	3-(difluoromethyl)-N-(7-fluoro-1-(hydroxymethyl)-1,3-dimethyl-2,3-dihydro-1H-inden-4-yl)-1H-pyrazole-4-carboxamide MW = 353 g/mol Found in limited amounts in goat muscle and milk and in very limited amounts in primary crops (sugar beet roots and leaves, forage, hay and wheat forage, hay and straw after hydrolysis, indicating that it is the glucosyl conjugate)	
1-OH-Met-N-DesMet-fluindapyr-gluc (Code: N/A) 1-hydroxymethyl-N-desmethyl-fluindapyr glucoside (plant) 1-hydroxymethyl N-desmethyl-fluindapyr-glucuronide (animal) M10 and M11 in animal metabolism studies	3-(difluoromethyl)-N-(7-fluoro-1-(hydroxymethyl)-1,3-dimethyl-2,3-dihydro-1H-inden-4-yl)-1H-pyrazole-4-carboxamide gluc MW-N-Ser-conjugate = 440 g/mol MW-N-Glu-conjugate = 515 g/mol Found in: goat liver and kidney and in limited amounts in wheat forage and hay and in soya bean and hay.	
N-DesMet-fluindapyr (Code: 510220) N-Desmethyl-fluindapyr M33 in animal studies	3-(difluoromethyl)-N-(7-fluoro-1,1,3-trimethyl-2,3-dihydro-1H-inden-4-yl)-1H-pyrazole-4-carboxamide MW=337 g/mol Found in: very limited amounts in primary crops, rotational crops, and some goat tissues (fat, muscle, and cream), and all hen matrices.	
N-DesMet-fluindapyr-glu (Code: N/A) N-Desmethyl-fluindapyr-glucuronide M6 and M7 in animal studies	3-(difluoromethyl)-N-(7-fluoro-1,1,3-trimethyl-2,3-dihydro-1H-inden-4-yl)-1H-pyrazole-4-carboxamide glucuronide MW = 513 g/mol Found in very limited amounts in goat kidney	
Pyrazole carboxylic acid (Code: 510147)	3-(difluoromethyl)-1-methyl-1H-pyrazole-4-carboxylic acid MW = 176 g/mol Found in very limited amounts in wheat feed matrices, grape fruit and leaves and rice grain and straw.	

Code	Name and Matrix	Structure
Pyrazole carboxamide (Code: 510151)	3- (difluoromethyl)- 1-methyl-1H-pyrazole-4- carboxamide MW = 175 g/mol Found in very limited amounts in wheat feed matrices, soya bean forage, sugar beet foliage and grape fruit and leaves.	
N-DesMet-pyrazole carboxylic acid (Code: 510219)	3- (difluoromethyl)- 1H-pyrazole-4- carboxylic acid MW = 162 g/mol Found in very limited amounts in sugar beet root and in some rotational crops	
N-DesMet-fluindapyr-N- ser (Code: N/A)	1-(2-amino-3-hydroxy-propanoyl)-3-(difluoromethyl)-N- (7-fluoro-1,1,3-trimethyl-indan-4-yl)pyrazole-4- carboxamide MW = 424 g/mol Found in soya bean forage and hay	
N-DesMet-fluindapyr- N1-Glu (Code: 510171) and DesMet-fluindapyr-N1- Glu-Mal (Code: N/A)	3-(difluoromethyl)-N-(7-fluoro-1,1,3-trimethyl-2,3-dihydro- 1H-inden-4-yl)-1H-pyrazole-4-carboxamide N1-Glu and Glu-Mal MW = 499 g/mol (glu) MW = 585 g/mol (glu-mal) Found in limited amounts in soya bean forage and hay	
2-OH-fluindapyr (Code: 510321) 2-Hydroxy-fluindapyr M27 in animal metabolism studies	3-(difluoromethyl)-N-(7-fluoro-2-hydroxy-1,1,3-trimethyl- 2,3-dihydro-1H-inden-4-yl)-1-methyl-1H-pyrazole-4- carboxamide MW = 367 g/mol Found in limited amounts in all goat and hen tissues	

Code	Name and Matrix	Structure
1-COOH-fluindapyr-glu (Code: N/A) 1-Carboxy-fluindapyr-glucuronide M14 in animal metabolism studies	4-(3-(difluoromethyl)-1-methyl-1H-pyrazole-4-carboxamido)-7-fluoro-1,3-dimethyl-2,3-dihydro-1H-indene-1-carboxylic acid glucuronide MW = 557 g/mol Found in goat liver and trace in kidney	 The structure shows a fluindapyr core with a difluoromethyl group and a methyl group on the pyrazole ring, and a 7-fluoro-1,3-dimethyl-2,3-dihydro-1H-indene-1-carboxylic acid moiety. The carboxylic acid group is linked to a glucuronic acid moiety via an ester bond.
1-OH-Met-dehydro-fluindapyr (Code: N/A) 1-hydroxymethyl-dehydro-fluindapyr M20 in animal metabolism studies	3-(difluoromethyl)-N-(7-fluoro-1-(hydroxymethyl)-1,3-dimethyl-1H-inden-4-yl)-1-methyl-1H-pyrazole-4-carboxamide MW = 365 g/mol Found in skimmed milk	 The structure shows a fluindapyr core with a difluoromethyl group and a methyl group on the pyrazole ring, and a 7-fluoro-1,3-dimethyl-1H-inden-4-yl moiety. The pyrazole ring is in its dehydro form (1H-pyrazole-4-carboxamide) and has a hydroxymethyl group at the 3-position.
Di-OH-fluindapyr (Code: N/A) Dihydroxy-fluindapyr M4 and M8 in animal metabolism studies	Chemical name: N/A MW = 383 g/mol Found in skimmed milk and goat muscle.	 The structure shows a fluindapyr core with a difluoromethyl group and a methyl group on the pyrazole ring, and a 7-fluoro-1,3-dimethyl-1H-inden-4-yl moiety. The pyrazole ring is in its dehydro form. The structure is shown with brackets and 'di-OH' indicating two hydroxyl groups on the indene ring.
Tri-OH-dehydro-fluindapyr (Code: N/A) Trihydroxy-dehydro-fluindapyr M2 and M3 in animal metabolism studies	Chemical name: N/A MW = 397 g/mol Found in skimmed milk.	 The structure shows a fluindapyr core with a difluoromethyl group and a methyl group on the pyrazole ring, and a 7-fluoro-1,3-dimethyl-1H-inden-4-yl moiety. The pyrazole ring is in its dehydro form. The structure is shown with brackets and 'tri-OH' indicating three hydroxyl groups on the indene ring.
1-OH-Met-N-DesMet-dehydro-fluindapyr (Code: N/A) 1-hydroxymethyl-N-desmethyl-dehydro-fluindapyr M12 in animal metabolism studies	3-(difluoromethyl)-N-(7-fluoro-1-(hydroxymethyl)-1,3-dimethyl-1H-inden-4-yl)-1H-pyrazole-4-carboxamide MW = 351 g/mol Found in skimmed milk and very limited amounts in goat muscle.	 The structure shows a fluindapyr core with a difluoromethyl group and a methyl group on the pyrazole ring, and a 7-fluoro-1,3-dimethyl-1H-inden-4-yl moiety. The pyrazole ring is in its dehydro form and has a hydroxymethyl group at the 3-position. The nitrogen at the 1-position of the pyrazole ring is unsubstituted.
1-SO ₄ -Met-N-DesMet-fluindapyr (Code: N/A) M39 and M40 in hen metabolism study	[4-[[3-(difluoromethyl)-1H-pyrazole-4-carbonyl]amino]-7-fluoro-1,3-dimethyl-indan-1-yl]methyl hydrogen sulfate MW = 433 g/mol Found in hen liver	 The structure shows a fluindapyr core with a difluoromethyl group and a methyl group on the pyrazole ring, and a 7-fluoro-1,3-dimethyl-1H-inden-4-yl moiety. The pyrazole ring is in its dehydro form. The 1-position of the pyrazole ring is unsubstituted. The 1-position of the indene ring is substituted with a methyl hydrogen sulfate group (-CH ₂ OSO ₃ H).

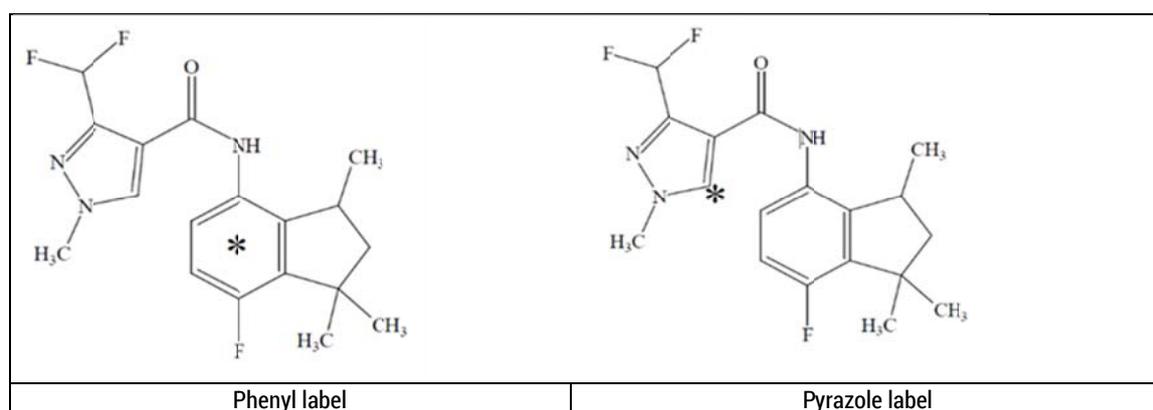
Code	Name and Matrix	Structure
1-SO ₄ -Met-fluindapyr (Code: N/A) M41 and M42 in hen metabolism study	[4-[[3-(difluoromethyl)-1-methyl-pyrazole-4-carbonyl]amino]-7-fluoro-1,3-dimethyl-indan-1-yl]methyl hydrogen sulfate Found in hen liver	
5'-OH-fluindapyr (Code: 510217) 5'-Hydroxy-fluindapyr M35 in hen metabolism study	3-(difluoromethyl)-N-(7-fluoro-5-hydroxy-1,1,3-trimethyl-2,3-dihydro-1H-inden-4-yl)-1-methyl-1H-pyrazole-4-carboxamide MW = 367 g/mol Found in at limited amounts in various hen tissues and eggs	

Physical and chemical properties

Fluindapyr is not volatile (2.89×10^{-5} Pa at 20 °C), relatively insoluble in water (1.63 mg/L), but appears to be more soluble in organic solvents (up to 325 g/L in acetone). It is hydrolytically stable at environmental conditions. Photolysis is not a significant route of degradation in water. The octanol/water partition coefficient $\log P_{ow}$ of 4.12 suggests a potential to partition into fat.

Plant metabolism

The Meeting received outdoor metabolism studies for fluindapyr after foliar applications, conducted with crops representative of four different groups: fruit (grape), root crops (sugar beet), cereal/grass (wheat and rice), pulses and oilseeds (soya bean). Fluindapyr was applied using [phenyl-¹⁴C] and [pyrazole-¹⁴C] labelled fluindapyr, as shown below. The results for both labels are presented as phenyl/pyrazole, unless indicated otherwise.



Grape

Phenyl or pyrazole labelled fluindapyr was applied as an EC formulation to grapes (variety: Thompson seedless), with two foliar spray applications at fruit development (BBCH stage 55 and 85, corresponding

with an re-treatment interval (RTI) of 123 days) at a rate of 237–313 g ai/ha per application. Each outdoor plot contained one plant.

At 14 days after the second application, total radioactive residues (TRR) were 0.089/0.36 mg eq/kg in grapes and 16/26 mg eq/kg in grape leaves. A fruit surface wash with methanol released 79/81 percent TRR, indicating that fluindapyr residues remained mainly on the surface of the grapes. Leaves and grapes were extracted with acetonitrile/water, followed by extraction with methanol/water. Part of the extract was partitioned against dichloromethane and subjected to hydrolysis with HCl, which did not release much more of unconjugated forms. Both conjugated and unconjugated forms could be identified before hydrolysis. The surface wash with methanol and extraction released most of the radioactivity for both labels in fruit (> 98.8 percent TRR) and in leaf (> 90 percent TRR) samples.

Approximately 99 percent TRR could be identified in grape berries and 88/92 percent TRR in grape leaves with both labels. Parent fluindapyr accounted for 63/65 percent TRR (0.056/0.24 mg/kg) in grapes and 38/54 percent TRR (5.9/14 mg/kg) in grape leaves. 1-OH-Met-fluindapyr and its conjugates accounted for 20 percent TRR (0.017/0.07 mg eq/kg) in grapes and 39/25 percent TRR (6.0/6.4 mg eq/kg) in grape leaves. A second metabolite found at significant concentrations was 3-OH-fluindapyr at levels of 15/12 percent TRR (0.013/0.04 mg eq/kg) in grapes and 12–9.3 percent TRR (1.8/2.4 mg eq/kg) in grape leaves. Minor metabolites were found in fruit and leaves, but none exceeded 0.2 percent TRR (< 0.001–0.064 mg eq/kg).

Chiral analysis of fluindapyr in leaves showed no significant change in the enantiomeric composition, indicating non-selective metabolic biotransformation. However, in grapes, fluindapyr present in the rinsing (79–81 percent of TRR) showed an enantiomeric ratio approximately 50:50 while in the extract this ratio was approximately 70:30.

Sugar beets

Phenyl or pyrazole labelled fluindapyr was applied as an EC formulation to sugar beet plants, with three foliar spray applications at root development (BBCH stage 35/38, 39/49, and 49, corresponding with RTI of 33 and 28 days between the subsequent applications) at a rate of 113-149 g ai/ha per application.

At 30 days after the last application (DALA), total radioactive residues were 0.084/0.122 mg eq/kg in mature sugar beet roots and 1.67/1.64 mg eq/kg in mature sugar beet foliage. Extraction with dichloromethane/water released most of the radioactivity for both labels in roots (90/92 percent TRR) and in foliage (92/93 percent TRR) samples. The aqueous fraction was subjected to acid hydrolysis to release the unconjugated forms of the conjugated metabolites. Exhaustive extraction with enzymes and acid/base released another 4.0–5.7 percent TRR.

Approximately 89/86 percent TRR could be identified in sugar beet root and 90/88 percent TRR in mature foliage with both labels.

Parent fluindapyr accounted for 43/50 percent TRR (0.036/0.062 mg/kg) in sugar beet roots and 18/15 percent TRR (1.5/1.4 mg/kg) in mature foliage. The 1-OH-Met-fluindapyr diastereomer 2 could not be distinguished from 1-COOH-fluindapyr, diastereomer 2, with the phenyl label and together accounted for 26 percent TRR (0.022 mg eq/kg) in mature sugar beet root, where an addition 8.4 percent TRR (0.007 mg eq/kg) accounted for the remaining 1-OH-Met-fluindapyr diastereomers in mature roots. 1-OH-Met-fluindapyr diastereomers in sugar beet foliage accounted for 66/62 percent TRR (1.1/1.0 mg eq/kg). The diastereomer 1 of COOH-fluindapyr accounted for 4.1/2.1 percent TRR (0.003 mg eq/kg) in sugar beet root. Metabolite 1-OH-Met-N-DesMet-fluindapyr accounted for 1.2/0.4 percent TRR and 1.8/1.7 percent TRR in sugar beet root and foliage, respectively, accounting for 0.001 mg eq/kg in roots and

0.029/0.028 mg eq/kg in foliage. Two other metabolites 3-OH-fluindapyr and N-DesMet-fluindapyr, either single or combined, were found, but below 10 percent TRR with only 3-OH-fluindapyr observed at levels above 0.01 mg eq/kg (2.0/1.3 percent TRR, 0.034/0.022 mg eq/kg) in sugar beet foliage. Finally, 3-OH-N-DesMet-fluindapyr was observed at low levels (0.24/0.64 percent TRR, 0.004/0.010 mg eq/kg) in sugar beet foliage.

Chiral analysis of fluindapyr showed no significant change in the enantiomeric composition.

Wheat

Phenyl or pyrazole labelled fluindapyr was applied as an EC formulation to wheat plants, with two foliar spray applications at BBCH stage 31–33 and BBCH 65 (RTI 28 days) at a rate of 124–130 g ai/ha per application. Plants were harvested at BBCH 47–49 (immature whole plants/forage stage and 3–4 days after the first application), BBCH 83 (21–22 DALA; immature whole plants/hay stage), mature grain and straw (41–42 DALA).

At 41–42 DALA, TRR were 0.020/0.038 mg eq/kg in wheat grain and 15/13 mg eq/kg in wheat straw. Total residues in wheat forage (3–4 days after the first application) and in wheat hay (21–22 DALA) were 1.2/2.2 and 5.5/7.4 mg eq/kg, respectively. Samples were extracted four times with acetone/water. Straw and grain were extracted a fifth time with acetone/HCl. Extracts from forage, hay and straw were sequentially partitioned with n-hexane and ethyl acetate. Most of the radioactivity for both labels was released in samples of grain (66/77 percent TRR), forage (99/97 percent TRR), hay (103/93 percent TRR), and straw (90/84 percent TRR). Exhaustive extraction with enzymes and acid/base released another 22/13 percent TRR in grain and 6.4/7.3 percent TRR in straw.

In wheat grain, 66/78 percent TRR could be identified, whereas 99/97 percent TRR, 103/93 percent TRR, and 90/85 percent TRR was identified in wheat forage, hay and straw, respectively.

Parent fluindapyr accounted for 46/56 percent TRR (0.0093/0.021 mg/kg) in wheat grain and for 37/31 percent TRR (0.46/0.66 mg/kg) in wheat forage, 31/28 percent TRR (1.7/2.1 mg/kg) in wheat hay, and 29/28 percent TRR (4.3/3.7 mg/kg) in wheat straw.

The 3-OH-fluindapyr metabolite accounted for 20/22 percent TRR (0.0042/0.0084 mg eq/kg) in wheat grain, 4.5/5.5 percent TRR (0.056/0.12 mg eq/kg) in wheat forage, 10/11 percent TRR (0.57/0.79 mg eq/kg) in wheat hay, and 12/14 percent TRR (1.8 mg eq/kg) in wheat straw.

Metabolite 1-OH-Met-fluindapyr (free and glucosyl and glucosyl sulphate conjugates) was not identified in grain, but found to be a major metabolite in wheat forage, hay and straw, ranging from 35–60 percent TRR with both labels (0.64–7.1 mg eq/kg). Metabolite 1-OH-Met-N-DesMet-fluindapyr as glucosyl conjugate was found at low levels in forage, hay and straw (0.38–5.1 percent TRR, 0.029–0.066 mg eq/kg) as were the pyrazole label specific metabolites pyrazole carboxylic acid and carboxamide with 2.9–3.8 percent TRR (0.082–0.42 mg eq/kg) and 0.40–2.9 percent TRR (0.0087–0.38 mg eq/kg), respectively.

Chiral analysis of fluindapyr showed an R:S change of 50:50 in the test formulations to a mean ratio of 66:34 in the forage, hay and straw samples. The radioactivity levels in grain extracts were too low to be analysed by chiral HPLC.

Rice

Phenyl or pyrazole labelled fluindapyr was applied as an EC formulation to rice plants, with two foliar spray applications at BBCH stage 33 and BBCH 75 (corresponding with an RTI of 70 days) at a rate of 114–122 g ai/ha per application. Samples of husked grain and straw were harvested at 58 DALA.

Total radioactive residues were 0.78/0.65 mg eq/kg in rice grain and 1.8/2.2 mg eq/kg in rice straw. Samples were extracted 3 times with acetonitrile/water followed by extraction with methanol/water. Part of the extract was partitioned with dichloromethane and the aqueous fraction subjected to hydrolysis with HCl. Similar identification results were found in the parallel extracts of dichloromethane and the aqueous fraction after acid hydrolysis. Extraction released most of the radioactivity for both labels in samples of rice grain and straw (93–98 percent TRR).

In husked rice grain and rice straw 94/91 percent TRR and 95/96 percent TRR could be identified, respectively. Fluindapyr accounted for 53/57 percent TRR (0.41/0.37 mg/kg) in husked rice grain and 55/56 percent TRR (1.0/1.2 mg/kg) in rice straw.

Metabolite 1-OH-Met-fluindapyr accounted for 22/17 percent TRR (0.17/0.11 mg eq/kg) and 23/19 percent TRR (0.43/0.21 mg eq/kg) in rice grain and rice straw, respectively.

The 3-OH-fluindapyr metabolite accounted for 9.1/8.2 percent TRR (0.072/0.053 mg eq/kg eq) in rice grain and for 11/11 percent TRR (0.20/0.25 mg eq/kg) in rice straw. Metabolite 1-COOH-fluindapyr was found at 4.2/4.0 percent TRR (0.033/0.026 mg eq/kg) in rice grains and 3.7/4.4 percent TRR (0.068/0.099 mg eq/kg) in rice straw. Low levels of N-DesMet-fluindapyr and dehydro-fluindapyr were found in rice grain (0.4–1.0 percent TRR) and rice straw (0.9–1.1 percent TRR), ranging from 0.003–0.006 mg eq/kg in rice grains to 0.016–0.025 mg eq/kg in rice straw.

Chiral analysis of fluindapyr in rice grain and straw indicated that a slight change in the original (50:50) enantiomeric ratio (R:S) took place and was determined to be approximately 60:40.

Soya bean

Phenyl or pyrazole labelled fluindapyr was applied as an EC formulation to soya bean plants, with three foliar spray applications at BBCH stage 15–16, BBCH 55–60, and BBCH 79 (corresponding with RTIs of 21 and 60 days, respectively) at a rate of 117–129 g ai/ha per application. Two additional plots were also treated at a higher rate of 667–676 g ai/ha for generation additional metabolized for identification purposes, if needed. Plants were grown in outdoor pots and samples of immature forage were taken at 21 days after the first application (28 prior to the second application), hay was harvested after two applications, and mature seeds were collected 30 DALA.

Total radioactive residues were 0.013/0.090 mg eq/kg in soya bean seed, and 0.30/0.51 mg eq/kg in soya bean forage and 1.8/1.6 mg eq/kg in soya bean hay. Samples were extracted 3 times with acetonitrile/water followed by extraction with methanol/water. Part of the extract was partitioned with dichloromethane and the aqueous fraction subjected to hydrolysis with HCl. Similar identification results were found in the parallel extracts of dichloromethane and the aqueous fraction after acid hydrolysis. Extraction with dichloromethane/water released most of the radioactivity for both labels in samples of soya bean seed, forage and hay (92–98 percent TRR). Exhaustive (enzyme and acid/base) extraction released another 2–3 percent TRR in soya bean hay.

Insufficient radioactivity was detected for characterization and identification of metabolites in soya bean seed.

Fluindapyr accounted for 5.7/5.9 percent TRR and 12 percent TRR (0.017/0.031 mg/kg and 0.22/0.19 mg/kg) in soya bean forage and hay, respectively. Free and conjugated 1-OH-Met-fluindapyr accounted for 31–40 percent TRR (0.12/0.47 mg eq/kg) in both RACs. Free and conjugated 1-OH-Met-N-DesMet-fluindapyr represented 9.5–12 percent TRR (0.034–0.17 mg eq/kg) in both matrices. The sum of DesMet-fluindapyr-N1-conjugates ranged from 14 to 18 percent TRR (0.046–0.33 mg eq/kg) in forage and hay. Metabolites found at lower concentrations were N-DesMet-fluindapyr-N-Ser (3.5–4.0 percent TRR,

0.012–0.062 mg eq/kg), 3-OH-fluindapyr (2.4–4 percent TRR, 0.012–0.077 mg eq/kg), N-DesMet-fluindapyr (1.0–4.6 percent TRR, 0.013–0.025 mg eq/kg)), dehydro-fluindapyr (0.046–0.13 percent TRR, 0–0.001 mg eq/kg), and pyrazole carboxamide (1.1 percent TRR (0.006 mg eq/kg) in forage only).

Chiral analysis of fluindapyr in soya bean hay and forage samples indicated that a slight change in enantiomeric ratio (R:S) took place and was determined to be approximately 60:40.

Summary of plant metabolism

Plant metabolism studies have been presented covering foliar treatments in grape, sugar beet, wheat, rice, pulses and soya bean. The application rates used in the metabolism studies with crops covering the current uses on cereals (wheat, sorghum, maize and rice) are slightly lower and RTIs are longer. However, exaggerated application rates were also used, showing similar distribution patterns.

The enantiomeric ratio R:S in some crops remained 50:50 (grape leaves and rinse, sugar beet foliage), however, in other crops a shift could be observed into a ratio ranging from 60:40 to 70:30 (grape, wheat forage/hay/straw, rice grain/straw, soya bean hay/forage).

The metabolic pathways of fluindapyr were similar in the crops investigated, mainly through hydroxylation and oxidative-N-demethylation, both followed by conjugation. Parent fluindapyr was a major residue in grapes, sugar beet root, wheat grain, and rice grain. Major identified metabolites were 1-OH-Met-fluindapyr (free and conjugated), 3-OH-fluindapyr, 1-OH-Met-N-DesMet-fluindapyr (free and conjugated) in soya bean forage only and DesMet-fluindapyr-conjugates in soya bean forage and hay only.

Environmental fate

The Meeting received information on hydrolytic stability, photochemical degradation in water and soil, aerobic soil metabolism, and soil degradation field studies for fluindapyr.

Hydrolysis

Radiolabelled fluindapyr, incubated in the dark in sterile aqueous buffered solutions at pH 4, 7, and 9 for 5 days at 50 °C remained stable. No degradation products were detected and the enantiomeric ratio remained unchanged. The results indicate that fluindapyr is hydrolytically stable at environmental conditions.

Photochemical degradation

In an aqueous photolysis study, [¹⁴C-phenyl]-fluindapyr and [¹⁴C-pyrazole]-fluindapyr was incubated in sterile non-buffered water under simulated sunlight at 25 ± 1.0 °C, equivalent to summer sunlight (55°North in June). The DT₅₀ of fluindapyr was calculated to be 4.3 and 2.9 years, with only minor degradation products identified. Two of the minor products were confirmed as 3-OH-fluindapyr and the pyrazole-amide. The distribution of the two enantiomers remained 50:50 throughout the entire irradiation duration.

In a soil photodegradation study [¹⁴C-pyrazole]- or [¹⁴C-phenyl]-labelled fluindapyr slowly degraded in the irradiated samples, with an associated increase of 3-OH-fluindapyr (up to 9.7 percent AR) and pyrazole-carboxamide (up to 7 percent AR after 15 days). The estimated photolysis DT₅₀ in clay loam soil was 54–61 experimental days, equivalent to 163–183 natural sunlight days at 50 °N.

In summary, the Meeting concluded that photodegradation contributes to some extent to the overall degradation of fluindapyr in soil, but photolysis of fluindapyr in water is insignificant.

Aerobic soil metabolism (laboratory studies)

The biotransformation of [¹⁴C-phenyl]- or [¹⁴C-pyrazole]-fluindapyr in soil was investigated in four European and four US soils under laboratory conditions. The equivalent of 127–128 g fluindapyr/ha was mixed with soil and incubated under aerobic conditions in the dark at 20 °C for 120–151 days.

The estimated DT₅₀ for fluindapyr ranged from 141 to 353 days in the various soils with both labels, with a geometric mean of 223 days. Three degradation products were identified above 5 percent AR; 3-OH-fluindapyr (max 15 percent AR at DAT-120), and *cis*-1-COOH-fluindapyr (max 13 percent AR at DAT-151) and *trans*-1-COOH-fluindapyr (max 11 percent AR at DAT-151). The enantiomeric ratio remained constant during the studies (approximately 50:50).

The aerobic degradation of the three soil metabolites 3-OH-fluindapyr, *cis*-1-COOH-fluindapyr and *trans*-1-COOH-fluindapyr and the photolytic soil metabolite pyrazole carboxamide was investigated under laboratory conditions for up to approximately 120 days in different soils from Europe or the United States in four studies. The DT₅₀ values for 3-OH-fluindapyr were >1000 days in three European soils and ranged from 794 to 1302 days in three US soils. The DT₅₀ values for *cis*- and *trans*-1-COOH-fluindapyr ranged from 102 to 320 days in three US soils, and ranged from 1.7 to 4.1 days in two European and two US soils for pyrazole carboxamide

Soil degradation (field studies)

The field dissipation of fluindapyr has been studied in Europe and the United States. Residues of fluindapyr were detected predominantly in the upper 15 cm of the soils, with incidental findings in the following 10–25/15–30 cm layers. The DT₅₀ for total residues ranged from 30 to 168 days, with a geometric DT₅₀ of 91 days.

Residues in succeeding or rotational crop

The Meeting received information on the metabolism of fluindapyr in wheat, carrot, and lettuce grown as confined rotational crops, and in a range of representative field crops grown in fluindapyr treated soil.

Confined rotational crop studies

In two confined rotational crop studies in Italy, soil was treated with either [¹⁴C-phenyl]- or [¹⁴C-pyrazole]-labelled fluindapyr at 360/387 g ai/ha (covering the current registered uses at a maximum seasonal rate of 300 g ai/ha) and planted with lettuce, carrots and wheat at plant-back intervals at 30 days, 120, and 300 days. The TRR in the different RACs were highest when using the pyrazole label declining from 0.037 (plant back interval (PBI) of 30 days) to 0.019 mg eq/kg (PBI 300 days) in carrot root (phenyl label) and increasing from 0.081 (PBI 30) to 0.11 (PBI 300) mg eq/kg (pyrazole label) in first to last rotation. Similar patterns was observed in carrot tops, with a decline from 0.18 to 0.075 mg eq/kg (phenyl) and increase from 1.1 to 1.7 mg eq/kg (pyrazole label); in immature lettuce, from 0.070 mg eq/kg to 0.046 mg eq/kg (phenyl) and 0.22 mg eq/kg to 0.25 mg eq/kg (pyrazole) and mature lettuce 0.081 to 0.044 mg eq/kg (phenyl) and 0.23 to 0.34 mg eq/kg (pyrazole).

Residues in wheat matrices were generally higher, remaining constant over the three rotations and the patterns between the two labels were similar: 1.5 to 0.73 mg eq/kg (phenyl) and 2.9 to 2.8 mg eq/kg (pyrazole) in wheat grain, 0.35 to 0.36 mg eq/kg (phenyl) and 0.54 to 0.37 mg eq/kg (pyrazole) in wheat forage; 0.82 to 0.62 mg eq/kg (phenyl) and 1.5 to 1.7 mg eq/kg (pyrazole) in rotated wheat hay; 2.0 to 1.3 mg eq/kg (phenyl) and 3.8 to 3.2 mg eq/kg (pyrazole) in wheat straw.

Extracted radioactivity from all different crop matrices was high and generally ranged from 83 to 99 percent TRR. Only the radioactivity in the PES of wheat straw and grain needed further investigation

and was present mainly as cellulose ^{14}C -incorporated natural products, representing 6–10 percent TRR in straw and 3–5 percent TRR in grain.

The identified residues (fluindapyr, 3-OH-fluindapyr, 1-COOH-fluindapyr (and its conjugates), 1-OH-Met-fluindapyr (and its conjugates), N-DesMet-fluindapyr (and its conjugates), N-DesMet-pyrazole carboxylic acid, pyrazole carboxylic acid, pyrazole carboxamide) were common in all crops but their magnitude varied depending on the individual crop, matrix and label.

In commodities relevant for human consumption and considering the phenyl label study, fluindapyr was one of the main components found, accounting for 2.8–20 percent TRR (0.006–0.015 mg eq/kg) in immature lettuce, 6.1–15 percent TRR (0.084–0.39 mg eq/kg) in wheat grain and up to 65–70 percent TRR (0.013–0.026 mg eq/kg) in carrots.

Metabolite 3-OH-fluindapyr accounted for 9.8–25 percent TRR (0.004–0.005 mg eq/kg) in carrot roots, 7.3–8.5 percent TRR (0.003–0.007 mg eq/kg) in (im)mature lettuce, and 11 percent TRR (0.092–0.17 mg eq/kg) in wheat grain.

Free and conjugated 1-OH-Met-fluindapyr accounted for 8.2–9.4 percent TRR (0.002–0.004 mg eq/kg) in first two rotations only in carrot roots, 23–34 percent TRR (0.011–0.027 mg eq/kg) in (im)mature lettuce, and 47–52 percent TRR (0.42–0.78 mg eq/kg) in wheat grain.

Free and conjugated 1-COOH-fluindapyr accounted for 9.5–9.6 percent TRR (0.003–0.004 mg eq/kg) in carrot roots, 16–34 percent TRR (0.012–0.018 mg eq/kg) in (im)mature lettuce, and 5.9–10.0 percent TRR (0.082–0.11 mg eq/kg) in wheat grain.

The pyrazole specific metabolites included (conjugates of) N-DesMet-pyrazole carboxylic acid, pyrazole carboxylic acid and pyrazole carboxamide. Free and conjugated N-DesMet-pyrazole carboxylic acid increased in time and represented the majority of the radioactivity in carrot roots, with 48–65 percent TRR (0.022–0.065 mg eq/kg) and in (im)mature lettuce with 62–82 percent TRR (0.12–0.21 mg eq/kg). In wheat grain, N-DesMet-pyrazole carboxylic acid accounted for 3–10 percent TRR (0.087–0.31 mg eq/kg), pyrazole carboxylic acid for 12–29 percent TRR (0.27–0.69 mg eq/kg) and pyrazole carboxamide for 1.7–16 percent TRR (0.050–0.45 mg eq/kg). Pyrazole carboxylic acid and pyrazole carboxamide were below 10 percent TRR in the other commodities, except in carrot roots at PBI 120 and 300 days (14–18 percent TRR) and in (im)mature lettuce at PBI 120 and 300 days (11–13 percent TRR).

In feed commodities, the levels of parent varied from 0.24–11 percent TRR (0.004–0.013 mg eq/kg) in carrot tops to 13–32 percent TRR (0.050–0.14 mg eq/kg) in wheat forage. The (conjugated) metabolite 1-OH-Met-fluindapyr represented a major part of the radioactive residue in the phenyl-label, ranging from 11–36 percent TRR (0.061–0.13 mg eq/kg) in wheat forage to 17–46 percent TRR (0.49–1.6 mg eq/kg) in wheat straw. In the pyrazole-label, free and conjugated pyrazole carboxylic acid was present in forage (13–24 percent TRR, 0.050–0.12 mg eq/kg) and straw (9.1–28 percent TRR, 0.34–0.89 mg eq/kg), while in carrot tops free and conjugated N-DesMet-pyrazole carboxylic acid was more pronounced (52–58 percent TRR, 0.64–0.99 mg eq/kg). 3-OH-fluindapyr, and free and conjugated pyrazole carboxamide, N-DesMet-fluindapyr, and 1-COOH-fluindapyr also contributed to the total radioactive residues, with levels depending on crop matrix and on PBI.

A third confined rotational crop study was performed using a single bare soil application of 356–360 g ai/ha and wheat as a rotational crop planted at PBI 30 and 120 days. This study confirmed the rather high concentrations TRR found in wheat commodities.

Field rotational crop studies

A series of field rotational crop studies was conducted in Northern Europe (NE), Southern Europe (SE) and the United States. Only the European studies analysed soil samples. In the four European trials, fluindapyr was incorporated into the soil at actual dose rates of 203–232 g ai/ha. This is lower than the anticipated seasonal rates of the currently registered uses of 300 g ai/ha for which crop rotation needs to be taken into account

Carrots/radish, wheat, lettuce, head cabbage, soya beans, and tomato plants were planted at intervals of 30 (± 3), 120 (± 10), and 270 (± 3) days after the application. In the United States trials conducted at 2 locations, fluindapyr was applied twice to soya beans, as the primary crop, at 124–128 g ai/ha/application, RTI 12–15 days (21 ± 2 days prior to typical harvest). At one site the seeds were harvested and the plant debris returned to the field and on the other site both seed and straw was removed. The plots were planted with the follow-on rotational crop of mustard, radish, or wheat at target PBIs of 30, 60, and 210 days.

Samples of mature commodities were analysed for fluindapyr and metabolites 3-OH-fluindapyr, DesMet-N1-fluindapyr-glucoside and free and conjugated 1-COOH-fluindapyr, pyrazole-carboxamide, pyrazole carboxylic acid and N-DesMet-pyrazole carboxylic acid.

In crops for human consumption, residues of fluindapyr and most of its metabolites were found incidentally, with fluindapyr only once at 0.022 mg/kg in radish roots at PBI of 30 days, pyrazole carboxylic acid in one trial at levels of 0.024–0.027 mg/kg on PBI 30, 120 and 300 days, and 1-COOH-fluindapyr once at 0.020 mg eq/kg in immature head cabbage at PHI 30 days and once at 0.018 mg eq/kg in mustard at PBI 30 days.

Quantified residues of fluindapyr were observed in samples of animal feed commodities at plant-back intervals up to 300 days, however, the findings were incidental and the identity of the metabolites varied between crop matrices. Fluindapyr was observed in wheat straw (0.012–0.022 mg/kg, study 1) and radish tops (< 0.001 –0.022 mg/kg, study 3) and metabolite 3-OH-fluindapyr in wheat straw (PBI 30–270 days, 0.012–0.034 mg eq/kg), soya bean hay (PBI 30–270 days, 0.010–0.024 mg eq/kg) and soya bean forage (PBI 120 days, 0.013 mg/kg). Free and conjugated 1-OH-Met-fluindapyr was found in wheat straw (PBI 30–270 days at < 0.01 –0.066 mg/k eq), wheat hay (PBI 30 days, 0.010–0.011 mg eq/kg), and radish leaves (< 0.01 –0.016 mg eq/kg). Metabolite 1-COOH-fluindapyr (free and conjugated) was a found in soya bean forage (0.014–0.017 mg eq/kg) and hay (< 0.01 –0.028 mg eq/kg) at PBI 30 and 120, as well as free and conjugated N-DesMet-pyrazole carboxylic acid.

The Meeting considered potential residues of 3-OH-fluindapyr, which is persistent in soil. Based on the assumption of a single treatment or subsequent annual applications at the maximum rate per year of 300 g ai/ha, the Meeting estimated soil concentrations of 0.012 and 0.036 mg/kg, respectively, taking into account information from the available European field dissipation studies. In two of the four European studies, the concentrations of 3-OH-fluindapyr in soil corresponded to concentrations expected after applying the single maximum rate per year (~ 0.012 mg/kg soil). In the two other studies, one soil contained approximately half of the expected soil concentration, whereas in the fourth study 3-OH-fluindapyr remained undetected. However, no clear relationship between soil concentrations for 3-OH-fluindapyr and its uptake into rotational crops was observed based on the plant samples analysed. Residues were found in feed commodities at up to 0.034 mg/kg, but were $< \text{LOQ}$ of 0.01 mg/kg in edible commodities.

The Meeting concluded that no systematic occurrence of 3-OH-fluindapyr in rotational crops is expected. Even at estimated plateau levels following year-long accumulation, residues in feed

commodities are expected at maximum concentrations of 0.1 mg/kg or lower, while quantifiable concentrations are not expected in commodities for human consumption.

None of the other metabolites have a potential to accumulate in soil. Considering the scattered and low levels found in both food and feed commodities, the Meeting concluded that potential residues found in rotational crops will not contribute significantly to the total dietary intake nor to the total dietary burden and need not be further considered.

One exception is the common metabolite N-DesMet-pyrazole carboxylic acid, which was observed at relevant exposure levels in several food crops. This metabolite is also a metabolite formed after use of other active substances, such as bixafen, benzovindiflupyr, and inpyrfluxam. The Meeting considered the residues of N-DesMet-pyrazole carboxylic acid observed in field rotational crop data after use with fluindapyr, bixafen (Report 2021- extra Meeting) and inpyrfluxam or estimated concentrations following direct treatment with benzovindiflupyr. The highest STMRs from each of the compounds were used for the exposure estimation, assuming no combined field treatments since the compounds belong to the same chemical group of fungicidal agents (Table 5.17.2).

Table 5.17.2 Overview of anticipated N-DesMet-pyrazole carboxylic acid residues in rotational crops found after use of both fluindapyr (F), bixafen (B), and inpyrfluxam (I) in field rotational crop studies or estimated concentrations following direct treatment with benzovindiflupyr (Ben)

Commodity group	Field rotational crop commodity	N-DPCA in mg/kg (highest concentrations per trial from all PBIs)	STMR, mg/kg
Root and tuber vegetables	Carrot and radish roots	F: < 0.01 (3), 0.014	F: 0.01 B: 0.016
	Carrot roots	B: < 0.01, < 0.01, 0.44	
	Potato tuber	B: 0.016, 0.016, 0.061, 0.064	
	Combined	B: < 0.01, < 0.01, 0.016, 0.016, 0.044, 0.061, 0.064	
Leafy crops and brassica (extrapolated to stalk and stem vegetables)	Lettuce (mature and immature)	F: < 0.01 (7), 0.028 B: < 0.01, 0.017, 0.092	F: 0.01 B: 0.01
	Cabbage (mature and immature)	F: < 0.01 (7), 0.025 B: < 0.01 (3), 0.01	
	Radish leaves	F: < 0.01, 0.020 I: 0.015 ^a	
	Carrot foliage	F: < 0.01, < 0.01	
	Combined	F: < 0.01 (15), 0.01 (2), 0.020, 0.025, 0.028 B: < 0.01 (6), 0.01, 0.017, 0.092, 0.18	
Fruiting vegetables	Tomato	F: < 0.01 (4)	F: 0.01 B: 0.01
	Courgettes	B: < 0.01 (2), 0.015, 0.023	
	Strawberries	B: < 0.01 (4)	
	Combined	B: < 0.01 (6), 0.015, 0.023	
Pulses (Extrapolated to legume vegetables and oil seeds)	Soya bean seed (dry)	F: < 0.01 (2), 0.065, 0.073 I: < 0.02 (7), 0.02, 0.023, 0.024, 0.026, 0.028, 0.032, 0.036, 0.037, 0.051, 0.062, 0.095, 0.13, 0.16, 0.19	F: 0.0375 I: 0.026 B: 0.0235
	Peas (dry)	B: < 0.01 (2), 0.037, 0.082	
Cereal grains	Wheat grain	F: < 0.01 (4)	F: 0.01 B: 0.01
	Barley/wheat	B: < 0.01 (3)	
	Maize	B: < 0.01 (3), 0.063	
	Combined	B: < 0.01 (6), 0.063	
Bulb vegetables	Leek	B: < 0.01 (2), 0.016, 0.034	B: 0.013
Oil seeds	Rape seed	B: < 0.01 (4)	B: 0.01

Commodity group	Field rotational crop commodity	N-DPCA in mg/kg (highest concentrations per trial from all PBIs)	STMR, mg/kg
Coffee, green	Direct treatment with benzovindiflupyr using metabolite:parent ratios from metabolism studies	Ben: < 0.01 (6)	Ben: 0.01

Notes:

^a Single value found in confined rotational crop study.

Summary of environmental fate

Fluindapyr is slowly photodegraded on the surface of soil, forming 3-OH-fluindapyr and pyrazole carboxamide. Laboratory soil degradation studies showed the formation of 3-OH-fluindapyr and *cis*- and *trans* 1-COOH-fluindapyr. Field studies showed DT₅₀s for total fluindapyr (1-COOH-fluindapyr, 3-OH-fluindapyr and pyrazole carboxylic acid) ranging from 55 to 168 days (geometric mean of 91 days), with 3-OH-fluindapyr being the predominant metabolite.

Confined laboratory studies indicate that, 3-OH-fluindapyr may be persistent in soil and have a potential for residue carry over to the following cropping season if application is performed annually. However, there was sufficient information for the Meeting to conclude that 3-OH-fluindapyr levels in edible commodities from rotational crops would remain below the LOQ of 0.01 mg/kg. Confined rotational crop studies indicated that in addition to parent and 3-OH-fluindapyr (free and conjugated), 1-COOH-fluindapyr, 1-OH-Met-fluindapyr, N-DesMet-fluindapyr, N-DesMet-pyrazole carboxylic acid, pyrazole carboxylic acid, and pyrazole carboxamide can be formed in both food and feed commodities. However, field rotational crop studies showed that none of the metabolites are expected in rotational crops at levels above 0.01 mg/kg, with exception of N-DesMet-pyrazole carboxylic acid, which is also formed after application of other fungicides within the same chemical class. The Meeting concluded that a TTC approach should be applied considering residues of this metabolite coming from the uses of the different fungicides.

Animal metabolism

The Meeting received animal metabolism studies on rats, lactating goats and laying hens, where animals were dosed with fluindapyr radiolabelled in the (phenyl ring) or the (e.g. pyrazole ring).

Rats

The metabolism of fluindapyr in rats was reviewed in the framework of the toxicological evaluation by the WHO Core Assessment Group of the 2022 JMPR.

Lactating goats

Two lactating goats were orally dosed by capsule once daily for 7–8 consecutive days with either pyrazole-labelled fluindapyr or phenyl-labelled fluindapyr at 7.3 or 7.5 ppm feed, corresponding to 0.35 or 0.23 mg/kg bw/day, respectively. The goats were sacrificed approximately 6 hours after the last dose. The majority of the total applied radioactivity (TAR) was recovered in the excreta (65–81 percent TAR), with lower levels in the GI tract (11–13 percent TAR). The radioactivity recovered in tissues (liver, kidney, muscle, and fat) accounted for 0.34 and 0.20 percent TAR, with the respective labels, with the highest amount in liver (0.27 percent and 0.16 percent TAR, respectively). A total of 0.017 and 0.034 percent TAR, respectively, was found in milk. Steady state conditions in milk were reached within 2–3 days of the first

dose. TRR levels were higher in cream (0.030–0.088 mg eq/kg) compared to skimmed milk (0.004–0.015 mg eq/kg).

Radioactive residues extracted with either ethyl acetate (skimmed milk) or hexane followed by acetonitrile (fat samples and milk cream), acetonitrile and acetonitrile/water or acetone/water (liver, kidney, and muscle) accounted for at least 78 percent TRR, and liver samples from the acetone/water extractions were further treated with β -glucuronidase. The PES from all matrices was found to contain < 10 percent TRR or a low residue level, therefore, no further characterization of unextracted residue was conducted.

Fluindapyr was the predominant compound in cream (75–93 percent TRR, 0.045–0.057 mg/kg), fat (74–75 percent TRR, 0.024–0.042 mg/kg), and muscle (32–39 percent TRR, 0.004–0.006 mg/kg), while it ranged from not detected (kidney) to 8.4 percent TRR in the other samples. Free and conjugated 1-OH-Met-fluindapyr was found in liver (up to 52 percent TRR and 0.13 mg eq/kg), kidney (up to 57 percent TRR and 0.059 mg eq/kg), and muscle (up to 41 percent TRR, 0.006 mg eq/kg). Free and conjugated 1-COOH-fluindapyr was found in liver (up to 27 percent TRR and 0.075 mg eq/kg) and kidney (up to 11 percent TRR and 0.011 mg eq/kg). Free and conjugated 1-OH-Met-N-DesMet-fluindapyr was identified in liver (up to 8.9 percent TRR and 0.025 mg eq/kg) and kidney (up to 24 percent TRR and 0.029 mg eq/kg). No individual metabolite in the remaining edible tissues (skimmed milk, cream, fat, or muscle) exceeded 0.01 mg eq/kg, although 1-OH-Met-fluindapyr and di-hydroxylated species accounted for 16 percent to 43 percent TRR in skimmed milk.

Chiral analysis of fluindapyr isolated from fat and cream, showed that the S/R enantiomeric ratio changed from about 50/50 to 35/65.

Laying hens

A group of laying hens was orally dosed by capsule with [phenyl- ^{14}C]-fluindapyr or [^{14}C -pyrazole]-fluindapyr for 9 consecutive days at 10 ppm feed, corresponding with a mean daily dose level of 0.64–0.66 mg/kg bw/day. Hens were sacrificed approximately 6 hours after the last dose. The majority of radioactivity (TAR radioactivity was recovered in the excreta (93–96 percent TAR), and a minor part in tissues (0.15–0.16 percent TAR) and eggs (0.11–0.12 percent TAR). The highest TRR in edible tissues was measured in the liver (0.11–0.12 mg eq/kg), followed by fat (0.079–0.10 mg eq/kg), skin (0.044–0.057 mg eq/kg), and muscle (0.010–0.013 mg eq/kg). Residues in eggs ranged from 0.019 to 0.10 mg eq/kg and reached a steady state at day 6.

Radioactive residues extracted with hexane followed by acetonitrile (fat and skin), hexane, followed by acetone:water and ethyl acetate (eggs), acetone/water and ethyl acetate (liver), acetonitrile and acetonitrile/water (muscle) was at least 89 percent TRR. Liver aqueous extract samples were further treated with acid (HCl) or enzymatic hydrolysis (sulfatase) to release SO_4 conjugates. The PES from all matrices was < 10 percent TRR and 0.05 mg eq/kg; therefore, no further characterization of unextracted residue was conducted.

Fluindapyr was the major component identified in skin (88–94 percent TRR, 0.041–0.050 mg/kg), fat (76–95 percent TRR, 0.073–0.090 mg/kg), egg (31–48 percent TRR, 0.018–0.028 mg/kg), and muscle (38 percent TRR, 0.004 mg/kg), but represented only about 5 percent TRR (0.005–0.006 mg/kg) in liver.

Metabolite N-DesMet-fluindapyr represented a large part of the radioactive residue in the liver (62 percent of the TRR, 0.067 mg eq/kg), of which a minor fraction was present as sulfate conjugate (< 2 percent of TRR). This metabolite was detected at even lower levels in the egg (up to 6.8 percent TRR, 0.004 mg eq/kg), fat (up to 2.0 percent TRR, 0.002 mg eq/kg), skin (up to 1.6 percent TRR, 0.001 mg eq/kg), and muscle (4.5 percent of TRR, < 0.001 mg eq/kg).

The 2 diastereomers of 1-OH-Met-fluindapyr and their sulfate conjugates represented 22 percent TRR in liver (0.026 mg eq/kg), 32 percent TRR in eggs (0.019 mg eq/kg), 11 percent TRR in fat (0.010 mg eq/kg), and 14 percent TRR in muscle (0.002 mg eq/kg), but less in skin (9.8 percent TRR, 0.004 mg eq/kg).

The 1-COOH-fluindapyr metabolite reached 12 percent TRR (0.001 mg eq/kg) in muscle and 7.2 percent TRR (0.008 mg eq/kg) in liver. The 2 diastereomers of 1-OH-Met-N-DesMet-fluindapyr and/or the corresponding sulfate conjugates reached 8.5 percent of TRR (0.010 mg eq/kg) in liver and 4 percent of TRR (< 0.001 mg eq/kg) in muscle.

Other metabolites generally represented less than 10 percent TRR and always at < 0.01 mg eq/kg, of which 2-OH-fluindapyr, 5'-OH-fluindapyr, 3-OH-fluindapyr, and 3-OH-Met-fluindapyr were identified in both phenyl and pyrazole extracts. A glycine conjugate of pyrazole carboxylic acid was detected at a trace level of 0.001 mg eq/kg (11.4 percent TRR) in muscle.

Chiral analysis of fluindapyr isolated from fat and skin, showed that the S/R enantiomeric ratio changed from about 50/50 to 18/82 in fat and to 23/77 in the skin.

Conclusions

The Meeting concluded that, in all species investigated (goats, hens and rats), TAR was predominantly eliminated in excreta. The metabolic profiles differed somewhat, both qualitatively and quantitatively between the species, with the goat metabolism being the most extensive one.

Metabolism involved mainly demethylation to N-DesMet-fluindapyr and hydroxylation to 1-OH-Met-fluindapyr, with further sulphation being (mainly in hen tissues) and glucuronidation (goat tissues). Hydroxylation leading to 3-OH and 5-OH species in hens and di-OH-fluindapyr species in goats was also observed.

Fluindapyr is the major component found in the majority of the goat and hen tissues and cream samples, but with lower levels in kidney and liver tissues and 1-OH-Met-fluindapyr was a major metabolite in tissues. Other metabolites include 1-COOH-fluindapyr (goat liver and kidney and hen liver and muscle), N-DesMet-fluindapyr in hen liver only, 1-OH-Met-N-DesMet-fluindapyr and its glucuronides in goat kidney, and 1-SO₄-Met-fluindapyr in hen liver.

Methods of analysis

The Meeting received description and validation data for analytical methods for determination of fluindapyr, 3-OH-fluindapyr, DesMet-fluindapyr-1N-glucoside, 1-OH-Met-fluindapyr, 1-OH-Met-N-DesMet-fluindapyr, and 1-COOH-fluindapyr in plant matrices and for fluindapyr, N-DesMet-fluindapyr, 1-OH-Met-fluindapyr, 1-COOH-fluindapyr, 1-OH-Met-N-DesMet-fluindapyr in animal commodities.

Plant commodities

Analytical methods are provided for the analysis of fluindapyr and/or metabolites in crops. The method selected for enforcement will depend on the compounds that are being analysed.

The QuEChERS (EN 15662:2009-2)-based method P3770G involves extraction with acetonitrile:water for direct analysis of fluindapyr, 3-OH-fluindapyr and DesMet-N-fluindapyr-glucoside by LC-MS/MS. For determination of 1-OH-Met-fluindapyr, 1-OH-Met-N-DesMet-fluindapyr and 1-COOH-fluindapyr, the extract was hydrolysed (1 hour at 60 °C) with HCl, the pH adjusted to 4 to 6 with NaOH, and cleaned-up by dispersive SPE (solid phase extraction) for quantification by LC-MS/MS. The method was fully validated for the determination of fluindapyr, 3-OH-fluindapyr, fluindapyr-DesMet-N-glucoside in the

range of 0.01 (LOQ) to 0.1 mg/kg in crops with high water content (sugar beet leaves, wheat forage), high starch content (sugar beet root), high acid content (grapes), high oil content (almond, pecan), high protein content (soya bean (dry seeds) and dry beans), and high starch content (wheat grain), and wheat straw and (dry and difficult matrix). An independent laboratory validation (ILV) was conducted to qualify this procedure as an enforcement method.

Corresponding radio-validation experiments demonstrated that Method P3770G was not suitable for the analysis of incurred residues of the metabolites 1-OH-Met-fluindapyr, 1-OH-Met-N-DesMet-fluindapyr, and 1-COOH-fluindapyr. Therefore, an alteration of the method was developed and validated (Method RA17.01), where the crop samples were extracted with water and acetonitrile, either by subsequent addition or combined addition (wheat straw) or acetonitrile followed by water (high protein). The analytes in the extract were hydrolysed with 37 percent HCl (two hours at 80 °C), the pH adjusted (4–5), acetone and water added, followed by clean-up with SPE and quantification by LC-MS/MS. Method RA.17.01 was fully validated for the determination of the (sum of) diastereomers 1-OH-Met-fluindapyr in crops with high oil content (almond and pecan nutmeat), high protein content (almond hulls, dry beans, soya bean seed), high acid content (grapes), high starch content (sugar beet roots, wheat grain and dry gluten) and high water content (sugar beet leaves and wheat forage), difficult matrices (wheat straw). A ILV was also performed

Both methods were subjected to radiovalidation, where incurred residues of fluindapyr were successfully recovered from samples of wheat forage, grain and straw. Analytes involved were 3-OH-fluindapyr, 1-OH-Met-fluindapyr, 1-OH-Met-fluindapyr (both only in wheat forage and straw), 1-OH-Met-N-DesMet-fluindapyr, cis- and trans-1-COOH-fluindapyr, N-DesMet-pyr-acid, pyrazole carboxylic acid and pyrazole carboxamide. In addition DesMet-N-fluindapyr N1-Glu was successfully recovered from soya bean hay.

The Meeting concluded that the methods were sufficiently validated and are suitable to measure fluindapyr and its metabolites in plant commodities.

Animal commodities

In Method 133SRUS16R0208, samples of muscle, liver, kidney and eggs are blended with acetonitrile (2×) followed by extraction with acetone/water, and milk was extracted with acetonitrile. For analysis of fluindapyr and N-DesMet-fluindapyr, the extract was diluted and analysed by LC-MS/MS. For analysis of 1-COOH-fluindapyr-, 1-OH-Met-fluindapyr, and 1-OH-Met-N-DesMet-fluindapyr, the extract was hydrolysed with 4 mol/L HCl (80 °C, 60 minutes), and cleaned-up by SPE before quantification by LC-MS/MS.

Fat was extracted with acetonitrile/hexane. For analysis of fluindapyr and N-DesMet-fluindapyr, the acetonitrile layer was diluted with water and cleaned-up by SPE before quantification. For analysis of 1-OH-Met-fluindapyr and 1-OH-Met-N-DesMet-fluindapyr, the acetonitrile layer was hydrolysed with 4 mol/L HCL (80 °C, 60 minutes) and cleaned-up before analysis by LC-MS/MS.

Method 133SRUS16R0208 was validated for the determination of fluindapyr, N-DesMet-fluindapyr, 1-OH-Met-fluindapyr (sum of both diastereomers), 1-OH-Met-N-DesMet-fluindapyr (sum of both diastereomers) in bovine muscle, fat, liver and kidney, and in poultry muscle, fat, liver and eggs in the range 0.01 (LOQ) to 0.1 mg/kg, and in the range of 0.005 (LOQ) to 0.05 mg/kg in milk. Validation was also conducted for 1-COOH-fluindapyr (sum of both diastereomers) in the range 0.01–0.1 mg/kg in bovine liver and kidney.

However, in a radiovalidation study, incurred residues of parent fluindapyr could not be successfully (max 28 percent) recovered from goat (milk, muscle, liver) and hen (egg, fat) matrices. 1-OH-Met-fluindapyr was successfully recovered from goat liver (110 percent) and egg (116 percent), 1-OH-

Met-N-DesMet-fluindapyr from goat liver (90 percent), but the recovery of 1-COOH (both isomers) was questionable (280 percent).

The Meeting concluded that the analytical method for animal commodities is fit for measuring 1-OH-Met-fluindapyr and 1-OH-Met-N-DesMet-fluindapyr, but is not fit for measuring residues of parent fluindapyr, 1-COOH-fluindapyr in animal matrices.

Stability of pesticide residues in stored analytical samples

The Meeting received information on storage stability of fluindapyr, 3-OH-fluindapyr, DesMet-fluindapyr-1N-glucoside, 1-OH-Met-fluindapyr, 1-OH-Met-N-DesMet-fluindapyr, and 1-COOH-fluindapyr in wheat grain, wheat straw, grapes, oil seed rape seed, oil seed rape whole plant, and wheat dry gluten and of fluindapyr in wheat forage and hay (0.1 mg/kg fortification level). The data showed that residues of fluindapyr and metabolites (except for wheat forage; not tested for metabolites) are stable for at least 36 months under frozen conditions in crop commodities representative of the high water (oil seed rape whole plant), high acid (grapes), high starch (wheat grain), and high oil (oil seed rapeseed) and high protein crops (wheat dry gluten).

The Meeting agreed that the demonstrated storage stability on various representative plant commodities covered the residue sample storage intervals used in the field trials considered by the current Meeting.

In addition, the Meeting received storage information of fluindapyr residues in animal matrices. Noting the uncertainties regarding the extraction efficiencies of the analytical method for fluindapyr and 1-COOH-fluindapyr, the Meeting cannot conclude on the storage stability of these analytes in animal commodities, except for 1-OH-Met-fluindapyr (both diastereomers) in liver and eggs and 1-OH-Met-N-Desmet-fluindapyr (both diastereomers) in liver,

Finally, the Meeting received storage stability information on spiked residue of fluindapyr in soil demonstrating that fluindapyr, 3-OH-fluindapyr, 1-COOH-fluindapyr, and pyrazole carboxylic acid are stable when stored frozen for period of 2 years.

Definition of the residue

Parent fluindapyr is a racemic mixture. In the absence of any indication that there is a difference in toxicology between the isomers of the parent or its metabolites, the Meeting concluded that they could be considered together and are therefore not reported individually.

Plant commodities

In the primary plant metabolism studies involving foliar applications, parent fluindapyr was the predominant residue, accounting for 63–65 percent TRR in grapes, 43–50 percent TRR in sugar beet roots, 46–56 percent TRR in wheat grains and 53–57 percent TRR in rice husked grain. Radioactive residues in soya bean seed were too low to detect any compound. Parent fluindapyr was also found in feed commodities, accounting for 15–18 percent TRR in sugar beet foliage to 31–37 percent TRR in wheat forage, with highest relative levels in rice straw (55–56 percent TRR).

Fluindapyr residues are not expected in rotational crops, and processing studies show that parent compound is also the main analyte in the processed commodities. Furthermore, suitable enforcement analytical methods exist to measure fluindapyr in plant commodities.

The Meeting concluded that fluindapyr is a suitable marker compound and decided to define the residue for compliance with the MRL for plants as fluindapyr.

In deciding which compounds should be included in the residue definition for dietary risk assessment of plant commodities, the Meeting considered the likely occurrence and the toxicological properties for the metabolites 1-OH-Met-fluindapyr (and its conjugates), 3-OH-fluindapyr, 1-COOH-fluindapyr, 1-OH-Met-N-DesMet-fluindapyr (and its conjugate), N-DesMet-fluindapyr (and its conjugates), dehydro-fluindapyr, pyrazole carboxylic acid, pyrazole carboxamide, 3-OH-N-DesMet-fluindapyr, and the rotational crop metabolite N-DesMet-pyrazole carboxylic acid.

The Meeting concluded that metabolites 1-OH-Met-fluindapyr and its conjugate and 3-OH-fluindapyr are covered by the health based reference values for parent.

In metabolism studies, 1-OH-Met-fluindapyr and its conjugates accounted for up to 20 percent TRR (0.017/0.07 mg eq/kg) in grapes, 25 percent TRR (0.031 mg eq/kg) in sugar beet roots, and up to 17/22 percent TRR (0.17/0.11 mg/kg eq) in rice grain. The compounds were not found in wheat grain, but contributed significantly to the total residue in wheat forage, hay and straw (35–60 percent TRR). In contrast, in the wheat field trials, these metabolites were observed in grain, sometimes within the same range as parent fluindapyr. In sorghum grain, these metabolites were quantified in GAP-compliant field trials, but were <LOQ in maize grain, sweet corn, almond and pecan. The Meeting concluded that 1-OH-Met-fluindapyr and its conjugates should be included in the residue definition for dietary risk assessment for plant commodities.

3-OH-fluindapyr accounted for 6.1/1.7 percent TRR (0.002/0.005 mg eq/kg) in sugar beet root, up to 12–15 percent TRR (0.013/0.043 mg eq/kg) in grapes and 20/22 percent TRR (0.0042/0.0084 mg eq/kg) in wheat grain in primary crop metabolism studies. In the GAP-compliant field trials with wheat and sorghum, 3-OH-fluindapyr was found in grains. However, considering that the metabolite generally contributes less than 5 percent (with peaks up to 8.7 percent) to the residue of toxicological concern in GAP compliant field trials with cereals and also more than 80 percent of the residue of concern is covered in grapes without inclusion of 3-OH-fluindapyr, the Meeting decided not to include the metabolite in the residue definition for dietary risk assessment.

1-COOH-fluindapyr, 1-OH-Met-N-DesMet-fluindapyr (and its N-conjugate), N-DesMet-fluindapyr and its conjugates, dehydro-fluindapyr, pyrazole carboxylic acid, pyrazole carboxamide, 3-OH-N-DesMet-fluindapyr were not consistently seen in all crops, contributed less than 6.1 percent TRR (0.005 mg eq/kg) individually, and the sum of them never exceed 10 percent TRR in any of the different primary crop metabolism studies. These metabolites were not further considered for the residue definition for dietary risk assessment for plant commodities.

The rotational crop metabolite N-DesMet-pyrazole carboxylic acid was found in several crops planted in rotation. Since the metabolite is a common metabolite, shared with fluxapyroxad, bixafen, benzovindiflupyr, and inpyrfluxam and is not covered by the health based reference values for fluindapyr, the Meeting concluded that the relevance of this metabolite should be evaluated against the TTC of a Cramer Class III compound (see Dietary Risk Assessment section)

The Meeting decided to define the residue for dietary risk assessment as the sum of fluindapyr and 1-OH-Met-fluindapyr and its conjugates, expressed as fluindapyr.

Animal commodities

Fluindapyr (parent) is a component found in the majority of the goat tissues and cream samples, but with rather low levels in kidney and liver. In poultry tissues the parent was observed in liver, muscle, skin and in eggs.

Noting that the analytical method used in the feeding studies is not fully suitable for quantification of the parent fluindapyr in animal commodities, the results of the dairy feeding studies were considered only qualitatively. In dairy cattle feeding studies, parent fluindapyr was observed in milk, liver and fat, but not muscle and kidney.

Parent fluindapyr is found in almost all goat and hen commodities in metabolism studies and is therefore a suitable marker compound.

The Meeting noted that no suitable analytical method exists to measure fluindapyr in animal commodities.

The Meeting decided to define the residue definition for compliance as fluindapyr.

The Log K_{ow} of fluindapyr is 4.1, indicating a potential to sequester into fatty matrices. In lactating goats, the ratio of fluindapyr in cream to skimmed milk was about 50 fold. It was 4 fold in fat to muscle in lactating goat, and approximately 15–18-fold in fat to muscle in laying hens. The Meeting considered the residue to be fat soluble.

In deciding which additional compounds should be included in the residue definition for risk assessment for animal commodities, the Meeting considered the likely occurrence of the compound at 10 percent TRR and/or absolute concentrations at ≥ 0.01 mg eq/kg, and their toxicity. Metabolites 1-OH-Met-fluindapyr, 1-COOH-fluindapyr, N-DesMet-fluindapyr, 1-OH-Met-N-DesMet-fluindapyr and its glucuronides, 1-SO₄-Met-fluindapyr, and 1-SO₄-Met-N-DesMet-fluindapyr were assessed. The Meeting concluded that all the metabolites, including their conjugates, are covered by the health based reference values for parent.

1-OH-Met-fluindapyr and its conjugates were found in all goat (up to 57 percent TRR) and hen tissues (up to 32 percent TRR) in the animal metabolism studies and were also observed in the animal feeding studies. The Meeting concluded that 1-OH-Met-fluindapyr and its conjugates should also be included in the residue definition for dietary risk assessment for all animal tissues.

1-COOH-fluindapyr and its conjugates were found in the animal metabolism studies only in goat liver and kidney (up to 21–27 percent TRR; 0.005–0.075 mg eq/kg) and were also observed in the goat feeding study in these matrices. The compound was observed in hen liver and muscle (up to 12 percent TRR), but at levels < 0.01 mg eq/kg. The Meeting concluded that 1-COOH-fluindapyr and its conjugates should be included in the residue definition for dietary risk assessment in mammalian tissues.

N-DesMet-fluindapyr was observed at high relative and absolute levels in hen liver (36–61 percent TRR; 0.042–0.066 mg eq/kg) and at low levels in goat cream, fat and muscle and in hen skin, fat, eggs, and muscle, ranging from 1.3 to 6.8 percent TRR (< 0.001–0.004 mg eq/kg). This finding was confirmed in the laying hen feeding study. The Meeting concluded that N-DesMet-fluindapyr should be included in the residue definition for dietary risk assessment.

1-OH-Met-N-DesMet-fluindapyr accounted for 1.9–2.1 percent TRR (< 0.001 mg eq/kg) in skimmed milk and for 4.7–5.2 percent TRR, but < 0.001 mg eq/kg in goat muscle. The glucuronide conjugates were found in goat liver (4.3–8.9 percent TRR) and goat kidney (13–24 percent TRR), at levels ranging from 0.010 to 0.025 mg eq/kg. The metabolite was found in hen liver (8.5/4.0 percent TRR; 0.010/0.020 mg eq/kg) and muscle (1.9/4.0 percent TRR: < 0.001 mg eq/kg), but not distinguishable from its sulfate conjugate. The metabolites were also found in goat liver and kidney and in hen liver samples in the farm animal feeding studies. The Meeting concluded that 1-OH-Met-N-DesMet-fluindapyr and its conjugates should be included in the residue definition for dietary risk assessment.

1-SO₄-Met-fluindapyr and 1-SO₄-Met-N-DesMet-fluindapyr were observed at 17–18 percent TRR and 4.1–8.6 percent TRR in hen liver, with levels ranging from 0.008–0.022 mg eq/kg. The metabolites are expected to add insignificantly to the dietary intake at realistic dietary burden levels. Therefore, the Meeting concluded that these metabolites need not be included in the residue definition for dietary risk assessment.

The Meeting decided to define the residue for dietary risk assessment for animal commodities as the sum of fluindapyr, 1-OH-Met-fluindapyr, 1-COOH-fluindapyr, 1-OH-Met-N-DesMet-fluindapyr and their conjugates and N-DesMet-fluindapyr, expressed as fluindapyr.

Summary of residue definitions

The Meeting recommended the following residue definitions for fluindapyr:

Definition of the residue for compliance with the MRL assessment for plant commodities:
fluindapyr

Definition of the residue for dietary risk assessment for plant commodities: *sum of fluindapyr and 3-(difluoromethyl)-N-[7-fluoro-1-(hydroxymethyl)-1,3-dimethyl-2,3-dihydro-1H-inden-4-yl]-1-methyl-1H-pyrazole-4-carboxamide (1-OH-Met-fluindapyr) and its conjugates, expressed as parent*

Definition of the residue for compliance with the MRL assessment for animal commodities:
fluindapyr

Definition of the residue for dietary risk assessment for animal commodities: *sum of fluindapyr, 4-(3-(difluoromethyl)-1-methyl-1H-pyrazole-4-carboxamido)-7-fluoro-1,3-dimethyl-2,3-dihydro-1H-indene-1-carboxylic acid (1-COOH-fluindapyr), 3-(difluoromethyl)-N-[7-fluoro-1-(hydroxymethyl)-1,3-dimethyl-2,3-dihydro-1H-inden-4-yl]-1-methyl-1H-pyrazole-4-carboxamide (1-OH-Met-fluindapyr), 3-(difluoromethyl)-N-[7-fluoro-1-(hydroxymethyl)-1,3-dimethyl-2,3-dihydro-1H-inden-4-yl]-1H-pyrazole-4-carboxamide (1-OH-Met-N-DesMet-fluindapyr) and their conjugates, and 3-(difluoromethyl)-N-(7-fluoro-1,1,3-trimethyl-2,3-dihydro-1H-inden-4-yl)-1H-pyrazole-4-carboxamide (N-DesMet-fluindapyr), expressed as fluindapyr.*

The residue is fat soluble.

Results of supervised residue trials on crops

The Meeting received supervised residue trial data for fluindapyr on almonds, maize, sorghum, sweet corn, wheat and tree nuts. Product labels were available from the United States.

When calculating the sum of fluindapyr and 1-OH-Met-fluindapyr for STMR and HR estimations, values < LOQ were assumed to be at the LOQ. As the metabolite is expressed as parent equivalents, no molecular weight conversion factor was needed.

The highest individual total residue values from the trials was used to derive HRs and the highest residues.

Cereal grains, Group of

The Meeting received supervised residue trials on wheat, sorghum, maize and sweet corn.

Wheat, similar grains, and pseudocereals without husks, Subgroup of

In the United States, the critical GAP for cereals grains, except rice, is 2 foliar applications of fluindapyr at 150 g ai/ha, with a retreatment interval (RTI) of 10 days and a pre-harvest interval (PHI) of 30 days for grain.

Seventeen field residue trials conducted in the United States in 2016 matched the GAP. The residue levels for MRL estimation in ranked order were (n=16): 0.010, 0.017, 0.018, 0.023, 0.025, 0.026, 0.029, 0.041, 0.053, 0.060, 0.087, 0.088, 0.10, 0.12, 0.19, and 0.26 mg/kg.

Total residue levels for dietary risk assessment in ranked order were (n=16): 0.020, 0.027, 0.040, 0.040, 0.044, 0.044, 0.059, 0.070, 0.078, 0.082, 0.097, 0.098, 0.13, 0.14, 0.20, and 0.27 mg/kg.

The Meeting estimated a maximum residue level of 0.4 mg/kg and an STMR of 0.074 mg/kg for fluindapyr in the Subgroup of Wheat, similar grains, and pseudocereals without husks.

Sorghum grain and millet, Subgroup of

In the United States, the critical GAP for sorghum is for 2 foliar applications of fluindapyr at 150 g ai/ha, with an RTI of 10 days and a PHI of 30 days for grain.

Eight field residue trials conducted in the United States in 2015 and 2016 matched the GAP. The residue levels for MRL estimation in ranked order were (n=8): 0.10, 0.24, 0.29, 0.34, 0.37, 0.37, 0.43, and 0.43 mg/kg.

Total residue levels for dietary risk assessment in ranked order were (n=8): 0.14, 0.29, 0.35, 0.38, 0.41, 0.42, 0.48, and 0.56 mg/kg.

Noting that the GAP of the United States label for cereal grains, except rice, is similar to the GAP for sorghum grain and includes millet, the Meeting estimated a maximum residue level of 1.0 mg/kg and an STMR of 0.395 mg/kg for fluindapyr in the Subgroup of Sorghum Grain and Millet.

Maize cereals, Subgroup of

In the United States, the critical GAP for maize cereals is for 2 foliar applications of fluindapyr at 150 g ai/ha, with an RTI of 10 days and a PHI of 30 days for grain.

Twenty field residue trials conducted in the United States in 2015 and 2016 matched the US GAP. The residue levels for MRL estimation in ranked order were (n=20): < 0.01 (20) mg/kg.

Total residue levels for dietary risk assessment in ranked order were (n=20): < 0.02 mg/kg.

Since no residues were observed in any of the residue field trials, the Meeting estimated a maximum residue level of 0.01(*) mg/kg and an STMR of 0.02 mg/kg for fluindapyr in the Subgroup of Maize cereals.

Sweet corns, Subgroup of

In the United States, the critical GAP for sweet corn is for 2 foliar applications of fluindapyr at 150 g ai/ha, with an RTI of 10 days and a PHI of 14 days for kernel + cobs with husks removed.

Eight field residue trials conducted in the United States in 2016 matched the US GAP. Residues were measured in kernels + cobs with husks removed. The residue levels for MRL estimation in ranked order were (n=8): < 0.01 (8) mg/kg.

Total residue levels for dietary risk assessment in ranked order were (n=8): < 0.02 mg/kg.

The Meeting estimated a maximum residue level of 0.01(*) mg/kg and an STMR and an HR of 0.02 mg/kg for fluindapyr in Sweet corn (corn-on-the cob) (kernels plus cob with husk removed).

Tree nuts, Group of

In the United States, the critical GAP for tree nuts is for 3 foliar applications of fluindapyr at 168 g ai/ha, with an RTI of 7 days and a PHI of 30 days. The Meeting received data on almonds and on pecan nuts.

Almonds

Five field residue trials conducted in the United States in 2016 matched the US GAP for tree nuts. The residue levels in almond nutmeat for MRL estimation in ranked order were (n=5): < 0.01 (2), 0.011, 0.018, and 0.022 mg/kg.

Total residue levels for dietary risk assessment in ranked order were (n=5): < 0.020 (2), 0.021, 0.028, and 0.032 mg/kg (highest individual value 0.035 mg/kg).

Pecan

Five field residue trials conducted in the United States in 2016 matched the US GAP for tree nuts. The residue levels in pecan nutmeat for MRL estimation in ranked order were (n=5): < 0.01 (3), 0.016, and 0.024 mg/kg.

Total residue levels for dietary risk assessment in ranked order were (n=5): < 0.020 (3), 0.025, and 0.034 mg/kg.

Statistical analysis showed that the residue data with almond and pecans were similar. The combined data for maximum residue estimation in ranked order were (n=10): < 0.01 (5), 0.011, 0.016, 0.018, 0.022, and 0.024 mg/kg.

The combined data for dietary risk assessment in ranked order were (n=10): < 0.020 (5), 0.021, 0.025, 0.028, 0.032, and 0.034 mg/kg.

Noting that both almond and pecan are representative commodities for tree nuts, the Meeting estimated a maximum residue level of 0.04 mg/kg and an STMR of 0.0205 mg/kg for fluindapyr for the Group of Tree nuts.

Residues in animal feeds*Forages and fodders**Wheat forage*

The critical GAP in the United States for cereals grains, except rice, allows for 2 foliar applications of fluindapyr at 150 g ai/ha, with an RTI of 10 days and a PHI of 7 days for forage.

Field residue trials on wheat forage, conducted in the United States in 2016, matched this GAP. Residue levels (parent only) in ranked order were (n=17): 0.16, 0.41, 0.54, 0.86, 1.4, 1.5, 1.5, 1.9, 2.2, 2.3, 2.4, 2.4, 2.4, 3.5, 4.2, 6.7, and 8.8 mg/kg (highest individual value 11 mg/kg).

Total residue levels (parent + 1-OH-Met-fluindapyr and its conjugates) for dietary intake calculations in ranked order were (n=17): 0.44, 0.60, 0.64, 1.2, 1.6, 1.6, 1.8, 2.2, 2.5, 2.5, 2.5, 2.6, 2.8, 3.7, 4.5, 6.9, and 9.2 mg/kg (highest individual value 12 mg/kg).

The Meeting estimated a median residue of 2.6 mg/kg (as received) and a highest residue of 12 mg/kg (as received) for wheat forage.

Wheat hay and wheat straw (both 88 percent dry matter)

The critical GAP in the United States for cereals grains, except rice, allows for 2 foliar applications of fluindapyr at 150 g ai/ha, with an RTI of 10 days and a PHI of 14 days (hay) and 30 days (straw).

Field residue trials on wheat hay, conducted in the United States in 2016, matched this GAP. The residue levels for MRL estimation in ranked order were (n=17): 0.072, 0.60, 0.63, 0.67, 0.69, 0.80, 0.82, 0.98, 1.2, 1.3, 1.3, 1.8, 1.8, 2.4, 2.4, 4.8, and 6.4 mg/kg (highest individual value 6.6 mg/kg).

Total residue levels (parent + 1-OH-Met-fluindapyr and its conjugates) for dietary burden calculations in ranked order were (n=17): 0.98, 0.99, 1.1, 1.2, 1.2, 1.4, 1.6, 1.8, 1.9, 1.9, 2.1, 2.3, 2.5, 2.6, 3.0, 6.6 and 6.9 mg/kg (highest individual value 7.1 mg/kg)

Field residue trials conducted with wheat straw in the United States in 2016 were performed with two foliar applications of fluindapyr at rates of 146-157 g ai/ha with an RTI of 9-12 days and harvested 30 DALA. The residue levels for MRL estimation in ranked order were (n=16): 0.16, 0.32, 0.34, 0.41, 0.54, 0.54, 0.79, 1.2, 1.4, 1.4, 1.9, 2.0, 2.1, 2.8, 9.6, and 11 mg/kg (highest individual value 12 mg/kg).

Total residue levels (parent + 1-OH-Met-fluindapyr and its conjugates) for dietary burden calculations in ranked order were (n=16): 0.22, 0.59, 0.61, 0.65, 0.83, 1.1, 1.7, 1.8, 1.8, 1.9, 2.1, 2.1, 2.4, 3.1, 10, and 12 mg/kg (highest individual value 13 mg/kg).

Based on the data set for straw, the Meeting estimated a maximum residue level of 15 mg/kg (dw) based on a dry matter content of 88 percent for Wheat, hay and/or straw.

The Meeting estimated a median residue of 1.9 mg/kg (as received) and highest residue of 7.1 mg/kg (as received) for fluindapyr in wheat hay and a median residue of 1.8 mg/kg (as received) and a highest residue of 13 mg/kg (as received) for fluindapyr in wheat straw.

Sorghum forage (35 percent dry matter)

The critical GAP in the United States for sorghum allows for 2 foliar applications of fluindapyr at 150 g ai/ha, with a RTI of 10 days with no livestock feeding restrictions.

Field residue trials on sorghum forage, conducted in the United States in 2015 and 2016, matched this GAP. Residue levels (parent only) in ranked order were (n=9): 0.24, 0.38, 0.42, 0.55, 0.62, 1.3, 2.4, 4.5, and 5.0 mg/kg (highest individual value 5.1 mg/kg).

Total residue levels (parent + 1-OH-Met-fluindapyr and its conjugates) for dietary burden calculations in ranked order were (n=9): 0.43, 0.46, 0.51, 0.66, 0.71, 1.4, 2.8, 4.7, and 5.1 mg/kg (highest individual value of 5.2 mg/kg).

The Meeting estimated a highest residue of 5.2 mg/kg (as received) and a median residue of 0.71 mg/kg (as received) for sorghum forage.

Sorghum stover (88 percent dry matter)

The critical GAP in the United States for sorghum allows for 2 foliar applications of fluindapyr at 150 g ai/ha, with an RTI of 10 days with a PHI of 30 days.

Field residue trials on sorghum stover, conducted in the United States in 2015 and 2016, matched this GAP. The residue levels for MRL estimation in ranked order were (n=8): 0.14, 0.16, 0.18, 0.21, 0.23, 0.44, 0.83, and 1.1 mg/kg (highest individual value of 1.7 mg/kg).

Total residue levels (parent + 1-OH-Met-fluindapyr and its conjugates) for dietary burden calculations in ranked order were (n=8): 0.19, 0.28, 0.32, 0.34, 0.45, 0.62, 0.95, and 1.8 mg/kg (highest individual value 2.4 mg/kg).

The Meeting estimated a maximum residue level of 3 mg/kg (dw), based on a dry matter content of 88 percent) for sorghum stover. The Meeting estimated a median residue of 0.395 mg/kg (as received) and a highest residue of 2.4 mg/kg (as received) for sorghum stover

Maize forage (40 percent dry matter)

The critical GAP in the United States for maize allows for 2 foliar applications of fluindapyr at 150 g ai/ha, with a RTI of 10 days and a PHI of 7 days.

Field residue trials on maize forage, conducted in the United States in 2015 and 2016, matched this GAP. Residue levels (parent only) in ranked order were (n=21): 0.077, 0.18, 0.23, 0.25, 0.33, 0.36, 0.44, 0.45, 0.48, 0.57, 0.73, 0.77, 0.79, 0.90, 0.96, 1.3, 1.4, 1.5, 1.8, 2.1, and 7.6 mg/kg (highest individual value 9.2 mg/kg).

Total residue levels (parent + 1-OH-Met-fluindapyr and its conjugates) for dietary burden calculations in ranked order were (n=21): 0.087, 0.21, 0.27, 0.35, 0.39, 0.46, 0.51, 0.56, 0.59, 0.64, 0.83, 0.86, 0.94, 0.97, 1.1, 1.4, 1.5, 1.5, 1.9, 2.3, and 8.2 mg/kg (highest individual residue 9.8 mg/kg).

The Meeting estimated a median residue of 0.83 mg/kg (as received) and a highest residue of 9.8 mg/kg (as received) for maize forage.

Maize stover (83 percent dry matter)

The critical GAP in the United States for maize allows for 2 foliar applications of fluindapyr at 150 g ai/ha, with an RTI of 10 days and a PHI of 10 days.

Field residue trials on maize forage, conducted in the United States in 2015 and 2016, matched this GAP. The residue levels for MRL estimation in ranked order were (n=20): < 0.01, 0.22, 0.34, 0.34, 0.36, 0.54, 0.55, 0.57, 0.60, 0.76, 0.84, 0.89, 0.89, 1.1, 1.4, 1.7, 1.7, 2.0, 2.4, and 2.6 mg/kg (highest residue 2.8 mg/kg).

Total residue levels (parent + 1-OH-Met-fluindapyr and its conjugates) for dietary burden calculations in ranked order were (n=20): < 0.02, 0.30, 0.44, 0.61, 0.64, 0.66, 0.76, 0.83, 0.82, 0.90, 1.0, 1.0, 1.2, 1.4, 1.8, 2.0, 2.2, 2.7, 2.6, and 2.8 mg/kg (highest individual value 3.0 mg/kg).

The Meeting estimated a maximum residue level of 5 mg/kg (dw) based on a dry matter content of 83 percent. The Meeting estimated a median residue of 0.95 mg/kg (as received) and a highest residue of 3.0 mg/kg (as received) for maize stover.

Sweet corn forage (48 percent dry matter)

The critical GAP in the United States for sweet corn allows for 2 foliar applications of fluindapyr at 150 g ai/ha, with an RTI of 10 days with no livestock feeding restrictions.

Eight field residue trials on sweet corn forage, conducted in the United States in 2016, matched this GAP. Residue levels (parent only) in ranked order were (n=8): 0.022, 0.14, 0.18, 0.25, 0.33, 0.77, 0.98, and 5.4 mg/kg. (highest individual value 6.8 mg/kg).

Total residue levels (parent + 1-OH-Met-fluindapyr and its conjugates) for dietary burden calculations in ranked order were (n=8): 0.069, 0.24, 0.27, 0.47, 0.89, 0.93, 1.1, and 5.5 mg/kg (highest individual residue 6.9 mg/kg).

The Meeting estimated a median residue of 0.68 mg/kg (as received) and a highest residue of 6.9 mg/kg (as received) for sweet corn forage.

Sweet corn stover (83 percent dry matter)

The critical GAP in the United States for sweet corn allows for 2 foliar applications of fluindapyr at 146 g ai/ha, with an RTI of 10 days and a PHI of 10 days.

Eight field residue trials on sweet corn forage, conducted in the United States in 2016, matched this GAP. The residue levels for MRL estimation in ranked order were (n=8): 0.17, 0.19, 0.26, 0.28, 0.63, 0.65, 1.3, and 13 mg/kg.

Total residue levels (parent + 1-OH-Met-fluindapyr and its conjugates) for dietary burden calculations in ranked order were (n=8): 0.46, 0.59, 0.65, 0.83, 0.88, 0.88, 1.7, and 13 mg/kg.

The Meeting estimated a maximum residue level of 30 mg/kg (dw), based on a dry matter content of 83 percent. The Meeting estimated a median residue of 0.855 mg/kg (as received) and a highest residue of 13 mg/kg (as received) for sweet corn stover.

Miscellaneous animal feed

Almond hulls (90 percent dry matter)

The same trials as for almond (nutmeat) were considered for almond hulls. Five trials on almonds matched the critical US GAP on tree nuts (3 foliar applications each at 168 g ai/ha, an RTI of 7 days and harvested 30 DALA).

Residue levels (parent only) in ranked order were (n=5): 1.7, 2.5, 3.4, 6.0, and 8.2 mg/kg. Total residue levels (parent + 1-OH-Met-fluindapyr and its conjugates) for dietary burden calculations in ranked order were (n=5): 2.1, 2.9, 3.4, 6.0, and 8.2 mg/kg.

The Meeting estimated a maximum residue level of 20 mg/kg (dw), based on a dry matter content of 90 percent and a median residue of 3.4 mg/kg (as received) for fluindapyr in almond hulls.

Fate of residues during processing

High temperature hydrolysis

The Meeting received information on the hydrolysis of fluindapyr simulating typical processing conditions (pH 4, 6 and 6 with 90, 100 and 10 °C for 20, 60 and 20 minutes). No significant hydrolysis of fluindapyr was observed at the conditions studied. The Meeting concluded that fluindapyr is stable under the conditions of pasteurization, boiling, baking and brewing, as well as sterilisation.

Residues in processed commodities

The fate of fluindapyr residues during commercial processing has been examined in wheat, sorghum, and maize. Processing factors derived for MRL estimation are based parent only. Processing factors derived for STMR estimation for food and median residue level estimation in feed are based on the residue definition for dietary risk assessment including total residue (parent + 1-OH-Met-fluindapyr). The results are shown in Table 5.17.3.

Table 5.17.3 Estimation of processing factors for commodities based on parent (MRL estimation) or parent + 1-OH-Met-fluindapyr (STMR and median residue level estimation)

Crop	Residue (mg/kg) in RAC		Processed commodity	Individual processing factors	Mean or best estimate PF	Residue (mg/kg) in processed commodity	
	MRL ^a	STMR ^b				MRL-P ^[a]	STMR-P or median residue-P ^b
Wheat	0.4	0.074	Whole meal flour	0.71, 0.81, 0.86, 1.0	0.845	-	0.063
			Total bran	0.95, 1.1, 1.4, 1.5	1.24	0.5 ^c	0.92
			White flour	0.28, 0.29, 0.30, 0.55	0.355	-	0.026
			Whole meal bread	0.44, 0.46, 0.54, 0.54	0.495	-	0.037
			Gluten feed meal	0.35, 0.37, 0.40, 0.71	0.458	-	0.034 ^d
			Germ	0.15, 0.42, 0.53, 0.60	0.425	-	0.031
Sorghum	1.0	0.395	Flour	0.42	0.42	-	0.17
			Aspirated grain fraction	6.9	6.9	7 ^e	2.7 ^f
Maize	0.01*	0.02	Flour	< 0.74	< 0.74	-	0.02
			Grits	< 0.8	< 0.8	-	0.02
			Meal	< 0.8	< 0.8	-	0.02
			Starch	< 0.8	< 0.8	-	0.02
			Refined bleached deodorized oil (wet milled)	1.1	1.1	-	0.022
			Refined bleached deodorized oil (dry milled)	1.8	1.8	0.03 ^g	0.36
Aspirated grain fraction	27	27	0.5 ^h	0.54 ⁱ			

Notes:^a Parent only.^b Parent + 1-OH-fluindapyr.^c MRL-P was based on the mean PF of 1.26 (individual values of 1.38, 1.51, 1.0 and 1.14) for parent only.^d A median residue-P of 0.025 was also derived for dietary burden estimation for MRL estimation, based on the individual PFs of 0.33, 0.41, 0.42 and 0.92, with a mean PF of 0.52 and a median residue based on parent only of 0.047 mg/kg.^e MRL-P was based on the single PF of 6.5 for parent only.^f A median residue-P of 2.31 was also derived for dietary burden estimation for MRL estimation, based on the single PF of 6.5 and a median residue based on parent only of 0.355 mg/kg.^g MRL-P was based on the single PF of 2.3 for parent only.^h MRL-P was based on the single PF of 44 for parent only.ⁱ A median residue-P of 0.44 was also derived for dietary burden estimation for MRL estimation, based on the single PF of 44 and a median residue STMR based on parent only of 0.01 mg/kg.

Residues in animal commodities**Farm animal feeding studies**

The Meeting received farm animal feeding studies in lactating cows and laying hens.

Noting the uncertainties regarding the analytical method used (limited extraction efficiency of parent fluindapyr in a radio validation study) in both the dairy cow and laying hen feeding studies, the Meeting concluded that the results cannot be used for quantitative estimation of maximum residue level, STMR and HR estimation. Therefore, no details of the study were summarized here.

Farm animal dietary burden

Dietary burdens were calculated for beef cattle, dairy cattle, broilers and laying poultry based on feed items evaluated by the current JMPR using the OECD diets listed in Appendix IX of the 2016 edition of the FAO Manual. The results are presented in Annex 6 of the 2022 JMPR Report and summarized below.

The Meeting performed two mean and maximum dietary burden calculations; one based on parent only for MRL estimation and one based on parent + 1-OH-Met-fluindapyr (and its conjugates) for STMR and HR estimations (Tables 5.17.4 and 5.17.5).

Table 5.17.4 Estimated maximum and mean dietary burdens of farm animals based on parent only for MRL estimation

	Animal dietary burden: fluindapyr, ppm of dry matter diet							
	United States-Canada		European Union		Australia		Japan	
	Max	Mean	Max	Mean	Max	Mean	Max	Mean
Beef cattle	3.772	3.965	25.66	4.202	44 ^①	12.84	0.176	0.176
Dairy cattle	15.11	10.369	18.17	3.809	35.6 ^②	12.84	11.64	7.117
Poultry–broiler	0.32	0.32	0.302	0.302	0.301	0.301	0.274	0.274
Poultry–layer	0.323	0.323	4.7 ^③	1.757	0.301	0.301	0.245	0.245

Notes:

- ① Highest maximum beef or dairy cattle dietary burden suitable for MRL estimates for mammalian tissues.
- ② Highest maximum dairy cattle dietary burden suitable for MRL estimates for mammalian milk.
- ③ Highest maximum poultry dietary burden suitable for MRL estimates for poultry tissues and eggs.

Table 5.17.5 Estimated maximum and mean dietary burdens of farm animals based on total intake

	Animal dietary burden: fluindapyr + 1-OH-Met-fluindapyr and its conjugates, ppm of dry matter diet							
	United States-Canada		European Union		Australia		Japan	
	Max	Mean	Max	Mean	Max	Mean	Max	Mean
Beef cattle	4.051	4.090	27.36	4.445	48 ^①	13.4	0.212	0.212
Dairy cattle	16.31	10.59	19.58	3.985	38.6	13.4 ^②	12.4	7.295
Poultry–broiler	0.37	0.37	0.341	0.341	0.341	0.341	0.31	0.31
Poultry–layer	0.365	0.365	5.138 ^③	1.824 ^④	0.341	0.341	0.281	0.281

Notes:

- ① Highest maximum beef or dairy cattle dietary burden suitable for HR estimates for mammalian tissues.
- ② Highest mean beef or dairy cattle dietary burden suitable for STMR estimates for mammalian tissues and milk.
- ③ Highest maximum poultry dietary burden suitable for HR estimates for poultry tissues and eggs.
- ④ Highest mean poultry dietary burden suitable for STMR estimates for poultry tissues and eggs.

Animal commodity maximum residue levels

In the absence of a suitable analytical method for animal commodities no MRLs for animal commodities were recommended

RECOMMENDATIONS

On the basis of the data obtained from supervised trials, the Meeting concluded that the residue levels listed in Annex 1 are suitable for establishing maximum residue limits and for IEDI and international estimate of short-term intakes assessments.

Definition of the residue for compliance with the MRL assessment for plant commodities:
fluindapyr

Definition of the residue for compliance with the MRL assessment for animal commodities:
fluindapyr

Definition of the residue for dietary risk assessment for plant commodities: *sum of fluindapyr and 3-(difluoromethyl)-N-[7-fluoro-1-(hydroxymethyl)-1,3-dimethyl-2,3-dihydro-1H-inden-4-yl]-1-methyl-1H-pyrazole-4-carboxamide (1-OH-Met-fluindapyr) and its conjugates, expressed as parent*

Definition of the residue for dietary risk assessment for animal commodities: *sum of fluindapyr, 4-(3-(difluoromethyl)-1-methyl-1H-pyrazole-4-carboxamido)-7-fluoro-1,3-dimethyl-2,3-dihydro-1H-indene-1-carboxylic acid (1-COOH-fluindapyr), 3-(difluoromethyl)-N-[7-fluoro-1-(hydroxymethyl)-1,3-dimethyl-2,3-dihydro-1H-inden-4-yl]-1-methyl-1H-pyrazole-4-carboxamide (1-OH-Met-fluindapyr), 3-(difluoromethyl)-N-[7-fluoro-1-(hydroxymethyl)-1,3-dimethyl-2,3-dihydro-1H-inden-4-yl]-1H-pyrazole-4-carboxamide (1-OH-Met-N-DesMet-fluindapyr) and their conjugates, and 3-(difluoromethyl)-N-(7-fluoro-1,1,3-trimethyl-2,3-dihydro-1H-inden-4-yl)-1H-pyrazole-4-carboxamide (N-DesMet-fluindapyr), , expressed as fluindapyr.*

The residue is fat-soluble.

FUTURE WORK

Information to demonstrate the extraction efficiency of fluindapyr and related metabolites in animal commodities.

DIETARY RISK ASSESSMENT***Long-term dietary exposure***

The ADI for fluindapyr is 0–0.04 mg/kg bw/day. The International Estimated Daily Intakes (IEDIs) for fluindapyr were estimated for the 17 GEMS/Food Consumption Cluster Diets using the STMR or STMR-P values estimated by the JMPR. The results are shown in Annex 3 of the 2022 JMPR Report.

The IEDIs ranged from 1–5 percent of the maximum ADI. The Meeting concluded that long-term dietary exposure to residues of fluindapyr from uses considered by the JMPR is unlikely to present a public health concern.

Acute dietary exposure

The ARfD for fluindapyr is 0.6 mg/kg bw. The International Estimate of Short Term Intakes (international estimate of short-term intakes) for fluindapyr were calculated for the food commodities and their processed commodities for which HRs/HR-Ps or STMRs/STMR-Ps were estimated by the present Meeting

and for which consumption data were available. The results are shown in Annex 4 of the 2022 JMPR Report.

The international estimate of short-term intake varied from 0–1 percent of the ARfD for children and 0–1 percent of the ARfD for the general population. The Meeting concluded that acute dietary exposure to residues of fluindapyr from uses considered by the present Meeting is unlikely to present a public health concern.

Threshold of toxicological concern (TTC) consideration for metabolites

The Meeting concluded that metabolite N-DesMet-pyrazole carboxylic acid, found in rotational crop studies (root crop and oil seeds), could be assessed using the TTC approach (Cramer Class III threshold of 1.5 µg/kg bw per day). The Meeting estimated a dietary exposure for metabolite N-DesMet-pyrazole carboxylic acid 0.366 µg/kg bw per day.

The Meeting concluded that the estimated dietary exposure to residues of N-DesMet-pyrazole carboxylic acid from uses considered by the current JMPR is below the TTC for Cramer Class III compounds and is unlikely to present a public health concern. Should further uses be considered in the future, these conclusions may need to be re-evaluated.

5.18 Flupyradifurone (285)

RESIDUE AND ANALYTICAL ASPECTS

Flupyradifurone, is a butenolide insecticide acting as an agonist of nicotinic acetylcholine receptor. It was first evaluated by the JMPR for toxicology in 2015 and for residues by the 2016, 2017 and 2019 JMPRs.

The 2015 Meeting established an ADI of 0–0.08 mg/kg bw and an ARfD of 0.2 mg/kg bw and the 2016 JMPR established the following residue definitions:-

- For compliance with the MRL (plant commodities): *Flupyradifurone*
- For estimation of dietary exposure (for plant commodities): Sum of flupyradifurone, difluoroacetic acid (DFA) and 6-chloronicotinic acid (6-CNA), expressed as parent equivalents
- For compliance with the MRL and for estimation of dietary exposure (animal commodities): *Sum of flupyradifurone and difluoroacetic acid, expressed as parent equivalents*

The residue is not fat-soluble.

The Fifty-second Session of the CCPR (2021) listed flupyradifurone for further evaluation by the 2022 JMPR and the current Meeting received revised GAP information and new supporting residue information from the manufacturer for mango, papaya, pineapple, sesame seeds and sunflower seeds.

Methods of analysis

A number of analytical methods (for enforcement and data collection) for plant and animal matrices were evaluated by the 2016 and 2019 Meeting, including the HPLC-MS/MS Method RV-001-P10-02 and RV-001-P10-03 and shown to be suitable for measuring residues of parent flupyradifurone, difluoroacetic acid (DFA), 6-chloronicotinic acid (6-CNA) and also difluoroethyl-amino-furanone (DFEAF) in a range of plant commodities with a high water content, high acid content, high oil content and high starch/protein content.

The current Meeting received validation and concurrent recovery data supporting the use of Method RV-001-P10-02 for mango and Method RV-001-P10-03 for pineapple fruit, juice and wet bran, sesame seed and oil and for sunflower seed, oil and meal.

Conclusions

The Meeting concluded that the analytical methods used in the supervised trials and processing studies provided to this Meeting were suitable for measuring residues of flupyradifurone and its DFA and 6-CNA metabolites, with LOQs of 0.01 mg/kg for all analytes and matrices except DFA (0.02–0.05 mg/kg). The Meeting also noted that the frozen sample storage periods in the trials were all within the acceptable (52 month) storage stability interval for high water, high acid, high oil, high protein, and high starch content matrices.

Results of supervised residue trials on crops

Supervised trials were available for the use of flupyradifurone on mango, papaya, pineapple, sesame seed and sunflower seed. Product labels were available from Australia, Brazil and the United States of America (United States).

Residue results are all expressed as flupyradifurone equivalents, using molecular weight conversion factors of 3.01 (DFA) and 1.83 (6-CNA). For dietary exposure estimation, total residues (the

sum of flupyradifurone, DFA and 6-CNA, expressed as parent equivalents) were calculated using the approach adopted by the 2016 JMPR:

“Where parent or DFA residues were not detected or were less than the LOQ (i.e. < 0.01 mg/kg for parent or 0.05 mg/kg for DFA) the LOQ value was utilized for maximum residue estimation and dietary intake assessment. For 6-CNA, values less than the LOQ were not added for calculation of total residues of flupyradifurone.”

Table 5.18.1 Approach followed for the summing of residues

Parent	DFA	6-CNA	Total
< 0.01	0.05	0.01	0.07
0.01	< 0.05	0.01	0.07
< 0.01	< 0.05	< 0.01	< 0.06
0.01	0.05	< 0.01	0.06
0.01	0.05	0.01	0.07

Mango

The critical GAP for flupyradifurone on mango in the United States is for foliar applications of 0.2 kg ai/ha, with a minimum retreatment interval of 14 days, a PHI of 1 day and a maximum seasonal application rate of 0.41 kg ai/ha. No trials matched this GAP.

The GAP for flupyradifurone on mango in Brazil is for up to 2 foliar applications of 0.2 kg ai/ha, with a minimum retreatment interval of 7 days and a PHI of 3 days.

In five independent trials on mangos, conducted in Brazil and matching the Brazilian GAP, flupyradifurone residues (for maximum residue level estimation) in whole fruit were: 0.14, 0.2, 0.22, 0.23 and 0.3 mg/kg.

For dietary exposure estimation, since the total residues (sum of flupyradifurone, DFA and 6-CNA, expressed as parent equivalents) did not appear reach a plateau in three of the five decline trials, the Meeting agreed it was not possible to estimate an STMR and HR for mango.

The Meeting estimated a maximum residue level of 0.7 mg/kg for flupyradifurone in Mango.

Papaya

The critical GAP for flupyradifurone on papaya in the United States is for foliar applications of 0.2 kg ai/ha, with a minimum retreatment interval of 14 days, a PHI of 1 day and a maximum seasonal application rate of 0.41 kg ai/ha. No trials matched this GAP.

The GAP for flupyradifurone on papaya in Brazil is for up to 2 foliar applications of 0.2 kg ai/ha, with a minimum retreatment interval of 7 days and a PHI of 3 days.

In five independent trials on papaya, conducted in Brazil and matching the Brazilian GAP, flupyradifurone residues in whole fruit (for maximum residue level estimation) were: 0.02, 0.068, 0.1, 0.11 and 0.2 mg/kg.

For dietary exposure estimation, since the total residue concentrations (sum of flupyradifurone, DFA and 6-CNA, expressed as parent equivalents) did not appear to reach a plateau in three of the five decline trials, the Meeting agreed it was not possible to estimate an STMR and HR for mango.

The Meeting estimated a maximum residue level of 0.4 mg/kg for flupyradifurone in Papaya.

Pineapple

The critical GAP for flupyradifurone on pineapple in the United States is for foliar applications of 0.2 kg ai/ha, with a minimum retreatment interval of 7 days, a PHI of 0 days and a maximum seasonal application rate of 0.41 kg ai/ha.

In five independent trials on pineapple, conducted in the United States and matching the US GAP, flupyradifurone residues in trimmed whole fruit (for maximum residue level estimation) were: 0.046, 0.062, 0.11, 0.12 and 0.155 mg/kg.

For dietary exposure estimation, total residues (sum of flupyradifurone, DFA and 6-CNA, expressed as parent equivalents) in trimmed whole fruit were (n = 5): 0.066, 0.082, 0.13, 0.14 and 0.175 mg/kg and the highest individual value was 0.19 mg/kg.

The Meeting estimated a maximum residue level of 0.3 mg/kg for flupyradifurone, an STMR of 0.13 mg/kg and an HR of 0.19 mg/kg for total residues in Pineapple.

Sesame seed

The GAP for flupyradifurone on sesame in the United States is for foliar applications of 0.2 kg ai/ha with a minimum retreatment interval of 10 days, a PHI of 14 days and a maximum seasonal application rate of 0.41 kg ai/ha.

In four independent trials on sesame (including one decline trial), conducted in the United States and matching the US GAP application rate and timing, flupyradifurone residues in sesame seed samples taken 14–19 DALA were: 0.1, 0.12, 0.38 and 1.1 mg/kg.

Based on the residue decline rate shown in the decline trial, the Meeting considered that residues in samples taken 19 DALA would be within 25 percent of the expected residues in samples taken 14 DALA (GAP), and agreed that the data set was sufficient to estimate a maximum residue level.

For dietary exposure estimation, total residues (sum of flupyradifurone, DFA and 6-CNA, expressed as parent equivalents) in sesame seed were (n=4): 0.38, 0.52, 1.2 and 2.0 mg/kg and the highest individual value was 2.0 mg/kg. The median residue was 0.86 mg/kg.

In field studies on succeeding crops evaluated by the 2016 JMPR, the overall mean and highest total residues in rape seed as a rotational crop were 0.16 mg/kg. The Meeting decided to add the mean residue found in rape seed as a rotational crop (0.16 mg/kg) to the median residue obtained from the sesame seed residue trials (0.86 mg/kg) to estimate an overall STMR of 1 mg/kg for total flupyradifurone residues in the sesame seed.

The Meeting estimated a maximum residue level of 3 mg/kg for flupyradifurone and an STMR of 1 mg/kg for total residues in Sesame seed.

Sunflower seed

The GAP for flupyradifurone in the United States on sunflowers (US sub-group 20B) is for foliar applications of 0.2 kg ai/ha with a minimum retreatment interval of 10 days, a PHI of 14 days and a maximum seasonal application rate of 0.41 kg ai/ha.

In eight independent trials on sunflower, conducted in the United States and matching the US GAP, flupyradifurone residues in sunflower seed (for maximum residue level estimation) were: 0.0135, 0.028, 0.028, 0.04, 0.16, 0.17, 0.25 and 0.44 mg/kg.

For dietary exposure estimation, total residues (sum of flupyradifurone, DFA and 6-CNA, expressed as parent equivalents) in sunflower seed were (n=8): 0.075, 0.078, 0.09, 0.096, 0.21, 0.22, 0.3 and 0.49 mg/kg. The median residue was 0.15 mg/kg.

The Meeting decided to add the mean residue found in rape seed as a rotational crop (0.16 mg/kg) to the median residue obtained from the sunflower seed residue trials (0.15 mg/kg) to estimate an overall STMR of 0.31 mg/kg for total flupyradifurone residues in the sunflower seeds subgroup.

The Meeting estimated a maximum residue level of 0.8 mg/kg for flupyradifurone and an overall STMR of 0.31 mg/kg for total residues in the subgroup of Sunflower seeds.

Fate of residues during processing

Residues in processed commodities

The current Meeting received information on the processing of pineapple, sesame seeds and sunflower seeds. Residues decreased in pineapple juice and sesame oil, but increased in sunflower oil.

Processing factors were calculated for total residues (dietary risk assessment) and for flupyradifurone+DFA (livestock dietary burden estimation).

For processed food commodities, STMR-Ps were calculated using the STMRs for the raw commodities and applying the calculated mean processing factors for total residues.

For sunflower oil, no processing factor for total residues could be estimated because significant residues of 6-CNA were found in the control samples.

Table 5.18.2 Calculated STMR-Ps and median-Ps for processed food and feed commodities

RAC	Processing factors		Flupyradifurone+DFA+6-CNA	Flupyradifurone + DFA
	Calculated Processing factors ^a	Best Estimate	STMR-P ^b (mg/kg)	median-P ^c (mg/kg)
Pineapple			STMR=0.13	median=0.13
Juice	0.34	0.34 ^b	0.044	
Wet bran	1.0	1.0 ^c		0.13
Sunflower seed			STMR=0.31	median=0.31
Meal	0.18	0.18 ^{c)}		0.056
Sesame seed			STMR=1.0	
Oil (crude)	0.13	0.13 ^b	0.13	

Notes:

^a The ratios of the residue in the processed item divided by the residue in the Raw Agricultural Commodity.

^b Flupyradifurone + DFA + 6-CNA, expressed as parent equivalents.

^c Flupyradifurone + DFA, expressed as parent equivalents.

Residues in animal commodities

Farm animal dietary burden

The maximum dietary burdens estimated by the 2016 JMPR were 72 ppm for beef, dairy cattle and 15 ppm for poultry.

Dietary burdens were calculated for beef cattle, dairy cattle, broilers and laying poultry based on feed items evaluated by the current and previous JMPRs and using the most recent version of the OECD livestock dietary burden calculator. The results are presented in Annex 6 and summarized below.

Table 5.18.3 Estimated maximum and mean dietary burdens of farm animals

Animal dietary burden: Sum of flupyradifurone+DFA residues (as parent), ppm dry matter diet								
	United States-Canada		European Union		Australia		Japan	
	Max	Mean	Max	Mean	Max	Mean	Max	Mean
Beef cattle	23	7.7	77 ^①	17	77	23 ^⑥	8.2	5.4
Dairy cattle	47	11	67	13	77 ^②	21 ^④	50	8.8
Poultry–broiler	2.9	2.9	4.8	3.5	4.0	4.0	2.7	2.7
Poultry–layer	2.9	2.9	17 ^⑤	6.2 ^⑥	4.0	4.0	2.4	2.4

Notes:

- ① Highest maximum cattle dietary burden suitable for HR and MRL estimates for mammalian tissues.
- ② Highest maximum dairy cattle dietary burden suitable for MRL estimates for mammalian milk.
- ③ Highest mean cattle dietary burden suitable for STMR estimates for mammalian tissues.
- ④ Highest mean dairy cattle dietary burden suitable for STMR estimates for milk.
- ⑤ Highest maximum poultry dietary burden suitable for HR and MRL estimates for poultry tissues and eggs.
- ⑥ Highest mean poultry dietary burden suitable for STMR estimates for poultry tissues and eggs.

Animal commodity maximum residue levels

Noting that the additional feed commodities considered by the Meeting increased the maximum dietary burdens estimated by the 2016 JMPR by less than 7 percent (cattle) and less than 10 percent (poultry), the Meeting agreed that the maximum residue levels, HRs and STMRs for cattle and poultry commodities need not be re-estimated.

RECOMMENDATIONS

On the basis of the data obtained from supervised trials, the Meeting concluded that the residue levels listed in Annex 1 are suitable for establishing maximum residue limits and for IEDI and international estimate of short-term intakes assessments.

Definition of the residue for compliance with the MRL for plant commodities: *Flupyradifurone*

Definition of the residue for dietary risk assessment for plant commodities: *Sum of flupyradifurone, difluoroacetic acid (DFA) and 6-chloronicotinic acid (6-CNA), expressed as parent equivalents.*

Definition of the residue for compliance with the MRL for animal commodities: *Sum of flupyradifurone and difluoroacetic acid, expressed as parent equivalents.*

Definition of the residue for dietary risk assessment for animal commodities: *Sum of flupyradifurone and difluoroacetic acid, expressed as parent equivalents.*

The residue is not fat-soluble.

DIETARY RISK ASSESSMENT***Long-term dietary exposure***

The ADI for flupyradifurone is 0–0.08 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for flupyradifurone were estimated for the 17 GEMS/Food Consumption Cluster Diets using the STMR or STMR-P values estimated by the JMPR. The results are shown in Annex 3 of the 2022 JMPR Report.

The IEDIs ranged from 6–20 percent of the maximum ADI. The Meeting concluded that long-term dietary exposure to residues of flupyradifurone from uses considered by the JMPR is unlikely to present a public health concern.

Acute dietary exposure

The ARfD for flupyradifurone is 0.2 mg/kg bw. The International Estimate of Short Term Intakes (international estimate of short-term intakes) for flupyradifurone were calculated for the food commodities and their processed commodities for which HRs/HR-Ps or STMRs/STMR-Ps were estimated by the present Meeting and for which consumption data were available. The results are shown in Annex 4 of the 2022 JMPR Report.

The international estimate of short-term intake varied from 0–8 percent of the ARfD for children and 0–5 percent of the ARfD for the general population. The Meeting concluded that acute dietary exposure to residues of flupyradifurone from uses considered by the present Meeting is unlikely to present a public health concern.

5.19 Flutriafol (248)

RESIDUE AND ANALYTICAL ASPECTS

Flutriafol, whose IUPAC name is *(RS)*-2,4'-difluoro-*alfa*-(1*H*-1,2,4-triazol-1-ylmethyl)benzhydryl alcohol, is a triazole fungicide. It was first evaluated for toxicology and residues by the 2011 JMPR. The ADI of flutriafol is 0–0.01 mg/kg bw and the ARfD is 0.05 mg/kg bw. The compound was evaluated by the 2015 JMPR for additional MRLs.

The following residue definitions for flutriafol were recommended by the 2011 JMPR and confirmed by the 2015 JMPR :

Definition of the residue for compliance with the MRL and dietary risk assessment for plant and animal commodities: *flutriafol*

The residue is fat soluble.

At the Fifty-first Session of the CCPR (2019), flutriafol was scheduled for evaluation of the additional uses for hops by the 2020 JMPR and postponed to the current JMPR. At the Forty-third Session of CAC (2020), flutriafol was scheduled for evaluation of additional use on almond, pecan, barley, sweet corn and rice by the 2021 JMPR. The current Meeting received new information on methods of analysis, storage studies, use patterns, supervised field trials and processing studies on hops, barley, rice, sweet corn, almond and pecan.

Methods of analysis

The Meeting received information on a method of analysis for supervised field trials.

Method #1 was for analysis of flutriafol in barley, sweet corn, rice and almond. Flutriafol was extracted with acetonitrile/water (7:3) and quantified by LC-MS/MS. The method was validated for flutriafol in barley (hay, grain and flour), sweet corn (forage, corn-on-the-cob and stover), rice (whole plant, straw, grain with husk, husked rice, husks, polished rice and bran) and almond (nutmeat and hulls) with an LOQ of 0.01 mg/kg.

Stability of pesticide residues in stored analytical samples

The 2011 JMPR concluded that when stored frozen flutriafol residues were stable for at least 5 months in soya bean seed; at least 12 months in apple, barley grains and coffee beans; for at least 23 months in grapes; for at least 24 months in cabbage and oilseed rape; and for at least 25 months in wheat (grains and straw), pea seed, and sugar beet root. The periods of demonstrated storage stability for flutriafol residues cover the frozen storage intervals used in the field trials.

Results of supervised residue trials on crops

Cereal grains, Group of

Barley

The critical GAP for flutriafol on barley in the United States is two foliar applications each at 0.128 kg ai/ha with a minimum interval between sprays of 7 days and a PHI of 30 days. In trials conducted in the United States matching the US GAP, residues of flutriafol in barley were (n=11): 0.11, 0.12, 0.15, 0.17, 0.18, 0.20, 0.23, 0.29, 0.34, 0.77 and 0.84 mg/kg.

The Meeting estimated a maximum residue level and STMR of 1.5 and 0.20 mg/kg, respectively.

Rice

The critical GAP for flutriafol on rice in Italy is one foliar application at 0.125 kg ai/ha and a PHI of 28 days. In trials conducted in Bulgaria, France, Italy, Portugal and Spain matching the Italian GAP, residues of flutriafol in rice grain(with husk; n=8) were: 0.57, 0.82, 0.87, 1.1 (3), 1.4 and 1.6 mg/kg.

The Meeting estimated a maximum residue level and STMR for rice grain of 4 and 1.1 mg/kg, respectively.

Residues of flutriafol in husked rice were (n=8): 0.13, 0.14, 0.29, 0.34, 0.39, 0.44, 0.49 and 0.54 mg/kg.

The Meeting estimated a maximum residue level and STMR for husked rice of 1 and 0.365 mg/kg, respectively.

In trials matching the Italian GAP, residues of flutriafol in polished rice were (n=4): 0.26, 0.38, 0.42 and 0.47 mg/kg. Corresponding processing factors for rice with rice grain to polished rice were 0.16-0.44 (median 0.36, See Processing section). The Meeting agreed to utilise the residue data on rice grain together with the median processing factor from rice grain to polished rice to estimate a maximum residue level and an STMR for polished rice of 1.5 [4×0.36] and 0.40 mg/kg [1.1×0.36], respectively.

Sweet corn (Corn-on-the-cob)

The critical GAP for flutriafol on sweet corn in the United States is for two foliar applications each at 0.128 kg ai/ha with a minimum interval between sprays of 7 days with a PHI of 7 days. The Meeting received 16 trials conducted in the United States. Of these trials only four matched the US cGAP, i.e., the majority consisted of an in-furrow application followed by foliar applications.

The Meeting noted that a rotational crop study provided to the 2011 JMPR indicated that uptake from soil may be significant, and could not use 12 of the provided trials to estimate the potential contribution from the in-furrow application to the final residue.

The Meeting could therefore not estimate a maximum residue level, STMR and HR of corn-on-the-cob due to an insufficient number of trials.

*Tree nuts, Group of**Almonds*

The critical GAP for flutriafol on almond in the United States is six foliar applications each at 0.128 kg ai/ha with a minimum interval between sprays of 7 days and a PHI of 14 days. In trials conducted in the United States matching the GAP, residues in flutriafol in almonds were (n=5): < 0.01, 0.012, 0.064, 0.066 and 0.41 mg/kg (highest individual value: 0.42 mg/kg).

The Meeting estimated a maximum residue level, STMR and HR for almonds of 0.8, 0.064 and 0.42 mg/kg, respectively.

Pecan

The critical GAP for flutriafol on tree nuts in the United States is four foliar applications each at 0.128 kg ai/ha with a minimum interval between sprays of 14 days and a PHI of 14 days.

Since no trials matched the GAP, the Meeting could not estimate a maximum residue level and STMR of pecans.

*Dried herbs, Group of**Hops, dry*

The critical GAP for hops in the United States allows four applications each at 0.128 kg ai/ha with a maximum seasonal rate of 0.51 kg ai/ha at a minimum interval of 14 days and a PHI of 7 day.

Data were available from supervised trials on hops (dried cones) in United States.

Residues in hops from independent trials in the United States with four applications of 0.13 kg ai/ha at intervals of 9–11 days at a total application rate of 0.51 kg ai/ha with a PHI of 7 days were (n=3): 4.6, 7.3 and 8.0 mg/kg.

The Meeting could not estimate maximum residue level and STMR for hops due to insufficient trial numbers.

Animal feed commodities*Barley, hay and/or straw*

The critical GAP for flutriafol on barley in the United States is two foliar applications each at 0.128 kg ai/ha with a minimum interval between sprays of 7 days and a PHI of 30 days (for straw) or 14 days (for hay).

In trials conducted in the United States matching the US GAP, residues of flutriafol in barley, straw (as received) were (n=11): 0.28, 0.49, 0.57, 0.64, 0.98, 1.0, 1.2 (2), 1.8, 3.4 and 5.9 mg/kg (highest individual value: 6.4 mg/kg).

In trials conducted in the United States matching the US GAP, residues of flutriafol in barley, hay (as received) were (n=12): 0.25, 0.32, 0.39, 0.54, 0.92, 0.93, 1.1, 1.7 (2), 1.9, 3.2 and 4.9 mg/kg (highest individual value: 5.0 mg/kg).

Based on data for straw which lead to a higher maximum residue level than data for hay, the Meeting estimated the maximum residue level of flutriafol in barley hay and/or straw of 10 mg/kg (dw, based on 89 percent DM content).

The Meeting estimated median and highest residue of flutriafol in barley, straw of 1.0 and 6.4 mg/kg, respectively (as received), and median and highest residue in barley, hay of 1.0, 5.0 mg/kg, respectively (as received).

Rice straw

The critical GAP for flutriafol on rice in Italy is one foliar application at 0.125 kg ai/ha and a PHI of 28 days.

In trials conducted in Bulgaria, France, Italy, Portugal and Spain matching the Italian GAP, residues of flutriafol in rice straw (as received) were (n=12): 0.45, 0.76, 0.92, 1.1 (2), 1.3, 1.4, 1.9 (2), 2.1, 2.4 and 4.0 mg/kg. The Meeting estimated the maximum residue level for flutriafol in rice straw of 6 mg/kg (dw, based on 90 percent DM content) and median and highest residue of 1.4 and 4.0 mg/kg, respectively (as received).

Sweet corn, stover

The critical GAP for flutriafol on sweet corn in the United States is two foliar applications each at 0.128 kg ai/ha with a minimum interval between sprays of 7 days and a PHI of 7 days.

In trials matching critical GAP, residues of flutriafol in sweet corn stover were (n=4): 0.50, 0.83, 2.1 and 4.1 mg/kg.

The Meeting noted that rotational crop study provided to 2011 JMPR indicated that uptake from soil may be significant and could not assume the impact from in-furrow application.

The Meeting considered four trials insufficient to estimate a maximum residue level for corn stover.

Almond hulls

The critical GAP for flutriafol on almond in the United States is six foliar applications each at 0.128 kg ai/ha with a minimum interval between sprays of 7 days and a PHI of 14 days.

In trials conducted in the United States matching the US GAP, residues of flutriafol in almond hulls (as received) were (n=5): 1.3, 1.8, 2.0, 4.0 and 6.7 mg/kg. The Meeting estimated the maximum residue level for flutriafol in almond hulls of 15 mg/kg (dw, based on 90 percent DM content) and median of 2.0 mg/kg, respectively (as received).

Fates of residues during processing

Processing

The Meeting estimated processing factors for flutriafol as follows. STMR-P and maximum residue levels for polished rice were derived from processing factors.

Table 5.19.1 Calculated STMR-Ps for processed food and feed commodities

RAC	Processed commodity	Processing factor	RAC STMR (mg/kg)	STMR-P or median (mg/kg)	Maximum residue level for RAC (mg/kg)	Maximum residue level for processed commodity (mg/kg)
Barley	Pealed barley	0.52	0.20	0.099	1.5	-
	Barley bran	0.92	0.20	0.17		-
	Barley flour	0.48	0.20	0.091		-
Rice grain with husk	Polished rice	0.36	1.1	0.40	4	1.5
	Husks	6.2	1.1	6.8 (as received)	4 (dw)	20 (dw)
	Rice bran	0.62	1.1	0.68 (as received)		

Residues in animal commodities

Farm animal dietary burden

The OECD diets include barley (straw and hay) and rice (straw, grain, husks and bran). Dietary burdens were calculated for beef cattle, dairy cattle, broilers and laying poultry based on feed items evaluated by the Meeting. The dietary burdens, estimated using the OECD diets listed in Appendix IX of the 2016 edition of the FAO Manual, are presented in Annex 6 and summarized below.

Table 5.19.2 Estimated maximum and mean dietary burdens of farm animals

	Animal dietary burden of flutriafol, ppm of dry matter diet							
	United States-Canada		European Union		Australia		Japan	
	Max	Mean	Max	Mean	Max	Mean	Max	Mean
Beef cattle	2.3	1.4	4.8	2.1	11 ^①	4.6 ^②	2.6	0.97
Dairy cattle	4.2	2.0	5.2	2.0	11 ^③	4.6 ^④	1.2	0.52
Poultry–broiler	0.44	0.44	0.24	0.24	0.78	0.78	0.23	0.23
Poultry–layer	0.44	0.44	1.2 ^⑤	0.49	0.78	0.78 ^⑥	0.21	0.21

Notes:

- ① Highest maximum beef cattle dietary burden suitable for MRL estimates for mammalian tissues.
- ② Highest mean beef cattle dietary burden suitable for STMR estimates for mammalian tissues.
- ③ Highest maximum dairy cattle dietary burden suitable for MRL estimates for mammalian milk.
- ④ Highest mean dairy cattle dietary burden suitable for STMR estimates for milk.
- ⑤ Highest maximum poultry dietary burden suitable for MRL estimates for poultry tissues and eggs.
- ⑥ Highest mean poultry dietary burden suitable for STMR estimates for poultry tissues and eggs.

Animal commodity maximum residue levels

The calculations used to estimate highest total residues for use in estimating maximum residue levels, STMR and HR values are shown below.

Table 5.19.3 Residues in milk and tissues from cattle dosed with flutriafol in the diet

Cattle	Feed Level (ppm) for milk residues	Residues (mg /kg) in milk	Feed Level (ppm) for tissue residues	Residues (mg /kg)			
				Muscle	Liver	Kidney	Fat
HR Determination (beef or dairy cattle)							
Feeding Study ^a	16	< 0.01	16	< 0.01	0.77	0.02	0.02
Dietary burden and estimate of highest residue	11	< 0.0069	11	< 0.0069	0.53	0.014	0.014
STMR determination (beef or dairy cattle)							
Feeding Study ^b	5	< 0.01	5	< 0.01	0.33	< 0.01	< 0.01
Dietary burden and estimate of highest residue	4.6	< 0.0029 ^c	4.6	< 0.0029 ^c	0.30	< 0.0092	< 0.0092

Notes:

- ^a Highest residues for tissues and mean residues for milk.
- ^b Mean residues for tissues and mean residues for milk.
- ^c Calculated based on the feeding study of feed level at 16 ppm.

Table 5.19.4 Residues in eggs and tissues from poultry dosed with flutriafol in the diet

Poultry	Feed Level (ppm) for egg residues	Residues (mg /kg) in egg	Feed Level (ppm) for tissue residues	Residues (mg /kg)		
				Muscle	Liver	Fat
HR Determination (poultry–broiler or layer)						
Feeding Study ^a	5	0.03	5	< 0.01	0.10	0.07
Dietary burden and	1.2	0.0072	1.2	< 0.0024	0.024	0.017

Poultry	Feed Level (ppm) for egg residues	Residues (mg /kg) in egg	Feed Level (ppm) for tissue residues	Residues (mg /kg)		
				Muscle	Liver	Fat
estimate of highest residue						
STMR determination (poultry–broiler or layer)						
Feeding Study ^b	5	0.03	5	< 0.01	0.07	0.06
Dietary burden and estimate of highest residue	0.78	0.0047	0.78	< 0.0016	0.011	0.0094

Notes:

^a Highest residues for tissues and mean residues for egg.

^b Mean residues for tissues and mean residues for egg.

The Meeting confirmed its decision in 2015 of maximum residue levels of 0.02 (fat) mg/kg for meat (from mammals other than marine mammals), 0.01 (*) mg/kg for milks, 0.02 mg/kg for mammalian fats (except milk fats) and 1 mg/kg for edible offal (mammalian).

The Meeting estimated maximum residue levels of 0.03 (fat) mg/kg for poultry meat and 0.03 mg/kg for poultry fats to replace previous recommendations, and confirmed its decision in 2015 of maximum residue levels of 0.03 mg/kg for poultry, edible offal of, and 0.01(*) mg/kg for eggs.

RECOMMENDATIONS

On the basis of the data from supervised trials the Meeting concluded that the residue levels listed in Annex 1 are suitable for establishing maximum residue limits and for IEDI and international estimate of short-term intakes assessment.

Definition of the residue for compliance with MRL and dietary intake for plant and animal commodities: *flutriafol*

The residue is fat soluble.

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The International Estimated Daily Intakes for the 17 GEMS/Food cluster diets, based on the recommendations of the current JMPR, were in the range 9–30 percent of the maximum ADI of 0.01 mg/kg bw for flutriafol. The results are shown in Annex 3 to the report.

The Meeting concluded that the long-term dietary exposure from residues of flutriafol, from uses that have been considered by the JMPR, is unlikely to present a public health concern.

Acute dietary exposure

The International Estimated Short Term Intake (international estimate of short-term intakes) for flutriafol was calculated. The results are shown in Annex 4 to the Report.

The international estimate of short-term intakes for flutriafol from the intake of the residue evaluated by the Meeting were 0–30 percent for general population and 0–70 percent for children of the ARfD (0.05 mg/kg bw). The Meeting concluded that acute dietary exposure from the residues of flutriafol, from uses that have been considered by the JMPR, is unlikely to present a public health concern.

5.20 Indoxacarb (216)

RESIDUE AND ANALYTICAL ASPECTS

Indoxacarb is an indeno-oxadiazine insecticide that is used for the control of lepidopteran and other insect pests. Indoxacarb was first evaluated by the 2005 JMPR when an ADI of 0–0.01 mg/kg bw and an ARfD of 0.1 mg/kg bw were established. The residue definition for compliance with the MRL for plant and animal commodities and dietary risk assessment for plant commodities is the sum of indoxacarb and its R enantiomer.

The residue definition for dietary risk assessment for animal commodities is: *sum of indoxacarb, its R enantiomer and methyl 7-chloro-2,5-dihydro-2-[[[4-(trifluoromethoxy)phenyl]amino] carbonyl]indeno[1,2-e][1,3,4]oxadiazine-4a(3H)- carboxylate, expressed as indoxacarb (IN-JT333).*

The residue is fat soluble.

Indoxacarb has been evaluated for additional uses in 2007, 2009 and 2013. At the Fifty-first Session of the CCPR, indoxacarb was scheduled for the evaluation by the current Meeting for additional uses on bush berries, okra, beans with pods, pulses, beetroot, maize and tree nuts. The present Meeting received information on residue analysis, storage stability, use pattern, supervised field trials and processing.

Methods of analysis

The Meeting received information on analytical method DuPont 36189, used in the supervised residue trials for maize and tree nuts. The method was also used to determine residues in the processed fractions of maize. The method involved extraction with hexane-acetonitrile with final determination achieved using LC-MS/MS. The Meeting concluded that the method was validated for dry commodities and crops of a high oil content with an LOQ of 0.01 mg/kg for the sum of indoxacarb and its R enantiomer.

The meeting also received additional validation data to support methods, previously considered by the JMPR, used in the residue trials and new storage stability studies. The Meeting concluded that the methods were validated and are suitable to measure indoxacarb and its R enantiomer in blueberries, snap beans (beans with pods), dry beans, beetroots and maize.

For peppers, no additional validation data were provided for analytical method AMR 3493-95. The Meeting noted that the JMPR previously concluded that this method was validated at an LOQ of 0.02 mg/kg for apple and that procedural recovery data generated in the trials for peppers (bell and non-bell) was acceptable. The Meeting concluded that the method was sufficiently validated for peppers with an LOQ of 0.02 mg/kg.

Stability of pesticide residues in stored analytical samples

The Meeting noted that the 2005 and 2009 JMPR considered storage stability data for a range of crops. Based on the overall data available, the Meeting concluded that indoxacarb (and its R enantiomer) are stable for at least 24 months (high water crops), 11 months (high protein), 18 (high starch) and 11 months (high oil crops).

This Meeting received additional information on storage stability of indoxacarb (and its R enantiomer) in blueberries, peppers, snap beans, dry beans, beetroots and maize. The Meeting agreed that the data were sufficient to support the storage stability of indoxacarb (and its R isomer) for at least 17 months (blueberries), 11 months (peppers), 7 months (fresh beans), 7 months (dry beans), 18 months (beetroots) and 13 months (maize grain).

Results of supervised residue trials on crops

Supervised trials were available for the use of indoxacarb on blueberries, peppers, snap beans, dry beans, beetroots, maize grain and tree nuts. The residue levels reported are the sum of indoxacarb and its R enantiomer.

Bushberries

Blueberries

The critical GAP for bushberries is from the United States and consists of 4 foliar applications each at 123 g ai/ha with a re-treatment interval (RTI) of 7 days and a PHI of 7 days.

Residues of indoxacarb in independent trials, conducted in the United States, approximating the critical GAP were (n= 11): 0.25, 0.28, 0.35, 0.37, 0.47, 0.58, 0.58, 0.77, 0.81, 0.84 and 1.04 mg/kg.

Noting that the registered use is on bushberries and blueberry is a representative of this subgroup the Meeting decided to make a recommendation for the Subgroup of bushberries. The Meeting estimated a maximum residue level of 2 mg/kg, a STMR of 0.58 mg/kg and a HR of 1.04 mg/kg for indoxacarb in the Bushberries subgroup.

Beans with pods, Subgroup of

Snap beans/ common beans with pods

The critical GAP for beans with pods, except soya beans is from the United States and consists of 4 foliar applications each at 123 g ai/ha with a RTI of 7 days and a PHI of 3 days.

Residues of indoxacarb in independent trials approximating the critical GAP were (n= 8): 0.11, 0.12, 0.13, 0.15, 0.17, 0.17, 0.20 and 0.59 mg/kg.

The Meeting noted that the registered use is on beans with pods, except soya beans. Therefore, the Meeting estimated a maximum residue level of 0.9 mg/kg, a STMR of 0.16 mg/kg and a HR of 0.59 mg/kg for indoxacarb in the subgroup of Beans with pods, except soya beans.

Pulses, Group of

Dry beans

The critical GAP for dry beans, except soya beans is from the United States and consists of 4 foliar applications each at 123 g ai/ha with a RTI of 7 days and a PHI of 7 days.

Residues of indoxacarb in independent trials, conducted in the United States, approximating the critical GAP were (n= 12): < 0.01 (7), 0.01, 0.011, 0.022, 0.03 and 0.07 mg/kg.

The Meeting estimated a maximum residue level of 0.09 mg/kg, a STMR of 0.01 mg/kg for indoxacarb in dry bean.

The Meeting noted that the 2005 JMPR estimated maximum residue levels of 0.5 mg/kg for soya bean (dry) and 0.2 mg/kg for mung bean (dry). The 2009 JMPR estimated a maximum residue level of 0.1 mg/kg for cowpea (dry). On the basis of the previous recommendations and the GAP considered by the current Meeting for dry beans being different to the GAPs previously considered for cowpea, mung beans and soya bean, the current Meeting estimated a maximum residue level of 0.09 mg/kg and a STMR of 0.01 mg/kg for indoxacarb in the subgroup of dry beans, except cowpea, mung bean and soya bean.

*Root and tuber vegetables, Group of**Beetroot*

The critical GAP for beetroot is from the United States and consists of 4 foliar applications each at 123 g ai/ha with a RTI of 3 days and a PHI of 7 days.

Residues of indoxacarb, in independent trials, conducted in the United States, approximating the critical GAP were (n= 5): 0.12, 0.13, 0.18, 0.19 and 0.22 mg/kg.

The Meeting estimated a maximum residue level of 0.5 mg/kg, a STMR of 0.18 mg/kg and a HR of 0.22 mg/kg for indoxacarb in beetroots.

*Cereal grains, Group of**Maize cereals, Subgroup of*

The critical GAP for maize (field and popcorn) is from the United States and consists of 2 applications each at 123 g ai/ha with a RTI of 5 days and a PHI of 14 days.

Residues of indoxacarb in independent trials, conducted in the United States, approximating the critical GAP on field corn were (n= 21): < 0.01 (19), 0.011 and 0.012 mg/kg.

Noting that the registered use is on maize (field) and maize (popcorn) the Meeting decided to make a recommendation for the Subgroup of maize cereals. The Meeting estimated a maximum residue level of 0.015 mg/kg and a STMR of 0.01 mg/kg for indoxacarb in the subgroup of Maize cereals.

Tree nuts, Group of

The critical GAP for tree nuts is from the United States and consists of 3 foliar applications each at 123 g ai/ha with a RTI of 7 days and a PHI of 5 days. The residue trials were conducted with 3×0.757 kg ai/ha, applied as a soil treatment, followed by 3 foliar applications at 124 g ai/ha with the RTI and PHI reflecting the GAP. The Meeting considered that the soil applications would not contribute significantly to residue levels at harvest and the trials could be used to support the GAP.

Almond

Six trials were conducted in the United States at a rate of 3×0.757 g ai/ha (applied as a soil treatment) along with 3×124 g ai/ha applied as a foliar treatment.

Residues of indoxacarb in independent trials approximating the critical GAP were (n=6): < 0.01, 0.011, 0.013, 0.016, 0.022 and 0.023 mg/kg

Pecan

Six trials were conducted in the United States at a rate of 3×0.757 g ai/ha (applied as a soil treatment) along with 3×124 g ai/ha applied as a foliar treatment

Residues of indoxacarb in independent trials approximating the critical GAP were (n=6): < 0.01, 0.01, 0.019, 0.028, 0.033 and 0.034 mg/kg

Pistachios

Residues of indoxacarb in independent trials approximating the critical GAP were (n=5): < 0.01 (2), 0.011, 0.018 and 0.045 mg/kg (highest individual value 0.046 mg/kg).

Summary–Tree nuts

Nothing that the median residues of indoxacarb for each tree nut type are within a 5- fold range and that there is no evidence of a difference in the residue populations for the different tree nuts by the Kruskal-Wallis test, the Meeting decided to make a recommendation for the Group of tree nuts based on the combined data.

Residues of indoxacarb in independent trials approximating the critical GAP were (n= 17): < 0.01 (5), 0.011 (3), 0.013, 0.016, 0.019, 0.022, 0.023, 0.028, 0.033, 0.034 and 0.045 mg/kg (highest individual value 0.046 mg/kg).

The Meeting estimated a maximum residue level of 0.07 mg/kg, a STMR of 0.013 mg/kg and a HR of 0.046 mg/kg for indoxacarb in tree nuts.

Residues in animal feeds

Bean forage

The critical GAP for bean forage is from the United States and consists of 4 applications each at 123 g ai/ha with a RTI of 7 days and a PHI of 3 days.

Residues of indoxacarb in independent trials, conducted in the United States, approximating the critical GAP were (n= 8): 6.8, 9, 10 (2), 12, 16.5, 17.4 and 32 mg/kg.

The Meeting estimated a median residue of 11 mg/kg and a highest residue of 32 mg/kg for indoxacarb in bean forage.

Maize forage

The critical GAP for maize forage is from the United States and consists of 2 applications each at 123 g ai/ha with a RTI of 5 days and a PHI of 1 day.

Residues of indoxacarb in independent trials, conducted in the United States, approximating the critical GAP were (n= 21): 0.78, 1.1, 1.2, 1.3 (3), 1.5 (4), 1.6, 1.7, 1.8, 2.0, 2.3 (2), 2.6, 2.7 (2), 2.8 and 3.4 mg/kg.

The Meeting estimated a median residue of 1.6 mg/kg (as received) and a highest residue of 3.4 mg/kg (as received) for indoxacarb in maize forage.

Maize stover

The critical GAP for maize fodder is from the United States and consists of 2 applications each at 123 g ai/ha with a RTI of 5 days and a PHI of 14 day.

Residues of indoxacarb in independent trials, conducted in the United States, approximating the critical GAP were (n= 21): 0.96, 1.1 (2), 1.3 (2), 1.6, 1.7 (2), 1.9, 2.4, 2.8, 3.0, 3.5, 3.7 (2), 3.8, 3.9, 4.2, 5.1, 5.9 and 9.1 mg/kg.

The Meeting noted that the residue levels in maize stover were covered by the GAP considered by the 2005 JMPR for sweet corn stover with a median residue of 3.7 mg/kg and a highest residue of 9.8 mg/kg. The Meeting noted that the previous recommendation was for maize fodder (dry). Therefore, the Meeting estimated a Maximum residue level of 25 mg/kg for maize stover based on the GAP for sweet corn stover and withdrew the previous recommendation of 25 mg/kg (dry) for maize fodder (dry).

Almond hulls

The critical GAP for tree nuts is from the United States and consists of 3 applications each at 123 g ai/ha with a RTI of 7 days and a PHI of 5 days.

Six trials were conducted in the United States at a rate of 3×0.757 g ai/ha (applied as a soil treatment) along with 3×124 g ai/ha applied as a foliar treatment. The residue trials were conducted with 3×0.757 kg ai/ha, applied as a soil treatment, followed by 3 foliar applications at 124 g ai/ha with the RTI and PHI reflecting the GAP. The Meeting considered that the soil applications would not contribute significantly to residue levels at harvest and the trials could be used to support the GAP.

Residues of indoxacarb in independent trials, conducted in the United States, approximating the critical GAP were (n= 6): 1.8, 2, 2.5, 2.8, 3.0 and 3.8 mg/kg.

The Meeting estimated a median residue of 2.65 mg/kg, a highest residue of 3.8 mg/kg and a maximum residue level of 9 mg/kg (dry weight) in almond hulls.

Fate of residues during processing

The Meeting received new information on the fate of indoxacarb (and its R enantiomer) residues during processing in maize. The Meeting noted that the individual processing factors for each processed fraction were significantly different and therefore decided not to estimate processing factors, MRLs, STMR-P and HR-P for processed commodities.

Residues in animal commodities*Farm animal feeding studies*

The 2005 JMPR considered a lactating dairy cow feeding study and the 2009 JMPR considered a laying hen feeding study.

Farm animal dietary burden

Dietary burdens were calculated for beef cattle, dairy cattle, broilers and laying poultry based on the sum residue of indoxacarb and its R enantiomer and the feed items considered by the current Meeting and evaluated by the JMPR in 2005, 2007 and 2009. Some processed and forage commodities do not appear in the Recommendations Table (because no maximum residue level is needed), but they are used in estimating livestock dietary burdens.

The dietary burdens, estimated using the OECD diets listed in Appendix IX of the 2016 edition of the FAO Manual, are presented in Annex 6 of the 2022 JMPR Report and summarized below.

Table 5.20.1 Estimated maximum and mean dietary burdens of farm animals

	Animal dietary burden: indoxacarb (and its R enantiomer) ppm of dry matter diet							
	United States-Canada		European Union		Australia		Japan	
	Max	Mean	Max	Mean	Max	Mean	Max	Mean
Beef cattle	8.769	3.503	23.36	12.4	72.06 ^①	25.26 ^②	4.329	1.629
Dairy cattle	21.78	8.273	33.45	11.89	71.06 ^②	24.60 ^③	15.01	6.007
Poultry–broiler	0.094	0.094	0.04	0.037	0.06	0.06	0.009	0.099
Poultry–layer	0.094	0.094	0.705 ^④	0.182 ^⑤	0.06	0.06	0.022	0.012

Notes:

- ① Highest maximum beef cattle dietary burden suitable for MRL estimates for mammalian tissues.
- ② Highest maximum dairy cattle dietary burden suitable for MRL estimates for mammalian milk.

- ③ Highest mean beef or dairy cattle dietary burden suitable for STMR estimates for mammalian tissues.
- ④ Highest mean dairy cattle dietary burden suitable for STMR estimates for milk.
- ⑤ Highest maximum poultry dietary burden suitable for MRL estimates for poultry tissues and eggs.
- ⑥ Highest mean poultry dietary burden suitable for STMR estimates for poultry tissues and eggs.

Animal commodity maximum residue levels

Cattle

Table 5.20.2 Animal commodity maximum residue levels for cattle

	Feed Level (ppm) for milk and cream residues	Total residues (mg /kg) in milk	Total residues (mg /kg) in cream	Feed Level (ppm) for tissue residues	Total residues † (mg /kg)			
					Muscle	Liver	Kidney	Fat
MRL Determination (beef or dairy cattle) - based on parent + R-enantiomer								
Feeding Study	75	0.163	2.2	75	0.093	0.019	0.049	1.9
Dietary burden and estimate of MRL	71.1	0.155	2.1	72.1	0.089	0.018	0.047	1.83

Notes:

† Total residue determined as indoxacarb and its R enantiomer in accordance with the residue definition for compliance with MRLs.

Table 5.20.3 Animal commodity highest and median residues for cattle

	Feed Level (ppm) for milk and cream residues	Total residues (mg /kg) in milk	Total residues (mg /kg) in cream	Feed Level (ppm) for tissue residues	Total residues † (mg /kg)			
					Muscle	Liver	Kidney	Fat
HR Determination (beef or dairy cattle) based on parent + R + IN-JT333, expressed as parent								
Feeding Study	75	0.20	2.3	75	0.103	0.029	0.059	1.98
Dietary burden and estimate of highest residue	71.1	0.19	2.2	72.1	0.099	0.028	0.057	1.90
STMR Determination (beef or dairy cattle) based on parent + R + IN-JT333, expressed as parent								
Feeding Study	75	0.173	2.1	75	0.076	0.028	0.049	1.95
	22.5	0.062	0.589	22.5	< 0.01	< 0.01 **	0.027	0.48
Dietary burden and estimate of median residue	24.6	0.068	0.68	25.3	0.026	< 0.01	0.03	0.66

Notes:

† Total residue determined as indoxacarb, its R enantiomer and IN-JT333, expressed as indoxacarb in accordance with the residue definition for risk assessment.

** Residues < 0.01 mg/kg except for one sample.

Based on indoxacarb and its R enantiomer in milk, the Meeting estimated a maximum residue of 0.2 mg/kg for indoxacarb for milk, replacing the previous recommendation of 0.1 mg/kg. For cream, the

Meeting estimated a HR of 2.2 mg/kg based on the sum of indoxacarb and its R enantiomer. On the assumption of 40 percent milk fat in cream, the Meeting estimated a maximum residue level of 6 mg/kg for milk fats, replacing the previous recommendation of 2 mg/kg.

Based on indoxacarb and its R enantiomer in tissues, the Meeting estimated maximum residue levels of 2 mg/kg for mammalian meat (fat) and of 0.05 mg/kg for edible offal (mammalian), which confirms the previous recommendations made by the 2009 JMPR. For fat the Meeting estimated a maximum residue level of 2 mg/kg.

Based on the mean estimated residues of indoxacarb, its R isomer and the metabolite IN-JT333 in milk and tissues, the Meeting estimated STMRs of 0.07 for milk, of 0.15 mg/kg for mammalian meat, of 0.03 mg/kg for edible offal (mammalian) and of 0.66 mg/kg for mammalian fat. The Meeting estimated an STMR of 0.68 mg/kg for cream and on the assumption of a fat content of 40 percent estimated an STMR of 1.7 mg/kg for milk fats.

Based on the highest estimated residues of indoxacarb, its R isomer and the metabolite IN-JT333 in tissues, the Meeting estimated HR of 0.46 mg/kg for mammalian meat, of 0.06 mg/kg for edible offal (mammalian) and of 1.90 mg/kg for mammalian fat.

Poultry

The new feed items considered by the current Meeting did not contribute significantly to the dietary burden of poultry and the Meeting confirmed its previous recommendations.

RECOMMENDATIONS

On the basis of the data obtained from supervised trials, the Meeting concluded that the residue levels listed in Annex 1 are suitable for establishing maximum residue limits and for IEDI and international estimate of short-term intakes assessments.

Definition of the residue for compliance with the MRL and dietary risk assessment for plant commodities: *the sum of indoxacarb and its R enantiomer*

Definition of the residue for compliance with the MRL for animal commodities: *the sum of indoxacarb and its R enantiomer*

Definition of the residue for dietary risk assessment for animal commodities: *sum of indoxacarb, its R enantiomer and methyl 7-chloro-2,5-dihydro-2-[[[4-(trifluoromethoxy)phenyl]amino]carbonyl]indeno[1,2-e][1,3,4]oxadiazine-4a(3H)- carboxylate (IN-JT333), expressed as indoxacarb.*

The residue is fat-soluble.

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The ADI for indoxacarb is 0–0.01 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for indoxacarb were estimated for the 17 GEMS/Food Consumption Cluster Diets using the STMR or STMR-P values estimated by the JMPR. The results are shown in Annex 3 of the 2021 JMPR Report.

The IEDIs ranged from 2–20 percent of the maximum ADI. The Meeting concluded that long-term dietary exposure to residues of indoxacarb from uses considered by the JMPR is unlikely to present a public health concern.

Acute dietary exposure

The ARfD for indoxacarb is 0.1 mg/kg bw. The International Estimate of Short Term Intakes (international estimate of short-term intakes) for indoxacarb were calculated for the food commodities and their processed commodities for which HRs/HR-Ps or STMRs/STMR-Ps were estimated by the current Meeting and for which consumption data were available. The results are shown in Annex 4 of the 2022 JMPR Report.

The international estimate of short-term intake varied from 0–20 percent of the ARfD for children and 0–10 percent of the ARfD for the general population. The Meeting concluded that acute dietary exposure to residues of indoxacarb from uses considered by the current Meeting is unlikely to present a public health concern.

5.21 Inpyrfluxam (329)

TOXICOLOGY

Inpyrfluxam (code S-2399) is the ISO common name for the *R* enantiomer of 3-(difluoromethyl)-1-methyl-*N*-[(3*R*)-1,1,3-trimethyl-2,3-dihydro-1*H*-inden-4-yl]-1*H*-pyrazole-4-carboxamide (IUPAC) with the Chemical Abstracts Service number 1352994-67-2. Inpyrfluxam belongs to the pyrazole carboxamide group of fungicides. It acts as a succinate dehydrogenase inhibitor (SDHI) at complex II in the mitochondrial respiratory chain. Inpyrfluxam has not previously been evaluated by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) and was reviewed by the present Meeting at the request of the Codex Committee on Pesticide Residues (CCPR).

All critical studies contained statements of compliance with good laboratory practice (GLP) and were conducted in accordance with relevant national or international test guidelines, unless otherwise indicated. No additional information from a literature search was identified that complemented the toxicological information provided for the current evaluation.

Biochemical aspects

Following administration of [¹⁴C]inpyrfluxam to rats by gavage at a single dose of 1 or 150 mg/kg bw, or repeated doses of 1 mg/kg bw of radiolabelled material for 14 days, [¹⁴C]inpyrfluxam was rapidly and nearly completely absorbed (c 97 percent). Concentrations in plasma then declined slowly with half-lives ranging between 12 and 17 hours. Most of the absorbed [¹⁴C]inpyrfluxam was excreted in either urine (up to 59 percent in females) or bile (up to 73 percent in males) following all dosing regimens. In biliary excretion studies, less than 3 percent of the radioactivity was excreted in faeces. At 168 hours after oral administration, the tissue concentrations of radioactivity (including the carcass) were about 0.2 percent of the administered dose (AD).

Inpyrfluxam was extensively metabolized with over 40 metabolites detected respectively in urine, in bile and in faeces. The main routes of metabolism were *N*-demethylation, oxidation of the 1',1'-dimethyl group of the indane ring, followed by further oxidation to the carboxylic acid, and glucuronide conjugation. Major rat metabolites are: 1'-CH₂OH-S-2840, 1'-CH₂OH-S-2840A, 1'-CH₂OH-S-2840B, 1',1'-bis(CH₂OH)-S-2840, 1'-CH₂OH-3'-OH-S-2840, as well as the *N*-des-Me form of 1'-CH₂OH-S-2840.

In vitro comparative metabolism studies conducted with liver microsomes from humans, male and female rats, and male and female dogs showed that there were no qualitative differences between species (although quantitative differences were apparent), and there was no unique human metabolite.

Toxicological data

The acute oral median lethal dose (LD₅₀) for inpyrfluxam was 180 mg/kg bw, and the dermal LD₅₀ was greater than 2000 mg/kg bw in rats. The inhalation median lethal concentration (LC₅₀) of inpyrfluxam was greater than 2.61 mg/L in rats. Inpyrfluxam was not a skin or eye irritant, was not skin sensitizing, nor phototoxic.

In mice and rats adaptive changes were seen in the liver. Thyroid effects were also observed. Adrenal effects were seen in rats and dogs, with dogs the most sensitive species.

In a 13-week dietary study in mice, inpyrfluxam was administered at dietary concentrations of 0, 200, 800, 3500 or 7000 ppm (equal to 0, 27, 111, 491 and 973 mg/kg bw per day for males, 0, 32, 130, 559 and 1097 mg/kg bw per day for females). The no-observed-adverse-effect level (NOAEL) was

3500 ppm (equal to 491 mg/kg bw per day) on the basis of follicular cell hypertrophy in the thyroid at 7000 ppm (equal to 973 mg/kg bw per day).

In a 13-week dietary study in rats, inpyrfluxam was administered at dietary concentrations of 0, 150, 500, 2000 or 4000 ppm (equal to 0, 9.72, 31.7, 123 and 255 mg/kg bw per day for males, 0, 11.5, 37.5, 144 and 292 mg/kg bw per day for females). The NOAEL was 500 ppm (equal to 37.5 mg/kg bw per day) based on decreased body weight, increased cortical cell vacuolation in the adrenals and interstitial gland vacuolation in the ovaries of females at 2000 ppm (equal to 292 mg/kg bw per day).

In a 90-day oral capsule study in dogs, inpyrfluxam was administered at 0, 40, 160 or 700/500 mg/kg bw per day. The NOAEL of 40 mg/kg bw per day was based on zona fasciculata cell vacuolation in the adrenals of males at 160 mg/kg bw per day.

In a 12-month oral capsule study in dogs, inpyrfluxam was administered at 0, 2, 6, 30 or 160 mg/kg bw per day. The NOAEL was 6 mg/kg bw per day based on histopathological changes (zona fasciculata cell vacuolation) in the adrenal gland at 30 mg/kg bw per day.

Mechanistic studies were performed in rats and mice which demonstrated hepatic enzyme induction

In a carcinogenicity study in mice, inpyrfluxam was administered for 78 weeks at dietary concentrations of 0, 700, 2000 or 7000/5000 ppm (equal to 0, 77, 224 and 775 mg/kg bw per day for males, 0, 69, 210 and 701 mg/kg bw per day for females). The top dose level was initially set at 7000 ppm however, but due to severe effects on body weight it was reduced to 5000 ppm after one year. The NOAEL for toxicity was 700 ppm (equal to 69 mg/kg bw per day) based on an increase in centrilobular hepatocellular hypertrophy in males, amyloid nephropathy in both sexes, and an increase in the incidence of amyloidosis in cervical lymph nodes and glandular stomach in females at 2000 ppm (equal to 210 mg/kg bw per day). The compound was not carcinogenic up to 7000/5000 ppm, the highest dose tested (equal to 701 mg/kg bw per day).

In a 104-week dietary toxicity study, rats received inpyrfluxam at dietary concentrations of 0, 150, 500 or 1500/1000 in females (the top dose level being reduced at week 46). Males received 0, 150, 500 or 2000 ppm This was equal to 0, 5.85, 19.4 and 78.4 mg/kg bw per day for males, 0, 7.45, 25.5 and 65.9 mg/kg bw per day for females. The NOAEL for toxicity was 500 ppm (equal to 19.4 mg/kg bw per day), on the basis of decreased body weight gain and feed efficiency, haematological changes in both sexes, and decreased body weight in females at 1500/1000 ppm (equal to 65.9 mg/kg bw per day). The compound was not carcinogenic up to the highest dose tested, 1500/1000 ppm (equal to 65.9 mg/kg bw per day).

The Meeting concluded that inpyrfluxam is not carcinogenic in mice or rats.

Inpyrfluxam was tested for genotoxicity in an adequate range of in vitro and in vivo assays. No evidence of genotoxicity was found.

The Meeting concluded that inpyrfluxam is unlikely to be genotoxic.

In view of the lack of genotoxicity and the absence of carcinogenicity in mice and rats, the Meeting concluded that inpyrfluxam is unlikely to pose a carcinogenic risk to humans.

In a two-generation rat reproduction study, inpyrfluxam was administered over two consecutive generations at dietary concentrations of 0, 150, 500 or 1250 ppm for parental females (equal to 0, 10.9, 35.5 and 86 mg/kg bw per day), and 0, 150, 500 and 2000 ppm for parental males (equal to 0, 6.6, 22 and 93 mg/kg bw per day). The NOAEL for parental toxicity was 500 ppm (equal to 22 mg/kg bw per day), based on decreased body weights in females and decreased body weight gain in both sexes at the LOAEL

of 1250 ppm (equal to 86 mg/kg bw per day). The NOAEL for reproductive toxicity was 1250 ppm (equal to 86 mg/kg bw per day) the highest dose tested. The NOAEL for offspring toxicity was also 500 ppm, estimated as approximately 22 mg/kg bw per day, based on decreased mean body weight of pups at 1250 ppm (estimated at 86 mg/kg bw per day).

In a developmental toxicity study in rats, inpyrfluxam was administered orally, via gavage, at doses of 0, 10, 25 or 80 mg/kg bw per day from gestation days (GDs) 6–19. The maternal NOAEL was 25 mg/kg bw per day, based on decreased adjusted body weight in dams at 80 mg/kg bw per day. The embryo/fetal NOAEL was 25 mg/kg bw per day, based on decreased mean body weights of fetuses at 80 mg/kg bw per day. Based on a single incidence of cyclopia observed at 80 mg/kg bw per day a follow-up study was conducted at 0 and 90 mg/kg bw per day. This fetal abnormality was not evident in the second study at 90 mg/kg bw per day.

In a developmental toxicity study in rabbits, inpyrfluxam was administered orally, via gavage, at doses of 0, 20, 60 or 200 mg/kg bw per day from GDs 6–27. The maternal NOAEL was 60 mg/kg bw per day based on decreased body weight gains, decreased mean food consumption and maternal abortion seen at 200 mg/kg bw per day. The NOAEL for embryo/fetal toxicity was 200 mg/kg bw per day, the highest tested dose.

The Meeting concluded that inpyrfluxam is not teratogenic.

In an acute neurotoxicity study in rats inpyrfluxam was administered by gavage at doses of 0, 30, 100 or 200 mg/kg bw. The NOAEL for systemic toxicity was 30 mg/kg bw based on reduced motor activity and body temperature at 100 mg/kg bw. The NOAEL for neurotoxicity was 200 mg/kg bw, the highest dose tested.

A subchronic neurotoxicity study was carried out in rats in which inpyrfluxam was administered at dietary concentrations of 0, 500, 2000 or 4000 ppm for males (equal to 0, 30.0, 118.9 and 240 mg/kg bw per day), and 0, 500, 1000 or 2000 ppm for females (equal to 0, 35.2, 68 and 133 mg/kg bw per day). The NOAEL for neurotoxicity was 2000 mg/kg bw (equal to 133 mg/kg bw per day), the highest dose tested. The NOAEL for systemic toxicity was 500 ppm (equal to 35.2 mg/kg bw per day) based on decreased body weight and food consumption at 1000 ppm (equal to 68 mg/kg bw per day).

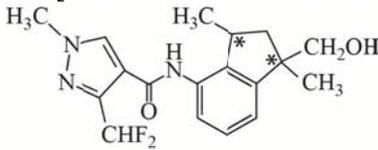
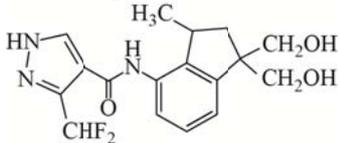
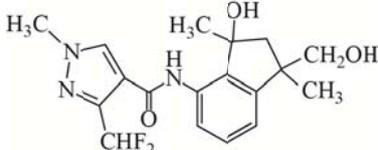
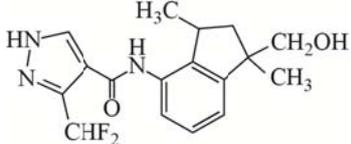
The Meeting concluded that inpyrfluxam is not neurotoxic.

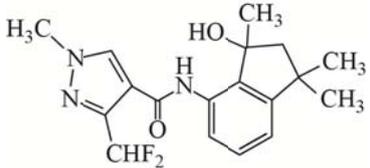
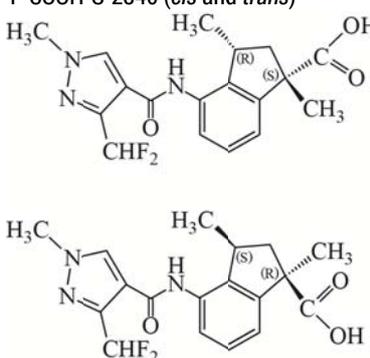
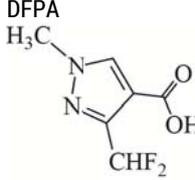
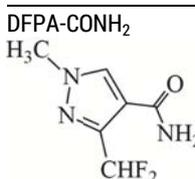
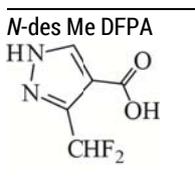
Inpyrfluxam's ability to interact with the estrogen, androgen and steroidogenesis pathways was investigated in two in vitro studies, and no effects were observed.

Toxicological data on metabolites and/or degradates

The metabolites of inpyrfluxam are summarized in the table below.

Summary overview of toxicological characterization of plant/livestock metabolites

Compound, codes and structure	Rat ADME Toxicity covered by toxicological properties of parent (>10 percent AD in rat biofluids or 10 percent TRR)?	Genotoxicity assessment (data, QSAR, read-across)	General toxicity	HBGV
<p>1'-CH₂OH-S-2840, 1'-CH₂OH-S-2840A and 1'-CH₂OH-S-2840B</p>  <p>All stereoisomers of above; differ only in disposition around two centres of chirality marked *</p>	<p>Yes Present in bile at 29 percent, (glucuronide form) in males and 14.5 percent in females Detected in plasma, liver and kidney In vitro metabolism; 36 percent in human, 41 percent in male rat, 16 percent in male dog, 11 percent in female dog</p>	Not genotoxic	Covered by parent	Covered by parent
<p>1',1'-bis(CH₂OH)-S-2840</p> 	<p>Yes Urine; 11 percent in males, 6.1 percent in females</p>	No	Covered by parent	Covered by parent
<p>1'-CH₂OH-3'-OH-S-2840</p> 	<p>Yes Bile as mixture with <i>N</i>-des-Me-1'-CH₂OH-S-2840, at up to 20.2 percent in males, 21.1 percent in females</p>	No	Covered by parent	Covered by parent
<p><i>N</i>-des-Me-1'-CH₂OH-S-2840</p> 	<p>Yes Urine at 7.3 percent in females Bile as mixture with 1'-CH₂OH-3'-OH-S-2840 at up to 20.2 percent in males, 21.1 percent in females</p>	No	Covered by parent	Covered by parent

Compound, codes and structure	Rat ADME Toxicity covered by toxicological properties of parent (>10 percent AD in rat biofluids or 10 percent TRR)?	Genotoxicity assessment (data, QSAR, read-across)	General toxicity	HBGV
3'-OH-S-2840 	No Detected in plasma, liver and kidney in male rats Less than 10 percent in vitro metabolism in rats and humans, <5 percent in dogs	Negative in a range of in vivo and in vitro tests	LD ₅₀ in rats >2000 mg/kg bw 90-day dietary study in rats, at 0, 500, 2000 or 4000 ppm (= 0, 32.2, 128 and 258 mg/kg bw/day for males, 0, 37.9, 157 and 291 mg/kg bw/day for females) NOAEL 500 ppm (32.2 mg/kg bw/day) based on decreased body weight and histopathological changes in liver, ovary and adrenal at 2000 ppm	Covered by parent.
1'-COOH-S-2840 (<i>cis</i> and <i>trans</i>) 	Yes Urine; up to 15 percent in males, 10.5 percent in females Detected in plasma, liver and kidney	Negative in a range of in vivo and in vitro tests	LD ₅₀ >2000 mg/kg bw Considered similar to parent	Covered by parent
DFPA 	No	No QSAR alerts not produced by parent	No data	Cramer class III TTC 1.5 µg/kg bw per day
DFPA-CONH ₂ 	No	No QSAR alerts not produced by parent	No data	Cramer class III TTC 1.5 µg/kg bw per day
N-des Me DFPA 	No	No QSAR alerts not produced by parent	No data	Cramer class III TTC 1.5 µg/kg bw per day

Microbiological data

There was no information available in the public domain and no experimental data were provided that addressed the possible impacts of inpyrfluxam residues on the human intestinal microbiome.

Human data

No information was provided on the health of workers involved in the manufacture or use of inpyrfluxam.

The Meeting concluded that the existing database on inpyrfluxam was adequate to characterize the potential hazards to the general population, including fetuses, infants and children

Toxicological evaluation

The Meeting established an acceptable daily intake (ADI) of 0–0.06 mg/kg bw based on the NOAEL of 6 mg/kg bw per day in the one-year dog study and using a safety factor of 100.

The Meeting established an acute reference dose (ARfD) of 0.3 mg/kg bw based on the NOAEL of 30 mg/kg bw in the acute neurotoxicity study in rats and using a safety factor of 100.

A toxicological monograph was prepared.

Levels relevant to risk assessment of inpyrfluxam

Species	Study	Effect	NOAEL	LOAEL
Mouse	78-week carcinogenicity ^a	Toxicity	700 ppm, equal to 69 mg/kg bw/day	2000 ppm, equal to 210 mg/kg bw/day
		Carcinogenicity	7000/5000 ppm equal to 701 mg/kg bw/day ^d	-
Rat	104-week toxicity and carcinogenicity ^a	Toxicity	500 ppm equal to 19.4 mg/kg bw/day	1500/1000 ppm (equal to 65.9 mg/kg bw/day)
		Carcinogenicity	1500/1000 ppm equal to 65.9 mg/kg bw/day ^d	-
	Two-generation reproductive toxicity study ^a	Reproduction/fertility	1250 ppm equal to 86 mg/kg bw/day ^d	-
		Parental toxicity	500 ppm equal to 22 mg/kg bw/day	1250 ppm equal to 86 mg/kg bw/day
		Offspring toxicity	500 ppm estimated at 22 mg/kg bw per day	1250 ppm estimated at 86 mg/kg bw/day
	Developmental toxicity study ^b	Maternal toxicity	25 mg/kg bw/day	80 mg/kg bw/day
		Developmental toxicity	25 mg/kg bw/day	80 mg/kg bw/day
	Acute oral neurotoxicity study ^b	Systemic toxicity	30 mg/kg bw	100 mg/kg bw
		Neurotoxicity	200 mg/kg bw	-
	90-day neurotoxicity study ^b	Systemic toxicity	500 ppm equal to 35.2 mg/kg bw/day	1000 ppm equal to 68 mg/kg bw/day
Neurotoxicity		2000 ppm equal to 133 mg/kg bw/day ^d	-	
Rabbit	Developmental toxicity study ^b	Maternal toxicity	60 mg/kg bw/day	200 mg/kg bw/day
		Developmental toxicity	200 mg/kg bw/day ^d	-

Dog	1-year toxicity study ^c	Toxicity	6 mg/kg bw/day	30 mg/kg bw/day
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Notes:

- ^a Dietary administration.
^b Gavage administration.
^c Gelatine capsule administration.
^d Highest dose tested.

Acceptable daily intake (ADI)*

0–0.06 mg/kg bw

Acute reference dose (ARfD)*

0.3 mg/kg bw

* Applies to inpyrfluxam, 1'-CH₂OH-S-2840 (free or conjugated), 1'-CH₂OH-S-2840A, 1'-CH₂OH-S-2840B, 1',1'-bis(CH₂OH)-S-2840, 1'-CH₂OH-3'-OH-S-2840, 3'-OH-S-2840 and 1'-COOH-S-2840

Information that would be useful for the continued evaluation of the compound

Results from epidemiological, occupational health and other such observational studies of human exposure.

Critical end-points for setting guidance values for exposure to inpyrfluxam**Absorption, distribution, excretion, and metabolism in mammals**

Rate and extent of oral absorption	Fast; T_{max} c 1 hour: almost entirely absorbed (c 97 percent)
Dermal absorption	No data available
Distribution	Distributed according to relative organ blood flow; highest amounts in liver, kidney, adrenals and heart
Rate and extent of excretion	Urinary and faecal elimination via the bile (c 97 percent); urinary excretion (up to 59 percent)
Potential for accumulation	No evidence of accumulation
Metabolism in mammals	Extensively metabolized. Main routes: <i>N</i> -demethylation, oxidation of the 1',1'-dimethyl group of the indane ring followed by further oxidation to carboxylic acid, and glucuronide conjugation Major metabolites: 1'-CH ₂ OH-S-2840 (and its conjugates), 1'-CH ₂ OH-S-2840A, 1'-CH ₂ OH-S-2840B, 1',1'-bis(CH ₂ OH)-S-2840, 1'-CH ₂ OH-3'-OH-S-2840
Toxicologically significant compounds (animals, plants, and the environment)	Inpyrfluxam, 1'-CH ₂ OH-S-2840 (free or conjugated), DFPA, DFPA-CONH ₂ , <i>N</i> -desmethyl-DFPA

Acute toxicity

Rat LD ₅₀ oral	50 < LD ₅₀ < 300mg/kg bw 180 mg/kg bw
Rat LD ₅₀ dermal	> 2000 mg/kg bw
Rat LC ₅₀ inhalation	> 2.61 mg/L air analytically determined (maximum attainable concentration)
Rabbit, skin irritation	Non-irritating

Rabbit, eye irritation	Mildly irritating
Guinea pig, skin sensitization	Non-sensitizing (Magnusson & Kligmann)
Short-term studies of toxicity	
Target/critical effect	Thyroid follicular cell hypertrophy (mouse) Vacuolization in adrenals (rat, dog) and ovaries (rat)
Lowest relevant oral NOAEL	6 mg/kg bw per day (dog)
Lowest relevant inhalation NOAEC	No data
Long-term studies of toxicity and carcinogenicity	
Target/critical effect	Systemic amyloidosis (mouse) Reduced body weights, feed efficiency, haematological changes (rat)
Lowest relevant oral NOAEL	19.4 mg/kg bw per day (rat)
Carcinogenicity	Not carcinogenic
Genotoxicity	Unlikely to be genotoxic
Reproductive toxicity	
Reproduction target/critical effect	Reduced body weight (gains) in parental animals and pups
Lowest relevant parental NOAEL	500 ppm (equal to 22 mg/kg bw per day)
Lowest relevant offspring NOAEL	500 ppm (approximately equivalent to 22 mg/kg bw per day)
Lowest relevant reproductive NOAEL	1250 ppm (equal to 86 mg/kg bw per day)
Developmental target/critical effect	Maternal: body weights (rat, rabbit), feed consumption and abortions (rabbit) Embryo/fetal: fetal body weights (rat)
Lowest relevant maternal NOAEL	25 mg/kg bw per day (rat)
Lowest relevant embryo/fetal NOAEL	25 mg/kg bw per day (rat)
Neurotoxicity	
Acute neurotoxicity NOAEL	200 mg/kg bw, the highest dose tested (rat)
Subchronic neurotoxicity NOAEL	90-day NOAEL: 133 mg/kg bw per day, highest dose tested (rat)
Developmental neurotoxicity	No data
Other toxicological studies	
Endocrine disruption potential	No effect in vitro on estrogen, androgen or steroidogenesis pathways
Mechanism studies	Effects on liver and thyroid in rodents may be related to hepatic enzyme induction
Studies on toxicologically relevant metabolites	
3'-OH-S-2840 and 1'-COOH-S-2840	Acute oral LD ₅₀ > 2000 mg/kg bw (rat)
3'-OH-S-2840	90-day oral NOAEL: 500 ppm equal to 32.2 mg/kg bw per day (rat)
3'-OH-S-2840 and 1'-COOH-S-2840	Negative reverse mutation test in bacterial systems Negative mammalian cell gene mutation Negative chromosome aberration
Microbiological data	No data available
Human data	Limited information; inpyrfluxam is a new substance

Summary

	Value	Study	Safety factor
ADI ^a	0–0.06 mg/kg bw	One-year study (dog)	100
ARfD ^a	0.3 mg/kg bw	Acute neurotoxicity study (rat)	100

Notes:

^a Applies to inpyrfluxam, 1'-CH₂OH-S-2840 (free or conjugated), 1'-CH₂OH-S-2840A, 1'-CH₂OH-S-2840B, 1',1'-bis(CH₂OH)-S-2840, 1'-CH₂OH-3'-OH-S-2840, 3'-OH-S-2840 and 1'-COOH-S-2840.

RESIDUE AND ANALYTICAL ASPECTS

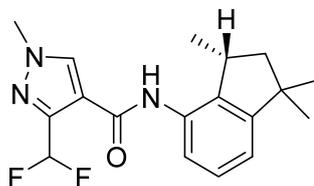
Inpyrfluxam is a broad spectrum fungicide belonging to the succinate dehydrogenase inhibitor (SDHI) group of fungicides, which mode of action involves inhibition of energy production processes in pathogenic fungi.

Inpyrfluxam has not previously been evaluated by JMPR and was scheduled at the Fifty-first Session of the CCPR (2019) for toxicology and residue evaluation as a new compound by the 2022 JMPR.

The Meeting received information on identity, physical-chemical properties, plant and animal metabolism, analytical methods, storage stability, use patterns, residues resulting from supervised trials, fate of residues in succeeding crops, fate of residues during processing and livestock feeding studies.

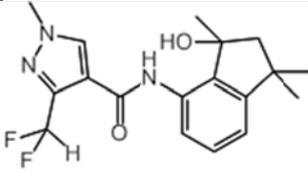
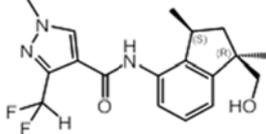
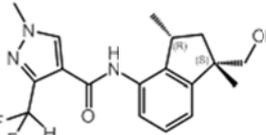
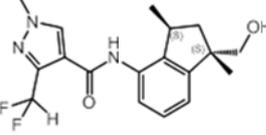
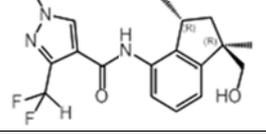
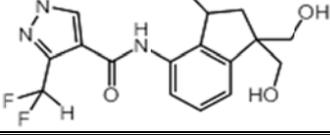
All critical studies contained statements of compliance with GLP and were conducted in accordance with relevant national or international test guidelines, unless otherwise specified.

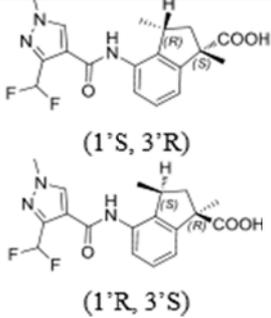
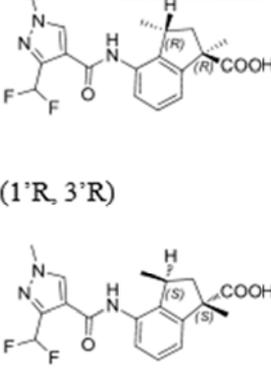
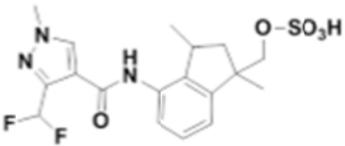
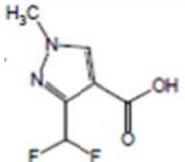
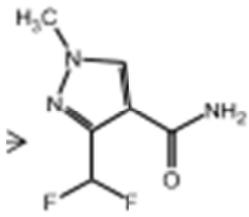
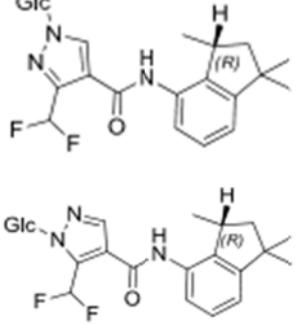
Inpyrfluxam (S-2399) is the ISO-approved common name for 3-(Difluoromethyl)-1-methyl-*N*-[(3*R*)-1,1,3-trimethyl-2,3-dihydro-1*H*-inden-4-yl]-1*H*-pyrazole-4-carboxamide with the CAS number 1352994-67-2.

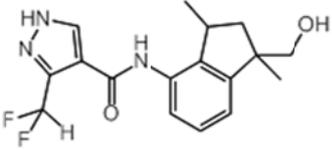
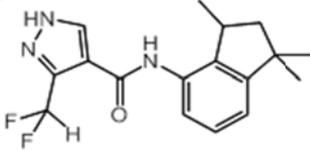
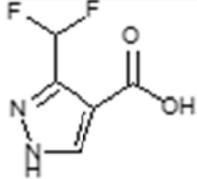


The abbreviations, chemical names, and structures discussed in the appraisal are summarized in Table 5.21.1.

Table 5.21.1 Abbreviations for the relevant compounds referred to in this document

Compound code (other names)	Name and matrix	Structure
Parent MW: 333.38	3-(Difluoromethyl)-1-methyl-N-[(3 <i>R</i>)-1,1,3-trimethyl-2,3-dihydro-1 <i>H</i> -inden-4-yl]-1 <i>H</i> -pyrazole-4-carboxamide Found in: plants (apple, soya, rice, potato, lettuce (RC), radish (RC), sorghum (RC)), animals (milk, goat tissues, eggs, hen tissues), environment (soil) MW: 333.38	
3'-OH-S-2840 MW: 349.4	3-(Difluoromethyl)-N-[3'-hydroxy-1',1',3'-trimethyl-2',3'-dihydro-1 <i>H</i> -inden-4-yl]-1-methyl-1 <i>H</i> -pyrazole-4-carboxamide Found in: plants (Apple, Soya forage, Soya hay, Soya pods, Soy beans, Immature rice, Rice straw, Rice hulls, Rice grain, Potato, Lettuce (RC), Radish (RC), Sorghum (RC)), animals (Hen eggs, Hen fat, Ruminant kidney, Ruminant fat), environment (Soil, Water)	
1'-CH ₂ OH-S-2840 MW: 366.4	Found in: plants (Potato), animals (Hen eggs, Hen liver, Hen muscle, Hen fat, Ruminant skimmed milk, Milk fat, Ruminant liver, Ruminant kidney, Ruminant muscle, Ruminant fat), environment (soil)	See below
1'-CH ₂ OH-S-2840A MW: 366.4	Found in: plants (Rice, Potato, Lettuce (RC), Radish (RC), Sorghum (RC)), animals (Goat tissues, Eggs, Hen tissues), environment (soil)	 
1'-CH ₂ OH-S-2840B MW: 366.4	Found in: plants (Apple, Soya, Rice, Potato, Lettuce (RC), Radish (RC), Sorghum (RC)), animals (Milk, Goat tissues, Eggs, Hen tissues), environment (soil)	 
1',1'-bis(CH ₂ OH)-S-2840 MW: 351.35	Found in: animals (Goat tissues)	

Compound code (other names)	Name and matrix	Structure
1'-COOH-S-2840 A MW: 363.4	Found in: plants (Potato, Lettuce (RC), Radish (RC), Sorghum (RC)), animals (Milk, Goat tissues, Eggs, Hen tissues), environment (soil)	 <p>(1'S, 3'R)</p> <p>(1'R, 3'S)</p>
1'-COOH-S-2840B MW: 363.4	Found in: plants (Potato, Lettuce (RC), Radish (RC), Sorghum (RC)), animals (Milk, Goat tissues, Eggs, Hen tissues), environment (soil)	 <p>(1'R, 3'R)</p> <p>(1'S, 3'S)</p>
1'-CH ₂ OH-S-2840-sulfate (sum of isomers) MW: 429.44	Found in: animals (Eggs, Hen tissues),	
DFPA MW: 176.12	3-(Difluoromethyl)-1-methyl-1H-pyrazole-4-carboxylic acid Found in: plants (Potato, Lettuce (RC), Radish (RC), Sorghum (RC)), animals (Goat tissues), environment (Soil, Water)	
DFPA-CONH ₂ MW: 175.1	3-(Difluoromethyl)-1-methyl-1H-pyrazole-4-carboxamide. Found in: plants (Rice, Lettuce (RC), Radish (RC), Sorghum (RC)), animals (Milk, Goat tissues, Eggs, Hen tissues), environment (Water)	
Glc-NDM-inpyrfluxam (sum of isomer) MW: 481.20	Found in: plants (Soya)	

Compound code (other names)	Name and matrix	Structure
Gly- 1'-CH ₂ OH-S-2840	Found in: animals (Immature rice, rice straw, rice hulls, rice grain)	Structure not elucidated.
N-des-Me-1'-CH ₂ OH-S-2840 MW: 335.35	Found in: Lettuce (RC), Radish (RC), Sorghum (RC)	
N-des-Me-S-2840 MW: 319.36	Found in: plants (Soya, Rice, Lettuce (RC), Radish (RC), Sorghum (RC)), animals (Eggs, hen tissues), environment (Soil)	
N-DesMet-pyrazole carboxylic acid (N-des-Me-DFPA) MW: 162.1	3-(Difluoromethyl)-1H-pyrazole-4-carboxylic acid AS238la Found in: plants (Soya, Rice, Potato, Lettuce (RC), Radish (RC), Sorghum (RC)), environment (Soil)	

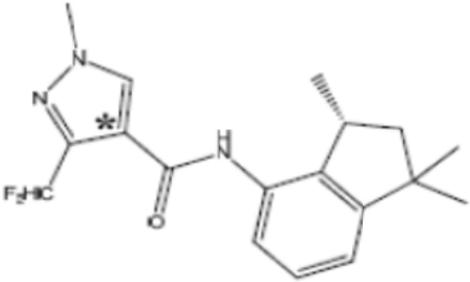
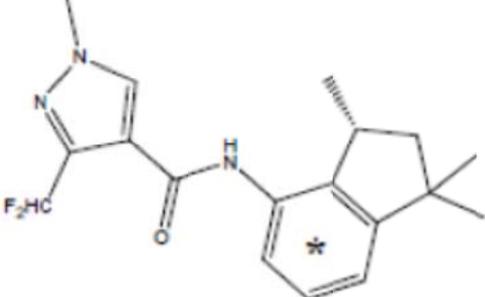
Physical chemical properties

Inpyrfluxam is not soluble in water (0.0164 g/L at 20 °C), but is soluble in acetone (621 g/L), methanol (368 g/L) and ethyl acetate 396 g/L). Inpyrfluxam is hydrolytically and photolytically stable. The compound has a LogPow of 3.65 suggesting potential accumulation in fat and a vapour pressure of 1.2×10^{-7} Pa at 25 °C suggesting that the compound is not volatile.

Plant metabolism

The Meeting received plant metabolism studies for inpyrfluxam in apple (fruit), soya bean and rapeseed (pulse and oilseed crops), maize, sorghum and rice (cereal crops) and potato (root crop). Inpyrfluxam was applied using either [pyrazolyl-4-¹⁴C]-inpyrfluxam or [phenyl-U-¹⁴C]-inpyrfluxam. In metabolism studies, total radioactive residues (TRR) are expressed in mg inpyrfluxam equivalents/kg.

Table 5.21.2 Overview of the different labels used in the plant metabolism studies

	
[Pyrazolyl-4- ¹⁴ C]-inpyrfluxam used in all primary metabolism studies.	[Phenyl-U- ¹⁴ C]-inpyrfluxam used in all primary metabolism studies.

The use patterns received include foliar application (apples, soya, sugar beet, rice and peanut), broadcast granular application (rice) and seed treatment (soya, sugar beet, rice, maize).

Apple

The metabolic fate of [pyrazolyl-4-¹⁴C]-inpyrfluxam and [phenyl-U-¹⁴C]-inpyrfluxam was investigated in apples following three foliar applications with approximate 10-day intervals 35, 24 and 14 days before harvest (BBCH stage not specified in the report) at an actual rate of 214–221 g ai/ha each.

Samples of apple fruits were collected 14 days after the final application. Fruits were rinsed with acetonitrile and separated into peel and flesh before homogenization. Processed samples were extracted twice with acetonitrile:water (1:1) and once with acetonitrile.

Extracted radioactivity was similar in both labels ranging between 95.9–96.3 percent TRR (0.25–0.3 mg eq/kg) in whole fruit (including apple rinse). The PES accounted for 3.6–4 percent TRR (0.01–0.011 mg eq/kg) and were not further analysed. The majority of radioactivity was recovered in the fruit rinse (58–64 percent TRR, 0.14–0.19 mg eq/kg) and peel (17–22 percent TRR, 0.052–0.055 mg eq/kg). Radioactivity in the flesh was markedly lower than in the peel for both treatment groups.

The major component identified was inpyrfluxam, representing 78–79 percent of the TRR (0.19–0.24 mg /kg). Minor metabolites identified were 3'-OH-S-2840 (11.5 percent TRR, 0.035 mg eq/kg) and 1-CH₂OH-S-2840 (5.6 percent TRR, 0.014 mg eq/kg).

Soya bean

The metabolic fate of [pyrazolyl-4-¹⁴C]-inpyrfluxam and [phenyl-U-¹⁴C]-inpyrfluxam was investigated in outdoor soya beans following two foliar applications with a 36-day interval (at BBCH 60 and 75) at actual rates 107–113 g ai/ha each.

Samples of soya bean forage and hay were collected 20 and 33 days after the final application as follows:

Forage was harvested at BBCH 75 and left to dry to soya bean hay, immature pods were taken at BBCH 77 and mature pods were taken at BBCH 89. Samples were separated into pods and seeds and a portion of mature bean pods were rinsed (with acetonitrile) before homogenization.

Homogenized samples were extracted twice with acetonitrile:water, and once with acetonitrile. The post-extraction solids (PES) were further submitted to either acidic or alkaline hydrolysis to release plant natural components (e.g. pectin (lignin, hemicellulose and cellulose).

Extracted radioactivity was similar in both labels being 100 percent TRR (1.71–2.37 mg eq/kg) in hay ranging between 99.8–99.9 percent TRR (1.39–1.5 mg eq/kg) in forage, 72.7–96.35 percent TRR (0.016–0.1 mg eq/kg) in immature seed, 100 percent TRR (0.61–0.71 mg eq/kg) in immature seed, 65.8–95.4 percent TRR (0.023–0.2 mg eq/kg) in mature pods and 92.5–94.6 percent TRR (0.59–1.04 mg eq/kg) in mature seeds.

Unextracted residues after hydrolysis accounted for 4.1–36.8 percent TRR (0.009–0.014 mg eq/kg) only for mature seeds and were not further characterized.

Parent inpyrfluxam was extensively metabolized in soya beans accounting for the major part of the residue in forage samples (40.3–50.5 percent TRR, 0.56–0.79 mg/kg) but declined as the plant matured. Residues of inpyrfluxam in hay were between 0.42–0.49 mg/kg (17.8–22.1 percent TRR), in immature pods levels ranged from 0.24–0.41 mg/kg (34–65.2 percent TRR) and in mature pods levels

ranged from 0.13–0.22 mg/kg (10.9–29.2 percent TRR), including the surface rinse fraction. Only trace levels of inpyrfluxam residues were detected in the soya bean seeds.

In forage, 3'-OH-S-2840 was present at the highest levels (15.3–22.1 percent TRR, 0.24–0.31 mg eq/kg), whilst 1'-CH₂OH-S-2840 was identified but in low levels below 3.7 percent TRR (0.058 mg eq/kg).

In hay, 3'-OH-S-2840 was present at the highest levels (14.3–14.7 percent TRR, 0.32–0.35 mg eq/kg), whilst *N*-des-Me-S-2840 was detected at low levels (\leq 2.4 percent TRR, 0.05 mg eq/kg). Also the metabolites 1'-CH₂OH-S-2840 (free and conjugated) and Glc-NDM-inpyrfluxam, were detected at minor levels.

In immature pods, metabolites 3'-OH-S-2840, *N*-des-Me-S-2840 and 1'-CH₂OH-S-2840 were found below 10 percent TRR but at levels up to 0.065 mg eq/kg, 0.042 mg eq/kg and 0.026 mg eq/kg respectively.

In immature seeds, *N*-DesMet-pyrazole carboxylic acid and *N*-des-Me-S-2840 were detected at levels below 10 percent TRR ($<$ 0.01 mg eq/kg). The majority of the residue (61.6 percent TRR, 0.067 mg eq/kg) was characterized as multiple polar components with a single component representing 4.6 percent TRR (0.005 mg eq/kg).

In mature pods, 3'-OH-S-2840 was identified as the most dominant metabolite at 11.6 percent TRR (0.086 mg eq/kg), whilst *N*-des-Me-S-2840 (3.9 percent TRR; up to 0.029 mg eq/kg) and 1'-CH₂OH-S-2840 (2.8 percent TRR; up to 0.021 mg eq/kg) were also characterized at lower levels. In the [pyrazolyl-¹⁴C] label, polar components were present at high levels (48.9 percent TRR, 0.59 mg eq/kg), with the highest component being no greater than 2.1 percent TRR (up to 0.032 mg eq/kg).

In mature seed, *N*-DesMet-pyrazole carboxylic acid (conjugated), was detected (17.5 percent TRR, 0.038 mg eq/kg). Metabolites 3'-OH-S-2840, Glc-NDM-inpyrfluxam and 1'-CH₂OH-S-2840 were detected at low levels ($<$ 10 percent TRR; \leq 0.001 mg eq/kg). The major fraction contained unretained polar components (11.7–63.8 percent TRR, 0.004–0.140 mg eq/kg).

Rice–foliar treatment

The metabolic fate of [pyrazolyl-4-¹⁴C] inpyrfluxam and [phenyl-U-¹⁴C]inpyrfluxam was investigated in outdoor rice following one foliar applications at actual rates 95–108.1 g ai/ha, 28 days (at BBCH 77) before normal commercial harvest.

Samples of the immature whole plant (BBCH not specified) were taken for analysis 14 days after application. Samples of rice heads and straw were collected 28 days after application (at normal commercial harvest). Rice heads were separated into husked rice and hulls.

Homogenized samples were extracted twice with acetonitrile:water and once with acetonitrile. The PES were further submitted to either acidic or alkaline hydrolysis.

Extracted radioactivity was similar in both labels, ranging between 99.3–99.7 percent TRR (0.29–0.37 mg eq/kg) in immature rice, 97.4–99.3 percent TRR (0.84–1.44 mg eq/kg) in straw, 96.9–98 percent TRR (1.4–1.5 mg eq/kg) in hulls and 95.3–95.9 percent TRR (0.063–0.047 mg eq/kg) in husked rice.

Unextracted residues after hydrolysis accounted for 0.6–3.2 percent TRR (0.002–0.054 mg eq/kg).

In immature rice plants, the only major component for both radiolabels detected in the neutral extract was parent inpyrfluxam, present at 81.2–86.7 percent TRR (0.25–0.31 mg/kg). The metabolite, 3'-OH-S-2840 was detected between 5.6–7.1 percent TRR (0.016–0.027 mg eq/kg), with trace levels of *N*-

des-Me-S-2840 and 1'-CH₂OH-S-2840 (two isomers) also detected in both labelled extracts. The acidic acetonitrile extracts for both labels contained predominantly parent (2.5–3.4 percent TRR, 0.007–0.013 mg/kg).

In husked rice, inpyrfluxam accounted for 60.6–78.6 percent TRR (0.038–0.039 mg/kg). Metabolites 3'-OH-S-2840 and Gly-1'-CH₂OH-S-2840 were also detected but at ≤ 0.01 mg eq/kg (up to 16 percent TRR).

In straw, inpyrfluxam was present as the major residue (67.7–77.8 percent TRR, 0.58–0.72 mg/kg). Metabolites 3'-OH-S-2840 (up to 12 percent TRR; 0.102 mg eq/kg), Gly-1'-CH₂OH-S-2840 (5.2 percent TRR; 0.040 mg eq/kg) and DFPA-CONH₂ (4.6 percent TRR; 0.039 mg eq/kg) were also present.

In rice hulls, residues were characterized as a mixture of inpyrfluxam at 52.5–41.8 percent TRR (0.64–0.88 mg/kg), 1'-CH₂OH-S-2840 at 18–33.9 percent TRR (0.52–0.28 mg eq/kg) and 3'-OH-S-2840 at 6–12 percent TRR (0.055–0.1 mg eq/kg) respectively.

Rice-granular treatment

The metabolic fate of [pyrazolyl-4-¹⁴C] inpyrfluxam and [phenyl-U-¹⁴C]inpyrfluxam was also investigated in rice grown in trays and transplanted at the 4 leaf stage of growth in outdoor plots. Inpyrfluxam was applied following one granular treatment at BBCH 13-14 at actual rate 400 g ai/ha.

Immature rice plants were harvested 30 days after treatment (BBCH 30) and mature rice plants were harvested 132 days after treatment (BBCH 89) and were separated into straw, hulls and husked rice.

Homogenized samples were extracted twice with acetonitrile:water and once with acetonitrile and PES were further submitted to either acidic or alkaline hydrolysis.

Extracted radioactivity was similar in both labels, being 100 percent TRR (1.9–3.9 mg eq/kg) in immature rice, 100 percent TRR (1.07–1.58 mg eq/kg) in straw, ranging from 91.1–93.2 percent TRR (0.14–0.16 mg eq/kg) in hulls and 40.4–55.6 percent TRR (0.005–0.006 mg eq/kg). Unextracted residues after hydrolysis accounted for 6.9 percent TRR (0.012 mg eq/kg) in hulls and 60 percent TRR (0.009 mg eq/kg) in husked rice but were not further identified.

In immature rice plants, parent inpyrfluxam accounted for a large proportion of the residues at 20–38.2 percent TRR (0.72–0.78 mg/kg). In addition, 1'-CH₂OH-S-2480 (5.8–6.2 percent TRR, 0.11–0.24 mg eq/kg), 3'-OH-S-2840 (1.2–3.6 percent TRR, 0.023–0.14 mg eq/kg) and DFPA-CONH₂ (2.2 percent TRR, 0.086 mg eq/kg) were identified. Glycosidic derivative of 1'-CH₂OH-S-2840, was present at 16.8–26.0 percent TRR (0.32–1.01 mg eq/kg).

In straw, parent inpyrfluxam accounted for 1.9–2.8 percent TRR (0.03 mg eq/kg). The major part of the residue was metabolite 1'-CH₂OH-S-2840 and its glycosidic derivatives (57.4–61.6 percent TRR (0.77–0.66 mg/kg), whilst metabolites *N*-des-Me-S-2840 (1.6 percent TRR, 0.025 mg eq/kg) and DFPA-CONH₂ (2.1 percent TRR, 0.034 mg eq/kg) in lower levels.

In rice hulls, parent inpyrfluxam was not detectable. Metabolite 1'-CH₂OH-S-2840 and its glycosidic conjugates (40.1–60.2 percent TRR, 0.031–0.085 mg eq/kg) were the main residues, followed by DFPA-CONH₂ (17.5 percent TRR, 0.031 mg eq/kg) and *N*-DesMet-pyrazole carboxylic acid (5.3 percent TRR, 0.009 mg eq/kg).

In husked rice, parent inpyrfluxam was not detectable. Metabolites DFPA, *N*-DesMet-pyrazole carboxylic acid and 1'-CH₂OH-S-2840 were detected at ≤ 0.002 mg eq/kg (up to 23.1 percent TRR).

Seed treatment

Maize

The metabolic fate of [pyrazolyl-4-¹⁴C] inpyrfluxam and [phenyl-U-¹⁴C]inpyrfluxam was investigated in outdoor maize following seed treatment at actual rates 22.1 g ai/tonne seeds and planted after 3–4 days.

Maize forage was sampled at late dough/early dent stage, sweet corn (kernels plus cob with husks removed at the milk/succulent stage, approximately 95 days after planting) whilst stover and grains were harvested at maturity. Grain was separated from the cob (approximately 126 days after planting) and grain-free mature cobs and stalks were processed as maize stover.

In all samples from both labels, TRR were not found above the LOQ (0.005 mg/kg), as a result no metabolite identification was attempted.

Sorghum

The metabolic fate of [pyrazolyl-4-¹⁴C] inpyrfluxam and [phenyl-U-¹⁴C]inpyrfluxam was investigated in outdoor sorghum following seed treatment at actual rates 50 g ai/tonne seeds.

Sorghum forage samples were collected at the soft dough to hard dough stage. The remaining plants were harvested at maturity and separated into grain and stover. In all samples from both labels, TRR were not found above the LOQ (0.005 mg/kg), thus no metabolite identification was attempted.

Rapeseed

The metabolic fate of [pyrazolyl-4-¹⁴C] inpyrfluxam and [phenyl-U-¹⁴C]inpyrfluxam was investigated in outdoor rapeseed following seed treatment at actual rates 5 g ai/tonne seeds and planted after 7 days.

Samples of mature seeds of rape seed, were harvested after 4 months from individual plots at BBCH 97–99 (approximately 161 days after planting).

In all samples from both labels, TRR were not found above the LOQ (0.005 mg/kg), thus no metabolite identification was attempted.

Potatoes

The metabolic fate of [pyrazolyl-4-¹⁴C] inpyrfluxam and [phenyl-U-¹⁴C]inpyrfluxam was investigated in potato following seed piece treatment at actual rates 50 g ai/tonne seeds and planted in outdoor plots at the same day.

Samples of the mature tubers were harvested at the appropriate growth stage (BBCH 49; 84–85 days from treatment and planting) and samples of foliage (collected at BBCH 48; 71–72 days from treatment and planting) were also taken from the plots.

Surface radioactivity was extracted into acetone and homogenized tuber samples were extracted twice with acetone and twice with acetone:water. To identify conjugates in tuber samples, the acetone extract was evaporated to dryness and dissolved in acetonitrile:water before being subjected to acid hydrolysis.

Extracted radioactivity was similar in both labels ranging between 87.9–93.4 percent TRR (0.011–0.039 mg eq/kg) in potato tubers. The PES accounted for 6.6–12.1 percent TRR (0.001–0.003 mg eq/kg).

In tubers, parent accounted for 5.8–15 percent TRR (0.002 mg eq/kg). Metabolite 1'-COOH-S-2840 accounted for 14.5–22.3 percent TRR (0.006–0.009 mg eq kg). Metabolites 1'-CH₂OH-S-2840, 3'-

OH-S-2840, DFPA and N-DesMet-pyrazole carboxylic acid were also detected but individually accounted for ≤ 0.004 mg eq/kg (≤ 10.2 percent TRR).

Low TRR values in tubers, in both labels, indicated that the uptake of inpyrfluxam from the treated seed pieces was low. Inpyrfluxam metabolized into a number of metabolites, none of which were present at levels above ≥ 0.01 mg/kg in the tuber tissue. Inpyrfluxam was shown to metabolize via the routes of oxidation, amide bond cleavage and conjugation in potato tubers.

Summary of plant metabolism

Plant metabolism studies were conducted in apple and soya bean (foliar spray), rice (foliar and granular treatments) and maize, sorghum rapeseed and potato (seed treatment) at rates that accommodate the anticipated maximum total seasonal GAP application rates.

Uptake and transport of inpyrfluxam in the maize, sorghum, oilseed and potato studies, after seed treatment, was low. Metabolism in soya bean, rice and apple proceeds via oxidation to form the hydroxylated components, 3'-OH-S-2840 and 1'-CH₂OH-S-2840 the latter forming multiple glycoside conjugates. The glycoside conjugates of 1'-CH₂OH-S-2840 are further transformed into plant constituents. DFPA-CONH₂ can be also formed from the degradation of 3'-OH-S-2840 and 1'-CH₂OH-S-2840, which is further metabolized into plant components. Additional minor pathways include the demethylation of inpyrfluxam or cleavage of the amide bond to DFPA which is rapidly demethylated to N-DesMet-pyrazole carboxylic acid followed by sugar conjugation and metabolism into multiple high polarity components.

Environmental fate

The Meeting received information on hydrolysis, aqueous photolysis, aerobic degradation in soil under laboratory conditions, soil field dissipation, confined and field rotational crops.

Hydrolysis

[Pyrazolyl-4-¹⁴C] inpyrfluxam incubated in the dark in sterile aqueous buffered solutions at pH 4, 7 and 9 for 5 days at 50 °C remained stable. No degradation products were detected and no change in ratio between the R- and S-isomers was observed. The results indicate that inpyrfluxam is hydrolytically stable at environmental conditions and hydrolysis is not considered a significant route of degradation.

Photochemical degradation

In an aqueous photolysis study, inpyrfluxam was minimally degraded under simulated sunlight in sterilised aqueous phosphate buffer pH 7 and in sterilised natural water. The formation of metabolites 3'-OH-S-2840 and DFPA-CONH₂ was observed below < 10 percent AR (applied radioactivity). The DT₅₀ values ranged from 36–88 days (69–579 sunlight days).

In a soil photodegradation study, the main degradation product was 3'-OH-S-2840 (mean maximum of 8.3 percent AR at day 13) and soil bound residues represented less than 3 percent AR. Isomerization from inpyrfluxam R-isomer to its S-isomer was not observed.

Based on the above, photolysis is not considered a significant route of degradation in water or the soil surface.

Soil metabolism

DT₅₀ values for inpyrfluxam in aerobic soil under laboratory conditions ranged from 101–1720 days with a geomean DT₅₀ of 348 days, indicating moderate persistence to persistence in soil resulting in the formation of two major metabolites (3'-OH-S-2840 and 1'-COOH-S-2840) and many minor metabolites.

Using the best fit kinetics for the parent molecule, calculated DT_{50} values for 3'-OH-S-2840 ranged from 78–843 (> 10,000 at Atwater soil) days and for 1'-COOH-S-2840 ranged from 34.2–669 (> 10,000 at Penn soil) days. However since the duration of the studies was short (120–182 days) and metabolites did not show significant decline during the incubation, there is significant uncertainty in the study, thus the Meeting concluded that the calculated DT_{50} are not reliable.

Soil field dissipation studies

The field soil dissipation of inpyrfluxam has been studied in Europe and the United States with DT_{50} values ranging from 78.1–419 days and 14.6–113 days, respectively, with an overall geometric mean DT_{50} of 117 days ($n = 9$). The DT_{50} values of the metabolites were assessed only in Europe, however residues below the LOQ were observed thus the Meeting concluded that the reliable DT_{50} could not be calculated.

Water/sediment degradation in the field

Inpyrfluxam degraded slowly under anaerobic (DT_{50} of 3537 and 3498 days) or aerobic (DT_{50} of 154 to 704 days depending on the study) aquatic conditions. Degradation was primarily to form 1'-COOH-S-2840 (0.9–13.1 percent AR) and 3'-OH-S-2840 (2.9–6.8 percent AR). In natural surface water, no significant degradation of inpyrfluxam was observed ($DT_{50} \geq 1.540$ days).

The dissipation, mobility and degradation of inpyrfluxam and its transformation products was investigated in an aquatic field dissipation study following planting of treated rice seed. Inpyrfluxam was applied at 10 g ai/100 kg seed or at 10 g ai/100 kg seed followed by foliar application 77 days after sowing at 100 g ai/ha. In the seed treatment only, inpyrfluxam was observed in the sediment and soil phases at very low concentrations up to 0.027 mg/kg, with no transformation product residues observed (<LOQ) at any sampling event. Formation of 1'-COOH-S-2840 in the water phase was observed at low concentrations up to 5.1 µg/L. In the seed treatment/foliar application study, inpyrfluxam was observed in the sediment and soil phases at very low concentrations up to 0.027 mg/kg, and no degradants were observed in the water, sediment or soil. Inpyrfluxam, dissipated rapidly from the system as a whole (paddy water and sediment) with a calculated DT_{50} of 0.064–0.87 days.

Confined rotational crop studies

[Phenyl- ^{14}C] inpyrfluxam and [pyrazolyl- ^{14}C] inpyrfluxam were applied to bare soil at a rate of approximately 235 g ai/ha. Lettuce, radish and sorghum were grown as rotational crops 30, 120 and 365 days after treatment, i.e., plant back intervals (PBI), and harvested according to normal agricultural practice.

TRR levels were lower in lettuce and radish samples at the 365 days PBI compared to the levels at 30 and 120 days PBI. The highest AR was observed in sorghum stover samples, with TRR of 0.69–0.7 mg eq/kg at 30 days PBI and 0.94–1.07 mg eq/kg at 120 days PBI, decreasing to 0.13–0.24 mg eq/kg at 365 days PBI. The sorghum forage contained considerably lower residue levels than the stover samples at all planting intervals.

Inpyrfluxam and its primary oxidation product 3'-OH-S-2840 (free and conjugated) was found in all crops except for sorghum grain. Inpyrfluxam was found in lettuce (up to 17.4 percent TRR; 0.011 mg/kg), radish tops (up to 12.3 percent TRR; 0.025 mg/kg), radish roots (up to 57.8 percent TRR; 0.045 mg/kg), sorghum forage (up to 3.4 percent TRR; 0.007 mg/kg) and sorghum stover (up to 1.8 percent TRR; 0.02 mg/kg). The major portion of metabolite 3'-OH-S-2840 was present in conjugated form accounting for up to 17.6 percent in lettuce (0.012 mg eq/kg), for up to 13.3 percent TRR in radish tops (0.017 mg eq/kg) and for up to 12.1 percent TRR sorghum stover (0.017 mg eq/kg). 1'-COOH-S-284, mostly conjugated, was found in lettuce (up to 14.6 percent TRR; 0.045 mg eq/kg), radish tops (up to

25.6 percent; 0.021 mg eq/kg), radish roots (up to 25.7 percent TRR; 0.06 mg eq/kg) and potatoes (up to 19.1 percent TRR; 0.005 mg eq/kg). 1'-CH₂OH-S-2840, mostly conjugated, was found in lettuce (up to 24.8 percent TRR; 0.024 mg eq/kg) and sorghum stover (15.5 percent TRR; 0.008 mg eq/kg). N-des-Me-S-2840, mostly in free form, was found in radish immature (up to 15.1 percent TRR; 0.027 mg eq/kg) and mature tops (up to 12.8 percent TRR; 0.039 mg eq/kg). N-des-Me-1'-CH₂OH-S-2840, mostly conjugated, was found in radish immature (14.7 percent TRR; 0.017 mg eq/kg) and mature tops (15 percent TRR; 0.056 mg eq/kg).

Field rotational crop studies

Inpyrfluxam and its metabolites are persistent in the environment and may contribute to residues in follow/rotational crops through uptake from soil. In assessing the potential uptake of residues, excluding apples, the maximal season rate was 200 g ai/ha for peanut, i.e., the highest seasonal application rate of the uses evaluated by the Meeting. The use pattern of inpyrfluxam in the United States for apple, maize, peanut, rice, soya bean and sugar beet includes a rotational interval of 9 months (120 days) and a restriction for livestock grazing (soya bean use). Five field rotational crop studies were conducted in Canada (1), Europe (1), and the United States (3).

In the European study inpyrfluxam was applied at a single rate of 240 g ai/ha on winter and spring barley. The crops were destroyed and incorporated in the soil whilst preparing the soil for rotational crops within 13–14 days of application. Follow-up crops lettuce, carrot and wheat or barley were planted at PBIs of 28, 120 and 350 days. Residues of inpyrfluxam and its metabolites were < 0.01 mg/kg in all rotated crop matrices at all PBIs except for cereal straw on 30 days PBI, residues were up to 0.017 mg eq/kg for 3'-OH-S-2840, up to 0.019 mg eq/kg for 1'-COOH-S-2840, up to 0.023 mg eq/kg for 1'-CH₂OH-S-2840 and up to 0.1 mg eq/kg for DFPA.

In the Canadian and one US study, inpyrfluxam was applied at a single rate of 100–120 g ai/ha on wheat. The crops, after growth to maturity, the wheat was harvested and either destroyed (Canadian study) or tilled into the ground near the treated plot (United States study). In the Canadian study, wheat, field peas and rapeseed were planted at PBIs of 328, 328 and 339 days and in the US study, wheat and rapeseed were planted at PBIs of 328 and 312 days. In two additional US studies inpyrfluxam was applied twice at a rate of 105–110 g ai/ha on soya bean. After growth to maturity the crops were tilled into the ground near the treated plot and sorghum and cotton planted at PBIs of 273–267 days. Residues of inpyrfluxam and its metabolites were < 0.01 mg/kg in all rotated crop matrices at all PBIs.

Summary of environmental fate

Inpyrfluxam is hydrolytically stable, does not photodegrade in aqueous buffered solutions or on the surface of soil. Aerobic degradation studies under laboratory conditions indicated a DT₅₀ of 101–331 days of inpyrfluxam in various soils, indicating moderate persistence to persistence in soil. Field dissipation studies confirmed the results, with DT₅₀ for inpyrfluxam residues ranging from 41.6 to 419 days (geometric mean of 117 days) in the Europe and the United States soils. 3'-OH-S-2840 and 1'-COOH-S-2840 were identified in soil, but reliable DT₅₀ values could not be calculated.

In the aquatic field dissipation studies, inpyrfluxam was observed in the sediment and soil phases at very low concentrations, as well as 1'-COOH-S-2840 in the water phase. Decline in the total aquatic system was very quick (<1 day DT₅₀). Based on the available studies, a soil plateau level estimation is not required as to address the residues in rotational crops.

Confined rotational crop studies indicate that inpyrfluxam was extensively metabolized into a large number of metabolites, but the residues were < 0.01 mg/kg in all rotated crop matrices at all PBI,

except wheat straw were 3'-OH-S-2840, 1'-COOH-S-2840, 1'-CO₂OH-S-2840 and DFPA were detected at quantitative levels.

In conclusion, no residues of inpyrfluxam are expected in rotated crops under the conditions investigated in the studies provided to the Meeting. Should a more cGAP or additional uses received in the future, the expectation of residues of inpyrfluxam in rotational crops may need to be re-evaluated.

Animal metabolism

The meeting received information on the fate of orally-dosed inpyrfluxam in rat, lactating goats and laying hens.

Laboratory animals

Metabolism in laboratory animals was summarized and evaluated by the WHO panel of the current Meeting.

Lactating goats

The metabolic fate of inpyrfluxam was investigated in lactating goats using [pyrazolyl-¹⁴C] inpyrfluxam and [phenyl-¹⁴C] inpyrfluxam. The compound was administered orally once daily (after morning milking) for five consecutive days at 0.51 mg/kg body weight/day (13.74 ppm feed per day) for [pyrazolyl-¹⁴C] inpyrfluxam and at 0.64 mg/kg body weight/day (15.74 ppm feed per day) for the [phenyl-¹⁴C] inpyrfluxam. Milk was collected twice daily during the dosing period and the goat was sacrificed ca. 6-7 hours after the final dose.

Muscle, liver and kidney samples were extracted twice with acetonitrile:water, once with acetonitrile and for liver and kidney, extracts were further characterized by enzyme hydrolysis using β -glucuronidase. Milk fat was extracted twice with hexane:acetone and once with acetone, while skimmed milk was extracted once with acetone. Fat samples were extracted once with hexane:acetone and twice with acetone.

The majority of the radioactive dose (≥ 76.5 percent of the administered dose (AD)) was found in excreta whilst the highest tissue radioactivity was in liver (up to 0.26 percent AD; 0.35 mg eq/kg) and kidney (up to 0.02 percent AD; 0.17 mg eq/kg). Radioactivity was qualitatively lower in the muscle (up to ≤ 0.01 percent AD; up to 0.024 mg eq/kg) and fat (up to ≤ 0.01 percent AD; up to 0.040 mg eq/kg). In whole milk, the radioactive residues ranged between 0.09–0.12 percent AD for both labels. Residue levels reached a plateau after the first dose (1st day) and very low levels (0.09–0.12 percent AD) were excreted in whole milk. Residues in milk fat were found at 0.011–0.042 mg eq/kg and in skimmed milk at 0.014–0.041 mg eq/kg.

The extraction efficiency was high in liver (up to 91.1 percent TRR; 0.31 mg eq/kg), kidney (up to 98.2 percent TRR; 0.17 mg eq/kg), muscle (up to 100 percent TRR ; up to 0.021 mg eq/kg) and fat (up to 96.6 percent TRR ; up to 0.041 mg eq/kg). The PES accounted between 1.9–28.6 percent TRR (≤ 0.001 –0.033 mg eq/kg) and were further characterized by β -glucuronidase.

Inpyrfluxam was only quantified at low levels in liver (up to 5.9 percent TRR; 0.019 mg/kg), milk fat (9.1 percent TRR; 0.002 mg/kg) and fat (up to 15.8 percent TRR; 0.004 mg/kg). The major metabolites in the tissue samples were 1'-COOH-S-2840 (up to 49.7 percent TRR; 0.13 mg eq/kg) and 1'-CH₂OH-S-2840 (up to 45.8 percent TRR; 0.079 mg eq/kg) As minor metabolites 3'-OH-S-2840 (up to 3.1 percent TRR; 0.005 mg eq/kg) and DFPA-CONH₂ (up to 11.2 percent TRR; 0.008 mg eq/kg) were also detected.

Residues of 1'-COOH-S-2840 were found in fat (up to 46.4 percent TRR; 0.018 mg eq/kg) and skimmed milk (up to 15.9 percent TRR; 0.006 mg eq/kg) and 1'-CH₂OH-S-2840 in fat (up to 35.6 percent TRR; 0.005 mg eq/kg).

Laying hens

The metabolic fate of inpyrfluxam was investigated in laying hens using [pyrazolyl-¹⁴C] inpyrfluxam and [phenyl-¹⁴C] inpyrfluxam. The compound was administered orally once daily for seven consecutive days at 12.44 ppm feed per day for [pyrazolyl-¹⁴C] inpyrfluxam and at 13.13 ppm feed per day for the [phenyl-¹⁴C] inpyrfluxam. Eggs and excreta were collected twice daily. The hens were sacrificed approximately 6 hours after the last dose administration.

Excreta, egg, liver, thigh and breast muscle samples were extracted twice with acetonitrile:water once with acetonitrile. Residues in liver extracts were further subjected to enzyme or chemical hydrolysis. Fat samples were extracted once with hexane:acetone and twice with acetone.

The majority of the radioactivity (80.3–81.7 percent AD) was found in excreta whilst the highest tissue radioactivity was found in liver (up to 0.22 percent AD; 0.526 mg eq/kg), in the gastrointestinal tract (up to 1.1 percent AD; 2.48 mg eq/kg) and less than 0.1 percent AD (up to 0.11 mg eq/kg) in the other tissues and eggs. In eggs, levels increased over the 7 day dosing period and plateau levels reached for both radiolabels by the end of day 7. The maximum radioactivity in egg was 0.033 mg/kg (0.01 percent AD).

TRR in eggs were 90–91.3 percent (0.023–0.02 mg eq/kg), with major residues being inpyrfluxam (11.5–11.9 percent TRR, 0.002 mg/kg) and 1'-CH₂OH-S-2840 (29.8–31.6 percent TRR, 0.006–0.008 mg eq/kg). Sulfate conjugates of 1'-CH₂OH-S-2840, 1'-COOH-S-2840, 3'-OH-S-2840 and *N*-des-Me-S-2840 were present at ≤ 9.2 percent TRR (≤ 0.002 mg/kg).

TRR in liver was between 91.4–94.3 percent (0.25–0.32 mg eq/kg), with sulphate conjugates of 1'-CH₂OH-S-2840 the major residue (up to 51.7 percent TRR; up to 0.16 mg eq/kg). Other metabolites identified (free and conjugated) were *N*-des-Me-S-2840 (up to 9.5 percent TRR; up to 0.024 mg eq/kg) and 1'-COOH-S-2840 (up to 11 percent TRR; up to 0.028 mg eq/kg).

TRR in fat (abdominal and subcutaneous) ranged between 96.8–99 percent (0.064–0.102 mg eq/kg), with inpyrfluxam accounting for up to 80.7 percent TRR (0.045–0.075 mg/kg), and sulphate conjugates of 1'-CH₂OH-S-2840 with up to 16.9 percent TRR (up to 0.014 mg eq/kg).

TRR in muscle (thigh and breast) were between 80–92.3 percent (0.012–0.023 mg/kg), with several metabolites identified, with sulphate conjugates of 1'-CH₂OH-S-2840 accounting for 47.7 percent TRR, but at low levels (≤ 0.011 mg/kg).

Summary of animal metabolism

The metabolism of inpyrfluxam in poultry and ruminants demonstrates a comparable metabolite profile. The majority of the administered dose was rapidly excreted and parent was extensively metabolized in several metabolites, proceeding via two main pathways: (a) Oxidation to form 1'-CH₂OH-S-2840 isomers, which is further transformed by conjugation to sulphate or glucuronic acid, or by oxidation to form 1'-COOH-S-2840 isomers and to 1',1'-bis-(CH₂OH)-S-2840. (b) *N*-demethylation to form *N*-des-Me-S-2840, amide cleavage to form DFPA-CONH₂ or oxidation to 3'-OH-S-2840.

Methods of analysis

Several analytical methods with minor modifications were available for the determination of inpyrfluxam and its metabolites (3'-OH-S-2840, 1'-CH₂OH-S-2840-A and B, DFPA-CONH₂ and 1'-COOH-S-2840-A and B, and N-DesMet-pyrazole carboxylic acid) in plant commodities (apple, maize grain, maize stover, maize forage, soya bean, wheat plant and grain, potato tubers, grapes, soya bean seeds, lettuce, carrot roots and tops). The methods (including RM-50C-1) involve extraction with acetonitrile/water, the extracts partitioned into hexane/ethyl acetate and purified with SPE. The extract was hydrolysed with HCl to release the conjugates before analysis. In method SUM-1701V used only for the determination of N-des-Me-S-2840, acetonitrile/water was used for the extraction and no clean-up step was performed. In all methods, residues were determined by LC-MS/MS with LOQs ranging from 0.005 to 0.02 mg/kg depending on the analyte and the matrix.

For animal commodities, the analytes were extracted with hexane/acetone (1:1) from egg/white/yolk, with hexane/acetone (4:1) from fat and with acetonitrile/water from liver/muscle. In muscle and liver, conjugates were hydrolysed with HCl and cleaned up with SPE (methods TPR-013 and TPR-015). Final quantification is by LC-MS/MS, with LOQs of 0.01 mg/kg for inpyrfluxam and 0.005 mg/kg for metabolites 1'-COOH-S-2840-A and -B and 1'-CH₂OH-S-2840 (A and B).

The extraction efficient of the enforcement QuEChERS method for the analysis of inpyrfluxam in plant and animal commodities, and methods RM-50C-1 and TPR-0013 used for data generation was evaluated. The QuEChERS method was investigated in rice grain, rice straw, soya bean pods and apples, muscle, liver, fat and milk, the RM-50C-1 in rice straw and radish tops and the TPR-0013 in milk, egg, muscle, liver and fat. The level of inpyrfluxam and metabolites extracted with the methods was similar to the level extracted by the original metabolism methods in all matrices.

In conclusion, the provided analytical methods are suitable for the analysis of inpyrfluxam and metabolites 3'-OH-S-2840, 1'-CH₂OH-S-2840 (A and B isomers), DFPA-CONH₂, N-DesMet-pyrazole carboxylic acid and 1'-COOH-S-2840 (A and B isomers) in plants and/or animal commodities.

Stability of pesticide residues in stored analytical samples

The Meeting received freezer storage stability data for inpyrfluxam and its metabolites (3'-OH-S-2840, DFPA, DFPA-CONH₂, N-DesMet-pyrazole carboxylic acid, N-des-Me-S-2840, N-des-Me-1'-CH₂OH-S-2840 (determined separately as A and B isomers), 1'-COOH-S-2840 (determined separately as A and B isomers) and 1'-CH₂OH-S-2840 (determined separately as A and B isomers)) in various plant and processing commodities. Samples were fortified with each analyte at 0.05 to 0.5 mg/kg levels.

Residues of inpyrfluxam and metabolites were stable for at least 679 days in high acid content (grapes), 683 days in high oil content (soya bean, maize oil), 672 days in high protein content (field bean), 681 days in high water content (cucumber, apple, maize forage and stover) and 679 days in high starch content (maize grain, corn starch, polished rice, potato starch, potato tuber, wheat grain and flour) crops.

This period covers the storage period of the samples from the supervised and processing studies.

Residues of inpyrfluxam, 1'-COOH-S-2840 (determined separately as A and B isomers), 1'-CH₂OH-S-2840 (determined separately as A and B isomers) in animal matrices (milk, muscle, liver, kidney and fat), with samples fortified with each analyte at 0.1 or 0.5 mg/kg levels. The analytes were shown to be stable for at least 75 day in milk, 29 days in muscle, liver and kidney and 31 days in fat, when stored under frozen conditions. This period covers the storage period of the samples from the feeding studies.

Definition of the residue

Plant commodities

The metabolism of inpyrfluxam was assessed in apple, potatoes, soya bean and rice, and found to be similar in all crops. The metabolism in rotational crops was similar to the metabolism observed in primary crops and the processing of inpyrfluxam is not expected to modify the nature of residues.

Inpyrfluxam was the predominant residue in apple (up to 79 percent TRR; 0.24 mg/kg), mature rice grain (up to 78.6 percent TRR; 0.039 mg/kg) and potato tubers (up to 15 percent TRR; 0.002 mg/kg), but was only found at very low concentrations in mature soya seed (up to 2 percent TRR; < 0.001 mg/kg). In feed commodities, parent was detected in soya bean forage (up to 50.5 percent TRR; 0.79 mg/kg), soya bean hay (up to 22.1 percent TRR; 0.5 mg/kg), immature pods (up to 65.2 percent TRR; 0.41 mg/kg), rice straw (up to 77.8 percent TRR; 0.72 mg/kg) and rice hulls (up to 52.5 percent TRR; 0.88 mg/kg). In the confined rotational crops study, parent was detected in mature lettuce (up to 26.9 percent; 0.027 mg/kg) and radish immature and mature roots (up to 58.9 percent; 0.045 mg/kg) at 30 to 365 days PBI.

Suitable analytical methods for enforcement are available for inpyrfluxam in plant matrices. The Meeting concluded that inpyrfluxam only should be considered as a suitable marker compound for enforcement purposes.

In deciding which compounds should be included in the residue definition for dietary risk assessment, the Meeting considered the likely occurrence of the compounds and the toxicological properties of the candidates 3'-OH-S-2840, 1'-CH₂OH-S-2840, 1'-COOH-S-2840, DFPA, N-DesMet-pyrazole carboxylic acid, DFPA-CONH₂ and N-des-Me-1'-CH₂OH-S-2840.

3'-OH-S-2840 was not found at significant levels in primary or rotational crop metabolism studies or field rotational crop studies. In residue trials, 3'-OH-S-2840 was detected in apple fruits at a maximum concentration of 0.08 mg/kg. In most trials, parent residues were at least 10–90 times higher compared to 3'-OH-S-2840.

1'-CH₂OH-S-2840 (free or conjugated), was not found in any food commodities at significant levels in primary crop metabolism studies, residue trials or field rotation crops studies. In the confined rotational crops study 1'-CH₂OH-S-2840 (free or conjugated) was detected only in lettuce (24.8 percent TRR; 0.024 mg/kg).

1'-COOH-S-2840 (free or conjugated) was not found in any food commodities at significant levels in primary crop metabolism studies or field rotation crops studies. In the confined rotational crops study, 1'-COOH-S-2840 (free or conjugated) was detected in lettuce (14.6 percent TRR; 0.045 mg/kg) and radish immature or mature tops (22.1 percent TRR; 0.026 mg/kg). In residue trials, the metabolite was found only in sugar beets root at a maximum of 0.028 mg/kg.

The toxicity of these metabolites is covered by the toxicological properties of the parent compound. The Meeting concluded that residues are low compared to inpyrfluxam, do not contribute significantly to the consumer exposure based on parent residues and decided that an inclusion into the residue definition for exposure purposes is unnecessary.

Metabolites DFPA (free and conjugated) and N-DesMet-pyrazole carboxylic acid (free and conjugated) are not covered by the health based reference values for inpyrfluxam, thus the Meeting assessed the relevance of these metabolites against the TTC Cramer Class III (0.0015 mg/kg bw per day).

N-DesMet-pyrazole carboxylic acid (free and conjugated) was found in the metabolism study in soya bean seeds (17.5 percent TRR; 0.038 mg eq/kg) and in residue trials was the only compound

detected in soya bean seeds at levels < 0.02 to 0.19 mg/kg (median residue: 0.026 mg/kg). In the confined rotational crops study, the metabolite was detected in radish tops (13.6 percent TRR; 0.015 mg/kg) but not detected in the field rotation crop studies. This metabolite is also a metabolite formed after use of other active substances, such as bixafen, fluxapyroxad, benzovindiflupyr, and fluindapyr. In the absence of overall information on the uses of all active substances and considering the lack of a specific health based reference value, the Meeting decided there was insufficient information to perform a combined risk assessment for residues resulting from use with all active substances leading to formation of N-DesMet-pyrazole carboxylic acid. The Meeting concluded that N-DesMet-pyrazole carboxylic acid could be assessed by TTC approach against the Cramer Class III and that the exposure should be based on the anticipated residues following use of each active substance, separately.

DFPA (free and conjugated) was not found in any food commodities at significant levels in primary crop metabolism studies, residue trials or field rotational crops studies. In the confined rotational crops study, DFPA (free or conjugated) was detected in immature lettuce and mature lettuce (29.1 percent TRR; 0.028 mg/kg).

In summary, the Meeting agreed that the residue definition for dietary risk assessment should be *inpyrfluxam*.

Animal commodities

Inpyrfluxam was observed in poultry fat (up to 81 percent TRR; 0.075 mg eq/kg), goat fat (up to 15.8 percent TRR; 0.004 mg eq/kg) and eggs (up to 11 percent TRR; 0.002 mg eq/kg). In the feeding studies, parent was only present at 0.017 mg/kg in poultry fat from the highest dose group but not in any other animal tissue, milk or eggs.

DFPA-CONH₂ was observed in poultry muscle (up to 15 percent TRR; 0.001 mg eq/kg) but was not found in the feeding studies.

1'-COOH-S-2840 (free and conjugates) was observed in poultry liver (up to 11 percent TRR; 0.028 mg eq/kg), poultry muscle (up to 14 percent TRR; 0.003 mg eq/kg), skimmed milk (up to 16 percent TRR; 0.006 mg eq/kg), goat liver (up to 42 percent TRR; 0.13 mg eq/kg), goat kidney (up to 50 percent TRR; 0.08 mg eq/kg), goat muscle (up to 32 percent TRR; 0.007 mg eq/kg) and goat fat (up to 39.7 percent TRR; 0.018 mg eq/kg). In the feeding studies, residues were present only at 0.01 mg/kg in poultry liver.

1'-CH₂OH-S-2840 (free or conjugated) was observed in poultry liver (up to 52 percent TRR; 0.164 mg eq/kg), poultry muscle (up to 51 percent TRR; 0.012 mg eq/kg), fat (up to 17 percent TRR; 0.014 mg eq/kg), eggs (up to 39 percent TRR; 0.009 mg eq/kg), goat liver (up to 25 percent TRR; 0.088 mg eq/kg), goat kidney (up to 37 percent TRR; 0.063 mg eq/kg) and goat muscle (up to 32 percent TRR; 0.007 mg eq/kg). In the feeding studies, residues were present at 0.012 mg/kg in egg yolk, 0.017 mg/kg in poultry liver, 0.014 mg/kg in goat liver and at 0.022 mg/kg in goat kidney.

3'-OH-S-2840 and N-des-Me-S-2840 were not found in any food commodities at levels > LOQ nor were residues found in the feeding studies.

Besides parent inpyrfluxam, 1'-CH₂OH-S-2840 (free or conjugated) was a major residue in most animal matrices and the predominant residue found in the livestock feeding studies. Suitable analytical methods for enforcement are available for inpyrfluxam and 1'-CH₂OH-S-2840 (free or conjugated) in animal matrices. The Meeting decided that the sum of both compounds represents a suitable marker for enforcement purposes in animal matrices.

For dietary exposure purposes, the only other metabolite found in feeding studies at quantified levels was 1'-COOH-S-2840 (free and conjugates) in poultry liver (0.01 mg/kg). Given its low occurrence and that its toxicity is covered by the health-based guidance values for parent inpyrfluxam, the Meeting decided that no inclusion into the residue definition is necessary.

Parent inpyrfluxam has an octanol-water partition coefficient of 3.65, suggesting potential accumulation in fat.

Parent and 1'-CH₂OH-S-2840 residues were predominantly found in liver and kidney commodities. In goats, concentrations between fat and muscle were close to the LOQ without clear tendency for accumulation in the fat. In poultry metabolism studies, fat contained approximately 30x higher residue concentrations compared to muscle. However, no accumulation was observed in milk fat or egg yolk. In the feeding studies, residues were generally low, not allowing estimation of ratios between fatty and non-fatty tissues. The Meeting decided that the residue is not fat-soluble.

In summary, the Meeting agreed that the residue definition for compliance with the MRL and dietary risk assessment for animal commodities should be: *inpyrfluxam and 1'-CH₂OH-S-2840 (free or conjugated) expressed as inpyrfluxam.*

The residue is not fat-soluble.

In deciding which compounds should be taken into consideration for estimation of livestock dietary burdens, the Meeting decided that inpyrfluxam and 1'-CH₂OH-S-2840 (free or conjugated) expressed as inpyrfluxam, should be taken into consideration for estimation of livestock dietary burden calculations since they are included in the residue definition for animal commodities and are found in feed commodities in metabolism (soya bean forage, soya bean hay, rice straw, rice hulls, sorghum forage, sorghum stover) and field studies (wheat straw, peanut hay) in primary and rotational crops.

Conclusion

Based on the above the Meeting recommended the following residue definitions:

Residue definition for compliance with the MRL and dietary exposure for plant commodities: *inpyrfluxam.*

Residue definition for compliance with the MRL and dietary exposure for animal commodities is *inpyrfluxam and 1'-CH₂OH-S-2840 (free or conjugated) expressed as inpyrfluxam.*

Residues to be included in the livestock dietary burden calculations: *inpyrfluxam and 1'-CH₂OH-S-2840 (free or conjugated) expressed as inpyrfluxam.*

Results of supervised residue trials on crops

The Meeting received supervised residue trial data for seed treatments and foliar applications of inpyrfluxam on apples, soya beans, maize, peanuts, sugar beets and rice.

In this appraisal, the following residue summaries are given:

- *Inpyrfluxam*: For maximum residue level estimation in plant commodities and dietary exposure calculations.
- *Inpyrfluxam and 1'-CH₂OH-S-2840 (free or conjugated) expressed as inpyrfluxam*: For dietary burden calculations. When the residues of the metabolite was <LOQ (0.02 mg/kg) then it was not taken into consideration in the animal dietary burden calculations
- *N-DesMet-pyrazole carboxylic acid*: For dietary exposure calculations based on TTC approach.

Apples

The critical GAP for inpyrfluxam on apples is from Japan, and consists of a maximum of three foliar applications at a rate of 9.25 g ai/hL with a re-treatment interval of 7 days and a PHI of 1 day.

Trials performed on apples from Japan matching this GAP were available. Residue levels in fruits in ranked order were (n = 8): 0.52, 0.72, 0.78, 0.84, 0.98, 1.23, 1.42, 1.88 mg/kg.

The Meeting estimated a maximum residue level of 4 mg/kg, an STMR of 0.91 mg/kg and an HR of 1.88 mg/kg for apples. Residues of metabolite 1'-CH₂OH-S-2840 were < 0.02 mg/kg in all trials.

Soya bean

The critical GAP for inpyrfluxam on soya beans is from United States and consists of a seed treatment up to 5 g ai/100 kg seeds and two foliar application at a rate of 75 g ai/ha (not before BBCH 14 or after BBCH 75–76) with an retreatment interval of 14 days and a PHI covered by the growth stage of the crop with a livestock grazing restriction: do not graze treated fields or feed treated hay to livestock.

In trials performed on soya beans in United States, the seeds were treated at 10 g ai/100 kg, followed by two applications at 100 g ai/ha (one at 200 g ai/ha) at BBCH above 75 and, in most cases. Residue levels in dry seeds were (n = 21): < 0.01 (21) mg/kg.

Since residues of inpyrfluxam were not detected in any overdosed trials, the Meeting estimated a maximum residue level of 0.01(*) mg/kg and an STMR of 0 mg/kg for soya bean (dry).

Residue levels of metabolite N-des-Me-DFPA in dry seeds were (n = 21): < 0.02 (7), 0.02, 0.023, 0.024, 0.026, 0.028, 0.032, 0.036, 0.037, 0.051, 0.062, 0.095, 0.13, 0.16, 0.19 mg/kg. Residues of metabolite 1'-CH₂OH-S-2840 were < 0.02 mg/kg in all trials.

Sugar beet

The critical GAP for inpyrfluxam on sugar beet is in the United States and consists of a seed treatment up to 0.1 g ai/100,000 seeds and up to two foliar applications at a rate of 50g ai/ha with a maximum seasonal rate of 100 g ai/ha (BBCH 12–18), an retreatment interval of 21 days and a PHI of 50 days.

In trials performed on sugar beets, the plant received two foliar application at 100 g ai/ha after the seed treatment. Residue levels in roots were (n = 15): < 0.01 (15) mg/kg.

Since residues of inpyrfluxam were not detected in any overdosed trials, the Meeting estimated a maximum residue level of 0.01(*) mg/kg, an STMR and HR of 0 for beet root. Residues of metabolite 1'-CH₂OH-S-2840 were < 0.02 mg/kg in all trials.

Rice

The critical GAP for inpyrfluxam on rice is from United States and consists of a seed treatment up to 10 g ai/100 kg seeds and one foliar application at a rate of 100 g ai/ha with a maximum seasonal rate of 100 g ai/ha (approximately 25–30 days after the permanent flood has been established) and PHI covered by the growth stage.

Trials performed on rice, according to this GAP, gave residue levels in husked rice of (n = 14): < 0.01 (15) mg/kg. Three trials conducted at approximately 500 g ai/ha gave the same results.

Since residues of inpyrfluxam were not detected in any trial, including the overdosed trials, the Meeting estimated a maximum residue level of 0.01(*) mg/kg, an STMR of 0 for husked rice. Residues of metabolite 1'-CH₂OH-S-2840 were < 0.02 mg/kg in all trials.

Sweet corn (Corn-on-the-cob)

The critical GAP for inpyrfluxam on maize is from United States and consists of a seed treatment up to 0.014 mg ai/seed and one in furrow application at a rate of 50 g ai/ha at planting and PHI covered by the growth stage.

Fourteen trials performed on maize in the United States matching this GAP and three additional trials at exaggerated rates of 100–260 g ai/ha were also available. Residue levels in kernels plus corn without husks in all trials were (n = 17): < 0.01 (17) mg/kg.

Since residues of inpyrfluxam were not detected in the trials including the overdosed trials and in primary plant metabolism studies, uptake and transport of inpyrfluxam in the maize, sorghum, oilseed and potato studies, where the seed was treated, was low, the Meeting estimated a maximum residue level of 0.01(*) mg/kg, an STMR and HR of 0 mg/kg for sweet corn. Residues of metabolite 1'-CH₂OH-S-2840 were < 0.02 mg/kg in all trials.

Peanut

The critical GAP for inpyrfluxam on peanuts is in the United States and consists of a maximum of four foliar applications at a rate of 100 g ai/ha (no earlier than 30 days after planting) with a maximum seasonal rate of 200 g ai/ha, an retreatment interval of 14–28 days and a PHI of 40 days.

Trials performed on peanuts from the United States according to GAP (2 × 100 g ai/ha) were available. Residue levels in nutmeal were (n = 13): < 0.01 (13) mg/kg.

The Meeting estimated a maximum residue level of 0.01(*) mg/kg, an STMR and HR of 0.01 mg/kg for peanuts. Residues of metabolite 1'-CH₂OH-S-2840 were < 0.02 mg/kg in all trials.

Maize

The critical GAP for inpyrfluxam on maize is from the United States and consists of a seed treatment up to 0.014 mg ai/seed and one in furrow application at a rate of 50 g ai/ha at planting and PHI covered by the growth stage.

Fourteen trials performed on maize from the United States matching the GAP and three trials at exaggerated rates of 100–260 g ai/ha were also available. Residue levels in all trials were (n = 17): < 0.01 (17) mg/kg.

Since residues of inpyrfluxam or the metabolites were not detected in the trials including the overdosed trials and in primary plant metabolism studies, uptake and transport of inpyrfluxam in the maize, sorghum, oilseed and potato studies, where the seed was treated, was low, the Meeting estimated a maximum residue level of 0.01(*) mg/kg, an STMR of 0 mg/kg for maize and popcorn, Residues of metabolite 1'-CH₂OH-S-2840 were < 0.02 mg/kg in all trials.

Animal Feed commodities

The total residue for estimating the median and highest residues in feed was inpyrfluxam + 1'-CH₂OH-S-2840 (free or conjugated), expressed as inpyrfluxam.

When the metabolite concentration was < 0.04 mg/kg, it was considered to be 0 in the calculation.

Maize forage-40 percent dry matter

The critical GAP for inpyrfluxam on maize is from the United States and consists of a seed treatment up to 0.014 mg ai/seed and one in furrow application at a rate of 50 g ai/ha at planting and PHI covered by the growth stage.

Trials performed on maize from the United States matching the US GAP were available. Residue levels in forage were (n = 29): < 0.01 (4), < 0.02 (25) mg/kg.

Residues of metabolite 1'-CH₂OH-S-2840, were < 0.04 mg/kg in all trials.

The Meeting estimated a highest residue of 0.02 mg/kg (as received) for inpyrfluxam in maize forage.

Maize stover-83 percent dry matter

The critical GAP for inpyrfluxam on maize is from the United States and consists of a seed treatment up to 0.014 mg ai/seed and one in furrow application at a rate of 50 g ai/ha at planting and PHI covered by the growth stage.

Trials performed on maize from the United States matching the US GAP were available. Residue levels in fodder were (n = 29): < 0.01 (4), < 0.02 (25) mg/kg. Residues of metabolite 1'-CH₂OH-S-2840 were < 0.04 mg/kg in all trials.

The Meeting estimated a maximum residue level of 0.02(*) mg/kg (based on a dry matter content of 83 percent), a median and highest residue of 0.02 mg/kg for inpyrfluxam in maize fodder (as received).

Peanut hay

The critical GAP for inpyrfluxam on peanuts is in the United States and consists of a maximum of four foliar applications at a rate of 100 g ai/ha (no earlier than 30 days after planting) with a maximum seasonal rate of 200 g ai/ha, an retreatment interval of 14–28 days and a PHI of 40 days.

Trials performed on peanuts from the United States matching GAP were available. Residue levels in hay were (n = 12): 0.083, 0.096, 0.134, 0.217, 0.218, 0.252, 0.338, 0.412, 0.422, 0.526, 0.731, and 1.23 mg/kg.

The Meeting estimated a maximum residue level of 3 mg/kg (as received), an median of 0.35 mg/kg and highest residue of 2 mg/kg for peanut hay (as received).

Levels of metabolite 1'-CH₂OH-S-2840 were (n = 12): 0.1, 0.12, 0.20, 0.24, 0.25, 0.32, 0.38, 0.44, 0.57, 0.94, 1.12 and 2 mg/kg.

Since metabolite 1'-CH₂OH-S-2840 is included in the residue definition for dietary risk assessment in animal commodities, residues of this metabolite (CF to parent = 1.1) were also taken into consideration as to estimate the median and highest residue for inpyrfluxam and 1'-CH₂OH-S-2840 (, free or conjugated) expressed as inpyrfluxam in peanut hay. Total residue levels were (n = 12): 0.1, 0.12, 0.20, 0.24, 0.25, 0.32, 0.38, 0.44, 0.57, 0.94, 1.12, 2 mg/kg.

The Meeting also estimated a median of 0.35 mg/kg and highest residue of 2 mg/kg for peanut hay (as received).

Fates of residues during processing

High temperature hydrolysis

The degradation of [Pyrazolyl-4-¹⁴C] inpyrfluxam and its metabolites [Pyrazolyl-4-¹⁴C] 3'-OH-S-2840 and [Pyrazolyl-4-¹⁴C] 1'-CH₂OH-S-2840 were studied under hydrolytic conditions at high temperatures in sterile aqueous buffers at pH 4, 5 and 6 for periods up to 60 minutes (20 minutes for pH 4 and 6) so as to simulate common processing practice (pasteurization, baking/brewing/boiling and sterilisation). Degradation of inpyrfluxam, 3'-OH-S-2840 and 1'-CH₂OH-S-2840 was not observed at any investigated condition. Chiral analysis showed the *R*-isomer of inpyrfluxam to account for 100 percent of the residue at all time points thus no isomerization occurred. The Meeting concluded that inpyrfluxam, is stable under hydrolytic conditions.

Residues in processed commodities

The fate of inpyrfluxam residues after processing has been examined in apple, soya bean, sugar beet, rice, maize and peanut.

For soya bean, sugar beet, rice, maize and peanut processed fractions no reliable PFs can be calculated, since the RAC and the processed commodities contained residues <LOQ. In rice, residues in RAC were also <LOQ however quantitative residues were observed in hulls and bran indicating that residues concentrated in the final processed commodities.

One study was conducted in rice and one study in apple. Maximum residue levels in processed commodities are only estimated when processing factor was higher than 1. The Meeting concluded that the processing factors based on apple data can be extrapolated to other processed pome commodities (pome fruit juice and wet pomace). The results are shown in Tables 5.21.3 and 5.21.4.

Table 5.21.3 Processing factors and median and highest residue values for inpyrfluxam used for estimation of maximum residue levels including livestock dietary burdens

Processed commodity	Raw commodity (median) mg/kg	Individual processing factors	Median residue-P (mg/kg)
Apple wet pomace	0.91	2.7	2.4
Rice Hulls	0	4.3	0
Rice bran (husked)	0	1.3	0

Table 5.21.4 Processing factors and STMR value for inpyrfluxam in apple juice

Processed commodity	Raw commodity (STMR)	Individual processing factors	Median or best estimate processing factor	STMR-P = STMR/RAC × PF (mg/kg)
Apple juice	0.91	0.125	0.125	0.114

The Meeting estimated a maximum residue level of 0.01(*) mg/kg for inpyrfluxam in rice hulls

Residues in animal commodities

In a feeding study in lactating cows, inpyrfluxam was fed via the diet, to three to six cows per dose group, for 29 consecutive days. The animals received equivalents of 2, 6, or 20 ppm of inpyrfluxam in the diet (DM). Residues of inpyrfluxam and metabolites 1'-COOH-S-2840 (A and B) and 1'-CH₂OH-S-2840 (A and B) were determined.

There was no transfer of residues of inpyrfluxam or its main metabolites (1'-COOH-S-2840 and 1'-CH₂OH-S-2840) at levels above the LOQ (0.01 mg/kg) in milk, skimmed milk or cream during or up to two

	Animal dietary burden: parent ppm of dry matter diet							
	United States-Canada		European Union		Australia		Japan	
	Max	Mean	Max	Mean	Max	Mean	Max	Mean
Poultry-layer	0	0	0	0	0	0	0	0

Notes:

- ① Highest maximum beef or dairy cattle dietary burden suitable for maximum residue level estimates for mammalian tissues.
- ② Highest mean beef or dairy cattle dietary burden suitable for STMR estimates for mammalian tissues and milk.

The Meeting used the calculated beef and dairy cattle maximum and mean dry weight dietary burdens of 2.62 ppm and 1.46 ppm for estimating residue levels in milk and ruminant tissues.

For poultry commodities, no feed items were applicable thus the calculated dry weight maximum and mean dietary burden and is 0 ppm dry weight in feed.

Animal commodity maximum residue levels

Ruminants

The calculations used to estimate maximum residue levels, STMR and HR values for cattle matrices are shown below.

Table 5.21.7 Anticipated residues of inpyrfluxam and 1'-CH₂OH-S-2840 (free or conjugated) expressed as inpyrfluxam in cattle commodities

	Feed Level (ppm) for milk residues	Total residues (mg eq/kg) in milk	Feed Level (ppm) for tissue residues	Total residues (mg eq/kg)			
				Muscle	Liver	Kidney	Fat
HR Determination (beef or dairy cattle)–Parent							
Feeding Study	2	0.02*	2	0.02*	0.02*	0.02*	0.02*
	6	0.02*	6	0.02*	0.02*	0.02*	0.02*
Dietary burden and estimate of highest residue	2.6	0.02*	2.6	0.02*	0.02*	0.02*	0.02*
STMR Determination (beef or dairy cattle)–Parent							
Feeding Study	2	0.02*	2	0.02*	0.02*	0.02*	0.02*
	6	0.02*	6	0.02*	0.02*	0.02*	0.02*
Dietary burden and estimate of highest residue	1.46	0.02*	1.46	0.02*	0.02*	0.02*	0.02*
MRL Determination (beef or dairy cattle)–Parent							
Feeding Study	2	0.01*	2	0.02*	0.02*	0.02*	0.02*
	6	0.01*	6	0.02*	0.02*	0.02*	0.02*
Dietary burden and estimate of highest residue	2.6	0.01*	2.6	0.02*	0.02*	0.02*	0.02*

The Meeting estimated maximum residue levels of 0.02(*) mg/kg in milk, meat (mammalian except marine mammals), mammalian fats, and edible offal.

The Meeting also estimated a STMR of 0 mg/kg for edible offal, muscle, kidney, fat and milk, and a HR of 0 mg/kg for edible offal, muscle, edible offal and fat.

Poultry

As the mean and maximum dietary burden for poultry is 0, no residues are expected in poultry commodities.

The Meeting estimated maximum residue levels of 0.02(*) mg/kg in poultry meat (muscle), poultry fat, poultry edible offal, and eggs. The Meeting also estimated a HR and STMR of 0 mg/kg for poultry edible offal, muscle, fat and eggs.

Recommendations

On the basis of the data from supervised trials, processing studies, storage stability studies and feeding studies the Meeting concluded that the residue levels listed in Annex 1 are suitable for establishing maximum residue limits and for IEDI and international estimate of short-term intakes assessments.

The residue definition for compliance with the MRL for plant commodities is *inpyrfluxam*.

The residue definition for dietary exposure for plant commodities is *inpyrfluxam*.

The residue definition for compliance with the MRL and dietary exposure for animal commodities is *inpyrfluxam* and *1'-CH₂OH-S-2840* (free or conjugated) expressed as *inpyrfluxam*.

The residue is not fat soluble.

Dietary risk assessment

Long-term dietary exposure

The ADI for inpyrfluxam is 0–0.06 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for fenpicoxamid were estimated for the 17 GEMS/Food Consumption Cluster Diets using the STMR or STMR-P values estimated by the JMPR. The results are shown in Annex 3 of the 2022 JMPR Report.

The IEDIs ranged from 0–5 percent of the maximum ADI. The Meeting concluded that long-term dietary exposure to residues of inpyrfluxam from uses considered by the JMPR is unlikely to present a public health concern.

Acute dietary exposure

The ARfD for inpyrfluxam is 0.3 mg/kg bw. The International Estimate of Short Term Intakes (international estimate of short-term intakes) for spiropidion were calculated for the food commodities and their processed commodities for which HRs/HR-Ps or STMRs/STMR-Ps were estimated by the present Meeting and for which consumption data were available. The results are shown in Annex 4 of the 2022 JMPR Report.

The international estimate of short-term intake varied from 0–40 percent of the ARfD for children and 0–10 percent of the ARfD for the general population. The Meeting concluded that acute dietary exposure to residues of inpyrfluxam from uses considered by the present Meeting is unlikely to present a public health concern.

Threshold of toxicological concern (TTC) consideration for metabolites

The metabolite N-DesMet-pyrazole carboxylic acid found in soya bean seeds (STMR of 0.026 mg/kg) was assessed using the TTC approach (Cramer Class III threshold of 1.5 µg/kg bw per day). The estimated a dietary exposure for metabolite N-DesMet-pyrazole carboxylic acid of 0.096 µg/kg bw for the uses of bixafen, fluxapyroxad, fluindapyr and benzovindiflupyr (Report 2022–fluindapyr).

The Meeting concluded that the estimated dietary exposure to residues of N-DesMet-pyrazole carboxylic acid from uses considered by the current JMPR is below the TTC for Cramer Class III compounds and is unlikely to present a public health concern. Should further uses be considered in the future, these conclusions may need to be re-evaluated.

5.22 Isoflucypram (330)

TOXICOLOGY

Isoflucypram (BCS-CN88460) is the International Organization for Standardization (ISO)-approved common name for *N*-(5-chloro-2-isopropylbenzyl)-*N*-cyclopropyl-3-(difluoromethyl)-5-fluoro-1-methyl-1*H*-pyrazole-4-carboxamide, with the Chemical Abstracts Service number 1255734-28-1. Isoflucypram is a novel broad-spectrum fungicide. The chemical class is *N*-cyclopropyl-*N*-benzyl-pyrazole-carboxamides and it is a succinate dehydrogenase inhibitor. Isoflucypram has not been evaluated previously by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) and was reviewed by the present Meeting at the request of the Codex Committee on Pesticide Residues (CCPR). All critical studies contained statements of compliance with good laboratory practice (GLP) and were conducted in accordance with relevant national or international test guidelines, unless otherwise specified. No additional information from a literature search was identified that complemented the toxicological information provided for the current assessment.

Biochemical aspects

Isoflucypram was rapidly absorbed in rats when administered orally. Maximum plasma concentration (C_{\max}) of radioactivity was reached at one hour post administration after a low single oral dose of 2 mg/kg body weight (bw), and at 2–4 hours with a high single oral dose of 200 mg/kg bw. The dose-normalized plasma C_{\max} after administration of the high dose was 3–4 fold lower than that after the low dose indicating reduced absorption at the high dose. Absorption in rats at the low dose was around 80 percent. Radiolabelled isoflucypram was distributed throughout the rats immediately after dosing, with the highest levels in liver and kidney. No relevant sex-related differences in distribution were observed. Isoflucypram was rapidly eliminated in both sexes. Excretion was mainly via faeces (greater than 80 percent), following excretion in bile (70 percent or more).

A number of metabolites were identified in samples from male and female rats. No relevant qualitative differences in the metabolite profile between sexes were observed in rats, although some desmethyl metabolites were excreted faster in males than in females. For the common metabolites the metabolite pattern was similar in all studies. The most important metabolic reactions of [*pyrazole-4-¹⁴C]isoflucypram were demethylation, hydroxylation, carboxylation and conjugation. Conjugates of isoflucypram-propanol (M01) and isoflucypram-desmethyl (M13) were identified at greater than 10 percent of absorbed dose. The metabolites identified at greater than 10 percent total radioactive residue (TRR) in plasma, liver and kidney were isoflucypram-cyclopropyl-pyrazole-carboxamide (M58), isoflucypram-desmethyl-carctic acid (M09), isoflucypram-desmethyl-carboxylic acid (M11) and isoflucypram-carboxylic acid (M12). Measurements in toxicity studies confirmed that M58 and M11 occurred at high concentrations in plasma.*

A comparative metabolism study was performed in vitro using liver microsomes from humans, dogs, rabbits, rats and mice. The metabolite patterns were comparable for human, mouse and rat liver microsome systems, but somewhat different with the dog and rabbit preparations. No unique human metabolite was detected.

Toxicological data

In rats, isoflucypram had an acute oral median lethal dose (LD_{50}) of greater than 2000 mg/kg bw, an acute dermal LD_{50} of greater than 2000 mg/kg bw and an acute inhalation median lethal concentration (LC_{50}) of 2.518 mg/L. Isoflucypram was non-irritating to the skin and mildly irritating to the eyes in rabbits. It was not skin sensitizing in a mouse local lymph node assay (LLNA).

The effects of isoflucypram in short- and long-term studies in mice, rats and dogs included decreased body weight gain, liver hypertrophy and changes related to thyroid hormones.

In a 90-day study, mice received isoflucypram in their diet at concentrations of 0, 100, 300 or 1000 ppm (equal to 0, 17.0, 51.0 and 168 mg/kg bw per day for males, 0, 19.5, 59.8, and 207 mg/kg bw per day for females). The no-observed-adverse-effect level (NOAEL) was 300 ppm (equal to 51.0 mg/kg bw per day) based on a slight decrease in body weight gain, liver weight increase and hepatocellular vacuolation in the centrilobular area at 1000 ppm (equal to 168 mg/kg bw per day).

In a 90-day study, rats received isoflucypram at dietary concentrations of 0, 100, 300 or 1000 ppm (equal to 0, 6.34, 18.4, 63.5 mg/kg bw per day for males, 0, 7.92, 21.9, 80.9 mg/kg bw per day for females). The NOAEL was 300 ppm (equal to 18.4 mg/kg bw per day) based on a reduction in body weight gains at 1000 ppm (equal to 63.5 mg/kg bw per day).

In a 13-week study, dogs received isoflucypram at dietary concentrations of 0, 170, 500 or 1500 ppm (equal to 0, 5.5, 15.9 and 50.4 mg/kg bw per day for males, 0, 5.5, 16.2 and 54.0 mg/kg bw per day for females). The NOAEL was 500 ppm (equal to 15.9 mg/kg bw per day) based on reduced body weight gain at 1500 ppm (equal to 50.4 mg/kg bw per day).

In a 52-week study, dogs received isoflucypram at dietary concentrations of 0, 150, 600 or 1800 ppm (equal to 0, 4.2, 18.8 and 60.2 mg/kg bw per day for males, 0, 4.2, 17.6 and 49.8 mg/kg bw/day for females). The NOAEL was 600 ppm (equal to 17.6 mg/kg bw per day) based on reduced body weight gain and liver effects with Kupffer cell pigmentation at 1800 ppm (equal to 49.8 mg/kg bw per day).

The overall NOAEL for the 13-week and 52-week toxicity studies in dogs was 600 ppm (equal to 17.6 mg/kg bw per day). The lowest-observed-adverse-effect level (LOAEL) was 1800 ppm (equal to 49.8 mg/kg bw per day).

In an 18-month chronic toxicity and carcinogenicity study, mice received isoflucypram at dietary concentrations of 0, 50, 250 or 1250 ppm (equal to 0, 5.9, 29.0 and 147 mg/kg bw per day for males, 0, 7.8, 38.1 and 190 mg/kg bw per day for females). The NOAEL for chronic toxicity was 250 ppm (equal to 29.0 mg/kg bw per day) based on reduced body weight gain and increased incidence of multinucleated hepatocytes at 1250 ppm (equal to 147 mg/kg bw per day). The NOAEL for carcinogenicity in mice was 1250 ppm (equal to 147 mg/kg bw per day), the highest dose tested.

In a two-year chronic toxicity and carcinogenicity study, rats received isoflucypram at dietary concentrations of 0, 30, 150 or 450 ppm for males (equal to 0, 1.24, 6.27 and 18.6 mg/kg bw per day), and 0, 30, 150 and 800 ppm for females (equal to 0, 1.75, 8.54 and 46.6 mg/kg bw per day). The NOAEL for chronic toxicity was 150 ppm (equal to 6.27 mg/kg bw per day) based on colloid alteration and pigmentation in the follicular epithelium of the thyroid, and increased incidence of hyperplasia in the adrenal medulla at 450 ppm (equal to 18.6 mg/kg bw per day). The NOAEL for carcinogenicity was 450 ppm equal to (18.6 mg/kg bw per day), the highest dose tested.

The Meeting concluded that isoflucypram is not carcinogenic in mice or rats.

Isoflucypram was tested for genotoxicity in an adequate range of in vitro and in vivo assays. No evidence of genotoxicity was found.

The Meeting concluded that isoflucypram is unlikely to be genotoxic.

In view of the lack of genotoxicity and the absence of carcinogenicity in mice and rats, the Meeting concluded that isoflucypram is unlikely to pose a carcinogenic risk to humans.

In a two-generation reproductive study, rats received isoflucypram at dietary concentrations of 0, 150, 450 or 1200 ppm for ten weeks before pairing, throughout pairing and gestation, and at 0, 75, 225 or

600 ppm during the lactation phase. This was to maintain actual intakes equal to 0, 11.3, 34.1 and 92.9 mg/kg bw per day (on the basis of the lowest intake for each group). The NOAEL for parental toxicity was 225 ppm (equal to 34.1 mg/kg bw per day) based on increased cholesterol and increased liver effects at 600 ppm (equal to 92.9 mg/kg bw per day). The NOAEL for effects on offspring was 225 ppm (equal to 34.1 mg/kg bw per day) based on the delay of vaginal opening at 600 ppm (equal to 92.9 mg/kg bw per day). The NOAEL for reproductive toxicity was 600 ppm (equal to 92.9 mg/kg bw per day), the highest dose tested.

In a developmental toxicity study, pregnant rats received isoflucypram by gavage at doses of 0, 25, 125 or 625 mg/kg bw per day from gestation day (GD) 6 to GD 20. The NOAEL for maternal toxicity was 125 mg/kg bw per day based on reduced feed consumption at 625 mg/kg bw per day. The NOAEL for embryo/fetal toxicity was 625 mg/kg bw per day, the highest dose tested.

In a developmental toxicity study, pregnant rabbits received isoflucypram by oral gavage at doses of 0, 10, 70 or 500 mg/kg bw per day from GD 6 to GD 28. The NOAEL for maternal toxicity was 70 mg/kg bw per day based on a slight increase in abortion, slight decrease in body weight and reduced food consumption during the early period of treatment at 500 mg/kg bw per day. The NOAEL for embryo/fetal toxicity was 500 mg/kg bw per day, the highest dose tested.

The Meeting concluded that isoflucypram is not teratogenic.

In an acute neurotoxicity study, rats received isoflucypram by oral gavage as a single dose of 0, 200, 600 or 2000 mg/kg bw. The NOAEL was 2000 mg/kg bw, the highest dose tested.

No subchronic neurotoxicity study was conducted. No findings indicative of neurotoxicity were observed in repeat-dose studies in mice, rats or dogs.

The Meeting concluded that isoflucypram is not neurotoxic.

No specific data were provided regarding immunotoxicity. In routine toxicity studies there was no evidence of effects on the immune system.

The Meeting concluded that isoflucypram is unlikely to be immunotoxic.

Isoflucypram was neither androgenic nor anti-androgenic in a Hershberger assay in rats, and neither estrogenic nor anti-estrogenic in a uterotrophic assay using immature rats.

Isoflucypram did not inhibit thyroperoxidase (TPO) activity using rat thyroidal microsomes or sodium/iodide symporter (NIS) activity in a cell line. Isoflucypram had no direct effects on the thyroid.

Thyroid effects through induction of liver metabolism enzymes were investigated using mice and rats. Isoflucypram induced CAR/PXR-mediated liver hypertrophy, and uridine diphosphate glucuronosyltransferase (UDP-GT), including bilirubin-UDP-GT activity and the expression of UDP-GT1A1 in the liver. Isoflucypram increased thyroid-stimulating hormone (TSH) levels and cell proliferation activity in the thyroid. These effects reversed after withdrawal of the treatment in rats. The mode of action (MOA) of the thyroid effect was considered to involve changes in the thyroid gland secondary to the excess elimination of thyroid hormones from the blood circulation due to the induction of UDP-GT in the liver.

Toxicological data on metabolites and/or degradates

The table below shows an overall summary of the toxicological characterization of the metabolites requested for residue definition.

Summary overview of toxicological characterization of plant/livestock metabolites

Compound, codes	Rat ADME Toxicity covered by toxicological properties of parent compound (content in rat biofluids >10 percent absorbed dose or 10 percent TRR)	Genotoxicity assessment (data, QSAR, read-across)	General toxicity	Health-based guidance values (HBGVs)
Isoflucypram (BCS-CN88460)	Parent	Not genotoxic (data)	Full dataset	ADI: 0.06 mg/kg bw/day
M01 Isoflucypram-propanol	Yes Conjugate >10 percent in bile	Not genotoxic as covered by parent	Covered by parent	Parent ADI
M02 Isoflucypram-2-propanol	No	Not genotoxic in QSAR analysis	No data	TTC Cramer class III value: 0.0015 mg/kg bw/day
M06 Isoflucypram-desmethyl- propanol	No	Not genotoxic (QSAR and RA)	No data	TTC Cramer class III value: 0.0015 mg/kg bw/day
M11 Isoflucypram-desmethyl- carboxylic acid	Yes >10 percent TRR in plasma, liver and kidney in ADME study	Not genotoxic as covered by parent	Covered by parent	Parent ADI
M12 Isoflucypram-carboxylic acid	Yes >10 percent TRR in plasma, liver and kidney in ADME study	Not genotoxic as covered by parent	Covered by parent	Parent ADI
M52 Isoflucypram-desfluoro- <i>N</i> - methyl-cyclopropyl-pyrazole- carboxamide-OH-Cys	No	Genotoxic alert (QSAR)	No data	Genotoxic TTC value: 0.0025µg/kg bw/day
M54 Isoflucypram-desfluoro- <i>N</i> - methyl-cyclopropyl-pyrazole- carboxamide-OH-GSH	No Structurally similar to M52	Genotoxic alert (QSAR) by read-across from M52	No data	Genotoxic TTC value: 0.0025µg/kg bw/day
M49 Isoflucypram- <i>N</i> -methyl- cyclopropyl-pyrazole- carboxamide	Not found in rats	Not genotoxic (QSAR and RA)	No data	Cramer class III value: 0.0015 mg/kg bw/day
M56 Isoflucypram-desfluoro- <i>N</i> - methyl-cyclopropyl-pyrazole- carboxamide-mercapto-Glyc	Not found in rats	Not genotoxic (QSAR and RA)	No data	TTC Cramer class III value: 0.0015 mg/kg bw/day
M57 Isoflucypram-desfluoro- <i>N</i> - methyl-cyclopropyl-pyrazole- carboxamide-mercapto-Glyc- MA	Not found in rats	Not genotoxic (QSAR and RA)	No data	TTC Cramer class III value: 0.0015 mg/kg bw/day
M62 Isoflucypram-cyclopropyl- pyrazole-carboxamide-Glyc (isomer 1 and 2)	Not found in rats It is M58-Glyc M58 is a rat major metabolite	Not genotoxic as covered by parent	Covered by parent	Parent ADI
M66 Isoflucypram-cyclopropyl- pyrazole-carboxamide-Ala	Not found in rats It is M58-Ala M58 is a rat major metabolite M58-Ala is considered to convert into M58 upon consumption	Not genotoxic as covered by parent Not genotoxic (QSAR and RA)	Covered by parent	Parent ADI

Compound, codes	Rat ADME Toxicity covered by toxicological properties of parent compound (content in rat biofluids >10 percent absorbed dose or 10 percent TRR)	Genotoxicity assessment (data, QSAR, read-across)	General toxicity	Health-based guidance values (HBGVs)
M67 Isoflucypram-desfluoro-cyclopropyl-pyrazole-carboxamide-Ala	Not found in rats It is desfluorinated M58-Ala M58 is a major metabolite in toxicity studies in mice, rats, rabbits and dogs. M58 is found >10 percent TRR in plasma, liver and kidney in ADME study in rats	Not genotoxic as covered by parent	Covered by parent	Parent ADI
M68 Isoflucypram-cyclopropyl-pyrazole-carboxamide-acetic acid	Not found in rats It is M58-acetic acid M58 is a major metabolite in toxicity studies in mice, rats, rabbits and dogs. M58 is found >10 percent TRR in plasma, liver and kidney in ADME study in rats	Not genotoxic as covered by parent	Covered by parent	Parent ADI
M69 Isoflucypram-cyclopropyl-pyrazole-carboxamide-OH-lactic acid (isomer 1 and 2)	M58-lactic acid M58 is a major metabolite in toxicity studies in mice, rats, rabbits and dogs. M58 is found >10 percent TRR in plasma, liver and kidney in ADME study in rats	Not genotoxic as covered by parent	Covered by parent	Parent ADI

Notes:

ADI: Acceptable daily intake.

RA: read across.

TRR: Total radioactive residue.

ADME: Absorption, distribution, metabolism and excretion.

QSAR: Quantitative structure–activity relationship.

BCS-CN45153, an impurity of isoflucypram

Two 28-day toxicity studies and a rat uterotrophic assay were provided but did not raise a concern relative to the parent.

Microbiological data

There was no information available in the public domain and no experimental data were provided which addressed the possible impact of isoflucypram residues on the human intestinal microbiome.

Human data

The sponsor provided information on medical surveillance manufacturing plant personnel and monitoring studies. There was no specific report related to isoflucypram.

The Meeting concluded that the existing database on isoflucypram was adequate to characterize the potential to the general population, including fetuses, infants and children.

Toxicological evaluation

The Meeting established an ADI of 0–0.06 mg/kg bw for isoflucypram based on a NOAEL of 6.27 mg/kg bw per day in the long-term study in rats and applying a safety factor of 100.

The Meeting concluded that it was not necessary to establish an ARfD for isoflucypram in view of its low acute oral toxicity and the absence of any other toxicological effects, including developmental toxicity, that would be likely to be elicited by a single dose.

A toxicological monograph was prepared.

Levels relevant to risk assessment of isoflucypram

Species	Study	Effect	NOAEL	LOAEL
Mouse	78-week study of toxicity and carcinogenicity ^a	Toxicity	250 ppm, equal to 29.0 mg/kg bw/day	1250 ppm, equal to 147 mg/kg bw/day
		Carcinogenicity	1250 ppm, equal to 147 mg/kg bw/day ^c	-
Rat	Acute neurotoxicity study ^b	Neurotoxicity	2000 mg/kg bw ^c	-
	90-day toxicity study ^a	Toxicity	300 ppm, equal to 18.4 mg/kg bw/day	1000 ppm, equal to 63.5 mg/kg bw/day
		Two-year studies of toxicity and carcinogenicity ^a	Toxicity	150 ppm, equal to 6.27 mg/kg bw/day
	Carcinogenicity		450 ppm, equal to 18.6 mg/kg bw/day ^c	-
	Two-generation study of reproductive toxicity ^a	Reproductive toxicity	1200/600 ppm, equal to 92.9 mg/kg bw/day ^c	-
		Parental toxicity	450/225 ppm, equal to 34.1 mg/kg bw/day	1200/600 ppm, equal to 92.9 mg/kg bw/day
		Offspring toxicity	450/225 ppm, equal to 34.1 mg/kg bw/day	1200/600 ppm, equal to 92.9 mg/kg bw/day
	Developmental toxicity study ^b	Maternal toxicity	125 mg/kg bw/day	625 mg/kg bw/day
Embryo/fetal toxicity		625 mg/kg bw/day ^c	-	
Rabbit	Developmental toxicity study ^b	Maternal toxicity	70 mg/kg bw/day	500 mg/kg bw/day
		Embryo/fetal toxicity	500 mg/kg bw/day ^c	-
Dog	13-week and one-year studies of toxicity ^{a, d}	Toxicity	600 ppm, equal to 17.6 mg/kg bw/day	1800 ppm, equal to 49.8 mg/kg bw/day

Notes:

^a Dietary administration.

^b Gavage administration.

^c Highest dose tested.

^d Two or more studies combined.

*Acceptable daily intake(ADI) for isoflucypram **

0–0.06 mg/kg bw

Acute reference dose (ARfD) for isoflucypram,

Not necessary

* Applies to isoflucypram, M01, M11, M12, M62, M66, M67, M68, M69

Critical end-points for setting guidance values for exposure to isoflucypram

Absorption, distribution, excretion and metabolism in mammals

Rate and extent of oral absorption	Rapid; approximately 80 percent
Dermal absorption	No data
Distribution	Wide; highest levels in liver and kidney
Potential for accumulation	No evidence of accumulation
Rate and extent of excretion	Rapid; nearly complete via urine, bile and faeces within 24 h
Metabolism in animals	Extensive demethylation, conjugation and carboxylation
Toxicologically significant compounds in animals and plants	Isoflucypram, M01, M02, M06, M11, M12, M49, M52, M54, M56, M57, , M62, M66, M67, M68, M69

Acute toxicity

Rat, LD ₅₀ , oral	>2000 mg/kg bw
Rat, LD ₅₀ , dermal	>2000 mg/kg bw
Rat, LC ₅₀ , inhalation	2.5 mg/L
Rabbit, dermal irritation	Irritating
Rabbit, ocular irritation	Mildly irritating
Mouse, dermal sensitization	Sensitizing (LLNA)

Short-term studies of toxicity

Target/critical effect	Body weight
Lowest relevant oral NOAEL	17.6 mg/kg bw per day (dog)
Lowest relevant dermal NOAEL	No data.
Lowest relevant inhalation NOAEC	No data.

Long-term studies of toxicity and carcinogenicity

Target/critical effect	Body weight, liver multinucleated cells, hyperplasia adrenals
Lowest relevant NOAEL	6.27 mg/kg bw per day (rat)
Carcinogenicity	Not carcinogenic

Genotoxicity

Unlikely to be genotoxic

Reproductive toxicity

Target/critical effect	Liver, increased cholesterol, increased liver weight, delayed vaginal opening
Lowest relevant parental NOAEL	34.1 mg/kg bw per day (rat)
Lowest relevant offspring NOAEL	34.1 mg/kg bw per day (rat)
Lowest relevant reproductive NOAEL	92.9 mg/kg bw per day (rat)

Developmental toxicity

Target/critical effect	Body weight, food consumption, abortion
Lowest relevant maternal NOAEL	70 mg/kg bw per day (rabbit)

Lowest relevant embryo/fetal NOAEL	500 mg/kg bw per day, highest dose tested (rabbit)
Neurotoxicity	
Acute neurotoxicity NOAEL	>2000 mg/kg bw, highest dose tested (rat)
Subchronic neurotoxicity NOAEL	No specific data but no evidence from routine studies
Developmental neurotoxicity NOAEL	No data
Other toxicological studies	
Immunotoxicity	No evidence from routine studies
Studies on toxicologically relevant metabolites	
Isoflucypram-carboxylic acid (BCS-CY26497, M12)	Unlikely to be genotoxic (Ames, chromosome aberration, micronucleus in vivo)
M02, M06, M07, M10, M36, M49, M50, M56, M57, M66, M67	Unlikely to be genotoxic (QSAR)
M52, M54	Genotoxic alert (QSAR)
Microbiological data	
No information available	
Human data	
No clinical cases or poisoning incidents had been recorded	

Summary

	Value	Study	Safety factor
ADI	0–0.06 mg/kg bw ^a	Two-year study of toxicity and carcinogenicity (rat)	100
ARfD	Not necessary		

Notes:

^a Applies to isoflucypram, M01, M11, M12, , M62, M66, M67, M68 and M69.

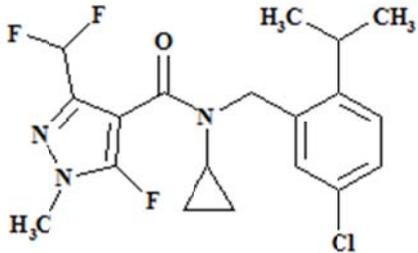
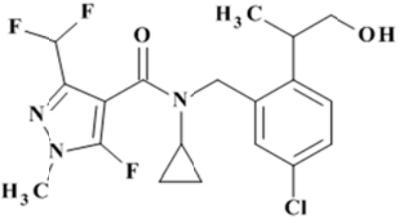
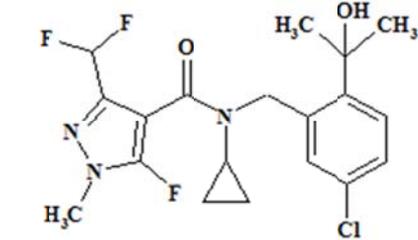
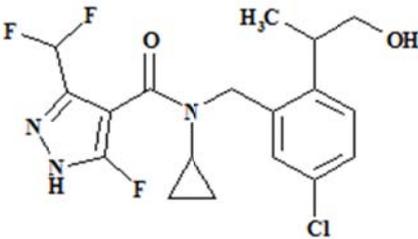
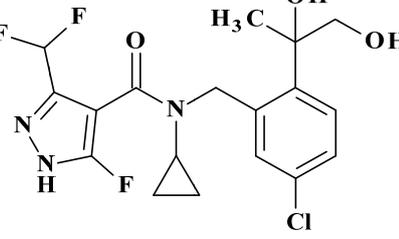
RESIDUE AND ANALYTICAL ASPECTS

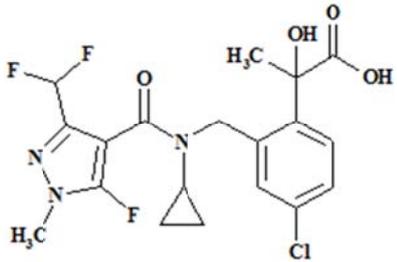
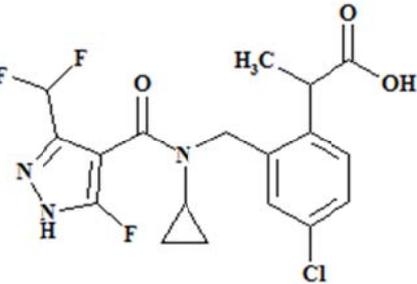
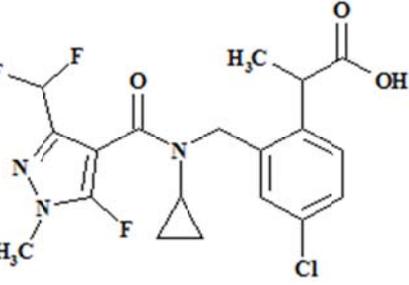
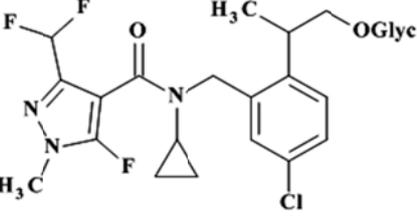
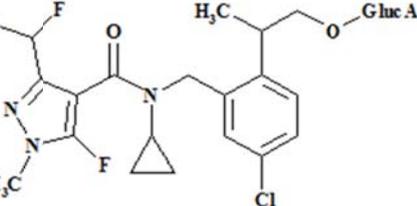
Isoflucypram is a novel broad-spectrum fungicide of the chemical class of N-cyclopropyl-N-benzyl-pyrazole-carboxamides. Isoflucypram is a succinate dehydrogenase (SDH) inhibitor.

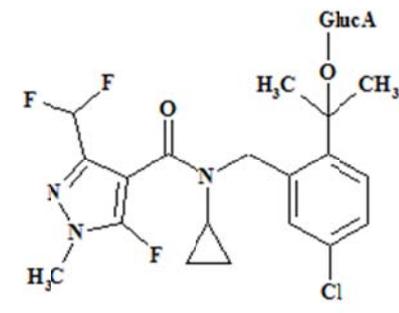
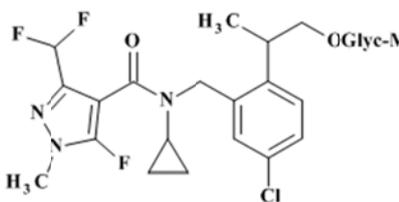
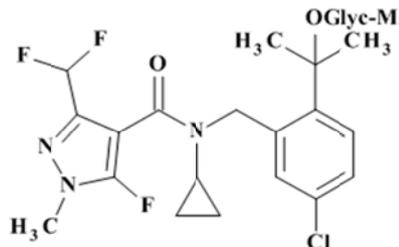
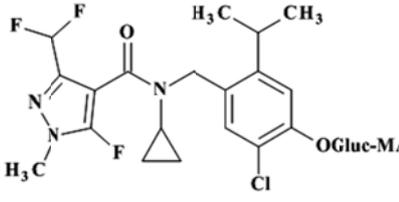
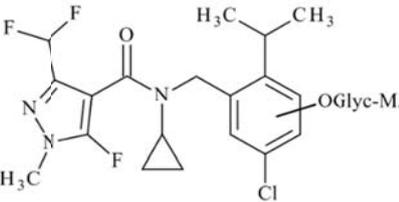
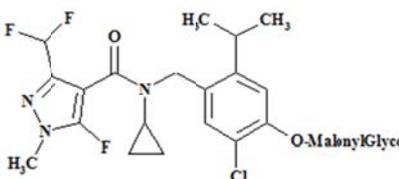
Isoflucypram was scheduled at the Fifty-first Session of the CCPR for evaluation as a new compound in 2020 and rescheduled to the 2022 JMPR. The 2022 Meeting established an ADI of 0–0.06 mg/kg bw/day and determined that an ARfD was unnecessary. Information on chemical identity, physical-chemical properties, metabolism and environmental fate, methods of residue analysis, storage stability, intended use patterns, supervised residue trials, fate of residues upon processing, and farm animal feeding studies were submitted for evaluation by the 2022 JMPR.

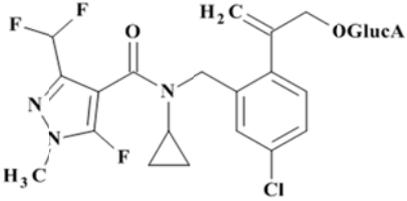
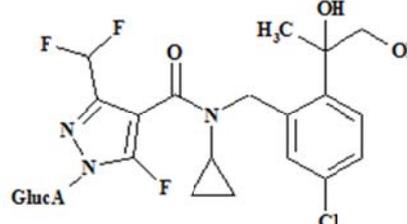
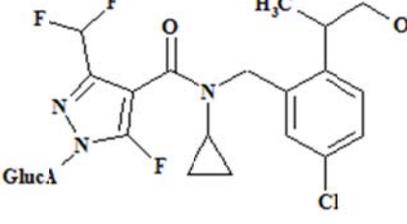
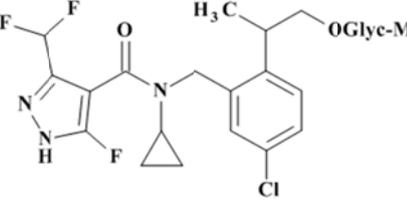
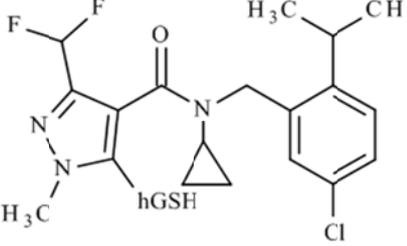
The chemical structures of isoflucypram and its metabolites/degradates relevant for the appraisal are shown below.

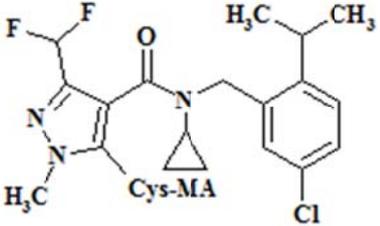
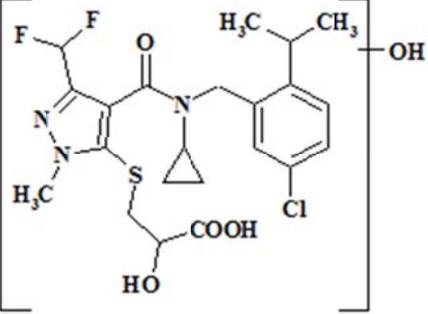
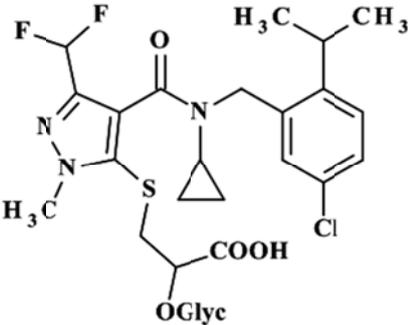
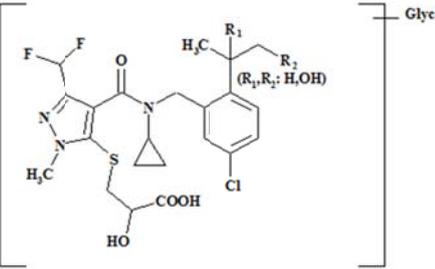
Table 5.22.1 Abbreviations used for relevant compounds referred to in the appraisal

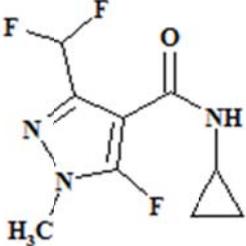
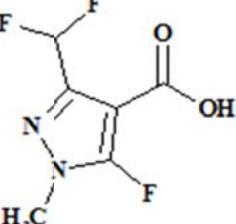
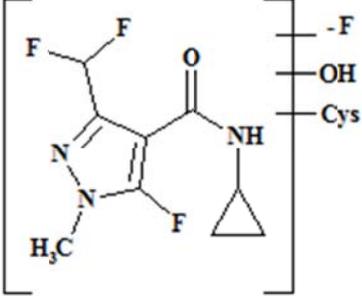
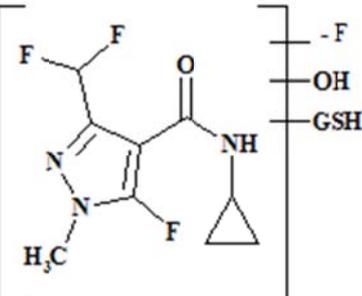
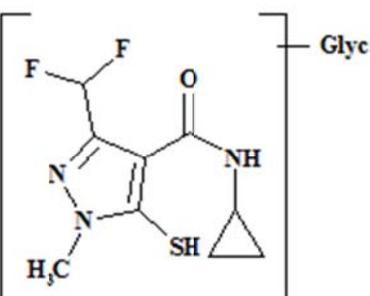
Code Name	Chemical Identity (IUPAC)	Structure
Isoflucypram	N-(5-chloro-2-isopropylbenzyl)-N-cyclopropyl-3-(difluoromethyl)-5-fluoro-1-methyl-1H-pyrazole-4-carboxamide	
M01 Isoflucypram-propanol	N-[5-chloro-2-(1-hydroxypropan-2-yl)benzyl]-N-cyclopropyl-3-(difluoromethyl)-5-fluoro-1-methyl-1H-pyrazole-4-carboxamide	
M02 Isoflucypram-2-propanol	2-(4-chloro-2-[(cyclopropyl{3-(difluoromethyl)-5-fluoro-1-methyl-1H-pyrazol-4-yl}-carbonyl)amino]-methyl]phenyl)propan-2-yl	
M06 Isoflucypram-desmethyl-propanol	N-[5-chloro-2-(1-hydroxypropan-2-yl)benzyl]-N-cyclopropyl-3-(difluoromethyl)-5-fluoro-1H-pyrazole-4-carboxamide	
M07 Isoflucypram-desmethyl-1,2-propandiol	N-[5-chloro-2-(1,2-dihydroxypropan-2-yl)benzyl]-N-cyclopropyl-3-(difluoromethyl)-5-fluoro-1H-pyrazole-4-carboxamide	

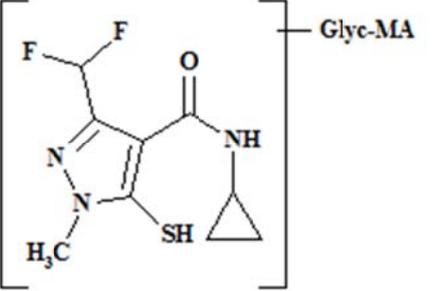
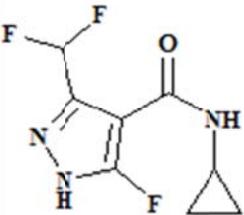
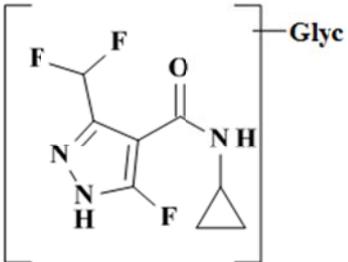
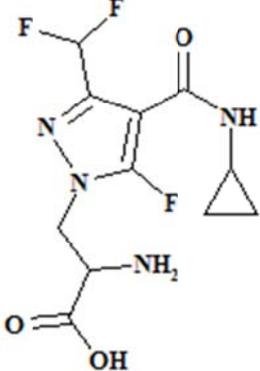
Code Name	Chemical Identity (IUPAC)	Structure
M10 Isoflucypram-lactic acid	2-{4-chloro-2-[(cyclopropyl{[3-(difluoromethyl)-5-fluoro-1-methyl-1H-pyrazol-4-yl]carbonyl}amino)methyl]phenyl}-2-hydroxypropanoic acid	
M11 Isoflucypram-desmethyl-carboxylic acid	2-{4-chloro-2-[(cyclopropyl{[3-(difluoromethyl)-5-fluoro-1H-pyrazol-4-yl]carbonyl}amino)methyl]phenyl}propanoic acid	
M12 Isoflucypram-carboxylic acid	2-{4-chloro-2-[(cyclopropyl{[3-(difluoromethyl)-5-fluoro-1-methyl-1H-pyrazol-4-yl]-carbonyl}amino)-methyl]phenyl}-propanoic acid	
M18 Isoflucypram-propanol-Glyc	N-{5-chloro-2-[1-(hexopyranosyloxy)propan-2-yl]benzyl}-N-cyclopropyl-3-(difluoromethyl)-5-fluoro-1-methyl-1H-pyrazole-4-carboxamide	
M19 Isoflucypram-propanol-GlucA (isomer 1 and 2)	2-{4-chloro-2-[(cyclopropyl{[3-(difluoromethyl)-5-fluoro-1-methyl-1H-pyrazol-4-yl]-carbonyl}amino)methyl]phenyl}propyl glucopyranosiduronic acid	

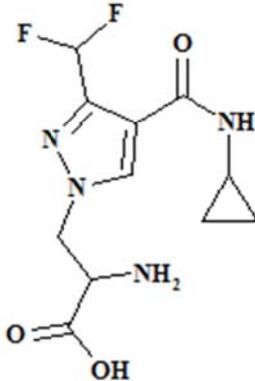
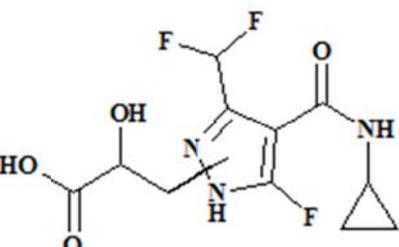
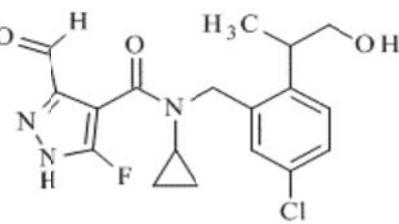
Code Name	Chemical Identity (IUPAC)	Structure
M20 Isoflucypram-2-propanol-GlucA	2-(4-chloro-2-[(cyclopropyl{[3-(difluoromethyl)-5-fluoro-1-methyl-1H-pyrazol-4-yl]carbonyl}amino)methyl]phenyl)propan-2-yl beta-D-glucopyranosiduronic acid	
M21 Isoflucypram-propanol-Glyc-MA	2-(4-chloro-2-[(cyclopropyl{[3-(difluoromethyl)-5-fluoro-1-methyl-1H-pyrazol-4-yl]-carbonyl}amino)methyl]phenyl)propyl 6-O-(carboxy acetyl)hexopyranoside	
M22 Isoflucypram-2-propanol-Glyc-MA	2-(4-chloro-2-[(cyclopropyl{[3-(difluoromethyl)-5-fluoro-1-methyl-1H-pyrazol-4-yl]-carbonyl}amino)-methyl]phenyl)propan-2-yl 6-O-(carboxy-acetyl)hexopyranoside	
M23 Isoflucypram-hydroxyphenyl-Gluc-MA	2-chloro-4-[(cyclopropyl{[3-(difluoromethyl)-5-fluoro-1-methyl-1H-pyrazol-4-yl]-carbonyl}amino)-methyl]-5-isopropyl-phenyl 6-O-(carboxyacetyl)-beta-D-glucopyranoside	
M23a Isoflucypram-OH-phenyl-Glyc-MA	-	
M24 Isoflucypram-hydroxyphenyl-Glyc-MA	2-chloro-4-[(cyclopropyl{[3-(difluoromethyl)-5-fluoro-1-methyl-1H-pyrazol-4-yl]-carbonyl}amino)-methyl]-5-isopropyl-phenyl 6-O-(carboxyacetyl)-hexopyranoside	

Code Name	Chemical Identity (IUPAC)	Structure
M25 Isoflucypram-propenol-GlucA	2-{4-chloro-2-[(cyclopropyl){3-(difluoromethyl)-5-fluoro-1-methyl-1H-pyrazol-4-yl]carbonyl}amino)methyl]phenyl}prop-2-en-1-yl beta-D-glucopyranosiduronic acid	
M36 Isoflucypram-desmethyl-1,2-propandiol-N-GlucA	N-[5-chloro-2-(1,2-dihydroxypropan-2-yl)benzyl]-N-cyclopropyl-3-(difluoromethyl)-5-fluoro-1-(glucopyranuronosyl)-1H-pyrazole-4-carboxamide	
M37 Isoflucypram-desmethyl-propanol-N-GlucA	N-[5-chloro-2-(1-hydroxypropan-2-yl)benzyl]-N-cyclopropyl-3-(difluoromethyl)-5-fluoro-1-(glucopyranuronosyl)-1H-pyrazole-4-carboxamide	
M41 Isoflucypram-desmethyl-propanol-Glyc-MA	2-{4-chloro-2-[(cyclopropyl){3-(difluoromethyl)-5-fluoro-1H-pyrazol-4-yl]carbonyl}amino)methyl]phenyl}propyl 6-O-(carboxyacetyl)hexopyranoside	
M44 Isoflucypram-desfluoro-homoGSH	gamma-glutamyl-S-{4-[(5-chloro-2-isopropylbenzyl)(cyclopropyl)carbonyl]-3-(difluoromethyl)-1-methyl-1H-pyrazol-5-yl}cysteinyl-beta-alanine	

Code Name	Chemical Identity (IUPAC)	Structure
<p>M45 Isoflucypram-desfluoro-Cys-MA</p>	<p>N-(carboxyacetyl)-S-{4-[(5-chloro-2-isopropylbenzyl)(cyclopropyl)carbamoyl]-3-(difluoromethyl)-1-methyl-1H-pyrazol-5-yl}cysteine</p>	
<p>M46 Isoflucypram-desfluoro-mercaptolactic acid-OH</p>	<p>-</p>	
<p>M47 Isoflucypram-desfluoro-mercaptolactic acid-Glyc</p>	<p>3-((4-[(5-chloro-2-isopropylbenzyl)(cyclopropyl)carbamoyl]-3-(difluoromethyl)-1-methyl-1H-pyrazol-5-yl)sulfanyl)-2-(hexopyranosyloxy)propanoic acid</p>	
<p>M48 Isoflucypram-desfluoro-mercaptolactic acid-propyl-OH-Glyc</p>	<p>-</p>	

Code Name	Chemical Identity (IUPAC)	Structure
<p>M49 BCS-CR60082 Isoflucypram-N-methyl-cyclopropyl-pyrazole-carboxamide</p>	<p>N-cyclopropyl-3-(difluoromethyl)-5-fluoro-1-methyl-1H-pyrazole-4-carboxamide</p>	
<p>M50 Isoflucypram-N-methyl-pyrazole-carboxylic acid</p>	<p>3-(difluoromethyl)-5-fluoro-1-methyl-pyrazole-4-carboxylic acid</p>	
<p>M52 Isoflucypram-desfluoro-N-methyl-cyclopropyl-pyrazole-carboxamide-OH-Cys</p>	<p>-</p>	
<p>M54 Isoflucypram-desfluoro-N-methyl-cyclopropyl-pyrazole-carboxamide-OH-GSH</p>	<p>-</p>	
<p>M56 Isoflucypram-desfluoro-N-methyl-cyclopropyl-pyrazole-carboxamide-mercapto-Glyc</p>	<p>-</p>	

Code Name	Chemical Identity (IUPAC)	Structure
<p>M57 Isoflucypram-desfluoro-N-methyl-cyclopropyl-pyrazole-carboxamide-mercapto-Glyc-MA</p>	-	
<p>M58 Isoflucypram-cyclopropyl-pyrazole-carboxamide</p>	N-cyclopropyl-3-(difluoromethyl)-5-fluoro-1H-pyrazole-4-carboxamide	
<p>M62 Isoflucypram-cyclopropyl-pyrazole-carboxamide-Glyc (isomer 1 and 2)</p>	-	
<p>M66 Isoflucypram-cyclopropyl-pyrazole-carboxamide-Ala</p>	3-[4-(cyclopropylcarbamoyl)-3-(difluoromethyl)-5-fluoro-1H-pyrazol-1-yl]alanine	

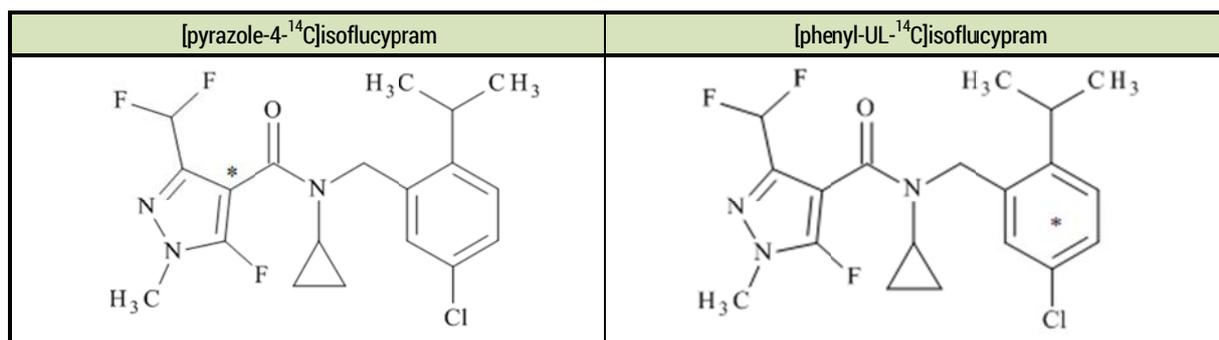
Code Name	Chemical Identity (IUPAC)	Structure
<p>M67 Isoflucypram-desfluoro-cyclopropyl-pyrazole-carboxamide-Ala</p>	<p>3-[4-(cyclopropylcarbamoyl)-3-(difluoromethyl)-1H-pyrazol-1-yl]alanine</p>	
<p>M69 Isoflucypram-cyclopropyl-pyrazole-carboxamide-OH-lactic acid (isomer 1 and 2)</p>	-	
<p>M77 Isoflucypram-desmethyl-propanol-aldehyde</p>	<p>N-[5-chloro-2-(1-hydroxypropan-2-yl)benzyl]-N-cyclopropyl-5-fluoro-3-formyl-1H-pyrazole-4-carboxamide</p>	

Physical-chemical properties

Isoflucypram is regarded as not volatile, it has a higher solubility in organic solvents compared to its solubility in water, and the partition coefficient ($\log P_{ow}=4.0$) indicates potential to sequester into fat.

Plant metabolism

The Meeting received studies describing the metabolism of isoflucypram in tomatoes, wheat, soya bean, and oilseed rape following foliar application, and in potatoes following application to potato seed pieces. The studies were conducted with isoflucypram radiolabelled at either the pyrazole or phenyl position, as shown below. All studies were conducted in a greenhouse and the compound was formulated as emulsifiable concentrate (EC).



Notes:

(*): Position of ¹⁴C-radiolabel.

Tomato

Isoflucypram was applied twice to tomatoes at BBCH 14–15 (78–79 g ai/ha) and BBCH 85–87 (78–89 g ai/ha). The interval between applications was 97–99 days. Tomato fruits were harvested 14 days after the last application.

The total radioactive residue (TRR) was 1.8× higher in the pyrazole study (0.17 mg eq/kg) as compared to the phenyl study (0.095 mg eq/kg). The main portion of the radioactivity was recovered in the surface wash, comprising 74–75 percent TRR (0.071–0.13 mg eq/kg). TRR in the acetonitrile (ACN)/water extract was 25–26 percent TRR (0.024–0.045 mg eq/kg), leaving ≤ 0.2 percent TRR (≤ 0.001 mg eq/kg) in the post-extraction solids (PES).

Isoflucypram was the only metabolite observed, comprising 97–98 percent TRR (0.094–0.17 mg/kg). There were no unknown peaks.

Wheat

Isoflucypram was applied twice to wheat, at BBCH 30 at 64–69 g ai/ha and at BBCH 69 at 66–67 g ai/ha. The interval between applications was 28–33 days. Wheat hay was harvested one day prior to the second application (BBCH 69) and allowed to dry for four days. Wheat straw and grain were harvested at maturity (BBCH 89) corresponding to 17–18 days between the final application and harvest.

Total radioactive residues (TRR) in both labels were similar and were highest in straw (16 mg eq/kg), hay (3.0–4.0 mg eq/kg) and grain (0.28–0.39 mg eq/kg). The conventional ACN/water extract released ≥ 94 percent TRR. The conventional extract of pyrazole-labelled wheat straw was subjected to microwave-assisted extraction, releasing an additional 4.7 percent TRR. The conventional extract of wheat hay and straw were hydrolysed with 1 mol/L hydrochloric acid (HCl) at 100 °C for 1 hour.

In wheat hay, parent isoflucypram was the major component representing 50–55 percent TRR (1.7–2.0 mg/kg). Identified metabolites included isoflucypram-propanol-Glyc-MA (7.5–10 percent TRR [0.23–0.41 mg eq/kg]), isoflucypram-desmethyl-propanol-Glyc-MA (2.5–2.7 percent TRR [0.081–0.10 mg eq/kg]), isoflucypram-propanol-Glyc (0.8–2.4 percent TRR [0.023–0.096 mg eq/kg]), and isoflucypram-propanol (0.7 percent TRR [0.021–0.029 mg eq/kg]). Up to 23 unknown metabolites were characterized in the extracts by their chromatographic behaviour, individually accounting for ≤ 3.1 percent TRR (≤ 0.13 mg eq/kg). PES accounted for ≤ 4.2 percent TRR (≤ 0.17 mg eq/kg).

In hydrolysed extract of wheat hay, parent isoflucypram was the major component representing 44–50 percent TRR (1.5–1.8 mg/kg). Remaining identified metabolites included isoflucypram-propanol (21–22 percent TRR [0.64–0.90 mg eq/kg]), isoflucypram-desmethyl-propanol (6.7–6.9 percent TRR

[0.20–0.28 mg eq/kg]), isoflucypram-propanol-Glyc-MA (0.90 percent TRR [0.036 mg eq/kg]), and isoflucypram-propanol-Glyc (0.60–0.80 percent TRR [0.019–0.031 mg eq/kg]).

In wheat straw, parent isoflucypram was the major component representing 62–64 percent TRR (9.9–10 mg/kg). Remaining identified metabolites included isoflucypram-propanol-Glyc-MA (5.0–6.7 percent TRR [0.808–1.042 mg eq/kg]), isoflucypram-propanol-Glyc (2.3–3.7 percent TRR [0.37–0.56 mg eq/kg]), isoflucypram-desmethyl-propanol-Glyc-MA (1.9–2.9 percent TRR [0.306–0.45 mg eq/kg]), isoflucypram-propanol (0.9–1.7 percent TRR [0.15–0.27 mg eq/kg]), and isoflucypram-desmethyl-propanol (0.30–1.1 percent TRR [0.052–0.17 mg eq/kg]). Up to 39 unknown metabolites were characterized in the extracts by their chromatographic behaviour, individually accounting for ≤ 2.1 percent TRR (≤ 0.35 mg eq/kg). TRR was successfully extracted as demonstrated by ≤ 4.8 percent TRR (0.77 mg eq/kg) remaining in the PES.

In the hydrolysed extract of wheat straw, parent isoflucypram was the major component representing 61–67 percent TRR (9.8–10 mg/kg). Remaining identified metabolites included isoflucypram-propanol (11–13 percent TRR [1.6–2.0 mg eq/kg]), isoflucypram-desmethyl-propanol (3.6–4.0 percent TRR [0.56–0.64 mg eq/kg]), isoflucypram-desmethyl-propanol-Glyc-MA (0.30 percent TRR [0.054 mg eq/kg]), isoflucypram-propanol-Glyc (0.20–0.30 percent TRR [0.024–0.053 mg eq/kg]), and isoflucypram-propanol-Glyc-MA (0.10–0.30 percent TRR [0.022–0.054 mg eq/kg]).

Wheat grain contained only parent isoflucypram, representing 92–93 percent TRR (0.26–0.35 mg/kg). There were no unknown peaks. TRR was successfully extracted as demonstrated by ≤ 6.5 percent TRR (0.025 mg eq/kg) remaining in the PES.

Soya bean

Isoflucypram was applied three times to soya bean plants, at BBCH 14 (54–59 g ai/ha), BBCH 51 (56–57 g ai/ha) and BBCH 84–85 (65–66 g ai/ha). Application interval was 6–8 days between applications one and two and 62–69 days between applications two and three. Soya bean forage was harvested at BBCH 49, corresponding to 5–6 days after the first application. Soya bean hay was harvested at BBCH 77, corresponding to 38–39 days after the second application, and allowed to dry for four days. Soya bean straw and seed were harvested at BBCH 96, corresponding to 21 days after the final application. TRR in forage was similar for both labels, but was 2.1–3.3 \times higher in the pyrazole study for remaining soya bean commodities. Radioactivity (phenyl/pyrazole) was highest in straw (8.5/18 mg eq/kg), followed by forage (3.9/4.4 mg eq/kg), hay (1.4/4.7 mg eq/kg) and seed (0.015/0.035 mg eq/kg). For both studies, ≥ 87 percent TRR was extracted in the conventional ACN/water extract, except for phenyl-label seed where 70 percent was extracted, possibly as a result of low overall TRR (0.015 mg eq/kg). Microwave-assisted extraction of soya bean forage, hay, and straw successfully released an additional 2.5–6.9 percent TRR. Soya bean hay extract from microwave-assisted extraction underwent partitioning against ethyl acetate, resulting in complete transfer of the radioactivity to the organic phase.

In soya bean forage, isoflucypram accounted for 19 percent TRR (0.76–0.82 mg/kg). Identified metabolites included isoflucypram-desfluoro-homoGSH (20–23 percent TRR, 0.79–1.0 mg eq/kg), isoflucypram-desfluoro-mercapto-lactic acid-OH (9.5–17 percent TRR, 0.42–0.67 mg eq/kg), isoflucypram-desfluoro-Cys-MA (8.2–9.2 percent TRR, 0.32–0.40 mg eq/kg), isoflucypram-desfluoro-mercapto-lactic acid-propyl-OH-Glyc (3.4–4.8 percent TRR, 0.15–0.19 mg eq/kg), and isoflucypram-desfluoro-mercapto-lactic acid-Glyc (2.7–3.0 percent TRR, 0.11–0.13 mg eq/kg). Up to 17 unknown peaks were characterized based on chromatographic behaviour, individually accounting for ≤ 3.9 percent TRR (≤ 0.17 mg eq/kg). PES accounted for ≤ 3.4 percent TRR (≤ 0.13 mg eq/kg).

In soya bean hay, isoflucypram accounted for 10 percent TRR (0.14–0.49 mg/kg). Identified metabolites included isoflucypram-desfluoro-Cys-MA (15–21 percent TRR, 0.29–0.72 mg eq/kg), isoflucypram-desfluoro-mercapto-lactic acid-propyl-OH-Glyc (15–18 percent TRR, 0.25–0.71 mg eq/kg), isoflucypram-desfluoro-mercapto-lactic acid-Glyc (11 percent TRR, 0.15–0.52 mg eq/kg), isoflucypram-desfluoro-homoGSH (7.8 percent TRR, 0.11–0.37 mg eq/kg), and isoflucypram-desfluoro-mercapto-lactic acid-OH (2.8–3.2 percent TRR, 0.040–0.15 mg eq/kg). Up to 13 unknown peaks were characterized based on chromatographic behaviour, individually accounting for ≤ 6.1 percent TRR (≤ 0.21 mg eq/kg). PES accounted for ≤ 5.7 percent TRR (≤ 0.27 mg eq/kg).

In soya bean straw, isoflucypram was the major component, representing 65–70 percent TRR (6.0–11 mg/kg). Remaining identified metabolites included isoflucypram-desfluoro-Cys-MA (4.3–4.6 percent TRR, 0.37–0.83 mg eq/kg), isoflucypram-desfluoro-homoGSH (2.8–4.8 percent TRR, 0.24–0.86 mg eq/kg), isoflucypram-desfluoro-mercapto-lactic acid-propyl-OH-Glyc (2.1–3.8 percent TRR, 0.18–0.69 mg eq/kg), isoflucypram-desfluoro-mercapto-lactic acid-Glyc (2.8–3.0 percent TRR, 0.24–0.53 mg eq/kg), and isoflucypram-desfluoro-mercapto-lactic acid-OH (1.9–2.5 percent TRR, 0.22–0.34 mg eq/kg). Up to 20 unknown peaks were characterized based on chromatographic behaviour, individually accounting for ≤ 2.8 percent TRR (≤ 0.33 mg eq/kg). PES accounted for ≤ 4.1 percent TRR (≤ 0.35 mg eq/kg).

In soya bean seed, parent isoflucypram was the only identified component, representing 67–77 percent TRR (0.011–0.027 mg/kg). There were no unknown peaks. Radioactivity remaining in the PES was ≤ 30 percent TRR (≤ 0.005 mg eq/kg).

Oilseed rape

Isoflucypram was applied twice to oilseed rape plants, at BBCH 14 at 63–64 g ai/ha and at BBCH 77 at 62–63 g ai/ha. The interval between applications was 84 days. Oilseed rape was harvested at BBCH 30 for intermediate harvest (whole plant) corresponding to two days after the first application. Oilseed rape forage was harvested at BBCH 55, 40 days after the first application and the plants and seed were harvested at maturity (BBCH 89), 21 days after the final application. TRR was similar between both labels. TRR was highest in intermediate harvest (3.3 and 4.8 mg eq/kg) and plants (3.9 and 4.1 mg eq/kg), followed by seed (0.099 and 0.13 mg eq/kg), and forage (0.008 and 0.012 mg eq/kg). The conventional ACN/water extract released ≥ 71 percent TRR. For seed, an additional 9.8–11 percent TRR was subsequently extracted with microwave-assistance. The purified extract for whole plant intermediate harvest was hydrolysed with 10 mol/L HCl for 1 hour.

In oilseed rape whole plant intermediate harvest, isoflucypram was the major component, representing 82–84 percent TRR (2.8–3.9 mg/kg). Identified metabolites included and isoflucypram-hydroxyphenyl-Glyc-MA (3.1–3.8 percent TRR, 0.13–0.15 mg eq/kg), isoflucypram-hydroxyphenyl-Gluc-MA (2.3 percent TRR, 0.077–0.11 mg eq/kg), isoflucypram-propanol-Glyc-MA (2.2–2.8 percent TRR, 0.071–0.13 mg eq/kg), and isoflucypram-2-propanol-Glyc-MA (1.6–2.2 percent TRR, 0.052–0.11 mg eq/kg). Up to 23 unknown peaks were characterized based on chromatographic behaviour, individually accounting for ≤ 1.5 percent TRR (≤ 0.072 mg eq/kg). Radioactivity remaining in the PES was ≤ 0.50 percent TRR (≤ 0.022 mg eq/kg).

Comparison of metabolic profiles before and after acid hydrolysis of mature plant intermediate harvest indicated cleavage of isoflucypram-hydroxyphenyl-Gluc-MA, isoflucypram-2-propanol-Glyc-MA, isoflucypram-propanol-Glyc-MA, and isoflucypram-hydroxyphenyl-Glyc-MA to less polar compounds.

In oilseed rape forage, no individual peak was observed above the background noise due to low radioactivity. Radioactivity remaining in the PES accounted for ≤ 23 percent TRR (≤ 0.002 mg eq/kg).

In oilseed rape mature plants, isoflucypram was the major component, representing 72–88 percent TRR (2.8–3.6 mg/kg). Identified metabolites included isoflucypram-hydroxyphenyl-Glyc-MA (1.0–3.1 percent TRR, 0.040–0.12 mg eq/kg), isoflucypram-2-propanol-Glyc-MA (0.90–4.6 percent TRR, 0.038–0.18 mg eq/kg), isoflucypram-hydroxyphenyl-Glyc-MA (0.70–2.2 percent TRR, 0.027–0.087 mg eq/kg), and isoflucypram-propanol-Glyc-MA (0.60–2.5 percent TRR, 0.025–0.097 mg eq/kg). Up to 39 unknown peaks were characterized based on chromatographic behaviour, individually accounting for ≤ 1.3 percent TRR (≤ 0.054 mg eq/kg). Radioactivity remaining in the PES was ≤ 3.8 percent TRR (≤ 0.15 mg eq/kg).

In oilseed rape seeds, parent was the only identified component, representing 71–74 percent TRR (0.070–0.093 mg/kg). There were no unknown peaks. Radioactivity remaining in the PES was ≤ 6.7 percent TRR (≤ 0.008 mg eq/kg).

Potatoes

Isoflucypram was applied to potato seed pieces prior to planting in at 28 g ai/ha (0.55 mg ai/ tuber and 50,000 plants/ha) for a low dose experiment and 274–280 g ai/ha (5.5 mg ai/tuber and 50,000 plants/ha) for a high dose experiment. Potato tubers and leaves were harvested at BBCH 97, corresponding to 119 days after planting.

TRR was higher in the pyrazole study by factors ranging from 1.5–7.5 \times . TRR was higher in leaves (0.050 and 0.37 mg eq/kg in the low dose experiment; 0.69 and 1.1 mg eq/kg in the high-dose experiment) than in tubers (0.002 and 0.009 mg eq/kg in the low dose experiment; 0.042 and 0.064 mg eq/kg in the high dose experiment). Radioactivity was not extracted in the low dose potato tuber experiments due to low TRRs. For all other matrices, conventional extraction with ACN/water released ≥ 82 percent TRR. Leaf extract from the low dose experiment and potato extract from the high dose experiment were further extracted with microwave assistance to release an additional 7.5 and 12.9 percent TRR, respectively.

In potato leaves, parent isoflucypram was a minor component accounting for 2.0–7.3 percent TRR (0.004–0.007 mg/kg) in the low dose experiment and 2.5–4.0 percent TRR (0.027 mg eq/kg) in the high dose experiment. Remaining identified metabolites included isoflucypram-2-propanol-Glyc-MA (14–29 percent TRR [0.014–0.053 mg eq/kg in the low dose experiment and 0.10–0.15 mg eq/kg in the high dose experiment]); isoflucypram-OH-phenyl-Glyc-MA (6.6–23 percent TRR [0.012–0.025 mg eq/kg in the low dose experiment and 0.10 mg eq/kg in the high dose experiment]); and isoflucypram-cyclopropyl-pyrazole-carboxamide (7.2–10.7 percent TRR [0.040 mg eq/kg in the low dose experiment and 0.077 mg eq/kg in the high dose experiment]). Up to 32 unknown metabolites were characterized based on chromatographic behaviour, individually accounting for ≤ 19.9 percent TRR (≤ 0.064 mg eq/kg). Radioactivity remaining in the PES was ≤ 7.4 percent TRR (≤ 0.073 mg eq/kg).

In potato tubers, parent isoflucypram was the main residue representing 69–86 percent TRR (0.029–0.056 mg/kg). The only remaining identified metabolite was isoflucypram-cyclopropyl-pyrazole-carboxamide (11 percent TRR [0.007 mg eq/kg]). There were no unidentified peaks and no radioactivity remaining in the PES.

Plant metabolism summary and conclusions

The metabolism of isoflucypram was evaluated in tomatoes, wheat, soya bean, and oilseed rape following 2–3 foliar directed applications and in potatoes following seed treatment.

Isoflucypram was the only residue observed in all food commodities (i.e., tomatoes, wheat grain, soya bean seed, oilseed rape seed, and potato tubers) representing 68–98 percent TRR. In oilseed rape intermediate harvest and mature plants, isoflucypram was partially metabolized (72–88 percent TRR)

with low levels (up to 4.6 percent TRR) of glucose-malonic acid and glycine-malonic acid conjugates of isoflucypram-propanol, isoflucypram-2-propanol, and isoflucypram-hydroxyphenyl observed. Parent isoflucypram was metabolized to a further extent in wheat hay and straw (50–64 percent TRR) with isoflucypram-propanol and isoflucypram-desmethyl-propanol, as well as their glycine and glycine-malonic acid conjugates, observed up to 10 percent TRR. Hydrolysis data suggest that the conjugated metabolites in oilseed and wheat commodities are hydrolysed to their free forms.

In soya bean forage, hay, and straw, isoflucypram was metabolized to a further extent, representing 10–70 percent TRR. Isoflucypram-desfluoro-Cys-MA, isoflucypram-desfluoro-homoGSH, isoflucypram-desfluoro-mercapto-lactic acid-propyl-OH-Glyc, isoflucypram-desfluoro-mercapto-lactic acid-Glyc, and isoflucypram-desfluoro-mercapto-lactic acid-OH were observed in concentrations up to 23 percent TRR. All identified soya bean metabolites follow a similar pathway resulting in defluorination and conjugation with a sulfur containing moiety. The Meeting noted that hydrolysis data for the soya bean extracts would be informative for concluding whether or not the metabolites observed in soya bean feeds are of interest for animal dietary burden calculations.

When isoflucypram was applied to potato seed pieces prior to planting, near full metabolism of parent was observed (2–7 percent TRR remaining) with the glycine-malonic acid conjugates of isoflucypram-OH-phenyl and isoflucypram-2-propanol observed up to 29 percent TRR. Following application to potato seed pieces prior to planting, parent isoflucypram represented 69–86 percent TRR in mature tubers with isoflucypram-cyclopropyl-pyrazole-carboxamide accounting for up to 11 percent TRR.

Environmental fate

Hydrolytic Degradation

Hydrolytic degradation of pyrazole-labelled isoflucypram was investigated in closed sterile aqueous buffer solutions at pH 4, 7, and 8.9 in the dark at 50.0 °C for 7 days. Isoflucypram was stable at all pH values, and no DT₅₀ values were calculated. Hydrolytic degradation is unlikely to contribute to the degradation of isoflucypram under typical environmental conditions.

Photodegradation

In the neutral buffer solution, isoflucypram degraded to 91 and 79 percent of the initial concentration after 150 days of irradiation

Aerobic degradation in soil

The route and rate of degradation of pyrazole (n=8) and phenyl (n=7) labelled isoflucypram were studied in laboratory soil under aerobic conditions in the dark at 20 °C for 120–125 days. The application rate was 75 g ai/ha for most trials, except for two of the pyrazole labelled trials (50 g ai/ha). Trials conducted at 75 g ai/ha were evaluated for degradation rate with the KinGUIII software under the FOCUS guideline. Isoflucypram followed single first order (SFO) degradation in all trials, with DT₅₀s ranging from 223 to 875 days (geometric mean = 446 days).

Isoflucypram-carboxylic acid was the only prominent degradate identified, increasing with time to a maximum of 10.9 percent of the applied radioactivity (AR) 120 days after treatment (DAT).

The degradation of isoflucypram-carboxylic acid was investigated in five different laboratory soils under aerobic conditions in the dark at 20°C for 120 days at a nominal rate of 4.12 µg/100 g dry soil. Dissipation kinetics were modelled with the KinGUIII software under the FOCUS guideline. Isoflucypram-

carboxylic acid dissipated following double first order in parallel (DFOP; $n=4$) or SFO ($n=1$) kinetics with DT_{50} s ranging from 17 to 27 days (geometric mean = 22 days).

Terrestrial Field Dissipation

The Meeting received 12 terrestrial field dissipation studies. Isoflucypram was applied to bare soil plots one or two times at rates ranging from 100–500 g ai/ha. Soil samples were collected at various intervals from 749 to 832 days after application to a maximum depth of 60–120 cm. Collected soil was partitioned into 10–15 cm horizons. The rate of isoflucypram degradation was evaluated with the KinGUII software under the FOCUS guideline. The Meeting excluded three DT_{50} values due to low r^2 and/or high χ^2 error values. The remaining acceptable DT_{50} values (first and second applications calculated separately, where applicable) ranged from 9 to 177 days (geometric mean = 46 days). One trial was best fit by SFO, six trials were best fit by DFOP, and four trials were best fit by first order multi-component (FOMC) dissipation.

Isoflucypram-carboxylic acid comprised up to 3.6 percent of the applied dose. Isoflucypram-carboxylic acid was only quantifiable in the top soil segment and peaked in concentration at 30–241 days after the first application.

Confined rotational crop studies

Isoflucypram was applied to bare sandy loam soil as a single spray application at a rate of 198–210 g ai/ha (2.6–2.8× the seasonal cGAP for field crops). Turnips, Swiss chard, and wheat were sown into the treated soil 30, 140, and 287 days after application. Immature samples of Swiss chard (BBCH 45), wheat forage (BBCH 29), and wheat hay (BBCH 75–83) and mature samples of turnip roots, turnip tops, Swiss chard, wheat straw, and wheat grain were harvested and analysed for TRR.

TRR in pyrazole labelled studies was consistently higher than phenyl labelled studies by a factor of 1.1× (immature Swiss chard) to 6.2× (wheat straw). In general, TRR was highest at the second plant-back interval (PBI), followed by the third PBI, and lowest at the first PBI. One notable exception is pyrazole-labelled wheat straw which followed an increasing trend with increasing PBIs. Across both studies, TRR was lowest (0.003–0.011 mg eq/kg) in turnip roots, wheat grain, and phenyl-labelled turnip tops; slightly higher (0.015–0.078 mg eq/kg) in high-water components of crops (pyrazole-labelled turnip tops, Swiss chard, and wheat forage); and highest (0.036–0.34 mg eq/kg) in dry components of crops (wheat hay and straw). The following samples incurred low TRR and were not extracted for residue identification: turnip tops (phenyl label, all PBIs), turnip roots (all samples), wheat grain (phenyl label, all PBIs; pyrazole label, 30-day PBI).

ACN/water extraction released 53–54 percent TRR from wheat grain and 78–98 percent TRR from the other matrices. The PES of wheat hay, wheat straw, and wheat grain were further extracted with microwave assistance with optional dioxane and 5 mol/L HCl, releasing an additional 5.5–32 percent TRR.

In the phenyl study, parent isoflucypram was the only structure identified in extracts prior to hydrolysis, accounting for ≤ 17 percent TRR (≤ 0.004 mg/kg) and decreasing in concentration with increasing PBIs. Up to 17 unknown peaks were characterized based on chromatographic behaviour, individually accounting for ≤ 31 percent TRR (≤ 0.009 mg eq/kg). Up to 11.7 percent TRR (≤ 0.007 mg eq/kg) remained in the PES.

In hydrolysed immature Swiss chard extract at the 30-day PBI, prominent metabolites included isoflucypram-propanol and isoflucypram-carboxylic acid accounting for 11 percent TRR (0.003 mg eq/kg) and 37 percent TRR (0.011 mg eq/kg), respectively. In hydrolysed mature Swiss chard extract at the 30-day PBI, prominent metabolites included isoflucypram, isoflucypram-propanol, and isoflucypram-carboxylic acid accounting for 17 percent TRR (0.003 mg eq/kg), 17 percent TRR (0.004 mg eq/kg), and

41 percent TRR (0.008 mg eq/kg), respectively. In hydrolysed wheat straw extract at the 30-day PBI, the only prominent metabolite was isoflucypram-carboxylic acid (11 percent TRR; 0.006 mg eq/kg).

In the pyrazole study, all identified metabolites contained only the pyrazole ring. Many metabolites shared structural similarities with sugar and/or amino acid conjugates. The Meeting did not receive hydrolysis data for the extracts. The Meeting assigned metabolites to one of the following groups based on structural similarities.

- Compounds containing the isoflucypram-cyclopropyl-pyrazole-carboxamide structure (including isoflucypram-cyclopropyl-pyrazole-carboxamide-Ala and isoflucypram-cyclopropyl-pyrazole-carboxamide-Glyc isomers 1 and 2)
- Compounds containing the isoflucypram-desfluoro-N-methyl-cyclopropyl-pyrazole-carboxamide-OH structure (including isoflucypram-desfluoro-N-methyl-cyclopropyl-pyrazole-carboxamide-OH-Cys and isoflucypram-desfluoro-N-methyl-cyclopropyl-pyrazole-carboxamide-OH-GSH)
- Compounds containing the isoflucypram-cyclopropyl-pyrazole-carboxamide-OH structure (including isoflucypram-cyclopropyl-pyrazole-carboxamide-OH-lactic acid isomers 1 and 2)
- Compounds containing the isoflucypram-desfluoro-N-methyl-cyclopropyl-pyrazole-carboxamide-mercapto structure (including isoflucypram-desfluoro-N-methyl-cyclopropyl-pyrazole-carboxamide-mercapto-Glyc and isoflucypram-desfluoro-N-methyl-cyclopropyl-pyrazole-carboxamide-mercapto-Glyc-MA)

The following metabolites are not included in the above groups and are summarized individually:

- BCS-CR60082
- Isoflucypram-desfluoro-cyclopropyl-pyrazole-carboxamide-Ala

In rotational turnip tops, parent isoflucypram was a minor residue representing 4.8 percent TRR (0.001 mg/kg) at the 30 day PBI and was not detected at other PBIs. Up to 9 unknown peaks were characterized based on chromatographic behaviour, individually accounting for ≤ 9.5 percent TRR (≤ 0.003 mg eq/kg). Radioactivity remaining in the PES was ≤ 7.7 percent TRR (≤ 0.002 mg eq/kg).

In rotational immature and mature Swiss chard, isoflucypram was a minor component representing ≤ 6 percent TRR (≤ 0.002 mg/kg). Compounds containing the isoflucypram-desfluoro-N-methyl-cyclopropyl-pyrazole-carboxamide-OH structure accounted for 23–57 percent TRR (0.015–0.020 mg eq/kg in immature Swiss chard and 0.013–0.015 mg eq/kg in mature Swiss chard). Up to 22 unknown peaks were characterized based on chromatographic behaviour, individually accounting for ≤ 11 percent TRR (≤ 0.007 mg eq/kg). Radioactivity remaining in the PES was ≤ 7.6 percent TRR (≤ 0.004 mg eq/kg).

In rotational wheat forage, parent isoflucypram was a minor component representing ≤ 7 percent TRR (≤ 0.003 mg/kg). Compounds containing the isoflucypram-cyclopropyl-pyrazole-carboxamide structure accounted for 19–30 percent TRR (0.009–0.023 mg eq/kg) and compounds containing the isoflucypram-desfluoro-N-methyl-cyclopropyl-pyrazole-carboxamide-OH structure accounted for 8.3–13 percent TRR (0.004–0.010 mg eq/kg). Up to 12 unknown peaks were characterized based on chromatographic behaviour, individually accounting for ≤ 9.0 percent TRR (≤ 0.007 mg eq/kg). Radioactivity remaining in the PES was ≤ 9.0 percent TRR (≤ 0.007 mg eq/kg). In rotational wheat hay, isoflucypram was not detected. Isoflucypram-desfluoro-cyclopropyl-pyrazole-carboxamide-Ala accounted for ND-4.8 percent TRR (ND-0.011 mg eq/kg), compounds containing the isoflucypram-desfluoro-N-methyl-cyclopropyl-pyrazole-carboxamide-mercapto accounted for 5.5–7.1 percent TRR (0.008–0.012 mg eq/kg), compounds containing the isoflucypram-cyclopropyl-pyrazole-carboxamide structure

accounted for 15–23 percent TRR (0.023–0.051 mg eq/kg), compounds containing the isoflucypram-desfluoro-N-methyl-cyclopropyl-pyrazole-carboxamide-OH structure accounted for 5.2–12 percent TRR (0.006–0.026 mg eq/kg), and compounds containing the isoflucypram-cyclopropyl-pyrazole-carboxamide-OH structure accounted for 3.2–12 percent TRR (0.007–0.022 mg eq/kg). Up to 17 unknown peaks were characterized based on chromatographic behaviour, individually accounting for ≤ 4.3 percent TRR (≤ 0.010 mg eq/kg). Radioactivity remaining in the PES was ≤ 4.3 percent TRR (≤ 0.010 mg eq/kg).

In rotational wheat hay, parent isoflucypram was not recovered. Isoflucypram-desfluoro-cyclopropyl-pyrazole-carboxamide-Ala accounted for ND–4.8 percent TRR (ND–0.011 mg eq/kg), compounds containing the isoflucypram-desfluoro-N-methyl-cyclopropyl-pyrazole-carboxamide-mercapto accounted for 5.5–7.1 percent TRR (0.008–0.012 mg eq/kg), compounds containing the isoflucypram-cyclopropyl-pyrazole-carboxamide structure accounted for 15–23 percent TRR (0.023–0.051 mg eq/kg), compounds containing the isoflucypram-desfluoro-N-methyl-cyclopropyl-pyrazole-carboxamide-OH structure accounted for 5.2–12 percent TRR (0.006–0.026 mg eq/kg), and compounds containing the isoflucypram-cyclopropyl-pyrazole-carboxamide-OH structure accounted for 3.2–12 percent TRR (0.007–0.022 mg eq/kg). Up to 17 unknown peaks were characterized based on chromatographic behaviour, individually accounting for ≤ 4.3 percent TRR (≤ 0.010 mg eq/kg). Radioactivity remaining in the PES was ≤ 4.3 percent TRR (≤ 0.010 mg eq/kg).

In rotational wheat straw, parent isoflucypram was not detected. BCS-CR60082 accounted for 2.8–7.0 percent TRR (0.007–0.020 mg eq/kg), isoflucypram-desfluoro-N-methyl-cyclopropyl-pyrazole-carboxamide-mercapto accounted for 4.9–9.2 percent TRR (0.012–0.018 mg eq/kg), compounds containing the isoflucypram-cyclopropyl-pyrazole-carboxamide structure accounted for 8.4–16 percent TRR (0.011–0.039 mg eq/kg), compounds containing the isoflucypram-desfluoro-N-methyl-cyclopropyl-pyrazole-carboxamide-OH structure accounted for 9.2–11 percent TRR (0.012–0.035 mg eq/kg), and compounds containing the isoflucypram-cyclopropyl-pyrazole-carboxamide-OH structure accounted for 5.9–12 percent TRR (0.015–0.037 mg eq/kg). Up to 18 unknown peaks were characterized based on chromatographic behaviour, individually accounting for ≤ 6.4 percent TRR (≤ 0.014 mg eq/kg). Radioactivity remaining in the PES was ≤ 6.4 percent TRR (≤ 0.014 mg eq/kg).

In rotational wheat grain, parent isoflucypram was not detected. Isoflucypram-desfluoro-cyclopropyl-pyrazole-carboxamide-Ala accounted for 13 percent TRR (0.002 mg eq/kg). Three unknown peaks were characterized based on chromatographic behaviour, individually accounting for ≤ 20 percent TRR (≤ 0.002 mg eq/kg). Radioactivity remaining in the PES was ≤ 20 percent TRR (≤ 0.002 mg eq/kg).

Field Rotational Crops

The Meeting received four independent rotational crop field trials following one broadcast application of an EC formulation of isoflucypram at 180 g ai/ha (2.4× the seasonal cGAP for cereal grains). Rotational crops of barley, carrot or turnips, and lettuce were planted in treated plots at PBIs of 21–34 days, 100–201 days, and 299–370 days and analysed for isoflucypram and BCS-CR60082. Soil samples (0–30 cm depth) were taken at from each plot at each PBI and analysed for isoflucypram and isoflucypram-carboxylic acid.

Average residues of isoflucypram were < 0.01 mg/kg in all samples, except carrot tops at one trial at the 106-day PBI (average residue of 0.066 mg/kg). Residues of BCS-CR60082 were < 0.01 mg eq/kg in all samples.

In soil samples, average residues of isoflucypram were between 0.011 and 0.049 mg/kg and average residues of isoflucypram-carboxylic acid were ≤ 0.002 mg eq/kg. Isoflucypram residues generally decreased with increased time between application and soil collection.

Environmental fate and rotational crops summary and conclusions

Isoflucypram is stable to hydrolytic degradation. In aerobic metabolism and terrestrial field dissipation studies, isoflucypram-carboxylic acid was observed at up to 10.9 percent AR or 3.6 percent, respectively. Neither isoflucypram nor isoflucypram-carboxylic acid are persistent in the soil, with geometric mean DT₅₀s of 46 days (field dissipation) and 22 days (aerobic metabolism), respectively.

While isoflucypram-carboxylic acid is a prominent soil metabolite, it is not observed in rotational crops as demonstrated by the confined rotational crops study.

In the confined rotational crops study, only the metabolite group containing the isoflucypram-desfluoro-N-methyl-cyclopropyl-pyrazole-carboxamide-OH structure was detected at levels higher than 0.01 mg eq/kg in food commodities (up to 0.015 mg eq/kg in mature Swiss chard). The Meeting concluded that, at the cGAP considered by the current Meeting, this group of metabolites may be present at an estimated residue level of 0.0054 mg eq/kg in rotational leafy crops.

The metabolites or groups of metabolites that exceeded 0.01 mg eq/kg in livestock feed items were isoflucypram-desfluoro-cyclopropyl-pyrazole-carboxamide-Ala (up to 0.011 mg eq/kg), compounds containing the isoflucypram-desfluoro-N-methyl-cyclopropyl-pyrazole-carboxamide-mercapto structure (up to 0.018 mg/kg), compounds containing the isoflucypram-cyclopropyl-pyrazole-carboxamide structure (up to 0.051 mg eq/kg), compounds containing the isoflucypram-desfluoro-N-methyl-cyclopropyl-pyrazole-carboxamide-OH structure (up to 0.035 mg eq/kg), and compounds containing the isoflucypram-cyclopropyl-pyrazole-carboxamide-OH structure (up to 0.037 mg eq/kg). Because the confined rotational crop trials were conducted at approximately 2.7× the cGAP considered by the current Meeting, the Meeting concluded that residues of these metabolites or groups of metabolites would not be expected to contribute significantly to the livestock dietary burdens and are not expected to be detected in animal tissues.

The field rotational crops study analysed residues of isoflucypram and BCS-CR60082. Residues of BCS-CR60082 were < 0.01 mg eq/kg in all crops, except isoflucypram in carrot tops at one trial (0.066 mg/kg). The Meeting noted that the study report attributed this value to spray drift from an application to an adjacent field rather than uptake from the soil. The Meeting concluded that residues of isoflucypram and BCS-CR60082 are not expected in rotational crops.

The Meeting noted that, should a higher cGAP be received in the future, the expectation of residues of the pyrazole metabolites in rotational crops may need to be re-evaluated.

Animal metabolism

The Meeting received studies describing the metabolism of isoflucypram in laboratory rats, lactating goats and laying hens.

Rats

The metabolism of isoflucypram in rats was reviewed in the framework of the toxicological evaluation by the WHO Core Assessment Group of the 2022 JMPR.

Lactating Goats

Lactating goats were orally dosed with pyrazole- and phenyl-labelled isoflucypram at 45 ppm or 21 ppm (dry feed) per day in the diet for five consecutive days. Approximately 0.03–0.06 percent of the administered dose (AD) was secreted with milk, correlating to TRRs ranging from 0.008–0.021 mg eq/kg. Per-day pooled milk samples reached a plateau after three days.

Approximately six hours after the final dose, animals were sacrificed and TRRs were determined in liver, kidney, muscle (pooled round and loin), and fat (pooled perirenal and omental). The sum of radioactive residues in edible fractions was 0.27–0.72 percent AD, correlating to TRRs of 0.35–0.72 mg eq/kg in liver, 0.18–0.19 mg eq/kg in kidney, 0.10 mg eq/kg in fat, and 0.011–0.038 mg eq/kg for muscle

Extraction with ACN/water and THF (for pyrazole-labelled milk only) released 89–100 percent TRR. Various matrices were partitioned against n-heptane resulting in low amounts of radioactivity in the organic phase (≤ 1.4 percent; ≤ 0.002 mg eq/kg). Liver and pyrazole-labelled muscle extracts were additionally extracted with microwave assistance and HCl (liver only), together releasing an additional 3.5–4.9 percent TRR.

In plateau-level milk, isoflucypram was the predominant residue, accounting for 33–34 percent TRR (0.004–0.005 mg/kg). The only prominent metabolite was isoflucypram-2-propanol (5.0–20 percent TRR [0.001–0.003 mg eq/kg]). Up to five unknown peaks were characterized based on chromatographic behaviour, individually accounting for ≤ 39 percent TRR (≤ 0.005 mg eq/kg). Radioactivity remaining in the PES was ≤ 1.5 percent TRR (< 0.001 mg eq/kg).

The majority of the radioactivity (approximately 87 percent TRR) in milk remained in the skimmed milk fraction in the pyrazole study, whereas it was evenly distributed between the skimmed milk and cream fractions in the phenyl study.

In muscle, isoflucypram was the predominant residue, accounting for 22 percent TRR (0.002–0.008 mg/kg). Prominent metabolites were isoflucypram-2-propanol (14–18 percent TRR, 0.002–0.006 mg eq/kg) and isoflucypram-propanol (9.0–10 percent TRR, 0.001–0.004 mg eq/kg). Up to 10 unknown peaks were characterized based on chromatographic behaviour between the conventional and exhaustive extract, individually accounting for ≤ 25 percent TRR (≤ 0.003 mg eq/kg). Radioactivity remaining in the PES was ≤ 6.4 percent TRR (≤ 0.002 mg eq/kg).

In fat, only the pyrazole label was studied due to lack of fat on the phenyl labelled goat, although no abnormality on feed consumption, weight, or common behaviour was observed. Isoflucypram was the predominant residue, at 59 percent TRR (0.061 mg/kg). The only prominent metabolite was isoflucypram-2-propanol, accounting for 17 percent TRR (0.017 mg eq/kg). Four unknown peaks were characterized based on chromatographic behaviour, individually accounting for ≤ 7.5 percent TRR (≤ 0.008 mg eq/kg). Radioactivity remaining in the PES was 1.7 percent TRR (0.002 mg eq/kg).

In liver, isoflucypram accounted for 3.5–5.3 percent TRR (0.018–0.025 mg/kg). Prominent metabolites were isoflucypram-2-propanol-GlucA (13–14 percent TRR, 0.045–0.099 mg eq/kg), isoflucypram-propanol-GlucA isomer 1 (8.8–13 percent TRR, 0.031–0.094 mg eq/kg), isoflucypram-propanol-GlucA isomer 2 (5.9–7.7 percent TRR, 0.021–0.055 mg eq/kg), isoflucypram-carboxylic acid (4.2–8.9 percent TRR, 0.015–0.064 mg eq/kg), isoflucypram-propanol (4.9–5.8 percent TRR, 0.017–0.042 mg eq/kg), isoflucypram-2-propanol (2.6–2.8 percent TRR, 0.010–0.019 mg eq/kg), and isoflucypram-lactic acid (1.3–1.6 percent TRR, 0.005–0.011 mg eq/kg). Up to 32 unknown peaks were characterized based on chromatographic behaviour between the conventional, exhaustive ACN/water and HCl extract, individually accounting for ≤ 6.7 percent TRR (≤ 0.029 mg eq/kg). Radioactivity remaining in the PES was ≤ 8.2 percent TRR (≤ 0.036 mg eq/kg).

Liver extracts were enzymatically cleaved with β -glucuronidase and arylsulfatase (20 hours at 37 °C) resulting in decreased concentrations of conjugates accompanied by increase concentrations of respective aglycones. Isoflucypram accounted for 4.7–6.1 percent TRR (0.016–0.044 mg/kg). Prominent metabolites were isoflucypram-propanol (18–21 percent TRR, 0.064–0.15 mg eq/kg), isoflucypram-2-propanol (12–13 percent TRR, 0.047–0.085 mg eq/kg), isoflucypram-carboxylic acid (10–12 percent TRR,

0.033–0.084 mg eq/kg), isoflucypram-desmethyl-propanol (4.3–4.6 percent TRR, 0.015–0.033 mg eq/kg), and isoflucypram-desmethyl-carboxylic acid (1.5–2.1 percent TRR, 0.005–0.016 mg eq/kg).

In kidney, isoflucypram was a minor compound accounting for 1.6–2.7 percent TRR (0.003–0.005 mg/kg). Prominent metabolites were isoflucypram-carboxylic acid (6.8–18 percent TRR, 0.012–0.034 mg eq/kg), isoflucypram-propanol-GlucA isomer 2 (7.0–8.6 percent TRR, 0.013–0.016 mg eq/kg), isoflucypram-lactic acid (4.2–6.1 percent TRR, 0.008–0.012 mg eq/kg), isoflucypram-propanol (2.5–5.6 percent TRR, 0.004–0.011 mg eq/kg), isoflucypram-propenol-GlucA (3.6–6.2 percent TRR, 0.007–0.011 mg eq/kg), and isoflucypram-N-methyl-pyrazole-carboxylic acid (5.8 percent TRR, 0.011 mg eq/kg). Up to 21 unknown peaks were characterized based on chromatographic behaviour, individually accounting for ≤ 9.1 percent TRR (≤ 0.017 mg eq/kg). Radioactivity remaining in the PES was ≤ 7.8 percent TRR (≤ 0.015 mg eq/kg).

Kidney extracts were enzymatically cleaved with β -glucuronidase and arylsulfatase (20 hours at 37 °C) resulting in decreased concentrations of conjugates accompanied by increased concentrations of respective aglycones. Isoflucypram accounted for 1.3–2.6 percent TRR (0.002–0.005 mg/kg). Prominent metabolites were isoflucypram-carboxylic acid (13–23 percent TRR, 0.023–0.044 mg eq/kg), isoflucypram-propanol (11–20 percent TRR, 0.020–0.037 mg eq/kg), isoflucypram-2-propanol (5.5–6.7 percent TRR, 0.010–0.013 mg eq/kg), isoflucypram-desmethyl-carboxylic acid (4.2–6.4 percent TRR, 0.008–0.012 mg eq/kg) and isoflucypram-desmethyl-propanol (4.6–5.0 percent TRR, 0.009 mg eq/kg).

Laying Hen

Laying hens were orally dosed with labelled isoflucypram at 17 ppm and 18 ppm (dry feed) per day for 14 consecutive days. Eggs were collected daily and 0.12–0.14 percent of the AD was recovered corresponding to 0.029–0.066 mg eq/kg TRR. TRR in eggs plateaued on Day 4–6.

Hens were sacrificed approximately six hours after the final dose. Radioactive residues in the tissues were approximately 0.22–0.24 percent AD, corresponding to TRRs of 0.37 mg eq/kg in liver, 0.36–0.39 mg eq/kg in kidney, 0.075–0.11 mg eq/kg in skin, 0.042–0.047 mg eq/kg in subcutaneous fat, 0.029 mg eq/kg in leg muscle, and 0.017–0.018 mg eq/kg in thorax muscle.

Extraction with ACN/water released 84–93 percent TRR. Liver PES underwent extractions with microwave assistance and HCl which together released an additional 15–16 percent TRR. Extracts from various matrices were partitioned with n-heptane resulting in low amounts of radioactivity in the organic phase (≤ 1.3 percent TRR; 0.001 mg eq/kg).

In eggs, parent isoflucypram was a minor component accounting for 3.7–6.4 percent TRR (0.002–0.003 mg/kg). Prominent metabolites were isoflucypram-propanol (34–35 percent TRR [0.017–0.018 mg eq/kg]) and isoflucypram-desmethyl-propanol (22–23 percent TRR [0.011 mg eq/kg]). Up to five unknown peaks were characterized based on chromatographic behaviour, individually accounting for ≤ 7.7 percent TRR (≤ 0.004 mg eq/kg). Radioactivity remaining in the PES was ≤ 7.2 percent TRR (≤ 0.004 mg eq/kg).

In muscle (thorax and leg analysed separately), parent compound was a minor component accounting for ≤ 2.9 percent TRR (0.001 mg/kg). Remaining prominent metabolites included isoflucypram-desmethyl-propanol (21–30 percent [0.004–0.009 mg eq/kg]), isoflucypram-desmethyl-1,2-propandiol (14–22 percent TRR [0.003–0.004 mg eq/kg]), isoflucypram-desmethyl-carboxylic acid (12–20 percent TRR [0.002–0.006 mg eq/kg]), and isoflucypram-carboxylic acid (6.6–11 percent TRR [0.001–0.003 mg eq/kg]). Up to four unknown peaks were characterized based on chromatographic behaviour, individually accounting for ≤ 19.5 percent TRR (≤ 0.004 mg eq/kg). Radioactivity was successfully extracted as demonstrated by ≤ 8.2 percent TRR (≤ 0.002 mg eq/kg) remaining in the PES.

In *fat*, isoflucypram was the predominant component representing 20–24 percent TRR (0.009–0.010 mg/kg). Prominent metabolites included isoflucypram-propanol (6.5–12 percent TRR [0.003–0.005 mg eq/kg]) and isoflucypram-desmethyl-propanol (8.0–10 percent TRR [0.004 mg eq/kg]). Up to seven unknown peaks were characterized based on chromatographic behaviour, individually accounting for ≤ 11.2 percent TRR (≤ 0.005 mg eq/kg). Radioactivity remaining in the PES was ≤ 8.2 percent TRR (≤ 0.004 mg eq/kg).

Parent compound was not detected in the *liver*. Prominent metabolites were isoflucypram-desmethyl-carboxylic acid (14–22 percent TRR [0.053–0.082 mg eq/kg]), isoflucypram-carboxylic acid (5.8–12 percent TRR [0.022–0.044 mg eq/kg]), isoflucypram-desmethyl-1,2-propandiol-N-GlucA (5.4–9.2 percent TRR [0.020–0.034 mg eq/kg]), isoflucypram-desmethyl-propanol-N-GlucA (6.1–11 percent TRR [0.023–0.040 mg eq/kg]), isoflucypram-desmethyl-1,2-propandiol (5.6–6.9 percent TRR [0.021–0.025 mg eq/kg]), isoflucypram-desmethyl-propanol (2.7–5.3 percent TRR [0.010–0.020 mg eq/kg]), and isoflucypram-desmethyl-2-propanol-N-GlucA (2.5–3.0 percent TRR [0.009–0.011 mg eq/kg]). Up to 27 unknown peaks were identified based on chromatographic behaviour in the conventional extract, exhaustive ACN/water extract, and exhaustive ACN/HCl extract, individually accounting for ≤ 8.4 percent TRR (≤ 0.031 mg eq/kg). Radioactivity remaining in the PES was ≤ 0.1 percent TRR (< 0.001 mg eq/kg).

Liver extracts were enzymatically cleaved with β -glucuronidase and arylsulfatase (96 hours at 37 °C). Parent compound was not identified in the hydrolysed extract. Prominent metabolites included isoflucypram-desmethyl-carboxylic acid (17–26 percent TRR [0.064–0.096 mg eq/kg]), isoflucypram-desmethyl-propanol (14–15 percent TRR [0.053–0.054 mg eq/kg]), isoflucypram-carboxylic acid (9.0–17 percent TRR [0.033–0.062 mg eq/kg]), and isoflucypram-desmethyl-1,2-propandiol (11–12 percent TRR [0.041–0.043 mg eq/kg]),

Animal metabolism summary and conclusions

The distribution and elimination of isoflucypram appeared to be similar in rats, goat and hens. Radioactivity was consistently observed at highest levels in the liver, followed by lower (rat and goat) or similar (hen) levels in kidney, followed by fat. Muscle had the lowest level of radioactivity in the goat and hen.

Isoflucypram was metabolized to a further extent in hens than in goats in all tissues. In fat, muscle, milk, and eggs, low overall radioactivity was observed and metabolites were generally unconjugated. In these matrices, the metabolic pathways differed between the goat and hen species with formation of isoflucypram-propanol and isoflucypram-2-propanol observed in ruminant fat, muscle, and milk (up to 20 percent TRR), and formation of isoflucypram-propanol, isoflucypram-desmethyl-propanol, isoflucypram-carboxylic acid, isoflucypram-desmethyl-carboxylic acid, and isoflucypram-desmethyl-1,2-propandiol (as well as its N-GlucA conjugate) observed in hen fat, muscle, and egg (up to 35 percent TRR).

Goat liver/kidney and hen liver contained little to no parent isoflucypram and a higher levels of conjugated metabolites. Isoflucypram-carboxylic acid was the only prominent metabolite common to all three matrices. Isoflucypram-propanol (free and/or GlucA conjugates) was prevalent in goat liver/kidney and trace in kidney liver. Isoflucypram-desmethyl-propanol (free and N-GlucA conjugate) and isoflucypram-desmethyl-carboxylic acid were prevalent in hen liver and trace in goat liver/kidney. In goat liver and kidney, common metabolites included isoflucypram-2-propanol (free and GlucA conjugate) and isoflucypram-lactic acid. The metabolites isoflucypram-N-methyl-pyrazole-carboxylic acid and isoflucypram-propenol-GlucA were found only in goat kidney. The metabolites isoflucypram-desmethyl-2-propanol-N-GlucA and isoflucypram-1,2-propandiol (free and N-GlucA conjugate) were found only in hen liver.

Methods of analysis

The Meeting received several analytical methods for quantitation of isoflucypram and various metabolites.

Plants

Method 01475 analysed isoflucypram and BCS-CR60082. Successful method validation was performed on tomato fruit, orange fruit, rape seed, wheat grain/straw, and dry bean seed. Samples are extracted twice with ACN/water (dry commodities left to soak in water for 20 minutes before addition of ACN in the first extraction). Internal standards are added and extracts are analysed by LC-MS/MS. The LOQ is 0.01 mg/kg for both analytes in all matrices. The ability of the method to extract incurred residues was successfully demonstrated based on comparison with samples from the primary and confined rotational crop metabolism studies.

Method LN-002-P16-01 uses the same extraction procedure as Method 01475 but only analyses isoflucypram. The method was successfully validated in tomato fruit, orange fruit, wheat grain, soya bean seed, and canola seed. The LOQ is 0.01 mg/kg in all matrices.

Method 01564 analyses isoflucypram, isoflucypram-desmethyl-propanol (free and conjugated), and isoflucypram-propanol (free and conjugated). Successful method validation was performed on wheat green material, grain, and straw. Samples are spiked with isotopic isoflucypram-desmethyl-propanol internal standard, 5 mol/L HCl is added, and samples are heated at 98 °C for 30 minutes followed by two extractions with ACN/water. Isotopic internal standards for isoflucypram and isoflucypram-propanol are added to the combined extracts for LC-MS/MS analysis. The LOQ is 0.01 mg/kg in all matrices. The ability of the method to extract residues and hydrolyse conjugates was successfully demonstrated based on comparison with samples from the wheat hay and straw metabolism studies.

Method 01520 uses the same extraction procedure as Method 01475; however, the only analyte is isoflucypram and the method does not use an internal standard. Successful method validation and Independent Laboratory Validation data were provided on tomato fruit, orange fruit, wheat grain, coffee green bean, oilseed rape seed, and dry bean seed. The LOQ is 0.01 mg/kg in all matrices.

The QuEChERS multi-residue successfully extracted incurred residues of isoflucypram in tomato fruit, soya bean seed/straw, and oilseed rape intermediate harvest/seed matrices based on comparison with samples from the crop metabolism studies. Extraction efficiency of the QuEChERS multi-residue method was unsuccessful in wheat hay/straw/grain and soya bean forage/hay matrices.

Animals

Method 01511 analyses parent isoflucypram as well as free isoflucypram-2-propanol, isoflucypram-carboxylic acid, isoflucypram-propanol, isoflucypram-desmethyl-propanol, and isoflucypram-desmethyl-carboxylic acid in animal matrices. The method also quantitates free and conjugated isoflucypram-propanol and isoflucypram-2-propanol in cow liver and kidney, and free and conjugated isoflucypram-desmethyl-propanol in hen liver.

For free analytes, samples are extracted with ACN/water, isotopic internal standards are added and samples are analysed by LC-MS/MS. Successful method validation was performed in eggs, milk, cow muscle/fat/liver/kidney, and hen liver. For free and conjugated analytes, samples are extracted with ACN/water, allowed to hydrolyse with β -glucuronidase and arylsulfatase at 37 °C, cleaned up by SPE, and analysed by LC-MS/MS. The LOQ is 0.005 mg eq/kg for milk, cream, and whey, and 0.01 mg/kg for all other matrices. The extraction solvent was the same as that used in the animal metabolism studies (≥ 92 percent TRR extracted).

The QuEChERS multi-residue method (Method 01300/M034) was successfully validated for milk, eggs, cattle muscle/fat/liver/kidney, and hen muscle. The LOQ is 0.005 mg eq/kg for milk, cream, and whey, and 0.01 mg/kg for all other matrices. Independent Laboratory Validation data were also submitted. The ability of the method to extract incurred residues was successfully demonstrated based on comparison with aged samples from the goat metabolism study.

In conclusion, methods are available for the analysis of isoflucypram and relevant metabolites in crop and animal matrices. The QuEChERS method is suitable for analysing isoflucypram in high-water and high-oil content crops and animal matrices but not suitable for high-starch content crops, cereal and oilseed animal feeds.

Stability of pesticide residues in stored analytical samples

The Meeting received two storage stability studies for isoflucypram and its metabolites in plants fortified at 0.1 or 0.2 mg/kg. Isoflucypram and BCS-CR60082 are stable during freezer storage (≤ -18 °C) for a period of at least 24–25 months in tomato fruit, bean dry seed, wheat grain, rape seed, and orange fruit. Isoflucypram and BCS-CR60082 are also stable following frozen storage for at least 25–26 months at -18 °C followed by six days of storage at -1 ± 2 °C. Isoflucypram-desmethyl-propanol and isoflucypram-propanol are stable in/on wheat grain, green material, and straw under frozen storage conditions (< -18 °C) for at least 30 months. The storage stability data support the storage durations and conditions of the submitted studies. All plant samples in the submitted studies were stored frozen for durations supported by the submitted studies. Storage stability data were not submitted for animal matrices. As dairy cow and laying hen matrices from the farm animal feeding studies were stored frozen for a maximum of 30 days, storage stability data are not needed.

Definition of the residue

Plant commodities

In plant metabolism studies, parent isoflucypram was a major residue in tomato, wheat, soya bean, oilseed rape, and potato tubers grown from treated potato seed pieces (10–98 percent TRR).

A suitable analytical method using LC-MS/MS is available to determine residues of isoflucypram in plant commodities.

The Meeting concluded that isoflucypram was a suitable marker for enforcement purposes.

In deciding which additional compounds should be included in the residue definition for risk assessment, the Meeting considered the likely occurrence of the compounds and the toxicological properties of the candidates. In metabolism studies, no metabolites were identified in the tomato, wheat grain, soya bean seed, oilseed rape seed, or potato tubers. Isoflucypram-propanol (free and conjugated) and isoflucypram-desmethyl-propanol (free and conjugated) were considered based residues in the wheat plants in the metabolism study and quantifiable residues in the wheat grain in supervised residue trials. Additionally, the Meeting considered the group of metabolites containing the isoflucypram-desfluoro-N-methyl-cyclopropyl-pyrazole-carboxamide-OH structure based on residues > 0.01 mg eq/kg in the confined rotational crop metabolism study.

Based on toxicological properties, isoflucypram-propanol (free and conjugated) is assumed to be covered by the isoflucypram HBGVs. In supervised residue trials matching the cGAP, isoflucypram-propanol (free and conjugated) was observed in cereal grains in three of 39 trials at concentrations of 0.011, 0.014, and 0.019 mg eq/kg with corresponding isoflucypram residues of 0.019, 0.01, and

0.01 mg/kg. Due to low occurrence of quantifiable residues, the Meeting concluded that isoflucypram-propanol should be excluded from in the residue definition for dietary risk assessment.

The Meeting concluded that isoflucypram-desmethyl-propanol (free and conjugated) could be assessed using the threshold of toxicological concern (TTC) approach Cramer Class III (1.5 µg/kg bw/day), results discussed under *animal commodities*).

The Meeting concluded that the metabolites isoflucypram-desfluoro-N-methyl-cyclopropyl-pyrazole-carboxamide-OH-Cys and isoflucypram-desfluoro-N-methyl-cyclopropyl-pyrazole-carboxamide-OH-GSH could be assessed using the TTC approach for genotoxicity (0.0025 µg/kg bw/day). As the metabolites are conjugates of the same structure, the Meeting combined exposures from both metabolites for the TTC assessment.

The Meeting estimated dietary exposures for isoflucypram-desfluoro-N-methyl-cyclopropyl-pyrazole-carboxamide-OH-Cys and isoflucypram-desfluoro-N-methyl-cyclopropyl-pyrazole-carboxamide-OH-GSH of 0.0004–0.0107 µg/kg bw per day, above the TTC for a compound with potential of genotoxicity.

Animal commodities

In the cattle feeding study, isoflucypram was detected in all matrices except kidney. Although isoflucypram was not observed in the hen feeding study, it was observed in the laying hen metabolism study as a major component of fat (20–24 percent TRR) and a minor component of eggs and muscle (2.3–6.4 percent TRR).

A suitable analytical method using LC-MS/MS is available to determine residues of isoflucypram in animal commodities.

The Meeting concluded that isoflucypram was a suitable marker for enforcement purposes.

In deciding which additional compounds should be included in the residue definition for risk assessment, the Meeting considered the likely occurrence of the compounds and the toxicological properties of the candidates. The metabolites isoflucypram-propanol (free and conjugated), isoflucypram-desmethyl-propanol (free and conjugated), isoflucypram-2-propanol (free and conjugated), isoflucypram-carboxylic acid, isoflucypram-desmethyl-carboxylic acid, isoflucypram-lactic acid, isoflucypram-desmethyl-1,2-propandiol, isoflucypram-desmethyl-1,2-propandiol-N-GlucA, isoflucypram-N-methyl-pyrazole-carboxylic acid, isoflucypram-propenol-Gluc-A, and isoflucypram-desmethyl-2-propanol-N-GlucA were > 10 percent TRR and/or > 0.01 mg eq/kg in the lactating goat and laying hen metabolism studies.

Isoflucypram-carboxylic acid, isoflucypram-desmethyl-carboxylic acid, and isoflucypram-propanol (free and conjugated) are considered to be covered by the HBGV for isoflucypram. These metabolites were analysed in the cattle and hen feeding studies and each were quantifiable in at least two matrices, representing a significant portion of the residues covered by the HBGV of isoflucypram. The Meeting concluded that these metabolites should be considered in the residue definition for dietary risk assessment.

Toxicological data are not available for isoflucypram-lactic acid, isoflucypram-desmethyl-1,2-propandiol, isoflucypram-desmethyl-1,2-propandiol-N-GlucA, isoflucypram-N-methyl-pyrazole-carboxylic acid, isoflucypram-propenol-GlucA, and isoflucypram-desmethyl-2-propanol-N-GlucA. These metabolites were not analysed in the feeding studies. Isoflucypram-lactic acid was quantifiable in liver and kidney in the lactating goat metabolism studies (0.011 and 0.012 mg eq/kg, respectively), isoflucypram-desmethyl-1,2-propandiol was quantifiable in all matrices in the laying hen metabolism studies (0.002–0.025 mg eq/kg), isoflucypram-desmethyl-1,2-propandiol-N-GlucA was quantifiable in all matrices in the

laying hen metabolism studies (0.001–0.034 mg eq/kg), isoflucypram-N-methyl-pyrazole-carboxylic acid was quantifiable in kidney in the goat metabolism study (0.011 mg eq/kg), isoflucypram-propenol-GlucA goat was quantifiable in kidney in the goat metabolism studies (0.007–0.01 mg eq/kg), and isoflucypram-desmethyl-2-propanol-N-GlucA was quantifiable in liver in the hen metabolism studies (0.009–0.011 mg eq/kg). Because these metabolites are present in low concentrations at the dietary burdens (≤ 0.00029 mg eq/kg), the Meeting concluded that they should be excluded from the residue definition for dietary risk assessment.

Isoflucypram-desmethyl-propanol (free and conjugated) and isoflucypram-2-propanol (free and conjugated) were quantifiable in at least one matrix in the feeding studies. The Meeting determined that these metabolites could be assessed using TTC Cramer Class III (1.5 $\mu\text{g}/\text{kg}$ bw/day). The Meeting estimated dietary exposures for isoflucypram-desmethyl-propanol (free and conjugated) of 0.0212–0.1827 $\mu\text{g}/\text{kg}$ bw/day and for isoflucypram-2-propanol of 0.0022–0.0194 $\mu\text{g}/\text{kg}$ bw/day, below the TTC for Cramer Class III.

Based on the above, the Meeting recommended the following residue definition:

Definition of the residue for compliance with the MRL for plant and animal commodities:
Isoflucypram.

Because dietary exposure to isoflucypram-desfluoro-N-methyl-cyclopropyl-pyrazole-carboxamide-OH-Cys and isoflucypram-desfluoro-N-methyl-cyclopropyl-pyrazole-carboxamide-OH-GSH were above the TTC for a compound with potential of genotoxicity, the Meeting could not reach a conclusion on a residue definition for dietary risk assessment.

Definition of the residue for dietary risk assessment for plant and animal commodities: A *conclusion could not be reached.*

In deciding whether isoflucypram is fat-soluble, the Meeting noted that the mean residues of isoflucypram at the highest dose tested in the lactating cow feeding study were < 0.01 mg/kg in muscle and 0.081 mg/kg in perirenal fat while residues in cream were 0.11–0.15 mg/kg compared to < 0.005 mg/kg in whey. The Meeting considered the residue to be fat-soluble.

Results of supervised residue trials on crops

The Meeting received supervised field trial data to support isoflucypram uses on wheat and barley.

Cereal Grains

Supervised residue trials are available from a number of European countries and New Zealand.

Barley

The cGAP for barley grain from New Zealand is one application at 75 g ai/ha up to BBCH 61 (56-day pre-harvest interval (PHI)). In independent trials approximating the cGAP, residues of isoflucypram were (n=21): < 0.010 (19), 0.013, and 0.10 mg/kg.

The Meeting estimated a maximum residue level of 0.1 mg/kg and a median value of 0.010 mg/kg for barley grain.

Wheat

The cGAP for wheat grain from New Zealand is one application at 75 g ai/ha up to BBCH 69 (42-day PHI). In independent trials approximating the cGAP, residues of isoflucypram were (n=42): < 0.01 (39), 0.015, 0.019, and 0.042 mg/kg.

The Meeting estimated a maximum residue level of 0.05 mg/kg and a median value of 0.010 mg/kg for wheat grain.

As the use pattern covers triticale, the Meeting decided to extrapolate the wheat grain maximum residue level and median value to triticale grain.

Residues in animal feeds

The barley and wheat supervised residue trials included residue data on commodities defined as “forage” and “green material.”

The Meeting noted that the percent dry matter in these samples collected at the cGAP PHI ranged from 29–91 percent for wheat and from 43–85 percent for barley, well above what the Meeting considers forage. The Meeting therefore considers this crop hay as opposed to forage.

Barley hay and straw

The cGAP for barley hay from New Zealand is one application at 75 g ai/ha up to BBCH 61 (42-day PHI).

Residues in barley hay were adjusted for percent dry matter (dw) in the submitted studies.

In independent trials approximating the cGAP, isoflucypram residues were (n=8): 0.094, 0.11, 0.24, 0.25, 0.32, 0.37, 0.48, and 0.51 mg/kg (dw).

In independent trials at 116 and 106 g ai/ha (1.5× the cGAP application rate), isoflucypram residues were (n=2): 0.23 and 0.14 mg/kg (dw). By applying a proportionality factor of 0.65 and 0.71, the residues were (n=2): 0.15 and 0.097 mg/kg.

Isoflucypram residues in hay (proportionality factors of 0.65–1.0× applied) were (n=10): 0.094, 0.097, 0.11, 0.15, 0.24, 0.32(2), 0.37, 0.47, and 0.50 mg/kg (dw).

The cGAP for barley straw/stubble from New Zealand is one application at 75 g ai/ha up to BBCH 61 (56-day PHI).

Residues from the trials were corrected with the reported percent dry matter. For trials for which this information was not available, a percent dry matter of 89 percent was assumed for correction.

In independent trials approximating the cGAP, residues of isoflucypram in straw were (n=20): 0.055, 0.088, 0.16, 0.18(3), 0.22, 0.26, 0.27(3), 0.33, 0.36, 0.38, 0.45, 0.46, 0.69, 0.96, 1.1(2) mg/kg (dw).

Based on the straw data, the Meeting estimated a median residue of 0.27 mg/kg and a highest residue of 1.1 mg/kg for isoflucypram in barley hay and straw.

Wheat hay and straw

The cGAP for wheat hay from New Zealand is one application at 75 g ai/ha up to BBCH 69 (28-day PHI).

For 34 of the trials conducted according to cGAP, percent dry matter was reported and residues were corrected accordingly. For the remaining eight trials, a percent dry matter of 54 percent was assumed and corrected by the Meeting, based on the average of the given percent dry matter from the 34 trials above.

In independent trials approximating the cGAP, isoflucypram residues were (n=42): < 0.010, 0.14(2), 0.16, 0.17, 0.19(2), 0.20(2), 0.22, 0.26, 0.29(2), 0.31(2), 0.33(3), 0.36, 0.38, 0.41, 0.44, 0.50, 0.62, 0.86, 0.90, 0.91, 0.95, 1.1(3), 1.2(4), 1.3(2), 1.5(3), 1.7, and 3.3 mg/kg (dw).

The cGAP for wheat straw/stubble from New Zealand is one application at 75 g ai/ha up to BBCH 69 (42-day PHI).

Residues from the trials were corrected with the reported percent dry matter. For trials for which this information was not available, a percent dry matter of 88 percent was assumed for correction.

In independent trials approximating the cGAP, residues of isoflucypram in straw were (n=37): < 0.010, 0.061, 0.081, 0.13, 0.14(3), 0.17, 0.22, 0.25(2), 0.27, 0.32, 0.35, 0.43, 0.44, 0.45, 0.47, 0.55, 0.60, 0.73, 0.93, 1.1, 1.3(2), 1.4, 1.5, 1.6(3), 1.8(2), 1.9, 2.2(2), 2.7, and 3.6 mg/kg (dw).

Based on straw data, the Meeting estimated a median residue of 0.55 mg/kg and a highest residue of 3.6 mg/kg for isoflucypram in wheat hay and straw.

'Barley hay and straw' and 'wheat hay and straw', as commodities moving in trade, may not always be readily distinguishable from each other. The Meeting agreed to use the wheat straw data (dw) for the maximum residue level estimation for both 'barley hay and/or straw (dw)' and 'wheat hay and/or straw (dw)'.

The Meeting estimated a maximum residue level of 5 mg/kg for isoflucypram in/on wheat hay and/or straw (dw), and barley hay and/or straw (dw).

As the use pattern covers triticale, the Meeting decided to extrapolate the estimated maximum residue level, median residue levels, and highest residue levels from wheat hay and straw to triticale hay and straw.

Fate of residues during processing

Nature of the residue in processed commodities

The Meeting received studies investigating radiolabelled isoflucypram, isoflucypram-desmethyl-propanol, and isoflucypram-propanol following temperatures and pH conditions simulating typical processing procedures.

Isoflucypram and isoflucypram-propanol were stable under conditions simulating pasteurization, baking/brewing/boiling, and sterilisation (test compounds were ≥ 98.0 percent TRR following all simulated processing procedures).

Isoflucypram-desmethyl-propanol was stable under conditions simulating pasteurization (approximately 99 percent TRR). Under conditions simulating baking/brewing/boiling, approximately 34 percent TRR was recovered as isoflucypram-desmethyl-propanol and approximately 66 percent TRR was identified as isoflucypram-desmethyl-propanol-aldehyde. Under conditions simulating sterilisation, isoflucypram-desmethyl-propanol was not recovered and approximately 98 percent TRR was recovered as isoflucypram-desmethyl-propanol-aldehyde.

Residues in processed commodities

The Meeting received studies evaluating the effect of processing on isoflucypram in barley and wheat. Isoflucypram was applied at 5× the cGAP application rate.

Calculated processing factors indicate with a '<' (less-than) sign when the residue in the processed commodity is below the LOQ of the analytical method. The calculation in these cases is based on the LOQ (0.01 mg/kg) of the analytical method and the residue concentration of the RAC. The STMR-P values are calculated by multiplying the PF with the RAC STMR value.

Table 5.22.2 Processing factors for isoflucypram

Raw Commodity (median)	Processed Commodity	Processing Factors	Median-P = Median _{RAC} X PF (mg/kg)
Barley grain (0.010 mg/kg)	Pearl Barley	< 0.67	0.0067
	Beer	< 0.67	0.0067
	Brewer's Grain	< 0.67	0.0067
Wheat grain (0.010 mg/kg)	Bran, processed	1.2	0.012
	White Flour	< 0.63	0.0063
	Whole Meal Flour	0.67	0.0067
	Germ	1.1	0.011
	Pasta, Dry	< 0.63	0.0063
	Pasta, Cooked	< 0.63	0.0063
	Gluten	0.94	0.0094
	Starch	< 0.63	0.0063
	White Bread	< 0.63	0.0063
	Whole Meal Bread	< 0.63	0.0063
	AGF	148	1.5

Residues in animal commodities

Dairy cow

The Meeting received a study investigating the magnitude of isoflucypram in milk, cream, whey, muscle, liver, kidney, and fat of dairy cows orally dosed with isoflucypram for 28 days. Doses were administered orally via gelatine capsule with a pill gun at 1.6 ppm, 4.2 ppm, 16 ppm, and 48 ppm (dry feed basis).

Animals were sacrificed within 24 hours after the final dose except for the depuration group, which were sacrificed 4, 7, or 14 days after the last dose. Residues of isoflucypram were < 0.005 mg/kg in milk from the 1.6, 4.2, and 16-ppm dosing levels and ranged from 0.006–0.009 mg/kg at the 48-ppm dose level. Isoflucypram partitioned into cream with residues ranging from 0.11–0.15 mg/kg compared to < 0.005 mg/kg in corresponding skim fraction.

Residues of isoflucypram were < 0.01 mg/kg in muscle and kidney at all dose levels. Residues of isoflucypram were < 0.01 mg/kg in fat at the 1.6 and 4.2-ppm dose levels, 0.034 mg/kg at the 16 ppm dose level, and 0.081 mg/kg at the 48 ppm dose level. Residues of isoflucypram were < 0.01 mg/kg in liver at the 1.6 and 4.2-ppm dose levels, < 0.011 mg/kg at the 16-ppm dose level, and < 0.016 mg/kg at the 48-ppm dose level.

Laying hen

The Meeting received a study investigating the magnitude of isoflucypram in eggs (whole, white, and yolk), muscle, liver, and fat with skin of laying hens orally dosed with isoflucypram for 28 days. Doses were administered orally via gelatine capsule at 0.53 ppm, 2.1 ppm, and 8.7 ppm (dry feed basis).

Animals were sacrificed within six hours after the final dose except for the depuration group, which were sacrificed 4, 7, or 14 days after the last dose. Residues of isoflucypram were < 0.01 mg/kg in all matrices at all dose levels.

Farm animal dietary burdens

Dietary burdens were calculated for beef cattle, dairy cattle, broilers, and laying poultry based on feed items evaluated by the JMPR by the current Meeting. The dietary burdens, estimated using the most

recent version of the OECD livestock dietary burden calculator, are presented in Annex 6 and summarized below.⁴

Table 5.22.3 Estimated maximum dietary burdens of farm animals

	Livestock dietary burden, isoflucypram, ppm of dry matter diet			
	Japan	United States-Canada	European Union	Australia
	Max	Max	Max	Max
Beef cattle	0.012	0.64	0.84	3.6 ^①
Dairy cattle	0.011	0.73	0.84	2.5 ^②
Poultry–broiler	0.002	0.012	0.012	0.012
Poultry–layer	0.004	0.012	0.37 ^③	0.009

Notes:

- ① Highest maximum beef cattle dietary burden suitable for MRL estimates for mammalian tissues.
- ② Highest maximum dairy cattle dietary burden suitable for MRL estimates for mammalian milk.
- ③ Highest maximum poultry dietary burden suitable for MRL estimates for poultry tissues and eggs.

Animal commodity estimations of maximum residue levels and dietary intake

Mammals (other than marine mammals)

The isoflucypram maximum dietary burdens for beef and dairy cattle were 3.6 and 2.5 ppm, respectively. Table 5.22.4 shows the anticipated isoflucypram residues in beef and dairy cattle for maximum residue level estimation.

Table 5.22.4 Residue of isoflucypram in mammals other than marine mammals for maximum residue level estimation

	Feed level (ppm) for milk residues	Isoflucypram residue (mg/kg) in milk	Feed level (ppm) for tissue residues	Isoflucypram residue (mg/kg) in tissues			
				Muscle	Liver	Kidney	Fat
Maximum residue level estimates for beef and dairy cattle							
Feeding study	4.18	< 0.005	4.18	< 0.01	< 0.01	< 0.01	< 0.01
Dietary burden and residue estimate	2.50	< 0.005 ^a	3.60	< 0.01	< 0.01	< 0.01	< 0.01

Notes:

- ^a Residue of < 0.005 mg/kg at the 15.5 ppm feeding level was used for the determination of the residue in milk fats.

The Meeting estimated the following maximum residue levels: 0.005(*) mg/kg for milks and milk fats and 0.01(*) mg/kg for meat (from mammals other than marine mammals), fat (from mammals other than marine mammals), and edible offal (mammalian).

Poultry

The isoflucypram maximum dietary burden for poultry is 0.37 ppm.

Table 5.22.5 shows the anticipated isoflucypram residues in poultry for maximum residue level estimation.

⁴ <http://www.fao.org/agriculture/crops/core-themes/theme/pests/pm/jmpr/jmpr-docs/en/>

Table 5.22.5 Residues of isoflucypram in poultry for maximum residue level estimation.

	Feed level (ppm) for egg residues	Isoflucypram residue (mg/kg) in eggs	Feed level (ppm) for tissue residues	Isoflucypram residue (mg/kg) in tissues			
				Muscle	Liver	Kidney	Fat
Maximum residue level estimates for poultry							
Feeding study	0.53	< 0.01	0.53	< 0.01	< 0.01	< 0.01	< 0.01
Dietary burden and residue estimate	0.37	< 0.01	0.37	< 0.01	< 0.01	< 0.01	< 0.01

The Meeting estimated maximum residue levels of 0.01(*) mg/kg for eggs, poultry meat, poultry fat, and poultry edible offal.

RECOMMENDATIONS

Summary of recommendations for isoflucypram

Definition of the residue for compliance with the MRL for plant and animal commodities: *Isoflucypram*.

Definition of the residue for dietary risk assessment for plant and animal commodities: *A conclusion could not be reached*.

The residue is fat-soluble.

DIETARY RISK ASSESSMENT

As the Meeting was unable to recommend residue definitions for dietary risk assessment for plants and animal commodities, chronic and acute dietary risk assessments could not be conducted.

FURTHER WORK OR INFORMATION

Desirable information

- Cereal grain processing data for isoflucypram-desmethyl-propanol.
- Hydrolysis of the extracts from the soya bean metabolism studies.

5.23 Mancozeb (050) -Dithiocarbamates (105)

RESIDUE AND ANALYTICAL ASPECTS

Mancozeb was evaluated in 1993 within the CCPR periodic review programme. Mancozeb was last evaluated for new MRLs by the 2014 Meeting.

Mancozeb was scheduled at the Fifty-first Session of the CCPR for the evaluation of additional MRLs by the 2021 Extra JMPR and was re-scheduled to the 2022 JMPR.

The mancozeb residue definition for compliance with MRLs in plants and animals is defined as total dithiocarbamates, determined as CS₂, evolved during acid digestion and expressed as mg CS₂/kg. Dithiocarbamate residues are not fat soluble.

In 1993, the JMPR established a group (alone or in any combination) ADI of 0–0.03 mg/kg bw for ethylene-bis-dithiocarbamates (EBDCs: mancozeb, maneb, metiram and zineb) and an ADI of 0–0.004 mg/kg bw for their metabolite ethylenethiourea (ETU). The parent EBDC and ETU are defined as the residues for evaluating dietary intake in plant and animal commodities. The Meeting is assessing combined residues of mancozeb and ETU using the ratio of the ADIs (7.5) to express residues in terms of mancozeb-toxicity-equivalents (MTE).

At present, there are no ARfDs established by the JMPR for EBDCs or ETU.

The current Meeting received information on analytical methods, storage stability, supervised residue trials, and processing (maize only) to support new MRLs in longan, soya bean, maize, rice, and cottonseed.

Methods of analysis

The Meeting received method validation for analysis of mancozeb (as CS₂) in maize kernels as well as concurrent recovery data for other matrices for which field trials were provided. All methods for analysis of CS₂ use the same basic principles: extraction of mancozeb into an acidified stannous chloride solution with isooctane, *in-situ* conversion of mancozeb to CS₂ which is captured in the isooctane, and analysis of the residue by GC-MS. While validation data for the full method were not provided for all matrix types reviewed by the Meeting, the Meeting agreed that extraction and CS₂ conversion step has been previously validated and that the trapping of CS₂ in organic solvent with analysis by GC has been shown to be a reliable technique^{5,6} for the analysis of CS₂. All methods were demonstrated to have adequate performance for recovery of mancozeb (as CS₂), with an LOQ of 0.056 mg/kg in all commodities tested, except for rice (0.028 mg/kg).

The Meeting also received concurrent recovery data for analysis of ETU in longan fruit, soya bean seed, maize, and cotton seed. Neither method validation nor radiovalidation data were provided.

Reported recoveries of ETU in longan fruit ranged from 91 to 104 percent at fortification levels ranging from 0.01 to 0.05 mg/kg, with RSD <7 percent. The description for the method used for the

⁵ Woodrow, J.E., Seiber, J.N., Fitzell, D. 1995. Analytical Method for the Dithiocarbamate Fungicides Ziram and Mancozeb in Air: Preliminary Field Results. *J. Agric. Food Chem.*, 43:1524–1539.

⁶ Abakerli, R.B., Sparrapan, R., Sawaya, A.C.H.F., Eberlin, M.N., Jara, J.L.P., Rodrigues, N.R., Fay, E.F., Luiz, A.J.B., Galvão, T.D.L., dos S. Martins, D., Yamanishi, O.K., Toledo, H.H.B. 2015. Carbon Disulfide Formation in Papaya Under Conditions of Dithiocarbamate Residue Analysis. *Food Chemistry*, 188:71–76.

analysis of ETU in longan fruit cites a modified QuEChERS method⁷ that uses alkaline acetonitrile as the extraction solvent. The information provided to the Meeting noted that QuEChERS was used for analysis of fruits but did not specify that alkaline acetonitrile was used in the analysis of ETU in longan fruit. Furthermore, there is no information available on the ability of the method to extract incurred residues of ETU. Noting that methods for the analysis of ETU reviewed by prior Meetings and found to be acceptable used non-polar solvents (dichloromethane) or alkaline polar solvents (aqueous ammonia (pH 11–12) + either methanol or ethanol, the Meeting agreed that it could not conclude on the suitability of the method for estimating residues of ETU in longan fruit.

Reported recoveries of ETU in soya bean seed and cotton seed ranged from 69 to 95 percent at fortification levels ranging from 0.1 to 1 mg/kg, with RSD <10 percent. Residues were extracted with methanol with analysis by LC-MS/MS. As noted above, methods previously considered adequate by the JMPR use alkaline methanol for the extraction of ETU. While suitable concurrent recoveries were obtained, there is no information available on the ability of the method to extract incurred residues of ETU. The Meeting agreed that it could not conclude on the suitability of the method for estimating residues of ETU in soya bean seed or cotton seed.

Stability of pesticide residues in stored analytical samples

Concurrent storage stability data were provided for residues of mancozeb in longan fruit. The data demonstrate that residues of mancozeb, analysed as CS₂, are stable in frozen longan fruit for at least 300 days. Samples from the longan trials were stored at ≤ 20 °C for a maximum of 300 days.

For other commodities considered by the present Meeting except rice, samples were kept in frozen storage for up to 42 days. The 1993 Meeting concluded that mancozeb residues are stable during frozen storage for a duration of at least 3 months in commodities similar to those being considered by the current Meeting. Rice samples were stored for up to 425 days. In a storage stability study in wheat reviewed by the 1993 JMPR, residues of mancozeb showed a slow decline beginning at six months and continuing until the end of the study at 24 months. The 1993 JMPR concluded that in wheat grain samples from a storage stability study, mancozeb stability was in the normally acceptable range for up to 2 years. The Current Meeting agreed the storage stability conclusion for wheat supported the storage duration for rice.

Results of supervised residue trials on crops

For estimating maximum residue levels, residues of mancozeb listed below are expressed as CS₂.

For estimating dietary exposure, combined residues of mancozeb and ETU (expressed as mancozeb toxicity-equivalents (MTE)) are calculated based on molecular weights and a potency factor for ETU of 7.5 (derived from the ratio of the ADI for mancozeb to that of ETU). The conversion factor for CS₂ to mancozeb is 1.777 (CS₂=76.1 g/mol; mancozeb = 541.0 g/mol; 4 molecules CS₂ per molecule mancozeb). However, the Meeting noted that in metabolism and field trials evaluated by previous Meetings, residues of ETU are consistently < 0.01 mg/kg and at least an order of magnitude less than residues of mancozeb (expressed as CS₂). Therefore, the Meeting agreed to assume residues of ETU in raw commodities were 0 mg/kg; thus, residues for dietary risk assessment for commodities that are consumed raw were derived directly from residues of mancozeb as 1.777×[CS₂]. Furthermore, the Meeting agreed that for RACs that are heated/cooked prior to consumption (i.e., soya bean, maize, rice, and

⁷ Zhou, L., Liu, X., Kang, S, Zhang, F., Pan, C. 2013. A Rapid Determination Method for Ethylenethiourea in Potato and Cucumber by Modified QuEChERS–High Performance Liquid Chromatography-Tandem Mass Spectrometry. *Food Chemistry*, 138:1355–1359

cottonseed), all residues of mancozeb would be converted to ETU; therefore, STMRs were estimated as 7.5 times the median residue of mancozeb in the RAC (equivalent to $13.33 \times [CS_2]$).

The Meeting received data from supervised residue trials and GAP information on longan, soya beans, maize, rice, and cotton.

Longan

The information provided for residues in longan fruit consisted of summary reports rather than complete study volumes. Nevertheless, sufficient details were provided to be able to evaluate the data for purposes of making recommendations.

The critical GAP for longan is from Thailand. The label allows three applications on a 7-day interval at a maximum spray concentration of 0.24 kg ai/hL and a spray rate of 5 L/tree, with a 14-day PHI.

Residues of CS_2 in the whole fruit (minus the pit) from independent trials matching the critical GAP were (n=5): 2.2, 4.0, 5.5, 6.0, and 7.0 mg/kg.

Based on the reported total sample size and weight (120 fruits, 2 kg) and on the reported weight of longan fruit pits (ca. 1.6 g), the Meeting estimated that the pit constitutes approximately 10 percent of the whole-fruit weight and agreed that an adjustment to the residues to account for weight of the pit is not necessary. The Meeting estimated a maximum residue level of 15 mg/kg for CS_2 in longan fruit.

The median residue of CS_2 was 5.5 mg/kg resulting in an STMR of 9.8 mg MTE/kg.

Soya bean

The critical GAP for soya beans is from Brazil and consists of three applications each at 2.4 kg ai/ha, on a 7-day interval, with a 30-day PHI.

Residues of CS_2 in seed from independent trials matching the critical GAP were (n=12): < 0.056 (8), 0.06, 0.11, 0.16, and 0.22 mg/kg.

The Meeting estimated a maximum residue level of 0.3 mg/kg for CS_2 in soya bean seed.

The median residue of CS_2 was < 0.056 mg/kg resulting in an STMR of 0.75 mg MTE/kg.

Maize

The critical GAP for maize is from Brazil and consists of three applications each at 2.25 kg ai/ha, on a 7-day interval, with a 30-day PHI.

Residues of CS_2 in kernels from independent trials matching the critical GAP were (n=10): < 0.056 (5), 0.069, 0.070, 0.073, 0.089, and 0.11 mg/kg.

The Meeting estimated a maximum residue level of 0.15 mg/kg for CS_2 in maize kernels.

The median residue of CS_2 was 0.0625 mg/kg resulting in an STMR of 0.83 mg MTE/kg.

Rice

The critical GAP for rice is from Brazil and consists of three applications each at 2.8 kg ai/ha, on a 10-day interval, with a 32-day PHI.

Residues of CS_2 in rice grain (paddy rice) from independent trials matching the critical GAP for application and harvest timing but with applications rates ranging from 1.4 to 2.2 kg ai/ha were (n=5): < 0.028 (2), 0.030, 0.22, and 0.32 mg/kg.

After scaling based on application rate (scaling factor range: 1.3–1.99), residues in rice grain from trials with quantifiable residues were (n=3): 0.060, 0.29, and 0.61 mg/kg.

The Meeting agreed that three trials were not sufficient to make a recommendation for rice.

Additional trials were conducted with application rates ranging from 1.2 to 1.5 kg ai/ha at intervals of 14 days and with harvest 34–35 DALA. Quantifiable residues from those trials were (n=5): 0.18, 0.20, 0.25, 0.38, and 0.70 mg/kg.

After scaling based on application rate (scaling factor range: 1.95–2.25), residues in rice grain from trials with quantifiable residues were (n=5): 0.39, 0.42, 0.48, 0.85, and 1.4 mg/kg.

There are too few data points from the first set of trials listed above to complete a statistical comparison of the two data sets. Based on the perceived similarity in the data sets, the Meeting agreed to combine the scaled results from the two sets of trials (n=8): 0.06, 0.29, 0.39, 0.42, 0.48, 0.61, 0.85, and 1.4 mg/kg. The Meeting estimated a maximum residue level of 3 mg/kg for rice grain.

Analysis of husked rice was included for two sites from the second set of trials. Residues in husked rice and rice grain were, respectively, 0.11 mg/kg and 0.38 mg/kg (Trial C94) and 0.14 mg/kg and 0.18 mg/kg (Trial CDb). The corresponding residue reduction factors were 0.289 and 0.778 (mean = 0.534). Applying the mean factor to the residues listed above for the consideration of the residues in rice grain gives the following residue estimates (n=8): 0.032, 0.15, 0.21, 0.22, 0.26, 0.33, 0.45, and 0.75 mg/kg for CS₂ in husked rice.

The Meeting estimated a maximum residue level of 1.5 mg/kg for CS₂ in husked rice.

The median residue of CS₂ was 0.24 mg/kg resulting in an STMR of 3.2 mg MTE/kg.

A processing study on rice is not available. The Meeting agreed to extrapolate the residue estimates from husked rice to polished rice. The Meeting estimated a maximum residue level of 1.5 mg/kg for CS₂ in polished rice and an STMR of 0.43 mg MTE/kg.

Cotton

The critical GAP for cotton is from Brazil and consists of 3 applications each at 2.25 kg ai/ha, on a 7-day interval, with a 30-day PHI.

Residues of CS₂ in undelinted seed from independent trials matching the critical GAP were (n=8): < 0.056 (4), 0.097, 0.11, 0.13, and 0.24 mg/kg.

The Meeting estimated a maximum residue level of 0.4 mg/kg for CS₂ in cottonseed (undelinted).

The median residue of CS₂ was < 0.056 mg/kg resulting in an STMR of 0.75 mg MTE/kg.

Fate of residues during processing

The 1993 Meeting evaluated the effects of processing on residues in a number of commodities, including maize. Residues in raw and processed commodities were <LOQ for both CS₂ (< 0.03 mg/kg) and ETU (< 0.01 mg/kg), and processing factors could not be calculated.

In the processing study provided to the current meeting, residues of CS₂ were <LOQ in one RAC sample and 0.41 mg/kg in the second RAC sample. Based on that second sample, the Meeting was able to calculate CS₂ processing factors, summarized below, for maize.

Table 5.23.1 Processing factors (as CS₂)

Crop	Commodity	Processing factor (CS ₂ only)
Maize	Kernels (max. residue level = 0.15 mg/kg; median = 0.11 mg MTE/kg)	--
	Grits	0.205
	Meal	0.873
	Flour	1.07
	Refined oil	< 0.122
	Starch	< 0.122

As no other processing data were available, the Meeting could not conclude on residue levels in processed commodities of soya bean, rice, or cotton.

The Meeting noted that processed commodities of maize, soya bean, rice, and cotton are heated during processing and/or prior to consumption. The Meeting therefore decided not to use empirical processing factors and to assume all residues of mancozeb in processed commodities would be converted to ETU. The Meeting agreed to derive STMRs for processed commodities based on the level of CS₂ in the RAC. The Meeting used the relative potency factor of 7.5 to convert STMRs in the RAC (as MTE) to STMRs in the processed commodities considered by the current Meeting.

The STMRs for processed commodities from RACs considered by the current meeting are:

Soya bean: 0.75 mg MTE/kg

Maize: 0.83 mg MTE/kg

Rice: 3.2 mg MTE/kg

Cotton: 0.75 mg MTE/kg

Residues in animal commodities

The 1993 Meeting recommended maximum residue levels for CS₂ in animal commodities as follows: milks 0.05(*) mg/kg, meat 0.02(*) mg/kg, mammalian edible offal 0.1 mg/kg, eggs 0.05(*) mg/kg, poultry meat 0.1 mg/kg, and poultry edible offal 0.1 mg/kg, noting that those recommendations should accommodate animals (ruminants and poultry) consuming up to 25 ppm CS₂ in their diet. A dietary burden was not provided by the 1993 Meeting. The recommendations from the 1993 Meeting included a large number of animal feed commodities, including cereal grains and fodders, with higher residues than those considered by the current Meeting. Therefore, the Meeting agreed that residues in soya bean, maize kernels, rice grain and cottonseed would not significantly change the dietary burdens for cattle or poultry. The Meeting confirmed is previous recommendations for residues in animal commodities.

RECOMMENDATIONS

On the basis of the data obtained from supervised trials, the Meeting concluded that it could not derive residues suitable for conducting dietary risk assessments. Based on the residue definitions, the residue levels listed in Annex 1 are suitable for establishing maximum residue limits and for IEDI assessment.

Definition of the residue for compliance with MRLs is total dithiocarbamates, determined as CS₂, evolved during acid digestion and expressed as mg CS₂/kg. Dithiocarbamate residues are not fat soluble.

Definition of the residue for dietary risk assessment is the parent EBDC and ETU. The Meeting is assessing combined residues of mancozeb and ETU using the ratio of the ADIs (7.5) to express residues in terms of mancozeb-toxicity-equivalents (MTE).

Dithiocarbamate residues are not fat-soluble

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The ADI for EBDCs, including mancozeb, is 0–0.03 mg/kg bw. The ADI for ETU is 0–0.004 mg/kg bw (= 7.5 × mancozeb maximum ADI). The International Estimated Daily Intakes (IEDIs) for mancozeb (including ETU) were estimated for the 17 GEMS/Food Consumption Cluster Diets using the STMR or STMR-P values estimated by the JMPR. The results are shown in Annex 3 of the 2022 JMPR Report.

The IEDIs ranged from 5–50 percent of the maximum ADI. The Meeting concluded that long-term dietary exposure to residues of ethylene-bis-dithiocarbamates from uses considered by the 2014 and current JMPR is unlikely to present a public health concern.

Acute dietary exposure

An ARfD for the EBDCs has not been established. The Meeting noted that the dithiocarbamates were last evaluated in 1993, which was prior to the JMPR establishing ARfDs.

FURTHER WORK OR INFORMATION

Desirable information

- Radiovalidation studies for analysis of ETU by QuEChERS or methods using methanol or ethanol (unaltered) to extract residues.
- Processing studies with soya bean, rice, and cotton, including analysis of ETU

5.24 Mandipropamid (231)

TOXICOLOGY

Mandipropamid is being evaluated by the current Meeting of the FAO/WHO Joint Meeting on Pesticide Residues (JMPR) following a request from the Codex Committee on Pesticide Residues (CCPR) for additional maximum residue limits (MRLs) on potatoes. New information on mandipropamid was made available by the sponsor, including genotoxicity studies for mandipropamid and studies of liver toxicity following single and repeated doses in rats treated with propargyl alcohol. As these studies would have had no effect on the health-based guidance values they were not reviewed by this Meeting. However, they should be provided for the periodic review of mandipropamid.

There was no information available in the public domain and no experimental data were provided which addressed the possible impact of mandipropamid residues on the human intestinal microbiome.

A toxicological monograph addendum was not prepared.

RESIDUE AND ANALYTICAL ASPECTS

Mandipropamid is a fungicide that belongs to the subset mandelamides in the class carboxylic acid amides. It is intended for the control of Oomycete fungal pathogens in a range of crops. It was first evaluated by JMPR in 2008. An ADI of 0–0.2 mg/kg bw was established and decided that an ARfD was unnecessary. The 2018 JMPR further concluded that metabolite SYN500003 should be assessed by TTC as Cramer Class III. The residue definition for compliance with the MRL and dietary risk assessment for plant and animal commodities is mandipropamid. The residue is not fat-soluble. Additional uses were evaluated by the 2013, 2018 and 2021 (extra) JMPR.

Mandipropamid was scheduled at the Fifty-first Session of the CCPR for the evaluation of additional uses in the 2021 JMPR and rescheduled to the 2022 JMPR. The Meeting received information on additional analytical methods, storage stability, high temperature hydrolysis, residues during processing (tomato), GAP information and residue trials for bulb onion, green onion, cucumber, summer squash, melon, tomato, ginseng and basil.

Methods of analysis

The Meeting received descriptive and validation data of analytical methods for residue of mandipropamid in plant and animal commodities.

In the method for determination of mandipropamid in plant, homogenized samples were extracted with acetonitrile: water (80:20), with clean-up with a solid phase extraction, residues were determined by LC-MS/MS. The method of analysis was validated at various fortification levels with an LOQ of 0.01 mg/kg for mandipropamid.

QuEChERS method was also validated for mandipropamid residue in plant and animal commodities with an LOQ of 0.01 mg/kg.

Stability of pesticide residues in stored analytical samples

The Meeting received information on the freezer storage stability of mandipropamid in plant (dried beans, ginseng and basil) and SYN500003 in plant (ginseng and potato). Storage stability results indicated that residues of mandipropamid were stable for up to 12 months in dried broad beans, and for at least 9

months in fresh ginseng, 30 months in dried ginseng and 23 months in basil under freezer conditions at about -18 °C or below.

The Meeting agreed that the demonstrated storage stability for mandipropamid covered the residue sample storage intervals used in the field trials.

Results of supervised residue trials on crops

The Meeting received supervised trial data for the foliar application of mandipropamid on bulb onion, spring onion, cucumber, melon, tomato, ginseng and basil. Residue trial data was made available from Canada, China, France, Germany, Italy, Spain, Switzerland and the United States.

Labels were available from China and the United States describing the registered uses of mandipropamid.

Bulb vegetables, Group of

The 2008 JMPR evaluated residue data for mandipropamid on bulb onion and spring onion conducted in the United States. The Meeting received new residue data for bulb onion and spring onion.

Bulb Onions, Subgroup of

Data were available from supervised trials on bulb onion in the United States.

The critical GAP for dry bulb vegetables in the United States (same GAP as that provided to the 2008 JMPR) allows a maximum seasonal rate of 0.59 kg ai/ha (maximum of 0.15 kg ai/ha per application) with a re-treatment interval (RTI) of 7 days and a PHI of 7 days.

Mandipropamid residues in bulb onion from independent trials (RTI: 6-8 days) conducted in 2004 (provided to the 2008 JMPR) in the United States matching the US GAP were (n=8): < 0.01 (5), 0.01, 0.02 and 0.03 mg/kg.

Mandipropamid residues in bulb onion from independent trials with a RTI of 4-6 days conducted in 2011 in the United States were (n=8): 0.012, 0.032, 0.062, 0.066, 0.068, 0.082, 0.11 and 0.21 mg/kg.

The trials in 2011 were conducted with a shorter RTI than that of the US GAP. The residue populations from trials with a RTI of 5 ± 1 days were significantly different from those from trials with a RTI of 7 ± 1 days according to statistical test (Mann-Whitney U-test).

Based on the residues in bulb onion from trials conducted in 2004 in the United States, the Meeting estimated a maximum residue level of 0.05 mg/kg and an STMR value of 0.01 mg/kg for the subgroup of bulb onions.

The Meeting withdrew the previous recommendation for onion, bulb of 0.1 mg/kg.

Spring onion

Data were available from supervised trials on spring onion in the United States.

The critical GAP for green onions in the United States (same GAP as that provided to the 2008 JMPR) allows a maximum seasonal rate of 0.44 kg ai/ha (maximum 0.15 kg ai/ha per application) with a RTI of 7 days and a PHI of 7 days.

Mandipropamid residues in spring onion from independent trials conducted in 2004 (provided to the 2008 JMPR) in the United States matching the US GAP were (n=3): 0.23, 0.40 and 1.4 mg/kg.

Mandipropamid residues in spring onion from independent trials with a RTI of 5 days conducted in 2011 in the United States were (n=3): 0.73, 1.6 and 3.7 mg/kg.

The trials in 2011 were conducted with a shorter RTI than that of the US GAP. The residue populations from trials with a RTI of 5 ± 1 days were significantly different from those from trials with a RTI of 7 ± 1 days according to statistical test (Mann-Whitney U-test).

The trials for spring onion in the United States were insufficient to estimate a maximum residue level for the commodity, since a minimum of five trials are need for spring onion. The Meeting could not estimate a maximum residue level for spring onion.

The Meeting withdrew the previous recommendation for spring onion of 7 mg/kg.

Fruiting vegetables, Cucurbits, Group of

Fruiting vegetables, Cucurbits–Cucumbers and Summer squashes, Subgroup of

The critical GAP for cucurbits in the United States (same GAP as that provided to the 2008 JMPR) allows a maximum seasonal rate of 0.59 kg ai/ha (maximum of 0.15 kg ai/ha per application) with a RTI of 7 days and a PHI of 0 day.

Cucumber

Data were available from supervised trials on cucumber in Italy, Spain and the United States.

Mandipropamid residues in cucumber from independent trials in Italy, Spain and the United States matching the US GAP were (n=17): 0.011, 0.013(2), 0.014, 0.02, 0.03, 0.033, 0.045, 0.05, 0.06 (2), 0.069, 0.07, 0.08 (3) and 0.14 mg/kg.

Squash, summer

Data were available from supervised trials on summer squash in the United States.

Mandipropamid residues in summer squash from independent trials in the United States matching the US GAP were (n=5): 0.014, 0.023, 0.030, 0.058 and 0.070 mg/kg.

To consider a maximum residue level for a group, residues in individual crops should be similar (e.g. medians should not differ by more than 5×). The Meeting agreed to estimate a maximum residue level for the subgroup of Fruiting vegetables, cucurbits–cucumbers and summer squashes. In considering whether to combine data to estimate a maximum residue level, the Meeting recognized that the residue populations from trials on cucumber and summer squash were not different according to statistical test (Mann-Whitney U-test). Therefore, the Meeting decided to combine the data from cucumber and summer squash to estimate a maximum residue level for fruiting vegetables, cucurbits–cucumber and summer squashes.

The combined mandipropamid residues in cucumber and summer squash were in rank order (n=22): 0.011, 0.013(2), 0.014 (2), 0.02, 0.023, 0.03 (2), 0.033, 0.045, 0.05, 0.058, 0.06 (2), 0.069, 0.07 (2), 0.08 (3) and 0.14 mg/kg.

The Meeting estimated a maximum residue level of 0.2 mg/kg and an STMR value of 0.0475 mg/kg for the subgroup of Fruiting vegetables, cucurbits–cucumber and summer squashes.

The Meeting withdrew the previous recommendations for cucumber of 0.2 mg/kg and summer squash of 0.2 mg/kg.

Fruiting vegetables, Cucurbits–Melons, Pumpkins and Winter Squashes, Subgroup of

Data were available from supervised trials on melons in France, Italy, Spain and the United States.

The critical GAP for cucurbits in the United States (same GAP as that provided to the 2008 JMPR) allows a maximum seasonal rate of 0.59 kg ai/ha (maximum 0.15 kg ai/ha per application) with a RTI of 7 days and a PHI of 0 day.

Mandipropamid residues in melons (whole fruit) from independent trials in France, Italy, Spain and the United States matching the US GAP were (n=13): 0.03, 0.045, 0.05, 0.06 (2), 0.07, 0.08, 0.097, 0.11 (2), 0.13, 0.17 and 0.23 mg/kg.

Mandipropamid residues in melons (flesh) from independent trials in France, Italy and Spain matching the US GAP were (n=8): < 0.01 (8) mg/kg.

Based on the residues in melon (whole fruit) from trials, the Meeting estimated a maximum residue level of 0.4 mg/kg, and based on the residues in melon (flesh) from trials the Meeting estimated an STMR value of 0.01 mg/kg for the subgroup of fruiting vegetables, cucurbits–melons, pumpkins and winter squashes.

The Meeting withdrew the previous recommendations for melons except watermelon of 0.5 mg/kg.

Fruiting vegetables, other than Cucurbits

The critical GAP for fruiting vegetables in the United States (same GAP as that provided to the 2008 JMPR) allows a maximum seasonal rate of 0.59 kg ai/ha (max 0.15 kg ai/ha per application) with a RTI of 7 days and a PHI of 1 day.

Peppers, Subgroup of

Data were available from supervised trials on peppers in the United States (provided to the 2008 JMPR).

Mandipropamid residues in bell pepper and non-bell pepper from independent outdoor trials in the United States matching the US GAP were (n=6+3): 0.041, 0.054, 0.062, 0.090, 0.13 and 0.33 mg/kg for bell pepper and 0.083, 0.16 and 0.37 mg/kg for non-bell pepper.

Based on the residues in peppers from trials in the United States, the Meeting estimated a maximum residue level of 0.7 mg/kg and an STMR value of 0.090 mg/kg for the subgroup of peppers (except *Martynia*, *Okra* and *Roselle*) to replace the previous recommendation for peppers of 1 mg/kg.

Peppers, Chili, dried

On the basis of the maximum residue level and the STMR for subgroup of peppers and default dehydration factor of 10, the Meeting estimated a maximum residue level and an STMR value of 7 and 0.9 mg/kg to replace the previous recommendation for peppers, chili, dried.

Tomatoes, Subgroup of

The critical GAP for fruiting vegetables for indoor use tomatoes in the United States (same GAP as that provided to the 2008 JMPR) allows a maximum seasonal rate of 0.59 kg ai/ha (max 0.15 kg ai/ha per application) with a RTI of 7 days and a PHI of 1 day.

Data were available from supervised trials on tomatoes in France, Germany, Italy, Spain, Switzerland and the United States.

Mandipropamid residues in tomatoes from independent indoor trials in France, Germany, Italy, Spain and Switzerland matching the US GAP were (n=14): 0.08, 0.13 (2), 0.14, 0.17, 0.18, 0.24, 0.28, 0.30, 0.33, 0.34, 0.45, 0.60 and 0.65 mg/kg.

Mandipropamid residues in tomato from independent outdoor trials in the United States matching the US GAP were (n=10): 0.016, 0.032, 0.047, 0.052, 0.056 (2), 0.065, 0.082, 0.10 and 0.18 mg/kg.

The residue populations from trials indoor and outdoor were significantly different according to statistical test (Mann-Whitney U-test).

Based on the residues in tomatoes from indoor trials, the Meeting estimated a maximum residue level of 1 mg/kg and an STMR value of 0.26 mg/kg for the subgroup of tomatoes.

The Meeting withdrew the previous recommendation for tomato of 0.3 mg/kg.

Eggplant and eggplant like commodities, Subgroup of

In comparison with the residues in peppers and tomatoes from outdoor trials, the dataset from peppers leads to the highest maximum residue level.

The Meeting agreed that the maximum residue level for the subgroup of peppers could be extrapolated to that of the subgroup of eggplants. The Meeting estimated a maximum residue level of 0.7 mg/kg and an STMR value of 0.090 mg/kg for the subgroup of eggplants.

Root and tuber vegetables

Ginseng and Ginseng, dried including red ginseng

Data were available from supervised trials on ginseng and dried ginseng in China.

The GAP for ginseng in China allows one application of 0.21 kg ai/ha with a PHI of 21 days.

Mandipropamid residues in fresh ginseng from independent trials in China matching Chinese GAP were (n=5): < 0.010 (3), 0.013 and 0.077 mg/kg.

Mandipropamid residues in dried and red ginseng from independent trials in China matching Chinese GAP were (n=5): 0.19, 0.23, 0.46, 0.49 and 2.2 mg/kg.

Data were available from supervised trials on dried ginseng in Canada and the United States.

The GAP for ginseng in the United States allows a maximum seasonal rate of 0.59 kg ai/ha (maximum of 0.15 kg ai/ha per application) with a RTI of 7 days and a PHI of 2 days.

Mandipropamid residues in dried ginseng from independent trials in Canada and the United States matching the US GAP were (n=4): 0.033, 0.035, 0.11 and 0.12 mg/kg.

Based on the residues in fresh ginseng from trials in China, the Meeting estimated a maximum residue level of 0.15 mg/kg and an STMR value of 0.010 mg/kg for ginseng.

Based on the residues in dried ginseng from trials in China, the Meeting estimated a maximum residue level of 4 mg/kg and an STMR value of 0.46 mg/kg for ginseng, dried including red ginseng.

Herbs and spices

Basil and Basil leaves, dried

Data were available from supervised trials on basil and dried basil in Canada and the United States.

The critical GAP for basil in the United States allows a maximum seasonal rate of 0.59 kg ai/ha (max 0.15 kg ai/ha per application) with a RTI of 7 days and a PHI of 1 day.

Mandipropamid residues in fresh basil from independent trials in Canada and the United States matching the US GAP were (n=6): 3.6, 6.5, 8.5, 9.0, 9.6 and 19 mg/kg.

Mandipropamid residues in dried basil from independent trials in Canada and the United States matching the US GAP were (n=6): 36, 48, 62, 63, 78 and 91 mg/kg.

Based on the residues in fresh basil from trials in Canada and the United States, the Meeting estimated a maximum residue level of 30 mg/kg and an STMR value of 8.75 mg/kg for basil, leaves.

Based on the residues in dried basil from trials in Canada and the United States, the Meeting estimated a maximum residue level of 200 mg/kg and an STMR value of 62.5 mg/kg for basil leaves, dried.

Fate of residues during processing

High temperature hydrolysis

The hydrolytic stability of [phenyl-U-¹⁴C]-SYN500003 was studied under conditions at high temperature in sterile aqueous buffers at pH 4, 5 and 6 for periods of up to 60 minutes so as to simulate common processing practices (pasteurization, baking/brewing/boiling, and sterilisation). SYN500003 was detected ranged from 97.5 to 100.4 percent of applied radioactivity at the investigated pH and temperature ranges. SYN500003 is considered stable under hydrolytic conditions at high temperatures.

Residues in processed commodities

The fate of mandipropamid residues has been examined in tomato processing studies. Estimated processing factors and the derived STMR-Ps are summarized in the Table below.

Table 5.24.1 Calculated STMR-Ps for processed food and feed commodities

Raw commodity (STMR)	Processed commodity	Processing factors # (Mean or best estimate processing factor)	STMR-P = STMR _{RAC} × PF (mg/kg)
Tomato [0.26 mg/kg]	Wet pomace	1.0	0.26
	Dry pomace	4.4	1.14
	Juice	1.0	0.26
	Puree	0.86, 0.92, 1.1, 1.5, 2.0 [1.1]	0.286
	Canned	0.39	0.101
	Paste	1.9, 2.6, 4.4, 5.9 [3.5]	0.91

Notes:

The factor is the ratio of the residue in processed commodity divided by the residue in the RAC.

Residues in animal commodities

The 2022 JMPR evaluated residues of mandipropamid in tomato wet pomace, which is listed in the OECD feeding table. The Meeting noted that the estimation did not result in a change of the dietary burdens of farm animals (20.8 ppm for cattle and 2 ppm for poultry). The previous recommendations of maximum residue level for animal commodities were maintained.

RECOMMENDATIONS

On the basis of the data from supervised trials, the Meeting concluded that the residue levels listed in Annex 1 are suitable for estimating maximum residue limits and for IEDI assessment.

Definition of the residue for plant and animal commodities (for compliance with the MRL and for estimation of dietary exposure): *mandipropamid*

The residue is not fat-soluble

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The ADI for mandipropamid is 0–0.2 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for mandipropamid were estimated for the 17 GEMS/Food Consumption Cluster Diets using the STMR or STMR-P values estimated by the JMPR. The results are shown in Annex 3 of the 2022 JMPR Report. The IEDIs ranged from 1–8 percent of the maximum ADI.

The Meeting concluded that long-term dietary exposure to residues of mandipropamid from uses considered by the JMPR is unlikely to present a public health concern.

Acute dietary exposure

The 2008 JMPR decided that an ARfD for mandipropamid was unnecessary. Therefore, the Meeting concluded that the acute dietary exposure to residues of mandipropamid from the uses considered is unlikely to present a public health concern.

Threshold of toxicological concern (TTC) consideration for metabolite SYN500003

At the 2018 JMPR, the Meeting agreed to utilize the TTC approach to assess the metabolite SYN500003 (Cramer Class III). The 2018 JMPR concluded that residues of SYN500003 were only expected in root and tubers vegetables.

In the Canadian and the US trials for dried ginseng, SYN500003 residues were < 0.005 mg/kg in all samples. The Meeting agreed that no additional exposure to SYN500003 is expected from ginseng and dried ginseng.

The Meeting concluded that SYN500003 is unlikely to present a public health concern.

5.25 Mefentrifluconazole (320)

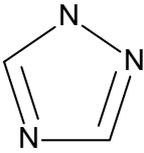
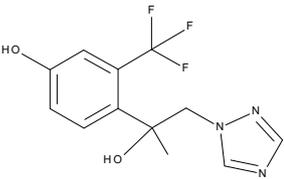
RESIDUE AND ANALYTICAL ASPECTS

Mefentrifluconazole, (2RS)-2-[4-(4-chlorophenoxy)-2-(trifluoromethyl)phenyl]-1-(1*H*-1,2,4-triazol-1-yl)propan-2-ol, is a triazole fungicide belonging to the group of the sterol biosynthesis inhibitors.

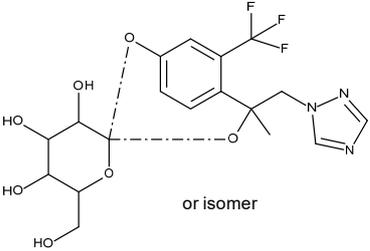
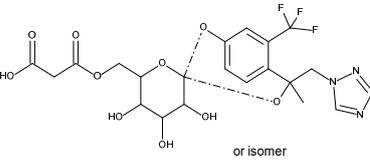
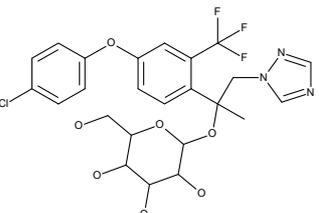
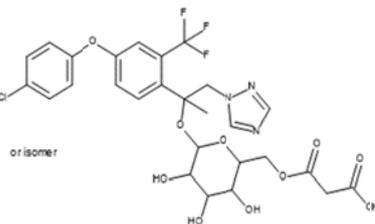
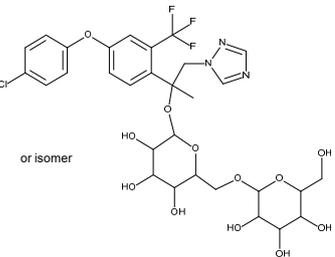
Mefentrifluconazole was scheduled at the Fifty-first Session of the CCPR for Evaluation for Residues and Toxicology by the 2020 JMPR, which was postponed to the 2021 JMPR Meeting, where an ADI of 0–0.04 mg/kg bw and an ARfD of 0.3 mg/kg bw were established. The Residue evaluation was rescheduled to the 2022 JMPR Meeting.

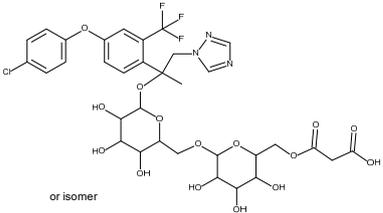
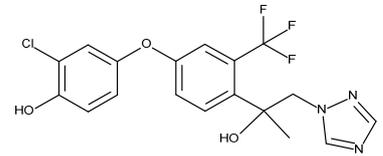
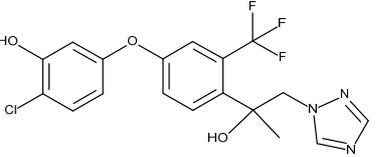
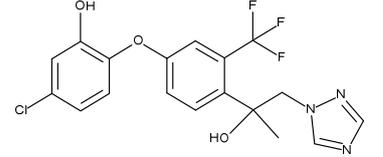
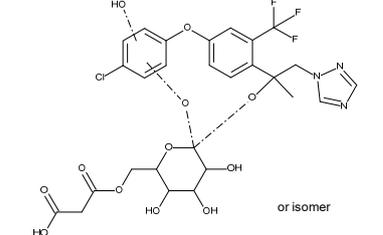
The Meeting received information from the manufacturer on physical and chemical properties, metabolism studies on plants and animals, environmental fate in soil, analytical method and stability in stored analytical samples, use patterns and supervised residue trials, processing studies and livestock feeding studies.

Table 5.25.1 Summary information on mefentrifluconazole and its metabolites mentioned in this appraisal

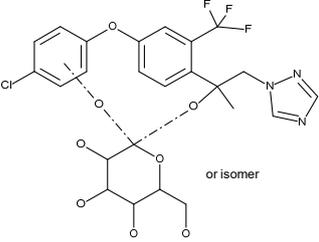
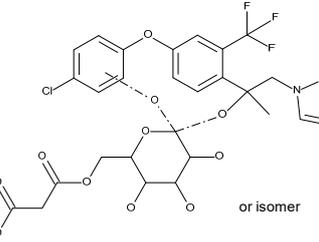
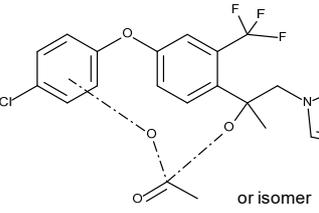
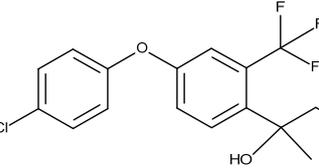
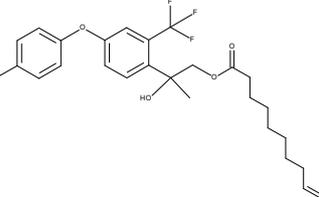
Code Number (Reg. Number)	Chemical Name	Molecular Structure	Occurrence in			
			Rat	Livestock (Hen & Goat)	Crop (Wheat, Grape & Soya bean)	Rotational Crops
Mefentrifluconazole (5834378)	(2RS)-2-[4-(4-chlorophenoxy)-2-(trifluoromethyl)phenyl]-1-(1 <i>H</i> -1,2,4-triazol-1-yl)propan-2-ol			X	X	
M750F001 (87084) 1,2,4-triazole	1,2,4-(1 <i>H</i>)-triazole		X	X	X	X
M750F003 (5924326)	4-[2-hydroxy-1-(1 <i>H</i> -1,2,4-triazol-1-yl)propan-2-yl]-3-(trifluoromethyl)phenol			X		

Mefentrifluconazole

Code Number (Reg. Number)	Chemical Name	Molecular Structure	Occurrence in			
			Rat	Livestock (Hen & Goat)	Crop (Wheat, Grape & Soya bean)	Rotational Crops
M750F009		 <p>or isomer</p>			X	
M750F010		 <p>or isomer</p>			X	
M750F011	2-[4-(4-chlorophenoxy)-2-(trifluoromethyl)phenyl]-1-(1 <i>H</i> -1,2,4-triazol-1-yl)propan-2-yl hexopyranoside				X	
M750F012	2-[4-(4-chlorophenoxy)-2-(trifluoromethyl)phenyl]-1-(1 <i>H</i> -1,2,4-triazol-1-yl)propan-2-yl 6-O-(carboxyacetyl)hexopyranoside	 <p>or isomer</p>			X	
M750F013	2-[4-(4-chlorophenoxy)-2-(trifluoromethyl)phenyl]-1-(1 <i>H</i> -1,2,4-triazol-1-yl)propan-2-yl 6-O-hexopyranosylhexopyranoside	 <p>or isomer</p>			X	

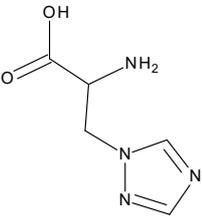
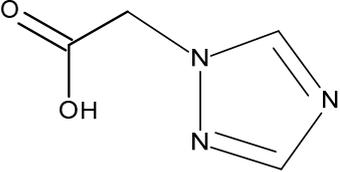
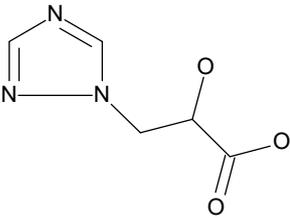
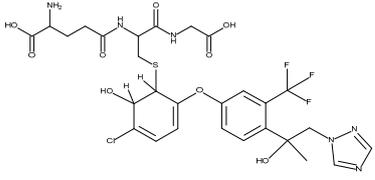
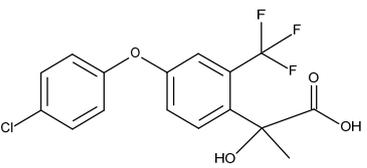
Code Number (Reg. Number)	Chemical Name	Molecular Structure	Occurrence in			
			Rat	Livestock (Hen & Goat)	Crop (Wheat, Grape & Soya bean)	Rotational Crops
M750F014	2-[4-(4-chlorophenoxy)-2-(trifluoromethyl)phenyl]-1-(1 <i>H</i> -1,2,4-triazol-1-yl)propan-2-yl 6-O-[6-O-(carboxyacetyl)hexopyranosyl]hexopyranoside				X	
M750F015 (6011549)	2-chloro-4-[4-[2-hydroxy-1-(1 <i>H</i> -1,2,4-triazol-1-yl)propan-2-yl]-3-(trifluoromethyl)phenoxy]phenol				X	
M750F016 (6010140)	2-chloro-5-[4-[2-hydroxy-1-(1 <i>H</i> -1,2,4-triazol-1-yl)propan-2-yl]-3-(trifluoromethyl)phenoxy]phenol				X	
M750F017 (6010139)	5-chloro-2-[4-[2-hydroxy-1-(1 <i>H</i> -1,2,4-triazol-1-yl)propan-2-yl]-3-(trifluoromethyl)phenoxy]phenol				X	
M750F018					X	

Mefentrifluconazole

Code Number (Reg. Number)	Chemical Name	Molecular Structure	Occurrence in			
			Rat	Livestock (Hen & Goat)	Crop (Wheat, Grape & Soya bean)	Rotational Crops
M750F019		 <p>or isomer</p>			X	
M750F020		 <p>or isomer</p>			X	
M750F021		 <p>or isomer</p>			X	
M750F022	2-[4-(4-chlorophenoxy)-2-(trifluoromethyl)phenyl]propane-1,2-diol			X		
M750F023	2-[4-(4-chlorophenoxy)-2-(trifluoromethyl)phenyl]-2-hydroxypropyl (9Z,11E)-octadeca-9,11-dienoate			X		

Code Number (Reg. Number)	Chemical Name	Molecular Structure	Occurrence in			
			Rat	Livestock (Hen & Goat)	Crop (Wheat, Grape & Soya bean)	Rotational Crops
M750F024	2-[4-(4-chlorophenoxy)-2-(trifluoromethyl)phenyl]-2-hydroxypropyl (9Z)-octadec-9-enoate			X		
M750F025 (6056452)	2-[4-(4-chlorophenoxy)-2-(trifluoromethyl)phenyl]-2-hydroxypropyl hexadecanoate			X		
M750F026					X	
M750F027					X	
M750F028	2-[4-(4-chlorophenoxy)-2-(trifluoromethyl)phenyl]-1-(1H-1,2,4-triazol-1-yl)propan-2-yl 6-O-pentofuranosylhexopyranoside				X	

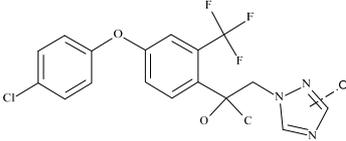
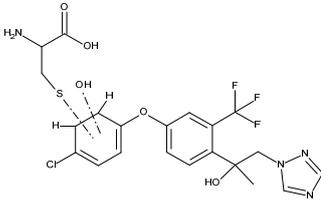
Mefentrifluconazole

Code Number (Reg. Number)	Chemical Name	Molecular Structure	Occurrence in			
			Rat	Livestock (Hen & Goat)	Crop (Wheat, Grape & Soya bean)	Rotational Crops
M750F029 (270412) Triazole alanine (TA)	2-amino-3-(1 <i>H</i> -1,2,4-triazol-1-yl)propionic acid				X	
M750F030 (137281) Triazole acetic acid (TAA)	(1 <i>H</i> -1,2,4-triazol-1-yl)acetic acid				X	
M750F031 (5050862) Triazole lactic acid, Triazole hydroxypropionic acid (TLA)	2-hydroxy-3-(1 <i>H</i> -1,2,4-triazol-1-yl)propanoic acid				X	
M750F034	gamma-glutamyl-S-(5-chloro-6-hydroxy-2-{4-[2-hydroxy-1-(1 <i>H</i> -1,2,4-triazol-1-yl)propan-2-yl]-3-(trifluoromethyl)phenoxy}cyclohexa-2,4-dien-1-yl)cysteinyglycine				X	
M750F038	(2 <i>R</i>)-2-[4-(4-chlorophenoxy)-2-(trifluoromethyl)phenyl]-2-hydroxypropanoic acid				X	

Code Number (Reg. Number)	Chemical Name	Molecular Structure	Occurrence in			
			Rat	Livestock (Hen & Goat)	Crop (Wheat, Grape & Soya bean)	Rotational Crops
M750F039	(2S)-2-[4-(4-chlorophenoxy)-2-(trifluoromethyl)phenyl]-3-(1 <i>H</i> -1,2,4-triazol-1-yl)propane-1,2-diol			X		
M750F040	(2S)-[4-(4-chlorophenoxy)-2-(trifluoromethyl)phenyl](hydroxy)acetic acid		X	X		
M750F041	3-chloro-6-[4-[2-hydroxy-1-(1 <i>H</i> -1,2,4-triazol-1-yl)propan-2-yl]-3-(trifluoromethyl)phenoxy]cyclohexa-3,5-diene-1,2-diol			X		
M750F042	2-[4-(4-chlorophenoxy)-2-(trifluoromethyl)phenyl]-2-hydroxy-3-(1 <i>H</i> -1,2,4-triazol-1-yl)propanoic acid			X		
M750F043	2-[4-(4-chlorophenoxy)-2-(trifluoromethyl)phenyl]-2-hydroxypropyl hydrogen sulfate		X	X		

Mefentrifluconazole

Code Number (Reg. Number)	Chemical Name	Molecular Structure	Occurrence in			
			Rat	Livestock (Hen & Goat)	Crop (Wheat, Grape & Soya bean)	Rotational Crops
M750F063		<p>or isomer (e.g. Cl- shift)</p>		X		
M750F064				X		
M750F068	2-[4-(4-chlorophenoxy)-2-(trifluoromethyl)phenyl]-1-(1 <i>H</i> -1,2,4-triazol-1-yl)propan-2-yl hexopyranosiduronic acid			X		
M750F072	2-[4-(4-chlorophenoxy)-2-(trifluoromethyl)phenyl]-2-hydroxy-3-(1 <i>H</i> -1,2,4-triazol-1-yl)propyl hydrogen sulfate			X		
M750F078		<p>or isomer (e.g. Cl- shift)</p>		X		

Code Number (Reg. Number)	Chemical Name	Molecular Structure	Occurrence in			
			Rat	Livestock (Hen & Goat)	Crop (Wheat, Grape & Soya bean)	Rotational Crops
M750F086				X		
M750F091				X		

Based on its physical chemical properties, mefentrifluconazole is slightly soluble in water and moderately soluble in non-polar solvents. It is likely to sequester to fatty matrices based on its Log Kow. It has low potential for volatilization. Hydrolysis and aqueous photolysis are unlikely to be important routes of degradation at environmentally relevant pH levels.

Plant metabolism

Mefentrifluconazole metabolism data were provided for grape, soya bean and wheat.

Grape

Three grapevines (variety *Müller-Thurgau*), grown outdoors, received three foliar treatments with either a 1:1 mixture of [¹⁴C-U-chlorophenyl:¹³C-U-chlorophenyl]-mefentrifluconazole or a 2:1 mixture of [¹⁴C-3(5)-triazole:¹³C-3(5)-triazole]-mefentrifluconazole at a rate of 150 g ai/ha with re-treatment intervals of 10–11 days. Grape leaves and clusters were harvested 12 days following the last application.

Total radioactive residues (TRR) in grape berries, leaves and stalks following combustion were 0.40–0.44 mg eq/kg, 7.24–8.86 mg eq/kg and 0.67–1.21 mg eq/kg, respectively.

Extraction of grape berries, leaves, and stalk samples with methanol (3×) and water (2×) released 87–90 percent TRR, 89–91 percent TRR, and 93–94 percent TRR, respectively. Hydrolysis of the post-extraction solids (PES) following various enzymatic treatments released an additional 2–5 percent TRR, which were not further analysed.

Mefentrifluconazole was the major identified residue in all matrices, accounting for 64–70 percent TRR (0.22–0.30 mg/kg) in berries, 60–70 percent TRR (4.43–5.11 mg eq/kg) in leaves, and 86–92 percent TRR (0.56–1.04 mg eq/kg) in stalks. Metabolite M750F019 was identified in berries, leaves, and stalks at 6–7 percent TRR (0.024–0.026 mg eq/kg), 14–21 percent TRR (1.068–1.55 mg eq/kg), and 2 percent TRR (0.015 mg eq/kg), respectively. The chlorophenyl-label-specific

metabolite M750F026 was identified as a minor metabolite in leaves only at 1 percent TRR (0.10 mg eq/kg).

Soya bean

Ten containers of soya bean plants (variety *Sultana*, 13 plants/container), cultivated indoors in a vegetation hall and subsequently moved into climatic chambers, received three foliar treatments with either a 1:1 mixture of [¹⁴C-U-chlorophenyl:¹³C-U-chlorophenyl]-mefentrifluconazole or a 2:1 mixture of [¹⁴C-3(5)-triazole:¹³C-3(5)-triazole]-mefentrifluconazole at a rate of 125 g ai/ha with re-treatment intervals of 17–19 days. Soya bean forage was harvested 19 days after the first application (just before the second application; BBCH growth stage of 71–72). At harvest, 47–48 days after the final application at BBCH growth stage 89, the mature pods were collected and manually opened in order to separate seeds from hulls. In addition green pods were also harvested and the remaining stems and leaves (matrix: rest of plant) were collected.

TRRs reported were highest in the rest of plant (16.0–19.9 mg eq/kg), followed by the green pods (8.86–16.0 mg eq/kg), forage (4.4–6.5 mg eq/kg), hulls (3.74–3.89 mg eq/kg) and seed (0.11–2.6 mg eq/kg).

Radioactivity released following extraction with methanol (3×) and water (2×) ranged between 91–93 percent, 69–74 percent, and 87–88 percent in soya bean forage, hull, and rest of plant, respectively. When extracted using acetonitrile:isohexane (1:1) and water, between 56–76 percent TRR were released from soya bean seeds and 78–83 percent from green pods. PES of forage, hulls, rest of plant and seeds were solubilized using various enzymatic treatments releasing 4–38 percent TRR. Unextracted residues of green pods were not hydrolysed.

Mefentrifluconazole (free and conjugated) was a major residue in forage, hulls and rest of plant, accounting for 60–83 percent TRR (3.18–13.70 mg/kg). The minor metabolites, M750F012 and M70F018/M750F020 (both free and conjugated), were identified at levels ranging from 0.03–6 percent TRR (0.01–0.97 mg eq/kg).

In green pods, mefentrifluconazole represented 69 percent TRR (5.98 mg/kg) while M750F012 and M70F018/M750F020 were each ≤4 percent (≤0.33 mg eq/kg).

Mefentrifluconazole (free) was a minor residue in seed, accounting for only 0.4–4 percent TRR (0.005–0.013 mg/kg). Triazole alanine (free and conjugated) was a major metabolite, accounting for 48 percent TRR (1.46 mg eq/kg). 1,2,4-Triazole and triazole lactic acid (both free) were identified at levels of 0.3 percent TRR (0.008 mg eq/kg) and 1 percent TRR (0.04 mg eq/kg), respectively.

Chiral analysis of forage, hull and rest of plant samples (C-label and T-label) confirmed that the racemic mixture (1:1 ratio of S-enantiomer and R-enantiomer) is essentially maintained, and hence that there is no significant change in the ratio of the mefentrifluconazole enantiomers. Chiral analysis was not conducted for seed/green pod since mefentrifluconazole was not present in quantifiable amounts.

Wheat

Twenty containers of spring wheat (variety *Thassos*, 10 containers per label), cultivated indoors in a vegetation hall/greenhouse, received two foliar treatments with either a 1:1 mixture of [¹⁴C-U-chlorophenyl:¹³C-U-chlorophenyl]-mefentrifluconazole or a 2:1 mixture of [¹⁴C-3(5)-triazole:¹³C-3(5)-triazole]-mefentrifluconazole at a rate of 150 g ai/ha with a re-treatment interval of 21 days. Wheat forage was harvested 15 days after the first application (just before the second application; BBCH growth stage 61). Straw and grain were harvested 35 days after the final application at BBCH growth stage 89.

Total radioactive residues (TRR) were highest in straw (14.3–24.3 mg eq/kg), followed by forage (2.5–2.6 mg eq/kg) and grain (0.06–0.07 mg eq/kg).

Forage and straw samples were extracted with methanol (3×) and water (2×). Wheat grain was extracted with acetonitrile:isohexane (1:1) and water. Solvent extracted radioactivity ranged between 95–96 percent TRR, 44–78 percent TRR, and 83–86 percent TRR in wheat forage, grain, and straw, respectively. The acetone precipitate of grain and the forage and straw post-extraction solids were subjected to solvent and enzymatic treatments releasing an additional 20–40 percent TRR for grain and 2–9 percent TRR for forage and straw.

In forage, mefentrifluconazole (free) accounted for 84–89 percent TRR (2.01–2.06 mg/kg). The minor metabolites, M750F009, M750F012, M750F019 and M750F018/M750F020, all present in the free form, collectively represented 3–4 percent TRR (0.06–0.09 mg eq/kg). In straw, mefentrifluconazole (free and conjugated) accounted for 59–68 percent TRR (9.6–14.3 mg/kg). The total concentration of the same metabolites ranged from 19–21 percent TRR (2.7–5.1 mg eq/kg), accounting for up to 0.4-fold the concentrations of mefentrifluconazole (free and conjugated). Mefentrifluconazole was not found in grain, and triazole alanine and triazole acetic acid were major metabolites accounting for 46 percent TRR (0.28 mg eq/kg) and 22 percent (0.13 mg eq/kg), respectively. 1,2,4-triazole was present at 1 percent TRR (0.006 mg eq/kg).

In summary, the unchanged parent is the predominant residue (>60 percent TRR) in mefentrifluconazole treated plants, notably in forage (wheat, soya bean), leaf/stalks (grapes), straw/hulls (wheat, soya bean), green pods (soya bean) and grapes. The enantiomer ratio of the two mefentrifluconazole isomers remained unchanged (racemic mixture). In wheat grain and soya bean seed, the unchanged parent is present at very low levels, and the predominant component of the residue is the group of triazole derived metabolites (triazole alanine [TA], triazole acetic acid [TAA], triazole lactic acid [TLA] and 1,2,4-triazole), formed via cleavage of the triazole bridge, with triazole alanine the most abundant compound. The metabolic pathway of mefentrifluconazole in plants is largely based on two main transformation steps: hydroxylation followed by conjugation and cleavage of the triazole bridge followed by conjugation.

Animal metabolism

The Meeting received animal metabolism studies with mefentrifluconazole in lactating goats, laying hens and rats.

Rats

Metabolism of mefentrifluconazole in rats was evaluated by the 2021 JMPR Meeting. Metabolism in the rat was extensive and complex with a total of 68 identified metabolites resulting from phase I and phase II reactions. Main metabolic pathways comprised hydroxylation, methylation and cleavage of the ether group or of the triazole ring from the parent molecule, often followed by conjugations. Most metabolites occurred at low concentrations and only very few of them, observed in the faeces, accounted for more than 30 percent of the dose. In urine, the most abundant metabolite was 1,2,4-triazole with a maximum abundance of 10 percent. In bile, the five main metabolites were all glucuronides which had been formed subsequent to hydroxylation. In faeces, there was a 1:1 ratio of the two isomers of mefentrifluconazole, whereas a shift towards the R-enantiomer was observed in methanolic liver and kidney extracts.

Lactating goats

The metabolism of chlorophenyl-U-¹⁴C-labelled, triazole-3-(5)-¹⁴C-labelled or trifluoromethylphenyl-ring-U-¹⁴C-labelled mefentrifluconazole was investigated in lactating goats. Animals were dosed orally once daily

for 12–14 consecutive days. The nominal daily doses were equivalent to 12 ppm in the diet. During the dosing period, urine and faeces were sampled once daily, while milk was collected twice daily. Liver, kidney, muscle and fat samples were collected after animal sacrifice, approximately 23 hours after administration of the last dose.

Most of the radioactivity was recovered in the excreta with urine containing 26–40 percent of the administered dose (AD) and faeces containing 34–50 percent of the AD. The radioactivity recovered in milk and tissues was low, each accounting for ≤ 2.2 percent of the AD. Plateau levels of radioactive residues in milk were reached within 5–6 days after administration of the first dose.

The calculated total radioactive residues (TRRs) in the pooled milk samples (144–288 hours) ranged from 0.029–0.273 mg eq/kg for whole milk, 0.016–0.270 mg eq/kg for skimmed milk and 0.207–0.521 mg eq/kg for cream. For tissues, TRRs were highest in liver (0.650–1.332 mg eq/kg), followed by kidney (0.352–0.422 mg eq/kg), composite fat sample (0.213–0.532 mg eq/kg) and composite muscle sample (0.047–0.223 mg eq/kg). In general, levels of radioactivity were lower in milk and muscle.

Extraction of whole milk with acetonitrile released the majority of the radioactivity (86–96 percent TRR). Mefentrifluconazole was the major residue, accounting for 44.5–47.5 percent TRR (0.014–0.028 mg/kg) as were 1,2,4-triazole (78 percent TRR; 0.214 mg eq/kg) and the metabolite M750F043 (14–25 percent TRR; 0.004–0.016 mg eq/kg). Three additional minor metabolites were identified: M750F022 (1–2 percent TRR; 0.001 mg eq/kg), M750F041 (6–7 percent TRR; 0.002–0.004 mg eq/kg) and M750F072 (6–11 percent TRR; 0.002–0.004 mg eq/kg). A similar metabolic profile was observed in skimmed milk and cream.

Isohexane extraction of the composite fat samples released the majority of the radioactivity (> 91 percent TRR) for all three labels. Mefentrifluconazole was the main component of the residues (85–88 percent TRR; 0.18–0.47 mg/kg). Metabolite M750F022 and 1,2,4-triazole were the only other metabolites detected in fat, at up to 6 percent TRR (0.031 mg eq/kg) and 5 percent TRR (0.01 mg eq/kg), respectively.

Extraction of composite muscle samples with methanol released greater than 92 percent TRR. Mefentrifluconazole and the 1,2,4-triazole were the predominant residues, accounting for 12–96 percent TRR (0.03–0.09 mg/kg) and 87 percent TRR (0.19 mg eq/kg), respectively. Metabolite M750F022 was observed at much lower levels (7 percent TRR; 0.003 mg eq/kg).

The remaining unextracted radioactivity (up to 9 percent TRR) was subjected to protease hydrolysis which released an additional 2–3 percent TRR (0.01–0.04 mg eq/kg). Mefentrifluconazole represented one of the main components of the residue (26–50 percent TRR; 0.17–0.62 mg/kg), together with the metabolite M750F016 (10–15 percent TRR; 0.065–0.20 mg eq/kg) and 1,2,4-triazole (32 percent TRR; 0.21 mg eq/kg). Metabolite M750F068, resulting from glucuronidation of the parent compound, was also observed in liver but at lower levels (3–4 percent TRR; 0.03–0.06 mg eq/kg). In addition, the minor metabolite M750F022 and its glucuronide derivative M750F038 accounted for 5–11 percent TRR (0.05–0.15 mg eq/kg).

Methanol extraction of kidney released greater than 96 percent TRR. Mefentrifluconazole accounted for 10–46 percent TRR (0.04–0.20 mg/kg). Major predominant metabolites included 1,2,4-triazole (68 percent TRR; 0.27 mg eq/kg), M750F038/M750F064 (co-eluting in one peak, sum: 27 percent TRR; 0.09 mg eq/kg; present in a 1:1 ratio), M750F068 (18 percent TRR; 0.06 mg eq/kg), M750F022 (6–14 percent TRR; 0.02–0.06 mg eq/kg) and M750F038 (11 percent TRR; 0.05 mg eq/kg). The metabolites M750F003, M750F015, M750F016 and M750F072 were also observed but none represented greater than 4 percent TRR (0.02 mg eq/kg).

While the ratio of both mefentrifluconazole isomers was approximately 50:50 in the doses administered to the animals and in the extracts of faeces, the relative amount of the (S)-isomer was lower compared to the (R)-isomer in cream, liver, fat, kidney and muscle, ranging from 20:80 percent to 30:70 percent. These findings demonstrated that matrix-specific differences were observed. This shift towards the R-enantiomer was also observed in the methanol extracts of liver and kidney in the rat metabolism study.

Laying hens

The metabolism of chlorophenyl-U-¹⁴C-labelled, triazole-3-(5)-¹⁴C-labelled or trifluoromethylphenyl-ring-U-¹⁴C-labelled mefentrifluconazole was investigated in laying hens. The test item was administered once daily by gavage (ten animals per label) for 14 consecutive days at a nominal dose of 12 ppm feed. During the dosing period, excreta were collected once daily, while eggs were collected twice daily after which they were separated into egg whites and egg yolks. Liver, kidney, muscle and fat samples were collected after animal sacrifice, 3–6 hours after administration of the last dose.

The radioactive residues in excreta accounted for 75–89 percent AD. Only ≤ 0.3 percent AD was retained in edible tissues and < 1 percent AD in egg. ¹⁴C-residues in egg yolk reached a plateau concentration within 7 days of dosing for all radiolabels. In egg white, ¹⁴C-residues reached a plateau within 3–7 days depending on the radiolabel.

Total radioactivity was highest in composite fat samples (0.21–1.1 mg eq/kg), followed by kidney (0.42–0.64 mg eq/kg), liver (0.31–0.58 mg eq/kg) and composite muscle samples (0.053–0.36 mg eq/kg).

Following sequential extractions of egg yolks with methanol and water, greater than 89 percent TRR was released. Mefentrifluconazole (6–44 percent TRR; 0.03–0.12 mg/kg), M750F022 (39–47 percent TRR; 0.19–0.29 mg eq/kg) and 1,2,4-triazole (41 percent TRR; 0.11 mg eq/kg) represented the major residues. The fatty acid conjugates of the metabolite M750F022 (sum of M750F023, M750F024 and/or M750F025) were also present but at lower levels (6–15 percent TRR; 0.03–0.09 mg eq/kg).

The radioactivity in egg whites following administration of the C- and TFMP- radiolabelled-mefentrifluconazole was ≤ 0.009 mg/kg eq, therefore, these were not subjected to further analysis. Egg whites from the T-label study were extracted with methanol and water which, released almost all of the radioactivity (98 percent TRR; 0.350 mg eq/kg). 1,2,4-Triazole was the only metabolite identified, accounting for the majority of the radioactivity (83 percent TRR; 0.297 mg eq/kg).

Methanol and/or methanol/water extraction of muscle samples released greater than 85 percent TRR. M750F022 (C/TFMP-labels: 50–77 percent TRR; 0.02–0.05 mg/kg) and 1,2,4-triazole (T-label: 91 percent TRR; 0.322 mg eq/kg) represented the main components. Mefentrifluconazole and the fatty acid conjugates of M750F022 (sum of M750F023, M750F024 and/or M750F025) were present in lower amounts, accounting for 6–7 percent TRR (0.003–0.005 mg eq/kg) and 10–20 percent TRR (0.007–0.010 mg eq/kg), respectively.

Sequential extraction of liver with methanol/water released 83–100 percent TRR. The predominant metabolites observed included M750F022 (29–37 percent TRR; 0.12–0.17 mg eq/kg), the glutathione conjugate, M750F034 (up to 20 percent TRR; 0.12 mg eq/kg), and the 1,2,4-triazole (85 percent TRR; 0.41 mg eq/kg). Mefentrifluconazole and the fatty acid conjugates of M750F022 (sum of M750F023, M750F024 and/or M750F025) accounted for 6–7 percent TRR (0.03 mg/kg) and 7–12 percent TRR (0.02–0.07 mg eq/kg), respectively.

Extraction of kidney with methanol released 79–99 percent TRR, with limited radioactivity released following subsequent extractions using isohexane or water. M750F022 (20 percent TRR; 0.09–0.12 mg eq/kg) and 1,2,4-triazole (66 percent TRR; 0.37 mg eq/kg) were identified as major metabolites. Conversely, the parent and the fatty acid conjugates of M750F022 (sum of M750F023, M750F024 and/or M750F025) were present in low amounts, each accounting for 4 percent TRR (0.017 mg/kg).

Extraction of fat (C- and TFMP label) using acetonitrile released 83–112 percent TRR, while extraction using methanol (T-label) released 102 percent TRR, with limited radioactivity released following subsequent extractions with isohexane or water. 1,2,4-Triazole (73 percent TRR; 0.14 mg eq/kg), the fatty acid conjugates of M750F022 (sum of M750F023, M750F024 and M750F025) (~42 percent TRR; 0.287–0.380 mg eq/kg) and the metabolite M750F022 (25–41 percent TRR; 0.18–0.37 mg eq/kg) accounted for the majority of the radioactivity. Mefentrifluconazole was present at lower levels (5–20 percent TRR; 0.04–0.10 mg/kg).

In summary, the metabolism of mefentrifluconazole in livestock and rats was qualitatively similar, based on two main transformation steps: hydroxylation followed by conjugation and cleavage followed by conjugation. Most of the radioactivity was eliminated via excreta. In goat and poultry matrices, mefentrifluconazole and 1,2,4-triazole were the predominant components of the residue. Metabolite M750F022 (and its fatty acid conjugates) was also a major component in poultry matrices.

Environmental fate in soil

The Meeting received information on soil aerobic metabolism, hydrolysis and photolysis properties of mefentrifluconazole. Studies were also received on the nature of [¹⁴C]-mefentrifluconazole in confined rotational crops and the magnitude of mefentrifluconazole in field rotational crops.

Aerobic soil metabolism (laboratory studies)

Mefentrifluconazole is persistent in soil with DT₅₀ ranging from 156 to >1000 days. However, the Meeting noted that the predicted DT₅₀ values were extrapolated well beyond the study duration (120 days) and should be treated with caution.

The metabolites 1,2,4-triazole and M750F003 were detected, reaching maximum amounts of 5.2 percent of the total applied radioactivity (TAR) and 2 percent TAR, respectively. A number of additional metabolites were detected, however, none exceeded 1 percent TAR at any sampling time.

Hydrolysis

Mefentrifluconazole is stable in aqueous solutions at environmentally relevant pHs of 5, 7 and 9.

Soil photolysis

Limited degradation of the parent compound was observed in both irradiated and dark control soil samples, hence photolysis was not an important route of dissipation.

Field Dissipation

The dissipation of mefentrifluconazole under field conditions has been studied in the United States (bare ground and turf-cropped soil), Europe (bare soil) and China (bare soil). Quantifiable residues of mefentrifluconazole were detected only in the first 20 cm of the soils. No residues above the LOQ were detected below 20 cm in any sample at any site. For bare soil, the overall geometric mean (non-normalized) DT₅₀ was estimated to be 149 days, indicating mefentrifluconazole is non-persistent to

moderately persistent. Therefore, the Meeting decided that mefentrifluconazole shows limited potential to accumulate in soil following application in consecutive years.

Confined rotational crops

[Chlorophenyl- U - ^{14}C] and [triazole-3(5)- ^{14}C]-labelled mefentrifluconazole, formulated as EC formulations, were applied to bare sandy loam soil, in plastic containers maintained in either a glass roofed vegetation hall, phytotron or in a glass house, at an application rate of 300 g ai/ha. Spinach (variety *Corvette*), white radish (variety *April Cross*) and spring wheat (*Thasos*) were sown 30/31, 120/122 and 364/365 days after the soil treatment. All crops were harvested at maturity and additional immature spinach samples as well as spring wheat forage samples (in part dried to hay) were collected 25–33 days and 49–55 days after planting (DAP), respectively.

Significant uptake and translocation of TRRs from soil into the secondary crops was observed over all plant-back intervals (PBI) and matrices (particularly spring wheat grain), which is due to the uptake and translocation of high amounts of triazole derivative metabolites (1,2,4-triazole, triazole alanine [TA], triazole acetic acid [TAA] and triazole lactic acid [TLA]). The highest levels of radioactive residues were found in spring wheat straw (30-day PBI) and in spring wheat grain, hay and straw after the 120/122-day PBI. The TRRs in spinach and white radish matrices were generally lower compared to those in wheat matrices. Overall, residues remained similar or decreased at longer PBIs, except for wheat grain where residues peaked at the 120-day PBI followed by a slight decrease by the 365-day PBI, yet still higher than the TRRs at the 30-day PBI.

In all tested matrices, except wheat grain, methanol released 26–96 percent TRR and water released an additional 1–34 percent TRR, while that released from wheat grain ranged from 7–49 percent and 8–53 percent TRR, respectively. PES underwent extensive hydrolysis using various solvents and enzymes, and analysis of the hydrolysates demonstrated that the radioactivity was associated with plant constituents.

Mefentrifluconazole was the main component detected in all tested samples, except grain. At 30/31-day PBI, residues accounted for 14–91 percent TRR (0.008–0.013 mg/kg) in immature and mature spinach, and 4–70 percent TRR (0.006–0.101 mg/kg) in the other matrices. At 120/122-day PBI, residues of the parent were 36–61 percent TRR (0.006–0.055 mg/kg) in immature and mature spinach, wheat forage, hay and straw, and at 364/365-day PBI, accounted for 1–41 percent TRR (0.0008–0.018 mg/kg) in wheat samples. No parent or metabolites were detected in radish roots or tops beyond the 30-day PBI.

In spinach and wheat, metabolites accounting for 2–80 percent TRR (0.0003–0.018 mg eq/kg), 5–83 percent TRR (0.0004–0.032 mg eq/kg) and 22–65 percent TRR (0.004–0.022 mg eq/kg) at 30-, 120- and 365-day PBIs, respectively, were characterized based on their chromatographic properties.

At longer PBIs, the parent was only detected in wheat hay (122-day PBI: 1.3 percent TRR; [0.030 mg/kg]) and straw (122-day PBI; 1 percent TRR; [0.014 mg/kg] and 365-day PBI; 1 percent TRR [0.008 mg/kg]).

In most cases, the main metabolite in the crop matrices (T-label) was triazole alanine (13–94 percent TRR; 0.022–0.982 mg eq/kg), followed by triazole lactic acid 9–39 percent TRR (0.005–0.807 mg eq/kg). The only exceptions were spring wheat hay (122 DAT) and spring wheat straw (all PBIs), where, triazole lactic acid was the most abundant component among all the analytes identified. In spring wheat grain, triazole alanine (42–73 percent TRR; 0.98–2.36 mg eq/kg) was the main component followed by triazole acetic acid (20–24 percent TRR; 0.46–0.69 mg eq/kg). The sum of the triazole derivative metabolites and 1,2,4-triazole in all secondary crops ranged from 65–101 percent TRR.

In summary, when rotational crops were cultivated on mefentrifluconazole-treated soil, the residues included mainly two components, the parent and triazole derivative metabolites (1,2,4-triazole, TA, TAA, TLA), the latter being generated by cleavage of the parent molecule at the triazole bridge.

Field rotational crops

Field rotational crop studies were conducted in the United States and Europe during the 2014 and 2015 growing seasons. In the United States, treated plots received three broadcast soil directed spray applications, with a 7-day retreatment interval, for a total rate of 595 to 614 kg ai/ha/season. In Europe, a single application was made to bare soil at up to 327 kg ai/ha. At intervals of 1, 3 (Europe only), 4 and 11/12 months following the last application to the bare soil, wheat, lettuce or broccoli, and carrot or radish were planted.

In the United States, mefentrifluconazole residues in wheat forage/hay/straw reached 2.38/0.53/0.06, 0.69/0.87/< 0.01, 1.13/2.65/0.02, and 1.57/1.97/0.01 mg/kg at 1, 3, 4 and 11 month PBIs, respectively. In radish tops/root, the residues reached 0.07/0.03, 0.04/0.02, 0.02/0.02 and < 0.01/< 0.01 mg/kg at 1, 3, 4 and 12 month PBIs, respectively. Residues in wheat grain and lettuce were < 0.01 mg/kg at all PBIs.

In Europe, residues of mefentrifluconazole in all tested crops, including a cereal grain (wheat), root crop (carrot and radish), leafy (lettuce and spinach) and Brassica (broccoli and cauliflower) vegetables were consistently below the LOQ of 0.01 mg/kg at all PBIs of 1, 4 and 12 months.

In summary, the environmental fate data demonstrated that mefentrifluconazole is relatively persistent in soil and is stable in aqueous solutions at environmentally relevant pHs. Photolysis of mefentrifluconazole on the soil surface is not anticipated to be an important dissipation process. The metabolism in rotational crops showed to be similar to that in primary crops with no rotational crop specific metabolites. Uptake of mefentrifluconazole in food commodities and wheat straw was very limited, however, measurable uptake into wheat forage and hay was observed.

No quantifiable residues of 1,2,4-triazole were observed in any of the tested crops. In general, residues of triazole alanine, triazole acetic acid and triazole lactic acid were higher in feed commodities than food commodities. In food commodities, triazole alanine was the highest among all triazole derivative metabolites, followed by triazole lactic acid and triazole acetic acid, all of which declined with increased PBI.

Methods of analysis

The Meeting received descriptions and validation data for three analytical methods capable of quantifying residues of mefentrifluconazole in diverse plant matrices. The samples were extracted with methanol/water/2 mol/L HCl (70/25/5), acetonitrile or methanol/water (80/20), the samples with hexane, cleaned-up with salts and dispersive SPE (QuEChERs), or injected directly in the LC-MS/MS. Average recoveries were in the range of 70–120 percent (with a few isolated exceptions) with RSD of \leq 20 percent. The methods were satisfactorily validated at LOQ of 0.01 mg/kg for all tested plant matrices, including cereals, citrus, coffee, soya beans, grapes and apple.

The Meeting also received descriptions and validation data for two methods for the analysis of mefentrifluconazole residues in animal matrices. In one method, samples were extracted with acetonitrile and iso-hexane (milk, cream, fat) or methanol/water/2N HCl (70/25/5) (muscle, kidney, liver and egg), and the other method uses QuEChERs. Residues were quantified by LC-MS/MS, and the methods were satisfactorily validated at a LOQ of 0.01 mg/kg.

Two methods to analyse the metabolite M750F022 and the fatty acid conjugate M750F025 (measured as M750F022) in hen matrices were provided. Samples were extracted with acetonitrile:isohexane, methanol/water/2 mol/L HCl (70/25/5) or methanol/water, the extracts cleaned up on SPE column, and residues quantified using GC-MS. The fatty acid conjugates of M750F022 were hydrolysed using NaOH (10 M). Recoveries of mefentrifluconazole and the metabolites M750F022 and M750F025 were acceptable, and the LOQ achieved for all animal commodities were 0.01 mg/kg for each analyte.

The methods for analysing mefentrifluconazole in plant matrices and mefentrifluconazole and the metabolites M750F022 and M750F025 in animal matrices were successfully validated by independent laboratories, demonstrating good reproducibility. Some of the plant-specific methods were also subjected to radiovalidation, where bioincurred residues of mefentrifluconazole were adequately recovered from samples of wheat forage, soya bean green pods and grapes collected from the metabolism studies, demonstrating the efficiency of the data collection analytical methods to extract incurred residues of mefentrifluconazole. The only exception was wheat straw, where the extraction efficiency was 59 percent likely due to the difference in extraction solvents between the metabolism study (methanol (3×) and water (2×)) and the analytical method (acetonitrile). For residues of mefentrifluconazole in animal matrices, extraction efficiencies were 80 percent or higher for milk, cream, muscle, kidney, fat, egg yolk and lower for liver (46 percent). For M750F022, extraction efficiencies were 90 percent or higher for milk, cream, kidney, fat and lower for egg yolk (66 percent), muscle (61 percent) and liver (46–50 percent). This was also likely due to the minor differences in extraction solvents between the metabolism study and the analytical method.

Stability of pesticide residues in stored analytical samples

Residues of mefentrifluconazole in samples fortified at 0.1 mg/kg were determined to be stable at ≤ -18 °C for at least 24 months in high water content commodities (tomato, apple, wheat whole plant), high oil content commodities (rapeseed), high protein content commodities (dry bean seed, dry pea seed, dry soya bean seed), high starch content commodities (potato tuber), high acid content commodities (grape, lemon), and wheat straw.

Residues of mefentrifluconazole and M750F022 (at 0.1 mg/kg) were stable at ≤ -18 °C for at least 6 months in milk, cream, eggs and bovine and poultry tissues.

These demonstrated storage stability intervals covered the storage durations of the crop field trials, processing studies and animal feeding studies.

Definition of the residue

Plant commodities

The nature of the mefentrifluconazole residues was investigated in grapes (leaves, stalks and berries), soya beans (green pods, hulls, seed, and rest of plant) and wheat (forage, grain, straw) following foliar treatment.

Mefentrifluconazole was the major analyte in all tested plant matrices (60–92 percent TRR; 0.22–14.3 mg/kg), except wheat grain and soya bean seed where the predominant metabolite was triazole alanine (free and conjugated: 46–48 percent; 0.28–1.5 mg eq/kg), a common metabolite of several triazole fungicides. As suitable analytical methods are available to analyse the parent compound, the Meeting considered that mefentrifluconazole was a suitable marker for monitoring compliance.

In deciding which compounds should be included in the residue definition for risk assessment, the Meeting considered the likely occurrence and toxicological properties of M750F019, found in grapes, as well as the triazole derivative metabolites found in soya bean seed and wheat grain.

M750F019 was not observed in the rat, however, its toxicity was considered to be covered by the health based guidance value (HBGV) of the parent compound, as noted in the 2021 JMPR Report. Furthermore, in the grape metabolism study, the ratio of M750F019 to the parent compound in grapes was 0.1, demonstrating a low contribution to the dietary exposure, compared to the parent compound.

Triazole derivative metabolites (1,2,4-triazole, triazole alanine, triazole lactic acid and triazole acetic acid) were found in significant amounts in wheat grain and soya bean seed from primary plant metabolism studies. Moreover, these metabolites were also frequently detected in control and treated crops from supervised field trials. The Meeting noted that these metabolites can arise from other sources and have toxicities known to be different from mefentrifluconazole. The Meeting concluded that these metabolites should be assessed separately, and were not further considered in the current evaluation.

The Meeting decided the residue definition for dietary risk assessment for plant commodities should be mefentrifluconazole.

Animal commodities

The nature of the mefentrifluconazole residues was investigated in lactating goats and laying hens. The metabolism of mefentrifluconazole was qualitatively similar in both animals, yet more extensive in goats.

Mefentrifluconazole (free and/or conjugated) was a major component of the residue in the goat (milk 3–48 percent TRR; kidney 10–46 percent TRR; muscle 12–96 percent TRR; liver 31–53 percent TRR; fat 85–88 percent TRR), but a minor component in the hen (egg yolk 6–44 percent TRR; muscle 6–7 percent TRR; fat 5–20 percent TRR; liver 10–26 percent TRR and kidney 4 percent TRR). Nevertheless, mefentrifluconazole (free and/or conjugated) was present in all tested livestock matrices which would make it a suitable marker for monitoring compliance.

Validated analytical methods are available for the determination of mefentrifluconazole in tissues, milk and eggs. The Meeting agreed the residue for compliance monitoring for tissues, milk and eggs should be mefentrifluconazole (free and conjugated).

In deciding which compounds should be included in the residue definition for risk assessment, the Meeting considered the likely occurrence and toxicological properties of the metabolites potentially contributing to the dietary risk.

Specific toxicological studies reviewed at the 2021 JMPR Meeting were only available for the metabolite M750F022, which was considered to have equal or lower toxicity than the parent compound. The Meeting concluded that the HBGVs apply to mefentrifluconazole and its metabolites M750F015, M750F016, M750F017, M750F019, M750F022, M750F038, M750F043, and M750F068, expressed as mefentrifluconazole. The current Meeting also concluded that two additional livestock metabolites (M750F064 and M750F034) are not of concern from the genotoxicity perspective and the HBGVs for parent mefentrifluconazole are also applicable.

1,2,4-Triazole was found in measurable amounts in lactating goat and laying hen metabolism studies (32–87 percent TRR; ≤ 0.4 mg eq/kg). 1,2,4-Triazole and triazole alanine were also frequently detected in control and treated samples of milk, eggs and tissues in the animal feeding studies. The Meeting concluded that these metabolites can arise from other sources and have toxicities known to be different from mefentrifluconazole. These metabolites should be assessed separately, considering their source and respective toxicities, and were not further considered in the current evaluation.

Only the major metabolites, M750F016, M750F043, M750F064 and M750F068, identified in milk, liver and kidney of the lactating goat metabolism study are being considered for the residue definition for risk assessment as the nature of the residues in fat were not further elucidated considering the low TRRs.

In goat muscle and fat tissues, the majority of the TRR was identified as parent mefentrifluconazole (85–96 percent TRR; 0.03–0.47 mg/kg). In liver, kidney and milk, the sum of mefentrifluconazole and M750F022 (including their conjugates M750F068, M750F064 and M750F043) represent 60 percent, 64 percent and 70 percent of the TRR, respectively, which cover more than 80 percent of the total compounds for which the HBGVs apply. The less prominent metabolite M750F016 found in liver does not contribute significantly to the overall dietary exposure or to the sum of mefentrifluconazole and M750F022 (free and conjugated) already taken into account for dietary risk assessment.

Only the major metabolites identified in the poultry metabolism study, M750F022 and its fatty acid conjugates (M750F023, M750F024 and M750F025) and M750F034 (sulfate conjugate of mefentrifluconazole) were considered.

The 2021 Meeting noted that the additional fatty acid side chains of the conjugates M750F023, M750F024 and M750F025 may cause differences in kinetics compared to the metabolite M750F022, and therefore, the Meeting concluded that the TTC approach for non-genotoxic compounds of Cramer Class III (1.5 µg/kg bw/day) should be considered for these metabolites.

For compounds covered by the parent HBGVs, metabolite M750F022 was the predominant component in all poultry tissues and eggs accounting for up to 10-fold the concentrations of the parent compound. In the laying hen feeding study, other than the parent compound, only M750F022 was investigated in eggs and tissues, where residues of this metabolite were equivalent to or higher than those of the parent compound at all feeding levels. Therefore, this metabolite will contribute to the overall dietary exposure to mefentrifluconazole and should be considered in combination with M750F034 (sulfate conjugate of mefentrifluconazole) in the residue definition for risk assessment.

The Meeting agreed that the suitable residue definition for risk assessment is the sum of mefentrifluconazole (free and conjugated) + M750F022 (free and conjugated), expressed as mefentrifluconazole.

Conclusions

Based on the above, the Meeting recommended the following residue definitions for mefentrifluconazole.

Definition of the residue for compliance with the MRL and for dietary exposure assessment for plant commodities: *Mefentrifluconazole*.

Definition of the residue for compliance with the MRL for animal commodities: *Mefentrifluconazole (free and conjugated)*.

Definition of the residue for dietary exposure assessment for animal commodities: *Sum of mefentrifluconazole (free and conjugated) + M750F022 (free and conjugated), expressed as mefentrifluconazole*.

In deciding whether the residue for monitoring compliance is fat-soluble, the Meeting noted that the mean residues of mefentrifluconazole at the highest dose tested in the lactating cow feeding study were 0.16 mg/kg in muscle and 1.7 mg/kg in perirenal fat while residues were 5× higher in cream compared to whole milk. In the laying hen feeding study, total mefentrifluconazole residues at the highest dose tested were 0.05 mg/kg in muscle and 0.53 mg/kg in fat.

The Meeting considered the residue is fat-soluble.

Results of supervised residue trials in crops

Citrus fruits, Group of

The critical GAP for the citrus fruits crop group is from the United States: 3×146 kg ai/ha, 14-day RTI, 0-day PHI. The Meeting received supervised residue trials conducted on whole orange, grapefruit and lemon in the United States, as well as two trials on orange and one trial on lemon conducted in Mexico, all matching the critical GAP.

Mefentrifluconazole residues in whole oranges in ranked order were (n = 14); 0.15, 0.17, 0.18, 0.19 (2), 0.20 (2), 0.23, 0.24, 0.29, 0.33, 0.46, 0.66 and 0.70 mg/kg.

Noting that oranges are the representative crop of the subgroup of oranges, the Meeting estimated a maximum residue level of 1 mg/kg, an STMR of 0.215 mg/kg, and an HR of 0.70 mg/kg for the Subgroup of oranges, sweet, sour.

Mefentrifluconazole residues in whole grapefruits in ranked order were (n = 6); 0.10, 0.13, 0.16, 0.19, 0.20 and 0.24 mg/kg.

Noting that grapefruits are representative of the subgroup of pummelo and grapefruits, the Meeting estimated a maximum residue level of 0.5 mg/kg, an STMR of 0.16 mg/kg and an HR of 0.24 mg/kg for the Subgroup of pummelo and grapefruits.

Mefentrifluconazole residues in whole lemons in ranked order were (n = 7): 0.30, 0.33 (2), 0.37, 0.44, 0.60 and 0.98 mg/kg.

Noting that lemons are the representative crop of the subgroup of lemons and limes, the Meeting estimated a maximum residue level of 1.5 mg/kg, an STMR of 0.37 mg/kg, and an HR of 0.98 mg/kg for the Subgroup of lemons and limes.

The GAP covers the group of citrus fruits, including use on mandarins. Although trials were not provided for mandarins, the Meeting noted that residues in lemons/limes have been shown to be similar to or greater than residues in mandarins. Therefore, the Meeting decided to extrapolate the residues from lemon and estimated a maximum residue level of 1.5 mg/kg, an STMR of 0.37 mg/kg, and an HR of 0.98 mg/kg, for the Subgroup of mandarins.

Pome fruits, Group of

The critical GAP for pome fruits is from the United States; 3×146 g ai/ha, 7-day RTI and a 0-day PHI. The Meeting received supervised residue trials conducted on apple and pear in Canada and the United States matching the critical GAP.

Mefentrifluconazole residues in apples in ranked order were (n = 13): < 0.01, 0.23, 0.26, 0.30 (2), 0.37, 0.39, 0.43 (2), 0.45, 0.46, 0.47 and 0.55 mg/kg.

Mefentrifluconazole residues in pears in ranked order were (n = 10): < 0.01, 0.30, 0.32, 0.34 (2), 0.40, 0.52, 0.68, 0.73 and 0.92 (highest 1.12) mg/kg.

The Meeting noted that the GAP covers the group of pome fruits except persimmon, Japanese and that median residues in apples and pears are within a 5-fold difference. The Mann-Whitney U-test also determined that the datasets were from the same population. Therefore, the Meeting decided to combine the two datasets of apples and pears.

Combined mefentrifluconazole residues in apples and pears were (n = 23): < 0.01 (2), 0.23, 0.26, 0.30 (3), 0.32, 0.34 (2), 0.37, 0.39, 0.40, 0.43 (2), 0.45, 0.46, 0.47, 0.52, 0.55, 0.68, 0.73 and 0.92 (highest 1.12) mg/kg.

The Meeting estimated a maximum residue level of 1.5 mg/kg, an STMR of 0.39 mg/kg, and an HR of 1.12 mg/kg (based on the highest residue of replicate samples) for the Group of pome fruits except persimmon, Japanese.

Stone Fruits, Group of

The critical GAP for stone fruits is from the United States; 3×146 g ai/ha, 7-day RTI and a 0-day PHI. The Meeting received supervised residue trials conducted on whole peaches, cherries and plums in Canada and the United States matching the critical GAP.

Mefentrifluconazole residues in whole peaches in ranked order were (n = 12): 0.36, 0.41, 0.42, 0.47, 0.48, 0.52, 0.60, 0.70, 0.72, 0.81 and 0.96 (2) (highest 1.04) mg/kg.

Noting that peaches are the representative crop of the subgroup of peaches, the Meeting estimated a maximum residue level of 2 mg/kg, an STMR value of 0.56 mg/kg, an HR of 1.04 mg/kg (based on the highest residue of replicate samples) for the Subgroup of peaches.

Mefentrifluconazole residues in sweet and tart cherries in ranked order were (n = 7): 0.04, 0.94, 1.0, 1.1, 1.4, 2.0 and 2.2 (highest 2.4) mg/kg.

Noting that cherries are the representative crop of the subgroup of cherries, the Meeting estimated a maximum residue level of 5 mg/kg, an STMR of 1.1 mg/kg and an HR of 2.4 mg/kg (based on the highest residue of replicate samples) for the Subgroup of cherries.

Mefentrifluconazole residues in plums in ranked order were (n = 9): < 0.01, 0.03, 0.13, 0.21, 0.26, 0.30, 0.32, 0.37 and 0.98 (highest 1.0) mg/kg.

Noting that plums are the representative crop of the subgroup of plums, the Meeting estimated a maximum residue level of 1.5 mg/kg, an STMR value of 0.26 mg/kg and an HR of 1.0 mg/kg (based on the highest residue of replicate samples) and for the Subgroup of plums.

Cane berries, Subgroup of

The critical GAP for cane berries is from the United States; 3×146 g ai/ha, 7-day RTI and a 0-day PHI. The Meeting received supervised residue trials conducted on blackberries in the United States matching the critical GAP.

Mefentrifluconazole residues in blackberries in ranked order were (n=6): 0.25, 0.35, 0.71, 1.2 and 1.3 (2) (highest of 1.62) mg/kg.

Noting that blackberries are the representative crop of the subgroup of cane berries, the Meeting estimated a maximum residue level of 3 mg/kg, an STMR value of 0.96 mg/kg and an HR of 1.62 mg/kg (based on the highest residue of replicate samples) for the Subgroup of cane berries.

Bush berries, Subgroup of

The critical GAP for bush berries is from the United States; 3×146 g ai/ha, 7-day RTI and a 0-day PHI. The Meeting received supervised residue trials conducted on blueberries in the United States matching the critical GAP.

Mefentrifluconazole residues in blueberries in ranked order were (n=9): 0.06, 0.18, 0.51, 0.56, 0.58, 0.68, 0.74, 0.77 and 3.16 (highest 3.24) mg/kg.

Noting that blueberries are the representative crop of the subgroup bush berries, the Meeting estimated a maximum residue level of 5 mg/kg, an STMR value of 0.58 mg/kg and an HR of 3.24 mg/kg (based on the highest residue of replicate samples) for the Subgroup of bush berries and extrapolated these values to elderberries and Guelder rose.

Grapes

The critical GAP for wine grapes is from the United States; 3×146 g ai/ha, 10-day RTI and a 14-day PHI. The Meeting received supervised residue trials conducted on wine grapes in Canada and the United States matching the critical GAP.

Mefentrifluconazole residues in grapes in ranked order were (n = 8): 0.25, 0.33, 0.38, 0.41, 0.67, 0.83, 1.0 and 1.1 mg/kg.

The Meeting estimated a maximum residue level of 2 mg/kg, an STMR value of 0.54 mg/kg and an HR of 1.1 mg/kg for wine grapes.

The critical GAP for table grapes is from the United States; 2×112 g ai/ha, 10-day RTI and a 14-day PHI. The Meeting received trials from the United States on table grapes where 3 foliar applications were made at 147–155 g ai/ha, 8–11-day RTIs, seasonal application rates of 449–460 g ai/ha and 14–21-day PHIs.

As supervised field trials were conducted at rates 2-fold greater than the critical GAP and the RTIs were longer, without suitable data to estimate half-lives, the Meeting concluded that the overall impact of these parameters on the residue was > 25 percent, and a maximum residue level could not be estimated for table grapes.

Low growing berries, Subgroup of

The critical GAP for low growing berries is from the United States; 3×146 g ai/ha, 7-day RTI and a 0-day PHI. The Meeting received supervised residue trials conducted on strawberries in the United States matching the critical GAP.

Mefentrifluconazole residues in strawberries in ranked order were (n = 11): < 0.01 (2), 0.08, 0.15, 0.24, 0.29, 0.43, 0.44, 0.50, 0.62 and 1.1 mg/kg.

Noting that strawberries are the representative crop of the subgroup of low growing berries, the Meeting estimated a maximum residue level of 2 mg/kg, an STMR value of 0.29 mg/kg and an HR of 1.1 mg/kg for the Subgroup of low growing berries.

Assorted tropical and sub-tropical fruits—inedible peel, Group of

Avocado

The critical GAP for avocado is from El Salvador; 3×120 g ai/ha, 14-day RTI and a 3-day PHI. The Meeting received supervised residue trials conducted on avocado in Brazil, Colombia and Mexico matching the critical GAP.

Mefentrifluconazole residues in pitted whole avocados, expressed as whole fruit, in ranked order were (n = 6): 0.10, 0.22, 0.32, 0.39, 0.42 and 0.50 mg/kg.

The Meeting estimated a maximum residue level of 1 mg/kg, an STMR value of 0.36 mg/kg and an HR of 0.50 mg/kg for avocados.

Banana

The critical GAP for bananas is from Ecuador; 4×140 g ai/ha, 14-day RTI and a 0-day PHI. The Meeting received supervised residue trials, conducted on bagged and unbagged bananas in Brazil, Colombia and Ecuador, where 5 foliar applications were made at a target rate of 140 g ai/ha, RTIs of 14 days, seasonal application rates of 700 g ai/ha and a DALA of 0 days.

The Meeting agreed that the first application in the trials made 70 days prior to harvest would not contribute significantly to residues at the time of harvest and considered suitable for estimating a maximum residue level.

Mefentrifluconazole residues in unbagged whole bananas in ranked order were (n=10): 0.04, 0.12, 0.16, 0.24, 0.35, 0.47, 0.54, 0.57, 0.65 and 0.74 mg/kg.

Mefentrifluconazole residues in the pulp of unbagged bananas in ranked order were (n=10): < 0.01, 0.01, 0.04, 0.05 (2), 0.06, 0.09, 0.14, and 0.21 (2) mg/kg.

The Meeting estimated a maximum residue level of 1.5 mg/kg, an STMR of 0.055 mg/kg and an HR of 0.21 mg/kg.

Mango

The critical GAP for mango is from China; 3×0.016 kg ai/hL, 10-day RTI and a 14-day PHI. The Meeting received supervised residue trials conducted on mango in China approximating the critical GAP.

Mefentrifluconazole residues in whole mangoes in ranked order were (n = 6): 0.12, 0.16 (2), 0.20, 0.22 and 0.28 mg/kg. Residues in pulp were all < 0.01 m/kg (n=6).

The Meeting estimated a maximum residue level of 0.6 mg/kg and an STMR and HR of 0.01 mg/kg.

Papaya

The critical GAP for papaya is from El Salvador; 2×120 g ai/ha, 14-day RTI and a 3-day PHI. The Meeting received supervised residue trials conducted on papaya in Mexico, Brazil and Colombia matching the critical GAP.

Mefentrifluconazole residues in whole papayas in ranked order were (n = 6): < 0.01, 0.04, 0.07 (2), 0.19 and 0.22 mg/kg.

The Meeting estimated a maximum residue level of 0.5 mg/kg, an STMR value of 0.07 mg/kg and an HR of 0.22 mg/kg for papayas.

Bulb vegetables, Group of

The critical GAP for bulb vegetables is from the United States; 3×146 g ai/ha, 7-day RTI and a 7-day PHI. The Meeting received supervised residue trials conducted on bulb onions and green onions in Canada and the United States matching the critical GAP.

Mefentrifluconazole residues in bulb onions in ranked order were (n=13): < 0.01, 0.01(2), 0.03 (2), 0.05 (2), 0.08, 0.09 (3), 0.10 and 0.11 mg/kg.

The Meeting estimated a maximum residue level of 0.2 mg/kg, an STMR of 0.05 mg/kg and an HR of 0.14 mg/kg (based on the highest residue of replicate samples) for the Subgroup of bulb onions.

Mefentrifluconazole residues in green onions in ranked order were (n=5): 0.11, 0.28, 0.39, 0.42 and 2.1 mg/kg.

The Meeting estimated a maximum residue level of 4 mg/kg, an STMR of 0.39 mg/kg and an HR of 2.2 mg/kg (based on the highest residue of replicate samples) for the Subgroup of green onions.

Fruiting vegetables–Cucurbits, Group of

The critical GAP for fruiting vegetables-cucurbits is from the United States for “cucurbit vegetables”; 3×146 g ai/ha, 7-day RTI and a 0-day PHI. The Meeting received supervised residue trials on cucumbers, summer squash and melons from Canada and the United States matching the critical GAP.

Mefentrifluconazole residues in cucumbers in ranked order were (n = 9): 0.01, 0.02, 0.03 (4), 0.04 (2) and 0.10 (highest 0.123) mg/kg.

Mefentrifluconazole residues in summer squashes in ranked order were (n = 8): 0.01(2), 0.04, 0.05 (3) and 0.09 (2) mg/kg.

The Meeting noted that the median residues of cucumbers and summer squashes were within 5-fold, and that the Mann-Whitney U-test determined the datasets were from the same population. Therefore, the Meeting decided to combine the two datasets of cucumbers and summer squashes.

The ranked order of the combined mefentrifluconazole residues in cucumbers and summer squashes were (n = 17): 0.01 (3), 0.02, 0.03 (4), 0.04 (3), 0.05 (3), 0.09 (2) and 0.10 (highest 0.123) mg/kg.

The Meeting estimated a maximum residue level of 0.15 mg/kg, an STMR of 0.035 mg/kg and an HR of 0.123 mg/kg (based on the highest residue of replicate samples) for the Subgroup of Fruiting vegetables, Cucurbits – Cucumbers and Summer squashes.

Mefentrifluconazole residues in whole muskmelons in ranked order were (n = 8): 0.11 (3), 0.14, 0.16, 0.17, 0.21 and 0.22 mg/kg.

Noting that melons is the representative crop of the melons, pumpkins and winter squashes crop subgroup, the Meeting estimated a maximum residue level of 0.5 mg/kg, an STMR of 0.15 mg/kg and an HR of 0.23 mg/kg (based on the highest residue of replicate samples) for the Subgroup of Fruiting vegetables, Cucurbits–Melons, Pumpkins and Winter squashes.

Fruiting vegetables, other than Cucurbits, Group of

The critical GAP for fruiting vegetables-other than cucurbits is from the United States for “fruiting vegetables”; 3×146 g ai/ha, 7-day RTI and a 0-day PHI. The Meeting received trials on cherry tomatoes, tomatoes, bell peppers and non-bell peppers from the United States matching the critical GAP.

Mefentrifluconazole residues in field tomatoes (including cherry tomatoes [CT]) in ranked order were (n= 19): 0.03, 0.04, 0.05 (2), 0.08, 0.09, 0.10, 0.11, 0.13^[CT], 0.14, 0.15 (2), 0.17, 0.19, 0.23, 0.25, 0.36^[CT], 0.37 and 0.41^[CT] (highest 0.45) mg/kg.

The Meeting estimated a maximum residue level of 0.7 mg/kg, an STMR of 0.14 mg/kg and an HR of 0.45 mg/kg (based on the highest residue of replicate samples) for the Subgroup of tomatoes.

Mefentrifluconazole residues in field bell peppers and non-bell peppers [NB] in ranked order were (n= 14): 0.04, 0.05, 0.06 (2), 0.20, 0.22, 0.24^[NB], 0.26^[NB], 0.30, 0.33^[NB], 0.39^[NB], 0.43, 0.60^[NB] and 0.73 (highest 0.84) mg/kg.

The Meeting estimated a maximum residue level of 1.5 mg/kg, an STMR of 0.25 mg/kg and an HR of 0.84 mg/kg (based on the highest residue of replicate samples) for the Subgroup of peppers (excluding martynia, okra and roselle).

The critical GAP from the United States for fruiting vegetables, other than cucurbits, also covers eggplants. The Meeting decided the pepper data could be used to extrapolate the maximum residue level of 1.5 mg/kg, the STMR of 0.25 mg/kg and the HR of 0.84 mg/kg for peppers to the Subgroup of eggplants.

Chili peppers, dried

Based on the estimated maximum residue level of 1.5 mg/kg for the Subgroup of peppers (excluding martynia, okra and roselle) and applying a default processing factor of 10, the Meeting estimated a maximum residue level of 15 mg/kg for peppers, chili, dried, together with an STMR of 2.5 mg/kg (0.25×10) and an HR of 8.4 (0.84×10) mg/kg.

Leafy vegetables (including Brassica leafy vegetables), Group of

The critical GAP for leafy vegetables (including Brassica leafy vegetables) is from the United States for "leafy vegetables"; 3×146 g ai/ha, 7 day-RTI, 0-day PHI. The Meeting received trials from Canada and the United States on head lettuce, leaf lettuce, cos lettuce, spinach, radish leaves and mustard greens. All trials matched the critical GAP, except those for radish leaves, which were harvested at a DALA of 7 days.

Mefentrifluconazole residues in head lettuce with wrapper leaves, in ranked order were (n = 8): 0.12, 0.27, 0.32, 0.89, 1.30, 1.50, 2.1 and 2.2 mg/kg. Residues in head lettuce without wrapper leaves were < 0.01, 0.05, 0.09 and 1.6 mg/kg.

Mefentrifluconazole residues in leaf lettuce in ranked order were (n = 7): 2.4, 2.7, 3.0, 4.2, 4.4, 6.4 and 7.2 mg/kg.

Mefentrifluconazole in one sample of cos lettuce was 2.3 mg/kg.

Mefentrifluconazole residues in spinach in ranked order were (n = 8): 3.8, 4.6, 4.9, 5.2, 11, 12 (2) and 17 (highest 18) mg/kg.

The Meeting noted that the GAP in the United States covers the subgroup of leafy vegetables and decided to explore the possibility of estimating a subgroup maximum residue level for mefentrifluconazole. The median residues in head lettuce with wrapper leaves, leaf lettuce and spinach differed by more than 5-fold and from the Kruskal-Wallis test, the datasets were not shown to be from the same residue population.

Therefore, the Meeting used the spinach dataset to estimate a maximum residue level of 30 mg/kg, an STMR of 8.1 mg/kg and an HR of 18 mg/kg (based on the highest residue of replicate samples) for the Subgroup of leafy greens.

The Meeting noted that the acute dietary exposure assessment showed that residues in leafy greens exceeded the ARfD of 0.3 mg/kg bw, at 140 percent for each amaranth leaves, chicory leaves and edible leaved chrysanthemums for Belgian toddlers, 130 percent for raw endive for Dutch children, 240 percent for cooked/boiled endive for Dutch toddlers, 140 percent for head lettuce for Dutch children and 120 percent for leaf lettuce for Dutch children. No alternative GAP was available.

Mefentrifluconazole residues in mustard greens in ranked order were (n = 4): 4.1, 5.0, 8.3 and 12 mg/kg.

The Meeting noted that the GAP in the United States for the subgroup of leafy vegetables includes Brassica leafy vegetables. The Meeting estimated a maximum residue level of 30 mg/kg, an STMR of 6.65 mg/kg and an HR of 12 mg/kg for the Subgroup of Leaves of Brassicaceae.

For dietary burden calculation, the Meeting estimated a median residue of 6.65 mg/kg and highest residue of 12 mg/kg for mustard greens and extrapolated the median and highest residues to kale leaves and rape forage.

The Meeting noted that the acute dietary exposure assessment showed that exposure from the consumption of mustard greens exceeded the ARfD of 0.3 mg/kg bw, at 240 percent for Chinese cabbage for Chinese children, 110 percent for kale for German children and 200 percent for mustard greens for Chinese children. No alternative GAP was available.

Legume vegetables, Group of

The critical GAP for legume vegetables, except soya bean and edamame, is from the United States; 3×146 g ai/ha, 7-day RTI and a 21-day PHI. The Meeting received trials on beans and peas with pods and succulent beans and peas without pods from Canada and the United States matching the critical GAP.

Beans with pods, Subgroup of

Mefentrifluconazole residues in beans with pods in ranked order were (n=6): ≤ 0.01 (5) and 0.03 mg/kg.

The Meeting estimated a maximum residue level of 0.05 mg/kg, an STMR of 0.01 mg/kg and an HR of 0.03 mg/kg for the Subgroup of beans with pods, except soya bean (succulent seeds in pods).

Peas with pods, Subgroup of

In trials approximating the critical GAP, mefentrifluconazole residues in peas with pods in ranked order were (n=9): ≤ 0.01 (5), 0.02, 0.03 (2) and 0.08 (highest 0.10) mg/kg.

The Meeting estimated a maximum residue level of 0.15 mg/kg, an STMR of 0.01 mg/kg and an HR of 0.10 (based on the highest residue of replicate samples) mg/kg for the Subgroup of peas with pods.

Succulent beans without pods, Subgroup of

In trials approximating the critical GAP, mefentrifluconazole residues in succulent beans without pods in ranked order were (n=6): ≤ 0.01 (5) and 0.02 mg/kg.

The Meeting estimated a maximum residue level of 0.03 mg/kg, an STMR of 0.01 mg/kg and an HR of 0.02 mg/kg for the Subgroup of succulent beans without pods, except soya bean (succulent seeds).

Succulent peas without pods, Subgroup of

In trials approximating the critical GAP, mefentrifluconazole residues in succulent peas without pods in ranked order were (n=9): ≤ 0.01 (9) mg/kg.

The Meeting estimated a maximum residue level of 0.01* mg/kg, an STMR of 0.01 mg/kg and an HR of 0.01 mg/kg for the Subgroup of succulent peas without pods.

Pulses, Group of

The critical GAP for pulses, except dry soybeans, is from the United States; 3×146 g ai/ha, 7-day RTI and a 21-day PHI. The Meeting received trials on dry beans, dry peas and dry lentils from Canada and the United States matching the critical GAP.

Dry beans, Subgroup of

Mefentrifluconazole residues in dry beans in ranked order were (n=10): ≤ 0.01 (7), 0.02 (2) and 0.05 mg/kg.

The Meeting estimated a maximum residue level of 0.07 mg/kg and an STMR of 0.01 mg/kg for the Subgroup of dry beans, except soya bean dry.

Dry peas, Subgroup of

In trials approximating the critical GAP, mefentrifluconazole residues in dry peas in ranked order were (n=8): < 0.01, 0.01 (3), 0.02 (3) and 0.09 mg/kg.

The Meeting estimated a maximum residue level of 0.15 mg/kg and an STMR of 0.015 mg/kg for the Subgroup of dry peas, except lentil (dry).

Dry lentils

In trials approximating the critical GAP, mefentrifluconazole residues in dry lentils in ranked order were (n=6): 0.04, 0.06, 0.14, 0.30, 0.55 and 0.68 mg/kg.

The Meeting estimated a maximum residue level of 1.5 mg/kg and an STMR of 0.22 mg/kg for lentils.

Soya beans (dry)

The critical GAP for dry soya beans is from the United States; 2×146 g ai/ha, 7-day RTI, 21-day PHI. The Meeting received supervised residue trials conducted on dry soya bean seeds in the United States matching the critical GAP.

Mefentrifluconazole residues in dry soya beans in ranked order were (n=17): < 0.01 (12), 0.01 (2), 0.03, 0.06 and 0.31 mg/kg.

The Meeting estimated a maximum residue level of 0.40 mg/kg and an STMR of 0.01 mg/kg for soya bean, dry.

Root and tuber vegetables, Group of

Root vegetables, Subgroup of

The critical GAP for root and tuber vegetables, except sugar beets, is from the United States; 3×146 g ai/ha, 7-day RTI, 7-day PHI. The Meeting received supervised residue trials conducted on carrots and radish in the United States matching the critical GAP.

Mefentrifluconazole residues in carrot roots in ranked order were (n=11): < 0.01 (2), 0.05, 0.06, 0.10, 0.11, 0.12, 0.15, 0.16, 0.22 and 0.24 mg/kg.

Mefentrifluconazole residues in radish roots in ranked order were (n=7): < 0.01, 0.03 (2), 0.08, 0.11, 0.13 and 0.38 (highest 0.40) mg/kg.

The Meeting noted that the GAP covers the group of root vegetables, except sugar beets. The median residues in carrot roots and radish roots are within a 5-fold difference and the Mann-Whitney U-test also determined that the datasets were from the same population. Therefore, the Meeting decided to combine the datasets for carrot roots and radish roots.

Combined mefentrifluconazole residues in carrot roots and radish roots were (n = 18): < 0.01 (3), 0.03 (2), 0.05, 0.06, 0.08, 0.10, 0.11, 0.11, 0.12, 0.13, 0.15, 0.16, 0.22, 0.24 and 0.38 (highest 0.40) mg/kg.

The Meeting estimated a maximum residue level of 0.5 mg/kg, an STMR of 0.105 mg/kg and an HR of 0.40 mg/kg for the Subgroup root vegetables, except sugar beets.

Sugar beet

The critical GAP for sugar beet is from the United States; 2×146 g ai/ha, 14-day RTI, 7-day PHI. The Meeting received supervised residue trials conducted on sugar beet roots in Canada and the United States where the RTI was 7 days and the sugar beet roots were harvested at DALAs of 14–21 days. Therefore, a maximum residue level could not be estimated for sugar beet roots.

Tuberous and corm vegetables, Subgroup of

The critical GAP for tuberous and corm vegetables is from the United States; 3×146 g ai/ha, 7-day RTI, 7-day PHI. The Meeting received supervised residue trials conducted on potatoes in Canada and the United States matching the critical GAP.

Mefentrifluconazole residues in potatoes in ranked order were (n = 19): < 0.01 (18) and 0.04 (highest 0.05) mg/kg.

Noting that potatoes are the representative crop of the subgroup tuberous and corm vegetables, the Meeting estimated a maximum residue level of 0.05 mg/kg, an STMR of 0.01 mg/kg and HR of 0.05 mg/kg for the Subgroup of tuberous and corm vegetables.

Wheat

The critical GAP for wheat, triticale and rye is from the United States; 2×146 g ai/ha, 14-day RTI, 21-day PHI. The Meeting received supervised residue trials conducted on wheat in Canada and the United States matching the critical GAP. The Meeting also received trials conducted in Europe, but none matched the critical GAP.

Mefentrifluconazole residues in wheat in ranked order were (n = 23): < 0.01, 0.02, 0.03 (3), 0.04 (2), 0.06, 0.08 (2), 0.09 (3), 0.10 (2), 0.11 (2), 0.12 (3), 0.13, 0.14, and 0.27 mg/kg.

The Meeting estimated a maximum residue level of 0.4 mg/kg and an STMR of 0.09 mg/kg for wheat grain.

Noting that the GAP covers triticale and rye, and wheat grain is the representative crop of the similar grains, and pseudocereals without husks crop subgroup, the Meeting decided to extrapolate the residues from wheat grain and estimated a maximum residue level of 0.4 mg/kg and an STMR of 0.09 mg/kg for triticale and rye.

Barley

The critical GAP for barley and oats is from the United States; 2×146 g ai/ha, 14-day RTI, 21-day PHI. The Meeting received supervised residue trials conducted on wheat in Canada and the United States matching the critical GAP. The Meeting also received trials conducted in Europe, but none matched the critical GAP.

Mefentrifluconazole residues in barley in ranked order were (n = 10): < 0.01, 0.20, 0.25, 0.34, 0.37, 0.48, 0.56, 0.71, 0.80, and 1.7 mg/kg.

The Meeting estimated a maximum residue level of 3 mg/kg and an STMR of 0.425 mg/kg for residues of mefentrifluconazole in barley grain.

Noting that the GAP covers oats, and barley grain is the representative crop of the similar grains, and pseudocereals with husks crop subgroup, the Meeting decided to extrapolate the residues from barley grain and estimated a maximum residue level of 3 mg/kg and an STMR of 0.425 mg/kg for oats.

Rice

The critical GAP for rice is from China; 2×12 g ai/ha, 5-day RTI, 21-day PHI. The Meeting received supervised residue trials conducted on rice in China matching the critical GAP. The Meeting also received trials conducted in Brazil and the United States, but none matched the critical GAP.

Mefentrifluconazole residues in rice grain in ranked order were (n = 12): 0.029, 0.65 (2), 0.75, 1.0, 1.1, 1.3, 1.4, 1.8, 2.3, and 2.5 (2) mg/kg.

Mefentrifluconazole residues in husked rice in ranked order were (n = 12): < 0.01, 0.08, 0.09, 0.10 (2), 0.11 (2), 0.19, 0.24, 0.47, 0.50, and 0.79 mg/kg.

The Meeting estimated a maximum residue level of 5 mg/kg and an STMR of 1.2 mg/kg for residues of mefentrifluconazole in rice.

The Meeting also estimated a maximum residue level of 1.5 mg/kg and an STMR of 0.11 mg/kg for residues of mefentrifluconazole in husked rice.

Sorghum

The critical GAP for sorghum and millet is from the United States; 2×146 g ai/ha, 14-day RTI, 21-day PHI. The Meeting received supervised residue trials conducted on sorghum in the United States matching the critical GAP.

Mefentrifluconazole residues in sorghum in ranked order were (n = 9): < 0.01, 0.18, 0.24, 0.31, 0.41, 0.42, 0.52, 0.78, and 1.2 mg/kg.

The Meeting estimated a maximum residue level of 2 mg/kg and an STMR of 0.41 mg/kg for residues of mefentrifluconazole in sorghum grain.

Noting that the GAP covers millet, and sorghum grain is the representative crop of sorghum grain and millet crop subgroup, the Meeting decided to extrapolate the residues from sorghum grain and estimated a maximum residue level of 2 mg/kg and an STMR of 0.41 mg/kg for millet.

Maize

The critical GAP for maize and popcorn is from the United States; 2×146 g ai/ha, 14-day RTI, 21-day PHI. The Meeting received supervised residue trials conducted on maize in the United States matching the critical GAP.

Mefentrifluconazole residues in maize in ranked order were (n = 17): < 0.01 (17) mg/kg.

The Meeting estimated a maximum residue level of 0.01* mg/kg and an STMR of 0.01 mg/kg for residues of mefentrifluconazole in maize.

Noting that the GAP covers popcorn, and maize is the representative crop of maize cereals crop subgroup, the Meeting decided to extrapolate the residues from maize and estimated a maximum residue level of 0.01(*) mg/kg and an STMR of 0.01 mg/kg for popcorn.

Sweet Corn

The critical GAP for sweet corn is from the United States; 3×146 g ai/ha, 14-day RTI, 21-day PHI. The Meeting received supervised residue trials conducted on sweet corn in the United States matching the critical GAP.

Mefentrifluconazole residues in sweet corn kernels plus cob with husks removed in ranked order were (n = 13): < 0.01 (9), and 0.02 (4) mg/kg.

The Meeting estimated a maximum residue level of 0.04 mg/kg and an STMR of 0.01 mg/kg and an HR of 0.02 mg/kg for residues of mefentrifluconazole in sweet corn (corn-on-the-cob) (kernels plus cob with husk removed).

Sugar cane

The critical GAP for sugar cane is from the United States; 2×146 g ai/ha, 14-day RTI and a 14-day PHI. The Meeting received supervised residue trials conducted on sugar cane in the United States matching the critical GAP. The Meeting also received trials conducted in Brazil, but none matched the critical GAP.

Mefentrifluconazole residues in sugar cane in ranked order were (n=8): 0.10, 0.25, 0.31, 0.36, 0.38, 0.42, 0.48 and 0.97 mg/kg.

The Meeting estimated a maximum residue level of 1.5 mg/kg and an STMR of 0.37 mg/kg for sugar cane.

Tree Nuts, Group of

The critical GAP for tree nuts is from the United States; 3×146 g ai/ha, 7-day RTI (all tree nuts, except pistachio) and 10-day RTI (pistachio) and a 14-day PHI. The Meeting received supervised residue trials conducted on pecans and almonds in the United States matching the critical GAP. For pistachios, the application rate and PHI of the residue trials matched the critical GAP, however, the RTIs were 7-days.

Mefentrifluconazole residues in pecans were in ranked order (5): < 0.01 (5) mg/kg.

Mefentrifluconazole residues in almonds were in ranked order (5): < 0.01 (4) and 0.02 mg/kg.

Mefentrifluconazole residues in pistachios were in ranked order (3): 0.01, 0.01 and 0.04 mg/kg.

The Meeting noted that the United States GAP covers the group of tree nuts. The median residues in pecans, almonds and pistachios are within a 5-fold difference and the Kruskal-Wallis test also determined that the datasets were from the same population. Despite the shorter RTI in the crop field trials for pistachios, the Meeting decided the combined dataset was suitable to estimate the maximum residue level, STMR and HR.

Combined mefentrifluconazole residues in pecans, almonds and pistachios were (n=13): < 0.01 (9), 0.01 (2), 0.02 and 0.04 mg/kg.

The Meeting estimated a maximum residue level of 0.06 mg/kg, an STMR of 0.01 mg/kg, and an HR of 0.06 mg/kg (based on the highest residue of replicate samples) for the Group of tree nuts.

Oilseeds and oilfruits, Group of

Small seed oilseeds, Sunflower seeds, Cotton seeds and Oilfruits, Subgroup of

The critical GAP for rapeseeds is from the United States; 2×146 g ai/ha, 14-day RTI and a 21-day PHI. The Meeting received supervised residue trials conducted on rapeseed in Canada and the United States matching the critical GAP.

Mefentrifluconazole residues in rapeseed in ranked order were (n=13): < 0.01, 0.01 (2), 0.04 (2), 0.05, 0.06 (2), 0.12, 0.15, 0.25 (2) and 0.74 mg/kg.

Noting that the US GAP covers the subgroup of rapeseeds and that rapeseeds are the representative crop of the subgroup small seed oilseeds, the Meeting estimated a maximum residue level of 1 mg/kg and an STMR of 0.06 mg/kg for the Subgroup of small seed oilseeds.

Sunflower seeds

The critical GAP for sunflower seeds is from the United States; 2×146 g ai/ha, 7-day RTI and a 21-day PHI. The Meeting received supervised residue trials conducted on sunflower seeds in Canada and the United States matching the critical GAP. The Meeting also received trials conducted in United States, but none matched the critical GAP.

Mefentrifluconazole residues in sunflower seeds in ranked order were (n=10): < 0.01 (4), 0.01 (2), 0.04, 0.05 and 0.06 (2) mg/kg.

Noting that the US GAP covers the subgroup of sunflower seeds and that sunflower seeds are the representative crop of the subgroup sunflower seeds, the Meeting estimated a maximum residue level of 0.15 mg/kg and an STMR of 0.01 mg/kg for the Subgroup of sunflower seeds.

Cotton seeds

The critical GAP for cotton seeds is from the United States; 3×146 g ai/ha, 7-day RTI and a 30-day PHI. The Meeting received supervised residue trials conducted on cotton seeds in the United States matching the critical GAP.

Mefentrifluconazole residues in cotton seeds in ranked order were (n=10): < 0.01, 0.01 (2), 0.03 (2), 0.04 (2), 0.05 (3), 0.10 and 0.12 mg/kg.

Noting that the US GAP covers the subgroup of cotton seeds and that cotton seeds are the representative crop of the subgroup cotton seeds, the Meeting estimated a maximum residue level of 0.2 mg/kg and an STMR of 0.04 mg/kg for the Subgroup of cottonseed.

Peanuts

The critical GAP for peanuts is from the United States; 3×202 g ai/ha, 14-day RTI and a 14-day PHI. The Meeting received supervised residue trials conducted on peanuts from the United States matching the critical GAP.

Mefentrifluconazole residues in peanuts were (n = 11): < 0.01 (11) mg/kg.

The Meeting estimated a maximum residue level of 0.01(*) mg/kg and an STMR value of 0.01 mg/kg for peanuts.

Coffee bean

The critical GAP for coffee bean is from Ecuador; 3×160 g ai/ha, 60-day RTI and a 45-day PHI. The Meeting received supervised residue trials conducted on coffee beans from South America matching the critical GAP.

Mefentrifluconazole residues in coffee beans in ranked order were (n = 19): < 0.01 (11), 0.01 (2), 0.02 (3), 0.07, 0.14 and 0.33 mg/kg.

The Meeting estimated a maximum residue level of 0.4 mg/kg and an STMR of 0.01 mg/kg for coffee beans.

Residues in animal feeds*Legume animal feeds*

The critical GAP for legume vegetables, except soya bean, is from the United States; 3×146 g ai/ha, 7-day RTI and a 21-day PHI for bean forage, bean hay, pea vines, and pea hay. The Meeting received trials on pea vines and hay from Canada and the United States matching the critical GAP.

Peas - Vines and hay

Mefentrifluconazole residues in pea vines in ranked order were (n=8): 0.8, 1.3, 2.2, 2.8, 4.3, 7.5, 9.5 and 10.2 mg/kg.

The Meeting estimated a median residue of 3.5 mg/kg and a highest residue of 10.3 mg/kg (based on the highest residue of replicate samples) for pea vines.

Mefentrifluconazole residues in pea hay in ranked order were (n=8): 4.4, 5.7, 6.3, 9.2, 10.3, 10.6, 11 and 12 (highest 13) mg/kg (dry weight).

The Meeting estimated a maximum residue level of 30 mg/kg, a median residue of 9.74 mg/kg and a highest residue of 13 mg/kg (based on the highest residue of replicate samples) for pea hay (dry weight).

Soya bean - Forage and hay

The critical GAP for soya beans is from the United States; 2×146 g ai/ha, 7-day RTI and a 14-day PHI for forage and 21-day PHI for hay.

Mefentrifluconazole residues in soya bean forage from trials matching the critical GAP were: 1.2 and 2.9 mg/kg.

The Meeting noted there were an insufficient number of trials approximating the critical GAP to estimate median and highest residues for soya bean forage.

Mefentrifluconazole residues in soya bean hay from trials matching the critical GAP were in ranked order (n=17): 1.1, 1.7, 2.3, 3.0, 3.2, 4.0, 4.1, 4.3, 4.5, 5.7, 6.0, 6.1, 7.1, 8.2, 8.8, 9.0 and 11 (highest 12) mg/kg (dry weight).

The Meeting estimated a maximum residue level of 20 mg/kg, a median residue of 4.5 mg/kg and a highest residue of 12 (based on the highest residue of replicate samples) for soya bean hay (dry weight).

Non-grass forages

The critical GAP for non-grass forages is from the United States; 3×146 g ai/ha, 7-day RTI and a 14-day PHI. The Meeting received trials on alfalfa forage and hay and clover forage and hay from the United States.

While supervised field trials were conducted according to the critical GAP, the RTIs between the second and third applications were significantly longer (14–48 days), without reliable data to estimate half-lives, the Meeting concluded that the overall impact of these parameters on the residue was >25 percent, and maximum residue levels, median residues and highest residues could not be estimated for alfalfa forage and hay or clover forage and hay.

*Straw and hay of cereal grains (including pseudocereals)**Wheat*

The critical GAP for wheat forage, hay and straw is from the US; 2×146 g ai/ha, 14-day RTI, and a 21-day PHI.

Mefentrifluconazole residues in wheat forage in ranked order were (n=24): < 0.01, 0.12, 0.28, 0.33, 0.56, 0.57, 0.63, 1.1, 1.2, 1.7, 2.5, 2.7, 2.8, 3.3, 3.6, 3.8, 4.0, 4.2 (2), 5.5, 5.9, 6.8, 7.8 and 9.6 mg/kg (dry weight).

Mefentrifluconazole residues in wheat hay in ranked order were (n=24): < 0.01, 0.12, 0.21, 0.23, 0.32, 0.54, 0.72, 1.0, 1.3, 1.5, 2.1 (2), 2.7, 3.5 (2), 3.6, 4.5, 4.7, 4.9, 5.4, 5.6, 5.7, 5.8 and 5.9 mg/kg (dry weight).

Mefentrifluconazole residues in wheat straw in ranked order were (n = 23): < 0.01, 2.8, 3.1, 3.5, 4.5, 5.3, 6.5, 6.8, 7.1, 8.7, 9.5, 10.3, 10.6, 10.8, 11.9, 12.1, 13.4, 14.3, 17.0, 17.1, 18.1, 18.4 and 25.7 mg/kg (dry weight).

Barley

The critical GAP for barley hay and straw is from the US; 2×146 g ai/ha, 14-day RTI, and a 21-day PHI.

Mefentrifluconazole residues in barley hay in ranked order were (n=9): 0.57, 5.3, 5.5, 6.8, 7.2, 8.0, 8.1, 9.1 and 11.1 mg/kg (dry weight).

Mefentrifluconazole residues in barley straw in ranked order were (n=10): < 0.01, 3.0, 3.8, 7.3, 8.1, 11.3, 13.8, 18.1, 20.9 and 22.7 mg/kg (dry weight).

Rice

The critical GAP for rice is from China; 2×12 g ai/ha, 5-day RTI, 21-day PHI. The Meeting received supervised residue trials conducted on rice in China matching the critical GAP.

Mefentrifluconazole residues in rice straw in ranked order were (n = 12): 0.12, 0.14, 1.1, 1.6, 2.2, 2.7, 3.4, 4.0, 4.7, 5.0, 7.3 and 10 mg/kg based on a dry matter content of 90 percent derived from the OECD 2018 feed calculator.

Mefentrifluconazole residues in rice husks in ranked order were (n = 12): 0.08, 2.5, 2.6, 3.0, 3.1, 4.4, 4.5, 5.7, 7.4, 9.3 and 9.4 (2) mg/kg.

Sorghum

The critical GAP for sorghum is from the United States; 2×146 g ai/ha, 14-day RTI and a 21-day PHI. The Meeting received supervised residue trials conducted on sorghum forage and fodder (stover) in the United States matching the critical GAP.

Mefentrifluconazole residues in sorghum forage in ranked order were (n = 9): < 0.01, 0.60, 0.76, 1.3, 1.7, 2.1, 3.4, 4.4, and 4.8 mg/kg (dry weight).

Mefentrifluconazole residues in sorghum stover in ranked order were (n=9): < 0.01, 1.2, 1.3, 3.2, 4.1, 4.4, 4.7, 6.3, and 9.1 mg/kg (dry weight).

Maize

The critical GAP for maize is from the United States; 2×146 g ai/ha, 14-day RTI and a 21-day PHI. The Meeting received supervised residue trials conducted on maize forage and fodder (stover) in the United States matching the critical GAP.

Mefentrifluconazole residues in maize forage in ranked order were (n = 17): < 0.01, 1.0, 1.3 (2), 1.6, 1.8, 2.4, 2.5, 3.1, 3.5, 3.7, 4.0, 4.1, 4.4, 4.7, 5.4, and 7.2 mg/kg (dry weight).

Mefentrifluconazole residues in maize stover in ranked order were (n=17): < 0.01, 3.0, 3.2, 3.7, 5.0, 5.2 (2), 6.3, 8.0, 8.1, 8.2, 8.3, 9.7, 9.9, 10, 11, and 12 mg/kg (dry weight).

Sweet corn

The critical GAP for maize is from the United States; 3×146 g ai/ha, 7-day RTI and a 21-day PHI. The Meeting received supervised residue trials conducted on sweet corn forage and fodder (stover) in Canada and the United States matching the critical GAP.

Mefentrifluconazole residues in sweet corn forage in ranked order were (n = 13): < 0.01, 1.6, 2.8, 3.5, 3.7, 4.1, 4.2, 4.3, 4.6, 5.5, 5.8, 6.4 and 6.6 mg/kg, based on a dry matter content of 48 percent derived from the OECD 2018 feed calculator.

Mefentrifluconazole residues in sweet corn stover in ranked order were (n=13): < 0.01 (2), 0.45, 0.84, 1.2, 1.3, 1.9, 2.4, 2.5, 3.1 (2), 3.3 and 4.2 mg/kg (dry weight).

The Meeting estimated residues in cereal forages as follows:

Wheat forage median residue of 2.75 mg/kg and highest residue of 9.6 mg/kg (dry weight),

Sorghum forage median residue of 1.7 mg/kg and highest residue of 4.8 mg/kg (dry weight),

Maize forage median residue of 3.1 mg/kg and highest residue of 7.2 mg/kg (dry weight), and

Sweet corn forage median residue of 4.2 mg/kg and highest residue of 6.6 mg/kg (dry weight).

Based on the similarity of residues and commodities within the group of straw and hay of cereal grains (including pseudocereals), the Meeting agreed to make a recommendation based on the trials giving the highest estimates. The Meeting estimated a maximum residue level of 50 mg/kg (dry weight; from barley straw), a median residue of 10.3 mg/kg (dry weight; from wheat straw) and a highest residue of 25.7 mg/kg (dry weight; from wheat straw) for straw and hay of cereal grains (including pseudocereals).

Grass forages

The critical GAP for grass forages is from the United States; 3×146 g ai/ha, 7-day RTI and a 0-day PHI. The Meeting received trials on forages of Bermuda grass, blue grass, brome grass and fescue from the United States. While supervised field trials were conducted according to the critical GAP in terms of application rate and harvest time, the RTIs were longer (14 days). Without reliable data to estimate half-lives, the Meeting concluded that the overall impact of these parameters on the residue was >25 percent, and maximum residue levels, median residues and highest residues could not be estimated for Bermuda grass, blue grass, brome grass and fescue forage and hay.

*Miscellaneous fodder and forage crop**Sugar beet tops*

The critical GAP for sugar beets is from the United States; 2×146 g ai/ha, 14-day RTI, 7-day PHI. The Meeting received supervised residue trials conducted on sugar beet tops in Canada and the United States where the RTI was 7 days and the sugar beet roots were harvested at DALAs of 14–21 days. Therefore, a maximum residue level could not be estimated for sugar beet tops.

Almond hulls

The critical GAP for tree nuts is from the United States; 3×123 g ai/ha, 7-day RTI (all tree nuts, except pistachio) and a 14-day PHI. The Meeting received supervised residue trials conducted on almonds in the United States matching the critical GAP.

Mefentrifluconazole residues in almond hulls were in ranked order (5): 1.1 (2), 1.2, and 1.7 (2) mg/kg.

The Meeting estimated a maximum residue level of 4 mg/kg and a median residue of 1.2 mg/kg.

Peanut hay

The critical GAP for peanuts is from the United States; 3×202 g ai/ha, 14-day RTI and a 14-day PHI. The Meeting received supervised residue trials conducted on peanuts from the United States matching the critical GAP.

Mefentrifluconazole residues in peanut hay were (n = 11): 3.1, 3.5, 4.4, 7.0, 7.1, 8.9, 9.3, 10.6, 14.2, 14.3 and 28.8 mg/kg (dry weight).

The Meeting estimated a maximum residue level of 40 mg/kg, a median residue of 8.9 and a highest residue of 30 mg/kg (based on the highest residue of replicate samples) for peanut hay (dry weight).

Fate of residues during processing*Effects on the nature of the residue during processing*

The Meeting received information on the hydrolysis of mefentrifluconazole under simulated processing conditions and the effects of processing on residues of mefentrifluconazole in several commodities.

High temperature hydrolysis

In studies on the hydrolytic stability of aqueous solutions of radiolabelled mefentrifluconazole, samples were incubated under three sets of conditions, each designed to simulate an appropriate process: 90 °C (pH 4, 20 minutes) to simulate pasteurization, 100 °C (pH 5, 60 minutes), to simulate boiling, baking and brewing, and 120 °C (pH 6, 20 minutes in the dark) to simulate sterilisation.

Under conditions representative of industrial and household processing procedures such as pasteurization (pH 4, 90 °C, 20 minutes), baking, boiling, brewing (pH 5, 100 °C, 60 minutes) and sterilisation (pH 6, 120 °C, 20 minutes), no degradation product exceeding 2 percent of total radioactivity was detected, demonstrating that mefentrifluconazole is hydrolytically stable. In addition, no change in the isomer ratio was observed. Therefore, the nature of the residue is not affected by processing operations.

Residues in processed commodities

The Meeting evaluated processing studies for oranges, apples, plums, peaches, grapes, strawberries, cucumbers, tomatoes, soya beans, sugar beets, potatoes, wheat, barley, rice, corn, cotton, and coffee. For field corn grain, no reliable processing factors can be calculated since the residues in the raw agricultural commodities (RAC) were <LOQ. Maximum residue levels (mrl) in processed commodities are only estimated when they are higher than the maximum residue levels for the RAC. Processing factors and residue estimates are summarized in Table 5.25.1. As the maximum residue level, STMR and HR in lemon were higher than orange, residues in lemons were used to calculate the residues in citrus processed commodities.

Table 5.25.1 Processing factors and residue estimates for mefentrifluconazole

Raw commodity	Residue in RAC, mg/kg			Processed commodity	Processing Factors		Residue in processed commodity, mg/kg		
	mrl	STMR	HR		Individual	Best estimate	mrl	STMR-P	HR-P
Lemon	1.5	0.37	0.98	Juice	< 0.02, < 0.01, < 0.02	0.02	-	0.007	
				Pulp	0.02, < 0.03, 0.02	0.02	-	0.007	0.020
				Dried pulp	0.15, 0.04, 0.11	0.11	-	0.04	
				Peel	2.6, 3.3, 2.6	2.6		0.96	2.5
				Oil	38, 71, 41	41	70	15.2	
				Marmalade	0.09, 0.12, 0.31	0.12	-	0.044	
Apple	1.5	0.39	1.12	Canned apples	0.05, < 0.13, 0.25	0.13	-	0.051	
				Fruit syrup	0.40, 0.88, 0.38	0.40	-	0.16	
				Apple sauce	0.05, < 0.13, 0.11	0.11	-	0.043	
				Dried apples	0.31, 0.25, 0.33	0.31	-	0.12	0.35
				Juice	0.09, < 0.13, 0.16	0.13	-	0.051	
				Wet pomace	3.10, 3.25, 2.36	3.10	-	1.2	
				Dried pomace	11.5, 9.88, 7.51	9.88	15	3.9	
Plum	1.5	0.26	1.0	Dried prune	2.57, 4.26, 4.08	4.1	7	1.1	4.1
				De-pitted plum	0.98, 1.16, 1.12	1.1	-	0.29	1.1
				Juice	0.08, 0.20, 0.15	0.15	-	0.039	
				Puree	0.76, 0.43, 0.56	0.56	-	0.15	
Grape-Wine	2	0.54	1.1	Rosé Wine Process					
				Dry pomace	3.13, 3.93, 3.09	3.13	-	1.7	
				Pasteurized juice	0.04, 0.05, 0.05	0.05	-	0.027	
				Rosé wine	0.02, 0.02, 0.03	0.02	-	0.011	
				Red Wine Process					
				Dry Pomace	5.21, 4.26, 3.55	4.26	9	2.3	
				Pasteurized juice	0.12, 0.13, 0.13	0.13	-	0.070	
Red wine	0.03, 0.02, 0.03	0.03	-	0.016					
Strawberry	2	0.29	1.1	Canned strawberries	0.93, 0.77, 1.18	0.93	-	0.27	
				Fruit syrup	0.20, 0.17, 0.30	0.20	-	0.058	
				Jam before cooking	0.48, 0.21, 0.38	0.38	-	0.11	
				Jam after cooking	0.48, 0.25, 0.43	0.43	-	0.12	
Cucumber	0.15	0.035	0.12	Canned gherkins	1.73, 0.52, 0.88	0.88	-	0.031	0.106
				Pickled gherkins	0.73, 0.26, 0.84	0.73	-	0.026	0.088
Tomato	0.7	0.14	0.45	Canned tomatoes	0.06, 0.08, 0.05	0.06	-	0.0084	0.027
				Ketchup after pasteurization	0.35, 0.68, 0.56	0.56	-	0.078	-
				Paste	1.00, 0.49, 0.46	0.49	-	0.069	-
				Peeled tomatoes	0.07, 0.06, 0.03	0.06	-	0.0084	0.027
				Puree	0.31, 0.28, 0.20	0.28	-	0.039	
Raw juice	0.11, 0.08, 0.08	0.08	-	0.011					

Raw commodity	Residue in RAC, mg/kg			Processed commodity	Processing Factors		Residue in processed commodity, mg/kg		
	mrl	STMR	HR		Individual	Best estimate	mrl	STMR-P	HR-P
				Sundried tomatoes	6.67, 9.17, 15.97	9.17	7	1.3	4.1
				Wet pomace	2.93, 1.75, 7.14	2.93	-	0.41	
Soya bean	0.4	0.01		Aspirated grain fraction	93	93		0.93	-
				Hulls	< 0.83	0.83	-	0.0083	-
				Meal (toasted)	< 0.83	0.83	-	0.0083	-
				Crude oil	1.0	1.0	-	0.01	-
				Tofu	< 0.83	0.83	-	0.0083	-
				Soy sauce	< 0.83	0.83	-	0.0083	-
				Pollards	< 0.83	0.83	-	0.0083	-
				Flour	< 0.83	0.83	-	0.0083	-
				Miso	< 0.83	0.83	-	0.0083	-
				Soy milk	< 0.83	0.83	-	0.0083	-
				Refined oil	< 0.83	0.83	-	0.0083	-
				Meal (untoasted)	< 0.83	0.83	-	0.0083	-
				Sugar beet	0.6	0.06		Molasses	0.88, 1.1, 0.53
Raw sugar	< 0.06, < 0.05, 0.10	0.06	-					0.0036	-
Affinated sugar	0.11, 0.11, 0.18	0.11	-					0.0066	-
Refined sugar	< 0.06, < 0.05, 0.10	0.06	-					0.0036	-
Dried pulp	4.75, 5.24, 3.24	4.75	3					0.29	-
Ensiled pulp	0.88, 1.14, 0.68	0.88	-					0.053	-
Potato	0.05	0.01	0.05	Peeled tuber	< 0.5, < 0.33	0.33	-	0.0033	0.0165
				Wet peel	1.5, 1.67	1.6	-	0.016	-
				Stove boiled-without peel	< 0.5, < 0.33	0.33	-	0.0033	0.0165
				Microwaved boiled-with peel	< 0.5, < 0.33	0.33	-	0.0033	0.0165
				Baked-with peel	<1.0, < 0.33	0.33	-	0.0033	0.0165
				Fried-without peel	< 0.5, < 0.33	0.33	-	0.0033	0.0165
				Crisps/chips-without peel	< 0.5, < 0.33	0.33	-	0.0033	0.0165
				Granules/flakes	< 0.5, < 0.33	0.33	-	0.0033	-
				Starch	< 0.5, < 0.33	0.33	-	0.0033	-
				Dried pulp-with peel	3.5, 1.33	2.4	-	0.024	0.096
Wheat forage		2.75 (dw)	9.6 (dw)	Wet silage	1.10, 1.44, 1.19	1.2	-	3.3	12
				Wilted silage	8.0, 4.7, 6.5	6.5	-	18	62
Wheat grain	0.4	0.09		Unprocessed bran	2.38, 3.71, 2.94	2.94	1.5	0.26	-
				Germ	0.85, 1.82, 1.12	1.12	0.5	0.10	-
				Shorts	2.62, 4.53, 3.53	3.53	1.5	0.32	-
				Gluten	0.55, < 0.59, 0.44	0.55	-	0.050	-
				Gluten meal	0.29, < 0.59, < 0.29	0.29	-	0.026	-
				Starch	< 0.08, < 0.59, < 0.29	0.29	-	0.026	-
				Whole meal flour	0.77, 1.00, 0.79	0.79	-	0.071	-
				Whole grain bread	0.54, < 0.59, 0.56	0.56	-	0.050	-
				Milled by-products	0.62, 1.12, 0.41	0.62	-	0.056	-
				Aspirated grain fractions	38.46, 21.76, 44.12	38.46	16	3.5	-
Barley	3	0.425		Pearled/pot barley	0.16, 0.12, 0.08	0.12	-	0.051	-
				Flour	4.5, 3.67, 3.18	3.67	15	1.6	-
				Unprocessed bran	4.25, 5.00, 5.45	5.00	15	2.1	-
				Brewing malt	0.50, 0.50, 0.30	0.50	-	0.21	-

Raw commodity	Residue in RAC, mg/kg			Processed commodity	Processing Factors		Residue in processed commodity, mg/kg		
	mrl	STMR	HR		Individual	Best estimate	mrl	STMR-P	HR-P
				Malt sprouts	1.68, 0.96, 0.30	0.96	-	0.41	-
				Beer	< 0.03, < 0.04, < 0.05	0.03	-	0.013	-
				Brewer's grain (dry)	2.38, 2.42, 2.14	2.38	8	1.0	-
				Brewer's yeast	0.19, 0.27, 0.19	0.19	-	0.081	-
Rice	5	1.2		Hulls	4.16, 4.92, 2.55	4.16	15	1.8	-
				Polished rice	0.06, 0.02, 0.01	0.02	-	0.0085	-
				Bran	0.58, 1.42, 1.04	1.04	-	0.44	-
Maize, forage		2.9 (dw)	7.2 (dw)	Silage	1.32, 0.86, 0.56	0.86	-	2.5	6.2
Cotton	0.2	0.04		Hulls	0.82, 0.13, 0.08	0.13	-	0.0052	-
				Meal	0.06, < 0.02, 0.004	0.02	-	0.0008	-
				Refined oil	< 0.05, < 0.02, 0.004	0.004	-	0.00016	-
Coffee	0.4	0.01		Concentrated liquor	0.06, 0.10, 0.08, 0.07	0.075	-	0.00075	-
				Instant coffee	0.18, 0.01, 0.16, 0.16	0.16	-	0.0016	-
				Roasted ground coffee	0.60, 0.93, 0.63, 0.58	0.615	-	0.0062	-

Using the estimated maximum residue level of 1.5 mg/kg for the subgroup of lemons and applying the processing factors of 2.6 for citrus dried peel and 41 for citrus oil, the Meeting estimated maximum residue levels of 4 mg/kg and 70 mg/kg for citrus dried peel and citrus oil, respectively.

Using the estimated maximum residue level of 1.5 mg/kg for pome fruits and applying the processing factor of 9.9 for dried pomace, the Meeting estimated a maximum residue level of 15 mg/kg for apple dried pomace.

Using the estimated maximum residue level of 1.5 mg/kg for the subgroup of plums and applying the processing factor of 4.1 for dried prune, the Meeting estimated a maximum residue level of 7 mg/kg for dried prune plum.

Using the estimated maximum residue level of 2 mg/kg for wine grapes and applying the processing factors of 4.26 for dry pomace, the Meeting estimated a maximum residue level of 9 mg/kg for grape dried pomace.

Using the estimated maximum residue level of 0.7 mg/kg for the subgroup of tomatoes applying the processing factor of 9.2 for sundried tomatoes, the Meeting estimated a maximum residue level of 7 mg/kg for dried tomatoes.

Using the estimated maximum residue level of 0.6 mg/kg for sugar beets and applying the processing factor of 4.75 for dried pulp, the Meeting estimated a maximum residue level of 3 mg/kg for sugar beet dried pulp.

Using the estimated maximum residue level of 0.4 mg/kg for wheat grain and applying the processing factors of 2.94 for wheat unprocessed bran, 1.12 for wheat germ, 3.53 for shorts and 38.5 for aspirated grain fractions, the Meeting estimated maximum residue levels of 1.5 mg/kg for wheat unprocessed bran, 0.5 mg/kg for wheat germ, 1.5 mg/kg for wheat shorts and 16 mg/kg for wheat aspirated grain fractions.

Using the estimated maximum residue level of 3 mg/kg for barley grain and applying the processing factors of 3.67 for barley flour, 5 for unprocessed barley bran and 2.38 for dry brewer's grain, the Meeting estimated maximum residue levels of 15 mg/kg for each barley flour and barley bran and 8 mg/kg for brewer's grain (dry).

Residues in animal commodities

The following adjustment factors were applied to the mefentrifluconazole residues in the livestock feeding studies, to account for both free and conjugated residues of mefentrifluconazole, which are only present in animal offal, for compliance with the MRL.

Ruminant liver: mefentrifluconazole residues \times 1.1

Ruminant kidney: mefentrifluconazole residues \times 1.6

Poultry liver: mefentrifluconazole residues \times 4.5

Similarly, the following adjustment factors were applied to the residues of mefentrifluconazole and M750F022 in the livestock feeding studies, to account for free and conjugated residues, where applicable, for dietary risk assessment:

Milk: mefentrifluconazole residues + M750F022 residues \times 7.45 \times 1.15 (MW factor)

Ruminant liver: mefentrifluconazole residues \times 1.1 + M750F022 residues \times 1.15 (MW factor)

Ruminant kidney: mefentrifluconazole residues \times 1.6 + M750F022 residues \times 5.6 \times 1.15 (MW factor)

Poultry commodities: mefentrifluconazole residues \times 4.5 + M750F022 residues \times 1.15 (MW factor)

Farm animal feed studies

The Meeting received a feeding study in dairy cattle where mefentrifluconazole was administered orally once daily to five groups of three lactating cattle for 28 days.

Based on mean daily feed consumption, the dosing levels were equivalent to 1.5, 7.5, 50 and 150 ppm (2 groups) in the feed. Milk was collected twice daily (am and pm sampling pooled) throughout the 28 days of dosing. On day 21, milk was also separated into cream and skimmed milk. Muscle, liver, kidney and fat samples were collected at sacrifice 22–24 hours after the final dose, except for one of the 150 ppm dose groups which were sacrificed three, seven and fourteen days after the final dose to monitor the decline of residue levels post dosing. Samples were analysed for the parent compound by LC-MS/MS (LOQ of 0.010 mg/kg).

At the lowest feeding level of 1.5 ppm, residues of mefentrifluconazole were below the LOQ in milk and muscle, however, they were measurable in liver, kidney and fat. The Metabolite M750F022 was not analysed in milk or any of the tissues at this lowest feeding level. A summary of the results are shown in Table 5.25.2. For the depuration study, measurable residues of mefentrifluconazole and M750F022 were observed in milk and tissues after three days of withdrawal, however, after seven and fourteen days of withdrawal, low or no residues above the limit of quantification of 0.01 mg/kg were detected, demonstrating a rapid excretion of mefentrifluconazole and M750F022.

Table 5.25.2 Residues of mefentrifluconazole in milk and tissues from lactating goats dosed at 7.5, 50 and 150 ppm mefentrifluconazole daily for 28 days (n=3 at each dose level)

	Mefentrifluconazole (free + conjugated) residues ^a (mg/kg)					
	Feeding level: 7.5 ppm		Feeding level: 50 ppm		Feeding level: 150 ppm	
	Mean	Max	Mean	Max	Mean	Max
Muscle	< 0.01	< 0.01	0.07	0.11	0.16	0.22
Liver	0.16	0.19	1.05	1.48	3.21	3.79
Kidney	0.08	0.12	0.47	0.82	2.10	3.06
Fat	0.05	0.08	0.65	0.9	1.71	2.29
Milk (Day 28)	< 0.01	< 0.01	0.05	0.06	0.21	0.25
	Mefentrifluconazole (free + conjugated) + M750F022 (free + conjugated) residues ^b (mg/kg)					
	Mean	Max	Mean	Max	Mean	Max
Muscle	< 0.01	< 0.01	0.08	0.12	0.18	0.24
Liver	0.17	0.20	1.08	1.51	3.26	3.85
Kidney	0.09	0.13	0.60	0.95	2.37	3.34
Fat	0.06	0.09	0.75	1.00	1.85	2.52
Milk (Day 28)	< 0.01	< 0.01	0.14	0.15	0.39	0.44

Notes:^a For MRL determination.^b For HR and STMR determination for dietary risk assessment.

The Meeting also received a feeding study in laying hens where mefentrifluconazole was administered orally once daily to 4 groups of 12 hens per group by gelatine capsule for 34 days, at dose levels equivalent to 1.5, 4.5 and 15 ppm (2 groups) in the feed. Eggs were collected twice daily (am and pm sampling pooled) throughout the 34 days of dosing. On day 24, egg samples from the 15 ppm level were separated into egg yolk and egg white. Muscle, liver, skin with fat and abdominal fat samples were collected at sacrifice 6 hours after the final dose, except for the hens of one of the 15 ppm group which were sacrificed two, seven and fourteen days after the final dose to monitor the decline of residue levels post dosing.

Samples were analysed for the parent compound by LC-MS/MS and for the metabolite M750F022 by GC-MS, with LOQs of 0.010 mg/kg.

Quantifiable residues of mefentrifluconazole were observed in eggs and muscle at the highest dose tested only. In fat and skin with fat, parent residues were measurable at the 4.5 ppm and 15 ppm feeding levels and in liver, residues were quantifiable at all feeding levels. Similarly, residues of M750F022 were measurable in eggs at 4.5 ppm and 15 ppm dosing levels, in muscle at the highest dose tested and in liver, fat and skin with fat at all feeding levels (except 0.15 ppm for liver and fat, where no residues were quantifiable). A summary of the results are shown in Table 5.25.3. For the depuration study, no measurable residues of mefentrifluconazole were observed in tissues after two days of withdrawal. In liver and skin no residues of M750F022 above the LOQ could be determined after seven days of withdrawal. In fat residue concentrations decreased steadily to below the LOQ (0.01 mg/kg) after 14 days of withdrawal.

Table 5.25.3 Residues of mefentrifluconazole (free and conjugated) in eggs and tissues from laying hens dosed at 1.5 ppm, 4.5 ppm and 15 ppm mefentrifluconazole daily for 28 days (n= 12 hens per dosing level)

Matrix	Maximum Residues of Mefentrifluconazole (free and conjugated) ^a (mg/kg)		
	Feeding level: 1.5 ppm	Feeding Level :4.5 ppm	Feeding level: 15 ppm
Muscle	< 0.01	< 0.01	0.03
Liver	0.08	0.09	0.90

Matrix	Maximum Residues of Mefentrifluconazole (free and conjugated) ^a (mg/kg)					
	Feeding level: 1.5 ppm		Feeding Level :4.5 ppm		Feeding level: 15 ppm	
Fat	< 0.01		0.025		0.25	
Eggs	< 0.01		< 0.01		0.04	
Matrix	Total Residues of Mefentrifluconazole (free and conjugated) and M750F022 (free and conjugated) ^b (mg/kg)					
	Feeding level: 1.5 ppm		Feeding Level :4.5 ppm		Feeding level: 15 ppm	
	Mean	Max	Mean	Max	Mean	Max
Muscle	< 0.01	< 0.01	< 0.01	< 0.01	0.05	0.07
Liver	0.07	0.10	0.10	0.13	0.61	1.13
Fat	0.05	0.06	0.10	0.11	0.53	0.66
Eggs	< 0.01	< 0.01	0.028	0.03	0.11	0.12

^a For MRL determination

^b For HR and STMR determination for dietary risk assessment

Farm animal dietary burden

Dietary burdens were calculated for beef cattle, dairy cattle, broilers and laying poultry based on feed items evaluated by the current JMPR Meeting. The dietary burdens, estimated using the most recent version of the OECD livestock dietary burden calculator, are presented in Annex 6 and summarized below.

Table 5.25.4 Estimated maximum and mean dietary burdens of farm animals

	Animal dietary burden: mefentrifluconazole, ppm of dry matter diet							
	United States-Canada		European Union		Australia		Japan	
	Max	Mean	Max	Mean	Max	Mean	Max	Mean
Beef cattle	4.7	2.3	36	18	60	22	15	6.1
Dairy cattle	23	10	36	17	67 ❶	28 ❷	10	4.0
Broilers	0.81	0.81	0.81	0.58	0.92	0.92	0.34	0.34
Layers	0.66	0.66	12 ❸	5 ❹	0.92	0.92	0.54	0.54

Notes:

- ❶ Highest maximum dairy cattle dietary burden suitable for MRL for milk and mammalian tissues and HR estimates for tissues.
- ❷ Highest mean dairy cattle dietary burden suitable for STMR estimates for milk and mammalian tissues.
- ❸ Highest maximum poultry dietary burden suitable for MRL and HR estimates for poultry tissues and eggs.
- ❹ Highest mean poultry dietary burden suitable for STMR estimates for poultry tissues and eggs.

Animal commodity maximum residue levels

Cattle

The calculations used to estimate maximum residue levels, STMR and HR values for cattle matrices are shown below.

Table 5.25.5 Estimated residues for maximum residue levels, HRs and STMRs for mefentrifluconazole in cattle commodities

Mefentrifluconazole feeding study	Feed level (ppm) for milk residues	Residues (mg/kg) in milk	Feed level (ppm) for tissue residues	Residues (mg/kg)			
				Muscle	Liver	Kidney	Fat
MRL ^a beef or dairy cattle							
Feeding study	50.00	0.05	50.00	0.11	1.48	0.82	0.90
	150.00	0.21	150.00	0.22	3.79	3.06	2.29

Mefentrifluconazole

Mefentrifluconazole feeding study	Feed level (ppm) for milk residues	Residues (mg/kg) in milk	Feed level (ppm) for tissue residues	Residues (mg/kg)			
				Muscle	Liver	Kidney	Fat
Dietary burden	67.00	0.08	67.00	0.13	1.87	1.20	1.14
HR ^b beef or dairy cattle							
Feeding study			50.00	0.12	1.51	0.95	1.00
			150.00	0.24	3.85	3.34	2.52
Dietary burden			67.00	0.14	1.91	1.36	1.26
STMR ^b beef or dairy cattle							
Feeding Study	7.50	< 0.01	7.50	< 0.01	0.17	0.09	0.06
	50.00	0.14	50.00	0.08	1.08	0.60	0.75
Dietary burden	28.00	0.07	28.00	0.04	0.61	0.34	0.39

Notes:

^a For MRL determination: Residues of mefentrifluconazole (free and conjugated).

^b For HR and STMR determination: Total residues of mefentrifluconazole (free and conjugated) and M750F022 (free and conjugated), expressed as parent equivalents.

Based on the calculated residues of mefentrifluconazole (free and conjugated) in milk and cattle tissues, the Meeting estimated maximum residue levels of 0.10 mg/kg in milks, 0.15 mg/kg in meat from mammals other than marine mammals, 1.5 mg/kg in mammalian fats and 2.0 mg/kg in mammalian offal (based on liver).

Based on the highest total residues of mefentrifluconazole (free and conjugated) and M750F022 (free and conjugated) in cattle tissues, the Meeting estimated HR values of 0.14 mg/kg in mammals other than marine mammals, 1.26 mg/kg in mammalian fats and 1.91 mg/kg in mammalian offal (based on liver).

Based on the mean total residues of mefentrifluconazole (free and conjugated) and M750F022 (free and conjugated) in milk and cattle tissues, the Meeting estimated STMR values of 0.07 mg/kg in milks, 0.04 mg/kg in mammals other than marine mammals, 0.39 mg/kg in mammalian fats and 0.61 mg/kg in mammalian edible offal (based on liver).

Poultry

The calculations used to estimate maximum residue levels, STMR and HR values for poultry matrices are shown below.

Table 5.25.6 Estimated residues for maximum residue levels, HRs and STMRs for mefentrifluconazole in poultry commodities

Mefentrifluconazole feeding study	Feed level (ppm) for egg residues	Residues (mg/kg) in egg	Feed level (ppm) for tissue residues	Residues (mg/kg)		
				Muscle	Liver	Fat
MRL ^a broiler or layer poultry						
Feeding study	4.50	< 0.01	4.50	< 0.01	0.09	0.03
	15.00	0.04	15.00	0.03	0.90	0.25
Dietary burden	12.00	0.031	12.00	0.024	0.67	0.187
HR ^b broiler or layer poultry						
Feeding study	4.50	0.03	4.50	< 0.01	0.13	0.11
	15.00	0.12	15.00	0.07	1.13	0.66
Dietary burden	12.00	0.094	12.00	0.053	0.844	0.503
STMR ^b broiler or layer poultry						
Feeding study	4.50	0.03	4.50	< 0.01	0.10	0.10
	15.00	0.11	15.00	0.05	0.61	0.53
Dietary burden	5.00	0.032	5.00	0.012	0.124	0.12

Notes:

^a For MRL determination: Residues of mefentrifluconazole (free and conjugated).

^b For HR and STMR determination: Total residues of mefentrifluconazole (free and conjugated) and M750F022 (free and conjugated), expressed as parent equivalents.

Based on these calculated residues of mefentrifluconazole (free and conjugated) in eggs and poultry tissues, the Meeting estimated maximum residue levels of 0.04 mg/kg in eggs and 0.03 mg/kg in poultry meat, 0.2 mg/kg in poultry fats and 0.7 mg/kg in poultry edible offal.

Based on the highest total residues of mefentrifluconazole (free and conjugated) and M750F022 (free and conjugated) in eggs and poultry tissues, the Meeting estimated HR values of 0.094 mg/kg in eggs, 0.053 mg/kg in poultry meat, 0.503 mg/kg in poultry fat and 0.844 mg/kg in poultry offal.

Based on the mean total residues of mefentrifluconazole (free and conjugated) and M750F022 (free and conjugated) in eggs and poultry tissues, the Meeting estimated STMR values of 0.032 mg/kg in eggs and 0.012 mg/kg in poultry meat, 0.124 mg/kg in poultry fat and 0.12 mg/kg in poultry edible offal.

RECOMMENDATIONS

On the basis of the data from supervised trials the Meeting concluded that the residue levels listed in Annex 1 are suitable for establishing maximum residue limits and for IEDI and international estimate of short-term intakes assessment.

Definition of the residue for compliance with the MRL and dietary risk assessment for plant commodities: *mefentrifluconazole*

Definition of the residue for compliance with the MRL for animal commodities: *mefentrifluconazole (free and conjugated)*

Definition of the residue for dietary risk assessment for animal commodities: sum of *mefentrifluconazole (free and conjugated)* + 2-[4-(4-chlorophenoxy)-2-(trifluoromethyl)phenyl]propane-1,2-diol (M750F022), *free and conjugated, expressed as mefentrifluconazole equivalents*. The molecular weight conversion factor to express M750F022 in mefentrifluconazole equivalents = 1.15.

The residue is fat soluble.

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The ADI for mefentrifluconazole is 0–0.04 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for mefentrifluconazole were estimated for the 17 GEMS/Food Consumption Cluster Diets using the STMR or STMR-P values estimated by the JMPR. The results are shown in Annex 3 of the 2022 JMPR Report.

The IEDIs ranged from 6–40 percent of the maximum ADI.

Acute dietary exposure

The ARfD for mefentrifluconazole is 0.3 mg/kg bw. The International Estimate of Short-Term Intakes (international estimate of short-term intakes) for mefentrifluconazole were calculated for the food commodities and their processed commodities for which HRs/HR-Ps or STMRs/STMR-Ps were estimated

by the present Meeting and for which consumption data were available. The results are shown in Annex 4 of the 2022 JMPR Report.

The international estimate of short-term intakes were at or less than 100 percent of the ARfD, except for:

Amaranth leaves, chicory leaves and edible leaved chrysanthemums (140 percent each for Belgian toddlers)

Raw endive (130 percent for Dutch children)

Cooked/boiled endive (240 percent for Dutch toddlers)

Cos lettuce (140 percent for Dutch children)

Head lettuce (140 percent for Dutch children)

Leaf lettuce (120 percent for Dutch children)

Chinese cabbage (240 percent for Chinese children)

Kale (110 percent for German children)

Mustard greens (200 percent for Chinese children)

The meeting concluded that acute dietary exposure to residues of mefentrifluconazole in commodities where the ARfD is exceeded may present a public health concern.

Threshold of toxicological concern (TTC) consideration for metabolites

The Meeting agreed that the fatty acid conjugates of M750F022 (M750F023, M750F024 and M750F025) identified in poultry matrices could be assessed using the TTC approach (Cramer Class III threshold of 1.5 µg/kg bw per day).

The current Meeting estimated dietary exposures for metabolite M750F023 of 0.056 µg/kg bw/day, for M750F024 of 0.034 µg/kg bw/day and for M750F025 of 0.033 µg/kg bw/day.

The Meeting concluded that the estimated dietary exposure to residues of M750F023, M750F024 and M750F025 from uses considered by the JMPR is below the TTC for Cramer Class III compounds and is unlikely to present a public health concern. Should further uses be considered in the future, these conclusions may need to be re-evaluated.

5.26 Metalaxyl (138)

RESIDUE AND ANALYTICAL ASPECTS

Metalaxyl is a racemic mixture of R- and S-enantiomers, where the R-enantiomer is the biologically active form, and metalaxyl-M consists of a minimum of 97 percent of the R-enantiomer.

The 2021 JMPR evaluated metalaxyl under the periodic review and metalaxyl-M for new uses. A single ADI and ARfD were also established by the same Meeting.

The residue definitions for metalaxyl and metalaxyl-M for plant commodities are:

Compliance with MRL: metalaxyl (sum of enantiomers)

Dietary risk assessment: metalaxyl (sum of enantiomers) and N-(2-hydroxymethyl-6-methylphenyl)-N-(methoxyacetyl)alanine methyl ester (M8; free and conjugated; sum of enantiomers), expressed as metalaxyl.

The present Meeting received analytical method, GAP information and residue trials for pineapple from the Government of Thailand. Additionally, data evaluated by the 2021 JMPR for dried ginseng was re-assessed.

Method of analysis

A summary report, provided to the Meeting, describe a GC-NPD method to analyse metalaxyl in pineapple. The method included extraction with acetone and dichloromethane, clean-up with silica gel column and was validated at a LOQ of 0.01 mg/kg. The method used in the analysis of field trial samples, however, does not include a clean-up step and has a reported LOQ of 0.02 mg/kg, with very limited validation data.

Results of supervised residue trials on crops

The estimated values for metalaxyl are intended to cover uses of metalaxyl-M. For dietary risk assessment, a factor of 1.3 is applied to STMR and HR values found in the fruits to account for the presence of metabolite M8 (free and conjugated). No factor is needed for bulb, root, and tuber crops or for crops when no residues are expected to be found.

Pineapple

Five residues trials were conducted with metalaxyl in Thailand in 2010 according to GAP (2×0.25 kg ai/ha, 60 days interval, and 14 days PHI). Residues were < 0.02 (2), 0.02, 0.03 and 0.06 mg/kg.

The Meeting estimates a maximum residue level of 0.1 mg/kg, a STMR of 0.026 mg/kg and a HR of 0.78 mg/kg for metalaxyl in pineapple.

Ginseng

The 2021 JMPR evaluated trials conducted with metalaxyl-M in the Republic of Korea (GAP of 0.08 kg ai/ha, 10-day interval, 14-day PHI) and recommended a MRL of 0.03(*) mg/kg for metalaxyl in ginseng.

Fresh ginseng samples were washed, dried in hot air to reach the water content under 14 percent and analysed. Residues were < 0.06 mg/kg (n= 9).

Based on the data evaluated by the 2021 JMPR, the Meeting estimates a maximum residue level of 0.06(*) mg/kg, and a STMR and HR of 0.06 mg/kg for metalaxyl in ginseng, dried including red ginseng.

RECOMENDATIONS

On the basis of the data from supervised trials, the Meeting concluded that the residue levels listed in Annex 1 are suitable for establishing maximum residue limits and for IEDI and international estimate of short-term intakes assessment.

Definition of the residue for metalaxyl and metalaxyl-M for compliance with the MRL for plant commodities: *metalaxyl (sum of enantiomers)*.

Definition of the residue for metalaxyl and metalaxyl-M for dietary risk assessment in plant commodities: *metalaxyl (sum of enantiomers) and N-(2-hydroxymethyl-6-methylphenyl)-N-(methoxyacetyl)alanine methyl ester (M8; free and conjugated; sum of enantiomers), expressed as metalaxyl.*

Definition of the residue for metalaxyl and metalaxyl-M for compliance with the MRL in animal commodities: *the sum of metalaxyl (sum of enantiomers) and metabolites (free + conjugated) M3 (N-(2,6-dimethylphenyl)-N-(hydroxyacetyl)alanine methyl ester) and M8 (N-(2-hydroxymethyl-6-methylphenyl)-N-(methoxyacetyl)alanine methyl ester (sum of enantiomers), expressed as metalaxyl.*

Definition of the residue for metalaxyl and metalaxyl-M for dietary risk assessment in animal commodities: *the sum of metalaxyl (sum of enantiomers) and metabolites (free + conjugated) M1 (N-(2,6-dimethylphenyl)-N-(methoxyacetyl) alanine), M3 (N-(2,6-dimethylphenyl)-N-(hydroxyacetyl)alanine methylester), M6 (N-(2,6-dimethylphenyl)-N-(hydroxyacetyl)alanine), M7 (N-(2,6-dimethyl- 5-hydroxyphenyl)-N-(methoxyacetyl)alanine methyl ester) and M8 (N-(2-hydroxymethyl-6-methylphenyl)-N-(methoxyacetyl)alanine methyl ester (sum of enantiomers), expressed as metalaxyl.*

The residue is not fat-soluble.

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The ADI for metalaxyl and metalaxyl-M (alone or in combination) is 0–0.08 mg/kg bw. The International Estimated Daily Intakes (IEDIs) estimated for the 17 GEMS/Food Consumption Cluster Diets estimated by the 2021 JMPR was not impacted by the recommendation made for pineapple by the current Meeting. No consumption data is available for ginseng, dried.

The Meeting concluded that long-term dietary exposure to residues of metalaxyl residues from the uses considered the JMPR is unlikely to present a public health concern.

Acute dietary exposure

The ARfD for metalaxyl is 0.5 mg/kg bw. The International Estimate of Short Term Intakes (international estimate of short-term intakes) for metalaxyl were calculated for pineapple and ginseng, dried. The results are shown in Annex 4 of the 2022 JMPR Report.

The international estimate of short-term intake varied from 0–1 percent of the ARfD for children and 0–1 percent for the general population. The Meeting concluded that acute dietary exposure to residues of metalaxyl from uses considered by the current Meeting is unlikely to present a public health concern.

5.27 Methidathion (051)

TOXICOLOGY

Methidathion is the International Organization for Standardization (ISO)–approved common name for *S*-2,3-dihydro-5-methoxy-2-oxo-1,3,4-thiadiazol-3-ylmethyl-*O,O*-dimethyl phosphorodithioate, with the Chemical Abstracts Service number 950-37-8. Methidathion is a broad-spectrum organophosphate insecticide that acts by inhibiting the activity of acetylcholinesterase (AChE).

The 1992 FAO/WHO Joint Meeting on Pesticide Residues (JMPR) established an acceptable daily intake (ADI) of 0–0.001 mg/kg body weight (bw) for methidathion on the basis of an overall no-observed-adverse-effect level (NOAEL) of 0.1 mg/kg bw per day in 90-day, one-year and two-year studies in dogs. A 100-fold safety factor was applied. At the 1997 Meeting, an acute reference dose (ARfD) of 0.01 mg/kg bw was established on the basis of a NOAEL of 0.1 mg/kg bw per day, the highest dose tested in a six-week study in humans, and a NOAEL of 1 mg/kg bw in an acute neurotoxicity study in rats. Safety factors were applied: 10 for the volunteer study and 100 for the acute neurotoxicity study in rats.

The evaluation by the present Meeting was conducted for the periodic review programme following a request from the Codex Committee on Pesticide Residues (CCPR). Several toxicity studies were provided to the present Meeting. These had been conducted in compliance with good laboratory practice (GLP) and in accordance with relevant national or international test guidelines, unless otherwise specified.

In a literature search via PubMed Central some new information on acute toxicity and genotoxicity was identified and included in the current toxicological evaluation. There was no new information available on effects in humans, including epidemiology.

Biochemical aspects

When radiolabelled methidathion was administered orally to rats, the radioactivity was rapidly absorbed to the extent of approximately 80 percent. No sex- or dose level-related differences were observed. The absorbed radioactivity was rapidly circulated systemically. The time to maximum concentration (T_{max}) in rats was 2–4 hours at a dose level of 0.25 mg/kg bw, and 2–6 hours at 2.5 mg/kg bw. Absorbed radioactivity was distributed widely but especially to the liver and kidneys. Elimination from the blood and tissues was biphasic, with a rapid initial phase (within 24 hours) followed by a slower terminal phase (72 hours at 0.25 mg/kg bw; 96 hours at 2.5 mg/kg bw). Main elimination routes were urine and as carbon-dioxide via the lungs. There were no significance differences in elimination patterns with regards to dose levels administered, pre-treatment or sex.

The major metabolic pathway of methidathion was cleavage of the heterocyclic moiety followed by further reactions. In rats, major metabolites were: RH (2,3-dihydro-5-methoxy-1,3,4-thiadiazol-2-one)-sulfide (GS-28368), RH-sulfoxide (GS-28370), RH-sulfone (GS-28369), and desmethyl methidathion.

Toxicological data

The acute oral median lethal dose (LD₅₀) for methidathion in rats was 50–300 mg/kg bw. The acute dermal LD₅₀ was greater than 2000 mg/kg bw. The acute inhalation median lethal concentration (LC₅₀) was 0.105–0.195 mg/L. Methidathion was not irritating to the skin or eyes of rabbits. Methidathion was sensitizing in a maximization test in Guinea pigs.

In single and repeat-dose oral toxicity studies with methidathion in mice, rats, rabbits and dogs, AChE inhibition in erythrocyte and brain and its related clinical signs were the major effects. Hepatotoxicity was observed at similar dose levels to those of AChE inhibition in mice and dogs.

In a 90-day oral toxicity study, rats were given methidathion at dietary concentrations of 0, 2, 6, 30 or 100 ppm (equal to 0, 0.13, 0.40, 2.05 and 7.04 mg/kg bw per day for males, 0, 0.16, 0.48, 2.50 and 9.02 mg/kg bw per day for females) The NOAEL was 2 ppm (equal to 0.16 mg/kg bw per day) based on a decrease in erythrocyte AChE at 6 ppm (equal to 0.48 mg/kg bw per day).

In a 90-day oral toxicity study in dogs given methidathion at dietary concentrations of 0, 0.5, 4, 45 or 140 ppm (equal to 0, 0.02, 0.16, 1.94 and 5.69 mg/kg bw per day for males, 0, 0.02, 0.19, 2.11 and 7.02 mg/kg bw per day for females) the NOAEL was 4 ppm (equal to 0.16 mg/kg bw per day) based on decreased erythrocyte AChE, hepatotoxicity-related changes in blood biochemistry and pathological finding at 45 ppm (equal to 1.94 mg/kg bw per day).

In a one-year oral toxicity study, dogs were given methidathion at dietary concentrations of 0, 0.5, 2, 4, 40 or 140 ppm (equal to 0, 0.02, 0.07, 0.15, 1.33 and 4.51 mg/kg bw per day for males, 0, 0.02, 0.07, 0.15, 1.39 and 4.90 mg/kg bw per day for females). The NOAEL was 4 ppm (equal to 0.15 mg/kg bw per day) based on a decrease in erythrocyte AChE activity, hepatotoxicity-related changes in blood biochemistry and pathological findings at 40 ppm (equal to 1.33 mg/kg bw per day).

The overall NOAEL for the 90-day and one-year dietary toxicity studies in dogs was 0.16 mg/kg bw per day, and the overall LOAEL 1.33 mg/kg bw per day.

In a two-year feeding toxicity study, mice were administered methidathion at dietary concentrations of 0, 3, 10, 50 or 100 ppm (equal to 0, 0.4, 1.4, 6.7 and 13.1 mg/kg bw per day for males, 0, 0.5, 1.6, 8.1 and 15.9 mg/kg bw per day for females). An interim kill in the 100 ppm groups at three months showed extensive liver toxicity. The NOAEL for chronic toxicity was 10 ppm (equal to 1.4 mg/kg bw per day) based on the hepatotoxic parameters of blood biochemistry and histopathological findings in males, and decreases in brain and erythrocyte AChE activity in both sexes at 50 ppm (equal to 6.7 mg/kg bw per day). The NOAEL for carcinogenicity in mice was 10 ppm (equal to 1.4 mg/kg bw per day) based on increased incidences of hepatocellular adenomas and carcinomas, and a combined incidence of these tumours in males at 50 ppm (equal to 6.7 mg/kg bw per day). No carcinogenicity was observed in female mice.

The Meeting considered that as preneoplastic lesions were seen in male mice during shorter duration studies, continuous stimulation by damage to the hepatobiliary system might be one factor leading to methidathion-induced hepatocarcinogenesis in male mice.

In a two-year combined chronic toxicity and carcinogenicity study, rats were administered methidathion at dietary concentrations of 0, 4, 40 or 100 ppm (equal to 0, 0.16, 1.72 and 4.91 mg/kg bw per day for males, 0, 0.22, 2.20 and 6.93 mg/kg bw per day for females). The NOAEL for chronic toxicity in rats was 4 ppm (equal to 0.16 mg/kg bw per day) based on decreases in erythrocyte and brain AChE activity, histopathological changes in the skin and lung at 40 ppm (equal to 1.72 mg/kg bw per day). The NOAEL for carcinogenicity in rats was 100 ppm (equal to 4.91 mg/kg bw per day) the highest dose tested.

The Meeting concluded that methidathion is carcinogenic in male mice but not in female mice or rats.

Methidathion was tested for genotoxicity in an adequate range of in vitro and in vivo assays. No evidence of genotoxicity was found.

The Meeting concluded that methidathion is unlikely to be genotoxic.

In view of the lack of genotoxicity, and the absence of carcinogenicity in rats and female mice, and the fact that the carcinogenicity in male mice exhibits a threshold, the Meeting concluded that methidathion is unlikely to pose a carcinogenic risk to humans via exposure from the diet.

In a two-generation study in rats methidathion was administered in the diet at concentrations of 0, 5, 25 or 50 ppm (equal to 0, 0.43, 2.21 and 4.33 mg/kg bw per day for males, 0, 0.47, 2.38 and 4.96 mg/kg bw per day for females). The NOAEL for parental toxicity was 5 ppm (equal to 0.47 mg/kg bw per day) based on cholinergic clinical signs in lactating females and lowered body weight in females at 25 ppm (equal to 2.38 mg/kg bw per day). The NOAEL for offspring toxicity was 5 ppm (equal to 0.43 mg/kg bw per day) based on lower body weight in F1 and F2 offspring at 25 ppm (equal to 2.21 mg/kg bw per day). The NOAEL for reproductive toxicity in rats was also 5 ppm (equal to 0.43 mg/kg bw per day) based on lower mating index in the F1 generation at 25 ppm (equal to 2.21 mg/kg bw per day).

In a development toxicity study, pregnant rats were administered methidathion at doses of 0, 0.25, 1.0 or 2.5 mg/kg bw once daily by gavage. Animals were dosed during gestation days (GDs) 6 to 15. The NOAEL for maternal toxicity was 1.0 mg/kg bw per day based on cholinergic clinical signs, decreased body weight gain and reduced food consumption at 2.5 mg/kg bw per day. The NOAEL for embryo/fetal effects was 2.5 mg/kg bw per day, the highest dose tested.

In a development toxicity study in rabbits, methidathion was administered daily by gavage to pregnant rabbits from GD 6 until GD 18 at doses of 0, 0.5, 1.5 or 3.0 mg/kg bw. The NOAEL for maternal toxicity and for embryo/fetal toxicity was 3.0 mg/kg bw per day, the highest dose tested.

In another developmental toxicity study, rabbits were administered methidathion by gavage at dose levels of 0, 2, 6 or 12 mg/kg bw per day from GD 7 to GD 19. The NOAEL for maternal toxicity was 6 mg/kg bw per day based on cholinergic clinical signs observed immediately after dosing at 12 mg/kg bw per day. The NOAEL for embryo/fetal effects was 12 mg/kg bw per day, the highest dose tested.

The Meeting concluded that methidathion is not teratogenic.

An acute neurotoxicity study was conducted in rats administered a single dose of methidathion by gavage at 0, 1, 4, 8 or 16 mg/kg bw. The NOAEL for acute neurotoxicity was 1 mg/kg bw based on a decrease in brain and erythrocyte AChE at 4 mg/kg bw.

A single-dose study was conducted in rats to investigate the inhibition of AChE. Methidathion was administered by gavage at doses of 0, 0.5, 1, 2.5, 5 or 10 mg/kg bw. The NOAEL for AChE inhibition was 1.0 mg/kg bw based on a decrease in erythrocyte AChE in females at 2.5 mg/kg bw.

In a subchronic neurotoxicity study in rats, methidathion was administered for 90 days at dietary concentrations of 0, 3, 10, 30 or 100 ppm (equal to 0, 0.18, 0.61, 1.86 and 6.36 mg/kg bw per day for males, 0, 0.20, 0.66, 2.01 and 7.19 mg/kg bw per day for females). The NOAEL was 3 ppm (equal to 0.18 mg/kg bw per day) based on the decrease in AChE activity in erythrocytes and cerebral cortex in males at 10 ppm (equal to 0.61 mg/kg bw per day).

In a delayed neurotoxicity study in hens, there was no evidence of delayed neuropathy.

The Meeting concluded that methidathion is neurotoxic.

No evidence of immunotoxicity was reported in routine toxicological studies with methidathion.

The Meeting concluded that methidathion is unlikely to be immunotoxic.

Toxicological data on metabolites and/or degradates**Summary overview of toxicological characterization of plant/livestock metabolites**

Compound, codes and structure	Rat ADME Toxicity covered by toxicological properties of parent compound (content in rat biofluids >10 percent absorbed dose or 10 percent TRR)?	Genotoxicity assessment (data, QSAR, read-across)	General toxicity	Health-based guidance values (HBGVs)
Methidathion (GS 13005)	Parent	Not genotoxic (data)	Full data-set LD ₅₀ : 35 mg/kg bw	Parent HBGVs ADI: 0–0.002 mg/kg bw ARfD: 0.01 mg/kg bw
Oxygen analogue of methidathion (GS 13007)	Not found in rats	Not genotoxic (QSAR and RA)	LD ₅₀ : 10 mg/kg bw Around 4-fold greater acute toxicity in vivo	Parent HBGVs with 4-fold additional factor
Desmethyl methidathion (GS 46572)	Yes >10 percent rat urine	Not genotoxic (QSAR and RA)	Covered by parent	Covered by parent ADI ARfD unnecessary
Cysteine conjugate of methidathion	No ≤10 percent in rat urine Downstream of GSH conjugate in ADME	Not genotoxic (QSAR and RA)	Covered by parent No common structure with that of AChE inhibitors	Covered by parent ADI ARfD unnecessary
RH (GS 12956) (2,3-dihydro-5-methoxy-1,3,4-thiadiazole-2-one)	No ≤10 percent in rat urine Upstream from RH-thiol	Not genotoxic (QSAR and RA)	Covered by the parent LD ₅₀ : 750 mg/kg bw No AChE inhibitory effect in vitro	Covered by parent ADI ARfD unnecessary
RH-thiol (GS32978)	No Precursor of RH-sulfide	Not genotoxic (QSAR and RA)	Covered by the parent No common structure with that of AChE inhibitors	Covered by parent ADI ARfD unnecessary
RH-sulfide (GS 28368)	Yes >10 percent in urine	Not genotoxic (QSAR and RA)	Covered by the parent LD ₅₀ : 1750 mg/kg bw No AChE inhibitory effect in vitro	Covered by parent ADI ARfD unnecessary
RH-sulfoxide (GS 28370)	Yes >10 percent rat urine	Not genotoxic (QSAR and RA)	Covered by the parent LD ₅₀ : 1110 mg/kg bw No AChE inhibitory effect in vitro	Covered by parent ADI ARfD unnecessary
RH-sulfone (GS 28369)	Yes >10 percent rat urine	Not genotoxic (QSAR and RA)	Covered by the parent LD ₅₀ :	Covered by parent ADI

Compound, codes and structure	Rat ADME Toxicity covered by toxicological properties of parent compound (content in rat biofluids >10 percent absorbed dose or 10 percent TRR)?	Genotoxicity assessment (data, QSAR, read-across)	General toxicity	Health-based guidance values (HBGVs)
			535 mg/kg bw No AChE inhibitory effect in vitro	ARfD unnecessary

Notes:

QSAR: Quantitative structure–activity relationship.

RA: Read across.

TRR: Total radioactive residue.

ADME: Absorption, distribution, metabolism and excretion.

ADI: Acceptable daily intake.

ARfD: Acute reference dose.

LD₅₀: Median lethal dose.

The Meeting concluded that the toxicities of RH-thiol, RH-sulfide, RH-sulfoxide and RH-sulfone were covered by the ADI of the parent, methidathion.

The Meeting considered that it was possible that all the metabolites described above show similar hepatotoxicity to methidathion (a noncritical end-point of methidathion); this could not be excluded, since it was noted by the Meeting that they all share with the parent a methoxythiazole ring structure. Once the phosphate group is removed, they are predicted to retain similar toxicity, not related to AChE-related activity. Therefore the hepatotoxicity potential of these metabolites would be covered by the ADI for methidathion.

Microbiological data

There was no information available in the public domain and no experimental data were provided which addressed the possible impact of methidathion residues on the human intestinal microbiome.

Human data

A human study had been evaluated by an earlier JMPR meeting. The current Meeting was made aware of information relating to the performance of this study that had become available since the review in 1997. No evidence of informed consent could be found and full protocol for the study was not available.

The present Meeting was unable to confirm that the study complied with the declaration of Helsinki and was ethically valid, even by its contemporary standards, and concluded that it would be inappropriate to use this study for assessment of methidathion.

Toxicological evaluation

The Meeting withdrew the previous ADI and established a new ADI for methidathion of 0–0.002 mg/kg bw based the overall NOAEL of 0.16 mg/kg bw per day in 90-day and one-year oral studies in dogs. A safety factor of 100 was applied. The NOAEL was supported by NOAELs from a 90-day neurotoxicity study in rats, a 90-day toxicity study in rats and a two-year toxicity study in rats. The margin between the upper bound ADI and the LOAEL for liver tumours in male mice is 3350.

The Meeting re-affirmed the ARfD of 0.01 mg/kg bw based on the NOAEL of 1 mg/kg bw in the acute neurotoxicity study in rats, and using a safety factor of 100.

The Meeting concluded that the oxygen analogue of methidathion was covered by the ADI and ARfD values for methidathion when an additional four-fold potency factor is used.

The Meeting concluded that the existing database on methidathion was adequate to characterize the potential hazards to the general population, including fetuses, infants and children.

A toxicological monograph addendum was prepared.

Levels relevant to risk assessment of methidathion

Species	Study	Effect	NOAEL	LOAEL
Mouse	22-month study of carcinogenicity ^a	Toxicity	10 ppm, equal to 1.4 mg/kg bw/day	50 ppm, equal to 6.7 mg/kg bw/day
		Carcinogenicity	10 ppm, equal to 1.4 mg/kg bw/day	50 ppm, equal to 6.7 mg/kg bw/day
Rat	90-day oral toxicity study ^a	Toxicity	2 ppm equal to 0.16 mg/kg bw/day	6 ppm equal to 0.48 mg/kg bw/day
	Two-year study of toxicity and carcinogenicity ^a	Toxicity	4 ppm, equal to 0.16 mg/kg bw/day	40 ppm, equal to 1.72 mg/kg bw/day
		Carcinogenicity	100 ppm, equal to 4.91 mg/kg bw/day ^e	-
	Two-generation study of reproductive toxicity ^{a,b}	Reproductive toxicity	5 ppm, equal to 0.43 mg/kg bw/day	25 ppm, equal to 2.21 mg/kg bw/day
		Parental toxicity	5 ppm, equal to 0.47 mg/kg bw/day	25 ppm, equal to 2.38 mg/kg bw/day
		Offspring toxicity	5 ppm, equal to 0.43 mg/kg bw/day	25 ppm, equal to 2.21 mg/kg bw/day
	Developmental toxicity study ^c	Maternal toxicity	1 mg/kg bw/day	2.5 mg/kg bw/day
Embryo/fetal toxicity		2.5 mg/kg bw/day ^e	-	
Acute neurotoxicity ^c	Neurotoxicity	1 mg/kg bw	4 mg/kg bw	
90-day neurotoxicity	Neurotoxicity	3 ppm equal to 0.182 mg/kg bw/day	10 ppm equal to 0.608 mg/kg bw/day	
Rabbit	Developmental toxicity study ^c	Maternal toxicity	3 mg/kg bw per day ^e	-
		Embryo/fetal toxicity	3 mg/kg bw per day ^e	-
Dog	90-day and 1-year study of toxicity ^{a,b}	Toxicity	4 ppm equal to 0.16 mg/kg bw/day	40 ppm equal to 1.33 mg/kg bw/day

Notes:

^a Dietary administration.

^b Two studies combined.

^c Gavage administration.

^d Capsule administration.

^e Highest dose tested.

Acceptable daily intake (ADI)*

0–0.002 mg/kg bw

* Applies to methidathion, RH, RH-thiol, RH-sulfide, RH-sulfoxide, RH-sulfone, desmethyl methidathion and the cysteine conjugate of methidathion, and also to the oxygen analogue of methidathion multiplied by four

Acute reference dose (ARfD)**

0.01 mg/kg bw

** Applies to methidathion, desmethyl methidathion, and the oxygen analogue (multiplied by four)

Information that would be useful for the continued evaluation of the compound

Results from epidemiological, occupational health and other such observational studies of human exposure.

Critical end-points for setting guidance values for exposure to methidathion**Absorption, distribution, excretion and metabolism in mammals**

Rate and extent of oral absorption	Rapid (T_{max} 2–6 h); and approximately 80 percent absorbed (rats);
Dermal absorption	No information.
Distribution	Extensive; highest concentrations in liver and kidney
Potential for accumulation	No evidence of accumulation
Rate and extent of excretion	Elimination was biphasic, with a rapid initial phase up to 24 hours followed by a slower terminal phase (72 hours at 0.25 mg/kg bw and 96 hours at 2.5 mg/kg bw)
Metabolism in animals	Cleavage of the heterocyclic moiety of methidathion after hydrolysis of the ether bond, conjugation with glutathione. CO ₂ was the main metabolite (rat)
Toxicologically significant compounds in animals and plants	Methidathion, RH, RH-thiol, RH-sulfide, RH-sulfoxide, RH-sulfone, desmethyl-methidathion, cysteine conjugate of methidathion (rat); Oxygen analogue of methidathion (plant)

Acute toxicity

Rat, LD ₅₀ , oral	50–300 mg/kg bw
Rat, LD ₅₀ , dermal	>2000 mg/kg bw
Rat, LC ₅₀ , inhalation	0.105–0.195 mg/L
Rabbit, dermal irritation	Not irritating
Rabbit, ocular irritation	Not irritating
Guinea pig, dermal sensitization	Sensitizing (maximization)

Short-term studies of toxicity

Target/critical effect	Inhibition of AChE in erythrocyte (mouse, rat, dog, rat) Hepatotoxicity (mouse, dog)
Lowest relevant oral NOAEL	0.16 mg/kg bw per day (dog)
Lowest relevant dermal NOAEL	No data
Lowest relevant inhalation NOAEC	No data

Long-term studies of toxicity and carcinogenicity	
Target/critical effect	Inhibition of AChE in erythrocyte and brain (mouse, rat) Hepatotoxicity, including tumours (mouse)
Lowest relevant NOAEL	0.16 mg/kg bw per day (rat)
Carcinogenicity	Carcinogenic in male mice ^a
Genotoxicity	
Unlikely to be genotoxic	
Reproductive toxicity	
Target/critical effect	Lower mating index (rat)
Lowest relevant reproductive NOAEL	0.43 mg/kg bw per day (rat)
Parent	0.47 mg/kg bw per day (rat)-
Offspring	0.43 mg/kg bw per day (rat)-
Developmental toxicity	
Developmental target/critical effect	Cholinergic clinical signs (rat, rabbit) Decreased body weight gain and feed consumption (rat)
Lowest relevant developmental NOAEL	2.5 mg/kg bw per day, highest dose tested (rat)
Neurotoxicity	
Acute neurotoxicity target/critical effect	AChE inhibition in the brain (rat)
Lowest relevant oral acute NOAEL	1 mg/kg bw (rat)
Subacute neurotoxicity target/critical effect	AChE inhibition in erythrocyte and the brain (rat)
Lowest relevant oral subacute NOAEL	0.18 mg/kg bw (rat)
Developmental neurotoxicity	No data
Delayed neurotoxicity	No delayed neuropathy (hen)
Immunotoxicity	
Unlikely to be immunotoxic; no evidence from routine studies	
Studies on toxicologically relevant metabolites	
Acute toxicity	
Oxygen analogue of methidathion	Acute oral LD ₅₀ : 10 mg/kg bw
RH-sulfide	LD ₅₀ : 1750 mg/kg bw
RH-sulfoxide	LD ₅₀ : 1100 mg/kg bw
RH-sulfone	LD ₅₀ : 535 mg/kg bw
Microbiological data	
No available data	
Human data	
No useable data available	

Notes:

^a Unlikely to pose a carcinogenic risk to humans via exposure from the diet.

Summary

	Value	Study	Safety factor
ADI ^a	0–0.002 mg/kg bw	90-day and one-year dog studies	100
ARfD ^b	0.01 mg/kg bw	Rat acute neurotoxicity study	100

Notes:

^a Applies to methidathion, RH, RH-thiol, RH-sulfoxide, RH-sulfide, RH-sulfone and desmethyl-methidathion, the cysteine conjugate of methidathion, and to the oxygen analogue of methidathion (multiplied by four).

^b Applies to methidathion, desmethyl-methidathion, and to the oxygen analogue of methidathion (multiplied by four).

RESIDUE AND ANALYTICAL ASPECTS

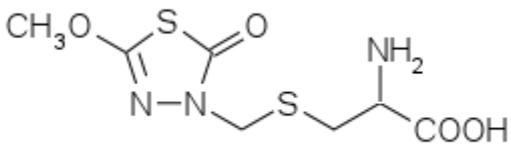
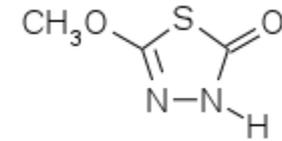
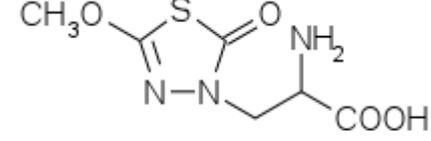
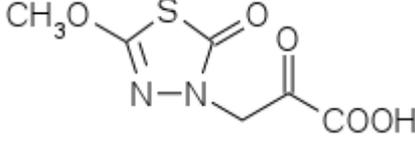
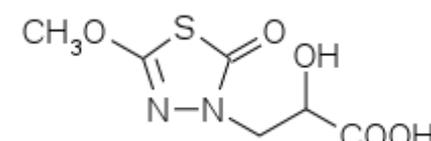
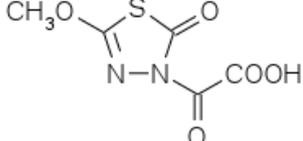
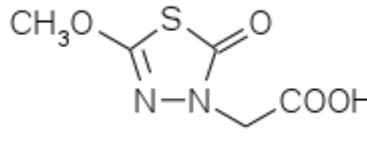
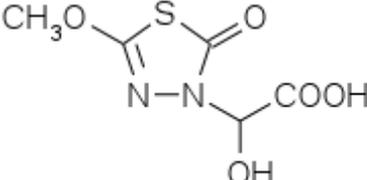
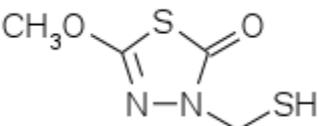
Methidathion, whose IUPAC name is S-2,3-dihydro-5-methoxy-2-oxo-1,3,4-thiadiazol-3-ylmethyl O,O-dimethyl phosphorodithioate, is an organophosphate insecticide. Its mode of action is by inhibition of acetylcholinesterase. Methidathion was last evaluated for residues in 1994.

At the Fifty-first Session of CCPR (2019) methidathion was scheduled for periodic re-evaluation by the 2020 JMPR but was postponed to the 2022 JMPR. The Meeting received the data for methidathion on plant and animal metabolism, methods of analysis, GAP information, and residues resulting from supervised trials on apple, cherry, grape, mandarin, mango and peach.

The code names, chemical names and chemical structures of the compounds are as follows.

Table 5.27.1 Summary information on compounds referred to in the appraisal

Compound code name and chemical name	Structure
Methidathion S-2,3-dihydro-5-methoxy-2-oxo-1,3,4-thiadiazol-3-ylmethyl O,O-dimethyl phosphorodithioate	
Desmethyl methidathion S-2,3-dihydro-5-methoxy-2-oxo-1,3,4-thiadiazol-3-ylmethyl O-methyl phosphorodithioate	
Oxygen analogue of methidathion S-2,3-dihydro-5-methoxy-2-oxo-1,3,4-thiadiazol-3-ylmethyl O,O-dimethyl phosphorothioate	
GS-20685 2,3-dihydro-3-hydroxymethyl-5-methoxy-1,3,4-thiadiazol-2-one	
Glutathione conjugate of GS-13005 RH-Glutathione conjugate 2,3-dihydro-5-methoxy-2-oxo-1,3,4-thiadiazol-3-ylmethyl-thioglutathione	

Compound code name and chemical name	Structure
Cysteine conjugate of GS-13005 RH-Cysteine conjugate 2-amino-3-(2,3-dihydro-5-methoxy-2-oxo-1,3,4-thiadiazol-3-ylmethylthioxy) propionic acid	
RH 2,3-dihydro-5-methoxy-1,3,4-thiadiazol-2-one	
RH-Alanine conjugate 2-amino-3-(2,3-dihydro-5-methoxy-2-oxo-1,3,4-thiadiazol-3-ylmethyl) propionic acid	
RH-Keto acid conjugate 2-oxo-3-(2,3-dihydro-5-methoxy-2-oxo-1,3,4-thiadiazol-3-ylmethyl) propionic acid	
RH-Lactic acid conjugate 3-(2,3-dihydro-5-methoxy-2-oxo-1,3,4-thiadiazol-3-ylmethyl)-2-hydroxypropionic acid	
RH-glyoxylic acid conjugate 2-(2,3-dihydro-5-methoxy-2-oxo-1,3,4-thiadiazol-3-yl) -2-oxo-acetic acid	
RH-Acetic acid conjugate 2-(2,3-dihydro-5-methoxy-2-oxo-1,3,4-thiadiazol-3-yl) acetic acid	
RH-Hydroxy acetic acid conjugate 2-(2,3-dihydro-5-methoxy-2-oxo-1,3,4-thiadiazol-3-yl)- 2-hydroxy-acetic acid	
RH-thiol 2,3-dihydro-5-methoxy-4-sulfanyl-1,3,4-thiadiazol-2-one	

Compound code name and chemical name	Structure
RH-sulfide 2,3-dihydro-5-methoxy-4-methylsulfanyl-1,3,4-thiadiazol-2-one	
RH-sulfoxide 2,3-dihydro-5-methoxy-4-methylsulfinyl-1,3,4-thiadiazol-2-one	
RH-sulfone 2,3-dihydro-5-methoxy-4-methylsulfonyl-1,3,4-thiadiazol-2-one	

With respect to the physical and chemical properties that may impact on residues in crops, methidathion is not regarded as volatile, it is unlikely to be fat soluble as the $\log P_{ow}$ is 2.2, and the hydrolysis half-life ranged from 13 days at pH 9 to 48 days at pH 7.

Plant metabolism

The Meeting received information on the fate of methidathion in oranges, tomatoes, common beans and alfalfa. In the metabolism studies, total radioactive residues (TRR) are expressed in mg methidathion equivalents/kg.

In a metabolism study on oranges, 2-carbonyl-¹⁴C-methidathion was applied twice to an orange tree under outdoor conditions as foliar spray at rates of 0.067 kg ai/ha. Oranges were harvested at maturity 159 days after last application (DALA), washed by water with surfactant, and peeled. In plant metabolism study, juice was prepared from the peeled fruit. Subsamples of each matrix were homogenized to determine the TRR.

Radioactivity was mainly located in peel (66 percent TRR, 1.0 mg eq/kg), followed by juice (22 percent TRR, 0.25 mg eq/kg) and pulp (11 percent TRR, 0.40 mg eq/kg). Residues in the aqueous surface wash were insignificant (0.5 percent TRR, < 0.01 mg eq/kg). Peel and pulp were extracted with methanol-water (9:1). From orange pulp, 17 percent TRR (0.068 mg eq/kg) was extracted and when partitioned with water-chloroform, 12 and 2.5 percent TRR (0.048 and 0.010 mg eq/kg) were found in water and chloroform phase, respectively. Residues in pulp were not further characterized.

Since only radioactivity in peel and juice was subject to identification, the Meeting could not calculate the metabolite composition for the whole fruit.

In orange peel, 65 percent TRR was extracted by aqueous methanol and the following compounds were identified methidathion (24 percent TRR, 0.25 mg eq/kg), RH-alanine conjugate (14 percent TRR, 0.14 mg eq/kg), conjugates of RH with acetic acid, lactic acid or hydroxy acetic acid (3.5–4.2 percent TRR, 0.04 mg eq/kg), and desmethyl-methidathion (1.7 percent TRR, 0.02 mg eq/kg). Unextracted residues in the orange peel were further treated by sequential acid (0.1 and 1 mol/L HCl) and base (5 mol/L NaOH) hydrolysis. After hydrolysis with 0.1 mol/L HCl, 1 mol/L HCl and base, 0.68 percent TRR

(0.007 mg eq/kg), 12 percent TRR (0.12 mg eq/kg) and 3.8 percent TRR (0.039 mg eq/kg), respectively, were extracted.

In orange juice, residues were predominantly aqueous soluble (94 percent TRR, 0.24 mg eq/kg). Parent methidathion was not detected. RH-alanine conjugate was predominant (72 percent TRR, 0.18 mg eq/kg), followed by RH-lactic acid conjugate (10 percent TRR, 0.03 mg eq/kg) and desmethyl-methidathion (3.1 percent TRR, < 0.01 mg/kg). In a metabolism study on tomatoes, the following compounds ¹⁴C-labelled at 2-carbonyl in thiadiazol ring were used: methidathion, desmethyl methidathion, RH-sulfide, RH-sulfoxide and RH-sulfone. Labelled compounds, at rates of 1–14 mg/kg for ¹⁴C-methidathion or a rate of 7 mg/kg for other compounds, were directly applied on the surface of detached semi-ripe tomato fruits. The fruit was stored at room temperature for 3–14 days (¹⁴C-methidathion) or 7 days (other compounds) and then extracted with acetone-water (9:1). When ¹⁴C-methidathion at a rate of 14 mg/kg was applied, 97 percent of applied radioactivity (AR, 12 mg eq/kg) was recovered 14 days after treatment (DAT). Desmethyl methidathion was the main residue (41 percent TRR, 4.8 mg eq/kg), followed by RH-cysteine conjugate (33 percent TRR, 3.8 mg eq/kg), methidathion (9.8 percent TRR, 1.1 mg eq/kg), its oxygen analogue (3.2 percent TRR, 0.37 mg eq/kg) and GS-20685 (0.43 percent TRR, 0.05 mg eq/kg).

In tomatoes treated with ¹⁴C-desmethyl methidathion (7 DAT), 93 percent AR (6.2 mg eq/kg) was recovered. Identified compounds were: unchanged desmethyl methidathion (52 percent TRR, 3.2 mg eq/kg), RH-cysteine conjugate (21 percent TRR, 1.3 mg eq/kg) and RH-sulfide (1.1 percent TRR, 0.07 mg eq/kg). In tomatoes treated with ¹⁴C-RH-sulfide (7 DAT), 96 percent AR (5.6 mg eq/kg) was recovered. Identified compounds were RH-sulfoxide (60 percent TRR, 3.4 mg eq/kg) and RH-cysteine conjugate (14 percent TRR, 0.78 mg eq/kg) and unchanged RH-sulfide (20 percent TRR, 1.1 mg eq/kg). In tomatoes treated with ¹⁴C-RH-sulfoxide (7 DAT), 95 percent AR (6.8 mg eq/kg) was recovered. Identified compounds were unchanged RH-sulfoxide (70 percent TRR, 4.7 mg eq/kg), RH-sulfone (16 percent TRR, 1.1 mg eq/kg), and RH-cysteine conjugate (7.7 percent TRR, 0.52 mg eq/kg). When ¹⁴C-RH-sulfone was applied, 96 percent AR (6.4 mg eq/kg) was recovered in the fruit, with 89 percent TRR (5.8 mg eq/kg) of unchanged RH-sulfone and 2.8 percent TRR (0.18 mg eq/kg) of RH-cysteine conjugate.

In a metabolism study on common beans, plants were cultivated in pots and methidathion ¹⁴C-labelled at 2-carbonyl, 3-methylene, O-methyl or 2-carbonyl-RH was topically applied to leaves. Samples were collected 7–16 days after the treatment. The samples were extracted with acetone-water (8:2) and partitioned with chloroform and radioactivity in the chloroform phase was identified by TLC. Aqueous phase was not further identified. During the experiment, ¹⁴CO₂ was collected in 2 mol/L NaOH traps. Radioactivity was found in chloroform phase (3.6–8.9 percent AR), water phase (20–55 percent AR), non-extracted (1.6–12 percent AR) and ¹⁴CO₂ (2.3–27 percent AR). When methidathion or methidathion oxygen analogue was applied, methidathion, oxygen analogue and RH were recovered in chloroform phase (1.3–6.0 percent AR, 0.15–up to 5.4 percent AR, respectively). When RH was applied, radioactivity was mainly found in water phase (55.3 percent AR) and 5.4 percent AR of RH was recovered. Further information is not available in the study on common beans.

In a metabolism study on alfalfa, plants were cultivated in field and 2-carbonyl-¹⁴C-methidathion was topically applied to leaves. Samples were collected 7–16 days after the treatment. The sample was extracted by acetone-water (8:2) and partitioned with chloroform and chloroform phase was identified by TLC. During the experiment, ¹⁴CO₂ was collected in 2 mol/L NaOH traps. Radioactivity was found in chloroform phase (33–56 percent AR), water phase (14–32 percent AR), non-extracted (2.9–6.4 percent AR) and ¹⁴CO₂ (14 percent AR). In chloroform phase, methidathion, its oxygen analogue and RH were 32–53, 0.33–0.86 and 0.43–1.7 percent AR, respectively. In water phase, RH conjugate was found. Further information is not available in the study on alfalfa.

Summary of plant metabolism

When methidathion was applied to oranges, the parent methidathion was found in peel (24 percent TRR, 0.25 mg eq/kg), but not in juice. Major metabolites were RH-alanine conjugate (14 percent TRR, 0.14 mg eq/kg in peel and 72 percent TRR, 0.18 mg eq/kg in juice) and RH-acetic acid, lactic acid or hydroxy acetic acid conjugate (3.7 percent TRR, 0.04 mg eq/kg in peel and 10 percent TRR, 0.03 mg eq/kg in juice). When methidathion was applied to tomato fruits, desmethyl-methidathion (39–42 percent TRR, 2.3–4.8 mg eq/kg), RH-cysteine conjugate (34–35 percent TRR, 2.1–3.8 mg eq/kg), parent methidathion (9.8 percent TRR, 1.1 mg eq/kg), and its oxygen analogue (3.2 percent TRR, 0.37 mg eq/kg). When tomatoes were treated with ¹⁴C-desmethyl methidathion, the major residues were unchanged desmethyl methidathion (52 percent TRR, 3.2 mg eq/kg) and RH-cysteine conjugate (21 percent TRR, 1.3 mg eq/kg) were the major metabolites. When methidathion was applied to common beans and alfalfa, parent methidathion (1.3–53 percent AR), its oxygen analogue (0.15–0.86 percent AR) and RH (\leq 1.7 percent AR) were found.

The Meeting noted that metabolites found in various plants were desmethyl-methidathion, the oxygen analogue of methidathion and RH or its conjugate, although some of them might not be observed depending on plant species. The Meeting concluded that the metabolic profiles between the species were qualitatively similar.

Animal metabolism

The Meeting received animal metabolism studies on rats, lactating cows and lactating goats.

Rats

The metabolism of methidathion in rats was reviewed in the framework of the toxicological evaluation by the WHO Core Assessment Group of the 2022 JMPR.

Cattle

In a metabolism study on lactating cow, 2-carbonyl-¹⁴C-methidathion was administered orally in capsules three times per day for 5 consecutive days at 1 mg/kg bw per day (equivalent to 32 ppm) and the cow was sacrificed 10 days after the last application (DALA). Radioactivity in milk increased to 0.5 mg eq/kg at 1 DALA and then decreased to 0.004 mg eq/kg at 10 DALA, and no clear plateau was observed. Through the study period, accumulated total radioactivity recovered from milk was 0.6 percent AR (0.5 mg eq/kg) and oxygen analogue of methidathion was not found in milk (LOD: 0.01 mg eq/kg). Radioactivity was detected in liver at 0.11 mg eq/kg, kidney at 0.04 mg eq/kg, omental fat at 0.03 mg eq/kg, and muscle, at 0.02 mg eq/kg after 10 days of post-dosing period. No identification or characterization was conducted.

In another study of metabolism on lactating cow, 2-carbonyl-¹⁴C-methidathion was administered orally once at 1.7 mg/kg bw (equivalent to 120 ppm). Radioactivity in milk collected after administration for 96 hours was 0.8 percent AR (0.53 mg eq/kg).

In the same study, an additional metabolism study on lactating cow was conducted. A cow was given orally 1.25 mg/kg daily of methidathion (non-labelled) for 16 days, and then 2-carbonyl-¹⁴C-methidathion was orally administered once at 1.7 mg/kg bw (equivalent to 61 ppm). Milk was collected at the end of 12 and 24 hours after administration. Radioactivity in the milk for 0–12 and 12–24 hours after the application of labelled methidathion was 1.2 and 0.7 percent AR, respectively. In both milk samples, methidathion was not detected, and RH-sulfone and RH-sulfoxide accounted for 3.4 and 0.9 percent of TRR in milk, respectively, of the total radioactivity in milk collected within 12 hours after application. Further identification for the rest of radioactivity (95.7 percent TRR of milk) was not conducted.

Goat

In a metabolism study on lactating goats, 0.88 mg/kg bw (equivalent to 38 ppm) of 2-carbonyl-¹⁴C-methidathion was once administered by stomach tube. At 3 DAT (72 hours after the single dose), 1 percent AR of radioactivity was found in milk. Methidathion or its oxygen analogue was not found in milk. No further identification or characterization was conducted.

Summary of animal metabolism

When single or multi dose of methidathion was orally administered to cattle, radioactivity was detected in the most of tissues and milk. In milk, RH-sulfone and RH-sulfoxide were detected (<5 percent AR total), and methidathion and its oxygen analogue were not detected. Since information on metabolites was insufficient in milk or tissues, it was not possible to estimate metabolic pathway in livestock.

Environmental fate

On soil surface, degradation of methidathion in soil followed first order kinetic degradation with half-lives of 1.7 days under the sunlight and 2.6–5.8 days in the dark, depending on the existence of microorganisms and surfactant. Neither RH nor the methidathion oxygen analogue was produced by light degradation. Further identification was not conducted. The Meeting concluded that degradation of methidathion was rapid in soil.

Methods of analysis

The Meeting received seven methods of analysis used for the determination of methidathion in the supervised field trials. Six of them were similar GC methods with some modifications and one was an LC-MS/MS method. In the validation studies, spiked samples were not analysed at day zero. However, since analysis of at least one sample within 1 month after spiking resulted in satisfactory recovery, the Meeting considered that the analytical values at day zero would be almost 100 percent of spike.

For GC methods, methidathion was extracted with acetone or ethyl acetate, cleaned up, and analysed using GC coupled with FID, ECD or FPD. The Meeting confirmed that the methods were validated for methidathion in mandarin, apple, peach and cherry with an LOQ of 0.1 or 0.2 mg/kg and mango with an LOQ of 0.005 mg/kg.

For the LC-MS/MS method, methidathion was extracted with acetone, cleaned-up, and analysed using LC-MS/MS. The Meeting confirmed that the method was validated for methidathion in peach, cherry and grape with an LOQ of 0.005 mg/kg and mango with a LOQ of 0.01 mg/kg.

Stability of pesticide residues in stored analytical samples

Stability studies on methidathion residues in fortified mandarin (up to 7 months), apple (up to 7 months), cherry (up to 2.5 months), peach (up to 9 months), grape (up to 10 months) and mango (up to 4 months) were available. Noting the various storage periods for matrices in the same group, the Meeting concluded that methidathion in high water and high acid content commodities stored at ≤ -20 °C was stable for at least 9 and 7 months, respectively. In supervised trials received at the current Meeting, all samples were kept frozen at ≤ -20 °C and analysed within 7 months from sampling except in two trials, where the data were not used in the assessment.

Definition of the residue

Plant commodities

In the metabolism studies on orange, tomato, common beans and alfalfa, parent methidathion was found in all primary crop commodities analysed (7.2 percent TRR in orange, 8.4–9.4 percent TRR in tomato, 1.3–6.0 percent AR in bean plant and 32–53 percent AR in alfalfa plant). The Meeting noted that suitable analytical methods exist to determine methidathion in plant commodities. The Meeting considered that parent methidathion was suitable marker for MRL-compliance.

Based on the plant metabolism studies, the following compounds could be included in the residue definition for dietary risk assessment: conjugate of RH with alanine, acetic acid, hydroxyacetic acid, lactic acid, methanol (GS-20685), cysteine and sulfoxide; desmethyl-methidathion and the oxygen analogue of methidathion.

For RH and its conjugates of alanine, lactic acid, acetic acid, hydroxyacetic acid, cysteine, methanol (GS-20685) or sulfoxide, the Meeting concluded that the same ADI as methidathion should apply (0-0.002 mg/kg bw) and no ARfD was necessary due to lack of phosphate moiety. The Meeting noted that the total levels of RH (free and conjugated) in the metabolism studies were significant: 7.2 percent TRR (0.26 mg eq/kg) in peel and 82 percent TRR (0.21 mg eq/kg) in juice in the study on oranges; 36–37 percent TRR (2.2–4.0 mg eq/kg) in the study on tomatoes; 0.55–0.66 percent AR in the study on beans; and 0.33–0.86 percent AR in the study on alfalfa. The Meeting concluded that these RH conjugated compounds should be included in the residue definition.

For desmethyl methidathion, the Meeting concluded that the same ADI and ARfD as methidathion should apply (ADI: 0–0.002 mg/kg bw, ARfD: 0.01 mg/kg bw). The Meeting noted that the level of desmethyl methidathion in the study on tomato was significant (39–42 percent TRR, 2.3–4.8 mg eq/kg). The Meeting concluded that desmethyl methidathion should be included in the residue definition.

For oxygen analogue, it was found in the metabolism study of tomato, bean and alfalfa but not in the study on orange. In the case of tomato, as the ratio of oxygen analogue (0.37 mg eq/kg) to the parent compound (1.14 mg eq/kg) was higher than 10 percent, the Meeting concluded that oxygen analogue should be included in the residue definition.

The Meeting concluded that since the mechanism of toxicity was similar to that of methidathion, oxygen analogue should be considered together with the parent methidathion for dietary risk assessment. As the potency of the oxygen analogue as an AChE inhibitor was considered to be about four times that of methidathion, the Meeting agreed to apply a potency factor of 4 to the residues of the oxygen analogue for long-term and short term risk assessment.

In conclusion, the definition of the residue for compliance with the MRL for plant commodities: *methidathion*.

The definition of the residue for long-term dietary exposure assessment for plant commodities: *sum of methidathion, S-2,3-dihydro-5-methoxy-2-oxo-1,3,4-thiadiazol-3-ylmethyl O-methyl phosphorodithioate (desmethyl methidathion) and 2,3-dihydro-5-methoxy-1,3,4-thiadiazol-2-one (RH; free and conjugate), and 4x S-2,3-dihydro-5-methoxy-2-oxo-1,3,4-thiadiazol-3-ylmethyl O,O-dimethyl phosphorothioate (oxygen analogue), expressed as methidathion.*

Definition of the residue for acute dietary exposure assessment for plant commodities: *sum of methidathion and 4x S-2,3-dihydro-5-methoxy-2-oxo-1,3,4-thiadiazol-3-ylmethyl O,O-dimethyl phosphorothioate, expressed as methidathion.*

Animal commodities

For cattle, parent methidathion was detected in muscle, kidney and fat but not in liver and milk. In addition, methidathion may be detected in egg yolk (See animal feeding study). The Meeting considered that parent methidathion alone was not a suitable marker for enforcement.

In the metabolism studies, a large portion of radioactivity was not identified. Due to lack of further information on metabolites, the Meeting could not establish residue definitions for animal commodities.

Results of supervised residue trials on crops

Since all the metabolites included in the residue definition for dietary risk assessment were not analysed in the supervised trials, and the information in the metabolism studies was not sufficient to estimate conversion factors, the Meeting could not estimate STMRs and HRs. The Meeting agreed to estimate maximum residue levels but not to recommend them for adoption.

Citrus fruits, Group of***Mandarins, Subgroup of***

The critical GAP for methidathion on mandarin in Japan is four foliar applications of 0.027 kg ai/hL and a PHI of 14 days.

No trials matched the Japanese GAP. The Meeting could not estimate a maximum residue level.

Pome fruits, Group of***Apple***

The critical GAP for methidathion on apple in Japan is for two foliar applications of 0.024 kg ai/hL with a PHI of 30 days.

In trials matching the GAP in Japan, residues of methidathion in apple were (n=7): < 0.1 (7) mg/kg. In trials with one application at 0.024 kg ai/hL and a PHI of 30 days at the same location as the trials with two applications, residues of methidathion in apple were higher than with two applications in 2 trials: 0.10 and 0.11 mg/kg. Therefore, residues of methidathion in apple were ((n=7): < 0.1 (5), 0.10 and 0.11 mg/kg.

In these supervised trials, the concentration was expressed on the basis of fruit weight after removal of core. The Meeting considered that the contribution of the core to the weight of the whole fruit is 9.8–14 percent and concluded that correcting the residue levels using this weight/weight ratio would lead to the same maximum residue level.

The Meeting estimated a maximum residue level of 0.2 mg/kg.

Since the analytical data for compounds in the residue definition were not sufficient in the supervised trials and metabolism study was not sufficient to estimate conversion factors, the Meeting could not conclude the assessment.

Pear

The Meeting could not estimate maximum residue level for pears since no data were available.

*Stone fruits**Cherries*

The critical GAP for methidathion on cherries in Japan is three foliar applications at 0.027 kg ai/hL and a PHI of 7 days. In trials matching the GAP conducted in Japan, residues of methidathion in cherries were (n=9): < 0.01 (2), 0.01, 0.02, 0.04, 0.05 and < 0.1(3) mg/kg.

In the supervised trials, the concentration was expressed on the basis of fruit weight after removal of seeds. The Meeting considered that the contribution of the seed to the weight of the whole fruit is less than 10 percent and concluded that correcting the residue levels using this weight/weight ratio would lead to the same maximum residue level.

The Meeting estimated a maximum residue level of 0.3 mg/kg.

Since analytical data for compounds in the residue definition were not sufficient in the supervised trials and metabolism study was not sufficient to estimate conversion factors, the Meeting could not conclude the assessment.

Peaches

In the critical GAP for methidathion on peaches in Japan is for 2 trunk injections (0.15 kg ai/hL) followed by two foliar applications of 0.024 kg ai/hL with a PHI of 21 days.

In trials matching the GAP, residues of methidathion in peaches were (n=4): 0.006, 0.011, 0.020 and < 0.1 mg/kg. The Meeting could not estimate a maximum residue level due to insufficient number of trials.

*Berries and other small fruits, Group of**Grapes*

The critical GAP for methidathion on grapes in Japan is two foliar applications at 0.024 kg ai/hL and a PHI of 14 days.

In trials matching the critical GAP conducted in Japan, residues of methidathion in grapes were (n=5): 0.008, 0.01, 0.02, 0.05 and 0.18 mg/kg. The Meeting could not estimate a maximum residue level due to insufficient number of trials.

*Tropical and sub-tropical fruits—inedible peel, Group of**Mango*

The critical GAP for methidathion on mangoes is in Japan and consists of two foliar applications of 0.027 kg ai/hL and a PHI of 45 days. In trials matching the GAP conducted in Japan, residues of methidathion in mango was (n=4) 0.02, < 0.03, 0.04 and 0.08 mg/kg.

In one supervised trial, mango was treated with three foliar applications at the same concentration and PHI as cGAP. In the trial, the residue of methidathion in mango was 0.007 mg/kg, which was lower than residue data from 3 applications. The Meeting assumed that the trial was considered to approximate GAP since the first application applied 59 days before harvest did not contribute to the residues at harvest.

In the trials on mango conducted in Japan approximating the GAP residue level were (n=5): 0.007, 0.02, < 0.03, 0.04 and 0.08 mg/kg.

The Meeting noted that in the supervised trials, the concentration was expressed as the basis of fruit weight after removal of seeds. The Meeting considered that the contribution of the seed to the weight of the whole fruit is less than 10 percent and concluded that correcting the residue levels using this weight/weight ratio would lead to the same maximum residue level.

The Meeting estimated a maximum residue level of 0.15 mg/kg.

Since the analytical data for compounds in the residue definition were not sufficient in the supervised trials and metabolism study was not sufficient to estimate conversion factors, the Meeting could not conclude the assessment.

Tea, green, black

The Meeting could not estimate a maximum residue level for tea, green, black since no data were available.

Fates of residues during processing

Processing study on grape to dried grape was available. Degradation of methidathion was observed in the process and the processing factors were 0.02–0.35, depending on the temperature of drying. The Meeting assumed the worst case scenario (50 °C, 72 hours) and the processing factor from grape to dried grape was estimated 0.35.

A study on degradation of methidathion in fruit juices (orange and peach) was available. When juices were stored at 40 °C, methidathion was reduced (half-life of 3.8–4.1 days), but degraded more slowly at lower temperatures (half-lives of =114–115 days at 15 °C and 330–385 days at 0 °C). At ambient temperature, the Meeting considered that the degradation of methidathion in juices at the shelf could be negligible.

Residues in animal commodities

Farm animal feeding studies

A dairy cow feeding study was available to the Meeting. Methidathion in gelatine capsule was administered orally twice daily to three groups of dairy cow (four for each) for 66 days at levels equivalent to 7.5, 15 or 30 ppm. The residue levels of methidathion and oxygen analogue of methidathion in milk and any tissues were < 0.01 mg/kg and < 0.025 mg/kg, respectively.

A laying hen feeding study was available in open literature. Feed containing methidathion at levels of 10, 50, 100 or 500 ppm were fed *ad libitum*. The residue was not detected in egg yolk from 10 ppm group hens (LOQ: 0.002 mg/kg). In 50 and 100 ppm group, low level of methidathion residues (< 0.02 mg/kg) were detected in egg yolk. No information on residues was available.

Farm animal dietary burden

From the commodities evaluated, the only processed commodity appearing in the OECD feed table was apple pomace. Since processing factors from apple to apple pomace for methidathion, desmethyl methidathion, oxygen analogue and RH (free+conjugate) were not available, the Meeting could not estimate the concentration of methidathion and its metabolites in animal commodities.

Animal commodity maximum residue levels

Since no conclusion could be reached on a residue definition for animal commodities, the Meeting withdrew all previous recommendations for animal commodity maximum residue levels for methidathion.

RECOMMENDATIONS

Definition of the residue for compliance with the MRL for plant commodities: methidathion

Definition of the residue for long-term dietary exposure assessment for plant commodities: sum of methidathion, S-2,3,-dihydro-5-methoxy-2-oxo-1,3,4-thiadiazol-3-ylmethyl O-methyl phosphorodithioate and 2,3-dihydro-5-methoxy-1,3,4-thiadiazol-2-one (free and conjugate), and 4× S-2,3-dihydro-5-methoxy-2-oxo-1,3,4-thiadiazol-3-ylmethyl O,O-dimethyl phosphorothioate, expressed as methidathion

Definition of the residue for acute dietary exposure assessment for plant commodities: sum of methidathion and 4× S-2,3-dihydro-5-methoxy-2-oxo-1,3,4-thiadiazol-3-ylmethyl O,O-dimethyl phosphorothioate, expressed as methidathion.

Definition of the residue for animal products (for compliance with the MRL and for dietary exposure assessment): **a conclusion could not be reached.**

The residue is not fat soluble.

DIETARY RISK ASSESSMENT

No recommendations were made at the present meeting as the Meeting could not reach a conclusion on the residue definitions for animal commodities and sufficient residue data for metabolites were not available. No dietary risk assessment was conducted.

5.28 Pyridate (315)

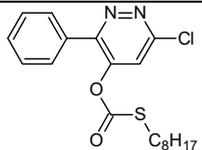
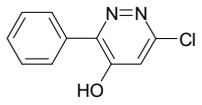
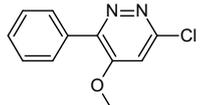
RESIDUE AND ANALYTICAL ASPECTS

Pyridate is an herbicide of the phenylpyridazine class used to control annual broad-leaved weeds. It acts by inhibiting the photosynthetic electron transport at the photosystem II. The IUPAC name of pyridate is 0-6-chloro-3-phenylpyridazine-4-yl S-octyl thiocarbonate

Pyridate was scheduled at the Fiftieth Session of the CCPR for evaluation as a new compound by the 2020 JMPR, reviewed by the 2019 JMPR for toxicology, where an ADI of 0–0.2 mg/kg bw and an ARfD of 2 mg/kg bw were established. The residue assessment was rescheduled to the current JMPR.

The Meeting received information on identity, physicochemical properties, metabolism (plant, confined rotational crops and animals), environmental fate, methods of residue analysis, freezer storage stability, registered use patterns, supervised residue trials, fate of residues in processing, and livestock feeding studies.

Table 5.28.1 Abbreviations used for relevant compounds referred to in the appraisal

Code	Name	Structure
Pyridate (CL 11344)	6-chloro-3-phenylpyridazine-4-yl-S-octyl-thiocarbonate	 378.9 g/mol
Pyridafol (CL 9673)	6-chloro-4-hydroxy-3-phenylpyridazine	 206.6 g/mol
Pyridafol-O-methyl (CL 9673-OMe; CL 9869)	6-chloro-4-methoxy-3-phenylpyridazine	 220.7 g/mol

Physical and chemical properties

Pyridate and pyridafol (CL 9673) are not volatile. Pyridate is hydrolytically and photolytically unstable, resulting in the cleavage of the ester bond leading to pyridafol. The n-octanol water partition coefficient (log P_{ow}) of pyridate is 4.0.

Plant metabolism

The Meeting received plant metabolism studies in broccoli, maize and peanuts following application of [4,5-pyridazine-¹⁴C]-radiolabelled pyridate.

Broccoli

[4,5-pyridazine-¹⁴C]-radiolabelled pyridate was foliar applied once at the 2–3 leaf stage using a rate of 1.8 kg ai/ha under combined greenhouse and outdoor conditions. Plant samples were taken at 0 (immediately after the treatment), 14, 45, 73, 94 and 108 DAT.

The TRR was highest at 20 mg eq/kg in leaves immediately after treatment and declined to 0.011 mg eq/kg in samples taken at 108 DAT. In the edible parts (flower heads), TRR was significantly lower at 0.009 mg eq/kg (DAT 75, 96, 108 combined).

Broccoli samples were extracted with acetone and acetone/water (8+2, v/v). Conjugates were hydrolysed with 2 mol/L hydrochloric acid and β -glucosidase in extracts. Extracted radioactivity in the leaves and edible parts (flowers) was high, ranging between 75–100 percent TRR.

Post-extracted solids (PES) in leaf samples (14 or 45 DAT) was further subjected to 2 mol/L acetic HCl and enzymatic hydrolysis for characterization of radioactivity in natural products, such as starch, proteins, pectin and lignin.

Characterization of the radioactivity in broccoli flowers was not performed due to their low radioactivity in the extract. Parent pyridate was a major identified residue in leaf samples from 0 and 14 DAT, accounting for 42–60 percent TRR (2.6–12 mg eq/kg), while in leaves from 45 DAT parent pyridate was not detected at all. As a major metabolite, pyridafol was detected in leaf samples from 0 and 14 DAT, accounting for 7.4–18 percent TRR (0.45–3.5 mg eq/kg). In addition, N- and O-glucoside conjugates of pyridafol were found as the predominant residue at 14 and 45 DAT (19–25 percent TRR, 0.06–1.5 mg eq/kg). Two unknown components were detected at significant levels in leaf samples from 14 and 45 DAT, in combination accounting for 7.1 percent (0.43 mg eq/kg) and 23 percent TRR (0.07 mg eq/kg), respectively. One of these was characterized as very polar and resistant to hydrolysis treatment. The other was also characterized as being highly polar and susceptible to hydrolysis with beta-glucosidase (no corresponding aglycon identified).

Maize

The Meeting received two studies with maize (study 1: indoors at nights and outdoors during daytime; study 2: only outdoors), both performed with [4,5-pyridazine-¹⁴C]-radiolabelled pyridate. Maize plants at BBCH 14–15 (study 1) or BBCH 16–17 (study 2) were treated once with pyridate at 1.8 (study 1) or 1.73 (study 2) kg ai/ha. Plant samples were taken at 0 (immediately after the treatment), 14, 45, 90 and 118 (study 1) or 148 (study 2) DAT.

Generally, the detected radioactivity was higher in study 2. In both studies the TRR was highest in leaves ranging between 17 mg eq/kg (study 1) and 168 mg eq/kg (study 2) at 0 DAT and declined to 0.5 mg eq/kg (study 1) at 108 DAT and 0.27 mg eq/kg (study 2) at 148 DAT. The radioactivity in newly grown plant parts was at least one order in magnitude lower in both studies at the respective sampling time points compared to the treated leaves, indicating limited translocation in the plant. In maize grain, the TRR was low in both studies ranging between 0.01–0.014 mg eq/kg.

In both studies, samples were solvent extracted with acetone and with acetone/water (8+2, v/v), followed by more harsh acidic or enzymatic hydrolysis of the PES. Solvent extracted radioactivity was high in the treated leaves from 0–14 DAT, ranging between 82–100 percent, but was lower in treated leaves from 45–108 DAT and in newly grown leaves, ranging between 24–75 percent TRR.

For maize grain, the radioactivity in the extract was < 0.01 mg eq/kg (study 1, 118 DAT) and no further analysis of the radioactivity was performed. No extraction was performed in grain samples from study 2 (148 DAT).

In the treated leaves from study 1 taken at 0 and 14 DAT, parent pyridate was a major identified residue, accounting for 82 percent TRR (14 mg eq/kg) and 11 percent TRR (0.31 mg eq/kg), respectively. In leaves taken at later DAT, parent pyridate was at or below the LOD.

As a major metabolite, pyridafol was detected in leaf samples taken at 0 and 14 DAT, accounting for 15–16 percent TRR (0.44–2.6 mg eq/kg), decreasing to levels of around or below the LOD in leaf samples taken at later DAT. Its N- and O-glucosides accounting for 5.4–7.0 percent TRR (0.07–0.15 mg eq/kg).

Two unknown components were detected at significant levels in leaf samples taken at 14–90 DAT, accounting for a total of 15–38 percent TRR (0.07–0.69 mg eq/kg). One compound was characterized as being highly polar and was susceptible to hydrolysis with beta-glucosidase (no corresponding aglycon identified). The other decomposed into many unknown compounds following acid hydrolysis, however none could be attributed to pyridafol.

In the treated leaves of study 2 (14 DAT only), neither parent pyridate (3.0 percent TRR; 0.80 mg eq/kg), nor pyridafol (5.3 percent TRR; 1.4 mg eq/kg) were identified as major residues. Instead, three unknown components accounted for 9.5 percent TRR (2.5 mg eq/kg), 20 percent TRR (5.3 mg eq/kg) and 41 percent TRR (11 mg eq/kg).

Peanut

[4,5-pyridazine-¹⁴C]-radiolabelled pyridate was foliar applied once to peanut plants (12.7 cm high) using a rate of 3.6 kg ai/ha under combined greenhouse and outdoor conditions. Plant samples were taken at 0 (immediately after the treatment), 14, 45 and 219 DAT.

The TRR was highest at in peanut forage taken immediately after treatment at 59 mg eq/kg and in hay from 45 DAT at 38 mg eq/kg. However, levels in both matrices declined to 0.22 mg eq/kg in forage and 1.5 mg eq/kg in hay taken at 219 DAT. In peanut hulls and nutmeat from 219 DAT, TRR levels were 0.36 mg eq/kg and 0.04 mg eq/kg, respectively.

The samples were extracted with acetone and acetone/water (8+2, v/v). Conjugates were hydrolysed with 2 mol/L hydrochloric acid and β -glucosidase. Extracted radioactivity was high from peanut forage taken at 0 and 14 DAT, ranging between 78–100 percent TRR, but lower for forage samples taken at later DAT, as well as for peanut hay and hulls ranging between 38–64 percent TRR. For nutmeat, the extracted radioactivity was even lower at 33 percent TRR.

The PES was further subjected to harsher treatments using acid and enzymatic hydrolysis as well as characterization of radioactivity into natural products for forage samples (45 DAT), demonstrating assignment to natural constituents such as starch, proteins, pectin and lignin.

Characterization of the residue in the nutmeat was not performed due to its low radioactivity in the extract.

Parent pyridate and pyridafol were major identified residues in forage samples from 0 DAT only, accounting for 86 percent TRR (51 mg eq/kg) and 10 percent TRR (6.2 mg eq/kg), respectively. In forage from later DAT, as well as in hay or hulls levels of pyridate and pyridafol were much lower (up to 4.6 percent TRR, 0.83 mg eq/kg) or non-detectable and also pyridafol-N or O-glucoside was found at low levels not exceeding 5.6 percent of the TRR (max. 1.1 mg eq/kg in hay). Two unknown components were detected at significant levels in forage (14–45 DAT), hay and hulls accounting for 14–19 percent TRR (1.4–5.4 mg eq/kg), 10–18 percent TRR (0.15–6.9 mg eq/kg) and 11 percent (0.04 mg eq/kg), respectively. One minor identified metabolite was pyridafol-OME at up to 4.7 percent TRR (0.07 mg eq/kg) in hay (215 DAT).

Alfalfa

Reference to an additional plant metabolism study for the use of pyridate on alfalfa was made in the storage stability study on incurred radioactive residues. The study was not provided to the Meeting.

In summary, the metabolic pathway of pyridate in broccoli, maize and peanut was similar. In all studies, pyridate did undergo rapid hydrolytic cleavage into pyridafol. Biotransformation of pyridafol occurred mainly by glucosidic conjugation, yielding in the pyridafol-N-glucoside and pyridafol-O-glucoside. Further degradation led to highly polar metabolites, before the radioactivity was incorporated into the carbon pool of natural plant constituents. Only limited translocation in the plant was observed.

Environmental fate

For the investigation of the environmental fate of pyridate, the Meeting received studies on hydrolysis, aerobic soil degradation, soil photolysis and on the behaviour in confined rotational crops.

Hydrolysis

Pyridate was shown to be susceptible to hydrolysis, by cleavage of the ester bond leading to pyridafol. DT₅₀ values at 25 °C ranged between 117 hours at pH 4 to 6.2 hours at pH 9. The Meeting concluded that hydrolysis of pyridate will be a significant route of degradation in the aquatic environment.

Aerobic soil metabolism

The rate of degradation of pyridate and its metabolite pyridafol was studied in various aerobic soils using [4,5-pyridazine-¹⁴C]-radiolabelled pyridate, pyridafol and pyridafol-OMe. Rapid degradation of pyridate was observed at 20°C with estimated half-lives ranging from 0.3 to 3.3 days. Metabolite pyridafol peaked at day 1 or 2 at a maximum of 72–91 percent AR and showed moderate degradation with half-lives ranging from 17–43 days. Additionally, metabolite, pyridafol-OMe was detected at up to 3.5–16 percent AR on day 7–70 and showed moderate degradation with half-lives ranging from 12–25 days. The Meeting concluded that pyridate and its metabolites are not persistent in soil.

Soil photolysis

The soil surface photolytic behaviour of pyridate and its metabolite pyridafol was studied in an aerobic soil using [4,5-pyridazine-¹⁴C]-radiolabelled pyridate. Under the assumption of average daylight of 12 hours, half-lives were estimated for pyridate and pyridafol at 1.8 days and 19 days respectively. Further degradation products were not identified. The Meeting concluded that photolysis is a significant degradation pathway for pyridate and moderately affects its metabolite pyridafol.

Rotational crop metabolism

Confined rotational crop studies

The Meeting received one confined rotational crop study under mixed outdoor and indoor conditions with lettuce, carrots and spring barley grown in rotation.

The study was conducted with [4,5-pyridazine-¹⁴C]-radiolabelled pyridate applied at a rate equivalent to 1.8 kg ai/ha to a silty loam soil and plant back intervals (PBIs) of 28 and 56 days. The nature and level of radioactive residues from the 28 day PBI were investigated in lettuce at 97 DAT, in carrots at 133 DAT and in barley at 163 DAT. In crops from the 56 day PBI residues were investigated in lettuce at 156 DAT, in carrots at 169 DAT and in barley at 209 DAT.

Radioactivity in plant samples was generally low (< 0.01 mg eq/kg), except for barely straw (up to 0.1 mg eq/kg) and barley grain (up to 0.030 mg eq/kg).

Samples were extracted with methanol and methanol/water (8+2, v/v). Conjugates present in the extracts were hydrolysed overnight with 2 mol/L HCl. The extractability for all samples was between 19 and 83 percent TRR. No characterization of the unextracted residue was performed.

Characterization and identification of the radioactivity was only performed in the extracts of barley straw. While no pyridate or metabolites could be identified, the main portion of the extracted radioactivity was allocated to saccharides.

The Meeting concluded that uptake from soil is low and pyridate is metabolized into highly polar metabolites, before the radioactivity was incorporated into the carbon pool.

Animal metabolism

The Meeting received animal metabolism studies on rats, lactating cows and goats and laying hens where animals were dosed with [4,5-pyridazine-¹⁴C]-radiolabelled pyridate.

Rats

The metabolism of pyridate in rats was reviewed in the framework of the toxicological evaluation by the WHO Core Assessment Group of the 2019 JMPR.

Cattle

[4,5-pyridazine-¹⁴C]-radiolabelled pyridate was administered once as a single dose of 0.3 mg/kg bw (equivalent in feed not stated) at day 1 and 14 by intra-ruminal injection to one cow. After administration of the first dose, urine and faeces were collected once daily for 7 consecutive days (except urine which was collected three times within the first 24 h). Milk was collected twice daily throughout the study. The animal was sacrificed approximately 6 hours after administration of the second dose and tissues were collected.

After three days, the elimination of administered radioactivity was complete. The main route occurred via urine (92 percent AR), followed by faeces (8.6 percent AR).

In organs and tissues, radioactivity was significantly lower with 1.957 mg eq/kg in the kidney, 0.138 mg eq/kg in the liver and < 0.0034 mg eq/kg in the muscle. In milk the total radioactivity was low too, reaching a maximum of 0.03 mg eq/kg after 7 hours. After 31 hours, no radioactivity was detected in any milk samples.

Characterization of the radioactivity in edible tissues was only done for liver and kidney. While no information was given on the extractability of the residue, co-chromatography of the extracts with reference standards identified pyridafol in kidney (level not given), as well as pyridafol-N- and O-glucoside (up to 0.1 mg eq/kg) in liver.

Goats

[4,5-pyridazine-¹⁴C]-radiolabelled pyridate was administered orally once daily to one lactating goat at 2.8 ppm (0.38 mg/kg bw and d) for 10 consecutive days. Urine and faeces were collected once daily, while milk was collected twice daily. The animal was sacrificed approximately 24 hours after the last dose and samples of organs, tissues and body fluids were collected.

The majority of the radioactivity was found in urine (95 percent AR) followed by faeces (6.5 percent AR). Radioactive residues in the edible tissues were low at 0.019 mg eq/kg and

0.033 mg eq/kg in liver and kidney, respectively. Similar levels were found in milk, ranging between 0.015–0.048 mg eq/kg. A plateau was reached in milk after 3 days of consecutive administration. Residues in muscle and fat were 0.003 mg eq/kg and 0.009 mg eq/kg, respectively.

Extraction with acetone/water (8+2, v/v) followed by acetone released 63 percent TRR (0.01 mg eq/kg) from liver and 87 percent TRR (0.027 mg eq/kg) from kidney. Since radioactivity was low, identification was only successful in kidney, where metabolites pyridafol and pyridafol-OMe were tentatively identified, present at 32 percent TRR (0.010 mg eq/kg) and 48 percent TRR (0.015 mg eq/kg), respectively. In milk only pyridafol was identified at 49–71 percent TRR (0.012–0.015 mg eq/kg).

Poultry

A metabolism study was performed with 6 laying hens and 6 broiler chickens receiving a single oral dose of [4,5-pyridazine-¹⁴C]-radiolabelled pyridate at 2.5–4.7 ppm (0.2 mg/kg bw and d). Excreta were collected once daily up to 96 h post dose, while eggs were collected twice daily if possible and separated in to egg yolk and white. All animals were sacrificed at 96 hours post dose. No individual organs or tissues were collected.

Within 24 hours post-dose, the majority of the radioactivity was found in excreta at 93–96 percent, increasing to 97–99 percent after 96 h, demonstrating fast elimination.

Detected radioactivity in egg yolks and egg whites was consistently <LOQ for throughout the sampling time of 0–96 h post dose, with the exception of egg whites collected at 24–48 h post dose with a mean of 0.004 mg eq/kg.

Since no organs or tissue were collected, no further identification or characterization of the radioactive residues was performed. However, in excreta, metabolites pyridafol and hydroxylated pyridafol accounted for up to 74 percent TRR and 44 percent TRR, respectively.

A second metabolism study was performed with 9 laying hens receiving [4,5-pyridazine-¹⁴C]-radiolabelled pyridate orally once daily for 5 consecutive days at ~3 ppm (0.19 mg/kg bw and d). Excreta and eggs were collected once daily and during the depuration phase additionally at 4, 8, and 24 hours after the last treatment. Eggs were separated in yolk and white. Three hens each were sacrificed at 8 hours, 3 days and 7 days after the final dose and organs, tissues and body fluids were collected.

Within 8–168 hours post-dose, the majority of the radioactivity was found in excreta at 93–96 percent AR, indicating rapid elimination. Radioactive residues in the edible matrices after 8 hours depuration were generally low, at 0.04 mg eq/kg in kidney, 0.02 mg eq/kg in liver and < 0.01 mg eq/kg in all other edible tissues. Similar levels were found in egg samples with maximum residues in yolks and whites at 0.007 mg eq/kg and 0.01 mg eq/kg, respectively.

No further identification or characterization of the radioactive residues in organs or tissues was performed.

In summary, the Meeting concluded that in all species investigated (cows, goats, hens and rats), the total administered radioactivity was predominantly eliminated in excreta. Information on the metabolic pathway was scarce, mostly due to the low levels of radioactivity in various organs and tissues, but seems comparable between species. The only metabolites identified in edible matrices were pyridafol, found in goat kidney and milk, and pyridafol-OMe in goat kidney.

Methods of analysis

The Meeting received information on analytical methods for pyridate in plant and animal matrices.

For matrices of plant origin, the basic principle of most methods, employed extraction with alkaline solution of acetone/ammonium acetate (5:1) + morpholine, converting pyridate to pyridafol. Conjugates were hydrolysed with sulfuric or hydrochloric acid. Clean up involved one or a combination of the following: partitioning between ammonium acetate and dichloromethane, clean up on a silica or C18 cartridge, solid-supported liquid-liquid partition with n-hexane/tert-butyl methyl ether (1:1, v/v). Pyridafol was determined by either HPLC with column switching technology and UV detection (LC-LC-UV) with an LOQ of 0.02 or 0.05 mg/kg (as pyridafol), or by LC-MS/MS in positive ESI mode with an LOQ of 0.05 mg/kg (as pyridate).

For matrices of animal origin, two methods were provided. The first method employed extraction with alkaline solution of acetone/ammonium acetate (5:1) + morpholine, hydrolysis of conjugates with sulfuric acid, followed by clean up employing partitioning with dichloromethane and SPE on a silica cartridge. Quantitation was done by LC-LC-UV with an LOQ of 0.03 mg/kg (as pyridafol). The second method involved extraction with acetonitrile/water (5:1) in the presence of morpholine and clean up by SPE on a C18 cartridge. Quantitation of pyridafol was done by LC-MS/MS in positive ESI mode with an LOQ of 0.03 mg/kg (spiked and expressed as pyridafol) or 0.05 mg/kg (spiked and expressed as pyridate).

The Meeting concluded that the presented methods were sufficiently validated and are suitable to measure the total residue of pyridate as pyridafol in plant and animal matrices commodities.

Stability of pesticide residues in stored analytical samples

The Meeting received information on storage stability of pyridate (expressed as the sum of pyridate, pyridafol and hydrolysable pyridafol conjugates) in incurred residues (radiolabelled and non-radiolabelled) from various raw plant commodities.

In a study with radiolabelled residues performed in high water commodities (maize leaves, peanut leaves, broccoli leaves and alfalfa), samples were analysed for total pyridate initially after 4–14 months and re-analysed after an additional 10–28 months. After the first sampling, total pyridate residues covered >99 percent of the TRR analysed by the total residue method. In the second analysis, 86–90 percent TRR were recovered, suggesting that total pyridate was stable for at least 30 month under deep freezer conditions for maize, broccoli and alfalfa leaves. In peanut forage, 69.5 percent of the residue was recovered after 32 months in the second analysis, which is also the maximum storage period tested in this study.

A second study was performed with non-radiolabelled incurred residues in high water commodities (maize plant, rape plant, field pea plant and onion greens). Within the study the samples were analysed for the first time after about 3 to 14 months after sampling, followed by a second analysis after 24 to 59 months. No significant degradation of residues was observed in the respective time interval (> 81 percent of the first analysis).

The Meeting noted that the first analysis did not occur within a short period after harvest to quantify the time zero residue levels. However, since stability of high water commodities was demonstrated in the radiolabelled study, the Meeting concluded that storage up to 14 months is covered by the radiolabelled storage stability study and subsequent months by the non-radiolabelled study.

The Meeting agreed that the demonstrated storage stability on high water plant commodities was at least 59 months and covered the residue sample storage intervals used in the field trials considered by the current Meeting. However, no storage stability data was provided for other plant commodities or animal commodities.

Definition of the residue

Plant commodities

In the plant metabolism studies conducted on broccoli, maize and peanut, no identification of the total radioactivity in broccoli flowers, maize grain or peanut nutmeat was performed.

In other matrices, parent pyridate was a major residue only in samples taken at 0/14 DAT (broccoli leaves 60/42 percent TRR; maize leaves 82/11 percent TRR; peanut forage 86 percent TRR). Significant levels of pyridafol were mainly found in samples taken at 0 DAT (peanut forage 10 percent TRR) and declined rapidly at later DATs. At higher sampling intervals, the N- and O-glucoside of pyridafol were quantified in all matrices, but in major amounts only in broccoli leaves at 19–25 percent TRR.

The Meeting noted that no suitable single marker compound is present at harvest to measure pyridate residues in plant commodities. However, analytical methodology is available capable to quantify the total residue of parent pyridate, its metabolite pyridafol and conjugates thereof.

The Meeting decided to set the residue definition for compliance with the MRL as the sum of pyridate, its hydrolysis product pyridafol and hydrolysable conjugates of pyridafol, expressed as pyridate.

In all matrices investigated, unknown components (two in broccoli leaves, two in maize leaves and three in peanut forage, hay and hull) were found in major amounts, representing up to 41 percent TRR (up to 11 mg eq/kg). Characterization of these unknown components indicated that they are not structurally related to pyridafol and are not analysed by the total residue method. The application of pyridate as a herbicide happens early in the growing season. Since the peak occurrence of these unknown components was observed primarily at 14 to 90 DAT, which corresponds to PHIs in the use patterns provided, the Meeting concluded that they are likely to be present in harvested commodities and therefore demand identification and consideration in the dietary risk assessment, depending on their toxicological properties. Although identification in metabolism studies was only performed in inedible matrices, major levels of unknown components were found in all crop matrices, suggesting general occurrence in plants. In addition, the Meeting noted that a metabolism study on alfalfa exists, which was not made available to the current Meeting.

Without identification of these unknown components found at significant levels and information on the metabolism of pyridate in alfalfa, the Meeting decided not to establish a residue definition for dietary exposure purposes for pyridate in plant matrices.

Animal commodities

In ruminant metabolism studies, performed in a lactating cow and a goat, parent pyridate was not detected. The hydrolysis product pyridafol was tentatively identified in the goat at 32 percent TRR in kidney and 49-71 percent TRR in milk as well as pyridafol-OMe in kidney at 48 percent TRR. In the cow, the presence of pyridafol in the kidney and the N- and O-glucosides of pyridafol in the liver were postulated.

In poultry metabolism studies, no identification or characterization of the radioactive residues in organs or tissues was performed. However, in excreta metabolites pyridafol and hydroxylated pyridafol accounted for up to 74 percent TRR and 44 percent TRR, respectively.

In radiolabelled farm animal feeding studies performed with lactating cows and laying hens, one individual component was potentially identified in edible tissues of the 10x dosing group with a retention time close to pyridafol. Additionally, pyridafol and its glucuronides were identified in urine and bile from the cow feeding study.

The Meeting noted that the rate of identification in animal metabolism studies was generally low and no suitable single marker compound is present to measure pyridate residues in animal commodities. However, analytical methodology is available capable to quantify the total residue of parent pyridate, its metabolite pyridafol and conjugates thereof, which is suitable for enforcement purposes.

Parent pyridate has a octanol-water partition coefficient of 4.0, suggesting potential accumulation in fat. However, in farm animal feeding studies, total residues in liver, kidney and muscle were generally higher than in fat. Also, no accumulation of residues in egg yolk compared to egg white was observed. Consequently, the Meeting decided that residues of total pyridate in animal commodities are not fat-soluble.

Pending information on the nature of unknown components in plant matrices, exposure of livestock animals via feed cannot be characterized. The Meeting decided not to establish a residue definition for dietary exposure purposes for pyridate in animal matrices.

The Meeting recommended the following residue definitions for pyridate:

Definition of the residue for compliance with the MRL for plant and animal commodities: *Sum of pyridate and 6-chloro-4-hydroxy-3-phenylpyridazine (pyridafol) (incl. conjugates), expressed as pyridate.*

Definition of the residue for dietary exposure purposes for plant and animal commodities: *Not established.*

The Meeting considers the residue not to be fat soluble.

Results of supervised residue trials on crops

Supervised trials were available for the use of pyridate on onion, bulb, leek, spring onion, broccoli, cabbage, kohlrabi, kale, chickpea, maize and sweet corn (corn-on –the-cob), as well as on alfalfa and clover.

Product labels were available from Germany, Austria, Italy and Netherlands

In some field trials, the residue was expressed as equivalents of metabolite pyridafol. In order to convert these residues into pyridate equivalents, a molar weight factor of 1.8 was applied ($M_{\text{Pyridate}}/M_{\text{pyridafol}} = 378.9 \text{ g/mol}^{-1}/206.6 \text{ g/mol}^{-1} = 1.8$).

The Meeting decided not to establish a residue definition for dietary exposure purposes for plants. Consequently, only maximum residue levels according to the residue definition for enforcement purposes are estimated, but no STMR or HR value.

Bulb vegetables, Group of

Onion, bulb

The critical GAP for bulb onions in Italy allows one foliar application of pyridate at 900 g ai/ha with a PHI of 21 days.

Field trials with bulb onion following GAP treatment (± 25 percent) were conducted in France and Italy. The ranked order of residues for estimating maximum residue levels and dietary risk assessment was ($n=3$): $< 0.01(2)$, 0.02 mg/kg .

Based on the lack of data matching the GAP, the Meeting concluded that no maximum residue level could be estimated for pyridate in onion based on the Italian GAP.

A GAP for onions in Austria was provided allowing a maximum of one foliar application of pyridate at 900 g ai/hL and a PHI of 56 days. One field trial with bulb onion following GAP treatment (± 25 percent) was conducted in Austria. The ranked order of residues for estimating maximum residue levels was (n=1): < 0.05 mg/kg.

Due to an insufficient number of supervised field trials matching the GAP, the Meeting concluded that no maximum residue level could be estimated for pyridate in bulb onion.

Leek

The critical GAP for leeks in Austria allows one foliar application of pyridate at 900 g ai/ha with a PHI of 28 days.

Field trials with leek following GAP treatment (± 25 percent) were conducted in France, Italy, Netherlands, Spain and Switzerland. The ranked order of residues for estimating maximum residue levels was (n=12): 0.04, 0.05, 0.051, 0.057, 0.06, 0.08, 0.11, 0.14, 0.20, 0.22, 0.63, 0.81 mg/kg.

The Meeting estimated a maximum residue level of 1.5 mg/kg for pyridate in leek.

Spring onion

The critical GAP for spring onion in Netherlands allows one foliar application of pyridate at 900 g ai/ha with and a PHI of 28 days.

Field trials with spring onion following GAP treatment (± 25 percent) were conducted in France, Germany, Greece, Spain and the United Kingdom. The ranked order of residues for estimating maximum residue levels was (n=6): < 0.01, 0.02, 0.04, 0.05, 0.07, 0.09 mg/kg.

The Meeting estimated a maximum residue level of 0.2 mg/kg for pyridate in spring onion.

Brassica vegetables (except brassica leafy vegetables), Group of

The critical GAP for brassica vegetables (cabbage, Brussels sprouts, broccoli, cauliflower, kohlrabi) in Austria allows one foliar application of pyridate at 900 g ai/ha with and a PHI of 42 days.

Broccoli

Field trials with broccoli following GAP treatment (± 25 percent) were conducted in Austria. The ranked order of residues for estimating maximum residue levels was (n=1): < 0.05 mg/kg.

Due to an insufficient number of supervised field trials matching the GAP, the Meeting concluded that no maximum residue level could be estimated for pyridate in broccoli.

Brussel spouts

No field trials with Brussel sprouts approximated GAP treatment (± 25 percent) and residues were only determined as pyridafol *per se*.

Due to an insufficient number of supervised field trials matching the GAP, the Meeting concluded that no maximum residue level could be estimated for pyridate in Brussel sprouts.

Cabbages, Head

Field trials with cabbages following GAP treatment (± 25 percent) were conducted in France, Germany, Greece, Spain and the United Kingdom. The ranked order of residues for estimating maximum residue levels was (n=16): < 0.01(4), 0.01, 0.02, < 0.05(4), 0.12, 0.38, 0.50, 0.57, 0.85, 0.95 mg/kg.

The Meeting estimated a maximum residue level of 1.5 mg/kg for pyridate in cabbage, head.

Cauliflower

No field trials with cauliflower approximated GAP treatment (± 25 percent) and residues were only determined as pyridafol *per se*.

Due to an insufficient number of supervised field trials matching the GAP, the Meeting concluded that no maximum residue level could be estimated for pyridate in cauliflower.

Kohlrabi

Field trials conducted with kohlrabi following GAP treatment (± 25 percent) were conducted in Austria. The ranked order of residues for estimating maximum residue levels was (n=1): < 0.05 mg/kg.

Based on the lack of data matching the GAP, the Meeting concluded that no maximum residue level could be estimated for pyridate in kohlrabi.

Kale

The critical GAP for kale in Austria allows one foliar application of pyridate at 900 g ai/ha with and a PHI of 42 days.

Field trials with kale following GAP treatment (± 25 percent) were conducted in France, Switzerland, and the United Kingdom. The ranked order of residues for estimating maximum residue levels was (n=7): < 0.05(4), 0.081, 0.092, 0.17 mg/kg.

The Meeting estimated a maximum residue level of 0.3 mg/kg for pyridate in kale.

Chick-pea (succulent seeds)

The critical GAP for chick-peas in Italy allows one foliar application of pyridate at 900 g ai/ha up to BBCH 19 with and a PHI of 45 days.

Field trials with chick-peas were conducted in France, Greece, Italy and Spain. The ranked order of residues in legume chick-pea seeds for estimating maximum residue levels was (n=6): < 0.05(6) mg/kg.

The Meeting estimated a maximum residue level of 0.05* mg/kg for pyridate in chickpeas (succulent seeds).

Pulses, Group of

Chick-pea (dry)

The critical GAP for chick-peas in Italy allows one foliar application of pyridate at 900 g ai/ha up to BBCH 19 with and a PHI of 45 days.

Field trials with chick-peas were conducted in France, Greece, Italy and Spain. The Meeting noted that storage intervals in all trials were longer than one months. No information on storage stability in high protein matrices was provided and therefore the Meeting could not assess the validity of the measured results.

Due to an insufficient number of supervised field trials matching the GAP, the Meeting concluded that no maximum residue level could be estimated for pyridate in chickpeas (dry).

*Cereal grains, Group of**Maize*

The critical GAP for maize in Netherlands allows one foliar application of pyridate at 900 g ai/ha at BBCH 16 and with the PHI covered by the conditions of use.

Field trials with maize following GAP treatment (± 25 percent) were conducted in France and Germany. The ranked order of residues for estimating maximum residue levels was (n=7): < 0.04, < 0.05(6) mg/kg.

The Meeting noted that no data on storage stability in high starch content matrices was available although field trial samples were stored for 3–16 months (4×3 months, 2×6 months and 1×16 months). Based on the provided metabolism studies on maize dosed at 2× GAP rate, the total radioactive residue in maize grain was low at 0.01–0.014 mg eq/kg. No further identification was undertaken in the samples and therefore the fraction of the TRR covered by the common moiety method remains unknown. However, given the rapid metabolism of pyridate, including the incorporation of the radioactivity into natural constituents, the Meeting concluded that the levels of the components covered by the residue definition are expected to be even lower. Also, field trial samples treated at 150 percent GAP rate also showed no residues in maize grain for pyridafol after 2 months of storage.

In view of the low radioactivity found in maize metabolism study and the analysis of trial samples according to the common moiety method, the Meeting decided to accept the trials without demonstration of storage stability and estimated a maximum residue level of 0.05(*) mg/kg for pyridate in maize grain.

Sweet corn (Corn-on-the-cob)

The critical GAP for sweet corn in Austria allows one foliar application of pyridate at 900 g ai/ha with and a PHI of 42 days.

Field trials with sweet corn following GAP treatment (± 25 percent) were conducted in France. The ranked order of residues in sweet corn (corn-on-the-cob) for estimating maximum residue levels was (n=1): < 0.05(1) mg/kg. The ranked order of residues in sweet corn (kernels) for estimating maximum residue levels was (n=2): < 0.05(2) mg/kg.

Alternatively, a GAP for sweet corn in Netherlands was provided, allowing one foliar application of pyridate at 900 g ai /ha at BBCH 16 and with the PHI covered by the conditions of use.

Field trials with sweet corn following GAP treatment (± 25 percent) were conducted in France. The ranked order of residues for estimating maximum residue levels was (n=10): < 0.04, < 0.05(9) mg/kg. The ranked order of residues in sweet corn (kernels) for estimating maximum residue levels was (n=2): < 0.05(2) mg/kg.

The Meeting noted that only the dataset for sweet corn (corn-on-the-cob) according to the GAP from Netherlands was sufficiently large and estimated a maximum residue level of 0.05(*) mg/kg for pyridate in sweet corn (corn-on-the-cob)

Residues in animal feeds*Alfalfa forage*

The critical GAP for alfalfa in Austria allows one foliar application of pyridate at 900 g ai/ha with and a PHI of 28 days.

Field trials with alfalfa following GAP treatment (± 25 percent) were conducted in Austria and France. The ranked order of residues was (n=5): < 0.05(2), 0.05, 0.23, 0.26 mg/kg.

Since alfalfa forage is utilised only as a feed items and insufficient data on the nature of residues relevant for calculating the livestock animal dietary burden are available, the Meeting did not estimate median or highest residues for pyridate.

Clover forage

The critical GAP for clover in Austria allows one foliar application of pyridate at 900 g ai /ha with and a PHI of 28 days.

Field trials with clover following GAP treatment (± 25 percent) were conducted in France and the United Kingdom. The ranked order of residues was (n=6): < 0.04, 0.12, 0.26, 1.0, 1.5(2) mg/kg.

Since clover forage is utilised only as a feed items and insufficient data on the nature of residues relevant for calculating the livestock animal dietary burden are available, the Meeting did not estimate median or highest residues for pyridate.

Maize forage

The critical GAP for maize in Netherlands allows one foliar application of pyridate at 900 g ai/ha at BBCH 16 and with the PHI covered by the conditions of use.

Field trials with maize following GAP treatment (± 25 percent) were conducted in France and Germany. The ranked order of residues in maize forage collected at growth stages typical for commercial harvest was (n=12): < 0.04(4), < 0.05(7) and 0.068 mg/kg.

Since maize forage is utilized only as a feed items and insufficient data on the nature of residues relevant for calculating the livestock animal dietary burden are available, the Meeting did not estimate median or highest residues for pyridate.

Maize stover

The critical GAP for maize in Netherlands allows one foliar application of pyridate at 900 g ai/ha at BBCH 16 and with the PHI covered by the conditions of use.

Field trials with maize following GAP treatment (± 25 percent) were conducted in France. The ranked order of residues in maize straw for estimating maximum residue levels was (n=5): < 0.04, < 0.05(4) mg/kg.

The Meeting estimated a maximum residue level of 0.05* mg/kg (DM) for pyridate in maize stover.

Fate of residues during processing

The Meeting received no information on the hydrolysis of pyridate, simulating typical processing conditions.

The fate of pyridate residues has been examined simulating commercial processing of maize and peanuts using radiolabelled pyridate. The TRRs in the RAC and in processed commodities (maize and peanut oil) were comparable. However, no components according to the residue definition were identified in the processed commodities and the nature of radioactivity remained unknown. Therefore, the Meeting decided that no processing factors addressing the residue definition for pyridate could be derived.

Residues in animal commodities

Farm animal feeding studies

The Meeting received feeding studies involving pyridate on lactating cows and laying hens using radiolabelled pyridate.

The study with lactating cows was conducted at treatment rates of 1, 3.3 and 10 ppm. Total radioactive residues in milk plateaued after one day in all dosing groups (0.003, 0.015 and 0.033 mg eq/kg, respectively). In edible tissues residues were highest in kidney ranging from 0.19 mg eq/kg (1×) to 1.9 mg eq/kg (10×). An individual component was only identified in muscle, kidney, liver and fat of the 10x dosing group with a retention time close to pyridafol. Additionally, pyridafol and its glucuronides were identified in urine and bile.

The study with laying hens was conducted at treatment rates of 1.3, 4 and 13 ppm. Total radioactive residues in eggs whites plateaued after two days in all dosing groups (0.005, 0.01 and 0.032 mg eq/kg respectively), while in egg yolks a plateau was reached after 5–7 days (0.003, 0.008 and 0.023 mg eq/kg, respectively). In edible tissues residues were highest in kidney ranging from 0.05 mg eq/kg (1×) to 0.23 mg eq kg (10×). An individual component was identified in egg yolk, kidney, liver and muscle of the 10x dosing group only, with a retention time close to pyridafol.

Farm animal dietary burden

Due to insufficient data on the nature of residues relevant for the livestock animal dietary burden, the Meeting decided that no calculation was possible.

Animal commodity maximum residue levels

The Meeting noted that the provided farm animal feeding studies lacked detailed residue data on components covered by the residue definition. Generally, only TRR levels were provided for milk, egg and various tissues, while the presence of metabolite pyridafol was only qualitatively described.

Therefore, the Meeting decided that no recommendations for animal commodities could be given based on the available information from farm animal feeding studies.

RECOMMENDATIONS

Definition of the residue for compliance with the MRL for plant and animal commodities: *Sum of pyridate and 6-chloro-4-hydroxy-3-phenylpridazine (pyridafol) (incl. conjugates), expressed as pyridate.*

Definition of the residue for dietary exposure purposes for plant and animal commodities: *Not established.*

The residue is not fat-soluble.

DIETARY RISK ASSESSMENT

As the Meeting was unable to recommend residue definitions for dietary risk assessment for plants and animal commodities, chronic and acute dietary risk assessments could not be conducted.

FURTHER WORK OR INFORMATION

Desirable information

- Submission of existing metabolism data for pyridate in alfalfa.

- Identification of major unknown components in all plant matrices from broccoli, maize and peanut metabolism studies.
- Data on the transfer of pyridate residues to farm animals (ruminants and poultry) are required, as the information provided was not sufficient to give recommendation for maximum residue levels in animal matrices.
- Storage stability information on commodities of high protein and starch content are required. Information on pyridate analytical methods targeting single compounds.
- Information on processed commodities.

5.29 Quinclorac (287)

RESIDUE AND ANALYTICAL ASPECTS

Quinclorac is a systemic herbicide used with uptake through roots and foliage and used to control annual grass and broadleaf weeds. It was evaluated by the 2015 JMPR for the first time for toxicology and for residues and re-evaluated in 2017 (R) for additional uses. The 2015 JMPR allocated an ADI of 0–0.4 mg/kg bw, and an ARfD of 2 mg/kg bw.

For plant commodities, the residue definition for compliance with MRLs is quinclorac plus quinclorac conjugates and the residue definition for the estimation of dietary risk assessment is quinclorac plus quinclorac conjugates plus quinclorac methyl ester expressed as quinclorac. The 2015 JMPR noted that quinclorac methyl ester has a toxicological potency up to 10 times that of quinclorac and agreed to multiply the quinclorac methyl ester residues with a factor of 10 to express it as quinclorac equivalents.

For animal commodities the residue definition for compliance with MRLs and for estimation of dietary risk assessment is quinclorac plus quinclorac conjugates. The residue is fat-soluble.

Quinclorac was scheduled at the Fifty-first Session of the CCPR for the re-assessment of residue trials for oil seed rape previously considered by the JMPR, which had used an unsuitable analytical method and could not be used for estimating a maximum residue level.

The current Meeting received information on a use pattern, the re-analysis of residue trial samples and commercial demonstration trials for rapeseed at the request of the CCPR51. A use pattern, new residue trials and additional validation data for cranberries were also received by the current Meeting.

Methods of analysis

The current Meeting considered additional procedural recovery data to support the analytical methods previously considered by the JMPR in 2015 and 2017.

Method D1607/01

Residues in cranberries and in oil seed rape were determined using method D1607/01 which was considered by the 2017 JMPR. This method employs three consecutive extraction procedures that allows the separate determination of quinclorac, quinclorac conjugates and quinclorac methyl ester. Final determination was by LC-MS/MS.

The 2017 JMPR concluded that this method was suitable for the analysis of quinclorac and quinclorac methyl ester residues in rape seed and forage. The LOQ for the sum of quinclorac and quinclorac conjugates residues was 0.01 mg/kg, and the LOQ for residues of quinclorac methyl ester was 0.01 mg/kg.

The current Meeting considered procedural recovery data for cranberries. The meeting concluded that method D1607/01 was suitable for the determination of quinclorac and quinclorac methyl ester residues in cranberries. The LOQ for residues for the sum of quinclorac and quinclorac conjugates is 0.02 mg/kg, and the LOQ for residues of quinclorac methyl ester is 0.01 mg/kg.

Multi-residue analytical method (Based on QuEChERS method for acidic herbicides)

The method was employed in the analysis of the rape seed samples from the commercial demonstration trials (=monitoring trials) provided to the current Meeting. The method is similar to the multi-residue

analytical method D1502/1 considered by the 2017 JMPR, although the initial extraction employed is different.

Samples were prepared by homogenizing with liquid nitrogen/dry ice. A subsample was hydrated with water and the pH was adjusted to >9 with NaOH. After shaking the sample for 30 minutes and centrifuging, an aliquot was removed and shaken with dichloromethane (DCM). The DCM was then discarded, the pH adjusted to ≤ 2 with sulfuric acid and extraction was achieved using acetonitrile and 'QuEChERS' salts. Final determination was by LC-MS/MS.

A radio-validation study considered by the 2015 JMPR showed that extraction with acetone/0.1 M NaOH converts the quinclorac methyl ester (if present) partly back into the parent compound. As this may result in an over estimation of parent levels in rapeseed the Meeting considered the method used in the monitoring trials as unsuitable for the estimation of maximum residue levels.

Stability of pesticide residues in stored analytical samples

The JMPR 2015 concluded that for quinclorac residues were stable in cranberries for at least 14 months of storage, covering storage intervals in the newly provided supervised field trials.

For rape seed samples, the 2015 JMPR concluded that quinclorac residues in oil seed rape are stable for at least 22 months. In the re-analysis of the rape seed samples from trials provided in 2017, maximum storage intervals after sampling were 670 days (=22 months).

Results of supervised residue trials on crops

Cranberries

The critical GAP is for the United States, which consists of two applications at 280 g ai/ha, a re-treatment interval (RTI) of 30 days and pre-harvest interval (PHI) of 60 days.

In 2015, four independent trials matching the GAP were assessed by the JMPR. The residues of quinclorac (including conjugates) were reported as (n=4): 0.16, 0.17, 0.18 and 0.67 mg/kg. The highest individual residue measured in cranberries was 0.68 mg/kg. Residues of quinclorac methyl ester were not determined.

The current Meeting noted that the selection of trial data in the 2015 Report does not correspond to the field trial results underlined correctly in the evaluation and instead of a value of 0.55 mg/kg a lower concentration of 0.16 mg/kg from a replicate trial was considered. Consequently, the corrected ranking of residues of quinclorac (including conjugates) was (n=4): 0.17, 0.18, 0.55 and 0.67 mg/kg. The highest individual residue measured in cranberries remains at 0.68 mg/kg.

The current Meeting received five additional new independent residue trials conducted in the United States in 2019 matching the cGAP. Residues of quinclorac (including conjugates) were (n = 5): 0.08, 0.09, 0.11, 0.26 and 0.56 mg/kg. Residues of quinclorac methyl ester were < 0.02(5) mg/kg.

Based on all trials, residues of quinclorac and its conjugates in cranberry for MRL estimation were (n=9): 0.08, 0.09, 0.11, 0.17, 0.18, 0.26, 0.55, 0.56 and 0.67 mg/kg.

The highest individual residue measured in cranberries was 0.68 mg/kg.

The Meeting estimated a maximum residue level of 1.5 mg/kg in cranberries confirming the previous recommendation.

Residues of quinclorac methyl ester were < 0.02 mg/kg in all five of the new trials considered by the current Meeting. In the supporting plant metabolism study on strawberries reviewed by the 2015

Meeting, quinclorac methyl ester residues were below the limit of detection at DAT 60, corresponding to the pre-harvest interval of the critical GAP. Therefore, the Meeting decided that to estimate residues for dietary exposure, a residue of 0.02 mg/kg for quinclorac methyl ester represents a conservative estimate and should be taken into account for the calculation for the total quinclorac residue in all supervised field trials without measurement of the analyte.

The total residue was calculated based on the formula: (quinclorac + quinclorac conjugate) + 10 × quinclorac methyl ester, all expressed as quinclorac.

Residues for dietary intake estimation in cranberries were (n=9): 0.28, 0.29, 0.31, *0.37*, *0.38*, 0.46, *0.75*, 0.76 and *0.87* mg/kg (values in italics involve no measurement of quinclorac methyl ester). The highest individual residue in cranberries is 0.88 mg/kg.

Based on this data set the Meeting estimated an STMR and HR value of 0.375 mg/kg and 0.88 mg/kg respectively.

Rape seed

The critical GAP is from Canada which allows one application of 100 g ai/ha with a PHI of 60 days.

No new supervised field trials were provided to the current Meeting.

The 2015 JMPR considered 17 residue trials conducted in 1997. As residues were determined using method D9708/1, which may overestimate the quinclorac level due to partial hydrolysis of the quinclorac methyl ester, the trials were not suitable for the estimation of a maximum residue level.

The 2017 JMPR considered nine additional residue trials conducted in 2016, which matched the cGAP for Canada, involving analysis with method D1607/01, measuring quinclorac methyl ester and quinclorac (incl. conjugates) separately, and estimated a maximum residue level of 0.15 mg/kg and an STMR of 0.64 mg/kg.

The current Meeting received information on the re-analysis of the samples from the 2016 trials with the intention to derive correction factors, allowing consideration of trials conducted in 1997. The samples were re-analysed using the following methods:

- Method D1607/01 involves three extractions 1) acetonitrile/water, 2) acetone/phosphate buffer pH 7, 3) 1 M NaOH at 100 °C for 1 hr, each extract analysed separately for parent (including parent released from conjugates) and the methyl-ester (considered by the 2017 JMPR);
- Method D9708/1 involves extraction with acetone/0.1 M NaOH for quinclorac and may convert the methyl ester partly to parent. Hence, it may overestimate the quinclorac residue level (considered by the 2015 JMPR);
- Method D9806 involves extraction with acetone for quinclorac methyl ester (considered by the 2015 JMPR).

The Meeting noted that re-analysis of quinclorac residues using method D9708/1 gave less than the validated LOQ of 0.05 mg/kg in seven of the nine trials. In the other two trials, method D9708/1 recovered 151–216 percent of the residue initially measured with method D 1607/01.

The Meeting noted a high variability in the results from both methods in combination with a validated LOQ for method D9708/1, too high for quantification of residues in most samples. Therefore, the Meeting decided not to derive analytical correction factors, which would introduce significant uncertainty to the estimations and does not follow its common assessment practice. The Meeting confirmed its

previous conclusion that the residue trials from 1997 are not suitable for estimating a maximum residue level.

In addition, the Meeting considered seven commercial demonstration trials (=targeted monitoring data) provided by the request of the CCPR51, conducted according to the Canadian GAP. Each trial consisted of two sub-plots at rates of 75 or 125 g ai/ha and involved analysis of four field samples for each sub-plot.

Residues of quinclorac were determined using the QuEChERS method for acidic herbicides. This included extraction using NaOH which is therefore likely to result in a portion of the quinclorac methyl ester (if present) being converted back into quinclorac.

Noting the potential overestimation of residues according to the residue definition for enforcement purposes, only five individual results (from two sub-plots) out of 56 total measurements exceeded the maximum residue level of 0.15 mg/kg recommended by the 2017 JMPR. In addition, lack of information on important trial parameters such as the dates of harvest and storage periods prior to analysis were noted. The Meeting decided the provided information was unsuitable for maximum residue level estimation.

The Meeting confirmed its previous recommendations of an MRL of 0.15 mg/kg, a median residues value for livestock feed of 0.017 mg/kg for rapeseed and an STMR of 0.64 mg/kg for the estimation of dietary intake, as well as for rape seed oil edible of 0.70 mg/kg

RECOMMENDATIONS

On the basis of the data from supervised trials, the Meeting concluded that the residue levels listed in Annex 1 are suitable for establishing maximum residue limits and for IEDI and international estimate of short-term intakes assessment.

For plant commodities, the residue definition for compliance with MRLs is quinclorac plus quinclorac conjugates. The residue definition for the estimation of dietary risk assessment is quinclorac plus quinclorac conjugates plus quinclorac methyl ester expressed as quinclorac. The 2015 JMPR noted that quinclorac methyl ester has a toxicological potency up to 10 times that of quinclorac and agreed to multiply the quinclorac methyl ester residues with a factor of 10 to express it as quinclorac equivalents.

For animal commodities, the residue definition for compliance with MRLs and for estimation of dietary risk assessment is quinclorac plus quinclorac conjugates. The residue is fat-soluble.

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The ADI for quinclorac is 0–0.4 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for quinclorac were estimated for the 17 GEMS/Food Consumption Cluster Diets using the STMR or STMR-P values estimated by the JMPR. The results are shown in Annex 3 of the 2022 JMPR Report.

The IEDIs ranged from 0–1 percent of the maximum ADI. The Meeting concluded that long-term dietary exposure to residues of quinclorac from uses considered by the JMPR is unlikely to present a public health concern

Acute dietary exposure

The ARfD for quinclorac is 2 mg/kg bw. The international estimate of short-term intakes for quinclorac were calculated for the food commodities and their processed commodities for which HRs/HR-Ps or STMRs/STMR-Ps were estimated by the present Meeting and for which consumption data were available. The results are shown in Annex 4 of the 2022 JMPR report.

The international estimate of short-term intakes were 0 percent of the ARfD for children and 0 percent of the ARfD for the general population. The Meeting concluded that acute dietary exposure to residues of quinclorac from uses considered by the present Meeting is unlikely to present a public health concern.

5.30 Quintozene (064)

TOXICOLOGY

Quintozene is the International Organization for Standardization (ISO)-approved common name for 1,2,3,4,5-pentachloro-6-nitrobenzene (IUPAC) and is also known as pentachloronitrobenzene (PCNB), Chemical Abstracts Service number 82-68-8.

Quintozene is a soil-applied fungicide and its fungicidal mode of action (MOA) is proposed to involve the inhibition of cellular peroxidation.

Quintozene was previously evaluated by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) in 1969, 1973, 1977 and 1995. An acceptable daily intake (ADI) of 0–0.01 mg/kg bw was established at JMPR 1995 on the basis of a no-observed-adverse-effect level (NOAEL) of 1 mg/kg bw per day in a two-year rat study, a mechanistic 90-day study in rats and a two-generation rat study. The establishment of an acute reference dose (ARfD) was not addressed. Quintozene was evaluated by the present Meeting within the periodic review program of the Codex Committee on Pesticide Residues (CCPR). The Meeting noted that a number of studies reviewed in 1995 were not made available for this review, but if these studies indicated critical aspects missing from the provided database, reference would be made to the 1995 JMPR conclusions. In the past, manufactured quintozene was frequently contaminated with high levels (up to 11 percent) of hexachlorobenzene (HCB). The current specification for HCB in quintozene has a limit of 0.1 percent of the contaminant, therefore the present review on the toxicity of quintozene is predicated mainly on data from studies of quintozene containing less than 0.1 percent HCB.

All critical studies were conducted to internationally recognized guidelines (generally Organisation for Economic Co-operation and Development, OECD) and complied with and good laboratory practice (GLP) or were otherwise quality-audited, except where indicated. No additional information from a literature search was identified that complemented the toxicological information provided for the current evaluation.

Biochemical aspects

Following the dosing of rats with radiolabelled quintozene at 5 mg/kg bw radioactivity levels in blood reached a maximum 12 hours post treatment, with a half-life of 21.8 hours. Radiolabel was mainly excreted via the faeces. An apparent sex difference was seen in urinary and faecal excretion: the total ¹⁴C activity in urine ranged from 7.8 percent to 12.3 percent in males and 23.9 percent to 38.3 percent in females, while total ¹⁴C activity in faeces ranged from 56.6 percent to 90.0 percent in males, and 37.9 percent to 76.0 percent in females. Biotransformation studies showed two general metabolic pathways. One involved the reduction of the nitro group to an amino group and subsequent formation of secondary metabolites, the second consisted of the replacement of the nitro group with a sulfur-containing group. No individual metabolite occurred in urine at levels above 10 percent of the administered dose (AD).

Toxicological data

The acute oral median lethal dose (LD₅₀) of quintozene in the rat was above 5000 mg/kg bw. The acute dermal LD₅₀ in rabbits was above 5000 mg/kg bw. The acute inhalation median lethal concentration (LC₅₀) in rat was above 6.49 mg/L. In rabbits quintozene was slightly irritating to the skin and minimally irritating to the eye, and it was a skin sensitizer in Guinea pigs.

In repeat-dose oral toxicity studies in rats and dogs the main effects were lower body weight, increased weight and histopathological changes in the liver, and histopathological changes in the thyroid.

In a 90-day rat study, quintozene was administered orally via gavage for five days a week at doses of 0, 5, 10, 100 or 1000 mg/kg bw per day. The NOAEL was 71 mg/kg bw per day (corrected for five day per week dosing) based on histopathological findings in the thyroid (follicular cell hypertrophy/hyperplasia) at 710 mg/kg bw per day (corrected value).

In a one-year dog study, quintozene was administered at dietary concentrations of 0, 15, 150 or 1500 ppm (equal to 0, 0.40, 4.31 and 40.05 mg/kg bw per day for males, 0, 0.44, 4.22 and 41.48 mg/kg bw per day for females). The NOAEL was 150 ppm (equal to 4.22 mg/kg bw per day) based on increased liver weight, increased alkaline phosphatase (ALP) activity and cholesterol, and liver histopathology (hepatocellular/hypertrophy) at 1500 ppm (equal to 40.05 mg/kg bw per day).

In a 103-week toxicity and carcinogenicity study in mice, quintozene was administered at dietary concentrations of 0, 2500 or 5000 ppm (equal to 0, 400 and 1000 mg/kg bw per day for males, 0, 600 and 1400 mg/kg bw per day for females). No neoplastic lesions related to treatment were observed, however survival in females was decreased to as low as 28 percent due to infection, which reduced the overall sensitivity of the study. Due to these infections, no chronic toxicity NOAEL could be identified. However, despite the infections, no evidence of carcinogenicity was reported.

In a two-year toxicity and carcinogenicity study in rats, quintozene was administered at dietary concentrations of 0, 100, 400 or 1200 ppm (equivalent to 0, 5, 20 and 60 mg/kg bw per day). The chronic toxicity NOAEL was 100 ppm (equivalent to 5 mg/kg bw per day) based on liver histopathology (enlargement of hepatocytes, hyaline intracytoplasmic bodies and centrilobular single cell necrosis) at 400 ppm (equal to 20 mg/kg bw per day). The NOAEL for carcinogenicity was 1200 ppm (equivalent to 60 mg/kg bw per day), the highest dose tested.

In a two-year toxicity and carcinogenicity study in rats, quintozene was administered by oral gavage at dose levels of 0, 5, 50, 500 or 1000 mg/kg bw per day. The NOAEL for chronic toxicity was 50 mg/kg bw per day based on decreased body weight and follicular cell hypertrophy/hyperplasia in the thyroid gland. The NOAEL for carcinogenicity was 1000 mg/kg bw per day, the highest dose tested.

In a two-year toxicity and carcinogenicity study in rats, quintozene was administered at dietary concentrations of 0, 20, 3000 or 6000 ppm (equal to 0, 0.91, 141 and 303 mg/kg bw per day for males, 0, 1.14, 179 and 370 mg/kg bw per day for females). The NOAEL for chronic toxicity was 20 ppm (equal to 0.91 mg/kg bw per day) based on histopathological findings of follicular cell hypertrophy and hyperplasia in the thyroid. The NOAEL for carcinogenicity was 20 ppm (equal to 0.91 mg/kg bw per day) based on thyroid follicular cell adenomas and carcinomas in males at 3000 ppm (equal to 141 mg/kg bw per day).

In a mechanistic study in male rats focusing on the thyroid, quintozene was administered at dietary concentrations of 0, 20 and 6000 ppm (equal to 0, 1.1 and 333 mg/kg bw per day) for up to 90 days, with an additional recovery group continuing for 90 days without treatment. At 6000 ppm serum triiodothyronine (T3) and thyroxine (T4) were decreased and thyroid-stimulating hormone (TSH) was increased: during the recovery period these values returned to normal. Hepatocellular hypertrophy was seen at 20 and 6000 ppm. A NOAEL was not identified as thyroid hypertrophy was seen at 20 ppm (equal to less than 1.1 mg/kg bw per day).

A mechanistic study in rats, focusing on biliary excretion of T4 and thyroid uptake of iodine, showed that quintozene produced both an increase in hepatobiliary clearance of T4 and a decrease in thyroidal iodine uptake. The weight of evidence suggests that the thyroid tumours following chronic

administration of quintozene developed by a non-genotoxic mechanism, possibly associated with chronic hormonal imbalances. A definitive case for human non-relevance of the MOA was not demonstrated.

The Meeting concluded that quintozene is carcinogenic in rats, but not in mice.

Quintozene was tested for genotoxicity in an adequate range of in vitro and in vivo assays. It gave positive response in the in vitro chromosome aberration assay, but was negative in the in vivo micronucleus assay.

The Meeting concluded that quintozene is unlikely to be genotoxic in vivo.

In view of the lack of genotoxicity in vivo, the absence of carcinogenicity in mice and the fact that the thyroid tumours in rats were increased at the two highest doses tested in only one of the three two-year studies, and that the mechanistic study indicated the MOA to be thyroid hormone disruption, the Meeting concluded that quintozene is unlikely to pose a carcinogenic risk to humans from the diet.

In a two-generation reproductive toxicity study in rats, quintozene was administered at dietary concentrations of 0, 20, 3000 or 6000 ppm (equal to 0, 1.1, 168 and 350 mg/kg bw per day for males, 0, 1.4, 221 and 459 mg/kg bw per day for females). The NOAEL for parental toxicity was 3000 ppm (equal to 168 mg/kg bw per day) based on decreased body weight and feed consumption. The NOAEL for reproductive toxicity was 6000 ppm (equal to 350 mg/kg bw per day), the highest dose tested. The NOAEL for offspring toxicity was 20 ppm (equal to 1.1 mg/kg bw per day) based on an increased incidence of undersized pups.

In a two-generation reproductive toxicity study in rats, quintozene was administered by oral gavage at dose levels of 0, 10, 100 or 1000 mg/kg bw per day. The parental NOAEL was 10 mg/kg bw per day based on follicular cell hypertrophy and hyperplasia in the thyroid of male rats. The NOAELs for offspring and reproductive toxicity were both 1000 mg/kg bw per day, the highest dose tested.

In a developmental toxicity study in rats, quintozene was administered by oral gavage at 0, 30, 600 or 1200 mg/kg bw per day from gestation day (GD) 6–15. The maternal and embryo/fetal NOAELs were both 1200 mg/kg bw per day, the highest dose tested.

In a developmental toxicity study in rats, quintozene was administered by oral gavage at doses of 0, 250, 750 or 1500 mg/kg bw per day from GD 6–15. The maternal NOAEL was 250 mg/kg bw per day based on decreased body weight gain and feed consumption at 750 mg/kg bw per day. The embryo/fetal NOAEL was 1500 mg/kg bw per day, the highest dose tested.

In a developmental toxicity study in rabbits, quintozene was administered by oral gavage at doses of 0, 100, 300 and 900 mg/kg bw per day from GD 6–18. The maternal NOAEL was 300 mg/kg bw per day based on decreased body weight gain and increased abortions at 900 mg/kg bw per day. The embryo/fetal NOAEL was 900 mg/kg bw per day, the highest dose tested.

The Meeting concluded that quintozene is not teratogenic.

No specific study on neurotoxicity was provided, but no evidence of neurotoxicity was reported in routine toxicological studies with quintozene.

The Meeting concluded that quintozene is unlikely to be neurotoxic.

No specific data were provided regarding immunotoxicity. In routine toxicity studies there was evidence of viral and bacterial infections being slightly more prevalent in animals treated with quintozene. However there was no evidence of direct effects on the immune system.

The Meeting concluded that quintozene is unlikely to be immunotoxic.

Studies on estrogen, androgen and steroidogenesis activity were provided and these showed negative results.

Toxicological data on metabolites and/or degradates

No data was available. If needed for assessment of residue metabolites, the threshold of toxicological concern (TTC) value for potentially genotoxic substances (0.0025 µg/kg bw per day) should be applied.

Microbiological data

There was no information available in the public domain, and no experimental data were provided that addressed the possible impact of quintozene residues on the human intestinal microbiome.

Human data

Evidence of skin sensitization was reported in a human patch test. In reports on manufacturing plant personnel, no adverse health effects were noted. No clinical cases or poisoning incidents had been recorded.

The Meeting concluded that the existing database on quintozene was adequate to characterize the potential hazards to the general population, including fetuses, infants and children.

Toxicological evaluation

The Meeting re-affirmed the ADI of 0–0.01 mg/kg bw established by the 1995 Meeting. The Meeting based the ADI on the NOAEL of 1.1 mg/kg bw per day seen in the two-generation study in rats, and 0.91 mg/kg bw per day from the two-year rat study (noting the large dose spacing to the LOAEL of 141 mg/kg bw per day). The Meeting noted that in the case of the LOAEL of 1.1 mg/kg bw per day in the mechanistic 90-day rat study, the LOAEL was based on minimal changes which were found not to progress in the two-year rat study. A safety factor of 100 was used. This gives a margin of 14 000 to the lowest dose causing tumours in rats.

The Meeting concluded that it was not necessary to establish an ARfD for quintozene in view of its low acute oral toxicity and the absence of developmental toxicity and any other toxicological effects that would be likely to be elicited by a single dose.

A toxicological monograph was prepared.

Levels relevant to risk assessment of quintozene

Species	Study	Effect	NOAEL	LOAEL
Rat	Two-year studies of toxicity and carcinogenicity ^a	Toxicity	20 ppm, equal to 0.91 mg/kg bw/day	3000 ppm, equal to 141 mg/kg bw/day
		Carcinogenicity	20 ppm, equal to 0.91 mg/kg bw/day	3000 ppm, equal to 141 mg/kg bw/day
	Two-generation study of reproductive toxicity ^a	Reproductive toxicity	6000 ppm, equal to 350 mg/kg bw/day ^c	-
		Parental toxicity	3000 ppm, equal to 168 mg/kg bw/day	6000 ppm, equal to 350 mg/kg bw/day
		Offspring toxicity	20 ppm, equal to 1.1 mg/kg bw/day	3000 ppm, equal to 168 mg/kg bw/day
	Two-generation study of reproductive	Reproductive toxicity	10 mg/kg bw/day	100 mg/kg bw/day

Species	Study	Effect	NOAEL	LOAEL
	toxicity ^b	Parental toxicity	1000 mg/kg bw/day ^c	-
		Offspring toxicity	1000 mg/kg bw/day ^c	-
	Developmental toxicity study ^b	Maternal toxicity	250 mg/kg bw/day	750 mg/kg bw/day
		Embryo and fetal toxicity	1500 mg/kg bw/day ^c	-
Rabbit	Developmental toxicity study ^b	Maternal toxicity	300 mg/kg bw/day	900 mg/kg bw/day
		Embryo and fetal toxicity	900 mg/kg bw/day ^c	-
Dog	One-year study of toxicity ^a	Toxicity	150 ppm, equal to 4.22 mg/kg bw/day	1500 ppm, equal to 40.05 mg/kg bw/day

Notes:

^a Dietary administration.

^b Gavage administration.

^c Highest dose tested.

Acceptable daily intake (ADI) for quintozene

0–0.01 mg/kg bw

Acute reference dose (ARfD) for quintozene

Not necessary

Information that would be useful for the continued evaluation of the compound

Results from epidemiological, occupational health and other such observational studies of human exposure.

Critical end-points for setting guidance values for exposure to quintozene

Absorption, distribution, excretion and metabolism in mammals

Rate and extent of oral absorption	T_{max} : 12 hours; <40 percent
Dermal absorption	No data available
Distribution	Limited data available
Potential for accumulation	No indication of accumulation
Rate and extent of excretion	Predominantly in faeces (38–91 percent), less in urine (7.8–38 percent); sex difference in faecal and urinary excretion
Metabolism in animals	Reduction of nitro group; replacement of nitro group with thiol group.
Toxicologically significant compounds in animals and plants	Quintozene

Acute toxicity

Rat, LD ₅₀ , oral	>5000 mg/kg bw
Rat, LD ₅₀ , dermal	>5000 mg/kg bw

Rat, LC ₅₀ , inhalation	>6.49 mg/L
Rabbit, dermal irritation	Slightly irritating
Rabbit, ocular irritation	Minimally irritating
Guinea-pig, dermal sensitization	Sensitizing (Buehler; maximization test)
Short-term studies of toxicity	
Target/critical effect	Body weight, liver, thyroid histopathology
Lowest relevant oral NOAEL	<1.1 mg/kg bw per day, lowest dose tested (rat)
Lowest relevant dermal NOAEL	No adequate data
Lowest relevant inhalation NOAEC	No data
Long-term studies of toxicity and carcinogenicity	
Target/critical effect	Liver and thyroid (rat)
Lowest relevant NOAEL	0.91 mg/kg bw per day (rat)
Carcinogenicity	Carcinogenic in rats ^a
Genotoxicity	
Unlikely to be genotoxic in vivo	
Reproductive toxicity	
Target/critical effect	Parental: thyroid histopathology Offspring: pups small in size
Lowest relevant parental NOAEL	10 mg/kg bw per day (rat)
Lowest relevant offspring NOAEL	1.1 mg/kg bw per day (rat)
Lowest relevant reproductive NOAEL	350 mg/kg bw per day, the highest dose tested (rat)
Developmental toxicity	
Target/critical effect	Body weight and food consumption (rat)
Lowest relevant maternal NOAEL	250 mg/kg bw per day (rat)
Lowest relevant embryo/fetal NOAEL	900 mg/kg bw per day, highest dose tested (rabbit)
Neurotoxicity	
Acute neurotoxicity NOAEL	No data; no evidence from routine studies
Subchronic neurotoxicity NOAEL	No data; no evidence from routine studies
Developmental neurotoxicity NOAEL	No data
Other toxicological studies	
Immunotoxicity	No data; no evidence from routine studies
Studies on toxicologically relevant metabolites	No data
Microbiological data	
No data	
Human data	
No clinical cases or poisoning incidents had been recorded Evidence of skin sensitization	

Notes:

^a Unlikely to pose a carcinogenic risk to humans via exposure from the diet.

Summary

	Value	Study	Safety factor
ADI	0–0.01 mg/kg bw ^a	Two-year study of toxicity and carcinogenicity (rat); two-generation reproductive toxicity (rat)	100
ARfD	Not necessary		

Notes:^a Applies to quintozene.**RESIDUE AND ANALYTICAL ASPECTS**

Quintozene (pentachloronitrobenzene-IUPAC name), is an aromatic fungicide, used as soil fungicide or for seed treatment of various vegetables, cereal grains, and oil seeds.

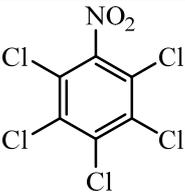
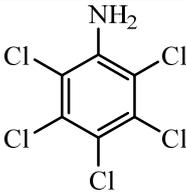
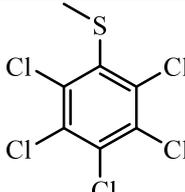
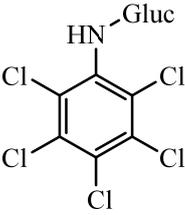
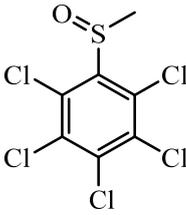
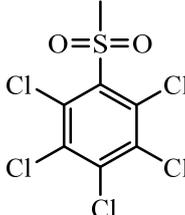
Quintozene was first evaluated by the JMPR in 1969 and reviewed under the CCPR periodic re-evaluation by the 1995 JMPR for toxicology and residues.

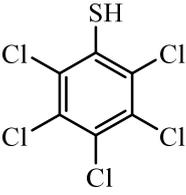
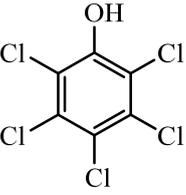
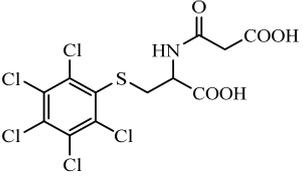
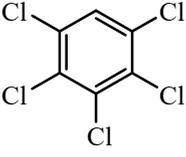
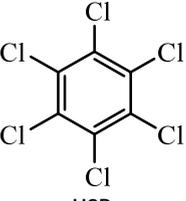
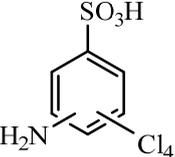
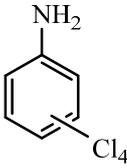
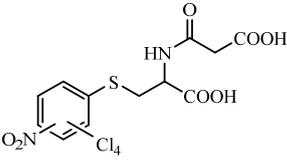
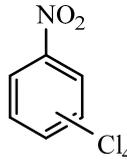
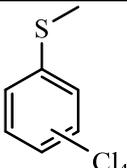
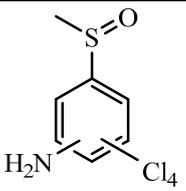
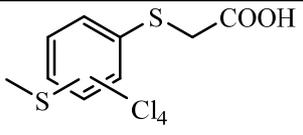
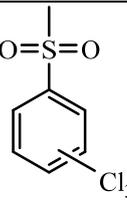
The Fifty-third Session of the Codex Alimentarius Commission (2020) approved the new work proposals including the priority list of pesticides for evaluation by the current Meeting, including periodic re-evaluation of quintozene.

The current Meeting received information on identity; chemical and physical properties; plant, rotational crop, and animal metabolism; environmental fate; residue analytical methods and storage stability; use pattern; supervised trials; processing; and animal feeding.

The following abbreviated names were used for the metabolites commonly found in plants and animals in the appraisal of quintozene.

Table 5.30.1 List of some compounds that are the basic structures of metabolites and conjugated metabolites referred to in the appraisal

 <p>Quintozene Pentachloronitrobenzene</p>	 <p>PCA Pentachloroaniline</p>	 <p>PCTA Methyl pentachlorophenyl sulfide</p>
 <p>PCA glucuronide N-(pentachloroaniline) glucuronide</p>	 <p>PCTASO=PCTA-sulfoxide</p>	 <p>PCTASO0=PCTA-sulfone</p>

 <p>PCTP Pentachlorothiophenol</p>	 <p>PCP Pentachlorophenol</p>	 <p>PCP-MayCys or PCPT-MayCys S-(Pentachlorophenyl) malonylcysteine</p>
 <p>PB Pentachlorobenzene</p>	 <p>HCB Hexachlorobenzene a</p>	 <p>AM TCB sulfonic acid Aminotetrachlorobenzene sulfonic acid</p>
 <p>TCA Tetrachloroaniline</p>	 <p>TCNP-MalCys S-(Tetrachloronitrophenyl) malonylcysteine</p>	 <p>TCNB isomers (2,3,4,5-, or 2,3,5,6-) tetrachloronitrobenzene</p>
 <p>TCTA Tetrachlorothioanisole</p>	 <p>TCA sulfoxide Tetrachloroaniline methyl sulfoxide</p>	 <p>MTCP-TAA S-[(methylthio)tetrachlorophenyl]-2-thioacetic acid</p>
 <p>C3MS Trichlorophenyl methyl sulfone</p>		

Notes:

^a Known impurity of quintozene. According to available information, hexachlorobenzene as an impurity is allowed up to 0.03–0.05 percent in TGAI in the countries where quintozene is registered (the 1995 JMPR reported the maximum to be 0.1 percent.).

Based on the information on physical and chemical properties, quintozene is volatile and more soluble in organic solvents than in water with a Log Pow of 5–6 at pH 7 and 25 °C. Quintozene is hydrolytically stable. Aqueous photolysis is likely to be a major degradation pathway of quintozene in the environment. Photodegradation products after irradiation were isomeric mixture of chlorinated hydroxybenzenes and/or chloronitrophenols.

Plant metabolism

The Meeting received information on the fate of quintozene labelled uniformly with ^{14}C in the phenyl ring (hereafter described as ^{14}C -quintozene) in cabbage, potato and peanut after pre-plant soil application. Residues in harvested seeds of maize, peas, sugar beet, wheat and soya bean were investigated after seed application of ^{14}C -quintozene.

Cabbage

When cabbage was grown in soil treated with ^{14}C -quintozene, the highest radioactivity levels of mature cabbage were found in the wrapper (outer) leaves in both of two studies.

In one study, 28-day old cabbage plants were transplanted in soil treated at 53.8 kg ai/ha and grown in a greenhouse. Samples were taken 49, 70 and 154 days after the application. Total radioactive residue (TRR) from combustion were 7.80, 5.24, 1.14 and 13.9 mg eq/kg in immature whole plants (48 DAT and 70 DAT), mature head and mature wrapper leaves. Extraction of wrapper leaves with methanol/water (80:20) and acetone recovered 57.5 and 14.7 percent TRR, totalling 72.2 percent of TRR). Post-extraction solids (PES) were subjected to HCl hydrolysis.

Seven metabolites were identified in the wrapper leaf extracts, among which two major metabolites were tetrachlorophenyl methyl (TCPM) sulfide (36 percent TRR) and sulfone (42 percent TRR). In this study quintozene was not found. Other identified metabolites, ring hydroxylated C3MS, NOHPA, PCTASO and PCTA, each accounted for 0.5–8.9 percent TRR.

In a second study, cabbages was sown immediately after the soil was treated at 33.7 kg ai/ha and grown outdoors. Immature cabbage samples were taken at 120 DAT and mature cabbage samples at 209 DAT. The mature cabbage samples were separated into whole head with wrapper leaves, head without wrapper leaves and wrapper leaves. TRR from combustion were 3.37, 0.28, 0.11 and 2.03 mg eq/kg for immature cabbage, mature whole cabbage, mature head and mature wrapper leaves, respectively. Extraction with hexane followed by methanol recovered 40–70 percent TRR. Samples were extracted 4.7 months and 32 months after harvest, which might affect the metabolite profile. From the cabbage extracts of immature cabbage, mature wrapper leaves and mature whole cabbage, quintozene, 5 metabolites and HCB were identified but the total identified accounted for only 5–18 percent TRR. Quintozenes was the most abundant residue accounting for 9.3 percent TRR (0.327 mg/kg) in the immature cabbage and was lower in the mature wrapper leaves. The only metabolites accounting for more than 10 percent TRR were the combined TCNP-MalCys and PCP-MalCys found mostly in methanol extract (12 percent TRR and 0.34 mg/kg in the wrapper leaves and lower in other portions). In this study, quintozene, PCTA, TCNP-MalCys and PCP-MalCys were found in all three matrices. PCA and PB were in the immature cabbage and mature wrapper leaves and 6-TCNB and HCB only in immature cabbage, which accounted for at most 1.1 percent TRR in mature cabbage.

Potato

Metabolism of quintozene in potato grown in soil treated with ^{14}C -quintozene pre-plant incorporation was investigated in three studies.

In the first study, potato plants were grown outdoor in soil treated with ^{14}C -quintozene at 21.1 kg ai/ha. Potatoes were harvested at early maturity, 11 weeks after planting. Subsamples were rinsed with water and separated into peel and flesh. TRR from combustion were 11.26, 0.76 and 2.39 mg eq/kg for peel, flesh and whole potato, respectively. Sum of TRR in the extracts and PES were 16.81, 0.41 and 0.63 mg eq/kg, differing significantly from the TRR values from combustion.

The samples were extracted with 80 percent methanol, and the extracts were partitioned with chloroform, ethyl ether and water, which recovered 50 percent, 78 percent and 95 percent TRR (based on the sum of the radioactivity in the extracts) from peel, flesh and whole potato, respectively.

In the peel, the most predominant residue was quintozene at 24 percent TRR (4.1 mg/kg) followed by PCA at 18 percent TRR (3.1 mg/kg), while in the whole potato tuber, quintozene was below the LOQ. In potato tuber, the most predominant residue was PCTP-MalCys at 32 percent TRR (0.20 mg/kg) followed by PCTP-Cys at 18 percent TRR (0.11 mg/kg) and PCTA at 9.5 percent TRR (0.06 mg/kg).

In the second study, potato plants were grown outdoors in soil treated with 30 kg ai/ha. Samples were collected at 92 DAT and 122 DAT for foliage, 122 DAT (early stage) and 154 DAT (mature stage) for potato tuber. TRR from combustion were 1.13–7.07 mg eq/kg in foliage, 11.25 mg eq/kg in immature tuber, and 1.37 mg eq/kg in mature tuber.

Samples were extracted with hexane and methanol at various timings up to 26 months after harvest, which might affect the metabolite profile. Extraction rates were 53–77 percent for all matrices. PES and extracts were subject to harsh HCl hydrolysis.

In potato foliage, level of identification was low, a total of 11.7 percent of TRR. PCA, PCTA and TCNP-MalCys and PCP-MalCys were found in minor amounts up to 7.5 percent TRR (0.37 mg eq/kg). In potato tubers, quintozene, 7 metabolites and HCB were identified. Parent quintozene was only detected in 122 DAT immature tubers at low levels (0.3–0.5 percent TRR, 0.02–0.06 mg/kg). In the mature tubers, the most abundant residue was PCA at 9.5 percent TRR (0.09 mg/kg) followed by TCNP-MalCys and PCP-MalCys together at 5.2 percent TRR (0.05 mg/kg) and PB at 4.7 percent TRR (0.05 mg/kg). The total identified was 23 percent TRR. In the immature tuber, PCA, PB and the sum of TCNP-MalCys and PCP-MalCys accounted for 6.0–15 percent TRR (0.68–1.08 mg/kg), 2.7–13 percent TRR (0.48–0.60 mg/kg) and 7.0–10 percent TRR (0.32–1.8 mg/kg), respectively with the total identified was 33–38 percent TRR.

The third study was conducted outdoor using the application at 22.4 kg ai/ha or 67.3 kg ai/ha. Samples of tuber, stem and foliage were collected at 95 DAT. However, only tuber samples were subjected to analysis. TRR in the whole tubers were 1.12 mg eq/ha and 3.54 mg eq/kg for the low and high rate, respectively.

A series of extraction (methanol, aqueous methanol and water) and partitioning (hexane and ethyl ether) extracted at least 90 percent TRR. The PES was treated with a variety of enzymes. Protease released about 40 percent of the TRR in PES and much of the radioactivity was associated with substances with molecular weight > 3000. The enzymes that hydrolyse carbohydrate released minimal amount of radioactivity.

Numerous metabolites at low levels were identified in the extracts/fractions. The total of identified residues accounted for 60–64 percent TRR. No single component accounted for higher than 10 percent TRR, except for PCP-MalCys from the high-rate application (10 percent TRR, 0.36 mg/kg). Although numerous metabolites (about 60) were identified at low levels, approximately one half of the identified radioactivity attributed to five components. The most abundant residues were: parent (7.5–8.0 percent TRR) and PCP-MalCys (9.8–10 percent TRR). Three other components were PCA (2.4–4.3 percent TRR), PCTA (2.7–3.5 percent TRR) and AM TCB sulfonic acid (3.9–4.8 percent TRR). The hexane fractions contained quintozene as the major component and 11 metabolites.

Peanut

In three studies on peanut metabolism, ¹⁴C-quintozene was applied as pre-plant soil incorporation treatment. In the third study, ¹⁴C-quintozene was also applied twice as band application at around pegging time.

In the first study ¹⁴C-quintozene was applied at 420 kg ai/ha (incorporation into top 15 cm of the soil), higher than the rates used in all other metabolism studies. Peanut plants were harvested 21 weeks after the application and separated into roots, vines, shells and nutmeat. TRR were 1520, 42.3, 128 and 5.16 mg eq/kg in roots, vines, shells and nutmeat, respectively.

Aqueous methanol extracted most of radioactive residues from vines, shells and nutmeat (94–100 percent TRR) while from roots, only 67 percent TRR was extracted. In the extracts, a total of three metabolites were identified. In nutmeat, only one metabolite was identified, which was PCP-MalCys at 6.7 percent TRR (0.26 mg/kg). PCP-MalCys was also a predominant metabolite in roots (33 percent TRR, 320 mg/kg), vines (20 percent TRR, 6.9 mg/kg) and shells (42 percent TRR, 47 mg/kg). TCA accounted for 25 percent (240 mg/kg), 14 percent (4.9 mg/kg), and 22 percent (26 mg/kg) of TRR, respectively in roots, vines and shells. In the same matrices, MTCP-TAA accounted for 8.7 percent (85 mg/kg), 14 percent (4.7 mg/kg) and 7.4 percent (3.4 mg/kg) respectively. Acid hydrolysis in methanolic HCl liberated more than 90 percent of radioactivity in the PES of vines, shells and nutmeat but the liberated radioactivity was not subject to identification.

In the second study, ¹⁴C-quintozene was applied at 37.9 kg ai/ha (incorporation into the top 7.6 cm of the soil). Immediately after the application, peanut was sown. Foliage samples were collected at 92 and 154 DAT while hulls and nutmeat samples were collected at 185 DAT. TRR were 3.50–3.97 mg eq/kg, 26.3 mg eq/kg and 2.00 mg eq/kg in foliage, hulls and nutmeat, respectively.

Extraction with hexane followed by methanol recovered 87 percent from nutmeat but 50–55 percent TRR from vines and shells.

From nutmeat extracts, a total of 66 percent TRR was identified (quintozene and 7 metabolites in hexane fraction; and quintozene and 3 metabolites in methanol fraction). PCA and PB each accounted for 17 percent TRR (0.36 mg/kg). TCNP-MalCys and PCP-MalCys together accounted for 13 percent TRR (0.27 mg/kg). Parent quintozene accounted for 5.7 percent TRR (0.12 mg/kg) and PCTA 9.5 percent TRR (0.20 mg/kg).

In hulls, 41 percent TRR was identified (quintozene and 7 metabolites, same as in nutmeat). The predominant residues were TCNP-MalCys and PCP-MalCys together accounting for 34 percent TRR (8.3 mg/kg). Other identified metabolites and quintozene each accounted for <4.0 percent TRR.

In vines, 32 percent TRR was identified (quintozene and 6 metabolites). The predominant residues were TCNP-MalCys and PCP-MalCys, together accounting for 27 percent TRR (1.09 mg/kg). Other identified metabolites and quintozene each accounted for <2.7 percent TRR.

HCl hydrolysis of the PES from vines and nutmeat did not release the significant amounts of radioactivity from the PES. HCl hydrolysis of the iso-octane or methanol extract of vines released 60 percent or 42 percent of the radioactivity respectively but released radioactivity was not identified.

In the third study, ¹⁴C-quintozene was applied in two treatment regimens: pre-plant soil incorporation treatment at 16.8 kg ai/ha after which peanut was sown; or two banded applications at 5.6 kg ai/ha, both at pegging time (68 days and 117 days after planting). Peanut was grown in greenhouse. Mature plants were collected either 193 DAT (pre-plant application) or 76 DALA (banded applications) and separated into vines (hay), shells, nutmeat and roots.

TRR from the pre-plant application and banded application were within 3-fold difference without clear indication about which of these two regimes gave rise to higher residues: 13.0–16.3, 1.72–2.14, 166–211, and 49–122 mg eq/kg respectively in hay, nutmeat, shells and roots.

A total of 94–100 percent of TRR was extracted from nutmeat and hay by a series of extraction with methanol/water (20:80) followed by acetone.

After two banded applications at pegging, quintozene in the extracts and after hydrolysis with methanolic HCl accounted for 97 percent TRR with trace amount of PCA in nutmeat.

In hay from the two banded applications, 92 percent TRR was identified. PCTP-MalCys was the predominant residue at 53 percent TRR followed by N-malonyl-S-(tetrachloroaminophenyl)-cysteine at 20 percent TRR and parent quintozene at 19 percent TRR.

Treated seeds

Seeds of maize, peas, sugar beet, wheat and soya bean were treated with ¹⁴C-quintozene and sown and grown in an open-sided greenhouse. After harvesting at respective commercial timing, radioactivity was measured in the harvested crops. There was uptake of radioactivity by all the crops with the highest radioactivity found in dry pea vines and soya bean stems at 1.8 and 1.5 mg eq/kg, respectively. While radioactivity above the LOQ was detected in vines, roots, hay, forage, and straw, none of the harvested seeds/grains from these crops contained residues above the minimum quantifiable limits. None of the samples were subjected to identification/ characterization.

Summary of plant metabolism

Metabolism of quintozene in plants after pre-plant soil incorporation application was studied on cabbage, potato and peanut. In the case of peanut, metabolism after two banded applications at pegging was also studied. In old studies on cabbage, potato and peanut, identified compounds were not consistent with newer studies and none of the compounds in the polar fraction was identified; or extraction took place 2 years or later after the harvest.

In the newer studies on potato, numerous compounds (about 60) were identified including those in the polar fractions. About 60–64 percent TRR was identified and approximately about one half of the identified radioactivity (27–30 percent TRR) was comprised of five compounds. PCP-MalCys and its esters together accounted for 10–13 percent TRR. This compound was also found in the old studies on cabbage, potato and peanut. Parent quintozene accounted for 7.5–8.0 percent TRR. PCA and PCTA accounted for 2.4–4.3 percent and 2.7–3.5 percent TRR respectively. AM TCB sulfonic acid accounted for 3.9–4.8 percent TRR. No other metabolites accounted for more than 2.8 percent TRR while the concentrations of many metabolites were higher than 0.01 mg/kg. PB was detected up to 1.9 percent TRR (up to 0.014 mg/kg).

Based on new data, the Meeting confirmed that the metabolism of quintozene in plants occurs through three routes: (1) dechlorination, replacing chlorine by hydrogen or hydroxyl to yield metabolites with less chlorine on the phenyl ring; (2) reduction of the nitro group to NHOH or elimination; or (3) displacement of the nitro group with sulfhydryl group of glutathione to give glutathione adducts or SH-containing amino acids, which are metabolized or oxidized to become sulfoxide, sulfone and sulfonic acid. They may be further metabolized to produce conjugates with glutathione, cysteine, malonylcysteine, glucose and others or incorporated into biomolecule.

Environmental fate

Aerobic degradation in soils

Quintozene in sandy loam soil degraded showing non-linear trend. A half-life of 189 days was calculated approximating first-order kinetics. The concentration of quintozene reached less than half of the initially applied in 60 days possibly due to its volatility. The major degradation products were PCA and PCTA. Other identified degradation products were PCTA sulfone and PCTA sulfoxide which occurred from oxidization of PCTA, and PB.

Quintozene was found to leach in small amounts (2–17 percent in four soil types) and only into the adjacent untreated soil zone.

Photodegradation in soil

There was gradual decline observed through one year in soil surface under photo-irradiation. A half-life of quintozene exposed to artificial sunlight was 28.5 days in sandy loam soil.

PCA and PCTA seemed major photodegradation products but they were found not only under irradiation but also in dark control and therefore in their formation photo irradiation does not play significant role.

Field dissipation

Field dissipation studies conducted in six locations in the United States with single application at rates ranging from 2.5 to 33.6 kg ai/ha or two applications each at 36.6 kg ai/ha indicated that quintozene dissipated with a geometric mean DT_{50} of 88 days and the total of quintozene, PCA, PCTA, PB and impurity HCB dissipated with a geometric mean DT_{50} of 360 days. These compounds were found in 0–15 cm layer soil at almost all the sampling intervals (up to 546 days). They were not found, or, if found, at very low levels in depths below 15 cm. The accumulation rates of the degradates were faster than their dissipation rates. These results indicate that quintozene itself is moderately persistent while the degradates are persistent.

Rotational crop metabolism

The Meeting received information on confined rotational crop studies and a field rotational crop study.

Confined rotational crop studies

Bare soil was treated with ^{14}C -quintozene with soil incorporation, and allowed to age for 30, 120 or 365 days as the plant-back intervals (PBI) before planting lettuce, turnips and wheat.

In the first study, after the 34 kg ai/ha application, succeeding crops were grown indoor and harvested at immature and mature growth stages. The TRR in mature plants after 31-day, 121-day or 365-day PBI were: lettuce, 1.6, 0.15 or 0.73 mg eq/kg; in turnip tops and roots, 3.6 and 20.3, 1.7 and 4.8, or 0.73 and 1.5 mg eq/kg respectively; and in wheat straw, hulls and grain, 22.9, 11.1 and 0.33; 22.2, 6.1 and 0.71; or 25.9, 8.0 and 0.38 mg eq/kg respectively. The TRR in 0–15 cm soil 2 h after the application were in a range of 6.56–14.3 mg eq/kg and showed some tendency to gradually decrease with aging.

Samples of lettuce and turnip tops and roots were centrifuged to remove water (treated as “aqueous extract”) and the remaining moist tissues were extracted with methanol/water (40:60) and the extracts were partitioned with chloroform, and the methanol fraction was combined with the “aqueous extract” for analysis. Samples of wheat materials were extracted with methanol and then water, and after adjusting to methanol/water ratio to 40/60, the extract was partitioned with chloroform. PES fractions of

wheat straw were hydrolysed with HCl, NaOH and cellulase. The extraction with methanol and acid hydrolysis of PES together recovered a total of 36.0–53.8 percent TRR from lettuce from all the PBIs; and 76.0 percent and 62.1 percent TRR from turnip roots and tops respectively from 365-day PBI; and 49.4–53.9 percent TRR in wheat hulls. The extraction with methanol and acid/base hydrolysis of the PES of wheat straw, recovered 61.6–67.5 percent TRR. While methanol extracted 36–67 percent TRR, acid hydrolysis released additional 9.4–19 percent TRR.

Residues of quintozene, PCA or PCTA were not found in any of lettuce, turnip tops and roots, or wheat straw and hulls. Those compounds found at higher than 0.01 mg/kg were: in all crops from all PBIs, N,N'-diacetyl-S,S'-(tetrachloro-p-phenylene)-dicysteine /C4CyCy; and in wheat straw and hulls from all PBIs, PCP-GSH; PCP-MalCys; TCP-diGSH; and N-acetyl-S-(pentachlorophenyl)-cysteine. The percentage of identified compounds in the TRR was low, 5.1–6.3 percent in lettuce; 4.3 percent in turnip roots, 12.3 percent in turnip tops, 12.1–16.9 percent in wheat straw, and 33.6–34.9 percent in wheat hulls.

In the second study, after 35 kg ai/ha application, succeeding crops were grown indoor and harvested at immature and mature growth stages. The TRR in mature plants after 31-day, 121-day or 365-day PBI were: mature lettuce, 3.0, 0.13, 0.45 mg eq/kg respectively, mature turnip tops and roots, 11.9 and 11.4, 1.3 and 5.8, or 0.91 and 1.9 mg eq/kg respectively; and mature wheat straw, hulls and grain, 27.7, 21.5 and 0.63, 13.4, 2.0 and 0.07 and 6.28, 19.3 and 1.2 mg/kg respectively. The TRR in soil immediately after treatment was in a range of 2.6–12.7 mg eq/kg.

Samples were extracted with hexane followed by methanol. These solvents extracted 77–80 percent TRR in lettuce from 121-day and 365-day PBI while only 10.8 percent TRR in lettuce from 30-day PBI; 47.1–67.0 percent and 50.1–71.8 percent TRR respectively from turnip tops and roots from all the PBIs; and 35.2–62.5 percent, 41.5–49.7 percent, and 29.6–34.2 percent TRR in wheat grain, hulls and straw respectively from all the PBIs. PES of turnip roots and tops from all PBIs and wheat matrices 365-day PBI were acid hydrolysed. Acid hydrolysis released 5.6–7.9 percent TRR and <5 percent TRR from the PES of turnip tops and turnip roots, respectively; and <1 percent - 30 percent TRR from the PES of wheat matrices.

Detailed identification was performed only on turnip roots from 31-day PBI. Quintozene, PCA, PCTA and PB were identified in the hexane extract at the maximum of 4.1 percent TRR and 0.69 mg/kg. In the methanol extract, S-(tetrachlorothiophenol)-N-malonylcysteine and PCP-MalCys together accounted for 16 percent TRR and 2.7 mg/kg. The identified residue accounted for 11.8 percent TRR in hexane fraction and 15.6 percent TRR in methanol fraction, totalling 27.9 percent TRR.

In the third study, after application at rates of 2.2, 11 and 34 kg ai/ha, succeeding crops were grown outdoor and harvested at immature and mature growth stages. The application rate of 11 kg ai/ha was used for all crops. After the 11 kg ai/ha application, TRR in mature plants after 30-, 120- or 365-day PBI (only 365-day PBI for turnip) were: lettuce, 0.15, 0.10 or 0.43 mg eq/kg; turnip tops and roots, 1.1 and 0.77 mg eq/kg (1st retrieval results); and wheat forage, grain, and straw, 3.0, 0.79 and 10.7; 3.4, 0.94 and 16.8; or 0.64, 0.14 and 4.6 mg eq/kg. The TRR in soil immediately after application of quintozene at 33.6 kg ai/ha were within a range of 2.6–12.7 mg eq/kg.

Samples were extracted using methanol followed by methanol/water (1:1), or methanol/water (1:1) alone, and the extracts were partitioned with chloroform, hexane followed by chloroform, or dichloromethane. Methanol and methanol/water, or methanol/water extracted a total of 56–77 percent TRR (27–44 percent TRR in chloroform fraction and 22–38 percent TRR in aqueous fraction) in lettuce; and 52–76 percent and 59–70 percent TRR respectively from wheat forage and wheat straw. However, from wheat grain, only 9.8–33 percent TRR were released.

The PES remaining after extraction were treated with sequential digestions with three groups of enzymes (pH 5 compatible enzymes, pH 7 compatible or pH 6 compatible enzymes and proteases) followed by base hydrolysis. The hydrolysis with enzymes and strong acid and or base released <10 percent TRR in each fraction, except protease and base treatment released up to 10.1 percent TRR and 16.8 percent TRR respectively from lettuce PES; pH 5 compatible enzyme, pH 6 compatible enzyme and base treatment released up to 42.0 percent TRR, 13.7 percent TRR and 23.6 percent TRR from the wheat grain PES. After these treatments, < 10 percent TRR remained in the PES of these commodities.

Residues of quintozene were found in lettuce at 21 percent TRR (max conc. 0.032 mg/kg) from 30-day PBI and decreased in terms of percent TRR and concentration as the aging of soil got longer (after 365-day PBI, around 1 percent TRR and < 0.01 mg/kg). It was also found in wheat straw (2.2 kg ai/ha, 120-day PBI) at 0.023 mg/kg but not in turnip. PCA was found in all three crops. There were numerous compounds identified in lettuce and wheat matrices but most of them at very low levels.

Field rotational crop study

Unlabelled quintozene was applied to bare soil simulating the maximum US GAP for peanut (2 × 5.6 kg ai/ha; not valid at the time of this evaluation). Lettuce and wheat were planted 30, 120 and 365 days after the second application, and turnip 365 days after the second application. Samples were obtained at mature growth stage, except that wheat forage was obtained at immature stage. Samples were extracted with acetone/hexane (50:50) and partitioned with water to obtain the hexane layer which was cleaned up using Florisil column for analysis of quintozene, PCA, PCTA, PB, HCB, TCA, PCTASO and TCTASOO.

Quintozene was detected above the LOQ of 0.005 mg/kg in the 30-day PBI and 120-day PBI lettuce at a maximum 0.013 mg/kg. Quintozenes were not found in any of wheat and related samples from any PBI or in turnip roots or tops from 365-day PBI (only PBI tested for turnip).

PCA was mostly below the LOQ but found above the LOQ in 30-day PBI lettuce (highest, 0.0092 mg/kg), 30-day PBI and 365-day PBI wheat forage (highest, 0.016 mg/kg) and turnip roots from 365-day PBI (highest, 0.014 mg/kg). PCTA was not found above the LOQ in any of the samples. PB, HCB, TCA, PCTASO, or TCTASOO were not found above the LOQ of 0.005 mg/kg in lettuce, turnip or wheat from all PBIs, except in 365-day PBI turnip roots TCA was found above the LOQ (highest, 0.010 mg/kg).

From 366- or 367-day PBI, no residues above the LOQ of 0.005 mg/kg of quintozene, PCTA, PCTASO, TCTASOO, PB or HCB were found in any portions of lettuce, turnip or wheat tested. PCA and TCA were found in the turnip roots at levels up to 0.014 mg/kg, PCA in wheat forage at the maximum 0.016 mg/kg.

Summary of rotational crop studies

In the confined rotational crop studies using the high application rates (up to 34.6 kg ai/ha pre-plant), similar metabolites as plant metabolism studies were identified showing complex metabolite profile, except that parent quintozene was either not found or found at low levels.

In the field study with unlabelled quintozene (2 × 5.6 kg ai/ha), quintozene was detected above the LOQ of 0.005 mg/kg in the 30-day PBI and 120-day PBI lettuce at a maximum 0.013 mg/kg. Quintozenes were not found in any of wheat and related samples from any PBI or in turnip roots or tops from 365-day PBI (only PBI tested for turnip). PCA was mostly below the LOQ with sporadic detection up to 0.0092 mg/kg in 30-day PBI in lettuce and up to 0.016 mg/kg in wheat forage. PCTA was not found above the LOQ in any of the samples. PB, HCB, TCA, PCTASO, or TCTASOO were not found above the LOQ of 0.005 mg/kg in lettuce, turnips or wheat from all PBIs, except that up to 0.01 mg/kg TCA was found in

365-day PBI turnip roots. At higher single application rate to the soil (such as 25 kg ai/ha on the provided label for cabbage and broccoli), residues of quintozene were expected above 0.01 mg/kg in lettuce and other leafy vegetable.

The metabolism of quintozene in rotational crops seems to follow similar pathway as in the plant metabolism.

Animal metabolism

The Meeting received information on metabolism in lactating goats and laying hens, in addition to metabolism in rats.

Rat

Metabolism studies on laboratory animals including rats were reviewed in the framework of toxicological evaluation by the current JMPR.

Lactating goats

In three studies with goats, ¹⁴C-quintozene was orally administered to lactating goats once daily for five consecutive days. The goats were sacrificed approximately 6 h after the final dose.

In the first study, two goats were dosed orally with ¹⁴C-quintozene in capsules at levels 25 or 50 mg/kg bw (equivalent to 714 and 947 ppm in the diet). The administered dose was eliminated in feces (36/41 percent of the total dose for 25 mg/kg bw goat/50 mg/kg bw goat) and urine (30/20 percent of total dose) within 48 h. A small amount was excreted in milk (0.34/0.21 percent of total dose). TRR in milk reached the highest level of 6.0/3.6 mg eq/kg on day 2 pm, after which TRR decreased. Liver, kidney and fat contained 13/13, 10/11, and 15–16/9.4–12.8 mg eq/kg respectively. Muscle contained much lower radioactivity of 0.54/0.48 mg eq/kg.

The samples of tissues were extracted with a mixture of chloroform, methanol and water, and the chloroform fraction was partitioned between acetonitrile and hexane. The milk samples and a portion of liver sample were extracted with chloroform/methanol (1:1) and the chloroform extracts were cleaned up with gel permeation column. From milk, kidney, muscle and fat following the administration of 25 mg/kg bw., 70.8–84.0 percent TRR were extracted in chloroform fraction while 4.3–18.0 percent TRR were found in the methanol/water fraction and PES contained 0–29.9 percent TRR. From liver using two slightly different extraction and partition systems, 24.2/31.4 percent TRR were extracted in chloroform fraction with 5.8/29.5 percent TRR in methanol/water fraction and PES contained 69.4/42.4 percent TRR, showing that the extraction system with chloroform/methanol was more efficient.

Chloroform fractions from the 25 mg/kg bw dose goat were subject to identification. Quintozene was extensively metabolized and it was not found in milk or tissues. PCA was identified as the main metabolite in milk (50 percent TRR, 3.0 mg/kg), kidney (31 percent TRR, 3.2 mg/kg), muscle (59 percent TRR, 0.32 mg/kg) and fat (49 percent TRR, 7.7 mg/kg). PCTA was identified at lessor amounts in milk (4.7 percent TRR, 0.28 mg/kg), kidney (2.8 percent TRR, 0.29 mg/kg), muscle (6.4 percent TRR, 0.04 mg/kg) and fat (1.5 percent TRR, 0.23 mg/kg). In liver, the majority of the radioactivity (40 percent TRR) was associated with an unknown polar metabolite released by base hydrolysis. As a result, PCA and PCTA accounted for 9.6 percent (1.3 mg/kg) and 1.3 percent (0.18 mg/kg) of TRR, respectively.

In the second study, two goats were dosed orally with ¹⁴C-quintozene in capsule at 20 or 50 mg/kg bw. The administered dose was eliminated in urine (33/38 percent of total dose for 20 mg/kg bw goat/50 mg/kg bw goat) and faeces (25/19 percent of the total dose). A small amount is excreted in milk (0.4 percent of total dose). TRR in milk reached a plateau on Day 2. Only 1.3/1.1 percent of total dose

remained in tissues, bile and urine in bladder. Kidney, liver, renal fat contained 32/49, 26/46 and 18–33 mg eq/kg. Muscle contained much lower levels of 1.1/2.3 mg eq/kg.

In milk from lower dose, hexane extracted 55 percent TRR with 31 percent TRR remaining in PES. In kidney and liver from lower dose, extraction with water/methanol/chloroform (1:2:1) recovered a total of 68 percent and 60 percent TRR leaving 16 percent and 46 percent TRR in the respective PES. Base hydrolysis of the PES released 10.0 percent and 4.8 percent TRR, respectively. In renal fat and omental fat from the lower dose, chloroform extracted 72.9 percent and 70.9 percent TRR respectively with 1.6 percent and 1.7 percent TRR in the PES. No extraction was conducted on muscle samples.

The extracts of kidney and liver of lower dose goat were subject to identification and characterization. The chloroform fraction of kidney contained quintozene (9.1 percent TRR, 2.9 mg/kg), followed 2,3,4,5-TCNB (0.5 percent TRR, 0.16 mg/kg). In the aqueous fraction, a smaller amount of quintozene was identified (0.5 percent TRR). The chloroform fraction of liver contained parent quintozene and PCA (together 8.3 percent TRR, 2.2 mg/kg), PCTA (5.4 percent TRR, 1.4 mg/kg) and 2,3,4,5-TCNB (1.0 percent TRR, 0.26 mg/kg). In the aqueous fraction, a smaller amount of quintozene and 2,3,4,5-TCNB were identified. Radioactivity in milk was not characterized.

In the third study, one goat was orally dosed with ^{14}C -quintozene at 50 mg/kg bw. The TRR in milk, kidney, liver, fat and muscle were 59, 49, 46, 22 and 2.2 mg eq/kg respectively.

Extraction of the 2nd day milk sample with ethyl acetate recovered 87 percent TRR. The kidney, liver and muscle samples were extracted with a mixture of methanol, chloroform and water and the PES was treated with protease. For kidney, chloroform fraction accounted for 46 percent TRR, aqueous fraction 28 percent TRR and PES 26 percent TRR of which 19 percent TRR was solubilized with protease (total of 93 percent TRR extracted). For liver, chloroform fraction accounted for 24 percent TRR, aqueous fraction 20 percent TRR and PES 56 percent TRR which was solubilized with protease. For muscle, 98 percent TRR was extracted. The renal and omental fat samples were extracted with chloroform and, after evaporation of chloroform, partitioned with acetonitrile and hexane. The acetonitrile fraction contained 84 percent of TRR. For milk, kidney, liver, muscle and fat, extractability was high from 84 to 100 percent TRR.

In kidneys, six metabolites were identified, among which PCA and PCA glucuronide accounted for 26 and 55 percent of the extracted residue. The four other metabolites were PCTP, tetrachloro(methylthio)benzenethiol, TCTA and TCA sulfoxide, each < 4.5 percent. In liver, also six metabolites were identified, mainly PCA (17 percent) and PCA-glucuronide (73 percent). Other four identified metabolites were PCPT dimer, N-pentachlorophenylhydroxyamine, PCPT and tetrachloro(methylthio) benzenethiol, each < 4.7 percent. In muscle, four metabolites were identified: PCA (46 percent), PCTA (11 percent) and TCTA/tetrachlorophenyl methyl sulfoxide (together, 42 percent). In fat and milk, only one metabolite was identified as PCA, 96–100 percent of the extracted. In this study, quintozene was not detected in milk or tissues.

Laying hens

Laying hens were orally dosed with ^{14}C -quintozene for five (first study) or six (second study) consecutive days. Birds were sacrificed approximately 6 h after the final dose.

In the first study, two groups of hens were dosed orally with ^{14}C -quintozene in capsule at 25 or 50 mg/kg bw (equivalent to 309 or 554 ppm in the diet). The majority of the total dose was recovered in excreta (65/71 percent TAR for 25 mg/kg bw group/50 mg/kg bw group) in four days, followed by GI tract and its contents (6.5/9.2 percent). Liver, kidneys, all eggs contained 0.03/0.04 percent, 0.02 percent and 0.01–0.02 percent of the total dose. In eggs, most of the radioactivity was found in egg yolk

(1.2/2.7 mg eq/kg at sacrifice), much higher than that in corresponding egg white (0.038/0.071 mg eq/kg). Kidneys, liver, abdominal fat and skin with fat contained 4.5/5.5, 2.0/2.4, 2.1/4.2 and 1.1–2.2 mg eq/kg respectively. Breast muscle contained 0.16/0.31 mg eq/kg, significantly lower than fat, as in the case of lactating goats.

Egg yolk, liver, kidney, fat and muscle were extracted with a mixture of chloroform, methanol and water. After evaporation, chloroform fraction was partitioned between acetonitrile and hexane. From liver of lower dose hens, 86.3 percent TRR were extracted and additional 10.8 percent TRR were released from PES by acid hydrolysis (total, 97.1 percent TRR). From kidney of the lower dose hens, 72 percent TRR was extracted and additional 19.1 percent TRR was released by base hydrolysis (total, 91.4 percent TRR). From fat, breast muscle and egg yolk at sacrifice, 103.5 percent, 97.0 percent and 33.5 percent TRR were extracted.

In liver extracts, quintozene, PCA and PCTA, each accounted for 3.2 percent, 0.45 percent and 1.5 percent TRR respectively. In kidney extracts, quintozene, PCA and PCTA were detected, each accounting for 0.80 percent, 2.7 percent and 0.23 percent TRR, respectively. The concentrations of these compounds were >0.01 mg/kg. The majority of the radioactivity in liver and kidney was not adequately identified or characterized.

In the second study, three groups of hens were dosed orally with ¹⁴C-quintozene in capsule at rates equivalent to 105, 273 and 512 ppm in the diet. The majority of the total dose was eliminated in the excreta (87–94 percent of administered dose) for three dose groups. The TRR in liver, kidneys, thigh muscle and fat in three dose groups were 0.87/2.72/3.81, 1.84/5.05/7.29, 0.13/0.36/0.71, 2.64/6.17/10.1 mg eq/kg respectively. TRR in day-5 egg yolk and white were 1.74/3.52/5.75, and 0.06/0.24/0.29 mg eq/kg, respectively.

The tissue and egg yolk samples were extracted with a mixture of chloroform, methanol and water. Except for fat sample, significant radioactivity remained in PES: 32.8 percent TRR for kidney, 35.2 percent TRR for liver, 25.9 percent TRR for thigh muscle, and 75.3 percent TRR for egg yolk obtained from the highest dose. In order to solubilize the radioactivity in the PES, acid and base hydrolysis and proteolytic enzyme treatment were attempted. Base hydrolysis was the most efficient in solubilizing radioactivity in PES, releasing: 79.9 percent in kidney, 104 percent in liver, 75.9 percent in thigh muscle but only 38.2 percent in egg yolk. Among proteolytic enzymes with different optimal pH, 116 percent, 55 percent and 81 percent of radioactivity in kidney PES were released by pepsin, trypsin and protease treatment respectively. These enzymes released only up to 17.1 percent of radioactivity in liver PES and up to 7.4 percent in egg yolk PES.

In fat, quintozene was the predominant residue accounting for 48 percent of extracted radioactivity. Other major metabolites included PCA (16 percent) and tetrachloromethylsulfanyliline (31 percent). In liver, PCTP (71 percent) and PCTASO (21 percent) were identified. Base hydrolysis of the liver PES released PCA and PCTA. In egg yolks, PCA (70 percent), PCTA (9 percent) and PCTP (18 percent) were identified. In muscle, the major radioactive residues were PCP thioacetate or TCTA sulfone (88 percent) with minor amounts of PCTA (8 percent). Quintozene was found only in fat.

Summary of animal metabolism

The metabolism of quintozene was investigated in lactating goats and laying hens. In general, the metabolic pathways in these species were similar to that in rats.

In goats, quintozene was metabolized mainly to PCA and its glucuronide conjugates. Other metabolites were formed in much smaller amounts. They were TCTA, PCTA, C4MX. Parent quintozene was not detected in any of the tissues.

In hens, PCA, PCTA, PCTP, PCTP conjugated with cysteine, malonylcysteine, pyruvate and acetate were identified. Other metabolites identified included TCTA, TCTASOO, PCTASO and tetrachloromethylsulfanyl aniline. Parent quintozene was detected in muscle (55.8 percent TRR) and fat (59.8 percent TRR) as predominant residue and in kidney and liver at low levels in one study, but detected only in fat at 48 percent of the extracted residue in another study.

The major metabolic pathway in animals involves (1) displacement of the nitro group by the sulfhydryl group of glutathione or SH-containing amino acids/peptides, followed by catabolic cleavage of the peptide, or by hydroxyl group; (2) reduction of the nitro group to produce N-hydroxypentachloroaniline and conjugated PCA; (3) dechlorination to yield tetrachloro- trichloro- phenyl compounds. The pathway has some commonality with the metabolism in plants.

Methods of analysis

The Meeting received information on the analytical methods using GC-ECD or GC-MS for the determination of residues of quintozene for data development and enforcement for broccoli, cabbage, peppers, tomato, green bean, dry bean, lettuce, potato, turnip roots and tops, wheat (forage, grain and straw), cotton seed and its processed products, peanut (whole, shell and nutmeat), cattle milk and tissues, and poultry eggs and tissues. The analytes include quintozene, PCA, PCTA, PB and impurity HCB. Some methods are capable of determining 2,3,4,5-TCNB and 2,3,5,6-TCNB.

In general, the methods for plant commodities employed extraction by homogenization with solvents containing hexane, such as 2-propanol/hexane, acetone/hexane or hexane alone, or acetonitrile/water, ethyl acetate and then partitioned into hexane fraction. After clean-up using either of Florisil, gel permeation, silica gel or SPE column, the hexane phase or reconstituted phase in other organic solvent was separated and quantified by GC-ECD or GC-MS. These methods were validated through recovery tests with the acceptable range of mean recoveries and RSD.. For the analytes mentioned above, the validated LOQ were in a range of 0.0005–0.01 mg/kg for each analyte.

One method for monitoring using the QuEChERS extraction, clean-up with SPE column, and GC-MS analysis was also validated for quintozene, PCA and PCTA with the LOQ of 0.01 mg/kg for broccoli and potato.

For quintozene, PCA, PCTA PB and HCB in animal commodities, the methods employed extraction by either acetone and then partitioned into hexane, or hexane alone, and without clean-up, analysis was conducted using GC-ECD with the LOQ in a range of 0.001–0.01 mg/kg. There was no full validation data provided to the Meeting. For analysis of these compounds in bovine and poultry commodities, procedural recovery data of the methods used in cattle and poultry feeding studies were available. In most of animal matrices, except bovine milk and egg yolk, recovery was examined by only single test on one or two fortification levels. For milk and egg yolk, four or five fortification levels were tested mostly in single or duplicate. In milk, quintozene showed recovery lower than 70 percent in 2 of 4 fortification levels. Therefore, the Meeting considered that the methods were not sufficiently validated and not fit-for-purpose.

Stability of pesticide residues in stored analytical samples

The Meeting received information on storage stability of quintozene, PCA, PCTA and PB and HCB in various commodities of high water content (broccoli, peppers, tomato, lettuce, snap bean, turnip tops and wheat immature whole plant), high protein content (kidney bean and soya bean), high starch content (potato, turnip root, corn and wheat grain), high oil content (cotton seed and peanut) and dry sample (wheat straw).

Table 5.30.2 Summary of frozen storage stability of quintozene, PCA, PCTA, PB and HCB is shown below

Category	Commodity	Duration of study (month)	Stable period (months) ^a				
			Quintozene	PCA	PCTA	PB	HCB
High water content	Broccoli	14	14	14	14	14	14
	Peppers	14	Up to 4	Up to 4	Up to 4	<2	Up to 4
	Tomato	14	14	14	14	14	14
	Lettuce	24	24	24	Up to 18	24	24
	Snap bean	23	Up to 3	23	Up to 3	Up to 3	Up to 3
	Turnip tops	24	24	24	Up to 18	24	24
	Wheat immature whole plant	24	24	24	24	24	Up to 18
High protein content	Kidney bean	14	14	14	14	Up to 6	14
	Soya bean	8	<2	<2	<2	<2	<2
High starch content	Potato	14	14	14	14	14	14
	Turnip root	14	24	24	24	24	24
	Corn	8	<2	<2	<2	<2	<2
	Wheat grain	24	24	24	24	24	24
High oil content	Cotton seed	18	18	18	18	18	18
	Peanut	14	14	14	14	14	14
Dry sample	Wheat straw	24	24	24	24	24	24

Notes:

^a Where the value of stable period is the same as the duration of study, this indicates that the fortified compound was stable at least for the months in this table. Where the term "up to" precedes the value of stable period, the fortified compound would not be stable after the months specified. The month value with the "<" symbol indicate that significant degradation occurred by the months described.

The storage periods in the storage stability studies on plant commodities cover the sample storage intervals in the residue trials.

Storage stability data were not available on animal commodities.

Definition of residue**Plant commodities**

The plant metabolism of quintozene was studied in cabbage, potato and peanut. As for cabbage, there were inconsistent results in two studies. In the first study, quintozene or PCA were not detected but two metabolites were identified which were not detected in the other study. In the other study, quintozene, PCA and PCTA were detected in immature cabbage and mature wrapper leaves at the maximum 0.05 mg/kg and 1.6 percent TRR. The total identified radioactivity was only up to 18 percent TRR. The highest reported component was the sum of TCNP-MalCys and PCP-MalCys at the maximum 12 percent TRR and 0.34 mg/kg but no separate values were available for each of them.

As for potato, a new metabolism study identified numerous compounds, including conjugates with GSH, cysteine, malonylcysteine, sulfoxide, sulfone, and others, at low levels. A total of 60–64 percent TRR was identified. Quintozenone, PCA and PCTA were identified and quantified but PCP-MalCys was the most abundant residue (10–12 percent TRR).

A new metabolism study on peanuts identified a total of 62 percent of TRR. Quintozenone was the most abundant residue in nutmeat at 62 percent TRR. In the older studies, PCP-MalCys was identified as the predominant residue (20–42 percent TRR) with smaller amount of quintozene, PCA and PCTA.

In the supervised residue trials, quintozene was detected generally at higher concentrations than PCA and PCTA, or at similar or slightly lower concentrations than PCA. PCTA was detected generally at lower levels than quintozene or PCA. In the trials on potato, in addition to quintozene, PCA and PCTA, PB, HCB, 2,3,4,5-TCNB and 2,3,5,6-TCNB were analysed. 2,3,4,5-TCNB and 2,3,5,6-TCNB were, when analysed, below the LOQ. Quintozenes were also detected at slightly higher than the LOQ of 0.005 mg/kg in succeeding lettuce in the field rotational crop study with the treatment of bare soil at a rate which is about one third of the maximum rate in available GAP.

Analytical methods were available to determine quintozene in plant commodities.

The Meeting therefore concluded that quintozene was a suitable marker for MRL-compliance.

For the residue definition for dietary risk assessment, the Meeting considered likely occurrence and toxicological relevance. While more than 80 compounds including many conjugates were identified, most of which were at low concentrations and contributions. The Meeting noted that while parent quintozene is not regarded as genotoxic, possibility of genotoxicity could not be excluded for all the metabolites, due to the lack of toxicological information on these metabolites and quantification of metabolites in rat metabolism. The Meeting considered that these metabolites could be assessed using the TTC approach for genotoxic compounds (0.0025 µg/kg bw/day).

The Meeting was unable to reach conclusion on residue definition for dietary risk assessment for plant commodities. due to concern of potential genotoxicity of all the metabolites.

Animal commodities

In the animal metabolism studies, parent quintozene was not detected in milk or any tissue of lactating goats in two of three studies. In laying hens, quintozene was detected at significant levels in tissues in one study but not in tissues other than fat in the other study. Therefore, quintozene alone is not a suitable marker.

PCA was the most predominant residue in tissues and milk, and egg yolk and fat. In chicken muscle, quintozene or PCA was not detected and the most predominant residue was PCP thioacetate or TCTA sulfone (88 percent of the extracted residue) followed by PCTA (8 percent of the extracted residue).

GC-ECD methods provided were not supported by full validation data and the Meeting considered it was not certain that these methods were fit-for-purpose to determine quintozene, PCA and PCTA in animal commodities. Therefore, it was not possible for the Meeting to establish residue definition for compliance with MRLs for animal commodities.

For the residue definition for dietary risk assessment, the Meeting considered likely occurrence and toxicological relevance. In the animal commodities, except egg yolk, the total of metabolites identified was relatively high in percentage of TRR, and comparing with plant commodities, the number of identified metabolites was relatively small. The Meeting noted that possibility of genotoxicity could not be excluded for all the metabolites, due to the lack of toxicological information on these metabolites and quantification of metabolites in rat metabolism. The Meeting considered that these metabolites could be assessed using the TTC approach for genotoxic compounds (0.0025 µg/kg bw/day).

The Meeting was unable to reach a conclusion on residue definition for dietary risk assessment for animal commodities. due to concern that exposure would exceed the TTC for genotoxicity of all the metabolites.

Conclusion

Based on the above, the Meeting recommended the following residue definition.

Definition of the residue for compliance with the MRL for plant commodities: *Quintozene*.

Results of supervised residue trials on crops

The Meeting received supervised trial data for quintozene residues on broccoli; cabbage, head; tomato; peppers; beans with and without pods; beans (dry); potato; cotton seed; and peanut conducted in the United States.

At the time of this evaluation, there were Codex MRLs for the following commodities but the current Meeting withdrew the previous recommendations: for barley; barley straw and fodder, dry; maize; maize fodder (dry); pea hay or pea fodder (dry); peas (dry); soya bean (dry); soya bean fodder; sugar beet; wheat; and wheat straw and fodder, dry since no GAP information or residue data were provided for these commodities.

The Meeting decided to withdraw the previous recommendations for quintozene on spices, fruits and berries; spices, roots and rhizomes, based on monitoring data .

Due to genotoxic concerns of all the metabolites, the Meeting estimated maximum residue levels based on provided supervised residue trials but they were not recommended for use as MRLs.

Broccoli

The critical GAP in the United States for broccoli (among the list of various Cole crops, but not for a group) allows one application of pre-plant banded soil application or broadcast application at 25 kg ai/ha.

The Meeting received 12 supervised trials conducted on broccoli in the United States during the growing season of 1988/89 and 2018/19.

In the trials, broadcast application and banded application of WP and GR formulations were used at rates (shown below for each residue value) that differ from the GAP rate. There were also direct seed treatment and transplant solution applications.

Since a number of the application rates used in the trials differed by more than 25 percent of the GAP rate, the Meeting decided to use the proportionality approach to estimate a maximum residue level and an STMR. Scaled residues were calculated using the formula below.

Scaled residue (mg/kg) = (residue in the trial, mg/kg) × 2.025 (kg ai/ha) / (rate used in the trial, kg ai/ha).

After each scaled residue value, the residue found in each trial and respective application rate are indicated in a pair of parentheses, e.g., (residue value in mg/kg, application rate in kg ai/ha).

Residues of quintozene from trials with banded application approximating the GAP in the United States were in rank order (n=7 scaled residues): 0.006 (0.005, 22.4), 0.008 (0.007, 22.4), 0.009 (0.008, 22.4), < 0.01 (< 0.01, 36.6), < 0.01 (0.13, 36.6), 0.024 (0.032, 36.6), and 0.026 (0.023, 22.4) mg/kg.

Residues of quintozene from trials with broadcast application approximating the GAP in the United States were in rank order (n=7 scaled residue): 0.005 (0.006, 33.6), 0.005 (0.006, 33.6), 0.006 (0.007, 33.6), < 0.01 (< 0.01, 36.6), < 0.01 (< 0.01, 36.6), 0.018 (0.024, 36.6), and 0.020 (0.027, 33.6) mg/kg.

Mann-Whitney U-test indicates that residues of quintozene from banded application and broadcast application were not significantly different. Therefore, the Meeting used the highest residue levels of quintozene from either banded or broadcast application in independent trials. Residues from independent trials were in rank order (n=7): 0.006, 0.008, 0.009, < 0.01, < 0.01, 0.024, and 0.026 mg/kg.

In a field rotational crop study with two applications each at 5.6 kg ai/ha, quintozene was detected above the LOQ of 0.005 mg/kg in lettuce from 30-day and 120-day PBI. The mean value was calculated using the residue data from all PBIs to be 0.0065 mg/kg (assuming that values < 0.005 mg/kg were at 0.005 mg/kg). After applying quintozene at 30 kg ai/ha, the highest maximum rate among available GAP, the mean residue in succeeding lettuce would be 0.017 mg/kg.

Adding 0.017 mg/kg, residue of quintozene from banded and broadcast application were: 0.023, 0.025, 0.026, < 0.027, < 0.027, 0.041 and 0.043 mg/kg.

The Meeting estimated a maximum residue level of 0.09 mg/kg for broccoli. The Meeting withdrew its previous recommendation of 0.05 mg/kg.

Cabbage, head

The critical GAP in the United States for cabbage (among the list of various Cole crops, but not for a group) is for one pre-plant banded soil application or broadcast application at 25 kg ai/ha.

The Meeting received 16 supervised trials conducted on cabbage in the United States during the growing season of 1987/88, 1988/89 and 1990/91.

In the trials, broadcast application and banded application of WP and GR formulations were used. There were also transplant solution applications.

Residues of quintozene from trials with banded application approximating the GAP in the United States were in rank order (n=15 including scaled residues): < 0.002, < 0.002, 0.002, 0.003, 0.003 (0.003, 24.7), 0.007, 0.009 (0.009, /24.7), < 0.01, < 0.01, < 0.01, < 0.01, < 0.01, 0.010 (0.009, 22.4), 0.013 (0.013, 24.7) and 0.042 (0.038, 22.4) mg/kg.

Residues of quintozene from trials with broadcast application approximating the GAP in the United States were in rank order (n=15 scaled residue): < 0.002 (0.002, 33.6), < 0.002 (0.003, 33.6), < 0.002 (0.003, 33.6), 0.003 (0.004, 33.6), 0.004 (0.005, 33.6), 0.007 (0.009, 33.6), 0.008 (0.010, /33.6), 0.008 (0.011, 33.6), < 0.01, < 0.01, < 0.01, < 0.01, < 0.01 (0.013, 33.6), 0.022 (0.030, 33.6), and 0.028 (0.037, 33.6) mg/kg.

Mann-Whitney U-test indicates that residues of quintozene from banded application and broadcast application were not significantly different. Therefore, the Meeting used the highest residue levels of quintozene from either banded or broadcast application in independent trials. Residues from independent trials were in rank order (n=15): < 0.002, < 0.002, 0.003, 0.004, 0.007, 0.008, 0.009, < 0.01, < 0.01, < 0.01, < 0.01, 0.013, 0.028 and 0.042 mg/kg.

In a field rotational crop study with two applications each at 5.6 kg ai/ha, quintozene was detected above the LOQ of 0.005 mg/kg in lettuce from 30-day and 120-day PBI, with the mean value of 0.0065 mg/kg calculated assuming that values < 0.005 mg/kg were at 0.005 mg/kg. After applying quintozene at 30 kg ai/ha, the highest maximum rate among available GAP, the mean residue in succeeding lettuce would be 0.017 mg/kg.

Adding 0.017 mg/kg, residues from independent trials according to GAP in the United States were: 0.019, 0.019, 0.020, 0.021, 0.024, 0.025, 0.026, 0.027, 0.027, 0.027, 0.027, 0.027, 0.027, 0.030, 0.045 and 0.059 mg/kg.

The Meeting estimated a maximum residue level of 0.08 mg/kg for cabbages, head. The Meeting withdrew its previous recommendation of 0.1 mg/kg for cabbages, head.

Tomato

Critical GAP for tomato was from Mexico, for a single application of quintozene at a maximum rate of 14.4 kg ai/ha in nursery. No trials matching this GAP were available.

GAP for tomato in Thailand allows spraying to soil, immediately after planting young tomato plant and repeating spraying every 14 days at least two times at a maximum spray concentration of 1.50 kg ai/hL. No trials matching this GAP were available.

GAP in Ecuador for kidney tomato allows the use of quintozene in greenhouse at 0.56 kg ai/ha with a PHI of 1 day (number of applications not specified). No trials matching this GAP were available.

The Meeting therefore decided to withdraw the previous recommendation of 0.02 mg/kg for tomato.

Peppers

The critical GAP for chili peppers is in Mexico which allows a single application in nursery situations.

The Meeting received nine supervised trials conducted in the United States during the growing seasons of 1987/1988 and 1988/89. In the trials, quintozene was applied to soil at the time of planting and only in two trials chili peppers were grown and harvested.

The Meeting considered that the trials did not match the GAP in Mexico. The Meeting withdrew the previous recommendation of 0.05 (*)mg/kg for peppers, sweet. Consequently, the Meeting also withdrew the previous recommendations on dried chili peppers (0.1 mg/kg).

Beans with pods, Beans, shelled and Beans (dry)

Critical GAP for beans in Mexico allows a single application at 8.64 kg ai/ha as band application at the beginning of flowering.

The Meeting received 20 supervised trials on beans with pods, three trials on shelled beans, 13 trials on beans (dry) conducted in the United States. Except for three trials on beans with pods using in-furrow application, other trials used 4 or 3 post-emergence applications. Finite residues were found in four trials on beans with pods and five trials on beans (dry). The Meeting considered that these trials did not match the critical GAP and could not be used for estimating a maximum residue level.

For in-furrow application at planting, critical GAP was from Mexico that allows a single banded application of 1.44 kg ai/ha at sowing.

In three in-furrow trials, the application was made once at 1.68 kg ai/ha and beans with pod were sampled. Residues of quintozene from trials approximating this GAP were: < 0.0005, 0.017 and 0.074 mg/kg. Since there were only three trials, the Meeting considered the information was not sufficient for estimating a maximum residue level.

The Meeting withdrew its previous recommendations for common bean (pods and/or immature seeds) at 0.1 mg/kg and for common beans (dry) at 0.02 mg/kg.

Potato

For in-furrow applications, the critical GAP is from the United States, which allows one application of quintozene at the maximum rate of 5.6 kg ai/kg, sprayed as a 22-cm band in the seed furrow at planting.

The Meeting received 37 supervised trials conducted on potato in the United States using in-furrow application at rates 11.2–13.1 kg ai/ha.

Residues of quintozene from the in-furrow application approximating US GAP with scaling (scaling factors from 5.6/14.0–5.6/4.12) were (n=37): < 0.01, < 0.01, 0.013, 0.013, 0.015, 0.020, 0.037, 0.038, 0.049, 0.056, 0.064, 0.068, 0.073, 0.081, 0.090, 0.093, 0.095, 0.099, 0.10, 0.10, 0.14, 0.14, 0.15, 0.16, 0.16, 0.16, 0.17, 0.18, 0.20, 0.22, 0.27, 0.35, 0.36, 0.38, 0.39, 0.44 and 0.79 mg/kg.

For chemigation, the critical GAP of United States allows two applications at the maximum rate of 2.8 kg ai/ha with a PHI of 28 days.

The Meeting received eight supervised trials conducted on potato in the United States using two chemigation applications at a rate of 2.8 kg ai/ha each.

Residues of quintozene from the chemigation application matching the US GAP were (n=8): < 0.01, < 0.01, 0.011, 0.017, 0.019 (0.037, 5.6), 0.026, 0.039 and 0.080 mg/kg.

For broadcast application, cGAP in Mexico allows one application at the maximum rate of 30.0 kg ai/ha. PHI was not specified. Twenty independent trials were conducted in the United States. Residues of quintozene from independent trials using the broadcast application and matching the GAP in Mexico were (n=20): < 0.002, 0.007, 0.007, 0.009, 0.014, 0.018, 0.044, 0.048, 0.067, 0.070, 0.074, 0.078, 0.087, 0.098, 0.11, 0.12, 0.14, 0.15, 0.19 and 0.66 mg/kg.

Among these three data populations, residues from chemigation were significantly lower than the other two populations. Residues from in-furrow application and those from broadcast applications were different according to Mann-Whitney U-test. As the residues from in-furrow application would lead to a higher maximum residue level, using this data population, the Meeting estimated a maximum residue level of 0.8 mg/kg for potato.

Cotton seed

Critical GAP in South Africa for cotton allowed one application of quintozene into furrow at the maximum rate of 5.25 kg ai/kg.

The Meeting received 23 supervised trials conducted on cotton in the United States during the growing seasons of 1987 to 1992. The trials used in-furrow application at planting or in five trials banded soil application at planting at a rate of 2.24 kg ai/ha. Residues of quintozene from the trials with banded soil application at 2.24 kg ai/ha were all below the LOQ of 0.01 mg/kg. The maximum residue level of quintozene from in-furrow application at 2.24 kg ai/ha was 0.012 mg/kg. Since residue levels were below the LOQ in most of the trials, there were only 3 finite values for scaling up to the GAP rate in South Africa. The Meeting concluded that information was insufficient to estimate maximum residue level for cotton seed.

Therefore, the Meeting decided to withdraw the previously recommended maximum residue level of 0.01 (*) mg/kg for cotton seed.

Peanut

Critical GAP for peanuts was from Mexico, which allows a single banded application at a rate of 1.92 kg ai/ha at sowing.

The Meeting received 36 supervised trials conducted on peanut in the United States conducted during the growing seasons of 1987 to 1992. In all the trials in the United States, two applications with quintozene were made during pegging time. The Meeting concluded that the trials did not match this GAP and decided to withdraw the previous recommendation of 0.5 mg/kg for peanut.

Residues arising from crop rotation

In a field rotational crop study using two applications of 5.6 kg ai/ha, quintozene was detected above the LOQ of 0.005 mg/kg in lettuce. Residues of quintozene were expected to occur in leafy vegetables and Brassica vegetables from crop rotation. Residues found from 30, 120 and 365-day PBI were: < 0.005 × 15, 0.053, 0.075, 0.0080, 0.0096, 0.0120, 0.0126 and 0.0133 mg/kg.

The critical maximum seasonal rate according to the available GAP is 30 kg ai/ha (Mexico). Finite residues were scaled to the rate of 30 kg ai/kg using the scaling factor of 30/11.2: 0.014, 0.020, 0.021, 0.026, 0.032, 0.034 and 0.037 mg/kg. Assuming that residues < 0.005 mg/kg were at 0.005 mg/kg, scaled residue of < 0.005 mg/kg would be 0.013 mg/kg

The Meeting estimated a maximum residue level of 0.08 mg/kg for a group of leafy vegetables and a group of Brassica vegetables (except Brassica leafy vegetables) (except broccoli and cabbage).

Fate of residues during processing

No information was available on high temperature hydrolysis.

Processing

The Meeting received information on residues in edible portions of potato and peanut, and processing of tomato, green beans, potato, cotton seed and peanut to various processed commodities.

Processing factors of quintozene for potato, for which maximum residue level was estimated, to its processed commodities potato are shown below.

Table 5.30.3 Potato processing factors

Commodity	n	Processing factor for quintozene	
		Individual	Best estimate
Potato		-	
Wet peel	8	2.0, 3.3, 5.6, 5.8, 7.6, 10, 11, 13	6.7
Dried peel	8	2.3, 13, 13, 14, 25, 16, 65, 75	19.5
Peeled potato	4	0.06, 0.10, 0.10, 0.14	0.10
French fries	2	1.9, 2.8	2.35
Crisps	10	0.13, 0.16, 0.23, 0.47, 0.80, 0.99, 1.3, 1.7, 1.8, 1.9	0.90
Dried flakes	2	0.14, 0.18	0.16
Flakes	8	0.02, 0.04, 0.04, 0.06, 0.06, 0.07, 0.09, 0.10,	0.06
Granules	8	0.00, 0.00, 0.01, < 0.02, < 0.02, < 0.02, 0.02, 0.04	0.02

Residues in animal commodities

Livestock feeding studies on lactating cows and laying hens were provided. However, due to the lack of full validation data on the analytical methods used, it was not possible to use the data for evaluation. Therefore, it was not possible to estimate maximum residue levels for animal commodities.

The Meeting withdrew its previous recommendations on chicken commodities: 0.1(*) mg/kg (fat) for chicken meat, 0.01(*) mg/kg for chicken, edible offal of, and 0.03 (*) mg/kg in eggs.

RECOMMENDATIONS

On the basis of the data from supervised trials, the Meeting agreed to the following residue definition.

Definition of the residue for compliance with the MRL for plant commodities: *Quintozene*.

The Meeting was unable to establish residue definition for compliance with MRLs for animal commodities.

The Meeting was also unable to reach a conclusion on residue definition for dietary risk assessment for plant and animal commodities. due to concern that exposure would exceed the TTC for genotoxicity of all the metabolites.

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The Meeting confirmed an ADI of 0–0.01 mg/kg for quintozene and ARfD was unnecessary.

As the Meeting was unable to conclude on the toxicological relevance of all the metabolites, the Meeting could not reach a conclusion on a residue definition for dietary risk assessment. As a result, long-term dietary exposure assessments could not be conducted.

Threshold of toxicological concern (TTC) consideration for metabolites

The Meeting noted that possibilities of genotoxicity could not be excluded from all the metabolites. They could be assessed using the TTC approach for genotoxicity (threshold of 0.0025 µg/kg bw per day for genotoxic compounds).

In one potato metabolism study and one confined rotational crop study, numerous non-polar and polar metabolites were identified. However, the percentage of identified radioactivity in confined rotational crop studies was relatively low mostly below 50 percent of TRR, except that in turnip roots about 80 percent TRR was identified. In a field rotational crop study, quintozene, PCA, PCTA, TCA TCTASOO and PCTASO, PB and HCB were analysed, among which quintozene, PCA and TCA were detected in food commodities.

PCA and PCTA were also analysed in supervised residue trials provided to the Meeting.

Dietary exposure was calculated for a number of the metabolites using the rotational crop studies and the IEDI spreadsheet and compared with the threshold of 0.0025 µg/kg bw per day. The calculated exposure may be underestimated due to the low percentage of identification. For the metabolites calculated, TTC for genotoxic compounds was exceeded. Two examples are shown below.

1. PCA

PCA was detected in many of metabolism studies and confined rotational crop studies. PCA concentrations in the extracts in the confined rotational crop studies were scaled from the application rates used in the studies to the highest possible application rate of 30 kg ai/ha.

PCA was detected in turnip roots and lettuce at 0.023–0.155 mg/kg and 0.018–0.12 mg/kg, respectively, after scaling.

Using the lowest quantified concentrations, the calculated chronic exposure from root and tuber vegetables, leafy vegetables and Brassica vegetables were in a range of 0.063–0.24 µg/kg bw, higher than the TTC for genotoxic compounds (0.0025 µg/kg bw).

2. TCA

TCA was detected in the field rotational crop study in turnip root at < 0.005–0.010 mg/kg. Since in the study the application rate was 2×5.6 kg ai/ha, while the highest possible application rate was 30 kg ai/ha, the Meeting applied the proportionality principle to scale up the residues. The scaled finite residues were: 0.0134, 0.0169, 0.190 and 0.0279 mg/kg. TCA was < 0.005 mg/kg in other rotated crops and not detected in confined rotational crop studies.

Using the lowest quantified residue after scaling, the calculated chronic exposure from root and tuber vegetables were in a range of 0.021–0.15 $\mu\text{g}/\text{kg}$ bw, higher than the TTC for genotoxic compounds (0.0025 $\mu\text{g}/\text{kg}$ bw).

The Meeting concluded that the chronic dietary exposure of many of metabolites arising from uses of quintozene considered by the Meeting exceeded the TTC for genotoxic compounds of 0.0025 $\mu\text{g}/\text{kg}$ bw/day and they may present a public health concern.

5.31 Spiromesifen (294)

RESIDUE AND ANALYTICAL ASPECTS

Spiromesifen is a contact insecticide-acaricide belonging to the titronic acid class of compounds. The mode of action is inhibition of lipid biosynthesis, especially triglycerides and free fatty acids.

Spiromesifen was first evaluated by the 2016 JMPR where an ADI of 0–0.03 mg/kg bw was established and an ARfD was determined to be unnecessary. The residue definition for compliance with MRLs for plant and animal commodities and for dietary risk assessment for animal commodities is *sum of spiromesifen and spiromesifen-enol, expressed as spiromesifen*. For dietary risk assessment for plant commodities, the residue definition is *sum of spiromesifen, spiromesifen-enol and 4-hydroxymethyl-spiromesifen-enol (free and conjugated), expressed as spiromesifen*. The residue is fat-soluble.

Spiromesifen was scheduled at the Fifty-second Session of the CCPR for evaluation of additional uses by the 2022 JMPR. The Meeting received information on GAP, analytical methods, storage stability data, processing studies and residue trials on oranges, mango, papaya, legume vegetables and pulses.

Methods of analysis

The Meeting received additional information on analytical methods for spiromesifen and spiromesifen-enol in plant commodities for data gathering.

LC-MS/MS method 00631 was evaluated by the 2016 JMPR and successfully validated in high water content (broccoli, cucumber, pepper, melon, beans, tomato), high starch content (corn/maize, sugar beet), high oil content (cotton), high acid content (strawberry) commodities and tea. Additional method validation data for the modified method 00631/M001 are available as part of the supervised residue trials relied upon in this submission. The Meeting concluded that this method is valid for the determination of spiromesifen and spiromesifen-enol with LOQ values at 0.01 mg/kg in mango, dry beans and at 0.05 mg/kg in succulent shelled beans and edible podded beans for each compound individually.

Another LC-MS/MS method BS001-P09-01, a modification of analytical method 00631, was evaluated by the 2016 JMPR and successfully validated in high starch content commodities (wheat: grain, aspirated grain fractions, bran, flour, germ, middling's, shorts; and sorghum: grain and aspirated grain fractions). Additional method validation data for the modified method BS001-P09-02 are available as part of the supervised residue trials relied upon in this submission. The Meeting concluded that this method is valid for the determination of spiromesifen and spiromesifen-enol with LOQ values at 0.01 mg/kg in orange whole fruit, pomace, dry pulp, juice, marmalade, peel, wet pulp and at 0.10 mg/kg in orange oil for each compound individually.

Stability of pesticide residues in stored analytical samples

The stability of spiromesifen spiromesifen-enol and metabolite 4-hydroxymethyl-Sp-enol residues under frozen conditions was investigated in high protein, high oil, high acid, high water and high starch content commodities by the 2016 JMPR. The total residues of spiromesifen and spiromesifen-enol were stable for at least 24 months in all matrices tested.

The current Meeting received additional storage stability data for spiromesifen and spiromesifen-enol under freezer storage conditions for dry beans, coffee beans and citrus fruits. The total residue (sum of spiromesifen and spiromesifen-enol) and spiromesifen-enol (per se) were demonstrated to be stable for at least 24 months in all matrices investigated. Parent spiromesifen (per se) was stable for at least 24

months in coffee beans and citrus fruits, but degraded significantly in dry beans within 30 days, resulting from the formation of spiromesifen-enol.

The samples analysed in the supervised residue trials included in this submission were stored for up to a maximum of 498 days (ca. 16 months) prior to analysis, therefore, the available data for the sum of spiromesifen and spiromesifen-enol is sufficient to cover these frozen storage intervals.

Results of supervised residue trials on crops

Oranges sweet, sour (subgroup)

The critical GAP for the use of spiromesifen on citrus fruits in Brazil is a single foliar spraying with 0.144 kg ai/ha and 21 days PHI.

Thirteen supervised field trials on oranges conducted in Brazil, matching the cGAP were provided. In whole fruits, residues for the sum of spiromesifen and spiromesifen-enol, expressed as spiromesifen were (n = 13): 0.021, < 0.024(2), 0.025, 0.041, 0.042, 0.043, 0.045, 0.047(2), 0.049, 0.100 and 0.103 mg/kg.

As oranges covered by the registered use correspond to the Codex subgroups for subgroup 1C (Oranges, Sweet, Sour) the Meeting decided to extrapolate the estimates from oranges to subgroup 1C (Oranges, Sweet, Sour).

The Meeting estimated a maximum residue level of 0.15 mg/kg and an STMR of 0.043 mg/kg for Subgroup of Oranges, Sweet, Sour.

Mango

The critical GAP for mango is from registrations in Brazil with three applications (minimum application interval of 7 days) at 0.144 kg ai/ha and a 5-day PHI.

Five supervised field trials conducted in Brazil, matching the cGAP were provided. In whole fruits, residues for the sum of spiromesifen and spiromesifen-enol, expressed as spiromesifen were (n = 5): 0.079, 0.115, 0.135, 0.200 and 0.225 mg/kg. All residue values in pulp were (n = 5): < LOQ (< 0.024(5) mg/kg).

The Meeting estimated a maximum residue level of 0.5 mg/kg for mango and an STMR of 0.024 mg/kg based on the residue values in mango pulp.

Papaya

The critical GAP for papaya is from registrations in Brazil with three applications (minimum application interval of 7 days) at 0.144 kg ai/ha and a 5-day PHI.

Five supervised field trials conducted in Brazil, matching the cGAP were provided. In whole fruits, residues for the sum of spiromesifen and spiromesifen-enol, expressed as spiromesifen were (n = 5): 0.046, 0.099, 0.13, 0.23, 0.33 mg/kg.

The Meeting estimated a maximum residue level of 0.7 mg/kg and an STMR of 0.13 mg/kg for papayas.

Beans with pods

The critical GAP for beans with pods is from registrations in Canada with three applications (minimum application interval of 7 days) at 0.144 kg ai/ha and a 1-day PHI.

Seven supervised field trials conducted in United States using a higher application rate (3×0.213 kg ai/ha) were provided. The Meeting agreed to use proportionality to scale down residues to the cGAP.

In beans with pods, unscaled residues of sum of spiromesifen and spiromesifen-enol expressed as spiromesifen were (n = 7): < 0.12, < 0.13, 0.14, 0.24, 0.28, 0.3, 0.44 mg/kg.

In beans with pods, scaled residues of sum of spiromesifen and spiromesifen-enol, expressed as spiromesifen were (n = 7): < 0.053, 0.091, < 0.12, 0.16, 0.18, 0.20 and 0.30 mg/kg.

The Meeting estimated a maximum residue level of 0.5 mg/kg and an STMR of 0.16 mg/kg for beans with pods.

Beans without pods

The critical GAP for beans without pods is from registrations in Canada with three applications (minimum application interval of 7 days) at 0.144 kg ai/ha and a 1-day PHI.

Seven supervised field trials conducted in United States using a higher application rate (3×0.213 kg ai/ha) were provided.

In beans without pods, residues of sum of spiromesifen and spiromesifen-enol, expressed as spiromesifen were (n = 7): < 0.12 (7)mg/kg.

The Meeting estimated a maximum residue level of 0.15(*) mg/kg and an STMR of 0.12(*) mg/kg for beans with pods.

Dry beans and soya beans

For dry beans, the critical GAP for dry beans is from registrations in Canada with three applications (minimum application interval of 7 days) at 0.144 kg ai/ha and a 10-day PHI.

Six supervised field trials conducted in the United States using a higher application rate (3×0.213 kg) were provided. In dry seeds residues for the sum of spiromesifen and spiromesifen-enol, expressed as spiromesifen were (n = 6): < 0.024 (6)mg/kg.

For soya beans, the critical GAP for soya beans is from registrations in Brazil with two applications (minimum application interval of 5 days) at 0.144 kg ai/ha and a 21-day PHI.

Nine supervised field trials conducted in Brazil, matching the cGAP were provided. In dry seeds residues for the sum of spiromesifen and spiromesifen-enol, expressed as spiromesifen were (n = 9): < 0.024 (9)mg/kg.

The Meeting noted that all residues in dry beans and soya beans were below the LOQ (0.024 mg/kg) and decided to propose estimates for the whole subgroup of dry beans.

The Meeting estimated a maximum residue level of 0.03(*) mg/kg and an STMR of 0.024 mg/kg for the subgroup of dry beans.

Animal feed items

Bean forage (green)

The critical GAP for beans is from registrations in Canada with three applications (minimum application interval of 7 days) at 0.144 kg ai/ha and a 1-day PHI.

Seven supervised field trials conducted in the United States at a higher application rate GAP (3×0.213 kg ai/ha, same treatment regime) were provided.

In foliage, unscaled residues of sum of spiromesifen and spiromesifen-enol expressed as spiromesifen (n = 7): 0.38, 0.43, 0.54, 0.58, 0.60, 0.82 and 0.86 mg/kg.

In foliage, scaled residues of sum of spiromesifen and spiromesifen-enol, expressed as spiromesifen were (n = 7): 0.26, 0.29, 0.37, 0.39, 0.41, 0.55 and 0.58 mg/kg.

The Meeting estimated a median residue of 0.39 mg/kg and a highest residue of 0.58 mg/kg for bean forage (as received) based on the scaled data set.

Fate of residues during processing

The Meeting received new processing studies on oranges and soya bean. Processed commodities from oranges (dry pulp, juice, marmalade, oil, dry pomace) and soya bean (flour, hulls, meal, milk, oil) were derived using simulated commercial practices. Processing factors and residue estimates are summarized below.

Table 5.31.1 Processing factors, STMR-Ps and HR-Ps for the sum of spiromesifen and spiromesifen-enol expressed as spiromesifen and used for dietary risk assessment and livestock dietary burden calculation

Raw commodity	Processed commodity	Individual processing factors	Median or best estimate processing factor	STMR-P (Median-P) = STMR RAC \times PF (mg/kg)	Maximum residue level for RAC (mg/kg)	Maximum residue level for processed commodity = maximum residue level \times PF (mg/kg) ^a
Oranges	Pulp, dry	0.7, <u>1.05</u> , <u>2.9</u> , 7.3	2	$0.043 \times 2 = 0.086$	0.15	$0.15 \times 2 = 0.3$
	Raw juice	< 0.03, < 0.11, < 0.2, < 0.2, < 0.2, < <u>0.3</u> , <u>0.3</u> , < 0.5, < 0.6, < 0.6, < 0.7	0.3	-	-	-
	Pasteurize Juice	< 0.03, < <u>0.06</u> , < <u>0.1</u> , < 0.11	< 0.08	$0.043 \times 0.08 = 0.0034$	-	-
	Marmalade	0.04, < <u>0.1</u> , <u>0.1</u> , 0.12,	0.1	$0.043 \times 0.1 = 0.0043$	-	-
	Orange oil, edible	133, <u>183</u> , <u>218</u> , 221	201	$0.043 \times 201 = 8.6$	0.15	$0.15 \times 201 = 30$
	Fruit, raw, without peel	< 0.06, < 0.1	< 0.08	$0.043 \times 0.08 = 0.0034$	-	-
	Pomace, dry	2.9, 7.3	5.1	$0.043 \times 5.1 = 0.22$	-	-
Soya bean	Milk	0.1, < 0.3	0.2	$0.024 \times 0.2 = 0.005$	-	-
	flour	0.14, < 0.3	0.22	$0.024 \times 0.22 = 0.0053$	-	-
	Oil (refined) ^b	< 0.1, < 0.3	0.2	$0.024 \times 0.2 = 0.005$	-	-
	Oil (crude) ^c	0.2, < 0.3	0.25	$0.024 \times 0.25 = 0.006$	0.03(*)	0.03(*)
	aspirated grain	194, 203	199	$0.024 \times 199 = 4.8$	-	-
	Meal	< 0.1, < 0.3	< 0.2	$0.024 \times 0.2 = 0.005$	0.03(*)	0.03(*)
	Hulls	1.1, 1.4	1.25	$0.024 \times 1.25 = 0.03$	0.03(*)	0.03(*)

Notes:

^a Calculated values are rounded according to the OECD rounding classes.

^b Solvent extracted RBD.

^c Cold pressed RBD.

The Meeting estimated a maximum residue level of 30 mg/kg for orange oil edible, 0.3 mg/kg for citrus pulp, dry and of 0.03(*) mg/kg for soya bean oil (crude), hulls, and meal.

Residues in animal commodities

Farm animal feeding studies

No additional information on transfer of residues to livestock was provided to the current Meeting. Please refer to the 2016 JMPR Report.

Estimated maximum and mean dietary burdens of livestock and animal commodities maximum residue levels

Dietary burdens were calculated for beef cattle, dairy cattle, broilers and laying poultry based on feed items evaluated by the Meeting. The dietary burdens, estimated using the most recent version of the OECD livestock dietary burden calculator, are presented in Annex 6 and summarized below. In the 2016 JMPR the calculations were made according to the animal diets listed in Appendix IX of the 2016 edition of the FAO Manual. Results of the estimated maximum and mean dietary burdens are summarized in Table 5.31.2.

Table 5.31.2 Estimated maximum and mean dietary burdens of farm animals

	Animal dietary burden: spiromesifen, ppm of dry matter diet							
	United States-Canada		European Union		Australia		Japan	
	Max	Mean	Max	Mean	Max	Mean	Max	Mean
Beef cattle	2.6	1.3	25.5	6.8	9.6	4.7	0.01	0.01
Dairy cattle	5.0	2.3	23.6	6	39.9 ^①	8.6 ^②	5.50	2.50
Poultry–broiler	0.01	0.01	0.02	0.02	0.07	0.07	0.002	0.002
Poultry–layer	0.01	0.01	0.62 ^{③⑤}	0.1 ^④	0.07	0.07	0.001	0.001

Notes:

- ① Suitable for estimation of maximum residue levels in meat and milk.
- ② Suitable for estimation of median residue levels in meat and milk.
- ③ Suitable for estimation of maximum residue levels in poultry meat.
- ④ Suitable for estimation of median residue levels in poultry meat and eggs.
- ⑤ Suitable for estimation of maximum residue levels in eggs.

The spiromesifen dietary burden reached a maximum level of 25.5 ppm of dry matter diet in beef cattle, 39.9 ppm diet in dairy cattle and 0.62 mg/kg diet in poultry. The mean dietary burdens were 6.8 mg/kg in beef cattle, 8.6 mg/kg diet in dairy cattle and 0.1 mg/kg in poultry. These results are similar to the previous livestock dietary burden calculations performed by the 2016 JMPR (highest maximum dietary burden was 25 ppm of dry matter diet in beef cattle, 40 ppm diet in dairy cattle and 5.3 mg/kg diet in poultry). The meeting confirmed its previous recommendations for animal commodities.

RECOMMENDATIONS

On the basis of the data from supervised trials, the Meeting concluded that the residue levels listed below are suitable for establishing maximum residue limits and for IEDI and international estimate of short-term intakes assessment.

The definition of the residue for compliance with the MRL for plant and animal commodities and for dietary risk assessment for animal commodities: *sum of spiromesifen and spiromesifen-enol, expressed as spiromesifen.*

The definition of the residue for dietary risk assessment for plant commodities: *sum of spiromesifen, spiromesifen-enol and 4-hydroxymethyl-spiromesifen-enol (free and conjugated), expressed as spiromesifen.*

The residue is fat-soluble.

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The ADI for spiromesifen is 0–0.03 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for spiromesifen were estimated for the 17 GEMS/Food Consumption Cluster Diets using the STMR or STMR-P values estimated by the JMPR. The results are shown in Annex 3 of the 2022 JMPR Report.

The IEDIs were 3–20 percent of the maximum ADI. The Meeting concluded that long-term dietary exposure to residues of spiromesifen from uses considered by the JMPR is unlikely to present a public health concern.

Short-term dietary exposure

The Meeting determined that an ARfD is not necessary for spiromesifen. The Meeting therefore concluded that the short-term dietary exposure to residues of spiromesifen resulting from uses that have been considered by the JMPR is unlikely to present a public health concern

5.32 Sulfoxaflor (252)

RESIDUE AND ANALYTICAL ASPECTS

Sulfoxaflor (ISO common name) is a broad-spectrum, sulfoximine insecticide with registered uses on multiple crops. It was evaluated for the first time by JMPR 2011, which established an acceptable daily intake (ADI) of 0–0.05 mg/kg bw and an acute reference dose (ARfD) of 0.3 mg/kg bw. Sulfoxaflor underwent subsequent evaluations by the JMPR in 2014, 2016, and 2021 (Extra). The 2022 JMPR agreed to consider additional residue data provided to support uses on globe artichoke and sunflower, for which the 2021 Extra Meeting was unable to make recommendations.

The definition of the residue in plants and animals for both compliance with MRLs and for dietary risk assessment is sulfoxaflor. The residue is not fat-soluble.

The current Meeting received information on residues in globe artichoke and sunflower to supplement trials evaluated at the 2021 Extra Meeting.

Methods of analysis

The Meeting received concurrent recovery data for use of a standard QuEChERS multiresidue method. The method was demonstrated to have adequate performance for sulfoxaflor from concurrent recovery samples of globe artichoke and sunflower seed, with an LOQ of 0.01 mg/kg. Metabolism studies evaluated by the 2011 JMPR showed high extraction efficiency (73–97 percent TRR) with similar solvent as that used in the QuEChERS method.

Stability of pesticide residues in stored analytical samples

Based on data provided to it, the 2021 Extra Meeting concluded that residues of sulfoxaflor are stable for at least 24 months in globe artichoke and in sunflower seeds during frozen storage. In the studies provided to the current Meeting, samples were stored at -20 °C for up to 3.4 months (globe artichoke) and 4.4 months (sunflower seed).

Results of supervised residue trials on crops

The Meeting received data from supervised residue trials in globe artichoke and sunflower. These data were to supplement studies reviewed by the 2021 Extra Meeting, which concluded that the numbers of trials for those crops were insufficient to make recommendations.

Globe artichoke

The critical GAP for globe artichoke is from the United States. The label provides for up to four applications, each at 101 g ai/ha, on a 7-day interval, with a 3-day PHI. The label also specifies an annual limit of 298 g ai/ha; thus, the critical GAP is three applications at the maximum rate.

Residue of sulfoxaflor in globe artichoke from the additional trial provided to the meeting was (n=1): 0.41 mg/kg. In independent trials evaluated by the 2021 Extra JMPR, residues were (n=3): 0.22, 0.23, and 0.26 mg/kg. Altogether, residues of sulfoxaflor in globe artichoke from independent trials matching the critical GAP were (n=4): 0.22, 0.23, 0.26, and 0.41 mg/kg.

The Meeting estimated a maximum residue level of 0.9 mg/kg, an STMR of 0.245 mg/kg, and an HR of 0.45 mg/kg (from a single sample) for sulfoxaflor in globe artichoke.

Subgroup of sunflower seeds

Sunflower seed

The critical GAP is from the United States on the sunflower subgroup of oilseeds and consists of two applications, each at 96 g ai/ha, with a 7-day re-treatment interval and a 14-day PHI.

Residues of sulfoxaflor in sunflower seeds from independent trials approximating the critical GAP were (n=5): 0.024, 0.047, 0.076, 0.092, and 0.19 mg/kg. In independent trials approximating the critical GAP and evaluated by the 2021 Extra JMPR, residues were (n=4): < 0.01, 0.013, 0.018, and 0.15 mg/kg. Altogether, residues of sulfoxaflor in sunflower seeds from independent trials approximating the critical GAP were (n=9): < 0.01, 0.013, 0.018, 0.024, 0.047, 0.076, 0.092, 0.15, and 0.19 mg/kg.

The Meeting estimated a maximum residue level of 0.4 mg/kg and a STMR of 0.047 mg/kg for residues of sulfoxaflor in sunflower seed. Noting that the registered use includes all commodities in the Codex Subgroup of sunflower seeds (SO 2091) and that sunflower seed is the recommended representative commodity, the Meeting agreed to extrapolate the recommendations to Subgroup 023B Sunflower Seeds.

Fate of residues during processing

The 2021 Extra Meeting evaluated a sunflower seed processing study and derived best-estimate processing factors of 0.71 for both sunflower meal and refined oil. Based on the STMR of 0.047 mg/kg in seed, the STMR-Ps for both meal and refined oil were 0.033 mg/kg.

Residues in animal commodities

The only animal feed item considered by the current Meeting was sunflower meal. Inclusion of sunflower meal in the animal dietary calculations did not change the maximum and mean burdens for cattle or poultry from those calculated by the 2014 JMPR (3.22 and 1.26 ppm respectively for cattle and 0.93 and 0.31 ppm respectively for poultry); therefore, the Meeting confirmed its previous recommendations for residues in animal commodities.

RECOMMENDATIONS

On the basis of the data obtained from supervised trials, the Meeting concluded that the residue levels listed in Annex 1 are suitable for establishing maximum residue limits and for IEDI and international estimate of short-term intakes assessments.

Definition of the residue for compliance with the MRL and for dietary risk assessment for plant and animal commodities: *sulfoxaflor*.

The residue is not fat-soluble.

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The ADI for sulfoxaflor is 0–0.05 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for sulfoxaflor were estimated for the 17 GEMS/Food Consumption Cluster Diets using the STMR or STMR-P values estimated by the JMPR. The results are shown in Annex 3 of the 2022 JMPR Report.

The IEDIs ranged from 1–7 percent of the maximum ADI. The Meeting concluded that long-term dietary exposure to residues of sulfoxaflor from uses considered by the JMPR is unlikely to present a public health concern.

Acute dietary exposure

The ARfD for sulfoxaflor is 0.3 mg/kg bw. The International Estimate of Short-Term Intakes (international estimate of short-term intakes) for sulfoxaflor were calculated for the food commodities and their processed commodities for which HRs/HR-Ps or STMRs/STMR-Ps were estimated by the present Meeting and for which consumption data were available. The results are shown in Annex 4 of the 2022 JMPR Report.

The international estimate of short-term intake varied from 0–2 percent of the ARfD for children and 0–1 percent for the general population. The Meeting concluded that acute dietary exposure to residues of sulfoxaflor from uses considered by the present Meeting is unlikely to present a public health concern.

5.33 Tetraniliprole (324)

TOXICOLOGY

Tetraniliprole is the ISO-approved common name for 1-(3-chloropyridin-2-yl)-*N*-[4-cyano-2-methyl-6-(methylcarbamoyl)phenyl]-3-[[5-(trifluoromethyl)-2*H*-tetrazol-2-yl]methyl]-1*H*-pyrazole-5-carboxamide (IUPAC), with the Chemical Abstract Service number 1229654-66-3.

Tetraniliprole is an anthranilic diamide-class insecticide. The proposed pesticidal mode of action (MOA) for tetraniliprole is by activation of ryanodine receptor channels, leading to internal calcium store depletion that impairs regulation of muscle contraction. Mammalian ryanodine receptors are substantially less sensitive to the effects of anthranilic diamides than are insect ryanodine receptors.

Tetraniliprole was evaluated for the first time by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) in 2021, when an ADI of 0–2 mg/kg body weight (bw) was established for tetraniliprole, BCS-CZ91631 and BCS-CQ63359. An ARfD was considered to be unnecessary. Tetraniliprole was evaluated at the current Meeting for maximum residue limits (MRLs), at the request of the Codex Committee on Pesticide Residues (CCPR). Additional information on the metabolites in the form of quantitative structure–activity relationship (QSAR) analysis of genotoxicity was provided by the sponsor.

Toxicological data on metabolites and/or degradates

In silico predictions of the genotoxicity of tetraniliprole-hydroxy-*N*-methyl (BCS-CZ91629; goat and hen), tetraniliprole-pyrazole-5-*N*-methyl-amide (BCS-CZ84317; goat and hen), tetraniliprole-desmethyl-amide (BCS-CN42374; goat), tetraniliprole-pyridinyl-pyrazole-5-carboxylic acid (BCS-CL73217; goat) and tetraniliprole-quinazolinone (BCS-CZ73507; goat) were provided to the present Meeting. The predictions were prepared using a QSAR program.

Tetraniliprole-desmethyl-amide (BCS-CN42374)

Based on its structural similarity to the parent, tetraniliprole-desmethyl-amide was predicted to be no more toxic than the parent.

Tetraniliprole-hydroxy-*N*-methyl (BCS-CZ91629)

This metabolite was considered to be covered by the parent as it is a major metabolite in the rat.

Tetraniliprole-pyrazole-5-*N*-methyl-amide (BCS-CZ84317), tetraniliprole-pyridinyl-pyrazole-5-carboxylic acid (BCS-CL73217) and tetraniliprole-quinazolinone (BCS-CZ73507)

These metabolites did not show any alerts for genotoxicity on QSAR analysis. However, they were considered insufficiently similar to the parent to read across their toxicity and hence the Cramer class III threshold of toxicological concern (TTC) of 1.5 µg/kg bw per day should be applied.

The Meeting concluded that the metabolite tetraniliprole-desmethyl-amide (BCS-CN42374) was unlikely to be more toxic than the parent on the basis of in silico data and its structural similarity to tetraniliprole. Hence the reference values of the parent are also applicable to tetraniliprole-desmethyl-amide.

Tetraniliprole-hydroxy-*N*-methyl (BCS-CZ91629) is a major metabolite in the rat and was therefore considered to be covered by the reference values of the parent.

For tetraniliprole-pyrazole-5-*N*-methyl-amide (BCS-CZ84317), tetraniliprole-pyridinyl-pyrazole-5-carboxylic acid (BCS-CL73217) and tetraniliprole-quinazolinone (BCS-CZ73507), the TTC value for Cramer class III of 1.5 µg/kg bw per day should be applied.

Microbiological data

There was no information available in the public domain and no experimental data were provided that addressed the possible impact of tetraniliprole residues on the human intestinal microbiome.

Toxicological evaluation

The Meeting concluded that the ADI of 0–2mg/kg bw established in 2021 applies to tetraniliprole, BCS-CQ63359, BCS-CZ91631, BCS-CZ91629 and BCS-CN42374. The 2021 conclusion that an ARfD was not necessary for tetraniliprole also applies to these metabolites.

A toxicological monograph addendum was prepared.

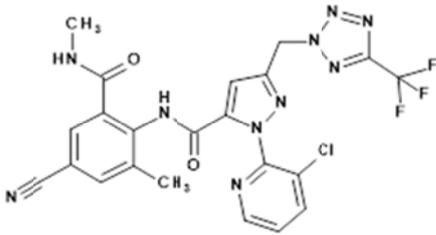
RESIDUE AND ANALYTICAL ASPECTS

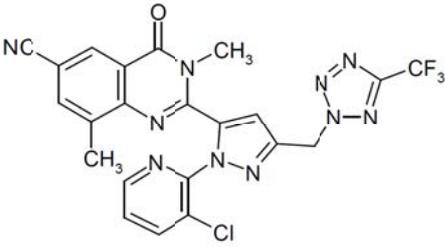
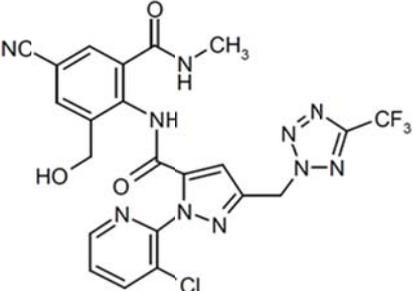
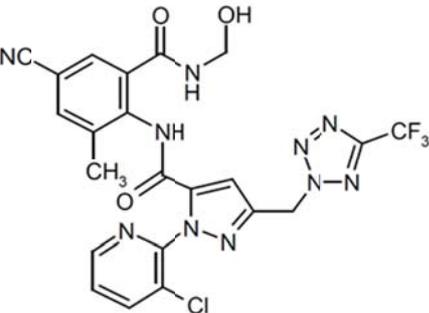
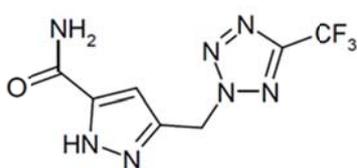
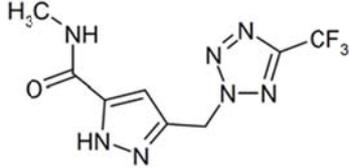
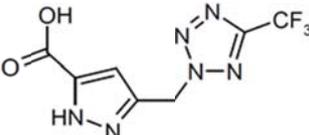
Tetraniliprole (ISO name) is a new broad spectrum fast acting insecticide. The IUPAC name for tetraniliprole is 1-(3-chloropyridin-2-yl)-*N*-[4-cyano-2-methyl-6-(methylcarbamoyl) phenyl]-3-[[5-(trifluoromethyl)-2*H*-tetrazol-2-yl]methyl]-1*H*-pyrazole-5-carboxamide. Tetraniliprole belongs to the anthranilic diamide chemical class. The mode of action of anthranilic diamides involves activating ryanodine receptors (RyRs), which play a critical role in muscle function.

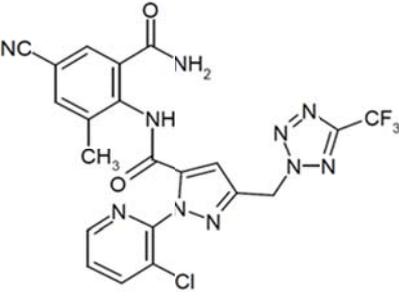
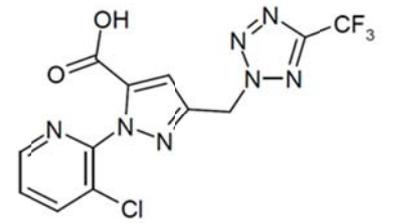
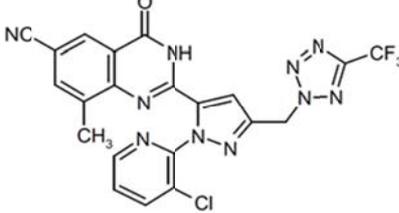
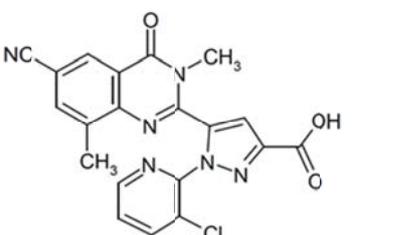
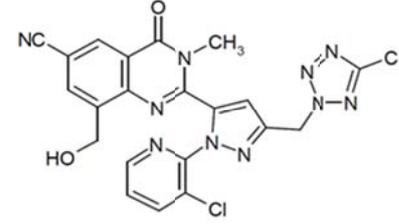
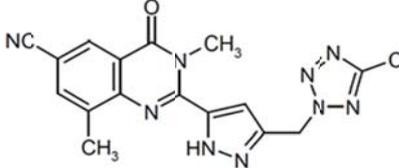
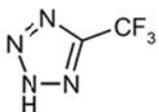
Tetraniliprole was scheduled at the Fifty-first Session of the CCPR (2019) for evaluation as a new compound by the 2020 JMPR, which was postponed to the 2021 JMPR for toxicology and to the 2022 JMPR for residues. The 2021 JMPR estimated an ADI of 0–2 mg/kg bw and concluded that an ARfD was not necessary.

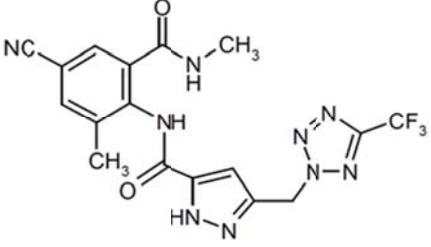
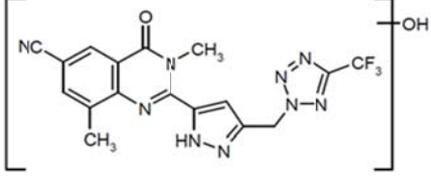
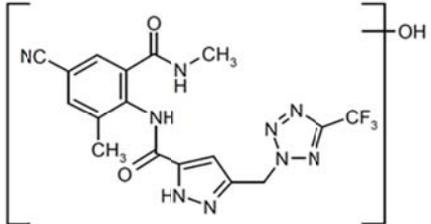
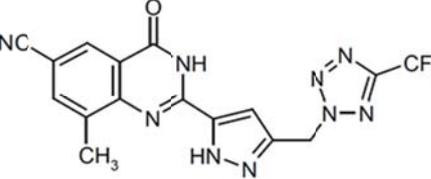
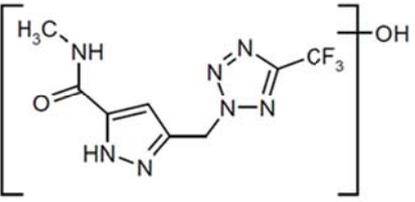
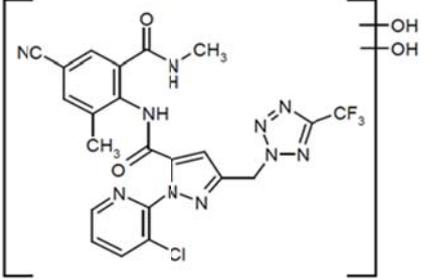
The Meeting received information on identity, physical chemical properties, plant and animal metabolism, aerobic soil degradation, residue analysis, storage stability, use patterns, residues resulting from supervised trials on citrus fruits, pome fruits, stone fruits, grapes, head and stem brassica vegetables, fruiting vegetables, leafy vegetables, soya beans, root and tuber vegetables, cereal grains, tree nuts, and rice, fate of residues during processing, and livestock feeding studies.

Table 5.33.1 The structure of tetraniliprole and of the major metabolites are shown below

Name	Abbreviation	Structure
Tetraniliprole	Tetraniliprole	 <p>The chemical structure of Tetraniliprole is a complex molecule. It features a central pyrazole ring substituted with a 3-chloropyridin-2-yl group, a methyl group, and a methylcarbamoyl group. The pyrazole ring is also substituted with a 5-(trifluoromethyl)-2H-tetrazol-2-ylmethyl group. The pyrazole ring is further substituted with a 4-cyano-2-methyl-6-(methylcarbamoyl) phenyl group.</p>

Name	Abbreviation	Structure
Tetraniliprole-N-methyl-quinazolinone	T-N-methyl-quinazolinone T-N-Met-quinazolinone	 <p>The structure shows a quinazolinone core with a methyl group on the nitrogen, a cyano group at the 6-position, and a methyl group at the 7-position. It is substituted at the 4-position with a pyrazole ring, which is further substituted at the 5-position with a chlorine atom and at the 3-position with a 1,2,4-triazole ring bearing a trifluoromethyl group.</p>
Tetraniliprole-benzylalcohol	T-benzyl-alcohol	 <p>The structure is similar to the N-methyl-quinazolinone but features a benzyl alcohol group (-CH2CH2OH) at the 7-position instead of a methyl group.</p>
Tetraniliprole-hydroxy-N-methyl	T-hydroxy-N-methyl T-OH-N-Met	 <p>The structure is similar to the N-methyl-quinazolinone but features a hydroxymethyl group (-CH2OH) on the nitrogen instead of a methyl group.</p>
Tetraniliprole-pyrazole-5-amide	T-pyrazole-5-amide	 <p>The structure shows a pyrazole ring substituted at the 5-position with an amide group (-CONH2) and at the 3-position with a 1,2,4-triazole ring bearing a trifluoromethyl group.</p>
Tetraniliprole-pyrazole-5-N-methyl-amide	T-pyrazole-5-N-methyl-amide	 <p>The structure is similar to the pyrazole-5-amide but features an N-methyl amide group (-CONHCH3) instead of a primary amide.</p>
Tetraniliprole-pyrazole-5-carboxylic acid	T-pyrazole-5-carboxylic acid	 <p>The structure is similar to the pyrazole-5-amide but features a carboxylic acid group (-COOH) instead of an amide group.</p>

Name	Abbreviation	Structure
Tetraniliprole-desmethyl-amide	T-desmethyl-amide T-DesMet-amide	
Tetraniliprole-pyridinyl-pyrazole-5-carboxylic acid	T-pyridinyl-pyrazole-5-carboxylic acid	
Tetraniliprole-quinazolinone	T-quinazolinone	
Tetraniliprole-N-methyl-quinazolinone-pyrazole-3-carboxylic acid	T-N-methyl-quinazolinone-pyrazole-3-carboxylic acid	
Tetraniliprole-N-methyl-quinazolinone-benzylalcohol	T-N-methyl-quinazolinone-benzylalcohol	
Tetraniliprole-despyridyl-N-methyl-quinazolinone	T-despyridyl-N-methyl-quinazolinone	
Tetrazole (conjugates)	Tetrazole (conjugates)	 -conjugate

Name	Abbreviation	Structure
Tetraniliprole-despyridyl	T-despyridyl	
Tetraniliprole-despyridyl-N-methyl-quinazolinone-hydroxy	T-despyridyl-N-methyl-quinazolinone-hydroxy	
Tetraniliprole-despyridyl-hydroxy	T-despyridyl-hydroxy	
Tetraniliprole-despyridyl-quinazolinone	T-despyridyl-quinazolinone	
Tetraniliprole-pyrazole-5-N-methylamide-hydroxy	T-pyrazole-5-N-methylamide-hydroxy	
Tetraniliprole-dihydroxy	T-dihydroxy	

Name	Abbreviation	Structure
Tetraniliprole-deschloro-desmethyl-amide	T-deschloro-desmethyl-amide	

Physical and chemical properties

Tetraniliprole is not volatile (3.2×10^{-6} mPa at 20 °C), relatively insoluble in water (1.0 mg/L pH4 and 7), but appears to be more soluble in organic solvents (up to 21.8 g/L in acetone). It is hydrolytically stable at environmental conditions (pH4 and 20 °C), but not at higher temperatures and higher pH. Aqueous photolysis is a significant route of degradation. The octanol/water partition coefficient log Pow of 2.6 suggests a slight potential to partition into fat.

Plant metabolism

The Meeting received plant metabolism studies for tetraniliprole after different types of application on apples (foliar application), tomatoes (soil drench application), potatoes (foliar applications or seed treatment in furrow), lettuce (foliar application), paddy rice (foliar application or granular in planting hole treatment) and maize (seed treatment) using [pyrazole-carboxamide- 14 C]- and/or [phenyl-carbamoyl- 14 C]-labelled tetraniliprole, as shown below. The results for both labels are presented as pyrazole-carboxamide/phenyl-carbamoyl, unless indicated otherwise.

Pyrazole-carboxamide label	Phenyl-carbamoyl label
[pyrazole-carboxamide- 14 C]-tetraniliprole	[phenyl-carbamoyl- 14 C]-tetraniliprole

Seed treatments and soil treatments (soil drench, in-furrow, granular)

Tomato-soil drench application (indoor)

Pyrazole-carboxamide or phenyl-carbamoyl labelled tetraniliprole was applied to greenhouse grown tomato plants, as a single soil drench application at BBCH stage 15–16. The application rate was equivalent to 156/153 g ai/ha (based on 20,000 plants/ha; 7.65–7.81 mg ai/plant). Soil characteristics were not reported.

In fruits and leaves collected at 83–99 days after treatment (DAT), total radioactive residue (TRR) were < 0.001 mg eq/kg (both labels) in fruits and 0.005/0.006 mg eq/kg in leaves indicating limited uptake from soil. Despite the limited amount of residue, the extraction efficiency with acetonitrile/water/formic acid seems to be high (> 90/> 86 percent TRR) for both fruit and leaf samples, with the main portion on partitioning detected in the organic phase 68/56 percent TRR in fruit and 76/78 percent TRR in leaves. The unextracted radioactivity was 9.3/13.5 percent TRR in fruits and 6.1/5.6 percent TRR in leaves (all < 0.001 mg eq/kg).

A total of 33/54 percent TRR and 58/64 percent TRR was identified in tomato fruit and leaves, respectively. The predominant radioactive residues in fruits and leaves were parent tetraniliprole accounting for 22/34 percent TRR in fruit and 24/27 percent TRR in leaves and tetraniliprole-N-methyl-quinazolinone at 11/20 percent TRR in fruits and 34/37 percent TRR in leaves. Apart from two unknown metabolites (15 percent TRR each) in fruit, the radioactivity was not further characterized (pyrazole-carboxamide label only). In leaves, six unknown metabolites were characterized, all less than 4.5 percent TRR and < 0.001 mg eq/kg (total 17.5/13.5 percent TRR and < 0.001 mg eq/kg).

Potato–seed treatment in furrow (outdoor)

Pyrazole-carboxamide labelled tetraniliprole was applied to potato tubers in the furrow at planting before covering the seeds with sandy loam soil. The actual application rate corresponded to 200 g ai/ha and potatoes were grown outdoors. Tubers were collected at 151 DAT (BBCH 99).

TRR amounted to 0.001 mg eq/kg indicating limited uptake from soil. No further investigation of the residues was performed.

Paddy rice–granular soil application (indoor)

Rice seedlings (BBCH 13–14, three to four leaves unfolded) were transplanted into containers filled with sandy loam soil treated with granular pyrazole-carboxamide or phenyl-carbamoyl labelled tetraniliprole at 205/211 g ai/ha. Rice forage (BBCH 34–35, 64 DAT), grain (husked rice), husks and straw (BBCH 89–92, 150 DAT) were collected for analysis.

Radioactive residues were low in husked rice, forage, husks and straw, totalling 0.003/0.004, 0.011/0.08, 0.026/0.018, 0.098/0.069 mg eq/kg, in each matrix respectively. The extraction efficiency with acetonitrile/water/formic acid ranged from 76/49 percent TRR in husked rice, to 91/91 percent TRR in straw. The unextracted radioactivity was highest in husked rice with 24/51 percent TRR (0.001/0.002 mg eq/kg) and ranged from 9.0 to 15 percent TRR (0.001–0.004 mg eq/kg) in straw, forage, and husks.

A total of 58/28 percent TRR (0.001/0.001 mg eq/kg) was identified in husked rice and ≥ 78 percent TRR (both labels) in the other matrices. The majority of the identified radioactivity was parent tetraniliprole (48/22 percent TRR, 0.001/0.001 mg eq/kg) in husked rice, accounting for ≥ 77 percent TRR (0.007–0.075 mg eq/kg) with both labels in the other matrices. A minor part of the radioactivity could be attributed to tetraniliprole-N-methyl-quinazolinone (3.9–14 percent TRR, < 0.001–0.014 mg eq/kg across all matrices). With the exception of one unknown in husked rice (17/21 percent TRR, 0.001/0.001 mg eq/kg), all other unknown metabolites were ≤ 4.6 percent TRR and ≤ 0.001 mg eq/kg.

Maize–seed treatment (outdoor)

Pyrazole-carboxamide labelled tetraniliprole was used as a seed treatment to maize grown outdoors in a sandy loam soil. Two different application rates were tested, corresponding to 63 or 150 g ai/ha. Maize forage was harvested at 98 DAT (BBCH 79–83) and mature plants at 145 DAT (BBCH 89).

Radioactive residues after both treatments were low in kernels (< 0.001 mg eq/kg) and forage (< 0.006 mg eq/kg) and amounted to 0.004 mg eq/kg (63 g ai/ha treatment) to 0.008 mg eq/kg (150 g ai/ha treatment) in fodder. Only the higher treatment fodder was subjected to extraction with acetonitrile/water/formic acid, with 76 percent TRR (0.006 mg eq/kg) extracted. The unextracted radioactivity was 24 percent TRR (0.002 mg eq/kg).

The extracted residues in fodder were identified as parent tetraniliprole and tetraniliprole-N-methyl-quinazolinone, representing 26 percent TRR (0.002 mg eq/kg) and 17 percent TRR (0.001 mg eq/kg), respectively. All other metabolites represented ≤ 0.001 mg eq/kg.

Apple–foliar application (indoor)

Pyrazole-carboxamide or phenyl-carbamoyl labelled tetraniliprole was applied to greenhouse grown apples trees, with two foliar spray applications at fruit development (BBCH stage 71 and 73) at a rate of 85–88 g ai/ha per application.

At 64 (fruit) and 66 (leaves) days after application, TRR were 0.18/0.52 mg eq/kg in apple fruits and 99 mg eq/kg in apple leaves. A fruit surface wash with dichloromethane released 92/97 percent TRR, indicating that tetraniliprole residues remained mainly on the surface of the apple fruits. The surface wash with dichloromethane and extraction with acetonitrile/water/formic acid released most of the radioactivity (> 99.5 percent TRR) for both labels in fruit and leaf samples.

Greater than 99 percent TRR could be identified in apple fruit and leaves with both labels. The only identified radioactive residue in fruits and leaves was parent tetraniliprole, accounting for 99.2/99.3 percent TRR in fruit and 98.6 percent TRR in leaves. Two to six minor metabolites were found in fruit and leaves, but none exceeded 0.3 percent TRR (< 0.001 mg eq/kg in fruits and 0.051–0.32 mg eq/kg in leaves).

Lettuce–foliar application (indoor)

Pyrazole-carboxamide or phenyl-carbamoyl labelled tetraniliprole was applied to greenhouse grown lettuce plants, with two foliar spray applications at BBCH stage 44/45. The application rate was 2 × 59–60 g ai/ha, with a retreatment interval of 7 days.

Lettuce was collected at BBCH 49, 7 days after the last application. Total radioactive residues were 4.1 mg eq/kg in lettuce with both labels. Extraction with acetonitrile/water/formic acid released a high level of radioactivity (> 99 percent TRR) with both labels.

A total of 99.5/99.1 percent TRR was identified as parent tetraniliprole. No metabolites were found.

Potato–foliar application (indoor)

Pyrazole-carboxamide or phenyl-carbamoyl labelled tetraniliprole was applied to greenhouse grown potato plants, with two applications at BBCH 38 and 97–99 and rates ranging from 101–105 g ai/ha, with a retreatment interval of 49 days. TRR were low at 0.001 mg eq/kg in potato tubers collected at 14 DAT. Extracted radioactivity of potato tubers with acetonitrile/water was high (79/75 percent TRR), and unextracted radioactivity was 21/25 percent TRR (equivalent with < 0.001 mg eq/kg).

A total of 38/55 percent TRR (both labels) could be identified (< 0.001 mg eq/kg). Tetraniliprole was the major component (29/42 percent TRR), followed by tetraniliprole-N-methyl-quinazolinone (9.0/13 percent TRR). All other metabolites represented < 0.001 mg eq/kg and, apart from one unknown (11.8 percent TRR), all were ≤ 5.3 percent TRR.

Paddy rice–foliar application (indoor)

Pyrazole-carboxamide or phenyl-carbamoyl labelled tetraniliprole was applied to greenhouse grown paddy rice, with two foliar spray applications of 50–52 g ai/ha each with an interval of 42 days, at BBCH 14 and BBCH 73–77 (early to late milk stage). Rice forage was harvested at 13 DAT (BBCH 34–35) and mature rice plants at 56 DAT (BBCH 89–92).

TRRs in rice kernels, forage, husks and straw amounted 0.040/0.024, 1.3/2.6, 2.5/2.1, 4.3/4.6 mg eq/kg, respectively. Extraction with acetonitrile/water/formic acid released high levels of radioactivity (≥ 93 percent TRR) for all matrices and with both labels. The unextracted radioactivity ranged from 0.4–1.7 percent TRR (equivalent with 0.015–0.022 mg eq/kg) in forage, husks and straw and was 6.3/7.3 percent TRR (equivalent with 0.002 mg eq/kg) in kernels.

A total of ≥ 92.7 percent TRR (both labels) was identified. The majority of the identified radioactivity was parent tetraniliprole (≥ 91 percent TRR with both labels in all matrices). A minor contribution to the total radioactivity was attributed to tetraniliprole-N-methyl-quinazolinone (0.7–3.7 percent TRR, < 0.001 –0.151 mg eq/kg). All other metabolites represented ≤ 0.8 percent TRR and ≤ 0.027 mg eq/kg.

Summary of plant metabolism

Tetraniliprole is only marginally taken up from the soil and translocated to other parts of the plants after seed treatment or soil applications (drench or granular). In foliar applications, the majority of the residue remains on the surface, and very limited metabolism in apples or lettuce (indoor foliar applications) was observed. The metabolic pathway involves cyclization in the parent molecule leading to tetraniliprole-N-methyl-quinazolinone, with highest levels in tomato fruits (up to 20 percent TRR but < 0.001 mg eq/kg) and tomato leaves (37 percent TRR, 0.002 mg eq/kg). This metabolite was also found in rat studies. Parent tetraniliprole was the major residue found in all crops.

Apart from one outdoor study in maize and another in potatoes (seed treatment in furrow), all studies were conducted indoor. The Meeting concluded that the indoor studies sufficiently cover outdoor uses (see photochemical degradation section).

Environmental fate

The Meeting received information on hydrolytic stability, photochemical degradation in water and soil, and aerobic soil metabolism studies for tetraniliprole. Soil degradation field studies were also provided.

Aqueous hydrolysis

Radiolabelled (pyrazole-carboxamide) tetraniliprole was incubated in the dark in sterile aqueous buffered solutions at pH 4, 7, and 9 for 30 days at 20, 25 and 50 °C. The results show that the DT_{50} of tetraniliprole depends both on the pH and temperature. Where tetraniliprole slowly degrades at 20 and 25 °C and pH 4 (265–287 days), the DT_{50} decreases with high pH to 58/39 days at pH 7 and 1.27 and 0.75 days at pH 9 at normal temperatures (20 and 25 °C). At higher temperatures the DT_{50} decreases to 10.9 days at pH 4 and to 3.74 and 0.04 days at pH 7 and 9, respectively.

One degradation product was identified as tetraniliprole-N-methyl-quinazolinone with a maximum amount of 99.6 percent of applied radioactivity (AR) (at DAT-30; pH 9, 20 °C). The Meeting concluded that hydrolysis is likely to be a minor path of degradation for tetraniliprole under environmental conditions.

Photochemical degradation

The photolysis in sterile water of pyrazole-carboxamide labelled tetraniliprole was studied under simulated sunlight in sterile aqueous acetate buffer (pH 4, 25 °C) with a DT₅₀ of 3.4 days, equivalent to 10.5 summer days in Arizona (approximately 34° latitude). Tetraniliprole was stable under dark conditions (DT₅₀ of 188.5 days). The major degradation product was tetraniliprole-deschloro-oxazine.

In two other studies, pyrazole-carboxamide or phenyl-carbamoyl labelled tetraniliprole was incubated in sterile natural waters (pH 8.0–8.5) at 25 °C under dark or simulated sunlight for 10–11 days. Tetraniliprole was readily degraded, with an estimated DT₅₀ of 0.7–0.8 days, similar to the non-irradiated (dark) samples (DT₅₀ of 0.3–0.8 days). Degradation product tetraniliprole-N-methyl-quinazolinone was the only compound observed in the dark samples (up to 92–99 percent after 10–11 days), whereas it reached levels up to max 39 percent AR (after 1 day) in the irradiated samples. In the irradiated samples other degradation products were also observed; tetraniliprole-deschloro-pyrazine (up to 37–39 percent AR at day 2), tetraniliprole -despyridyl-N-methyl-quinazolinone (up to 7 percent AR), tetraniliprole-deschloro-pyrazine (up to 27 percent AR at day 2) and tetraniliprole-pyrazole-5-carboxylic acid up to 18 percent AR at day 10).

The Meeting concluded that aqueous photolysis is a significant route of degradation, which was similar for dark and irradiated samples but the metabolic profile differed significantly.

In a soil photodegradation study, [pyrazole-carboxamide-¹⁴C]-tetraniliprole was applied to a thin layer of silt loam soil (at a rate equivalent to about 200 g ai/ha). Tetraniliprole was slightly photolysed, decreasing from 93 percent AR (day 1) to 77 percent AR (day 11). Tetraniliprole-N-methyl-quinazolinone was the degradation product observed. The estimated photolysis DT₅₀ was 27 days, equivalent to 82 summer days in Arizona. The Meeting concluded that photodegradation is, at the most, only a minor path of degradation in soil.

In summary, aqueous photolysis and hydrolysis at higher pHs are significant routes of degradation, although it was not possible to distinguish between the effects caused by pH or by photolysis. Residue decline trials performed outdoor in apples (at 0–14 DAT) and rice straw (at 38–53 DAT) show that tetraniliprole is stable over > 14 days. The Meeting concluded that photolysis does not play an important role in degradation of the tetraniliprole on outdoor crops, including seed treatments and foliar treatments (sprayed on the leaves) in paddy rice.

Aerobic soil metabolism

The biotransformation of [pyrazole-carboxamide-¹⁴C]-tetraniliprole was investigated in four German soils and in six United States soils under laboratory conditions. The equivalent of 200 g tetraniliprole/ha was mixed with soil and incubated under aerobic conditions in the dark at 20 °C for 119–120 days.

The two main degradation products were tetraniliprole-carboxylic acid (up to 48 percent AR) and tetraniliprole-N-methyl-quinazolinone (up to 33 percent AR). Additionally, tetraniliprole-quinazolinone-carboxylic acid (up to 6.5 percent AR), tetraniliprole-amide (up to 6.96 percent AR), tetraniliprole-desmethyl-amide-carboxylic acid (up to 12 percent AR), and tetraniliprole-N-methyl-quinazolinone-carboxylic acid (up to 11 percent AR) were found, but each not exceeding 12 percent AR at any sampling interval. The estimated DT₅₀ for tetraniliprole ranged from 18 to 183 days.

The biotransformation of [pyrazole-carboxamide-¹⁴C]-tetraniliprole was investigated in an Italian paddy soil under laboratory conditions. The equivalent of 200 g tetraniliprole/ha was mixed with soil and water and incubated under anaerobic/aerobic conditions in the dark at 25 °C for 181 days.

Tetraniliprole-N-methyl-quinazolinone was the only identified degradation product (maximum 48 percent AR at DAT-140). Other unidentified residues amounted to a total maximum of 6.3 percent AR, with no single component exceeding 3.6 percent AR at any sampling interval. The estimated DT_{50} for tetraniliprole was 4.4 days in water and 84 days in the entire soil/water system.

The Meeting concluded that, under laboratory conditions, tetraniliprole is moderately persistent to persistent in soil and soil/water systems.

Rotational crop metabolism

The Meeting received information on the metabolism of tetraniliprole in wheat, turnip and Swiss chard grown as confined rotational crops and in a range of representative field crops grown in tetraniliprole treated soil.

Confined rotational crop studies

In two confined rotational crop studies, soil was treated with either [phenyl-carbamoyl- ^{14}C]- or [pyrazole-carboxamide- ^{14}C]-labelled tetraniliprole at 213/209 g ai/ha, and planted with wheat, turnip, and Swiss chard at plant-back intervals (PBI) of 30, 168, and 286 days. The TRR in the different RACs were generally low and decreased significantly from the 1st to the 3rd PBI. Residues in wheat matrices were generally higher, with exception of grain (no detected residues). Residues declined from 0.060/0.057 to 0.007/0.014 mg eq/kg in forage, from 0.16/0.21 to 0.028/0.064 mg eq/kg in hay and from 0.12/0.26 mg eq/kg to 0.035/0.110 mg eq/kg in straw. Residues in mature Swiss chard declined from 0.047/0.052 mg eq/kg at PBI of 30 days to 0.008/0.016 mg eq/kg at of PBI 286 days. In turnip leaves and turnip roots residue levels were even lower, ranging from 0.001 to 0.008 mg eq/kg, regardless of PBI.

Samples were extracted with acetonitrile/water/formic acid, with extraction efficiency ranging from 77 to 99 percent TRR with both labels. Post-extraction solids (PES) of wheat hay from the 1st and 2nd rotation and straw from the 1st rotation were exhaustively extracted using microwave assistance with a mixture of acetonitrile/water and formic acid and, in case of wheat hay of the 2nd rotation, subsequently with 0.1 mol/L hydrochloric acid. The residues in the acetonitrile/water mixture were further characterized by partitioning against ethyl acetate. The radioactive residues in the organic and aqueous phases amounted to $\leq 0.010/\leq 0.016$ mg eq/kg with the respective labels (6.4–15 percent TRR with both labels).

The predominant residue in all matrices at all PBIs was parent tetraniliprole, ranging from 40–88 percent TRR (0.003–0.15 mg eq/kg) at PBI of 30 days to 8.8–52 percent TRR (0.001–0.017 mg eq/kg) at PBI of 286.

In food commodities, tetraniliprole-carboxylic acid contributes significantly to the total residue (up to 28 percent TRR, 0.004 mg eq/kg) at 168 days PBI in Swiss chard and to 18 percent TRR (< 0.001 mg eq/kg) in turnip roots at 30 days PBI. The same applies for tetraniliprole-dihydroxy (up to 30 percent TRR, 0.005 mg eq/kg) in mature Swiss chard at 286 days PBI, but the metabolite was not found in roots. Tetraniliprole-desmethyl-amide-carboxylic-acid was found at 31 percent TRR in Swiss chard at 286 days PBI and at 18 percent TRR (< 0.001 mg eq/kg) in turnip roots at 30 days PBI. Tetraniliprole-N-methyl-quinazolinone contributed up to 14 percent TRR (0.002 mg eq/kg) in immature Swiss chard, 9.0 percent TRR (0.001 mg eq/kg) in mature Swiss chard and up to 16 percent TRR (0.001 mg eq/kg) in turnip roots (30 days PBI). Finally, tetraniliprole-despyridyl-N-methyl-quinazolinone-pyrazole-3-carboxylic acid was observed in Swiss chard at 2.9–16 percent TRR (< 0.001 –0.008 mg eq/kg), but was not found in turnip roots

Matrix	N	Tetraniliprole		Tetraniliprole-N-methyl-quinazolinone		Total ^a	
		max (mg/kg)	median (mg/kg)	max (mg eq/kg)	median (mg eq/kg)	max (mg/kg)	median (mg/kg)
Wheat/barley straw ^f	30	0.097 ^b	< 0.01	0.038 ^b	< 0.01	0.14 ^b	< 0.01
Alfalfa forage (3 cuttings) ^g	33	0.013	< 0.01	< 0.01	< 0.01	0.013	< 0.01
Alfalfa hay (3 cuttings)	33	0.051 ^b	< 0.01	0.015 ^b	< 0.01	0.066 ^b	< 0.01

Notes:

^a Total residue expressed as tetraniliprole.

^b Single highest value.

^c Based on beans, peas and soya bean data also representative for trefoil, vetch, clover, and lespedeza; forage also representative for silage and vines.

^d Based on wheat data and also representative for barley, oat, rye, triticale; forage is also representative for silage.

^e Based on sorghum data, also representative for millet; forage also representative for silage.

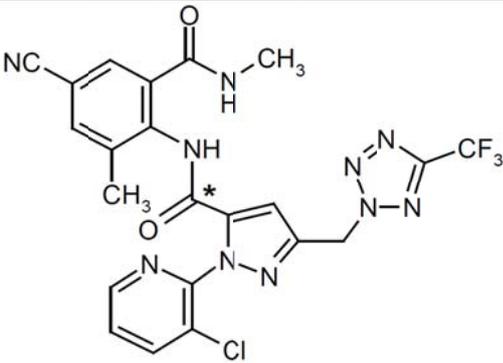
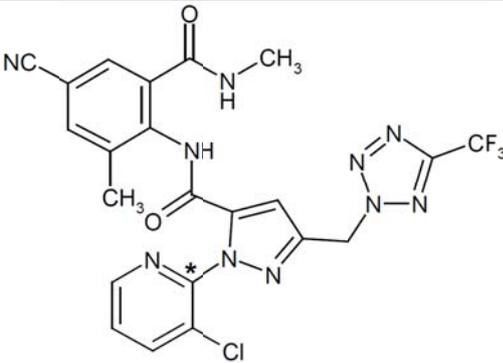
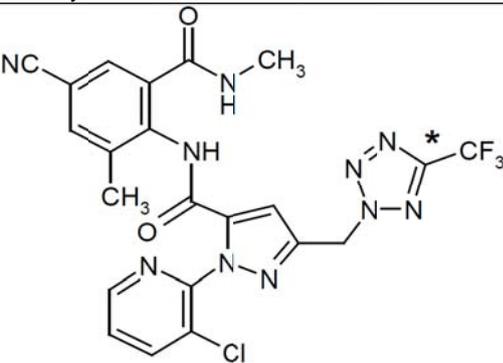
^f Based on wheat and barley data, also representative for oat, rye and triticale.

^g Forage is also representative for alfalfa silage.

The Meeting concluded that maximum residue levels should be estimated for crops that might be planted in rotation, for which no primary uses are in place (see section on residues from rotational crops to consider for animal feeds).

Animal metabolism

The Meeting received animal metabolism studies on rats, lactating goats and laying hens, where animals were dosed with tetraniliprole radiolabelled at the pyrazole-carboxamide site, the pyridinyl-ring, or the tetrazolyl-ring.

Pyrazole-carboxamide label	Pyridinyl label
	
[pyrazole-carboxamide- ¹⁴ C]-tetraniliprole	[pyridinyl-2- ¹⁴ C]-tetraniliprole
Tetrazolyl label	
	
[tetrazolyl- ¹⁴ C]-tetraniliprole	

Rats

The metabolism of tetraniliprole in rats was reviewed in the framework of the toxicological evaluation by the WHO Core Assessment Group of the 2020 JMPR.

Lactating goats

In a series of three separate studies, lactating goats (one per study) were dosed orally by capsule once each morning for 5 consecutive days after milking with [pyrazole-carboxamide-¹⁴C]-tetraniliprole, [pyridinyl-2-¹⁴C]-tetraniliprole, or [tetrazolyl-¹⁴C]-tetraniliprole at dose of a ca 1 mg/kg bw/day, corresponding to a rate of 27, 21 or 38 ppm dry feed for each label, respectively. The goats were sacrificed 5.5 to 6 hours after the last dose. The quantitative results of the three studies are reported without correction for the differences in dose levels.

Most of the radioactivity was excreted in the faeces (61–69 percent of total applied radioactivity, TAR) and urine (20–3.3 percent TAR), 1.1–1.3 percent TAR (0.24–0.42 mg eq/kg) in milk and 1.8–2.4 percent TAR in tissues, with approximately 26–32 percent TAR likely to be still present in the gastrointestinal tract.

The highest levels of radioactivity were found in liver (0.42–0.57 percent TAR, 0.88–1.2 mg eq/kg) and fat (0.89–1.4 percent TAR, 0.39–0.60 mg eq/kg), followed by kidney (0.020–0.10 percent TAR, 0.24–0.33 mg eq/kg) and muscle (0.49–0.72 percent TAR, 0.086–0.12 mg eq/kg). The milk samples contained higher residues and reached a plateau (0.28–0.43 mg eq/kg) at approximately 60–96 hours after the first dose.

Using acetonitrile/water mixture, residues were efficiently extracted from milk and tissues (89–100 percent TRR). For liver, an additional 8.8–11 percent TRR was released using microwave assisted extraction. Low amounts of radioactivity (\leq 0.7–1.0 percent TRR) remained in the PES of all commodities.

Parent tetraniliprole was the predominant residue in milk (64–70 percent TRR, 0.16–0.27 mg/kg), muscle (65–66 percent TRR, 0.057–0.064 mg/kg), liver (55–62 percent TRR, 0.54–0.55 mg/kg), and kidney (69–71 percent TRR, 0.17–0.18 mg/kg) and was a major component in fat (24–28 percent TRR, 0.094–0.16 mg /kg). Tetraniliprole-N-methyl-quinazolinone was the main metabolite in fat (67–72 percent TRR, 0.28–0.40 mg eq/kg) and muscle (28 percent TRR, 0.024–0.028 mg eq/kg). It was also a found in milk (11–13 percent TRR, $<$ 0.026–0.056 mg eq/kg) and kidney (13–14 percent TRR, 0.033–0.044 mg eq/kg), and to a minor extent in liver (2.2–5.6 percent TRR, $<$ 0.036–0.067 mg eq/kg) when using the pyridinyl or tetrazolyl-label.

Another prominent metabolite was tetraniliprole-benzylalcohol, with 9.0–11 percent TRR (0.022–0.045 mg eq/kg) in milk, 6.9–8.9 percent TRR (0.060–0.11 mg eq/kg) in liver and 3.6–6.2 percent TRR (0.009–0.020 mg eq/kg) in kidney. Metabolite tetraniliprole-hydroxy-N-methyl was found in milk (3.5–5.0 percent TRR, 0.008–0.019 mg eq/kg), liver (6.4–8.9 percent TRR, 0.061–0.088 mg eq/kg) and kidney (3.0–3.7 percent TRR, 0.007–0.009 mg eq/kg). Tetraniliprole-desmethyl-amide was only found in the liver of the goats treated with the pyridinyl or tetrazolyl-label (4.5–7.7 percent TRR, 0.055–0.067 mg eq/kg).

Several metabolites were identified, each accounting for \leq 3.9 percent TRR, but some with absolute levels above 0.01 mg eq/kg; metabolites tetraniliprole-N-methyl-quinazolinone-pyrazole-3-carboxylic acid, tetraniliprole-pyridinyl-pyrazole-5-carboxylic acid (once 0.012 mg eq/kg in kidney with one label), tetraniliprole-N-methyl quinazolinone-benzylalcohol, tetraniliprole-desmethyl-amide (0.021 and 0.046 mg eq/kg in liver with two labels and 0.013 mg eq/kg in milk and kidney and 0.045 mg eq/kg in liver

with one label) and tetraniliprole-quinazolinone (0.013 and 0.026 mg eq/kg in milk and liver with one label).

Pyrazole-carboxamide label specific metabolites were tetraniliprole-pyrazole-5-amide, tetraniliprole-pyrazole-5-N-methyl-amide and tetraniliprole-5-carboxylic acid and were detected only in milk and liver (≤ 1.8 percent TRR). Tetrazolyl-specific metabolites were not identified.

Laying hens

In a series of three separate studies, six laying hens in each study were dosed orally once each morning for 14 consecutive days with [pyrazole-carboxamide- ^{14}C]-tetraniliprole, [pyridinyl-2- ^{14}C]-tetraniliprole, or [tetrazolyl- ^{14}C]-tetraniliprole at rate of 18–19 ppm dry feed (approx. 1 mg/kg bw/day) and were sacrificed about 6 hours after the last dose.

Most of the radioactivity was excreted (91–92 percent TAR), with approximately 7–8 percent TAR likely to be still present in the gastro-intestinal tract. An average amount of ca 0.2 percent TAR was found in eggs and 0.2–0.4 percent TAR in tissues. TRR were 0.48–0.77 mg eq/kg in liver, 0.033–0.098 mg eq/kg in kidney, 0.028–0.095 mg eq/kg in subcutaneous fat, 0.035–0.078 mg eq/kg in skin and 0.017–0.031 mg eq/kg in skeletal muscle. In eggs, it ranged from 0.005 to 0.011 mg eq/kg at day one to 0.091–0.10 mg eq/kg at sacrifice. A residue plateau-level of 0.084–0.089 mg eq/kg was reached approximately seven to nine days after the first dose and decreased rapidly after cessation of the treatment.

Using acetonitrile/water, or methanol in case of fat, residues were efficiently extracted from fat (86 percent TRR), but less efficiently from eggs (54 percent TRR), muscle (44 percent TRR), and liver (34 percent TRR). Eggs, liver, and muscle (pyridinyl-label) were further extracted using microwave, releasing another 12–46 percent TRR from eggs, 41–66 percent TRR from liver, and 56 percent TRR from muscle. Final PES for the pyridinyl label were 9.7 percent TRR (0.008 mg eq/kg) in eggs (tetrazolyl-label only), 5.9–11.4 percent TRR (0.002 mg eq/kg) in muscle and 0.3 percent TRR (< 0.001 mg eq/kg) in fat for both other labels, and were not further characterized.

In the pyridinyl-label study, parent tetraniliprole was the predominant residue in fat (55 percent TRR, 0.015 mg eq/kg), and was also found in egg (14 percent TRR, 0.012 mg eq/kg), but less in liver and muscle (1.6 and 3.7 percent TRR, 0.12 and 0.001 mg eq/kg). Tetraniliprole-dihydroxy was the only metabolite observed at levels > 10 percent TRR (15 percent TRR, 0.004 mg eq/kg), but only in hen fat. All other metabolites were below 6.5 percent TRR.

In the pyrazole-carboxamide label study, parent tetraniliprole accounted for 10–26 percent TRR in fat (up to 0.012 mg/kg), for 10 percent TRR in muscle and egg (0.002 and 0.008 mg/kg) and for 4.8 percent TRR (0.023 mg/kg) in liver. Metabolite tetraniliprole-despyridyl-N-methyl-quinazolinone was the major compound in eggs (36 percent TRR, 0.030 mg eq/kg) and fat (63 percent TRR, 0.029 mg eq/kg) and was found in liver (12 percent TRR, 0.065 mg eq/kg) and muscle (8.6 percent TRR, 0.001 mg eq/kg). In muscle, tetraniliprole-pyrazole-5-N-methyl-amide contributed to 40 percent TRR (0.007 mg eq/kg), but accounted for 5.5 percent TRR or less in other tissues. Tetraniliprole-pyrazole-5-amide accounted for 13 percent TRR (0.002 mg eq/kg) in muscle, but for less than 3 percent TRR (up to 0.005 mg eq/kg) in other tissues.

In the tetrazolyl-label study, parent tetraniliprole accounted for 10 percent TRR or more only in fat (26 percent TRR, 0.025 mg eq/kg) with levels of 4.2, 4.2 and 9.4 percent TRR in eggs, liver, and muscle, respectively. Tetraniliprole-despyridyl-N-methyl-quinazolinone was the major compound in eggs (27 percent TRR, 0.023 mg eq/kg) and fat (62 percent TRR, 0.059 mg eq/kg) and was found in liver (8.4 percent TRR, 0.065 mg eq/kg) and muscle (6.8 percent TRR, 0.002 mg eq/kg). In muscle, the metabolite tetraniliprole-pyrazole-5-N-methyl-amide contributed to 17.6 percent TRR (0.005 mg eq/kg),

but to 5.8 percent TRR or less in other tissues. Tetraniliprole-pyrazole-5-amide also accounted for 9.7 percent TRR (0.003 mg eq/kg) in muscle, but for less than 3.5 percent TRR (0.027 mg eq/kg) in other tissues.

Other metabolites that were identified with the different labels accounted for < 10 percent TRR. Tetraniliprole-benzylalcohol-Gluc was found in eggs and liver (1.3–6.5 percent TRR, 0.001–0.047 mg eq/kg), and tetraniliprole-dihydroxy (1.1–15 percent TRR, < 0.001–0.009 mg eq/kg), tetraniliprole-benzylalcohol (0.5–8.1 percent TRR, < 0.001–0.062 mg eq/kg), tetraniliprole-hydroxy-N-methyl (1.3–3.9 percent TRR, < 0.001–0.030 mg eq/kg), and tetraniliprole-N-methyl-quinazolinone (3.1–7.4 percent TRR, < 0.01 mg eq/kg) in eggs only.

The pyrazole-carboxamide and the tetrazolyl-label specific metabolites < 10 percent TRR were tetraniliprole-pyrazole-5-N-methyl-amide-hydroxy (0.5–3.2 percent TRR, 0.001–0.016 mg eq/kg) in all matrices, except fat, tetraniliprole-pyrazole-5-carboxylic acid (5.0–7.6 percent TRR, 0.037–0.039 mg eq/kg) in liver only, tetraniliprole-despyridyl (1.9–9.7 percent TRR, 0.001–0.074 mg eq/kg) in all matrices, tetraniliprole-despyridyl-N-methyl-quinazolinone-hydroxy and tetraniliprole-despyridyl-hydroxy (1.1–9.3 percent TRR, < 0.001–0.069 mg eq/kg (mixture of both metabolites)) in eggs, liver and fat (pyrazole-carboxamide label only), and tetraniliprole-despyridyl-quinazolinone (1.0–7.0 percent TRR, < 0.001–0.044 mg eq/kg) in eggs, fat and liver.

The pyridinyl-specific metabolite deschloro-desmethyl-amide accounted for 1.7–4.5 percent TRR (< 0.001–0.022 mg eq/kg). A large portion of unknown pyridinyl-labelled metabolites was found in the polar HPLC region of eggs and liver. There were no metabolites detected by HPLC analysis in the microwave assisted extract of muscle (0.014 mg eq/kg, 56.1 percent TRR), due to the low radioactivity in the sample and the high number of metabolites, as demonstrated in liver.

The tetrazolyl-label specific metabolite tetraniliprole-tetrazole and its conjugates was found in eggs, muscle, fat and liver with levels ranging from (0.8–15 percent TRR). The sum of tetraniliprole-tetrazole and its conjugates was highest in eggs and muscle (23–29 percent, 0.009–0.019 mg eq/kg), but also observed in fat and liver (3.3–5.5 percent TRR, 0.005–0.025 mg eq/kg).

Summary of animal metabolism

The principal metabolic reactions of tetraniliprole in the lactating goat are:

- intra-molecular condensation (cyclization) of parent compound leading to quinazolinone compounds;
- hydroxylation in the methyl group of the phenyl moiety leading to tetraniliprole-benzylalcohol and the N-methyl moiety leading to tetraniliprole hydroxy-N-methyl;
- demethylation of the N-methyl group to form tetraniliprole-quinazolinone and tetraniliprole-desmethyl-amide;
- cleavage of the pyridine ring leading to tetraniliprole-pyrazole-5-amide (PC- and tetra-label) followed by further oxidation to a tetraniliprole-pyrazole-5-carboxylic acid or by methylation leading to tetraniliprole-N-methyl-amide;
- cleavage of the phenyl ring to form tetraniliprole-pyridinyl-pyrazole-5-carboxylic acid;
- cleavage of the tetrazole ring followed by oxidation leading to tetraniliprole-N-methyl-quinazolinone-3-carboxylic acid.

The principal metabolic reactions of tetraniliprole in the laying hens are:

- cleavage of the pyridine ring, leading to despyridyl compounds;

- intra-molecular condensation of despyridyl compounds and parent compound leading to the quinazolinone compounds;
- cleavage of the tetrazole ring, followed by conjugation (tetra-label only);
- hydroxylations, leading to mono- and/or dihydroxy compounds such as tetraniliprole-dihydroxy, tetraniliprole-despyridyl-hydroxy, tetraniliprole-despyridyl-N-methyl-quinazolinone-hydroxy, and tetraniliprole-pyrazole-5-N-methyl-amide-hydroxy;
- conjugation with glucuronic acid after hydroxylation to tetraniliprole-benzylalcohol;
- cleavage of the phenyl moiety, leading to tetraniliprole-5-amide followed by methylation into tetraniliprole-pyrazole-5-N-methyl-amide followed by hydroxylation (tetraniliprole-pyrazole-5-N-methyl-amide-hydroxy);
- demethylation of the N-methyl group after intra-molecular condensation (cyclization) of tetraniliprole-despyridyl to form tetraniliprole-despyridyl-quinazolinone.

The Meeting concluded that the total administered radioactivity was readily absorbed and extensively metabolized in goats and hens. Considering the very low levels of (other) metabolites observed in hen, the Meeting concluded that a single residue definition for animal commodities can be proposed.

Tetraniliprole (parent) is a major component in all goat tissues (24–71 percent TRR), in poultry fat (26–55 percent TRR) and in eggs (4.2–14 percent TRR), but contributes to the overall residue to a minor extent in poultry muscle (3.7–10 percent TRR) and poultry liver (1.6–4.2 percent TRR).

Tetraniliprole-N-methyl-quinazolinone is a major metabolite in goat tissues (11–67 percent TRR) except liver (2.2–5.6 percent TRR) and was observed in poultry studies in eggs only (3.1–7.4 percent TRR).

Tetraniliprole-benzylalcohol is a major metabolite in goat milk (9–11 percent TRR). Several other minor metabolites are observed in goat tissues, but all accounting for less than 10 percent TRR, though a number of them represent > 0.01 mg eq/kg.

Tetraniliprole despyridyl-N-methyl-quinazolinone contributes significantly to the total residue in eggs (27–36 percent TRR), poultry fat (63 percent TRR) and poultry liver (8.5–12 percent TRR), and contributes less to the total residue in poultry muscle (6.8–8.6 percent TRR). Tetraniliprole-pyrazole-5-N-methyl-amide is a major component in poultry muscle (18–40 percent TRR) and contributes less to the total residue in poultry liver, fat, and eggs (4.6–6 percent TRR). Tetrazole conjugates contributed significantly to the total residue in eggs (23 percent TRR) and poultry muscle (29 percent TRR), but less in poultry fat (5.5 percent TR) and poultry liver (3.3 percent TRR).

Methods of analysis

The Meeting received information on analytical methods for tetraniliprole residues in plant and animal matrices.

For plant matrices, analytical methods for measuring residues of tetraniliprole and tetraniliprole-N-methyl-quinazolinone generally involved extraction with water and acetonitrile, followed by quantification with LC-MS/MS. The method has been successfully validated for commodities with high water, high acid, high oil, high starch/dry and high protein content with a LOQ of 0.01 mg/kg each.

For animal matrices, analytical methods for measuring residues of tetraniliprole, tetraniliprole-N-methyl-quinazolinone and tetraniliprole-benzylalcohol involve two extractions with acetonitrile/water,

followed by drying and reconstitution in 0.1 percent aqueous formic acid. Residues were determined by LC-MS/MS. The method has been fully validated for animal tissues, eggs and milk, with an LOQ of 0.01 mg/kg for all analytes in all matrices.

The Meeting concluded that the presented methods were sufficiently validated and are suitable to measure tetraniliprole, tetraniliprole-*N*-methyl-quinazolinone in plant and animal commodities and tetraniliprole-benzylalcohol in animal commodities.

The Meeting noted that a modified version of QuEChERS multiresidue (MRM) enforcement method 01463 for determination of tetraniliprole and tetraniliprole-*N*-methyl-quinazolinone in plant commodities is confirmed as being a suitable enforcement method, with acceptable recovery rates at relevant fortification levels. The method was validated in tomato, grapes, wheat grain, dry bean seed and rape seed, with an LOQ of 0.01 mg/kg each for both parent and metabolite.

Stability of pesticide residues in stored analytical samples

The Meeting received information on storage stability of tetraniliprole and tetraniliprole-*N*-methyl-quinazolinone in raw and processed plant commodities. No freezer storage stability data were submitted on animal matrices, but samples from the animal feeding studies were processed and analysed within 30 days and the samples from the radiolabelled metabolism studies were processed within 5 months of sampling.

The storage stability studies showed that tetraniliprole and tetraniliprole-*N*-methyl-quinazolinone (at 0.2 mg/kg) were stable when stored frozen for at least 24 months in crop commodities representative of the high water (tomato), high acid (grape), high starch (wheat grain), high protein (dry bean) and high oil (rape seed seed) commodity groups.

The Meeting agreed that the demonstrated storage stability on various representative plant commodities covered the residue sample storage intervals used in the field trials considered by the current Meeting.

Definition of the residue

Plant commodities

In the plant metabolism studies involving foliar applications (apples, potato, lettuce, paddy rice), soil drench application (tomato), granular in planting hole applications (rice) and seed treatments (potato and maize), in confined rotational crop metabolism studies and in processing studies, tetraniliprole was the major component (apple, tomato, lettuce, tomato, potato) of the radioactive residue.

Tetraniliprole is found in all primary crop commodities and is considered suitable as a marker compound. The Meeting noted that suitable analytical methods exist to measure tetraniliprole in plant commodities. The Meeting decided to define the residue for compliance with the MRL as tetraniliprole.

In deciding which additional compounds should be included in the residue definition for dietary risk assessment, tetraniliprole-*N*-methyl-quinazolinone is the only compound identified in relevant amounts in plant matrices. This metabolite was found at up to 20 percent TRR in tomato, rice grain and potatoes, but generally at levels ≤ 0.01 mg eq/kg in food commodities, which was confirmed in the supervised field trials, in which it was only found occasionally above the LOQ of 0.01 mg/kg, with tetraniliprole being present at levels about an order of magnitude higher.

A high temperature hydrolysis study shows that, though stable during pasteurization, tetraniliprole is not stable under baking/brewing/boiling (BBB) (pH 5, 100 °C, 60 minutes) and sterilisation

(pH 6, 120 °C, 20 minutes) conditions. Under these conditions 65–68 percent and 1.1–1.5 percent AR was recovered as parent and 27–30 percent AR and 94 percent AR as tetraniliprole-N-methyl-quinazolinone, respectively. Processing under heating indicated conversion of parent tetraniliprole into tetraniliprole-N-methyl-quinazolinone, e.g., mustard greens (up to 20 percent TRR), broccoli (up to 29 percent TRR), tomato paste (23–48 percent TRR), and soya bean meal (up to 81 percent TRR).

Tetraniliprole-N-methyl-quinazolinone was found in the rat and is covered by the health based guidance value of parent tetraniliprole.

The Meeting concluded that tetraniliprole-N-methyl-quinazolinone may occur in primary and rotational crops and that the metabolite contributes significantly to the residue in processed commodities. Hence the Meeting agreed to define a residue definition for dietary risk assessment for plant commodities is tetraniliprole and tetraniliprole-N-methyl-quinazolinone, expressed as tetraniliprole.

Animal commodities

Tetraniliprole is a major component in all goat tissues (24–71 percent TRR), poultry fat (26–55 percent TRR) and eggs (4.2–14 percent TRR), but it contributes little to the overall residue in poultry muscle (3.7–10 percent TRR) and liver (1.6–4.2 percent TRR). Parent tetraniliprole is also the major component in all cattle tissues and milk.

The Meeting noted that suitable analytical methods exist to measure tetraniliprole in animal commodities and decided to define the residue for compliance with the MRL as tetraniliprole.

Tetraniliprole has a Log Kow of 2.6, indicating a low to moderate potential to sequester into fatty matrices. The ratios of concentrations of muscle to fat (1:1.3–2.1) and skim milk to cream (1:3) indicate only a very slight tendency to concentrate in fat.

The Meeting considered the residue not to be fat soluble.

In deciding which compound should be included in the residue definition for dietary risk assessment, the Meeting noted that the tetraniliprole was metabolized into numerous components, of which 17 were accounted for > 10 percent TRR and/or > 0.01 mg eq/kg. The metabolites were considered in three categories, either covered by the toxicity of the parent, suitable for assessment by the TTC approach following Cramer Class III or by the TTC approach for genotoxic compounds.

The 2021 and 2022 JMPR Meeting concluded that the following metabolites are covered by the health based guidance values for tetraniliprole and should be considered for inclusion in the residue definition:

Tetraniliprole-N-methyl-quinazolinone contributes significantly to the total residue in goat tissues (11–72 percent TRR), except liver (2.2–5.6 percent TRR) and was observed in poultry studies in eggs only (3.1–7.4 percent TRR). The Meeting agreed that the metabolite should be included in the residue definition for dietary risk assessment.

Tetraniliprole-benzylalcohol contributed significantly to the total residue in goat milk (9–11 percent TRR, 0.022–0.045 mg eq/kg), and to a lesser extent in other goat and poultry matrices (1.3–8.1 percent TRR, 0.001–0.062 mg eq/kg). This metabolite also contributes to the total residue in dairy feeding studies in milk (36–66 percent of parent), liver (6.6–8.8 percent of parent), kidney (5.0–6.3 percent of parent). The Meeting agreed that the metabolite tetraniliprole-benzylalcohol should be included in the residue definition for dietary risk assessment.

Tetraniliprole-hydroxy-N-methyl was found in all goat (3.0–8.9 percent TRR, 0.007–0.088 mg eq/kg) and poultry matrices (1.3–3.9 percent TRR, < 0.001–0.030 mg eq/kg), except fats.

However, since this analyte would contribute only little to the total residues (tetraniliprole + tetraniliprole-N-methyl-quinazolinone + tetraniliprole-benzylalcohol), the Meeting agreed that the metabolite does not need to be included in the residue definition for dietary risk assessment.

Tetraniliprole-desmethyl-amide was found in all goat matrices at levels ranging from 0.2 to 7.7 percent TRR (0.001–0.067 mg eq/kg). However, since it would contribute only little to the total residues (tetraniliprole + tetraniliprole-N-methyl-quinazolinone + tetraniliprole-benzylalcohol), the Meeting agreed that the metabolite does not need to be included in the residue definition for dietary risk assessment.

The 2021 and 2022 JMPR Meetings concluded that the TTC Cramer Class III could be applied (no indication for genotoxicity) for the following metabolites: tetraniliprole-pyrazole-5-carboxylic acid, tetraniliprole-N-methyl-quinazolinone-benzylalcohol, tetraniliprole-despyridyl-N-methyl-quinazolinone, tetraniliprole-pyrazole-5-amide, tetraniliprole-N-methyl-quinazolinone-pyrazole-3-carboxylic acid (2021 JMPR), tetraniliprole-desmethyl-amide, tetraniliprole-quinazolinone, tetraniliprole-pyridinyl-pyrazole-5-carboxylic acid, and T-pyrazole-5-N-methyl-amide (2022 JMPR)

In the absence of toxicological data for a number of (poultry specific) metabolites, the 2022 JMPR concluded that the remaining should be assessed under the TTC approach for genotoxic compounds; tetraniliprole-despyridyl, tetrazole-conjugates, tetraniliprole-despyridyl-N-methyl-quinazolinone-hydroxy and tetraniliprole-despyridyl-hydroxy (mixture of both metabolites), tetraniliprole-despyridyl-quinazolinone, tetraniliprole-pyrazole-5-N-methyl-amide-hydroxy, tetraniliprole-deschloro-desmethyl-amide.

The Meeting concluded that for dietary risk assessment in animal commodities, the residue definition should be the sum of tetraniliprole, tetraniliprole-N-methyl-quinazolinone and tetraniliprole-benzylalcohol, expressed as tetraniliprole.

The Meeting agreed that:

The residue definition for tetraniliprole for compliance with the MRL in plant and animal commodities is: *Tetraniliprole*.

The definition of the residue for dietary risk assessment for plant commodities: *Tetraniliprole + tetraniliprole-N-methyl-quinazolinone, expressed as tetraniliprole*.

Definition of the residue for dietary risk assessment for animal commodities: *Tetraniliprole + tetraniliprole-N-methyl-quinazolinone + tetraniliprole-benzylalcohol, expressed as tetraniliprole*.

Results of supervised residue trials on crops

Supervised trials were available for the use of tetraniliprole on citrus fruit (orange, mandarin, lemon, and grapefruit), pome fruit (apple and pear), stone fruit (cherry, peach plum), grapes, flowerhead brassicas (broccoli and cauliflower) and head brassicas (head cabbage), fruiting vegetables (tomato, peppers), leafy vegetables (lettuce head, lettuce leaf, spinach, mustard greens), pulses (dry soya beans), tuberous and corm vegetables (potato), cereal grains (rice, maize, sweet corn), tree nuts (almonds and pecans).

GAP information was available from Canada and the United States (foliar treatment of pome fruit, stone fruit, small fruit vine climbing, brassica vegetables, except leafy vegetables, fruiting vegetables other than cucurbits, leafy vegetables, soya bean, tuberous and corm vegetables, maize cereals, sweet corn, tree nuts), Republic of Korea (foliar treatment on apple, pear, and sweet persimmon), India (foliar treatment on soya bean and rice) and Japan (seed treatment on rice).

In this appraisal the term 'total residues' refers to the sum of tetraniliprole and tetraniliprole-N-methyl-quinazolinone, and was used to estimate STMR, HR, median and highest residues. Since residues in the evaluation were expressed as parent equivalents, no conversion factor is needed. Parent constitutes the majority of the tetraniliprole residues in most RACs, with low metabolite levels, except for feed and processed commodities subjected to heating.

To estimate the total residues, where residues tetraniliprole-N-methyl-quinazolinone are < LOQ it was assumed to be zero, except when both parent and metabolite were < LOQ and in that case the total was taken as < LOQ. The method for calculating the total residue for various situations is illustrated below.

Tetraniliprole	Tetraniliprole-N-methyl-quinazolinone	Tetraniliprole + Tetraniliprole-N-methyl-quinazolinone
0.29	0.02	0.31
0.039	< 0.01	0.039
< 0.01	< 0.01	< 0.01

Citrus fruits, Group of

GAP for tetraniliprole in the United States for citrus fruit includes three different uses, a single soil or single drip chemigation application at 120 g ai/ha, a single soil or drip chemigation application at 120 g ai/ha followed by single foliar application at 60 g ai/ha, and three foliar applications at 60 g ai/ha each. Trials were submitted in support of the combined soil and foliar applications and the triple foliar applications. Based on the results of these field trials the Meeting decided that the critical GAP in the United States for citrus fruit is three foliar applications at 60 g ai/ha, with a re-treatment interval of 5 days and a PHI of 1 day.

Pummelo and Grapefruits, Subgroup of

A total of six independent supervised residue trials on grapefruits matching the critical US GAP were conducted in the United States. Residues of tetraniliprole both for MRL and risk assessment in ranked order were (n=6): 0.039, 0.071, 0.081, 0.11, 0.19 and 0.49 mg/kg in whole fruit.

Noting that grapefruit is a representative crop for the subgroup of pummelo and grapefruits the Meeting estimated a maximum residue level of 0.9 mg/kg and an STMR of 0.091 mg/kg for tetraniliprole in the Subgroup of Pummelo and Grapefruits (including Shaddock-like hybrids, among other Grapefruit).

Lemons and Limes, Subgroup of

Independent supervised residue trials on lemons matching the US GAP were conducted in the United States. Residues of tetraniliprole both for MRL and risk assessment in ranked order were (n=5): 0.062, 0.13, 0.19, 0.20 and 0.77 mg/kg in whole fruit.

Noting that lemons is a representative crop for the subgroup of lemons and limes the Meeting estimated a maximum residue level of 1.5 mg/kg and an STMR of 0.19 mg/kg for tetraniliprole in the Subgroup of Lemons and Limes (including Citron).

Mandarins, Subgroup of

Independent supervised residue trials on mandarin matching the US GAP were conducted in United States. Residues of tetraniliprole both for MRL and risk assessment in ranked order were (n=4): 0.17, 0.18, 0.19 and 0.54 mg/kg in whole fruit.

Noting that mandarin is a representative crop for the subgroup of mandarins the Meeting estimated a maximum residue level of 1.0 mg/kg and an STMR of 0.185 mg/kg for tetraniliprole in the Subgroup of Mandarins (including Mandarin-like hybrids).

Oranges, Sweet, Sour, Subgroup of

A total of eight independent supervised residue trials on oranges matching the US GAP were conducted in United States. Residues of tetraniliprole both for MRL and risk assessment in ranked order were (n=8): 0.044, 0.066, 0.13, 0.14, 0.14, 0.15, 0.16, and 0.29 mg/kg in whole fruit.

Noting that orange is a representative crop for the subgroup of oranges, sweet, sour the Meeting estimated a maximum residue level of 0.5 mg/kg. Using the processing factor for peeling of 0.11 (see section on processing) the Meeting estimated an STMR of 0.015 mg/kg in orange flesh for tetraniliprole in the Subgroup of Oranges, Sweet, Sour (including Orange-like hybrids).

Pome fruit, Group of

The critical GAP for pome fruit is in Canada and the United States allowing three foliar applications at 60 g ai/ha, with a re-treatment interval of 7 days and a PHI of 7 days. Trials conducted in Australia did not match this critical GAP.

In trials conducted in apples in Canada and the United States approximating the GAP, tetraniliprole residues both for MRL and risk assessment were (n=12): 0.064, 0.092, 0.10, 0.11, 0.11, 0.13, 0.15, 0.15, 0.16, 0.17, 0.17 and 0.20 mg/kg.

In trials conducted in pears in Canada and the United States approximating the GAP, tetraniliprole residues were (n=8): 0.044, 0.048, 0.080, 0.081, 0.13, 0.14, 0.16 and 0.24 mg/kg.

Noting that the median residues of tetraniliprole, for apples and pears from the United States and Canadian trials are within a 5-fold range, and that there is no evidence of a difference in the residue populations across the pome fruit types by Mann-Whitney test, the Meeting decided to make a recommendation for the Group of Pome fruit based on the combined data.

The combined apple and pear data for tetraniliprole residues, both for MRL and risk assessment, in ranked order, were (n=20): 0.044, 0.048, 0.064, 0.080, 0.081, 0.092, 0.10, 0.11, 0.11, 0.13, 0.13, 0.14, 0.15, 0.15, 0.16, 0.16, 0.17, 0.17, 0.20 and 0.24 mg/kg.

Noting that the US GAP is for the group of pome fruits, which does not include Japanese persimmon, the Meeting estimated a maximum residue level of 0.4 mg/kg and an STMR of 0.13 mg/kg for tetraniliprole in the Group of Pome Fruits, excluding Japanese persimmon.

Stone fruit, Group of

The critical GAP for stone fruit in Canada and the United States allows three foliar applications at 60 g ai/ha, with a retreatment interval of 7 days and a PHI of 5 days.

Field trials were available on cherries, peaches and plums, and the fruit was analysed without stone. At the 2017 JMPR Meeting, it was concluded that the contribution of the pit to the weight of the whole fruit of cherries, plums and peaches is approximately 10 percent. Correcting the residue levels for tetraniliprole using this weight/weight ratio would lead to the same rounded residue levels, so no adjustment was made on the residues.

Cherries, Subgroup of

In trials conducted in Canada and the United States matching GAP, tetraniliprole residues both for MRL and risk assessment were (n=11): 0.085, 0.12, 0.24, 0.27, 0.28, 0.29, 0.38, 0.44, 0.49, 0.56, and 0.66 mg/kg.

The Meeting estimated a maximum residue level of 1.5 mg/kg and an STMR of 0.29 mg/kg in the Subgroup of Cherries.

Peaches, Subgroup of

In trials conducted in Canada and the United States matching the GAP, tetraniliprole residues both for MRL and risk assessment were (n=15): 0.030, 0.041, 0.056, 0.064, 0.070, 0.080, 0.086, 0.089, 0.091, 0.095, 0.15, 0.15, 0.21, 0.38, and 0.44 mg/kg.

The Meeting estimated a maximum residue level of 0.7 mg/kg and an STMR of 0.089 mg/kg for tetraniliprole in the Subgroup of Peaches (including Nectarines and Apricots).

Plums, Subgroup of

In trials conducted in Canada and the United States matching the GAP, tetraniliprole residues both for MRL and risk assessment were (n=8): < 0.01, 0.012, 0.016, 0.026, 0.039, 0.081, 0.11, and 0.13 mg/kg.

The Meeting estimated a maximum residue level of 0.3 mg/kg and an STMR of 0.033 mg/kg for tetraniliprole in the Subgroup of Plums.

Small fruit vine climbing, Subgroup of

The critical GAP for small fruit vine climbing in Canada and the United States allows four foliar applications at 45 g ai/ha, with a retreatment interval of 7 days and a PHI of 14 days.

In trials conducted on grapes in Canada and the United States matching the GAP, tetraniliprole residues both for MRL and risk assessment were (n=10): 0.20, 0.25, 0.26, 0.27, 0.27, 0.28, 0.29, 0.39, 0.82 and 0.92 mg/kg.

Noting that grapes is a representative commodity for the subgroup, the Meeting estimated a maximum residue level of 1.5 mg/kg and an STMR of 0.275 mg/kg for tetraniliprole in the Subgroup of Small fruit vine climbing.

Brassica vegetables, except brassica leafy vegetables

The critical GAP for Brassica vegetables, except brassica leafy vegetables in Canada and the United States allows four foliar applications at 45 g ai/ha, with a retreatment interval of 5 days and a PHI of 1 day.

Flowerhead brassicas, Subgroup of

Residue trials performed in the United States on broccoli and cauliflower matching the GAP, tetraniliprole residues both for MRL and risk assessment were:

Broccoli (n=5): 0.11, 0.14, 0.15, 0.18, and 0.24 mg/kg.

Cauliflower (n=5): 0.036, 0.066, 0.11, 0.16, and 0.19 mg/kg.

Noting that broccoli and cauliflower are representative commodities for flowerhead brassicas, that median residues are within a 5-fold range and the residue populations are similar according to the

Mann-Whitney test, the Meeting decided to combine the data as (n=10): 0.036, 0.066, 0.11, 0.11, 0.14, 0.15, 0.16, 0.18, 0.19, and 0.24 mg/kg.

The Meeting estimated a maximum residue level of 0.5 mg/kg and an STMR of 0.145 in the Subgroup of Flowerhead Brassicas.

Cabbages, Head

In trials conducted in the United States matching the GAP, tetraniliprole residues in head cabbages with wrapper leaves, both for MRL and dietary burden calculation, in ranked order, were (n=10): 0.046, 0.073, 0.087, 0.096, 0.12, 0.15, 0.31, 0.35, 0.48, and 1.1 mg/kg (1.2 highest individual value).

Residues of tetraniliprole in head cabbages without wrapper leaves for STMR estimation in ranked order, were (n=10): < 0.01 (3), 0.010, 0.011, 0.013, 0.020, 0.020, 0.024, and 0.026 m/kg.

The Meeting estimated a maximum residue level of 2.0 mg/kg and an STMR of 0.012 for tetraniliprole in Cabbages, head.

The Meeting also estimated a median and highest residue level of 0.135 mg/kg and 1.2 mg/kg, respectively, for Cabbages, Head with wrapper leaves.

Fruiting vegetables, other than Cucurbits

The critical GAP for fruiting vegetables in Canada and the United States allows four foliar applications at 45 g ai/ha, with a retreatment interval of 5 days and a PHI of 1 day.

Data were available from supervised residue trials in tomato (including a variety of fruit sizes, ranging from 28-450 gram, including trials with cherry tomatoes) in the United States.

In trials matching the GAP tetraniliprole residues, both for MRL and risk assessment, were (n=16): 0.030, 0.034, 0.042, 0.042, 0.053, 0.053, 0.057, 0.064, 0.066, 0.075, 0.079, 0.080, 0.12, 0.22, 0.23 and 0.32 mg/kg (highest individual value 0.35 mg/kg).

In trials conducted in peppers, including trials with chili peppers in the United States matching the GAP, tetraniliprole residues, both for MRL and risk assessment, were (n=12): 0.011, 0.024, 0.041, 0.048, 0.075, 0.077, 0.079, 0.087, 0.093, 0.11, 0.15 and 0.20 mg/kg.

Noting that residue data on small and large varieties of tomatoes and sweet and chili peppers are available, that the median residues of tetraniliprole, for tomatoes and peppers are within a 5-fold range, and that there is no evidence of a difference in the residue populations across the fruiting vegetable types by Mann-Whitney test, the Meeting decided to make a recommendation for the Group of Fruiting vegetables, other than Cucurbits based on the combined data.

The combined data for tetraniliprole, in ranked order, were (n=28): 0.011, 0.024, 0.030, 0.034, 0.041, 0.042 (2), 0.048, 0.053 (2), 0.057, 0.064, 0.066, 0.075 (2), 0.077, 0.079 (2), 0.080, 0.087, 0.093, 0.11, 0.12, 0.15, 0.20, 0.22, 0.23, and 0.32 mg/kg.

The Meeting estimated a maximum residue level of 0.4 mg/kg and an STMR of 0.075 mg/kg for tetraniliprole in the Group of Fruiting vegetables, other than Cucurbits, excluding okra, martynia and roselle.

Chili peppers, dried

Based on the estimated maximum residue level of 0.4 mg/kg for the Group of Fruiting vegetables and applying a default processing factor of 10, the Meeting estimated a maximum residue level of 4 mg/kg for peppers, chili, dried, together with a STMR of 0.75 mg/kg.

Leafy vegetables (including Brassica leafy vegetables)

The critical GAP for Brassica vegetables, except brassica leafy vegetables in Canada and the United States allows four foliar applications at 45 g ai/ha, with a re-treatment interval of 5 days and a PHI of 1 day. The Meeting received data on head lettuce, leaf lettuce, spinach and mustard greens.

Leafy greens, Subgroup of

Data were available from supervised residue trials in head lettuce, leaf lettuce and spinach in the United States. The trials did not match the Canadian or US GAP, because the RTIs ranged from 2–4 days. Decline data indicate a slow decline, indicating that the duration of the retreatment intervals has an impact on the final residue level.

The Meeting was unable to make a recommendation for the Subgroup of Leafy greens.

Brassica leafy vegetables, Subgroup of

In trials conducted in United States matching the GAP, tetraniliprole residues, both for MRL and risk assessment, in mustard greens were (n=5): 3.2, 3.6, 4.0, 4.2, and 7.3 mg/kg.

Noting that mustard greens is representative for brassica leafy vegetables, the Meeting estimated a maximum residue level of 15 mg/kg, an STMR and a median residue level of 4.0 mg/kg and a highest residue of 7.3 mg/kg for tetraniliprole in the Subgroup of Leaves of Brassicaceae.

Soya beans, dry

The US GAP for soya beans includes either a single in-furrow soil application at 200 g ai/ha (PHI not applicable), 4 foliar applications at 50 g ai/ha, with a retreatment interval of 3 days, and PHI of 14 days, or a combination of both, with a maximum of 200 g ai/ha per season. The Meeting concluded that the critical US GAP for soya beans is 4 foliar applications at 50 g ai/ha, with a retreatment interval of 3 days and a PHI of 14 days.

Trials conducted in Canada and the United States matching the critical GAP, tetraniliprole residues, both for MRL and risk assessment, in dry soya bean seeds were (n=20): < 0.01 (3), 0.012, 0.012, 0.016, 0.018, 0.018, 0.025, 0.026, 0.026, 0.030, 0.033, 0.037, 0.038, 0.048, 0.053, 0.092, 0.13, and 0.14 mg/kg.

The Meeting estimated a maximum residue level of 0.2 mg/kg and an STMR of 0.026 mg/kg for tetraniliprole in Soya bean (dry).

Tuberous and corm vegetables, Group of

The critical US GAP for tuberous and corm vegetables is a single in-furrow application at 200 g ai/ha (PHI not applicable).

Potato

In trials conducted in Canada and the United States matching the GAP, tetraniliprole residues, both for MRL and risk assessment, in ranked order were (n=18): < 0.01 (16), 0.012 and 0.015 mg/kg (highest individual level 0.017 mg/kg).

Noting that potato is a representative crop for tuberous and corm vegetables, the Meeting estimated a maximum residue level of 0.02 mg/kg and an STMR of 0.01 mg/kg for tetraniliprole in the Subgroup of Tuberous and corm vegetables.

Rice

The critical GAP for rice is from India, which allows 2 foliar applications at 60 g ai/ha, with a RTI of 11 days and a PHI of 43 days, but trials conducted in Brazil, India, Thailand and Vietnam did not match this GAP. Applying proportionality to trials showing residues (>0.01 mg/kg) with 2 foliar applications at 40 g ai/ha with identical RTI (11 days) and would still result in a too limited data set (n=2) for estimation of a maximum residue level.

The Japanese GAP for rice consists of a single seed treatment at 264 g ai/ha. Trials performed in India, Thailand and Vietnam approximating this GAP were available.

Tetraniliprole, residues, both for MRL and risk assessment, in rice grain were (n=12): < 0.01 (11) and 0.013 mg/kg.

Tetraniliprole, residues, both for MRL and risk assessment, in husked rice were (n=12): < 0.01 (12) mg/kg.

The Meeting estimated a maximum residue level of 0.02 mg/kg and an STMR of 0.01 mg/kg for tetraniliprole in Subgroup of Rice cereals.

The Meeting estimated a maximum residue level of 0.01(*) mg/kg and an STMR of 0.01 mg/kg for tetraniliprole in Rice, husked.

Noting that residue levels in polished rice are usually lower than residue levels in husked rice, which was confirmed in the processing study submitted to the current Meeting, the Meeting decided to extrapolate the MRL of 0.01(*) mg/kg and STMR of 0.01 mg/kg for Rice, husked to Rice, polished.

Maize cereals, Subgroup of

The critical GAP in the United States for maize (field corn, popcorn) is 4 foliar applications at 50 g ai/ha with a retreatment interval of 7 days and a PHI of 14 days.

In residue trials in maize/field corn from Canada and the United States matching this GAP, tetraniliprole residues, both for MRL and risk assessment, were (n=15): < 0.01 (14) and 0.011 (0.012 highest individual value) mg/kg.

The Meeting estimated a maximum residue level of 0.015 mg/kg and an STMR of 0.01 mg/kg for tetraniliprole in the Subgroup of Maize cereals.

Sweet Corn (corn-on-the-cob)

The critical GAP for sweet corn in the United States is 4 foliar applications at 50 g ai/ha with a retreatment interval of 7 days and a PHI of 1 day.

In residue trials conducted in sweet corn according to GAP in Canada and the United States, tetraniliprole residues, both for MRL and risk assessment, were (n=14): < 0.01 (14) mg/kg.

The Meeting estimated a maximum residue level of 0.01(*) mg/kg and an STMR of 0.01 mg/kg for tetraniliprole for Sweet Corn (corn-on-the-cob) (kernels plus cob with husk removed).

Tree nuts, Group of

The critical GAP for tree nuts in Canada and the United States allows for 4 foliar applications at 45 g ai/ha, with an RTI of 7 days and a PHI of 10 days. Data were available from supervised residue trials in almond and pecan in Canada and the United States matching the GAP.

Residues of tetraniliprole, both for MRL and risk assessment, in almonds were (n=3): < 0.01 (1), 0.010, and 0.015 mg/kg.

Residues of tetraniliprole, both for MRL and risk assessment, in pecans were (n=6): < 0.01 (6) mg/kg.

Noting that the median residues of tetraniliprole, in almonds and pecans are within a 5-fold range and that there is no evidence of a difference in the residue populations by Mann-Whitney test, the Meeting decided to combine the results as (n=9): < 0.01 (7), 0.010, and 0.015 mg/kg.

Considering that a high number of residue levels below the LOQ of 0.01 mg/kg results in a higher statistical uncertainty, the Meeting decided to estimate the maximum residue level based on 2 × HR, leading to a higher value than would be calculated with the OECD calculator.

Noting that almond and pecan are two representative crops for the group, the Meeting estimated a maximum residue level of 0.03 mg/kg and an STMR of 0.01 mg/kg for tetraniliprole in the Group of Tree Nuts.

Residues in animal feeds

Soya bean forage (56 percent dry matter) and hay (85 percent dry matter)

The Canadian and United States labels have a feeding restriction for soya bean forage and hay after foliar use, but not after in-furrow soil treatment or seed treatment. The critical GAP in the United States for soya beans as relates to soya bean forage and hay is in-furrow-treatment at 200 g ai/ha.

In three trials on soya bean forage conducted according to this GAP, tetraniliprole residue levels, both for MRL and dietary burden estimations, were (n=3): < 0.01 (2) and 0.031 mg/kg.

The Meeting concluded that three trials are insufficient to estimate a median and highest residue level for tetraniliprole in soya bean forage and hay.

Since residue levels were observed in soya bean forage and hay when planted in crop rotation, maximum residue levels estimated in that section are applicable for soya bean forage and hay in the absence of sufficient data after primary use.

Rice straw (90 percent dry matter)

The critical GAP for rice in India allows for 2 foliar applications at 60 g ai/ha, with an RTI of 11 days and a PHI of 43 day. Supervised residue trials conducted in rice in Brazil, India, Thailand and Vietnam used a lower application rate (2 × 40 g ai/ha) or a higher number of applications (3 × 60 g ai/ha). The Meeting agreed to use the trials with the lower application rates by applying proportionality.

Unscaled tetraniliprole residue levels in rice straw from supervised residue trials conducted at 2 × 40 g ai/ha (RTI 10-12 days and harvested at 43 DALA) were (n=6): 0.24, 0.26, 1.6, 1.9, 3.5, and 5.0 mg/kg (highest individual value of 5.1 mg/kg). Scaled tetraniliprole residues for MRL estimation were (n=6): 0.36, 0.39, 2.4, 2.8, 5.2, and 7.5 (highest individual value 7.6 mg/kg) on an as received basis.

Unscaled total tetraniliprole residue levels were (n=6): 0.26, 0.29, 1.7, 2.0, 3.6, and 5.4 mg/kg (highest individual value of 5.5 mg/kg). Scaled total tetraniliprole residues for median and highest residue estimation in ranked order were (n=6): 0.39, 0.44, 2.6, 3.0, 5.4 and 8.1 mg/kg (highest individual value 8.2 mg/kg) on as received basis.

Assuming a default of 90 percent dry matter, the Meeting estimated a maximum residue level of 20 (dw) mg/kg for tetraniliprole in rice straw.

Based on the total tetraniliprole residues, the Meeting estimated a median and highest residue level of 2.8 mg/kg and 8.2 mg/kg for tetraniliprole in rice straw on an as received basis for dietary burden calculations.

The Meeting noted that residues may occur in rice planted in rotation. However, the residues from prior uses will not contribute significantly to the total residue and were not included in the calculation.

Rice whole crop silage (40 percent dry matter)

The critical GAP for rice in India allows for 2 foliar applications at 60 g ai/ha, with a RTI of 11 days and a PHI of 43. Data were available from supervised residue trials in rice in Brazil, India, Thailand and Vietnam but trials were conducted at 2 × 40 g ai/ha. The Meeting agreed to apply the proportionality approach using the data at PHI is 0 days for crop silage.

Unscaled tetraniliprole residue and unscaled total residue levels were the same in supervised residue with application rates of 2 × 40 g ai/ha (RTI 10-12 days and harvested at 0 DALA) and were (n=5): 1.2, 1.7, 1.8, 1.9, and 3.1 mg/kg (highest individual value of 3.5 mg/kg). Both scaled tetraniliprole residues and scaled total residues were the same and were (n=5): 1.8, 2.6, 2.7, 2.8, and 4.6 mg/kg (highest individual value of 5.2 mg/kg).

The Meeting estimated a median and highest residue level of 2.7 mg/kg and 5.2 mg/kg, respectively for tetraniliprole in rice whole crop silage on an as received basis for dietary burden calculations, both for subsequent maximum residue level and STMR estimations in animal commodities.

The Meeting noted that residues may occur in rice planted in rotation. However, the residues from prior uses will not contribute significantly to the total residue and were not included in the calculation.

Maize/ field corn forage (40 percent dry matter) or sweet corn forage (48 percent dry matter)

The critical GAP in the United States for maize (field corn, sweet corn, popcorn) is 4 foliar applications at 50 gai/ha with a retreatment interval of 7 days and a PHI of 14 days (field corn, popcorn) and 1 day PHI for sweet corn, with a restriction not to feed forage or stover within PHI 14 days.

Tetraniliprole residue levels in maize/field corn forage (PHI=14 days) from trials conducted according to GAP in Canada and the United States were (n=19): < 0.01, 0.040, 0.11, 0.19, 0.24, 0.44, 0.44, 0.48, 0.49, 0.53, 0.55, 0.68, 0.96, 1.1, 1.3, 1.3, 1.4, 2.2, 3.1 mg/kg (highest individual value of 3.6 mg/kg).

Tetraniliprole residue levels in sweet corn forage conducted according to GAP (PHI=14 days) were (n=2): 2.1 and 2.2 mg/kg.

Total tetraniliprole residue levels in maize/field corn forage (PHI=14 days) were (n=19): < 0.01, 0.040, 0.11, 0.19, 0.24, 0.44, 0.44, 0.49, 0.50, 0.53, 0.55, 0.68, 0.97, 1.1, 1.3, 1.3, 1.4, 2.2, 3.1 (highest individual value 3.6 mg/kg).

Total tetraniliprole residue levels in sweet corn forage (PHI=14 days) were (n=2): 2.1 and 2.2 mg/kg.

Noting that the residue levels of sweet corn forage fall within the range of field corn forage, the Meeting decided to combine the data. The combined total tetraniliprole residues for median and highest residue estimation, in ranked order, were (n=21): < 0.01, 0.040, 0.11, 0.19, 0.24, 0.44, 0.44, 0.49, 0.50, 0.53, 0.55, 0.68, 0.97, 1.1, 1.3, 1.3, 1.4, 2.1, 2.2, 2.2, 3.1 (highest individual value 3.6 mg/kg).

The Meeting estimated a median residue of 0.55 mg/kg and a highest residue of 3.6 mg/kg for tetraniliprole in maize forage on an as received basis.

The Meeting noted that residues may occur in maize/field corn or sweet corn planted in rotation. However, the residues from prior uses will not contribute significantly to the total residue and were not included in the calculation.

Maize/field corn or sweet corn stover (83 percent dry matter)

The critical GAP in the United States for maize (field corn, sweet corn, popcorn) is 4 foliar applications at 50 g ai/ha with a retreatment interval of 7 days and a PHI of 14 days (field corn, popcorn, and corn grown for seed) and 1 day for sweet corn, with a withholding period of 14 days.

Tetraniliprole residue levels in maize/field corn stover (PHI=14-21 days) from trials conducted according to GAP were (n=21): < 0.01, 0.20, 0.28, 0.37, 0.80, 1.1, 2.3, 2.4, 2.5, 2.6, 2.9, 2.9, 2.9, 3.1, 3.2, 4.3, 4.4, 5.9, 7.9, 9.1, and 10 mg/kg.

Tetraniliprole residue levels in sweet corn stover (PHI=14-36 days) from trials conducted according to GAP were (n=14): < 0.01, 0.014, 0.13, 0.54, 0.72, 0.80, 1.2, 1.4, 1.4, 2.2, 2.5, 5.4, 7.9, and 16 mg/kg (17 mg/kg highest individual value).

Recognizing that normally the dataset with highest levels would be used for median and highest residue estimation the Meeting decided to combine the datasets as that results in the highest median residue.

The combined tetraniliprole residues in field corn and sweet corn stover are (n=35): < 0.01 (2), 0.014, 0.13, 0.20, 0.28, 0.37, 0.54, 0.72, 0.80, 0.80, 1.1, 1.2, 1.4, 1.4, 2.2, 2.3, 2.4, 2.5, 2.5, 2.6, 2.9, 2.9, 2.9, 3.1, 3.2, 4.3, 4.4, 5.4, 5.9, 7.9, 7.9, 9.1, 10, and 16 mg/kg (highest individual value 17 mg/kg).

Total tetraniliprole residues for median and highest residue estimation, in ranked order, are (n=35): < 0.01 (2), 0.014, 0.16, 0.21, 0.28, 0.39, 0.56, 0.80, 0.82, 0.87, 1.1, 1.3, 1.4, 1.5, 2.3 (2), 2.5, 2.5, 2.6 (2), 2.9, 3.0, 3.0, 3.2, 3.3, 4.3, 4.4, 5.5, 6.1, 8.0, 8.0, 9.1, 10, and 16 mg/kg (highest individual value 17 mg/kg).

The Meeting estimated a maximum residue level of 30 mg/kg (dw), based on a dry matter content of 83 percent for maize corn stover.

The Meeting estimated a median residue of 2.5 mg/kg and a highest residue of 17 mg/kg for tetraniliprole in maize stover and sweet corn stover on an as received basis for dietary burden calculations.

The Meeting noted that residues may occur in maize/field corn or sweet corn planted in rotation. However, the residues from prior uses will not contribute significantly to the total residue and were not included in the calculation.

Almond hulls

The critical GAP in Canada and the United States for tree nuts is 4 foliar applications at 45 g ai/ha with a retreatment interval of 7 days and a PHI of 10 days. In trials matching the GAP, tetraniliprole residues, both for maximum residue and median residue level estimation, in almond hulls are (n=5): 0.22, 0.77, 0.80, 1.1, and 1.8 mg/kg.

Based on a dry matter content of 90 percent the Meeting estimated a maximum residue level of 4 mg/kg (dw). The Meeting estimated a median residue level of 0.80 for tetraniliprole in almond hulls on an as received basis for the dietary burden calculations.

Residues from rotational crops to consider for animal feeds

Rotational crop studies indicate that residue can be expected in feed commodities grown in crop rotation. Residues were found in forage and hay from legume vegetables (beans, peas, soya bean and alfalfa) and in forage, hay and straw from cereals (wheat, barley and sorghum). The findings were combined in the two major crop groups to estimate a maximum residue level and median and highest residue levels.

Table 5.33.3 Maximum and mean residues found in feed commodities from rotational crops

Matrix	N	Tetraniliprole		Tetraniliprole-N-methyl-quinazolinone		Total ^a	
		max (mg/kg)	median (mg/kg)	max (mg/kg)	median (mg/kg)	max (mg/kg)	median (mg/kg)
Legume feeds with high water content (forage and silage) ^b	58	0.056	< 0.01	< 0.01	< 0.01	0.066 ^d	< 0.01
Legume feeds with low water content (hay) ^b	58	0.19	< 0.01	0.026	< 0.01	0.22	< 0.01
Cereal grains (including pseudocereals) feed products with high water (≥ 20 percent) content (forage and silage) ^c	28	0.030	< 0.01	< 0.01	< 0.01	0.030	< 0.01
Cereal grains (including pseudocereals) feed products with low water (<20 percent) content (hay, straw)	67	0.097	< 0.01	0.038	< 0.01	0.14	< 0.01

Notes:

^a Total residue expressed as tetraniliprole.

^b Based on data in alfalfa, beans, peas and soya bean data.

^c Based on wheat, barley and sorghum data.

^d In alfalfa one value of 0.051 mg/kg tetraniliprole + 0.015 mg/kg tetraniliprole N-methyl-quinazolinone also added to 0.066 mg/kg.

The Meeting estimated a median and highest residue level of 0.01 and 0.066 mg/kg (parent + tetraniliprole-N-methyl-quinazolinone), respectively, for the Subgroup of Products of legume feeds with high water (≥ 20 percent) content (forage and silage).

The Meeting estimated a maximum residue level (parent only) of 0.3 mg/kg for the Subgroup of Products of legume feeds with low (< 20 percent) water content (hay), and a median and highest residue level of 0.01 and 0.21 mg/kg (parent + tetraniliprole-N-methyl-quinazolinone), respectively.

The Meeting estimated a median and highest residue level of 0.01 and 0.030 mg/kg (parent + tetraniliprole-N-methyl-quinazolinone), respectively, for the Subgroup of Cereal grains (including pseudocereals) feed products, excluding maize, corn and rice, with high water (≥ 20 percent) content (forage and silage).

The Meeting estimated a maximum residue level of 0.2 mg/kg for the Subgroup of Cereal grains (including pseudocereals) feed products, excluding maize, corn and rice with low water (< 20 percent) content (hay, straw), and a median and highest residue level of 0.01 and 0.14 mg/kg (parent + tetraniliprole-N-methyl-quinazolinone), respectively.

Fate of residues during processing

The Meeting received information on the hydrolysis of tetraniliprole as well as information on the fate of tetraniliprole residues during processing in oranges, apples, plums, grapes, broccoli, tomatoes, mustard greens, soya bean, potato, field corn, and rice.

High temperature hydrolysis

The hydrolysis of [pyrazole-carboxamide-¹⁴C]-Tetraniliprole and [phenyl-carbamoyl-¹⁴C]-tetraniliprole was studied in sterile buffered aqueous solutions under conditions simulating pasteurization, baking/brewing/boiling, and sterilisation.

Tetraniliprole was shown to be stable under the condition representing pasteurization (pH 4, 90 °C, 20 minutes) with 90–95 percent AR recovered. Under baking/brewing/boiling (BBB) (pH 5, 100 °C, 60 minutes) and sterilisation (pH 6, 120 °C, 20 minutes) conditions, 65–68 percent and 1.1–1.5 percent AR was recovered as parent at the end of incubation, respectively. Tetraniliprole-N-methyl-quinazolinone was the major degradation product, accounting for 27 to 30 percent AR under BBB conditions and 94 percent AR under sterilisation conditions. Two other metabolites, pyrazole-5-N-methyl-amide and desamino-methyl-carboxylic acid, were also found, but these were present in lower amounts (maximum 3 percent AR)

Processing

Estimated processing factors based on total residues (parent plus tetraniliprole-N-methyl-quinazolinone) for the commodities considered at this Meeting are summarized below, together with STMR-P values. Since two dietary burdens will be estimated, one for maximum residue level estimations (parent only=P) in animal commodities and one for STMR estimations (T: total residues, including parent and tetraniliprole-N-methyl-quinazolinone), sometimes two median values for processed feed commodities were estimated, when processing factors differed).

Table 5.33.4 Calculated STMRs based on parent plus tetraniliprole-N-methyl-quinazolinone for processed food and feed commodities and for parent only (P) in feed commodities, where different PF were derived

Raw commodity (STMR)	Processed commodity	Individual processing factors	Mean or best estimate	STMR-P = STMR _{RAC} × PF (mg/kg)
Orange [0.14 mg/kg]	Peel	2.6, 3.0	2.8	0.39
	Peeled orange (flesh)	0.081, 0.13	0.11	0.015
	Juice ^a	< 0.02, < 0.03	< 0.02	0.01
	Marmalade	< 0.03, 0.021	0.021	0.01
	Cold extracted peel oil	6.2, 12	9.1	1.27
	Dried pulp ^b	0.96, 1.3 (P: 0.96, 1.2)	1.1	0.15
Apple [0.13 mg/kg]	Juice ^a	0.31, 0.69	0.5	0.065
	Sauce	< 0.019, < 0.030	< 0.019	0.01
	Dried apple	0.032, 0.052	0.042	0.01
	Wet pomace (40 percent DM)	1.6, 1.8	1.7	0.22
	Dry pomace (≈90 percent DM)	6.8, 7.3	7.0	0.91
Plum [0.033 mg/kg]	Prune =dried plum	3.6, 4.6	4.1	0.125
Grape	Juice ^a	0.14, 0.17, 0.24, 0.25, 0.31, 0.36	0.245	0.067

Raw commodity (STMR)	Processed commodity	Individual processing factors	Mean or best estimate	STMR-P = STMR _{RAC} × PF (mg/kg)
[0.275 mg/kg]	Wine at bottling (white)	0.17, 0.39	0.28	0.077
	Wine at bottling (red)	0.45, 0.57	0.51	0.14
	Wine at first taste (white)	0.21, 0.27	0.24	0.066
	Wine at first taste (red)	0.30, 0.54	0.42	0.12
	Must	0.22, 0.58, 0.62, 0.86	0.57	0.16
	Dried grape	P: 0.92, 1.6 T: 0.94, 1.6	1.26 1.27	0.35
	Wet pomace (≈15 percent DM) ^c	2.1, 2.2, 2.5, 2.8	2.4	0.65
	Dry pomace (90 percent DM)	P: 3.0, 4.9, 7.7, 7.9 T: 3.0, 5.0, 7.9, 8.2	P: 5.9 T: 6.0	P: 1.62 T: 1.65
Broccoli [0.145 mg/kg]	Washed and cooked	0.49	0.49	0.071
Tomato [0.075 mg/kg]	Raw/fresh puree	0.59, 1.1	0.84	0.063
	Paste	P: 1.9, 5.1 T: 3.7, 6.7	P: 3.5 T: 5.2	0.39
Mustard greens [4.0 mg/kg]	Washed and cooked	0.18	0.18	0.72
Soya bean [0.026 mg/kg]	Refined bleached deodorized oil	< 0.02	< 0.02	< 0.01
	Toasted meal	P: 0.027 T: 0.14	P: 0.027 T: 0.14	P: 0.01 T: 0.01
	Hulls	4.2	4.2	0.11
	Aspirated grain fraction	33	33	0.86
Potato [0.01 mg/kg]	Crisps	< 0.3 ^[ff] , < 0.5 ^[ff] , < 1 ^[ff]	< 0.3	0.01
	Flakes	< 0.3 ^[ff] , < 0.5 ^[ff] , < 1 ^[ff]	< 0.3	0.01
	Peeled	< 0.3 ^[ff] , < 0.5 ^[ff] , < 1 ^[ff]	< 0.3	0.01
	Steamed and mashed without peel	< 0.3 ^[ff] , < 0.5 ^[ff] , < 1 ^[ff]	< 0.3	0.01
	Cooked with peel	< 0.3 ^[ff] , < 0.5 ^[ff] , < 1 ^[ff]	< 0.3	0.01
	Cooked without peel	< 0.3 ^[ff] , < 0.5 ^[ff] , < 1 ^[ff]	< 0.3	0.01
	Peel	P: < 0.3 ^[ff] , < 1 ^[ff] , 2.3 ^[ff] T: < 1 ^[ff] , 4.6 ^[ff] , 5.0 ^[ff]	P: 2.3 T: 4.8	P: 0.023 T: 0.048
Rice grain [0.01 mg/kg]	Bran	0.28, 0.29	0.285	0.01
	Hulls	2.8, 5.4	4.1	0.041
Field corn/maize [0.01 mg/kg]	Flour	1.2	1.2	0.012
	Grits	< 0.6	< 0.6	0.01
	Meal	1.1	1.1	0.011
	Starch	< 0.6	< 0.6	0.01
	Refined bleached deodorised oil (wet milled)	< 0.6	< 0.6	0.01
	Refined bleached deodorised oil (dry milled)	< 0.6	< 0.6	0.01
	Aspirated grain fractions	4.6	4.6	0.046

Notes:

^a Highest value selected from limed dry pomace, wet pomace and dry pomace.

^b Highest value of either pasteurized or raw juice.

^c Results in highest residue in dietary burden calculation.

^[f] Foliar application.

^[if] In-furrow application.

Using the estimated maximum residue level of 0.5 mg/kg for oranges and applying the processing factor of 9.1 (based on parent only), the Meeting estimated a maximum residue level of 5 mg/kg for tetraniliprole in orange oil, edible.

Using the estimated maximum residue level of 0.3 mg/kg for plums and applying the processing factor of 4.1 (based on parent only), the Meeting estimated a maximum residue level of 1.5 mg/kg for tetraniliprole in prune, dried.

Using the estimated maximum residue level of 1.5 mg/kg for grapes and applying the processing factor of 1.3 (based on parent only), the Meeting estimated a maximum residue level of 2 mg/kg for tetraniliprole in dried grapes.

Using the estimated maximum residue level of 0.4 mg/kg for tomatoes and applying the processing factor of 3.5 (based on parent only), the Meeting estimated a maximum residue level of 1.5 mg/kg for tetraniliprole in tomato paste.

Residues in animal commodities*Farm animal feeding studies*

The Meeting received one feeding study involving tetraniliprole in lactating cows. No poultry feeding study was submitted.

In the dairy cow feeding study, four groups of lactating Holstein cows (3 cows/group) were dosed orally once daily via capsule corresponding with a feeding rate of 0.94, 9.3, 28, or 94 ppm tetraniliprole in feed/day (dry weight) for 29 consecutive days. Milk was collected twice daily and pooled samples were taken at intervals throughout the study period. The animals were sacrificed within 3 to 8 hours after the last dose and samples of liver, kidney, muscle and fat (mesenteric, subcutaneous, and perirenal) were collected for analysis. Samples were stored frozen for up to 20 days before extraction and were analysed within 7 days for tetraniliprole, tetraniliprole-N-methyl-quinazolinone or tetraniliprole-benzylalcohol.

Tetraniliprole residues in milk above the LOQ were found in the milk samples of the animals in the three highest dose groups. Residues of parent tetraniliprole reached a plateau after approximately 7–10 days, with mean (day 7–28) levels of 0.047, 0.10 and 0.18 mg/kg at 9.3 ppm, 28 ppm and 94 ppm feeding levels, respectively.

Similar patterns were found for both metabolites, though at lower concentrations compared to parent. The mean (day 7–28) concentrations for tetraniliprole-N-methyl-quinazolinone were 0.031, 0.073, and 0.10 mg/kg, for the three highest dose groups respectively. And for tetraniliprole-benzylalcohol the mean concentrations found were 0.025, 0.048, and 0.069 mg/kg, respectively. Mean (day 7–28) total residue levels in milk were 0.10, 0.22 and 0.36 mg/kg, respectively.

At 0.94 ppm, parent tetraniliprole was only observed in the liver (0.025–0.037 mg/kg, mean 0.031 mg/kg) and tetraniliprole-N-methyl-quinazolinone was observed in fat tissues only (< 0.01–0.033 mg/kg).

Both parent and metabolite tetraniliprole-N-methyl-quinazolinone were observed in all other tissues at the three higher feeding levels (9.3, 28, and 94 ppm), whereas the benzylalcohol metabolite was only observed in liver in the mid and high dose groups (28 and 94 ppm) and kidney in the high dose group (94 ppm). The total residues below represents the sum of parent tetraniliprole + tetraniliprole-N-methyl-quinazolinone + tetraniliprole benzylalcohol.

At 9.3 ppm, the highest concentration of parent was 0.37 mg/kg in liver, 0.067 mg/kg in kidney, 0.023 mg/kg in muscle, and 0.063 mg/kg in fats. Total highest residues were 0.41 (mean 0.37) mg/kg in liver, 0.10 (mean 0.085) mg/kg in kidney, 0.043 (mean 0.041) mg/kg in muscle, 0.26 (highest mean 0.20) mg/kg in three fats. The results across the three different fat types were similar for both parent and total residues.

At 28 ppm, the highest concentration of parent was 0.87 mg/kg in liver, 0.19 mg/kg in kidney, 0.060 mg/kg in muscle, and 0.12 mg/kg in fats. Total highest residues were 0.97 (mean 0.70) mg/kg in liver, 0.27 (mean 0.19) mg/kg in kidney, 0.094 (mean 0.075) mg/kg in muscle, and 0.83 (highest mean 0.54) mg/kg in three fats.

At 94 ppm, the highest concentration of parent was 1.5 mg/kg in liver, 0.28 mg/kg in kidney, 0.090 mg/kg in muscle, and 0.22 mg/kg in fats. Total highest residues were 1.7 (mean 1.4) mg/kg in liver, 0.34 (mean 0.31) mg/kg in kidney, 0.16 (mean 0.14) mg/kg in muscle, 1.2 (highest mean 0.77) mg/kg in three fats.

Farm animal dietary burden

The dietary burden was based on the intake of tetraniliprole for maximum residue estimation. An additional dietary burden calculation based on the intake of tetraniliprole + tetraniliprole-N-methyl-quinazolinone was calculated for STMR and HR estimation. Residues found in feed commodities in both supervised residue trials and field rotational crops studies and processing studies were used for dietary burden calculations (see the various tables at the appropriate sections throughout the appraisal).

Dietary burdens were calculated for beef cattle, dairy cattle, broilers and laying poultry based on feed items evaluated by the JMPR in 2022. The dietary burdens, estimated using the OECD diets listed in Appendix IX of the 2016 edition of the FAO Manual, are presented in Annex 6 and summarized below.

Table 5.33.5 Estimated maximum and mean dietary burdens of farm animals

	Animal dietary burden: tetraniliprole, ppm of dry matter diet							
	United States-Canada		European Union		Australia		Japan	
	Max	Mean	Max	Mean	Max	Mean	Max	Mean
Beef cattle	3.21	0.55	19.8	6.8	13.6	3.2	4.9	1.8
Dairy cattle	6.05	1.091	17.6	6.6	29.46 ^{①②}	12.7	11.2	3.73
Poultry—broiler	0.015	0.015	0.026	0.026	0.014	0.014	0.012	0.012
Poultry—layer	0.015	0.015	0.47 ^{③④}	0.077	0.014	0.014	0.013	0.013

Notes:

- ① Highest maximum beef or dairy cattle dietary burden suitable for MRL estimates for mammalian tissues.
- ② Highest maximum dairy cattle dietary burden suitable for MRL estimates for mammalian milk.
- ③ Highest maximum poultry dietary burden suitable for MRL estimates for poultry tissues.
- ④ Highest maximum poultry dietary burden suitable for MRL estimates for poultry eggs.

Table 5.33.6 Estimated maximum and mean dietary burdens of farm animals for STMR calculation

	Animal dietary burden: tetraniliprole + tetraniliprole-N-methyl-quinazolinone, ppm of dry matter diet							
	United States-Canada		European Union		Australia		Japan	
	Max	Mean	Max	Mean	Max	Mean	Max	Mean
Beef cattle	3.22	0.57	19.8	6.85	13.61	3.34	5.25	1.91
Dairy cattle	6.07	1.08	17.56	6.617	29.46	12.76 ^{①②}	11.2	3.73
Poultry-broiler	0.015	0.015	0.026	0.026	0.014	0.014	0.012	0.012
Poultry-layer	0.015	0.015	0.47	0.077 ^{③④}	0.014	0.014	0.013	0.017

Notes:

- ① Highest mean beef or dairy cattle dietary burden suitable for STMR estimates for mammalian tissues.
- ② Highest mean dairy cattle dietary burden suitable for STMR estimates for mammalian milk.
- ③ Highest mean poultry dietary burden suitable for STMR estimates for poultry tissues.
- ④ Highest mean poultry burden suitable for STMR estimates for poultry eggs.

Animal commodity maximum residue levels

Cattle

For beef and dairy cattle, a maximum and mean dietary burden of 33.7 and 12 ppm were estimated. For a maximum residue level estimation, the highest residues in the tissues and the mean residues in milk (day 7–28) were calculated by taking the maximum dietary burden (33.7 ppm) and interpolation of the highest (tissues) and mean (milk, day 7–28) residue levels (parent only) found in the individual animals in the feeding study at 28 and 94 ppm.

The STMR values for the tissues and milk were calculated from the mean dietary burden level of 12 ppm by interpolation of the mean total residue levels (parent, tetraniliprole-N-methyl-quinazolinone, and tetraniliprole-benzylalcohol) found in milk and tissues of animals dosed at 9.4 and 28 ppm.

Table 5.33.7 Residues in milk and tissues from cattle dosed with tetraniliprole in the diet

Tetraniliprole feeding study	Feed level (ppm) for milk residues	Residues (mg/kg) in milk	Feed level (ppm) for tissue residues	Residues (mg/kg)			
				Muscle	Liver	Kidney	Fat
MRL (beef or dairy cattle); parent only							
Feeding study	28	0.10	28	0.060	0.87	0.19	0.12
	94	0.18	94	0.090	1.50	0.28	0.22
Dietary burden and high residue	29.46	0.10	29.46	0.061	0.88	0.19	0.12
STMR Determination (beef or dairy cattle); parent + tetraniliprole-N-methyl-quinazolinone + tetraniliprole-benzylalcohol, expressed as tetraniliprole							
Feeding study	9.3	0.10	9.3	0.041	0.37	0.085	0.20
	28	0.22	28	0.075	0.70	0.19	0.54
Dietary burden and residue estimate	12.76	0.12	12.76	0.047	0.43	0.10	0.26

The Meeting concluded that residues > 0.01 mg/kg are expected in milk, muscle, liver, kidney and fat and estimated maximum residue levels of 0.15 mg/kg for milk, 0.1 mg/kg for meat ($0.8 \times 0.061 + 0.2 \times 0.12 = 0.728$ mg/kg), 1.0 mg/kg for edible offal (based on liver), and 0.15 mg/kg for fat.

For estimating dietary exposure to total residues, calculated STMRs are: 0.12 mg/kg for milk, 0.047 mg/kg for muscle, 0.43 mg/kg for liver, 0.10 mg/kg for kidney, and 0.26 mg/kg for fat.

Poultry

For poultry a maximum (parent only) and mean (parent + tetraniliprole-N-methyl-quinazolinone) dietary burden of 0.47 and 0.077 ppm, respectively were estimated, respectively. However, no feeding study in laying hens was provided.

The laying hen metabolism studies involved administration of approximately 18 ppm tetraniliprole in the diet, which is about 36 times overdosed compared to the expected maximum dietary burden (maximum of 0.5 ppm). Scaling of the highest residue (parent+tetraniliprole-N-methyl-quinazolinone + tetraniliprole-benzylalcohol (+conjugates)) found in poultry tissues and eggs (0.12 mg eq/kg) to the maximum dietary burden would result in residues at up to a maximum of 0.0033 mg eq/kg.

Acknowledging that there might be some exposure and a feeding study is preferred, the Meeting concluded that no residues > 0.01 mg/kg are expected in eggs and poultry tissues and estimated maximum residue levels of 0.01(*) mg/kg or poultry meat, eggs, fat and edible offal as well as STMRs values of 0.01 mg/kg.

RECOMMENDATIONS

On the basis of the data obtained from supervised trials, the Meeting concluded that the residue levels listed in Annex 1 are suitable for establishing maximum residue limits and for IEDI, international estimate of short-term intakes and GECDE assessments.

Definition of the residue for compliance with the MRL for plant commodities: *tetraniliprole*.

Definition of the residue for dietary risk assessment for plant commodities: *tetraniliprole + tetraniliprole-N-methyl-quinazolinone, expressed as tetraniliprole*.

Definition of the residue for compliance with the MRL for animal commodities: *tetraniliprole*.

Definition of the residue for dietary risk assessment for animal commodities: *tetraniliprole + tetraniliprole-N-methyl-quinazolinone + tetraniliprole-benzylalcohol, expressed as tetraniliprole*.

The residue is not fat-soluble.

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The ADI for tetraniliprole is 0–2 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for tetraniliprole were estimated for the 17 GEMS/Food Consumption Cluster Diets using the STMR or STMR-P values estimated by the JMPR. The results are shown in Annex 3 of the 2022 JMPR Report.

The IEDIs ranged from 0–0 percent of the maximum ADI. The Meeting concluded that long-term dietary exposure to residues of tetraniliprole from uses considered by the JMPR is unlikely to present a public health concern.

Acute dietary exposure

The 2021 JMPR decided that an ARfD for tetraniliprole was unnecessary. The Meeting therefore concluded that the acute dietary exposure to residues of tetraniliprole from the uses considered is unlikely to present a public health concern.

Threshold of toxicological concern (TTC) consideration for metabolites

At the JMPR 2021 Meeting the WHO concluded that for the metabolites T-pyrazole-5-carboxylic acid, T-N-methyl-quinazolinone-benzylalcohol, T-despyridyl-N-methyl-quinazolinone, T-pyrazole-5-amide, and T-N-methyl-quinazolinone-pyrazole-3-carboxylic acid the TTC Cramer Class III could be applied (no indication for genotoxicity).

For the current Meeting additional information was provided to the WHO. For three metabolites T-quinazolinone, T-pyridinyl-pyrazole-5-carboxylic acid, and T-pyrazole-5-N-methyl-amide the 2022 WHO concluded that the TTC Cramer Class III could be applied (no indication for genotoxicity) for these metabolites.

The exposure based on the residue levels found in animal commodities from the goat and laying hen metabolism studies, resulted in the following maximum long-term exposures (T= tetraniliprole). It is noted that the exposure levels were not corrected for the dose levels used in the goat study (slightly under dosed) but were corrected for the dose levels used in the laying hen study (36 times over dosed):

TTC III (< µg/kg bw)

T-quinazolinone (goat)	0.11 µg/kg bw
T-pyrazole-5-carboxylic acid (goat and poultry)	0.07 µg/kg bw
T-N-methyl-quinazolinone-benzylalcohol (goat)	0.033 µg/kg bw
T-pyridinyl-pyrazole-5-carboxylic acid (goat)	0.03 µg/kg bw
T-despyridyl-N-methyl-quinazolinone (poultry)	0.03 µg/kg bw
T-pyrazole-5-N-methyl-amide (goat and poultry)	0.02 µg/kg bw
T-pyrazole-5-amide (poultry and goat liver only)	0.01 µg/kg bw
T-N-methyl-quinazolinone-pyrazole-3-carboxylic acid (goat)	0.0023 µg/kg bw

The Meeting concluded that the exposures to these metabolites are below the TTC for Cramer Class 3 compounds of 1.5 µg/kg bw/day and were unlikely to present a health concern from the uses evaluated by the current Meeting.

In addition, for a number of poultry specific metabolites no toxicity data was available. The Meeting decided these should be assessed using the TTC approach for genotoxic compounds (below the threshold of 0.0025 µg/kg bw/day).

TTC for genotoxic compounds (< 0.0025 µg/kg bw—corrected for dietary burden)

T-despyridyl (poultry)	0.00034 µg/kg bw
Tetrazole-conjugates (poultry)	0.00063 µg/kg bw
T-despyridyl-N-methyl-quinazolinone-hydroxy/	0.00019 µg/kg bw

T-despyridyl-hydroxy (poultry)	
T-deschloro-desmethyl-amide (poultry)	0.00015 µg/kg bw
T-despyridyl-quinazolinone (poultry)	0.00014 µg/kg bw
T-pyrazole-5-N-methyl-amide-hydroxy (poultry)	0.000094 µg/kg bw
T--deschloro-desmethyl-amide	0.00015 µg/kg bw

The Meeting concluded that these poultry metabolites are below the TTC for genotoxic compound and were unlikely to present a health concern from the uses evaluated by the current Meeting.

Should further uses be considered in the future, these conclusions may need to be re-evaluated.

5.34 Triflumuron (317)

TOXICOLOGY

Triflumuron was evaluated by the Joint FAO/WHO Meeting of Pesticide Residues (JMPR) in 2019; it was evaluated by the current Meeting in support of an FAO panel review of triflumuron to conclude on residue definitions for dietary risk assessment for plant and animal commodities.

The following new information on triflumuron metabolites was provided: Ames test for triflumuron metabolite M01, an in vitro micronucleus test in human lymphocytes for metabolite M01 and an in silico genotoxicity assessment of triflumuron and its crop metabolite M04.

All critical studies contained statements of compliance with good laboratory practice (GLP) and were conducted in accordance with relevant national or international test guidelines, unless otherwise specified.

Toxicological data on metabolites and/or degradates

The plant metabolite M01 was negative for genotoxicity in an Ames test and in an in vitro micronucleus test in human lymphocytes.

In silico predictions demonstrated that the only genotoxicity alerts given by M04 were also given by triflumuron and hence the Meeting concluded that M04 is unlikely to be genotoxic in vivo, as this had been the conclusion for triflumuron.

No toxicity data are available for metabolite M01 and M04.

The Meeting concluded that dietary exposure to M01 and M04 should be compared to the TTC value for Cramer class III that is 1.5 µg/kg body weight per day.

A toxicological monograph addendum was not prepared.

RESIDUE AND ANALYTICAL ASPECTS

Triflumuron is a benzoylurea insecticide. The mode of action is insect growth regulation by inhibiting the synthesis of chitin in insect larvae that are about to moult and interfering with the moulting hormone system. The IUPAC name for triflumuron is 1-(2-chlorobenzoyl)-3-[4-trifluoromethoxyphenyl]urea.

The 2019 JMPR evaluated triflumuron as a new compound and concluded that the definition of the residue compliance with the MRL for animal and plant commodities was: *triflumuron*.

The residue is fat soluble.

However, the Meeting was unable to conclude on residue definitions for dietary exposure assessment for plant and animal commodities due to concerns over potential genotoxicity of two metabolites: M01 and M04.

The current Meeting received toxicological data for M01 and M04 and concluded that these compounds could be assessed using the threshold of the Cramer Class III of 1.5 µg/kg bw/day.

Definition of the residue

Plant commodities

The 2019 JMPR considered the plant metabolism studies on apple, tomato, soya bean and potato.

In deciding which compounds should be included in the residue definition for dietary risk assessment, the Meeting noted that no metabolites exceeded 10 percent TRR or 0.01 mg eq/kg in the metabolism studies on apples and tomatoes. In the metabolism study on soya bean, M02 and M07 exceeded 10 percent TRR and 0.01 mg eq/kg after acid hydrolysis of the unextracted residue. In the plant metabolism study on potatoes, M02 exceeded 10 percent TRR and 0.01 mg/kg after acid hydrolysis of the unextracted residue.

For M02, similar toxicity to parent triflumuron was assumed and the ADI for triflumuron (0–0.008 mg/kg bw) should apply. The 2019 JMPR concluded that M02 (free and conjugated) should be included in the residue definition.

For M07, the Meeting established a separate ADI of 0–0.02 mg/kg bw and ARfD of 0.02 mg/kg bw to be applicable. The Meeting concluded that M07 (free and conjugate) should be included in the residue definition. The 2019 JMPR also noted that increase of M07 and M08 during processing was not necessary to be considered.

In conclusion, the residue definition for plant commodities for dietary risk assessment should be sum of triflumuron and M02 (expressed as triflumuron), and M07 (assessed separately).

Animal commodities

The 2019 JMPR considered the animal metabolism studies on lactating goat and laying hen.

In deciding which compounds should be included in the residue definition for risk assessment, the Meeting noted that among the animal commodities tested, the residues that exceeded 10 percent TRR and 0.01 mg eq/kg were: in lactating goat, M03 and M04 (free and conjugated) in kidneys, and in laying hens, M02 in kidneys.

The 2019 JMPR concluded that it was not necessary to include M02 and M03 in the residue definition for animal products for dietary risk assessment. The current Meeting concluded that M04 could be assessed using the threshold of the Cramer Class III of 1.5 µg/kg bw/day. Therefore, the residue definition for animal commodities for dietary risk assessment should be triflumuron.

Conclusion

The Meeting concluded that residue definition for triflumuron should be as follows:

Definition of the residue for compliance with MRL for plant and animal commodities: *triflumuron*

Definition of the residue for dietary risk assessment for plant commodities: *sum of triflumuron and M02 (expressed as triflumuron), and M07 (assessed separately).*

Definition of the residue for dietary risk assessment for animal commodities: *triflumuron*

Results of supervised residue trials on crops

The 2019 Meeting noted that M02 (free and conjugated) and M07 (free and conjugated) were not analysed in the supervised trials and decided to estimate these concentrations using the following conversion factors derived from metabolism study:

- concentration of M02 (free and conjugate) in soya bean: 2.1 times (0.064 mg eq/kg/ 0.030 mg eq/kg) higher than parent triflumuron (expressed as triflumuron).
- concentration of M07 (free and conjugated) in soya bean: 2.5 times (0.10 mg eq/kg/ 0.040 mg eq/kg) higher than parent (expressed as triflumuron). Considering the ratio of molecular weight (191.2/358.7), the concentration of M07 expressed as the compound should be calculated as $\times 1.4$ of triflumuron.

Soya bean

The critical GAP for triflumuron on soya bean in Colombia is two applications at 0.077 kg ai/ha with a minimum interval between sprays of 15 days and a PHI of 21 days. In trials matching the Colombian GAP, residues of triflumuron in soya beans were (n=9): < 0.01 (3), 0.011, 0.014 (2), 0.048, 0.051 and 0.055 mg/kg.

The Meeting estimated a maximum residue level of 0.1 mg/kg.

The Meeting estimated STMR for triflumuron+M02 of 0.043 mg/kg ($(1+2.1) \times 0.014$) and for M07 of 0.020 mg/kg (1.4×0.014).

Residues in animal commodities

Animal commodity maximum residue levels

Cattle

The 2019 Meeting noted that no residues were detected in milk at 2× the dietary burden for dairy cattle or in tissues at the approximate dietary burden for beef cattle. The Meeting estimated maximum residue levels of 0.01(*) mg/kg for milks, 0.05(*) mg/kg for mammalian offal, 0.1(*) (fat) for meat, mammalian and 0.1(*) mg/kg for mammalian fat.

The current Meeting estimated STMRs of 0 mg/kg for milks, 0.05 mg/kg for mammalian offal, 0.1 mg/kg for meat, mammalian and 0.1 mg/kg for mammalian fat.

Poultry

Table 5.34.1 Maximum residue levels of triflumuron in poultry commodities

	Feed Level (ppm) for eggs residues	Triflumuron (mg /kg) in eggs	Feed Level (ppm) for tissue residues	Triflumuron (mg /kg)			
				Muscle	Liver	Kidney	Fat
HR Determination (broiler or laying hen)							
Metabolism Study	100	0.57	100	0.73	6.2	1.8	26
Dietary burden and estimate of highest residue	1.5	0.0085	1.5	0.011	0.093	0.027	0.39
Dietary burden and estimate of STMR residue	1.5	0.0085	1.5	0.011	0.093	0.027	0.39

The Meeting noted that no feeding study for laying hen was available. The Meeting considered the metabolism study where hens were administered triflumuron for 5 days at rates 67× the estimated dietary burdens. Noting the magnitude of the estimated residues and the large difference in the feeding

level used in the metabolism study compared to the dietary burden, the Meeting decided that the metabolism study could not be used to estimate maximum residue levels with confidence.

RECOMMENDATIONS

On the basis of the data from supervised trials the Meeting concluded that the residue levels listed in Annex 1 are suitable for establishing maximum residue limits and for IEDI and international estimate of short-term intakes assessment.

Definition of the residue for compliance with MRL for plant and animal commodities: *triflumuron*.

Definition of the residue for dietary risk assessment for plant commodities: *sum of triflumuron and 2-chlorobenzoic acid (M02), expressed as triflumuron and 4-trifluoromethoxyaniline (M07)* assessed separately.

Definition of the residue for dietary risk assessment for animal commodities: *triflumuron*.

The residue is fat-soluble.

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The ADIs for triflumuron (triflumuron+M02) and M07 are 0–0.008 and 0–0.02 mg/kg bw, respectively. The International Estimated Daily Intakes (IEDIs) were estimated for the 17 GEMS/Food Consumption Cluster Diets using the STMR or STMR-P values estimated by the current and earlier JMPR. The results are shown in Annex 3 of the 2022 JMPR Report.

The IEDIs ranged from 0–4 percent of the maximum ADI for sum of triflumuron and 2-chlorobenzoic acid (M02), and was 0 percent of the maximum ADI for 4-trifluoromethoxyaniline (M07).

The Meeting concluded that long-term dietary exposure to residues of triflumuron from uses considered by the JMPR is unlikely to present a public health concern.

Acute dietary exposure

The ARfD for triflumuron and 2-chlorobenzoic acid (M02) is not necessary.

The ARfD for 4-trifluoromethoxyaniline (M07) is 0.02 mg/kg bw. The International Estimated Short Term Intake (international estimate of short-term intake) for M07 was calculated. The results are shown in Annex 4 to the Report.

The international estimate of short-term intakes for M07 from the intake of the residue evaluated by the Meeting were 0–1 percent for general population and children of the ARfD (0.02 mg/kg bw).

The Meeting concluded that acute dietary exposure from the residues of triflumuron, from uses that have been considered by the JMPR, is unlikely to present a public health concern.

Threshold of toxicological concern (TTC) consideration for metabolites

The Meeting agreed metabolites 2-chlorobenzamide (M01) and 1-(2-chloro-3-hydroxybenzoyl)-3-[4-trifluoromethoxyphenyl]urea (M04) could be assessed using the TTC approach (Cramer Class III threshold of 1.5 µg/kg bw/d). The 2019 Meeting estimated maximum long-term exposures of 0.046 and 0.0041 µg/kg bw/d for M01 and M04, respectively. Both of the estimated exposures are below the threshold of toxicological concern for Cramer Class III compounds. The Meeting concluded that M01 and M04 were unlikely to present a dietary exposure concern from the uses.

Annex 1: Acceptable daily intakes, acute reference doses, recommended maximum residue levels, supervised trials median residue values and other values recorded by the 2022 JMPR Meeting.

	CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
Afidopyropen (312) ADI: 0–0.08 mg/kg bw ARfD: 0.2 mg/kg bw (women of childbearing age) ARfD: 0.3 mg/kg bw (Adults and children)	AL 1020	Alfalfa, fodder	8 (dw)	-	Median: 4.13 (ar)	Highest: 5.46 (ar)
	AL 1031	Clover, fodder	10 (dw)	-	Median: 3.5 (ar)	Highest: 8.55 (ar)
	AS 0162	Grass, hay	15 (dw)	-	Median: 6.32 (dw)	Highest: 14.9 (dw)
	MO 0096	Edible offal (mammalian)	0.3	0.3	liver: 0.25 Kidney: 0.13	liver: 0.45 kidney: 0.15
	PE 0112	Eggs	0.03	0.01*	0.138	0.149
	MF 0100	Mammalian fats (except milk fats)	0.01*	0.01*	0.13	0.15
	MM 0095	Meat (from mammals other than marine mammals)	0.01*	0.01*	muscle: 0.21 fat: 0.13	muscle: 0.34 fat: 0.15
	ML 0106	Milks	0.001*	0.001*	0.024	
	PO 0111	Poultry, edible offal of	0.02	0.01*	0.156 (liver)	0.22 (liver)
	PF 0111	Poultry, fats	0.015	0.01*	0.138	0.16
	PM 0110	Poultry, meat	0.01*	0.01*	0.13	0.134
	GC 0651	Sorghum	0.2	-	0.0365	
	AS 0651	Sorghum, stover	0.3 (dw)	-	Median: 0.0505 (ar)	Highest: 0.155 (ar)
		Strawberries	0.15	-	0.0539	0.0778
(ar)–as received Definition of the residue for compliance with the MRL for plant and animal commodities: <i>afidopyropen</i> Definition of the residue for dietary risk assessment for plant commodities: <i>sum of afidopyropen + dimer of [(3R,6R,6aR,12S,12bR)-3-[(cyclopropanecarbonyl)oxy]-6,12-dihydroxy-4,6a,12b-trimethyl-11-oxo-9-(pyridin-3-yl)-1,3,4,4a,5,6,6a,12,12a,12b-decahydro-2H,11H-naphtho[2,1-b]pyrano[3,4-e]pyran-4-yl]methyl rac-cyclopropanecarboxylate (M007)</i> Definition of the residue for dietary risk assessment for animal commodities, except liver: <i>afidopyropen + M001 + CPCA and its carnitine conjugate, expressed as afidopyropen</i> Definition of the residue for dietary risk assessment for liver: <i>afidopyropen + M001 + M017 + CPCA and its carnitine conjugate, expressed as afidopyropen</i> <i>The residue is not fat-soluble</i>						
Azoxystrobin (229) ADI: 0–0.2 mg/kg bw ARfD: Unnecessary	FI 0345	Mango	4 (Po)	0.7	0.035	
	FI 0350	Papaya	4 (Po)	0.3	0.1	
	VR 0596	Sugar beet	4 (Po)	--	1.35	
	VR 0075	Root and tuber vegetables, Group of (except potato)	W	1	0.23	
	VR 0075	Root and tuber vegetables, Group of (except potato and	1	--	0.23	

	CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
		sugar beet)				
	DM 0596	Sugar beet molasses	--	--	0.27	
	DM 3523	Sugar beet refined sugar	--	--	0.023	
<p>Definition of the residue for compliance with the MRL and for dietary risk assessment for plant and animal commodities: <i>azoxystrobin</i></p> <p>The residue is fat-soluble.</p>						
Benzovindiflupyr (261) ADI: 0–0.05 mg/kg bw ARfD: 0.1 mg/kg bw	FB 0020	Blueberries	2		0.65	0.98
	DV 0604	Ginseng, dried including red ginseng	0.3		0.081	0.16
	DT 0604	Ginseng, dried	0.3		0.081	0.16
	AS 3358	Maize stover	7 (dw)		Median 1.6 (ar)	Highest 2.9 (ar)
	AS 0656	Popcorn stover	7 (dw)		Median 1.6 (ar)	Highest 2.9 (ar)
	GC 0645	Maize	0.02		0.01	
	GC 0656	Popcorn	0.02		0.01	
	CF 1255	Maize flour			0.0025	
		Maize grits			0.0025	
	OR 0645	Maize oil, edible			0.0050	
		Maize starch			0.0025	
	CF 3517	Maize gluten			0.0075	
	Maize bran, unprocessed			0.0050		
<p>(ar)—as received; (dw)—dry weight</p> <p>Definition of the residue for compliance with the MRL and dietary risk assessment for plant and animal commodities: <i>benzovindiflupyr</i></p> <p>The residue is fat-soluble.</p>						
Benzpyrimoxan (325)* ADI: 0–0.1 mg/kg bw ARfD: Unnecessary						
<p>Definition of the residue for compliance with the MRL for plant commodities: <i>Benzpyrimoxan</i></p> <p>Definition of the residue for dietary risk assessment for plant commodities: <i>Sum of benzpyrimoxan and benzpyrimoxan-2-OH, expressed as benzpyrimoxan</i></p> <p>Definition of the residue for compliance with the MRL and dietary risk assessment for animal commodities: <i>Sum of benzpyrimoxan, benzpyrimoxan-acid and benzpyrimoxan-acid-2-OH, expressed as benzpyrimoxan</i></p> <p>The residue is not fat-soluble.</p>						
Bifenthrin (178) ADI: 0–0.01 mg/kg bw ARfD: 0.01 mg/kg bw	FI 0326	Avocado	0.5		0.089	0.23
	FP 0009	Group of Pome fruits (except persimmon, Japanese)#	0.7#		0.195	0.45
	SO 0697	Peanut	0.05*		0.05	
	HS 0444	Pepper, chilli, dry	4	5	0.98	2.2
	FI 0355	Pomegranate	0.5		0.165	0.22
	VO 20046	Eggplant, Subgroup of	0.4		0.12	0.31
	FS 2001	Peaches, Subgroup of #	0.8#		0.22	0.49

	CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
	VO 0051	Peppers, Subgroup of (except okra, martynia and roselle)	0.4	0.5	0.12	0.31
	JF 0226	Apple juice			0.0096	
	OR 0697	Peanut oil, edible			0.05	
# On the basis of information provided to the JMPR it was concluded that the estimated acute dietary exposure to residues of bifenthrin for the consumption of Peaches, Subgroup of and Pome fruit, Group of (except Japanese persimmon) may present a public health concern						
Definition of the residue for compliance with the MRL and for dietary risk assessment for animal and plant commodities is <i>bifenthrin</i> (sum of isomers).						
The residue is fat-soluble.						
Broflanilide (326)* ADI: 0–0.02 mg/kg bw ARfD: Unnecessary	VB 0041	Cabbages, Head	2	-	0.19	
	VB 0467	Chinese cabbage, (type Pe-tsai)	2	-	0.19	
	SB 0716	Coffee bean, green	0.01	-	0.0023	-
	MO 0105	Edible offal (mammalian)	0.03	-	0.02	-
	PE 0112	Eggs	0.03	-	0.02	-
	GC 0080	Cereal grains, Group of (except rice)	0.001*	-	0 (cereal grains) 0.001 (sweet corns)	-
	AS 3569	Maize, bran	0.002	-	0	-
	CF 1255	Maize, flour	0.002	-	0	-
	MF 0100	Mammalian fats	0.15	-	0.033	-
	MM 0095	Meat (from mammals other than marine mammals)	0.15 (fat)	-	0.02 (muscle) 0.033 (fat)	-
	FM 0183	Milk fats	0.4	-	0.08	-
	ML 0106	Milks	0.015	-	0.004	-
	VR 0591	Radish, Japanese	0.01*	-	0.01	-
	PO 0111	Poultry edible offal	0.03	-	0.02	-
	PM 0110	Poultry meat	0.02*	-	0.02 (muscle) 0.034 (fat)	-
	PF 0111	Poultry fats	0.15	-	0.034	-
	VR 2071	Subgroup of tuberous and corm vegetables	0.04	-	0.00175	
	AS 3304	Subgroup of cereal grains (including pseudocereals) feed products with low water (<20 percent) content (hay, straw), except rice feed products	0.01 (dw)	-	Median 0.001 (ar)	Highest 0.0016 (ar)
	CF 1210	Wheat, germ	0.002	-	0	-
		Coffee bean, instant coffee	-	-	0.0002	
	SM 0716	Coffee bean, roasted	-	-	0.0019	

	CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
	OR 0645	Maize oil, edible	-	-	0	
		Maize starch	-	-	0	
		Maize germ	-	-	0	
		Potato, starch	-	-	0.0005	
	CF 1211	Wheat, flour	-	-	0	
	CF 3522	Wheat, gluten meal	-	-	0	
		Wheat starch	-	-	0	
	CP 1212	Wheat, wholemeal bread	-	-	0	
<p>(ar)–as received; (dw)–dry weight</p> <p>Definition of the residue for compliance with the MRL and dietary risk assessment for plant commodities: <i>Broflanilide</i></p> <p>Definition of the residue for compliance with the MRL and dietary risk assessment for animal commodities: <i>Sum of broflanilide plus 3-benzamido-N-[2-bromo-4-(perfluoropropan-2-yl)-6-(trifluoromethyl)phenyl]-2-fluorobenzamide (DM-8007), expressed as broflanilide</i></p> <p><i>The residue is fat-soluble</i></p>						
Chlorantraniliprole (230) ADI: 0–2 mg/kg bw ARfD: Unnecessary	FI0326	Avocado	0.3		0.083	
	DT1114	Tea, green, black (black, fermented and dried)	80		24.5	
		Tea infusion			0.20	
<p>Definition of the residue for compliance with the MRL and for dietary risk assessment for plant and animal commodities: <i>chlorantraniliprole</i>.</p> <p><i>The residue is fat-soluble.</i></p>						
Chloromequat (015) ADI: 0–0.05 mg/kg bw ARfD: 0.05 mg/kg bw	GC 0640	Barley	2	2	0.37	-
	AS 0640	Barley, hay and/or straw	200 (dw)		Median: 34.5 (hay) 8.25 (straw) (ar)	Highest: 73 (hay) 32 (straw) (ar)
		Barley, straw and fodder, dry	W	50 (dw)		
	MO 0105	Edible offal (mammalian)	0.5	1	0.036 (liver) 0.20 (kidney)	0.11 (liver) 0.40 (kidney)
	PE 0269	Eggs	0.2	0.1	0.049	0.094
	MF 0100	Mammalian fats (except milk fats)	0.1	0.1	0.04	0.043
	MM 0095	Meat (from mammals other than marine mammals)	0.2	0.2	0.04 (muscle) 0.04 (fat)	0.085 (muscle) 0.043 (fat)
	ML 0095	Milks	0.2	0.3	0.069	-
	PF 0111	Poultry fats	0.04*	0.04*	0.04	0.04
	PM 0111	Poultry meat	0.04*	0.04*	0.04 (muscle, fat)	0.04 (muscle, fat)
	PO 0111	Poultry, edible offal of	0.2	0.1	0.043	0.085
	GC 0654	Wheat	4	2	0.855	-

	CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
	CM 0654	Wheat bran, unprocessed	10	7	2.3	-
	AS 0654	Wheat, hay and/or straw	200 (dw)	80 (dw)	Median: 42.5 (hay) 20.5 (straw) (ar)	Highest: 117 (hay) 55 (straw) (ar)
	CF 1210	Wheat germ	20	-	4.3	
	CF 1211	Wheat, flour			0.16	
	CF 1212	Wheat wholemeal			0.855	
		Wheat wholemeal bread			0.46	
	CF 0640	Barley bran, processed			0.34	
	CM 0640	Barley, pearled (pot barley)			0.12	
	CF 3511	Barley, flour			0.066	
		Barley malt			0.33	
		Barley beer			0.074	
<p>(ar)–as received; (dw)–dry weight</p> <p>Definition of the residue (for compliance with the MRL and dietary risk assessment) in plant and animal commodities: <i>chlormequat cation</i>.</p> <p>The residue is not fat soluble.</p>						
Diazinon** ADI: 0–0.005 mg/kg bw ARfD: 0.03 mg/kg bw	AM 0660	Almond hulls	W	5		
	TN 0660	Almonds	W	0.05		
	FB 0264	Blackberries	W	0.1		
	FB 4079	Boysenberry	W	0.1		
	VB 0400	Broccoli	W	0.5		
	VB 0041	Cabbage, head	W	0.5		
	VC 4199	Cantaloupe	W	0.2		
	VR 0577	Carrot	W	0.5		
	FS 0013	Cherries	W	1		
	PE 0840	Chicken eggs	W	0.02*		
	PM 0840	Chicken meat	W	0.02*		
	PO 0840	Chicken, edible offal of	W	0.02*		
	VL 0467	Chinese cabbage	W	0.05		
	VP 0526	Common bean Pods and/or immature seeds)	W	0.2		
	FB 0265	Cranberry	W	0.2		
	VC 0424	Cucumber	W	0.1		
	FB 0021	Currants, black, red and white	W	0.2		
	VP 0529	Garden pea, shelled (succulent seed)	W	0.2		
	MM 0814	Goat meat	W	2 (fat)†		
	DH 1100	Hops, dry	W	0.5		
VL 0480	Kale (including collards, curly, scotch and thousand-headed kale; not including marrow-stem	W	0.05			

	CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
		kele)				
	MO 0098	Kidney of cattle, goats, pigs and sheep	W	0.03†		
	FI 0341	Kiwifruit	W	0.2		
	VB 0405	Kohlrabi	W	0.2		
	VL 0482	Lettuce, head	W	0.5		
	VL 0483	Lettuce, leaf	W	0.5		
	MO 0099	Liver of cattle, goat, pigs and sheep	W	0.03†		
	GC 0646	Maize	W	0.02*		
	MM 0097	Meat of cattle, pigs and sheep	W	2 (fat)†		
	ML 0106	Milks	W	0.02		
	VA 0385	Onion, bulb	W	0.05		
	FS 0247	Peach	W	0.2		
	HS 0444	Peppers chili, dried	W	0.5		
	VO 0445	Peppers, sweet	W	0.05		
	FI 0353	Pineapple	W	0.1		
	FS 0014	Plums	W	1		
	FP 0009	Pome fruits	W	0.3		
	VR 0589	Potato	W	0.01*		
	DF 0014	Prunes, dried	W	2		
	VR 0494	Radish	W	0.1		
	FB 0272	Raspberries, red, black	W	0.2		
	HS 0191	Spices, fruit and berries	W	0.1*		
	HS 0193	Spices, roots and rhizomes	W	0.5		
	HS 0190	Spices, seeds	W	5		
	VL 0502	Spinach	W	0.5		
	VA 0389	Spring onion	W	1		
	VC 0431	Squash, summer	W	0.05		
	FB 0275	Strawberry	W	0.1		
	VR 0596	Sugar beet	W	0.1		
	VO 0447	Sweet corn (corn on the cob)	W	0.02		
	VO 0448	Tomato	W	0.5		
	TN 0578	Walnuts	W	0.01*		
<p>† The Codex MRL accommodated external animal treatment</p> <p>The definition of the residue for compliance with the MRL for plant commodities: <i>diazinon</i>.</p> <p>The Meeting was unable to conclude on a residue definition for dietary risk assessment for plant commodities.</p> <p>The Meeting was unable to conclude on a residue definition for compliance with the MRL and for dietary risk assessment for animal commodities.</p>						
Difenoconazole (224) ADI: 0–0.01 mg/kg bw ARfD: 0.3 mg/kg bw	VO 2704	Goji berry	5	-	0.65	2.4
	DV 2704	Goji berry, dried	15	-	1.6	5.5
	VO 0050	Group of fruiting vegetables other than cucurbits (except	W	0.6	0.14	0.39

	CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
		peppers, chili)				
	VO 0050	Group of fruiting vegetables other than cucurbits (except goji berry and pepper, chili)	0.6	-	0.14	0.39
	VR 2950	Pencil yam	0.02	-	0.01	0.01
		Pencil yam, dried	0.07	-	0.029	0.029
	HS 0784	Ginger, rhizome	0.2	-	0.022	0.1
	DV 0784	Ginger rhizome, dried	1.5	-	0.13	-
	DT 1114	Tea, green, black (black, fermented and dried)	20	20	4.86	
<p>Definition of the residue for compliance with the MRL and for dietary risk assessment for plant commodities: <i>difenoconazole</i>.</p> <p>Definition of the residue for compliance with the MRL and for dietary risk assessment for animal commodities: <i>sum of difenoconazole and 1-[2-chloro-4-(4-chloro-phenoxy)-phenyl]-2-(1,2,4-triazol)-1-yl-ethanol</i>, expressed as <i>difenoconazole</i>.</p> <p>The residue is fat-soluble.</p>						

	CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR _{chronic} or STMR-P _{chronic} mg/kg	STMR _{acute} or STMR-P _{acute} mg/kg	HR or HR-P mg/kg
			New	Previous			
Dimethoate (027)/ Omethoate (055) ADI: 0–0.001 mg/kg bw ARfD: 0.02 mg/kg bw	FC 0003	Mandarins, Subgroup of	2		0.081	0.16	0.19
	FC 0004	Oranges, Subgroup of ^a	2		0.31	0.32	0.4
	FI 0236	Avocado	2		0.11	0.37	0.49
	VB 0402	Brussels sprouts	0.1		0.086	0.23	0.25
	VO 0448	Tomato	0.01(*)		0.0175	0.055	0.055
	VP 0544	Yard-long bean (pods)	0.07		0.175	0.55	0.55
	VD 2065	Dry beans, Subgroup of (except soya bean)	0.7		0.175	0.38	
	SO 0495	Rape seed	0.15		0.0775	0.23	
	GC 0654	Wheat	0.06		0.011	0.032	
	CF 0654	Wheat bran, processed	0.3		0.041	0.11	
	CF 1210	Wheat germ	0.2		0.025	0.065	
	MO 0105	Edible offal (Mammalian)	0.001(*)		0 (liver) 0 (kidney)		0 (liver) 0 (kidney)
	MF 0100	Mammalian fats (except milk fats)	0.03		0.003		0.027
	MM 0095	Meat (from mammals other than marine mammals)	0.001(*)		0 (muscle) 0 (fat)		0 (muscle) 0 (fat)
	ML 0106	Milks	0.001(*)		0.0025	0.01	
	PE 0112	Eggs	0.001(*)		0		0
PF 0111	Poultry fats	0.001(*)		0		0	
PM 0110	Poultry meat	0.001(*)		0		0	
PO 0111	Poultry, Edible offal of	0.001(*)		0		0	

	CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR _{chronic} or STMR-P _{chronic} mg/kg	STMR _{acute} or STMR-P _{acute} mg/kg	HR or HR-P mg/kg
			New	Previous			
	AS 0654	Wheat, hay and/or straw	4 dw		Median: 0.06 (dw)		Highest: 2.7 (dw)
	AB 0001	Citrus pulp, dry [FEED]	5		1.36		
	JF 0004	Orange juice			0.088	0.093	
	OR 0004	Orange oil, edible			0.12	0.13	
		Orange molasses			3.6	3.8	
		Wheat Wholemeal flour			0.006	0.016	
		Wheat White flour			0.0042	0.14	
STMR(-P) _{chronic}	Expressed as toxic equivalent residues (dimethoate + 2.5×omethoate)						
STMR(-P) _{acute}	Expressed as toxic equivalent residues (dimethoate + 10×omethoate)						
HR	Expressed as toxic equivalent residues (dimethoate + 10×omethoate)						
Median	median total residue (sum of dimethoate and omethoate) for livestock dietary burden estimation						
<p>^a On the basis of the information provided to the JMPR it was concluded that the estimated acute dietary exposure to residues of dimethoate and omethoate for the consumption of commodities in the subgroup of oranges may present a public health concern</p> <p>Dimethoate (see also omethoate)</p> <p>Definition of the residue for compliance with the MRL for plant and animal commodities: <i>Dimethoate and omethoate (measured and reported separately)</i></p> <p>Definition of the residue for dietary risk assessment for plant and animal commodities: Sum of dimethoate plus 2.5× omethoate for long-term dietary exposure and the sum of dimethoate plus 10× omethoate for acute dietary exposure.</p> <p>The residue is not fat-soluble.</p>							

	CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
Omethoate (055) ADI: 0–0.0004 mg/kg bw ARfD: 0.002 mg/kg bw	FC 0003	Mandarins, Subgroup of	0.02			
	FC 0004	Oranges, Subgroup of ^a	0.02			
	FI 0236	Avocado	0.15			
	VB 0402	Brussels sprouts	0.03			
	VO 0448	Tomato	0.01			
	VP 0544	Yard-long bean (pods)	0.05			
	VD 2065	Dry beans, Subgroup of (except soya bean)	0.08			
	SO 0495	Rape seed	0.03			
	GC 0654	Wheat	0.03			
	CF 0654	Wheat bran, processed	0.105			
	CF 1210	Wheat germ	0.06			
	AS 0654	Wheat hay and/or straw	0.3 dw			
	AB 0001	Citrus pulp, dry	0.032			

	CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
	MO 0105	Edible offal (Mammalian)	0.005			
	MF 0100	Mammalian fats (except milk fats)	0.003			
	MM 0095	Meat (from mammals other than marine mammals)	0.005			
	ML 0106	Milks	0.0015			
	PE 0112	Eggs	0.001(*)			
	PF 0111	Poultry fats	0.001(*)			
	PM 0110	Poultry meat	0.001(*)			
	PO 0111	Poultry, Edible offal of	0.001(*)			
<p>^a On the basis of the information provided to the JMPR it was concluded that the estimated acute dietary exposure to residues of dimethoate and omethoate for the consumption of commodities in the subgroup of oranges may present a public health concern</p> <p>Omethoate (from the use of dimethoate)</p>						
Emamectin benzoate (247) ADI: 0–0.0005 mg/kg bw ARfD: 0.02 mg/kg bw	HH 0722	Basil, leaves	0.06	-	0.0045	0.032
	DH 0722	Basil leaves, dry	0.4	-	0.029	0.205
	VL 0054	Brassica leafy vegetables, subgroup of	0.2	-	0.01	0.219
	VA 2605	Chives	0.01	-	0.001	0.006
	DH 2605	Chive, dried	0.05	-	0.005	0.025
	VB 0042	Flowerhead Brassicas, subgroup of	0.007	-	0.002	0.004
	MF 0100	Mammalian fats (except milk fats)	0.02	0.02	0.002	0.012
	MM 0095	Meat (from mammals other than marine mammals)	0.005	0.004	0.002	0.0046
	ML 0106	Milks	0.003	0.002	0.0005	-
	MO 0105	Edible offal (mammalian)	0.1	0.08	0.0071	0.088
	VL 0502	Spinach	0.05	-	0.006	0.036
	VD 0541	Soya bean (dry)	0.001*	-	0	
	DT 1114	Tea, Black, Green, dried and fermented	0.1	-	0.009	
		Tea infusion	-	-	0.000018	
Definition of the residue for compliance with the MRL and for dietary risk assessment for plant and animal commodities: <i>emamectin B1a benzoate</i> . <i>The residue is not fat soluble.</i>						
Famoxadone (208) ADI: 0–0.006 mg/kg bw ARfD: 0.6 mg/kg bw	VC 0424	Cucumber	W	0.2		
	MU 1100	Hops, dried	50	--	13	
	HS 0444	Peppers chili, dried	50		4.7	37
	VO 0444	Peppers, chili	5	--	0.47	3.7
	VO 0445	Peppers, sweet (including pimento or pimienta)	5	--	0.47	3.7
	VC 0431	Squash, Summer	W	0.2		
	VA 2031	Subgroup of bulb onions	0.4	--	0.02	0.23
	FB 2005	Subgroup of cane berries	10	--	1.1	6.6

	CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
	VC 2039	Subgroup of fruiting vegetables, cucurbits–cucumbers and summer squashes	0.6	--	0.17	0.37
	VO 0448	Tomato	2	2	0.1	1.1
Definition of the residue for compliance with the MRL and dietary risk assessment for plant and animal commodities: <i>famoxadone</i> . <i>The residue is fat-soluble.</i>						
Fenazaquin (297)	FC 0002	Lemons and Limes (incl. Citron), Subgroup of	0.3		0.01 (Kumquat 0.08)	0.01 (Kumquat 0.12)
ADI: 0–0.05 mg/kg bw	FC 0004	Oranges, Sweet, Sour (incl. Orange-like hybrids), Subgroup of	0.4		0.01	0.01
ARfD: 0.1 mg/kg bw	FC 0005	Pummelo and Grapefruits (incl. Shaddock-like hybrids, among others Grapefruit), Subgroup of	0.3		0.01	0.01
	FC 0003	Mandarins (incl. Mandarin-like hybrids), Subgroup of	0.3		0.01	0.01
	OR 0001	Citrus oil, edible	40		9.84	
	FP 0226	Apples	0.3		0.08	0.18
	FS 0014	Plums, Subgroup of	0.5		0.145	0.25
	DF 0014	Prune, dried	3		0.7	1.2
	FS 2001	Peaches (incl. Nectarine and Apricots), Subgroup of	1.5		0.38	1.2
	FB 2005	Cane berries, Subgroup of	0.7		0.18	0.41
	FB 2006	Bush berries, Subgroup of	0.8		0.235	0.42
	FB 2008	Small fruit vine climbing, Subgroup of	0.7		0.19	0.4
	DF 0269	Dried grapes (=Currants, Raisins and Sultanas)	1.5		0.42	0.88
	FB 2009	Low growing berries, Subgroup of	2		0.49	1.2
	FI 0326	Avocado	0.15		0.01	0.01
	VC 0045	Fruiting vegetables, Cucurbits, Group of	0.3		0.06	0.19
	VO 2045	Tomatoes, Subgroup of	0.3		0.052	0.19
	VO 0051	Peppers, Subgroup of (except martynia, okra and roselle)	0.3		0.079	0.22
	HS 0444	Peppers Chili, dried	3		0.79	2.2
	VO 2046	Eggplants, Subgroup of	0.3		0.079	0.22
	MO 0105	Edible offal (Mammalian)	0.02 (*)		0.00056 (liver)	0.0065 (liver)
	MF 0100	Mammalian fats (except milk fats)	0.02 (*)		0.00065	0.00081
	MM 0095	Meat (from mammals other than marine mammals)	0.02 (†) (fat)		0	0
	ML 0106	Milks	0.02 (†) (fat)		0	
	FM 0183	Milk fats	0.02 (†) (fat)		0	

	CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
		Grape wine (red)			0.0038	
	JF 0269	Grape juice			0.027	
	JF 0204	Lemon juice			0.0008	0.01
	JF 0004	Orange juice			0.00125	
	JF 0203	Grapefruit juice			0.0007	
	FCT7003	Mandarin juice			0.0008	
	DM 0448	Tomato paste			0.047	
	DM 0448	Tomato puree			0.021	
<p>Definition of the residue for compliance with the MRL and for dietary risk assessment for plant commodities: <i>Fenazaquin</i>.</p> <p>Definition of the residue for compliance with the MRL for animal commodities: <i>Sum of fenazaquin and 2-hydroxy-fenazaquin acid, expressed as fenazaquin equivalents</i>.</p> <p>Definition of the residue for dietary risk assessment for animal commodities: <i>Sum of fenazaquin, and 2-hydroxy-fenazaquin acid and tautomeric forms of 4-hydroxyquinazoline, expressed as fenazaquin equivalents</i>.</p> <p><i>The residue is fat-soluble</i></p>						
Fluazaindolizine (327)* ADI: 0–0.3 mg/kg bw ARfD: 1 mg/kg bw	VB 0040	Brassica vegetables (except Brassica leafy vegetables), Group of	0.02		0.04335	0.0705
	VA 2605	Bulb vegetables	0.04		0.0674	0.8281
	VR 0577	Carrot	0.4		0.1485	1.973
	GC 0080	Cereal grains, Group of	0.03		0.0676	
	AS 0081	Cereal grains (including pseudocereals) feed products with low water (<20 percent) content (hay and/or straw)	0.09 (dw)		Median: 0.073 (ar)	Highest: 0.0553 (ar)
	VC 2039	Cucumbers and summer squashes, Subgroup of	0.15		0.1092	0.3674
	MO 0105	Edible offal (Mammalian)	0.01		0.1657 (kidney)	0.7592 (kidney)
	VO 2046	Eggplant, Subgroup of	0.15		0.0748	0.963
	PE0112	Eggs	0.01*		0.0006	0.00263
	VL 0053	Leafy vegetables (including Brassica leafy vegetables), Group of	0.04		0.3880	1.388
	VP 0060	Legume vegetables, Group of [immature seeds with pods]	0.04		0.0709	0.1589
	MF 0100	Mammalian fats (except milk fats)	0.01*		0.0092	0.0431
		Maize flour			0.0366	
		Maize grits			0.0144	
		Maize refined oil			0	
		Maize starch			0	
	MM 0095	Meat (from mammals other than marine mammals)	0.01*		0.0089 muscle 0.0092 fat	0.0415 muscle 0.0431 fat
VC 2040	Melons, pumpkins and winter squashes, Subgroup of	0.1		0.1348	0.3937	

	CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
	ML 0106	Milks	0.01*		0.0029	
	FM 0183	Milk fats	0.01*		0.0033	
	SO 0088	Oilseeds and oilfruits, Group of	0.04		0.0656	
	HS 0444	Peppers, Chili, dried	0.3		0.74	3.102
	VO 0051	Peppers, Subgroup of (except martynia, okra, roselle)	0.03		0.074	0.3102
		Potatoes, baked microwaved unpeeled			0.1661	1.3600
		Potatoes, boiled unpeeled			0.0560	0.6538
		Potatoes, boiled peeled			0.0343	0.3695
		Potato, crisps			0.0673	0.6757
		Potato, dried flakes			0.0956	1.0275
		Potato, french fries peeled			0.0319	0.3213
		Potato, french fries unpeeled			0.1215	1.0607
	PO0111	Poultry, Edible offal of	0.02		0.024 (liver)	0.1182 (liver)
	VD 0070	Pulses, Group of	0.09		0.0656	
	PF0111	Poultry fats	0.01*		0.00063	0.0032
	PM 0110	Poultry meat	0.01*		0.0014 muscle 0.00063 fat	0.0071 muscle 0.0032 fat
	AM 3538	Rape seed, hay, and/or straw	0.05 (dw)			
	VR 2070	Root vegetables [except carrot]	0.04		0.1935	0.9322
	VS 0078	Stalk and stem vegetables	0.04		0.0674	0.8281
		Soya bean refined oil			0	
	FB 0275	Strawberries	0.015		0.0530	0.1416
		Strawberry juice			0.0142	
		Strawberry canned			0.0081	0.0419
		Strawberry jam			0.0040	0.0210
		Strawberry dehydrated fruit			0.0830	0.4297
		Strawberry frozen			0.0121	0.0629
	AL 3301	Subgroup of Products of legume feeds with low water (<20 percent) content (hay)	0.17 (dw)		Median: 0.0274 (ar)	Highest: 0.0848 (ar)
	VO 2045	Tomato, Subgroup of	0.15		0.0748	0.963
		Tomato canned			0.0711	0.9389
	DV 04489	Tomato dried	0.5		0.4624	6.6960
		Tomato juice			0.0590	
		Tomato paste			0.2476	3.5309
		Tomato purée			0.1268	1.8056
	VR 2071	Tuberous and corm vegetables, Subgroup of	0.2		0.1231	0.7356
		Wheat bran (unprocessed)			0	
		Wheat flour			0	
		Wheat germ			0	

	CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
<p>Definition of the residue for compliance with the MRL for plant and animal commodities: <i>fluazaindolizine</i>.</p> <p>Definition of the residue for dietary risk assessment for plant commodities:</p> <p>fluazaindolizine, and free and conjugated forms of the following compounds: 2-chloro-5-hydroxybenzenesulfonamide (IN-A5760), 2-chloro-5-methoxybenzenesulfonamide (IN-F4106), 8-chloro-6-(trifluoromethyl)imidazo[1,2-a]pyridine-2-carboxylic acid (IN-QEK31), 3-[[[(2-chloro-5-methoxyphenyl)sulfonyl]amino]-L-alanine (IN-QZY47), 8-chloro-N-[(2-chloro-5-hydroxyphenyl)sulfonyl]-6-(trifluoromethyl)imidazo[1,2-a]pyridine-2-carboxamide (IN-REG72), 8-chloro-6-(trifluoromethyl)imidazo[1,2-a]pyridine-2-carboxamide (IN-RYC33) and 3-[[[(2-chloro-5-methoxyphenyl)sulfonyl]amino]-(2R)-hydroxypropanoic acid (IN-TMQ01) (expressed as fluazaindolizine). <i>This can be implemented by taking the maximum of the sum of compounds containing the imidazopyridine ring and hydrolysed using acid to IN-A5760, IN-F4106, IN-QZY47 and IN-TMQ01 (expressed as fluazaindolizine) OR compounds containing the phenyl ring and hydrolysed to 8-chloro-6-(trifluoromethyl)imidazo[1,2-a]pyridine-2-carboxylic acid (IN-QEK31) (expressed as fluazaindolizine).</i></p> <p>Definition of the residue for dietary risk assessment for animal commodities: the sum of fluazaindolizine, 2-chloro-5-hydroxybenzenesulfonamide (IN-A5760), 2-chloro-5-methoxybenzenesulfonamide (IN-F4106), and 3-[[[(2-chloro-5-methoxyphenyl)sulfonyl]amino]-(2R)-hydroxypropanoic acid (IN-TMQ01) (expressed as fluazaindolizine).</p> <p><i>The residue is not fat-soluble</i></p>						
Fludioxonil (211) ADI: 0–0.4 mg/kg bw ARfD: Unnecessary	AM 0660	Almond hulls	20		1.8	
	OR 0660	Almond oil	0.3		0.015	
	FI 0327	Banana	2 (Po)		0.013	
	VD 0071	Beans (dry)	W	0.5		
	VP 0061	Beans (<i>Phaseolus</i> spp.) immature pods and succulent seeds	W	0.6		
	VP 2060	Beans with pods, Subgroup of (except soya beans (succulent seeds in pods))	0.8		0.055	
	VD 0524	Chick-pea (dry)	W	0.3		
	VD 2065	Dry beans, Subgroup of (except soya beans)	0.3		0.029	
	VD 2066	Dry peas, Subgroup of	0.3		0.11	
	MO 0105	Edible offal (mammalian)	0.15	0.1	0.037	
	VD 0533	Lentil (dry)	W	0.3		
	FI 0345	Mango	7 (Po)	2	0.04	
	MF 0100	Mammalian fats (except milk fats)	0.02	0.02	0.006	
	MM 0095	Meat (from mammals other than marine mammals)	0.02	0.02	fat 0.006 muscle 0.006	
	ML 0106	Milks	0.07	0.04	0.016	
	FI 0350	Papaya	5 (Po)		0.15	
	VD 0072	Peas (dry)	W	0.07		
	VP 0063	Peas (pods and succulent=immature seeds)	W	0.3		
	VP 2061	Peas with pods, Subgroup of	0.8		0.055	
	VP 4453	Snap beans (young pods)	W	0.6		
VR 0596	Sugar beet	4 (Po)		1.1		
TN 0085	Tree nuts (except Canarium nut, Chilean hazelnut, and pistachios)	0.3		0.01		
		Almonds, roasted			0.008	

	CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
	DM 0596	Sugar beet molasses			0.62	
	DM 3523	Sugar beet, sugar refined			0.11	
<p>Definition of the residue for compliance with the MRL and for dietary risk assessment for plant commodities: <i>fludioxonil</i>.</p> <p>Definition of the residue for compliance with the MRL and for dietary risk assessment for animal commodities: <i>sum of fludioxonil and its benzopyrrole metabolites, determined as 2,2-difluoro-benzo[1,3]dioxole-4-carboxylic acid and expressed as fludioxonil</i>.</p> <p>The residue is fat-soluble.</p>						
Fluindapyr (328)* ADI: 0–0.04 mg/kg bw ARfD: 0.6 mg/kg bw	AM 0660	Almond hulls	20 (dw)		Median: 3.4	-
	GC 2091	Maize cereals, Subgroup of	0.01*		0.02	0.02
	AS 3558	Maize, stover	5 (dw)		Median: 0.95 (ar)	Highest: 3.0 (ar)
	GC 2089	Sorghum Grain and Millet, Subgroup of	1		0.395	-
	AS 3561	Sorghum, stover	3 (dw)		Median: 0.395	Highest: 2.4
	GC 0447	Sweet corn (corn-on-the cob) (kernels plus cob with husk removed)	0.01*		0.02	0.02
	AS 3563	Sweet corn, stover	30 (dw)		0.855	13 (ar)
	TN 0085	Tree nuts, Group of	0.04		0.0205	
	GC 2086	Wheat, similar grains, and pseudo cereals without husks, Subgroup of	0.4		0.074	-
	AS 0654	Wheat, hay and/or straw	15 (dw)	-	Median: hay: 1.9 (ar) straw: 1.8 (ar)	Median: hay: 7.1 (ar) straw: 13 (ar)
	CF 1255	Maize, flour	-	-	0.02	
	-	Maize, grits	-	-	0.02	
	CF 0645	Maize, meal	-	-	0.02	
	-	Maize, starch	-	-	0.02	
	OR 0645	Maize, refined deodorized oil	-		0.036	
	CF 3520	Sorghum, Grain, flour	-	-	0.17	
	CF 0654	Wheat, bran, processed	-	-	0.92	
	CF 3522	Wheat, gluten meal	-	-	0.034	
	CF 1210	Wheat, germ	-	-	0.031	
	CF 1212	Wheat, whole meal	-	-	0.063	
	CF 1211	Wheat, flour	-	-	0.026	
-	Wheat, wholemeal bread	-	-	0.037		
<p>(ar)–as received; (dw)–dry weight</p> <p>Definition of the residue for compliance with the MRL assessment for plant commodities: <i>fluindapyr</i></p>						

	CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
<p>Definition of the residue for compliance with the MRL assessment for animal commodities: <i>fluindapyr</i></p> <p>Definition of the residue for dietary risk assessment for plant commodities: <i>sum of fluindapyr and 3-(difluoromethyl)-N-[7-fluoro-1-(hydroxymethyl)-1,3-dimethyl-2,3-dihydro-1H-inden-4-yl]-1-methyl-1H-pyrazole-4-carboxamide (1-OH-Met-fluindapyr) and its conjugates, expressed as parent</i></p> <p>Definition of the residue for dietary risk assessment for animal commodities: <i>sum of fluindapyr, 4-(3-(difluoromethyl)-1-methyl-1H-pyrazole-4-carboxamido)-7-fluoro-1,3-dimethyl-2,3-dihydro-1H-indene-1-carboxylic acid (1-COOH-fluindapyr), 3-(difluoromethyl)-N-[7-fluoro-1-(hydroxymethyl)-1,3-dimethyl-2,3-dihydro-1H-inden-4-yl]-1-methyl-1H-pyrazole-4-carboxamide (1-OH-Met-fluindapyr), 3-(difluoromethyl)-N-[7-fluoro-1-(hydroxymethyl)-1,3-dimethyl-2,3-dihydro-1H-inden-4-yl]-1H-pyrazole-4-carboxamide (1-OH-Met-N-DesMet-fluindapyr) and their conjugates, and 3-(difluoromethyl)-N-(7-fluoro-1,1,3-trimethyl-2,3-dihydro-1H-inden-4-yl)-1H-pyrazole-4-carboxamide (N-DesMet-fluindapyr), , expressed as fluindapyr.</i></p> <p><i>The residue is fat-soluble.</i></p>						
Flupyradifurone (285) ADI: 0–0.08 mg/kg bw ARfD: 0.2 mg/kg bw	FI 0353	Pineapple	0.3		0.13	0.19
	SO 2091	Sunflower seeds (subgroup)	0.8		0.31	
	SO 0700	Sesame seed	3		1	
	OC 7000	Sesame seed oil (crude)			0.13	
	JF 0341	Pineapple juice			0.044	
<p>Definition of the residue for compliance with the MRL for plant commodities: <i>Flupyradifurone</i></p> <p>Definition of the residue for dietary risk assessment for plant commodities: Sum of flupyradifurone, difluoroacetic acid (DFA) and 6-chloronicotinic acid (6-CNA), expressed as parent equivalents.</p> <p>Definition of the residue for compliance with the MRL for animal commodities: Sum of flupyradifurone and difluoroacetic acid, expressed as parent equivalents.</p> <p>Definition of the residue for dietary risk assessment for animal commodities: Sum of flupyradifurone and difluoroacetic acid, expressed as parent equivalents</p> <p><i>The residue is not fat-soluble.</i></p>						
Flutriafol (248) ADI: 0–0.01 mg/kg bw ARfD: 0.05 mg/kg bw	TN 0660	Almonds	0.8		0.064	0.42
	GC0640	Barley	1.5		0.2	
	MO0105	Edible offal, mammalian	1	1	0.3	0.53
	PE0112	Eggs	0.01(*)	0.01(*)	0.0047	0.0072
	MF0100	Mammalian fats (except milk fat)	0.02	0.02	0.0092	0.014
	MM0095	Meat (from mammals other than marine mammals)	0.02(fat)	0.02(fat)	0.0042	0.0083
	ML0106	Milks	0.01(*)	0.01(*)	0.0047	0.0066
	PO0111	Poultry, edible offal of	0.03	0.03	0.011	0.024
	PF0111	Poultry fats	0.03	0.02	0.0094	0.017
	PM0110	Poultry meat	0.03(fat)	0.01(*)	0.0043	0.0048
	CM0649	Rice, husked	1		0.37	
	CM1205	Rice, polished	1.5		0.40	
	AM0660	Almond hulls	15 (dw)		2.00 (ar)	
	AS0640	Barley hay and/or straw	10 (dw)		Median: 1.0 (ar)	Highest: Straw: 6.4 (ar) Hay: 5.0 (ar)
	GC0649	Rice	4		1.1	
AS0649	Rice, hay and/or straw	6 (dw)		Median:	Highest:	

	CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
					1.40 (ar)	4.0 (ar)
	AS 3570	Rice, hulls (husks)	20 (dw)		Median: 6.8 (ar)	
	CM0640	Barley, pearled			0.099	
	CF0640	Barley bran, processed			0.17	
	CM1206	Rice bran, unprocessed			0.068 (ar)	
(ar)–as received Definition of the residue for compliance with the MRL and dietary risk assessment for plant and animal commodities: <i>flutriafol</i> The residue is fat-soluble.						
Indoxacarb (216) ADI: 0–0.01 mg/kg bw ARfD: 0.1 mg/kg bw	AM 0660	Almond hulls	9 (dw)	-	2.65	3.80
	FB 2006	Bushberries, Subgroup of	2	-	0.58	1.04
	VD 2065	Beans, dry, Subgroup of (except cowpea, mung bean and soya bean),	0.09	-	0.01	
	VP 2060	Beans with pods, Subgroup of (except soya bean)	0.9	-	0.16	0.59
	VR 0574	Beetroot	0.5	-	0.18	0.22
	MO 0105	Edible offal (Mammalian)	0.05	0.05	0.03	0.06
	MF 0100	Mammalian fats (except milk fats)	2	-	0.66	1.9
	GC 2091	Maize cereals, Subgroup of	0.015	-	0.01	
	AS 0645	Maize fodder (dry)	W	25		
	AS 3558	Maize, stover	25 (dw)	-	Median: 3.7	Highest: 9.8
	MM 0095	Meat (from mammals other than marine mammals)	2 (fat)	2 (fat)	0.15	0.46
	ML 0106	Milks	0.2	0.1	0.07	-
	FM 0183	Milk fats	6	2	1.7	-
	TN 0085	Tree nuts	0.07	-	0.013	0.046
(ar)–as received; (dw)–dry weight Definition of the residue for compliance with the MRL and dietary risk assessment for plant commodities: the sum of indoxacarb and its R enantiomer Definition of the residue for compliance with the MRL for animal commodities: the sum of indoxacarb and its R enantiomer Definition of the residue for dietary risk assessment for animal commodities: sum of indoxacarb, its R enantiomer and methyl 7-chloro-2,5-dihydro-2-[[[4- (trifluoromethoxy)phenyl]amino]carbonyl]indeno[1,2-e][1,3,4]oxadiazine-4a(3H)- carboxylate (IN-JT333), expressed as indoxacarb. The residue is fat-soluble.						
Inpyrfluxam (329)* ADI: 0–0.06 mg/kg bw ARfD: 0.3 mg/kg bw	FP 0226	Apples	4		0.91	1.88
	VD 0541	Soya bean (dry)	0.01 (*)		0	-
	VR 0596	Sugar beet	0.01 (*)		0	0
	GC 0649	Husked rice	0.01 (*)		0	
	GC 0645	Maize grain	0.01 (*)		0	-
	GC 0656	Popcorn	0.01 (*)		0	-
	GC 0447	Sweet corn (Corn-on-the-cob) (kernels plus cob with husk)	0.01 (*)		0	0

	CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
		removed)				
	SO 0697	Peanut	0.01(*)		0.01	0.01
	AL 0697	Peanut, hay and/or straw	3		Median: 0.35 (ar)	Highest: 2 (ar)
	AS 3558	Maize stover	0.02(*)		Median: 0.02 (ar)	Highest: 0.02 (ar)
	MM 0095	Meat from mammals other than marine mammals	0.02(*)		0	0
	MF 0100	Mammalian fats	0.02(*)		0	0
	MO 0105	Edible offal (mammalian)	0.02(*)		0	0
	ML 0106	Milk	0.02(*)		0	0
	PM 0110	Poultry meat	0.02(*)		0	0
	PF 0111	Poultry fat	0.02(*)		0	0
	PO 0111	Poultry edible offal	0.02(*)		0	0
	PE 0112	Eggs	0.02(*)		0	0
	JF 0226	Apple, juice	-		0.11	-
<p>The definition of the residue for compliance with the MRL for plant commodities is <i>inpyrfluxam</i>.</p> <p>The definition of the residue for dietary risk assessment for plant commodities is <i>inpyrfluxam</i>.</p> <p>The definition of the residue for compliance with the MRL and dietary risk assessment for animal commodities is <i>inpyrfluxam</i> and <i>1'-CH₂OH-S-2840</i> (free or conjugated) expressed as <i>inpyrfluxam</i>.</p> <p>The residue is not fat soluble.</p>						
Isoflucypram (330)*						
ADI: 0–0.06 mg/kg bw						
ARfD: Unnecessary						
<p>Definition of the residue for compliance with the MRL for plant and animal commodities: <i>Isoflucypram</i>.</p> <p>Definition of the residue for dietary risk assessment for plant and animal commodities: <i>A conclusion could not be reached</i>.</p> <p>The residue is fat-soluble.</p>						
Mancozeb (050)/ Dithiocarbamates (105) ADI: 0–0.03 mg/kg bw ADI: 0–0.004 mg/kg bw (ETU) ARfD: Not established	SO 0691	Cottonseed	0.3		0.75	
	FI 0342	Longan	15		9.8	
	GC 0645	Maize	0.15		0.83	
	GC 0649	Rice grain	3			
	CM 0649	Rice, husked	1.5		3.2	
	CM 1205	Rice, polished	1.5		3.2	
	VD 0541	Soya bean (dry)	0.3		0.75	
		Soya bean—all processed commodities			0.75	
		Maize—all processed commodities			0.83	
		Rice—all processed commodities			3.2	
	Cottonseed—all processed commodities			0.75		
<p>Definition of the residue for compliance with the MRL in plant and animal commodities: Total dithiocarbamates, determined as</p>						

	CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
<p>CS₂, evolved during acid digestion and expressed as mg CS₂/kg.</p> <p>Definition of the residue for dietary risk assessment in plant and animal commodities: mancozeb plus ethylenethiourea (ETU)</p> <p>The Meeting assessed combined residues of mancozeb and ETU using the ratio of the ADIs (7.5) to express residues in terms of mancozeb-toxicity-equivalents (MTE).</p> <p>Dithiocarbamate residues are not fat-soluble</p>						
Mandipropamid (231) ADI: 0–0.2 mg/kg bw ARfD: Unnecessary	HH 0722	Basil, leaves	30		8.75	
	DH 0722	Basil leaves, dried	200		62.5	
	VA 2031	Bulb Onions, Subgroup of	0.05		0.01	
	VC 0424	Cucumber	W	0.2		
	VO 2046	Eggplants, Subgroup of	0.7		0.09	
	VC 2039	Fruiting vegetables, Cucurbits–Cucumber and Summer squashes, Subgroup of	0.2		0.0475	
	VC 2040	Fruiting vegetables, Cucurbits–Melons, Pumpkins and Winter squashes, Subgroup of	0.4		0.01	
	VR 0604	Ginseng	0.15		0.01	
	DV 0604	Ginseng, dried including red ginseng	4		0.46	
	VC 0046	Melon, except watermelon	W	0.5		
	VA 0385	Onion, bulb	W	0.1		
	VO 0051	Peppers, Subgroup of (except Martynia, Okra and Roselle)	0.7	1	0.09	
	HS 0444	Peppers, Chili, dried	7	10	0.9	
	VA 0389	Spring onion	W	7		
	VC 0431	Squash, summer	W	0.2		
	VO 0448	Tomato	W	0.3		
	VO 2045	Tomatoes, Subgroup of	1		0.26	
		Tomato, canned			0.101	
	JF 0448	Tomato juice			0.26	
		Tomato paste			0.91	
DM 0448	Tomato puree			0.286		
<p>Definition of the residue for compliance with the MRL and for estimation of dietary exposure for plant and animal commodities: <i>mandipropamid</i></p> <p>The residue is not fat-soluble</p>						
Mefentrifluconazole (320)* ADI: 0–0.04 mg/kg bw ARfD: 0.3 mg/kg bw	AM 0660	Almond, hulls	4		1.2	
	AB 0226	Apple dried pomace	15		3.9	
	FI 0326	Avocado	1		0.36	0.5
	FI 0327	Banana	1.5		0.055 (pulp)	0.21 (pulp)
	GC 0640	Barley	3		0.425	

	CCN	Commodity	Recommended Maximum residue level (mg/kg)		STM or STM-P mg/kg	HR or HR-P mg/kg
			New	Previous		
	CM 3510	Barley bran, unprocessed	15		2.1	
	CF 3511	Barley, flour	15		1.6	
	VP 2060	Beans with pods, except soya bean (succulent seeds in pods), Subgroup of	0.05		0.01	0.03
	VA 2031	Bulb Onions, Subgroup of	0.2		0.05	0.14
	FB 2006	Bush berries, Subgroup of	5		0.58	3.24
	FB 2005	Cane berries, Subgroup of	3		0.96	1.62
	FS 0013	Cherries, Subgroup of	5		1.1	2.4
	OR 0001	Citrus oil, edible	70		15.2	
	SB 0716	Coffee bean	0.4		0.01	
	SO 0691	Cottonseed, Subgroup of	0.2		0.04	
	AS 3564	Dried distiller's grain from barley	8		1	
	VD 2065	Dry beans, except soya bean (dry), Subgroup of	0.07		0.01	
	VD 2066	Dry peas, except lentil (dry), Subgroup of	0.15		0.015	
	MO 0105	Edible offal (mammalian)	2		0.61 (liver) 0.34 (kidney)	1.91 (liver) 1.36 (kidney)
	VO 2046	Eggplants, Subgroup of	1.5		0.25	0.84
	PE 0112	Eggs	0.04		0.032	0.094
	FB 0267	Elderberries	5		0.58	3.24
	VC 2039	Fruiting vegetables, Cucurbits - Cucumbers and Summer squashes, Subgroup of	0.15		0.035	0.123
	VC 2040	Fruiting vegetables, Cucurbits - Melons, Pumpkins and Winter Squashes, Subgroup of	0.5		0.15	0.23
	AB 0269	Grape, dried pomace	9		2.3	
	VA 2032	Green Onions, Subgroup of	4		0.39	2.2
	FB 2254	Guelder rose	5		0.58	3.24
	VL 2050	Leafy greens ^a , Subgroup of	30		8.1	18
	VL 0054	Leaves of Brassicaceae ^a , Subgroup of	30		6.65	12
	FC 0002	Lemons and Limes (including Citron), Subgroup of	1.5		0.37	0.98
	VD 0533	Lentil (dry)	1.5		0.22	
	FB 2009	Low growing berries, Subgroup of	2		0.29	1.1
	GC 0645	Maize	0.01*		0.01	
	MF 0100	Mammalian fats (except milk fats)	1.5		0.39	1.26
	FC 0003	Mandarins (including Mandarin-like hybrids), Subgroup of	1.5		0.37	0.98
	FI 0345	Mango	0.6		0.01	0.01
	MM 0095	Meat (from mammals other than	0.15 (fat)		0.04	0.14

	CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
		marine mammals)			(muscle) 0.39 (fat)	(muscle) 1.26 (fat)
	ML 0106	Milks	0.1		0.07	
	GC 0646	Millet	2		0.41	
	GC 0647	Oats	3		0.425	
	FC 0004	Oranges, Sweet, Sour (including Orange-like hybrids), Subgroup of	1		0.215	0.7
	FI 0350	Papaya	0.5		0.07	0.22
	AL 0072	Pea, hay and/or straw	30 (dry weight)		9.74	13
	FS 2001	Peaches (including Nectarine and Apricots), Subgroup of	2		0.56	1.04
	SO 0697	Peanut	0.01*		0.01	
	AL 0697	Peanut, hay and/or straw	40 (dry weight)		8.9	30
	VP 2061	Peas with pods, Subgroup of	0.15		0.01	0.1
	HS 0444	Peppers, Chili, dried	15		2.5	8.4
	VO 0051	Peppers, except martynia, okra and roselle, Subgroup of	1.5		0.25	0.84
	FS 0014	Plums (including fresh Prunes), Subgroup of	1.5		0.26	1
	FP 0009	Pome fruits except persimmon, Japanese, Group of	1.5		0.39	1.12
	GC 0656	Popcorn	0.01*		0.01	
	PO 0111	Poultry, edible offal	0.7		0.12	0.844
	PF 0111	Poultry, fats	0.2		0.124	0.503
	PM 0110	Poultry, meat	0.03 (fat)		0.012 (muscle) 0.124 (fat)	0.053 (muscle) 0.50 (fat)
	DF 0014	Prune, dried	7		1.1	4.1
	FC 0005	Pummelo and Grapefruits (including Shaddock-like hybrids, among others Grapefruit), Subgroup of	0.5		0.16	0.24
	GC 0649	Rice	5		1.2	
	CM 0649	Rice, husked	1.5		0.11	
	CM 0649	Rice, husked	1.5		0.11	
	VR 2070	Root vegetables, except sugar beet, Subgroup of	0.5		0.105	0.4
	GC 0650	Rye	0.4		0.09	
	SO 2090	Small seed oilseeds, Subgroup of	1		0.06	
	GC 0651	Sorghum Grain	2		0.41	
	VD 0541	Soya bean (dry)	0.4		0.01	
	AL 0541	Soya bean, hay and/or straw	20 (dry weight)		4.5	12
	AS 0081	Straw and hay of cereal grains	50 (dry weight)		10.3	25.7
	VP 2062	Succulent beans without pods,	0.03		0.01	0.02

	CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
		except soya bean (succulent seeds), Subgroup of				
	VP 2063	Succulent peas without pods, Subgroup of	0.01*		0.01	0.01
	GS 0659	Sugar cane	1.5		0.37	
	SO 2091	Sunflower seeds, Subgroup of	0.15		0.01	
	GC 0447	Sweet corn (Corn-on-the-cob) (kernels plus cob with husk removed)	0.04		0.01	0.02
	DV 0448	Tomato, dried	7		1.3	4.1
	VO 2045	Tomatoes, Subgroup of	0.7		0.14	0.45
	TN 0085	Tree nuts, Group of	0.06		0.01	0.06
	GC 0653	Triticale	0.4		0.09	
	VR 2071	Tuberous and corm vegetables, Subgroup of	0.05		0.01	0.05
	GC 0654	Wheat	0.4		0.09	
	CF 3521	Wheat aspirated grain fractions	16		3.5	
	CM 0654	Wheat bran, unprocessed	1.5		0.26	
	CF 1210	Wheat, germ	0.5		0.1	
	CF 3515	Wheat, shorts (cereal grain milling by-product)	1.5		0.32	
	FB 1236	Wine-grapes	2		0.54	1.1
		Apple fruit syrup			0.16	0.45
		Apple sauce			0.043	
	DF 0226	Apple, dried			0.12	0.35
	JF 0226	Apple, juice			0.051	
		Barley, beer			0.13	
		Barley, brewing malt			0.21	
	CM 0640	Barley, pearled			0.051	
		Canned apples			0.051	
		Canned strawberries			0.27	
	JF 0001	Citrus juice			0.007	
		Citrus marmalade			0.044	
		Citrus peel			0.96	2.5
		Citrus pulp			0.007	0.02
		Coffee beans, concentrated liquor			0.00075	
		Coffee beans, instant coffee			0.0016	
	SM 0716	Coffee beans, roasted			0.0062	
	OR 0691	Cotton seed oil, edible			0.00016	
	JF 0269	Grape, juice			0.07	
	-	Grape, wine (red)			0.016	

	CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
		Grape, wine (white)			0.011	
		Pickled gherkins			0.026	0.088
	DV 0589	Potato flakes/granules			0.0033	
		Potato, baked with peel			0.0033	0.0165
		Potato, crisps/chips–without peel			0.0033	0.0165
		Potato, fried without peel			0.0033	0.0165
		Potato, peeled tuber			0.0033	0.0165
		Potato, starch			0.0033	
		Potato, stove boiled -without peel			0.0033	0.0165
		Prune juice			0.039	
		Prune puree			0.15	
	CM 1206	Rice bran, unprocessed			0.44	
	CM 1205	Rice, polished			0.0085	
	OC 0541	Soya bean oil, crude			0.01	
	OR 0541	Soya bean oil, refined			0.0083	
		Soya bean, flour			0.0083	
		Soya bean, miso			0.0083	
		Soya bean, soya sauce			0.0083	
		Soya bean, tofu			0.0083	
		Strawberry fruit syrup			0.058	0.22
		Strawberry jam			0.12	
	DM 0448	Tomato puree			0.039	
		Tomato, canned			0.0084	0.027
	JF 0448	Tomato, juice			0.011	
	VW 0448	Tomato, paste			0.069	
		Wheat gluten			0.05	
		Wheat starch			0.026	
	CF 1212	Wheat, whole meal flour			0.071	
		Whole grain bread			0.05	
<p>^a On the basis of the information provided to the JMPR it was concluded that the estimated acute dietary exposure to residues of mefenftrifluconazole for the consumption of commodities from the subgroups of Leafy greens and Leaves of Brassicaceae may present a public health concern</p> <p>Definition of the residue for compliance with the MRL and dietary risk assessment for plant commodities: <i>mefenftrifluconazole</i> Definition of the residue for compliance with the MRL for animal commodities: <i>mefenftrifluconazole (free and conjugated)</i> Definition of the residue for dietary risk assessment for animal commodities: sum of <i>mefenftrifluconazole (free and conjugated)</i> + 2-[4-(4-chlorophenoxy)-2-(trifluoromethyl)phenyl]propane-1,2-diol (M750F022), <i>free and conjugated</i>, expressed as <i>mefenftrifluconazole equivalents</i>. The molecular weight conversion factor to express M750F022 in mefenftrifluconazole equivalents = 1.15. The residue is fat soluble.</p>						
Metalaxyl (138)	FI 0353	Pineapple	0.1 (M)		0.026	0.078
ADI: 0–0.08 mg/kg bw	DV 0604	Ginseng, dried including red ginseng	0.06* (MM)		0.06	0.06

	CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
ARfD: 0.5 mg/kg bw						
Residue data that was the basis for the estimation: metalaxyl (M), metalaxyl-M (MM)						
Definition of the residue for compliance with the MRL for plant commodities: <i>metalaxyl (sum of enantiomers)</i>						
Definition of the residue for dietary risk assessment in plant commodities: Metalaxyl (sum of enantiomers) and N-(2-hydroxymethyl-6-methylphenyl)-N-(methoxyacetyl)alanine methyl ester (M8; free and conjugated; sum of enantiomers), expressed as metalaxyl.						
Definition of the residue for compliance with the MRL in animal commodities: Sum of metalaxyl (sum of enantiomers) and metabolites (free + conjugated) M3 (N-(2,6-dimethylphenyl)-N-(hydroxyacetyl)alanine methyl ester) and M8 (N-(2-hydroxymethyl-6-methylphenyl)-N-(methoxyacetyl)alanine methyl ester (sum of enantiomers), expressed as metalaxyl.						
Definition of the residue for dietary risk assessment in animal commodities: Sum of metalaxyl (sum of enantiomers) and metabolites (free + conjugated) M1 (N-(2,6-dimethylphenyl)-N-(methoxyacetyl) alanine), M3 (N-(2,6-dimethylphenyl)-N-(hydroxyacetyl)alanine methyl ester), M6 (N-(2,6-dimethylphenyl)-N-(hydroxyacetyl)alanine), M7 (N-(2,6-dimethyl-5-hydroxyphenyl)-N-(methoxyacetyl)alanine methyl ester) and M8 (N-(2-hydroxymethyl-6-methylphenyl)-N-(methoxyacetyl)alanine methyl ester (sum of enantiomers), expressed as metalaxyl.						
The residue is not fat-soluble						
Methidathion (051)** ADI: 0–0.002 mg/kg bw ARfD: 0.01 mg/kg bw	FC 0226	Apple	W	0.5		
	FS 0013	Cherries, Subgroup of	W	0.2		
	FB 0269	Grapes	W	1		
	FC 0206	Mandarins (including mandarin like hybrids)(subgroup)	W	5		
	FP 0230	Pear	W	1		
	DT 1114	Tea, green, black (black, fermented and dried)	W	0.5		
Definition of the residue for compliance with the MRL for plant commodities: methidathion						
Definition of the residue for long-term dietary exposure assessment for plant commodities: <i>sum of methidathion, S-2,3-dihydro-5-methoxy-2-oxo-1,3,4-thiadiazol-3-ylmethyl O-methyl phosphorodithioate and 2,3-dihydro-5-methoxy-1,3,4-thiadiazol-2-one (free and conjugate), and 4x S-2,3-dihydro-5-methoxy-2-oxo-1,3,4-thiadiazol-3-ylmethyl O,O-dimethyl phosphorothioate, expressed as methidathion</i>						
Definition of the residue for acute dietary exposure assessment for plant commodities: <i>sum of methidathion and 4x S-2,3-dihydro-5-methoxy-2-oxo-1,3,4-thiadiazol-3-ylmethyl O,O-dimethyl phosphorothioate, expressed as methidathion.</i>						
The Meeting was unable to reach a conclusion on the residue definitions for compliance with the MRL and dietary risk assessment for animal commodities.						
The residue is not fat soluble.						
Pyridate (315)* ADI: 0–0.2 mg/kg bw ARfD: 2 mg/kg bw						
Definition of the residue for compliance with the MRL for plant and animal commodities: Sum of pyridate and 6-chloro-4-hydroxy-3-phenylpyridazine (pyridafol) (incl. conjugates), expressed as pyridate						
The Meeting was unable to reach a conclusion on the residue definitions for dietary risk assessment for plant and animal commodities.						
The residue is not fat-soluble.						
Quinlorac (287) ADI: 0–0.4 mg/kg bw ARfD: 2 mg/kg bw	FB 0265	Cranberries	1.5	1.5	0.375	0.88
	SO 0495	Rape seeds	0.15	0.15	0.64 (median: 0.017 for	

	CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
					feed calc.)	
	OR 0495	Rape seed oil, edible			0.70	
<p>Definition of the residue for compliance with the MRL for plant commodities: quinclorac plus quinclorac conjugates</p> <p>Definition of the residue for dietary risk assessment for plant commodities: quinclorac plus quinclorac conjugates plus quinclorac methyl ester expressed as quinclorac.</p> <p>Definition of the residue for compliance with the MRL and dietary risk assessment for animal commodities: quinclorac plus quinclorac conjugates.</p> <p>The residue is fat-soluble.</p>						
Quintozene (064)** ADI: 0–0.01 mg/kg bw ARfD: Unnecessary	GC 0640	Barley	W	0.01 (*)		
	AS 0640	Barley straw and fodder, Dry	W	0.01(*)		
	VB 0400	Broccoli	W	0.05		
	VB 0041	Cabbages, head	W	0.1		
	PM 0840	Chicken meat	W	0.1 (*) fat		
	PO 084-	Chicken, Edible offal of	W	0.1 (*)		
	VD 0526	Common bean (dry)	W	0.02		
	VP 0526	Common bean (pods and/or immature seeds)	W	0.1		
	SO 0691	Cotton seed	W	0.01		
	PE 0112	Eggs	W	0.03 (*)		
	GC 0645	Maize	W	0.01 (*)		
	AS 0645	Maize fodder (dry)	W	0.01		
	AL 0072	Pea hay or pea fodder (dry)	W	0.05		
	SO 0697	Peanut	W	0.5		
	VD 0072	Peas (dry)	W	0.01		
	HS 0444	Peppers Chili, dried	W	0.1		
	VO 0445	Peppers, Sweet (including pimento or pimiento)	W	0.05 (*)		
	HS 0191	Spices, Fruits and Berries	W	0.02		
	HS 0193	Spices, Roots and Rhizomes	W	2		
	HS 0190	Spices, seeds	W	0.1		
VD 0541	Soya bean (dry)	W	0.01 (*)			
VR 0598	Sugar beet	W	0.01 (*)			
VO 0448	Tomato	W	0.02			
CG 0654	Wheat	W	0.01			
AS 0654	Wheat straw and fodder, dry	W	0.03			
<p>Definition of the residue for compliance with the MRL for plant commodities: Quintozene.</p> <p>The Meeting was unable to reach a conclusion on the residue definition for dietary risk assessment in plant commodities.</p> <p>The Meeting was unable to reach a conclusion on the residue definition for compliance with the MRL or dietary risk assessment for animal commodities</p>						
Spiromesifen (294) ADI: 0–0.03 mg/kg bw ARfD: Unnecessary	FC 0004	Oranges, Sweet, Sour, Subgroup of	0.15		0.043	
	FI 0345	Mango	0.5		0.024	
	FI 0350	Papaya	0.7		0.13	

	CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
	VP 0061	Beans with pods (Phaseolus spp.) immature pods and succulent seeds)	0.5		0.16	
	VP 0062	Beans without pods (Phaseolus spp.) (succulent seeds)	0.15(*)		0.12(*)	
	VD 2065	Dry beans, Subgroup of	0.03(*)		0.024	
	OR 0004	Orange oil, edible	30		8.6	
	MM 0095	Meat (from mammals other than marine mammals)	0.15	0.15	0.01	
	ML 0106	Milks	0.015	0.015	0.0021	
	ML 0100	Mammalian fats (except milk fats	0.15	0.15	0.017	
	MO 0105	Edible offal(mammalian)	0.3	0.3	0.055	
	PO 0111	Poultry, edible offal	0.05	0.05	0.05	
	PF 0111	Poultry, fats	0.02	0.02	0.01	
	PM 0110	Poultry, meat	0.02	0.02	0.01	
	PE 0112	Eggs	0.02	0.02	0.01	
	OC 0541	Soya bean oil, crude	0.03*		0.006	
	AB 0001	Citrus pulp, dried	0.3		0.086	
	AL 3538	Soya bean, hulls	0.03*		0.03	
	AL 3539	Soya bean meal	0.03*		0.005	
<p>Definition of the residue for compliance with the MRL for plant and animal commodities and for dietary risk assessment for animal commodities: <i>sum of spiromesifen and spiromesifen-enol, expressed as spiromesifen.</i></p> <p>Definition of the residue for dietary risk assessment for plant commodities: <i>sum of spiromesifen, spiromesifen-enol and 4-hydroxymethyl-spiromesifen-enol (free and conjugated), expressed as spiromesifen.</i></p> <p>The residue is fat-soluble.</p>						
Sulfoxaflor(252) ADI: 0–0.05 mg/kg bw ARfD: 0.3 mg/kg bw	VS 0620	Globe artichoke	0.9		0.245	0.45
	SO 2091	Sunflower seeds, Subgroup of	0.4		0.047	
	OR 0702	Sunflower seed oil, edible	--	--	0.033	--
<p>Definition of the residue for compliance with the MRL and for dietary risk assessment for plant and animal commodities: <i>sulfoxaflor.</i></p> <p><i>The residue is not fat-soluble.</i></p>						
Tetraniliprole (324)* ADI: 0–2 mg/kg bw ARfD: Unnecessary	AM 0660	Almond hulls	4 (dw)	-	Median: 0.80 (ar)	
	VB 0041	Cabbages, Head	2	-	0.012, Median: 0.135	Highest: 1.2
	AS 3304	Cereal grains (including pseudocereals) feed products with low water (<20 percent) content (hay and/or straw) Subgroup of, excluding rice, maize/field corn, and sweet corn)	0.2 (dw)	-	Median: 0.01 (ar)	Highest: 0.14 (ar)
	FS 0013	Cherries, Subgroup of	1.5	-	0.29	
	MO 0105	Edible offal (Mammalian)	1	-	kidney: 0.10	

	CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
					liver: 0.43	
	PE 0112	Eggs	0.01*	-	0	
	VB 0042	Flowerhead Brassicas, Subgroup of	0.5	-	0.145	
	VO 0050	Fruiting vegetables, other than Cucurbits, Group of, excluding okra, martynia and roselle	0.4	-	0.075	
	VL 0054	Leaves of Brassicaceae, Subgroup of	15	-	4	
	FC 0002	Lemons and Limes (including Citron), Subgroup of	1.5		0.19	
	GC 2091	Maize cereals, Subgroup of	0.015	-	0.01	
	AS 3558	Maize stover	30 (dw)		Median: 2.5 (ar)	Highest: 17 (ar)
	MF 0100	Mammalian fats (except milk fats)	0.15	-	0.26	
	FC 0003	Mandarins (including Mandarin-like hybrids), Subgroup of	1	-	0.185	
	MM 0095	Meat (from mammals other than marine mammals)	0.1	-	muscle: 0.047 fat: 0.26	
	ML 0106	Milks	0.15	-	0.12	
	FC 0004	Oranges, Sweet, Sour (including Orange-like hybrids), Subgroup of	0.5	-	0.015#	
	FS 2001	Peaches (including Nectarines and Apricots), Subgroup of	0.7	-	0.089	
	FS 0014	Plums, Subgroup of	0.3	-	0.033	
	FP 0009	Pome fruits, Group of, excluding Japanese persimmon	0.4	-	0.13	
	PO 0111	Poultry, edible offal	0.01*	-	0	
	PF 0111	Poultry, fats	0.01*	-	0	
	PM 0110	Poultry, meat	0.01*	-	muscle: 0 fat: 0	
	AL 3301	Products of legume feeds with low water (<20 percent) content (hay), Subgroup of	0.3 (dw)	-	Median: 0.01 (ar)	Highest: 0.22 (ar)
	FC 0005	Pummelos and Grapefruits (including Shaddock-like hybrids, among others grapefruit), Subgroup of	0.9	-	0.091	
	GC 2088	Rice cereals, Subgroup of	0.02	-	0.01	
	CM 0649	Rice, husked	0.01*	-	0.01	
	CM 1205	Rice, polished	0.01*	-	0.01	
	AS 0649	Rice, hay and/or straw	20 (dw)	-	Median: 2.8 (ar)	Highest: 8.2 (ar)
	FB 2008	Small fruit vine climbing, Subgroup of	1.5	-	0.275	
	VD 0541	Soya bean (dry)	0.2	-	0.026	

	CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
	GC 0447	Sweet Corn (corn-on-the-cob)	0.01*	-	0.01	
	TN 0085	Tree nuts, Group of	0.03	-	0.01	
	VR 2071	Tuberous and corm vegetables, Subgroup of	0.02	-	0.01	
	HS 0444	Peppers, Chili, dried	4	-	0.75	
	DF 0269	Grape, dried (=Currants, Raisins, and Sultanas)	2	-	0.35	
	OR 0004	Orange oil, edible	5	-	1.27	
	DF 0014	Prune, dried	1.5	-	0.125	
	DM 0448	Tomato paste	1.5		0.39	
	CF 1255	Maize flour	-	-	0.012	
	CF 0645	Maize, meal	--		0.011	
	-	Maize grits	-	-	0.01	
	-	Maize starch	-	-	0.01	
	OR 0645	Maize, refined bleached deodorized oil	-	-	0.01	
	JF 0009	Group of Pome Fruit, juices	-	-	0.065	
	-	Group of Pome Fruit, sauce	-	-	0.01	
	DF 0009	Group of Pome Fruit, dried	-	-	0.01	
	JF 0269	Grape, juice	-	-	0.067	
	-	Grape, wine	-	-	0.14	
	-	Grape, must	-	-	0.16	
	JF 0004	Orange, juice	-	-	0.01	
	-	Orange, marmalade	-	-	0.01	
	-	Orange, peeled	-	-	0.015	
	HS 3382	Orange, peel	-	-	0.39	
	-	Potato, crisps	-	-	0.01	
<p>(ar)–as received; (dw)–dry weight; #STMR for flesh only based on 0.14 mg/kg x PF of 0.11</p> <p>Definition of the residue for compliance with the MRL for plant commodities: <i>tetraniliprole</i>.</p> <p>Definition of the residue for dietary risk assessment for plant commodities: <i>tetraniliprole + tetraniliprole-N-methyl-quinazolinone, expressed as tetraniliprole</i>.</p> <p>Definition of the residue for compliance with the MRL for animal commodities: <i>tetraniliprole</i>.</p> <p>Definition of the residue for dietary risk assessment for animal commodities: <i>tetraniliprole + tetraniliprole-N-methyl-quinazolinone + tetraniliprole-benzylalcohol, expressed as tetraniliprole</i>.</p> <p><i>The residue is not fat-soluble.</i></p>						
Triflumuron (317)	VD 0541	Soya bean (dry)	0.1		0.043 (triflumuron+M02) 0.020 (M07)	

	CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
ADI: 0–0.008 mg/kg bw ARfD: Unnecessary 4-trifluoromethoxyaniline (metabolite M07) ADI: 0-0.02 mg/kg bw ARfD: 0.02 mg/kg bw	ML 0106	Milks	0.01(*)		0	
	MO 0105	Edible offal (Mammalian)	0.05(*)		0.05	
	MM 0095	Meat (from mammals other than marine mammals)	0.1(*) (fat)		0.1	
	MF 0100	Mammalian fats (except milk fats)	0.1(*)		0.1	
	OR 0541	Soya bean oil, refined			0.0043 (triflumuron+M02) 0.0020 (M07)	
Definition of the residue for compliance with the MRL for plant and animal commodities: triflumuron Definition of the residue for dietary risk assessment for plant commodities: sum of triflumuron and 2-chlorobenzoic acid (M02), expressed as triflumuron and 4-trifluoromethoxyaniline (M07) assessed separately. Definition of the residue for dietary risk assessment for animal commodities: triflumuron The residue is fat-soluble						

Annex 2: Index of reports and evaluations of pesticides by the JMPR

Numbers in parentheses after the names of pesticides are Codex classification numbers. The abbreviations used are:

T, evaluation of toxicology

R, evaluation of residue and analytical aspects

E, evaluation of effects on the environment

Abamectin (177)	1992 (T,R), 1994 (T,R), 1995 (T), 1997 (T,R), 2000 (R), 2015 (R), 2017 (T), 2018 (R)
Acephate (095)	1976 (T,R), 1979 (R), 1981 (R), 1982 (T), 1984 (T,R), 1987 (T), 1988 (T), 1990 (T,R), 1991 (corr. to 1990 R evaluation), 1994 (R), 1996 (R), 2002 (T), 2003 (R), 2004 (corr. to 2003 report), 2005 (T), 2006 (R), 2011 (R)
Acetamiprid (246)	2011 (T, R), 2012 (R), 2015 (R), 2017 (R), 2021 (R)
Acetochlor (280)	2015 (T, R), 2019 (T, R)
Acibenzolar-S-methyl (288)	2016 (T, R)
Acrylonitrile	1965 (T, R)
Afidopyropen (312)	2019 (T, R), 2021 (R), 2022 (R)
Aldicarb (117)	1979 (T, R), 1982 (T,R), 1985 (R), 1988 (R), 1990 (R), 1991 (corr. to 1990 evaluation), 1992 (T), 1993 (R), 1994 (R), 1996 (R), 2001 (R), 2002 (R), 2006 (R)
Aldrin (001)	1965 (T), 1966 (T, R), 1967 (R), 1974 (R), 1975 (R), 1977 (T), 1990 (R), 1992 (R)
Allethrin	1965 (T, R)
Ametoctradin (253)	2012 (T, R)
Aminocarb (134)	1978 (T, R), 1979 (T, R)
Aminocyclopyrachlor (272)	2014 (T, R)
Aminomethylphosphonic acid (AMPA, 198)	1997 (T, R)
Aminopyralid (220)	2006 (T, R), 2007 (T,R)
Amitraz (122)	1980 (T, R), 1983 (R), 1984 (T,R), 1985 (R), 1986 (R), 1989 (R), 1990 (T,R), 1991 (R & corr. to 1990 R evaluation), 1998 (T)
Amitrole (079)	1974 (T, R), 1977 (T), 1993 (T, R), 1997 (T), 1998 (R)
Anilazine (163)	1989 (T, R), 1992 (R)
Atrazine	2007 (T)

Azinphos-ethyl (068)	1973 (T, R), 1983 (R)
Azinphos-methyl (002)	1965 (T), 1968 (T, R), 1972 (R), 1973 (T), 1974 (R), 1991 (T, R), 1992 (corr. to 1991 report), 1993 (R), 1995 (R), 2007 (T)
Azocyclotin (129)	1979 (R), 1981 (T), 1982 (R), 1983 (R), 1985 (R), 1989 (T,R), 1991 (R), 1994 (T), 2005 (T,R)
Azoxystrobin (229)	2008 (T,R), 2011 (R), 2012 (R), 2013 (R), 2017 (R), 2019 (R), 2022 (R)
Benalaxyl (155)	1986 (R), 1987 (T), 1988 (R), 1992 (R), 1993 (R), 2005 (T), 2009 (R)
Bendiocarb (137)	1982 (T,R), 1984 (T,R), 1989 (R), 1990 (R)
Benomyl (069)	1973 (T,R), 1975 (T,R), 1978 (T,R), 1983 (T,R), 1988 (R), 1990 (R), 1994 (R), 1995 (T,E), 1998 (R)
Bentazone (172)	1991 (T,R), 1992 (corr. to 1991 report, Annex I), 1994 (R), 1995 (R), 1998 (T,R), 1999 (corr. to 1998 report), 2004 (T), 2012 (T), 2013 (R), 2016 (T), 2018 (R)
Benzovindiflupyr (261)	2013 (T), 2014 (R), 2016 (R), 2019 (R), 2022 (T, R)
Benzpyrimoxan (325)	2022 (T, R)
BHC (technical-grade)	1965 (T), 1968 (T,R), 1973 (T,R) (see also Lindane)
Bicyclopyrone (295)	2017 (T, R)
Bifenazate (219)	2006 (T,R), 2008 (R), 2010 (R)
Bifenthrin (178)	1992 (T,R), 1995 (R), 1996 (R), 1997 (R), 2009 (T), 2010 (R), 2015 (R), 2019 (R), 2022 (R)
Binapacryl (003)	1969 (T,R), 1974 (R), 1982 (T), 1984 (R), 1985 (T,R)
Bioresmethrin (093)	1975 (R), 1976 (T,R), 1991 (T,R)
Biphenyl	See Diphenyl
Bitertanol (144)	1983 (T), 1984 (R), 1986 (R), 1987 (T), 1988 (R), 1989 (R), 1991 (R), 1998 (T), 1999 (R), 2002 (R)
Bixafen (262)	2013 (T,R), 2016 (R), 2021 (R)
Boscalid (221)	2006 (T,R), 2008 (R), 2010 (R), 2019 (T, R)
Broflanilide (326)	2022 (T, R)
Bromide ion (047)	1968 (R), 1969 (T, R), 1971 (R), 1979 (R), 1981 (R), 1983 (R), 1988 (T, R), 1989 (R), 1992 (R)
Bromomethane (052)	1965 (T, R), 1966 (T,R), 1967 (R), 1968 (T,R), 1971 (R), 1979 (R), 1985 (R), 1992 (R)
Bromophos (004)	1972 (T,R), 1975 (R), 1977 (T,R), 1982 (R), 1984 (R), 1985 (R)
Bromophos-ethyl (005)	1972 (T,R), 1975 (T,R), 1977 (R)

Bromopropylate (070)	1973 (T,R), 1993 (T,R)
Butocarboxim (139)	1983 (R), 1984 (T), 1985 (T), 1986 (R)
Buprofezin (173)	1991 (T,R), 1995 (R), 1996 (corr. to 1995 report.), 1999 (R), 2008 (T,R), 2009 (R), 2012 (R), 2014 (R), 2016 (R), 2019 (T, R)
sec-Butylamine (089)	1975 (T,R), 1977 (R), 1978 (T,R), 1979 (R), 1980 (R), 1981 (T), 1984 (T,R: withdrawal of temporary ADI, but no evaluation)
Cadusafos (174)	1991 (T,R), 1992 (R), 1992 (R), 2009 (R), 2010 (R)
Campheclor (071)	1968 (T,R), 1973 (T,R)
Captafol (006)	1969 (T,R), 1973 (T,R), 1974 (R), 1976 (R), 1977 (T,R), 1982 (T), 1985 (T,R), 1986 (corr. to 1985 report), 1990 (R), 1999 (ARfD)
Captan (007)	1965 (T), 1969 (T,R), 1973 (T), 1974 (R), 1977 (T,R), 1978 (T,R), 1980 (R), 1982 (T), 1984 (T,R), 1986 (R), 1987 (R and corr. to 1986 R evaluation), 1990 (T,R), 1991 (corr. to 1990 R evaluation), 1994 (R), 1995 (T), 1997 (R), 2000 (R), 2004 (T), 2007 (T), 2017 (R)
Carbaryl (008)	1965 (T), 1966 (T,R), 1967 (T,R), 1968 (R), 1969 (T,R), 1970 (R), 1973 (T,R), 1975 (R), 1976 (R), 1977 (R), 1979 (R), 1984 (R), 1996 (T), 2001 (T), 2002 (R), 2007 (R)
Carbendazim (072)	1973 (T,R), 1976 (R), 1977 (T), 1978 (R), 1983 (T,R), 1985 (T,R), 1987 (R), 1988 (R), 1990 (R), 1994 (R), 1995 (T,E), 1998 (T,R), 2003 (R), 2005 (T), 2012 (R)
Carbofuran (096)	1976 (T,R), 1979 (T,R), 1980 (T), 1982 (T), 1991 (R), 1993 (R), 1996 (T), 1997 (R), 1999 (corr. to 1997 report), 2002 (T,R), 2003 (R) (See also carbosulfan), 2004 (R), 2008 (T), 2009 (R)
Carbon disulfide (009)	1965 (T,R), 1967 (R), 1968 (R), 1971 (R), 1985 (R)
Carbon tetrachloride (010)	1965 (T,R), 1967 (R), 1968 (T,R), 1971 (R), 1979 (R), 1985 (R)
Carbophenothion (011)	1972 (T,R), 1976 (T,R), 1977 (T,R), 1979 (T,R), 1980 (T,R), 1983 (R)
Carbosulfan (145)	1984 (T,R), 1986 (T), 1991 (R), 1992 (corr. to 1991 report), 1993 (R), 1997 (R), 1999 (R), 2002 (R), 2003 (T,R), 2004 (R, corr. to 2003 report)
Cartap (097)	1976 (T,R), 1978 (T,R), 1995 (T,R)
Chinomethionat (080)	1968 (T,R) (as oxythioquinox), 1974 (T,R), 1977 (T,R), 1981 (T,R), 1983 (R), 1984 (T,R), 1987 (T)
Chlorantraniliprole (230)	2008 (T,R), 2010 (R), 2013 (R), 2014 (R), 2016 (R), 2019 (R), 2022 (R)

Chlorbenside	1965 (T)
Chlordane (012)	1965 (T), 1967 (T,R), 1969 (R), 1970 (T,R), 1972 (R), 1974 (R), 1977 (T,R), 1982 (T), 1984 (T,R), 1986 (T)
Chlordimeform (013)	1971 (T,R), 1975 (T,R), 1977 (T), 1978 (T,R), 1979 (T), 1980 (T), 1985 (T), 1986 (R), 1987 (T)
Chlorfenapyr (254)	2013 (T), 2018 (T,R)
Chlorfenson	1965 (T)
Chlorfenvinphos (014)	1971 (T,R), 1984 (R), 1994 (T), 1996 (R)
Chlormequat (015)	1970 (T,R), 1972 (T,R), 1976 (R), 1985 (R), 1994 (T,R), 1997 (T), 1999 (ARfD), 2000 (R), 2017 (T, R), 2022 (R)
Chlorobenzilate (016)	1965 (T), 1968 (T,R), 1972 (R), 1975 (R), 1977 (R), 1980 (T)
Chloropicrin	1965 (T,R)
Chloropropylate	1968 (T,R), 1972 (R)
Chlorothalonil (081)	1974 (T,R), 1977 (T,R), 1978 (R), 1979 (T,R), 1981 (T,R), 1983 (T,R), 1984 (corr. to 1983 report and T evaluation), 1985 (T,R), 1987 (T), 1988 (R), 1990 (T,R), 1991 (corr. to 1990 evaluation), 1992 (T), 1993 (R), 1997 (R), 2009 (T), 2010 (R), 2012 (R), 2015 (R), 2019 (T, R)
Chlorpropham (201)	1965 (T), 2000 (T), 2001 (R), 2005 (T), 2008 (R)
Chlorpyrifos (017)	1972 (T,R), 1974 (R), 1975 (R), 1977 (T,R), 1981 (R), 1982 (T,R), 1983 (R), 1989 (R), 1995 (R), 1999 (T), 2000 (R), 2004 (R), 2006 (R), 2021 (R)
Chlorpyrifos-methyl (090)	1975 (T,R), 1976 (R, Annex I only), 1979 (R), 1990 (R), 1991 (T,R), 1992 (T and corr. to 1991 report), 1993 (R), 1994 (R), 2001 (T), 2009 (R)
Chlorthion	1965 (T)
Clethodim (187)	1994 (T,R), 1997 (R), 1999 (R), 2002 (R), 2019 (T, R)
Clofentezine (156)	1986 (T,R), 1987 (R), 1989 (R), 1990 (R), 1992 (R), 2005 (T), 2007 (R), 2021 (R)
Clothianidin (238)	2010 (T,R), 2011 (R), 2014 (R), 2021 (R)
Coumaphos (018)	1968 (T,R), 1972 (R), 1975 (R), 1978 (R), 1980 (T,R), 1983 (R), 1987 (T), 1990 (T,R)
Crufomate (019)	1968 (T,R), 1972 (R)
Cyanophenfos (091)	1975 (T,R), 1978 (T: ADI extended, but no evaluation), 1980 (T), 1982 (R), 1983 (T)
Cyantraniliprole (263)	2013 (T,R), 2015 (R), 2018 (R)
Cyazofamid (281)	2015 (T, R), 2018 (R)

Cyclaniliprole (296)	2017 (T, R), 2019 (R)
Cycloxydim (179)	1992 (T,R), 1993 (R), 2009 (T), 2012 (R)
Cyflumetofen (273)	2014 (T,R)
Cyfluthrin (157)	1986 (R), 1987 (T and corr. to 1986 report), 1989 (R), 1990 (R), 1992 (R), 2006 (T), 2007 (R)
Cyhalothrin (including lambda-cyhalothrin)(146)	1984 (T,R), 1986 (R), 1988 (R), 2007 (T), 2008 (R), 2015 (R), 2018 (T), 2019 (R)
Cyhexatin (067)	1970 (T,R), 1973 (T,R), 1974 (R), 1975 (R), 1977 (T), 1978 (T,R), 1980 (T), 1981 (T), 1982 (R), 1983 (R), 1985 (R), 1988 (T), 1989 (T), 1991 (T,R), 1992 (R), 1994 (T), 2005 (T,R)
Cypermethrin (118)	1979 (T,R), 1981 (T,R), 1982 (R), 1983 (R), 1984 (R), 1985 (R), 1986 (R), 1987 (corr. to 1986 evaluation), 1988 (R), 1990 (R), 2006 (T), 2008 (R), 2009 (R), 2011 (R), 2019 (R), 2021 (R)
Cyproconazole (239)	2010 (T,R), 2013 (R)
Cyprodinil (207)	2003 (T,R), 2004 (corr. to 2003 report), 2013 (R), 2015 (R), 2017 (R), 2018 (R), 2019 (T, R), 2021 (R)
Cyromazine (169)	1990 (T,R), 1991 (corr. to 1990 R evaluation), 1992 (R), 2006 (T), 2007 (R), 2012 (R)
2,4-D (020)	1970 (T,R), 1971 (T,R), 1974 (T,R), 1975 (T,R), 1980 (R), 1985 (R), 1986 (R), 1987 (corr. to 1986 report, Annex I), 1996 (T), 1997 (E), 1998 (R), 2001 (R), 2017 (R)
Daminozide (104)	1977 (T,R), 1983 (T), 1989 (T,R), 1991 (T)
DDT (021)	1965 (T), 1966 (T,R), 1967 (T,R), 1968 (T,R), 1969 (T,R), 1978 (R), 1979 (T), 1980 (T), 1983 (T), 1984 (T), 1993 (R), 1994 (R), 1996 (R)
Deltamethrin (135)	1980 (T,R), 1981 (T,R), 1982 (T,R), 1984 (R), 1985 (R), 1986 (R), 1987 (R), 1988 (R), 1990 (R), 1992 (R), 2000 (T), 2002 (R), 2016 (R)
Demeton (092)	1965 (T), 1967 (R), 1975 (R), 1982 (T)
Demeton-S-methyl (073)	1973 (T,R), 1979 (R), 1982 (T), 1984 (T,R), 1989 (T,R), 1992 (R), 1998 (R)
Demeton-S-methylsulfon (164)	1973 (T,R), 1982 (T), 1984 (T,R), 1989 (T,R), 1992 (R)
Dialifos (098)	1976 (T,R), 1982 (T), 1985 (R)
Diazinon (022)	1965 (T), 1966 (T), 1967 (R), 1968 (T,R), 1970 (T,R), 1975 (R), 1979 (R), 1993 (T,R), 1994 (R), 1996 (R), 1999 (R), 2001 (T), 2006 (T,R), 2016 (T), 2022 (R)
1,2-Dibromoethane (023)	1965 (T,R), 1966 (T,R), 1967 (R), 1968 (R), 1971 (R), 1979 (R), 1985 (R)

Dicamba (240)	2010 (T,R), 2011 (R), 2012 (R), 2013 (R), 2019 (T, R)
Dichlobenil (274)	2014 (T,R)
Dicloran (083)	2003 (R)
Dichlorfluamid (082)	1969 (T,R), 1974 (T,R), 1977 (T,R), 1979 (T,R), 1981 (R), 1982 (R), 1983 (T,R), 1985 (R)
1,2-Dichloroethane (024)	1965 (T,R), 1967 (R), 1971 (R), 1979 (R), 1985 (R)
Dichlorvos (025)	1965 (T,R), 1966 (T,R), 1967 (T,R), 1969 (R), 1970 (T,R), 1974 (R), 1977 (T), 1993 (T,R), 2011 (T), 2012 (R)
Dicloran (083)	1974 (T,R), 1977 (T,R), 1998 (T,R)
Dicofol (026)	1968 (T,R), 1970 (R), 1974 (R), 1992 (T,R), 1994 (R), 2011 (T), 2012 (R)
Dieldrin (001)	1965 (T), 1966 (T,R), 1967 (T,R), 1968 (R), 1969 (R), 1970 (T,R), 1974 (R), 1975 (R), 1977 (T), 1990 (R), 1992 (R)
Difenoconazole (224)	2007 (T,R), 2010 (R), 2013 (R), 2015 (R), 2017 (R), 2021 (R), 2022 (R)
Diflubenzuron (130)	1981 (T,R), 1983 (R), 1984 (T,R), 1985 (T,R), 1988 (R), 2001 (T), 2002 (R), 2011 (R)
Dimethenamid-P (214)	2005 (T,R)
Dimethipin (151)	1985 (T,R), 1987 (T,R), 1988 (T,R), 1999 (T), 2001 (R), 2004 (T)
Dimethoate (027)	1965 (T), 1966 (T), 1967 (T,R), 1970 (R), 1973 (R in evaluation of formothion), 1977 (R), 1978 (R), 1983 (R) 1984 (T,R), 1986 (R), 1987 (T,R), 1988 (R), 1990 (R), 1991 (corr. to 1990 evaluation), 1994 (R), 1996 (T), 1998 (R), 2003 (T,R), 2004 (corr. to 2003 report), 2006 (R), 2008 (R), 2019 (T, R), 2022 (T, R)
Dimethomorph (225)	2007 (T,R), 2014 (R), 2016 (R)
Dimethrin	1965 (T)
Dinocap (087)	1969 (T,R), 1974 (T,R), 1989 (T,R), 1992 (R), 1998 (R), 1999 (R), 2000 (T), 2001 (R)
Dinotefuran (255)	2012 (T,R)
Dioxathion (028)	1968 (T,R), 1972 (R)
Diphenyl (029)	1966 (T,R), 1967 (T)
Diphenylamine (030)	1969 (T,R), 1976 (T,R), 1979 (R), 1982 (T), 1984 (T,R), 1998 (T), 2001 (R), 2003 (R), 2008 (R)
Diquat (031)	1970 (T,R), 1972 (T,R), 1976 (R), 1977 (T,R), 1978 (R), 1994 (R), 2013 (T,R), 2018 (R)

Disulfoton (074)	1973 (T,R), 1975 (T,R), 1979 (R), 1981 (R), 1984 (R), 1991 (T,R), 1992 (corr. to 1991 report, Annex I), 1994 (R), 1996 (T), 1998 (R), 2006 (R)
Dithianon (180)	1992 (T,R), 1995 (R), 1996 (corr. to 1995 report), 2010 (T), 2013 (T,R)
Dithiocarbamates (105)	1965 (T), 1967 (T,R), 1970 (T,R), 1983 (R propineb, thiram), 1984 (R propineb), 1985 (R), 1987 (T thiram), 1988 (R thiram), 1990 (R), 1991 (corr. to 1990 evaluation), 1992 (T thiram), 1993 (T,R), 1995 (R), 1996 (T,R ferbam, ziram; R thiram), 2004 (R), 2012 (R), 2014 (R)
4,6-Dinitro- <i>ortho</i> -cresol (DNOC)	1965 (T)
Dodine (084)	1974 (T,R), 1976 (T,R), 1977 (R), 2000 (T), 2003 (R), 2004 (corr. to 2003 report)
Edifenphos (099)	1976 (T,R), 1979 (T,R), 1981 (T,R)
Emamectin benzoate (247)	2011 (T,R), 2014 (R), 2022 (R)
Endosulfan (032)	1965 (T), 1967 (T,R), 1968 (T,R), 1971 (R), 1974 (R), 1975 (R), 1982 (T), 1985 (T,R), 1989 (T,R), 1993 (R), 1998 (T), 2006 (R), 2010 (R)
Endrin (033)	1965 (T), 1970 (T,R), 1974 (R), 1975 (R), 1990 (R), 1992 (R)
Esfenvalerate (204)	2002 (T,R)
Ethephon (106)	1977 (T,R), 1978 (T,R), 1983 (R), 1985 (R), 1993 (T), 1994 (R), 1995 (T), 1997 (T), 2002 (T), 2015 (T, R)
Ethiofencarb (107)	1977 (T,R), 1978 (R), 1981 (R), 1982 (T,R), 1983 (R)
Ethion (034)	1968 (T,R), 1969 (R), 1970 (R), 1972 (T,R), 1975 (R), 1982 (T), 1983 (R), 1985 (T), 1986 (T), 1989 (T), 1990 (T), 1994 (R), 2021 (T, R)
Ethiprole (304)	2018 (T, R), 2021 (R)
Ethoprophos (149)	1983 (T), 1984 (R), 1987 (T), 1999 (T), 2004 (R)
Ethoxyquin (035)	1969 (T,R), 1998 (T), 1999 (R), 2005 (T), 2008 (R)
Ethylene dibromide	See 1,2-Dibromoethane
Ethylene dichloride	See 1,2-Dichloroethane
Ethylene oxide	1965 (T,R), 1968 (T,R), 1971 (R)
Ethylenethiourea (ETU) (108)	1974 (R), 1977 (T,R), 1986 (T,R), 1987 (R), 1988 (T,R), 1990 (R), 1993 (T,R)
Etofenprox (184)	1993 (T,R), 2011 (T,R)
Etoxazole (241)	2010 (T,R), 2011 (R)

Etrimfos (123)	1980 (T,R), 1982 (T,R), 1986 (T,R), 1987 (R), 1988 (R), 1989 (R), 1990 (R)
Famoxadone (208)	2003 (T,R), 2022 (R)
Fenamidone (264)	2013 (T), 2014 (T,R)
Fenamiphos (085)	1974 (T,R), 1977 (R), 1978 (R), 1980 (R), 1985 (T), 1987 (T), 1997 (T), 1999 (R), 2002 (T), 2006 (R)
Fenarimol (192)	1995 (T,R,E), 1996 (R and corr. to 1995 report)
Fenazaquin (297)	2017 (T, R), 2019 (R), 2022 (R)
Fenbuconazole (197)	1997 (T,R), 2009 (R), 2012 (T), 2013 (R), 2021 (R)
Fenbutatin oxide (109)	1977 (T,R), 1979 (R), 1992 (T), 1993 (R)
Fenchlorfos (036)	1968 (T,R), 1972 (R), 1983 (R)
Fenhexamid (215)	2005 (T,R), 2021 (R)
Fenitrothion (037)	1969 (T,R), 1974 (T,R), 1976 (R), 1977 (T,R), 1979 (R), 1982 (T), 1983 (R), 1984 (T,R), 1986 (T,R), 1987 (R and corr. to 1986 R evaluation), 1988 (T), 1989 (R), 2000 (T), 2003 (R), 2004 (R, corr. to 2003 report), 2007 (T,R)
Fenpicoxamid (305)	2018 (T,R), 2021 (T, R)
Fenpropathrin (185)	1993 (T,R), 2006 (R), 2012 (T), 2014 (R)
Fenpropimorph (188)	1994 (T), 1995 (R), 1999 (R), 2001 (T), 2004 (T), 2016 (T), 2017 (T, R)
Fenpyrazamine (298)	2017 (R, T)
Fenpyroximate (193)	1995 (T,R), 1996 (corr. to 1995 report), 1999 (R), 2004 (T), 2007 (T), 2010 (R), 2013 (R), 2017 (T, R), 2018 (R), 2021 (T, R)
Fensulfothion (038)	1972 (T,R), 1982 (T), 1983 (R)
Fenthion (039)	1971 (T,R), 1975 (T,R), 1977 (R), 1978 (T,R), 1979 (T), 1980 (T), 1983 (R), 1989 (R), 1995 (T,R,E), 1996 (corr. to 1995 report), 1997 (T), 2000 (R)
Fentin compounds (040)	1965 (T), 1970 (T,R), 1972 (R), 1986 (R), 1991 (T,R), 1993 (R), 1994 (R)
Fenvalerate (119)	1979 (T,R), 1981 (T,R), 1982 (T), 1984 (T,R), 1985 (R), 1986 (T,R), 1987 (R and corr. to 1986 report), 1988 (R), 1990 (R), 1991 (corr. to 1990 R evaluation), 2012 (T,R)
Ferbam	See Dithiocarbamates, 1965 (T), 1967 (T,R), 1996 (T,R)
Fipronil (202)	1997 (T), 2000 (T), 2001 (R), 2016 (R), 2021 (T, R)
Fipronil-desulfinyl	1997 (T), 2021 (T, R)
Flonicamid (282)	2015 (T,R), 2016 (R), 2017 (R), 2019 (R)
Fluazaindolizine (327)	2022 (T, R)

Fluazifop-P-butyl	2016 (T,R), 2019 (R)
Fluazinam (306)	2018 (T,R)
Flubendiamide (242)	2010 (T,R)
Flucythrinate (152)	1985 (T,R), 1987 (R), 1988 (R), 1989 (R), 1990 (R), 1993 (R)
Fludioxonil (211)	2004 (T,R), 2006 (R), 2010 (R), 2012 (R), 2013 (R), 2018 (R), 2022 (T, R)
Fluensulfone (265)	2013 (T), 2014 (T,R), 2016 (T,R), 2017 (R), 2019 (R), 2021 (R)
Flufenoxuron (275)	2014 (T,R)
Fluindapyr (328)	2022 (T, R)
Flumethrin (195)	1996 (T,R)
Fluopicolide (235)	2009 (T,R), 2014 (R)
Fluopyram (243)	2010 (T,R), 2012 (R), 2014 (R), 2015 (R), 2017 (R), 2021 (R)
Flupyradifurone (285)	2015 (T), 2016 (R), 2017 (R), 2019 (R), 2022 (R)
Flusilazole (165)	1989 (T,R), 1990 (R), 1991 (R), 1993 (R), 1995 (T), 2007 (T, R)
Flutianil (319)	2021 (T, R)
Flutolanil (205)	2002 (T,R), 2013 (R)
Flutriafol (248)	2011 (T,R), 2015 (R), 2022 (R)
Fluxapyroxad (256)	2012 (T,R), 2015 (R), 2018 (T,R)
Folpet (041)	1969 (T,R), 1973 (T), 1974 (R), 1982 (T), 1984 (T,R), 1986 (T), 1987 (R), 1990 (T,R), 1991 (corr. to 1990 R evaluation), 1993 (T,R), 1994 (R), 1995 (T), 1997 (R), 1998 (R), 1999 (R) , 2002 (T), 2004 (T), 2007 (T)
Formothion (042)	1969 (T,R), 1972 (R), 1973 (T,R), 1978 (R), 1998 (R)
Fosetyl Aluminium (302)	2017 (T, R), 2019 (R)
Glufosinate-ammonium (175)	1991 (T,R), 1992 (corr. to 1991 report, Annex I), 1994 (R), 1998 (R), 1999 (T,R), 2012 (T,R), 2014 (R)
Glyphosate (158)	1986 (T,R), 1987 (R and corr. to 1986 report), 1988 (R), 1994 (R), 1997 (T,R), 2004 (T), 2005 (R), 2011 (T,R), 2013 (R), 2016 (T), 2019 (R)
Guazatine (114)	1978 (T,R), 1980 (R), 1997 (T,R)
Haloxypop (194)	1995 (T,R), 1996 (R and corr. to 1995 report), 2001 (R), 2006 (T), 2009 (R)

Heptachlor (043)	1965 (T), 1966 (T,R), 1967 (R), 1968 (R), 1969 (R), 1970 (T,R), 1974 (R), 1975 (R), 1977 (R), 1987 (R), 1991 (T,R), 1992 (corr. to 1991 report, Annex I), 1993 (R), 1994 (R)
Hexachlorobenzene (044)	1969 (T,R), 1973 (T,R), 1974 (T,R), 1978 (T), 1985 (R)
Hexaconazole (170)	1990 (T,R), 1991 (R and corr. to 1990 R evaluation), 1993 (R)
Hexythiazox (176)	1991 (T,R), 1994 (R), 1998 (R), 2008 (T), 2009 (R)
Hydrogen cyanide (045)	1965 (T,R)
Hydrogen phosphide (046)	1965 (T,R), 1966 (T,R), 1967 (R), 1969 (R), 1971 (R)
Imazalil (110)	1977 (T,R), 1980 (T,R), 1984 (T,R), 1985 (T,R), 1986 (T), 1988 (R), 1989 (R), 1991 (T), 1994 (R), 2000 (T), 2001 (T), 2005 (T), 2018 (T,R), 2021 (R)
Imazamox (276)	2014 (T,R), 2017 (R)
Imazapic (266)	2013 (T,R), 2015 (R)
Imazapyr (267)	2013 (T,R), 2015 (R), 2017 (R)
Imazethapyr (289)	2016 (T,R)
Imidacloprid (206)	2001 (T), 2002 (R), 2006 (R), 2008 (R), 2012 (R), 2015 (R), 2017 (R)
Indoxacarb (216)	2005 (T,R), 2007 (R), 2009 (R), 2012 (R), 2013 (R), 2022 (R)
Inpyrfluxam(329)	2022 (T, R)
Isoflucypram (330)	2022 (T, R)
Iprodione (111)	1977 (T,R), 1980 (R), 1992 (T), 1994 (R), 1995 (T), 2001 (R)
Isofenphos (131)	1981 (T,R), 1982 (T,R), 1984 (R), 1985 (R), 1986 (T,R), 1988 (R), 1992 (R)
Isofetamid (290)	2016 (T,R), 2018 (R)
Isoprothiolane (299)	2017 (T, R), 2021 (R), 2021 (T)
Isopyrazam (249)	2011 (T,R), 2017 (R)
Isoxaflutole (268)	2013 (T,R), 2021 (R)
Kresoxim-methyl (199)	1998 (T,R), 2001 (R), 2018 (T,R), 2019 (R)
Lead arsenate	1965 (T), 1968 (T,R)
Leptophos (088)	1974 (T,R), 1975 (T,R), 1978 (T,R)
Lindane (048)	1965 (T), 1966 (T,R), 1967 (R), 1968 (R), 1969 (R), 1970 (T,R, published as Annex VI to 1971 evaluations), 1973 (T,R), 1974 (R), 1975 (R), 1977 (T,R), 1978 (R), 1979 (R), 1989 (T,R), 1997 (T), 2002 (T), 2003 (R), 2004 (corr. to 2003 report), 2015 (R)

Lufenuron (286)	2015 (T, R), 2018 (R)
Malathion (049)	1965 (T), 1966 (T,R), 1967 (corr. to 1966 R evaluation), 1968 (R), 1969 (R), 1970 (R), 1973 (R), 1975 (R), 1977 (R), 1984 (R), 1997 (T), 1999 (R), 2000 (R), 2003 (T), 2004 (R), 2005 (R), 2008 (R), 2013 (R), 2016 (T)
Maleic hydrazide (102)	1976 (T,R), 1977 (T,R), 1980 (T), 1984 (T,R), 1996 (T), 1998 (R)
Mancozeb (050)	1967 (T,R), 1970 (T,R), 1974 (R), 1977 (R), 1980 (T,R), 1993 (T,R), 2022 (T, R)
Mandestrobin (307)	2018 (T,R), 2019 (R)
Mandipropamid (231)	2008 (T,R), 2013 (R), 2018 (R), 2021 (R), 2022 (T, R)
Maneb	See Dithiocarbamates, 1965 (T), 1967 (T,R), 1987 (T), 1993 (T,R)
MCPA (257)	2012 (T,R)
Mecarbam (124)	1980 (T,R), 1983 (T,R), 1985 (T,R), 1986 (T,R), 1987 (R)
Mefentrifluconazole (320)	2021 (T), 2022 (R)
Meptyldinocap (244)	2010 (T, R)
Mesotrione (277)	2014 (T, R), 2019 (T, R)
Metaflumizone (236)	2009 (T, R), 2019 (T, R)
Metalaxyl (138)	1982 (T, R), 1984 (R), 1985 (R), 1986 (R), 1987 (R), 1989 (R), 1990 (R), 1992 (R), 1995 (R), 2021 (T, R), 2022 (R)
Metalaxyl –M (212)	2002 (T), 2004 (R), 2021 (R)
Metconazole (313)	2019 (T, R), 2021(R)
Methacrifos (125)	1980 (T,R), 1982 (T), 1986 (T), 1988 (T), 1990 (T,R), 1992 (R)
Methamidophos (100)	1976 (T,R), 1979 (R), 1981 (R), 1982 (T,R), 1984 (R), 1985 (T), 1989 (R), 1990 (T,R), 1994 (R), 1996 (R), 1997 (R), 2002 (T), 2003 (R), 2004 (R, corr. to 2003 report)
Methidathion (051)	1972 (T,R), 1975 (T,R), 1979 (R), 1992 (T,R), 1994 (R), 1997 (T), 2022 (T, R)
Methiocarb (132)	1981 (T,R), 1983 (T,R), 1984 (T), 1985 (T), 1986 (R), 1987 (T,R), 1988 (R), 1998 (T), 1999 (R), 2005 (R)
Methomyl (094)	1975 (R), 1976 (R), 1977 (R), 1978 (R), 1986 (T,R), 1987 (R), 1988 (R), 1989 (T,R), 1990 (R), 1991 (R), 2001 (T,R), 2004 (R), 2008 (R)
Methoprene (147)	1984 (T,R), 1986 (R), 1987 (T and corr. to 1986 report), 1988 (R), 1989 (R), 2001 (T), 2005 (R), 2016 (R), 2019 (R), 2021 (R)
Methoxychlor	1965 (T), 1977 (T)

Methoxyfenozide (209)	2003 (T,R), 2004 (corr. to 2003 report), 2006 (R), 2009 (R), 2012 (R), 2021 (R)
Methyl bromide (052)	See Bromomethane
Metrafenone (278)	2014 (T,R), 2016 (R)
Metiram (186)	1993 (T), 1995 (R)
Mevinphos (053)	1965 (T), 1972 (T,R), 1996 (T), 1997 (E,R), 2000 (R)
MGK (264)	1967 (T,R)
Monocrotophos (054)	1972 (T,R), 1975 (T,R), 1991 (T,R), 1993 (T), 1994 (R)
Myclobutanil (181)	1992 (T,R), 1997 (R), 1998 (R), (2001 (R)), 2014 (T,R)
Nabam	See Dithiocarbamates, 1965 (T), 1976 (T,R)
Natamycin (300)	2017 (T, R)
Nitrofen (140)	1983 (T,R)
Norflurazon (308)	2018 (T,R)
Novaluron (217)	2005 (T,R), 2010 (R)
Omethoate (055)	1971 (T,R), 1975 (T,R), 1978 (T,R), 1979 (T), 1981 (T,R), 1984 (R), 1985 (T), 1986 (R), 1987 (R), 1988 (R), 1990 (R), 1998 (R)
Organomercury compounds	1965 (T), 1966 (T,R), 1967 (T,R)
Oxamyl (126)	1980 (T,R), 1983 (R), 1984 (T), 1985 (T,R), 1986 (R), 2002 (T,R), 2017 (T, R)
Oxathiapiprolin (291)	2016 (T,R), 2018 (R)
Oxydemeton-methyl (166)	1965 (T, as demeton-S-methyl sulfoxide), 1967 (T), 1968 (R), 1973 (T,R), 1982 (T), 1984 (T,R), 1989 (T,R), 1992 (R), 1998 (R), 1999 (corr. to 1992 report), 2002 (T), 2004 (R)
Oxythioquinox	See Chinomethionat
Paclobutrazol (161)	1988 (T,R), 1989 (R)
Paraquat (057)	1970 (T,R), 1972 (T,R), 1976 (T,R), 1978 (R), 1981 (R), 1982 (T), 1985 (T), 1986 (T), 2003 (T), 2004 (R), 2009 (R)
Parathion (058)	1965 (T), 1967 (T,R), 1969 (R), 1970 (R), 1984 (R), 1991 (R), 1995 (T,R), 1997 (R), 2000 (R)
Parathion-methyl (059)	1965 (T), 1968 (T, R), 1972 (R), 1975 (T,R), 1978 (T,R), 1979 (T), 1980 (T), 1982 (T), 1984 (T,R), 1991 (R), 1992 (R), 1994 (R), 1995 (T), 2000 (R), 2003 (R)
Penconazole (182)	1992 (T, R), 1995 (R), 2015 (T), 2016 (R)
Pendimethalin (292)	2016 (T, R), 2019 (R), 2021 (R)

Penthiopyrad (253)	2011 (T), 2012 (R), 2013 (R), 2019 (R)
Permethrin (120)	1979 (T, R), 1980 (R), 1981 (T,R), 1982 (R), 1983 (R), 1984 (R), 1985 (R), 1986 (T,R), 1987 (T), 1988 (R), 1989 (R), 1991 (R), 1992 (corr. to 1991 report), 1999 (T)
2-Phenylphenol (056)	1969 (T,R), 1975 (R), 1983 (T), 1985 (T,R), 1989 (T), 1990 (T,R), 1999 (T,R), 2002 (R)
Phenothrin (127)	1979 (R), 1980 (T,R), 1982 (T), 1984 (T), 1987 (R), 1988 (T,R)
Phenthoate (128)	1980 (T,R), 1981 (R), 1984 (T)
Phorate (112)	1977 (T,R), 1982 (T), 1983 (T), 1984 (R), 1985 (T), 1990 (R), 1991 (R), 1992 (R), 1993 (T), 1994 (T), 1996 (T), 2004 (T), 2005 (R), 2012 (R), 2014 (R)
Phosalone (060)	1972 (T,R), 1975 (R), 1976 (R), 1993 (T), 1994 (R), 1997 (T), 1999 (R), 2001 (T)
Phosmet (103)	1976 (R), 1977 (corr. to 1976 R evaluation), 1978 (T,R), 1979 (T,R), 1981 (R), 1984 (R), 1985 (R), 1986 (R), 1987 (R and corr. to 1986 R evaluation), 1988 (R), 1994 (T), 1997 (R), 1998 (T), 2002 (R), 2003 (R), 2007 (R)
Phosphine	See Hydrogen phosphide
Phosphamidon (061)	1965 (T), 1966 (T), 1968 (T,R), 1969 (R), 1972 (R), 1974 (R), 1982 (T), 1985 (T), 1986 (T)
Phosphonic acid (301)	2017 (T, R)
Phoxim (141)	1982 (T), 1983 (R), 1984 (T,R), 1986 (R), 1987 (R), 1988 (R)
Picoxystrobin (258)	2012 (T,R), 2013 (R), 2016 (R), 2017 (R), 2019 (R)
Pinoxaden (293)	2016 (T,R)
Piperonyl butoxide (062)	1965 (T,R), 1966 (T,R), 1967 (R), 1969 (R), 1972 (T,R), 1992 (T,R), 1995 (T), 2001 (R), 2002 (R)
Pirimicarb (101)	1976 (T,R), 1978 (T,R), 1979 (R), 1981 (T,R), 1982 (T), 1985 (R), 2004 (T), 2006 (R)
Pirimiphos-methyl (086)	1974 (T,R), 1976 (T,R), 1977 (R), 1979 (R), 1983 (R), 1985 (R), 1992 (T), 1994 (R), 2003 (R), 2004 (R, corr. to 2003 report), 2006 (T)
Prochloraz (142)	1983 (T,R), 1985 (R), 1987 (R), 1988 (R), 1989 (R), 1990 (R), 1991 (corr. to 1990 report, Annex I, and R evaluation), 1992 (R), 2001 (T), 2004 (R), 2009 (R)
Procymidone(136)	1981 (R), 1982 (T), 1989 (T,R), 1990 (R), 1991 (corr. to 1990 Annex I), 1993 (R), 1998 (R), 2007 (T)
Profenofos (171)	1990 (T,R), 1992 (R), 1994 (R), 1995 (R), 2007 (T), 2008 (R), 2011 (R), 2018 (R)

Propamocarb (148)	1984 (T,R), 1986 (T,R), 1987 (R), 2005 (T), 2006 (R), 2014 (R), 2018 (R)
Propargite (113)	1977 (T,R), 1978 (R), 1979 (R), 1980 (T,R), 1982 (T,R), 1999 (T), 2002 (R), 2006 (R)
Propham (183)	1965 (T), 1992 (T,R)
Propiconazole (160)	1987 (T, R), 1991 (R), 1994 (R), 2004 (T), 2006 (R), 2007 (R), 2013 (R), 2014 (R), 2015 (R), 2017 (R), 2018 (R)
Propineb	1977 (T, R), 1980 (T), 1983 (T), 1984 (R), 1985 (T, R), 1993 (T, R), 2004 (R)
Propoxur (075)	1973 (T, R), 1977 (R), 1981 (R), 1983 (R), 1989 (T), 1991 (R), 1996 (R)
Propylene oxide (250)	2011 (T, R), 2017 (T, R)
Propylenethiourea (PTU, 150)	1993 (T, R), 1994 (R), 1999 (T)
Prothioconazole (232)	2008 (T, R), 2009 (R), 2014 (R), 2017 (R), 2021 (R)
Pydiflumetofen (309)	2018 (T, R), 2019 (R), 2021 (R)
Pyflubumide (314)	2019 (T, R)
Pymetrozine (279)	2014 (T, R)
Pyraclostrobin (210)	2003 (T), 2004 (R), 2006 (R), 2011 (R), 2012 (R), 2014 (R), 2018 (T, R)
Pyrasulfotole (321)	2021 (T, R)
Pyraziflumid (322)	2021 (T, R)
Pyrazophos (153)	1985 (T, R), 1987 (R), 1992 (T,R), 1993 (R)
Pyrethrins (063)	1965 (T), 1966 (T, R), 1967 (R), 1968 (R), 1969 (R), 1970 (T), 1972 (T,R), 1974 (R), 1999 (T), 2000 (R), 2003 (T,R), 2005 (R)
Pyridate (315)	2019 (T), 2022 (R)
Pyrifluquinazon (316)	2019 (T, R)
Pyrimethanil (226)	2007 (T, R), 2013 (R)
Pyriofenone (310)	2018 (T, R), 2019 (R)
Pyriproxyfen (200)	1999 (R, T), 2000 (R), 2001 (T), 2018 (R), 2019 (R)
Quinclorac (287)	2015 (T, R), 2017 (R), 2022 (R)
Quinoxifen (223)	2006 (T, R), 2021 (R)
Quintozene (064)	1969 (T, R), 1973 (T,R), 1974 (R), 1975 (T,R), 1976 (Annex I, corr. to 1975 R evaluation), 1977 (T,R), 1995 (T,R), 1998 (R), 2022 (T, R)
Saflufenacil (251)	2011 (T, R), 2016 (R), 2017 (R)
Sedaxane (259)	2012 (T, R), 2014 (R)

Spices	2004 (R), 2005 (R), 2007 (R), 2010 (R), 2015 (R), 2019 (R)
Spinetoram (233)	2008 (T, R), 2012 (R), 2017 (R), 2021 (R)
Spinosad (203)	2001 (T, R), 2004 (R), 2008 (R), 2011 (R)
Spirodiclofen (237)	2009 (T, R)
Spiromesifen (294)	2016 (T, R), 2021 (R), 2022 (R)
Spiropidion (323)	2021 (T, R)
Spirotetramat (234)	2008 (T, R), 2011 (R), 2012 (R), 2013 (R), 2015 (R), 2019 (R)
Sulfoxaflor (252)	2011 (T, R), 2013 (R), 2014 (R), 2016 (R), 2018 (R), 2021 (R)
Sulfuryl fluoride (218)	2005 (T, R)
2,4,5-T (121)	1970 (T,R), 1979 (T,R), 1981 (T)
Tebuconazole (189)	1994 (T, R), 1996 (corr. to Annex II of 1995 report), 1997 (R), 2008 (R), 2010 (T), 2011 (R), 2015 (R), 2017 (R), 2019 (R), 2021 (R)
Tebufenozide (196)	1996 (T, R), 1997 (R), 1999 (R), 2001 (T, R), 2003 (T)
Tecnazine (115)	1974 (T, R), 1978 (T, R), 1981 (R), 1983 (T), 1987 (R), 1989 (R), 1994 (T, R)
Teflubenzuron (190)	1994 (T), 1996 (R), 2016 (T, R)
Temephos	2006 (T)
Terbufos (167)	1989 (T, R), 1990 (T,R), 2003 (T), 2005 (R)
Tetraniliprole (324)	2021 (T), 2022 (T, R)
Thiabendazole (065)	1970 (T, R), 1971 (R), 1972 (R), 1975 (R), 1977 (T,R), 1979 (R), 1981 (R), 1997 (R), 2000 (R), 2006 (T,R), 2019 (T, R)
Thiacloprid (223)	2006 (T, R)
Thiamethoxam (245)	2010 (T, R), 2011 (R), 2012 (R), 2014 (R), 2021 (R)
Thiodicarb (154)	1985 (T, R), 1986 (T), 1987 (R), 1988 (R), 2000 (T), 2001 (R)
Thiometon (076)	1969 (T, R), 1973 (T,R), 1976 (R), 1979 (T,R), 1988 (R)
Thiophanate-methyl (077)	1973 (T, R), 1975 (T, R), 1977 (T), 1978 (R), 1988 (R), 2002 (R), 1990 (R), 1994 (R), 1995 (T,E), 1998 (T,R), 2006 (T), 2017 (T)
Thiram (105)	See Dithiocarbamates, 1965 (T), 1967 (T, R), 1970 (T,R), 1974 (T), 1977 (T), 1983 (R), 1984 (R), 1985 (T,R), 1987 (T), 1988 (R), 1989 (R), 1992 (T), 1996 (R)

Tioxazafen (211)	2018 (T, R)
Tolclofos-methyl (191)	1994 (T, R), 1996 (corr. to Annex II of 1995 report), 2019 (T, R)
Tolfenpyrad (269)	2013 (T), 2016 (R)
Tolyfluanid (162)	1988 (T, R), 1990 (R), 1991 (corr. to 1990 report), 2002 (T, R), 2003 (R)
Toxaphene	See Camphechlor
Triadimefon (133)	1979 (R), 1981 (T, R), 1983 (T,R), 1984 (R), 1985 (T,R), 1986 (R), 1987 (R and corr. to 1986 R evaluation), 1988 (R), 1989 (R), 1992 (R), 1995 (R), 2004 (T), 2007 (R)
Triadimenol (168)	1989 (T, R), 1992 (R), 1995 (R), 2004 (T), 2007 (R), 2014 (R)
Triazolylalanine	1989 (T, R)
Triazophos (143)	1982 (T), 1983 (R), 1984 (corr. to 1983 report, Annex I), 1986 (T, R), 1990 (R), 1991 (T and corr. to 1990 R evaluation), 1992 (R), 1993 (T, R), 2002 (T), 2007 (R), 2010 (R), 2013 (R)
Trichlorfon (066)	1971 (T,R), 1975 (T,R), 1978 (T,R), 1987 (R)
Trichloronat	1971 (T,R)
Trichloroethylene	1968 (R)
Tricyclohexyltin hydroxide	See Cyhexatin
Trifloxystrobin (213)	2004 (T, R), 2012 (R), 2015 (R), 2017 (R), 2021 (R)
Triflumezopyrim (303)	2017 (T, R)
Triflumuron (317)	2022 (T, R)
Triflumizole (270)	2013 (T, R)
Triforine (116)	1977 (T), 1978 (T, R), 1997 (T), 2004 (R), 2014 (T,R)
Trinexapac-ethyl (271)	2013 (T,R), 2021(T, R)
Triphenyltin compounds	See Fentin compounds
Vamidothion (078)	1973 (T, R), 1982 (T), 1985 (T, R), 1987 (R), 1988 (T), 1990 (R), 1992 (R)
Vinclozolin (159)	1986 (T, R), 1987 (R and corr. to 1986 report and R evaluation), 1988 (T, R), 1989 (R), 1990 (R), 1992 (R), 1995 (T)
Zineb (105)	See Dithiocarbamates, 1965 (T), 1967 (T, R), 1993 (T)
Ziram (105)	See Dithiocarbamates, 1965 (T), 1967 (T, R), 1996 (T,R)
Zoxamide (227)	2007 (T, R), 2009 (R)

Annex 3: International estimated daily intakes (IEDIs) of pesticide residues

AFIDOPYROPEN (312)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.08 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day							
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
FC 0001	Group of Citrus fruit, raw (incl kumquat commodities)	RAC	0.0535	32.25	1.73	11.67	0.62	16.70	0.89	76.01	4.07	33.90	1.81	92.97	4.97
JF 0001	Group of Citrus fruit, juice	PP	0.012	1.30	0.02	2.37	0.03	0.22	0.00	13.88	0.17	0.75	0.01	2.63	0.03
FP 0226	Apple, raw (incl cider, excl juice)	RAC	0.021	13.49	0.28	26.63	0.56	15.05	0.32	16.28	0.34	6.47	0.14	47.88	1.01
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.013	0.32	0.00	3.07	0.04	0.07	0.00	5.00	0.07	0.29	0.00	5.57	0.07
FP 0228	Loquat, raw (incl processed) (i.e. Japanese medlar)	RAC	0.021	0.59	0.01	0.36	0.01	0.46	0.01	1.88	0.04	NC	-	1.15	0.02
FP 0229	Medlar, raw (incl processed)	RAC	0.021	0.47	0.01	0.29	0.01	0.36	0.01	1.49	0.03	NC	-	0.92	0.02
FP 0230	Pear, raw	RAC	0.021	2.16	0.05	6.24	0.13	0.05	0.00	4.07	0.09	1.16	0.02	5.34	0.11
FP 0231	Quince, raw	RAC	0.021	0.73	0.02	0.54	0.01	0.01	0.00	0.07	0.00	0.06	0.00	1.31	0.03
FS 0013	Subgroup of Cherries, raw	RAC	0.02	0.92	0.02	9.15	0.18	0.01	0.00	0.61	0.01	0.06	0.00	6.64	0.13
FS 0014	Subgroup of Plums, raw (incl dried plums)	RAC	0.02	2.67	0.05	8.77	0.18	0.07	0.00	3.03	0.06	0.70	0.01	4.34	0.09
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.02	8.01	0.16	5.87	0.12	0.18	0.00	8.19	0.16	1.64	0.03	22.46	0.45
FB 0275	Strawberry, raw	RAC	0.0539	0.70	0.04	2.01	0.11	0.04	0.00	1.36	0.07	0.37	0.02	2.53	0.14
VB 0042	Subgroup of Flowerhead Brassica, raw	RAC	0.13	2.54	0.33	0.49	0.06	0.01	0.00	3.57	0.46	7.79	1.01	3.12	0.41
VB 0041	Cabbages, head, raw	RAC	0.02	2.73	0.05	27.92	0.56	0.55	0.01	4.47	0.09	4.27	0.09	10.25	0.21
VC 0424	Cucumber, raw	RAC	0.17	8.01	1.36	30.66	5.21	1.45	0.25	19.84	3.37	0.27	0.05	34.92	5.94
VC 0431	Squash, Summer (Courgette, Marrow, Zucchini, Zucchini), raw	RAC	0.039	0.78	0.03	2.06	0.08	0.30	0.01	1.61	0.06	2.25	0.09	2.36	0.09
VC 2040	Subgroup of Melons, Pumpkins and Winter squashes	RAC	0.027	42.62	1.15	46.85	1.26	4.21	0.11	67.02	1.81	12.84	0.35	110.47	2.98
VO 0448	Tomato, raw	RAC	0.03	41.73	1.25	75.65	2.27	10.66	0.32	82.87	2.49	24.75	0.74	200.93	6.03
-	Tomato, canned (& peeled)	PP	0.016	0.20	0.00	0.31	0.00	0.02	0.00	1.11	0.02	0.11	0.00	1.50	0.02
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.016	2.34	0.04	1.33	0.02	1.57	0.03	4.24	0.07	0.34	0.01	2.83	0.05
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.0026	0.29	0.00	0.29	0.00	0.01	0.00	0.38	0.00	0.05	0.00	0.14	0.00
VO 0051	Subgroup of peppers, raw (Capsicum spp. Only), excl okra	RAC	0.036	5.42	0.20	9.91	0.36	3.97	0.14	7.63	0.27	2.59	0.09	23.68	0.85
VO 0440	Egg plant, raw (i.e. aubergine)	RAC	0.03	5.58	0.17	4.31	0.13	0.89	0.03	9.31	0.28	13.64	0.41	20.12	0.60
VL 2050	Subgroup of Leafy greens	RAC	0.88	3.93	3.46	5.28	4.65	3.07	2.70	14.53	12.79	8.25	7.26	12.75	11.22
VL 0054	Subgroup of Leaves of Brassicaceae, raw	RAC	2.5	2.63	6.58	9.27	23.18	1.86	4.65	5.82	14.55	19.53	48.83	4.90	12.25
VD 0541	Soya bean, dry, raw (incl paste, incl curd, incl oil, incl sauce)	RAC	0.02	72.79	1.46	59.05	1.18	20.55	0.41	74.20	1.48	61.12	1.22	73.24	1.46
VR 2071	Subgroup of tuberous and corm vegetables, raw (incl processed)	RAC	0	63.11	0.00	316.33	0.00	651.91	0.00	72.06	0.00	84.88	0.00	132.70	0.00

Annex 3

AFIDOPYROPEN (312)		International Estimated Daily Intake (IEDI)		ADI = 0 - 0.08 mg/kg bw																							
Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day																			
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake												
VS 2080	Subgroup of stems and petioles	RAC	0.54	3.11	1.68	5.52	2.98	3.42	1.85	8.29	4.48	0.02	0.01	4.00	2.16												
GC 0651	Sorghum, raw (incl flour, incl beer) (i.e. Chicken corn, Dari seed, Durra, Feterita)	RAC	0.0365	4.34	0.16	0.01	0.00	16.25	0.59	15.82	0.58	10.97	0.40	2.92	0.11												
TN 0085	Group of Tree nuts, raw (incl processed)	RAC	0.02	4.06	0.08	3.27	0.07	7.01	0.14	13.93	0.28	14.01	0.28	9.36	0.19												
SO 0691	Cotton seed, raw (incl oil)	RAC	0.02	20.53	0.41	9.80	0.20	6.42	0.13	4.73	0.09	7.14	0.14	18.68	0.37												
HH 0756	Coriander leaves (cilantro), raw	RAC	2.5	0.13	0.33	0.23	0.58	0.14	0.35	0.35	0.88	NC	-	0.17	0.43												
HH 0730	Dill leaves, raw	RAC	2.5	0.16	0.40	0.29	0.73	0.18	0.45	0.44	1.10	NC	-	0.21	0.53												
HH 0740	Parsley leaves, raw (incl dried)	RAC	2.5	0.60	1.50	1.07	2.68	0.66	1.65	1.60	4.00	NC	-	0.77	1.93												
HS 0784	Ginger, rhizome, raw incl dried	RAC	0	0.25	0.00	0.01	0.00	0.16	0.00	1.16	0.00	0.59	0.00	0.01	0.00												
HS 0794	Turmeric, root, raw (incl dried)	RAC	0	0.04	0.00	0.01	0.00	0.01	0.00	0.17	0.00	0.17	0.00	0.09	0.00												
HS 0444	Peppers, chili, dried	PP	0.36	0.42	0.15	0.53	0.19	0.84	0.30	0.50	0.18	0.95	0.34	0.37	0.13												
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80 % as muscle	RAC	0.21	24.96	5.24	57.95	12.17	16.70	3.51	38.38	8.06	26.46	5.56	29.00	6.09												
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20 % as fat	RAC	0.13	6.24	0.81	14.49	1.88	4.18	0.54	9.60	1.25	6.62	0.86	7.25	0.94												
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.13	3.29	0.43	6.14	0.80	0.82	0.11	1.57	0.20	2.23	0.29	1.07	0.14												
MO 0105	Edible offal (mammalian), raw	RAC	0.25	4.79	1.20	9.68	2.42	2.97	0.74	5.49	1.37	3.84	0.96	5.03	1.26												
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.024	289.65	6.95	485.88	11.66	26.92	0.65	239.03	5.74	199.91	4.80	180.53	4.33												
PM 0110	Poultry meat, raw (incl prepared)	RAC	0.13	14.63	1.90	29.76	3.87	8.04	1.05	129.68	16.86	25.04	3.26	35.66	4.64												
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.138	0.10	0.01	0.10	0.01	NC	-	0.10	0.01	0.10	0.01	0.10	0.01												
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.156	0.12	0.02	0.12	0.02	0.11	0.02	5.37	0.84	0.24	0.04	0.10	0.02												
PE 0112	Eggs, raw, (incl dried)	RAC	0.138	7.84	1.08	23.08	3.19	2.88	0.40	14.89	2.05	9.81	1.35	14.83	2.05												
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-												
Total intake (ug/person)=				40.8				84.4				22.4				90.8				80.5				74.5			
Bodyweight per region (kg bw) =				60				60				60				60				60							
ADI (ug/person)=				4800				4800				4800				4800				4800							
%ADI=				0.9 %				1.8 %				0.5 %				1.9 %				1.7 %				1.6 %			
Rounded %ADI=				1 %				2 %				0 %				2 %				2 %							

Annex 3

AFIDOPYROPEN (312)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.08 mg/kg bw

Codex Code	Commodity description	Expras	STMR mg/kg	Diets as g/person/day		Intake as ug/person/day									
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
FC 0001	Group of Citrus fruit, raw (incl kumquat commodities)	RAC	0.0535	38.66	2.07	54.93	2.94	26.36	1.41	51.46	2.75	51.06	2.73	466.36	24.95
JF 0001	Group of Citrus fruit, juice	PP	0.012	36.84	0.44	3.75	0.05	0.30	0.00	21.62	0.26	21.82	0.26	46.67	0.56
FP 0226	Apple, raw (incl cider, excl juice)	RAC	0.021	41.14	0.86	56.49	1.19	26.64	0.56	31.58	0.66	51.94	1.09	3.05	0.06
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.013	14.88	0.19	11.98	0.16	0.15	0.00	9.98	0.13	30.32	0.39	3.47	0.05
FP 0228	Loquat, raw (incl processed) (i.e. Japanese medlar)	RAC	0.021	0.96	0.02	NC	-	NC	-	3.92	0.08	NC	-	2.49	0.05
FP 0229	Medlar, raw (incl processed)	RAC	0.021	NC	-	NC	-	NC	-	NC	-	NC	-	1.98	0.04
FP 0230	Pear, raw	RAC	0.021	8.79	0.18	8.44	0.18	12.37	0.26	9.60	0.20	10.27	0.22	0.23	0.00
FP 0231	Quince, raw	RAC	0.021	0.19	0.00	0.18	0.00	0.11	0.00	0.04	0.00	0.28	0.01	NC	-
FS 0013	Subgroup of Cherries, raw	RAC	0.02	1.40	0.03	4.21	0.08	0.04	0.00	2.93	0.06	1.50	0.03	NC	-
FS 0014	Subgroup of Plums, raw (incl dried plums)	RAC	0.02	5.55	0.11	4.37	0.09	6.08	0.12	3.66	0.07	3.93	0.08	0.46	0.01
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.02	13.03	0.26	16.29	0.33	8.29	0.17	12.95	0.26	5.35	0.11	0.04	0.00
FB 0275	Strawberry, raw	RAC	0.0539	4.49	0.24	5.66	0.31	0.02	0.00	6.63	0.36	5.75	0.31	0.05	0.00
VB 0042	Subgroup of Flowerhead Brassica, raw	RAC	0.13	9.50	1.24	6.77	0.88	NC	-	3.21	0.42	9.36	1.22	0.75	0.10
VB 0041	Cabbages, head, raw	RAC	0.02	8.97	0.18	27.12	0.54	1.44	0.03	24.96	0.50	4.55	0.09	11.23	0.22
VC 0424	Cucumber, raw	RAC	0.17	6.72	1.14	11.03	1.88	32.10	5.46	15.10	2.57	4.05	0.69	9.57	1.63
VC 0431	Squash, Summer (Courgette, Marrow, Zucchetti, Zucchini), raw	RAC	0.039	NC	-	NC	-	5.48	0.21	NC	-	NC	-	1.03	0.04
VC 2040	Subgroup of Melons, Pumpkins and Winter squashes	RAC	0.027	20.68	0.56	25.00	0.68	85.72	2.31	34.31	0.93	11.54	0.31	23.32	0.63
VO 0448	Tomato, raw	RAC	0.03	32.13	0.96	51.27	1.54	34.92	1.05	73.37	2.20	15.15	0.45	8.88	0.27
-	Tomato, canned (& peeled)	PP	0.016	7.57	0.12	2.66	0.04	0.30	0.00	0.97	0.02	7.31	0.12	0.41	0.01
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.016	4.96	0.08	3.20	0.05	0.15	0.00	1.61	0.03	6.88	0.11	0.52	0.01
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.0026	0.80	0.00	0.07	0.00	0.05	0.00	0.61	0.00	0.40	0.00	0.08	0.00
VO 0051	Subgroup of peppers, raw (Capsicum spp. Only), excl okra	RAC	0.036	5.57	0.20	14.00	0.50	16.50	0.59	8.80	0.32	6.44	0.23	3.44	0.12
VO 0440	Egg plant, raw (i.e. aubergine)	RAC	0.03	1.01	0.03	1.69	0.05	21.37	0.64	3.00	0.09	1.40	0.04	NC	-
VL 2050	Subgroup of Leafy greens	RAC	0.88	18.38	16.17	18.73	16.48	82.36	72.48	25.32	22.28	17.60	15.49	7.37	6.49
VL 0054	Subgroup of Leaves of Brassicaceae, raw	RAC	2.5	0.10	0.25	NC	-	26.78	66.95	5.00	12.50	0.58	1.45	5.68	14.20
VD 0541	Soya bean, dry, raw (incl paste, incl curd, incl oil, incl sauce)	RAC	0.02	106.33	2.13	117.78	2.36	42.12	0.84	195.70	3.91	222.52	4.45	80.47	1.61
VR 2071	Subgroup of tuberous and corm vegetables, raw (incl processed)	RAC	0	226.09	0.00	234.58	0.00	161.10	0.00	185.04	0.00	234.85	0.00	100.25	0.00
VS 2080	Subgroup of stems and petioles	RAC	0.54	9.31	5.03	8.57	4.63	NC	-	3.88	2.10	24.46	13.21	5.89	3.18
GC 0651	Sorghum, raw (incl flour, incl beer) (i.e. Chicken corn, Dari seed, Durra, Feterita)	RAC	0.0365	NC	-	NC	-	1.44	0.05	1.15	0.04	NC	-	7.12	0.26

Annex 3

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AFIDOPYROPEN (312)		International Estimated Daily Intake (IEDI)		ADI = 0 - 0.08 mg/kg bw																							
Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day																			
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake												
TN 0085	Group of Tree nuts, raw (incl processed)	RAC	0.02	8.52	0.17	8.94	0.18	15.09	0.30	9.60	0.19	14.57	0.29	26.26	0.53												
SO 0691	Cotton seed, raw (incl oil)	RAC	0.02	10.71	0.21	4.23	0.08	7.19	0.14	7.54	0.15	5.66	0.11	2.38	0.05												
HH 0756	Coriander leaves (cilantro), raw	RAC	2.5	NC	-	NC	-	5.66	14.15	NC	-	NC	-	0.25	0.63												
HH 0730	Dill leaves, raw	RAC	2.5	0.48	1.20	0.01	0.03	NC	-	1.17	2.93	NC	-	0.31	0.78												
HH 0740	Parsley leaves, raw (incl dried)	RAC	2.5	1.43	3.58	2.14	5.35	NC	-	2.54	6.35	0.78	1.95	1.14	2.85												
HS 0784	Ginger, rhizome, raw incl dried	RAC	0	0.27	0.00	0.07	0.00	0.54	0.00	0.69	0.00	0.58	0.00	0.56	0.00												
HS 0794	Turmeric, root, raw (incl dried)	RAC	0	NC	-	NC	-	NC	-	NC	-	0.08	0.00	0.02	0.00												
HS 0444	Peppers, chili, dried	PP	0.36	0.11	0.04	0.21	0.08	0.36	0.13	0.21	0.08	0.25	0.09	0.15	0.05												
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80 % as muscle	RAC	0.21	112.02	23.53	120.71	25.35	63.46	13.33	88.99	18.69	96.24	20.21	41.02	8.61												
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20 % as fat	RAC	0.13	28.01	3.64	30.18	3.92	15.86	2.06	22.25	2.89	24.06	3.13	10.25	1.33												
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.13	6.44	0.84	15.51	2.02	3.79	0.49	8.29	1.08	18.44	2.40	8.00	1.04												
MO 0105	Edible offal (mammalian), raw	RAC	0.25	15.17	3.79	5.19	1.30	6.30	1.58	6.78	1.70	3.32	0.83	3.17	0.79												
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.024	388.92	9.33	335.88	8.06	49.15	1.18	331.25	7.95	468.56	11.25	245.45	5.89												
PM 0110	Poultry meat, raw (incl prepared)	RAC	0.13	73.76	9.59	53.86	7.00	23.98	3.12	87.12	11.33	53.38	6.94	84.45	10.98												
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.138	0.10	0.01	0.10	0.01	NC	-	0.10	0.01	0.71	0.10	NC	-												
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.156	0.33	0.05	0.72	0.11	0.27	0.04	0.35	0.05	0.80	0.12	NC	-												
PE 0112	Eggs, raw, (incl dried)	RAC	0.138	25.84	3.57	29.53	4.08	28.05	3.87	33.19	4.58	36.44	5.03	8.89	1.23												
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-												
Total intake (ug/person)=				92.1				92.5				193.5				110.7				95.5				89.2			
Bodyweight per region (kg bw) =				60				60				55				60				60							
ADI (ug/person)=				4800				4800				4400				4800				4800							
%ADI=				1.9 %				1.9 %				4.4 %				2.3 %				2.0 %				1.9 %			
Rounded %ADI=				2 %				2 %				4 %				2 %				2 %							

Annex 3

AFIDOPYROPEN (312)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.08 mg/kg bw

Codex Code	Commodity description	Expras	STMR mg/kg	Diets: g/person/day		Intake = daily intake: ug/person							
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
FC 0001	Group of Citrus fruit, raw (incl kumquat commodities)	RAC	0.0535	20.93	1.12	2.35	0.13	30.71	1.64	0.15	0.01	4.45	0.24
JF 0001	Group of Citrus fruit, juice	PP	0.012	0.11	0.00	0.29	0.00	13.55	0.16	0.14	0.00	0.33	0.00
FP 0226	Apple, raw (incl cider, excl juice)	RAC	0.021	66.67	1.40	2.06	0.04	55.83	1.17	188.29	3.95	1.38	0.03
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.013	0.03	0.00	0.10	0.00	7.19	0.09	0.03	0.00	NC	-
FP 0228	Loquat, raw (incl processed) (i.e. Japanese medlar)	RAC	0.021	0.94	0.02	4.68	0.10	NC	-	0.50	0.01	3.08	0.06
FP 0229	Medlar, raw (incl processed)	RAC	0.021	0.75	0.02	3.73	0.08	4.87	0.10	0.40	0.01	2.45	0.05
FP 0230	Pear, raw	RAC	0.021	0.07	0.00	0.14	0.00	9.45	0.20	0.01	0.00	0.14	0.00
FP 0231	Quince, raw	RAC	0.021	NC	-	NC	-	0.65	0.01	NC	-	NC	-
FS 0013	Subgroup of Cherries, raw	RAC	0.02	0.01	0.00	0.01	0.00	5.96	0.12	0.01	0.00	NC	-
FS 0014	Subgroup of Plums, raw (incl dried plums)	RAC	0.02	0.07	0.00	0.02	0.00	16.65	0.33	0.01	0.00	NC	-
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.02	0.02	0.00	0.01	0.00	10.76	0.22	0.01	0.00	NC	-
FB 0275	Strawberry, raw	RAC	0.0539	0.01	0.00	0.01	0.00	3.35	0.18	0.01	0.00	0.01	0.00
VB 0042	Subgroup of Flowerhead Brassica, raw	RAC	0.13	0.02	0.00	0.02	0.00	4.86	0.63	0.01	0.00	NC	-
VB 0041	Cabbages, head, raw	RAC	0.02	3.82	0.08	2.99	0.06	49.16	0.98	0.01	0.00	NC	-
VC 0424	Cucumber, raw	RAC	0.17	0.68	0.12	1.81	0.31	10.40	1.77	0.01	0.00	0.04	0.01
VC 0431	Squash, Summer (Courgette, Marrow, Zucchini, Zucchini), raw	RAC	0.039	0.09	0.00	1.01	0.04	NC	-	1.91	0.07	NC	-
VC 2040	Subgroup of Melons, Pumpkins and Winter squashes	RAC	0.027	5.04	0.14	6.54	0.18	38.26	1.03	11.70	0.32	NC	-
VO 0448	Tomato, raw	RAC	0.03	12.99	0.39	4.79	0.14	58.40	1.75	0.92	0.03	0.09	0.00
-	Tomato, canned (& peeled)	PP	0.016	0.07	0.00	0.08	0.00	2.42	0.04	0.07	0.00	NC	-
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.016	0.58	0.01	0.22	0.00	2.21	0.04	0.24	0.00	3.10	0.05
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.0026	0.05	0.00	0.01	0.00	0.42	0.00	0.01	0.00	0.02	0.00
VO 0051	Subgroup of peppers, raw (Capsicum spp. Only), excl okra	RAC	0.036	4.72	0.17	4.83	0.17	16.30	0.59	0.01	0.00	NC	-
VO 0440	Egg plant, raw (i.e. aubergine)	RAC	0.03	1.31	0.04	8.26	0.25	3.95	0.12	0.01	0.00	NC	-
VL 2050	Subgroup of Leafy greens	RAC	0.88	4.99	4.39	3.29	2.90	7.53	6.63	3.05	2.68	6.09	5.36
VL 0054	Subgroup of Leaves of Brassicaceae, raw	RAC	2.5	3.58	8.95	2.64	6.60	NC	-	1.83	4.58	3.65	9.13
VD 0541	Soya bean, dry, raw (incl paste, incl curd, incl oil, incl sauce)	RAC	0.02	15.80	0.32	14.29	0.29	104.36	2.09	17.11	0.34	35.20	0.70
VR 2071	Subgroup of tuberous and corm vegetables, raw (incl processed)	RAC	0	250.41	0.00	208.74	0.00	213.64	0.00	602.70	0.00	388.95	0.00
VS 2080	Subgroup of stems and petioles	RAC	0.54	5.33	2.88	3.85	2.08	5.80	3.13	3.60	1.94	7.20	3.89
GC 0651	Sorghum, raw (incl flour, incl beer) (i.e. Chicken corn, Dari seed, Durra, Feterita)	RAC	0.0365	89.16	3.25	2.02	0.07	NC	-	35.38	1.29	NC	-
TN 0085	Group of Tree nuts, raw (incl processed)	RAC	0.02	4.39	0.09	135.53	2.71	6.11	0.12	0.72	0.01	317.74	6.35

Annex 3

AFIDOPYROPEN (312)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.08 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day		Intake = daily intake: ug/person							
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
SO 0691	Cotton seed, raw (incl oil)	RAC	0.02	8.14	0.16	0.32	0.01	2.84	0.06	2.69	0.05	0.97	0.02
HH 0756	Coriander leaves (cilantro), raw	RAC	2.5	0.22	0.55	0.16	0.40	NC	-	0.15	0.38	0.30	0.75
HH 0730	Dill leaves, raw	RAC	2.5	0.28	0.70	0.20	0.50	0.65	1.63	0.19	0.48	0.38	0.95
HH 0740	Parsley leaves, raw (incl dried)	RAC	2.5	1.03	2.58	0.74	1.85	1.87	4.68	0.70	1.75	1.39	3.48
HS 0784	Ginger, rhizome, raw incl dried	RAC	0	0.75	0.00	0.68	0.00	0.06	0.00	0.02	0.00	0.01	0.00
HS 0794	Turmeric, root, raw (incl dried)	RAC	0	0.02	0.00	0.12	0.00	0.17	0.00	0.01	0.00	0.10	0.00
HS 0444	Peppers, chili, dried	PP	0.36	0.58	0.21	1.27	0.46	1.21	0.44	0.12	0.04	NC	-
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80 % as muscle	RAC	0.21	23.34	4.90	40.71	8.55	97.15	20.40	18.06	3.79	57.71	12.12
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20 % as fat	RAC	0.13	5.84	0.76	10.18	1.32	24.29	3.16	4.52	0.59	14.43	1.88
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.13	1.05	0.14	1.14	0.15	18.69	2.43	0.94	0.12	3.12	0.41
MO 0105	Edible offal (mammalian), raw	RAC	0.25	4.64	1.16	1.97	0.49	10.01	2.50	3.27	0.82	3.98	1.00
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.024	108.75	2.61	70.31	1.69	436.11	10.47	61.55	1.48	79.09	1.90
PM 0110	Poultry meat, raw (incl prepared)	RAC	0.13	3.92	0.51	12.03	1.56	57.07	7.42	5.03	0.65	55.56	7.22
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.138	NC	-	NC	-	0.32	0.04	NC	-	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.156	0.10	0.02	0.70	0.11	0.97	0.15	0.10	0.02	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0.138	3.84	0.53	4.41	0.61	27.25	3.76	1.13	0.16	7.39	1.02
-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total intake (ug/person)=				38.2		33.9		80.3		25.6		56.6	
Bodyweight per region (kg bw) =				60		60		60		60		60	
ADI (ug/person)=				4800		4800		4800		4800		4800	
%ADI=				0.8 %		0.7 %		1.7 %		0.5 %		1.2 %	
Rounded %ADI=				1 %		1 %		2 %		1 %		1 %	

Annex 3

AZOXYSTROBIN (229)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.2 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day							
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
FC 0001	Group of Citrus fruit, raw (incl kumquat commodities)	RAC	4.9	32.25	158.03	11.67	57.18	16.70	81.83	76.01	372.45	33.90	166.11	92.97	455.55
JF 0001	Group of Citrus fruit, juice	PP	0.39	1.30	0.51	2.37	0.92	0.22	0.09	13.88	5.41	0.75	0.29	2.63	1.03
FS 0013	Subgroup of Cherries, raw	RAC	0.74	0.92	0.68	9.15	6.77	0.01	0.01	0.61	0.45	0.06	0.04	6.64	4.91
FS 0014	Subgroup of Plums, raw	RAC	0.74	2.40	1.78	8.60	6.36	0.06	0.04	2.52	1.86	0.58	0.43	4.16	3.08
DF 0014	Plums, dried (prunes)	PP	0.14	0.09	0.01	0.06	0.01	0.01	0.00	0.18	0.03	0.04	0.01	0.06	0.01
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.74	8.01	5.93	5.87	4.34	0.18	0.13	8.19	6.06	1.64	1.21	22.46	16.62
FB 0018	Group of Berries and other small fruits, raw (incl processed)	RAC	1	18.53	18.53	33.67	33.67	3.65	3.65	28.70	28.70	9.72	9.72	74.91	74.91
FB 0269	Grapes, raw (incl must, excl dried, excl juice, excl wine)	RAC	0.53	13.02	6.90	9.25	4.90	0.03	0.02	16.91	8.96	3.70	1.96	54.44	28.85
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	0.24	0.51	0.12	0.51	0.12	0.01	0.00	1.27	0.30	0.12	0.03	2.07	0.50
JF 0269	Grape juice (from wine grapes)	PP	0.19	0.14	0.03	0.29	0.06	0.05	0.01	0.30	0.06	0.24	0.05	0.05	0.01
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.36	0.67	0.24	12.53	4.51	2.01	0.72	1.21	0.44	3.53	1.27	4.01	1.44
FB 0265	Cranberry, raw	RAC	0.23	0.02	0.00	0.01	0.00	NC	-	0.03	0.01	0.01	0.00	0.01	0.00
FB 0275	Strawberry, raw	RAC	1.3	0.70	0.91	2.01	2.61	0.04	0.05	1.36	1.77	0.37	0.48	2.53	3.29
FT 0289	Carambola, raw	RAC	0.023	0.01	0.00	0.01	0.00	0.01	0.00	0.01	0.00	NC	-	0.01	0.00
FT 0336	Guava, raw	RAC	0.055	0.47	0.03	0.01	0.00	0.48	0.03	0.49	0.03	4.42	0.24	0.06	0.00
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.03	5.23	0.16	6.94	0.21	99.45	2.98	32.47	0.97	48.30	1.45	24.70	0.74
FI 0345	Mango, raw (incl canned mango, incl mango juice)	RAC	0.035	10.48	0.37	0.01	0.00	7.24	0.25	6.87	0.24	19.98	0.70	6.25	0.22
FI 0350	Papaya, raw	RAC	0.1	0.35	0.04	0.01	0.00	3.05	0.31	0.80	0.08	7.28	0.73	1.00	0.10
FI 2540	Pitaya, raw (i.e dragon fruit or pitahaya)	RAC	0.041	0.01	0.00	0.01	0.00	0.01	0.00	0.01	0.00	NC	-	0.01	0.00
VA 0035	Group of Bulb vegetables, raw	RAC	2.2	34.29	75.44	46.37	102.01	4.73	10.41	41.36	90.99	21.08	46.38	52.54	115.59
VB 0040	Group of Brassica vegetables (excl Brassica leafy vegetables), raw	RAC	1.2	6.43	7.72	40.26	48.31	0.80	0.96	9.94	11.93	12.07	14.48	17.73	21.28
VC 0424	Cucumber, raw	RAC	0.17	8.01	1.36	30.66	5.21	1.45	0.25	19.84	3.37	0.27	0.05	34.92	5.94
VC 0425	Gherkin, raw	RAC	0.17	1.73	0.29	6.64	1.13	0.31	0.05	4.29	0.73	0.29	0.05	7.56	1.29
VC 0431	Squash, Summer (Courgette, Marrow, Zucchini, Zucchini), raw	RAC	0.17	0.78	0.13	2.06	0.35	0.30	0.05	1.61	0.27	2.25	0.38	2.36	0.40
VC 0046	Melons, except watermelon, raw (Cantaloupe)	RAC	0.02	8.90	0.18	8.64	0.17	0.80	0.02	17.90	0.36	2.80	0.06	29.17	0.58
VC 0429	Pumpkins, raw	RAC	0.02	4.76	0.10	12.56	0.25	1.85	0.04	9.86	0.20	5.11	0.10	14.39	0.29
VC 0432	Watermelon, raw	RAC	0.02	28.96	0.58	25.65	0.51	1.56	0.03	39.26	0.79	4.94	0.10	66.90	1.34
VO 0448	Tomato, raw	RAC	0.35	41.73	14.61	75.65	26.48	10.66	3.73	82.87	29.00	24.75	8.66	200.93	70.33
-	Tomato, canned (& peeled)	PP	0.05	0.20	0.01	0.31	0.02	0.02	0.00	1.11	0.06	0.11	0.01	1.50	0.08
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	1.1	2.34	2.57	1.33	1.46	1.57	1.73	4.24	4.66	0.34	0.37	2.83	3.11
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.16	0.29	0.05	0.29	0.05	0.01	0.00	0.38	0.06	0.05	0.01	0.14	0.02

Annex 3

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AZOXYSTROBIN (229)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.2 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day							
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
				VO 0051	Subgroup of peppers, raw (incl dried sweet peppers, excl dried chili peppers), incl okra	RAC	0.35	10.45	3.66	13.74	4.81	13.81	4.83	14.53	5.09
VO 2046	Subgroup of eggplants	RAC	0.35	5.58	1.95	4.31	1.51	0.89	0.31	9.31	3.26	13.64	4.77	20.12	7.04
VL 0483	Lettuce, leaf, raw	RAC	0.28	0.53	0.15	0.36	0.10	0.16	0.04	6.21	1.74	1.90	0.53	6.05	1.69
VL 0463	Cassava leaves, raw	RAC	0.23	NC	-	NC	-	0.65	0.15	0.01	0.00	NC	-	NC	-
VL 2832	Witloof chicory (sprouts)	RAC	0.05	0.03	0.00	0.02	0.00	0.01	0.00	0.36	0.02	0.06	0.00	0.35	0.02
VP 0060	Group of Legume vegetables, raw	RAC	1	7.73	7.73	1.53	1.53	0.51	0.51	2.95	2.95	5.08	5.08	12.86	12.86
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	0.01	2.39	0.02	1.61	0.02	10.47	0.10	1.84	0.02	12.90	0.13	7.44	0.07
VD 0523	Broad bean, dry, raw (incl horse-bean, field bean) (Vicia faba)	RAC	0.01	1.27	0.01	0.01	0.00	0.12	0.00	2.49	0.02	0.23	0.00	5.54	0.06
VD 0527	Cowpea, dry, raw (Vigna sinensis, Dolichos sinensis)	RAC	0.01	0.05	0.00	NC	-	1.74	0.02	0.01	0.00	0.01	0.00	0.07	0.00
VD 0541	Soya bean, dry, raw (incl flour, incl paste, incl curd, incl oil, excl sauce)	RAC	0.06	72.79	4.37	59.05	3.54	20.55	1.23	74.06	4.44	61.11	3.67	73.23	4.39
OR 0541	Soya oil, refined	PP	0.05	12.99	0.65	10.43	0.52	3.63	0.18	13.10	0.66	10.70	0.54	13.10	0.66
-	Beans (dry) NES: including inter alia lablab or hyacinth bean (Dolichos spp.); jack or sword bean (Canavalia spp.); winged bean (Psophocarpus tetragonolobus); guar bean (Cyamopsis tetragonoloba); velvet bean (Stizolobium spp.); yam bean (Pachyrrhizus erosus)	RAC	0.01	1.70	0.02	0.01	0.00	3.00	0.03	1.80	0.02	1.64	0.02	1.33	0.01
VD 2066	Subgroup of dry peas, raw	RAC	0.01	9.09	0.09	3.35	0.03	1.06	0.01	9.48	0.09	15.11	0.15	10.58	0.11
VD 2067	Subgroup of dry underground pulses, raw	RAC	0.01	NC	-	NC	-	0.20	0.00	NC	-	NC	-	NC	-
VR 0574	Beetroot, raw	RAC	0.23	3.42	0.79	6.06	1.39	3.75	0.86	9.11	2.10	NC	-	4.39	1.01
VR 0575	Burdock, greater or edible, raw	RAC	0.23	0.03	0.01	0.06	0.01	0.04	0.01	0.09	0.02	NC	-	0.04	0.01
VR 0577	Carrots, raw	RAC	0.23	9.51	2.19	30.78	7.08	0.37	0.09	8.75	2.01	2.80	0.64	6.10	1.40
VR 0578	Celeriac, raw	RAC	0.23	1.70	0.39	3.01	0.69	1.87	0.43	4.53	1.04	NC	-	2.19	0.50
VR 0469	Chicory, roots, raw	RAC	0.23	0.01	0.00	0.20	0.05	0.01	0.00	0.01	0.00	0.02	0.00	0.01	0.00
VR 0583	Horseradish, raw	RAC	0.23	0.51	0.12	0.91	0.21	0.56	0.13	1.37	0.32	NC	-	0.66	0.15
VR 0587	Parsley turnip-rooted, raw	RAC	0.23	0.32	0.07	0.57	0.13	0.35	0.08	0.85	0.20	NC	-	0.41	0.09
VR 0588	Parsnip, raw	RAC	0.23	0.59	0.14	1.05	0.24	0.65	0.15	1.58	0.36	NC	-	0.76	0.17
VR 0494	Radish roots, raw	RAC	0.23	2.31	0.53	4.09	0.94	2.53	0.58	6.15	1.41	5.88	1.35	2.97	0.68
VR 0591	Japanese radish, raw (i.e. Chinese radish, Daikon)	RAC	0.23	1.90	0.44	3.36	0.77	2.08	0.48	5.06	1.16	NC	-	2.44	0.56
VR 0498	Salsify, raw (i.e. Oysterplant)	RAC	0.23	0.21	0.05	0.37	0.09	0.23	0.05	0.55	0.13	NC	-	0.27	0.06
VR 0596	Sugar beet, raw	RAC	1.35	NC	-	NC	-	NC	-	NC	-	0.01	0.01	NC	-
-	Sugar beet, sugar	PP	0.023	0.02	0.00	NC	-	0.01	0.00	0.09	0.00	0.07	0.00	12.63	0.29
VR 0573	Arrowroot, raw	RAC	0.23	1.53	0.35	0.01	0.00	0.93	0.21	1.33	0.31	0.47	0.11	0.02	0.00
VR 0463	Cassava raw (incl starch, incl tapioca, incl flour)	RAC	0.23	0.08	0.02	0.01	0.00	482.56	110.99	0.99	0.23	25.75	5.92	3.29	0.76

Annex 3

AZOXYSTROBIN (229)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.2 mg/kg bw

Codex Code	Commodity description	Expr as	STMTR mg/kg	Diets as g/person/day				Intake as ug/person/day							
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
	(i.e. Manioc)														
VR 0463	Cassava raw (incl starch, incl flour, excl tapioca) (i.e Manioc)	RAC	0.23	0.02	0.00	0.01	0.00	478.42	110.04	0.70	0.16	25.39	5.84	3.28	0.75
VR 0463	Cassava raw (incl starch, incl tapioca, excl flour) (i.e. Manioc)	RAC	0.23	0.08	0.02	0.01	0.00	306.72	70.55	0.97	0.22	11.51	2.65	3.29	0.76
VR 0463	Cassava raw (incl tapioca, incl flour, excl starch) (i.e. Manioc)	RAC	0.23	0.06	0.01	NC	-	482.53	110.98	0.99	0.23	25.37	5.84	3.29	0.76
VR 0463	Cassava raw (incl starch, excl tapioca, excl flour) (i.e. Manioc)	RAC	0.23	0.02	0.00	0.01	0.00	302.58	69.59	0.68	0.16	11.15	2.56	3.28	0.75
VR 0463	Cassava raw (incl tapioca, excl flour, excl starch) (i.e. Manioc)	RAC	0.23	0.06	0.01	NC	-	306.70	70.54	0.97	0.22	11.13	2.56	3.29	0.76
VR 0463	Cassava raw (incl flour, excl tapioca, excl starch) (i.e. Manioc)	RAC	0.23	0.01	0.00	NC	-	478.39	110.03	0.70	0.16	25.02	5.75	3.28	0.75
VR 0463	Cassava, raw (i.e. Manioc)	RAC	0.23	NC	-	NC	-	302.56	69.59	0.68	0.16	10.77	2.48	3.28	0.75
-	Cassava, flour	PP	0.23	0.01	0.00	NC	-	49.23	11.32	0.01	0.00	3.99	0.92	NC	-
-	Cassava, starch	PP	0.23	0.01	0.00	0.01	0.00	0.01	0.00	NC	-	0.11	0.03	NC	-
-	Cassava, tapioca	PP	0.23	0.02	0.00	NC	-	1.16	0.27	0.08	0.02	0.10	0.02	0.01	0.00
VR 0585	Jerusalem artichoke, raw (i.e. Topinambur)	RAC	0.23	1.57	0.36	0.01	0.00	0.96	0.22	1.36	0.31	0.48	0.11	0.02	0.00
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	2.3	59.74	137.40	316.14	727.12	9.78	22.49	60.26	138.60	54.12	124.48	119.82	275.59
VR 0508	Sweet potato, raw (incl dried)	RAC	0.23	0.18	0.04	0.18	0.04	42.16	9.70	1.61	0.37	3.06	0.70	6.67	1.53
VR 0504	Tannia, raw (i.e. Tanier, Yautia)	RAC	0.23	NC	-	NC	-	NC	-	0.01	0.00	0.26	0.06	1.27	0.29
VR 0505	Taro, raw (i.e. Dasheen, Eddoe)	RAC	0.23	0.01	0.00	NC	-	25.12	5.78	0.04	0.01	0.01	0.00	0.97	0.22
VR 0600	Yams, raw (incl dried)	RAC	0.23	0.02	0.00	NC	-	90.40	20.79	6.45	1.48	0.74	0.17	0.65	0.15
VR 3001	Chinese water chestnut, raw	RAC	0.23	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VS 0624	Celery	RAC	0.43	2.14	0.92	3.79	1.63	2.35	1.01	5.69	2.45	0.02	0.01	2.75	1.18
VS 0621	Asparagus, raw	RAC	0.01	0.01	0.00	0.01	0.00	0.01	0.00	0.03	0.00	0.07	0.00	0.21	0.00
VS 0620	Artichoke globe, raw	RAC	1.8	0.69	1.24	0.01	0.02	0.01	0.02	0.32	0.58	0.26	0.47	1.21	2.18
GC 0650	Rye, raw (incl flour)	RAC	0.01	0.13	0.00	19.38	0.19	0.10	0.00	0.12	0.00	0.03	0.00	2.15	0.02
GC 0653	Triticale, raw (incl flour)	RAC	0.01	NC	-	NC	-	NC	-	0.01	0.00	0.39	0.00	NC	-
GC 0654	Wheat, raw (incl meslin)	RAC	0.01	0.01	0.00	1.12	0.01	NC	-	0.01	0.00	0.56	0.01	NC	-
CP 1212	Wheat, wholemeal bread	PP	0.001	0.01	0.00	0.01	0.00	0.01	0.00	0.01	0.00	0.03	0.00	0.01	0.00
CP 1211	Wheat, white bread	PP	0.001	0.25	0.00	0.63	0.00	0.12	0.00	0.43	0.00	1.39	0.00	0.22	0.00
CF 1211	Wheat, white flour (incl white flour products: starch, gluten, macaroni, pastry)	PP	0.003	301.24	0.90	268.64	0.81	30.21	0.09	222.51	0.67	134.73	0.40	343.12	1.03
GC 0640	Barley, raw (incl malt extract, incl pot&pearled, incl flour & grits, excl beer, excl malt)	RAC	0.05	18.86	0.94	11.93	0.60	0.18	0.01	0.23	0.01	2.25	0.11	0.72	0.04
-	Barley beer	PP	0.002	4.87	0.01	93.78	0.19	24.28	0.05	12.76	0.03	39.28	0.08	18.15	0.04
-	Barley Malt	PP	0.01	0.09	0.00	1.04	0.01	0.18	0.00	0.33	0.00	0.04	0.00	0.10	0.00
GC 0647	Oats, raw (incl rolled)	RAC	0.05	0.05	0.00	7.05	0.35	0.10	0.01	1.71	0.09	0.96	0.05	0.04	0.00

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AZOXYSTROBIN (229)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.2 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day							
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
CM 0649 (GC 0649)	Rice, husked, dry (incl flour, incl oil, incl beverages, incl starch, excl polished)	REP	0.68	1.26	0.86	1.58	1.07	31.05	21.11	5.43	3.69	0.90	0.61	2.18	1.48
CM 1205	Rice polished, dry	PP	0.06	34.21	2.05	10.39	0.62	41.72	2.50	82.38	4.94	150.24	9.01	70.47	4.23
GC 0651	Sorghum, raw (incl flour, incl beer) (i.e. Chicken corn, Dari seed, Durra, Feterita)	RAC	1.85	4.34	8.03	0.01	0.02	16.25	30.06	15.82	29.27	10.97	20.29	2.92	5.40
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl beer, incl germ, incl starch, excl flour, excl oil)	RAC	0.01	0.97	0.01	0.24	0.00	1.58	0.02	4.10	0.04	2.56	0.03	13.31	0.13
CF 1255	Maize, flour (white flour and wholemeal flour)	PP	0.01	22.72	0.23	35.61	0.36	87.27	0.87	34.92	0.35	46.71	0.47	49.12	0.49
-	Maize beer	PP	0.01	NC	-	NC	-	4.61	0.05	NC	-	NC	-	NC	-
OR 0645	Maize oil	PP	0.06	0.96	0.06	0.85	0.05	0.29	0.02	5.42	0.33	0.42	0.03	2.10	0.13
GS 0659	Sugar cane, raw	RAC	0.01	38.16	0.38	NC	-	12.58	0.13	0.34	0.00	17.79	0.18	42.78	0.43
-	Sugar cane, molasses	PP	0.005	NC	-	NC	-	NC	-	NC	-	0.01	0.00	NC	-
-	Sugar cane, sugar (incl non-centrifugal sugar, incl refined sugar and maltose)	PP	0.003	61.52	0.18	86.27	0.26	18.80	0.06	80.02	0.24	66.39	0.20	56.32	0.17
TN 0660	Almonds, nutmeat	RAC	0.01	1.38	0.01	0.08	0.00	0.01	0.00	1.00	0.01	0.06	0.00	0.81	0.01
TN 0662	Brazil nuts, nutmeat	RAC	0.01	0.01	0.00	0.01	0.00	0.03	0.00	0.02	0.00	0.02	0.00	0.01	0.00
TN 0295	Cashew nuts, nutmeat	RAC	0.01	0.01	0.00	0.02	0.00	0.24	0.00	0.47	0.00	0.32	0.00	0.05	0.00
TN 0664	Chestnut, raw	RAC	0.01	0.03	0.00	0.02	0.00	0.01	0.00	0.31	0.00	0.09	0.00	0.67	0.01
TN 0665	Coconut, nutmeat (incl. copra, incl desiccated, incl oil)	RAC	0.01	1.73	0.02	1.20	0.01	6.63	0.07	10.18	0.10	13.07	0.13	2.98	0.03
TN 0666	Hazelnuts, nutmeat	RAC	0.01	0.03	0.00	0.13	0.00	0.01	0.00	0.11	0.00	0.01	0.00	1.11	0.01
TN 0669	Macadamia nuts, nutmeat (i.e. Queensland nuts)	RAC	0.01	0.01	0.00	0.01	0.00	0.01	0.00	0.04	0.00	NC	-	0.03	0.00
TN 0672	Pecan, nutmeat	RAC	0.01	0.05	0.00	0.05	0.00	0.02	0.00	0.14	0.00	0.09	0.00	0.13	0.00
TN 0673	Pine nut, nutmeat (i.e. pignolia nuts)	RAC	0.01	0.18	0.00	0.18	0.00	0.08	0.00	0.49	0.00	0.25	0.00	0.43	0.00
TN 0675	Pistachio nut, nutmeat	RAC	0.44	0.41	0.18	0.07	0.03	0.01	0.00	0.85	0.37	0.02	0.01	1.08	0.48
TN 0678	Walnut, nutmeat	RAC	0.01	0.23	0.00	1.49	0.01	0.01	0.00	0.33	0.00	0.07	0.00	2.06	0.02
SO 0495	Rape seed, raw (incl oil)	RAC	0.02	0.93	0.02	1.16	0.02	0.49	0.01	2.53	0.05	9.32	0.19	2.02	0.04
SO 0702	Sunflower seed, raw	RAC	0.04	0.09	0.00	0.33	0.01	0.09	0.00	0.24	0.01	0.02	0.00	0.01	0.00
OR 0702	Sunflower seed oil, edible	PP	0.01	2.97	0.03	14.42	0.14	0.43	0.00	3.46	0.03	2.20	0.02	5.53	0.06
SO 0691	Cotton seed, raw (incl oil)	RAC	0.01	20.53	0.21	9.80	0.10	6.42	0.06	4.73	0.05	7.14	0.07	18.68	0.19
SO 0697	Peanuts, nutmeat, raw (incl roasted, incl butter, excl oil)	RAC	0.01	0.46	0.00	1.21	0.01	6.64	0.07	2.71	0.03	1.26	0.01	1.84	0.02
OR 0697	Peanut oil, edible	PP	0.03	0.36	0.01	0.01	0.00	2.57	0.08	0.07	0.00	2.29	0.07	0.36	0.01
SB 0716	Coffee bean, raw (i.e. green coffee)	RAC	0.01	0.96	0.01	0.16	0.00	0.91	0.01	0.27	0.00	1.37	0.01	0.46	0.00
SM 0716	Coffee bean, roasted	PP	0.006	0.19	0.00	0.91	0.01	0.16	0.00	2.50	0.02	0.39	0.00	0.40	0.00
-	Coffee bean, instant coffee (incl essences and concentrates)	PP	0.0106	0.07	0.00	0.94	0.01	0.07	0.00	0.70	0.01	0.07	0.00	0.29	0.00
HH 0092	Group of Herbs, raw (incl dried)	RAC	23	1.69	38.87	1.91	43.93	1.18	27.14	3.35	77.05	0.55	12.65	1.64	37.72

Annex 3

AZOXYSTROBIN (229)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.2 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day																			
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake												
HS 0444	Peppers, chili, dried	PP	3.5	0.42	1.47	0.53	1.86	0.84	2.94	0.50	1.75	0.95	3.33	0.37	1.30												
DH 1100	Hops, dry	RAC	11	0.01	0.11	0.04	0.44	0.01	0.11	0.01	0.11	NC	-	0.01	0.11												
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80 % as muscle	RAC	0.01	24.96	0.25	57.95	0.58	16.70	0.17	38.38	0.38	26.46	0.26	29.00	0.29												
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20 % as fat	RAC	0.02	6.24	0.12	14.49	0.29	4.18	0.08	9.60	0.19	6.62	0.13	7.25	0.15												
MO 0105	Edible offal (mammalian), raw	RAC	0.02	4.79	0.10	9.68	0.19	2.97	0.06	5.49	0.11	3.84	0.08	5.03	0.10												
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.01	289.65	2.90	485.88	4.86	26.92	0.27	239.03	2.39	199.91	2.00	180.53	1.81												
PM 0110	Poultry meat, raw (incl prepared)	RAC	0	14.63	0.00	29.76	0.00	8.04	0.00	129.68	0.00	25.04	0.00	35.66	0.00												
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0	0.12	0.00	0.12	0.00	0.11	0.00	5.37	0.00	0.24	0.00	0.10	0.00												
PE 0112	Eggs, raw, (incl dried)	RAC	0	7.84	0.00	23.08	0.00	2.88	0.00	14.89	0.00	9.81	0.00	14.83	0.00												
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-												
Total intake (ug/person)=				519.0				1117.2				997.8				865.3				488.7				1196.3			
Bodyweight per region (kg bw) =				60				60				60				60				60							
ADI (ug/person)=				12000				12000				12000				12000				12000							
%ADI=				4.3 %				9.3 %				8.3 %				7.2 %				4.1 %				10.0 %			
Rounded %ADI=				4 %				9 %				8 %				7 %				4 %				10 %			

AZOXYSTROBIN (229)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.2 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day							
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
FC 0001	Group of Citrus fruit, raw (incl kumquat commodities)	RAC	4.9	38.66	189.43	54.93	269.16	26.36	129.16	51.46	252.15	51.06	250.19	466.36	2285.16
JF 0001	Group of Citrus fruit, juice	PP	0.39	36.84	14.37	3.75	1.46	0.30	0.12	21.62	8.43	21.82	8.51	46.67	18.20
FS 0013	Subgroup of Cherries, raw	RAC	0.74	1.40	1.04	4.21	3.12	0.04	0.03	2.93	2.17	1.50	1.11	NC	-
FS 0014	Subgroup of Plums, raw	RAC	0.74	3.75	2.78	3.33	2.46	5.94	4.40	2.64	1.95	2.50	1.85	0.06	0.04
DF 0014	Plums, dried (prunes)	PP	0.14	0.61	0.09	0.35	0.05	0.05	0.01	0.35	0.05	0.49	0.07	0.13	0.02
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.74	13.03	9.64	16.29	12.05	8.29	6.13	12.95	9.58	5.35	3.96	0.04	0.03
FB 0018	Group of Berries and other small fruits, raw (incl processed)	RAC	1	156.91	156.91	118.51	118.51	8.10	8.10	64.22	64.22	117.23	117.23	15.04	15.04
FB 0269	Grapes, raw (incl must, excl dried, excl juice, excl wine)	RAC	0.53	6.48	3.43	11.31	5.99	5.21	2.76	9.50	5.04	4.66	2.47	0.78	0.41
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	0.24	3.09	0.74	1.51	0.36	0.03	0.01	1.38	0.33	4.26	1.02	0.42	0.10

Annex 3

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AZOXYSTROBIN (229)		International Estimated Daily Intake (IEDI)						ADI = 0 - 0.2 mg/kg bw							
Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day							
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
JF 0269	Grape juice (from wine grapes)	PP	0.19	0.56	0.11	1.96	0.37	0.02	0.00	2.24	0.43	2.27	0.43	0.34	0.06
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.36	88.93	32.01	62.41	22.47	1.84	0.66	25.07	9.03	61.17	22.02	5.84	2.10
FB 0265	Cranberry, raw	RAC	0.23	0.06	0.01	0.01	0.00	0.01	0.00	1.22	0.28	0.11	0.03	NC	-
FB 0275	Strawberry, raw	RAC	1.3	4.49	5.84	5.66	7.36	0.02	0.03	6.63	8.62	5.75	7.48	0.05	0.07
FT 0289	Carambola, raw	RAC	0.023	NC	-	0.01	0.00	0.05	0.00	NC	-	NC	-	NC	-
FT 0336	Guava, raw	RAC	0.055	0.01	0.00	NC	-	0.42	0.02	NC	-	NC	-	NC	-
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.03	25.76	0.77	23.65	0.71	23.83	0.71	24.37	0.73	19.43	0.58	101.55	3.05
FI 0345	Mango, raw (incl canned mango, incl mango juice)	RAC	0.035	1.80	0.06	0.63	0.02	10.05	0.35	1.07	0.04	3.52	0.12	16.44	0.58
FI 0350	Papaya, raw	RAC	0.1	0.31	0.03	0.18	0.02	1.50	0.15	0.51	0.05	0.54	0.05	1.08	0.11
FI 2540	Pitaya, raw (i.e dragon fruit or pitahaya)	RAC	0.041	NC	-	NC	-	0.08	0.00	NC	-	NC	-	NC	-
VA 0035	Group of Bulb vegetables, raw	RAC	2.2	26.24	57.73	36.47	80.23	39.29	86.44	39.37	86.61	29.12	64.06	20.21	44.46
VB 0040	Group of Brassica vegetables (excl Brassica leafy vegetables), raw	RAC	1.2	20.71	24.85	39.81	47.77	25.06	30.07	37.93	45.52	18.12	21.74	16.74	20.09
VC 0424	Cucumber, raw	RAC	0.17	6.72	1.14	11.03	1.88	32.10	5.46	15.10	2.57	4.05	0.69	9.57	1.63
VC 0425	Gherkin, raw	RAC	0.17	0.41	0.07	5.89	1.00	NC	-	0.06	0.01	0.37	0.06	2.07	0.35
VC 0431	Squash, Summer (Courgette, Marrow, Zucchini, Zucchini), raw	RAC	0.17	NC	-	NC	-	5.48	0.93	NC	-	NC	-	1.03	0.18
VC 0046	Melons, except watermelon, raw (Cantaloupe)	RAC	0.02	9.20	0.18	11.95	0.24	14.63	0.29	8.99	0.18	7.86	0.16	2.46	0.05
VC 0429	Pumpkins, raw	RAC	0.02	6.88	0.14	3.23	0.06	2.59	0.05	12.12	0.24	1.68	0.03	6.30	0.13
VC 0432	Watermelon, raw	RAC	0.02	4.60	0.09	9.82	0.20	68.50	1.37	13.19	0.26	1.99	0.04	14.56	0.29
VO 0448	Tomato, raw	RAC	0.35	32.13	11.25	51.27	17.94	34.92	12.22	73.37	25.68	15.15	5.30	8.88	3.11
-	Tomato, canned (& peeled)	PP	0.05	7.57	0.38	2.66	0.13	0.30	0.02	0.97	0.05	7.31	0.37	0.41	0.02
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	1.1	4.96	5.46	3.20	3.52	0.15	0.17	1.61	1.77	6.88	7.57	0.52	0.57
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.16	0.80	0.13	0.07	0.01	0.05	0.01	0.61	0.10	0.40	0.06	0.08	0.01
VO 0051	Subgroup of peppers, raw (incl dried sweet peppers, excl dried chilipeppers), incl okra	RAC	0.35	6.39	2.24	15.53	5.44	19.13	6.70	10.53	3.69	8.29	2.90	5.25	1.84
VO 2046	Subgroup of eggplants	RAC	0.35	1.01	0.35	1.69	0.59	21.37	7.48	3.00	1.05	1.40	0.49	NC	-
VL 0483	Lettuce, leaf, raw	RAC	0.28	14.50	4.06	11.76	3.29	13.14	3.68	19.50	5.46	4.81	1.35	2.23	0.62
VL 0463	Cassava leaves, raw	RAC	0.23	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VL 2832	Witloof chicory (sprouts)	RAC	0.05	1.50	0.08	0.95	0.05	NC	-	1.84	0.09	0.65	0.03	0.13	0.01
VP 0060	Group of Legume vegetables, raw	RAC	1	18.21	18.21	8.91	8.91	7.22	7.22	10.04	10.04	23.22	23.22	0.17	0.17
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	0.01	1.51	0.02	1.50	0.02	1.90	0.02	5.11	0.05	1.36	0.01	23.43	0.23
VD 0523	Broad bean, dry, raw (incl horse-bean, field bean) (Vicia faba)	RAC	0.01	0.02	0.00	0.01	0.00	1.16	0.01	0.40	0.00	NC	-	0.06	0.00
VD 0527	Cowpea, dry, raw (Vigna sinensis, Dolichos sinensis)	RAC	0.01	NC	-	NC	-	0.16	0.00	0.01	0.00	NC	-	NC	-
VD 0541	Soya bean, dry, raw (incl flour, incl paste, incl curd, incl oil, excl sauce)	RAC	0.06	106.15	6.37	117.67	7.06	40.94	2.46	193.94	11.64	222.48	13.35	80.19	4.81
OR 0541	Soya oil, refined	PP	0.05	19.06	0.95	21.06	1.05	5.94	0.30	33.78	1.69	40.05	2.00	13.39	0.67

Annex 3

AZOXYSTROBIN (229)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.2 mg/kg bw

Codex Code	Commodity description	STMR		Diets as g/person/day						Intake as ug/person/day					
		Expr as	mg/kg	G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
-	Beans (dry) NES: including inter alia lablab or hyacinth bean (<i>Dolichos</i> spp.); jack or sword bean (<i>Canavalia</i> spp.); winged bean (<i>Psophocarpus tetragonolobus</i>); guar bean (<i>Cyamopsis tetragonoloba</i>); velvet bean (<i>Stizolobium</i> spp.); yam bean (<i>Pachyrhizus erosus</i>)	RAC	0.01	0.01	0.00	NC	-	0.57	0.01	0.11	0.00	0.16	0.00	0.94	0.01
VD 2066	Subgroup of dry peas, raw	RAC	0.01	5.01	0.05	3.76	0.04	1.82	0.02	3.44	0.03	3.49	0.03	5.15	0.05
VD 2067	Subgroup of dry underground pulses, raw	RAC	0.01	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VR 0574	Beetroot, raw	RAC	0.23	9.91	2.28	6.34	1.46	NC	-	9.65	2.22	19.11	4.40	6.47	1.49
VR 0575	Burdock, greater or edible, raw	RAC	0.23	NC	-	NC	-	NC	-	0.48	0.11	NC	-	0.06	0.01
VR 0577	Carrots, raw	RAC	0.23	26.26	6.04	27.13	6.24	10.07	2.32	16.49	3.79	44.69	10.28	8.75	2.01
VR 0578	Celeriac, raw	RAC	0.23	2.97	0.68	1.79	0.41	NC	-	0.06	0.01	16.91	3.89	3.22	0.74
VR 0469	Chicory, roots, raw	RAC	0.23	0.01	0.00	0.51	0.12	0.01	0.00	0.01	0.00	21.12	4.86	NC	-
VR 0583	Horseradish, raw	RAC	0.23	0.01	0.00	0.42	0.10	13.01	2.99	0.26	0.06	2.70	0.62	0.97	0.22
VR 0587	Parsley turnip-rooted, raw	RAC	0.23	NC	-	NC	-	NC	-	NC	-	NC	-	0.61	0.14
VR 0588	Parsnip, raw	RAC	0.23	4.42	1.02	0.06	0.01	NC	-	NC	-	NC	-	1.12	0.26
VR 0494	Radish roots, raw	RAC	0.23	3.83	0.88	11.99	2.76	NC	-	5.26	1.21	2.19	0.50	4.37	1.01
VR 0591	Japanese radish, raw (i.e. Chinese radish, Daikon)	RAC	0.23	NC	-	NC	-	26.64	6.13	18.92	4.35	NC	-	3.59	0.83
VR 0498	Salsify, raw (i.e. Oysterplant)	RAC	0.23	1.02	0.23	0.52	0.12	NC	-	NC	-	2.08	0.48	0.39	0.09
VR 0596	Sugar beet, raw	RAC	1.35	0.01	0.01	NC	-	0.01	0.01	0.01	0.01	NC	-	NC	-
-	Sugar beet, sugar	PP	0.023	0.01	0.00	NC	-	0.01	0.00	NC	-	NC	-	NC	-
VR 0573	Arrowroot, raw	RAC	0.23	0.02	0.00	0.01	0.00	2.05	0.47	0.21	0.05	NC	-	0.76	0.17
VR 0463	Cassava raw (incl starch, incl tapioca, incl flour) (i.e. Manioc)	RAC	0.23	0.01	0.00	NC	-	20.96	4.82	0.14	0.03	NC	-	9.62	2.21
VR 0463	Cassava raw (incl starch, incl flour, excl tapioca) (i.e. Manioc)	RAC	0.23	0.01	0.00	NC	-	17.67	4.06	0.01	0.00	NC	-	9.62	2.21
VR 0463	Cassava raw (incl starch, incl tapioca, excl flour) (i.e. Manioc)	RAC	0.23	NC	-	NC	-	19.91	4.58	0.13	0.03	NC	-	9.62	2.21
VR 0463	Cassava raw (incl tapioca, incl flour, excl starch) (i.e. Manioc)	RAC	0.23	0.01	0.00	NC	-	20.96	4.82	0.14	0.03	NC	-	9.62	2.21
VR 0463	Cassava raw (incl starch, excl tapioca, excl flour) (i.e. Manioc)	RAC	0.23	NC	-	NC	-	16.62	3.82	NC	-	NC	-	9.62	2.21
VR 0463	Cassava raw (incl tapioca, excl flour, excl starch) (i.e. Manioc)	RAC	0.23	NC	-	NC	-	19.90	4.58	0.13	0.03	NC	-	9.62	2.21
VR 0463	Cassava raw (incl flour, excl tapioca, excl starch) (i.e. Manioc)	RAC	0.23	0.01	0.00	NC	-	17.67	4.06	0.01	0.00	NC	-	9.62	2.21
VR 0463	Cassava, raw (i.e. Manioc)	RAC	0.23	NC	-	NC	-	16.61	3.82	NC	-	NC	-	9.62	2.21
-	Cassava, flour	PP	0.23	0.01	0.00	NC	-	0.29	0.07	0.01	0.00	NC	-	NC	-
-	Cassava, starch	PP	0.23	NC	-	NC	-	0.01	0.00	NC	-	NC	-	NC	-
-	Cassava, tapioca	PP	0.23	NC	-	NC	-	0.92	0.21	0.04	0.01	NC	-	NC	-

Annex 3

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AZOXYSTROBIN (229)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.2 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day		Intake as ug/person/day									
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
VR 0585	Jerusalem artichoke, raw (i.e. Topinambur)	RAC	0.23	0.11	0.03	0.01	0.00	NC	-	0.22	0.05	NC	-	0.78	0.18
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	2.3	225.03	517.57	234.24	538.75	71.48	164.40	177.55	408.37	234.55	539.47	37.71	86.73
VR 0508	Sweet potato, raw (incl dried)	RAC	0.23	0.93	0.21	0.32	0.07	64.65	14.87	5.37	1.24	0.30	0.07	3.13	0.72
VR 0504	Tannia, raw (i.e. Tanier, Yautia)	RAC	0.23	NC	-	NC	-	NC	-	0.01	0.00	NC	-	10.74	2.47
VR 0505	Taro, raw (i.e. Dasheen, Eddoe)	RAC	0.23	NC	-	NC	-	1.93	0.44	0.84	0.19	NC	-	19.94	4.59
VR 0600	Yams, raw (incl dried)	RAC	0.23	NC	-	NC	-	0.03	0.01	0.71	0.16	NC	-	17.57	4.04
VR 3001	Chinese water chestnut, raw	RAC	0.23	NC	-	NC	-	3.42	0.79	NC	-	NC	-	NC	-
VS 0624	Celery	RAC	0.43	7.68	3.30	2.85	1.23	NC	-	3.34	1.44	16.83	7.24	4.04	1.74
VS 0621	Asparagus, raw	RAC	0.01	0.84	0.01	2.08	0.02	7.11	0.07	1.01	0.01	1.69	0.02	0.04	0.00
VS 0620	Artichoke globe, raw	RAC	1.8	0.98	1.76	3.65	6.57	0.07	0.13	1.67	3.01	0.26	0.47	NC	-
GC 0650	Rye, raw (incl flour)	RAC	0.01	3.21	0.03	35.38	0.35	0.21	0.00	6.50	0.07	1.49	0.01	NC	-
GC 0653	Triticale, raw (incl flour)	RAC	0.01	0.01	0.00	0.17	0.00	0.29	0.00	0.01	0.00	NC	-	NC	-
GC 0654	Wheat, raw (incl meslin)	RAC	0.01	NC	-	NC	-	NC	-	0.01	0.00	NC	-	NC	-
CP 1212	Wheat, wholemeal bread	PP	0.001	0.03	0.00	0.01	0.00	0.01	0.00	0.01	0.00	0.05	0.00	0.02	0.00
CP 1211	Wheat, white bread	PP	0.001	1.30	0.00	0.46	0.00	0.06	0.00	0.22	0.00	2.44	0.00	0.77	0.00
CF 1211	Wheat, white flour (incl white flour products: starch, gluten, macaroni, pastry)	PP	0.003	198.08	0.59	193.03	0.58	106.24	0.32	185.09	0.56	168.67	0.51	131.59	0.39
GC 0640	Barley, raw (incl malt extract, incl pot&pearled, incl flour & grits, excl beer, excl malt)	RAC	0.05	1.69	0.08	4.15	0.21	0.60	0.03	2.39	0.12	2.14	0.11	0.63	0.03
-	Barley beer	PP	0.002	180.21	0.36	259.46	0.52	45.91	0.09	172.36	0.34	234.42	0.47	65.30	0.13
-	Barley Malt	PP	0.01	0.19	0.00	NC	-	0.04	0.00	0.08	0.00	NC	-	2.14	0.02
GC 0647	Oats, raw (incl rolled)	RAC	0.05	7.50	0.38	6.26	0.31	0.15	0.01	4.87	0.24	3.16	0.16	2.98	0.15
CM 0649 (GC 0649)	Rice, husked, dry (incl flour, incl oil, incl beverages, incl starch, excl polished)	REP	0.68	3.70	2.52	2.11	1.43	1.51	1.03	1.75	1.19	0.29	0.20	5.12	3.48
CM 1205	Rice polished, dry	PP	0.06	13.38	0.80	10.80	0.65	262.08	15.72	57.16	3.43	12.83	0.77	62.78	3.77
GC 0651	Sorghum, raw (incl flour, incl beer) (i.e. Chicken corn, Dari seed, Durra, Feterita)	RAC	1.85	NC	-	NC	-	1.44	2.66	1.15	2.13	NC	-	7.12	13.17
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl beer, incl germ, incl starch, excl flour, excl oil)	RAC	0.01	0.10	0.00	9.93	0.10	1.71	0.02	21.57	0.22	0.33	0.00	0.05	0.00
CF 1255	Maize, flour (white flour and wholemeal flour)	PP	0.01	14.27	0.14	12.86	0.13	19.71	0.20	12.55	0.13	4.21	0.04	52.30	0.52
-	Maize beer	PP	0.01	NC	-	NC	-	NC	-	1.99	0.02	NC	-	NC	-
OR 0645	Maize oil	PP	0.06	0.90	0.05	0.47	0.03	0.15	0.01	3.01	0.18	1.86	0.11	0.36	0.02
GS 0659	Sugar cane, raw	RAC	0.01	NC	-	NC	-	4.27	0.04	0.01	0.00	NC	-	3.24	0.03
-	Sugar cane, molasses	PP	0.005	NC	-	NC	-	0.08	0.00	NC	-	NC	-	NC	-
-	Sugar cane, sugar (incl non-centrifugal sugar, incl refined sugar and maltose)	PP	0.003	92.24	0.28	95.72	0.29	24.12	0.07	77.39	0.23	117.73	0.35	100.67	0.30
TN 0660	Almonds, nutmeat	RAC	0.01	0.81	0.01	2.21	0.02	0.03	0.00	1.02	0.01	1.47	0.01	NC	-
TN 0662	Brazil nuts, nutmeat	RAC	0.01	0.12	0.00	0.05	0.00	0.01	0.00	0.05	0.00	0.13	0.00	NC	-
TN 0295	Cashew nuts, nutmeat	RAC	0.01	0.59	0.01	0.23	0.00	0.18	0.00	0.52	0.01	1.75	0.02	2.78	0.03

Annex 3

AZOXYSTROBIN (229)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.2 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day																			
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake												
TN 0664	Chestnut, raw	RAC	0.01	0.34	0.00	0.21	0.00	1.14	0.01	0.52	0.01	0.09	0.00	NC	-												
TN 0665	Coconut, nutmeat (incl. copra, incl desiccated, incl oil)	RAC	0.01	4.13	0.04	2.73	0.03	13.15	0.13	5.85	0.06	6.92	0.07	22.24	0.22												
TN 0666	Hazelnuts, nutmeat	RAC	0.01	0.45	0.00	1.12	0.01	0.02	0.00	0.34	0.00	1.63	0.02	NC	-												
TN 0669	Macadamia nuts, nutmeat (i.e. Queensland nuts)	RAC	0.01	NC	-	0.40	0.00	NC	-	NC	-	NC	-	0.07	0.00												
TN 0672	Pecan, nutmeat	RAC	0.01	0.38	0.00	NC	-	NC	-	0.27	0.00	NC	-	0.26	0.00												
TN 0673	Pine nut, nutmeat (i.e. pignolia nuts)	RAC	0.01	0.99	0.01	0.66	0.01	0.22	0.00	0.27	0.00	1.89	0.02	0.89	0.01												
TN 0675	Pistachio nut, nutmeat	RAC	0.44	0.35	0.15	0.48	0.21	0.07	0.03	0.39	0.17	0.23	0.10	0.02	0.01												
TN 0678	Walnut, nutmeat	RAC	0.01	0.34	0.00	0.84	0.01	0.28	0.00	0.39	0.00	0.45	0.00	NC	-												
SO 0495	Rape seed, raw (incl oil)	RAC	0.02	32.68	0.65	19.91	0.40	7.83	0.16	15.69	0.31	NC	-	NC	-												
SO 0702	Sunflower seed, raw	RAC	0.04	0.01	0.00	1.32	0.05	0.03	0.00	1.17	0.05	NC	-	0.02	0.00												
OR 0702	Sunflower seed oil, edible	PP	0.01	9.50	0.10	11.37	0.11	0.49	0.00	5.15	0.05	2.63	0.03	2.80	0.03												
SO 0691	Cotton seed, raw (incl oil)	RAC	0.01	10.71	0.11	4.23	0.04	7.19	0.07	7.54	0.08	5.66	0.06	2.38	0.02												
SO 0697	Peanuts, nutmeat, raw (incl roasted, incl butter, excl oil)	RAC	0.01	3.26	0.03	2.22	0.02	5.38	0.05	4.85	0.05	1.54	0.02	1.82	0.02												
OR 0697	Peanut oil, edible	PP	0.03	1.02	0.03	0.23	0.01	1.81	0.05	0.42	0.01	5.23	0.16	0.01	0.00												
SB 0716	Coffee bean, raw (i.e. green coffee)	RAC	0.01	0.60	0.01	NC	-	0.62	0.01	1.71	0.02	NC	-	3.51	0.04												
SM 0716	Coffee bean, roasted	PP	0.006	7.02	0.04	9.75	0.06	0.02	0.00	5.09	0.03	13.38	0.08	0.77	0.00												
-	Coffee bean, instant coffee (incl essences and concentrates)	PP	0.0106	0.75	0.01	0.30	0.00	0.04	0.00	0.67	0.01	2.43	0.03	1.43	0.02												
HH 0092	Group of Herbs, raw (incl dried)	RAC	23	2.61	60.03	2.31	53.13	8.89	204.47	3.92	90.16	1.16	26.68	2.06	47.38												
HS 0444	Peppers, chili, dried	PP	3.5	0.11	0.39	0.21	0.74	0.36	1.26	0.21	0.74	0.25	0.88	0.15	0.53												
DH 1100	Hops, dry	RAC	11	NC	-	NC	-	0.02	0.22	0.02	0.22	NC	-	NC	-												
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80 % as muscle	RAC	0.01	112.02	1.12	120.71	1.21	63.46	0.63	88.99	0.89	96.24	0.96	41.02	0.41												
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20 % as fat	RAC	0.02	28.01	0.56	30.18	0.60	15.86	0.32	22.25	0.44	24.06	0.48	10.25	0.21												
MO 0105	Edible offal (mammalian), raw	RAC	0.02	15.17	0.30	5.19	0.10	6.30	0.13	6.78	0.14	3.32	0.07	3.17	0.06												
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.01	388.92	3.89	335.88	3.36	49.15	0.49	331.25	3.31	468.56	4.69	245.45	2.45												
PM 0110	Poultry meat, raw (incl prepared)	RAC	0	73.76	0.00	53.86	0.00	23.98	0.00	87.12	0.00	53.38	0.00	84.45	0.00												
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0	0.33	0.00	0.72	0.00	0.27	0.00	0.35	0.00	0.80	0.00	NC	-												
PE 0112	Eggs, raw, (incl dried)	RAC	0	25.84	0.00	29.53	0.00	28.05	0.00	33.19	0.00	36.44	0.00	8.89	0.00												
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-												
Total intake (ug/person)=				1157.8				1246.1				773.3				1091.9				1170.0				2602.9			
Bodyweight per region (kg bw) =				60				60				55				60				60							
ADI (ug/person)=				12000				12000				11000				12000				12000							
%ADI=				9.6 %				10.4 %				7.0 %				9.1 %				9.7 %				21.7 %			
Rounded %ADI=				10 %				10 %				7 %				9 %				10 %				20 %			

Annex 3

099

AZOXYSTROBIN (229)		International Estimated Daily Intake (IEDI)										ADI = 0 - 0.2 mg/kg bw	
Codex Code	Commodity description	Expras	STMR mg/kg	Diets: g/person/day		Intake = daily intake: ug/person							
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
FC 0001	Group of Citrus fruit, raw (incl kumquat commodities)	RAC	4.9	20.93	102.56	2.35	11.52	30.71	150.48	0.15	0.74	4.45	21.81
JF 0001	Group of Citrus fruit, juice	PP	0.39	0.11	0.04	0.29	0.11	13.55	5.28	0.14	0.05	0.33	0.13
FS 0013	Subgroup of Cherries, raw	RAC	0.74	0.01	0.01	0.01	0.01	5.96	4.41	0.01	0.01	NC	-
FS 0014	Subgroup of Plums, raw	RAC	0.74	0.07	0.05	0.01	0.01	15.56	11.51	0.01	0.01	NC	-
DF 0014	Plums, dried (prunes)	PP	0.14	0.01	0.00	0.01	0.00	0.37	0.05	0.01	0.00	NC	-
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.74	0.02	0.01	0.01	0.01	10.76	7.96	0.01	0.01	NC	-
FB 0018	Group of Berries and other small fruits, raw (incl processed)	RAC	1	2.14	2.14	19.92	19.92	114.85	114.85	1.55	1.55	49.22	49.22
FB 0269	Grapes, raw (incl must, excl dried, excl juice, excl wine)	RAC	0.53	0.14	0.07	0.36	0.19	15.33	8.12	0.01	0.01	0.28	0.15
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	0.24	0.01	0.00	0.13	0.03	1.06	0.25	0.01	0.00	0.03	0.01
JF 0269	Grape juice (from wine grapes)	PP	0.19	0.01	0.00	0.01	0.00	0.41	0.08	0.01	0.00	NC	-
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.36	0.31	0.11	0.23	0.08	60.43	21.75	0.52	0.19	31.91	11.49
FB 0265	Cranberry, raw	RAC	0.23	NC	-	NC	-	0.03	0.01	NC	-	NC	-
FB 0275	Strawberry, raw	RAC	1.3	0.01	0.01	0.01	0.01	3.35	4.36	0.01	0.01	0.01	0.01
FT 0289	Carambola, raw	RAC	0.023	0.01	0.00	0.01	0.00	NC	-	0.01	0.00	0.04	0.00
FT 0336	Guava, raw	RAC	0.055	0.10	0.01	0.08	0.00	NC	-	0.14	0.01	3.11	0.17
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.03	44.80	1.34	118.17	3.55	25.25	0.76	454.49	13.63	310.23	9.31
FI 0345	Mango, raw (incl canned mango, incl mango juice)	RAC	0.035	12.25	0.43	6.83	0.24	0.76	0.03	0.01	0.00	20.12	0.70
FI 0350	Papaya, raw	RAC	0.1	6.47	0.65	0.25	0.03	0.19	0.02	0.01	0.00	26.42	2.64
FI 2540	Pitaya, raw (i.e dragon fruit or pitahaya)	RAC	0.041	0.01	0.00	0.01	0.00	NC	-	0.01	0.00	0.04	0.00
VA 0035	Group of Bulb vegetables, raw	RAC	2.2	11.28	24.82	23.80	52.36	36.11	79.44	9.66	21.25	8.69	19.12
VB 0040	Group of Brassica vegetables (excl Brassica leafy vegetables), raw	RAC	1.2	5.46	6.55	4.28	5.14	58.72	70.46	0.02	0.02	NC	-
VC 0424	Cucumber, raw	RAC	0.17	0.68	0.12	1.81	0.31	10.40	1.77	0.01	0.00	0.04	0.01
VC 0425	Gherkin, raw	RAC	0.17	0.15	0.03	0.39	0.07	3.15	0.54	0.01	0.00	0.01	0.00
VC 0431	Squash, Summer (Courgette, Marrow, Zucchini, Zucchini), raw	RAC	0.17	0.09	0.02	1.01	0.17	NC	-	1.91	0.32	NC	-
VC 0046	Melons, except watermelon, raw (Cantaloupe)	RAC	0.02	0.19	0.00	0.10	0.00	4.98	0.10	0.01	0.00	NC	-
VC 0429	Pumpkins, raw	RAC	0.02	0.56	0.01	6.14	0.12	4.59	0.09	11.70	0.23	NC	-
VC 0432	Watermelon, raw	RAC	0.02	4.29	0.09	0.30	0.01	28.70	0.57	0.01	0.00	NC	-
VO 0448	Tomato, raw	RAC	0.35	12.99	4.55	4.79	1.68	58.40	20.44	0.92	0.32	0.09	0.03
-	Tomato, canned (& peeled)	PP	0.05	0.07	0.00	0.08	0.00	2.42	0.12	0.07	0.00	NC	-
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	1.1	0.58	0.64	0.22	0.24	2.21	2.43	0.24	0.26	3.10	3.41
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.16	0.05	0.01	0.01	0.00	0.42	0.07	0.01	0.00	0.02	0.00

Annex 3

AZOXYSTROBIN (229)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.2 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day		Intake = daily intake: ug/person							
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
VO 0051	Subgroup of peppers, raw (incl dried sweet peppers, excl dried chilipeppers), incl okra	RAC	0.35	15.20	5.32	14.23	4.98	25.14	8.80	0.91	0.32	NC	-
VO 2046	Subgroup of eggplants	RAC	0.35	1.31	0.46	8.26	2.89	3.95	1.38	0.01	0.00	NC	-
VL 0483	Lettuce, leaf, raw	RAC	0.28	0.29	0.08	0.03	0.01	6.71	1.88	0.01	0.00	NC	-
VL 0463	Cassava leaves, raw	RAC	0.23	NC	-	NC	-	NC	-	NC	-	NC	-
VL 2832	Witloof chicory (sprouts)	RAC	0.05	0.02	0.00	0.01	0.00	0.01	0.00	0.01	0.00	NC	-
VP 0060	Group of Legume vegetables, raw	RAC	1	0.58	0.58	3.16	3.16	10.38	10.38	0.04	0.04	NC	-
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	0.01	7.11	0.07	2.33	0.02	3.76	0.04	44.70	0.45	3.27	0.03
VD 0523	Broad bean, dry, raw (incl horse-bean, field bean) (Vicia faba)	RAC	0.01	3.70	0.04	0.03	0.00	0.17	0.00	0.01	0.00	NC	-
VD 0527	Cowpea, dry, raw (Vigna sinensis, Dolichos sinensis)	RAC	0.01	12.77	0.13	0.99	0.01	0.01	0.00	4.33	0.04	NC	-
VD 0541	Soya bean, dry, raw (incl flour, incl paste, incl curd, incl oil, excl sauce)	RAC	0.06	15.80	0.95	14.24	0.85	104.29	6.26	17.11	1.03	34.98	2.10
OR 0541	Soya oil, refined	PP	0.05	2.32	0.12	2.54	0.13	18.70	0.94	2.51	0.13	6.29	0.31
-	Beans (dry) NES: including inter alia lablab or hyacinth bean (Dolichos spp.); jack or sword bean (Canavalia spp.); winged bean (Psophocarpus tetragonolobus); guar bean (Cyamopsis tetragonoloba); velvet bean (Stizolobium spp.); yam bean (Pachyrrhizus erosus)	RAC	0.01	2.54	0.03	1.77	0.02	0.03	0.00	0.03	0.00	3.99	0.04
VD 2066	Subgroup of dry peas, raw	RAC	0.01	4.43	0.04	11.36	0.11	4.22	0.04	9.36	0.09	1.21	0.01
VD 2067	Subgroup of dry underground pulses, raw	RAC	0.01	0.20	0.00	NC	-	NC	-	NC	-	NC	-
VR 0574	Beetroot, raw	RAC	0.23	5.86	1.35	4.23	0.97	9.46	2.18	3.96	0.91	7.91	1.82
VR 0575	Burdock, greater or edible, raw	RAC	0.23	0.06	0.01	0.04	0.01	NC	-	0.04	0.01	0.08	0.02
VR 0577	Carrots, raw	RAC	0.23	2.07	0.48	3.00	0.69	25.29	5.82	0.05	0.01	NC	-
VR 0578	Celeriac, raw	RAC	0.23	2.91	0.67	2.10	0.48	7.59	1.75	1.97	0.45	3.93	0.90
VR 0469	Chicory, roots, raw	RAC	0.23	0.01	0.00	0.03	0.01	0.10	0.02	NC	-	NC	-
VR 0583	Horseradish, raw	RAC	0.23	0.88	0.20	0.63	0.14	0.54	0.12	0.59	0.14	1.19	0.27
VR 0587	Parsley turnip-rooted, raw	RAC	0.23	0.55	0.13	0.40	0.09	4.29	0.99	0.37	0.09	0.74	0.17
VR 0588	Parsnip, raw	RAC	0.23	1.02	0.23	0.74	0.17	3.50	0.81	0.69	0.16	1.37	0.32
VR 0494	Radish roots, raw	RAC	0.23	3.96	0.91	2.86	0.66	3.30	0.76	2.67	0.61	5.34	1.23
VR 0591	Japanese radish, raw (i.e. Chinese radish, Daikon)	RAC	0.23	3.25	0.75	2.35	0.54	NC	-	2.20	0.51	4.39	1.01
VR 0498	Salsify, raw (i.e. Oysterplant)	RAC	0.23	0.36	0.08	0.26	0.06	NC	-	0.24	0.06	0.48	0.11
VR 0596	Sugar beet, raw	RAC	1.35	0.01	0.01	NC	-	NC	-	NC	-	NC	-
-	Sugar beet, sugar	PP	0.023	0.56	0.01	0.24	0.01	NC	-	NC	-	5.13	0.12
VR 0573	Arrowroot, raw	RAC	0.23	13.83	3.18	18.24	4.20	0.01	0.00	0.05	0.01	19.60	4.51
VR 0463	Cassava raw (incl starch, incl tapioca, incl flour) (i.e. Manioc)	RAC	0.23	91.92	21.14	34.12	7.85	NC	-	259.92	59.78	45.48	10.46
VR 0463	Cassava raw (incl starch, incl flour, excl tapioca) (i.e. Manioc)	RAC	0.23	87.78	20.19	33.53	7.71	NC	-	259.92	59.78	45.48	10.46

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AZOXYSTROBIN (229)		International Estimated Daily Intake (IEDI)		ADI = 0 - 0.2 mg/kg bw									
Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day				Intake = daily intake: ug/person					
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
VR 0463	Cassava raw (incl starch, incl tapioca, excl flour) (i.e. Manioc)	RAC	0.23	41.16	9.47	34.12	7.85	NC	-	203.39	46.78	45.48	10.46
VR 0463	Cassava raw (incl tapioca, incl flour, excl starch) (i.e. Manioc)	RAC	0.23	91.92	21.14	34.05	7.83	NC	-	259.92	59.78	45.48	10.46
VR 0463	Cassava raw (incl starch, excl tapioca, excl flour) (i.e. Manioc)	RAC	0.23	37.02	8.51	33.53	7.71	NC	-	203.39	46.78	45.48	10.46
VR 0463	Cassava raw (incl tapioca, excl flour, excl starch) (i.e. Manioc)	RAC	0.23	41.16	9.47	34.05	7.83	NC	-	203.38	46.78	45.48	10.46
VR 0463	Cassava raw (incl flour, excl tapioca, excl starch) (i.e. Manioc)	RAC	0.23	87.77	20.19	33.46	7.70	NC	-	259.92	59.78	45.48	10.46
VR 0463	Cassava, raw (i.e. Manioc)	RAC	0.23	37.01	8.51	33.46	7.70	NC	-	203.38	46.78	45.48	10.46
-	Cassava, flour	PP	0.23	14.21	3.27	NC	-	NC	-	15.83	3.64	NC	-
-	Cassava, starch	PP	0.23	0.01	0.00	0.02	0.00	NC	-	0.01	0.00	NC	-
-	Cassava, tapioca	PP	0.23	1.16	0.27	0.16	0.04	NC	-	0.01	0.00	NC	-
VR 0585	Jerusalem artichoke, raw (i.e. Topinambur)	RAC	0.23	14.22	3.27	18.75	4.31	0.01	0.00	0.06	0.01	20.14	4.63
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	2.3	23.96	55.11	13.56	31.19	213.41	490.84	104.35	240.01	8.56	19.69
VR 0508	Sweet potato, raw (incl dried)	RAC	0.23	28.83	6.63	61.55	14.16	0.15	0.03	221.94	51.05	NC	-
VR 0504	Tannia, raw (i.e. Tanier, Yautia)	RAC	0.23	NC	-	NC	-	0.01	0.00	NC	-	NC	-
VR 0505	Taro, raw (i.e. Dasheen, Eddoe)	RAC	0.23	6.71	1.54	31.91	7.34	NC	-	10.73	2.47	264.31	60.79
VR 0600	Yams, raw (incl dried)	RAC	0.23	70.93	16.31	30.62	7.04	0.07	0.02	5.65	1.30	30.85	7.10
VR 3001	Chinese water chestnut, raw	RAC	0.23	NC	-	NC	-	NC	-	NC	-	NC	-
VS 0624	Celery	RAC	0.43	3.66	1.57	2.65	1.14	4.84	2.08	2.47	1.06	4.94	2.12
VS 0621	Asparagus, raw	RAC	0.01	0.01	0.00	0.01	0.00	0.17	0.00	0.01	0.00	NC	-
VS 0620	Artichoke globe, raw	RAC	1.8	0.01	0.02	NC	-	0.08	0.14	0.01	0.02	NC	-
GC 0650	Rye, raw (incl flour)	RAC	0.01	0.03	0.00	0.01	0.00	13.95	0.14	0.01	0.00	0.88	0.01
GC 0653	Triticale, raw (incl flour)	RAC	0.01	0.01	0.00	NC	-	NC	-	NC	-	NC	-
GC 0654	Wheat, raw (incl meslin)	RAC	0.01	NC	-	NC	-	NC	-	NC	-	0.97	0.01
CP 1212	Wheat, wholemeal bread	PP	0.001	0.01	0.00	0.01	0.00	0.03	0.00	0.01	0.00	0.01	0.00
CP 1211	Wheat, white bread	PP	0.001	0.43	0.00	0.41	0.00	1.56	0.00	0.11	0.00	0.07	0.00
CF 1211	Wheat, white flour (incl white flour products: starch, gluten, macaroni, pastry)	PP	0.003	44.78	0.13	86.96	0.26	214.05	0.64	20.31	0.06	103.60	0.31
GC 0640	Barley, raw (incl malt extract, incl pot&pearled, incl flour & grits, excl beer, excl malt)	RAC	0.05	8.49	0.42	0.02	0.00	3.01	0.15	0.01	0.00	0.11	0.01
-	Barley beer	PP	0.002	16.25	0.03	11.36	0.02	225.21	0.45	19.49	0.04	52.17	0.10
-	Barley Malt	PP	0.01	0.01	0.00	0.11	0.00	0.67	0.01	0.01	0.00	4.61	0.05
GC 0647	Oats, raw (incl rolled)	RAC	0.05	0.37	0.02	0.07	0.00	2.79	0.14	0.10	0.01	NC	-
CM 0649 (GC 0649)	Rice, husked, dry (incl flour, incl oil, incl beverages, incl starch, excl polished)	REP	0.68	13.58	9.23	4.29	2.92	2.17	1.48	0.01	0.01	8.84	6.01
CM 1205	Rice polished, dry	PP	0.06	30.20	1.81	218.34	13.10	12.77	0.77	15.24	0.91	51.35	3.08

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AZOXYSTROBIN (229)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.2 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day		Intake = daily intake: ug/person							
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
GC 0651	Sorghum, raw (incl flour, incl beer) (i.e. Chicken corn, Dari seed, Durra, Feterita)	RAC	1.85	89.16	164.95	2.02	3.74	NC	-	35.38	65.45	NC	-
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl beer, incl germ, incl starch, excl flour, excl oil)	RAC	0.01	0.58	0.01	0.52	0.01	3.26	0.03	7.96	0.08	NC	-
CF 1255	Maize, flour (white flour and wholemeal flour)	PP	0.01	94.34	0.94	8.09	0.08	28.03	0.28	55.94	0.56	28.07	0.28
-	Maize beer	PP	0.01	1.03	0.01	NC	-	NC	-	40.94	0.41	NC	-
OR 0645	Maize oil	PP	0.06	0.33	0.02	0.07	0.00	0.81	0.05	0.01	0.00	NC	-
GS 0659	Sugar cane, raw	RAC	0.01	5.62	0.06	50.91	0.51	NC	-	11.04	0.11	0.10	0.00
-	Sugar cane, molasses	PP	0.005	NC	-	NC	-	NC	-	NC	-	NC	-
-	Sugar cane, sugar (incl non-centrifugal sugar, incl refined sugar and maltose)	PP	0.003	28.13	0.08	55.38	0.17	78.09	0.23	18.04	0.05	45.60	0.14
TN 0660	Almonds, nutmeat	RAC	0.01	0.01	0.00	0.01	0.00	0.61	0.01	0.01	0.00	NC	-
TN 0662	Brazil nuts, nutmeat	RAC	0.01	0.01	0.00	0.01	0.00	0.02	0.00	0.01	0.00	NC	-
TN 0295	Cashew nuts, nutmeat	RAC	0.01	0.91	0.01	0.14	0.00	0.11	0.00	0.01	0.00	NC	-
TN 0664	Chestnut, raw	RAC	0.01	0.01	0.00	0.01	0.00	0.75	0.01	0.01	0.00	NC	-
TN 0665	Coconut, nutmeat (incl. copra, incl desiccated, incl oil)	RAC	0.01	2.77	0.03	134.37	1.34	2.81	0.03	0.70	0.01	317.67	3.18
TN 0666	Hazelnuts, nutmeat	RAC	0.01	0.01	0.00	0.01	0.00	0.21	0.00	0.01	0.00	NC	-
TN 0669	Macadamia nuts, nutmeat (i.e. Queensland nuts)	RAC	0.01	0.04	0.00	0.05	0.00	NC	-	0.01	0.00	0.01	0.00
TN 0672	Pecan, nutmeat	RAC	0.01	0.15	0.00	0.22	0.00	0.31	0.00	0.01	0.00	0.01	0.00
TN 0673	Pine nut, nutmeat (i.e. pignolia nuts)	RAC	0.01	0.51	0.01	0.74	0.01	0.36	0.00	0.01	0.00	0.05	0.00
TN 0675	Pistachio nut, nutmeat	RAC	0.44	0.01	0.00	0.01	0.00	0.15	0.07	0.01	0.00	NC	-
TN 0678	Walnut, nutmeat	RAC	0.01	0.01	0.00	0.01	0.00	0.81	0.01	0.01	0.00	NC	-
SO 0495	Rape seed, raw (incl oil)	RAC	0.02	0.19	0.00	0.07	0.00	12.07	0.24	0.08	0.00	NC	-
SO 0702	Sunflower seed, raw	RAC	0.04	0.02	0.00	0.01	0.00	0.03	0.00	2.23	0.09	NC	-
OR 0702	Sunflower seed oil, edible	PP	0.01	0.37	0.00	0.09	0.00	12.98	0.13	4.01	0.04	0.20	0.00
SO 0691	Cotton seed, raw (incl oil)	RAC	0.01	8.14	0.08	0.32	0.00	2.84	0.03	2.69	0.03	0.97	0.01
SO 0697	Peanuts, nutmeat, raw (incl roasted, incl butter, excl oil)	RAC	0.01	7.14	0.07	0.45	0.00	1.87	0.02	6.22	0.06	0.53	0.01
OR 0697	Peanut oil, edible	PP	0.03	5.02	0.15	0.05	0.00	0.17	0.01	0.29	0.01	NC	-
SB 0716	Coffee bean, raw (i.e. green coffee)	RAC	0.01	0.83	0.01	0.69	0.01	1.09	0.01	2.91	0.03	0.82	0.01
SM 0716	Coffee bean, roasted	PP	0.006	0.02	0.00	0.41	0.00	7.50	0.05	0.01	0.00	0.06	0.00
-	Coffee bean, instant coffee (incl essences and concentrates)	PP	0.0106	0.03	0.00	0.05	0.00	0.60	0.01	0.01	0.00	5.53	0.06
HH 0092	Group of Herbs, raw (incl dried)	RAC	23	1.85	42.55	1.67	38.41	2.80	64.40	1.24	28.52	2.75	63.25
HS 0444	Peppers, chili, dried	PP	3.5	0.58	2.03	1.27	4.45	1.21	4.24	0.12	0.42	NC	-
DH 1100	Hops, dry	RAC	11	NC	-	NC	-	0.04	0.44	NC	-	NC	-
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80 % as muscle	RAC	0.01	23.34	0.23	40.71	0.41	97.15	0.97	18.06	0.18	57.71	0.58

Annex 3

AZOXYSTROBIN (229)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.2 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day		Intake = daily intake: ug/person							
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20 % as fat	RAC	0.02	5.84	0.12	10.18	0.20	24.29	0.49	4.52	0.09	14.43	0.29
MO 0105	Edible offal (mammalian), raw	RAC	0.02	4.64	0.09	1.97	0.04	10.01	0.20	3.27	0.07	3.98	0.08
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.01	108.75	1.09	70.31	0.70	436.11	4.36	61.55	0.62	79.09	0.79
PM 0110	Poultry meat, raw (incl prepared)	RAC	0	3.92	0.00	12.03	0.00	57.07	0.00	5.03	0.00	55.56	0.00
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0	0.10	0.00	0.70	0.00	0.97	0.00	0.10	0.00	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0	3.84	0.00	4.41	0.00	27.25	0.00	1.13	0.00	7.39	0.00
-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total intake (ug/person)=				590.9		309.8		1121.3		867.4		387.4	
Bodyweight per region (kg bw) =				60		60		60		60		60	
ADI (ug/person)=				12000		12000		12000		12000		12000	
%ADI=				4.9 %		2.6 %		9.3 %		7.2 %		3.2 %	
Rounded %ADI=				5 %		3 %		9 %		7 %		3 %	

Annex 3

BENZOVINDIFLUPYR (261)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.05 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day							
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
FP 0009	Group of Pome fruits, raw (incl apple cider, excl apple juice)	RAC	0.057	19.35	1.10	34.06	1.94	17.87	1.02	25.74	1.47	7.69	0.44	56.85	3.24
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.00342	0.32	0.00	3.07	0.01	0.07	0.00	5.00	0.02	0.29	0.00	5.57	0.02
FB 0020	Blueberries, raw	RAC	0.65	0.01	0.01	0.03	0.02	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01
FB 0269	Grapes, raw (i.e. table grapes)	RAC	0.23	12.68	2.92	9.12	2.10	0.03	0.01	16.88	3.88	3.70	0.85	54.42	12.52
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	0.552	0.51	0.28	0.51	0.28	0.01	0.01	1.27	0.70	0.12	0.07	2.07	1.14
JF 0269	Grape juice (from wine grapes)	PP	0.01725	0.14	0.00	0.29	0.01	0.05	0.00	0.30	0.01	0.24	0.00	0.05	0.00
-	Graps must (from wine-grapes)	PP	0.1518	0.33	0.05	0.13	0.02	0.01	0.00	0.02	0.00	0.01	0.00	0.02	0.00
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.0184	0.67	0.01	12.53	0.23	2.01	0.04	1.21	0.02	3.53	0.06	4.01	0.07
VA 2031	Subgroup of bulb onions	RAC	0.01	31.65	0.32	43.28	0.43	3.68	0.04	38.48	0.38	20.46	0.20	47.29	0.47
VC 0045	Group of Fruiting vegetables, cucurbits, raw	RAC	0.023	53.14	1.22	86.21	1.98	6.28	0.14	92.76	2.13	15.64	0.36	155.30	3.57
VO 0448	Tomato, raw	RAC	0.089	41.73	3.71	75.65	6.73	10.66	0.95	82.87	7.38	24.75	2.20	200.93	17.88
-	Tomato, canned (& peeled)	PP	0.00267	0.20	0.00	0.31	0.00	0.02	0.00	1.11	0.00	0.11	0.00	1.50	0.00
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.03738	2.34	0.09	1.33	0.05	1.57	0.06	4.24	0.16	0.34	0.01	2.83	0.11
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.00801	0.29	0.00	0.29	0.00	0.01	0.00	0.38	0.00	0.05	0.00	0.14	0.00
VO 0051	Subgroup of peppers, raw (incl dried sweet peppers, excl dried chillipeppers), incl okra	RAC	0.089	10.45	0.93	13.74	1.22	13.81	1.23	14.53	1.29	15.25	1.36	27.93	2.49
VO 2046	Subgroup of eggplants	RAC	0.089	5.58	0.50	4.31	0.38	0.89	0.08	9.31	0.83	13.64	1.21	20.12	1.79
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	0.01	2.39	0.02	1.61	0.02	10.47	0.10	1.84	0.02	12.90	0.13	7.44	0.07
VD 0523	Broad bean, dry, raw (incl horse-bean, field bean) (Vicia faba)	RAC	0.01	1.27	0.01	0.01	0.00	0.12	0.00	2.49	0.02	0.23	0.00	5.54	0.06
VD 0527	Cowpea, dry, raw (Vigna sinensis, Dolichos sinensis)	RAC	0.01	0.05	0.00	NC	-	1.74	0.02	0.01	0.00	0.01	0.00	0.07	0.00
VD 0541	Soya bean, dry, raw (Glycine soja)	RAC	0.01	0.58	0.01	0.05	0.00	0.37	0.00	0.03	0.00	1.65	0.02	0.30	0.00
-	Soya paste (i.e. miso)	PP	0.0013	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
-	Soya curd (i.e. tofu)	PP	0.0033	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
OR 0541	Soya oil, refined	PP	0.0064	12.99	0.08	10.43	0.07	3.63	0.02	13.10	0.08	10.70	0.07	13.10	0.08
-	Soya sauce	PP	0.0023	0.01	0.00	0.02	0.00	0.01	0.00	0.34	0.00	0.03	0.00	0.01	0.00
-	Soya flour	PP	0.0024	0.05	0.00	0.86	0.00	0.02	0.00	1.02	0.00	0.01	0.00	0.15	0.00
-	Beans (dry) NES: including inter alia lablab or hyacinth bean (Dolichos spp.); jack or sword bean (Canavalia spp.); winged bean (Psophocarpus tetragonolobus); guar bean (Cyamopsis tetragonoloba); velvet bean (Stizolobium spp.); yam bean (Pachyrrhizus erosus)	RAC	0.01	1.70	0.02	0.01	0.00	3.00	0.03	1.80	0.02	1.64	0.02	1.33	0.01
VD 2066	Subgroup of dry peas, raw	RAC	0.012	9.09	0.11	3.35	0.04	1.06	0.01	9.48	0.11	15.11	0.18	10.58	0.13

Annex 3

999

BENZOVINDIFLUPYR (261)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.05 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day							
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
				VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.01	59.74	0.60	316.14	3.16	9.78	0.10	60.26	0.60
GC 0650	Rye, raw (incl flour)	RAC	0.023	0.13	0.00	19.38	0.45	0.10	0.00	0.12	0.00	0.03	0.00	2.15	0.05
GC 0653	Triticale, raw (incl flour)	RAC	0.023	NC	-	NC	-	NC	-	0.01	0.00	0.39	0.01	NC	-
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, excl germ, excl wholemeal bread, excl white flour products, excl white bread)	RAC	0.023	0.01	0.00	1.12	0.03	NC	-	0.03	0.00	0.56	0.01	NC	-
CF 1210	Wheat, germ	PP	0.023	NC	-	NC	-	0.01	0.00	0.01	0.00	0.14	0.00	0.01	0.00
CP 1212	Wheat, wholemeal bread	PP	0.0115	0.01	0.00	0.01	0.00	0.01	0.00	0.01	0.00	0.03	0.00	0.01	0.00
CP 1211	Wheat, white bread	PP	0.00759	0.25	0.00	0.63	0.00	0.12	0.00	0.43	0.00	1.39	0.01	0.22	0.00
CF 1211	Wheat, white flour (incl white flour products: starch, gluten, macaroni, pastry)	PP	0.00759	301.24	2.29	268.64	2.04	30.21	0.23	222.51	1.69	134.73	1.02	343.12	2.60
GC 0640	Barley, raw (incl malt extract, incl beer, incl malt, excl pot&pearled, excl flour & grits)	RAC	0.21	3.55	0.75	19.31	4.06	4.98	1.05	3.02	0.63	7.85	1.65	3.98	0.84
-	Barley, pot&pearled	PP	0.0966	7.12	0.69	7.34	0.71	0.02	0.00	0.03	0.00	0.67	0.06	0.20	0.02
-	Barley, flour (white flour and wholemeal flour)	PP	0.084	2.93	0.25	0.30	0.03	0.02	0.00	0.01	0.00	0.48	0.04	0.01	0.00
GC 0647	Oats, raw (incl rolled)	RAC	0.21	0.05	0.01	7.05	1.48	0.10	0.02	1.71	0.36	0.96	0.20	0.04	0.01
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl beer, incl germ, excl flour, excl oil, excl starch)	RAC	0.01	0.84	0.01	0.24	0.00	1.56	0.02	0.46	0.00	2.44	0.02	13.13	0.13
CF 1255	Maize, flour (white flour and wholemeal flour)	PP	0.0025	22.72	0.06	35.61	0.09	87.27	0.22	34.92	0.09	46.71	0.12	49.12	0.12
-	Maize starch	PP	0.0025	0.08	0.00	NC	-	0.01	0.00	2.29	0.01	0.08	0.00	0.11	0.00
OR 0645	Maize oil	PP	0.005	0.96	0.00	0.85	0.00	0.29	0.00	5.42	0.03	0.42	0.00	2.10	0.01
GC 0447	Sweet corn on the cob, raw (incl frozen kernels, incl canned kernels)	RAC	0.01	0.14	0.00	0.94	0.01	5.70	0.06	2.61	0.03	1.94	0.02	0.22	0.00
GS 0659	Sugar cane, raw	RAC	0.069	38.16	2.63	NC	-	12.58	0.87	0.34	0.02	17.79	1.23	42.78	2.95
-	Sugar cane, molasses	PP	0.02277	NC	-	NC	-	NC	-	NC	-	0.01	0.00	NC	-
-	Sugar cane, sugar (incl non-centrifugal sugar, incl refined sugar and maltose)	PP	0.01725	61.52	1.06	86.27	1.49	18.80	0.32	80.02	1.38	66.39	1.15	56.32	0.97
SO 0495	Rape seed, raw	RAC	0.023	0.02	0.00	NC	-	NC	-	0.01	0.00	0.75	0.02	0.01	0.00
OR 0495	Rape seed oil, edible	PP	0.02254	0.35	0.01	0.44	0.01	0.19	0.00	0.97	0.02	3.28	0.07	0.77	0.02
SO 0697	Peanuts, nutmeat, raw (incl roasted, excl oil, excl butter)	RAC	0.01	0.46	0.00	1.21	0.01	6.64	0.07	2.52	0.03	1.25	0.01	1.83	0.02
OR 0697	Peanut oil, edible	PP	0.016	0.36	0.01	0.01	0.00	2.57	0.04	0.07	0.00	2.29	0.04	0.36	0.01
-	Peanut butter	PP	0.0057	0.01	0.00	0.01	0.00	0.01	0.00	0.19	0.00	0.01	0.00	0.01	0.00
SB 0716	Coffee bean, raw (i.e. green coffee)	RAC	0.015	0.96	0.01	0.16	0.00	0.91	0.01	0.27	0.00	1.37	0.02	0.46	0.01
SM 0716	Coffee bean, roasted	PP	0.0063	0.19	0.00	0.91	0.01	0.16	0.00	2.50	0.02	0.39	0.00	0.40	0.00
-	Coffee bean, instant coffee (incl essences and concentrates)	PP	0.0075	0.07	0.00	0.94	0.01	0.07	0.00	0.70	0.01	0.07	0.00	0.29	0.00
-	Coffee bean, substitutes, containing coffee	PP	0.015	0.01	0.00	0.01	0.00	0.16	0.00	0.17	0.00	0.02	0.00	0.03	0.00

Annex 3

BENZOVINDIFLUPYR (261)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.05 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day																			
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake												
HS 0444	Peppers, chili, dried	PP	0.89	0.42	0.37	0.53	0.47	0.84	0.75	0.50	0.45	0.95	0.85	0.37	0.33												
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80 % as muscle	RAC	0.01	24.96	0.25	57.95	0.58	16.70	0.17	38.38	0.38	26.46	0.26	29.00	0.29												
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20 % as fat	RAC	0.010	6.24	0.06	14.49	0.14	4.18	0.04	9.60	0.10	6.62	0.07	7.25	0.07												
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.010	3.29	0.03	6.14	0.06	0.82	0.01	1.57	0.02	2.23	0.02	1.07	0.01												
MO 0105	Edible offal (mammalian), raw	RAC	0.012	4.79	0.06	9.68	0.12	2.97	0.04	5.49	0.07	3.84	0.05	5.03	0.06												
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.01	289.65	2.90	485.88	4.86	26.92	0.27	239.03	2.39	199.91	2.00	180.53	1.81												
PM 0110	Poultry meat, raw (incl prepared) - 90 % as muscle	RAC	0.01	13.17	0.13	26.78	0.27	7.24	0.07	116.71	1.17	22.54	0.23	32.09	0.32												
PM 0110	Poultry meat, raw (incl prepared) - 10 % as fat	RAC	0.01	1.46	0.01	2.98	0.03	0.80	0.01	12.97	0.13	2.50	0.03	3.57	0.04												
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.01	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.10	0.00	0.10	0.00												
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.01	0.12	0.00	0.12	0.00	0.11	0.00	5.37	0.05	0.24	0.00	0.10	0.00												
PE 0112	Eggs, raw, (incl dried)	RAC	0.01	7.84	0.08	23.08	0.23	2.88	0.03	14.89	0.15	9.81	0.10	14.83	0.15												
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-												
Total intake (ug/person)=				23.7				35.9				8.2				28.4				17.1				55.7			
Bodyweight per region (kg bw) =				60				60				60				60				60							
ADI (ug/person)=				3000				3000				3000				3000				3000							
%ADI=				0.79 %				1.20 %				0.27 %				0.95 %				0.57 %				1.86 %			
Rounded %ADI=				1 %				1 %				0 %				1 %				1 %				2 %			

BENZOVINDIFLUPYR (261)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.05 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day							
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
FP 0009	Group of Pome fruits, raw (incl apple cider, excl apple juice)	RAC	0.057	51.09	2.91	65.40	3.73	42.71	2.43	45.29	2.58	62.51	3.56	7.74	0.44
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.00342	14.88	0.05	11.98	0.04	0.15	0.00	9.98	0.03	30.32	0.10	3.47	0.01
FB 0020	Blueberries, raw	RAC	0.65	0.04	0.03	0.23	0.15	0.01	0.01	0.83	0.54	0.33	0.21	NC	-
FB 0269	Grapes, raw (i.e. table grapes)	RAC	0.23	6.33	1.46	11.22	2.58	5.21	1.20	9.38	2.16	4.55	1.05	0.78	0.18
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	0.552	3.09	1.71	1.51	0.83	0.03	0.02	1.38	0.76	4.26	2.35	0.42	0.23
JF 0269	Grape juice (from wine grapes)	PP	0.01725	0.56	0.01	1.96	0.03	0.02	0.00	2.24	0.04	2.27	0.04	0.34	0.01

Annex 3

899

BENZOVINDIFLUPYR (261)			International Estimated Daily Intake (IEDI)				ADI = 0 - 0.05 mg/kg bw								
Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day							
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
-	Graps must (from wine-grapes)	PP	0.1518	0.16	0.02	0.09	0.01	0.01	0.00	0.12	0.02	0.11	0.02	NC	-
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.0184	88.93	1.64	62.41	1.15	1.84	0.03	25.07	0.46	61.17	1.13	5.84	0.11
VA 2031	Subgroup of bulb onions	RAC	0.01	20.67	0.21	31.32	0.31	37.52	0.38	35.08	0.35	11.77	0.12	13.74	0.14
VC 0045	Group of Fruiting vegetables, cucurbits, raw	RAC	0.023	27.81	0.64	41.93	0.96	123.30	2.84	49.47	1.14	15.95	0.37	35.99	0.83
VO 0448	Tomato, raw	RAC	0.089	32.13	2.86	51.27	4.56	34.92	3.11	73.37	6.53	15.15	1.35	8.88	0.79
-	Tomato, canned (& peeled)	PP	0.00267	7.57	0.02	2.66	0.01	0.30	0.00	0.97	0.00	7.31	0.02	0.41	0.00
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.03738	4.96	0.19	3.20	0.12	0.15	0.01	1.61	0.06	6.88	0.26	0.52	0.02
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.00801	0.80	0.01	0.07	0.00	0.05	0.00	0.61	0.00	0.40	0.00	0.08	0.00
VO 0051	Subgroup of peppers, raw (incl dried sweet peppers, excl dried chilipeppers), incl okra	RAC	0.089	6.39	0.57	15.53	1.38	19.13	1.70	10.53	0.94	8.29	0.74	5.25	0.47
VO 2046	Subgroup of eggplants	RAC	0.089	1.01	0.09	1.69	0.15	21.37	1.90	3.00	0.27	1.40	0.12	NC	-
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	0.01	1.51	0.02	1.50	0.02	1.90	0.02	5.11	0.05	1.36	0.01	23.43	0.23
VD 0523	Broad bean, dry, raw (incl horse-bean, field bean) (Vicia faba)	RAC	0.01	0.02	0.00	0.01	0.00	1.16	0.01	0.40	0.00	NC	-	0.06	0.00
VD 0527	Cowpea, dry, raw (Vigna sinensis, Dolichos sinensis)	RAC	0.01	NC	-	NC	-	0.16	0.00	0.01	0.00	NC	-	NC	-
VD 0541	Soya bean, dry, raw (Glycine soja)	RAC	0.01	0.02	0.00	0.33	0.00	6.64	0.07	3.94	0.04	NC	-	5.78	0.06
-	Soya paste (i.e. miso)	PP	0.0013	NC	-	NC	-	NC	-	1.87	0.00	NC	-	NC	-
-	Soya curd (i.e. tofu)	PP	0.0033	NC	-	NC	-	0.68	0.00	0.87	0.00	NC	-	NC	-
OR 0541	Soya oil, refined	PP	0.0064	19.06	0.12	21.06	0.13	5.94	0.04	33.78	0.22	40.05	0.26	13.39	0.09
-	Soya sauce	PP	0.0023	0.45	0.00	0.29	0.00	2.93	0.01	4.35	0.01	0.09	0.00	0.70	0.00
-	Soya flour	PP	0.0024	0.22	0.00	0.27	0.00	0.29	0.00	0.17	0.00	NC	-	NC	-
-	Beans (dry) NES: including inter alia lablab or hyacinth bean (Dolichos spp.); jack or sword bean (Canavalia spp.); winged bean (Psophocarpus tetragonolobus); guar bean (Cyamopsis tetragonoloba); velvet bean (Stizolobium spp.); yam bean (Pachyrrhizus erosus)	RAC	0.01	0.01	0.00	NC	-	0.57	0.01	0.11	0.00	0.16	0.00	0.94	0.01
VD 2066	Subgroup of dry peas, raw	RAC	0.012	5.01	0.06	3.76	0.05	1.82	0.02	3.44	0.04	3.49	0.04	5.15	0.06
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.01	225.03	2.25	234.24	2.34	71.48	0.71	177.55	1.78	234.55	2.35	37.71	0.38
GC 0650	Rye, raw (incl flour)	RAC	0.023	3.21	0.07	35.38	0.81	0.21	0.00	6.50	0.15	1.49	0.03	NC	-
GC 0653	Triticale, raw (incl flour)	RAC	0.023	0.01	0.00	0.17	0.00	0.29	0.01	0.01	0.00	NC	-	NC	-
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, excl germ, excl wholemeal bread, excl white flour products, excl white bread)	RAC	0.023	NC	-	NC	-	0.02	0.00	0.83	0.02	NC	-	NC	-
CF 1210	Wheat, germ	PP	0.023	0.97	0.02	0.10	0.00	0.03	0.00	0.01	0.00	NC	-	0.04	0.00
CP 1212	Wheat, wholemeal bread	PP	0.0115	0.03	0.00	0.01	0.00	0.01	0.00	0.01	0.00	0.05	0.00	0.02	0.00

Annex 3

BENZOVINDIFLUPYR (261)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.05 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day							
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
CP 1211	Wheat, white bread	PP	0.00759	1.30	0.01	0.46	0.00	0.06	0.00	0.22	0.00	2.44	0.02	0.77	0.01
CF 1211	Wheat, white flour (incl white flour products: starch, gluten, macaroni, pastry)	PP	0.00759	198.08	1.50	193.03	1.47	106.24	0.81	185.09	1.40	168.67	1.28	131.59	1.00
GC 0640	Barley, raw (incl malt extract, incl beer, incl malt, excl pot&pearled, excl flour & grits)	RAC	0.21	35.17	7.39	49.45	10.38	8.86	1.86	34.31	7.21	44.87	9.42	15.82	3.32
-	Barley, pot&pearled	PP	0.0966	0.57	0.06	2.56	0.25	0.33	0.03	0.56	0.05	0.36	0.03	NC	-
-	Barley, flour (white flour and wholemeal flour)	PP	0.084	0.08	0.01	0.03	0.00	0.01	0.00	0.05	0.00	0.68	0.06	0.05	0.00
GC 0647	Oats, raw (incl rolled)	RAC	0.21	7.50	1.58	6.26	1.31	0.15	0.03	4.87	1.02	3.16	0.66	2.98	0.63
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl beer, incl germ, excl flour, excl oil, excl starch)	RAC	0.01	0.10	0.00	9.93	0.10	1.40	0.01	10.26	0.10	0.33	0.00	0.05	0.00
CF 1255	Maize, flour (white flour and wholemeal flour)	PP	0.0025	14.27	0.04	12.86	0.03	19.71	0.05	12.55	0.03	4.21	0.01	52.30	0.13
-	Maize starch	PP	0.0025	NC	-	NC	-	0.19	0.00	7.13	0.02	NC	-	NC	-
OR 0645	Maize oil	PP	0.005	0.90	0.00	0.47	0.00	0.15	0.00	3.01	0.02	1.86	0.01	0.36	0.00
GC 0447	Sweet corn on the cob, raw (incl frozen kernels, incl canned kernels)	RAC	0.01	11.43	0.11	3.71	0.04	0.74	0.01	13.63	0.14	3.07	0.03	1.50	0.02
GS 0659	Sugar cane, raw	RAC	0.069	NC	-	NC	-	4.27	0.29	0.01	0.00	NC	-	3.24	0.22
-	Sugar cane, molasses	PP	0.02277	NC	-	NC	-	0.08	0.00	NC	-	NC	-	NC	-
-	Sugar cane, sugar (incl non-centrifugal sugar, incl refined sugar and maltose)	PP	0.01725	92.24	1.59	95.72	1.65	24.12	0.42	77.39	1.33	117.73	2.03	100.67	1.74
SO 0495	Rape seed, raw	RAC	0.023	NC	-	NC	-	0.01	0.00	NC	-	NC	-	NC	-
OR 0495	Rape seed oil, edible	PP	0.02254	12.52	0.28	7.63	0.17	3.00	0.07	6.01	0.14	NC	-	NC	-
SO 0697	Peanuts, nutmeat, raw (incl roasted, excl oil, excl butter)	RAC	0.01	3.19	0.03	2.19	0.02	5.36	0.05	4.82	0.05	1.40	0.01	1.06	0.01
OR 0697	Peanut oil, edible	PP	0.016	1.02	0.02	0.23	0.00	1.81	0.03	0.42	0.01	5.23	0.08	0.01	0.00
-	Peanut butter	PP	0.0057	0.07	0.00	0.04	0.00	0.01	0.00	0.03	0.00	0.15	0.00	0.75	0.00
SB 0716	Coffee bean, raw (i.e. green coffee)	RAC	0.015	0.60	0.01	NC	-	0.62	0.01	1.71	0.03	NC	-	3.51	0.05
SM 0716	Coffee bean, roasted	PP	0.0063	7.02	0.04	9.75	0.06	0.02	0.00	5.09	0.03	13.38	0.08	0.77	0.00
-	Coffee bean, instant coffee (incl essences and concentrates)	PP	0.0075	0.75	0.01	0.30	0.00	0.04	0.00	0.67	0.01	2.43	0.02	1.43	0.01
-	Coffee bean, substitutes, containing coffee	PP	0.015	0.08	0.00	0.09	0.00	0.02	0.00	0.02	0.00	0.07	0.00	0.15	0.00
HS 0444	Peppers, chili, dried	PP	0.89	0.11	0.10	0.21	0.19	0.36	0.32	0.21	0.19	0.25	0.22	0.15	0.13
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80 % as muscle	RAC	0.01	112.02	1.12	120.71	1.21	63.46	0.63	88.99	0.89	96.24	0.96	41.02	0.41
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20 % as fat	RAC	0.010	28.01	0.28	30.18	0.30	15.86	0.16	22.25	0.22	24.06	0.24	10.25	0.10
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.010	6.44	0.06	15.51	0.16	3.79	0.04	8.29	0.08	18.44	0.18	8.00	0.08
MO	Edible offal (mammalian), raw	RAC	0.012	15.17	0.18	5.19	0.06	6.30	0.08	6.78	0.08	3.32	0.04	3.17	0.04

Annex 3

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BENZOVINDIFLUPYR (261)				International Estimated Daily Intake (IEDI)						ADI = 0 - 0.05 mg/kg bw																	
Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day																			
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake												
0105																											
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.01	388.92	3.89	335.88	3.36	49.15	0.49	331.25	3.31	468.56	4.69	245.45	2.45												
PM 0110	Poultry meat, raw (incl prepared) - 90 % as muscle	RAC	0.01	66.38	0.66	48.47	0.48	21.58	0.22	78.41	0.78	48.04	0.48	76.01	0.76												
PM 0110	Poultry meat, raw (incl prepared) - 10 % as fat	RAC	0.01	7.38	0.07	5.39	0.05	2.40	0.02	8.71	0.09	5.34	0.05	8.45	0.08												
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.01	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.71	0.01	NC	-												
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.01	0.33	0.00	0.72	0.01	0.27	0.00	0.35	0.00	0.80	0.01	NC	-												
PE 0112	Eggs, raw, (incl dried)	RAC	0.01	25.84	0.26	29.53	0.30	28.05	0.28	33.19	0.33	36.44	0.36	8.89	0.09												
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-												
Total intake (ug/person)=				34.3				41.0				20.4				35.8				35.1				15.4			
Bodyweight per region (kg bw) =				60				60				55				60				60				60			
ADI (ug/person)=				3000				3000				2750				3000				3000				3000			
%ADI=				1.14 %				1.37 %				0.74 %				1.19 %				1.17 %				0.51 %			
Rounded %ADI=				1 %				1 %				1 %				1 %				1 %				1 %			

BENZOVINDIFLUPYR (261)				International Estimated Daily Intake (IEDI)						ADI = 0 - 0.05 mg/kg bw					
Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day				Intake = daily intake: ug/person							
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake		
FP 0009	Group of Pome fruits, raw (incl apple cider, excl apple juice)	RAC	0.057	68.85	3.92	10.93	0.62	70.82	4.04	189.78	10.82	19.56	1.11		
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.00342	0.03	0.00	0.10	0.00	7.19	0.02	0.03	0.00	NC	-		
FB 0020	Blueberries, raw	RAC	0.65	NC	-	NC	-	0.20	0.13	NC	-	NC	-		
FB 0269	Grapes, raw (i.e. table grapes)	RAC	0.23	0.14	0.03	0.36	0.08	15.22	3.50	0.01	0.00	0.09	0.02		
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	0.552	0.01	0.01	0.13	0.07	1.06	0.59	0.01	0.01	0.03	0.02		
JF 0269	Grape juice (from wine grapes)	PP	0.01725	0.01	0.00	0.01	0.00	0.41	0.01	0.01	0.00	NC	-		
-	Graps must (from wine-grapes)	PP	0.1518	0.01	0.00	0.01	0.00	0.11	0.02	0.01	0.00	0.19	0.03		
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.0184	0.31	0.01	0.23	0.00	60.43	1.11	0.52	0.01	31.91	0.59		
VA 2031	Subgroup of bulb onions	RAC	0.01	9.83	0.10	22.30	0.22	34.69	0.35	9.65	0.10	2.39	0.02		
VC 0045	Group of Fruiting vegetables, cucurbits, raw	RAC	0.023	5.96	0.14	9.74	0.22	51.82	1.19	13.61	0.31	0.05	0.00		
VO 0448	Tomato, raw	RAC	0.089	12.99	1.16	4.79	0.43	58.40	5.20	0.92	0.08	0.09	0.01		
-	Tomato, canned (& peeled)	PP	0.00267	0.07	0.00	0.08	0.00	2.42	0.01	0.07	0.00	NC	-		
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.03738	0.58	0.02	0.22	0.01	2.21	0.08	0.24	0.01	3.10	0.12		
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.00801	0.05	0.00	0.01	0.00	0.42	0.00	0.01	0.00	0.02	0.00		
VO 0051	Subgroup of peppers, raw (incl dried sweet	RAC	0.089	15.20	1.35	14.23	1.27	25.14	2.24	0.91	0.08	NC	-		

Annex 3

BENZOVINDIFLUPYR (261)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.05 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day		Intake = daily intake: ug/person							
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
	peppers, excl dried chilipeppers), incl okra												
VO 2046	Subgroup of eggplants	RAC	0.089	1.31	0.12	8.26	0.74	3.95	0.35	0.01	0.00	NC	-
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	0.01	7.11	0.07	2.33	0.02	3.76	0.04	44.70	0.45	3.27	0.03
VD 0523	Broad bean, dry, raw (incl horse-bean, field bean) (Vicia faba)	RAC	0.01	3.70	0.04	0.03	0.00	0.17	0.00	0.01	0.00	NC	-
VD 0527	Cowpea, dry, raw (Vigna sinensis, Dolichos sinensis)	RAC	0.01	12.77	0.13	0.99	0.01	0.01	0.00	4.33	0.04	NC	-
VD 0541	Soya bean, dry, raw (Glycine soja)	RAC	0.01	2.76	0.03	0.07	0.00	0.33	0.00	3.16	0.03	NC	-
-	Soya paste (i.e. miso)	PP	0.0013	NC	-	NC	-	NC	-	NC	-	NC	-
-	Soya curd (i.e. tofu)	PP	0.0033	NC	-	NC	-	NC	-	NC	-	NC	-
OR 0541	Soya oil, refined	PP	0.0064	2.32	0.01	2.54	0.02	18.70	0.12	2.51	0.02	6.29	0.04
-	Soya sauce	PP	0.0023	0.01	0.00	0.13	0.00	0.17	0.00	0.01	0.00	0.56	0.00
-	Soya flour	PP	0.0024	0.11	0.00	0.08	0.00	0.07	0.00	0.01	0.00	0.03	0.00
-	Beans (dry) NES: including inter alia lablab or hyacinth bean (Dolichos spp.); jack or sword bean (Canavalia spp.); winged bean (Psophocarpus tetragonolobus); guar bean (Cyamopsis tetragonoloba); velvet bean (Stizolobium spp.); yam bean (Pachyrrhizus erosus)	RAC	0.01	2.54	0.03	1.77	0.02	0.03	0.00	0.03	0.00	3.99	0.04
VD 2066	Subgroup of dry peas, raw	RAC	0.012	4.43	0.05	11.36	0.14	4.22	0.05	9.36	0.11	1.21	0.01
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.01	23.96	0.24	13.56	0.14	213.41	2.13	104.35	1.04	8.56	0.09
GC 0650	Rye, raw (incl flour)	RAC	0.023	0.03	0.00	0.01	0.00	13.95	0.32	0.01	0.00	0.88	0.02
GC 0653	Triticale, raw (incl flour)	RAC	0.023	0.01	0.00	NC	-	NC	-	NC	-	NC	-
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, excl germ, excl wholemeal bread, excl white flour products, excl white bread)	RAC	0.023	0.01	0.00	NC	-	NC	-	NC	-	0.97	0.02
CF 1210	Wheat, germ	PP	0.023	0.04	0.00	0.01	0.00	0.01	0.00	0.01	0.00	NC	-
CP 1212	Wheat, wholemeal bread	PP	0.0115	0.01	0.00	0.01	0.00	0.03	0.00	0.01	0.00	0.01	0.00
CP 1211	Wheat, white bread	PP	0.00759	0.43	0.00	0.41	0.00	1.56	0.01	0.11	0.00	0.07	0.00
CF 1211	Wheat, white flour (incl white flour products: starch, gluten, macaroni, pastry)	PP	0.00759	44.78	0.34	86.96	0.66	214.05	1.62	20.31	0.15	103.60	0.79
GC 0640	Barley, raw (incl malt extract, incl beer, incl malt, excl pot&pearled, excl flour & grits)	RAC	0.21	3.15	0.66	2.31	0.49	43.92	9.22	3.72	0.78	16.26	3.41
-	Barley, pot&pearled	PP	0.0966	5.46	0.53	0.01	0.00	1.44	0.14	0.01	0.00	NC	-
-	Barley, flour (white flour and wholemeal flour)	PP	0.084	0.02	0.00	NC	-	0.32	0.03	0.01	0.00	NC	-
GC 0647	Oats, raw (incl rolled)	RAC	0.21	0.37	0.08	0.07	0.01	2.79	0.59	0.10	0.02	NC	-
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl beer, incl germ, excl flour, excl oil, excl starch)	RAC	0.01	0.55	0.01	0.51	0.01	3.26	0.03	7.96	0.08	NC	-
CF 1255	Maize, flour (white flour and wholemeal flour)	PP	0.0025	94.34	0.24	8.09	0.02	28.03	0.07	55.94	0.14	28.07	0.07
-	Maize starch	PP	0.0025	0.02	0.00	0.01	0.00	NC	-	NC	-	NC	-

Annex 3

BENZOVINDIFLUPYR (261)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.05 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day		Intake = daily intake: ug/person							
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
OR 0645	Maize oil	PP	0.005	0.33	0.00	0.07	0.00	0.81	0.00	0.01	0.00	NC	-
GC 0447	Sweet corn on the cob, raw (incl frozen kernels, incl canned kernels)	RAC	0.01	3.63	0.04	20.50	0.21	8.78	0.09	0.02	0.00	0.17	0.00
GS 0659	Sugar cane, raw	RAC	0.069	5.62	0.39	50.91	3.51	NC	-	11.04	0.76	0.10	0.01
-	Sugar cane, molasses	PP	0.02277	NC	-	NC	-	NC	-	NC	-	NC	-
-	Sugar cane, sugar (incl non-centrifugal sugar, incl refined sugar and maltose)	PP	0.01725	28.13	0.49	55.38	0.96	78.09	1.35	18.04	0.31	45.60	0.79
SO 0495	Rape seed, raw	RAC	0.023	NC	-	0.01	0.00	NC	-	NC	-	NC	-
OR 0495	Rape seed oil, edible	PP	0.02254	0.07	0.00	0.03	0.00	4.62	0.10	0.03	0.00	NC	-
SO 0697	Peanuts, nutmeat, raw (incl roasted, excl oil, excl butter)	RAC	0.01	7.14	0.07	0.42	0.00	1.83	0.02	6.22	0.06	0.53	0.01
OR 0697	Peanut oil, edible	PP	0.016	5.02	0.08	0.05	0.00	0.17	0.00	0.29	0.00	NC	-
-	Peanut butter	PP	0.0057	0.01	0.00	0.03	0.00	0.05	0.00	NC	-	NC	-
SB 0716	Coffee bean, raw (i.e. green coffee)	RAC	0.015	0.83	0.01	0.69	0.01	1.09	0.02	2.91	0.04	0.82	0.01
SM 0716	Coffee bean, roasted	PP	0.0063	0.02	0.00	0.41	0.00	7.50	0.05	0.01	0.00	0.06	0.00
-	Coffee bean, instant coffee (incl essences and concentrates)	PP	0.0075	0.03	0.00	0.05	0.00	0.60	0.00	0.01	0.00	5.53	0.04
-	Coffee bean, substitutes, containing coffee	PP	0.015	0.01	0.00	0.03	0.00	0.13	0.00	0.01	0.00	NC	-
HS 0444	Peppers, chili, dried	PP	0.89	0.58	0.52	1.27	1.13	1.21	1.08	0.12	0.11	NC	-
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80 % as muscle	RAC	0.01	23.34	0.23	40.71	0.41	97.15	0.97	18.06	0.18	57.71	0.58
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20 % as fat	RAC	0.010	5.84	0.06	10.18	0.10	24.29	0.24	4.52	0.05	14.43	0.14
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.010	1.05	0.01	1.14	0.01	18.69	0.19	0.94	0.01	3.12	0.03
MO 0105	Edible offal (mammalian), raw	RAC	0.012	4.64	0.06	1.97	0.02	10.01	0.12	3.27	0.04	3.98	0.05
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.01	108.75	1.09	70.31	0.70	436.11	4.36	61.55	0.62	79.09	0.79
PM 0110	Poultry meat, raw (incl prepared) - 90 % as muscle	RAC	0.01	3.53	0.04	10.83	0.11	51.36	0.51	4.53	0.05	50.00	0.50
PM 0110	Poultry meat, raw (incl prepared) - 10 % as fat	RAC	0.01	0.39	0.00	1.20	0.01	5.71	0.06	0.50	0.01	5.56	0.06
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.01	NC	-	NC	-	0.32	0.00	NC	-	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.01	0.10	0.00	0.70	0.01	0.97	0.01	0.10	0.00	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0.01	3.84	0.04	4.41	0.04	27.25	0.27	1.13	0.01	7.39	0.07
-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total intake (ug/person)=				12.4		12.4		42.7		16.5		9.5	
Bodyweight per region (kg bw) =				60		60		60		60		60	
ADI (ug/person)=				3000		3000		3000		3000		3000	
%ADI=				0.41 %		0.41 %		1.42 %		0.55 %		0.32 %	
Rounded %ADI=				0 %		0 %		1 %		1 %		0 %	

Annex 3

BIFENTHRIN (178)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.01 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day							
				G01		G02		G03		G04		G05		G06	
				diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
FC 0001	Group of Citrus fruit, raw (incl citrus fruit juice, incl kumquat commodities)	RAC	0.05	34.91	1.75	16.51	0.83	17.23	0.86	104.48	5.22	35.57	1.78	98.49	4.92
FP 0009	Group of Pome fruits, raw (incl apple cider, excl apple juice)	RAC	0.195	19.35	3.77	34.06	6.64	17.87	3.48	25.74	5.02	7.69	1.50	56.85	11.09
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.0096	0.32	0.00	3.07	0.03	0.07	0.00	5.00	0.05	0.29	0.00	5.57	0.05
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.22	8.01	1.76	5.87	1.29	0.18	0.04	8.19	1.80	1.64	0.36	22.46	4.94
FB 0264	Blackberries, raw	RAC	0.29	0.35	0.10	0.11	0.03	0.01	0.00	0.02	0.01	0.01	0.00	1.23	0.36
FB 0266	Dewberries, incl boysen- & loganberry, raw	RAC	0.29	0.01	0.00	0.01	0.00	0.01	0.00	0.01	0.00	0.01	0.00	0.01	0.00
FB 0272	Raspberries, red, black, raw	RAC	0.29	0.07	0.02	0.93	0.27	0.01	0.00	0.01	0.00	0.01	0.00	0.01	0.00
FB 0020	Blueberries, raw	RAC	0.67	0.01	0.01	0.03	0.02	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01
FB 0269	Grapes, raw (incl must, incl dried, incl juice, incl wine)	RAC	0.06	16.25	0.98	28.96	1.74	2.87	0.17	24.22	1.45	9.33	0.56	68.64	4.12
FB 0275	Strawberry, raw	RAC	0.46	0.70	0.32	2.01	0.92	0.04	0.02	1.36	0.63	0.37	0.17	2.53	1.16
FI 0326	Avocado, raw	RAC	0.089	0.13	0.01	0.03	0.00	2.05	0.18	2.54	0.23	2.34	0.21	0.12	0.01
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.01	5.23	0.05	6.94	0.07	99.45	0.99	32.47	0.32	48.30	0.48	24.70	0.25
FI 0345	Mango, raw	RAC	0.01	10.38	0.10	0.01	0.00	7.24	0.07	6.85	0.07	19.53	0.20	4.52	0.05
FI 0350	Papaya, raw	RAC	0.01	0.35	0.00	0.01	0.00	3.05	0.03	0.80	0.01	7.28	0.07	1.00	0.01
FI 0355	Pomegranate, raw, (incl processed)	RAC	0.165	3.40	0.56	2.10	0.35	2.65	0.44	10.89	1.80	NC	-	6.67	1.10
VB 0040	Group of Brassica vegetables (excl Brassica leafy vegetables), raw	RAC	0.115	6.43	0.74	40.26	4.63	0.80	0.09	9.94	1.14	12.07	1.39	17.73	2.04
VO 0448	Tomato, raw (incl juice, incl canned, excl paste)	RAC	0.06	42.41	2.54	76.50	4.59	10.69	0.64	85.07	5.10	24.98	1.50	203.44	12.21
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.04	2.34	0.09	1.33	0.05	1.57	0.06	4.24	0.17	0.34	0.01	2.83	0.11
VO 0051	Subgroup of peppers, raw (incl dried sweet peppers, excl dried chilipeppers), excl okra	RAC	0.12	8.48	1.02	13.74	1.65	10.13	1.22	11.29	1.35	9.52	1.14	26.36	3.16
VO 0442	Okra, raw (i.e. Lady's Finger, Gombo)	RAC	0.07	1.97	0.14	NC	-	3.68	0.26	3.24	0.23	5.72	0.40	1.57	0.11
VO 2046	Subgroup of eggplants	RAC	0.12	5.58	0.67	4.31	0.52	0.89	0.11	9.31	1.12	13.64	1.64	20.12	2.41
VL 0485	Mustard greens, raw (i.e. Indian mustard, Amsoi, mustard cabbage)	RAC	1.16	0.03	0.03	0.31	0.36	0.01	0.01	0.05	0.06	0.47	0.55	0.11	0.13
VL 0494	Radish leaves, raw	RAC	1.75	0.26	0.46	0.45	0.79	0.28	0.49	0.68	1.19	NC	-	0.33	0.58
VD 0070	Group of Pulses, raw (incl processed)	RAC	0.05	87.29	4.36	64.04	3.20	37.15	1.86	89.82	4.49	91.02	4.55	98.20	4.91
OR 0541	Soya oil, refined	PP	0.05	12.99	0.65	10.43	0.52	3.63	0.18	13.10	0.66	10.70	0.54	13.10	0.66
VR 0075	Group of Root and tuber vegetables, raw (incl processed)	RAC	0.05	87.83	4.39	374.04	18.70	668.92	33.45	121.64	6.08	94.20	4.71	247.11	12.36
VS 0624	Celery	RAC	0.7	2.14	1.50	3.79	2.65	2.35	1.65	5.69	3.98	0.02	0.01	2.75	1.93
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, incl germ, incl wholemeal bread, incl white flour products, incl white bread)	RAC	0.25	381.15	95.29	341.55	85.39	38.35	9.59	281.89	70.47	172.83	43.21	434.07	108.52
GC 0654	Wheat, raw (incl meslin)	RAC	0.25	0.01	0.00	1.12	0.28	NC	-	0.01	0.00	0.56	0.14	NC	-
-	Wheat, bulgur	PP	0.25	NC	-	NC	-	NC	-	0.03	0.01	NC	-	NC	-

Annex 3

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BIFENTHRIN (178)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.01 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day																			
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake												
CF 1210	Wheat, germ	PP	0.45	NC	-	NC	-	0.01	0.00	0.01	0.00	0.14	0.06	0.01	0.00												
CP 1212	Wheat, wholemeal bread	PP	0.19	0.01	0.00	0.01	0.00	0.01	0.00	0.01	0.00	0.03	0.01	0.01	0.00												
CP 1211	Wheat, white bread	PP	0.061	0.25	0.02	0.63	0.04	0.12	0.01	0.43	0.03	1.39	0.08	0.22	0.01												
-	Wheat, Fermented Beverages (Korean jakju and takju)	PP	0.25	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-												
CF 1211	Wheat, white flour (incl white flour products: starch, gluten, macaroni, pastry)	PP	0.078	301.24	23.50	268.64	20.95	30.21	2.36	222.51	17.36	134.73	10.51	343.12	26.76												
TN 0085	Group of Tree nuts, raw (incl processed)	RAC	0.05	4.06	0.20	3.27	0.16	7.01	0.35	13.93	0.70	14.01	0.70	9.36	0.47												
SO 0495	Rape seed, raw	RAC	0.05	0.02	0.00	NC	-	NC	-	0.01	0.00	0.75	0.04	0.01	0.00												
OR 0495	Rape seed oil, edible	PP	0.08	0.35	0.03	0.44	0.04	0.19	0.02	0.97	0.08	3.28	0.26	0.77	0.06												
OR 0691	Cotton seed oil, edible	PP	0.005	3.22	0.02	1.54	0.01	1.01	0.01	0.74	0.00	1.12	0.01	2.93	0.01												
SO 0697	Peanuts, nutmeat, raw (incl roasted, incl oil, incl butter)	RAC	0.05	1.30	0.07	1.23	0.06	12.62	0.63	2.87	0.14	6.59	0.33	2.67	0.13												
OR 0697	Peanut oil, edible	PP	0.05	0.36	0.02	0.01	0.00	2.57	0.13	0.07	0.00	2.29	0.11	0.36	0.02												
HS 0444	Peppers, chili, dried	PP	0.84	0.42	0.35	0.53	0.45	0.84	0.71	0.50	0.42	0.95	0.80	0.37	0.31												
DH 1100	Hops, dry	RAC	1.9	0.01	0.02	0.04	0.08	0.01	0.02	0.01	0.02	NC	-	0.01	0.02												
DT 1114	Tea, green or black, fermented and dried, (including concentrates)	RAC	5.2	2.28	11.86	1.98	10.30	0.46	2.39	2.43	12.64	1.29	6.71	3.04	15.81												
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80 % as muscle	RAC	0.07	24.96	1.75	57.95	4.06	16.70	1.17	38.38	2.69	26.46	1.85	29.00	2.03												
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20 % as fat	RAC	0.59	6.24	3.68	14.49	8.55	4.18	2.46	9.60	5.66	6.62	3.90	7.25	4.28												
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.59	3.29	1.94	6.14	3.62	0.82	0.48	1.57	0.93	2.23	1.32	1.07	0.63												
MO 0105	Edible offal (mammalian), raw	RAC	0.07	4.79	0.34	9.68	0.68	2.97	0.21	5.49	0.38	3.84	0.27	5.03	0.35												
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.053	289.65	15.35	485.88	25.75	26.92	1.43	239.03	12.67	199.91	10.60	180.53	9.57												
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-												
Total intake (ug/person)=				180.5				210.3				68.3				166.4				102.7				237.7			
Bodyweight per region (kg bw) =				60				60				60				60				60				60			
ADI (ug/person)=				600				600				600				600				600				600			
%ADI=				30.1 %				35.0 %				11.4 %				27.7 %				17.1 %				39.6 %			
Rounded %ADI=				30 %				40 %				10 %				30 %				20 %				40 %			

Annex 3

BIFENTHRIN (178)		International Estimated Daily Intake (IEDI)										ADI = 0 - 0.01 mg/kg bw			
Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day							
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
FC 0001	Group of Citrus fruit, raw (incl citrus fruit juice, incl kumquat commodities)	RAC	0.05	114.42	5.72	62.91	3.15	26.97	1.35	96.72	4.84	96.22	4.81	563.19	28.16
FP 0009	Group of Pome fruits, raw (incl apple cider, excl apple juice)	RAC	0.195	51.09	9.96	65.40	12.75	42.71	8.33	45.29	8.83	62.51	12.19	7.74	1.51
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.0096	14.88	0.14	11.98	0.12	0.15	0.00	9.98	0.10	30.32	0.29	3.47	0.03
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.22	13.03	2.87	16.29	3.58	8.29	1.82	12.95	2.85	5.35	1.18	0.04	0.01
FB 0264	Blackberries, raw	RAC	0.29	0.09	0.03	0.52	0.15	0.14	0.04	0.24	0.07	NC	-	0.01	0.00
FB 0266	Dewberries, incl boysen- & loganberry, raw	RAC	0.29	0.01	0.00	NC	-	0.01	0.00	0.01	0.00	NC	-	0.01	0.00
FB 0272	Raspberries, red, black, raw	RAC	0.29	0.47	0.14	0.91	0.26	0.01	0.00	0.99	0.29	1.14	0.33	NC	-
FB 0020	Blueberries, raw	RAC	0.67	0.04	0.03	0.23	0.15	0.01	0.01	0.83	0.56	0.33	0.22	NC	-
FB 0269	Grapes, raw (incl must, incl dried, incl juice, incl wine)	RAC	0.06	142.23	8.53	105.77	6.35	7.87	0.47	52.44	3.15	109.22	6.55	10.96	0.66
FB 0275	Strawberry, raw	RAC	0.46	4.49	2.07	5.66	2.60	0.02	0.01	6.63	3.05	5.75	2.65	0.05	0.02
FI 0326	Avocado, raw	RAC	0.089	2.65	0.24	0.87	0.08	0.46	0.04	1.64	0.15	1.30	0.12	0.96	0.09
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.01	25.76	0.26	23.65	0.24	23.83	0.24	24.37	0.24	19.43	0.19	101.55	1.02
FI 0345	Mango, raw	RAC	0.01	1.80	0.02	0.63	0.01	9.73	0.10	1.07	0.01	3.52	0.04	16.44	0.16
FI 0350	Papaya, raw	RAC	0.01	0.31	0.00	0.18	0.00	1.50	0.02	0.51	0.01	0.54	0.01	1.08	0.01
FI 0355	Pomegranate, raw, (incl processed)	RAC	0.165	7.91	1.31	9.72	1.60	7.67	1.27	5.26	0.87	9.04	1.49	14.43	2.38
VB 0040	Group of Brassica vegetables (excl Brassica leafy vegetables), raw	RAC	0.115	20.71	2.38	39.81	4.58	25.06	2.88	37.93	4.36	18.12	2.08	16.74	1.93
VO 0448	Tomato, raw (incl juice, incl canned, excl paste)	RAC	0.06	44.88	2.69	55.49	3.33	35.44	2.13	75.65	4.54	27.00	1.62	9.61	0.58
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.04	4.96	0.20	3.20	0.13	0.15	0.01	1.61	0.06	6.88	0.28	0.52	0.02
VO 0051	Subgroup of peppers, raw (incl dried sweet peppers, excl dried chilipeppers), excl okra	RAC	0.12	6.39	0.77	15.53	1.86	19.09	2.29	10.36	1.24	8.29	0.99	4.53	0.54
VO 0442	Okra, raw (i.e. Lady's Finger, Gombo)	RAC	0.07	NC	-	NC	-	0.04	0.00	0.17	0.01	NC	-	0.72	0.05
VO 2046	Subgroup of eggplants	RAC	0.12	1.01	0.12	1.69	0.20	21.37	2.56	3.00	0.36	1.40	0.17	NC	-
VL 0485	Mustard greens, raw (i.e. Indian mustard, Amsoi, mustard cabbage)	RAC	1.16	NC	-	NC	-	NC	-	NC	-	NC	-	0.13	0.15
VL 0494	Radish leaves, raw	RAC	1.75	NC	-	NC	-	NC	-	3.78	6.62	NC	-	0.48	0.84
VD 0070	Group of Pulses, raw (incl processed)	RAC	0.05	112.88	5.64	123.05	6.15	47.73	2.39	204.75	10.24	227.52	11.38	110.05	5.50
OR 0541	Soya oil, refined	PP	0.05	19.06	0.95	21.06	1.05	5.94	0.30	33.78	1.69	40.05	2.00	13.39	0.67
VR 0075	Group of Root and tuber vegetables, raw (incl processed)	RAC	0.05	290.31	14.52	300.35	15.02	214.25	10.71	242.72	12.14	348.67	17.43	137.52	6.88
VS 0624	Celery	RAC	0.7	7.68	5.38	2.85	2.00	NC	-	3.34	2.34	16.83	11.78	4.04	2.83
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, incl germ, incl wholemeal bread, incl white flour products, incl white bread)	RAC	0.25	253.07	63.27	244.73	61.18	134.44	33.61	235.10	58.78	216.39	54.10	167.40	41.85

Annex 3

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BIFENTHRIN (178)		International Estimated Daily Intake (IEDI)						ADI = 0 - 0.01 mg/kg bw																			
Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day																			
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake												
GC 0654	Wheat, raw (incl meslin)	RAC	0.25	NC	-	NC	-	NC	-	0.01	0.00	NC	-	NC	-												
-	Wheat, bulgur	PP	0.25	NC	-	NC	-	0.01	0.00	NC	-	NC	-	NC	-												
CF 1210	Wheat, germ	PP	0.45	0.97	0.44	0.10	0.05	0.03	0.01	0.01	0.00	NC	-	0.04	0.02												
CP 1212	Wheat, wholemeal bread	PP	0.19	0.03	0.01	0.01	0.00	0.01	0.00	0.01	0.00	0.05	0.01	0.02	0.00												
CP 1211	Wheat, white bread	PP	0.061	1.30	0.08	0.46	0.03	0.06	0.00	0.22	0.01	2.44	0.15	0.77	0.05												
-	Wheat, Fermented Beverages (Korean jakju and takju)	PP	0.25	NC	-	NC	-	NC	-	4.36	1.09	NC	-	NC	-												
CF 1211	Wheat, white flour (incl white flour products: starch, gluten, macaroni, pastry)	PP	0.078	198.08	15.45	193.03	15.06	106.24	8.29	185.09	14.44	168.67	13.16	131.59	10.26												
TN 0085	Group of Tree nuts, raw (incl processed)	RAC	0.05	8.52	0.43	8.94	0.45	15.09	0.75	9.60	0.48	14.57	0.73	26.26	1.31												
SO 0495	Rape seed, raw	RAC	0.05	NC	-	NC	-	0.01	0.00	NC	-	NC	-	NC	-												
OR 0495	Rape seed oil, edible	PP	0.08	12.52	1.00	7.63	0.61	3.00	0.24	6.01	0.48	NC	-	NC	-												
OR 0691	Cotton seed oil, edible	PP	0.005	1.68	0.01	0.66	0.00	1.13	0.01	1.18	0.01	0.89	0.00	0.37	0.00												
SO 0697	Peanuts, nutmeat, raw (incl roasted, incl oil, incl butter)	RAC	0.05	5.63	0.28	2.75	0.14	9.58	0.48	5.82	0.29	13.71	0.69	1.84	0.09												
OR 0697	Peanut oil, edible	PP	0.05	1.02	0.05	0.23	0.01	1.81	0.09	0.42	0.02	5.23	0.26	0.01	0.00												
HS 0444	Peppers, chili, dried	PP	0.84	0.11	0.09	0.21	0.18	0.36	0.30	0.21	0.18	0.25	0.21	0.15	0.13												
DH 1100	Hops, dry	RAC	1.9	NC	-	NC	-	0.02	0.04	0.02	0.04	NC	-	NC	-												
DT 1114	Tea, green or black, fermented and dried, (including concentrates)	RAC	5.2	2.91	15.13	1.73	9.00	1.14	5.93	1.85	9.62	2.29	11.91	0.74	3.85												
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80 % as muscle	RAC	0.07	112.02	7.84	120.71	8.45	63.46	4.44	88.99	6.23	96.24	6.74	41.02	2.87												
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20 % as fat	RAC	0.59	28.01	16.52	30.18	17.81	15.86	9.36	22.25	13.13	24.06	14.20	10.25	6.05												
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.59	6.44	3.80	15.51	9.15	3.79	2.24	8.29	4.89	18.44	10.88	8.00	4.72												
MO 0105	Edible offal (mammalian), raw	RAC	0.07	15.17	1.06	5.19	0.36	6.30	0.44	6.78	0.47	3.32	0.23	3.17	0.22												
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.053	388.92	20.61	335.88	17.80	49.15	2.60	331.25	17.56	468.56	24.83	245.45	13.01												
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-												
Total intake (ug/person)=				210.0				205.6				105.8				196.3				215.9				138.5			
Bodyweight per region (kg bw) =				60				60				55				60				60							
ADI (ug/person)=				600				600				550				600				600							
%ADI=				35.0 %				34.3 %				19.2 %				32.7 %				36.0 %				23.1 %			
Rounded %ADI=				40 %				30 %				20 %				30 %				40 %				20 %			

Annex 3

BIFENTHRIN (178)		International Estimated Daily Intake (IEDI)						ADI = 0 - 0.01 mg/kg bw					
Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day		Intake = daily intake: ug/person							
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
FC 0001	Group of Citrus fruit, raw (incl citrus fruit juice, incl kumquat commodities)	RAC	0.05	21.16	1.06	2.94	0.15	58.52	2.93	0.44	0.02	5.13	0.26
FP 0009	Group of Pome fruits, raw (incl apple cider, excl apple juice)	RAC	0.195	68.85	13.43	10.93	2.13	70.82	13.81	189.78	37.01	19.56	3.81
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.0096	0.03	0.00	0.10	0.00	7.19	0.07	0.03	0.00	NC	-
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.22	0.02	0.00	0.01	0.00	10.76	2.37	0.01	0.00	NC	-
FB 0264	Blackberries, raw	RAC	0.29	0.01	0.00	7.29	2.11	0.25	0.07	0.01	0.00	NC	-
FB 0266	Dewberries, incl boysen- & loganberry, raw	RAC	0.29	0.01	0.00	0.01	0.00	NC	-	0.01	0.00	NC	-
FB 0272	Raspberries, red, black, raw	RAC	0.29	0.01	0.00	0.01	0.00	2.04	0.59	0.01	0.00	NC	-
FB 0020	Blueberries, raw	RAC	0.67	NC	-	NC	-	0.20	0.13	NC	-	NC	-
FB 0269	Grapes, raw (incl must, incl dried, incl juice, incl wine)	RAC	0.06	0.60	0.04	1.26	0.08	103.25	6.20	0.74	0.04	44.23	2.65
FB 0275	Strawberry, raw	RAC	0.46	0.01	0.00	0.01	0.00	3.35	1.54	0.01	0.00	0.01	0.00
FI 0326	Avocado, raw	RAC	0.089	1.12	0.10	0.01	0.00	0.84	0.07	0.01	0.00	6.60	0.59
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.01	44.80	0.45	118.17	1.18	25.25	0.25	454.49	4.54	310.23	3.10
FI 0345	Mango, raw	RAC	0.01	12.25	0.12	6.74	0.07	0.76	0.01	0.01	0.00	20.12	0.20
FI 0350	Papaya, raw	RAC	0.01	6.47	0.06	0.25	0.00	0.19	0.00	0.01	0.00	26.42	0.26
FI 0355	Pomegranate, raw, (incl processed)	RAC	0.165	5.49	0.91	27.17	4.48	NC	-	2.89	0.48	17.87	2.95
VB 0040	Group of Brassica vegetables (excl Brassica leafy vegetables), raw	RAC	0.115	5.46	0.63	4.28	0.49	58.72	6.75	0.02	0.00	NC	-
VO 0448	Tomato, raw (incl juice, incl canned, excl paste)	RAC	0.06	13.17	0.79	4.92	0.30	62.69	3.76	1.04	0.06	0.11	0.01
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.04	0.58	0.02	0.22	0.01	2.21	0.09	0.24	0.01	3.10	0.12
VO 0051	Subgroup of peppers, raw (incl dried sweet peppers, excl dried chilipeppers), excl okra	RAC	0.12	8.97	1.08	14.13	1.70	25.14	3.02	0.91	0.11	NC	-
VO 0442	Okra, raw (i.e. Lady's Finger, Gombo)	RAC	0.07	6.23	0.44	0.10	0.01	NC	-	NC	-	NC	-
VO 2046	Subgroup of eggplants	RAC	0.12	1.31	0.16	8.26	0.99	3.95	0.47	0.01	0.00	NC	-
VL 0485	Mustard greens, raw (i.e. Indian mustard, Amsoi, mustard cabbage)	RAC	1.16	0.04	0.05	0.03	0.03	NC	-	0.01	0.01	NC	-
VL 0494	Radish leaves, raw	RAC	1.75	0.44	0.77	0.32	0.56	NC	-	0.30	0.53	0.59	1.03
VD 0070	Group of Pulses, raw (incl processed)	RAC	0.05	46.57	2.33	30.77	1.54	112.53	5.63	75.53	3.78	43.68	2.18
OR 0541	Soya oil, refined	PP	0.05	2.32	0.12	2.54	0.13	18.70	0.94	2.51	0.13	6.29	0.31
VR 0075	Group of Root and tuber vegetables, raw (incl processed)	RAC	0.05	282.25	14.11	232.11	11.61	281.91	14.10	620.21	31.01	459.96	23.00
VS 0624	Celery	RAC	0.7	3.66	2.56	2.65	1.86	4.84	3.39	2.47	1.73	4.94	3.46
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, incl germ, incl wholemeal bread, incl white flour products, incl white bread)	RAC	0.25	57.20	14.30	110.47	27.62	272.62	68.16	25.82	6.46	132.04	33.01
GC 0654	Wheat, raw (incl meslin)	RAC	0.25	NC	-	NC	-	NC	-	NC	-	0.97	0.24
-	Wheat, bulgur	PP	0.25	0.01	0.00	NC	-	NC	-	NC	-	NC	-

Annex 3

BIFENTHRIN (178)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.01 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day		Intake = daily intake: ug/person									
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake		
CF 1210	Wheat, germ	PP	0.45	0.04	0.02	0.01	0.00	0.01	0.00	0.01	0.00	0.01	0.00	NC	-
CP 1212	Wheat, wholemeal bread	PP	0.19	0.01	0.00	0.01	0.00	0.03	0.01	0.01	0.00	0.01	0.00	0.01	0.00
CP 1211	Wheat, white bread	PP	0.061	0.43	0.03	0.41	0.03	1.56	0.10	0.11	0.01	0.07	0.00		
-	Wheat, Fermented Beverages (Korean jakju and takju)	PP	0.25	NC	-	NC	-	NC	-	NC	-	NC	-		
CF 1211	Wheat, white flour (incl white flour products: starch, gluten, macaroni, pastry)	PP	0.078	44.78	3.49	86.96	6.78	214.05	16.70	20.31	1.58	103.60	8.08		
TN 0085	Group of Tree nuts, raw (incl processed)	RAC	0.05	4.39	0.22	135.53	6.78	6.11	0.31	0.72	0.04	317.74	15.89		
SO 0495	Rape seed, raw	RAC	0.05	NC	-	0.01	0.00	NC	-	NC	-	NC	-		
OR 0495	Rape seed oil, edible	PP	0.08	0.07	0.01	0.03	0.00	4.62	0.37	0.03	0.00	NC	-		
OR 0691	Cotton seed oil, edible	PP	0.005	1.28	0.01	0.05	0.00	0.45	0.00	0.42	0.00	0.15	0.00		
SO 0697	Peanuts, nutmeat, raw (incl roasted, incl oil, incl butter)	RAC	0.05	18.82	0.94	0.57	0.03	2.28	0.11	6.90	0.35	0.53	0.03		
OR 0697	Peanut oil, edible	PP	0.05	5.02	0.25	0.05	0.00	0.17	0.01	0.29	0.01	NC	-		
HS 0444	Peppers, chili, dried	PP	0.84	0.58	0.49	1.27	1.07	1.21	1.02	0.12	0.10	NC	-		
DH 1100	Hops, dry	RAC	1.9	NC	-	NC	-	0.04	0.08	NC	-	NC	-		
DT 1114	Tea, green or black, fermented and dried, (including concentrates)	RAC	5.2	0.53	2.76	5.25	27.30	0.86	4.47	0.56	2.91	0.88	4.58		
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80 % as muscle	RAC	0.07	23.34	1.63	40.71	2.85	97.15	6.80	18.06	1.26	57.71	4.04		
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20 % as fat	RAC	0.59	5.84	3.44	10.18	6.01	24.29	14.33	4.52	2.66	14.43	8.51		
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.59	1.05	0.62	1.14	0.67	18.69	11.03	0.94	0.55	3.12	1.84		
MO 0105	Edible offal (mammalian), raw	RAC	0.07	4.64	0.32	1.97	0.14	10.01	0.70	3.27	0.23	3.98	0.28		
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.053	108.75	5.76	70.31	3.73	436.11	23.11	61.55	3.26	79.09	4.19		
-	-	-	-	-	-	-	-	-	-	-	-	-	-		
Total intake (ug/person)=				73.5		112.4		213.5		98.9		124.6			
Bodyweight per region (kg bw) =				60		60		60		60		60			
ADI (ug/person)=				600		600		600		600		600			
%ADI=				12.3 %		18.7 %		35.6 %		16.5 %		20.8 %			
Rounded %ADI=				10 %		20 %		40 %		20 %		20 %			

Annex 3

BROFLANILIDE (326)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.02 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day		Intake as ug/person/day									
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
VB 0041	Cabbages, head, raw	RAC	0.19	2.73	0.52	27.92	5.30	0.55	0.10	4.47	0.85	4.27	0.81	10.25	1.95
VB 0467	Chinese cabbage, type pe-tsai, raw	RAC	0.19	0.45	0.09	4.56	0.87	0.09	0.02	0.73	0.14	NC	-	1.67	0.32
VR 0591	Japanese radish, raw (i.e. Chinese radish, Daikon)	RAC	0.01	1.90	0.02	3.36	0.03	2.08	0.02	5.06	0.05	NC	-	2.44	0.02
VR 0573	Arrowroot, raw	RAC	0.00175	1.53	0.00	0.01	0.00	0.93	0.00	1.33	0.00	0.47	0.00	0.02	0.00
VR 0463	Cassava raw (incl starch, incl tapioca, incl flour) (i.e. Manioc)	RAC	0.00175	0.08	0.00	0.01	0.00	482.56	0.84	0.99	0.00	25.75	0.05	3.29	0.01
VR 0585	Jerusalem artichoke, raw (i.e. Topinambur)	RAC	0.00175	1.57	0.00	0.01	0.00	0.96	0.00	1.36	0.00	0.48	0.00	0.02	0.00
VR 0589	Potato, raw (incl flour, incl frozen, incl tapioca, excl starch)	RAC	0.00175	59.60	0.10	316.10	0.55	9.77	0.02	59.59	0.10	54.12	0.09	119.82	0.21
-	Potato, starch	PP	0.0003	0.03	0.00	0.01	0.00	0.01	0.00	0.15	0.00	0.01	0.00	0.01	0.00
VR 0508	Sweet potato, raw (incl dried)	RAC	0.00175	0.18	0.00	0.18	0.00	42.16	0.07	1.61	0.00	3.06	0.01	6.67	0.01
VR 0504	Tannia, raw (i.e. Tanier, Yautia)	RAC	0.00175	NC	-	NC	-	NC	-	0.01	0.00	0.26	0.00	1.27	0.00
VR 0505	Taro, raw (i.e. Dasheen, Eddoe)	RAC	0.00175	0.01	0.00	NC	-	25.12	0.04	0.04	0.00	0.01	0.00	0.97	0.00
VR 0600	Yams, raw (incl dried)	RAC	0.00175	0.02	0.00	NC	-	90.40	0.16	6.45	0.01	0.74	0.00	0.65	0.00
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, excl germ, excl wholemeal bread, excl white flour products, excl white bread)	RAC	0	0.01	0.00	1.12	0.00	NC	-	0.03	0.00	0.56	0.00	NC	-
CF 1210	Wheat, germ	PP	0	NC	-	NC	-	0.01	0.00	0.01	0.00	0.14	0.00	0.01	0.00
CP 1212	Wheat, wholemeal bread	PP	0	0.01	0.00	0.01	0.00	0.01	0.00	0.01	0.00	0.03	0.00	0.01	0.00
CF 1211	Wheat, white flour (incl white flour products: starch, gluten, macaroni, pastry)	PP	0	301.24	0.00	268.64	0.00	30.21	0.00	222.51	0.00	134.73	0.00	343.12	0.00
GC 2087	Subgroup of barley, similar grains, and pseudocereals with husks, raw (including processed)	RAC	0	19.96	0.00	38.62	0.00	5.13	0.00	4.81	0.00	10.80	0.00	4.44	0.00
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl beer, excl flour, excl oil, excl germ, excl starch)	RAC	0	0.84	0.00	0.24	0.00	1.56	0.00	0.46	0.00	2.21	0.00	13.13	0.00
CF 1255	Maize, flour (white flour and wholemeal flour)	PP	0	22.72	0.00	35.61	0.00	87.27	0.00	34.92	0.00	46.71	0.00	49.12	0.00
-	Maize, germ	PP	0	0.01	0.00	NC	-	0.01	0.00	0.01	0.00	0.22	0.00	NC	-
-	Maize starch	PP	0	0.08	0.00	NC	-	0.01	0.00	2.29	0.00	0.08	0.00	0.11	0.00
OR 0645	Maize oil	PP	0	0.96	0.00	0.85	0.00	0.29	0.00	5.42	0.00	0.42	0.00	2.10	0.00
GC 2090	Subgroup of Sweet Corns	RAC	0.001	0.14	0.00	0.94	0.00	5.70	0.01	2.61	0.00	1.94	0.00	0.22	0.00
SB 0716	Coffee bean, raw (i.e. green coffee)	RAC	0.0023	0.96	0.00	0.16	0.00	0.91	0.00	0.27	0.00	1.37	0.00	0.46	0.00
SM 0716	Coffee bean, roasted	PP	0.0019	0.19	0.00	0.91	0.00	0.16	0.00	2.50	0.00	0.39	0.00	0.40	0.00
-	Coffee bean, instant coffee (incl essences and concentrates)	PP	0.0002	0.07	0.00	0.94	0.00	0.07	0.00	0.70	0.00	0.07	0.00	0.29	0.00
MM 0095	MEAT FROM MAMMALS other than marine	RAC	0.02	24.96	0.50	57.95	1.16	16.70	0.33	38.38	0.77	26.46	0.53	29.00	0.58

Annex 3

089

BROFLANILIDE (326)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.02 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day							
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
	mammals, raw (incl prepared meat) -80 % as muscle														
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20 % as fat	RAC	0.033	6.24	0.21	14.49	0.48	4.18	0.14	9.60	0.32	6.62	0.22	7.25	0.24
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.033	3.29	0.11	6.14	0.20	0.82	0.03	1.57	0.05	2.23	0.07	1.07	0.04
MO 0105	Edible offal (mammalian), raw	RAC	0.02	4.79	0.10	9.68	0.19	2.97	0.06	5.49	0.11	3.84	0.08	5.03	0.10
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.004	289.65	1.16	485.88	1.94	26.92	0.11	239.03	0.96	199.91	0.80	180.53	0.72
PM 0110	Poultry meat, raw (incl prepared) - 90 % as muscle	RAC	0.02	13.17	0.26	26.78	0.54	7.24	0.14	116.71	2.33	22.54	0.45	32.09	0.64
PM 0110	Poultry meat, raw (incl prepared) - 10 % as fat	RAC	0.034	1.46	0.05	2.98	0.10	0.80	0.03	12.97	0.44	2.50	0.09	3.57	0.12
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.034	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.10	0.00	0.10	0.00
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.02	0.12	0.00	0.12	0.00	0.11	0.00	5.37	0.11	0.24	0.00	0.10	0.00
PE 0112	Eggs, raw, (incl dried)	RAC	0.02	7.84	0.16	23.08	0.46	2.88	0.06	14.89	0.30	9.81	0.20	14.83	0.30
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total intake (ug/person)=				3.3		11.8		2.2		6.6		3.4		5.3	
Bodyweight per region (kg bw) =				60		60		60		60		60		60	
ADI (ug/person)=				1200		1200		1200		1200		1200		1200	
%ADI=				0.3 %		1.0 %		0.2 %		0.5 %		0.3 %		0.4 %	
Rounded %ADI=				0 %		1 %		0 %		1 %		0 %		0 %	

BROFLANILIDE (326)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.02 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day							
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
VB 0041	Cabbages, head, raw	RAC	0.19	8.97	1.70	27.12	5.15	1.44	0.27	24.96	4.74	4.55	0.86	11.23	2.13
VB 0467	Chinese cabbage, type pe-tsai, raw	RAC	0.19	NC	-	NC	-	17.39	3.30	9.44	1.79	NC	-	1.83	0.35
VR 0591	Japanese radish, raw (i.e. Chinese radish, Daikon)	RAC	0.01	NC	-	NC	-	26.64	0.27	18.92	0.19	NC	-	3.59	0.04
VR 0573	Arrowroot, raw	RAC	0.00175	0.02	0.00	0.01	0.00	2.05	0.00	0.21	0.00	NC	-	0.76	0.00
VR 0463	Cassava raw (incl starch, incl tapioca, incl flour) (i.e. Manioc)	RAC	0.00175	0.01	0.00	NC	-	20.96	0.04	0.14	0.00	NC	-	9.62	0.02
VR 0585	Jerusalem artichoke, raw (i.e. Topinambur)	RAC	0.00175	0.11	0.00	0.01	0.00	NC	-	0.22	0.00	NC	-	0.78	0.00
VR 0589	Potato, raw (incl flour, incl frozen, incl tapioca, excl starch)	RAC	0.00175	225.03	0.39	226.35	0.40	71.26	0.12	173.36	0.30	234.55	0.41	37.71	0.07
-	Potato, starch	PP	0.0003	NC	-	1.74	0.00	0.05	0.00	0.92	0.00	NC	-	NC	-
VR 0508	Sweet potato, raw (incl dried)	RAC	0.00175	0.93	0.00	0.32	0.00	64.65	0.11	5.37	0.01	0.30	0.00	3.13	0.01
VR 0504	Tannia, raw (i.e. Tannier, Yautia)	RAC	0.00175	NC	-	NC	-	NC	-	0.01	0.00	NC	-	10.74	0.02

Annex 3

BROFLANILIDE (326)				International Estimated Daily Intake (IEDI)				ADI = 0 - 0.02 mg/kg bw							
Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day							
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
VR 0505	Taro, raw (i.e. Dasheen, Eddoe)	RAC	0.00175	NC	-	NC	-	1.93	0.00	0.84	0.00	NC	-	19.94	0.03
VR 0600	Yams, raw (incl dried)	RAC	0.00175	NC	-	NC	-	0.03	0.00	0.71	0.00	NC	-	17.57	0.03
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, excl germ, excl wholemeal bread, excl white flour products, excl white bread)	RAC	0	NC	-	NC	-	0.02	0.00	0.83	0.00	NC	-	NC	-
CF 1210	Wheat, germ	PP	0	0.97	0.00	0.10	0.00	0.03	0.00	0.01	0.00	NC	-	0.04	0.00
CP 1212	Wheat, wholemeal bread	PP	0	0.03	0.00	0.01	0.00	0.01	0.00	0.01	0.00	0.05	0.00	0.02	0.00
CF 1211	Wheat, white flour (incl white flour products: starch, gluten, macaroni, pastry)	PP	0	198.08	0.00	193.03	0.00	106.24	0.00	185.09	0.00	168.67	0.00	131.59	0.00
GC 2087	Subgroup of barley, similar grains, and pseudocereals with husks, raw (including processed)	RAC	0	43.68	0.00	60.49	0.00	9.72	0.00	40.47	0.00	49.83	0.00	18.90	0.00
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl beer, excl flour, excl oil, excl germ, excl starch)	RAC	0	0.10	0.00	9.93	0.00	1.40	0.00	10.26	0.00	0.33	0.00	0.04	0.00
CF 1255	Maize, flour (white flour and wholemeal flour)	PP	0	14.27	0.00	12.86	0.00	19.71	0.00	12.55	0.00	4.21	0.00	52.30	0.00
-	Maize, germ	PP	0	0.01	0.00	NC	-	NC	-	0.01	0.00	NC	-	0.01	0.00
-	Maize starch	PP	0	NC	-	NC	-	0.19	0.00	7.13	0.00	NC	-	NC	-
OR 0645	Maize oil	PP	0	0.90	0.00	0.47	0.00	0.15	0.00	3.01	0.00	1.86	0.00	0.36	0.00
GC 2090	Subgroup of Sweet Corns	RAC	0.001	11.43	0.01	3.71	0.00	0.74	0.00	13.63	0.01	3.07	0.00	1.50	0.00
SB 0716	Coffee bean, raw (i.e. green coffee)	RAC	0.0023	0.60	0.00	NC	-	0.62	0.00	1.71	0.00	NC	-	3.51	0.01
SM 0716	Coffee bean, roasted	PP	0.0019	7.02	0.01	9.75	0.02	0.02	0.00	5.09	0.01	13.38	0.03	0.77	0.00
-	Coffee bean, instant coffee (incl essences and concentrates)	PP	0.0002	0.75	0.00	0.30	0.00	0.04	0.00	0.67	0.00	2.43	0.00	1.43	0.00
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80 % as muscle	RAC	0.02	112.02	2.24	120.71	2.41	63.46	1.27	88.99	1.78	96.24	1.92	41.02	0.82
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20 % as fat	RAC	0.033	28.01	0.92	30.18	1.00	15.86	0.52	22.25	0.73	24.06	0.79	10.25	0.34
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.033	6.44	0.21	15.51	0.51	3.79	0.13	8.29	0.27	18.44	0.61	8.00	0.26
MO 0105	Edible offal (mammalian), raw	RAC	0.02	15.17	0.30	5.19	0.10	6.30	0.13	6.78	0.14	3.32	0.07	3.17	0.06
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.004	388.92	1.56	335.88	1.34	49.15	0.20	331.25	1.33	468.56	1.87	245.45	0.98
PM 0110	Poultry meat, raw (incl prepared) - 90 % as muscle	RAC	0.02	66.38	1.33	48.47	0.97	21.58	0.43	78.41	1.57	48.04	0.96	76.01	1.52
PM 0110	Poultry meat, raw (incl prepared) - 10 % as fat	RAC	0.034	7.38	0.25	5.39	0.18	2.40	0.08	8.71	0.30	5.34	0.18	8.45	0.29
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.034	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.71	0.02	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.02	0.33	0.01	0.72	0.01	0.27	0.01	0.35	0.01	0.80	0.02	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0.02	25.84	0.52	29.53	0.59	28.05	0.56	33.19	0.66	36.44	0.73	8.89	0.18

Annex 3

BROFLANILIDE (326)				International Estimated Daily Intake (IEDI)				ADI = 0 - 0.02 mg/kg bw					
Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day					
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake
-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (ug/person)=			9.5		12.7		7.4		13.9		8.5	7.2
	Bodyweight per region (kg bw) =			60		60		55		60		60	60
	ADI (ug/person)=			1200		1200		1100		1200		1200	1200
	%ADI=			0.8 %		1.1 %		0.7 %		1.2 %		0.7 %	0.6 %
	Rounded %ADI=			1 %		1 %		1 %		1 %		1 %	1 %

BROFLANILIDE (326)				International Estimated Daily Intake (IEDI)				ADI = 0 - 0.02 mg/kg bw					
Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day				Intake = daily intake: ug/person					
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
VB 0041	Cabbages, head, raw	RAC	0.19	3.82	0.73	2.99	0.57	49.16	9.34	0.01	0.00	NC	-
VB 0467	Chinese cabbage, type pe-tsai, raw	RAC	0.19	0.62	0.12	0.49	0.09	NC	-	0.01	0.00	NC	-
VR 0591	Japanese radish, raw (i.e. Chinese radish, Daikon)	RAC	0.01	3.25	0.03	2.35	0.02	NC	-	2.20	0.02	4.39	0.04
VR 0573	Arrowroot, raw	RAC	0.00175	13.83	0.02	18.24	0.03	0.01	0.00	0.05	0.00	19.60	0.03
VR 0463	Cassava raw (incl starch, incl tapioca, incl flour) (i.e. Manioc)	RAC	0.00175	91.92	0.16	34.12	0.06	NC	-	259.92	0.45	45.48	0.08
VR 0585	Jerusalem artichoke, raw (i.e. Topinambur)	RAC	0.00175	14.22	0.02	18.75	0.03	0.01	0.00	0.06	0.00	20.14	0.04
VR 0589	Potato, raw (incl flour, incl frozen, incl tapioca, excl starch)	RAC	0.00175	23.96	0.04	13.54	0.02	213.41	0.37	104.35	0.18	8.56	0.01
-	Potato, starch	PP	0.0003	0.01	0.00	0.01	0.00	NC	-	NC	-	NC	-
VR 0508	Sweet potato, raw (incl dried)	RAC	0.00175	28.83	0.05	61.55	0.11	0.15	0.00	221.94	0.39	NC	-
VR 0504	Tannia, raw (i.e. Tanier, Yautia)	RAC	0.00175	NC	-	NC	-	0.01	0.00	NC	-	NC	-
VR 0505	Taro, raw (i.e. Dasheen, Eddoe)	RAC	0.00175	6.71	0.01	31.91	0.06	NC	-	10.73	0.02	264.31	0.46
VR 0600	Yams, raw (incl dried)	RAC	0.00175	70.93	0.12	30.62	0.05	0.07	0.00	5.65	0.01	30.85	0.05
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, excl germ, excl wholemeal bread, excl white flour products, excl white bread)	RAC	0	0.01	0.00	NC	-	NC	-	NC	-	0.97	0.00
CF 1210	Wheat, germ	PP	0	0.04	0.00	0.01	0.00	0.01	0.00	0.01	0.00	NC	-
CP 1212	Wheat, wholemeal bread	PP	0	0.01	0.00	0.01	0.00	0.03	0.00	0.01	0.00	0.01	0.00
CF 1211	Wheat, white flour (incl white flour products: starch, gluten, macaroni, pastry)	PP	0	44.78	0.00	86.96	0.00	214.05	0.00	20.31	0.00	103.60	0.00
GC 2087	Subgroup of barley, similar grains, and pseudocereals with husks, raw (including processed)	RAC	0	11.99	0.00	5.22	0.00	49.50	0.00	3.82	0.00	16.26	0.00
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl beer, excl flour, excl oil, excl germ, excl starch)	RAC	0	0.54	0.00	0.51	0.00	3.26	0.00	7.96	0.00	NC	-

Annex 3

BROFLANILIDE (326)				International Estimated Daily Intake (IEDI)				ADI = 0 - 0.02 mg/kg bw					
Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day			Intake = daily intake: ug/person						
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
CF 1255	Maize, flour (white flour and wholemeal flour)	PP	0	94.34	0.00	8.09	0.00	28.03	0.00	55.94	0.00	28.07	0.00
-	Maize, germ	PP	0	0.01	0.00	NC	-	NC	-	NC	-	NC	-
-	Maize starch	PP	0	0.02	0.00	0.01	0.00	NC	-	NC	-	NC	-
OR 0645	Maize oil	PP	0	0.33	0.00	0.07	0.00	0.81	0.00	0.01	0.00	NC	-
GC 2090	Subgroup of Sweet Corns	RAC	0.001	3.63	0.00	20.50	0.02	8.78	0.01	0.02	0.00	0.17	0.00
SB 0716	Coffee bean, raw (i.e. green coffee)	RAC	0.0023	0.83	0.00	0.69	0.00	1.09	0.00	2.91	0.01	0.82	0.00
SM 0716	Coffee bean, roasted	PP	0.0019	0.02	0.00	0.41	0.00	7.50	0.01	0.01	0.00	0.06	0.00
-	Coffee bean, instant coffee (incl essences and concentrates)	PP	0.0002	0.03	0.00	0.05	0.00	0.60	0.00	0.01	0.00	5.53	0.00
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80 % as muscle	RAC	0.02	23.34	0.47	40.71	0.81	97.15	1.94	18.06	0.36	57.71	1.15
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20 % as fat	RAC	0.033	5.84	0.19	10.18	0.34	24.29	0.80	4.52	0.15	14.43	0.48
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.033	1.05	0.03	1.14	0.04	18.69	0.62	0.94	0.03	3.12	0.10
MO 0105	Edible offal (mammalian), raw	RAC	0.02	4.64	0.09	1.97	0.04	10.01	0.20	3.27	0.07	3.98	0.08
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.004	108.75	0.44	70.31	0.28	436.11	1.74	61.55	0.25	79.09	0.32
PM 0110	Poultry meat, raw (incl prepared) - 90 % as muscle	RAC	0.02	3.53	0.07	10.83	0.22	51.36	1.03	4.53	0.09	50.00	1.00
PM 0110	Poultry meat, raw (incl prepared) - 10 % as fat	RAC	0.034	0.39	0.01	1.20	0.04	5.71	0.19	0.50	0.02	5.56	0.19
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.034	NC	-	NC	-	0.32	0.01	NC	-	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.02	0.10	0.00	0.70	0.01	0.97	0.02	0.10	0.00	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0.02	3.84	0.08	4.41	0.09	27.25	0.55	1.13	0.02	7.39	0.15
-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total intake (ug/person)=							2.7	2.9	16.8	2.1	4.2		
Bodyweight per region (kg bw) =							60	60	60	60	60		
ADI (ug/person)=							1200	1200	1200	1200	1200		
%ADI=							0.2 %	0.2 %	1.4 %	0.2 %	0.3 %		
Rounded %ADI=							0 %	0 %	1 %	0 %	0 %		

Annex 3

684

CHLORANTRANILIPROLE (230)

International Estimated Daily Intake (IEDI)

ADI = 0 - 2 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day							
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
FC 0001	Group of Citrus fruit, raw (incl citrus fruit juice, incl kumquat commodities)	RAC	0.06	34.91	2.09	16.51	0.99	17.23	1.03	104.48	6.27	35.57	2.13	98.49	5.91
FP 0009	Group of Pome fruits, raw (incl. apple juice, incl apple cider)	RAC	0.07	19.79	1.39	38.25	2.68	17.96	1.26	32.56	2.28	8.08	0.57	64.45	4.51
FS 0012	Group of Stone fruits, raw (incl dried plums, incl dried apricots)	RAC	0.2	11.60	2.32	23.79	4.76	0.25	0.05	11.84	2.37	2.41	0.48	33.44	6.69
FB 0018	Group of Berries and other small fruits, raw (incl processed)	RAC	0.119	18.53	2.21	33.67	4.01	3.65	0.43	28.70	3.42	9.72	1.16	74.91	8.91
FI 0326	Avocado, raw	RAC	0.089	0.13	0.01	0.03	0.00	2.05	0.18	2.54	0.23	2.34	0.21	0.12	0.01
FI 0355	Pomegranate, raw, (incl processed)	RAC	0.11	3.40	0.37	2.10	0.23	2.65	0.29	10.89	1.20	NC	-	6.67	0.73
VC 0045	Group of Fruiting vegetables, cucurbits, raw	RAC	0.065	53.14	3.45	86.21	5.60	6.28	0.41	92.76	6.03	15.64	1.02	155.30	10.09
VO 0050	Group of Fruiting vegetables other than cucurbits, raw, (incl processed commodities, excl dried chilli peppers)	RAC	0.066	67.79	4.47	99.85	6.59	31.70	2.09	125.86	8.31	55.22	3.64	262.82	17.35
VL 0053	Group of Leafy vegetables, raw	RAC	7.3	8.47	61.83	22.36	163.23	7.74	56.50	25.51	186.22	45.77	334.12	21.22	154.91
VL 0494	Radish leaves, raw	RAC	10.5	0.26	2.73	0.45	4.73	0.28	2.94	0.68	7.14	NC	-	0.33	3.47
VP 0061	Beans with pods (Phaseolus spp): (immature pods + succulent seeds)	RAC	0.16	0.68	0.11	NC	-	NC	-	0.39	0.06	0.22	0.04	0.49	0.08
VP 2062	Subgroup of succulent beans without pods (all commodities within this group)	RAC	0.545	5.07	2.76	1.02	0.56	0.49	0.27	1.78	0.97	1.19	0.65	8.57	4.67
VP 0064	Peas without pods (Pisum spp) (succulent seeds)	RAC	0.025	1.97	0.05	0.51	0.01	0.02	0.00	0.79	0.02	3.68	0.09	3.80	0.10
VD 2065	Subgroup of dry beans, raw (incl processed)	RAC	0.0305	78.20	2.39	60.68	1.85	35.89	1.09	80.34	2.45	75.90	2.31	87.62	2.67
VD 0541	Soya bean, dry, raw (incl paste, incl curd, incl oil, incl sauce)	RAC	0.01	72.79	0.73	59.05	0.59	20.55	0.21	74.20	0.74	61.12	0.61	73.24	0.73
VD 2066	Subgroup of dry peas, raw	RAC	0.0305	9.09	0.28	3.35	0.10	1.06	0.03	9.48	0.29	15.11	0.46	10.58	0.32
VR 0075	Group of Root and tuber vegetables, raw (incl processed)	RAC	0.01	87.83	0.88	374.04	3.74	668.92	6.69	121.64	1.22	94.20	0.94	247.11	2.47
VR 0577	Carrots, raw	RAC	0.02	9.51	0.19	30.78	0.62	0.37	0.01	8.75	0.18	2.80	0.06	6.10	0.12
VR 0494	Radish roots, raw	RAC	0.055	2.31	0.13	4.09	0.22	2.53	0.14	6.15	0.34	5.88	0.32	2.97	0.16
VS 0624	Celery	RAC	2.1	2.14	4.49	3.79	7.96	2.35	4.94	5.69	11.95	0.02	0.04	2.75	5.78
VS 0620	Artichoke globe, raw	RAC	0.56	0.69	0.39	0.01	0.01	0.01	0.01	0.32	0.18	0.26	0.15	1.21	0.68
GC 0081	Cereal grains, excl pseudocereals, excl sweet corn (incl processed)	RAC	0.01	484.29	4.84	463.29	4.63	256.66	2.57	484.19	4.84	467.54	4.68	613.74	6.14
CF 1210	Wheat, germ	PP	0.012	NC	-	NC	-	0.01	0.00	0.01	0.00	0.14	0.00	0.01	0.00
CF 1211	Wheat, white flour (incl white flour products: starch, gluten, macaroni, pastry)	PP	0.004	301.24	1.20	268.64	1.07	30.21	0.12	222.51	0.89	134.73	0.54	343.12	1.37
CM 0649	Rice, husked, dry (incl flour, incl oil, incl	REP	0.115	1.26	0.14	1.58	0.18	31.05	3.57	5.43	0.62	0.90	0.10	2.18	0.25

Annex 3

CHLORANTRANILIPROLE (230)

International Estimated Daily Intake (IEDI)

ADI = 0 - 2 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day		Intake as ug/person/day									
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
(GC 0649)	beverages, incl starch, excl polished)														
CM 1205	Rice polished, dry	PP	0.013	34.21	0.44	10.39	0.14	41.72	0.54	82.38	1.07	150.24	1.95	70.47	0.92
GC 0447	Sweet corn on the cob, raw (incl frozen kernels, incl canned kernels)	RAC	0.01	0.14	0.00	0.94	0.01	5.70	0.06	2.61	0.03	1.94	0.02	0.22	0.00
GS 0659	Sugar cane, raw (incl sugar, incl molasses)	RAC	0.145	99.68	14.45	86.27	12.51	31.38	4.55	80.36	11.65	84.18	12.21	99.10	14.37
TN 0085	Group of Tree nuts, raw (incl processed)	RAC	0.01	4.06	0.04	3.27	0.03	7.01	0.07	13.93	0.14	14.01	0.14	9.36	0.09
SO 0495	Rape seed, raw (incl oil)	RAC	0.295	0.93	0.27	1.16	0.34	0.49	0.14	2.53	0.75	9.32	2.75	2.02	0.60
SO 0702	Sunflower seed, raw (incl oil)	RAC	0.185	7.40	1.37	35.86	6.63	1.15	0.21	8.76	1.62	5.45	1.01	13.62	2.52
SO 0691	Cotton seed, raw (incl oil)	RAC	0.049	20.53	1.01	9.80	0.48	6.42	0.31	4.73	0.23	7.14	0.35	18.68	0.92
SO 0697	Peanuts, nutmeat, raw (incl roasted, incl oil, incl butter)	RAC	0.01	1.30	0.01	1.23	0.01	12.62	0.13	2.87	0.03	6.59	0.07	2.67	0.03
SO 0696	Palm fruit (African Oil Palm), raw (incl oil)	RAC	0.195	28.87	5.63	1.09	0.21	53.08	10.35	80.61	15.72	24.20	4.72	17.72	3.46
SB 0716	Coffee bean raw (incl roasted, incl instant coffee, incl substitutes)	RAC	0.015	1.36	0.02	3.59	0.05	1.44	0.02	5.18	0.08	2.02	0.03	1.70	0.03
HH 0738	Mint, raw	RAC	4.6	0.50	2.30	0.01	0.05	NC	-	NC	-	NC	-	NC	-
HS 0444	Peppers, chili, dried	PP	0.46	0.42	0.19	0.53	0.24	0.84	0.39	0.50	0.23	0.95	0.44	0.37	0.17
DH 1100	Hops, dry	RAC	10.9	0.01	0.11	0.04	0.44	0.01	0.11	0.01	0.11	NC	-	0.01	0.11
DT 1114	Tea, green or black, fermented and dried, (including concentrates)	RAC	24	2.28	54.72	1.98	47.52	0.46	11.04	2.43	58.32	1.29	30.96	3.04	72.96
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80 % as muscle	RAC	0.009	24.96	0.22	57.95	0.52	16.70	0.15	38.38	0.35	26.46	0.24	29.00	0.26
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20 % as fat	RAC	0.05	6.24	0.31	14.49	0.72	4.18	0.21	9.60	0.48	6.62	0.33	7.25	0.36
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.049	3.29	0.16	6.14	0.30	0.82	0.04	1.57	0.08	2.23	0.11	1.07	0.05
MO 0105	Edible offal (mammalian), raw	RAC	0.047	4.79	0.23	9.68	0.45	2.97	0.14	5.49	0.26	3.84	0.18	5.03	0.24
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.006	289.65	1.74	485.88	2.92	26.92	0.16	239.03	1.43	199.91	1.20	180.53	1.08
PM 0110	Poultry meat, raw (incl prepared)	RAC	0.008	14.63	0.12	29.76	0.24	8.04	0.06	129.68	1.04	25.04	0.20	35.66	0.29
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.031	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.10	0.00	0.10	0.00
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.028	0.12	0.00	0.12	0.00	0.11	0.00	5.37	0.15	0.24	0.01	0.10	0.00
PE 0112	Eggs, raw, (incl dried)	RAC	0.099	7.84	0.78	23.08	2.28	2.88	0.29	14.89	1.47	9.81	0.97	14.83	1.47
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total intake (ug/person)=				183.6		290.5		113.8		343.4		412.2		338.0	
Bodyweight per region (kg bw) =				60		60		60		60		60		60	
ADI (ug/person)=				120000		120000		120000		120000		120000		120000	
%ADI=				0.2 %		0.2 %		0.1 %		0.3 %		0.3 %		0.3 %	
Rounded %ADI=				0 %		0 %		0 %		0 %		0 %		0 %	

Annex 3

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CHLORANTRANILIPROLE (230)				International Estimated Daily Intake (IEDI)				ADI = 0 - 2 mg/kg bw							
Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day							
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
FC 0001	Group of Citrus fruit, raw (incl citrus fruit juice, incl kumquat commodities)	RAC	0.06	114.42	6.87	62.91	3.77	26.97	1.62	96.72	5.80	96.22	5.77	563.19	33.79
FP 0009	Group of Pome fruits, raw (incl. apple juice, incl apple cider)	RAC	0.07	71.38	5.00	81.73	5.72	42.91	3.00	58.89	4.12	103.85	7.27	12.48	0.87
FS 0012	Group of Stone fruits, raw (incl dried plums, incl dried apricots)	RAC	0.2	19.98	4.00	24.87	4.97	14.41	2.88	19.54	3.91	10.78	2.16	0.50	0.10
FB 0018	Group of Berries and other small fruits, raw (incl processed)	RAC	0.119	156.91	18.67	118.51	14.10	8.10	0.96	64.22	7.64	117.23	13.95	15.04	1.79
FI 0326	Avocado, raw	RAC	0.089	2.65	0.24	0.87	0.08	0.46	0.04	1.64	0.15	1.30	0.12	0.96	0.09
FI 0355	Pomegranate, raw, (incl processed)	RAC	0.11	7.91	0.87	9.72	1.07	7.67	0.84	5.26	0.58	9.04	0.99	14.43	1.59
VC 0045	Group of Fruiting vegetables, cucurbits, raw	RAC	0.065	27.81	1.81	41.93	2.73	123.30	8.01	49.47	3.22	15.95	1.04	35.99	2.34
VO 0050	Group of Fruiting vegetables other than cucurbits, raw, (incl processed commodities, excl dried chilli peppers)	RAC	0.066	72.14	4.76	85.53	5.64	76.55	5.05	95.63	6.31	64.19	4.24	16.94	1.12
VL 0053	Group of Leafy vegetables, raw	RAC	7.3	18.83	137.46	21.85	159.51	121.23	884.98	43.09	314.56	18.18	132.71	18.32	133.74
VL 0494	Radish leaves, raw	RAC	10.5	NC	-	NC	-	NC	-	3.78	39.69	NC	-	0.48	5.04
VP 0061	Beans with pods (Phaseolus spp): (immature pods + succulent seeds)	RAC	0.16	5.07	0.81	0.83	0.13	0.17	0.03	3.70	0.59	NC	-	NC	-
VP 2062	Subgroup of succulent beans without pods (all commodities within this group)	RAC	0.545	2.42	1.32	6.09	3.32	4.33	2.36	2.09	1.14	18.99	10.35	0.17	0.09
VP 0064	Peas without pods (Pisum spp) (succulent seeds)	RAC	0.025	10.72	0.27	1.99	0.05	2.72	0.07	4.26	0.11	4.23	0.11	NC	-
VD 2065	Subgroup of dry beans, raw (incl processed)	RAC	0.0305	107.87	3.29	119.29	3.64	45.91	1.40	201.31	6.14	224.04	6.83	104.90	3.20
VD 0541	Soya bean, dry, raw (incl paste, incl curd, incl oil, incl sauce)	RAC	0.01	106.33	1.06	117.78	1.18	42.12	0.42	195.70	1.96	222.52	2.23	80.47	0.80
VD 2066	Subgroup of dry peas, raw	RAC	0.0305	5.01	0.15	3.76	0.11	1.82	0.06	3.44	0.10	3.49	0.11	5.15	0.16
VR 0075	Group of Root and tuber vegetables, raw (incl processed)	RAC	0.01	290.31	2.90	300.35	3.00	214.25	2.14	242.72	2.43	348.67	3.49	137.52	1.38
VR 0577	Carrots, raw	RAC	0.02	26.26	0.53	27.13	0.54	10.07	0.20	16.49	0.33	44.69	0.89	8.75	0.18
VR 0494	Radish roots, raw	RAC	0.055	3.83	0.21	11.99	0.66	NC	-	5.26	0.29	2.19	0.12	4.37	0.24
VS 0624	Celery	RAC	2.1	7.68	16.13	2.85	5.99	NC	-	3.34	7.01	16.83	35.34	4.04	8.48
VS 0620	Artichoke globe, raw	RAC	0.56	0.98	0.55	3.65	2.04	0.07	0.04	1.67	0.94	0.26	0.15	NC	-
GC 0081	Cereal grains, excl pseudocereals, excl sweet corn (incl processed)	RAC	0.01	334.19	3.34	381.67	3.82	513.41	5.13	388.74	3.89	292.24	2.92	358.47	3.58
CF 1210	Wheat, germ	PP	0.012	0.97	0.01	0.10	0.00	0.03	0.00	0.01	0.00	NC	-	0.04	0.00
CF 1211	Wheat, white flour (incl white flour products: starch, gluten, macaroni, pastry)	PP	0.004	198.08	0.79	193.03	0.77	106.24	0.42	185.09	0.74	168.67	0.67	131.59	0.53
CM 0649 (GC 0649)	Rice, husked, dry (incl flour, incl oil, incl beverages, incl starch, excl polished)	REP	0.115	3.70	0.43	2.11	0.24	1.51	0.17	1.75	0.20	0.29	0.03	5.12	0.59
CM 1205	Rice polished, dry	PP	0.013	13.38	0.17	10.80	0.14	262.08	3.41	57.16	0.74	12.83	0.17	62.78	0.82

Annex 3

CHLORANTRANILIPROLE (230)				International Estimated Daily Intake (IEDI)				ADI = 0 - 2 mg/kg bw																			
Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day																			
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake												
GC 0447	Sweet corn on the cob, raw (incl frozen kernels, incl canned kernels)	RAC	0.01	11.43	0.11	3.71	0.04	0.74	0.01	13.63	0.14	3.07	0.03	1.50	0.02												
GS 0659	Sugar cane, raw (incl sugar, incl molasses)	RAC	0.145	92.24	13.37	95.72	13.88	28.47	4.13	77.39	11.22	117.73	17.07	103.90	15.07												
TN 0085	Group of Tree nuts, raw (incl processed)	RAC	0.01	8.52	0.09	8.94	0.09	15.09	0.15	9.60	0.10	14.57	0.15	26.26	0.26												
SO 0495	Rape seed, raw (incl oil)	RAC	0.295	32.68	9.64	19.91	5.87	7.83	2.31	15.69	4.63	NC	-	NC	-												
SO 0702	Sunflower seed, raw (incl oil)	RAC	0.185	23.40	4.33	29.33	5.43	1.24	0.23	13.85	2.56	6.48	1.20	6.91	1.28												
SO 0691	Cotton seed, raw (incl oil)	RAC	0.049	10.71	0.52	4.23	0.21	7.19	0.35	7.54	0.37	5.66	0.28	2.38	0.12												
SO 0697	Peanuts, nutmeat, raw (incl roasted, incl oil, incl butter)	RAC	0.01	5.63	0.06	2.75	0.03	9.58	0.10	5.82	0.06	13.71	0.14	1.84	0.02												
SO 0696	Palm fruit (African Oil Palm), raw (incl oil)	RAC	0.195	12.11	2.36	1.38	0.27	24.43	4.76	6.52	1.27	14.27	2.78	1.35	0.26												
SB 0716	Coffee bean raw (incl roasted, incl instant coffee, incl substitutes)	RAC	0.015	10.90	0.16	12.44	0.19	0.77	0.01	9.48	0.14	22.07	0.33	8.15	0.12												
HH 0738	Mint, raw	RAC	4.6	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-												
HS 0444	Peppers, chili, dried	PP	0.46	0.11	0.05	0.21	0.10	0.36	0.17	0.21	0.10	0.25	0.12	0.15	0.07												
DH 1100	Hops, dry	RAC	10.9	NC	-	NC	-	0.02	0.22	0.02	0.22	NC	-	NC	-												
DT 1114	Tea, green or black, fermented and dried, (including concentrates)	RAC	24	2.91	69.84	1.73	41.52	1.14	27.36	1.85	44.40	2.29	54.96	0.74	17.76												
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80 % as muscle	RAC	0.009	112.02	1.01	120.71	1.09	63.46	0.57	88.99	0.80	96.24	0.87	41.02	0.37												
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20 % as fat	RAC	0.05	28.01	1.40	30.18	1.51	15.86	0.79	22.25	1.11	24.06	1.20	10.25	0.51												
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.049	6.44	0.32	15.51	0.76	3.79	0.19	8.29	0.41	18.44	0.90	8.00	0.39												
MO 0105	Edible offal (mammalian), raw	RAC	0.047	15.17	0.71	5.19	0.24	6.30	0.30	6.78	0.32	3.32	0.16	3.17	0.15												
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.006	388.92	2.33	335.88	2.02	49.15	0.29	331.25	1.99	468.56	2.81	245.45	1.47												
PM 0110	Poultry meat, raw (incl prepared)	RAC	0.008	73.76	0.59	53.86	0.43	23.98	0.19	87.12	0.70	53.38	0.43	84.45	0.68												
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.031	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.71	0.02	NC	-												
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.028	0.33	0.01	0.72	0.02	0.27	0.01	0.35	0.01	0.80	0.02	NC	-												
PE 0112	Eggs, raw, (incl dried)	RAC	0.099	25.84	2.56	29.53	2.92	28.05	2.78	33.19	3.29	36.44	3.61	8.89	0.88												
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-												
Total intake (ug/person)=				321.1				299.8				968.2				486.4				318.7				239.9			
Bodyweight per region (kg bw) =				60				60				55				60				60							
ADI (ug/person)=				120000				120000				110000				120000				120000							
%ADI=				0.3 %				0.2 %				0.9 %				0.4 %				0.3 %				0.2 %			
Rounded %ADI=				0 %				0 %				1 %				0 %				0 %							

Annex 3

CHLORANTRANILIPROLE (230)

International Estimated Daily Intake (IEDI)

ADI = 0 - 2 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day		Intake = daily intake: ug/person							
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
FC 0001	Group of Citrus fruit, raw (incl citrus fruit juice, incl kumquat commodities)	RAC	0.06	21.16	1.27	2.94	0.18	58.52	3.51	0.44	0.03	5.13	0.31
FP 0009	Group of Pome fruits, raw (incl. apple juice, incl apple cider)	RAC	0.07	68.89	4.82	11.06	0.77	80.62	5.64	189.82	13.29	19.56	1.37
FS 0012	Group of Stone fruits, raw (incl dried plums, incl dried apricots)	RAC	0.2	0.09	0.02	0.03	0.01	33.36	6.67	0.01	0.00	NC	-
FB 0018	Group of Berries and other small fruits, raw (incl processed)	RAC	0.119	2.14	0.25	19.92	2.37	114.85	13.67	1.55	0.18	49.22	5.86
FI 0326	Avocado, raw	RAC	0.089	1.12	0.10	0.01	0.00	0.84	0.07	0.01	0.00	6.60	0.59
FI 0355	Pomegranate, raw, (incl processed)	RAC	0.11	5.49	0.60	27.17	2.99	NC	-	2.89	0.32	17.87	1.97
VC 0045	Group of Fruiting vegetables, cucurbits, raw	RAC	0.065	5.96	0.39	9.74	0.63	51.82	3.37	13.61	0.88	0.05	0.00
VO 0050	Group of Fruiting vegetables other than cucurbits, raw, (incl processed commodities, excl dried chilli peppers)	RAC	0.066	32.01	2.11	28.27	1.87	100.61	6.64	2.91	0.19	12.50	0.83
VL 0053	Group of Leafy vegetables, raw	RAC	7.3	12.42	90.67	8.75	63.88	7.53	54.97	7.07	51.61	14.11	103.00
VL 0494	Radish leaves, raw	RAC	10.5	0.44	4.62	0.32	3.36	NC	-	0.30	3.15	0.59	6.20
VP 0061	Beans with pods (Phaseolus spp): (immature pods + succulent seeds)	RAC	0.16	NC	-	NC	-	NC	-	NC	-	NC	-
VP 2062	Subgroup of succulent beans without pods (all commodities within this group)	RAC	0.545	0.37	0.20	3.14	1.71	4.88	2.66	0.01	0.01	NC	-
VP 0064	Peas without pods (Pisum spp) (succulent seeds)	RAC	0.025	0.21	0.01	0.02	0.00	5.51	0.14	0.02	0.00	NC	-
VD 2065	Subgroup of dry beans, raw (incl processed)	RAC	0.0305	41.93	1.28	19.42	0.59	108.31	3.30	66.18	2.02	42.47	1.30
VD 0541	Soya bean, dry, raw (incl paste, incl curd, incl oil, incl sauce)	RAC	0.01	15.80	0.16	14.29	0.14	104.36	1.04	17.11	0.17	35.20	0.35
VD 2066	Subgroup of dry peas, raw	RAC	0.0305	4.43	0.14	11.36	0.35	4.22	0.13	9.36	0.29	1.21	0.04
VR 0075	Group of Root and tuber vegetables, raw (incl processed)	RAC	0.01	282.25	2.82	232.11	2.32	281.91	2.82	620.21	6.20	459.96	4.60
VR 0577	Carrots, raw	RAC	0.02	2.07	0.04	3.00	0.06	25.29	0.51	0.05	0.00	NC	-
VR 0494	Radish roots, raw	RAC	0.055	3.96	0.22	2.86	0.16	3.30	0.18	2.67	0.15	5.34	0.29
VS 0624	Celery	RAC	2.1	3.66	7.69	2.65	5.57	4.84	10.16	2.47	5.19	4.94	10.37
VS 0620	Artichoke globe, raw	RAC	0.56	0.01	0.01	NC	-	0.08	0.04	0.01	0.01	NC	-
GC 0081	Cereal grains, excl pseudocereals, excl sweet corn (incl processed)	RAC	0.01	403.37	4.03	393.72	3.94	394.01	3.94	195.27	1.95	263.09	2.63
CF 1210	Wheat, germ	PP	0.012	0.04	0.00	0.01	0.00	0.01	0.00	0.01	0.00	NC	-
CF 1211	Wheat, white flour (incl white flour products: starch, gluten, macaroni, pastry)	PP	0.004	44.78	0.18	86.96	0.35	214.05	0.86	20.31	0.08	103.60	0.41
CM 0649 (GC 0649)	Rice, husked, dry (incl flour, incl oil, incl beverages, incl starch, excl polished)	REP	0.115	13.58	1.56	4.29	0.49	2.17	0.25	0.01	0.00	8.84	1.02

Annex 3

CHLORANTRANILIPROLE (230)

International Estimated Daily Intake (IEDI)

ADI = 0 - 2 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day		Intake = daily intake: ug/person							
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
CM 1205	Rice polished, dry	PP	0.013	30.20	0.39	218.34	2.84	12.77	0.17	15.24	0.20	51.35	0.67
GC 0447	Sweet corn on the cob, raw (incl frozen kernels, incl canned kernels)	RAC	0.01	3.63	0.04	20.50	0.21	8.78	0.09	0.02	0.00	0.17	0.00
GS 0659	Sugar cane, raw (incl sugar, incl molasses)	RAC	0.145	33.75	4.89	106.29	15.41	78.09	11.32	29.09	4.22	45.70	6.63
TN 0085	Group of Tree nuts, raw (incl processed)	RAC	0.01	4.39	0.04	135.53	1.36	6.11	0.06	0.72	0.01	317.74	3.18
SO 0495	Rape seed, raw (incl oil)	RAC	0.295	0.19	0.06	0.07	0.02	12.07	3.56	0.08	0.02	NC	-
SO 0702	Sunflower seed, raw (incl oil)	RAC	0.185	0.94	0.17	0.22	0.04	32.01	5.92	12.12	2.24	0.48	0.09
SO 0691	Cotton seed, raw (incl oil)	RAC	0.049	8.14	0.40	0.32	0.02	2.84	0.14	2.69	0.13	0.97	0.05
SO 0697	Peanuts, nutmeat, raw (incl roasted, incl oil, incl butter)	RAC	0.01	18.82	0.19	0.57	0.01	2.28	0.02	6.90	0.07	0.53	0.01
SO 0696	Palm fruit (African Oil Palm), raw (incl oil)	RAC	0.195	36.35	7.09	7.16	1.40	2.99	0.58	22.89	4.46	28.38	5.53
SB 0716	Coffee bean raw (incl roasted, incl instant coffee, incl substitutes)	RAC	0.015	0.95	0.01	1.32	0.02	11.64	0.17	2.96	0.04	14.73	0.22
HH 0738	Mint, raw	RAC	4.6	NC	-	NC	-	NC	-	NC	-	NC	-
HS 0444	Peppers, chili, dried	PP	0.46	0.58	0.27	1.27	0.58	1.21	0.56	0.12	0.06	NC	-
DH 1100	Hops, dry	RAC	10.9	NC	-	NC	-	0.04	0.44	NC	-	NC	-
DT 1114	Tea, green or black, fermented and dried, (including concentrates)	RAC	24	0.53	12.72	5.25	126.00	0.86	20.64	0.56	13.44	0.88	21.12
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80 % as muscle	RAC	0.009	23.34	0.21	40.71	0.37	97.15	0.87	18.06	0.16	57.71	0.52
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20 % as fat	RAC	0.05	5.84	0.29	10.18	0.51	24.29	1.21	4.52	0.23	14.43	0.72
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.049	1.05	0.05	1.14	0.06	18.69	0.92	0.94	0.05	3.12	0.15
MO 0105	Edible offal (mammalian), raw	RAC	0.047	4.64	0.22	1.97	0.09	10.01	0.47	3.27	0.15	3.98	0.19
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.006	108.75	0.65	70.31	0.42	436.11	2.62	61.55	0.37	79.09	0.47
PM 0110	Poultry meat, raw (incl prepared)	RAC	0.008	3.92	0.03	12.03	0.10	57.07	0.46	5.03	0.04	55.56	0.44
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.031	NC	-	NC	-	0.32	0.01	NC	-	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.028	0.10	0.00	0.70	0.02	0.97	0.03	0.10	0.00	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0.099	3.84	0.38	4.41	0.44	27.25	2.70	1.13	0.11	7.39	0.73
-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total intake (ug/person)=				151.3		241.6		173.5		111.7		181.8	
Bodyweight per region (kg bw) =				60		60		60		60		60	
ADI (ug/person)=				120000		120000		120000		120000		120000	
%ADI=				0.1 %		0.2 %		0.1 %		0.1 %		0.2 %	
Rounded %ADI=				0 %		0 %		0 %		0 %		0 %	

Annex 3

069

CHLORMEQUAT (015)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.04 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day																			
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake												
FB 0269	Grapes, raw (incl must, incl dried, incl juice, incl wine)	RAC	0.04	16.25	0.65	28.96	1.16	2.87	0.11	24.22	0.97	9.33	0.37	68.64	2.75												
GC 0650	Rye, raw (incl flour)	RAC	1.1	0.13	0.14	19.38	21.32	0.10	0.11	0.12	0.13	0.03	0.03	2.15	2.37												
GC 0653	Triticale, raw (incl flour)	RAC	0.92	NC	-	NC	-	NC	-	0.01	0.01	0.39	0.36	NC	-												
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, incl white flour products, incl white bread, excl germ, excl wholemeal bread)	RAC	0.855	381.15	325.88	341.54	292.02	38.34	32.78	281.87	241.00	172.65	147.62	434.06	371.12												
CF 1210	Wheat, germ	PP	4.3	NC	-	NC	-	0.01	0.04	0.01	0.04	0.14	0.60	0.01	0.04												
CP 1212	Wheat, wholemeal bread	PP	0.46	0.01	0.00	0.01	0.00	0.01	0.00	0.01	0.00	0.03	0.01	0.01	0.00												
CF 1211	Wheat, white flour (incl white flour products: starch, gluten, macaroni, pastry)	PP	0.16	301.24	48.20	268.64	42.98	30.21	4.83	222.51	35.60	134.73	21.56	343.12	54.90												
GC 0640	Barley, raw	RAC	0.37	2.49	0.92	NC	-	0.02	0.01	0.03	0.01	0.18	0.07	0.38	0.14												
-	Barley, pot&pearled	PP	0.12	7.12	0.85	7.34	0.88	0.02	0.00	0.03	0.00	0.67	0.08	0.20	0.02												
-	Barley, flour (white flour and wholemeal flour)	PP	0.066	2.93	0.19	0.30	0.02	0.02	0.00	0.01	0.00	0.48	0.03	0.01	0.00												
-	Barley beer	PP	0.074	4.87	0.36	93.78	6.94	24.28	1.80	12.76	0.94	39.28	2.91	18.15	1.34												
-	Barley Malt	PP	0.33	0.09	0.03	1.04	0.34	0.18	0.06	0.33	0.11	0.04	0.01	0.10	0.03												
GC 0647	Oats, raw	RAC	1.3	0.01	0.01	NC	-	0.01	0.01	0.45	0.59	0.01	0.01	0.01	0.01												
GC 0647	Oats, rolled (i.e. oatmeal dry)	PP	1.04	0.03	0.03	3.88	4.04	0.05	0.05	0.69	0.72	0.53	0.55	0.02	0.02												
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80 % as muscle	RAC	0.04	24.96	1.00	57.95	2.32	16.70	0.67	38.38	1.54	26.46	1.06	29.00	1.16												
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20 % as fat	RAC	0.04	6.24	0.25	14.49	0.58	4.18	0.17	9.60	0.38	6.62	0.26	7.25	0.29												
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.04	3.29	0.13	6.14	0.25	0.82	0.03	1.57	0.06	2.23	0.09	1.07	0.04												
MO 0105	Edible offal (mammalian), raw	RAC	0.2	4.79	0.96	9.68	1.94	2.97	0.59	5.49	1.10	3.84	0.77	5.03	1.01												
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.069	289.65	19.99	485.88	33.53	26.92	1.86	239.03	16.49	199.91	13.79	180.53	12.46												
PM 0110	Poultry meat, raw (incl prepared) - 90 % as muscle	RAC	0.04	13.17	0.53	26.78	1.07	7.24	0.29	116.71	4.67	22.54	0.90	32.09	1.28												
PM 0110	Poultry meat, raw (incl prepared) - 10 % as fat	RAC	0.04	1.46	0.06	2.98	0.12	0.80	0.03	12.97	0.52	2.50	0.10	3.57	0.14												
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.04	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.10	0.00	0.10	0.00												
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.043	0.12	0.01	0.12	0.01	0.11	0.00	5.37	0.23	0.24	0.01	0.10	0.00												
PE 0112	Eggs, raw, (incl dried)	RAC	0.049	7.84	0.38	23.08	1.13	2.88	0.14	14.89	0.73	9.81	0.48	14.83	0.73												
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-												
Total intake (ug/person)=				400.6				410.6				43.6				305.9				191.7				449.9			
Bodyweight per region (kg bw) =				60				60				60				60				60							
ADI (ug/person)=				2328				2328				2328				2328				2328							
%ADI=				17.2 %				17.6 %				1.9 %				13.1 %				8.2 %				19.3 %			
Rounded %ADI=				20 %				20 %				2 %				10 %				8 %				20 %			

Annex 3

CHLORMEQUAT (015)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.04 mg/kg bw

Codex Code	Commodity description	STMR Expr as mg/kg	Diets as g/person/day						Intake as ug/person/day						
			G07		G08		G09		G10		G11		G12		
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	
FB 0269	Grapes, raw (incl must, incl dried, incl juice, incl wine)	RAC	0.04	142.23	5.69	105.77	4.23	7.87	0.31	52.44	2.10	109.22	4.37	10.96	0.44
GC 0650	Rye, raw (incl flour)	RAC	1.1	3.21	3.53	35.38	38.92	0.21	0.23	6.50	7.15	1.49	1.64	NC	-
GC 0653	Triticale, raw (incl flour)	RAC	0.92	0.01	0.01	0.17	0.16	0.29	0.27	0.01	0.01	NC	-	NC	-
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, incl white flour products, incl white bread, excl germ, excl wholemeal bread)	RAC	0.855	252.06	215.51	244.62	209.15	134.41	114.92	235.10	201.01	216.33	184.96	167.34	143.08
CF 1210	Wheat, germ	PP	4.3	0.97	4.17	0.10	0.43	0.03	0.13	0.01	0.04	NC	-	0.04	0.17
CP 1212	Wheat, wholemeal bread	PP	0.46	0.03	0.01	0.01	0.00	0.01	0.00	0.01	0.00	0.05	0.02	0.02	0.01
CF 1211	Wheat, white flour (incl white flour products: starch, gluten, macaroni, pastry)	PP	0.16	198.08	31.69	193.03	30.88	106.24	17.00	185.09	29.61	168.67	26.99	131.59	21.05
GC 0640	Barley, raw	RAC	0.37	0.01	0.00	NC	-	0.03	0.01	1.36	0.50	NC	-	NC	-
-	Barley, pot&pearled	PP	0.12	0.57	0.07	2.56	0.31	0.33	0.04	0.56	0.07	0.36	0.04	NC	-
-	Barley, flour (white flour and wholemeal flour)	PP	0.066	0.08	0.01	0.03	0.00	0.01	0.00	0.05	0.00	0.68	0.04	0.05	0.00
-	Barley beer	PP	0.074	180.21	13.34	259.46	19.20	45.91	3.40	172.36	12.75	234.42	17.35	65.30	4.83
-	Barley Malt	PP	0.33	0.19	0.06	NC	-	0.04	0.01	0.08	0.03	NC	-	2.14	0.71
GC 0647	Oats, raw	RAC	1.3	NC	-	NC	-	0.01	0.01	0.01	0.01	NC	-	0.23	0.30
GC 0647	Oats, rolled (i.e. oatmeal dry)	PP	1.04	4.12	4.28	3.44	3.58	0.08	0.08	2.67	2.78	1.74	1.81	1.51	1.57
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80 % as muscle	RAC	0.04	112.02	4.48	120.71	4.83	63.46	2.54	88.99	3.56	96.24	3.85	41.02	1.64
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20 % as fat	RAC	0.04	28.01	1.12	30.18	1.21	15.86	0.63	22.25	0.89	24.06	0.96	10.25	0.41
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.04	6.44	0.26	15.51	0.62	3.79	0.15	8.29	0.33	18.44	0.74	8.00	0.32
MO 0105	Edible offal (mammalian), raw	RAC	0.2	15.17	3.03	5.19	1.04	6.30	1.26	6.78	1.36	3.32	0.66	3.17	0.63
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.069	388.92	26.84	335.88	23.18	49.15	3.39	331.25	22.86	468.56	32.33	245.45	16.94
PM 0110	Poultry meat, raw (incl prepared) - 90 % as muscle	RAC	0.04	66.38	2.66	48.47	1.94	21.58	0.86	78.41	3.14	48.04	1.92	76.01	3.04
PM 0110	Poultry meat, raw (incl prepared) - 10 % as fat	RAC	0.04	7.38	0.30	5.39	0.22	2.40	0.10	8.71	0.35	5.34	0.21	8.45	0.34
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.04	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.71	0.03	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.043	0.33	0.01	0.72	0.03	0.27	0.01	0.35	0.02	0.80	0.03	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0.049	25.84	1.27	29.53	1.45	28.05	1.37	33.19	1.63	36.44	1.79	8.89	0.44
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total intake (ug/person)=				318.3		341.4		146.7		290.2		279.8		195.9	
Bodyweight per region (kg bw) =				60		60		55		60		60		60	
ADI (ug/person)=				2328		2328		2134		2328		2328		2328	
%ADI=				13.7 %		14.7 %		6.9 %		12.5 %		12.0 %		8.4 %	
Rounded %ADI=				10 %		10 %		7 %		10 %		10 %		8 %	

Annex 3

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CHLORMEQUAT (015)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.04 mg/kg bw

Codex Code	Commodity description	Expras	STMR mg/kg	Diets: g/person/day		Intake = daily intake: ug/person							
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
FB 0269	Grapes, raw (incl must, incl dried, incl juice, incl wine)	RAC	0.04	0.60	0.02	1.26	0.05	103.25	4.13	0.74	0.03	44.23	1.77
GC 0650	Rye, raw (incl flour)	RAC	1.1	0.03	0.03	0.01	0.01	13.95	15.35	0.01	0.01	0.88	0.97
GC 0653	Triticale, raw (incl flour)	RAC	0.92	0.01	0.01	NC	-	NC	-	NC	-	NC	-
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, incl white flour products, incl white bread, excl germ, excl wholemeal bread)	RAC	0.855	57.15	48.86	110.46	94.44	272.58	233.06	25.81	22.07	132.04	112.89
CF 1210	Wheat, germ	PP	4.3	0.04	0.17	0.01	0.04	0.01	0.04	0.01	0.04	NC	-
CP 1212	Wheat, wholemeal bread	PP	0.46	0.01	0.00	0.01	0.00	0.03	0.01	0.01	0.00	0.01	0.00
CF 1211	Wheat, white flour (incl white flour products: starch, gluten, macaroni, pastry)	PP	0.16	44.78	7.16	86.96	13.91	214.05	34.25	20.31	3.25	103.60	16.58
GC 0640	Barley, raw	RAC	0.37	0.01	0.00	0.01	0.00	0.16	0.06	NC	-	NC	-
-	Barley, pot&pearled	PP	0.12	5.46	0.66	0.01	0.00	1.44	0.17	0.01	0.00	NC	-
-	Barley, flour (white flour and wholemeal flour)	PP	0.066	0.02	0.00	NC	-	0.32	0.02	0.01	0.00	NC	-
-	Barley beer	PP	0.074	16.25	1.20	11.36	0.84	225.21	16.67	19.49	1.44	52.17	3.86
-	Barley Malt	PP	0.33	0.01	0.00	0.11	0.04	0.67	0.22	0.01	0.00	4.61	1.52
GC 0647	Oats, raw	RAC	1.3	0.01	0.01	0.02	0.03	NC	-	0.09	0.12	NC	-
GC 0647	Oats, rolled (i.e. oatmeal dry)	PP	1.04	0.20	0.21	0.03	0.03	1.54	1.60	0.01	0.01	NC	-
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80 % as muscle	RAC	0.04	23.34	0.93	40.71	1.63	97.15	3.89	18.06	0.72	57.71	2.31
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20 % as fat	RAC	0.04	5.84	0.23	10.18	0.41	24.29	0.97	4.52	0.18	14.43	0.58
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.04	1.05	0.04	1.14	0.05	18.69	0.75	0.94	0.04	3.12	0.12
MO 0105	Edible offal (mammalian), raw	RAC	0.2	4.64	0.93	1.97	0.39	10.01	2.00	3.27	0.65	3.98	0.80
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.069	108.75	7.50	70.31	4.85	436.11	30.09	61.55	4.25	79.09	5.46
PM 0110	Poultry meat, raw (incl prepared) - 90 % as muscle	RAC	0.04	3.53	0.14	10.83	0.43	51.36	2.05	4.53	0.18	50.00	2.00
PM 0110	Poultry meat, raw (incl prepared) - 10 % as fat	RAC	0.04	0.39	0.02	1.20	0.05	5.71	0.23	0.50	0.02	5.56	0.22
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.04	NC	-	NC	-	0.32	0.01	NC	-	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.043	0.10	0.00	0.70	0.03	0.97	0.04	0.10	0.00	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0.049	3.84	0.19	4.41	0.22	27.25	1.34	1.13	0.06	7.39	0.36
-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total intake (ug/person)=				68.3		117.5		346.9		33.1		149.4	
Bodyweight per region (kg bw) =				60		60		60		60		60	
ADI (ug/person)=				2328		2328		2328		2328		2328	
%ADI=				2.9 %		5.0 %		14.9 %		1.4 %		6.4 %	
Rounded %ADI=				3 %		5 %		10 %		1 %		6 %	

Annex 3

DIFENCONAZOLE (224)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.01 mg/kg bw

Codex Code	Commodity description	Expras	STMR mg/kg	Diets as g/person/day		Intake as ug/person/day									
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
FC 0001	Group of Citrus fruit, raw (incl kumquat commodities)	RAC	0.16	32.25	5.16	11.67	1.87	16.70	2.67	76.01	12.16	33.90	5.42	92.97	14.88
JF 0001	Group of Citrus fruit, juice	PP	0.002	1.30	0.00	2.37	0.00	0.22	0.00	13.88	0.03	0.75	0.00	2.63	0.01
FP 0009	Group of Pome fruits, raw (incl. apple juice, incl apple cider)	RAC	0.86	19.79	17.02	38.25	32.90	17.96	15.45	32.56	28.00	8.08	6.95	64.45	55.43
FS 0013	Subgroup of Cherries, raw	RAC	0.04	0.92	0.04	9.15	0.37	0.01	0.00	0.61	0.02	0.06	0.00	6.64	0.27
FS 0014	Subgroup of Plums, raw (incl dried plums)	RAC	0.04	2.67	0.11	8.77	0.35	0.07	0.00	3.03	0.12	0.70	0.03	4.34	0.17
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.15	8.01	1.20	5.87	0.88	0.18	0.03	8.19	1.23	1.64	0.25	22.46	3.37
FB 0020	Blueberries, raw	RAC	1	0.01	0.01	0.03	0.03	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01
FB 0269	Grapes, raw (incl must, excl dried, excl juice, excl wine)	RAC	0.52	13.02	6.77	9.25	4.81	0.03	0.02	16.91	8.79	3.70	1.92	54.44	28.31
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	1.1	0.51	0.56	0.51	0.56	0.01	0.01	1.27	1.40	0.12	0.13	2.07	2.28
JF 0269	Grape juice (from wine grapes)	PP	0.24	0.14	0.03	0.29	0.07	0.05	0.01	0.30	0.07	0.24	0.06	0.05	0.01
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.094	0.67	0.06	12.53	1.18	2.01	0.19	1.21	0.11	3.53	0.33	4.01	0.38
FB 0265	Cranberry, raw	RAC	0.2	0.02	0.00	0.01	0.00	NC	-	0.03	0.01	0.01	0.00	0.01	0.00
FB 0275	Strawberry, raw	RAC	0.42	0.70	0.29	2.01	0.84	0.04	0.02	1.36	0.57	0.37	0.16	2.53	1.06
FT 0305	Table olives, raw (incl preserved)	RAC	0.465	0.70	0.33	0.32	0.15	0.01	0.00	1.53	0.71	0.17	0.08	1.85	0.86
FT 0336	Guava, raw	RAC	0.0335	0.47	0.02	0.01	0.00	0.48	0.02	0.49	0.02	4.42	0.15	0.06	0.00
FI 0326	Avocado, raw	RAC	0.05	0.13	0.01	0.03	0.00	2.05	0.10	2.54	0.13	2.34	0.12	0.12	0.01
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.02	5.23	0.10	6.94	0.14	99.45	1.99	32.47	0.65	48.30	0.97	24.70	0.49
FI 0345	Mango, raw (incl canned mango, incl mango juice)	RAC	0.03	10.48	0.31	0.01	0.00	7.24	0.22	6.87	0.21	19.98	0.60	6.25	0.19
FI 0350	Papaya, raw	RAC	0.065	0.35	0.02	0.01	0.00	3.05	0.20	0.80	0.05	7.28	0.47	1.00	0.07
FI 2540	Pitaya, raw (i.e dragon fruit or pitahaya)	RAC	0.034	0.01	0.00	0.01	0.00	0.01	0.00	0.01	0.00	NC	-	0.01	0.00
FI 0351	Passion fruit, raw	RAC	0.01	0.58	0.01	0.01	0.00	0.59	0.01	0.60	0.01	0.18	0.00	0.08	0.00
-	Onions, dry, raw	RAC	0.015	29.36	0.44	37.50	0.56	3.56	0.05	34.78	0.52	18.81	0.28	43.38	0.65
VA 0384	Leek, raw	RAC	0.08	0.18	0.01	1.59	0.13	0.03	0.00	0.28	0.02	0.01	0.00	3.21	0.26
-	Onions, green, raw	RAC	2.8	2.45	6.86	1.49	4.17	1.02	2.86	2.60	7.28	0.60	1.68	2.03	5.68
VB 0040	Group of Brassica vegetables (excl Brassica leafy vegetables), raw	RAC	0.35	6.43	2.25	40.26	14.09	0.80	0.28	9.94	3.48	12.07	4.22	17.73	6.21
VC 0424	Cucumber, raw	RAC	0.04	8.01	0.32	30.66	1.23	1.45	0.06	19.84	0.79	0.27	0.01	34.92	1.40
VC 0425	Gherkin, raw	RAC	0.04	1.73	0.07	6.64	0.27	0.31	0.01	4.29	0.17	0.29	0.01	7.56	0.30
VC 0431	Squash, Summer (Courgette, Marrow, Zucchini, Zucchini), raw	RAC	0.04	0.78	0.03	2.06	0.08	0.30	0.01	1.61	0.06	2.25	0.09	2.36	0.09
VC 0046	Melons, except watermelon, raw (Cantaloupe)	RAC	0.14	8.90	1.25	8.64	1.21	0.80	0.11	17.90	2.51	2.80	0.39	29.17	4.08
VC 0432	Watermelon, raw	RAC	0.01	28.96	0.29	25.65	0.26	1.56	0.02	39.26	0.39	4.94	0.05	66.90	0.67
VO 0448	Tomato, raw	RAC	0.1	41.73	4.17	75.65	7.57	10.66	1.07	82.87	8.29	24.75	2.48	200.93	20.09

Annex 3

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DIFENOCONAZOLE (224)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.01 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day							
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
-	Tomato, canned (& peeled)	PP	0.01	0.20	0.00	0.31	0.00	0.02	0.00	1.11	0.01	0.11	0.00	1.50	0.02
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.22	2.34	0.51	1.33	0.29	1.57	0.35	4.24	0.93	0.34	0.07	2.83	0.62
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.031	0.29	0.01	0.29	0.01	0.01	0.00	0.38	0.01	0.05	0.00	0.14	0.00
VO 0442	Okra, raw (i.e. Lady's Finger, Gombo)	RAC	0.14	1.97	0.28	NC	-	3.68	0.52	3.24	0.45	5.72	0.80	1.57	0.22
VO 0444	Peppers, chili, raw	RAC	0.24	3.99	0.96	7.30	1.75	2.93	0.70	5.62	1.35	NC	-	17.44	4.19
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.14	4.49	0.63	6.44	0.90	7.21	1.01	5.68	0.80	9.52	1.33	8.92	1.25
VO 0440	Egg plant, raw (i.e. aubergine)	RAC	0.14	5.58	0.78	4.31	0.60	0.89	0.12	9.31	1.30	13.64	1.91	20.12	2.82
VL 0483	Lettuce, leaf, raw	RAC	0.41	0.53	0.22	0.36	0.15	0.16	0.07	6.21	2.55	1.90	0.78	6.05	2.48
VP 0060	Group of Legume vegetables, raw	RAC	0.07	7.73	0.54	1.53	0.11	0.51	0.04	2.95	0.21	5.08	0.36	12.86	0.90
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	0.011	2.39	0.03	1.61	0.02	10.47	0.12	1.84	0.02	12.90	0.14	7.44	0.08
VD 0523	Broad bean, dry, raw (incl horse-bean, field bean) (Vicia faba)	RAC	0.011	1.27	0.01	0.01	0.00	0.12	0.00	2.49	0.03	0.23	0.00	5.54	0.06
VD 0541	Soya bean, dry, raw (incl flour, incl paste, incl curd, incl sauce, excl oil)	RAC	0.01	0.63	0.01	1.09	0.01	0.40	0.00	1.40	0.01	1.68	0.02	0.48	0.00
OR 0541	Soya oil, refined	PP	0.08	12.99	1.04	10.43	0.83	3.63	0.29	13.10	1.05	10.70	0.86	13.10	1.05
-	Beans (dry) NES: including inter alia lablab or hyacinth bean (Dolichos spp.); jack or sword bean (Canavalia spp.); winged bean (Psophocarpus tetragonolobus); guar bean (Cyamopsis tetragonoloba); velvet bean (Stizolobium spp.); yam bean (Pachyrrhizus erosus)	RAC	0.028	1.70	0.05	0.01	0.00	3.00	0.08	1.80	0.05	1.64	0.05	1.33	0.04
VD 0533	Lentil (dry) (Lens spp), raw	RAC	0.028	2.12	0.06	0.01	0.00	0.03	0.00	3.21	0.09	1.60	0.04	4.90	0.14
VD 0537	Pigeon pea (dry) (Cajanus spp), raw	RAC	0.028	NC	-	NC	-	0.10	0.00	0.07	0.00	3.38	0.09	NC	-
VR 0577	Carrots, raw	RAC	0.05	9.51	0.48	30.78	1.54	0.37	0.02	8.75	0.44	2.80	0.14	6.10	0.31
VR 0578	Celeriac, raw	RAC	0.12	1.70	0.20	3.01	0.36	1.87	0.22	4.53	0.54	NC	-	2.19	0.26
VR 0596	Sugar beet, raw (incl sugar)	RAC	0.02	0.13	0.00	NC	-	0.08	0.00	0.66	0.01	0.47	0.01	88.94	1.78
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	1.2	59.74	71.69	316.14	379.37	9.78	11.74	60.26	72.31	54.12	64.94	119.82	143.78
VS 0624	Celery	RAC	0.14	2.14	0.30	3.79	0.53	2.35	0.33	5.69	0.80	0.02	0.00	2.75	0.39
VS 0621	Asparagus, raw	RAC	0.02	0.01	0.00	0.01	0.00	0.01	0.00	0.03	0.00	0.07	0.00	0.21	0.00
VS 0620	Artichoke globe, raw	RAC	0.51	0.69	0.35	0.01	0.01	0.01	0.01	0.32	0.16	0.26	0.13	1.21	0.62
CM 0649 (GC 0649)	Rice, husked, dry (incl flour, incl oil, incl beverages, incl starch, excl polished)	REP	1.1	1.26	1.39	1.58	1.74	31.05	34.16	5.43	5.97	0.90	0.99	2.18	2.40
CM 1205	Rice polished, dry	PP	0.0086	34.21	0.29	10.39	0.09	41.72	0.36	82.38	0.71	150.24	1.29	70.47	0.61
GC 0447	Sweet corn on the cob, raw (incl frozen kernels, incl canned kernels)	RAC	0.01	0.14	0.00	0.94	0.01	5.70	0.06	2.61	0.03	1.94	0.02	0.22	0.00
TN 0085	Group of Tree nuts, raw (incl processed)	RAC	0.01	4.06	0.04	3.27	0.03	7.01	0.07	13.93	0.14	14.01	0.14	9.36	0.09

Annex 3

DIFENCONAZOLE (224)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.01 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day																			
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake												
SO 0495	Rape seed, raw	RAC	0.03	0.02	0.00	NC	-	NC	-	0.01	0.00	0.75	0.02	0.01	0.00												
OR 0495	Rape seed oil, edible	PP	0.002	0.35	0.00	0.44	0.00	0.19	0.00	0.97	0.00	3.28	0.01	0.77	0.00												
SO 0702	Sunflower seed, raw (incl oil)	RAC	0.01	7.40	0.07	35.86	0.36	1.15	0.01	8.76	0.09	5.45	0.05	13.62	0.14												
OR 0691	Cotton seed oil, edible	PP	0.0014	3.22	0.00	1.54	0.00	1.01	0.00	0.74	0.00	1.12	0.00	2.93	0.00												
SO 0697	Peanuts, nutmeat, raw (incl roasted, incl oil, incl butter)	RAC	0	1.30	0.00	1.23	0.00	12.62	0.00	2.87	0.00	6.59	0.00	2.67	0.00												
SO 0305	Olives for oil production, raw	RAC	0.456	1.47	0.67	0.67	0.31	NC	-	1.26	0.57	0.04	0.02	7.63	3.48												
-	Olive oil (virgin and residue oil)	PP	0.7	2.17	1.52	0.13	0.09	0.05	0.04	1.32	0.92	0.10	0.07	2.76	1.93												
SB 0716	Coffee bean raw (incl roasted, incl instant coffee, incl substitutes)	RAC	0.01	1.36	0.01	3.59	0.04	1.44	0.01	5.18	0.05	2.02	0.02	1.70	0.02												
HS 0784	Ginger, rhizome, raw incl dried	RAC	0.13	0.25	0.03	0.01	0.00	0.16	0.02	1.16	0.15	0.59	0.08	0.01	0.00												
HS 0444	Peppers, chili, dried	PP	1.1	0.42	0.46	0.53	0.58	0.84	0.92	0.50	0.55	0.95	1.05	0.37	0.41												
DT 1114	Tea, green or black, fermented and dried, (including concentrates)	RAC	4.85	2.28	11.06	1.98	9.60	0.46	2.23	2.43	11.79	1.29	6.26	3.04	14.74												
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80 % as muscle	RAC	0.047	24.96	1.17	57.95	2.72	16.70	0.79	38.38	1.80	26.46	1.24	29.00	1.36												
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20 % as fat	RAC	0.14	6.24	0.87	14.49	2.03	4.18	0.58	9.60	1.34	6.62	0.93	7.25	1.02												
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.14	3.29	0.46	6.14	0.86	0.82	0.11	1.57	0.22	2.23	0.31	1.07	0.15												
MO 0105	Edible offal (mammalian), raw	RAC	0.71	4.79	3.40	9.68	6.87	2.97	2.11	5.49	3.90	3.84	2.73	5.03	3.57												
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.011	289.65	3.19	485.88	5.34	26.92	0.30	239.03	2.63	199.91	2.20	180.53	1.99												
PM 0110	Poultry meat, raw (incl prepared)	RAC	0.0002	14.63	0.00	29.76	0.01	8.04	0.00	129.68	0.03	25.04	0.01	35.66	0.01												
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.0002	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.10	0.00	0.10	0.00												
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.0002	0.12	0.00	0.12	0.00	0.11	0.00	5.37	0.00	0.24	0.00	0.10	0.00												
PE 0112	Eggs, raw, (incl dried)	RAC	0.011	7.84	0.09	23.08	0.25	2.88	0.03	14.89	0.16	9.81	0.11	14.83	0.16												
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-												
Total intake (ug/person)=				150.6				491.1				82.8				192.0				116.1				340.3			
Bodyweight per region (kg bw) =				60				60				60				60				60							
ADI (ug/person)=				600				600				600				600				600							
%ADI=				25.1 %				81.9 %				13.8 %				32.0 %				19.3 %				56.7 %			
Rounded %ADI=				30 %				80 %				10 %				30 %				20 %				60 %			

Annex 3

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DIFENOCONAZOLE (224)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.01 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day							
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
FC 0001	Group of Citrus fruit, raw (incl kumquat commodities)	RAC	0.16	38.66	6.19	54.93	8.79	26.36	4.22	51.46	8.23	51.06	8.17	466.36	74.62
JF 0001	Group of Citrus fruit, juice	PP	0.002	36.84	0.07	3.75	0.01	0.30	0.00	21.62	0.04	21.82	0.04	46.67	0.09
FP 0009	Group of Pome fruits, raw (incl. apple juice, incl apple cider)	RAC	0.86	71.38	61.39	81.73	70.29	42.91	36.90	58.89	50.65	103.85	89.31	12.48	10.73
FS 0013	Subgroup of Cherries, raw	RAC	0.04	1.40	0.06	4.21	0.17	0.04	0.00	2.93	0.12	1.50	0.06	NC	-
FS 0014	Subgroup of Plums, raw (incl dried plums)	RAC	0.04	5.55	0.22	4.37	0.17	6.08	0.24	3.66	0.15	3.93	0.16	0.46	0.02
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.15	13.03	1.95	16.29	2.44	8.29	1.24	12.95	1.94	5.35	0.80	0.04	0.01
FB 0020	Blueberries, raw	RAC	1	0.04	0.04	0.23	0.23	0.01	0.01	0.83	0.83	0.33	0.33	NC	-
FB 0269	Grapes, raw (incl must, excl dried, excl juice, excl wine)	RAC	0.52	6.48	3.37	11.31	5.88	5.21	2.71	9.50	4.94	4.66	2.42	0.78	0.41
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	1.1	3.09	3.40	1.51	1.66	0.03	0.03	1.38	1.52	4.26	4.69	0.42	0.46
JF 0269	Grape juice (from wine grapes)	PP	0.24	0.56	0.13	1.96	0.47	0.02	0.00	2.24	0.54	2.27	0.54	0.34	0.08
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.094	88.93	8.36	62.41	5.87	1.84	0.17	25.07	2.36	61.17	5.75	5.84	0.55
FB 0265	Cranberry, raw	RAC	0.2	0.06	0.01	0.01	0.00	0.01	0.00	1.22	0.24	0.11	0.02	NC	-
FB 0275	Strawberry, raw	RAC	0.42	4.49	1.89	5.66	2.38	0.02	0.01	6.63	2.78	5.75	2.42	0.05	0.02
FT 0305	Table olives, raw (incl preserved)	RAC	0.465	2.00	0.93	2.48	1.15	0.01	0.00	1.21	0.56	1.64	0.76	0.27	0.13
FT 0336	Guava, raw	RAC	0.0335	0.01	0.00	NC	-	0.42	0.01	NC	-	NC	-	NC	-
FI 0326	Avocado, raw	RAC	0.05	2.65	0.13	0.87	0.04	0.46	0.02	1.64	0.08	1.30	0.07	0.96	0.05
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.02	25.76	0.52	23.65	0.47	23.83	0.48	24.37	0.49	19.43	0.39	101.55	2.03
FI 0345	Mango, raw (incl canned mango, incl mango juice)	RAC	0.03	1.80	0.05	0.63	0.02	10.05	0.30	1.07	0.03	3.52	0.11	16.44	0.49
FI 0350	Papaya, raw	RAC	0.065	0.31	0.02	0.18	0.01	1.50	0.10	0.51	0.03	0.54	0.04	1.08	0.07
FI 2540	Pitaya, raw (i.e dragon fruit or pitahaya)	RAC	0.034	NC	-	NC	-	0.08	0.00	NC	-	NC	-	NC	-
FI 0351	Passion fruit, raw	RAC	0.01	0.01	0.00	0.01	0.00	NC	-	NC	-	0.02	0.00	NC	-
-	Onions, dry, raw	RAC	0.015	19.69	0.30	29.83	0.45	24.64	0.37	31.35	0.47	9.72	0.15	12.59	0.19
VA 0384	Leek, raw	RAC	0.08	4.01	0.32	4.41	0.35	0.72	0.06	0.54	0.04	16.41	1.31	0.03	0.00
-	Onions, green, raw	RAC	2.8	1.55	4.34	0.74	2.07	1.05	2.94	3.74	10.47	0.94	2.63	6.45	18.06
VB 0040	Group of Brassica vegetables (excl Brassica leafy vegetables), raw	RAC	0.35	20.71	7.25	39.81	13.93	25.06	8.77	37.93	13.28	18.12	6.34	16.74	5.86
VC 0424	Cucumber, raw	RAC	0.04	6.72	0.27	11.03	0.44	32.10	1.28	15.10	0.60	4.05	0.16	9.57	0.38
VC 0425	Gherkin, raw	RAC	0.04	0.41	0.02	5.89	0.24	NC	-	0.06	0.00	0.37	0.01	2.07	0.08
VC 0431	Squash, Summer (Courgette, Marrow, Zucchini, Zucchini), raw	RAC	0.04	NC	-	NC	-	5.48	0.22	NC	-	NC	-	1.03	0.04
VC 0046	Melons, except watermelon, raw (Cantaloupe)	RAC	0.14	9.20	1.29	11.95	1.67	14.63	2.05	8.99	1.26	7.86	1.10	2.46	0.34
VC 0432	Watermelon, raw	RAC	0.01	4.60	0.05	9.82	0.10	68.50	0.69	13.19	0.13	1.99	0.02	14.56	0.15
VO 0448	Tomato, raw	RAC	0.1	32.13	3.21	51.27	5.13	34.92	3.49	73.37	7.34	15.15	1.52	8.88	0.89

Annex 3

DIFENOCONAZOLE (224)			International Estimated Daily Intake (IEDI)						ADI = 0 - 0.01 mg/kg bw						
Codex Code	Commodity description	Expr as	STM ^R mg/kg	Diets as g/person/day				Intake as ug/person/day							
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
-	Tomato, canned (& peeled)	PP	0.01	7.57	0.08	2.66	0.03	0.30	0.00	0.97	0.01	7.31	0.07	0.41	0.00
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.22	4.96	1.09	3.20	0.70	0.15	0.03	1.61	0.35	6.88	1.51	0.52	0.11
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.031	0.80	0.02	0.07	0.00	0.05	0.00	0.61	0.02	0.40	0.01	0.08	0.00
VO 0442	Okra, raw (i.e. Lady's Finger, Gombo)	RAC	0.14	NC	-	NC	-	0.04	0.01	0.17	0.02	NC	-	0.72	0.10
VO 0444	Peppers, chili, raw	RAC	0.24	5.57	1.34	14.00	3.36	8.25	1.98	5.77	1.38	6.44	1.55	2.53	0.61
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.14	0.82	0.11	1.53	0.21	10.85	1.52	4.59	0.64	1.84	0.26	2.00	0.28
VO 0440	Egg plant, raw (i.e. aubergine)	RAC	0.14	1.01	0.14	1.69	0.24	21.37	2.99	3.00	0.42	1.40	0.20	NC	-
VL 0483	Lettuce, leaf, raw	RAC	0.41	14.50	5.95	11.76	4.82	13.14	5.39	19.50	8.00	4.81	1.97	2.23	0.91
VP 0060	Group of Legume vegetables, raw	RAC	0.07	18.21	1.27	8.91	0.62	7.22	0.51	10.04	0.70	23.22	1.63	0.17	0.01
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	0.011	1.51	0.02	1.50	0.02	1.90	0.02	5.11	0.06	1.36	0.01	23.43	0.26
VD 0523	Broad bean, dry, raw (incl horse-bean, field bean) (Vicia faba)	RAC	0.011	0.02	0.00	0.01	0.00	1.16	0.01	0.40	0.00	NC	-	0.06	0.00
VD 0541	Soya bean, dry, raw (incl flour, incl paste, incl curd, incl sauce, excl oil)	RAC	0.01	0.47	0.00	0.77	0.01	9.12	0.09	8.05	0.08	0.04	0.00	6.06	0.06
OR 0541	Soya oil, refined	PP	0.08	19.06	1.52	21.06	1.68	5.94	0.48	33.78	2.70	40.05	3.20	13.39	1.07
-	Beans (dry) NES: including inter alia lablab or hyacinth bean (Dolichos spp.); jack or sword bean (Canavalia spp.); winged bean (Psophocarpus tetragonolobus); guar bean (Cyamopsis tetragonoloba); velvet bean (Stizolobium spp.); yam bean (Pachyrrhizus erosus)	RAC	0.028	0.01	0.00	NC	-	0.57	0.02	0.11	0.00	0.16	0.00	0.94	0.03
VD 0533	Lentil (dry) (Lens spp), raw	RAC	0.028	0.95	0.03	1.18	0.03	0.40	0.01	0.96	0.03	0.71	0.02	1.28	0.04
VD 0537	Pigeon pea (dry) (Cajanus spp), raw	RAC	0.028	NC	-	NC	-	0.20	0.01	NC	-	NC	-	NC	-
VR 0577	Carrots, raw	RAC	0.05	26.26	1.31	27.13	1.36	10.07	0.50	16.49	0.82	44.69	2.23	8.75	0.44
VR 0578	Celeriac, raw	RAC	0.12	2.97	0.36	1.79	0.21	NC	-	0.06	0.01	16.91	2.03	3.22	0.39
VR 0596	Sugar beet, raw (incl sugar)	RAC	0.02	0.01	0.00	NC	-	0.01	0.00	0.01	0.00	NC	-	NC	-
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	1.2	225.03	270.04	234.24	281.09	71.48	85.78	177.55	213.06	234.55	281.46	37.71	45.25
VS 0624	Celery	RAC	0.14	7.68	1.08	2.85	0.40	NC	-	3.34	0.47	16.83	2.36	4.04	0.57
VS 0621	Asparagus, raw	RAC	0.02	0.84	0.02	2.08	0.04	7.11	0.14	1.01	0.02	1.69	0.03	0.04	0.00
VS 0620	Artichoke globe, raw	RAC	0.51	0.98	0.50	3.65	1.86	0.07	0.04	1.67	0.85	0.26	0.13	NC	-
CM 0649 (GC 0649)	Rice, husked, dry (incl flour, incl oil, incl beverages, incl starch, excl polished)	REP	1.1	3.70	4.07	2.11	2.32	1.51	1.66	1.75	1.93	0.29	0.32	5.12	5.63
CM 1205	Rice polished, dry	PP	0.0086	13.38	0.12	10.80	0.09	262.08	2.25	57.16	0.49	12.83	0.11	62.78	0.54
GC 0447	Sweet corn on the cob, raw (incl frozen kernels, incl canned kernels)	RAC	0.01	11.43	0.11	3.71	0.04	0.74	0.01	13.63	0.14	3.07	0.03	1.50	0.02
TN 0085	Group of Tree nuts, raw (incl processed)	RAC	0.01	8.52	0.09	8.94	0.09	15.09	0.15	9.60	0.10	14.57	0.15	26.26	0.26

Annex 3

DIFENOCONAZOLE (224)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.01 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day		Intake as ug/person/day									
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
SO 0495	Rape seed, raw	RAC	0.03	NC	-	NC	-	0.01	0.00	NC	-	NC	-	NC	-
OR 0495	Rape seed oil, edible	PP	0.002	12.52	0.03	7.63	0.02	3.00	0.01	6.01	0.01	NC	-	NC	-
SO 0702	Sunflower seed, raw (incl oil)	RAC	0.01	23.40	0.23	29.33	0.29	1.24	0.01	13.85	0.14	6.48	0.06	6.91	0.07
OR 0691	Cotton seed oil, edible	PP	0.0014	1.68	0.00	0.66	0.00	1.13	0.00	1.18	0.00	0.89	0.00	0.37	0.00
SO 0697	Peanuts, nutmeat, raw (incl roasted, incl oil, incl butter)	RAC	0	5.63	0.00	2.75	0.00	9.58	0.00	5.82	0.00	13.71	0.00	1.84	0.00
SO 0305	Olives for oil production, raw	RAC	0.456	0.35	0.16	0.01	0.00	0.01	0.00	0.57	0.26	0.06	0.03	NC	-
-	Olive oil (virgin and residue oil)	PP	0.7	3.40	2.38	9.49	6.64	0.02	0.01	4.28	3.00	2.74	1.92	0.48	0.34
SB 0716	Coffee bean raw (incl roasted, incl instant coffee, incl substitutes)	RAC	0.01	10.90	0.11	12.44	0.12	0.77	0.01	9.48	0.09	22.07	0.22	8.15	0.08
HS 0784	Ginger, rhizome, raw incl dried	RAC	0.13	0.27	0.04	0.07	0.01	0.54	0.07	0.69	0.09	0.58	0.08	0.56	0.07
HS 0444	Peppers, chili, dried	PP	1.1	0.11	0.12	0.21	0.23	0.36	0.40	0.21	0.23	0.25	0.28	0.15	0.17
DT 1114	Tea, green or black, fermented and dried, (including concentrates)	RAC	4.85	2.91	14.11	1.73	8.39	1.14	5.53	1.85	8.97	2.29	11.11	0.74	3.59
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80 % as muscle	RAC	0.047	112.02	5.27	120.71	5.67	63.46	2.98	88.99	4.18	96.24	4.52	41.02	1.93
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20 % as fat	RAC	0.14	28.01	3.92	30.18	4.22	15.86	2.22	22.25	3.11	24.06	3.37	10.25	1.44
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.14	6.44	0.90	15.51	2.17	3.79	0.53	8.29	1.16	18.44	2.58	8.00	1.12
MO 0105	Edible offal (mammalian), raw	RAC	0.71	15.17	10.77	5.19	3.68	6.30	4.47	6.78	4.81	3.32	2.36	3.17	2.25
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.011	388.92	4.28	335.88	3.69	49.15	0.54	331.25	3.64	468.56	5.15	245.45	2.70
PM 0110	Poultry meat, raw (incl prepared)	RAC	0.0002	73.76	0.01	53.86	0.01	23.98	0.00	87.12	0.02	53.38	0.01	84.45	0.02
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.0002	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.71	0.00	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.0002	0.33	0.00	0.72	0.00	0.27	0.00	0.35	0.00	0.80	0.00	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0.011	25.84	0.28	29.53	0.32	28.05	0.31	33.19	0.37	36.44	0.40	8.89	0.10
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total intake (ug/person)=				437.6		459.2		187.0		371.5		460.7		186.2	
Bodyweight per region (kg bw) =				60		60		55		60		60		60	
ADI (ug/person)=				600		600		550		600		600		600	
%ADI=				72.9 %		76.5 %		34.0 %		61.9 %		76.8 %		31.0 %	
Rounded %ADI=				70 %		80 %		30 %		60 %		80 %		30 %	

Annex 3

DIFENOCONAZOLE (224)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.01 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day		Intake = daily intake: ug/person							
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
				FC 0001	Group of Citrus fruit, raw (incl kumquat commodities)	RAC	0.16	20.93	3.35	2.35	0.38	30.71	4.91
JF 0001	Group of Citrus fruit, juice	PP	0.002	0.11	0.00	0.29	0.00	13.55	0.03	0.14	0.00	0.33	0.00
FP 0009	Group of Pome fruits, raw (incl. apple juice, incl apple cider)	RAC	0.86	68.89	59.25	11.06	9.51	80.62	69.33	189.82	163.25	19.56	16.82
FS 0013	Subgroup of Cherries, raw	RAC	0.04	0.01	0.00	0.01	0.00	5.96	0.24	0.01	0.00	NC	-
FS 0014	Subgroup of Plums, raw (incl dried plums)	RAC	0.04	0.07	0.00	0.02	0.00	16.65	0.67	0.01	0.00	NC	-
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.15	0.02	0.00	0.01	0.00	10.76	1.61	0.01	0.00	NC	-
FB 0020	Blueberries, raw	RAC	1	NC	-	NC	-	0.20	0.20	NC	-	NC	-
FB 0269	Grapes, raw (incl must, excl dried, excl juice, excl wine)	RAC	0.52	0.14	0.07	0.36	0.19	15.33	7.97	0.01	0.01	0.28	0.15
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	1.1	0.01	0.01	0.13	0.14	1.06	1.17	0.01	0.01	0.03	0.03
JF 0269	Grape juice (from wine grapes)	PP	0.24	0.01	0.00	0.01	0.00	0.41	0.10	0.01	0.00	NC	-
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.094	0.31	0.03	0.23	0.02	60.43	5.68	0.52	0.05	31.91	3.00
FB 0265	Cranberry, raw	RAC	0.2	NC	-	NC	-	0.03	0.01	NC	-	NC	-
FB 0275	Strawberry, raw	RAC	0.42	0.01	0.00	0.01	0.00	3.35	1.41	0.01	0.00	0.01	0.00
FT 0305	Table olives, raw (incl preserved)	RAC	0.465	0.01	0.00	0.01	0.00	1.75	0.81	0.01	0.00	0.24	0.11
FT 0336	Guava, raw	RAC	0.0335	0.10	0.00	0.08	0.00	NC	-	0.14	0.00	3.11	0.10
FI 0326	Avocado, raw	RAC	0.05	1.12	0.06	0.01	0.00	0.84	0.04	0.01	0.00	6.60	0.33
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.02	44.80	0.90	118.17	2.36	25.25	0.51	454.49	9.09	310.23	6.20
FI 0345	Mango, raw (incl canned mango, incl mango juice)	RAC	0.03	12.25	0.37	6.83	0.20	0.76	0.02	0.01	0.00	20.12	0.60
FI 0350	Papaya, raw	RAC	0.065	6.47	0.42	0.25	0.02	0.19	0.01	0.01	0.00	26.42	1.72
FI 2540	Pitaya, raw (i.e dragon fruit or pitahaya)	RAC	0.034	0.01	0.00	0.01	0.00	NC	-	0.01	0.00	0.04	0.00
FI 0351	Passion fruit, raw	RAC	0.01	0.12	0.00	0.10	0.00	0.01	0.00	0.18	0.00	3.81	0.04
-	Onions, dry, raw	RAC	0.015	9.01	0.14	20.24	0.30	30.90	0.46	9.61	0.14	2.11	0.03
VA 0384	Leek, raw	RAC	0.08	0.02	0.00	1.44	0.12	1.22	0.10	0.01	0.00	NC	-
-	Onions, green, raw	RAC	2.8	1.43	4.00	0.05	0.14	0.20	0.56	NC	-	6.30	17.64
VB 0040	Group of Brassica vegetables (excl Brassica leafy vegetables), raw	RAC	0.35	5.46	1.91	4.28	1.50	58.72	20.55	0.02	0.01	NC	-
VC 0424	Cucumber, raw	RAC	0.04	0.68	0.03	1.81	0.07	10.40	0.42	0.01	0.00	0.04	0.00
VC 0425	Gherkin, raw	RAC	0.04	0.15	0.01	0.39	0.02	3.15	0.13	0.01	0.00	0.01	0.00
VC 0431	Squash, Summer (Courgette, Marrow, Zucchini, Zucchini), raw	RAC	0.04	0.09	0.00	1.01	0.04	NC	-	1.91	0.08	NC	-
VC 0046	Melons, except watermelon, raw (Cantaloupe)	RAC	0.14	0.19	0.03	0.10	0.01	4.98	0.70	0.01	0.00	NC	-
VC 0432	Watermelon, raw	RAC	0.01	4.29	0.04	0.30	0.00	28.70	0.29	0.01	0.00	NC	-
VO 0448	Tomato, raw	RAC	0.1	12.99	1.30	4.79	0.48	58.40	5.84	0.92	0.09	0.09	0.01
-	Tomato, canned (& peeled)	PP	0.01	0.07	0.00	0.08	0.00	2.42	0.02	0.07	0.00	NC	-
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.22	0.58	0.13	0.22	0.05	2.21	0.49	0.24	0.05	3.10	0.68

Annex 3

700

DIFENOCONAZOLE (224)		International Estimated Daily Intake (IEDI)						ADI = 0 - 0.01 mg/kg bw					
Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day				Intake = daily intake: ug/person					
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.031	0.05	0.00	0.01	0.00	0.42	0.01	0.01	0.00	0.02	0.00
VO 0442	Okra, raw (i.e. Lady's Finger, Gombo)	RAC	0.14	6.23	0.87	0.10	0.01	NC	-	NC	-	NC	-
VO 0444	Peppers, chili, raw	RAC	0.24	3.47	0.83	3.56	0.85	16.30	3.91	0.01	0.00	NC	-
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.14	5.49	0.77	10.57	1.48	8.84	1.24	0.91	0.13	NC	-
VO 0440	Egg plant, raw (i.e. aubergine)	RAC	0.14	1.31	0.18	8.26	1.16	3.95	0.55	0.01	0.00	NC	-
VL 0483	Lettuce, leaf, raw	RAC	0.41	0.29	0.12	0.03	0.01	6.71	2.75	0.01	0.00	NC	-
VP 0060	Group of Legume vegetables, raw	RAC	0.07	0.58	0.04	3.16	0.22	10.38	0.73	0.04	0.00	NC	-
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	0.011	7.11	0.08	2.33	0.03	3.76	0.04	44.70	0.49	3.27	0.04
VD 0523	Broad bean, dry, raw (incl horse-bean, field bean) (Vicia faba)	RAC	0.011	3.70	0.04	0.03	0.00	0.17	0.00	0.01	0.00	NC	-
VD 0541	Soya bean, dry, raw (incl flour, incl paste, incl curd, incl sauce, excl oil)	RAC	0.01	2.89	0.03	0.21	0.00	0.48	0.00	3.16	0.03	0.26	0.00
OR 0541	Soya oil, refined	PP	0.08	2.32	0.19	2.54	0.20	18.70	1.50	2.51	0.20	6.29	0.50
-	Beans (dry) NES: including inter alia lablab or hyacinth bean (Dolichos spp.); jack or sword bean (Canavalia spp.); winged bean (Psophocarpus tetragonolobus); guar bean (Cyamopsis tetragonoloba); velvet bean (Stizolobium spp.); yam bean (Pachyrrhizus erosus)	RAC	0.028	2.54	0.07	1.77	0.05	0.03	0.00	0.03	0.00	3.99	0.11
VD 0533	Lentil (dry) (Lens spp), raw	RAC	0.028	0.67	0.02	7.26	0.20	0.37	0.01	0.08	0.00	NC	-
VD 0537	Pigeon pea (dry) (Cajanus spp), raw	RAC	0.028	1.14	0.03	0.03	0.00	NC	-	5.53	0.15	NC	-
VR 0577	Carrots, raw	RAC	0.05	2.07	0.10	3.00	0.15	25.29	1.26	0.05	0.00	NC	-
VR 0578	Celeriac, raw	RAC	0.12	2.91	0.35	2.10	0.25	7.59	0.91	1.97	0.24	3.93	0.47
VR 0596	Sugar beet, raw (incl sugar)	RAC	0.02	3.93	0.08	1.68	0.03	NC	-	NC	-	36.12	0.72
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	1.2	23.96	28.75	13.56	16.27	213.41	256.09	104.35	125.22	8.56	10.27
VS 0624	Celery	RAC	0.14	3.66	0.51	2.65	0.37	4.84	0.68	2.47	0.35	4.94	0.69
VS 0621	Asparagus, raw	RAC	0.02	0.01	0.00	0.01	0.00	0.17	0.00	0.01	0.00	NC	-
VS 0620	Artichoke globe, raw	RAC	0.51	0.01	0.01	NC	-	0.08	0.04	0.01	0.01	NC	-
CM 0649 (GC 0649)	Rice, husked, dry (incl flour, incl oil, incl beverages, incl starch, excl polished)	REP	1.1	13.58	14.94	4.29	4.72	2.17	2.39	0.01	0.01	8.84	9.72
CM 1205	Rice polished, dry	PP	0.0086	30.20	0.26	218.34	1.88	12.77	0.11	15.24	0.13	51.35	0.44
GC 0447	Sweet corn on the cob, raw (incl frozen kernels, incl canned kernels)	RAC	0.01	3.63	0.04	20.50	0.21	8.78	0.09	0.02	0.00	0.17	0.00
TN 0085	Group of Tree nuts, raw (incl processed)	RAC	0.01	4.39	0.04	135.53	1.36	6.11	0.06	0.72	0.01	317.74	3.18
SO 0495	Rape seed, raw	RAC	0.03	NC	-	0.01	0.00	NC	-	NC	-	NC	-
OR 0495	Rape seed oil, edible	PP	0.002	0.07	0.00	0.03	0.00	4.62	0.01	0.03	0.00	NC	-
SO 0702	Sunflower seed, raw (incl oil)	RAC	0.01	0.94	0.01	0.22	0.00	32.01	0.32	12.12	0.12	0.48	0.00
OR 0691	Cotton seed oil, edible	PP	0.0014	1.28	0.00	0.05	0.00	0.45	0.00	0.42	0.00	0.15	0.00
SO 0697	Peanuts, nutmeat, raw (incl roasted, incl oil, incl	RAC	0	18.82	0.00	0.57	0.00	2.28	0.00	6.90	0.00	0.53	0.00

Annex 3

DIFENOCONAZOLE (224)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.01 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day		Intake = daily intake: ug/person							
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
	butter)												
SO 0305	Olives for oil production, raw	RAC	0.456	NC	-	NC	-	0.02	0.01	NC	-	NC	-
-	Olive oil (virgin and residue oil)	PP	0.7	0.03	0.02	0.02	0.01	2.14	1.50	0.01	0.01	0.10	0.07
SB 0716	Coffee bean raw (incl roasted, incl instant coffee, incl substitutes)	RAC	0.01	0.95	0.01	1.32	0.01	11.64	0.12	2.96	0.03	14.73	0.15
HS 0784	Ginger, rhizome, raw incl dried	RAC	0.13	0.75	0.10	0.68	0.09	0.06	0.01	0.02	0.00	0.01	0.00
HS 0444	Peppers, chili, dried	PP	1.1	0.58	0.64	1.27	1.40	1.21	1.33	0.12	0.13	NC	-
DT 1114	Tea, green or black, fermented and dried, (including concentrates)	RAC	4.85	0.53	2.57	5.25	25.46	0.86	4.17	0.56	2.72	0.88	4.27
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80 % as muscle	RAC	0.047	23.34	1.10	40.71	1.91	97.15	4.57	18.06	0.85	57.71	2.71
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20 % as fat	RAC	0.14	5.84	0.82	10.18	1.42	24.29	3.40	4.52	0.63	14.43	2.02
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.14	1.05	0.15	1.14	0.16	18.69	2.62	0.94	0.13	3.12	0.44
MO 0105	Edible offal (mammalian), raw	RAC	0.71	4.64	3.29	1.97	1.40	10.01	7.11	3.27	2.32	3.98	2.83
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.011	108.75	1.20	70.31	0.77	436.11	4.80	61.55	0.68	79.09	0.87
PM 0110	Poultry meat, raw (incl prepared)	RAC	0.0002	3.92	0.00	12.03	0.00	57.07	0.01	5.03	0.00	55.56	0.01
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.0002	NC	-	NC	-	0.32	0.00	NC	-	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.0002	0.10	0.00	0.70	0.00	0.97	0.00	0.10	0.00	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0.011	3.84	0.04	4.41	0.05	27.25	0.30	1.13	0.01	7.39	0.08
-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total intake (ug/person)=					130.4	77.7	426.9	307.4	87.8				
Bodyweight per region (kg bw) =					60	60	60	60	60				
ADI (ug/person)=					600	600	600	600	600				
%ADI=					21.7 %	13.0 %	71.2 %	51.2 %	14.6 %				
Rounded %ADI=					20 %	10 %	70 %	50 %	10 %				

Annex 3

702

DIMETHOATE (27)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.001 mg/kg bw

Codex Code	Commodity description	Expr as	STMTR mg/kg	Diets as g/person/day		Intake as ug/person/day									
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
				FC 0003	Subgroup of Mandarins, raw (incl mandarin juice)	RAC	0.081	6.18	0.50	3.66	0.30	0.25	0.02	6.82	0.55
FC 0004	Subgroup of Oranges, sweet, sour, raw	RAC	0.31	20.66	6.40	5.23	1.62	11.90	3.69	37.90	11.75	21.16	6.56	56.46	17.50
JF 0004	Subgroup of Oranges, juice (single strength, incl. concentrated)	PP	0.088	1.27	0.11	2.20	0.19	0.09	0.01	11.81	1.04	0.46	0.04	1.69	0.15
FI 0326	Avocado, raw	RAC	0.11	0.13	0.01	0.03	0.00	2.05	0.23	2.54	0.28	2.34	0.26	0.12	0.01
VB 0402	Brussels sprouts, raw	RAC	0.086	0.63	0.05	6.41	0.55	0.13	0.01	1.03	0.09	NC	-	2.35	0.20
VO 2045	Subgroup of tomatoes, raw (incl processed) (Lycopersicum spp. Only)	RAC	0.0175	51.75	0.91	81.80	1.43	16.99	0.30	102.02	1.79	26.32	0.46	214.77	3.76
VP 0061	Beans with pods (Phaseolus spp): (immature pods + succulent seeds)	RAC	0.175	0.68	0.12	NC	-	NC	-	0.39	0.07	0.22	0.04	0.49	0.09
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	0.175	2.39	0.42	1.61	0.28	10.47	1.83	1.84	0.32	12.90	2.26	7.44	1.30
VD 0523	Broad bean, dry, raw (incl horse-bean, field bean) (Vicia faba)	RAC	0.175	1.27	0.22	0.01	0.00	0.12	0.02	2.49	0.44	0.23	0.04	5.54	0.97
VD 0527	Cowpea, dry, raw (Vigna sinensis, Dolichos sinensis)	RAC	0.175	0.05	0.01	NC	-	1.74	0.30	0.01	0.00	0.01	0.00	0.07	0.01
-	Beans (dry) NES: including inter alia lablab or hyacinth bean (Dolichos spp.); jack or sword bean (Canavalia spp.); winged bean (Psophocarpus tetragonolobus); guar bean (Cyamopsis tetragonoloba); velvet bean (Stizolobium spp.); yam bean (Pachyrrhizus erosus)	RAC	0.175	1.70	0.30	0.01	0.00	3.00	0.53	1.80	0.32	1.64	0.29	1.33	0.23
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, excl germ, excl wholemeal bread, excl white flour products, excl white bread)	RAC	0.011	0.01	0.00	1.12	0.01	NC	-	0.03	0.00	0.56	0.01	NC	-
CF 1210	Wheat, germ	PP	0.025	NC	-	NC	-	0.01	0.00	0.01	0.00	0.14	0.00	0.01	0.00
CP 1212	Wheat, wholemeal bread	PP	0.006	0.01	0.00	0.01	0.00	0.01	0.00	0.01	0.00	0.03	0.00	0.01	0.00
CF 1211	Wheat, white flour (incl white flour products: starch, gluten, macaroni, pastry)	PP	0.0042	301.24	1.27	268.64	1.13	30.21	0.13	222.51	0.93	134.73	0.57	343.12	1.44
SO 0495	Rape seed, raw (incl oil)	RAC	0.0775	0.93	0.07	1.16	0.09	0.49	0.04	2.53	0.20	9.32	0.72	2.02	0.16
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80 % as muscle	RAC	0.0025	24.96	0.06	57.95	0.14	16.70	0.04	38.38	0.10	26.46	0.07	29.00	0.07
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20 % as fat	RAC	0.003	6.24	0.02	14.49	0.04	4.18	0.01	9.60	0.03	6.62	0.02	7.25	0.02
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.003	3.29	0.01	6.14	0.02	0.82	0.00	1.57	0.00	2.23	0.01	1.07	0.00
MO 0105	Edible offal (mammalian), raw	RAC	0.0025	4.79	0.01	9.68	0.02	2.97	0.01	5.49	0.01	3.84	0.01	5.03	0.01
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.0025	289.65	0.72	485.88	1.21	26.92	0.07	239.03	0.60	199.91	0.50	180.53	0.45

Annex 3

DIMETHOATE (27)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.001 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day		Intake as ug/person/day										
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake	
PM 0110	Poultry meat, raw (incl prepared)	RAC	0	14.63	0.00	29.76	0.00	8.04	0.00	129.68	0.00	25.04	0.00	35.66	0.00	
PF 0111	Poultry fat, raw (incl rendered)	RAC	0	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.10	0.00	0.10	0.00	
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0	0.12	0.00	0.12	0.00	0.11	0.00	5.37	0.00	0.24	0.00	0.10	0.00	
PE 0112	Eggs, raw, (incl dried)	RAC	0	7.84	0.00	23.08	0.00	2.88	0.00	14.89	0.00	9.81	0.00	14.83	0.00	
Total intake (ug/person)=					11.2		7.1		7.2		18.5		12.1		28.0	
Bodyweight per region (kg bw) =					60		60		60		60		60		60	
ADI (ug/person)=					60		60		60		60		60		60	
%ADI=					18.7 %		11.8 %		12.1 %		30.8 %		20.2 %		46.6 %	
Rounded %ADI=					20 %		10 %		10 %		30 %		20 %		50 %	

DIMETHOATE (27)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.001 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day		Intake as ug/person/day									
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
FC 0003	Subgroup of Mandarins, raw (incl mandarin juice)	RAC	0.081	12.42	1.01	14.99	1.21	16.08	1.30	10.78	0.87	9.94	0.81	NC	-
FC 0004	Subgroup of Oranges, sweet, sour, raw	RAC	0.31	15.68	4.86	24.00	7.44	6.80	2.11	29.09	9.02	15.39	4.77	160.47	49.75
JF 0004	Subgroup of Oranges, juice (single strength, incl. concentrated)	PP	0.088	33.31	2.93	1.78	0.16	0.28	0.02	18.97	1.67	14.01	1.23	13.36	1.18
FI 0326	Avocado, raw	RAC	0.11	2.65	0.29	0.87	0.10	0.46	0.05	1.64	0.18	1.30	0.14	0.96	0.11
VB 0402	Brussels sprouts, raw	RAC	0.086	2.24	0.19	2.67	0.23	6.23	0.54	0.32	0.03	4.19	0.36	2.58	0.22
VO 2045	Subgroup of tomatoes, raw (incl processed) (Lycopersicum spp. Only)	RAC	0.0175	64.74	1.13	68.31	1.20	36.05	0.63	82.09	1.44	54.50	0.95	11.69	0.20
VP 0061	Beans with pods (Phaseolus spp): (immature pods + succulent seeds)	RAC	0.175	5.07	0.89	0.83	0.15	0.17	0.03	3.70	0.65	NC	-	NC	-
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	0.175	1.51	0.26	1.50	0.26	1.90	0.33	5.11	0.89	1.36	0.24	23.43	4.10
VD 0523	Broad bean, dry, raw (incl horse-bean, field bean) (Vicia faba)	RAC	0.175	0.02	0.00	0.01	0.00	1.16	0.20	0.40	0.07	NC	-	0.06	0.01
VD 0527	Cowpea, dry, raw (Vigna sinensis, Dolichos sinensis)	RAC	0.175	NC	-	NC	-	0.16	0.03	0.01	0.00	NC	-	NC	-
-	Beans (dry) NES: including inter alia lablab or hyacinth bean (Dolichos spp.); jack or sword bean (Canavalia spp.); winged bean (Psophocarpus tetragonolobus); guar bean (Cyamopsis tetragonoloba); velvet bean (Stizolobium spp.); yam bean (Pachyrrhizus erosus)	RAC	0.175	0.01	0.00	NC	-	0.57	0.10	0.11	0.02	0.16	0.03	0.94	0.16
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, excl germ, excl wholemeal bread, excl white flour products, excl white bread)	RAC	0.011	NC	-	NC	-	0.02	0.00	0.83	0.01	NC	-	NC	-
CF 1210	Wheat, germ	PP	0.025	0.97	0.02	0.10	0.00	0.03	0.00	0.01	0.00	NC	-	0.04	0.00

Annex 3

DIMETHOATE (27)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.001 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day							
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
CP 1212	Wheat, wholemeal bread	PP	0.006	0.03	0.00	0.01	0.00	0.01	0.00	0.01	0.00	0.05	0.00	0.02	0.00
CF 1211	Wheat, white flour (incl white flour products: starch, gluten, macaroni, pastry)	PP	0.0042	198.08	0.83	193.03	0.81	106.24	0.45	185.09	0.78	168.67	0.71	131.59	0.55
SO 0495	Rape seed, raw (incl oil)	RAC	0.0775	32.68	2.53	19.91	1.54	7.83	0.61	15.69	1.22	NC	-	NC	-
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80 % as muscle	RAC	0.0025	112.02	0.28	120.71	0.30	63.46	0.16	88.99	0.22	96.24	0.24	41.02	0.10
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20 % as fat	RAC	0.003	28.01	0.08	30.18	0.09	15.86	0.05	22.25	0.07	24.06	0.07	10.25	0.03
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.003	6.44	0.02	15.51	0.05	3.79	0.01	8.29	0.02	18.44	0.06	8.00	0.02
MO 0105	Edible offal (mammalian), raw	RAC	0.0025	15.17	0.04	5.19	0.01	6.30	0.02	6.78	0.02	3.32	0.01	3.17	0.01
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.0025	388.92	0.97	335.88	0.84	49.15	0.12	331.25	0.83	468.56	1.17	245.45	0.61
PM 0110	Poultry meat, raw (incl prepared)	RAC	0	73.76	0.00	53.86	0.00	23.98	0.00	87.12	0.00	53.38	0.00	84.45	0.00
PF 0111	Poultry fat, raw (incl rendered)	RAC	0	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.71	0.00	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0	0.33	0.00	0.72	0.00	0.27	0.00	0.35	0.00	0.80	0.00	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0	25.84	0.00	29.53	0.00	28.05	0.00	33.19	0.00	36.44	0.00	8.89	0.00

Total intake (ug/person)=	16.4	14.4	6.8	18.0	10.8	57.1
Bodyweight per region (kg bw) =	60	60	55	60	60	60
ADI (ug/person)=	60	60	55	60	60	60
%ADI=	27.3 %	24.0 %	12.3 %	30.0 %	18.0 %	95.1 %
Rounded %ADI=	30 %	20 %	10 %	30 %	20 %	100 %

DIMETHOATE (27)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.001 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day				Intake = daily intake: ug/person							
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake		
FC 0003	Subgroup of Mandarins, raw (incl mandarin juice)	RAC	0.081	0.16	0.01	0.27	0.02	9.06	0.73	0.01	0.00	0.02	0.00		
FC 0004	Subgroup of Oranges, sweet, sour, raw	RAC	0.31	1.18	0.37	1.11	0.34	14.28	4.43	0.05	0.02	1.08	0.33		
JF 0004	Subgroup of Oranges, juice (single strength, incl. concentrated)	PP	0.088	0.08	0.01	0.26	0.02	12.61	1.11	0.14	0.01	0.33	0.03		
FI 0326	Avocado, raw	RAC	0.11	1.12	0.12	0.01	0.00	0.84	0.09	0.01	0.00	6.60	0.73		
VB 0402	Brussels sprouts, raw	RAC	0.086	0.88	0.08	0.69	0.06	2.89	0.25	0.01	0.00	NC	-		
VO 2045	Subgroup of tomatoes, raw (incl processed) (Lycopersicum spp. Only)	RAC	0.0175	15.50	0.27	5.78	0.10	71.52	1.25	2.00	0.04	12.50	0.22		
VP 0061	Beans with pods (Phaseolus spp): (immature pods + succulent seeds)	RAC	0.175	NC	-	NC	-	NC	-	NC	-	NC	-		
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	0.175	7.11	1.24	2.33	0.41	3.76	0.66	44.70	7.82	3.27	0.57		

Annex 3

DIMETHOATE (27)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.001 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day		Intake = daily intake: ug/person							
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
VD 0523	Broad bean, dry, raw (incl horse-bean, field bean) (Vicia faba)	RAC	0.175	3.70	0.65	0.03	0.01	0.17	0.03	0.01	0.00	NC	-
VD 0527	Cowpea, dry, raw (Vigna sinensis, Dolichos sinensis)	RAC	0.175	12.77	2.23	0.99	0.17	0.01	0.00	4.33	0.76	NC	-
-	Beans (dry) NES: including inter alia lablab or hyacinth bean (Dolichos spp.); jack or sword bean (Canavalia spp.); winged bean (Psophocarpus tetragonolobus); guar bean (Cyamopsis tetragonoloba); velvet bean (Stizolobium spp.); yam bean (Pachyrrhizus erosus)	RAC	0.175	2.54	0.44	1.77	0.31	0.03	0.01	0.03	0.01	3.99	0.70
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, excl germ, excl wholemeal bread, excl white flour products, excl white bread)	RAC	0.011	0.01	0.00	NC	-	NC	-	NC	-	0.97	0.01
CF 1210	Wheat, germ	PP	0.025	0.04	0.00	0.01	0.00	0.01	0.00	0.01	0.00	NC	-
CP 1212	Wheat, wholemeal bread	PP	0.006	0.01	0.00	0.01	0.00	0.03	0.00	0.01	0.00	0.01	0.00
CF 1211	Wheat, white flour (incl white flour products: starch, gluten, macaroni, pastry)	PP	0.0042	44.78	0.19	86.96	0.37	214.05	0.90	20.31	0.09	103.60	0.44
SO 0495	Rape seed, raw (incl oil)	RAC	0.0775	0.19	0.01	0.07	0.01	12.07	0.94	0.08	0.01	NC	-
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80 % as muscle	RAC	0.0025	23.34	0.06	40.71	0.10	97.15	0.24	18.06	0.05	57.71	0.14
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20 % as fat	RAC	0.003	5.84	0.02	10.18	0.03	24.29	0.07	4.52	0.01	14.43	0.04
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.003	1.05	0.00	1.14	0.00	18.69	0.06	0.94	0.00	3.12	0.01
MO 0105	Edible offal (mammalian), raw	RAC	0.0025	4.64	0.01	1.97	0.00	10.01	0.03	3.27	0.01	3.98	0.01
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.0025	108.75	0.27	70.31	0.18	436.11	1.09	61.55	0.15	79.09	0.20
PM 0110	Poultry meat, raw (incl prepared)	RAC	0	3.92	0.00	12.03	0.00	57.07	0.00	5.03	0.00	55.56	0.00
PF 0111	Poultry fat, raw (incl rendered)	RAC	0	NC	-	NC	-	0.32	0.00	NC	-	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0	0.10	0.00	0.70	0.00	0.97	0.00	0.10	0.00	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0	3.84	0.00	4.41	0.00	27.25	0.00	1.13	0.00	7.39	0.00

Total intake (ug/person)=	6.0	2.1	11.9	9.0	3.4
Bodyweight per region (kg bw) =	60	60	60	60	60
ADI (ug/person)=	60	60	60	60	60
%ADI=	10.0 %	3.6 %	19.8 %	14.9 %	5.7 %
Rounded %ADI=	10 %	4 %	20 %	10 %	6 %

Annex 3

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EMAMECTIN BENZOATE (247)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.0005 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day							
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
FP 0009	Group of Pomefruits, raw	RAC	0.004	19.24	0.08	33.89	0.14	3.34	0.01	25.53	0.10	7.59	0.03	56.76	0.23
FP 0226	Apple, raw (incl juice, excl cider)	RAC	0.0028	13.83	0.04	30.65	0.09	0.61	0.00	22.89	0.06	6.76	0.02	55.39	0.16
-	Peaches and nectarines, raw	RAC	0.0095	2.87	0.03	2.21	0.02	0.15	0.00	5.94	0.06	1.47	0.01	15.66	0.15
FB 0269	Grapes, raw (incl must, incl dried, incl juice, incl wine)	RAC	0.0025	16.25	0.04	28.96	0.07	2.87	0.01	24.22	0.06	9.33	0.02	68.64	0.17
VB 0042	Subgroup of Flowerhead Brassica, raw	RAC	0.002	2.54	0.01	0.49	0.00	0.01	0.00	3.57	0.01	7.79	0.02	3.12	0.01
VC 0045	Group of Fruiting vegetables, cucurbits, raw	RAC	0.001	53.14	0.05	86.21	0.09	6.28	0.01	92.76	0.09	15.64	0.02	155.30	0.16
VO 0050	Group of Fruiting vegetables other than cucurbits, raw, (incl processed commodities, excl dried chilli peppers)	RAC	0.003	67.79	0.20	99.85	0.30	31.70	0.10	125.86	0.38	55.22	0.17	262.82	0.79
VL 0483	Lettuce, leaf, raw	RAC	0.2	0.53	0.11	0.36	0.07	0.16	0.03	6.21	1.24	1.90	0.38	6.05	1.21
VL 0502	Spinach, raw	RAC	0.006	0.74	0.00	0.22	0.00	0.02	0.00	0.91	0.01	0.04	0.00	2.92	0.02
VL 0054	Subgroup of Leaves of Brassicaceae, raw	RAC	0.01	2.63	0.03	9.27	0.09	1.86	0.02	5.82	0.06	19.53	0.20	4.90	0.05
VP 0061	Beans with pods (Phaseolus spp): (immature pods + succulent seeds)	RAC	0.001	0.68	0.00	NC	-	NC	-	0.39	0.00	0.22	0.00	0.49	0.00
VD 0541	Soya bean, dry, raw (incl paste, incl curd, incl oil, incl sauce)	RAC	0	72.79	0.00	59.05	0.00	20.55	0.00	74.20	0.00	61.12	0.00	73.24	0.00
TN 0085	Group of Tree nuts raw, excl coconut commodities	RAC	0	2.33	0.00	2.07	0.00	0.39	0.00	3.75	0.00	0.93	0.00	6.38	0.00
SO 0495	Rape seed, raw (incl oil)	RAC	0	0.93	0.00	1.16	0.00	0.49	0.00	2.53	0.00	9.32	0.00	2.02	0.00
SO 0691	Cotton seed, raw (incl oil)	RAC	0.002	20.53	0.04	9.80	0.02	6.42	0.01	4.73	0.01	7.14	0.01	18.68	0.04
OR 0691	Cotton seed oil, edible	PP	0.00078	3.22	0.00	1.54	0.00	1.01	0.00	0.74	0.00	1.12	0.00	2.93	0.00
HH 0722	Basil leaves, raw (incl dried)	RAC	0.0045	0.14	0.00	0.26	0.00	0.16	0.00	0.38	0.00	NC	-	0.19	0.00
HS 0444	Peppers, chili, dried	PP	0.03	0.42	0.01	0.53	0.02	0.84	0.03	0.50	0.02	0.95	0.03	0.37	0.01
DT 1114	Tea, green or black, fermented and dried	RAC	0.009	2.28	0.02	1.92	0.02	0.46	0.00	2.40	0.02	1.29	0.01	3.04	0.03
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80 % as muscle	RAC	0.002	24.96	0.05	57.95	0.12	16.70	0.03	38.38	0.08	26.46	0.05	29.00	0.06
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20 % as fat	RAC	0.002	6.24	0.01	14.49	0.03	4.18	0.01	9.60	0.02	6.62	0.01	7.25	0.01
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.002	3.29	0.01	6.14	0.01	0.82	0.00	1.57	0.00	2.23	0.00	1.07	0.00
MO 0105	Edible offal (mammalian), raw	RAC	0.0071	4.79	0.03	9.68	0.07	2.97	0.02	5.49	0.04	3.84	0.03	5.03	0.04
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.0005	289.65	0.14	485.88	0.24	26.92	0.01	239.03	0.12	199.91	0.10	180.53	0.09
PM 0110	Poultry meat, raw (incl prepared)	RAC	0	14.63	0.00	29.76	0.00	8.04	0.00	129.68	0.00	25.04	0.00	35.66	0.00
PF 0111	Poultry fat, raw (incl rendered)	RAC	0	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.10	0.00	0.10	0.00
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0	0.12	0.00	0.12	0.00	0.11	0.00	5.37	0.00	0.24	0.00	0.10	0.00

Annex 3

EMAMECTIN BENZOATE (247)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.0005 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day		Intake as ug/person/day									
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
PE 0112	Eggs, raw, (incl dried)	RAC	0	7.84	0.00	23.08	0.00	2.88	0.00	14.89	0.00	9.81	0.00	14.83	0.00
WD 0120	Diadromous fish (e.g. salmon, trout)	RAC	0.03666667	1.99	0.07	1.93	0.07	6.26	0.23	3.41	0.13	6.59	0.24	8.73	0.32
Total intake (ug/person)=				1.0		1.5		0.5		2.5		1.4		3.5	
Bodyweight per region (kg bw) =				60		60		60		60		60		60	
ADI (ug/person)=				30		30		30		30		30		30	
%ADI=				3.3 %		4.9 %		1.8 %		8.3 %		4.5 %		11.8 %	
Rounded %ADI=				3 %		5 %		2 %		8 %		5 %		10 %	

EMAMECTIN BENZOATE (247)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.0005 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day		Intake as ug/person/day									
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
FP 0009	Group of Pomefruits, raw	RAC	0.004	37.39	0.15	58.13	0.23	37.64	0.15	44.80	0.18	62.17	0.25	6.47	0.03
FP 0226	Apple, raw (incl juice, excl cider)	RAC	0.0028	47.74	0.13	65.54	0.18	21.78	0.06	44.69	0.13	92.94	0.26	6.51	0.02
-	Peaches and nectarines, raw	RAC	0.0095	8.76	0.08	12.98	0.12	8.23	0.08	10.09	0.10	3.64	0.03	0.04	0.00
FB 0269	Grapes, raw (incl must, incl dried, incl juice, incl wine)	RAC	0.0025	142.23	0.36	105.77	0.26	7.87	0.02	52.44	0.13	109.22	0.27	10.96	0.03
VB 0042	Subgroup of Flowerhead Brassica, raw	RAC	0.002	9.50	0.02	6.77	0.01	NC	-	3.21	0.01	9.36	0.02	0.75	0.00
VC 0045	Group of Fruiting vegetables, cucurbits, raw	RAC	0.001	27.81	0.03	41.93	0.04	123.30	0.12	49.47	0.05	15.95	0.02	35.99	0.04
VO 0050	Group of Fruiting vegetables other than cucurbits, raw, (incl processed commodities, excl dried chilli peppers)	RAC	0.003	72.14	0.22	85.53	0.26	76.55	0.23	95.63	0.29	64.19	0.19	16.94	0.05
VL 0483	Lettuce, leaf, raw	RAC	0.2	14.50	2.90	11.76	2.35	13.14	2.63	19.50	3.90	4.81	0.96	2.23	0.45
VL 0502	Spinach, raw	RAC	0.006	2.20	0.01	1.76	0.01	13.38	0.08	2.94	0.02	5.53	0.03	0.02	0.00
VL 0054	Subgroup of Leaves of Brassicaceae, raw	RAC	0.01	0.10	0.00	NC	-	26.78	0.27	5.00	0.05	0.58	0.01	5.68	0.06
VP 0061	Beans with pods (Phaseolus spp): (immature pods + succulent seeds)	RAC	0.001	5.07	0.01	0.83	0.00	0.17	0.00	3.70	0.00	NC	-	NC	-
VD 0541	Soya bean, dry, raw (incl paste, incl curd, incl oil, incl sauce)	RAC	0	106.33	0.00	117.78	0.00	42.12	0.00	195.70	0.00	222.52	0.00	80.47	0.00
TN 0085	Group of Tree nuts raw, excl coconut commodities	RAC	0	4.38	0.00	6.21	0.00	1.94	0.00	3.76	0.00	7.65	0.00	4.01	0.00
SO 0495	Rape seed, raw (incl oil)	RAC	0	32.68	0.00	19.91	0.00	7.83	0.00	15.69	0.00	NC	-	NC	-
SO 0691	Cotton seed, raw (incl oil)	RAC	0.002	10.71	0.02	4.23	0.01	7.19	0.01	7.54	0.02	5.66	0.01	2.38	0.00
OR 0691	Cotton seed oil, edible	PP	0.00078	1.68	0.00	0.66	0.00	1.13	0.00	1.18	0.00	0.89	0.00	0.37	0.00
HH 0722	Basil leaves, raw (incl dried)	RAC	0.0045	0.52	0.00	0.05	0.00	3.23	0.01	0.18	0.00	0.12	0.00	0.27	0.00
HS 0444	Peppers, chili, dried	PP	0.03	0.11	0.00	0.21	0.01	0.36	0.01	0.21	0.01	0.25	0.01	0.15	0.00
DT 1114	Tea, green or black, fermented and dried	RAC	0.009	2.71	0.02	0.82	0.01	1.14	0.01	1.59	0.01	1.82	0.02	0.53	0.00

Annex 3

EMAMECTIN BENZOATE (247)				International Estimated Daily Intake (IEDI)						ADI = 0 - 0.0005 mg/kg bw					
Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day							
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80 % as muscle	RAC	0.002	112.02	0.22	120.71	0.24	63.46	0.13	88.99	0.18	96.24	0.19	41.02	0.08
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20 % as fat	RAC	0.002	28.01	0.06	30.18	0.06	15.86	0.03	22.25	0.04	24.06	0.05	10.25	0.02
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.002	6.44	0.01	15.51	0.03	3.79	0.01	8.29	0.02	18.44	0.04	8.00	0.02
MO 0105	Edible offal (mammalian), raw	RAC	0.0071	15.17	0.11	5.19	0.04	6.30	0.04	6.78	0.05	3.32	0.02	3.17	0.02
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.0005	388.92	0.19	335.88	0.17	49.15	0.02	331.25	0.17	468.56	0.23	245.45	0.12
PM 0110	Poultry meat, raw (incl prepared)	RAC	0	73.76	0.00	53.86	0.00	23.98	0.00	87.12	0.00	53.38	0.00	84.45	0.00
PF 0111	Poultry fat, raw (incl rendered)	RAC	0	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.71	0.00	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0	0.33	0.00	0.72	0.00	0.27	0.00	0.35	0.00	0.80	0.00	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0	25.84	0.00	29.53	0.00	28.05	0.00	33.19	0.00	36.44	0.00	8.89	0.00
WD 0120	Diadromous fish (e.g. salmon, trout)	RAC	0.03666667	4.88	0.18	2.35	0.09	27.05	0.99	3.03	0.11	0.84	0.03	2.71	0.10
Total intake (ug/person)=				4.7		4.1		4.9		5.4		2.6		1.0	
Bodyweight per region (kg bw) =				60		60		55		60		60		60	
ADI (ug/person)=				30		30		27.5		30		30		30	
%ADI=				15.8 %		13.8 %		17.9 %		18.2 %		8.8 %		3.5 %	
Rounded %ADI=				20 %		10 %		20 %		20 %		9 %		3 %	

EMAMECTIN BENZOATE (247)				International Estimated Daily Intake (IEDI)						ADI = 0 - 0.0005 mg/kg bw					
Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day				Intake = daily intake: ug/person							
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake		
FP 0009	Group of Pomefruits, raw	RAC	0.004	2.39	0.01	10.93	0.04	69.47	0.28	1.59	0.01	19.56	0.08		
FP 0226	Apple, raw (incl juice, excl cider)	RAC	0.0028	0.25	0.00	2.18	0.01	64.28	0.18	0.15	0.00	1.38	0.00		
-	Peaches and nectarines, raw	RAC	0.0095	0.02	0.00	0.01	0.00	7.47	0.07	0.01	0.00	NC	-		
FB 0269	Grapes, raw (incl must, incl dried, incl juice, incl wine)	RAC	0.0025	0.60	0.00	1.26	0.00	103.25	0.26	0.74	0.00	44.23	0.11		
VB 0042	Subgroup of Flowerhead Brassica, raw	RAC	0.002	0.02	0.00	0.02	0.00	4.86	0.01	0.01	0.00	NC	-		
VC 0045	Group of Fruiting vegetables, cucurbits, raw	RAC	0.001	5.96	0.01	9.74	0.01	51.82	0.05	13.61	0.01	0.05	0.00		
VO 0050	Group of Fruiting vegetables other than cucurbits, raw, (incl processed commodities, excl dried chilli peppers)	RAC	0.003	32.01	0.10	28.27	0.08	100.61	0.30	2.91	0.01	12.50	0.04		
VL 0483	Lettuce, leaf, raw	RAC	0.2	0.29	0.06	0.03	0.01	6.71	1.34	0.01	0.00	NC	-		
VL 0502	Spinach, raw	RAC	0.006	0.17	0.00	0.01	0.00	0.81	0.00	0.01	0.00	NC	-		
VL 0054	Subgroup of Leaves of Brassicaceae, raw	RAC	0.01	3.58	0.04	2.64	0.03	NC	-	1.83	0.02	3.65	0.04		

Annex 3

EMAMECTIN BENZOATE (247)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.0005 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day		Intake = daily intake: ug/person							
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
VP 0061	Beans with pods (Phaseolus spp): (immature pods + succulent seeds)	RAC	0.001	NC	-	NC	-	NC	-	NC	-	NC	-
VD 0541	Soya bean, dry, raw (incl paste, incl curd, incl oil, incl sauce)	RAC	0	15.80	0.00	14.29	0.00	104.36	0.00	17.11	0.00	35.20	0.00
TN 0085	Group of Tree nuts raw, excl coconut commodities	RAC	0	1.61	0.00	1.16	0.00	3.31	0.00	0.02	0.00	0.07	0.00
SO 0495	Rape seed, raw (incl oil)	RAC	0	0.19	0.00	0.07	0.00	12.07	0.00	0.08	0.00	NC	-
SO 0691	Cotton seed, raw (incl oil)	RAC	0.002	8.14	0.02	0.32	0.00	2.84	0.01	2.69	0.01	0.97	0.00
OR 0691	Cotton seed oil, edible	PP	0.00078	1.28	0.00	0.05	0.00	0.45	0.00	0.42	0.00	0.15	0.00
HH 0722	Basil leaves, raw (incl dried)	RAC	0.0045	0.25	0.00	0.18	0.00	0.13	0.00	0.17	0.00	0.33	0.00
HS 0444	Peppers, chili, dried	PP	0.03	0.58	0.02	1.27	0.04	1.21	0.04	0.12	0.00	NC	-
DT 1114	Tea, green or black, fermented and dried	RAC	0.009	0.53	0.00	5.25	0.05	0.63	0.01	0.56	0.01	0.82	0.01
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80 % as muscle	RAC	0.002	23.34	0.05	40.71	0.08	97.15	0.19	18.06	0.04	57.71	0.12
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20 % as fat	RAC	0.002	5.84	0.01	10.18	0.02	24.29	0.05	4.52	0.01	14.43	0.03
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.002	1.05	0.00	1.14	0.00	18.69	0.04	0.94	0.00	3.12	0.01
MO 0105	Edible offal (mammalian), raw	RAC	0.0071	4.64	0.03	1.97	0.01	10.01	0.07	3.27	0.02	3.98	0.03
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.0005	108.75	0.05	70.31	0.04	436.11	0.22	61.55	0.03	79.09	0.04
PM 0110	Poultry meat, raw (incl prepared)	RAC	0	3.92	0.00	12.03	0.00	57.07	0.00	5.03	0.00	55.56	0.00
PF 0111	Poultry fat, raw (incl rendered)	RAC	0	NC	-	NC	-	0.32	0.00	NC	-	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0	0.10	0.00	0.70	0.00	0.97	0.00	0.10	0.00	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0	3.84	0.00	4.41	0.00	27.25	0.00	1.13	0.00	7.39	0.00
WD 0120	Diadromous fish (e.g. salmon, trout)	RAC	0.03666667	3.43	0.13	4.13	0.15	1.77	0.06	18.43	0.68	0.10	0.00

Total intake (ug/person)=	0.5	0.6	3.2	0.8	0.5
Bodyweight per region (kg bw) =	60	60	60	60	60
ADI (ug/person)=	30	30	30	30	30
%ADI=	1.7 %	1.9 %	10.6 %	2.8 %	1.7 %
Rounded %ADI=	2 %	2 %	10 %	3 %	2 %

Annex 3

FAMOXADONE (208)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.006 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day								
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake	
FB 2005	Subgroup of Caneberries, raw	RAC	1.1	0.42	0.46	1.05	1.16	0.01	0.01	0.02	0.02	0.02	0.02	1.24	1.36	
FB 0269	Grapes, raw (incl must, excl dried, excl juice, excl wine)	RAC	0.54	13.02	7.03	9.25	5.00	0.03	0.02	16.91	9.13	3.70	2.00	54.44	29.40	
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	1.03	0.51	0.53	0.51	0.53	0.01	0.01	1.27	1.31	0.12	0.12	2.07	2.13	
JF 0269	Grape juice (from wine grapes)	PP	0.005	0.14	0.00	0.29	0.00	0.05	0.00	0.30	0.00	0.24	0.00	0.05	0.00	
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.005	0.67	0.00	12.53	0.06	2.01	0.01	1.21	0.01	3.53	0.02	4.01	0.02	
VA 2031	Subgroup of bulb onions	RAC	0.02	31.65	0.63	43.28	0.87	3.68	0.07	38.48	0.77	20.46	0.41	47.29	0.95	
VC 2039	Subgroup of Cucumbers and Squashes, raw	RAC	0.17	10.52	1.79	39.36	6.69	2.07	0.35	25.74	4.38	2.80	0.48	44.83	7.62	
VO 0448	Tomato, raw (incl canned, excl juice, excl paste)	RAC	0.1	42.04	4.20	76.13	7.61	10.69	1.07	84.59	8.46	24.92	2.49	203.27	20.33	
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.13	2.34	0.30	1.33	0.17	1.57	0.20	4.24	0.55	0.34	0.04	2.83	0.37	
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.022	0.29	0.01	0.29	0.01	0.01	0.00	0.38	0.01	0.05	0.00	0.14	0.00	
VO 0444	Peppers, chili, raw	RAC	0.47	3.99	1.88	7.30	3.43	2.93	1.38	5.62	2.64	NC	-	17.44	8.20	
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.47	4.49	2.11	6.44	3.03	7.21	3.39	5.68	2.67	9.52	4.47	8.92	4.19	
GC 0654	Wheat, raw (incl meslin)	RAC	0.02	0.01	0.00	1.12	0.02	NC	-	0.01	0.00	0.56	0.01	NC	-	
-	Wheat, bulgur	PP	0.02	NC	-	NC	-	NC	-	0.03	0.00	NC	-	NC	-	
CF 1210	Wheat, germ	PP	0.02	NC	-	NC	-	0.01	0.00	0.01	0.00	0.14	0.00	0.01	0.00	
CP 1212	Wheat, wholemeal bread	PP	0.02	0.01	0.00	0.01	0.00	0.01	0.00	0.01	0.00	0.03	0.00	0.01	0.00	
CP 1211	Wheat, white bread	PP	0.01	0.25	0.00	0.63	0.01	0.12	0.00	0.43	0.00	1.39	0.01	0.22	0.00	
-	Wheat, Fermented Beverages (Korean jakju and takju)	PP	0.02	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-	
CF 1211	Wheat, white flour (incl white flour products: starch, gluten, macaroni, pastry)	PP	0.01	301.24	3.01	268.64	2.69	30.21	0.30	222.51	2.23	134.73	1.35	343.12	3.43	
GC 0640	Barley, raw (incl malt extract, incl pot&pearled, incl flour & grits, incl malt, excl beer)	RAC	0.02	18.98	0.38	13.35	0.27	0.42	0.01	0.67	0.01	2.30	0.05	0.86	0.02	
-	Barley beer	PP	0.008	4.87	0.04	93.78	0.75	24.28	0.19	12.76	0.10	39.28	0.31	18.15	0.15	
HS 0444	Peppers, chili, dried	PP	4.7	0.42	1.97	0.53	2.49	0.84	3.95	0.50	2.35	0.95	4.47	0.37	1.74	
DH 1100	Hops, dry	RAC	13	0.01	0.13	0.04	0.52	0.01	0.13	0.01	0.13	NC	-	0.01	0.13	
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80 % as muscle	RAC	0.005	24.96	0.12	57.95	0.29	16.70	0.08	38.38	0.19	26.46	0.13	29.00	0.15	
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20 % as fat	RAC	0.07	6.24	0.44	14.49	1.01	4.18	0.29	9.60	0.67	6.62	0.46	7.25	0.51	
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.07	3.29	0.23	6.14	0.43	0.82	0.06	1.57	0.11	2.23	0.16	1.07	0.07	
MO 0105	Edible offal (mammalian), raw	RAC	0.046	4.79	0.22	9.68	0.45	2.97	0.14	5.49	0.25	3.84	0.18	5.03	0.23	
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.009	289.65	2.61	485.88	4.37	26.92	0.24	239.03	2.15	199.91	1.80	180.53	1.62	
Total intake (ug/person)=				28.1				41.8		11.9		38.1		19.0		82.6

Annex 3

FAMOXADONE (208)				International Estimated Daily Intake (IEDI)						ADI = 0 - 0.006 mg/kg bw							
Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day									
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake		
	Bodyweight per region (kg bw) =				60		60		60		60		60		60		60
	ADI (ug/person)=				360		360		360		360		360		360		360
	%ADI=				7.8 %		11.6 %		3.3 %		10.6 %		5.3 %		22.9 %		
	Rounded %ADI=				8 %		10 %		3 %		10 %		5 %		20 %		

FAMOXADONE (208)				International Estimated Daily Intake (IEDI)						ADI = 0 - 0.006 mg/kg bw							
Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day									
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake		
FB 2005	Subgroup of Caneberries, raw	RAC	1.1	0.56	0.62	1.43	1.57	0.14	0.15	1.23	1.35	1.14	1.25	0.01	0.01		
FB 0269	Grapes, raw (incl must, excl dried, excl juice, excl wine)	RAC	0.54	6.48	3.50	11.31	6.11	5.21	2.81	9.50	5.13	4.66	2.52	0.78	0.42		
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	1.03	3.09	3.18	1.51	1.56	0.03	0.03	1.38	1.42	4.26	4.39	0.42	0.43		
JF 0269	Grape juice (from wine grapes)	PP	0.005	0.56	0.00	1.96	0.01	0.02	0.00	2.24	0.01	2.27	0.01	0.34	0.00		
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.005	88.93	0.44	62.41	0.31	1.84	0.01	25.07	0.13	61.17	0.31	5.84	0.03		
VA 2031	Subgroup of bulb onions	RAC	0.02	20.67	0.41	31.32	0.63	37.52	0.75	35.08	0.70	11.77	0.24	13.74	0.27		
VC 2039	Subgroup of Cucumbers and Squashes, raw	RAC	0.17	7.14	1.21	16.92	2.88	37.58	6.39	15.16	2.58	4.42	0.75	12.67	2.15		
VO 0448	Tomato, raw (incl canned, excl juice, excl paste)	RAC	0.1	43.88	4.39	55.41	5.54	35.38	3.54	74.88	7.49	26.50	2.65	9.51	0.95		
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.13	4.96	0.64	3.20	0.42	0.15	0.02	1.61	0.21	6.88	0.89	0.52	0.07		
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.022	0.80	0.02	0.07	0.00	0.05	0.00	0.61	0.01	0.40	0.01	0.08	0.00		
VO 0444	Peppers, chili, raw	RAC	0.47	5.57	2.62	14.00	6.58	8.25	3.88	5.77	2.71	6.44	3.03	2.53	1.19		
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.47	0.82	0.39	1.53	0.72	10.85	5.10	4.59	2.16	1.84	0.86	2.00	0.94		
GC 0654	Wheat, raw (incl meslin)	RAC	0.02	NC	-	NC	-	NC	-	0.01	0.00	NC	-	NC	-		
-	Wheat, bulgur	PP	0.02	NC	-	NC	-	0.01	0.00	NC	-	NC	-	NC	-		
CF 1210	Wheat, germ	PP	0.02	0.97	0.02	0.10	0.00	0.03	0.00	0.01	0.00	NC	-	0.04	0.00		
CP 1212	Wheat, wholemeal bread	PP	0.02	0.03	0.00	0.01	0.00	0.01	0.00	0.01	0.00	0.05	0.00	0.02	0.00		
CP 1211	Wheat, white bread	PP	0.01	1.30	0.01	0.46	0.00	0.06	0.00	0.22	0.00	2.44	0.02	0.77	0.01		
-	Wheat, Fermented Beverages (Korean jakju and takju)	PP	0.02	NC	-	NC	-	NC	-	4.36	0.09	NC	-	NC	-		
CF 1211	Wheat, white flour (incl white flour products: starch, gluten, macaroni, pastry)	PP	0.01	198.08	1.98	193.03	1.93	106.24	1.06	185.09	1.85	168.67	1.69	131.59	1.32		
GC 0640	Barley, raw (incl malt extract, incl pot&pearled, incl flour & grits, incl malt, excl beer)	RAC	0.02	1.94	0.04	4.15	0.08	0.66	0.01	2.50	0.05	2.14	0.04	3.52	0.07		
-	Barley beer	PP	0.008	180.21	1.44	259.46	2.08	45.91	0.37	172.36	1.38	234.42	1.88	65.30	0.52		
HS 0444	Peppers, chili, dried	PP	4.7	0.11	0.52	0.21	0.99	0.36	1.69	0.21	0.99	0.25	1.18	0.15	0.71		

Annex 3

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FAMOxadONE (208)		International Estimated Daily Intake (IEDI)						ADI = 0 - 0.006 mg/kg bw																			
Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day																			
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake												
DH 1100	Hops, dry	RAC	13	NC	-	NC	-	0.02	0.26	0.02	0.26	NC	-	NC	-												
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80 % as muscle	RAC	0.005	112.02	0.56	120.71	0.60	63.46	0.32	88.99	0.44	96.24	0.48	41.02	0.21												
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20 % as fat	RAC	0.07	28.01	1.96	30.18	2.11	15.86	1.11	22.25	1.56	24.06	1.68	10.25	0.72												
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.07	6.44	0.45	15.51	1.09	3.79	0.27	8.29	0.58	18.44	1.29	8.00	0.56												
MO 0105	Edible offal (mammalian), raw	RAC	0.046	15.17	0.70	5.19	0.24	6.30	0.29	6.78	0.31	3.32	0.15	3.17	0.15												
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.009	388.92	3.50	335.88	3.02	49.15	0.44	331.25	2.98	468.56	4.22	245.45	2.21												
Total intake (ug/person)=				28.6				38.5				28.5				34.4				29.5				12.9			
Bodyweight per region (kg bw) =				60				60				55				60				60							
ADI (ug/person)=				360				360				330				360				360							
%ADI=				7.9 %				10.7 %				8.6 %				9.6 %				8.2 %				3.6 %			
Rounded %ADI=				8 %				10 %				9 %				10 %				8 %				4 %			

FAMOxadONE (208)		International Estimated Daily Intake (IEDI)						ADI = 0 - 0.006 mg/kg bw							
Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day				Intake = daily intake: ug/person							
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake		
FB 2005	Subgroup of Caneberries, raw	RAC	1.1	0.01	0.01	7.30	8.03	2.29	2.52	0.01	0.01	NC	-		
FB 0269	Grapes, raw (incl must, excl dried, excl juice, excl wine)	RAC	0.54	0.14	0.08	0.36	0.19	15.33	8.28	0.01	0.01	0.28	0.15		
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	1.03	0.01	0.01	0.13	0.13	1.06	1.09	0.01	0.01	0.03	0.03		
JF 0269	Grape juice (from wine grapes)	PP	0.005	0.01	0.00	0.01	0.00	0.41	0.00	0.01	0.00	NC	-		
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.005	0.31	0.00	0.23	0.00	60.43	0.30	0.52	0.00	31.91	0.16		
VA 2031	Subgroup of bulb onions	RAC	0.02	9.83	0.20	22.30	0.45	34.69	0.69	9.65	0.19	2.39	0.05		
VC 2039	Subgroup of Cucumbers and Squashes, raw	RAC	0.17	0.92	0.16	3.20	0.54	13.55	2.30	1.91	0.32	0.05	0.01		
VO 0448	Tomato, raw (incl canned, excl juice, excl paste)	RAC	0.1	13.10	1.31	4.90	0.49	62.16	6.22	1.04	0.10	0.09	0.01		
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.13	0.58	0.08	0.22	0.03	2.21	0.29	0.24	0.03	3.10	0.40		
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.022	0.05	0.00	0.01	0.00	0.42	0.01	0.01	0.00	0.02	0.00		
VO 0444	Peppers, chili, raw	RAC	0.47	3.47	1.63	3.56	1.67	16.30	7.66	0.01	0.00	NC	-		
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.47	5.49	2.58	10.57	4.97	8.84	4.15	0.91	0.43	NC	-		
GC 0654	Wheat, raw (incl meslin)	RAC	0.02	NC	-	NC	-	NC	-	NC	-	0.97	0.02		

Annex 3

FAMOXADONE (208)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.006 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day		Intake = daily intake: ug/person							
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
-	Wheat, bulgur	PP	0.02	0.01	0.00	NC	-	NC	-	NC	-	NC	-
CF 1210	Wheat, germ	PP	0.02	0.04	0.00	0.01	0.00	0.01	0.00	0.01	0.00	NC	-
CP 1212	Wheat, wholemeal bread	PP	0.02	0.01	0.00	0.01	0.00	0.03	0.00	0.01	0.00	0.01	0.00
CP 1211	Wheat, white bread	PP	0.01	0.43	0.00	0.41	0.00	1.56	0.02	0.11	0.00	0.07	0.00
-	Wheat, Fermented Beverages (Korean jakju and takju)	PP	0.02	NC	-	NC	-	NC	-	NC	-	NC	-
CF 1211	Wheat, white flour (incl white flour products: starch, gluten, macaroni, pastry)	PP	0.01	44.78	0.45	86.96	0.87	214.05	2.14	20.31	0.20	103.60	1.04
GC 0640	Barley, raw (incl malt extract, incl pot&pearled, incl flour & grits, incl malt, excl beer)	RAC	0.02	8.50	0.17	0.17	0.00	3.92	0.08	0.02	0.00	6.34	0.13
-	Barley beer	PP	0.008	16.25	0.13	11.36	0.09	225.21	1.80	19.49	0.16	52.17	0.42
HS 0444	Peppers, chili, dried	PP	4.7	0.58	2.73	1.27	5.97	1.21	5.69	0.12	0.56	NC	-
DH 1100	Hops, dry	RAC	13	NC	-	NC	-	0.04	0.52	NC	-	NC	-
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80 % as muscle	RAC	0.005	23.34	0.12	40.71	0.20	97.15	0.49	18.06	0.09	57.71	0.29
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20 % as fat	RAC	0.07	5.84	0.41	10.18	0.71	24.29	1.70	4.52	0.32	14.43	1.01
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.07	1.05	0.07	1.14	0.08	18.69	1.31	0.94	0.07	3.12	0.22
MO 0105	Edible offal (mammalian), raw	RAC	0.046	4.64	0.21	1.97	0.09	10.01	0.46	3.27	0.15	3.98	0.18
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.009	108.75	0.98	70.31	0.63	436.11	3.92	61.55	0.55	79.09	0.71
-	-	-	-	-	-	-	-	-	-	-	-	-	-

Total intake (ug/person)=	11.3	25.2	51.6	3.2	4.8
Bodyweight per region (kg bw) =	60	60	60	60	60
ADI (ug/person)=	360	360	360	360	360
%ADI=	3.1 %	7.0 %	14.3 %	0.9 %	1.3 %
Rounded %ADI=	3 %	7 %	10 %	1 %	1 %

Annex 3

FENAZAQUIN (297)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.05 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day							
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
				FC 0002	Subgroup of Lemons and limes, raw (excl kumquat commodities)	RAC	0.01	2.42	0.02	2.15	0.02	0.43	0.00	10.74	0.11
FC 0303	Kumquats, raw (incl juice)	RAC	0.08	2.36	0.19	0.27	0.02	3.19	0.26	14.44	1.16	1.66	0.13	1.71	0.14
-	Lemon, juice (single strength, incl. concentrated)	PP	0.0008	0.01	0.00	0.01	0.00	0.11	0.00	0.09	0.00	0.18	0.00	0.17	0.00
FC 0003	Subgroup of Mandarins, raw	RAC	0.01	6.18	0.06	3.66	0.04	0.25	0.00	6.82	0.07	3.49	0.03	19.38	0.19
-	Subgroup of Mandarins, juice	PP	0.008	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
FC 0004	Subgroup of Oranges, sweet, sour, raw	RAC	0.01	20.66	0.21	5.23	0.05	11.90	0.12	37.90	0.38	21.16	0.21	56.46	0.56
JF 0004	Subgroup of Oranges, juice (single strength, incl. concentrated)	PP	0.00125	1.27	0.00	2.20	0.00	0.09	0.00	11.81	0.01	0.46	0.00	1.69	0.00
FC 0005	Subgroup of Pummelo and grapefruits, raw	RAC	0.01	0.64	0.01	0.35	0.00	0.93	0.01	6.10	0.06	1.01	0.01	1.36	0.01
JF 0203	Grapefruits, juice (single strength, incl. concentrated)	PP	0.0007	0.01	0.00	0.16	0.00	0.02	0.00	1.97	0.00	0.12	0.00	0.77	0.00
FP 0226	Apple, raw (incl juice, incl cider)	RAC	0.08	13.94	1.12	30.81	2.46	15.14	1.21	23.10	1.85	6.86	0.55	55.48	4.44
FS 0013	Subgroup of Cherries, raw	RAC	0.56	0.92	0.52	9.15	5.12	0.01	0.01	0.61	0.34	0.06	0.03	6.64	3.72
FS 0014	Subgroup of Plums, raw	RAC	0.145	2.40	0.35	8.60	1.25	0.06	0.01	2.52	0.37	0.58	0.08	4.16	0.60
DF 0014	Plums, dried (prunes)	PP	0.7	0.09	0.06	0.06	0.04	0.01	0.01	0.18	0.13	0.04	0.03	0.06	0.04
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.38	8.01	3.04	5.87	2.23	0.18	0.07	8.19	3.11	1.64	0.62	22.46	8.53
FB 2005	Subgroup of Caneberries, raw	RAC	0.18	0.42	0.08	1.05	0.19	0.01	0.00	0.02	0.00	0.02	0.00	1.24	0.22
FB 2006	Subgroup of Bush berries, raw (including processed)	RAC	0.235	0.53	0.12	1.31	0.31	0.40	0.09	1.66	0.39	0.01	0.00	0.99	0.23
FB 0269	Grapes, raw (incl must, excl dried, excl juice, excl wine)	RAC	0.19	13.02	2.47	9.25	1.76	0.03	0.01	16.91	3.21	3.70	0.70	54.44	10.34
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	0.42	0.51	0.21	0.51	0.21	0.01	0.00	1.27	0.53	0.12	0.05	2.07	0.87
JF 0269	Grape juice (from wine grapes)	PP	0.027	0.14	0.00	0.29	0.01	0.05	0.00	0.30	0.01	0.24	0.01	0.05	0.00
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.0038	0.67	0.00	12.53	0.05	2.01	0.01	1.21	0.00	3.53	0.01	4.01	0.02
FB 2009	Subgroup of Low growing berries, raw	RAC	0.49	0.71	0.35	2.02	0.99	0.04	0.02	1.39	0.68	0.37	0.18	2.53	1.24
FI 0326	Avocado, raw	RAC	0.01	0.13	0.00	0.03	0.00	2.05	0.02	2.54	0.03	2.34	0.02	0.12	0.00
VC 0045	Group of Fruiting vegetables, cucurbits, raw	RAC	0.06	53.14	3.19	86.21	5.17	6.28	0.38	92.76	5.57	15.64	0.94	155.30	9.32
VO 0448	Tomato, raw (incl juice, incl canned, excl paste)	RAC	0.052	42.41	2.21	76.50	3.98	10.69	0.56	85.07	4.42	24.98	1.30	203.44	10.58
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.047	2.34	0.11	1.33	0.06	1.57	0.07	4.24	0.20	0.34	0.02	2.83	0.13
VO 0051	Subgroup of peppers, raw (incl dried sweet peppers, excl dried chilipeppers), excl okra	RAC	0.079	8.48	0.67	13.74	1.09	10.13	0.80	11.29	0.89	9.52	0.75	26.36	2.08
VO 2046	Subgroup of eggplants	RAC	0.079	5.58	0.44	4.31	0.34	0.89	0.07	9.31	0.74	13.64	1.08	20.12	1.59
TN 0085	Group of Tree nuts raw, excl coconut commodities	RAC	0.01	2.33	0.02	2.07	0.02	0.39	0.00	3.75	0.04	0.93	0.01	6.38	0.06
HS 0444	Peppers, chili, dried	PP	0.79	0.42	0.33	0.53	0.42	0.84	0.66	0.50	0.40	0.95	0.75	0.37	0.29
DH 1100	Hops, dry	RAC	9	0.01	0.09	0.04	0.36	0.01	0.09	0.01	0.09	NC	-	0.01	0.09

Annex 3

FENAZAQUIN (297)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.05 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day																			
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake												
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80 % as muscle	RAC	0	24.96	0.00	57.95	0.00	16.70	0.00	38.38	0.00	26.46	0.00	29.00	0.00												
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20 % as fat	RAC	0.00065	6.24	0.00	14.49	0.01	4.18	0.00	9.60	0.01	6.62	0.00	7.25	0.00												
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.00065	3.29	0.00	6.14	0.00	0.82	0.00	1.57	0.00	2.23	0.00	1.07	0.00												
MO 0105	Edible offal (mammalian), raw	RAC	0.00056	4.79	0.00	9.68	0.01	2.97	0.00	5.49	0.00	3.84	0.00	5.03	0.00												
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0	289.65	0.00	485.88	0.00	26.92	0.00	239.03	0.00	199.91	0.00	180.53	0.00												
Total intake (ug/person)=				15.9				26.2				4.5				24.8				7.6				55.5			
Bodyweight per region (kg bw) =				60				60				60				60				60							
ADI (ug/person)=				3000				3000				3000				3000				3000							
%ADI=				0.5 %				0.9 %				0.1 %				0.8 %				0.3 %				1.8 %			
Rounded %ADI=				1 %				1 %				0 %				1 %				0 %				2 %			

FENAZAQUIN (297)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.05 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day							
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
FC 0002	Subgroup of Lemons and limes, raw (excl kumquat commodities)	RAC	0.01	3.78	0.04	8.84	0.09	0.92	0.01	6.71	0.07	4.09	0.04	4.57	0.05
FC 0303	Kumquats, raw (incl juice)	RAC	0.08	4.67	0.37	5.86	0.47	1.96	0.16	1.45	0.12	17.05	1.36	1.37	0.11
-	Lemon, juice (single strength, incl. concentrated)	PP	0.0008	0.60	0.00	0.36	0.00	0.01	0.00	1.49	0.00	0.43	0.00	0.24	0.00
FC 0003	Subgroup of Mandarins, raw	RAC	0.01	12.34	0.12	14.99	0.15	16.08	0.16	10.76	0.11	9.94	0.10	NC	-
-	Subgroup of Mandarins, juice	PP	0.008	0.04	0.00	NC	-	0.01	0.00	0.01	0.00	NC	-	NC	-
FC 0004	Subgroup of Oranges, sweet, sour, raw	RAC	0.01	15.68	0.16	24.00	0.24	6.80	0.07	29.09	0.29	15.39	0.15	160.47	1.60
JF 0004	Subgroup of Oranges, juice (single strength, incl. concentrated)	PP	0.00125	33.31	0.04	1.78	0.00	0.28	0.00	18.97	0.02	14.01	0.02	13.36	0.02
FC 0005	Subgroup of Pummelo and grapefruits, raw	RAC	0.01	2.19	0.02	1.24	0.01	0.60	0.01	3.44	0.03	4.60	0.05	299.96	3.00
JF 0203	Grapefruits, juice (single strength, incl. concentrated)	PP	0.0007	2.89	0.00	1.61	0.00	0.02	0.00	1.15	0.00	7.39	0.01	33.07	0.02
FP 0226	Apple, raw (incl juice, incl cider)	RAC	0.08	61.44	4.92	72.81	5.82	26.84	2.15	45.18	3.61	93.28	7.46	7.78	0.62
FS 0013	Subgroup of Cherries, raw	RAC	0.56	1.40	0.78	4.21	2.36	0.04	0.02	2.93	1.64	1.50	0.84	NC	-
FS 0014	Subgroup of Plums, raw	RAC	0.145	3.75	0.54	3.33	0.48	5.94	0.86	2.64	0.38	2.50	0.36	0.06	0.01
DF 0014	Plums, dried (prunes)	PP	0.7	0.61	0.43	0.35	0.25	0.05	0.04	0.35	0.25	0.49	0.34	0.13	0.09
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.38	13.03	4.95	16.29	6.19	8.29	3.15	12.95	4.92	5.35	2.03	0.04	0.02
FB 2005	Subgroup of Caneberries, raw	RAC	0.18	0.56	0.10	1.43	0.26	0.14	0.03	1.23	0.22	1.14	0.21	0.01	0.00

Annex 3

FENAZAQUIN (297)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.05 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day		Intake = daily intake: ug/person							
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
				FC 0002	Subgroup of Lemons and limes, raw (excl kumquat commodities)	RAC	0.01	0.61	0.01	0.73	0.01	4.01	0.04
FC 0303	Kumquats, raw (incl juice)	RAC	0.08	18.35	1.47	0.23	0.02	1.78	0.14	0.08	0.01	3.35	0.27
-	Lemon, juice (single strength, incl. concentrated)	PP	0.0008	0.01	0.00	0.01	0.00	0.16	0.00	0.01	0.00	NC	-
FC 0003	Subgroup of Mandarins, raw	RAC	0.01	0.16	0.00	0.27	0.00	9.06	0.09	0.01	0.00	0.02	0.00
-	Subgroup of Mandarins, juice	PP	0.008	0.01	0.00	NC	-	NC	-	NC	-	NC	-
FC 0004	Subgroup of Oranges, sweet, sour, raw	RAC	0.01	1.18	0.01	1.11	0.01	14.28	0.14	0.05	0.00	1.08	0.01
JF 0004	Subgroup of Oranges, juice (single strength, incl. concentrated)	PP	0.00125	0.08	0.00	0.26	0.00	12.61	0.02	0.14	0.00	0.33	0.00
FC 0005	Subgroup of Pummelo and grapefruits, raw	RAC	0.01	0.63	0.01	0.01	0.00	1.58	0.02	0.01	0.00	NC	-
JF 0203	Grapefruits, juice (single strength, incl. concentrated)	PP	0.0007	0.03	0.00	0.02	0.00	0.78	0.00	0.01	0.00	NC	-
FP 0226	Apple, raw (incl juice, incl cider)	RAC	0.08	66.71	5.34	2.19	0.18	65.63	5.25	188.34	15.07	1.38	0.11
FS 0013	Subgroup of Cherries, raw	RAC	0.56	0.01	0.01	0.01	0.01	5.96	3.34	0.01	0.01	NC	-
FS 0014	Subgroup of Plums, raw	RAC	0.145	0.07	0.01	0.01	0.00	15.56	2.26	0.01	0.00	NC	-
DF 0014	Plums, dried (prunes)	PP	0.7	0.01	0.01	0.01	0.01	0.37	0.26	0.01	0.01	NC	-
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.38	0.02	0.01	0.01	0.00	10.76	4.09	0.01	0.00	NC	-
FB 2005	Subgroup of Caneberries, raw	RAC	0.18	0.01	0.00	7.30	1.31	2.29	0.41	0.01	0.00	NC	-
FB 2006	Subgroup of Bush berries, raw (including processed)	RAC	0.235	0.82	0.19	4.05	0.95	5.94	1.40	0.43	0.10	2.66	0.63
FB 0269	Grapes, raw (incl must, excl dried, excl juice, excl wine)	RAC	0.19	0.14	0.03	0.36	0.07	15.33	2.91	0.01	0.00	0.28	0.05
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	0.42	0.01	0.00	0.13	0.05	1.06	0.45	0.01	0.00	0.03	0.01
JF 0269	Grape juice (from wine grapes)	PP	0.027	0.01	0.00	0.01	0.00	0.41	0.01	0.01	0.00	NC	-
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.0038	0.31	0.00	0.23	0.00	60.43	0.23	0.52	0.00	31.91	0.12
FB 2009	Subgroup of Low growing berries, raw	RAC	0.49	0.01	0.00	0.01	0.00	3.37	1.65	0.01	0.00	0.01	0.00
FI 0326	Avocado, raw	RAC	0.01	1.12	0.01	0.01	0.00	0.84	0.01	0.01	0.00	6.60	0.07
VC 0045	Group of Fruiting vegetables, cucurbits, raw	RAC	0.06	5.96	0.36	9.74	0.58	51.82	3.11	13.61	0.82	0.05	0.00
VO 0448	Tomato, raw (incl juice, incl canned, excl paste)	RAC	0.052	13.17	0.68	4.92	0.26	62.69	3.26	1.04	0.05	0.11	0.01
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.047	0.58	0.03	0.22	0.01	2.21	0.10	0.24	0.01	3.10	0.15
VO 0051	Subgroup of peppers, raw (incl dried sweet peppers, excl dried chilipeppers), excl okra	RAC	0.079	8.97	0.71	14.13	1.12	25.14	1.99	0.91	0.07	NC	-
VO 2046	Subgroup of eggplants	RAC	0.079	1.31	0.10	8.26	0.65	3.95	0.31	0.01	0.00	NC	-
TN 0085	Group of Tree nuts raw, excl coconut commodities	RAC	0.01	1.61	0.02	1.16	0.01	3.31	0.03	0.02	0.00	0.07	0.00
HS 0444	Peppers, chili, dried	PP	0.79	0.58	0.46	1.27	1.00	1.21	0.96	0.12	0.09	NC	-
DH 1100	Hops, dry	RAC	9	NC	-	NC	-	0.04	0.36	NC	-	NC	-
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80 % as muscle	RAC	0	23.34	0.00	40.71	0.00	97.15	0.00	18.06	0.00	57.71	0.00
MM 0095	MEAT FROM MAMMALS other than marine	RAC	0.00065	5.84	0.00	10.18	0.01	24.29	0.02	4.52	0.00	14.43	0.01

Annex 3

FENAZAQUIN (297)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.05 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day		Intake = daily intake: ug/person							
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
	mammals, raw (incl prepared meat) - 20 % as fat												
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.00065	1.05	0.00	1.14	0.00	18.69	0.01	0.94	0.00	3.12	0.00
MO 0105	Edible offal (mammalian), raw	RAC	0.00056	4.64	0.00	1.97	0.00	10.01	0.01	3.27	0.00	3.98	0.00
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0	108.75	0.00	70.31	0.00	436.11	0.00	61.55	0.00	79.09	0.00
-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total intake (ug/person)=					9.5		6.3		32.9		16.3		1.4
Bodyweight per region (kg bw) =					60		60		60		60		60
ADI (ug/person)=					3000		3000		3000		3000		3000
%ADI=					0.3 %		0.2 %		1.1 %		0.5 %		0.0 %
Rounded %ADI=					0 %		0 %		1 %		1 %		0 %

Annex 3

FLUAZAINDOLIZINE (327)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.3 mg/kg bw

Codex Code	Commodity description	Expr as	STM ^R mg/kg	Diets as g/person/day				Intake as ug/person/day							
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
				FB 0275	Strawberry, raw	RAC	0.053	0.70	0.04	2.01	0.11	0.04	0.00	1.36	0.07
VA 0035	Group of Bulb vegetables, raw	RAC	0.0674	34.29	2.31	46.37	3.13	4.73	0.32	41.36	2.79	21.08	1.42	52.54	3.54
VB 0040	Group of Brassica vegetables (excl Brassica leafy vegetables), raw	RAC	0.04335	6.43	0.28	40.26	1.75	0.80	0.03	9.94	0.43	12.07	0.52	17.73	0.77
VC 2039	Subgroup of Cucumbers and Squashes, raw	RAC	0.1092	10.52	1.15	39.36	4.30	2.07	0.23	25.74	2.81	2.80	0.31	44.83	4.90
VC 2040	Subgroup of Melons, Pumpkins and Winter squashes	RAC	0.1348	42.62	5.75	46.85	6.32	4.21	0.57	67.02	9.03	12.84	1.73	110.47	14.89
VO 2045	Subgroup of tomatoes, raw (incl processed) (Lycopersicum spp. Only)	RAC	0.0748	51.75	3.87	81.80	6.12	16.99	1.27	102.02	7.63	26.32	1.97	214.77	16.06
VO 0448	Tomato, raw	RAC	0.0748	41.73	3.12	75.65	5.66	10.66	0.80	82.87	6.20	24.75	1.85	200.93	15.03
-	Tomato, canned (& peeled)	PP	0.0711	0.20	0.01	0.31	0.02	0.02	0.00	1.11	0.08	0.11	0.01	1.50	0.11
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.2476	2.34	0.58	1.33	0.33	1.57	0.39	4.24	1.05	0.34	0.08	2.83	0.70
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.059	0.29	0.02	0.29	0.02	0.01	0.00	0.38	0.02	0.05	0.00	0.14	0.01
VO 0051	Subgroup of peppers, raw (incl dried sweet peppers, excl dried chilipeppers), excl okra	RAC	0.074	8.48	0.63	13.74	1.02	10.13	0.75	11.29	0.84	9.52	0.70	26.36	1.95
VO 2046	Subgroup of eggplants	RAC	0.0748	5.58	0.42	4.31	0.32	0.89	0.07	9.31	0.70	13.64	1.02	20.12	1.50
VL 0053	Group of Leafy vegetables, raw	RAC	0.388	8.47	3.29	22.36	8.68	7.74	3.00	25.51	9.90	45.77	17.76	21.22	8.23
VP 0060	Group of Legume vegetables, raw	RAC	0.0709	7.73	0.55	1.53	0.11	0.51	0.04	2.95	0.21	5.08	0.36	12.86	0.91
VD 0070	Group of Pulses, raw (incl processed)	RAC	0.0656	87.29	5.73	64.04	4.20	37.15	2.44	89.82	5.89	91.02	5.97	98.20	6.44
OR 0541	Soya oil, refined	PP	0	12.99	0.00	10.43	0.00	3.63	0.00	13.10	0.00	10.70	0.00	13.10	0.00
VR 0574	Beetroot, raw	RAC	0.1935	3.42	0.66	6.06	1.17	3.75	0.73	9.11	1.76	NC	-	4.39	0.85
VR 0575	Burdock, greater or edible, raw	RAC	0.1935	0.03	0.01	0.06	0.01	0.04	0.01	0.09	0.02	NC	-	0.04	0.01
VR 0577	Carrots, raw	RAC	0.1485	9.51	1.41	30.78	4.57	0.37	0.05	8.75	1.30	2.80	0.42	6.10	0.91
VR 0578	Celeriac, raw	RAC	0.1935	1.70	0.33	3.01	0.58	1.87	0.36	4.53	0.88	NC	-	2.19	0.42
VR 0469	Chicory, roots, raw	RAC	0.1935	0.01	0.00	0.20	0.04	0.01	0.00	0.01	0.00	0.02	0.00	0.01	0.00
VR 0583	Horseradish, raw	RAC	0.1935	0.51	0.10	0.91	0.18	0.56	0.11	1.37	0.27	NC	-	0.66	0.13
VR 0587	Parsley turnip-rooted, raw	RAC	0.1935	0.32	0.06	0.57	0.11	0.35	0.07	0.85	0.16	NC	-	0.41	0.08
VR 0588	Parsnip, raw	RAC	0.1935	0.59	0.11	1.05	0.20	0.65	0.13	1.58	0.31	NC	-	0.76	0.15
VR 0494	Radish roots, raw	RAC	0.1935	2.31	0.45	4.09	0.79	2.53	0.49	6.15	1.19	5.88	1.14	2.97	0.57
VR 0591	Japanese radish, raw (i.e. Chinese radish, Daikon)	RAC	0.1935	1.90	0.37	3.36	0.65	2.08	0.40	5.06	0.98	NC	-	2.44	0.47
VR 0498	Salsify, raw (i.e. Oysterplant)	RAC	0.1935	0.21	0.04	0.37	0.07	0.23	0.04	0.55	0.11	NC	-	0.27	0.05
VR 0596	Sugar beet, raw (incl sugar)	RAC	0.1935	0.13	0.03	NC	-	0.08	0.02	0.66	0.13	0.47	0.09	88.94	17.21
VR 0596	Sugar beet, raw	RAC	0.1935	NC	-	NC	-	NC	-	NC	-	0.01	0.00	NC	-
-	Sugar beet, sugar	PP	0.1935	0.02	0.00	NC	-	0.01	0.00	0.09	0.02	0.07	0.01	12.63	2.44
VR 0497	Swede, raw (i.e. Rutabaga)	RAC	0.1935	1.58	0.31	2.80	0.54	1.74	0.34	4.21	0.81	NC	-	2.03	0.39
VR 0506	Turnip, garden, raw	RAC	0.1935	2.50	0.48	4.44	0.86	2.75	0.53	6.67	1.29	0.14	0.03	3.22	0.62
VR 2071	Subgroup of tuberous and corm vegetables, raw	RAC	0.1231	63.11	7.77	316.33	38.94	651.91	80.25	72.06	8.87	84.88	10.45	132.70	16.34

Annex 3

720

FLUAZAINDOLIZINE (327)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.3 mg/kg bw

Codex Code	Commodity description	Expr as	STM mg/kg	Diets as g/person/day				Intake as ug/person/day							
				G01		G02		G03		G04		G05		G06	
				diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
	(incl processed)														
VS 0078	Group of Stalk and stem vegetables, raw	RAC	0.0674	6.03	0.41	9.47	0.64	5.86	0.39	14.55	0.98	2.61	0.18	8.27	0.56
GC 0080	Group of Cereal grains, raw, (incl processed) (incl sweet corn)	RAC	0.0676	484.43	32.75	464.63	31.41	262.36	17.74	486.81	32.91	469.62	31.75	614.04	41.51
GC 0654	Wheat, raw (incl meslin)	RAC	0.0676	0.01	0.00	1.12	0.08	NC	-	0.01	0.00	0.56	0.04	NC	-
-	Wheat, bulgur	PP	0.0676	NC	-	NC	-	NC	-	0.03	0.00	NC	-	NC	-
CP 1212	Wheat, wholemeal bread	PP	0.0676	0.01	0.00	0.01	0.00	0.01	0.00	0.01	0.00	0.03	0.00	0.01	0.00
-	Wheat, Fermented Beverages (Korean jakju and takju)	PP	0.0676	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
CF 1211	Wheat, white flour (incl white flour products: starch, gluten, macaroni, pastry)	PP	0	301.24	0.00	268.64	0.00	30.21	0.00	222.51	0.00	134.73	0.00	343.12	0.00
GC 2087	Subgroup of barley, similar grains, and pseudocereals with husks, raw (including processed)	RAC	0.0676	19.96	1.35	38.62	2.61	5.13	0.35	4.81	0.33	10.80	0.73	4.44	0.30
GC 0641	Buckwheat, raw (incl flour)	RAC	0.0676	NC	-	0.40	0.03	0.01	0.00	0.01	0.00	0.07	0.00	0.09	0.01
GC 0647	Oats, raw (incl rolled)	RAC	0.0676	0.05	0.00	7.05	0.48	0.10	0.01	1.71	0.12	0.96	0.06	0.04	0.00
GC 2088	Subgroup of rice cereals	REP	0.0676	45.40	3.07	14.99	1.01	84.88	5.74	111.73	7.55	194.75	13.17	93.12	6.29
GC 2089	Subgroup of Sorghum Grain and Millet	RAC	0.0676	5.80	0.39	2.32	0.16	23.09	1.56	16.72	1.13	27.14	1.83	2.92	0.20
GC 0651	Sorghum, raw (incl flour, incl beer) (i.e. Chicken corn, Dari seed, Durra, Feterita)	RAC	0.0676	4.34	0.29	0.01	0.00	16.25	1.10	15.82	1.07	10.97	0.74	2.92	0.20
GC 0645	Maize, raw	RAC	0.0676	0.62	0.04	NC	-	0.55	0.04	NC	-	1.24	0.08	12.33	0.83
CF 1255	Maize, flour (white flour and wholemeal flour)	PP	0.0366	22.72	0.83	35.61	1.30	87.27	3.19	34.92	1.28	46.71	1.71	49.12	1.80
-	Maize starch	PP	0	0.08	0.00	NC	-	0.01	0.00	2.29	0.00	0.08	0.00	0.11	0.00
-	Maize, glucose, isoglucose and Dextrose	PP	0.0676	0.22	0.01	0.24	0.02	0.13	0.01	0.46	0.03	0.97	0.07	0.80	0.05
-	Maize beer	PP	0.0676	NC	-	NC	-	4.61	0.31	NC	-	NC	-	NC	-
OR 0645	Maize oil	PP	0.0676	0.96	0.06	0.85	0.06	0.29	0.02	5.42	0.37	0.42	0.03	2.10	0.14
-	Cereals, NES, raw (including processed) : canagua, quihuicha, Job's tears and wild rice	RAC	0.0676	2.04	0.14	2.99	0.20	1.86	0.13	19.17	1.30	3.33	0.23	1.66	0.11
GC 2090	Subgroup of Sweet Corns	RAC	0.676	0.14	0.09	0.94	0.64	5.70	3.85	2.61	1.76	1.94	1.31	0.22	0.15
SO 0088	Group of Oilseeds & Oilfruits, raw (incl processed)	RAC	0.0656	78.79	5.17	54.57	3.58	96.08	6.30	137.03	8.99	60.49	3.97	88.56	5.81
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80 % as muscle	RAC	0.0096	24.96	0.24	57.95	0.56	16.70	0.16	38.38	0.37	26.46	0.25	29.00	0.28
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20 % as fat	RAC	0.0098	6.24	0.06	14.49	0.14	4.18	0.04	9.60	0.09	6.62	0.06	7.25	0.07
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.0098	3.29	0.03	6.14	0.06	0.82	0.01	1.57	0.02	2.23	0.02	1.07	0.01
MO 0105	Edible offal (mammalian), raw	RAC	0.2217	4.79	1.06	9.68	2.15	2.97	0.66	5.49	1.22	3.84	0.85	5.03	1.12
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.0033	289.65	0.96	485.88	1.60	26.92	0.09	239.03	0.79	199.91	0.66	180.53	0.60

Annex 3

FLUAZAINDOLIZINE (327)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.3 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day		Intake as ug/person/day										
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake	
PM 0110	Poultry meat, raw (incl prepared) - 90 % as muscle	RAC	0.0021	13.17	0.03	26.78	0.06	7.24	0.02	116.71	0.25	22.54	0.05	32.09	0.07	
PM 0110	Poultry meat, raw (incl prepared) - 10 % as fat	RAC	0.00093	1.46	0.00	2.98	0.00	0.80	0.00	12.97	0.01	2.50	0.00	3.57	0.00	
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.0032	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.10	0.00	0.10	0.00	
038	POULTRY, EDIBLE OFFAL OF	-	0.035	-	-	-	-	-	-	-	-	-	-	-	-	
PE 0112	Eggs, raw, (incl dried)	RAC	0.00263	7.84	0.02	23.08	0.06	2.88	0.01	14.89	0.04	9.81	0.03	14.83	0.04	
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Total intake (ug/person)=					86.9		137.6		135.1		126.3		103.7		176.0	
Bodyweight per region (kg bw) =					60		60		60		60		60		60	
ADI (ug/person)=					18000		18000		18000		18000		18000		18000	
%ADI=					0.5 %		0.8 %		0.8 %		0.7 %		0.6 %		1.0 %	
Rounded %ADI=					0 %		1 %		1 %		1 %		1 %		1 %	

FLUAZAINDOLIZINE (327)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.3 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day		Intake as ug/person/day									
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
FB 0275	Strawberry, raw	RAC	0.053	4.49	0.24	5.66	0.30	0.02	0.00	6.63	0.35	5.75	0.30	0.05	0.00
VA 0035	Group of Bulb vegetables, raw	RAC	0.0674	26.24	1.77	36.47	2.46	39.29	2.65	39.37	2.65	29.12	1.96	20.21	1.36
VB 0040	Group of Brassica vegetables (excl Brassica leafy vegetables), raw	RAC	0.04335	20.71	0.90	39.81	1.73	25.06	1.09	37.93	1.64	18.12	0.79	16.74	0.73
VC 2039	Subgroup of Cucumbers and Squashes, raw	RAC	0.1092	7.14	0.78	16.92	1.85	37.58	4.10	15.16	1.66	4.42	0.48	12.67	1.38
VC 2040	Subgroup of Melons, Pumpkins and Winter squashes	RAC	0.1348	20.68	2.79	25.00	3.37	85.72	11.56	34.31	4.62	11.54	1.56	23.32	3.14
VO 2045	Subgroup of tomatoes, raw (incl processed) (Lycopersicum spp. Only)	RAC	0.0748	64.74	4.84	68.31	5.11	36.05	2.70	82.09	6.14	54.50	4.08	11.69	0.87
VO 0448	Tomato, raw	RAC	0.0748	32.13	2.40	51.27	3.83	34.92	2.61	73.37	5.49	15.15	1.13	8.88	0.66
-	Tomato, canned (& peeled)	PP	0.0711	7.57	0.54	2.66	0.19	0.30	0.02	0.97	0.07	7.31	0.52	0.41	0.03
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.2476	4.96	1.23	3.20	0.79	0.15	0.04	1.61	0.40	6.88	1.70	0.52	0.13
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.059	0.80	0.05	0.07	0.00	0.05	0.00	0.61	0.04	0.40	0.02	0.08	0.00
VO 0051	Subgroup of peppers, raw (incl dried sweet peppers, excl dried chilipeppers), excl okra	RAC	0.074	6.39	0.47	15.53	1.15	19.09	1.41	10.36	0.77	8.29	0.61	4.53	0.34
VO 2046	Subgroup of eggplants	RAC	0.0748	1.01	0.08	1.69	0.13	21.37	1.60	3.00	0.22	1.40	0.10	NC	-
VL 0053	Group of Leafy vegetables, raw	RAC	0.388	18.83	7.31	21.85	8.48	121.23	47.04	43.09	16.72	18.18	7.05	18.32	7.11
VP 0060	Group of Legume vegetables, raw	RAC	0.0709	18.21	1.29	8.91	0.63	7.22	0.51	10.04	0.71	23.22	1.65	0.17	0.01
VD 0070	Group of Pulses, raw (incl processed)	RAC	0.0656	112.88	7.40	123.05	8.07	47.73	3.13	204.75	13.43	227.52	14.93	110.05	7.22

Annex 3

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FLUAZAINDOLIZINE (327)		International Estimated Daily Intake (IEDI)						ADI = 0 - 0.3 mg/kg bw							
Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day							
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
OR 0541	Soya oil, refined	PP	0	19.06	0.00	21.06	0.00	5.94	0.00	33.78	0.00	40.05	0.00	13.39	0.00
VR 0574	Beetroot, raw	RAC	0.1935	9.91	1.92	6.34	1.23	NC	-	9.65	1.87	19.11	3.70	6.47	1.25
VR 0575	Burdock, greater or edible, raw	RAC	0.1935	NC	-	NC	-	NC	-	0.48	0.09	NC	-	0.06	0.01
VR 0577	Carrots, raw	RAC	0.1485	26.26	3.90	27.13	4.03	10.07	1.50	16.49	2.45	44.69	6.64	8.75	1.30
VR 0578	Celeriac, raw	RAC	0.1935	2.97	0.57	1.79	0.35	NC	-	0.06	0.01	16.91	3.27	3.22	0.62
VR 0469	Chicory, roots, raw	RAC	0.1935	0.01	0.00	0.51	0.10	0.01	0.00	0.01	0.00	21.12	4.09	NC	-
VR 0583	Horseradish, raw	RAC	0.1935	0.01	0.00	0.42	0.08	13.01	2.52	0.26	0.05	2.70	0.52	0.97	0.19
VR 0587	Parsley turnip-rooted, raw	RAC	0.1935	NC	-	NC	-	NC	-	NC	-	NC	-	0.61	0.12
VR 0588	Parsnip, raw	RAC	0.1935	4.42	0.86	0.06	0.01	NC	-	NC	-	NC	-	1.12	0.22
VR 0494	Radish roots, raw	RAC	0.1935	3.83	0.74	11.99	2.32	NC	-	5.26	1.02	2.19	0.42	4.37	0.85
VR 0591	Japanese radish, raw (i.e. Chinese radish, Daikon)	RAC	0.1935	NC	-	NC	-	26.64	5.15	18.92	3.66	NC	-	3.59	0.69
VR 0498	Salsify, raw (i.e. Oysterplant)	RAC	0.1935	1.02	0.20	0.52	0.10	NC	-	NC	-	2.08	0.40	0.39	0.08
VR 0596	Sugar beet, raw (incl sugar)	RAC	0.1935	0.01	0.00	NC	-	0.01	0.00	0.01	0.00	NC	-	NC	-
VR 0596	Sugar beet, raw	RAC	0.1935	0.01	0.00	NC	-	0.01	0.00	0.01	0.00	NC	-	NC	-
-	Sugar beet, sugar	PP	0.1935	0.01	0.00	NC	-	0.01	0.00	NC	-	NC	-	NC	-
VR 0497	Swede, raw (i.e. Rutabaga)	RAC	0.1935	10.01	1.94	1.66	0.32	NC	-	NC	-	3.06	0.59	2.99	0.58
VR 0506	Turnip, garden, raw	RAC	0.1935	5.78	1.12	15.35	2.97	NC	-	6.54	1.27	1.95	0.38	4.73	0.92
VR 2071	Subgroup of tuberous and corm vegetables, raw (incl processed)	RAC	0.1231	226.09	27.83	234.58	28.88	161.10	19.83	185.04	22.78	234.85	28.91	100.25	12.34
VS 0078	Group of Stalk and stem vegetables, raw	RAC	0.0674	12.56	0.85	15.57	1.05	72.50	4.89	8.11	0.55	28.79	1.94	10.13	0.68
GC 0080	Group of Cereal grains, raw, (incl processed) (incl sweet corn)	RAC	0.0676	345.63	23.36	386.16	26.10	514.33	34.77	402.72	27.22	295.30	19.96	359.97	24.33
GC 0654	Wheat, raw (incl meslin)	RAC	0.0676	NC	-	NC	-	NC	-	0.01	0.00	NC	-	NC	-
-	Wheat, bulgur	PP	0.0676	NC	-	NC	-	0.01	0.00	NC	-	NC	-	NC	-
CP 1212	Wheat, wholemeal bread	PP	0.0676	0.03	0.00	0.01	0.00	0.01	0.00	0.01	0.00	0.05	0.00	0.02	0.00
-	Wheat, Fermented Beverages (Korean jakju and takju)	PP	0.0676	NC	-	NC	-	NC	-	4.36	0.29	NC	-	NC	-
CF 1211	Wheat, white flour (incl white flour products: starch, gluten, macaroni, pastry)	PP	0	198.08	0.00	193.03	0.00	106.24	0.00	185.09	0.00	168.67	0.00	131.59	0.00
GC 2087	Subgroup of barley, similar grains, and pseudocereals with husks, raw (including processed)	RAC	0.0676	43.68	2.95	60.49	4.09	9.72	0.66	40.47	2.74	49.83	3.37	18.90	1.28
GC 0641	Buckwheat, raw (incl flour)	RAC	0.0676	0.01	0.00	0.79	0.05	0.18	0.01	0.35	0.02	NC	-	NC	-
GC 0647	Oats, raw (incl rolled)	RAC	0.0676	7.50	0.51	6.26	0.42	0.15	0.01	4.87	0.33	3.16	0.21	2.98	0.20
GC 2088	Subgroup of rice cereals	REP	0.0676	20.96	1.42	16.04	1.08	339.67	22.96	75.51	5.10	16.86	1.14	86.13	5.82
GC 2089	Subgroup of Sorghum Grain and Millet	RAC	0.0676	0.03	0.00	0.16	0.01	3.19	0.22	1.85	0.13	NC	-	7.12	0.48
GC 0651	Sorghum, raw (incl flour, incl beer) (i.e. Chicken corn, Dari seed, Durra, Feterita)	RAC	0.0676	NC	-	NC	-	1.44	0.10	1.15	0.08	NC	-	7.12	0.48
GC 0645	Maize, raw	RAC	0.0676	NC	-	NC	-	1.35	0.09	NC	-	NC	-	NC	-
CF 1255	Maize, flour (white flour and wholemeal flour)	PP	0.0366	14.27	0.52	12.86	0.47	19.71	0.72	12.55	0.46	4.21	0.15	52.30	1.91

Annex 3

FLUAZAINDOLIZINE (327)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.3 mg/kg bw

Codex Code	Commodity description	Expr as	STM ^R mg/kg	Diets as g/person/day				Intake as ug/person/day																			
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake												
-	Maize starch	PP	0	NC	-	NC	-	0.19	0.00	7.13	0.00	NC	-	NC	-												
-	Maize, glucose, isoglucose and Dextrose	PP	0.0676	0.10	0.01	9.93	0.67	0.05	0.00	9.88	0.67	0.33	0.02	0.04	0.00												
-	Maize beer	PP	0.0676	NC	-	NC	-	NC	-	1.99	0.13	NC	-	NC	-												
OR 0645	Maize oil	PP	0.0676	0.90	0.06	0.47	0.03	0.15	0.01	3.01	0.20	1.86	0.13	0.36	0.02												
-	Cereals, NES, raw (including processed) : canagua, quihuicha, Job's tears and wild rice	RAC	0.0676	6.17	0.42	3.01	0.20	0.76	0.05	3.30	0.22	3.38	0.23	15.84	1.07												
GC 2090	Subgroup of Sweet Corns	RAC	0.676	11.43	7.73	3.71	2.51	0.74	0.50	13.63	9.21	3.07	2.08	1.50	1.01												
SO 0088	Group of Oilseeds & Oilfruits, raw (incl processed)	RAC	0.0656	108.59	7.12	112.13	7.36	64.09	4.20	81.53	5.35	66.09	4.34	20.02	1.31												
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80 % as muscle	RAC	0.0096	112.02	1.08	120.71	1.16	63.46	0.61	88.99	0.85	96.24	0.92	41.02	0.39												
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20 % as fat	RAC	0.0098	28.01	0.27	30.18	0.30	15.86	0.16	22.25	0.22	24.06	0.24	10.25	0.10												
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.0098	6.44	0.06	15.51	0.15	3.79	0.04	8.29	0.08	18.44	0.18	8.00	0.08												
MO 0105	Edible offal (mammalian), raw	RAC	0.2217	15.17	3.36	5.19	1.15	6.30	1.40	6.78	1.50	3.32	0.74	3.17	0.70												
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.0033	388.92	1.28	335.88	1.11	49.15	0.16	331.25	1.09	468.56	1.55	245.45	0.81												
PM 0110	Poultry meat, raw (incl prepared) - 90 % as muscle	RAC	0.0021	66.38	0.14	48.47	0.10	21.58	0.05	78.41	0.16	48.04	0.10	76.01	0.16												
PM 0110	Poultry meat, raw (incl prepared) - 10 % as fat	RAC	0.00093	7.38	0.01	5.39	0.01	2.40	0.00	8.71	0.01	5.34	0.00	8.45	0.01												
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.0032	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.71	0.00	NC	-												
038	POULTRY, EDIBLE OFFAL OF	-	0.035	-	-	-	-	-	-	-	-	-	-	-	-												
PE 0112	Eggs, raw, (incl dried)	RAC	0.00263	25.84	0.07	29.53	0.08	28.05	0.07	33.19	0.09	36.44	0.10	8.89	0.02												
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-												
Total intake (ug/person)=				122.4				126.6				179.1				144.8				123.2				83.1			
Bodyweight per region (kg bw) =				60				60				55				60				60							
ADI (ug/person)=				18000				18000				16500				18000				18000							
%ADI=				0.7 %				0.7 %				1.1 %				0.8 %				0.7 %				0.5 %			
Rounded %ADI=				1 %				1 %				1 %				1 %				1 %				0 %			

Annex 3

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FLUAZAINDOLIZINE (327)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.3 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day		Intake = daily intake: ug/person							
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
FB 0275	Strawberry, raw	RAC	0.053	0.01	0.00	0.01	0.00	3.35	0.18	0.01	0.00	0.01	0.00
VA 0035	Group of Bulb vegetables, raw	RAC	0.0674	11.28	0.76	23.80	1.60	36.11	2.43	9.66	0.65	8.69	0.59
VB 0040	Group of Brassica vegetables (excl Brassica leafy vegetables), raw	RAC	0.04335	5.46	0.24	4.28	0.19	58.72	2.55	0.02	0.00	NC	-
VC 2039	Subgroup of Cucumbers and Squashes, raw	RAC	0.1092	0.92	0.10	3.20	0.35	13.55	1.48	1.91	0.21	0.05	0.01
VC 2040	Subgroup of Melons, Pumpkins and Winter squashes	RAC	0.1348	5.04	0.68	6.54	0.88	38.26	5.16	11.70	1.58	NC	-
VO 2045	Subgroup of tomatoes, raw (incl processed) (Lycopersicum spp. Only)	RAC	0.0748	15.50	1.16	5.78	0.43	71.52	5.35	2.00	0.15	12.50	0.94
VO 0448	Tomato, raw	RAC	0.0748	12.99	0.97	4.79	0.36	58.40	4.37	0.92	0.07	0.09	0.01
-	Tomato, canned (& peeled)	PP	0.0711	0.07	0.00	0.08	0.01	2.42	0.17	0.07	0.00	NC	-
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.2476	0.58	0.14	0.22	0.05	2.21	0.55	0.24	0.06	3.10	0.77
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.059	0.05	0.00	0.01	0.00	0.42	0.02	0.01	0.00	0.02	0.00
VO 0051	Subgroup of peppers, raw (incl dried sweet peppers, excl dried chilipeppers), excl okra	RAC	0.074	8.97	0.66	14.13	1.05	25.14	1.86	0.91	0.07	NC	-
VO 2046	Subgroup of eggplants	RAC	0.0748	1.31	0.10	8.26	0.62	3.95	0.30	0.01	0.00	NC	-
VL 0053	Group of Leafy vegetables, raw	RAC	0.388	12.42	4.82	8.75	3.40	7.53	2.92	7.07	2.74	14.11	5.47
VP 0060	Group of Legume vegetables, raw	RAC	0.0709	0.58	0.04	3.16	0.22	10.38	0.74	0.04	0.00	NC	-
VD 0070	Group of Pulses, raw (incl processed)	RAC	0.0656	46.57	3.05	30.77	2.02	112.53	7.38	75.53	4.95	43.68	2.87
OR 0541	Soya oil, refined	PP	0	2.32	0.00	2.54	0.00	18.70	0.00	2.51	0.00	6.29	0.00
VR 0574	Beetroot, raw	RAC	0.1935	5.86	1.13	4.23	0.82	9.46	1.83	3.96	0.77	7.91	1.53
VR 0575	Burdock, greater or edible, raw	RAC	0.1935	0.06	0.01	0.04	0.01	NC	-	0.04	0.01	0.08	0.02
VR 0577	Carrots, raw	RAC	0.1485	2.07	0.31	3.00	0.45	25.29	3.76	0.05	0.01	NC	-
VR 0578	Celeriac, raw	RAC	0.1935	2.91	0.56	2.10	0.41	7.59	1.47	1.97	0.38	3.93	0.76
VR 0469	Chicory, roots, raw	RAC	0.1935	0.01	0.00	0.03	0.01	0.10	0.02	NC	-	NC	-
VR 0583	Horseradish, raw	RAC	0.1935	0.88	0.17	0.63	0.12	0.54	0.10	0.59	0.11	1.19	0.23
VR 0587	Parsley turnip-rooted, raw	RAC	0.1935	0.55	0.11	0.40	0.08	4.29	0.83	0.37	0.07	0.74	0.14
VR 0588	Parsnip, raw	RAC	0.1935	1.02	0.20	0.74	0.14	3.50	0.68	0.69	0.13	1.37	0.27
VR 0494	Radish roots, raw	RAC	0.1935	3.96	0.77	2.86	0.55	3.30	0.64	2.67	0.52	5.34	1.03
VR 0591	Japanese radish, raw (i.e. Chinese radish, Daikon)	RAC	0.1935	3.25	0.63	2.35	0.45	NC	-	2.20	0.43	4.39	0.85
VR 0498	Salsify, raw (i.e. Oysterplant)	RAC	0.1935	0.36	0.07	0.26	0.05	NC	-	0.24	0.05	0.48	0.09
VR 0596	Sugar beet, raw (incl sugar)	RAC	0.1935	3.93	0.76	1.68	0.33	NC	-	NC	-	36.12	6.99
VR 0596	Sugar beet, raw	RAC	0.1935	0.01	0.00	NC	-	NC	-	NC	-	NC	-
-	Sugar beet, sugar	PP	0.1935	0.56	0.11	0.24	0.05	NC	-	NC	-	5.13	0.99
VR 0497	Swede, raw (i.e. Rutabaga)	RAC	0.1935	2.71	0.52	1.96	0.38	7.80	1.51	1.83	0.35	3.66	0.71
VR 0506	Turnip, garden, raw	RAC	0.1935	4.29	0.83	3.10	0.60	6.41	1.24	2.90	0.56	5.79	1.12
VR 2071	Subgroup of tuberous and corm vegetables, raw (incl processed)	RAC	0.1231	250.41	30.83	208.74	25.70	213.64	26.30	602.70	74.19	388.95	47.88
VS 0078	Group of Stalk and stem vegetables, raw	RAC	0.0674	9.14	0.62	6.60	0.44	7.58	0.51	6.18	0.42	12.34	0.83

Annex 3

FLUAZAINDOLIZINE (327)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.3 mg/kg bw

Codex Code	Commodity description	Expr as	STM ^R mg/kg	Diets: g/person/day		Intake = daily intake: ug/person							
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
GC 0080	Group of Cereal grains, raw, (incl processed) (incl sweet corn)	RAC	0.0676	407.04	27.52	417.04	28.19	402.79	27.23	195.30	13.20	263.26	17.80
GC 0654	Wheat, raw (incl meslin)	RAC	0.0676	NC	-	NC	-	NC	-	NC	-	0.97	0.07
-	Wheat, bulgur	PP	0.0676	0.01	0.00	NC	-	NC	-	NC	-	NC	-
CP 1212	Wheat, wholemeal bread	PP	0.0676	0.01	0.00	0.01	0.00	0.03	0.00	0.01	0.00	0.01	0.00
-	Wheat, Fermented Beverages (Korean jakju and takju)	PP	0.0676	NC	-	NC	-	NC	-	NC	-	NC	-
CF 1211	Wheat, white flour (incl white flour products: starch, gluten, macaroni, pastry)	PP	0	44.78	0.00	86.96	0.00	214.05	0.00	20.31	0.00	103.60	0.00
GC 2087	Subgroup of barley, similar grains, and pseudocereals with husks, raw (including processed)	RAC	0.0676	11.99	0.81	5.22	0.35	49.50	3.35	3.82	0.26	16.26	1.10
GC 0641	Buckwheat, raw (incl flour)	RAC	0.0676	0.04	0.00	2.82	0.19	0.01	0.00	0.01	0.00	NC	-
GC 0647	Oats, raw (incl rolled)	RAC	0.0676	0.37	0.03	0.07	0.00	2.79	0.19	0.10	0.01	NC	-
GC 2088	Subgroup of rice cereals	REP	0.0676	52.55	3.55	286.02	19.33	18.64	1.26	19.67	1.33	75.09	5.08
GC 2089	Subgroup of Sorghum Grain and Millet	RAC	0.0676	150.90	10.20	2.80	0.19	NC	-	68.93	4.66	NC	-
GC 0651	Sorghum, raw (incl flour, incl beer) (i.e. Chicken corn, Dari seed, Durra, Feterita)	RAC	0.0676	89.16	6.03	2.02	0.14	NC	-	35.38	2.39	NC	-
GC 0645	Maize, raw	RAC	0.0676	NC	-	0.01	0.00	0.03	0.00	NC	-	NC	-
CF 1255	Maize, flour (white flour and wholemeal flour)	PP	0.0366	94.34	3.45	8.09	0.30	28.03	1.03	55.94	2.05	28.07	1.03
-	Maize starch	PP	0	0.02	0.00	0.01	0.00	NC	-	NC	-	NC	-
-	Maize, glucose, isoglucose and Dextrose	PP	0.0676	0.35	0.02	0.51	0.03	3.23	0.22	0.18	0.01	NC	-
-	Maize beer	PP	0.0676	1.03	0.07	NC	-	NC	-	40.94	2.77	NC	-
OR 0645	Maize oil	PP	0.0676	0.33	0.02	0.07	0.00	0.81	0.05	0.01	0.00	NC	-
-	Cereals, NES, raw (including processed) : canagua, quihuicha, Job's tears and wild rice	RAC	0.0676	17.71	1.20	2.00	0.14	9.61	0.65	0.45	0.03	4.55	0.31
GC 2090	Subgroup of Sweet Corns	RAC	0.676	3.63	2.45	20.50	13.86	8.78	5.94	0.02	0.01	0.17	0.11
SO 0088	Group of Oilseeds & Oilfruits, raw (incl processed)	RAC	0.0656	130.71	8.57	22.07	1.45	69.33	4.55	55.22	3.62	84.31	5.53
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80 % as muscle	RAC	0.0096	23.34	0.22	40.71	0.39	97.15	0.93	18.06	0.17	57.71	0.55
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20 % as fat	RAC	0.0098	5.84	0.06	10.18	0.10	24.29	0.24	4.52	0.04	14.43	0.14
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.0098	1.05	0.01	1.14	0.01	18.69	0.18	0.94	0.01	3.12	0.03
MO 0105	Edible offal (mammalian), raw	RAC	0.2217	4.64	1.03	1.97	0.44	10.01	2.22	3.27	0.72	3.98	0.88
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.0033	108.75	0.36	70.31	0.23	436.11	1.44	61.55	0.20	79.09	0.26
PM 0110	Poultry meat, raw (incl prepared) - 90 % as muscle	RAC	0.0021	3.53	0.01	10.83	0.02	51.36	0.11	4.53	0.01	50.00	0.11
PM 0110	Poultry meat, raw (incl prepared) - 10 % as fat	RAC	0.00093	0.39	0.00	1.20	0.00	5.71	0.01	0.50	0.00	5.56	0.01
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.0032	NC	-	NC	-	0.32	0.00	NC	-	NC	-

Annex 3

FLUAZAINDOLIZINE (327)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.3 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day		Intake = daily intake: ug/person							
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
038	POULTRY, EDIBLE OFFAL OF	-	0.035	-	-	-	-	-	-	-	-	-	-
PE 0112	Eggs, raw, (incl dried)	RAC	0.00263	3.84	0.01	4.41	0.01	27.25	0.07	1.13	0.00	7.39	0.02
-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total intake (ug/person)=				116.0		107.1		124.0		120.0		107.1	
Bodyweight per region (kg bw) =				60		60		60		60		60	
ADi (ug/person)=				18000		18000		18000		18000		18000	
%ADI=				0.6 %		0.6 %		0.7 %		0.7 %		0.6 %	
Rounded %ADI=				1 %		1 %		1 %		1 %		1 %	

Annex 3

FLUDIOXONIL + metabolites for HBGV (211)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.4 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day							
				G01		G02		G03		G04		G05		G06	
				diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
FC 0001	Group of Citrus fruit, raw (incl kumquat commodities)	RAC	0.41	32.25	13.22	11.67	4.78	16.70	6.85	76.01	31.16	33.90	13.90	92.97	38.12
JF 0001	Group of Citrus fruit, juice	PP	0.64	1.30	0.83	2.37	1.52	0.22	0.14	13.88	8.88	0.75	0.48	2.63	1.68
FP 0009	Group of Pome fruits, raw (incl apple cider, excl apple juice)	RAC	2.1	19.35	40.64	34.06	71.53	17.87	37.53	25.74	54.05	7.69	16.15	56.85	119.39
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.17	0.32	0.05	3.07	0.52	0.07	0.01	5.00	0.85	0.29	0.05	5.57	0.95
FS 0012	Group of Stone fruits, raw (incl dried apricots, excl dried plums)	RAC	0.8	11.33	9.06	23.62	18.90	0.24	0.19	11.32	9.06	2.28	1.82	33.26	26.61
DF 0014	Plums, dried (prunes)	PP	0.96	0.09	0.09	0.06	0.06	0.01	0.01	0.18	0.17	0.04	0.04	0.06	0.06
FB 0264	Blackberries, raw	RAC	1.3	0.35	0.46	0.11	0.14	0.01	0.01	0.02	0.03	0.01	0.01	1.23	1.60
FB 0266	Dewberries, incl boysen- & loganberry, raw	RAC	1.3	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01
FB 0272	Raspberries, red, black, raw	RAC	1.3	0.07	0.09	0.93	1.21	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01
FB 0020	Blueberries, raw	RAC	0.78	0.01	0.01	0.03	0.02	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01
FB 0021	Currants, Black, Red, White, raw	RAC	0.806	0.02	0.02	0.74	0.60	0.01	0.01	0.03	0.02	0.01	0.01	0.01	0.01
FB 0269	Grapes, raw (incl must, excl dried, excl juice, excl wine)	RAC	0.28	13.02	3.65	9.25	2.59	0.03	0.01	16.91	4.73	3.70	1.04	54.44	15.24
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	0.31	0.51	0.16	0.51	0.16	0.01	0.00	1.27	0.39	0.12	0.04	2.07	0.64
JF 0269	Grape juice (from wine grapes)	PP	0.26	0.14	0.04	0.29	0.08	0.05	0.01	0.30	0.08	0.24	0.06	0.05	0.01
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.08	0.67	0.05	12.53	1.00	2.01	0.16	1.21	0.10	3.53	0.28	4.01	0.32
FB 0275	Strawberry, raw	RAC	0.351	0.70	0.25	2.01	0.71	0.04	0.01	1.36	0.48	0.37	0.13	2.53	0.89
FT 0336	Guava, raw	RAC	0.1625	0.47	0.08	0.01	0.00	0.48	0.08	0.49	0.08	4.42	0.72	0.06	0.01
FI 0326	Avocado, raw	RAC	0.013	0.13	0.00	0.03	0.00	2.05	0.03	2.54	0.03	2.34	0.03	0.12	0.00
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.013	5.23	0.07	6.94	0.09	99.45	1.29	32.47	0.42	48.30	0.63	24.70	0.32
FI 0345	Mango, raw (incl canned mango, incl mango juice)	RAC	0.04	10.48	0.42	0.01	0.00	7.24	0.29	6.87	0.27	19.98	0.80	6.25	0.25
FI 0350	Papaya, raw	RAC	0.15	0.35	0.05	0.01	0.00	3.05	0.46	0.80	0.12	7.28	1.09	1.00	0.15
FI 0355	Pomegranate, raw, (incl processed)	RAC	1.75	3.40	5.95	2.10	3.68	2.65	4.64	10.89	19.06	NC	-	6.67	11.67
FI 0353	Pineapple, raw (incl canned pineapple, incl pineapple juice, incl dried pineapple)	RAC	2	0.61	1.22	1.56	3.12	7.89	15.78	9.36	18.72	8.76	17.52	1.30	2.60
FI 0341	Kiwifruit, raw	RAC	7.2	0.03	0.22	0.36	2.59	0.01	0.07	1.17	8.42	0.06	0.43	0.69	4.97
VA 2031	Subgroup of bulb onions	RAC	0.06	31.65	1.90	43.28	2.60	3.68	0.22	38.48	2.31	20.46	1.23	47.29	2.84
VA 2032	Subgroup of Green Onions	RAC	0.21	2.64	0.55	3.09	0.65	1.05	0.22	2.89	0.61	0.61	0.13	5.24	1.10
VB 0400	Broccoli, raw	RAC	0.23	0.88	0.20	0.17	0.04	0.01	0.00	1.25	0.29	3.00	0.69	1.09	0.25
VB 0041	Cabbages, head, raw	RAC	0.24	2.73	0.66	27.92	6.70	0.55	0.13	4.47	1.07	4.27	1.02	10.25	2.46
VC 0045	Group of Fruiting vegetables, cucurbits, raw	RAC	0.0845	53.14	4.49	86.21	7.28	6.28	0.53	92.76	7.84	15.64	1.32	155.30	13.12
VO 0448	Tomato, raw (incl canned, excl juice, excl paste)	RAC	0.605	42.04	25.43	76.13	46.06	10.69	6.47	84.59	51.18	24.92	15.08	203.27	122.98
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.028	2.34	0.07	1.33	0.04	1.57	0.04	4.24	0.12	0.34	0.01	2.83	0.08
JF 0448	Tomato, juice (single strength, incl	PP	0.026	0.29	0.01	0.29	0.01	0.01	0.00	0.38	0.01	0.05	0.00	0.14	0.00

Annex 3

FLUDIOXONIL + metabolites for HBGV (211)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.4 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day								
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake	
	concentrated)															
VO 0051	Subgroup of peppers, raw (incl dried sweet peppers, excl dried chilipeppers), excl okra	RAC	0.234	8.48	1.98	13.74	3.22	10.13	2.37	11.29	2.64	9.52	2.23	26.36	6.17	
VO 0440	Egg plant, raw (i.e. aubergine)	RAC	0.078	5.58	0.44	4.31	0.34	0.89	0.07	9.31	0.73	13.64	1.06	20.12	1.57	
VL 0483	Lettuce, leaf, raw	RAC	8.312	0.53	4.41	0.36	2.99	0.16	1.33	6.21	51.62	1.90	15.79	6.05	50.29	
VL 0502	Spinach, raw	RAC	5.812	0.74	4.30	0.22	1.28	0.02	0.12	0.91	5.29	0.04	0.23	2.92	16.97	
VL 0401	Broccoli, Chinese, raw (i.e. kailan)	RAC	1.2	0.42	0.50	0.08	0.10	0.01	0.01	0.60	0.72	NC	-	0.52	0.62	
VL 0472	Cress, garden, raw	RAC	1.2	0.06	0.07	0.10	0.12	0.06	0.07	0.15	0.18	NC	-	0.07	0.08	
VL 0480	Kale (Borecole, Collards), raw	RAC	1.2	0.57	0.68	5.77	6.92	0.11	0.13	0.92	1.10	5.25	6.30	2.12	2.54	
VL 0485	Mustard greens, raw (i.e. Indian mustard, Amsoi, mustard cabbage)	RAC	1.212	0.03	0.04	0.31	0.38	0.01	0.01	0.05	0.06	0.47	0.57	0.11	0.13	
VL 0494	Radish leaves, raw	RAC	3.809	0.26	0.99	0.45	1.71	0.28	1.07	0.68	2.59	NC	-	0.33	1.26	
VL 0495	Rape greens, raw	RAC	1.2	0.03	0.04	0.31	0.37	0.01	0.01	0.05	0.06	NC	-	0.11	0.13	
VL 0496	Rucola, raw (i.e. Arrugula, Rocket salad, Roquette)	RAC	1.2	1.27	1.52	2.25	2.70	1.39	1.67	3.38	4.06	13.81	16.57	1.63	1.96	
VL 2052	Subgroup of Leaves of Root and Tuber Vegetables	RAC	0.009	0.18	0.00	0.31	0.00	0.84	0.01	0.47	0.00	2.06	0.02	0.23	0.00	
VL 0473	Watercress, raw	RAC	1.2	1.21	1.45	2.15	2.58	1.33	1.60	3.24	3.89	11.36	13.63	1.56	1.87	
VP 2060	Subgroup of beans with pods (all commodities within this group)	RAC	0.1595	0.68	0.11	NC	-	NC	-	0.39	0.06	0.22	0.04	0.49	0.08	
VP 0062	Beans without pods: (Phaseolus spp.) (succulent seeds), raw	RAC	0.058	1.56	0.09	0.60	0.03	0.49	0.03	1.18	0.07	0.90	0.05	7.79	0.45	
VP 0064	Peas without pods (Pisum spp) (succulent seeds)	RAC	0.058	1.97	0.11	0.51	0.03	0.02	0.00	0.79	0.05	3.68	0.21	3.80	0.22	
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	0.0841	2.39	0.20	1.61	0.14	10.47	0.88	1.84	0.15	12.90	1.08	7.44	0.63	
VD 0523	Broad bean, dry, raw (incl horse-bean, field bean) (Vicia faba)	RAC	0.0841	1.27	0.11	0.01	0.00	0.12	0.01	2.49	0.21	0.23	0.02	5.54	0.47	
VD 0527	Cowpea, dry, raw (Vigna sinensis, Dolichos sinensis)	RAC	0.0841	0.05	0.00	NC	-	1.74	0.15	0.01	0.00	0.01	0.00	0.07	0.01	
VD 0541	Soya bean, dry, raw (incl paste, incl curd, incl oil, incl sauce)	RAC	0.029	72.79	2.11	59.05	1.71	20.55	0.60	74.20	2.15	61.12	1.77	73.24	2.12	
-	Beans (dry) NES: including inter alia lablab or hyacinth bean (Dolichos spp.); jack or sword bean (Canavalia spp.); winged bean (Psophocarpus tetragonolobus); guar bean (Cyamopsis tetragonoloba); velvet bean (Stizolobium spp.); yam bean (Pachyrrhizus erosus)	RAC	0.0841	1.70	0.14	0.01	0.00	3.00	0.25	1.80	0.15	1.64	0.14	1.33	0.11	
VD 2066	Subgroup of dry peas, raw	RAC	0.319	9.09	2.90	3.35	1.07	1.06	0.34	9.48	3.02	15.11	4.82	10.58	3.38	
VR 0574	Beetroot, raw	RAC	0.008	3.42	0.03	6.06	0.05	3.75	0.03	9.11	0.07	NC	-	4.39	0.04	

Annex 3

FLUDIOXONIL + metabolites for HBGV (211)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.4 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day							
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
				VR 0575	Burdock, greater or edible, raw	RAC	0.008	0.03	0.00	0.06	0.00	0.04	0.00	0.09	0.00
VR 0577	Carrots, raw	RAC	0.293	9.51	2.79	30.78	9.02	0.37	0.11	8.75	2.56	2.80	0.82	6.10	1.79
VR 0578	Celeriac, raw	RAC	0.008	1.70	0.01	3.01	0.02	1.87	0.01	4.53	0.04	NC	-	2.19	0.02
VR 0469	Chicory, roots, raw	RAC	0.008	0.01	0.00	0.20	0.00	0.01	0.00	0.01	0.00	0.02	0.00	0.01	0.00
VR 0583	Horseradish, raw	RAC	0.008	0.51	0.00	0.91	0.01	0.56	0.00	1.37	0.01	NC	-	0.66	0.01
VR 0587	Parsley turnip-rooted, raw	RAC	0.008	0.32	0.00	0.57	0.00	0.35	0.00	0.85	0.01	NC	-	0.41	0.00
VR 0588	Parsnip, raw	RAC	0.008	0.59	0.00	1.05	0.01	0.65	0.01	1.58	0.01	NC	-	0.76	0.01
VR 0494	Radish roots, raw	RAC	0.098	2.31	0.23	4.09	0.40	2.53	0.25	6.15	0.60	5.88	0.58	2.97	0.29
VR 0591	Japanese radish, raw (i.e. Chinese radish, Daikon)	RAC	0.008	1.90	0.02	3.36	0.03	2.08	0.02	5.06	0.04	NC	-	2.44	0.02
VR 0498	Salsify, raw (i.e. Oysterplant)	RAC	0.008	0.21	0.00	0.37	0.00	0.23	0.00	0.55	0.00	NC	-	0.27	0.00
VR 0596	Sugar beet, raw (incl sugar)	RAC	0.008	0.13	0.00	NC	-	0.08	0.00	0.66	0.01	0.47	0.00	88.94	0.71
VR 0596	Sugar beet, raw	RAC	1.108	NC	-	NC	-	NC	-	NC	-	0.01	0.01	NC	-
-	Sugar beet, sugar	PP	0.118	0.02	0.00	NC	-	0.01	0.00	0.09	0.01	0.07	0.01	12.63	1.49
VR 0497	Swede, raw (i.e. Rutabaga)	RAC	0.008	1.58	0.01	2.80	0.02	1.74	0.01	4.21	0.03	NC	-	2.03	0.02
VR 0506	Turnip, garden, raw	RAC	0.008	2.50	0.02	4.44	0.04	2.75	0.02	6.67	0.05	0.14	0.00	3.22	0.03
VR 2071	Subgroup of tuberous and corm vegetables, raw (incl processed)	RAC	0.008	63.11	0.50	316.33	2.53	651.91	5.22	72.06	0.58	84.88	0.68	132.70	1.06
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	1.408	59.74	84.11	316.14	445.13	9.78	13.77	60.26	84.85	54.12	76.20	119.82	168.71
VR 0508	Sweet potato, raw (incl dried)	RAC	3.508	0.18	0.63	0.18	0.63	42.16	147.90	1.61	5.65	3.06	10.73	6.67	23.40
VR 0600	Yams, raw (incl dried)	RAC	3.508	0.02	0.07	NC	-	90.40	317.12	6.45	22.63	0.74	2.60	0.65	2.28
VS 0624	Celery	RAC	4.55	2.14	9.74	3.79	17.24	2.35	10.69	5.69	25.89	0.02	0.09	2.75	12.51
GC 0080	Group of Cereal grains, raw, (incl processed) (incl sweet corn)	RAC	0.02	484.43	9.69	464.63	9.29	262.36	5.25	486.81	9.74	469.62	9.39	614.04	12.28
GC 0447	Sweet corn on the cob, raw (incl frozen kernels, incl canned kernels)	RAC	0.01	0.14	0.00	0.94	0.01	5.70	0.06	2.61	0.03	1.94	0.02	0.22	0.00
TN 0660	Almonds, nutmeat	RAC	0.013	1.38	0.02	0.08	0.00	0.01	0.00	1.00	0.01	0.06	0.00	0.81	0.01
TN 0662	Brazil nuts, nutmeat	RAC	0.013	0.01	0.00	0.01	0.00	0.03	0.00	0.02	0.00	0.02	0.00	0.01	0.00
TN 0295	Cashew nuts, nutmeat	RAC	0.013	0.01	0.00	0.02	0.00	0.24	0.00	0.47	0.01	0.32	0.00	0.05	0.00
TN 0664	Chestnut, raw	RAC	0.013	0.03	0.00	0.02	0.00	0.01	0.00	0.31	0.00	0.09	0.00	0.67	0.01
TN 0665	Coconut, nutmeat (incl. copra, incl desiccated, incl oil)	RAC	0.013	1.73	0.02	1.20	0.02	6.63	0.09	10.18	0.13	13.07	0.17	2.98	0.04
TN 0666	Hazelnuts, nutmeat	RAC	0.013	0.03	0.00	0.13	0.00	0.01	0.00	0.11	0.00	0.01	0.00	1.11	0.01
TN 0669	Macadamia nuts, nutmeat (i.e. Queensland nuts)	RAC	0.013	0.01	0.00	0.01	0.00	0.01	0.00	0.04	0.00	NC	-	0.03	0.00
TN 0672	Pecan, nutmeat	RAC	0.013	0.05	0.00	0.05	0.00	0.02	0.00	0.14	0.00	0.09	0.00	0.13	0.00
TN 0673	Pine nut, nutmeat (i.e. pignolia nuts)	RAC	0.013	0.18	0.00	0.18	0.00	0.08	0.00	0.49	0.01	0.25	0.00	0.43	0.01
TN 0675	Pistachio nut, nutmeat	RAC	0.065	0.41	0.03	0.07	0.00	0.01	0.00	0.85	0.06	0.02	0.00	1.08	0.07
TN 0678	Walnut, nutmeat	RAC	0.013	0.23	0.00	1.49	0.02	0.01	0.00	0.33	0.00	0.07	0.00	2.06	0.03

Annex 3

FLUDIOXONIL + metabolites for HBGV (211)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.4 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day		Intake as ug/person/day									
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
SO 0495	Rape seed, raw (incl oil)	RAC	0.02	0.93	0.02	1.16	0.02	0.49	0.01	2.53	0.05	9.32	0.19	2.02	0.04
SO 0691	Cotton seed, raw (incl oil)	RAC	0.05	20.53	1.03	9.80	0.49	6.42	0.32	4.73	0.24	7.14	0.36	18.68	0.93
HH 0092	Group of Herbs, raw (incl dried)	RAC	2.65	1.69	4.48	1.91	5.06	1.18	3.13	3.35	8.88	0.55	1.46	1.64	4.35
HS 0444	Peppers, chili, dried	PP	1.56	0.42	0.66	0.53	0.83	0.84	1.31	0.50	0.78	0.95	1.48	0.37	0.58
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80 % as muscle	RAC	0.006	24.96	0.15	57.95	0.35	16.70	0.10	38.38	0.23	26.46	0.16	29.00	0.17
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20 % as fat	RAC	0.006	6.24	0.04	14.49	0.09	4.18	0.03	9.60	0.06	6.62	0.04	7.25	0.04
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.006	3.29	0.02	6.14	0.04	0.82	0.00	1.57	0.01	2.23	0.01	1.07	0.01
MO 0105	Edible offal (mammalian), raw	RAC	0.037	4.79	0.18	9.68	0.36	2.97	0.11	5.49	0.20	3.84	0.14	5.03	0.19
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.016	289.65	4.63	485.88	7.77	26.92	0.43	239.03	3.82	199.91	3.20	180.53	2.89
PM 0110	Poultry meat, raw (incl prepared)	RAC	0	14.63	0.00	29.76	0.00	8.04	0.00	129.68	0.00	25.04	0.00	35.66	0.00
PF 0111	Poultry fat, raw (incl rendered)	RAC	0	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.10	0.00	0.10	0.00
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.028	0.12	0.00	0.12	0.00	0.11	0.00	5.37	0.15	0.24	0.01	0.10	0.00
PE 0112	Eggs, raw, (incl dried)	RAC	0.01	7.84	0.08	23.08	0.23	2.88	0.03	14.89	0.15	9.81	0.10	14.83	0.15
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total intake (ug/person)=				251.4		702.1		592.0		467.0		247.7		693.6	
Bodyweight per region (kg bw) =				60		60		60		60		60		60	
ADI (ug/person)=				24000		24000		24000		24000		24000		24000	
%ADI=				1.0 %		2.9 %		2.5 %		1.9 %		1.0 %		2.9 %	
Rounded %ADI=				1 %		3 %		2 %		2 %		1 %		3 %	

FLUDIOXONIL + metabolites for HBGV (211)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.4 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day		Intake as ug/person/day									
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
FC 0001	Group of Citrus fruit, raw (incl kumquat commodities)	RAC	0.41	38.66	15.85	54.93	22.52	26.36	10.81	51.46	21.10	51.06	20.93	466.36	191.21
JF 0001	Group of Citrus fruit, juice	PP	0.64	36.84	23.58	3.75	2.40	0.30	0.19	21.62	13.84	21.82	13.96	46.67	29.87
FP 0009	Group of Pome fruits, raw (incl apple cider, excl apple juice)	RAC	2.1	51.09	107.29	65.40	137.34	42.71	89.69	45.29	95.11	62.51	131.27	7.74	16.25
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.17	14.88	2.53	11.98	2.04	0.15	0.03	9.98	1.70	30.32	5.15	3.47	0.59
FS 0012	Group of Stone fruits, raw (incl dried apricots, excl dried plums)	RAC	0.8	18.18	14.54	23.83	19.06	14.27	11.42	18.52	14.82	9.35	7.48	0.11	0.09

Annex 3

FLUDIOXONIL + metabolites for HBGV (211)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.4 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day							
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
DF 0014	Plums, dried (prunes)	PP	0.96	0.61	0.59	0.35	0.34	0.05	0.05	0.35	0.34	0.49	0.47	0.13	0.12
FB 0264	Blackberries, raw	RAC	1.3	0.09	0.12	0.52	0.68	0.14	0.18	0.24	0.31	NC	-	0.01	0.01
FB 0266	Dewberries, incl boysen- & loganberry, raw	RAC	1.3	0.01	0.01	NC	-	0.01	0.01	0.01	0.01	NC	-	0.01	0.01
FB 0272	Raspberries, red, black, raw	RAC	1.3	0.47	0.61	0.91	1.18	0.01	0.01	0.99	1.29	1.14	1.48	NC	-
FB 0020	Blueberries, raw	RAC	0.78	0.04	0.03	0.23	0.18	0.01	0.01	0.83	0.65	0.33	0.26	NC	-
FB 0021	Currants, Black, Red, White, raw	RAC	0.806	0.48	0.39	4.23	3.41	NC	-	1.51	1.22	0.49	0.39	NC	-
FB 0269	Grapes, raw (incl must, excl dried, excl juice, excl wine)	RAC	0.28	6.48	1.81	11.31	3.17	5.21	1.46	9.50	2.66	4.66	1.30	0.78	0.22
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	0.31	3.09	0.96	1.51	0.47	0.03	0.01	1.38	0.43	4.26	1.32	0.42	0.13
JF 0269	Grape juice (from wine grapes)	PP	0.26	0.56	0.15	1.96	0.51	0.02	0.01	2.24	0.58	2.27	0.59	0.34	0.09
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.08	88.93	7.11	62.41	4.99	1.84	0.15	25.07	2.01	61.17	4.89	5.84	0.47
FB 0275	Strawberry, raw	RAC	0.351	4.49	1.58	5.66	1.99	0.02	0.01	6.63	2.33	5.75	2.02	0.05	0.02
FT 0336	Guava, raw	RAC	0.1625	0.01	0.00	NC	-	0.42	0.07	NC	-	NC	-	NC	-
FI 0326	Avocado, raw	RAC	0.013	2.65	0.03	0.87	0.01	0.46	0.01	1.64	0.02	1.30	0.02	0.96	0.01
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.013	25.76	0.33	23.65	0.31	23.83	0.31	24.37	0.32	19.43	0.25	101.55	1.32
FI 0345	Mango, raw (incl canned mango, incl mango juice)	RAC	0.04	1.80	0.07	0.63	0.03	10.05	0.40	1.07	0.04	3.52	0.14	16.44	0.66
FI 0350	Papaya, raw	RAC	0.15	0.31	0.05	0.18	0.03	1.50	0.23	0.51	0.08	0.54	0.08	1.08	0.16
FI 0355	Pomegranate, raw, (incl processed)	RAC	1.75	7.91	13.84	9.72	17.01	7.67	13.42	5.26	9.21	9.04	15.82	14.43	25.25
FI 0353	Pineapple, raw (incl canned pineapple, incl pineapple juice, incl dried pineapple)	RAC	2	13.13	26.26	11.13	22.26	6.94	13.88	14.36	28.72	36.74	73.48	18.81	37.62
FI 0341	Kiwifruit, raw	RAC	7.2	2.46	17.71	3.62	26.06	0.04	0.29	1.48	10.66	7.43	53.50	0.03	0.22
VA 2031	Subgroup of bulb onions	RAC	0.06	20.67	1.24	31.32	1.88	37.52	2.25	35.08	2.10	11.77	0.71	13.74	0.82
VA 2032	Subgroup of Green Onions	RAC	0.21	5.57	1.17	5.15	1.08	1.77	0.37	4.28	0.90	17.34	3.64	6.48	1.36
VB 0400	Broccoli, raw	RAC	0.23	4.24	0.98	1.76	0.40	NC	-	0.51	0.12	3.79	0.87	0.26	0.06
VB 0041	Cabbages, head, raw	RAC	0.24	8.97	2.15	27.12	6.51	1.44	0.35	24.96	5.99	4.55	1.09	11.23	2.70
VC 0045	Group of Fruiting vegetables, cucurbits, raw	RAC	0.0845	27.81	2.35	41.93	3.54	123.30	10.42	49.47	4.18	15.95	1.35	35.99	3.04
VO 0448	Tomato, raw (incl canned, excl juice, excl paste)	RAC	0.605	43.88	26.55	55.41	33.52	35.38	21.40	74.88	45.30	26.50	16.03	9.51	5.75
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.028	4.96	0.14	3.20	0.09	0.15	0.00	1.61	0.05	6.88	0.19	0.52	0.01
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.026	0.80	0.02	0.07	0.00	0.05	0.00	0.61	0.02	0.40	0.01	0.08	0.00
VO 0051	Subgroup of peppers, raw (incl dried sweet peppers, excl dried chilipeppers), excl okra	RAC	0.234	6.39	1.50	15.53	3.63	19.09	4.47	10.36	2.42	8.29	1.94	4.53	1.06
VO 0440	Egg plant, raw (i.e. aubergine)	RAC	0.078	1.01	0.08	1.69	0.13	21.37	1.67	3.00	0.23	1.40	0.11	NC	-
VL 0483	Lettuce, leaf, raw	RAC	8.312	14.50	120.52	11.76	97.75	13.14	109.22	19.50	162.08	4.81	39.98	2.23	18.54
VL 0502	Spinach, raw	RAC	5.812	2.20	12.79	1.76	10.23	13.38	77.76	2.94	17.09	5.53	32.14	0.02	0.12
VL 0401	Broccoli, Chinese, raw (i.e. kailan)	RAC	1.2	NC	-	NC	-	9.03	10.84	NC	-	NC	-	0.12	0.14
VL 0472	Cress, garden, raw	RAC	1.2	0.10	0.12	NC	-	1.27	1.52	0.13	0.16	0.21	0.25	0.10	0.12
VL 0480	Kale (Borecole, Collards), raw	RAC	1.2	NC	-	NC	-	14.54	17.45	NC	-	NC	-	2.32	2.78

Annex 3

732

FLUDIOXONIL + metabolites for HBGV (211)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.4 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day							
				G07		G08		G09		G10		G11		G12	
				diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
VL 0485	Mustard greens, raw (i.e. Indian mustard, Amsoi, mustard cabbage)	RAC	1.212	NC	-	NC	-	NC	-	NC	-	NC	-	0.13	0.16
VL 0494	Radish leaves, raw	RAC	3.809	NC	-	NC	-	NC	-	3.78	14.40	NC	-	0.48	1.83
VL 0495	Rape greens, raw	RAC	1.2	NC	-	NC	-	1.93	2.32	NC	-	NC	-	0.12	0.14
VL 0496	Rucola, raw (i.e. Arrugula, Rocket salad, Roquette)	RAC	1.2	NC	-	NC	-	NC	-	1.09	1.31	0.38	0.46	2.40	2.88
VL 2052	Subgroup of Leaves of Root and Tuber Vegetables	RAC	0.009	NC	-	NC	-	NC	-	NC	-	NC	-	0.33	0.00
VL 0473	Watercress, raw	RAC	1.2	0.35	0.42	3.13	3.76	0.32	0.38	NC	-	NC	-	2.30	2.76
VP 2060	Subgroup of beans with pods (all commodities within this group)	RAC	0.1595	5.07	0.81	0.83	0.13	0.17	0.03	3.70	0.59	NC	-	NC	-
VP 0062	Beans without pods: (Phaseolus spp.) (succulent seeds), raw	RAC	0.058	2.21	0.13	5.25	0.30	4.17	0.24	1.61	0.09	16.95	0.98	0.17	0.01
VP 0064	Peas without pods (Pisum spp) (succulent seeds)	RAC	0.058	10.72	0.62	1.99	0.12	2.72	0.16	4.26	0.25	4.23	0.25	NC	-
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	0.0841	1.51	0.13	1.50	0.13	1.90	0.16	5.11	0.43	1.36	0.11	23.43	1.97
VD 0523	Broad bean, dry, raw (incl horse-bean, field bean) (Vicia faba)	RAC	0.0841	0.02	0.00	0.01	0.00	1.16	0.10	0.40	0.03	NC	-	0.06	0.01
VD 0527	Cowpea, dry, raw (Vigna sinensis, Dolichos sinensis)	RAC	0.0841	NC	-	NC	-	0.16	0.01	0.01	0.00	NC	-	NC	-
VD 0541	Soya bean, dry, raw (incl paste, incl curd, incl oil, incl sauce)	RAC	0.029	106.33	3.08	117.78	3.42	42.12	1.22	195.70	5.68	222.52	6.45	80.47	2.33
-	Beans (dry) NES: including inter alia lablab or hyacinth bean (Dolichos spp.); jack or sword bean (Canavalia spp.); winged bean (Psophocarpus tetragonolobus); guar bean (Cyamopsis tetragonoloba); velvet bean (Stizolobium spp.); yam bean (Pachyrrhizus erosus)	RAC	0.0841	0.01	0.00	NC	-	0.57	0.05	0.11	0.01	0.16	0.01	0.94	0.08
VD 2066	Subgroup of dry peas, raw	RAC	0.319	5.01	1.60	3.76	1.20	1.82	0.58	3.44	1.10	3.49	1.11	5.15	1.64
VR 0574	Beetroot, raw	RAC	0.008	9.91	0.08	6.34	0.05	NC	-	9.65	0.08	19.11	0.15	6.47	0.05
VR 0575	Burdock, greater or edible, raw	RAC	0.008	NC	-	NC	-	NC	-	0.48	0.00	NC	-	0.06	0.00
VR 0577	Carrots, raw	RAC	0.293	26.26	7.69	27.13	7.95	10.07	2.95	16.49	4.83	44.69	13.09	8.75	2.56
VR 0578	Celeriac, raw	RAC	0.008	2.97	0.02	1.79	0.01	NC	-	0.06	0.00	16.91	0.14	3.22	0.03
VR 0469	Chicory, roots, raw	RAC	0.008	0.01	0.00	0.51	0.00	0.01	0.00	0.01	0.00	21.12	0.17	NC	-
VR 0583	Horseradish, raw	RAC	0.008	0.01	0.00	0.42	0.00	13.01	0.10	0.26	0.00	2.70	0.02	0.97	0.01
VR 0587	Parsley turnip-rooted, raw	RAC	0.008	NC	-	NC	-	NC	-	NC	-	NC	-	0.61	0.00
VR 0588	Parsnip, raw	RAC	0.008	4.42	0.04	0.06	0.00	NC	-	NC	-	NC	-	1.12	0.01
VR 0494	Radish roots, raw	RAC	0.098	3.83	0.38	11.99	1.18	NC	-	5.26	0.52	2.19	0.21	4.37	0.43
VR 0591	Japanese radish, raw (i.e. Chinese radish, Daikon)	RAC	0.008	NC	-	NC	-	26.64	0.21	18.92	0.15	NC	-	3.59	0.03
VR 0498	Salsify, raw (i.e. Oysterplant)	RAC	0.008	1.02	0.01	0.52	0.00	NC	-	NC	-	2.08	0.02	0.39	0.00

Annex 3

FLUDIOXONIL + metabolites for HBGV (211)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.4 mg/kg bw

Codex Code	Commodity description	Expr as	STM ^R mg/kg	Diets as g/person/day				Intake as ug/person/day							
				G07		G08		G09		G10		G11		G12	
				diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
VR 0596	Sugar beet, raw (incl sugar)	RAC	0.008	0.01	0.00	NC	-	0.01	0.00	0.01	0.00	NC	-	NC	-
VR 0596	Sugar beet, raw	RAC	1.108	0.01	0.01	NC	-	0.01	0.01	0.01	0.01	NC	-	NC	-
-	Sugar beet, sugar	PP	0.118	0.01	0.00	NC	-	0.01	0.00	NC	-	NC	-	NC	-
VR 0497	Swede, raw (i.e. Rutabaga)	RAC	0.008	10.01	0.08	1.66	0.01	NC	-	NC	-	3.06	0.02	2.99	0.02
VR 0506	Turnip, garden, raw	RAC	0.008	5.78	0.05	15.35	0.12	NC	-	6.54	0.05	1.95	0.02	4.73	0.04
VR 2071	Subgroup of tuberous and corm vegetables, raw (incl processed)	RAC	0.008	226.09	1.81	234.58	1.88	161.10	1.29	185.04	1.48	234.85	1.88	100.25	0.80
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	1.408	225.03	316.84	234.24	329.81	71.48	100.64	177.55	249.99	234.55	330.25	37.71	53.10
VR 0508	Sweet potato, raw (incl dried)	RAC	3.508	0.93	3.26	0.32	1.12	64.65	226.79	5.37	18.84	0.30	1.05	3.13	10.98
VR 0600	Yams, raw (incl dried)	RAC	3.508	NC	-	NC	-	0.03	0.11	0.71	2.49	NC	-	17.57	61.64
VS 0624	Celery	RAC	4.55	7.68	34.94	2.85	12.97	NC	-	3.34	15.20	16.83	76.58	4.04	18.38
GC 0080	Group of Cereal grains, raw, (incl processed) (incl sweet corn)	RAC	0.02	345.63	6.91	386.16	7.72	514.33	10.29	402.72	8.05	295.30	5.91	359.97	7.20
GC 0447	Sweet corn on the cob, raw (incl frozen kernels, incl canned kernels)	RAC	0.01	11.43	0.11	3.71	0.04	0.74	0.01	13.63	0.14	3.07	0.03	1.50	0.02
TN 0660	Almonds, nutmeat	RAC	0.013	0.81	0.01	2.21	0.03	0.03	0.00	1.02	0.01	1.47	0.02	NC	-
TN 0662	Brazil nuts, nutmeat	RAC	0.013	0.12	0.00	0.05	0.00	0.01	0.00	0.05	0.00	0.13	0.00	NC	-
TN 0295	Cashew nuts, nutmeat	RAC	0.013	0.59	0.01	0.23	0.00	0.18	0.00	0.52	0.01	1.75	0.02	2.78	0.04
TN 0664	Chestnut, raw	RAC	0.013	0.34	0.00	0.21	0.00	1.14	0.01	0.52	0.01	0.09	0.00	NC	-
TN 0665	Coconut, nutmeat (incl. copra, incl desiccated, incl oil)	RAC	0.013	4.13	0.05	2.73	0.04	13.15	0.17	5.85	0.08	6.92	0.09	22.24	0.29
TN 0666	Hazelnuts, nutmeat	RAC	0.013	0.45	0.01	1.12	0.01	0.02	0.00	0.34	0.00	1.63	0.02	NC	-
TN 0669	Macadamia nuts, nutmeat (i.e. Queensland nuts)	RAC	0.013	NC	-	0.40	0.01	NC	-	NC	-	NC	-	0.07	0.00
TN 0672	Pecan, nutmeat	RAC	0.013	0.38	0.00	NC	-	NC	-	0.27	0.00	NC	-	0.26	0.00
TN 0673	Pine nut, nutmeat (i.e. pignolia nuts)	RAC	0.013	0.99	0.01	0.66	0.01	0.22	0.00	0.27	0.00	1.89	0.02	0.89	0.01
TN 0675	Pistachio nut, nutmeat	RAC	0.065	0.35	0.02	0.48	0.03	0.07	0.00	0.39	0.03	0.23	0.01	0.02	0.00
TN 0678	Walnut, nutmeat	RAC	0.013	0.34	0.00	0.84	0.01	0.28	0.00	0.39	0.01	0.45	0.01	NC	-
SO 0495	Rape seed, raw (incl oil)	RAC	0.02	32.68	0.65	19.91	0.40	7.83	0.16	15.69	0.31	NC	-	NC	-
SO 0691	Cotton seed, raw (incl oil)	RAC	0.05	10.71	0.54	4.23	0.21	7.19	0.36	7.54	0.38	5.66	0.28	2.38	0.12
HH 0092	Group of Herbs, raw (incl dried)	RAC	2.65	2.61	6.92	2.31	6.12	8.89	23.56	3.92	10.39	1.16	3.07	2.06	5.46
HS 0444	Peppers, chili, dried	PP	1.56	0.11	0.17	0.21	0.33	0.36	0.56	0.21	0.33	0.25	0.39	0.15	0.23
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80 % as muscle	RAC	0.006	112.02	0.67	120.71	0.72	63.46	0.38	88.99	0.53	96.24	0.58	41.02	0.25
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20 % as fat	RAC	0.006	28.01	0.17	30.18	0.18	15.86	0.10	22.25	0.13	24.06	0.14	10.25	0.06
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.006	6.44	0.04	15.51	0.09	3.79	0.02	8.29	0.05	18.44	0.11	8.00	0.05
MO	Edible offal (mammalian), raw	RAC	0.037	15.17	0.56	5.19	0.19	6.30	0.23	6.78	0.25	3.32	0.12	3.17	0.12

Annex 3

FLUDIOXONIL + metabolites for HBGV (211)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.4 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day																			
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake												
0105																											
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.016	388.92	6.22	335.88	5.37	49.15	0.79	331.25	5.30	468.56	7.50	245.45	3.93												
PM 0110	Poultry meat, raw (incl prepared)	RAC	0	73.76	0.00	53.86	0.00	23.98	0.00	87.12	0.00	53.38	0.00	84.45	0.00												
PF 0111	Poultry fat, raw (incl rendered)	RAC	0	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.71	0.00	NC	-												
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.028	0.33	0.01	0.72	0.02	0.27	0.01	0.35	0.01	0.80	0.02	NC	-												
PE 0112	Eggs, raw, (incl dried)	RAC	0.01	25.84	0.26	29.53	0.30	28.05	0.28	33.19	0.33	36.44	0.36	8.89	0.09												
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-												
Total intake (ug/person)=				800.4				810.8				774.6				791.9				884.8				520.6			
Bodyweight per region (kg bw) =				60				60				55				60				60							
ADI (ug/person)=				24000				24000				22000				24000				24000							
%ADI=				3.3 %				3.4 %				3.5 %				3.3 %				3.7 %				2.2 %			
Rounded %ADI=				3 %				3 %				4 %				3 %				4 %				2 %			

FLUDIOXONIL + metabolites for HBGV (211)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.4 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day				Intake = daily intake: ug/person							
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake		
FC 0001	Group of Citrus fruit, raw (incl kumquat commodities)	RAC	0.41	20.93	8.58	2.35	0.96	30.71	12.59	0.15	0.06	4.45	1.82		
JF 0001	Group of Citrus fruit, juice	PP	0.64	0.11	0.07	0.29	0.19	13.55	8.67	0.14	0.09	0.33	0.21		
FP 0009	Group of Pome fruits, raw (incl apple cider, excl apple juice)	RAC	2.1	68.85	144.59	10.93	22.95	70.82	148.72	189.78	398.54	19.56	41.08		
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.17	0.03	0.01	0.10	0.02	7.19	1.22	0.03	0.01	NC	-		
FS 0012	Group of Stone fruits, raw (incl dried apricots, excl dried plums)	RAC	0.8	0.09	0.07	0.02	0.02	32.27	25.82	0.01	0.01	NC	-		
DF 0014	Plums, dried (prunes)	PP	0.96	0.01	0.01	0.01	0.01	0.37	0.36	0.01	0.01	NC	-		
FB 0264	Blackberries, raw	RAC	1.3	0.01	0.01	7.29	9.48	0.25	0.33	0.01	0.01	NC	-		
FB 0266	Dewberries, incl boysen- & loganberry, raw	RAC	1.3	0.01	0.01	0.01	0.01	NC	-	0.01	0.01	NC	-		
FB 0272	Raspberries, red, black, raw	RAC	1.3	0.01	0.01	0.01	0.01	2.04	2.65	0.01	0.01	NC	-		
FB 0020	Blueberries, raw	RAC	0.78	NC	-	NC	-	0.20	0.16	NC	-	NC	-		
FB 0021	Currants, Black, Red, White, raw	RAC	0.806	0.01	0.01	NC	-	0.74	0.60	NC	-	NC	-		
FB 0269	Grapes, raw (incl must, excl dried, excl juice, excl wine)	RAC	0.28	0.14	0.04	0.36	0.10	15.33	4.29	0.01	0.00	0.28	0.08		
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	0.31	0.01	0.00	0.13	0.04	1.06	0.33	0.01	0.00	0.03	0.01		
JF 0269	Grape juice (from wine grapes)	PP	0.26	0.01	0.00	0.01	0.00	0.41	0.11	0.01	0.00	NC	-		
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.08	0.31	0.02	0.23	0.02	60.43	4.83	0.52	0.04	31.91	2.55		

Annex 3

FLUDIOXONIL + metabolites for HBGV (211)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.4 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day		Intake = daily intake: ug/person							
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
				FB 0275	Strawberry, raw	RAC	0.351	0.01	0.00	0.01	0.00	3.35	1.18
FT 0336	Guava, raw	RAC	0.1625	0.10	0.02	0.08	0.01	NC	-	0.14	0.02	3.11	0.51
FI 0326	Avocado, raw	RAC	0.013	1.12	0.01	0.01	0.00	0.84	0.01	0.01	0.00	6.60	0.09
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.013	44.80	0.58	118.17	1.54	25.25	0.33	454.49	5.91	310.23	4.03
FI 0345	Mango, raw (incl canned mango, incl mango juice)	RAC	0.04	12.25	0.49	6.83	0.27	0.76	0.03	0.01	0.00	20.12	0.80
FI 0350	Papaya, raw	RAC	0.15	6.47	0.97	0.25	0.04	0.19	0.03	0.01	0.00	26.42	3.96
FI 0355	Pomegranate, raw, (incl processed)	RAC	1.75	5.49	9.61	27.17	47.55	NC	-	2.89	5.06	17.87	31.27
FI 0353	Pineapple, raw (incl canned pineapple, incl pineapple juice, incl dried pineapple)	RAC	2	8.51	17.02	6.27	12.54	6.89	13.78	0.18	0.36	24.94	49.88
FI 0341	Kiwifruit, raw	RAC	7.2	0.01	0.07	0.01	0.07	2.00	14.40	0.01	0.07	NC	-
VA 2031	Subgroup of bulb onions	RAC	0.06	9.83	0.59	22.30	1.34	34.69	2.08	9.65	0.58	2.39	0.14
VA 2032	Subgroup of Green Onions	RAC	0.21	1.45	0.30	1.50	0.32	1.42	0.30	0.01	0.00	6.30	1.32
VB 0400	Broccoli, raw	RAC	0.23	0.01	0.00	0.01	0.00	2.13	0.49	0.01	0.00	NC	-
VB 0041	Cabbages, head, raw	RAC	0.24	3.82	0.92	2.99	0.72	49.16	11.80	0.01	0.00	NC	-
VC 0045	Group of Fruiting vegetables, cucurbits, raw	RAC	0.0845	5.96	0.50	9.74	0.82	51.82	4.38	13.61	1.15	0.05	0.00
VO 0448	Tomato, raw (incl canned, excl juice, excl paste)	RAC	0.605	13.10	7.93	4.90	2.96	62.16	37.61	1.04	0.63	0.09	0.05
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.028	0.58	0.02	0.22	0.01	2.21	0.06	0.24	0.01	3.10	0.09
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.026	0.05	0.00	0.01	0.00	0.42	0.01	0.01	0.00	0.02	0.00
VO 0051	Subgroup of peppers, raw (incl dried sweet peppers, excl dried chilipeppers), excl okra	RAC	0.234	8.97	2.10	14.13	3.31	25.14	5.88	0.91	0.21	NC	-
VO 0440	Egg plant, raw (i.e. aubergine)	RAC	0.078	1.31	0.10	8.26	0.64	3.95	0.31	0.01	0.00	NC	-
VL 0483	Lettuce, leaf, raw	RAC	8.312	0.29	2.41	0.03	0.25	6.71	55.77	0.01	0.08	NC	-
VL 0502	Spinach, raw	RAC	5.812	0.17	0.99	0.01	0.06	0.81	4.71	0.01	0.06	NC	-
VL 0401	Broccoli, Chinese, raw (i.e. kailan)	RAC	1.2	0.01	0.01	0.01	0.01	NC	-	0.01	0.01	NC	-
VL 0472	Cress, garden, raw	RAC	1.2	0.09	0.11	0.07	0.08	NC	-	0.06	0.07	0.13	0.16
VL 0480	Kale (Borecole, Collards), raw	RAC	1.2	0.79	0.95	0.62	0.74	NC	-	0.01	0.01	NC	-
VL 0485	Mustard greens, raw (i.e. Indian mustard, Amsoi, mustard cabbage)	RAC	1.212	0.04	0.05	0.03	0.04	NC	-	0.01	0.01	NC	-
VL 0494	Radish leaves, raw	RAC	3.809	0.44	1.68	0.32	1.22	NC	-	0.30	1.14	0.59	2.25
VL 0495	Rape greens, raw	RAC	1.2	0.04	0.05	0.03	0.04	NC	-	0.01	0.01	NC	-
VL 0496	Rucola, raw (i.e. Arrugula, Rocket salad, Roquette)	RAC	1.2	2.17	2.60	1.57	1.88	NC	-	1.47	1.76	2.93	3.52
VL 2052	Subgroup of Leaves of Root and Tuber Vegetables	RAC	0.009	0.30	0.00	0.22	0.00	NC	-	0.20	0.00	0.41	0.00
VL 0473	Watercress, raw	RAC	1.2	2.08	2.50	1.50	1.80	0.01	0.01	1.41	1.69	2.81	3.37
VP 2060	Subgroup of beans with pods (all commodities within this group)	RAC	0.1595	NC	-	NC	-	NC	-	NC	-	NC	-
VP 0062	Beans without pods: (Phaseolus spp.) (succulent seeds), raw	RAC	0.058	0.30	0.02	3.13	0.18	4.11	0.24	0.01	0.00	NC	-
VP 0064	Peas without pods (Pisum spp) (succulent seeds)	RAC	0.058	0.21	0.01	0.02	0.00	5.51	0.32	0.02	0.00	NC	-
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	0.0841	7.11	0.60	2.33	0.20	3.76	0.32	44.70	3.76	3.27	0.28

Annex 3

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FLUDIOXONIL + metabolites for HBGV (211)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.4 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day		Intake = daily intake: ug/person							
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
				VD 0523	Broad bean, dry, raw (incl horse-bean, field bean) (Vicia faba)	RAC	0.0841	3.70	0.31	0.03	0.00	0.17	0.01
VD 0527	Cowpea, dry, raw (Vigna sinensis, Dolichos sinensis)	RAC	0.0841	12.77	1.07	0.99	0.08	0.01	0.00	4.33	0.36	NC	-
VD 0541	Soya bean, dry, raw (incl paste, incl curd, incl oil, incl sauce)	RAC	0.029	15.80	0.46	14.29	0.41	104.36	3.03	17.11	0.50	35.20	1.02
-	Beans (dry) NES: including inter alia lablab or hyacinth bean (Dolichos spp.); jack or sword bean (Canavalia spp.); winged bean (Psophocarpus tetragonolobus); guar bean (Cyamopsis tetragonoloba); velvet bean (Stizolobium spp.); yam bean (Pachyrrhizus erosus)	RAC	0.0841	2.54	0.21	1.77	0.15	0.03	0.00	0.03	0.00	3.99	0.34
VD 2066	Subgroup of dry peas, raw	RAC	0.319	4.43	1.41	11.36	3.62	4.22	1.35	9.36	2.99	1.21	0.39
VR 0574	Beetroot, raw	RAC	0.008	5.86	0.05	4.23	0.03	9.46	0.08	3.96	0.03	7.91	0.06
VR 0575	Burdock, greater or edible, raw	RAC	0.008	0.06	0.00	0.04	0.00	NC	-	0.04	0.00	0.08	0.00
VR 0577	Carrots, raw	RAC	0.293	2.07	0.61	3.00	0.88	25.29	7.41	0.05	0.01	NC	-
VR 0578	Celeriac, raw	RAC	0.008	2.91	0.02	2.10	0.02	7.59	0.06	1.97	0.02	3.93	0.03
VR 0469	Chicory, roots, raw	RAC	0.008	0.01	0.00	0.03	0.00	0.10	0.00	NC	-	NC	-
VR 0583	Horseradish, raw	RAC	0.008	0.88	0.01	0.63	0.01	0.54	0.00	0.59	0.00	1.19	0.01
VR 0587	Parsley turnip-rooted, raw	RAC	0.008	0.55	0.00	0.40	0.00	4.29	0.03	0.37	0.00	0.74	0.01
VR 0588	Parsnip, raw	RAC	0.008	1.02	0.01	0.74	0.01	3.50	0.03	0.69	0.01	1.37	0.01
VR 0494	Radish roots, raw	RAC	0.098	3.96	0.39	2.86	0.28	3.30	0.32	2.67	0.26	5.34	0.52
VR 0591	Japanese radish, raw (i.e. Chinese radish, Daikon)	RAC	0.008	3.25	0.03	2.35	0.02	NC	-	2.20	0.02	4.39	0.04
VR 0498	Salsify, raw (i.e. Oysterplant)	RAC	0.008	0.36	0.00	0.26	0.00	NC	-	0.24	0.00	0.48	0.00
VR 0596	Sugar beet, raw (incl sugar)	RAC	0.008	3.93	0.03	1.68	0.01	NC	-	NC	-	36.12	0.29
VR 0596	Sugar beet, raw	RAC	1.108	0.01	0.01	NC	-	NC	-	NC	-	NC	-
-	Sugar beet, sugar	PP	0.118	0.56	0.07	0.24	0.03	NC	-	NC	-	5.13	0.61
VR 0497	Swede, raw (i.e. Rutabaga)	RAC	0.008	2.71	0.02	1.96	0.02	7.80	0.06	1.83	0.01	3.66	0.03
VR 0506	Turnip, garden, raw	RAC	0.008	4.29	0.03	3.10	0.02	6.41	0.05	2.90	0.02	5.79	0.05
VR 2071	Subgroup of tuberous and corm vegetables, raw (incl processed)	RAC	0.008	250.41	2.00	208.74	1.67	213.64	1.71	602.70	4.82	388.95	3.11
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	1.408	23.96	33.74	13.56	19.09	213.41	300.48	104.35	146.92	8.56	12.05
VR 0508	Sweet potato, raw (incl dried)	RAC	3.508	28.83	101.14	61.55	215.92	0.15	0.53	221.94	778.57	NC	-
VR 0600	Yams, raw (incl dried)	RAC	3.508	70.93	248.82	30.62	107.41	0.07	0.25	5.65	19.82	30.85	108.22
VS 0624	Celery	RAC	4.55	3.66	16.65	2.65	12.06	4.84	22.02	2.47	11.24	4.94	22.48
GC 0080	Group of Cereal grains, raw, (incl processed) (incl sweet corn)	RAC	0.02	407.04	8.14	417.04	8.34	402.79	8.06	195.30	3.91	263.26	5.27
GC 0447	Sweet corn on the cob, raw (incl frozen kernels, incl canned kernels)	RAC	0.01	3.63	0.04	20.50	0.21	8.78	0.09	0.02	0.00	0.17	0.00
TN 0660	Almonds, nutmeat	RAC	0.013	0.01	0.00	0.01	0.00	0.61	0.01	0.01	0.00	NC	-

Annex 3

FLUDIOXONIL + metabolites for HBGV (211)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.4 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day										Intake = daily intake: ug/person	
				G13		G14		G15		G16		G17		G17 diet	G17 intake
				diet	intake	diet	intake	diet	intake	diet	intake	diet	intake		
TN 0662	Brazil nuts, nutmeat	RAC	0.013	0.01	0.00	0.01	0.00	0.02	0.00	0.01	0.00	NC	-		
TN 0295	Cashew nuts, nutmeat	RAC	0.013	0.91	0.01	0.14	0.00	0.11	0.00	0.01	0.00	NC	-		
TN 0664	Chestnut, raw	RAC	0.013	0.01	0.00	0.01	0.00	0.75	0.01	0.01	0.00	NC	-		
TN 0665	Coconut, nutmeat (incl. copra, incl desiccated, incl oil)	RAC	0.013	2.77	0.04	134.37	1.75	2.81	0.04	0.70	0.01	317.67	4.13		
TN 0666	Hazelnuts, nutmeat	RAC	0.013	0.01	0.00	0.01	0.00	0.21	0.00	0.01	0.00	NC	-		
TN 0669	Macadamia nuts, nutmeat (i.e. Queensland nuts)	RAC	0.013	0.04	0.00	0.05	0.00	NC	-	0.01	0.00	0.01	0.00		
TN 0672	Pecan, nutmeat	RAC	0.013	0.15	0.00	0.22	0.00	0.31	0.00	0.01	0.00	0.01	0.00		
TN 0673	Pine nut, nutmeat (i.e. pignolia nuts)	RAC	0.013	0.51	0.01	0.74	0.01	0.36	0.00	0.01	0.00	0.05	0.00		
TN 0675	Pistachio nut, nutmeat	RAC	0.065	0.01	0.00	0.01	0.00	0.15	0.01	0.01	0.00	NC	-		
TN 0678	Walnut, nutmeat	RAC	0.013	0.01	0.00	0.01	0.00	0.81	0.01	0.01	0.00	NC	-		
SO 0495	Rape seed, raw (incl oil)	RAC	0.02	0.19	0.00	0.07	0.00	12.07	0.24	0.08	0.00	NC	-		
SO 0691	Cotton seed, raw (incl oil)	RAC	0.05	8.14	0.41	0.32	0.02	2.84	0.14	2.69	0.13	0.97	0.05		
HH 0092	Group of Herbs, raw (incl dried)	RAC	2.65	1.85	4.90	1.67	4.43	2.80	7.42	1.24	3.29	2.75	7.29		
HS 0444	Peppers, chili, dried	PP	1.56	0.58	0.90	1.27	1.98	1.21	1.89	0.12	0.19	NC	-		
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80 % as muscle	RAC	0.006	23.34	0.14	40.71	0.24	97.15	0.58	18.06	0.11	57.71	0.35		
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20 % as fat	RAC	0.006	5.84	0.04	10.18	0.06	24.29	0.15	4.52	0.03	14.43	0.09		
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.006	1.05	0.01	1.14	0.01	18.69	0.11	0.94	0.01	3.12	0.02		
MO 0105	Edible offal (mammalian), raw	RAC	0.037	4.64	0.17	1.97	0.07	10.01	0.37	3.27	0.12	3.98	0.15		
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.016	108.75	1.74	70.31	1.12	436.11	6.98	61.55	0.98	79.09	1.27		
PM 0110	Poultry meat, raw (incl prepared)	RAC	0	3.92	0.00	12.03	0.00	57.07	0.00	5.03	0.00	55.56	0.00		
PF 0111	Poultry fat, raw (incl rendered)	RAC	0	NC	-	NC	-	0.32	0.00	NC	-	NC	-		
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.028	0.10	0.00	0.70	0.02	0.97	0.03	0.10	0.00	NC	-		
PE 0112	Eggs, raw, (incl dried)	RAC	0.01	3.84	0.04	4.41	0.04	27.25	0.27	1.13	0.01	7.39	0.07		
-	-	-	-	-	-	-	-	-	-	-	-	-	-		
Total intake (ug/person)=				630.3		492.5		728.5		1395.8		315.4			
Bodyweight per region (kg bw) =				60		60		60		60		60			
ADI (ug/person)=				24000		24000		24000		24000		24000			
%ADI=				2.6 %		2.1 %		3.0 %		5.8 %		1.3 %			
Rounded %ADI=				3 %		2 %		3 %		6 %		1 %			

Annex 3

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FLUINDAPYR (328)

International Estimated Daily Intake (IEDI)

ADI = 0–0.04 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day						Intake as ug/person/day					
				G01		G02		G03		G04		G05		G06	
				diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
GC 0648	Quinoa, raw	RAC	0.074	NC	-	NC	-	NC	-	NC	-	0.07	0.01	NC	-
GC 0650	Rye, raw (incl flour)	RAC	0.074	0.13	0.01	19.38	1.43	0.10	0.01	0.12	0.01	0.03	0.00	2.15	0.16
GC 0653	Triticale, raw (incl flour)	RAC	0.074	NC	-	NC	-	NC	-	0.01	0.00	0.39	0.03	NC	-
GC 0654	Wheat, raw (incl meslin)	RAC	0.074	0.01	0.00	1.12	0.08	NC	-	0.01	0.00	0.56	0.04	NC	-
-	Wheat, bulgur	PP	0.074	NC	-	NC	-	NC	-	0.03	0.00	NC	-	NC	-
CF 1210	Wheat, germ	PP	0.031	NC	-	NC	-	0.01	0.00	0.01	0.00	0.14	0.00	0.01	0.00
CP 1212	Wheat, wholemeal bread	PP	0.037	0.01	0.00	0.01	0.00	0.01	0.00	0.01	0.00	0.03	0.00	0.01	0.00
CP 1211	Wheat, white bread	PP	0.026	0.25	0.01	0.63	0.02	0.12	0.00	0.43	0.01	1.39	0.04	0.22	0.01
-	Wheat, Fermented Beverages (Korean jakju and takju)	PP	0.074	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
CF 1211	Wheat, white flour	PP	0.026	299.27	7.78	263.32	6.85	27.93	0.73	214.18	5.57	133.47	3.47	340.03	8.84
-	Wheat, starch	PP	0.074	0.02	0.00	NC	-	0.01	0.00	0.05	0.00	0.13	0.01	0.01	0.00
-	Wheat, gluten	PP	0.034	0.01	0.00	0.01	0.00	0.01	0.00	0.27	0.01	0.01	0.00	0.03	0.00
-	Wheat, macaroni, dry	PP	0.026	0.72	0.02	2.20	0.06	1.22	0.03	3.99	0.10	0.53	0.01	1.66	0.04
-	Wheat, pastry, baked	PP	0.026	1.21	0.03	3.13	0.08	1.05	0.03	4.02	0.10	0.60	0.02	1.40	0.04
GC 0646	Millet, raw (incl flour, incl beer)	RAC	0.395	1.46	0.58	2.32	0.92	5.84	2.31	0.89	0.35	16.17	6.39	0.01	0.00
GC 0651	Sorghum, raw (incl beer, excl flour)(i.e. Chicken corn, Dari seed, Durra, Feterita)	RAC	0.395	NC	-	0.01	0.00	3.34	1.32	0.01	0.00	NC	-	NC	-
-	Sorghum, flour (white flour and wholemeal flour)	PP	0.17	3.91	0.66	NC	-	11.62	1.98	14.24	2.42	9.87	1.68	2.62	0.45
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl flour, incl beer, incl germ, incl starch, excl oil)	RAC	0.02	28.85	0.58	43.93	0.88	108.66	2.17	46.94	0.94	59.87	1.20	73.58	1.47
OR 0645	Maize oil	PP	0.036	0.96	0.03	0.85	0.03	0.29	0.01	5.42	0.20	0.42	0.02	2.10	0.08
GC 0447	Sweet corn on the cob, raw (incl frozen kernels, incl canned kernels)	RAC	0.02	0.14	0.00	0.94	0.02	5.70	0.11	2.61	0.05	1.94	0.04	0.22	0.00
TN 0085	Group of Tree nuts, raw (incl processed)	RAC	0.0205	4.06	0.08	3.27	0.07	7.01	0.14	13.93	0.29	14.01	0.29	9.36	0.19
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total intake (ug/person)=				9.8		10.4		8.8		10.1		13.2		11.3	
Bodyweight per region (kg bw) =				60		60		60		60		60		60	
ADI (ug/person)=				2400		2400		2400		2400		2400		2400	
%ADI=				0.4 %		0.4 %		0.4 %		0.4 %		0.6 %		0.5 %	
Rounded %ADI=				0 %		0 %		0 %		0 %		1 %		0 %	

Annex 3

FLUINDAPYR (328)

International Estimated Daily Intake (IEDI)

ADI = 0–0.04 mg/kg bw

Codex Code	Commodity description	Expras	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day							
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
GC 0648	Quinoa, raw	RAC	0.074	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
GC 0650	Rye, raw (incl flour)	RAC	0.074	3.21	0.24	35.38	2.62	0.21	0.02	6.50	0.48	1.49	0.11	NC	-
GC 0653	Triticale, raw (incl flour)	RAC	0.074	0.01	0.00	0.17	0.01	0.29	0.02	0.01	0.00	NC	-	NC	-
GC 0654	Wheat, raw (incl meslin)	RAC	0.074	NC	-	NC	-	NC	-	0.01	0.00	NC	-	NC	-
-	Wheat, bulgur	PP	0.074	NC	-	NC	-	0.01	0.00	NC	-	NC	-	NC	-
CF 1210	Wheat, germ	PP	0.031	0.97	0.03	0.10	0.00	0.03	0.00	0.01	0.00	NC	-	0.04	0.00
CP 1212	Wheat, wholemeal bread	PP	0.037	0.03	0.00	0.01	0.00	0.01	0.00	0.01	0.00	0.05	0.00	0.02	0.00
CP 1211	Wheat, white bread	PP	0.026	1.30	0.03	0.46	0.01	0.06	0.00	0.22	0.01	2.44	0.06	0.77	0.02
-	Wheat, Fermented Beverages (Korean jakju and takju)	PP	0.074	NC	-	NC	-	NC	-	4.36	0.32	NC	-	NC	-
CF 1211	Wheat, white flour	PP	0.026	182.77	4.75	187.54	4.88	103.82	2.70	180.42	4.69	164.00	4.26	118.84	3.09
-	Wheat, starch	PP	0.074	NC	-	NC	-	0.01	0.00	0.31	0.02	NC	-	NC	-
-	Wheat, gluten	PP	0.034	0.68	0.02	NC	-	0.01	0.00	0.01	0.00	NC	-	NC	-
-	Wheat, macaroni, dry	PP	0.026	6.71	0.17	4.98	0.13	2.12	0.06	1.90	0.05	2.89	0.08	4.12	0.11
-	Wheat, pastry, baked	PP	0.026	7.93	0.21	0.51	0.01	0.29	0.01	2.44	0.06	1.78	0.05	8.64	0.22
GC 0646	Millet, raw (incl flour, incl beer)	RAC	0.395	0.03	0.01	0.16	0.06	1.75	0.69	0.69	0.27	NC	-	NC	-
GC 0651	Sorghum, raw (incl beer, excl flour)(i.e. Chicken corn, Dari seed, Durra, Feterita)	RAC	0.395	NC	-	NC	-	0.01	0.00	1.15	0.45	NC	-	7.12	2.81
-	Sorghum, flour (white flour and wholemeal flour)	PP	0.17	NC	-	NC	-	1.29	0.22	0.01	0.00	NC	-	NC	-
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl flour, incl beer, incl germ, incl starch, excl oil)	RAC	0.02	17.61	0.35	25.71	0.51	25.89	0.52	36.98	0.74	5.49	0.11	64.23	1.28
OR 0645	Maize oil	PP	0.036	0.90	0.03	0.47	0.02	0.15	0.01	3.01	0.11	1.86	0.07	0.36	0.01
GC 0447	Sweet corn on the cob, raw (incl frozen kernels, incl canned kernels)	RAC	0.02	11.43	0.23	3.71	0.07	0.74	0.01	13.63	0.27	3.07	0.06	1.50	0.03
TN 0085	Group of Tree nuts, raw (incl processed)	RAC	0.0205	8.52	0.17	8.94	0.18	15.09	0.31	9.60	0.20	14.57	0.30	26.26	0.54
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total intake (ug/person)=				6.3		8.5		4.6		7.7		5.1		8.1	
Bodyweight per region (kg bw) =				60		60		55		60		60		60	
ADI (ug/person)=				2400		2400		2200		2400		2400		2400	
%ADI=				0.3 %		0.4 %		0.2 %		0.3 %		0.2 %		0.3 %	
Rounded %ADI=				0 %		0 %		0 %		0 %		0 %		0 %	

Annex 3

740

FLUINDAPYR (328)

International Estimated Daily Intake (IEDI)

ADI = 0–0.04 mg/kg bw

Codex Code	Commodity description	Expras	STMR mg/kg	Diets: g/person/day		Intake = daily intake: ug/person							
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
GC 0648	Quinoa, raw	RAC	0.074	NC	-	NC	-	NC	-	NC	-	NC	-
GC 0650	Rye, raw (incl flour)	RAC	0.074	0.03	0.00	0.01	0.00	13.95	1.03	0.01	0.00	0.88	0.07
GC 0653	Triticale, raw (incl flour)	RAC	0.074	0.01	0.00	NC	-	NC	-	NC	-	NC	-
GC 0654	Wheat, raw (incl meslin)	RAC	0.074	NC	-	NC	-	NC	-	NC	-	0.97	0.07
-	Wheat, bulgur	PP	0.074	0.01	0.00	NC	-	NC	-	NC	-	NC	-
CF 1210	Wheat, germ	PP	0.031	0.04	0.00	0.01	0.00	0.01	0.00	0.01	0.00	NC	-
CP 1212	Wheat, wholemeal bread	PP	0.037	0.01	0.00	0.01	0.00	0.03	0.00	0.01	0.00	0.01	0.00
CP 1211	Wheat, white bread	PP	0.026	0.43	0.01	0.41	0.01	1.56	0.04	0.11	0.00	0.07	0.00
-	Wheat, Fermented Beverages (Korean jakju and takju)	PP	0.074	NC	-	NC	-	NC	-	NC	-	NC	-
CF 1211	Wheat, white flour	PP	0.026	43.75	1.14	85.81	2.23	206.68	5.37	19.38	0.50	92.92	2.42
-	Wheat, starch	PP	0.074	0.01	0.00	0.02	0.00	NC	-	NC	-	NC	-
-	Wheat, gluten	PP	0.034	0.01	0.00	0.01	0.00	0.01	0.00	0.01	0.00	0.19	0.01
-	Wheat, macaroni, dry	PP	0.026	0.52	0.01	0.63	0.02	2.99	0.08	0.26	0.01	5.18	0.13
-	Wheat, pastry, baked	PP	0.026	0.51	0.01	0.51	0.01	4.36	0.11	0.67	0.02	5.32	0.14
GC 0646	Millet, raw (incl flour, incl beer)	RAC	0.395	61.13	24.15	0.78	0.31	NC	-	33.55	13.25	NC	-
GC 0651	Sorghum, raw (incl beer, excl flour)(i.e. Chicken corn, Dari seed, Durra, Feterita)	RAC	0.395	4.73	1.87	NC	-	NC	-	13.36	5.28	NC	-
-	Sorghum, flour (white flour and wholemeal flour)	PP	0.17	75.99	12.92	1.82	0.31	NC	-	19.82	3.37	NC	-
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl flour, incl beer, incl germ, incl starch, excl oil)	RAC	0.02	116.33	2.33	10.45	0.21	37.65	0.75	76.60	1.53	34.44	0.69
OR 0645	Maize oil	PP	0.036	0.33	0.01	0.07	0.00	0.81	0.03	0.01	0.00	NC	-
GC 0447	Sweet corn on the cob, raw (incl frozen kernels, incl canned kernels)	RAC	0.02	3.63	0.07	20.50	0.41	8.78	0.18	0.02	0.00	0.17	0.00
TN 0085	Group of Tree nuts, raw (incl processed)	RAC	0.0205	4.39	0.09	135.53	2.78	6.11	0.13	0.72	0.01	317.74	6.51
-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total intake (ug/person)=				42.6		6.3		7.7		24.0		10.0	
Bodyweight per region (kg bw) =				60		60		60		60		60	
ADI (ug/person)=				2400		2400		2400		2400		2400	
%ADI=				1.8 %		0.3 %		0.3 %		1.0 %		0.4 %	
Rounded %ADI=				2 %		0 %		0 %		1 %		0 %	

Annex 3

FLUPYRADIFURONE (285)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.08 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day						Intake as ug/person/day					
				G01		G02		G03		G04		G05		G06	
				diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
JF 0001	Group of Citrus fruit, juice	PP	0.068	1.30	0.09	2.37	0.16	0.22	0.01	13.88	0.94	0.75	0.05	2.63	0.18
FC 0002	Subgroup of Lemons and limes, raw (incl kumquat commodities)	RAC	0.32	4.78	1.53	2.42	0.77	3.61	1.16	25.18	8.06	8.25	2.64	15.77	5.05
FC 0003	Subgroup of Mandarins, raw	RAC	0.44	6.18	2.72	3.66	1.61	0.25	0.11	6.82	3.00	3.49	1.54	19.38	8.53
FC 0004	Subgroup of Oranges, sweet, sour, raw	RAC	0.505	20.66	10.43	5.23	2.64	11.90	6.01	37.90	19.14	21.16	10.69	56.46	28.51
FC 0005	Subgroup of Pummelo and grapefruits, raw	RAC	0.21	0.64	0.13	0.35	0.07	0.93	0.20	6.10	1.28	1.01	0.21	1.36	0.29
FP 0009	Group of Pome fruits, raw (incl apple cider, excl apple juice)	RAC	0.45	19.35	8.71	34.06	15.33	17.87	8.04	25.74	11.58	7.69	3.46	56.85	25.58
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.14	0.32	0.04	3.07	0.43	0.07	0.01	5.00	0.70	0.29	0.04	5.57	0.78
FS 0013	Subgroup of Cherries, raw	RAC	0.555	0.92	0.51	9.15	5.08	0.01	0.01	0.61	0.34	0.06	0.03	6.64	3.69
FS 0014	Subgroup of Plums, raw	RAC	0.23	2.40	0.55	8.60	1.98	0.06	0.01	2.52	0.58	0.58	0.13	4.16	0.96
DF 0014	Plums, dried (prunes)	PP	1.15	0.09	0.10	0.06	0.07	0.01	0.01	0.18	0.21	0.04	0.05	0.06	0.07
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.39	8.01	3.12	5.87	2.29	0.18	0.07	8.19	3.19	1.64	0.64	22.46	8.76
FB 2005	Subgroup of Caneberries, raw	RAC	1.4	0.42	0.59	1.05	1.47	0.01	0.01	0.02	0.03	0.02	0.03	1.24	1.74
FB 2006	Subgroup of Bush berries, raw (including processed)	RAC	0.725	0.53	0.38	1.31	0.95	0.40	0.29	1.66	1.20	0.01	0.01	0.99	0.72
FB 0269	Grapes, raw (i.e. table grapes)	RAC	0.63	12.68	7.99	9.12	5.75	0.03	0.02	16.88	10.63	3.70	2.33	54.42	34.28
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	1.6	0.51	0.82	0.51	0.82	0.01	0.02	1.27	2.03	0.12	0.19	2.07	3.31
JF 0269	Grape juice (from wine grapes)	PP	0.43	0.14	0.06	0.29	0.12	0.05	0.02	0.30	0.13	0.24	0.10	0.05	0.02
-	Graps must (from wine-grapes)	PP	0.44	0.33	0.15	0.13	0.06	0.01	0.00	0.02	0.01	0.01	0.00	0.02	0.01
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.26	0.67	0.17	12.53	3.26	2.01	0.52	1.21	0.31	3.53	0.92	4.01	1.04
FB 0275	Strawberry, raw	RAC	1.505	0.70	1.05	2.01	3.03	0.04	0.06	1.36	2.05	0.37	0.56	2.53	3.81
FI 0326	Avocado, raw	RAC	0.28	0.13	0.04	0.03	0.01	2.05	0.57	2.54	0.71	2.34	0.66	0.12	0.03
FI 0353	Pineapple, raw (incl canned pineapple, incl dried pineapple, excl pineapple juice)	RAC	0.13	0.54	0.07	0.58	0.08	7.69	1.00	6.02	0.78	8.26	1.07	0.82	0.11
JF 0341	Pineapple juice (single strength, incl concentrated)	PP	0.044	0.04	0.00	0.57	0.03	0.12	0.01	1.96	0.09	0.29	0.01	0.28	0.01
VA 0035	Group of Bulb vegetables, raw	RAC	0.18	34.29	6.17	46.37	8.35	4.73	0.85	41.36	7.44	21.08	3.79	52.54	9.46
VB 0404	Cauliflower, raw	RAC	0.48	1.65	0.79	0.32	0.15	0.01	0.00	2.33	1.12	4.79	2.30	2.03	0.97
VB 0041	Cabbages, head, raw	RAC	0.79	2.73	2.16	27.92	22.06	0.55	0.43	4.47	3.53	4.27	3.37	10.25	8.10
VC 0431	Squash, Summer (Courgette, Marrow, Zucchetti, Zucchini), raw	RAC	0.655	0.78	0.51	2.06	1.35	0.30	0.20	1.61	1.05	2.25	1.47	2.36	1.55
VC 0046	Melons, except watermelon, raw (Cantaloupe)	RAC	0.57	8.90	5.07	8.64	4.92	0.80	0.46	17.90	10.20	2.80	1.60	29.17	16.63
VO 0448	Tomato, raw (incl canned, excl juice, excl paste)	RAC	0.71	42.04	29.85	76.13	54.05	10.69	7.59	84.59	60.06	24.92	17.69	203.27	144.32
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	1.3	2.34	3.04	1.33	1.73	1.57	2.04	4.24	5.51	0.34	0.44	2.83	3.68
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.48	0.29	0.14	0.29	0.14	0.01	0.00	0.38	0.18	0.05	0.02	0.14	0.07
VO 0051	Subgroup of peppers, raw (incl dried sweet	RAC	0.68	8.48	5.77	13.74	9.34	10.13	6.89	11.29	7.68	9.52	6.47	26.36	17.92

Annex 3

FLUPYRADIFURONE (285)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.08 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day							
				G01		G02		G03		G04		G05		G06	
				diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
	peppers, excl dried chilipeppers), excl okra														
VL 0483	Lettuce, leaf, raw	RAC	2.6	0.53	1.38	0.36	0.94	0.16	0.42	6.21	16.15	1.90	4.94	6.05	15.73
VL 0502	Spinach, raw	RAC	8.5	0.74	6.29	0.22	1.87	0.02	0.17	0.91	7.74	0.04	0.34	2.92	24.82
VL 0485	Mustard greens, raw (i.e. Indian mustard, Amsoi, mustard cabbage)	RAC	12	0.03	0.36	0.31	3.72	0.01	0.12	0.05	0.60	0.47	5.64	0.11	1.32
VP 0061	Beans with pods (Phaseolus spp): (immature pods + succulent seeds)	RAC	2.63	0.68	1.79	NC	-	NC	-	0.39	1.03	0.22	0.58	0.49	1.29
VP 0062	Beans without pods: (Phaseolus spp.) (succulent seeds), raw	RAC	1.17	1.56	1.83	0.60	0.70	0.49	0.57	1.18	1.38	0.90	1.05	7.79	9.11
VP 0064	Peas without pods (Pisum spp) (succulent seeds)	RAC	2.78	1.97	5.48	0.51	1.42	0.02	0.06	0.79	2.20	3.68	10.23	3.80	10.56
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	3.22	2.39	7.70	1.61	5.18	10.47	33.71	1.84	5.92	12.90	41.54	7.44	23.96
VD 0523	Broad bean, dry, raw (incl horse-bean, field bean) (Vicia faba)	RAC	2.49	1.27	3.16	0.01	0.02	0.12	0.30	2.49	6.20	0.23	0.57	5.54	13.79
VD 0541	Soya bean, dry, raw (Glycine soja)	RAC	3.44	0.58	2.00	0.05	0.17	0.37	1.27	0.03	0.10	1.65	5.68	0.30	1.03
-	Soya paste (i.e. miso)	PP	3.44	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
-	Soya curd (i.e. tofu)	PP	3.44	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
OR 0541	Soya oil, refined	PP	0.13	12.99	1.69	10.43	1.36	3.63	0.47	13.10	1.70	10.70	1.39	13.10	1.70
-	Soya sauce	PP	3.44	0.01	0.03	0.02	0.07	0.01	0.03	0.34	1.17	0.03	0.10	0.01	0.03
-	Soya flour	PP	5.3	0.05	0.27	0.86	4.56	0.02	0.11	1.02	5.41	0.01	0.05	0.15	0.80
VD 0072	Peas (dry) (Pisum spp), raw	RAC	3.605	1.62	5.84	3.22	11.61	0.92	3.32	1.50	5.41	2.90	10.45	0.17	0.61
VD 0524	Chick-pea (dry) (Cicer spp), raw	RAC	2.49	5.34	13.30	0.13	0.32	0.01	0.02	4.69	11.68	7.24	18.03	5.52	13.74
VD 0533	Lentil (dry) (Lens spp), raw	RAC	2.49	2.12	5.28	0.01	0.02	0.03	0.07	3.21	7.99	1.60	3.98	4.90	12.20
VD 0537	Pigeon pea (dry) (Cajanus spp), raw	RAC	2.49	NC	-	NC	-	0.10	0.25	0.07	0.17	3.38	8.42	NC	-
VR 0075	Group of Root and tuber vegetables, raw (incl processed)	RAC	0.29	87.83	25.47	374.04	108.47	668.92	193.99	121.64	35.28	94.20	27.32	247.11	71.66
-	Potato, starch	PP	0.16	0.03	0.00	0.01	0.00	0.01	0.00	0.15	0.02	0.01	0.00	0.01	0.00
VS 0624	Celery	RAC	2.38	2.14	5.09	3.79	9.02	2.35	5.59	5.69	13.54	0.02	0.05	2.75	6.55
GC 0648	Quinoa, raw	RAC	1.315	NC	-	NC	-	NC	-	NC	-	0.07	0.09	NC	-
GC 0650	Rye, raw (incl flour)	RAC	1.315	0.13	0.17	19.38	25.48	0.10	0.13	0.12	0.16	0.03	0.04	2.15	2.83
GC 0653	Triticale, raw (incl flour)	RAC	1.315	NC	-	NC	-	NC	-	0.01	0.01	0.39	0.51	NC	-
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, excl germ, excl wholemeal bread, excl white flour products, excl white bread)	RAC	1.315	0.01	0.01	1.12	1.47	NC	-	0.03	0.04	0.56	0.74	NC	-
CF 1210	Wheat, germ	PP	1.64	NC	-	NC	-	0.01	0.02	0.01	0.02	0.14	0.23	0.01	0.02
CP 1212	Wheat, wholemeal bread	PP	1.05	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.03	0.03	0.01	0.01
CP 1211	Wheat, white bread	PP	0.42	0.25	0.11	0.63	0.26	0.12	0.05	0.43	0.18	1.39	0.58	0.22	0.09
CF 1211	Wheat, white flour	PP	0.59	299.27	176.57	263.32	155.36	27.93	16.48	214.18	126.37	133.47	78.75	340.03	200.62
-	Wheat, starch	PP	0.034	0.02	0.00	NC	-	0.01	0.00	0.05	0.00	0.13	0.00	0.01	0.00
-	Wheat, gluten	PP	0.53	0.01	0.01	0.01	0.01	0.01	0.01	0.27	0.14	0.01	0.01	0.03	0.02

Annex 3

FLUPYRADIFURONE (285)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.08 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day							
				G01		G02		G03		G04		G05		G06	
				diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
GC 0640	Barley, raw (incl malt extract, incl flour & grits, excl pot&pearled, excl beer, excl malt)	RAC	1.315	7.91	10.40	0.64	0.84	0.15	0.20	0.18	0.24	1.21	1.59	0.41	0.54
-	Barley, pot&pearled	PP	0.16	7.12	1.14	7.34	1.17	0.02	0.00	0.03	0.00	0.67	0.11	0.20	0.03
-	Barley beer	PP	0.099	4.87	0.48	93.78	9.28	24.28	2.40	12.76	1.26	39.28	3.89	18.15	1.80
-	Barley Malt	PP	0.64	0.09	0.06	1.04	0.67	0.18	0.12	0.33	0.21	0.04	0.03	0.10	0.06
GC 0641	Buckwheat, raw (incl flour)	RAC	1.315	NC	-	0.40	0.53	0.01	0.01	0.01	0.01	0.07	0.09	0.09	0.12
GC 0647	Oats, raw (incl rolled)	RAC	1.315	0.05	0.07	7.05	9.27	0.10	0.13	1.71	2.25	0.96	1.26	0.04	0.05
GC 2089	Subgroup of Sorghum Grain and Millet	RAC	1.315	5.80	7.63	2.32	3.05	23.09	30.36	16.72	21.99	27.14	35.69	2.92	3.84
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl germ, excl flour, excl oil, excl beer, excl starch)	RAC	0.49	0.84	0.41	0.24	0.12	0.68	0.33	0.46	0.23	2.44	1.20	13.13	6.43
CF 1255	Maize, flour (white flour and wholemeal flour)	PP	0.44	22.72	10.00	35.61	15.67	87.27	38.40	34.92	15.36	46.71	20.55	49.12	21.61
-	Maize, germ	PP	0.51	0.01	0.01	NC	-	0.01	0.01	0.01	0.01	0.22	0.11	NC	-
-	Maize starch	PP	0.44	0.08	0.04	NC	-	0.01	0.00	2.29	1.01	0.08	0.04	0.11	0.05
OR 0645	Maize oil	PP	0.44	0.96	0.42	0.85	0.37	0.29	0.13	5.42	2.38	0.42	0.18	2.10	0.92
GC 0447	Sweet corn on the cob, raw (incl frozen kernels, incl canned kernels)	RAC	0.56	0.14	0.08	0.94	0.53	5.70	3.19	2.61	1.46	1.94	1.09	0.22	0.12
TN 0672	Pecan, nutmeat	RAC	0.06	0.05	0.00	0.05	0.00	0.02	0.00	0.14	0.01	0.09	0.01	0.13	0.01
SO 0700	Sesame seed, raw	RAC	1	0.73	0.73	0.01	0.01	0.48	0.48	1.62	1.62	0.25	0.25	1.29	1.29
OR 0700	Sesame seed oil, edible	PP	0.13	0.17	0.02	0.01	0.00	0.02	0.00	0.94	0.12	0.21	0.03	0.53	0.07
SO 2091	Subgroup of Sunflower seeds, raw	RAC	0.31	0.09	0.03	0.33	0.10	0.09	0.03	0.24	0.07	0.02	0.01	0.01	0.00
OR 0691	Cotton seed oil, edible	PP	0.079	3.22	0.25	1.54	0.12	1.01	0.08	0.74	0.06	1.12	0.09	2.93	0.23
SO 0697	Peanuts, nutmeat, raw	RAC	0.225	0.40	0.09	1.01	0.23	6.60	1.49	1.47	0.33	1.17	0.26	1.82	0.41
-	Peanuts, roasted	PP	0.17	0.06	0.01	0.19	0.03	0.04	0.01	1.05	0.18	0.08	0.01	0.02	0.00
OR 0697	Peanut oil, edible	PP	0.13	0.36	0.05	0.01	0.00	2.57	0.33	0.07	0.01	2.29	0.30	0.36	0.05
-	Peanut butter	PP	0.17	0.01	0.00	0.01	0.00	0.01	0.00	0.19	0.03	0.01	0.00	0.01	0.00
SB 0715	Cacao bean, raw (incl roasted, incl powder, incl butter, incl nes products)	RAC	0.071	0.72	0.05	4.20	0.30	0.60	0.04	4.21	0.30	0.42	0.03	0.78	0.06
DM 0715	cacao powder	PP	0.116	0.11	0.01	0.06	0.01	0.19	0.02	0.79	0.09	0.27	0.03	0.34	0.04
SB 0716	Coffee bean, raw (i.e. green coffee)	RAC	0.295	0.96	0.28	0.16	0.05	0.91	0.27	0.27	0.08	1.37	0.40	0.46	0.14
SM 0716	Coffee bean, roasted	PP	0.21	0.19	0.04	0.91	0.19	0.16	0.03	2.50	0.53	0.39	0.08	0.40	0.08
-	Coffee bean, instant coffee (incl essences and concentrates)	PP	0.94	0.07	0.07	0.94	0.88	0.07	0.07	0.70	0.66	0.07	0.07	0.29	0.27
DH 1100	Hops, dry	RAC	3.55	0.01	0.04	0.04	0.14	0.01	0.04	0.01	0.04	NC	-	0.01	0.04
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)	RAC	0.3	31.20	9.36	72.44	21.73	20.88	6.26	47.98	14.39	33.08	9.92	36.25	10.88
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80 % as muscle	RAC	0.15	24.96	3.74	57.95	8.69	16.70	2.51	38.38	5.76	26.46	3.97	29.00	4.35
MF 0100	Mammalian fats, raw, excl milk fats (incl	RAC	0.15	3.29	0.49	6.14	0.92	0.82	0.12	1.57	0.24	2.23	0.33	1.07	0.16

Annex 3

FLUPYRADIFURONE (285)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.08 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day		Intake as ug/person/day										
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake	
	rendered fats)															
MO 0105	Edible offal (mammalian), raw	RAC	0.87	4.79	4.17	9.68	8.42	2.97	2.58	5.49	4.78	3.84	3.34	5.03	4.38	
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.11	289.65	31.86	485.88	53.45	26.92	2.96	239.03	26.29	199.91	21.99	180.53	19.86	
PM 0110	Poultry meat, raw (incl prepared) - 90 % as muscle	RAC	0.27	13.17	3.56	26.78	7.23	7.24	1.95	116.71	31.51	22.54	6.08	32.09	8.67	
PM 0110	Poultry meat, raw (incl prepared) - 10 % as fat	RAC	0.11	1.46	0.16	2.98	0.33	0.80	0.09	12.97	1.43	2.50	0.28	3.57	0.39	
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.11	0.10	0.01	0.10	0.01	NC	-	0.10	0.01	0.10	0.01	0.10	0.01	
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.39	0.12	0.05	0.12	0.05	0.11	0.04	5.37	2.09	0.24	0.09	0.10	0.04	
PE 0112	Eggs, raw, (incl dried)	RAC	0.15	7.84	1.18	23.08	3.46	2.88	0.43	14.89	2.23	9.81	1.47	14.83	2.22	
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Total intake (ug/person)=				443.6		628.0		388.9		553.7		398.8		831.9		
Bodyweight per region (kg bw) =				60		60		60		60		60		60		
ADI (ug/person)=				4800		4800		4800		4800		4800		4800		
%ADI=				9.2 %		13.1 %		8.1 %		11.5 %		8.3 %		17.3 %		
Rounded %ADI=				9 %		10 %		8 %		10 %		8 %		20 %		

FLUPYRADIFURONE (285)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.08 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day		Intake as ug/person/day									
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
JF 0001	Group of Citrus fruit, juice	PP	0.068	36.84	2.51	3.75	0.26	0.30	0.02	21.62	1.47	21.82	1.48	46.67	3.17
FC 0002	Subgroup of Lemons and limes, raw (incl kumquat commodities)	RAC	0.32	8.45	2.70	14.69	4.70	2.88	0.92	8.16	2.61	21.14	6.76	5.93	1.90
FC 0003	Subgroup of Mandarins, raw	RAC	0.44	12.34	5.43	14.99	6.60	16.08	7.08	10.76	4.73	9.94	4.37	NC	-
FC 0004	Subgroup of Oranges, sweet, sour, raw	RAC	0.505	15.68	7.92	24.00	12.12	6.80	3.43	29.09	14.69	15.39	7.77	160.47	81.04
FC 0005	Subgroup of Pummelo and grapefruits, raw	RAC	0.21	2.19	0.46	1.24	0.26	0.60	0.13	3.44	0.72	4.60	0.97	299.96	62.99
FP 0009	Group of Pome fruits, raw (incl apple cider, excl apple juice)	RAC	0.45	51.09	22.99	65.40	29.43	42.71	19.22	45.29	20.38	62.51	28.13	7.74	3.48
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.14	14.88	2.08	11.98	1.68	0.15	0.02	9.98	1.40	30.32	4.24	3.47	0.49
FS 0013	Subgroup of Cherries, raw	RAC	0.555	1.40	0.78	4.21	2.34	0.04	0.02	2.93	1.63	1.50	0.83	NC	-
FS 0014	Subgroup of Plums, raw	RAC	0.23	3.75	0.86	3.33	0.77	5.94	1.37	2.64	0.61	2.50	0.58	0.06	0.01
DF 0014	Plums, dried (prunes)	PP	1.15	0.61	0.70	0.35	0.40	0.05	0.06	0.35	0.40	0.49	0.56	0.13	0.15
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.39	13.03	5.08	16.29	6.35	8.29	3.23	12.95	5.05	5.35	2.09	0.04	0.02
FB 2005	Subgroup of Caneberries, raw	RAC	1.4	0.56	0.78	1.43	2.00	0.14	0.20	1.23	1.72	1.14	1.60	0.01	0.01
FB 2006	Subgroup of Bush berries, raw (including processed)	RAC	0.725	1.31	0.95	5.50	3.99	0.01	0.01	2.57	1.86	0.82	0.59	2.15	1.56
FB 0269	Grapes, raw (i.e. table grapes)	RAC	0.63	6.33	3.99	11.22	7.07	5.21	3.28	9.38	5.91	4.55	2.87	0.78	0.49

Annex 3

FLUPYRADIFURONE (285)			International Estimated Daily Intake (IEDI)				ADI = 0 - 0.08 mg/kg bw									
Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day								
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake	
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	1.6	3.09	4.94	1.51	2.42	0.03	0.05	1.38	2.21	4.26	6.82	0.42	0.67	
JF 0269	Grape juice (from wine grapes)	PP	0.43	0.56	0.24	1.96	0.84	0.02	0.01	2.24	0.96	2.27	0.98	0.34	0.15	
-	Graps must (from wine-grapes)	PP	0.44	0.16	0.07	0.09	0.04	0.01	0.00	0.12	0.05	0.11	0.05	NC	-	
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.26	88.93	23.12	62.41	16.23	1.84	0.48	25.07	6.52	61.17	15.90	5.84	1.52	
FB 0275	Strawberry, raw	RAC	1.505	4.49	6.76	5.66	8.52	0.02	0.03	6.63	9.98	5.75	8.65	0.05	0.08	
FI 0326	Avocado, raw	RAC	0.28	2.65	0.74	0.87	0.24	0.46	0.13	1.64	0.46	1.30	0.36	0.96	0.27	
FI 0353	Pineapple, raw (incl canned pineapple, incl dried pineapple, excl pineapple juice)	RAC	0.13	8.17	1.06	7.53	0.98	5.95	0.77	7.61	0.99	8.17	1.06	16.18	2.10	
JF 0341	Pineapple juice (single strength, incl concentrated)	PP	0.044	2.91	0.13	2.11	0.09	0.58	0.03	3.95	0.17	16.73	0.74	1.54	0.07	
VA 0035	Group of Bulb vegetables, raw	RAC	0.18	26.24	4.72	36.47	6.56	39.29	7.07	39.37	7.09	29.12	5.24	20.21	3.64	
VB 0404	Cauliflower, raw	RAC	0.48	5.27	2.53	5.01	2.40	NC	-	2.70	1.30	5.57	2.67	0.49	0.24	
VB 0041	Cabbages, head, raw	RAC	0.79	8.97	7.09	27.12	21.42	1.44	1.14	24.96	19.72	4.55	3.59	11.23	8.87	
VC 0431	Squash, Summer (Courgette, Marrow, Zucchetti, Zucchini), raw	RAC	0.655	NC	-	NC	-	5.48	3.59	NC	-	NC	-	1.03	0.67	
VC 0046	Melons, except watermelon, raw (Cantaloupe)	RAC	0.57	9.20	5.24	11.95	6.81	14.63	8.34	8.99	5.12	7.86	4.48	2.46	1.40	
VO 0448	Tomato, raw (incl canned, excl juice, excl paste)	RAC	0.71	43.88	31.15	55.41	39.34	35.38	25.12	74.88	53.16	26.50	18.82	9.51	6.75	
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	1.3	4.96	6.45	3.20	4.16	0.15	0.20	1.61	2.09	6.88	8.94	0.52	0.68	
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.48	0.80	0.38	0.07	0.03	0.05	0.02	0.61	0.29	0.40	0.19	0.08	0.04	
VO 0051	Subgroup of peppers, raw (incl dried sweet peppers, excl dried chilipeppers), excl okra	RAC	0.68	6.39	4.35	15.53	10.56	19.09	12.98	10.36	7.04	8.29	5.64	4.53	3.08	
VL 0483	Lettuce, leaf, raw	RAC	2.6	14.50	37.70	11.76	30.58	13.14	34.16	19.50	50.70	4.81	12.51	2.23	5.80	
VL 0502	Spinach, raw	RAC	8.5	2.20	18.70	1.76	14.96	13.38	113.73	2.94	24.99	5.53	47.01	0.02	0.17	
VL 0485	Mustard greens, raw (i.e. Indian mustard, Amsoi, mustard cabbage)	RAC	12	NC	-	NC	-	NC	-	NC	-	NC	-	0.13	1.56	
VP 0061	Beans with pods (Phaseolus spp): (immature pods + succulent seeds)	RAC	2.63	5.07	13.33	0.83	2.18	0.17	0.45	3.70	9.73	NC	-	NC	-	
VP 0062	Beans without pods: (Phaseolus spp.) (succulent seeds), raw	RAC	1.17	2.21	2.59	5.25	6.14	4.17	4.88	1.61	1.88	16.95	19.83	0.17	0.20	
VP 0064	Peas without pods (Pisum spp) (succulent seeds)	RAC	2.78	10.72	29.80	1.99	5.53	2.72	7.56	4.26	11.84	4.23	11.76	NC	-	
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	3.22	1.51	4.86	1.50	4.83	1.90	6.12	5.11	16.45	1.36	4.38	23.43	75.44	
VD 0523	Broad bean, dry, raw (incl horse-bean, field bean) (Vicia faba)	RAC	2.49	0.02	0.05	0.01	0.02	1.16	2.89	0.40	1.00	NC	-	0.06	0.15	
VD 0541	Soya bean, dry, raw (Glycine soja)	RAC	3.44	0.02	0.07	0.33	1.14	6.64	22.84	3.94	13.55	NC	-	5.78	19.88	
-	Soya paste (i.e. miso)	PP	3.44	NC	-	NC	-	NC	-	1.87	6.43	NC	-	NC	-	
-	Soya curd (i.e. tofu)	PP	3.44	NC	-	NC	-	0.68	2.34	0.87	2.99	NC	-	NC	-	
OR 0541	Soya oil, refined	PP	0.13	19.06	2.48	21.06	2.74	5.94	0.77	33.78	4.39	40.05	5.21	13.39	1.74	
-	Soya sauce	PP	3.44	0.45	1.55	0.29	1.00	2.93	10.08	4.35	14.96	0.09	0.31	0.70	2.41	

Annex 3

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FLUPYRADIFURONE (285)			International Estimated Daily Intake (IEDI)						ADI = 0 - 0.08 mg/kg bw						
Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day							
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
-	Soya flour	PP	5.3	0.22	1.17	0.27	1.43	0.29	1.54	0.17	0.90	NC	-	NC	-
VD 0072	Peas (dry) (Pisum spp), raw	RAC	3.605	3.80	13.70	1.25	4.51	0.90	3.24	2.33	8.40	2.70	9.73	3.83	13.81
VD 0524	Chick-pea (dry) (Cicer spp), raw	RAC	2.49	0.27	0.67	1.33	3.31	0.32	0.80	0.15	0.37	0.08	0.20	0.04	0.10
VD 0533	Lentil (dry) (Lens spp), raw	RAC	2.49	0.95	2.37	1.18	2.94	0.40	1.00	0.96	2.39	0.71	1.77	1.28	3.19
VD 0537	Pigeon pea (dry) (Cajanus spp), raw	RAC	2.49	NC	-	NC	-	0.20	0.50	NC	-	NC	-	NC	-
VR 0075	Group of Root and tuber vegetables, raw (incl processed)	RAC	0.29	290.31	84.19	300.35	87.10	214.25	62.13	242.72	70.39	348.67	101.11	137.52	39.88
-	Potato, starch	PP	0.16	NC	-	1.74	0.28	0.05	0.01	0.92	0.15	NC	-	NC	-
VS 0624	Celery	RAC	2.38	7.68	18.28	2.85	6.78	NC	-	3.34	7.95	16.83	40.06	4.04	9.62
GC 0648	Quinoa, raw	RAC	1.315	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
GC 0650	Rye, raw (incl flour)	RAC	1.315	3.21	4.22	35.38	46.52	0.21	0.28	6.50	8.55	1.49	1.96	NC	-
GC 0653	Triticale, raw (incl flour)	RAC	1.315	0.01	0.01	0.17	0.22	0.29	0.38	0.01	0.01	NC	-	NC	-
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, excl germ, excl wholemeal bread, excl white flour products, excl white bread)	RAC	1.315	NC	-	NC	-	0.02	0.03	0.83	1.09	NC	-	NC	-
CF 1210	Wheat, germ	PP	1.64	0.97	1.59	0.10	0.16	0.03	0.05	0.01	0.02	NC	-	0.04	0.07
CP 1212	Wheat, wholemeal bread	PP	1.05	0.03	0.03	0.01	0.01	0.01	0.01	0.01	0.01	0.05	0.05	0.02	0.02
CP 1211	Wheat, white bread	PP	0.42	1.30	0.55	0.46	0.19	0.06	0.03	0.22	0.09	2.44	1.02	0.77	0.32
CF 1211	Wheat, white flour	PP	0.59	182.77	107.83	187.54	110.65	103.82	61.25	180.42	106.45	164.00	96.76	118.84	70.12
-	Wheat, starch	PP	0.034	NC	-	NC	-	0.01	0.00	0.31	0.01	NC	-	NC	-
-	Wheat, gluten	PP	0.53	0.68	0.36	NC	-	0.01	0.01	0.01	0.01	NC	-	NC	-
GC 0640	Barley, raw (incl malt extract, incl flour & grits, excl pot&pearled, excl beer, excl malt)	RAC	1.315	0.82	1.08	0.21	0.28	0.09	0.12	1.53	2.01	1.58	2.08	0.63	0.83
-	Barley, pot&pearled	PP	0.16	0.57	0.09	2.56	0.41	0.33	0.05	0.56	0.09	0.36	0.06	NC	-
-	Barley beer	PP	0.099	180.21	17.84	259.46	25.69	45.91	4.55	172.36	17.06	234.42	23.21	65.30	6.46
-	Barley Malt	PP	0.64	0.19	0.12	NC	-	0.04	0.03	0.08	0.05	NC	-	2.14	1.37
GC 0641	Buckwheat, raw (incl flour)	RAC	1.315	0.01	0.01	0.79	1.04	0.18	0.24	0.35	0.46	NC	-	NC	-
GC 0647	Oats, raw (incl rolled)	RAC	1.315	7.50	9.86	6.26	8.23	0.15	0.20	4.87	6.40	3.16	4.16	2.98	3.92
GC 2089	Subgroup of Sorghum Grain and Millet	RAC	1.315	0.03	0.04	0.16	0.21	3.19	4.19	1.85	2.43	NC	-	7.12	9.36
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl germ, excl flour, excl oil, excl beer, excl starch)	RAC	0.49	0.10	0.05	9.93	4.87	1.40	0.69	9.88	4.84	0.33	0.16	0.05	0.02
CF 1255	Maize, flour (white flour and wholemeal flour)	PP	0.44	14.27	6.28	12.86	5.66	19.71	8.67	12.55	5.52	4.21	1.85	52.30	23.01
-	Maize, germ	PP	0.51	0.01	0.01	NC	-	NC	-	0.01	0.01	NC	-	0.01	0.01
-	Maize starch	PP	0.44	NC	-	NC	-	0.19	0.08	7.13	3.14	NC	-	NC	-
OR 0645	Maize oil	PP	0.44	0.90	0.40	0.47	0.21	0.15	0.07	3.01	1.32	1.86	0.82	0.36	0.16
GC 0447	Sweet corn on the cob, raw (incl frozen kernels, incl canned kernels)	RAC	0.56	11.43	6.40	3.71	2.08	0.74	0.41	13.63	7.63	3.07	1.72	1.50	0.84
TN 0672	Pecan, nutmeat	RAC	0.06	0.38	0.02	NC	-	NC	-	0.27	0.02	NC	-	0.26	0.02
SO 0700	Sesame seed, raw	RAC	1	0.15	0.15	0.08	0.08	0.41	0.41	0.54	0.54	0.08	0.08	0.01	0.01

Annex 3

FLUPYRADIFURONE (285)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.08 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day							
				G07		G08		G09		G10		G11		G12	
				diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
OR 0700	Sesame seed oil, edible	PP	0.13	0.17	0.02	0.01	0.00	0.40	0.05	0.11	0.01	NC	-	0.05	0.01
SO 2091	Subgroup of Sunflower seeds, raw	RAC	0.31	0.01	0.00	1.32	0.41	0.03	0.01	1.18	0.37	NC	-	0.02	0.01
OR 0691	Cotton seed oil, edible	PP	0.079	1.68	0.13	0.66	0.05	1.13	0.09	1.18	0.09	0.89	0.07	0.37	0.03
SO 0697	Peanuts, nutmeat, raw	RAC	0.225	2.39	0.54	2.05	0.46	5.25	1.18	4.39	0.99	1.30	0.29	0.62	0.14
-	Peanuts, roasted	PP	0.17	0.80	0.14	0.14	0.02	0.11	0.02	0.43	0.07	0.10	0.02	0.45	0.08
OR 0697	Peanut oil, edible	PP	0.13	1.02	0.13	0.23	0.03	1.81	0.24	0.42	0.05	5.23	0.68	0.01	0.00
-	Peanut butter	PP	0.17	0.07	0.01	0.04	0.01	0.01	0.00	0.03	0.01	0.15	0.03	0.75	0.13
SB 0715	Cacao bean, raw (incl roasted, incl powder, incl butter, incl paste, incl nes products)	RAC	0.071	7.54	0.54	5.59	0.40	0.29	0.02	4.14	0.29	1.27	0.09	5.29	0.38
DM 0715	cacao powder	PP	0.116	2.78	0.32	1.82	0.21	0.20	0.02	1.66	0.19	0.04	0.00	0.74	0.09
SB 0716	Coffee bean, raw (i.e. green coffee)	RAC	0.295	0.60	0.18	NC	-	0.62	0.18	1.71	0.50	NC	-	3.51	1.04
SM 0716	Coffee bean, roasted	PP	0.21	7.02	1.47	9.75	2.05	0.02	0.00	5.09	1.07	13.38	2.81	0.77	0.16
-	Coffee bean, instant coffee (incl essences and concentrates)	PP	0.94	0.75	0.71	0.30	0.28	0.04	0.04	0.67	0.63	2.43	2.28	1.43	1.34
DH 1100	Hops, dry	RAC	3.55	NC	-	NC	-	0.02	0.07	0.02	0.07	NC	-	NC	-
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)	RAC	0.3	140.03	42.01	150.89	45.27	79.32	23.80	111.24	33.37	120.30	36.09	51.27	15.38
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80 % as muscle	RAC	0.15	112.02	16.80	120.71	18.11	63.46	9.52	88.99	13.35	96.24	14.44	41.02	6.15
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.15	6.44	0.97	15.51	2.33	3.79	0.57	8.29	1.24	18.44	2.77	8.00	1.20
MO 0105	Edible offal (mammalian), raw	RAC	0.87	15.17	13.20	5.19	4.52	6.30	5.48	6.78	5.90	3.32	2.89	3.17	2.76
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.11	388.92	42.78	335.88	36.95	49.15	5.41	331.25	36.44	468.56	51.54	245.45	27.00
PM 0110	Poultry meat, raw (incl prepared) - 90 % as muscle	RAC	0.27	66.38	17.92	48.47	13.09	21.58	5.83	78.41	21.17	48.04	12.97	76.01	20.52
PM 0110	Poultry meat, raw (incl prepared) - 10 % as fat	RAC	0.11	7.38	0.81	5.39	0.59	2.40	0.26	8.71	0.96	5.34	0.59	8.45	0.93
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.11	0.10	0.01	0.10	0.01	NC	-	0.10	0.01	0.71	0.08	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.39	0.33	0.13	0.72	0.28	0.27	0.11	0.35	0.14	0.80	0.31	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0.15	25.84	3.88	29.53	4.43	28.05	4.21	33.19	4.98	36.44	5.47	8.89	1.33
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total intake (ug/person)=				687.4		710.1		512.8		719.5		668.2		554.7	
Bodyweight per region (kg bw) =				60		60		55		60		60		60	
ADI (ug/person)=				4800		4800		4400		4800		4800		4800	
%ADI=				14.3 %		14.8 %		11.7 %		15.0 %		13.9 %		11.6 %	
Rounded %ADI=				10 %		10 %		10 %		10 %		10 %		10 %	

Annex 3

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FLUPYRADIFURONE (285)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.08 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day		Intake = daily intake: ug/person							
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
JF 0001	Group of Citrus fruit, juice	PP	0.068	0.11	0.01	0.29	0.02	13.55	0.92	0.14	0.01	0.33	0.02
FC 0002	Subgroup of Lemons and limes, raw (incl kumquat commodities)	RAC	0.32	18.96	6.07	0.97	0.31	5.79	1.85	0.09	0.03	3.35	1.07
FC 0003	Subgroup of Mandarins, raw	RAC	0.44	0.16	0.07	0.27	0.12	9.06	3.99	0.01	0.00	0.02	0.01
FC 0004	Subgroup of Oranges, sweet, sour, raw	RAC	0.505	1.18	0.60	1.11	0.56	14.28	7.21	0.05	0.03	1.08	0.55
FC 0005	Subgroup of Pummelo and grapefruits, raw	RAC	0.21	0.63	0.13	0.01	0.00	1.58	0.33	0.01	0.00	NC	-
FP 0009	Group of Pome fruits, raw (incl apple cider, excl apple juice)	RAC	0.45	68.85	30.98	10.93	4.92	70.82	31.87	189.78	85.40	19.56	8.80
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.14	0.03	0.00	0.10	0.01	7.19	1.01	0.03	0.00	NC	-
FS 0013	Subgroup of Cherries, raw	RAC	0.555	0.01	0.01	0.01	0.01	5.96	3.31	0.01	0.01	NC	-
FS 0014	Subgroup of Plums, raw	RAC	0.23	0.07	0.02	0.01	0.00	15.56	3.58	0.01	0.00	NC	-
DF 0014	Plums, dried (prunes)	PP	1.15	0.01	0.01	0.01	0.01	0.37	0.43	0.01	0.01	NC	-
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.39	0.02	0.01	0.01	0.00	10.76	4.20	0.01	0.00	NC	-
FB 2005	Subgroup of Caneberries, raw	RAC	1.4	0.01	0.01	7.30	10.22	2.29	3.21	0.01	0.01	NC	-
FB 2006	Subgroup of Bush berries, raw (including processed)	RAC	0.725	0.82	0.59	4.05	2.94	5.94	4.31	0.43	0.31	2.66	1.93
FB 0269	Grapes, raw (i.e. table grapes)	RAC	0.63	0.14	0.09	0.36	0.23	15.22	9.59	0.01	0.01	0.09	0.06
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	1.6	0.01	0.02	0.13	0.21	1.06	1.70	0.01	0.02	0.03	0.05
JF 0269	Grape juice (from wine grapes)	PP	0.43	0.01	0.00	0.01	0.00	0.41	0.18	0.01	0.00	NC	-
-	Graps must (from wine-grapes)	PP	0.44	0.01	0.00	0.01	0.00	0.11	0.05	0.01	0.00	0.19	0.08
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.26	0.31	0.08	0.23	0.06	60.43	15.71	0.52	0.14	31.91	8.30
FB 0275	Strawberry, raw	RAC	1.505	0.01	0.02	0.01	0.02	3.35	5.04	0.01	0.02	0.01	0.02
FI 0326	Avocado, raw	RAC	0.28	1.12	0.31	0.01	0.00	0.84	0.24	0.01	0.00	6.60	1.85
FI 0353	Pineapple, raw (incl canned pineapple, incl dried pineapple, excl pineapple juice)	RAC	0.13	7.68	1.00	6.15	0.80	4.79	0.62	0.15	0.02	24.94	3.24
JF 0341	Pineapple juice (single strength, incl concentrated)	PP	0.044	0.49	0.02	0.07	0.00	1.23	0.05	0.02	0.00	NC	-
VA 0035	Group of Bulb vegetables, raw	RAC	0.18	11.28	2.03	23.80	4.28	36.11	6.50	9.66	1.74	8.69	1.56
VB 0404	Cauliflower, raw	RAC	0.48	0.01	0.00	0.01	0.00	2.73	1.31	0.01	0.00	NC	-
VB 0041	Cabbages, head, raw	RAC	0.79	3.82	3.02	2.99	2.36	49.16	38.84	0.01	0.01	NC	-
VC 0431	Squash, Summer (Courgette, Marrow, Zucchini, Zucchini), raw	RAC	0.655	0.09	0.06	1.01	0.66	NC	-	1.91	1.25	NC	-
VC 0046	Melons, except watermelon, raw (Cantaloupe)	RAC	0.57	0.19	0.11	0.10	0.06	4.98	2.84	0.01	0.01	NC	-
VO 0448	Tomato, raw (incl canned, excl juice, excl paste)	RAC	0.71	13.10	9.30	4.90	3.48	62.16	44.13	1.04	0.74	0.09	0.06
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	1.3	0.58	0.75	0.22	0.29	2.21	2.87	0.24	0.31	3.10	4.03
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.48	0.05	0.02	0.01	0.00	0.42	0.20	0.01	0.00	0.02	0.01
VO 0051	Subgroup of peppers, raw (incl dried sweet	RAC	0.68	8.97	6.10	14.13	9.61	25.14	17.10	0.91	0.62	NC	-

Annex 3

FLUPYRADIFURONE (285)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.08 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day										
				Intake = daily intake: ug/person										
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake	
	peppers, excl dried chilipeppers), excl okra													
VL 0483	Lettuce, leaf, raw	RAC	2.6	0.29	0.75	0.03	0.08	6.71	17.45	0.01	0.03	NC	-	
VL 0502	Spinach, raw	RAC	8.5	0.17	1.45	0.01	0.09	0.81	6.89	0.01	0.09	NC	-	
VL 0485	Mustard greens, raw (i.e. Indian mustard, Amsoi, mustard cabbage)	RAC	12	0.04	0.48	0.03	0.36	NC	-	0.01	0.12	NC	-	
VP 0061	Beans with pods (Phaseolus spp): (immature pods + succulent seeds)	RAC	2.63	NC	-	NC	-	NC	-	NC	-	NC	-	
VP 0062	Beans without pods: (Phaseolus spp.) (succulent seeds), raw	RAC	1.17	0.30	0.35	3.13	3.66	4.11	4.81	0.01	0.01	NC	-	
VP 0064	Peas without pods (Pisum spp) (succulent seeds)	RAC	2.78	0.21	0.58	0.02	0.06	5.51	15.32	0.02	0.06	NC	-	
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	3.22	7.11	22.89	2.33	7.50	3.76	12.11	44.70	143.93	3.27	10.53	
VD 0523	Broad bean, dry, raw (incl horse-bean, field bean) (Vicia faba)	RAC	2.49	3.70	9.21	0.03	0.07	0.17	0.42	0.01	0.02	NC	-	
VD 0541	Soya bean, dry, raw (Glycine soja)	RAC	3.44	2.76	9.49	0.07	0.24	0.33	1.14	3.16	10.87	NC	-	
-	Soya paste (i.e. miso)	PP	3.44	NC	-	NC	-	NC	-	NC	-	NC	-	
-	Soya curd (i.e. tofu)	PP	3.44	NC	-	NC	-	NC	-	NC	-	NC	-	
OR 0541	Soya oil, refined	PP	0.13	2.32	0.30	2.54	0.33	18.70	2.43	2.51	0.33	6.29	0.82	
-	Soya sauce	PP	3.44	0.01	0.03	0.13	0.45	0.17	0.58	0.01	0.03	0.56	1.93	
-	Soya flour	PP	5.3	0.11	0.58	0.08	0.42	0.07	0.37	0.01	0.05	0.03	0.16	
VD 0072	Peas (dry) (Pisum spp), raw	RAC	3.605	1.53	5.52	2.52	9.08	3.52	12.69	3.56	12.83	0.74	2.67	
VD 0524	Chick-pea (dry) (Cicer spp), raw	RAC	2.49	1.09	2.71	1.56	3.88	0.33	0.82	0.18	0.45	0.47	1.17	
VD 0533	Lentil (dry) (Lens spp), raw	RAC	2.49	0.67	1.67	7.26	18.08	0.37	0.92	0.08	0.20	NC	-	
VD 0537	Pigeon pea (dry) (Cajanus spp), raw	RAC	2.49	1.14	2.84	0.03	0.07	NC	-	5.53	13.77	NC	-	
VR 0075	Group of Root and tuber vegetables, raw (incl processed)	RAC	0.29	282.25	81.85	232.11	67.31	281.91	81.75	620.21	179.86	459.96	133.39	
-	Potato, starch	PP	0.16	0.01	0.00	0.01	0.00	NC	-	NC	-	NC	-	
VS 0624	Celery	RAC	2.38	3.66	8.71	2.65	6.31	4.84	11.52	2.47	5.88	4.94	11.76	
GC 0648	Quinoa, raw	RAC	1.315	NC	-	NC	-	NC	-	NC	-	NC	-	
GC 0650	Rye, raw (incl flour)	RAC	1.315	0.03	0.04	0.01	0.01	13.95	18.34	0.01	0.01	0.88	1.16	
GC 0653	Triticale, raw (incl flour)	RAC	1.315	0.01	0.01	NC	-	NC	-	NC	-	NC	-	
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, excl germ, excl wholemeal bread, excl white flour products, excl white bread)	RAC	1.315	0.01	0.01	NC	-	NC	-	NC	-	0.97	1.28	
CF 1210	Wheat, germ	PP	1.64	0.04	0.07	0.01	0.02	0.01	0.02	0.01	0.02	NC	-	
CP 1212	Wheat, wholemeal bread	PP	1.05	0.01	0.01	0.01	0.01	0.03	0.03	0.01	0.01	0.01	0.01	
CP 1211	Wheat, white bread	PP	0.42	0.43	0.18	0.41	0.17	1.56	0.66	0.11	0.05	0.07	0.03	
CF 1211	Wheat, white flour	PP	0.59	43.75	25.81	85.81	50.63	206.68	121.94	19.38	11.43	92.92	54.82	
-	Wheat, starch	PP	0.034	0.01	0.00	0.02	0.00	NC	-	NC	-	NC	-	
-	Wheat, gluten	PP	0.53	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.19	0.10	
GC 0640	Barley, raw (incl malt extract, incl flour & grits, excl	RAC	1.315	0.09	0.12	0.01	0.01	0.80	1.05	0.01	0.01	0.11	0.14	

Annex 3

750

FLUPYRADIFURONE (285)				International Estimated Daily Intake (IEDI)				ADI = 0 - 0.08 mg/kg bw					
Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day		Intake = daily intake: ug/person							
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
	pot&pearled, excl beer, excl malt)												
-	Barley, pot&pearled	PP	0.16	5.46	0.87	0.01	0.00	1.44	0.23	0.01	0.00	NC	-
-	Barley beer	PP	0.099	16.25	1.61	11.36	1.12	225.21	22.30	19.49	1.93	52.17	5.16
-	Barley Malt	PP	0.64	0.01	0.01	0.11	0.07	0.67	0.43	0.01	0.01	4.61	2.95
GC 0641	Buckwheat, raw (incl flour)	RAC	1.315	0.04	0.05	2.82	3.71	0.01	0.01	0.01	0.01	NC	-
GC 0647	Oats, raw (incl rolled)	RAC	1.315	0.37	0.49	0.07	0.09	2.79	3.67	0.10	0.13	NC	-
GC 2089	Subgroup of Sorghum Grain and Millet	RAC	1.315	150.90	198.43	2.80	3.68	NC	-	68.93	90.64	NC	-
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl germ, excl flour, excl oil, excl beer, excl starch)	RAC	0.49	0.35	0.17	0.51	0.25	3.26	1.60	0.18	0.09	NC	-
CF 1255	Maize, flour (white flour and wholemeal flour)	PP	0.44	94.34	41.51	8.09	3.56	28.03	12.33	55.94	24.61	28.07	12.35
-	Maize, germ	PP	0.51	0.01	0.01	NC	-	NC	-	NC	-	NC	-
-	Maize starch	PP	0.44	0.02	0.01	0.01	0.00	NC	-	NC	-	NC	-
OR 0645	Maize oil	PP	0.44	0.33	0.15	0.07	0.03	0.81	0.36	0.01	0.00	NC	-
GC 0447	Sweet corn on the cob, raw (incl frozen kernels, incl canned kernels)	RAC	0.56	3.63	2.03	20.50	11.48	8.78	4.92	0.02	0.01	0.17	0.10
TN 0672	Pecan, nutmeat	RAC	0.06	0.15	0.01	0.22	0.01	0.31	0.02	0.01	0.00	0.01	0.00
SO 0700	Sesame seed, raw	RAC	1	0.89	0.89	0.34	0.34	0.16	0.16	5.13	5.13	NC	-
OR 0700	Sesame seed oil, edible	PP	0.13	0.52	0.07	0.11	0.01	0.04	0.01	1.70	0.22	NC	-
SO 2091	Subgroup of Sunflower seeds, raw	RAC	0.31	0.06	0.02	0.01	0.00	0.03	0.01	2.23	0.69	NC	-
OR 0691	Cotton seed oil, edible	PP	0.079	1.28	0.10	0.05	0.00	0.45	0.04	0.42	0.03	0.15	0.01
SO 0697	Peanuts, nutmeat, raw	RAC	0.225	7.12	1.60	0.32	0.07	1.34	0.30	6.21	1.40	0.53	0.12
-	Peanuts, roasted	PP	0.17	0.02	0.00	0.10	0.02	0.48	0.08	0.01	0.00	NC	-
OR 0697	Peanut oil, edible	PP	0.13	5.02	0.65	0.05	0.01	0.17	0.02	0.29	0.04	NC	-
-	Peanut butter	PP	0.17	0.01	0.00	0.03	0.01	0.05	0.01	NC	-	NC	-
SB 0715	Cacao bean, raw (incl roasted, incl powder, incl butter, incl paste, incl nes products)	RAC	0.071	0.11	0.01	0.89	0.06	6.28	0.45	0.17	0.01	2.31	0.16
DM 0715	cacao powder	PP	0.116	0.05	0.01	0.20	0.02	1.17	0.14	0.01	0.00	1.80	0.21
SB 0716	Coffee bean, raw (i.e. green coffee)	RAC	0.295	0.83	0.24	0.69	0.20	1.09	0.32	2.91	0.86	0.82	0.24
SM 0716	Coffee bean, roasted	PP	0.21	0.02	0.00	0.41	0.09	7.50	1.58	0.01	0.00	0.06	0.01
-	Coffee bean, instant coffee (incl essences and concentrates)	PP	0.94	0.03	0.03	0.05	0.05	0.60	0.56	0.01	0.01	5.53	5.20
DH 1100	Hops, dry	RAC	3.55	NC	-	NC	-	0.04	0.14	NC	-	NC	-
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)	RAC	0.3	29.18	8.75	50.89	15.27	121.44	36.43	22.58	6.77	72.14	21.64
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80 % as muscle	RAC	0.15	23.34	3.50	40.71	6.11	97.15	14.57	18.06	2.71	57.71	8.66
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.15	1.05	0.16	1.14	0.17	18.69	2.80	0.94	0.14	3.12	0.47
MO 0105	Edible offal (mammalian), raw	RAC	0.87	4.64	4.04	1.97	1.71	10.01	8.71	3.27	2.84	3.98	3.46

Annex 3

FLUPYRADIFURONE (285)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.08 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day										
				Intake = daily intake: ug/person										
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake	
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.11	108.75	11.96	70.31	7.73	436.11	47.97	61.55	6.77	79.09	8.70	
PM 0110	Poultry meat, raw (incl prepared) - 90 % as muscle	RAC	0.27	3.53	0.95	10.83	2.92	51.36	13.87	4.53	1.22	50.00	13.50	
PM 0110	Poultry meat, raw (incl prepared) - 10 % as fat	RAC	0.11	0.39	0.04	1.20	0.13	5.71	0.63	0.50	0.06	5.56	0.61	
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.11	NC	-	NC	-	0.32	0.04	NC	-	NC	-	
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.39	0.10	0.04	0.70	0.27	0.97	0.38	0.10	0.04	NC	-	
PE 0112	Eggs, raw, (incl dried)	RAC	0.15	3.84	0.58	4.41	0.66	27.25	4.09	1.13	0.17	7.39	1.11	
-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Total intake (ug/person)=						516.1		269.9		703.6		617.3		336.3
Bodyweight per region (kg bw) =						60		60		60		60		60
ADI (ug/person)=						4800		4800		4800		4800		4800
%ADI=						10.8 %		5.6 %		14.7 %		12.9 %		7.0 %
Rounded %ADI=						10 %		6 %		10 %		10 %		7 %

Annex 3

752

FLUTRIAFOL (248)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.01 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day							
				G01		G02		G03		G04		G05		G06	
				diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
FP 0009	Group of Pome fruits, raw (incl apple cider, excl apple juice)	RAC	0.08	19.35	1.55	34.06	2.72	17.87	1.43	25.74	2.06	7.69	0.62	56.85	4.55
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.038	0.32	0.01	3.07	0.12	0.07	0.00	5.00	0.19	0.29	0.01	5.57	0.21
FS 0013	Subgroup of Cherries, raw	RAC	0.335	0.92	0.31	9.15	3.07	0.01	0.00	0.61	0.20	0.06	0.02	6.64	2.22
FS 0014	Subgroup of Plums, raw	RAC	0.075	2.40	0.18	8.60	0.65	0.06	0.00	2.52	0.19	0.58	0.04	4.16	0.31
DF 0014	Plums, dried (prunes)	PP	0.165	0.09	0.01	0.06	0.01	0.01	0.00	0.18	0.03	0.04	0.01	0.06	0.01
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.17	8.01	1.36	5.87	1.00	0.18	0.03	8.19	1.39	1.64	0.28	22.46	3.82
FB 0269	Grapes, raw (incl must, incl juice, excl dried, excl wine)	RAC	0.21	13.19	2.77	9.61	2.02	0.09	0.02	17.28	3.63	4.00	0.84	54.50	11.45
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	0.59	0.51	0.30	0.51	0.30	0.01	0.01	1.27	0.75	0.12	0.07	2.07	1.22
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.3528	0.67	0.24	12.53	4.42	2.01	0.71	1.21	0.43	3.53	1.25	4.01	1.41
FB 0275	Strawberry, raw	RAC	0.42	0.70	0.29	2.01	0.84	0.04	0.02	1.36	0.57	0.37	0.16	2.53	1.06
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.05	5.23	0.26	6.94	0.35	99.45	4.97	32.47	1.62	48.30	2.42	24.70	1.24
VB 0040	Group of Brassica vegetables (excl Brassica leafy vegetables), raw	RAC	0.14	6.43	0.90	40.26	5.64	0.80	0.11	9.94	1.39	12.07	1.69	17.73	2.48
VC 0045	Group of Fruiting vegetables, cucurbits, raw	RAC	0.09	53.14	4.78	86.21	7.76	6.28	0.57	92.76	8.35	15.64	1.41	155.30	13.98
VO 0448	Tomato, raw (incl juice, incl canned, excl paste)	RAC	0.1	42.41	4.24	76.50	7.65	10.69	1.07	85.07	8.51	24.98	2.50	203.44	20.34
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.286	2.34	0.67	1.33	0.38	1.57	0.45	4.24	1.21	0.34	0.10	2.83	0.81
VO 0051	Subgroup of peppers, raw (incl dried sweet peppers, excl dried chilipeppers), incl okra	RAC	0.28	10.45	2.93	13.74	3.85	13.81	3.87	14.53	4.07	15.25	4.27	27.93	7.82
VL 0483	Lettuce, leaf, raw	RAC	0.34	0.53	0.18	0.36	0.12	0.16	0.05	6.21	2.11	1.90	0.65	6.05	2.06
VL 0502	Spinach, raw	RAC	1.665	0.74	1.23	0.22	0.37	0.02	0.03	0.91	1.52	0.04	0.07	2.92	4.86
VL 0485	Mustard greens, raw (i.e. Indian mustard, Amsoi, mustard cabbage)	RAC	2.12	0.03	0.06	0.31	0.66	0.01	0.02	0.05	0.11	0.47	1.00	0.11	0.23
VD 0541	Soya bean, dry, raw (incl flour, incl paste, incl curd, incl sauce, excl oil)	RAC	0.055	0.63	0.03	1.09	0.06	0.40	0.02	1.40	0.08	1.68	0.09	0.48	0.03
OR 0541	Soya oil, refined	PP	0.072	12.99	0.94	10.43	0.75	3.63	0.26	13.10	0.94	10.70	0.77	13.10	0.94
VR 0596	Sugar beet, raw (incl sugar)	RAC	0.01	0.13	0.00	NC	-	0.08	0.00	0.66	0.01	0.47	0.00	88.94	0.89
VS 0624	Celery	RAC	0.78	2.14	1.67	3.79	2.96	2.35	1.83	5.69	4.44	0.02	0.02	2.75	2.15
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, excl germ, excl wholemeal bread, excl white flour products, excl white bread)	RAC	0.015	0.01	0.00	1.12	0.02	NC	-	0.03	0.00	0.56	0.01	NC	-
CF 1210	Wheat, germ	PP	0.042	NC	-	NC	-	0.01	0.00	0.01	0.00	0.14	0.01	0.01	0.00
CF 1211	Wheat, white flour	PP	0.005	299.27	1.50	263.32	1.32	27.93	0.14	214.18	1.07	133.47	0.67	340.03	1.70
GC 0640	Barley, raw (incl malt extract, incl pot&pearled, incl flour & grits, incl beer, incl malt)	RAC	0.2	19.91	3.98	31.16	6.23	5.04	1.01	3.10	0.62	9.77	1.95	4.31	0.86
CM 0649 (GC 0649)	Rice, husked, dry (incl flour, incl oil, incl starch, excl beverages, excl polished)	REP	0.36	1.26	0.45	1.58	0.57	31.05	11.18	5.43	1.95	0.90	0.32	2.18	0.78

Annex 3

FLUTRIAFOL (248)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.01 mg/kg bw

Codex Code	Commodity description	Expr as	STM ^R mg/kg	Diets as g/person/day						Intake as ug/person/day					
				G01		G02		G03		G04		G05		G06	
				diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
CM 1205	Rice polished, dry	PP	0.4	34.21	13.68	10.39	4.16	41.72	16.69	82.38	32.95	150.24	60.10	70.47	28.19
GC 0651	Sorghum, raw (incl flour, incl beer) (i.e. Chicken corn, Dari seed, Durra, Feterita)	RAC	0.27	4.34	1.17	0.01	0.00	16.25	4.39	15.82	4.27	10.97	2.96	2.92	0.79
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl flour, incl oil, incl beer, incl germ, incl starch)	RAC	0	29.81	0.00	44.77	0.00	108.95	0.00	52.37	0.00	60.28	0.00	75.69	0.00
TN 0660	Almonds, nutmeat	RAC	0.064	1.38	0.09	0.08	0.01	0.01	0.00	1.00	0.06	0.06	0.00	0.81	0.05
TN 0672	Pecan, nutmeat	RAC	0.01	0.05	0.00	0.05	0.00	0.02	0.00	0.14	0.00	0.09	0.00	0.13	0.00
SO 0495	Rape seed, raw (incl oil)	RAC	0.1	0.93	0.09	1.16	0.12	0.49	0.05	2.53	0.25	9.32	0.93	2.02	0.20
SO 0691	Cotton seed, raw (incl oil)	RAC	0.08	20.53	1.64	9.80	0.78	6.42	0.51	4.73	0.38	7.14	0.57	18.68	1.49
OR 0691	Cotton seed oil, edible	PP	0.0064	3.22	0.02	1.54	0.01	1.01	0.01	0.74	0.00	1.12	0.01	2.93	0.02
SO 0697	Peanuts, nutmeat, raw (incl roasted, incl oil, incl butter)	RAC	0.02	1.30	0.03	1.23	0.02	12.62	0.25	2.87	0.06	6.59	0.13	2.67	0.05
SB 0716	Coffee bean raw (incl roasted, incl instant coffee, incl substitutes)	RAC	0.05	1.36	0.07	3.59	0.18	1.44	0.07	5.18	0.26	2.02	0.10	1.70	0.09
HS 0444	Peppers, chili, dried	PP	0.28	0.42	0.12	0.53	0.15	0.84	0.24	0.50	0.14	0.95	0.27	0.37	0.10
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)	RAC	0.01	31.20	0.31	72.44	0.72	20.88	0.21	47.98	0.48	33.08	0.33	36.25	0.36
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.0092	3.29	0.03	6.14	0.06	0.82	0.01	1.57	0.01	2.23	0.02	1.07	0.01
MO 0105	Edible offal (mammalian), raw	RAC	0.3	4.79	1.44	9.68	2.90	2.97	0.89	5.49	1.65	3.84	1.15	5.03	1.51
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.0047	289.65	1.36	485.88	2.28	26.92	0.13	239.03	1.12	199.91	0.94	180.53	0.85
PM 0110	Poultry meat, raw (incl prepared)	RAC	0.0043	14.63	0.06	29.76	0.13	8.04	0.03	129.68	0.56	25.04	0.11	35.66	0.15
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.0094	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.10	0.00	0.10	0.00
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.011	0.12	0.00	0.12	0.00	0.11	0.00	5.37	0.06	0.24	0.00	0.10	0.00
PE 0112	Eggs, raw, (incl dried)	RAC	0.0047	7.84	0.04	23.08	0.11	2.88	0.01	14.89	0.07	9.81	0.05	14.83	0.07
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total intake (ug/person)=					51.0		65.4		51.3		89.8		88.9		121.4
Bodyweight per region (kg bw) =					60		60		60		60		60		60
ADI (ug/person)=					600		600		600		600		600		600
%ADI=					8.5 %		10.9 %		8.5 %		15.0 %		14.8 %		20.2 %
Rounded %ADI=					9 %		10 %		9 %		10 %		10 %		20 %

Annex 3

754

FLUTRIAFOL (248)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.01 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day							
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
FP 0009	Group of Pome fruits, raw (incl apple cider, excl apple juice)	RAC	0.08	51.09	4.09	65.40	5.23	42.71	3.42	45.29	3.62	62.51	5.00	7.74	0.62
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.038	14.88	0.57	11.98	0.46	0.15	0.01	9.98	0.38	30.32	1.15	3.47	0.13
FS 0013	Subgroup of Cherries, raw	RAC	0.335	1.40	0.47	4.21	1.41	0.04	0.01	2.93	0.98	1.50	0.50	NC	-
FS 0014	Subgroup of Plums, raw	RAC	0.075	3.75	0.28	3.33	0.25	5.94	0.45	2.64	0.20	2.50	0.19	0.06	0.00
DF 0014	Plums, dried (prunes)	PP	0.165	0.61	0.10	0.35	0.06	0.05	0.01	0.35	0.06	0.49	0.08	0.13	0.02
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.17	13.03	2.22	16.29	2.77	8.29	1.41	12.95	2.20	5.35	0.91	0.04	0.01
FB 0269	Grapes, raw (incl must, incl juice, excl dried, excl wine)	RAC	0.21	7.18	1.51	13.73	2.88	5.24	1.10	12.27	2.58	7.46	1.57	1.21	0.25
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	0.59	3.09	1.82	1.51	0.89	0.03	0.02	1.38	0.81	4.26	2.51	0.42	0.25
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.3528	88.93	31.37	62.41	22.02	1.84	0.65	25.07	8.84	61.17	21.58	5.84	2.06
FB 0275	Strawberry, raw	RAC	0.42	4.49	1.89	5.66	2.38	0.02	0.01	6.63	2.78	5.75	2.42	0.05	0.02
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.05	25.76	1.29	23.65	1.18	23.83	1.19	24.37	1.22	19.43	0.97	101.55	5.08
VB 0040	Group of Brassica vegetables (excl Brassica leafy vegetables), raw	RAC	0.14	20.71	2.90	39.81	5.57	25.06	3.51	37.93	5.31	18.12	2.54	16.74	2.34
VC 0045	Group of Fruiting vegetables, cucurbits, raw	RAC	0.09	27.81	2.50	41.93	3.77	123.30	11.10	49.47	4.45	15.95	1.44	35.99	3.24
VO 0448	Tomato, raw (incl juice, incl canned, excl paste)	RAC	0.1	44.88	4.49	55.49	5.55	35.44	3.54	75.65	7.57	27.00	2.70	9.61	0.96
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.286	4.96	1.42	3.20	0.92	0.15	0.04	1.61	0.46	6.88	1.97	0.52	0.15
VO 0051	Subgroup of peppers, raw (incl dried sweet peppers, excl dried chilipeppers), incl okra	RAC	0.28	6.39	1.79	15.53	4.35	19.13	5.36	10.53	2.95	8.29	2.32	5.25	1.47
VL 0483	Lettuce, leaf, raw	RAC	0.34	14.50	4.93	11.76	4.00	13.14	4.47	19.50	6.63	4.81	1.64	2.23	0.76
VL 0502	Spinach, raw	RAC	1.665	2.20	3.66	1.76	2.93	13.38	22.28	2.94	4.90	5.53	9.21	0.02	0.03
VL 0485	Mustard greens, raw (i.e. Indian mustard, Amsoi, mustard cabbage)	RAC	2.12	NC	-	NC	-	NC	-	NC	-	NC	-	0.13	0.28
VD 0541	Soya bean, dry, raw (incl flour, incl paste, incl curd, incl sauce, excl oil)	RAC	0.055	0.47	0.03	0.77	0.04	9.12	0.50	8.05	0.44	0.04	0.00	6.06	0.33
OR 0541	Soya oil, refined	PP	0.072	19.06	1.37	21.06	1.52	5.94	0.43	33.78	2.43	40.05	2.88	13.39	0.96
VR 0596	Sugar beet, raw (incl sugar)	RAC	0.01	0.01	0.00	NC	-	0.01	0.00	0.01	0.00	NC	-	NC	-
VS 0624	Celery	RAC	0.78	7.68	5.99	2.85	2.22	NC	-	3.34	2.61	16.83	13.13	4.04	3.15
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, excl germ, excl wholemeal bread, excl white flour products, excl white bread)	RAC	0.015	NC	-	NC	-	0.02	0.00	0.83	0.01	NC	-	NC	-
CF 1210	Wheat, germ	PP	0.042	0.97	0.04	0.10	0.00	0.03	0.00	0.01	0.00	NC	-	0.04	0.00
CF 1211	Wheat, white flour	PP	0.005	182.77	0.91	187.54	0.94	103.82	0.52	180.42	0.90	164.00	0.82	118.84	0.59
GC 0640	Barley, raw (incl malt extract, incl pot&pearled, incl flour & grits, incl beer, incl malt)	RAC	0.2	36.18	7.24	53.45	10.69	9.39	1.88	35.25	7.05	46.68	9.34	15.92	3.18

Annex 3

FLUTRIAFOL (248)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.01 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day																			
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake												
CM 0649 (GC 0649)	Rice, husked, dry (incl flour, incl oil, incl starch, excl beverages, excl polished)	REP	0.36	3.70	1.33	2.11	0.76	1.50	0.54	1.22	0.44	0.29	0.10	5.12	1.84												
CM 1205	Rice polished, dry	PP	0.4	13.38	5.35	10.80	4.32	262.08	104.83	57.16	22.86	12.83	5.13	62.78	25.11												
GC 0651	Sorghum, raw (incl flour, incl beer) (i.e. Chicken corn, Dari seed, Durra, Feterita)	RAC	0.27	NC	-	NC	-	1.44	0.39	1.15	0.31	NC	-	7.12	1.92												
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl flour, incl oil, incl beer, incl germ, incl starch)	RAC	0	18.51	0.00	26.18	0.00	26.04	0.00	39.99	0.00	7.36	0.00	64.58	0.00												
TN 0660	Almonds, nutmeat	RAC	0.064	0.81	0.05	2.21	0.14	0.03	0.00	1.02	0.07	1.47	0.09	NC	-												
TN 0672	Pecan, nutmeat	RAC	0.01	0.38	0.00	NC	-	NC	-	0.27	0.00	NC	-	0.26	0.00												
SO 0495	Rape seed, raw (incl oil)	RAC	0.1	32.68	3.27	19.91	1.99	7.83	0.78	15.69	1.57	NC	-	NC	-												
SO 0691	Cotton seed, raw (incl oil)	RAC	0.08	10.71	0.86	4.23	0.34	7.19	0.58	7.54	0.60	5.66	0.45	2.38	0.19												
OR 0691	Cotton seed oil, edible	PP	0.0064	1.68	0.01	0.66	0.00	1.13	0.01	1.18	0.01	0.89	0.01	0.37	0.00												
SO 0697	Peanuts, nutmeat, raw (incl roasted, incl oil, incl butter)	RAC	0.02	5.63	0.11	2.75	0.06	9.58	0.19	5.82	0.12	13.71	0.27	1.84	0.04												
SB 0716	Coffee bean raw (incl roasted, incl instant coffee, incl substitutes)	RAC	0.05	10.90	0.55	12.44	0.62	0.77	0.04	9.48	0.47	22.07	1.10	8.15	0.41												
HS 0444	Peppers, chili, dried	PP	0.28	0.11	0.03	0.21	0.06	0.36	0.10	0.21	0.06	0.25	0.07	0.15	0.04												
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)	RAC	0.01	140.03	1.40	150.89	1.51	79.32	0.79	111.24	1.11	120.30	1.20	51.27	0.51												
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.0092	6.44	0.06	15.51	0.14	3.79	0.03	8.29	0.08	18.44	0.17	8.00	0.07												
MO 0105	Edible offal (mammalian), raw	RAC	0.3	15.17	4.55	5.19	1.56	6.30	1.89	6.78	2.03	3.32	1.00	3.17	0.95												
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.0047	388.92	1.83	335.88	1.58	49.15	0.23	331.25	1.56	468.56	2.20	245.45	1.15												
PM 0110	Poultry meat, raw (incl prepared)	RAC	0.0043	73.76	0.32	53.86	0.23	23.98	0.10	87.12	0.37	53.38	0.23	84.45	0.36												
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.0094	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.71	0.01	NC	-												
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.011	0.33	0.00	0.72	0.01	0.27	0.00	0.35	0.00	0.80	0.01	NC	-												
PE 0112	Eggs, raw, (incl dried)	RAC	0.0047	25.84	0.12	29.53	0.14	28.05	0.13	33.19	0.16	36.44	0.17	8.89	0.04												
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-												
Total intake (ug/person)=				102.7				95.5				172.5				101.2				97.1				58.6			
Bodyweight per region (kg bw) =				60				60				55				60				60							
ADI (ug/person)=				600				600				550				600				600							
%ADI=				17.1 %				15.9 %				31.4 %				16.9 %				9.8 %							
Rounded %ADI=				20 %				20 %				30 %				20 %				10 %							

Annex 3

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FLUTRIAFOL (248)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.01 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day		Intake = daily intake: ug/person							
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
FP 0009	Group of Pome fruits, raw (incl apple cider, excl apple juice)	RAC	0.08	68.85	5.51	10.93	0.87	70.82	5.67	189.78	15.18	19.56	1.56
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.038	0.03	0.00	0.10	0.00	7.19	0.27	0.03	0.00	NC	-
FS 0013	Subgroup of Cherries, raw	RAC	0.335	0.01	0.00	0.01	0.00	5.96	2.00	0.01	0.00	NC	-
FS 0014	Subgroup of Plums, raw	RAC	0.075	0.07	0.01	0.01	0.00	15.56	1.17	0.01	0.00	NC	-
DF 0014	Plums, dried (prunes)	PP	0.165	0.01	0.00	0.01	0.00	0.37	0.06	0.01	0.00	NC	-
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.17	0.02	0.00	0.01	0.00	10.76	1.83	0.01	0.00	NC	-
FB 0269	Grapes, raw (incl must, incl juice, excl dried, excl wine)	RAC	0.21	0.15	0.03	0.38	0.08	15.84	3.33	0.01	0.00	0.28	0.06
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	0.59	0.01	0.01	0.13	0.08	1.06	0.63	0.01	0.01	0.03	0.02
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.3528	0.31	0.11	0.23	0.08	60.43	21.32	0.52	0.18	31.91	11.26
FB 0275	Strawberry, raw	RAC	0.42	0.01	0.00	0.01	0.00	3.35	1.41	0.01	0.00	0.01	0.00
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.05	44.80	2.24	118.17	5.91	25.25	1.26	454.49	22.72	310.23	15.51
VB 0040	Group of Brassica vegetables (excl Brassica leafy vegetables), raw	RAC	0.14	5.46	0.76	4.28	0.60	58.72	8.22	0.02	0.00	NC	-
VC 0045	Group of Fruiting vegetables, cucurbits, raw	RAC	0.09	5.96	0.54	9.74	0.88	51.82	4.66	13.61	1.22	0.05	0.00
VO 0448	Tomato, raw (incl juice, incl canned, excl paste)	RAC	0.1	13.17	1.32	4.92	0.49	62.69	6.27	1.04	0.10	0.11	0.01
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.286	0.58	0.17	0.22	0.06	2.21	0.63	0.24	0.07	3.10	0.89
VO 0051	Subgroup of peppers, raw (incl dried sweet peppers, excl dried chilipeppers), incl okra	RAC	0.28	15.20	4.26	14.23	3.98	25.14	7.04	0.91	0.25	NC	-
VL 0483	Lettuce, leaf, raw	RAC	0.34	0.29	0.10	0.03	0.01	6.71	2.28	0.01	0.00	NC	-
VL 0502	Spinach, raw	RAC	1.665	0.17	0.28	0.01	0.02	0.81	1.35	0.01	0.02	NC	-
VL 0485	Mustard greens, raw (i.e. Indian mustard, Amsoi, mustard cabbage)	RAC	2.12	0.04	0.08	0.03	0.06	NC	-	0.01	0.02	NC	-
VD 0541	Soya bean, dry, raw (incl flour, incl paste, incl curd, incl sauce, excl oil)	RAC	0.055	2.89	0.16	0.21	0.01	0.48	0.03	3.16	0.17	0.26	0.01
OR 0541	Soya oil, refined	PP	0.072	2.32	0.17	2.54	0.18	18.70	1.35	2.51	0.18	6.29	0.45
VR 0596	Sugar beet, raw (incl sugar)	RAC	0.01	3.93	0.04	1.68	0.02	NC	-	NC	-	36.12	0.36
VS 0624	Celery	RAC	0.78	3.66	2.85	2.65	2.07	4.84	3.78	2.47	1.93	4.94	3.85
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, excl germ, excl wholemeal bread, excl white flour products, excl white bread)	RAC	0.015	0.01	0.00	NC	-	NC	-	NC	-	0.97	0.01
CF 1210	Wheat, germ	PP	0.042	0.04	0.00	0.01	0.00	0.01	0.00	0.01	0.00	NC	-
CF 1211	Wheat, white flour	PP	0.005	43.75	0.22	85.81	0.43	206.68	1.03	19.38	0.10	92.92	0.46
GC 0640	Barley, raw (incl malt extract, incl pot&pearled, incl flour & grits, incl beer, incl malt)	RAC	0.2	11.58	2.32	2.33	0.47	46.71	9.34	3.72	0.74	16.26	3.25

Annex 3

FLUTRIAFOL (248)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.01 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day		Intake = daily intake: ug/person							
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
CM 0649 (GC 0649)	Rice, husked, dry (incl flour, incl oil, incl starch, excl beverages, excl polished)	REP	0.36	13.58	4.89	4.29	1.54	2.17	0.78	0.01	0.00	8.84	3.18
CM 1205	Rice polished, dry	PP	0.4	30.20	12.08	218.34	87.34	12.77	5.11	15.24	6.10	51.35	20.54
GC 0651	Sorghum, raw (incl flour, incl beer) (i.e. Chicken corn, Dari seed, Durra, Feterita)	RAC	0.27	89.16	24.07	2.02	0.55	NC	-	35.38	9.55	NC	-
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl flour, incl oil, incl beer, incl germ, incl starch)	RAC	0	116.66	0.00	10.52	0.00	38.46	0.00	76.60	0.00	34.44	0.00
TN 0660	Almonds, nutmeat	RAC	0.064	0.01	0.00	0.01	0.00	0.61	0.04	0.01	0.00	NC	-
TN 0672	Pecan, nutmeat	RAC	0.01	0.15	0.00	0.22	0.00	0.31	0.00	0.01	0.00	0.01	0.00
SO 0495	Rape seed, raw (incl oil)	RAC	0.1	0.19	0.02	0.07	0.01	12.07	1.21	0.08	0.01	NC	-
SO 0691	Cotton seed, raw (incl oil)	RAC	0.08	8.14	0.65	0.32	0.03	2.84	0.23	2.69	0.22	0.97	0.08
OR 0691	Cotton seed oil, edible	PP	0.0064	1.28	0.01	0.05	0.00	0.45	0.00	0.42	0.00	0.15	0.00
SO 0697	Peanuts, nutmeat, raw (incl roasted, incl oil, incl butter)	RAC	0.02	18.82	0.38	0.57	0.01	2.28	0.05	6.90	0.14	0.53	0.01
SB 0716	Coffee bean raw (incl roasted, incl instant coffee, incl substitutes)	RAC	0.05	0.95	0.05	1.32	0.07	11.64	0.58	2.96	0.15	14.73	0.74
HS 0444	Peppers, chili, dried	PP	0.28	0.58	0.16	1.27	0.36	1.21	0.34	0.12	0.03	NC	-
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)	RAC	0.01	29.18	0.29	50.89	0.51	121.44	1.21	22.58	0.23	72.14	0.72
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.0092	1.05	0.01	1.14	0.01	18.69	0.17	0.94	0.01	3.12	0.03
MO 0105	Edible offal (mammalian), raw	RAC	0.3	4.64	1.39	1.97	0.59	10.01	3.00	3.27	0.98	3.98	1.19
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.0047	108.75	0.51	70.31	0.33	436.11	2.05	61.55	0.29	79.09	0.37
PM 0110	Poultry meat, raw (incl prepared)	RAC	0.0043	3.92	0.02	12.03	0.05	57.07	0.25	5.03	0.02	55.56	0.24
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.0094	NC	-	NC	-	0.32	0.00	NC	-	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.011	0.10	0.00	0.70	0.01	0.97	0.01	0.10	0.00	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0.0047	3.84	0.02	4.41	0.02	27.25	0.13	1.13	0.01	7.39	0.03
-	-	-	-	-	-	-	-	-	-	-	-	-	-

Total intake (ug/person)=	65.7	107.7	100.1	60.7	64.9
Bodyweight per region (kg bw) =	60	60	60	60	60
ADI (ug/person)=	600	600	600	600	600
%ADI=	11.0 %	18.0 %	16.7 %	10.1 %	10.8 %
Rounded %ADI=	10 %	20 %	20 %	10 %	10 %

Annex 3

758

INDOXACARB (216)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.01 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day							
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
				FP 0226	Apple, raw	RAC	0.21	13.39	2.81	26.46	5.56	0.52	0.11	16.07	3.37
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.011	0.32	0.00	3.07	0.03	0.07	0.00	5.00	0.06	0.29	0.00	5.57	0.06
FP 0230	Pear, raw	RAC	0.051	2.16	0.11	6.24	0.32	0.05	0.00	4.07	0.21	1.16	0.06	5.34	0.27
FS 0012	Group of Stone fruits, raw (incl dried plums, incl dried apricots)	RAC	0.17	11.60	1.97	23.79	4.04	0.25	0.04	11.84	2.01	2.41	0.41	33.44	5.68
DF 0014	Plums, dried (prunes)	PP	0.68	0.09	0.06	0.06	0.04	0.01	0.01	0.18	0.12	0.04	0.03	0.06	0.04
FB 2006	Subgroup of Bush berries, raw (including processed)	RAC	0.58	0.53	0.31	1.31	0.76	0.40	0.23	1.66	0.96	0.01	0.01	0.99	0.57
FB 0269	Grapes, raw (i.e. table grapes)	RAC	0.3	12.68	3.80	9.12	2.74	0.03	0.01	16.88	5.06	3.70	1.11	54.42	16.33
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	0.81	0.51	0.41	0.51	0.41	0.01	0.01	1.27	1.03	0.12	0.10	2.07	1.68
JF 0269	Grape juice (from wine grapes)	PP	0.002	0.14	0.00	0.29	0.00	0.05	0.00	0.30	0.00	0.24	0.00	0.05	0.00
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.018	0.67	0.01	12.53	0.23	2.01	0.04	1.21	0.02	3.53	0.06	4.01	0.07
FB 0265	Cranberry, raw	RAC	0.15	0.02	0.00	0.01	0.00	NC	-	0.03	0.00	0.01	0.00	0.01	0.00
VB 0400	Broccoli, raw	RAC	0.055	0.88	0.05	0.17	0.01	0.01	0.00	1.25	0.07	3.00	0.17	1.09	0.06
VB 0404	Cauliflower, raw	RAC	0.02	1.65	0.03	0.32	0.01	0.01	0.00	2.33	0.05	4.79	0.10	2.03	0.04
VB 0041	Cabbages, head, raw	RAC	0.435	2.73	1.19	27.92	12.15	0.55	0.24	4.47	1.94	4.27	1.86	10.25	4.46
VC 0424	Cucumber, raw	RAC	0.06	8.01	0.48	30.66	1.84	1.45	0.09	19.84	1.19	0.27	0.02	34.92	2.10
VC 0425	Gherkin, raw	RAC	0.06	1.73	0.10	6.64	0.40	0.31	0.02	4.29	0.26	0.29	0.02	7.56	0.45
VC 0431	Squash, Summer (Courgette, Marrow, Zucchini, Zucchini), raw	RAC	0.06	0.78	0.05	2.06	0.12	0.30	0.02	1.61	0.10	2.25	0.14	2.36	0.14
VC 0046	Melons, except watermelon, raw (Cantaloupe)	RAC	0.02	8.90	0.18	8.64	0.17	0.80	0.02	17.90	0.36	2.80	0.06	29.17	0.58
VC 0429	Pumpkins, raw	RAC	0.02	4.76	0.10	12.56	0.25	1.85	0.04	9.86	0.20	5.11	0.10	14.39	0.29
VC 0432	Watermelon, raw	RAC	0.02	28.96	0.58	25.65	0.51	1.56	0.03	39.26	0.79	4.94	0.10	66.90	1.34
VO 0448	Tomato, raw	RAC	0.11	41.73	4.59	75.65	8.32	10.66	1.17	82.87	9.12	24.75	2.72	200.93	22.10
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.21	2.34	0.49	1.33	0.28	1.57	0.33	4.24	0.89	0.34	0.07	2.83	0.59
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.022	0.29	0.01	0.29	0.01	0.01	0.00	0.38	0.01	0.05	0.00	0.14	0.00
VO 0051	Subgroup of peppers, raw (incl dried sweet peppers, excl dried chilipeppers), incl okra	RAC	0.038	10.45	0.40	13.74	0.52	13.81	0.52	14.53	0.55	15.25	0.58	27.93	1.06
VO 2046	Subgroup of eggplants	RAC	0.11	5.58	0.61	4.31	0.47	0.89	0.10	9.31	1.02	13.64	1.50	20.12	2.21
VL 0483	Lettuce, leaf, raw	RAC	0.52	0.53	0.28	0.36	0.19	0.16	0.08	6.21	3.23	1.90	0.99	6.05	3.15
VP 2060	Subgroup of beans with pods (all commodities within this group)	RAC	0.16	0.68	0.11	NC	-	NC	-	0.39	0.06	0.22	0.04	0.49	0.08
VD 0523	Broad bean, dry, raw (incl horse-bean, field bean) (Vicia faba)	RAC	0.01	1.27	0.01	0.01	0.00	0.12	0.00	2.49	0.02	0.23	0.00	5.54	0.06
VD 0527	Cowpea, dry, raw (Vigna sinensis, Dolichos sinensis)	RAC	0.02	0.05	0.00	NC	-	1.74	0.03	0.01	0.00	0.01	0.00	0.07	0.00
VD 0541	Soya bean, dry, raw (incl flour, incl paste, incl	RAC	0.027	0.63	0.02	1.09	0.03	0.40	0.01	1.40	0.04	1.68	0.05	0.48	0.01

Annex 3

INDOXACARB (216)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.01 mg/kg bw

Codex Code	Commodity description	Expr as	STM ^R mg/kg	Diets as g/person/day				Intake as ug/person/day																			
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake												
	curd, incl sauce, excl oil)																										
OR 0541	Soya oil, refined	PP	0.018	12.99	0.23	10.43	0.19	3.63	0.07	13.10	0.24	10.70	0.19	13.10	0.24												
VD 0524	Chick-pea (dry) (Cicer spp), raw	RAC	0.02	5.34	0.11	0.13	0.00	0.01	0.00	4.69	0.09	7.24	0.14	5.52	0.11												
VR 0574	Beetroot, raw	RAC	0.18	3.42	0.62	6.06	1.09	3.75	0.68	9.11	1.64	NC	-	4.39	0.79												
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.01	59.74	0.60	316.14	3.16	9.78	0.10	60.26	0.60	54.12	0.54	119.82	1.20												
GC 2091	Subgroup of Maize Cereals	RAC	0.01	29.81	0.30	44.77	0.45	108.95	1.09	52.37	0.52	60.28	0.60	75.69	0.76												
GC 2090	Subgroup of Sweet Corns	RAC	0.01	0.14	0.00	0.94	0.01	5.70	0.06	2.61	0.03	1.94	0.02	0.22	0.00												
TN 0085	Group of Tree nuts, raw (incl processed)	RAC	0.013	4.06	0.05	3.27	0.04	7.01	0.09	13.93	0.18	14.01	0.18	9.36	0.12												
OR 0691	Cotton seed oil, edible	PP	0.013	3.22	0.04	1.54	0.02	1.01	0.01	0.74	0.01	1.12	0.01	2.93	0.04												
SO 0697	Peanuts, nutmeat, raw (incl roasted, incl butter, excl oil)	RAC	0.01	0.46	0.00	1.21	0.01	6.64	0.07	2.71	0.03	1.26	0.01	1.84	0.02												
OR 0697	Peanut oil, edible	PP	0.003	0.36	0.00	0.01	0.00	2.57	0.01	0.07	0.00	2.29	0.01	0.36	0.00												
HH 0738	Mint, raw	RAC	3.5	0.50	1.75	0.01	0.04	NC	-	NC	-	NC	-	NC	-												
-	Teas and herbal teas, dried (incl concentrates)	RAC	0.41	2.39	0.98	1.99	0.82	1.47	0.60	2.46	1.01	2.31	0.95	3.06	1.25												
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80 % as muscle	RAC	0.15	24.96	3.74	57.95	8.69	16.70	2.51	38.38	5.76	26.46	3.97	29.00	4.35												
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20 % as fat	RAC	0.66	6.24	4.12	14.49	9.56	4.18	2.76	9.60	6.33	6.62	4.37	7.25	4.79												
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.66	3.29	2.17	6.14	4.05	0.82	0.54	1.57	1.04	2.23	1.47	1.07	0.71												
MO 0105	Edible offal (mammalian), raw	RAC	0.03	4.79	0.14	9.68	0.29	2.97	0.09	5.49	0.16	3.84	0.12	5.03	0.15												
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.07	289.65	20.28	485.88	34.01	26.92	1.88	239.03	16.73	199.91	13.99	180.53	12.64												
PM 0110	Poultry meat, raw (incl prepared) - 90 % as muscle	RAC	0	13.17	0.00	26.78	0.00	7.24	0.00	116.71	0.00	22.54	0.00	32.09	0.00												
PM 0110	Poultry meat, raw (incl prepared) - 10 % as fat	RAC	0.025	1.46	0.04	2.98	0.07	0.80	0.02	12.97	0.32	2.50	0.06	3.57	0.09												
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0	0.12	0.00	0.12	0.00	0.11	0.00	5.37	0.00	0.24	0.00	0.10	0.00												
PE 0112	Eggs, raw, (incl dried)	RAC	0.01	7.84	0.08	23.08	0.23	2.88	0.03	14.89	0.15	9.81	0.10	14.83	0.15												
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-												
Total intake (ug/person)=				54.0				102.1				13.7				67.6				38.3				100.9			
Bodyweight per region (kg bw) =				60				60				60				60				60							
ADI (ug/person)=				600				600				600				600				600							
%ADI=				9.0 %				17.0 %				2.3 %				11.3 %				6.4 %				16.8 %			
Rounded %ADI=				9 %				20 %				2 %				10 %				6 %				20 %			

Annex 3

760

INDOXACARB (216)			International Estimated Daily Intake (IEDI)				ADI = 0 - 0.01 mg/kg bw								
Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day							
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
FP 0226	Apple, raw	RAC	0.21	27.44	5.76	49.21	10.33	21.57	4.53	31.09	6.53	51.60	10.84	1.77	0.37
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.011	14.88	0.16	11.98	0.13	0.15	0.00	9.98	0.11	30.32	0.33	3.47	0.04
FP 0230	Pear, raw	RAC	0.051	8.79	0.45	8.44	0.43	12.37	0.63	9.60	0.49	10.27	0.52	0.23	0.01
FS 0012	Group of Stone fruits, raw (incl dried plums, incl dried apricots)	RAC	0.17	19.98	3.40	24.87	4.23	14.41	2.45	19.54	3.32	10.78	1.83	0.50	0.09
DF 0014	Plums, dried (prunes)	PP	0.68	0.61	0.41	0.35	0.24	0.05	0.03	0.35	0.24	0.49	0.33	0.13	0.09
FB 2006	Subgroup of Bush berries, raw (including processed)	RAC	0.58	1.31	0.76	5.50	3.19	0.01	0.01	2.57	1.49	0.82	0.48	2.15	1.25
FB 0269	Grapes, raw (i.e. table grapes)	RAC	0.3	6.33	1.90	11.22	3.37	5.21	1.56	9.38	2.81	4.55	1.37	0.78	0.23
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	0.81	3.09	2.50	1.51	1.22	0.03	0.02	1.38	1.12	4.26	3.45	0.42	0.34
JF 0269	Grape juice (from wine grapes)	PP	0.002	0.56	0.00	1.96	0.00	0.02	0.00	2.24	0.00	2.27	0.00	0.34	0.00
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.018	88.93	1.60	62.41	1.12	1.84	0.03	25.07	0.45	61.17	1.10	5.84	0.11
FB 0265	Cranberry, raw	RAC	0.15	0.06	0.01	0.01	0.00	0.01	0.00	1.22	0.18	0.11	0.02	NC	-
VB 0400	Broccoli, raw	RAC	0.055	4.24	0.23	1.76	0.10	NC	-	0.51	0.03	3.79	0.21	0.26	0.01
VB 0404	Cauliflower, raw	RAC	0.02	5.27	0.11	5.01	0.10	NC	-	2.70	0.05	5.57	0.11	0.49	0.01
VB 0041	Cabbages, head, raw	RAC	0.435	8.97	3.90	27.12	11.80	1.44	0.63	24.96	10.86	4.55	1.98	11.23	4.89
VC 0424	Cucumber, raw	RAC	0.06	6.72	0.40	11.03	0.66	32.10	1.93	15.10	0.91	4.05	0.24	9.57	0.57
VC 0425	Gherkin, raw	RAC	0.06	0.41	0.02	5.89	0.35	NC	-	0.06	0.00	0.37	0.02	2.07	0.12
VC 0431	Squash, Summer (Courgette, Marrow, Zucchetti, Zucchini), raw	RAC	0.06	NC	-	NC	-	5.48	0.33	NC	-	NC	-	1.03	0.06
VC 0046	Melons, except watermelon, raw (Cantaloupe)	RAC	0.02	9.20	0.18	11.95	0.24	14.63	0.29	8.99	0.18	7.86	0.16	2.46	0.05
VC 0429	Pumpkins, raw	RAC	0.02	6.88	0.14	3.23	0.06	2.59	0.05	12.12	0.24	1.68	0.03	6.30	0.13
VC 0432	Watermelon, raw	RAC	0.02	4.60	0.09	9.82	0.20	68.50	1.37	13.19	0.26	1.99	0.04	14.56	0.29
VO 0448	Tomato, raw	RAC	0.11	32.13	3.53	51.27	5.64	34.92	3.84	73.37	8.07	15.15	1.67	8.88	0.98
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.21	4.96	1.04	3.20	0.67	0.15	0.03	1.61	0.34	6.88	1.44	0.52	0.11
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.022	0.80	0.02	0.07	0.00	0.05	0.00	0.61	0.01	0.40	0.01	0.08	0.00
VO 0051	Subgroup of peppers, raw (incl dried sweet peppers, excl dried chilipeppers), incl okra	RAC	0.038	6.39	0.24	15.53	0.59	19.13	0.73	10.53	0.40	8.29	0.32	5.25	0.20
VO 2046	Subgroup of eggplants	RAC	0.11	1.01	0.11	1.69	0.19	21.37	2.35	3.00	0.33	1.40	0.15	NC	-
VL 0483	Lettuce, leaf, raw	RAC	0.52	14.50	7.54	11.76	6.12	13.14	6.83	19.50	10.14	4.81	2.50	2.23	1.16
VP 2060	Subgroup of beans with pods (all commodities within this group)	RAC	0.16	5.07	0.81	0.83	0.13	0.17	0.03	3.70	0.59	NC	-	NC	-
VD 0523	Broad bean, dry, raw (incl horse-bean, field bean) (Vicia faba)	RAC	0.01	0.02	0.00	0.01	0.00	1.16	0.01	0.40	0.00	NC	-	0.06	0.00
VD 0527	Cowpea, dry, raw (Vigna sinensis, Dolichos sinensis)	RAC	0.02	NC	-	NC	-	0.16	0.00	0.01	0.00	NC	-	NC	-

Annex 3

INDOXACARB (216)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.01 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day							
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
VD 0541	Soya bean, dry, raw (incl flour, incl paste, incl curd, incl sauce, excl oil)	RAC	0.027	0.47	0.01	0.77	0.02	9.12	0.25	8.05	0.22	0.04	0.00	6.06	0.16
OR 0541	Soya oil, refined	PP	0.018	19.06	0.34	21.06	0.38	5.94	0.11	33.78	0.61	40.05	0.72	13.39	0.24
VD 0524	Chick-pea (dry) (Cicer spp), raw	RAC	0.02	0.27	0.01	1.33	0.03	0.32	0.01	0.15	0.00	0.08	0.00	0.04	0.00
VR 0574	Beetroot, raw	RAC	0.18	9.91	1.78	6.34	1.14	NC	-	9.65	1.74	19.11	3.44	6.47	1.16
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.01	225.03	2.25	234.24	2.34	71.48	0.71	177.55	1.78	234.55	2.35	37.71	0.38
GC 2091	Subgroup of Maize Cereals	RAC	0.01	18.51	0.19	26.18	0.26	26.04	0.26	39.99	0.40	7.36	0.07	64.58	0.65
GC 2090	Subgroup of Sweet Corns	RAC	0.01	11.43	0.11	3.71	0.04	0.74	0.01	13.63	0.14	3.07	0.03	1.50	0.02
TN 0085	Group of Tree nuts, raw (incl processed)	RAC	0.013	8.52	0.11	8.94	0.12	15.09	0.20	9.60	0.12	14.57	0.19	26.26	0.34
OR 0691	Cotton seed oil, edible	PP	0.013	1.68	0.02	0.66	0.01	1.13	0.01	1.18	0.02	0.89	0.01	0.37	0.00
SO 0697	Peanuts, nutmeat, raw (incl roasted, incl butter, excl oil)	RAC	0.01	3.26	0.03	2.22	0.02	5.38	0.05	4.85	0.05	1.54	0.02	1.82	0.02
OR 0697	Peanut oil, edible	PP	0.003	1.02	0.00	0.23	0.00	1.81	0.01	0.42	0.00	5.23	0.02	0.01	0.00
HH 0738	Mint, raw	RAC	3.5	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
-	Teas and herbal teas, dried (incl concentrates)	RAC	0.41	3.37	1.38	1.75	0.72	1.12	0.46	1.86	0.76	2.30	0.94	0.75	0.31
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80 % as muscle	RAC	0.15	112.02	16.80	120.71	18.11	63.46	9.52	88.99	13.35	96.24	14.44	41.02	6.15
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20 % as fat	RAC	0.66	28.01	18.48	30.18	19.92	15.86	10.47	22.25	14.68	24.06	15.88	10.25	6.77
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.66	6.44	4.25	15.51	10.24	3.79	2.50	8.29	5.47	18.44	12.17	8.00	5.28
MO 0105	Edible offal (mammalian), raw	RAC	0.03	15.17	0.46	5.19	0.16	6.30	0.19	6.78	0.20	3.32	0.10	3.17	0.10
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.07	388.92	27.22	335.88	23.51	49.15	3.44	331.25	23.19	468.56	32.80	245.45	17.18
PM 0110	Poultry meat, raw (incl prepared) - 90 % as muscle	RAC	0	66.38	0.00	48.47	0.00	21.58	0.00	78.41	0.00	48.04	0.00	76.01	0.00
PM 0110	Poultry meat, raw (incl prepared) - 10 % as fat	RAC	0.025	7.38	0.18	5.39	0.13	2.40	0.06	8.71	0.22	5.34	0.13	8.45	0.21
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0	0.33	0.00	0.72	0.00	0.27	0.00	0.35	0.00	0.80	0.00	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0.01	25.84	0.26	29.53	0.30	28.05	0.28	33.19	0.33	36.44	0.36	8.89	0.09
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total intake (ug/person)=				109.2		128.5		56.2		112.4		112.8		50.2	
Bodyweight per region (kg bw) =				60		60		55		60		60		60	
ADI (ug/person)=				600		600		550		600		600		600	
%ADI=				18.2 %		21.4 %		10.2 %		18.7 %		18.8 %		8.4 %	
Rounded %ADI=				20 %		20 %		10 %		20 %		20 %		8 %	

Annex 3

762

INDOXACARB (216)				International Estimated Daily Intake (IEDI)				ADI = 0 - 0.01 mg/kg bw					
Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day		Intake = daily intake: ug/person							
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
FP 0226	Apple, raw	RAC	0.21	0.21	0.04	2.05	0.43	54.48	11.44	0.10	0.02	1.38	0.29
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.011	0.03	0.00	0.10	0.00	7.19	0.08	0.03	0.00	NC	-
FP 0230	Pear, raw	RAC	0.051	0.07	0.00	0.14	0.01	9.45	0.48	0.01	0.00	0.14	0.01
FS 0012	Group of Stone fruits, raw (incl dried plums, incl dried apricots)	RAC	0.17	0.09	0.02	0.03	0.01	33.36	5.67	0.01	0.00	NC	-
DF 0014	Plums, dried (prunes)	PP	0.68	0.01	0.01	0.01	0.01	0.37	0.25	0.01	0.01	NC	-
FB 2006	Subgroup of Bush berries, raw (including processed)	RAC	0.58	0.82	0.48	4.05	2.35	5.94	3.45	0.43	0.25	2.66	1.54
FB 0269	Grapes, raw (i.e. table grapes)	RAC	0.3	0.14	0.04	0.36	0.11	15.22	4.57	0.01	0.00	0.09	0.03
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	0.81	0.01	0.01	0.13	0.11	1.06	0.86	0.01	0.01	0.03	0.02
JF 0269	Grape juice (from wine grapes)	PP	0.002	0.01	0.00	0.01	0.00	0.41	0.00	0.01	0.00	NC	-
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.018	0.31	0.01	0.23	0.00	60.43	1.09	0.52	0.01	31.91	0.57
FB 0265	Cranberry, raw	RAC	0.15	NC	-	NC	-	0.03	0.00	NC	-	NC	-
VB 0400	Broccoli, raw	RAC	0.055	0.01	0.00	0.01	0.00	2.13	0.12	0.01	0.00	NC	-
VB 0404	Cauliflower, raw	RAC	0.02	0.01	0.00	0.01	0.00	2.73	0.05	0.01	0.00	NC	-
VB 0041	Cabbages, head, raw	RAC	0.435	3.82	1.66	2.99	1.30	49.16	21.38	0.01	0.00	NC	-
VC 0424	Cucumber, raw	RAC	0.06	0.68	0.04	1.81	0.11	10.40	0.62	0.01	0.00	0.04	0.00
VC 0425	Gherkin, raw	RAC	0.06	0.15	0.01	0.39	0.02	3.15	0.19	0.01	0.00	0.01	0.00
VC 0431	Squash, Summer (Courgette, Marrow, Zucchini, Zucchini), raw	RAC	0.06	0.09	0.01	1.01	0.06	NC	-	1.91	0.11	NC	-
VC 0046	Melons, except watermelon, raw (Cantaloupe)	RAC	0.02	0.19	0.00	0.10	0.00	4.98	0.10	0.01	0.00	NC	-
VC 0429	Pumpkins, raw	RAC	0.02	0.56	0.01	6.14	0.12	4.59	0.09	11.70	0.23	NC	-
VC 0432	Watermelon, raw	RAC	0.02	4.29	0.09	0.30	0.01	28.70	0.57	0.01	0.00	NC	-
VO 0448	Tomato, raw	RAC	0.11	12.99	1.43	4.79	0.53	58.40	6.42	0.92	0.10	0.09	0.01
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.21	0.58	0.12	0.22	0.05	2.21	0.46	0.24	0.05	3.10	0.65
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.022	0.05	0.00	0.01	0.00	0.42	0.01	0.01	0.00	0.02	0.00
VO 0051	Subgroup of peppers, raw (incl dried sweet peppers, excl dried chilipeppers), incl okra	RAC	0.038	15.20	0.58	14.23	0.54	25.14	0.96	0.91	0.03	NC	-
VO 2046	Subgroup of eggplants	RAC	0.11	1.31	0.14	8.26	0.91	3.95	0.43	0.01	0.00	NC	-
VL 0483	Lettuce, leaf, raw	RAC	0.52	0.29	0.15	0.03	0.02	6.71	3.49	0.01	0.01	NC	-
VP 2060	Subgroup of beans with pods (all commodities within this group)	RAC	0.16	NC	-	NC	-	NC	-	NC	-	NC	-
VD 0523	Broad bean, dry, raw (incl horse-bean, field bean) (Vicia faba)	RAC	0.01	3.70	0.04	0.03	0.00	0.17	0.00	0.01	0.00	NC	-
VD 0527	Cowpea, dry, raw (Vigna sinensis, Dolichos sinensis)	RAC	0.02	12.77	0.26	0.99	0.02	0.01	0.00	4.33	0.09	NC	-
VD 0541	Soya bean, dry, raw (incl flour, incl paste, incl curd, incl sauce, excl oil)	RAC	0.027	2.89	0.08	0.21	0.01	0.48	0.01	3.16	0.09	0.26	0.01

Annex 3

INDOXACARB (216)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.01 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day		Intake = daily intake: ug/person							
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
OR 0541	Soya oil, refined	PP	0.018	2.32	0.04	2.54	0.05	18.70	0.34	2.51	0.05	6.29	0.11
VD 0524	Chick-pea (dry) (Cicer spp), raw	RAC	0.02	1.09	0.02	1.56	0.03	0.33	0.01	0.18	0.00	0.47	0.01
VR 0574	Beetroot, raw	RAC	0.18	5.86	1.05	4.23	0.76	9.46	1.70	3.96	0.71	7.91	1.42
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.01	23.96	0.24	13.56	0.14	213.41	2.13	104.35	1.04	8.56	0.09
GC 2091	Subgroup of Maize Cereals	RAC	0.01	116.66	1.17	10.52	0.11	38.46	0.38	76.60	0.77	34.44	0.34
GC 2090	Subgroup of Sweet Corns	RAC	0.01	3.63	0.04	20.50	0.21	8.78	0.09	0.02	0.00	0.17	0.00
TN 0085	Group of Tree nuts, raw (incl processed)	RAC	0.013	4.39	0.06	135.53	1.76	6.11	0.08	0.72	0.01	317.74	4.13
OR 0691	Cotton seed oil, edible	PP	0.013	1.28	0.02	0.05	0.00	0.45	0.01	0.42	0.01	0.15	0.00
SO 0697	Peanuts, nutmeat, raw (incl roasted, incl butter, excl oil)	RAC	0.01	7.14	0.07	0.45	0.00	1.87	0.02	6.22	0.06	0.53	0.01
OR 0697	Peanut oil, edible	PP	0.003	5.02	0.02	0.05	0.00	0.17	0.00	0.29	0.00	NC	-
HH 0738	Mint, raw	RAC	3.5	NC	-	NC	-	NC	-	NC	-	NC	-
-	Teas and herbal teas, dried (incl concentrates)	RAC	0.41	1.62	0.66	5.25	2.15	0.87	0.36	0.56	0.23	0.88	0.36
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80 % as muscle	RAC	0.15	23.34	3.50	40.71	6.11	97.15	14.57	18.06	2.71	57.71	8.66
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20 % as fat	RAC	0.66	5.84	3.85	10.18	6.72	24.29	16.03	4.52	2.98	14.43	9.52
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.66	1.05	0.69	1.14	0.75	18.69	12.34	0.94	0.62	3.12	2.06
MO 0105	Edible offal (mammalian), raw	RAC	0.03	4.64	0.14	1.97	0.06	10.01	0.30	3.27	0.10	3.98	0.12
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.07	108.75	7.61	70.31	4.92	436.11	30.53	61.55	4.31	79.09	5.54
PM 0110	Poultry meat, raw (incl prepared) - 90 % as muscle	RAC	0	3.53	0.00	10.83	0.00	51.36	0.00	4.53	0.00	50.00	0.00
PM 0110	Poultry meat, raw (incl prepared) - 10 % as fat	RAC	0.025	0.39	0.01	1.20	0.03	5.71	0.14	0.50	0.01	5.56	0.14
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0	0.10	0.00	0.70	0.00	0.97	0.00	0.10	0.00	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0.01	3.84	0.04	4.41	0.04	27.25	0.27	1.13	0.01	7.39	0.07
-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total intake (ug/person)=				24.4		30.5		142.1		14.6		35.7	
Bodyweight per region (kg bw) =				60		60		60		60		60	
ADI (ug/person)=				600		600		600		600		600	
%ADI=				4.1 %		5.1 %		23.7 %		2.4 %		6.0 %	
Rounded %ADI=				4 %		5 %		20 %		2 %		6 %	

Annex 3

INPYRFLUXAM (329)

International Estimated Daily Intake (IEDI)

ADI = 0 - 000 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day		Intake as ug/person/day									
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
					0.34 %		0.68 %		0.38 %		0.43 %		0.17 %		1.23 %
		%ADI=			0 %		1 %		0 %		0 %		0 %		1 %
		Rounded %ADI=													

INPYRFLUXAM (329)

International Estimated Daily Intake (IEDI)

ADI = 0 - 000 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day							
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
FP 0226	Apple, raw (incl cider, excl juice)	RAC	0.91	41.14	37.44	56.49	51.41	26.64	24.24	31.58	28.74	51.94	47.27	3.05	2.78
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.11	14.88	1.64	11.98	1.32	0.15	0.02	9.98	1.10	30.32	3.34	3.47	0.38
VD 0541	Soya bean, dry, raw (incl paste, incl curd, incl oil, incl sauce)	RAC	0	106.33	0.00	117.78	0.00	42.12	0.00	195.70	0.00	222.52	0.00	80.47	0.00
VR 0596	Sugar beet, raw (incl sugar)	RAC	0	0.01	0.00	NC	-	0.01	0.00	0.01	0.00	NC	-	NC	-
CM 0649 (GC 0649)	Rice, husked, dry (incl polished, incl flour, incl starch, incl oil, incl beverages)	REP	0	20.96	0.00	16.04	0.00	339.67	0.00	75.51	0.00	16.86	0.00	86.13	0.00
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl flour, incl oil, incl beer, incl germ, incl starch)	RAC	0	18.51	0.00	26.18	0.00	26.04	0.00	39.99	0.00	7.36	0.00	64.58	0.00
GC 0447	Sweet corn on the cob, raw (incl frozen kernels, incl canned kernels)	RAC	0	11.43	0.00	3.71	0.00	0.74	0.00	13.63	0.00	3.07	0.00	1.50	0.00
SO 0697	Peanuts, nutmeat, raw (incl roasted, incl oil, incl butter)	RAC	0.01	5.63	0.06	2.75	0.03	9.58	0.10	5.82	0.06	13.71	0.14	1.84	0.02
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80 % as muscle	RAC	0	112.02	0.00	120.71	0.00	63.46	0.00	88.99	0.00	96.24	0.00	41.02	0.00
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20 % as fat	RAC	0	28.01	0.00	30.18	0.00	15.86	0.00	22.25	0.00	24.06	0.00	10.25	0.00
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0	6.44	0.00	15.51	0.00	3.79	0.00	8.29	0.00	18.44	0.00	8.00	0.00
MO 0105	Edible offal (mammalian), raw	RAC	0	15.17	0.00	5.19	0.00	6.30	0.00	6.78	0.00	3.32	0.00	3.17	0.00
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0	388.92	0.00	335.88	0.00	49.15	0.00	331.25	0.00	468.56	0.00	245.45	0.00
PM 0110	Poultry meat, raw (incl prepared) - 90 % as muscle	RAC	0	66.38	0.00	48.47	0.00	21.58	0.00	78.41	0.00	48.04	0.00	76.01	0.00
PM 0110	Poultry meat, raw (incl prepared) - 10 % as fat	RAC	0	7.38	0.00	5.39	0.00	2.40	0.00	8.71	0.00	5.34	0.00	8.45	0.00
PF 0111	Poultry fat, raw (incl rendered)	RAC	0	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.71	0.00	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0	0.33	0.00	0.72	0.00	0.27	0.00	0.35	0.00	0.80	0.00	NC	-

Annex 3

INPYRFLUXAM (329) International Estimated Daily Intake (IEDI) ADI = 0 - 000 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day		Intake as ug/person/day									
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
PE 0112	Eggs, raw, (incl dried)	RAC	0	25.84	0.00	29.53	0.00	28.05	0.00	33.19	0.00	36.44	0.00	8.89	0.00
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total intake (ug/person)=				39.1		52.8		24.4		29.9		50.7		3.2	
Bodyweight per region (kg bw) =				60		60		55		60		60		60	
ADI (ug/person)=				3600		3600		3300		3600		3600		3600	
%ADI=				1.09 %		1.47 %		0.74 %		0.83 %		1.41 %		0.09 %	
Rounded %ADI=				1 %		1 %		1 %		1 %		1 %		0 %	

INPYRFLUXAM (329) International Estimated Daily Intake (IEDI) ADI = 0 - 000 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day		Intake = daily intake: ug/person							
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
FP 0226	Apple, raw (incl cider, excl juice)	RAC	0.91	66.67	60.67	2.06	1.87	55.83	50.81	188.29	171.34	1.38	1.26
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.11	0.03	0.00	0.10	0.01	7.19	0.79	0.03	0.00	NC	-
VD 0541	Soya bean, dry, raw (incl paste, incl curd, incl oil, incl sauce)	RAC	0	15.80	0.00	14.29	0.00	104.36	0.00	17.11	0.00	35.20	0.00
VR 0596	Sugar beet, raw (incl sugar)	RAC	0	3.93	0.00	1.68	0.00	NC	-	NC	-	36.12	0.00
CM 0649 (GC 0649)	Rice, husked, dry (incl polished, incl flour, incl starch, incl oil, incl beverages)	REP	0	52.55	0.00	286.02	0.00	18.64	0.00	19.67	0.00	75.09	0.00
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl flour, incl oil, incl beer, incl germ, incl starch)	RAC	0	116.66	0.00	10.52	0.00	38.46	0.00	76.60	0.00	34.44	0.00
GC 0447	Sweet corn on the cob, raw (incl frozen kernels, incl canned kernels)	RAC	0	3.63	0.00	20.50	0.00	8.78	0.00	0.02	0.00	0.17	0.00
SO 0697	Peanuts, nutmeat, raw (incl roasted, incl oil, incl butter)	RAC	0.01	18.82	0.19	0.57	0.01	2.28	0.02	6.90	0.07	0.53	0.01
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80 % as muscle	RAC	0	23.34	0.00	40.71	0.00	97.15	0.00	18.06	0.00	57.71	0.00
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20 % as fat	RAC	0	5.84	0.00	10.18	0.00	24.29	0.00	4.52	0.00	14.43	0.00
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0	1.05	0.00	1.14	0.00	18.69	0.00	0.94	0.00	3.12	0.00
MO 0105	Edible offal (mammalian), raw	RAC	0	4.64	0.00	1.97	0.00	10.01	0.00	3.27	0.00	3.98	0.00
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0	108.75	0.00	70.31	0.00	436.11	0.00	61.55	0.00	79.09	0.00
PM 0110	Poultry meat, raw (incl prepared) - 90 % as muscle	RAC	0	3.53	0.00	10.83	0.00	51.36	0.00	4.53	0.00	50.00	0.00
PM 0110	Poultry meat, raw (incl prepared) - 10 % as fat	RAC	0	0.39	0.00	1.20	0.00	5.71	0.00	0.50	0.00	5.56	0.00
PF 0111	Poultry fat, raw (incl rendered)	RAC	0	NC	-	NC	-	0.32	0.00	NC	-	NC	-

Annex 3

INPYRFLUXAM (329)

International Estimated Daily Intake (IEDI)

ADI = 0 - 000 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day		Intake = daily intake: ug/person							
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0	0.10	0.00	0.70	0.00	0.97	0.00	0.10	0.00	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0	3.84	0.00	4.41	0.00	27.25	0.00	1.13	0.00	7.39	0.00
-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total intake (ug/person)=				60.9		1.9		51.6		171.4		1.3	
Bodyweight per region (kg bw) =				60		60		60		60		60	
ADI (ug/person)=				3600		3600		3600		3600		3600	
%ADI=				1.69 %		0.05 %		1.43 %		4.76 %		0.04 %	
Rounded %ADI=				2 %		0 %		1 %		5 %		0 %	

Annex 3

MANCOZEB/DITHIOCARBAMATES (105)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.03 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day																			
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake												
				FI 0342	Longan, raw	RAC	9.8	0.04	0.39	0.01	0.10	0.04	0.39	0.04	0.39	NC	-	0.01	0.10								
VO 0444	Peppers, chili, raw	RAC	1.4	3.99	5.59	7.30	10.22	2.93	4.10	5.62	7.87	NC	-	17.44	24.42												
VD 0541	Soya bean, dry, raw (Glycine soja)	RAC	0.75	0.58	0.44	0.05	0.04	0.37	0.28	0.03	0.02	1.65	1.24	0.30	0.23												
-	Soya paste (i.e. miso)	PP	0.75	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-												
-	Soya curd (i.e. tofu)	PP	0.75	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-												
OR 0541	Soya oil, refined	PP	0.75	12.99	9.74	10.43	7.82	3.63	2.72	13.10	9.83	10.70	8.03	13.10	9.83												
-	Soya sauce	PP	0.75	0.01	0.01	0.02	0.02	0.01	0.01	0.34	0.26	0.03	0.02	0.01	0.01												
-	Soya flour	PP	0.75	0.05	0.04	0.86	0.65	0.02	0.02	1.02	0.77	0.01	0.01	0.15	0.11												
CM 0649 (GC 0649)	Rice, husked, dry (incl paddy rice)	REP	3.2	1.17	3.74	1.30	4.16	31.05	99.36	4.79	15.33	0.25	0.80	2.16	6.91												
CM 1205	Rice polished, dry	PP	3.2	34.21	109.47	10.39	33.25	41.72	133.50	82.38	263.62	150.24	480.77	70.47	225.50												
-	Rice flour	PP	3.2	0.05	0.16	0.22	0.70	0.01	0.03	0.50	1.60	0.22	0.70	0.02	0.06												
-	Rice, starch	PP	3.2	0.01	0.03	0.01	0.03	NC	-	0.01	0.03	NC	-	0.01	0.03												
-	Rice bran oil	PP	3.2	0.03	0.10	NC	-	NC	-	NC	-	0.36	1.15	NC	-												
-	Rice, Fermented Beverages (rice wine, sake)	PP	3.2	NC	-	NC	-	NC	-	NC	-	0.01	0.03	NC	-												
GC 0645	Maize, raw	RAC	0.83	0.62	0.51	NC	-	0.55	0.46	NC	-	1.24	1.03	12.33	10.23												
CF 1255	Maize, flour (white flour and wholemeal flour)	PP	0.83	22.72	18.86	35.61	29.56	87.27	72.43	34.92	28.98	46.71	38.77	49.12	40.77												
-	Maize, germ	PP	0.83	0.01	0.01	NC	-	0.01	0.01	0.01	0.01	0.22	0.18	NC	-												
-	Maize starch	PP	0.83	0.08	0.07	NC	-	0.01	0.01	2.29	1.90	0.08	0.07	0.11	0.09												
-	Maize, glucose, isoglucose and Dextrose	PP	0.83	0.22	0.18	0.24	0.20	0.13	0.11	0.46	0.38	0.97	0.81	0.80	0.66												
-	Maize beer	PP	0.83	NC	-	NC	-	4.61	3.83	NC	-	NC	-	NC	-												
OR 0645	Maize oil	PP	0.83	0.96	0.80	0.85	0.71	0.29	0.24	5.42	4.50	0.42	0.35	2.10	1.74												
OR 0691	Cotton seed oil, edible	PP	0.75	3.22	2.42	1.54	1.16	1.01	0.76	0.74	0.56	1.12	0.84	2.93	2.20												
HS 0779	Coriander, seed	RAC	0.18	0.08	0.01	0.01	0.00	0.01	0.00	0.19	0.03	0.04	0.01	0.05	0.01												
HS 0780	Cumin, seed	RAC	6.4	0.08	0.51	0.01	0.06	0.01	0.06	0.19	1.22	0.04	0.26	0.05	0.32												
HS 0790	Pepper (black, white, pink, green)	RAC	0.18	0.08	0.01	0.13	0.02	0.05	0.01	0.36	0.06	0.17	0.03	0.13	0.02												
HS 0444	Peppers, chili, dried	PP	9.8	0.42	4.12	0.53	5.19	0.84	8.23	0.50	4.90	0.95	9.31	0.37	3.63												
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-												
Total intake (ug/person)=				157.2				93.9				326.6				342.2				544.4				326.9			
Bodyweight per region (kg bw) =				60				60				60				60				60							
ADI (ug/person)=				1800				1800				1800				1800				1800							
%ADI=				8.7 %				5.2 %				18.1 %				19.0 %				30.2 %				18.2 %			
Rounded %ADI=				9 %				5 %				20 %				20 %				30 %				20 %			

Annex 3

MANCOZEB/DITHIOCARBAMATES (105)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.03 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day								
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake	
FI 0342	Longan, raw	RAC	9.8	NC	-	NC	-	0.61	5.98	NC	-	NC	-	NC	-	
VO 0444	Peppers, chili, raw	RAC	1.4	5.57	7.80	14.00	19.60	8.25	11.55	5.77	8.08	6.44	9.02	2.53	3.54	
VD 0541	Soya bean, dry, raw (Glycine soja)	RAC	0.75	0.02	0.02	0.33	0.25	6.64	4.98	3.94	2.96	NC	-	5.78	4.34	
-	Soya paste (i.e. miso)	PP	0.75	NC	-	NC	-	NC	-	1.87	1.40	NC	-	NC	-	
-	Soya curd (i.e. tofu)	PP	0.75	NC	-	NC	-	0.68	0.51	0.87	0.65	NC	-	NC	-	
OR 0541	Soya oil, refined	PP	0.75	19.06	14.30	21.06	15.80	5.94	4.46	33.78	25.34	40.05	30.04	13.39	10.04	
-	Soya sauce	PP	0.75	0.45	0.34	0.29	0.22	2.93	2.20	4.35	3.26	0.09	0.07	0.70	0.53	
-	Soya flour	PP	0.75	0.22	0.17	0.27	0.20	0.29	0.22	0.17	0.13	NC	-	NC	-	
CM 0649 (GC 0649)	Rice, husked, dry (incl paddy rice)	REP	3.2	2.43	7.78	1.62	5.18	0.42	1.34	1.06	3.39	NC	-	5.02	16.06	
CM 1205	Rice polished, dry	PP	3.2	13.38	42.82	10.80	34.56	262.08	838.66	57.16	182.91	12.83	41.06	62.78	200.90	
-	Rice flour	PP	3.2	0.98	3.14	0.38	1.22	0.72	2.30	0.05	0.16	0.23	0.74	0.07	0.22	
-	Rice, starch	PP	3.2	NC	-	NC	-	0.01	0.03	NC	-	NC	-	0.01	0.03	
-	Rice bran oil	PP	3.2	NC	-	NC	-	0.15	0.48	0.10	0.32	NC	-	NC	-	
-	Rice, Fermented Beverages (rice wine, sake)	PP	3.2	NC	-	NC	-	0.03	0.10	2.77	8.86	NC	-	NC	-	
GC 0645	Maize, raw	RAC	0.83	NC	-	NC	-	1.35	1.12	NC	-	NC	-	NC	-	
CF 1255	Maize, flour (white flour and wholemeal flour)	PP	0.83	14.27	11.84	12.86	10.67	19.71	16.36	12.55	10.42	4.21	3.49	52.30	43.41	
-	Maize, germ	PP	0.83	0.01	0.01	NC	-	NC	-	0.01	0.01	NC	-	0.01	0.01	
-	Maize starch	PP	0.83	NC	-	NC	-	0.19	0.16	7.13	5.92	NC	-	NC	-	
-	Maize, glucose, isoglucose and Dextrose	PP	0.83	0.10	0.08	9.93	8.24	0.05	0.04	9.88	8.20	0.33	0.27	0.04	0.03	
-	Maize beer	PP	0.83	NC	-	NC	-	NC	-	1.99	1.65	NC	-	NC	-	
OR 0645	Maize oil	PP	0.83	0.90	0.75	0.47	0.39	0.15	0.12	3.01	2.50	1.86	1.54	0.36	0.30	
OR 0691	Cotton seed oil, edible	PP	0.75	1.68	1.26	0.66	0.50	1.13	0.85	1.18	0.89	0.89	0.67	0.37	0.28	
HS 0779	Coriander, seed	RAC	0.18	0.11	0.02	0.04	0.01	NC	-	0.02	0.00	0.06	0.01	0.01	0.00	
HS 0780	Cumin, seed	RAC	6.4	0.11	0.70	0.04	0.26	NC	-	0.02	0.13	0.06	0.38	0.01	0.06	
HS 0790	Pepper (black, white, pink, green)	RAC	0.18	0.31	0.06	0.41	0.07	0.12	0.02	0.34	0.06	0.70	0.13	0.89	0.16	
HS 0444	Peppers, chili, dried	PP	9.8	0.11	1.08	0.21	2.06	0.36	3.53	0.21	2.06	0.25	2.45	0.15	1.47	
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Total intake (ug/person)=					92.1		99.2		895.0		269.3		89.9		281.4	
Bodyweight per region (kg bw) =					60		60		55		60		60		60	
ADI (ug/person)=					1800		1800		1650		1800		1800		1800	
%ADI=					5.1 %		5.5 %		54.2 %		15.0 %		5.0 %		15.6 %	
Rounded %ADI=					5 %		6 %		50 %		10 %		5 %		20 %	

Annex 3

770

MANCOZEB/DITHIOCARBAMATES (105)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.03 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day		Intake = daily intake: ug/person							
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
FI 0342	Longan, raw	RAC	9.8	0.01	0.10	0.01	0.10	NC	-	0.01	0.10	0.27	2.65
VO 0444	Peppers, chili, raw	RAC	1.4	3.47	4.86	3.56	4.98	16.30	22.82	0.01	0.01	NC	-
VD 0541	Soya bean, dry, raw (Glycine soja)	RAC	0.75	2.76	2.07	0.07	0.05	0.33	0.25	3.16	2.37	NC	-
-	Soya paste (i.e. miso)	PP	0.75	NC	-	NC	-	NC	-	NC	-	NC	-
-	Soya curd (i.e. tofu)	PP	0.75	NC	-	NC	-	NC	-	NC	-	NC	-
OR 0541	Soya oil, refined	PP	0.75	2.32	1.74	2.54	1.91	18.70	14.03	2.51	1.88	6.29	4.72
-	Soya sauce	PP	0.75	0.01	0.01	0.13	0.10	0.17	0.13	0.01	0.01	0.56	0.42
-	Soya flour	PP	0.75	0.11	0.08	0.08	0.06	0.07	0.05	0.01	0.01	0.03	0.02
CM 0649 (GC 0649)	Rice, husked, dry (incl paddy rice)	REP	3.2	13.53	43.30	3.48	11.14	1.96	6.27	0.01	0.03	8.84	28.29
CM 1205	Rice polished, dry	PP	3.2	30.20	96.64	218.34	698.69	12.77	40.86	15.24	48.77	51.35	164.32
-	Rice flour	PP	3.2	0.03	0.10	0.13	0.42	0.16	0.51	0.01	0.03	NC	-
-	Rice, starch	PP	3.2	0.01	0.03	0.04	0.13	NC	-	NC	-	NC	-
-	Rice bran oil	PP	3.2	NC	-	0.60	1.92	NC	-	NC	-	NC	-
-	Rice, Fermented Beverages (rice wine, sake)	PP	3.2	NC	-	NC	-	NC	-	NC	-	NC	-
GC 0645	Maize, raw	RAC	0.83	NC	-	0.01	0.01	0.03	0.02	NC	-	NC	-
CF 1255	Maize, flour (white flour and wholemeal flour)	PP	0.83	94.34	78.30	8.09	6.71	28.03	23.26	55.94	46.43	28.07	23.30
-	Maize, germ	PP	0.83	0.01	0.01	NC	-	NC	-	NC	-	NC	-
-	Maize starch	PP	0.83	0.02	0.02	0.01	0.01	NC	-	NC	-	NC	-
-	Maize, glucose, isoglucose and Dextrose	PP	0.83	0.35	0.29	0.51	0.42	3.23	2.68	0.18	0.15	NC	-
-	Maize beer	PP	0.83	1.03	0.85	NC	-	NC	-	40.94	33.98	NC	-
OR 0645	Maize oil	PP	0.83	0.33	0.27	0.07	0.06	0.81	0.67	0.01	0.01	NC	-
OR 0691	Cotton seed oil, edible	PP	0.75	1.28	0.96	0.05	0.04	0.45	0.34	0.42	0.32	0.15	0.11
HS 0779	Coriander, seed	RAC	0.18	0.01	0.00	0.25	0.05	NC	-	0.01	0.00	0.01	0.00
HS 0780	Cumin, seed	RAC	6.4	0.01	0.06	0.25	1.60	NC	-	0.01	0.06	0.01	0.06
HS 0790	Pepper (black, white, pink, green)	RAC	0.18	0.05	0.01	1.12	0.20	0.24	0.04	0.14	0.03	0.18	0.03
HS 0444	Peppers, chili, dried	PP	9.8	0.58	5.68	1.27	12.45	1.21	11.86	0.12	1.18	NC	-
-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total intake (ug/person)=				235.4		741.0		123.8		135.4		223.9	
Bodyweight per region (kg bw) =				60		60		60		60		60	
ADI (ug/person)=				1800		1800		1800		1800		1800	
%ADI=				13.1 %		41.2 %		6.9 %		7.5 %		12.4 %	
Rounded %ADI=				10 %		40 %		7 %		8 %		10 %	

Annex 3

MANDIPROPAMID (231)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.2 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day							
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
FC 0002	Subgroup of Lemons and limes, raw (incl kumquat commodities)	RAC	0.01	4.78	0.05	2.42	0.02	3.61	0.04	25.18	0.25	8.25	0.08	15.77	0.16
-	Lemon, juice (single strength, incl. concentrated)	PP	0.0042	0.01	0.00	0.01	0.00	0.11	0.00	0.09	0.00	0.18	0.00	0.17	0.00
FC 0003	Subgroup of Mandarins, raw	RAC	0.01	6.18	0.06	3.66	0.04	0.25	0.00	6.82	0.07	3.49	0.03	19.38	0.19
-	Subgroup of Mandarins, juice	PP	0.0042	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
FC 0004	Subgroup of Oranges, sweet, sour, raw	RAC	0.01	20.66	0.21	5.23	0.05	11.90	0.12	37.90	0.38	21.16	0.21	56.46	0.56
JF 0004	Subgroup of Oranges, juice (single strength, incl. concentrated)	PP	0.0043	1.27	0.01	2.20	0.01	0.09	0.00	11.81	0.05	0.46	0.00	1.69	0.01
FC 0005	Subgroup of Pummelo and grapefruits, raw	RAC	0.01	0.64	0.01	0.35	0.00	0.93	0.01	6.10	0.06	1.01	0.01	1.36	0.01
JF 0203	Grapefruits, juice (single strength, incl. concentrated)	PP	0.0024	0.01	0.00	0.16	0.00	0.02	0.00	1.97	0.00	0.12	0.00	0.77	0.00
FB 0269	Grapes, raw (incl must, excl dried, excl juice, excl wine)	RAC	0.51	13.02	6.64	9.25	4.72	0.03	0.02	16.91	8.62	3.70	1.89	54.44	27.76
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	1.68	0.51	0.86	0.51	0.86	0.01	0.02	1.27	2.13	0.12	0.20	2.07	3.48
JF 0269	Grape juice (from wine grapes)	PP	0.14	0.14	0.02	0.29	0.04	0.05	0.01	0.30	0.04	0.24	0.03	0.05	0.01
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.366	0.67	0.25	12.53	4.59	2.01	0.74	1.21	0.44	3.53	1.29	4.01	1.47
VA 2031	Subgroup of bulb onions	RAC	0.01	31.65	0.32	43.28	0.43	3.68	0.04	38.48	0.38	20.46	0.20	47.29	0.47
VB 0400	Broccoli, raw	RAC	0.435	0.88	0.38	0.17	0.07	0.01	0.00	1.25	0.54	3.00	1.31	1.09	0.47
VB 0041	Cabbages, head, raw	RAC	0.01	2.73	0.03	27.92	0.28	0.55	0.01	4.47	0.04	4.27	0.04	10.25	0.10
VC 2039	Subgroup of Cucumbers and Squashes, raw	RAC	0.0475	10.52	0.50	39.36	1.87	2.07	0.10	25.74	1.22	2.80	0.13	44.83	2.13
VC 2040	Subgroup of Melons, Pumpkins and Winter squashes	RAC	0.01	42.62	0.43	46.85	0.47	4.21	0.04	67.02	0.67	12.84	0.13	110.47	1.10
VO 0448	Tomato, raw	RAC	0.26	41.73	10.85	75.65	19.67	10.66	2.77	82.87	21.55	24.75	6.44	200.93	52.24
-	Tomato, canned (& peeled)	PP	0.101	0.20	0.02	0.31	0.03	0.02	0.00	1.11	0.11	0.11	0.01	1.50	0.15
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.91	2.34	2.13	1.33	1.21	1.57	1.43	4.24	3.86	0.34	0.31	2.83	2.58
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.26	0.29	0.08	0.29	0.08	0.01	0.00	0.38	0.10	0.05	0.01	0.14	0.04
VO 0051	Subgroup of peppers, raw (incl dried sweet peppers, excl dried chilipeppers), excl okra	RAC	0.09	8.48	0.76	13.74	1.24	10.13	0.91	11.29	1.02	9.52	0.86	26.36	2.37
VO 2046	Subgroup of eggplants	RAC	0.09	5.58	0.50	4.31	0.39	0.89	0.08	9.31	0.84	13.64	1.23	20.12	1.81
VL 0053	Group of Leafy vegetables, raw	RAC	5.65	8.47	47.86	22.36	126.33	7.74	43.73	25.51	144.13	45.77	258.60	21.22	119.89
VP 2060	Subgroup of beans with pods (all commodities within this group)	RAC	0.22	0.68	0.15	NC	-	NC	-	0.39	0.09	0.22	0.05	0.49	0.11
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.0185	59.74	1.11	316.14	5.85	9.78	0.18	60.26	1.11	54.12	1.00	119.82	2.22
VS 0624	Celery	RAC	2.7	2.14	5.78	3.79	10.23	2.35	6.35	5.69	15.36	0.02	0.05	2.75	7.43
SB 0715	Cacao bean, raw (incl roasted)	RAC	0.01	0.01	0.00	0.30	0.00	0.10	0.00	0.01	0.00	0.01	0.00	0.01	0.00

Annex 3

MANDIPROPAMID (231)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.2 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day																			
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake												
DM 0715	cacao powder	PP	0.005	0.11	0.00	0.06	0.00	0.19	0.00	0.79	0.00	0.27	0.00	0.34	0.00												
DM 1215	cacao butter	PP	0.005	0.01	0.00	0.28	0.00	0.01	0.00	0.01	0.00	0.01	0.00	0.01	0.00												
HH 0722	Basil leaves, raw (incl dried)	RAC	62.5	0.14	8.75	0.26	16.25	0.16	10.00	0.38	23.75	NC	-	0.19	11.88												
HS 0444	Peppers, chili, dried	PP	0.9	0.42	0.38	0.53	0.48	0.84	0.76	0.50	0.45	0.95	0.86	0.37	0.33												
DH 1100	Hops, dry	RAC	28.5	0.01	0.29	0.04	1.14	0.01	0.29	0.01	0.29	NC	-	0.01	0.29												
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)	RAC	0	31.20	0.00	72.44	0.00	20.88	0.00	47.98	0.00	33.08	0.00	36.25	0.00												
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.0064	3.29	0.02	6.14	0.04	0.82	0.01	1.57	0.01	2.23	0.01	1.07	0.01												
MO 0105	Edible offal (mammalian), raw	RAC	0.0022	4.79	0.01	9.68	0.02	2.97	0.01	5.49	0.01	3.84	0.01	5.03	0.01												
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0	289.65	0.00	485.88	0.00	26.92	0.00	239.03	0.00	199.91	0.00	180.53	0.00												
PM 0110	Poultry meat, raw (incl prepared)	RAC	0	14.63	0.00	29.76	0.00	8.04	0.00	129.68	0.00	25.04	0.00	35.66	0.00												
PF 0111	Poultry fat, raw (incl rendered)	RAC	0	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.10	0.00	0.10	0.00												
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0	0.12	0.00	0.12	0.00	0.11	0.00	5.37	0.00	0.24	0.00	0.10	0.00												
PE 0112	Eggs, raw, (incl dried)	RAC	0	7.84	0.00	23.08	0.00	2.88	0.00	14.89	0.00	9.81	0.00	14.83	0.00												
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-												
Total intake (ug/person)=				88.4				196.4				67.6				227.6				275.0				239.3			
Bodyweight per region (kg bw) =				60				60				60				60				60							
ADI (ug/person)=				12000				12000				12000				12000				12000							
%ADI=				0.7 %				1.6 %				0.6 %				1.9 %				2.3 %				2.0 %			
Rounded %ADI=				1 %				2 %				1 %				2 %				2 %							

MANDIPROPAMID (231)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.2 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day							
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
FC 0002	Subgroup of Lemons and limes, raw (incl kumquat commodities)	RAC	0.01	8.45	0.08	14.69	0.15	2.88	0.03	8.16	0.08	21.14	0.21	5.93	0.06
-	Lemon, juice (single strength, incl. concentrated)	PP	0.0042	0.60	0.00	0.36	0.00	0.01	0.00	1.49	0.01	0.43	0.00	0.24	0.00
FC 0003	Subgroup of Mandarins, raw	RAC	0.01	12.34	0.12	14.99	0.15	16.08	0.16	10.76	0.11	9.94	0.10	NC	-
-	Subgroup of Mandarins, juice	PP	0.0042	0.04	0.00	NC	-	0.01	0.00	0.01	0.00	NC	-	NC	-
FC 0004	Subgroup of Oranges, sweet, sour, raw	RAC	0.01	15.68	0.16	24.00	0.24	6.80	0.07	29.09	0.29	15.39	0.15	160.47	1.60
JF 0004	Subgroup of Oranges, juice (single strength, incl. concentrated)	PP	0.0043	33.31	0.14	1.78	0.01	0.28	0.00	18.97	0.08	14.01	0.06	13.36	0.06
FC 0005	Subgroup of Pummelo and grapefruits, raw	RAC	0.01	2.19	0.02	1.24	0.01	0.60	0.01	3.44	0.03	4.60	0.05	299.96	3.00
JF 0203	Grapefruits, juice (single strength, incl. concentrated)	PP	0.0024	2.89	0.01	1.61	0.00	0.02	0.00	1.15	0.00	7.39	0.02	33.07	0.08

Annex 3

MANDIPROPAMID (231)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.2 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day							
				G07		G08		G09		G10		G11		G12	
				diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
FB 0269	Grapes, raw (incl must, excl dried, excl juice, excl wine)	RAC	0.51	6.48	3.30	11.31	5.77	5.21	2.66	9.50	4.85	4.66	2.38	0.78	0.40
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	1.68	3.09	5.19	1.51	2.54	0.03	0.05	1.38	2.32	4.26	7.16	0.42	0.71
JF 0269	Grape juice (from wine grapes)	PP	0.14	0.56	0.08	1.96	0.27	0.02	0.00	2.24	0.31	2.27	0.32	0.34	0.05
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.366	88.93	32.55	62.41	22.84	1.84	0.67	25.07	9.18	61.17	22.39	5.84	2.14
VA 2031	Subgroup of bulb onions	RAC	0.01	20.67	0.21	31.32	0.31	37.52	0.38	35.08	0.35	11.77	0.12	13.74	0.14
VB 0400	Broccoli, raw	RAC	0.435	4.24	1.84	1.76	0.77	NC	-	0.51	0.22	3.79	1.65	0.26	0.11
VB 0041	Cabbages, head, raw	RAC	0.01	8.97	0.09	27.12	0.27	1.44	0.01	24.96	0.25	4.55	0.05	11.23	0.11
VC 2039	Subgroup of Cucumbers and Squashes, raw	RAC	0.0475	7.14	0.34	16.92	0.80	37.58	1.79	15.16	0.72	4.42	0.21	12.67	0.60
VC 2040	Subgroup of Melons, Pumpkins and Winter squashes	RAC	0.01	20.68	0.21	25.00	0.25	85.72	0.86	34.31	0.34	11.54	0.12	23.32	0.23
VO 0448	Tomato, raw	RAC	0.26	32.13	8.35	51.27	13.33	34.92	9.08	73.37	19.08	15.15	3.94	8.88	2.31
-	Tomato, canned (& peeled)	PP	0.101	7.57	0.76	2.66	0.27	0.30	0.03	0.97	0.10	7.31	0.74	0.41	0.04
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.91	4.96	4.51	3.20	2.91	0.15	0.14	1.61	1.47	6.88	6.26	0.52	0.47
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.26	0.80	0.21	0.07	0.02	0.05	0.01	0.61	0.16	0.40	0.10	0.08	0.02
VO 0051	Subgroup of peppers, raw (incl dried sweet peppers, excl dried chilipeppers), excl okra	RAC	0.09	6.39	0.58	15.53	1.40	19.09	1.72	10.36	0.93	8.29	0.75	4.53	0.41
VO 2046	Subgroup of eggplants	RAC	0.09	1.01	0.09	1.69	0.15	21.37	1.92	3.00	0.27	1.40	0.13	NC	-
VL 0053	Group of Leafy vegetables, raw	RAC	5.65	18.83	106.39	21.85	123.45	121.23	684.95	43.09	243.46	18.18	102.72	18.32	103.51
VP 2060	Subgroup of beans with pods (all commodities within this group)	RAC	0.22	5.07	1.12	0.83	0.18	0.17	0.04	3.70	0.81	NC	-	NC	-
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.0185	225.03	4.16	234.24	4.33	71.48	1.32	177.55	3.28	234.55	4.34	37.71	0.70
VS 0624	Celery	RAC	2.7	7.68	20.74	2.85	7.70	NC	-	3.34	9.02	16.83	45.44	4.04	10.91
SB 0715	Cacao bean, raw (incl roasted)	RAC	0.01	NC	-	NC	-	0.01	0.00	0.26	0.00	NC	-	1.41	0.01
DM 0715	cacao powder	PP	0.005	2.78	0.01	1.82	0.01	0.20	0.00	1.66	0.01	0.04	0.00	0.74	0.00
DM 1215	cacao butter	PP	0.005	0.98	0.00	0.59	0.00	0.01	0.00	0.06	0.00	1.05	0.01	NC	-
HH 0722	Basil leaves, raw (incl dried)	RAC	62.5	0.52	32.50	0.05	3.13	3.23	201.88	0.18	11.25	0.12	7.50	0.27	16.88
HS 0444	Peppers, chili, dried	PP	0.9	0.11	0.10	0.21	0.19	0.36	0.32	0.21	0.19	0.25	0.23	0.15	0.14
DH 1100	Hops, dry	RAC	28.5	NC	-	NC	-	0.02	0.57	0.02	0.57	NC	-	NC	-
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)	RAC	0	140.03	0.00	150.89	0.00	79.32	0.00	111.24	0.00	120.30	0.00	51.27	0.00
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.0064	6.44	0.04	15.51	0.10	3.79	0.02	8.29	0.05	18.44	0.12	8.00	0.05
MO 0105	Edible offal (mammalian), raw	RAC	0.0022	15.17	0.03	5.19	0.01	6.30	0.01	6.78	0.01	3.32	0.01	3.17	0.01
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0	388.92	0.00	335.88	0.00	49.15	0.00	331.25	0.00	468.56	0.00	245.45	0.00
PM 0110	Poultry meat, raw (incl prepared)	RAC	0	73.76	0.00	53.86	0.00	23.98	0.00	87.12	0.00	53.38	0.00	84.45	0.00

Annex 3

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MANDIPROPAMID (231)		International Estimated Daily Intake (IEDI)						ADI = 0 - 0.2 mg/kg bw																			
Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day																			
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake												
PF 0111	Poultry fat, raw (incl rendered)	RAC	0	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.71	0.00	NC	-												
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0	0.33	0.00	0.72	0.00	0.27	0.00	0.35	0.00	0.80	0.00	NC	-												
PE 0112	Eggs, raw, (incl dried)	RAC	0	25.84	0.00	29.53	0.00	28.05	0.00	33.19	0.00	36.44	0.00	8.89	0.00												
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-												
Total intake (ug/person)=				224.0				191.6				908.7				309.8				207.2				144.7			
Bodyweight per region (kg bw) =				60				60				55				60				60							
ADI (ug/person)=				12000				12000				11000				12000				12000							
%ADI=				1.9 %				1.6 %				8.3 %				2.6 %				1.7 %				1.2 %			
Rounded %ADI=				2 %				2 %				8 %				3 %				2 %				1 %			

MANDIPROPAMID (231)		International Estimated Daily Intake (IEDI)						ADI = 0 - 0.2 mg/kg bw							
Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day				Intake = daily intake: ug/person							
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake		
FC 0002	Subgroup of Lemons and limes, raw (incl kumquat commodities)	RAC	0.01	18.96	0.19	0.97	0.01	5.79	0.06	0.09	0.00	3.35	0.03		
-	Lemon, juice (single strength, incl. concentrated)	PP	0.0042	0.01	0.00	0.01	0.00	0.16	0.00	0.01	0.00	NC	-		
FC 0003	Subgroup of Mandarins, raw	RAC	0.01	0.16	0.00	0.27	0.00	9.06	0.09	0.01	0.00	0.02	0.00		
-	Subgroup of Mandarins, juice	PP	0.0042	0.01	0.00	NC	-	NC	-	NC	-	NC	-		
FC 0004	Subgroup of Oranges, sweet, sour, raw	RAC	0.01	1.18	0.01	1.11	0.01	14.28	0.14	0.05	0.00	1.08	0.01		
JF 0004	Subgroup of Oranges, juice (single strength, incl. concentrated)	PP	0.0043	0.08	0.00	0.26	0.00	12.61	0.05	0.14	0.00	0.33	0.00		
FC 0005	Subgroup of Pummelo and grapefruits, raw	RAC	0.01	0.63	0.01	0.01	0.00	1.58	0.02	0.01	0.00	NC	-		
JF 0203	Grapefruits, juice (single strength, incl. concentrated)	PP	0.0024	0.03	0.00	0.02	0.00	0.78	0.00	0.01	0.00	NC	-		
FB 0269	Grapes, raw (incl must, excl dried, excl juice, excl wine)	RAC	0.51	0.14	0.07	0.36	0.18	15.33	7.82	0.01	0.01	0.28	0.14		
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	1.68	0.01	0.02	0.13	0.22	1.06	1.78	0.01	0.02	0.03	0.05		
JF 0269	Grape juice (from wine grapes)	PP	0.14	0.01	0.00	0.01	0.00	0.41	0.06	0.01	0.00	NC	-		
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.366	0.31	0.11	0.23	0.08	60.43	22.12	0.52	0.19	31.91	11.68		
VA 2031	Subgroup of bulb onions	RAC	0.01	9.83	0.10	22.30	0.22	34.69	0.35	9.65	0.10	2.39	0.02		
VB 0400	Broccoli, raw	RAC	0.435	0.01	0.00	0.01	0.00	2.13	0.93	0.01	0.00	NC	-		
VB 0041	Cabbages, head, raw	RAC	0.01	3.82	0.04	2.99	0.03	49.16	0.49	0.01	0.00	NC	-		
VC 2039	Subgroup of Cucumbers and Squashes, raw	RAC	0.0475	0.92	0.04	3.20	0.15	13.55	0.64	1.91	0.09	0.05	0.00		
VC 2040	Subgroup of Melons, Pumpkins and Winter squashes	RAC	0.01	5.04	0.05	6.54	0.07	38.26	0.38	11.70	0.12	NC	-		

Annex 3

MANDIPROPAMID (231)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.2 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day		Intake = daily intake: ug/person							
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
VO 0448	Tomato, raw	RAC	0.26	12.99	3.38	4.79	1.25	58.40	15.18	0.92	0.24	0.09	0.02
-	Tomato, canned (& peeled)	PP	0.101	0.07	0.01	0.08	0.01	2.42	0.24	0.07	0.01	NC	-
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.91	0.58	0.53	0.22	0.20	2.21	2.01	0.24	0.22	3.10	2.82
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.26	0.05	0.01	0.01	0.00	0.42	0.11	0.01	0.00	0.02	0.01
VO 0051	Subgroup of peppers, raw (incl dried sweet peppers, excl dried chilipeppers), excl okra	RAC	0.09	8.97	0.81	14.13	1.27	25.14	2.26	0.91	0.08	NC	-
VO 2046	Subgroup of eggplants	RAC	0.09	1.31	0.12	8.26	0.74	3.95	0.36	0.01	0.00	NC	-
VL 0053	Group of Leafy vegetables, raw	RAC	5.65	12.42	70.17	8.75	49.44	7.53	42.54	7.07	39.95	14.11	79.72
VP 2060	Subgroup of beans with pods (all commodities within this group)	RAC	0.22	NC	-	NC	-	NC	-	NC	-	NC	-
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.0185	23.96	0.44	13.56	0.25	213.41	3.95	104.35	1.93	8.56	0.16
VS 0624	Celery	RAC	2.7	3.66	9.88	2.65	7.16	4.84	13.07	2.47	6.67	4.94	13.34
SB 0715	Cacao bean, raw (incl roasted)	RAC	0.01	0.01	0.00	0.53	0.01	0.33	0.00	0.08	0.00	NC	-
DM 0715	cacao powder	PP	0.005	0.05	0.00	0.20	0.00	1.17	0.01	0.01	0.00	1.80	0.01
DM 1215	cacao butter	PP	0.005	0.01	0.00	0.01	0.00	0.38	0.00	0.01	0.00	NC	-
HH 0722	Basil leaves, raw (incl dried)	RAC	62.5	0.25	15.63	0.18	11.25	0.13	8.13	0.17	10.63	0.33	20.63
HS 0444	Peppers, chili, dried	PP	0.9	0.58	0.52	1.27	1.14	1.21	1.09	0.12	0.11	NC	-
DH 1100	Hops, dry	RAC	28.5	NC	-	NC	-	0.04	1.14	NC	-	NC	-
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)	RAC	0	29.18	0.00	50.89	0.00	121.44	0.00	22.58	0.00	72.14	0.00
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.0064	1.05	0.01	1.14	0.01	18.69	0.12	0.94	0.01	3.12	0.02
MO 0105	Edible offal (mammalian), raw	RAC	0.0022	4.64	0.01	1.97	0.00	10.01	0.02	3.27	0.01	3.98	0.01
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0	108.75	0.00	70.31	0.00	436.11	0.00	61.55	0.00	79.09	0.00
PM 0110	Poultry meat, raw (incl prepared)	RAC	0	3.92	0.00	12.03	0.00	57.07	0.00	5.03	0.00	55.56	0.00
PF 0111	Poultry fat, raw (incl rendered)	RAC	0	NC	-	NC	-	0.32	0.00	NC	-	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0	0.10	0.00	0.70	0.00	0.97	0.00	0.10	0.00	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0	3.84	0.00	4.41	0.00	27.25	0.00	1.13	0.00	7.39	0.00
-	-	-	-	-	-	-	-	-	-	-	-	-	-

Total intake (ug/person)=		102.2	73.7	125.2	60.4	128.7
Bodyweight per region (kg bw) =		60	60	60	60	60
ADI (ug/person)=		12000	12000	12000	12000	12000
%ADI=		0.9 %	0.6 %	1.0 %	0.5 %	1.1 %
Rounded %ADI=		1 %	1 %	1 %	1 %	1 %

Annex 3

MEFENTRIFLUCONAZOLE (320)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.04 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day							
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
FC 0002	Subgroup of Lemons and limes, raw (incl kumquat commodities)	RAC	0.37	4.78	1.77	2.42	0.90	3.61	1.34	25.18	9.32	8.25	3.05	15.77	5.83
-	Lemon, juice (single strength, incl. concentrated)	PP	0.007	0.01	0.00	0.01	0.00	0.11	0.00	0.09	0.00	0.18	0.00	0.17	0.00
FC 0003	Subgroup of Mandarins, raw	RAC	0.37	6.18	2.29	3.66	1.35	0.25	0.09	6.82	2.52	3.49	1.29	19.38	7.17
-	Subgroup of Mandarins, juice	PP	0.007	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
FC 0004	Subgroup of Oranges, sweet, sour, raw	RAC	0.215	20.66	4.44	5.23	1.12	11.90	2.56	37.90	8.15	21.16	4.55	56.46	12.14
JF 0004	Subgroup of Oranges, juice (single strength, incl. concentrated)	PP	0.007	1.27	0.01	2.20	0.02	0.09	0.00	11.81	0.08	0.46	0.00	1.69	0.01
FC 0005	Subgroup of Pummelo and grapefruits, raw	RAC	0.16	0.64	0.10	0.35	0.06	0.93	0.15	6.10	0.98	1.01	0.16	1.36	0.22
JF 0203	Grapefruits, juice (single strength, incl. concentrated)	PP	0.007	0.01	0.00	0.16	0.00	0.02	0.00	1.97	0.01	0.12	0.00	0.77	0.01
FP 0226	Apple, raw	RAC	0.39	13.39	5.22	26.46	10.32	0.52	0.20	16.07	6.27	6.37	2.48	47.79	18.64
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.051	0.32	0.02	3.07	0.16	0.07	0.00	5.00	0.26	0.29	0.01	5.57	0.28
FP 0228	Loquat, raw (incl processed) (i.e. Japanese medlar)	RAC	0.39	0.59	0.23	0.36	0.14	0.46	0.18	1.88	0.73	NC	-	1.15	0.45
FP 0229	Medlar, raw (incl processed)	RAC	0.39	0.47	0.18	0.29	0.11	0.36	0.14	1.49	0.58	NC	-	0.92	0.36
FP 0230	Pear, raw	RAC	0.39	2.16	0.84	6.24	2.43	0.05	0.02	4.07	1.59	1.16	0.45	5.34	2.08
FP 0231	Quince, raw	RAC	0.39	0.73	0.28	0.54	0.21	0.01	0.00	0.07	0.03	0.06	0.02	1.31	0.51
FS 0013	Subgroup of Cherries, raw	RAC	1.1	0.92	1.01	9.15	10.07	0.01	0.01	0.61	0.67	0.06	0.07	6.64	7.30
FS 0014	Subgroup of Plums, raw	RAC	0.26	2.40	0.62	8.60	2.24	0.06	0.02	2.52	0.66	0.58	0.15	4.16	1.08
DF 0014	Plums, dried (prunes)	PP	1.1	0.09	0.10	0.06	0.07	0.01	0.01	0.18	0.20	0.04	0.04	0.06	0.07
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.56	8.01	4.49	5.87	3.29	0.18	0.10	8.19	4.59	1.64	0.92	22.46	12.58
FB 2005	Subgroup of Caneberries, raw	RAC	0.96	0.42	0.40	1.05	1.01	0.01	0.01	0.02	0.02	0.02	0.02	1.24	1.19
FB 2006	Subgroup of Bush berries, raw (including processed)	RAC	0.58	0.53	0.31	1.31	0.76	0.40	0.23	1.66	0.96	0.01	0.01	0.99	0.57
FB 0267	Elderberries, raw (incl processed)	RAC	0.58	0.44	0.26	0.27	0.16	0.34	0.20	1.41	0.82	NC	-	0.87	0.50
FB 0269	Grapes, raw (incl must, excl dried, excl juice, excl wine)	RAC	0.54	13.02	7.03	9.25	5.00	0.03	0.02	16.91	9.13	3.70	2.00	54.44	29.40
JF 0269	Grape juice (from wine grapes)	PP	0.07	0.14	0.01	0.29	0.02	0.05	0.00	0.30	0.02	0.24	0.02	0.05	0.00
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.016	0.67	0.01	12.53	0.20	2.01	0.03	1.21	0.02	3.53	0.06	4.01	0.06
FB 2009	Subgroup of Low growing berries, raw	RAC	0.29	0.71	0.21	2.02	0.59	0.04	0.01	1.39	0.40	0.37	0.11	2.53	0.73
FI 0326	Avocado, raw	RAC	0.36	0.13	0.05	0.03	0.01	2.05	0.74	2.54	0.91	2.34	0.84	0.12	0.04
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.055	5.23	0.29	6.94	0.38	99.45	5.47	32.47	1.79	48.30	2.66	24.70	1.36
FI 0345	Mango, raw (incl canned mango, incl mango juice)	RAC	0.01	10.48	0.10	0.01	0.00	7.24	0.07	6.87	0.07	19.98	0.20	6.25	0.06
FI 0350	Papaya, raw	RAC	0.07	0.35	0.02	0.01	0.00	3.05	0.21	0.80	0.06	7.28	0.51	1.00	0.07
VA 2031	Subgroup of bulb onions	RAC	0.05	31.65	1.58	43.28	2.16	3.68	0.18	38.48	1.92	20.46	1.02	47.29	2.36
VA 2032	Subgroup of Green Onions	RAC	0.39	2.64	1.03	3.09	1.21	1.05	0.41	2.89	1.13	0.61	0.24	5.24	2.04
VC 2039	Subgroup of Cucumbers and Squashes, raw	RAC	0.035	10.52	0.37	39.36	1.38	2.07	0.07	25.74	0.90	2.80	0.10	44.83	1.57

Annex 3

MEFENTRIFLUCONAZOLE (320)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.04 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day							
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
VC 2040	Subgroup of Melons, Pumpkins and Winter squashes	RAC	0.15	42.62	6.39	46.85	7.03	4.21	0.63	67.02	10.05	12.84	1.93	110.47	16.57
VO 0448	Tomato, raw	RAC	0.14	41.73	5.84	75.65	10.59	10.66	1.49	82.87	11.60	24.75	3.47	200.93	28.13
-	Tomato, canned (& peeled)	PP	0.0084	0.20	0.00	0.31	0.00	0.02	0.00	1.11	0.01	0.11	0.00	1.50	0.01
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.069	2.34	0.16	1.33	0.09	1.57	0.11	4.24	0.29	0.34	0.02	2.83	0.20
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.011	0.29	0.00	0.29	0.00	0.01	0.00	0.38	0.00	0.05	0.00	0.14	0.00
VO 0051	Subgroup of peppers, raw (Capsicum spp. Only), excl okra	RAC	0.25	5.42	1.36	9.91	2.48	3.97	0.99	7.63	1.91	2.59	0.65	23.68	5.92
VO 2046	Subgroup of eggplants	RAC	0.25	5.58	1.40	4.31	1.08	0.89	0.22	9.31	2.33	13.64	3.41	20.12	5.03
VL 2050	Subgroup of Leafy greens	RAC	8.1	3.93	31.83	5.28	42.77	3.07	24.87	14.53	117.69	8.25	66.83	12.75	103.28
VL 0054	Subgroup of Leaves of Brassicaceae, raw	RAC	6.65	2.63	17.49	9.27	61.65	1.86	12.37	5.82	38.70	19.53	129.87	4.90	32.59
VP 2060	Subgroup of beans with pods (all commodities within this group)	RAC	0.01	0.68	0.01	NC	-	NC	-	0.39	0.00	0.22	0.00	0.49	0.00
VP 2062	Subgroup of succulent beans without pods (all commodities within this group)	RAC	0.01	5.07	0.05	1.02	0.01	0.49	0.00	1.78	0.02	1.19	0.01	8.57	0.09
VP 2063	Subgroup of succulent peas without pods	RAC	0.01	1.97	0.02	0.51	0.01	0.02	0.00	0.79	0.01	3.68	0.04	3.80	0.04
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	0.01	2.39	0.02	1.61	0.02	10.47	0.10	1.84	0.02	12.90	0.13	7.44	0.07
VD 0523	Broad bean, dry, raw (incl horse-bean, field bean) (Vicia faba)	RAC	0.01	1.27	0.01	0.01	0.00	0.12	0.00	2.49	0.02	0.23	0.00	5.54	0.06
VD 0527	Cowpea, dry, raw (Vigna sinensis, Dolichos sinensis)	RAC	0.01	0.05	0.00	NC	-	1.74	0.02	0.01	0.00	0.01	0.00	0.07	0.00
VD 0541	Soya bean, dry, raw (Glycine soja)	RAC	0.01	0.58	0.01	0.05	0.00	0.37	0.00	0.03	0.00	1.65	0.02	0.30	0.00
-	Soya paste (i.e. miso)	PP	0.0083	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
-	Soya curd (i.e. tofu)	PP	0.0083	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
OR 0541	Soya oil, refined	PP	0.0083	12.99	0.11	10.43	0.09	3.63	0.03	13.10	0.11	10.70	0.09	13.10	0.11
-	Soya sauce	PP	0.0083	0.01	0.00	0.02	0.00	0.01	0.00	0.34	0.00	0.03	0.00	0.01	0.00
-	Soya flour	PP	0.0083	0.05	0.00	0.86	0.01	0.02	0.00	1.02	0.01	0.01	0.00	0.15	0.00
-	Beans (dry) NES: including inter alia lablab or hyacinth bean (Dolichos spp.); jack or sword bean (Canavalia spp.); winged bean (Psophocarpus tetragonolobus); guar bean (Cyamopsis tetragonoloba); velvet bean (Stizolobium spp.); yam bean (Pachyrrhizus erosus)	RAC	0.01	1.70	0.02	0.01	0.00	3.00	0.03	1.80	0.02	1.64	0.02	1.33	0.01
VD 0072	Peas (dry) (Pisum spp), raw	RAC	0.015	1.62	0.02	3.22	0.05	0.92	0.01	1.50	0.02	2.90	0.04	0.17	0.00
VD 0524	Chick-pea (dry) (Cicer spp), raw	RAC	0.015	5.34	0.08	0.13	0.00	0.01	0.00	4.69	0.07	7.24	0.11	5.52	0.08
VD 0533	Lentil (dry) (Lens spp), raw	RAC	0.22	2.12	0.47	0.01	0.00	0.03	0.01	3.21	0.71	1.60	0.35	4.90	1.08
VD 0537	Pigeon pea (dry) (Cajanus spp), raw	RAC	0.015	NC	-	NC	-	0.10	0.00	0.07	0.00	3.38	0.05	NC	-

Annex 3

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MEFENTRIFLUCONAZOLE (320)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.04 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day							
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
VR 0574	Beetroot, raw	RAC	0.105	3.42	0.36	6.06	0.64	3.75	0.39	9.11	0.96	NC	-	4.39	0.46
VR 0575	Burdock, greater or edible, raw	RAC	0.105	0.03	0.00	0.06	0.01	0.04	0.00	0.09	0.01	NC	-	0.04	0.00
VR 0577	Carrots, raw	RAC	0.105	9.51	1.00	30.78	3.23	0.37	0.04	8.75	0.92	2.80	0.29	6.10	0.64
VR 0578	Celeriac, raw	RAC	0.105	1.70	0.18	3.01	0.32	1.87	0.20	4.53	0.48	NC	-	2.19	0.23
VR 0469	Chicory, roots, raw	RAC	0.105	0.01	0.00	0.20	0.02	0.01	0.00	0.01	0.00	0.02	0.00	0.01	0.00
VR 0583	Horseradish, raw	RAC	0.105	0.51	0.05	0.91	0.10	0.56	0.06	1.37	0.14	NC	-	0.66	0.07
VR 0587	Parsley turnip-rooted, raw	RAC	0.105	0.32	0.03	0.57	0.06	0.35	0.04	0.85	0.09	NC	-	0.41	0.04
VR 0588	Parsnip, raw	RAC	0.105	0.59	0.06	1.05	0.11	0.65	0.07	1.58	0.17	NC	-	0.76	0.08
VR 0494	Radish roots, raw	RAC	0.105	2.31	0.24	4.09	0.43	2.53	0.27	6.15	0.65	5.88	0.62	2.97	0.31
VR 0591	Japanese radish, raw (i.e. Chinese radish, Daikon)	RAC	0.105	1.90	0.20	3.36	0.35	2.08	0.22	5.06	0.53	NC	-	2.44	0.26
VR 0498	Salsify, raw (i.e. Oysterplant)	RAC	0.105	0.21	0.02	0.37	0.04	0.23	0.02	0.55	0.06	NC	-	0.27	0.03
VR 0497	Swede, raw (i.e. Rutabaga)	RAC	0.105	1.58	0.17	2.80	0.29	1.74	0.18	4.21	0.44	NC	-	2.03	0.21
VR 0506	Turnip, garden, raw	RAC	0.105	2.50	0.26	4.44	0.47	2.75	0.29	6.67	0.70	0.14	0.01	3.22	0.34
VR 0573	Arrowroot, raw	RAC	0.01	1.53	0.02	0.01	0.00	0.93	0.01	1.33	0.01	0.47	0.00	0.02	0.00
VR 0463	Cassava raw (incl starch, incl tapioca, incl flour) (i.e. Manioc)	RAC	0.01	0.08	0.00	0.01	0.00	482.56	4.83	0.99	0.01	25.75	0.26	3.29	0.03
VR 0463	Cassava raw (incl starch, incl flour, excl tapioca) (i.e. Manioc)	RAC	0.01	0.02	0.00	0.01	0.00	478.42	4.78	0.70	0.01	25.39	0.25	3.28	0.03
VR 0463	Cassava raw (incl starch, incl tapioca, excl flour) (i.e. Manioc)	RAC	0.01	0.08	0.00	0.01	0.00	306.72	3.07	0.97	0.01	11.51	0.12	3.29	0.03
VR 0463	Cassava raw (incl tapioca, incl flour, excl starch) (i.e. Manioc)	RAC	0.01	0.06	0.00	NC	-	482.53	4.83	0.99	0.01	25.37	0.25	3.29	0.03
VR 0463	Cassava raw (incl starch, excl tapioca, excl flour) (i.e. Manioc)	RAC	0.01	0.02	0.00	0.01	0.00	302.58	3.03	0.68	0.01	11.15	0.11	3.28	0.03
VR 0463	Cassava raw (incl tapioca, excl flour, excl starch) (i.e. Manioc)	RAC	0.01	0.06	0.00	NC	-	306.70	3.07	0.97	0.01	11.13	0.11	3.29	0.03
VR 0463	Cassava raw (incl flour, excl tapioca, excl starch) (i.e. Manioc)	RAC	0.01	0.01	0.00	NC	-	478.39	4.78	0.70	0.01	25.02	0.25	3.28	0.03
VR 0463	Cassava, raw (i.e. Manioc)	RAC	0.01	NC	-	NC	-	302.56	3.03	0.68	0.01	10.77	0.11	3.28	0.03
-	Cassava, flour	PP	0.01	0.01	0.00	NC	-	49.23	0.49	0.01	0.00	3.99	0.04	NC	-
-	Cassava, starch	PP	0.01	0.01	0.00	0.01	0.00	0.01	0.00	NC	-	0.11	0.00	NC	-
-	Cassava, tapioca	PP	0.01	0.02	0.00	NC	-	1.16	0.01	0.08	0.00	0.10	0.00	0.01	0.00
VR 0585	Jerusalem artichoke, raw (i.e. Topinambur)	RAC	0.01	1.57	0.02	0.01	0.00	0.96	0.01	1.36	0.01	0.48	0.00	0.02	0.00
VR 0589	Potato, raw (incl flour, incl frozen, incl tapioca, excl starch)	RAC	0.01	59.60	0.60	316.10	3.16	9.77	0.10	59.59	0.60	54.12	0.54	119.82	1.20
-	Potato, starch	PP	0.0033	0.03	0.00	0.01	0.00	0.01	0.00	0.15	0.00	0.01	0.00	0.01	0.00
VR 0508	Sweet potato, raw (incl dried)	RAC	0.01	0.18	0.00	0.18	0.00	42.16	0.42	1.61	0.02	3.06	0.03	6.67	0.07
VR 0504	Tannia, raw (i.e. Tanier, Yautia)	RAC	0.01	NC	-	NC	-	NC	-	0.01	0.00	0.26	0.00	1.27	0.01
VR 0505	Taro, raw (i.e. Dasheen, Eddoe)	RAC	0.01	0.01	0.00	NC	-	25.12	0.25	0.04	0.00	0.01	0.00	0.97	0.01

Annex 3

MEFENTRIFLUCONAZOLE (320)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.04 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day							
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
VR 0600	Yams, raw (incl dried)	RAC	0.01	0.02	0.00	NC	-	90.40	0.90	6.45	0.06	0.74	0.01	0.65	0.01
GC 0650	Rye, raw	RAC	0.09	NC	-	NC	-	0.02	0.00	0.01	0.00	0.01	0.00	0.01	0.00
CF 1250	Rye, flour (white flour and wholemeal flour)	PP	0.071	0.11	0.01	15.51	1.10	0.06	0.00	0.10	0.01	0.03	0.00	1.72	0.12
GC 0653	Triticale, raw	RAC	0.09	NC	-	NC	-	NC	-	0.01	0.00	NC	-	NC	-
GC 0653	Triticale, flour (white flour and wholemeal flour)	PP	0.071	NC	-	NC	-	NC	-	NC	-	0.31	0.02	NC	-
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, incl white flour products, incl white bread, excl germ, excl wholemeal bread)	RAC	0.09	381.15	34.30	341.54	30.74	38.34	3.45	281.87	25.37	172.65	15.54	434.06	39.07
CF 1210	Wheat, germ	PP	0.1	NC	-	NC	-	0.01	0.00	0.01	0.00	0.14	0.01	0.01	0.00
CP 1212	Wheat, wholemeal bread	PP	0.05	0.01	0.00	0.01	0.00	0.01	0.00	0.01	0.00	0.03	0.00	0.01	0.00
-	Wheat, starch	PP	0.026	0.02	0.00	NC	-	0.01	0.00	0.05	0.00	0.13	0.00	0.01	0.00
-	Wheat, gluten	PP	0.05	0.01	0.00	0.01	0.00	0.01	0.00	0.27	0.01	0.01	0.00	0.03	0.00
GC 0640	Barley, raw	RAC	0.425	2.49	1.06	NC	-	0.02	0.01	0.03	0.01	0.18	0.08	0.38	0.16
-	Barley, pot&pearled	PP	0.051	7.12	0.36	7.34	0.37	0.02	0.00	0.03	0.00	0.67	0.03	0.20	0.01
-	Barley, flour (white flour and wholemeal flour)	PP	1.6	2.93	4.69	0.30	0.48	0.02	0.03	0.01	0.02	0.48	0.77	0.01	0.02
-	Barley beer	PP	0.013	4.87	0.06	93.78	1.22	24.28	0.32	12.76	0.17	39.28	0.51	18.15	0.24
-	Barley Malt	PP	0.21	0.09	0.02	1.04	0.22	0.18	0.04	0.33	0.07	0.04	0.01	0.10	0.02
GC 0647	Oats, raw (incl rolled)	RAC	0.425	0.05	0.02	7.05	3.00	0.10	0.04	1.71	0.73	0.96	0.41	0.04	0.02
CM 0649 (GC 0649)	Rice, husked, dry (incl flour, incl oil, incl beverages, incl starch, excl polished)	REP	0.11	1.26	0.14	1.58	0.17	31.05	3.42	5.43	0.60	0.90	0.10	2.18	0.24
CM 0649 (GC 0649)	Rice, husked, dry (incl paddy rice)	REP	0.11	1.17	0.13	1.30	0.14	31.05	3.42	4.79	0.53	0.25	0.03	2.16	0.24
CM 1205	Rice polished, dry	PP	0.0085	34.21	0.29	10.39	0.09	41.72	0.35	82.38	0.70	150.24	1.28	70.47	0.60
GC 0646	Millet, raw (incl flour, incl beer)	RAC	0.41	1.46	0.60	2.32	0.95	5.84	2.39	0.89	0.36	16.17	6.63	0.01	0.00
GC 0651	Sorghum, raw (incl flour, incl beer) (i.e. Chicken corn, Dari seed, Durra, Feterita)	RAC	0.41	4.34	1.78	0.01	0.00	16.25	6.66	15.82	6.49	10.97	4.50	2.92	1.20
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl flour, incl oil, incl beer, incl germ, incl starch)	RAC	0.01	29.81	0.30	44.77	0.45	108.95	1.09	52.37	0.52	60.28	0.60	75.69	0.76
GC 0447	Sweet corn on the cob, raw (incl frozen kernels, incl canned kernels)	RAC	0.01	0.14	0.00	0.94	0.01	5.70	0.06	2.61	0.03	1.94	0.02	0.22	0.00
GS 0659	Sugar cane, raw (incl sugar, incl molasses)	RAC	0.37	99.68	36.88	86.27	31.92	31.38	11.61	80.36	29.73	84.18	31.15	99.10	36.67
TN 0085	Group of Tree nuts, raw (incl processed)	RAC	0.01	4.06	0.04	3.27	0.03	7.01	0.07	13.93	0.14	14.01	0.14	9.36	0.09
SO 2090	Subgroup of Small seed oilseeds, raw (incl processed)	RAC	0.06	2.19	0.13	1.22	0.07	1.05	0.06	7.10	0.43	10.29	0.62	4.83	0.29
SO 2091	Subgroup of Sunflower seeds, raw (incl processed)	RAC	0.01	7.43	0.07	36.06	0.36	1.15	0.01	8.77	0.09	5.74	0.06	13.63	0.14
OR 0691	Cotton seed oil, edible	PP	0.00016	3.22	0.00	1.54	0.00	1.01	0.00	0.74	0.00	1.12	0.00	2.93	0.00
SO 0697	Peanuts, nutmeat, raw (incl roasted, incl oil, incl butter)	RAC	0.01	1.30	0.01	1.23	0.01	12.62	0.13	2.87	0.03	6.59	0.07	2.67	0.03

Annex 3

MEFENTRIFLUCONAZOLE (320)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.04 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day							
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
SB 0716	Coffee bean, raw (i.e. green coffee)	RAC	0.01	0.96	0.01	0.16	0.00	0.91	0.01	0.27	0.00	1.37	0.01	0.46	0.00
SM 0716	Coffee bean, roasted	PP	0.0062	0.19	0.00	0.91	0.01	0.16	0.00	2.50	0.02	0.39	0.00	0.40	0.00
-	Coffee bean, instant coffee (incl essences and concentrates)	PP	0.0016	0.07	0.00	0.94	0.00	0.07	0.00	0.70	0.00	0.07	0.00	0.29	0.00
HS 0444	Peppers, chili, dried	PP	2.5	0.42	1.05	0.53	1.33	0.84	2.10	0.50	1.25	0.95	2.38	0.37	0.93
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80 % as muscle	RAC	0.04	24.96	1.00	57.95	2.32	16.70	0.67	38.38	1.54	26.46	1.06	29.00	1.16
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20 % as fat	RAC	0.39	6.24	2.43	14.49	5.65	4.18	1.63	9.60	3.74	6.62	2.58	7.25	2.83
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.39	3.29	1.28	6.14	2.39	0.82	0.32	1.57	0.61	2.23	0.87	1.07	0.42
MO 0105	Edible offal (mammalian), raw	RAC	0.61	4.79	2.92	9.68	5.90	2.97	1.81	5.49	3.35	3.84	2.34	5.03	3.07
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.07	289.65	20.28	485.88	34.01	26.92	1.88	239.03	16.73	199.91	13.99	180.53	12.64
PM 0110	Poultry meat, raw (incl prepared) - 90 % as muscle	RAC	0.012	13.17	0.16	26.78	0.32	7.24	0.09	116.71	1.40	22.54	0.27	32.09	0.39
PM 0110	Poultry meat, raw (incl prepared) - 10 % as fat	RAC	0.124	1.46	0.18	2.98	0.37	0.80	0.10	12.97	1.61	2.50	0.31	3.57	0.44
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.124	0.10	0.01	0.10	0.01	NC	-	0.10	0.01	0.10	0.01	0.10	0.01
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.12	0.12	0.01	0.12	0.01	0.11	0.01	5.37	0.64	0.24	0.03	0.10	0.01
PE 0112	Eggs, raw, (incl dried)	RAC	0.032	7.84	0.25	23.08	0.74	2.88	0.09	14.89	0.48	9.81	0.31	14.83	0.47
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total intake (ug/person)=				212.3		304.8		130.6		341.7		317.8		408.5	
Bodyweight per region (kg bw) =				60		60		60		60		60		60	
ADI (ug/person)=				2400		2400		2400		2400		2400		2400	
%ADI=				8.8 %		12.7 %		5.4 %		14.2 %		13.2 %		17.0 %	
Rounded %ADI=				9 %		10 %		5 %		10 %		10 %		20 %	

MEFENTRIFLUCONAZOLE (320)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.04 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day							
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
FC 0002	Subgroup of Lemons and limes, raw (incl kumquat commodities)	RAC	0.37	8.45	3.13	14.69	5.44	2.88	1.07	8.16	3.02	21.14	7.82	5.93	2.19
-	Lemon, juice (single strength, incl. concentrated)	PP	0.007	0.60	0.00	0.36	0.00	0.01	0.00	1.49	0.01	0.43	0.00	0.24	0.00
FC 0003	Subgroup of Mandarins, raw	RAC	0.37	12.34	4.57	14.99	5.55	16.08	5.95	10.76	3.98	9.94	3.68	NC	-
-	Subgroup of Mandarins, juice	PP	0.007	0.04	0.00	NC	-	0.01	0.00	0.01	0.00	NC	-	NC	-
FC 0004	Subgroup of Oranges, sweet, sour, raw	RAC	0.215	15.68	3.37	24.00	5.16	6.80	1.46	29.09	6.25	15.39	3.31	160.47	34.50

Annex 3

MEFENTRIFLUCONAZOLE (320)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.04 mg/kg bw

Codex Code	Commodity description	STMR Expr as mg/kg		Diets as g/person/day				Intake as ug/person/day							
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
JF 0004	Subgroup of Oranges, juice (single strength, incl. concentrated)	PP	0.007	33.31	0.23	1.78	0.01	0.28	0.00	18.97	0.13	14.01	0.10	13.36	0.09
FC 0005	Subgroup of Pummelo and grapefruits, raw	RAC	0.16	2.19	0.35	1.24	0.20	0.60	0.10	3.44	0.55	4.60	0.74	299.96	47.99
JF 0203	Grapefruits, juice (single strength, incl. concentrated)	PP	0.007	2.89	0.02	1.61	0.01	0.02	0.00	1.15	0.01	7.39	0.05	33.07	0.23
FP 0226	Apple, raw	RAC	0.39	27.44	10.70	49.21	19.19	21.57	8.41	31.09	12.13	51.60	20.12	1.77	0.69
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.051	14.88	0.76	11.98	0.61	0.15	0.01	9.98	0.51	30.32	1.55	3.47	0.18
FP 0228	Loquat, raw (incl processed) (i.e. Japanese medlar)	RAC	0.39	0.96	0.37	NC	-	NC	-	3.92	1.53	NC	-	2.49	0.97
FP 0229	Medlar, raw (incl processed)	RAC	0.39	NC	-	NC	-	NC	-	NC	-	NC	-	1.98	0.77
FP 0230	Pear, raw	RAC	0.39	8.79	3.43	8.44	3.29	12.37	4.82	9.60	3.74	10.27	4.01	0.23	0.09
FP 0231	Quince, raw	RAC	0.39	0.19	0.07	0.18	0.07	0.11	0.04	0.04	0.02	0.28	0.11	NC	-
FS 0013	Subgroup of Cherries, raw	RAC	1.1	1.40	1.54	4.21	4.63	0.04	0.04	2.93	3.22	1.50	1.65	NC	-
FS 0014	Subgroup of Plums, raw	RAC	0.26	3.75	0.98	3.33	0.87	5.94	1.54	2.64	0.69	2.50	0.65	0.06	0.02
DF 0014	Plums, dried (prunes)	PP	1.1	0.61	0.67	0.35	0.39	0.05	0.06	0.35	0.39	0.49	0.54	0.13	0.14
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.56	13.03	7.30	16.29	9.12	8.29	4.64	12.95	7.25	5.35	3.00	0.04	0.02
FB 2005	Subgroup of Caneberries, raw	RAC	0.96	0.56	0.54	1.43	1.37	0.14	0.13	1.23	1.18	1.14	1.09	0.01	0.01
FB 2006	Subgroup of Bush berries, raw (including processed)	RAC	0.58	1.31	0.76	5.50	3.19	0.01	0.01	2.57	1.49	0.82	0.48	2.15	1.25
FB 0267	Elderberries, raw (incl processed)	RAC	0.58	8.20	4.76	0.14	0.08	NC	-	NC	-	NC	-	1.87	1.08
FB 0269	Grapes, raw (incl must, excl dried, excl juice, excl wine)	RAC	0.54	6.48	3.50	11.31	6.11	5.21	2.81	9.50	5.13	4.66	2.52	0.78	0.42
JF 0269	Grape juice (from wine grapes)	PP	0.07	0.56	0.04	1.96	0.14	0.02	0.00	2.24	0.16	2.27	0.16	0.34	0.02
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.016	88.93	1.42	62.41	1.00	1.84	0.03	25.07	0.40	61.17	0.98	5.84	0.09
FB 2009	Subgroup of Low growing berries, raw	RAC	0.29	4.55	1.32	5.66	1.64	0.02	0.01	7.85	2.28	5.86	1.70	0.05	0.01
FI 0326	Avocado, raw	RAC	0.36	2.65	0.95	0.87	0.31	0.46	0.17	1.64	0.59	1.30	0.47	0.96	0.35
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.055	25.76	1.42	23.65	1.30	23.83	1.31	24.37	1.34	19.43	1.07	101.55	5.59
FI 0345	Mango, raw (incl canned mango, incl mango juice)	RAC	0.01	1.80	0.02	0.63	0.01	10.05	0.10	1.07	0.01	3.52	0.04	16.44	0.16
FI 0350	Papaya, raw	RAC	0.07	0.31	0.02	0.18	0.01	1.50	0.11	0.51	0.04	0.54	0.04	1.08	0.08
VA 2031	Subgroup of bulb onions	RAC	0.05	20.67	1.03	31.32	1.57	37.52	1.88	35.08	1.75	11.77	0.59	13.74	0.69
VA 2032	Subgroup of Green Onions	RAC	0.39	5.57	2.17	5.15	2.01	1.77	0.69	4.28	1.67	17.34	6.76	6.48	2.53
VC 2039	Subgroup of Cucumbers and Squashes, raw	RAC	0.035	7.14	0.25	16.92	0.59	37.58	1.32	15.16	0.53	4.42	0.15	12.67	0.44
VC 2040	Subgroup of Melons, Pumpkins and Winter squashes	RAC	0.15	20.68	3.10	25.00	3.75	85.72	12.86	34.31	5.15	11.54	1.73	23.32	3.50
VO 0448	Tomato, raw	RAC	0.14	32.13	4.50	51.27	7.18	34.92	4.89	73.37	10.27	15.15	2.12	8.88	1.24
-	Tomato, canned (& peeled)	PP	0.0084	7.57	0.06	2.66	0.02	0.30	0.00	0.97	0.01	7.31	0.06	0.41	0.00
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.069	4.96	0.34	3.20	0.22	0.15	0.01	1.61	0.11	6.88	0.47	0.52	0.04
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.011	0.80	0.01	0.07	0.00	0.05	0.00	0.61	0.01	0.40	0.00	0.08	0.00
VO 0051	Subgroup of peppers, raw (Capsicum spp. Only), excl okra	RAC	0.25	5.57	1.39	14.00	3.50	16.50	4.13	8.80	2.20	6.44	1.61	3.44	0.86

Annex 3

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MEFENTRIFLUCONAZOLE (320)		International Estimated Daily Intake (IEDI)						ADI = 0 - 0.04 mg/kg bw							
Codex Code	Commodity description	STMR		Diets as g/person/day				Intake as ug/person/day							
		Expr as mg/kg		G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
VO 2046	Subgroup of eggplants	RAC	0.25	1.01	0.25	1.69	0.42	21.37	5.34	3.00	0.75	1.40	0.35	NC	-
VL 2050	Subgroup of Leafy greens	RAC	8.1	18.38	148.88	18.73	151.71	82.36	667.12	25.32	205.09	17.60	142.56	7.37	59.70
VL 0054	Subgroup of Leaves of Brassicaceae, raw	RAC	6.65	0.10	0.67	NC	-	26.78	178.09	5.00	33.25	0.58	3.86	5.68	37.77
VP 2060	Subgroup of beans with pods (all commodities within this group)	RAC	0.01	5.07	0.05	0.83	0.01	0.17	0.00	3.70	0.04	NC	-	NC	-
VP 2062	Subgroup of succulent beans without pods (all commodities within this group)	RAC	0.01	2.42	0.02	6.09	0.06	4.33	0.04	2.09	0.02	18.99	0.19	0.17	0.00
VP 2063	Subgroup of succulent peas without pods	RAC	0.01	10.72	0.11	1.99	0.02	2.72	0.03	4.26	0.04	4.23	0.04	NC	-
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	0.01	1.51	0.02	1.50	0.02	1.90	0.02	5.11	0.05	1.36	0.01	23.43	0.23
VD 0523	Broad bean, dry, raw (incl horse-bean, field bean) (Vicia faba)	RAC	0.01	0.02	0.00	0.01	0.00	1.16	0.01	0.40	0.00	NC	-	0.06	0.00
VD 0527	Cowpea, dry, raw (Vigna sinensis, Dolichos sinensis)	RAC	0.01	NC	-	NC	-	0.16	0.00	0.01	0.00	NC	-	NC	-
VD 0541	Soya bean, dry, raw (Glycine soja)	RAC	0.01	0.02	0.00	0.33	0.00	6.64	0.07	3.94	0.04	NC	-	5.78	0.06
-	Soya paste (i.e. miso)	PP	0.0083	NC	-	NC	-	NC	-	1.87	0.02	NC	-	NC	-
-	Soya curd (i.e. tofu)	PP	0.0083	NC	-	NC	-	0.68	0.01	0.87	0.01	NC	-	NC	-
OR 0541	Soya oil, refined	PP	0.0083	19.06	0.16	21.06	0.17	5.94	0.05	33.78	0.28	40.05	0.33	13.39	0.11
-	Soya sauce	PP	0.0083	0.45	0.00	0.29	0.00	2.93	0.02	4.35	0.04	0.09	0.00	0.70	0.01
-	Soya flour	PP	0.0083	0.22	0.00	0.27	0.00	0.29	0.00	0.17	0.00	NC	-	NC	-
-	Beans (dry) NES: including inter alia lablab or hyacinth bean (Dolichos spp.); jack or sword bean (Canavalia spp.); winged bean (Psophocarpus tetragonolobus); guar bean (Cyamopsis tetragonoloba); velvet bean (Stizolobium spp.); yam bean (Pachyrrhizus erosus)	RAC	0.01	0.01	0.00	NC	-	0.57	0.01	0.11	0.00	0.16	0.00	0.94	0.01
VD 0072	Peas (dry) (Pisum spp), raw	RAC	0.015	3.80	0.06	1.25	0.02	0.90	0.01	2.33	0.03	2.70	0.04	3.83	0.06
VD 0524	Chick-pea (dry) (Cicer spp), raw	RAC	0.015	0.27	0.00	1.33	0.02	0.32	0.00	0.15	0.00	0.08	0.00	0.04	0.00
VD 0533	Lentil (dry) (Lens spp), raw	RAC	0.22	0.95	0.21	1.18	0.26	0.40	0.09	0.96	0.21	0.71	0.16	1.28	0.28
VD 0537	Pigeon pea (dry) (Cajanus spp), raw	RAC	0.015	NC	-	NC	-	0.20	0.00	NC	-	NC	-	NC	-
VR 0574	Beetroot, raw	RAC	0.105	9.91	1.04	6.34	0.67	NC	-	9.65	1.01	19.11	2.01	6.47	0.68
VR 0575	Burdock, greater or edible, raw	RAC	0.105	NC	-	NC	-	NC	-	0.48	0.05	NC	-	0.06	0.01
VR 0577	Carrots, raw	RAC	0.105	26.26	2.76	27.13	2.85	10.07	1.06	16.49	1.73	44.69	4.69	8.75	0.92
VR 0578	Celeriac, raw	RAC	0.105	2.97	0.31	1.79	0.19	NC	-	0.06	0.01	16.91	1.78	3.22	0.34
VR 0469	Chicory, roots, raw	RAC	0.105	0.01	0.00	0.51	0.05	0.01	0.00	0.01	0.00	21.12	2.22	NC	-
VR 0583	Horseradish, raw	RAC	0.105	0.01	0.00	0.42	0.04	13.01	1.37	0.26	0.03	2.70	0.28	0.97	0.10
VR 0587	Parsley turnip-rooted, raw	RAC	0.105	NC	-	NC	-	NC	-	NC	-	NC	-	0.61	0.06
VR 0588	Parsnip, raw	RAC	0.105	4.42	0.46	0.06	0.01	NC	-	NC	-	NC	-	1.12	0.12
VR 0494	Radish roots, raw	RAC	0.105	3.83	0.40	11.99	1.26	NC	-	5.26	0.55	2.19	0.23	4.37	0.46
VR 0591	Japanese radish, raw (i.e. Chinese radish, Daikon)	RAC	0.105	NC	-	NC	-	26.64	2.80	18.92	1.99	NC	-	3.59	0.38
VR 0498	Salsify, raw (i.e. Oysterplant)	RAC	0.105	1.02	0.11	0.52	0.05	NC	-	NC	-	2.08	0.22	0.39	0.04

Annex 3

MEFENTRIFLUCONAZOLE (320)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.04 mg/kg bw

Codex Code	Commodity description	STMR Expr as mg/kg		Diets as g/person/day						Intake as ug/person/day					
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
VR 0497	Swede, raw (i.e. Rutabaga)	RAC	0.105	10.01	1.05	1.66	0.17	NC	-	NC	-	3.06	0.32	2.99	0.31
VR 0506	Turnip, garden, raw	RAC	0.105	5.78	0.61	15.35	1.61	NC	-	6.54	0.69	1.95	0.20	4.73	0.50
VR 0573	Arrowroot, raw	RAC	0.01	0.02	0.00	0.01	0.00	2.05	0.02	0.21	0.00	NC	-	0.76	0.01
VR 0463	Cassava raw (incl starch, incl tapioca, incl flour) (i.e. Manioc)	RAC	0.01	0.01	0.00	NC	-	20.96	0.21	0.14	0.00	NC	-	9.62	0.10
VR 0463	Cassava raw (incl starch, incl flour, excl tapioca) (i.e. Manioc)	RAC	0.01	0.01	0.00	NC	-	17.67	0.18	0.01	0.00	NC	-	9.62	0.10
VR 0463	Cassava raw (incl starch, incl tapioca, excl flour) (i.e. Manioc)	RAC	0.01	NC	-	NC	-	19.91	0.20	0.13	0.00	NC	-	9.62	0.10
VR 0463	Cassava raw (incl tapioca, incl flour, excl starch) (i.e. Manioc)	RAC	0.01	0.01	0.00	NC	-	20.96	0.21	0.14	0.00	NC	-	9.62	0.10
VR 0463	Cassava raw (incl starch, excl tapioca, excl flour) (i.e. Manioc)	RAC	0.01	NC	-	NC	-	16.62	0.17	NC	-	NC	-	9.62	0.10
VR 0463	Cassava raw (incl tapioca, excl flour, excl starch) (i.e. Manioc)	RAC	0.01	NC	-	NC	-	19.90	0.20	0.13	0.00	NC	-	9.62	0.10
VR 0463	Cassava raw (incl flour, excl tapioca, excl starch) (i.e. Manioc)	RAC	0.01	0.01	0.00	NC	-	17.67	0.18	0.01	0.00	NC	-	9.62	0.10
VR 0463	Cassava, raw (i.e. Manioc)	RAC	0.01	NC	-	NC	-	16.61	0.17	NC	-	NC	-	9.62	0.10
-	Cassava, flour	PP	0.01	0.01	0.00	NC	-	0.29	0.00	0.01	0.00	NC	-	NC	-
-	Cassava, starch	PP	0.01	NC	-	NC	-	0.01	0.00	NC	-	NC	-	NC	-
-	Cassava, tapioca	PP	0.01	NC	-	NC	-	0.92	0.01	0.04	0.00	NC	-	NC	-
VR 0585	Jerusalem artichoke, raw (i.e. Topinambur)	RAC	0.01	0.11	0.00	0.01	0.00	NC	-	0.22	0.00	NC	-	0.78	0.01
VR 0589	Potato, raw (incl flour, incl frozen, incl tapioca, excl starch)	RAC	0.01	225.03	2.25	226.35	2.26	71.26	0.71	173.36	1.73	234.55	2.35	37.71	0.38
-	Potato, starch	PP	0.0033	NC	-	1.74	0.01	0.05	0.00	0.92	0.00	NC	-	NC	-
VR 0508	Sweet potato, raw (incl dried)	RAC	0.01	0.93	0.01	0.32	0.00	64.65	0.65	5.37	0.05	0.30	0.00	3.13	0.03
VR 0504	Tannia, raw (i.e. Tanier, Yautia)	RAC	0.01	NC	-	NC	-	NC	-	0.01	0.00	NC	-	10.74	0.11
VR 0505	Taro, raw (i.e. Dasheen, Eddoe)	RAC	0.01	NC	-	NC	-	1.93	0.02	0.84	0.01	NC	-	19.94	0.20
VR 0600	Yams, raw (incl dried)	RAC	0.01	NC	-	NC	-	0.03	0.00	0.71	0.01	NC	-	17.57	0.18
GC 0650	Rye, raw	RAC	0.09	0.01	0.00	NC	-	0.06	0.01	0.01	0.00	NC	-	NC	-
CF 1250	Rye, flour (white flour and wholemeal flour)	PP	0.071	2.57	0.18	28.31	2.01	0.12	0.01	5.20	0.37	1.20	0.09	NC	-
GC 0653	Triticale, raw	RAC	0.09	NC	-	NC	-	0.01	0.00	0.01	0.00	NC	-	NC	-
GC 0653	Triticale, flour (white flour and wholemeal flour)	PP	0.071	0.01	0.00	0.14	0.01	0.23	0.02	NC	-	NC	-	NC	-
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, incl white flour products, incl white bread, excl germ, excl wholemeal bread)	RAC	0.09	252.06	22.69	244.62	22.02	134.41	12.10	235.10	21.16	216.33	19.47	167.34	15.06
CF 1210	Wheat, germ	PP	0.1	0.97	0.10	0.10	0.01	0.03	0.00	0.01	0.00	NC	-	0.04	0.00
CP 1212	Wheat, wholemeal bread	PP	0.05	0.03	0.00	0.01	0.00	0.01	0.00	0.01	0.00	0.05	0.00	0.02	0.00
-	Wheat, starch	PP	0.026	NC	-	NC	-	0.01	0.00	0.31	0.01	NC	-	NC	-
-	Wheat, gluten	PP	0.05	0.68	0.03	NC	-	0.01	0.00	0.01	0.00	NC	-	NC	-

Annex 3

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MEFENTRIFLUCONAZOLE (320)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.04 mg/kg bw

Codex Code	Commodity description	STMR Expr as mg/kg		Diets as g/person/day						Intake as ug/person/day					
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
GC 0640	Barley, raw	RAC	0.425	0.01	0.00	NC	-	0.03	0.01	1.36	0.58	NC	-	NC	-
-	Barley, pot&pearled	PP	0.051	0.57	0.03	2.56	0.13	0.33	0.02	0.56	0.03	0.36	0.02	NC	-
-	Barley, flour (white flour and wholemeal flour)	PP	1.6	0.08	0.13	0.03	0.05	0.01	0.02	0.05	0.08	0.68	1.09	0.05	0.08
-	Barley beer	PP	0.013	180.21	2.34	259.46	3.37	45.91	0.60	172.36	2.24	234.42	3.05	65.30	0.85
-	Barley Malt	PP	0.21	0.19	0.04	NC	-	0.04	0.01	0.08	0.02	NC	-	2.14	0.45
GC 0647	Oats, raw (incl rolled)	RAC	0.425	7.50	3.19	6.26	2.66	0.15	0.06	4.87	2.07	3.16	1.34	2.98	1.27
CM 0649 (GC 0649)	Rice, husked, dry (incl flour, incl oil, incl beverages, incl starch, excl polished)	REP	0.11	3.70	0.41	2.11	0.23	1.51	0.17	1.75	0.19	0.29	0.03	5.12	0.56
CM 0649 (GC 0649)	Rice, husked, dry (incl paddy rice)	REP	0.11	2.43	0.27	1.62	0.18	0.42	0.05	1.06	0.12	NC	-	5.02	0.55
CM 1205	Rice polished, dry	PP	0.0085	13.38	0.11	10.80	0.09	262.08	2.23	57.16	0.49	12.83	0.11	62.78	0.53
GC 0646	Millet, raw (incl flour, incl beer)	RAC	0.41	0.03	0.01	0.16	0.07	1.75	0.72	0.69	0.28	NC	-	NC	-
GC 0651	Sorghum, raw (incl flour, incl beer) (i.e. Chicken corn, Dari seed, Durra, Feterita)	RAC	0.41	NC	-	NC	-	1.44	0.59	1.15	0.47	NC	-	7.12	2.92
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl flour, incl oil, incl beer, incl germ, incl starch)	RAC	0.01	18.51	0.19	26.18	0.26	26.04	0.26	39.99	0.40	7.36	0.07	64.58	0.65
GC 0447	Sweet corn on the cob, raw (incl frozen kernels, incl canned kernels)	RAC	0.01	11.43	0.11	3.71	0.04	0.74	0.01	13.63	0.14	3.07	0.03	1.50	0.02
GS 0659	Sugar cane, raw (incl sugar, incl molasses)	RAC	0.37	92.24	34.13	95.72	35.42	28.47	10.53	77.39	28.63	117.73	43.56	103.90	38.44
TN 0085	Group of Tree nuts, raw (incl processed)	RAC	0.01	8.52	0.09	8.94	0.09	15.09	0.15	9.60	0.10	14.57	0.15	26.26	0.26
SO 2090	Subgroup of Small seed oilseeds, raw (incl processed)	RAC	0.06	33.60	2.02	20.72	1.24	9.72	0.58	17.21	1.03	1.11	0.07	0.54	0.03
SO 2091	Subgroup of Sunflower seeds, raw (incl processed)	RAC	0.01	23.43	0.23	29.34	0.29	1.24	0.01	14.00	0.14	6.48	0.06	6.91	0.07
OR 0691	Cotton seed oil, edible	PP	0.00016	1.68	0.00	0.66	0.00	1.13	0.00	1.18	0.00	0.89	0.00	0.37	0.00
SO 0697	Peanuts, nutmeat, raw (incl roasted, incl oil, incl butter)	RAC	0.01	5.63	0.06	2.75	0.03	9.58	0.10	5.82	0.06	13.71	0.14	1.84	0.02
SB 0716	Coffee bean, raw (i.e. green coffee)	RAC	0.01	0.60	0.01	NC	-	0.62	0.01	1.71	0.02	NC	-	3.51	0.04
SM 0716	Coffee bean, roasted	PP	0.0062	7.02	0.04	9.75	0.06	0.02	0.00	5.09	0.03	13.38	0.08	0.77	0.00
-	Coffee bean, instant coffee (incl essences and concentrates)	PP	0.0016	0.75	0.00	0.30	0.00	0.04	0.00	0.67	0.00	2.43	0.00	1.43	0.00
HS 0444	Peppers, chili, dried	PP	2.5	0.11	0.28	0.21	0.53	0.36	0.90	0.21	0.53	0.25	0.63	0.15	0.38
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80 % as muscle	RAC	0.04	112.02	4.48	120.71	4.83	63.46	2.54	88.99	3.56	96.24	3.85	41.02	1.64
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20 % as fat	RAC	0.39	28.01	10.92	30.18	11.77	15.86	6.19	22.25	8.68	24.06	9.38	10.25	4.00
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.39	6.44	2.51	15.51	6.05	3.79	1.48	8.29	3.23	18.44	7.19	8.00	3.12
MO 0105	Edible offal (mammalian), raw	RAC	0.61	15.17	9.25	5.19	3.17	6.30	3.84	6.78	4.14	3.32	2.03	3.17	1.93
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.07	388.92	27.22	335.88	23.51	49.15	3.44	331.25	23.19	468.56	32.80	245.45	17.18

Annex 3

MEFENTRIFLUCONAZOLE (320)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.04 mg/kg bw

Codex Code	Commodity description	STMR Expr as mg/kg	Diets as g/person/day				Intake as ug/person/day								
			G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake	
PM 0110	Poultry meat, raw (incl prepared) - 90 % as muscle	RAC	0.012	66.38	0.80	48.47	0.58	21.58	0.26	78.41	0.94	48.04	0.58	76.01	0.91
PM 0110	Poultry meat, raw (incl prepared) - 10 % as fat	RAC	0.124	7.38	0.91	5.39	0.67	2.40	0.30	8.71	1.08	5.34	0.66	8.45	1.05
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.124	0.10	0.01	0.10	0.01	NC	-	0.10	0.01	0.71	0.09	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.12	0.33	0.04	0.72	0.09	0.27	0.03	0.35	0.04	0.80	0.10	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0.032	25.84	0.83	29.53	0.94	28.05	0.90	33.19	1.06	36.44	1.17	8.89	0.28
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total intake (ug/person)=				348.2		370.8		965.8		430.6		359.0		302.4	
Bodyweight per region (kg bw) =				60		60		55		60		60		60	
ADI (ug/person)=				2400		2400		2200		2400		2400		2400	
%ADI=				14.5 %		15.5 %		43.9 %		17.9 %		15.0 %		12.6 %	
Rounded %ADI=				10 %		20 %		40 %		20 %		10 %		10 %	

MEFENTRIFLUCONAZOLE (320)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.04 mg/kg bw

Codex Code	Commodity description	STMR Expr as mg/kg	Diets: g/person/day				Intake = daily intake: ug/person							
			G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake		
FC 0002	Subgroup of Lemons and limes, raw (incl kumquat commodities)	RAC	0.37	18.96	7.02	0.97	0.36	5.79	2.14	0.09	0.03	3.35	1.24	
-	Lemon, juice (single strength, incl. concentrated)	PP	0.007	0.01	0.00	0.01	0.00	0.16	0.00	0.01	0.00	NC	-	
FC 0003	Subgroup of Mandarins, raw	RAC	0.37	0.16	0.06	0.27	0.10	9.06	3.35	0.01	0.00	0.02	0.01	
-	Subgroup of Mandarins, juice	PP	0.007	0.01	0.00	NC	-	NC	-	NC	-	NC	-	
FC 0004	Subgroup of Oranges, sweet, sour, raw	RAC	0.215	1.18	0.25	1.11	0.24	14.28	3.07	0.05	0.01	1.08	0.23	
JF 0004	Subgroup of Oranges, juice (single strength, incl. concentrated)	PP	0.007	0.08	0.00	0.26	0.00	12.61	0.09	0.14	0.00	0.33	0.00	
FC 0005	Subgroup of Pummelo and grapefruits, raw	RAC	0.16	0.63	0.10	0.01	0.00	1.58	0.25	0.01	0.00	NC	-	
JF 0203	Grapefruits, juice (single strength, incl. concentrated)	PP	0.007	0.03	0.00	0.02	0.00	0.78	0.01	0.01	0.00	NC	-	
FP 0226	Apple, raw	RAC	0.39	0.21	0.08	2.05	0.80	54.48	21.25	0.10	0.04	1.38	0.54	
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.051	0.03	0.00	0.10	0.01	7.19	0.37	0.03	0.00	NC	-	
FP 0228	Loquat, raw (incl processed) (i.e. Japanese medlar)	RAC	0.39	0.94	0.37	4.68	1.83	NC	-	0.50	0.20	3.08	1.20	
FP 0229	Medlar, raw (incl processed)	RAC	0.39	0.75	0.29	3.73	1.45	4.87	1.90	0.40	0.16	2.45	0.96	
FP 0230	Pear, raw	RAC	0.39	0.07	0.03	0.14	0.05	9.45	3.69	0.01	0.00	0.14	0.05	
FP 0231	Quince, raw	RAC	0.39	NC	-	NC	-	0.65	0.25	NC	-	NC	-	
FS 0013	Subgroup of Cherries, raw	RAC	1.1	0.01	0.01	0.01	0.01	5.96	6.56	0.01	0.01	NC	-	
FS 0014	Subgroup of Plums, raw	RAC	0.26	0.07	0.02	0.01	0.00	15.56	4.05	0.01	0.00	NC	-	
DF 0014	Plums, dried (prunes)	PP	1.1	0.01	0.01	0.01	0.01	0.37	0.41	0.01	0.01	NC	-	
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.56	0.02	0.01	0.01	0.01	10.76	6.03	0.01	0.01	NC	-	

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MEFENTRIFLUCONAZOLE (320)				International Estimated Daily Intake (IEDI)				ADI = 0 - 0.04 mg/kg bw					
Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day				Intake = daily intake: ug/person					
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
FB 2005	Subgroup of Caneberries, raw	RAC	0.96	0.01	0.01	7.30	7.01	2.29	2.20	0.01	0.01	NC	-
FB 2006	Subgroup of Bush berries, raw (including processed)	RAC	0.58	0.82	0.48	4.05	2.35	5.94	3.45	0.43	0.25	2.66	1.54
FB 0267	Elderberries, raw (incl processed)	RAC	0.58	0.71	0.41	3.52	2.04	NC	-	0.38	0.22	2.32	1.35
FB 0269	Grapes, raw (incl must, excl dried, excl juice, excl wine)	RAC	0.54	0.14	0.08	0.36	0.19	15.33	8.28	0.01	0.01	0.28	0.15
JF 0269	Grape juice (from wine grapes)	PP	0.07	0.01	0.00	0.01	0.00	0.41	0.03	0.01	0.00	NC	-
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.016	0.31	0.00	0.23	0.00	60.43	0.97	0.52	0.01	31.91	0.51
FB 2009	Subgroup of Low growing berries, raw	RAC	0.29	0.01	0.00	0.01	0.00	3.37	0.98	0.01	0.00	0.01	0.00
FI 0326	Avocado, raw	RAC	0.36	1.12	0.40	0.01	0.00	0.84	0.30	0.01	0.00	6.60	2.38
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.055	44.80	2.46	118.17	6.50	25.25	1.39	454.49	25.00	310.23	17.06
FI 0345	Mango, raw (incl canned mango, incl mango juice)	RAC	0.01	12.25	0.12	6.83	0.07	0.76	0.01	0.01	0.00	20.12	0.20
FI 0350	Papaya, raw	RAC	0.07	6.47	0.45	0.25	0.02	0.19	0.01	0.01	0.00	26.42	1.85
VA 2031	Subgroup of bulb onions	RAC	0.05	9.83	0.49	22.30	1.12	34.69	1.73	9.65	0.48	2.39	0.12
VA 2032	Subgroup of Green Onions	RAC	0.39	1.45	0.57	1.50	0.59	1.42	0.55	0.01	0.00	6.30	2.46
VC 2039	Subgroup of Cucumbers and Squashes, raw	RAC	0.035	0.92	0.03	3.20	0.11	13.55	0.47	1.91	0.07	0.05	0.00
VC 2040	Subgroup of Melons, Pumpkins and Winter squashes	RAC	0.15	5.04	0.76	6.54	0.98	38.26	5.74	11.70	1.76	NC	-
VO 0448	Tomato, raw	RAC	0.14	12.99	1.82	4.79	0.67	58.40	8.18	0.92	0.13	0.09	0.01
-	Tomato, canned (& peeled)	PP	0.0084	0.07	0.00	0.08	0.00	2.42	0.02	0.07	0.00	NC	-
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.069	0.58	0.04	0.22	0.02	2.21	0.15	0.24	0.02	3.10	0.21
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.011	0.05	0.00	0.01	0.00	0.42	0.00	0.01	0.00	0.02	0.00
VO 0051	Subgroup of peppers, raw (Capsicum spp. Only), excl okra	RAC	0.25	4.72	1.18	4.83	1.21	16.30	4.08	0.01	0.00	NC	-
VO 2046	Subgroup of eggplants	RAC	0.25	1.31	0.33	8.26	2.07	3.95	0.99	0.01	0.00	NC	-
VL 2050	Subgroup of Leafy greens	RAC	8.1	4.99	40.42	3.29	26.65	7.53	60.99	3.05	24.71	6.09	49.33
VL 0054	Subgroup of Leaves of Brassicaceae, raw	RAC	6.65	3.58	23.81	2.64	17.56	NC	-	1.83	12.17	3.65	24.27
VP 2060	Subgroup of beans with pods (all commodities within this group)	RAC	0.01	NC	-	NC	-	NC	-	NC	-	NC	-
VP 2062	Subgroup of succulent beans without pods (all commodities within this group)	RAC	0.01	0.37	0.00	3.14	0.03	4.88	0.05	0.01	0.00	NC	-
VP 2063	Subgroup of succulent peas without pods	RAC	0.01	0.21	0.00	0.02	0.00	5.51	0.06	0.02	0.00	NC	-
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	0.01	7.11	0.07	2.33	0.02	3.76	0.04	44.70	0.45	3.27	0.03
VD 0523	Broad bean, dry, raw (incl horse-bean, field bean) (Vicia faba)	RAC	0.01	3.70	0.04	0.03	0.00	0.17	0.00	0.01	0.00	NC	-
VD 0527	Cowpea, dry, raw (Vigna sinensis, Dolichos sinensis)	RAC	0.01	12.77	0.13	0.99	0.01	0.01	0.00	4.33	0.04	NC	-
VD 0541	Soya bean, dry, raw (Glycine soja)	RAC	0.01	2.76	0.03	0.07	0.00	0.33	0.00	3.16	0.03	NC	-
-	Soya paste (i.e. miso)	PP	0.0083	NC	-	NC	-	NC	-	NC	-	NC	-
-	Soya curd (i.e. tofu)	PP	0.0083	NC	-	NC	-	NC	-	NC	-	NC	-
OR 0541	Soya oil, refined	PP	0.0083	2.32	0.02	2.54	0.02	18.70	0.16	2.51	0.02	6.29	0.05

Annex 3

MEFENTRIFLUCONAZOLE (320)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.04 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day		Intake = daily intake: ug/person							
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
-	Soya sauce	PP	0.0083	0.01	0.00	0.13	0.00	0.17	0.00	0.01	0.00	0.56	0.00
-	Soya flour	PP	0.0083	0.11	0.00	0.08	0.00	0.07	0.00	0.01	0.00	0.03	0.00
-	Beans (dry) NES: including inter alia lablab or hyacinth bean (<i>Dolichos</i> spp.); jack or sword bean (<i>Canavalia</i> spp.); winged bean (<i>Psophocarpus tetragonolobus</i>); guar bean (<i>Cyamopsis tetragonoloba</i>); velvet bean (<i>Stizolobium</i> spp.); yam bean (<i>Pachyrrhizus erosus</i>)	RAC	0.01	2.54	0.03	1.77	0.02	0.03	0.00	0.03	0.00	3.99	0.04
VD 0072	Peas (dry) (<i>Pisum</i> spp), raw	RAC	0.015	1.53	0.02	2.52	0.04	3.52	0.05	3.56	0.05	0.74	0.01
VD 0524	Chick-pea (dry) (<i>Cicer</i> spp), raw	RAC	0.015	1.09	0.02	1.56	0.02	0.33	0.00	0.18	0.00	0.47	0.01
VD 0533	Lentil (dry) (<i>Lens</i> spp), raw	RAC	0.22	0.67	0.15	7.26	1.60	0.37	0.08	0.08	0.02	NC	-
VD 0537	Pigeon pea (dry) (<i>Cajanus</i> spp), raw	RAC	0.015	1.14	0.02	0.03	0.00	NC	-	5.53	0.08	NC	-
VR 0574	Beetroot, raw	RAC	0.105	5.86	0.62	4.23	0.44	9.46	0.99	3.96	0.42	7.91	0.83
VR 0575	Burdock, greater or edible, raw	RAC	0.105	0.06	0.01	0.04	0.00	NC	-	0.04	0.00	0.08	0.01
VR 0577	Carrots, raw	RAC	0.105	2.07	0.22	3.00	0.32	25.29	2.66	0.05	0.01	NC	-
VR 0578	Celeriac, raw	RAC	0.105	2.91	0.31	2.10	0.22	7.59	0.80	1.97	0.21	3.93	0.41
VR 0469	Chicory, roots, raw	RAC	0.105	0.01	0.00	0.03	0.00	0.10	0.01	NC	-	NC	-
VR 0583	Horseradish, raw	RAC	0.105	0.88	0.09	0.63	0.07	0.54	0.06	0.59	0.06	1.19	0.12
VR 0587	Parsley turnip-rooted, raw	RAC	0.105	0.55	0.06	0.40	0.04	4.29	0.45	0.37	0.04	0.74	0.08
VR 0588	Parsnip, raw	RAC	0.105	1.02	0.11	0.74	0.08	3.50	0.37	0.69	0.07	1.37	0.14
VR 0494	Radish roots, raw	RAC	0.105	3.96	0.42	2.86	0.30	3.30	0.35	2.67	0.28	5.34	0.56
VR 0591	Japanese radish, raw (i.e. Chinese radish, Daikon)	RAC	0.105	3.25	0.34	2.35	0.25	NC	-	2.20	0.23	4.39	0.46
VR 0498	Salsify, raw (i.e. Oysterplant)	RAC	0.105	0.36	0.04	0.26	0.03	NC	-	0.24	0.03	0.48	0.05
VR 0497	Swede, raw (i.e. Rutabaga)	RAC	0.105	2.71	0.28	1.96	0.21	7.80	0.82	1.83	0.19	3.66	0.38
VR 0506	Turnip, garden, raw	RAC	0.105	4.29	0.45	3.10	0.33	6.41	0.67	2.90	0.30	5.79	0.61
VR 0573	Arrowroot, raw	RAC	0.01	13.83	0.14	18.24	0.18	0.01	0.00	0.05	0.00	19.60	0.20
VR 0463	Cassava raw (incl starch, incl tapioca, incl flour) (i.e. Manioc)	RAC	0.01	91.92	0.92	34.12	0.34	NC	-	259.92	2.60	45.48	0.45
VR 0463	Cassava raw (incl starch, incl flour, excl tapioca) (i.e. Manioc)	RAC	0.01	87.78	0.88	33.53	0.34	NC	-	259.92	2.60	45.48	0.45
VR 0463	Cassava raw (incl starch, incl tapioca, excl flour) (i.e. Manioc)	RAC	0.01	41.16	0.41	34.12	0.34	NC	-	203.39	2.03	45.48	0.45
VR 0463	Cassava raw (incl tapioca, incl flour, excl starch) (i.e. Manioc)	RAC	0.01	91.92	0.92	34.05	0.34	NC	-	259.92	2.60	45.48	0.45
VR 0463	Cassava raw (incl starch, excl tapioca, excl flour) (i.e. Manioc)	RAC	0.01	37.02	0.37	33.53	0.34	NC	-	203.39	2.03	45.48	0.45
VR 0463	Cassava raw (incl tapioca, excl flour, excl starch) (i.e. Manioc)	RAC	0.01	41.16	0.41	34.05	0.34	NC	-	203.38	2.03	45.48	0.45
VR 0463	Cassava raw (incl flour, excl tapioca, excl starch) (i.e. Manioc)	RAC	0.01	87.77	0.88	33.46	0.33	NC	-	259.92	2.60	45.48	0.45

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MEFENTRIFLUCONAZOLE (320)				International Estimated Daily Intake (IEDI)				ADI = 0 - 0.04 mg/kg bw					
Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day				Intake = daily intake: ug/person					
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
VR 0463	Cassava, raw (i.e. Manioc)	RAC	0.01	37.01	0.37	33.46	0.33	NC	-	203.38	2.03	45.48	0.45
-	Cassava, flour	PP	0.01	14.21	0.14	NC	-	NC	-	15.83	0.16	NC	-
-	Cassava, starch	PP	0.01	0.01	0.00	0.02	0.00	NC	-	0.01	0.00	NC	-
-	Cassava, tapioca	PP	0.01	1.16	0.01	0.16	0.00	NC	-	0.01	0.00	NC	-
VR 0585	Jerusalem artichoke, raw (i.e. Topinambur)	RAC	0.01	14.22	0.14	18.75	0.19	0.01	0.00	0.06	0.00	20.14	0.20
VR 0589	Potato, raw (incl flour, incl frozen, incl tapioca, excl starch)	RAC	0.01	23.96	0.24	13.54	0.14	213.41	2.13	104.35	1.04	8.56	0.09
-	Potato, starch	PP	0.0033	0.01	0.00	0.01	0.00	NC	-	NC	-	NC	-
VR 0508	Sweet potato, raw (incl dried)	RAC	0.01	28.83	0.29	61.55	0.62	0.15	0.00	221.94	2.22	NC	-
VR 0504	Tannia, raw (i.e. Tanier, Yautia)	RAC	0.01	NC	-	NC	-	0.01	0.00	NC	-	NC	-
VR 0505	Taro, raw (i.e. Dasheen, Eddoe)	RAC	0.01	6.71	0.07	31.91	0.32	NC	-	10.73	0.11	264.31	2.64
VR 0600	Yams, raw (incl dried)	RAC	0.01	70.93	0.71	30.62	0.31	0.07	0.00	5.65	0.06	30.85	0.31
GC 0650	Rye, raw	RAC	0.09	0.01	0.00	NC	-	NC	-	0.01	0.00	NC	-
CF 1250	Rye, flour (white flour and wholemeal flour)	PP	0.071	0.02	0.00	0.01	0.00	11.16	0.79	0.01	0.00	0.70	0.05
GC 0653	Triticale, raw	RAC	0.09	0.01	0.00	NC	-	NC	-	NC	-	NC	-
GC 0653	Triticale, flour (white flour and wholemeal flour)	PP	0.071	NC	-	NC	-	NC	-	NC	-	NC	-
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, incl white flour products, incl white bread, excl germ, excl wholemeal bread)	RAC	0.09	57.15	5.14	110.46	9.94	272.58	24.53	25.81	2.32	132.04	11.88
CF 1210	Wheat, germ	PP	0.1	0.04	0.00	0.01	0.00	0.01	0.00	0.01	0.00	NC	-
CP 1212	Wheat, wholemeal bread	PP	0.05	0.01	0.00	0.01	0.00	0.03	0.00	0.01	0.00	0.01	0.00
-	Wheat, starch	PP	0.026	0.01	0.00	0.02	0.00	NC	-	NC	-	NC	-
-	Wheat, gluten	PP	0.05	0.01	0.00	0.01	0.00	0.01	0.00	0.01	0.00	0.19	0.01
GC 0640	Barley, raw	RAC	0.425	0.01	0.00	0.01	0.00	0.16	0.07	NC	-	NC	-
-	Barley, pot&pearled	PP	0.051	5.46	0.28	0.01	0.00	1.44	0.07	0.01	0.00	NC	-
-	Barley, flour (white flour and wholemeal flour)	PP	1.6	0.02	0.03	NC	-	0.32	0.51	0.01	0.02	NC	-
-	Barley beer	PP	0.013	16.25	0.21	11.36	0.15	225.21	2.93	19.49	0.25	52.17	0.68
-	Barley Malt	PP	0.21	0.01	0.00	0.11	0.02	0.67	0.14	0.01	0.00	4.61	0.97
GC 0647	Oats, raw (incl rolled)	RAC	0.425	0.37	0.16	0.07	0.03	2.79	1.19	0.10	0.04	NC	-
CM 0649 (GC 0649)	Rice, husked, dry (incl flour, incl oil, incl beverages, incl starch, excl polished)	REP	0.11	13.58	1.49	4.29	0.47	2.17	0.24	0.01	0.00	8.84	0.97
CM 0649 (GC 0649)	Rice, husked, dry (incl paddy rice)	REP	0.11	13.53	1.49	3.48	0.38	1.96	0.22	0.01	0.00	8.84	0.97
CM 1205	Rice polished, dry	PP	0.0085	30.20	0.26	218.34	1.86	12.77	0.11	15.24	0.13	51.35	0.44
GC 0646	Millet, raw (incl flour, incl beer)	RAC	0.41	61.13	25.06	0.78	0.32	NC	-	33.55	13.76	NC	-
GC 0651	Sorghum, raw (incl flour, incl beer) (i.e. Chicken corn, Dari seed, Durra, Feterita)	RAC	0.41	89.16	36.56	2.02	0.83	NC	-	35.38	14.51	NC	-
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl flour, incl oil, incl beer, incl germ, incl starch)	RAC	0.01	116.66	1.17	10.52	0.11	38.46	0.38	76.60	0.77	34.44	0.34
GC 0447	Sweet corn on the cob, raw (incl frozen kernels, incl	RAC	0.01	3.63	0.04	20.50	0.21	8.78	0.09	0.02	0.00	0.17	0.00

Annex 3

MEFENTRIFLUCONAZOLE (320)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.04 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day		Intake = daily intake: ug/person							
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
	canned kernels)												
GS 0659	Sugar cane, raw (incl sugar, incl molasses)	RAC	0.37	33.75	12.49	106.29	39.33	78.09	28.89	29.09	10.76	45.70	16.91
TN 0085	Group of Tree nuts, raw (incl processed)	RAC	0.01	4.39	0.04	135.53	1.36	6.11	0.06	0.72	0.01	317.74	3.18
SO 2090	Subgroup of Small seed oilseeds, raw (incl processed)	RAC	0.06	2.63	0.16	0.93	0.06	12.79	0.77	9.98	0.60	0.01	0.00
SO 2091	Subgroup of Sunflower seeds, raw (incl processed)	RAC	0.01	0.99	0.01	0.22	0.00	32.01	0.32	12.12	0.12	0.48	0.00
OR 0691	Cotton seed oil, edible	PP	0.00016	1.28	0.00	0.05	0.00	0.45	0.00	0.42	0.00	0.15	0.00
SO 0697	Peanuts, nutmeat, raw (incl roasted, incl oil, incl butter)	RAC	0.01	18.82	0.19	0.57	0.01	2.28	0.02	6.90	0.07	0.53	0.01
SB 0716	Coffee bean, raw (i.e. green coffee)	RAC	0.01	0.83	0.01	0.69	0.01	1.09	0.01	2.91	0.03	0.82	0.01
SM 0716	Coffee bean, roasted	PP	0.0062	0.02	0.00	0.41	0.00	7.50	0.05	0.01	0.00	0.06	0.00
-	Coffee bean, instant coffee (incl essences and concentrates)	PP	0.0016	0.03	0.00	0.05	0.00	0.60	0.00	0.01	0.00	5.53	0.01
HS 0444	Peppers, chili, dried	PP	2.5	0.58	1.45	1.27	3.18	1.21	3.03	0.12	0.30	NC	-
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80 % as muscle	RAC	0.04	23.34	0.93	40.71	1.63	97.15	3.89	18.06	0.72	57.71	2.31
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20 % as fat	RAC	0.39	5.84	2.28	10.18	3.97	24.29	9.47	4.52	1.76	14.43	5.63
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.39	1.05	0.41	1.14	0.44	18.69	7.29	0.94	0.37	3.12	1.22
MO 0105	Edible offal (mammalian), raw	RAC	0.61	4.64	2.83	1.97	1.20	10.01	6.11	3.27	1.99	3.98	2.43
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.07	108.75	7.61	70.31	4.92	436.11	30.53	61.55	4.31	79.09	5.54
PM 0110	Poultry meat, raw (incl prepared) - 90 % as muscle	RAC	0.012	3.53	0.04	10.83	0.13	51.36	0.62	4.53	0.05	50.00	0.60
PM 0110	Poultry meat, raw (incl prepared) - 10 % as fat	RAC	0.124	0.39	0.05	1.20	0.15	5.71	0.71	0.50	0.06	5.56	0.69
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.124	NC	-	NC	-	0.32	0.04	NC	-	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.12	0.10	0.01	0.70	0.08	0.97	0.12	0.10	0.01	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0.032	3.84	0.12	4.41	0.14	27.25	0.87	1.13	0.04	7.39	0.24
-	-	-		-	-	-	-	-	-	-	-	-	-
Total intake (ug/person)=					193.0		153.4		287.7		143.0		171.6
Bodyweight per region (kg bw) =					60		60		60		60		60
ADI (ug/person)=					2400		2400		2400		2400		2400
%ADI=					8.0 %		6.4 %		12.0 %		6.0 %		7.2 %
Rounded %ADI=					8 %		6 %		10 %		6 %		7 %

QUINCLORAC (287)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.4 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day																			
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake												
FB 0265	Cranberry, raw	RAC	0.375	0.02	0.01	0.01	0.00	NC	-	0.03	0.01	0.01	0.00	0.01	0.00												
VS 0627	Rhubarb	RAC	0.36	0.73	0.26	1.30	0.47	0.80	0.29	1.95	0.70	NC	-	0.94	0.34												
CM 0649 (GC 0649)	Rice, husked, dry (incl flour, incl oil, incl beverages, incl starch, excl polished)	REP	1.45	1.26	1.83	1.58	2.29	31.05	45.02	5.43	7.87	0.90	1.31	2.18	3.16												
CM 1205	Rice polished, dry	PP	1.1	34.21	37.63	10.39	11.43	41.72	45.89	82.38	90.62	150.24	165.26	70.47	77.52												
SO 0495	Rape seed, raw	RAC	0.64	0.02	0.01	NC	-	NC	-	0.01	0.01	0.75	0.48	0.01	0.01												
OR 0495	Rape seed oil, edible	PP	0.7	0.35	0.25	0.44	0.31	0.19	0.13	0.97	0.68	3.28	2.30	0.77	0.54												
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80 % as muscle	RAC	0	24.96	0.00	57.95	0.00	16.70	0.00	38.38	0.00	26.46	0.00	29.00	0.00												
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20 % as fat	RAC	0.05	6.24	0.31	14.49	0.72	4.18	0.21	9.60	0.48	6.62	0.33	7.25	0.36												
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.05	3.29	0.16	6.14	0.31	0.82	0.04	1.57	0.08	2.23	0.11	1.07	0.05												
MO 0105	Edible offal (mammalian), raw	RAC	0.052	4.79	0.25	9.68	0.50	2.97	0.15	5.49	0.29	3.84	0.20	5.03	0.26												
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0	289.65	0.00	485.88	0.00	26.92	0.00	239.03	0.00	199.91	0.00	180.53	0.00												
PM 0110	Poultry meat, raw (incl prepared) - 90 % as muscle	RAC	0	13.17	0.00	26.78	0.00	7.24	0.00	116.71	0.00	22.54	0.00	32.09	0.00												
PM 0110	Poultry meat, raw (incl prepared) - 10 % as fat	RAC	0.05	1.46	0.07	2.98	0.15	0.80	0.04	12.97	0.65	2.50	0.13	3.57	0.18												
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.05	0.10	0.01	0.10	0.01	NC	-	0.10	0.01	0.10	0.01	0.10	0.01												
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.05	0.12	0.01	0.12	0.01	0.11	0.01	5.37	0.27	0.24	0.01	0.10	0.01												
PE 0112	Eggs, raw, (incl dried)	RAC	0	7.84	0.00	23.08	0.00	2.88	0.00	14.89	0.00	9.81	0.00	14.83	0.00												
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-												
Total intake (ug/person)=				40.8				16.2				91.8				101.7				170.1				82.4			
Bodyweight per region (kg bw) =				60				60				60				60				60							
ADI (ug/person)=				24000				24000				24000				24000				24000							
%ADI=				0.2 %				0.1 %				0.4 %				0.4 %				0.7 %				0.3 %			
Rounded %ADI=				0 %				0 %				0 %				0 %				1 %				0 %			

Annex 3

QUINCLORAC (287)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.4 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day																			
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake												
FB 0265	Cranberry, raw	RAC	0.375	0.06	0.02	0.01	0.00	0.01	0.00	1.22	0.46	0.11	0.04	NC	-												
VS 0627	Rhubarb	RAC	0.36	1.61	0.58	2.23	0.80	NC	-	0.52	0.19	7.63	2.75	1.39	0.50												
CM 0649 (GC 0649)	Rice, husked, dry (incl flour, incl oil, incl beverages, incl starch, excl polished)	REP	1.45	3.70	5.37	2.11	3.06	1.51	2.19	1.75	2.54	0.29	0.42	5.12	7.42												
CM 1205	Rice polished, dry	PP	1.1	13.38	14.72	10.80	11.88	262.08	288.29	57.16	62.88	12.83	14.11	62.78	69.06												
SO 0495	Rape seed, raw	RAC	0.64	NC	-	NC	-	0.01	0.01	NC	-	NC	-	NC	-												
OR 0495	Rape seed oil, edible	PP	0.7	12.52	8.76	7.63	5.34	3.00	2.10	6.01	4.21	NC	-	NC	-												
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80 % as muscle	RAC	0	112.02	0.00	120.71	0.00	63.46	0.00	88.99	0.00	96.24	0.00	41.02	0.00												
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20 % as fat	RAC	0.05	28.01	1.40	30.18	1.51	15.86	0.79	22.25	1.11	24.06	1.20	10.25	0.51												
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.05	6.44	0.32	15.51	0.78	3.79	0.19	8.29	0.41	18.44	0.92	8.00	0.40												
MO 0105	Edible offal (mammalian), raw	RAC	0.052	15.17	0.79	5.19	0.27	6.30	0.33	6.78	0.35	3.32	0.17	3.17	0.16												
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0	388.92	0.00	335.88	0.00	49.15	0.00	331.25	0.00	468.56	0.00	245.45	0.00												
PM 0110	Poultry meat, raw (incl prepared) - 90 % as muscle	RAC	0	66.38	0.00	48.47	0.00	21.58	0.00	78.41	0.00	48.04	0.00	76.01	0.00												
PM 0110	Poultry meat, raw (incl prepared) - 10 % as fat	RAC	0.05	7.38	0.37	5.39	0.27	2.40	0.12	8.71	0.44	5.34	0.27	8.45	0.42												
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.05	0.10	0.01	0.10	0.01	NC	-	0.10	0.01	0.71	0.04	NC	-												
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.05	0.33	0.02	0.72	0.04	0.27	0.01	0.35	0.02	0.80	0.04	NC	-												
PE 0112	Eggs, raw, (incl dried)	RAC	0	25.84	0.00	29.53	0.00	28.05	0.00	33.19	0.00	36.44	0.00	8.89	0.00												
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-												
Total intake (ug/person)=				32.4				24.0				294.0				72.6				20.0				78.5			
Bodyweight per region (kg bw) =				60				60				55				60				60							
ADI (ug/person)=				24000				24000				22000				24000				24000							
%ADI=				0.1 %				0.1 %				1.3 %				0.3 %				0.1 %				0.3 %			
Rounded %ADI=				0 %				0 %				1 %				0 %				0 %							

Annex 3

QUINCLORAC (287)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.4 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day		Intake = daily intake: ug/person							
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
FB 0265	Cranberry, raw	RAC	0.375	NC	-	NC	-	0.03	0.01	NC	-	NC	-
VS 0627	Rhubarb	RAC	0.36	1.26	0.45	0.91	0.33	0.96	0.35	0.85	0.31	1.70	0.61
CM 0649 (GC 0649)	Rice, husked, dry (incl flour, incl oil, incl beverages, incl starch, excl polished)	REP	1.45	13.58	19.69	4.29	6.22	2.17	3.15	0.01	0.01	8.84	12.82
CM 1205	Rice polished, dry	PP	1.1	30.20	33.22	218.34	240.17	12.77	14.05	15.24	16.76	51.35	56.49
SO 0495	Rape seed, raw	RAC	0.64	NC	-	0.01	0.01	NC	-	NC	-	NC	-
OR 0495	Rape seed oil, edible	PP	0.7	0.07	0.05	0.03	0.02	4.62	3.23	0.03	0.02	NC	-
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80 % as muscle	RAC	0	23.34	0.00	40.71	0.00	97.15	0.00	18.06	0.00	57.71	0.00
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20 % as fat	RAC	0.05	5.84	0.29	10.18	0.51	24.29	1.21	4.52	0.23	14.43	0.72
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.05	1.05	0.05	1.14	0.06	18.69	0.93	0.94	0.05	3.12	0.16
MO 0105	Edible offal (mammalian), raw	RAC	0.052	4.64	0.24	1.97	0.10	10.01	0.52	3.27	0.17	3.98	0.21
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0	108.75	0.00	70.31	0.00	436.11	0.00	61.55	0.00	79.09	0.00
PM 0110	Poultry meat, raw (incl prepared) - 90 % as muscle	RAC	0	3.53	0.00	10.83	0.00	51.36	0.00	4.53	0.00	50.00	0.00
PM 0110	Poultry meat, raw (incl prepared) - 10 % as fat	RAC	0.05	0.39	0.02	1.20	0.06	5.71	0.29	0.50	0.03	5.56	0.28
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.05	NC	-	NC	-	0.32	0.02	NC	-	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.05	0.10	0.01	0.70	0.04	0.97	0.05	0.10	0.01	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0	3.84	0.00	4.41	0.00	27.25	0.00	1.13	0.00	7.39	0.00
-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total intake (ug/person)=				54.0		247.5		23.8		17.6		71.3	
Bodyweight per region (kg bw) =				60		60		60		60		60	
ADI (ug/person)=				24000		24000		24000		24000		24000	
%ADI=				0.2 %		1.0 %		0.1 %		0.1 %		0.3 %	
Rounded %ADI=				0 %		1 %		0 %		0 %		0 %	

Annex 3

SPIROMESIFEN (294)

International Estimated Daily Intake (IEDI)

ADI = 0–0.03 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day							
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
				FC 0004	Subgroup of Oranges, sweet, sour, raw	RAC	0.043	20.66	0.89	5.23	0.22	11.90	0.51	37.90	1.63
JF 0004	Subgroup of Oranges, juice (single strength, incl. concentrated)	PP	0.0034	1.27	0.00	2.20	0.01	0.09	0.00	11.81	0.04	0.46	0.00	1.69	0.01
FB 2009	Subgroup of Low growing berries, raw	RAC	0.52	0.71	0.37	2.02	1.05	0.04	0.02	1.39	0.72	0.37	0.19	2.53	1.32
FI 0345	Mango, raw (incl canned mango, incl mango juice)	RAC	0.024	10.48	0.25	0.01	0.00	7.24	0.17	6.87	0.16	19.98	0.48	6.25	0.15
FI 0350	Papaya, raw	RAC	0.13	0.35	0.05	0.01	0.00	3.05	0.40	0.80	0.10	7.28	0.95	1.00	0.13
VB 0040	Group of Brassica vegetables (excl Brassica leafy vegetables), raw	RAC	0.21	6.43	1.35	40.26	8.45	0.80	0.17	9.94	2.09	12.07	2.53	17.73	3.72
VC 0045	Group of Fruiting vegetables, cucurbits, raw	RAC	0.021	53.14	1.12	86.21	1.81	6.28	0.13	92.76	1.95	15.64	0.33	155.30	3.26
VC 0424	Cucumber, raw	RAC	0.05	8.01	0.40	30.66	1.53	1.45	0.07	19.84	0.99	0.27	0.01	34.92	1.75
VC 0046	Melons, except watermelon, raw (Cantaloupe)	RAC	0.075	8.90	0.67	8.64	0.65	0.80	0.06	17.90	1.34	2.80	0.21	29.17	2.19
VO 0448	Tomato, raw (incl juice, incl canned, excl paste)	RAC	0.165	42.41	7.00	76.50	12.62	10.69	1.76	85.07	14.04	24.98	4.12	203.44	33.57
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.43	2.34	1.01	1.33	0.57	1.57	0.68	4.24	1.82	0.34	0.15	2.83	1.22
VO 0051	Subgroup of peppers, raw (incl dried sweet peppers, excl dried chilipeppers), excl okra	RAC	0.097	8.48	0.82	13.74	1.33	10.13	0.98	11.29	1.10	9.52	0.92	26.36	2.56
VO 0442	Okra, raw (i.e. Lady's Finger, Gombo)	RAC	0.097	1.97	0.19	NC	-	3.68	0.36	3.24	0.31	5.72	0.55	1.57	0.15
VO 0440	Egg plant, raw (i.e. aubergine)	RAC	0.165	5.58	0.92	4.31	0.71	0.89	0.15	9.31	1.54	13.64	2.25	20.12	3.32
VL 0053	Group of Leafy vegetables, raw	RAC	2.06	8.47	17.45	22.36	46.06	7.74	15.94	25.51	52.55	45.77	94.29	21.22	43.71
VL 0054	Subgroup of Leaves of Brassicaceae, raw	RAC	2.06	2.63	5.42	9.27	19.10	1.86	3.83	5.82	11.99	19.53	40.23	4.90	10.09
VP 0061	Beans with pods (Phaseolus spp): (immature pods + succulent seeds)	RAC	0.16	0.68	0.11	NC	-	NC	-	0.39	0.06	0.22	0.04	0.49	0.08
VP 0062	Beans without pods: (Phaseolus spp.) (succulent seeds), raw	RAC	0.12	1.56	0.19	0.60	0.07	0.49	0.06	1.18	0.14	0.90	0.11	7.79	0.93
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	0.024	2.39	0.06	1.61	0.04	10.47	0.25	1.84	0.04	12.90	0.31	7.44	0.18
VD 0541	Soya bean, dry, raw (Glycine soja)	RAC	0.024	0.58	0.01	0.05	0.00	0.37	0.01	0.03	0.00	1.65	0.04	0.30	0.01
-	Soya paste (i.e. miso)	PP	0.024	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
-	Soya curd (i.e. tofu)	PP	0.024	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
OR 0541	Soya oil, refined	PP	0.005	12.99	0.06	10.43	0.05	3.63	0.02	13.10	0.07	10.70	0.05	13.10	0.07
-	Soya sauce	PP	0.024	0.01	0.00	0.02	0.00	0.01	0.00	0.34	0.01	0.03	0.00	0.01	0.00
-	Soya flour	PP	0.0053	0.05	0.00	0.86	0.00	0.02	0.00	1.02	0.01	0.01	0.00	0.15	0.00
VR 0463	Cassava raw (incl starch, incl tapioca, incl flour) (i.e. Manioc)	RAC	0.01	0.08	0.00	0.01	0.00	482.56	4.83	0.99	0.01	25.75	0.26	3.29	0.03
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.01	59.74	0.60	316.14	3.16	9.78	0.10	60.26	0.60	54.12	0.54	119.82	1.20
VR 0508	Sweet potato, raw (incl dried)	RAC	0.01	0.18	0.00	0.18	0.00	42.16	0.42	1.61	0.02	3.06	0.03	6.67	0.07
GC 0080	Group of Cereal grains, raw, (incl processed)	RAC	0	484.43	0.00	464.63	0.00	262.36	0.00	486.81	0.00	469.62	0.00	614.04	0.00

Annex 3

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SPIROMESIFEN (294)

International Estimated Daily Intake (IEDI)

ADI = 0–0.03 mg/kg bw

Codex Code	Commodity description	Expr as	STM ^R mg/kg	Diets as g/person/day				Intake as ug/person/day								
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake	
	(incl sweet corn)															
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl flour, incl oil, incl beer, incl germ, incl starch)	RAC	0	29.81	0.00	44.77	0.00	108.95	0.00	52.37	0.00	60.28	0.00	75.69	0.00	
GC 0447	Sweet corn on the cob, raw (incl frozen kernels, incl canned kernels)	RAC	0	0.14	0.00	0.94	0.00	5.70	0.00	2.61	0.00	1.94	0.00	0.22	0.00	
SO 0691	Cotton seed, raw (incl oil)	RAC	0.11	20.53	2.26	9.80	1.08	6.42	0.71	4.73	0.52	7.14	0.79	18.68	2.05	
SB 0716	Coffee bean raw (incl roasted, incl instant coffee, incl substitutes)	RAC	0.02	1.36	0.03	3.59	0.07	1.44	0.03	5.18	0.10	2.02	0.04	1.70	0.03	
HS 0444	Peppers, chili, dried	PP	0.55	0.42	0.23	0.53	0.29	0.84	0.46	0.50	0.28	0.95	0.52	0.37	0.20	
DT 1114	Tea, green or black, fermented and dried, (including concentrates)	RAC	18.5	2.28	42.18	1.98	36.63	0.46	8.51	2.43	44.96	1.29	23.87	3.04	56.24	
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80 % as muscle	RAC	0.01	24.96	0.25	57.95	0.58	16.70	0.17	38.38	0.38	26.46	0.26	29.00	0.29	
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20 % as fat	RAC	0.017	6.24	0.11	14.49	0.25	4.18	0.07	9.60	0.16	6.62	0.11	7.25	0.12	
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.017	3.29	0.06	6.14	0.10	0.82	0.01	1.57	0.03	2.23	0.04	1.07	0.02	
MO 0105	Edible offal (mammalian), raw	RAC	0.055	4.79	0.26	9.68	0.53	2.97	0.16	5.49	0.30	3.84	0.21	5.03	0.28	
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.0021	289.65	0.61	485.88	1.02	26.92	0.06	239.03	0.50	199.91	0.42	180.53	0.38	
PM 0110	Poultry meat, raw (incl prepared)	RAC	0.01	14.63	0.15	29.76	0.30	8.04	0.08	129.68	1.30	25.04	0.25	35.66	0.36	
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.01	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.10	0.00	0.10	0.00	
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.05	0.12	0.01	0.12	0.01	0.11	0.01	5.37	0.27	0.24	0.01	0.10	0.01	
PE 0112	Eggs, raw, (incl dried)	RAC	0.01	7.84	0.08	23.08	0.23	2.88	0.03	14.89	0.15	9.81	0.10	14.83	0.15	
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
	Total intake (ug/person)=				85.1		138.5		41.2		142.3		176.1		172.3	
	Bodyweight per region (kg bw) =				60		60		60		60		60		60	
	ADI (ug/person)=				1800		1800		1800		1800		1800		1800	
	%ADI=				4.7 %		7.7 %		2.3 %		7.9 %		9.8 %		9.6 %	
	Rounded %ADI=				5 %		8 %		2 %		8 %		10 %		10 %	

Annex 3

SPIROMESIFEN (294)

International Estimated Daily Intake (IEDI)

ADI = 0–0.03 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day							
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
				FC 0004	Subgroup of Oranges, sweet, sour, raw	RAC	0.043	15.68	0.67	24.00	1.03	6.80	0.29	29.09	1.25
JF 0004	Subgroup of Oranges, juice (single strength, incl. concentrated)	PP	0.0034	33.31	0.11	1.78	0.01	0.28	0.00	18.97	0.06	14.01	0.05	13.36	0.05
FB 2009	Subgroup of Low growing berries, raw	RAC	0.52	4.55	2.37	5.66	2.94	0.02	0.01	7.85	4.08	5.86	3.05	0.05	0.03
FI 0345	Mango, raw (incl canned mango, incl mango juice)	RAC	0.024	1.80	0.04	0.63	0.02	10.05	0.24	1.07	0.03	3.52	0.08	16.44	0.39
FI 0350	Papaya, raw	RAC	0.13	0.31	0.04	0.18	0.02	1.50	0.20	0.51	0.07	0.54	0.07	1.08	0.14
VB 0040	Group of Brassica vegetables (excl Brassica leafy vegetables), raw	RAC	0.21	20.71	4.35	39.81	8.36	25.06	5.26	37.93	7.97	18.12	3.81	16.74	3.52
VC 0045	Group of Fruiting vegetables, cucurbits, raw	RAC	0.021	27.81	0.58	41.93	0.88	123.30	2.59	49.47	1.04	15.95	0.33	35.99	0.76
VC 0424	Cucumber, raw	RAC	0.05	6.72	0.34	11.03	0.55	32.10	1.61	15.10	0.76	4.05	0.20	9.57	0.48
VC 0046	Melons, except watermelon, raw (Cantaloupe)	RAC	0.075	9.20	0.69	11.95	0.90	14.63	1.10	8.99	0.67	7.86	0.59	2.46	0.18
VO 0448	Tomato, raw (incl juice, incl canned, excl paste)	RAC	0.165	44.88	7.41	55.49	9.16	35.44	5.85	75.65	12.48	27.00	4.46	9.61	1.59
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.43	4.96	2.13	3.20	1.38	0.15	0.06	1.61	0.69	6.88	2.96	0.52	0.22
VO 0051	Subgroup of peppers, raw (incl dried sweet peppers, excl dried chillipeppers), excl okra	RAC	0.097	6.39	0.62	15.53	1.51	19.09	1.85	10.36	1.00	8.29	0.80	4.53	0.44
VO 0442	Okra, raw (i.e. Lady's Finger, Gombo)	RAC	0.097	NC	-	NC	-	0.04	0.00	0.17	0.02	NC	-	0.72	0.07
VO 0440	Egg plant, raw (i.e. aubergine)	RAC	0.165	1.01	0.17	1.69	0.28	21.37	3.53	3.00	0.50	1.40	0.23	NC	-
VL 0053	Group of Leafy vegetables, raw	RAC	2.06	18.83	38.79	21.85	45.01	121.23	249.73	43.09	88.77	18.18	37.45	18.32	37.74
VL 0054	Subgroup of Leaves of Brassicaceae, raw	RAC	2.06	0.10	0.21	NC	-	26.78	55.17	5.00	10.30	0.58	1.19	5.68	11.70
VP 0061	Beans with pods (Phaseolus spp): (immature pods + succulent seeds)	RAC	0.16	5.07	0.81	0.83	0.13	0.17	0.03	3.70	0.59	NC	-	NC	-
VP 0062	Beans without pods: (Phaseolus spp.) (succulent seeds), raw	RAC	0.12	2.21	0.27	5.25	0.63	4.17	0.50	1.61	0.19	16.95	2.03	0.17	0.02
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	0.024	1.51	0.04	1.50	0.04	1.90	0.05	5.11	0.12	1.36	0.03	23.43	0.56
VD 0541	Soya bean, dry, raw (Glycine soja)	RAC	0.024	0.02	0.00	0.33	0.01	6.64	0.16	3.94	0.09	NC	-	5.78	0.14
-	Soya paste (i.e. miso)	PP	0.024	NC	-	NC	-	NC	-	1.87	0.04	NC	-	NC	-
-	Soya curd (i.e. tofu)	PP	0.024	NC	-	NC	-	0.68	0.02	0.87	0.02	NC	-	NC	-
OR 0541	Soya oil, refined	PP	0.005	19.06	0.10	21.06	0.11	5.94	0.03	33.78	0.17	40.05	0.20	13.39	0.07
-	Soya sauce	PP	0.024	0.45	0.01	0.29	0.01	2.93	0.07	4.35	0.10	0.09	0.00	0.70	0.02
-	Soya flour	PP	0.0053	0.22	0.00	0.27	0.00	0.29	0.00	0.17	0.00	NC	-	NC	-
VR 0463	Cassava raw (incl starch, incl tapioca, incl flour) (i.e. Manioc)	RAC	0.01	0.01	0.00	NC	-	20.96	0.21	0.14	0.00	NC	-	9.62	0.10
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.01	225.03	2.25	234.24	2.34	71.48	0.71	177.55	1.78	234.55	2.35	37.71	0.38
VR 0508	Sweet potato, raw (incl dried)	RAC	0.01	0.93	0.01	0.32	0.00	64.65	0.65	5.37	0.05	0.30	0.00	3.13	0.03
GC 0080	Group of Cereal grains, raw, (incl processed) (incl	RAC	0	345.63	0.00	386.16	0.00	514.33	0.00	402.72	0.00	295.30	0.00	359.97	0.00

Annex 3

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SPIROMESIFEN (294)

International Estimated Daily Intake (IEDI)

ADI = 0–0.03 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day							
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
	sweet corn)														
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl flour, incl oil, incl beer, incl germ, incl starch)	RAC	0	18.51	0.00	26.18	0.00	26.04	0.00	39.99	0.00	7.36	0.00	64.58	0.00
GC 0447	Sweet corn on the cob, raw (incl frozen kernels, incl canned kernels)	RAC	0	11.43	0.00	3.71	0.00	0.74	0.00	13.63	0.00	3.07	0.00	1.50	0.00
SO 0691	Cotton seed, raw (incl oil)	RAC	0.11	10.71	1.18	4.23	0.47	7.19	0.79	7.54	0.83	5.66	0.62	2.38	0.26
SB 0716	Coffee bean raw (incl roasted, incl instant coffee, incl substitutes)	RAC	0.02	10.90	0.22	12.44	0.25	0.77	0.02	9.48	0.19	22.07	0.44	8.15	0.16
HS 0444	Peppers, chili, dried	PP	0.55	0.11	0.06	0.21	0.12	0.36	0.20	0.21	0.12	0.25	0.14	0.15	0.08
DT 1114	Tea, green or black, fermented and dried, (including concentrates)	RAC	18.5	2.91	53.84	1.73	32.01	1.14	21.09	1.85	34.23	2.29	42.37	0.74	13.69
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80 % as muscle	RAC	0.01	112.02	1.12	120.71	1.21	63.46	0.63	88.99	0.89	96.24	0.96	41.02	0.41
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20 % as fat	RAC	0.017	28.01	0.48	30.18	0.51	15.86	0.27	22.25	0.38	24.06	0.41	10.25	0.17
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.017	6.44	0.11	15.51	0.26	3.79	0.06	8.29	0.14	18.44	0.31	8.00	0.14
MO 0105	Edible offal (mammalian), raw	RAC	0.055	15.17	0.83	5.19	0.29	6.30	0.35	6.78	0.37	3.32	0.18	3.17	0.17
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.0021	388.92	0.82	335.88	0.71	49.15	0.10	331.25	0.70	468.56	0.98	245.45	0.52
PM 0110	Poultry meat, raw (incl prepared)	RAC	0.01	73.76	0.74	53.86	0.54	23.98	0.24	87.12	0.87	53.38	0.53	84.45	0.84
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.01	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.71	0.01	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.05	0.33	0.02	0.72	0.04	0.27	0.01	0.35	0.02	0.80	0.04	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0.01	25.84	0.26	29.53	0.30	28.05	0.28	33.19	0.33	36.44	0.36	8.89	0.09
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (ug/person)=			121.7		112.0		354.0		171.9		107.9		82.1	
	Bodyweight per region (kg bw) =			60		60		55		60		60		60	
	ADI (ug/person)=			1800		1800		1650		1800		1800		1800	
	%ADI=			6.8 %		6.2 %		21.5 %		9.6 %		6.0 %		4.6 %	
	Rounded %ADI=			7 %		6 %		20 %		10 %		6 %		5 %	

Annex 3

SPIROMESIFEN (294)

International Estimated Daily Intake (IEDI)

ADI = 0–0.03 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day		Intake = daily intake: ug/person							
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
FC 0004	Subgroup of Oranges, sweet, sour, raw	RAC	0.043	1.18	0.05	1.11	0.05	14.28	0.61	0.05	0.00	1.08	0.05
JF 0004	Subgroup of Oranges, juice (single strength, incl. concentrated)	PP	0.0034	0.08	0.00	0.26	0.00	12.61	0.04	0.14	0.00	0.33	0.00
FB 2009	Subgroup of Low growing berries, raw	RAC	0.52	0.01	0.01	0.01	0.01	3.37	1.75	0.01	0.01	0.01	0.01
FI 0345	Mango, raw (incl canned mango, incl mango juice)	RAC	0.024	12.25	0.29	6.83	0.16	0.76	0.02	0.01	0.00	20.12	0.48
FI 0350	Papaya, raw	RAC	0.13	6.47	0.84	0.25	0.03	0.19	0.02	0.01	0.00	26.42	3.43
VB 0040	Group of Brassica vegetables (excl Brassica leafy vegetables), raw	RAC	0.21	5.46	1.15	4.28	0.90	58.72	12.33	0.02	0.00	NC	-
VC 0045	Group of Fruiting vegetables, cucurbits, raw	RAC	0.021	5.96	0.13	9.74	0.20	51.82	1.09	13.61	0.29	0.05	0.00
VC 0424	Cucumber, raw	RAC	0.05	0.68	0.03	1.81	0.09	10.40	0.52	0.01	0.00	0.04	0.00
VC 0046	Melons, except watermelon, raw (Cantaloupe)	RAC	0.075	0.19	0.01	0.10	0.01	4.98	0.37	0.01	0.00	NC	-
VO 0448	Tomato, raw (incl juice, incl canned, excl paste)	RAC	0.165	13.17	2.17	4.92	0.81	62.69	10.34	1.04	0.17	0.11	0.02
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.43	0.58	0.25	0.22	0.09	2.21	0.95	0.24	0.10	3.10	1.33
VO 0051	Subgroup of peppers, raw (incl dried sweet peppers, excl dried chilipeppers), excl okra	RAC	0.097	8.97	0.87	14.13	1.37	25.14	2.44	0.91	0.09	NC	-
VO 0442	Okra, raw (i.e. Lady's Finger, Gombo)	RAC	0.097	6.23	0.60	0.10	0.01	NC	-	NC	-	NC	-
VO 0440	Egg plant, raw (i.e. aubergine)	RAC	0.165	1.31	0.22	8.26	1.36	3.95	0.65	0.01	0.00	NC	-
VL 0053	Group of Leafy vegetables, raw	RAC	2.06	12.42	25.59	8.75	18.03	7.53	15.51	7.07	14.56	14.11	29.07
VL 0054	Subgroup of Leaves of Brassicaceae, raw	RAC	2.06	3.58	7.37	2.64	5.44	NC	-	1.83	3.77	3.65	7.52
VP 0061	Beans with pods (Phaseolus spp): (immature pods + succulent seeds)	RAC	0.16	NC	-	NC	-	NC	-	NC	-	NC	-
VP 0062	Beans without pods: (Phaseolus spp.) (succulent seeds), raw	RAC	0.12	0.30	0.04	3.13	0.38	4.11	0.49	0.01	0.00	NC	-
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	0.024	7.11	0.17	2.33	0.06	3.76	0.09	44.70	1.07	3.27	0.08
VD 0541	Soya bean, dry, raw (Glycine soja)	RAC	0.024	2.76	0.07	0.07	0.00	0.33	0.01	3.16	0.08	NC	-
-	Soya paste (i.e. miso)	PP	0.024	NC	-	NC	-	NC	-	NC	-	NC	-
-	Soya curd (i.e. tofu)	PP	0.024	NC	-	NC	-	NC	-	NC	-	NC	-
OR 0541	Soya oil, refined	PP	0.005	2.32	0.01	2.54	0.01	18.70	0.09	2.51	0.01	6.29	0.03
-	Soya sauce	PP	0.024	0.01	0.00	0.13	0.00	0.17	0.00	0.01	0.00	0.56	0.01
-	Soya flour	PP	0.0053	0.11	0.00	0.08	0.00	0.07	0.00	0.01	0.00	0.03	0.00
VR 0463	Cassava raw (incl starch, incl tapioca, incl flour) (i.e. Manioc)	RAC	0.01	91.92	0.92	34.12	0.34	NC	-	259.92	2.60	45.48	0.45
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.01	23.96	0.24	13.56	0.14	213.41	2.13	104.35	1.04	8.56	0.09
VR 0508	Sweet potato, raw (incl dried)	RAC	0.01	28.83	0.29	61.55	0.62	0.15	0.00	221.94	2.22	NC	-
GC 0080	Group of Cereal grains, raw, (incl processed) (incl sweet corn)	RAC	0	407.04	0.00	417.04	0.00	402.79	0.00	195.30	0.00	263.26	0.00

Annex 3

798

SPIROMESIFEN (294)

International Estimated Daily Intake (IEDI)

ADI = 0–0.03 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day		Intake = daily intake: ug/person							
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl flour, incl oil, incl beer, incl germ, incl starch)	RAC	0	116.66	0.00	10.52	0.00	38.46	0.00	76.60	0.00	34.44	0.00
GC 0447	Sweet corn on the cob, raw (incl frozen kernels, incl canned kernels)	RAC	0	3.63	0.00	20.50	0.00	8.78	0.00	0.02	0.00	0.17	0.00
SO 0691	Cotton seed, raw (incl oil)	RAC	0.11	8.14	0.90	0.32	0.04	2.84	0.31	2.69	0.30	0.97	0.11
SB 0716	Coffee bean raw (incl roasted, incl instant coffee, incl substitutes)	RAC	0.02	0.95	0.02	1.32	0.03	11.64	0.23	2.96	0.06	14.73	0.29
HS 0444	Peppers, chili, dried	PP	0.55	0.58	0.32	1.27	0.70	1.21	0.67	0.12	0.07	NC	-
DT 1114	Tea, green or black, fermented and dried, (including concentrates)	RAC	18.5	0.53	9.81	5.25	97.13	0.86	15.91	0.56	10.36	0.88	16.28
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80 % as muscle	RAC	0.01	23.34	0.23	40.71	0.41	97.15	0.97	18.06	0.18	57.71	0.58
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20 % as fat	RAC	0.017	5.84	0.10	10.18	0.17	24.29	0.41	4.52	0.08	14.43	0.25
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.017	1.05	0.02	1.14	0.02	18.69	0.32	0.94	0.02	3.12	0.05
MO 0105	Edible offal (mammalian), raw	RAC	0.055	4.64	0.26	1.97	0.11	10.01	0.55	3.27	0.18	3.98	0.22
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.0021	108.75	0.23	70.31	0.15	436.11	0.92	61.55	0.13	79.09	0.17
PM 0110	Poultry meat, raw (incl prepared)	RAC	0.01	3.92	0.04	12.03	0.12	57.07	0.57	5.03	0.05	55.56	0.56
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.01	NC	-	NC	-	0.32	0.00	NC	-	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.05	0.10	0.01	0.70	0.04	0.97	0.05	0.10	0.01	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0.01	3.84	0.04	4.41	0.04	27.25	0.27	1.13	0.01	7.39	0.07
-	-	-	-	-	-	-	-	-	-	-	-	-	-

Total intake (ug/person)=	53.3	129.0	70.7	37.5	61.1
Bodyweight per region (kg bw) =	60	60	60	60	60
ADI (ug/person)=	1800	1800	1800	1800	1800
%ADI=	3.0 %	7.2 %	3.9 %	2.1 %	3.4 %
Rounded %ADI=	3 %	7 %	4 %	2 %	3 %

Annex 3

SULFOXAFLOR (252)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.05 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day							
				G01		G02		G03		G04		G05		G06	
				diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
FC 0002	Subgroup of Lemons and limes, raw (incl lemon juice) (incl kumquat commodities)	RAC	0.038	4.82	0.18	2.45	0.09	3.93	0.15	25.44	0.97	8.74	0.33	16.23	0.62
FC 0003	Subgroup of Mandarins, raw (incl mandarin juice)	RAC	0.26	6.18	1.61	3.66	0.95	0.25	0.07	6.82	1.77	3.49	0.91	19.38	5.04
FC 0004	Subgroup of Oranges, sweet, sour, raw	RAC	0.26	20.66	5.37	5.23	1.36	11.90	3.09	37.90	9.85	21.16	5.50	56.46	14.68
JF 0004	Subgroup of Oranges, juice (single strength, incl. concentrated)	PP	0.022	1.27	0.03	2.20	0.05	0.09	0.00	11.81	0.26	0.46	0.01	1.69	0.04
FC 0005	Subgroup of Pummelo and grapefruits, raw (incl grapefruit juice)	RAC	0.0125	0.66	0.01	0.69	0.01	0.96	0.01	10.20	0.13	1.25	0.02	2.97	0.04
FP 0009	Group of Pome fruits, raw (incl apple cider, excl apple juice)	RAC	0.07	19.35	1.35	34.06	2.38	17.87	1.25	25.74	1.80	7.69	0.54	56.85	3.98
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.027	0.32	0.01	3.07	0.08	0.07	0.00	5.00	0.14	0.29	0.01	5.57	0.15
FS 0013	Subgroup of Cherries, raw	RAC	0.34	0.92	0.31	9.15	3.11	0.01	0.00	0.61	0.21	0.06	0.02	6.64	2.26
FS 0014	Subgroup of Plums, raw (incl dried plums)	RAC	0.038	2.67	0.10	8.77	0.33	0.07	0.00	3.03	0.12	0.70	0.03	4.34	0.16
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.061	8.01	0.49	5.87	0.36	0.18	0.01	8.19	0.50	1.64	0.10	22.46	1.37
FB 2005	Subgroup of Caneberries, raw	RAC	0.44	0.42	0.18	1.05	0.46	0.01	0.00	0.02	0.01	0.02	0.01	1.24	0.55
FB 2006	Subgroup of Bush berries, raw (including processed)	RAC	0.39	0.53	0.21	1.31	0.51	0.40	0.16	1.66	0.65	0.01	0.00	0.99	0.39
FB 0267	Elderberries, raw (incl processed)	RAC	0.39	0.44	0.17	0.27	0.11	0.34	0.13	1.41	0.55	NC	-	0.87	0.34
FB 0269	Grapes, raw (incl must, incl juice, excl dried, excl wine)	RAC	0.14	13.19	1.85	9.61	1.35	0.09	0.01	17.28	2.42	4.00	0.56	54.50	7.63
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	0.49	0.51	0.25	0.51	0.25	0.01	0.00	1.27	0.62	0.12	0.06	2.07	1.01
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.098	0.67	0.07	12.53	1.23	2.01	0.20	1.21	0.12	3.53	0.35	4.01	0.39
FB 0275	Strawberry, raw	RAC	0.19	0.70	0.13	2.01	0.38	0.04	0.01	1.36	0.26	0.37	0.07	2.53	0.48
FI 0326	Avocado, raw	RAC	0.011	0.13	0.00	0.03	0.00	2.05	0.02	2.54	0.03	2.34	0.03	0.12	0.00
FI 0345	Mango, raw (incl canned mango, incl mango juice)	RAC	0.022	10.48	0.23	0.01	0.00	7.24	0.16	6.87	0.15	19.98	0.44	6.25	0.14
VA 0381	Garlic, raw	RAC	0.01	2.29	0.02	5.78	0.06	0.11	0.00	3.69	0.04	1.65	0.02	3.91	0.04
-	Onions, dry, raw	RAC	0	29.36	0.00	37.50	0.00	3.56	0.00	34.78	0.00	18.81	0.00	43.38	0.00
-	Onions, green, raw	RAC	0.11	2.45	0.27	1.49	0.16	1.02	0.11	2.60	0.29	0.60	0.07	2.03	0.22
VB 0400	Broccoli, raw	RAC	0.074	0.88	0.07	0.17	0.01	0.01	0.00	1.25	0.09	3.00	0.22	1.09	0.08
VB 0404	Cauliflower, raw	RAC	0.012	1.65	0.02	0.32	0.00	0.01	0.00	2.33	0.03	4.79	0.06	2.03	0.02
VB 0041	Cabbages, head, raw	RAC	0.099	2.73	0.27	27.92	2.76	0.55	0.05	4.47	0.44	4.27	0.42	10.25	1.01
VB 0467	Chinese cabbage, type pe-tsai, raw	RAC	1.2	0.45	0.54	4.56	5.47	0.09	0.11	0.73	0.88	NC	-	1.67	2.00
VC 0045	Group of Fruiting vegetables, cucurbits, raw	RAC	0.029	53.14	1.54	86.21	2.50	6.28	0.18	92.76	2.69	15.64	0.45	155.30	4.50
VO 0448	Tomato, raw (incl canned, excl juice, excl paste)	RAC	0.11	42.04	4.62	76.13	8.37	10.69	1.18	84.59	9.30	24.92	2.74	203.27	22.36
-	Tomato, paste (i.e. concentrated tomato)	PP	0.23	2.34	0.54	1.33	0.31	1.57	0.36	4.24	0.98	0.34	0.08	2.83	0.65

Annex 3

800

SULFOXAFLOR (252)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.05 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day							
				G01		G02		G03		G04		G05		G06	
				diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
	sauce/puree)														
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.052	0.29	0.02	0.29	0.02	0.01	0.00	0.38	0.02	0.05	0.00	0.14	0.01
VO 0442	Okra, raw (i.e. Lady's Finger, Gombo)	RAC	0.11	1.97	0.22	NC	-	3.68	0.40	3.24	0.36	5.72	0.63	1.57	0.17
VO 0444	Peppers, chili, raw	RAC	0.11	3.99	0.44	7.30	0.80	2.93	0.32	5.62	0.62	NC	-	17.44	1.92
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.11	4.49	0.49	6.44	0.71	7.21	0.79	5.68	0.62	9.52	1.05	8.92	0.98
VO 0440	Egg plant, raw (i.e. aubergine)	RAC	0.11	5.58	0.61	4.31	0.47	0.89	0.10	9.31	1.02	13.64	1.50	20.12	2.21
VL 2050	Subgroup of Leafy greens	RAC	1.2	3.93	4.72	5.28	6.34	3.07	3.68	14.53	17.44	8.25	9.90	12.75	15.30
VL 0054	Subgroup of Leaves of Brassicaceae, raw	RAC	1.2	2.63	3.16	9.27	11.12	1.86	2.23	5.82	6.98	19.53	23.44	4.90	5.88
VL 2052	Subgroup of Leaves of Root and Tuber Vegetables	RAC	1.2	0.18	0.22	0.31	0.37	0.84	1.01	0.47	0.56	2.06	2.47	0.23	0.28
VL 2053	Subgroup of Leaves of trees, shrubs and vines	RAC	1.2	0.39	0.47	0.69	0.83	0.43	0.52	1.04	1.25	4.57	5.48	0.50	0.60
VL 0507	Kang kung, raw (i.e. Water spinach)	RAC	1.2	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VL 0473	Watercress, raw	RAC	1	1.21	1.21	2.15	2.15	1.33	1.33	3.24	3.24	11.36	11.36	1.56	1.56
-	Water parsley, raw	RAC	1.2	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	0.075	2.39	0.18	1.61	0.12	10.47	0.79	1.84	0.14	12.90	0.97	7.44	0.56
VD 0541	Soya bean, dry, raw (incl flour, incl paste, incl curd, incl sauce, excl oil)	RAC	0.011	0.63	0.01	1.09	0.01	0.40	0.00	1.40	0.02	1.68	0.02	0.48	0.01
OR 0541	Soya oil, refined	PP	0.0033	12.99	0.04	10.43	0.03	3.63	0.01	13.10	0.04	10.70	0.04	13.10	0.04
VR 0574	Beetroot, raw	RAC	0.01	3.42	0.03	6.06	0.06	3.75	0.04	9.11	0.09	NC	-	4.39	0.04
VR 0575	Burdock, greater or edible, raw	RAC	0.01	0.03	0.00	0.06	0.00	0.04	0.00	0.09	0.00	NC	-	0.04	0.00
VR 0577	Carrots, raw	RAC	0.01	9.51	0.10	30.78	0.31	0.37	0.00	8.75	0.09	2.80	0.03	6.10	0.06
VR 0578	Celeriac, raw	RAC	0.01	1.70	0.02	3.01	0.03	1.87	0.02	4.53	0.05	NC	-	2.19	0.02
VR 0469	Chicory, roots, raw	RAC	0.01	0.01	0.00	0.20	0.00	0.01	0.00	0.01	0.00	0.02	0.00	0.01	0.00
VR 0583	Horseradish, raw	RAC	0.01	0.51	0.01	0.91	0.01	0.56	0.01	1.37	0.01	NC	-	0.66	0.01
VR 0587	Parsley turnip-rooted, raw	RAC	0.01	0.32	0.00	0.57	0.01	0.35	0.00	0.85	0.01	NC	-	0.41	0.00
VR 0588	Parsnip, raw	RAC	0.01	0.59	0.01	1.05	0.01	0.65	0.01	1.58	0.02	NC	-	0.76	0.01
VR 0494	Radish roots, raw	RAC	0.01	2.31	0.02	4.09	0.04	2.53	0.03	6.15	0.06	5.88	0.06	2.97	0.03
VR 0591	Japanese radish, raw (i.e. Chinese radish, Daikon)	RAC	0.01	1.90	0.02	3.36	0.03	2.08	0.02	5.06	0.05	NC	-	2.44	0.02
VR 0498	Salsify, raw (i.e. Oysterplant)	RAC	0.01	0.21	0.00	0.37	0.00	0.23	0.00	0.55	0.01	NC	-	0.27	0.00
VR 0596	Sugar beet, raw	RAC	0.014	NC	-	NC	-	NC	-	NC	-	0.01	0.00	NC	-
-	Sugar beet, sugar	PP	0.025	0.02	0.00	NC	-	0.01	0.00	0.09	0.00	0.07	0.00	12.63	0.32
VR 0497	Swede, raw (i.e. Rutabaga)	RAC	0.01	1.58	0.02	2.80	0.03	1.74	0.02	4.21	0.04	NC	-	2.03	0.02
VR 0506	Turnip, garden, raw	RAC	0.01	2.50	0.03	4.44	0.04	2.75	0.03	6.67	0.07	0.14	0.00	3.22	0.03
VR 0573	Arrowroot, raw	RAC	0.01	1.53	0.02	0.01	0.00	0.93	0.01	1.33	0.01	0.47	0.00	0.02	0.00
VR 0463	Cassava raw (incl starch, incl tapioca, incl flour) (i.e. Manioc)	RAC	0.01	0.08	0.00	0.01	0.00	482.56	4.83	0.99	0.01	25.75	0.26	3.29	0.03
VR 0585	Jerusalem artichoke, raw (i.e. Topinambur)	RAC	0.01	1.57	0.02	0.01	0.00	0.96	0.01	1.36	0.01	0.48	0.00	0.02	0.00
VR 0589	Potato, raw (incl flour, incl frozen, incl starch,	RAC	0.01	59.74	0.60	316.14	3.16	9.78	0.10	60.26	0.60	54.12	0.54	119.82	1.20

Annex 3

SULFOXAFLOR (252)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.05 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Intake as ug/person/day											
				Diets as g/person/day				Intake as ug/person/day							
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
	incl tapioca)														
VR 0508	Sweet potato, raw (incl dried)	RAC	0.01	0.18	0.00	0.18	0.00	42.16	0.42	1.61	0.02	3.06	0.03	6.67	0.07
VR 0504	Tannia, raw (i.e. Tanier, Yautia)	RAC	0.01	NC	-	NC	-	NC	-	0.01	0.00	0.26	0.00	1.27	0.01
VR 0505	Taro, raw (i.e. Dasheen, Eddoe)	RAC	0.01	0.01	0.00	NC	-	25.12	0.25	0.04	0.00	0.01	0.00	0.97	0.01
VR 0600	Yams, raw (incl dried)	RAC	0.01	0.02	0.00	NC	-	90.40	0.90	6.45	0.06	0.74	0.01	0.65	0.01
VR 2072	Subgroup of Aquatic root and tuber vegetables	RAC	0.01	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VS 0624	Celery	RAC	0.19	2.14	0.41	3.79	0.72	2.35	0.45	5.69	1.08	0.02	0.00	2.75	0.52
VS 0621	Asparagus, raw	RAC	0.01	0.01	0.00	0.01	0.00	0.01	0.00	0.03	0.00	0.07	0.00	0.21	0.00
VS 0620	Artichoke globe, raw	RAC	0.245	0.69	0.17	0.01	0.00	0.01	0.00	0.32	0.08	0.26	0.06	1.21	0.30
GC 0653	Triticale, raw (incl flour)	RAC	0.025	NC	-	NC	-	NC	-	0.01	0.00	0.39	0.01	NC	-
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, incl germ, incl wholemeal bread, incl white flour products, incl white bread)	RAC	0.025	381.15	9.53	341.55	8.54	38.35	0.96	281.89	7.05	172.83	4.32	434.07	10.85
GC 0640	Barley, raw (incl malt extract, incl flour & grits, incl malt, excl pot&pearled, excl beer)	RAC	0.063	8.03	0.51	2.05	0.13	0.39	0.02	0.62	0.04	1.27	0.08	0.56	0.04
-	Barley, pot&pearled	PP	0.032	7.12	0.23	7.34	0.23	0.02	0.00	0.03	0.00	0.67	0.02	0.20	0.01
SO 0495	Rape seed, raw	RAC	0.045	0.02	0.00	NC	-	NC	-	0.01	0.00	0.75	0.03	0.01	0.00
OR 0495	Rape seed oil, edible	PP	0.014	0.35	0.00	0.44	0.01	0.19	0.00	0.97	0.01	3.28	0.05	0.77	0.01
SO 0702	Sunflower seed, raw	RAC	0.047	0.09	0.00	0.33	0.02	0.09	0.00	0.24	0.01	0.02	0.00	0.01	0.00
OR 0702	Sunflower seed oil, edible	PP	0.033	2.97	0.10	14.42	0.48	0.43	0.01	3.46	0.11	2.20	0.07	5.53	0.18
OR 0691	Cotton seed oil, edible	PP	0.002	3.22	0.01	1.54	0.00	1.01	0.00	0.74	0.00	1.12	0.00	2.93	0.01
SB 0716	Coffee bean, raw (i.e. green coffee)	RAC	0.035	0.96	0.03	0.16	0.01	0.91	0.03	0.27	0.01	1.37	0.05	0.46	0.02
SM 0716	Coffee bean, roasted	PP	0.0167	0.19	0.00	0.91	0.02	0.16	0.00	2.50	0.04	0.39	0.01	0.40	0.01
-	Coffee bean, instant coffee (incl essences and concentrates)	PP	0.084	0.07	0.01	0.94	0.08	0.07	0.01	0.70	0.06	0.07	0.01	0.29	0.02
HS 0444	Peppers, chili, dried	PP	1.1	0.42	0.46	0.53	0.58	0.84	0.92	0.50	0.55	0.95	1.05	0.37	0.41
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80 % as muscle	RAC	0.045	24.96	1.12	57.95	2.61	16.70	0.75	38.38	1.73	26.46	1.19	29.00	1.31
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20 % as fat	RAC	0.03	6.24	0.19	14.49	0.43	4.18	0.13	9.60	0.29	6.62	0.20	7.25	0.22
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.03	3.29	0.10	6.14	0.18	0.82	0.02	1.57	0.05	2.23	0.07	1.07	0.03
MO 0105	Edible offal (mammalian), raw	RAC	0.13	4.79	0.62	9.68	1.26	2.97	0.39	5.49	0.71	3.84	0.50	5.03	0.65
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.05	289.65	14.48	485.88	24.29	26.92	1.35	239.03	11.95	199.91	10.00	180.53	9.03
PM 0110	Poultry meat, raw (incl prepared) - 90 % as muscle	RAC	0.015	13.17	0.20	26.78	0.40	7.24	0.11	116.71	1.75	22.54	0.34	32.09	0.48
PM 0110	Poultry meat, raw (incl prepared) - 10 % as fat	RAC	0.005	1.46	0.01	2.98	0.01	0.80	0.00	12.97	0.06	2.50	0.01	3.57	0.02
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.005	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.10	0.00	0.10	0.00
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.046	0.12	0.01	0.12	0.01	0.11	0.01	5.37	0.25	0.24	0.01	0.10	0.00

Annex 3

SULFOXAFLOR (252)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.05 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day							
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
PE 0112	Eggs, raw, (incl dried)	RAC	0.013	7.84	0.10	23.08	0.30	2.88	0.04	14.89	0.19	9.81	0.13	14.83	0.19
Total intake (ug/person)=				61.4		99.7		30.4		94.8		89.0		125.9	
Bodyweight per region (kg bw) =				60		60		60		60		60		60	
ADI (ug/person)=				3000		3000		3000		3000		3000		3000	
%ADI=				2.0 %		3.3 %		1.0 %		3.2 %		3.0 %		4.2 %	
Rounded %ADI=				2 %		3 %		1 %		3 %		3 %		4 %	

SULFOXAFLOR (252)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.05 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day							
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
FC 0002	Subgroup of Lemons and limes, raw (incl lemon juice) (incl kumquat commodities)	RAC	0.038	10.12	0.38	15.69	0.60	2.88	0.11	12.30	0.47	22.32	0.85	6.59	0.25
FC 0003	Subgroup of Mandarins, raw (incl mandarin juice)	RAC	0.26	12.42	3.23	14.99	3.90	16.08	4.18	10.78	2.80	9.94	2.58	NC	-
FC 0004	Subgroup of Oranges, sweet, sour, raw	RAC	0.26	15.68	4.08	24.00	6.24	6.80	1.77	29.09	7.56	15.39	4.00	160.47	41.72
JF 0004	Subgroup of Oranges, juice (single strength, incl. concentrated)	PP	0.022	33.31	0.73	1.78	0.04	0.28	0.01	18.97	0.42	14.01	0.31	13.36	0.29
FC 0005	Subgroup of Pummelo and grapefruits, raw (incl grapefruit juice)	RAC	0.0125	8.21	0.10	4.60	0.06	0.64	0.01	5.85	0.07	19.98	0.25	368.86	4.61
FP 0009	Group of Pome fruits, raw (incl apple cider, excl apple juice)	RAC	0.07	51.09	3.58	65.40	4.58	42.71	2.99	45.29	3.17	62.51	4.38	7.74	0.54
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.027	14.88	0.40	11.98	0.32	0.15	0.00	9.98	0.27	30.32	0.82	3.47	0.09
FS 0013	Subgroup of Cherries, raw	RAC	0.34	1.40	0.48	4.21	1.43	0.04	0.01	2.93	1.00	1.50	0.51	NC	-
FS 0014	Subgroup of Plums, raw (incl dried plums)	RAC	0.038	5.55	0.21	4.37	0.17	6.08	0.23	3.66	0.14	3.93	0.15	0.46	0.02
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.061	13.03	0.79	16.29	0.99	8.29	0.51	12.95	0.79	5.35	0.33	0.04	0.00
FB 2005	Subgroup of Caneberries, raw	RAC	0.44	0.56	0.25	1.43	0.63	0.14	0.06	1.23	0.54	1.14	0.50	0.01	0.00
FB 2006	Subgroup of Bush berries, raw (including processed)	RAC	0.39	1.31	0.51	5.50	2.15	0.01	0.00	2.57	1.00	0.82	0.32	2.15	0.84
FB 0267	Elderberries, raw (incl processed)	RAC	0.39	8.20	3.20	0.14	0.05	NC	-	NC	-	NC	-	1.87	0.73
FB 0269	Grapes, raw (incl must, incl juice, excl dried, excl wine)	RAC	0.14	7.18	1.01	13.73	1.92	5.24	0.73	12.27	1.72	7.46	1.04	1.21	0.17
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	0.49	3.09	1.51	1.51	0.74	0.03	0.01	1.38	0.68	4.26	2.09	0.42	0.21
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.098	88.93	8.72	62.41	6.12	1.84	0.18	25.07	2.46	61.17	5.99	5.84	0.57
FB 0275	Strawberry, raw	RAC	0.19	4.49	0.85	5.66	1.08	0.02	0.00	6.63	1.26	5.75	1.09	0.05	0.01
FI 0326	Avocado, raw	RAC	0.011	2.65	0.03	0.87	0.01	0.46	0.01	1.64	0.02	1.30	0.01	0.96	0.01
FI 0345	Mango, raw (incl canned mango, incl mango)	RAC	0.022	1.80	0.04	0.63	0.01	10.05	0.22	1.07	0.02	3.52	0.08	16.44	0.36

Annex 3

SULFOXAFLOR (252)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.05 mg/kg bw

Codex Code	Commodity description	Expr as	STM ^R mg/kg	Diets as g/person/day				Intake as ug/person/day							
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
	(juice)														
VA 0381	Garlic, raw	RAC	0.01	0.98	0.01	1.49	0.01	12.88	0.13	3.74	0.04	2.05	0.02	1.14	0.01
-	Onions, dry, raw	RAC	0	19.69	0.00	29.83	0.00	24.64	0.00	31.35	0.00	9.72	0.00	12.59	0.00
-	Onions, green, raw	RAC	0.11	1.55	0.17	0.74	0.08	1.05	0.12	3.74	0.41	0.94	0.10	6.45	0.71
VB 0400	Broccoli, raw	RAC	0.074	4.24	0.31	1.76	0.13	NC	-	0.51	0.04	3.79	0.28	0.26	0.02
VB 0404	Cauliflower, raw	RAC	0.012	5.27	0.06	5.01	0.06	NC	-	2.70	0.03	5.57	0.07	0.49	0.01
VB 0041	Cabbages, head, raw	RAC	0.099	8.97	0.89	27.12	2.68	1.44	0.14	24.96	2.47	4.55	0.45	11.23	1.11
VB 0467	Chinese cabbage, type pe-tsai, raw	RAC	1.2	NC	-	NC	-	17.39	20.87	9.44	11.33	NC	-	1.83	2.20
VC 0045	Group of Fruiting vegetables, cucurbits, raw	RAC	0.029	27.81	0.81	41.93	1.22	123.30	3.58	49.47	1.43	15.95	0.46	35.99	1.04
VO 0448	Tomato, raw (incl canned, excl juice, excl paste)	RAC	0.11	43.88	4.83	55.41	6.10	35.38	3.89	74.88	8.24	26.50	2.92	9.51	1.05
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.23	4.96	1.14	3.20	0.74	0.15	0.03	1.61	0.37	6.88	1.58	0.52	0.12
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.052	0.80	0.04	0.07	0.00	0.05	0.00	0.61	0.03	0.40	0.02	0.08	0.00
VO 0442	Okra, raw (i.e. Lady's Finger, Gombo)	RAC	0.11	NC	-	NC	-	0.04	0.00	0.17	0.02	NC	-	0.72	0.08
VO 0444	Peppers, chili, raw	RAC	0.11	5.57	0.61	14.00	1.54	8.25	0.91	5.77	0.63	6.44	0.71	2.53	0.28
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.11	0.82	0.09	1.53	0.17	10.85	1.19	4.59	0.50	1.84	0.20	2.00	0.22
VO 0440	Egg plant, raw (i.e. aubergine)	RAC	0.11	1.01	0.11	1.69	0.19	21.37	2.35	3.00	0.33	1.40	0.15	NC	-
VL 2050	Subgroup of Leafy greens	RAC	1.2	18.38	22.06	18.73	22.48	82.36	98.83	25.32	30.38	17.60	21.12	7.37	8.84
VL 0054	Subgroup of Leaves of Brassicaceae, raw	RAC	1.2	0.10	0.12	NC	-	26.78	32.14	5.00	6.00	0.58	0.70	5.68	6.82
VL 2052	Subgroup of Leaves of Root and Tuber Vegetables	RAC	1.2	NC	-	NC	-	NC	-	NC	-	NC	-	0.33	0.40
VL 2053	Subgroup of Leaves of trees, shrubs and vines	RAC	1.2	NC	-	NC	-	NC	-	NC	-	NC	-	0.74	0.89
VL 0507	Kang kung, raw (i.e. Water spinach)	RAC	1.2	NC	-	NC	-	3.42	4.10	NC	-	NC	-	NC	-
VL 0473	Watercress, raw	RAC	1	0.35	0.35	3.13	3.13	0.32	0.32	NC	-	NC	-	2.30	2.30
-	Water parsley, raw	RAC	1.2	NC	-	NC	-	NC	-	1.79	2.15	NC	-	NC	-
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	0.075	1.51	0.11	1.50	0.11	1.90	0.14	5.11	0.38	1.36	0.10	23.43	1.76
VD 0541	Soya bean, dry, raw (incl flour, incl paste, incl curd, incl sauce, excl oil)	RAC	0.011	0.47	0.01	0.77	0.01	9.12	0.10	8.05	0.09	0.04	0.00	6.06	0.07
OR 0541	Soya oil, refined	PP	0.0033	19.06	0.06	21.06	0.07	5.94	0.02	33.78	0.11	40.05	0.13	13.39	0.04
VR 0574	Beetroot, raw	RAC	0.01	9.91	0.10	6.34	0.06	NC	-	9.65	0.10	19.11	0.19	6.47	0.06
VR 0575	Burdock, greater or edible, raw	RAC	0.01	NC	-	NC	-	NC	-	0.48	0.00	NC	-	0.06	0.00
VR 0577	Carrots, raw	RAC	0.01	26.26	0.26	27.13	0.27	10.07	0.10	16.49	0.16	44.69	0.45	8.75	0.09
VR 0578	Celeriac, raw	RAC	0.01	2.97	0.03	1.79	0.02	NC	-	0.06	0.00	16.91	0.17	3.22	0.03
VR 0469	Chicory, roots, raw	RAC	0.01	0.01	0.00	0.51	0.01	0.01	0.00	0.01	0.00	21.12	0.21	NC	-
VR 0583	Horseradish, raw	RAC	0.01	0.01	0.00	0.42	0.00	13.01	0.13	0.26	0.00	2.70	0.03	0.97	0.01
VR 0587	Parsley turnip-rooted, raw	RAC	0.01	NC	-	NC	-	NC	-	NC	-	NC	-	0.61	0.01
VR 0588	Parsnip, raw	RAC	0.01	4.42	0.04	0.06	0.00	NC	-	NC	-	NC	-	1.12	0.01
VR 0494	Radish roots, raw	RAC	0.01	3.83	0.04	11.99	0.12	NC	-	5.26	0.05	2.19	0.02	4.37	0.04
VR 0591	Japanese radish, raw (i.e. Chinese radish, Daikon)	RAC	0.01	NC	-	NC	-	26.64	0.27	18.92	0.19	NC	-	3.59	0.04
VR 0498	Salsify, raw (i.e. Oysterplant)	RAC	0.01	1.02	0.01	0.52	0.01	NC	-	NC	-	2.08	0.02	0.39	0.00

Annex 3

SULFOXAFLOR (252)		International Estimated Daily Intake (IEDI)						ADI = 0 - 0.05 mg/kg bw							
Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day							
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
VR 0596	Sugar beet, raw	RAC	0.014	0.01	0.00	NC	-	0.01	0.00	0.01	0.00	NC	-	NC	-
-	Sugar beet, sugar	PP	0.025	0.01	0.00	NC	-	0.01	0.00	NC	-	NC	-	NC	-
VR 0497	Swede, raw (i.e. Rutabaga)	RAC	0.01	10.01	0.10	1.66	0.02	NC	-	NC	-	3.06	0.03	2.99	0.03
VR 0506	Turnip, garden, raw	RAC	0.01	5.78	0.06	15.35	0.15	NC	-	6.54	0.07	1.95	0.02	4.73	0.05
VR 0573	Arrowroot, raw	RAC	0.01	0.02	0.00	0.01	0.00	2.05	0.02	0.21	0.00	NC	-	0.76	0.01
VR 0463	Cassava raw (incl starch, incl tapioca, incl flour) (i.e. Manioc)	RAC	0.01	0.01	0.00	NC	-	20.96	0.21	0.14	0.00	NC	-	9.62	0.10
VR 0585	Jerusalem artichoke, raw (i.e. Topinambur)	RAC	0.01	0.11	0.00	0.01	0.00	NC	-	0.22	0.00	NC	-	0.78	0.01
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.01	225.03	2.25	234.24	2.34	71.48	0.71	177.55	1.78	234.55	2.35	37.71	0.38
VR 0508	Sweet potato, raw (incl dried)	RAC	0.01	0.93	0.01	0.32	0.00	64.65	0.65	5.37	0.05	0.30	0.00	3.13	0.03
VR 0504	Tannia, raw (i.e. Tania, Yautia)	RAC	0.01	NC	-	NC	-	NC	-	0.01	0.00	NC	-	10.74	0.11
VR 0505	Taro, raw (i.e. Dasheen, Eddoe)	RAC	0.01	NC	-	NC	-	1.93	0.02	0.84	0.01	NC	-	19.94	0.20
VR 0600	Yams, raw (incl dried)	RAC	0.01	NC	-	NC	-	0.03	0.00	0.71	0.01	NC	-	17.57	0.18
VR 2072	Subgroup of Aquatic root and tuber vegetables	RAC	0.01	NC	-	NC	-	3.42	0.03	NC	-	NC	-	NC	-
VS 0624	Celery	RAC	0.19	7.68	1.46	2.85	0.54	NC	-	3.34	0.63	16.83	3.20	4.04	0.77
VS 0621	Asparagus, raw	RAC	0.01	0.84	0.01	2.08	0.02	7.11	0.07	1.01	0.01	1.69	0.02	0.04	0.00
VS 0620	Artichoke globe, raw	RAC	0.245	0.98	0.24	3.65	0.89	0.07	0.02	1.67	0.41	0.26	0.06	NC	-
GC 0653	Triticale, raw (incl flour)	RAC	0.025	0.01	0.00	0.17	0.00	0.29	0.01	0.01	0.00	NC	-	NC	-
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, incl germ, incl wholemeal bread, incl white flour products, incl white bread)	RAC	0.025	253.07	6.33	244.73	6.12	134.44	3.36	235.10	5.88	216.39	5.41	167.40	4.19
GC 0640	Barley, raw (incl malt extract, incl flour & grits, incl malt, excl pot&pearled, excl beer)	RAC	0.063	1.07	0.07	0.21	0.01	0.15	0.01	1.64	0.10	1.58	0.10	3.52	0.22
-	Barley, pot&pearled	PP	0.032	0.57	0.02	2.56	0.08	0.33	0.01	0.56	0.02	0.36	0.01	NC	-
SO 0495	Rape seed, raw	RAC	0.045	NC	-	NC	-	0.01	0.00	NC	-	NC	-	NC	-
OR 0495	Rape seed oil, edible	PP	0.014	12.52	0.18	7.63	0.11	3.00	0.04	6.01	0.08	NC	-	NC	-
SO 0702	Sunflower seed, raw	RAC	0.047	0.01	0.00	1.32	0.06	0.03	0.00	1.17	0.05	NC	-	0.02	0.00
OR 0702	Sunflower seed oil, edible	PP	0.033	9.50	0.31	11.37	0.38	0.49	0.02	5.15	0.17	2.63	0.09	2.80	0.09
OR 0691	Cotton seed oil, edible	PP	0.002	1.68	0.00	0.66	0.00	1.13	0.00	1.18	0.00	0.89	0.00	0.37	0.00
SB 0716	Coffee bean, raw (i.e. green coffee)	RAC	0.035	0.60	0.02	NC	-	0.62	0.02	1.71	0.06	NC	-	3.51	0.12
SM 0716	Coffee bean, roasted	PP	0.0167	7.02	0.12	9.75	0.16	0.02	0.00	5.09	0.09	13.38	0.22	0.77	0.01
-	Coffee bean, instant coffee (incl essences and concentrates)	PP	0.084	0.75	0.06	0.30	0.03	0.04	0.00	0.67	0.06	2.43	0.20	1.43	0.12
HS 0444	Peppers, chili, dried	PP	1.1	0.11	0.12	0.21	0.23	0.36	0.40	0.21	0.23	0.25	0.28	0.15	0.17
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80 % as muscle	RAC	0.045	112.02	5.04	120.71	5.43	63.46	2.86	88.99	4.00	96.24	4.33	41.02	1.85
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20 % as fat	RAC	0.03	28.01	0.84	30.18	0.91	15.86	0.48	22.25	0.67	24.06	0.72	10.25	0.31

Annex 3

SULFOXAFLO (252)				International Estimated Daily Intake (IEDI)				ADI = 0 - 0.05 mg/kg bw																			
Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day																			
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake												
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.03	6.44	0.19	15.51	0.47	3.79	0.11	8.29	0.25	18.44	0.55	8.00	0.24												
MO 0105	Edible offal (mammalian), raw	RAC	0.13	15.17	1.97	5.19	0.67	6.30	0.82	6.78	0.88	3.32	0.43	3.17	0.41												
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.05	388.92	19.45	335.88	16.79	49.15	2.46	331.25	16.56	468.56	23.43	245.45	12.27												
PM 0110	Poultry meat, raw (incl prepared) - 90 % as muscle	RAC	0.015	66.38	1.00	48.47	0.73	21.58	0.32	78.41	1.18	48.04	0.72	76.01	1.14												
PM 0110	Poultry meat, raw (incl prepared) - 10 % as fat	RAC	0.005	7.38	0.04	5.39	0.03	2.40	0.01	8.71	0.04	5.34	0.03	8.45	0.04												
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.005	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.71	0.00	NC	-												
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.046	0.33	0.02	0.72	0.03	0.27	0.01	0.35	0.02	0.80	0.04	NC	-												
PE 0112	Eggs, raw, (incl dried)	RAC	0.013	25.84	0.34	29.53	0.38	28.05	0.36	33.19	0.43	36.44	0.47	8.89	0.12												
Total intake (ug/person)=				102.6				106.8				193.4				123.6				98.1				101.8			
Bodyweight per region (kg bw) =				60				60				55				60				60							
ADI (ug/person)=				3000				3000				2750				3000				3000							
%ADI=				3.4 %				3.6 %				7.0 %				4.1 %				3.3 %				3.4 %			
Rounded %ADI=				3 %				4 %				7 %				4 %				3 %							

SULFOXAFLO (252)				International Estimated Daily Intake (IEDI)				ADI = 0 - 0.05 mg/kg bw							
Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day				Intake = daily intake: ug/person							
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake		
FC 0002	Subgroup of Lemons and limes, raw (incl lemon juice) (incl kumquat commodities)	RAC	0.038	18.97	0.72	0.97	0.04	6.23	0.24	0.09	0.00	3.35	0.13		
FC 0003	Subgroup of Mandarins, raw (incl mandarin juice)	RAC	0.26	0.16	0.04	0.27	0.07	9.06	2.36	0.01	0.00	0.02	0.01		
FC 0004	Subgroup of Oranges, sweet, sour, raw	RAC	0.26	1.18	0.31	1.11	0.29	14.28	3.71	0.05	0.01	1.08	0.28		
JF 0004	Subgroup of Oranges, juice (single strength, incl. concentrated)	PP	0.022	0.08	0.00	0.26	0.01	12.61	0.28	0.14	0.00	0.33	0.01		
FC 0005	Subgroup of Pummelo and grapefruits, raw (incl grapefruit juice)	RAC	0.0125	0.68	0.01	0.05	0.00	3.21	0.04	0.01	0.00	NC	-		
FP 0009	Group of Pome fruits, raw (incl apple cider, excl apple juice)	RAC	0.07	68.85	4.82	10.93	0.77	70.82	4.96	189.78	13.28	19.56	1.37		
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.027	0.03	0.00	0.10	0.00	7.19	0.19	0.03	0.00	NC	-		
FS 0013	Subgroup of Cherries, raw	RAC	0.34	0.01	0.00	0.01	0.00	5.96	2.03	0.01	0.00	NC	-		
FS 0014	Subgroup of Plums, raw (incl dried plums)	RAC	0.038	0.07	0.00	0.02	0.00	16.65	0.63	0.01	0.00	NC	-		
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.061	0.02	0.00	0.01	0.00	10.76	0.66	0.01	0.00	NC	-		
FB 2005	Subgroup of Caneberries, raw	RAC	0.44	0.01	0.00	7.30	3.21	2.29	1.01	0.01	0.00	NC	-		
FB 2006	Subgroup of Bush berries, raw (including processed)	RAC	0.39	0.82	0.32	4.05	1.58	5.94	2.32	0.43	0.17	2.66	1.04		

Annex 3

SULFOXAFLOR (252)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.05 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day		Intake = daily intake: ug/person							
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
FB 0267	Elderberries, raw (incl processed)	RAC	0.39	0.71	0.28	3.52	1.37	NC	-	0.38	0.15	2.32	0.90
FB 0269	Grapes, raw (incl must, incl juice, excl dried, excl wine)	RAC	0.14	0.15	0.02	0.38	0.05	15.84	2.22	0.01	0.00	0.28	0.04
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	0.49	0.01	0.00	0.13	0.06	1.06	0.52	0.01	0.00	0.03	0.01
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.098	0.31	0.03	0.23	0.02	60.43	5.92	0.52	0.05	31.91	3.13
FB 0275	Strawberry, raw	RAC	0.19	0.01	0.00	0.01	0.00	3.35	0.64	0.01	0.00	0.01	0.00
FI 0326	Avocado, raw	RAC	0.011	1.12	0.01	0.01	0.00	0.84	0.01	0.01	0.00	6.60	0.07
FI 0345	Mango, raw (incl canned mango, incl mango juice)	RAC	0.022	12.25	0.27	6.83	0.15	0.76	0.02	0.01	0.00	20.12	0.44
VA 0381	Garlic, raw	RAC	0.01	0.82	0.01	2.06	0.02	3.79	0.04	0.03	0.00	0.29	0.00
-	Onions, dry, raw	RAC	0	9.01	0.00	20.24	0.00	30.90	0.00	9.61	0.00	2.11	0.00
-	Onions, green, raw	RAC	0.11	1.43	0.16	0.05	0.01	0.20	0.02	NC	-	6.30	0.69
VB 0400	Broccoli, raw	RAC	0.074	0.01	0.00	0.01	0.00	2.13	0.16	0.01	0.00	NC	-
VB 0404	Cauliflower, raw	RAC	0.012	0.01	0.00	0.01	0.00	2.73	0.03	0.01	0.00	NC	-
VB 0041	Cabbages, head, raw	RAC	0.099	3.82	0.38	2.99	0.30	49.16	4.87	0.01	0.00	NC	-
VB 0467	Chinese cabbage, type pe-tsai, raw	RAC	1.2	0.62	0.74	0.49	0.59	NC	-	0.01	0.01	NC	-
VC 0045	Group of Fruiting vegetables, cucurbits, raw	RAC	0.029	5.96	0.17	9.74	0.28	51.82	1.50	13.61	0.39	0.05	0.00
VO 0448	Tomato, raw (incl canned, excl juice, excl paste)	RAC	0.11	13.10	1.44	4.90	0.54	62.16	6.84	1.04	0.11	0.09	0.01
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.23	0.58	0.13	0.22	0.05	2.21	0.51	0.24	0.06	3.10	0.71
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.052	0.05	0.00	0.01	0.00	0.42	0.02	0.01	0.00	0.02	0.00
VO 0442	Okra, raw (i.e. Lady's Finger, Gombo)	RAC	0.11	6.23	0.69	0.10	0.01	NC	-	NC	-	NC	-
VO 0444	Peppers, chili, raw	RAC	0.11	3.47	0.38	3.56	0.39	16.30	1.79	0.01	0.00	NC	-
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.11	5.49	0.60	10.57	1.16	8.84	0.97	0.91	0.10	NC	-
VO 0440	Egg plant, raw (i.e. aubergine)	RAC	0.11	1.31	0.14	8.26	0.91	3.95	0.43	0.01	0.00	NC	-
VL 2050	Subgroup of Leafy greens	RAC	1.2	4.99	5.99	3.29	3.95	7.53	9.04	3.05	3.66	6.09	7.31
VL 0054	Subgroup of Leaves of Brassicaceae, raw	RAC	1.2	3.58	4.30	2.64	3.17	NC	-	1.83	2.20	3.65	4.38
VL 2052	Subgroup of Leaves of Root and Tuber Vegetables	RAC	1.2	0.30	0.36	0.22	0.26	NC	-	0.20	0.24	0.41	0.49
VL 2053	Subgroup of Leaves of trees, shrubs and vines	RAC	1.2	0.67	0.80	0.48	0.58	NC	-	0.45	0.54	0.90	1.08
VL 0507	Kang kung, raw (i.e. Water spinach)	RAC	1.2	NC	-	NC	-	NC	-	NC	-	NC	-
VL 0473	Watercress, raw	RAC	1	2.08	2.08	1.50	1.50	0.01	0.01	1.41	1.41	2.81	2.81
-	Water parsley, raw	RAC	1.2	NC	-	NC	-	NC	-	NC	-	NC	-
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	0.075	7.11	0.53	2.33	0.17	3.76	0.28	44.70	3.35	3.27	0.25
VD 0541	Soya bean, dry, raw (incl flour, incl paste, incl curd, incl sauce, excl oil)	RAC	0.011	2.89	0.03	0.21	0.00	0.48	0.01	3.16	0.03	0.26	0.00
OR 0541	Soya oil, refined	PP	0.0033	2.32	0.01	2.54	0.01	18.70	0.06	2.51	0.01	6.29	0.02
VR 0574	Beetroot, raw	RAC	0.01	5.86	0.06	4.23	0.04	9.46	0.09	3.96	0.04	7.91	0.08
VR 0575	Burdock, greater or edible, raw	RAC	0.01	0.06	0.00	0.04	0.00	NC	-	0.04	0.00	0.08	0.00
VR 0577	Carrots, raw	RAC	0.01	2.07	0.02	3.00	0.03	25.29	0.25	0.05	0.00	NC	-
VR 0578	Celeriac, raw	RAC	0.01	2.91	0.03	2.10	0.02	7.59	0.08	1.97	0.02	3.93	0.04

Annex 3

SULFOXAFLOR (252)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.05 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day		Intake = daily intake: ug/person							
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
				VR 0469	Chicory, roots, raw	RAC	0.01	0.01	0.00	0.03	0.00	0.10	0.00
VR 0583	Horseradish, raw	RAC	0.01	0.88	0.01	0.63	0.01	0.54	0.01	0.59	0.01	1.19	0.01
VR 0587	Parsley turnip-rooted, raw	RAC	0.01	0.55	0.01	0.40	0.00	4.29	0.04	0.37	0.00	0.74	0.01
VR 0588	Parsnip, raw	RAC	0.01	1.02	0.01	0.74	0.01	3.50	0.04	0.69	0.01	1.37	0.01
VR 0494	Radish roots, raw	RAC	0.01	3.96	0.04	2.86	0.03	3.30	0.03	2.67	0.03	5.34	0.05
VR 0591	Japanese radish, raw (i.e. Chinese radish, Daikon)	RAC	0.01	3.25	0.03	2.35	0.02	NC	-	2.20	0.02	4.39	0.04
VR 0498	Salsify, raw (i.e. Oysterplant)	RAC	0.01	0.36	0.00	0.26	0.00	NC	-	0.24	0.00	0.48	0.00
VR 0596	Sugar beet, raw	RAC	0.014	0.01	0.00	NC	-	NC	-	NC	-	NC	-
-	Sugar beet, sugar	PP	0.025	0.56	0.01	0.24	0.01	NC	-	NC	-	5.13	0.13
VR 0497	Swede, raw (i.e. Rutabaga)	RAC	0.01	2.71	0.03	1.96	0.02	7.80	0.08	1.83	0.02	3.66	0.04
VR 0506	Turnip, garden, raw	RAC	0.01	4.29	0.04	3.10	0.03	6.41	0.06	2.90	0.03	5.79	0.06
VR 0573	Arrowroot, raw	RAC	0.01	13.83	0.14	18.24	0.18	0.01	0.00	0.05	0.00	19.60	0.20
VR 0463	Cassava raw (incl starch, incl tapioca, incl flour) (i.e. Manioc)	RAC	0.01	91.92	0.92	34.12	0.34	NC	-	259.92	2.60	45.48	0.45
VR 0585	Jerusalem artichoke, raw (i.e. Topinambur)	RAC	0.01	14.22	0.14	18.75	0.19	0.01	0.00	0.06	0.00	20.14	0.20
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.01	23.96	0.24	13.56	0.14	213.41	2.13	104.35	1.04	8.56	0.09
VR 0508	Sweet potato, raw (incl dried)	RAC	0.01	28.83	0.29	61.55	0.62	0.15	0.00	221.94	2.22	NC	-
VR 0504	Tannia, raw (i.e. Tanier, Yautia)	RAC	0.01	NC	-	NC	-	0.01	0.00	NC	-	NC	-
VR 0505	Taro, raw (i.e. Dasheen, Eddoe)	RAC	0.01	6.71	0.07	31.91	0.32	NC	-	10.73	0.11	264.31	2.64
VR 0600	Yams, raw (incl dried)	RAC	0.01	70.93	0.71	30.62	0.31	0.07	0.00	5.65	0.06	30.85	0.31
VR 2072	Subgroup of Aquatic root and tuber vegetables	RAC	0.01	NC	-	NC	-	NC	-	NC	-	NC	-
VS 0624	Celery	RAC	0.19	3.66	0.70	2.65	0.50	4.84	0.92	2.47	0.47	4.94	0.94
VS 0621	Asparagus, raw	RAC	0.01	0.01	0.00	0.01	0.00	0.17	0.00	0.01	0.00	NC	-
VS 0620	Artichoke globe, raw	RAC	0.245	0.01	0.00	NC	-	0.08	0.02	0.01	0.00	NC	-
GC 0653	Triticale, raw (incl flour)	RAC	0.025	0.01	0.00	NC	-	NC	-	NC	-	NC	-
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, incl germ, incl wholemeal bread, incl white flour products, incl white bread)	RAC	0.025	57.20	1.43	110.47	2.76	272.62	6.82	25.82	0.65	132.04	3.30
GC 0640	Barley, raw (incl malt extract, incl flour & grits, incl malt, excl pot&pearled, excl beer)	RAC	0.063	0.10	0.01	0.15	0.01	1.71	0.11	0.02	0.00	6.34	0.40
-	Barley, pot&pearled	PP	0.032	5.46	0.17	0.01	0.00	1.44	0.05	0.01	0.00	NC	-
SO 0495	Rape seed, raw	RAC	0.045	NC	-	0.01	0.00	NC	-	NC	-	NC	-
OR 0495	Rape seed oil, edible	PP	0.014	0.07	0.00	0.03	0.00	4.62	0.06	0.03	0.00	NC	-
SO 0702	Sunflower seed, raw	RAC	0.047	0.02	0.00	0.01	0.00	0.03	0.00	2.23	0.10	NC	-
OR 0702	Sunflower seed oil, edible	PP	0.033	0.37	0.01	0.09	0.00	12.98	0.43	4.01	0.13	0.20	0.01
OR 0691	Cotton seed oil, edible	PP	0.002	1.28	0.00	0.05	0.00	0.45	0.00	0.42	0.00	0.15	0.00
SB 0716	Coffee bean, raw (i.e. green coffee)	RAC	0.035	0.83	0.03	0.69	0.02	1.09	0.04	2.91	0.10	0.82	0.03
SM 0716	Coffee bean, roasted	PP	0.0167	0.02	0.00	0.41	0.01	7.50	0.13	0.01	0.00	0.06	0.00
-	Coffee bean, instant coffee (incl essences and	PP	0.084	0.03	0.00	0.05	0.00	0.60	0.05	0.01	0.00	5.53	0.46

Annex 3

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SULFOXAFLOR (252)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.05 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day		Intake = daily intake: ug/person								
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake	
	concentrates)													
HS 0444	Peppers, chili, dried	PP	1.1	0.58	0.64	1.27	1.40	1.21	1.33	0.12	0.13	NC	-	
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80 % as muscle	RAC	0.045	23.34	1.05	40.71	1.83	97.15	4.37	18.06	0.81	57.71	2.60	
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20 % as fat	RAC	0.03	5.84	0.18	10.18	0.31	24.29	0.73	4.52	0.14	14.43	0.43	
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.03	1.05	0.03	1.14	0.03	18.69	0.56	0.94	0.03	3.12	0.09	
MO 0105	Edible offal (mammalian), raw	RAC	0.13	4.64	0.60	1.97	0.26	10.01	1.30	3.27	0.43	3.98	0.52	
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.05	108.75	5.44	70.31	3.52	436.11	21.81	61.55	3.08	79.09	3.95	
PM 0110	Poultry meat, raw (incl prepared) - 90 % as muscle	RAC	0.015	3.53	0.05	10.83	0.16	51.36	0.77	4.53	0.07	50.00	0.75	
PM 0110	Poultry meat, raw (incl prepared) - 10 % as fat	RAC	0.005	0.39	0.00	1.20	0.01	5.71	0.03	0.50	0.00	5.56	0.03	
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.005	NC	-	NC	-	0.32	0.00	NC	-	NC	-	
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.046	0.10	0.00	0.70	0.03	0.97	0.04	0.10	0.00	NC	-	
PE 0112	Eggs, raw, (incl dried)	RAC	0.013	3.84	0.05	4.41	0.06	27.25	0.35	1.13	0.01	7.39	0.10	
	Total intake (ug/person)=				39.0		34.8		97.1		38.2		43.2	
	Bodyweight per region (kg bw) =						60		60		60		60	
	ADI (ug/person)=						3000		3000		3000		3000	
	%ADI=						1.3 %		1.2 %		3.2 %		1.3 %	
	Rounded %ADI=						1 %		1 %		3 %		1 %	

Annex 3

TETRANILIPROLE (324)

International Estimated Daily Intake (IEDI)

ADI = 0 - 2 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day							
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
				FC 0002	Subgroup of Lemons and limes, raw (incl lemon juice) (incl kumquat commodities)	RAC	0.19	4.82	0.92	2.45	0.47	3.93	0.75	25.44	4.83
FC 0003	Subgroup of Mandarins, raw (incl mandarin juice)	RAC	0.185	6.18	1.14	3.66	0.68	0.25	0.05	6.82	1.26	3.49	0.65	19.38	3.59
FC 0004	Subgroup of Oranges, sweet, sour, raw	RAC	0.015	20.66	0.31	5.23	0.08	11.90	0.18	37.90	0.57	21.16	0.32	56.46	0.85
JF 0004	Subgroup of Oranges, juice (single strength, incl. concentrated)	PP	0.01	1.27	0.01	2.20	0.02	0.09	0.00	11.81	0.12	0.46	0.00	1.69	0.02
FC 0005	Subgroup of Pummelo and grapefruits, raw (incl grapefruit juice)	RAC	0.091	0.66	0.06	0.69	0.06	0.96	0.09	10.20	0.93	1.25	0.11	2.97	0.27
FP 0226	Apple, raw (incl cider, excl juice)	RAC	0.13	13.49	1.75	26.63	3.46	15.05	1.96	16.28	2.12	6.47	0.84	47.88	6.22
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.065	0.32	0.02	3.07	0.20	0.07	0.00	5.00	0.33	0.29	0.02	5.57	0.36
FP 0228	Loquat, raw (incl processed) (i.e. Japanese medlar)	RAC	0.13	0.59	0.08	0.36	0.05	0.46	0.06	1.88	0.24	NC	-	1.15	0.15
FP 0229	Medlar, raw (incl processed)	RAC	0.13	0.47	0.06	0.29	0.04	0.36	0.05	1.49	0.19	NC	-	0.92	0.12
FP 0230	Pear, raw	RAC	0.13	2.16	0.28	6.24	0.81	0.05	0.01	4.07	0.53	1.16	0.15	5.34	0.69
FP 0231	Quince, raw	RAC	0.13	0.73	0.09	0.54	0.07	0.01	0.00	0.07	0.01	0.06	0.01	1.31	0.17
FS 0013	Subgroup of Cherries, raw	RAC	0.29	0.92	0.27	9.15	2.65	0.01	0.00	0.61	0.18	0.06	0.02	6.64	1.93
FS 0014	Subgroup of Plums, raw	RAC	0.033	2.40	0.08	8.60	0.28	0.06	0.00	2.52	0.08	0.58	0.02	4.16	0.14
DF 0014	Plums, dried (prunes)	PP	0.125	0.09	0.01	0.06	0.01	0.01	0.00	0.18	0.02	0.04	0.01	0.06	0.01
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.089	8.01	0.71	5.87	0.52	0.18	0.02	8.19	0.73	1.64	0.15	22.46	2.00
FB 0269	Grapes, raw (i.e. table grapes)	RAC	0.275	12.68	3.49	9.12	2.51	0.03	0.01	16.88	4.64	3.70	1.02	54.42	14.97
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	0.35	0.51	0.18	0.51	0.18	0.01	0.00	1.27	0.44	0.12	0.04	2.07	0.72
JF 0269	Grape juice (from wine grapes)	PP	0.067	0.14	0.01	0.29	0.02	0.05	0.00	0.30	0.02	0.24	0.02	0.05	0.00
-	Graps must (from wine-grapes)	PP	0.16	0.33	0.05	0.13	0.02	0.01	0.00	0.02	0.00	0.01	0.00	0.02	0.00
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.14	0.67	0.09	12.53	1.75	2.01	0.28	1.21	0.17	3.53	0.49	4.01	0.56
VB 0042	Subgroup of Flowerhead Brassica, raw	RAC	0.145	2.54	0.37	0.49	0.07	0.01	0.00	3.57	0.52	7.79	1.13	3.12	0.45
VB 0041	Cabbages, head, raw	RAC	0.012	2.73	0.03	27.92	0.34	0.55	0.01	4.47	0.05	4.27	0.05	10.25	0.12
VO 0448	Tomato, raw (incl juice, incl canned, excl paste)	RAC	0.075	42.41	3.18	76.50	5.74	10.69	0.80	85.07	6.38	24.98	1.87	203.44	15.26
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.39	2.34	0.91	1.33	0.52	1.57	0.61	4.24	1.65	0.34	0.13	2.83	1.10
VO 0444	Peppers, chili, raw	RAC	0.075	3.99	0.30	7.30	0.55	2.93	0.22	5.62	0.42	NC	-	17.44	1.31
VO 0445	Peppers, sweet, raw	RAC	0.075	1.43	0.11	2.61	0.20	1.05	0.08	2.01	0.15	2.59	0.19	6.24	0.47
-	Peppers, sweet, dried	PP	0.75	0.42	0.32	0.53	0.40	0.84	0.63	0.50	0.38	0.95	0.71	0.37	0.28
VO 0440	Egg plant, raw (i.e. aubergine)	RAC	0.075	5.58	0.42	4.31	0.32	0.89	0.07	9.31	0.70	13.64	1.02	20.12	1.51
VL 0054	Subgroup of Leaves of Brassicaceae, raw	RAC	4	2.63	10.52	9.27	37.08	1.86	7.44	5.82	23.28	19.53	78.12	4.90	19.60
VD 0541	Soya bean, dry, raw (incl paste, incl curd, incl	RAC	0.026	72.79	1.89	59.05	1.54	20.55	0.53	74.20	1.93	61.12	1.59	73.24	1.90

Annex 3

TETRANILIPROLE (324)				International Estimated Daily Intake (IEDI)				ADI = 0 - 2 mg/kg bw							
Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day							
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
FC 0002	Subgroup of Lemons and limes, raw (incl lemon juice) (incl kumquat commodities)	RAC	0.19	10.12	1.92	15.69	2.98	2.88	0.55	12.30	2.34	22.32	4.24	6.59	1.25
FC 0003	Subgroup of Mandarins, raw (incl mandarin juice)	RAC	0.185	12.42	2.30	14.99	2.77	16.08	2.97	10.78	1.99	9.94	1.84	NC	-
FC 0004	Subgroup of Oranges, sweet, sour, raw	RAC	0.015	15.68	0.24	24.00	0.36	6.80	0.10	29.09	0.44	15.39	0.23	160.47	2.41
JF 0004	Subgroup of Oranges, juice (single strength, incl. concentrated)	PP	0.01	33.31	0.33	1.78	0.02	0.28	0.00	18.97	0.19	14.01	0.14	13.36	0.13
FC 0005	Subgroup of Pummelo and grapefruits, raw (incl grapefruit juice)	RAC	0.091	8.21	0.75	4.60	0.42	0.64	0.06	5.85	0.53	19.98	1.82	368.86	33.57
FP 0226	Apple, raw (incl cider, excl juice)	RAC	0.13	41.14	5.35	56.49	7.34	26.64	3.46	31.58	4.11	51.94	6.75	3.05	0.40
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.065	14.88	0.97	11.98	0.78	0.15	0.01	9.98	0.65	30.32	1.97	3.47	0.23
FP 0228	Loquat, raw (incl processed) (i.e. Japanese medlar)	RAC	0.13	0.96	0.12	NC	-	NC	-	3.92	0.51	NC	-	2.49	0.32
FP 0229	Medlar, raw (incl processed)	RAC	0.13	NC	-	NC	-	NC	-	NC	-	NC	-	1.98	0.26
FP 0230	Pear, raw	RAC	0.13	8.79	1.14	8.44	1.10	12.37	1.61	9.60	1.25	10.27	1.34	0.23	0.03
FP 0231	Quince, raw	RAC	0.13	0.19	0.02	0.18	0.02	0.11	0.01	0.04	0.01	0.28	0.04	NC	-
FS 0013	Subgroup of Cherries, raw	RAC	0.29	1.40	0.41	4.21	1.22	0.04	0.01	2.93	0.85	1.50	0.44	NC	-
FS 0014	Subgroup of Plums, raw	RAC	0.033	3.75	0.12	3.33	0.11	5.94	0.20	2.64	0.09	2.50	0.08	0.06	0.00
DF 0014	Plums, dried (prunes)	PP	0.125	0.61	0.08	0.35	0.04	0.05	0.01	0.35	0.04	0.49	0.06	0.13	0.02
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.089	13.03	1.16	16.29	1.45	8.29	0.74	12.95	1.15	5.35	0.48	0.04	0.00
FB 0269	Grapes, raw (i.e. table grapes)	RAC	0.275	6.33	1.74	11.22	3.09	5.21	1.43	9.38	2.58	4.55	1.25	0.78	0.21
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	0.35	3.09	1.08	1.51	0.53	0.03	0.01	1.38	0.48	4.26	1.49	0.42	0.15
JF 0269	Grape juice (from wine grapes)	PP	0.067	0.56	0.04	1.96	0.13	0.02	0.00	2.24	0.15	2.27	0.15	0.34	0.02
-	Graps must (from wine-grapes)	PP	0.16	0.16	0.03	0.09	0.01	0.01	0.00	0.12	0.02	0.11	0.02	NC	-
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.14	88.93	12.45	62.41	8.74	1.84	0.26	25.07	3.51	61.17	8.56	5.84	0.82
VB 0042	Subgroup of Flowerhead Brassica, raw	RAC	0.145	9.50	1.38	6.77	0.98	NC	-	3.21	0.47	9.36	1.36	0.75	0.11
VB 0041	Cabbages, head, raw	RAC	0.012	8.97	0.11	27.12	0.33	1.44	0.02	24.96	0.30	4.55	0.05	11.23	0.13
VO 0448	Tomato, raw (incl juice, incl canned, excl paste)	RAC	0.075	44.88	3.37	55.49	4.16	35.44	2.66	75.65	5.67	27.00	2.03	9.61	0.72
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.39	4.96	1.93	3.20	1.25	0.15	0.06	1.61	0.63	6.88	2.68	0.52	0.20
VO 0444	Peppers, chili, raw	RAC	0.075	5.57	0.42	14.00	1.05	8.25	0.62	5.77	0.43	6.44	0.48	2.53	0.19
VO 0445	Peppers, sweet, raw	RAC	0.075	NC	-	NC	-	8.25	0.62	3.03	0.23	NC	-	0.91	0.07
-	Peppers, sweet, dried	PP	0.75	0.11	0.08	0.21	0.16	0.36	0.27	0.21	0.16	0.25	0.19	0.15	0.11
VO 0440	Egg plant, raw (i.e. aubergine)	RAC	0.075	1.01	0.08	1.69	0.13	21.37	1.60	3.00	0.23	1.40	0.11	NC	-
VL 0054	Subgroup of Leaves of Brassicaceae, raw	RAC	4	0.10	0.40	NC	-	26.78	107.12	5.00	20.00	0.58	2.32	5.68	22.72
VD 0541	Soya bean, dry, raw (incl paste, incl curd, incl oil, incl sauce)	RAC	0.026	106.33	2.76	117.78	3.06	42.12	1.10	195.70	5.09	222.52	5.79	80.47	2.09
VR 2071	Subgroup of tuberous and corm vegetables, raw (incl processed)	RAC	0.01	226.09	2.26	234.58	2.35	161.10	1.61	185.04	1.85	234.85	2.35	100.25	1.00

Annex 3

812

TETRANILIPROLE (324)

International Estimated Daily Intake (IEDI)

ADI = 0 - 2 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as ug/person/day																			
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake												
CM 0649 (GC 0649)	Rice, husked, dry (incl polished, incl flour, incl starch, incl oil, incl beverages)	REP	0.01	20.96	0.21	16.04	0.16	339.67	3.40	75.51	0.76	16.86	0.17	86.13	0.86												
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl beer, incl germ, excl flour, excl oil, excl starch)	RAC	0.01	0.10	0.00	9.93	0.10	1.40	0.01	10.26	0.10	0.33	0.00	0.05	0.00												
CF 1255	Maize, flour (white flour and wholemeal flour)	PP	0.012	14.27	0.17	12.86	0.15	19.71	0.24	12.55	0.15	4.21	0.05	52.30	0.63												
-	Maize starch	PP	0.01	NC	-	NC	-	0.19	0.00	7.13	0.07	NC	-	NC	-												
OR 0645	Maize oil	PP	0.01	0.90	0.01	0.47	0.00	0.15	0.00	3.01	0.03	1.86	0.02	0.36	0.00												
GC 2090	Subgroup of Sweet Corns	RAC	0.01	11.43	0.11	3.71	0.04	0.74	0.01	13.63	0.14	3.07	0.03	1.50	0.02												
TN 0085	Group of Tree nuts, raw (incl processed)	RAC	0.01	8.52	0.09	8.94	0.09	15.09	0.15	9.60	0.10	14.57	0.15	26.26	0.26												
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80 % as muscle	RAC	0.047	112.02	5.27	120.71	5.67	63.46	2.98	88.99	4.18	96.24	4.52	41.02	1.93												
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20 % as fat	RAC	0.26	28.01	7.28	30.18	7.85	15.86	4.12	22.25	5.78	24.06	6.26	10.25	2.67												
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.26	6.44	1.67	15.51	4.03	3.79	0.99	8.29	2.16	18.44	4.79	8.00	2.08												
MO 0105	Edible offal (mammalian), raw	RAC	0.42	15.17	6.37	5.19	2.18	6.30	2.65	6.78	2.85	3.32	1.39	3.17	1.33												
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.12	388.92	46.67	335.88	40.31	49.15	5.90	331.25	39.75	468.56	56.23	245.45	29.45												
PM 0110	Poultry meat, raw (incl prepared) - 90 % as muscle	RAC	0.01	66.38	0.66	48.47	0.48	21.58	0.22	78.41	0.78	48.04	0.48	76.01	0.76												
PM 0110	Poultry meat, raw (incl prepared) - 10 % as fat	RAC	0.01	7.38	0.07	5.39	0.05	2.40	0.02	8.71	0.09	5.34	0.05	8.45	0.08												
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.01	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.71	0.01	NC	-												
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.01	0.33	0.00	0.72	0.01	0.27	0.00	0.35	0.00	0.80	0.01	NC	-												
PE 0112	Eggs, raw, (incl dried)	RAC	0.01	25.84	0.26	29.53	0.30	28.05	0.28	33.19	0.33	36.44	0.36	8.89	0.09												
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-												
Total intake (ug/person)=				111.6				105.7				147.9				113.0				122.5				107.2			
Bodyweight per region (kg bw) =				60				60				55				60				60							
ADI (ug/person)=				120000				120000				110000				120000				120000							
%ADI=				0.1 %				0.1 %				0.1 %				0.1 %				0.1 %							
Rounded %ADI=				0 %				0 %				0 %				0 %				0 %							

Annex 3

TETRANILIPROLE (324)

International Estimated Daily Intake (IEDI)

ADI = 0 - 2 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day									
				Intake = daily intake: ug/person									
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
FC 0002	Subgroup of Lemons and limes, raw (incl lemon juice) (incl kumquat commodities)	RAC	0.19	18.97	3.60	0.97	0.18	6.23	1.18	0.09	0.02	3.35	0.64
FC 0003	Subgroup of Mandarins, raw (incl mandarin juice)	RAC	0.185	0.16	0.03	0.27	0.05	9.06	1.68	0.01	0.00	0.02	0.00
FC 0004	Subgroup of Oranges, sweet, sour, raw	RAC	0.015	1.18	0.02	1.11	0.02	14.28	0.21	0.05	0.00	1.08	0.02
JF 0004	Subgroup of Oranges, juice (single strength, incl. concentrated)	PP	0.01	0.08	0.00	0.26	0.00	12.61	0.13	0.14	0.00	0.33	0.00
FC 0005	Subgroup of Pummelo and grapefruits, raw (incl grapefruit juice)	RAC	0.091	0.68	0.06	0.05	0.00	3.21	0.29	0.01	0.00	NC	-
FP 0226	Apple, raw (incl cider, excl juice)	RAC	0.13	66.67	8.67	2.06	0.27	55.83	7.26	188.29	24.48	1.38	0.18
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.065	0.03	0.00	0.10	0.01	7.19	0.47	0.03	0.00	NC	-
FP 0228	Loquat, raw (incl processed) (i.e. Japanese medlar)	RAC	0.13	0.94	0.12	4.68	0.61	NC	-	0.50	0.07	3.08	0.40
FP 0229	Medlar, raw (incl processed)	RAC	0.13	0.75	0.10	3.73	0.48	4.87	0.63	0.40	0.05	2.45	0.32
FP 0230	Pear, raw	RAC	0.13	0.07	0.01	0.14	0.02	9.45	1.23	0.01	0.00	0.14	0.02
FP 0231	Quince, raw	RAC	0.13	NC	-	NC	-	0.65	0.08	NC	-	NC	-
FS 0013	Subgroup of Cherries, raw	RAC	0.29	0.01	0.00	0.01	0.00	5.96	1.73	0.01	0.00	NC	-
FS 0014	Subgroup of Plums, raw	RAC	0.033	0.07	0.00	0.01	0.00	15.56	0.51	0.01	0.00	NC	-
DF 0014	Plums, dried (prunes)	PP	0.125	0.01	0.00	0.01	0.00	0.37	0.05	0.01	0.00	NC	-
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.089	0.02	0.00	0.01	0.00	10.76	0.96	0.01	0.00	NC	-
FB 0269	Grapes, raw (i.e. table grapes)	RAC	0.275	0.14	0.04	0.36	0.10	15.22	4.19	0.01	0.00	0.09	0.02
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	0.35	0.01	0.00	0.13	0.05	1.06	0.37	0.01	0.00	0.03	0.01
JF 0269	Grape juice (from wine grapes)	PP	0.067	0.01	0.00	0.01	0.00	0.41	0.03	0.01	0.00	NC	-
-	Graps must (from wine-grapes)	PP	0.16	0.01	0.00	0.01	0.00	0.11	0.02	0.01	0.00	0.19	0.03
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.14	0.31	0.04	0.23	0.03	60.43	8.46	0.52	0.07	31.91	4.47
VB 0042	Subgroup of Flowerhead Brassica, raw	RAC	0.145	0.02	0.00	0.02	0.00	4.86	0.70	0.01	0.00	NC	-
VB 0041	Cabbages, head, raw	RAC	0.012	3.82	0.05	2.99	0.04	49.16	0.59	0.01	0.00	NC	-
VO 0448	Tomato, raw (incl juice, incl canned, excl paste)	RAC	0.075	13.17	0.99	4.92	0.37	62.69	4.70	1.04	0.08	0.11	0.01
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.39	0.58	0.23	0.22	0.09	2.21	0.86	0.24	0.09	3.10	1.21
VO 0444	Peppers, chili, raw	RAC	0.075	3.47	0.26	3.56	0.27	16.30	1.22	0.01	0.00	NC	-
VO 0445	Peppers, sweet, raw	RAC	0.075	1.24	0.09	1.27	0.10	NC	-	0.01	0.00	NC	-
-	Peppers, sweet, dried	PP	0.75	0.58	0.44	1.27	0.95	1.21	0.91	0.12	0.09	NC	-
VO 0440	Egg plant, raw (i.e. aubergine)	RAC	0.075	1.31	0.10	8.26	0.62	3.95	0.30	0.01	0.00	NC	-
VL 0054	Subgroup of Leaves of Brassicaceae, raw	RAC	4	3.58	14.32	2.64	10.56	NC	-	1.83	7.32	3.65	14.60
VD 0541	Soya bean, dry, raw (incl paste, incl curd, incl oil, incl sauce)	RAC	0.026	15.80	0.41	14.29	0.37	104.36	2.71	17.11	0.44	35.20	0.92
VR 2071	Subgroup of tuberous and corm vegetables, raw (incl processed)	RAC	0.01	250.41	2.50	208.74	2.09	213.64	2.14	602.70	6.03	388.95	3.89

Annex 3

TETRANILIPROLE (324)

International Estimated Daily Intake (IEDI)

ADI = 0 - 2 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day		Intake = daily intake: ug/person							
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
				CM 0649 (GC 0649)	Rice, husked, dry (incl polished, incl flour, incl starch, incl oil, incl beverages)	REP	0.01	52.55	0.53	286.02	2.86	18.64	0.19
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl beer, incl germ, excl flour, excl oil, excl starch)	RAC	0.01	0.55	0.01	0.51	0.01	3.26	0.03	7.96	0.08	NC	-
CF 1255	Maize, flour (white flour and wholemeal flour)	PP	0.012	94.34	1.13	8.09	0.10	28.03	0.34	55.94	0.67	28.07	0.34
-	Maize starch	PP	0.01	0.02	0.00	0.01	0.00	NC	-	NC	-	NC	-
OR 0645	Maize oil	PP	0.01	0.33	0.00	0.07	0.00	0.81	0.01	0.01	0.00	NC	-
GC 2090	Subgroup of Sweet Corns	RAC	0.01	3.63	0.04	20.50	0.21	8.78	0.09	0.02	0.00	0.17	0.00
TN 0085	Group of Tree nuts, raw (incl processed)	RAC	0.01	4.39	0.04	135.53	1.36	6.11	0.06	0.72	0.01	317.74	3.18
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80 % as muscle	RAC	0.047	23.34	1.10	40.71	1.91	97.15	4.57	18.06	0.85	57.71	2.71
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20 % as fat	RAC	0.26	5.84	1.52	10.18	2.65	24.29	6.31	4.52	1.17	14.43	3.75
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.26	1.05	0.27	1.14	0.30	18.69	4.86	0.94	0.24	3.12	0.81
MO 0105	Edible offal (mammalian), raw	RAC	0.42	4.64	1.95	1.97	0.83	10.01	4.20	3.27	1.37	3.98	1.67
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.12	108.75	13.05	70.31	8.44	436.11	52.33	61.55	7.39	79.09	9.49
PM 0110	Poultry meat, raw (incl prepared) - 90 % as muscle	RAC	0.01	3.53	0.04	10.83	0.11	51.36	0.51	4.53	0.05	50.00	0.50
PM 0110	Poultry meat, raw (incl prepared) - 10 % as fat	RAC	0.01	0.39	0.00	1.20	0.01	5.71	0.06	0.50	0.01	5.56	0.06
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.01	NC	-	NC	-	0.32	0.00	NC	-	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.01	0.10	0.00	0.70	0.01	0.97	0.01	0.10	0.00	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0.01	3.84	0.04	4.41	0.04	27.25	0.27	1.13	0.01	7.39	0.07
-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total intake (ug/person)=				51.7		36.0		117.2		50.8		49.9	
Bodyweight per region (kg bw) =				60		60		60		60		60	
ADI (ug/person)=				120000		120000		120000		120000		120000	
%ADI=				0.0 %		0.0 %		0.1 %		0.0 %		0.0 %	
Rounded %ADI=				0 %		0 %		0 %		0 %		0 %	

Annex 3

TRIFLUMURON (317)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.008 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day		Intake as ug/person/day										
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake	
VD 0541	Soya bean, dry, raw (incl flour, incl paste, incl curd, incl sauce, excl oil)	RAC	0.043	0.63	0.03	1.09	0.05	0.40	0.02	1.40	0.06	1.68	0.07	0.48	0.02	
OR 0541	Soya oil, refined	PP	0.0043	12.99	0.06	10.43	0.04	3.63	0.02	13.10	0.06	10.70	0.05	13.10	0.06	
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)	RAC	0.1	31.20	3.12	72.44	7.24	20.88	2.09	47.98	4.80	33.08	3.31	36.25	3.63	
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.1	3.29	0.33	6.14	0.61	0.82	0.08	1.57	0.16	2.23	0.22	1.07	0.11	
MO 0105	Edible offal (mammalian), raw	RAC	0.05	4.79	0.24	9.68	0.48	2.97	0.15	5.49	0.27	3.84	0.19	5.03	0.25	
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0	289.65	0.00	485.88	0.00	26.92	0.00	239.03	0.00	199.91	0.00	180.53	0.00	
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Total intake (ug/person)=						3.8		8.4		2.4		5.3		3.8		4.1
Bodyweight per region (kg bw) =						60		60		60		60		60		60
ADI (ug/person)=						480		480		480		480		480		480
%ADI=						0.8 %		1.8 %		0.5 %		1.1 %		0.8 %		0.8 %
Rounded %ADI=						1 %		2 %		0 %		1 %		1 %		1 %

TRIFLUMURON (317)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.008 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day		Intake as ug/person/day										
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake	
VD 0541	Soya bean, dry, raw (incl flour, incl paste, incl curd, incl sauce, excl oil)	RAC	0.043	0.47	0.02	0.77	0.03	9.12	0.39	8.05	0.35	0.04	0.00	6.06	0.26	
OR 0541	Soya oil, refined	PP	0.0043	19.06	0.08	21.06	0.09	5.94	0.03	33.78	0.15	40.05	0.17	13.39	0.06	
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)	RAC	0.1	140.03	14.00	150.89	15.09	79.32	7.93	111.24	11.12	120.30	12.03	51.27	5.13	
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.1	6.44	0.64	15.51	1.55	3.79	0.38	8.29	0.83	18.44	1.84	8.00	0.80	
MO 0105	Edible offal (mammalian), raw	RAC	0.05	15.17	0.76	5.19	0.26	6.30	0.32	6.78	0.34	3.32	0.17	3.17	0.16	
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0	388.92	0.00	335.88	0.00	49.15	0.00	331.25	0.00	468.56	0.00	245.45	0.00	
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Total intake (ug/person)=						15.5		17.0		9.0		12.8		14.2		6.4
Bodyweight per region (kg bw) =						60		60		55		60		60		60
ADI (ug/person)=						480		480		440		480		480		480
%ADI=						3.2 %		3.5 %		2.1 %		2.7 %		3.0 %		1.3 %
Rounded %ADI=						3 %		4 %		2 %		3 %		3 %		1 %

Annex 3

4-trifluoromethoxyaniline () International Estimated Daily Intake (IEDI) ADI = 0 - 0.02 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day		Intake as ug/person/day									
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
VD 0541	Soya bean, dry, raw (incl flour, incl paste, incl curd, incl sauce, excl oil)	RAC	0.02	0.47	0.01	0.77	0.02	9.12	0.18	8.05	0.16	0.04	0.00	6.06	0.12
OR 0541	Soya oil, refined	PP	0.002	19.06	0.04	21.06	0.04	5.94	0.01	33.78	0.07	40.05	0.08	13.39	0.03
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total intake (ug/person)=					0.0	0.1	0.2	0.2	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Bodyweight per region (kg bw) =					60	60	55	60	60	60	60	60	60	60	60
ADI (ug/person)=					1200	1200	1100	1200	1200	1200	1200	1200	1200	1200	1200
%ADI=					0.0 %	0.0 %	0.0 %	0.0 %	0.0 %	0.0 %	0.0 %	0.0 %	0.0 %	0.0 %	0.0 %
Rounded %ADI=					0 %	0 %	0 %	0 %	0 %	0 %	0 %	0 %	0 %	0 %	0 %

4-trifluoromethoxyaniline () International Estimated Daily Intake (IEDI) ADI = 0 - 0.02 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day		Intake = daily intake: ug/person							
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
VD 0541	Soya bean, dry, raw (incl flour, incl paste, incl curd, incl sauce, excl oil)	RAC	0.02	2.89	0.06	0.21	0.00	0.48	0.01	3.16	0.06	0.26	0.01
OR 0541	Soya oil, refined	PP	0.002	2.32	0.00	2.54	0.01	18.70	0.04	2.51	0.01	6.29	0.01
-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total intake (ug/person)=					0.1	0.0	0.0	0.0	0.1	0.0	0.1	0.0	
Bodyweight per region (kg bw) =					60	60	60	60	60	60	60	60	
ADI (ug/person)=					1200	1200	1200	1200	1200	1200	1200	1200	
%ADI=					0.0 %	0.0 %	0.0 %	0.0 %	0.0 %	0.0 %	0.0 %	0.0 %	
Rounded %ADI=					0 %	0 %	0 %	0 %	0 %	0 %	0 %	0 %	

Annex 4: International Estimate of Short-Term Intakes (international estimate of short-term intakes) of pesticide residues

AFIDOPYROPEN (312)

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

international estimate of short-term intakes

Maximum %ARFD:

2 %
all
1 %
gen pop
2 %
child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	international estimate of short-term intakes µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
FB 0275	Strawberry (all commodities)	highest utilization: Raw with skin	0.0539	0.0778	1.000	NL	toddler, 8-20 m	52	166.73	18	NR	1	0.03 - 1,27	0 % - 0 %	0 % - 0 %	0 % - 0 %
GC 0651	Sorghum grain (Chicken corn, Dari seed, Durra, Feterita) (all commodities)	highest utilization: cooked/boiled	0.0365	0	0.400	CN	Gen pop, > 1 yrs	356	1348.67	<25	NR	3	0.06 - 0.37	0 % - 0 %	0 % - 0 %	0 % - 0 %
MM 0095	Meat from mammals other than marine mammals	Total	NA	NA	1.000	CN	Child, 1-6 yrs	4329	261.46	NR	NR	1	NA	2 %	1 %	2 %
MM 0095	Meat from mammals other than marine mammals: 20 % as fat	Total	0.13	0.15	1.000	CN	Child, 1-6 yrs	4329	52.29	NR	NR	1	0.486	0 %	0 %	0 %
MM 0095	Meat from mammals other than marine mammals: 80 % as muscle	Total	0.21	0.34	1.000	CN	Child, 1-6 yrs	4329	209.17	NR	NR	1	4.407	1 %	1 %	1 %
MF 0100	Mammalian fats (except milk fats)	Total	0.13	0.15	1.000	PRIMO-UK	infant	P97.5	18.10	NR	NR	1	0.312	0 %	0 %	0 %
MO 0105	Edible offal (mammalian)	Total	0.25	0.45	1.000	ZA	Gen pop, > 10 yrs	-	523.58	NR	NR	1	4.230	1 %	1 %	1 %
ML 0106	Milks	Total	0.024		1.000	PRIMO-UK	infant	P97.5	1080.70	NR	NR	3	2.981	1 %	0 %	1 %
PM 0110	Poultry meat	Total	NA	NA	1.000	CN	Child, 1-6 yrs	175	347.00	NR	NR	1	NA	1 %	1 %	1 %
PM 0110	Poultry meat: 10 % as fat	Total	0.13	0.134	1.000	CN	Child, 1-6 yrs	175	34.70	NR	NR	1	0.288	0 %	0 %	0 %
PM 0110	Poultry meat: 90 % as muscle	Total	0.13	0.134	1.000	CN	Child, 1-6 yrs	175	312.30	NR	NR	1	2.594	1 %	0 %	1 %

AFIDOPYROPEN (312)

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

international estimate of short-term intakes

Maximum %ARfD:

2 %
all
1 %
gen pop
2 %
child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	international estimate of short-term intakes µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
PF 0111	Poultry, fats	Total	0.138	0.16	1.000	CA	Child, <6 yrs	66	49.38	NR	NR	1	0.464	0 %	0 %	0 %
PO 0111	Poultry, edible offal (includes kidney and liver)	Total	0.156	0.22	1.000	CN	Gen pop, > 1 yrs	421	345.63	NR	NR	1	1.429	0 %	0 %	0 %
PE 0112	Eggs	Total	0.138	0.149	1.000	PRIMO-UK	infant	P97.5	108.00	NR	NR	1	1.850	1 %	0 %	1 %

AFIDOPYROPEN (312) Women of childbearing age

Acute RfD= 0.2 mg/kg bw (200 µg/kg bw)

international estimate of short-term intakes

Maximum %ARfD:

1 %
women

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	international estimate of short-term intakes µg/kg bw/day	% acute RfD rounded
FB 0275	Strawberry (all commodities)	highest utilization: juice (pasteurised)	0.0539	0.0778	1.000	BR	Gen pop, > 10 yrs	279	871.50	NR	NR	3	0.01 - 0.73	0 % - 0 %
GC 0651	Sorghum grain (Chicken corn, Dari seed, Durra, Feterita) (all commodities)	highest utilization: cooked/boiled	0.0365	0	0.400	CN	Gen pop, > 1 yrs	356	1348.67	<25	NR	3	0.01 - 0.37	0 % - 0 %
MM 0095	Meat from mammals other than marine mammals	Total	NA	NA	1.000	AU	gen pop, > 2 yrs	16	496.39	NR	NR	1	NA	1 %
MM 0095	Meat from mammals other than marine	Total	0.13	0.15	1.000	AU	gen pop, > 2 yrs	16	99.28	NR	NR	1	0.222	0 %

Annex 4

AFIDOPYROPEN (312) Women of childbearing age

international estimate of short-term intakes

Acute RfD= 0.2 mg/kg bw (200 µg/kg bw)

Maximum %ARfD:

1 %

women

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	international estimate of short-term intakes µg/kg bw/day	% acute RfD rounded	
	mammals: 20 % as fat														
MM 0095	Meat from mammals other than marine mammals: 80 % as muscle	Total	0.21	0.34	1.000	AU	gen pop, > 2 yrs	16	397.11		NR	NR	1	2.015	1 %
MF 0100	Mammalian fats (except milk fats)	Total	0.13	0.15	1.000	US	women, 13-49 yrs	6730	45.60		NR	NR	1	0.093	0 %
MO 0105	Edible offal (mammalian)	Total	0.25	0.45	1.000	PRIMO-DE	women, 14-50 yrs	P100	188.92		NR	NR	1	1.260	1 %
ML 0106	Milks	Total	0.024		1.000	AU	gen pop, > 2 yrs	13566	3235.19		NR	NR	3	1.159	1 %
PM 0110	Poultry meat	Total	NA	NA	1.000	PRIMO-UK	vegetarian	P97.5	783.50		NR	NR	1	NA	1 %
PM 0110	Poultry meat: 10 % as fat	Total	0.13	0.134	1.000	PRIMO-UK	vegetarian	P97.5	78.35		NR	NR	1	0.157	0 %
PM 0110	Poultry meat: 90 % as muscle	Total	0.13	0.134	1.000	PRIMO-UK	vegetarian	P97.5	705.15		NR	NR	1	1.417	1 %
PF 0111	Poultry, fats	Total	0.138	0.16	1.000	CA	women, 15-49 yrs	195	78.63		NR	NR	1	0.191	0 %
PO 0111	Poultry, edible offal (includes kidney and liver)	Total	0.156	0.22	1.000	CN	gen pop, > 1 yrs	421	345.63		NR	NR	1	1.429	1 %
PE 0112	Eggs	Total	0.138	0.149	1.000	CN	gen pop, > 1 yrs	454	339.57		NR	NR	1	0.951	0 %

BENZOVINDIFLUPYR (261)

Acute RfD= 0.1 mg/kg bw (100 µg/kg bw)

international estimate of short-term intakes

Maximum %ARfD:

10 % 9 % 10 %
all gen pop child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	international estimate of short-term intakes µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
FB 0020	Blueberries (all commodities)	highest utilization: Total	0.65	0.98	1.00	CA	Child, <6 yrs	189	176.21	<25	NR	1	0.09 - 11.22	0 % - 10 %	0 % - 9 %	0 % - 10 %
GC 0645	Maize (corn) (all commodities)	highest utilization: flakes	0.01	0	1.00	CA	Child, <6 yrs	190	539.23	NR	NR	3	0 - 0.34	0 % - 0 %	0 % - 0 %	0 % - 0 %
DT 9999	Ginseng root, dried	Total		0.16	1.00	PRIMO-EFSA	adults	E	36.00	<25	NR	1	0.096	0 %	0 %	0 %

BIFENTHRIN (178)

Acute RfD= 0.01 mg/kg bw (10 µg/kg bw)

international estimate of short-term intakes

Maximum %ARfD:

310 % 100 % 310 %
all gen pop child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	international estimate of short-term intakes µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
FP 0226	Apple	Total		0.45	1.000	AU	Child, 2-6 yrs	1997	668.41	153	3	2a	23.065	230 %	100 %	230 %
FP 0226	Apple	raw with peel (incl consumption without peel)		0.45	1.000	CN	Child, 1-6 yrs	1314	403.39	255	3	2a	25.473	250 %	100 %	250 %

Annex 4

BIFENTHRIN (178)

Acute RfD= 0.01 mg/kg bw (10 µg/kg bw)

international estimate of short-term intakes
Maximum %ARfD:

310 % 100 % 310 %
all gen pop child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	international estimate of short-term intakes µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
FP 0226	Apple (all other commodities)	highest utilization: canned babyfood	0.0096 - 0.195	0.45	1.000	NL	toddler, 8-20 m	390	348.40	NR	NR	3	0.52 - 6.66	5 - 70 %	3 - 40 %	5 - 70 %
FP 2220	Azarole (Mediterranean medlar) (all commodities)	highest utilization: juice (pasteurised)	0.195	0.45	1.000	PRIMO-DE	child	P97.5	89.63	NR	NR	3	0.41 - 1.08	4 % - 10 %	0 % - 0 %	4 % - 10 %
FP 0227	Crab-apple (all commodities)	highest utilization: Total	0	0.45	1.000	PRIMO-NL	toddler	P97.5	209.40	<25	NR	1	4.13 - 9.24	40 % - 90 %	40 % - 50 %	90 % - 90 %
FP 0228	Loquat (Japanese medlar) (all commodities)	highest utilization: raw without peel	0	0.45	1.000	JP	Gen pop, > 1 yrs	113	326.40	49	3	2a	0.8 - 3.52	8 % - 40 %	8 % - 40 %	0 % - 0 %
FP 0229	Medlar (all commodities)	highest utilization: Total	0	0.45	1.000	PRIMO-ES	child	P97.5	116.99	60	3	2a	3.09 - 3.09	30 % - 30 %	20 % - 20 %	30 % - 30 %
FP 0230	Pear	Total		0.45	1.000	CA	Child, <6 yrs	175	498.28	255	3	2a	31.169	310 %	80 %	310 %
FP 0230	Pear	raw with peel (incl consumption without peel)		0.45	1.000	CN	Child, 1-6 yrs	413	418.33	255	3	2a	25.890	260 %	100 %	260 %
FP 0230	Pear (all other commodities)	highest utilization: canned/preserved	0.195	0.45	1.000	NL	Child, 2-6 yrs	E	138.50	48	3	2a	0.05 - 6.35	1 - 60 %	0 - 40 %	1 - 60 %
FP 0231	Quince (all commodities)	highest utilization: Total	0.195	0.45	1.000	PRIMO-ES	child	P97.5	169.60	301	3	2b	0 - 6.64	0 % - 70 %	0 % - 40 %	0 % - 70 %
FS 0240	Apricot	Total		0.49	1.000	PRIMO-DE	child	P95	264.86	50	3	2a	11.070	110 %	30 %	110 %
FS 0240	Apricot (all other commodities)	highest utilization: raw with peel (incl consumption without peel)	0.22	0.49	1.000	AU	Gen pop, > 2 yrs	77	1056.90	55	3	2a	0.09 - 8.53	1 - 90 %	1 - 90 %	1 - 90 %
FS 2237	Japanese apricot (ume)	Total		0.49	1.000	JP	Child, 1-6 yrs	25	25.50	<25	NR	1	0.690	7 %	3 %	7 %

Annex 4

BIFENTHRIN (178)

Acute RfD= 0.01 mg/kg bw (10 µg/kg bw)

international estimate of short-term intakes
Maximum %ARfD:

310 % 100 % 310 %
all gen pop child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	international estimate of short-term intakes µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
FS 0245	Nectarine	Total		0.49	1.000	CA	Child, <6 yrs	37	353.22	128	3	2a	18.309	180 %	60 %	180 %
FS 0245	Nectarine	raw with peel (incl consumption without peel)		0.49	1.000	NL	toddler, 8-20 m	6	183.60	131	3	2a	21.401	210 %	60 %	210 %
FS 0245	Nectarine (all other commodities)	highest utilization: canned/preserved	0.22	0.49	1.000	NL	Child, 2-6 yrs	E	118.50	60	3	2a	0.09 - 6.35	1 - 60 %	0 - 20 %	1 - 60 %
FS 0247	Peach	Total		0.49	1.000	PRIMO-NL	toddler	P100	183.60	131	3	2a	21.401	210 %	100 %	210 %
FS 0247	Peach	raw with peel (incl consumption without peel)		0.49	1.000	JP	Child, 1-6 yrs	76	306.00	255	3	2a	25.796	260 %	70 %	260 %
FS 0247	Peach (all other commodities)	highest utilization: canned/preserved	0.22	0.49	1.000	PRIMO-NL	child	E	118.50	60	3	2a	0.09 - 6.35	1 - 60 %	0 - 20 %	1 - 60 %
FI 0326	Avocado (all commodities)	highest utilization: Total	0	0.23	1.000	AU	Child, 2-6 yrs	182	229.90	171	3	2a	3.54 - 6.93	40 % - 70 %	30 % - 40 %	30 % - 70 %
FI 0355	Pomegranate (Granate apple) (all commodities)	highest utilization: Total	0.165	0.22	1.000	PRIMO-NL	child	E	144.70	158	3	2b	0.45 - 5.19	4 % - 50 %	30 % - 40 %	4 % - 50 %
VO 0444	Peppers, chili (all commodities)	highest utilization: raw with skin	0.12	0.31	1.000	CN	Gen pop, > 1 yrs	1743	295.71	43	3	2a	0 - 2.23	0 % - 20 %	0 % - 20 %	0 % - 2 %
VO 0445	Peppers, sweet (incl. pimiento) (Bell pepper, Paprika) (all other commodities)	highest utilization: Total	0.12	0.31	1.000	PRIMO-DE	child	P97.5	137.28	155	3	2b	0.02 - 7.91	1 - 80 %	1 - 20 %	1 - 80 %
VO 0445	Peppers, sweet (incl. pimiento) (Bell pepper, Paprika)	raw with skin		0.31	1.000	CN	Child, 1-6 yrs	1002	169.85	170	3	2b	9.789	100 %	40 %	100 %
VO 0440	Egg plant (Aubergine)	highest utilization:	0.12	0.31	1.000	AU	Child, 2-6	29	128.25	318	3	2b	0.14 - 6.28	1 - 60 %	1 - 50 %	1 - 60 %

Annex 4

BIFENTHRIN (178)

Acute RfD= 0.01 mg/kg bw (10 µg/kg bw)

international estimate of short-term intakes
Maximum %ARfD:

310 % 100 % 310 %
all gen pop child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	international estimate of short-term intakes µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
	(all other commodities)	Total					yrs									
VO 0440	Egg plant (Aubergine)	raw with skin		0.31	1.000	CN	Child, 1-6 yrs	969	253.44	444	3	2b	14.607	150 %	80 %	150 %
SO 0697	Peanut, shelled (groundnut) (all commodities)	highest utilization: raw incl roasted	0.05	0.05	1.000	CN	Child, 1-6 yrs	290	163.07	<25	NR	3	0.03 - 0.51	0 % - 5 %	0 % - 3 %	0 % - 5 %

Annex 4

CHLORMEQUAT (015)

Acute RfD= 0.0388 mg/kg bw (39 µg/kg bw)

international estimate of short-term intakes
Maximum %ARfD:

60 % 30 % 60 %
all gen pop child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	international estimate of short-term intakes µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded	
GC 0654	Wheat (all commodities)	highest utilization: flakes	0.16 - 4.3	0	0.800	CA	Child, <6 yrs	1909	539.23		NR	NR	3	1.24 - 23.46	3 % - 60 %	0 % - 30 %	3 % - 60 %
GC 0640	Barley (all commodities)	highest utilization: flakes	0.066 - 0.37	0	0.800	CA	Child, <6 yrs	1909	539.23		NR	NR	3	0.03 - 10.15	0 % - 30 %	0 % - 10 %	0 % - 30 %
MM 0095	Meat from mammals other than marine mammals: 20 % as fat	Total	0.085		1.000	CN	Child, 1-6 yrs	302	52.97		NR	NR	1	ND	-	-	-
MM 0095	Meat from mammals other than marine mammals: 80 % as muscle	Total	0.043		1.000	CN	Child, 1-6 yrs	302	211.87		NR	NR	1	ND	-	-	-
MF 0100	Mammalian fats (except milk fats)	Total	0.043		1.000	PRIMO-FR	adult	P97.5	134.79		NR	NR	1	ND	-	-	-
MO 0105	Edible offal (mammalian)	Total	0.4		1.000	ZA	Gen pop, > 10 yrs	-	523.58		NR	NR	1	ND	-	-	-
ML 0106	Milks	Total	0.069		1.000	PRIMO-UK	infant	P97.5	1080.70		NR	NR	3	8.571	20 %	9 %	20 %
PM 0110	Poultry meat: 10 % as fat	Total	0.04		1.000	CN	Child, 1-6 yrs	175	34.70		NR	NR	1	ND	-	-	-
PM 0110	Poultry meat: 90 % as muscle	Total	0.04		1.000	CN	Child, 1-6 yrs	175	312.30		NR	NR	1	ND	-	-	-
PF 0111	Poultry, fats	Total	0.04		1.000	CA	Child, <6 yrs	66	49.38		NR	NR	1	ND	-	-	-
PO 0111	Poultry, edible offal (includes kidney, liver and skin)	Total	0.085		1.000	CN	Gen pop, > 1 yrs	421	345.63		NR	NR	1	ND	-	-	-
PE 0112	Eggs	Total	0.094		1.000	PRIMO-UK	infant	P97.5	108.00		NR	NR	1	ND	-	-	-

Annex 4

DIFENOCONAZOLE (224)

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

international estimate of short-term intakes

Maximum %ARfD:

3 % 0 % 3 %
all gen pop child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	international estimate of short-term intakes µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
VO 2704	Goji berry (all commodities)	highest utilization: Dried	1.6	2.4 - 5.5	1.000	AU	Child, 2-6 yrs	1	28.36	<25	NR	1	2.29 - 8.21	1 % - 3 %	0 % - 0 %	1 % - 3 %
VR 0600	Yams (all commodities)	highest utilization: Total	0	0.01	1.000	PRIMO-UK	adult	P97.5	693.70	365	3	2a	0.07 - 0.19	0 % - 0 %	0 % - 0 %	0 % - 0 %
HS 0784	Ginger, rhizome (all commodities)	highest utilization: Total	0.022 - 0.13	0.1	1.000	CN	Gen pop, > 1 yrs	1652	231.42	208	3	2a	0 - 1.22	0 % - 0 %	0 % - 0 %	0 % - 0 %

DIMETHOATE (027)

Acute RfD= 0.02 mg/kg bw (20 µg/kg bw)

international estimate of short-term intakes

Maximum %ARfD:

120 % 70 % 120 %
all gen pop child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	international estimate of short-term intakes µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
FC 0003	Subgroup of Mandarins (incl mandarin-like hybrids) (all commodities)	highest utilization: raw, without peel	0.16	0.19	1.000	CN	Child, 1-6 yrs	151	586.75	124	3	2a	0.03 - 9.84	0 % - 50 %	0 % - 20 %	0 % - 50 %
FC 0004	Subgroup of Oranges, sweet, sour (incl orange-like hybrids)	Total		0.4	1.000	AU	Child, 2-6 yrs	1735	800.83	156	3	2a	23.420	120 %	70 %	120 %
FC 0004	Subgroup of Oranges, sweet, sour (incl	highest utilization: raw, without peel	0.093 - 0.32	0.4	1.000	DE	Child, 2-4 yrs	92	238.40	121	3	2a	0.21 - 11.91	1 - 60 %	0 - 30 %	1 - 60 %

Annex 4

DIMETHOATE (027)

Acute RfD= 0.02 mg/kg bw (20 µg/kg bw)

international estimate of short-term intakes

Maximum %ARfD:

120 % 70 % 120 %
all gen pop child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	international estimate of short-term intakes µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
	orange-like hybrids) (all other commodities)															
FI 0326	Avocado (all commodities)	highest utilization: Total	0	0.49	1.000	AU	Child, 2-6 yrs	182	229.90	171	3	2a	7.55 - 14.77	40 % - 70 %	30 % - 40 %	40 % - 70 %
VB 0402	Brussels sprouts (all commodities)	highest utilization: cooked/boiled	0.23	0.25	1.000	PRIMO-NL	toddler	P90	103.80	<25	NR	1	0.01 - 2.54	0 % - 10 %	0 % - 9 %	0 % - 10 %
VO 0448	Tomato (all commodities)	highest utilization: raw with peel	0.055	0.055	1.000	CN	Child, 1-6 yrs	1117	263.76	175	3	2a	0.29 - 2.09	1 % - 10 %	1 % - 4 %	1 % - 10 %
VP 0061	Beans with pods (Phaseolus spp): (immature pods + succulent seeds) (all commodities)	highest utilization: Total	0.55	0.55	1.000	CA	Child, <6 yrs	261	203.31	<25	NR	1	0.83 - 7.43	4 % - 40 %	2 % - 20 %	4 % - 40 %
VD 0071	Beans (dry) (Phaseolus spp) (all commodities)	highest utilization: Total	0.55	0	1.000	PRIMO-UK	infant	P97.5	159.00	<25	NR	3	1.09 - 10.05	5 % - 50 %	1 % - 30 %	2 % - 50 %
VD 0523	Broad bean (dry) (Vicia spp) (all commodities)	highest utilization: Total	0.55	0	1.000	PRIMO-UK	infant	P97.5	159.00	<25	NR	3	0.37 - 10.05	2 % - 50 %	1 % - 20 %	2 % - 50 %
VD 0531	Lablab bean (dry) (Lablab spp) (all commodities)	highest utilization: Total	0.55	0	1.000	PRIMO-UK	infant	P97.5	159.00	<25	NR	3	4.02 - 10.05	20 % - 50 %	20 % - 20 %	50 % - 50 %
GC 0654	Wheat (all commodities)	highest utilization: flour (cereals)	0.016 - 0.14	0	1.000	CN	Child, 1-6 yrs	3556	415.87	NR	NR	3	0.04 - 3.61	0 % - 20 %	0 % - 10 %	0 % - 20 %
SO 0495	Rape seed (Canola) (all commodities)	highest utilization: Oil (refined)	0.23	0	1.000	CA	Child, <6 yrs	1127	26.46	NR	NR	3	0.2 - 0.38	1 % - 2 %	0 % - 1 %	1 % - 2 %
HS 3382	Orange, peel	Oil (refined)	0.12		1.000	NL	Gen pop, > 1 yrs	0	NC	NR	NR	3	NC	NC	NC	NC
MM 0095	Meat from mammals other than marine mammals	Total	NA	NA	1.000	CN	Child, 1-6 yrs	4329	261.46	NR	NR	1	NA	3 %	2 %	3 %

DIMETHOATE (027)

Acute RfD= 0.02 mg/kg bw (20 µg/kg bw)

international estimate of short-term intakes
Maximum %ARfD:

120 % 70 % 120 %
all gen pop child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	international estimate of short-term intakes µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded	
MM 0095	Meat from mammals other than marine mammals: 20 % as fat	Total		0.047	1.000	CN	Child, 1-6 yrs	4329	52.29		NR	NR	1	0.152	1 %	1 %	1 %
MM 0095	Meat from mammals other than marine mammals: 80 % as muscle	Total		0.03	1.000	CN	Child, 1-6 yrs	4329	209.17		NR	NR	1	0.389	2 %	1 %	2 %
MF 0100	Mammalian fats (except milk fats)	Total		0.047	1.000	PRIMO-UK	infant	P97.5	18.10		NR	NR	1	0.098	0 %	0 %	0 %
MO 0105	Edible offal (mammalian)	Total		0.031	1.000	ZA	Gen pop, > 10 yrs	-	523.58		NR	NR	1	0.291	1 %	1 %	1 %
ML 0106	Milks	Total	0.01		1.000	PRIMO-UK	infant	P97.5	1080.70		NR	NR	3	1.242	6 %	2 %	6 %

EMAMECTIN BENZOATE (247)

Acute RfD= 0.02 mg/kg bw (20 µg/kg bw)

international estimate of short-term intakes
Maximum %ARfD:

70 % 60 % 70 %
all gen pop child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	international estimate of short-term intakes µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded	
VA 2605	Chives (all commodities)	highest utilization: Total	0.001	0.006	1.000	PRIMO-CZ	Child, child, 7-10 yrs	P97.5	26.49	<25		NR	1	0 - 0	0 % - 0 %	0 % - 0 %	0 % - 0 %
VB 0400	Broccoli (all commodities)	highest utilization: cooked/boiled	0.002	0.004	1.000	PRIMO-NL	toddler	P97.5	160.70	286		3	2b	0 - 0.19	0 % - 1 %	0 % - 0 %	0 % - 1 %
VB 0404	Cauliflower (all commodities)	highest utilization: cooked/boiled	0.002	0.004	1.000	PRIMO-NL	toddler	P97.5	142.00	749		3	2b	0 - 0.17	0 % - 1 %	0 % - 0 %	0 % - 1 %

Annex 4

EMAMECTIN BENZOATE (247)

Acute RfD= 0.02 mg/kg bw (20 µg/kg bw)

international estimate of short-term intakes
Maximum %ARfD:

70 % all
60 % gen pop
70 % child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	international estimate of short-term intakes µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
VL 0502	Spinach (all commodities)	highest utilization: Total	0.006	0.036	1.000	PRIMO-BE	toddler	P97.5	402.30	<25	NR	1	0 - 0.81	0 % - 4 %	0 % - 3 %	0 % - 4 %
013B	Brassica leafy vegetables	-	0.01	0.219	-	-	-	-	-	-	-	-	-	-	-	-
VL 0401	Broccoli, Chinese (i.e. kailan) (all commodities)	highest utilization: raw	0	0.219	1.000	CN	Child, 1-6 yrs	334	222.48	311	3	2b	5.47 - 9.06	30 % - 50 %	20 % - 20 %	30 % - 50 %
VL 0466	Chinese cabbage (type Pak-choi) (i.e. celery mustard) (all commodities)	highest utilization: raw	0.01	0.219	1.000	CN	Child, 1-6 yrs	1966	327.07	1548	3	2b	0 - 13.32	0 % - 70 %	0 % - 40 %	0 % - 70 %
VL 0472	Cress, Garden (all commodities)	highest utilization: raw	0	0.219	1.000	CN	Gen pop, > 1 yrs	1443	352.50	<25	NR	1	0.08 - 1.45	0 % - 7 %	0 % - 7 %	0 % - 0 %
VL 0468	Flowering white cabbage (Choisum) (all commodities)	highest utilization: Total	0.01	0.219	1.000	PRIMO-BE	toddler	P97.5	148.10	186	3	2b	0.03 - 5.47	0 % - 30 %	0 % - 20 %	30 % - 30 %
VL 0480	Kale (Borecole, Collards) (all commodities)	highest utilization: Total	0.01	0.219	1.000	PRIMO-DE	child	P100	142.12	672	3	2b	0.02 - 5.78	0 % - 30 %	0 % - 20 %	0 % - 30 %
VL 0481	Komatsuna	Total		0.219	1.000	PRIMO-BE	toddler	P100	114.40	<25	NR	1	1.408	7 %	6 %	7 %
VL 2781	Mizuna	Total		2.19	1.000	PRIMO-BE	toddler	P100	114.40	<25	NR	1	14.075	70 %	60 %	70 %
VL 0485	Mustard greens (Indian mustard, Amsoi, mustard cabbage, red mustards) (all commodities)	highest utilization: raw	0.01	0.219	1.000	CN	Child, 1-6 yrs	635	299.31	245	3	2a	0.04 - 10.71	0 % - 50 %	0 % - 20 %	20 % - 50 %
VL 0494	Radish leaves	Total		0.219	1.000	PRIMO-DE	child	P100	142.12	<25	NR	1	1.927	10 %	4 %	10 %
VL	Rape greens	highest utilization:	0	0.219	1.000	PRIMO-	child	P100	142.12	<25	NR	1	0.85 - 1.93	4 % -	4 % -	6 % -

Annex 4

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EMAMECTIN BENZOATE (247)

Acute RfD= 0.02 mg/kg bw (20 µg/kg bw)

international estimate of short-term intakes
Maximum %ARfD:70 %
all
60 %
gen pop
70 %
child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	international estimate of short-term intakes µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded	
0495	(all commodities)	Total				DE								10 %	4 %	10 %	
VL 0496	Rucola (Arrugula, Rocket salad, Roquette, Roman rocket) (all commodities)	highest utilization: Total	0	0.219	1.000	PRIMO-DE	child	P100	43.44	<25		NR	1	0.26 - 0.59	1 % - 3 %	1 % - 8 %	3 % - 3 %
VL 0506	Turnip greens (Namenia, Tendergreen) (all commodities)	highest utilization: Total	0	0.219	1.000	PRIMO-BE	toddler	P100	114.40	35		3	2a	0.36 - 2.27	2 % - 10 %	1 % - 7 %	2 % - 10 %
VD 0541	Soya bean (dry) (Glycine spp) (all commodities)	highest utilization: Total	0	0	1.000	CN	Child, 1-6 yrs	179	239.05	<25		NR	3	0 - 0	0 % - 0 %	0 % - 0 %	0 % - 0 %
HH 0722	Basil, leaves (all commodities)	highest utilization: Total	0.0045 - 0.029	0.032 - 0.205	1.000	AU	Child, 2-16 yrs	143	44.19	<25		NR	1	0 - 0.04	0 % - 0 %	0 % - 0 %	0 % - 0 %
DT 1114	Tea, green, black (black, fermented and dried) (all commodities)	highest utilization: Total	0.000018 - 0.009	0	1.000	PRIMO-IE	child	P97.5	30.60	<25		NR	3	0 - 0.01	0 % - 0 %	0 % - 0 %	0 % - 0 %
MM 0095	Meat from mammals other than marine mammals: 20 % as fat	Total		0.012	1.000	CN	Child, 1-6 yrs	4329	52.29	NR		NR	1	0.039	0 %	0 %	0 %
MM 0095	Meat from mammals other than marine mammals: 80 % as muscle	Total		0.0046	1.000	CN	Child, 1-6 yrs	4329	209.17	NR		NR	1	0.060	0 %	0 %	0 %
MF 0100	Mammalian fats (except milk fats)	Total		0.012	1.000	PRIMO-UK	infant	P97.5	18.10	NR		NR	1	0.025	0 %	0 %	0 %
MO 0105	Edible offal (mammalian)	Total		0.088	1.000	ZA	Gen pop, > 10 yrs	-	523.58	NR		NR	1	0.827	4 %	4 %	4 %
ML	Milks	Total	0.0005		1.000	PRIMO-	infant	P97.5	1080.70	NR		NR	3	0.062	0 %	0 %	0 %

Annex 4

EMAMECTIN BENZOATE (247)

Acute RfD= 0.02 mg/kg bw (20 µg/kg bw)

international estimate of short-term intakes

Maximum %ARfD:

70 % all
60 % gen pop
70 % child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	international estimate of short-term intakes µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
0106						UK										
WD 0120	Diadromous fish	Total		0.1	1.000	AU	Child, 2-6 yrs	53	208.25	NR	NR	1	1.096	5 %	4 %	5 %

FAMOXADONE (208)

Acute RfD= 0.6 mg/kg bw (600 µg/kg bw)

international estimate of short-term intakes

Maximum %ARfD:

20 % all
9 % gen pop
20 % child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	international estimate of short-term intakes µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
FB 0264	Blackberries (all commodities)	highest utilization: Total	1.1	6.6	1.000	PRIMO-UK	toddler	P97.5	155.40	<25	NR	1	0.19 - 70.73	0 % - 10 %	0 % - 9 %	0 % - 10 %
FB 0266	Dewberries (incl Boysenberry, Loganberry) (all commodities)	highest utilization: Total	0	6.6	1.000	PRIMO-UK	toddler	P97.5	25.50	<25	NR	1	11.61 - 11.61	2 % - 2 %	2 % - 2 %	2 % - 2 %
FB 0272	Raspberries, red, black (all commodities)	highest utilization: Total	1.1	6.6	1.000	PRIMO-IE	child	P97.5	184.76	<25	NR	1	0.74 - 60.97	0 % - 10 %	0 % - 6 %	0 % - 10 %
VA 0381	Garlic (all commodities)	highest utilization: raw without skin	0.02	0.23	1.000	CN	Child, 1-6 yrs	290	174.44	62	3	2a	0 - 4.26	0 % - 1 %	0 % - 0 %	0 % - 1 %
VA 0385	Onion, bulb (all commodities)	highest utilization: raw without skin	0.02	0.23	1.000	JP	Child, 1-6 yrs	748	102.00	244	3	2b	0.01 - 4.29	0 % - 1 %	0 % - 0 %	0 % - 1 %
VA 0386	Onion, Chinese (all commodities)	highest utilization: raw	0	0.23	1.000	CN	Child, 1-6 yrs	196	136.53	130	3	2a	2.24 - 5.64	0 % - 1 %	0 % - 0 %	0 % - 1 %
VA 0388	Shallot (all commodities)	highest utilization: raw without skin	0.02	0.23	1.000	CN	Child, 1-6 yrs	480	115.81	51	3	2a	0.02 - 3.12	0 % - 1 %	0 % - 0 %	0 % - 1 %
VC 0421	Bitter melon (Balsam	highest utilization:	0	0.46	1.000	CN	Gen pop, >	1387	400.21	608	3	2b	3.34 - 10.38	1 % - 1 %	1 % - 0 %	0 % - 2 %

Annex 4

FAMOXADONE (208)

Acute RfD= 0.6 mg/kg bw (600 µg/kg bw)

international estimate of short-term intakes
Maximum %ARfD:

20 % 9 % 20 %
all gen pop child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	international estimate of short-term intakes µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
	pear, Bitter cucumber, Bitter gourd) (all commodities)	raw without peel					1 yrs							2 %	2 %	
VC 0422	Bottle gourd (Cucuzzi) (all commodities)	highest utilization: raw with skin	0	0.46	1.000	CN	Gen pop, > 1 yrs	519	453.00	325	3	2a	9.17 - 9.53	2 % - 2 %	1 % - 2 %	2 % - 2 %
VC 0423	Chayote (Christophine) (all commodities)	highest utilization: raw with skin	0	0.46	1.000	CN	Child, 1-6 yrs	124	284.75	197	3	2a	15.72 - 19.37	3 % - 3 %	1 % - 1 %	3 % - 3 %
VC 0424	Cucumber (all commodities)	highest utilization: raw with skin	0.17	0.37	1.000	CN	Child, 1-6 yrs	340	212.11	458	3	2b	0.06 - 14.59	0 % - 2 %	0 % - 1 %	0 % - 2 %
VC 0425	Gherkin (all commodities)	highest utilization: raw with skin	0.17	0.37	1.000	JP	Child, 1-6 yrs	484	91.80	55	3	2a	0.13 - 4.42	0 % - 1 %	0 % - 1 %	0 % - 1 %
VC 0427	Loofah, Angled (Sinkwa, Sinkwa towel gourd) (all commodities)	highest utilization: raw without peel	0	0.37	1.000	TH	Child, 3-6 yrs	759	129.62	133	3	2b	7.37 - 8.41	1 % - 1 %	1 % - 1 %	1 % - 1 %
VC 0428	Loofah, Smooth (all commodities)	highest utilization: raw without peel	0	0.37	1.000	CN	Child, 1-6 yrs	196	296.64	133	3	2a	12.9 - 12.9	2 % - 2 %	1 % - 1 %	2 % - 2 %
VC 0430	Snake gourd (all commodities)	highest utilization: raw without peel	0	0.37	1.000	TH	Child, 3-6 yrs	759	129.62	133	3	2b	7.37 - 8.41	1 % - 1 %	1 % - 1 %	1 % - 1 %
VC 0431	Squash, Summer (Courgette, Marrow, Zucchetti, Zucchini) (all commodities)	highest utilization: Total	0.17	0.37	1.000	US	Child, < 6 yrs	252	149.52	186	3	2b	0.11 - 11.45	0 % - 2 %	0 % - 1 %	0 % - 2 %
VO 0444	Peppers, chili (all commodities)	highest utilization: raw with skin	0.47 - 4.7	3.7 - 37	1.000	CN	Gen pop, > 1 yrs	1743	295.71	43	3	2a	0.01 - 26.56	0 % - 4 %	0 % - 4 %	0 % - 1 %
VO 0445	Peppers, sweet (incl. pimiento) (Bell pepper, Paprika) (all commodities)	highest utilization: raw with skin	0.47	3.7	1.000	CN	Child, 1-6 yrs	1002	169.85	170	3	2b	0.08 - 116.84	0 % - 20 %	0 % - 7 %	0 % - 20 %
DH 1100	Hops, dry (all commodities)	highest utilization: raw = dried	13	0	1.000	US	Gen pop, 0-85 yrs	3162	24.49	<25	NR	3	1.45 - 4.5	0 % - 1 %	0 % - 1 %	0 % - 0 %

Annex 4

FENAZAQUIN (297)

Acute RfD= 0.1 mg/kg bw (100 µg/kg bw)

international estimate of short-term intakes
Maximum %ARfD:

60 % 20 % 60 %
all gen pop child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	international estimate of short-term intakes µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
FC 0303	Kumquats (all commodities)	highest utilization: Total	0	0.12	1.000	JP	Gen pop, > 1 yrs	135	120.00	<25	NR	1	0.02 - 0.29	0 % - 0 %	0 % - 0 %	0 % - 0 %
FC 0204	Lemon (all commodities)	highest utilization: Total	0.008 - 0.01	0.01	1.000	PRIMO-DE	child	P95	125.50	71	3	2a	0.01 - 0.17	0 % - 0 %	0 % - 0 %	0 % - 0 %
FC 0205	Lime (all commodities)	highest utilization: Total	0.008 - 0.01	0.01	1.000	AU	Gen pop, > 2 yrs	579	259.21	49	3	2a	0 - 0.05	0 % - 0 %	0 % - 0 %	0 % - 0 %
FC 0003	Subgroup of Mandarins (incl mandarin-like hybrids) (all commodities)	highest utilization: raw, without peel	0.0008 - 0.01	0.01	1.000	CN	Child, 1-6 yrs	151	586.75	124	3	2a	0 - 0.52	0 % - 1 %	0 % - 0 %	0 % - 1 %
FC 0004	Subgroup of Oranges, sweet, sour (incl orange-like hybrids) (all commodities)	highest utilization: Total	0.00125 - 0.01	0.01	1.000	AU	Child, 2-6 yrs	1735	800.83	156	3	2a	0.01 - 0.59	0 % - 1 %	0 % - 0 %	0 % - 1 %
FC 0005	Subgroup of Pummelo and Grapefruits (incl Shaddock-like hybrids, among others Grapefruit) (all commodities)	highest utilization: Total	0.0007 - 0.01	0.01	1.000	PRIMO-DE	child	P90	253.56	270	3	2b	0 - 0.47	0 % - 0 %	0 % - 0 %	0 % - 0 %
FP 0226	Apple (all commodities)	highest utilization: raw with peel (incl consumption without peel)	0.08	0.18	1.000	CN	Child, 1-6 yrs	1314	403.39	255	3	2a	0.41 - 10.19	0 % - 10 %	0 % - 4 %	0 % - 10 %
FS 0014	Subgroup of Plums (all commodities)	highest utilization: dried (prunes)	0.145 - 0.7	0.25 - 1.2	1.000	AU	Child, 2-6 yrs	13	447.59	10	NR	1	0.07 - 28.27	0 % - 30 %	0 % - 9 %	0 % - 30 %
FS 0240	Apricot (all commodities)	highest utilization: Total	0.38	1.2	1.000	PRIMO-DE	child	P95	264.86	50	3	2a	0.16 - 27.11	0 % - 30 %	0 % - 20 %	0 % - 30 %

Annex 4

FENZAQUIN (297)

Acute RfD= 0.1 mg/kg bw (100 µg/kg bw)

international estimate of short-term intakes
Maximum %ARfD:

60 % 20 % 60 %
all gen pop child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	international estimate of short-term intakes µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
FS 2237	Japanese apricot (ume)	Total		1.2	1.000	JP	Child, 1-6 yrs	25	25.50	<25	NR	1	1.691	2 %	1 %	2 %
FS 0245	Nectarine (all commodities)	highest utilization: raw with peel (incl consumption without peel)	0.38	1.2	1.000	NL	toddler, 8-20 m	6	183.60	131	3	2a	0.16 - 52.41	0 % - 50 %	0 % - 20 %	0 % - 50 %
FS 0247	Peach (all commodities)	highest utilization: raw with peel (incl consumption without peel)	0.38	1.2	1.000	JP	Child, 1-6 yrs	76	306.00	255	3	2a	0.16 - 63.17	0 % - 60 %	0 % - 20 %	0 % - 60 %
FB 0264	Blackberries (all commodities)	highest utilization: Total	0.18	0.41	1.000	PRIMO-UK	toddler	P97.5	155.40	<25	NR	1	0.03 - 4.39	0 % - 4 %	0 % - 3 %	0 % - 4 %
FB 0266	Dewberries (incl Boysenberry, Loganberry) (all commodities)	highest utilization: Total	0	0.41	1.000	PRIMO-UK	toddler	P97.5	25.50	<25	NR	1	0.72 - 0.72	1 % - 1 %	1 % - 1 %	1 % - 1 %
FB 0272	Raspberries, red, black (all commodities)	highest utilization: Total	0.18	0.41	1.000	PRIMO-IE	child	P97.5	184.76	<25	NR	1	0.12 - 3.79	0 % - 4 %	0 % - 2 %	0 % - 4 %
FB 0020	Blueberries (all commodities)	highest utilization: Total	0.235	0.42	1.000	CA	Child, <6 yrs	189	176.21	<25	NR	1	0.03 - 4.81	0 % - 5 %	0 % - 4 %	0 % - 5 %
FB 0021	Currants, black, red, white (all commodities)	highest utilization: juice (pasteurised)	0.235	0.42	1.000	PRIMO-NL	child	E	525.80	NR	NR	3	0.15 - 6.72	0 % - 7 %	0 % - 5 %	0 % - 7 %
FB 0268	Gooseberry (all commodities)	highest utilization: Total	0.235	0.42	1.000	PRIMO-DE	child	P100	94.96	<25	NR	1	0.04 - 2.47	0 % - 2 %	0 % - 2 %	0 % - 2 %
FB 0273	Rose hips (all commodities)	highest utilization: jam (incl jelly)	0.235	0.42	1.000	CA	Child, <6 yrs	443	78.10	NR	NR	3	0.15 - 1.19	0 % - 1 %	0 % - 1 %	0 % - 1 %
FB 1235	Table grapes (all commodities)	highest utilization: raw with skin	0.19	0.4 - 0.88	1.000	CN	Child, 1-6 yrs	232	366.72	637	3	2b	1.21 - 27.27	1 % - 30 %	0 % - 10 %	1 % - 30 %
FB 1236	Wine grapes (all commodities)	highest utilization: Total	0.0038 - 0.19	0	1.000	PRIMO-UK	adult	P97.5	1802.62	NR	NR	3	0.06 - 4.51	0 % - 5 %	0 % - 5 %	0 % - 2 %
FB 0265	Cranberry	highest utilization:	0.49	1.2	1.000	AU	Child, 2-16	103	279.66	<25	NR	1	0.01 - 8.83	0 % -	0 % -	0 % - 9 %

Annex 4

FENZAQUIN (297)

Acute RfD= 0.1 mg/kg bw (100 µg/kg bw)

international estimate of short-term intakes

Maximum %ARfD:

60 % all gen pop 20 % child 60 %

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	international estimate of short-term intakes µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
	(all commodities)	Total					ys							9 %	3 %	
FB 0275	Strawberry (all commodities)	highest utilization: Raw with skin	0.49	1.2	1.000	NL	toddler, 8-20 m	52	166.73	18	NR	1	0.28 - 19.62	0 % - 20 %	0 % - 10 %	0 % - 20 %
FI 0326	Avocado (all commodities)	highest utilization: Total	0	0.01	1.000	AU	Child, 2-6 yrs	182	229.90	171	3	2a	0.15 - 0.3	0 % - 0 %	0 % - 0 %	0 % - 0 %
VC 0421	Bitter melon (Balsam pear, Bitter cucumber, Bitter gourd) (all commodities)	highest utilization: raw without peel	0	0.19	1.000	CN	Gen pop, > 1 yrs	1387	400.21	608	3	2b	1.38 - 4.29	1 % - 4 %	1 % - 4 %	1 % - 4 %
VC 0422	Bottle gourd (Cucuzzi) (all commodities)	highest utilization: raw with skin	0	0.19	1.000	CN	Gen pop, > 1 yrs	519	453.00	325	3	2a	3.79 - 3.94	4 % - 4 %	2 % - 4 %	4 % - 4 %
VC 0423	Chayote (Christophine) (all commodities)	highest utilization: raw with skin	0	0.19	1.000	CN	Child, 1-6 yrs	124	284.75	197	3	2a	6.49 - 8	6 % - 8 %	3 % - 3 %	6 % - 8 %
VC 0424	Cucumber (all commodities)	highest utilization: raw with skin	0.06	0.19	1.000	CN	Child, 1-6 yrs	340	212.11	458	3	2b	0.02 - 7.49	0 % - 7 %	0 % - 5 %	0 % - 7 %
VC 0425	Gherkin (all commodities)	highest utilization: raw with skin	0.06	0.19	1.000	JP	Child, 1-6 yrs	484	91.80	55	3	2a	0.04 - 2.27	0 % - 2 %	0 % - 2 %	0 % - 2 %
VC 0427	Loofah, Angled (Sinkwa, Sinkwa towel gourd) (all commodities)	highest utilization: raw without peel	0	0.19	1.000	TH	Child, 3-6 yrs	759	129.62	133	3	2b	3.79 - 4.32	4 % - 4 %	2 % - 2 %	4 % - 4 %
VC 0428	Loofah, Smooth (all commodities)	highest utilization: raw without peel	0	0.19	1.000	CN	Child, 1-6 yrs	196	296.64	133	3	2a	6.63 - 6.63	7 % - 7 %	3 % - 3 %	7 % - 7 %
VC 0430	Snake gourd (all commodities)	highest utilization: raw without peel	0	0.19	1.000	TH	Child, 3-6 yrs	759	129.62	133	3	2b	3.79 - 4.32	4 % - 4 %	2 % - 2 %	4 % - 4 %
VC 0431	Squash, Summer (Courgette, Marrow, Zucchetti, Zucchini) (all commodities)	highest utilization: Total	0.06	0.19	1.000	US	Child, < 6 yrs	252	149.52	186	3	2b	0.04 - 5.88	0 % - 6 %	0 % - 3 %	0 % - 6 %
VC 0046	Melons, except watermelon (Cantaloupe)	highest utilization: Total	0.06	0.19	1.000	PRIMO-BE	toddler	P100	540.00	540	3	2b	0 - 17.29	0 % - 20 %	0 % - 9 %	0 % - 20 %

Annex 4

FENZAQUIN (297)

Acute RfD= 0.1 mg/kg bw (100 µg/kg bw)

international estimate of short-term intakes
Maximum %ARfD:

60 % 20 % 60 %
all gen pop child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	international estimate of short-term intakes µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
	(all commodities)															
VC 0429	Pumpkins (all commodities)	highest utilization: raw without peel	0.06	0.19	1.000	CN	Child, 1-6 yrs	561	322.71	1852	3	2b	0.1 - 11.4	0 % - 10 %	0 % - 8 %	0 % - 10 %
VC 0432	Watermelon (all commodities)	highest utilization: Total	0.06	0.19	1.000	CA	Child, <6 yrs	171	953.64	4302	3	2b	16.4 - 35.23	20 % - 40 %	20 % - 20 %	20 % - 40 %
VO 2704	Goji berry (all commodities)	highest utilization: Dried	0	0.19	3.000	AU	Child, 2-6 yrs	1	28.36	<25	NR	1	0.18 - 0.85	0 % - 1 %	0 % - 0 %	0 % - 1 %
VO 0448	Tomato (all commodities)	highest utilization: raw with peel	0.021 - 0.052	0.19	1.000	CN	Child, 1-6 yrs	1117	263.76	175	3	2a	0.2 - 7.22	0 % - 7 %	0 % - 3 %	0 % - 7 %
VO 0444	Peppers, chili (all commodities)	highest utilization: raw with skin	0.079	0.22 - 2.2	1.000	CN	Gen pop, > 1 yrs	1743	295.71	43	3	2a	0 - 1.58	0 % - 2 %	0 % - 2 %	0 % - 0 %
VO 0445	Peppers, sweet (incl. pimiento) (Bell pepper, Paprika) (all commodities)	highest utilization: raw with skin	0.097	0.22	1.000	CN	Child, 1-6 yrs	1002	169.85	170	3	2b	0.02 - 6.95	0 % - 7 %	0 % - 3 %	0 % - 7 %
VO 0440	Egg plant (Aubergine) (all commodities)	highest utilization: raw with skin	0.079	0.22	1.000	CN	Child, 1-6 yrs	969	253.44	444	3	2b	0.09 - 10.37	0 % - 10 %	0 % - 6 %	0 % - 10 %
HS 3381	Lemon, peel	Oil (refined)	9.84		1.000	NL	Gen pop, > 1 yrs	0	NC	NR	NR	3	NC	NC	NC	NC
HS 3382	Orange, peel	Oil (refined)	9.84		1.000	NL	Gen pop, > 1 yrs	0	NC	NR	NR	3	NC	NC	NC	NC
MM 0095	Meat from mammals other than marine mammals	Total	NA	NA	1.000	CN	Child, 1-6 yrs	4329	261.46	NR	NR	1	NA	0 %	0 %	0 %
MM 0095	Meat from mammals other than marine mammals: 20 % as fat	Total		0.00081	1.000	CN	Child, 1-6 yrs	4329	52.29	NR	NR	1	0.003	0 %	0 %	0 %
MM 0095	Meat from mammals other than marine mammals: 80 % as muscle	Total		0	1.000	CN	Child, 1-6 yrs	4329	209.17	NR	NR	1	0.000	0 %	0 %	0 %
MF 0100	Mammalian fats	Total		0.00081	1.000	PRIMO-	infant	P97.5	18.10	NR	NR	1	0.002	0 %	0 %	0 %

Annex 4

FENZAQUIN (297)

Acute RfD= 0.1 mg/kg bw (100 µg/kg bw)

international estimate of short-term intakes
Maximum %ARfD:

60 % 20 % 60 %
all gen pop child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	international estimate of short-term intakes µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded	
	(except milk fats)					UK											
MO 0105	Edible offal (mammalian)	Total		0.0011	1.000	ZA	Gen pop, > 10 yrs	-	523.58		NR	NR	1	0.010	0 %	0 %	0 %
ML 0106	Milks	Total	0		1.000	PRIMO-UK	infant	P97.5	1080.70		NR	NR	3	0.000	0 %	0 %	0 %

FLUAZAINDOLIZINE (327)

Acute RfD= 1 mg/kg bw (1000 µg/kg bw)

international estimate of short-term intakes
Maximum %ARfD:

9 % 5 % 9 %
all gen pop child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	international estimate of short-term intakes µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
FB 0275	Strawberry (all commodities)	highest utilization: Raw with skin	0.004 - 0.053	0.0419 - 0.4297	1.000	NL	toddler, 8-20 m	52	166.73	18	NR	1	0.02 - 2.31	0 % - 0 %	0 % - 0 %	0 % - 0 %
VA 0381	Garlic (all commodities)	highest utilization: raw without skin	0.0674	0.8281	1.000	CN	Child, 1-6 yrs	290	174.44	62	3	2a	0 - 15.34	0 % - 2 %	0 % - 1 %	0 % - 2 %
VA 0385	Onion, bulb (all commodities)	highest utilization: raw without skin	0.0674	0.8281	1.000	JP	Child, 1-6 yrs	748	102.00	244	3	2b	0.02 - 15.45	0 % - 2 %	0 % - 1 %	0 % - 2 %
VA 0386	Onion, Chinese (all commodities)	highest utilization: raw	0	0.8281	1.000	CN	Child, 1-6 yrs	196	136.53	130	3	2a	8.07 - 20.31	1 % - 2 %	1 % - 1 %	1 % - 2 %
VA 0388	Shallot (all commodities)	highest utilization: raw without skin	0.0674	0.8281	1.000	CN	Child, 1-6 yrs	480	115.81	51	3	2a	0.05 - 11.22	0 % - 1 %	0 % - 0 %	0 % - 1 %
VA 2605	Chives (all commodities)	highest utilization: Total	0	0.8281	1.000	PRIMO-CZ	Child, child, 7-10 yrs	P97.5	26.49	<25	NR	1	0.16 - 0.68	0 % - 0 %	0 % - 0 %	0 % - 0 %
VA 0384	Leek	highest utilization:	0.0674	0.8281	1.000	CN	Child, 1-6	401	149.40	176	3	2b	0.01 - 23	0 % - 0 %	0 % - 0 %	0 % - 0 %

Annex 4

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FLUAZAINDOLIZINE (327)

Acute RfD= 1 mg/kg bw (1000 µg/kg bw)

international estimate of short-term intakes

Maximum %ARfD:

9 %
all
5 %
gen pop
9 %
child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	international estimate of short-term intakes µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
	(all commodities)	raw					yrs							2 %	1 %	2 %
VA 0387	Onion, Welsh (Japanese bunching onion, Multiplying onion) (all commodities)	highest utilization: Total	0	0.8281	1.000	PRIMO-UK	child, 4-6 yrs	P97.5	93.60	38	3	2a	5.22 - 6.85	1 % - 1 %	0 % - 0 %	1 % - 1 %
VA 0389	Spring onion (all commodities)	highest utilization: Total	0	0.8281	1.000	PRIMO-UK	child, 4-6 yrs	P97.5	93.60	38	3	2a	2.56 - 6.85	0 % - 1 %	0 % - 0 %	0 % - 1 %
VB 0400	Broccoli (all commodities)	highest utilization: cooked/boiled	0.04335	0.0705	1.000	PRIMO-NL	toddler	P97.5	160.70	286	3	2b	0.08 - 3.33	0 % - 0 %	0 % - 0 %	0 % - 0 %
VB 0404	Cauliflower (all commodities)	highest utilization: cooked/boiled	0.04335	0.0705	1.000	PRIMO-NL	toddler	P97.5	142.00	749	3	2b	0.01 - 2.94	0 % - 0 %	0 % - 0 %	0 % - 0 %
VB 0402	Brussels sprouts (all commodities)	highest utilization: cooked/boiled	0.04335	0.0705	1.000	PRIMO-NL	toddler	P90	103.80	<25	NR	1	0 - 0.72	0 % - 0 %	0 % - 0 %	0 % - 0 %
VB 0041	Cabbages, head (all commodities)	highest utilization: raw	0.04335	0.0705	1.000	CN	Child, 1-6 yrs	287	255.54	1403	3	2b	0.03 - 3.35	0 % - 0 %	0 % - 0 %	0 % - 0 %
VB 0467	Chinese cabbage (type Pe-tsai) (all commodities)	highest utilization: Total	0.04335	0.0705	1.000	CN	Child, 1-6 yrs	2788	336.16	2162	3	2b	0.01 - 4.41	0 % - 0 %	0 % - 0 %	0 % - 0 %
VB 0405	Kohlrabi (all commodities)	highest utilization: Total	0	0.0705	1.000	PRIMO-DE	child	P95	167.96	265	3	2b	0.22 - 2.2	0 % - 0 %	0 % - 0 %	0 % - 0 %
011A	Cucumbers and Summer squashes	-	0.1092	0.3674	-	-	-	-	-	-	-	-	-	-	-	-
VC 0421	Bitter melon (Balsam pear, Bitter cucumber, Bitter gourd) (all commodities)	highest utilization: raw without peel	0	0.3674	1.000	CN	Gen pop, > 1 yrs	1387	400.21	608	3	2b	2.67 - 8.29	0 % - 1 %	0 % - 1 %	0 % - 1 %
VC 0422	Bottle gourd (Cucuzzi) (all commodities)	highest utilization: raw with skin	0	0.3674	1.000	CN	Gen pop, > 1 yrs	519	453.00	325	3	2a	7.32 - 7.61	1 % - 1 %	0 % - 1 %	1 % - 1 %
VC 0423	Chayote (Christophine) (all commodities)	highest utilization: raw with skin	0	0.3674	1.000	CN	Child, 1-6 yrs	124	284.75	197	3	2a	12.56 - 15.47	1 % - 2 %	1 % - 1 %	1 % - 2 %
VC 0424	Cucumber	highest utilization:	0.1092	0.3674	1.000	CN	Child, 1-6	340	212.11	458	3	2b	0.04 - 14.49	0 % - 0 %	0 % - 0 %	0 % - 0 %

Annex 4

FLUAZAINDOLIZINE (327)

Acute RfD= 1 mg/kg bw (1000 µg/kg bw)

international estimate of short-term intakes
Maximum %ARfD:

9 % 5 % 9 %
all gen pop child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	international estimate of short-term intakes µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded	
	(all commodities)	raw with skin					yrs							1 %	1 %	1 %	
VC 0425	Gherkin (all commodities)	highest utilization: raw with skin	0.1092	0.3674	1.000	JP	Child, 1-6 yrs	484	91.80		55	3	2a	0.08 - 4.39	0 % - 0 %	0 % - 0 %	0 % - 0 %
VC 0427	Loofah, Angled (Sinkwa, Sinkwa towel gourd) (all commodities)	highest utilization: raw without peel	0	0.3674	1.000	TH	Child, 3-6 yrs	759	129.62		133	3	2b	7.32 - 8.35	1 % - 1 %	0 % - 0 %	1 % - 1 %
VC 0428	Loofah, Smooth (all commodities)	highest utilization: raw without peel	0	0.3674	1.000	CN	Child, 1-6 yrs	196	296.64		133	3	2a	12.81 - 12.81	1 % - 1 %	1 % - 1 %	1 % - 1 %
VC 0430	Snake gourd (all commodities)	highest utilization: raw without peel	0	0.3674	1.000	TH	Child, 3-6 yrs	759	129.62		133	3	2b	7.32 - 8.35	1 % - 1 %	0 % - 0 %	1 % - 1 %
VC 0431	Squash, Summer (Courgette, Marrow, Zucchini, Zucchini) (all commodities)	highest utilization: Total	0.1092	0.3674	1.000	US	Child, < 6 yrs	252	149.52		186	3	2b	0.07 - 11.37	0 % - 1 %	0 % - 1 %	0 % - 1 %
VC 0046	Melons, except watermelon (Cantaloupe) (all commodities)	highest utilization: Total	0.1348	0.3937	1.000	PRIMO-BE	toddler	P100	540.00		540	3	2b	0.01 - 35.83	0 % - 4 %	0 % - 2 %	0 % - 4 %
VC 0429	Pumpkins (all commodities)	highest utilization: raw without peel	0.1348	0.3937	1.000	CN	Child, 1-6 yrs	561	322.71		1852	3	2b	0.22 - 23.62	0 % - 2 %	0 % - 2 %	0 % - 2 %
VC 0432	Watermelon (all commodities)	highest utilization: Total	0.1348	0.3937	1.000	CA	Child, <6 yrs	171	953.64		4302	3	2b	33.98 - 73	3 % - 7 %	3 % - 5 %	3 % - 7 %
VO 2704	Goji berry (all commodities)	highest utilization: Dried	0	0.963	3.000	AU	Child, 2-6 yrs	1	28.36		<25	NR	1	0.92 - 4.31	0 % - 0 %	0 % - 0 %	0 % - 0 %
VO 0448	Tomato (all commodities)	highest utilization: raw with peel	0.059 - 0.2476	0.9389 - 6.696	1.000	CN	Child, 1-6 yrs	1117	263.76		175	3	2a	0.39 - 36.58	0 % - 4 %	0 % - 1 %	0 % - 4 %
VO 0444	Peppers, chili (all commodities)	highest utilization: raw with skin	0.074	0.3102 - 3.102	1.000	CN	Gen pop, > 1 yrs	1743	295.71		43	3	2a	0 - 2.23	0 % - 0 %	0 % - 0 %	0 % - 0 %
VO 0445	Peppers, sweet (incl. pimiento) (Bell pepper, Paprika)	highest utilization: raw with skin	0.074	0.3102	1.000	CN	Child, 1-6 yrs	1002	169.85		170	3	2b	0.01 - 9.8	0 % - 1 %	0 % - 0 %	0 % - 1 %

Annex 4

FLUAZAINDOLIZINE (327)

Acute RfD= 1 mg/kg bw (1000 µg/kg bw)

international estimate of short-term intakes
Maximum %ARfD:

9 % 5 % 9 %
all gen pop child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	international estimate of short-term intakes µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
	(all commodities)															
VO 0440	Egg plant (Aubergine) (all commodities)	highest utilization: raw with skin	0.0748	0.963	1.000	CN	Child, 1-6 yrs	969	253.44	444	3	2b	0.08 - 45.38	0 % - 5 %	0 % - 2 %	0 % - 5 %
VO 0443	Pepino (Melon pear, Tree melon)	Total		0.963	1.000	PRIMO-NL	Gen pop	P95	424.02	340	3	2a	16.143	2 %	2 %	1 %
VO 2713	Scarlet eggplant (gilo, Ethiopian eggplant) (all commodities)	highest utilization: Total	0	0.963	1.000	PRIMO-NL	Gen pop	P95	424.02	28	3	2a	6.23 - 7.04	1 % - 1 %	1 % - 1 %	1 % - 1 %
VL 0460	Amaranth leaves (Bledo) (all commodities)	highest utilization: Total	0	1.388	1.000	PRIMO-BE	toddler	P97.5	402.30	<25	NR	1	15.17 - 31.37	2 % - 3 %	1 % - 2 %	3 % - 3 %
VL 0464	Chard (Beet leaves, Silver beet)	Total	0.388		1.000	CA	Gen pop, all ages	32	259.56	977	3	2b	ND	-	-	-
VL 0465	Chervil (all commodities)	highest utilization: Total	0.388	1.388	1.000	PRIMO-BE	toddler	P100	23.00	<25	NR	1	0.04 - 1.79	0 % - 0 %	0 % - 0 %	0 % - 0 %
VL 0469	Chicory leaves (green and red cultivars) (Sugar loaf) (all commodities)	highest utilization: Total	0	1.388	1.000	PRIMO-BE	toddler	P100	143.00	440	3	2b	21.25 - 33.45	2 % - 3 %	1 % - 2 %	2 % - 3 %
VL 2752	Chrysanthemum, edible leaved (all commodities)	highest utilization: Total	0	1.388	1.000	PRIMO-BE	toddler	P97.5	402.30	<25	NR	1	8.68 - 31.37	1 % - 3 %	1 % - 1 %	3 % - 3 %
VL 0470	Corn salad (Lambs lettuce) (all commodities)	highest utilization: Total	0	1.388	1.000	PRIMO-BE	toddler	P100	50.00	<25	NR	1	1.17 - 3.9	0 % - 0 %	0 % - 0 %	0 % - 0 %
VL 0510	Cos lettuce (all commodities)	highest utilization: Total	0.388	1.388	1.000	PRIMO-NL	child	P97.5	140.10	290	3	2b	0.23 - 31.71	0 % - 3 %	0 % - 2 %	0 % - 3 %
VL 0474	Dandelion (Laiteron, Pissenlit) (all commodities)	highest utilization: Total	0	1.388	1.000	PRIMO-BE	toddler	P100	143.00	35	3	2a	2.53 - 16.61	0 % - 2 %	0 % - 1 %	2 % - 2 %
VL 0476	Endive (i.e. Scarole) (all commodities)	highest utilization: cooked/boiled	0.388	1.388	1.000	PRIMO-NL	toddler	P95	135.20	251	3	2b	1.55 - 55.19	0 % - 6 %	0 % - 2 %	0 % - 6 %

Annex 4

FLUAZAINDOLIZINE (327)

Acute RfD= 1 mg/kg bw (1000 µg/kg bw)

international estimate of short-term intakes
Maximum %ARfD:

9 % 5 % 9 %
all gen pop child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	international estimate of short-term intakes µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
VL 0482	Lettuce, head (all commodities)	highest utilization: Total	0.388	1.388	1.000	PRIMO-NL	child	P97.5	140.10	290	3	2b	0.23 - 31.71	0 % - 3 %	0 % - 1 %	0 % - 3 %
VL 0483	Lettuce, leaf (all commodities)	highest utilization: Total	0.388	1.388	1.000	CN	Child, 1-6 yrs	243	387.25	305	3	2a	0.23 - 85.85	0 % - 9 %	0 % - 3 %	0 % - 9 %
VL 0492	Purslane (all commodities)	highest utilization: cooked/boiled	0	1.388	1.000	PRIMO-NL	Gen pop	P100	271.20	<25	NR	1	1.51 - 5.72	0 % - 1 %	0 % - 1 %	0 % - 0 %
VL 0501	Sowthistle (all commodities)	highest utilization: raw	0	1.388	1.000	CN	Gen pop, > 1 yrs	1187	592.49	35	3	2a	17.28 - 17.28	2 % - 2 %	2 % - 2 %	0 % - 0 %
VL 0502	Spinach (all commodities)	highest utilization: Total	0.388	1.388	1.000	PRIMO-BE	toddler	P97.5	402.30	<25	NR	1	0.04 - 31.37	0 % - 3 %	0 % - 2 %	0 % - 3 %
VL 0401	Broccoli, Chinese (i.e. kailan) (all commodities)	highest utilization: raw	0	1.388	1.000	CN	Child, 1-6 yrs	334	222.48	311	3	2b	34.65 - 57.41	3 % - 6 %	2 % - 3 %	3 % - 6 %
VL 0466	Chinese cabbage (type Pak-choi) (i.e. celery mustard) (all commodities)	highest utilization: raw	0.388	1.388	1.000	CN	Child, 1-6 yrs	1966	327.07	1548	3	2b	0.11 - 84.41	0 % - 8 %	0 % - 5 %	0 % - 8 %
VL 0472	Cress, Garden (all commodities)	highest utilization: raw	0	1.388	1.000	CN	Gen pop, > 1 yrs	1443	352.50	<25	NR	1	0.52 - 9.19	0 % - 1 %	0 % - 1 %	0 % - 0 %
VL 0468	Flowering white cabbage (Choisum) (all commodities)	highest utilization: Total	0.388	1.388	1.000	PRIMO-BE	toddler	P97.5	148.10	186	3	2b	1.28 - 34.65	0 % - 3 %	0 % - 3 %	3 % - 3 %
VL 0480	Kale (Borecole, Collards) (all commodities)	highest utilization: Total	0.388	1.388	1.000	PRIMO-DE	child	P100	142.12	672	3	2b	0.74 - 36.64	0 % - 4 %	0 % - 2 %	0 % - 4 %
VL 0481	Komatsuna	Total		1.388	1.000	PRIMO-BE	toddler	P100	114.40	<25	NR	1	8.921	1 %	1 %	1 %
VL 2781	Mizuna	Total		1.388	1.000	PRIMO-BE	toddler	P100	114.40	<25	NR	1	8.921	1 %	1 %	1 %
VL 0485	Mustard greens (Indian mustard, Amsoi, mustard cabbage, red)	highest utilization: raw	0.388	1.388	1.000	CN	Child, 1-6 yrs	635	299.31	245	3	2a	1.68 - 67.86	0 % - 7 %	0 % - 3 %	3 % - 7 %

Annex 4

FLUAZAINDOLIZINE (327)

Acute RfD= 1 mg/kg bw (1000 µg/kg bw)

international estimate of short-term intakes
Maximum %ARfD:

9 % 5 % 9 %
all gen pop child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	international estimate of short-term intakes µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
	mustards) (all commodities)															
VL 0494	Radish leaves	Total		1.388	1.000	PRIMO-DE	child	P100	142.12	<25	NR	1	12.214	1 %	1 %	1 %
VL 0495	Rape greens (all commodities)	highest utilization: Total	0	1.388	1.000	PRIMO-DE	child	P100	142.12	<25	NR	1	5.38 - 12.21	1 % - 1 %	1 % - 1 %	1 % - 1 %
VL 0496	Rucola (Arrugula, Rocket salad, Roquette, Roman rocket) (all commodities)	highest utilization: Total	0	1.388	1.000	PRIMO-DE	child	P100	43.44	<25	NR	1	1.64 - 3.73	0 % - 0 %	0 % - 1 %	0 % - 0 %
VL 0506	Turnip greens (Namenia, Tendergreen) (all commodities)	highest utilization: Total	0	1.388	1.000	PRIMO-BE	toddler	P100	114.40	35	3	2a	2.28 - 14.38	0 % - 1 %	0 % - 1 %	0 % - 1 %
VL 0505	Taro leaves (all commodities)	highest utilization: raw	0	1.388	1.000	NL	Gen pop, > 1 yrs	E	77.78	86	3	2b	1.51 - 4.92	0 % - 0 %	0 % - 0 %	0 % - 0 %
VL 0269	Grape leaves (all commodities)	highest utilization: Total	0	1.388	1.000	US	Gen pop, 0-85 yrs	5	70.30	<25	NR	1	1.16 - 1.38	0 % - 0 %	0 % - 0 %	0 % - 0 %
VL 0507	Kangkung (water spinach) (all commodities)	highest utilization: raw	0	1.388	1.000	CN	Child, 1-6 yrs	183	270.70	86	3	2a	4.92 - 38.04	0 % - 4 %	0 % - 2 %	0 % - 4 %
VL 0473	Watercress (all commodities)	highest utilization: raw	0	1.388	1.000	BR	gen pop, > 10 yrs	97	90.92	255	3	2b	1.64 - 5.86	0 % - 1 %	0 % - 1 %	0 % - 0 %
VL 9999	Seaweed (all commodities)	highest utilization: Total	0	1.388	1.000	CN	Gen pop, > 1 yrs	961	181.79	<25	NR	1	0.21 - 4.74	0 % - 0 %	0 % - 0 %	0 % - 0 %
VL 2832	Witloof chicory sprouts (Belgian endives) (all commodities)	highest utilization: cooked/boiled	0.388	1.388	1.000	PRIMO-NL	toddler	P97.5	160.65	124	3	2a	0.02 - 55.61	0 % - 6 %	0 % - 2 %	0 % - 6 %
VP 0061	Beans with pods (Phaseolus spp): (immature pods +	highest utilization: Total	0.0709	0.1589	1.000	CA	Child, <6 yrs	261	203.31	<25	NR	1	0.11 - 2.15	0 % - 0 %	0 % - 0 %	0 % - 0 %

Annex 4

FLUAZAINDOLIZINE (327)

Acute RfD= 1 mg/kg bw (1000 µg/kg bw)

international estimate of short-term intakes
Maximum %ARfD:

9 % 5 % 9 %
all gen pop child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	international estimate of short-term intakes µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
	succulent seeds) (all commodities)															
VP 0522	Broad bean with pods (immature pods + succulent seeds) (Vicia spp) (all commodities)	highest utilization: Total	0	0.1589	1.000	PRIMO-NL	toddler	E	116.60	<25	NR	1	0.44 - 1.82	0 % - 0 %	0 % - 0 %	0 % - 0 %
VP 0542	Sword bean with pods (immature pods + succulent seeds) (Canavalia spp) (all commodities)	highest utilization: cooked/boiled	0	0.1589	1.000	CN	Gen pop, > 1 yrs	891	316.83	<25	NR	1	0.95 - 0.95	0 % - 0 %	0 % - 0 %	0 % - 0 %
VP 0063	Peas with pods (Pisum spp) immature pods + succulent seeds) (all commodities)	highest utilization: cooked/boiled	0.0709	0.1589	1.000	CN	Child, 1-6 yrs	1056	290.21	6	NR	1	1.3 - 2.86	0 % - 0 %	0 % - 0 %	0 % - 0 %
VP 0553	Lentil with pods (immature pods + succulent seeds) (Lens spp) (all commodities)	highest utilization: cooked/boiled	0	0.1589	1.000	CN	Child, 1-6 yrs	371	345.76	<25	NR	1	0.91 - 3.41	0 % - 0 %	0 % - 0 %	0 % - 0 %
VP 0523	Broad bean without pods (succulent seeds) (Vicia spp)	Total	0.0709	0.1589	1.000	PRIMO-IE	child	P97.5	157.79	<25	NR	1	1.254	0 %	0 %	0 %
VP 0541	Soya bean without pods (succulent seeds) (Glycine max)	Total	0.0709	0.1589	1.000	PRIMO-IE	child	P97.5	157.79	<25	NR	1	1.254	0 %	0 %	0 %
VP 0064	Peas without pods (Pisum spp) (succulent seeds)	Total	0.0709	0.1589	1.000	PRIMO-UK	infant	P97.5	71.30	<25	NR	1	1.302	0 %	0 %	0 %
VP 0520	Bambara groundnut without pods	Total		0.1589	1.000	AU	Gen pop, > 2 yrs	22	186.07	<25	NR	1	0.441	0 %	0 %	-

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FLUAZAINDOLIZINE (327)

Acute RfD= 1 mg/kg bw (1000 µg/kg bw)

international estimate of short-term intakes
Maximum %ARfD:

9 % 5 % 9 %
all gen pop child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	international estimate of short-term intakes µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
	(succulent seeds) (Vigna subterranea)															
VD 0071	Beans (dry) (Phaseolus spp) (all commodities)	highest utilization: Total	0.0656	0	1.000	PRIMO-UK	infant	P97.5	159.00	<25	NR	3	0.13 - 1.2	0 % - 0 %	0 % - 0 %	0 % - 0 %
VD 0523	Broad bean (dry) (Vicia spp) (all commodities)	highest utilization: Total	0.0656	0	1.000	PRIMO-UK	infant	P97.5	159.00	<25	NR	3	0.04 - 1.2	0 % - 0 %	0 % - 0 %	0 % - 0 %
VD 0531	Lablab bean (dry) (Lablab spp) (all commodities)	highest utilization: Total	0.0656	0	1.000	PRIMO-UK	infant	P97.5	159.00	<25	NR	3	0.48 - 1.2	0 % - 0 %	0 % - 0 %	0 % - 0 %
VD 0541	Soya bean (dry) (Glycine spp) (all commodities)	highest utilization: Total	0 - 0.0656	0	1.000	CN	Child, 1-6 yrs	179	239.05	<25	NR	3	0 - 0.97	0 % - 0 %	0 % - 0 %	0 % - 0 %
VD 0072	Peas (dry) (Pisum spp) (all commodities)	highest utilization: cooked/boiled	0.0656	0	0.400	CN	Gen pop, > 1 yrs	268	1673.82	<25	NR	3	0.05 - 0.83	0 % - 0 %	0 % - 0 %	0 % - 0 %
VD 0524	Chick-pea (dry) (Cicer spp) (all commodities)	highest utilization: canned/preserved	0.0656	0	0.400	PRIMO-NL	child	P100	328.80	<25	NR	3	0.05 - 0.47	0 % - 0 %	0 % - 0 %	0 % - 0 %
VD 0533	Lentil (dry) (Lens spp) (all commodities)	highest utilization: Total	0.0656	0	1.000	PRIMO-UK	Child, 11-14 yrs	P97.5	321.50	<25	NR	3	0.13 - 0.44	0 % - 0 %	0 % - 0 %	0 % - 0 %
VD 0537	Pigeon pea (dry) (Cajanus spp)	Total	0.0656		1.000	PRIMO-UK	child, 11-14 yrs	P97.5	315.00	<25	NR	3	0.431	0 %	0 %	0 %
VR 0574	Beetroot (all commodities)	highest utilization: Total	0.1935	0.9322	1.000	AU	Child, 2-6 yrs	53	314.08	135	3	2a	0.12 - 28.7	0 % - 3 %	0 % - 1 %	0 % - 3 %
VR 0575	Burdock, greater or edible	Total		0.9322	1.000	PRIMO-BE	toddler	P100	99.90	75	3	2a	13.127	1 %	0 %	1 %
VR 0577	Carrot (all commodities)	highest utilization: raw with skin	0.1485	1.973	1.000	CN	Child, 1-6 yrs	400	234.68	300	3	2b	0.02 - 86.09	0 % - 9 %	0 % - 4 %	0 % - 9 %
VR 0578	Celeriac (Turnip rooted celery) (all commodities)	highest utilization: Total	0.1935	0.9322	1.000	PRIMO-BE	toddler	P100	196.90	749	3	2b	0.04 - 30.94	0 % - 3 %	0 % - 1 %	0 % - 3 %

Annex 4

FLUAZAINDOLIZINE (327)

Acute RfD= 1 mg/kg bw (1000 µg/kg bw)

international estimate of short-term intakes
Maximum %ARfD:

9 % 5 % 9 %
all gen pop child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	international estimate of short-term intakes µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
VR 0469	Chicory, roots (all commodities)	highest utilization: Total	0.1935	0.9322	1.000	AU	Gen pop, > 2 yrs	175	26.16	48	3	2b	0.14 - 1.09	0 % - 0 %	0 % - 0 %	0 % - 0 %
VR 0583	Horseradish (all commodities)	highest utilization: Total	0	0.9322	1.000	PRIMO-DE	Gen pop	P97.5	79.50	220	3	2b	0.04 - 2.91	0 % - 0 %	0 % - 0 %	0 % - 0 %
VR 0587	Parsley, turnip-rooted (Hamburg roots) (all commodities)	highest utilization: Total	0.1935	0.9322	1.000	PRIMO-NL	Gen pop	P97.5	96.60	140	3	2b	1.37 - 4.11	0 % - 0 %	0 % - 0 %	0 % - 0 %
VR 0588	Parsnip (all commodities)	highest utilization: cooked/boiled (without skin)	0.1935	0.9322	1.000	PRIMO-NL	child	E	133.30	227	3	2b	2.13 - 20.26	0 % - 2 %	0 % - 1 %	1 % - 2 %
VR 0494	Radish (all commodities)	highest utilization: Total	0.1935	0.9322	1.000	PRIMO-NL	child	E	64.40	172	3	2b	0.02 - 9.79	0 % - 1 %	0 % - 0 %	0 % - 1 %
VR 0590	Radish, black (all commodities)	highest utilization: Total	0.1935	0.9322	1.000	PRIMO-NL	child	E	64.40	172	3	2b	0.02 - 9.79	0 % - 1 %	0 % - 0 %	0 % - 1 %
VR 0591	Radish, Japanese (Chinese radish, Daikon) (all commodities)	highest utilization: raw without skin	0.1935	0.9322	1.000	CN	Child, 1-6 yrs	1187	293.37	1000	3	2b	0.02 - 50.85	0 % - 5 %	0 % - 3 %	0 % - 5 %
VR 0498	Salsify (Oyster plant) (all commodities)	highest utilization: Total	0.1935	0.9322	1.000	PRIMO-BE	toddler	P100	99.90	75	3	2a	0.01 - 13.13	0 % - 1 %	0 % - 0 %	0 % - 1 %
VR 0596	Sugar beet (all commodities)	highest utilization: composite foods; unspecified ind processed	0.1935	0	1.000	NL	Child, 2-6 yrs	2554	168.93	NR	NR	3	0.44 - 1.78	0 % - 0 %	0 % - 0 %	0 % - 0 %
VR 0497	Swede (Rutabaga) (all commodities)	highest utilization: Total	0.1935	0.9322	1.000	PRIMO-UK	infant	P97.5	90.00	500	3	2b	0.01 - 28.93	0 % - 3 %	0 % - 2 %	0 % - 3 %
VR 0506	Turnip, garden (all commodities)	highest utilization: cooked/boiled (without peel)	0.1935	0.9322	1.000	PRIMO-NL	child	E	133.31	176	3	2b	1.42 - 20.26	0 % - 2 %	0 % - 1 %	0 % - 2 %
VR 0573	Arrowroot (all commodities)	highest utilization: starch	0.1231	0.7356	1.000	PRIMO-NL	child	E	12.40	NR	NR	3	0.02 - 0.08	0 % - 0 %	0 % - 0 %	0 % - 0 %
VR 0463	Cassava (Manioc)	highest utilization:	0.1231	0.7356	1.000	PRIMO-	Gen pop	E	250.00	356	3	2b	0.11 - 8.38	0 % - 0 %	0 % - 0 %	0 % - 0 %

Annex 4

FLUAZAINDOLIZINE (327)

Acute RfD= 1 mg/kg bw (1000 µg/kg bw)

international estimate of short-term intakes
Maximum %ARfD:

9 % 5 % 9 %
all gen pop child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	international estimate of short-term intakes µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
	(all commodities)	cooked/boiled (without peel)				NL								1 %	1 %	1 %
VR 0585	Jerusalem artichoke (i.e. Topinambur) (all commodities)	highest utilization: cooked/boiled (without peel)	0	0.7356	1.000	PRIMO-NL	child	E	133.30	56	3	2a	4.04 - 9.81	0 % - 1 %	0 % - 0 %	1 % - 1 %
VR 0589	Potato (all commodities)	highest utilization: Total	0.0319 - 0.1231	0.3965 - 0.7356	1.000	PRIMO-UK	infant	P97.5	191.10	216	3	2b	0.08 - 48.47	0 % - 5 %	0 % - 1 %	0 % - 5 %
VR 0508	Sweet potato (all commodities)	highest utilization: Total	0.1231	0.7356	1.000	CA	Child, <6 yrs	91	358.61	546	3	2b	0.87 - 61.99	0 % - 6 %	0 % - 3 %	2 % - 6 %
VR 0504	Tannia (Tanier, Yautia) (all commodities)	highest utilization: cooked/boiled (without peel)	0.1231	0.7356	1.000	NL	Gen pop, > 1 yrs	E	249.97	170	3	2a	0.08 - 6.6	0 % - 1 %	0 % - 1 %	0 % - 0 %
VR 0505	Taro (Dasheen, Eddoe) (all commodities)	highest utilization: cooked/boiled (without peel)	0	0.7356	1.000	CN	Child, 1-6 yrs	199	384.18	668	3	2b	5.45 - 52.54	1 % - 5 %	1 % - 2 %	0 % - 5 %
VR 0600	Yams (all commodities)	highest utilization: Total	0	0.7356	1.000	PRIMO-UK	adult	P97.5	693.70	365	3	2a	5.33 - 13.78	1 % - 1 %	1 % - 1 %	1 % - 2 %
VS 0623	Cardoon (all commodities)	highest utilization: cooked/boiled	0	0.8281	1.000	PRIMO-NL	Gen pop	E	200.00	100	3	2a	3.68 - 5.03	0 % - 1 %	0 % - 1 %	0 % - 0 %
VS 0624	Celery (all commodities)	highest utilization: raw	0.0674	0.8281	1.000	CN	Child, 1-6 yrs	454	180.29	861	3	2b	0 - 27.76	0 % - 3 %	0 % - 2 %	0 % - 3 %
VS 0380	Fennel, bulb (Florence fennel) (all commodities)	highest utilization: cooked/boiled	0.0674	0.8281	1.000	PRIMO-NL	child	E	166.80	251	3	2b	0 - 22.52	0 % - 2 %	0 % - 1 %	0 % - 2 %
VS 0627	Rhubarb (all commodities)	highest utilization: Total	0.0674	0.8281	1.000	AU	gen pop, > 2 yrs	58	539.42	57	3	2a	0.55 - 8.07	0 % - 1 %	0 % - 1 %	0 % - 1 %
VS 0621	Asparagus (all commodities)	highest utilization: Total	0.0674	0.8281	1.000	US	Child, < 6 yrs	23	279.99	9	NR	1	8.08 - 15.99	1 % - 2 %	0 % - 1 %	1 % - 2 %
VS 0622	Bamboo shoots (all commodities)	highest utilization: cooked/boiled without peel	0.0674	0.8281	1.000	TH	Child, 3-6 yrs	526	150.82	616	3	2b	0.01 - 21.91	0 % - 2 %	0 % - 2 %	0 % - 2 %
VS 0620	Artichoke globe	highest utilization:	0	0.8281	1.000	US	Child, < 6	2	117.23	51	3	2a	3.36 - 12.54	0 % -	0 % -	0 % -

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FLUAZAINDOLIZINE (327)

Acute RfD= 1 mg/kg bw (1000 µg/kg bw)

international estimate of short-term intakes
Maximum %ARfD:

9 % 5 % 9 %
all gen pop child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	international estimate of short-term intakes µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded	
	(all commodities)	Total					yrs							1 %	1 %	1 %	
VS 0626	Palm hearts (all commodities)	highest utilization: canned/preserved	0	0.8281	1.000	BR	Gen pop, > 10 yrs	28	200.14		100	3	2a	2.81 - 5.13	0 % - 1 %	0 % - 1 %	0 % - 0 %
GC 0648	Quinoa	Total	0.0676		1.000	PRIMO-FI	child 3 yrs	P97.5	75.69		<25	NR	3	0.337	0 %	0 %	0 %
GC 0650	Rye (all commodities)	highest utilization: flakes	0.0676	0	1.000	CA	Child, <6 yrs	1909	539.23		NR	NR	3	0.1 - 2.32	0 % - 0 %	0 % - 0 %	0 % - 0 %
GC 0653	Triticale	Total	0.0676		1.000	PRIMO-UK	child, 4-6 yrs	P97.5	296.20		<25	NR	3	0.977	0 %	0 %	0 %
GC 0654	Wheat (all commodities)	highest utilization: flakes	0 - 0.0676	0	1.000	CA	Child, <6 yrs	1909	539.23		NR	NR	3	0 - 2.32	0 % - 0 %	0 % - 0 %	0 % - 0 %
GC 0640	Barley (all commodities)	highest utilization: flakes	0.0676	0	1.000	CA	Child, <6 yrs	1909	539.23		NR	NR	3	0.01 - 2.32	0 % - 0 %	0 % - 0 %	0 % - 0 %
GC 0641	Buckwheat (all commodities)	highest utilization: flakes	0.0676	0	1.000	CA	Child, <6 yrs	1909	539.23		NR	NR	3	0.04 - 2.32	0 % - 0 %	0 % - 0 %	0 % - 0 %
GC 0647	Oats (all commodities)	highest utilization: flakes (rolled oats)	0.0676	0	1.000	CA	Child, <6 yrs	1909	539.23		NR	NR	3	0.04 - 2.32	0 % - 0 %	0 % - 0 %	0 % - 0 %
GC 0649	Rice (all commodities)	highest utilization: Total	0.0676	0	1.000	CA	Child, <6 yrs	666	461.40		<25	NR	3	0 - 2.04	0 % - 0 %	0 % - 0 %	0 % - 0 %
GC 0655	Wild rice (all commodities)	highest utilization: cooked/boiled	0.0676	0	0.400	CN	Child, 1-6 yrs	129	552.59		<25	NR	3	0.85 - 0.93	0 % - 0 %	0 % - 0 %	0 % - 0 %
GC 0644	Job's tears (all commodities)	highest utilization: cooked/boiled	0.0676	0	0.300	TH	Child, 3-6 yrs	134	85.50		<25	NR	3	0.09 - 0.1	0 % - 0 %	0 % - 0 %	0 % - 0 %
GC 0646	Millet (common millet, proso millet) (all commodities)	highest utilization: Total	0.0676	0	1.000	CN	Child, 1-6 yrs	826	219.53		<25	NR	3	0.05 - 0.92	0 % - 0 %	0 % - 0 %	0 % - 0 %
GC 0651	Sorghum grain (Chicken corn, Dari seed, Durra, Feterita) (all commodities)	highest utilization: cooked/boiled	0.0676	0	0.400	CN	Gen pop, > 1 yrs	356	1348.67		<25	NR	3	0.11 - 0.69	0 % - 0 %	0 % - 0 %	0 % - 0 %
GC 0645	Maize (corn) (all commodities)	highest utilization: flakes	0 - 0.0676	0	1.000	CA	Child, <6 yrs	1909	539.23		NR	NR	3	0 - 2.32	0 % - 0 %	0 % - 0 %	0 % - 0 %

Annex 4

FLUAZAINDOLIZINE (327)

Acute RfD= 1 mg/kg bw (1000 µg/kg bw)

international estimate of short-term intakes
Maximum %ARfD:

9 % 5 % 9 %
all gen pop child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	international estimate of short-term intakes µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
GC 0656	Popcorn (i.e. maize destined for popcorn preparation) (all commodities)	highest utilization: Total	0.0676	0	1.000	AU	Child, 2-6 yrs	120	73.67	<25	NR	3	0.21 - 0.26	0 % - 0 %	0 % - 0 %	0 % - 0 %
GC 3081	Baby corn	Total	0.0676		1.000	PRIMO-UK	toddler	P97.5	90.05	<25	NR	1	ND	-	-	-
GC 0447	Sweet corn (corn-on-the-cob) (kernels plus cob with husks removed) (all commodities)	highest utilization: canned/preserved (kernels)	0.0676	0	1.000	CA	Child, <6 yrs	289	153.76	NR	NR	3	0.06 - 0.67	0 % - 0 %	0 % - 0 %	0 % - 0 %
GC 1275	Sweet corn (whole kernel without cob or husk) (all commodities)	highest utilization: canned/preserved (kernels)	0.0676	0	1.000	CA	Child, <6 yrs	289	153.76	NR	NR	3	0.06 - 0.67	0 % - 0 %	0 % - 0 %	0 % - 0 %
SO 0090	Subgroup of mustard seeds (all commodities)	highest utilization: Total	0.0656	0	1.000	PRIMO-CZ	Child, child, 7-10 yrs	P97.5	32.95	<25	NR	3	0 - 0.07	0 % - 0 %	0 % - 0 %	0 % - 0 %
SO 3140	Borage seeds (all commodities)	highest utilization: raw	0.0656	0	1.000	DE	Gen pop, 14-80 yrs	2	42.00	<25	NR	3	0.03 - 0.04	0 % - 0 %	0 % - 0 %	0 % - 0 %
SO 0693	Linseed (Flax-seed) (all commodities)	highest utilization: Total	0.0656	0	1.000	CA	Gen pop, all ages	291	81.08	<25	NR	3	0.02 - 0.07	0 % - 0 %	0 % - 0 %	0 % - 0 %
SO 0698	Poppy seed (all commodities)	highest utilization: Total	0.0656	0	1.000	PRIMO-DE	women, 14-50 yrs	P97.5	47.23	<25	NR	3	0 - 0.05	0 % - 0 %	0 % - 0 %	0 % - 0 %
SO 0495	Rape seed (Canola) (all commodities)	highest utilization: Oil (refined)	0.0656	0	1.000	CA	Child, <6 yrs	1127	26.46	NR	NR	3	0.06 - 0.11	0 % - 0 %	0 % - 0 %	0 % - 0 %
SO 0700	Sesame seed (all commodities)	highest utilization: butter/paste (nuts/oilseeds)	0.0656	0	1.000	CN	Gen pop, > 1 yrs	174	151.21	NR	NR	3	0.01 - 0.19	0 % - 0 %	0 % - 0 %	0 % - 0 %
SO 0699	Safflower seed (all commodities)	highest utilization: Total	0.0656	0	1.000	PRIMO-DE	child	P95	49.74	<25	NR	3	0 - 0.2	0 % - 0 %	0 % - 0 %	0 % - 0 %
SO 0702	Sunflower seed	highest utilization:	0.0656	0	1.000	CA	women,	121	296.25	<25	NR	3	0.04 - 0.3	0 % - 0 %	0 % - 0 %	0 % - 0 %

Annex 4

FLUAZAINDOUZINE (327)

Acute RfD= 1 mg/kg bw (1000 µg/kg bw)

international estimate of short-term intakes

Maximum %ARfD:

9 % 5 % 9 %
all gen pop child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	international estimate of short-term intakes µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded	
	(all commodities)	Total					15-49 yrs							0 %	0 %	0 %	
SO 0691	Cotton seed (all commodities)	highest utilization: Oil (refined)	0.0656	0	1.000	US	Child, < 6 yrs	6354	3.13		NR	NR	3	0.01 - 0.01	0 % - 0 %	0 % - 0 %	0 % - 0 %
SO 3153	Grape seed (all commodities)	highest utilization: Oil (refined)	0.0656	0	1.000	NL	Child, 2-6 yrs	E	3.81		NR	NR	3	0.01 - 0.01	0 % - 0 %	0 % - 0 %	0 % - 0 %
SO 3154	Hemp seed	Total	0.0656		1.000	PRIMO-FR	Child, 11-14 yrs	P95	4.63		<25	NR	3	0.007	0 %	0 %	0 %
SO 3155	Melon seed (all commodities)	highest utilization: raw (incl roasted)	0.0656	0	1.000	CN	Gen pop, > 1 yrs	128	158.10		<25	NR	3	0 - 0.19	0 % - 0 %	0 % - 0 %	0 % - 0 %
SO 0696	Palm nut (palm kernels) (all commodities)	highest utilization: Total	0.0656	0	1.000	PRIMO-DE	child	P90	27.13		<25	NR	3	0.06 - 0.11	0 % - 0 %	0 % - 0 %	0 % - 0 %
SO 0697	Peanut, shelled (groundnut) (all commodities)	highest utilization: raw incl roasted	0.0656	0	1.000	CN	Child, 1-6 yrs	290	163.07		<25	NR	3	0.04 - 0.66	0 % - 0 %	0 % - 0 %	0 % - 0 %
SO 3156	Pumpkin seed (all commodities)	highest utilization: raw (incl roasted)	0.0656	0	1.000	CN	Gen pop, > 1 yrs	128	158.10		<25	NR	3	0 - 0.19	0 % - 0 %	0 % - 0 %	0 % - 0 %
SO 0305	Olives for oil production (all commodities)	highest utilization: Total	0.0656	0	1.000	PRIMO-ES	child	P97.5	44.15		<25	NR	3	0.01 - 0.08	0 % - 0 %	0 % - 0 %	0 % - 0 %
SO 3160	Palm fruit (African oil palm) (all commodities)	highest utilization: Total	0.0656	0	1.000	PRIMO-DE	Gen pop	P97.5	336.00		NR	NR	3	0.07 - 0.29	0 % - 0 %	0 % - 0 %	0 % - 0 %
MM 0095	Meat from mammals other than marine mammals	Total	NA	NA	1.000	CN	Child, 1-6 yrs	4329	261.46		NR	NR	1	NA	0 %	0 %	0 %
MM 0095	Meat from mammals other than marine mammals: 20 % as fat	Total		0.0431	1.000	CN	Child, 1-6 yrs	4329	52.29		NR	NR	1	0.140	0 %	0 %	0 %
MM 0095	Meat from mammals other than marine mammals: 80 % as	Total		0.0415	1.000	CN	Child, 1-6 yrs	4329	209.17		NR	NR	1	0.538	0 %	0 %	0 %

Annex 4

FLUAZAINDOUZINE (327)

Acute RfD= 1 mg/kg bw (1000 µg/kg bw)

international estimate of short-term intakes
Maximum %ARfD:

9 % 5 % 9 %
all gen pop child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	international estimate of short-term intakes µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded	
	muscle																
MF 0100	Mammalian fats (except milk fats)	Total		0.0431	1.000	PRIMO-UK	infant	P97.5	18.10		NR	NR	1	0.090	0 %	0 %	0 %
MO 0105	Edible offal (mammalian)	Total		0.7592	1.000	ZA	Gen pop, > 10 yrs	-	523.58		NR	NR	1	7.136	1 %	1 %	1 %
ML 0106	Milks	Total	0.0033		1.000	PRIMO-UK	infant	P97.5	1080.70		NR	NR	3	0.410	0 %	0 %	0 %
FM 0812	Cattle milk fat	Total	0.0033		1.000	BR	Gen pop, > 10 yrs	441	150.00		NR	NR	3	0.008	0 %	0 %	0 %
PM 0110	Poultry meat: 10 % as fat	Total		0.00263	1.000	CN	Child, 1-6 yrs	175	34.70		NR	NR	1	0.006	0 %	0 %	0 %
PM 0110	Poultry meat: 90 % as muscle	Total		0.0071	1.000	CN	Child, 1-6 yrs	175	312.30		NR	NR	1	0.137	0 %	0 %	0 %
PF 0111	Poultry, fats	Total		0.00263	1.000	CA	Child, <6 yrs	66	49.38		NR	NR	1	0.008	0 %	0 %	0 %
PO 0111	Poultry, edible offal (includes kidney and liver)	Total		0.1182	1.000	CN	Gen pop, > 1 yrs	421	345.63		NR	NR	1	0.768	0 %	0 %	0 %
PE 0112	Eggs	Total		0.00263	1.000	PRIMO-UK	infant	P97.5	108.00		NR	NR	1	0.033	0 %	0 %	0 %

Annex 4

FLUINDAPYR (328)

Acute RfD= 0.6 mg/kg bw (600 µg/kg bw)

international estimate of short-term intakes
Maximum %ARfD:

1 % 1 % 1 %
all gen pop child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	international estimate of short-term intakes µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
GC 0648	Quinoa	Total	0.074		1.000	PRIMO-FI	child 3 yrs	P97.5	75.69	<25	NR	3	0.368	0 %	0 %	0 %
GC 0650	Rye (all commodities)	highest utilization: flakes	0.074	0	1.000	CA	Child, <6 yrs	1909	539.23	NR	NR	3	0.11 - 2,54	0 % - 0 %	0 % - 0 %	0 % - 0 %
GC 0653	Triticale	Total	0.074		1.000	PRIMO-UK	child, 4-6 yrs	P97.5	296.20	<25	NR	3	1.069	0 %	0 %	0 %
GC 0654	Wheat (all commodities)	highest utilization: flakes	0.026 - 0.92	0	1.000	CA	Child, <6 yrs	1909	539.23	NR	NR	3	0.02 - 2,54	0 % - 0 %	0 % - 0 %	0 % - 0 %
GC 0644	Job's tears (all commodities)	highest utilization: cooked/boiled	0.395	0	0.300	TH	Child, 3-6 yrs	134	85.50	<25	NR	3	0.55 - 0.59	0 % - 0 %	0 % - 0 %	0 % - 0 %
GC 0646	Millet (common millet, proso millet) (all commodities)	highest utilization: Total	0.395	0	1.000	CN	Child, 1-6 yrs	826	219.53	<25	NR	3	0.28 - 5,37	0 % - 1 %	0 % - 1 %	0 % - 1 %
GC 0651	Sorghum grain (Chicken corn, Dari seed, Durra, Feterita) (all commodities)	highest utilization: cooked/boiled	0.17 - 0.395	0	0.400	CN	Gen pop, > 1 yrs	356	1348.67	<25	NR	3	0.27 - 4	0 % - 1 %	1 % - 1 %	0 % - 0 %
GC 0645	Maize (corn) (all commodities)	highest utilization: flakes	0.02 - 0.036	0	1.000	CA	Child, <6 yrs	1909	539.23	NR	NR	3	0.01 - 0.69	0 % - 0 %	0 % - 0 %	0 % - 0 %
GC 0656	Popcorn (i.e. maize destined for popcorn preparation) (all commodities)	highest utilization: Total	0.02	0	1.000	AU	Child, 2-6 yrs	120	73.67	<25	NR	3	0.06 - 0.08	0 % - 0 %	0 % - 0 %	0 % - 0 %
GC 0447	Sweet corn (corn-on-the-cob) (kernels plus cob with husks removed) (all commodities)	highest utilization: cooked/boiled (corn-on-the-cob)	0.02	0.02	1.000	TH	Child, 3-6 yrs	1383	196.99	191	3	2a	0.02 - 0.68	0 % - 0 %	0 % - 0 %	0 % - 0 %
GC 1275	Sweet corn (whole kernel without cob or	highest utilization: canned/preserved	0.02	0.02	1.000	CA	Child, <6 yrs	289	153.76	NR	NR	3	0.02 - 0.2	0 % - 0 %	0 % - 0 %	0 % - 0 %

Annex 4

FLUINDAPYR (328)

Acute RfD= 0.6 mg/kg bw (600 µg/kg bw)

international estimate of short-term intakes
Maximum %ARfD:

1 % all
1 % gen pop
1 % child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	international estimate of short-term intakes µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
	husk) (all commodities)	(kernels)														
TN 0660	Almonds (all commodities)	highest utilization: Total	0.0205	0.034	1.000	CA	Child, <6 yrs	62	63.32	<25	NR	1	0 - 0.13	0 % - 0 %	0 % - 0 %	0 % - 0 %
TN 0662	Brazil nut (all commodities)	highest utilization: Total	0	0.034	1.000	PRIMO-UK	child, 4-6 yrs	P97.5	17.80	<25	NR	1	0.03 - 0.03	0 % - 0 %	0 % - 0 %	0 % - 0 %
TN 0295	Cashew nut (all commodities)	highest utilization: raw incl roasted	0.0205	0.034	1.000	TH	child, 3-6 yrs	374	98.84	<25	NR	1	0.1 - 0.2	0 % - 0 %	0 % - 0 %	0 % - 0 %
TN 0664	Chestnut (all commodities)	highest utilization: Total	0	0.034	1.000	CN	Gen pop, > 1 yrs	807	475.25	<25	NR	1	0.08 - 0.3	0 % - 0 %	0 % - 0 %	0 % - 0 %
TN 0665	Coconut (all commodities)	highest utilization: raw (i.e. nutmeat)	0.0205	0.034	1.000	TH	child, 3-6 yrs	826	423.40	383	3	2a	0.01 - 2,36	0 % - 0 %	0 % - 0 %	0 % - 0 %
TN 0666	Hazelnut (all commodities)	highest utilization: Total	0.0205	0.034	1.000	PRIMO-IE	child	P97.5	65.42	<25	NR	1	0.01 - 0.11	0 % - 0 %	0 % - 0 %	0 % - 0 %
TN 0669	Macadamia nut (all commodities)	highest utilization: Total	0.0205	0.034	1.000	PRIMO-DE	women, 14-50 yrs	P100	141.69	<25	NR	1	0 - 0.07	0 % - 0 %	0 % - 0 %	0 % - 0 %
TN 0672	Pecan (all commodities)	highest utilization: Total	0.0205	0.034	1.000	PRIMO-DE	child	P100	44.41	<25	NR	1	0.02 - 0.09	0 % - 0 %	0 % - 0 %	0 % - 0 %
TN 0673	Pine nut (all commodities)	highest utilization: Total	0	0.034	1.000	BR	Gen pop, > 10 yrs	47	200.00	<25	NR	1	0.02 - 0.11	0 % - 0 %	0 % - 0 %	0 % - 0 %
TN 0675	Pistachio nut (all commodities)	highest utilization: Total	0.0205	0.034	1.000	PRIMO-IE	child	P97.5	115.86	<25	NR	1	0 - 0.2	0 % - 0 %	0 % - 0 %	0 % - 0 %
TN 0678	Walnut (all commodities)	highest utilization: Total	0.0205	0.034	1.000	PRIMO-BE	toddler	P100	60.00	<25	NR	1	0 - 0.11	0 % - 0 %	0 % - 0 %	0 % - 0 %

Annex 4

FLUPYRADIFURONE (285)

Acute RfD= 0.2 mg/kg bw (200 µg/kg bw)

international estimate of short-term intakes

Maximum %ARfD:

8 % 5 % 8 %
all gen pop child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	international estimate of short-term intakes µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
FI 0353	Pineapple (all commodities)	highest utilization: raw without peel	0.044 - 0.13	0.19	1.000	JP	Child, 1-6 yrs	67	499.80	1116	3	2b	0.03 - 16.76	0 % - 8 %	0 % - 5 %	0 % - 8 %
SO 0700	Sesame seed (all commodities)	highest utilization: butter/paste (nuts/oilseeds)	0.13 - 1	0	1.000	CN	Gen pop, > 1 yrs	174	151.21	NR	NR	3	0.08 - 2.84	0 % - 1 %	0 % - 1 %	0 % - 1 %
SO 0699	Safflower seed (all commodities)	highest utilization: Total	0.31	0	1.000	PRIMO-DE	child	P95	49.74	<25	NR	3	0 - 0.95	0 % - 0 %	0 % - 0 %	0 % - 0 %
SO 0702	Sunflower seed (all commodities)	highest utilization: Total	0.31	0	1.000	CA	women, 15-49 yrs	121	296.25	<25	NR	3	0.17 - 1.44	0 % - 1 %	0 % - 1 %	0 % - 0 %

FLUTRIAFOL (248)

Acute RfD= 0.05 mg/kg bw (50 µg/kg bw)

international estimate of short-term intakes

Maximum %ARfD:

80 % 40 % 80 %
all gen pop child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	international estimate of short-term intakes µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
GC 0640	Barley (all commodities)	highest utilization: beer	0.17 - 0.2	0	0.190	CA	Gen pop, all ages	2514	21271.20	NR	NR	3	0.02 - 10.27	0 % - 20 %	0 % - 20 %	0 % - 10 %
GC 0649	Rice (all commodities)	highest utilization: Total	0.36 - 1.25	0	1.000	CA	Child, <6 yrs	666	461.40	<25	NR	3	0.07 - 37.75	0 % - 80 %	0 % - 40 %	0 % - 80 %
TN 0660	Almonds (all commodities)	highest utilization: Total	0.064	0.42	1.000	CA	Child, <6 yrs	62	63.32	<25	NR	1	0 - 1.65	0 % - 3 %	0 % - 1 %	0 % - 3 %
PF 0111	Poultry, fats	Total		0.025	1.000	CA	Child, <6 yrs	66	49.38	NR	NR	1	0.073	0 %	0 %	0 %
PO 0111	Poultry, edible offal	Total		0.036	1.000	CN	Gen pop, >	421	345.63	NR	NR	1	0.234	0 %	0 %	0 %

Annex 4

FLUTRIAFOL (248)

Acute RfD= 0.05 mg/kg bw (50 µg/kg bw)

international estimate of short-term intakes
Maximum %ARfD:

80 % 40 % 80 %
all gen pop child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	international estimate of short-term intakes µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded	
	(includes kidney, liver and skin)						1 yrs										
PE 0112	Eggs	Total		0.011	1.000	PRIMO-UK	infant	P97.5	108.00		NR	NR	1	0.137	0 %	0 %	0 %

INDOXACARB (216)

Acute RfD= 0.1 mg/kg bw (100 µg/kg bw)

INTERNATIONAL ESTIMATE OF SHORT-TERM INTAKES

Maximum %ARfD:

20 % 10 % 20 %
all gen pop child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	international estimate of short-term intakes µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
FB 0020	Blueberries (all commodities)	highest utilization: Total	0.58	1.04	1.000	CA	Child, <6 yrs	189	176.21	<25	NR	1	0.08 - 11.9	0 % - 10 %	0 % - 9 %	0 % - 10 %
FB 0021	Currants, black, red, white (all commodities)	highest utilization: juice (pasteurised)	0.58	1.04	1.000	PRIMO-NL	child	E	525.80	NR	NR	3	0.38 - 16.57	0 % - 20 %	0 % - 10 %	0 % - 20 %
FB 0268	Gooseberry (all commodities)	highest utilization: Total	0.58	1.04	1.000	PRIMO-DE	child	P100	94.96	<25	NR	1	0.11 - 6.12	0 % - 6 %	0 % - 5 %	0 % - 6 %
FB 0273	Rose hips (all commodities)	highest utilization: jam (incl jelly)	0.58	1.04	1.000	CA	Child, <6 yrs	443	78.10	NR	NR	3	0.37 - 2.95	0 % - 3 %	0 % - 2 %	0 % - 3 %
VP 0061	Beans with pods (Phaseolus spp): (immature pods + succulent seeds) (all commodities)	highest utilization: Total	0.16	0.59	1.000	CA	Child, <6 yrs	261	203.31	<25	NR	1	0.24 - 7.97	0 % - 8 %	0 % - 5 %	0 % - 8 %
VP 0522	Broad bean with pods (immature pods)	highest utilization: Total	0	0.59	1.000	PRIMO-NL	toddler	E	116.60	<25	NR	1	1.63 - 6.74	2 % - 7 %	2 % - 5 %	0 % - 7 %

Annex 4

INDOXACARB (216)

INTERNATIONAL ESTIMATE OF SHORT-TERM INTAKES

Acute RfD= 0.1 mg/kg bw (100 µg/kg bw)

Maximum %ARFD:

20 % 10 % 20 %
all gen pop child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	international estimate of short-term intakes µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
	+ succulent seeds) (Vicia spp) (all commodities)															
VP 0542	Sword bean with pods (immature pods + succulent seeds) (Canavalia spp) (all commodities)	highest utilization: cooked/boiled	0	0.59	1.000	CN	Gen pop, > 1 yrs	891	316.83	<25	NR	1	3.51 - 3.51	4 % - 4 %	4 % - 4 %	0 % - 0 %
VD 0071	Beans (dry) (Phaseolus spp) (all commodities)	highest utilization: Total	0.01	0	1.000	PRIMO-UK	infant	P97.5	159.00	<25	NR	3	0.02 - 0.18	0 % - 0 %	0 % - 0 %	0 % - 0 %
VD 0523	Broad bean (dry) (Vicia spp) (all commodities)	highest utilization: Total	0.01	0	1.000	PRIMO-UK	infant	P97.5	159.00	<25	NR	3	0.01 - 0.18	0 % - 0 %	0 % - 0 %	0 % - 0 %
VD 0531	Lablab bean (dry) (Lablab spp) (all commodities)	highest utilization: Total	0.01	0	1.000	PRIMO-UK	infant	P97.5	159.00	<25	NR	3	0.07 - 0.18	0 % - 0 %	0 % - 0 %	0 % - 0 %
VR 0574	Beetroot (all commodities)	highest utilization: Total	0.18	0.22	1.000	AU	Child, 2-6 yrs	53	314.08	135	3	2a	0.11 - 6.77	0 % - 7 %	0 % - 2 %	0 % - 7 %
GC 0645	Maize (corn) (all commodities)	highest utilization: flakes	0.01 - 0.019	0	1.000	CA	Child, <6 yrs	1909	539.23	NR	NR	3	0.01 - 0.34	0 % - 0 %	0 % - 0 %	0 % - 0 %
GC 0656	Popcorn (i.e. maize destined for popcorn preparation) (all commodities)	highest utilization: Total	0.01	0	1.000	AU	Child, 2-6 yrs	120	73.67	<25	NR	3	0.03 - 0.04	0 % - 0 %	0 % - 0 %	0 % - 0 %
TN 0660	Almonds (all commodities)	highest utilization: Total	0.013	0.046	1.000	CA	Child, <6 yrs	62	63.32	<25	NR	1	0 - 0.18	0 % - 0 %	0 % - 0 %	0 % - 0 %
TN 0662	Brazil nut (all commodities)	highest utilization: Total	0	0.046	1.000	PRIMO-UK	child, 4-6 yrs	P97.5	17.80	<25	NR	1	0.03 - 0.04	0 % - 0 %	0 % - 0 %	0 % - 0 %
TN 0295	Cashew nut (all commodities)	highest utilization: raw incl roasted	0.013	0.046	1.000	TH	child, 3-6 yrs	374	98.84	<25	NR	1	0.13 - 0.27	0 % - 0 %	0 % - 0 %	0 % - 0 %
TN	Chestnut	highest utilization:	0	0.046	1.000	CN	Gen pop, >	807	475.25	<25	NR	1	0.11 - 0.41	0 % - 0 %	0 % - 0 %	0 % - 0 %

Annex 4

INDOXACARB (216)

INTERNATIONAL ESTIMATE OF SHORT-TERM INTAKES

Acute RfD= 0.1 mg/kg bw (100 µg/kg bw)

Maximum %ARFD:

20 % 10 % 20 %
all gen pop child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	international estimate of short-term intakes µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
0664	(all commodities)	Total					1 yrs							0 %	0 %	0 %
TN 0665	Coconut (all commodities)	highest utilization: raw (i.e. nutmeat)	0.013	0.046	1.000	TH	child, 3-6 yrs	826	423.40	383	3	2a	0.01 - 3.2	0 % - 3 %	0 % - 1 %	0 % - 3 %
TN 0666	Hazelnut (all commodities)	highest utilization: Total	0.013	0.046	1.000	PRIMO-IE	child	P97.5	65.42	<25	NR	1	0.01 - 0.15	0 % - 0 %	0 % - 0 %	0 % - 0 %
TN 0669	Macadamia nut (all commodities)	highest utilization: Total	0.013	0.046	1.000	PRIMO-DE	women, 14-50 yrs	P100	141.69	<25	NR	1	0 - 0.1	0 % - 0 %	0 % - 0 %	0 % - 0 %
TN 0672	Pecan (all commodities)	highest utilization: Total	0.013	0.046	1.000	PRIMO-DE	child	P100	44.41	<25	NR	1	0.03 - 0.13	0 % - 0 %	0 % - 0 %	0 % - 0 %
TN 0673	Pine nut (all commodities)	highest utilization: Total	0	0.046	1.000	BR	Gen pop, > 10 yrs	47	200.00	<25	NR	1	0.03 - 0.14	0 % - 0 %	0 % - 0 %	0 % - 0 %
TN 0675	Pistachio nut (all commodities)	highest utilization: Total	0.013	0.046	1.000	PRIMO-IE	child	P97.5	115.86	<25	NR	1	0 - 0.27	0 % - 0 %	0 % - 0 %	0 % - 0 %
TN 0678	Walnut (all commodities)	highest utilization: Total	0.013	0.046	1.000	PRIMO-BE	toddler	P100	60.00	<25	NR	1	0 - 0.16	0 % - 0 %	0 % - 0 %	0 % - 0 %
MM 0095	Meat from mammals other than marine mammals	Total	NA	NA	1.000	CN	Child, 1-6 yrs	4329	261.46	NR	NR	1	NA	10 %	9 %	10 %
MM 0095	Meat from mammals other than marine mammals: 20 % as fat	Total		1.9	1.000	CN	Child, 1-6 yrs	4329	52.29	NR	NR	1	6.157	6 %	4 %	6 %
MM 0095	Meat from mammals other than marine mammals: 80 % as muscle	Total		0.46	1.000	CN	Child, 1-6 yrs	4329	209.17	NR	NR	1	5.963	6 %	4 %	6 %
MF 0100	Mammalian fats (except milk fats)	Total		1.9	1.000	PRIMO-UK	infant	P97.5	18.10	NR	NR	1	3.953	4 %	4 %	4 %
MO 0105	Edible offal (mammalian)	Total		0.06	1.000	ZA	Gen pop, > 10 yrs	-	523.58	NR	NR	1	0.564	1 %	1 %	0 %
ML 0106	Milks	Total	0.07		1.000	PRIMO-UK	infant	P97.5	1080.70	NR	NR	3	8.695	9 %	3 %	9 %

Annex 4

INDOXACARB (216)

INTERNATIONAL ESTIMATE OF SHORT-TERM INTAKES

Acute RfD= 0.1 mg/kg bw (100 µg/kg bw)

Maximum %ARFD:

20 % 10 % 20 %
all gen pop child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	international estimate of short-term intakes µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
FM 0812	Cattle milk fat	Total	1.7		1.000	BR	Gen pop, > 10 yrs	441	150.00	NR	NR	3	3.950	4 %	4 %	4 %

INPYRFLUXAM (329)

INTERNATIONAL ESTIMATE OF SHORT-TERM INTAKES

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

Maximum %ARFD:

40 % 10 % 40 %
all gen pop child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	international estimate of short-term intakes µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
FP 0226	Apple (all commodities)	highest utilization: raw with peel (incl consumption without peel)	0.11 - 0.91	1,88	1.000	CN	Child, 1-6 yrs	1314	403.39	255	3	2a	4,62 - 106,42	2 % - 40 %	1 % - 10 %	2 % - 40 %
VD 0541	Soya bean (dry) (Glycine spp) (all commodities)	highest utilization: Total	0	0	1.000	CN	Child, 1-6 yrs	179	239.05	<25	NR	3	0 - 0	0 % - 0 %	0 % - 0 %	0 % - 0 %
VR 0596	Sugar beet (all commodities)	highest utilization: sugar	0	0	1.000	PRIMO-NL	child	P97.5	168.90	NR	NR	3	0 - 0	0 % - 0 %	0 % - 0 %	0 % - 0 %
GC 0649	Rice (all commodities)	highest utilization: Total	0	0	1.000	CA	Child, <6 yrs	666	461.40	<25	NR	3	0 - 0	0 % - 0 %	0 % - 0 %	0 % - 0 %
GC 0645	Maize (corn) (all commodities)	highest utilization: flakes	0	0	1.000	CA	Child, <6 yrs	1909	539.23	NR	NR	3	0 - 0	0 % - 0 %	0 % - 0 %	0 % - 0 %
GC 0656	Popcorn (i.e. maize destined for	highest utilization: Total	0	0	1.000	AU	Child, 2-6 yrs	120	73.67	<25	NR	3	0 - 0	0 % - 0 %	0 % - 0 %	0 % - 0 %

INPYRFLUXAM (329)

INTERNATIONAL ESTIMATE OF SHORT-TERM INTAKES

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

Maximum %ARFD:

40 % 10 % 40 %
all gen pop child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population n group	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	international estimate of short-term intakes µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded	
	popcorn preparation (all commodities)															
GC 0447	Sweet corn (corn-on-the-cob) (kernels plus cob with husks removed) (all commodities)	highest utilization: Total	0	0	1.000	AU	Child, 2-6 yrs	629	140.48	177	3	2b	0 - 0	0 % - 0 %	0 % - 0 %	0 % - 0 %
SO 0697	Peanut, shelled (groundnut) (all commodities)	highest utilization: raw incl roasted	0.01	0	1.000	CN	Child, 1-6 yrs	290	163.07	<25	NR	3	0.01 - 0.1	0 % - 0 %	0 % - 0 %	0 % - 0 %
MM 0095	Meat from mammals other than marine mammals	Total	NA	NA	1.000	CN	Child, 1-6 yrs	4329	261.46	NR	NR	1	NA	0 %	0 %	0 %
MM 0095	Meat from mammals other than marine mammals: 20 % as fat	Total		0	1.000	CN	Child, 1-6 yrs	4329	52.29	NR	NR	1	0.000	0 %	0 %	0 %
MM 0095	Meat from mammals other than marine mammals: 80 % as muscle	Total		0	1.000	CN	Child, 1-6 yrs	4329	209.17	NR	NR	1	0.000	0 %	0 %	0 %
MF 0100	Mammalian fats (except milk fats)	Total		0	1.000	PRIMO-UK	infant	P97.5	18.10	NR	NR	1	0.000	0 %	0 %	0 %
MO 0105	Edible offal (mammalian)	Total		0	1.000	ZA	Gen pop, > 10 yrs	-	523.58	NR	NR	1	0.000	0 %	0 %	0 %
ML 0106	Milks	Total	0		1.000	PRIMO-UK	infant	P97.5	1080.70	NR	NR	3	0.000	0 %	0 %	0 %

Annex 4

INPYRFLUXAM (329)

INTERNATIONAL ESTIMATE OF SHORT-TERM INTAKES

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

Maximum %ARFD:

40 % 10 % 40 %
all gen pop child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country Population n group			Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	international estimate of short-term intakes µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
						Country	Population	n group								
PM 0110	Poultry meat	Total	NA	NA	1.000	CN	Child, 1-6 yrs	175	347.00	NR	1	NA	0 %	0 %	0 %	
PM 0110	Poultry meat: 10 % as fat	Total		0	1.000	CN	Child, 1-6 yrs	175	34.70	NR	1	0.000	0 %	0 %	0 %	
PM 0110	Poultry meat: 90 % as muscle	Total		0	1.000	CN	Child, 1-6 yrs	175	312.30	NR	1	0.000	0 %	0 %	0 %	
PF 0111	Poultry, fats	Total		0	1.000	CA	Child, <6 yrs	66	49.38	NR	1	0.000	0 %	0 %	0 %	
PO 0111	Poultry, edible offal (includes kidney and liver)	Total		0	1.000	CN	Gen pop, > 1 yrs	421	345.63	NR	1	0.000	0 %	0 %	0 %	
PE 0112	Eggs	Total		0	1.000	PRIMO-UK	infant	P97.5	108.00	NR	1	0.000	0 %	0 %	0 %	

MEFENTRIFLUCONAZOLE (320)

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

international estimate of short-term
intakes

Maximum %ARfD:

370 % 140 % 370 %
all gen child
pop

Code x Code	Commodity	Processing	STMR or STMR- P mg/kg	HR or HR-P mg/k g	DCF	Coun try	Populatio n group	n	Large portion, g/perso n	Unit weight, edible portion, g	Varia - bility facto r	Cas e	internation al estimate of short- term intakes µg/kg bw/day	% acute RfD rounde d	% acute RfD rounde d	% acute RfD rounde d
FC 0303	Kumquats (all commodities)	highest utilization: Total	0	0,98	1.00 0	JP	Gen pop, > 1 yrs	135	120.00	<25	NR	1	0,18 - 2,34	0 % - 1 %	0 % - 1 %	1 % - 1 %
FC 0204	Lemon (all commodities)	highest utilization: Total	0,007 - 0,37	0,02 - 0,98	1.00 0	PRIMO -DE	child	P95	125.50	71	3	2a	0,01 - 16,27	0 % - 5 %	0 % - 2 %	0 % - 5 %
FC 0205	Lime (all commodities)	highest utilization: Total	0,007 - 0,37	0,98	1.00 0	AU	Gen pop, > 2 yrs	579	259.21	49	3	2a	0,01 - 5,22	0 % - 2 %	0 % - 2 %	0 % - 3 %
FC 0003	Subgroup of Mandarins (incl mandarin- like hybrids) (all commodities)	highest utilization: Total	0,007 - 0,37	0,02 - 0,98	1.00 0	CA	Child, <6 yrs	84	316.63	124	3	2a	0,08 - 34,99	0 % - 10 %	0 % - 4 %	0 % - 10 %
FC 0004	Subgroup of Oranges, sweet, sour (incl orange- like hybrids) (all commodities)	highest utilization: Total	0,007 - 0,215	0,02 - 0,7	1.00 0	AU	Child, 2-6 yrs	1735	800.83	156	3	2a	0,14 - 40,98	0 % - 10 %	0 % - 8 %	0 % - 10 %
FC 0005	Subgroup of Pummelo and Grapefruits (incl Shaddock-like hybrids, among others	highest utilization: Total	0,007 - 0,16	0,02 - 0,24	1.00 0	PRIMO -DE	child	P90	253.56	270	3	2b	0,03 - 11,3	0 % - 4 %	0 % - 2 %	0 % - 4 %

Annex 4

MEFENTRIFLUCONAZOLE (320)

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

international estimate of short-term intakes

Maximum %ARfD:

370 % all gen pop 140 % 370 % child

Code x Code	Commodity	Processing	STMR or STMR- P mg/kg	HR or HR-P mg/kg	DCF	Coun try	Populatio n group	Large portion, g/person	Unit weight, edible portion, g	Varia- - bility facto r	Cas e	internation al estimate of short- term intakes µg/kg bw/day	% acute RfD rounde d	% acute RfD rounde d	% acute RfD rounde d	
	Grapefruit) (all commodities)															
FP 0226	Apple (all commodities)	highest utilization: raw with peel (incl consumption without peel)	0,043 - 0,39	0,35 - 1,12	1.00 0	CN	Child, 1-6 yrs	1314	403.39	255	3	2a	0,45 - 63,4	0 % - 20 %	0 % - 8 %	0 % - 20 %
FP 2220	Azarole (Mediterranean medlar) (all commodities)	highest utilization: Total	0,051	1,12	1.00 0	PRIMO -DE	child	P95	14.54	<25	NR	1	0,28 - 1,01	0 % - 0 %	0 % - 0 %	0 % - 0 %
FP 0227	Crab-apple (all commodities)	highest utilization: Total	0	1,12	1.00 0	PRIMO -NL	toddler	P97. 5	209.40	<25	NR	1	10,28 - 22,99	3 % - 8 %	3 % - 4 %	8 % - 8 %
FP 0228	Loquat (Japanese medlar) (all commodities)	highest utilization: raw without peel	0	1,12	1.00 0	JP	Gen pop, > 1 yrs	113	326.40	49	3	2a	1,98 - 8,77	1 % - 3 %	1 % - 3 %	0 % - 0 %
FP 0229	Medlar (all commodities)	highest utilization: Total	0	1,12	1.00 0	PRIMO -ES	child	P97. 5	116.99	60	3	2a	7,7 - 7,7	3 % - 3 %	1 % - 1 %	3 % - 3 %
FP 0230	Pear (all commodities)	highest utilization: Total	0,043 - 0,39	0,35 - 1,12	1.00 0	CA	Child, <6 yrs	175	498.28	255	3	2a	0,05 - 77,58	0 % - 30 %	0 % - 8 %	0 % - 30 %
FP 0231	Quince (all commodities)	highest utilization:	0,39	1,12	1.00 0	PRIMO -ES	child	P97. 5	169.60	301	3	2b	0,01 - 16,53	0 % - 6 %	0 % - 3 %	0 % - 6 %

Annex 4

MEFENTRIFLUCONAZOLE (320)

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

international estimate of short-term intakes

Maximum %ARfD:

370 % all gen pop 140 % acute RfD rounded 370 % child

Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	Population	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	international estimate of short-term intakes µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
	commodities)	Total														
FS 0013	Subgroup of Cherries (all commodities)	highest utilization: Total	1,1	2,4	1.000	PRIMO -DK	child	P97.5	269.00	<25	NR	1	0,45 - 29,35	0 % - 10 %	0 % - 9 %	0 % - 10 %
FS 0014	Subgroup of Plums (all commodities)	highest utilization: dried (prunes)	0,039 - 1,1	1 - 4,1	1.000	AU	Child, 2-6 yrs	13	447.59	10	NR	1	0,12 - 96,58	0 % - 30 %	0 % - 10 %	0 % - 30 %
FS 0302	Jujube, Chinese	Total		1	1.000	PRIMO -DE	women, 14-50 yrs	P97.5	879.13	15	NR	1	13.030	4 %	4 %	3 %
FS 0240	Apricot (all commodities)	highest utilization: Total	0,56	1,04	1.000	PRIMO -DE	child	P95	264.86	50	3	2a	0,24 - 23,5	0 % - 8 %	0 % - 6 %	0 % - 8 %
FS 2237	Japanese apricot (ume)	Total		1.04	1.000	JP	Child, 1-6 yrs	25	25.50	<25	NR	1	1.465	0 %	0 %	0 %
FS 0245	Nectarine (all commodities)	highest utilization: raw with peel (incl consumption without peel)	0,56	1,04	1.000	NL	toddler, 8-20 m	6	183.60	131	3	2a	0,23 - 45,42	0 % - 20 %	0 % - 4 %	0 % - 20 %
FS 0247	Peach (all commodities)	highest utilization: raw with peel (incl consumption without peel)	0,56	1,04	1.000	JP	Child, 1-6 yrs	76	306.00	255	3	2a	0,23 - 54,75	0 % - 20 %	0 % - 7 %	0 % - 20 %
FB 0264	Blackberries (all)	highest utilization:	0,96	1,62	1.000	PRIMO -UK	toddler	P97.5	155.40	<25	NR	1	0,17 - 17,36	0 % - 6 %	0 % - 4 %	0 % - 6 %

Annex 4

MEFENTRIFLUCONAZOLE (320)

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

international estimate of short-term intakes

Maximum %ARfD:

370 % all gen pop 140 % child 370 %

Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	international estimate of short-term intakes µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded	
	commodities)	Total														
FB 0266	Dewberries (incl Boysenberry, Loganberry) (all commodities)	highest utilization: Total	0	1,62	1.000	PRIMO-UK	toddler	P97.5	25.50	<25	NR	1	2,85 - 2,85	1 % - 1 %	1 % - 1 %	1 % - 1 %
FB 0272	Raspberries, red, black (all commodities)	highest utilization: Total	0,96	1,62	1.000	PRIMO-IE	child	P97.5	184.76	<25	NR	1	0,53 - 14,97	0 % - 5 %	0 % - 3 %	0 % - 5 %
FB 0020	Blueberries (all commodities)	highest utilization: Total	0,58	3,2	1.000	CA	Child, <6 yrs	189	176.21	<25	NR	1	0,08 - 36,63	0 % - 10 %	0 % - 10 %	0 % - 10 %
FB 0021	Currants, black, red, white (all commodities)	highest utilization: Total	0,58	3,2	1.000	AU	Gen pop, > 2 yrs	322	797.60	<25	NR	1	0,38 - 38,09	0 % - 10 %	0 % - 10 %	0 % - 10 %
FB 0268	Gooseberry (all commodities)	highest utilization: Total	0,58	3,2	1.000	PRIMO-DE	child	P100	94.96	<25	NR	1	0,11 - 18,82	0 % - 6 %	0 % - 5 %	0 % - 6 %
FB 0273	Rose hips (all commodities)	highest utilization: Total	0,58	3,2	1.000	PRIMO-FI	women	P97.5	156.60	<25	NR	1	0,37 - 7,04	0 % - 2 %	0 % - 2 %	0 % - 1 %
FB 0267	Elderberries (all commodities)	highest utilization: Total	0,58	3,2	1.000	CN	Gen pop, > 1 yrs	136	420.22	29	3	2a	0,4 - 28,75	0 % - 10 %	0 % - 10 %	0 % - 3 %
FB 1236	Wine grapes (all)	highest utilization: Total	0,011 - 0,54	0	1.000	PRIMO-UK	adult	P97.5	1802.62	NR	NR	3	0,16 - 12,81	0 % - 4 %	0 % - 4 %	0 % - 2 %

MEFENTRIFLUCONAZOLE (320)

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

international estimate of short-term intakes

Maximum %ARfD:

370 % all gen 140 % pop 370 % child

Code x Code	Commodity	Processing	STMR or STMR- P mg/kg	HR or HR-P mg/kg	DCF	Coun- try	Populatio- n group	Large portion, g/person	Unit weight, edible portion, g	Varia- - bility facto- r	Cas- e	internation- al estimate of short- term intakes µg/kg bw/day	% acute RfD rounde- d	% acute RfD rounde- d	% acute RfD rounde- d	
	commodities)	Total														
FB 0265	Cranberry (all commodities)	highest utilization: Total	0,12 - 0,29	1,1	1.00 0	AU	Child, 2- 16 yrs	103	279.66	<25	NR	1	0 - 8,1	0 % - 3 %	0 % - 1 %	0 % - 3 %
FB 0275	Strawberry (all commodities)	highest utilization: Raw with skin	0,12 - 0,29	1,1	1.00 0	NL	toddler, 8-20 m	52	166.73	18	NR	1	0,16 - 17,98	0 % - 6 %	0 % - 3 %	0 % - 6 %
FI 0326	Avocado (all commodities)	highest utilization: Total	0	0,5	1.00 0	AU	Child, 2-6 yrs	182	229.90	171	3	2a	7,7 - 15,07	3 % - 5 %	2 % - 3 %	2 % - 5 %
FI 0327	Banana (incl Dwarf banana & Plantain) (all commodities)	highest utilization: raw without peel	0,055	0,21	1.00 0	CN	Child, 1-6 yrs	286	455.81	767	3	2b	0,03 - 17,8	0 % - 6 %	0 % - 3 %	0 % - 6 %
FI 0345	Mango (all commodities)	highest utilization: raw without peel	0,01	0,01	1.00 0	NL	toddler, 8-20 m	11	160.43	289	3	2b	0 - 0,47	0 % - 0 %	0 % - 0 %	0 % - 0 %
FI 0350	Papaya (all commodities)	highest utilization: Total	0,07	0,22	1.00 0	US	Child, < 6 yrs	86	167.57	204	3	2b	0,12 - 7,63	0 % - 3 %	0 % - 2 %	0 % - 3 %
VA 0381	Garlic (all commodities)	highest utilization: raw without skin	0,05	0,14	1.00 0	CN	Child, 1-6 yrs	290	174.44	62	3	2a	0 - 2,59	0 % - 1 %	0 % - 0 %	0 % - 1 %
VA 0385	Onion, bulb (all commodities)	highest utilization: raw without skin	0,05	0,14	1.00 0	JP	Child, 1-6 yrs	748	102.00	244	3	2b	0,02 - 2,61	0 % - 1 %	0 % - 0 %	0 % - 1 %

Annex 4

MEFENTRIFLUCONAZOLE (320)

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

international estimate of short-term intakes
Maximum %ARfD:

370 % all gen pop
140 % acute RfD
370 % acute RfD child

Code x Code	Commodity	Processing	STMR or STMR- P mg/kg	HR or HR-P mg/k g	DCF	Coun try	Populatio n group	n	Large portion, g/person	Unit weight, edible portion, g	Vari- - bility facto r	Cas e	internation al estimate of short- term intakes µg/kg bw/day	% acute RfD rounde d	% acute RfD rounde d	% acute RfD rounde d
VA 0386	Onion, Chinese (all commodities)	highest utilization: raw	0	0,14	1.00 0	CN	Child, 1-6 yrs	196	136.53	130	3	2a	1,36 - 3,43	0 % - 1 %	0 % - 0 %	0 % - 1 %
VA 0388	Shallot (all commodities)	highest utilization: raw without skin	0,05	0,14	1.00 0	CN	Child, 1-6 yrs	480	115.81	51	3	2a	0,04 - 1,9	0 % - 1 %	0 % - 0 %	0 % - 1 %
VA 2605	Chives (all commodities)	highest utilization: Total	0	2,2	1.00 0	PRIMO -CZ	Child, child, 7- 10 yrs	P97. 5	26.49	<25	NR	1	0,42 - 1,8	0 % - 1 %	0 % - 0 %	0 % - 1 %
VA 0384	Leek (all commodities)	highest utilization: raw	0,39	2,2	1.00 0	CN	Child, 1-6 yrs	401	149.40	176	3	2b	0,04 - 61,11	0 % - 20 %	0 % - 9 %	0 % - 20 %
VA 0387	Onion, Welsh (Japanese bunching onion, Multiplying onion) (all commodities)	highest utilization: Total	0	2,2	1.00 0	PRIMO -UK	child, 4-6 yrs	P97. 5	93.60	38	3	2a	13,86 - 18,2	5 % - 6 %	2 % - 3 %	5 % - 6 %
VA 0389	Spring onion (all commodities)	highest utilization: Total	0	2,2	1.00 0	PRIMO -UK	child, 4-6 yrs	P97. 5	93.60	38	3	2a	6,8 - 18,2	2 % - 6 %	1 % - 2 %	2 % - 6 %
VC 0421	Bitter melon (Balsam pear, Bitter cucumber, Bitter gourd) (all	highest utilization: raw without peel	0	0,12	1.00 0	CN	Gen pop, > 1 yrs	1387	400.21	608	3	2b	0,87 - 2,71	0 % - 1 %	0 % - 1 %	0 % - 1 %

Annex 4

MEFENTRIFLUCONAZOLE (320)

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

international estimate of short-term intakes

Maximum %ARfD:

370 % all gen pop 140 % child 370 %

Code x Code	Commodity	Processing	STMR or STMR- P mg/kg	HR or HR-P mg/kg	DCF	Coun try	Populatio n group	n	Large portion, g/person	Unit weight, edible portion, g	Varia - bility facto r	Cas e	internation al estimate of short- term intakes µg/kg bw/day	% acute RfD rounde d	% acute RfD rounde d	% acute RfD rounde d
	commodities)															
VC 0422	Bottle gourd (Cucuzzi) (all commodities)	highest utilization: raw with skin	0	0,12	1.00 0	CN	Gen pop, > 1 yrs	519	453.00	325	3	2a	2,39 - 2,49	1 % - 1 %	0 % - 1 %	1 % - 1 %
VC 0423	Chayote (Christophine) (all commodities)	highest utilization: raw with skin	0	0,12	1.00 0	CN	Child, 1-6 yrs	124	284.75	197	3	2a	4,1 - 5,05	1 % - 2 %	1 % - 1 %	1 % - 2 %
VC 0424	Cucumber (all commodities)	highest utilization: raw with skin	0,035	0,12	1.00 0	CN	Child, 1-6 yrs	340	212.11	458	3	2b	0,01 - 4,73	0 % - 2 %	0 % - 1 %	0 % - 2 %
VC 0425	Gherkin (all commodities)	highest utilization: raw with skin	0,035	0,088 - 0,12	1.00 0	JP	Child, 1-6 yrs	484	91.80	55	3	2a	0,03 - 1,43	0 % - 0 %	0 % - 0 %	0 % - 0 %
VC 0427	Loofah, Angled (Sinkwa, Sinkwa towel gourd) (all commodities)	highest utilization: raw without peel	0	0,12	1.00 0	TH	Child, 3-6 yrs	759	129.62	133	3	2b	2,39 - 2,73	1 % - 1 %	0 % - 0 %	1 % - 1 %
VC 0428	Loofah, Smooth (all commodities)	highest utilization: raw without peel	0	0,12	1.00 0	CN	Child, 1-6 yrs	196	296.64	133	3	2a	4,18 - 4,18	1 % - 1 %	1 % - 1 %	1 % - 1 %
VC 0430	Snake gourd (all commodities)	highest utilization: raw without peel	0	0,12	1.00 0	TH	Child, 3-6 yrs	759	129.62	133	3	2b	2,39 - 2,73	1 % - 1 %	0 % - 0 %	1 % - 1 %
VC	Squash,	highest	0,035	0,12	1.00	US	Child, < 6	252	149.52	186	3	2b	0,02 - 3,71	0 % -	0 % -	0 % -

Annex 4

MEFENTRIFLUCONAZOLE (320)

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

international estimate of short-term intakes

Maximum %ARfD:

370 % all gen pop 140 % child 370 %

Code x Code	Commodity	Processing	STMR or STMR- P mg/kg	HR or HR-P mg/k g	DCF	Coun try	Populatio n group	Large portion, g/perso n	Unit weight, edible portion, g	Vari - bility facto r	Cas e	internation al estimate of short- term intakes µg/kg bw/day	% acute RfD rounde d	% acute RfD rounde d	% acute RfD rounde d	
0431	Summer (Courgette, Marrow, Zucchini, Zucchini) (all commodities)	utilization: Total			0		yrs						1 %	1 %	1 %	
VC 0046	Melons, except watermelon (Cantaloupe) (all commodities)	highest utilization: Total	0,15	0,23	1.00 0	PRIMO -BE	toddler	P100	540.00	540	3	2b	0,01 - 20,93	0 % - 7 %	0 % - 4 %	0 % - 7 %
VC 0429	Pumpkins (all commodities)	highest utilization: raw without peel	0,15	0,23	1.00 0	CN	Child, 1-6 yrs	561	322.71	1852	3	2b	0,24 - 13,8	0 % - 5 %	0 % - 3 %	0 % - 5 %
VC 0432	Watermelon (all commodities)	highest utilization: Total	0,15	0,23	1.00 0	CA	Child, <6 yrs	171	953.64	4302	3	2b	19,85 - 42,65	7 % - 10 %	7 % - 10 %	7 % - 10 %
VO 2704	Goji berry (all commodities)	highest utilization: Dried	0	0,45	3.00 0	AU	Child, 2-6 yrs	1	28.36	<25	NR	1	0,43 - 2,01	0 % - 1 %	0 % - 0 %	0 % - 1 %
VO 0448	Tomato (all commodities)	highest utilization: raw with peel	0,0084 - 0,14	0,027 - 4,1	1.00 0	CN	Child, 1-6 yrs	1117	263.76	175	3	2a	0,09 - 17,09	0 % - 6 %	0 % - 2 %	0 % - 6 %
VO 0444	Peppers, chili (all commodities)	highest utilization: raw with skin	0,25	0,84 - 8,4	1.00 0	CN	Gen pop, > 1 yrs	1743	295.71	43	3	2a	0,01 - 6,03	0 % - 2 %	0 % - 2 %	0 % - 0 %
VO 0445	Peppers, sweet (incl. pimiento)	highest utilization:	0,25	0,84	1.00 0	CN	Child, 1-6 yrs	1002	169.85	170	3	2b	0,04 - 26,53	0 % - 9 %	0 % - 3 %	0 % - 9 %

Annex 4

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MEFENTRIFLUCONAZOLE (320)

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

international estimate of short-term
intakes

Maximum %ARfD:

370 % 140 % 370 %
all gen pop child

Code x Code	Commodity	Processing	STMR or STMR- P mg/kg	HR or HR-P mg/kg	DCF	Coun try	Populatio n group	Large portion, g/person	Unit weight, edible portion, g	Varia - bility facto r	Cas e	internation al estimate of short- term intakes µg/kg bw/day	% acute RfD rounde d	% acute RfD rounde d	% acute RfD rounde d	
	(Bell pepper, Paprika) (all commodities)	raw with skin														
VO 0440	Egg plant (Aubergine) (all commodities)	highest utilization: raw with skin	0,25	0,84	1.00 0	CN	Child, 1-6 yrs	969	253.44	444	3	2b	0,28 - 39,58	0 % - 10 %	0 % - 7 %	0 % - 10 %
VO 0443	Pepino (Melon pear, Tree melon)	Total		0,84	1.00 0	PRIMO -NL	Gen pop	P95	424.02	340	3	2a	14.081	5 %	5 %	4 %
VO 2713	Scarlet eggplant (gilo, Ethiopian eggplant) (all commodities)	highest utilization: Total	0	0,84	1.00 0	PRIMO -NL	Gen pop	P95	424.02	28	3	2a	5,43 - 6,14	2 % - 2 %	2 % - 2 %	2 % - 2 %
VL 0460	Amaranth leaves (Bledo)	Total		18	1.00 0	PRIMO -BE	toddler	P97. 5	402.30	<25	NR	1	406.820	140 %	30 %	140 %
VL 0460	Amaranth leaves (Bledo)	raw		18	1.00 0	CN	Gen pop, > 1 yrs	714	581.72	<25	NR	1	196.721	70 %	70 %	NC
VL 0464	Chard (Beet leaves, Silver beet) (all commodities)	highest utilization: cooked/boiled	0	18	1.00 0	PRIMO -NL	child	P100	81.80	105	3	2b	63,83 - 240,07	20 % - 80 %	20 % - 80 %	50 % - 80 %
VL 0465	Chervil (all commodities)	highest utilization: Total	8,1	18	1.00 0	PRIMO -BE	toddler	P100	23.00	<25	NR	1	0,92 - 23,26	0 % - 8 %	0 % - 1 %	0 % - 8 %
VL	Chicory leaves	Total		18	1.00	PRIMO	toddler	P100	143.00	440	3	2b	433.820	140 %	80 %	140 %

Annex 4

MEFENTRIFLUCONAZOLE (320)

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

international estimate of short-term intakes

Maximum %ARfD:

370 % all gen pop 140 % child 370 %

Code x Code	Commodity	Processing	STMR or STMR- P mg/kg	HR or HR-P mg/kg	DCF	Coun try	Populatio n group	Large portion, g/person	Unit weight, edible portion, g	Varia - bility facto r	Cas e	internation al estimate of short- term intakes µg/kg bw/day	% acute RfD rounde d	% acute RfD rounde d	% acute RfD rounde d	
0469	(green and red cultivars) (Sugar loaf)				0	-BE										
VL 0469	Chicory leaves (green and red cultivars) (Sugar loaf)	raw		18	1.00 0	DE	Child, 2-4 yrs	16	82.40	280	3	2b	275.517	90 %	30 %	90 %
VL 2752	Chrysanthemu m, edible leaved	Total		18	1.00 0	PRIMO -BE	toddler	P97. 5	402.30	<25	NR	1	406.820	140 %	20 %	140 %
VL 2752	Chrysanthemu m, edible leaved	raw		18	1.00 0	CN	Gen pop, > 1 yrs	993	332.67	<25	NR	1	112.500	40 %	40 %	-
VL 0470	Corn salad (Lambs lettuce) (all commodities)	highest utilization: Total	0	18	1.00 0	PRIMO -BE	toddler	P100	50.00	<25	NR	1	15,23 - 50,56	5 % - 20 %	5 % - 10 %	0 % - 20 %
VL 0510	Cos lettuce	Total		18	1.00 0	PRIMO -NL	child	P97. 5	140.10	290	3	2b	411.163	140 %	70 %	140 %
VL 0510	Cos lettuce	raw		18	1.00 0	NL	Child, 2-6 yrs	91	140.10	290	3	2b	411.156	140 %	40 %	140 %
VL 0510	Cos lettuce (all other commodities)	highest utilization: cooked/boiled	8,1	18	1.00 0	NL	Gen pop, > 1 yrs	2	220.89	194	3	2a	4,76 - 166,57	2 - 60 %	2 - 60 %	1 %
VL 0474	Dandelion (Laiteron, Pissenlit) (all commodities)	highest utilization: Total	0	18	1.00 0	PRIMO -BE	toddler	P100	143.00	35	3	2a	32,79 - 215,39	10 % - 70 %	10 % - 40 %	70 % - 70 %

Annex 4

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MEFENTRIFLUCONAZOLE (320)

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

international estimate of short-term intakes

Maximum %ARfD:

370 %
140 %
370 %
all gen pop child

Code x Code	Commodity	Processing	STMR or STMR- P mg/kg	HR or HR-P mg/kg	DCF	Coun- try	Populatio- n group	n	Large portion, g/person	Unit weight, edible portion, g	Varia- - bility facto- r	Cas- e	internation- al estimate of short- term intakes µg/kg bw/day	% acute RfD rounde- d	% acute RfD rounde- d	% acute RfD rounde- d
VL 0476	Endive (i.e. Scarole)	Total		18	1.00 0	PRIMO -BE	toddler	P100	143.00	440	3	2b	433.820	140 %	80 %	140 %
VL 0476	Endive (i.e. Escarole)	raw		18	1.00 0	NL	Child, 2-6 yrs	35	133.34	375	3	2b	391.338	130 %	90 %	130 %
VL 0476	Endive (i.e. Escarole)	cooked/boiled		18	1.00 0	PRIMO -NL	toddler	P95	135.20	251	3	2b	715.765	240 %	80 %	240 %
VL 0476	Endive (i.e. Scarole) (all other commodities)	highest utilization: frozen	8,1		1.00 0	NL	Child, 2-6 yrs	E	150.00	NR	NR	3	32,27 - 66,03	10 - 20 %	1 - 8 %	10 - 20 %
VL 0482	Lettuce, head	Total		18	1.00 0	PRIMO -NL	child	P97. 5	140.10	290	3	2b	411.163	140 %	50 %	140 %
VL 0482	Lettuce, head	raw		18	1.00 0	NL	Child, 2-6 yrs	91	140.10	339	3	2b	411.156	140 %	40 %	140 %
VL 0482	Lettuce, head (all other commodities)	highest utilization: cooked/boiled	8,1	18	1.00 0	NL	Gen pop, > 1 yrs	2	220.89	227	3	2b	4,76 - 181,28	2 - 60 %	2 - 60 %	1 %
VL 0483	Lettuce, leaf	Total		18	1.00 0	CN	Child, 1-6 yrs	243	387.25	305	3	2a	1113.286	370 %	120 %	370 %
VL 0483	Lettuce, leaf	raw		18	1.00 0	NL	Child, 2-6 yrs	91	140.10	118	3	2a	367.452	120 %	40 %	120 %
VL 0483	Lettuce, leaf (all other commodities)	highest utilization: cooked/boiled	8,1	18	1.00 0	NL	Gen pop, > 1 yrs	2	220.89	79	3	2a	4,76 - 103,65	2 - 30 %	2 - 30 %	1 %
VL 0492	Purslane (all commodities)	highest utilization: cooked/boiled	0	18	1.00 0	PRIMO -NL	Gen pop	P100	271.20	<25	NR	1	19,64 - 74,19	7 % - 20 %	7 % - 20 %	0 % - 0 %
VL 0501	Sowthistle (all commodities)	highest utilization: raw	0	18	1.00 0	CN	Gen pop, > 1 yrs	1187	592.49	35	3	2a	224,04 - 224,04	70 % - 70 %	70 % - 70 %	0 % - 0 %

Annex 4

MEFENTRIFLUCONAZOLE (320)

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

international estimate of short-term intakes
Maximum %ARfD:

370 % all gen pop 140 % acute RfD rounded 370 % child

Code x Code	Commodity	Processing	STMR or STMR- P mg/kg	HR or HR-P mg/kg	DCF	Coun- try	Populatio- n group	n	Large portion, g/person	Unit weight, edible portion, g	Vari- - ability facto- r	Cas- e	internation- al estimate of short- term intakes µg/kg bw/day	% acute RfD rounde- d	% acute RfD rounde- d	% acute RfD rounde- d
VL 0502	Spinach	Total		18	1.00 0	PRIMO -BE	toddler	P97. 5	402.30	<25	NR	1	406.820	140 %	90 %	140 %
VL 0502	Spinach (all other commodities)	highest utilization: raw	8,1	18	1.00 0	JP	Child, 1-6 yrs	229	86.70	90	3	2b	0,81 - 278,68	0 - 90 %	0 - 40 %	0 - 90 %
VL 0401	Broccoli, Chinese (i.e. kailan)	Total		12	1.00 0	PRIMO -BE	toddler	P97. 5	148.10	186	3	2b	299.528	100 %	60 %	100 %
VL 0401	Broccoli, Chinese (i.e. kailan)	raw		12	1.00 0	CN	Child, 1-6 yrs	334	222.48	311	3	2b	496.366	170 %	80 %	170 %
VL 0466	Chinese cabbage (type Pak-choi) (i.e. celery mustard) (all other commodities)	highest utilization: Total	6,65	12	1.00 0	CA	Gen pop, all ages	341	428.62	1548	3	2b	1,9 - 244,27	1 - 80 %	1 - 80 %	2 - 80 %
VL 0466	Chinese cabbage (type Pak-choi) (i.e. celery mustard)	raw		12	1.00 0	CN	Child, 1-6 yrs	1966	327.07	1548	3	2b	729.730	240 %	140 %	240 %
VL 0472	Cress, Garden (all commodities)	highest utilization: raw	0	12	1.00 0	CN	Gen pop, > 1 yrs	1443	352.50	<25	NR	1	4,53 - 79,47	2 % - 30 %	2 % - 30 %	0 % - 1 %
VL 0468	Flowering white cabbage (Choisum)	Total		12	1.00 0	PRIMO -BE	toddler	P97. 5	148.10	186	3	2b	299.528	100 %	60 %	100 %
VL	Flowering	raw		12	1.00	CN	Gen pop,	1639	556.56	300	3	2a	260.744	90 %	90 %	-

MEFENTRIFLUCONAZOLE (320)

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

international estimate of short-term intakes

Maximum %ARfD:

370 %
140 %
370 %
all gen pop child

Code x Code	Commodity	Processing	STMR or STMR- P mg/kg	HR or HR-P mg/kg	DCF	Coun try	Populatio n group	Large portion, g/person	Unit weight, edible portion, g	Vari- - bility facto r	Cas e	internation al estimate of short- term intakes µg/kg bw/day	% acute RfD rounde d	% acute RfD rounde d	% acute RfD rounde d	
0468	white cabbage (Choisum)				0		> 1 yrs									
VL 0468	Flowering white cabbage (Choisum)	pickled/salted	6.65		1.00 0	CN	Gen pop, > 1 yrs	183	175.21	NR	NR	3	21.889	7 %	7 %	-
VL 0480	Kale (Borecole, Collards)	Total		12	1.00 0	PRIMO -DE	child	P100	142.12	672	3	2b	316.800	110 %	60 %	110 %
VL 0480	Kale (Borecole, Collards) (all other commodities)	highest utilization: cooked/boiled	6,65	12	1.00 0	PRIMO -NL	child	E	101.50	538	3	2b	12,64 - 198,59	4 - 70 %	4 - 20 %	20 - 70 %
VL 0481	Komatsuna	Total		12	1.00 0	PRIMO -BE	toddler	P100	114.40	<25	NR	1	77.124	30 %	20 %	30 %
VL 2781	Mizuna	Total		12	1.00 0	PRIMO -BE	toddler	P100	114.40	<25	NR	1	77.124	30 %	20 %	30 %
VL 0485	Mustard greens (Indian mustard, Amsoi, mustard cabbage, red mustards) (all other commodities)	highest utilization: Total	6,65	12	1.00 0	PRIMO -BE	toddler	P100	114.40	245	3	2b	28,76 - 231,37	10 - 80 %	10 - 50 %	80 %
VL 0485	Mustard greens (Indian mustard, Amsoi, mustard cabbage, red	raw		12	1.00 0	CN	Child, 1-6 yrs	635	299.31	245	3	2a	586.644	200 %	80 %	200 %

Annex 4

MEFENTRIFLUCONAZOLE (320)

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

international estimate of short-term intakes

Maximum %ARfD:

370 % all gen pop 140 % child 370 %

Code x Code	Commodity	Processing	STMR or STMR- P mg/kg	HR or HR-P mg/kg	DCF	Coun try	Populatio n group	Large portion, g/person	Unit weight, edible portion, g	Varia - bility facto r	Cas e	internation al estimate of short- term intakes µg/kg bw/day	% acute RfD rounde d	% acute RfD rounde d	% acute RfD rounde d	
	mustards)															
VL 0494	Radish leaves	Total		12	1.00 0	PRIMO -DE	child	P100	142.12	<25	NR	1	105.600	40 %	20 %	40 %
VL 0495	Rape greens (all commodities)	highest utilization: Total	0	12	1.00 0	PRIMO -DE	child	P100	142.12	<25	NR	1	46,51 - 105,6	20 % - 40 %	20 % - 20 %	20 % - 40 %
VL 0496	Rucola (Arrugula, Rocket salad, Roquette, Roman rocket) (all commodities)	highest utilization: Total	0	12	1.00 0	PRIMO -DE	child	P100	43.44	<25	NR	1	14,18 - 32,28	5 % - 10 %	5 % - 30 %	10 % - 10 %
VL 0506	Turnip greens (Namenia, Tendergreen) (all commodities)	highest utilization: Total	0	12	1.00 0	PRIMO -BE	toddler	P100	114.40	35	3	2a	19,68 - 124,31	7 % - 40 %	5 % - 20 %	7 % - 40 %
VP 0061	Beans with pods (Phaseolus spp): (immature pods + succulent seeds) (all commodities)	highest utilization: Total	0,01	0,03	1.00 0	CA	Child, <6 yrs	261	203.31	<25	NR	1	0,02 - 0,41	0 % - 0 %	0 % - 0 %	0 % - 0 %
VP 0522	Broad bean with pods	highest utilization:	0	0,03	1.00 0	PRIMO -NL	toddler	E	116.60	<25	NR	1	0,08 - 0,34	0 % - 0 %	0 % - 0 %	0 % - 0 %

Annex 4

MEFENTRIFLUCONAZOLE (320)

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

international estimate of short-term intakes

Maximum %ARfD:

370 % all gen pop 140 % child 370 %

Code x Code	Commodity	Processing	STMR or STMR- P mg/kg	HR or HR-P mg/kg	DCF	Coun try	Populatio n group	n	Large portion, g/person	Unit weight, edible portion, g	Vari- - bility facto r	Cas e	internation al estimate of short- term intakes µg/kg bw/day	% acute RfD rounde d	% acute RfD rounde d	% acute RfD rounde d
	(immature pods + succulent seeds) (Vicia spp) (all commodities)	Total														
VP 0542	Sword bean with pods (immature pods + succulent seeds) (Canavalia spp) (all commodities)	highest utilization: cooked/boiled	0	0,03	1.00 0	CN	Gen pop, > 1 yrs	891	316.83	<25	NR	1	0,18 - 0,18	0 % - 0 %	0 % - 0 %	0 % - 0 %
VP 0063	Peas with pods (Pisum spp) immature pods + succulent seeds) (all commodities)	highest utilization: cooked/boiled	0,01	0,1	1.00 0	CN	Child, 1-6 yrs	1056	290.21	6	NR	1	0,82 - 1,8	0 % - 1 %	0 % - 0 %	0 % - 1 %
VP 0553	Lentil with pods (immature pods + succulent seeds) (Lens	highest utilization: cooked/boiled	0	0,1	1.00 0	CN	Child, 1-6 yrs	371	345.76	<25	NR	1	0,58 - 2,14	0 % - 1 %	0 % - 0 %	0 % - 1 %

Annex 4

MEFENTRIFLUCONAZOLE (320)

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

international estimate of short-term intakes
Maximum %ARfD:

370 % all gen pop
140 % child
370 % child

Code x Code	Commodity	Processing	STMR or STMR- P mg/kg	HR or HR-P mg/kg	DCF	Coun try	Populatio n group	Large portion, g/person	Unit weight, edible portion, g	Varia - bility facto r	Cas e	internation al estimate of short- term intakes µg/kg bw/day	% acute RfD rounde d	% acute RfD rounde d	% acute RfD rounde d	
	spp) (all commodities)															
VP 0062	Beans without pods: (Phaseolus spp.) (succulent seeds) (all commodities)	highest utilization: Total	0,01	0,02	1.00 0	PRIMO -IE	child	P97. 5	157.79	<25	NR	1	0 - 0,16	0 % - 0 %	0 % - 0 %	0 % - 0 %
VP 0523	Broad bean without pods (succulent seeds) (Vicia spp) (all commodities)	highest utilization: Total	0,01	0,02	1.00 0	PRIMO -IE	child	P97. 5	157.79	<25	NR	1	0 - 0,16	0 % - 0 %	0 % - 0 %	0 % - 0 %
VP 0064	Peas without pods (Pisum spp) (succulent seeds) (all commodities)	highest utilization: Total	0,01	0,01	1.00 0	PRIMO -UK	infant	P97. 5	71.30	<25	NR	1	0,01 - 0,08	0 % - 0 %	0 % - 0 %	0 % - 0 %
VD 0071	Beans (dry) (Phaseolus spp) (all commodities)	highest utilization: Total	0,01	0	1.00 0	PRIMO -UK	infant	P97. 5	159.00	<25	NR	3	0,02 - 0,18	0 % - 0 %	0 % - 0 %	0 % - 0 %

Annex 4

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MEFENTRIFLUCONAZOLE (320)

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

international estimate of short-term
intakes

Maximum %ARfD:

370 % 140 % 370 %
all gen pop child

Code x Code	Commodity	Processing	STMR or STMR- P mg/kg	HR or HR-P mg/kg	DCF	Coun try	Populatio n group	n	Large portion, g/person	Unit weight, edible portion, g	Varia - bility facto r	Cas e	internation al estimate of short- term intakes µg/kg bw/day	% acute RfD rounde d	% acute RfD rounde d	% acute RfD rounde d
VD 0523	Broad bean (dry) (Vicia spp) (all commodities)	highest utilization: Total	0,01	0	1.00 0	PRIMO -UK	infant	P97. 5	159.00	<25	NR	3	0,01 - 0,18	0 % - 0 %	0 % - 0 %	0 % - 0 %
VD 0531	Lablab bean (dry) (Lablab spp) (all commodities)	highest utilization: Total	0,01	0,05	1.00 0	PRIMO -UK	infant	P97. 5	159.00	<25	NR	3	0,07 - 0,18	0 % - 0 %	0 % - 0 %	0 % - 0 %
VD 0541	Soya bean (dry) (Glycine spp) (all commodities)	highest utilization: soya bean milk	0,0083 - 0,01	0	1.00 0	US	Child, < 6 yrs	138	1757.7 5	NR	NR	3	0 - 1,01	0 % - 0 %	0 % - 0 %	0 % - 0 %
VD 0072	Peas (dry) (Pisum spp) (all commodities)	highest utilization: cooked/boiled	0,015	0	0.40 0	CN	Gen pop, > 1 yrs	268	1673.8 2	<25	NR	3	0,01 - 0,19	0 % - 0 %	0 % - 0 %	0 % - 0 %
VD 0524	Chick-pea (dry) (Cicer spp) (all commodities)	highest utilization: canned/preserv ed	0,015	0	0.40 0	PRIMO -NL	child	P100	328.80	<25	NR	3	0,01 - 0,11	0 % - 0 %	0 % - 0 %	0 % - 0 %
VD 0533	Lentil (dry) (Lens spp) (all commodities)	highest utilization: Total	0,22	0	1.00 0	PRIMO -UK	Child, 11- 14 yrs	P97. 5	321.50	<25	NR	3	0,43 - 1,47	0 % - 0 %	0 % - 0 %	0 % - 0 %
VD 0537	Pigeon pea (dry) (Cajanus spp)	Total	0.015		1.00 0	PRIMO -UK	child, 11- 14 yrs	P97. 5	315.00	<25	NR	3	0.098	0 %	0 %	0 %

Annex 4

MEFENTRIFLUCONAZOLE (320)

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

international estimate of short-term intakes

Maximum %ARfD:

370 % all gen pop 140 % child 370 %

Code x Code	Commodity	Processing	STMR or STMR- P mg/kg	HR or HR-P mg/kg	DCF	Coun try	Populatio n group	n	Large portion, g/person	Unit weight, edible portion, g	Varia - bility facto r	Cas e	internation al estimate of short- term intakes µg/kg bw/day	% acute RfD rounde d	% acute RfD rounde d	% acute RfD rounde d
VR 0574	Beetroot (all commodities)	highest utilization: Total	0,105	0,4	1.00 0	AU	Child, 2-6 yrs	53	314.08	135	3	2a	0,06 - 12,32	0 % - 4 %	0 % - 1 %	0 % - 4 %
VR 0575	Burdock, greater or edible	Total		0.4	1.00 0	PRIMO -BE	toddler	P100	99.90	75	3	2a	5.633	2 %	1 %	2 %
VR 0577	Carrot (all commodities)	highest utilization: raw with skin	0,105	0,4	1.00 0	CN	Child, 1-6 yrs	400	234.68	300	3	2b	0,01 - 17,45	0 % - 6 %	0 % - 2 %	0 % - 6 %
VR 0578	Celeriac (Turnip rooted celery) (all commodities)	highest utilization: Total	0,105	0,4	1.00 0	PRIMO -BE	toddler	P100	196.90	749	3	2b	0,02 - 13,27	0 % - 4 %	0 % - 1 %	0 % - 4 %
VR 0469	Chicory, roots (all commodities)	highest utilization: Total	0,105	0,4	1.00 0	AU	Gen pop, > 2 yrs	175	26.16	48	3	2b	0,08 - 0,47	0 % - 0 %	0 % - 0 %	0 % - 0 %
VR 0583	Horseradish (all commodities)	highest utilization: Total	0	0,4	1.00 0	PRIMO -DE	Gen pop	P97. 5	79.50	220	3	2b	0,02 - 1,25	0 % - 0 %	0 % - 0 %	0 % - 0 %
VR 0587	Parsley, turnip- rooted (Hamburg roots) (all commodities)	highest utilization: Total	0,105	0,4	1.00 0	PRIMO -NL	Gen pop	P97. 5	96.60	140	3	2b	0,74 - 1,76	0 % - 1 %	0 % - 1 %	0 % - 0 %
VR 0588	Parsnip (all commodities)	highest utilization: cooked/boiled (without skin)	0,105	0,4	1.00 0	PRIMO -NL	child	E	133.30	227	3	2b	0,91 - 8,69	0 % - 3 %	0 % - 1 %	2 % - 3 %

MEFENTRIFLUCONAZOLE (320)

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

international estimate of short-term
intakes

Maximum %ARfD:

370 % 140 % 370 %
all gen pop child

Code x Code	Commodity	Processing	STMR or STMR- P mg/kg	HR or HR-P mg/kg	DCF	Coun try	Populatio n group	n	Large portion, g/person	Unit weight, edible portion, g	Varia - bility facto r	Cas e	internation al estimate of short- term intakes µg/kg bw/day	% acute RfD rounde d	% acute RfD rounde d	% acute RfD rounde d
VR 0494	Radish (all commodities)	highest utilization: Total	0,105	0,4	1.00 0	PRIMO -NL	child	E	64.40	172	3	2b	0,01 - 4,2	0 % - 1 %	0 % - 1 %	0 % - 1 %
VR 0590	Radish, black (all commodities)	highest utilization: Total	0,105	0,4	1.00 0	PRIMO -NL	child	E	64.40	172	3	2b	0,01 - 4,2	0 % - 1 %	0 % - 1 %	0 % - 1 %
VR 0591	Radish, Japanese (Chinese radish, Daikon) (all commodities)	highest utilization: raw without skin	0,105	0,4	1.00 0	CN	Child, 1-6 yrs	1187	293.37	1000	3	2b	0,01 - 21,82	0 % - 7 %	0 % - 4 %	0 % - 7 %
VR 0498	Salsify (Oyster plant) (all commodities)	highest utilization: Total	0,105	0,4	1.00 0	PRIMO -BE	toddler	P100	99.90	75	3	2a	0 - 5,63	0 % - 2 %	0 % - 1 %	0 % - 2 %
VR 0497	Swede (Rutabaga) (all commodities)	highest utilization: Total	0,105	0,4	1.00 0	PRIMO -UK	infant	P97. 5	90.00	500	3	2b	0,01 - 12,41	0 % - 4 %	0 % - 3 %	0 % - 4 %
VR 0506	Turnip, garden (all commodities)	highest utilization: cooked/boiled (without peel)	0,105	0,4	1.00 0	PRIMO -NL	child	E	133.31	176	3	2b	0,77 - 8,69	0 % - 3 %	0 % - 1 %	0 % - 3 %
VR 0573	Arrowroot (all commodities)	highest utilization: starch	0,01	0,016 5 - 0,05	1.00 0	PRIMO -NL	child	E	12.40	NR	NR	3	0 - 0,01	0 % - 0 %	0 % - 0 %	0 % - 0 %
VR 0463	Cassava (Manioc) (all)	highest utilization: Total	0,0033 - 0,01	0,016 5 - 0,05	1.00 0	BR	Gen pop, > 10 yrs	2957	529.20	83	3	2a	0 - 0,54	0 % - 0 %	0 % - 0 %	0 % - 0 %

Annex 4

MEFENTRIFLUCONAZOLE (320)

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

international estimate of short-term intakes

Maximum %ARfD:

370 % all gen pop 140 % child 370 %

Code x Code	Commodity	Processing	STMR or STMR- P mg/kg	HR or HR-P mg/k g	DCF	Coun try	Populatio n group	n	Large portion, g/perso n	Unit weight, edible portion, g	Varia - bility facto r	Cas e	internation al estimate of short- term intakes µg/kg bw/day	% acute RfD rounde d	% acute RfD rounde d	% acute RfD rounde d
	commodities)															
VR 0585	Jerusalem artichoke (i.e. Topinambur) (all commodities)	highest utilization: Total	0	0,016 5 - 0,05	1.00 0	PRIMO -FI	women	P97. 5	253.42	69	3	2a	0,22 - 0,27	0 % - 0 %	0 % - 0 %	0 % - 0 %
VR 0589	Potato (all commodities)	highest utilization: Total	0,0033 - 0,01	0,016 5 - 0,05	1.00 0	PRIMO -UK	infant	P97. 5	191.10	216	3	2b	0 - 3,29	0 % - 1 %	0 % - 0 %	0 % - 1 %
VR 0508	Sweet potato (all commodities)	highest utilization: Total	0,01	0,016 5 - 0,05	1.00 0	CA	Child, <6 yrs	91	358.61	546	3	2b	0,07 - 4,21	0 % - 1 %	0 % - 1 %	0 % - 1 %
VR 0504	Tannia (Tanier, Yautia) (all commodities)	highest utilization: Total	0,0033 - 0,01	0,016 5 - 0,05	1.00 0	PRIMO -NL	child	P95	29.30	170	3	2b	0 - 0,24	0 % - 0 %	0 % - 0 %	0 % - 0 %
VR 0505	Taro (Dasheen, Eddoe) (all commodities)	highest utilization: cooked/boiled (without peel)	0	0,016 5 - 0,05	1.00 0	CN	Child, 1-6 yrs	199	384.18	668	3	2b	0,37 - 1,18	0 % - 0 %	0 % - 0 %	0 % - 0 %
VR 0600	Yams (all commodities)	highest utilization: Total	0	0,016 5 - 0,05	1.00 0	PRIMO -UK	adult	P97. 5	693.70	365	3	2a	0,12 - 0,94	0 % - 0 %	0 % - 0 %	0 % - 0 %
GC 0650	Rye (all commodities)	highest utilization: flakes	0,09	0	1.00 0	CA	Child, <6 yrs	1909	539.23	NR	NR	3	0,13 - 3,09	0 % - 1 %	0 % - 0 %	0 % - 1 %
GC 0653	Triticale	Total	0.09		1.00 0	PRIMO -UK	child, 4-6 yrs	P97. 5	296.20	<25	NR	3	1.300	0 %	0 %	0 %
GC 0654	Wheat (all	highest utilization:	0,05 - 0,26	0	1.00 0	CA	Child, <6 yrs	1909	539.23	NR	NR	3	0,06 - 3,09	0 % - 1 %	0 % - 0 %	0 % - 1 %

MEFENTRIFLUCONAZOLE (320)

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

international estimate of short-term intakes

Maximum %ARfD:

370 %
140 %
370 %
all gen pop child

Code x Code	Commodity	Processing	STMR or STMR- P mg/kg	HR or HR-P mg/kg	DCF	Coun try	Populatio n group	n	Large portion, g/perso n	Unit weight, edible portion, g	Varia - bility facto r	Cas e	internation al estimate of short- term intakes µg/kg bw/day	% acute RfD rounde d	% acute RfD rounde d	% acute RfD rounde d
	commodities)	flakes														
GC 0640	Barley (all commodities)	highest utilization: flakes	0,013 - 2,1	0	1.00 0	CA	Child, <6 yrs	1909	539.23	NR	NR	3	0,04 - 14,58	0 % - 5 %	0 % - 1 %	0 % - 5 %
GC 0647	Oats (all commodities)	highest utilization: flakes (rolled oats)	0,425 - 2,1	0	1.00 0	CA	Child, <6 yrs	1909	539.23	NR	NR	3	0,24 - 14,58	0 % - 5 %	0 % - 1 %	0 % - 5 %
GC 0649	Rice (all commodities)	highest utilization: Total	0,0085 - 0,44	0	1.00 0	CA	Child, <6 yrs	666	461.40	<25	NR	3	0,01 - 3,32	0 % - 1 %	0 % - 1 %	0 % - 1 %
GC 0646	Millet (common millet, proso millet) (all commodities)	highest utilization: Total	0,41	0	1.00 0	CN	Child, 1-6 yrs	826	219.53	<25	NR	3	0,29 - 5,58	0 % - 2 %	0 % - 1 %	0 % - 2 %
GC 0651	Sorghum grain (Chicken corn, Dari seed, Durra, Feterita) (all commodities)	highest utilization: cooked/boiled	0,41	0	0.40 0	CN	Gen pop, > 1 yrs	356	1348.6 7	<25	NR	3	0,64 - 4,16	0 % - 1 %	0 % - 1 %	0 % - 0 %
GC 0645	Maize (corn) (all commodities)	highest utilization: flakes	0,01	0	1.00 0	CA	Child, <6 yrs	1909	539.23	NR	NR	3	0,01 - 0,34	0 % - 0 %	0 % - 0 %	0 % - 0 %
GC 0656	Popcorn (i.e. maize destined for popcorn preparation)	highest utilization: Total	0,01	0	1.00 0	AU	Child, 2-6 yrs	120	73.67	<25	NR	3	0,03 - 0,04	0 % - 0 %	0 % - 0 %	0 % - 0 %

Annex 4

MEFENTRIFLUCONAZOLE (320)

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

international estimate of short-term intakes

Maximum %ARfD:

370 % all gen pop 140 % 370 % child

Code x Code	Commodity	Processing	STMR or STMR- P mg/kg	HR or HR-P mg/kg	DCF	Coun try	Populatio n group	Large portion, g/person	Unit weight, edible portion, g	Varia - bility facto r	Cas e	internation al estimate of short- term intakes µg/kg bw/day	% acute RfD rounde d	% acute RfD rounde d	% acute RfD rounde d	
	(all commodities)															
GC 0447	Sweet corn (corn-on-the-cob) (kernels plus cob with husks removed) (all commodities)	highest utilization: cooked/boiled (corn-on-the-cob)	0,01	0,02	1.000	TH	Child, 3-6 yrs	1383	196.99	191	3	2a	0,01 - 0,68	0 % - 0 %	0 % - 0 %	0 % - 0 %
GC 1275	Sweet corn (whole kernel without cob or husk) (all commodities)	highest utilization: canned/preserved (kernels)	0,01	0,02	1.000	CA	Child, <6 yrs	289	153.76	NR	NR	3	0,01 - 0,1	0 % - 0 %	0 % - 0 %	0 % - 0 %
GS 0659	Sugar cane (all commodities)	highest utilization: thick juice	0,37	0	1.000	CN	Gen pop, > 1 yrs	436	1817.52	NR	NR	3	0,57 - 12,63	0 % - 4 %	0 % - 4 %	0 % - 1 %
TN 0660	Almonds (all commodities)	highest utilization: Total	0,01	0,06	1.000	CA	Child, <6 yrs	62	63.32	<25	NR	1	0 - 0,24	0 % - 0 %	0 % - 0 %	0 % - 0 %
TN 0662	Brazil nut (all commodities)	highest utilization: Total	0	0,06	1.000	PRIMO-UK	child, 4-6 yrs	P97.5	17.80	<25	NR	1	0,05 - 0,05	0 % - 0 %	0 % - 0 %	0 % - 0 %
TN 0295	Cashew nut (all commodities)	highest utilization: raw incl roasted	0,01	0,06	1.000	TH	child, 3-6 yrs	374	98.84	<25	NR	1	0,17 - 0,35	0 % - 0 %	0 % - 0 %	0 % - 0 %
TN 0664	Chestnut (all)	highest utilization:	0	0,06	1.000	CN	Gen pop, > 1 yrs	807	475.25	<25	NR	1	0,15 - 0,54	0 % - 0 %	0 % - 0 %	0 % - 0 %

Annex 4

MEFENTRIFLUCONAZOLE (320)

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

international estimate of short-term intakes

Maximum %ARfD:

370 % all gen 140 % pop 370 % child

Code x Code	Commodity	Processing	STMR or STMR- P mg/kg	HR or HR-P mg/kg	DCF	Coun try	Populatio n group	n	Large portion, g/person	Unit weight, edible portion, g	Varia - bility facto r	Cas e	internation al estimate of short- term intakes µg/kg bw/day	% acute RfD rounde d	% acute RfD rounde d	% acute RfD rounde d
	commodities)	Total														
TN 0665	Coconut (all commodities)	highest utilization: raw (i.e. nutmeat)	0,01	0,06	1.00 0	TH	child, 3-6 yrs	826	423.40	383	3	2a	0,01 - 4,17	0 % - 1 %	0 % - 1 %	0 % - 1 %
TN 0666	Hazelnut (all commodities)	highest utilization: Total	0,01	0,06	1.00 0	PRIMO -IE	child	P97. 5	65.42	<25	NR	1	0,01 - 0,2	0 % - 0 %	0 % - 0 %	0 % - 0 %
TN 0669	Macadamia nut (all commodities)	highest utilization: Total	0,01	0,06	1.00 0	PRIMO -DE	women, 14-50 yrs	P100	141.69	<25	NR	1	0 - 0,13	0 % - 0 %	0 % - 0 %	0 % - 0 %
TN 0672	Pecan (all commodities)	highest utilization: Total	0,01	0,06	1.00 0	PRIMO -DE	child	P100	44.41	<25	NR	1	0,04 - 0,17	0 % - 0 %	0 % - 0 %	0 % - 0 %
TN 0673	Pine nut (all commodities)	highest utilization: Total	0	0,06	1.00 0	BR	Gen pop, > 10 yrs	47	200.00	<25	NR	1	0,03 - 0,19	0 % - 0 %	0 % - 0 %	0 % - 0 %
TN 0675	Pistachio nut (all commodities)	highest utilization: Total	0,01	0,06	1.00 0	PRIMO -IE	child	P97. 5	115.86	<25	NR	1	0 - 0,35	0 % - 0 %	0 % - 0 %	0 % - 0 %
TN 0678	Walnut (all commodities)	highest utilization: Total	0,01	0,06	1.00 0	PRIMO -BE	toddler	P100	60.00	<25	NR	1	0 - 0,2	0 % - 0 %	0 % - 0 %	0 % - 0 %
SO 0090	Subgroup of mustard seeds (all commodities)	highest utilization: Total	0,06	0	1.00 0	PRIMO -CZ	Child, child, 7- 10 yrs	P97. 5	32.95	<25	NR	3	0 - 0,06	0 % - 0 %	0 % - 0 %	0 % - 0 %
SO 3140	Borage seeds (all	highest utilization:	0,06	0	1.00 0	DE	Gen pop, 14-80 yrs	2	42.00	<25	NR	3	0,03 - 0,03	0 % - 0 %	0 % - 0 %	0 % - 0 %

Annex 4

MEFENTRIFLUCONAZOLE (320)

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

international estimate of short-term intakes
Maximum %ARfD:

370 % all gen pop 140 % 370 % child

Code x Code	Commodity	Processing	STMR or STMR- P mg/kg	HR or HR-P mg/k g	DCF	Coun try	Populatio n group	Large portion, g/perso n	Unit weight, edible portion, g	Varia - bility facto r	Cas e	internation al estimate of short- term intakes µg/kg bw/day	% acute RfD rounde d	% acute RfD rounde d	% acute RfD rounde d	
	commodities)	raw														
SO 0693	Linseed (Flax- seed) (all commodities)	highest utilization: Total	0,06	0	1.00 0	CA	Gen pop, all ages	291	81.08	<25	NR	3	0,02 - 0,07	0 % - 0 %	0 % - 0 %	0 % - 0 %
SO 0698	Poppy seed (all commodities)	highest utilization: Total	0,06	0	1.00 0	PRIMO -DE	women, 14-50 yrs	P97. 5	47.23	<25	NR	3	0 - 0,04	0 % - 0 %	0 % - 0 %	0 % - 0 %
SO 0495	Rape seed (Canola) (all commodities)	highest utilization: Oil (refined)	0,06	0	1.00 0	CA	Child, <6 yrs	1127	26.46	NR	NR	3	0,05 - 0,1	0 % - 0 %	0 % - 0 %	0 % - 0 %
SO 0700	Sesame seed (all commodities)	highest utilization: butter/paste (nuts/oilseeds)	0,06	0	1.00 0	CN	Gen pop, > 1 yrs	174	151.21	NR	NR	3	0,01 - 0,17	0 % - 0 %	0 % - 0 %	0 % - 0 %
SO 0699	Safflower seed (all commodities)	highest utilization: Total	0,01	0	1.00 0	PRIMO -DE	child	P95	49.74	<25	NR	3	0 - 0,03	0 % - 0 %	0 % - 0 %	0 % - 0 %
SO 0702	Sunflower seed (all commodities)	highest utilization: Total	0,01	0	1.00 0	CA	women, 15-49 yrs	121	296.25	<25	NR	3	0,01 - 0,05	0 % - 0 %	0 % - 0 %	0 % - 0 %
SO 0691	Cotton seed (all commodities)	highest utilization: Oil (refined)	0,0001 6 - 0,04	0	1.00 0	US	Child, < 6 yrs	6354	3.13	NR	NR	3	0 - 0	0 % - 0 %	0 % - 0 %	0 % - 0 %
SO 0697	Peanut, shelled (groundnut) (all commodities)	highest utilization: raw incl roasted	0,01	0	1.00 0	CN	Child, 1-6 yrs	290	163.07	<25	NR	3	0,01 - 0,1	0 % - 0 %	0 % - 0 %	0 % - 0 %

Annex 4

MEFENTRIFLUCONAZOLE (320)

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

international estimate of short-term intakes

Maximum %ARfD:

370 % all gen pop 140 % child 370 %

Code x Code	Commodity	Processing	STMR or STMR- P mg/kg	HR or HR-P mg/kg	DCF	Coun try	Populatio n group	n	Large portion, g/person	Unit weight, edible portion, g	Vari- - ability facto r	Cas e	internation al estimate of short- term intakes µg/kg bw/day	% acute RfD rounde d	% acute RfD rounde d	% acute RfD rounde d
SB 0716	Coffee bean (all commodities)	highest utilization: Total	0,0007 5 - 0,01	0	1.00 0	PRIMO -EFSA	adults	E	45.00	<25	NR	3	0 - 0,01	0 % - 0 %	0 % - 0 %	0 % - 0 %
HS 3381	Lemon, peel (all commodities)	highest utilization: raw peel (C. limon Burm.f.)	0,96	2,5	1.00 0	AU	Child, 2-6 yrs	602	1.15	67	3	2b	0,45 - 0,45	0 % - 0 %	0 % - 0 %	0 % - 0 %
HS 3382	Orange, peel (all commodities)	highest utilization: raw peel (C. sinensis Osbeck)	0,96	2,5	1.00 0	AU	Gen pop, > 2 yrs	698	15.10	49	3	2b	1,69 - 1,69	1 % - 1 %	1 % - 1 %	0 % - 0 %
MM 0095	Meat from mammals other than marine mammals	Total	NA	NA	1.00 0	CN	Child, 1-6 yrs	4329	261.46	NR	NR	1	NA	2 %	1 %	2 %
MM 0095	Meat from mammals other than marine mammals: 20 % as fat	Total		1.26	1.00 0	CN	Child, 1-6 yrs	4329	52.29	NR	NR	1	4.083	1 %	1 %	1 %
MM 0095	Meat from mammals other than marine mammals: 80 % as	Total		0.14	1.00 0	CN	Child, 1-6 yrs	4329	209.17	NR	NR	1	1.815	1 %	0 %	1 %

Annex 4

MEFENTRIFLUCONAZOLE (320)

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

international estimate of short-term intakes

Maximum %ARfD:

370 % all gen pop 140 % 370 % child

Code x Code	Commodity	Processing	STMR or STMR- P mg/kg	HR or HR-P mg/kg	DCF	Coun- try	Populatio- n group	Large portion, g/person	Unit weight, edible portion, g	Varia- - bility facto- r	Cas- e	internation- al estimate of short- term intakes µg/kg bw/day	% acute RfD rounde- d	% acute RfD rounde- d	% acute RfD rounde- d	
	muscle															
MF 0100	Mammalian fats (except milk fats)	Total		1.26	1.00 0	PRIMO -UK	infant	P97. 5	18.10	NR	NR	1	2.621	1 %	1 %	1 %
MO 0105	Edible offal (mammalian)	Total		1.91	1.00 0	ZA	Gen pop, > 10 yrs	-	523.58	NR	NR	1	17.954	6 %	6 %	5 %
ML 0106	Milks	Total	0.07		1.00 0	PRIMO -UK	infant	P97. 5	1080.7 0	NR	NR	3	8.695	3 %	1 %	3 %
PM 0110	Poultry meat	Total	NA	NA	1.00 0	CN	Child, 1-6 yrs	175	347.00	NR	NR	1	NA	1 %	0 %	1 %
PM 0110	Poultry meat: 10 % as fat	Total		0.5	1.00 0	CN	Child, 1-6 yrs	175	34.70	NR	NR	1	1.075	0 %	0 %	0 %
PM 0110	Poultry meat: 90 % as muscle	Total		0.053	1.00 0	CN	Child, 1-6 yrs	175	312.30	NR	NR	1	1.026	0 %	0 %	0 %
PF 0111	Poultry, fats	Total		0.503	1.00 0	CA	Child, <6 yrs	66	49.38	NR	NR	1	1.460	0 %	0 %	0 %
PO 0111	Poultry, edible offal (includes kidney and liver)	Total		0.844	1.00 0	CN	Gen pop, > 1 yrs	421	345.63	NR	NR	1	5.481	2 %	2 %	1 %
PE 0112	Eggs	Total		0.094	1.00 0	PRIMO -UK	infant	P97. 5	108.00	NR	NR	1	1.167	0 %	0 %	0 %

METALAXYL (138)

Acute RfD= 0,08 mg/kg bw (80 µg/kg bw)

international estimate of short-term intakes

Maximum %ARfD:

9 % 6 % 9 %

Annex 4

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	international estimate of short-term intakes µg/kg bw/day	all	gen pop	child
														% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
FI 0353	Pineapple (all commodities)	highest utilization: raw without peel	0,026	0,078	1.000	JP	Child, 1-6 yrs	67	499.80	1116	3	2b	0.01-6.88	0% - 1%	0% - 1%	0% - 1%
DT 9999	Ginseng root, dried	Total		0.06	1.000	PRIMO-EFSA	adults	E	36.00	<25	NR	1	0.036	0%	0%	0%

Annex 4

QUINCLORAC (287)

INTERNATIONAL ESTIMATE OF SHORT-TERM INTAKES

Acute RfD= 2 mg/kg bw (2000 µg/kg bw)

Maximum %ARfD:

0 % 0 % 0 %
all gen pop child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	international estimate of short-term intakes µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
FB 0265	Cranberry	Total	0.375	0.88	1.000	AU	Child, 2-16 yrs	103	279.66	<25	NR	1	6.476	0 %	0 %	0 %
SO 0495	Rape seed (Canola) (all commodities)	highest utilization: Oil (refined)	0.64 - 0.7	0	1.000	CA	Child, <6 yrs	1127	26.46	NR	NR	3	0.88 - 1,14	0 % - 0 %	0 % - 0 %	0 % - 0 %

SULFOXAFLOR (252)

INTERNATIONAL ESTIMATE OF SHORT-TERM INTAKES

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

Maximum %ARfD:

2 % 1 % 2 %
all gen pop child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	international estimate of short-term intakes µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
VS 0620	Artichoke globe (all commodities)	highest utilization: Total	0	0.45	1.000	US	Child, < 6 yrs	2	117.23	51	3	2a	1.83 - 6.82	1 % - 2 %	1 % - 1 %	0 % - 2 %
SO 0702	Sunflower seed (all commodities)	highest utilization: Total	0.033 - 0.047	0	1.000	CA	women, 15-49 yrs	121	296.25	<25	NR	3	0.03 - 0.22	0 % - 0 %	0 % - 0 %	0 % - 0 %

TRIFLUMURON (317) METABOLITE M07

INTERNATIONAL ESTIMATE OF SHORT-TERM INTAKES

Acute RfD= 0.02 mg/kg bw (20 µg/kg bw)

Maximum %ARfD:

1 % 1 % 1 %
all gen pop child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country Population n			Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	international estimate of short-term intakes µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
						Country	Population	n								
VD 0541	Soya bean (dry) (Glycine spp) (all commodities)	highest utilization: Total	0.02	0	1.000	CN	Child, 1-6 yrs	179	239.05	<25	NR	3	0 - 0.3	0 % - 1 %	0 % - 1 %	0 % - 1 %

Annex 5: Reports and other documents resulting from previous joint meetings of the FAO panel of experts on pesticide residues in food and the environment and the WHO core assessment group on pesticide residues.

1. Principles governing consumer safety in relation to pesticide residues. Report of a meeting of a WHO Expert Committee on Pesticide Residues held jointly with the FAO Panel of Experts on the Use of Pesticides in Agriculture. FAO Plant Production and Protection Division Report, No. PL/1961/11; WHO Technical Report Series, No. 240, 1962.
2. Evaluation of the toxicity of pesticide residues in food. Report of a Joint Meeting of the FAO Committee on Pesticides in Agriculture and the WHO Expert Committee on Pesticide Residues. FAO Meeting Report, No. PL/1963/13; WHO/Food Add./23, 1964.
3. Evaluation of the toxicity of pesticide residues in food. Report of the Second Joint Meeting of the FAO Committee on Pesticides in Agriculture and the WHO Expert Committee on Pesticide Residues. FAO Meeting Report, No. PL/1965/10; WHO/Food Add./26.65, 1965.
4. Evaluation of the toxicity of pesticide residues in food. FAO Meeting Report, No. PL/1965/10/1; WHO/Food Add./27.65, 1965.
5. Evaluation of the hazards to consumers resulting from the use of fumigants in the protection of food. FAO Meeting Report, No. PL/1965/10/2; WHO/Food Add./28.65, 1965.
6. Pesticide residues in food. Joint report of the FAO Working Party on Pesticide Residues and the WHO Expert Committee on Pesticide Residues. FAO Agricultural Studies, No. 73; WHO Technical Report Series, No. 370, 1967.
7. Evaluation of some pesticide residues in food. FAO/PL:CP/15; WHO/Food Add./67.32, 1967.
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9. 1967 Evaluations of some pesticide residues in food. FAO/PL:1967/M/11/1; WHO/Food Add./68.30, 1968.
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13. 1969 Evaluations of some pesticide residues in food. FAO/PL:1969/M/17/1; WHO/Food Add./70.38, 1970.
14. Pesticide residues in food. Report of the 1970 Joint Meeting of the FAO Working Party of Experts on Pesticide Residues and the WHO Expert Committee on Pesticide Residues. FAO Agricultural Studies, No. 87; WHO Technical Report Series, No. 4574, 1971.

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Annex 6: Livestock dietary burden calculations

Afidopyropen (312)

ESTIMATED MAXIMUM DIETARY BURDEN													
BEEF CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Kale leaves	AM/AV	4.8	HR	15	32.00		20				6.4		
Grass forage (fresh)	AF/AS	4.12	HR	25	16.48		50	100	5		8.24	16.48	0.824
Grass hay	AF/AS	14.9	HR	100	14.90	15			35	2.235			5.215
Clover hay	AL	8.55	HR	89	9.61	15	30			1.441	2.882		
Alfalfa hay	AL	5.46	HR	89	6.13				10				0.613
Cotton gin byproducts	AM/AV	0.65	HR	90	0.72	5				0.036			
Citrus dried pulp	AB	0.13	STMR	91	0.14	10				0.014			
Sorghum, grain grain	GC	0.0365	STMR	86	0.04	40			35	0.017			0.015
Soybean asp gr fn	SM	0.02	STMR	85	0.02	5				0.001			
Soybean meal	SM	0.02	STMR	92	0.02				15				0.003
Soybean hulls	SM	0.02	STMR	90	0.02	10				0.002			
Total						100	100	100	100	3.747	17.52	16.48	6.671

DAIRY CATTLE													
													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Kale leaves	AM/AV	4.8	HR	15	32.00		20	40			6.4	12.8	
Grass forage (fresh)	AF/AS	4.12	HR	25	16.48	45	60	60	10	7.416	9.888	9.888	1.648
Grass hay	AF/AS	14.9	HR	100	14.90				60				8.94
Clover hay	AL	8.55	HR	89	9.61	20	20			1.921	1.921		
Alfalfa hay	AL	5.46	HR	89	6.13				25				1.534
Sorghum, grain forage	AF/AS	0.255	HR	35	0.73				5				0.036
Apple pomace, wet	AB	0.084	STMR	40	0.21	10				0.021			
Almond hulls	AM/AV	0.064	STMR	90	0.07	10				0.007			
Sorghum, grain grain	GC	0.0365	STMR	86	0.04	15				0.006			
Total						100	100	100	100	9.372	18.21	22.69	12.16

POULTRY BROILER													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Sorghum, grain grain	GC	0.0365	STMR	86	0.04	75	70	70	65	0.032	0.03	0.03	0.028
Soybean meal	SM	0.02	STMR	92	0.02	25	30	25	35	0.005	0.007	0.005	0.008
Cotton meal	SM	0.0052	STMR	89	0.01			5				0.00029	
Total						100	100	100	100	0.037	0.036	0.035	0.035

POULTRY LAYER													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Clover hay	AL	8.55	HR	89	9.61		10				0.961		
Cabbage heads, leaves	AM/AV	0.39	HR	15	2.60		5				0.13		
Sorghum, grain forage	AF/AS	0.255	HR	35	0.73		10				0.073		
Sorghum, grain grain	GC	0.0365	STMR	86	0.04	75	70	70	55	0.032	0.03	0.03	0.023
Soybean meal	SM	0.02	STMR	92	0.02	25	5	25	30	0.005	0.001	0.005	0.007
Cotton meal	SM	0.0052	STMR	89	0.01			5				0.00029	
Total						100	100	100	85	0.037	1.194	0.035	0.03

Afidopyropen (312)

ESTIMATED MEAN DIETARY BURDEN													
BEEF CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Kale leaves	AM/AV	2.5	STMR/STMR-P	15	16.67		20				3.333		
Grass forage (fresh)	AF/AS	1.98	STMR/STMR-P	25	7.92		50	100	5		3.96	7.92	0.396
Grass hay	AF/AS	6.32	STMR/STMR-P	100	6.32	15			35	0.948			2.212
Alfalfa hay	AL	4.13	STMR/STMR-P	89	4.64	15			10	0.696067			0.464
Clover forage	AL	1.39	STMR/STMR-P	30	4.63		30				1.39		
Cotton gin by-products	AM/AV	1	STMR/STMR-P	90	1.11	5				0.055556			
Citrus dried pulp	AB	0.13	STMR/STMR-P	91	0.14	10				0.014286			
Sorghum, grain grain	GC	0.0365	STMR/STMR-P	86	0.04	40			35	0.016977			0.015

ESTIMATED MEAN DIETARY BURDEN														
BEEF CATTLE													MEAN	
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
Soybean aspg rfn	SM	0.02	STMR/STMR-P	85	0.02	5					0.001			
Soybean meal	SM	0.02	STMR/STMR-P	92	0.02				15					0.003
Soybean hulls	SM	0.02	STMR/STMR-P	90	0.02	10					0.002			
Total						100	100	100	100	1.734	8.683	7.92	3.09	

DAIRY CATTLE														MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Kale leaves	AM/AV	2.5	STMR/STMR-P	15	16.67		20	40			3.333	6.667		
Grass forage (fresh)	AF/AS	1.98	STMR/STMR-P	25	7.92	45	60	60	10	3.564	4.752	4.752	0.792	
Grass hay	AF/AS	6.32	STMR/STMR-P	100	6.32	0			60	0				3.792
Alfalfa hay	AL	4.13	STMR/STMR-P	89	4.64	20	20		25	0.92809	0.928			1.16
Apple pomace, wet	AB	0.084	STMR/STMR-P	40	0.21	10				0.021				
Sorghum, grain forage	AF/AS	0.05	STMR/STMR-P	35	0.14	0			5	0				0.007
Almond hulls	AM/AV	0.064	STMR/STMR-P	90	0.07	10				0.007111				
Sorghum, grain grain	GC	0.0365	STMR/STMR-P	86	0.04	15				0.006366				
Total						100	100	100	100	4.526567	9.013	11.42	5.751	

POULTRY BROILER														MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Sorghum, grain grain	GC	0.0365	STMR/STMR-P	86	0.04	75	70	70	65	0.03	0.03	0.03	0.028	
Soybean meal	SM	0.02	STMR/STMR-P	92	0.02	25	30	25	35	0.01	0.007	0.005	0.008	
Cotton meal	SM	0.0052	STMR/STMR-P	89	0.01			5				3E-04		
Total						100	100	100	100	0.04	0.036	0.035	0.035	

POULTRY LAYER														MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Clover forage	AL	1.39	STMR/STMR-P	30	4.63		10				0.463			

POULTRY LAYER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
Cabbage heads, leaves	AM/AV	0.0865	STMR/STMR-P	15	0.58	5				0.029			
Sorghum, grain forage	AF/AS	0.05	STMR/STMR-P	35	0.14	10				0.014			
Sorghum, grain grain	GC	0.0365	STMR/STMR-P	86	0.04	75	70	70	55	0.031831	0.03	0.03	0.023
Soybean meal	SM	0.02	STMR/STMR-P	92	0.02	25	5	25	30	0.005435	0.001	0.005	0.007
Cotton meal	SM	0.0052	STMR/STMR-P	89	0.01	5				3E-04			
Total						100	100	100	85	0.037266	0.537	0.035	0.03

AZOXYSTROBIN (229)

ESTIMATED MAXIMUM DIETARY BURDEN													
BEEF CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Beet, sugar tops	AM/AV	44	HR	23	191.30		20				38.26		
Sorghum, grain asp gr fn	CM/CF	92.5	STMR	85	108.82	5		20		5.441		21.76	
Soybean silage	AL	23	HR	30	76.67			80				61.33	
Sorghum, grain silage	AF/AS	12	HR	21	57.14	15				8.571			
Pea vines	AL	9.4	HR	25	37.60		20				7.52		
Sorghum, grain forage	AF/AS	12	HR	35	34.29		20				6.857		
Cowpea forage	AL	9.4	HR	30	31.33		15				4.7		
Corn, field stover	AF/AS	21	HR	83	25.30		5				1.265		
Pea silage	AL	9.4	HR	40	23.50		20				4.7		
Potato culls	VR	3.8	HR	20	19.00	30				5.700			
Potato process waste	AB	2.08	STMR	12	17.33	30				5.200			
Rice straw	AF/AS	9.9	HR	90	11.00				55				6.05
Soybean asp gr fn	SM	3	STMR	85	3.53	5				0.176			
Sorghum, grain grain	GC	1.85	STMR	86	2.15	15			35	0.323			0.75
Rice bran/pollard	CM/CF	0.82	STMR	90	0.91				10				0.091
Total						100	100	100	100	25.412	63.3	83.1	6.894

DAIRY CATTLE														MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Beet, sugar tops	AM/AV	44	HR	23	191.30		30				57.39			
Soybean silage	AL	23	HR	30	76.67	20		40		15.333		30.67		
Sorghum, grain silage	AF/AS	12	HR	21	57.14	40			10	22.857			5.714	
Pea vines	AL	9.4	HR	25	37.60		20				7.52			
Sorghum, grain forage	AF/AS	12	HR	35	34.29		20	60	30		6.857	20.57	10.29	
Cowpea forage	AL	9.4	HR	30	31.33		30				9.4			
Potato culls	VR	3.8	HR	20	19.00	10				1.900				
Corn, field forage/silage	AF/AS	7.2	HR	40	18.00	30			10	5.400			1.8	
Sorghum, grain grain	GC	1.85	STMR	86	2.15				30				0.645	
Rice bran/pollard	CM/CF	0.82	STMR	90	0.91				10				0.091	
Beet, sugar dried pulp	AB	0.635	STMR	88	0.72				10				0.072	
Total						100	100	100	100	45.490	81.17	51.24	18.61	

POULTRY BROILER														MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Potato culls	VR	3.8	HR	20	19.00		10				1.9			
Potato dried pulp	AB	10.1	STMR	88	11.48		20				2.295			
Sorghum, grain grain	GC	1.85	STMR	86	2.15	75	70	70	65	1.613	1.506	1.506	1.398	
Rice bran/pollard	CM/CF	0.82	STMR	90	0.91	10		20	5	0.091		0.182	0.046	
Soybean seed	VD	0.06	STMR	89	0.07	15		10		0.010		0.007		
Corn, field grain	GC	0.01	STMR	88	0.01				30				0.003	
Total						100	100	100	100	1.71	5.701	1.695	1.447	

POULTRY LAYER														MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Beet, sugar tops	AM/AV	44	HR	23	191.30		5				9.565			
Soybean silage	AL	23	HR	30	76.67		10				7.667			
Sorghum, grain forage	AF/AS	12	HR	35	34.29		10				3.429			
Potato culls	VR	3.8	HR	20	19.00		10				1.9			
Potato dried	AB	10.1	STMR	88	11.48		15				1.722			

POULTRY LAYER													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
pulp													
Sorghum, grain grain	GC	1.85	STMR	86	2.15	75	50	70	55	1.613	1.076	1.506	1.183
Rice bran/pollard	CM/CF	0.82	STMR	90	0.91	10		20	20	0.091		0.182	0.182
Soybean seed	VD	0.06	STMR	89	0.07	15		10		0.010		0.007	
Corn, field grain	GC	0.01	STMR	88	0.01				25				0.00
Total						100	100	100	100	1.715	25.36	1.695	1.368

AZOXYSTROBIN (229)

ESTIMATED MEAN DIETARY BURDEN													
BEEF CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Sorghum, grain asp gr fn	CM/CF	92.5	STMR/STMR-P	85	108.82	5		20		5.441176		21.76	
Beet, sugar tops	AM/AV	16	STMR/STMR-P	23	69.57		20				13.91		
Soybean hay	AL	31	STMR/STMR-P	85	36.47			80				29.18	
Potato process waste	AB	2.08	STMR/STMR-P	12	17.33	30	40			5.2	6.933		
Pea vines	AL	3.35	STMR/STMR-P	25	13.40		20				2.68		
Potato culls	VR	2.3	STMR/STMR-P	20	11.50	30	20			3.45	2.3		
Sorghum, grain silage	AF/AS	1.6	STMR/STMR-P	21	7.62	15				1.142857			
Soybean asp gr fn	SM	3	STMR/STMR-P	85	3.53	5				0.176471			
Sorghum, grain grain	GC	1.85	STMR/STMR-P	86	2.15	15			35	0.323			0.753
Rice straw	AF/AS	1.5	STMR/STMR-P	90	1.67				55				0.917
Rice bran/pollard	CM/CF	0.82	STMR/STMR-P	90	0.91				10				0.091
Total						100	100	100	100	15.733	25.83	50.94	1.761

DAIRY CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Beet, sugar tops	AM/AV	16	STMR/STMR-P	23	69.57		30	0			20.87	0	
Soybean hay	AL	31	STMR/STMR-P	85	36.47	20		40		7.294118		14.59	
Tomato pomace,wet	AB	4.05	STMR/STMR-P	20	20.25	0		10		0		2.025	
Potato process waste	AB	2.08	STMR/STMR-P	12	17.33	10	30			1.733333	5.2		
Pea vines	AL	3.35	STMR/STMR-P	25	13.40	0	20			0	2.68		
Potato culls	VR	2.3	STMR/STMR-P	20	11.50	10	20	10		1.15	2.3	1.15	
Cowpea forage	AL	3.35	STMR/STMR-P	30	11.17	0		40		0		4.467	
Sorghum, grain silage	AF/AS	1.6	STMR/STMR-P	21	7.62	40			10	3.047619			0.762
Sorghum, grain forage	AF/AS	1.6	STMR/STMR-P	35	4.57	0			30	0			1.371
Corn, field forage/silage	AF/AS	1.6	STMR/STMR-P	40	4.00	20			10	0.8			0.4
Sorghum, grain grain	GC	1.85	STMR/STMR-P	86	2.15	0			30	0			0.645
Rice straw	AF/AS	1.5	STMR/STMR-P	90	1.67	0			20	0			0.333
Total						100	100	100	100	14.02507	31.05	22.23	3.512

POULTRY BROILER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Potato culls	VR	2.3	STMR/STMR-P	20	11.50		10				1.15		
Potato dried pulp	AB	10.1	STMR/STMR-P	88	11.48		20				2.295		
Sorghum, grain grain	GC	1.85	STMR/STMR-P	86	2.15	75	70	70	65	1.61	1.506	1.506	1.398
Rice bran/pollard	CM/CF	0.82	STMR/STMR-P	90	0.91	10		20	5	0.09		0.182	0.046
Soybean seed	VD	0.06	STMR/STMR-P	89	0.07	15		10		0.01		0.007	
Corn, field grain	GC	0.01	STMR/STMR-P	88	0.01				30				0.003
Total						100	100	100	100	1.71	4.951	1.695	1.447

POULTRY LAYER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Beet, sugar tops	AM/AV	16	STMR/STMR-P	23	69.57		5				3.478		
Soybean hay	AL	31	STMR/STMR-P	85	36.47		10				3.647		
Potato culls	VR	2.3	STMR/STMR-P	20	11.50		10				1.15		
Potato dried pulp	AB	10.1	STMR/STMR-P	88	11.48		15				1.722		
Wheat forage	AF/AS	1.9	STMR/STMR-P	25	7.60		10				0.76		
Sorghum, grain grain	GC	1.85	STMR/STMR-P	86	2.15	75	50	70	55	1.613372	1.076	1.506	1.183
Rice bran/pollard	CM/CF	0.82	STMR/STMR-P	90	0.91	10		20	20	0.091111		0.182	0.182
Soybean seed	VD	0.06	STMR/STMR-P	89	0.07	15		10		0.010112		0.007	
Corn, field grain	GC	0.01	STMR/STMR-P	88	0.01				25				0.00
Total						100	100	100	100	1.714596	11.83	1.695	1.368

BENZOVINDIFLUPYR (261)

ESTIMATED MAXIMUM DIETARY BURDEN													
BEEF CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Wheat forage	AF/AS	3.7	HR	25	14.80		20	100			2.96	14.8	
Barley hay	AF/AS	12	HR	88	13.64	15				2.045			
Barley silage	AF/AS	12	HR	88	13.64		10			1.364			
Trefoil hay	AL	3.9	HR	85	4.59	15	20			0.688	0.918		
Vetch hay	AL	3.9	HR	85	4.59		5		5	0.229		0.229	
Cowpea hay	AL	3.9	HR	86	4.53		10			0.453			
Alfalfa hay	AL	3.9	HR	89	4.38				5				0.219
Alfalfa forage	AL	0.97	HR	35	2.77		35			0.97			
Wheat asp gr fn	CM/CF	1.656	STMR	85	1.95	5				0.097			
Potato process waste	AB	0.048	STMR	12	0.40	30				0.120			
Barley grain	GC	0.21	STMR	88	0.24	35			70	0.084			0.167
Brewer's grain dried	SM	0.21	STMR	92	0.23				20				0.046
Total						100	100	100	100	3.035	6.894	14.8	0.661

DAIRY CATTLE														MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Wheat forage	AF/AS	3.7	HR	25	14.80	20	20	60		2.960	2.96	8.88		
Barley silage	AF/AS	12	HR	88	13.64		10				1.364			
Rye straw	AF/AS	12	HR	88	13.64				5				0.682	
Triticale hay	AF/AS	12	HR	88	13.64			40				5.455		
Oat hay	AF/AS	12	HR	90	13.33	10				1.333				
Peanut hay	AL	7.5	HR	85	8.82	15				1.324				
Trefoil hay	AL	3.9	HR	85	4.59	25	40			1.147	1.835			
Vetch hay	AL	3.9	HR	85	4.59				25				1.147	
Vetch silage	AL	3.9	HR	85	4.59				35				1.606	
Cowpea hay	AL	3.9	HR	86	4.53		30				1.36			
Lespedeza hay	AL	3.9	HR	88	4.43	30				1.330				
Barley grain	GC	0.21	STMR	88	0.24				35				0.084	
Total						100	100	100	100	8.093	7.519	14.33	3.52	

POULTRY BROILER														MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Potato dried pulp	AB	0.048	STMR	12	0.40		20				0.08			
Barley grain	GC	0.21	STMR	88	0.24	75	70	15	10	0.179	0.167	0.036	0.024	
Brewer's grain dried	SM	0.21	STMR	92	0.23		10				0.023			
Distiller's grain dried	SM	0.21	STMR	92	0.23				5				0.011	
Barley bran fractions	CM/CF	0.0819	STMR	90	0.09	8				0.007				
Wheat milled bypds	CM/CF	0.0529	STMR	88	0.06	17		20	5	0.010		0.012	0.003	
Rye grain	GC	0.023	STMR	88	0.03			35				0.009		
Wheat grain	GC	0.023	STMR	89	0.03			30				0.008		
Corn, field grain	GC	0.01	STMR	88	0.01				60				0.007	
Corn, pop grain	GC	0.01	STMR	88	0.01				20				0.002	
Total						100	100	100	100	0.196	0.27	0.065	0.047	

POULTRY LAYER														MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Wheat forage	AF/AS	3.7	HR	25	14.80		10				1.48			
Trefoil hay	AL	3.9	HR	85	4.59		10				0.459			

POULTRY LAYER													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Potato dried pulp	AB	0.048	STMR	12	0.40		15				0.06		
Barley grain	GC	0.21	STMR	88	0.24	75	65	15		0.179	0.155	0.036	
Distiller's grain dried	SM	0.21	STMR	92	0.23				5				0.011
Barley bran fractions	CM/CF	0.0819	STMR	90	0.09				5				0.005
Wheat milled bypds	CM/CF	0.0529	STMR	88	0.06	25		20	25	0.015		0.012	0.015
Rye grain	GC	0.023	STMR	88	0.03			20				0.005	
Wheat grain	GC	0.023	STMR	89	0.03			45				0.012	
Rape meal	SM	0.01219	STMR	88	0.01				10				0.001
Corn, field grain	GC	0.01	STMR	88	0.01				55				0.006
Total						100	100	100	100	0.194	2.154	0.065	0.039

BENZOVINDIFLUPYR (261)

ESTIMATED MEAN DIETARY BURDEN													
BEEF CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Wheat forage	AF/AS	1.05	STMR/STMR-P	25	4.20		20	100			0.84	4.2	
Barley hay	AF/AS	3.4	STMR/STMR-P	88	3.86	15				0.579545			
Barley silage	AF/AS	3.4	STMR/STMR-P	88	3.86		10				0.386		
Trefoil hay	AL	2.2	STMR/STMR-P	85	2.59	15	20			0.388235	0.518		
Vetch hay	AL	2.2	STMR/STMR-P	85	2.59		5		5		0.129		0.129
Cowpea hay	AL	2.2	STMR/STMR-P	86	2.56		10				0.256		
Alfalfa hay	AL	2.2	STMR/STMR-P	89	2.47				5				0.124
Wheat asp gr fn	CM/CF	1.656	STMR/STMR-P	85	1.95	5				0.097412			
Alfalfa forage	AL	0.43	STMR/STMR-P	35	1.23		35				0.43		
Potato process waste	AB	0.048	STMR/STMR-P	12	0.40	30				0.120			
Barley grain	GC	0.21	STMR/STMR-P	88	0.24	35			70	0.084			0.167
Brewer's	SM	0.21	STMR/STMR-P	92	0.23				20				0.046

ESTIMATED MEAN DIETARY BURDEN													
BEEF CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
grain dried			P										
Total						100	100	100	100	1.269	2.559	4.200	0.466

DAIRY CATTLE													
													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Wheat forage	AF/AS	1.05	STMR/STMR-P	25	4.20	20	20	60		0.84	0.84	2.52	
Barley silage	AF/AS	3.4	STMR/STMR-P	88	3.86	0	10			0	0.386		
Rye straw	AF/AS	3.4	STMR/STMR-P	88	3.86	0			5	0			0.193
Triticale hay	AF/AS	3.4	STMR/STMR-P	88	3.86	0		40		0		1.545	
Oat hay	AF/AS	3.4	STMR/STMR-P	90	3.78	10				0.377778			
Peanut hay	AL	2.25	STMR/STMR-P	85	2.65	15				0.397059			
Trefoil hay	AL	2.2	STMR/STMR-P	85	2.59	25	40			0.647059	1.035		
Vetch hay	AL	2.2	STMR/STMR-P	85	2.59	0			25	0			0.647
Vetch silage	AL	2.2	STMR/STMR-P	85	2.59	0			35	0			0.906
Cowpea hay	AL	2.2	STMR/STMR-P	86	2.56	0	30			0	0.767		
Lespedeza hay	AL	2.2	STMR/STMR-P	88	2.50	30				0.75			
Barley grain	GC	0.21	STMR/STMR-P	88	0.24	0			35	0			0.084
Total						100	100	100	100	3.01	3.03	4.07	1.83

POULTRY BROILER													
													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Potato dried pulp	AB	0.048	STMR/STMR-P	12	0.40		20				0.08		
Barley grain	GC	0.21	STMR/STMR-P	88	0.24	75	70	15	10	0.18	0.167	0.036	0.024
Brewer's grain dried	SM	0.21	STMR/STMR-P	92	0.23		10				0.023		
Distiller's	SM	0.21	STMR/STMR-P	92	0.23				5				0.011

POULTRY BROILER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
grain dried			P										
Barley bran fractions	CM/CF	0.0819	STMR/STMR-P	90	0.09	8				0.01			
Wheat milled bypdts	CM/CF	0.0529	STMR/STMR-P	88	0.06	17		20	5	0.01		0.012	0.003
Rye grain	GC	0.023	STMR/STMR-P	88	0.03			35				0.009	
Wheat grain	GC	0.023	STMR/STMR-P	89	0.03			30				0.008	
Corn, field grain	GC	0.01	STMR/STMR-P	88	0.01				60				0.007
Corn, pop grain	GC	0.01	STMR/STMR-P	88	0.01				20				0.002
Total						100	100	100	100	0.196	0.270	0.065	0.047

POULTRY LAYER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Wheat forage	AF/AS	1.05	STMR/STMR-P	25	4.20		10				0.42		
Trefoil hay	AL	2.2	STMR/STMR-P	85	2.59		10				0.259		
Potato dried pulp	AB	0.048	STMR/STMR-P	12	0.40		15				0.06		
Barley grain	GC	0.21	STMR/STMR-P	88	0.24	75	65	15		0.178977	0.155	0.036	
Distiller's grain dried	SM	0.21	STMR/STMR-P	92	0.23				5				0.011
Barley bran fractions	CM/CF	0.0819	STMR/STMR-P	90	0.09				5				0.005
Wheat milled bypdts	CM/CF	0.0529	STMR/STMR-P	88	0.06	25		20	25	0.015028		0.012	0.015
Rye grain	GC	0.023	STMR/STMR-P	88	0.03			20				0.005	
Wheat grain	GC	0.023	STMR/STMR-P	89	0.03			45				0.012	
Rape meal	SM	0.01219	STMR/STMR-P	88	0.01				10				0.001
Corn, field grain	GC	0.01	STMR/STMR-P	88	0.01				55				0.006
Total						100	100	100	100	0.194	0.894	0.065	0.039

BIFENTHRIN (178)

ESTIMATED MAXIMUM DIETARY BURDEN													
BEEF CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Cabbage heads, leaves	AM/AV	3.1	HR	15	20.67		20				4.133		
Soybean asp gr fn	SM	9.5	STMR	85	11.18	5				0.559			
Corn, field stover	AF/AS	5.5	HR	100	5.50	15	25	40		0.825	1.375	2.2	
Corn, field forage/silage	AF/AS	2	HR	40	5.00		55	60			2.75	3	
Wheat milled bypds	CM/CF	0.79	STMR	88	0.90	40			55	0.359			0.494
Wheat grain	GC	0.25	STMR	89	0.28	20			25	0.056			0.07
Distiller's grain dried	SM	0.25	STMR	92	0.27	20			10	0.054			0.027
Soybean seed	VD	0.05	STMR	89	0.06				10				0.006
Total						100	100	100	100	1.853	8.258	5.2	0.597

DAIRY CATTLE													
													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Cabbage heads, leaves	AM/AV	3.1	HR	15	20.67		20				4.133		
Corn, field stover	AF/AS	5.5	HR	100	5.50	15	20	40		0.825	1.1	2.2	
Rye straw	AF/AS	4.5	HR	88	5.11				5				0.256
Corn, field forage/silage	AF/AS	2	HR	40	5.00	30	40	60	45	1.500	2	3	2.25
Apple pomace, wet	AB	0.5	STMR	40	1.25	10	10			0.125	0.125		
Wheat milled bypds	CM/CF	0.79	STMR	88	0.90	30	10		45	0.269	0.09		0.404
Carrot culls	VR	0.05	HR	12	0.42	10				0.042			
Pea hay	AL	0.39	HR	100	0.39	5				0.020			
Wheat grain	GC	0.25	STMR	89	0.28				5				0.014
Total						100	100	100	100	2.780	7.448	5.2	2.924

POULTRY BROILER													
													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Wheat milled bypds	CM/CF	0.79	STMR	88	0.90	50	20	20	5	0.449	0.18	0.18	0.045
Swede roots	VR	0.05	HR	10	0.50		10				0.05		
Wheat grain	GC	0.25	STMR	89	0.28	50	70	70	10	0.140	0.197	0.197	0.028
Distiller's grain dried	SM	0.25	STMR	92	0.27				5				0.014
Lupin seed meal	SM	0.05	STMR	85	0.06			10				0.006	
Soybean meal	SM	0.01	STMR	92	0.01				30				0.003
Total						100	100	100	50	0.59	0.426	0.382	0.09

POULTRY LAYER													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Cabbage heads, leaves	AM/AV	3.1	HR	15	20.67		5				1.033		
Wheat milled bypdts	CM/CF	0.79	STMR	88	0.90	50	20	20	30	0.449	0.18	0.18	0.269
Wheat straw	AF/AS	0.45	HR	88	0.51		10				0.051		
Swede roots	VR	0.05	HR	10	0.50		10				0.05		
Pea hay	AL	0.39	HR	100	0.39		10				0.039		
Wheat grain	GC	0.25	STMR	89	0.28	50	45	55		0.140	0.126	0.154	
Distiller's grain dried	SM	0.25	STMR	92	0.27				5				0.014
Lupin seed meal	SM	0.05	STMR	85	0.06			20				0.012	
Cowpea seed	VD	0.05	STMR	88	0.06			5				0.003	
Rape meal	SM	0.027	STMR	88	0.03				10				0.003
Soybean meal	SM	0.01	STMR	92	0.01				15				0.002
Total						100	100	100	60	0.589	1.479	0.349	0.288

BIFENTHRIN (178)

ESTIMATED MEAN DIETARY BURDEN													
BEEF CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Soybean asp gr fn	SM	9.5	STMR/STMR-P	85	11.18	5				0.558824			
Cabbage heads, leaves	AM/AV	1.5	STMR/STMR-P	15	10.00		20				2		
Rye straw	AF/AS	2.6	STMR/STMR-P	88	2.95	10	20	20		0.295455	0.591	0.591	
Oat straw	AF/AS	2.6	STMR/STMR-P	90	2.89			60				1.733	
Corn, field stover	AF/AS	2.2	STMR/STMR-P	100	2.20	5	5	20		0.11	0.11	0.44	
Corn, field forage/silage	AF/AS	0.585	STMR/STMR-P	40	1.46		55				0.804		
Wheat milled bypdts	CM/CF	0.79	STMR/STMR-P	88	0.90	40			55	0.359091			0.494
Wheat grain	GC	0.25	STMR/STMR-P	89	0.28	20			25	0.05618			0.07
Distiller's grain dried	SM	0.25	STMR/STMR-P	92	0.27	20			10	0.054			0.027
Soybean seed	VD	0.05	STMR/STMR-P	89	0.06				10				0.006
Total						100	100	100	100	1.434	3.505	2.764	0.597

DAIRY CATTLE														MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Cabbage heads, leaves	AM/AV	1.5	STMR/STMR-P	15	10.00		20	0			2	0		
Rye straw	AF/AS	2.6	STMR/STMR-P	88	2.95	10	20	20	5	0.295455	0.591	0.591	0.148	
Oat straw	AF/AS	2.6	STMR/STMR-P	90	2.89	0		40		0		1.156		
Corn, field stover	AF/AS	2.2	STMR/STMR-P	100	2.20	5				0.11				
Corn, field forage/silage	AF/AS	0.585	STMR/STMR-P	40	1.46	30	40	40	45	0.43875	0.585	0.585	0.658	
Apple pomace, wet	AB	0.5	STMR/STMR-P	40	1.25	10	10			0.125	0.125			
Wheat milled bypds	CM/CF	0.79	STMR/STMR-P	88	0.90	30	10		45	0.269318	0.09		0.404	
Carrot culls	VR	0.05	STMR/STMR-P	12	0.42	10				0.041667				
Turnip roots	VR	0.05	STMR/STMR-P	15	0.33	5				0.016667				
Wheat grain	GC	0.25	STMR/STMR-P	89	0.28	0			5	0			0.014	
Total						100	100	100	100	1.296856	3.391	2.331	1.224	

POULTRY BROILER														MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Wheat milled bypds	CM/CF	0.79	STMR/STMR-P	88	0.90	50	20	20	5	0.45	0.18	0.18	0.045	
Swede roots	VR	0.05	STMR/STMR-P	10	0.50		10				0.05			
Wheat grain	GC	0.25	STMR/STMR-P	89	0.28	50	70	70	10	0.14	0.197	0.197	0.028	
Distiller's grain dried	SM	0.25	STMR/STMR-P	92	0.27				5				0.014	
Lupin seed meal	SM	0.05	STMR/STMR-P	85	0.06			10				0.006		
Soybean meal	SM	0.01	STMR/STMR-P	92	0.01				30				0.003	
Total						100	100	100	50	0.59	0.426	0.382	0.09	

POULTRY LAYER														MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Cabbage heads, leaves	AM/AV	1.5	STMR/STMR-P	15	10.00		5				0.5			
Wheat milled bypds	CM/CF	0.79	STMR/STMR-P	88	0.90	50	20	20	30	0.448864	0.18	0.18	0.269	
Swede roots	VR	0.05	STMR/STMR-P	10	0.50		10				0.05			
Wheat straw	AF/AS	0.26	STMR/STMR-P	88	0.30		10				0.03			
Wheat grain	GC	0.25	STMR/STMR-P	89	0.28	50	55	55		0.140449	0.154	0.154		
Distiller's	SM	0.25	STMR/STMR-P	92	0.27				5				0.014	

POULTRY LAYER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
grain dried													
Lupin seed meal	SM	0.05	STMR/STMR-P	85	0.06			20					0.012
Cowpea seed	VD	0.05	STMR/STMR-P	88	0.06			5					0.003
Rape meal	SM	0.027	STMR/STMR-P	88	0.03				10				0.00
Soybean meal	SM	0.01	STMR/STMR-P	92	0.01				15				0.002
Total						100	100	100	60	0.589313	0.914	0.349	0.288

BROFLANILIDE (326)

ESTIMATED MAXIMUM DIETARY BURDEN													
BEEF CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Cabbage heads, leaves	AM/AV	0.95	HR	15	6.33		20				1.267		
Potato culls	VR	0.034	HR	20	0.17	30	30	10		0.051	0.051	0.017	
Wheat forage	AF/AS	0.001	HR	25	0.00		20	90			8E-04	0.004	
Corn, field forage/silage	AF/AS	0.001	HR	40	0.00	15	30			0.000	8E-04		
Potato process waste	AB	0.0003	STMR	12	0.00	30				0.001			
Total						75	100	100		0.052	1.319	0.021	

DAIRY CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Cabbage heads, leaves	AM/AV	0.95	HR	15	6.33		20				1.267		
Potato culls	VR	0.034	HR	20	0.17	10	30	10		0.017	0.051	0.017	
Wheat forage	AF/AS	0.001	HR	25	0.00	20	20	60		0.001	8E-04	0.002	
Corn, field forage/silage	AF/AS	0.001	HR	40	0.00	25	30	30	50	0.001	8E-04	8E-04	0.001
Potato process waste	AB	0.0003	STMR	12	0.00	10				0.000			
Total						65	100	100	50	0.019	1.319	0.02	0.001

POULTRY BROILER														MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Potato culls	VR	0.034	HR	20	0.17		10				0.017			
Potato dried pulp	AB	0.0022	STMR	88	0.00		20				5E-04			
Total							30				0.018			

POULTRY LAYER														MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Cabbage heads, leaves	AM/AV	0.95	HR	15	6.33		5				0.317			
Potato culls	VR	0.034	HR	20	0.17		10				0.017			
Wheat forage	AF/AS	0.001	HR	25	0.00		10				4E-04			
Potato dried pulp	AB	0.0022	STMR	88	0.00		15				4E-04			
Total							40				0.334			

BROFLANILIDE (326)

ESTIMATED MEAN DIETARY BURDEN														MEAN
BEEF CATTLE														
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Cabbage heads, leaves	AM/AV	0.19	STMR/STMR-P	15	1.27		20				0.253			
Potato culls	VR	0.00175	STMR/STMR-P	20	0.01	30	30	10		0.002625	0.003	9E-04		
Wheat forage	AF/AS	0.001	STMR/STMR-P	25	0.00		20	90			8E-04	0.004		
Corn, field forage/silage	AF/AS	0.001	STMR/STMR-P	40	0.00	15	30			0.000375	8E-04			
Potato process waste	AB	0.0003	STMR/STMR-P	12	0.00	30				0.00075				
Total						75	100	100		0.00375	0.258	0.004		

DAIRY CATTLE														MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Cabbage heads, leaves	AM/AV	0.19	STMR/STMR-P	15	1.27		20	0			0.253	0		
Potato culls	VR	0.00175	STMR/STMR-P	20	0.01	10	30	10		0.000875	0.003	9E-04		
Wheat forage	AF/AS	0.001	STMR/STMR-P	25	0.00	20	20	60		0.0008	8E-04	0.002		

DAIRY CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
			P										
Corn, field forage/silage	AF/AS	0.001	STMR/STMR-P	40	0.00	25	30	30	50	0.000625	8E-04	8E-04	0.001
Potato process waste	AB	0.0003	STMR/STMR-P	12	0.00	10				0.00025			
Total						65	100	100	50	0.00255	0.258	0.004	0.001

POULTRY BROILER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Potato culls	VR	0.00175	STMR/STMR-P	20	0.01		10				9E-04		
Potato dried pulp	AB	0.0022	STMR/STMR-P	88	0.00		20				5E-04		
Total							30				0.001		

POULTRY LAYER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Cabbage heads, leaves	AM/AV	0.19	STMR/STMR-P	15	1.27		5				0.063		
Potato culls	VR	0.00175	STMR/STMR-P	20	0.01		10				9E-04		
Wheat forage	AF/AS	0.001	STMR/STMR-P	25	0.00		10				4E-04		
Potato dried pulp	AB	0.0022	STMR/STMR-P	88	0.00		15				4E-04		
Total							40				0.065		

DIMETHOATE (027)

ESTIMATED MAXIMUM DIETARY BURDEN													
BEEF CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Wheat forage	AF/AS	4.4	HR	25	17.60		20	100			3.52	17.6	
Wheat straw	AF/AS	2.7	HR	100	2.70	10				0.270			
Citrus dried pulp	AB	1.35	STMR	91	1.48	10	5			0.148	0.074		
Bean seed	VD	0.1	STMR	88	0.11		20				0.023		
Wheat grain	GC	0.008	STMR	89	0.01	20	40		25	0.002	0.004		0.002
Total						40	85	100	25	0.420	3.62	17.6	0.002

DAIRY CATTLE													
													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Wheat forage	AF/AS	4.4	HR	25	17.60	20	20	60		3.520	3.52	10.56	
Citrus dried pulp	AB	1.35	STMR	91	1.48	10	20	30		0.148	0.297	0.445	
Bean seed	VD	0.1	STMR	88	0.11		20	10			0.023	0.011	
Wheat grain	GC	0.008	STMR	89	0.01	20	40		10	0.002	0.004		0.0009
Total						50	100	100	10	3.670	3.843	11.02	0.0009

POULTRY BROILER													
													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Bean seed	VD	0.1	STMR	88	0.11		20	70			0.023	0.08	
Wheat grain	GC	0.008	STMR	89	0.01	75	70	30	10	0.007	0.006	0.003	0.0009
Total						75	90	100	10	0.007	0.029	0.082	9E-04

POULTRY LAYER													
													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Wheat forage	AF/AS	4.4	HR	25	17.60		10				1.76		
Bean seed	VD	0.1	STMR	88	0.11		20	70			0.023	0.08	
Wheat grain	GC	0.008	STMR	89	0.01	75	70	30		0.007	0.006	0.003	
Total						75	100	100		0.007	1.789	0.082	

DIMETHOATE (027)

ESTIMATED MEAN DIETARY BURDEN													
BEEF CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Wheat forage	AF/AS	0.76	STMR/STMR-P	25	3.04		20	100			0.608	3.04	
Citrus dried pulp	AB	1.35	STMR/STMR-P	91	1.48	10	5			0.148352	0.074		
Bean seed	VD	0.1	STMR/STMR-P	88	0.11		20				0.023		
Wheat straw	AF/AS	0.06	STMR/STMR-P	100	0.06	10				0.006			
Wheat grain	GC	0.008	STMR/STMR-P	89	0.01	20	40		25	0.001798	0.004		0.002
Total						40	85	100	25	0.156149	0.708	3.04	0.002

DAIRY CATTLE													
													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Wheat forage	AF/AS	0.76	STMR/STMR-P	25	3.04	20	20	60		0.608	0.608	1.824	
Citrus dried pulp	AB	1.35	STMR/STMR-P	91	1.48	10	20	30		0.148352	0.297	0.445	
Bean seed	VD	0.1	STMR/STMR-P	88	0.11	0	20	10		0	0.023	0.011	
Wheat grain	GC	0.008	STMR/STMR-P	89	0.01	20	40		10	0.001798	0.004		0.0009
Total						50	100	100	10	0.758149	0.931	2.28	0.0009

POULTRY BROILER													
													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Bean seed	VD	0.1	STMR/STMR-P	88	0.11		20	70			0.023	0.08	
Wheat grain	GC	0.008	STMR/STMR-P	89	0.01	75	70	30	10	0.01	0.006	0.003	0.0009
Total						75	90	100	10	0.01	0.029	0.082	0.0009

POULTRY LAYER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Wheat forage	AF/AS	0.76	STMR/STMR-P	25	3.04		10				0.304		
Bean seed	VD	0.1	STMR/STMR-P	88	0.11		20	70			0.023	0.08	
Wheat grain	GC	0.008	STMR/STMR-P	89	0.01	75	70	30		0.006742	0.006	0.003	
Total						75	100	100		0.006742	0.333	0.082	

EMAMECTIN BENZOATE (247)

ESTIMATED MAXIMUM DIETARY BURDEN													
BEEF CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Bean vines	AL	0.093	HR	35	0.27			60				0.159	
Apple pomace, wet	AB	0.0204	STMR	40	0.05		20	20			0.01	0.01	
Almond hulls	AM/AV	0.0315	STMR	90	0.04			10				0.004	
Soybean asp gr fn	SM	0.0026	STMR	85	0.00	5				0.000			
Cotton undelinted seed	SO	0.002	STMR	88	0.00			10				2E-04	
Cotton hulls	SM	0.002	STMR	90	0.00	5				0.0001			
Total						10	20	100		0.0003	0.0102	0.1734	

DAIRY CATTLE													
													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Bean vines	AL	0.093	HR	35	0.27		20	70			0.053	0.186	
Apple pomace, wet	AB	0.0204	STMR	40	0.05	10	10	10		0.005	0.005	0.005	
Almond hulls	AM/AV	0.0315	STMR	90	0.04	10		10		0.004		0.004	
Cotton undelinted seed	SO	0.002	STMR	88	0.00	10	10	10		0.000	2E-04	2E-04	
Total						30	40	100		0.0088	0.0585	0.1948	

EMAMECTIN BENZOATE (247)

ESTIMATED MEAN DIETARY BURDEN													
BEEF CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Apple pomace, wet	AB	0.0204	STMR/STMR-P	40	0.05		20	20			0.0102	0.0102	
Almond hulls	AM/AV	0.0315	STMR/STMR-P	90	0.04			10				0.0035	
Bean vines	AL	0.008	STMR/STMR-P	35	0.02			60				0.0137143	
Soybean asp gr fn	SM	0.0026	STMR/STMR-P	85	0.00	5				0.000153			
Cotton undelinted seed	SO	0.002	STMR/STMR-P	88	0.00			10				0.0002273	
Cotton hulls	SM	0.002	STMR/STMR-P	90	0.00	5				0.000111			
Total						10	20	100		0.0003	0.01020	0.0276	

DAIRY CATTLE													
													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Apple pomace, wet	AB	0.0204	STMR/STMR-P	40	0.05	10	10	10		0.0051	0.0051	0	
Almond hulls	AM/AV	0.0315	STMR/STMR-P	90	0.04	10		10		0.0035		0.00350	
Bean vines	AL	0.008	STMR/STMR-P	35	0.02	0	20	70		0	0.00457	0.01600	
Cotton undelinted seed	SO	0.002	STMR/STMR-P	88	0.00	10	10	10		0.000227	0.00023	0.0002273	
Total						30	40	100		0.008827	0.0099	0.02483	

FENZAQUIN (287)

ESTIMATED MAXIMUM DIETARY BURDEN													
BEEF CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Almond hulls	AM/AV	1.2	STMR	90	1.33			10				0.1333	
Tomato pomace,wet	AB	0.052	STMR	20	0.26			10				0.026	
Apple pomace, wet	AB	0.08	STMR	40	0.20		20	10			0.04	0.02	
Citrus dried pulp	AB	0.027	STMR	91	0.03	10		10		0.003		0.003	
Total						10	20	40		0.003	0.04	0.1823	

DAIRY CATTLE													
													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Almond hulls	AM/AV	1.2	STMR	90	1.33	10		10		0.133		0.1333	
Tomato pomace,wet	AB	0.052	STMR	20	0.26			10				0.026	
Apple pomace, wet	AB	0.08	STMR	40	0.20	10	10			0.020	0.02		
Citrus dried pulp	AB	0.027	STMR	91	0.03		10	20			0.003	0.0059	
Total						20	20	40		0.153	0.023	0.1653	

FENZAQUIN (287)

ESTIMATED MEAN DIETARY BURDEN													
BEEF CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Almond hulls	AM/AV	1.2	STMR/STMR-P	90	1.33			10				0.13333	
Tomato pomace,wet	AB	0.052	STMR/STMR-P	20	0.26			10				0.026	
Apple pomace, wet	AB	0.08	STMR/STMR-P	40	0.20		20	10			0.04	0.02	
Citrus dried pulp	AB	0.027	STMR/STMR-P	91	0.03	10		10		0.003		0.00297	
Total						10	20	40		0.003	0.04	0.1823	

DAIRY CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Almond hulls	AM/AV	1.2	STMR/STMR-P	90	1.33	10	0	10		0.1333	0	0.13333	
Tomato pomace,wet	AB	0.052	STMR/STMR-P	20	0.26	0		10		0		0.026	
Apple pomace, wet	AB	0.08	STMR/STMR-P	40	0.20	10	10			0.02	0.02		
Citrus dried pulp	AB	0.027	STMR/STMR-P	91	0.03	0	10	20		0	0.003	0.00593	
Total						20	20	40		0.1533	0.023	0.16527	

FLUAZINDOLIZINE (327)

ESTIMATED MAXIMUM DIETARY BURDEN													
BEEF CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Carrot culls	VR	0.265	HR	12	2.21		15	5			0.331	0.11	
Potato culls	VR	0.16	HR	20	0.80	30	15	5		0.240	0.12	0.04	
Pea vines	AL	0.0848	HR	25	0.34		20	60			0.068	0.204	
Cabbage heads, leaves	AM/AV	0.0179	HR	15	0.12		20				0.024		
Soybean hay	AL	0.0848	HR	85	0.10			30				0.03	
Trefoil hay	AL	0.0848	HR	85	0.10	15				0.015			
Cowpea hay	AL	0.0848	HR	86	0.10		30				0.03		
Alfalfa hay	AL	0.0848	HR	89	0.10				10				0.01
Grass forage (fresh)	AF/AS	0.0179	HR	25	0.07				5				0.004
Corn, field stover	AF/AS	0.0553	HR	83	0.07	15				0.010			
Grass hay	AF/AS	0.0553	HR	88	0.06				35				0.022
Barley grain	GC	0.0072	STMR	88	0.01	40			50	0.003			0.004
Total						100	100	100	100	0.268	0.573	0.384	0.039

DAIRY CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Carrot culls	VR	0.265	HR	12	2.21	10	15	5		0.221	0.331	0.11	
Potato culls	VR	0.16	HR	20	0.80		15	5			0.12	0.04	
Pea vines	AL	0.0848	HR	25	0.34	10	20	40		0.034	0.068	0.136	
Cabbage heads, leaves	AM/AV	0.0179	HR	15	0.12		20				0.024		
Kale leaves	AM/AV	0.0179	HR	15	0.12			40				0.048	
Peanut hay	AL	0.0974	HR	85	0.11	5		10		0.006		0.011	
Soybean hay	AL	0.0848	HR	85	0.10	5				0.005			

DAIRY CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Trefoil hay	AL	0.0848	HR	85	0.10	20	30			0.020	0.03		
Alfalfa hay	AL	0.0848	HR	89	0.10				25				0.024
Grass forage (fresh)	AF/AS	0.0179	HR	25	0.07	45			10	0.032			0.007
Grass hay	AF/AS	0.0553	HR	88	0.06				65				0.041
Clover forage	AL	0.0178	HR	30	0.06	5				0.003			
Total						100	100	100	100	0.321	0.573	0.35	0.07

POULTRY BROILER													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Carrot culls	VR	0.265	HR	12	2.21		10				0.221		
Bean seed	VD	0.0094	STMR	88	0.01		20	70			0.002	0.007	
Cowpea seed	VD	0.0094	STMR	88	0.01	10				0.001			
Pea seed	VD	0.0094	STMR	90	0.01	10				0.001			
Barley grain	GC	0.0072	STMR	88	0.01	75	70	15	10	0.006	0.006	0.001	8E-04
Corn, field grain	GC	0.0072	STMR	88	0.01				60				0.005
Total						95	100	85	70	0.01	0.229	0.009	0.006

POULTRY LAYER													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Carrot culls	VR	0.265	HR	12	2.21		10				0.221		
Pea vines	AL	0.0848	HR	25	0.34		10				0.034		
Cabbage heads, leaves	AM/AV	0.0179	HR	15	0.12		5				0.006		
Wheat forage	AF/AS	0.0179	HR	25	0.07		10				0.007		
Rape forage	AM/AV	0.0075	HR	30	0.03		5				0.001		
Bean seed	VD	0.0094	STMR	88	0.01		20	70			0.002	0.007	
Cowpea seed	VD	0.0094	STMR	88	0.01	10				0.001			
Pea seed	VD	0.0094	STMR	90	0.01	10				0.001			
Barley grain	GC	0.0072	STMR	88	0.01	75	40	15		0.006	0.003	0.001	
Corn, field grain	GC	0.0072	STMR	88	0.01				80				0.007
Total						95	100	85	80	0.008	0.275	0.009	0.007

FLUAZAINDOLIZINE (327)

ESTIMATED MEAN DIETARY BURDEN													
BEEF CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Potato culls	VR	0.028	STMR/STMR-P	20	0.14	30	30	10		0.042	0.042	0.014	
Cabbage heads, leaves	AM/AV	0.0178	STMR/STMR-P	15	0.12		20				0.024		
Pea vines	AL	0.0274	STMR/STMR-P	25	0.11		20	60			0.022	0.066	
Tomato pomace,wet	AB	0.0125	STMR/STMR-P	20	0.06			10				0.006	
Turnip tops (leaves)	AM/AV	0.0178	STMR/STMR-P	30	0.06		30	20			0.018	0.012	
Alfalfa hay	AL	0.0274	STMR/STMR-P	89	0.03	15			10	0.004617978			0.003
Grass forage (fresh)	AF/AS	0.0072	STMR/STMR-P	25	0.03				5				0.001
Sorghum, grain forage	AF/AS	0.0072	STMR/STMR-P	35	0.02	15				0.003085714			
Soybean hulls	SM	0.00459	STMR/STMR-P	90	0.01	15			5	0.001			3E-04
Total						75	100	100	20	0.050	0.105	0.098	0.005

DAIRY CATTLE													
													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Potato culls	VR	0.028	STMR/STMR-P	20	0.14	10	30	10		0.014	0.042	0.014	
Cabbage heads, leaves	AM/AV	0.0178	STMR/STMR-P	15	0.12	0	20			0	0.024		
Kale leaves	AM/AV	0.0178	STMR/STMR-P	15	0.12	0		40		0		0.047	
Pea vines	AL	0.0274	STMR/STMR-P	25	0.11	10	20	40		0.01096	0.022	0.044	
Tomato pomace,wet	AB	0.0125	STMR/STMR-P	20	0.06	0		10		0		0.006	
Turnip tops (leaves)	AM/AV	0.0178	STMR/STMR-P	30	0.06	30				0.0178			
Lespedeza forage	AL	0.0107	STMR/STMR-P	22	0.05	30				0.014590909			
Clover forage	AL	0.0107	STMR/STMR-P	30	0.04	0	30			0	0.011		
Alfalfa hay	AL	0.0274	STMR/STMR-P	89	0.03	0			25	0			0.008
Grass forage (fresh)	AF/AS	0.0072	STMR/STMR-P	25	0.03	20			10	0.00576			0.003
Sorghum, grain forage	AF/AS	0.0072	STMR/STMR-P	35	0.02	0			30	0			0.006
Corn, field forage/silage	AF/AS	0.0072	STMR/STMR-P	40	0.02	0			35	0			0.006
Total						100	100	100	100	0.063110909	0.098	0.112	0.023

POULTRY BROILER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Potato culls	VR	0.028	STMR/STMR-P	20	0.14		10				0.014		
Bean seed	VD	0.0094	STMR/STMR-P	88	0.01		20	70			0.002	0.007	
Cowpea seed	VD	0.0094	STMR/STMR-P	88	0.01	10				0.001			
Pea seed	VD	0.0094	STMR/STMR-P	90	0.01	10				0.001			
Soybean hulls	SM	0.00459	STMR/STMR-P	90	0.01		5				3E-04		
Total						20	35	70		0.002	0.016	0.007	

POULTRY LAYER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Potato culls	VR	0.028	STMR/STMR-P	20	0.14		10				0.014		
Cabbage heads, leaves	AM/AV	0.0178	STMR/STMR-P	15	0.12		5				0.006		
Pea vines	AL	0.0274	STMR/STMR-P	25	0.11		10				0.011		
Wheat forage	AF/AS	0.0072	STMR/STMR-P	25	0.03		10				0.003		
Bean seed	VD	0.0094	STMR/STMR-P	88	0.01		20	70			0.002	0.007	
Cowpea seed	VD	0.0094	STMR/STMR-P	88	0.01	10				0.001068182			
Pea seed	VD	0.0094	STMR/STMR-P	90	0.01	10				0.001044444			
Soybean hulls	SM	0.00459	STMR/STMR-P	90	0.01		5				3E-04		
Total						20	60	70		0.002	0.036	0.007	

IN F4106

ESTIMATED MAXIMUM DIETARY BURDEN													
BEEF CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Carrot culls	VR	0.1489	HR	12	1.24		15	5			0.186	0.062	
Peanut hay	AL	0.8342	HR	85	0.98			60				0.589	
Soybean hay	AL	0.8342	HR	85	0.98			35				0.343	
Cowpea hay	AL	0.8342	HR	86	0.97		35				0.34		
Lespedeza hay	AL	0.8342	HR	88	0.95	15				0.142			
Alfalfa hay	AL	0.8342	HR	89	0.94				10				0.094
Corn, field stover	AF/AS	0.5487	HR	83	0.66	15	25			0.099	0.165		
Cabbage heads, leaves	AM/AV	0.0954	HR	15	0.64		20				0.127		
Grass hay	AF/AS	0.5487	HR	88	0.62		5		40		0.031		0.249
Potato culls	VR	0.1127	HR	20	0.56	30				0.169			
Corn gluten meal	CM/CF	0.0139	STMR	40	0.03	40				0.014			
Soybean meal	SM	0.0226	STMR	92	0.02				50				0.012

ESTIMATED MAXIMUM DIETARY BURDEN													
BEEF CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Total						100	100	100	100	0.424	0.849	0.994	0.355

DAIRY CATTLE													
DAIRY CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Carrot culls	VR	0.1489	HR	12	1.24	10	15	5		0.124	0.186	0.062	
Peanut hay	AL	0.8342	HR	85	0.98	15		60		0.147		0.589	
Soybean hay	AL	0.8342	HR	85	0.98	5				0.049			
Cowpea hay	AL	0.8342	HR	86	0.97		35				0.34		
Lespedeza hay	AL	0.8342	HR	88	0.95	20				0.190			
Pea hay	AL	0.8342	HR	88	0.95			35				0.332	
Alfalfa hay	AL	0.8342	HR	89	0.94		5		25		0.047		0.234
Corn, field stover	AF/AS	0.5487	HR	83	0.66	15	20			0.099	0.132		
Millet hay	AF/AS	0.5487	HR	85	0.65	5				0.032			
Cabbage heads, leaves	AM/AV	0.0954	HR	15	0.64		20				0.127		
Grass hay	AF/AS	0.5487	HR	88	0.62	30	5		70	0.187	0.031		0.436
Grass forage (fresh)	AF/AS	0.0974	HR	25	0.39				5				0.019
Total						100	100	100	100	0.828	0.863	0.98	0.69

POULTRY BROILER													
POULTRY BROILER													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Carrot culls	VR	0.1489	HR	12	1.24		10				0.124		
Corn gluten meal	CM/CF	0.0139	STMR	40	0.03		10				0.003		
Soybean meal	SM	0.0226	STMR	92	0.02	25	40	25	35	0.006	0.01	0.006	0.009
Sorghum, grain grain	GC	0.0204	STMR	86	0.02	75	40	70	65	0.018	0.009	0.017	0.015
Bean seed	VD	0.0202	STMR	88	0.02			5				0.001	
Total						100	100	100	100	0.024	0.147	0.024	0.024

POULTRY LAYER													
POULTRY LAYER													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Carrot culls	VR	0.1489	HR	12	1.24		10				0.124		
Soybean hay	AL	0.8342	HR	85	0.98		10				0.098		
Cabbage heads, leaves	AM/AV	0.0954	HR	15	0.64		5				0.032		
Barley straw	AF/AS	0.5487	HR	89	0.62		5				0.031		
Wheat forage	AF/AS	0.0974	HR	25	0.39		5				0.019		
Rape forage	AM/AV	0.0209	HR	30	0.07		5				0.003		

POULTRY LAYER													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Corn gluten meal	CM/CF	0.0139	STMR	40	0.03		10		10		0.003		0.003
Soybean meal	SM	0.0226	STMR	92	0.02	25	25	25	30	0.006	0.006	0.006	0.007
Sorghum, grain grain	GC	0.0204	STMR	86	0.02	75	25	70	55	0.02	0.006	0.017	0.01
Bean seed	VD	0.0202	STMR	88	0.02			5				0.001	
Total						100	100	100	95	0.024	0.323	0.024	0.024

IN F4106

ESTIMATED MEAN DIETARY BURDEN													
BEEF CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Cabbage heads, leaves	AM/AV	0.0501	STMR/STMR-P	15	0.33		20				0.067		
Clover forage	AL	0.0934	STMR/STMR-P	30	0.31		30	100			0.093	0.311	
Cowpea hay	AL	0.1687	STMR/STMR-P	86	0.20		5				0.01		
Lespedeza hay	AL	0.1687	STMR/STMR-P	88	0.19	15				0.028755682			
Alfalfa hay	AL	0.1687	STMR/STMR-P	89	0.19				10				0.019
Carrot culls	VR	0.0207	STMR/STMR-P	12	0.17		15				0.026		
Potato culls	VR	0.0337	STMR/STMR-P	20	0.17	30	15			0.05055	0.025		
Turnip tops (leaves)	AM/AV	0.0501	STMR/STMR-P	30	0.17		15				0.025		
Corn, field stover	AF/AS	0.1328	STMR/STMR-P	83	0.16	15				0.024			
Grass hay	AF/AS	0.1328	STMR/STMR-P	88	0.15				40				0.06
Corn gluten meal	CM/CF	0.0139	STMR/STMR-P	40	0.03	40				0.014			
Soybean meal	SM	0.0226	STMR/STMR-P	92	0.02				50				0.012
Total						100	100	100	100	0.117	0.246	0.311	0.092

DAIRY CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Cabbage heads, leaves	AM/AV	0.0501	STMR/STMR-P	15	0.33		20	0			0.067	0	
Kale leaves	AM/AV	0.0501	STMR/STMR-P	15	0.33	0		40		0		0.134	
Clover forage	AL	0.0934	STMR/STMR-P	30	0.31	20	40	60		0.062266667	0.125	0.187	
Lespedeza hay	AL	0.1687	STMR/STMR-P	88	0.19	20				0.038340909			
Alfalfa hay	AL	0.1687	STMR/STMR-P	89	0.19	0			25	0			0.047
Carrot culls	VR	0.0207	STMR/STMR-P	12	0.17	10	15			0.01725	0.026		
Potato culls	VR	0.0337	STMR/STMR-P	20	0.17	0	25			0	0.042		
Turnip tops (leaves)	AM/AV	0.0501	STMR/STMR-P	30	0.17	30				0.0501			
Corn, field stover	AF/AS	0.1328	STMR/STMR-P	83	0.16	15				0.024			
Millet hay	AF/AS	0.1328	STMR/STMR-P	85	0.16	5				0.007811765			
Grass hay	AF/AS	0.1328	STMR/STMR-P	88	0.15	0			70	0			0.106
Grass forage (fresh)	AF/AS	0.0281	STMR/STMR-P	25	0.11	0			5	0			0.006
Total						100	100	100	100	0.19976934	0.259	0.32	0.159

POULTRY BROILER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Carrot culls	VR	0.0207	STMR/STMR-P	12	0.17		10				0.017		
Corn gluten meal	CM/CF	0.0139	STMR/STMR-P	40	0.03		10				0.003		
Soybean meal	SM	0.0226	STMR/STMR-P	92	0.02	25	40	25	35	0.006	0.01	0.006	0.009
Sorghum, grain grain	GC	0.0204	STMR/STMR-P	86	0.02	75	40	70	65	0.018	0.009	0.017	0.015
Bean seed	VD	0.0202	STMR/STMR-P	88	0.02			5				0.001	
Total						100	100	100	100	0.02	0.04	0.024	0.024

POULTRY LAYER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Cabbage heads, leaves	AM/AV	0.0501	STMR/STMR-P	15	0.33		5				0.017		
Clover forage	AL	0.0934	STMR/STMR-P	30	0.31		10				0.031		
Carrot culls	VR	0.0207	STMR/STMR-P	12	0.17		10				0.017		
Barley straw	AF/AS	0.1328	STMR/STMR-P	89	0.15		5				0.007		
Wheat forage	AF/AS	0.0281	STMR/STMR-P	25	0.11		5				0.006		
Rape forage	AM/AV	0.0205	STMR/STMR-P	30	0.07		5				0.003		
Corn gluten meal	CM/CF	0.0139	STMR/STMR-P	40	0.03		10		10		0.003		0.003
Soybean meal	SM	0.0226	STMR/STMR-P	92	0.02	25	25	25	30	0.006141304	0.006	0.006	0.007
Sorghum, grain grain	GC	0.0204	STMR/STMR-P	86	0.02	75	25	70	55	0.018	0.006	0.017	0.01
Bean seed	VD	0.0202	STMR/STMR-P	88	0.02			5				0.001	
Total						100	100	100	95	0.023932002	0.097	0.024	0.024

IN-QZY47

ESTIMATED MAXIMUM DIETARY BURDEN													MAX
BEEF CATTLE													
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Pea vines	AL	1.6035	HR	25	6.41		20	60			1.283	3.848	
Carrot culls	VR	0.5	HR	12	4.17		15	5			0.625	0.208	
Soybean hay	AL	1.6035	HR	85	1.89			35				0.66	
Cowpea hay	AL	1.6035	HR	86	1.86		15				0.28		
Lespedeza hay	AL	1.6035	HR	88	1.82	15				0.273			
Alfalfa hay	AL	1.6035	HR	89	1.80				10				0.18
Cabbage heads, leaves	AM/AV	0.2276	HR	15	1.52		20				0.303		
Cowpea forage	AL	0.3391	HR	30	1.13		30				0.339		
Potato culls	VR	0.072	HR	20	0.36	30				0.108			
Grass forage (fresh)	AF/AS	0.0254	HR	25	0.10				5				0.005
Sorghum, grain forage	AF/AS	0.0254	HR	35	0.07	15				0.011			
Grass hay	AF/AS	0.0315	HR	88	0.04				35				0.013
Soybean seed	VD	0.0084	STMR	89	0.01	5			15	0.000			0.001
Barley grain	GC	0.0072	STMR	88	0.01	35			35	0.003			0.00
Total						100	100	100	100	0.396	2.83	4.717	0.202

DAIRY CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Pea vines	AL	1.6035	HR	25	6.41	10	20	40		0.641	1.283	2.566	
Carrot culls	VR	0.5	HR	12	4.17	10	15	5		0.417	0.625	0.208	
Peanut hay	AL	1.6035	HR	85	1.89	5		55		0.094		1.038	
Soybean hay	AL	1.6035	HR	85	1.89	5				0.094			
Cowpea hay	AL	1.6035	HR	86	1.86		15				0.28		
Lespedeza hay	AL	1.6035	HR	88	1.82	20				0.364			
Alfalfa hay	AL	1.6035	HR	89	1.80		5		25		0.09		0.45
Cabbage heads, leaves	AM/AV	0.2276	HR	15	1.52		20				0.303		
Clover forage	AL	0.3391	HR	30	1.13		25				0.283		
Turnip tops (leaves)	AM/AV	0.2276	HR	30	0.76	30				0.228			
Grass forage (fresh)	AF/AS	0.0254	HR	25	0.10	20			10	0.020			0.01
Sorghum, grain forage	AF/AS	0.0254	HR	35	0.07				30				0.022
Corn, field forage/silage	AF/AS	0.0254	HR	40	0.06				35				0.02
Total						100	100	100	100	1.859	2.864	3.811	0.505

POULTRY BROILER													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Carrot culls	VR	0.5	HR	12	4.17		10				0.417		
Bean seed	VD	0.0084	STMR	88	0.01		20	70			0.002	0.007	
Cowpea seed	VD	0.0084	STMR	88	0.01	10				0.001			
Pea seed	VD	0.0084	STMR	90	0.01	10				0.001			
Barley grain	GC	0.0072	STMR	88	0.01	75	70	15	10	0.006	0.006	0.001	8E-04
Corn, field grain	GC	0.0072	STMR	88	0.01				60				0.005
Total						95	100	85	70	0.01	0.424	0.008	0.006

POULTRY LAYER													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Pea vines	AL	1.6035	HR	25	6.41		10				0.641		
Carrot culls	VR	0.5	HR	12	4.17		10				0.417		
Cabbage heads, leaves	AM/AV	0.2276	HR	15	1.52		5				0.076		
Rape forage	AM/AV	0.0462	HR	30	0.15		5				0.008		
Wheat forage	AF/AS	0.0254	HR	25	0.10		10				0.01		
Bean seed	VD	0.0084	STMR	88	0.01		20	70			0.002	0.007	
Cowpea seed	VD	0.0084	STMR	88	0.01	10				0.001			
Pea seed	VD	0.0084	STMR	90	0.01	10				0.001			
Barley grain	GC	0.0072	STMR	88	0.01	75	40	15		0.01	0.003	0.001	
Corn, field grain	GC	0.0072	STMR	88	0.01				80				0.007
Total						95	100	85	80	0.008	1.157	0.008	0.007

IN-QZY47

ESTIMATED MEAN DIETARY BURDEN													
BEEF CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Pea vines	AL	0.3296	STMR/STMR-P	25	1.32		20	60			0.264	0.791	
Cabbage heads, leaves	AM/AV	0.0824	STMR/STMR-P	15	0.55		20				0.11		
Soybean hay	AL	0.3296	STMR/STMR-P	85	0.39			40				0.155	
Cowpea hay	AL	0.3296	STMR/STMR-P	86	0.38		15				0.057		
Lespedeza hay	AL	0.3296	STMR/STMR-P	88	0.37	15				0.056181818			
Alfalfa hay	AL	0.3296	STMR/STMR-P	89	0.37				10				0.037
Alfalfa forage	AL	0.1062	STMR/STMR-P	35	0.30		45				0.137		
Potato culls	VR	0.011	STMR/STMR-P	20	0.06	30				0.0165			
Grass forage (fresh)	AF/AS	0.00905	STMR/STMR-P	25	0.04				5				0.002
Sorghum, grain forage	AF/AS	0.00905	STMR/STMR-P	35	0.03	15				0.004			
Total						60	100	100	15	0.077	0.568	0.946	0.039

DAIRY CATTLE													
													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Pea vines	AL	0.3296	STMR/STMR-P	25	1.32	10	20	40		0.13184	0.264	0.527	
Cabbage heads, leaves	AM/AV	0.0824	STMR/STMR-P	15	0.55	0	20			0	0.11		
Kale leaves	AM/AV	0.0824	STMR/STMR-P	15	0.55	0		40		0		0.22	
Lespedeza forage	AL	0.1062	STMR/STMR-P	22	0.48	30		20		0.144818182		0.097	
Cowpea hay	AL	0.3296	STMR/STMR-P	86	0.38	0	15			0	0.057		
Alfalfa hay	AL	0.3296	STMR/STMR-P	89	0.37	0	5		25	0	0.019		0.093
Turnip tops (leaves)	AM/AV	0.0824	STMR/STMR-P	30	0.27	30				0.0824			
Carrot culls	VR	0.031	STMR/STMR-P	12	0.26	10	15			0.025833333	0.039		
Turnip roots	VR	0.0179	STMR/STMR-P	15	0.12	0	5			0	0.006		
Potato culls	VR	0.011	STMR/STMR-P	20	0.06	0	20			0	0.011		

DAIRY CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Grass forage (fresh)	AF/AS	0.00905	STMR/STMR-P	25	0.04	20			10	0.00724			0.004
Sorghum, grain forage	AF/AS	0.00905	STMR/STMR-P	35	0.03	0			30	0			0.008
Corn, field forage/silage	AF/AS	0.00905	STMR/STMR-P	40	0.02	0			35	0			0.008
Total						100	100	100	100	0.392131515	0.505	0.844	0.112

POULTRY BROILER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Carrot culls	VR	0.031	STMR/STMR-P	12	0.26		10				0.026		
Bean seed	VD	0.0084	STMR/STMR-P	88	0.01		20	70			0.002	0.007	
Cowpea seed	VD	0.0084	STMR/STMR-P	88	0.01	10				0.001			
Total						10	30	70		0.001	0.028	0.007	

POULTRY LAYER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Pea vines	AL	0.3296	STMR/STMR-P	25	1.32		10				0.132		
Cabbage heads, leaves	AM/AV	0.0824	STMR/STMR-P	15	0.55		5				0.027		
Carrot culls	VR	0.031	STMR/STMR-P	12	0.26		10				0.026		
Rape forage	AM/AV	0.011	STMR/STMR-P	30	0.04		5				0.002		
Wheat forage	AF/AS	0.00905	STMR/STMR-P	25	0.04		10				0.004		
Bean seed	VD	0.0084	STMR/STMR-P	88	0.01		20	70			0.002	0.007	
Cowpea seed	VD	0.0084	STMR/STMR-P	88	0.01	10				0.000954545			
Total						10	60	70		0.000954545	0.193	0.007	

IN-TMQ01

ESTIMATED MAXIMUM DIETARY BURDEN													
BEEF CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Carrot culls	VR	0.595	HR	12	4.96		15	5			0.744	0.248	
Cabbage heads, leaves	AM/AV	0.4819	HR	15	3.21		20				0.643		
Potato culls	VR	0.3685	HR	20	1.84	30	15	5		0.553	0.276	0.092	
Turnip tops (leaves)	AM/AV	0.4819	HR	30	1.61		20	80			0.321	1.285	
Corn, field stover	AF/AS	0.6133	HR	83	0.74	15	25	10		0.111	0.185	0.074	
Grass hay	AF/AS	0.6133	HR	88	0.70		5		40		0.035		0.279
Lespedeza hay	AL	0.115	HR	88	0.13	15				0.020			
Alfalfa hay	AL	0.115	HR	89	0.13				10				0.013
Corn gluten meal	CM/CF	0.00945	STMR	40	0.02	40				0.009			
Barley grain	GC	0.0073	STMR	88	0.01				50				0.004
Total						100	100	100	100	0.693	2.204	1.699	0.296

DAIRY CATTLE													
													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Carrot culls	VR	0.595	HR	12	4.96	10	15	5		0.496	0.744	0.248	
Cabbage heads, leaves	AM/AV	0.4819	HR	15	3.21		20				0.643		
Kale leaves	AM/AV	0.4819	HR	15	3.21			40				1.285	
Potato culls	VR	0.3685	HR	20	1.84		15	5			0.276	0.092	
Turnip tops (leaves)	AM/AV	0.4819	HR	30	1.61	30				0.482			
Corn, field stover	AF/AS	0.6133	HR	83	0.74	15	20	40		0.111	0.148	0.296	
Millet hay	AF/AS	0.6133	HR	85	0.72	5		10		0.036		0.072	
Grass hay	AF/AS	0.6133	HR	88	0.70	40	30		70	0.279	0.209		0.488
Sorghum, grain forage	AF/AS	0.1611	HR	35	0.46				30				0.138
Total						100	100	100	100	1.403	2.02	1.993	0.626

POULTRY BROILER													
													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Carrot culls	VR	0.595	HR	12	4.96		10				0.496		
Corn gluten meal	CM/CF	0.00945	STMR	40	0.02		10				0.002		
Barley grain	GC	0.0073	STMR	88	0.01	75	70	15	10	0.006	0.006	0.001	8E-04
Corn, field grain	GC	0.0073	STMR	88	0.01				60				0.005
Bean seed	VD	0.0051	STMR	88	0.01		10	70			6E-04	0.004	
Cowpea seed	VD	0.0051	STMR	88	0.01	10				0.001			
Total						85	100	85	70	0.01	0.505	0.005	0.006

POULTRY LAYER													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Carrot culls	VR	0.595	HR	12	4.96		10				0.496		
Cabbage heads, leaves	AM/AV	0.4819	HR	15	3.21		5				0.161		
Barley straw	AF/AS	0.6133	HR	89	0.69		5				0.034		
Wheat forage	AF/AS	0.1611	HR	25	0.64		5				0.032		
Pea vines	AL	0.115	HR	25	0.46		10				0.046		
Rape forage	AM/AV	0.0079	HR	30	0.03		5				0.001		
Corn gluten meal	CM/CF	0.00945	STMR	40	0.02		10		10		0.002		0.002
Barley grain	GC	0.0073	STMR	88	0.01	75	50	15		0.006	0.004	0.001	
Corn, field grain	GC	0.0073	STMR	88	0.01				80				0.007
Bean seed	VD	0.0051	STMR	88	0.01			70				0.004	
Cowpea seed	VD	0.0051	STMR	88	0.01	10				0.001			
Total						85	100	85	90	0.007	0.777	0.005	0.009

IN-TMQ01

ESTIMATED MEAN DIETARY BURDEN													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Potato culls	VR	0.335	STMR/STMR-P	20	1.68	30	30	10		0.5025	0.503	0.168	
Cabbage heads, leaves	AM/AV	0.1472	STMR/STMR-P	15	0.98		20				0.196		
Turnip tops (leaves)	AM/AV	0.1472	STMR/STMR-P	30	0.49		20	80			0.098	0.393	
Grass forage (fresh)	AF/AS	0.0656	STMR/STMR-P	25	0.26		30	10	5		0.079	0.026	0.013
Sorghum, grain forage	AF/AS	0.0656	STMR/STMR-P	35	0.19	15				0.028114286			
Grass hay	AF/AS	0.1067	STMR/STMR-P	88	0.12				35				0.042
Alfalfa hay	AL	0.0109	STMR/STMR-P	89	0.01	15			10	0.001837079			0.001
Barley grain	GC	0.0073	STMR/STMR-P	88	0.01	40			50	0.003318182			0.004
Total						100	100	100	100	0.536	0.876	0.586	0.061

DAIRY CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Potato culls	VR	0.335	STMR/STMR-P	20	1.68	10	30	10		0.1675	0.503	0.168	
Cabbage heads, leaves	AM/AV	0.1472	STMR/STMR-P	15	0.98	0	20				0.196		
Kale leaves	AM/AV	0.1472	STMR/STMR-P	15	0.98	0		40		0		0.393	
Turnip tops (leaves)	AM/AV	0.1472	STMR/STMR-P	30	0.49	30				0.1472			
Grass forage	AF/AS	0.0656	STMR/STMR-P	25	0.26	45	50	50	10	0.11808	0.131	0.131	0.026

DAIRY CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
(fresh)													
Sorghum, grain forage	AF/AS	0.0656	STMR/STMR-P	35	0.19	0			30	0			0.056
Corn, field forage/silage	AF/AS	0.0656	STMR/STMR-P	40	0.16	0			10	0			0.016
Grass hay	AF/AS	0.1067	STMR/STMR-P	88	0.12	0			50	0			0.061
Pea vines	AL	0.0109	STMR/STMR-P	25	0.04	10				0.00436			
Lespedeza forage	AL	0.0072	STMR/STMR-P	22	0.03	5				0.001636364			
Total						100	100	100	100	0.438776364	0.83	0.691	0.159

POULTRY BROILER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Potato culls	VR	0.335	STMR/STMR-P	20	1.68		10				0.168		
Barley grain	GC	0.0073	STMR/STMR-P	88	0.01	75	70	15	10	0.006	0.006	0.001	8E-04
Corn, field grain	GC	0.0073	STMR/STMR-P	88	0.01				60				0.005
Bean seed	VD	0.0051	STMR/STMR-P	88	0.01		20	70			0.001	0.004	
Cowpea seed	VD	0.0051	STMR/STMR-P	88	0.01	10				0.00			
Total						85	100	85	70	0.01	0.174	0.005	0.006

POULTRY LAYER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Potato culls	VR	0.335	STMR/STMR-P	20	1.68		10				0.168		
Cabbage heads, leaves	AM/AV	0.1472	STMR/STMR-P	15	0.98		5				0.049		
Wheat forage	AF/AS	0.0656	STMR/STMR-P	25	0.26		10				0.026		
Pea vines	AL	0.0109	STMR/STMR-P	25	0.04		10				0.004		
Barley grain	GC	0.0073	STMR/STMR-P	88	0.01	75	65	15		0.006221591	0.005	0.001	
Corn, field grain	GC	0.0073	STMR/STMR-P	88	0.01				80				0.007
Bean seed	VD	0.0051	STMR/STMR-P	88	0.01			70				0.004	
Cowpea seed	VD	0.0051	STMR/STMR-P	88	0.01	10				0.000579545			
Total						85	100	85	80	0.007	0.253	0.005	0.01

IN-UJV12

ESTIMATED MAXIMUM DIETARY BURDEN													
BEEF CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Pea vines	AL	0.3559	HR	25	1.42		20	60			0.285	0.854	
Soybean hay	AL	0.3559	HR	85	0.42			40				0.167	
Cowpea hay	AL	0.3559	HR	86	0.41		15				0.062		
Lespedeza hay	AL	0.3559	HR	88	0.40	15				0.061			
Cabbage heads, leaves	AM/AV	0.0602	HR	15	0.40		20				0.08		
Alfalfa hay	AL	0.3559	HR	89	0.40				10				0.04
Turnip tops (leaves)	AM/AV	0.0602	HR	30	0.20		20				0.04		
Alfalfa forage	AL	0.0651	HR	35	0.19		25				0.047		
Potato culls	VR	0.0205	HR	20	0.10	30				0.031			
Grass forage (fresh)	AF/AS	0.0179	HR	25	0.07				5				0.004
Sorghum, grain forage	AF/AS	0.0179	HR	35	0.05	15				0.008			
Grass hay	AF/AS	0.0384	HR	88	0.04				35				0.015
Corn gluten meal	CM/CF	0.00702	STMR	40	0.02	40				0.007			
Barley grain	GC	0.0072	STMR	88	0.01				50				0.00
Total						100	100	100	100	0.106	0.514	1.022	0.063

DAIRY CATTLE													
													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Pea vines	AL	0.3559	HR	25	1.42	10	20	40		0.142	0.285	0.569	
Peanut hay	AL	0.3559	HR	85	0.42	5		20		0.021		0.084	
Soybean hay	AL	0.3559	HR	85	0.42	5				0.021			
Cowpea hay	AL	0.3559	HR	86	0.41		15	40			0.062	0.166	
Lespedeza hay	AL	0.3559	HR	88	0.40	20				0.081			
Cabbage heads, leaves	AM/AV	0.0602	HR	15	0.40		20				0.08		
Alfalfa hay	AL	0.3559	HR	89	0.40		5		25		0.02		0.1
Turnip tops (leaves)	AM/AV	0.0602	HR	30	0.20	30				0.060			
Potato culls	VR	0.0205	HR	20	0.10	10	30			0.010	0.031		
Grass forage (fresh)	AF/AS	0.0179	HR	25	0.07	20	10		10	0.014	0.007		0.007
Sorghum, grain forage	AF/AS	0.0179	HR	35	0.05				30				0.015
Corn, field forage/silage	AF/AS	0.0179	HR	40	0.04				35				0.016
Total						100	100	100	100	0.350	0.485	0.82	0.14

POULTRY BROILER													
													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Potato culls	VR	0.0205	HR	20	0.10		10				0.01		
Corn gluten meal	CM/CF	0.00702	STMR	40	0.02		10				0.002		
Barley grain	GC	0.0072	STMR	88	0.01	75	70	15	10	0.006	0.006	0.001	8E-04
Bean seed	VD	0.0073	STMR	88	0.01		10	70			8E-04	0.006	

POULTRY BROILER													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Total						75	100	85	10	0.006	0.019	0.007	8E-04

POULTRY LAYER													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Pea vines	AL	0.3559	HR	25	1.42		10				0.142		
Cabbage heads, leaves	AM/AV	0.0602	HR	15	0.40		5				0.02		
Potato culls	VR	0.0205	HR	20	0.10		10				0.01		
Wheat forage	AF/AS	0.0179	HR	25	0.07		10				0.007		
Rape forage	AM/AV	0.0072	HR	30	0.02		5				0.001		
Corn gluten meal	CM/CF	0.00702	STMR	40	0.02		10		10		0.002		0.002
Barley grain	GC	0.0072	STMR	88	0.01	75	50	15		0.006	0.004	0.001	
Bean seed	VD	0.0073	STMR	88	0.01			70				0.006	
Total						75	100	85	10	0.01	0.187	0.007	0.00

IN-UJV12

ESTIMATED MEAN DIETARY BURDEN													
BEEF CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Pea vines	AL	0.0669	STMR/STMR-P	25	0.27		20	60			0.054	0.161	
Cabbage heads, leaves	AM/AV	0.0182	STMR/STMR-P	15	0.12		20				0.024		
Carrot culls	VR	0.01	STMR/STMR-P	12	0.08		15	5			0.013	0.004	
Potato culls	VR	0.016	STMR/STMR-P	20	0.08	30	15	5		0.024	0.012	0.004	
Soybean hay	AL	0.0669	STMR/STMR-P	85	0.08			30				0.024	
Cowpea hay	AL	0.0669	STMR/STMR-P	86	0.08		30				0.023		
Lespedeza hay	AL	0.0669	STMR/STMR-P	88	0.08	15				0.011403409			
Alfalfa hay	AL	0.0669	STMR/STMR-P	89	0.08				10				0.008
Grass forage (fresh)	AF/AS	0.0072	STMR/STMR-P	25	0.03				5				0.001
Sorghum, grain forage	AF/AS	0.0072	STMR/STMR-P	35	0.02	15				0.003			
Corn gluten meal	CM/CF	0.00702	STMR/STMR-P	40	0.02	40				0.007			
Total						100	100	100	15	0.046	0.126	0.192	0.009

DAIRY CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Pea vines	AL	0.0669	STMR/STMR-P	25	0.27	10	20	40		0.02676	0.054	0.107	
Cabbage heads, leaves	AM/AV	0.0182	STMR/STMR-P	15	0.12	0	20			0	0.024		
Kale leaves	AM/AV	0.0182	STMR/STMR-P	15	0.12	0		40		0		0.049	
Carrot culls	VR	0.01	STMR/STMR-P	12	0.08	10	15	5		0.008333333	0.013	0.004	
Lespedeza forage	AL	0.0178	STMR/STMR-P	22	0.08	30		15		0.024272727		0.012	
Potato culls	VR	0.016	STMR/STMR-P	20	0.08	0	15			0	0.012		
Cowpea hay	AL	0.0669	STMR/STMR-P	86	0.08	0	30			0	0.023		
Alfalfa hay	AL	0.0669	STMR/STMR-P	89	0.08	0			25	0			0.019
Turnip tops (leaves)	AM/AV	0.0182	STMR/STMR-P	30	0.06	30				0.0182			
Grass forage (fresh)	AF/AS	0.0072	STMR/STMR-P	25	0.03	20			10	0.00576			0.003
Sorghum, grain forage	AF/AS	0.0072	STMR/STMR-P	35	0.02	0			30	0			0.006
Corn, field forage/silage	AF/AS	0.0072	STMR/STMR-P	40	0.02	0			35	0			0.006
Total						100	100	100	100	0.083326061	0.126	0.172	0.034

POULTRY BROILER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Carrot culls	VR	0.01	STMR/STMR-P	12	0.08		10				0.008		
Corn gluten meal	CM/CF	0.00702	STMR/STMR-P	40	0.02		10				0.002		
Total							20				0.01		

POULTRY LAYER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Pea vines	AL	0.0669	STMR/STMR-P	25	0.27		10				0.027		
Cabbage heads, leaves	AM/AV	0.0182	STMR/STMR-P	15	0.12		5				0.006		
Carrot culls	VR	0.01	STMR/STMR-P	12	0.08		10				0.008		
Wheat forage	AF/AS	0.0072	STMR/STMR-P	25	0.03		10				0.003		
Corn gluten meal	CM/CF	0.00702	STMR/STMR-P	40	0.02		10		10		0.002		0.002
Total							45		10		0.046		0.002

IN-UNS90

ESTIMATED MAXIMUM DIETARY BURDEN													
BEEF CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Cabbage heads, leaves	AM/AV	0.6782	HR	15	4.52		20				0.904		
Turnip tops (leaves)	AM/AV	0.6782	HR	30	2.26		20	80			0.452	1.809	
Grass forage (fresh)	AF/AS	0.4361	HR	25	1.74		50	20	5		0.872	0.349	0.087
Sorghum, grain forage	AF/AS	0.4361	HR	35	1.25	15				0.187			
Corn, field forage/silage	AF/AS	0.4361	HR	40	1.09		10				0.109		
Grass hay	AF/AS	0.8673	HR	88	0.99				35				0.345
Potato culls	VR	0.01	HR	20	0.05	30				0.015			
Lespedeza hay	AL	0.02	HR	88	0.02	15				0.003			
Alfalfa hay	AL	0.02	HR	89	0.02				10				0.002
Barley grain	GC	0.0073	STMR	88	0.01	40			50	0.003			0.004
Total						100	100	100	100	0.209	2.338	2.157	0.439

ESTIMATED MAXIMUM DIETARY BURDEN													
DAIRY CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Cabbage heads, leaves	AM/AV	0.6782	HR	15	4.52		20				0.904		
Kale leaves	AM/AV	0.6782	HR	15	4.52			40				1.809	
Turnip tops (leaves)	AM/AV	0.6782	HR	30	2.26	30				0.678			
Grass forage (fresh)	AF/AS	0.4361	HR	25	1.74	45	60	60	10	0.785	1.047	1.047	0.174
Sorghum, grain forage	AF/AS	0.4361	HR	35	1.25				30				0.374
Corn, field forage/silage	AF/AS	0.4361	HR	40	1.09				10				0.109
Grass hay	AF/AS	0.8673	HR	88	0.99				50				0.493
Carrot culls	VR	0.049	HR	12	0.41	10	15			0.041	0.061		
Lespedeza forage	AL	0.0178	HR	22	0.08	15				0.012			
Pea vines	AL	0.02	HR	25	0.08		5				0.004		
Total						100	100	100	100	1.516	2.016	2.855	1.15

ESTIMATED MAXIMUM DIETARY BURDEN													
POULTRY BROILER													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Carrot culls	VR	0.049	HR	12	0.41		10				0.041		
Barley grain	GC	0.0073	STMR	88	0.01	75	70	15	10	0.006	0.006	0.001	8E-04
Corn, field grain	GC	0.0073	STMR	88	0.01				60				0.005
Corn gluten meal	CM/CF	0.00268	STMR	40	0.01		10				0.0007		
Bean seed	VD	0.0051	STMR	88	0.01		10	70			0.0006	0.004	
Cowpea seed	VD	0.0051	STMR	88	0.01	10				0.001			
Total						85	100	85	70	0.01	0.048	0.005	0.006

POULTRY LAYER													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Cabbage heads, leaves	AM/AV	0.6782	HR	15	4.52		5				0.226		
Wheat forage	AF/AS	0.4361	HR	25	1.74		10				0.174		
Carrot culls	VR	0.049	HR	12	0.41		10				0.041		
Rape forage	AM/AV	0.0319	HR	30	0.11		5				0.005		
Pea vines	AL	0.02	HR	25	0.08		10				0.008		
Barley grain	GC	0.0073	STMR	88	0.01	75	60	15		0.006	0.005	0.001	
Corn, field grain	GC	0.0073	STMR	88	0.01				80				0.007
Corn gluten meal	CM/CF	0.00268	STMR	40	0.01				10				0.0007
Bean seed	VD	0.0051	STMR	88	0.01			70				0.004	
Cowpea seed	VD	0.0051	STMR	88	0.01	10				0.001			
Total						85	100	85	90	0.007	0.46	0.005	0.007

IN-UNS90

ESTIMATED MEAN DIETARY BURDEN													
BEEF CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Cabbage heads, leaves	AM/AV	0.1175	STMR/STMR-P	15	0.78		20				0.157		
Grass forage (fresh)	AF/AS	0.112	STMR/STMR-P	25	0.45		50	100	5		0.224	0.448	0.022
Turnip tops (leaves)	AM/AV	0.1175	STMR/STMR-P	30	0.39		30				0.118		
Sorghum, grain forage	AF/AS	0.112	STMR/STMR-P	35	0.32	15				0.048			
Grass hay	AF/AS	0.2204	STMR/STMR-P	88	0.25				35				0.088
Potato culls	VR	0.01	STMR/STMR-P	20	0.05	30				0.015			
Alfalfa hay	AL	0.0067	STMR/STMR-P	89	0.01	15			10	0.001129213			0.0008
Corn gluten meal	CM/CF	0.00268	STMR/STMR-P	40	0.01	40				0.00268			
Total						100	100	100	50	0.067	0.498	0.448	0.111

DAIRY CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Cabbage heads, leaves	AM/AV	0.1175	STMR/STMR-P	15	0.78		20	0			0.157	0	
Kale leaves	AM/AV	0.1175	STMR/STMR-P	15	0.78	0		40		0		0.313	
Grass forage (fresh)	AF/AS	0.112	STMR/STMR-P	25	0.45	45	60	60	10	0.2016	0.269	0.269	0.045
Turnip tops (leaves)	AM/AV	0.1175	STMR/STMR-P	30	0.39	30				0.1175			

DAIRY CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Sorghum, grain forage	AF/AS	0.112	STMR/STMR-P	35	0.32	0			30	0			0.096
Corn, field forage/silage	AF/AS	0.112	STMR/STMR-P	40	0.28	0			10	0			0.028
Grass hay	AF/AS	0.2204	STMR/STMR-P	88	0.25	0			50	0			0.125
Carrot culls	VR	0.01	STMR/STMR-P	12	0.08	10	15			0.0083	0.013		
Potato culls	VR	0.01	STMR/STMR-P	20	0.05	0	5			0	0.003		
Lespedeza forage	AL	0.0072	STMR/STMR-P	22	0.03	15				0.00491			
Total						100	100	100	100	0.33234	0.44	0.582	0.294

POULTRY BROILER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Carrot culls	VR	0.01	STMR/STMR-P	12	0.08		10				0.008		
Corn gluten meal	CM/CF	0.00268	STMR/STMR-P	40	0.01		10				0.0007		
Bean seed	VD	0.0051	STMR/STMR-P	88	0.01		20	70			0.001	0.004	
Cowpea seed	VD	0.0051	STMR/STMR-P	88	0.01	10				0.001			
Total						10	40	70		0.00	0.01	0.004	

POULTRY LAYER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Cabbage heads, leaves	AM/AV	0.1175	STMR/STMR-P	15	0.78		5				0.039		
Wheat forage	AF/AS	0.112	STMR/STMR-P	25	0.45		10				0.045		
Carrot culls	VR	0.01	STMR/STMR-P	12	0.08		10				0.008		
Pea vines	AL	0.0067	STMR/STMR-P	25	0.03		10				0.003		
Rape forage	AM/AV	0.0081	STMR/STMR-P	30	0.03		5				0.001		
Corn gluten meal	CM/CF	0.00268	STMR/STMR-P	40	0.01		10		10		0.0007		0.0007
Bean seed	VD	0.0051	STMR/STMR-P	88	0.01		20	70			0.001	0.004	
Cowpea seed	VD	0.0051	STMR/STMR-P	88	0.01	10				0.00058			
Total						10	70	70	10	0.001	0.098	0.004	0.00

FLUINDAPYR (328)

ESTIMATED MAXIMUM DIETARY BURDEN													
BEEF CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Wheat forage	AF/AS	11	HR	25	44.00		20	100			8.8	44	
Corn, field forage/silage	AF/AS	9.2	HR	40	23.00	15	60			3.450	13.8		
Corn, pop stover	AF/AS	13	HR	85	15.29		20				3.059		
Sorghum, grain asp gr fn	CM/CF	2.3	STMR	85	2.71	5				0.135			
Sorghum, grain grain	GC	0.355	STMR	86	0.41	40			35	0.165			0.144
Wheat gluten meal	CM/CF	0.025	STMR	40	0.06	5				0.003			
Wheat milled bypdt	CM/CF	0.047	STMR	88	0.05	35			55	0.019			0.029
Corn gluten feed	CM/CF	0.01	STMR	40	0.03				10				0.003
Total						100	100	100	100	3.772	25.66	44	0.176

DAIRY CATTLE													
													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Wheat forage	AF/AS	11	HR	25	44.00	20	20	60		8.800	8.8	26.4	
Corn, field forage/silage	AF/AS	9.2	HR	40	23.00	25	40	40	50	5.750	9.2	9.2	11.5
Almond hulls	AM/AV	3.4	STMR	90	3.78	10				0.378			
Sorghum, grain grain	GC	0.355	STMR	86	0.41	45	40		30	0.186	0.165		0.124
Wheat milled bypdt	CM/CF	0.047	STMR	88	0.05				20				0.011
Total						100	100	100	100	15.114	18.17	35.6	11.63

POULTRY BROILER													
													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Sorghum, grain grain	GC	0.355	STMR	86	0.41	75	70	70	65	0.310	0.289	0.289	0.268
Wheat gluten meal	CM/CF	0.025	STMR	40	0.06		10				0.006		
Wheat milled bypdt	CM/CF	0.047	STMR	88	0.05	25	10	20	5	0.013	0.005	0.011	0.003
Corn, field milled bypdt	CM/CF	0.01	STMR	85	0.01		10				0.001		
Corn, field grain	GC	0.01	STMR	88	0.01				30				0.003
Corn, field hominy meal	CM/CF	0.01	STMR	88	0.01			10				0.001	
Total						100	100	100	100	0.32	0.302	0.301	0.274

POULTRY LAYER													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Wheat forage	AF/AS	11	HR	25	44.00		10				4.4		
Sorghum, grain grain	GC	0.355	STMR	86	0.41	75	70	70	55	0.310	0.289	0.289	0.227
Wheat gluten meal	CM/CF	0.025	STMR	40	0.06		10				0.006		
Wheat milled bypdts	CM/CF	0.047	STMR	88	0.05	25	10	20	30	0.013	0.005	0.011	0.016
Corn, field grain	GC	0.01	STMR	88	0.01				15				0.002
Corn, field hominy meal	CM/CF	0.01	STMR	88	0.01			10				0.001	
Total						100	100	100	100	0.323	4.701	0.301	0.245

FLUINDAPYR (328)

ESTIMATED MEAN DIETARY BURDEN													
BEEF CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Sorghum, grain silage	AF/AS	5.1	STMR/STMR-P	21	24.29	15				3.642857			
Sorghum, grain forage	AF/AS	5.1	STMR/STMR-P	35	14.57		20	70			2.914	10.2	
Wheat forage	AF/AS	2.2	STMR/STMR-P	25	8.80			30				2.64	
Sorghum, grain asp gr fn	CM/CF	2.3	STMR/STMR-P	85	2.71	5				0.135294			
Corn, field forage/silage	AF/AS	0.73	STMR/STMR-P	40	1.83		60				1.095		
Corn, field stover	AF/AS	0.8	STMR/STMR-P	83	0.96		20				0.193		
Sorghum, grain grain	GC	0.355	STMR/STMR-P	86	0.41	40			35	0.165116			0.144
Wheat gluten meal	CM/CF	0.025	STMR/STMR-P	40	0.06	5				0.003125			
Wheat milled bypdts	CM/CF	0.047	STMR/STMR-P	88	0.05	35			55	0.019			0.029
Corn gluten feed	CM/CF	0.01	STMR/STMR-P	40	0.03				10				0.003
Total						100	100	100	100	3.965	4.202	12.84	0.176

DAIRY CATTLE														MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Sorghum, grain silage	AF/AS	5.1	STMR/STMR-P	21	24.29	40	0	0	10	9.714286	0	0	2.429	
Sorghum, grain forage	AF/AS	5.1	STMR/STMR-P	35	14.57	0	20	70	30	0	2.914	10.2	4.371	
Wheat forage	AF/AS	2.2	STMR/STMR-P	25	8.80	0		30		0		2.64		
Almond hulls	AM/AV	3.4	STMR/STMR-P	90	3.78	10				0.377778				
Corn, field forage/silage	AF/AS	0.73	STMR/STMR-P	40	1.83	5	40		10	0.09125	0.73		0.183	
Sorghum, grain grain	GC	0.355	STMR/STMR-P	86	0.41	45	40		30	0.185756	0.165		0.124	
Wheat milled bypds	CM/CF	0.047	STMR/STMR-P	88	0.05	0			20	0			0.011	
Total						100	100	100	100	10.36907	3.809	12.84	7.117	

POULTRY BROILER														MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Sorghum, grain grain	GC	0.355	STMR/STMR-P	86	0.41	75	70	70	65	0.31	0.289	0.289	0.268	
Wheat gluten meal	CM/CF	0.025	STMR/STMR-P	40	0.06		10				0.006			
Wheat milled bypds	CM/CF	0.047	STMR/STMR-P	88	0.05	25	10	20	5	0.01	0.005	0.011	0.003	
Corn, field milled bypds	CM/CF	0.01	STMR/STMR-P	85	0.01		10				0.001			
Corn, field grain	GC	0.01	STMR/STMR-P	88	0.01				30				0.003	
Corn, field hominy meal	CM/CF	0.01	STMR/STMR-P	88	0.01			10				0.001		
Total						100	100	100	100	0.32	0.302	0.301	0.274	

POULTRY LAYER														MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Sorghum, grain forage	AF/AS	5.1	STMR/STMR-P	35	14.57		10				1.457			
Sorghum, grain grain	GC	0.355	STMR/STMR-P	86	0.41	75	70	70	55	0.309593	0.289	0.289	0.227	
Wheat gluten meal	CM/CF	0.025	STMR/STMR-P	40	0.06		10				0.006			

POULTRY LAYER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Wheat milled bypds	CM/CF	0.047	STMR/STMR-P	88	0.05	25	10	20	30	0.013352	0.005	0.011	0.016
Corn, field grain	GC	0.01	STMR/STMR-P	88	0.01				15				0.002
Corn, field hominy meal	CM/CF	0.01	STMR/STMR-P	88	0.01			10				0.001	
Total						100	100	100	100	0.322945	1.758	0.301	0.245

FLUINDAPYR (328) + 1-OH-FLUINDAPYR

ESTIMATED MAXIMUM DIETARY BURDEN													
BEEF CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Wheat forage	AF/AS	12	HR	25	48.00		20	100			9.6	48	
Corn, field forage/silage	AF/AS	9.8	HR	40	24.50	15	60			3.675	14.7		
Corn, pop stover	AF/AS	13	HR	85	15.29		20				3.059		
Sorghum, grain asp gr fn	CM/CF	2.7	STMR	85	3.18	5				0.159			
Sorghum, grain grain	GC	0.395	STMR	86	0.46	40			35	0.184			0.161
Wheat milled bypds	CM/CF	0.074	STMR	88	0.08	35			55	0.029			0.046
Wheat gluten meal	CM/CF	0.031	STMR	40	0.08	5				0.004			
Corn gluten feed	CM/CF	0.02	STMR	40	0.05				10				0.005
Total						100	100	100	100	4.051	27.36	48	0.212

DAIRY CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Wheat forage	AF/AS	12	HR	25	48.00	20	20	60		9.600	9.6	28.8	
Corn, field forage/silage	AF/AS	9.8	HR	40	24.50	25	40	40	50	6.125	9.8	9.8	12.25
Almond hulls	AM/AV	3.4	STMR	90	3.78	10				0.378			
Sorghum, grain grain	GC	0.395	STMR	86	0.46	45	40		30	0.207	0.184		0.138
Wheat milled bypds	CM/CF	0.074	STMR	88	0.08				20				0.017
Total						100	100	100	100	16.309	19.58	38.6	12.4

POULTRY BROILER													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Sorghum, grain grain	GC	0.395	STMR	86	0.46	75	70	70	65	0.344	0.322	0.322	0.299
Wheat milled bypds	CM/CF	0.074	STMR	88	0.08	25	20	20	5	0.021	0.017	0.017	0.004
Corn, field milled bypds	CM/CF	0.02	STMR	85	0.02		10			0.002			
Corn, field grain	GC	0.02	STMR	88	0.02				30				0.007
Corn, field hominy meal	CM/CF	0.02	STMR	88	0.02			10				0.002	
Total						100	100	100	100	0.365	0.341	0.341	0.31

POULTRY LAYER													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Wheat forage	AF/AS	12	HR	25	48.00		10				4.8		
Sorghum, grain grain	GC	0.395	STMR	86	0.46	75	70	70	55	0.344	0.322	0.322	0.253
Wheat milled bypds	CM/CF	0.074	STMR	88	0.08	25	20	20	30	0.021	0.017	0.017	0.025
Corn, field grain	GC	0.02	STMR	88	0.02				15				0.003
Corn, field hominy meal	CM/CF	0.02	STMR	88	0.02			10				0.002	
Total						100	100	100	100	0.365	5.138	0.341	0.281

FLUINDAPYR (328) + 1-OH-FLUINDAPYR

ESTIMATED MEAN DIETARY BURDEN													MEAN
BEEF CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Sorghum, grain silage	AF/AS	5.2	STMR/STMR-P	21	24.76	15				3.714286			
Sorghum, grain forage	AF/AS	5.2	STMR/STMR-P	35	14.86		20	70			2.971	10.4	
Wheat forage	AF/AS	2.5	STMR/STMR-P	25	10.00			30				3	
Sorghum, grain asp gr fn	CM/CF	2.7	STMR/STMR-P	85	3.18	5				0.158824			
Corn, field forage/silage	AF/AS	0.83	STMR/STMR-P	40	2.08		60				1.245		
Corn, field stover	AF/AS	0.95	STMR/STMR-P	83	1.14		20				0.229		
Sorghum, grain grain	GC	0.395	STMR/STMR-P	86	0.46	40			35	0.183721			0.161
Wheat milled	CM/CF	0.074	STMR/STMR-P	88	0.08	35			55	0.029432			0.046

ESTIMATED MEAN DIETARY BURDEN													
BEEF CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
by	pdts												
Wheat gluten meal	CM/CF	0.031	STMR/STMR-P	40	0.08	5					0.004		
Corn gluten feed	CM/CF	0.02	STMR/STMR-P	40	0.05				10				0.005
Total						100	100	100	100	4.090	4.445	13.4	0.212

DAIRY CATTLE														MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Sorghum, grain silage	AF/AS	5.2	STMR/STMR-P	21	24.76	40	0	0	10	9.904762	0	0	2.476	
Sorghum, grain forage	AF/AS	5.2	STMR/STMR-P	35	14.86	0	20	70	30	0	2.971	10.4	4.457	
Wheat forage	AF/AS	2.5	STMR/STMR-P	25	10.00	0		30		0		3		
Almond hulls	AM/AV	3.4	STMR/STMR-P	90	3.78	10				0.377778				
Corn, field forage/silage	AF/AS	0.83	STMR/STMR-P	40	2.08	5	40		10	0.10375	0.83		0.208	
Sorghum, grain grain	GC	0.395	STMR/STMR-P	86	0.46	45	40		30	0.206686	0.184		0.138	
Wheat milled bypdts	CM/CF	0.074	STMR/STMR-P	88	0.08	0			20	0			0.017	
Total						100	100	100	100	10.59298	3.985	13.4	7.295	

POULTRY BROILER														MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Sorghum, grain grain	GC	0.395	STMR/STMR-P	86	0.46	75	70	70	65	0.34	0.322	0.322	0.299	
Wheat milled bypdts	CM/CF	0.074	STMR/STMR-P	88	0.08	25	20	20	5	0.02	0.017	0.017	0.004	
Corn, field milled bypdts	CM/CF	0.02	STMR/STMR-P	85	0.02		10			0.002				
Corn, field grain	GC	0.02	STMR/STMR-P	88	0.02				30				0.007	
Corn, field hominy meal	CM/CF	0.02	STMR/STMR-P	88	0.02			10				0.002		
Total						100	100	100	100	0.37	0.341	0.341	0.31	

POULTRY LAYER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Sorghum, grain forage	AF/AS	5.2	STMR/STMR-P	35	14.86		10				1.486		
Sorghum, grain grain	GC	0.395	STMR/STMR-P	86	0.46	75	70	70	55	0.344477	0.322	0.322	0.253
Wheat milled bypds	CM/CF	0.074	STMR/STMR-P	88	0.08	25	20	20	30	0.021023	0.017	0.017	0.025
Corn, field grain	GC	0.02	STMR/STMR-P	88	0.02				15				0.003
Corn, field hominy meal	CM/CF	0.02	STMR/STMR-P	88	0.02			10				0.002	
Total						100	100	100	100	0.365499	1.824	0.341	0.281

FLUTRIAFOL (248)

ESTIMATED MAXIMUM DIETARY BURDEN													
BEEF CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Corn, field stover	AF/AS	10	HR	83	12.05	15	25	40		1.807	3.012	4.819	
Peanut hay	AL	8.9	HR	85	10.47			60				6.282	
Barley straw	AF/AS	6.4	HR	89	7.19		5				0.36		
Beet, sugar tops	AM/AV	1.5	HR	23	6.52		20				1.304		
Rice straw	AF/AS	4	HR	90	4.44				55				2.444
Sorghum, grain asp gr fn	CM/CF	2.16	STMR	85	2.54	5				0.127			
Rice grain	GC	1.1	STMR	88	1.25	20				0.250			
Apple pomace, wet	AB	0.15	STMR	40	0.38		20				0.075		
Sorghum, grain grain	GC	0.27	STMR	86	0.31	20	30		35	0.063	0.094		0.11
Soybean asp gr fn	SM	0.094	STMR	85	0.11	5				0.006			
Soybean meal	SM	0.072	STMR	92	0.08				10				0.008
Rice bran/pollard	CM/CF	0.068	STMR	90	0.08	10				0.008			
Soybean seed	VD	0.055	STMR	89	0.06	5				0.003			
Soybean hulls	SM	0.053	STMR	90	0.06	10				0.006			
Wheat milled	CM/CF	0.032	STMR	88	0.04	10				0.004			

ESTIMATED MAXIMUM DIETARY BURDEN													
BEEF CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
bypdts													
Total						100	100	100	100	2.273	4.845	11.1	2.562

DAIRY CATTLE													
													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Corn, field stover	AF/AS	10	HR	83	12.05	15	20	40		1.807	2.41	4.819	
Peanut hay	AL	8.9	HR	85	10.47	15		60		1.571		6.282	
Barley straw	AF/AS	6.4	HR	89	7.19		10				0.719		
Beet, sugar tops	AM/AV	1.5	HR	23	6.52		30				1.957		
Barley hay	AF/AS	5	HR	88	5.68	5				0.284			
Rice straw	AF/AS	4	HR	90	4.44				25				1.111
Almond hulls	AM/AV	2	STMR	90	2.22	10				0.222			
Rice grain	GC	1.1	STMR	88	1.25	20				0.250			
Apple pomace, wet	AB	0.15	STMR	40	0.38	10	10			0.038	0.038		
Sorghum, grain grain	GC	0.27	STMR	86	0.31	25	30		30	0.078	0.094		0.094
Soybean meal	SM	0.072	STMR	92	0.08				45				0.035
Total						100	100	100	100	4.250	5.217	11.1	1.241

POULTRY BROILER													
													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Rice grain	GC	1.1	STMR	88	1.25	20		50		0.250		0.625	
Sorghum, grain grain	GC	0.27	STMR	86	0.31	55	70	50	65	0.173	0.22	0.157	0.204
Soybean meal	SM	0.072	STMR	92	0.08	25	30		35	0.020	0.023		0.027
Total						100	100	100	100	0.442	0.243	0.782	0.231

POULTRY LAYER													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Barley straw	AF/AS	6.4	HR	89	7.19		5				0.36		
Beet, sugar tops	AM/AV	1.5	HR	23	6.52		5				0.326		
Wheat hay	AF/AS	4.1	HR	88	4.66		5				0.233		
Rice grain	GC	1.1	STMR	88	1.25	20		50		0.250		0.625	
Sorghum, grain grain	GC	0.27	STMR	86	0.31	55	70	50	55	0.173	0.22	0.157	0.173
Soybean meal	SM	0.072	STMR	92	0.08	25	15		30	0.020	0.012		0.023
Rice bran/pollard	CM/CF	0.068	STMR	90	0.08				15				0.011
Total						100	100	100	100	0.442	1.15	0.782	0.207

FLUTRIAFOL (248)

ESTIMATED MEAN DIETARY BURDEN													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Corn, field stover	AF/AS	4.9	STMR/STMR-P	83	5.90	15	25	40		0.885542	1.476	2.361	
Grape pomace, wet	AB	0.725	STMR/STMR-P	15	4.83			20				0.967	
Peanut hay	AL	2.6	STMR/STMR-P	85	3.06			40				1.224	
Sorghum, grain asp gr fn	CM/CF	2.16	STMR/STMR-P	85	2.54	5				0.127059			
Beet, sugar tops	AM/AV	0.424	STMR/STMR-P	23	1.84		20				0.369		
Rice straw	AF/AS	1.4	STMR/STMR-P	90	1.56				55				0.856
Rice grain	GC	1.1	STMR/STMR-P	88	1.25	20				0.25			
Barley straw	AF/AS	1	STMR/STMR-P	89	1.12		5				0.056		
Apple pomace, wet	AB	0.15	STMR/STMR-P	40	0.38		20				0.075		
Sorghum, grain grain	GC	0.27	STMR/STMR-P	86	0.31	20	30		35	0.063	0.094		0.11
Soybean asp gr fn	SM	0.094	STMR/STMR-P	85	0.11	5				0.006			
Soybean meal	SM	0.072	STMR/STMR-P	92	0.08				10				0.008
Rice bran/pollard	CM/CF	0.068	STMR/STMR-P	90	0.08	10				0.008			
Soybean seed	VD	0.055	STMR/STMR-P	89	0.06	5				0.003			
Soybean hulls	SM	0.053	STMR/STMR-P	90	0.06	10				0.0059			
Wheat milled bypds	CM/CF	0.032	STMR/STMR-P	88	0.04	10				0.003636			
Total						100	100	100	100	1.351092	2.07	4.552	0.973

DAIRY CATTLE														MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Corn, field stover	AF/AS	4.9	STMR/STMR-P	83	5.90	15	20	40		0.885542	1.181	2.361		
Grape pomace, wet	AB	0.725	STMR/STMR-P	15	4.83	0		20		0		0.967		
Peanut hay	AL	2.6	STMR/STMR-P	85	3.06	15		40		0.458824		1.224		
Almond hulls	AM/AV	2	STMR/STMR-P	90	2.22	10				0.222222				
Beet, sugar tops	AM/AV	0.424	STMR/STMR-P	23	1.84	0	30			0	0.553			
Wheat hay	AF/AS	1.45	STMR/STMR-P	88	1.65	5				0.082386				
Rice straw	AF/AS	1.4	STMR/STMR-P	90	1.56	0			25	0			0.389	
Rice grain	GC	1.1	STMR/STMR-P	88	1.25	20				0.25				
Barley straw	AF/AS	1	STMR/STMR-P	89	1.12	0	10			0	0.112			
Apple pomace, wet	AB	0.15	STMR/STMR-P	40	0.38	10	10			0.0375	0.038			
Sorghum, grain grain	GC	0.27	STMR/STMR-P	86	0.31	25	30		30	0.078488	0.094		0.094	
Soybean meal	SM	0.072	STMR/STMR-P	92	0.08	0			45	0			0.035	
Total						100	100	100	100	2.014963	1.978	4.552	0.518	

POULTRY BROILER														MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Rice grain	GC	1.1	STMR/STMR-P	88	1.25	20		50		0.25		0.625		
Sorghum, grain grain	GC	0.27	STMR/STMR-P	86	0.31	55	70	50	65	0.17	0.22	0.157	0.204	
Soybean meal	SM	0.072	STMR/STMR-P	92	0.08	25	30		35	0.02	0.023		0.027	
Total						100	100	100	100	0.44	0.243	0.782	0.231	

POULTRY LAYER														MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Beet, sugar tops	AM/AV	0.424	STMR/STMR-P	23	1.84		5				0.092			
Wheat hay	AF/AS	1.45	STMR/STMR-P	88	1.65		10				0.165			
Rice grain	GC	1.1	STMR/STMR-P	88	1.25	20		50		0.25		0.625		
Sorghum, grain grain	GC	0.27	STMR/STMR-P	86	0.31	55	70	50	55	0.172674	0.22	0.157	0.173	
Soybean meal	SM	0.072	STMR/STMR-P	92	0.08	25	15		30	0.019565	0.012		0.023	
Rice bran/pollard	CM/CF	0.068	STMR/STMR-P	90	0.08				15				0.011	
Total						100	100	100	100	0.44224	0.488	0.782	0.207	

INDOXACARB (216)

ESTIMATED MAXIMUM DIETARY BURDEN													
BEEF CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Bean vines	AL	32	HR	35	91.43			60				54.86	
Alfalfa hay	AL	43	HR	100	43.00	15		40	10	6.450		17.2	4.3
Alfalfa forage	AL	28	HR	100	28.00		70				19.6		
Cabbage heads, leaves	AM/AV	2	HR	15	13.33		20				2.667		
Cotton gin byproducts	AM/AV	11	HR	90	12.22	5				0.611			
Corn, field stover	AF/AS	9.1	HR	83	10.96	15	10			1.645	1.096		
Cotton meal	SM	0.36	STMR	89	0.40	5				0.020			
Soybean hulls	SM	0.23	STMR	90	0.26	10			5	0.026			0.013
Potato culls	VR	0.0085	HR	20	0.04	30				0.013			
Soybean seed	VD	0.027	STMR	89	0.03	5			15	0.002			0.005
Corn gluten feed	CM/CF	0.01	STMR	40	0.03	15			25	0.004			0.006
Corn, field grain	GC	0.01	STMR	88	0.01				45				0.005
Total						100	100	100	100	8.769	23.36	72.06	4.329

DAIRY CATTLE													
													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Bean vines	AL	32	HR	35	91.43		20	70			18.29	64	
Peanut hay	AL	45	HR	100	45.00	15				6.750			
Alfalfa hay	AL	43	HR	100	43.00	5	20		25	2.150	8.6		10.75
Corn, sweet cannery waste	AF/AS	9.8	HR	30	32.67	10		10		3.267		3.267	
Corn, sweet forage	AF/AS	9.1	HR	48	18.96	35		20		6.635		3.792	
Cabbage heads, leaves	AM/AV	2	HR	15	13.33		20				2.667		
Corn, field stover	AF/AS	9.1	HR	83	10.96		20				2.193		
Corn, field forage/silage	AF/AS	3.4	HR	40	8.50	35	20		50	2.975	1.7		4.25
Soybean seed	VD	0.027	STMR	89	0.03				10				0.003

DAIRY CATTLE														MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Corn gluten feed	CM/CF	0.01	STMR	40	0.03				15					0.004
Total						100	100	100	100	21.777	33.45	71.06	15.01	

POULTRY BROILER														MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Cotton meal	SM	0.36	STMR	89	0.40	20	5	10		0.081	0.02	0.04		
Potato culls	VR	0.0085	HR	20	0.04		10				0.004			
Soybean seed	VD	0.027	STMR	89	0.03	20	20	15		0.006	0.006	0.005		
Corn gluten feed	CM/CF	0.01	STMR	40	0.03		10				0.003			
Bean seed	VD	0.02	STMR	88	0.02			55				0.013		
Corn, field milled bypds	CM/CF	0.01	STMR	85	0.01	50	55			0.006	0.006			
Corn, field grain	GC	0.01	STMR	88	0.01	10			70	0.00				0.008
Corn, field hominy meal	CM/CF	0.01	STMR	88	0.01			20				0.002		
Soybean meal	SM	0.0038	STMR	92	0.00				30					0.001
Total						100	100	100	100	0.094	0.04	0.06	0.009	

POULTRY LAYER														MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Cabbage heads, leaves	AM/AV	2	HR	15	13.33		5				0.667			
Cotton meal	SM	0.36	STMR	89	0.40	20	5	10		0.081	0.02	0.04		
Potato culls	VR	0.0085	HR	20	0.04		10				0.004			
Soybean seed	VD	0.027	STMR	89	0.03	20	15	15		0.006	0.005	0.005		
Corn gluten feed	CM/CF	0.01	STMR	40	0.03				10					0.003
Corn gluten meal	CM/CF	0.01	STMR	40	0.03		10				0.003			
Bean seed	VD	0.02	STMR	88	0.02		5	55			0.001	0.013		
Corn, field milled bypds	CM/CF	0.01	STMR	85	0.01	50	40			0.006	0.005			

POULTRY LAYER													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Corn, field grain	GC	0.01	STMR	88	0.01	10	10		80	0.00	0.001		0.01
Corn, field hominy meal	CM/CF	0.01	STMR	88	0.01			20				0.002	
Soybean meal	SM	0.0038	STMR	92	0.00				10				4E-04
Total						100	100	100	100	0.094	0.705	0.06	0.012

INDOXACARB (216)

ESTIMATED MEAN DIETARY BURDEN													
BEEF CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Bean vines	AL	11	STMR/STMR-P	35	31.43			60				18.86	
Alfalfa forage	AL	16	STMR/STMR-P	100	16.00		70	40			11.2	6.4	
Alfalfa hay	AL	16	STMR/STMR-P	100	16.00	15			10	2.4			1.6
Cotton gin byproducts	AM/AV	8	STMR/STMR-P	90	8.89	5				0.444444			
Corn, field forage/silage	AF/AS	1.6	STMR/STMR-P	40	4.00	15	30			0.6	1.2		
Cotton meal	SM	0.36	STMR/STMR-P	89	0.40	5				0.020225			
Soybean hulls	SM	0.23	STMR/STMR-P	90	0.26	10			5	0.025556			0.013
Soybean seed	VD	0.027	STMR/STMR-P	89	0.03	5			15	0.001517			0.005
Corn gluten feed	CM/CF	0.01	STMR/STMR-P	40	0.03	45			25	0.011			0.006
Corn, field grain	GC	0.01	STMR/STMR-P	88	0.01				45				0.005
Total						100	100	100	100	3.503	12.4	25.26	1.629

DAIRY CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Bean vines	AL	11	STMR/STMR-P	35	31.43		20	70			6.286	22	
Peanut hay	AL	18	STMR/STMR-P	100	18.00	15				2.7			
Alfalfa forage	AL	16	STMR/STMR-P	100	16.00	5	20			0.8	3.2		
Alfalfa hay	AL	16	STMR/STMR-P	100	16.00	0			25	0			4
Corn, sweet cannery waste	AF/AS	3.7	STMR/STMR-P	30	12.33	10		10		1.233333		1.233	
Corn, sweet stover	AF/AS	7.8	STMR/STMR-P	100	7.80	5		10		0.39		0.78	
Corn, sweet forage	AF/AS	2.8	STMR/STMR-P	48	5.83	30		10		1.75		0.583	
Corn, field forage/silage	AF/AS	1.6	STMR/STMR-P	40	4.00	35	60		50	1.4	2.4		2
Soybean seed	VD	0.027	STMR/STMR-P	89	0.03	0			10	0			0.003

DAIRY CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Corn gluten feed	CM/CF	0.01	STMR/STMR-P	40	0.03	0			15	0			0.004
Total						100	100	100	100	8.273333	11.89	24.6	6.007

POULTRY BROILER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Cotton meal	SM	0.36	STMR/STMR-P	89	0.40	20	5	10		0.08	0.02	0.04	
Soybean seed	VD	0.027	STMR/STMR-P	89	0.03	20	20	15		0.01	0.006	0.005	
Corn gluten feed	CM/CF	0.01	STMR/STMR-P	40	0.03		10				0.003		
Bean seed	VD	0.02	STMR/STMR-P	88	0.02			55				0.013	
Potato culls	VR	0.003	STMR/STMR-P	20	0.02		10				0.002		
Corn, field milled bypdts	CM/CF	0.01	STMR/STMR-P	85	0.01	50	55			0.01	0.006		
Corn, field grain	GC	0.01	STMR/STMR-P	88	0.01	10			70	0.00			0.008
Corn, field hominy meal	CM/CF	0.01	STMR/STMR-P	88	0.01			20				0.002	
Soybean meal	SM	0.0038	STMR/STMR-P	92	0.00			30					0.001
Total						100	100	100	100	0.093985	0.037	0.06	0.009

POULTRY LAYER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Cabbage heads, leaves	AM/AV	0.44	STMR/STMR-P	15	2.93		5				0.147		
Cotton meal	SM	0.36	STMR/STMR-P	89	0.40	20	5	10		0.080899	0.02	0.04	
Soybean seed	VD	0.027	STMR/STMR-P	89	0.03	20	15	15		0.006067	0.005	0.005	
Corn gluten feed	CM/CF	0.01	STMR/STMR-P	40	0.03				10				0.003
Corn gluten meal	CM/CF	0.01	STMR/STMR-P	40	0.03		10				0.003		
Bean seed	VD	0.02	STMR/STMR-P	88	0.02		5	55			0.001	0.013	
Potato culls	VR	0.003	STMR/STMR-P	20	0.02		10				0.002		
Corn, field milled bypdts	CM/CF	0.01	STMR/STMR-P	85	0.01	50	40			0.005882	0.005		
Corn, field grain	GC	0.01	STMR/STMR-P	88	0.01	10	10		80	0.001	0.001		0.01
Corn, field hominy meal	CM/CF	0.01	STMR/STMR-P	88	0.01			20				0.002	
Soybean meal	SM	0.0038	STMR/STMR-P	92	0.00			10					4E-04
Total						100	100	100	100	0.093985	0.182	0.06	0.012

INPYRFLUXAM (329)

ESTIMATED MAXIMUM DIETARY BURDEN													
BEEF CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Apple pomace, wet	AB	2.4	STMR	40	6.00		20	20			1.2	1.2	
Peanut hay	AL	2	HR	85	2.35			60				1.412	
Corn, field forage/silage	AF/AS	0.02	HR	40	0.05	15	80	20		0.008	0.04	0.01	
Total						15	100	100		0.008	1.24	2.622	

DAIRY CATTLE														MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Apple pomace, wet	AB	2.4	STMR	40	6.00	10	10	10		0.600	0.6	0.6		
Peanut hay	AL	2	HR	85	2.35	15		60		0.353		1.412		
Corn, field forage/silage	AF/AS	0.02	HR	40	0.05	45	60	30	50	0.023	0.03	0.015	0.025	
Total						70	70	100	50	0.975	0.63	2.027	0.025	

INPYRFLUXAM (329)

ESTIMATED MEAN DIETARY BURDEN													
BEEF CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Apple pomace, wet	AB	2.4	STMR/STMR-P	40	6.00		20	20			1.2	1.2	
Peanut hay	AL	0.35	STMR/STMR-P	85	0.41			60				0.247	
Corn, field forage/silage	AF/AS	0.02	STMR/STMR-P	40	0.05	15	80	20		0.0075	0.04	0.01	
Total						15	100	100		0.0075	1.24	1.457	

DAIRY CATTLE														MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Apple pomace, wet	AB	2.4	STMR/STMR-P	40	6.00	10	10	10		0.6	0.6	0.6		
Peanut hay	AL	0.35	STMR/STMR-P	85	0.41	15		60		0.061765		0.247		
Corn, field forage/silage	AF/AS	0.02	STMR/STMR-P	40	0.05	45	60	30	50	0.0225	0.03	0.015	0.025	

DAIRY CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Total						70	70	100	50	0.684265	0.63	0.862	0.025

MEFENTRIFLUCONAZOLE (320)

ESTIMATED MAXIMUM DIETARY BURDEN													
BEEF CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Kale leaves	AM/AV	12	HR	15	80.00		20				16		
Wheat silage	AF/AS	62	HR	100	62.00			90				55.8	
Pea vines	AL	10	HR	25	40.00		20	10			8	4	
Rye forage	AF/AS	9.6	HR	30	32.00		20				6.4		
Barley hay	AF/AS	25.7	HR	100	25.70	15				3.855			
Barley straw	AF/AS	25.7	HR	100	25.70		10				2.57		
Rice straw	AF/AS	25.7	HR	100	25.70				55				14.14
Pea hay	AL	13	HR	100	13.00		5				0.65		
Corn, field forage/silage	AF/AS	7.2	HR	100	7.20		25				1.8		
Wheat asp gr fn	CM/CF	3.5	STMR	85	4.12	5				0.206			
Barley bran fractions	CM/CF	2.1	STMR	90	2.33				10				0.233
Rice grain	GC	1.2	STMR	88	1.36	20				0.273			
Soybean asp gr fn	SM	0.93	STMR	85	1.09	5				0.055			
Brewer's grain dried	SM	1	STMR	92	1.09				35				0.38
Sugarcane molasses	DM	0.37	STMR	75	0.49	10				0.049			
Rice bran/pollard	CM/CF	0.44	STMR	90	0.49	10				0.049			
Barley grain	GC	0.425	STMR	88	0.48	35				0.169			
Total						100	100	100	100	4.656	35.42	59.8	14.75

DAIRY CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Kale leaves	AM/AV	12	HR	15	80.00		20	40			16	32	
Wheat silage	AF/AS	62	HR	100	62.00			50				31	
Pea vines	AL	10	HR	25	40.00	10	20	10		4.000	8	4	
Rape forage	AM/AV	12	HR	30	40.00	10				4.000			
Rye forage	AF/AS	9.6	HR	30	32.00	20	20			6.400	6.4		

DAIRY CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Peanut hay	AL	30	HR	100	30.00	5				1.500			
Barley straw	AF/AS	25.7	HR	100	25.70		10				2.57		
Oat hay	AF/AS	25.7	HR	100	25.70	10			5	2.570			1.285
Rice straw	AF/AS	25.7	HR	100	25.70				20				5.14
Sorghum, grain forage	AF/AS	4.8	HR	35	13.71	10			15	1.371			2.057
Pea hay	AL	13	HR	100	13.00		10				1.3		
Soybean hay	AL	12	HR	100	12.00	5				0.600			
Corn, field forage/silage	AF/AS	7.2	HR	100	7.20	30	20		10	2.160	1.44		0.72
Brewer's grain dried	SM	1	STMR	92	1.09				40				0.435
Rice bran/pollard	CM/CF	0.44	STMR	90	0.49				10				0.049
Total						100	100	100	100	22.601	35.71	67	9.686

POULTRY BROILER													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Carrot culls	VR	0.38	HR	12	3.17		10				0.317		
Barley bran fractions	CM/CF	2.1	STMR	90	2.33	8				0.187			
Rice grain	GC	1.2	STMR	88	1.36	20		50		0.273			0.682
Brewer's grain dried	SM	1	STMR	92	1.09		10				0.109		
Rice bran/pollard	CM/CF	0.44	STMR	90	0.49	2	10	20	5	0.010	0.049	0.098	0.024
Barley grain	GC	0.425	STMR	88	0.48	70	70		10	0.338	0.338		0.048
Sorghum, grain grain	GC	0.41	STMR	86	0.48			30	55			0.143	0.262
Corn, field grain	GC	0.01	STMR	88	0.01				30				0.003
Total						100	100	100	100	0.807	0.812	0.923	0.338

POULTRY LAYER													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Pea vines	AL	10	HR	25	40.00		10				4		
Rape forage	AM/AV	12	HR	30	40.00		10				4		
Rye forage	AF/AS	9.6	HR	30	32.00		10				3.2		
Carrot culls	VR	0.38	HR	12	3.17		10				0.317		
Barley bran fractions	CM/CF	2.1	STMR	90	2.33				5				0.117

POULTRY LAYER													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Rice grain	GC	1.2	STMR	88	1.36	20		50		0.273		0.682	
Brewer's grain dried	SM	1	STMR	92	1.09		10			0.109			
Rice bran/pollard	CM/CF	0.44	STMR	90	0.49	10	5	20	15	0.049	0.024	0.098	0.073
Barley grain	GC	0.425	STMR	88	0.48	70	45			0.34	0.217		
Sorghum, grain grain	GC	0.41	STMR	86	0.48			30	55			0.143	0.262
Wheat milled bypds	CM/CF	0.32	STMR	88	0.36				25				0.091
Total						100	100	100	100	0.660	11.87	0.923	0.543

MEFENTRIFLUCONAZOLE (320)

ESTIMATED MEAN DIETARY BURDEN													
BEEF CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Kale leaves	AM/AV	6.65	STMR/STMR-P	15	44.33		20				8.867		
Rape forage	AM/AV	6.65	STMR/STMR-P	30	22.17			100				22.17	
Pea vines	AL	3.5	STMR/STMR-P	25	14.00		20				2.8		
Barley hay	AF/AS	10.3	STMR/STMR-P	100	10.30	15				1.545			
Barley straw	AF/AS	10.3	STMR/STMR-P	100	10.30		30				3.09		
Rice straw	AF/AS	10.3	STMR/STMR-P	100	10.30				55				5.665
Pea hay	AL	9	STMR/STMR-P	100	9.00		5				0.45		
Wheat asp gr fn	CM/CF	3.5	STMR/STMR-P	85	4.12	5				0.2059			
Corn, field forage/silage	AF/AS	3.1	STMR/STMR-P	100	3.10		25				0.775		
Barley bran fractions	CM/CF	2.1	STMR/STMR-P	90	2.33				10				0.233
Rice grain	GC	1.2	STMR/STMR-P	88	1.36	20				0.273			
Soybean asp gr fn	SM	0.93	STMR/STMR-P	85	1.09	5				0.055			
Brewer's grain dried	SM	1	STMR/STMR-P	92	1.09				35				0.38
Sugarcane molasses	DM	0.37	STMR/STMR-P	75	0.49	10				0.049			
Rice bran/pollard	CM/CF	0.44	STMR/STMR-P	90	0.49	10				0.0489			
Barley grain	GC	0.425	STMR/STMR-P	88	0.48	35				0.1690			
Total						100	100	100	100	2.345572	15.98	22.17	6.279

DAIRY CATTLE														MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Kale leaves	AM/AV	6.65	STMR/STMR-P	15	44.33		20	40			8.867	17.73		
Rape forage	AM/AV	6.65	STMR/STMR-P	30	22.17	10				2.216667				
Wheat silage	AF/AS	18	STMR/STMR-P	100	18.00	0		50		0		9		
Grape pomace, wet	AB	2.3	STMR/STMR-P	15	15.33	0		10		0		1.533		
Pea vines	AL	3.5	STMR/STMR-P	25	14.00	10	20			1.4	2.8			
Barley hay	AF/AS	10.3	STMR/STMR-P	100	10.30	20				2.06				
Barley straw	AF/AS	10.3	STMR/STMR-P	100	10.30	0	30			0	3.09			
Oat hay	AF/AS	10.3	STMR/STMR-P	100	10.30	10			5	1.03			0.515	
Rice straw	AF/AS	10.3	STMR/STMR-P	100	10.30	0			20	0			2.06	
Pea hay	AL	9	STMR/STMR-P	100	9.00	0	10			0	0.9			
Peanut hay	AL	8	STMR/STMR-P	100	8.00	5				0.4				
Sorghum, grain forage	AF/AS	1.7	STMR/STMR-P	35	4.86	10			15	0.4857			0.729	
Soybean hay	AL	4.5	STMR/STMR-P	100	4.50	5				0.225				
Corn, sweet forage	AF/AS	4.2	STMR/STMR-P	100	4.20	30				1.26				
Corn, field forage/silage	AF/AS	3.1	STMR/STMR-P	100	3.10	0	20		10	0.00	0.62		0.31	
Brewer's grain dried	SM	1	STMR/STMR-P	92	1.09	0			40	0			0.435	
Rice bran/pollard	CM/CF	0.44	STMR/STMR-P	90	0.49	0			10	0			0.049	
Total						100	100	100	100	9.077	16.28	28.27	4.097	

POULTRY BROILER														MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Barley bran fractions	CM/CF	2.1	STMR/STMR-P	90	2.33	8				0.19				
Rice grain	GC	1.2	STMR/STMR-P	88	1.36	20		50		0.27		0.682		
Brewer's grain dried	SM	1	STMR/STMR-P	92	1.09		10				0.109			
Carrot culls	VR	0.1	STMR/STMR-P	12	0.83		10				0.083			
Rice bran/pollard	CM/CF	0.44	STMR/STMR-P	90	0.49	2	10	20	5	0.01	0.049	0.098	0.024	
Barley grain	GC	0.425	STMR/STMR-P	88	0.48	70	70		10	0.34	0.338		0.048	
Sorghum, grain grain	GC	0.41	STMR/STMR-P	86	0.48			30	55			0.143	0.262	
Corn, field grain	GC	0.01	STMR/STMR-P	88	0.01				30				0.003	
Total						100	100	100	100	0.807	0.579	0.923	0.338	

POULTRY LAYER														MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Rape forage	AM/AV	6.65	STMR/STMR-P	30	22.17		10				2.217			
Pea vines	AL	3.5	STMR/STMR-P	25	14.00		10				1.4			
Barley straw	AF/AS	10.3	STMR/STMR-P	100	10.30		5				0.515			
Wheat hay	AF/AS	10.3	STMR/STMR-P	100	10.30		5				0.515			
Barley bran fractions	CM/CF	2.1	STMR/STMR-P	90	2.33				5					0.117
Rice grain	GC	1.2	STMR/STMR-P	88	1.36	20		50		0.2727			0.682	
Brewer's grain dried	SM	1	STMR/STMR-P	92	1.09		10				0.109			
Carrot culls	VR	0.1	STMR/STMR-P	12	0.83		10				0.083			
Rice bran/pollard	CM/CF	0.44	STMR/STMR-P	90	0.49	10	5	20	15	0.049	0.024	0.098	0.07	
Barley grain	GC	0.425	STMR/STMR-P	88	0.48	70	45			0.3381	0.217			
Sorghum, grain grain	GC	0.41	STMR/STMR-P	86	0.48			30	55			0.143	0.262	
Wheat milled bypdt	CM/CF	0.32	STMR/STMR-P	88	0.36				25				0.091	
Total						100	100	100	100	0.6597	5.08	0.923	0.543	

PYRIDATE (315)

ESTIMATED MAXIMUM DIETARY BURDEN														MAX
BEEF CATTLE														
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Cabbage heads, leaves	AM/AV	1.5	HR	15	10.00		20					2		
Clover forage	AL	1.5	HR	30	5.00		30	100			1.5	5		
Alfalfa forage	AL	0.26	HR	35	0.74		50				0.371			
Corn, field forage/silage	AF/AS	0.068	HR	40	0.17	15				0.026				
Corn, field grain	GC	0.05	STMR	88	0.06	80			75	0.045			0.043	
Total						95	100	100	75	0.071	3.871	5	0.043	

DAIRY CATTLE														MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Cabbage	AM/AV	1.5	HR	15	10.00		20					2		

DAIRY CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
heads, leaves													
Clover forage	AL	1.5	HR	30	5.00	20	40	60		1.000	2	3	
Kale leaves	AM/AV	0.17	HR	15	1.13			40				0.453	
Corn, field forage/silage	AF/AS	0.068	HR	40	0.17	45	40		50	0.077	0.068		0.085
Corn, field grain	GC	0.05	STMR	88	0.06	35			50	0.020			0.028
Total						100	100	100	100	1.096	4.068	3.453	0.113

POULTRY BROILER													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Corn, field grain	GC	0.05	STMR	88	0.06	75	70		70	0.043	0.04		0.04
Total						75	70		70	0.043	0.04		0.04

POULTRY LAYER													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Cabbage heads, leaves	AM/AV	1.5	HR	15	10.00		5				0.5		
Clover forage	AL	1.5	HR	30	5.00		10				0.5		
Corn, field grain	GC	0.05	STMR	88	0.06	75	70		80	0.043	0.04		0.045
Total						75	85		80	0.043	1.04		0.045

PYRIDATE (315)

ESTIMATED MEAN DIETARY BURDEN													MEAN
BEEF CATTLE													
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Clover forage	AL	0.63	STMR/STMR-P	30	2.10		30	100			0.63	2.1	
Cabbage heads, leaves	AM/AV	0.05	STMR/STMR-P	15	0.33		20				0.067		

ESTIMATED MEAN DIETARY BURDEN													
BEEF CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Alfalfa forage	AL	0.05	STMR/STMR-P	35	0.14		50				0.071		
Corn, field forage/silage	AF/AS	0.05	STMR/STMR-P	40	0.13	15				0.01875			
Corn, field grain	GC	0.05	STMR/STMR-P	88	0.06	80			75	0.045455			0.043
Total						95	100	100	75	0.064205	0.768	2.1	0.043

DAIRY CATTLE													
													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Clover forage	AL	0.63	STMR/STMR-P	30	2.10	20	40	60		0.42	0.84	1.26	
Cabbage heads, leaves	AM/AV	0.05	STMR/STMR-P	15	0.33	0	20			0	0.067		
Kale leaves	AM/AV	0.05	STMR/STMR-P	15	0.33	0		40		0		0.133	
Corn, field forage/silage	AF/AS	0.05	STMR/STMR-P	40	0.13	45	40		50	0.05625	0.05		0.063
Corn, field grain	GC	0.05	STMR/STMR-P	88	0.06	35			50	0.019886			0.028
Total						100	100	100	100	0.496136	0.957	1.393	0.091

POULTRY BROILER													
													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Corn, field grain	GC	0.05	STMR/STMR-P	88	0.06	75	70		70	0.04	0.04		0.04
Total						75	70		70	0.04	0.04		0.04

POULTRY LAYER													
													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Clover forage	AL	0.63	STMR/STMR-P	30	2.10		10				0.21		
Cabbage heads, leaves	AM/AV	0.05	STMR/STMR-P	15	0.33		5				0.017		
Corn, field grain	GC	0.05	STMR/STMR-P	88	0.06	75	70		80	0.042614	0.04		0.045
Total						75	85		80	0.042614	0.266		0.045

SPIROMESIFEN (294)

ESTIMATED MAXIMUM DIETARY BURDEN													
BEEF CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Kale leaves	AM/AV	12.5	HR	15	83.33		20				16.67		
Cotton gin byproducts	AM/AV	12	HR	90	13.33	5				0.667			
Corn, field forage/silage	AF/AS	4.4	HR	40	11.00	15	80	80		1.650	8.8	8.8	
Tomato pomace,wet	AB	1.2	STMR	20	6.00			10				0.6	
Soybean asp gr fn	SM	4.8	STMR	85	5.65	5				0.282			
Bean vines	AL	0.58	HR	35	1.66			10				0.166	
Citrus dried pulp	AB	0.086	STMR	91	0.09	10				0.009			
Potato culls	VR	0.01	HR	20	0.05	30				0.015			
Cotton hulls	SM	0.04	STMR	90	0.04	5				0.002			
Soybean hulls	SM	0.025	STMR	90	0.03	5			5	0.001			0.001
Soybean seed	VD	0.02	STMR	89	0.02	5			15	0.001			0.003
Soybean meal	SM	0.005	STMR	92	0.01				60				0.003
Total						80	100	100	80	2.63	25.47	9.566	0.01

ESTIMATED MAXIMUM DIETARY BURDEN													
DAIRY CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Kale leaves	AM/AV	12.5	HR	15	83.33		20	40			16.67	33.33	
Corn, field forage/silage	AF/AS	4.4	HR	40	11.00	45	60	60	50	4.950	6.6	6.6	5.5
Bean vines	AL	0.58	HR	35	1.66		20				0.331		
Cotton undelinted seed	SO	0.11	STMR	88	0.13	10				0.013			
Citrus dried pulp	AB	0.086	STMR	91	0.09	10				0.009			
Potato culls	VR	0.01	HR	20	0.05	10				0.005			
Soybean hulls	SM	0.025	STMR	90	0.03	10				0.003			
Soybean seed	VD	0.02	STMR	89	0.02	10			10	0.002			0.002
Cotton meal	SM	0.02	STMR	89	0.02	10			10	0.002247			0.002
Soybean meal	SM	0.005	STMR	92	0.01				40				0.002
Total						105	100	100	110	4.984	23.6	39.93	5.507

POULTRY BROILER														MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Potato culls	VR	0.01	HR	20	0.05		10				0.005			
Soybean hulls	SM	0.025	STMR	90	0.03		5				0.001			
Cassava/tapioca roots	VR	0.01	HR	37	0.03		10				0.003			
Bean seed	VD	0.024	STMR	88	0.03		20	70			0.005	0.019		
Soybean seed	VD	0.02	STMR	89	0.02	20				0.004				
Cotton meal	SM	0.02	STMR	89	0.02	20		10		0.00		0.00		
Potato dried pulp	AB	0.01	STMR	88	0.01		20				0.002			
Soybean meal	SM	0.005	STMR	92	0.01	5	35	20	35	0.000	0.002	0.001	0.002	
Total						45	100	100	35	0.009	0.019	0.022	0.002	

POULTRY LAYER														MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Cabbage heads, leaves	AM/AV	1.8	HR	15	12.00		5				0.6			
Potato culls	VR	0.01	HR	20	0.05		10				0.005			
Soybean hulls	SM	0.025	STMR	90	0.03		5				0.001			
Cassava/tapioca roots	VR	0.01	HR	37	0.03		5				0.001			
Bean seed	VD	0.024	STMR	88	0.03		20	70			0.005	0.019		
Soybean seed	VD	0.02	STMR	89	0.02	20				0.004				
Cotton meal	SM	0.02	STMR	89	0.02	20		10		0.004		0.002		
Potato dried pulp	AB	0.01	STMR	88	0.01		15				0.00			
Soybean meal	SM	0.005	STMR	92	0.01	5	20	20	30	0.00	0.001	0.001	0.00	
Total						45	80	100	30	0.009	0.616	0.022	0.002	

SPIROMESIFEN (294)

ESTIMATED MEAN DIETARY BURDEN														MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Kale leaves	AM/AV	2.06	STMR/STMR-P	15	13.73		20				2.747			
Tomato pomace, wet	AB	1.2	STMR/STMR-P	20	6.00			10				0.6		
Soybean asp gr fn	SM	4.8	STMR/STMR-P	85	5.65	5				0.282353				
Corn, field	AF/AS	2	STMR/STMR-P	40	5.00	15	80	80		0.75	4	4		

ESTIMATED MEAN DIETARY BURDEN													
BEEF CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
forage/silage			P										
Cotton gin byproducts	AM/AV	3.65	STMR/STMR-P	90	4.06	5				0.202778			
Bean vines	AL	0.39	STMR/STMR-P	35	1.11			10				0.111	
Citrus dried pulp	AB	0.086	STMR/STMR-P	91	0.09	10				0.009451			
Potato culls	VR	0.01	STMR/STMR-P	20	0.05	30				0.015			
Cotton hulls	SM	0.04	STMR/STMR-P	90	0.04	5				0.002			
Soybean hulls	SM	0.025	STMR/STMR-P	90	0.03	5			5	0.001			0.001
Soybean seed	VD	0.02	STMR/STMR-P	89	0.02	5			15	0.001			0.003
Soybean meal	SM	0.005	STMR/STMR-P	92	0.01				60				0.003
Total						80	100	100	80	1.26	6.75	4.711	0.01

DAIRY CATTLE													
													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Kale leaves	AM/AV	2.06	STMR/STMR-P	15	13.73		20	40			2.747	5.493	
Tomato pomace,wet	AB	1.2	STMR/STMR-P	20	6.00	0		10		0		0.6	
Corn, field forage/silage	AF/AS	2	STMR/STMR-P	40	5.00	45	60	50	50	2.25	3	2.5	2.5
Bean vines	AL	0.39	STMR/STMR-P	35	1.11	0	20			0	0.223		
Cotton undelinted seed	SO	0.11	STMR/STMR-P	88	0.13	10				0.0125			
Citrus dried pulp	AB	0.086	STMR/STMR-P	91	0.09	10				0.009451			
Potato culls	VR	0.01	STMR/STMR-P	20	0.05	10				0.005			
Soybean hulls	SM	0.025	STMR/STMR-P	90	0.03	10				0.002778			
Soybean seed	VD	0.02	STMR/STMR-P	89	0.02	10			10	0.002247			0.002
Cotton meal	SM	0.02	STMR/STMR-P	89	0.02	5				0.001124			
Soybean meal	SM	0.005	STMR/STMR-P	92	0.01	0			40	0			0.002
Total						100	100	100	100	2.283099	5.97	8.593	2.504

POULTRY BROILER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Potato culls	VR	0.01	STMR/STMR-P	20	0.05		10				0.005		
Soybean hulls	SM	0.025	STMR/STMR-P	90	0.03		5				0.001		
Cassava/tapioca roots	VR	0.01	STMR/STMR-P	37	0.03		10				0.003		
Bean seed	VD	0.024	STMR/STMR-P	88	0.03		20	70			0.005	0.019	
Soybean seed	VD	0.02	STMR/STMR-P	89	0.02	20				0.00			
Cotton meal	SM	0.02	STMR/STMR-P	89	0.02	20		10		0.00		0.00	
Potato dried pulp	AB	0.01	STMR/STMR-P	88	0.01		20				0.002		
Soybean meal	SM	0.005	STMR/STMR-P	92	0.01	5	35	20	35	0.000272	0.002	0.001	0.002
Total						45	100	100	35	0.009261	0.019	0.022	0.002

POULTRY LAYER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Cabbage heads, leaves	AM/AV	0.21	STMR/STMR-P	15	1.40		5				0.07		
Potato culls	VR	0.01	STMR/STMR-P	20	0.05		10				0.005		
Soybean hulls	SM	0.025	STMR/STMR-P	90	0.03		5				0.001		
Cassava/tapioca roots	VR	0.01	STMR/STMR-P	37	0.03		5				0.001		
Bean seed	VD	0.024	STMR/STMR-P	88	0.03		20	70			0.005	0.019	
Soybean seed	VD	0.02	STMR/STMR-P	89	0.02	20				0.004494			
Cotton meal	SM	0.02	STMR/STMR-P	89	0.02	20		10		0.004494		0.002	
Potato dried pulp	AB	0.01	STMR/STMR-P	88	0.01		15				0.00		
Soybean meal	SM	0.005	STMR/STMR-P	92	0.01	5	20	20	30	0.000	0.001	0.001	0.00
Total						45	80	100	30	0.009261	0.086	0.022	0.002

SULFOXAFLOR (252)

ESTIMATED MAXIMUM DIETARY BURDEN													
BEEF CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Beet, sugar tops	AM/AV	1.6	HR	23	6.96		20				1.391		
Cotton gin byproducts	AM/AV	4	HR	90	4.44	5				0.222222			
Soybean forage	AL	1.7	HR	56	3.04			100				3.036	
Citrus dried pulp	AB	2.16	STMR	91	2.37	10	5			0.237363	0.119		
Barley hay	AF/AS	1.8	HR	88	2.05	15				0.306818			
Wheat hay	AF/AS	1.8	HR	88	2.05		20				0.409		
Barley straw	AF/AS	1.8	HR	89	2.02		10				0.202		
Soybean asp gr fn	SM	1	STMR	85	1.18	5				0.058824			
Wheat asp gr fn	CM/CF	0.53	STMR	85	0.62	5				0.031176			
Carrot culls	VR	0.03	HR	12	0.25		15				0.038		
Beet, sugar molasses	DM	0.14	STMR	75	0.19	10	10			0.018667	0.019		
Apple pomace, wet	AB	0.074	STMR	40	0.19		15				0.028		
Swede roots	VR	0.01	HR	10	0.10		5				0.005		
Rape meal	SM	0.086	STMR	88	0.10				15				0.015
Barley grain	GC	0.063	STMR	88	0.07	50			70	0.035795			0.05
Barley bran fractions	CM/CF	0.063	STMR	90	0.07				10				0.007
Soybean meal	SM	0.014	STMR	92	0.02				5				0.00076
Total						100	100	100	100	0.910865	2.21	3.036	0.073

DAIRY CATTLE													
													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Beet, sugar tops	AM/AV	1.6	HR	23	6.96		30				2.087		
Soybean forage	AL	1.7	HR	56	3.04	20		40		0.607143		1.214	
Citrus dried pulp	AB	2.16	STMR	91	2.37	10	20	30		0.237363	0.475	0.712	
Barley hay	AF/AS	1.8	HR	88	2.05	20		30		0.409091		0.614	
Barley straw	AF/AS	1.8	HR	89	2.02		30				0.607		
Carrot culls	VR	0.03	HR	12	0.25	10	15			0.025	0.038		
Beet, sugar molasses	DM	0.14	STMR	75	0.19	10	5			0.018667	0.009		
Canola meal	SM	0.086	STMR	88	0.10	10				0.009773			

DAIRY CATTLE														MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Rape meal	SM	0.086	STMR	88	0.10				25				0.024	
Barley grain	GC	0.063	STMR	88	0.07	20			40	0.014318			0.029	
Beet, sugar dried pulp	AB	0.042	STMR	88	0.05				35				0.017	
Total						100	100	100	100	1.321354	3.215	2.54	0.07	

POULTRY BROILER														MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Carrot culls	VR	0.03	HR	12	0.25		10				0.025			
Canola meal	SM	0.086	STMR	88	0.10	15	18	5		0.014659	0.018	0.005		
Rape meal	SM	0.086	STMR	88	0.10				5				0.005	
Bean seed	VD	0.075	STMR	88	0.09		20	70			0.017	0.06		
Barley grain	GC	0.063	STMR	88	0.07	75	52	15	10	0.053693	0.037	0.011	0.007	
Sunflower meal	SM	0.033	STMR	92	0.04	10		10		0.003587		0.004		
Soybean meal	SM	0.014	STMR	92	0.02				30				0.005	
Wheat milled bypds	CM/CF	0.01	STMR	88	0.01				5				0.00057	
Total						100	100	100	50	0.071939	0.097	0.079	0.017	

POULTRY LAYER														MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Beet, sugar tops	AM/AV	1.6	HR	23	6.96		5				0.348			
Soybean forage	AL	1.7	HR	56	3.04		10				0.304			
Wheat hay	AF/AS	1.8	HR	88	2.05		10				0.205			
Carrot culls	VR	0.03	HR	12	0.25		10				0.025			
Canola meal	SM	0.086	STMR	88	0.10	15	10	5		0.014659	0.01	0.005		
Rape meal	SM	0.086	STMR	88	0.10				15				0.015	
Bean seed	VD	0.075	STMR	88	0.09		20	70			0.017	0.06		
Barley grain	GC	0.063	STMR	88	0.07	75	35	15		0.053693	0.025	0.011		
Barley bran fractions	CM/CF	0.063	STMR	90	0.07				5				0.004	
Sunflower meal	SM	0.033	STMR	92	0.04	10		10		0.003587		0.004		
Soybean meal	SM	0.014	STMR	92	0.02				15				0.002	
Wheat milled bypds	CM/CF	0.01	STMR	88	0.01				25				0.003	

POULTRY LAYER													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Total						100	100	100	60	0.071939	0.933	0.079	0.023

SULFOXAFLOR (252)

ESTIMATED MEAN DIETARY BURDEN													
BEEF CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Citrus dried pulp	AB	2.16	STMR/STMR-P	91	2.37	10	5	30		0.2374	0.119	0.712	
Beet, sugar tops	AM/AV	0.42	STMR/STMR-P	23	1.83		20				0.365		
Soybean asp gr fn	SM	1	STMR/STMR-P	85	1.18	5				0.0588			
Soybean hay	AL	0.67	STMR/STMR-P	85	0.79			70				0.552	
Wheat forage	AF/AS	0.19	STMR/STMR-P	25	0.76		20				0.152		
Wheat asp gr fn	CM/CF	0.53	STMR/STMR-P	85	0.62	5				0.0313			
Beet, sugar molasses	DM	0.14	STMR/STMR-P	75	0.19	10	10			0.0187	0.019		
Apple pomace, wet	AB	0.074	STMR/STMR-P	40	0.19		15				0.028		
Cotton gin byproducts	AM/AV	0.15	STMR/STMR-P	90	0.17	5				0.0083			
Barley hay	AF/AS	0.14	STMR/STMR-P	88	0.16	15				0.02394			
Barley straw	AF/AS	0.14	STMR/STMR-P	89	0.16		10				0.016		
Swede roots	VR	0.01	STMR/STMR-P	10	0.10		20				0.02		
Rape meal	SM	0.086	STMR/STMR-P	88	0.10				15				0.0147
Barley grain	GC	0.063	STMR/STMR-P	88	0.07	50			70	0.0358			0.0501
Barley bran fractions	CM/CF	0.063	STMR/STMR-P	90	0.07				10				0.007
Soybean meal	SM	0.014	STMR/STMR-P	92	0.02				5				0.0008
Total						100	100	100	100	0.4140	0.718	1.264	0.0725

DAIRY CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Citrus dried pulp	AB	2.16	STMR/STMR-P	91	2.37	10	20	30		0.2374	0.475	0.712	
Beet, sugar tops	AM/AV	0.42	STMR/STMR-P	23	1.83	0	30			0	0.548		
Soybean hay	AL	0.67	STMR/STMR-P	85	0.79	20		40		0.1577		0.315	
Wheat forage	AF/AS	0.19	STMR/STMR-P	25	0.76	20	20	30		0.152	0.152	0.228	
Beet, sugar molasses	DM	0.14	STMR/STMR-P	75	0.19	10	10			0.01867	0.019		
Barley straw	AF/AS	0.14	STMR/STMR-P	89	0.16	0	10			0	0.016		
Swede roots	VR	0.01	STMR/STMR-P	10	0.10	0	10			0	0.01		
Canola meal	SM	0.086	STMR/STMR-P	88	0.10	10				0.0098			

DAIRY CATTLE														MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Rape meal	SM	0.086	STMR/STMR-P	88	0.10	0			25	0			0.0244	
Carrot culls	VR	0.01	STMR/STMR-P	12	0.08	10				0.0083				
Barley grain	GC	0.063	STMR/STMR-P	88	0.07	20			40	0.0143			0.0286	
Beet, sugar dried pulp	AB	0.042	STMR/STMR-P	88	0.05	0			35	0			0.0167	
Total						100	100	100	100	0.598101	1.219	1.255	0.0698	

POULTRY BROILER														MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Swede roots	VR	0.01	STMR/STMR-P	10	0.10		10				0.01			
Canola meal	SM	0.086	STMR/STMR-P	88	0.10	15	18	5		0.014659	0.018	0.005		
Rape meal	SM	0.086	STMR/STMR-P	88	0.10				5				0.0049	
Bean seed	VD	0.075	STMR/STMR-P	88	0.09		20	70			0.017	0.06		
Barley grain	GC	0.063	STMR/STMR-P	88	0.07	75	52	15	10	0.0537	0.037	0.011	0.0072	
Sunflower meal	SM	0.033	STMR/STMR-P	92	0.04	10		10		0.0036		0.004		
Soybean meal	SM	0.014	STMR/STMR-P	92	0.02				30				0.0046	
Wheat milled bypdts	CM/CF	0.01	STMR/STMR-P	88	0.01				5				0.0006	
Total						100	100	100	50	0.0719	0.082	0.079	0.0172	

POULTRY LAYER														MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Beet, sugar tops	AM/AV	0.42	STMR/STMR-P	23	1.83		5				0.091			
Soybean hay	AL	0.67	STMR/STMR-P	85	0.79		10				0.079			
Wheat forage	AF/AS	0.19	STMR/STMR-P	25	0.76		10				0.076			
Swede roots	VR	0.01	STMR/STMR-P	10	0.10		10				0.01			
Canola meal	SM	0.086	STMR/STMR-P	88	0.10	15	10	5		0.014659	0.01	0.005		
Rape meal	SM	0.086	STMR/STMR-P	88	0.10				15				0.0147	
Bean seed	VD	0.075	STMR/STMR-P	88	0.09		20	70			0.017	0.06		
Barley grain	GC	0.063	STMR/STMR-P	88	0.07	75	35	15		0.053693	0.025	0.011		
Barley bran fractions	CM/CF	0.063	STMR/STMR-P	90	0.07				5				0.0035	
Sunflower meal	SM	0.033	STMR/STMR-P	92	0.04	10		10		0.003587		0.004		
Soybean meal	SM	0.014	STMR/STMR-P	92	0.02				15				0.0023	
Wheat milled bypdts	CM/CF	0.01	STMR/STMR-P	88	0.01				25				0.0028	
Total						100	100	100	60	0.071939	0.308	0.079	0.0233	

TETRANILIPROLE (324) (parent only)

ESTIMATED MAXIMUM DIETARY BURDEN													
BEEF CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Potato process waste	AB	0.01	STMR	12	0.08	20					0.017		
Corn, field asp gr fn	CM/CF	0.046	STMR	85	0.05	5				0.003			
Potato culls	VR	0.01	HR	20	0.05	20				0.010			
Soybean seed	VD	0.026	STMR	89	0.03				15				0.004
Soybean okara	SM	0.026	STMR	92	0.03				15				0.004
Total						100	100	100	100	3.214	19.8	13.59	4.909

DAIRY CATTLE													
													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Kale leaves	AM/AV	7.3	HR	15	48.67		20	40			9.733	19.47	
Corn, field stover	AF/AS	17	HR	83	20.48	15	20	40		3.072	4.096	8.193	
Rice whole crop silage	AF/AS	5.2	HR	40	13.00				55				7.15
Corn, field forage/silage	AF/AS	3.6	HR	40	9.00	30	40	20	45	2.700	3.6	1.8	4.05
Apple pomace, wet	AB	0.91	STMR	90	1.01	10	10			0.101	0.101		
Almond hulls	AM/AV	0.81	STMR	90	0.90	10				0.090			
Lespedeza forage	AL	0.056	HR	22	0.25	35				0.089			
Grass forage (fresh)	AF/AS	0.056	HR	25	0.22		10				0.022		
Total						100	100	100	100	6.052	17.55	29.46	11.2

POULTRY BROILER													
													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Total						100	100	100	100	0.015	0.026	0.014	0.012

POULTRY LAYER													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Total						100	100	100	100	0.015	0.466	0.014	0.013

TETRANILIPOLE (324) (parent only)

ESTIMATED MEAN DIETARY BURDEN													
BEEF CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Potato culls	VR	0.01	STMR/STMR-P	20	0.05	30				0.015			
Sorghum, grain silage	AF/AS	0.01	STMR/STMR-P	21	0.05	5				0.002			
Soybean seed	VD	0.026	STMR/STMR-P	89	0.03				15				0.004
Soybean okara	SM	0.026	STMR/STMR-P	92	0.03				25				0.0071
Total						100	100	100	100	0.549782	6.785	3.179	1.8

DAIRY CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Kale leaves	AM/AV	4	STMR/STMR-P	15	26.67		20	40			5.333	10.67	
Rice whole crop silage	AF/AS	2.7	STMR/STMR-P	40	6.75	0			55	0			3.713
Grape pomace, wet	AB	0.65	STMR/STMR-P	15	4.33	0		20		0		0.867	
Corn, field stover	AF/AS	2.4	STMR/STMR-P	83	2.89	15	20	40		0.433735	0.578	1.157	
Corn, field forage/silage	AF/AS	0.53	STMR/STMR-P	40	1.33	30	40			0.3975	0.53		
Apple pomace, wet	AB	0.91	STMR/STMR-P	90	1.01	10	10			0.101111	0.101		
Almond hulls	AM/AV	0.81	STMR/STMR-P	90	0.90	10				0.09			
Citrus dried pulp	AB	0.15	STMR/STMR-P	91	0.16	0	10			0	0.016		
Soybean hulls	SM	0.11	STMR/STMR-P	90	0.12	10				0.012222			
Potato culls	VR	0.01	STMR/STMR-P	20	0.05	10				0.005			
Sorghum, grain silage	AF/AS	0.01	STMR/STMR-P	21	0.05	15				0.007143			
Vetch silage	AL	0.01	STMR/STMR-P	30	0.03	0			45	0			0.015
Total						100	100	100	100	1.046711	6.559	12.69	3.728

POULTRY BROILER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Total						100	100	100	100	0.015319	0.026	0.014	0.012

POULTRY LAYER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Total						100	100	100	100	0.015319	0.076	0.014	0.013

TETRANILIPROLE (324) (parent + metabolites)

ESTIMATED MAXIMUM DIETARY BURDEN													
BEEF CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Potato process waste	AB	0.01	STMR	12	0.08	20				0.017			
Corn, field asp gr fn	CM/CF	0.046	STMR	85	0.05	5				0.003			
Potato culls	VR	0.01	HR	20	0.05	20				0.010			
Soybean seed	VD	0.026	STMR	89	0.03				15				0.004
Soybean okara	SM	0.026	STMR	92	0.03				15				0.004
Total						100	100	100	100	3.220	19.8	13.61	5.246

DAIRY CATTLE														MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Kale leaves	AM/AV	7.3	HR	15	48.67		20	40			9.733	19.47		
Corn, field stover	AF/AS	17	HR	83	20.48	15	20	40		3.072	4.096	8.193		
Rice whole crop silage	AF/AS	5.2	HR	40	13.00				55				7.15	
Corn, field forage/silage	AF/AS	3.6	HR	40	9.00	30	40	20	45	2.700	3.6	1.8	4.05	

DAIRY CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Apple pomace, wet	AB	0.91	STMR	90	1.01	10	10			0.101	0.101		
Almond hulls	AM/AV	0.8	STMR	90	0.89	10				0.089			
Lespedeza forage	AL	0.066	HR	22	0.30	35				0.105			
Grass forage (fresh)	AF/AS	0.066	HR	25	0.26		10				0.026		
Total						100	100	100	100	6.067	17.56	29.46	11.2

POULTRY BROILER													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Total						100	100	100	100	0.015	0.026	0.014	0.012

POULTRY LAYER													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Total						100	100	100	100	0.015	0.475	0.014	0.013

TETRANILIPROLE (324) (parent + metabolites)

ESTIMATED MEAN DIETARY BURDEN													
BEEF CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Potato culls	VR	0.01	STMR/STMR-P	20	0.05	30				0.015			
Sorghum, grain silage	AF/AS	0.01	STMR/STMR-P	21	0.05	5				0.002			
Soybean seed	VD	0.026	STMR/STMR-P	89	0.03				15				0.004
Soybean okara	SM	0.026	STMR/STMR-P	92	0.03				25				0.0071
Total						100	100	100	100	0.567855	6.853	3.336	1.911

DAIRY CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Kale leaves	AM/AV	4	STMR/STMR-P	15	26.67		20	40			5.333	10.67	
Rice whole crop silage	AF/AS	2.7	STMR/STMR-P	40	6.75	0			55	0			3.713
Grape pomace, wet	AB	0.65	STMR/STMR-P	15	4.33	0		20		0		0.867	
Rice straw	AF/AS	2.8	STMR/STMR-P	90	3.11	0	5	20		0	0.156	0.622	
Corn, field stover	AF/AS	2.5	STMR/STMR-P	83	3.01	15	15	20		0.451807	0.452	0.602	
Corn, field forage/silage	AF/AS	0.55	STMR/STMR-P	40	1.38	30	40			0.4125	0.55		
Apple pomace, wet	AB	0.91	STMR/STMR-P	90	1.01	10	10			0.101111	0.101		
Almond hulls	AM/AV	0.8	STMR/STMR-P	90	0.89	10				0.088889			
Citrus dried pulp	AB	0.15	STMR/STMR-P	91	0.16	0	10			0	0.016		
Soybean hulls	SM	0.11	STMR/STMR-P	90	0.12	10				0.012222			
Potato culls	VR	0.01	STMR/STMR-P	20	0.05	10				0.005			
Sorghum, grain silage	AF/AS	0.01	STMR/STMR-P	21	0.05	15				0.007143			
Vetch silage	AL	0.01	STMR/STMR-P	30	0.03	0			45	0			0.015
Total						100	100	100	100	1.078672	6.608	12.76	3.728

POULTRY BROILER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Total						100	100	100	100	0.015319	0.026	0.014	0.012

POULTRY LAYER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Total						100	100	100	100	0.015319	0.076	0.014	0.013



The annual Joint Meeting of the Food and Agriculture Organization of the United Nations (FAO) Panel of Experts on Pesticide Residues in Food and the Environment and the World Health Organization (WHO) Core Assessment Group on Pesticide Residues (JMPR) was held in Rome, Italy, from 13 to 22 September. The FAO panel of experts had met in preparatory sessions from 8 to 12 September. The Meeting was held in pursuance of recommendations made by previous Meetings and accepted by the governing bodies of FAO and WHO that studies should be undertaken jointly by experts to evaluate possible hazards to humans arising from the occurrence of pesticide residues in foods. During the meeting the FAO Panel of Experts was responsible for reviewing pesticide use patterns (use of good agricultural practices), data on the chemistry and composition of the pesticides and methods of analysis for pesticide residues and for estimating the maximum residue levels that might occur as a result of the use of the pesticides according to good agricultural use practices. The WHO Core Assessment Group was responsible for reviewing toxicological and related data and for estimating, where possible and appropriate, acceptable daily intakes (ADIs) and acute reference doses (ARfDs) of the pesticides for humans. This report contains information on ADIs, ARfDs, maximum residue levels, and general principles for the evaluation of pesticides. The recommendations of the Joint Meeting, including further research and information, are proposed for use by Member governments of the respective agencies and other interested parties.

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