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Pesticide residues in food 2011

Joint FAO/WHO Meeting on Pesticide Residues

REPORT 2011

World Health Organization

Food and Agriculture Organization of the United Nations

Pesticide residues in food 2011

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Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues
Geneva, Switzerland, 20–29 September 2011

WORLD HEALTH ORGANIZATION
FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS
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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

LIST OF PARTICIPANTS

2011 JOINT FAO/WHO MEETING ON PESTICIDE RESIDUES
GENEVA, 20–29 SEPTEMBER 2011

FAO Members

Dr Ursula Banasiak, Federal Institute for Risk Assessment, Thielallee 88-92, D-14195 Berlin, Germany

Professor Eloisa Dutra Caldas, Pharmaceutical Sciences Department, College of Health Sciences, University of Brasilia, Campus Universitário Darci Ribeiro, 70919-970 Brasília/DF, Brazil *(FAO Rapporteur)*

Mr David Lunn, Principal Advisor (Plants and Residues), Assurances and Standards Group, New Zealand Food Safety Authority, PO Box 2835, Wellington, New Zealand

Dr Dugald MacLachlan, Residues and Food Safety, Food Division, Biosecurity Services Group, Australian Government Department of Agriculture, Fisheries and Forestry, GPO Box 858, Canberra, ACT 2601, Australia *(FAO Chairman)*

Dr Yukiko Yamada, Deputy Director-General, Food Safety and Consumer Affairs Bureau, Ministry of Agriculture, Forestry and Fisheries, 1-2-1 Kasumigaseki, Chiyoda-ku, Tokyo 100-8950, Japan

WHO Members

Professor Alan R. Boobis, Centre for Pharmacology and Therapeutics, Division of Experimental Medicine, Department of Medicine, Faculty of Medicine, Imperial College London, Hammersmith Campus, Ducane Road, London W12 0NN, England *(WHO Chairman)*

Dr Vicki L. Dellarco, Office of Pesticide Programs (7501P), United States Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460, United States of America (USA) *(WHO Rapporteur)*

Dr Douglas B. McGregor, Toxicity Evaluation Consultants, Aberdour, Scotland

Professor Angelo Moretto, Department of Environmental and Occupational Health, University of Milan, International Centre for Pesticides and Health Risk Prevention, Luigi Sacco Hospital, Via Stephenson 94, 20157 Milan, Italy

Dr Roland Solecki, Chemical Safety Division, Steering of Procedures and Overall Assessment, Federal Institute for Risk Assessment, Thielallee 88-92, D-14195 Berlin, Germany

Dr Maria Tasheva, Associate Professor Toxicologist, Sofia, Bulgaria

Secretariat

Ms Catherine Adcock, Head, Toxicology Section 2, Health Effects Division II, Health Evaluation Directorate, Pest Management Regulatory Agency, 2720 Riverside Drive, Address Locator: 6605E, Ottawa, Ontario, Canada K1A 0K9 (WHO Temporary Adviser)

Professor Árpád Ambrus, Hungarian Food Safety Office, Gyali ut 2-6, 1097 Budapest, Hungary (FAO Temporary Adviser)

Mr Kevin Bodnaruk, 26/12 Phillip Mall, West Pymble, NSW 2073, Australia (FAO Editor)

Ms Gracia Brisco, Codex Secretariat, Food and Agriculture Organization of the United Nations (FAO), Viale delle Terme di Caracalla, 00153 Rome, Italy

Dr Ian Dewhurst, Chemicals Regulation Directorate, Mallard House, King's Pool, 3 Peasholme Green, York YO1 7PX, England (WHO Temporary Adviser)

Dr William Donovan, United States Environmental Protection Agency, MC 7509C, 1200 Pennsylvania Avenue NW, Washington, DC 20460, USA (FAO Temporary Adviser)

Dr Yibing He, Department of Science and Education, Ministry of Agriculture, No. 11 Nong Zhan Guan Nanli, Beijing - 100125, China (FAO Temporary Adviser)

Mr Makoto Irie, Plant Product Safety Division, Food Safety and Consumer Affairs Bureau, Ministry of Agriculture, Forestry and Fisheries, 1-2-1 Kasumigaseki, Chiyoda-ku, Tokyo 100-8950, Japan (FAO Temporary Adviser)

Dr Debabrata Kanungo, Chairman, Scientific Panel on Residues of Pesticides and Antibiotics, Food Safety and Standard Authority of India, Nityakshetra, 294 / Sector – 21D, Faridabad – 121005, India (WHO Temporary Adviser)

Dr Matthew O'Mullane, Food Standards Australia New Zealand, PO Box 7186, Canberra BC, ACT 2610, Australia (WHO Temporary Adviser)

Dr Rudolf Pfeil, Toxicology of Pesticides and Biocides, Federal Institute for Risk Assessment, Thielallee 88-92, D-14195 Berlin, Germany (WHO Temporary Adviser)

Dr Xiongwu Qiao, Shanxi Academy of Agricultural Sciences, 2 Changfeng Street, Taiyuan, Shanxi 030006, China (FAO Temporary Adviser)

Ms Jeannie Richards, 15 bis rue Georges Musy, 71100 Saint Remy, France (FAO Temporary Advisor)

Dr Prakashchandra V. Shah, Chief, Inert Ingredient Assessment Branch, Registration Division, Office of Pesticide Programs, United States Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460, USA (WHO Temporary Adviser)

Dr Weili Shan, Residues Division, Institute for Control of Agrochemicals, Ministry of Agriculture, Maizidian 22, Chaoyang District, Beijing 100125, China (FAO Temporary Adviser)

Ms Marla Sheffer, 1553 Marcoux Drive, Orleans, Ontario, Canada KIE 2K5 (WHO Editor)

Dr Angelika Tritscher, Department of Food Safety and Zoonoses (FOS), World Health Organization, 1211 Geneva 27, Switzerland (WHO Joint Secretariat)

Ms Trijntje van der Velde, National Institute for Public Health and the Environment (RIVM), PO Box 1, 3720 BA Bilthoven, the Netherlands (FAO Temporary Adviser)

Dr Philippe Verger, Department of Food Safety and Zoonoses (FOS), World Health Organization, 1211 Geneva 27, Switzerland (WHO Joint Secretariat)

Dr Gerrit Wolterink, Centre for Substances and Integrated Risk Assessment, National Institute for Public Health and the Environment (RIVM), Antonie van Leeuwenhoeklaan 9, PO Box 1, 3720 BA Bilthoven, the Netherlands (WHO Temporary Adviser)

Ms Yong Zhen Yang, Plant Production and Protection Division (AGP), Food and Agriculture Organization of the United Nations (FAO), Viale delle Terme di Caracalla, 00153 Rome, Italy (FAO Joint Secretary)

Dr Midori Yoshida, Section Chief, Division of Pathology, Biological Safety Research Centre, National Institute of Health Sciences, Ministry of Health, Labour and Welfare, 1-18-1 Kamiyoga, Setagaya-ku, Tokyo 158-8501, Japan (WHO Temporary Adviser)

Dr Jürg Zarn, Swiss Federal Office of Public Health, Nutritional and Toxicological Risks Section, Stauffacherstrasse 101, CH-8004 Zurich, Switzerland (WHO Temporary Adviser)

ABBREVIATIONS

AChE	acetylcholinesterase
ACTH	adrenocorticotropic hormone
ADI	acceptable daily intake
ae	acid equivalent
ai	active ingredient
ALT	alanine aminotransferase
AMPA	aminomethylphosphonic acid
AP	alkaline phosphatase
AR	applied radioactivity
ARe	androgen receptor
ARfD	acute reference dose
asp gr fn	aspirated grain fraction
AST	aspartate aminotransferase
AU	Australia
BBCH	**B**iologischen Bundesanstalt, **B**undessortenamt und **CH**emische Industrie
BMD	benchmark dose
BMDL	lower limit on the benchmark dose
BROD	benzyloxyresorufin-*O*-dealkylase
bw	body weight
CAC	Codex Alimentarius Commission
CAR	constitutive androstane receptor
CAS	Chemical Abstracts Service
CCN	Codex classification number (for compounds or commodities)
CCPR	Codex Committee on Pesticide Residues
ChE	cholinesterase
C_{max}	maximum concentration
CXL	Codex MRL
CYP	cytochrome P450
DAP	days after planting
DAT	days after treatment
DCSA	3,6-dichlorosalicylic acid
DDT	dichlorodiphenyltrichloroethane
DM	dry matter

DM-PCA	3-trifluoromethyl-1H-pyrazole-4-carboxylic acid
DNA	deoxyribonucleic acid
DT_{50}	time required for 50% dissipation of the initial concentration
dw	dry weight
ECD	electron capture detector
EC_{50}	the concentration of agonist that elicits a response that is 50% of the possible maximum
EPO	early post-emergence
EPSPS	5-enolpyruvylshikimate-3-phosphate synthase
ER	estrogen receptor
EROD	ethoxyresorufin-*O*-deethylase
EtOAc	ethyl acetate
EU	European Union
F_0	parental generation
F_1	first filial generation
F_2	second filial generation
FAO	Food and Agriculture Organization of the United Nations
FPD	flame photometric detector
fw	fresh weight
GAP	good agricultural practice
GAT	glyphosate-N-acetyltransferase
GC	gas chromatography
GC-ECD	gas chromatography with electron capture detection
GC-FPD	gas chromatography with flame photometric detection
GC/MS	gas chromatography/mass spectrometry
GC/TSD	gas chromatography with thermionic sensitive detection
GD	gestation day
GEMS/Food	Global Environment Monitoring System – Food Contamination Monitoring and Assessment Programme
GLC	gas liquid chromatography
GLP	good laboratory practice
GPC	gel permeation chromatography
HPLC	high performance liquid chromatography
HR	highest residue in the edible portion of a commodity found in trials used to estimate a maximum residue level in the commodity
HR-P	highest residue in a processed commodity calculated by multiplying the HR of the raw commodity by the corresponding processing factor
IEDI	international estimated daily intake

IESTI	international estimate of short-term dietary intake
IPCS	International Programme on Chemical Safety
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
JMPS	Joint FAO/WHO Meeting on Pesticide Specifications
JP	Japan
LC	liquid chromatography
LC_{50}	median lethal concentration
LD_{50}	median lethal dose
LH	luteinizing hormone
LHR	luteinizing hormone receptor
LOAEC	lowest-observed-adverse-effect concentration
LOAEL	lowest-observed-adverse-effect level
LOD	limit of detection
LOQ	limit of quantification
LPO	late post-emergence
MFO	mixed-function oxidase
MG	methylguanidine
MOA	mode of action
MRL	maximum residue limit; maximum residue level
MS	mass spectrometry
MS/MS	tandem mass spectrometry
nAChR	nicotinic acetylcholine receptor
NOAEC	no-observed-adverse-effect concentration
NOAEL	no-observed-adverse-effect level
NOEL	no-observed-effect level
NPD	nitrogen phosphorus detector
NTE	neuropathy target esterase
OECD	Organisation for Economic Co-operation and Development
PAM	1-methyl-3-trifluoromethyl-1H-pyrazole-4-carboxamide
PBI	plant back interval
PCA	1-methyl-3-trifluoromethyl-1H-pyrazole-4-carboxylic acid
Pf	processing factor
PH	pre-harvest

PHI	pre-harvest interval
ppm	parts per million
PRE	pre-emergence
PROD	pentoxyresorufin-*O*-deethylase
PXR	pregnane X receptor
RAC	raw agricultural commodity
RSD	relative standard deviation
RTI	re-treatment interval
SC	suspension concentrate
STMR	supervised trials median residue
STMR-P	supervised trials median residue in a processed commodity calculated by multiplying the STMR of the raw commodity by the corresponding processing factor
T_3	triiodothyronine
T_4	thyroxine
T_{max}	time to reach maximum concentration
TAR	total administered radioactivity
TF	transfer factor
TLC	thin-layer chromatography
TRIS	tris(hydroxymethyl)aminomethane
TRR	total radioactive residues
UGT	uridine diphosphate glucuronosyltransferase
UK	United Kingdom
USA	United States of America
US/CAN	United States and Canada
US-FDA	USA – Food and Drug Administration
WG	wettable granule
WHO	World Health Organization

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 submitted 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 submitted 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.

PESTICIDE RESIDUES IN FOOD

REPORT OF THE 2011 JOINT FAO/WHO MEETING OF EXPERTS

1. INTRODUCTION

The Joint FAO/WHO Meeting on Pesticide Residues (JMPR) met at the headquarters of the World Health Organization (WHO) in Geneva, Switzerland, from 20 to 29 September 2011. The meeting was opened by Dr Maged Younes, Director, Department of Food Safety and Zoonoses, WHO, on behalf of the Directors General of WHO and the Food and Agriculture Organization of the United Nations (FAO). Dr Younes acknowledged the impressive and successful work of this programme for the past 50 years and the important role that the work of the Meeting plays in the establishment of international food safety standards, thereby contributing to the improvement of public health. The provision of independent scientific advice as the basis for public health decision-making is at the core of WHO's work, and, as such, the experts attending the meeting are contributing directly to the goals of the Organization. In closing, Dr Younes noted the challenging task ahead for this Meeting and gratefully acknowledged the invaluable contribution of the experts, including the tremendous efforts put into the preparation of the meeting.

During the meeting, the FAO Panel of Experts on Pesticide Residues in Food 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. The WHO Core Assessment Group on Pesticide Residues was responsible for reviewing toxicological and related data in order to establish acceptable daily intakes (ADIs) and acute reference doses (ARfDs), where necessary and possible.

The Meeting evaluated 26 pesticides, including eight new compounds and four compounds that were re-evaluated for toxicity or residues, or both, within the periodic review programme of the Codex Committee on Pesticide Residues (CCPR). The Meeting established ADIs and ARfDs, estimated maximum residue levels and recommended them for use by CCPR, and estimated supervised trials median residue (STMR) and highest residue (HR) levels as a basis for estimating dietary intakes.

The Meeting also estimated the dietary intakes (both short term and long term) of the pesticides reviewed and, on this basis, performed a dietary risk assessment in relation to their ADIs or ARfDs. Cases in which ADIs or ARfDs may be exceeded were clearly indicated in order to facilitate the decision-making process by CCPR. The rationale for methodologies for long- and short-term dietary risk assessment are described in detail in the FAO Manual on the submission and evaluation of pesticide residue data for the estimation of MRLs in food and feed (2009).

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

1.1 DECLARATION OF INTERESTS

The Secretariat informed the Committee that all experts participating in the 2011 JMPR had completed declaration-of-interest forms and that no conflicts had been identified.

Dr McGregor had prepared, in 2006, an opinion on the carcinogenicity and mutagenicity of dichlorvos for the sponsor. Dr Kanungo, as an official of the Government of India, participated in the preparation of the dossier submitted to the JMPR on dicofol.

The JMPR confirmed that these declarations should not be considered as conflicts of interest and that the considered experts should not participate in the discussion about the respective compounds.

2. GENERAL CONSIDERATIONS

2.1 GENERAL DISCUSSIONS RELATED TO THE TOXICOLOGICAL EVALUATION OF COMPOUNDS

The World Health Organization (WHO) Core Assessment Group on Pesticide Residues discussed several items relevant to the toxicological evaluation of agricultural pesticides.

The group agreed on the need to update the guidance for monographers, to take account of changes in process since it was last published and to use the opportunity to improve and harmonize the monograph format to facilitate data submission and exchange of evaluations.

Current practices in rounding when expressing health-based guidance values (acceptable daily intake [ADI], acute reference dose [ARfD]) were also discussed, and the current Joint FAO/WHO Meeting on Pesticide Residues (JMPR) practice was confirmed.

After a brief presentation by Dr Andy Hart on ongoing activities on how to more systematically express the uncertainty underlying hazard assessments, the group decided that it would be beneficial to explore ways to more systematically express underlying uncertainties. For this, it was recommended that one or two JMPR experts should participate in the ongoing activity within WHO/International Programme on Chemical Safety (IPCS). The group also recommended that the Joint FAO/WHO Expert Committee on Food Additives (JECFA) should consider this approach.

Following a brief presentation regarding ongoing activities in the United States of America on high-throughput screening assays (Tox21), the group decided to form a small working group to develop a draft position for JMPR on the use of such data in risk assessment, for discussion at the next meeting.

The group further agreed to form another small working group to define the scope of the need to develop further guidance on minor and adaptive effects, as a follow-up to previous discussions held at the 2006 meeting, for further discussion at the next meeting. Practical experience from the work of JMPR will serve as guidance when developing this scope.

2.2 UPDATE OF THE AUTOMATED SPREADSHEET APPLICATIONS FOR THE CALCULATION OF DIETARY INTAKE: NEW LARGE PORTION DATA

The 2003 Meeting of the JMPR agreed to adopt automated spreadsheet applications for the calculation of dietary intake in order to harmonize and facilitate the estimation process. The spreadsheet applications were constructed by RIVM (National Institute for Public Health and the Environment), of the Netherlands in cooperation with WHO/GEMS/Food incorporating available consumption data into Excel spreadsheets and, where possible, linking this consumption data to the Codex Commodities for which maximum residue levels, HR(-P)s and STMR(-P)s are estimated. The spreadsheets are used to calculate the IEDI and IESTI using the formulas as described in Chapter 7 of the 2009 FAO Manual[1]. To use the spreadsheets, estimates made by JMPR (ADI, ARfD, STMR(-P), HR(-P), and when necessary maximum residue level values) are entered according to the manual

[1] FAO Manual (2009), Submission and evaluation of pesticide residues data for the estimation of maximum residue levels in food and feed. 6.7 Estimation of group maximum residue levels STMR and HR values for plant commodities. FAO Plant Production and Protection paper 197, p 97–101

attached to the spreadsheets. The calculations and generation of a final table are then performed automatically.

In its 2010 Report, JMPR highlighted the importance of having contemporary consumption data to ensure reliable risk assessments (General Considerations 2.2 and 2.3). Some issues were identified with respect to the Large Portion (LP) database:

- In the current GEMS/Food LP database, several regions of the world are not, or not very well, represented.
- The GEMS/Food LP data are sometimes older than those used by the same country in national or regional assessments (e.g., Europe).

As a result WHO/GEMS/Food requested the provision of current national large portion data for acute dietary risk assessments (March 2011). The governments of Australia, France, Germany, Netherlands and Thailand provided new or updated information on large portion data and/or commodity unit weights and percent edible portions. Large portion data already available to JMPR and provided by the governments of Japan, South Africa, the UK and the USA were retained. Unit weight and edible portion data previously provided to the JMPR by the governments of Belgium, Japan, Sweden, the UK and the USA were retained.

The population age groups for which large portion data have been provided differed between countries. Large portion data are now available for general population (all, 1 years and above, 2 years and above, 3 years and above, 10 years and above, 16–64 years, 14–80 years), women of childbearing age (14–50 years), and children of various ages ranging from babies to teenagers (6 years and under, 8–20 months, 1–5 years, 1–6 years, 1.5–4.5 years, 2–4 years, 2–6 years, 3–6 years, 2–16 years). Given the availability of data sets for different population groups, the IESTI spreadsheet calculations are now based on the highest large portion (based on g/kg bw/d), for each commodity, chosen from all population groups. The data were accepted as received, i.e., no quality checking was done as the responsibility for the data lies with the respective national governments.

Large portion data provided were either expressed as raw agricultural commodity (e.g., orange with peel), as raw edible portion (e.g., peeled orange) or as processed product (e.g., orange juice). To enable the selection of the highest large portion, for a certain commodity, from different countries, all large portion data needs to be expressed in the same way. For this reason the submitted large portion data were modified so that the large portion data for raw consumed commodities and aggregated commodities are expressed as raw edible portion, while the large portion data for individual processed commodities are expressed as processed product.

Until recently the IESTI calculations were only done for aggregated large portion data (i.e., raw plus unspecified processed commodities). With the new data it is now possible to do IESTI calculations for individual raw and processed commodities (e.g., raw apples, apple juice, apple sauce, dried apples) as well as for aggregated large portion data (e.g., sum of raw apples, apple juice and dried apples). Large portion data for individual raw and individual processed commodities are listed separately from aggregate large portion data in the spreadsheet.

Generally the large portion data for the aggregated commodities will result in the highest IESTI for a certain commodity. When the ARfD is exceeded for the aggregated commodities, possibilities exist to refine the IESTI calculation by calculating the IESTI for all individual raw and processed commodities by making use of the processing factors derived from processing studies. However, since the aggregate large portion data and the large portion data for the individual commodities come from different countries, the outcome of such refinements, using individual commodities, may not be related to the outcome of the corresponding aggregated commodities. Conclusions on health concern should take this into account.

The spreadsheet applications will be available on the WHO website. http://www.who.int/foodsafety/chem/acute_data/en/index1.html. The call for data is still open and the spreadsheet will be updated when new data become available.

2.3 MAXIMUM RESIDUE LEVEL ESTIMATION USING THE PROPORTIONALITY APPROACH

The 2010 JMPR proposed an approach on the use of proportionality in maximum residue level estimation (General Consideration 2.8 of the 2010 JMPR Report). This approach based on suggestions of some delegations of the 2010 CCPR: JMPR could have recommended maximum residue levels for a number of commodities when the supporting residue data were from trials involving treatments more than 25% higher than the authorized GAP maximum application rates (CCPR, Report of the Forty-second Session, April 2010, ALINORM 10/33/24, paragraph 72).

At its Forty-third Session, the CCPR agreed that it would be useful if the JMPR could elaborate maximum residue level proposals with and without making use of the concept of proportionality so that the results could be compared. (CCPR, Report of the Forty-third Session, April 2011, paragraph 86).

The 2011 JMPR made use of the proportionality approach to estimate maximum residue levels for dicamba in soya beans, etofenprox in grapes, flutriafol in grapes and hexythiazox in strawberries as well as of a median residue for diflubenzuron in almond hulls to estimate the animal dietary burden. Recommendations for these commodities could not have been made without using the proportionality approach.

The table below shows the results with and without scaling of residue data for consideration by the CCPR. The table columns are described as follows: (1) the critical GAP on which the evaluation was based; (2) the application rate used in the corresponding supervised residue trials; (3) the scaling factor (GAP application rate ÷ actual application rate); (4) the residue data points selected from the supervised trials without scaling with residues derived according to GAP underlined; (5) the residue data points selected from the supervised trials if scaled; (6) the estimated maximum residue level without making use of the concept of proportionality; and (7) the estimated maximum residue level based on the use of proportionality.

Treatment		Scaling factor (3)	Residue data (mg/kg)		Maximum residue level (mg/kg)	
GAP, country (1)	Rate, kg ai/ha (2)		not scaled (4)	scaled (5)	Without scaling (6)	With scaling (7)
Dicamba in soya bean (dry)						
1.12 kg ai/ha	2.24	0.5	0.07	0.035	No proposal	5
Pre-harvest	2.24	0.5	0.07	0.035		
treatment	2.24	0.5	0.08	0.04		
	2.24	0.5	0.10	0.05		
USA	2.24	0.5	0.14	0.07		
	2.24	0.5	0.17	0.085		
	2.24	0.5	0.27	0.135		
	2.24	0.5	0.28	0.14		
	2.24	0.5	0.46	0.23		
	2.24	0.5	0.48	0.24		
	2.24	0.5	0.55	0.275		
	2.24	0.5	0.65	0.325		
	2.24	0.5	0.68	0.34		
	2.24	0.5	0.70	0.35		
	2.24	0.5	0.81	0.405		
	2.24	0.5	1.0	0.50		
	2.24	0.5	1.3	0.65		
	2.24	0.5	1.4	0.70		
	2.24	0.5	1.43	0.715		
	2.24	0.5	1.9	0.95		

Treatment		Scaling factor (3)	Residue data (mg/kg)		Maximum residue level (mg/kg)	
GAP, country (1)	Rate, kg ai/ha (2)		not scaled (4)	scaled (5)	Without scaling (6)	With scaling (7)
	2.24	0.5	2.1	1.05		
	2.24	0.5	3.3	1.65		
	2.24	0.5	8.1	4.05		
Etofenprox in grapes						
0.028 kg ai/hL	0.015	1.87	0.25	0.47	No proposal	4
	0.015	1.87	0.29	0.54		
Italy	0.015	1.87	0.35	0.65		
	0.015	1.87	0.38	0.71		
	0.015	1.87	0.39	0.73		
	0.015	1.87	0.39	0.73		
	0.015	1.87	0.53	0.99		
	0.015	1.87	0.63	1.2		
	0.015	1.87	0.96	1.8		
	0.015	1.87	1.37	2.6		
	in kg ai/hL					
Diflubenzuron in almond hulls						
4×0.28 kg	4×0.28	1	2.1	2.1		1.15
	4×0.28	1	4.0	4.0		
USA	4×0.56	0.5	1.0	0.5		Median
	4×0.56	0.5	1.6	0.8		residue
	4×0.56	0.5	2.1	1.05		for animal
	4×0.56	0.5	2.3	1.15		dietary
	4×0.56	0.5	4.4	2.2		burden
Flutriafol in grapes						
6×0.073-0.091	7×0.128	0.71	0.12	0.09	No proposal	0.8
kg ai/ha	7×0.128	0.71	0.21	0.15		
	7×0.128	0.71	0.21	0.15		
USA	7×0.128	0.71	0.25	0.18		
	7×0.128	0.71	0.28	0.20		
	7×0.128	0.71	0.30	0.21		
	7×0.128	0.71	0.30	0.21		
	7×0.128	0.71	0.31	0.22		
	7×0.128	0.71	0.35	0.25		
	7×0.128	0.71	0.37	0.26		
	7×0.128	0.71	0.43	0.31		
	7×0.128	0.71	0.61	0.43		
	7×0.128	0.71	0.86	0.61		
Hexythiazox in strawberry						
1× 0.21	0.07	3	0.18	0.54	No proposal	6
kg ai/ha	0.14	1.5	0.19	0.29		
	0.17	1.23	0.50	0.62		
USA	0.21	1	0.13	0.13		
	0.21	1	0.17	0.17		
	0.21	1	0.30	0.30		
	0.21	1	1.8	1.80		
	0.28	0.75	0.87	0.65		
	0.28	0.75	5.5	4.1		

2.4 GEOGRAPHICAL ZONES AND ESTIMATION OF MAXIMUM RESIDUE LEVELS

At the 2003 JMPR, the Meeting considered the Zoning Report[2] and agreed with the conclusion that the impact of climatic zones on pesticide residues is small, and residue data derived from similar use patterns and growing conditions may be compared regardless of the geographical location of the trials.

The JMPR has used trials complying with GAP irrespective of geographical location, but on a case-by-case basis. Recognizing the experience gained since 2003, the Meeting agreed that from 2012, geographical location should not be a barrier in selecting trials for estimation of maximum residue levels. However, the Meeting noted that there will be cases where regional differences in cultural practices will need to be considered.

Sulfoxaflor data were used to illustrate MRL estimates obtained using geographical zones (Current JMPR Practice) and assuming residues do not primarily depend on zones (Global Dataset Method). This comparison is provided in the attached "MRL Estimates for Sulfoxaflor" table. Combining data from different geographical zones results in MRL estimates based on larger data sets that more accurately reflect data variability and are more appropriate for use with statistical-based MRL calculations.

MRL Estimates for Sulfoxaflor

	Current Practice		Global Dataset Method	
Crop/Crop Group	# Trials	MRL (mg/kg)	# Trials	MRL (mg/kg)
Carrot	4	No MRL[a]	11	0.05
Dry Bean	4	No MRL[a]	6	0.2
Common Bean	3	No MRL[a]	6	4
Citrus Fruit	10	0.9	26	0.7
Pome Fruit	18	0.4	36	0.5
Stone Fruit	6	3	14	3
Tree Nuts	6	0.015	6	0.015
Fruiting Vegetables, Cucurbit	6	0.5	16	0.4
Fruiting Vegetables, other than cucurbits (except sweet corn and mushroom)	11	1.5	20	0.7
Leafy Vegetables	6	6	7	6
Root and Tuber Vegetables [b]	8	0.03	11	0.05
Barley	6	0.6	25	0.4
Barley straw and fodder, dry	11	3	36	2
Broccoli	5	3	15	2
Cabbages, Head	6	0.4	14	0.5
Cauliflower	6	0.04	10	0.07
Celery	6	1.5	6	1.5
Cotton seed	6	0.4	22	0.2
Garlic	Extrapolated [c]	0.01*	Extrapolated [c]	0.01*
Grapes	12	2	33	2
Dried Grape	Processing [d]	6	Processing	6
Okra	Extrapolated [c]	1.5	Extrapolated [c]	0.7
Onion, bulb	6	0.01*	6	0.01*
Spring onion	6	0.7	6	0.7
Dried chili pepper	Extrapolated [c]	15	Extrapolated [c]	7
Pistachio nut	Extrapolated [c]	0.015	Extrapolated [c]	0.015
Rape seed	8	0.15	14	0.4
Soya bean fodder	15	3	19	2
Soya bean (immature seed)	14	0.3	18	0.2
Strawberry	9	0.5	13	0.7

[2] Report of the OECD/FAO Zoning Project Series on Pesticides, Number 19, ENV/JM/MONO(2003)4 16 May 2003[www.oecd/dataoecd/27/0/2955870.pdf]

	Current Practice		Global Dataset Method	
Crop/Crop Group	# Trials	MRL (mg/kg)	# Trials	MRL (mg/kg)
Triticale	Extrapolated [c]	0.2	Extrapolated [c]	0.15
Watercress	6	6	7	6
Wheat	6	0.2	33	0.15
Wheat straw and fodder, dry	11	3	36	2

[a] No recommendation due to insufficient number of trials.

[b] Except carrot for regional; with carrot for global.

[c] Extrapolated from another crop.

[d] From processing study.

Note: Identical MRL recommendations for mammals (0.3 meat; 0.6 offal), milk (0.2), poultry (0.1 meat; 0.3 offal), and eggs (0.1).

3. RESPONSES TO SPECIFIC CONCERNS RAISED BY THE CODEX COMMITTEE ON PESTICIDE RESIDUES (CCPR)

The Meeting noted that the information supplied on some of the concern forms submitted by CCPR Members was inadequate to permit JMPR to clearly identify the critical issues underlying the concerns. Consequently, the Meeting had great difficulty in determining the issues involved, raising the possibility that the response provided by the Meeting might not actually address the true concern. The Meeting requested that any future concerns submitted to JMPR should be accompanied by comprehensive and transparent supporting information. If such information is not provided, the Meeting might be forced to conclude that it is not able to provide a meaningful response.

3.1 BIFENTHRIN (178)

Concern No. 1

Background

At the Forty-second Session of the Codex Committee on Pesticide Residues (CCPR), concern was raised by the Kenya Plant Health Inspectorate Service regarding the acute reference dose (ARfD) for bifenthrin established by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) in 2009. Information was also provided by the sponsor regarding this concern in 2011.

The toxicity of bifenthrin was first evaluated by the 1992 JMPR. The 2009 JMPR reviewed bifenthrin within the periodic review programme of CCPR and established an ARfD of 0.01 mg/kg body weight (bw) based on a threshold dose (an estimate of the highest no-effect level at which treated rats would not display any decrease in motor activity) of 1.3 mg/kg bw in an acute rat gavage study for a decrease in motor activity from the published study by Wolansky *et al.* (2006) and using a safety factor of 100[3]. Although this study was conducted with male rats only, it was considered appropriate, as there was no evidence of sex differences in the bifenthrin database. This ARfD was supported by the gavage study of developmental toxicity in rats in which the no-observed-adverse-effect level (NOAEL) of 1.0 mg/kg bw per day was based on the increased fetal and litter incidences of hydroureter without hydronephrosis seen at the highest dose of 2.0 mg/kg bw per day and was thereby also protective of developmental effects[4].

The 2011 JMPR agreed to reconsider the ARfD for bifenthrin based upon the concern form submitted by Member State Kenya (Annex 5, reference *119*). The Meeting also considered the "Comprehensive Rationale for Establishing an ARfD for Bifenthrin" submitted by the sponsor in support of the concern raised.

[3] Wolansky MJ, Gennings C & Crofton KM (2006). Relative potencies for acute effects of pyrethroids on motor function in rats. Toxicological Sciences, 89(1):271–277.

[4] DeProspo JR (1984a). Teratology study in rats with FMC 54800 technical. FMC A83-1091.

Concern from Kenya

"The studies used for the derivation of the ARfD may not be most appropriate and therefore resulting in an overly conservative ARfD. In particular, we would like to highlight a number of areas which would require a scientific re-evaluation:

- Effect of dosing in corn oil and the influence of corn oil volume on toxicity
- The lack of consideration of using a benchmark dose approach
- Use of a lower safety factor (50) is justified due to toxicokinetic factor
- Lack of statistics used in the Wolansky (2006) study
- The use of NOEL from the DeProspero (1984) study which is not appropriate for an ARfD
- The use of non-statistically significant teratogenic endpoints"

Comments by JMPR

- Effect of dosing in corn oil and the influence of corn oil volume on toxicity

The JMPR agrees that use of corn oil as a vehicle and the dosing volume of corn oil can influence the toxic potency of pyrethroids. It is not unusual for some standard test guideline studies to be conducted using gavage dosing and corn oil as vehicle. The data from such studies have been used for the derivation of ARfDs previously, including for several pyrethroids, by the JMPR. Further, several types of vehicles are used in pyrethroid gavage studies, and corn oil is used most often. The rationale of vehicle/dose volume in the Wolansky *et al*. (2006) study is consistent with the routine dosing volume used in many laboratories.

In fact, the study proposed by the sponsor for establishing the ARfD was conducted using corn oil as the vehicle.

- The lack of consideration of using a benchmark dose approach

The Meeting acknowledges that benchmark dose (BMD) modelling provides a more quantitative analysis of uncertainty in the dose–response relationship than the NOAEL/lowest-observed-adverse-effect level (LOAEL) process. However, in the case of the motor activity data in Wolansky *et al*. (2006), the BMD can only be modelled down to a 30% response due to variability in the measurements. The lower limit on the benchmark dose (BMDL) of 4 mg/kg bw per day proposed by the sponsor for bifenthrin would need to be adjusted to allow for the fact that the BMD is based on a 30% response. Further, the BMDL of 4 mg/kg bw per day would not be sufficiently protective of developmental effects at 2.0 mg/kg bw per day in a developmental toxicity study in rats (gavage). Suitable adjustment of the BMDL for a 30% response rather than the conventional 5% response will result in a reference value similar to the "threshold dose" of 1.3 mg/kg bw given in Wolansky *et al*. (2006).

- Use of a lower safety factor (50) is justified due to toxicokinetic factor

When considering the safety factors for acute toxicological effects dependent on the peak concentration in plasma (C_{max}), the compound needs to have toxicokinetic properties that result in rapid absorption and elimination and toxicodynamic properties such that there is no opportunity for cumulative effects to result from one exposure to another. These properties are not supported by the

data provided by the sponsor in the case of bifenthrin. The Meeting in 2009 did consider the Selim (1986) study[5]. In this study, radioactivity peaked 4 and 6 hours after the administration of doses of 5.4 and 35 mg/kg bw, respectively. Ten hours after dosing, the chemical concentration in blood declined to less than 50% of the concentration at peak in both doses. The data from Selim (1986) showed a slow decline of radioactivity. The 2009 JMPR did not apply a compound-specific C_{max} adjustment factor. The current Meeting confirmed this view and concluded that there are inadequate pharmacokinetic data to support such a factor. Additionally, the relationship between C_{max} and the developmental toxicity of bifenthrin is unknown.

- Lack of statistics used in the Wolansky (2006) study

The non-linear exponential threshold additivity model was used in Wolansky *et al*. (2006) to obtain the threshold dose and its 95% confidence intervals for each individual chemical. This threshold dose represents an estimate of the highest no-effect level at which treated rats would not display any decrease in motor activity. As stated in Wolansky *et al*. (2006), the adequacy of the fit of the additivity model to the data on single chemicals was assessed graphically and through goodness-of-fit statistics. As stated previously, a $BMDL_{30}$ would have to be adjusted, which would result in a value similar to the threshold dose value reported in Wolansky *et al*. (2006) (see comment on BMD above).

- The use of NOEL from the DeProspero (1984) study which is not appropriate for an ARfD

The Meeting assumes that "NOEL" (no-observed-effect level) in the statement of concern meant NOAEL. In the developmental toxicity study in rats via gavage (DeProspo, 1984a), the NOAEL was 1.0 mg/kg bw per day, based on the 3-fold increased incidence of hydroureter at 2.0 mg/kg bw per day. Furthermore, the litter incidences for hydroureter without hydronephrosis were 0/23, 0/24, 0/25 and 5/23 at 0, 0.5, 1.0 and 2.0 mg/kg bw per day, respectively. As this effect was not observed in the concurrent control and positive control study and increased in incidence in both fetuses and litters, and because of the lack of historical control data and lack of detailed description of the effects, including photographs, in the study report, the Meeting concluded that the effect of treatment with bifenthrin cannot be dismissed. The JMPR has no evidence to conclude that these effects could not occur following a single-dose exposure during the critical window of fetal development.

The sponsor points out that the developmental effects of bifenthrin were not observed in the dietary developmental toxicity study in rats[6]. The JMPR notes, however, that differences in response due to route of administration are not unusual. Unless there is information to the contrary, an effect is not disregarded based on route of administration. The sponsor also notes that these effects were not seen in the developmental toxicity study in rabbits.[7] Species differences in response are also not unusual, and, unless there is information to the contrary, the most sensitive species is used to establish health-based guidance values. The sponsor further points out that these developmental effects were not found in the reproductive toxicity study[8] and the developmental neurotoxicity toxicity study in rats[9]. However, these effects were not looked for in these studies.

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[5] Selim S (1986). The kinetics of FMC 54800 in the blood of rats following a single oral dose. FMC PC-0048. February 1986.

[6] Watt B & Freeman C (2001). Bifenthrin technical: prenatal developmental toxicity study in rats. FMC A2000-5263.

[7] DeProspo JR (1984b). Teratology study in rabbits with FMC 54800 technical. FMC A83-1092.

[8] DeProspo JR (1986). Multi-generation reproduction study with FMC 54800 technical in rats. FMC A83-977.

[9] Nemec MD (2006). A dietary developmental neurotoxicity study of bifenthrin technical in rats. FMC A2004-5860.

- The use of non-statistically significant teratogenic endpoint

Although statistical significance was not achieved for increases in the incidence of hydroureter without hydronephrosis, the fetal and litter incidences were increased at the highest dose level of 2.0 mg/kg bw per day and therefore cannot be ignored, especially because the effect was very rare and not seen in the concurrent controls. No historical control data were provided to the Meeting. In addition, higher doses were not tested in the developmental toxicity study in rats; therefore, the dose–response relationship cannot be assessed. The JMPR has no evidence to conclude that these effects could not occur following a single-dose exposure during the critical window of fetal development.

Conclusion

Based on the data available during the 2009 JMPR and having considered the rationale provided by the sponsor on behalf of Kenya, the 2011 Meeting confirmed the AfRD of 0.01 mg/kg bw established by the 2009 JMPR.

Concern No. 2

Background

At the Forty-third Session of the CCPR, the Delegation of the European Community (EC) raised concerns regarding the maximum residue level proposal for bifenthrin in strawberry. A concern form was submitted.

Evaluation by the 2010 JMPR

The 2010 JMPR estimated a maximum residue level for bifenthrin in strawberries of 3 mg/kg to replace the previous recommendation of 1 mg/kg. The Meeting estimated an STMR of 0.46 mg/kg and an HR of 2.3 mg/kg.

The 2010 JMPR noted that the ARfD is exceeded for children (430%) and the general population (230%) following the short-term dietary intake calculation. No alternative GAP was available.

Comment by the 2011 JMPR

With regards to the evaluation of bifenthrin residues in strawberry, the procedure undertaken by the JMPR was as follows:

- the estimation of a maximum residue level for proposal as a Codex MRL (3 mg/kg);
- the calculation of the dietary intake on the basis of the STMR (0.46 mg/kg) for long-term and the HR (2.3 mg/kg) for the short-term intake, with the result that the ARfD was exceeded;
- then consideration of any available alternative GAP, with no alternative GAP available in this instance.

The outcome of this process was indicated in the Report of the 2010 JMPR, in that it was stated that the ARfD was exceeded and that no alternative GAP for bifenthrin use in strawberry was available.

The JMPR as risk assessors, therefore, prepared the relevant information for the consideration by the CCPR, the risk managers, with respect to decision making.

Based on the evaluation of the JMPR, it was noted in the Report of the Forty-third Session of the CCPR that: "*Due to short term intake concern identified by JMPR, the Committee decided to*

retain the proposed draft MRL for strawberry at Step 4, awaiting data from the manufacturer to support a review of alternative GAP by JMPR in 2014[10]".

3.2 INDOXACARB (216)

Indoxacarb, an indeno-oxadiazine insecticide used for control of Lepidoptera and other pests, was first evaluated by the 2005 JMPR, with additional commodities and commodity groups being considered at the 2007 and 2009 JMPR Meetings. An ADI of 0–0.01 mg/kg body weight and an ARfD of 0.1 mg/kg body weight were established by the 2005 JMPR.

The 2005 Meeting recommended maximum residue levels for a range of commodities, including levels of 7 mg/kg for head lettuce and 15 mg/kg for leaf lettuce but was not able to calculate the IESTI for leaf lettuce because leaf lettuce unit weight data were not available at that time.

The Thirty-eighth CCPR, in 2006, advanced the proposed draft MRL of 15 mg/kg for leafy lettuce to Step 5, noting the acute dietary intake concerns for children expressed by the EC [Alinorm 06/29/24 - para 135]. This draft MRL was subsequently advanced to Step 8 by the Thirty-ninth CCPR in 2007.

In 2009, new consumption data were available to JMPR, including information on leaf lettuce consumption, and the 2009 Meeting calculated the IESTIs for leaf lettuce (60% of the ARfD for the general population and 150% of the ARfD for children) and noted that there were limited opportunities to refine the consumption estimate or the intake risk estimate and that there was no alternative GAP available.

The Fortieth CCPR, in 2010, in addition to advancing a number of new and revised MRLs, requested JMPR to conduct an alternative GAP evaluation for leafy lettuce and the Forty-first CCPR scheduled this evaluation for this JMPR Meeting.

New GAP information was provided by the manufacturer and the Meeting reviewed the data submitted to the 2005 JMPR on leafy lettuce in light of this new GAP.

Results of supervised trials on crops

The GAP in Italy is for up to 3 applications of 0.038 kg ai/ha with a PHI of 1 day.

In three trials conducted in France and Greece, involving 6 applications of 0.038 kg ai/ha, PHI 1 day, residues were: 0.36, 0.75 and 1.25 mg/kg.

The Meeting agreed that the data were not sufficient to recommend a maximum residue level to support an alternative GAP for indoxacarb on leafy lettuce.

[10] Report of the Forty-third Session of the CCPR, paragraph 53, Beijing, 4-9 April 2011, REP11-PR-Rev

4. DIETARY RISK ASSESSMENT FOR PESTICIDE RESIDUES IN FOOD

Assessment of risk from long-term dietary intake

At the present Meeting, risks associated with long-term dietary intake were assessed for compounds for which MRLs were recommended and STMRs/STMR-Ps values estimated. International estimated daily intakes (IEDIs) were calculated by multiplying the concentrations of residues (STMRs and STMR-Ps) by the average daily per capita consumption estimated for each commodity on the basis of the 13 GEMS/Food Consumption cluster diets[11]. IEDIs are expressed as a percentage of the ADI for a 55 kg or 60 kg person, depending on the cluster diet.

New evaluations

Acetamiprid, emamectin-benzoate, flutriafol, isopyrazam, propylene oxide, saflufenacil and sulfoxaflor were evaluated for toxicology and residues for the first time by the JMPR. The Meeting established ADIs and conducted long-term dietary risk assessments for all these compounds, except propylene oxide. For this compound, no dietary risk assessment was performed as no residue recommendation was made.

Penthiopyrad was evaluated only for toxicology and an ADI was established. The long-term dietary risk assessment for this compound will be considered during the evaluation for residues at a subsequent Meeting.

Periodic re-evaluations

Etofenprox and tebuconazole were evaluated for toxicology (etofenprox) and for residues under the Periodic Re-evaluation Programme. ADI was established for etofenprox at this Meeting and for tebuconazole in 2010, and long-term dietary risk assessments were conducted.

Dichlorvos and dicofol were evaluated only for toxicology and long-term dietary risk assessment for these compounds will be considered during the periodic review for residues at subsequent Meetings.

Evaluations

Acephate, azoxystrobin, cypermethrins, dicamba, diflubenzuron, etoxazole, glyphosate, hexythiazox, profenofos, pyraclostrobin, spinosad and spirotetramat were evaluated for residues and long-term dietary risk assessments were conducted for these compounds. Two glyphosate metabolites found in some genetically modified crops were evaluated for toxicology, and were included in the ADI for glyphosate previously established.

The outcome of the evaluation of indoxacarb and thiamethoxam performed at this Meeting was such that the long-term dietary assessment was not necessary.

A summary of the long-term dietary risk assessments conducted by the present meeting is shown on Table 1. The detailed calculations of long-term dietary intakes are given in Annex 3. The percentages are rounded to one whole number up to 9 and to the nearest 10 above that. Percentages above 100 should not necessarily be interpreted as giving rise to a health concern because of the conservative assumptions used in the assessments. Calculations of dietary intake can be further

[11] http://www.who.int/foodsafety/chem/gems/en/index1.html

refined at the national level by taking into account more detailed information, as described in the Guidelines for predicting intake of pesticide residues[12].

Table 1 Summary of long-term dietary of risk assessments conducted by the 2011 JMPR

CCPR code	Compound Name	ADI (mg/kg bw)	Range of IEDI, as % of maximum ADI
95	Acephate	0-0.03	2–10
246	Acetamiprid	0–0.07	0–3
229	Azoxystrobin	0–0.2	2–10
247	Emamectin benzoate	0–0.0005	0–20
118	Cypermethrins	0–0.02	7–30
240	Dicamba	0–0.3	0–1
130	Diflubenzuron	0–0.02	2–10
184	Etofenprox	0–0.03	1–3
241	Etoxazole	0–0.05	0–1
248	Flutriafol	0–0.01	0–7
158	Glyphosate	0–1	0–2
176	Hexythiazox	0–0.03	0–3
249	Isopyrazam	0–0.06	0
171	Profenofos	0–0.03	2–10
210	Pyraclostrobin	0–0.03	1–9
251	Saflufenacil	0–0.05	0
203	Spinosad	0–0.02	10–40
252	Sulfoxaflor	0–0.05	1–8
234	Spirotetramat	0–0.05	2–20
189	Tebuconazole	0–0.03	3–10

Assessment of risk from short-term dietary intake

At the present Meeting, risks associated with short-term dietary intake were assessed for compounds for which MRLs were recommended and STMR/STMR-P and HR/HR-P values estimated. The procedures used for calculating the International estimated short-term intake (IESTI) are described in detail in Chapter 3 of the 2003 JMPR report. Detailed guidance on setting ARfD is described in Section 2.1 of the 2004 JMPR report[13].

Data on the consumption of large portions were provided to GEMS/Food by the governments of Australia, France, Germany, The Netherlands, Japan, South Africa, Thailand, the UK and the USA. Data on unit weights and per cent edible portions were provided by the governments of Belgium, France, Japan, Sweden, the UK and the USA. As a result of a WHO/GEMS/Food request to provide or update national large portion data on March 2011, the governments of Australia, France, Germany, Netherlands and Thailand provided new or updated information on large portion data and/or commodity unit weights and percent edible portions. Large portion data have been provided for several different population groups: general population (all, 1 and above, 2 and above, 3 and above, 10 and above, 16–64 years, 14–80 years), women of childbearing age (14–50 years), and children of various ages (6 years and under, 8–20 months, 1–5 years, 1–6 years, 1.5–4.5 years, 2–4 years, 2–6 years, 3–6 years, 2–16 years). For each commodity, the highest large portion data from all different

[12] WHO (1997) Guidelines for predicting dietary intake of pesticide residues. 2nd Revised Edition, GEMS/Food Document WHO/FSF/FOS/97.7, Geneva

[13] Pesticide Residues in Food–2004. Report of the JMPR 2004, FAO Plant Production and Protection Paper 178. Rome, Italy, 20–29 September 2004

population groups was included in the spreadsheet for the calculation of the IESTI. The spreadsheet application is available at http://www.who.int/foodsafety/chem/acute_data/en/index1.html.

New evaluations

Acetamiprid, emamectin-benzoate, flutriafol, isopyrazam, propylene oxide, and sulfoxaflor were evaluated for toxicology and residues for the first time by the JMPR. The Meeting established ARfDs and conducted short-term dietary risk assessments for these compounds, except propylene oxide. For this compound, no dietary risk assessment was performed as no residue recommendation was made.

Penthiopyrad was evaluated only for toxicology and ARfD was established. The short-term dietary risk assessment for this compound will be considered during the evaluation for residues at a subsequent Meeting.

The Meeting considered the establishment of ARfD not necessary for saflufenacil and short-term dietary risk assessment was not performed for this compound.

Periodic re-evaluations

Etofenprox and tebuconazole were evaluated for toxicology (etofenprox) and residues under the Periodic Re-evaluation Programme. ARfD was established for etofenprox at this Meeting and for tebuconazole in 2010 and short-term dietary risk assessments were conducted.

Dichlorvos and dicofol were evaluated only for toxicology and short-term dietary risk assessment for these compounds will be considered during the periodic review for residues at subsequent Meetings.

Evaluations

Acephate, cypermethrin, dicamba, profenofos, pyraclostrobin and spirotetramat were evaluated for residues and short-term dietary risk assessments were conducted for these compounds.

The outcome of the evaluation of clothianidin, indoxacarb and thiamethoxam performed at this Meeting was such that the short-term dietary assessment was not necessary.

On the basis of data received by the present or previous Meetings, the establishment of ARfD was considered not necessary for azoxystrobin, diflubenzuron, etoxazole; glyphosate, hexythiazox and spinosad, and short-term dietary risk assessment for these compounds were not performed.

Table 2 shows the maximum percentage of the ARfD found in the short-term dietary risk assessments for each compound. The percentages are rounded to one whole number up to 9 and to nearest 10 above that. Percentages above 100 should not necessarily be interpreted as giving rise to a health concern because of the conservative assumptions used in the assessments. The detailed calculations of short-term dietary intakes are given in Annex 4.

Table 2 Maximum percentage of the ARfD found in the short-term dietary risk assessments conducted by the 2011 JMPR

CCPR code	Compound Name	ARfD (mg/kg bw)	Max. percentage of ARfD	
			Commodity (% ARfD)	Population
095	Acephate	0.1	Rice (4%)	Children, 1–6
246	Acetamiprid	0.1	Spinach (180%)	Children, 1–5
247	Emamectin benzoate	0.03	Lettuce (50%)	Children, 2–6
118	Cypermethrin	0.04	Asparagus (8%)	Children, 1–6
240	Dicamba	0.5	Soya bean (0%)	all
184	Etofenprox	1	Grape (10%)	Children, 0–6
248	Flutriafol	0.05	Grape (50%)	Children, 0–6
249	Isopyrazam	0.3	All (0%)	all
171	Profenofos	1	Chili pepper (0%)	all

CCPR code	Compound Name	ARfD (mg/kg bw)	Max. percentage of ARfD	
			Commodity (% ARfD)	Population
210	Pyraclostrobin	0.05	Artichoke globe (50%)	Children, 3–6
252	Sulfoxaflor	0.3	Spinach (70%)	Children, 1–5
234	Spirotetramat	1.0	Spinach (40%)	Children, 1–5
189	Tebuconazole	0.3	Grape (70%)	Children, 0–6

Possible risk assessment refinement when the IESTI exceeds the ARfD

Acetamiprid in spinach

The ARfD for acetamiprid established by the Meeting was based on a single dose acute neurotoxicity study, supported by acute maternal toxic effects observed in a developmental neurotoxicity study, and it is unlikely that it could be refined.

The estimated IESTI of acetamiprid reached 180% of the ARfD based on the consumption of 420 g of spinach, raw and processed, by children 1–5 years (14.2 kg bw). The Meeting did not receive information on how much raw spinach is accounted for in the consumption figure, and noted that it is more likely that children 1–5 years consume processed spinach (cooked or canned). If it is assumed that the consumption of 420 g is all due to processed spinach, the IESTI represents 20% of the ARfD. Furthermore, the consumption of more than 190 g (representing 100% of the ARfD) only of raw spinach by a child 1–5 years is considered unlikely.

5. EVALUATION OF DATA FOR ACCEPTABLE DAILY INTAKE AND ACUTE DIETARY INTAKE FOR HUMANS, MAXIMUM RESIDUE LEVELS AND SUPERVISED TRIALS MEDIAN RESIDUE VALUES

5.1 ACEPHATE (095) AND METHAMIDIPHOS (100)

Acephate, a broad spectrum organophosphorus insecticide, has been evaluated many times by JMPR since 1976. It was reviewed for residues under the Periodic Re-evaluation Programme in 2003. The 2005 JMPR established an ADI of 0–0.03 mg/kg bw and an ARfD of 0.1 mg/kg bw to replace the previous recommendations.

The 2003 JMPR recommended the following residue definitions for acephate:

Definition of the residue for compliance with MRLs for plant and animal commodities: *acephate.*

Definition of residues for estimation of dietary intake for plant and animal commodities: *acephate and methamidophos.*

Acephate was included in the Priority List at the Forty-second Session of the CCPR in 2010 for the estimation of a maximum residue level for rice by the 2011 JMPR. Summary data were provided by the Government of People's Republic of China for estimation of an MRL for rice.

Plant metabolism

The 2003 JMPR reviewed plant metabolism studies on bean, cabbage and tomato seedlings, cotton and beans. No information was available on metabolism of acephate in rice. Taking into consideration information on metabolism of other plants and environmental fate in soil and water-sediment systems evaluated by the 2003 JMPR, the present Meeting considered that metabolism of acephate in rice would be similar to that in other plants.

Analytical methods

Analysis of acephate and methamidophos in rice involves extraction of ground husked rice with a mixture of acetonitrile and water (70:5), evaporation of the supernatant at 40 ˚C, dissolving the resulting dry matter in acetone, and quantitation of acephate and methamidophos using gas chromatography equipped with FPD. This method follows a similar approach to the methods reviewed by the 2003 JMPR.

The method was tested for recovery using husked rice, husk and straw as matrices resulting in acceptable recovery and RSD. The LOQ was 0.01–0.025 mg/kg for acephate and 0.01–0.05 mg/kg for methamidophos, depending on the participating laboratories.

Stability of pesticide residues in stored analytical samples

When spiked at 1 mg/kg, acephate and methamidophos in husked rice were stable for at least 360 days, the longest storage period tested, at -15 to -20 ˚C. About 85% of spiked acephate and 84% of spiked methamidophos remained after 360 days.

In the supervised residue trials, samples were analysed within one month of freezing.

Results of supervised trials on crops

The Meeting received information of supervised field trials of acephate on rice conducted in eight provinces in China in 2009.

The OECD MRL calculator was used as a tool to assist in the estimation of maximum residue levels from the selected residue data set obtained from the supervised residue trials. As a first step, the Meeting reviewed trial conditions and other relevant factors related to each data set to arrive at a best estimate of the maximum residue level using expert judgement. Then, the OECD calculator was employed. If the statistical calculation spreadsheet suggested a different value, a brief explanation of the derivation was supplied.

Rice

Residues of acephate and methamidophos arising from the use of acephate on rice were analysed in husked rice dried in two different ways from the applications of 2 similar formulations in the supervised trials.

The GAP in China allows the maximum of two applications at the maximum application rate of 1.01 kg ai/ha (30% EC) or 1.13 kg ai/ha (75% SP) with the PHI of 45 days.

Rice grains were harvested at their maturity and dried in two ways to reduce the moisture content to ≤ 13.5%. Immediately after the moisture content reached this level, rice grains were husked and the resulting husked rice was analysed. Husks from trials matching GAP were also analysed.

The residue concentrations in the trials conducted in Zhejiang Province were always significantly higher than those from trials conducted in other regions but this did not seem to be caused by analytical errors. The laboratory involved in the analysis of samples from the Zhejiang trials produced acceptable recoveries using the analytical method mentioned above. The Meeting agreed that there was no reason to disregard these values in the estimation of maximum residue levels.

As the Meeting considered trials in the same location with the same variety and timing, similar formulations and similar application rates not independent, the highest residue value of the four values in one location were selected and used for estimating a maximum residue level.

Residues of acephate selected as above were in rank order: < 0.025, 0.04, 0.04, 0.04, 0.07, 0.09, 0.10 and 0.69 mg/kg.

The Meeting estimated a maximum residue level at 1 mg/kg for acephate in husked rice.

The Meeting estimated a median residue at 0.055 mg/kg for acephate in husked rice for the purpose of calculating animal dietary burdens.

Residues of methamidophos selected as above were in rank order: 0.02, < 0.025, < 0.025, < 0.05, < 0.05, 0.05, 0.05 and 0.38 mg/kg.

The Meeting estimated a maximum residue level at 0.6 mg/kg for methamidophos in husked rice.

It also estimated a median residue at 0.025 mg/kg for methamidophos in husked rice for the purpose of calculating animal dietary burdens.

As the residue definition for estimation of dietary intake for plant and animal commodities was “acephate and methamidophos”, the combined adjusted residues of acephate and methamidophos were calculated after scaling the methamidophos residues to account for the difference in toxicity with the factors derived from the ratios of respective maximum ADI and ARfD values. These factors are 7.5 (maximum ADI of acephate and methamidophos, 0.03 and 0.004 mg/kg bw) and 10 (ARfD of acephate and methamidophos, 0.1 and 0.01 mg/kg bw) respectively for long-term and short-term intake estimates. The highest calculated value from each of eight locations was selected for estimating STMRs. For summing up, if acephate or methamidophos residues were below the LOQ, LOQ value of each was used.

For the estimation of long-term dietary intake, the calculated values of “acephate + 7.5 × methamidophos” were: 0.20, 0.21, 0.23, 0.40, 0.41, 0.45, 0.47 and 3.54 mg/kg. The Meeting estimated an STMR of 0.405 mg/kg for the estimation of long-term dietary intake.

For the estimation of short-term dietary intake, the calculated values of "acephate + 10 × methamidophos" were: 0.25, 0.28, 0.29, 0.53, 0.54, 0.56, 0.59 and 4.49 mg/kg. The Meeting estimated an STMR of 0.535 mg/kg for the estimation of short-term dietary intake.

Rice straw

Residues of acephate and methamidophos (arising from the use of acephate on rice) in straw from the application of 2 similar formulations in the supervised trials matching GAP were analysed.

Highest residues of acephate in each of the eight trial locations were in rank order: < 0.01, < 0.01, < 0.01, < 0.025, < 0.025, 0.08, 0.10 and 0.14 mg/kg.

The Meeting estimated a maximum residue level, highest residue and median residue at 0.3 mg/kg, 0.14 mg/kg and 0.025 mg/kg respectively for acephate in rice straw and fodder, dry.

Highest residues of methamidophos in each of the eight trial locations are in rank order: < 0.01, 0.01, < 0.025, < 0.025, 0.04, < 0.05, < 0.05 and 0.05 mg/kg.

The Meeting estimated a maximum residue level, highest residue and median residue at 0.1 mg/kg, 0.05 mg/kg, 0.0325 mg/kg respectively for methamidophos in rice straw and fodder, dry.

Fate of residues during processing

The Meeting received information on processing of husked rice to polished rice.

The mean processing factors were calculated for "acephate + (7.5 × methamidophos)" and "acephate + (10 × methamidophos)" to be 0.81 and 0.82 respectively.

STMR-Ps for polished rice were calculated using the STMRs of husked rice and these processing factors. An STMR for polished rice for long-term intake estimation was calculated to be 0.33 mg/kg. An STMR for polished rice for short-term intake estimation was calculated to be 0.44 mg/kg.

The mean processing factors were calculated for polished rice to be 0.63 and 0.85 respectively for acephate and methamidophos. An STMR of 0.021 mg/kg was calculated for methamidophos in polished rice.

No data were available to estimate processing factors or STMR-Ps for rice bran.

Residues in animal commodities

Farm animal dietary burden

Rice and/or its straw may be fed to dairy cattle, beef cattle, broilers and layers. The maximum and mean dietary burdens were calculated using the highest residue, STMR/STMR-P or median residue of acephate or methamidophos in commodities for which maximum residue levels were recommended and processed products thereof on a basis of the OECD Animal Feeding Table.

Resulting maximum and mean dietary burdens for beef and dairy cattle were smaller than those calculated for acephate in 2003 (2.2 and 1.1 ppm for maximum and mean dietary burden of beef cattle and dairy cattle respectively) because of the revision of the OECD Animal Feeding Table, or identical to those calculated for methamidophos.

Resulting maximum and mean dietary burdens for broilers and layers were larger than those calculated in 2003 (0.0067 ppm for the maximum and mean dietary burden of poultry for acephate and 0.0022 ppm for the maximum and mean dietary burden of poultry for methamidophos) but still much smaller than 3 ppm in diet dry matter, after feeding of which no residues above LOQ were found in any of edible tissues and eggs.

The Meeting concluded that there was no need to re-evaluate maximum residue levels, STMRs or HRs for commodities of animal origin.

Summary of livestock dietary burdens calculated (ppm of dry matter diet)

Acephate	US-Canada		EU		Australia		Japan	
	max	Mean	max	Mean	max	Mean	max	mean
Beef cattle	0.05	0.05	1.12	1.11	1.18[a]	1.11[b]	0.10	0.03
Dairy cattle	0.56	0.56	0.58	0.57	0.59[c]	0.57[d]	0.056	0.024
Broilers	0.02	0.02	0.04	0.04	0.05	0.05	0.01	0.01
Layers	0.02	0.02	0.02	0.02	0.05[e]	0.05[f]	0.01	0.01
Methamidophos	US-Canada		EU		Australia		Japan	
	max	Mean	max	Mean	Max	Mean	max	mean
Beef cattle	0.01	0.01	0.05	0.05	0.08[a]	0.07[b]	0.04	0.03
Dairy cattle	0.03	0.03	0.03	0.03	0.04[c]	0.04[d]	0.03	0.02
Broilers	0.01	0.01	0.01	0.01	0.02	0.02	0.01	0.01
Layers	0.01	0.01	0.01	0.01	0.02[e]	0.02[f]	0.01	0.01

[a] Suitable for estimating maximum residue levels for meat, fat and edible offal of cattle.

[b] Suitable for estimating STMRs for meat, fat and edible offal of cattle.

[c] Suitable for estimating maximum residue levels for milk of cattle.

[d] Suitable for estimating STMRs for milk of cattle.

[e] Suitable for estimating maximum residue levels for meat, fat and edible offal of poultry and eggs.

[f] Suitable for estimating STMRs for meat, fat and edible offal of poultry and eggs.

DIETARY RISK ASSESSMENT

Dietary intake estimates for the combined adjusted residues utilizing the scaling factors were compared with the maximum ADI and ARfD of acephate.

Long-term intake

The International Estimated Dietary Intakes (IEDIs) of acephate were calculated for the 13 GEMS/Food cluster diets using STMRs and STMRPs estimated by the 2003, 2006 and current Meeting (Annex 3). The ADI is 0–0.03 mg/kg bw and the calculated IEDIs were 2–10% of the maximum ADI. The Meeting concluded that the long-term intake of residues of acephate (and methamidophos arising from use of acephate) resulting from the uses of acephate considered by the 2003, 2006 and current JMPR is unlikely to present a public health concern.

Short-term intake

The International Estimated Short-Term Intakes (IESTI) of acephate (and methamidophos arising from use of acephate) were calculated for husked rice and polished rice using STMRs estimated by the current Meeting (Annex 4). The ARfD is 0.1 mg/kg bw and the calculated IESTIs were 3–4% of the ARfD. The Meeting concluded that the short-term intake of residues of acephate, when used in ways that have been considered by the current JMPR, is unlikely to present a public health concern.

5.2 ACETAMIPRID (246)

TOXICOLOGY

Acetamiprid is the International Organization for Standardization (ISO)–approved name for (*E*)-N^1-[(6-chloro-3-pyridyl)methyl]-N^2-cyano-N^1-methyl acetamidine (International Union of Pure and Applied Chemistry). Its Chemical Abstracts Service number is 135410-20-7. Acetamiprid is a neonicotinoid insecticide that is used for the control of sucking-type insects on leafy vegetables, fruiting vegetables, cole crops, citrus fruits, pome fruits, grapes, cotton and ornamental plants and flowers. Acetamiprid is being reviewed for the first time by the Joint FAO/WHO Meeting on Pesticide Residues at the request of the Codex Committee on Pesticide Residues.

All critical studies contained statements of compliance with good laboratory practice.

Biochemical aspects

Acetamiprid is rapidly absorbed, with a maximum concentration in blood being achieved in approximately 2–3 hours. The extent of absorption was more than 90% of the administered radioactivity. Acetamiprid is widely distributed in the tissues, with highest concentrations being found in the adrenal gland, liver and kidney following oral administration to the rat. The concentration of radioactivity in the brain was lower than the concentration in blood at all time points. No sex differences were observed. The major route of elimination was via urine (53–65%). The recovery of the radioactivity excreted in the bile was less than 20% of the administered dose, which suggests that the bile is not a major route of excretion. The disappearance of radioactivity from the body of the rat was rapid, and there was no indication of accumulation in any tissue. Less than 1% of the administered radioactivity remained in the tissues by day 4 following dosing. The major radioactive compounds in the excreta of rats were acetamiprid (~5–7%), the demethylated compound IM-2-1 (~15–20%), the nicotinic acid derivative IC-O (~8–11%) and the IC-O glycine conjugate IC-O-Gly (~10%). In addition, MeS-IC-O, IM-1-4, IM-2-4, IM-O, IM-1-3 and IM-2-3 were detected, each at less than 2% of the dose. There were several unknown compounds in the urine, with a maximum abundance of 1%. The main metabolic pathway of acetamiprid in rats is the transformation to IM-2-1 by demethylation. IM-2-1 is further metabolized to IC-O, with the release of IS-1-1 and IS-2-1 after cleavage from the side-chains of NI-25 (parent compound) and IM-2-1.

Toxicological data

In mice and rats, the oral median lethal dose (LD_{50}) was in the range of 140–417 mg/kg body weight (bw). Dose-related reversible toxic signs (crouching, tremor, convulsion and mydriasis) were observed. The dermal LD_{50} in rats was greater than 2000 mg/kg bw. When acetamiprid was administered by inhalation through nose-only exposure, the median lethal concentration (LC_{50}) was greater than 1.15 mg/L of air. Mydriasis in many rats and tremor and convulsion in a few rats were observed when acetamiprid was administered by the oral route, and these effects disappeared after 1 day. Acetamiprid was not an irritant in studies of ocular or dermal irritation in rabbits or a dermal sensitizer in the Magnusson and Kligman maximization test in guinea-pigs.

Short-term studies of oral toxicity in mice, rats and dogs were conducted using acetamiprid. These studies are characterized by similar toxic responses, such as decreased feed consumption and body weight.

In a 13-week study in mice, the no-observed-adverse-effect level (NOAEL) was 400 ppm (equal to 53.2 mg/kg bw per day), on the basis of a significant decrease in total cholesterol level in females at 800 ppm (equal to 106.1 mg/kg bw per day). Tremor, decreased body weight gain, decreased feed consumption, decreased haemoglobin concentration, decreased serum total cholesterol

and glucose levels, decreased urinary pH, increased liver to body weight ratio and centrilobular hypertrophy were observed at higher doses.

In a 90-day study of oral toxicity in rats, the NOAEL was 200 ppm (equal to 12.4 mg/kg bw per day), on the basis of decreased body weight gain, decreased feed consumption and increased serum total cholesterol levels at 800 ppm (equal to 50.8 mg/kg bw per day).

In three oral dog studies (4 weeks, 90 days and 1 year), initial body weight losses and decreased body weight gains were observed in males and females receiving the highest dietary concentrations of acetamiprid. In the 4-week study, the NOAEL was 22 mg/kg bw per day. However, an overall NOAEL for the other two oral dog studies was 800 ppm (equal to 32 mg/kg bw per day).

In an 18-month study of toxicity and carcinogenicity in mice, decreased feed consumption was observed in males and females at 1200 ppm. At 400 ppm in males, body weights were decreased, and the body weight gain was statistically significantly decreased compared with controls through 13 weeks of study. At the end of 18 months, mean relative liver weights were increased in males and females receiving 1200 ppm and also in females receiving 400 ppm. On microscopic examination, treatment-related hepatocellular hypertrophy was seen in male and female mice receiving 1200 ppm after 12 and 18 months of treatment. These microscopic findings are considered to be an adaptive response of the liver to exposure to acetamiprid. The NOAEL was 130 ppm (equal to 20.3 mg/kg bw per day), based on transient decreased body weight observed at 400 ppm (equal to 65.6 mg/kg bw per day) in males. There was no evidence of any carcinogenic effect in mice.

The 2-year study of toxicity and carcinogenicity in rats demonstrated an increased incidence of clinical signs, such as rales, hunched posture and laboured breathing, in the 400 and 1000 ppm dose groups. The body weights of the 1000 ppm males and females and the 400 ppm females (until week 100) were statistically significantly lower than those of controls during the study. Trace to mild centrilobular hepatocellular hypertrophy and vacuolation were seen at 400 ppm and above. Incidences of mammary gland adenocarcinomas and hyperplasias were increased in females at 1000 ppm (equal to 60 mg/kg bw per day); however, incidence levels were within normal limits for ageing Crl:CD rats, and therefore these lesions are considered to be unlikely to be due to an endocrine or carcinogen effect of acetamiprid. Because the observation of rales at 160 ppm was not correlated to the other clinical signs, such as laboured breathing, moribundity, hunched posture and decreased activity, the NOAEL in this study was 160 ppm (equal to 7.1 mg/kg bw per day), based on hepatocyte vacuolation at 400 ppm (equal to 17.5 mg/kg bw per day). Acetamiprid was not carcinogenic in rats.

Acetamiprid was tested for genotoxicity in an adequate range of assays, both in vitro and in vivo. No significant result is obtained in these tests, except for chromosomal aberration induction in vitro. In vivo, there was no confirmation of chromosomal aberration in a number of tests, and there was no evidence of induction of deoxyribonucleic acid (DNA) damage.

The Meeting concluded that acetamiprid is unlikely to be genotoxic in vivo.

In view of the lack of genotoxicity in vivo and the absence of carcinogenicity in rats and mice, the Meeting concluded that acetamiprid is unlikely to pose a carcinogenic risk to humans.

In a two-generation study in rats, the NOAEL for systemic parental toxicity was 100 ppm (equal to 6.67 mg/kg bw per day), on the basis of a decline in body weights and feed consumption and an increased incidence of hepatocellular hypertrophy and vacuolation at 280 ppm (equal to 18.9 mg/kg bw per day) and above. The NOAEL for offspring toxicity was 280 ppm (equal to 13.9 mg/kg bw per day), on the basis of decreases in body weight gain in both generations and reduced postnatal survival in the F_2 offspring at 800 ppm (equal to 38.7 mg/kg bw per day). However, there are no effects on reproduction with treatment up to 800 ppm (equal to 38.7 mg/kg bw per day), the highest dose tested.

In a study of developmental toxicity in rats, the NOAEL for maternal toxicity was 16 mg/kg bw per day, based on decreased feed consumption and body weight gain during the treatment period in maternal rats in the 50 mg/kg bw per day group at scheduled sacrifice. The developmental NOAEL

in rats was 16 mg/kg bw per day, based on the increased incidence of fetuses with shortening of the 13th rib at 50 mg/kg bw per day.

In a study of developmental toxicity in rabbits, the NOAEL for maternal toxicity was 15 mg/kg bw per day, based on decreased feed consumption and body weight gain during the treatment period at 30 mg/kg bw per day. The developmental NOAEL was 30 mg/kg bw per day, the highest dose tested.

The Meeting concluded that acetamiprid was not teratogenic in rats or rabbits.

In an acute oral neurotoxicity study, increased urination frequency and reduced locomotor activity were observed at doses of 30 mg/kg bw and above. Other clinical signs of neurotoxicity (e.g., hunching, tremors) were observed at higher doses. No apparent effects on sensory systems or evidence of neuropathology was seen. The NOAEL was 10 mg/kg bw, based on evidence of increased urination frequency (males) and a statistically significant reduction of locomotor activity (males) at 30 mg/kg bw.

A 13-week dietary neurotoxicity study in rats did not result in any changes that were considered indicative of neurotoxicity. The NOAEL was 200 ppm (equal to 14.8 mg/kg bw per day), on the basis of lower body weights and feed consumption at 800 ppm (equal to 59.7 mg/kg bw per day).

A developmental neurotoxicity study in rats revealed the NOAEL for maternal toxicity, developmental toxicity and developmental neurotoxicity to be 10 mg/kg bw per day, based on a reduction in body weight gain in dams during the first 3 days of dosing (gestation days 6–9), decreased feed consumption in F_0 animals, early postnatal mortality, reduced post-weaning body weights and deficits in auditory startle response without neuropathology or changes in brain morphometry in F_1 animals at 45 mg/kg bw per day.

Acetamiprid did not cause delayed neuropathy in hens.

Studies for immunotoxicity in mice (highest dose tested was 157 mg/kg bw per day) and rats (highest dose tested was 67.7 mg/kg bw per day) indicated no specific effect on immune function as assessed by the measurement of antigen-specific T cell–dependent antibody formation.

Toxicological data on impurities and metabolites

Acute toxicity studies and studies of genotoxicity have been undertaken for four compounds that are present as impurities in technical acetamiprid. None of them were genotoxic in a number of assays, and they had acute oral LD_{50} values in rats between 603 and greater than 5000 mg/kg bw. Nine compounds identified as plant metabolites are IM-1-3, IM-1-4, IM-2-1, IM-2-3, IM-2-4, IM-0, IC-0, IS-1-1 and IS-2-1. None were genotoxic in a number of assays, and they had acute oral LD_{50} values in rats between 900 and greater than 5000 mg/kg bw. The NOAEL following repeated exposure of rats to diets containing IM-1-4 for 13 weeks was 600 ppm (equal to 36.5 mg/kg bw per day), based on effects on spleen (increased pigments in splenic sinusoids) at 1800 ppm (112.2 mg/kg bw per day) in treated males. The NOAEL for IM-0 in a 13-week study in rats was 800 ppm (equal to 48.9 mg/kg bw per day), on the basis of eosinophilic intranuclear inclusions seen in proximal tubular epithelium of kidneys at 4000 ppm (250.1 mg/kg bw per day) in males. All the impurities and metabolites were of lesser toxicity than the parent (acetamiprid).

No adverse health effects or poisoning in manufacturing plant personnel or in operators and workers exposed to acetamiprid have been reported.

Three cases of intentional poisoning with acetamiprid formulation have been reported. In one case, the concentration of acetamiprid in blood was measured at the time of reporting for treatment. In all cases, some signs similar to those associated with acute organophosphate intoxication were reported. Supportive treatments for a variety of signs were sufficient for recovery, and all recovered within 24–48 hours of the initiation of treatment.

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

Toxicological evaluation

The Meeting established an acceptable daily intake (ADI) of 0–0.07 mg/kg bw on the basis of the NOAEL of 7.1 mg/kg bw per day from the 2-year study of toxicity and carcinogenicity in rats, based on clinical signs and hepatocyte vacuolation seen at 17.5 mg/kg bw per day. A safety factor of 100 was applied. This ADI was supported by the NOAEL of 6.67 mg/kg bw per day observed in a two-generation study of reproductive toxicity in rats on the basis of decreased parental body weight gain and feed consumption and hepatocyte vacuolation at 18.9 mg/kg bw per day.

The Meeting established an acute reference dose (ARfD) of 0.1 mg/kg bw on the basis of a NOAEL of 10 mg/kg bw in an acute neurotoxicity study in rats, based on evidence of neurotoxicity, decreased locomotor activity and increased urination frequency. This ARfD was supported by the NOAEL for maternal toxicity in the developmental neurotoxicity study of 10 mg/kg bw per day, based on reduced body weight gain in dams during the first 3 days of dosing (gestation days 6–9).

A toxicological monograph was prepared.

Levels relevant to risk assessment

Species	Study	Effect	NOAEL	LOAEL
Mouse	Eighteen-month study of toxicity and carcinogenicity [a]	Toxicity	130 ppm, equal to 20.3 mg/kg bw per day	400 ppm, equal to 65.6 mg/kg bw per day
		Carcinogenicity	1200 ppm, equal to 214.6 mg/kg bw per day [b]	—
Rat	Two-year study of toxicity and carcinogenicity[a]	Toxicity	160 ppm, equal to 7.1 mg/kg bw per day	400 ppm, equal to 17.5 mg/kg bw per day
		Carcinogenicity	1000 ppm, equal to 60 mg/kg bw per day[b]	—
	Two-generation study of reproductive toxicity[a]	Offspring toxicity	280 ppm, equal to 13.9 mg/kg bw per day	800 ppm, equal to 38.7 mg/kg bw per day
		Reproductive toxicity	800 ppm, equal to 38.7 mg/kg bw per day[b]	—
		Parental toxicity	100 ppm, equal to 6.67 mg/kg bw per day	280 ppm, equal to 18.9 mg/kg bw per day
	Developmental toxicity study[c]	Maternal toxicity	16 mg/kg bw per day	50 mg/kg bw per day
		Embryo and fetal toxicity	16 mg/kg bw per day	50 mg/kg bw per day
	Acute neurotoxicity study[c]	Acute neurotoxicity	10 mg/kg bw	30 mg/kg bw
	Developmental neurotoxicity study[c]	Developmental neurotoxicity	10 mg/kg bw per day	45 mg/kg bw per day
Rabbit	Developmental toxicity	Maternal toxicity	15 mg/kg bw per day	30 mg/kg bw per day

Species	Study	Effect	NOAEL	LOAEL
	study[c]	Embryo and fetal toxicity	30 mg/kg bw per day[b]	—
Dog	Ninety-day and 1-year studies of toxicity[a,d]	Toxicity	800 ppm, equal to 32 mg/kg bw per day	1500 ppm, equal to 55 mg/kg bw per day

[a] Dietary administration.

[b] Highest dose tested.

[c] Gavage administration.

[d] Two studies combined.

Estimate of acceptable daily intake for humans

0–0.07 mg/kg bw

Estimate of acute reference dose

0.1 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 acetamiprid

Absorption, distribution, excretion and metabolism in mammals	
Rate and extent of oral absorption	Rapid and almost completely absorbed (> 90%)
Distribution	Widely distributed; highest concentrations in adrenal, liver and kidney
Potential for accumulation	No evidence of accumulation
Rate and extent of excretion	Rapid, more than 90% within 96 h, mainly via urine
Metabolism in animals	Moderately metabolized; the major radioactive compounds in the excreta of rats were acetamiprid itself and IC-O glycine conjugate
Toxicologically significant compounds (animals, plants and the environment)	Acetamiprid (parent compound)
Acute toxicity	
Rat, LD_{50}, oral	140–417 mg/kg bw
Rat, LD_{50}, dermal	> 2000 mg/kg bw
Rat, LC_{50}, inhalation	> 0.30 mg/L (whole-body exposure) > 1.15 mg/L (nose-only exposure)
Rabbit, dermal irritation	Non-irritant
Rabbit, ocular irritation	Non-irritant
Guinea-pig, dermal sensitization (Magnusson and Kligman test)	Non-sensitizer

Short-term studies of toxicity	
Target/critical effect	Increased cholesterol, decreased body weight, decreased feed consumption
Lowest relevant oral NOAEL	53.2 mg/kg bw per day (13-week study in mice)
Genotoxicity	
	Not genotoxic in vivo
Long-term studies of toxicity and carcinogenicity	
Target/critical effect	Increased clinical signs; hepatic vacuolation
Lowest relevant NOAEL	7.1 mg/kg bw per day (rats)
Carcinogenicity	Not carcinogenic in rats or mice
Reproductive toxicity	
Reproduction target/critical effect	None
Lowest relevant reproductive NOAEL	38.7 mg/kg bw per day, highest dose tested
Developmental target/critical effect	Skeletal anomalies
Lowest relevant developmental NOAEL	16 mg/kg bw per day (rat)
Neurotoxicity/delayed neurotoxicity	
Acute neurotoxicity target/critical effect	Motor activity and increased frequency of urination
Lowest relevant acute neurotoxic NOAEL	10 mg/kg bw
Subchronic neurotoxicity target/critical effect	Not neurotoxic (rats)
Developmental neurotoxicity target/critical effect	Deficits in auditory startle response
Lowest relevant developmental neurotoxic NOAEL	10 mg/kg bw per day (rat)
Immunotoxicity	
28-day immunotoxicity	Not immunotoxic (mice and rats)
Medical data	
	No significant health effects were reported among manufacturing personnel; however, three cases of intentional poisoning have been reported with some signs similar to those of acute organophosphate poisoning

Summary

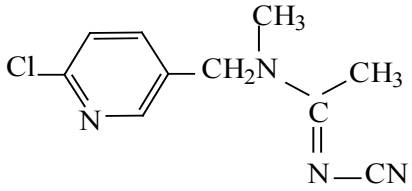
	Value	**Study**	**Safety factor**
ADI	0–0.07 mg/kg bw	Two-year rat study (supported by parental toxicity in the multigeneration rat reproduction study)	100
ARfD	0.1 mg/kg bw	Acute neurotoxicity, rat (supported by maternal toxicity in the developmental neurotoxicity rat study)	100

RESIDUE ND ANALYTICAL ASPECTS

Acetamiprid is a neonicotinoid insecticide with contact and stomach action against a range of *Hemiptera*, *Thysanoptera* and *Lepidoptera* plant pests, acting as an agonist of the nicotinic acetylcholine receptor in the insect central nervous system. It exhibits translaminar activity in plants and is authorised for use in North America, Europe and in a number of countries in Asia and the Pacific.

Residue and analytical aspects of acetamiprid were considered for the first time by the present meeting. The manufacturer submitted studies on metabolism, analytical methods, authorised uses, supervised field trials, the effects of processing, freezer storage stability, environmental fate in soil and rotational crop residues.

Acetamiprid, (*(E)*-N^1-[(6-chloro-3-pyridyl)methyl]-N^2-cyano-N^1-methylacetamidine) is partially soluble in water (3-4 g/litre), stable to hydrolysis and photolysis, has a log P_{OW} of 0.8 and is soluble in acetone, methanol, ethanol, dichloromethane, and acetonitrile.



The following abbreviations are used for the metabolites discussed below:

IM-1-2	N^2-carbamoyl-N^1- [(6-chloro-3-pyridyl)methyl]-N^1-methylacetamidine
IM-1-3	*N*-[(6-chloro-3-pyridyl)methyl]-*N*-methylacetamide
IM-1-4	*N*-methyl(6-chloro-3-pyridyl)methylamine
IM-2-1	N^1-[(6-chloro-3-pyridyl)methyl]-N^2-cyanoacetamidine
IM-2-2	N^2-carbamoyl-N^1- [(6-chloro-3-pyridyl)methyl]-acetamidine
IM-2-3	*N*-[(6-chloro-3-pyridyl)methyl]acetamide
IM-2-4	(6-chloro-3-pyridyl)methylamine
IM-2-5	*N*1-(6-Chloropyridin-3-ylmethyl)-acetamidine
IM-0	(6-chloro-3-pyridyl)methanol
IM-0-Glc	(6-chloro-3-pyridyl)methyl-β-D-glucopyranoside
IC-0	6-chloronicotinic acid

Animal metabolism

The Meeting received acetamiprid metabolism studies on animals (rats, lactating goats and laying hens) using ^{14}C-acetamiprid (labelled in the 2 and 6 positions of the pyrimidine ring).

In rats, acetamiprid is rapidly and almost completely absorbed and is widely distributed into the tissues, being found at highest concentrations in GI tract, adrenal gland, liver and kidney, following oral administration to the rat. The major route of elimination was via the urine and bile (relevant but not a major route in excreta). The disappearance of radioactivity from the body of the rat was rapid and there was no indication of accumulation in any tissue. Less than 1% of the administered radioactivity was left in the tissues by day four following dosing. The major radioactive compounds in the excreta of rats were acetamiprid (approx. 5–7%); the demethylated compound IM-2-

1(approximately 15–20%), the nicotinic acid derivative IC-O (approximately 8–11%) and the IC-O glycine conjugate IC-O-Gly (approximately 10%). In addition, MeS-IC-O, IM-1-4, IM-2-4, IM-O, IM-1-3 and IM-2-3 were detected, but they were less than 2% of dose. There were several unknown compounds in urine with a maximum abundance of 1%.

The main metabolic pathway of acetamiprid in rats is the transformation to IM-2-1 by demethylation which is further metabolized to IC-O with the release of IS-1-1 and IS-2-1 after the cleavage from the side chains of IN-25 and IM-2-1.

Lactating goats were orally dosed twice daily for 7 days with encapsulated [pyridine-2, 6-^{14}C]-acetamiprid at dietary equivalent levels of 1.0 ppm or 8.6 ppm per day. At the end of the 7-day dosing period, the goats were sacrificed 22 hours after the last administration.

Most of the administered radioactivity (AR) was excreted via urine or faeces (about 95–99% AR) and less than 1% AR in milk (reaching a plateau after about 3 days). In tissues, radioactivity did not exceed 1.6% AR and in milk, about 94–96% TRR was found in the whey with about 3–5% TRR occuring in milk fat and precipitated milk proteins.

The predominant residue in milk, liver and kidney was the IM-2-1 metabolite (70–89% TRR) and in muscle, the major residue was IM-2-2 (about 50% TRR), with the IM-2-3 and IM-2-4 metabolites also being found at 6% and 13% TRR respectively. Acetamiprid (parent) was only found in milk, at less than 10% TRR and < 0.005 mg/kg.

Laying hens (five hens per dose group) were dosed each morning for 14 days with [pyridine-2, 6-^{14}C]-acetamiprid at dietary equivalent levels of 1.1 ppm or 12.5 ppm. At the end of the 14-day dosing period, the hens were sacrificed about 24 hours after the last administration.

Most of the applied radioactivity was excreted or found in the cage wash (93–97% AR). Small amounts of radioactivity were detected in edible organs/tissues (0.7–0.8% AR) with about 1.3% AR found in eggs (reaching a plateau after about 8–11 days). In liver and skin, residues were about 0.1% AR and 0.3% AR in muscle.

The IM-2-1 metabolite was the predominant residue, at 83–86% TRR in egg white, about 60% TRR in egg yolk, 65–69% TRR in liver and 53–62% TRR in muscle and skin. The other metabolite found at more than 10% TRR was the IM-2-3 in muscle (17– 21% TRR). Metabolite IM-2-5 was the predominant residue in egg yolks (27% TRR) and IC-0 was found in skin at about 13% TRR. Acetamiprid (parent) was not found in any tissues or in eggs.

In summary, acetamiprid metabolism in animals is similar, with more than 95% of the residues being eliminated in excreta and less than 2% remaining in tissues or present in eggs or milk. Residues of the parent acetamiprid were not found (except at low levels in milk), and the predominant residue in most animal products was the IM-2-1 (53–89% TRR) with IM-2-2 occurring in goat muscle at about 50% TRR). The IM-2-4 and IM-2-3 metabolites were also found in muscle at 13–21% TRR, with the IM-2-5 metabolite being found at about 27% TRR in egg yolks.

The proposed metabolic breakdown of acetamiprid in both goats and hens involves degradation to IC-0 or demethylation to IM-2-1 with the IM-1-2 metabolite converting to the amide (IM-2-2) or IM-2-3 and the subsequent formation of the IM-2-4 and IM-2-5 metabolites.

Plant metabolism

The meeting received plant metabolism studies in apples, eggplant, cabbage, cotton and carrot following foliar applications of [pyridine-2, 6-^{14}C]-acetamiprid and an additional study with cabbages treated with [CN-^{14}C]-acetamiprid (both as a foliar application and a soil treatment).

In apple fruit, more than 98% of the radioactivity was recovered from the surface wash and extracts of fruit. Residues in surface washes decreased from more than 99% to about 12% TRR after 14 days and to about 6% TRR for fruit sampled 28 and 62 days after treatment. Residues in flesh increased to 48% TRR after 14 days and to about 78% TRR at the end of the 62-day study period.

Acetamiprid (parent) was the predominant residue, making up more than 79% TRR. Minor metabolites (IM-2-1 and IM-0-Glc) were found at maximum 3.7%TRR and 1.8%TRR, respectively.

For apple leaves, more than 98% of the radioactivity was recovered from the surface wash and extracts from leaves. Initial residues in surface washes decreased from 99% to about 43% TRR at the end of the 90-day study period and the residues in the leaf extracts increased to about 51% TRR (11.8 mg/kg eq). Translocated radioactivity in untreated leaves was less 0.04 mg/kg.

The majority of the radioactivity was the unchanged acetamiprid, making up 90% or more of the TRR in the first 14 days after treatment, declining to 49% TRR after 90 days. The main metabolite found above 5% TRR was the IM-2-1 metabolite, present at about 10% TRR after 62 days and about 16% TRR after 90 days. The only other metabolite present at more than 5% TRR was IM-0-Glc (max 8.3% TRR at day-90).

For eggplant, most of the radioactivity was found in the surface washes (79–75% TRR for leaves and 84–70% TRR for fruit), with 20–30% TRR present in the extracts from washed fruit and leaves. Translocated radioactivity was negligible. Acetamiprid was the major residue, making up about 85–89% TRR in leaves and 94–95% TRR in fruit. Of the three identified metabolites, IM-2-1 was present in fruit at 0.4% TRR and 1.8% TRR in leaves and the IM-0 metabolite and its glycoside were identified in leaves at 0.6% TRR and 4.6% TRR respectively.

For cabbages following foliar treatments with [pyridine-2, 6-^{14}C]-acetamiprid, surface residues decreased to 30-50% TRR in the 28 days after treatment and to about 12% at the end of the study period (day-63). Residues in the extracts from washed plants increased accordingly, from 15% TRR (day-0) to 83.5% TRR (day-63). Acetamiprid was the major residue component in leaves, found at about 67–91% TRR with residues of the IM-2-1 metabolite increasing over the study period to a maximum of about 7% TRR (day-63). No parent residues were measured in mature cabbage heads with the wrapper leaves removed, with the major residue being the IC-0 metabolite (about 46% TRR or 0.03 mg/kg).

In cabbages grown in soil treated with [pyridine-2, 6-^{14}C]-acetamiprid, radioactivity was readily translocated into leaves, reaching levels of about 2–3 × the root concentrations during the 28-day study period. Acetamiprid was also the only major residue in both leaves and roots, initially found at about 90% TRR (leaves) and 78% TRR (roots), decreasing to 60% TRR (leaves) and 50% TRR (roots) after 28 days. The IM-1-4 metabolite was the only other identified metabolite present at more than 5% TRR, being found in roots after 28 days.

An additional study on cabbages treated with a foliar application of [CN-^{14}C-acetamiprid] reported similar results. Surface residues decreased from an initial 86% TRR down to about 16% TRR after 63 days, with residues in the extracts from washed leaves increasing to about 78% TRR at the end of the study period. The major residue was the unchanged acetamiprid, making up more than 98% TRR (to day-7) and about 65% TRR by day-68.

For carrots treated twice with [pyridine-2, 6-^{14}C]-acetamiprid as foliar sprays, total radioactivity in carrots (including tops) at harvest was less than 0.1 mg/kg acetamiprid equivalents, mostly in the tops (0.44 mg/kg), with about 0.08 mg/kg in the roots. The main components found at harvest (2 weeks after the second treatment), in the carrot tops were IM-0-Glc (33% TRR), the parent acetamiprid (27% TRR) and IM-1-4 (15% TRR) with no other components exceeding 6% TRR. In the carrot roots the main components were acetamiprid (30-34% TRR and 0.03 mg/kg) and IC-0 (17–31% TRR and 0.02 mg/kg).

In cotton seed and gin trash from plants treated with four foliar applications of [pyridine-2, 6-^{14}C]-acetamiprid at 7 day intervals, the parent compound was the major residue identified in gin trash, found at 50% TRR (1.4 mg/kg) in the 14-day PHI samples and at 45% TRR (0.71 mg/kg) in the 28-day PHI samples.. The IC-0 metabolite was the predominant residue in cotton seed, found in the 14-day PHI samples at 46% TRR (0.69 mg/kg), decreasing to 24% TRR (0.27 mg/kg) in the 28-day samples.

In summary, the predominant residue in plant part exposed to foliar treatments is the parent compound, with low levels of the IM-2-1 metabolite being a common component in the plants studied, but generally at levels of 10% TRR or less. Acetamiprid is also the predominant residue in cabbage and carrot roots following soil treatments. The other significant metabolite found in plant parts not directly treated was the IC-0 cleavage product, found in cabbage heads (0.03 mg/kg), carrot roots (0.04 mg/kg) and cotton seed (up to 0.69 mg/kg).

The proposed metabolic breakdown of acetamiprid in plants following foliar application involves demethylation to IM-2-1 and further degradation to IC-0-Glc, or conversion of the parent compound to IM-0, with subsequent conjugation with glucose to form the IM-0-Glc. Degradation can also involve formation of the IM-1-2 metabolite which rapidly degrades to IM-1-3 and either IM-2-3 or IM-1-4, both of which degrade to IC-0.

Environmental fate

The Meeting received information the environmental metabolism and behaviour of acetamiprid in soil and rotational crops.

The estimated aerobic soil metabolism half-life for acetamiprid at 25 °C was about 8.2 days with a significant amount of $^{14}CO_2$ (up to about 19% of the applied dose) being measured during the study. The metabolite IM-1-4 was a major component of the radioactive residue, increasing to about 73% after 120 days and slowly decreasing thereafter. Two minor metabolites, IM-1-3 and IC-0 were also identified but at less than 5% of the applied dose during the study.

In three soils treated with the equivalent of 0.1 kg ai/ha [^{14}C-2, 6-pyridine]-acetamiprid and incubated in the dark for intervals up to 6 months, acetamiprid residues degraded rapidly, with estimated aerobic soil metabolism half-lives of about 1–8 days. The IM-1-4 metabolite was the major residue in soil, present at about 54–72% AR after 6 months.

Residues in succeeding crops

In rotational crop metabolism studies involving radish, lettuce, sorghum and wheat grown in a sandy loam soil treated (bare ground) with [pyridine-2, 6-^{14}C]-acetamiprid and aged for various intervals (up to 1 year), radioactive residues in samples from all plant-back intervals were less than 0.1 mg/kg parent equivalents except sorghum fodder from the 60-day plant-back interval (0.115 mg/kg). Acetamiprid was not found in any of the matrices and all metabolites were present at less than 0.05 mg/kg in any matrix at any rotation, the highest being IM-1-4 at 0.04 mg/kg in the first plant-back sorghum forage.

The Meeting agreed that residues of acetamiprid would not be expected in rotational crops.

Analytical methods

Several analytical methods have been reported for the analysis of acetamiprid and its IM-2-1 (desmethyl) metabolite in animal and plant matrices. The principle of most methods involves extraction steps using methanol or acetonitrile, liquid/liquid partition (commonly hexane) and further extraction into methylene chloride, column chromatographic clean-up (silica gel, Florisil and C18) and analysis by HPLC (animal and plant matrices) or by GC/ECD or LC-MS/MS (plant matrices).

The methods have been validated for plant and animal matrices with LOQs of 0.05 mg/kg for citrus commodities, liver and kidney and 0.01 mg/kg for other plant and animal commodities.

Based on the results of validation studies and the concurrent recovery rates achieved in the supervised field trials, the available analytical methods are considered suitable for determining residues of acetamiprid and its IM-2-1 metabolite.

Based on an investigation with orange as a test matrix, the US-FDA PAM 1 multi-residue method was shown to be unsuitable for measuring acetamiprid residues in plant commodities.

The multi-residue QuEChERS method using GCMS and/or liquid chromatography coupled with tandem mass spectrum detection (LC-MS/MS) was validated at the LOQ of 0.01 mg/kg for determining acetamiprid residues in dry, high water, acid, oily and high sugar content matrices and in animal matrices.

Stability of pesticide residues in stored analytical samples

Residue stability in stored analytical samples was investigated for a range of representative substrates covering those with a high water content (apple, cabbage, cucumber, grape, lettuce, tomato) a high starch content (potato), a high oil content (cotton seed) and a high acid content (orange) and their processed fractions, stored at ambient temperatures and at freezer temperatures.

In samples fortified with acetamiprid at levels of 0.5 mg/kg or 0.1 mg/kg and stored at either at room temperature for up to 7 days or frozen for up to 12 months (16 months for lettuce and 8 months for potatoes), residues were stable in all samples at the end of the storage periods, both at ambient temperature and under freezer conditions.

In the supervised field trials, frozen storage intervals between sampling and analysis were less than the storage periods in these stability studies, except for one citrus trial (15 months), two tomato trials (13–14 months) and three celery trials (17 months). The Meeting considered that any residue degradation during these extended storage intervals would be negligible.

Definition of the residue

In livestock metabolism studies (goats, hens), residues of the parent acetamiprid were not found (except at low levels in milk), and the predominant residue in most animal products was the IM-2-1 (53–89% TRR). The IM-2-2 metabolite was the predominant residue (about 50% TRR) in goat muscle, with the IM-2-4 metabolite also present at about 13% TRR. The IM-2-5 metabolite was the predominant residue in eggs (9% TRR). Residues in fat were too low to be characterised.

For MRL compliance, the IM-2-1 metabolite is the predominant residue in milk, liver, kidney poultry muscle and skin and eggs, and is a major residue component in goat muscle. Based on the significance of this metabolite in all animal matrices and because the parent compound was only found in milk (and then only at low levels), the Meeting considered the use of the IM-2-1 metabolite as a marker residue for MRL compliance.

For dietary intake risk assessment, in addition to the IM-2-1 metabolite, other significant residue components above 10% TRR are IM-2-2 (the amide of IM-2-1, found only in goat muscle at up to 0.03 mg/kg), the IM-2-5 metabolite (the imide of IM-2-1, found only in egg yolk at up to 0.24 mg/kg) and the cleavage product IM-2-4, found only in goat muscle at up to 0.008 mg/kg.

Noting that these three metabolites were not found in any other edible animal products; that current analytical methods did not exist to measure these compounds and that at the low levels expected, they are not likely to contribute significantly to the dietary exposure, the Meeting agreed that these metabolites need not be included in the residue definition for dietary risk assessment.

The Meeting recommended that for animal commodities, the residue definition for both dietary intake assessment and MRL compliance should be the sum of acetamiprid and its IM-2-1 metabolite, expressed as acetamiprid.

Based on the results of the cattle feeding study, where residues in muscle and fat were of the same order, and considering the ratio of radioactive residues in milk whey and milk fat/proteins (95:4) in the lactating goat metabolism study, the Meeting agreed that acetamiprid is not fat soluble. The log K_{ow} of acetamiprid (log K_{ow} 0.8) supports this conclusion.

In plants, the metabolism of acetamiprid has been studied in vegetables (cabbage, eggplant, carrots), in fruit (apples) and cotton. In all crops studied, the parent compound is the major residue component following foliar applications, initially as a surface residue and subsequently being taken up into the treated leaf or fruit, with little further translocation. The only significant metabolite identified in the studies was the desmethyl metabolite (IM-2-1), found at less than 10% TRR in edible crop parts.

The other metabolite found in edible plant parts not directly treated (e.g., carrot roots, cabbage heads, cotton seed) was the IC-0 cleavage product, present in carrot roots at 26% TRR and being the predominant residue in cabbage heads and cotton seed (24-46% TRR). This metabolite (6-chloronicotinic acid) was found in significant quantities (24–28 % TRR) in rat metabolism and with an oral LD_{50} > 5000, of is of lower acute toxicity than the parent compound and does not exhibit any genotoxic potential. The Meeting noted that IC-0 is also a metabolite of other neonicotinoids and agreed it should be excluded from the residue definition.

The Meeting recommended that for MRL-compliance and dietary intake risk assessment, the residue definition for plant commodities should be acetamiprid.

Definition of the residue for plant commodities (for compliance with the MRL and estimation of dietary intake): *acetamiprid*

Definition of the residue for animal commodities (for compliance with the MRL and estimation of dietary intake): *acetamiprid and N-desmethyl-acetamiprid, expressed as acetamiprid*

The residue is not fat soluble

Results of supervised trials on crops

The Meeting received supervised trial data for foliar applications of acetamiprid (SP and WP formulations) on a range of fruit, nut, vegetable and cotton crops, conducted mainly in Europe and North America.

The OECD MRL calculator was used as a tool to assist in the estimation of maximum residue levels from the selected residue data set obtained from the supervised residue trials. As a first step, the Meeting reviewed all relevant factors related to each data set in arriving at a best estimate of the maximum residue level using expert judgement. Then the OECD calculator was employed. If the statistical calculation spreadsheet suggested a different value from that recommended by the Meeting, a brief explanation of the deviation was supplied.

Citrus fruits

Residue data were provided to the Meeting from trials in Italy and Spain on lemons, mandarins and oranges involving 2–3 applications of 0.01 kg ai/hL.

GAP for citrus fruits in Spain is for foliar applications of up to 0.01 kg ai/hL and a PHI of 14 days, with a maximum of two applications/season.

In citrus trials from Italy and Spain matching this Spanish GAP, acetamiprid residues in lemons were : 0.09, 0.15 and 0.45 mg/kg.

In mandarins, residues were: 0.14, 0.17, 0.19, 0.25, 0.25, 0.26 and 0.44 mg/kg. The Meeting noted that in 2 of the Spanish trials (in bold), the 1st of 3 applications was applied more than 100 days before harvest and agreed to include these results because the contribution from these initial sprays would be negligible.

In oranges, residues were: 0.09, 0.1, 0.12, 0.22, 0.28, 0.28, 0.39 and 0.4 mg/kg.

The Meeting noted that these data sets were similar and agreed to combine them to estimate a group maximum residue level, STMR and HR for citrus fruit.

The combined data set from trials on lemons, oranges and mandarins (whole fruit) matching the GAP in Spain for citrus fruits is: 0.09, 0.09, 0.1, 0.12, 0.14, 0.15, 0.17, 0.19, 0.22, 0.25, 0.25, 0.26, 0.28, 0.28, 0.39, 0.4, 0.44 and 0.45 mg/kg (n = 18)

The Meeting estimated an STMR of 0.25 mg/kg, an HR of 0.45 mg/kg and recommended a maximum residue level of 0.8 mg/kg for acetamiprid in citrus fruit.

Pome fruits

Residue data were provided to the Meeting from trials in the USA on apples and pears. GAP for pome fruit in USA is for a maximum of four foliar applications of up to 0.168 kg ai/ha and a PHI of 7 days.

In trials on apples from the USA matching this GAP, acetamiprid residues were: 0.12, 0.12, 0.14, 0.14, 0.16, 0.18, 0.19, 0.22, 0.23, 0.25, 0.25, 0.26, 0.27, 0.28, 0.31, 0.55 and 0.59 mg/kg.

In trials on pears from USA matching this GAP, acetamiprid residues were: 0.09, 0.09, 0.15, 0.17, 0.2, 0.25, 0.31, 0.32 and 0.32 mg/kg.

The Meeting noted that these data sets were from similar populations and agreed combine them to estimate a group maximum residue level, STMR and HR for pip fruit. The combined data set for apples and pears is: 0.09, 0.09, 0.12, 0.12, 0.14, 0.14, 0.15, 0.16, 0.17, 0.18, 0.19, 0.2, 0.22, 0.23, 0.25, 0.25, 0.25, 0.26, 0.27, 0.28, 0.31, 0.31, 0.32, 0.32, 0.55 and 0.59 mg/kg (n = 26).

The Meeting estimated an STMR of 0.225 mg/kg, an HR of 0.59 mg/kg and recommended a maximum residue level of 0.8 mg/kg for acetamiprid in pome fruits.

Stone fruits

Residue data were provided to the Meeting from trials in USA on cherries, peaches and plums. GAP in USA for stone fruits is for a maximum of four foliar applications of up to 0.168 kg ai/ha and a PHI of 7 days.

In trials on cherries from the USA matching this GAP, acetamiprid residues (in fruit without stones) were: 0.1, 0.29, 0.36, 0.42, 0.48, 0.54, 0.68 and 0.88 mg/kg (n = 8).

The Meeting estimated an STMR of 0.45 mg/kg, an HR of 0.88 mg/kg and recommended a maximum residue level of 1.5 mg/kg for acetamiprid in cherries.

In trials on peaches from the USA matching this GAP, acetamiprid residues (in fruit without stones) were: 0.11, 0.16, 0.18, 0.19, 0.2, 0.2, 0.22, 0.23, 0.34 and 0.44 mg/kg (n = 10).

The Meeting estimated an STMR of 0.2 mg/kg, an HR of 0.44 mg/kg and recommended a maximum residue level of 0.7 mg/kg for acetamiprid for peaches and agreed to extrapolate these recommendations to nectarines.

In trials on plums from the USA matching this GAP, acetamiprid residues (in fruit without stones) were: 0.01, 0.02, 0.04, 0.04, 0.06 and 0.11 mg/kg (n = 6).

The Meeting estimated an STMR of 0.04 mg/kg, an HR of 0.11 mg/kg and recommended a maximum residue level of 0.2 mg/kg for acetamiprid in plums (including prunes).

Berries and other small fruits

Residue data were provided to the Meeting from trials in USA and Canada on grapes, strawberries, blackberries, boysenberries and raspberries.

GAP in USA for grapes and small vine fruits is for a maximum of two foliar applications of up to 0.112 kg ai/ha and a PHI of 3 days.

In trials on grapes from USA matching this GAP, acetamiprid residues in grape bunches were: 0.01, 0.03, 0.04, 0.04, 0.05, 0.06, 0.07, 0.08, 0.08, 0.09, 0.11, 0.13, 0.15, 0.16, 0.20, 0.22, 0.23 and 0.25 mg/kg (n = 18).

The Meeting estimated an STMR of 0.085 mg/kg, an HR of 0.25 mg/kg and recommended a maximum residue level of 0.5 mg/kg for acetamiprid in grapes.

GAP in USA for bush and caneberries (including strawberries and low-bush blueberries) is for a maximum of two foliar applications of up to 0.146 kg ai/ha and a PHI of 1 day.

In trials on strawberries from Canada and the USA matching this GAP, acetamiprid residues in fruit (without sepals) were: 0.03, 0.04, 0.05, 0.06, 0.09, 0.11, 0.12, 0.24, 0.24 and 0.24 mg/kg (n = 10).

The Meeting estimated an STMR of 0.1 mg/kg, an HR of 0.24 mg/kg and recommended a maximum residue level of 0.5 mg/kg for acetamiprid in strawberries.

GAP in USA for bush berries (including low-bush and high-bush blueberries) and cane berries (including blackberries, raspberries and cultivars/hybrids) is for a maximum of five foliar applications of up to 0.112 kg ai/ha and a PHI of 1 day.

In trials on blueberries from USA matching this GAP for bush berries, residues in fruit were: 0.09, 0.2, 0.25, 0.48, 0.49 and 0.62 mg/kg (n = 6).

In trials on blackberries, raspberries and boysenberries from USA matching this GAP for cane berries, residues in fruit were: 0.53, 0.56, 0.64, 0.78 and 1.0 mg/kg (n = 5).

The Meeting agreed to use the data for blackberries, raspberries and boysenberries to propose a group maximum residue level for berries and other small fruit (except grapes and strawberries)

The Meeting estimated an STMR of 0.64 mg/kg, an HR of 1.0 mg/kg and recommended a maximum residue level of 2 mg/kg for acetamiprid in berries and other small fruit except grapes and strawberries

Bulb vegetables

Residue data were provided to the Meeting from trials in USA and Canada on bulb onions and spring onions.

GAP in USA for bulb vegetables (including onions and spring onions) is for a maximum of four foliar applications of up to 0.168 kg ai/ha and a PHI of 7 days.

In trials on onions from USA matching this GAP, acetamiprid residues in onion bulbs were: < 0.01, < 0.01, < 0.01, < 0.01, < 0.01 and 0.01 mg/kg (n = 6).

The Meeting estimated an STMR of 0.01 mg/kg, an HR of 0.01 mg/kg and recommended a maximum residue level of 0.02 mg/kg for acetamiprid for bulb onions and agreed to extrapolate these recommendations to garlic.

The OECD Calculator proposed a maximum residue level of 0.015 mg/kg but as one of the replicate analytical samples contained 0.018 mg/kg, the Meeting recommended a higher level of 0.02 mg/kg.

In trials on spring onions from USA matching this GAP, residues were: 0.05, 0.38 and 2 mg/kg.

The Meeting estimated an STMR of 0.38 mg/kg, an HR of 2 mg/kg and recommended a maximum residue level of 5 mg/kg for acetamiprid in spring onions.

Brassica vegetables

Residue data were provided to the Meeting from trials in USA on broccoli and head cabbage.

GAP in USA for cole crops (including broccoli and head cabbage) is for a maximum of five foliar applications of up to 0.084 kg ai/ha and a PHI of 7 days.

In trials on broccoli from USA matching this GAP, acetamiprid residues in broccoli were: 0.01, 0.01, 0.02, 0.02, 0.02, 0.03, 0.05, 0.09 and 0.22 mg/kg (n = 9).

The Meeting agreed to extrapolate these results to other flower-head brassicas and estimated an STMR of 0.02 mg/kg, an HR of 0.22 mg/kg and recommended a group maximum residue level of 0.4 mg/kg for acetamiprid in flower-head brassicas.

In trials on head cabbage from USA matching this GAP, acetamiprid residues in cabbage heads (with wrapper leaves) were: 0.03, 0.03, 0.06, 0.07, 0.07, 0.11, 0.11, 0.11, 0.13 and 0.5 mg/kg (n = 10).

The Meeting recommended a maximum residue level of 0.7 mg/kg for acetamiprid in head cabbages and for use in calculating the animal dietary burden, estimated a median residue of 0.09 mg/kg, and a highest residue of 0.5 mg/kg.

In the same trials on head cabbage from the USA matching the USA GAP, acetamiprid residues in cabbage heads without wrapper leaves were: < 0.01, < 0.01, < 0.01, 0.01, 0.02, 0.02, 0.02, 0.03, 0.03 and 0.05 mg/kg (n = 10)

The Meeting estimated an STMR of 0.02 mg/kg and an HR of 0.05 mg/kg for acetamiprid in head cabbages (for dietary intake risk assessment).

Fruiting vegetables, Cucurbits

Residue data were provided to the Meeting from trials in USA on cucumber, summer squash and melons.

GAP in USA for cucurbits is for a maximum of five foliar applications of up to 0.112 kg ai/ha and a PHI of 0 days.

In trials on cucumbers from USA matching this GAP, acetamiprid residues were: 0.02, 0.02, 0.03, 0.03, 0.04 and 0.09 mg/kg.

In trials on summer squash from USA matching this GAP, acetamiprid residues were: 0.05, 0.06, 0.06, 0.09 and 0.11 mg/kg.

In trials on melons from USA matching this GAP, acetamiprid residues were: 0.02, 0.02, 0.04, 0.06, 0.08 and 0.1 mg/kg.

The Meeting noted that these data sets for cucumbers and summer squash (representing cucurbits with edible peel) and melons (representing cucurbits with inedible peel) were similar and agreed to combine them to recommend a group maximum residue level, STMR and HR for cucurbits.

The combined data set for cucumbers, summer squash and melons is: 0.02, 0.02, 0.02, 0.02, 0.03, 0.03, 0.04, 0.04, 0.05, 0.06, 0.06, 0.06, 0.08, 0.09, 0.09, 0.1 and 0.11 mg/kg (n = 17).

The Meeting estimated an STMR of 0.05 mg/kg, an HR of 0.11 mg/kg and recommended a maximum residue level of 0.2 mg/kg for acetamiprid in fruiting vegetables, cucurbits.

Fruiting vegetables, other than Cucurbits

Residue data were provided to the Meeting from trials in USA on tomatoes, sweet peppers and chili peppers.

GAP in USA for fruiting vegetables (including tomatoes and peppers) is for a maximum of four foliar applications of up to 0.084 kg ai/ha and a PHI of 7 days. A GAP also exists in USA for indoor tomatoes, applying acetamiprid as a single soil application through drip irrigation systems, using up to 0.084 kg ai/ha (3.4 g ai/1000 plants) and with a PHI of 1 day.

In trials on field tomatoes from USA matching this foliar application GAP, acetamiprid residues in tomatoes were: < 0.01, < 0.01, < 0.01, 0.01, 0.01, 0.02, 0.03, 0.03, 0.03, 0.03, 0.04, 0.04, 0.04, 0.06, 0.06, 0.08, 0.09 and 0.1 mg/kg.

In trials on indoor tomatoes from USA matching the US drip irrigation GAP, acetamiprid residues in tomatoes were: < 0.01, 0.04 and 0.05 mg/kg.

In trials on sweet peppers from USA matching this foliar application GAP, acetamiprid residues were: 0.01, 0.02, 0.03, 0.03, 0.04, 0.06, 0.07 and 0.09 mg/kg.

In trials on chili peppers from USA matching this foliar application GAP, acetamiprid residues were: 0.06, 0.08 and 0.14 mg/kg.

The Meeting noted that the data sets from foliar applications to field tomatoes, sweet peppers and chili peppers were similar and agreed combine them to estimate a group maximum residue level, STMR and HR for fruiting vegetables other than Cucurbits.

The combined data set for tomatoes, sweet peppers and chili peppers is: < 0.01, < 0.01, < 0.01, 0.01, 0.01, 0.01, 0.02, 0.02, 0.03, 0.03, 0.03, 0.03, 0.03, 0.03, 0.04, 0.04, 0.04, 0.04, 0.06, 0.06, 0.06, 0.06, 0.07, 0.08, 0.08, 0.09, 0.09, 0.1 and 0.14 mg/kg (n = 29).

The Meeting estimated an STMR of 0.04 mg/kg, an HR of 0.14 mg/kg and recommended a maximum residue level of 0.2 mg/kg for acetamiprid in fruiting vegetables, other than cucurbits (except sweet corn and mushrooms).

For dried chili peppers, using the combined data set for the fruiting vegetables (except cucurbits) and a dehydration factor of 10, the Meeting estimated an STMR of 0.4 mg/kg, an HR of 1.4 mg/kg and recommended a maximum residue level of 2 mg/kg for acetamiprid in dried chili peppers.

Leafy vegetables

Residue data were provided to the Meeting from trials in USA on head and leaf lettuce, spinach and mustard greens and from trials in Europe on field lettuce and protected lettuce.

GAP in Italy, France and Spain for leafy vegetables (or lettuce and other similar salad vegetables) is for a maximum of two foliar applications of up to 0.05 kg ai/ha and a PHI of 7 days (or 3 days for indoor crops in Italy).

In trials on field lettuce from France, Spain and Italy matching this GAP, acetamiprid residues in lettuce were: 0.04, 0.06, 0.06, 0.1, 0.11, 0.14 and 0.17 mg/kg.

In trials on field lettuce from France, Germany and UK matching this GAP, acetamiprid residues in lettuce were: 0.08, 0.14, 0.15, 0.16, 0.24, 0.25, 0.28 and 0.31 mg/kg.

In trials on protected lettuce from France, Germany, Italy and UK matching the Italian GAP (2 × 0.05 kg ai/ha, PHI 3 days), residues in lettuce were: 0.33, 0.33, 0.41, 0.5, 0.78, 0.88, 0.88 and 1.9 mg/kg (n = 8).

GAP in USA for leafy vegetables is for a maximum of five foliar applications of up to 0.084 kg ai/ha and a PHI of 7 days.

In trials on field grown head lettuce from USA matching this GAP, acetamiprid residues in head lettuce (with wrapper leaves) were: 0.06, 0.14, 0.26, 0.28, 0.38, 0.42, 0.65 and 0.68 mg/kg.

In trials on field grown leaf lettuce from USA matching this GAP, acetamiprid residues in leaf lettuce were: 0.11, 0.12, 0.3, 0.41, 0.46, 0.61, 0.87 and 0.96 mg/kg.

In trials on spinach from USA matching this GAP, acetamiprid residues were: 0.03, 0.04, 0.21, 0.46, 0.55, 1.1, 2.1 and 2.5 mg/kg (n = 8).

In trials on mustard greens from USA matching this GAP, acetamiprid residues were: 0.11, 0.18, 0.19, 0.3, 0.43, 0.49, 0.68, 0.74 and 1.1 mg/kg.

The Meeting noted that the data sets for head lettuce, leaf lettuce, spinach and mustard greens matching the USA GAP were similar and considered estimating a group maximum residue level, STMR and HR for leafy vegetables based on the spinach data.

However, noting that for spinach the proposed maximum residue level would result in an IESTI that exceeded the ARfD by 180%, the Meeting agreed to estimate a group maximum residue level for leafy vegetables except spinach, based on the data for indoor lettuce matching the Italian GAP.

The Meeting estimated an STMR of 0.64 mg/kg, an HR of 1.9 mg/kg and recommended a maximum residue level of 3 mg/kg for acetamiprid in leafy vegetables except spinach.

For spinach, the Meeting proposed a maximum residue level of 5 mg/kg and estimated an STMR of 0.51 mg/kg and an HR of 2.5 mg/kg, noting that this would result in an exceedance of the ARfD and that an alternative GAP for spinach could not be identified.

Legume vegetables

Residue data were provided to the Meeting from trials in USA on beans and peas (with and without pods).

GAP in USA for legume vegetables is for a maximum of three foliar applications of up to 0.112 kg ai/ha and a PHI of 7 days.

In trials on beans from USA matching this GAP, acetamiprid residues in beans (without pods) were: 0.02, 0.03, 0.04, 0.08, 0.11 and 0.18 mg/kg.

In trials on peas from USA matching this GAP, acetamiprid residues in peas (without pods) were: < 0.01, 0.01, 0.02, 0.02, 0.03, 0.03 mg/kg.

The Meeting estimated an STMR of 0.03 mg/kg, an HR of 0.18 mg/kg and recommended a maximum residue level of 0.3 mg/kg for acetamiprid in peas, shelled and for beans, shelled.

In trials on beans from USA matching the USA GAP for legume vegetables (3× 0.112 kg ai/ha, PHI 7 days), acetamiprid residues in beans (with pods) were: < 0.01, < 0.01, < 0.01, < 0.01, 0.02 and 0.18 mg/kg.

The Meeting estimated an STMR of 0.01 mg/kg, an HR of 0.18 mg/kg and recommended a maximum residue level of 0.4 mg/kg for acetamiprid in beans, except broad bean and soya bean.

In trials on peas in USA matching this GAP, acetamiprid residues in peas (with pods) were: 0.08, 0.13 and 0.27 mg/kg.

The Meeting agreed the data were not sufficient to recommend a maximum residue level for acetamiprid in peas (with pods).

Stalk and stem vegetables

Residue data were provided to the Meeting from trials in USA on celery.

GAP in USA for leafy vegetables (including celery) is for a maximum of five foliar applications of up to 0.084 kg ai/ha and a PHI of 7 days.

In trials on celery from USA matching this GAP, acetamiprid residues in celery stalks and leaves were: 0.08, 0.17, 0.27, 0.27, 0.32, 0.41, 0.51 and 0.78 mg/kg (n = 8).

The Meeting estimated an STMR of 0.3 mg/kg, an HR of 0.78 mg/kg and recommended a maximum residue level of 1.5 mg/kg for acetamiprid in celery.

Tree nuts

Residue data were provided to the Meeting from trials in USA on almonds and pecans.

GAP in USA for tree nuts (including almonds and pecans) is for a maximum of four foliar applications of up to 0.2 kg ai/ha and a PHI of 14 days.

In trials on almonds in USA matching this GAP, acetamiprid residues in nut meat were: < 0.01, < 0.01, < 0.01, 0.01, 0.01 and 0.02 mg/kg.

In trials on pecans in USA matching this GAP, acetamiprid residues in nut meat were: < 0.01, < 0.01, < 0.01, < 0.01, 0.01 and 0.05 mg/kg.

The Meeting noted that these data sets for almonds and pecans were similar and agreed to combine them to support a group maximum residue level. The combined data set is: < 0.01, < 0.01, < 0.01, < 0.01, < 0.01, < 0.01, < 0.01, 0.01, 0.01, 0.01, 0.02 and 0.05 (n = 12).

The Meeting estimated an STMR of 0.01 mg/kg, an HR of 0.05 mg/kg and recommended a maximum residue level of 0.06 mg/kg for acetamiprid in tree nuts.

Oil seeds

Residue data were provided to the Meeting from trials in USA on cotton.

GAP in USA for cotton is for a maximum of four foliar applications of up to 0.112 kg ai/ha and a PHI of 28 days.

In trials on cotton in USA matching this GAP, acetamiprid residues in cotton seed were: < 0.01, 0.02, 0.02, 0.03, 0.05, 0.06, 0.09, 0.09, 0.1, 0.1, 0.12, 0.14, 0.36 and 0.5 mg/kg (n = 14).

The Meeting estimated an STMR of 0.09 mg/kg and recommended a maximum residue level of 0.7 mg/kg for acetamiprid in cotton seed.

Animal feeds

Almond hulls

In trials on almonds in USA matching the USA GAP, acetamiprid residues in almond hulls (as received) were: 0.22, 0.78, 0.78, 1.9, 2.0 and 3.8 mg/kg.

The Meeting estimated a median residue of 1.34 mg/kg for almond hulls.

Cotton gin trash

In trials on cotton in USA matching this GAP, acetamiprid residues in cotton gin trash were: 0.39, 1.5, 1.9, 1.9, 2.7, 3.0, 3.6, 3.9, 3.9, 4.0, 5.8, 6.5, 7.3 and 18 mg/kg (n = 14).

The Meeting estimated a median residue of 3.6 mg/kg and a highest residue of 18 mg/kg for acetamiprid for cotton gin trash.

Fate of residues during processing

The effect of processing on the nature of residues was investigated in buffer solutions under a range of hydrolysis conditions. Acetamiprid was shown to be stable for at least 35 days in buffer solutions at pH 4, 5, 7 and 9, incubated at up to 45 °C.

The fate of acetamiprid residues has been examined in a number of studies with oranges, tomatoes, apples, cotton seed and plums, reflecting household and simulated commercial processing.

A summary of processing factors (PF) derived from the data on the above commodities is shown below. Based on the estimations made on the raw agricultural commodities, STMR-Ps and HR-Ps were estimated by multiplying the STMR of the raw commodity by the PF. Maximum residue levels were only estimated for commodities with a Codex code and of importance in international trade.

Summary of selected processing factors for acetamiprid

Raw agricultural commodity (RAC)	STMR (mg/kg)	HR (mg/kg)	Processed commodity	Processing factor	STMR-P	HR-P
Oranges	0.25		Juice [a]	< 0.13	0.03	
			Pulp	0.24	0.05	
			Pulp, dry	2.8	0.7	
			Peel	2.83	0.71	
			Oil [a]	< 0.16	0.04	
Apple	0.23		Juice	0.88	0.2	
			Wet pomace	1.34	0.31	
Plums	0.04	0.11	Dried prunes	2.96	0.12	0.32
Grape	0.085		Juice	1.5	0.13	
			Raisins	0.93	0.08	0.23
Tomatoes	0.4		Purée	1.4	0.56	
			Paste	3.1	1.24	
Cotton	0.09		Meal	0.38	0.03	
			Hulls	0.79	0.07	
			Refined Oil [a]	< 0.04	0.004	

[a] Residues below LOQ

The Meeting recommended a maximum residue level of 0.6 mg/kg for dried prunes, based on the recommended maximum residue level for plums (0.2 mg/kg) and an average processing factor of 2.9.

Residues in animal commodities

Farm animal dietary burden

The Meeting estimated the dietary burden of acetamiprid in farm animals on the basis of the diets listed in Annex 6 of the 2009 JMPR Report (OECD Feedstuffs Derived from Field Crops) and the STMR or highest residue levels estimated at the present Meeting. Dietary burden calculations are provided in Annex 6 and are summarized below.

Animal dietary burden for acetamiprid, ppm of dry matter diet

	Maximum Dietary Burden	Mean Dietary Burden
Beef cattle	1.085	0.435
Dairy cattle	0.836	0.413
Poultry broiler	0.007	0.007
Poultry layer	0.168	0.032

Farm animal feeding studies

Dairy cows

The Meeting received information on the residue levels arising in animal tissues and milk when dairy cows were dosed with acetamiprid for 28 days at 5.77, 17.4 and 58.6 ppm in the diet.

In milk, average residues (3 animals) of acetamiprid in whole milk from treated animals were < 0.02 in the low dose group (5.77 ppm) and were found at up to 0.21 mg/kg in the higher dose groups. Residues of IM-2-1 (the predominant residue) were 0.03–0.06 mg/kg in the low dose group and up to 0.95 mg/kg in the higher dose groups. Residue concentrations of acetamiprid in whole milk increased rapidly, reaching a plateau within 1 day with concentrations of IM-2-1 reaching a plateau at about 7–8 days.

In liver and kidney, acetamiprid residues were < 0.05 mg/kg in the low dose group and up to 0.25 mg/kg in the higher dose groups. Residues of acetamiprid in muscle and fat were < 0.01 mg/kg in the low dose group and did not exceed about 0.1 mg/kg and 0.06 mg/kg respectively in the higher dose groups.

The predominant residue in all tissues was the IM-2-1 metabolite, with highest residues in liver and kidney (0.1–0.2 mg/kg – low dose) and up to about 2.4 mg/kg in higher dose groups. Levels of about 0.05 mg/kg were present in muscle and fat (low dose group); these increasing to 1.0 mg/kg in muscle and 0.65 mg/kg in fat in the higher dose groups.

Residues of total acetamiprid (parent+IM-2-1) in the low dose group averaged 0.24 mg/kg (kidney), < 0.15 mg/kg (liver), 0.048 mg/kg (muscle), 0.037 mg/kg (fat) and 0.063 mg/kg (milk) and generally increased proportionally in the higher dose groups. Maximum residues in individual (low dose) animals were < 0.25 mg/kg mg/kg (kidney), < 0.15 mg/kg (liver), < 0.05 mg/kg (muscle) and < 0.072 mg/kg (fat).

Laying hens

A feeding study was also conducted with laying hens, fed 1.16 ppm, 3.55 ppm or 12 ppm acetamiprid daily for 28 days.

In eggs, residues of acetamiprid were not detectable or < 0.01 mg/kg in all dose groups, with the IM-2-1 metabolite being found at up to 0.33 mg/kg in the 12 ppm dose group, reaching a plateau at about day 8.

In tissues, acetamiprid was also not detected in any dose group, with IM-2-1 metabolite being found only in liver (< 0.1 mg/kg) in the low dose group and in the high dose group at levels of up to 0.5 mg/kg in liver, up to 0.075 mg/kg in muscle and up to 0.012 mg/kg in fat.

Animal commodity maximum residue levels

Cattle

For maximum residue level estimation, the high residues of acetamiprid plus IM-2-1 in tissues were calculated by extrapolating the maximum dietary burden (1.085 ppm) from the lowest feeding level (5.77 ppm) in the dairy cow feeding study and using the highest tissue concentrations of total acetamiprid from individual animals within those feeding groups.

The STMR values for the tissues were calculated by extrapolating the STMR dietary burden (0.435 ppm) from the lowest feeding level in the dairy cow feeding study and using the mean tissue concentrations of total acetamiprid from those feeding groups.

For milk maximum residue level estimation, the high residues in the milk were calculated by extrapolating the maximum dietary burden for dairy cattle (0.836 ppm) from the lowest feeding level (5.77 ppm) in the dairy cow feeding study and using the mean milk concentrations of total acetamiprid from this feeding group.

The STMR value for milk was calculated by extrapolating the mean dietary burden for dairy cows (0.413 ppm) from the lowest feeding level (5.77 ppm) in the dairy cow feeding study and using the mean milk concentrations of total acetamiprid from this feeding group.

	Acetamiprid feed level (ppm) for milk residues	Total acetamiprid residues (mg/kg) in milk	Acetamiprid feed level (ppm) for tissue residues	Total acetamiprid residues (mg/kg) in:			
				Muscle	Liver	Kidney	Fat
Maximum residue level for beef or dairy cattle							
Feeding study [a]	5.77	0.063	5.77	0.05	0.15	0.25	0.07
Dietary burden and residue estimate	0.836	0.009	1.085	0.009	0.028	0.047	0.013
STMR beef or dairy cattle							
Feeding study [b]	5.77	0.063	5.77	0.048	0.15	0.24	0.037
Dietary burden and residue estimate	0.413	0.004	0.435	0.004	0.011	0.018	0.003

[a] Highest residues for tissues and mean residues for milk

[b] Mean residues for tissues and for milk

The Meeting estimated maximum residue levels of 0.02 mg/kg for acetamiprid in meat (from mammals other than marine mammals), 0.02 mg/kg for mammalian fat, 0.05 mg/kg for edible offal (mammalian) and 0.02 mg/kg for milks.

Estimated STMRs are 0.004 mg/kg for mammalian muscle, 0.003 mg/kg for mammalian fat, 0.011 mg/kg for mammalian liver, 0.018 mg/kg for mammalian kidney and 0.004 mg/kg for milks.

Estimated HRs are 0.01 mg/kg for mammalian fat, 0.007 mg/kg for mammalian muscle, 0.022 mg/kg for mammalian liver, 0.036 mg/kg for mammalian kidney and 0.009 mg/kg for milks.

Poultry

In lowest dose feeding study (1.16 ppm), residues of acetamiprid were not detectable in eggs or any poultry tissues and the combined residues of acetamiprid and IM-2-1 averaged 0.027 mg/kg in eggs, were < 0.01 mg/kg in muscle and fat and was up to 0.09 mg/kg in liver.

Noting that the maximum dietary burden for poultry layers (0.168 ppm) is about 7 times lower than the lowest dose in the feeding study, the Meeting concluded that residues of acetamiprid and its IM-2-1 metabolite would not be expected in eggs.

For poultry liver, muscle and fat, based on a maximum dietary burden of 0.032 ppm (more than 36 times lower than the lowest dose feeding study, the Meeting concluded that residues of acetamiprid and its IM-2-1 metabolite would not be expected in poultry edible tissues above the LOQs of 0.05 mg/kg (liver) and 0.01 mg/kg (muscle and fat).

The Meeting estimated maximum residue levels of 0.01 (*) mg/kg for acetamiprid in poultry meat, poultry fat, and eggs and 0.05 mg/kg for poultry edible offal.

Estimated HRs and STMRs for dietary intake estimation for acetamiprid are 0.0 mg/kg for poultry eggs, meat and fat and for poultry edible offal, the Meeting estimated an HR of 0.01 mg/kg and an STMR of 0.0 mg/kg.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Daily Intake (IEDI) for acetamiprid was calculated for the food commodities for which STMRs or HRs were estimated and for which consumption data were available. The results are shown in Annex 3.

The International Estimated Daily Intakes of acetamiprid for the 13 GEMS/Food regional diets, based on estimated STMRs were 0–3% of the maximum ADI of 0.07 mg/kg bw (Annex 3). The

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

Short-term intake

The International Estimated Short-term Intake (IESTI) for acetamiprid was calculated for the food commodities for which STMRs or HRs were estimated and for which consumption data were available (Annex 4).

For spinach, the IESTI represented 180% of the ARfD of 0.1 mg/kg bw. On the basis of the information provided to the JMPR it was not possible to conclude that the estimate of short-term intake of acetamiprid, from the consumption of spinach, was less than the ARfD. The Meeting noted that an alternative GAP for spinach was not available.

For the other commodities considered by the JMPR, the IESTI represented 0–80% of the ARfD and the Meeting concluded that the short-term intake of residues of acetamiprid, when used in ways that have been considered by the JMPR (other than spinach), is unlikely to present a public health concern.

5.3 AZOXYSTROBIN (229)

RESIDUE AND ANALYTICAL ASPECTS

Azoxystrobin was evaluated by the JMPR at the first time in 2008 when an ADI of 0–0.2 mg/kg bw per day was established. The Meeting decided that an ARfD was unnecessary. In addition, the 2008 JMPR concluded that the residue definition for plant commodities for compliance with MRL values and for consumer risk assessments was parent azoxystrobin. Maximum residue levels, STMRs and STMR-Ps for 82 commodities or commodity groups were estimated.

The compound was listed by the Forty-second Session of the CCPR for the review of additional maximum residue level. The 2011 JMPR received residue data for passion fruit, okra, ginseng and coffee beans.

Analytical methods

The Meeting received information on analytical methods used for the determination of azoxystrobin residues in samples derived from supervised trials on passion fruit, coffee beans, ginseng roots and for ginseng processed commodities.

In the methods the macerated samples are typically extracted by blending with acetonitrile or ethyl acetate. The extract is cleaned by a solid phase clean-up (e.g., Florisil, alumina, sodium sulphate). The residue is determined by LC-MS/MS or by GLC with ECD or MS detection. LOQs are 0.01 mg/kg for passion fruit and coffee beans. In case of ginseng and its processed products, the LOQs are 0.003 mg/kg for fresh ginseng, 0.007 mg/kg for dried and red ginseng as well as for ethanol and water extracts of dried and red ginseng.

The freezer storage stability studies carried out with fresh ginseng and ginseng processed products showed that the residues were stable for the longest period (days) for which the samples were stored at or below -20 ºC. The studies reported by the 2008 JMPR cover the other sample materials evaluated by the present Meeting.

Results of supervised trials on crops

The OECD calculator was used as a tool in the estimation of the maximum residue level from the selected residue data set obtained from trials conducted according to GAP. As a first step, the Meeting reviewed all relevant factors related to each data set in arriving at a best estimate of the maximum residue level using expert judgement. Then, the OECD calculator was employed. If the statistical calculation spreadsheet suggested a different value from that recommended by the JMPR, a brief explanation of the deviation was provided.

Passion fruit

As part of the field trials conducted within the Pesticide Initiative Programme that aimed to provide data for establishing import tolerances in the European Union, azoxystrobin was applied as foliar spray treatment with 3 × 0.19 kg ai/kg and a PHI of 3 days in five trials carried out in Kenya. The residues in whole fruits were 0.68, 1.06, 1.15, 1.49 and 2.14 mg/kg.

The application conditions were based on the requirement to provide appropriate control of passion fruit diseases. However, supplied data was not supported by labels or official declarations of approved use. Therefore, the Meeting could not estimate a maximum residue level for azoxystrobin in passion fruit.

Okra

As part of the field trials conducted within the Pesticide Initiative Programme aiming to provide data for establishing import tolerances in the European Union, azoxystrobin was applied as foliar spray treatment with two or three applications at 0.16 kg ai/kg and a PHI of 2 days in two trials carried out in Côte d'Ivoire. The residues found after three applications were 0.03 and 0.48 mg/kg and after two applications 0.07, 0.1, 0.25 and 0.32 mg/kg at a PHI of two days. Detailed information on the analytical methods used was not submitted.

The application conditions were based on the requirement of appropriate control of diseases in okra, but were not supported by labels or official declarations of approved uses from Côte d'Ivoire. The trials from Côte d'Ivoire were also not according to the GAP of Kenya for vegetables (3 × 0.075–0.125 kg ai/kg, no information on PHI). Based on the data submitted, the Meeting could not estimate a maximum residue level for azoxystrobin in okra.

Nevertheless, the 2008 JMPR estimated a maximum residue level for fruiting vegetables, other than cucurbits, except fungi and sweet corn, of 3 mg/kg and an STMR of 0.35 mg/kg. This recommendation is applicable for okra.

Ginseng

The maximum GAP in Korea permits 4 foliar applications of azoxystrobin at 10 days interval at a rate of 0.01 kg ai/hL with a PHI of 7 days.

Ready to harvest ginseng plantations of 4–6 years old were treated 4 times at 10 days interval with 0.34–0.56 kg ai/ha in 3400–5556 L water/ha, equivalent to 0.01 kg ai/hL spray concentration. The root samples were collected 7 days after the last application on each field. The residues in fresh ginseng roots were: 0.012, 0.022, <u>0.025</u>, <u>0.0257</u>, 0.03 and 0.05 mg/kg.

The Meeting estimated a maximum residue level of 0.1 mg/kg and an STMR of 0.025 mg/kg.

Coffee beans

In Brazil, the registered use of azoxystrobin in coffee is as a foliar spray treatment of 2 × 0.15 kg ai/ha (interval 90 days) or 3 × 0.1 kg ai/ha (interval 60 days) and a PHI of 30 days. Four Brazilian trials with treatments of 3 × 0.15 kg ai/ha and 15 trials with 3 × 0.10–0.12 kg ai/ha were available. The spray intervals in the trials were about 60 days and the PHI 28–30 days.

The residues after treatment with;

- 3 × 0.10 kg ai/ha were: < <u>0.01</u> (7), 0.01 (2) mg/kg
- 3 × 0.12 kg ai/ha were: < 0.01 (6) mg/kg
- 3 × 0.15 kg ai/ha were: < 0.01 (4) mg/kg.

The Meeting estimated for azoxystrobin residues in coffee beans a maximum residue level of 0.02 mg/kg and an STMR of 0.01 mg/kg.

Fate of residues during processing

Fresh ginseng roots were dried to produce dried or red ginseng, which was extracted for about 18 hours with ethanol at 70 ºC or water at 85 ºC. The solvent was evaporated to reach Brix levels of 65 ºBx for the ethanol extract and 72 ºBx for the water extract.

The following median processing factors were calculated: 3 for dried ginseng, 2 for red ginseng, 5.2 for ethanol extract of dried ginseng, 4.8 for water extract of dried ginseng, 4.9 for ethanol extract of red ginseng and 2 for water extract of red ginseng.

Based on the STMR of 0.025 mg/kg for fresh ginseng roots, the Meeting estimated the following STMR-P-values: 0.075 mg/kg for dried ginseng, 0.05 mg/kg for red ginseng, 0.13 mg/kg for ethanol extract of dried ginseng, 0.12 mg/kg for the water extract of dried ginseng, 0.12 mg/kg for the ethanol extract of red ginseng and 0.05 mg/kg for the water extract of red ginseng.

The Meeting estimated a maximum residue level of 0.5 mg/kg for ginseng, processed products (dried, red, ethanol and water extracts).

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Dietary Intakes (IEDIs) of azoxystrobin were calculated for the 13 GEMS/Food cluster diets using STMRs and STMR-Ps estimated by the JMPR in 2008 and the current Meeting. The ADI is 0–0.2 mg/kg bw and the calculated IEDIs were 2–10 % of the maximum ADI. The results are shown in Annex 3. The Meeting concluded that the long-term intake of residues of azoxystrobin resulting from the uses considered by the JMPR is unlikely to present a public health concern.

Short-term intake

The 2008 Meeting decided that an ARfD for azoxystrobin is unnecessary and concluded that the short-term intake of residues resulting from the use of azoxystrobin is unlikely to present a public health concern.

5.4 CLOTHIANIDIN (238) / THIAMETHOXAM (245)

RESIDUE AND ANALYTICAL ASPECTS

Residue and analytical aspects of clothianidin were considered for the first time by the 2010 JMPR Meeting. The 2010 Meeting established an acceptable daily intake (ADI) of 0–0.1 mg/kg bw per day and estimated the acute reference dose (ARfD) as 0.6 mg/kg bw. The 2010 Meeting defined the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities as sum of clothianidin and its Z-isomer. The residue is considered not fat soluble.

In 2011 the manufacturer requested JMPR to reconsider the residue definition for clothianidin since the Z-isomer cannot be isolated as such and the Z-isomer should not be included in the residue definition. JMPR agreed to re-evaluate the clothianidin residue definition during the 2011 JMPR meeting. The manufacturer submitted new spectral data to elucidate the equilibrium between clothianidin and its Z-isomer. As the results apply equally to clothianidin and the thiamethoxam metabolite CGA 322704, the Meeting decided to consider the expression of residue definitions for both compounds.

Chemical structure

The Meeting received quantum mechanical calculations, NMR data and X-ray data to elucidate the equilibrium between clothianidin and its Z-isomer.

Quantum mechanical calculations revealed that the E-isomer form is the most stable form and that at room temperature an equilibrium of 1.5% Z-isomer and 98.5% E-isomer (E/Z ratio 66:1) in water is formed. The calculated transition state barriers between the E- and Z-isomer forms (with 10.5 kJ/mol energy difference) corresponding to the variation of three torsonial angles are 58.6, 46.0 and 62.8 kJ/mol, respectively. These transition state barriers are so low that the conversion between the E- and Z-isomer forms at room temperature is rapid and an equilibrium is formed rapidly. The E/Z equilibrium with a ratio of E:Z of 66:1 is formed irrespective whether the starting material is an E/Z mixture (thiamethoxam metabolite CGA 322704) or the E-isomer (clothianidin).

In order to verify the theoretical calculations, NMR experiments at low temperatures were performed with a clothianidin solution in deuterated acetonitrile. As the measurement temperature goes down from room temperature to -4 °C, the lifetime of the unfavoured Z-isomer is increased for a time long, enough to be detected by NMR. Based on spectral data it was confirmed that the E-isomer form is the most prominent form in equilibrium. An E/Z equilibrium with an E/Z ratio of 27:1 is formed in a deuterated acetonitrile solution at –40 °C. At ambient temperature there is no chance to isolate the Z-isomer, because it will always immediately transform back to the E-isomer.

Definition of the residue

The compound clothianidin is equivalent to the E form of CGA 322704, a metabolite arising from thiamethoxam use. Thiamethoxam exists as an E/Z mixture and the 2010 JMPR had insufficient data to conclude on the E/Z equilibrium of the CGA 322704 metabolite. The JMPR 2010 included the Z-isomer in the residue definition.

Based on the additionally submitted structural studies, an E/Z equilibrium with a ratio of E:Z of 27:1 at -40 °C is formed irrespective whether the starting material is an E/Z mixture (thiamethoxam metabolite CGA 322704) or the E-isomer (clothianidin). These new study results demonstrate that experimental separation of the minor Z-isomer from the E-isomer is not possible at ambient temperature because the Z-isomer will always immediately transform back to the E-isomer. For this reason, the Z-isomer of CGA 322704 need not be mentioned in the residue definition for either clothianidin or thiamethoxam.

The Meeting recommended the following as revised residue definition for clothianidin:

Definition of the residue for compliance with the MRL or for estimation of the dietary intake for plant commodities: *clothianidin*

Definition of the residue for compliance with the MRL or for estimation of the dietary intake for animal commodities: *clothianidin.*

The Meeting recommended the following as revised residue definition for thiamethoxam:

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

Definition of the residue for estimation of the dietary intake for plant and animal commodities (except poultry*): thiamethoxam and clothianidin* (considered separately)

Definition of the residue for estimation of the dietary intake for poultry: *sum of thiamethoxam, CGA 265307 and MU3, expressed as thiamethoxam; and clothianidin* (clothianidin to be considered separately from thiamethoxam).

The changes above do not impact on the recommendations for clothianidin and thiamethoxam nor the dietary risk assessments made by the 2010 JMPR.

5.5 CYPERMETHRINS (INCLUDING ALPHA- AND ZETA-CYPERMETHRIN) (118)

RESIDUE AND ANALYTICAL ASPECTS

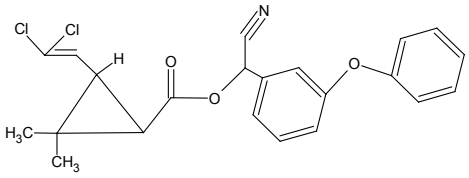
Cypermethrins was evaluated by JMPR 1979 (T, R), 1981 (T, R), 1982 (R), 1983 (R), 1984 (R), 1985 (R), 1986 (R), 1987 (corr. to 1986 evaluation), 1988 (R), 1990 (R), 2006 (T), 2008 (R) and 2009 (R). The last periodic review for toxicology was in 2006 and for residues in 2008 and included cypermethrin, alpha-cypermethrin and zeta-cypermethrin. The 2006 Meeting estimated the acceptable daily intake (ADI) as 0–0.02 mg/kg bw and estimated the acute reference dose (ARfD) as 0.04 mg/kg bw. The 2008 Meeting defined the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities as cypermethrin (sum of isomers). The residue is fat soluble. In 2009 additional information on the use of cypermethrin was submitted and evaluated. Cypermethrin was listed by the Forty-second Session of the CCPR[14] for the evaluation of 2011 JMPR for additional maximum residue levels.

The Meeting received information on zeta-cypermethrin from the manufacturer on storage stability, residue analysis, use patterns, residues resulting from supervised trials on citrus fruits and tree nuts, and fates of residue during processing. In addition, the Meeting received information on cypermethrin on residue analysis, use patterns, and residues resulting from supervised trials on asparagus and pomelo from Thailand. China and India submitted information on cypermethrin about storage stability, residue analysis, use patterns, residues resulting from supervised trials on teas, and on fates of residue during processing (China). Furthermore, the Meeting received information from Japan on use patterns of cypermethrin.

Chemical name

(Zeta)-Cypermethrin or (*RS*)-α-cyano-3-phenoxybenzyl-(1*RS*,3*RS*;1*RS*,3*RS*)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate or (*RS*)-α-cyano-3-phenoxybenzyl-(1*RS*)-cis-trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate

Structural formula:



Cypermethrin and zeta-cypermethrin are similar pyrethroid insecticides with the same basic chemical formula and molecular weight. Both products are mixtures of eight individual isomers that only differ in the structural orientation of their chemical bonds.

Analytical methods

The Meeting received description and validation data for analytical methods of cypermethrin and zeta-cypermethrin.

The extended revision of GC-ECD/GC-MS method DFG S19 was submitted to the Meeting as multiresidue enforcement method. This method was already shown to be valid for the

[14] ALINORM 10/33/24

determination of cypermethrin in various plant matrices. The method is now shown to be valid for the determination of zeta-cypermethrin in plant material with high water content and/or high acid content (LOQ = 0.01 mg/kg).

In addition, seven GC-ECD analytical methods were received for use in the supervised residue trials, processing studies and storage stability studies for the determination of cypermethrin or zeta-cypermethrin in plant material (LOQ varied between 0.01, 0.025 and 0.05 mg/kg). The Meeting noted that for two of the methods recoveries were acceptable, but there were only a limited number of samples (1–2 per concentration level).

Stability of pesticide residues in stored analytical samples

The Meeting received information on the stability of cypermethrin in plant commodities stored frozen. The 2008 Meeting considered storage stability studies of cypermethrin and zeta-cypermethrin mutually supportive.

In additional studies provided for the present Meeting, cypermethrin was shown to be stable when stored at -18 °C for at least 18 months in crops with high water content (apple, lettuce and tomatoes) and high oil content (soya beans). Storage at +25 and +4 °C showed no degradation of cypermethrin residues in tea samples (dried tea leaves as traded) for a period of at least 4 months. Since the cypermethrins do not dissociate in water, storage stability on crops with high water content can be extrapolated to crops with high acid content.

Samples from supervised residue trials on citrus fruits, asparagus and tea were either analysed directly after harvest or were analysed within the storage stability periods indicated above.

Results of supervised trials on crops

The Meeting received supervised trials data for zeta-cypermethrin on oranges, lemons, grapefruit, almonds and pecans, and for cypermethrin on pomelo, asparagus and tea.

In 2008 trials were available for alpha-cypermethrin on citrus fruits, almonds and tea but no suitable GAP was available to evaluate them. Since no suitable GAP is available in 2011, these trials cannot be used here and they will not be mentioned in the text below.

The recommendations proposed by the Meeting were verified using the OECD MRL calculator. For all trials the outcome of the OECD MRL calculator agreed with the recommendation made by the Meeting.

Citrus fruits

Field trials for zeta-cypermethrin or cypermethrin treatment on shaddocks and pomelos were conducted in the Thailand (pomelo) and the USA (grapefruit).

Critical GAP for cypermethrin on pomelos in Thailand is for four foliar spray applications at 12 g ai/hl at a 7-day interval and PHI 14 days. In trials from Thailand (4 × 9.4 g hL, PHI 14 days) matching this GAP cypermethrin (sum of isomers) residues in pomelo whole fruit were 0.11, 0.11, 0.14, 0.16, 0.18 and 0.25 mg/kg (n = 6).

Critical GAP for zeta-cypermethrin on citrus fruits in the USA is for an unspecified number of ground or aerial applications to foliage at 56 g ai/ha (max 224 g ai/ha per season) with an interval of at least 14 days and PHI 1 day. In trials from the USA (4 × 56 g ai/ha, PHI 1 day, interval 14 days) matching this GAP cypermethrin (sum of isomers) residues in grapefruit whole fruit were 0.05, 0.06, 0.12, 0.12, 0.16 and 0.20 mg/kg (n = 6). In two of the trials residues were also measured in the pulp and showed that cypermethrin (sum of isomers) residues were < 0.05 (2) mg/kg.

Since the GAPs for Thailand and the USA are different, the data on grapefruit and pomelo cannot be combined. Since the highest residue is found in the Thai dataset, the Meeting agreed to use

the Thai dataset for pomelo. The Meeting estimated a maximum residue level of 0.5 mg/kg for shaddocks and pomelos and an STMR of 0.05 mg/kg and an HR of 0.05 mg/kg based on the residues in the pulp from trials in the USA.

Field trials with zeta-cypermethrin treatment on oranges were conducted in the USA and Italy.

Critical GAP for zeta-cypermethrin on citrus fruits in the USA is for an unspecified number of ground or aerial applications to foliage at 56 g ai/ha (maximum of 224 g ai/ha per season) with an interval of at least 14 days and PHI 1 day. In trials from the USA (4 × 56 g ai/ha, PHI 1 day, interval 14 days) matching this GAP cypermethrin (sum of isomers) residues in orange whole fruit were < 0.05, < 0.05, < 0.05, < 0.05, < 0.05, 0.13, 0.14, 0.14, 0.14, 0.14, 0.15 and 0.16 mg/kg (n = 12). Where residues were higher at longer PHIs these were selected instead. In four of the trials residues were also measured in the pulp and showed that cypermethrin (sum of isomers) residues were < 0.05 (4) mg/kg.

No GAP matched the field trial conducted in Italy.

Field trials with zeta-cypermethrin treatment on lemons were conducted in the USA and Italy.

Critical GAP for zeta-cypermethrin on citrus fruits in the USA is for an unspecified number of ground or aerial applications to foliage at 56 g ai/ha (maximum 224 g ai/ha per season) with an interval of at least 14 days and PHI 1 day. In trials from the USA (4 × 56 g ai/ha, PHI 1 day, interval 14 days) matching this GAP cypermethrin (sum or isomers) residues in lemon whole fruit were 0.06, 0.07, 0.08, 0.08 and 0.08 mg/kg (n = 5). In two of the trials residues were also measured in the pulp and showed that cypermethrin (sum of isomers) residues were < 0.05 (2) mg/kg.

No GAP matched the field trial conducted in Italy.

The Meeting noted that the datasets for oranges and lemons matching USA GAP for citrus fruit were from similar populations (Mann-Whitney U test). Since residue behaviour within the citrus fruit group is expected to be similar, the Meeting agreed that the datasets for oranges and lemons could be combined to estimate a maximum residue level for citrus fruits, except shaddocks and pomelos. Cypermethrin residues in oranges and lemons (whole fruit) were: < 0.05, < 0.05, < 0.05, < 0.05, < 0.05, 0.06, 0.07, 0.08, 0.08, 0.08, 0.08, 0.13, 0.14, 0.14, 0.14, 0.14, 0.15 and 0.16 mg/kg (n = 17).

Based on the dataset matching the GAP of the USA, the Meeting estimated a maximum residue level of 0.3 mg/kg for citrus fruits, except shaddocks and pomelos. The Meeting estimated an STMR of 0.05 mg/kg and an HR of 0.05 mg/kg based on residues in the pulp from trials in the USA.

Stem vegetables

The JMPR 2008 Meeting estimated an STMR value and an HR value of 0.01 and 0.01 mg/kg, respectively, for cypermethrin residues in asparagus. The estimated maximum residue level was 0.01* mg/kg for asparagus. These estimations were based on seven alpha-cypermethrin trials on asparagus in France with conditions in line with German GAP for asparagus (0.0125 kg ai/ha) and no specified PHI). In addition, Thailand provided data in 2008 on two asparagus trials with cypermethrin treatments. However, these trials were considered insufficient for estimating a maximum residue level.

Additional field trials for cypermethrin treatments to asparagus were conducted in Thailand with the same GAP as the trials provided to the 2008 JMPR Meeting.

Critical GAP for asparagus in Thailand is for an unspecified number of foliar spray applications at 25 g ai/hL and a PHI of 3 days. In trials from Thailand (2–3 × 25 g ai/hL, PHI 3 days) matching this GAP from both the 2008 and the 2011 datasets cypermethrin (sum of isomers) residues in green asparagus were: 0.01, 0.03, 0.06, 0.09, 0.09, 0.18 and 0.20 mg/kg (n = 7).

Since the GAP from Thailand resulted in higher residues than the GAP of Germany, the Meeting decided to withdraw the previous maximum residue level recommendation. Based on the dataset matching the Thai GAP, the Meeting estimated a maximum residue level of 0.4 mg/kg for asparagus to replace the previous recommendation of 0.01* mg/kg. The Meeting estimated an STMR of 0.09 mg/kg and an HR of 0.20 mg/kg.

Tree nuts

Field trials for zeta-cypermethrin treatment on almonds were conducted in the USA.

Critical GAP for zeta-cypermethrin on tree nuts in the USA is for an unspecified number of ground or aerial foliar applications at 56 g ai/ha (maximum of 280 g ai/ha per season) with a treatment interval of 7 days and a PHI of 7 days. In trials from the USA (5 × 56 g ai/ha, PHI 7 days, interval 7 days) matching this GAP cypermethrin (sum of isomers) residues in almond nutmeat were: < 0.05, < 0.05, < 0.05, < 0.05 and < 0.05 mg/kg (n = 5).

Field trials for zeta-cypermethrin treatment on pecans were conducted in the USA.

Critical GAP for zeta-cypermethrin on tree nuts in the USA is for an unspecified number of ground or aerial foliar applications at 56 g ai/ha (maximum of 280 g ai/ha per season) with an interval of 7 days and a PHI of 7 days. In trials from the USA (5 × 56 g ai/ha, PHI 7 days, interval 7 days) matching this GAP cypermethrin (sum of isomers) residues in pecan nutmeat were: < 0.05, < 0.05, < 0.05, < 0.05 and < 0.05 mg/kg (n = 5).

The Meeting agreed that the USA data sets for almonds and pecans are similar and could be combined to estimate a maximum residue level for tree nuts. The combined dataset resulted in the following residues: < 0.05 (10) mg/kg.

Based on the dataset for almonds and pecans. matching USA GAP, the Meeting estimated a maximum residue level of 0.05* mg/kg for tree nuts and an STMR value of 0.05 mg/kg and an HR value of 0.05 mg/kg for tree nuts.

Miscellaneous fodder and forage crops

Field trials for zeta-cypermethrin treatment on almond hulls were conducted in the USA.

Critical GAP for zeta-cypermethrin on tree nuts in the USA is for an unspecified number of ground or aerial foliar applications at 56 g ai/ha (maximum of 280 g ai/ha per season) with an interval of 7 days and PHI 7 days. In trials from the USA (5 × 56 g ai/ha, PHI 7 days, interval 7 days) matching this GAP cypermethrin (sum of isomers) residues in almond hulls were: 0.90, 0.95, 2.3, 2.4 and 2.7 mg/kg, as received (n = 5).

Based on these data, the Meeting estimated a median value of 2.3 mg/kg.

Teas

Field trials for cypermethrin treatment on tea were conducted in China and India. Directly after picking the fresh tea leaves, the tea was processed into dried tea leaves as traded. Residues listed here are for the processed tea.

Critical GAP for cypermethrin on tea in China is for one spray application at 45 g ai/ha and a PHI of 7 days. In trials from China (45 g ai/ha, PHI 7 days) matching this GAP cypermethrin (sum of isomers) residues in green processed tea were: 1.6, 3.9, 4.9 and 5.6 mg/kg (n = 4). In trials from China matching this GAP, cypermethrin (sum of isomers) residues in black processed tea were 1.6 and 3.6 mg/kg (n = 2). The Meeting agreed that the data sets for green and black processed tea are similar and could be combined to form the following dataset for green and black processed tea: 1.6, 1.6, 3.6, 3.9, 4.9 and 5.6 mg/kg (n = 6).

Critical GAP for cypermethrin on tea in India is for one foliar spray application at 63 g ai/ha and a PHI of 7 days. In trials from India (63 g ai/ha, PHI 7 days) matching this GAP cypermethrin residues in black processed tea were 1.1 and 2.0 mg/kg (n = 2).

Since the highest residue is found in the Chinese dataset, the Meeting decided to use the tea data corresponding to the GAP of China. Residues for green and black processed tea were: 1.6, 1.6, 3.6, 3.9, 4.9 and 5.6 mg/kg (n = 6).

Based on the dataset for green and black processed tea matching Chinese GAP, the Meeting estimated a maximum residue level of 15 mg/kg for tea, green, black (black, fermented and dried) and an STMR value of 3.75 mg/kg.

Fate of residues in storage

The effect of storage on cypermethrin residues in processed tea (dried tea leaves as traded) at +4 °C and +25 °C on cypermethrin residues was investigated by determination of degradation rates. After 4 months of storage the degradation rates were 3.3–5.6% for storage at +25 °C and 2.1–3.5% for storage at +4 °C.

The Meeting, therefore, concluded that storage for 4 months at room temperature or under cold storage did not influence the fate of cypermethrin residues in processed tea.

Fate of residues during processing

In the 2008 Report of the JMPR it was shown that alpha-cypermethrin and cypermethrin residues were stable during hydrolysis conditions simulating pasteurization, baking, brewing and boiling. The 2008 JMPR Meeting calculated processing factors for a number of food processes. Additional processing studies with (zeta-) cypermethrin were submitted for oranges and tea in the 2011 Meeting.

Cypermethrin (sum of isomers) residue levels in dried orange pomace (0.22 and 0.32 mg/kg) and orange oil (0.50 and 0.63 mg/kg) were higher than in the corresponding RAC (< 0.05 mg/kg). Processing factors could not be derived for the processing of oranges in orange juice, orange oil or dried pulp (pomace) as cypermethrin (sum of isomers) residues in the RAC were below the LOQ (< 0.05 mg/kg).

For the processing of tea (dried tea leaves as traded) into tea infusion, processing factors could be derived. In the table below relevant processing factors for tea infusion are summarized. The STMR-P is calculated as $STMR_{RAC}$ × processing factor.

Commodity	Processed fraction	Processing factors (n = 4)	Best estimate
Tea (black)	Tea infusion (3 g/450 mL, 20 min)	0.0083, 0.0085, 0.0088, 0.011	0.0099
Tea (green)	Tea infusion (3 g/450 mL, 20 min)	0.0086, 0.010, 0.011, 0.013	
Tea (black)	Tea infusion (3 g/150 mL, 5 min)	< 0.089, < 0.13	

Livestock dietary burden

For estimating the livestock dietary burden, relevant trials were received by the present Meeting involving almond hulls. These feed commodities are additional to the feed commodities already taken into account at the 2008 and 2009 JMPR Meetings. The present Meeting estimated the dietary burden of cypermethrin residues on the basis of the 2009 livestock diets as listed in the FAO manual appendix IX (OECD feedstuff table). Calculation from highest residue, STMR (some bulk commodities) and STMR-P values provides the levels in feed suitable for estimating maximum residue levels, while calculation from STMR and STMR-P values from feed is suitable for estimating STMR values for animal commodities.

All plant commodities used in the dietary burden calculation are listed below. Dietary burden for livestock might be underestimated, since residue data are not available for several feedstuff derived from crops treated with cypermethrin.

Codex Group	CROP	FEED STUFF	Highest residue	STMR	DM (%)
AL	Alfalfa	forage	11	3.65	35
AL	Alfalfa	hay	20	11.5	100
AF/AS	Barley	forage	1.4	0.39	30
AF/AS	Barley	straw	6.9	3.6	100
AL	Bean	vines	2.1	0.71	35
AM/AV	Beet, sugar	tops	8.3	1.5	100
AM/AV	Cabbage	heads, leaves	0.65	0.02	15
AF/AS	Corn, field	forage/silage	0.1	0.05	40
AF/AS	Corn, field	stover	6.9	3.6	100
AF/AS	Corn, pop	stover	6.9	3.6	100
AF/AS	Corn, sweet	forage	0.1	0.05	48
AF/AS	Corn, sweet	stover	6.9	3.6	100
AL	Cow pea	forage	0.86	0.45	30
AL	Cow pea	hay	1.1	0.42	100
AM/AV	Kale	leaves	0.52	0.07	15
AF/AS	Millet	straw	6.9	3.6	100
AF/AS	Oat	straw	6.9	3.6	100
AL	Pea	vines	0.86	0.45	25
AL	Pea	hay	1.1	0.42	100
AM/AV	Rape	forage	0.24	0.05	30
AF/AS	Rice	straw	6.9	3.6	100
AF/AS	Rye	straw	6.9	3.6	100
AF/AS	Sorghum, grain	stover	6.9	3.6	100
AF/AS	Triticale	straw	6.9	3.6	100
AF/AS	Wheat	forage	1.4	0.38	25
AF/AS	Wheat	straw	6.9	3.6	100
VR	Carrot	culls	0.01	0.01	12
VR	Cassava/tapioca	roots	0.01	0.01	37
VR	Potato	culls	0.01	0.01	20
VR	Swede	roots	0.01	0.01	10
VR	Turnip	roots	0.01	0.01	15
GC	Barley	grain	–	1.38	88
VD	Bean	seed	–	0.05	88
GC	Corn, field	grain	–	0.035	88
GC	Corn, pop	grain	–	0.035	88
VD	Cowpea	seed	–	0.05	88
VD	Lupin	seed	–	0.05	88
GC	Millet	grain	–	0.035	88
GC	Oat	grain	–	1.38	89
VD	Pea	seed	–	0.05	90
GC	Rice	grain	–	0.57	88
GC	Rye	grain	–	1.38	88
GC	Sorghum, grain	grain	–	0.035	86
VD	Soya bean	seed	–	0.05	89
GC	Triticale	grain	–	0035	89
VD	Vetch	seed	–	0.05	89
GC	Wheat	grain	–	1.38	89
AM/AV	Almond	hulls	–	2.3	90
SO	Cotton	undelinted seed		0.05	88
AM/AV	Cotton	gin by-products	0.55	0.36	90
AB	Grape	pomace, wet	–	0.032	15
CM/CF	Wheat	milled by-products	–	3.45	88

Dietary burden calculations for beef cattle, dairy cattle, broilers and laying poultry are provided in Annex 6. A mean and maximum dietary burden for livestock, based on cypermethrin use, is shown in the table below.

Animal dietary burden for cypermethrin, expressed as ppm of dry matter diet

	US	EU	AU	JPN	Overall	
	max	max	max	max	max	
beef cattle	6.07	24.4	31.4	4.71	31.4 (AU)	[a]
dairy cattle	9.35	17.1	21.6	7.23	21.6 (AU)	[b]
poultry broiler	2.74	1.89	2.03	1.96	2.74 (US)	
poultry layer	2.74	3.10	2.03	1.20	3.10 (EU)	[c,d]
	mean	mean	mean	mean	mean	
beef cattle	4.30	8.48	11.3	3.86	11.3 (AU)	[a]
dairy cattle	4.66	6.86	8.47	5.11	8.47 (AU)	[b]
poultry broiler	2.74	1.89	2.03	0.91	2.74 (US)	
poultry layer	2.74	2.26	2.03	1.20	2.74 (US)	[c,d]

[a] Highest mean and maximum beef or dairy cattle dietary burden suitable for maximum residue level and STMR estimates for mammalian meat.

[b] Highest mean and maximum dairy cattle dietary burden suitable for maximum residue level and STMR estimates for milk.

[c] Highest mean and maximum poultry broiler or poultry layer dietary burden suitable for maximum residue level and STMR estimates for poultry meat.

[d] Highest mean and maximum poultry layer suitable for maximum residue level and STMR estimates for eggs.

Livestock feeding studies

Livestock feeding studies with alpha-cypermethrin, zeta-cypermethrin and cypermethrin for cattle and poultry have been submitted and evaluated by JMPR 2008.

Residues in animal commodities

Cattle

The estimated mean and maximum dietary burden for beef and dairy cattle remained the same compared with estimates from JMPR 2009, so there is no change in estimated maximum residue levels, STMRs and HRs for mammalian meat, fat, offal and milk.

Poultry

The estimated mean dietary burden for broiler and layer poultry (2.74 ppm) remained the same compared with estimates from JMPR 2009, so there is no change in estimated STMR values for poultry meat, fats, edible offal and eggs.

The estimated maximum dietary burden for broiler and laying poultry (3.10 ppm) was lower than estimated at JMPR 2009 (3.89 ppm). This lower value was due only to the 2009 change in livestock diets. For maximum residue level estimation, the high residues in eggs, muscle, liver and fat were calculated by interpolating the maximum dietary burden (3.10 ppm) between the relevant feeding levels (0, 1.6 and 7.2 ppm) from the alpha-cypermethrin laying hen feeding study and using the highest meat and egg concentrations from those feeding groups (see table below).

				Residues (mg/kg) in:		
	Feed level (ppm) for egg residues	Residues (ng/g) in eggs	Feed level (ppm) for tissue residues	Muscle	Liver	Fat
Maximum residue level - layer and broiler poultry						
Feeding study [a,b]	0 7.2	0 0.011	0 7.2	0 < 0.05	0 < 0.05	0 0.088

Dietary burden and residue estimate	3.10	0.0047	3.10	0.022	0.022	0.038

[a] highest residues for tissues and eggs

[b] residues were interpolated between 0 and 7.2 ppm feed, because the 1.6 ppm level resulted in residues below LOQ for all matrices.

The Meeting estimated an HR value of 0.022 mg/kg in muscle and liver and an HR of 0.038 mg/kg for fat.

The Meeting estimated a maximum residue level of 0.1 mg/kg for poultry meat (fat) and poultry fats and 0.05* mg/kg for edible offal of poultry. These recommendations take into account that cypermethrin is fat-soluble, and that higher residues could be expected in the fat of broilers in line with the decision taken in JMPR 2008.

The Meeting estimated an HR value of 0.0047 mg/kg for eggs and a maximum residue level of 0.01* mg/kg for eggs.

DIETARY RISK ASSESSMENT

Long-term intake

Based on the evaluation of cypermethrin, alpha-cypermethrin and zeta-cypermethrin, maximum residue levels, HRs and STMRs were estimated for raw and processed commodities in JMPR 2008, 2009 and at the present Meeting. When data on consumption were available for the listed food commodities, dietary intakes were calculated for the GEMS/Food Consumption Cluster Diets. The results are shown in Annex 3.

The IEDI of in the 13 GEMS/Food cluster diets, based on the estimated STMRs were in the range 7–30% of the maximum ADI of 0.02 mg/kg bw. The Meeting concluded that the long-term intake of residues of cypermethrins from uses considered by the Meeting is unlikely to present a public health concern.

Short-term intake

The International Estimated Short Term Intake (IESTI) for cypermethrin, alpha-cypermethrin and zeta-cypermethrin was calculated for the food commodities (and their processing factors) for which maximum residue levels, STMRs and HRs were estimated at the present Meeting. The results are shown in Annex 4.

The IESTI varied from 0–8% of the ARfD (0.04 mg/kg bw). The Meeting concluded that the short-term intake of residues of cypermethrins from uses considered by the Meeting is unlikely to present a public health concern.

5.6 DICAMBA (240)

RESIDUE AND ANALYTICAL ASPECTS

Dicamba, a systemic broad-spectrum herbicide used in a variety of crops, it was first evaluated by the JMPR in 2010. The 2010 Meeting estimated an ADI of 0–0.3 mg/kg bw/day and an ARfD of 0.5 mg/kg bw. It recommended the following residue definition for plant and animal commodities:

Definition of the residue for plant commodities (for compliance with the MRL): *Dicamba*

Definition of the residue for plant commodities (for estimation of dietary intake): *Sum of dicamba and 5-OH dicamba expressed as dicamba*

Definition of the residue for animal commodities (for compliance with the MRL and for estimation of dietary intake): *Sum of dicamba and DCSA*.

The 2010 Meeting estimated maximum residue levels for 21 commodities, which were adopted as Codex MRLs by the Codex Alimentarius Commission in 2011 (REP 11/CAC, Appendix III, Part 2).

The 2010 JMPR received information on metabolism, method of analysis, storage stability, supervised residue trials and processing studies on soya beans. However, supervised trials were conducted in the USA with PHI of 7 days while the approved US label at that time indicated a PHI of 14 days. As no trials matched this GAP, the Meeting could not estimate a maximum residue level for soya bean (dry).

The label of one formulation, relevant to the trials, has since been revised and approved with a PHI of 7 days, matching that of the supervised trials. The current Meeting was therefore able to evaluate the trial data on soya beans provided to the 2010 Meeting against the newly approved use on soya beans in the USA.

Results of supervised trials on crops

The information on supervised field trials of dicamba on soya beans conducted in the USA were received and summarized by the 2010 JMPR. All trials were conducted in the USA.

For all analytes and matrices, generally the LOQ was 0.01 mg/kg unless as otherwise stated. In summing for total residues, if dicamba and/or 5-OH dicamba were below the LOQ, the LOQ value of each was used for calculation.

Soya bean

A total of 23 trials were conducted. The new US GAP allows two different applications: an application of 0.56 kg ai/ha as a broadcast spray made approximately 14 days prior to planting and an application of 1.12 kg ai/ha applied 7 days prior to harvest. The maximum total application rate per season is 2.24 kg ai/ha.

In the supervised trials, pre-plant application of 0.56 kg ai/ha 14 days before planting and pre-harvest application of 2.24 kg ai/ha 7 days before harvest were made. The pre-harvest application rate was two times the GAP rate.

As foliar pre-harvest application was used throughout the supervised trials, the Meeting agreed to apply the proportionality approach to estimate a maximum residue level for soya bean (dry).

Residues of dicamba from trials with a pre-harvest application rate of 2.24 kg ai/ha and a PHI of 7 days, in ranked order were: 0.07, 0.07, 0.08, 0.10, 0.14, 0.17, 0.27, 0.28, 0.46, 0.48, 0.55, 0.65, 0.68, 0.70, 0.81, 1.00, 1.30, 1.40, 1.43, 1.90, 2.10, 3.30 and 8.1 mg/kg.

Applying a factor of 0.5 to estimate residues of dicamba 7 days after a pre-harvest application at the GAP rate of 1.12 kg ai/ha, residues of dicamba were estimated to be: 0.035, 0.035, 0.04, 0.05,

0.07, 0.085, 0.135, 0.14, 0.23, 0.24, 0.275, 0.325, 0.34, 0.35, 0.405, 0.50, 0.65, 0.70, 0.715, 0.95, 1.05, 1.65 and 4.05 mg/kg.

Based on these residue concentrations, the Meeting estimated a maximum residue level of 5 mg/kg for soya bean (dry). The Meeting also estimated a median residue for the purpose of calculating animal dietary burdens at 0.325 mg/kg.

The OECD Calculator indicated a maximum residue level of 4 mg/kg. However, the highest residue concentration calculated from all the supervised trials was 4.05 mg/kg. Normally the JMPR would not set a maximum residue level lower than the highest actual residue concentration, and therefore it recommended a maximum residue level of 5 mg/kg. .

Corresponding total residues of dicamba and 5-OH dicamba in ranked order were: 0.04, 0.04, 0.045, 0.055, 0.075, 0.09, 0.14, 0.145, 0.245, 0.255, 0.28, 0.335, 0.345, 0.355, 0.41, 0.505, 0.655, 0.72, 0.835, 0.975, 1.055, 1.81 and 4.055 mg/kg.

The Meeting estimated an STMR of 0.335 mg/kg.

Soya bean forage and hay

Soya bean forage and hay samples were collected before the second application was made to avoid abscission. Therefore, residues in these commodities came from pre-plant application only.

The label prohibits the use of fodder or hay after a pre-harvest application.

Since the residues from the pre-plant application were expected to be very low and harvesting soya bean plants before harvesting soya bean seeds does not seem to be a common practice, the Meeting confirmed the decision of the 2010 JMPR that there was no need for estimating a maximum residue level for soya bean forage and hay.

Fate of residues during processing

The 2010 Meeting received information on processing of soya beans to meal and oil.

Processing factor calculated for refined oil and its STMR-Ps are shown below:

Product	Processing factor		STMR/STMR-P (mg/kg)
	Dicamba	Total residues	
Soya bean			0.335
Refined oil	< 0.019	< 0.036	0.012

As there is no concentration of dicamba and 5-OH dicamba observed in refined oil, the estimation of a maximum residue level is not necessary for this commodity.

On the basis of the processing factor of 0.35, a median residue of 0.117 mg/kg was calculated for soya bean meal, which may be used as a livestock feed item.

Residue concentration was observed in soya bean hulls and grain dust which may also be used as animal feeds. The processing factors of dicamba calculated for these commodities were 3.9 and 676 respectively. From these factors, median residues in soya bean hulls and grain dust for the estimation of animal burden were calculated to be 1.3 and 226 mg/kg respectively.

Residues in animal commodities

Estimation of dietary burdens

Soya beans and processed soya bean products may be fed to dairy cattle, beef cattle, broilers and layers. The maximum and mean dietary burdens were calculated using the highest residue,

STMR/STMR-Ps or median residue of dicamba in commodities for which maximum residue levels were recommended by the 2010 and current JMPR and their processed products on a basis of the OECD Animal Feeding Table.

5-OH Dicamba was not included in the calculation of animal burden as its concentrations in animal feeding items were very low and the feeding study with 5-OH dicamba resulted in very low uptake of 5-OH (< 0.01 mg/kg) into tissues, milk or blood of cattle at a dose equivalent to 59 ppm in the diet.

The resulting maximum and mean dietary burdens to be used for estimating maximum residue levels for commodities of animal origin (both mammals and poultry) were identical to those of the 2010 JMPR.

The Meeting concluded that there was no need to re-evaluate maximum residue levels, STMRs or HRs for commodities of animal origin.

The HR for poultry fat estimated by the 2010 JMPR was corrected to be 0.020 mg/kg.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Dietary Intakes (IEDIs) of dicamba were calculated for the 13 GEMS/Food cluster diets using STMRs and STMRPs estimated by the 2010 and current Meeting (Annex 3). The ADI is 0-0.3 mg/kg bw and the calculated IEDIs were 0-1% of the maximum ADI. The Meeting concluded that the long-term intake of residues of dicamba resulting from the uses considered by the current JMPR is unlikely to present a public health concern.

Short-term intake

The International Estimated Short-Term Intakes (IESTI) of dicamba were calculated for food commodity and its processed commodity using STMRs/STMR-Ps or HRs/HR-Ps estimated by the current Meeting (Annex 4). The ARfD is 0.5 mg/kg bw and the calculated IESTIs were 0% of the ARfD. The Meeting concluded that the short-term intake of residues of dicamba, when used in ways that have been considered by the JMPR, is unlikely to present a public health concern.

5.7 DICHLORVOS (025)

TOXICOLOGY

Dichlorvos is the International Organization for Standardization (ISO)–approved common name for 2,2-dichlorovinyl dimethyl phosphate (International Union of Pure and Applied Chemistry) or 2,2-dichloroethenyl dimethyl phosphate (Chemical Abstracts Service No. 62-73-7). It is a broad-spectrum organophosphorus insecticide, and, like other organophosphorus compounds, its mode of action is via the inhibition of cholinesterase (ChE) activity. The toxicity of dichlorvos was evaluated by the Joint FAO/WHO Meeting on Pesticide Residues in 1965, 1966, 1967, 1970, 1977 and 1993. An acceptable daily intake (ADI) of 0–0.004 mg/kg body weight (bw) was established by the 1966 Meeting and maintained by all subsequent Meetings. Dichlorvos was reviewed by the present Meeting within the periodic review programme of the Codex Committee on Pesticide Residues.

All pivotal studies contained certificates of compliance with principles of good laboratory practice or good clinical practice and the Declaration of Helsinki, as appropriate.

Biochemical aspects

Following oral dosing with ^{14}C-labelled dichlorvos, similar patterns of excretion of radioactivity were observed in mice, rats, hamsters and humans. Excretion was also similar in male and female rats and following both oral and intravenous dosing. Recovery of radioactivity was greater than 90%, with the majority excreted within 24 hours of dosing. The main excretion pathways of radioactivity were via carbon dioxide (30% in mice and humans, 50% in hamsters, up to 60% in rats) and urine (30% in mice, up to 17% in rats, 20% in hamsters and 8% in humans). Relatively low levels of radioactivity were detected in faeces (3% in mice, 5% in hamsters and 13% in rats). The detection of radioactivity in the carcass of mice (30%), rats (26%) and hamsters (15%) is likely due to the incorporation of ^{14}C into protein. Based on the level of radioactivity in carbon dioxide, urine, the carcass and tissues following oral dosing, absorption was estimated to be 92–95% in rats. Analysis of urine identified similar levels of hippuric acid in mice, hamsters and humans (< 1% of the administered dose); desmethyl dichlorvos was detected in mouse and human urine at ~19% and 2%, respectively; and urea was detected at concentrations below 1% in both mouse and human urine. In rats, the levels of hippuric acid and urea were less than 6% and 3–30% of total faecal radioactivity and 4–24% and 19–33% of total urinary radioactivity, respectively; no other metabolites were identified in excreta, which may be due to their volatility or degradation. In rats, approximately 6–13% of urinary metabolites were glucuronidated.

The in vitro half-life of dichlorvos in human blood was less than 15 minutes at 37 ºC.

The level of dermal absorption in rats was 22–30%, which occurred within 10 hours of exposure.

Toxicological data

As with other organophosphorus insecticides, inhibition of ChE activity is the most sensitive toxicological end-point following acute or repeated exposures to dichlorvos.

Dichlorvos has marked acute oral toxicity. In acute oral dosing studies, clinical signs and deaths occurred rapidly in rats and rabbits. Consistent with the cholinergic effects observed with other organophosphorus compounds, signs of acute intoxication with dichlorvos included salivation, lacrimation, dyspnoea and tachypnoea (muscarinic effects), muscle tremors, clonic–tonic spasms, lethargy, paresis, splayed gait, prostration/lateral positioning (nicotinic effects), and restlessness, ataxia and coma (central nervous system effects).

The results of acute toxicity studies evaluated by the current Meeting were consistent with the acute toxicity profile of dichlorvos established by previous Meetings. The oral median lethal dose (LD_{50}) in rats was 57–108 mg/kg bw, whereas the oral LD_{50} in rabbits was 74 mg/kg bw. The dermal LD_{50} in rats was 210 mg/kg bw. In rats and mice, median lethal concentration (LC_{50}) values were 0.23 and greater than 0.22 mg/L, respectively, for head-only exposure to dichlorvos aerosols. It was not possible to determine the skin and eye irritancy potential of dichlorvos because of high levels of toxicity in the study animals. In a non-guideline study, dichlorvos was classifiable as a skin sensitizer in guinea-pigs (maximization test).

The main toxicological findings in repeated-dose studies in rats and dogs were inhibition of ChE activity and, at higher doses, reduced body weight gain and signs of neurotoxicity. In short-term studies of toxicity of less than 12 months' duration, the no-observed-adverse-effect level (NOAEL) for inhibition of erythrocyte acetylcholinesterase (AChE) activity was 0.1 mg/kg bw per day in rats and 0.05 mg/kg bw per day in dogs. The NOAEL for inhibition of brain ChE activity was 1.5 mg/kg bw per day in rats and 0.05 mg/kg bw per day in dogs. Toxicity observed in rats and dogs was limited to the characteristic muscarinic signs (salivation or vomiting) and reduced body weight gain. The effect doses for these clinical signs in short-term studies correlated with moderate levels of inhibition of brain ChE activity (up to ~50%).

Previous Meetings have evaluated more than 10 carcinogenicity studies conducted in mice and rats that received dichlorvos orally (diet, drinking-water or gavage) or by inhalation. The majority of the oral dosing studies and all of the inhalation studies found no evidence of carcinogenicity. The 1993 Meeting concluded that the occurrence of a small number of forestomach lesions in B6C3F1 mice (papillomas) in a United States National Toxicology Program study was attributable to the localized effect of dichlorvos administered by corn oil gavage. The 1993 Meeting concluded that dichlorvos would not result in chronic human health hazards at doses below those that result in AChE inhibition.

No new long-term studies of toxicity or carcinogenicity were considered by the current Meeting. Two drinking-water studies conducted in mice and rats were resubmitted, as the studies now had an improved English translation and had been statistically reanalysed by the authors. Dichlorvos was not carcinogenic under the conditions of either study. In the mouse study, observations of squamous cell hyperplasia, with apparent progression to papillomas in males, suggested treatment-related proliferative changes in the glandular region of the stomach. However, the same findings were not observed in females and were not corroborated by findings from a gavage study using the same mouse strain in which papillomas were observed in the forestomach of females.

Numerous in vitro and in vivo experiments have tested the genotoxic potential of dichlorvos. The 1993 Meeting concluded that dichlorvos and its major metabolite, dichloro-acetaldehyde, had been adequately tested in in vitro and in vivo genotoxicity assays. Unpublished genotoxicity studies evaluated by the current Meeting indicated that dichlorvos was mutagenic to mouse lymphoma cells in vitro (the mutation frequency higher in the absence of exogenous metabolic activation), whereas five unpublished in vivo assays detected no evidence of genotoxicity (mouse dominant lethal assay, mouse chromosomal aberration assay in bone marrow and spermatocytes, sister chromatid exchanges in mice and mouse micronucleus test). Published studies reported a genotoxic response for a number of in vitro end-points, including mutations, chromosomal aberrations, micronuclei, sister chromatid exchanges and deoxyribonucleic acid (DNA) damage. In those published in vivo studies considered suitable for regulatory purposes, dichlorvos was not genotoxic. The consistently negative in vivo genotoxicity response can be attributed to the rapid metabolism of dichlorvos, which limits systemic exposure to intact dichlorvos at concentrations likely to lead to direct interactions with DNA. The occurrence of mutations in the liver of transgenic mice administered repeated intraperitoneal doses is consistent with a mechanism of genotoxicity resulting from high localized tissue concentrations of unmetabolized dichlorvos; in humans, scenarios of prolonged systemic exposure to unmetabolized dichlorvos are highly unlikely.

The Meeting noted the weight of evidence from previously considered carcinogenicity studies, which indicated that dichlorvos possesses no systemic genotoxic potential. Further, the 1993 Meeting noted that dichlorvos methylated DNA in vitro at a rate that is 8–9 orders of magnitude lower than the rate of phosphorylation. Therefore, DNA alkylation is unlikely to occur at doses of dichlorvos that are not inhibitory to erythrocyte/brain ChE activities.

The Meeting concluded that dichlorvos is unlikely to be genotoxic in vivo.

In the absence of an in vivo genotoxic response and any carcinogenic response relevant to humans, the Meeting concluded that dichlorvos is unlikely to pose a carcinogenic risk to humans.

In a two-generation study of reproductive toxicity in rats, in which exposure was via the drinking-water, treatment-related effects included the inhibition of ChE activity and reduced body weight gain. The inhibition of brain ChE activity in parental males and females (up to 50% at the highest dose) was not associated with cholinergic signs. The NOAEL for parental toxicity was 0.5 mg/kg bw per day, based on the inhibition of brain ChE activity at 2 mg/kg bw per day. The NOAEL for offspring toxicity was 2 mg/kg bw per day, based on lower pup weights in both generations at 8 mg/kg bw per day. The NOAEL for reproductive toxicity was 2 mg/kg bw per day, based on reduced fertility and pregnancy indices, increased stillbirths in the F_2 generation and abnormal cycling in F_1 maternal rats at 8 mg/kg bw per day.

Non-guideline studies reported effects on rat sperm following repeated gavage doses of 2–10 mg/kg bw per day, but these were considered to be of questionable biological relevance due to methodological limitations.

In an in vitro assay, dichlorvos did not bind to the human or mouse estrogen receptor and bound with only very low affinity to the human and mouse androgen receptors.

In studies of developmental toxicity with dichlorvos following gavage dosing, teratogenicity was not observed at doses up to 21 and 7 mg/kg bw per day in rats and rabbits, respectively. Maternal toxicity, including cholinergic signs and deaths, was observed at lower doses. In rats, the NOAEL for maternal toxicity was 3 mg/kg bw per day, based on the occurrence of clinical signs (tremors and prone positioning) and reduced body weight gain at 21 mg/kg bw per day. In rabbits, the NOAEL for maternal toxicity was 0.1 mg/kg bw per day, based on the occurrence of deaths at 2.5 mg/kg bw per day and above. It was noted that these deaths occurred at doses lower than the oral LD_{50} for rabbits.

The Meeting concluded that dichlorvos did not cause developmental toxicity and that it was not teratogenic.

In studies of delayed neurotoxicity, dichlorvos was administered by gavage to hens either as a single dose of 16.5 mg/kg bw or as repeated doses of up to 3 mg/kg bw per day for 28 days; there was no evidence of delayed neuropathy. The previous Meeting noted that dichlorvos caused delayed polyneuropathy in hens at doses much higher than the LD_{50}, and cases of delayed polyneuropathy were reported in humans following severe, life-threatening intoxications. A supplementary in vitro study confirmed that dichlorvos is a more potent inhibitor of AChE activity than of neuropathy target esterase (NTE) activity. The Meeting concluded that dichlorvos can cause delayed polyneuropathy in humans, but only after acute poisoning causing a severe cholinergic syndrome that would be lethal if not properly treated.

In studies of neurotoxicity in rats, dichlorvos was administered as a single dose of up to 70 mg/kg bw or as repeated doses of up to 15 mg/kg bw per day. The NOAEL following a single gavage dose was 0.5 mg/kg bw, based on clinical signs of neurotoxicity at 35 mg/kg bw observed during the functional observational battery 15 minutes after dosing; no signs of neurotoxicity were observed 7 or 14 days after dosing. Following repeated gavage doses of up to 15 mg/kg bw per day for 13 weeks, clinical signs of neurotoxicity were observed within 15 minutes of dosing throughout the study, at and above 7.5 mg/kg bw per day. These signs coincided with the inhibition of ChE activity in erythrocytes and brain.

Dichlorvos did not cause developmental neurotoxicity following repeated gavage doses of up to 7.5 mg/kg bw per day. In the range-finding study, inhibition of brain ChE activity occurred in dams (~60%) and pups (~20%) during gestation only, in the absence of clinical signs. In the main and supplementary studies, in which no analysis of ChE activity was undertaken, the NOAEL for maternal and offspring toxicity was 7.5 mg/kg bw per day, the highest tested dose.

In studies investigating the inhibition of ChE activity in rats following an acute gavage dose up to 35 mg/kg bw, the NOAEL for the inhibition of erythrocyte and brain AChE activities was 1 mg/kg bw. At the next highest dose of 5 mg/kg bw, inhibition of erythrocyte and brain AChE activities co-occurred (~30%), whereas clinical signs were not observed until the level of inhibition reached approximately 50% (at and above 15 mg/kg bw). There was no difference in erythrocyte and brain ChE inhibition between rat pups of different ages or between rat pups and adults. Following an acute gavage dose of dichlorvos of 15 mg/kg bw, maximum inhibition of erythrocyte and brain ChE activities was measured at 1–3 hours after dosing, with recovery apparent from 8 hours post-dosing. This observation is consistent with the half-life of spontaneous reactivation of erythrocyte AChE activity reported in previous monographs of approximately 2 hours; in comparison, the half-life of reactivation of human erythrocyte AChE activity is approximately15 days. Following 7 consecutive gavage doses of up to 15 mg/kg bw per day, inhibition of erythrocyte and brain AChE activities occurred at and above 5 mg/kg bw per day; the NOAEL was 0.1 mg/kg bw per day.

The Meeting considered new studies in male volunteers in which dichlorvos was ingested in gelatine capsules either as an acute dose or as short-term repeated doses. No inhibition of erythrocyte AChE activity occurred in six volunteers following a single dose of 0.5 mg/kg bw. These same six volunteers then ingested 0.3 mg/kg bw per day for 12 or 15 days. However, dosing was stopped because inhibition of erythrocyte AChE activity exceeded 20% in four subjects (the mean maximum level of inhibition was ~30%); the NOAEL was less than 0.3 mg/kg bw per day. The recovery of erythrocyte AChE activity to near pre-treatment levels occurred approximately 40 days after the cessation of treatment. In a second acute dose study conducted in a different group of six volunteers, the NOAEL was 1 mg/kg bw, based on the absence of erythrocyte AChE inhibition, adverse events or effects on body temperature at this dose. In a 21-day study conducted in a different six volunteers at a dose of 0.1 mg/kg bw per day, there was a time-related decrease in erythrocyte AChE activity, which reached a mean of 16% on day 18. Although dosing continued for a further 3 days, AChE activity was not analysed again until 4–9 days after the final dose, and therefore there is some uncertainty about whether steady state had been fully reached. Further, three of the six volunteers had a greater than 20% level of erythrocyte AChE inhibition on day 18 or during the post-treatment period, and on this basis, the Meeting concluded that a clear NOAEL had not been demonstrated.

In an occupational study, 15% of flower workers (males and females) tested positive for dichlorvos in a skin patch test.

In workers who were exposed to dichlorvos for short periods of time during the manufacture of vaporization units, recovery of plasma and erythrocyte ChE activities took approximately 50 and 82 days, respectively.

Epidemiological studies provided no evidence for the association of parental pesticide exposure with the development of childhood cancer (cohort of 1218) or the lifetime risk of cancer in pesticide applicators (cohort of 4613).

Case reports provided additional clinical observations in humans following acute cholinergic crisis. These observations included four cases of delayed extrapyramidal syndrome, isolated bilateral vocal cord paralysis with intermediate syndrome and two cases of pancreatitis, one with the possible development of a pseudocyst. In a study involving 41 severely poisoned patients, dichlorvos caused reversible myocardial dysfunction.

In three separately reported cases of fatal ingestion, dichlorvos was detected in various human tissues. However, a meaningful comparison between the cases was difficult because of differences in the ingested dose and sampling interval. A relatively high concentration of dichlorvos was uniquely

detected in the spleen or heart in separate cases, whereas the majority of dichlorvos was detected in the stomach contents. Relatively low concentrations were detected in the liver, brain, blood and urine.

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

Toxicological evaluation

The Meeting confirmed the current ADI of 0–0.004 mg/kg bw based on the NOAEL of 0.04 mg/kg bw per day for the inhibition of erythrocyte AChE activity in a 21-day study in male volunteers (Annex 5, reference *70*). The ADI was previously based on the NOAEL of 0.033 mg/kg bw per day in a 28-day study in male volunteers for the same end-point (Annex 5, reference *9*) and before that on the NOAEL of 0.37 mg/kg bw per day in a 90-day study in dogs for the inhibition of brain ChE activity (Annex 5, reference *7*).

The Meeting considered two new studies conducted in male volunteers at doses higher than those tested in the two pivotal human studies underpinning the current ADI. Neither study was considered a suitable basis for an ADI, because clear NOAELs had not been demonstrated. The Meeting considered the ADI to be protective for other, non-neurotoxic effects of dichlorvos observed in short- and long-term studies with repeated doses and in studies of reproductive and developmental toxicity, where the use of an interspecies safety factor of 10 would be appropriate. The absence of any age- or sex-specific differences in ChE inhibition in rats confirmed the current ADI to be protective of the entire population.

The Meeting established an acute reference dose (ARfD) of 0.1 mg/kg bw, based on the NOAEL of 1 mg/kg bw for erythrocyte AChE inhibition in the acute oral study in male volunteers and using a 10-fold intraspecies safety factor. The NOAEL is supported by observations in two other volunteer studies in which no erythrocyte AChE inhibition occurred 1 day after dosing at 0.5 and 0.1 mg/kg bw, respectively.

An addendum to the toxicological monograph was prepared.

Levels relevant to risk assessment

Species	Study	Effect	NOAEL	LOAEL
Rat	Acute toxicity study[a]	Toxicity (inhibition of brain ChE activity)	1 mg/kg bw	5 mg/kg bw
	Acute neurotoxicity study[a]	Toxicity (clinical signs)	0.5 mg/kg bw	35 mg/kg bw
	Developmental toxicity study[a]	Maternal toxicity	3 mg/kg bw per day	21 mg/kg bw per day
		Embryo and fetal toxicity	21 mg/kg bw per day[b]	—
	Developmental neurotoxicity study[a]	Developmental neurotoxicity, maternal toxicity and offspring toxicity	7.5 mg/kg bw per day[b]	—
	Thirteen-week toxicity study[c]	Toxicity (inhibition of brain ChE activity and clinical signs)	1.5 mg/kg bw per day	15 mg/kg bw per day
	Thirteen-week neurotoxicity study[a]	Toxicity (inhibition of brain ChE activity and clinical signs)	0.1 mg/kg bw per day	7.5 mg/kg bw per day
	Two-generation	Reproductive toxicity	2 mg/kg bw per day	8 mg/kg bw per day

Species	Study	Effect	NOAEL	LOAEL
	reproduction study[d]	Parental toxicity	0.5 mg/kg bw per day	2 mg/kg bw per day
		Offspring toxicity	2 mg/kg bw per day	8 mg/kg bw per day
Rabbit	Developmental toxicity study[a]	Maternal toxicity	0.1 mg/kg bw per day	2.5 mg/kg bw per day
		Embryo and fetal toxicity	7 mg/kg bw per day[b]	—
Dog	One-year toxicity study[e]	Toxicity (inhibition of brain ChE activity and clinical signs)	0.05 mg/kg bw per day	1 mg/kg bw per day
Human	Acute toxicity study[e]	Toxicity (inhibition of erythrocyte AChE activity)	1 mg/kg bw[b]	—
	Twenty-one-day toxicity study[e]	Toxicity (inhibition of erythrocyte AChE activity)	—	0.1 mg/kg bw per day[e]
	Twenty-one-day toxicity study[e,f]	Toxicity (inhibition of erythrocyte AChE activity)	0.04 mg/kg bw per day[b]	—
	Twenty-eight-day toxicity study[e,g]	Toxicity (inhibition of erythrocyte AChE activity)	0.033 mg/kg bw per day[b]	—

[a] Gavage administration.

[b] Highest dose tested.

[c] Dietary administration.

[d] Administration in drinking-water.

[e] Administration in capsules.

[f] Evaluated previously (Annex 5, reference *70*).

[g] Evaluated previously (Annex 5, reference *9*).

Estimate of acceptable daily intake for humans

0–0.004 mg/kg bw

Estimate of acute reference dose

0.1 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 exposures

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

Absorption, distribution, excretion and metabolism in mammals

Rate and extent of oral absorption	Rapid (T_{max} < 0.5 h) and essentially complete (92–95% in rats)

Dermal absorption	22–30% within 10 h (rats)
Distribution	Distributes to most tissues; highest levels of radiolabel detected in the carcass and liver, with lower levels in the blood and kidneys
Potential for accumulation	Low; no evidence of accumulation
Rate and extent of excretion	Rapid (within 24 h) and extensive excretion of radiolabel (mainly via carbon dioxide and urine)
Metabolism in animals	Extensive by hydrolysis and demethylation (in vitro half-life in human blood < 15 min)
Toxicologically significant compounds (animals, plants and the environment)	Dichlorvos, dichloro-acetaldehyde
Acute toxicity	
Rat, LD_{50}, oral	57–108 mg/kg bw
Rat, LD_{50}, dermal	210 mg/kg bw
Rat, LC_{50}, inhalation	0.23 mg/L (4 h, head-only exposure)
Rabbit, dermal irritation	Not assessed due to high toxicity
Rabbit, ocular irritation	Not assessed due to high toxicity
Human, skin sensitization (skin patch test)	Skin sensitizer
Short-term studies of toxicity	
Target/critical effect	Cholinesterase inhibition
Lowest relevant oral NOAEL	0.05 mg/kg bw per day (dogs)
Lowest relevant dermal NOAEL	No new data
Lowest relevant inhalation NOAEC	No new data
Genotoxicity	
	Not genotoxic in vivo following oral dosing
Long-term studies of toxicity and carcinogenicity	
Target/critical effect	Cholinesterase inhibition
Lowest relevant oral NOAEL	No new data
Carcinogenicity	Unlikely to pose a carcinogenic risk to humans
Reproductive toxicity	
Reproduction target/critical effect	Reduced fertility and pregnancy indices, increased stillbirths and abnormal cycling in maternal rats
Lowest relevant reproductive NOAEL	2 mg/kg bw per day (rats)
Developmental target/critical effect	No developmental toxicity, including teratogenicity (rats, rabbits)
Lowest relevant developmental NOAEL	21 mg/kg bw per day (rats), 7 mg/kg bw per day (rabbits); highest doses tested

Neurotoxicity/delayed neurotoxicity	
Neurotoxicity	Neurotoxic due to cholinesterase inhibition
	No evidence of delayed neuropathy up to 16.5 mg/kg bw (hens) or 70 mg/kg bw (rats), the highest doses tested
	Very weak inhibitor of NTE activity in vitro
Lowest relevant oral NOAEL	0.1 mg/kg bw per day (13-week rat study)
Developmental neurotoxicity	No evidence of developmental neurotoxicity up to 7.5 mg/kg bw per day (rats), highest dose tested
Medical data	
	No epidemiological evidence of increased cancer risk in agricultural workers or their children
	Poisoning case reports suggest extrapyramidal syndrome, isolated bilateral vocal cord paralysis, pancreatitis and myocardial dysfunction following acute cholinergic crisis
	Many human volunteer data available with the critical effect of ChE inhibition
	Evidence of polyneuropathy following severe, life-threatening intoxications

Summary

	Value	**Study**	**Safety factor**
ADI	0–0.004 mg/kg bw	Human, 21-day oral dosing study	10
ARfD	0.1 mg/kg bw	Human, study of acute oral toxicity	10

5.8 DICOFOL (026)

TOXICOLOGY

Dicofol is the International Organization for Standardization (ISO)–approved name of 2,2,2-trichloro-1,1-bis(4-chlorophenyl) ethanol (International Union of Pure and Applied Chemistry). Its Chemical Abstracts Service number is 115-32-2. Dicofol is structurally similar to dichlorodiphenyltrichloroethane (DDT). It is a non-systemic acaricide that acts by stimulating axonal transmission of nervous signals.

Dicofol was evaluated by the Joint FAO/WHO Meeting on Pesticide Residues in 1968 and in 1992, when an acceptable daily intake (ADI) of 0–0.002 mg/kg body weight (bw) was established. It was reviewed by the present Meeting within the periodic review programme of the Codex Committee on Pesticide Residues. Relevant parts of the most recent monograph have been incorporated into this toxicological evaluation. New studies on acute and short-term dermal toxicity, dermal hypersensitivity, skin and eye irritation, acute and subchronic neurotoxicity and reproductive toxicity, as well as supplementary studies on reproductive toxicity, carcinogenicity and mutagenicity, were provided and reviewed.

All pivotal studies with dicofol were certified as complying with good laboratory practice.

Biochemical aspects

Dicofol was almost completely and rapidly absorbed from the gastrointestinal tract within 24 hours following an oral dose in rats. Fat contained the highest concentration of dicofol, followed by adrenals, thyroid, liver and whole blood. After a single oral dose, the maximum tissue levels were reached 24–48 hours post-dosing, and the maximum excretion level was attained between 24 and 96 hours after dosing (half-life of 30 hours). The elimination of dicofol from the body was relatively slow, with greater than 65% of administered radioactivity still present in the carcass after 48 hours. Excretion occurred via faeces and urine, faeces being the main route of elimination. There is some indication of accumulation of dicofol in fat. Although dicofol accounts for most of the radioactivity in fat, it is only a minor component of the radioactivity in urine and faeces, indicating extensive metabolism after mobilization. The main metabolites are dichlorobenzhydrol (in males), FW-152 and hydroxyl dichlorobenzophenone (especially in females). Significant conjugation with glycine also occurs.

Toxicological data

The acute oral toxicity (median lethal dose [LD_{50}]) was 669 mg/kg bw in mice, 578 mg/kg bw in rats, 1810 mg/kg bw in rabbits and greater than 4000 mg/kg bw in dogs. Clinical signs of toxicity include decreased spontaneous motor activity, ataxia, passiveness, somnolence, prostration and occasionally tremors. In rabbits, dicofol was a slight to moderate irritant for skin and eyes. It gave a positive response for skin sensitization in a modified Buehler test in guinea-pigs.

In a single-dose gavage study in rats, the no-observed-adverse-effect level (NOAEL) was 15 mg/kg bw, based on decreased feed intake and hypertrophy of the adrenal zona fasciculata at 75 mg/kg bw.

The primary effects of dicofol after short- or long-term exposure were body weight reduction associated with decreased feed intake and increased liver weight accompanied by increased hepatic mixed-function oxidase (MFO) activity and liver hypertrophy in mice, rats and dogs, increased serum alanine aminotransferase (ALT) and serum alkaline phosphatase (AP) activities and hepatocellular necrosis at higher doses. Increases in hepatocyte hypertrophy and liver weight with no other effects were considered to be adaptive and not treated as adverse effects; other histopathological findings in the liver, such as fatty vacuolation and necrosis, were treated as adverse. At high doses, changes in the kidneys, adrenals, heart and testes were also observed in rodents. Reduced serum cortisone levels were seen in dogs, indicating disturbances in adrenocorticoid metabolism.

The short-term effects of dicofol were studied in 90-day feeding studies in mice, rats and dogs and in a 1-year feeding study in dogs.

In a 13-week dietary study in mice, slightly reduced final body weights in both sexes, increased hepatic MFO activity in both sexes and increased absolute and relative liver weights in females (by 20% and 25%) were observed at 125 ppm. At a dose of 250 ppm and above, dicofol induced hepatocellular hypertrophy in both sexes, increased ALT activity in males and females (by 68% and 78%, respectively) and decreased absolute kidney weight in females by 10%. At 500 and 1000 ppm, degenerative changes in the kidney of females, adrenal cortical hypertrophy and hepatocellular necrosis and vacuolation were observed. The no-observed-adverse-effect level (NOAEL) was 125 ppm (equal to 18 mg/kg bw per day), based on increased ALT activity and other liver effects at 250 ppm (equal to 38 mg/kg bw per day).

In a 13-week feeding study in rats, a dose of 1500 ppm caused death in 5 of 10 male and 8 of 10 female rats. The feed intake and mean body weights were significantly decreased in males and females fed diets containing 500 ppm and above. Clinical signs of scant droppings, soft faeces and/or faeces with mucus were seen in females at 500 ppm. Changes in haematology and clinical chemistry parameters and liver hypertrophy accompanied by increased liver weight were observed at 500 ppm and above. Kidney and adrenal weights were also significantly increased. The incidence and severity of thyroid follicular cell hypertrophy (minimal to marked) were increased in males at 10 ppm and above, but the end-point was considered to be of doubtful toxicological significance, as no changes in thyroid stimulating hormone, thyroxine or triiodothyronine were observed in a long-term toxicity study in rats. The NOAEL was 100 ppm (equal to 6.5 mg/kg bw per day), based on the reduction in mean body weights at 500 ppm (equal to 32 mg/kg bw per day) in both sexes.

In a 13-week dietary study in dogs, the highest tested concentration of 1000 ppm caused death in five of six dogs of each sex. Clinical signs of toxicity (laboured breathing, inactivity, dehydration, red-tinged diarrhoea, incoordination and excessive salivation) were observed at 300 ppm and above. ALT activity was significantly increased at 1000 ppm, and serum AP activity was increased at 300 ppm and above in females. Dicofol at 300 ppm and above caused prolongation of the QT interval. In male dogs fed dietary concentrations of 300 or 1000 ppm, a decrease in spermatogenesis (3/6 and 5/6 males, respectively) and an increase in mean hepatic weights were observed. Gross lesions, as well as microscopic lesions in the liver, testes and heart, were observed at 1000 ppm in both sexes. Dicofol at dietary concentrations of 100 ppm and above caused reduced cortisol response to adrenocorticotropic hormone (ACTH). The NOAEL was 10 ppm (equal to 0.29 mg/kg bw per day), based on reduced cortisol response to ACTH challenge at 100 ppm (equal to 3.3 mg/kg bw per day).

In a 52-week dietary study in dogs, adverse findings occurred only at the highest tested concentration of 180 ppm and were more prominent in males than in females. This concentration resulted in increased serum AP activity and cholesterol levels in males, decreased albumin in both sexes and a significant increase in lactate dehydrogenase activity in females at week 39. Relative (to body and brain weight) liver weights were increased in males but were unchanged in females. Baseline cortisol blood levels were normal, but cortisol response to ACTH challenge (20 units of ACTH; cortisol measured 30 and 90 minutes after challenge) was markedly decreased in both sexes at 180 ppm. Minimal to mild hepatocellular hypertrophy was observed in five of six dogs of each sex. The NOAEL was 30 ppm (equal to 0.82 mg/kg bw per day), based on histological and clinical chemistry changes at 180 ppm (equal to 5.4 mg/kg bw per day).

The overall NOAEL for the two dog studies was considered to be 30 ppm (equal to 0.82 mg/kg bw per day), with an overall lowest-observed-adverse-effect level (LOAEL) of 100 ppm (equal to 3.3 mg/kg bw per day).

In a 78-week toxicity and carcinogenicity study in mice, using time-weighted average dietary concentrations of 264 or 528 ppm (equivalent to 40 or 80 mg/kg bw per day) in males and of 122 and 243 ppm (equivalent to 18 and 36 mg/kg bw per day) in females, an increased number of liver adenomas and carcinomas was observed in males at 264 and 528 ppm. The incidence of hepatocellular carcinomas was increased at both doses compared with controls, but there was no pair-wise or trend significance. No treatment-related tumours were observed in female mice at doses up to 243 ppm. Survival in male and female mice was not affected in this study. There was a decrease in the body weights of high-dose females. The body weights of male mice were not affected. The NOAEL in female mice was 122 ppm (equivalent to 18 mg/kg bw per day), based on decreased body weight at 243 ppm (equivalent to 36 mg/kg bw per day). A NOAEL in male mice was not observed. The LOAEL in male mice was 264 ppm (equivalent to 40 mg/kg bw per day), based on the increase in hepatocellular adenomas.

In a 78-week carcinogenicity study in rats, using time-weighted average dietary concentrations of 470 or 940 ppm (equivalent to 24 and 47 mg/kg bw per day) for males and of 380 or 760 ppm (equivalent to 19 and 38 mg/kg bw per day) for females, no treatment-related clinical signs were observed, and no neoplastic or non-neoplastic lesions were associated with dicofol treatment. The NOAEL in this study was 760 ppm (equivalent to 38 mg/kg bw per day), the highest dose tested.

In a 2-year study in rats, terminal body weights were decreased in both males and females at 250 ppm. Both male and female rats fed with dietary concentrations of dicofol of 50 and 250 ppm had decreased feed consumption, increased MFO activity and increased relative liver weight. Treatment-related microscopic changes in the liver, which included hepatocellular necrosis, and vacuolation in adrenal glands were also observed in animals of both sexes that received dicofol at 50 and 250 ppm. The NOAEL was 5 ppm (equal to 0.22 mg/kg bw per day), based on histopathological changes in the liver and adrenal gland at 50 ppm (equal to 2.2 mg/kg bw per day). No treatment-related tumours were observed in this study.

The Meeting concluded that dicofol causes liver tumours in male mice at doses associated with significant enzyme induction and liver hypertrophy, which are anticipated to exhibit a threshold response.

Dicofol gave a negative response in an adequate range of in vitro genotoxicity and in vivo chromosomal aberration tests.

The Meeting concluded that dicofol is unlikely to be genotoxic.

On the basis of the absence of genotoxicity, the absence of carcinogenic effects in rats and the expectation that the adenomas present in mice will exhibit a threshold, the Meeting concluded that dicofol is unlikely to pose a carcinogenic risk to humans at anticipated dietary exposure levels.

In a two-generation reproduction study in rats, F_0 females receiving 125 or 250 ppm showed reduced body weight gain and feed consumption. Treatment-related vacuolation was observed in the liver, ovaries and adrenal glands of F_0 and F_1 parental rats. Offspring toxicity was observed in F_1 and F_2 pups at 125 and 250 ppm. Viability was reduced in F_1 pups at 250 ppm and in F_2 pups at 125 and 250 ppm. The NOAEL for reproductive toxicity was 25 ppm (equal to 2.1 mg/kg bw per day), based on decreased viability at 125 ppm (equal to 10 mg/kg bw per day). The NOAEL for parental toxicity was 5 ppm (equal to 0.5 mg/kg bw per day), based on histopathological changes in the liver and ovaries at 25 ppm (equal to 2.1 mg/kg bw per day). The NOAEL for offspring toxicity was 25 ppm (equal to 2.1 mg/kg bw per day), based on decreased viability index and increased number of litters, with all offspring dying at 125 ppm (equal to 10 mg/kg bw per day).

In an enhanced one-generation study on reproduction in rats, a transient decrease in body weights, organ weight changes (liver, kidney and ovary) and histopathological changes in the liver were observed at the highest dose tested. No treatment-related effects on sperm parameters or other reproductive organs (estrous cycle, sexual maturation) were observed at doses up to 125 ppm. The NOAEL for parental toxicity was 25 ppm (equal to 1.7 mg/kg bw per day), based on the transient decrease in body weight, organ weight changes and histopathological findings in the liver seen at 125 ppm (equal to 8.7 mg/kg bw per day). The NOAEL for reproductive and offspring toxicity was 125 ppm (equal to 8.7 mg/kg bw per day), the highest dose tested.

In a developmental toxicity study in rats, the maternal toxicity NOAEL was 2.5 mg/kg bw per day, based on a statistically significant reduction in maternal body weight gain, decreased feed consumption and feed efficiency and increased relative liver weight at 25 mg/kg bw per day. The increased incidence of salivation observed at 2.5 and 25 mg/kg bw was not confirmed in the range-finding developmental study or an acute neurotoxicity study. Therefore, this was not considered to be related to treatment. The NOAEL for embryotoxicity and teratogenicity was 25 mg/kg bw per day, the highest dose tested.

In a study of developmental toxicity in rabbits, the NOAEL was 4 mg/kg bw per day, based on abnormal faeces (dried, soft or liquid), decreased feed consumption, maternal weight loss, a significant increase in the incidences of abortion (4/19, control 1/18) and increased relative liver weight at 40 mg/kg bw per day. No treatment-related effects on fetal viability, average fetal body weights or external, soft tissue or skeletal examination were observed at doses up to 40 mg/kg bw per day. The NOAEL for embryo and fetal toxicity was 40 mg/kg bw per day, the highest dose tested.

The Meeting concluded that dicofol was not teratogenic.

In an acute neurotoxicity study, the NOAEL was 15 mg/kg bw per day. At 75 and 350 mg/kg bw per day, reduced body weights and feed consumption were observed in both male and female rats; an increased number of rats in these groups had urine-stained or faecal-stained fur. Male and female

rats given the 350 mg/kg bw per day dose had ataxia, other signs of sensorimotor dysfunction and decreased motor activity within the week after treatment. However, these effects were not evident 2 weeks after administration. The neurohistological evaluation of rats in the 350 mg/kg bw per day dose group did not reveal any pathology related to the test substance.

The NOAEL from a 90-day neurotoxicity study was 5 ppm (equivalent to 0.2 mg/kg bw per day), based on affected parameters in the functional observational battery, altered absolute and relative organ weights and reduced body weight, feed consumption values and motor activity at 100 ppm (equal to 6.7 mg/kg bw per day). The neurohistological examination of the 500 ppm group rats did not reveal any pathology related to the test substance.

Reports of cases of acute poisoning indicate that dicofol causes signs and symptoms such as nausea, dizziness, vomiting, confusion and lethargy. The symptoms resolved within 3 weeks. Epidemiological studies on children exposed to dicofol, among other chemicals, were inconclusive.

The Meeting concluded that the existing database on dicofol was adequate to characterize the potential hazard to fetuses, infants and children.

Toxicological evaluation

After evaluation of new information and re-evaluation of previous data, the Meeting confirmed the ADI of 0–0.002 mg/kg bw derived from the NOAEL in the 2-year toxicity and carcinogenicity study in rats of 0.22 mg/kg bw per day, based on histopathological changes in the liver and adrenal gland. A safety factor of 100 was applied. The ADI is supported by the NOAEL of 0.2 mg/kg bw per day from the 90-day neurotoxicity study in rats. There is a margin of 20 000 between the maximum ADI and the LOAEL for liver adenomas in the male mouse.

An acute reference dose (ARfD) of 0.2 mg/kg bw was established on the basis of the NOAEL of 15 mg/kg bw in the acute neurotoxicity study in rats, based on decreased body weight and decreased feed intake at 75 mg/kg bw. This ARfD was supported by the NOAEL of 15 mg/kg bw in a single-dose oral toxicity study in rats, based on decreased feed intake and hypertrophy of adrenal zona fasciculata at 75 mg/kg bw. Although these effects were mild, they were observed in two studies, and therefore 75 mg/kg bw was considered a marginal LOAEL. A safety factor of 100 was applied.

An addendum to the toxicological monograph was prepared.

Levels relevant to risk assessment

Species	Study	Effect	NOAEL	LOAEL
Mouse	Thirteen-week study of toxicity[a]	Toxicity	125 ppm, equal to 18 mg/kg bw per day	250 ppm, equal to 38 mg/kg bw per day
	Seventy-eight-week study of toxicity and carcinogenicity[a]	Toxicity	122 ppm, equivalent to 18 mg/kg bw per day	243 ppm, equivalent to 36 mg/kg bw per day
		Carcinogenicity[b]	—	264 ppm, equivalent to 40 mg/kg bw per

Species	Study	Effect	NOAEL	LOAEL
				day[c]
Rat	Thirteen-week study of toxicity[a]	Toxicity	100 ppm, equal to 6.5 mg/kg bw per day	500 ppm, equal to 32 mg/kg/bw
	Two-year studies of toxicity and carcinogenicity[a,d]	Toxicity	5 ppm, equal to 0.22 mg/kg bw per day	50 ppm, equal to 2.2 mg/kg bw per day
		Carcinogenicity	250 ppm, equal to 14 mg/kg bw per day[e]	—
	Single oral dose toxicity[f]	Toxicity	15 mg/kg bw per day	75 mg/kg bw per day
	Two-generation study of reproductive toxicity[a]	Parental toxicity	5 ppm, equal to 0.5 mg/kg bw per day	25 ppm, equal to 2.1 mg/kg bw per day
		Reproductive toxicity	25 ppm, equal to 2.1 mg/kg bw per day	125, equal to 10 mg/kg bw per day
		Offspring toxicity	25 ppm, equal to 2.1 mg/kg bw per day	125 ppm equal to 10 mg/kg bw per day
	One-generation study of reproduction[a]	Parental toxicity	25 ppm, equal to 1.7 mg/kg bw per day	125 ppm, equal to 8.7 mg/kg bw per day
		Reproductive toxicity	125 ppm, equal to 8.7 mg/kg bw per day[e]	—
		Offspring toxicity	125 ppm, equal to 8.7 mg/kg bw per day[e]	—
	Developmental toxicity[f]	Maternal toxicity	2.5 mg/kg bw per day	25 mg/kg bw per day
		Embryo and fetal toxicity	25 mg/kg bw per day[e]	—
	Acute neurotoxicity[f]	Neurotoxicity	15 mg/kg bw per day	75 mg/kg bw per day
	Ninety-day neurotoxicity study[a]	Neurotoxicity	5 ppm, equivalent to 0.2 mg/kg bw per day	100 ppm, equivalent to 6.7 mg/kg bw per day
Rabbit	Developmental toxicity[f]	Maternal toxicity	4 mg/kg bw per day	40 mg/kg bw per day
		Embryo and fetal toxicity	40 mg/kg bw per day[e]	—
Dog	Thirteen-week and 1-year studies of toxicity[a,d]	Toxicity	30 ppm, equal to 0.82 mg/kg bw per day	100 ppm, equal to 3.3 mg/kg bw per day

[a] Dietary administration.

[b] Male liver adenomas only.

[c] Lowest dose tested.

[d] Two or more studies combined.

[e] Highest dose tested.

[f] Gavage administration.

Estimate of acceptable daily intake for humans

0–0.002 mg/kg bw

Estimate of acute reference dose

0.2 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 dicofol

Absorption, distribution, excretion and metabolism in mammals	
Rate and extent of oral absorption	Extensively absorbed from the gastrointestinal tract within 24 h
Distribution	Adipose tissue > adrenal gland > thyroid > liver > whole blood
Potential for accumulation	Slightly, in fat
Rate and extent of excretion	Majority excreted within 96 h, primarily in faeces
Metabolism in animals	Metabolism involved dechlorination and oxidation of the ethanol moiety and hydroxylation of the aromatic rings
Toxicologically significant compounds (animals, plants and the environment)	Dicofol
Acute toxicity	
Rat, LD_{50}, oral	578 mg/kg bw (purity 94–96%)
Rat, LD_{50}, dermal	> 5000 mg/kg bw
Rat, LC_{50}, inhalation	> 5.0 mg/L
Rabbit, skin irritation	Slight to moderately irritating
Rabbit, eye irritation	Slight to moderately irritating
Guinea-pig, skin sensitization (Buehler test)	Slight to moderate sensitizer
Short-term studies of toxicity	
Target/critical effect	Decreased body weight; reduced cortisol response (dogs)
Lowest relevant oral NOAEL	0.82 mg/kg bw per day (dogs)
Lowest relevant dermal NOAEL	3 mg/kg bw per day (90-day study in dogs)
Lowest relevant inhalation NOAEC	Not available

Genotoxicity	
	Not genotoxic
Long-term studies of toxicity and carcinogenicity	
Target/critical effect	Decreased body weight, hepatocellular necrosis, increased ALT and AP
Lowest relevant NOAEL	0.22 mg/kg bw per day (2-year toxicity/carcinogenicity study in rats)
Carcinogenicity	Unlikely to pose a carcinogenic risk to humans at anticipated dietary exposure levels
Reproductive toxicity	
Reproduction target/critical effect	Decreased viability index (rats)
Lowest relevant reproductive NOAEL	2.1 mg/kg bw per day
Developmental target/critical effect	None
Lowest relevant developmental NOAEL	40 mg/kg bw per day (highest dose tested)
Neurotoxicity/delayed neurotoxicity	
Acute neurotoxicity target/critical effect	Ataxia, decreased motor activity at systemically toxic dose
Lowest relevant acute neurotoxicity NOAEL	15 mg/kg bw
Subchronic neurotoxicity target/critical effect	Decreased motor activity at systemically toxic doses
Lowest relevant subchronic neurotoxicity NOAEL	0.2 mg/kg bw per day (90-day neurotoxicity study)
Other toxicological studies	
	No data
Medical data	
	Reversible neurological effects and nonspecific symptoms after acute poisoning

Summary

	Value	Study	Safety factor
ADI	0–0.002 mg/kg bw	Chronic toxicity/carcinogenicity study in rats supported by the 90-day neurotoxicity study in rats	100
ARfD	0.2 mg/kg bw	Acute neurotoxicity study in rats	100

5.9 DIFLUBENZURON (130)

RESIDUE AND ANALYTICAL ASPECTS

Diflubenzuron [1-(4-chlorophenyl)-3-(2,6-difluorobenzoyl)urea] is an agricultural insect growth regulator. It was originally evaluated by the JMPR in 1981 and re-evaluated for residues several times up to 1988.

Under the periodic review program, toxicology data was re-evaluated by JMPR in 2001. The original ADI of 0–0.02 mg/kg bw/day was re-confirmed and an acute reference dose was unnecessary. The compound was re-evaluated for residues by the JMPR in 2002.

This Meeting received information on the residue analysis, storage stability, use patterns and supervised field residue trials for peaches, plums, peppers, mustard greens, barley, wheat, almond, pecan and peanut.

Analytical methods

The Meeting received details of several analytical methods used in supervised residue trials and in studies on storage stability, which are primarily based on the methods previously reviewed by JMPR in 2002, with some modifications to minimize matrix interference. All methods are single methods for determination of diflubenzuron.

For determination of diflubenzuron, HPLC analysis with UV detection was validated for almond, mustard greens, peppers, peanuts, barley and wheat. The limits of quantification were 0.005 or 0.05 mg/kg for almond hulls, 0.05 mg/kg for almond nutmeat, mustard green, peach, peanut nutmeat and oil, wheat and wheat processed commodities, 0.005 mg/kg for peppers, 0.5 mg/kg for peanut meal and peanut hay. GC-ECD analysis was validated for peppers with an LOQ of 0.05 mg/kg.

Stability of residues in stored analytical samples

The Meeting received data on the stability of residues in plant products (almond nutmeat and hulls, peach, plum, mustard greens, peanut nutmeat, peanut hay, peanut meal, peanut oil, wheat forage, wheat hay, wheat grain, wheat straw, wheat flour and wheat germ) in the corresponding supervised residue trials. The storage stability data covered the period of storage of field samples for residue analysis. The lowest freezer temperature was -24 ºC. The average freezer temperature was -18 ºC.

Diflubenzuron residues in fortified samples were stable over a period of 13 months frozen storage for peaches, 12 months for peppers and 14 months for mustard greens. Residues in fortified samples of wheat grain were stable for 296 days, barley straw for 301 days, wheat forage for 422 days and wheat hay for 337 days of frozen storage.

For wheat processed commodities, diflubenzuron residue is also stable in wheat flour for 6 months and wheat germ for 12 months of frozen storage.

In almond nutmeat, diflubenzuron residues were stable over a period of 12 months of frozen storage.

In peanuts, diflubenzuron was stable in nutmeat for 295 days, hay for 356 days, peanut meal for 643 days, and refined oil for 365days.

Results of supervised trials on crops

The Meeting received supervised residue trials data following foliar application of diflubenzuron on peaches, plums, peppers, mustard greens, barley, wheat, almonds, pecans and peanuts.

Residues of diflubenzuron were reported in all studies. Supervised field trials conducted with different formulations (wettable powders, suspensions concentrates and wettable granules), but with identical crop varieties, locations and spray dates were not considered as independent. The highest result according to the corresponding GAP was selected in these cases. Where multiple samples were taken from a single plot and individual results are reported, the mean value is used for estimation of maximum residue level.

The OECD calculator was used as a tool in the estimation of the maximum residue level from the selected residue data set obtained from trials conducted according to GAP. As a first step, the Meeting reviewed all relevant factors related to each data set in arriving at a best estimate of the maximum residue level using expert judgment. Then, the OECD calculator was employed. If the statistical calculation spreadsheet suggested a different value from that recommended by the JMPR, a brief explanation of the deviation was supplied.

Peaches and Plums

Five field trials on peaches and three trials on plums conducted in 2005 in the USA matched the critical USA GAP for stone fruit, which is two applications at a rate of 0.28 kg ai/ha (interval 14 days) with a PHI of 14 days.

Residues of diflubenzuron in peaches from trials matching GAP, in ranked order, were (n = 5): 0.12, 0.17, 0.20, 0.21 and 0.23 mg/kg.

The ranked order of diflubenzuron residue data in plums matching GAP were (n = 3): 0.08, 0.17 and 0.17 mg/kg.

Individually there were insufficient trials from each crop to estimate commodity maximum residue levels. As the residue levels found were from similar populations, the Meeting agreed that the two data sets could be used for mutual support and decided to combine the data for evaluation. Residues found on peaches and plums, in ranked order, were (n = 8): 0.08, 0.12, 0.17, 0.17, 0.17, 0.20, 0.21 and 0.23 mg/kg.

The Meeting agreed to estimate an STMR of 0.17 mg/kg, and recommended a maximum residue level of 0.5 mg/kg for diflubenzuron in peaches and plums (including prunes). Further the Meeting agreed to extrapolate these recommendations to nectarines.

Mustard greens

Eight field trials on mustard greens were conducted in the USA during 2001 growing season matched the USA GAP, which is a maximum of four foliar applications at a rate of 0.07 kg ai/ha with a PHI of 7 days.

Residues of diflubenzuron found on mustard greens, in ranked order, were (n = 8): < 0.05, 1.0, 1.1, 1.2, 1.5, 2.1, 2.5 and 6.8 mg/kg.

The Meeting agreed to estimate an STMR of 1.35 mg/kg, and recommended a maximum residue level of 10 mg/kg for mustard greens.

Sweet peppers

Six field trials on sweet peppers and three field trials on chili peppers were conducted in the USA in 1997 according to the GAP of the USA, i.e., a maximum of five foliar applications at a rate of 0.14 kg ai/ha with a PHI of 7 days.

Residues of diflubenzuron found on sweet peppers, in ranked order, were (n = 6): 0.07, 0.07, 0.08, 0.24, 0.24, and 0.33 mg/kg.

The ranked order of diflubenzuron residue data in chili peppers were (n = 3): 0.25, 0.92 and 0.94 mg/kg.

It was considered that the datasets for sweet peppers and chili peppers were not from similar residue populations and as a consequence could not be combined. On the basis of the data fro sweet peppers the Meeting agreed to estimate an STMR of 0.16 mg/kg, and recommended a maximum residue level of 0.7 mg/kg for sweet peppers.

As chili peppers are a minor crop, the Meeting agreed to estimate an STMR of 0.92 mg/kg, and recommended a maximum residue level of 3 mg/kg for chili peppers.

On the basis of the STMR and maximum residue level for chili peppers and the default dehydration factor of 7, the Meeting estimated an STMR of 6.44 mg/kg, and recommended a maximum residue level of 20 mg/kg for chili peppers, dry.

Cereal grains

Wheat and barley

Seven field trials on barley and three field trials on wheat were conducted in the USA between 2002 and 2003 growing seasons following the USA GAP for barley, wheat, oats and triticale, which is a maximum of one foliar application at a rate of 0.07 kg ai/ha up to boot stage (BBCH 41).

The diflubenzuron residue data in barley grain from trial according to GAP were (n = 7): < 0.05, < 0.05, < 0.05, < 0.05, < 0.05, < 0.05 and < 0.05 mg/kg.

The diflubenzuron residue data in wheat grain from trial according to GAP were (n = 3): < 0.05, < 0.05 and < 0.05 mg/kg.

As the applications from seven trials on barley and three trials on wheat before boot stage (BBCH 41) resulted in residue data below the LOQ of 0.05 mg/kg, the Meeting decided to combine the two datasets together for the evaluation.

The Meeting agreed to estimate an STMR of 0.05 mg/kg, and recommended a maximum residue level of 0.05* mg/kg for barley and wheat, and agreed to extrapolate these recommendation to oats and triticale.

Tree nuts

Almonds and pecans

For almonds, five field trials in 1998 and two field trials in 2003 were conducted in the USA, and for pecan five trials were conducted in 1999 in the USA.

In almond nutmeat, two trials followed the USA GAP for tree nuts, which is a maximum of four foliar applications at a rate of 0.28 kg ai/ha with PHI 28 days, the residue data were 0.033 and 0.048 mg/kg. The LOQ for these trials was 0.005 mg/kg.

Five trials were conducted with twice rate at PHI of 28 days and all residue data were below LOQ of 0.05 mg/kg.

In pecan kernels, all residue data in five trials with twice rate at PHI of 28 days were below LOQ of 0.05 mg/kg

The Meeting agreed to combine all residue data for the evaluation. The diflubenzuron residue data in almond nutmeat and pecan kernels from trial were (n = 12): 0.033, 0.048 and < 0.05 (10) mg/kg.

Considering the maximum residue value on individual replicate sample prior to averaging up to 0.089 mg/kg (mean trial value was 0.045 mg/kg), the Meeting agreed to estimate an STMR of 0.05 mg/kg, and recommended a maximum residue level of 0.2 mg/kg for tree nuts.

Peanuts

Field trials were conducted in the USA in the 2001 growing season following the USA GAP of a maximum of three foliar applications at a rate of 0.14 kg ai/ha with PHI of 28 days.

The ranked order of diflubenzuron residue data in peanut nutmeat were (n = 9): < 0.05, < 0.05, < 0.05, < 0.05, < 0.05, < 0.05, < 0.05, 0.05 and 0.06 mg/kg.

The Meeting agreed to estimate an STMR of 0.05 mg/kg, and recommended a maximum residue level of 0.15 mg/kg for peanut nutmeat.

Animal feed commodities

Hay or fodder (dry) of grasses

Seven field trials on barley and three field trials on wheat were conducted in the USA between 2002 and 2003 growing seasons following the USA GAP for barley, wheat, oats and triticale, which is a maximum of one foliar application at a rate of 0.07 kg ai/ha up to boot stage.

In barley hay, the diflubenzuron residue data from trial matching GAP were (n = 7): 0.11, 0.46, 0.58, 0.61, 0.64, 0.74 and 1.4 mg/kg.

Residues of diflubenzuron found in wheat hay following treatments complying with the US GAP were (n = 3): 0.18, 0.88 and 1.2 mg/kg.

The Meeting agreed that the residues found in wheat and barley were from the same population and could be combined for evaluation. The ranked order of diflubenzuron residues found in barley and wheat hay were (n = 10): 0.11, 0.18, 0.46, 0.58, 0.61, 0.64, 0.74, 0.88, 1.2 and 1.4 mg/kg.

The Meeting agreed to estimate a median residue of 0.625 mg/kg, a highest residue of 1.4 mg/kg, and recommend a maximum residue level of 3 mg/kg for hay or fodder (dry) of grasses.

Straw and fodder (dry) of cereal grain

Seven field trials on barley and three field trials on wheat were conducted in the USA between 2002 and 2003 growing seasons matching the GAP of the USA in barley, wheat, oats and triticale, which is a maximum of one foliar application at a rate of 0.07 kg ai/ha up to boot stage.

In barley straw, the diflubenzuron residue data from trial matching GAP were (n = 7): < 0.05, 0.12, 0.18, 0.30, 0.46, 0.54 and 0.56 mg/kg.

In wheat straw, the diflubenzuron residue data from trial matching GAP were (n = 3): 0.06, 0.28 and 0.90 mg/kg.

The Meeting agreed that the residues found in wheat and barley were from the same population and could be combined for evaluation. The ranked order of diflubenzuron residues found in barley and wheat straw were (n = 10): < 0.05, 0.06, 0.12, 0.18, 0.28, 0.30, 0.46, 0.54, 0.56 and 0.90 mg/kg.

The Meeting agreed to estimate a median residue of 0.29 mg/kg, a highest residue of 0.90 mg/kg, and recommend a maximum residue level of 1.5 mg/kg for straw and fodder (dry) of cereal grain.

Almond hulls

Field trials in 1998 and four field trials in 2003 on almonds were conducted in the USA complying with the GAP of the USA, i.e., a maximum of four foliar applications at a rate of 0.28 kg ai/ha with a PHI of 28 days.

Residues in almond hulls from two trials, matching the US GAP, were 2.1 mg/kg and 4.0 mg/kg.

Five trials were conducted at a double rate (0.56 kg ai/ha) and a PHI of 28 days. Residue data from these trials were: 1.0, 1.6, 2.1, 2.3 and 4.4 mg/kg. The Meeting agreed that the results from these trials could be scaled to match the US GAP (0.28 kg ai/ha application rate) by dividing by 2 (0.56/0.28). The proportionally adjusted residues in almond hull were: 0.5, 0.8, 1.05, 1.15 and 2.2 mg/kg.

The Meeting agreed that the two dataset matching the USA GAP were not significantly different and could be combined for evaluation. The combined residue data were (n = 7): 0.5, 0.8, 1.05, 1.15, 2.1, 2.2 and 4.0 mg/kg.

The Meeting agreed to estimate a median residue of 1.15 mg/kg.

Peanut hay

Field trials were conducted in the USA in 2001 growing season following the USA GAP, i.e., 3 × 0.14 kg ai/ha with a PHI of 28 days.

The ranked order of diflubenzuron residue concentrations in peanut hay were (n = 8): 1.6, 1.9, 2.6, 7.1, 7.9, 8.4, 17.0 and 18.4 mg/kg.

The Meeting agreed to estimate a median residue of 7.5 mg/kg, a highest residue of 18.4 mg/kg and recommended a maximum residue level of 40 mg/kg for peanut hay.

Fate of residues during processing

The Meeting did not receive any information on the fate of incurred residue of diflubenzuron in processing of relevant commodities.

Residues of animal commodities

Farm animal dietary burden

In 2002, the JMPR estimated the dietary burden from residues in wet pomace of apples, grass forage, rice grain and rice straw of diflubenzuron residues in farm animals from the diets listed in Appendix IX of the FAO Manual (FAO, 2002).

The present Meeting estimated the dietary burden of diflubenzuron in farm animals on the basis of the diets listed in Appendix X of the FAO Manual (OECD Feedstuffs Derived from Field Crops, FAO, 2009). Calculation from the highest residues, the STMRs (some bulk commodities) and STMR-P values provides the levels in feed suitable for estimating maximum residue levels, while calculation from the STMRs and STMR-P values for feed is suitable for estimating STMR values for animal commodities. Dietary burden calculations for beef cattle, dairy cattle, broilers and laying poultry are provided in Annex 6.

The present Meeting calculated the dietary burdens from residues in wet pomace of apples, grass forage, rice grain, rice straw, barley and wheat grain, hay, straw, almond hulls, and peanut hay. The results are summarized in the following table.

	Livestock dietary burden, diflubenzuron, ppm of dry matter diet			
	US/CAN	EU	Australia	Japan

	max	mean	max	mean	max	mean	max	mean
Beef cattle	0.27	0.13	11.52	4.82	20.99[a]	8.11[b]	1.41	0.38
Dairy cattle	13.45	5.19	12.77	4.73	20.99[c]	8.02[d]	2.14	0.69
Poultry-broiler	0.04	0.04	0.04	0.04	0.04	0.04	0.006	0.006
Poultry-layer	0.04	0.04	2.05[e]	0.71[f]	0.04	0.04		

[a] Highest maximum beef or dairy cattle burden suitable for maximum residue level estimates for mammalian meat

[b] Highest mean beef or dairy cattle dietary burden suitable for STMR estimates for mammalian meat.

[c] Highest maximum dairy cattle dietary burden suitable for maximum residue level estimates for milk.

[d] Highest mean dairy cattle dietary burden suitable for STMR estimates for milk.

[e] Highest maximum poultry dietary burden suitable for maximum residue level estimates for poultry meat and eggs.

[f] Highest mean poultry dietary burden suitable for STMR estimates for poultry meat and eggs.

The dietary burdens were recalculated using the OECD tables and the addition of barley and wheat grain, hay straw, almond hulls, and peanut hay to the animal feed diet did not significantly increase the dietary burden value. The Meeting decided that it is not necessary to re-evaluated animal commodities for maximum residue levels.

DIETARY RISK ASSESSMENT

Long-term intake

The acceptable daily intake (ADI) of 0–0.02 mg/kg bw/day based on the NOAEL for haematological effects of 2 mg/kg bw per day in a 2-year studies in rats and the 52-week study in dogs was re-confirmed by 2001 JMPR.

International Estimated Daily Intake (IEDI) was calculated for commodities of human consumption for which STMRs for diflubenzuron were estimated. Results are presented in Annex 3. The IEDI for the 13 GEMS/Food cluster diets were only 2–10% of the maximum ADI. The intake of residues of diflubenzuron resulting from its proposed uses is unlikely to present a public health concern.

Short-term intake

The JMPR in 2001 concluded that it was unnecessary to establish an ARfD, and therefore the short-term intake of diflubenzuron residues is unlikely to present a public health concern.

5.10 EMAMECTIN BENZOATE (247)

TOXICOLOGY

Emamectin benzoate is the International Organization for Standardization (ISO)–approved name for (4″*R*)-4″-deoxy-4″-(methylamino)avermectin B1 benzoate, with Chemical Abstracts Service No. 155569-91-8. It is a macrocyclic lactone insecticide derived from the avermectin series of natural products. It is a mixture of at least 90% (4″*R*)-4″-deoxy-4″-(methylamino)avermectin B1a benzoate and at most 10% (4 *R*)-4″-deoxy-4″-(methylamino)avermectin B1b benzoate salts. Emamectin is structurally similar to abamectin and ivermectin.

Emamectin was originally developed as the hydrochloride salt MK 243 (L-656,748-010V), but the commercial product was subsequently changed to the benzoate salt MK 244 (L-656,748-038W) and benzoate hydrate (L-656,748-052S) because of superior storage and handling characteristics. Studies were performed with emamectin benzoate, unless stated otherwise. Emamectin is being evaluated for the first time by the Joint FAO/WHO Meeting on Pesticide Residues at the request of the Codex Committee on Pesticide Residues.

All critical studies complied with good laboratory practice.

Biochemical aspects

After administration of a single oral dose (0.5 mg/kg body weight [bw]) of emamectin to rats, maximum concentrations in blood and plasma were reached after 4–12 hours, and emamectin was eliminated with plasma half-lives of 20–51 hours. Comparison of area under the curve values following oral and intravenous dosing indicated that the oral absorption of emamectin benzoate was 55–74%. There is no consistent evidence for a sex difference in oral absorption. The radiolabel was widely distributed to the tissues, with the highest levels in small intestine, caecum, spleen, liver, lung and adrenals at 3 hours and in pituitary gland, sublingual glands, Harderian glands, large intestine and lung at 24 hours. The lowest concentrations were found in the brain and spinal cord. Excretion occurred predominantly through faeces, most between 24 and 48 hours after dosing. After 2–3 days, more than 90% of the administered dose of 0.5 mg/kg bw was excreted. Following oral or intravenous administration, emamectin was excreted via bile (2–17%), and only a very small amount was excreted in urine (~1%); the major and remaining portion was excreted in the faeces through efflux transportation into the intestinal tract. Intestinal secretion of emamectin is the main route of elimination, which is consistent with the known role of p-glycoprotein as an efflux transporter of avermectins. Following a single oral dose of 20 mg/kg bw, the maximum concentrations in blood and plasma were reached after 5–8 hours and were approximately 40 times higher than those observed after a single low dose. Also in these high-dose rats, radioactivity levels in other tissues were 40–100 times higher and excretion from the body took 2 days longer in comparison with the low-dose rats. Therefore, these kinetic parameters indicate dose proportionality. Tissue distribution and the proportions eliminated by different routes were similar following the single low and high doses. Administration with a repeated low dose of 0.5 mg/kg bw per day for 14 days resulted in similar kinetics as compared with a single low dose. A steady state with a maximum concentration in plasma 2 times higher than after a single low dose was reached at the seventh dose. Tissue distribution after the repeated low dose was similar to that observed after a single low dose, but with 2 times higher radioactivity levels. Comparison of blood kinetics and excretion between the benzoate hydrate and benzoate salt and between the benzoate salt and hydrochloride salt in dogs indicates that they have similar absorption and kinetics in the blood and similar route and rates of excretion. One metabolite, AB1a, is formed by *N*-demethylation of emamectin and accounts for up to 30% of the administered dose.

Toxicological data

The median lethal dose (LD_{50}) values for emamectin benzoate dissolved in carboxymethylcellulose were 53–237 mg/kg bw in two rat studies. The LD_{50} for emamectin benzoate hydrate dissolved in carboxymethylcellulose was 58 mg/kg bw. LD_{50} values for emamectin hydrochloride, using water as vehicle, were 67–88 mg/kg bw in two rat studies. Signs of toxicity at high doses included ptosis, hypoactivity, tremors, ataxia, salivation, irritability, bradypnoea, diarrhoea, anogenital staining, reduced faecal volume and weight loss. The LD_{50} for dermal toxicity was 500–2000 mg/kg bw in rats, and the 4-hour acute inhalation median lethal concentration (LC_{50}) was 0.663 mg/L in female rats, but greater than 1.049 mg/L in male rats. Emamectin was slightly irritating to the skin and moderately irritating to the eye of rabbits. Emamectin was not a skin sensitizer in a local lymph node assay in mice.

The primary effect of emamectin was neurotoxicity, as observed in acute neurotoxicity studies in rats and in short-term toxicity studies in rats, rabbits and dogs. In a 13-week dietary range-finding study and a 14-day dietary neurotoxicity study in mice, no signs of neurotoxicity were observed at doses up to 15 mg/kg bw per day.

In a 90-day dietary study with emamectin hydrochloride in rats, the no-observed-adverse-effect level (NOAEL) was 0.5 mg/kg bw per day, based on cytoplasmic vacuolation of neurons in the brain observed in males at 2.5 mg/kg bw per day.

In a 14-week gavage study with emamectin hydrochloride and a 1-year oral (gavage) study in dogs, the overall NOAEL was 0.25 mg/kg bw per day, based on histological changes in the brain, spinal cord and sciatic nerve and clinical signs of neurotoxicity at 0.5 mg/kg bw per day.

In several studies, changes in body weight gain and feed consumption were observed. A decrease in body weight gain was observed in mice, rats and dogs at doses equal to or greater than 5.0, 2.5 and 0.75 mg/kg bw, respectively. However, increased body weight gain was also observed in several studies in rats at 1.0–2.5 mg/kg bw per day. Such increases in body weight gain have been observed previously upon treatment with ivermectin and are generally characteristic of avermectins. As the mechanism by which avermectins increase body weight gain is unknown, the Meeting considered that this effect should be considered potentially adverse and could not be disregarded.

In a 1-year dietary study in rats, the NOAEL was 0.1 mg/kg bw per day, based on increased body weight gain observed at 1.0 mg/kg bw per day.

In a 79-week study in mice, the NOAEL was 2.5 mg/kg bw per day, based on clinical signs of toxicity and reduced body weight gain observed at 5.1 mg/kg bw per day. No effect of emamectin on tumour incidence was found at doses up to and including 7.6 mg/kg bw per day, the highest dose tested.

In a 2-year study in rats, the NOAEL was 0.25 mg/kg bw per day, based on an increase in body weight gain and increases in triglyceride concentrations in serum and relative kidney weight at 1.0 mg/kg bw per day. No increased incidence of tumours was observed at doses up to 2.5 mg/kg bw per day, the highest dose tested.

The overall NOAEL for the 1-year and 2-year dietary studies in rats was 0.25 mg/kg bw per day, based on the effects observed at 1.0 mg/kg bw per day.

The Meeting concluded that emamectin is not carcinogenic in rodents.

Emamectin was tested in an adequate range of in vitro genotoxicity tests and one in vivo test. No evidence for genotoxicity was observed in any test.

The Meeting concluded that emamectin is unlikely to be genotoxic.

In view of the lack of genotoxicity and the absence of carcinogenicity in rats and mice, the Meeting concluded that emamectin is unlikely to pose a carcinogenic risk to humans.

A two-generation study of reproductive toxicity in the rat was performed with doses of 0, 0.1, 0.6 and 3.6 mg/kg bw per day. Based on marked clinical signs of toxicity observed in F_{1a} pups, the high dose was reduced to 1.8 mg/kg bw per day during the course of the study. The NOAEL for parental toxicity was 0.6 mg/kg bw per day, based on decreased body weight gain, decreased feed consumption and neuron degeneration observed at 3.6 (reduced to 1.8) mg/kg bw per day. The NOAEL for reproductive toxicity was 0.6 mg/kg bw per day, based on decreased fecundity at 3.6 (reduced to 1.8) mg/kg bw per day. The NOAEL for offspring toxicity was 0.6 mg/kg bw per day, based on clinical signs of neurotoxicity, decreased body weight gain and neuron degeneration observed at 3.6 (reduced to 1.8) mg/kg bw per day.

Other emamectin-like substances also induce postnatal toxicity in rats over a time period similar to that observed with emamectin. For these closely related compounds, it has been shown that these effects are a direct consequence of low p-glycoprotein levels in the neonatal rat brain and incomplete development of the blood–brain barrier. In the developing human fetus, adult levels of p-glycoprotein expression are attained by about 28 weeks of gestation, reflecting the integrity of the blood–brain barrier prior to birth. Therefore, the Meeting considered that human neonates are less susceptible than neonatal rats to neurotoxicity induced by emamectin. The NOAEL for offspring toxicity established from the study of reproductive toxicity in rats is therefore considered to be sufficiently protective for the developing human fetus and neonate.

In a developmental toxicity study in rats, the NOAEL for maternal toxicity was 2 mg/kg bw per day, based on reduced body weight gain at 4 mg/kg bw per day during gestation days 14–20. The NOAEL for fetal toxicity was 4 mg/kg bw per day, based on an increase in fetal resorptions, decreased fetal weight and an increased number of fetuses with skeletal variations and incomplete ossification at 8 mg/kg bw per day.

In a developmental toxicity study in rabbits, the NOAEL for maternal toxicity was 3 mg/kg bw per day, based on clinical signs (mydriasis, decreased pupillary reaction) and decreased body weight gain from gestation days 12 to 28 at 6 mg/kg bw per day. The NOAEL for developmental toxicity in rabbits was 6 mg/kg bw per day, the highest dose tested.

The Meeting concluded that emamectin was not teratogenic in rats or rabbits.

In two acute oral (gavage) neurotoxicity studies in rats, one using emamectin hydrochloride and the other using emamectin benzoate, the overall NOAEL was 5 mg/kg bw, based on clinical signs of neurotoxicity (tremors and irritability) starting at 10 mg/kg bw. At higher doses, salivation, ataxia, bradypnoea, decreased activity, urine staining, loss of righting reflex, hypothermia, ptosis, moist stools and hyperactivity were observed. Degeneration of the white matter in the brains and spinal cord, degeneration of the sciatic nerve and decreased body weight gain were observed at single doses of 25 mg/kg bw and higher.

In a 14-week dietary neurotoxicity study in rats, emamectin induced clinical signs (body tremors, salivation, slightly soiled, urine staining) and changes in the functional observational battery test (tremors, soiled fur, decreased rearing, salivation, abnormal gait, impaired mobility, reduced limb strength or grip strength, reduced righting reflex) at a dose of 4.74 mg/kg bw per day. These signs were first observed during week 7 of treatment. Histological examination of these rats showed degeneration of neurons and white matter in the brain, spinal cord and sciatic nerve and atrophic skeletal muscles. Furthermore, body weight gain and feed consumption were decreased. The NOAEL in this study was 0.95 mg/kg bw per day.

In a developmental neurotoxicity study using emamectin benzoate hydrate, the NOAEL for maternal toxicity was 0.6 mg/kg bw per day, based on an increase in body weight gain during gestation at 2.5 mg/kg bw per day. The NOAEL for offspring toxicity was 0.6 mg/kg bw per day, based on clinical signs (head tremors, body tremors, hindlimb extension, hindlimb splay), decreased motor activity, decreased sensorimotor reflexes and decreased weight gain observed at 2.5 mg/kg bw per day. Clinical signs of toxicity were not observed until postnatal day 6.

A toxicokinetic study and a 2-week neurotoxicity study were performed with CF-1 mice, which are deficient in expression of p-glycoprotein (*Mdr1a* gene). The toxicokinetic study showed increased emamectin concentrations in the brain and slower excretion rates as compared with wild-type mice. In the 2-week neurotoxicity study, the NOAEL was 0.12 mg/kg bw per day, based on mortality and clinical signs of neurotoxicity at 0.34 mg/kg bw per day. Wild-type CD-1 mice did not show mortality or clinical signs of neurotoxicity at 1.7 mg/kg bw, the highest dose tested. The absence of p-glycoprotein has never been shown in humans, and heterozygosity still results in functional p-glycoprotein. The results from CF-1 mice are therefore considered not relevant for human risk assessment. It was previously concluded by WHO that the CF-1 polymorphic mouse is not an appropriate model for human risk assessment for avermectins.

No data on the effects of emamectin in humans were provided.

The Meeting concluded that the existing database on emamectin is sufficient to characterize the potential hazards to fetuses, infants and children.

Toxicological evaluation

The Meeting established an acceptable daily intake (ADI) for emamectin benzoate of 0–0.0005 mg/kg bw on the basis of an overall NOAEL of 0.25 mg/kg bw per day in the 1-year and 2-year rat studies, for increased body weight gain, triglyceride concentrations in serum and relative kidney weight at 1.0 mg/kg bw per day, and on the basis of an overall NOAEL of 0.25 mg/kg bw per day in 14- and 53-week toxicity studies in dogs, for histological changes in the brain, spinal cord and sciatic nerve and clinical signs of neurotoxicity at 0.5 mg/kg bw per day, using a safety factor of 500. An additional safety factor of 5 was applied to the default safety factor of 100, as a number of studies in mice, rats and dogs show steep dose–response curves and irreversible histopathological effects in neural tissue at the lowest-observed-adverse-effect level (LOAEL). A NOAEL based predominantly on such histopathological changes is considered to be less sensitive than the observation of clinical signs. Moreover, in the 1-year dog study, animals were killed in extremis at doses that were only 3 times higher than the NOAEL in this study.

The Meeting established an acute reference dose (ARfD) of 0.03 mg/kg bw for emamectin benzoate, based on a NOAEL of 5 mg/kg bw for clinical signs of neurotoxicity (tremors and irritability) observed in an acute neurotoxicity study in rats at 10 mg/kg bw. A safety factor of 200 was applied, which includes a 2-fold factor based on serious histopathological observations of degeneration of neurons in brain, spinal cord and sciatic nerve at 25 mg/kg bw. Observations of toxicity observed in neonatal rats in reproductive toxicity studies and a developmental neurotoxicity study were considered not relevant for setting an ARfD, as these effects are a direct consequence of low p-glycoprotein levels in the neonatal rat brain and incomplete development of the blood–brain barrier. In the developing human fetus, adult levels of p-glycoprotein expression are attained by about 28 weeks of gestation, reflecting the integrity of the blood–brain barrier prior to birth.

A toxicological monograph was prepared.

Levels relevant for risk assessment

Species	Study	Effect	NOAEL	LOAEL
Mouse	Seventy-nine-week study of toxicity and carcinogenicity[a]	Toxicity	2.5 mg/kg bw per day	5.1 mg/kg bw per day
		Carcinogenicity	5.1 mg/kg bw per day[b]	—
Rat	Fourteen-week study of toxicity[a]	Toxicity	0.5 mg/kg bw per day	2.5 mg/kg bw per day
	One-year study of toxicity and 2-year study of toxicity	Toxicity[c]	0.25 mg/kg bw per day	1.0 mg/kg bw per day
		Carcinogenicity	2.5 mg/kg bw per day[b]	—

Species	Study	Effect	NOAEL	LOAEL
	and carcinogenicity[a]			
	Two-generation study of reproductive toxicity[a]	Parental toxicity	0.6 mg/kg bw per day	1.8/3.6 mg/kg bw per day[c]
		Offspring toxicity	0.6 mg/kg bw per day	1.8/3.6 mg/kg bw per day[c]
		Reproductive toxicity	0.6 mg/kg bw per day	1.8/3.6 mg/kg bw per day[c]
	Developmental toxicity study[d]	Maternal toxicity	2 mg/kg bw per day	4 mg/kg bw per day
		Embryo and fetal toxicity	4 mg/kg bw per day	8 mg/kg bw per day
	Acute neurotoxicity studies[e]	Neurotoxicity	5 mg/kg bw	10 mg/kg bw
	Developmental neurotoxicity study[a]	Maternal toxicity	0.6 mg/kg bw per day	2.5 mg/kg bw per day
		Offspring toxicity	0.6 mg/kg bw per day	2.5 mg/kg bw per day
Rabbit	Developmental toxicity study[d]	Maternal toxicity	3 mg/kg bw per day	6 mg/kg bw per day
		Embryo and fetal toxicity	6 mg/kg bw per day[b]	—
Dog	Fourteen-week and 1-year studies of toxicity[d,e]	Toxicity	0.25 mg/kg bw per day	0.5 mg/kg bw per day

[a] Dietary administration. Dietary concentrations of emamectin were adjusted over the course of the study in order to obtain the required daily doses (mg/kg bw per day) for the different dose groups and sexes. Therefore, ppm values are not presented.

[b] Highest dose tested.

[c] Based on marked clinical signs of toxicity observed in F_{1a} pups, the high dose of 3.6 mg/kg bw per day was reduced to 1.8 mg/kg bw per day during the course of the study.

[d] Gavage administration.

[e] Two studies combined.

Estimate of acceptable daily intake for humans

0–0.0005 mg/kg bw

Estimate of acute reference dose

0.03 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 exposures in humans

Critical end-points for setting guidance values for exposure to emamectin benzoate

Absorption, distribution, excretion and metabolism in mammals	
Rate and extent of oral absorption	55–74% (female rats)
Distribution	Widely distributed (rats)

Potential for accumulation	Low
Rate and extent of excretion	At 0.5 mg/kg bw, > 90% excretion within 72 h, mainly via faeces through efflux transportation from the blood to the intestine; ~1% excretion in urine (rats)
	Plasma half-lives (0.5 mg/kg bw): 20–51 h
	Plasma half-lives (20 mg/kg bw): 35–36 h
Bioequivalence	Emamectin benzoate hydrate, benzoate salt and hydrochloride salt have similar oral absorption, blood kinetics and excretion (dogs)
Metabolism in animals	Limited, metabolism via N-demethylation to form the metabolite AB1 (rat)
Toxicologically significant compounds (animals, plants and the environment)	Emamectin benzoate
Acute toxicity	
Rat, LD50, oral	Emamectin benzoate dissolved in carboxymethylcellulose: 53–237 mg/kg bw
	Emamectin benzoate hydrate dissolved in carboxymethylcellulose: 58 mg/kg bw
	Emamectin hydrochloride dissolved in water: 67–88 mg/kg bw
Rat, LD50, dermal	500–1000 mg/kg bw (males), 1893 mg/kg bw (females)
Rat, LC50, inhalation	> 1.049 mg/L (males), 0.663 mg/L (females)
Rabbit, dermal irritation	Slightly irritating to the skin
Rabbit, ocular irritation	Moderately irritating to the eye
Mice, dermal sensitization (local lymph node assay)	Not sensitizing
Short-term studies of toxicity	
Target/critical effect	Nervous system (clinical signs, lesions in brain, spinal cord, sciatic nerve) (rat, rabbit, dog)
	Body weight increase (rat)
Lowest relevant oral NOAEL	0.25 mg/kg bw per day (dog), 0.1 mg/kg bw per day (rat)
Lowest relevant dermal NOAEL	No data
Lowest relevant inhalatory NOAEC	No data
Genotoxicity	
	Not genotoxic
Long-term studies of toxicity and carcinogenicity	
Target/critical effect	Increased body weight gain (both sexes), increased relative kidney weight in males, increased serum triglyceride levels in females (rats)
Lowest relevant NOAEL	0.25 mg/kg bw per day (rat)
Carcinogenicity	Not carcinogenic (mouse, rat)
Reproductive toxicity	
Reproduction target/critical effect	Decreased fecundity
Lowest relevant reproductive NOAEL	0.6 mg/kg bw per day (rat)

Developmental target / critical effect	Decreased fetal weight, increased number of skeletal variations and delayed ossification
Lowest relevant developmental NOAEL	4 mg/kg bw per day (rat)
Neurotoxicity/delayed neurotoxicity	
Acute oral neurotoxicity, NOAEL	5.0 mg/kg bw (rat); tremors, irritability
Acute dermal neurotoxicity, NOAEL	< 500 mg/kg bw (rabbit, lowest dose tested); degeneration of brain, spinal cord, peripheral nerve, tremors, mydriasis
Ninety-day neurotoxicity, NOAEL	0.95 mg/kg bw per day (rat); tremors, degeneration and vacuolation in brain, spinal cord, sciatic nerve
Developmental neurotoxicity, NOAEL	0.6 mg/kg bw per day (rat, offspring); reduced weight gain, tremors, hindlimb extension/splay, decreased motor activity, delayed development of sex organs
Medical data	
	No data

Summary

	Value	Study	Safety factor
ADI	0–0.0005 mg/kg bw	One-year and 2-year studies of toxicity in rat; 14-week and 1-year studies of toxicity in dogs	500
ARfD	0.03 mg/kg bw	Acute neurotoxicity study in rats	200

RESIDUE AND ANALYTICAL ASPECTS

Residue and analytical aspects of emamectin benzoate were considered for the first time by the present Meeting. The toxicological and residue evaluation was scheduled for the 2011 JMPR by the Forty-second Session of the 2010 CCPR (ALINORM 10/33/24).

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 has registered uses in many countries on fruits, vegetables, cereals, tree nuts, oilseeds, herbs and tea.

Other related avermectins are abamectin, ivermectin, doramectin and eprinomectin of which abamectin has been evaluated before by JMPR and abamectin and the other avermectins have been evaluated by JECFA.

The manufacturer supplied information on identity, metabolism, storage stability, residue analysis, use pattern, residues resulting from supervised trials on pome fruit, stone fruit, grapes, brassica vegetables, fruiting vegetables, leafy vegetables, legume vegetables, cottonseed, fate of residues during processing, and livestock feeding studies. In addition, Japan supplied information on use patterns.

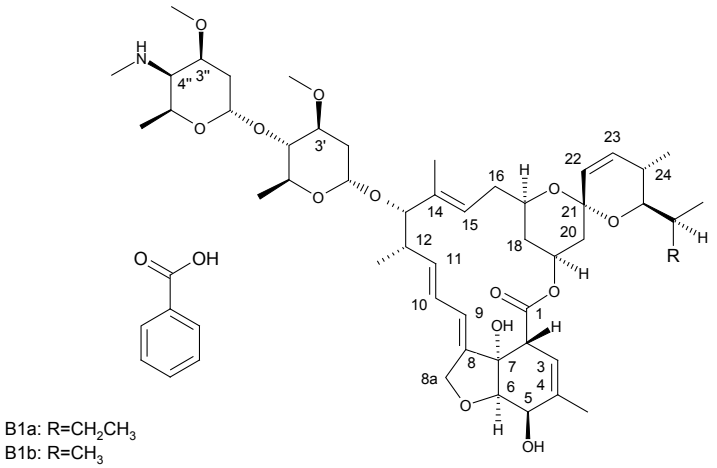
Chemical name

Emamectin exists in various forms: as emamectin (free base), as emamectin benzoate salt (MK244) and as emamectin hydrochloride (MK243). Emamectin benzoate exists as the anhydrous and various hydrated forms having different crystal morphologies. The amount of water is nonstoichiometric.

Experiments described in this evaluation were carried out with a non-specified hydrate form of the emamectin benzoate salt.

Emamectin benzoate (MK-0244) is the common name for 4"-deoxy-4"-epi-methylamino-avermectin B1 (MAB1), which is a mixture of 4"-deoxy-4"-epi-methylamino-avermectin B1a benzoate (MAB1a or emamectin B1a benzoate) and 4"-deoxy-4"-epi-methylamino-avermectin B1b benzoate (MAB1b or emamectin B1b benzoate). The avermectins in emamectin benzoate are specified as a ratio MAB1a:MAB1b=90:10 (w/w) and differ by a methylene group at the C26 alkyl substituent: $–CH_2CH_3$ for MAB1a and $-CH_3$ for MAB1b.

Structural formula:



R = CH_2CH_3 for emamectin B1a benzoate; R = CH_3 for emamectin B1b benzoate

Metabolites referred to in the appraisal by codes:

8,9-ZMa/b	8,9-Z isomer of emamectin B1a or B1b
AB1a/b	des-N-methyl derivative of emamectin B1a or B1b
MFB1a/b	N-formyl derivative of emamectin B1a or B1b
8,9-ZMFB1a/b	8,9-Z isomer of MFB1a/b
FAB1a/b	N-formyl-des-N-methyl derivative of emamectin B1a or B1b
8a-OHMAB1a/b	8a-hydroxy derivative of emamectin B1a or B1b
8a-OHMFB1a/b	8a-hydroxy derivative of MFB1a/b
8a-OXOMAB1a/b	8a-oxo derivative of emamectin B1a or B1b
8a-OXOMFB1a/b	8a-oxo derivative of MFB1a/b
15-OHB1a/b	15OH derivative of emamectin B1a or B1b
24-OH MAB1a/b	24-hydroxymethyl derivative of emamectin B1a or B1b
24-OH AB1a/b	24-hydroxymethyl derivative of AB1a/b
MSB1a/b	monosaccharide B1a or B1b;
OXIB1a/b	4"-oxime-avermectin B1a or B1b
ACROB1a/b	4"-deoxy-4"-epi-(N-propenal-N-methyl)-avermectin B1a or B1b
di-epoxide	10,11-14,15-di-epoxide derivative of emamectin B1a or B1b
milbemectin B	aglycone of B1a or B1b

Animal metabolism

The Meeting received results of animal metabolism studies in lactating goats and in laying hens. Experiments were carried out with the emamectin B1a benzoate variant only, labelled as [5-^{3}H] emamectin B1a benzoate and [25-^{14}C] emamectin B1a benzoate. Residues are expressed as emamectin B1a benzoate equivalents.

Metabolism in laboratory animals was summarized and evaluated by the WHO panel of the JMPR in 2011.

Lactating goats, orally treated once daily for 7 consecutive days with radio-labelled emamectin B1a benzoate, were sacrificed 10 hours after the last dose. Three goats received an actual dose rate of 8.5 ± 1.1 mg ai/kg feed (0.50 mg ai/kg bw) of [5-^{3}H]emamectin benzoate daily. One goat received 9.6 mg ai/kg feed (0.66 mg ai/kg bw) of a mixture of 5-^{3}H-emamectin benzoate plus [25-^{14}C]emamectin benzoate daily. Nearly all radioactivity (94–105% of the total administered radioactivity, TAR) was accounted for in the faeces and GI tract contents of all four goats. The contribution from urine, milk and tissues was 1% TAR. The average radioactivity levels from the ^{3}H dosed goats were 1.0 mg/kg eq (liver), 0.50 mg/kg eq (kidney), 0.12 mg/kg eq (leg muscle), 0.096 mg/kg eq (loin muscle), 0.28 mg/kg eq (omental fat) and 0.28 mg/kg eq (renal fat), respectively. There was no significant difference in tissue radioactivity levels from ^{3}H-and ^{14}C-emamectin benzoate treated goats. Radioactivity levels in whole milk during days 1–7 ranged from 0.007–0.057 mg/kg eq in the [^{3}H] and]^{3}H/^{14}C] dosed goats. Radioactivity levels in afternoon milk were higher than residue levels in morning milk (just before the next dosing). Average radioactivity levels in combined afternoon/morning milk increased slightly (factor 2.4) during the treatment period and a plateau was not reached within 7 days of treatment. Radioactivity levels in skim milk ranged from 0.006–0.040 mg/kg eq for ^{3}H and ^{3}H/^{14}C dosed goats, while radioactivity levels in cream ranged from 0.040–0.35 mg/kg eq for ^{3}H and ^{3}H/^{14}C dosed goats. Total radioactive residues in cream were on average 6.3 fold higher than in whole milk for the ^{3}H and ^{3}H/^{14}C treated goats.

Radioactivity was characterized in all tissues and milk. A total of 70–83% and 56–82% of the total radioactivity (TRR) could be identified in tissues and milk. Parent emamectin B1a benzoate was the major compound found at 76–78% (liver), 75–77% (kidney), 64–80% (muscle), 73–82% (fat) and 54–79% (milk) of the total radioactivity, respectively. A single metabolite (AB1a) was consistently identified in tissues and milk (0.74–7.8% TRR). Two minor metabolites (each < 3% TRR) of unknown identity, one very polar and one less polar than emamectin B1a benzoate, were inconsistently detected in liver and milk. Part of the extractable residue in tissues and milk remained unidentified (6.2–18% TRR in tissues and 16–38% TRR in milk). Up to 12% TRR remained unextracted.

Ten laying hens, orally treated once daily for 7 consecutive days with radio-labelled emamectin B1a benzoate were sacrificed 20 hours after the last dose. Hens were treated with a mixture of radio-labelled [5-^{3}H] emamectin B1a benzoate and [25-^{14}C] emamectin B1a benzoate at an actual dose rate of 12.8 mg/kg ai in feed/day (equivalent to 1 mg ai/kg bw/day). Total recovery of the applied dose was 78/72% for [^{3}H] and [^{14}C] treatments. The majority of the radioactivity was found in the excreta, GI tract contents and cage wash (92/92% ^{3}H/^{14}C TRR), while 2.5/2.6% ^{3}H/^{14}C TRR was found in tissues (liver, kidney, muscle and fat), 1.8/1.7% [^{3}H/^{14}C] TRR in ovaries and 1.4/1.5% [^{3}H/^{14}C] TRR in egg yolk. Egg white did not contain radioactivity. The radioactivity levels were on average for ^{3}H/^{14}C 3.1/3.1 mg/kg eq in liver, 0.70/0.65 mg/kg eq in kidney, 0.78/0.64 mg/kg eq in abdominal fat, 0.45/0.40 mg/kg eq in muscle fat with adhering skin, 0.15/0.13 mg/kg eq thigh muscle and 0.067/0.061 mg/kg eq in breast muscle. While residue levels in the egg white remained negligible (maximum 0.021/0.004 mg/kg eq, ^{3}H/^{14}C), residue levels in the egg yolk generally increased with treatment period from an average of 0.002/0.001 mg/kg eq [^{3}H/^{14}C] in specimens collected the day after the initial dose (day 2) to an average of 3.1/2.4 mg/kg eq [^{3}H/^{14}C] in specimens collected after application of the last dose (pre-euthanasia).

Radioactivity was characterized in liver, muscle, fat and eggs. At least 74% of the total radioactivity (TRR) could be identified in tissues and eggs. Residues identified in tissues and eggs were parent emamectin B1a benzoate, AB1a, 24-OH MAB1a, and fatty acid conjugates of both 24-OH MAB1a and 24-OH AB1a. The proportion of ^{3}H/^{14}C emamectin B1a benzoate was 37/39% TRR in liver, 60/59% TRR in muscle fat with adhering skin, 58/58% TRR in abdominal fat, 57/49% TRR in thigh muscle, 63/67% TRR in breast muscle and 13/13% to 41/40% in egg yolks. The major metabolites in tissues and eggs were a group of eight fatty acid conjugates of 24-OH MAB1a, ranging

from 32–57% TRR in egg yolks, 22–26% in liver and fat, 15/16% in thigh muscle and to 5.2/5.1% TRR in breast muscle. Finally, minor amounts of AB1a (0.9–3.3% TRR), 24-OH MAB1a (1.3–6.3% TRR) and a group of eight fatty acid conjugates of 24-OH AB1a (0.9–4.8% TRR) were found in all tissues and egg yolks, while 24-OH AB1a was not detected. Upon treatment with lipase, the fatty acid conjugate ester bonds could be cleaved and subsequently 24-OH MAB1a and 24-OH AB1a could be released. Part of the extractable residue in tissues and eggs remained unidentified (11–22% of the total radioactivity). Up to 13% of the total radioactivity remained unextracted.

Animal metabolism summary

Metabolism of emamectin B1a benzoate in livestock involves small changes to the emamectin molecular structure like N-demethylation and hydroxylation followed by conjugation. The emamectin structure itself stays intact. Emamectin B1a benzoate was not extensively metabolised in either rats or goats. In goats emamectin B1a benzoate was the major compound found at 54–82% of the total radioactivity in goat liver, kidney, muscle, fat and milk. The only reported metabolite was AB1a, ranging from 0.74–7.8% TRR in tissues and milk. In chickens, emamectin benzoate was metabolised more intensely with parent remaining as 13–60% TRR and the major metabolite being 24-OH MAB1a. In tissues and egg yolk, nearly all of the 24-OH MAB1a was present as fatty acid conjugates (1.3–6.3% TRR as unconjugated form, 5.1–57%TRR as conjugate), which could be released by lipase treatment. Minor amounts of AB1a (0.9–3.3% TRR), 24-OH MAB1a (1.3–6.3% TRR) and a group of eight fatty acid conjugates of 24-OH AB1a (0.9–4.8% TRR) were found in all tissues and egg yolks, while 24-OH AB1a was not detected. Fatty acid conjugates of 24-OH AB1a could be released by lipase treatment. The poultry specific metabolites 24-OH MAB1a and 24-OH AB1a were not found in rats.

Plant metabolism

The Meeting received information on the fate of emamectin B1a benzoate after foliar spray treatment of fruits (pear trees), leafy crops (lettuce, head cabbage) and cereals (maize). Radio-labelled studies were carried out with the emamectin B1a benzoate variant only, labelled as 23-^{14}C emamectin B1a benzoate in pear and 3, 7, 11, 13, 23-^{14}C-emamectin B1a benzoate for the other crops. Residues are expressed as emamectin B1a benzoate equivalents.

Outdoors grown pear trees were sprayed three times with an SG formulation of [23-^{14}C] emamectin B1a benzoate at a spray concentration 10 g ai/hL (1× rate) or 100 g ai/hL (10× rate) containing 0.125% non-ionic surfactant. Dose rates were equivalent to 3× 16.8 g ai/ha (1× rate) and 3× 168 g ai/ha (10× rate) with an interval of 7 days each. Total radioactive residues in mature fruit samples for the 1×/10× rate were 0.020/0.13 mg/kg eq harvested 48 hours after the first application, 0.15/1.7 mg/kg eq at 14 days after the last application (DAT) and 0.071/1.3 mg/kg eq at DAT = 28 days. The 14 and 28 day fruit samples were 81–89% extractable with methanol/water.

Extracts were fractionated in an 'avermectin-like' fraction and a 'polar fraction'. Parent emamectin B1a benzoate was the only identified component in the 'avermectin-like' fraction ranging from 20–27% TRR in the 48 hour samples to 4.2–8.8% TRR at DAT = 14 and 28. Many unidentified compounds were present in the 'avermectin-like' fraction, none exceeding 0.01 mg/kg eq (1× rate), 0.014 mg/kg eq (10× rate, 48 hours) or 10% TRR (10× rate, day 14 and 28). A significant portion in the polar fraction comprised simple sugars (fructose, glucose, sucrose, maltose, galactose and xylose) and combined sugars with incorporated radioactivity ranging from 9–38% TRR. Radioactivity in the post-extraction solids corresponded to 3.2–13.9% TRR. With more stringent extraction procedures more than half the total radioactivity in the remaining solids was released, with no single fraction accounting for more than 0.005 mg/kg eq (3.7% TRR) in the 1× rate samples and 0.06 mg/kg eq (4.3% TRR) in the 10× rate samples.

Outdoors grown head lettuce was sprayed eight times with an EC formulation of [3, 7, 11, 13, 23-^{14}C]-emamectin B1a benzoate at a spray concentration 6 g ai/hL (1× rate) or 30 g ai/hL (5× rate).

Dose rates were equivalent to 8× 16.8 g ai/ha (1× rate) and 8× 84.0 g ai/ha (5× rate) with an interval of 7 days each. The distribution of radioactive residue from 1× and 5× rate treated crops at all DATs was approximately 25–80% in the head plus wrapper leaves (RAC), 20–75% in the dead leaves, and less than 1% in the roots. Total radioactive residues in the head plus wrapper leaves (RAC) declined from 0.36 to 0.081 mg/kg eq at DAT 0 and 10 for the 1× rate and declined from 1.6 to 0.62 mg/kg at DAT 0 and 10 for the 5× rate. The residue in the RAC was 74–88% extractable with methanol/water. The majority of the radioactivity (> 85% TRR) was located in the wrapper leaves at all PHIs with little translocation to head leaves. The removal of a large proportion of residue by the MeOH rinsing procedure (> 46% TRR) indicated that much of the extractable residue was located on the crop surface.

The major identified component was parent emamectin B1a benzoate (maximum 29% TRR), which decreased with PHI (minimum 2.9% TRR). An unresolved polar fraction (26–58% TRR), which increased with PHI, consisted of a complex mixture of unidentified minor components. Further treatment of the polar fraction indicated the absence of acid-hydrolysable, glucose conjugates or glucuronide conjugates of parent or known metabolites. Most of the remaining radioactivity co-eluted with one of the 'avermectin like' primary metabolites of the parent (MSB1a, FAB1a, MFB1a, 8a-OXOMAB1a, 8a-OHMAB1a, 15-OHB1a, AB1a, and 8,9-ZMa), none of which exceeded 5% TRR (0.01 mg/kg eq) at or after 3 days PHI. The sum of the identified avermectin-like primary metabolites was 5.4–27% TRR and was in the same order of magnitude as the parent compound. Approximately 6.5–12% TRR of the extract remained uncharacterised. Radioactivity in the post-extraction solids corresponded to 12–26% TRR. More stringent extraction attempts released approximately 7% TRR, which was assumed to be associated with lignin and a further 5–10% TRR, which was assumed to be associated with glucose derived from cellulose.

Outdoors grown head cabbage was sprayed eight times with an EC formulation of [3, 7, 11, 13, 23-^{14}C]-emamectin B1a benzoate at a spray concentration 6 g ai/hL (1× rate) or 30 g ai/hL (5× rate) or only once at 120 g ai/hL (20× rate). Dose rates were equivalent to 8× 16.8 g ai/ha (1× rate), 8× 84.0 g ai/ha (5× rate) with an interval of 7 days each or 1× 334 g ai/ha (20× rate). The distribution of radioactive residue from 1× and 5× rate treated crops at all DATs was approximately 70–90% in the head plus wrapper leaves (RAC), 16–33% in the dead leaves, and less than 1% in the roots. Total radioactive residues in the head plus wrapper leaves (RAC) declined from 0.45 to 0.20 mg/kg eq at DAT 0 and 10 for the 1× rate and declined from 2.9 to 1.3 mg/kg at DAT 0 and 10 for the 5× rate. The residue in the RAC was 78–91% extractable with methanol/water. The majority of the radioactivity (> 99% TRR) was located in the wrapper leaves with little translocation to the head. The removal of a large proportion of residue by the MeOH rinsing procedure (39–48% TRR) indicated that much of the extractable residue was located on the crop surface.

The major identified component was parent emamectin B1a benzoate (maximum 34% TRR), which decreased with PHI (minimum 3.2% TRR). A polar fraction (21–58% TRR) consisted of a complex mixture with numerous unidentified minor components (< 5% TRR). Further treatment of the polar fraction indicated the absence of acid-hydrolysable or glucose conjugates of parent or known metabolites. Most of the remaining radioactivity co-eluted with one of the 'avermectin like' primary metabolites of the parent (MSB1a, FAB1a, MFB1a, 8a-OXOMAB1a, 8a-OHMAB1a, AB1a, and 8,9-ZMa), none of which exceeded 10% TRR at or after 3 days PHI. In addition low amounts of 8,9-ZMFB1a, OXIB1a, ACROB1a (tentative), 8a-OHMFB1a (tentative) and 8a-OXOMFB1a (tentative) were identified in 5× rate plants. The sum of the identified avermectin-like primary metabolites was 9.0–32% TRR and was in the same order of magnitude as the parent compound. Approximately 8–13% TRR of the extract remained uncharacterized. Radioactivity in the post-extraction solids corresponded to 20% TRR. More stringent extraction attempts resulted in nearly quantitative release of radioactivity, and radioactivity appeared to be incorporated into glucose and protein.

Outdoors grown sweet corn was sprayed six times with an EC formulation of [3, 7, 11, 13, 23-^{14}C]-emamectin B1a benzoate at a spray concentration 4 g ai/hL (1× rate) or 20 g ai/hL (5× rate) or only once at 80 g ai/hL (20× rate). Dose rates were equivalent to 8× 16.8 g ai/ha (1× rate), 8×

84.0 g ai/ha (5× rate) with an interval of 3–5 days each or 1× 334 g ai/ha (20× rate). At harvest more than 98% of the intercepted radioactivity was located in parts of the crop directly exposed to the spray applications: leaf plus stalk and husk plus silk. Total radioactive residues in the leaf plus stalk (forage) ranged from 0.90–1.2 mg/kg eq at DAT 0–1–3–7 for the 1× rate, 3.5–5.9 mg/kg at DAT 0–1–3–7 for the 5× rate and 3.5–3.8 mg/kg eq at DAT 1–3 for the 20× rate. Total radioactive residues in the sweet corn kernels ranged from 0.018–0.023 mg/kg eq at DAT 0–1–3–7 for the 1× rate, 0.076–0.084 mg/kg at DAT 0–1–3–7 for the 5× rate and < 0.02 mg/kg eq at DAT 1–3 for the 20× rate. There was no significant decline in TRR with PHI in any plant part. The residue in the forage (leaf/stalk, husk) was 74–89% extractable with methanol/water, while extractability was lower (28–52% TRR) in protected parts of the crop (cob and kernels). The removal of a large proportion of residue by the MeOH rinsing procedure (49–57% TRR) from leaf/stalk and husk samples indicated that much of the extractable residue was located on the crop surface.

In sweet corn kernels and cobs from 1× and 5× rate samples, the extractable radioactivity was found almost entirely in the polar fraction (22–53% TRR), with parent emamectin B1a benzoate either absent or at very low concentrations (< 0.008 mg/kg). In forage (leaf plus stalk, husks) from 1× and 5× rate samples the major identified component was parent emamectin B1a benzoate (maximum 23% TRR), which decreased with PHI (minimum 3.1% TRR). The polar fraction (52–70% TRR for leaves/stalk and 22–53% TRR for husk, kernels and cobs) was characterized as a highly complex mixture of sugars (fructose, xylose and galactose in leaves/stalks (22% TRR) and fructose, glucose, sucrose and galactose in kernels and cobs (22–26%TRR)) and unidentified non-sugar metabolites. Acid hydrolysis indicated that conjugates of emamectin B1a benzoate and its avermectin-like metabolites were absent. Most of the remaining radioactivity in the leaf/stalk and husk extracts co-eluted with one of the 'avermectin like' primary metabolites of the parent (MSB1a, FAB1a, MFB1a, 8a-OXOMAB1a, 8a-OHMAB1a, AB1a, and 8,9-ZMa), none of which exceeded 5% TRR. In addition low amounts of 8,9-ZMFB1a and OXIB1a were identified. The sum of the identified avermectin-like primary metabolites was 4.7–16% TRR and was in the same order of magnitude as the parent compound. Furthermore, a large number of unidentified minor residue components were found, none individually exceeding 1.5% TRR. Radioactivity in the post-extraction solids corresponded to 12–17% TRR for leafs/stalks and 54–72% TRR in kernels. More stringent extraction attempts resulted in nearly quantitative release of radioactivity, and radioactivity appeared to be incorporated into plant natural products including phytoglycogen, starch, cellulose, protein and (for leaf/stalks and husks) possibly lignin.

Plant metabolism summary

In fruit, leafy vegetables and cereal forage, parent emamectin B1a benzoate was the only residue identified at significant quantities (2.6–34% TRR, depending on PHI). In cereal grains residues were low and residues could not be assigned to any avermectin-like compound. On the outer surface of leafy vegetables and cereal forage emamectin B1a benzoate metabolises to a large number of ‘avermectin-like’ compounds, none of which contribute more than 10% of the TRR. When summed, these avermectin-like compounds add up to amounts approximately equal to or slightly higher than the parent compound (ratio increasing to factor 2 with PHI). None of the avermectin-like metabolites (except AB1a) was found in rats or livestock. In fruit, leafy vegetables, cereal forage and cereal grains emamectin B1a benzoate undergoes extensive degradation resulting in low concentrations of many polar products (total 21–70% TRR), none of which corresponds to hydrolysable conjugates of either emamectin B1a benzoate or avermectin-like metabolites. A significant portion of these polar products (9.0–38% TRR) was shown to be sugars (xylose, glucose, galactose, sucrose, fructose and maltose). Plant metabolism of these polar residues then incorporates radioactivity into a range of natural plant components like phytoglycogen, starch, cellulose, protein and lignin. Since the majority of the radioactivity was located on the exposed plant parts (e.g., cabbage wrapper leaves) and did not translocate to more hidden plant parts (e.g., cabbage heads), emamectin B1a benzoate is considered non-systemic in plants.

Environmental fate in soil

The Meeting received information on soil photolysis and on rotational crops.

Soil photolysis

The degradation profile for [23-^{14}C]-emamectin B1a benzoate and [23-^{14}C]-emamectin B1b benzoate in a sandy loam soil during a 30 day exposure to artificial sunlight at 25 °C was similar to the dark control. The DT_{50} was 12–19 days in the irradiated samples and 30–34 days in the dark controls, indicating that the rate of degradation was faster in the irradiated samples. Emamectin benzoate degrades to some 'avermectin-like' compounds (FAB1a/b, MFB1a/b, AB1a/b) as well as a large number of unidentified compounds, none of which contribute more than 10% of the applied radioactivity.

The degradation profile for [3, 7, 11, 13, 23-^{14}C]-emamectin B1a benzoate in a sandy loam soil during a 30 day exposure at 25 ºC to artificial sunlight was similar to the dark control. The DT_{50} was 5 days in the irradiated samples and 8 days in the dark controls, indicating that the rate of degradation was faster in the irradiated samples. Emamectin benzoate degrades to some 'avermectin-like' compounds (MSB1a, FAB1a, MFB1a, 8a-OXOMAB1a, 8a-OHMAB1a, AB1a and 8,9-ZMa) as well as a large number of unidentified compounds, none of which contribute more than 10% of the applied radioactivity.

To identify the compounds that are the result of photo-degradation alone, [3,7,11,13,23]-^{14}C-emamectin B1a benzoate was exposed to artificial sunlight on a glass plate during 96 hours. Emamectin benzoate degraded completely in this period: < 0.1% of the applied radioactivity (TAR) remained. Only AB1a (< 0.3% TAR) and benzoic acid (12% TAR) could be identified. The remaining part of the radioactivity (84–85% TAR) were polar photo-degradates, which are considered to be an extremely heterogeneous mixture of very minor and highly degraded residues without any resemblance to the macrocycle of the parent molecule.

These studies confirm that photolysis plays an important role in the degradation of emamectin B1a benzoate and emamectin B1b benzoate.

Rotational crops

In a confined rotational crop study, [3, 7, 11, 13, 23-^{14}C]-emamectin B1a benzoate was sprayed on a sandy loam soil in six weekly applications of 168 g ai/ha. The application was outdoors in Madera, CA, USA. Rotational crops were sown 30, 120/141 and 365 days after application, representing first, second and third rotations. No residues were detected in lettuce, carrot roots and barley forage after first-second-third rotations, while total radioactivity was < 0.009–0.009–< 0.009 mg/kg eq in carrot tops and barley grain, and 0.016–0.030–< 0.009 mg/kg eq in wheat straw after first-second-third rotations. No parent emamectin B1a benzoate and no avermectin-like metabolites could be detected. Residues were characterised as more polar than the parent.

From this study it can be concluded that residues are unlikely to be found in rotational or succeeding crops.

Analytical methods

The Meeting received description and validation data for analytical methods of emamectin B1a benzoate and emamectin B1b benzoate in plant and animal commodities as well as for four of the avermectin-like metabolites 8,9-ZMa, AB1a, MFB1a, and FAB1a in plant commodities.

Four single residue analytical methods were proposed to the Meeting as post-registration monitoring and enforcement methods for emamectin B1a benzoate and emamectin B1b benzoate in plant commodities (RAM 465/01, AVARD 244-92-3) and animal commodities (RAM 489/01 and AVARD 244-95-1). All methods are considered sufficiently validated for the determination

emamectin B1a benzoate and emamectin B1b benzoate. The LOQ ranged from 0.001–0.005 mg/kg. Two methods for plant commodities have been subjected to independent method validation. Compatibility of emamectin B1a benzoate and emamectin B1b benzoate in an existing multi-residue HPLC-MS method (e.g., DFG S19) was not tested, but is desirable.

Method RAM 465/01 and RAM 489/01 and modifications thereof are also sufficiently validated for the avermectin-like metabolites 8,9-ZMa, AB1a, MFB1a, and FAB1a. The LOQ for these methods was 0.001 mg/kg for each matrix and analyte.

HPLC-fluorescence method AVARD 244-92-3 and AVARD 244-95-1 and modifications thereof are considered less suitable for enforcement, since the method cannot discriminate between emamectin B1a benzoate and 8,9-ZMa and between emamectin B1b benzoate and 8,9-ZMb. Residues for parent compound may be overestimated. Although the method claims to quantify also the avermectin-like metabolites AB1a/b, MFB1a/b, and FAB1a/b, recoveries for these analytes are very often below the 70% limit, precision (RSD) was very often above the 20% limit and MFB1a/b and FAB1a/b cannot be separated from each other. Therefore the method is considered not valid for the avermectin-like metabolites.

Method AVARD 244-92-3 was radio-validated using samples from the cabbage metabolism study. Extraction efficiency for the sum of emamectin B1a benzoate and 8,9-ZMa using method AVARD 244-92-3 had similar efficiency compared to the extraction methods used in the metabolism study.

Method AVARD 244-95-3 was radio-validated using samples from the goat metabolism study. Extraction efficiency for the sum of emamectin B1a and 8,9-ZMa using method AVARD 244-95-3 had similar extraction efficiency for goat liver and goat milk as compared to the extraction methods used in the metabolism study.

In addition to the enforcement methods, one additional HPLC-fluorescence method was reported for cottonseeds (AVARD 244-96-01) with an LOQ of 0.002 mg/kg. As for the other HPLC-fluorescence methods the method cannot discriminate between emamectin B1a benzoate and 8,9-ZMa and residues for emamectin B1a benzoate may be overestimated.

Stability of pesticide residues in stored analytical samples

The Meeting received information on the stability of emamectin B1a benzoate and emamectin B1b benzoate and four avermectin-like metabolites 8,9-ZMa, AB1a, MFB1a, and FAB1a in plant commodities stored frozen. No storage stability studies were provided for animal commodities. Since the samples from the animal feeding study were stored longer than 30 days (73 days) after slaughter, it is desirable to have storage stability studies on animal commodities.

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 (273 days) in plant commodities with high oil content (cottonseed), and special plant commodities (cotton gin trash). Storage stability of commodities with high acid content (grapes) and processed commodities (apple pomace and apple juice) has not been reported, but is desirable.

Avermectin-like metabolites 8,9-ZMa, AB1a, MFB1a, and FAB1a were stable when stored at –20 °C or lower for at least 18 months in plant commodities with high water content (tomatoes and green beans with pods), at least 18 months commodities with high starch content (potatoes), while 8,9-ZMa was stable for at least 6 months in commodities with high oil content (cottonseed), and special commodities (cotton gin trash).

All crop commodities from supervised residue trials were analysed within the verified storage stability period, except almond nutmeat (7.2 months). For these commodities the Meeting decided to accept the trials. The storage temperatures in the supervised trials varied. Since parent is shown to be

stable for a long period of time, trials where temperatures during storage were raised to –1 °C, were not rejected.

Definition of the residue

The composition of the residue was investigated for emamectin B1a benzoate in ruminants (lactating goats), poultry (laying hens), fruits (pear), leafy crops (lettuce and head cabbage) and cereals (sweet corn).

Based on the available livestock studies, emamectin B1a benzoate was the major compound found at 54–82% of the total radioactivity in goat livers, kidneys, muscle, fat and milk. In chickens, emamectin B1a benzoate was metabolised more intensely with parent accounting for 13–60% TRR and the major metabolite being the poultry specific 24-OH MAB1a. In tissues and egg yolk, nearly all of the 24-OH MAB1a was present as fatty acid conjugates (1.3–6.3% TRR as unconjugated form, 5.1–57% TRR as conjugate), which could be released by lipase treatment. Other poultry specific metabolites, not found in rats, were fatty acid conjugates of 24-OH AB1a (0.9–4.8% TRR) which could be released by lipase treatment. Inclusion of these poultry specific metabolites 24-OH MAB1a and 24-OH AB1a and their fatty acid conjugates in the residue definition for dietary risk assessment for poultry commodities is considered below.

Since poultry is not exposed to emamectin benzoate from uses considered by the present Meeting, no residues are anticipated in poultry tissues and eggs not even if the dietary burden increases because of possible future changes in the intended use pattern for emamectin. As there is no reasonable expectation of emamectin and its poultry specific metabolites, the Meeting concluded that the residue definition for animal commodities for enforcement and for dietary risk assessment should only include the parent compound.

In the goat metabolism study the distribution of emamectin B1a benzoate in the goat tissues shows a slight preference for fat tissue: emamectin B1a benzoate was found at levels of 0.070–0.11 mg/kg in muscle and 0.22–0.28 mg/kg in fat. In the cow feeding study, emamectin B1a benzoate levels were < 0.002–0.0058 mg/kg in muscle and 0.0021–0.013 mg/kg in fat at the 0.03–0.30 ppm dose levels. In the metabolism study on lactating goats, total radioactive residues in cream were on average 6.3 fold higher than in whole milk. The distribution of the emamectin B1a benzoate itself was not investigated in this study. In the cow feeding study emamectin B1a benzoate levels in cream were 3–10 fold higher than in whole milk and also the log K_{ow} for emamectin benzoate of 5.0 at pH 7 does suggest fat solubility. However, in the cow feeding study emamectin B1a benzoate levels in skim milk (1.2–3.0 mg/kg, 0.30 ppm dose) were only slightly lower than in whole milk (1.7–5.3 mg/kg, 0.30 ppm dose). Since there is only a slight preference for fat in both tissues and milk, the Meeting considers the residue in animal commodities (i.e., emamectin B1a benzoate) not fat soluble.

Based on the available comparative plant metabolism studies, parent emamectin B1a benzoate is the major component (2.6–34% TRR, depending on PHI) in fruits, leafy vegetables and cereal forage. In cereal grains residues were low and residues could not be assigned to any avermectin-like compound. In leafy vegetables and cereal forage emamectin B1a benzoate metabolises to a large number of 'avermectin-like' compounds, none of which contribute more than 10% of the TRR (MSB1a, FAB1a, MFB1a, 8a-OXOMAB1a, 8a-OHMAB1a, 15-OHB1a, AB1a, 8,9-ZMa, 8,9-ZMFB1a, OXIB1a, ACROB1a (tentative), 8a-OHMFB1a (tentative) and 8a-OXOMFB1a (tentative)). None of the avermectin-like metabolites (except AB1a) was found in rats or livestock. Inclusion of these 13 plant specific avermectin-like metabolites in the residue definition for risk assessment of plant commodities is considered below.

In the metabolism studies, eight of the 13 identified avermectin-like metabolites have been quantified (MSB1a, FAB1a, MFB1a, 15-OHB1a, 8a-OXOMAB1a, 8a-OHMAB1a, AB1a and 8,9-ZMa). Each of the eight avermectin-like metabolites at PHI 3–10 days in the leafy crop parts is present at levels below 10% TRR and at levels below parent emamectin B1a benzoate (ratio avermectin-like/parent of 0.2–0.7). When summed, this results in ratios of avermectin-like/parent of

0.9–1.9 (PHI 3d), 1.3–2.5 (PHI 7 d), 2.1–2.8 (PHI 10d) in lettuce, head cabbage and sweet corn forage.

Four of the 13 avermectin-like metabolites (8,9-ZMa, AB1a, MFB1a and FAB1a) have been quantified in the supervised residue trials. Parent emamectin B1a benzoate was generally found at low levels (< 0.001–0.079 mg/kg) in fruits, brassica (PHI > 1d), fruiting vegetables, green beans with pods, tree nuts and cottonseed. Individual avermectin-like metabolites ranged from < 0.001–0.009 mg/kg in these commodities. Only in brassica (PHI 0–1d), lettuce, mustard greens, immature cauliflower plants, bean vines and almond hulls higher levels of emamectin B1a benzoate were found (< 0.001–1.2 mg/kg) and consequently also higher levels of avermectin-like metabolites were found (< 0.001–0.160 mg/kg). Taking all commodities together, the ratios of the four avermectin-like metabolites to parent ranged from 0.00–0.78 (median 0.05 and n = 353), where the emamectin B1a benzoate concentration was at least 0.01 mg/kg. When looking at individual commodities, the median ratios of the four avermectin-like metabolites to parent ranged from 0.00–0.08 for most commodities. Higher median ratios were found for peaches (0.11), head lettuce (0.12), leaf lettuce (0.12), almond hulls (0.27), whole cauliflower plants (0.15), nectarine flesh (0.14), and peach flesh (0.13). When the same four metabolites were summed in the metabolism studies, ratios of the avermectin-like metabolites were only slightly lower than when all eight quantified avermectin like metabolites were included, indicating that the most prominent avermectin-like residues have been quantified in the supervised residue trials.

Supervised residue trials are considered to be more representative for residue levels in commodities than metabolism studies and because levels of avermectin-like metabolites in the supervised residue trials do not contribute substantially to the residue level in commodities (sum of emamectin B1a benzoate and 13 avermectin-like metabolites only a factor 1.00–1.27 higher than emamectin B1a benzoate, depending on commodity), the Meeting agreed that the avermectin-like metabolites need not be included in the residue definition for risk assessment for plant commodities.

The Meeting recommended the following residue definitions for emamectin benzoate:

Definition of the residue for compliance with the MRL or for estimation of the dietary intake for plant and animal commodities: emamectin B1a benzoate.

The Meeting considers the residue not fat soluble.

Results of supervised trials on crops

The Meeting received supervised trials data for emamectin benzoate on apples, pears, nectarines, peaches, grapes, (sprouting) broccoli, cauliflower, head cabbages, cucumber, melons, tomatoes, sweet peppers, Cos lettuce, head lettuce, leaf lettuce, mustard greens, fresh beans with pods, almonds, pecans and cottonseed.

In some trials (apple, pear and grapes) the number of applications was higher than according to GAP. For trials where a sample was taken just before the last application it could be shown that the residues had declined to 4–33% of the emamectin B1a benzoate residues just after the last treatment. This shows that the number of applications does not have a significant effect on the final residue levels. For this reason, the Meeting decided to include trials with an exaggerated number of applications.

In those trials where residues levels were higher at higher PHI than required for critical GAP, these residues were selected instead of the residues at the critical GAP PHI. In trials on the same location where the only difference was the addition of an adjuvant, the maximum value is selected for each of the trial locations. In trials on the same location with the same dose rate in kg ai/ha, where the only difference is the spray volume (i.e., spray concentration), the maximum value is selected for each of the trial locations.

Since in all USA trials (except tree nuts) residues were measured as the sum of emamectin B1a benzoate and the 8,9-ZMa isomer, the residues do not comply with the residue definition. Since

the ratio between the 8,9-ZMa isomer and emamectin B1a benzoate ranged from 0.001–0.18 in various supervised residue trials, where emamectin B1a benzoate was > 0.01 mg/kg, the Meeting decided to use these trials.

The recommendations proposed by the Meeting were compared using the OECD MRL calculator. For those trials where the outcome of the OECD MRL calculator was different from the recommendation made by the Meeting, a rationale is provided for this deviation.

Pome fruits

Field trials involving apples were performed in Italy, Spain, France, Switzerland and the USA.

Critical GAP for apples in Italy is for two foliar spray applications (interval 7 days) at 38.0 g ai/ha and PHI 7 days. In trials from Italy and Spain (3× 29–40 g ai/ha, interval 6–7 days and PHI 7 days) matching this GAP emamectin B1a benzoate residues in apple whole fruit were < 0.001, < 0.001, 0.002, 0.003, 0.004, 0.004, 0.005 and 0.005 mg/kg (n = 8).

Critical GAP for apples in Hungary is for three foliar spray applications (interval 7 days) at 4.75 g ai/hL and PHI 3 days. In trials from Northern France and Switzerland (3 × 3.7–4.2 g ai/hL, interval 6–8 days and PHI 3 days) matching this GAP emamectin B1a benzoate residues in apple whole fruit were 0.004, 0.006, 0.006 and 0.009 mg/kg (n = 4).

Critical GAP for pome fruit in the USA is for an unspecified number of foliar spray applications at 16.8 g ai/ha (max 50.4 g ai/ha per season and interval 7 days) and PHI 14 days. In trials from the USA (3× 17 g ai/ha; interval 7 days and PHI 14–15 days) matching this GAP emamectin B1a benzoate residues in apple whole fruit were < 0.005 (13) mg/kg (n = 13).

The Meeting noted that the GAPs for Italy, Hungary and the USA for apples are different and that data cannot be combined. Although the highest residue is found in the dataset matching Hungarian GAP, this dataset had an insufficient number of data to support a recommendation for apples or pome fruit. The Italian dataset resulted in the next highest residues and the Meeting decided to use only the apple dataset matching Italian GAP.

Field trials involving pears were performed in Spain, France and the USA.

Critical GAP for pears in Italy is for two foliar spray applications (interval 7 days) at 38.0 g ai/ha and PHI 7 days. In trials from Spain (3× 33–38 g ai/ha, interval 7 days and PHI 7 days) matching this GAP emamectin B1a benzoate residues in pear whole fruit were: 0.008 and 0.011 mg/kg (n = 2).

Critical GAP for pears in Hungary is for three foliar spray applications (interval 7 days) at 4.75 g ai/hL and PHI 3 days. In trials from Northern France (3 × 3.7–3.8 g ai/hL, interval 7 days and PHI 3 days) matching this GAP emamectin B1a benzoate residues in pear whole fruit: 0.001 and 0.001 mg/kg (n = 2).

Critical GAP for pome fruit in the USA is for an unspecified number of foliar spray applications at 16.8 g ai/ha (max 50.4 g ai/ha per season and interval 7 days) and PHI 14 days. In trials from the USA (3 × 17 g ai/ha; interval 7 days and PHI 14 days) matching this GAP emamectin B1a benzoate residues in pear whole fruit were < 0.005 (3) and 0.006 (3) mg/kg (n = 5).

The Meeting noted that the GAPs for Italy, Hungary and the USA for pears are different and that data cannot be combined. Each of the datasets has an insufficient number of data to support a recommendation for pears or pome fruit. Since the dataset matching Italian GAP has the highest residue, the Meeting decided to use only the pear dataset matching Italian GAP.

The Meeting noted that Italian GAPs for apples and pears are identical and that the datasets for apples and pears matching Italian GAP were from similar populations (Mann-Whitney U test). Since residue behaviour within the pome fruit group is expected to be similar, the Meeting agreed that the datasets for apples and pears matching Italian GAP could be combined. Emamectin B1a benzoate

residues in apples and pears were: < 0.001, < 0.001, 0.002, 0.003, 0.004, 0.004, 0.005, 0.005, 0.008 and 0.011 mg/kg (n = 10).

The Meeting agreed that the Italian data for apples and pears could be used to support a pome fruit commodity maximum residue level recommendation and estimated a maximum residue level of 0.02 mg/kg on pome fruit and estimated an STMR of 0.004 mg/kg and an HR of 0.011 mg/kg.

Stone fruits

Field trials involving nectarines were performed in Spain.

Critical GAP for peaches & nectarines in Italy is for three foliar spray applications (interval 7 days) at 38.0 g ai/ha and PHI 7 days. In trials from Spain (3× 34–40 g ai/ha, interval 7 days and PHI 7 days) matching this GAP emamectin B1a benzoate residues in nectarine whole fruit were 0.009 and 0.014 mg/kg (n = 2). Corresponding residues in the edible portion (flesh, i.e., fruit without stone and stem but with peel) resulted in: 0.011 and 0.015 mg/kg (n = 2).

Field trials involving peaches were performed in France and Italy.

Critical GAP for peaches & nectarines in Italy is for three foliar spray applications (interval 7 days) at 38.0 g ai/ha and PHI 7 days. In trials from Southern France and Spain (3× 29–38 g ai/ha, interval 7 days and PHI 7 days) matching this GAP emamectin B1a benzoate residues in peach whole fruit were 0.002, 0.003, 0.005, 0.008, 0.009 and 0.010 mg/kg (n = 6). Corresponding residues in the edible portion (flesh, i.e., fruit without stone and stem but with peel) resulted in: 0.002, 0.004, 0.006, 0.009, 0.010 and 0.011 mg/kg (n = 6).

Since residue behaviour for nectarines and peaches is expected to be similar and Italian GAPs for nectarine and peach are identical, the Meeting agreed that the datasets for nectarines and peaches matching Italian GAP could be combined. Emamectin B1a benzoate residues in nectarines and peaches (whole fruit) were: 0.002, 0.003, 0.005, 0.008, 0.009, 0.009, 0.010 and 0.014 mg/kg (n = 8). Corresponding residues in the edible portion (flesh, i.e., fruit without stone and stem but with peel) resulted in: 0.002, 0.004, 0.006, 0.009, 0.010, 0.011 (2) and 0.015 mg/kg (n = 8).

The Meeting agreed that the datasets for nectarines and peaches matching Italian GAP could be used to support a nectarine and peach commodity maximum residue level recommendation. The Meeting estimated a maximum residue level of 0.03 mg/kg on nectarines and peaches and estimated an STMR of 0.0095 mg/kg and an HR of 0.015 mg/kg.

Grapes

Field trials involving grapes were performed in Italy, Spain, France and Switzerland.

Critical GAP for grapes in Italy is for three foliar spray applications (interval 14 days) at 14.2 g ai/ha and PHI 7 days. In trials from Italy, Spain and Southern France (4 × 12–16 g ai/ha, interval 10–15 days and PHI 7 days) matching this GAP emamectin B1a benzoate residues in grape bunches were < 0.001 (3), 0.002, 0.003, 0.009, 0.014 and 0.022 mg/kg (n = 8).

Critical GAP for grapes in Hungary is for three foliar spray applications (interval 10 days) at 14.2 g ai/ha and PHI 7 days. In trials from Northern France and Switzerland (4 × 12–15 g ai/ha, interval 10-14 days and PHI 6–7 days) matching this GAP emamectin B1a benzoate residues in grape bunches were < 0.001 (2), 0.001, 0.003, 0.004 and 0.005 mg/kg (n = 6).

The Meeting noted that the GAP for the Italian and Hungarian datasets was the same. Since the datasets were from similar populations (Mann-Whitney U test), the Meeting agreed that they could be combined. Emamectin B1a benzoate residues in grape bunches were < 0.001 (5), 0.001, 0.002, 0.003, 0.003, 0.004, 0.005, 0.009, 0.014 and 0.022 mg/kg (n = 14).

The Meeting agreed that the combined datasets for grapes matching Italian and Hungarian GAP could be used to support a grape maximum residue level recommendation and estimated a

maximum residue level of 0.03 mg/kg on grapes and estimated an STMR of 0.0025 mg/kg and an HR of 0.022 mg/kg.

Brassica vegetables

Field trials involving broccoli and sprouting broccoli were performed in Spain, France, Germany, United Kingdom, Switzerland and the USA.

Critical GAP for broccoli in Italy is for three foliar spray applications (interval 7 days) at 14.2 g ai/ha and PHI 3 days. In field trials performed in Spain and Southern France (3 × 15 g ai/ha, interval 7 days and PHI 3 days, without adjuvant) matching this GAP emamectin B1a benzoate residues in broccoli and sprouting broccoli (inflorescence) were 0.001 and 0.002 mg/kg (n = 2).

Trials performed in Germany, United Kingdom and Switzerland did not match with any GAP.

Critical GAP for brassica head and stem vegetables in the USA is for an unspecified number of foliar spray applications at 16.8 g ai/ha (max 101 g ai/ha per season, interval 7 days) and PHI 7 days. In broccoli trials from the USA (6–7 × 17–18 g ai/ha; interval 7 days and PHI 6–8 days) matching this GAP emamectin B1a benzoate residues in broccoli (inflorescence) were < 0.005 (3) mg/kg (n = 3).

Field trials involving cauliflower were performed in France, Germany, the United Kingdom and the USA.

Critical GAP for cauliflower in Italy is for three foliar spray applications (interval 7 days) at 14.2 g ai/ha and PHI 3 days. In field trials performed in Southern France (3 × 14–15 g ai/ha, interval 7 days and PHI 3 days) matching this GAP emamectin B1a benzoate residues in cauliflower (inflorescence) were < 0.001 (3) and 0.001 mg/kg (n = 4).

Trials performed in Northern France, Germany and the United Kingdom did not match with any GAP.

Critical GAP for brassica head and stem vegetables in the USA is for an unspecified number of foliar spray applications at 16.8 g ai/ha (max 101 g ai/ha per season, interval 7 days) and PHI 7 days. In cauliflower trials from the USA (9 × 17 g ai/ha; interval 7 days and PHI 6–8 days) matching this GAP emamectin B1a benzoate residues in cauliflower (inflorescence) were < 0.005 mg/kg (n = 1).

Field trials involving head cabbage were performed in Italy, France and the USA.

Critical GAP for head cabbage in Italy is for three foliar spray applications (interval 7 days) at 14.2 g ai/ha and PHI 3 days. In field trials performed in Italy and Southern France (3 × 15–16 g ai/ha, interval 7–8 days and PHI 3 days, without adjuvant) matching this GAP emamectin B1a benzoate residues in head cabbage (whole plant) were < 0.001 (3) and 0.002 mg/kg (n = 4).

Critical GAP for brassica head and stem vegetables in the USA is for an unspecified number of foliar spray applications at 16.8 g ai/ha (max 101 g ai/ha per season and interval 7 days) and PHI 7 days. In head cabbage trials from the USA (6–7 × 17 g ai/ha; interval 6–8 days and PHI 7 days) matching this GAP emamectin B1a benzoate residues in head cabbage (heads only) were < 0.005, < 0.005 and 0.020 mg/kg (n = 3).

The Meeting noted that the GAPs for Italy and the USA were different and therefore trials from the same commodities could not be combined. Data from each of the individual commodities were insufficient to propose a recommendation and combination of USA data for broccoli, cauliflower and head cabbage was not possible because residue distribution differed. The Meeting agreed that the data were insufficient to make a recommendation for brassica vegetables or each of the individual commodities (broccoli, cauliflower and head cabbage).

Fruiting vegetables, Cucurbits

Indoor trials involving cucumbers were performed in Spain, France and Switzerland.

Critical GAP for cucumbers & summer squash in Hungary is for three foliar spray applications (interval 7 days) at 19.0 g ai/ha and PHI 3 days. In indoor trials performed in Spain, Northern France and Switzerland (3× 14–21 g ai/ha, interval 7 days and PHI 3 days) matching this GAP emamectin B1a benzoate residues in cucumber were < 0.001 (2), 0.001 (3) and 0.002 (2) mg/kg (n = 7).

Field trials involving melons were performed in Italy and Spain, but these trials did not match with any GAP.

Indoor trials involving melons were performed in Spain and France.

Critical GAP for melons, watermelons, pumpkins and summer squash in Hungary is for three foliar spray applications (interval 7 days) at 19.0 g ai/ha and PHI 3 days. In indoor trials performed in Spain, Southern France and Northern France (3 × 15–20 g ai/ha, interval 7 days and PHI 3 days) matching this GAP emamectin B1a benzoate residues in melons (whole fruit) were: < 0.001, 0.001 (2), 0.002 (2), 0.003 and 0.004 mg/kg (n = 7). Corresponding residues in the edible portion (pulp) were: < 0.001, < 0.001, < 0.001, ≤ 0.001, < 0.001, < 0.001 and 0.002 mg/kg (n = 7).

The Meeting noted that the Hungarian GAPs for cucumbers, summer squash, melons, watermelons, pumpkins and summer squash cover the whole Codex group of cucurbits and that the trials matching the Hungarian GAPs for cucumbers and melons resulted in similar residues for each of the commodities. The Meeting agreed to propose a group maximum residue level for cucurbits, based on the residue data for melons. Emamectin B1a benzoate residues in melons (whole fruit) were: < 0.001, 0.001, 0.001, 0.002, 0.002, 0.003 and 0.004 mg/kg (n = 7). Corresponding residues in the edible portion (pulp) were: < 0.001, < 0.001, < 0.001, ≤ 0.001, < 0.001, < 0.001 and 0.002 mg/kg (n = 7).

The Meeting agreed that the dataset for melons matching Hungarian GAP could be used to support a maximum residue level recommendation for cucurbits and estimated a maximum residue level of 0.007 mg/kg in/on cucurbits. For cucurbits with edible peel, the Meeting estimated an STMR of 0.001 mg/kg and an HR of 0.002 mg/kg based on the cucumber data. For cucurbits with inedible peel, the Meeting estimated an STMR of 0.001 mg/kg and an HR of 0.002 mg/kg, based on the edible portion data of melons.

The value using the OECD calculator (0.01 mg/kg) was higher than the estimate of 0.007 mg/kg made by the Meeting. The Meeting considers the 0.007 mg/kg value a better estimate, given the values found in the various trials and given that the unrounded MRL estimate of the OECD calculator is 0.0066 mg/kg. It appears that the OECD calculator is not able to propose MRLs below 0.01 mg/kg.

Fruiting vegetables, other than Cucurbits

Field trials involving tomatoes were performed in Spain and France.

Critical GAP for tomatoes in Italy is for three foliar spray applications (interval 7 days) at 14.2 g ai/ha and PHI 3 days. In field trials performed in Spain and Southern France (3 × 14–15 g ai/ha, interval 6–8 days and PHI 3 days) matching this GAP emamectin B1a benzoate residues in tomatoes (whole fruit) were: < 0.001 (2), 0.001 and 0.002 mg/kg (n = 4).

Critical GAP for tomatoes in Hungary is for three foliar spray applications (interval 7 days) at 19.0 g ai/ha and PHI 3 days. In field trials performed in Northern France (3 × 20–21 g ai/ha, interval 7 days and PHI 3 days) matching this GAP emamectin B1a benzoate residues in tomatoes (whole fruit) were: < 0.001 (3) and 0.002 mg/kg (n = 4).

The Meeting noted that the GAPs for Italy and Hungary for tomatoes are different and therefore data cannot be combined. Since the GAP for Hungary can be considered worst case, the Meeting agreed to use only the field-grown tomato dataset matching Hungarian GAP.

Indoor trials involving tomatoes were performed in Italy, Spain, France and the United Kingdom.

Critical GAP for tomatoes in Hungary is for three foliar spray applications (interval 7 days) at 19.0 g ai/ha and PHI 3 days. In indoor trials performed in Italy, Spain, France and the UK (3 × 14–21 g ai/ha, interval 7 days and PHI 3 days) matching this GAP emamectin B1a benzoate residues in tomatoes (whole fruit) were: < 0.001, 0.001 (2), 0.002, 0.003 and 0.004 mg/kg (n = 6) for standard sized tomatoes and 0.003, 0.004 (2), 0.006, 0.007 and 0.008 (2) mg/kg (n = 7) for cherry tomatoes. Since the datasets for standard size tomatoes and cherry tomatoes were from different populations (Mann-Whitney U test), the data cannot be combined. Since the cherry tomato dataset had higher residues, the Meeting decided to use only the cherry tomato data. This resulted in the following dataset for indoor-grown tomatoes: 0.003, 0.004 (2), 0.006, 0.007 and 0.008 (2) mg/kg (n = 7).

The Meeting noted that the residues for field and indoor grown tomatoes resulted from the same Hungarian GAP. Since the datasets were from different populations (Mann-Whitney U test) datasets cannot be combined. The Meeting agreed to use the indoor cherry tomato data to represent field and indoor grown tomatoes. This resulted in the following dataset for field and indoor grown tomatoes: 0.003, 0.004 (2), 0.007, 0.006 and 0.008 (2) mg/kg (n = 7).

Field trials involving sweet peppers were performed in Italy, Spain and France, but trials did not match with any GAP.

Indoor trials involving sweet peppers were performed in Spain, France and the United Kingdom.

Critical GAP for peppers in Hungary is for three foliar spray applications (interval 7 days) at 19.0 g ai/ha and PHI 3 days. In indoor trials performed in Spain, France and the UK (3 × 15–20 g ai/ha, interval 7 days and PHI 3 days) matching this GAP emamectin B1a benzoate residues in sweet peppers (whole fruit) were: < 0.001 (2), 0.002, 0.003 (2), 0.004, 0.007 and 0.013 mg/kg (n = 8).

The Meeting noted that trials matching the Hungarian GAPs for tomatoes and sweet peppers resulted in similar residues for each of the commodities. The Meeting agreed to propose a group maximum residue level for fruiting vegetables other than cucurbits except sweet corn and mushrooms, based on the residue data for sweet peppers. Emamectin B1a benzoate residues in sweet peppers were: < 0.001, < 0.001, 0.002, 0.003, 0.003, 0.004, 0.007 and 0.013 mg/kg (n = 8).

The Meeting estimated a maximum residue level of 0.02 mg/kg in/on fruiting vegetables other than cucurbits except sweet corn and mushrooms and estimated an STMR of 0.003 mg/kg and an HR of 0.013 mg/kg.

The JMPR manual (section 6.9.2) explains that a generic factor may be used for conversion of residues from fresh peppers to dried chilli peppers. The factor is 10 for the estimation of residue levels of pesticides in dried chilli peppers from the HR values estimated for residues in or on sweet peppers.

The Meeting agreed to apply the default factor of 10 for dried chilli peppers to the STMR (0.003 mg/kg) and HR (0.013 mg/kg) values for fruiting vegetables other than cucurbits except sweet corn and mushrooms (based on sweet pepper data) and estimated a maximum residue level, an STMR and an HR in dried chilli peppers of 0.2, 0.03 and 0.13 mg/kg respectively.

Leafy vegetables

Field trials involving Cos lettuce were performed in Italy, Spain and France.

Critical GAP for lettuce and other salad plants in Italy is for three foliar spray applications (interval 7 days) at 14.2 g ai/ha and PHI 3 days. In field trials performed in Italy, Spain and Southern

France (3 × 14–15 g ai/ha, interval 6–9 days and PHI 3 days) matching this GAP emamectin B1a benzoate residues in Cos lettuce were: 0.030, 0.033, 0.042, 0.10 and 0.11 mg/kg (n = 5).

Indoor trials involving Cos lettuce were performed in Italy and France.

Critical GAP for lettuce and other salad plants in Italy is for three foliar spray applications (interval 7 days) at 14.2 g ai/ha and PHI 3 days. In indoor trials performed in Italy and Northern France (3 × 14–15 g ai/ha, interval 7 days and PHI 3 days) matching this GAP emamectin B1a benzoate residues in Cos lettuce were: 0.052, 0.30 and 0.33 mg/kg (n = 3).

The Meeting noted that the residues for field and indoor grown Cos lettuce resulted from the same Italian GAP. Since the datasets were from similar populations (Mann-Whitney U test) the Meeting agreed to combine the datasets. This resulted in the following dataset for field and indoor grown Cos lettuce: 0.030, 0.033, 0.042, 0.052, 0.10, 0.11, 0.30 and 0.33 mg/kg (n = 8)

Field trials involving head lettuce were performed in France, Switzerland and the USA.

Critical GAP for lettuce and other salad plants in Italy is for three foliar spray applications (interval 7 days) at 14.2 g ai/ha and PHI 3 days. In field trials performed in Southern France (3 × 14–15 g ai/ha, interval 7 days and PHI 3 days) matching this GAP emamectin B1a benzoate residues in field-grown head lettuce were: 0.004 mg/kg (n = 1).

Critical GAP for lettuce in Hungary is for three foliar spray applications (interval 7 days) at 19.0 g ai/ha and PHI 3 days. In field trials performed in Northern France and Switzerland (3 × 14–16 g ai/ha, interval 6–7 days and PHI 3 days) matching this GAP emamectin B1a benzoate residues in field-grown head lettuce were: 0.005, 0.007 and 0.016 mg/kg (n = 3).

Critical GAP for leafy vegetables except brassica in the USA is for an unspecified number of foliar spray applications (interval 7 days, total 101 g ai/ha per season) at 16.8 g ai/ha and PHI 7 days. In field trials performed in the USA (6 × 17 g ai/ha, interval 3–8 days and PHI 7 days) matching this GAP emamectin B1a benzoate residues in field-grown head lettuce were: 0.0052, 0.015 and 0.016 mg/kg (n = 3).

The Meeting noted that the GAPs for Italy, Hungary and the USA were different and therefore datasets cannot be combined. Since the Hungarian GAP can be considered worst case, the Meeting agreed to use the dataset matching Hungarian GAP. This resulted in the following dataset for field grown head lettuce: 0.005, 0.007 and 0.016 mg/kg (n = 3).

Indoor trials involving head lettuce were performed in Italy, France, Switzerland and the UK.

Critical GAP for lettuce and other salad plants in Italy is for three foliar spray applications (interval 7 days) at 14.2 g ai/ha and PHI 3 days. In indoor trials performed in Italy, Northern France, Switzerland and the UK (3 × 15–16 g ai/ha, interval 7 days and PHI 3 days) matching this GAP emamectin B1a benzoate residues in indoor-grown head lettuce were: 0.060, 0.15, 0.16, 0.20, 0.26, 0.40 and 0.62 mg/kg (n = 7).

The Meeting noted that the residues for field and indoor grown head lettuce resulted from different GAPs and therefore datasets cannot be combined. Since the dataset for indoor grown head lettuce matching Italian GAP resulted in higher residues, the Meeting agreed to use the dataset for indoor grown head lettuce to represent residues in field and indoor grown head lettuce. This resulted in the following dataset for field and indoor grown head lettuce: 0.060, 0.15, 0.16, 0.20, 0.26, 0.40 and 0.62 mg/kg (n = 7).

Field trials involving leaf lettuce were performed in France.

Critical GAP for lettuce and other salad plants in Italy is for three foliar spray applications (interval 7 days) at 14.2 g ai/ha and PHI 3 days. In field trials performed in Southern France (3× 15 g ai/ha, interval 7 days and PHI 3 days) matching this GAP emamectin B1a benzoate residues in field-grown leaf lettuce were: 0.007 mg/kg (n = 1).

Critical GAP for lettuce in Hungary is for three foliar spray applications (interval 7 days) at 19.0 g ai/ha and PHI 3 days. In field trials performed in Northern France (3 × 14–16 g ai/ha, interval 7 days and PHI 3 days) matching this GAP emamectin B1a benzoate residues in field-grown leaf lettuce were: 0.004 mg/kg (n = 1).

The Meeting noted that the GAPs for Italy and Hungary for lettuce are different and therefore data sets cannot be combined. Since the Italian dataset resulted in highest residues, the Meeting agreed that the dataset matching Italian GAP represented field grown leaf lettuce: 0.007 mg/kg (n = 1).

Indoor trials involving leaf lettuce were performed in Italy.

Critical GAP for lettuce and other salad plants in Italy is for three foliar spray applications (interval 7 days) at 14.2 g ai/ha and PHI 3 days. In indoor trials performed in Italy (3 × 15 g ai/ha, interval 7 days and PHI 3 days) matching this GAP emamectin B1a benzoate residues in indoor-grown leaf lettuce were: 0.18 mg/kg (n = 1).

The Meeting noted that the residues for field and indoor grown leaf lettuce resulted from the same Italian GAP and agreed to combine the datasets to represent residues in field grown and indoor grown leaf lettuce. This resulted in the following dataset for leaf lettuce: 0.007 and 0.18 mg/kg (n = 2).

The Meeting agreed that the dataset for head lettuce matching Italian GAP could be used to support a maximum residue level recommendation for all lettuce varieties and estimated a maximum residue level of 1 mg/kg in/on Cos lettuce, leaf lettuce and head lettuce and estimated an STMR of 0.20 mg/kg and an HR of 0.62 mg/kg.

Field trials involving mustard greens were performed in the USA.

Critical GAP for brassica leafy vegetables in the USA is for an unspecified number of foliar spray applications at 16.8 g ai/ha (max 101 g ai/ha per season and interval 7 days) and PHI 14 days. In mustard green trials from the USA (6 × 17 g ai/ha; interval 6–8 days and PHI 14 days) matching this GAP emamectin B1a benzoate residues in mustard greens were < 0.005 (2), 0.0085, 0.011, 0.014 and 0.11 mg/kg (n = 6).

The Meeting agreed that the dataset for mustard greens matching USA GAP could be used to support a maximum residue level recommendation for mustard greens and estimated a maximum residue level of 0.2 mg/kg in/on mustard greens and estimated an STMR of 0.010 mg/kg and an HR of 0.11 mg/kg.

Legume vegetables

Field trials involving beans with pods were performed in Spain, France and the UK.

Trials performed in Spain and France did not match with any GAP.

Critical GAP for common beans in Hungary is for three foliar spray applications (interval 7 days) at 19.0 g ai/ha and PHI 3 days. In field trials performed in Northern France and the United Kingdom (3 × 19–21 g ai/ha, interval 7–8 days and PHI 3 days) matching this GAP emamectin B1a benzoate residues in common beans were: < 0.001, < 0.001, < 0.001, ≤ 0.001, 0.001, 0.001, 0.001 and 0.009 mg/kg (n = 8).

The Meeting agreed that the dataset for common beans matching Hungarian GAP could be used to support a maximum residue level recommendation for beans, except broad bean and soya beans, green pods and immature seeds, and estimated a maximum residue level of 0.015 mg/kg in/on beans, and estimated an STMR of 0.001 mg/kg and an HR of 0.009 mg/kg.

Tree nuts

Field trials involving almonds were performed in the USA.

Critical GAP for tree nuts in the USA is for three foliar spray applications at 16.8 g ai/ha (max 50.4 g ai/ha per season, interval 7 days) and PHI 14 days. In almond trials from the USA (3 × 17 g ai/ha; interval 7 days and PHI 14 days, with adjuvant) matching this GAP emamectin B1a benzoate residues in almonds (nutmeat) were < 0.001 mg/kg (n = 1).

Field trials involving pecans were performed in the USA.

Critical GAP for tree nuts in the USA is for three foliar spray applications at 16.8 g ai/ha (max 50.4 g ai/ha per season, interval 7 days) and PHI 14 days. In pecan trials from the USA (3 × 17 g ai/ha; interval 7 days and PHI 14 days, with adjuvant) matching this GAP emamectin B1a benzoate residues in pecans (nutmeat) were < 0.001 mg/kg (n = 1).

The dataset for almonds and pecans is considered insufficient to support a recommendation. The Meeting could not estimate an STMR or HR for almonds, pecans or tree nuts.

Oilseed

Field trials involving cotton undelinted seed were performed in the USA.

Critical GAP for cotton in the USA is for an unspecified number of foliar spray applications at 16.8 g ai/ha (max 67.4 g ai/ha per season, interval 5 days) and PHI 21 days. In cotton trials from the USA (4 × 17 g ai/ha; interval 4–6 days and PHI 20–24 days) matching this GAP emamectin B1a benzoate residues in cotton undelinted seed were: < 0.002 (8) mg/kg (n = 8).

The Meeting agreed that the dataset for cotton matching USA GAP could be used to support a maximum residue level recommendation for cotton seed and estimated a maximum residue level of 0.002* mg/kg in/on cotton seed and estimated an STMR of 0.002 mg/kg and an HR of 0.002 mg/kg.

The value using the OECD calculator (0.01 mg/kg) was higher than the estimate of 0.002 mg/kg made by the Meeting. The Meeting considers the 0.002 mg/kg value a better estimate, given the values found in the various trials and given that the unrounded MRL estimate of the OECD calculator is 0.0020 mg/kg. It seems that the OECD calculator is not able to propose MRLs below 0.01 mg/kg.

Legume animal feeds

Field trials involving bean forage (green) were performed in Spain, France and the UK. Trials on bean fodder were not submitted.

Trials performed in Spain and France did not match with any GAP.

Critical GAP for common beans in Hungary is for three foliar spray applications (interval 7 days) at 19.0 g ai/ha and PHI 3 days. In field trials performed in Northern France and the United Kingdom (3 × 19–21 g ai/ha, interval 7–8 days and PHI 3 days) matching this GAP emamectin B1a benzoate residues in bean forage (green) were: 0.002, 0.005, 0.006, 0.007, 0.009, 0.039, 0.058 and 0.093 mg/kg, as received (n = 8).

The Meeting agreed that the dataset for bean vines matching Hungarian GAP could be used and estimated a median residue of 0.008 mg/kg and a high residue of 0.093 mg/kg in/on bean forage (green). Since green bean forage is not traded, a maximum residue level estimation is not required.

Miscellaneous fodder and forage crops

Field trials involving almond hulls were performed in the USA.

Critical GAP for tree nuts in the USA is for three foliar spray applications at 16.8 g ai/ha (max 50.4 g ai/ha per season and interval 7 days) and PHI 14 days. In almond trials from the USA (3 × 17 g ai/ha; interval 7 days and PHI 14 days, with adjuvant) matching this GAP emamectin B1a benzoate residues in almonds (nutmeat) were 0.043 mg/kg, as received (n = 1).

The dataset for almond hulls is considered insufficient to support a recommendation. The Meeting could not estimate a median residue for almond hulls.

Field trials involving cotton gin by-products were performed in the USA.

Critical GAP for cotton in the USA is for an unspecified number of foliar spray applications at 16.8 g ai/ha (max 67.4 g ai/ha per season, interval 5 days) and PHI 21 days. In cotton trials from the USA (4 × 17 g ai/ha; interval 4–6 days, PHI 20–24 days) matching this GAP emamectin B1a benzoate residues in cotton gin by-products were: 0.0022, 0.0025 and 0.0038 mg/kg (n = 3).

The dataset for cotton gin by-products is considered insufficient to support a recommendation. The Meeting could not estimate a median or highest residue for cotton gin by-products.

Fate of residues during processing

Information on the fate of residues during processing by radioactivity studies showed that 23-^{14}C emamectin B1a benzoate undergoes limited hydrolysis under standard conditions used to simulate food processing operations. Break down products formed were the monosaccharide MSB1a (pH 5, 100 °C and pH 6, 120 °C), the aglycone milbemectin B (pH 5, 100 °C)) and the des-N-methyl derivative AB1a (pH 6, 120 °C). The extent of hydrolysis of emamectin B1a benzoate increases with pH and temperature, but all breakdown products are < 10% applied radioactivity under the standard processing conditions used. The Meeting agreed that the residue definition does not need adaption for processed commodities.

Processing studies with emamectin benzoate were undertaken for apples and cottonseed. In the table below, relevant processing factors for these commodities are summarized.

Using the $STMR_{RAC}$ obtained from emamectin benzoate use, the Meeting estimated STMR-Ps for processed commodities as listed below. The Meeting considered the appropriate STMR-P to be used in the livestock dietary burden calculation or dietary intake calculation. An HR-P is not required for processed commodities.

Commodity	Processing factors (PF)	STMR-P = $STMR_{RAC}$× PF mg/kg
Apple pomace (wet)	5.1 (n = 1)	0.004 × 5.1 = 0.0051 (pome fruits)
Apple juice	< 0.7 (n = 1)	0.004 × 0.7 = 0.0028 (pome fruits)
Cottonseed meal	< 0.1 (n = 1)	0.002 × 0.1 = 0.0002 (cottonseed)
Cottonseed hulls	0.28 (n = 1)	0.002 × 0.28 = 0.00056 (cottonseed)
Cottonseed, refined oil	0.38 (n = 1)	0.002 × 0.38 = 0.00076 (cottonseed)

Livestock dietary burden

The Meeting estimated the dietary burden of emamectin benzoate residues on the basis of the livestock diets listed in the FAO manual appendix IX (OECD feedstuff table). Calculation from highest residue, STMR (some bulk commodities) and STMR-P values provides the levels in feed suitable for estimating maximum residue levels, while calculation from STMR and STMR-P values from feed is suitable for estimating STMR values for animal commodities.

All plant commodities used in the dietary burden calculation are listed below. Dietary burden for livestock might be underestimated, since residue data are not available for several feedstuff derived from crops treated with emamectin benzoate.

Codex Group	CROP	FEED STUFF	Highest residue	STMR or STMR-P	DM (%)

AL	Bean	vines	0.093	0.008	35
AB	Apple	pomace, wet	–	0.0051	40
SO	Cotton	undelinted seed	0.002	0.002	88
SM	Cotton	hulls	–	0.00056	90
SM	Cotton	meal	–	0.0002	89

Dietary burden calculations for beef cattle, dairy cattle, broilers and laying poultry are provided in Annex 6. A mean and maximum dietary burden for livestock, based on emamectin benzoate use, is shown in the table below.

Animal dietary burden for emamectin benzoate, expressed as ppm of dry matter diet

	US	EU	AU	JPN	overall	
	max	max	max	max	max	
beef cattle	0.000062	0.0026	0.16	–	0.16 (AU)	
dairy cattle	0.0015	0.055	0.19	–	0.19 (AU)	[a,b]
poultry broiler	–	–	–	–	–	
poultry layer	–	–	–	–	–	–
	mean	mean	mean	mean	mean	
beef cattle	0.000062	0.0026	0.017	–	0.017 (AU)	
dairy cattle	0.0015	0.0061	0.018	–	0.018 (AU)	[a,b]
poultry broiler	–	–	–	–	–	
poultry layer	–	–	–	–	–	–

[a] Highest mean and maximum beef or dairy cattle dietary burden suitable for maximum residue level and STMR estimates for mammalian meat.

[b] Highest mean and maximum dairy cattle dietary burden suitable for maximum residue level and STMR estimates for milk.

Livestock feeding studies

The Meeting received a feeding study on lactating cows.

Four groups of three lactating Holstein-Friesian cows were dosed once daily via capsules at levels of 0.00, 0.03, 0.09 and 0.30 ppm dry weight feed for 28 consecutive days. Milk was collected throughout the study and tissues were collected on day 28 within 24 hours after the last dose. Residues in milk achieved a plateau level after approximately 5 consecutive days of dosing. Since the analytical method cannot discriminate between emamectin B1a benzoate and 8,9-ZMa, residues are the sum of both. Since metabolism studies have shown that 8,9-ZMa is not formed in livestock, values in the table represent mean and highest residues of emamectin B1a benzoate only.

Animal commodity	Dose level (ppm feed)	Mean Residue (mg/kg)	Highest Residue (mg/kg)
Liver	0.03	0.0086	0.010
	0.09	0.029	0.029
	0.3	0.097	0.12
Kidney	0.03	0.0037	0.0040
	0.09	0.012	0.013
	0.3	0.037	0.042
Fat	0.03	0.0021	0.0022
	0.09	0.0047	0.0066
	0.3	0.013	0.015
Muscle	0.03	< 0.002	< 0.002
	0.09	< 0.002	0.0020
	0.3	0.0058	0.0061
Milk	0.03	< 0.5 ng/g	–
	0.09	0.8 ng/g	–
	0.3	3.2 ng/g	–

Residues in animal commodities

Cattle

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 (see table below).

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 (see table below).

				Residues (mg/kg) in			
	Feed level (ppm) for milk residues	Residues (ng/g) in milk	Feed level (ppm) for tissue residues	Muscle	Liver	Kidney	Fat
Maximum residue level - beef or dairy cattle							
Feeding study a	0.09 0.30	0.8 3.2	0.09 0.30	0.0020 0.0061	0.029 0.12	0.013 0.042	0.0066 0.015
Dietary burden and residue estimate b	0.19	1.9	0.19	0.0040	0.072	0.027	0.011
STMR beef or dairy cattle							
Feeding study b	0 0.03	0 < 0.5	0 0.03	0 < 0.002	0 0.0086	0 0.0037	0 0.0021
Dietary burden and residue estimate	0.018	< 0.5	0.018	< 0.002	0.0052	0.0022	< 0.002

[a] highest residues for tissues and mean residues for milk

[b] mean residues for tissues and mean residues for milk

The Meeting estimated a maximum residue level for emamectin B1a benzoate of 0.004 mg/kg in meat from mammals other than marine mammals, 0.08 mg/kg in mammalian offal, 0.02 mg/kg in mammalian fat and 0.002 mg/kg in milks. The residue in animal commodities is considered not fat-soluble.

The Meeting estimated an STMR of 0.002 mg/kg in meat from mammals other than marine mammals, 0.006 mg/kg in mammalian offal, 0.002 mg/kg in mammalian fat and 0.0005 mg/kg in milks. The Meeting estimated an HR of 0.004 mg/kg in meat from mammals other than marine mammals, 0.072 mg/kg in mammalian offal, 0.011 mg/kg in mammalian fat.

Poultry

Since poultry is not exposed to emamectin benzoate from uses considered by the Meeting, a maximum residue level, STMR or HR is not considered necessary for poultry.

FURTHER WORK OR INFORMATION

Desirable

- Verification that emamectin B1a benzoate can or cannot be included in an existing multi-residue method for enforcement.
- Storage stability studies on animal commodities for at least 3 months at -20 °C.
- Storage stability studies on commodities with high acid content (grapes), and processed commodities (apple pomace, apple juice).

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Daily Intakes (IEDI) for emamectin benzoate was calculated from recommendations for STMRs for raw and processed commodities in combination with consumption data for corresponding food commodities. The results are shown in Annex 3.

The IEDI of in the 13 GEMS/Food cluster diets, based on the estimated STMRs were in the range 0–20% of the maximum ADI of 0.0005 mg/kg bw per day, expressed as emamectin benzoate. The Meeting concluded that the long-term intake of residues of emamectin benzoate from uses considered by the Meeting is unlikely to present a public health concern.

Short-term intake

The International Estimated Short Term Intake (IESTI) for emamectin benzoate was calculated from recommendations for STMRs and hours for raw and processed commodities in combination with consumption data for corresponding food commodities. The results are shown in Annex 4.

The IESTI for the diets submitted for 2011 JMPR represented 0–50% of the ARfD (0.03 mg/kg bw, expressed as emamectin benzoate). The Meeting concluded that the short-term intake of residues of emamectin benzoate from uses considered by the Meeting is unlikely to present a public health concern.

5.11 ETOFENPROX (184)

TOXICOLOGY

Etofenprox is the International Organization for Standardization (ISO)–approved name for 2-(4-ethoxyphenyl)-2-methylpropyl 3-phenoxybenzyl ether (International Union of Pure and Applied Chemistry), with the Chemical Abstracts Service No. 80844-07-1.

Similar to pyrethroids, etofenprox acts on ion channels of the insect nervous system. It is used as an insecticide with contact and stomach action against many pests on a broad range of crops.

Etofenprox was evaluated previously by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) in 1993, when an acceptable daily intake (ADI) of 0–0.03 mg/kg body weight (bw) was established based on a carcinogenicity study in mice and using a 100-fold safety factor. It was reviewed at the present Meeting as part of the periodic review programme of the Codex Committee on Pesticide Residues. Since the last review by JMPR, the following new studies of etofenprox have been submitted: an absorption, distribution, metabolism and excretion study in male rats, acute oral and dermal toxicity studies in rats, a 4-week dermal toxicity study in rabbits, a 4-week dietary mechanistic study on thyroid function and hepatic microsomal enzyme induction in rats, a developmental toxicity study in rabbits, acute and subacute (90-day) neurotoxicity studies in rats, a developmental neurotoxicity study in rats and 4-week immunotoxicity studies in mice and rats. In addition, oral and dermal acute toxicity studies, a 13-week toxicity study and genotoxicity studies of a plant metabolite of etofenprox, 2-(4-ethoxyphenyl)-2-methylpropyl 3-phenoxybenzoate (α-CO), were conducted.

All critical studies complied with good laboratory practice.

Biochemical aspects

In rats given a single oral dose of 1:1 [^{14}C]etofenprox mixtures labelled on either side of the ether linkage, absorption was rapid but incomplete, to the extent of approximately 64–68% of the dose at 30 mg/kg bw and 48–58% of the dose at 180 mg/kg bw. The time to reach maximum concentrations in plasma was 3–5 hours. Distribution to the tissues was extensive after 7 daily doses of 30 mg/kg bw, with tissue concentrations reaching their maxima 4 hours after the last dose. Highest concentrations were found in fat, adrenals, liver, ovaries and thyroid. Apart from the gastrointestinal tract, which contained much unabsorbed material, concentrations elsewhere, including brain, were low. Etofenprox crossed the placenta to the fetus, but placental and fetal concentrations were low relative to maternal plasma concentrations, and elimination from the placenta and the fetus was rapid. Unmetabolized etofenprox was secreted into maternal milk. Depletion from the tissues was rapid except from fat, in which estimated half-lives were approximately 5 and 8.5 days in males and females, respectively. In rats with bile duct cannulae, radiolabelled etofenprox administered at 30 mg/kg bw to males and 180 mg/kg bw to males and females was rapidly eliminated, with almost 90% combined excreted in the bile (10–15%) and faeces (75–78%) and approximately 1–3% in the urine within 48 hours; females receiving 30 mg/kg bw eliminated the radioactivity differently, with 30%, 50% and 3% appearing in bile, faeces and urine, respectively, in 0–48 hours. This difference was not observed in rats without cannulae. The routes and extent of elimination of etofenprox and its metabolites were independent of the dose level and the sex of the rats. No unchanged etofenprox or a key primary metabolite, α-CO, has been recovered from urine.

In dogs given the 1:1 [^{14}C]etofenprox mixture orally, the rate of absorption of radioactivity was quite variable, with maximum plasma concentrations occurring 0.25–6 hours after dosing. The extent of absorption was approximately 40–50%. This was followed by approximately 90% faecal elimination (excretion and non-absorbed etofenprox combined) and 10% urinary excretion, almost all occurring within 24 hours. Very high concentrations were found in bile, none of which was due to parent etofenprox.

In rats, no unchanged etofenprox was found in urine, whereas in faeces, it was one of the major components, most likely due to unabsorbed material. Cleavage of the etofenprox molecule did not appear to be a significant metabolic process, although a significant number of radiolabelled entities were not identified. In faeces, desethyletofenprox occurred at 19.5–25.1% of the dose, and etofenprox hydroxylated in the 4′ position of the phenoxybenzyl moiety occurred at 7.2–13.8% of the dose. Other primary metabolic steps involved oxidation of carbons on either side of the ether linkage, one product of which, α-CO, is a major metabolite or degradation product isolated during plant and soil and photodegradation studies. These carbonyls appear to be rapidly metabolized to scission products, some of which (m-PB-acid, m-PB-alc and 4 -OH-PB) are shared with other pesticides. Glucuronide and sulfate conjugates were also found.

Toxicological data

The acute oral and dermal median lethal dose (LD_{50}) values in rats are both greater than 2000 mg/kg bw. The acute oral LD_{50} value in the dog is greater than 5000 mg/kg bw. The acute 4-hour inhalation median lethal concentration (LC_{50}) value in the rat is greater than 5.88 mg/L. Etofenprox was not irritating to rabbit skin or rabbit eyes. Etofenprox was not a skin sensitizer in the guinea-pig maximization test.

The liver is a common target for the toxicity of etofenprox in mouse, rat and dog. The liver, kidneys and haemolymphoreticular system were identified as target organs in the mouse. The no-observed-adverse-effect level (NOAEL) in a 90-day toxicity study in mice was 3000 ppm (equal to 375 mg/kg bw per day), based on increased mortality and the occurrence of reduced body weight gain and feed consumption, increased water consumption, minor haematological effects, histopathological alterations indicative of kidney damage and minor changes in liver at 15 000 ppm (equal to 1975 mg/kg bw per day).

The liver and thyroid gland were the target organs in the rat. In a 90-day toxicity study in rats, the NOAEL was 300 ppm (equal to 20 mg/kg bw per day), based on liver toxicity (hepatocyte enlargement and clinical evidence of liver dysfunction affecting fat metabolism and the synthesis of blood clotting factors) and thyroid toxicity (an increase in the number of thyroid microfollicles and reduced levels of circulating thyroxine [T_4]) at 1800 ppm (equal to 120 mg/kg bw per day).

The NOAEL in a 1-year dog study was 1000 ppm (equal to 32.2 mg/kg bw per day), based on hepatotoxicity, including increased liver weights in both sexes and histopathological alterations in females at 10 000 ppm (equal to 339 mg/kg bw per day). The hepatic effects were reversible.

The carcinogenic potential of etofenprox was studied in mice and rats. In the 2-year toxicity and carcinogenicity study in mice, the NOAEL for non-neoplastic effects was 30 ppm (equal to 3.1 mg/kg bw per day), based on an increased incidence of dilated/basophilic renal cortical tubules at 100 ppm (equal to 10.4 mg/kg bw per day). At higher doses, the renal lesions were characterized as an increased incidence of cortical scarring and pale coloration, organ enlargement, dilated or cystic Bowman's capsules, dilated medullary tubules, focal loss of tubules, prominent interstitial papillary tissue and papillary mineralization. There were also small increases in reticulum cell sarcomas in female mice at 100 ppm and above. These reticulum cell sarcomas were not considered treatment related because of a lack of a dose–response relationship, and they are common tumours in rats. The combined incidence of renal cortical adenomas and carcinomas was marginally non-statistically significantly increased in males at 700 and 4900 ppm. Nevertheless, these tumours are rare in mice and were slightly above the historical control range. Therefore, they were considered treatment-related tumours. It is plausible that the continuous stimulation by chronic renal toxicity was responsible for renal tumour development. The NOAEL for carcinogenicity in mice was 100 ppm (equal to 10.4 mg/kg bw per day), based on renal cortical tumours at 700 ppm (equal to 75.2 mg/kg bw per day).

In the chronic toxicity and carcinogenicity study in rats, the NOAEL for non-neoplastic effects was 100 ppm (equal to 3.7 mg/kg bw per day), based on an increase in foci or areas of

eosinophilic hepatocytes in males and vacuolated hepatocytes in females and reduced body weight gain in males at 700 ppm (equal to 25.5 mg/kg bw per day). The thyroid follicular cell adenomas and carcinomas combined were statistically significantly increased in females at 4900 ppm. Increased thyroid follicular cell adenomas and carcinomas combined were also observed in males at 4900 ppm, but statistical significance was not achieved. The NOAEL for carcinogenic effects in female rats was 700 ppm (equal to 34.3 mg/kg bw per day), based on an increased incidence of thyroid follicular cell adenomas at 4900 ppm (equal to 249.1 mg/kg bw per day).

A mechanistic study in rats was conducted to clarify the relationship between a primary effect of etofenprox on hepatic microsomal induction and thyroid follicular cell adenoma development. Etofenprox increased uridine diphosphate glucuronosyltransferase (UGT) activity in the liver, which would be expected to increase excretion of T_4 from the blood. Decreased serum T_4 levels were observed with a consequent increase in thyroid stimulating hormone activity, which would be expected to result in follicular cell hyperplasia and, if sustained, tumour development. Rodents are particularly sensitive to the induction of thyroid follicular cell tumours, firstly because of the easy induction of UGT and secondly because of rapid T_4 metabolism in the absence of a specific thyroxine-binding globulin. In other species, this provides a buffering capacity that better controls the dynamic equilibrium of hormones in the pituitary–hypothalamic–thyroid axis.

Based on mode of action analysis for thyroid follicular tumours, the Meeting concluded that these tumours were not relevant for human risk assessment.

The potential genotoxicity of etofenprox was tested in an adequate range of in vitro and in vivo genotoxicity studies. No evidence of genotoxic potential was found.

The Meeting concluded that etofenprox was unlikely to be genotoxic.

On the basis of the absence of genotoxicity, the absence of carcinogenicity in rats by a mode of action relevant to humans and carcinogenicity in mice likely to be secondary to renal toxicity at exposure levels of unlikely human relevance, the Meeting concluded that etofenprox is unlikely to pose a carcinogenic risk to humans.

No reproductive toxicity was observed in two multigeneration reproduction studies in rats at doses up to 4900 ppm (equal to 246 mg/kg bw per day) when administered through the diet and 5000 mg/kg bw per day when administered by gavage. The NOAEL for parental toxicity was 700 ppm (equal to 37 mg/kg bw per day), based on the occurrence of reduced weight gain, increased kidney, liver and thyroid weights and histopathological findings in the liver, kidneys and thyroid at 4900 ppm (equal to 246 mg/kg bw per day). The NOAEL for offspring toxicity was 700 ppm (equal to 37 mg/kg bw per day), based on the occurrence of increased kidney weights in females in the F_{2b} generation at 4900 ppm (equal to 246 mg/kg bw per day).

In a modified developmental toxicity study, rats were administered etofenprox by gavage during gestation days 6–17. The maternal toxicity NOAEL in rats was 250 mg/kg bw per day, based on decreased body weights and clinical signs at the lowest-observed-adverse-effect level (LOAEL) of 5000 mg/kg bw per day, the highest dose tested. The developmental NOAEL was 5000 mg/kg bw per day, the highest dose tested.

In two developmental toxicity studies conducted in rabbits, the overall NOAEL for developmental toxicity and maternal toxicity was 100 mg/kg bw per day, based on the occurrence of reduced maternal body weight gain and feed consumption on gestation day 6 (first day of dosing), mortality and increased post-implantation loss and intrauterine growth retardation at the high dose of 250 mg/kg bw per day.

The Meeting concluded that etofenprox is not teratogenic in rats or rabbits.

No evidence of neurotoxicity was observed in an acute neurotoxicity study in rats at doses up to 2000 mg/kg bw. No evidence of systemic toxicity, including neurotoxicity, was observed in a 13-week neurotoxicity study in rats at doses up to 10 000 ppm (equal to 604 mg/kg bw per day). In a developmental neurotoxicity study in rats, the NOAEL for maternal toxicity was 700 ppm (equal to

57 mg/kg bw per day), based on an increased incidence of rearing behaviour in the functional observational battery at 2100 ppm (equal to 169 mg/kg bw per day). The NOAEL for offspring toxicity was 250 ppm (equal to 28.4 mg/kg bw per day), based on eye abnormalities (increased incidences of dark or opaque and/or enlarged, prominent eyes and a subcutaneous haemorrhagic lesion) in both sexes seen at 700 ppm (equal to 57 mg/kg bw per day). The ocular toxicity seen in these studies is the outcome of the subcutaneous haemorrhage. There was no evidence of neurotoxicity in the offspring.

In immunotoxicity studies in mice and rats, no evidence of immunotoxicity was observed at doses up to 1116 and 1053 mg/kg bw per day in mice and rats, respectively.

Toxicological data on metabolite

Toxicity studies of a plant metabolite of etofenprox, α-CO, were conducted. α-CO has low acute oral and dermal toxicity in the rat. The LD_{50} values are greater than 5000 mg/kg bw and greater than 2000 mg/kg bw for oral and dermal toxicity, respectively.

The lowest NOAEL for α-CO in 4-week and 13-week dietary studies in rats was 54 mg/kg bw per day, based on the effects on the liver, kidney and thyroid in a 13-week dietary study at 10 000 ppm (equal to 805 mg/kg bw per day). The toxicological profile of α-CO is similar to that of etofenprox, but its toxicity is lower than that of the parent (20 mg/kg bw per day). α-CO is not genotoxic.

There were no reports of adverse health effects in manufacturing plant personnel. Also, there were no reports of poisoning with etofenprox.

The Meeting concluded that the existing database on etofenprox was adequate to characterize the potential risk to fetuses, infants and children.

Toxicological evaluation

The Meeting confirmed the ADI of 0–0.03 mg/kg bw on the basis of the NOAEL of 3.1 mg/kg bw per day from the 108-week carcinogenicity study in mice based on renal toxicity (an increased incidence of dilated and basophilic renal tubules) at 10.4 mg/kg bw per day and using a safety factor of 100. The ADI was supported by the NOAEL of 3.7 mg/kg bw per day from the 2-year toxicity and carcinogenicity study in rats, based on an increase in foci or areas of eosinophilic hepatocytes in males and vacuolated hepatocytes in females and reduced body weight gain in males at 25.5 mg/kg bw per day. This ADI is adequately protective of renal cortical tumours occurring at higher doses in mice.

The Meeting established an acute reference dose (ARfD) of 1 mg/kg bw on the basis of the overall NOAEL of 100 mg/kg bw per day from the two developmental toxicity studies in rabbits, based on the occurrence of reduced maternal body weight gain and feed consumption during the early dosing period (gestation day 6) and increased post-implantation loss, which could occur after a single exposure, and using a safety factor of 100.

A toxicological monograph was prepared.

Levels relevant to risk assessment

Species	Study	Effect	NOAEL	LOAEL
Mouse	Two-year study of toxicity and carcinogenicity[a]	Toxicity	30 ppm, equal to 3.1 mg/kg bw per day	100 ppm, equal to 10.4 mg/kg bw per day
		Carcinogenicity	100 ppm, equal to 10.4 mg/kg bw per	700 ppm, equal to 75.2 mg/kg bw per

Species	Study	Effect	NOAEL	LOAEL
			day	day
Rat	Two-year study of toxicity and carcinogenicity[a]	Toxicity	100 ppm, equal to 3.7 mg/kg bw per day	700 ppm, equal to 25.5 mg/kg bw per day
		Carcinogenicity	700 ppm, equal to 34.3 mg/kg bw per day (females)	4900 ppm, equal to 249.1 mg/kg bw per day (females)
	Multigeneration study of reproductive toxicity[a]	Parental toxicity	700 ppm, equal to 37 mg/kg bw per day	4900 ppm, equal to 246 mg/kg bw per day
		Offspring toxicity	700 ppm, equal to 37 mg/kg bw per day	4900 ppm, equal to 246 mg/kg bw per day
		Reproductive toxicity	4900 ppm, equal to 246 mg/kg bw per day[b]	—
	Developmental toxicity study[c]	Maternal toxicity	250 mg/kg bw per day	5000 mg/kg bw per day
		Embryo and fetal toxicity	5000 mg/kg bw per day[b]	—
Rabbit	Developmental toxicity studies[c,d]	Maternal toxicity	100 mg/kg bw per day	250 mg/kg bw day
		Embryo and fetal toxicity	100 mg/kg bw per day	250 mg/kg bw day
Dog	One-year studies of toxicity[a,d]	Toxicity	1000 ppm, equal to 32.2 mg/kg bw per day	10 000 ppm, equal to 339 mg/kg bw per day

[a] Dietary administration.

[b] Highest dose tested.

[c] Gavage administration.

[d] Two or more studies combined.

Estimate of acceptable daily intake for humans

0–0.03 mg/kg bw

Estimate of acute reference dose

1 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 etofenprox

Absorption, distribution, excretion and metabolism in mammals	
Rate and extent of oral absorption	Rapid but incomplete, ~50%
Dermal absorption	Not available
Distribution	Distributed throughout the body; highest concentrations in fat, adrenals, liver, ovaries and thyroid
Potential for accumulation	None
Rate and extent of excretion	Rapid and extensive
Metabolism in animals	Desethyletofenprox and hydroxylated etofenprox
Toxicologically significant compounds (animals, plants and the environment)	Parent
Acute toxicity	
Rat, LD_{50}, oral	> 2000 mg/kg bw
Rat, LD_{50}, dermal	> 2000 mg/kg bw
Rat, LC_{50}, inhalation	> 5.88 mg/L
Rabbit, skin irritation	Non-irritating
Rabbit, eye irritation	Non-irritating
Guinea-pig, skin sensitization (maximization test)	Not a sensitizer
Short-term studies of toxicity	
Target/critical effect	Liver, reduced body weight
Lowest relevant oral NOAEL	20 mg/kg bw per day (13-week toxicity study in rats)
Lowest relevant dermal NOAEL	1000 mg/kg bw per day (rabbits, highest dose tested)
Lowest relevant inhalation NOAEC	0.21 mg/L (13-week inhalation study in rats)
Genotoxicity	
	Not genotoxic
Long-term studies of toxicity and carcinogenicity	
Target/critical effect	Kidney, liver, haematology, body weights
Lowest relevant NOAEL	3.1 mg/kg bw per day (carcinogenicity study in mice)
Carcinogenicity	Unlikely to pose carcinogenic risk to humans at dietary exposure levels
Reproductive toxicity	
Reproduction target/critical effect	Kidney/increased kidney weight
Lowest relevant reproductive NOAEL	246 mg/kg bw per day, the highest dose tested (multigeneration study in rats)
Developmental target/critical effect	Abortions and post-implantation loss
Lowest relevant developmental NOAEL	100 mg/kg bw per day (rabbits)
Neurotoxicity/delayed neurotoxicity	
Acute neurotoxicity	Not neurotoxic (rats)
Subacute neurotoxicity	Not neurotoxic (13-week study in rats)

Neurodevelopmental toxicity	Not neurodevelopmental toxicant (rats)
Immunotoxicity studies	
	Not immunotoxic (rats and mice)
Medical data	
	No adverse effects have been reported
Mechanistic studies	
	Studies on the thyroid axis that demonstrate a tumour mode of action not relevant to humans

Summary

	Value	**Study**	**Safety factor**
ADI	0–0.03 mg/kg bw	Two-year carcinogenicity study in mice, supported by the 2-year toxicity and carcinogenicity study in rats	100
ARfD	1 mg/kg bw	Developmental studies in rabbits	100

5.12 ETOXAZOLE (241)

RESIDUE AND ANALYTICAL ASPECTS

Etoxazole was reviewed for the first time by the JMPR in 2010 where it was noted that during frozen storage residues of etoxazole in several matrices were not stable. Additionally, it was identified that residues might also decompose during sample preparation.

Nevertheless, the 2010 Meeting decided to use the results of residue trials, for those commodities where the storage stability was demonstrated, to estimate maximum residue levels. The Meeting did not recommend the maximum residue levels for pome fruits, stone fruits, strawberry, melons, tomato, cotton seed and cotton gin trash as the storage stability of samples from field trials could not be demonstrated.

The USA submitted a concern following the Forty-third CCPR. No new storage stability data was received. The USA agreed that the storage stability studies demonstrate that etoxazole residues diminish on frozen storage in the matrices apple, stone fruits, strawberry and melon (except watermelon). However, in each case the residue decline as indicated by the storage stability recovery data, demonstrated a relatively low standard deviation of 10% or less. Therefore, the USA requested that JMPR consider making use of the submitted residue field trial data together with appropriate storage stability correction factor(s) to allow for maximum residue level recommendations for these crops. Alternatively, if the use of storage stability correction factors was considered inappropriate, the US requested that JMPR considered correcting the residue levels in the storage stability studies with the concurrent method recovery values reported.

The USA noted that since etoxazole was a reduced risk chemical it would be preferable to use correction factors to estimate maximum residue levels rather than set none for these crops. Furthermore, since the residues were not stable in frozen storage in these crop matrices, they would likely decline faster when the treated commodity was not held in frozen storage as would be the typical practice in commercial operations. Also the JMPR had determined that the residue definition for MRL compliance and dietary intake was parent etoxazole only; thus reducing potential concerns about metabolites/degradates formed during degradation during storage.

Comment by the JMPR

According to the FAO Manual (2009), if more than 30% of the residue is lost during storage prior to analysis, residues from studies involving similar storage periods may not be valid (page 65). It has not been JMPR practice to adjust residue data for possible losses during frozen storage. JMPR would prefer not to encourage the submission of supervised trials data from samples stored for intervals and under conditions where substantial portions of the original residues may have degraded. JMPR considers it preferable to control the problem at the planning stage, i.e., arrangements should be made to operate within storage intervals and temperatures where the residue is known to be stable.

The FAO Manual (2009) states that procedural recoveries (samples spiked and analysed at the time a stored sample is analysed) should be used to decide on the validity of the batch of analyses. The analytical results for the stored sample should not be adjusted for the procedural recoveries (page 66). This is the JMPR practice and it is essentially in line with best analytical practice. The 1999 IUPAC report on Harmonised Guidelines for the Use of Recovery Information in Analytical Measurement (Pure & Applied Chemistry, 71:337-348 (1999)) noted "There is a tendency for the role of Internal Quality Control (IQC) to be confused with the simple estimation of recovery (where deemed appropriate). It is better to regard IQC results solely as a means of checking that the analytical process remains in control. The recovery estimated at method validation time is usually more accurate for application to subsequent in-control runs, because more time can be spent on studying their typical levels and variability."

The Meeting concluded that the residue data should, therefore, not be corrected by procedural recoveries. However, the current Meeting agreed to reconsider the trial data.

Pome fruits

Two independent freezer storage stability studies of etoxazole were conducted on apples. The storage stability study, in which the samples were fortified with etoxazole at 0.1 mg/kg, demonstrated that the residues were stable for 7 months (78% remaining). Another storage stability study, which the samples were fortified at 0.01 mg/kg, indicated that the residues were stable for 41 days (70% remaining). The Meeting took into account the interval (8–95 days) between sampling and analysis, and evaluated the residues of trials on apple and pear based on the marginally acceptable storage stability data.

Apple

Etoxazole is registered in Greece, Italy and Spain for use apples as a foliar application with a maximum rate of 0.055 kg ai/ha and a PHI of 28 days. Residues in apples from trials with an acceptable storage intervals from trials in France, Greece, Italy and Spain, matching GAP were (n = 9): < 0.01 (7), 0.01 and 0.04 mg/kg.

Pear

Etoxazole is registered in Greece for use pears as a foliar application with a maximum rate of 0.055 kg ai/ha and a PHI of 28 days. Residues in pears from trials with the acceptable storage intervals for samples from trials in France and Greece matching GAP were (n = 4): < 0.01 (4) mg/kg.

Since the residue populations from the European trials on apples and pears were similar, the Meeting decided to combine the data. The residues from trials in France, Greece, Italy and Spain matching the GAP of Greece were: (n = 13) < 0.01 (11), 0.01 and 0.04 mg/kg.

Based on the trials from France, Greece, Italy and Spain, the Meeting estimated a maximum residue level and an STMR value for etoxazole in pome fruits of 0.07 and 0.01 mg/kg respectively.

The OECD calculator estimated a maximum residue level of 0.05 mg/kg. However, the Meeting recommended a value of 0.07 mg/kg because the result of the OECD calculator was considered too close to the highest residue value.

Stone fruits

Cherries

A freezer storage stability study was conducted on cherries in which control samples were fortified with etoxazole and analysed both prior to and concurrently with field-treated samples. Storage stability samples fortified at 0.10 mg/kg etoxazole were analysed after 193 days and yielded recoveries (percent remaining) that averaged 64%, i.e., storage stability of etoxazole residues in cherries was not demonstrated in this study.

The Meeting confirmed its previous conclusion.

Plums

A freezer storage stability study was conducted on plums, in which control samples were fortified with etoxazole and analysed both prior to and concurrently with field-treated samples. Storage stability samples of plums, fortified at 0.10 mg/kg etoxazole, were analysed after 207 days, and yielded recoveries (percent remaining) that averaged 43%, i.e., storage stability of etoxazole residues in plums was not demonstrated in the study.

The Meeting confirmed its previous conclusion.

Peach

A freezer storage stability study was conducted on peaches, in which control samples were fortified with etoxazole and analysed both prior to and concurrently with field-treated samples. Storage stability samples fortified at 0.10 mg/kg etoxazole were analysed after 278 days and yielded recoveries (percent remaining) that averaged 50%, i.e., storage stability of etoxazole residues in trials for peaches was not demonstrated in the study.

The Meeting confirmed its previous conclusion.

Strawberry

A freezer storage stability study was conducted on strawberries, in which aliquots of control samples, fortified with a solution of etoxazole at 0.01 mg/kg, were weighed into storage bags and placed in a freezer for 90 days. Residues of etoxazole were found to be unstable in strawberries, with 50–63% of the applied material recovered following 32–90 days of frozen storage. The storage stability of etoxazole residues for strawberries was not demonstrated in this study.

The Meeting confirmed its previous conclusion.

Melons, except Watermelon

A freezer storage stability study was conducted on melons (cantaloupe). Aliquots of control samples, fortified with a solution of etoxazole at 0.01 mg/kg, were weighed into storage bags and placed in a freezer for 126 days. Residues of etoxazole were found to be unstable in cantaloupe with 55–63% of the applied material recovered following frozen storage for a period of 50–126 days, i.e., the storage stability of etoxazole residues in melons (cantaloupe) was not demonstrated in the study.

The Meeting confirmed its previous conclusion.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Dietary Intakes (IEDIs) of etoxazole were calculated for the 13 GEMS/Food cluster diets using STMRs/STMR-Ps estimated by the current Meeting (Annex 3). The ADI is 0–0.05 mg/kg bw and the calculated IEDIs were 0–1% of the maximum ADI. The Meeting concluded that the long-term intakes of residues of etoxazole, resulting from the uses considered by current JMPR, are unlikely to present a public health concern.

Short-term intake

The 2010 JMPR concluded that an ARfD was unnecessary. The Meeting therefore decided that the short-term intake of residues of etoxazole is unlikely to present a public health concern.

5.13 FLUTRIAFOL (248)

TOXICOLOGY

Flutriafol is the International Organization for Standardization (ISO)–approved name for (*RS*)-2,4′-difluoro-α-(1H-1,2,4-triazol-1-ylmethyl)benzhydryl alcohol (International Union of Pure and Applied Chemistry), which has the Chemical Abstracts Service No. 76674-21-0. Flutriafol is a contact and systemic fungicide belonging to the triazole class. It is used on a wide range of cereal crops and as a seed treatment. Its fungicidal mechanism of action is the inhibition of ergosterol biosynthesis and thus disruption of fungal cell wall synthesis.

Flutriafol was reviewed for the first time by the Joint FAO/WHO Meeting on Pesticide Residues at the request of the Codex Committee on Pesticide Residues. All critical studies contained statements of compliance with good laboratory practice.

Biochemical aspects

Flutriafol is rapidly and extensively absorbed following oral administration to the rat at dose levels of 5 or 250 mg/kg body weight (bw) in polyethylene glycol 600. Based on values for urinary and biliary excretion, oral absorption is greater than 90%. Flutriafol and/or its metabolites are widely distributed, with highest levels of radioactivity associated with red blood cells. Data from studies with repeated administration indicate that there is unlikely to be any bioaccumulation. Flutriafol is extensively metabolized in the rat, with only trace levels of unchanged parent detected in excreta following oral administration. The initial stage of metabolism is oxidation of the 2-fluorophenyl ring, followed by conjugation. Excretion was predominantly within 24 hours at 5 mg/kg bw, with similar amounts of radiolabel present in the urine and faeces. Biliary excretion was extensive (~80%), with evidence for enterohepatic circulation.

Toxicological data

Flutriafol has acute oral median lethal dose (LD_{50}) values of 1140–1480 mg/kg bw in the rat. Acute oral toxicity was higher in the mouse, rabbit and guinea-pig (LD_{50}s 179–400 mg/kg bw). Lower acute toxicity was seen via the dermal (LD_{50} > 2000 mg/kg bw in rabbits) and inhalation (median lethal concentration [LC_{50}] > 5.2 mg/L) routes. Flutriafol was not irritating to rat or rabbit skin but was a mild irritant to rabbit eyes; all ocular effects had resolved within 72 hours. Flutriafol did not produce any evidence of skin sensitization in a Magnusson and Kligman assay in guinea-pigs or in a local lymph node assay in mice.

The red blood cell and liver were identified as targets of flutriafol toxicity in short-term oral toxicity studies in the rat, mouse and dog. Increases in hepatocyte hypertrophy and liver weight with no other effects were considered to be adaptive and not treated as adverse effects; other histopathological findings in the liver, such as fatty vacuolation or necrosis, were treated as adverse. Reduced body weights, weight gains and/or feed consumption were also seen at high dose levels in all three species. Effects on haematological parameters consistent with mild microcytic anaemia were seen in the rat and mouse; such effects were less marked in the dog. In a 29-day study, the majority of mice exposed at 1500 ppm died. Increased liver weights and hepatocytic vacuolation were seen at intermediate doses. Hepatocytic lipid accumulation was seen at all dose levels; the lowest-observed-adverse-effect level (LOAEL) was 50 ppm (equivalent to 7.5 mg/kg bw per day). Hepatotoxicity in the rat at high dose levels was characterized by elevated serum alanine aminotransferase (ALT) and aspartate aminotransferase (AST) activities, the disruption of lipid metabolism, increased liver weight, altered pigmentation and granulation, centrilobular hepatocyte hypertrophy and vacuolation, fatty change, focal necrosis and hydropic degeneration. At lower dose levels, findings of increased liver weight, centrilobular hepatocyte hypertrophy, elevated hepatic aminopyrine-*N*-demethylase activity and proliferation of the smooth endoplasmic reticulum are consistent with an adaptive effect. The no-

observed-adverse-effect level (NOAEL) in the 90-day rat study was 200 ppm (equal to 13 mg/kg bw per day). In the dog, hepatotoxicity was characterized by elevated serum alkaline phosphatase activity, perturbation of lipid metabolism, increased liver weight and (in the 1-year study) granular, swollen liver, hepatocytic vacuolation and lipid accumulation. The NOAELs for the 90-day and 1-year dog studies were both 5 mg/kg bw per day.

In a 28-day dermal toxicity study in rats, there were no systemic effects; the NOAEL was 1000 mg/kg bw per day. The NOAEL for local effects was 250 mg/kg bw per day, based on erythema and flaking of the skin at the application site.

The liver was identified as the target organ of flutriafol toxicity following chronic administration to the rat and mouse. Hepatotoxicity in the 2-year mouse study was characterized by increased liver weight and fatty change; the incidence of liver adenoma was marginally increased in males at the top dose level, but was within the historical control range. The NOAEL in the 2-year mouse study was 10 ppm (equal to 1.2 mg/kg bw per day), based on centrilobular fatty changes in the liver at 50 ppm (equal to 6 mg/kg bw per day). Flutriafol was not carcinogenic in mice.

Toxicity in the chronic rat study was characterized by clinical chemistry findings (reduced serum triglycerides and alkaline phosphatase activity and increased ALT activity in males; increased serum cholesterol in females) at 2000 ppm and increased liver weight and fatty change at 200 ppm and above. Incidences of liver adenoma and carcinoma were slightly increased at the top dose level, but were within historical control ranges. Evidence of anaemia was seen at the high dose level; effects on red blood cell parameters were accompanied in females by reduced serum iron concentration, elevated total iron binding capacity and haemosiderin accumulation in the spleen and liver. The NOAEL in the 2-year rat study was 20 ppm (equal to 1.0 mg/kg bw per day), based on increased fatty change and weight of the liver in males at 200 ppm (equal to 10 mg/kg bw per day). Flutriafol was not carcinogenic in rats.

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

Flutriafol has been tested for genotoxicity in an adequate range of in vitro and in vivo studies. Equivocal results were seen in two reverse mutation assays with mouse lymphoma L5178Y cells. The remaining in vitro and all the in vivo tests were negative.

The Meeting concluded that flutriafol is unlikely to be genotoxic.

Based on the absence of genotoxicity and absence of treatment-related carcinogenicity in mice and rats, the Meeting concluded that flutriafol is unlikely to be carcinogenic in humans.

Two reproductive toxicity studies in rats are available. Evidence of reproductive toxicity was seen in the first two-generation rat study; mean litter size was lower at the top dose level of 1000 ppm, and there was a reduced fertility index at the mating for the F_{1a} litter. The NOAEL for reproduction was 240 ppm (equal to 14 mg/kg bw per day). Minor maternal body weight effects and hepatotoxicity (fatty change) were seen at 240 ppm in both sexes. The NOAEL for parental toxicity was 60 ppm (equal to 3.5 mg/kg bw per day). Fatty changes in the liver were also seen in pups at the top dose level. The NOAEL for offspring toxicity was 240 ppm (equal to 14 mg/kg bw per day). Similar findings were seen in the range-finding component of the more recent rat reproductive toxicity study. Post-implantation losses (13%) were increased at doses causing mild to moderate maternal toxicity in the preliminary reproduction study at 240 ppm (equal to 13 mg/kg bw per day) and above. NOAELs for parental, pup and reproductive effects were 60 ppm (approximately 4 mg/kg bw per day). However, in the main study, there were no effects on reproduction, offspring or parents at the highest dose tested, 300 ppm (equal to 16 mg/kg bw per day). The Meeting concluded that the overall NOAELs from the two main reproductive toxicity studies for reproductive and offspring toxicity were 16 mg/kg bw per day.

There are four rat developmental toxicity studies on flutriafol. In the first guideline-compliant study, effects on the fetal skeleton mainly consistent with delayed ossification were seen at all dose levels; the LOAEL was 10 mg/kg bw per day. At the top dose level of 125 mg/kg bw per day, there

were reductions in body weight gain (20–50%), feed consumption (~15%) and litter size (30%), the latter associated with increased post-implantation loss (33%). In both subsequent range-finding studies, there were marked increases in skeletal anomalies (especially of the hyoid) and reduced ossification, as well as single incidences of cleft palate at the top dose levels of each study (150 and 100 mg/kg bw per day). Marked maternal toxicity, clinical signs, body weight deficits and fetal resorptions were seen at the top dose levels. In the second guideline-compliant study, there was a single incidence of cleft palate at the top dose level of 75 mg/kg bw per day, a dose that also produced significantly reduced maternal body weight gain (~30%), increases in post-implantation loss (3-fold), skeletal anomalies (including the hyoid bone and supernumerary ribs) and delayed ossification. The NOAELs in this study for both developmental and maternal toxicity were 10 mg/kg bw per day.

Cleft palate is a very rare finding in rats that has been seen at high dose levels with a number of triazole compounds. The presence of single incidences of cleft palate in three of the rat developmental toxicity studies, although not statistically significant in isolation, cannot be discounted when the database is considered as a whole. Litter sizes at the top dose levels were significantly lower as a result of post-implantation loss, which could reduce the number of malformed fetuses observed at caesarean section. The NOAEL for teratogenicity in the rat was 10 mg/kg bw per day, based on the findings of cleft palate at and above 75 mg/kg bw per day.

In a rabbit developmental toxicity study, there was evidence of clinical signs, reduced maternal body weight gain (30%), reduced litter size (40%) and delayed ossification at the highest dose level of 15 mg/kg bw per day. One fetus at the top dose level and one at the intermediate dose level had multiple malformations that could not be unequivocally linked to flutriafol administration. The NOAELs for maternal and developmental toxicity were 7.5 mg/kg bw per day.

The Meeting concluded that flutriafol is teratogenic in rats.

In an acute neurotoxicity study in rats, there was no evidence of neuropathy at 750 mg/kg bw, the highest dose tested. The NOAEL for acute neurotoxicity was 250 mg/kg bw, based on altered functional observational battery and motor activity findings on day 1 at 750 mg/kg bw. The NOAEL for general toxicity was less than 125 mg/kg bw, based on transient reductions in body weight gain in males at all doses.

In a repeated-dose neurotoxicity study, there were no signs of neuropathy or neurotoxicity at 3000 ppm (equal to 172 mg/kg bw per day), the highest dose tested. The NOAEL for general toxicity was 500 ppm (equal to 29 mg/kg bw per day), based on reductions in body weight gain at the start of the study at 1500 ppm (equal to 84 mg/kg bw per day) and above.

In a 28-day immunotoxicity study in female mice, there was no reduction in the immunoglobulin M response to challenge with sheep red blood cells or changes in spleen or thymus weights. The NOAEL for immunotoxicity was 1000 ppm (equal to 208 mg/kg bw per day), the highest dose tested. The NOAEL for general toxicity was 50 ppm (equal to 9.8 mg/kg bw per day), based on reduced erythrocyte mean cell volume and hepatotoxicity at 250 ppm (equal to 47 mg/kg bw per day).

Medical monitoring of production plant workers has not identified any cases of occupational illness related to flutriafol.

The Meeting concluded that the available database on flutriafol is adequate to characterize the potential risk to fetuses, infants and children.

Toxicological evaluation

The Meeting established an acceptable daily intake (ADI) of 0–0.01 mg/kg bw on the basis of the NOAEL of 1.0 mg/kg bw per day in the 2-year rat study, based on increases in fatty changes and increased weights of the liver in males at 10 mg/kg bw per day. A safety factor of 100 was applied. The ADI is supported by the NOAEL in the carcinogenicity study in mice of 1.2 mg/kg bw per day,

based on the increased incidence and severity of hepatic centrilobular fatty change in males at 6 mg/kg bw per day.

The Meeting established an acute reference dose (ARfD) of 0.05 mg/kg bw on the basis of the NOAEL of 5 mg/kg bw per day in the 90-day and 1-year toxicity studies in dogs based on reduced body weight gain (males) or body weight loss (females) after 1 week (the first time of measurement) and subsequently reduced body weight gain during the early part of the study, although feed consumption was unaffected by treatment. A safety factor of 100 was applied. This provides a margin of greater than 1000 between the ARfD and the LOAEL for cleft palate in rats (75 mg/kg bw per day).

A toxicological monograph was prepared.

Levels relevant to risk assessment

Species	Study	Effect	NOAEL	LOAEL
Mouse	Two-year study of toxicity and carcinogenicity[a]	Toxicity	10 ppm, equal to 1.2 mg/kg bw per day	50 ppm, equal to 6 mg/kg bw per day
		Carcinogenicity	200 ppm, equal to 25 mg/kg bw per day[b]	—
Rat	Ninety-day study of toxicity[a]	Toxicity	200 ppm, equal to 13 mg/kg bw per day	2000 ppm, equal to 148 mg/kg bw per day
	Two-year study of toxicity and carcinogenicity[a]	Toxicity	20 ppm, equal to 1.0 mg/kg bw per day	200 ppm, equal to 10 mg/kg bw per day
		Carcinogenicity	2000 ppm, equal to 103 mg/kg bw per day[b]	—
	Multigeneration studies of reproductive toxicity[a,c]	Reproductive toxicity	300 ppm, equal to 16 mg/kg bw per day	1000 ppm, equal to 56 mg/kg bw per day
		Parental toxicity	60 ppm, equal to 3.5 mg/kg bw per day	240 ppm, equal to 14 mg/kg bw per day
		Offspring toxicity	300 ppm, equal to 16 mg/kg bw per day	1000 ppm, equal to 56 mg/kg bw per day
	Developmental toxicity study[d]	Maternal toxicity	10 mg/kg bw per day	75 mg/kg bw per day
		Embryo and fetal toxicity	10 mg/kg bw per day	75 mg/kg bw per day
Rabbit	Developmental toxicity study[d]	Maternal toxicity	7.5 mg/kg bw per day	15 mg/kg bw per day
		Embryo and fetal toxicity	7.5 mg/kg bw per day	15 mg/kg bw per day
Dog	Ninety-day and 1-year studies of toxicity[c,e]	Toxicity	5 mg/kg bw per day	15 mg/kg bw per day

[a] Dietary administration.

[b] Highest dose tested.

[c] Two studies combined.

[d] Gavage administration.

[e] Capsule administration.

Estimate of acceptable daily intake for humans

0–0.01 mg/kg bw

Estimate of acute reference dose

0.05 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 flutriafol

Absorption, distribution, excretion and metabolism in mammals	
Rate and extent of oral absorption	Rapid and extensive absorption: > 90% based on urinary and biliary excretion
Dermal absorption, rat (125 g/l suspension concentrate formulation)	~1% concentrate; ~10% in use dilutions; 8 h exposure and 9-day monitoring
Distribution	Widely distributed; highest levels in red blood cells
Potential for accumulation	No evidence for accumulation
Rate and extent of excretion	Rapid, equally in urine and faeces; extensive biliary excretion (~80%) with enterohepatic circulation
Metabolism in animals	Extensive metabolism; only trace amount of unchanged parent detected
Toxicologically significant compounds (animals, plants and the environment)	Flutriafol
Acute toxicity	
Rat, LD_{50}, oral	1140–1480 mg/kg bw
Rabbit, LD_{50}, dermal	> 2000 mg/kg bw
Rat, LC_{50}, inhalation	> 5.2 mg/L
Rabbit, dermal irritation	Non-irritant
Rabbit, ocular irritation	Mild irritant
Guinea-pig, dermal sensitization (Magnusson and Kligman)	No evidence
Mouse, dermal sensitization (local lymph node assay)	No evidence
Short-term studies of toxicity	
Target/critical effect	Body weights (from start of dosing); red blood cells (anaemia) and liver (weight, clinical chemistry, fatty change)
Lowest relevant oral NOAEL	5 mg/kg bw per day (90-day and 1-year dog studies)
Lowest relevant dermal NOAEL	1000 mg/kg bw per day (systemic; rats)
Lowest relevant inhalation NOAEC	No data
Long-term studies of toxicity and carcinogenicity	
Target/critical effect	Liver (increased weight and fatty change)
Lowest relevant NOAEL	1.0 mg/kg bw per day (rat); 1.2 mg/kg bw per day (mouse)
Carcinogenicity	Not carcinogenic

Genotoxicity	
	Some equivocal in vitro results; negative in vivo; considered unlikely to be genotoxic
Reproductive toxicity	
Reproduction target/critical effect	Reduced litter size
Lowest relevant reproductive NOAEL	16 mg/kg bw per day
Developmental target/critical effect	Reduced litter size, delayed ossification (rat and rabbit); hyoid abnormalities (rat); cleft palate (rat)
Lowest relevant developmental NOAEL	7.5 mg/kg bw per day (rabbit); 10 mg/kg bw per day (rat)
Neurotoxicity/delayed neurotoxicity	
Acute study	Altered functional observation battery and motor activity; neurotoxicity NOAEL 250 mg/kg bw (rat)
Ninety-day study	Not neurotoxic
Other toxicological studies	
Immunotoxicity	Not immunotoxic (female mice)
Medical data	
	No adverse effects reported in production plant operators

Summary

	Value	Study	Safety factor
ADI	0–0.01 mg/kg bw	Two-year rat study (supported by 2-year mouse study)	100
ARfD	0.05 mg/kg bw	Ninety-day and 1-year studies in dogs	100

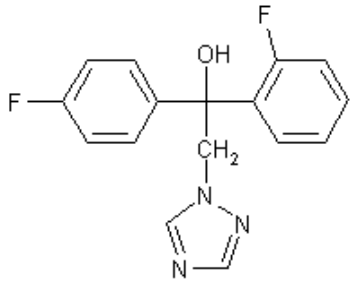
RESIDUE AND ANALYTICAL ASPECTS

Residue and analytical aspects of flutriafol were considered for the first time by the present Meeting. The residue evaluation was scheduled for the 2011 JMPR by the Forty-second Session of the CCPR (ALINORM 10/33/24)

Flutriafol is a triazole fungicide used in many crops for control of a broad spectrum of leaf and cereal ear diseases, particularly embryo borne diseases, e.g., bunts and smuts. The Meeting received information on identity, animal and plant metabolism, environmental fate in soil, rotational crops, analytical methods, storage stability, use patterns, supervised trials, farm animal feeding studies and fates of residues in processing.

(*RS*)-2,4′-difluoro-α-(1*H*-1,2,4-triazol-1-ylmethyl)benzhydryl alcohol

Structural formula:



Flutriafol is a 1:1 mixture of the enantiomers.

In this appraisal, the following abbreviated names were used for metabolites.

M1B	4-hydroxyflutriafol
M1D	4-hydroxy-5-methoxyflutriafol
M2B	flutriafol-(trans)-dihydrodiol
M5	Mixture of two isomeric hydroxyflutriafol derivatives
R5a	Hexose conjugated flutriafol
C6	Defluorinated flutriafol
1,2,4-Triazole	1*H*-1,2,4-triazole
Triazole alanine	1,2,4-triazoyl-3-alanine
Triazole acetic acid	1*H*-1,2,4-triazol-1-ylacetic acid

Animal metabolism

The Meeting received results of animal metabolism studies with flutriafol in rats, lactating cows and laying hens. The metabolism and distribution of flutriafol in animals were investigated using [^{14}C-carbinol] and [^{14}C-triazole]-labelled flutriafol.

In rats, flutriafol was extensively absorbed following a single oral administration of 5 or 250 mg/kg dose. Bile was shown to be the major route of elimination of administered radioactivity excreted via this route over three days. Excretion of the dose was rapid at both dose levels and urinary excretion was the major route, accounting for 50–68% daily dose in the repeat dose animals and 61–68% for the single dose animals. The remaining radioactivity was excreted in the faeces (29–55%) with less than 6% dose remaining in the tissues 168 hours after the final repeat dose was administered and less than 0.8% 168 hours after the single dose. Only a minor amount of cleavage of the triazole moiety from the flutriafol molecule occurred. Furthermore, no metabolism was detected in the triazole group or in the 4-fluorophenyl ring of molecule. All identified metabolites were shown to be hydroxylated derivatives of the 2-fluorophenyl ring. Three of the major urinary metabolites were identified as a 3,4-(cis)- and the two M2B metabolites of flutriafol. The bulk of remaining urinary radioactivity was attributable to glucuronide conjugates, the two main aglycones were identified as M1B and M1D. Metabolism in rats was summarized and evaluated by the WHO panel of the JMPR in 2011.

A lactating cow were dosed with [^{14}C-triazole]-flutriafol at 40 mg/animal/day, equivalent to approximately 2 ppm in the diet for 7 consecutive days. Gelatine capsules containing ^{14}C-triazole flutriafol absorbed onto powdered maize were introduced directly into the stomach via a stomach tube. Most of the administered radioactivity was excreted in the urine and faeces (45 and 33% of the dose).

Radioactive residues in muscle and fat (subcutaneous, omental and perirenal) were insignificant (< 0.01 mg/kg equivalent to flutriafol). The liver, kidney and heart contained residues of 0.29, 0.061 and 0.011 mg/kg equivalent to flutriafol, respectively. A total of 0.1% of the radioactivity administered to the cow was collected in the milk over the 7 day dosing period. The radioactive residue in the milk gradually increased to 0.007 mg/L (flutriafol equivalent) by Day 4 of the study, and maintained this level until the end of the study.

A small amount of parent flutriafol and M1B were contained in the milk. No compound in this fraction accounted for more than 6% of TRR in the milk. Most of the radioactivity in the milk (75%) was associated with polar, water soluble metabolites which were converted to oraganosoluble fractions by extensive hydrolysis conditions. Parent flutriafol was identified (29% TRR) and no individual compound accounted for more than 10% of TRR in the liver. However, M1B was detected (23% TRR) and no individual compound accounted for more than 10% of TRR in the kidney. The radioactive residues were too low to identify the compound in muscle and fat.

Laying hens were orally dosed with [^{14}C-triazole]- or [^{14}C-carbinol]-flutriafol at doses equivalent to 13.9 or 11.6 ppm in the feed for 7 consecutive days. Most of the administered doses (89.7% for triazole label and 91.2% for the carbinol label) were recovered in the excreta at sacrifice. The radioactive residues in egg appeared to reach plateau concentrations by the end of the study, and ranged from 0.134 mg/kg (carbinol label) to 0.204 mg/kg (triazole label). The TRR values were the highest for liver (0.36–0.41 mg/kg), followed by muscle (0.01–0.06 mg/kg) and fat (0.02–0.04 mg/kg).

Parent flutriafol was the most abundant component of the residue (carbinol label: 0.088–0.119 mg/kg, 65.7–74.8% TRR, triazole label: 0.099–0.103 mg/kg, 48.3–50.5% TRR) in the eggs. 1,2,4-Triazole was also detected in the eggs (0.056–0.060 mg/kg, 27.5–29.3% TRR) and muscle (0.048 mg/kg, 75.0% TRR). Flutriafol was detected in liver at low concentrations (0.007–0.013 mg/kg, 1.9–3.2% TRR) and 1,2,4-Triazole was present in liver at 0.057 mg/kg (13.9% TRR). Flutriafol was found in fat (0.012–0.028 mg/kg, 75.0–80.0% TRR) but no flutriafol was detected in muscle.

In the lactating cow and laying hen studies, flutriafol was metabolized to several metabolites. All metabolites detected in the metabolism of the lactating cow were also found in the metabolism of rats. The major metabolic processes in laying hens were the binding of flutriafol to liver proteins, the formation of hydroxyl flutriafol derivatives (fluorophenyl moiety), and the formation of free 1,2,4-Triazole.

Plant metabolism

The Meeting received plant metabolism studies performed on apples, sugar beet, cereals (wheat and barley) and oilseed rape using [^{14}C-triazole]- or [^{14}C-carbinol]-flutriafol.

In an apple metabolism study, apple trees were treated once at a rate of 0.12 kg ai/ha. The application rate was equivalent to 1 × the single application rate for apples. Samples of fruit and foliage were taken at a typical harvest time, 64 days after application. TRR values in apple fruits from the two radiolabelled forms of the test substance were similar with most of the radioactivity (72–78% TRR, equivalent to 0.030–0.051 mg/kg) extracted using acetonitrile or acetonitrile/water (1:1, v/v). Unextracted radioactivity comprised 18 to 23% TRR (0.009–0.012 mg/kg). Flutriafol comprised 50 to 56% TRR (0.023–0.032 mg/kg). The total unknowns comprised 22% TRR (0.013 mg/kg) in the triazole labelled sample and 9% TRR (0.003 mg/kg) in the carbinol labelled sample. The largest individual unknowns comprised only 5% and 3% TRR (0.003 and 0.001 mg/kg) respectively.

In attempt to confirm the presence of trace levels of triazole alanine and triazole acetic acid in apple fruit, the foliage from the [^{14}C-triazole]-flutriafol application was analysed since this contained higher radioactive residues. The results showed that flutriafol comprised 48% TRR (2.00 mg/kg). Triazole alanine was present at low level in the foliage extract (0.13 mg/kg) and comparison of chromatograms from fruit and foliage confirmed that triazole alanine was present in the fruit extracts

at trace levels. As with the fruit extracts, the presence of trace levels of Triazole acetic acid could not be confirmed. The radioactive residue was predominantly flutriafol. The triazole alanine metabolite is known to oxidise to triazole acetic acid in plants, however it did not appear that triazole acetic acid was present in apple extracts. The free 1,2,4-Triazole metabolite was not detected in the fruit or foliage samples.

In a sugar beet metabolism study, sugar beets grown in containers outdoors were sprayed at a rate of 0.125 kg ai/ha. Samples of foliage and beet (root) were taken within three hours after application and at 16 and 21 days after treatment (DAT). The TRRs in foliage samples taken just after application were 1.37 and 1.27 mg/kg for the [^{14}C-triazole] and [^{14}C-carbinol] radiolabels, respectively. No significant residue was observed in the root. In the 16 DAT sample, TRRs were 0.342 and 0.381 mg/kg in the foliage for [^{14}C-triazole] and [^{14}C-carbinol] radiolabels, respectively. The TRR of the root from the 16 DAT samples was≤ 0.005 mg/kg in both labelled forms. At harvest (21 DAT), the TRRs were 0.747 and 0.596 mg/kg in the foliage, and 0.009 and 0.005 mg/kg in the root for [^{14}C-triazole] and [^{14}C-carbinol] radiolabels, respectively. Flutriafol was the major residue in foliage samples, accounting for 69.2 and 70.8% TRR (0.412 and 0.519 mg/kg) at harvest, no other radioactive metabolite at harvest represented more than 5.4 and 5.0% TRR (0.033 and 0.038 mg/kg). There had been no cleavage of the flutriafol molecule that resulted in separation of the [^{14}C-carbinol] and [^{14}C-triazole] radiolabel positions. One metabolite of flutriafol in foliage extracts of sugar beet was identified as a hexose conjugate of flutriafol. This component represented a maximum of 0.026 mg/kg, 4.4% TRR at harvest (21 DAT).

In a cereal metabolism study, wheat and barley plants, grown both in a greenhouse and in the field, were treated at a rates of 0.081–0.105 kg ai/ha. In the greenhouse, both plants were treated with ^{14}C-flutriafol just prior ear emergence. In the field, ^{14}C-triazole-labelled flutriafol was applied to wheat just before ear emergence and to barley just after ear emergence. ^{14}C-carbinol-labelled flutriafol was applied just before ear emergence to barley and just after ear emergence to wheat.

At maturity in the greenhouse study no residues of flutriafol (< 0.005 mg/kg) were detected in the grain. Following application of ^{14}C-triazole-labelled flutriafol, triazole alanine accounted for 40–48% of the TRR in the grain (0.08 and 0.04 mg/kg in barley and wheat respectively) and triazole acetic acid was also characterised as a significant metabolite (0.04 and < 0.01 mg/kg in barley and wheat respectively). TRRs in barley and wheat grain following ^{14}C-carbinol-labelled flutriafol applications were considerably lower (0.02 and 0.01 mg/kg respectively) than those of ^{14}C-triazole-labelled flutriafol applications (0.41 and 0.18 mg/kg respectively). In barley straw, flutriafol was the major radioactive component, and accounted for 63% of the TRR (1.3 mg/kg).

At maturity in the field study, the TRR in the wheat grain, following the ^{14}C-triazole-labelled flutriafol application, was 0.05 mg/kg and no flutriafol was detected (< 0.0002 mg/kg). Triazole alanine and triazole acetic acid accounted for 58 and 26% of this residue, respectively. The TRR in barley grain was 0.10 mg/kg. Flutriafol, triazole alanine and triazole acetic acid accounted for 24, 8 and 5% of this residue respectively. The TRRs in the grain in both plants following ^{14}C-carbinol-labelled flutriafol applications were less than 0.01 mg/kg.

Radioactive residues in the straw ranged from 0.12 to 0.72 mg/kg. Flutriafol was the major component (57% in wheat straw from ^{14}C-triazole-labelled flutriafol treatment). Radioactive residues in the straw were of a similar level for greenhouse and field-grown plants. Flutriafol was the dominant component of the radioactive residue. Triazole alanine and Triazole acetic acid were not detected in the straw. Some (16–40%) of the radioactive residue was not extractable.

In an oilseed rape metabolism study, oilseed rape plants grown in containers outdoors were sprayed at a rate of 0.125 kg ai/ha. The plants were treated at the early pod set growth stage, i.e., approximately 10% of the potential pods had formed. Plants were sampled just after treatment (0 DAT), at three intermediate stages (7, 14 and 21 DAT) and at harvest (42 DAT). The TRR and the nature of the radioactive residue were investigated in the whole plant taken just after application, in

the separated pods and remaining plant at the intermediate sampling (14 DAT) and in the separated seeds and remaining plant at harvest.

The TRR in the forage samples (whole plant) taken just after treatment (0 DAT) were 0.782 and 1.50 mg/kg for the [^{14}C-triazole] and [^{14}C-carbinol] radiolabels, respectively. At the pod development stage (14 DAT), TRRs were 0.751 and 0.779 mg/kg in the pods, and 1.17 and 1.60 mg/kg in the remaining plant. At harvest (42 DAT), TRRs were 1.32 and 0.729 mg/kg in the seeds, and 0.246 and 0.355 mg/kg in the remaining plant ([^{14}C-triazole] and [^{14}C-carbinol] radiolabels, respectively).

In the seeds at 42 DAT, flutriafol was the only radioactive component in the hexane extracts, accounting for 31.5 and 27.2% TRR (0.415 and 0.198 mg/kg) for the [^{14}C-triazole] and [^{14}C-carbinol] radiolabels, respectively. Flutriafol was the major radioactive component in the subsequent solvent/water extracts of the seeds, accounting for 29.8 and 27.4% TRR (0.392 and 0.200 mg/kg, [^{14}C-triazole] and [^{14}C-carbinol] radiolabels, respectively). Flutriafol was present in the enzyme extracts, in the weak base extracts and in the strong acid and strong base extracts. In total, flutriafol accounted for 6.3 and 7.3% TRR (0.082 and 0.054 mg/kg) in the acid and base extracts of seeds for the [^{14}C-triazole] and [^{14}C-carbinol] radiolabels, respectively.

Components R5a accounted for 3.8% TRR (0.028 mg/kg) in seeds of plants treated with [^{14}C-carbinol] flutriafol, and for 3.8% TRR (0.050 mg/kg) in seeds of plants treated with [^{14}C-triazole] flutriafol. Component C6, which was present in the strong acid and strong base extracts only, accounted for a total of 3.0 and 2.9% TRR (0.039 and 0.021 mg/kg, [^{14}C-triazole] and [^{14}C-carbinol] radiolabels, respectively). Unidentified radioactive components in these seed extracts did not individually represent more than 10% TRR.

In the forage samples taken at 0 DAT, and in the remaining plant samples at 14 DAT and 42 DAT, most of the residues were extractable by acetonitrile/water. In the pods and seeds, significant residues were released only by successive additional enzyme and acid/base treatments. Flutriafol was found both in the initial acetonitrile/water extracts and in the further enzyme/acid/base extracts, suggesting some binding to the plant matrix. A hexose conjugate of flutriafol was released by acetonitrile/water, while the other identified residue, a defluorinated flutriafol, was found only in the further extracts. All extractable residues contained both the carbinol carbon and triazole ring radiolabel centres indicating that no cleavage of the flutriafol molecule had occurred.

In the plant metabolism studies on apples, sugar beet, cereals (wheat and barley) and oilseed rape, flutriafol is the major component of the residues found in apples, sugar beet (forage), cereals (straw) and oilseed rape (seed and remaining plant). In wheat grain, the major components of the residues are triazole alanine and triazole acetic acid. In barley grain, flutriafol was the major component with low levels of 0.002 and 0.02 mg/kg. Radioactivity in sugar beet root was too low to characterize.

Environmental fate in soil

The Meeting received information on aerobic soil metabolism, soil photolysis and on rotational crops.

Aerobic soil metabolism and degradation has been studied in six different soils at a nominal average temperature of 20 °C for 252 days. Flutriafol is slowly degraded in laboratory incubated soils. Approximately 85% remained after 252 days in a loamy sand and a sandy clay loam.

The photodegradation of flutriafol was investigated on a sandy loam soil. After 7 days photochemical reactor irradiation, 60–67% of the total radioactivity applied to the soil plates was characterized as flutriafol. 1,2,4-Triazole and 2,4'-difluorobenzophenone accounted for 2–3% of the radioactive residues. After 30 days irradiation in natural sunlight, 75–82% of the applied radioactivity was characterized as flutriafol. The photodegradation products formed were similar to those seen after artificial irradiation and accounted for 7–10% of the applied radioactivity. Flutriafol appears to be relatively photochemically stable on a dry soil surface.

In a confined rotational crop study, wheat, peas, sugar beet and oilseed rape were planted at 30, 120 and 365 days after a soil application of [^{14}C-triazole] and [^{14}C-carbinol]-flutriafol at 0.125 kg ai/ha. The major components found were flutriafol, triazole alanine and triazole acetic acid. Small levels of M1B (1.5–2.5% TRR) were found in the wheat straw and sugar beet foliage.

Another confined rotational crop study was conducted using [^{14}C-triazole] and [^{14}C-carbinol] - flutriafol with lettuce, radish, and wheat planted at 30, 120 and 365 days after application to soil at 0.26 kg ai/ha. Residues in crops planted 120 DAT to soil had similar TRR values to those found in crops planted 30 DAT. Radish tops had higher residues than the corresponding radish roots samples, indicating that flutriafol and its metabolites were translocated within the xylem of the plant tissue. The TRR in the vegetative portions of wheat increased with maturity, in the order forage < hay < straw. Flutriafol was a significant component of the residue in all treated crop samples, ranging from barely detectable in wheat grain (0.003 to 0.009 mg/kg) to a high of 0.416 mg/kg in one straw sample. Triazole lactic acid and triazole alanine were detected in various commodities, present at more than 10% TRR for any individual commodity. Triazole alanine was detected as a major compound in wheat grains, and triazole acetic acid was also found at > 10% TRR.

Residues in field rotational crops were studied at sites in the UK. A foliar spray was applied at four sites in the first year at 0.188 kg ai/ha and in each subsequent year at 0.25 kg ai/ha. After five consecutive years of application, with a total rate applied of 1.188 kg ai/ha, sugar beet, fodder beet, potato, carrot and spring barley, as rotational crops, were sown/planted on the test sites in the sixth growth season and grown to maturity. Sugar beet roots, fodder beet roots, potatoes and carrots from each of the sites contained non-detectable or low residues of flutriafol, i.e., < 0.01–0.02 mg/kg. Foliage samples of sugar beet and fodder beet also contained non-detectable or low residues, < 0.01–0.08 mg/kg. Grain from the spring barley contained a low residue of flutriafol, 0.05 mg/kg. Residues of flutriafol in the spring barley straw samples were 0.38 mg/kg.

The additional field rotational crop studies were carried out using the plots treated at the highest rate (4.0 kg ai/ha) at three trial sites in the UK. The field studies were designed to provide samples of potato, sunflower, maize, spring barley, spring wheat, oilseed rape, pea, cabbage, carrot and sugar beet grown in soil with artificially high levels of aged flutriafol residues, close to or in excess of the maximum predicted concentration in soil after 26 years continuous application of the maximum label rate (0.156 kg ai/ha) of field crops. The soil at the trial sites used had been treated in 1988 with a single application of flutriafol at a nominal rate of 4.0 kg ai/ha. The rotational crops were sown in 1991 and grown to maturity. Representative samples of the crops were taken at harvest and analysed for residues of flutriafol and its major metabolites triazole alanine and triazole acetic acid. No residues (< 0.05 mg/kg) of flutriafol were detected in the potato tuber, sunflower seeds, maize grains, rape seeds and pea seeds. Residues of flutriafol were found at low concentrations in the grain of spring barley (< 0.03–0.07 mg/kg), spring wheat (< 0.03–0.03 mg/kg), cabbage heads (< 0.05–0.12 mg/kg), carrot roots (< 0.05–0.13 mg/kg), sugar beet roots (< 0.01–0.03 mg/kg), maize straw (0.16–0.31 mg/kg) and sugar beet foliage (0.03–0.42 mg/kg). Residues in the spring barley straw (0.24–1.5 mg/kg), the spring wheat straw (0.29–2.5 mg/kg) and pea haulm (0.28–3.8 mg/kg) were found at higher levels of flutriafol. The samples of spring wheat grain (0.28–3.0 mg/kg), rape seeds (0.59–17 mg/kg) and pea seeds (0.15–7.7 mg/kg) contained high residues of triazole alanine.

Residues of flutriafol and triazole alanine may be found in rotational crops.

Analytical methods

The Meeting received description and validation data for analytical methods for residues of parent flutriafol and triazole metabolites (1,2,4-Triazole, triazole alanine and triazole acetic acid) in raw agricultural commodities, processed commodities, feed commodities and animal commodities. In most of the methods for determination of flutriafol, homogenized samples were extracted with acetonitrile/water (for plant materials) and acetonitrile (for animal commodities), and the extract was cleaned up with liquid–liquid partition followed by column chromatography using SPE (for plant

materials) or gel permeation chromatography (for animal materials). Residues were determined by gas chromatography with NPD or MSD, or HPLC with MS/MS. The methods of analysis for a range of substrates were validated with LOQs of the 0.01 mg/kg for flutriafol.

The multiresidue method DFG Method S19 (modified version) with GC employing TSD, NPD or MSD was validated for flutriafol in plant materials. LOQs were 0.01–0.05 mg/kg for flutriafol.

The Meeting received LC-MS/MS method of analysis for triazole metabolites in plant and animal materials. The method was specific for each metabolite. The method was validated with an LOQ of 0.01 mg/kg for all analytes.

Stability of pesticide residues in stored analytical samples

The Meeting received information on the freezer storage stability of flutriafol residues in plants (apple, grape, cabbage, sugar beet root, pea seed, soya bean, barley grain, wheat and oilseed rape), processed commodities (apple juice, soya bean meal and refined oil) and animal commodities (milk, eggs, muscle and fat).

The Meeting also received information on the freezer storage stability of triazole metabolites in apple (fruit and juice), milk, eggs, muscle and fat.

Storage stability results indicate that flutriafol residues were stable for at least 4 months in animal commodities, for at least 5 months in soya bean seed, for 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, sugar beet root. The results also indicate that triazole metabolite residues were stable for at least 4 months in apple fruits and juice, and for at least 5 months in animal commodities.

The periods of storage stability studies cover the sample storage intervals of residue trials.

Definition of the residue

In the lactating cow metabolism study, TRRs in liver (0.29 mg/kg), kidney (0.06 mg/kg) and heart (0.01 mg/kg) were higher than those in milk and other tissues (< 0.01 mg/kg). Flutriafol is the major component of the residue in liver (29% TRR). However, M1B is the major component of the residue in kidney (23% TRR) but at low level. In the laying hen metabolism study, TRRs were the highest for liver (0.36–0.41 mg/kg), followed by muscle (0.01–0.06 mg/kg) and fat (0.02–0.04 mg/kg). Flutriafol is the major residue component in eggs and fat (48–80% TRR).

1,2,4-Triazole was found in muscle (75.0% TRR) and liver (13.9% TRR) of laying hens. However, according to farm animal feeding studies, concentrations of 1,2,4-Triazole, triazole alanine and triazole acetic acid were < 0.01 mg/kg.

The Meeting decided that parent flutriafol is a suitable analyte for enforcement purposes and dietary risk assessment in animal commodities.

The octanol/water coefficient (log P_{ow}) of flutriafol is 2.3 at 20 °C. In the lactating cow metabolism and feeding studies, flutriafol residues were < 0.01 mg/kg in muscle and fat. However, in the laying hen metabolism and feeding studies, flutriafol residues in fat were at least 3 times higher than those in muscle. The Meeting considered flutriafol was fat soluble.

The plant metabolism studies of flutriafol were conducted with fruit (apple), root vegetables (sugar beet), cereals (wheat and barley) and oilseeds (rape). Each study was conducted with both triazole- and carbinol-radiolabelled flutriafol. Parent flutriafol was always the major component (24–71% TRR) in all matrices except wheat grains at harvest. Triazole alanine and triazole acetic acid accounted for 58 and 28% of TRR (0.05 mg/kg) in wheat grains. No other radioactive components in the extracts from plant matrices were individually present at more than 10% TRR.

The 2007 JMPR noted that 1,2,4-Triazole, triazole acetic acid and triazole alanine may be derived from several sources. In a situation in which the metabolites arise from multiple triazole fungicides, they cannot be included in the residue definition. Since the metabolite cannot be linked to a specific triazole fungicide, they would have to be evaluated on their own.

Field trials conducted in the USA indicated that triazole alanine and triazole acetic acid were found in plant matrices. However, 1,2,4-Triazole was not detected in samples (except one trial) above LOQ. These findings agree with the information obtained from the metabolism studies. The relatively low level of the residues in food commodities and the low toxicity of triazole alanine and triazole acetic acid do not justify their inclusion for dietary risk assessment.

The Meeting decided that parent flutriafol is a suitable analyte for enforcement purposes and dietary risk assessment in plant commodities.

The Meeting recommended the following residue definition:

Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities: *flutriafol*

The Meeting considers the residue is fat soluble

Results of supervised trials on crops

The Meeting received supervised trial data for the foliar application of flutriafol on apples, grapes, bananas, sweet peppers, soya beans, wheat, peanuts and coffee. Residue trial data was made available from European countries, the countries of Latin America and the USA.

Labels were available from Argentina, Australia, Belarus, Brazil, Chile, Columbia, Croatia, Estonia, Italy, Kazakhstan, Lithuania, Malaysia, Mexico, Moldova, Romania, Russia, South Africa, Spain, Taiwan, the Ukraine and the USA describing the registered uses of flutriafol.

The OECD calculator was used as a tool to assist in the estimation of maximum residue levels from the selected residue data set obtained from the supervised residue trials. As a first step, the Meeting reviewed the trial conditions and other relevant factors related to each data set to arrive at a best estimate of the maximum residue level using expert judgement. Then the OECD calculator was employed. If the statistical calculation spreadsheet suggested a different value, a brief explanation of the deviation was supplied.

Pome fruits

Data were available from supervised trials on apples in European countries and the USA.

In Italy, flutriafol is registered for apples at two foliar applications of 0.030 kg ai/ha with a PHI of 21 days. However, the residue trials on apples conducted in Greece, Italy, France and Spain did not match the GAP of Italy.

The GAP on pome fruit of the USA is a maximum four foliar applications at a maximum rate of 0.12 kg ai/ha with a PHI of 14 days. Flutriafol residues in apples from trials in the USA matching GAP were (n = 16): 0.03, 0.04, 0.05 (3), 0.06 (3), 0.08 (2), 0.09, 0.10 (2), 0.12 (2) and 0.16 mg/kg.

Based on the trials for apples in the USA, the Meeting estimated a maximum residue level, an STMR value and an HR value for flutriafol in pome fruit of 0.3, 0.07 and 0.16 mg/kg respectively.

Grapes

Data were available from supervised trials on grapes from a number of European countries and the USA.

In the Ukraine, flutriafol is registered for use on grapes at two foliar applications of 0.025 kg ai/ha with a PHI of 45 days. In Romania, flutriafol is registered for use on grapes at six foliar applications of 0.038 kg ai/ha with a PHI of 30 days. However, the residue trials on grapes conducted in Greece, Italy, France and Spain did not match the GAP of the Ukraine or that of Romania.

The GAP on grapes of the USA allows a maximum six foliar applications at a maximum rate of 0.073–0.091 kg ai/ha with a PHI of 14 days. The Meeting concluded that the additional spray would have little influence on the final residue. The Meeting decided to use the principle of proportionality, as described in the JMPR Report 2010, to estimate a maximum residue level, an STMR value and an HR value for grapes.

Residues in grapes from the US trials at 0.128 kg ai/ha were (n = 13): 0.12, 0.21 (2), 0.25, 0.28, 0.30 (2), 0.31, 0.35, 0.37, 0.43, 0.61 and 0.86 mg/kg. Scaled residues in grapes were (scaling factor 0.71; 0.128➔0.091 kg ai/ha): 0.09, 0.15 (2), 0.18, 0.20, 0.21 (2), 0.22, 0.25, 0.26, 0.31, 0.43 and 0.61 mg/kg.

Based on the scaled residues in grapes, the Meeting estimated a maximum residue level, an STMR value and an HR value of 0.8, 0.21 and 0.61 mg/kg, respectively.

Banana

Data were available from supervised trials on bananas from a number of South American countries.

In Columbia, flutriafol is registered for use as a foliar application to bananas at a rate of 0.1 kg ai/ha with a PHI of 0 days. The number of applications is not specified on the registered label of Columbia. The results from unbagged bananas in each trial were used to estimate a maximum residue level, an STMR and an HR value for banana. In all trials conducted, residue concentrations in bagged banana were never higher than those in unbagged banana. Residues in whole fruit of unbagged banana from trials matching GAP of Columbia were (n = 12): 0.01, 0.02 (2), 0.05, 0.07 (2), 0.09, 0.10 (2), 0.14 and 0.17 (2) mg/kg.

Based on the residues in whole fruit of unbagged banana, the Meeting estimated a maximum residue level for flutriafol in banana of 0.3 mg/kg.

Residues in unbagged banana pulp from trials matching the GAP of Columbia were (n = 12): 0.01, 0.02, 0.04 (2), 0.05 (4), 0.07, 0.08 (2) and 0.09 mg/kg.

Based on the residues in unbagged banana pulp, the Meeting estimated an STMR and an HR values for flutriafol in banana of 0.05 and 0.09 mg/kg respectively.

Sweet peppers

Data were available from supervised trials on sweet peppers in Spain.

In Spain, flutriafol is registered for use of three foliar applications on sweet peppers at a rate of 0.019 kg ai/hL with a PHI of 1day. Because residues decline was slow, the Meeting decided to use the available 0 day PHI data. Residues in sweet peppers from trials in greenhouse approximately matching GAP of Spain were (n = 8): 0.15, 0.19, 0.24, 0.26, 0.29, 0.32 and 0.41 (2) mg/kg.

Based on the trials for sweet peppers in Spain, the Meeting estimated a maximum residue level, an STMR and HR values for flutriafol in sweet peppers of 1, 0.28 and 0.41 mg/kg, respectively.

The normal Meeting procedure is to round the value to the nearest units for maximum residue levels. Rounding up the value of 0.9 mg/kg obtained from the OECD calculator results in 1 mg/kg, which coincides with the recommendation of the current Meeting.

Soya bean

Data were available from supervised trials on soya bean in Brazil and the USA.

In Brazil, flutriafol is registered for use on soya bean at two foliar applications of 0.125 kg ai/ha with a PHI of 28 days. Residues in soya bean seeds from trials matching Brazilian GAP were (n = 3): < 0.05 (3) mg/kg. However, the numbers of trials on soya bean, matching Brazilian GAP, were considered insufficient to estimate a maximum residue level for the commodity.

Trials from the USA on soya bean were reported for the foliar application of a SC formulation (GAP: three foliar applications of a maximum rate of 0.128 kg ai/ha, 0.256 kg ai/ha per season, PHI of 21 day). Flutriafol residues in soya bean seeds from trials in the USA matching GAP were (n = 20): < 0.01, 0.01, 0.02 (3), 0.03, 0.04 (3), 0.05, 0.06 (2), 0.07, 0.08 (3), 0.11, 0.17, 0.19 and 0.30 mg/kg.

Based on the trials on soya beans in the USA, the Meeting estimated a maximum residue level and an STMR value for flutriafol in soya bean seeds of 0.4 and 0.055 mg/kg, respectively.

Wheat

Data were available from supervised trials on wheat in European countries and the USA.

In Lithuania, flutriafol is registered for use on wheat at two foliar applications of 0.125 kg ai/ha with a PHI of 30 days. Residue in wheat grains from trial in Northern France and UK matching GAP of Lithuania was < 0.01 mg/kg. However, the trials for wheat matching the GAP of Lithuania were insufficient to estimate a maximum residue level for the commodity.

In Spain, flutriafol is registered for use on wheat at the foliar application of 0.125 kg ai/ha between the end of stem elongation and flowering. The frequency of application is not specified in the registration label. Residues in wheat grains from trials in South France and Spain matching the GAP of Spain were (n = 8): < 0.01 (2), 0.01 (2), 0.02 (2), 0.04 and 0.1 mg/kg.

Trials from the USA on wheat were reported for the foliar application of a SC formulation (GAP: two foliar applications of a maximum rate of 0.128 kg ai/ha, PHI of 30 day). However, flutriafol residue trials on wheat in the USA did not match the GAP of the USA.

Based on the trials for wheat in Southern France and Spain, the Meeting estimated a maximum residue level, an STMR value for flutriafol in wheat grains of 0.15 and 0.015 mg/kg respectively.

Peanuts

Data were available from supervised trials on peanuts from the USA.

Trials from the USA on peanuts were reported for the foliar application of a SC formulation (GAP: four foliar applications of a maximum rate of 0.128 kg ai/ha, PHI of 7 day). Flutriafol residues in peanut nutmeat from trials in the USA matching GAP were (n = 13): < 0.01 (2), 0.01 (2), 0.02 (4), 0.03 (2), 0.04 (2) and 0.08 mg/kg.

Based on the trials for peanuts from the USA, the Meeting estimated a maximum residue level and an STMR value for flutriafol in peanut nutmeats of 0.15 and 0.02 mg/kg respectively.

The OECD calculator estimated a maximum residue level of 0.1 mg/kg. However, the Meeting recommended 0.15 mg/kg because the result of the OECD calculator was too close to the highest residue value.

Coffee beans

Data were available from supervised trials on coffee in Brazil, Columbia, Guatemala and Vietnam.

Trials from Brazil on coffee were reported for the foliar application of a SC formulation. (GAP: initial soil application of a rate of 0.69 kg ai/ha followed by two foliar applications of a rate of 0.25 kg ai/ha, PHI of 30 day). Flutriafol residues in coffee beans from trials in Brazil, Columbia and Guatemala matching GAP of Brazil were (n = 8): 0.01, 0.04, < 0.05 (4), 0.05 and 0.10 mg/kg.

Based on the trials for coffee in Brazil, Columbia and Guatemala, the Meeting estimated a maximum residue level and an STMR value for flutriafol in coffee beans of 0.15 and 0.05 mg/kg respectively.

Animal feedstuffs

Wheat forage and straw

Data were available from supervised trials on wheat in European countries and the USA.

In Lithuania, flutriafol is registered for use on wheat at two foliar applications of 0.125 kg ai/ha with a PHI of 30 days. Residues in wheat whole plant from trial in Northern France and UK matching GAP of Lithuania were (n = 3): 0.16 (2) and 0.17 mg/kg. Residues in wheat straw from trials in Northern France and UK matching GAP of Lithuania were 0.44 mg/kg. However, the trials for wheat matching the GAP of Lithuania were insufficient to estimate a maximum residue level for the commodity.

In Spain, flutriafol is registered for use on wheat at the foliar application of 0.125 kg ai/ha between the end of stem elongation and flowering. The frequency of application and the timing of harvest for forage are not specified in the registration label. Residues in wheat straw from trials in Southern France and Spain matching GAP of Spain were (n = 8): 0.15, 0.35, 0.55, 1.4, 1.5, 1.9, 3.6 and 4.1 mg/kg (fresh weight basis).

Based on the residues in wheat straw from trials in Southern France and Spain, the Meeting estimated a maximum residue level, a median residue value and a highest residue value for flutriafol in wheat straw and fodder, dry of 8, 1.45 and 4.1 mg/kg respectively.

Trials from the USA on wheat were reported for the foliar application of a SC formulation (GAP: two foliar applications of a maximum rate of 0.128 kg ai/ha, PHI of 0 day for wheat forage). Residues in wheat forage from trials in the USA matching GAP were (n = 20): 4.0, 4.1, 4.2, 5.1, 5.2, 5.5, 5.6, 5.7, 7.3, 7.6, 8.4, 8.6, 9.2, 9.3, 11 (2), 13 (2), 16 and 19 mg/kg (fresh weight basis).

Based on the residues in wheat forage from trials in the USA, the Meeting estimated a median residue value and a highest residue value for flutriafol in wheat forage of 8.0 and 19 mg/kg respectively.

Peanut fodder

Data were available from supervised residue trials on peanut in the USA

Trials from the USA on peanut were reported for the foliar application of a SC formulation (GAP: four foliar applications of a maximum rate of 0.128 kg ai/ha, PHI of 7 day). Flutriafol residues in peanut hay from trials in the USA matching GAP were (n = 13): 0.74, 1.5, 1.7, 2.0, 2.1, 2.5, 2.6, 3.1, 4.3, 7.3, 7.7, 8.8 and 8.9 mg/kg (fresh weight basis).

Based on the trials for peanut in the USA, the Meeting estimated a maximum residue level, a median residue value and a highest residue value for flutriafol in peanut fodder of 20, 2.6 and 8.9 mg/kg respectively.

Rotational crops

The Meeting noted that residues may occur in rotational crops. However, available field rotational crop studies were not adequate to propose maximum residue levels to cover rotational crops.

Fate of residues during processing

The fate of flutriafol residues has been examined in apple, grapes, soya bean seeds, wheat grains and peanut nutmeats processing studies. Based on the results of processing studies conducted in the USA, processing factors were calculated for apples, grapes, sweet peppers, soya bean, wheat and peanut. Estimated processing factors and the derived STMR-Ps are summarized in the Table below.

Processing factors, STMR-P and HR-P for food and feed

Raw agricultural commodity (RAC)	Processed commodity	Calculated processing factors	PF (Mean or best estimate)	RAC STMR (mg/kg)	STMR-P (mg/kg)	RAC HR (mg/kg)	HR-P (mg/kg)
Apple	Juice	0.50, 0.45	0.48	0.07	0.034	0.16	
	Wet pomace	1.9, 1.9	1.9		0.13		
	Dry pomace	10, 8.5	9.3		0.65		1.5
Grape	Juice	0.63	0.63	0.21	0.13	0.61	
	Raisin	2.8	2.8		0.59		1.7
Sweet pepper	Preserved	0.57, 0.67, 0.74 (2), 0.79, 1.1, 1.3, 1.4	0.77	0.28	0.22	0.41	0.32
Soya bean	Meal	1.3	1.3	0.055	0.072		
	Refined oil	1.3	1.3		0.072		
	Hulls	0.97	0.97		0.053		
	Aspirated grain fraction	1.7	1.7		0.094		
Wheat	Bran	2.1	2.1	0.015	0.032		
	Flour	0.33	0.33		0.005		
	Germ	2.8	2.8		0.042		
	Aspirated grain fraction	13	13		0.20		
Peanut	Meal	0.79	0.79	0.02	0.016		
	Refined oil	1.4	1.4		0.028		
Coffee	Roasted coffee beans	0.95	0.95	0.05	0.048		

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

The Meeting estimated a maximum residue level of 2 mg/kg (0.8 × 2.8 = 2.2 mg/kg) for raisins, 0.3 mg/kg (0.15 × 2.1 = 0.315 mg/kg) for wheat bran by the processing factor.

On the basis of the STMR and HR for sweet peppers and default dehydration factor of 10, the Meeting estimated at an STMR value and an HR value for dried chili peppers of 2.7 and 4.1 mg/kg respectively. Based on the maximum residue level of sweet peppers, the Meeting recommended a maximum residue level of 10 mg/kg for chili peppers (dry).

Residue in animal commodities

Farm animal dietary burden

The Meeting estimated the dietary burden of flutriafol in farm animals on the basis of the diets listed in Appendix IX of the FAO Manual 2009. Calculation from highest residue, STMR (some bulk commodities) and STMR-P values provides levels in feed suitable for estimating maximum residue levels, while calculation from STMR and STMR-P values for feed is suitable for estimating STMR values for animal commodities. The percentage dry matter is taken as 100% when the highest residue levels and STMRs are already expressed in a dry weight basis.

Estimated maximum and mean dietary burdens of farm animals

Dietary burden calculations for beef cattle, dairy cattle, broilers and laying poultry are provided in Appendix IX of the FAO manual. The calculations were made according to the animal diets from US-Canada, EU, Australia and Japan in the Table (Appendix IX of the FAO manual).

Livestock dietary burden, flutriafol, ppm of dry matter diet

	US-Canada		EU		Australia		Japan	
	Max	Mean	Max	Mean	Max	Mean	Max	Mean
Beef cattle	0.50	0.19	15	6.5	76[a]	32[b]	0.064	0.064
Dairy cattle	17	6.9	15	6.5	50	20[c]	0.055	0.055
Poultry-broiler	0.041	0.041	0.050	0.050	0.039	0.039	0.029	0.029
Poultry-layer	0.041	0.041	7.6[d]	3.2[e]	0.038	0.038	0.024	0.024

[a] Highest maximum beef or dairy cattle dietary burden suitable for maximum residue level estimates for mammalian meat and milk

[b] Highest mean beef or dairy cattle dietary burden suitable for STMR estimates for mammalian meat

[c] Highest mean dairy cattle dietary burden suitable for STMR estimates for milk

[d] Highest maximum poultry dietary burden suitable for maximum residue level estimates for poultry meat and eggs

[e] Highest mean poultry dietary burden suitable for STMR estimates for poultry meat and eggs

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 flutriafol residues in the animal diet.

Lactating dairy cows

Holstein dairy cows were dosed with flutriafol for 29 days at the equivalent of 0.5, 1.5 and 5.0 ppm in the diet. Residues of flutriafol were below the LOQ (0.01 mg/kg) in whole milk at the 5.0 ppm feeding level. Kidney, muscle and fat contained no residue (< 0.01 mg/kg) of flutriafol at 0.5 and 5.0 ppm feeding levels. Liver contained flutriafol residues of < 0.01–0.04 mg/kg at the 0.5 ppm feeding level, 0.09–0.10 mg/kg at the 1.5 ppm level and 0.23–0.39 mg/kg at the 5.0 ppm level respectively.

Laying hens

Laying hens were dosed with flutriafol for 29 days at the equivalent of 0.5, 1.5 and 5.0 ppm in the diet. Residues of flutriafol were below the LOQ (0.01 mg/kg) in eggs at the 0.5 ppm feeding level. At the 5.0 ppm level, flutriafol residues in eggs were 0.02–0.04 mg/kg from day 3 to day 28. Muscle contained no residue (< 0.01 mg/kg) of flutriafol at 0.5 and 5.0 ppm feeding levels. Liver contained no residues (< 0.01 mg/kg) of flutriafol at 0.5 feeding level and 0.03–0.10 mg/kg at the 5.0 ppm level. Fat contained no residues (< 0.01 mg/kg) of flutriafol at 0.5 feeding level and 0.05–0.07 mg/kg at the 5.0 ppm level.

Animal commodities maximum residue levels

For MRL estimation, the residue in animal commodities is flutriafol.

The maximum dietary burden for beef and dairy cattle is 76 ppm and is much higher than the highest dose level in the feeding study of 5.0 ppm. In a feeding study, in which flutriafol equivalent to 5.0 ppm in the diet was dosed to lactating cows for 29 consecutive days, no flutriafol residues were detected in kidney, muscle, fat and milk (< 0.01 mg/kg). The Meeting considered it is not applicable to extrapolate the residues in kidney, liver, muscle, fat and milk at a dietary burden of 76 ppm from the results of the feeding study.

The Meeting could not estimate a maximum residue level of mammalian meat, mammalian edible offal and milk.

The maximum dietary burden for broiler and layer poultry is 7.6 and is higher than the highest dose level in the feeding study of 5.0 ppm. In a feeding study, in which flutriafol equivalent to 5.0 ppm in the diet was dosed to laying hens for 29 consecutive days, no flutriafol residues were detected in muscle (< 0.01 mg/kg). The Meeting considered it is not applicable to extrapolate the residues in muscle at a dietary burden of 7.6 ppm from the results of the feeding study.

The Meeting could not estimate a maximum residue level of poultry meat, poultry edible offal and eggs.

FURTHER WORK OR INFORMATION

Desirable

- Field rotational crop studies suitable for estimation of maximum residue levels for rotational crops.
- Animal feeding studies covering the estimated maximum dietary burden of farm animals.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Dietary Intakes (IEDIs) of flutriafol were calculated for the 13 GEMS/Food cluster diets using STMRs/STMR-Ps estimated by the current Meeting (Annex 3). The ADI is 0–0.01 mg/kg bw and the calculated IEDIs were 0–7% of the maximum ADI (0.01 mg/kg bw). The Meeting concluded that the long-term intakes of residues of flutriafol, resulting from the uses considered by current JMPR, are unlikely to present a public health concern.

Short-term intake

The International Estimated Short-Term Intakes (IESTI) of flutriafol were calculated for food commodities and their processed commodities using HRs/HR-Ps or STMRs/STMR-Ps estimated by the current Meeting (Annex 4). The ARfD is 0.05 mg/kg bw and the calculated IESTIs were a maximum of 50% of the ARfD. The Meeting concluded that the short-term intake of residues of flutriafol, when used in ways that have been considered by the JMPR, is unlikely to present a public health concern.

5.14 GLYPHOSATE (158) AND METABOLITES

TOXICOLOGY

Glyphosate (*N*-(phosphonomethyl)glycine) is a non-selective systemic herbicide that was last evaluated by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) in 2004, when a group acceptable daily intake (ADI) for glyphosate and aminomethylphosphonic acid (AMPA), the main metabolite of glyphosate, of 0–1 mg/kg body weight (bw) was established based on a no-observed-adverse-effect level (NOAEL) of 100 mg/kg bw per day for salivary gland alterations in a long-term study of toxicity and carcinogenicity in rats and a safety factor of 100. The 2004 JMPR concluded that it was not necessary to establish an acute reference dose (ARfD) for glyphosate.

Metabolism studies in genetically modified soya beans and maize containing the glyphosate-*N*-acetyltransferase (*GAT*) gene demonstrated that new metabolites are formed that were not observed in conventional crops. The major metabolite in the new maize and soya bean varieties was *N*-acetyl-glyphosate, whereas glyphosate, *N*-acetyl-AMPA and AMPA were found in low concentrations in the edible parts of the crops. The present Meeting was asked by the Codex Committee on Pesticide Residues to evaluate newly submitted studies on toxicokinetics and metabolism, acute oral toxicity, subchronic toxicity and genotoxicity for *N*-acetyl-glyphosate and on acute oral toxicity and genotoxicity for *N*-acetyl-AMPA.

All pivotal studies were certified as complying with good laboratory practice or an approved quality assurance programme.

Biochemical aspects

[^{14}C]*N*-acetyl-glyphosate was rapidly and incompletely (approximately 66%) absorbed in rats following a single oral dose of 15 mg/kg bw. The maximum concentration of radioactivity in plasma was reached after 2 hours, and the half-life for elimination from plasma was 15.6 hours. Elimination was mainly via urine (66.1%) and, to a lesser extent, faeces (26.4%); more than 90% of the total radioactivity was eliminated by 48 hours post-dosing. *N*-Acetyl-glyphosate was metabolized to a very limited extent. One metabolite, glyphosate (< 1% of the total radioactivity), was detected in faeces after a single oral dose of 15 mg/kg bw, whereas glyphosate and *N*-acetyl-AMPA were found in urine following subchronic exposure at dose levels of 56 mg/kg bw per day and above.

Toxicological data

N-Acetyl-glyphosate

N-Acetyl-glyphosate was of low acute oral toxicity; the median lethal dose (LD_{50}) was greater than 5000 mg/kg bw in rats.

In a 90-day study of toxicity with *N*-acetyl-glyphosate in rats, the NOAEL was 4500 ppm (equal to 283 mg/kg bw per day), based on slightly decreased body weight gains in male rats at 18 000 ppm (equal to 1157 mg/kg bw per day).

N-Acetyl-glyphosate was tested for genotoxicity in vitro and in vivo in an adequate range of assays; it was not found to be genotoxic in mammalian and microbial test systems.

The Meeting concluded that *N*-acetyl-glyphosate was unlikely to be genotoxic.

The Meeting concluded that *N*-acetyl-glyphosate is of no greater toxicological concern than the parent glyphosate, based on the structural similarity of *N*-acetyl-glyphosate with glyphosate and supported by the following considerations: 1) *N*-acetylation is a common detoxification pathway of xenobiotic compounds in mammals; therefore, *N*-acetyl-glyphosate is expected to be of similar

toxicity to or lower toxicity than glyphosate; 2) a structure–activity relationships analysis indicates that the *N*-acetylated group is not a structural alert for carcinogenicity, mutagenicity or endocrine effects; and 3) the toxicological data for *N*-acetyl-glyphosate show low acute toxicity, low subchronic toxicity (with no organ toxicity in rats at doses up to 1157 mg/kg bw per day) and a lack of genotoxicity.

N-Acetyl-AMPA

N-Acetyl-AMPA was of low acute oral toxicity; the LD_{50} was greater than 5000 mg/kg bw in rats.

N-Acetyl-AMPA was tested for genotoxicity in vitro and in vivo in an adequate range of assays; it was not found to be genotoxic in mammalian or microbial test systems.

The Meeting concluded that *N*-acetyl-AMPA was unlikely to be genotoxic.

The Meeting concluded that the toxicity of *N*-acetyl-AMPA is low and of limited concern, based on the structural similarity of *N*-acetyl-AMPA with AMPA and supported by the following considerations: 1) *N*-acetyl-AMPA is a charged molecule at physiological pH and is expected to be poorly absorbed from the gastrointestinal tract; 2) *N*-acetylation is a common detoxification pathway of xenobiotic compounds in mammals; therefore, *N*-acetyl-AMPA is expected to be of similar toxicity to or lower toxicity than AMPA or glyphosate; and 3) a structure–activity relationships analysis indicates that the *N*-acetylated group is not a structural alert for carcinogenicity, mutagenicity or endocrine effects.

Toxicological evaluation

The Meeting concluded that the group ADI of 0–1 mg/kg bw established by the 2004 JMPR for glyphosate and AMPA may also be applied to *N*-acetyl-glyphosate and *N*-acetyl-AMPA, as the available toxicological data showed that these plant metabolites have no greater toxicity than the parent glyphosate.

The 2004 JMPR decided that an ARfD for glyphosate was unnecessary. The present Meeting confirmed that it is not necessary to establish an ARfD for *N*-acetyl-glyphosate or *N*-acetyl-AMPA in view of their low acute toxicity and the absence of any toxicological effects that would be likely to be elicited by a single dose.

An addendum to the toxicological monograph was prepared.

Estimate of acceptable daily intake for humans

0–1 mg/kg bw (for the sum of glyphosate, *N*-acetyl-glyphosate, AMPA and *N*-acetyl-AMPA)

Estimate of acute reference dose

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

RESIDUE AND ANALYTICAL ASPECTS

Glyphosate is an herbicide with uses on many crops, conventional and glyphosate tolerant. Glyphosate has been evaluated several times with the initial evaluation in 1986 and the latest in 2005 (Periodic re-evaluation Programme of the Thirty-fourth Session of the CCPR for residue review). The Meeting of 2005 established a residue definition for compliance with MRLs as "glyphosate" and a definition of the residue for the estimation of the dietary intake as "sum of glyphosate and AMPA, expressed as glyphosate" for both plant and animal commodities. The toxicology of glyphosate was re-evaluated by the 2004 JMPR which estimated group ADI of 0–1 mg/kg bw for the sum of glyphosate and AMPA. The same Meeting concluded that an ARfD did not need to be derived.

Glyphosate is used on conventional and glyphosate tolerant crops. Different types of glyphosate tolerant crops can be distinguished. Glyphosate tolerant crops containing the modified 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) gene are referred to here as EPSPS crops and those containing the glyphosate-N-acetyltransferase (*GAT*) gene will be referred to as *gat* crops. EPSPS crops are tolerant to glyphosate but essentially metabolise glyphosate in the same way as conventional crops. Both EPSPS genetically modified crops and conventional crops have been evaluated by the 2005 JMPR. For the current evaluation in addition to data on conventional crops and EPSPS crops, data have been submitted covering the use on genetically modified crops containing the *GAT* trait. These crops inactivate glyphosate by converting it to *N*-acetyl-glyphosate, a different metabolic pathway than for the crops described by the 2005 JMPR.

The Meeting received information on *N*-acetyl-glyphosate (the main metabolite expected to be formed in plants) metabolism in animals, on glyphosate metabolism in genetically modified maize and soya beans containing the *GAT* trait, methods of residue analysis, freezer storage stability, GAP information, supervised residue trials on conventional (dry peas) and EPSPS glyphosate tolerant crops (sweet corn and sugar beets) and *gat* crops (maize and soya beans), fate of residue during storage and processing, and livestock feeding studies with *N*-acetyl-glyphosate.

To assist uniform interpretation of GAP application rates have been expressed in terms of glyphosate acid equivalents (ae), unless indicated otherwise.

Metabolites referred to in the appraisal were addressed by their common names,

N-acetyl-glyphosate	*N*-acetyl-*N*-(phosphonomethyl)glycine
AMPA	aminomethylphosphonic acid
N-acetyl AMPA	[(acetylamino)methyl]phosphonic acid.

Animal metabolism

The metabolism of glyphosate was evaluated by the 2005 JMPR. The current Meeting received metabolism studies for *N*-acetyl-glyphosate, the main glyphosate metabolite in genetically modified maize and soya beans containing the *gat* trait, in lactating goats and laying hens. Metabolism of *N*-acetyl-glyphosate in laboratory animals was summarized and evaluated by the WHO panel of the JMPR 2011.

A lactating goat was orally treated twice daily for 5 consecutive days with [^{14}C]-*N*-acetyl-glyphosate at a dose equivalent to 205 ppm (mg test substance equivalent/kg feed) per day. Approximately 88% of the administered dose was recovered with the majority in the excreta (87.7% of the dose). Faeces, urine and cage wash contained 74, 11 and 2.3% of the total administered dose,

respectively. Composite milk (day 1–5), liver and kidney each contained < 0.1% TRR of the administered dose. The radioactivity in the tissues ranged from 0.05 in muscle to 4.69 mg/kg *N*-acetyl-glyphosate equivalents in kidney. TRR values in milk were 0.030 to 0.036 mg/kg *N*-acetyl-glyphosate equivalents during the dosing period. Plateau levels in milk were reached after 24 hours.

Unchanged *N*-acetyl-glyphosate was the major residue in all tissues. Low levels of glyphosate, AMPA and *N*-acetyl AMPA were also detected. *N*-acetyl-glyphosate accounted for 53% TRR in fat, 77% in kidney, 55% in liver, 40% in milk and 17% in muscle. The minor metabolites glyphosate, AMPA and *N*-acetyl AMPA, accounted for no more than 15% TRR in liver, 8.4% liver and 6.6% fat, respectively.

Six laying hens were orally treated twice daily for 7 consecutive days with [^{14}C]-*N*-acetyl-glyphosate at a dose equivalent to 63 ppm (mg test substance equivalent/kg feed) per day and were sacrificed 6 hours after the last dose. The recovery of the total administered dose in excreta, eggs, and tissues was 90.2%. The majority (90.1%) of the dose was eliminated in the excreta. Eggs and edible tissues contained ~ 0.1% of the total administered dose. The radioactivity in the tissues ranged from 0.04 mg/kg *N*-acetyl-glyphosate equivalents in muscle and 0.05 mg/kg *N*-acetyl-glyphosate equivalents in fat, to 0.51 mg/kg *N*-acetyl-glyphosate equivalents in liver. The concentrations in whole eggs ranged from 0.05 mg/kg *N*-acetyl-glyphosate equivalents after 48 hours, to 0.36 mg/kg *N*-acetyl-glyphosate equivalents after 158 hours. Higher levels were observed in the egg yolks than in the whites.

Unchanged *N*-acetyl-glyphosate was the principle residue in egg yolks (68% TRR, 0.16 mg/kg), liver (64% TRR, 0.32 mg/kg), fat and muscle (25 and 23% TRR respectively, both 0.01 mg/kg), and was detected in egg whites in trace levels (41% TRR, < 0.01 mg/kg). Glyphosate was identified in fat (39% TRR, 0.023 mg/kg), egg yolks (5.7% TRR, 0.013 mg/kg) and liver (16% TRR, 0.084 mg/kg), and detected in muscle and egg whites at < 0.01 mg/kg (7.2% TRR and 11% TRR, respectively). AMPA was found in liver (6.7% TRR, 0.03 mg/kg), muscle and fat (17 and 11 %TRR respectively, both 0.01 mg/kg) and egg yolks (0.91 %TRR, < 0.01 mg/kg). *N*-acetyl AMPA was identified in fat and liver at 0.01 and 0.02 mg/kg, 10 and 4.0 %TRR respectively and at trace levels in egg whites, egg yolks and muscle. *N*-acetyl-glyphosate and glyphosate were the only residues eliminated to any significant extent in the excreta.

The absorbed dose of *N*-acetyl-glyphosate was not extensively metabolized in cattle and hens. Two basic metabolic pathways are proposed, both leading to AMPA. One route via de-acetylation to form glyphosate, which can be further metabolized to AMPA and one route where *N*-acetyl-glyphosate is metabolized to *N*-acetyl AMPA, which is further de-acetylated to form AMPA.

The metabolism for *N*-acetyl-glyphosate proposed for ruminants and laying hens is consistent with that for rats with regard to the conversion into glyphosate. A small difference between rats and livestock was that AMPA and *N*-acetyl AMPA were not detected in the rat metabolism studies. However, rats dosed with glyphosate show it can be metabolized in the rat to AMPA. Glyphosate, *N*-acetyl-glyphosate and AMPA are poorly absorbed from the gastrointestinal tract and rapidly and essentially completely excreted. Neither molecule accumulates in mammalian systems. It is predicted that *N*-acetyl AMPA will exhibit similar absorption, distribution and metabolism characteristics as glyphosate and its two metabolites.

Plant metabolism

The Meeting received plant metabolism studies for glyphosate treatments on genetically modified maize and soya beans; both contain the *gat* trait.

The metabolic fate of [^{14}C]glyphosate in *GAT* maize plants was examined following a single pre-emergence soil application followed by three foliar applications (each 1.1 kg ai/ha at three different growth stages). Maize plants were harvested as immature foliage (immediately prior to the first foliar application), then as forage (prior to the last application) and finally at maturity (7 days PHI) whereupon plants were separated into stover, cob and grain fractions.

The TRRs in immature maize foliage were low (0.02 mg/kg glyphosate equivalents) indicating that low levels of radioactive soil residues were incorporated by the developing plant. In maize forage (one pre-emergence application and two foliar applications) the TRR was 3.48 mg/kg glyphosate equivalents. The major components in maize forage were glyphosate (58% TRR) and *N*-acetyl-glyphosate (27% TRR). AMPA and *N*-acetyl-AMPA were present at 4.0% TRR and 1.7% TRR respectively. The major components in maize stover were glyphosate (74.9% TRR) and *N*-acetyl-glyphosate (17.8% TRR) with AMPA and *N*-acetyl AMPA also identified but at much lower levels (4.4% and 1.3% TRR respectively). The major component in maize cobs and grain was *N*-acetyl-glyphosate which accounted for 63.8% TRR (0.44 mg/kg) and 51.2% TRR (0.14 mg/kg) respectively. *N*-acetyl-AMPA was the second most prominent metabolite present in cobs and grains at 5.0% TRR and 9.4% TRR, respectively. Glyphosate and AMPA were detected in grains at 6.1% TRR (0.02 mg/kg) and 0.1% TRR (< 0.01 mg/kg), respectively.

The metabolic fate of [^{14}C]glyphosate in *GAT* soya bean plants was examined following a single pre-emergence soil application of 3.4 kg ai./ha, followed by three foliar applications at 1.4, 2.4 and 0.9 kg ai/ha at three different growth stages. Soya bean plants were harvested at typical forage and hay harvests, immediately prior to the final application and at maturity (PHI 14 days).

AMPA was the major extractable metabolite in soya bean forage, accounting for 39.3% TRR (0.17 mg/kg glyphosate equivalents). Glyphosate and *N*-acetyl-glyphosate were also detected accounting for 9.1% TRR and 1.9% TRR respectively. The TRR in hay (one pre-emergent application and one foliar application) was 13.44 mg/kg glyphosate equivalents. Glyphosate was the major residue in soya bean hay samples, accounting for 72.5% TRR. *N*-acetyl-glyphosate (19.2% TRR), AMPA (5.3% TRR) and N-acetyl-AMPA (0.7% TRR) were also detected.

At early harvest (typical of forage and hay harvest), plants were separated into soya bean seeds (1.90 mg/kg glyphosate equivalents) and soya bean foliage/pods (11.22 mg/kg glyphosate equivalents). *N*-Acetyl-glyphosate was the major radioactive component detected in the early-harvest grain accounting for 60.6% TRR with glyphosate (22.7% TRR) and AMPA (5.3% TRR) also detected. Glyphosate and *N*-acetyl-glyphosate were the major radioactive components detected in the early harvest foliage accounting for 43.6% TRR (4.89 mg/kg) and 42.0% TRR (4.70 mg/kg), respectively. AMPA (7.4% TRR) and N-acetyl-AMPA (2.2% TRR) were also detected.

At mature harvest, plants were separated into grain (3.14 mg/kg glyphosate equivalents), pods (17.75 mg/kg glyphosate equivalents) and foliage (straw) (22.09 mg/kg glyphosate equivalents). *N*-acetyl-glyphosate was the major radioactive component detected in the mature grain accounting for 56.9% TRR. Glyphosate (3.2% TRR), AMPA (11.2% TRR) and N-acetyl AMPA (23.5%) were also detected. Glyphosate was the major radioactive component detected in the mature pods accounting for 56.9% TRR with *N*-acetyl-glyphosate (27.7% TRR), AMPA (10.2% TRR) and *N*-acetyl AMPA (3.3% TRR) also detected. Glyphosate was the major radioactive component detected in the mature foliage accounting for 53.4% TRR, 11.79 mg/kg glyphosate equivalents. *N*-acetyl-glyphosate (31.9% TRR), AMPA (10.3% TRR) and N-acetyl AMPA (1.4% TRR) were also detected.

Low levels of radioactivity that was not extracted were associated with the plants' cellulose and lignin fractions.

The proposed pathway of glyphosate in plants with the *gat* trait is deactivation to *N*-acetyl glyphosate which can be further metabolised to *N*-acetyl-AMPA and AMPA. A smaller part of glyphosate may be directly metabolised to AMPA. The pathway differs from that observed with conventional and EPSPS modified crops, where glyphosate is predominantly metabolised to AMPA. *N*-acetyl-glyphosate is only formed at trace levels, if at all in those crops.

Analytical methods

The Meeting received description and validation data for analytical methods for residue analysis of glyphosate and its metabolites in various plant commodities using LC-MS-MS. The method also quantifies the metabolites resulting from metabolism of glyphosate in genetically modified crops

containing the *gat* trait, being *N*-acetyl-glyphosate, AMPA and *N*-acetyl AMPA. The LOQs are 0.05 mg/kg.

For animal commodities an LC/MS/MS method was developed and validated to determine *N*-acetyl-glyphosate and the metabolites glyphosate, *N*-acetyl AMPA and AMPA residues in milk, eggs, muscle, kidney, liver and fat. The LOQ is 0.025 mg/kg glyphosate equivalents for residues in milk, egg and muscle and 0.05 mg/kg glyphosate equivalents for liver, kidney and fat.

Multi-residue methods are currently not validated for glyphosate and its metabolites.

Stability of pesticide residues in stored analytical samples

The Meeting received information on the stability of glyphosate and its residues in samples stored frozen.

It was concluded that glyphosate, *N*-acetyl-glyphosate and AMPA residues are stable for at least 12 months in maize forage, and grain, and for at least 23 months in maize stover when stored frozen at -20 °C. In addition, residues of *N*-acetyl AMPA are stable frozen (-20 °C) for at least 23 months in maize forage, stover, and grain.

Glyphosate, *N*-acetyl-glyphosate and AMPA residues in soya bean forage, seed, and hay are stable when stored at -20 °C for at least 12 months. Residues of *N*-acetyl AMPA in forage, seed and hay have also been shown to be stable for a period of at least 18 months when stored frozen at -20 °C.

The stability of *N*-acetyl-glyphosate, glyphosate, AMPA, and *N*-acetyl AMPA stored frozen (nominal -20 °C) in animal tissues (liver, kidney, fat, and muscle matrices) was also determined. The results indicate that glyphosate, *N*-acetyl-glyphosate, AMPA, and *N*-acetyl AMPA are stable for at least 80 days in animal tissues when stored frozen for a period greater than the longest storage interval prior to analysis of each tissue matrix.

The periods of demonstrated stability cover the frozen storage intervals used in the residue studies.

Definition of the residue

As established at the 2005 JMPR, glyphosate is not metabolised in rats, lactating goats and laying hens and is mainly excreted unchanged. Some traces of AMPA were found, but microbial degradation after oral absorption could have been responsible for that.

Livestock metabolism studies with *N*-acetyl-glyphosate, a major plant metabolite of glyphosate in glyphosate tolerant crops (*GAT* trait), were performed in rats, lactating goats and laying hens. This compound was not extensively metabolised. However, two metabolic pathways could be proposed, both of which lead to AMPA via formation of glyphosate or *N*-acetyl AMPA. As a consequence all four metabolites could be found, with *N*-acetyl-glyphosate being the major residue. These findings are confirmed in the farm animal feeding studies with *N*-acetyl-glyphosate where the only quantifiable residue was *N*-acetyl-glyphosate in tissues, eggs and milk, except in kidney tissue of dairy cows in which case AMPA and *N*-acetyl AMPA were also detected.

When considered together with glyphosate, *N*-acetyl-glyphosate is expected to be a minor component of livestock dietary burden, present only when feed is derived from *GAT* crops and when present to be at levels that are lower than parent glyphosate in animal commodities. The Meeting concluded that the previously derived residue definition for enforcement in animal commodities of "glyphosate" should be replaced by "the sum of glyphosate and N-acetyl-glyphosate".

The 2005 JMPR reviewed glyphosate metabolism studies in conventional coffee, corn, cotton, soya beans, wheat, pasture grasses and alfalfa crops as well as on the glyphosate tolerant (EPSPS varieties) cotton, soya beans and sugar beet crops. The patterns of metabolites were similar in different species of plants as well as in conventional and EPSPS crops. The main component of the

residue was glyphosate and the main metabolite found was AMPA. These findings are consistent with the residue distribution as observed in the supervised residue trials with EPSPS sweet corn and sugar beet as well as in the field trials with conventional peas (dry) submitted for the current evaluation.

Radioactivity in tolerant maize and soya beans containing the *GAT* trait treated with [^{14}C]glyphosate was due to glyphosate and AMPA, *N*-acetyl glyphosate and *N*-acetyl-AMPA in both maize and soya beans.

For maize cobs and grain *N*-acetyl-glyphosate is the major component (64% and 51% TRR), followed by *N* acetyl AMPA (5 and 9.4% TRR). In maize forage and stover the major component was parent glyphosate (58% and 75 % TRR), followed by *N*-acetyl-glyphosate (27%and 18% TRR),

In *GAT* soya bean seeds *N*-acetyl-glyphosate was the major component of the residue (61% TRR), followed by glyphosate (23% TRR) and AMPA (5.3% TRR). In *GAT* soya bean forage AMPA was the major metabolite (39% TRR) while in soya bean hay glyphosate (73% TRR) was the major component.

To accommodate the use of glyphosate on plants containing the *GAT* trait the Meeting concluded that the previously established residue definition for enforcement in plants of "glyphosate" should be replaced by "the sum of glyphosate and N-acetyl-glyphosate expressed as glyphosate for soya bean and maize crops and remain "glyphosate" for all other crops.

The 2005 JMPR concluded that in conventional crops and the glyphosate tolerant EPSPS crops, glyphosate together with AMPA should be regarded as the residues of toxicological concern. Based on the available toxicological data for glyphosate, *N*-acetyl glyphosate and AMPA and the structural similarity of *N*-acetyl AMPA with the three other compounds, the Meeting concluded that *N*-acetyl-glyphosate, *N*-acetyl AMPA and AMPA were of no greater toxicological concern than glyphosate and set a group ADI of 0–1 mg/kg bw for the sum of glyphosate, *N*-acetyl-glyphosate, AMPA and *N*-acetyl AMPA. The previously established residue definition for dietary risk assessment for plant and animal commodities of "the sum of glyphosate and AMPA, expressed as glyphosate" should be replaced by "the sum of glyphosate, N-acetyl-glyphosate, AMPA and N-acetyl AMPA, expressed as glyphosate" for both plant and animal commodities.

Based on the above the Meeting agreed to replace the previous definitions for glyphosate as follows:

For plants and animals:

Definition of the residue for compliance with the MRL (for plant commodities): for soya bean and maize—*sum of glyphosate and N-acetyl-glyphosate, expressed as glyphosate.*

for other crops—*glyphosate*.

Definition of the residue for compliance with MRL (for animal commodities): *sum of glyphosate and N-acetyl-glyphosate, expressed as glyphosate*

Definition of glyphosate residue for estimation of dietary intake: *sum of glyphosate, AMPA, N-acetyl-glyphosate and N-acetyl AMPA, expressed as glyphosate.*

The changes in definition of the residues for enforcement and for dietary risk assessment will not influence the maximum residue levels, STMRs and highest residues established so far. The levels derived so far are for conventional and EPSPS crops for which N-acetyl-glyphosate and N-acetyl AMPA, if formed, are only minor components of the residue present at < 2% TRR.

Results of supervised trials on crops

The Meeting received supervised residue trial data for glyphosate on glyphosate tolerant sweet corn (EPSPS trait), glyphosate tolerant soya bean (*GAT* trait), conventional peas (dry), glyphosate tolerant sugar beet (EPSPS trait), glyphosate tolerant maize (*GAT* trait), glyphosate tolerant sweet corn forage and stover (EPSPS trait) and glyphosate tolerant sugar beet tops (EPSPS trait).

Glyphosate may be applied prior to crop emergence (pre-emergence = PRE), shortly after crop emergence (early post emergence = EPO), between EPO and a few weeks before harvest (late post-emergence = LPO), and prior to harvest (pre-harvest = PH).

When applied pre-harvest, residues in the raw agricultural commodity (RAC) are mainly determined by applications made during the growth stages of the plant rather than as a consequence of pre-emergence applications. For commodities that are exposed to glyphosate as pre-emergence, post-emergence and pre-harvest applications, the post-emergence and pre-harvest sprays have the greatest influence on residues. The highest residue from any trial at the location and carried out with different numbers of applications and rates and timings of application, but within the range permitted by GAP, was selected.

The limits of quantification of glyphosate and AMPA are typically 0.05 mg/kg.

In general, data from conventional crops and genetically modified crops cannot be combined since application rates in genetically modified crops are usually higher than in conventional crops. The data were only combined when the GAP-s were similar.

For estimation of maximum residue levels for soya beans and maize crops glyphosate and *N*-acetyl glyphosate levels are summed and expressed as glyphosate equivalents.

The values used for the estimation of maximum residue level are underlined.

For estimation of residue levels for dietary risk assessment in conventional crops and glyphosate tolerant crops (EPSPS varieties) glyphosate and AMPA form the total residue, since *N*-acetyl-glyphosate and *N*-acetyl AMPA are not formed. When glyphosate and AMPA are summed, AMPA was converted to glyphosate acid equivalents (AMPA mg/kg × 1.5). The Meeting concluded that generally if AMPA residues are < 0.05 mg/kg, the LOQ level is not summed with glyphosate because AMPA residues are typically much less than glyphosate. If both glyphosate and AMPA are < LOQ, then the sum is < LOQ of glyphosate. This is also the case for glyphosate tolerant sugar beet (EPSPS variety). The exception is where there is evidence that AMPA residues are comparable to glyphosate residues such as for glyphosate tolerant sweet corn (EPSPS variety). In that situation the LOQs are summed and if both glyphosate and AMPA residues are < LOQ and the level reported as less than the sum of the LOQs for glyphosate and AMPA.

For estimation of the residue levels for dietary risk assessment of glyphosate in *GAT* crops, in general, all four analytes are present in significant amounts. In the *GAT* modified soya beans, *N*-acetyl glyphosate is the major residue found in soya bean seed, followed by *N*-acetyl AMPA and glyphosate. AMPA occurs in lower levels. However, as AMPA does occur in levels above LOQ in a small number of residue trials the LOQ for AMPA is included in the sum of residues when AMPA is reported as < LOQ. In maize with the *GAT* trait *N*-acetyl glyphosate residue levels were found to be the major residue in grain. Since in a small number of trials glyphosate residues were also observed the LOQ for both *N*-acetyl glyphosate and glyphosate were included in the calculation of the total residue when residues were reported as < LOQ. Because all AMPA and *N*-acetyl AMPA residue levels were below LOQ and the metabolism study suggests they are components, when present at < LOQ the LOQs for these metabolites were not included in the calculation of the total residue for dietary risk assessment for maize.

The OECD calculator was used as a tool in the estimation of the maximum residue level from the selected residue data set obtained from trials conducted according to GAP. As a first step, the Meeting reviewed all relevant factors related to each data set in arriving at a best estimate of the maximum residue level using expert judgement. Then, the OECD calculator was employed. If the statistical calculation spreadsheet suggested a different value from that recommended by the JMPR, a brief explanation of the deviation was provided.

Fruiting vegetables

Sweet corn

Field trials involving glyphosate tolerant sweet corn (EPSPS variety) conducted in the USA and Canada were available to the Meeting.

The GAP for sweet corn in the USA is ≥ 1 LPO (late post emergence) applications, maximum of 1.7 kg ai/ha per application (PHI 30 days), with a total in-crop maximum of 5.2 kg ai/ha. In the trials matching this GAP the glyphosate residues reported as free acid equivalent in ranked order were (n = 14) 0.11, 0.12, 0.13, 0.13, 0.14, 0.15, 0.24, 0.24, 0.28, 0.30, 0.60, 0.70, 1.2 and 2.3 mg/kg. The Meeting agreed that the USA and Canadian data set could be used to support a maximum residue level recommendation and estimated a maximum residue level of 3 mg/kg for glyphosate on corn-on-the-cob.

Total residues in ranked order were (n = 14) 0.18, 0.20, 0.20, 0.22, 0.22, 0.23, 0.32, 0.33, 0.43, 0.43, 0.78, 1.0, 1.3 and 2.8 mg/kg. The STMR for total residues is 0.325 mg/kg.

Pulses

The Meeting received a request to re-evaluate previously submitted data on lentils, in combination with the data on dried peas and dried beans and new trials in dried peas, and to consider extrapolation of the pea and bean data to support a maximum residue level recommendation for lentils. The Meeting noted extrapolation based on peas (dry) would lead to a higher maximum residue level estimation. The previously evaluated data for peas (dry) and lentils together with newly submitted data for peas (dry) are summarized below.

Lentils

The 2005 JMPR reviewed two trials on conventional lentils, conducted in Canada and matching the GAP of Canada (1 pre-harvest (PH) application of 0.9 kg ai/ha, when crop has 30% grain moisture content and lowermost pods are brown with seed rattle, PHI 7–14 days). Residues of glyphosate reported were < 0.05 and 3.0 mg/kg and for AMPA < 0.05 mg/kg. The total residues (glyphosate and AMPA) were < 0.05 mg/kg and 3.0 mg/kg.

Peas (dry)

Residue data from trials in conventional peas (dry) in the UK, Belgium, Denmark and Canada were evaluated against the GAPs of the UK and Canada by the 2005 JMPR and combined. GAP in Canada is a single PH application of 0.9 kg glyphosate ai/ha when grain moisture is < 30% (PHI 7–14 days). GAP in the UK is a single PH application of 1.4 kg ai/ha when grain moisture is < 30% (PHI 7 days). Glyphosate residues in ranked order were (n = 11): 0.13, 0.16, 0.17, 0.17, 0.5, 0.5, 0.82, 1.4, 1.7, 1.8, and 2.1 mg/kg. Based on these data an MRL of 5 mg/kg was estimated.

When measured, AMPA residues were all < 0.05 (4) mg/kg. The STMR was estimated to be 0.5 mg/kg.

The current Meeting received five additional field trials in conventional peas (dry), performed in three locations in the USA in 1998, matching the USA GAP for 1 PH application of up to 2.55 kg ai/ha, PHI 7 days, and with grain moisture≤ 30%. Glyphosate residues (glyphosate only) in grains in ranked order were: 0.70, 0.77, 1.1, 3.4, and 4.2 mg/kg (n = 5) at PHI 7. The data are insufficient to estimate a new maximum residue level and STMR for conventional peas (dry) based on the USA GAP.

Data from peas (dry) can both be used to extrapolate to other members of the group pulses that have similar GAP such as lentils. The Meeting proposed to use the dataset from peas that support

the Canadian GAP of 1 PH application of 0.9 kg ai/ha, grain moisture≤ 30%, PHI 7–14 days. The Meeting extrapolated the residues on peas (dry) to estimate a maximum residue level of 5 mg/kg, an STMR of 0.5 mg/kg, respectively for lentils.

Soya beans

The 2005 JMPR reviewed field trials conducted according to USA GAP in both conventional and glyphosate tolerant soya beans (EPSPS varieties) and concluded them to be similar residue populations for the purpose of estimating MRLs and combined the datasets. The USA GAP for conventional soya beans was 4.3 kg ai/ha PRE, 4.2 kg ai/ha PH, with a PHI of 7 days. The USA GAP for glyphosate tolerant soya beans (EPSPS variety) was 0.43–4.2 kg ai/ha PRE, 1.7 kg ai/ha LPO, 0.83 kg ai/ha PH (combined LPO + PH < 2.5 kg ai/ha), with a PHI of 14 days. Glyphosate residues in ranked order were (n = 36): 0.27, 0.28, 0.34, 0.37, 0.42, 0.44, 0.45, 0.51, 0.56, 0.60, 0.70, 1.0, 1.1, 1.4, 1.4, 1.5, 1.7, 1.8, 1.9, 1.9, 1.9, 2.0, 2.6, 2.7, 2.7, 3.0, 3.3, 3.5, 3.6, 3.7, 4.4, 5.3, 5.4, 5.6, 13 and 17 mg/kg. The 2005 JMPR used the data to confirm the previous maximum residue level of glyphosate in soya beans of 20 mg/kg.

Total residues (glyphosate and AMPA only) were (n = 36): 0.45, 0.59, 0.78, 0.89, 1.0, 1.1, 1.1, 1.2, 1.2, 1.5, 1.6, 2.4, 3.2, 4.0, 4.0, 4.3, 4.7, 4.9, 5.1, 5.4, 5.7, 6.2, 6.6, 7.1, 7.2, 7.6, 7.6, 7.9, 8.2, 8.5, 11, 11, 11, 16, 17 and 20 mg/kg. The highest residue and STMR for total residues were estimated to be 20 and 5.0, respectively.

The current Meeting received field trials performed in the USA and Canada involving glyphosate tolerant soya beans containing the *GAT* trait. GAP for USA and Canada is for 1 pre-emergence application (0.44–4.2 kg ai/ha PRE), followed by three field applications, with a maximum application of 1.76 kg ai/ha at LPO (late post emergence) and the last application PH (pre harvest) not exceeding 0.88 kg ai/ha (PHI 14 days). The Meeting noted that the pre-emergence applications were conducted at a lower rate (mostly 3.2–3.9 kg ai/ha) than indicated by GAP of 4.2 kg ai/ha. However, as established by the 2005 JMPR the difference in application rates at pre-emergence account for less than 10% difference in the residue at harvest and the later post-emergence sprays determine the residue. At one trial location the crop was damaged due to a hurricane and heavy rain fall. Residues in this trial were considerably higher than samples collected from other sites and the results for this site are not considered further.

Residues in the remaining trials matching USA GAP (late post emergence application 1.76 kg ai/ha and pre-harvest application 0.88 kg ai/ha, PHI 14 days) in soya bean seeds were 0.1, 0.34, 0.49, 0.69, 0.89, 0.92, 1.2, 1.5, 1.7, 1.7, 1.7, 1.8, 2.4, 2.4, 3.1, 3.1, 5, 5, 5.8, 5.9, 6 and 7.8 mg/kg (n = 22). The Meeting noted that the use of glyphosate on soya beans containing the *GAT* trait is covered by the previous recommendation of 20 mg/kg for soya bean (dry).

Root and tuber vegetables

Sugar beets

The current Meeting received field trials involving glyphosate tolerant sugar beets containing the EPSPS gene conducted in Canada and the USA.

GAP for these glyphosate tolerant sugar beets in the USA is ≥ 1 PRE applications, total max 4.2 kg ai/ha, 2 LPO of 1.3 kg ai/ha, and 2 PH applications of 0.9 kg ai/ha, PHI 30 days and total in crop application rate (LPO and PH) of 3.9 kg ai/ha. The Canadian GAP consists of 1 × PRE applications and up to 4 × LPO applications at 0.9 kg ai/ha, PHI 30 days, and a total in crop application rate (for LPO) of 3.6 kg ai/ha. The pre-emergence application was not considered to attribute significantly by the Meeting of 2005.

In trials performed in Canada matching the GAP (4 × 0.9 kg ai/ha, PHI 30 days) glyphosate residues in sugar beet roots in ranked order were (n = 4): 3.1, 3.5, 5.7 and 7.1 mg/kg.

In trials matching the USA GAP (2 × 1.3 kg ai/ha LPO and 2× 0.9 kg ai/ha PH, PHI 30 days) glyphosate residues (glyphosate only) in ranked order were (n = 12): 0.62, 0.90, 2.0, 2.2, 2.6, 2.9, 3.2, 3.3, 4.6, 4.8, 5.0 and 5.5 mg/kg.

The Meeting noted that the last two critical applications of the Canadian and USA GAP were similar and that the trials conducted in Canada with a lower application rate led to higher residues. The Meeting decided to combine the results. Glyphosate residues in ranked order were (n = 16): 0.62, 0.9, 2, 2.2, 2.6, 2.9, 3.1, 3.2, 3.3, 3.5, 4.6, 4.8, 5, 5.5, 5.7 and 7.1 mg/kg. The Meeting estimated a maximum residue level of 15 mg/kg.

The total residues in ranked order were (n = 16) 0.7, 0.98, 2.1, 2.3, 2.7, 3, 3.1, 3.4, 3.4, 3.5, 4.8, 5, 5.3, 5.8, 5.8 and 7.3 mg/kg. The highest residue and STMR for total residues are 7.3 and 3.4 mg/kg for glyphosate tolerant sugar beet.

Maize

The 2005 JMPR reviewed trials on conventional maize conducted in the USA (GAP of 0.43–4.5 kg ai/ha PRE, 0.87 kg ai/ha directed spray when crop > 30 cm tall and 2.5 kg ai/ha PH grain moisture < 35%, with a PHI of 7 days). From 21 trials that approximated the USA GAP, which involved a single pre-harvest application to conventional maize, glyphosate residues of < 0.05 (12), 0.05 (2), 0.06 (2), 0.07, 0.09, 0.54, and 3.0 mg/kg were found. Corresponding total residues were < 0.12 (11), < 0.14 (2), 0.14, < 0.16, 0.19, < 0.23, 0.25, < 0.26, < 0.62 and 3.0 mg/kg, respectively. The 2005 JMPR estimated a maximum residue level for conventional maize of 5 mg/kg, an STMR of < 0.12 and a highest residue of 3.0 mg/kg. None of the submitted trials on glyphosate tolerant maize matched the USA GAP.

The current Meeting received field trials involving glyphosate tolerant maize (containing the *GAT* trait) performed in the USA and Canada.

GAP in the USA and Canada is PRE up to a total of 4.2 kg ai/ha, 1–4 LPO in-crop applications of 0.88–1.3 kg ai/ha (total in-crop max 2.6 kg ai/ha), PH application ≤ 0.88 kg ai/ha (PHI 7 days). In trials from Canada and the USA matching this GAP, total glyphosate residues in maize grains were (n = 27) < 0.1, < 0.1, < 0.1, < 0.1, < 0.1, < 0.1, < 0.1, < 0.1, < 0.1, < 0.1, < 0.1, < 0.1, < 0.1, < 0.1, 0.1, 0.1, 0.11, 0.11, 0.11, 0.12, 0.13, 0.15, 0.2, 0.21, 0.3 and 0.56 mg/kg.

Since the GAPs are different for conventional and glyphosate tolerant crops, the datasets cannot be combined. The dataset of conventional maize gives rise to a higher maximum residue level. The Meeting confirms the previous recommendation of a maximum residue level for glyphosate in maize of 5 mg/kg based on the conventional maize data set. The previously derived highest residue and STMR for total residues in conventional maize of 3.0 and < 0.12 mg/kg, respectively are confirmed.

Animal feedstuffs

Straw, forage and fodder of cereal grains and grasses

Maize forage and stover

For the 2005 JMPR evaluation trials on conventional maize were conducted in the USA (GAP 4.2 kg ai/ha PRE; 0.87 kg ai/ha hooded sprayers; 2.5 kg ai/ha pre-harvest grain moisture < 35%, PHI 7 days). Glyphosate residues in stover/fodder 7 days after a pre-harvest application according to US GAP were (n = 21) 2.1, 2.6, 3.4, 3.7, 4.8, 6.7, 8.4, 8.8, 11, 18, 23, 28, 35, 43, 43, 44, 53, 54, 55, 82, and 92 mg/kg. Total residues were (n = 21) 2.1, 2.6, 3.5, 3.8, 4.8, 6.8, 8.8, 9.0, 11, 18, 24, 29, 36, 44, 45, 45, 54, 55, 56, 83 and 93 mg/kg.

Additionally, the review of 2005 reported trials conducted on glyphosate tolerant maize (EPSPS trait) according to the USA GAP (4.2 kg ai/ha PRE; 1.7 kg ai/ha LPO, allowing a minimum of 50 days between application and harvest of corn forage; 0.87 kg ai/ha PH < 30% grain moisture, combined LPO + PH < 2.5 kg ai/ha, PHI 7 days).

Seventeen trials on forage but no trials on tolerant maize fodder matched GAP. Glyphosate residues in forage were (n = 17): 0.30, 0.50, 0.54, 0.66, 0.73, 0.79, 0.87, 0.92, 1.1, 1.1, 1.2, 1.3, 1.3, 1.8, 1.8, 2.2 and 4.6 mg/kg. Total residues were: 0.35, 0.50, 0.54, 0.75, 0.78, 0.84, 0.92, 0.98, 1.2, 1.2, 1.3, 1.4, 1.4, 1.9, 1.9, 2.4 and 4.7 mg/kg (n = 17).

Using the residue trials for conventional maize crops, the 2005 JMPR recommended a maximum residue level of 150 mg/kg (dry weight basis) for maize fodder based on a highest residue of 111 mg/kg (92 mg/kg ÷ 0.83 default dry matter content). The 2005 JMPR also estimated a highest residue of 93 mg/kg and a median residue of 24 mg/kg for total residues in maize fodder, both on an 'as received' basis. The highest and median residues for total residues in maize forage were 4.7 and 1.2 mg/kg respectively, both on an 'as received' basis.

For the current evaluation the Meeting received field trials involving glyphosate tolerant maize (*GAT* trait) performed in the USA and Canada.

GAP in the USA and Canada:≥ 1 PRE applications up to a total of 4.2 kg ai/ha, 1–4 LPO in crop applications of 0.88–1.3 kg ai/ha (max total in-crop application 2.6 kg ai/ha), pre-harvest application ≤ 0.88 kg ai/ha, PHI 7 days. For forage the last application (LPO) should be made at least 50 days before harvest.

In the trials matching the GAP, glyphosate residues in maize stover (*GAT* trait) on an as received basis were (n = 26): 2.2, 2.6, 2.9, 3.1, 3.7, 4.7, 5.0, 5.1, 5.2, 5.8, 8.4, 9.3, 9.6, 10, 11, 11, 13, 14, 14, 17, 17, 20, 20, 25, 28 and 32 mg/kg.

Residues in stover from glyphosate tolerant maize (*GAT* trait) were lower than previously evaluated for conventional and tolerant (EPSPS trait) maize. The Meeting confirms its previous estimation of a maximum residue level for maize stover (fodder) of 150 mg/kg (dry weight basis) and the estimated highest residue of 93 mg/kg and median of 24 mg/kg, both on as received basis.

For trials matching the USA GAP for glyphosate tolerant (*GAT* trait) maize forage (PHI for harvest for forage of 50 days) glyphosate residue levels (fresh weight basis) in ranked order were 0.37, 0.46, 0.50, 0.64, 0.66, 0.68, 0.70, 0.88, 0.69, 1.1, 1.2, 1.6, 1.6, 3.6, 3.8 and 4.8 mg/kg (n = 16).

The median and highest residues (fresh weight basis) are 0.923 and 4.75 mg/kg respectively.

The Meeting noted the currently estimated median and highest residue values of 0.923 and 4.75 mg/kg (fresh weight basis) are not significantly different to the estimates of the 2005 JMPR (STMR 1.2 mg/kg and highest residue 4.7 mg/kg).

Sweet corn forage

The current Meeting received trials on glyphosate tolerant sweet corn (EPSPS trait) forage and stover performed in the USA and Canada.

No GAP for Canada was available. GAP for (sweet) corn forage in the USA is≥ 1 LPO/PH applications with a maximum of 1.7 kg ai/ha, PHI 30 days, with a total in-crop maximum of 5.2 kg ai/ha. The Meeting agreed that the US and Canadian data could be evaluated against the US GAP. The Meeting considered that the pre-harvest application is the critical application that would give rise to the residues in forage. In the trials matching the USA GAP the total residues (fresh weight basis) in sweet corn forage in ranked order were (n = 14) 0.53, 0.91, 1.3, 1.4, 1.5, 1.8, 1.9, 1.9, 2, 2.5, 2.7, 4, 5.6 and 5.8 mg/kg

The Meeting estimated a median residue of 1.9 mg/kg and a highest residue of 5.8 mg/kg for glyphosate (fresh weight basis) in glyphosate tolerant sweet corn forage containing the EPSPS trait.

Miscellaneous fodder and forage crops

Soya bean forage and fodder

Residue levels occurring in forage and stover of glyphosate tolerant soya beans (*GAT* trait) were evaluated but the USA GAP excludes grazing and harvest of treated crops for forage and hay.

Sugar beet tops

For the evaluation of 2005, trials were provided on sugar beet (glyphosate tolerant) from the US (GAP 0.43–4.2 kg ai/ha PRE, 0.43–1.3 kg ai/ha LPO, 0.43–0.87 kg ai/ha PH, PHI 30 days). No trials matched GAP.

For the current evaluation the Meeting received trials on glyphosate tolerant sugar beet tops (EPSPS trait) performed in the USA and Canada.

USA GAP is ≥ 1 PRE applications, with a total maximum of ≤ 4.2 kg ai/ha, followed by up to 2 LPO applications (≤ 1.3 kg ai/ha, max 2.2 kg ai/ha) and up to two PH applications (≤ 0.87 kg ai/ha, max 1.7 kg ai/ha), PHI 30 days, and total in-crop application rate (LPO and PH combined of 3.9 kg ai/ha). The Canadian GAP consists of up to ≤ 4 LPO/PH at 0.9 kg ai/ha, PHI 30 days, and a total in-crop application rate of 1.8 kg ai/ha.

The pre-emergence application was not considered to contribute significantly by the Meeting of 2005. In trials performed in Canada matching the GAP (4× 0.9 kg ai/ha, PHI 30 days) total glyphosate residues in sugar beet tops (fresh weight basis) in ranked order were (n = 4) 2.3, 2.5, 3.2 and 5.4 mg/kg.

In trials matching the USA GAP (2× 1.3 kg ai/ha post emergence and 2× 0.9 kg ai/ha pre-harvest, PHI 30 days) total glyphosate residues (fresh weight basis) in ranked order were (n = 12) 0.61, 0.89, 1.5, 1.6, 1.7, 1.8, 1.9, 2.2, 2.4, 2.6, 2.7 and 2.8 mg/kg.

The Meeting noted that the last two applications of the Canadian and USA GAP were similar and decided by the Meeting to combine the results. The combined data in ranked order are 0.61, 0.89, 1.5, 1.6, 1.7, 1.8, 1.9, 2.2, 2.3, 2.4, 2.5, 2.6, 2.7, 2.8, 3.2 and 5.4 mg/kg (n = 16). A median residue of 2.25 mg/kg and a highest residue of 5.4 mg/kg for glyphosate (fresh weight basis) in glyphosate tolerant sugar beet tops were estimated.

Fate of residues during processing

The Meeting received information on the nature of residues under simulated processing conditions on the fate of incurred residues of glyphosate during the processing of soya bean seeds and corn grain. A study of the nature of the residue of *N*-acetyl-glyphosate under simulated processing conditions (pasteurization, baking/brewing/boiling, sterilization) showed N-acetyl-glyphosate was stable.

Processing studies were available for maize and soya beans genetically modified to contain the *GAT* gene and containing incurred residues. Calculated processing factors for total glyphosate acid equivalents (combined results of the parent compound and three metabolites) are summarized below.

Summary of calculated processing factors for *GAT* crops

Commodity	processing factors (PF)	processing factor (median or best estimate)		Median-P
Soya bean (HR = 20; STMR = 5 mg ai/kg, total residue)				
aspirated grain fraction	6.3, 44	25		125
refined oil	–	–		–
Meal	0.7	0.7		3.5
Hulls	5.1	5.1		25.5
Maize (HR = 3; STMR = 0.12 mg ai/kg, total residue)				

Commodity	processing factors (PF)	processing factor (median or best estimate)		Median-P
Soya bean (HR = 20; STMR = 5 mg ai/kg, total residue)				
aspirated grain fraction	11	11		1.32
Starch	–	–		–
Grits	0.93, 0.74	0.84		0.10
Flour	1.2, 0.85	1.0		0.12
Refined oil (wet milling)	–	–		–
Refined oil (dry milling)	–	–		–
Meal (dry milling)	1.1, 0.97	1.0		0.12

The 2005 JMPR estimated processing factors in glyphosate tolerant sugar beet processed commodities, but did not include the results in the appraisal, since no maximum residue level, HR and STMR could be derived for glyphosate tolerant sugar beet (EPSPS trait) at that time. Since these residue levels are established in the current evaluation, the processing factors as determined in 2005 have been summarized in the table below, including the HR-Ps and STMR-Ps.

Summary of processing factors

Commodity	processing factor	processing factor (median or best estimate		Median-P
Sugar beet (HR = 7.3; STMR = 3.4 mg ai/kg, total residue)				
Wet pulp	0.08, 0.06	0.07		0.24
Dry pulp	0.73, 0.50	0.62		2.1
Molasses	< 0.01	< 0.01	–	–
Sugar, Refined	< 0.01	< 0.01	–	–

Residues in animal commodities

Farm animal dietary burden

The Meeting received information on the residue levels arising in animal tissues and milk when dairy cows were fed *N*-acetyl-glyphosate at total dietary levels of 44, 130, 437 and 1179 ppm *N*-acetyl-glyphosate for 28 consecutive days. No residues were detected in milk (LOQ 0.025 mg/kg) in the samples analysed at all dose levels and time intervals. The highest total residues (mean in brackets) in liver, kidney, fat and muscle from the highest dose animals were 0.52 (0.42), 3.6 (3.2), 0.22 (0.12) and 0.053 (0.051) mg/kg respectively.

The Meeting also received information on the residue levels arising in animal tissues and eggs, when laying hens were fed a diet containing *N*-acetyl-glyphosate at total dietary levels of approximately 22, 77, 214 and 782 ppm dry weight feed for 35 consecutive days.

Residues above LOQ (0.025 mg/kg) were detected in tissues and eggs at all dose levels. The highest total residues (mean in brackets) in liver, fat, muscle and eggs from the highest dose animals were 5.2 (4.3), 1.9 (1.3), 0.58 (0.41) and 0.88 (0.60) mg/kg respectively.

Animal commodity maximum residue levels

The current evaluation has not led to recommendations that would alter the dietary burdens calculated using the livestock intake figures employed by the 2005 JMPR. The glyphosate dietary burdens for cattle (dairy and beef) were based on grass, cotton seed and barley grain while those for poultry were based on barley, soya bean grain and soya bean hulls. The estimates for both the highest and mean residue levels for soya bean grain and hulls have not changed from those used by the 2005 JMPR

though crops containing the *GAT* trait may contain some *N*-acetyl-glyphosate. However, calculations indicate the contribution to the dietary burden for estimation of maximum residue levels is less than 10% and as such do not warrant a re-evaluation of animal commodity maximum residues levels.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Daily Intakes (IEDI) of glyphosate for the 13 GEMS/Food regional diets, based on estimated STMRs were in the range 0–2% of the maximum ADI of 1 mg/kg bw for the sum of glyphosate, N-acetyl glyphosate, AMPA and N-acetyl AMPA, expressed as glyphosate. The Meeting concluded that the long-term intake of residues of glyphosate, N-acetyl glyphosate, AMPA and N-acetyl AMPA from uses that have been considered by the JMPR is unlikely to present a public health concern. The results are shown in Annex 4 of the JMPR 2011 Report.

Short-term intake

The International Estimated Short Term Intake (IESTI) of glyphosate was not calculated. The 2004 and 2005 JMPR concluded that it was unnecessary to establish an ARfD for glyphosate. The Meeting therefore concluded that short-term dietary of glyphosate residues is unlikely to present a risk to consumers.

5.15 HEXYTHIAZOX (176)

RESIDUE AND ANALYTICAL ASPECTS

Hexythiazox is a non-systemic insecticide and miticide first evaluated by the JMPR in 1991 and a number of times subsequently. It was recently reviewed for toxicology by the 2008 JMPR within the periodic review program of the CCPR. An ADI of 0–0.03 mg/kg bw was established. An ARfD was not considered necessary by the Meeting. It was then reviewed for residues by the 2009 JMPR as part of the periodic review program. Additional GAP information, analytical method (hops only), residue data and processing information for strawberries, hops and tea were submitted for evaluation by the present Meeting.

Analytical methods

The 2011 Meeting received additional information on the analysis of hexythiazox in hops.

The method submitted involves analysis of hexythiazox in combination with the metabolite trans-5-(4-chlorophenyl)-4-methyl-2-oxothiazolidine (PT-1-3) using gas chromatography and either ECD or MSD detection. The data indicated a very high recovery (> 150%), when external standard in solvent is used. Matrix based external standard gave acceptable recoveries of 110% up to 115%. The LOQ for this method was validated at 0.5 mg/kg.

Stability of pesticide residues in stored analytical samples

The 2011 Meeting received additional information on the storage stability in hops and beer.

Although the procedural recoveries gave some variation during the whole storage period, the Meeting concluded that hexythiazox residues in hops (fresh and dry) and spent hops are stable for at least 24 months.

In beer a significant degradation was observed after 12 months or more. The Meeting concluded that hexythiazox in beer is stable for a period of up to 6 months only, still providing more than 70% of the initial residue remaining.

Results of supervised trials on crops

New data were submitted for strawberries, hops and tea.

The OECD calculator was used as a tool in the estimation of the maximum residue level from the selected residue data set obtained from trials conducted according to GAP. As a first step, the Meeting reviewed all relevant factors related to each data set in arriving at a best estimate of the maximum residue level using expert judgement. Then, the OECD calculator was employed. If the statistical calculation spreadsheet suggested a different value from that recommended by the JMPR, a brief explanation of the deviation was provided.

Strawberries

In the USA hexythiazox is approved for use on strawberries with one spray application at 0.21 kg ai/ha and a PHI of 3 days. Various supervised field trials were submitted involving treatment of strawberries at lower and higher application rates. At a PHI of 3 days, hexythiazox residues in fruit were:

- for 0.07 kg ai/ha: 0.18 mg/kg
- for 0.14 kg ai/ha: 0.19 mg/kg
- for 0.17 kg ai/ha: 0.50 mg/kg

- for 0.21 kg ai/ha: 0.13, 0.17, 0.3, 1.8 mg/kg
- for 0.28 kg ai/ha: 0.87, 5.5 mg/kg.

However, the five data points matching the US GAP (± 25%: application rates 0.17–0.21 kg ai/ha) are not sufficient to estimate a maximum residue level. Applying the principle of proportionality to the US data set, the residues in strawberries following scaling were:

- for 0.07 kg ai/ha (scaling factor 3) 0.07➔0.21 kg ai/ha: 0.54 mg/kg
- for 0.14 kg ai/ha (scaling factor 1.5) 0.14➔0.21 kg ai/ha: 0.29 mg/kg
- for 0.17 kg ai/ha (scaling factor 1.23) 0.17➔0.21 kg ai/ha: 0.62 mg/kg
- for 0.21 kg ai/ha (no scaling): 0.13, 0.17, 0.3, 1.8 mg/kg
- for 0.28 kg ai/ha (scaling factor 0.75) 0.28➔0.21 kg ai/ha: 0.65, 4.1 mg/kg.

The total range of residues in strawberry fruits (n = 9) was: 0.13, 0.17, 0.29, 0.30, 0.54, 0.62, 0.65, 1.8 and 4.1 mg/kg.

The application of proportionality resulted in nine data points being available to estimate a maximum residue level. Based on the total dataset, according to the US GAP, the Meeting estimated a maximum residue level of 6 mg/kg for hexythiazox in strawberries and an STMR of 0.54 mg/kg.

Hops, dry

In Germany hexythiazox is approved for use on hops as a single application at 0.0045 kg ai/hL with a PHI of 28 days. In corresponding supervised field trials conducted in Germany residues in dried hops were (n = 9): 0.61, 0.64, 0.71, 0.79, 0.79, 0.88, 0.93, 1.3 and 1.5 mg/kg.

The Meeting estimated a maximum residue level of 3 mg/kg for hexythiazox in hops (dried cones) and an STMR of 0.79 mg/kg.

Tea

For tea a GAP from India was reported involving two treatments at 0.025 kg ai/ha each with no specified PHI. Eight Indian supervised field trials carried out in 2008 and 2009 corresponding to this GAP were submitted.

The residue in dry tea green or black, fermented) after 0 days were (n = 8): 3.2, 3.7, 4.1, 4.5, 4.6, 4.8, 4.9 and 5.2 mg/kg.

The Meeting estimated a maximum residue level of 15 mg/kg for hexythiazox in tea (green or black, fermented) and an STMR of 4.55 mg/kg.

Fate of residues during processing

The Meeting received information on the fate of hexythiazox residues during the processing of strawberries to canned fruits and jam, of hops to beer and of tea to tea infusions. The processing factors and the derived STMR-P values are summarized as follows:

RAC	Processed commodity	Calculated processing factors	PF (median or best estimate)	RAC STMR, mg/kg	STMR-P mg/kg
Strawberry	Canned fruit	0.36, 0.4, 0.52, 0.99	0.46	0.54	0.248
	Jam	0.5, 0.54, 0.79, 1.1	0.665	0.54	0.359
Hops	Beer	< 0.03, < 0.04, < 0.05, < 0.06	<0.045	0.79	0.036
Tea	Infusion, green tea	0.02(3), < 0.03, 0.03(5), < 0.04, 0.04(4), 0.05, 0.05, 0.06, 0.06, < 0.07, < 0.08, < 0.09, < 0.1, < 0.1, < 0.25	0.04	4.55	0.182

RAC	Processed commodity	Calculated processing factors	PF (median or best estimate)	RAC STMR, mg/kg	STMR-P mg/kg
	Infusion, fermented tea	0.01, 0.02(6), 0.03(6), <0.04, 0.05, 0.05, < 0.07, 0.07, < 0.08, < 0.09, < 0.1, < 0.1, < 0.25, 0.34	0.03	4.55	0.137

Residues in animal commodities

Since strawberries, hops or tea are not potential animal feed items, the recommendations for animal commodities as made by the 2009 Meeting are still valid.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Dietary Intakes (IEDIs) of hexythiazox were calculated for the 13 GEMS/Food cluster diets using STMRs and STMR-Ps estimated by the JMPR in 2009 and the current Meeting. The ADI is 0–0.03 mg/kg bw and the calculated IEDIs were 0–3 % of the maximum ADI. The results are shown in Annex 3. The Meeting concluded that the long-term intakes of residues of hexythiazox, resulting from the uses considered by the JMPR, are unlikely to present a public health concern.

Short-term intake

The 2008 Meeting decided that an ARfD for hexythiazox is unnecessary and concluded that the short-term intake of residues resulting from the use of hexythiazox is unlikely to present a public health concern.

5.16 ISOPYRAZAM (249)

TOXICOLOGY

Isopyrazam is the provisional International Organization for Standardization (ISO)–approved name for a mixture of two *syn*-isomers of 3-(difluoromethyl)-1-methyl-*N*-[(1*RS*,4*SR*,9*RS*)-1,2,3,4-tetrahydro-9-isopropyl-1,4-methanonaphthalen-5-yl]pyrazole-4-carboxamide and two *anti*-isomers of 3-(difluoromethyl)-1-methyl-*N*-[(1*RS*,4*SR*,9*SR*)-1,2,3,4-tetrahydro-9-isopropyl-1,4-methanonaphthalen-5-yl]pyrazole-4-carboxamide (Chemical Abstracts Service No. 881685-58-1). It is a new broad-spectrum fungicide of the ortho-substituted phenyl amides, acting by inhibition of succinate dehydrogenase. It has not been evaluated previously by the Joint FAO/WHO Meeting on Pesticide Residues and was reviewed at the present Meeting at the request of the Forty-second Session of the Codex Committee on Pesticide Residues.

All the pivotal studies met the requirements of the relevant Organisation for Economic Co-operation and Development or national test guidelines and were certified as complying with good laboratory practice.

Biochemical aspects

Isopyrazam administered to rats at 1 or 75 mg/kg body weight (bw) was rapidly absorbed, with peak levels of radiolabel occurring in plasma within 3–6 hours post-dosing. Approximately 70% of the dose was absorbed at 1 and 75 mg/kg bw. The terminal half-life of the labelled material was 5–9 hours. No saturation of absorption was observed, but the area under the curve increased disproportionately with dose, indicating saturation of elimination at higher doses. In the low-dose group, 91–97% of the absorbed dose was excreted within 48 hours after administration. Highest residues were identified in the liver, kidney, thyroid and adrenals. The major route of excretion was by bile, accounting for approximately 65–90% of the absorbed dose, with the rest being excreted in urine within 48 hours. After repeated dosing, no accumulation of radioactivity in rats was observed. There were no significant differences between the toxicokinetic parameters of the two diastereoisomers *syn* and *anti*. The predominant metabolic pathway for isopyrazam and its *N*-demethylated metabolite is hydroxylation in the bicyclic-isopropyl moiety, followed by further oxidation to form the carboxylic acid or to give rise to multiple hydroxyl moieties with subsequent formation of glucuronic acid or sulfate conjugates. The structure of isopyrazam provides the potential for stereoisomerization of most metabolites.

Toxicological data

Isopyrazam technical with a *syn*:*anti* ratio of up to 69.7:30.3 is of low acute oral toxicity. The oral median lethal dose (LD_{50}) was greater than 2000 mg/kg bw in female rats. However, as the oral LD_{50} of pure *anti* isomer or of a 50:50 *syn*:*anti* batch was 310.2 mg/kg bw in female rats, there seems to be an isomeric difference in toxicity at very high dose levels. By dermal application, the LD_{50} of a 92.8:7.2 *syn*:*anti* batch was greater than 5000 mg/kg bw, and the median lethal concentration (LC_{50}) in an inhalation study was greater than 5.28 mg/L. Isopyrazam was not irritating to the skin and, initially, only slightly irritating to the eye. Isopyrazam showed skin sensitizing potential in a mouse local lymph node assay.

In repeated-dose studies in mice, rats and dogs, the main effects were changes in clinical chemistry (plasma protein, cholesterol, triglycerides, liver enzymes) and haematological parameters (red blood cell counts, haemoglobin, haematocrit), effects on the liver (hepatocellular hypertrophy) and body weight changes.

In a 13-week mouse feeding study with dietary concentrations up to 7000 ppm, reduced body weight gain in spite of higher feed consumption was observed. Red blood cell parameters were

reduced and platelet counts were increased, particularly at the high dose. In females, a few clinical chemistry parameters were elevated. Relative liver weights were increased, and hepatocellular hypertrophy was observed. For one male and one female high-dose animal, necrotic liver nodules were noted. The no-observed-adverse-effect level (NOAEL) was 2500 ppm (equal to 390.8 mg/kg bw per day), based on haematological changes at 7000 ppm (equal to 1328.8 mg/kg bw per day).

In a study to compare the toxicity of the *syn* and *anti* conformation isomers of isopyrazam, pure *syn* epimer, pure *anti* epimer and 1:1 *syn*:*anti* epimer were administered to rats at up to 5000 ppm for 4 weeks in the diet. With pure *anti* and 1:1 *syn*:*anti*, feed intake and body weight gain were reduced. Haematological and clinical chemistry parameters were affected with all three compounds, but more severely with pure *anti* and 1:1 *syn*:*anti*. Liver weights were increased in females in all dosed groups and in males at 2000 ppm and above. The Meeting considered the liver findings as adaptive effects and not toxicologically relevant. All compounds in both sexes mildly elevated the total hepatic cytochrome P450 (CYP) content and mildly increased 7-ethoxyresorufin-*O*-deethylase (EROD; CYP1A) activity, but markedly increased pentoxyresorufin-*O*-deethylase (PROD; CYP2B) activity. The NOAEL for pure *syn* was 2000 ppm (equal to 176.7 mg/kg bw per day), based on reduced body weight gain and increased cholesterol levels at 5000 ppm (equal to 437.3 mg/kg bw per day). The NOAEL for pure *anti* and 1:1 *syn*:*anti* was 500 ppm (equal to 45.2 mg/kg bw per day), based on reduced body weight gain and increased cholesterol levels at 2000 ppm (equal to 176.7 mg/kg bw per day). In two further 4-week rat feeding studies with slightly different isopyrazam batches (*syn*:*anti* ratios of 89:11 and 92.8:7.2), the NOAELs were 500 ppm (equal to 46.1 mg/kg bw per day) and 300 ppm (equal to 28.1 mg/kg bw per day), based on body weight changes, clinical chemistry and haematological changes at 2000 ppm (equal to 174.9 mg/kg bw per day) and above.

In a 13-week rat feeding study with dietary concentrations of isopyrazam (92.8:7.2 *syn*:*anti*) of up to 6000 ppm, reduced feed consumption and body weight gain were noted. Relative liver weight increases were accompanied by hepatocellular hypertrophy. Relative brain weights were decreased in both sexes at the highest dose level. Triglyceride and bilirubin levels were decreased at 1500 ppm and above. The NOAEL was 300 ppm (equal to 21.3 mg/kg bw per day), based on clinical chemistry changes at 1500 ppm (equal to 106.3 mg/kg bw per day). In a comparative 13-week rat feeding study with dietary concentrations of two batches of isopyrazam (*syn*:*anti* ratios 92.8:7.2 and 69.7:30.3) up to 2000 ppm, the NOAEL for both compounds was 250 ppm (equal to 20.5 mg/kg bw per day), based on body weight effects and hepatocellular hypertrophy and vacuolation at 2000 ppm (equal to 161.0 mg/kg bw per day).

In dogs, two 13-week gelatine capsule gavage studies were performed with two batches of isopyrazam (*syn*:*anti* ratios 92.8:7.2 and 69.7:30.3). In the first study with isopyrazam *syn*:*anti* 92.8:7.2, several behavioural changes, reduced feed consumption and body weight gain, changes in clinical chemistry parameters and increases in liver weights were noted. The NOAEL in this study was 30 mg/kg bw per day, based on behavioural changes and liver weight increases at 100 mg/kg bw per day. In the second study with isopyrazam *syn*:*anti* 69.7:30.3, the NOAEL was 30 mg/kg bw per day, based on clinical observations and initial body weight loss at 250 mg/kg bw per day. In a 52-week gelatine capsule gavage study with isopyrazam (*syn*:*anti* 92.8:7.2), no clinical signs were observed. Initially reduced feed consumption and lower body weights were noted throughout the study. Some clinical chemistry parameters showed occasional modest changes but were without any histopathological correlates or other signs of toxicity. The NOAEL in this study was 25 mg/kg bw per day, based on changes in clinical chemistry parameters and in liver weight at higher dose levels. The overall NOAEL for the effects of isopyrazam with a *syn*:*anti* ratio down to 69.7:30.3 in the 3-month and 1-year studies in dogs was 30 mg/kg bw per day.

In an 18-month feeding study in mice with dietary concentrations of isopyrazam (*syn*:*anti* 92.8:7.2) up to 3500 ppm, the incidence of males with eye discharge was elevated at 3500 ppm. Also at 3500 ppm, body weight gain was reduced in both sexes, body weight–adjusted spleen weights were decreased and liver weights were increased. At 500 ppm, the incidence of periportal hepatocellular hypertrophy in females was increased. At 3500 ppm, the incidences of epithelial eosinophilic droplets

in the nasal cavity of males and in the gall bladder of females were elevated. The incidences of benign or malignant tumours were not increased at any dose. The NOAEL was 70 ppm (equal to 9.9 mg/kg bw per day), based on periportal hepatocellular hypertrophy in females at 500 ppm (equal to 56.2 mg/kg bw per day).

Isopyrazam was not carcinogenic in mice.

In a 104-week feeding study in rats with dietary concentrations up to 3000 ppm isopyrazam (*syn*:*anti* 92.8:7.2), body weight gain was decreased in all dosed females and in high-dose males. In both sexes, haematological parameters were changed and the prothrombin time was reduced, and in females, the activated partial thromboplastin time was prolonged at 500 ppm and above. There were changes in some clinical chemistry parameters (e.g., urea, triglyceride and bilirubin levels in females) in all dose groups. At terminal kill, female brain weights at 3000 ppm were increased, and liver weights in both sexes were increased at 500 and 3000 ppm. Adrenal weights in females were decreased at 3000 ppm. The incidences of foci of eosinophilic hepatocytes were increased statistically significantly at 500 ppm and above in both sexes. The hepatocellular pigmentation in all dosed females and in high-dose males was not considered to be of toxicological relevance at the lowest dose because it was of minimal severity. The increased centrilobular hepatocellular hypertrophy observed at all dose levels in both sexes was considered to represent adaptive changes and not to be of toxicological significance. In females at 3000 ppm, there was an increase in hepatocellular adenoma (17%), and at 3000 ppm, one hepatocellular carcinoma was found in each sex. In the high-dose females, the incidence of uterine endometrial adenocarcinoma was increased (23%). The NOAEL was 100 ppm (equal to 5.5 mg/kg bw per day), based on reduced body weight gain in females and foci of eosinophilic hepatocytes and clinical chemistry changes of equivocal toxicological significance in both sexes at 500 ppm (equal to 27.6 mg/kg bw per day).

Isopyrazam was carcinogenic in female rats at the highest dose tested.

The potential genotoxicity of isopyrazam was tested in an adequate range of in vitro and in vivo studies, providing no evidence of genotoxic potential.

The Meeting concluded that isopyrazam is unlikely to be genotoxic.

In mechanistic studies to evaluate possible modes of action for liver tumours in female rats, isopyrazam was shown to induce CYP2B and CYP3A activities and replicative deoxyribonucleic acid (DNA) synthesis in female rat hepatocytes in vitro with a significantly higher potency than phenobarbital. CYP3A was also induced with a high potency in female human hepatocytes in vitro, whereas phenobarbital showed a weak induction potential. In a 14-day feeding study in rats, CYP1A- and CYP2B-dependent activities were induced significantly at all three time points (3, 8 and 14 days after treatment with 500 or 3000 ppm), whereas CYP3A- and CYP4A-dependent activities were not induced. The significant in vivo CYP1A induction and the very high potency CYP2B (in vitro and in vivo) and CYP3A induction (in vitro) for isopyrazam suggest more than phenobarbital-like enzyme induction. Although microsomal enzyme induction was observed, no clear mode of action was identified that could be causally linked to the liver adenoma in female rats.

In an in vitro test with human estrogen receptor α, isopyrazam did not show significant binding capacity. Isopyrazam was negative in a rat uterotrophic assay. Therefore, an estrogen-like mode of action as a possible explanation for the uterine endometrial adenocarcinoma is not supported.

On the basis of the absence of genotoxicity and the absence of carcinogenicity in mice and the fact that an increase in the incidences of hepatocellular adenoma and uterine endometrial adenocarcinoma in female rats occurred only at the highest dose tested, the Meeting concluded that isopyrazam is unlikely to pose a carcinogenic risk to humans at dietary exposure levels.

In a two-generation study of reproductive toxicity in rats at dietary concentrations up to 3000 ppm isopyrazam (*syn*:*anti* 92.8:7.2), F_0 and F_1 rats had decreased body weight gains at 500 and 3000 ppm. Hepatocellular hypertrophy and increases in liver weights were noted in F_0 and F_1 animals at 500 ppm and above. In F_0 males at 500 ppm and above, thyroid weights were increased statistically

significantly. In F_0 and F_1 females at 3000 ppm, weights of the uterus with cervix were decreased statistically significantly. Kidney weights in F_1 animals were dose-relatedly increased at all dose levels in both sexes, statistically significantly in females at all dose levels and in males at 3000 ppm. Ovary weights in high-dose F_0 and F_1 females were statistically significantly decreased. F_{1A} and F_{2A} pup body weights were reduced. At 500 ppm and above, mean total litter weights were reduced. F_1 males at 3000 ppm showed statistically significantly delayed preputial (2.3 days) separation, and F_1 females at 3000 ppm showed statistically significantly delayed vaginal opening (2 days). Whereas the males showed statistically significantly reduced body weights (7%), the body weights of females were unchanged. The NOAEL for parental toxicity was 100 ppm (equal to 8.1 mg/kg bw per day), based on decreased body weight gain and organ weight changes at 500 ppm (equal to 40.6 mg/kg bw per day) in parental F_0 and F_1 animals. The NOAEL for postnatal developmental toxicity was 100 ppm (equal to 8.1 mg/kg bw per day), based on decreased mean total litter weights at 500 ppm (equal to 40.6 mg/kg bw per day). The NOAEL for reproductive performance was 3000 ppm (equal to 239.1 mg/kg bw per day), the highest dose tested.

In a study on the developmental toxicity of isopyrazam (*syn*:*anti* 92.8:7.2) in rats at dose levels up to 250 mg/kg bw per day administered by gavage, two high-dose dams were killed in extremis on gestation days (GD) 20 and 21 because they were showing severe signs of toxicity. The high dose group animals showed reduced feed consumption and reduced body weight gain, and fetal body weights were decreased in this group. In the 250 mg/kg bw per day group, one fetus with hydroencephalus and microphthalmia was observed, and in another litter, a fetus with hydrocephalus only was noted. Non-ossified cervical centra and incomplete xiphoid cartilage were noted at 75 mg/kg bw per day and above. The NOAEL for maternal toxicity was 75 mg/kg bw per day, based on reduced body weight gain and clinical signs of toxicity at 250 mg/kg bw per day. The NOAEL for developmental toxicity was 20 mg/kg bw, based on delayed or absent ossification in cervical centra at 75 mg/kg bw per day.

In a study on the developmental toxicity of isopyrazam (*syn*:*anti* 69.7:30.3) in rats at dose levels up to 200 mg/kg bw per day administered by gavage, ventral recumbency and sedation were noted in all dams at 200 mg/kg bw per day, from the first day of treatment (GD 4) throughout the first week. Feed consumption and body weight gain were reduced from GD 4 in animals at 75 mg/kg bw per day and above. At 75 mg/kg bw per day and above, fetal body weights were lower than those of controls. One fetus at 200 mg/kg bw per day was found with diaphragmatic hernia. Increased incidences of delayed or absent ossification of cervical vertebral bodies were observed at 200 mg/kg bw per day and of incompletely ossified sternebrae at 75 mg/kg bw per day and above. Additionally, non-ossified structures in forelimbs and hindlimbs were identified. The NOAEL for maternal and developmental toxicity was 20 mg/kg bw per day, based on clinical signs and reduced body weight gain in dams and lower fetal body weights at 75 mg/kg bw per day.

In two range-finding studies on the developmental toxicity of isopyrazam (*syn*:*anti* 92.8:7.2) in Himalayan rabbits at dose levels up to 1000 mg/kg bw per day, no maternal toxicity was observed. In fetuses, the incidences of small eyes, malrotated and flexed limbs and changes in the skull were increased at 400 mg/kg bw per day and above.

In a third range-finding study on the developmental toxicity of isopyrazam (*syn*:*anti* 92.8:7.2) in New Zealand White rabbits at dose levels up to 1000 mg/kg bw per day, maternal toxicity was noted at all dose levels from 400 to 1000 mg/kg bw per day, as dams had decreased body weight gain, increased liver weights, hepatocellular hypertrophy and changes in clinical chemistry parameters. At the high dose, fetal body weight was reduced and early resorptions were increased. Small eyes were noted in fetuses at 1000 mg/kg bw per day. Furthermore, absent gall bladders, extra papillary muscle in the heart and variations of major blood vessels were observed.

In a definitive study on the developmental toxicity of isopyrazam (*syn*:*anti* 92.8:7.2) in New Zealand White rabbits at dose levels up to 500 mg/kg bw per day, hepatocellular vacuolation was observed at 500 mg/kg bw per day. One fetus in the 500 mg/kg bw per day group had bilateral microphthalmia. The NOAEL for maternal toxicity was 150 mg/kg bw per day, based on

hepatocellular vacuolation at 500 mg/kg bw per day. The developmental NOAEL was 150 mg/kg bw per day, based on a single observation of bilateral microphthalmia at 500 mg/kg bw per day.

A low incidence of microphthalmia was consistently observed in dose range–finding and main studies in two different rabbit strains. Microphthalmia is a very rare finding in the rabbit strains used. Thus, the Meeting concluded that the low incidences of microphthalmia in treated rabbits could not be discounted.

The Meeting concluded that isopyrazam was teratogenic in rabbits.

In an acute neurotoxicity study in rats administered isopyrazam (*syn*:*anti* 69.7:30.3) at doses ranging from 30 to 2000 mg/kg bw, nonspecific and transient effects were apparent within 3 hours after dosing in all dose groups, with a dose-dependent increase in the incidence and severity of rigidity. The NOAEL was 30 mg/kg bw, based on clinical signs of toxicity at 250 mg/kg bw. The NOAEL for acute neurotoxicity was 2000 mg/kg bw, the highest dose tested.

In a 13-week rat feeding study of the neurotoxicity of isopyrazam (*syn*:*anti* 69.7:30.3) with dietary concentrations up to 6000 ppm, no behavioural or histological evidence for neurotoxicity was observed. The NOAEL was 1500 ppm (equal to 98.01 mg/kg bw per day), based on decreased body weight gain in females at 6000 ppm (equal to 382.26 mg/kg bw per day). The NOAEL for subchronic neurotoxicity was 6000 ppm (equal to 382.26 mg/kg bw per day), the highest dose tested.

Toxicological data on metabolites

CSCD465008, a soil and plant metabolite, and CSCD459488, a rat, soil, plant and aquatic metabolite, were investigated in acute and subacute toxicity studies and an adequate range of in vitro genotoxicity studies. CSCD459488 was also investigated in a developmental toxicity study in rabbits.

CSCD465008 and CSCD459488 were both of low acute oral toxicity, with LD_{50} values greater than 2000 mg/kg bw, and did not give any evidence of genotoxic potential.

In a 4-week rat feeding study with dietary concentrations of CSCD465008 up to 12 000 ppm, no evidence for toxicity or for induction of EROD or PROD activity was observed. The NOAEL was 12 000 ppm (equal to 1018 mg/kg bw per day), the highest dose tested.

In a 4-week rat feeding study with dietary concentrations of CSCD459488 up to 10 000 ppm, the liver weights were increased at 300 ppm and above, and increased incidences of centrilobular hepatocyte hypertrophy and follicular cell hypertrophy of the thyroid were noted at 4000 ppm and above. Total hepatic microsomal P450 content was approximately doubled in males in the 4000 and 10 000 ppm groups and only slightly elevated in females in the same dose groups. EROD and PROD activities were statistically significantly increased at all dose levels. The NOAEL was 300 ppm (equal to 27 mg/kg bw per day), based on liver weight changes greater than 10% at higher doses.

In a study on the developmental toxicity of CSCD459488 in New Zealand White rabbits at dose levels up to 1000 mg/kg bw per day, maternal liver weights were increased at all dose levels. In the high-dose group, late resorptions per litter were increased primarily due to three resorptions in one female. The maternal NOAEL was 150 mg/kg bw per day, based on significant liver weight increases (> 20%) at higher dose levels. The NOAEL for developmental toxicity was 1000 mg/kg bw per day, the highest dose tested.

No reports on exposure of personnel working with isopyrazam were submitted.

The Meeting concluded that the existing database on isopyrazam was adequate to characterize the potential hazard to fetuses, infants and children.

Toxicological evaluation

The Meeting established an ADI of 0–0.06 mg/kg bw derived from the NOAEL of 5.5 mg/kg bw per day in the 104-week rat feeding study on the basis of decreased body weight gain in females and foci of eosinophilic hepatocytes and clinical chemistry changes (triglycerides, bilirubin) of equivocal toxicological significance in both sexes at 27.6 mg/kg bw per day. A safety factor of 100 was applied. The ADI is supported by the NOAEL of 9.9 mg/kg bw per day in the mouse 80-week feeding study, based on periportal hepatocellular hypertrophy in females at 500 ppm (equal to 56.2 mg/kg bw per day). The margin between the maximum ADI and the LOAEL at 232.8 mg/kg bw per day for uterine and liver tumours in female rats is approximately 3900.

The Meeting established an ARfD of 0.3 mg/kg bw derived from the NOAEL of 30 mg/kg bw in the rat acute neurotoxicity study, on the basis of nonspecific clinical signs of toxicity (weak appearance and decreased activity) at 250 mg/kg bw. A safety factor of 100 was applied. In a rat developmental toxicity study, the NOAEL of 20 mg/kg bw per day for maternal and developmental toxicity was based on reduced body weight gain in dams only on day 4 of treatment. The margin between the ARfD and the LOAEL at 500 mg/kg bw per day for teratogenic effects (microphthalmia) in rabbits is approximately 1700.

A toxicological monograph was prepared.

Levels relevant to risk assessment

Species	Study	Effect	NOAEL	LOAEL
Mouse	Eighteen-month study of toxicity and carcinogenicity[a]	Toxicity	70 ppm, equal to 9.9 mg/kg bw per day	500 ppm, equal to 56.2 mg/kg bw per day
		Carcinogenicity	3500 ppm, equal to 432.6 mg/kg bw per day[b]	—
Rat	Acute neurotoxicity[c]	Toxicity	30 mg/kg bw	250 mg/kg bw
	Two-year study of toxicity and carcinogenicity[a]	Toxicity	100 ppm, equal to 5.5 mg/kg bw per day	500 ppm, equal to 27.6 mg/kg bw per day
		Carcinogenicity	500 ppm, equal to 34.9 mg/kg bw per day	3000 ppm, equal to 232.8 mg/kg bw per day
	Two-generation study of reproductive toxicity[a]	Reproductive toxicity	3000 ppm, equal to 239.1 mg/kg bw per day[b]	—
		Parental toxicity	100 ppm, equal to 8.1 mg/kg bw per day	500 ppm, equal to 40.6 mg/kg bw per day
		Offspring toxicity	100 ppm, equal to 8.1 mg/kg bw per day	500 ppm, equal to 40.6 mg/kg bw per day
	Developmental toxicity study[c]	Maternal toxicity	20 mg/kg bw per day	75 mg/kg bw per day
		Embryo and fetal toxicity	20 mg/kg bw per day	75 mg/kg bw per day
Rabbit	Developmental toxicity study[c]	Maternal toxicity	150 mg/kg bw per day	500 mg/kg bw per day
		Embryo and fetal toxicity	150 mg/kg bw per day	500 mg/kg bw per day
Dog	Thirteen-week and 1-year studies of toxicity[c,d]	Toxicity	30 mg/kg bw per day	100 mg/kg bw per day

[a] Dietary administration.

[b] Highest dose tested.

[c] Gavage administration.

[d] Three studies combined.

Estimate of acceptable daily intake for humans

0–0.06 mg/kg bw

Estimate of acute reference dose

0.3 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 exposures

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

Absorption, distribution, excretion and metabolism in mammals	
Rate and extent of oral absorption	Rapid, 70%
Dermal absorption	No data
Distribution	Extensive, highest levels in liver
Potential for accumulation	Low, no evidence of accumulation
Rate and extent of excretion	Rapid, close to 100% within 48 h, mainly via bile
Metabolism in animals	Extensive, primarily via hydroxylation at bicyclic-isopropyl moiety
Toxicologically significant compounds (animals, plants and the environment)	Isopyrazam, CSCD459488
Acute toxicity	
Rat, LD_{50}, oral	> 2000 mg/kg bw (69.7:30.3 *syn*:*anti*)
Rat, LD_{50}, oral	310.2 mg/kg bw (50:50 *syn*:*anti* and pure *anti*)
Rat, LD_{50}, dermal	> 5000 mg/kg bw (92.8:7.2 *syn*:*anti*)
Rat, LC_{50}, inhalation	> 5.28 mg/L (69.7:30.3 *syn*:*anti*)
Rabbit, dermal irritation	Not irritating
Rabbit, ocular irritation	Slightly irritating
Mouse, skin sensitization (local lymph node assay)	Sensitizing potential
Short-term studies of toxicity	
Target/critical effect	Body weight changes and liver toxicity (rat)
Lowest relevant oral NOAEL	250 ppm, equal to 20.3 mg/kg bw per day (rat)
Lowest relevant dermal NOAEL	No data
Lowest relevant inhalation NOAEL	No data

Genotoxicity	
	Not genotoxic
Long-term studies of toxicity and carcinogenicity	
Target/critical effect	Clinical chemistry, body weight (rat)
Lowest relevant NOAEL	5.5 mg/kg bw per day (rat)
Carcinogenicity	Unlikely to pose a carcinogenic risk at dietary exposure levels
Reproductive toxicity	
Reproduction target/critical effect	No reproductive effects
Lowest relevant reproductive NOAEL	239.1 mg/kg bw per day (rat), highest dose tested
Developmental target/critical effect	Decreased fetal body weights (rat), microphthalmia (rabbit)
Lowest relevant developmental NOAEL	20 mg/kg bw per day (rat), 150 mg/kg bw per day (rabbit)
Neurotoxicity/delayed neurotoxicity	
	No evidence in acute or subchronic neurotoxicity studies
Other toxicological studies	
Studies on metabolites	In rat 4-week feeding studies, CSCD465008 was less toxic than the parent and CSCD459488 was of similar toxicity to the parent
Medical data	
	No reports submitted

Summary

	Value	Study	Safety factor
ADI	0–0.06 mg/kg bw	Two-year study in rats	100
ARfD	0.3 mg/kg bw	Acute neurotoxicity study in rats	100

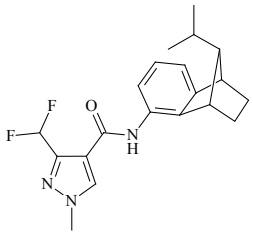
RESIDUE AND ANALYTICAL ASPECTS

Isopyrazam is a broad-spectrum foliar fungicide belonging to the chemical class of ortho-substituted phenyl amides. It controls a wide range of fungal pathogens.

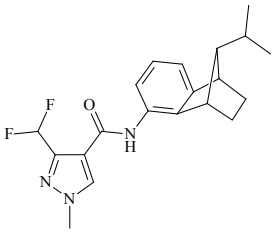
The Meeting received information on physical and chemical properties, animal and plant metabolism, environmental fate, analytical methods, storage stability, use patterns, processing and farm animal feeding.

Isopyrazam contains two diastereoisomers designated syn- and anti-isomers. Both of these isomers are biologically active and the specification for technical isopyrazam covers the range of syn:anti isomer ratios from 70:30 to 100:0.

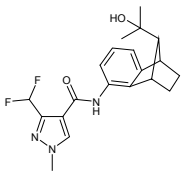
syn-isomer



anti-isomer

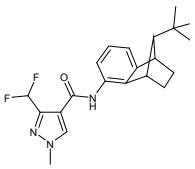


In this Appraisal, the following abbreviated names were used.



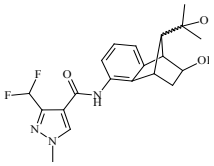
CSCD459488

Hydroxylated syn-isomer (tertiary alcohol)



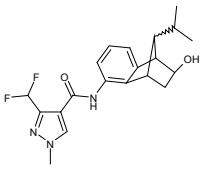
CSCD459489

Hydroxylated anti-isomer (tertiary alcohol)



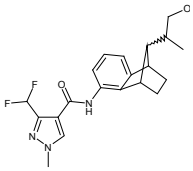
CSCD656800

Dihydroxylated isopyrazam



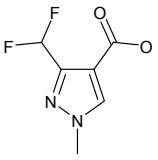
CSCD563692

Hydroxylated isopyrazam (secondary alcohol)



CSCD563691

Hydroxylated isopyrazam (primary alcohol)



CSAA798670

3-Difluoromethyl-1-methyl-1H-pyrazole-4-carboxylic acid

Animal metabolism

The Meeting received information on the fate of orally-dosed isopyrazam in rats, lactating goats and laying hens.

For the animal metabolism studies, three types of radioactive isopyrazam were used: isopyrazam uniformly labelled with ^{14}C on phenyl ring and with syn/anti ratio of 70:30 or 95:5; and one with ^{14}C at position 5 of pyrazole ring with syn/anti ratio of approximately 95:5. In addition, in a goat metabolism study, CSCD 459488 labelled at position 5 of pyrazole ring with ^{14}C was used.

In metabolism studies, total radioactive residues are expressed in mg/kg isopyrazam equivalents unless otherwise stated.

Metabolism of isopyrazam in rats

Metabolism studies on laboratory animals including rats were reviewed in the framework of toxicological evaluation by the current Meeting.

When radio-labelled isopyrazam was administered once at 1 or 75 mg/kg bw to rats, approximately 70% of the dose was absorbed. Most of the absorbed dose was excreted within 24 hours after administration, 65–90% via bile and the rest via urine. Highest residues were identified in the liver, kidney, thyroid and adrenals. After repeated dosing, no accumulation of radioactivity was observed in rats. There were no significant differences between the toxicokinetic parameters of syn- and anti isomers. The predominant metabolic pathway for isopyrazam or its N-demethylated metabolite is hydroxylation in the bicyclic-isopropyl moiety, followed by further oxidation to form

carboxylic acid and/or to give rise to multiple hydroxylated metabolites with subsequent formation of glucuronic acid or sulphate conjugates.

Metabolism of isopyrazam in lactating goats

The three types of [^{14}C]isopyrazam were administered orally to three groups of lactating goats (each type of radio-labelled isopyrazam to each different group) at a dose equivalent to a dietary concentration of 30 ppm (in dry matter) daily for seven consecutive days. Of the total administered radioactivity (TAR), 60–63% and 12–13% was eliminated via faeces and urine, respectively. Administration of radio-labelled isopyrazam with different ^{14}C position or syn/anti ratio did not reveal any significant difference in the excretion. Total recovered radioactivity was 80–84% of the TAR.

Radioactivity in the Day 5 am milk was 0.055–0.076 mg/kg from the use of three different types of radioactive isopyrazam.

Total radioactive residues (TRR) in tissues except liver after sacrifice (16 hours after the last dose) were similar regardless of the label position or the syn/anti ratio. In the liver, TRR (0.331 mg/kg) after administration of phenyl-labelled isopyrazam of syn/anti ratio of 70:30 was about one half of the TRR (0.604 and 0.612 mg/kg) after administration of pheyl-labelled or pyrazole-labelled isopyrazam of syn/anti ratio of 95:5. In other tissues, TRR were 0.143–0.189 mg/kg in the kidney, 0.022–0.032 mg/kg in the muscle, and 0.012–0.020 mg/kg in the fat.

In the milk, liver, kidney and muscle extracts, parent compound was a minor component with the maximum of 0.0063 mg/kg (1.9% TRR) in the liver or 8.6% of TRR (0.0019 mg/kg) in the muscle from the administration of three different types of radio-labelled isopyrazam.

In the fat, the parent compound was predominant at 40–51% of TRR but the concentration was very low at 0.005–0.010 mg/kg.

The major residue was CSCD656800, dihydroxylated isopyrazam, in the extracts of milk (15–32% of TRR; 0.008–0.019 mg/kg), liver (6–17% of TRR; 0.020–0.104 mg/kg), kidney (13–25% of TRR; 0.023–0.038 mg/kg) and muscle (29–44% of TRR; 0.007–0.013 mg/kg). CSCD656800 was not detected in the fat extracts. In the liver, CSCD656800 existed as glucuronide or sulphate conjugates.

No other identified metabolites existed at quantifiable concentrations. All identified metabolites contained both the pyrazole and phenyl moieties indicating that there was no or little cleavage of amide in metabolism.

Treatment of the liver extraction debris with protease released a significant portion of radioactivity which was composed of multiple minor metabolites.

Metabolism of CSCD459488 in lactating goats

Metabolism of CSCD459488, hydroxylated syn-isomer of isopyrazam and major metabolite in wheat, grapes and lettuce, was studied by orally administering pyrazole-labelled CSCD459488 at a dose equivalent to dietary concentration of 12 ppm to lactating goats daily for seven consecutive days. The major portion of administered radioactivity was excreted via faeces (57% of TAR) and urine (30% of TAR).

Radioactivity in the Day 6 pm milk was 0.123 mg/kg in CSCD459488 equivalents. After sacrifice, the highest radioactivity was found in the liver at 0.457 mg/kg followed by kidney at 0.246 mg/kg, muscle at 0.038 mg/kg, and fat at 0.007 mg/kg.

In this study, the predominant metabolite was CSCD656800 in the milk and all the tissues tested (33–56% of TRR). The highest concentration was found in the liver at 0.159 mg/kg (36% of TRR) where the majority of CSCD656800 existed as conjugates.

CSCD459488 was detected in the milk and all the tissues tested but at only very low levels (< 0.001–0.007 mg/kg; 0.1–6.2% of TRR) and in conjugated forms.

Metabolism of isopyrazam in laying hens

The three types of [^{14}C]isopyrazam were administered orally to three groups of laying hens (each type of radio-labelled isopyrazam to each different group) at a dose equivalent to a dietary concentration of 11 ppm (in dry matter) daily for 14 consecutive days. Of the total administered radioactivity (TAR), 88–93% was eliminated in excreta. Administration of radio-labelled isopyrazam with different ^{14}C position or syn/anti ratio did not reveal any significant difference in the excretion. Total recovered radioactivity was 91–95% of the TAR.

TRR in the composite egg white and egg yolk samples obtained in Days 7–14 from hens dosed with radio-labelled isopyrazam with syn/anti ratio of 95:5 were 0.017 and 0.039–0.042 mg/kg, respectively. On the other hand, when phenyl-labelled isopyrazam with syn/anti ratio of 70:30 was administered, TRR in the composite egg white and egg yolk samples were higher at 0.024 and 0.080 mg/kg respectively.

The TRR in tissues after sacrifice (16 hours after the last dose) were 0.119–0.143 mg/kg, 0.004–0.006 mg/kg, 0.008–0.020 mg/kg and 0.011–0.020 mg/kg in liver, muscle, skin and attached fat, and peritoneal fat, respectively.

Parent isopyrazam was detected in all fat samples and in egg yolk samples (from administration of pyrazole-labeled isopyrazam with the syn/anti ratio of 95:5 and phenyl-labelled isopyrazam with the syn/anti ratio of 70:30) and in liver (from administration of pyrazole-labelled isopyrazam with the syn/anti ratio of 95:5) but the concentrations were < 0.01 mg/kg (< 5% of TRR in egg yolk and liver; up to 21% TRR in fat).

From the egg and liver samples, three metabolites were identified: CSCD656800 (dihydroxylated isopyrazam), hydroxy CSCD459489 and unsaturated carboxylic acid. None of them existed in a concentration higher than 0.012 mg/kg but CSCD656800 contributed up to 29% of TRR in egg white. Detection of hydroxyl CSCD459489 (anti configuration) in egg and liver samples from treatment with the syn/anti ratio of 70:30 was consistent with the larger proportion of anti-isomer administered in the experiment.

Treatment of the liver extraction debris with protease followed by 0.1 NHCl released a significant portion of radioactivity which was composed of multiple minor metabolites.

No other identified metabolites existed at quantifiable concentrations. All identified metabolites contained both the pyrazole and phenyl moieties indicating that there was no or little cleavage of amide in metabolism.

The metabolic pathway in lactating goats and laying hens was similar to the one in rats. The primary metabolism of isopyrazam in these animals, in relation to edible tissues, milk and eggs, proceeded through hydroxylation of the isopropyl group and bicyclic portion of the molecule; and then oxidation of primary alcohols to form carboxylic acids and/or multiple hydroxyl moieties which subsequently converted into glucuronic acid or sulphate conjugates.

No significant inter-conversion of the two isomers of isopyrazam occurred in metabolism.

Plant metabolism

The Meeting received information on the fate of isopyrazam after foliar applications on wheat, grape and lettuce.

For the plant metabolism studies, three types of radioactive isopyrazam were used: isopyrazam uniformly labelled with ^{14}C on phenyl ring and with syn/anti ratio of 70:30 or 96:4; and one with ^{14}C at position 5 of pyrazole ring with syn/anti ratio of 96:4.

Wheat

Wheat grown in pots in glasshouse was treated three times (approximating BBCH 31, BBCH 39 and BBCH 69) with foliar spray application of the three types of isopyrazam separately at a rate of 125 g ai/ha.

Total radioactive residues (TRR) in forage collected 13 days after the second application were 4.75–7.09 mg/kg, and in grain and straw collected 4–48 days after the last application were 0.031–0.059 mg/kg and 14.1–20.8 mg/kg respectively. This indicates that translocation to grains is very small.

Application of radio-labelled isopyrazam with different ^{14}C position did not result in significant difference in the TRR while the application of isopyrazam with the syn/anti ratio of 70:30 resulted in significantly lower TRR.

Parent isopyrazam was the major residue: 4.50–5.81 mg/kg (79–91% of TRR) in forage, 8.56–15.5 mg/kg (61–69% of TRR) in straw, and 0.021–0.037 mg/kg (53–66% of TRR) in grain.

In grain, no identified metabolites existed in excess of 0.0013 mg/kg (< 5% of TRR).

In straw, the most significant metabolite was CSCD459488 (tertiary alcohol) at 1.01–1.94 mg/kg (7.3–9.7% of TRR). This compound was also found in forage and grain but at lower concentrations: 0.020–0.15 mg/kg (0.4–2.4% of TRR) in forage and 0.0004–0.0008 mg/kg (1.2–1.4% of TRR) in grain.

In straw, CSCD563692 (secondary alcohol) and CSCD563691 (primary alcohol) were also identified but both of them were less than 5% of TRR (up to 0.760 and 0.540 mg/kg respectively). These compounds were also found in forage at lower levels.

A dihydroxylated compound was also identified but accounted for less than 5% of TRR in forage, straw and grain. A number of additional components were identified as the N-demethylated isopyrazam and unsaturated products (< 5% of TRR).

Major portions of the above mentioned metabolites were released after pectinase treatment indicating their presence in conjugated form.

Grapes

Grape vines in the field were given a single foliar application of either of phenyl-labelled or pyrazole-labelled isopyrazam (syn/anti ratio of 70:30) at a nominal rate of 400 g ai/ha. Grape berries were harvested 21 days after the application.

Total radioactive residues (TRR) in unwashed grape berries were 0.156 and 0.147 mg/kg for the pheny-labelled and pyrazole-labelled isopyrazam application respectively. The TRR in the vine leaves were 11.0 and 3.77 mg/kg for the pheny-labelled and pyrazole-labelled isopyrazam application respectively. Residue concentrations were much lower in berries than in leaves.

Parent isopyrazam is the major component of the residues from the both treatments at 0.116–0.131 mg/kg (89–90% of TRR) in grape berries. In leaf samples, parent compound was present at 10.1 mg/kg (91% of TRR) from treatment with phenyl-labelled isopyrazam and 3.25 mg/kg (86% of TRR) from pyrazole-labelled isopyrazam. The syn/anti ratio of isopyrazam in fruit and leaf fractions was approximately 70:30 in the HPLC analysis indicating no significant change in ratio from the applied isopyrazam.

The metabolites CSCD563692 (secondary alcohol), CSCD610195 (primary alcohol) and CSCD459488 (syn-form tertiary alcohol) were found in berries. Corresponding anti-form CSCD459489, dihydroxylated metabolite CSCD656800 and N-demethylated metabolites were found in leaves only. None of them accounted for more than 5% of TRR (individually up to 0.110 mg/kg in leaf).

Lettuce

Lettuce grown outdoors was treated three times (BBCH < 40, 42 and 46) with phenyl-labelled or pyrazole-labelled isopyrazam at a nominal application rate of 125 g ai/ha. Lettuce was harvested 3 (early harvest) or 14 days (normal harvest) after the last application.

The total radioactive residues in lettuce were 1.54–1.56 mg/kg 3 days after the last application but decreased to 0.22–0.31 mg/kg at full maturity, 14 days after the last application.

Also in lettuce, parent isopyrazam was the major component of residues: 1.03–1.09 mg/kg (66–71% of TRR) in early harvest and 0.100–0.108 mg/kg (35–45% of TRR) in normal harvest.

CSCD459488 (tertiary alcohol), mostly in a conjugated form, was the most significant metabolite: 0.009–0.022 mg/kg (0.6–1.4% of TRR) in early harvest and 0.031–0.053 mg/kg (14–17% of TRR) in normal harvest. This indicates biotransformation of isopyrazam into CSCD459488.

There were a number of minor metabolites characterized in lettuce from both harvest timings from the both treatments. They were hydrolyzed, N-demethylated or cleaved compounds and existed at very low levels.

The studies on wheat, grape and lettuce indicate that the metabolism of isopyrazam in these plants was qualitatively the same. The position of radiolabel or the syn/anti ratio of isopyrazam did not reveal significant difference in metabolic profiles.

In all plants tested, parent compound was the major residue component with a number of hydrolyzed or N-demethylated metabolites identified or characterized.

In plants, isopyrazam undergoes hydroxylation of the isopropyl group to produce a variety of alcohol products with CSCD459488 as the major metabolite; conjugation of these metabolites with natural carbohydrates; or N-demethylation of the pyrazole ring. None of the metabolites, except CSCD459488 in lettuce leaf (14–17% of TRR) and wheat straw (7.3–9.7% of TRR), accounted for more than 5% of TRR.

Environmental fate in soil

Since isopyrazam is a fungicide with foliar applications and its uses are currently limited to cereals and bananas, the Meeting reviewed hydrolysis and succeeding crop studies.

Hydrolysis

Isopyrazam was stable for 30 days at 25 °C at pH 5, 7 and 9 and for 5 days at 50 °C at pH 4, 5, 7 and 9.

Residues in succeeding crops

A confined study was conducted to examine the nature and levels of residues of isopyrazam in succeeding crops. A single application of either pyrazole-labelled or pheyl-labelled isopyrazam (syn/anti ratio of 96:4) was made to sandy loam soil in containers at a nominal rate of 375 g ai/ha, higher than the proposed maximum annual application rate of 250 g ai/ha.

At each rotational interval of 30, 90 and 300 days after treatment (DAT), spring wheat, lettuce and turnips were sown into the treated soil, grown in glasshouses, and harvested at maturity.

Following application of isopyrazam to soil and aging of the treated soil for up to 300 days, uptake of radioactivity into rotational crops was most significant in straw, hay and forage of wheat (0.80–1.02 mg/kg for 30-day plant back interval, 0.35–0.40 mg/kg for 90-day plant back interval (no harvest for 30-day plant back interval), and 0.073–0.154 mg/kg for 30-day plant back interval, respectively). The uptake gradually decreased in samples as plant back interval increased. In wheat grain, turnip roots and leaves, and lettuce, uptake of radioactivity was much smaller (0.012–

0.023 mg/kg, 0.016–0.018 mg/kg, 0.026–0.051 mg/kg, and 0.010–0.023 mg/kg respectively for 30-day plant back interval).

In general, the metabolism of isopyrazam in succeeding crops was similar to that in primary crops but parent compound accounted for a much lower percentage of the residue in the confined study (< 10% of TRR) and was not predominant residue. The only exception was turnip roots, where unchanged parent accounted for up to 34% TRR, but this represented a residue of only 0.0055 mg/kg. CSCD459488 was detected in all rotational crop commodities and reached 22–25% TRR in wheat straw and hay (0.17 mg/kg in straw and 0.090 mg/kg in hay). Pyrazole-specific half-molecule metabolites (CSAA798670 and its N-demethylated compound) were relatively more abundant in the confined succeeding crop study (CSAA798679 up to 48% TRR and 0.025 mg/kg in turnip foliage; and CSCD465008 up to 14% TRR and 0.003 mg/kg in turnip root) indicating that cleavage of the amide bond of isopyrazam seem to play some role in succeeding crops while they were negligible in the primary crops receiving foliar applications.

Four field trials were conducted to investigate the magnitude of the residues of isopyrazam and its metabolites in succeeding or rotational crops. Isopyrazam was applied three times to primary crops of wheat at a nominal rate of 125 g ai/ha, giving a total application rate of 375 g ai/ha, i.e., higher than the proposed maximum annual application rate of 250 g ai/ha.

Neither syn-isomer nor anti-isomer of isopyrazam was detected at or above the LOQ of 0.005 mg/kg in any of the succeeding crops (barley, carrots and spinach) from all plant-back intervals up to about one year, except in one trial where residues of syn-isomer were found at very low levels (0.005–0.006 mg/kg) in the carrot roots, barley forage and whole barley plant samples from the first (28-day) plant-back interval. CSCD459488 (hydroxylated syn-isomer) was found at low levels (up to 0.054 mg/kg in barley straw) while CSCD459489 (hydroxylated anti-isomer) or CSAA798670 was not found in any of the rotational crops.

CSCD465008 was found in all crops and at slightly higher levels (up to 0.15 mg/kg in carrot leaves).

The metabolic pathway in rotational crops is similar to that in primary crops but parent compound represented a much lower percentage of the residue and pyrazole-specific metabolites account for a higher proportion of the residue in rotational crops. Of these, CSAA798670 was not found in any of the field rotational crop studies.

The Meeting concluded that isopyrazam residue was not expected to be found above the LOQ in barley grains, carrot roots and spinach leaves. CSCD459488 or CSCD465008 were not detected more than 0.01 mg/kg in barley grains and carrot roots while these were found in spinach at 0.015 and 0.06 mg/kg respectively. These residues were found at higher concentrations in barley forage, hay and straw and carrot leaves.

Analytical methods

Analytical methods for determination of residues of isopyrazam and its metabolites were developed for a wide range of matrices of plant and animal origin.

In general, the methods for data generation employ extraction by homogenization with a mixture of acetonitrile and water (mostly 80:20 v/v), clean-up with solid phase extraction or a process of centrifugation and dilution, and determination of analytes using LC-MS/MS or, in one method, GC-MS/MS.

A number of methods for plant matrices were successfully validated for each isomer of isopyrazam at LOQ (0.005 mg/kg for each analyte) and higher concentrations in barley grain, forage and straw, ryegrass, apples, carrots, spinach, tomatoes, oranges, potatoes, lentils, sunflower seeds, rapeseed, bran bread and beer.

One method was successfully validated for determination of monohydroxylated metabolites (CSCD459488 and CSCD459489) of isopyrazam at LOQ of 0.005 mg/kg and above for barley grain, forage, straw, apples, carrots, spinach, rapeseed, lentils, bran, bread and beer. This method involves hydrolysis with 0.1 M HCl at 60 °C for 3 hours.

Another method was successfully validated for CSCD465008 and CSAA798670 at LOQ of 0.01 mg/kg and above in barley grain, forage and straw, carrot leaves and roots, and spinach. This method involves hydrolysis with pectinase at pH 5 at 37 °C for 16–20 hours and partition with hexane.

For commodities of animal origin, one method was successfully validated for the determination of each isomer of isopyrazam at 0.005 mg/kg and above in eggs, milk, muscle, liver, kidney and fat. Another method determines isopyrazam and its metabolites in commodities of animal origin as the common moiety CSAA798670; i.e., this method determines not only isopyrazam but any metabolites hydrolysable to CSAA798670. The analytical procedure involves hydrolysis of acetonitrile + water extract with 12 M potassium hydroxide solution at 100 °C for 3 hours. The method was successfully validated for the determination of isopyrazam and its metabolites hydrolysable to CSAA798670 at 0.005 mg/kg in CSAA798670 equivalents and above in eggs, milk, muscle, liver, kidney and fat.

For enforcement, a multi-residue method DFG-S19 was investigated for monitoring of isopyrazam in plant and animal commodities using GC-MSD (selected ion monitoring) or LC-MS/MS (positive or negative multiple reaction monitoring). DFG-S19 using negative multiple reaction monitoring LC-MS/MS was successfully validated in-house and independently for the determination of isopyrazam (determined as syn- and anti-isomer separately) at 0.005 mg/kg and above (plant commodities) or 0.0025 mg/kg and above (animal commodities) for each isomer, In the case of wheat grain, the method could only be validated at 0.05 mg/kg when ion m/z 316 was monitored with GC-MSD in an independent laboratory validation.

Both GC-MSD and LC-MS/MS are specific and either of them can be used for quantification of residues. However, only the negative multiple reaction monitoring LC-MS/MS received full validation and independent laboratory validation.

Stability of pesticide residues in stored analytical samples

The stability of isopyrazam residues during storage of samples frozen at approximately -15 to -20 ºC was investigated in a range of plant and animal matrices: tomato fruit, rape seeds, lentil seeds, potato tubers, barley grain, barley straw, ryegrass forage and spinach leaves; and milk, eggs, liver, kidney, muscle and fat.

Compounds tested were: both isomers of isopyrazam, CSCD459488, CSCD459489, CSCD465008 and CSAA798670. Each compound was spiked to matrices at 0.5 mg/kg.

All of the compounds tested were found stable (> 70% remaining) at least for the following storage periods tested: in plant commodities, both isomers of isopyrazam, 24 months; CSCD459488, 11 months; CSCD459489, 28 months; and CSCD45008 and CSAA798670, 12 months; and in animal commodities, both isomers of isopyrazam, 14 months; and isopyrazam and metabolites hydrolysable to CSAA798670, 12 months.

The storage durations of samples from the supervised field trials were within the above storage periods.

Definition of the residue

In animal metabolism studies, parent isopyrazam was detected in all the tissues tested, milk and eggs at concentrations < 0.01 mg/kg. It was metabolized extensively and accounted for < 9% of TRR in milk, eggs and tissues other than fat, and up to 51% of TRR in fat.

Sufficiently validated multi-residue LC-MS/MS or GC-MSD method was available for determining the parent compound as the two separate isomers in animal commodities for enforcement. A number of LC-MS/MS methods were validated for analysing isopyrazam in animal commodities.

CSCD656800 (dihydroxylated metabolite) was found in all tissues (except fat), milk and eggs as a major metabolite at significant concentrations (up to 0.104 mg/kg in goat liver) and accounted for 6–44% of TRR in goats and 1.0–29% of TRR in hens. While CSCD656800 was the major metabolite in animals, it is difficult to obtain analytical standard material for this compound and CDCD656800 was not separately analysed in the animal feeding study due to the lack of validated specific analytical methods.

An LC-MS/MS method was validated for analysing parent compound and any metabolites (including CSCD656800) hydrolysable to the common moiety (CSAA798670) in animal commodities. However, the Meeting noted that CSAA798670 moiety is not specific to isopyrazam and may arise from the use of other pesticides containing this moiety, such as sedaxane.

The Meeting therefore concluded that the parent isopyrazam was suitable residue definition for enforcement.

For estimation of dietary intakes, the Meeting considered inclusion of CSCD656800 in the residue definition for animal commodities but it was not possible to include it as no specific analytical method was available. Its contribution to dietary exposure would be no more than 1% of the maximum ADI or ARfD even when uses were expanded.

In plant metabolism, parent isopyrazam was the predominant residue component (53–66% in wheat grain, 86–91% in grape berries and 35–45% in lettuce).

While CSCD459488 was the most significant metabolite in wheat foliage (< 10% of TRR), grapes (< 5% of TRR) and lettuce (14–17% of TRR), it was found at levels below 5% of TRR in wheat grain and grape berries. However, CSCD459488 was found in the supervised residue trials on bananas, barley and wheat, where, in some trials, CSCD459488 was found at levels approaching that of isopyrazam (e.g., 0.026 mg/kg of isopyrazam and 0.022 mg/kg of CSCD459488 in barley grain). CSCD459488 was considered to be of similar toxicity as the parent.

Sufficiently validated multi-residue LC-MS/MS or GC-MSD methods were available for determining the parent compound as the two separate isomers in plant commodities for enforcement.

A number of LC-MS/MS methods were successfully validated for analysing parent or CSCD459488 in plant commodities.

The Meeting therefore concluded that the parent isopyrazam was a suitable residue for enforcement.

For estimation of dietary intakes, the Meeting decided to include CSCD459488, the major metabolite, in the residue definition for plant commodities.

The syn-isomer of isopyrazam has log P_{ow} of 4.1 and the anti-isomer 4.4. In the goat metabolism studies, the isopyrazam concentrations in fat were ~ 5–9 times higher than those in muscle. In the cattle feeding study, the isopyrazam concentrations in cream were about eight times those in whole milk. In the hen metabolism study, isopyrazam was found only in egg yolk samples but not in egg white samples. The Meeting considered isopyrazam residues to be fat-soluble.

The Meeting recommended the following residue definition for plant and animal commodities:

Definition of the residue for plant commodities (for compliance with the MRL): *Isopyrazam (sum of syn-isomer and anti-isomer)*

Definition of the residue (for estimation of dietary intake) for plant commodities: *Sum of isopyrazam and 3-difluoromethyl-1-methyl-1H-pyrazole-4-carboxylic acid [9-(1-hydroxyl-1-*

methylethyl)-(1RS, 4RS, 9RS)-1,2,3,4-tetrahydro-1,4-methanonaphthalen-5-yl]amide expressed as isopyrazam

Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for animal commodities: *Isopyrazam (sum of syn-isomer and anti-isomer)*

The residue is considered fat-soluble.

Results of supervised trials on crops

The Meeting received supervised trial data for isopyrazam on bananas, barley, and wheat.

For all matrices, the LOQ was 0.005 mg/kg for each isomer of isopyrazam and CSCD459488. In the summing of the total residues, if syn- and anti-isomers and CSCD459488 were below the LOQ, the LOQ value of each was used for the calculation.

The OECD MRL calculator was used as a tool to assist in the estimation of maximum residue levels from the selected residue data set obtained from the supervised residue trials. As a first step, the Meeting reviewed trial conditions and other relevant factors related to each data set to arrive at a best estimate of the maximum residue level using expert judgement. Then, the OECD calculator was employed. If the statistical calculation spreadsheet suggested a different value, a brief explanation of the derivation was supplied.

Bananas

A total of 12 supervised trials were conducted on bananas in 2008 in Columbia, Costa Rica, Guatemala and Honduras. Isopyrazam was applied five times (or in one case, six) at a rate of 75 g ai/ha, with an interval between applications of 10 days. Applications were made to both bagged and unbagged bananas. Results from unbagged bananas in each trial were used to estimate a maximum residue level and STMR/HR as in all trials conducted, residue concentrations in bagged banana were never higher than those in unbagged bananas.

The GAP in Columbia allows five foliar applications at a rate of 75 g ai/ha with PHI of 0 days.

Residues of isopyrazam from trials matching he Columbian GAP in banana fruit were: < 0.01, < 0.01, < 0.01, 0.011, 0.012, 0.013, 0.015, 0.016, 0.017, 0.022, 0.034 and 0.04 mg/kg.

The Meeting estimated a maximum residue level of 0.06 mg/kg.

Corresponding total residues of isopyrazam and CSCD459488 in the pulp of unbagged banana were all < 0.015 mg/kg. After six applications instead of five applications, total residues in pulp were < 0.015 mg/kg regardless of whether banana fruit was bagged or unbagged.

The Meeting estimated an STMR and HR for banana pulp at 0.015 and 0.015 mg/kg respectively.

Barley

A total of 21 trials were conducted on barley: three in 2008 in New Zealand, two in 2006 in Switzerland, eight in 2006 and 2007 in France, three in 2006 and 2007 in Germany, one in 2007 in the United Kingdom, two in 2006 and 2007 in Italy, and two in 2006 and 2007 in Spain.

The registered use on barley in New Zealand allows two foliar applications per season prior to BBCH growth stage 59 (ear emergence) at a rate of 75 g ai/ha with a PHI of not shorter than 42 days.

In the three trials conducted in New Zealand, isopyrazam was applied twice at rates approximating 75, 125 and 250 g ai/ha with PHI of 41 or 42 days.

Residues of isopyrazam from trials matching GAP in New Zealand were: < 0.01, < 0.01 and 0.018 mg/kg.

The registered use of isopyrazam on barley in the United Kingdom (UK) allows two foliar applications per season between growth stages 30 and 61 (before beginning of flowering), each at a rate of 125 g ai/ha isopyrazam.

Residues of isopyrazam from the trials conducted in Northern France, Germany, Switzerland and the United Kingdom matching GAP of the UK were (n = 8): 0.014, 0.016, 0.017, 0.020, 0.024, 0.026, 0.026 and 0.035 mg/kg.

The Meeting estimated a maximum residue level of 0.07 mg/kg for barley. The Meeting also estimated a median residue of 0.022 mg/kg for the purpose of calculating animal dietary burdens.

Corresponding total residues of isopyrazam and CSCD459488 were: 0.020, 0.022, 0.029, 0.032, 0.043, 0.046, 0.048 and 0.058 mg/kg.

The Meeting estimated an STMR at 0.0375 mg/kg.

Wheat

A total of 25 trials were conducted on wheat: three in 2008 in New Zealand, ten in 2006 and 2007 in France, five in 2006 and 2007 in Germany, one in 2007 in the United Kingdom, two in 2006 and 2007 in Italy, and four in 2006 and 2007 in Spain.

The registered use of isopyrazam on wheat in New Zealand allows two foliar applications per season prior to BBCH growth stage 69 (end of flowering) at rates of 75–125 g ai/ha and a PHI of not shorter than 42 days.

In the three trials conducted in New Zealand, isopyrazam was applied twice at rates approximating 75, 125 and 250 g ai/ha with PHI of 42 days.

Residues of isopyrazam from trials matching GAP in New Zealand were: < 0.01, < 0.01 and 0.020 mg/kg.

The registered use of isopyrazam on wheat, rye and triticale in the United Kingdom allows two foliar applications per season between growth stages 30 and 71 (before grain watery ripe stage), each at a rate of 125 g ai/ha isopyrazam.

In most of the trials, isopyrazam was applied three times instead of twice. Therefore, the trials were not in compliance with the GAP of the UK. The isopyrazam concentrations in whole plants immediately before the third application were on average about 15% of those on the day of the third application. The Meeting decided to use data from these trials for estimating a maximum residue level in wheat if the contribution of isopyrazam from the second application was below 25% of residues after the third application.

Residues of isopyrazam from these trials conducted in Northern France, Germany and the United Kingdom were (n = 11): < 0.01 (7), 0.012, 0.012, 0.014 and 0.017 mg/kg.

The Meeting estimated a maximum residue level of 0.03 mg/kg for wheat.

The Meeting estimated a median residue level of 0.01 mg/kg for the purpose of calculating animal dietary burdens.

Corresponding total residues of isopyrazam and CSCD459488 were: < 0.015 (7), 0.018, 0.019, 0.019 and 0.026 mg/kg.

The Meeting estimated an STMR at 0.015 mg/kg.

As GAP in the UK covers not only wheat but also rye and triticale, the Meeting decided to extrapolate the maximum residue level, median residue and highest residue for wheat to rye and triticale.

Barley straw and fodder, dry, and forage

The registered use on barley in New Zealand allows two foliar applications per season prior to BBCH growth stage 59 (ear emergence) at a rate of 75 g ai/ha. The PHI is 28 days for forage and 42 days for straw.

Residues of isopyrazam in straw from trials matching GAP in New Zealand were: < 0.01, 0.925 and 1.37 mg/kg.

Residues of isopyrazam in forage from trials matching GAP in New Zealand were: 0.13, 0.304 and 0.655 mg/kg.

Residues of isopyrazam in straw from appropriate trials conducted in Northern Europe matching UK GAP were (n = 8): 0.076, 0.129, 0.349, 0.362, 0.495, 0.679, 0.838 and 1.06 mg/kg.

The Meeting estimated a highest and median residue at 1.06 and 0.356 mg/kg, respectively, for the purpose of calculating animal dietary burdens.

Although a maximum residue level for barley straw and fodder would be 2 mg/kg, as barley and wheat straw are not distinguishable in trade, the Meeting recommended to use a maximum residue level for wheat straw and fodder at 3 mg/kg to cover barley straw and fodder, dry (see next section).

As for forage, since there is no description about PHI for forage, the Meeting selected the highest residue concentration from each trial conducted in Northern Europe in compliance with UK GAP. These residue concentrations were (n = 7): 2.14, 2.26, 2.30, 2.45, 2.93, 3.26 and 3.63 mg/kg.

The Meeting estimated a highest residue and median residue at 3.63 mg/kg and 2.45 mg/kg (as received) respectively for the purpose of calculating animal dietary burdens.

Wheat straw and fodder, dry, and forage

The registered use on barley in New Zealand allows two foliar applications per season prior to BBCH growth stage 69 (end of flowering) at rates of 75–125 g ai/ha. PHI is 28 days for forage and 42 days for straw.

Residues of isopyrazam in straw from trials matching GAP in New Zealand were: 0.284, 0.993 and 1.79 mg/kg.

Residues of isopyrazam in forage from trials matching GAP in New Zealand were: 0.9, 0.397 and 0.835 mg/kg.

Residues of isopyrazam in straw from trials conducted in Northern Europe approximating UK GAP were (n = 11): 0.113, 0.260, 0.288, 0.921, 0.947, 0.952, 0.977, 1.06, 1.11, 1.41 and 1.51 mg/kg.

The Meeting estimated a maximum residue level of 3 mg/kg. The Meeting estimated a highest and median residue at 1.51 and 0.952 mg/kg for the purpose of calculating animal dietary burdens.

As for forage, since there is no description about PHI for forage, the Meeting selected the highest residue concentration from each trial conducted in compliance with GAP. These residue concentrations were (n = 9): 1.17, 1.33, 1.53, 1.88, 2.10, 2.22, 2.25, 2.46 and 2.95 mg/kg.

The Meeting estimated a highest residue and median residue at 2.95 mg/kg and 2.10 mg/kg (as received) respectively for the purpose of calculating animal dietary burdens.

As GAP in the UK covers not only wheat but also rye and triticale, the Meeting decided to extrapolate the maximum residue level for wheat straw and fodder, dry to rye straw and fodder, dry. The median and highest residues for wheat straw and fodder, dry, and for forage were extrapolated to straw and fodder, and forage of rye and triticale.

Fate of residues during processing

High temperature hydrolysis

A high-temperature aqueous hydrolysis study was conducted to determine the nature of degradates of isopyrazam in processed commodities or by-products under conditions typical of common processing practices.

After heating at 90, 100 or 120 °C in acetate buffers of pH 4 and 6 for 20 minutes or in a buffer of pH 5 for 60 minutes, about 95% of recovered radioactivity (> 95% of the initial radioactivity) was isopyrazam. This indicated that isopyrazam was stable against hydrolysis under the above mentioned conditions.

Processing

The Meeting received information on processing of barley to beer and pot barley, and wheat to flour, bread, germ and related by-products.

Processing factors were calculated for the processed commodities of barley and wheat and are shown in the table below. STMR-Ps were calculated for processed commodities of barley and wheat for which maximum residue levels were estimated.

Processed Orange Product	Median Processing factor		STMR-P
	Isopyrazam	Isopyrazam and CSCD459488	
Barley			(0.0375)
Malt	0.55	0.59	0.022
Beer	< 0.13	< 0.12	0.0045
Pot barley	0.37	0.33	0.012
Wheat			(0.015)
Bran (unprocessed)	4.07	4.39	0.066
White flour	0.20	0.23	0.0035
Wholemeal flour	0.73	0.81	0.012
Wholemeal bread	0.50	0.55	0.0083
Wheat germ	0.19	0.25	0.0038

As the residue concentration is higher in bran than in wheat grain, the Meeting estimated a maximum residue level of 0.15 mg/kg by multiplying the maximum residue level for wheat (0.03 mg/kg) by 4.07. A median residue was calculated to be 0.041 mg/kg for the purpose of estimating animal dietary burdens.

Residues in animal commodities

Farm animal dietary burden

Grain, straw and forage of barley, wheat, rye and triticale, and wheat bran may be fed to dairy cattle, beef cattle, broilers and layers. The maximum and mean dietary burdens were calculated using the highest residues or median residues of isopyrazam estimated at the current Meeting on a basis of the OECD Animal Feeding Table.

Summary of livestock dietary burdens (ppm of dry matter diet)

	US-Canada		EU		Australia		Japan	
	max	mean	max	Mean	max	mean	Max	mean
Beef cattle	0.20	0.14	3.65	2.52	12.0[a]	8.40[b]	0.04	0.04
Dairy cattle	2.39	1.71	3.65	2.52	12.0[c]	7.84[d]	0.12	0.09

	US-Canada		EU		Australia		Japan	
	max	mean	max	Mean	max	mean	Max	mean
Broilers	0.04	0.04	0.03	0.03	0.02	0.02	0.00	0.00
Layers	0.04	0.04	1.21[e]	0.87[f]	0.02	0.02	0.01	0.01

[a] Suitable for estimating maximum residue levels for meat, fat and edible offal of cattle.

[b] Suitable for estimating STMRs for meat, fat and edible offal of cattle.

[c] Suitable for estimating maximum residue levels for milk.

[d] Suitable for estimating STMRs for milk.

[e] Suitable for estimating maximum residue levels for meat, fat and edible offal of poultry and eggs.

[f] Suitable for estimating STMRs for meat, fat and edible offal of poultry and eggs.

Residues in milk and cattle tissues

Lactating dairy cows were dosed daily for 28 consecutive days via gelatin capsules containing isopyrazam (15–137 ppm in diet corresponding to 1×, 3× and 10×). The syn/anti ratio was approximately 70:30.

In whole milk samples from the 1× and 3× groups, isopyrazam residues were not found above LOQ. However, isopyrazam was found at a slightly higher level than LOQ in milk samples from the 10× group. Isopyrazam was found in cream samples at < 0.01–0.010, 0.018–0.040 and 0.048–0.141 mg/kg from 1×, 3× and 10× group respectively.

The isopyrazam residues in liver were < 0.01–0.010, 0.019–0.036 and 0.092–0.174 mg/kg from the 1×, 3× and 10× groups, respectively, and the isopyrazam residues in kidney were < 0.01,0.01–0.012 and 0.018–0.042 mg/kg from the 1×, 3× and 10× groups, respectively.

The highest mean residues of isopyrazam in muscle occurred in diaphragm muscle, where residues were < 0.01, 0.010 and 0.024 mg/kg from the 1×, 3× and 10× groups, respectively.

The highest mean residues of isopyrazam in fat were detected in renal fat, where residues were < 0.01, 0.034 and 0.120 mg/kg from the 1×, 3× and 10× groups, respectively.

Residues of CSAA798670, resulting from the hydrolysis of isopyrazam and structurally-related metabolites were also analysed.

CSAA798670 was present in all milk and tissue samples from treated cows and were generally dose dependent. No residues of this common moiety above the limit of quantification of the method (0.005 mg/kg) were seen in any samples of milk or tissues from the control animal.

Residues of CSAA798670 in whole milk, expressed as isopyrazam equivalents, reached a maximum after 3 days of dosing in all three dose groups with mean CSAA798670 residues of 0.039, 0.120 and 0.340 mg/kg from the 1×, 3× and 10× groups, respectively. The mean residues decreased by day 5 to 0.026, 0.067 and 0.184 mg/kg from the 1×, 3× and 10× groups, respectively, and remained approximately at that level during the remainder of the dosing period.

Residue levels in cream were higher than in skimmed milk. The mean residues of CSAA798670 in skimmed milk, expressed as isopyrazam equivalents, were 0.022, 0.069 and 0.189 mg/kg, from the 1×, 3× and 10× groups, respectively. The mean residues in cream were 0.024, 0.081 and 0.262 mg/kg from the 1×, 3× and 10× groups, respectively.

The mean CSAA798670 residues in liver, expressed as isopyrazam equivalents, were 0.219, 0.597 and 1.907 mg/kg from the 1×, 3× and 10× groups, respectively, and the mean residues in kidney were 0.060, 0.162 and 0.658 mg/kg from the 1×, 3× and 10× groups, respectively.

The highest mean residues of CSAA798670 in muscle expressed as isopyrazam equivalents were detected in diaphragm muscle, where residues were 0.022, 0.052 and 0.174 mg/kg from the 1×, 3× and 10× groups, respectively.

The highest mean residues of CSAA798670 in fat expressed as isopyrazam equivalents were detected in renal fat, where residues were 0.028, 0.089 and 0.346 mg/kg from the 1×, 3× and 10× groups, respectively.

Using the dietary burdens for beef and dairy cattle and the results in the lactating cattle feeding study, the maximum residue levels and STMRs were estimated. The calculated residues in cattle tissues and milk are summarized below.

	Feed level (ppm) for milk residues	Residues in milk (mg/kg)	Residues in cream (mg/kg)	Feed level (ppm) for tissue residues	Residues (mg/kg) in			
					Muscle	Liver	Kidney	Fat
Maximum residue level, beef or dairy cattle								
Feeding study [a]	15	< 0.01	0.01	15	< 0.01	0.01	< 0.01	< 0.01
Dietary burden and residue estimate	12	< 0.008	< 0.008	12	< 0.008	0.008	< 0.008	< 0.008
STMR beef or dairy cattle								
Feeding study [b]	15	< 0.01	< 0.01	15	< 0.01	< 0.01	< 0.01	< 0.01
Dietary burden and residue estimate	7.8	0.0042	0.0042	8.4	0.0056	0.0056	0.0056	0.0056

[a] Highest residues for tissues and mean residue for milk

[b] Mean residues for tissues and milk

The Meeting estimated a maximum residue level for isopyrazam in milks, mammalian meat and mammalian fats (except milk fats) at 0.01* mg/kg, and for milk fats at 0.02 mg/kg. The Meeting also estimated a maximum residue level of 0.02 mg/kg for edible offal (mammalian) on a basis of residues in liver.

STMRs were estimated to be 0.0056 mg/kg for mammalian meat, liver, kidney and mammalian fats (except milk fats) and 0.0042 mg/kg for milks and milk fats. HRs were estimated to be 0.008 mg/kg for mammalian meat, liver, kidney and mammalian fat (except milk fats).

Residues in eggs and poultry tissues

No feeding study on laying hens was conducted as the expected dietary burden for hens was low.

In the hen metabolism study conducted at an actual dose of 11 ppm dry matter in the feed, the highest residue (as total radioactive residue, TRR) found was 0.164 mg/kg in parent equivalent in liver.

In the extracts of egg white, egg yolk, liver, skin and attached fat, and peritoneal fat, the highest concentration of isopyrazam observed was 0.004 mg/kg. Muscle was not subject to characterization or identification of radioactive residues as the TRR in muscle was 0.004–0.006 mg/kg in isopyrazam equivalents.

As the calculated maximum and mean dietary burden for estimating a maximum residue level and STMR/HRs for poultry were 1.21 and 0.87 ppm, significantly lower than 11 ppm, the Meeting estimated a maximum residue level of 0.01* mg/kg for isopyrazam in eggs, poultry meat, edible offal of poultry and fat.

STMRs were estimated to be at LOQ of 0.01 mg/kg for eggs, poultry meat, liver and fat. HRs were also estimated to be 0.01 mg/kg (same level as the maximum residue levels) for these commodities.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Dietary Intakes (IEDIs) of isopyrazam were calculated for the 13 GEMS/Food cluster diets using STMRs and STMR-Ps estimated by the current Meeting (Annex 3). The ADI is 0–0.06 mg/kg bw and the calculated IEDIs were 0% of the maximum ADI. The Meeting concluded that the long-term intake of residues of isopyrazam resulting from the uses considered by the current JMPR is unlikely to present a public health concern.

Short-term intake

The International Estimated Short-Term Intakes (IESTI) of isopyrazam were calculated for food commodities and their processed commodities using HRs/HR-Ps or STMRs/STMR-Ps estimated by the current Meeting (Annex 4). The ARfD is 0.3 mg/kg bw and the calculated IESTIs were 0% of the ARfD. The Meeting concluded that the short-term intake of residues of isopyrazam, when used in ways that have been considered by the JMPR, is unlikely to present a public health concern.

5.17 PENTHIOPYRAD (253)

TOXICOLOGY

Penthiopyrad is the International Organization for Standardization (ISO)–approved name for *N*-[2-(1,3-dimethylbutyl)-3-thienyl]-1-methyl-3-(trifluoromethyl)-1H-pyrazole-4-carboxamide (9CI) (Chemical Abstracts Service No. 183675-82-3). It is a new fungicide that belongs to the carboxamide class. Its proposed fungicidal mode of action is inhibition of succinate dehydrogenase, resulting in the inhibition of the citric acid cycle and mitochondrial electron transport pathways. Penthiopyrad has not been evaluated previously by the Joint FAO/WHO Meeting on Pesticide Residues and was reviewed at the present Meeting at the request of the Codex Committee on Pesticide Residues.

All the pivotal studies contained certificates of compliance with good laboratory practice.

Biochemical aspects

The absorption, distribution, metabolism and excretion of penthiopyrad were investigated in rats. ^{14}C-labelled penthiopyrad was rapidly and extensively absorbed from the gastrointestinal tract of rats following oral dosing. The extent of absorption was approximately 80–90% of the administered dose, independent of dose and sex. Maximum concentrations of radioactivity in plasma were observed within 0.5 hour of dosing for the low-dose group (10 mg/kg body weight [bw]) and within 1.3 hours for the high-dose group (100 mg/kg bw). Maximum tissue levels occurred within 1 hour post-dosing, with the highest concentrations of radioactivity found in liver, fat, lymph nodes and kidneys of rats. Very little penthiopyrad was retained in the tissues. There were no major sex-related differences in the pattern of excretion. Faecal excretion was the primary route of elimination, and excretion was rapid, with the majority excreted by all routes 24 hours after dosing (74.8–85.0%).

Extensive metabolism occurred at numerous positions within the molecule, including thienyl ring oxidation and conjugation with glutathione, thienyl ring opening, *N*-demethylation and alkyl side-chain hydroxylation, followed by oxidation to carboxylic acids and glucuronidation. The most abundant metabolite in both urine and faeces was formed as the result of *N*-demethylation and oxidation of the methyl moiety of the alkyl side-chain. The most abundant metabolites found in bile were formed as a result of thienyl ring oxidation to 753-F-DO, followed by its conjugation with glutathione and the catabolism of this product. Other significant metabolites in bile were glucuronic acid conjugates of the intermediate demethylated and hydroxylated metabolites. Four metabolites containing the pyrazole moiety following cleavage from the thienyl moiety were excreted in both urine and faeces. The two acids, 1-methyl-3-trifluoromethyl-1H-pyrazole-4-carboxylic acid (PCA) and 3-trifluoromethyl-1H-pyrazole-4-carboxylic acid (DM-PCA), are likely formed by amide hydrolysis from 1-methyl-3-trifluoromethyl-1H-pyrazole-4-carboxamide (PAM) and DM-PAM. PAM and subsequent metabolites account for less than 1% of the administered dose. The thienyl ring appears to be completely degraded.

Toxicological data

The median lethal dose (LD_{50}) in rats treated orally and dermally with penthiopyrad was greater than 2000 mg/kg bw. The median lethal concentration (LC_{50}) in rats treated by inhalation was greater than 5.7 mg/L of air. Penthiopyrad was not irritating to the skin of rabbits, was minimally irritating to the eyes of rabbits and was not sensitizing under the conditions of the maximization test in guinea-pigs.

Following repeated dietary dosing, the liver was the main target organ in mice, rats and dogs. In several studies, increased liver weight, liver enlargement and centrilobular hepatocellular hypertrophy were observed, as well as indications of hepatotoxicity in the form of alterations in clinical chemistry (elevated serum levels of liver enzymes, cholesterol, triglycerides and protein). The pattern of liver effects changed with dose, but not with duration of dosing. Haematological changes

(decreases in red blood cells, haemoglobin and haematocrit) were observed in mice, rats and dogs at doses higher than those causing liver toxicity. The thyroid was also a target organ in mice, rats and dogs, with effects observed only at the highest doses tested. In mice, thyroid follicular cell hypertrophy was observed in both sexes at 997/1027 mg/kg bw per day in males and females, respectively, whereas in dogs, increased thyroid weights were observed in females of the 90-day study at 864 mg/kg bw per day. In longer-term studies in rats, thyroid follicular cell hypertrophy was observed in the 1-year and multigeneration reproduction studies at the highest doses tested. Adrenal cortical hypertrophy was found in both the 90-day and 1-year dog studies at the highest doses tested. Adrenal effects were not observed in mice and were found in rats only with longer-term dosing (i.e. the reproductive toxicity study and long-term study beginning at 6 months).

The no-observed-adverse-effect level (NOAEL) in the 90-day rat study was 40 mg/kg bw per day, based on liver effects (increased serum levels of phospholipids and gamma-glutamyltranspeptidase, absolute and relative liver weights and incidences of centrilobular hepatocellular hypertrophy, Kupffer cell proliferation and hepatocellular degeneration). The NOAEL in the 90-day mouse study was 100 mg/kg bw per day, and the overall NOAEL in the dog studies was 76.7 mg/kg bw per day, in both cases based on liver effects.

In the 18-month carcinogenicity study in mice, the NOAEL was 60 mg/kg bw per day, based on effects in the liver and thyroid at the lowest-observed-adverse-effect level (LOAEL) of 200 mg/kg bw per day. There was a marginal increase in hepatocellular adenomas and carcinomas at the highest dose tested in comparison with concurrent controls; however, the incidences were similar to historical control values, and no other histopathology of the liver was observed. The concurrent control value for adenomas was lower than the historical control range. The Meeting concluded that penthiopyrad was not carcinogenic in mice.

In the 2-year rat study, the NOAEL was 27 mg/kg bw per day, based on reduced body weight gain in females and hepatic periportal fatty degeneration in males at 83 mg/kg bw per day. Effects on the kidneys (various elements of chronic progressive nephropathy, including interstitial fibrosis and renal glomerulosclerosis) were observed in male rats of all groups, including controls. The incidence, but not the severity, of this rat-specific condition was increased to similar extents in all treatment groups. The incidence of thyroid follicular cell adenomas in males was increased at the highest dose tested compared with controls (3/50, 1/50, 6/48, 2/49 and 9/49, respectively); this incidence also slightly exceeded the historical control range. There was no increase in follicular cell carcinomas. No other histopathology of the thyroid was observed in this study; however, follicular cell hypertrophy was observed at higher doses in the 1-year and multigeneration reproduction studies in rats. The Meeting concluded that high doses of penthiopyrad caused follicular cell adenomas in the thyroid.

Hepatocellular adenomas and carcinomas and follicular cell adenomas of the thyroid are common in male mice and rats, respectively. Special studies were conducted to examine liver and thyroid effects in the mouse and rat. These studies showed that penthiopyrad increased microsomal protein and cytochrome P450 activity in the liver of both mice and rats. Changes in thyroid hormones and uridine diphosphate glucuronosyltransferase activity were not concordant with the dose response for the tumours.

Penthiopyrad was adequately tested for genotoxicity in vitro and in vivo in a range of assays. Negative results were observed in all genotoxicity studies.

The Meeting concluded that penthiopyrad was unlikely to be genotoxic.

The Meeting concluded that penthiopyrad is unlikely to pose a carcinogenic risk to humans at anticipated dietary residue levels, as it was not carcinogenic in the mouse and as thyroid follicular cell adenomas in male rats are common, their incidence is only slightly increased and, in the absence of genotoxic potential, the end-point would be anticipated to exhibit a threshold.

No effects on reproduction were noted in a multigeneration reproduction study in the rat. However, there was a decrease in body weight of the offspring during early lactation in both

generations at 278 mg/kg bw per day, the highest dose tested. Also at this dose, there was a slight, but statistically significant, delay in time to preputial separation. Furthermore, at this dose, there were decreases in thymus and spleen weights, with no histopathological correlates. Effects were observed in parental animals at the intermediate and high doses and included decreased body weight and body weight gain and increased adrenal weight with adrenal cortical hypertrophy. At the high dose only, effects on the thyroid were also observed, comprising increased thyroid weight and follicular cell hypertrophy. The NOAEL for parental toxicity was 200 ppm (equal to 11 mg/kg bw per day), based on decreased body weight gain and effects on the adrenals, whereas the NOAEL for offspring toxicity was 1000 ppm (equal to 54 mg/kg bw per day), based on reduced body weight and body weight gain, delay in preputial separation and a statistically significant decrease in absolute thymus weights at 5000 ppm (equal to 278 mg/kg bw per day). The NOAEL for reproductive toxicity was 5000 ppm (equal to 278 mg/kg bw per day), the highest dose tested.

In a developmental toxicity study in rats, increased early resorptions and post-implantation loss and decreased live young per litter and litter weight were observed when pregnant rats were dosed at 1000 mg/kg bw per day. Reductions in body weight and feed consumption were observed in maternal animals at this dose. The NOAEL for maternal and developmental toxicity in rats was 250 mg/kg bw per day. In rabbits, there was one abortion at the high dose (225 mg/kg bw per day), which occurred in the presence of a marked reduction in feed consumption and body weight in that dam. Litter and fetal weights were also reduced at the high dose, resulting in decreased gravid uterine weight. The NOAEL for maternal and developmental toxicity in rabbits was 75 mg/kg bw per day.

The Meeting concluded that penthiopyrad was not teratogenic in rats or rabbits.

In an acute neurotoxicity study, the NOAEL was 125 mg/kg bw based on clinical signs of neurotoxicity at doses of 500 mg/kg bw (decreased motor activity and body temperature, unsteady gait, hunched posture); however, there was no histological evidence of damage to the central or peripheral nervous system. There was no evidence of neurotoxicity in the 90-day neurotoxicity study. A developmental neurotoxicity study revealed no maternal effects at 500 mg/kg bw per day, the highest dose tested. In contrast, the NOAEL for offspring toxicity was 100 mg/kg bw per day, based on decreased body weight at doses of 250 mg/kg bw per day and higher.

In a 4-week immunotoxicity study in mice, the NOAEL for immunotoxicity was 250 mg/kg bw per day, based on decreased plaque-forming cells in the spleen at 1000 mg/kg bw per day. In a 4-week immunotoxicity study in rats, no adverse effects were observed at any dose up to 700 mg/kg bw per day, the highest dose tested.

Toxicological data on metabolites

A variety of metabolites were also assessed for toxicity. These are minor metabolites in rats that are also found in livestock, plants and soil. The oral LD_{50} in rats for the metabolite DM-PCA was greater than 2000 mg/kg bw. In a 90-day feeding study in rats, the NOAEL for DM-PCA was 4000 ppm (equal to 258 mg/kg bw per day), based on reduced body weight gain and feed consumption at 16 000 ppm (equal to 1200 mg/kg bw per day), the highest dose tested. DM-PCA was not genotoxic in any of an adequate range of in vitro genotoxicity assays.

The oral LD_{50} in rats for the metabolite PCA was greater than 2000 mg/kg bw. In a 14-day oral gavage study of PCA in rats, the NOAEL was 1000 mg/kg bw per day, the highest dose tested. PCA was not genotoxic in any of an adequate range of in vitro and in vivo genotoxicity assays. The metabolite PAM was more acutely toxic than the parent and PCA, with an LD_{50} estimated between 300 and 2000 mg/kg bw by the oral route in rats. PAM was negative in the Ames assay but was positive without activation in a mouse lymphoma assay, in which small colony mutant frequencies were increased. It induced chromosomal aberrations in mammalian cells in the absence of activation in vitro, but this clastogenicity was not confirmed in an in vivo micronucleus assay. Overall, the weight of evidence suggests that PAM has low potential for genotoxicity in vivo.

The oral LD_{50} in rats for the metabolite *N*-[5-hydroxy-5-(1,3-dimethylbutyl)-2-oxo-2,5-dihydrothiophen-4-yl]-1-methyl-3-trifluoromethyl-1*H*-pyrazole-4-carboxamide (753-T-DO) was > 2000 mg/kg bw. The acute oral toxicity of the metabolite *N*-[2-(3-hydroxy-1,3-dimethyl-butyl)thiophen-3-yl]-1-methyl-3-trifluoromethyl-1H-pyrazole-4-carboxamide (753-A-OH) has not been assessed. Neither 753-T-DO nor 753-A-OH was genotoxic in three in vitro assays to assess gene mutations and chromosomal aberrations.

The metabolites were not considered to be more toxic than penthiopyrad, with the exception of PAM, which was more acutely toxic than penthiopyrad and was genotoxic in vitro, but not in vivo.

There were no reports of adverse health effects in manufacturing plant personnel or in operators and workers exposed to penthiopyrad formulations during their use. Also, there was no evidence to support any findings in relation to poisoning with penthiopyrad.

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

Toxicological evaluation

The Meeting established an acceptable daily intake (ADI) of 0–0.1 mg/kg bw on the basis of a NOAEL of 11 mg/kg bw per day in the multigeneration reproduction study in rats for decreased body weight gain in F_1 males and adrenal effects in F_1 females (increased weight and cortical hypertrophy). A safety factor of 100 was applied.

The Meeting established an acute reference dose (ARfD) of 1 mg/kg bw on the basis of a NOAEL of 125 mg/kg bw in the acute neurotoxicity study in rats for clinical signs of neurotoxicity (e.g., decreased motor activity and body temperature, hunched posture, unsteady gait). A safety factor of 100 was applied.

A toxicological monograph was prepared.

Levels relevant to risk assessment

Species	Study	Effect	NOAEL	LOAEL
Mouse	Eighteen-month study of toxicity and carcinogenicity[a]	Toxicity	60 mg/kg bw per day	200 mg/kg bw per day
		Carcinogenicity	600 mg/kg bw per day[b]	—
Rat	Two-year study of toxicity and carcinogenicity[a]	Toxicity	27 mg/kg bw per day	83 mg/kg bw per day
		Carcinogenicity	83 mg/kg bw per day	250 mg/kg bw per day
	Two-generation study of reproductive toxicity[a]	Parental toxicity	11 mg/kg bw per day	54 mg/kg bw per day
		Offspring toxicity	54 mg/kg bw per day	278 mg/kg bw per day
		Reproductive toxicity	278 mg/kg bw per day[b]	—
	Developmental toxicity study[c]	Maternal toxicity	250 mg/kg bw per day	1000 mg/kg bw per day
		Embryo and fetal toxicity	250 mg/kg bw per day	1000 mg/kg bw per day
	Acute neurotoxicity study[c]	Neurotoxicity	125 mg/kg bw	500 mg/kg bw
Rabbit	Developmental toxicity study[c]	Maternal toxicity	75 mg/kg bw per day	225 mg/kg bw per day
		Embryo and fetal	75 mg/kg bw per day	225 mg/kg bw per day

Species	Study	Effect	NOAEL	LOAEL
		toxicity		
Dog	Thirteen-week and 1-year studies of toxicity[a,d]	Toxicity	3000 ppm, equal to 76.7 mg/kg bw per day	15 000 ppm, equal to 445 mg/kg bw per day

[a] Dietary administration.

[b] Highest dose tested.

[c] Gavage administration.

[d] Two studies combined.

Estimate of acceptable daily intake for humans

0–0.1 mg/kg bw

Estimate of acute reference dose

1 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 penthiopyrad

Absorption, distribution, excretion and metabolism in mammals	
Rate and extent of oral absorption	Rapid; ~90%
Distribution	Widely distributed; highest concentrations in liver
Rate and extent of excretion	Largely complete within 24 h; primarily via faeces (70–85%, bile 30–54%) and to a lesser extent urine (8–17%)
Potential for accumulation	No evidence of accumulation
Metabolism in mammals	Extensive
Toxicologically significant compounds (animals, plants and the environment)	Parent compound, PAM
Acute toxicity	
Rat LD_{50}, oral	> 2000 mg/kg bw
Rat, LD_{50}, dermal	> 2000 mg/kg bw
Rat, LC_{50}, inhalation (whole-body exposure)	> 5.7 mg/L
Rabbit, dermal irritation	Not irritating
Rabbit, ocular irritation	Minimally irritating
Guinea-pig, dermal sensitization (Magnusson and Kligman)	Not sensitizing
Short-term studies of toxicity	
Target/critical effect	Liver (clinical chemistry changes), thyroid (increased weights, hypertrophy), adrenal (increased weights, hypertrophy)

Lowest relevant oral NOAEL	40 mg/kg bw per day (90-day study in rats)
Lowest relevant dermal NOAEL	1000 mg/kg bw per day (28-day study in rats)
Lowest relevant inhalation NOAEL	No data
Genotoxicity	
	No evidence for genotoxic potential
Long-term studies of toxicity and carcinogenicity	
Target/critical effect	Body weight, liver (periportal fatty degeneration)
Lowest relevant oral NOAEL	27 mg/kg bw per day (2-year study in rats)
Carcinogenicity	Unlikely to pose a carcinogenic risk to humans at anticipated dietary exposure levels
Reproductive toxicity	
Reproduction target/critical effect	No effect on fertility at highest dose tested; decrease in body weight in pups and slight delay in sexual maturation at parentally toxic dose
Lowest relevant reproductive NOAEL	278 mg/kg bw per day (highest dose tested) for reproductive effects (rats)
	11 mg/kg bw per day for systemic toxicity in parent (rats)
	54 mg/kg bw per day for offspring toxicity (decreased body weight) (rats)
Developmental target/critical effect	Decreased fetal weight at maternally toxic dose
Lowest relevant developmental NOAEL	75 mg/kg bw per day (rabbits)
Neurotoxicity/delayed neurotoxicity	
Neurotoxicity target/critical effect	Decreased motor activity, hunched posture, unsteady gait
Lowest relevant neurotoxicity NOAEL	125 mg/kg bw (acute neurotoxicity study, rats)
Immunotoxicity	
	Not immunotoxic (mice and rats)
Medical data	
	No data

Summary

	Value	**Study**	**Safety factor**
ADI	0–0.1 mg/kg bw	Rat, two-generation reproduction study	100
ARfD	1 mg/kg bw	Rat, acute neurotoxicity study	100

5.18 PROFENOFOS (171)

RESIDUE AND ANALYTICAL ASPECTS

Profenofos, an organophosphorus insecticide, was first evaluated in 1990 as a new compound. It was re-evaluated in the 2007 JMPR for toxicology and in the 2008 JMPR for residue. The 2007 JMPR evaluated profenofos for toxicology under the Periodic Review Programme and recommended the current ADI of 0–0.03 mg/kg bw and ARfD of 1 mg/kg bw. The 2008 JMPR evaluated profenofos for residue under the Periodic Review Programme and concluded that the definition of residue for compliance with MRLs and for estimation of dietary intake was profenofos. It recommended the withdrawal of previously recommended maximum residue levels for peppers, chili and peppers, chili (dried) due to insufficient data provided to the Meeting. The current Meeting received information on GAP from Thailand and residue trial data on chili peppers from Singapore and Thailand.

Results of supervised trials on crops

Chili peppers

Profenofos is registered for use on chili peppers in Thailand at a foliar application of 0.10 kg ai/hL with a PHI of 21 days. Residues in chili peppers from Singapore's trials matching GAP of Thailand were 0.56 and 0.70 mg/kg. Residues in chili peppers from Thai trials, matching the GAP of Thailand, were: (n = 6): 0.44, 0.56, 0.86, 1.12, 1.17 and 1.42 mg/kg. The residues evaluated according to the Thai GAP in ranked order, were: 0.44, 0.56, 0.56, 0.70, 0.86, 1.12, 1.17 and 1.42 mg/kg.

Based on the trials for chili peppers in Singapore and Thailand, the Meeting estimated a maximum residue level, an STMR value and an HR value for profenofos in chili peppers of 3, 0.78 and 1.42 mg/kg respectively.

The OECD calculator estimated a maximum residue level of 3 mg/kg, which coincides with the recommendation of the current Meeting.

On the basis of the STMR and HR for chili peppers and the default dehydration factor of 7, the Meeting estimated an STMR value and an HR value for dried chili peppers of 5.46 and 9.94 mg/kg respectively. Based on the maximum residue level of chili peppers, the Meeting recommended a maximum residue level of 20 mg/kg for chili peppers (dry).

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Dietary Intakes (IEDIs) of profenofos were calculated for the 13 GEMS/Food cluster diets using STMRs/STMR-Ps estimated by the current Meeting (Annex 3). The ADI is 0–0.03 mg/kg bw and the calculated IEDIs were 2–10% of the maximum ADI (0.3 mg/kg bw). The Meeting concluded that the long-term intake of residues of profenofos resulting from the uses considered by current JMPR is unlikely to present a public health concern.

Short-term intake

The International Estimated Short-Term Intakes (IESTI) of profenofos were calculated for food commodities and their processed commodities using HRs/HR-Ps or STMRs/STMR-Ps estimated by the current Meeting (Annex 4). The ARfD is 1 mg/kg and the calculated IESTI was 0% of the ARfD.

The Meeting concluded that the short-term intake of residues of profenofos, when used in ways that have been considered by the JMPR, is unlikely to present a public health concern.

5.19 PROPYLENE OXIDE (250)

TOXICOLOGY

Propylene oxide is the International Organization for Standardization (ISO)–approved name for methyloxirane (International Union of Pure and Applied Chemistry) (Chemical Abstracts Service No. 75-56-9). Propylene oxide is a highly reactive, volatile compound (boiling point 34 ºC) that is used, as a gas or pressurized liquid, for fumigation and sterilization to control insect infestations and microbial spoilage in a range of food commodities (e.g., herbs, spices and nuts). The primary residues detected after propylene oxide use are propylene oxide, propylene chlorohydrin (chloropropanol), propylene bromohydrin (bromopropanol) and propylene glycol.

Propylene oxide was reviewed for the first time by the Joint FAO/WHO Meeting on Pesticide Residues at the request of the Codex Committee on Pesticide Residues.

The database for propylene oxide and propylene chlorohydrin consists mainly of published papers, often with limited levels of detail and no statements of compliance with good laboratory practice.

Biochemical aspects

There are no reliable in vivo data on the kinetics or biotransformation of propylene oxide. By analogy with ethylene oxide, it is likely that propylene oxide is rapidly and extensively absorbed via the inhalation route. Oral exposure to propylene oxide is likely to result in hydrolysis to propylene glycol in the stomach. In vitro work has shown that propylene oxide hydrolyses significantly more rapidly in human synthetic gastric juice (pH 1.48; half-life ~2 minutes) than in rat synthetic gastric juice (pH 4.8; half-life > 2 hours). Absorbed propylene oxide is likely to be hydrolysed to propylene glycol by epoxide hydrolase or bind to non-protein sulfhydryl groups, such as glutathione. There are no data that permit comparison of systemic exposures to propylene oxide by the inhalation and oral routes. It is expected that inhalation exposures to propylene oxide will result in greater systemic levels than equivalent oral exposures when account is taken of the likely hydrolysis rates in the human stomach combined with kinetic data on propylene oxide levels in blood following inhalation exposure and a physiologically based pharmacokinetic model for inhalation exposures to propylene oxide.

For the purposes of this assessment, a simplistic conversion between inhalation exposures and oral dosing has been performed. This conversion assumed standard breathing rates and volumes, a body weight (bw) of 250 g and 100% absorption via each exposure route. The conversion resulted in an atmospheric concentration of 100 ppm (240 mg/m^3) inhaled for 6 hours/day, 5 days/week, being approximately equivalent to an oral dose of 40 mg/kg bw per day in rats and 80 mg/kg bw per day in mice. This is likely to be a conservative estimate for systemic propylene oxide exposures via the oral route.

Toxicological data

The acute toxicity of propylene oxide has been investigated orally (median lethal doses [LD_{50}s] 300–1000 mg/kg bw), dermally (LD_{50}s 950–1250 mg/kg bw) and by inhalation (median lethal concentration [LC_{50}] 1–9.5 mg/L). Propylene oxide is an irritant to skin, respiratory tract and eyes. There are no data on its sensitizing potential.

Short-term studies of toxicity with propylene oxide have been performed in mice and rats, mainly via the inhalation route, in which no systemic effects other than body weight deficits were evident. No effects on the nasal cavity were reported in rats or mice exposed for 14 weeks (6 hours/day, 5 days/week) at up to 500 ppm. In a gavage study in rats dosed 18 times in 24 days,

reduced body weight gain, gastric irritation and hepatotoxicity were reported at 300 mg/kg bw per day, with a no-observed-adverse-effect level (NOAEL) of 200 mg/kg bw per day.

In a chronic toxicity and carcinogenicity study in mice exposed via inhalation at 200 or 400 ppm for 6 hours/day, 5 days/week, survival was reduced at both concentrations. Body weights were significantly lower in the 400 ppm groups during the second half of the study. Inflammation of the nasal epithelia was seen in all treated groups. Low incidences of squamous cell carcinoma and adenocarcinoma of the nasal epithelia were present in high-dose animals. There was also an increase in haemangiosarcoma and haemangioma of the vascular plexus below the nasal epithelium. An increase in mammary gland adenocarcinoma was seen in females, which was statistically significant in the high-dose group when corrected for survival; the incidences are within the historical control range and considered to be not clearly treatment related. A no-observed-adverse-effect concentration (NOAEC) for site of contact toxicity cannot be derived for this study due to the inflammation of the nasal epithelia seen at both concentrations. The NOAEC for carcinogenicity is 200 ppm (~160 mg/kg bw per day orally), based on the nasal tumours seen at 400 ppm (~320 mg/kg bw per day orally). The NOAEC for systemic toxicity is 200 ppm (~160 mg/kg bw per day orally), based on reduced body weight gain at 400 ppm (320 mg/kg bw per day orally).

In a published 150-week study, female rats were exposed to propylene oxide by gavage twice a week at 15 or 60 mg/kg bw per administration (equal to 4.3 or 17 mg/kg bw per day). The extent of the tissues examined and level of reporting are less than those carried out in a normal regulatory study, with minimal or no reporting of body weights, clinical signs or non-neoplastic lesions. Within the limitations of the investigative procedure, the only organ with an increased incidence of non-neoplastic lesions (hyperkeratosis) or tumours was the stomach/forestomach (data not presented separately). The incidence of squamous cell carcinoma in the stomach/forestomach showed a clear dose–response relationship. The lowest dose level gave a slight increase in squamous cell carcinoma of the stomach/forestomach. The NOAEL for carcinogenicity was less than 4.3 mg/kg bw per day. The study did not demonstrate a NOAEL for chronic toxicity because of the presence of hyperkeratosis at 4.3 mg/kg bw per day, the lowest dose tested.

In a 28-month inhalation study in rats, survival was reduced in the 300 ppm groups and in 100 ppm females at the end of the study (after week 115). Body weights were reduced in the 300 ppm groups. Increases in relative liver weights (10–15%) were statistically significant at 300 ppm in males sacrificed at 24 and 28 months and in females sacrificed at 24 months. Local effects on the basal mucosa, nasal turbinates and olfactory epithelium were seen at 300 ppm and occasionally at 100 ppm from 12 months onwards. Non-neoplastic findings were seen in the heart, liver, lung and kidneys at 300 ppm; the effects at 100 and 30 ppm are unclear due to the limited number of tissues examined. There were no increases in tumour incidence in the nose or respiratory tract. Increased incidences of mammary gland fibroadenomas and thyroid tumours (follicular cell adenoma and parafollicular cell adenoma) were recorded in the 300 ppm groups. The incidences of multiple mammary gland tumours were increased in all treated female groups but were reported to be within the historical range. A NOAEC for systemic effects was 100 ppm (~40 mg/kg bw per day orally), based on body weight gain reductions at 300 ppm (~120 mg/kg bw per day orally). The increased mortality at 100 ppm at week 115 is not considered relevant, as this is beyond the normal lifespan of laboratory rats.

In a second chronic inhalation study, rats were exposed to propylene oxide for 6 hours/day, 5 days/week, for 2 years. Body weights were slightly lower (< 10%) in the 400 ppm groups than in controls. Inflammation of the nasal cavity was increased at 400 ppm and in males at 200 ppm. Tumours of the nasal cavity (papillary adenoma) were increased in both sexes at 400 ppm, outside the historical control range. Other tumours showing increased incidences were mammary gland, uterus and thyroid tumours in females. The uterine stromal sarcoma incidences were above the historical control range at both concentrations of propylene oxide, but did not exhibit a dose–response relationship. The thyroid gland C-cell tumours were at the upper end of the historical control range, and as there was no related increase in hyperplasia, the relationship to propylene oxide is considered equivocal. The mammary gland tumours were not increased statistically significantly and were within

the historical control range, but are consistent with results in other studies, and their relationship to propylene oxide is equivocal. The NOAEC for tumours is 200 ppm (~80 mg/kg bw per day orally), based on the increase in papillary adenomas of the nasal cavity at 400 ppm (~160 mg/kg bw per day orally). The NOAEC for chronic site of contact toxicity is less than 200 ppm (~80 mg/kg bw per day orally), based on nasal cavity inflammation. For systemic toxicity, the NOAEC is 200 ppm (~80 mg/kg bw per day orally), based on reduced body weight gain at 400 ppm (~160 mg/kg bw per day orally).

Evidence of carcinogenicity was seen in long-term studies of toxicity and carcinogenicity with propylene oxide in rats via both oral (stomach/forestomach) and inhalation routes (nasal cavity and mammary tumours) and in mice via inhalation (nasal cavity and mammary tumours). The relevance of these tumours to human exposures to relatively low levels of propylene oxide via the diet is equivocal. In vitro work has shown that propylene oxide hydrolyses significantly more rapidly in human synthetic gastric juice than in rat synthetic gastric juice. This indicates that the stomach tumours seen in the rat gavage study might be associated with a much more prolonged exposure to propylene oxide than would occur in humans.

Similarly, for the nasal cavity tumours seen in the inhalation studies with rats and mice, these could be associated with chronic irritation of the epithelial cells and depletion of sulfhydryl groups and not relevant to oral exposures. However, there have been no specific mechanistic investigations to demonstrate that site of contact mutagenic effects do not occur. A threshold concentration for nasal tumours in chronic studies appears to be 300 ppm (720 mg/m^3), which is consistent with data on non-protein sulfhydryl group depletion in nasal mucosa.

In mice and rats exposed to propylene oxide by inhalation, increases in mammary tumours were noted, but these were reported to be within the historical control ranges.

The Meeting concluded that there was no convincing evidence that propylene oxide caused systemic tumorigenicity in mice and rats.

The potential genotoxicity of propylene oxide has been investigated in an adequate battery of tests in vitro and in vivo. Positive results were seen in a range of in vitro assays. In vivo assays (for micronuclei and dominant lethal mutations) using oral administration were negative; positive results were seen following high-dose intraperitoneal administration in mice and a high-concentration inhalation study in fruit flies. There are no in vivo data from tissues directly exposed to propylene oxide rather than its metabolites. Propylene oxide produces deoxyribonucleic acid (DNA) adducts (primarily N^7G, plus N^3A, N^3C and N^1A) in respiratory mucosa and liver of exposed rats, and 1-hydroxypropyl-adenine was reported in the leukocytes of a group of propylene oxide production plant workers.

The Meeting concluded that propylene oxide is genotoxic in vitro but is unlikely to be genotoxic via the oral route due to hydrolysis to propylene glycol in the stomach.

The Meeting concluded that propylene oxide is carcinogenic to experimental animals at the site of initial contact, but because of the likely rapid hydrolysis to propylene glycol in the human stomach and negative genotoxicity in vivo via oral administration, it is unlikely to be carcinogenic to humans following exposure via the oral route to propylene oxide residues in the diet.

No oral studies of reproductive toxicity or developmental toxicity are available. In a rat reproductive toxicity study using inhalation exposure, there were no effects reported on mating performance, fertility, litter size, pup survival or development at the highest concentration tested (300 ppm, 6 hours/day, 5 days/week). Reduced body weight gain was seen in parental animals and pups at 300 ppm. The NOAEC for reproductive toxicity was 300 ppm (~120 mg/kg bw per day orally), the highest dose tested. The NOAEC for parental and pup toxicity was 100 ppm (~40 mg/kg bw per day orally), based on reduced body weight gain at 300 ppm (~120 mg/kg bw per day orally).

The Meeting concluded that propylene oxide does not adversely affect reproduction via the inhalation route at exposure concentrations producing parental toxicity.

In a well-reported developmental toxicity study, rats were exposed to propylene oxide at 0, 100, 300 or 500 ppm for 6 hours/day on days 6–15 of gestation. Maternal body weight gain was reduced at 500 ppm. There was no increase in malformations, and the NOAEC for teratogenicity was 500 ppm (~260 mg/kg bw per day orally)[15]. There were no effects on litter size, post-implantation losses, fetal viability or litter size. The only significant developmental finding was an increase in accessory cervical ribs at 500 ppm. The NOAECs for maternal and developmental effects were both 300 ppm (~160 mg/kg bw per day orally). In a limited developmental toxicity study, rats were exposed by inhalation to a single concentration of propylene oxide (500 ppm) for 7 hours/day during various phases of gestation. Body weight gain was reduced in treated animals, whereas kidney, liver, lung and spleen weights were increased. There were decreases reported in corpora lutea, implantation sites and live fetus weights, length and numbers. The only visceral, skeletal or external alterations were increased incidences of wavy ribs and reduced ossification of the ribs and vertebrae in the exposed groups. The single air concentration tested (500 ppm; ~200 mg/kg bw per day orally) is a NOAEC for teratogenicity and a lowest-observed-adverse-effect concentration (LOAEC) for maternal and developmental toxicity. In an almost identical study in rabbits, there were reductions reported in maternal body weight gain, histopathological changes in a number of organs and increases in resorptions and minor skeletal abnormalities. There were no reported increases in malformations. The single concentration tested (500 ppm; ~75 mg/kg bw per day orally) is reported to be a NOAEC for teratogenicity and a LOAEC for maternal and developmental toxicity in rabbits.

The Meeting concluded that propylene oxide produced developmental toxicity via the inhalation route, but the available evidence indicated that it was not teratogenic.

Hydroxypropylvaline adducts of haemoglobin have been detected in workers in industrial facilities using or producing propylene oxide. 1-Hydroxypropyl-adenine was reported in the leukocytes of a group of propylene oxide production plant workers. Epidemiological studies of workers exposed to propylene oxide as well as other chemicals have been inconclusive.

Biochemical and toxicological data on propylene chlorohydrin

Propylene chlorohydrin (1-chloro-2-propanol, 2-chloro-1-propanol) is a plant metabolite formed following the use of propylene oxide. Data have been generated on a 3:1 mixture of 1-chloro-2-propanol and 2-chloro-1-propanol.

Biochemical aspects

Limited, qualitative data indicate that propylene chlorohydrin is absorbed following oral administration, conjugated to glucuronic acid or glutathione and excreted in the urine.

Toxicological data

The acute toxicity of propylene chlorohydrin has been investigated via the oral route (rat LD_{50} 200–250 mg/kg bw), the dermal route (rabbit LD_{50} 500 mg/kg bw) and inhalation (LC_{50} > 3.8 mg/L). Propylene chlorohydrin is not irritating to rabbit skin but is a severe eye irritant. There are no data on its skin sensitizing potential.

In a 14-day drinking-water study in mice, reductions in body weight were seen at the top dose level (10,000 mg/L). Alterations in pancreatic acinar cells and pancreatic degeneration and hepatocyte vacuolation were reported at 3300 mg/L and above. The NOAEL was 330 mg/L (equivalent to 33 mg/kg bw per day), based on hepatocyte vacuolation at 1000 mg/L (equivalent to 100 mg/kg bw

[15] Different conversion rate, as exposures occurred every day as opposed to 5 days/week.

per day). In a subsequent 14-week study, findings were similar (including pancreatic acinar cell degeneration and fatty change of the pancreas), but it was not possible to identify a NOAEL due to hepatocyte vacuolation at the lowest dose tested, 33 mg/L (equal to 7 mg/kg bw per day).

In a 14-day drinking-water study in rats, reduced body weight was seen at high dose levels. Indications of red cell effects (splenic haematopoiesis, bone marrow atrophy) and pancreatic degeneration/acinar cell changes were seen at 1000 mg/L (equal to 100 mg/kg bw per day). A NOAEL could not be determined due to the limited investigations at dose levels below 1000 mg/L (equal to 100 mg/kg bw per day). In an equivalent 14-week study, body weight, erythrocyte, pancreas and liver effects were seen at 1000 mg/L, with a NOAEL of 330 mg/L (equal to 35 mg/kg bw per day).

Chronic toxicity and carcinogenicity studies have been performed in mice and rats exposed to propylene chlorohydrin in the drinking-water for 2 years. In both of the studies, there were no indications of carcinogenicity or general toxicity, including of the pancreas and liver. Haematological and clinical chemistry examinations were not performed. The NOAELs were the highest concentrations tested, 1000 mg/L (equal to 100 mg/kg bw per day) in mice and 650 mg/L (equal to 34 mg/kg bw per day) in rats.

The potential genotoxicity of propylene chlorohydrin has been investigated in an adequate battery of tests in vitro and in vivo. Positive results were seen in a range of in vitro assays. Negative results were seen in vivo with oral administration, although a mutation assay in *Drosophila* using injection administration was positive.

The Meeting concluded that propylene chlorohydrin is genotoxic in vitro but unlikely to be genotoxic in vivo.

Taking note of the absence of genotoxicity in vivo in mammals and the absence of carcinogenicity in rats and mice, the Meeting concluded that propylene chlorohydrin is unlikely to be carcinogenic to humans.

In a “continuous breeding”, reproductive toxicity study, rats were exposed to propylene chlorohydrin in drinking-water over two generations. Reduced body weight gain was seen in dams and pups at 650 mg/L. There were no adverse effects on reproduction or pup viability at any dose level. An increase in numbers of abnormal sperm and slightly extended estrus were reported in parental animals at 1300 mg/L, but these were without any reproductive consequence and are considered not to be adverse. The reproductive NOAEL was 1300 mg/L (equal to 130 mg/kg bw per day), the highest dose tested. The NOAEL for parental toxicity was 300 mg/L (equal to 30 mg/kg bw per day), based on reduced body weights at 650 mg/L (equal to 65 mg/kg bw per day). The NOAEL for offspring toxicity was 300 mg/L (equal to 30 mg/kg bw per day), based on reduced body weight gain at 650 mg/L (equal to 65 mg/kg bw per day).

The Meeting concluded that propylene chlorohydrin is not toxic to reproduction.

In a limited developmental toxicity study, propylene chlorohydrin was administered to five pregnant rats per group. Fetuses were examined only for gross external abnormalities. Maternal body weight gain was reduced at the top dose level of 125 mg/kg bw per day. There were no treatment-related increases in external findings and no effects on viable fetal numbers. This study is inadequate, with respect to group size and extent of investigations, to permit identification of a NOAEL for developmental toxicity.

Epidemiological studies of workers in plants producing propylene chlorohydrin and other chlorinated hydrocarbons identified an excess of mortality due to pancreatic cancer, leukaemia, and all lymphatic and haematopoietic cancers. The involvement, if any, of propylene chlorohydrin in these effects is unclear.

Toxicological data on propylene bromohydrin

Propylene bromohydrin (1-bromo-2-propanol; 2-bromo-1-propanol) is a plant metabolite formed following the use of propylene oxide. No in vivo toxicity data were available for evaluation. Genotoxicity data show that propylene bromohydrin is genotoxic in vitro. Comparative data indicate that in some bacterial mutagenicity tests, the bromopropanol derivatives are more potent mutagens than the equivalent chloro- compounds.

Toxicological data on propylene glycol

Propylene glycol (1,2-propanediol) is a plant metabolite formed following the use of propylene oxide. It is also an approved food additive (e.g., E1520). It was reviewed by the Joint FAO/WHO Expert Committee on Food Additives in 2002,[16] when an acceptable daily intake (ADI) of 0–25 mg/kg bw was derived.

The Meeting concluded that the existing database on propylene oxide was adequate to characterize the potential hazards to fetuses, infants and children by the inhalation route. Taking account of the likely hydrolysis to propylene glycol following oral exposure, the inhalation studies are considered to provide adequate reassurance for potential risks to fetuses, infants and children via the oral route.

The Meeting concluded that the existing database on propylene chlorohydrin was adequate to characterize the potential hazards to infants and children, but not to fetuses.

Toxicological evaluation

Propylene oxide

The Meeting established an ADI of 0–0.04 mg/kg bw derived from the NOAEC for systemic effects (reduced body weight gain) in the chronic inhalation studies in rats of 100 ppm (equivalent to approximately 40 mg/kg bw per day orally) supported by the NOAEC of 100 ppm (equivalent to approximately 40 mg/kg bw per day orally) for offspring and parental toxicity (reduced body weight gain) in the reproductive toxicity study in rats. Kinetic and metabolic data indicate that there is likely to be greater systemic exposure to propylene oxide following inhalation exposures relative to equivalent oral exposures; thus, the extrapolation is likely to be conservative. A safety factor of 1000 was applied. An additional factor of 10 was applied to the default safety factor of 100 to address the limitations in the database. The 150-week oral study in rats was not used in the establishment of the ADI, as there was limited investigation of non-neoplastic systemic effects and the critical findings reported were local effects in the rat stomach that are considered not relevant to human exposures to propylene oxide residues in the diet.

The Meeting established an acute reference dose (ARfD) of 0.04 mg/kg bw on the same basis as the ADI. The Meeting concluded that there was inadequate information to support the derivation of a value based on specific acute effects.

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[16] *Evaluation of certain food additives and contaminants* (Fifty-seventh report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 909, 2002.

Propylene chlorohydrin

The Meeting could not establish an ADI or ARfD for propylene chlorohydrin due to the absence of any reliable data to characterize the hazards to fetuses. The chemical properties and toxicity profile of propylene chlorohydrin are different from those of propylene oxide, and it is not possible to read across between the two compounds.

Propylene bromohydrin

The Meeting could not establish an ADI or ARfD for propylene bromohydrin due to the absence of any in vivo data. The chemical properties of propylene bromohydrin are different from those of propylene oxide, and it is not possible to read across between the two compounds.

A toxicological monograph was prepared.

Levels relevant to risk assessment of propylene oxide

Species	Study	Effect	NOAEL/C	LOAEL/C
Mouse	Two-year study of toxicity and carcinogenicity[a]	Systemic toxicity	200 ppm (~160 mg/kg bw per day orally)[b]	400 ppm (~320 mg/kg bw per day orally)[b]
		Carcinogenicity	200 ppm (~160 mg/kg bw per day orally)[b]	400 ppm (~320 mg/kg bw per day orally)[b]
Rat	Twenty-eight-month study of toxicity and carcinogenicity[a]	Systemic toxicity	100 ppm[c] (~40 mg/kg bw per day orally)[b]	300 ppm (~120 mg/kg bw per day orally)[b]
		Carcinogenicity	300 ppm[d] (~120 mg/kg bw per day orally)[b]	—
	Two-year study of toxicity and carcinogenicity[a]	Systemic toxicity	200 ppm (~80 mg/kg bw per day orally)[b]	400 ppm (~160 mg/kg bw per day orally)[b]
		Carcinogenicity	200 ppm (~80 mg/kg bw per day orally)[b]	400 ppm (~160 mg/kg bw per day orally)[b]
	Multigeneration study of reproductive toxicity[a]	Reproductive toxicity	300 ppm[d] (~120 mg/kg bw per day orally)[b]	—
		Parental toxicity	100 ppm (~40 mg/kg bw per day orally)[b]	300 ppm (~120 mg/kg bw per day orally)[b]
		Offspring toxicity	100 ppm (~40 mg/kg bw per day orally)[b]	300 ppm (~120 mg/kg bw per day orally)[b]
	Developmental toxicity study[a]	Maternal toxicity	300 ppm (~160 mg/kg bw per	500 ppm (~260 mg/kg bw per day

Species	Study	Effect	NOAEL/C	LOAEL/C
			day orally)[e]	orally)[e]
		Embryo and fetal toxicity	300 ppm	500 ppm
			(~160 mg/kg bw per day orally)[e]	(~260 mg/kg bw per day orally)[e]
Rabbit	Developmental toxicity study[a]	Maternal toxicity	—	500 ppm[f]
				(~75 mg/kg bw per day orally)
		Embryo and fetal toxicity	—	500 ppm[f]
				(~75 mg/kg bw per day orally)

[a] Inhalation exposure.

[b] Assuming 100 ppm = 240 mg/m^3; 100% absorption; 250 g body weight; standard breathing rates and volumes; exposures for 6 hours/day, 5 days/week.

[c] Limited examination.

[d] Highest concentration tested.

[e] Assuming 100 ppm = 240 mg/m^3; 100% absorption; 250 g body weight; standard breathing rates and volumes; exposures for 6 hours/day on gestation days 6–15.

[f] Lowest concentration tested.

Levels relevant to risk assessment of propylene chlorohydrin

Species	Study	Effect	NOAEL	LOAEL
Mouse	Fourteen-week toxicity[a]	Toxicity	—	7 mg/kg bw per day[b]
	Two-year study of toxicity and carcinogenicity[a]	Toxicity	100 mg/kg bw per day[c]	—
		Carcinogenicity	100 mg/kg bw per day[c]	—
Rat	Two-year study of toxicity and carcinogenicity[a]	Toxicity	34 mg/kg bw per day[c]	—
		Carcinogenicity	34 mg/kg bw per day[c]	—
	Multigeneration study of reproductive toxicity[a]	Reproductive toxicity	130 mg/kg bw per day[c]	—
		Parental toxicity	30 mg/kg bw per day	65 mg/kg bw per day
		Offspring toxicity	30 mg/kg bw per day	65 mg/kg bw per day

[a] Drinking-water administration.

[b] Lowest dose tested.

[c] Highest dose tested.

Estimate of acceptable daily intake for humans

0–0.04 mg/kg bw for propylene oxide

No ADI could be established for propylene chlorohydrin or propylene bromohydrin.

Estimate of acute reference dose

0.04 mg/kg bw for propylene oxide

No ARfD could be established for propylene chlorohydrin or propylene bromohydrin.

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
- Developmental toxicity data via the oral route for propylene chlorohydrin
- Sufficient information to evaluate the potential toxicity of propylene bromohydrin residues in the diet
- For further information, see Environmental Health Criteria 240[17].

Critical end-points for setting guidance values for exposure to propylene oxide

Absorption, distribution, excretion and metabolism in mammals	
Rate and extent of oral absorption	No data
Dermal absorption (human skin in vitro)	No data
Distribution	No data
Potential for accumulation	Unlikely
Rate and extent of excretion	No data
Metabolism in animals	Hydrolysed to propylene glycol or conjugated
Toxicologically significant compounds (animals, plants and the environment)	Propylene oxide, propylene chlorohydrin, propylene bromohydrin
Acute toxicity	
Rat, LD_{50}, oral	300–1000 mg/kg bw
Rat, LD_{50}, dermal	950 mg/kg bw
Rat, LC_{50}, inhalation	3.2–3.4 mg/L (4 h, nose only)
Rabbit, dermal irritation	Severe
Rabbit, ocular irritation	Moderate to severe
Dermal sensitization	No data
Short-term studies of toxicity	
Target/critical effect	Body weight gain
Lowest relevant oral NOAEL	200 mg/kg bw per day (rats)
Lowest relevant dermal NOAEL	No data
Lowest relevant inhalation NOAEC	250 ppm (600 mg/m^3) (mice and rats)

[17] *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, 2009 (Environmental Health Criteria 240).

Genotoxicity	
	Genotoxic in vitro; unlikely to be genotoxic in humans at dietary exposure levels
Long-term studies of toxicity and carcinogenicity	
Target/critical effect	Site of contact irritation (nasal cavity inflammation; stomach hyperkeratosis); systemic toxicity (reduced body weight gain)
Lowest relevant LOAEL	4.3 mg/kg bw per day (lowest dose tested) (rat)
Lowest relevant NOAEC (systemic toxicity)	100 ppm (rat) (~40 mg/kg bw per day oral)
Carcinogenicity	Site of contact tumours (nasal cavity; stomach)
Reproductive toxicity	
Reproduction target/critical effect	None
Lowest relevant reproductive NOAEC	300 ppm (rat) (~120 mg/kg bw per day oral)
Developmental target/critical effect	Accessory cervical ribs (rat)
Lowest relevant developmental NOAEC	300 ppm (rat) (~120 mg/kg bw per day oral)
Neurotoxicity/delayed neurotoxicity	
	No data
Other toxicological studies	
	DNA and haemoglobin adduct formation in rats and humans; depletion of non-protein sulfhydryl groups
Medical data	
	Epidemiological studies of production plant workers inconclusive

Critical end-points for setting guidance values for exposure to propylene chlorohydrin

Absorption, distribution, excretion and metabolism in mammals	
Rate and extent of oral absorption	> 11% (limited information)
Dermal absorption (human skin in vitro)	No data
Distribution	No data
Potential for accumulation	Unlikely
Rate and extent of excretion	> 11% (urine, rabbit)
Metabolism in animals	Glucuronide and glutathione conjugates
Toxicologically significant compounds (animals, plants and the environment)	Propylene chlorohydrin
Acute toxicity	
Rat, LD_{50}, oral	200–250 mg/kg bw
Rat, LD_{50}, dermal	500 mg/kg bw
Rat, LC_{50}, inhalation	> 3.8 mg/L (6 h)
Rabbit, dermal irritation	Not irritating

Rabbit, ocular irritation	Severe
Dermal sensitization	No data
Short-term studies of toxicity	
Target/critical effect	Liver (hepatocyte vacuolation); pancreas (acinar cell alterations)
Lowest relevant oral NOAEL	35 mg/kg bw per day (rat)
Lowest relevant dermal NOAEL	No data
Lowest relevant inhalation NOAEC	No data
Genotoxicity	
	Genotoxic in vitro; unlikely to be genotoxic in vivo
Long-term studies of toxicity and carcinogenicity	
Target/critical effect	None
Lowest relevant NOAEL	34 mg/kg bw per day (highest dose tested) (rat)
	100 mg/kg bw per day (highest dose tested) (mouse)
Carcinogenicity	Not carcinogenic
Reproductive toxicity	
Reproduction target/critical effect	None
Lowest relevant reproductive NOAEL	130 mg/kg bw per day (highest dose tested)
Developmental target/critical effect	Inadequate data
Lowest relevant developmental NOAEC	Inadequate data
Neurotoxicity/delayed neurotoxicity	
	No data
Other toxicological studies	
	No data
Medical data	
	Epidemiological studies of production plant workers inconclusive

Summary for propylene oxide

	Value	Study	Safety factor
ADI	0–0.04 mg/kg bw	Rat chronic inhalation	1000
ARfD	0.04 mg/kg bw	Same basis as ADI; insufficient data to establish a value for specific acute effects	1000

Summary for propylene chlorohydrin

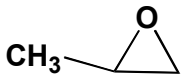
	Value	Study	Safety factor
ADI	None established		
ARfD	None established		

RESIDUE AND ANALYTICAL ASPECTS

Propylene oxide is used in agriculture as an insecticidal fumigant and sterilant to control bacteria contamination, mould contamination, insect infestations, and microbial spoilage of food products as well as to control insects in non-food products. Propylene oxide is also a commercially important industrial chemical finding application as an intermediate for a wide array of products. At the Forty-second Session of the CCPR (2010), it was scheduled for evaluation as a new compound by 2011 JMPR.

Residue studies were submitted by the manufacturers for support of the following commodities: cereal grains (maize, wheat), tree nuts, cocoa, herbs and spices, dried vegetables (onion and garlic) and dried fruit (raisins, figs and prunes).

Propylene oxide is methyloxirane.



The following abbreviations are used for the metabolites discussed below:

PPO = propylene oxide

PCH = propylene chlorohydrin, (1-chloro-2-propanol and 2-chloro-1-propanol)

PBH = propylene bromohydrin, (1-bromo-2-propanol and 2-bromo-1-propanol)

PPG = 1,2 propanediol

Animal metabolism

No data for livestock are available on the absorption following oral dosing with propylene oxide. However, data from rats on other routes of administration enable conclusions on the metabolism of PPO to be made. Two metabolic pathways are suggested: 1) conjugation with glutathione via glutathione epoxide transferase; 2) hydrolysis by epoxide hydrolase to 1,2-propanediol (propylene glycol, PPG). PPG can be excreted as such or metabolized to lactic and pyruvic acid. Propylene oxide is a direct alkylating agent that forms DNA (N-2-hydroxypropyl-guanosine, N-2-hydroxypropyl-guanosine) and protein adducts (hemoglobin alkylation at the cysteine, histidine or valine) residues. Assuming a 100% alveolar absorption and first-order kinetics, a half-life of 40 minutes was estimated for the elimination of PPO in rats. Under *in vitro* conditions, the half-life of PPO in human gastric juice (pH 1.46 and 37 °C) is approximately 1.9 minutes while in rat gastric juice (pH 4.8) it is 347 minutes.

Plant metabolism

Limited data were available of the metabolism of propylene oxide in plants and fumigated plant-based commodities. The Meeting concluded, based on the similarity in reactions and chemistry between ethylene oxide and propylene oxide and reported degradates from studies with unlabelled PPO, that in addition to PPO residues of PPG (free and conjugated), PCH and PBH are formed upon and after postharvest fumigation of plant-based commodities. In commodities that contain salt the PPO will react with chloride ions to form PCH. Similarly, bromide ions present react with PPO to form PBH. Reaction with water present in fumigated samples can produce PPG. In addition, PPO may react with exposed -COOH, $-NH_2$, -OH and -SH groups present in natural constituents to give the corresponding hydroxy-propyl compounds.

Environmental fate

Propylene oxide is a post-harvest fumigant and sterilant and is not expected to be released into the environment such that significant levels will be found in soil and water. In addition, PPO is hydrolysed in water at 25 °C with a half-life of 10.7 to 14.6 days. The rate of hydrolysis is increased in the presence of acid or base. Propylene oxide is not expected to be present or persist in the environment.

Analytical methods

Methods are available for the analysis of PPO and PCH in plant commodities. Samples are ground under cryogenic conditions (liquid nitrogen), transferred to a vial, the vial sealed and the PPO residues desorbed by heating. Powdered samples do not need the grinding step and can be added directly to the vial. The volatilized PPO equilibrates in the headspace of the vial which is then sampled by an automated headspace sampler and injected onto a GC-FID system. Quantitation was achieved by comparison with a calibration curve consisting of fortified matrix samples. It was reported that headspace analysis should occur within 1 hour of sample preparation for nuts or 2 hours for cocoa, herbs and spices. An LOQ of 0.1 mg/kg was attained for most matrices.

Residues of PCH (1-chloro-2-propanol and 2-chloro-1-propanol) and PBH (1-bromo-2-propanol and 2-bromo-1-propanol) are extracted with acetone and quantitated via gas chromatography with electrolytic conductivity detection (GC-ELCD). Detector response is not linear over the fortification range and a quadratic model was used for the standard curve. An LOQ of 1 mg/kg has been demonstrated for most commodities.

Stability of pesticide residues in stored analytical samples

No data were provided on the stability of residues of PPO, PCH, PBH or PPG when samples were stored frozen. In most of the supervised residue trials samples were analysed on the day of collection or soon after, in which case the samples were stored at 2 °C or -20 °C until analysis.

Definition of the residue

Following fumigation, the major components of the residue observed in trials are PPO, PCH, PBH and PPG. In nuts and cocoa PCH and PBH were present at levels that are about 10% of the PPO level while PCH levels were the same or much greater that PPO in spices and dried fruit. Levels of PPG were about the same as those of PPO in nuts but much greater than PPO in cocoa and spices. PBH residues were similar in magnitude relative to PCH residues in almonds, pecans, walnuts and cocoa powder but much lower in herbs and spices.

The Meeting considered that although PPG was often present at the highest concentration, PPG is much less toxic than PPO and PCH and is not required to be included in the residue for dietary risk assessment. The residues of concern for dietary risk assessment are PPO, PCH and PBH. Based on differences in toxicological effects, PPO and PCH/PBH are assessed separately and the residues are not combined for estimation of dietary risk exposure.

The Meeting recommended that the residue definition for plant and animal commodities, for compliance with MRLs should be propylene oxide.

The Meeting recommended that the residue definition for plant and animal commodities, for dietary risk assessment should be propylene oxide, propylene chlorohydrins and propylene

bromohydrin. Propylene chlorohydrin and propylene bromohydrin to be considered separately from propylene oxide.

The log K_{ow} of propylene oxide (log K_{ow} 2.9, pH 7) suggests that PPO is likely to be borderline fat soluble however, the predicted distribution of residues in the rat study suggested the residues are not fat soluble[18].

Definition of the residue (for compliance with MRL): *propylene oxide*.

Definition of the residue (for estimation of dietary intake): *propylene oxide, propylene chlorohydrin and propylene bromohydrin. Propylene chlorohydrin and propylene bromohydrin to be considered separately from propylene oxide.*

The residue is not considered fat soluble.

Results of supervised trials on crops

Residue trials, including data from published scientific papers, were available for the use of PPO on: cereal grains, tree nuts, spices and herbs, dried garlic, dried onion, cocoa beans and dried fruit. No GAP was available to assess trials on cereal grains and these trials are not considered further.

Residues are reported below for PPO with corresponding values for PCH reported in brackets. During fumigation almost all the PPO is absorbed by the commodity being fumigated, at least for initial fumigation chamber PPO concentrations in the range 0.0125 to 0.1 g ai/L. The load ratio (volume occupied by material for fumigation to total chamber volume) may have an influence on the final residues. In the residue trials the load was generally 50% capacity. Factors important in determining residues of the related fumigant ethylene oxide are also likely to be relevant to propylene oxide. Important factors include: the total amount and concentration of propylene oxide, the composition of the treatment mixture, temperature, the type of commodity and its moisture content, pH, permeability, and particle size, and the method of packaging as well as aeration and storage conditions after treatment.

Tree nuts

Data were available from supervised trials on almonds, pecans and walnuts in the USA. The GAP of the USA is for fumigation of tree nuts at 2 g ai/L for up to six hours and a post fumigation interval (PFI) of 28 days if off-gasing at 25 °C otherwise the product can be released if residues have declined to below 300 mg/kg. Residues in tree nuts from trials in the USA matching GAP were: 273 (PCH 3.0) for shelled almonds, 37 (PCH 8.2) mg/kg for pecan pieces and 209 (PCH 7.4) mg/kg for walnut pieces.

To be able to estimate a maximum residue level according to the use pattern, sufficient trials are required to estimate a maximum level or to be confident that residues remain below 300 mg/kg at 28 days or more of off-gasing at 25 °C. The number of trials that comply with maximum GAP are too few to estimate a maximum residue level. The Meeting also noted that data from commercial fumigations where shelled almond nuts were fumigated at a lower rate suggest PPO residues in almonds decline rapidly during the first 15 days of off-gasing and only slowly thereafter. If

[18] Csanády GA, Filser JG (2009) A Physiological Toxicokinetic Model for Inhaled Propylene Oxide in Rat and Human with Special Emphasis on the Nose. Toxicology Sciences 95: 37–62. (tissue:blood partitionratios; fat:blood 1.06, muscle:blood 0.84)

proportionality were to apply to fumigation, the commercial results also suggest residues of PPO may be higher than 300 mg/kg at PFIs of greater than 28 days. The Meeting considered the data inadequate to estimate maximum residue levels for PPO and PCH in tree nuts.

Dried fruit

Data were available from supervised trials on dried fruit in the USA.

The GAP of the USA is for fumigation of figs, prunes and raisins at 0.2 g ai/L for up to 48 hours and off-gasing at ≥25 °C for 48 hours prior to shipment. No trials complied with GAP.

Herbs and Spices

Data were available from supervised trials on a variety of dried herbs, spices as well as dried vegetables in the USA. The GAP of the USA is for fumigation of processed spices at 2 g ai/L for up to 12 hours and off-gasing at≥ 25 °C for 48 hours prior to shipment with earlier release possible if residues of PPO are less than 300 mg/kg. Clarification was sought from the US EPA regarding the commodities covered by processed spices in the US. The term processed spices is applied to herbs and spices as well as dried onions and dried garlic. Residues in black pepper complying with GAP were 93 (PCH not reported) mg/kg while those in onion powder were 15.2 (PCH not reported) mg/kg. Residues of PPO in an additional trial on celery seed sampled at 4 rather than 2 days after fumigation were 69 (PCH not reported) mg/kg while day 0 residues in the same trial were 126 (PCH 474) mg/kg. Residues in dried basil sampled at day 4 rather than day 2 after fumigation were 164 (PCH not reported) mg/kg and on day zero 372 (PCH 6670) mg/kg.

To be able to estimate a maximum residue level according to the use pattern, sufficient trials are required or to be confident that residues remain below 300 mg/kg after off-gasing at 25 °C for 48 hours. The Meeting considered whether or not the available data provided confidence that residues at a post fumigation interval of 48 hours would be below 300 mg/kg. Account was taken of trials conducted in 1995 that were not adequate to resolve questions over their use for estimation of maximum residue levels but did show a large variation in residues of PPO in treated spices, dried vegetables and dried herbs and that residues at 48 hours after fumigation may exceed 300 mg/kg. The Meeting concluded the small number of supervised residue trials that comply with GAP were not sufficient to estimate a maximum residue level for herbs and spices, for dried garlic and dried onion or for dried chili powder.

Cocoa Powder

The GAP of the USA is for fumigation of cocoa beans and cocoa powder at 2 g ai/L for up to 4 hours and off-gasing at≥ 25 °C for 48 hours prior to shipment with earlier release if residues of PPO are less than 300 mg/kg. The residues of PPO for supervised trials conducted on cocoa powder that complied with GAP of the USA are: 71.8 (PCH 11.6) and 136 (PCH 12.5) mg/kg. The Meeting considered two trials as insufficient for the purposes of estimating maximum residue levels.

Animal feedstuffs

No animal feed items were considered by the current Meeting.

Fate of residues during processing

No data is available on the effect of processing on the nature of residues.

Residues in animal commodities

No animal feed commodities were considered at by the current Meeting. No data were supplied for the transfer of residues from feed to foods of animal origin. Propylene oxide is degraded to PPG in the stomach such that should livestock be exposed, no residues are anticipated to transfer from feed to tissues, milk or eggs.

FURTHER WORK OR INFORMATION

Desirable

Additional trials conducted according to GAP to support estimation of maximum residue levels.

5.20 PYRACLOSTROBIN (210)

RESIDUE AND ANALYTICAL ASPECTS

Pyraclostrobin was first evaluated by JMPR in 2003 when an ADI of 0–0.03mg/kg bw and an ARfD of 0.05 mg/kg bw were established, and subsequently evaluated in 2004 and 2006 for the estimation of a number of maximum residue levels. The 2004 JMPR proposed pyraclostrobin as the residue definition for compliance with MRLs and for dietary intake, for both plant and animal commodities.

At the Forty-second Session of the CCPR, pyraclostrobin was scheduled for the evaluation of 2011 JMPR for additional maximum residue levels.

Analytical methods

The Meeting received descriptions and validation data for analytical methods for residues of pyraclostrobin in raw agricultural commodities, processed commodities and feed commodities. Numerous recovery data on a wide range of substrates were provided from validation testing of the methods, which showed that the methods were valid over the relevant concentration ranges. Pyraclostrobin was determined by LC-MS-MS and the reported LOQs ranged from 0.01 mg/kg to 0.02 mg/kg in plant matrices and 0.05 mg/kg in poultry tissues.

Results of supervised trials on crops

The Meeting received supervised trials data for pyraclostrobin uses on citrus fruits, cherries, plums, peaches, blackberries, raspberries, blueberries, currants, strawberries, avocado, papaya, onions, summer squash, cucumber, cantaloupe, artichoke, oat, rye, wheat, sorghum, pecan, almond, canola, cotton, sunflower and alfalfa.

The OECD calculator was used as a tool in the estimation of the maximum residue level from the selected residue data set obtained from the supervised trials. As a first step, the Meeting reviewed all relevant factors related to each data set in arriving at a best estimate of the maximum residue level using expert judgement. Then the OECD calculator was employed. If the statistical calculation spreadsheet suggested a different value from that recommended by the Meeting, a brief explanation of the deviation was supplied.

Citrus fruits

The 2004 JMPR evaluated numerous trials carried out in Argentina and the USA and estimated maximum residue levels for citrus fruits (1 mg/kg). New data were available from supervised trials on grapefruit, lemons, mandarins and oranges from Spain and the USA.

Grapefruit

The US GAP for citrus fruits allows a maximum of three spray applications at 0.147–0.245 kg ai/ha with a 0 day PHI.

Six grapefruit trials at maximum GAP, where residues found, median underlined, were: 0.06, 0.07, <u>0.09</u>, <u>0.11</u>, 0.24, and 0.59 mg/kg.

Lemon

The US GAP for citrus fruits allows a maximum of three spray applications at 0.147–0.245 kg ai/ha, 0 day PHI.

Five lemon trials at maximum GAP, where residues found, median underlined, were: 0.52, 0.54, <u>0.56</u>, 0.74 and 0.90 mg/kg.

Mandarin

Spanish GAP allows a maximum of four spray applications at 0.075–0.225 kg ai/ha, with a 7 day PHI.

Six mandarin trials at maximum GAP, where residues found, median underlined, were: 0.25, 0.52, 0.54, 0.76, 0.87, and 1.15 mg/kg.

Oranges

Spanish GAP allows a maximum of four spray applications at 0.075–0.225kg ai/ha, 7 day PHI; the GAP of the US for citrus fruits allows four foliar spray applications at 0.075–0.225 kg ai/ha, 0 day PHI.

In eight orange trials from Spain with application conditions in line with GAP, the ranked order pyraclostrobin residues, median underlined, were 0.24, 0.29, 0.34, 0.39, 0.58, 0.60, 1.10 and 1.31 mg/kg.

In thirteen orange trials from the USA, matching GAP conditions, pyraclostrobin residues were 0.17, 0.19, 0.23, 0.24, 0.25, 0.26, 0.28, 0.30, 0.42, 0.47, 0.61, 0.79 and 1.13 mg/kg.

The ranked order of pyraclostrobin residues in orange pulp, from the US trials, median underlined, were: < 0.02(7), 0.02(3), 0.05 and 0.07(2) mg/kg.

On the basis of the median ratio of 0.077 between pulp and whole fruit, corresponding calculated pyraclostrobin residues in orange pulp from the Spanish trials, median underlined, were: 0.02, 0.02, 0.03, 0.03, 0.04, 0.05, 0.08 and 0.10 mg/kg.

The Meeting noted that oranges had the highest residues in this citrus group and decided to recommend a maximum residue level of 2 mg/kg for pyraclostrobin in citrus fruits, an STMR of 0.035 mg/kg and an HR of 0.10 mg/kg on the basis of Spanish residue data in the pulp for dietary intake calculations, and estimate an STMR of 0.485 mg/kg for the estimation of STMR-P for processed commodities of oranges.

The Meeting agreed to withdraw the previous recommendation of 1 mg/kg for citrus fruits.

Stone fruits

The 2004 JMPR evaluated numerous trials carried out in US and estimated maximum residue levels for stone fruits (1 mg/kg). New data were available from supervised trials on cherries conducted in the USA and for peach and plum from Canada and the USA.

Cherries

Canadian GAP allows five spray applications at 0.134 kg ai/ha with a 10 day PHI. The GAP for the USA allows five spray applications at 0.134 kg ai/ha with a 0 day PHI.

Twelve sour or sweet cherry trials from the US and one sour cherry trial from Canada matched the US GAP. Residues found, in rank order, median underlined, were: 0.03, 0.27, 0.38, 0.42, 0.47, 0.50, 0.51, 0.56, 0.63, 0.82, 1.06, 1.08 and 1.57 mg/kg.

The Meeting estimated a maximum residue level of 3 mg/kg, an STMR of 0.51 mg/kg and HR of 1.57 mg/kg for pyraclostrobin in cherries.

Peaches

Canadian GAP consists of five spray applications at 0.134 kg ai/ha with a 10 day PHI. The GAP of France allows two spray applications at 0.05 kg ai/ha and a 3 day PHI. Germany GAP consists of three spray applications at 0.0168 kg ai/ha, 7 days PHI. For Italy and Spain the current GAP is three

spray applications at 0.04–0.05 kg ai/ha, 3 days PHI. The GAP of the USA is five spray applications at 0.134 kg ai/ha and a 0 day PHI.

Ten supervised trials were conducted on peaches in France, Italy and Spain in 2003 and 2004. The Meeting agreed to combine all data from France (5), Italy (2) and Spain (3) against the Italian or Spanish GAP, pyraclostrobin residues, median underlined, were: < 0.02, 0.03, 0.04, 0.05, 0.07 (2), 0.08, 0.11, 0.12and 0.13 mg/kg.

In 19 peach trials, at maximum US GAP, residues found, in ranked order, median underlined, were: 0.08, 0.11, 0.15, 0.15, 0.16 (2), 0.21, 0.23, 0.28, 0.31, 0.31, 0.34, 0.35, 0.41, 0.43, 0.48, 0.53, 0.61 and 1.75 mg/kg.

The US GAP would lead to an estimated maximum residue level of 2 mg/kg, an STMR of 0.31 mg/kg and an HR of 1.75 mg/kg for peaches. This residue level would result in an estimated intake of 150% of the ARfD.

Consequently, in accordance with the principles of alternative GAP, the Meeting considered the next lowest GAP and used the residues in European trials complying with Italian or Spanish GAP for the estimation of maximum residue level of 0.3 mg/kg, an STMR of 0.07 mg/kg and an HR of 0.13 mg/kg for peaches and nectarines.

Plums

The GAP of the USA consists of five spray applications at 0.134 kg ai/ha and a 0 day PHI.

Fifteen trials were carried out on plums in Canada (2) and the US (13) matching the US GAP. The residues found in rank order, median underlined, were: 0.02(2), 0.04, 0.05, 0.06, 0.07, 0.09 (2), 0.12, 0.19, 0.22, 0.34, 0.38 and 0.40(2) mg/kg.

The Meeting estimated a maximum residue level of 0.8 mg/kg, an STMR of 0.09 mg/kg and HR of 0.40 mg/kg for pyraclostrobin in plums.

The Meeting decided to withdraw its previous recommendations made for stone fruits (1 mg/kg).

Berries and other small fruits

The 2004 and 2006 JMPR evaluated numerous trials in blueberries, raspberries and strawberries carried out in the USA and Canada, and estimated maximum residue levels for blueberry (1 mg/kg), raspberry (2 mg/kg) and strawberry (0.5 mg/kg). New data were available for assessment from supervised trials on blackberry, blueberry, raspberry and strawberry conducted in Canada and the US.

Blackberries

The US GAP consists of five spray applications at 0.196 kg ai/ha, 0 day PHI.

From four blackberries trials, at GAP, residues found were: 0.35, 0.51, 0.87 and 1.32 mg/kg.

Raspberries

The Canadian GAP allows five spray applications at 0.166–0.205 kg ai/ha, 0 days PHI. The US GAP is for five spray applications at 0.196 kg ai/ha, 0 day PHI.

From nine raspberries trials (one trial in Canada and eight trials in the USA) at GAP, pyraclostrobin residues found, in ranked order, were: 0.40, 0.63, 0.78, 0.86, 0.88, 0.88, 1.04, 1.10 and 1.23 mg/kg.

The Meeting noted that residue levels from the same GAP were similar for blackberry and raspberry and agreed to combine all data to support a maximum residue level for blackberry and

raspberry. The ranked order of concentrations, median underlined, was 0.35, 0.40, 0.51, 0.63, 0.78, 0.86, 0.87, 0.88, 0.88, 1.04, 1.10, 1.23 and 1.32 mg/kg. The Meeting estimated a maximum residue level, an STMR and an HR value for pyraclostrobin in blackberry and raspberry of 3, 0.87 and 1.32 mg/kg, respectively. The recommendation for a maximum residue level of 3 mg/kg for raspberries replaces the previous recommendation of 2 mg/kg.

Blueberries

The Canadian GAP allows five spray applications at 0.166–0.205 kg ai/ha, 0 days PHI. The GAP of the USA consists of five spray applications at 0.196 kg ai/ha, and a 0 day PHI.

From 11 blueberries trials (three trials in Canada and eight trials in the US) at GAP, residues found, median underlined, were: 0.19, 0.30, 0.33, 0.35, 0.57, 0.78, 1.16, 1.37, 1.62, 2.02 and 2.08 mg/kg.

The Meeting estimated a maximum residue level of 4 mg/kg, an STMR of 0.78 mg/kg and HR of 2.08 mg/kg for pyraclostrobin in blueberries. The recommendation for a maximum residue level of 4 mg/kg for blueberries replaces the previous recommendation of 1 mg/kg.

Currants

The GAP of Germany allows a maximum of three spray applications at 0.067 kg ai/ha, with a PHI of 14 days. The GAP of Italy consists of two spray applications at 0.10 kg ai/ha, and a 3 day PHI.

A total of 16 trials on currants were available from France (2), Germany (12), Italy (1) and the UK (1).

Two trials from France and one trial from Italy were conducted on currants matching Italian GAP. The ranked order of residues was 0.25, 0.58 and 0.62 mg/kg.

Pyraclostrobin residues from German trials matching the GAP of that country, median underlined, were: 0.03, 0.04, 0.08, 0.10, 0.11, 0.17, 0.20, 0.20, 0.22, 0.27, 0.73 and 1.30 mg/kg.

Based on the German data, the Meeting estimated a maximum residue level of 2 mg/kg, an STMR of 0.185 mg/kg and an HR of 1.30 mg/kg.

Strawberries

The GAP of the USA allows a maximum of five spray applications at 0.168–0.196 kg ai/ha, with a 0 day PHI.

From 11 strawberries trials, at GAP, residues found, median underlined, were: 0.06, 0.12, 0.13, 0.15, 0.16, 0.20, 0.24, 0.31, 0.43, 0.73 and 0.75 mg/kg.

The Meeting estimated a maximum residue level of 1.5 mg/kg, an STMR of 0.20 mg/kg and HR of 0.75 mg/kg for pyraclostrobin in strawberries. The Meeting agreed to withdraw the previous recommendation of 0.5 mg/kg on strawberries.

Assorted tropical and sub-tropical fruits-inedible peel

Avocados

The US GAP allows two spray applications at 0.148 kg ai/ha, with a 0 day PHI.

No residue trials matching the GAP of the USA were available. Consequently, the Meeting agreed that a maximum residue level for avocado could not be recommended.

Papaya

The GAP of Brazil allows four spray applications at 0.010 kg ai/hL with a 7 day PHI.

From eight trials on papaya available from Brazil, residues found, median underlined, were: < 0.05 (7) and 0.06 mg/kg.

The Meeting agreed to estimate a maximum residue level of 0.15 mg/kg, an STMR of 0.05 mg/kg and an HR of 0.06 mg/kg. The recommendation for a maximum residue level of 0.15 mg/kg for papaya replaces the previous recommendation of 0.05* mg/kg. The Meeting agreed to withdraw the previous recommendation of 0.05* mg/kg on papaya.

Bulb vegetables

The 2004 JMPR evaluated numerous trials carried out in the USA and estimated maximum residue levels for bulb onion (0.2 mg/kg) and garlic (0.05* mg/kg). New data were available from supervised trials on bulb onion and spring onions conducted in Canada and the USA.

Bulb onions

The GAP of Canada allows a maximum of six spray applications at 0.128–0.166 kg ai/ha, at a PHI of 7 days. The US GAP consists of six spray applications at 0.112–0.168 kg ai/ha, with a 7 day PHI.

From 12 bulb onions trials (five trials in Canada and seven trials in US) at GAP, residues found, median underlined, were: < 0.02, 0.02(4), 0.03, 0.09, 0.11, 0.42, 0.43, 0.61 and 0.62 mg/kg.

The Meeting estimated a maximum residue level of 1.5 mg/kg, an STMR of 0.06 mg/kg and HR of 0.62 mg/kg for pyraclostrobin in bulb onions. The Meeting agreed to withdraw the previous recommendation of 0.2 mg/kg.

Garlic

The GAP of Brazil consists of four spray applications at 0.12 kg ai/ha with a 7 day PHI.

Seven trials on garlic were available from Brazil complying with the GAP of that country. Residues found, median underlined, were: < 0.02(4), 0.03, 0.05 and 0.09 mg/kg.

The Meeting agreed to estimate a maximum residue level of 0.15 mg/kg, an STMR of 0.02 mg/kg and an HR of 0.09 mg/kg, respectively. The Meeting agreed to withdraw the previous recommendation of 0.05* mg/kg on garlic.

Spring onions

The GAP of the US allows a maximum of six spray applications at 0.112–0.168 kg ai/ha, with a 7 day PHI.

Seven spring onions trials (one trial in Canada and six trials in US) complied with the US GAP. Residues found were: 0.05(2), 0.33, 0.42, 0.52, 0.58 and 0.60 mg/kg.

The Meeting estimated a maximum residue level of 1.5 mg/kg, an STMR of 0.42 mg/kg and HR of 0.60 mg/kg for pyraclostrobin in spring onions. Use of the OECD calculator resulted in a value of 1.5 mg/kg.

Fruiting vegetables, Cucurbits

The 2004 and 2006 JMPR evaluated numerous trials carried out in Brazil and the USA, and estimated maximum residue levels for cucumber (0.5 mg/kg) and summer squash (0.3 mg/kg). New data were available from supervised trials on cucumbers and summer squash from the USA. The US GAP for

cucurbits (including cucumber, summer squash and melons) consists of four spray applications at 0.112–0.224 kg ai/ha, with a 0 day PHI.

Cucumbers

The data from four field cucumbers trials conducted in the USA and complying with US GAP, were available. Residues found were: 0.02, 0.05, 0.06 and 0.10 mg/kg.

The 2004 and 2006 JMPR reported cucumber trials carried out in Brazil and US in line with GAP. The ranked order residues in cucumbers from US were 0.02, 0.03, 0.05, 0.06, 0.07, 0.09, 0.12, 0.14 and 0.41 mg/kg. Taking into account the new supervised trials from the USA, the ranked order of residues from US supervised trials, median underlined, were: 0.02(2), 0.03, 0.05(2), <u>0.06</u>(2), 0.07, 0.09, 0.10, 0.12, 0.14 and 0.41 mg/kg.

Squash, Summer

Data from four summer squash trials, complying with US GAP, were available. Residues found were: 0.09, 0.09, 0.12 and 0.22 mg/kg.

The 2004 JMPR reported US trials conducted with the maximum GAP. The residues in summer squash, in ranked order, were: 0.03, 0.07, 0.14, 0.17 and 0.18 mg/kg. Taking into account new supervised trials from the USA, in ranked order the combined residues were: 0.03, 0.07, 0.09(2), 0.12, 0.14, 0.17, 0.18 and 0.22 mg/kg.

Melons, except Watermelon

The 2006 JMPR evaluated eight trials carried out in US, and estimated a maximum residue levels for cantaloupe (0.2 mg/kg). New data were available from supervised trials on cantaloupe from the USA.

Six cantaloupe trials at GAP, where residues found were: 0.05, 0.09, 0.10, 0.12, 0.14 and 0.28 mg/kg.

The 2006 JMPR reported cantaloupe trials carried out in US in line with US GAP. The ranked order residues in cantaloupe from the USA were: 0.05, 0.08, 0.09, 0.10, 0.11, 0.12 (2) and 0.13 mg/kg. Taking into account the new supervised trials from US, the ranked order of residue concentrations were: 0.05(2), 0.08, 0.09(2), 0.10(2), 0.11, 0.12(3), 0.13, 0.14 and 0.28 mg/kg.

On the basis of the median ratio of 0.50 between flesh and whole fruit, from Spanish trials corresponding calculated pyraclostrobin residues in melon flesh from US trials, median underlined, were: 0.025 (2), 0.04, 0.045(2), <u>0.05</u> (2), <u>0.055</u>, 0.06(3), 0.065, 0.07, and 0.14 mg/kg.

The Meeting agreed to replace the previous the maximum residue level recommendation of 0.5 mg/kg on cucumber, and the previous recommendation of 0.3 mg/kg on cantaloupe (melon except watermelon) and 0.3 mg/kg on summer squash with a crop group estimate. Based on the cucumber residue data, the Meeting estimated a maximum residue level of 0.5 mg/kg for cucurbits.

For dietary intake calculation, the Meeting agreed to estimate an STMR of 0.06 mg/kg and HR of 0.41 mg/kg for fruiting vegetables, cucurbits edible peel and an STMR of 0.0525 mg/kg and HR of 0.14 mg/kg for fruiting vegetables, cucurbits-inedible peel, respectively.

Artichoke, globe

The GAP of France consists of 2 applications at a rate of 0.10 kg ai/ha and a 3 day PHI.

A total of 19 artichoke trials were available from France (7), Germany (2), Greece (1), Italy (3), the Netherlands (3) and Spain (3) complying with the French GAP. Residues found, median underlined, were: 0.04, 0.08, 0.13(3), 0.19, 0.22(2), 0.24, <u>0.25</u>, 0.27(2), 0.32, 0.33, 0.34, 0.36, 0.49, 0.60 and 1.44 mg/kg.

The Meeting estimated a maximum residue level of 2 mg/kg, an STMR of 0.25 mg/kg and an HR of 1.44 mg/kg, for pyraclostrobin in globe artichoke.

Cereal grains

The 2004 and 2006 the JMPR evaluated numerous trials carried out in Brazil, Canada, Europe and the USA, and estimated maximum residue levels for barley (0.5 mg/kg), maize (0.02* mg/kg), oats (0.5 mg/kg), spelt (0.2 mg/kg) and wheat (0.2 mg/kg). New data were available from supervised trials on barley, oat, rye, sorghum and wheat from the USA.

Oats

Canadian GAP consists of two spray applications at 0.075–0.10 kg ai/ha not later than the end of flowering. The US GAP allows two spray applications at 0.098–0.147 kg ai/ha not later than the beginning of flowering (Feekes 10.5, Zadok's 59).

Residues from eight US trials and four Canadian trials, complying with the GAP of the USA, in ranked order, were: < 0.02, 0.11, 0.14, 0.15, 0.26, 0.30, 0.33, 0.33, 0.36, 0.40, 0.40 and 0.59 mg/kg.

Barley

The GAP of the USA consists of two spray applications at 0.098–0.147 kg ai/ha not later than the beginning of flowering (Feekes 10.5, Zadok's 59).

Four additional barley trials were conducted in US at the new GAP, where residues found were: 0.39, 0.50, 0.56 and 0.62 mg/kg.

The Meeting noted that residue levels from trials complying with the same GAP were similar for barley and oats and agreed to combine the data sets to support a maximum residue level for barley and oats. The ranked order of residues, median underlined, were: < 0.02, 0.11, 0.14, 0.15, 0.26, 0.30, 0.33, <u>0.33</u>, <u>0.36</u>, 0.39, 0.40, 0.40, 0.50, 0.56, 0.59 and 0.62 mg/kg. The Meeting estimated a maximum residue level and an STMR for pyraclostrobin in barley and oats of 1 and 0.345mg/kg, respectively. The Meeting agreed to withdraw its previous recommendation for barley and oats of 0.5 mg/kg.

Wheat

The GAP of France GAP allows two spray applications at 0.25 kg ai/ha with a 35 day PHI. German GAP consists of two spray applications at 0.25 kg ai/ha, 35 day PHI. The GAP of the USA consists of two spray applications at 0.147 kg ai/ha not later than 25% flowering.

Four additional wheat trials were conducted in France, Germany, Greece and Spain, but not in line with French or German GAP.

Only one additional wheat trial was conducted in the USA at the new US GAP, where the residue found was < 0.02 mg/kg.

The Meeting noted that the 2004 JMPR recommended a maximum residue level of 0.2 mg/kg accommodates the new residue data from US for wheat grain.

Rye

The Meeting received the data from five supervised trials for rye. The Meeting considered that five trials were not sufficient to allow the estimation of a maximum residue level in rye. However, as rye is a registered crop in Germany with the same GAP as that of wheat and triticale the Meeting agreed to extrapolate the existing maximum residue level (0.2 mg/kg) and STMR (0.02 mg/kg) values of wheat to rye and triticale.

Sorghum

The GAP of the USA allows the use of pyraclostrobin as a seed treatment at 0.01–0.02 kg ai/100 kg seeds, and as a single spray application at 0.098–0.196 kg ai/ha, not later than 25% flowering.

In 12 sorghum trials complying with US GAP, residues found, median underlined, were: < 0.02(2), <u>0.02</u>(4), <u>0.03</u>(2), 0.05, 0.08, 0.10 and 0.34 mg/kg.

The Meeting estimated a maximum residue level of 0.5 mg/kg and an STMR of 0.025 mg/kg for pyraclostrobin in sorghum.

Tree nuts

The 2004 JMPR evaluated numerous trials carried out in Brazil and US, and estimated maximum residue levels for almond (0.02* mg/kg), pecan (0.02* mg/kg) and pistachio (1 mg/kg). New data were available from supervised trials on almonds from the USA.

Almonds

The US GAP allows four spray application at 0.133 kg ai/ha, with a 25 day PHI.

In ten almond trials complying with US GAP, residues found, median underlined, were: < <u>0.02</u> (10) mg/kg.

The 2004 JMPR reported five pecan trials carried out in US in line with GAP. All residue levels in pecan were < 0.02 mg/kg. Noting that the residue levels from the same GAP are similar on almonds and pecans, the Meeting agreed to combine the almond and pecan data in mutual support and estimate a maximum residue level of 0.02* mg/kg, an STMR of 0 mg/kg and an HR of 0.02 mg/kg for tree nuts except pistachio. The Meeting agreed to withdraw the previous recommendations of 0.02* mg/kg on almonds and pecans.

Oilseeds

The 2004 and 2006 JMPR evaluated numerous trials carried out in Brazil and the USA, and estimated maximum residue levels for peanuts (0.05* mg/kg) and sunflower seed (0.3 mg/kg). New data were available from supervised trials on rape seed and sunflowers in Canada and the USA.

Cotton

The US GAP allows three spray applications at 0.098–0.196 kg ai/ha, with a 30 day PHI.

In 12 trials carried out in the USA, treatments consisted of a single at-planting in-furrow application to cotton at 0.22–0.23 kg ai/ha, followed 96–159 days later by three broadcast foliar applications at 0.22–0.27 kg ai/ha. The ranked order of residues found, median underlined, were: < 0.02(3), 0.02(3), 0.03, 0.06(2), 0.08, 0.10 and 0.13 mg/kg.

Rape seed

The US GAP allows two spray applications at 0.222 kg ai/ha, with a 21 day PHI.

Four trials carried out in the USA and 12 trials carried out in Canada matched the US GAP. Residues found, median underlined, were: < 0.02(6), <u>0.03</u>(2), <u>0.04</u>(2), 0.06, 0.08, 0.09, 0.10, 0.14 and 0.20 mg/kg.

Sunflower seed

The US GAP allows two spray applications at 0.222 kg ai/ha, with a 21 day PHI.

In eight trials carried out in the USA, matching GAP, residues found, in ranked order with median underlined, were: < 0.04, 0.04, 0.05, 0.06 (2), 0.08, 0.12 and 0.2 mg/kg.

The 2006 JMPR reported eight sunflower trials carried out in the US in line with GAP. The ranked order of residue levels in sunflower seed was: < 0.02, 0.02, 0.04, 0.05, 0.06(2), 0.10 and 0.22 mg/kg. Noting that sunflower had the highest residues in the above oilseed group and the Meeting agreed to estimate a maximum residue level of 0.4 mg/kg and an STMR of 0.055 mg/kg for oil seed except peanuts. The previous recommendation (0.3 mg/kg) for sunflower seed should be withdrawn.

Animal feedstuffs

Alfalfa forage

The GAP of the USA consists of a maximum of three spray applications at 0.098–0.147 kg ai/ha with a 14 day PHI.

Twelve alfalfa trials were available complying with GAP. Residues in alfalfa forage, (median underlined) were: 1.15, 1.22, 1.23, 1.24, 1.56, 1.65, 1.90, 2.73, 3.20, 3.23, 4.70 and 6.61 mg/kg.

The Meeting estimated a median residue of 1.775 mg/kg and a highest residue of 6.61mg/kg for pyraclostrobin in alfalfa forage (fresh weight).

Alfalfa fodder

Supervised trials data were available from alfalfa hay from USA. Residues, in ranked order, on alfalfa hay were: 3.86, 4.23, 4.45, 4.92, 6.81, 7.10, 7.81, 9.49, 9.84, 11.37, 12.87 and 19.83 mg/kg.

On a dry-weight basis (dry matter (DM) = 89%), pyraclostrobin residues in dry alfalfa hay, were: 4.34, 4.75, 5.00, 5.53, 7.65, 7.98, 8.78, 10.66, 11.06, 12.78, 14.46 and 22.28 mg/kg.

The Meeting estimated a maximum residue level of 30 mg/kg, a median residue of 8.38 mg/kg and a highest residue of 22.28 mg/kg for pyraclostrobin in alfalfa fodder.

Sorghum forage

The US GAP allows a seed treatment at 0.01–0.02 kg ai/100 kg seeds plus one foliar spray application at 0.098–0.196 kg ai/ha, not later than 25% flowering.

Supervised trials data were available for sorghum forage from the USA. The ranked order of concentrations on forage (fresh weight), median underlined, were: < 0.02, 0.12, 0.14, 0.22, 0.26, 0.28, 0.33, 0.44, 0.45, 0.92, 1.08 and 1.33 mg/kg.

The Meeting estimated a median and a highest residue value for pyraclostrobin in sorghum forage (fresh weight) of 0.305 and 1.33 mg/kg, respectively.

Straw and fodder of cereal grain (dry)

Oats straw and fodder

The GAP of the US allows two spray applications at 0.098–0.147 kg ai/ha not later than the beginning of flowering (Feekes 10.5, Zadok's 59).

Eight trials were conducted in the US and four trials were conducted in Canada matching US GAP. The ranked order of residues found on oat hay were: 2.12, 2.92, 2.93, 4.40, 4.86, 5.31, 5.50, 6.04, 6.11, 6.81, 7.67 and 12.96 mg/kg.

On a dry-weight basis (DM = 90%), pyraclostrobin residues in dry oats hay, were: 2.36, 3.24, 3.26, 4.89, 5.40, 5.90, 6.11, 6.71, 6.79, 7.57, 8.52and 14.40 mg/kg.

Supervised trials data were available from oat straw from USA. The ranked order of concentrations on oat straw was: 2.32, 2.33, 2.66, 2.98, 3.19, 3.23, 3.57, 4.06, 4.76, 5.02, 6.62 and 11.08 mg/kg.

On a dry-weight basis (DM = 90%), pyraclostrobin residues in oats straw and fodder, dry, were: 2.58, 2.59, 2.96, 3.31, 3.54, 3.59, 3.97, 4.51, 5.29, 5.58, 7.36 and 12.31 mg/kg.

Barley straw

The US GAP allows two spray applications at 0.098–0.147 kg ai/ha, not later than the beginning of flowering (Feekes 10.5, Zadok's 59).

Four new barley trials were conducted in US complying with GAP. Residues found were: 1.49, 2.14, 2.26 and 3.00 mg/kg.

Wheat straw

Spanish and Greek GAPs were not available. The GAP of France consists of two spray applications at 0.25 kg ai/ha, 35 day PHI. German GAP is two spray applications at 0.25 kg ai/ha, no later than BBCH 61 (beginning of flowering). US GAP allows two spray applications at 0.147 kg ai/ha not later than 25% flowering.

Four wheat trials were available from France, Germany, Greece and Spain but did not match not French or German GAP.

Only one additional wheat trial was conducted in US matching US GAP, where the residue was 0.14 mg/kg.

The Meeting noted that the additional data submitted were insufficient for the estimation of a new maximum residue level.

Sorghum straw

The US GAP allows seed treatment at 0.01–0.02 kg ai/100 kg seeds, and one spray application at 0.098–0.196 kg ai/ha, not later than 25% flowering.

The ranked order of concentrations on sorghum straw, median underlined, were: < 0.02, 0.04(2), 0.05, 0.06 (2), 0.08(2), 0.09, 0.11, 0.19 and 0.57 mg/kg.

On a dry-weight basis (DM = 88%), pyraclostrobin residues in dry sorghum straw were: < 0.02, 0.05(2), 0.06, 0.07(2), 0.09(2), 0.10, 0.13, 0.22 and 0.65 mg/kg.

The Meeting noted the 2004 JMPR recommended a maximum residue level of 30 mg/kg for dry straw and fodder of cereal grain and that this recommendation covers the highest residue from the data submitted on oats, barley straw, wheat straw and sorghum straw to the current Meeting.

Almonds hulls

The GAP of the US GAP allows four spray application at 0.133 kg ai/ha, 25 day PHI.

Supervised trials data for almond hulls were available from USA. The ranked order of concentrations on hulls, median underlined, were: 1.06, 1.09, 1.14, 1.14, 1.23, 1.56, 1.61, 3.10, 3.12 and 4.79 mg/kg.

On a dry-weight basis (DM = 90%), pyraclostrobin residues in almond hulls, dry, were: 1.18, 1.21, 1.27, 1.27, 1.37, 1.73, 1.79, 3.44, 3.47 and 5.32 mg/kg.

The Meeting estimated a median of 1.55 mg/kg and a highest residue of 5.32 mg/kg for pyraclostrobin in almond hulls. The previous maximum residue level recommendation (2 mg/kg) for almond hulls is withdrawn as the policy is to use the information in dietary burden calculations, but not to propose maximum residue levels for almond hulls which, it is understood, are not traded internationally.

Cotton gin by-products

The US GAP allows three spray applications at 0.098–0.196 kg ai/ha, with a 30 day PHI.

Six trials carried out in the USA in which a single at-planting in-furrow application to cotton was made at 0.22–0.23 kg ai/ha, then followed 96–159 days later by three broadcast foliar applications at 0.22–0.27 kg as/ha. The ranked order of residues, median underlined, were: 0.94, 1.54, 1.56, 1.59, 2.60 and 16.73 mg/kg. Taking into account that a single in-furrow application at planting would not affect the residues and based on the residue data derived from trials performed in accordance with the US GAP, the Meeting estimated a median and highest residue levels of 1.575 mg/kg and 16.73 mg/kg, respectively.

Fate of residues during processing

The Meeting received information on the fate of pyraclostrobin residues during the processing of oranges for juice, pomace and oil; plums for puree and prunes; cherries for canned cherries and juice; strawberries for canned strawberries and jam; barley for brewing malt, malt germ, beer and pearl barley; wheat for flour, bran and germ; rape seed for meal and refined oil; sunflower for meal and refined oil; soya bean for hulls, meal and refined oil.

Calculated processing factors are summarized in the following table. Factors are indicated with a "<" (less than) sign when the residue in the processed commodity is below the LOQ of the analytical method. The calculation is then made on the LOQ of the analytical method and the residue concentration of the RAC (raw agricultural commodity).

Raw agricultural commodity (RAC)	Processed commodity	Median or best estimate	RAC STMR/HR	STMR-P/HR-P
Orange	Peel	4.60	0.485	2.23
	Pomace (wet)	1.41		0.68
	Pomace (dry)	6.95		3.37
	Juice (pasteur.)	0.08		0.04
	marmalade	0.18		0.09
	Canned orange	0.11		0.05
	Oil	6.24	0.34	3.03
Plums	Puree	1.87	0.09	0.17
	Prune	4.59	0.09/0.40	0.41/1.84
Cherries	Canned cherries	1.00	0.51	0.51
	Juice	0.16		0.08
Currants	Juice (pasteurised)	0.035	0.185	0.013
	Currants (canned)	0.375		0.069
	Jame	0.415		0.077
Strawberries	Canned fruit	0.40	0.20	0.08
	Jam	0.21		0.04
Barley	Brewing malt	1.17	0.345	0.40
	Malt germ	2.33		0.80
	beer	< 0.67		0.23
	Pearl barley	< 0.67		0.23
Wheat	Bran	0.91	0.02	0.018
Rape seed (canola)	Meal	1.00	0.04	0.04
	Refined oil	1.33		0.053

Raw agricultural commodity (RAC)	Processed commodity	Median or best estimate	RAC STMR/HR	STMR-P/HR-P
Cotton seed	Meal	0.18	0.025	0.0045
	Hulls	0.18		0.0045
	Refined oil	0.18		0.0045
Soya bean	Hulls	1.67	0.02	0.03
	Meal	< 0.67		0.01
	Refined oil	< 0.67		0.01

The Meeting estimated a maximum residue level of 10 mg/kg and STMR-P of 3.03 mg/kg for pyraclostrobin in orange oil.

Residues in animal commodities

Farm animal dietary burden

The Meeting estimated the dietary burden of pyraclostrobin in livestock on the basis of the diets listed in OECD Feed Table 2009 (available from the FAO website: http//www.fao.org/agriculture/crops/core-themes/theme/pests/pm/jmpr/jmpr-docs/en/). Based on new data, the dietary burdens are higher than those by the 2004 JMPR. Calculation from highest residue, STMR and STMP-P values provides the levels in feed suitable for estimating maximum residue levels, while calculation from STMR and STMR-P values for feed is suitable for estimating STMR values for animal commodities.

Estimated maximum and mean dietary burdens of farm animals

Dietary burden calculations for beef cattle, dairy cattle, broilers and layer are provided in Annex 6.

The summarized calculations and the highest dietary burdens are selected for maximum residue level and STMR estimates on animal commodities.

		Animal dietary burden, pyraclostrobin, ppm of dry matter diet			
		US-CAN	EU	Australia	Japan
Beef cattle	Max	7.73	21.91	26.10 [a]	2.44
	Mean	1.64	11.86	15.59 [b]	1.05
Dairy cattle	Max	12.56	22.44	26.10 [c]	8.02
	Mean	3.83	14.19 [d]	13.63	2.52
Poultry - broiler	Max	0.27	0.26	0.08	0.97
	Mean	0.27	0.26	0.08	0.28
Poultry - layer	Max	0.27	5.70 [e]	0.08	0.02
	Mean	0.27	3.62 [f]	0.08	0.02

[a] Highest maximum beef or dairy cattle dietary burden suitable for maximum residue level estimates for mammalian meat.

[b] Highest mean beef or dairy cattle dietary burden suitable for STMR estimates for mammalian meat.

[c] Highest maximum dairy cattle dietary burden suitable for maximum residue level estimates for mammalian milk.

[d] Highest mean dairy cattle dietary burden suitable for STMR estimates for mammalian milk.

[e] Highest maximum poultry dietary burden suitable for maximum residue level estimates for poultry meat and eggs.

[f] Highest mean poultry dietary burden suitable for STMR estimates for meat and eggs.

Farm animal feeding

The lactating goat metabolism study was used to evaluate the dietary burden for ruminants by 2004 JMPR. In this metabolism study, in which ^{14}C-pyraclostrobin equivalent to 12–50 ppm in the diet was orally administered to lactating goats for 5 consecutive days, the highest residue (0.082 mg/kg) was found in fat, 0.047 mg/kg in milk, 0.089 mg/kg in muscle, 0.07 mg/kg in liver and 0.074 mg/kg in kidney.

The resulting maximum dietary burdens for beef and dairy cattle with residues in additional feedstuffs were slightly different to those with previous residues in feedstuffs using the OECD animal feeds table. The resulting maximum dietary burdens for poultry using the OECD animal feeds table is much higher than that of previous estimates. However, the Meeting noted that in the study of metabolism in laying hens, pyraclostrobin was not detected in tissues (< 0.002 mg/kg) or eggs (< 0.002 mg/kg) at a feeding level of 12 mg/kg, which was over 2 times higher than the calculated dietary burden (5.70 ppm).

The Meeting agreed that the residues based on new animal dietary burdens were covered by the existing recommendations for animal commodities.

DIETARY RISK ASSESSMENT

Long-term intake

The evaluation of pyraclostrobin resulted in recommendations for maximum residue level and STMR values for raw and processed commodities. Data on consumption were available for 77 food commodities and were used to calculate dietary intake. The results are shown in Annex 3.

The International Estimated Daily Intakes (IEDIs) of pyraclostrobin, based on the STMRs estimated, were 1–9% of the maximum ADI of 0.03 mg/kg bw for the thirteen GEMS/Food cluster diets. The Meeting concluded that the long-term intake of residues of pyraclostrobin resulting from its uses that have been considered by JMPR is unlikely to present a public health concern.

Short-term intake

The IESTI of pyraclostrobin calculated on the basis of the recommendations made by the JMPR represented 50% of the ARfD (0.05 mg/kg bw).

The Meeting therefore concluded that the short-term intake of pyraclostrobin residues, when used in ways that have been considered by the JMPR, is unlikely to present a public health concern.

5.21 SAFLUFENACIL (251)

TOXICOLOGY

Saflufenacil is the International Organization for Standardization (ISO)–approved name for *N*′-[2-chloro-4-fluoro-5-(3-methyl-2,6-dioxo-4-(trifluoromethyl)-3,6-dihydro-1(2H)-pyrimidinyl)benzoyl]-*N*-isopropyl-*N*-methylsulfamide (International Union of Pure and Applied Chemistry), for which the Chemical Abstracts Service number is 372137-35-4. Saflufenacil is a new herbicide from the uracil family of herbicides, acting as a protoporphyrinogen IX oxidase (PPO) inhibitor. Saflufenacil has not been evaluated previously by the Joint FAO/WHO Meeting on Pesticide Residues and was reviewed at the present Meeting at the request of the Codex Committee on Pesticide Residues.

All pivotal studies with saflufenacil were certified as complying with good laboratory practice unless otherwise stated.

Biochemical aspects

Absorption, distribution, excretion and metabolism of orally administered (gavage) saflufenacil were studied in male and female rats using [phenyl-U-^{14}C]- and [uracil-4-^{14}C]-labelled saflufenacil. The time to reach the maximum concentration of radioactive material in plasma was less than 1 hour. Thereafter, the plasma level of radioactivity declined rapidly, and only residual radioactivity was detected at 168 hours (0.2% of the administered dose). The area under the plasma concentration–time curve values indicated a sex difference, with up to 3-fold higher internal exposures for males than for females. Saflufenacil was rapidly and extensively (> 97%) absorbed from the gastrointestinal tract and rapidly excreted from the body in urine and faeces (> 97% of the administered dose) within 168 hours. The majority of excretion occurred in the first 24–48 hours, and excretion was complete by 96 hours. In 48 hours, bile duct–cannulated rats excreted approximately 76% and 60% of the administered dose in the bile in males and females, respectively. The urinary and biliary excretion data suggested that significant enterohepatic circulation of saflufenacil had occurred. Within 1 hour after oral administration of [^{14}C]saflufenacil, the highest radioactivity was found in the liver, gastrointestinal tract, liver, kidney, lung and thyroid.

The unchanged parent compound accounted for 10.9–48.2% and 48.7–88.9% of the administered dose for male and female rats, respectively. The predominant metabolic reactions of saflufenacil in the rat were demethylation of the uracil ring system, stepwise degradation of the *N*-methyl-*N*-isopropylsulfonamide to form an unsubstituted sulfonamide and cleavage of the uracil ring with loss of a three-carbon fragment to form an *N*-methylurea attached to the phenyl ring. The major metabolites identified in the urine of male and female rats were M800H01 (3.5–9.1% of the dose) and M800H07 (0.6–4.6% of the dose), respectively. In faeces, the parent compound accounted for 3–16% of the dose. The main metabolite in faeces was M800H01, which amounted to 18–44% and 1–3% of the dose in male and female rats, respectively.

Toxicological data

The median lethal dose (LD_{50}) in rats treated orally and dermally with saflufenacil was greater than 2000 mg/kg body weight (bw). The median lethal concentration (LC_{50}) in rats treated by inhalation (nose only) was greater than 5.3 mg/L. Saflufenacil was minimally irritating to the eyes and non-irritating to the skin of rabbits. Saflufenacil was not a skin sensitizer in guinea-pigs, as determined by the Magnusson and Kligman (maximization) test.

Short-term toxicity studies in mice, rats and dogs showed similar profiles of toxicity with respect to blood and liver. Males were more susceptible than females. The haematological effects were mostly related to the pesticidal mode of action of saflufenacil (i.e. inhibition of PPO). Effects indicative of this included increased total porphyrins in urine, faeces and liver, as well as increased

total bilirubin and urinary bilinogen. Decreased haematological parameters indicative of microcytic hypochromic anaemia (MHA) are consistent with this mode of action. Indicators of MHA included increased normoblasts, reticulocytes and polychromasia, increased microcytosis and anisoscytosis, increased spleen weight, extramedullary haematopoiesis in liver and spleen (iron storage) and erythroid hyperplasia in bone marrow. At higher doses, an indication of liver toxicity, which included increased serum liver enzymes, centrilobular fatty change and lymphoid cell infiltration, was observed.

In 28-day and 90-day toxicity studies in mice, MHA, altered clinical chemistry (increased alanine aminotransferase, aspartate aminotransferase, urea and total bilirubin) (28-day study) and liver pathology (increased weight and centrilobular fatty change) were observed. In addition, decreased body weight and body weight gain were observed in the 90-day toxicity study. The no-observed-adverse-effect level (NOAEL) in the 28-day and 90-day studies of toxicity in mice was 50 ppm (equal to 12.5 mg/kg bw per day). The lowest-observed-adverse-effect level (LOAEL) in the 28-day and 90-day toxicity studies in mice was 150 ppm (equal to 36.7 mg/kg bw per day).

In a 28-day toxicity study in rats, the NOAEL was 150 ppm (equal to 13.4 mg/kg bw per day), based on MHA at 1350 ppm (equal to 110 mg/kg bw per day). In addition to MHA, decreased total protein and decreased globulin were observed in a 90-day toxicity study in rats. The NOAEL in the 90-day toxicity study was 150 ppm (equal to 10.5 mg/kg bw per day), and the LOAEL was 450 ppm (equal to 32.3 mg/kg bw per day).

In a 28-day toxicity study in dogs, the NOAEL was 30 mg/kg bw per day, based on MHA at 100 mg/kg bw per day. The NOAEL in a 90-day toxicity study in dogs was 10 mg/kg bw per day, based on MHA in both sexes at 50 mg/kg bw per day. At the highest dose tested, more severe anaemia was seen, along with decreased body weight and body weight gain and dark brown/red brown discoloured faeces. In a 1-year toxicity study in dogs, the NOAEL was 20 mg/kg bw per day, based on discoloured faeces, lower body weight in males, decreased feed consumption, MHA, increased serum alkaline phosphatase activity and lowered total blood protein and albumin levels at 80 mg/kg bw per day. The overall NOAEL for the 90-day and 1-year toxicity studies in dogs was 20 mg/kg bw per day.

The carcinogenic potential of saflufenacil was studied in mice and rats. In mice, there was unusually high mortality in controls and all dose groups after approximately 16 months (485 days) of treatment. However, survival was adequate to assess the carcinogenic potential of saflufenacil. The early mortality was greatest in the control and low-dose male mice and was clearly unrelated to test substance treatment. There were no treatment-related effects on clinical signs of toxicity, mortality, body weight and body weight gain, feed consumption and feed efficiency, gross pathology or organ weights. The NOAEL was 25 ppm (equal to 4.6 mg/kg bw per day), based on MHA seen in the satellite group (killed at 10 months) at 75 and 150 ppm (equal to 13.8 and 38.1 mg/kg bw per day) in males and females, respectively. No treatment-related tumours were observed in mice.

In a 2-year study of toxicity and carcinogenicity in rats, the NOAEL was 100 ppm (equal to 6.2 mg/kg bw per day), on the basis of decreased body weight and body weight gains (males), anogenital region smeared with urine in females and MHA in males and females at 500 ppm (equal to 24.2 mg/kg bw per day). No treatment-related tumours were observed in rats.

The Meeting concluded that saflufenacil was not carcinogenic in mice or rats.

Saflufenacil gave a negative response in an adequate range of in vitro and in vivo genotoxicity tests, except for a positive finding that occurred with metabolic activation in an in vitro chromosomal aberration assay in mammalian cells. In contrast, no clastogenicity was observed in an in vivo mouse micronucleus assay.

The Meeting concluded that saflufenacil was unlikely to be genotoxic in vivo.

On the basis of the absence of genotoxicity in vivo and the absence of carcinogenicity in mice and rats, the Meeting concluded that saflufenacil is unlikely to pose a carcinogenic risk to humans.

In a two-generation study of reproductive toxicity in rats, reproductive parameters were not affected at the highest dose tested (50 mg/kg bw per day). The NOAEL for parental systemic toxicity was 15 mg/kg bw per day, based on adverse effects on feed intake, body weight gain and MHA at 50 mg/kg bw per day. The NOAEL for offspring toxicity was 15 mg/kg bw per day, based on the increased number of stillborn pups and increased pup mortality during the early phase of lactation, reduced pup weight gains and indications of MHA at 50 mg/kg bw per day.

In a developmental toxicity study in rats, the NOAEL for maternal toxicity was 20 mg/kg bw per day, based on MHA at 60 mg/kg bw per day. The developmental toxicity NOAEL was 5 mg/kg bw per day, based on decreased fetal body weights in males and females, an increased incidence of skeletal anomalies and delayed ossification at 20 mg/kg bw per day. In a developmental toxicity study in rabbits, the NOAEL for maternal toxicity was 200 mg/kg bw per day, based on increased mortality, clinical signs (lateral positioning, poor general state, abortion, blood in bedding, discoloured and no urination and reduced or no defecation) and increased necropsy findings (stomach ulcerations, lack of faeces, increase in pale livers and kidneys, empty stomachs, enlarged bladders and assorted findings on implantations in dams that aborted or were moribund) at 600 mg/kg bw per day. The developmental toxicity NOAEL was 200 mg/kg bw per day, based on a decrease in total litters and total live fetuses and live fetuses per dam at 600 mg/kg bw per day.

The Meeting concluded that saflufenacil is not teratogenic in rats or rabbits.

In an acute neurotoxicity study in rats via gavage, no effects on functional observational battery, motor activity or neuropathology were observed at doses up to 2000 mg/kg bw. For systemic toxicity, the NOAEL was 5000 mg/kg bw for male rats, based on the decreased motor activity, representing mild and transient systemic toxicity, likely due to general malaise, at 2000 mg/kg bw, the highest dose tested.

In a 90-day dietary study of neurotoxicity in rats, no effects on functional observational battery parameters, motor activity or neuropathology were observed in males and females at doses up to 1000 and 1350 ppm, respectively (equal to 66.2 and 101 mg/kg bw per day for male and female rats, respectively). The NOAEL for systemic toxicity was 250 ppm (equal to 16.6 mg/kg bw per day), based on MHA at 1000 ppm (equal to 66.2 mg/kg bw per day).

In an immunotoxicity study, no evidence of immunotoxicity was observed in male mice treated with saflufenacil in the diet for 4 weeks at doses up to 250 ppm (equal to 52 mg/kg bw per day).

Two dietary toxicity studies were conducted in rats to evaluate the effects of saflufenacil administration on porphyrin levels in plasma, urine, faeces and liver and also to evaluate the reversibility of porphyrin levels. Total porphyrin measurements showed significantly higher total porphyrin levels in the faeces of the males at 5 and 25 ppm (equivalent to 0.5 and 2.5 mg/kg bw per day, respectively) and of the females at 25 ppm (equivalent to 2.5 mg/kg bw per day). These findings are considered to be treatment related and are a consequence of increased accumulation and excretion of porphyrins due to inhibition of PPO by saflufenacil. In the recovery study, during a treatment-free recovery period of 2 weeks, the statistically significant increases in total porphyrins in the faeces of both sexes returned to normal. Most of the haematological parameters indicated their complete reversibility.

In studies in rats, bioavailability and toxicity were comparable between hydrated and anhydrate crystalline forms of saflufenacil.

An in vitro study was conducted to investigate the inhibitory effects of saflufenacil on PPO in the liver mitochondrial preparations from female rats, mice, rabbits and human donors. The results of this study indicated that rats are approximately 14 and 16 times more susceptible than humans and rabbits, respectively, to PPO inhibition. This difference in species susceptibility is consistent with the absence of haematological effects in rabbits at doses at least 14 times the NOAEL for these effects in rats.

No adverse effects due to occupational exposure to saflufenacil were reported in employees having contact with the active substance.

The Meeting concluded that the existing database on saflufenacil was adequate to characterize the potential risk to fetuses, infants and children.

Toxicological evaluation

The Meeting established an acceptable daily intake (ADI) of 0–0.05 mg/kg bw on the basis of a NOAEL of 4.6 mg/kg bw per day in the carcinogenicity study in mice, based on MHA at 13.8 mg/kg bw per day, and using a safety factor of 100. This ADI was supported by the NOAEL of 6.2 mg/kg bw per day observed in the chronic toxicity and carcinogenicity study in rats, on the basis of MHA and anogenital region smeared with urine in female rats seen at 31.4 mg/kg bw per day. It is further supported by the NOAEL of 5 mg/kg bw per day observed in the developmental toxicity study in rats on the basis of increased skeletal anomalies at 20 mg/kg bw per day.

The Meeting concluded that it was not necessary to establish an acute reference dose (ARfD) for saflufenacil in view of its low acute toxicity and the absence of developmental toxicity or any other toxicological effects that would be likely to be elicited by a single dose. MHA is not considered to be an appropriate end-point to establish an ARfD because it is not expected to appear after single exposure due to the mechanism of toxicity by which it is produced.

A toxicological monograph was prepared.

Levels relevant to risk assessment

Species	Study	Effect	NOAEL	LOAEL
Mice	Sixteen-month study of toxicity and carcinogenicity[a]	Toxicity	25 ppm, equal to 4.6 mg/kg bw per day	75 ppm, equal to 13.8 mg/kg bw per day
		Carcinogenicity	75 ppm, equal to 13.8 mg/kg bw per day[b]	—
Rat	Two-year study of toxicity and carcinogenicity[a]	Toxicity	100 ppm, equal to 6.2 mg/kg bw per day	500 ppm, equal to 24.2 mg/kg bw per day
		Carcinogenicity	500 ppm, equal to 24.2 mg/kg bw per day[b]	—
	Two-generation study of reproductive toxicity[a]	Parental toxicity	15 mg/kg bw per day	50 mg/kg bw per day
		Reproductive toxicity	50 mg/kg bw per day[b]	—
		Offspring toxicity	15 mg/kg bw per day	50 mg/kg bw per day
	Developmental toxicity study[c]	Maternal toxicity	20 mg/kg bw per day	60 mg/kg bw per day
		Embryo and foetal toxicity	5 mg/kg bw per day	20 mg/kg bw per day
	Acute neurotoxicity study[c]	Systemic toxicity	500 mg/kg bw	2000 mg/kg bw
		Neurotoxicity	2000 mg/kg bw[b]	—
Rabbit	Developmental toxicity study[c]	Maternal toxicity	200 mg/kg bw per day	600 mg/kg bw per day
		Embryo and fetal toxicity	200 mg/kg bw per day	600 mg/kg bw per day
Dog	Ninety-day and 1-year studies of toxicity[a,d]	Toxicity	20 mg/kg bw per day	50 mg/kg bw per day

[a] Dietary administration.

[b] Highest dose tested.

[c] Gavage administration.

[d] Two or more studies combined.

Estimate of acceptable daily intake for humans

0–0.05 mg/kg bw

Estimate of acute reference dose

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 saflufenacil

Absorption, distribution, excretion and metabolism in mammals	
Rate and extent of oral absorption	Rapidly absorbed, complete within 168 h
Dermal absorption	No data available
Distribution	Widely distributed in tissues; highest residues in liver, gastrointestinal tract, liver, kidney, lung and thyroid
Potential for accumulation	None
Rate and extent of excretion	Rapid and extensive
Metabolism in animals	Moderately metabolized
Toxicologically significant compounds (animals, plants and environment)	Saflufenacil
Acute toxicity	
Rat, LD_{50}, oral	> 2000 mg/kg bw (female rats)
Rat, LD_{50}, dermal	> 2000 mg/kg bw
Rat, LC_{50}, inhalation	> 5.3 mg/L (4 h exposure, nose only)
Rabbit, dermal irritation	Non-irritating
Rabbit, ocular irritation	Minimally irritating
Guinea-pig, dermal sensitization (Magnusson and Kligman test)	Not a sensitizer
Short-term studies of toxicity	
Target/critical effect	MHA (mice, rats and dogs)
Lowest relevant oral NOAEL	10.5 mg/kg bw per day (90-day study of toxicity in rats)
Lowest relevant dermal NOAEL	1000 mg/kg bw per day (rats)
Lowest relevant inhalation NOAEC	Not available
Long-term studies of toxicity and carcinogenicity	
Target/critical effect	MHA

Lowest relevant NOAEL	4.6 mg/kg bw per day (carcinogenicity study in mice)
Carcinogenicity	Not carcinogenic in mice and rats
Genotoxicity	
	Not genotoxic in vivo
Reproductive toxicity	
Reproduction target/critical effect	None
Lowest relevant reproductive NOAEL	50 mg/kg bw per day (rats; highest dose tested)
Developmental target/critical effect	Developmental toxicity, including skeletal anomalies in rats
Lowest relevant developmental NOAEL	5 mg/kg bw per day (rats)
Neurotoxicity/delayed neurotoxicity	
Neurotoxicity target/critical effect	Not neurotoxic (acute and 90-day studies in rats)
Lowest relevant neurotoxicity NOAEL	66.2 mg/kg bw per day, highest dose tested
Mechanistic data	
	Mechanistic studies indicating species differences in PPO inhibition and reversibility of porphyria
Medical data	
	No adverse effects reported

Summary

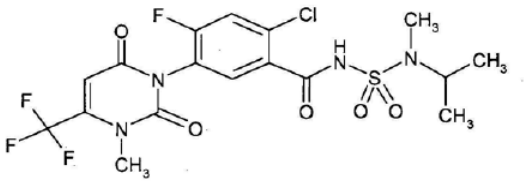
	Value	Study	Safety factor
ADI	0–0.05 mg/kg bw	Carcinogenicity study in mice supported by 2-year study of toxicity and carcinogenicity in rats and developmental toxicity study in rats	100
ARfD		Not necessary	

RESIDUE AND ANALYTICAL ASPECTS

Saflufenacil is a new herbicide applied for contact and residual control of broad leaf weeds and is used in many crops in pre- and post-emergence, or desiccation. It is evaluated by the JMPR for the first time.

The Meeting received information from the manufacturer on metabolism in animals, plants, soil and water, analytical methods, effect of storage and processing and animal transfer studies. Residue data derived from supervised trials on a variety of crops, including fruits, tree nuts, potatoes, legume vegetables, cereals, oil seeds, coffee, sugar cane and follow up crops were also submitted.

The IUPAC name of saflufenacil is N'-[2-chloro-4-fluoro-5-(3-methyl-2,6-dioxo-4-(trifluoromethyl)-3,6-dihydro-1(2H)-pyrimidinyl)benzoyl]-N-isopropyl-N-methylsulfamide



Metabolism

The metabolism and distribution of saflufenacil in plants and animals were investigated using the active substance radio labelled in the phenyl ring and the uracil ring.

The following abbreviations are used for the metabolites discussed:

Metabolite Code	Chemical Name
M800H01	N'-[2-chloro-4-fluoro-5-(3-methyl-2,6-dioxo-4-(trifluoromethyl)-3,6-dihydro-1(2H)-pyrimidinyl)benzoyl]-N-isopropylsulfamide
M800H02	N'-[2-chloro-5-(2,6-dioxo-4-(trifluoromethyl)-3,6-dihydropyrimidin-1(2H)-yl)-4-fluorobenzoyl]-N-isopropyl-N-methylsulfamide
M800H03	N'-[2-chloro-5-(2,6-dioxo-4-(trifluoromethyl)-3,6-dihydro-1(2H)-pyrimidinyl)-4-fluorobenzoyl]-N-isopropyl-N-methylsulfamide
M800H04	(2E)-3-{4-chloro-2-fluoro-5-[({[isopropyl(methyl)amino]sulfonyl}amino) carbonyl]phenyl)amino]carbonyl(methylamino)}-4,4,4-trifluorobut-2-enoic acid
M800H05	N'-[2-chloro-4-fluoro-5-(3-methyl-2,6-dioxo-4-(trifluoromethyl)-3,6-dihydro-1(2H)-pyrimidinyl)benzoyl]-sulfamide
M800H07	N-{4-chloro-2-fluoro-5-[({[isopropyl(methyl)amino]sulfonyl}amino)carbonyl]phenyl}-N'-methylurea
M800H08	N'-[2-chloro-4-fluoro-5-(3-methyl-2,6-dioxo-4-(trifluoromethyl)tetrahydro-1(2H)-pyrimidinyl)benzoyl]-N-isopropyl-N-methylsulfamide
M800H09	N'-[2-chloro-5-(2,6-dioxo-4-(trifluoromethyl)-3,6-dihydro-1(2H)-pyrimidinyl)-4-fluorobenzoyl]-sulfamide
M800H10	N'-[2-chloro-5-(2,6-dioxo-4-(trifluoromethyl)-3,6-dihydro-1(2H)-pyrimidinyl)-4-fluorobenzoyl]-N-methylsulfamide
M800H11	N'-[2-chloro-5-(2,6-dioxo-4-(trifluoromethyl)-3,6-dihydro-1(2H)-pyrimidinyl)-4-fluorobenzoyl]-N-isopropylsulfamide
M800H15	N-{4-chloro-2-fluoro-5-[({[isopropyl(methyl)amino]sulfonyl}amino)carbonyl]phenyl}-4-4-4-trifluoro-3,3-dihydroxybutanamide
M800H17	N-{4-chloro-2-fluoro-5-[({[isopropyl(methyl)amino]sulfonyl}amino)carbonyl]phenyl}-N-(methylamino)carbonyl-4,4,4-trifluoro-3-oxo-butanamide
M800H18	N-{4-chloro-2-fluoro-5-[({[isopropylamino]sulfonyl}amino)carbonyl]phenyl}-N'-methylurea
M800H22	3-[({4-chloro-2-fluoro-5-[({[isopropyl(methyl)amino]sulfonyl}amino)carbonyl]anilino}carbonyl) (methyl)amino]-4,4,4-trifluorobutanoic acid
M800H26	N-Methyl-2,2,2-trifluoroacetamide
M800H29 (TFA)	Trifluoroacetic acid (or its Na salt)

Metabolite Code	Chemical Name
M800H31	3-[carboxy(methyl)amino]-4,4,4-trifluorobutanoic acid
M800H33	Trifluoroacetone
M800H34	N-{4-chloro-2-fluoro-5-[([aminosulfonyl]amino)carbonyl] phenyl}-N'-methylurea
M800H35	N-[4-chloro-2-fluoro-5-({[(isopropylamino)sulfonyl]amino} carbonyl)phenyl]urea
M800H36	Not IUPAC classified due to ambiguous hydroxyl position
M800H37	N-{4-chloro-2-fluoro-5-[({[ethyl(methyl)amino]sulfonyl}amino) carbonyl]phenyl}-N'-methylurea

Animal metabolism

Animal metabolism studies were conducted with saflufenacil on lactating goats and laying hens. The metabolism in rats performed as part of toxicological studies is reported under toxicology.

Lactating goats

Two-year old lactating goats dosed with [phenyl-U-^{14}C] saflufenacil were administered 18.4 mg/day, equivalent to 13.9 ppm in the feed. The animal dosed with [uracil-4-^{14}C] saflufenacil received a dose of 17.8 mg/day, equivalent to 13.4 ppm in the feed.

Production of urine and faeces was recorded once daily and production of milk twice daily (in the afternoon and in the morning before dosing). Animals were sacrificed within 24 h of the last dose. Liver, kidney, blood, adipose tissue, muscle, GI tract with contents and bile were collected. The total recovery of radioactivity was found to be 91.83% in the phenyl-label group and 89.89% in the uracil-label group.

Radioactivity in milk amounted to 0.001–0.005% and 0.002–0.009% of the radioactivity administered for the phenyl-labelled and the uracil-labelled [^{14}C]saflufenacil, respectively. Concentrations of radioactivity in milk stayed relatively constant after three application days ranging from 0.004–0.019 mg eq/kg and 0.006–0.024 mg eq/kg for the phenyl-labelled and the uracil-labelled [^{14}C]saflufenacil, respectively.

At sacrifice, highest concentrations of radioactivity were found in liver and bile. Residue concentrations of phenyl-labelled and uracil-labelled [^{14}C]saflufenacil in liver and bile samples were 0.962 and 3.832 mg eq/kg, and 0.634 and 1.461 mg eq/kg, respectively. In adipose tissue and muscle, 0.010 mg eq/kg and 0.017 mg eq/kg, as well as 0.008 mg eq/kg and 0.011 mg eq/kg were found for the phenyl-labelled and the uracil-labelled [^{14}C]saflufenacil, respectively.

Saflufenacil was transformed to a number of metabolites after administration to the goats. Following the application of phenyl and uracil labelled compound the TRR was 0.008 mg/kg and 0.011 mg/kg in muscle, 0.01 mg/kg and 0.017 mg/kg in fat, 0.13 mg/kg and 0.17 mg/kg in kidney, 0.962 mg/kg and 3.832 mg/kg in liver, 0.006 mg/kg and 0.012 mg/kg in milk, respectively. The unchanged parent compound was found as the predominant compound in muscle (44.2% and 56.7%), fat (44.1% and 65.1%), kidney (73.8% and 71.3%), liver (80.2% and 75.7%) whilst in milk its proportion was somewhat lower (47% and 25.4%) following the dosing with phenyl and uracil labelled compounds, respectively. In addition, metabolites M800H01, M800H03, M800H04 and M800H10 were present in few percentages, except M800H10 in milk (39–40%).

The metabolism of the active substance saflufenacil in lactating goats is characterized by several dealkylation steps (phase I reactions), which occurred at two sites of the molecule:

N-demethylation at the N-isopropyl-N-methylsulfamide side chain resulting in metabolite M800H01, and N-demethylation at the uracil ring producing M800H02. Both demethylation reactions formed metabolite M800H11. Elimination of the N-isopropyl group converted the parent compound to M800H03. This reaction furthermore transformed metabolite M800H01 to M800H05, and metabolite M800H02 to M800H10. The metabolites M800H05 and M800H10 could also be formed by the respective demethylation of metabolite M800H03. An additional transformation was hydrolytic opening of the uracil ring of saflufenacil to form metabolite M800H04. Degradation of the resulting side chain generated metabolite M800H07 with its N-methyl-amide group. This metabolite was only detected with the phenyl label. The metabolites are rapidly excreted, along with parent, and do not readily accumulate in tissues or milk. The residues in edible tissues and milk were low. All relevant metabolites were identified and a comprehensive metabolic pathway was elucidated.

Laying hens

Phenyl-U-[^{14}C] saflufenacil or uracil-[^{14}C] saflufenacil was administered orally by gavage once a day to two groups of eight laying hens for 10 consecutive days at a nominal rate of 12 mg/kg feed. The total recovery of radioactivity was found to be 88.76% in the phenyl-[^{14}C]-label group and 83.67% in the uracil-[^{14}C]-label group.

The eggs were collected in the afternoon after administration and in the morning before the administration. The radioactivity was determined in liver, adipose tissue, blood, muscles (leg and chest muscles), gastrointestinal tract (skin and contents). All samples were extracted and analysed within approximately four months after sampling. The extractability of radioactivity from all matrices was greater than 80%. The metabolic fate of approximately 75–80% of the total administered radioactivity considering both labels of saflufenacil could be elucidated.

Excreta contained 85.14% of the phenyl-labelled [^{14}C]saflufenacil administered (uracil-[^{14}C]label: 78.10%). Radioactivity recovered from excreta and cage wash amounted to 88.07% (phenyl-[^{14}C]-label) and 82.96% (uracil-[^{14}C]-label) of the total radioactivity administered.

In eggs, 0.029% (phenyl-[^{14}C]-label) and 0.046% (uracil-[^{14}C]-label) of the total radioactivity administered were found. With both labels, egg concentrations increased continuously up to day 6 and remained unchanged (0.01–0.012 mg/kg for phenyl and 0.016–0.018 mg/kg for uracil labels) until day 10, indicating that a steady state was reached.

At sacrifice, 23 h after the last administration, highest organ concentrations of radioactivity were found in liver (phenyl-[^{14}C]-label: 0.062 mg/kg; uracil-[^{14}C]-label: 0.060 mg/kg,). Residue concentrations of phenyl and uracil labelled [^{14}C]-material in muscles (0.011 mg/kg, 0.011 mg/kg), adipose tissue (0.011 mg/kg, 0.011 mg/kg), eggs (0.012 mg/kg, 0.018 mg/kg) in fat (0.011 mg/kg, 0.011 mg/kg) and in liver (0.062 mg/kg, 0.06 mg/kg) respectively.

The parent compound was the major residue (in muscle 54.7% of TRR, 0.006 mg/kg), fat (26.1%, 0.002 mg/kg) and liver (47.4%, 0.029 mg/kg). In eggs M800H10 amounted to 67.6% of TRR corresponding to 0.008 mg/kg (saflufenacil 20.8%, 0.002 mg/kg). Altogether, < 1% of the total radioactivity administered could be found in the tissues and organs analysed for both radiolabels.

The metabolic reactions are in good accordance with the metabolism of saflufenacil in rats and in lactating goats and hens.

Plant metabolism

Metabolism of saflufenacil was studied in maize, soya beans and tomatoes applying phenyl and uracil labelled compounds.

Maize

Maize plants were grown in soil treated once at a nominal application rate of 200 g ai/ha directly on the bare soil after sowing (pre-emergence treatment). Forage samples were taken 42 and 101/102 days after treatment (DAT) (at the growth stages BBCH 18 and 85). Maize husks, cob, grain and straw (stover) were harvested at 133 days after treatment (BBCH 89).

The highest level of total radioactive residues (TRR) for the phenyl label was detected in maize husks (0.215 mg/kg), followed by stover (0.096 mg/kg). Lower residue levels were found in maize forage 42 DAT (0.018 mg/kg), forage 101 DAT (0.029 mg/kg), cob (0.016 mg/kg) and grain (0.020 mg/kg). In the case of the uracil label, the highest amount of TRR was detected in corn straw (stover) (0.553 mg/kg). Maize husks contained 0.226 mg/kg, forage sampled 102 DAT contained 0.149 mg/kg and maize forage 42 DAT contained 0.039 mg/kg. In maize grain and cob, 0.049 mg/kg and 0.065 mg/kg were found, respectively. Extractability of radioactive residues with methanol and water ranged from 60 to 96% of the TRR), with the exception of cob and grain (phenyl label, ~ 19% TRR each).

In the experiments with the phenyl label, metabolites M800H09, M800H34 and M800H10 were the major components in the matrices sampled at harvest and in maize forage 101 DAT (up to 21.4% TRR). In maize forage sampled 42 DAT (phenyl label), the main components were M800H09, M800H10, M800H01, M800H03 and M800H05 (11% to 20% TRR). At harvest the parent saflufenacil was non-detectable in maize grain, cob and straw (< 0.0005) and present in husk in traces (0.0001 mg/kg), the metabolite M800H11 was found in portions of 1.6% to 4.6% TRR (< 0.0005–0.004 mg/kg).

In the case of the uracil label, the polar metabolite M800H29 (trifluoroacetic acid) was the predominant constituent of the methanol extracts of all plant matrices investigated (64% to 88% TRR, grain: 30.5% TRR, 0.004 mg/kg). Since the potentially corresponding [^{14}C]phenyl-labelled metabolites as counter parts of M800H29 were not detected at adequate quantities, the occurrence of TFA could be explained by the uptake of this metabolite or a respective precursor molecule from the soil. The parent saflufenacil was not detectable in maize grain and any of the other samples and metabolite M800H11 was present at ≤ 0.5% of TRR.

Saflufenacil is metabolized in maize plants by the following main transformation reactions: N-demethylation at the uracil ring; stepwise degradation (N-dealkylation) of the N-methyl-N-isopropyl group to NH_2 forming a sulfonamide group and hydrolytic cleavage of the uracil ring generating a urea side chain.

Soya beans

Pre-emergence treatment

Soya bean plants were grown in soil treated once at a nominal application rate of 150 g ai/ha directly on the bare soil after sowing (pre-emergence treatment). Soya bean forage samples were taken at 39/40 DAT (days after treatment). Soya bean beans, pods (hull), and straw were harvested at 95 DAT.

Following the application of phenyl and uracil labelled compounds the TRR expressed as mg/kg were in forage (0.086, 0.38), bean (0.038, 0.22), pod (0.18, 2.0) and straw (0.43, 1.2), respectively. The extractable radioactive residues ranged from 60% to 98% of TRR.

In soya bean forage sampled 39 DAT (phenyl label), the parent compound was present at 23.5% TRR (0.019 mg/kg). The parent compound and the metabolites M800H01, M800H03, M800H05 and M800H37 were found in portions of up to 6.5% TRR in the other matrices. M800H11 and M800H35 were found up to 13% of TRR in forage, bean and pod and 24.9% and 15.6% of TRR in straw. The corresponding concentrations expressed as mg/kg were in forage (0.005, 0.004), bean (0.001), pod (0.016, 0.023) and straw (0.11, 0.067), respectively. The parent saflufenacil was present in matured beans at 0.002 mg/kg.

In the case of the uracil label, the polar metabolite M800H29 was the predominant constituent of the extracts of all plant matrices investigated (85.2% in forage 65.4% in beans, 75.9% in pods and 69.2% in straw.

Pre-harvest (late season) use

Soya bean leaves, stems, pods and seeds were harvested at *7* days after the foliar application of [^{14}C]uracil labelled saflufenacil at a rate of 100 g ai/ha. The TRR were 0.419 mg/kg in stem, 1.86 mg/kg in pod, 0.043 mg/kg in seed and 17.9 mg/kg in leaves. The extractable radioactive residues ranged between 75.6% and 97.6% of TRR.

The unchanged parent compound was identified with 73% and 76% of the TRR in the extracts of stem and pod, with 64% TRR in leaves and with 26% of the TRR in seed (0.011 mg/kg). Four metabolites were identified in soya bean matrices. The most abundant metabolite identified in all soya bean matrices was M800H02 (5% to 26% of the TRR). The metabolites M800H01 and M800H03 were mainly detected in soya bean leaves (9% to 14% TRR) and in minor portions in soya bean pod (< 1% to 3% TRR). The metabolite M800H11 was detected in all matrices (3% to 10% TRR).

Tomatoes

The metabolism study was conducted with phenyl- and uracil- labelled saflufenacil applied on bare soil before planting of tomato plants at a nominal application rate of 100 g ai/ha. Tomato plants were sampled 68 and 113 days after application. Mature tomato fruits were harvested 113 days after treatment.

The total radioactive residues in tomato plants sampled 68 days after treatment accounted for 0.089 mg/kg (phenyl label) and 0.131 mg/kg (uracil label). In tomato plants at harvest (113 DAT), the radioactive residues were 0.113 mg/kg for the phenyl label and 0.138 mg/kg for the uracil label. In tomato fruits (113 DAT), the residue levels were significantly lower, accounting for 0.015 mg/kg (phenyl label) and 0.037 mg/kg (uracil label). Extractability of radioactive residues with methanol and water was good and generally amounted to 80–100% of the TRR.

In the methanol extract of tomato plants sampled at day 68 (phenyl label), the unchanged parent compound was the most abundant component, accounting for 29% TRR. Major metabolites were M800H07 (14% TRR) and M800H11 (13% TRR). Other metabolites were detected at minor quantities below 7% TRR: M800H01, M800H02, M800H09, M800H10 and M800H35. The methanol extract of tomato plants at harvest (phenyl label) contained the parent compound at a significantly lower concentration (11% TRR). The following metabolites were identified as minor metabolites at 6% TRR or below: M800H01, M800H02, M800H07, M800H09, M800H10, M800H11 and M800H35. The harvested tomato fruits contained the parent compound in traces < 0.0005 mg/kg, all metabolites were non-detectable.

Following the treatment with uracil labelled saflufenacil, the tomato plants contained the parent compound, M800H10 and M800H11 metabolites in ≤ 8.5% of TRR and M800H29 was the major residue component (82.2% and 51.7% of TRR at days 68 and 113, respectively). The fruit contained only M800H29 in detectable amounts (0.004 mg/kg). The parent saflufenacil amounted to 0.7% of TRR (< 0.0005 mg/kg). The formation of natural sugar compounds after complete breakdown of the test substance was proven for tomato fruit.

In summary, the metabolite pathway of saflufenacil in animals and plant materials is qualitatively similar. The metabolism of the active substance saflufenacil is characterized by several dealkylation steps (phase I reactions), which occurred at two sites of the molecule: N-demethylation at the N-isopropyl-N-methylsulfamide side chain resulting in metabolite M800H01, and N-demethylation at the uracil ring producing M800H02. Both demethylation reactions formed metabolite M800H11. Elimination of the N-isopropyl group converted the parent compound to M800H03. This reaction furthermore transformed metabolite M800H01 to M800H05, and metabolite

M800H02 to M800H10. The metabolites M800H05 and M800H10 could also be formed by the respective demethylation of metabolite M800H03. An additional transformation was hydrolytic opening of the uracil ring of saflufenacil to form metabolite M800H04.

In the case of the uracil label, the polar metabolite M800H29 (trifluoroacetic acid) was the predominant constituent of the methanol extracts of plant matrices investigated. The occurrence of TFA was explained by the uptake of this metabolite or a respective precursor molecule from the soil.

Environmental fate

The fate and behaviour of saflufenacil and its metabolites in the environment was investigated under various conditions using the uracil ring- and phenyl ring labelled saflufenacil.

Aerobic degradation

The aerobic degradation of [^{14}C]uracil and phenyl-labelled saflufenacil was studied on sandy loam, silty clay loam, silt loam, and loamy sand soils treated approximately at the proposed maximum use rate of 400 g ai/ha. Following the application of uracil labelled saflufenacil M800H01, M800H02, M800H08, M800H22, M800H26 and M800H31 were identified. Their proportion ranged during the study. M800H02 occurred in largest proportion amounting to 26.4% of total administered radioactivity (TAR) by the end of the study (334 days).

In case of phenyl label, M800H01, M800H02, M800H07, M800H08 and M800H22 were identified. The M800H08 was present in largest proportion in the four soils (14.5–55% of TAR).

The average aerobic degradation DT_{50} values for saflufenacil approximately ranged from 4 days to 22 days in the four soils.

Field trials conducted at various location of USA revealed that the major route of dissipation of saflufenacil in bare soil was degradation by aerobic processes. The DT_{50} and DT_{90} values ranged between 1.36–32.2 days and 4.52–118 days, respectively.

Different metabolites were present at very low concentrations or were not detectable at all. The rate of mineralisation is low and up to 15% of the applied test material is converted to carbon dioxide and other organic volatiles within 365 days. Soil bound residues increased with time during test period.

Photolysis on soil surface

Photolysis of U-[^{14}C]phenyl label] saflufenacil in a light/dark experiment and [^{14}C] uracil and U-[^{14}C] phenyl label] saflufenacil in a continuous irradiation experiment was studied using a loamy sand soil.

In the light/dark experiment saflufenacil in the dark control samples accounted for approximately 97.7% at 0 DAT and decreased to 65.2% TAR at 30 DAT. From the irradiated samples, saflufenacil accounted for approximately 97.7% at 0 DAT and decreased to 43.1% TAR after 30 days of light/dark irradiation. Under the conditions of the study which were similar to the real field situation, there were no major degradation products from the irradiated samples, for either label, which were greater than 10% TAR at any time during the experiment. There were 10 minor products (< 10% TAR) observed.

In the continuous irradiation experiment saflufenacil accounted for approximately 96.43–97.80% at 0 DAT and decreased to 70.21–73.25% TAR at 15 DAT (in the dark control samples of both labels). For the irradiated samples of both labels, saflufenacil accounted for approximately 96.43–97.80% at 0 DAT and decreased to 50.64–58.03% TAR after 15 days of continuous irradiation. The only one major transformation product was an unidentified and unstable product that degraded quickly to M800H01. Minor amounts of M800H01, M800H07, M800H08 and M800H17 were also tentatively identified by HPLC.

Under the dark conditions, saflufenacil undergoes microbial reactions similar to those in aerobic soil metabolism. Saflufenacil was mainly converted to M800H08 and M800H07, as seen in the aerobic soil metabolism study. In addition, the loss of the methyl group on the sulfonylurea side chain of parent to form M800H01 was also observed. There was one major degradation product from the dark samples, and seven other minor products, none of which exceeded 5% TAR at any time during the experimental period. The major dark control product was identified as M800H08.

The DT_{50} for true phototransformation could be calculated as 66 days for the phenyl labelled saflufenacil in the light/dark cycle and 43 and 41 days for the phenyl and uracil labels, respectively, for continuous irradiation.

Saflufenacil undergoes photolysis on soil mainly via demethylation at the sulfonylurea side chain of parent to form M800H01, followed by the demethylation of the uracil ring and the cleavage of the sulfamide side chain. Photolysis also resulted in the opening and fragmentation of the uracil ring to form M800H07. Ultimately all the products could be further degraded to CO_2, but CO_2 production was less than 3% for any of the experiments.

Degradation in aquatic system

The hydrolysis of U-[^{14}C phenyl label] saflufenacil and [^{14}C uracil label] saflufenacil was investigated in dark at 25 °C in 0.01 N sterile buffer solutions at pH 5 (acetate), pH 7 (TRIS) and pH 9 (TRIS).

Saflufenacil was stable to hydrolysis in buffer at pH 5, and no half-life was determined. It degraded slowly in buffer at pH 7 reaching an average of 89% TAR and 94% TAR at 30 DAT for the phenyl and uracil label treatments, respectively. At pH 8 the degradation was rapid.

The photolysis of [^{14}C]saflufenacil (phenyl and uracil label) was conducted in aqueous buffer (pH 5, 0.01 M) and natural water (pH 7.1) at 22 ± 1 °C. The treated solutions (10 mg/kg saflufenacil) were continuously exposed to artificial sunlight (filtered Xenon lamp) for about 20 days for the photolysis conducted in aqueous buffer and 21 days for the natural water.

Saflufenacil degraded rapidly under photolytic conditions with half-lives of 26.8–35.2 and 9.7–9.8 days from the pH5 buffer and the natural water, respectively. Saflufenacil is fairly stable in both pH5 buffer and the natural water in the dark, although trifluoroacetone (M800H33) and M800H07 were found in the latter.

From the pH 5 buffer there are several minor photoproducts formed from both the phenyl and uracil labels; however, only one of them exceeds 10% TAR, but only after 20 days of constant irradiation. This unknown was < 10% TAR in the natural water. In the natural water, there are two major photoproducts formed from the uracil label and identified as trifluoroacetic acid (M800H29) and M800H33 and several other minor photoproducts (none of them exceeds 10% TAR) from both labels.

Saflufenacil degrades in water under photolytic conditions by the opening of the uracil ring followed by the fragmentation of the uracil ring to form M800H04, M800H15, M800H07, M800H33, and M800H29. Hydroxylation of the trifluoromethyl group and the cleavage of the sulfonylurea side chain result in other minor degradation products.

Crop rotation studies

Studies with labelled saflufenacil

The metabolism of saflufenacil was investigated in rotational crops after one single application of the test substance in the EC formulation at a nominal application rate of 150 g ai/ha. Treatment was performed with either [phenyl-U-^{14}C]- or [^{14}C]-[uracil-4-^{14}C]-saflufenacil by spraying onto bare loamy sand soil. After soil aging periods of 30, 58, 120 and 365 days and ploughing saflufenacil,

lettuce, white radish and spring wheat were planted/sowed and cultivated under natural climatic conditions.

Plant samples were harvested at maturity, and additional wheat forage samples were taken 48 to 68 day after planting (DAP). Soil samples were taken after ploughing and after harvest of the mature crops for each plant-back interval.

The total radioactive residues (calculated as the sum of extractable and non-extractable residues, ERR + RRR) in lettuce head (phenyl label) were below or equal to 0.010 mg/kg for all plant-back intervals. In the case of the uracil label, the TRR in lettuce head reached values between 0.078 mg/kg and 0.092 mg/kg after plant-back intervals of 30, 58 and 120 days, and only 0.002 mg/kg after 365 days of soil aging.

The TRR levels in white radish root did not exceed 0.005 mg/kg for all plant-back intervals in the case of the phenyl label. For the uracil label, the TRR in white radish root accounted for 0.034 to 0.038 mg/kg after soil aging periods of 30 and 58 days and for 0.008 to 0.010 mg/kg after the longer plant-back intervals.

In white radish top, higher TRR levels of 0.025 mg/kg (30 DAP), 0.014 mg/kg (58 and 120 DAP) and 0.007 mg/kg (365 DAP) were found for the phenyl label. In the case of the uracil label, the TRR in white radish top were also higher compared to root, accounting for 0.167 and 0.205 mg/kg after 30 and 58 days, and reaching lower levels of 0.046 and 0.087 mg/kg after 120 days and 365 days of soil aging, respectively.

The highest residue levels were detected in spring wheat chaff after a plant-back interval of 30 days (0.383 mg/kg for the phenyl label, 1.604 mg/kg for the uracil label). After longer periods of soil aging (120 and 365 days), the residues in wheat chaff were lower (0.068 and 0.114 mg/kg for the phenyl label, 0.629 mg/kg and 0.439 mg/kg for the uracil label, respectively).

The residue levels in wheat straw (0.089 to 0.125 mg/kg for the phenyl label, 0.196 to 0.356 mg/kg for the uracil label) and forage (decreasing with time from 0.048 to 0.011 mg/kg for the phenyl label and from 0.183 to 0.017 mg/kg for the uracil label) were generally lower compared to chaff.

In spring wheat grain, TRR levels of 0.017 mg/kg (30 DAP), 0.006 mg/kg (120 DAP) and 0.044 mg/kg (365 DAP) were found for the phenyl label. In the case of the uracil label, the residues in grain accounted for 0.370 mg/kg (30 DAP), 0.094 mg/kg (120 DAP) and 0.116 mg/kg (365 DAP).

In summary, the predominant metabolites in the case of the phenyl label were M800H35, M800H05, M800H01, M800H11 and M800H10 (and/or an unknown medium polar component), representing stepwise degradation of the molecule by N-dealkylation reactions and by hydrolytic cleavage of the uracil ring generating an urea side chain. For the [^{14}C]uracil label, M800H29 as trifluoroacetic acid was the predominant metabolite. Since [^{14}C]phenyl-labelled metabolites as counter parts have not been detected at corresponding quantities, the occurrence of TFA could be explained by uptake of this metabolite or a respective precursor molecule from the soil. Most of the metabolites were found at low levels (< 0.1 mg/kg), except for metabolite M800H35 in spring wheat chaff (0.162 mg/kg at 30 DAP, phenyl label) and metabolite M800H29 in spring wheat chaff (0.32 mg/kg at 30 DAP, uracil label; 0.12 mg/kg at 120 DAP, uracil label). The unchanged parent compound was not detectable in wheat grain (< 0.000 mg/kg) and detected at very low quantities (≤ 5% TRR) in other matrices, except for lettuce head (13.7%, 0.001 mg/kg at30 DAP) and white radish top (13.8%, 0.004 mg/kg at 30 DAP) and 8.4% (0.001 mg/kg at 120 DAP) when phenyl labelled saflufenacil was applied.

Field studies

In 2006–2007 six trials (two for each representative crop) were conducted in representative rotational crops (radish, lettuce, and wheat) in the USA.

Saflufenacil (70% WG) was applied as a single pre-emergence application to the soil (at the time of sowing wheat as primary crop) at 0.148–0.154 kg ai/ha. At 4, 6 and 9 months after treatment, the primary crop was destroyed (removed) and the representative rotational crops were planted at a number of time intervals post-treatment.

The residues of saflufenacil, M800H11 and M800H35 were below 0.01 mg/kg (LOQ) in all samples of wheat (forage, hay, grain and straw), radish (tops and root), and lettuce (leaves) harvested from plant-back intervals of 119–125, 180–183, and 270–274 days.

The results of the studies indicate that no detectable residue deriving from the use of saflufenacil can be expected in follow-up crops.

Analytical methods

Information was available on efficiency of extraction, analytical methods for saflufenacil and its metabolites (M800H11 and M800H35) in plants and parent saflufenacil in animal commodities.

Efficiency of extraction

A study was designed to investigate the influence of different solvent mixtures on the extractability and accountability of plant matrices.

The solvent systems were used sequentially: acetonitrile/water 70:30 (v/v), methanol/water 70:30 (v:v), methanol and water. The plant samples used were soya bean forage, pod and straw after pre-emergence treatment with [^{14}C]saflufenacil (phenyl ring labelled) obtained from a soya bean metabolism study.

The extractability behaviour was comparable when using mixtures of acetonitrile/water or methanol/water or methanol and water sequentially on different soya bean matrices like forage, pod and straw. The extraction efficiency was highest for forage and straw using methanol and water sequentially.

The relative quantities of the specified analytes (saflufenacil, M800H11 and M800H35) determined by the residue analytical method were very similar after HPLC analysis of the different extracts obtained after extraction with acetonitrile/water or methanol/water mixtures or with methanol and water applied sequentially.

The results indicate that methanol/water, or acetonitrile/water, were the most suitable solvent systems for extraction and characterization. These systems released most of the total radioactive residues, and residues of concern, and the quantitative results were comparable with those obtained in the original metabolism study.

The use of acetonitrile was shown in the livestock metabolism studies to be suitable for extraction of saflufenacil residues of in animal matrices. Multiple extractions did not contribute significantly to the extraction of the parent saflufenacil.

Analytical methods used in supervised trials

BASF Method D0603/02 was developed for the analysis of residues of saflufenacil and its metabolites M800H11 and M800H35 in plant matrices.

Residues of saflufenacil and its metabolites are extracted from crop matrices (except oil) with methanol-water (70:30, v/v). The oil matrices are extracted with acetonitrile. The residues are determined using LC/MS/MS.

For quantitation ion, the mean recoveries of saflufenacil, and its metabolites, M800H11 and M800H35 in different plant matrices were generally between 70 and 120% within each fortification level. Standard deviations of the recovery were generally less than 15% for quantitation ion.

Good linearity was observed in the range of 0.05 to 0.5 ng/mL for all three analytes. The LOQ for saflufenacil residues is 0.01 mg/kg for each analyte in/on food matrices and 0.025 mg/kg each in/on feed matrices. The mean recoveries obtained at 0.01 mg/kg (LOQ) and 0.1 mg/kg level ranged from 74.3% to 93.6%. The relative standard deviation (RSD) ranged between 1.9% and 9.1%.

Method No L0073/01 was developed and validated for the determination of saflufenacil in liver, kidney, muscle, fat, milk, cream, skimmed milk and eggs. The sample materials are extracted with acetonitrile, partitioned into dichloromethane, evaporated and dissolved in methanol/water mixture.

The final determination is performed by HPLC-MS/MS. The recovery of saflufenacil tested at 0.01 and 0.1 mg/kg level ranged between 74–95% for both transition ions. The reproducibility of the procedure was good (RSD < 10%). The LOQ was 0.01 mg/kg for all matrices.

A study was conducted to evaluate the capability of the FDA multi-residue methods to analyse for residues of saflufenacil, M800H11 and M800H35, but the tests indicated that the method is not suitable for the determination of the targeted residues.

In conclusion, suitable analytical methods are available for the determination of parent saflufenacil and its metabolites (M800H11 and M800H35) in plant matrices and for the parent saflufenacil in animal tissues and milk.

Stability of pesticide residues in stored analytical samples

The stability of residues in samples stored at ≤ –18 ºC was tested as part of the metabolism studies on maize, soya beans and tomatoes by comparing the HPLC chromatographic patterns during the studies. No significant change of the metabolic patterns was observed during co-chromatographic investigations. The composition of the residues in the plant materials remained stable for a period of approximately 16 to 21 months. The extracts were stored for a period of approximately 10 to 13 months.

The stability of residues in stored samples was tested by conducting storage stability studies using spiked samples of plant and animal origin.

Samples of maize (grain, forage and stover), soya beans (seed, forage and hay), oranges (fruit, pulp, juice and oil), radish roots, raisins and garbanzo beans (seeds), spiked separately with saflufenacil, M800H11 or M800H35 at a level of 1.0 mg/kg for each analyte, were stored at < -5 °C for a duration of 548–553 days. Under these conditions, residues of parent and the metabolites appeared to be stable in each crop matrix tested. The data indicate that residues of saflufenacil and its metabolites at < -5 °C are stable for at least 18 months in maize (grain, forage and stover), soya beans (seeds, forage and hay), oranges (fruit, pulp, juice and oil), radish roots, raisins and chick peas .

Storage stability of saflufenacil at -18 °C in milk and bovine tissues such as muscle, liver, kidney and fat was tested at 0.01 and 0.1 mg/kg level. In addition, the stability in the dosing solution was tested. The study, covering the period between sampling and extraction, showed that saflufenacil was stable in milk, muscle, liver, kidney and fat. No decline in concentration of saflufenacil in the extracts and dosing solutions was observed.

Definition of the residue

Residues in animal matrices

Animal metabolism studies were conducted with saflufenacil on lactating goats and laying hens. In these studies, it was found that saflufenacil was transformed to a number of metabolites. All relevant metabolites were identified. The unchanged parent compound was the predominant residue component in the cases of administration of phenyl-labelled saflufenacil in muscle and fat (0.004 mg/kg; 44% of TRR), milk (0.003 mg/kg; 47% of TRR), kidney (0.096 mg/kg; 74 % of TRR)

and liver (0.77 mg/kg; 80% of TRR). Following the administration of uracil-labelled saflufenacil the parent saflufenacil was also present in largest proportion in muscle, fat, kidney and liver (57–76% of TRR). In milk the M800H10 was present at highest concentration (0.005 mg/kg) and the parent saflufenacil was second at 0.003 mg/kg level.

Metabolites M800H04 and M800H10 detected at quantities above 10% TRR within the animal metabolism studies conducted at highly exaggerated dose levels, are not considered relevant, because they would not be detectable in food items of animal origin when considering realistic feeding levels resulting from good agricultural practice.

The definition of residues in animal commodities for both enforcement and risk assessment purposes is: saflufenacil

The log P_{ow} of the parent compound is 2.6. The residues were present in fat and muscle at about the same concentration indicating that the residue is not fat soluble.

Residues in plant matrices

Metabolism studies in maize, soya beans and tomatoes were conducted to determine the metabolic fate of saflufenacil in plants after pre-emergence and pre-plant application as well as pre-harvest use for crop desiccation use.

Pre-plant, pre-emergence directed application to bare soil or to weeds in plantations of orchards and vineyards:

Following the application of labelled saflufenacil at exaggerated rates (2–4×) directly on the bare soil after sowing/planting the residues of saflufenacil were generally low. The parent saflufenacil was not detectable (< 0.0005 mg/kg) in maize cob, grain and stover, and it was present at 0.001 mg/kg level in husk and forage at day 133. M800H11 was present in maize forage at 0.002 mg/kg at days 42 and 102, and in husk and stover at 0.003–0.004 mg/kg level. M800H35 could not be identified during the study.

In tomato fruits at harvest the parent saflufenacil, M800H11 and M800H35 were not present in detectable amounts (< 0.0005 mg/kg). The parent saflufenacil was the predominant residue in tomato plants 8.5–11% of TRR, while M800H11 and M800H35 residues were present in 5.8–5.9% of TRR.

In soya beans, the parent saflufenacil was the predominant residue in forage at day 39, but M800H11 and M800H35 were present in larger proportion in pod (9–13% of TRR) and straw (25–16% of TRR) at 95-day samples. The seed did not contain any detectable residues.

The results of supervised trials provide additional information on the levels of residues in food commodities. Samples of oranges, apples, cherries, peaches, plums, grapes, bananas, mangoes and sweet corn, cereal grains, potato sugar cane, tree nuts and coffee beans, maize forage and stover and almond hull derived from treatments according to GAP no residues were detectable at any pre-harvest intervals.

Pre-harvest (desiccant harvesting aid) applications:

In a soya beans metabolism study, with application at seven days before harvest, the parent saflufenacil was the predominant residue in soya bean leaves, stem and pod (64–76% of TRR) and in seed (26% of TRR, 0.011 mg/kg). M800H11 was present in much lower proportion (2.7–10% of TRR, 0.004 mg/kg)

In supervised trials the metabolites M800H11 and M800H35 were not found above LOQ, in any of the succulent or dried bean, dried pea, soya bean, cotton seed, and cotton gin by-product samples regardless of the PHI. In canola seed the M800H35 residues were below the LOQ of 0.01 mg/kg in all samples. M800H11 residues were < 0.01 in 12 samples. Where M800H11 was

detectable in 0.01–0.055 mg/kg concentration range, it amounted to 4.3% and 53% of the parent saflufenacil (ranging between 0.021–0.48mg/kg).

In sunflower seeds M800H35 was not detected in any of the samples taken between 3 and 20 days after last application. At day 7 only one sample contained detectable M800H11 residue (0.066 mg/kg) amounting to 13% of the parent saflufenacil (0.50 mg/kg) being in the same sample. In other two samples taken at 14 day the M800H11 were present in concentrations amounting to 19% and 22% of the parent compound except one trial where it was present five times higher concentration than the parent compound (0.065 mg/kg).

The Meeting noted that the majority of the commodities treated directly or grown in treated soil did not contain detectable residues at all. The metabolite M800H11 occurred at or below 53% of the parent compound. M800H35 was present in detectable amount only in desiccated pea vine samples.

Taking into account that the residues of parent saflufenacil provide sufficient information on the compliance with GAP, and the M800H11 and M800H35 metabolites are non-detected or present at very low concentration, the Meeting decided, that

The definition of residue in plant commodities for both enforcement and risk assessment purposes is: saflufenacil.

Results of supervised trials on crops

Residue data were submitted by the manufacturer from supervised trials conducted on citrus fruits, pome fruits, stone fruits, berries and small fruits, assorted tropical and sub-tropical fruits—inedible peel, fruiting vegetables, legume vegetables, pulses, root and tuber vegetables, cereals, grasses for sugar or syrup production, tree nuts, oilseeds, seeds for beverages and sweets. The trials were generally conducted at maximum GAP and well documented.

In case of applications on bare soil at early growing season (pre-emergence, pre-planting) The Meeting concluded that the commercial harvesting time of the crop is the relevant primary factor affecting the residues and not the PHI n case of applications on bare soil at early growing season (pre-emergence, pre-planting).

Samples were analysed within the period tested for storage stability of residues. The residues of parent saflufenacil, M800H11 and M800H35 were determined in all samples with method D0603/02 or equivalent. The LOQ for each compound was 0.01 mg/kg, unless otherwise stated. The performance of the methods was verified with concurrent recovery studies.

Where trial plots were at the same location (side-by-side trials), the higher residues were considered from the replicate results. The average of residues measured in replicate samples taken from one field is reported hereunder, and they were used for estimation of the residue levels.

The OECD MRL calculator was used for calculation of maximum residue levels. The reasons for deviation are indicated under corresponding recommendations.

Citrus fruits

Trials were conducted on sweet oranges (12), lemons (5) and grapefruit (6) in five states of the USA. Saflufenacil was applied in WG formulation three times as spray directed to weeds at a rate of 0.05 kg ai/ha with a re-treatment interval of 20–22 days in compliance with US GAP (1–3 broadcast, banded or spot spraying application at 0.05 kg ai/ha (max. annual dose 0.15) and 0 day PHI).

Saflufenacil residues were present below the LOQ of 0.01 mg/kg in all samples.

Three trials were performed in Brazil in oranges applying saflufenacil three times as spray directed to weeds at a rate of 49 g ai/ha in a spray volume of 200 L/ha. Citrus fruit were taken 7 days

after the last application. (No GAP.) Saflufenacil residues were present below the calculated limit of detection (< 0.002 mg/kg) in all samples.

Based on the US trial data the Meeting estimated a maximum residue level of 0.01* mg/kg and STMR of 0 mg/kg for citrus fruits.

Pome fruits

Fifteen trials in apples and 10 trials in pears were conducted in the USA according to GAP (1–3 broadcast applications directed to weeds at 0.025–0.05 kg ai/ha (max annual dose 0.15) and 0 day PHI. In addition three trials were performed in Brazil (no GAP).

No residues were detectable in any of the samples taken at day 0 up to 14 days.

Based on the US trial data the Meeting estimated a maximum residue level of 0.01* mg/kg and STMR of 0 mg/kg for pome fruits.

Stone fruits

In the USA six trials in cherries (3 tart, 3 sweet), 13 in peaches and 10 in plums were conducted according to US GAP for stone fruits (1–3 Broadcast banded or spot spraying applications directed to weeds at 0.05 kg ai/ha (max annual dose 0.15) and 0 day PHI). None of the samples taken between day 0 and 21 contained detectable residues (< 0.01 mg/kg).

For stone fruits, the Meeting estimated a maximum residue level of 0.01* mg/kg and STMR values of 0 mg/kg.

Berries and other small fruits

Twelve trials were conducted in the USA in grapes according to US GAP (1–3 Broadcast banded or spot spraying applications directed to weeds at 0.025 kg ai/ha (max annual dose 0.075 kg ai/ha) and 0 day PHI). Two trials were conducted in Brazil in grapes (no GAP).

None of the samples taken 0–17 days after last application contained detectable residues (< 0.01 mg/kg).

Based on the US trial data, the Meeting estimated a maximum residue level of 0.01* mg/kg and STMR of 0 mg/kg for grapes.

Assorted tropical and sub-tropical fruits—inedible peel

Bananas

Four trials were conducted in bananas in Brazil where plantations were sprayed with saflufenacil as a directed application to weeds at a rate of 0.049 kg ai/ha. Fruits were taken directly after last application and a day later (No GAP). None of the samples contained detectable residues < 0.01 mg/kg for parent and < 0.003 mg/kg for metabolites.

Ten supervised trials in bananas were conducted in Costa Rica (two trials), Columbia (one trial), Ecuador (three trials), Guatemala (one trial), Honduras (two trials), and Panama (one trial). Applications of saflufenacil directed to weeds were performed five times at rates between 0.072 and 0.08 kg ai/ha in a spray volume of 191–213 L/ha and re-treatment intervals of 20 ± 5 days. Banana fruit were sampled directly after the application and one day later. Saflufenacil is registered in Columbia with one application directed to weeds at 0.028–0.039 kg ai/ha, the PHI is not specified. Five applications were made at 0.08 kg ai/ha instead of the maximum 3 at 0.05 kg ai/ha, but the residues in all samples were below LOQ/LOD.

The Meeting noted that in the Central American trials five applications were made instead of one, and at 0.08 kg ai/ha instead of 0.05 kg ai/ha, but the residues in all samples were below LOQ/LOD.

As the samples did not contain any detectable residues, the Meeting estimated a maximum residue level of 0.01* mg/kg and STMR of 0 mg/kg for bananas.

Mangoes

Four supervised trials were conducted in Brazil applying saflufenacil three times as a directed spray to weeds. None of the samples contained detectable residues: < 0.01 mg/kg for parent, < 0.01–0.003 mg/kg for metabolites. As the product is not registered in Brazil, the residue data could not be evaluated.

Sweet corn

Five residue trials in sweet corn were conducted in the USA with a single application of saflufenacil either incorporated into the soil before planting or applied post-planting pre-emergence at 0.15 kg ai/ha. (GAP: ≥ 1 ground or aerial spraying applications at 0.065–0.1 kg ai/ha, max annual dose 0.15 kg ai/ha, and 80 day PHI)

The residues were below the LOQ of 0.01 mg/kg in all samples taken 91–106 days after treatment.

The Meeting estimated a maximum residue level of 0.01* mg/kg and STMR of 0 mg/kg for sweet corn.

Legume Vegetables, Pulses

Beans, dry

Five trials were conducted in Brazil in beans. The first application was done at a rate of 0.098 kg ai/ha on the day of sowing; the second (0.098 kg ai/ha) took place before harvest as a desiccant. Bean seed samples were taken at PHI of 7 days after the last application, and in three trials also after 0, 3, 10 and 14 days. None of the 17 dried bean samples contained any detectable residues (< 0.01 mg/kg) regardless of the PHI of 0–14 days. (No GAP).

Ten trials in beans were conducted in the USA and Canada applying saflufenacil at 0.05 kg ai/ha as a single late season treatment. Samples of mature dried bean seed were harvested at a 2-day pre-harvest interval (PHI). (GAP: 1× 50 g, as pre-harvest desiccant, PHI 2 days.)

The average residues of parent saflufenacil in dried bean seed sampled in US trials at the 2 day PHI were: < 0.01 (5), 0.01, 0.046, 0.096, 0.136, and 0.157 mg/kg. The maximum residue detected in one of the replicate samples from a single pot was 0.23 mg/kg.

The Meeting estimated a maximum residue level of 0.3 mg/kg and STMR value of 0.01 mg/kg for dried bean seeds.

Peas and soya bean immature seed with or without pods

Thirteen trials on peas and 11 trials on chick peas were conducted in the USA and Canada as pre-plant or pre-emergence application of saflufenacil directed to soil at 0.1 kg ai/ha rate according to the maximum annual label rate for peas in the USA (USA GAP: ≥ 1 ground or aerial spraying applications at 0.025–0.05 kg ai/ha, maximum annual dose 0.05–0.1, and a 65 day PHI). Succulent seed samples with and without pod were taken 63–81 days after the application.

None of the 28 succulent pea (with or without pods) samples contained detectable residues (< 0.01 mg/kg), regardless of the PHI.

Fifteen trials were conducted in the USA on soya beans with a single broadcast, pre-plant incorporated or pre-emergence application of saflufenacil (70% WG) at 0.10 kg ai/ha. (US GAP: > 1 Pre-plant or pre-emergence application at 14 days intervals at 0.025 kg ai/ha and seasonal maximum rate of 0.1 kg/ha with PHI of 65 days).

The immature soya bean (succulent seed with pod and succulent seed without pod) samples were harvested at 62–119 days after treatment

Succulent soya beans seed samples (42) with or without pods at 62–126 days did not contain detectable residues.

The Meeting estimated a maximum residue level and STMR of 0.01 mg/kg for immature seeds of peas (with or without pods) and immature soya beans seeds.

Peas, dry

Thirteen trials on peas and 11 trials on chick peas were conducted in the USA and Canada as pre-plant or pre-emergence application of saflufenacil at 0.1 kg ai/ha rate according to maximum annual label rate for peas in the USA (USA GAP: ≥ 1 ground or aerial spraying applications at 0.025–0.05 kg ai/ha, max annual dose 0.05–0.1, and 65 day PHI). Dried seed samples were taken at harvest 82–117 DAT.

None of the 22 dried pea samples, and 11 dried chick pea samples contained detectable residues (< 0.01 mg/kg), regardless of the PHI.

Further, nine pea trials were conducted in the USA and Canada with a single late season application of saflufenacil as a desiccant at 0.05 kg ai/ha. (US GAP ≥ 1 ground or aerial spraying applications at 0.025–0.05 kg ai/ha, max annual dose 0.05 kg ai/ha, and 3 day PHI). Samples of mature pea dried seed and vines were harvested at a 2–4 day pre-harvest interval (PHI).

Three days after one late season application of saflufenacil at 0.05 kg ai/ha, the average residues of parent saflufenacil in two replicate dried pea seed samples were: < 0.01 (3), 0.01, 0.0.02, and 0.03 mg/kg.

The maximum of saflufenacil residue measured in one of the replicate samples from a single trial was 0.05 mg/kg at day 2 and 0.03 mg/kg at day 3.

For dried pea and chickpea seeds, the Meeting estimated a maximum residue level of 0.05 mg/kg and STMR of 0.01 mg/kg.

Soya beans

Twenty trials were conducted in the USA and Canada with a single late-season broadcast application of the 70% water-dispersible granule (WG) formulation of saflufenacil as a harvest aid/ desiccant at 0.05 kg ai/ha. (US GAP:≥ 1 application at 0.025–0.05 kg ai/ha, max annual rate 0.05 kg ai/ha, 3-day PHI.)

The average parent saflufenacil residues in dry soya bean seed samples at a 3-day PHI were: < 0.01 (14), 0.01 (2), 0.015 (2), 0.02 and 0.05 mg/kg.

Five trials were performed with saflufenacil in Brazil. The first application took place on the day of the planting at a rate of 0.049 kg ai/ha. The second application at a rate of 0.098 g ai/ha was applied to the crop as a pre-harvest desiccant. Soya bean seed was sampled 7 days after the last application. In three trials samples were also collected at 0, 3, 10 and 14 DAT. Soya bean seed samples contained 0.01, 0.02 and 0.03 mg/kg parent saflufenacil residues at day 0. Soya bean samples taken at days 3–14 did not contain any detectable saflufenacil residues, i.e., < 0.01 mg/kg (No GAP).

Based on the US trials, the Meeting estimated a maximum residue level of 0.07 mg/kg and STMR of 0.01 mg/kg for dried soya bean seeds

(OECD calculator gave 0.05 mg/kg which is equal to the highest residues in two samples.)

Potatoes

In Brazil four trials were conducted on potatoes applying saflufenacil as a WG formulation once at a rate of 98 g ai/ha as a pre-harvest desiccant. Potato tubers were sampled 7 days after treatment, and in two trials at 0, 3, 10 and 14 DAT. In potato tubers, saflufenacil residues were not detected above their calculated limit of detection, i.e., 0.009 mg/kg, throughout the study.

As the compound is not registered in Brazil, a maximum residue level could not be estimated.

Cereals

In the USA and Canada a total of 61 trials were conducted in wheat (25), barley (6), sorghum (9), rice (6) and field corn (15) with saflufenacil applied as a single broadcast pre-plant incorporated or pre-emergence application to the soil surface at 0.142–0.158 kg ai/ha. The cereal RAC samples were collected at commercial maturity. The US GAP permits ≥ 1 applications at 0.05–0.13 kg ai/ha (maximum annual rate 0.15 kg ai/ha) with PHI of 80 days for maize; ≥ 1 applications at 0.05–0.1 kg ai/ha (maximum annual rate 0.15 kg ai/ha) with a PHI of 30 days for barley, sorghum, rice and wheat.

In all trials no samples of wheat (64) taken 76–280 DAT, barley (12) taken 81–100 DAT, sorghum (18) taken 68–150 DAT, maize (32) taken 118–158 DAT and rice grains (12) taken 121–146 DAT contained detectable residues, i.e., < 0.01 mg/kg.

In Brazil two trials in wheat and four trials in rice were conducted applying saflufenacil once at a rate of 0.049 kg ai/ha at planting. No samples contained detectable residues in wheat or rice grain taken at normal harvest maturity (No GAP).

Based on the US data, the Meeting estimated a maximum residue level 0.01* mg/kg and STMR of 0 mg/kg for cereal grains.

Sugarcane

In Brazil five trials were conducted in sugar cane applying saflufenacil once at a rate of 98 g ai/ha as pre-harvest desiccant. Sugar cane stalk samples were taken after 7 and 10 days, and in two trials also after 0, 14 and 21 days.

In sugar cane stalk between 0 and 14 DAT residues of parent saflufenacil were below its calculated limit of detection (0.006 mg/kg) or below LOQ (0.01 mg/kg). After 21 days, no residues of saflufenacil were detected above LOD.

As the compound is not registered in Brazil, the maximum residue levels could not be estimated.

Tree nuts

In the USA five trials were conducted in almonds and five in pecans applying saflufenacil three times as broadcast applications to the orchard floor at a rate of 0.05 kg ai/ha. The last application made on the day of harvest. The US GAP permits up to 3 treatments at 0.05 kg ai/ha rate (annual maximum of 0.15 kg ai/ha) with a 7-day PHI.

No residues were detected in any of the samples taken between 0 and 28 days after last application.

For tree nuts, the Meeting estimated a maximum residue level, of 0.01* mg/kg and an STMR of 0 mg/kg.

Oilseeds

Cotton

In the USA 12 trials were conducted in cotton applying saflufenacil once as at-planting pre-emergence broadcast spray to the soil. The application rate was between 0.024–0.036 kg ai/ha and 0.049–0.072 kg ai/ha. The US GAP permits ≥ 1 application at 0.013–0.05 kg ai/ha with maximum annual rate of 0.05 kg/ha and a PHI of 5 days.

Undelinted cotton seed samples (24 for low rate and 22 for high rate) harvested at normal maturity did not contain any residues above the limit of quantitation (0.01 mg/kg).

In 2009, a study was conducted in the US with 12 trials in cotton in which saflufenacil was applied as a single late-season, broadcast application as a harvest aid/ desiccant at a rate of 0.05 kg ai/ha. Cotton seed samples were taken 5 days after the application, in one trial samples were also collected 1, 4, 5, 10 and 15 days after treatment.

In the US trials matching GAP, the residues in undelinted cotton seed were: < 0.01, 0.02, 0.025 (3), 0.075, 0.095, and 0.125 mg/kg.

In Brazil four trials were conducted in cotton applying saflufenacil three times: the first application took place on the day of planting, the second as a post-emergent directed spray, both applications were made at a rate of 0.049 kg ai/ha. The third application was done pre-harvest as desiccant at a rate of 0.098 kg ai/ha. Cotton seed samples were taken at the PHI of 7 days, in two trials and 0, 3, 10 and 14 DAT (there is no GAP).

The residues in delineated cotton seed samples at 7-day PHI were: < 0.01, 0.02, 0.02 and 0.09 mg/kg

Based on the US late season trial data the Meeting estimated a maximum residue level of 0.2 mg/kg and a STMR of 0.025 mg/kg for cotton seed.

Rape seed

In Canada and the USA 16 trials were conducted with a single late-season, broadcast application of the 70% water-dispersible granule (WG) formulation of saflufenacil as a harvest aid/ desiccant at 0.049–0.051 kg ai/ha. The US GAP permits one application at 0.053–0.178 kg ai/ha maximum seasonal rate 0.05 kg ai/ha, PHI 3 days (allowing up to 7 days for optimum desiccation effect depending on environmental conditions).

In addition, at three trial sites, a bridging comparison plot was treated in the same manner with a single late-season, broadcast application of a 342 g/L suspension concentrate (SC) formulation of saflufenacil applied as a harvest aid /desiccant at 0.046–0.052 kg ai/ha. The bridging trials comparing the two formulations (WG vs. SC) demonstrated that there was no observable difference in residues in canola treated with the two formulations.

The residues of parent saflufenacil in dried seeds at 3 days PHI were in rank order: 0.017, 0.0215, 0.044, 0.044, 0.0445, 0.0555, 0.0595, 0.066, 0.068, 0.0695, 0.096, 0.098, 0.0995, and 0.429 mg/kg. The highest residue observed in one of the replicate samples was 0.48 mg/kg.

For rape seed the Meeting estimated a maximum residue level of 0.6 mg/kg and a STMR of 0.054 mg/kg (the OECD calculator's estimate of 0.5 mg/kg does not cover adequately the maximum residue observed).

Sunflowers

In the USA eight trials were conducted in sunflowers applying saflufenacil in two late-season, over-the-top broadcast applications at a rate of 0.05 kg ai/ha and a re-treatment interval of 7 days. The US GAP permits ≥ 1 treatments with 0.025–0.05 kg ai/ha (maximum annual rate 0.1 kg ai/ha and a 7 day PHI).

The average residues of parent saflufenacil in replicate samples taken between 6 and 8 DAT were: 0.056, 0.0586, 0.0644, 0.089, 0.152, 0.163, 0.19, and 0.437 mg/kg

In Brazil four trials were conducted applying saflufenacil once at a rate of 0.098 kg ai/ha as pre-harvest desiccant. Sunflower seeds were taken 7 (the PHI) and 10 days after the last application, in two trials also after 0, 3 and 14 DAT. The residues of saflufenacil in sunflower seed samples taken 7 days after treatment were: < 0.01, < 0.01, 0.04 and 0.07 mg/kg (There is no GAP).

Based on the residue data obtained in the US trials, the Meeting estimated a maximum residue level of 0.7 mg/kg, and a STMR of 0.12 mg/kg for sunflower seed.

Coffee

In Brazil three trials were conducted in coffee applying saflufenacil three times directed to weeds at a rate of 0.049 kg ai/ha. Coffee grains were taken 7 days after the last application. (No GAP.)

Further trials were conducted in Costa Rica (2), Columbia (2) and Mexico (1) with four direct to base applications at rates between 0.098 and 0.104 kg ai/ha. Samples of commercially mature coffee beans (red coffee cherries) were harvested at a 0-day or 1-day pre-harvest interval (PHI) and processed according to typical commercial practices to produce the coffee raw agricultural commodity (RAC), green bean. (Columbian GAP permits one treatment at 0.028–0.03 kg ai/ha PHI is not specified.)

In all trials the residues of saflufenacil in coffee bean samples were below the limit of detection (0.003 mg/kg) or below quantitation (0.01 mg/kg).

Taking into account that no residue was detectable in any samples, the Meeting estimated a maximum residue level, of 0.01 mg/kg and a STMR of 0 mg/kg for green coffee beans.

Animal feeds

The details of the trials are provided under the respective commodities.

Soya bean forage and hay

In soya beans 15 trials were conducted in the USA with a pre-plant incorporated or pre-emergence application at 0.10 kg ai/ha. In soya bean forage and hay residues were all below the LOQ of < 0.025 mg/kg.

Based on the residue data in soya bean forage, the Meeting estimated a highest residue of 0.025 mg/kg and median of 0.025 mg/kg.

Straw, fodder and forage of cereals

The residues in forage, hay and straw samples derived from of all trials (25 in wheat, 9 in sorghum) were below the LOQ of 0.025 mg/kg at all PHI-s.

The Meeting considered that the results are applicable to barley as well.

For wheat, barley and sorghum forage, fodder and straw, the Meeting estimated a highest reside and median of 0.025 mg/kg.

For wheat, barley and sorghum straw and fodder, the Meeting estimated a maximum residue level of 0.05 mg/kg.

The results of 15 field trials on field corn indicated that the residues were below the LOQ of 0.025 mg/kg in maize forage sampled 86–114 days and maize stover sampled 120–158 days after the single pre-plant treatment at max GAP.

For maize forage and stover, the Meeting estimated a highest reside and median of 0.025 mg/kg.

For maize fodder, the Meeting estimated a maximum residue level of 0.05 mg/kg.

Almond hulls

The results of five field trials on almonds indicated that the residues were below the LOQ of 0.025 mg/kg in almond hulls sampled 7–28 days after the last of three treatments at maximum GAP.

For almond hulls, the Meeting estimated highest residue and median residue of 0.025 mg/kg.

Cotton gin by-product

The average residues of saflufenacil in cotton gin by-product samples, taken 5 days after last treatment, were in rank order: 0.09, 0.18, 0.19, 0.215, 1.84 and 2.08 mg/kg.

The highest residue observed in one of the replicate samples was 2.25 mg/kg

For cotton gin by-product, the Meeting estimated a median residue of 0.2025 mg/kg.

Fate of residues during processing

Studies were conducted for determination of the residues of saflufenacil in processed products of soya beans.

The processing factors, Pf, estimated by the meeting and the corresponding STMR-P values are summarized hereunder.

RAC	Processed product	Pf	STMR for RAC mg/kg	STMR-P, mg/kg
Soya beans	refined soya bean oil	0.25	0.01	0.0025
	soya bean meal	0.65	0.01	0.0065
	soya bean hulls	7.9	0.01	0.079
Sunflower	refined sunflower oil	0.03	0.12	0.0036
	sunflower meal	0.8	0.12	0.096

Field trials were conducted on oranges, apples, plums, wheat, maize, rice and cotton at exaggerated and maximum GAP rates. The saflufenacil residues were not detectable in the RAC samples, indicating that no processing studies were necessary.

Nevertheless, residues in citrus oil were determined because of the 1000× theoretical concentration factor for this commodity. Residues were < 0.01 mg/kg in the two oil samples derived from the orange fruit samples.

Residues in animal commodities

Farm animal dietary burden

Maximum residue level recommendations are not made for some processed and forage commodities as no maximum residue level is needed) but they are used in estimating livestock dietary burdens. Those commodities are listed here.

Commodity	High residue (mg/kg)	Median (mg/kg)
Almond hull		0.025
Cotton gin by-products	2.25	0.215
Maize forage and stover	0.025	0.025
Soya bean forage	0.025	0.025
Soya bean hulls		0.079
Soya bean meal		0.0065
Straw and fodder, forage of cereals	0.025	0.025
Sunflower meal		0.096

Applying the OECD feed table for maximum proportion of agricultural commodities in animal feed (FAO Manual 2nd ed 2009, appendix IX) the maximum and mean saflufenacil intake was calculated from the estimated high and STMR residues. Residue data from field pea vines were not taken into consideration because following the desiccation treatment it is practically dry and not used for feed. **(**The vines used for feed contains about 25% dry matter.)

	Livestock dietary burden, saflufenacil, ppm of dry matter diet							
	US-Canada		EU		Australia		Japan	
	max	mean	max	mean	max	mean	max	mean
Beef cattle	0.157[a]	0.043	0.078	0.080	0.101	0.101[b]	0.019	0.011
Dairy cattle	0.080	0.080	0.059	0.061	0.096	0.096[c]	0.041	0.011
Poultry, broilers	0.035	0.035	0.021	0.021	0.026	0.025	0.013	0.010
Poultry, layers	0.035	0.035	0.037[d]	0.037[e]	0.026	0.025	0.009	0.009

[a] Highest maximum beef or dairy cattle dietary burden suitable for Maximum residue level estimates for mammalian meat.

[b] Highest mean beef or dairy cattle dietary burden suitable for STMR estimates for mammalian meat.

[c] Highest mean dairy cattle dietary burden suitable for STMR estimates for milk.

[d] Highest maximum broiler or layer poultry dietary burden suitable for Maximum residue level estimates for poultry meat and edible offal and eggs

[e] Highest mean broiler or layer poultry dietary burden suitable for STMR estimates for poultry meat and edible offal and eggs

Lactating dairy cows

The saflufenacil was administered orally to 14 lactating cows over a period of 28 days. Based on the proposed usage of the test substance as pre-emergence treatment and a maximal anticipated dietary intake from feed, the target dose level of 0.1 ppm in feed (1×) was determined. The actual dose levels of 0.15 ppm (1×), 0.48 ppm (3×) and 1.7 ppm (10×) were calculated based on actual feed intake.

No residues were detected in any milk specimens at any of the dosing levels.

No residues were detected in muscle or fat specimens at any of the dosing levels.

In the liver samples from the 1× dose group, the residue levels ranged from 0.17 mg/kg to 0.26 mg/kg (mean 0.21 mg/kg). In the 3× dose group, the residue levels ranged from 0.67 mg/kg to 0.88 mg/kg (mean 0.77 mg/kg). In the 10× dose group, the residue levels ranged from 2.09 mg/kg to 3.49 mg/kg (mean 2.61 mg/kg). A good correlation between feeding level and residue level was obtained for liver. Residues in the 10× dose group were 1.66 mg/kg and 0.34 mg/kg after 2 and 7 days of withdrawal, respectively.

No residues were detected in the kidney samples at the 1× dose level. Residues at the 3× dose level were 0.02 mg/kg; those at the 10× dose level ranged from 0.03 to 0.04 mg/kg (mean 0.04 mg/kg). The residues in the 10× group declined to 0.03 mg/kg after 2 days of withdrawal and were below the LOQ after 7 days of withdrawal.

The residues expected in animal commodities based on the calculated animal burden are shown in the table below.

	Feed level (ppm) for milk residues	Residues (mg/kg) in milk	Feed level (ppm) for tissue residues	Residues (mg/kg) in			
				Muscle	Liver	Kidney	Fat
Maximum residue level beef or dairy cattle							
Feeding study [a]	0.15	< 0.01	0.15	< 0.01	0.26	< 0.01	< 0.01
Dietary burden and residue estimate	0.096	< 0.01	0.157	< 0.01	0.26	< 0.01	< 0.01
STMR beef or dairy cattle							
Feeding study [b]	0.15	< 0.01	0.15	< 0.01	0.21	< 0.01	< 0.01
Dietary burden and residue estimate	0.096	< 0.01	0.101	< 0.01	0.14	< 0.01	< 0.01

[a] Highest residues for tissues and mean residue for milk

[b] Mean residues for tissues and milk

The Meeting estimated maximum residue levels of 0.01 mg/kg for milk and milk cream, muscle and fat, 0.01 mg/kg kidney, and 0.3 mg/kg for edible offal of mammals based on residues in liver. The estimated STMR and HR values are 0.01 mg/kg for milk and milk cream and muscle, and HR of 0.26 mg/kg and STMR of 0.14 mg/kg for edible offal of mammals.

Laying hens

The calculated feed burden for poultry based on feed items with highest residues resulted in 0.035 ppm total dry matter feed. Thus, the trigger value of 0.1 mg/kg dry matter feed for conducting a farm animal feeding study was not reached.

In addition, it can be concluded from the data of the hen metabolism study that there are no residues to expect in any of the edible hen matrices assuming a hen feeding level of 0.035 ppm dry matter feed. This feeding level would be lower by a factor of more than 300 compared to the feeding level of 12.6–12.7 mg/kg in the hen metabolism study.

Therefore, by extrapolation from the residue levels in the metabolism study the residues in a hen feeding study would be far below the LOQ of 0.01 mg/kg of the residue analytical method for any of the edible hen matrices even at a 10× feeding level. Thus a hen feeding study has not been conducted.

Establishment of maximum residue limit for poultry product is not necessary.

DIETARY RISK ASSESSMENT

Long-term intake

The evaluation of saflufenacil resulted in recommendations for maximum residue levels and STMR values for raw and processed commodities. Where data on consumption were available for the listed food commodities, dietary intakes were calculated for the 13 GEMS/Food Consumption Cluster Diets. The results are shown in Annex 3.

The IEDIs in the thirteen Cluster Diets, based on estimated STMRs were 0% of the maximum ADI of 0.05 mg/kg bw. The Meeting concluded that the long-term intake of residues of saflufenacil from uses that have been considered by the JMPR is unlikely to present a public health concern.

Short-term intake

The Meeting concluded that establishment of acute reference dose is not necessary. The estimation of short-term intake of residues of saflufenacil was not necessary.

5.22 SPINOSAD (203)

RESIDUE AND ANALYTICAL ASPECTS

Spinosad was first evaluated by the JMPR in 2001 for toxicology and residues and then in 2004 and 2008 for residues. An ADI of 0–0.02 mg/kg bw was estimated and an acute reference dose was determined to be unnecessary.

The 2011 Meeting received residues studies from the manufacturer to support additional maximum residue levels for various berries, bulb vegetables, tree nuts and hops. Residues data were also submitted by COLEACP-PIP to support maximum residue levels for papaya, passionfruit, okra and French beans.

Analytical methods

The analytical methods provided with the supervised trials are generally based on the two methods previously reviewed by JMPR in 2001, namely HPLC and immunoassay.

The HPLC methods, after an extraction specific to the matrix, follow a reasonably standard clean-up, with determination based on UV or MS detection. These methods allow measurement of the individual spinosyns and provide data on spinosyns A, D, K, B and B of D in residue trials. Spinosyn A usually contributes most of the residue, and some HPLC methods concentrate on spinosyns A and D. The LOQ for most substrates is 0.01 mg/kg.

Immunoassay methods, after an extraction designed for the matrix, may or may not require clean-up before the final colorimetric determination. The methods are specific and measure the sum of the spinosyns and their metabolites. When the HPLC and immunoassay methods were tested side-by-side, the agreement was usually good. The LOQ for most substrates is 0.01 mg/kg.

Results of supervised trials on crops

The OECD calculator was used as a tool in the estimation of the maximum residue level from the selected residue data set obtained from trials conducted according to GAP. As a first step, the Meeting reviewed all relevant factors related to each data set in arriving at a best estimate of the maximum residue level using expert judgement. Then, the OECD calculator was employed. If the statistical calculation spreadsheet suggested a different value from that recommended by the JMPR, a brief explanation of the deviation was provided.

Blueberries

The Meeting received data for blueberries from supervised trials conducted in the USA and Australia. The Australian trial did not conform to Australian GAP (1-day PHI) and was not considered further.

The GAP in the USA consists of up to 6 applications at 105 g ai/ha (for a total seasonal maximum of 504 g ai/ha) and a PHI of 3 days. The residues that correspond to USA GAP are in ranked order (n = 5): 0.041, 0.084, 0.11, 0.16, and 0.18 mg/kg. The Meeting estimated a maximum residue level of 0.4 mg/kg for spinosad on blueberries. The STMR is 0.11 mg/kg.

Cranberry

Data on cranberries were reviewed by the JMPR in 2008. However, the Meeting decided that since none of the trials matched any GAP available at that time, no estimate could be made for a maximum residue level for spinosad in cranberries. The GAP in the USA has since changed and the same trials are now re-evaluated against the new GAP.

Six supervised trials were conducted in the USA and Canada in 1999, according to maximum GAP of the USA (three foliar applications at 175 g ai/ha with a PHI of 21 days).

All residue values were < 0.01 mg/kg. The Meeting estimated an MRL for spinosad on cranberry of 0.02 mg/kg. The STMR is 0.01 mg/kg.

Raspberries

The Meeting received data from supervised trials on raspberries, conducted in the USA, Switzerland and the UK.

The GAP in the USA is up to 6 applications at a rate of 105g ai/ha (or a seasonal maximum of 504 g ai/ha) and a PHI of 1 day. Spinosad residues in raspberries in US trials conducted according to USA GAP were 0.07 and 0.42 mg/kg and in one trial on boysenberries residues were 1.8 mg/kg.

Four supervised trials on raspberries (two in Switzerland and two in the UK) were conducted during 2007 according to the GAP in Belgium, which is up to 2 applications at 9.6 g ai/hL and a PHI of 3 days.

The ranked order of residues from supervised trials in Switzerland and the UK according to GAP was: < 0.01, 0.14, 0.14 and 0.42 mg/kg.

Although residues were higher in trials from the USA, the Meeting considered that there were an insufficient number of trials to recommend a maximum residue level for raspberries. Using the trials from Europe matching the GAP of Belgium the Meeting estimated a maximum residue level of 1 mg/kg and an STMR of 0.14 mg/kg and agreed to extrapolate these estimates to dewberries and blackberries.

Papaya

As part of the Pesticide Initiative Project field trials from Côte d'Ivoire and Ghana were conducted where spinosad was applied as foliar sprays to papaya (3 × 96g ai/ha with intervals of 56 and 77 days).

Residues observed in rank order at a 3 day PHI were;

- after the first application: <0.01, 0.012, 0.085, 0.12, 0.15, 0.23 mg/kg,
- after the second application: 0.023, 0.029, 0.13, 0.14, 0.15, 0.17 mg/kg
- and after the last application: 0.012, 0.019 mg/kg.

While the application conditions for the trials were based on the requirement for appropriate control of pests, they were not supported by an official label or an official declaration of approved use. In the absence of evidence for an approved GAP, the Meeting could not estimate a maximum residue level for spinosad in papaya.

Passionfruit

Three supervised trials were conducted in Kenya during 2005/2006 and two in 2007 matching the Kenyan GAP (96g ai/ha with a 1-day PHI and with the number of applications not specified).

The ranked order of residues from supervised trials complying with GAP was: 0.080, 0.11, 0.23, 0.33 and 0.33 mg/kg. The Meeting estimated a MRL for spinosad on passionfruit of 0.7 mg/kg. The STMR is 0.23 mg/kg.

Onions, bulb

The Meeting received a total of twenty supervised trials on bulb onions from France (9), Italy (4), the UK (2), Brazil (3) and New Zealand (2) and eleven on spring onions from France (5), Germany (2),

Italy (1) and the USA (3). As there is no GAP for onions in New Zealand, the data from that country was not considered further. For the other countries the GAP for onions is applicable to both bulb and spring (green) onions.

The GAP in Brazil for bulb onions is up to 3 applications at 96 g ai/ha with a PHI of 1 day. Residues from trials according to the GAP were below the LOQ of 0.01 mg/kg (n = 3).

The GAP in France is 2 applications at 96 g ai/ha and a PHI of 7 days.

Residues in bulb onions from trials from the UK, France and Italy, approximating GAP from France (n = 15) are: < 0.01(10), 0.02, 0.03, < 0.05(3) mg/kg.

The Meeting estimated a maximum residue level of 0.1 mg/kg for spinosad in bulb onions. The STMR is 0.01 mg/kg.

Spring onions

The Meeting received data from eleven supervised trials conducted on spring onions in USA and France, Germany and Italy.

In France GAP for onions is 2 applications of spinosad at 96 g ai/ha and a PHI of 7 days. Residues in spring onions from trials from France, Germany and Italy approximating GAP of France in ranked order (n = 8) were: < 0.01 (3), 0.01, 0.01, 0.02, 0.03 and 0.11 mg/kg.

The GAP in the USA is up to 5 applications at a maximum rate of 140 g ai/ha (maximum seasonal rate of 504 g ai/ha) and a PHI of 1 day. The residues from the USA trials in ranked order were: 0.11, 0.2 and 1.5 mg/kg.

As residues in trials matching the GAP of the USA would lead to the higher maximum residue level the Meeting used the data from the USA trials to estimate a maximum residue level of 4 mg/kg for spinosad in spring onions. The STMR is 0.2 mg/kg.

Okra

Field trials on okra from Côte d'Ivoire were conducted within the Pesticide Initiative Project aiming to provide data for establishing import MRLs in the European Union. Spinosad was applied as foliar sprays to okra (1 or 2 applications of spinosad at 160 g ai/ha at a 14-day interval and a PHI of 2 days). The residues at two days after the last application were 0.05, 0.35, and 0.61 mg/kg.

While the application conditions for the trials were based on the requirement for appropriate control of pests, they were not supported by an official label or an official declaration of approved use. In the absence of evidence of an approved GAP, the Meeting could not estimate a maximum residue level for spinosad in okra.

Green beans

Three supervised trials were conducted in Kenya and Senegal, but did not match the GAP of Kenya (96 g ai/ ha and a PHI of 1 day). Consequently, the Meeting was unable to estimate a maximum residue level, HR or STMR.

Tree nuts

Almonds

Data from supervised trials on almonds conducted in the USA (GAP of 180 g ai/ha with a PHI of 14 days) were reviewed by the 2001 JMPR and Codex MRLs of 0.01* mg/kg for nutmeat and 2 mg/kg for almond hulls have been established. The GAP has since changed and new trials were evaluated by the Meeting.

The new GAP for almonds in the USA is up to 3 applications at a maximum rate of 175 g ai/ha with a PHI of 1 day. Supervised trials on almonds were conducted in the USA that matched the revised GAP. Residues of spinosad in almond nutmeat were in rank order: < 0.01, < 0.02, < 0.02, 0.032, 0.044, and 0.047 mg/kg.

Pecans

The Meeting received data from four trials conducted on pecans in the USA, however the trials did not match the new US GAP.

Walnuts

Data were received from two supervised trials conducted in Italy. The GAP for tree nuts in Italy is up to 3 applications at a rate of 216 g ai/ha with a PHI of 7 days. Residues corresponding to GAP were below the LOQ of 0.005 (2) mg/kg. The Meeting considered two trials to insufficient to estimate a maximum residue level for walnuts.

The Meeting agreed to use the data on almonds from the USA to estimate a maximum residue level of 0.07 mg/kg for tree nuts and an STMR of 0.026 mg/kg. The recommendation replaces the previous recommendation of 0.01* mg/kg for almonds.

Hops, dry

Two supervised trials were conducted on basil in the USA. The data were provided to support a maximum residue level for hops. The Meeting agreed that data for basil were not relevant for hops.

Animal feed commodities

Almond hulls

Residues of spinosad in almond hulls from trials conducted according to the GAP of the USA in ranked order were: 0.62, 0.76, 0.95, 3.5, 4.5 and 5.1 mg/kg. The median residue is 2.23 mg/kg. The Meeting considered that almond hulls are not traded and agreed to withdraw its previous recommendation of 2 mg/kg for almond hulls.

Residues in animal commodities

Almond hulls are the only commodity in the present evaluation which can be considered as a beef and dairy cattle feed item and are not consumed by poultry. Maximum and mean dietary burdens for beef and dairy cattle were recalculated to determine if the resulting higher residues on almond hulls from the updated USA GAP would change the dietary burdens previously estimated by JMPR. The dietary burdens were estimated using the OECD diets listed in Appendix IX of the 2009 edition of the FAO Manual.

The increased residue levels for almond hulls do not change the previously estimated maximum dietary burden of spinosad in cattle and the corresponding previous recommendations on animal commodities will remain the same.

DIETARY RISK ASSESSMENT

Long-term intake

The evaluation of spinosad resulted in recommendations for new MRLs and STMR values for raw and processed commodities. Data on consumption were available for 71 food commodities from this and previous evaluations and were used to calculate dietary intake. The results are shown in Annex 3.

The IEDIs in the five GEMS/Food regional diets, based on estimated STMRs were 10–40% of the maximum ADI (0.02 mg/kg bw). The Meeting concluded that long-term intake of residues of spinosad from uses that have been considered by the JMPR is unlikely to present a public health concern.

Short-term intake

The 2001 JMPR concluded that it was unnecessary to establish an ARfD for spinosad. The Meeting therefore concluded that short-term dietary intake of spinosad residues is unlikely to present a risk to consumers.

5.23 SPIROTETRAMAT (234)

RESIDUE AND ANALYTICAL ASPECTS

Spirotetramat was first evaluated by the JMPR in 2008. An ADI of 0-0.05 mg/kg bw and an acute reference dose of 1.0 mg/kg bw were established. Maximum residue levels were recommended for many crops and animal commodities.

The manufacturer has submitted additional data for mangoes, kiwifruit, papaya, litchi, avocado, guava, onions, edible beans and peas with pods, succulent shelled beans and peas, pulses including soya beans and cotton. Animal feed residues data have been provided for legumes and pulses. Cotton and soya bean processing studies have also been submitted.

Analytical methods

Suitable analytical methods were available for quantifying spirotetramat residues including the metabolites spirotetramat -enol, spirotetramat -ketohydroxy, spirotetramat -mono-hydroxy and spirotetramat enol-Glc in plant matrices by HPLC-MS/MS. The limits of quantification (LOQ) for plant commodities are generally 0.01 to 0.02 mg/kg (as parent equivalents) for each analyte.

Stability of pesticide residues in stored analytical samples

Samples from the residue trials were stored for periods less than the period of stability demonstrated in studies submitted to JMPR 2008. Since the storage stability data from JMPR 2008 cover a diverse range of crops and demonstrated stability of all analytes for up to 2 years, it is considered that these data should be sufficient to cover the storage stability of all the samples.

Results of supervised trials on crops

The Meeting received supervised trials data from the foliar application of spirotetramat as an oil dispersion (OD) or suspension concentrate formulation (SC) to a variety of tropical fruit crops, legume vegetables, pulses and cotton. Brussels sprouts data which were submitted for the 2008 JMPR are also re-evaluated here as revised GAP has become available.

The 2008 JMPR established the following residue definitions for spirotetramat.

Residue for enforcement plant commodities: spirotetramat plus spirotetramat enol, expressed as spirotetramat.

Residue for dietary intake plant commodities: spirotetramat plus the metabolites enol, ketohydroxy, enol glucoside, and monohydroxy, expressed as spirotetramat.

Residue for enforcement and dietary intake animal commodities: spirotetramat enol, expressed as spirotetramat

Consequently, in the discussions below residues of spirotetramat plus enol are considered first for estimation of maximum residue levels followed by total residues (spirotetramat plus the metabolites enol, ketohydroxy, enol glucoside, and monohydroxy, expressed as spirotetramat) for estimation of STMR and HR values for dietary risk assessment.

Assorted tropical and sub-tropical fruits – inedible peel

Residue trials were conducted in avocado at five sites in the USA (2), Mexico (1) and Chile (2). Residues of spirotetramat plus enol in two trials from Chile, matching GAP of that country (3 × 300 g ai/ha, PHI 3 days) were 0.18 and 0.35 mg/kg. In three trials from Mexico and the USA that matched the GAP of Mexico (3 applications at 288 g ai/ ha with a 14-day retreatment interval, 1-day PHI)

residues of spirotetramat plus enol were 0.069, 0.13, and 0.20 mg/kg. There are insufficient data to estimate a maximum residue level for avocado.

Residue trials were conducted in guava at two sites in Mexico according to the GAP for USA for various tropical fruits (3 applications at 175 g ai/ ha with a 14-day retreatment interval, 1-day PHI). The ranked order of residues of spirotetramat plus enol from supervised trials collected 1 day after the last application is 0.54 and 0.92 mg/kg.

The Meeting considered the number of trials insufficient to estimate a maximum residue level.

Residue trials were conducted in litchi at three sites in Mexico according to the GAP for USA for various tropical fruits (3 applications at 175 g ai/ ha with a 14-day retreatment interval, 1-day PHI). The ranked order of residues of spirotetramat plus enol from supervised trials collected 1 day after the last application was 0.76, 0.85 and 5.2 mg/kg. The Meeting estimated a maximum residue level of 15 mg/kg for litchi.

The ranked order of total residues of spirotetramat from supervised trials collected 1 day after the last application was 1.3, 1.6 and 6.0 mg/kg. The Meeting estimated an STMR of 1.6 mg/kg and an HR of 6.0 mg/kg for total residues of spirotetramat for use in dietary intake calculations.

Residue trials were conducted in papaya at four sites in Mexico according to Mexican GAP (3 applications at 288 g ai/ha with a 14-day retreatment interval, 1-day PHI). The ranked order of residues of spirotetramat plus enol from supervised trials collected 1 day after the last application was 0.09, 0.096, 0.17 and 0.18 mg/kg. The Meeting estimated a maximum residue level of 0.4 mg/kg for papaya.

The ranked order of total residues of spirotetramat from supervised trials collected 1 day after the last application was 0.13, 0.13, 0.21 and 0.22 mg/kg. The Meeting estimated an STMR of 0.17 mg/kg and an HR of 0.22 mg/kg for total residues of spirotetramat in papaya for use in dietary intake calculations.

Four supervised trials on mango conducted in Australia that complied with GAP in that country (2 × 9.6 g ai/hL, 21-day intervals with a 14-day PHI) were made available to the Meeting. The ranked order of residues of spirotetramat-plus-enol, on a whole fruit basis, from trials matching Australian GAP is 0.05, 0.06, 0.07 and 0.16 mg/kg. The Meeting estimated a maximum residue level of 0.3 mg/kg for mango.

The ranked order of total residues of spirotetramat on a pulp and skin basis from trials matching Australian GAP was 0.12 0.14, 0.18 and 0.25 mg/kg. The Meeting estimated an STMR of 0.16 mg/kg and an HR of 0.25 mg/kg for total residues of spirotetramat in mango for use in dietary intake calculations.

Five supervised trials were conducted in kiwifruit in New Zealand in which 2 applications of spirotetramat were made at 4.8 g ai/hL. The GAP in New Zealand consists of 3 applications of spirotetramat at 4.8 g ai/hL. The first application should be pre-flowering, the 2nd at fruit set and the 3rd application at 21 days after fruit set. The trials can be considered as matching this GAP.

No residues of either spirotetramat or -enol were detected at harvest (129–156 days after last application); individual compound LOQs were both 0.02 mg/kg. The Meeting estimated a maximum residue level of 0.02* mg/kg for residues of spirotetramat in kiwifruit.

The ranked order of total residues of spirotetramat from supervised trials collected at harvest (129–156 days) after the last application was < 0.054, 0.054, < 0.055, < 0.055 and 0.066 mg/kg. The Meeting estimated an STMR of 0.055 mg/kg and an HR of 0.066 mg/kg for total residues of spirotetramat in kiwifruit for use in dietary intake calculations.

Onions, bulb

Trials were conducted on onions in Australia according to GAP (2 applications at 48g ai/ha with a PHI of 7 days). The ranked order of residues of spirotetramat plus enol from supervised trials according to Australian GAP were: < 0.04 (3), 0.04, 0.08, 0.10 and 0.21 mg/kg. The Meeting estimated a maximum residue level of 0.4 mg/kg for residues of spirotetramat in bulb onions.

The ranked order of total residues of spirotetramat from supervised trials according to GAP was < 0.11 (3), 0.11, 0.15 and 0.16 and 0.27 mg/kg (STMR = 0.11 mg/kg). For onions, bulb the HR is 0.27 mg/kg and the STMR is 0.11 mg/kg.

Brussels sprouts

Eight supervised trials (seven locations) were conducted in Europe (Germany, France and the United Kingdom) during 2004–2005, in which 3 applications of spirotetramat were made to Brussels sprouts at 72g ai/ha. The GAP for the United Kingdom, Belgium, Ireland and Austria allows 2 applications at 75 g ai/ha with a PHI of 3 days.

The Meeting considered the influence of two sprays compared to three sprays on the final residue in determining whether or not the trials matched GAP and noted only a slow decline in residues. As three foliar applications were used in the trials and the additional application would affect the final residue, none of the trials are considered to approximate GAP.

Trials were also conducted at two sites in Australia in which 3 applications of spirotetramat were made to Brussels sprouts according to Australian GAP (3 applications at 96 g ai/ha with a PHI of 3 days). The ranked order of residues of spirotetramat plus enol from supervised trials according to Australian GAP was 0.07 and 0.15 mg/kg. The Meeting considered the number of trials inadequate to estimate a maximum residue level.

Legume vegetables

Residue trials were conducted in peas with pods at three different sites in the USA and in beans with pods (snap beans, podded) at six different sites in the USA according to the critical US GAP (application at 88 g ai/ha – maximum of 175 g ai/ha per season with a 1-day PHI).

The ranked order of residues of spirotetramat plus enol in beans with pods at a 1-day PHI from supervised trials was 0.059, 0.17, 0.37, 0.43, 0.53 and 0.67 mg/kg.

The ranked order of total residues of spirotetramat in beans with pods at a 1-day PHI from supervised trials was 0.15, 0.26, 0.47, 0.54, 0.80 and 0.84 mg/kg.

The ranked order of residues of spirotetramat plus enol in peas with pods at a 1-day PHI was 0.58, 0.66 and 1.2 mg/kg.

The ranked order of total residues of spirotetramat in peas with pods at a 1-day PHI from supervised trials was 0.63, 0.74 and 1.3 mg/kg.

Residue trials were also conducted in garden peas (succulent seeds of shelled peas) and Lima beans at 6 different sites in the USA according to the critical US GAP (application at 88 g ai/ha – maximum of 175 g ai/ha per season with a 1-day PHI).

The ranked order of residues of spirotetramat plus enol in succulent seeds of shelled peas at a 1-day PHI from supervised trials was 0.36, 0.40, 0.43, 0.52, 0.56 and 0.59 mg/kg.

The ranked order of total residues of spirotetramat in succulent seeds of shelled peas at a 1-day PHI from supervised trials was 0.45, 0.49, 0.55, 0.62, 0.74 and 0.76 mg/kg.

The ranked order of residues of spirotetramat plus enol in succulent seeds of shelled Lima beans at a 1-day PHI from supervised trials was 0.079, 0.10, 0.18, 0.19, 0.23 and 0.33 mg/kg.

The ranked order of total residues of spirotetramat in succulent seeds of shelled beans at a 1-day PHI from supervised trials was 0.11, 0.13, 0.24, 0.25, 0.31 and 0.44 mg/kg.

The Meeting noted residue trial data are available from the USA for peas with pods, beans with pods as well as shelled peas and beans, all members of the legume vegetables crop group. The USA use pattern is for the crop group legume vegetables. The Meeting decided to estimate a maximum residue level for legume vegetables based on spirotetramat residues in beans with pods. The Meeting estimated a maximum residue level of 1.5 mg/kg for residues of spirotetramat in legume vegetables. For the purpose of dietary intake assessment the HR is 0.84 mg/kg and the STMR is 0.505 mg/kg for legume vegetables, also based on residues in common beans.

Soya bean

Residue trials were conducted at nineteen different sites in the USA and Canada, according to the critical US GAP (application at 88g ai/ha – maximum of 175g ai/ha per season with a 21-day PHI).

The ranked order of total spirotetramat plus enol residues found in soya bean seeds according to the critical US GAP was 0.042, 0.045, 0.061, 0.071, 0.13, 0.13, 0.15, 0.27, 0.33, 0.39, 0.41, 0.75, 0.76, 1.0, 1.1, 1.5, 1.5, 2.0 and 2.2 mg/kg. The Meeting estimated a maximum residue level for spirotetramat on soya bean (dry) of 4 mg/kg.

The ranked order of total residues of spirotetramat in soya bean seeds according to the critical US GAP was 0.072, 0.075, 0.091, 0.11, 0.16, 0.16, 0.18, 0.30, 0.36, 0.45, 0.48, 0.82, 0.84, 1.0, 1.2, 1.6, 1.6, 2.2 and 2.7 mg/kg. The HR is 2.7 mg/kg and the STMR is 0.45 mg/kg.

Dried shelled peas and beans

Trials in peas were conducted in USA during 2007–2008 at five different sites, according to US GAP (application at 88g ai/ha – maximum of 175g ai/ha per season with a 7-day PHI).

The ranked order of residues of spirotetramat plus enol in dry shelled pea seeds at a 7-day PHI from supervised trials was 0.039, 0.21, 0.23, 0.72, and 1.0 mg/kg.

The ranked order of total residues of spirotetramat in dry shelled pea seeds at a 7-day PHI from supervised trials was 0.069, 0.24, 0.26, 0.78 and 1.1 mg/kg.

Trials in beans (cowpeas) were conducted in USA during 2007–2008 at eight different sites, according to US GAP (application at 88g ai/ha – maximum of 175g ai/ha per season with a 7-day PHI).

The ranked order of residues of spirotetramat plus enol in dry shelled bean seeds at USA GAP (7-day PHI) from supervised trials was < 0.02, < 0.02, 0.026, 0.063, 0.067, 0.11, 0.48, 0.54 and 0.73 mg/kg.

The ranked order of total residues of spirotetramat in dry shelled bean seeds at USA GAP (7-day PHI) from supervised trials was < 0.05, 0.05, 0.056, 0.14, 0.17, 0.18, 0.52, 0.80 and 1.2 mg/kg.

The Meeting considered the residue data for beans (dry) and peas (dry) can be combined (Mann-Whitney test) to recommend a maximum residue level for the group pulses (except soya bean).

The ranked order of residues of spirotetramat plus enol in dry shelled bean and pea seeds at USA GAP from supervised trials were: < 0.02, < 0.02, 0.026, 0.039, 0.063, 0.067, 0.11, 0.21, 0.23, 0.48, 0.54, 0.72, 0.73 and 1.0 mg/kg. The Meeting estimated a maximum residue level for spirotetramat in pulses (except soya beans) of 2 mg/kg. The ranked order of total residues of spirotetramat in dry shelled bean and pea seeds at USA GAP from supervised trials was < 0.05, 0.05, 0.056, 0.069, 0.14, 0.17, 0.18, 0.24, 0.26, 0.52, 0.78, 0.80, 1.1 and 1.2 mg/kg. The HR is 1.2 mg/kg and the STMR is 0.21 mg/kg.

Cotton seed

Residue trials were conducted at eleven different sites in the USA, ten according to the critical US GAP (application at 88 g ai/ha – maximum of 175 g ai/ha per season with a 21-day PHI).

The ranked order of total spirotetramat plus enol residues found in cotton seeds according to the critical US GAP was (n = 10): < 0.02, < 0.02, 0.02, 0.030, 0.033, 0.049, 0.052, 0.092, 0.094 and 0.26 mg/kg. The Meeting estimated a maximum residue level for spirotetramat on cotton seed of 0.4 mg/kg.

The ranked order of total residues of spirotetramat in cotton seeds according to the critical US GAP was < 0.05, 0.055, 0.057, 0.077, 0.079, 0.11, 0.12, 0.13, 0.13 and 0.29 mg/kg. The STMR is 0.095 mg/kg.

Animal feeds

The Meeting received supervised trials data for a variety of animal feeds (soya bean forage and hay, various legume animal feeds and cotton gin by-products).

Legume animal feeds (bean hay and forage, pea hay and vines)

Residue trials on soya beans were conducted at nineteen different sites in the USA and Canada, according to the critical US GAP (application at 88g ai/ha – maximum of 175g ai/ha per season with a 3-day PHI for forage and hay). The ranked order of total residues of spirotetramat found in soya bean forage (wet weight) according to the critical US GAP were: 0.66, 1.2, 1.7, 2.2, 2.3, 2.7, 2.7, 2.9, 3.3, 3.3, 3.6, 3.7, 3.9, 4.6, 4.7, 4.8, 5.1, 6.6 and 6.6 mg/kg. Correcting the data for dry matter contents the ranked order of total residues of spirotetramat found in soya bean forage (dry weight) according to the critical US GAP was 3.0, 7.4, 11,13, 14, 14, 16, 16, 17, 19, 19, 20, 20, 24, 25, 28, 29, 33 and 40 mg/kg. The highest and median residues for calculating livestock dietary burden are 40 and 19 mg/kg respectively (dry weight basis).

The ranked order of total residues of spirotetramat found in soya bean hay (wet weight) according to the critical US GAP was 1.7, 1.7, 1.9, 4.3, 4.9, 5.0, 5.4, 5.8, 6.5, 8.2, 8.5, 8.9, 9.0, 9.6, 10, 10, 10, 12 and 12 mg/kg. Correcting the data for reported dry matter contents results in total residues of spirotetramat found in soya bean hay (dry weight) of 2.5, 2.9, 3.6, 7.0, 7.6, 9.1, 9.1, 9.8, 11, 12, 12, 13, 13, 14, 14, 15, 15, 15 and 17 mg/kg.

The ranked order of total residues of spirotetramat found in cowpea forage (wet weight) according to the critical US GAP was 2.0, 2.2, 2.7, 2.7, 3.4 and 4.1 mg/kg. When corrected for dry matter, total residues of spirotetramat found in cowpea forage (dry weight) were 5.1, 5.3, 6.9, 7.9, 10 and 12 mg/kg.

The ranked order of total residues of spirotetramat found in cowpea hay (wet weight) matching the critical US GAP were: 0.28, 1.0, 1.1, 1.1, 2.1 and 2.6 mg/kg. On correcting for dry matter, total residues of spirotetramat were 0.39, 1.3, 1.6, 1.9, 2.6 and 3.9 mg/kg.

The ranked order of total residues of spirotetramat found in pea hay (wet weight) according to the critical US GAP *mg/kg* was 0.49, 0.61, 1.4, 5.2 and 5.7 mg/kg and when converted to a dry matter basis 0.88, 1.1, 1.8, 8.0 and 9.7 mg/kg.

The ranked order of total residues of spirotetramat found in pea vines (wet weight) according to the critical US GAP was 0.19, 0.31, 0.85, 1.9 and 3.1 mg/kg. On correction for dry mater content, the ranked order of total residues of spirotetramat were: 0.66, 1.1, 2.7, 5.3 and 11 mg/kg.

The Meeting considered the legume animal feed residue data could support a maximum residue level for the group legume animal feeds based on the commodity with the highest residues, i.e., soya bean hay. The ranked order of total residues of spirotetramat in soya bean hay (dry weight) were 2.5, 2.9, 3.6, 7.0, 7.6, 9.1, 9.1, 9.8, 11, 12, 12, 13, 13, 14, 14, 15, 15, 15 and 17 mg/kg. The

Meeting estimated a maximum residue level for spirotetramat on legume animal feed of 30 mg/kg (dry weight). The highest residue is 17 mg/kg and the median is 12 mg/kg.

Cotton gin by-products (gin trash)

The ranked order of total residues of spirotetramat in cotton gin by-products (wet weight) according to the critical US GAP was 0.16, 0.51, 0.67, 1.2 and 4.9 mg/kg and when corrected for dry matter content were: 0.20, 0.60, 0.79, 1.5 and 5.9 mg/kg. The highest residue is 5.9 mg/kg and the median is 0.79 mg/kg.

Fate of residues during processing

The Meeting received processing studies for cottonseed and soya beans.

The processing factors derived from the processing studies and the resulting STMR-Ps and HR-Ps are summarized in the table below. The processing factors are the ratio of the residue in the processed commodity divided by the residue in the raw agricultural commodity (RAC). Processing factors were calculated for total spirotetramat residues, required for estimating residues in processed commodities for dietary risk assessment and also for spirotetramat +enol required for estimating residues for compliance. For most commodities the two processing factors were comparable.

Of the traded commodities, the only commodity for which there was significant increase in residues measured using the compliance definition was cottonseed meal. Based on the maximum residue level of 0.4 mg/kg (spirotetramat + enol) in cottonseed and a processing factor of 2.28 for cottonseed meal, (0.4 × 2.3 = 0.92 mg/kg) the Meeting estimated a maximum residue level for spirotetramat in cotton seed meal of 1 mg/kg.

Processing factors (PF) from the processing of cottonseed and soya beans

	Processed Commodity	PF Total residue [a]	STMR/ STMR-P or median	HR/ HR-P or highest	PF spirotetramat + enol[b]
Cottonseed	Cottonseed	-	0.095	0.29	-
	Meal	1.25	0.12	0.36	2.28
	Hull	1.05	0.10	0.30	0.55
	Oil, refined	< 1	0	0	< 1
Soya bean	Soya bean	-	0.45	2.7	-
	Aspirated Grain Fractions	4.12	1.9	11.1	3.0
	Meal	1.37	0.62	3.7	1.33
	Hull	< 1	0.40	2.4	< 1
	Oil, refined	< 1	0	0	< 1
	Defatted flour	1.01	0.46	2.7	< 1
	Soya milk	< 1	0.06	0.34	< 1

[a] The factor is the ratio of the total residue (parent spirotetramat plus four metabolites, calculated as spirotetramat) in the processed item divided by the total residue in the RAC

[b] The factor is the ratio of the spirotetramat + enol in the processed item divided by spirotetramat + enol in the RAC

Processed commodity STMR-Ps and HR-Ps were calculated on the basis of the total parent residue PF.

Residues in animal commodities

Farm animal dietary burden

Dietary burden calculations for beef cattle and dairy cattle and poultry are provided below. The dietary burdens were estimated using the OECD diets listed in Appendix IX of the 2009 edition of the FAO Manual.

Potential cattle feed items include: almond hulls, apple pomace, citrus pulp, grape pomace, potato culls and dried pulp, cabbage heads, cotton seed, cotton seed meal and hulls, cotton gin by-products, soya bean forage and fodder (hay), soya beans, soya bean meal and hulls, soya bean aspirated grain fractions, bean and pea seed, bean vines and pea vines and hay.

Potential poultry feed items include: potato culls and dried pulp, cabbage heads, cotton seed meal, soya bean forage and hay, soya beans, soya bean meal and hulls, bean and pea seed, pea vines and hay.

Summary of livestock dietary burden (ppm of dry matter diet)

	US-Canada		EU		Australia		Japan	
	max	mean	Max	mean	max	Mean	max	Mean
Beef cattle	1.2	0.43	6.3	3.3	40[a]	19[c]	0.51	0.51
Dairy cattle	9.00	4.6	6.2	3.2	22[b]	11[d]	0.45	0.45
Poultry Broiler	1.02	0.27	0.59	0.43	0.39	0.39	0.24	0.24
Poultry Layer	1.02	0.27	4.8[e]	2.3[f]	0.39	0.39	0.20	0.20

[a] Highest maximum beef or dairy cattle dietary burden suitable for MRL estimates for mammalian meat

[b] Highest maximum dairy cattle dietary burden suitable for MRL estimates for mammalian milk

[c] Highest mean beef or dairy cattle dietary burden suitable for STMR estimates for mammalian meat.

[d] Highest mean dairy cattle dietary burden suitable for STMR estimates for milk.

[e] Highest maximum poultry dietary burden suitable for MRL estimates for poultry meat and eggs.

[f] Highest mean poultry dietary burden suitable for STMR estimates for poultry meat and eggs.

Animal commodity maximum residue levels

A lactating dairy cow feeding study was reported by the 2008 JMPR where cows were dosed orally for 29 consecutive days with spirotetramat at target dose rates (based on feed dry weight) of 3, 9 or 30 ppm. The maximum dietary burden for beef cattle is 40 ppm and is higher than the highest dose level in the feeding study of 30 ppm. Residues in kidney (the tissue with highest residues) in the cattle feeding study show a linear relationship (R^2 = 0.9998) with dose. The Meeting considered it acceptable to assume proportionality of dose *vs.* residues for the tissues and milk and extrapolate the results from the 30 pm feed level to estimate residues in tissues at a dietary burden of 40 ppm.

	Feed level	Residues	Feed level	Residues (mg/kg) in			
	(ppm) for milk residues	(mg/kg) in milk	(ppm) for tissue residues	Muscle	Liver	Kidney	Fat
MRL beef or dairy cattle							
Feeding study [a]	30	0.005	30	0.014	0.038	0.41	0.032
Dietary burden and residue estimate	22	< 0.005	40	0.019	0.051	0.55	0.043
STMR beef or dairy cattle							
Feeding study [b]	9 30	< 0.005 < 0.005	9 30	0.0034 0.0088	0.012 0.030	0.072 0.26	0.008 0.016
Dietary burden and residue estimate	11	< 0.005	19	0.006	0.021	0.16	0.012

[a] highest residues for tissues and mean residues for milk

[b] mean residues for tissues and mean residues for milk

The Meeting estimated the following STMR values: milk 0.005 mg/kg; muscle 0.006 mg/kg; edible offal (based on kidney) 0.16 mg/kg and fat 0.012 mg/kg.

The Meeting estimated the following HR values: milk 0.005 mg/kg; muscle 0.019 mg/kg; edible offal (based on kidney) 0.55 mg/kg and fat 0.043 mg/kg.

The Meeting estimated the following maximum residue levels: milk – 0.01 mg/kg; meat (mammalian except marine) – 0.05 mg/kg and edible offal – 1 mg/kg to replace its previous recommendations of: milk – 0.005* mg/kg; meat (mammalian except marine) – 0.01* mg/kg and edible offal – 0.03 mg/kg.

A poultry feeding study was not available however, in the poultry metabolism study evaluated by the 2008 JMPR where laying hens were dosed at 1.01 mg/kg bw day (12.9 ppm in the diet), residues of spirotetramat-enol in muscle (0.001 mg/kg), fat (0.001 mg/kg) and liver (0.009 mg/kg) were all < 0.01 mg/kg. Residues in eggs were 0.013 mg/kg.

The maximum dietary burden of poultry is 4.8 ppm. Scaling the results of the metabolism study for the poultry dietary burden the Meeting estimated the following HR values: muscle 0.00037 mg/kg, fat 0.00037 mg/kg, liver 0.0033 mg/kg and eggs 0.0048 mg/kg.

The Meeting estimated the following maximum residue levels for poultry commodities: poultry meat 0.01 (*) mg/kg; poultry edible offal 0.01 mg/kg and eggs 0.01 mg/kg.

The mean dietary burden of poultry is 2.3 ppm. The Meeting estimated the following STMR values: poultry meat 0 mg/kg; poultry fat 0 mg/kg; poultry edible offal (based on liver) 0.0016 mg/kg and eggs 0.0023 mg/kg.

DIETARY RISK ASSESSMENT

Long-term intake

The evaluation of spirotetramat has resulted in recommendations for MRLs and STMRs for raw and processed commodities. Consumption data were available for 37 food commodities and were used in the dietary intake calculation. The results are shown in Annex 3. The International Estimated Daily Intakes for the 13 GEMS/Food regional diets, based on estimated STMRs were in the range 2–20% of the maximum ADI of 0.05 mg/kg bw (Annex 3).

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

Short-term intake

The International Estimated Short-term Intake (IESTI) for spirotetramat was calculated for the food commodities (and their processing fractions) for which maximum residue levels and HRs were estimated and for which consumption data were available. The results are shown in Annex 4. The IESTI was a maximum of 40% of the ARfD (1.0 mg/kg bw).

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

5.24 SULFOXAFLOR (252)

TOXICOLOGY

Sulfoxaflor is the International Organization for Standardization (ISO)–approved name for [methyl(oxo){1-[6-(trifluoromethyl)-3-pyridyl]ethyl}-λ^6-sulfanylidene]cyanamide (International Union of Pure and Applied Chemistry) (Chemical Abstracts Service No. 946578-00-3), a novel insecticide from the sulfoximine class. Sulfoxaflor contains two chiral centres (the sulfur atom and the carbon atom attached to position 3 of the pyridine ring) and is a mixture of the four possible stereoisomers. Both (*E*)- and (*Z*)-isomers (involving the S=N double bond and the cyano group) exist, but they rapidly interconvert at ambient temperatures. Sulfoxaflor is effective against a wide range of sap-feeding insects and exerts its insecticidal activity as an agonist at the insect nicotinic acetylcholine receptor (nAChR), which plays a central role in the mediation of fast excitatory synaptic transmission in the insect central nervous system. Sulfoxaflor has not been evaluated previously by the Joint FAO/WHO Meeting on Pesticide Residues and was reviewed at the present Meeting at the request of the Codex Committee on Pesticide Residues.

All pivotal studies were certified as complying with good laboratory practice or an approved quality assurance programme.

Biochemical aspects

In rats given sulfoxaflor labelled with ^{14}C at the pyridine ring orally by gavage, absorption was rapid and accounted for at least 93% of the total recovered radioactivity after a single dose of 5 mg/kg body weight (bw) or 100 mg/kg bw; the maximum plasma concentrations of radiolabelled material were reached after 0.5–1.6 hours and after 1.3–2.3 hours, respectively. Radiolabel was widely distributed throughout the body. Elimination of the radiolabel was mainly via the urine (≥ 92%). After intravenous administration, faecal excretion accounted for up to 9% of total excretion. Elimination of the radiolabel from plasma was bi-exponential, with most of the elimination occurring during the alpha phase, with a half-life of 4–6 hours, whereas the half-life of the beta phase was 39–45 hours. Residues in tissues 168 hours after a single oral or intravenous dose as well as after repeated oral dosing accounted for less than 1.3% of the administered dose, with liver, kidney and erythrocytes containing the highest concentrations of residues.

Sulfoxaflor was metabolized to only a very limited extent. The metabolism included oxidative cleavage of the parent molecule, leading to metabolite X11721061, which was subsequently conjugated with glucuronic acid. This was the only metabolite identified in urine, accounting for 3–4% of the administered dose.

Toxicological data

The median lethal dose (LD_{50}) in rats treated orally with sulfoxaflor was 1000 mg/kg bw. The dermal LD_{50} in rats was greater than 5000 mg/kg bw, and the inhalation median lethal concentration (LC_{50}) in rats was greater than 2.09 mg/L. Sulfoxaflor was not a skin irritant in rabbits, was not irritating to the eye of rabbits and was not a skin sensitizer in the local lymph node assay in mice.

At least in part as a result of its unpleasant smell, sulfoxaflor is of limited oral palatability, so that repeated-dose studies by dietary as well as gavage administration were dose limited by effects on feed intake and consequent body weight reductions.

Following repeated administration of sulfoxaflor to mice and rats, the liver was the main target organ, and males were affected more than females. The effects noted at lower doses (increased liver weights, hepatocellular hypertrophy) were consistent with the induction of hepatic cytochrome P450, whereas effects observed at higher doses included hepatocellular degeneration or necrosis and

related clinical chemistry findings (e.g., increased serum levels of liver enzymes, cholesterol or triglycerides). In mice, the adrenals were an additional target, with hypertrophy and/or vacuolization of the zona fasciculata. In dogs, gavage administration gave the highest achievable doses, but the only effects were decreases in feed consumption and body weight gain and increased incidences of soft or watery faeces.

In a 28-day study in mice, the no-observed-adverse-effect level (NOAEL) was 300 ppm (equal to 43.9 mg/kg bw per day), based on effects in the liver (increased serum alanine aminotransferase, vacuolization/fatty change of hepatocytes) at 1500 ppm (equal to 230 mg/kg bw per day). In a 90-day study in mice, the NOAEL was 100 ppm (equal to 12.8 mg/kg bw per day), based on effects in the liver (vacuolization/fatty change of hepatocytes) and the adrenals (hypertrophy and/or vacuolization of the zona fasciculata) observed in males at 750 ppm (equal to 98 mg/kg bw per day) and in females at 1500 ppm (equal to 247 mg/kg bw per day).

In a 28-day study in rats, the NOAEL was 300 ppm (equal to 24.8 mg/kg bw per day), based on marginal liver toxicity (increased serum cholesterol and total protein levels) in males at 1000 ppm (equal to 79.4 mg/kg bw per day). In a 90-day study in rats, the NOAEL was 100 ppm (equal to 6.36 mg/kg bw per day), based on effects in the liver (increased serum cholesterol level, vacuolization/fatty change of hepatocytes) in males at 750 ppm (equal to 47.6 mg/kg bw per day). After a 28-day recovery phase, very slight histopathological changes in the liver (hypertrophy and fatty change of hepatocytes) were seen in males at 1500 ppm (equal to 94.9 mg/kg bw per day).

In a 90-day oral gavage study in dogs, the NOAEL was 6 mg/kg bw per day, based on decreased feed consumption and decreased body weights during the first week of exposure at 10 mg/kg bw per day. After reduction of this dose to 6 mg/kg bw per day on study day 5, no treatment-related adverse effects were observed. In a 1-year oral gavage study in dogs, the NOAEL was 6 mg/kg bw per day, the highest dose tested. The increased incidences of soft/watery faeces in two males at this dose were not considered adverse, as these changes were not accompanied by any other toxicological effect. Also, the slight decreases in feed consumption and body weight in two females during the first 2 weeks of dosing at 6 mg/kg bw per day were not considered adverse, as there were no changes during the remainder of the study. The overall NOAEL for the 90-day and 1-year studies was 6 mg/kg bw per day.

Long-term studies of toxicity and carcinogenicity were conducted in mice and rats. In an 18-month study of carcinogenicity in mice, the NOAEL for carcinogenicity was 100 ppm (equal to 10.4 mg/kg bw per day), based on an increased incidence of hepatocellular adenomas and/or carcinomas in males at 750 ppm (equal to 79.6 mg/kg bw per day). The NOAEL for non-neoplastic changes was 100 ppm (equal to 10.4 mg/kg bw per day), based on liver toxicity (vacuolization/fatty change of hepatocytes) in males at 750 ppm (equal to 79.6 mg/kg bw per day).

In a series of mechanistic studies in mice, including C57BL/6J “knockout” mice for pregnane X receptor (PXR) and constitutive androstane receptor (CAR) and C57BL/6J mice “humanized” for PXR and CAR, it was demonstrated that sulfoxaflor was a relatively potent phenobarbital-like inducer of hepatic P450 enzymes via activation of CAR and possibly, to some extent, PXR. This was apparent at the messenger ribonucleic acid, protein and enzyme activity level. Activation of the mouse CAR (and possibly PXR) resulted in increased hepatocyte hypertrophy and proliferation. The human CAR (and possibly PXR) supported modest P450 induction and hepatic hypertrophy by sulfoxaflor, but did not support any effect on hepatocyte proliferation.

In a 24-month study of toxicity and carcinogenicity in Fischer 344 rats, the NOAEL for carcinogenicity was 100 ppm (equal to 4.24 mg/kg bw per day), based on an increased incidence of hepatocellular adenomas in males at 500 ppm (equal to 21.3 mg/kg bw per day). Also at 500 ppm, there was an increased incidence of bilateral Leydig (interstitial) cell adenomas of the testes, whereas there was no effect on the incidence of combined unilateral/bilateral Leydig cell adenomas. The size and weight of the testes and the size of Leydig cell adenomas were increased at 100 and 500 ppm and were associated with the secondary changes in the testes and epididymides listed below. The NOAEL

for non-neoplastic effects was 25 ppm (equal to 1.04 mg/kg bw per day), based on changes in the testes (increased testes weights, increased incidence of severe bilateral atrophy of seminiferous tubules) and epididymides (decreased epididymal weights, increased incidence of severe bilateral decreased spermatic elements of the epididymides) in males at 100 ppm (equal to 4.24 mg/kg bw per day). In females, the NOAEL for non-neoplastic effects was 100 ppm (equal to 5.13 mg/kg bw per day), based on hepatocellular degeneration at 750 ppm (equal to 39.0 mg/kg bw per day).

In a mechanistic study on liver tumorigenesis in rats, 3-day or 7-day exposure to sulfoxaflor at dietary concentrations up to 1500 ppm (equal to 83–102 mg/kg bw per day) resulted in increased liver weights, increased cell proliferation in the centrilobular and midzonal regions of the hepatic lobules, marked induction of Cyp2b1 gene expression and hepatic activities of pentoxyresorufin-O-deethylase (PROD) and benzyloxyresorufin-O-deethylase (BROD), and moderate induction of Cyp2b2 and Cyp3a3 expression levels. The pattern of changes was phenobarbital-like, as evidenced by the CAR- and PXR-related molecular, enzymatic and proliferative responses.

The Meeting concluded that for the liver tumours in both mice and rats, there was sufficient evidence to support the proposed phenobarbital-like mode of action (MOA). In particular, sulfoxaflor exhibited clearly higher activity towards rodent CAR than towards human CAR. The marked qualitative and quantitative species differences in the key events in the MOA for neoplasia in response to CAR activation allowed for the conclusion that the sulfoxaflor-induced liver tumours in rats and mice are not relevant to humans.

In a mechanistic study conducted to examine the potential MOA for the Leydig cell effects seen in the rat carcinogenicity study, 8-week exposure of male Fischer 344 rats to sulfoxaflor at dietary concentrations up to 500 ppm (equal to 28 mg/kg bw per day) resulted in decreased serum prolactin and increased serum luteinizing hormone (LH) and testosterone levels and in decreased testis LH receptor (LHR) and prolactin receptor gene expression at week 4, but not at week 2 or week 8. Treatment had no effect on the percentage of Leydig cells with intracellular staining of LHR, biliary excretion of [^{14}C]testosterone, serum 17β-estradiol level or any measured gene in the steroidogenic pathway. Because Fischer 344 rats are particularly susceptible to effects on Leydig cells, analogous treatment of male Sprague-Dawley rats was performed, resulting in increased serum LH and testosterone levels at week 2 and a decrease in serum prolactin level at week 4.

In a mechanistic study using intracerebral microdialysis in rats, sulfoxaflor infusion (0.4 and 2 mmol/L) evoked dose-related increases in the extracellular level of dopamine in the mediobasal hypothalamus, with a maximal rise of 39%, 40 minutes after the onset of infusion at 2 mmol/L.

In a further mechanistic study on Leydig cell effects, sulfoxaflor did not bind to the estrogen receptor (ER) alpha and had weak binding affinity to the androgen receptor (AR), whereas it did not show any agonism or antagonism in the ER and ARe transactivation assays. In addition, there was no evidence for aromatase inhibition by sulfoxaflor.

Although the proposed MOA—that sulfoxaflor can act as a dopamine agonist in the central nervous system and may inhibit prolactin release in the pituitary (an MOA for the induction of Leydig cell tumours that is considered to be not relevant to humans)—has not been completely demonstrated, the Meeting concluded that the increased incidences of bilateral Leydig cell adenomas in male rats are of low relevance to humans, as there are large qualitative and quantitative differences between rats and humans regarding Leydig cell responses to hormonal stimuli. In addition, these effects occurred only at high doses, did not occur in mice and would be anticipated to exhibit a threshold. As a consequence, the secondary changes in the testes and epididymides would not be relevant to the dietary risk assessment of sulfoxaflor.

Sulfoxaflor was tested for genotoxicity in vitro and in vivo in an adequate range of assays. It was not found to be genotoxic in mammalian or microbial test systems.

The Meeting concluded that sulfoxaflor was unlikely to be genotoxic.

On the basis of the absence of genotoxicity, the human non-relevance of the liver tumours in both mice and rats and the fact that the Leydig cell responses observed in rats are unlikely to be relevant to humans, the Meeting concluded that sulfoxaflor is unlikely to pose a carcinogenic risk to humans at dietary exposure levels.

In a reproduction/developmental toxicity screening study in rats, the NOAEL for both parental toxicity and effects on offspring was 100 ppm (equal to 8.26 mg/kg bw per day), based on decreased body weight gains in females during the first week of gestation and reduced pup survival at 500 ppm (equal to 40.7 mg/kg bw per day).

In a two-generation reproductive toxicity study in rats, the NOAEL for effects on fertility was 400 ppm (equal to 24.6 mg/kg bw per day), the highest dose tested. The NOAEL for parental toxicity was 100 ppm (equal to 6.07 mg/kg bw per day), based on liver toxicity (increase in vacuolization/fatty change of centrilobular hepatocytes) in F0 males at 400 ppm (equal to 24.6 mg/kg bw per day). The NOAEL for offspring toxicity was 100 ppm (equal to 6.07 mg/kg bw per day), based on reduced pup survival and delayed preputial separation (puberty onset) in F2 males at 400 ppm (equal to 24.6 mg/kg bw per day).

In a cross-fostering study conducted to assess whether the observed effects of sulfoxaflor on neonatal survival in rats resulted from in utero and/or lactational exposure, all offspring from dams exposed to sulfoxaflor (1000 ppm, equal to 60–81 mg/kg bw per day) prior to birth died by postnatal day 4, irrespective of whether they were cross-fostered to control or treated foster dams. There was no effect on survival for pups exposed only after birth. Thus, the effect of sulfoxaflor on pup survival was due to in utero, not lactational, exposure.

In a developmental toxicity study in rats, the NOAEL for maternal toxicity was 150 ppm (equal to 11.5 mg/kg bw per day), based on decreased body weight and body weight gain and decreased feed consumption at 1000 ppm (equal to 70.2 mg/kg bw per day). The NOAEL for developmental toxicity was 150 ppm (equal to 11.5 mg/kg bw per day), based on increases in several fetal abnormalities (forelimb flexure, hindlimb rotation, bent clavicle, fused sternebrae, convoluted ureter and hydroureter) at 1000 ppm (equal to 70.2 mg/kg bw per day).

A series of special studies conducted to determine the critical window of developmental susceptibility of rat fetuses demonstrated that late gestational exposure (i.e. from gestation day 20 to gestation day 21 or 22) of dams to sulfoxaflor (1000 ppm, equal to 36–39 mg/kg bw per day) resulted in reduced neonatal survival and limb abnormalities seen in pups at postnatal days 1–3, whereas no limb abnormalities were observed at postnatal day 4 in the same litters. Offspring from dams exposed (at 1000 ppm, equal to 43–77 mg/kg bw per day) up to gestation day 19 did not show any limb abnormalities or reduced neonatal survival.

Histopathological evaluation of fetal lung samples from the prenatal developmental toxicity study in rats did not reveal any morphological abnormalities that could have contributed to the sulfoxaflor-induced neonatal mortality in rat pups.

In mechanistic studies conducted to test the hypothesis that the limb abnormalities and bent clavicles in rat fetuses are mediated by the pharmacological agonist action of sulfoxaflor at the fetal neuromuscular junction nAChR, radioligand binding and electrophysiological examination revealed that sulfoxaflor is an agonist of the rat fetal muscle nAChR (which contains the rat γ subunit), whereas it has no agonist activity on the equivalent human fetal nAChR (containing the human γ subunit) or on the rat or human adult muscle nAChR (containing the rat or human ε subunit). In rodents, replacement of the γ subunit by the ε subunit commences late during the first postnatal week and is largely complete by the end of the second postnatal week, whereas in humans, the switch from γ to ε subunit expression occurs predominantly during the late fetal period. These results were considered to support the hypothesis that sulfoxaflor induces fetal abnormalities and neonatal death in rats via its pharmacological action on the fetal muscle nAChR. This receptor develops functional expression between gestation days 16 and 17 in the rat, resulting in synchronized fetal limb movements and diaphragmatic responsiveness important for the transition to extrauterine respiration.

Two developmental toxicity range-finding studies in rabbits demonstrated that administration of sulfoxaflor in the diet afforded a greater applied maximally tolerated dose (1000 ppm, equal to 36.6 mg/kg bw per day) relative to gavage (15 mg/kg bw per day caused excessive maternal toxicity). Thus, dietary administration of sulfoxaflor was chosen for the main developmental toxicity study.

In a developmental toxicity study in rabbits, the NOAEL for maternal toxicity was 150 ppm (equal to 6.6 mg/kg bw per day), based on decreased faeces and decreases in body weight gain and feed consumption at 750 ppm (equal to 31.9 mg/kg bw per day). The NOAEL for prenatal developmental toxicity was 750 ppm (equal to 31.9 mg/kg bw per day), the highest dose tested.

In a special study conducted to assess the effects of sulfoxaflor on neonatal survival in rabbits, dams were exposed to sulfoxaflor (750 ppm, equal to 29 mg/kg bw per day) from gestation day 7 through the initiation of parturition and allowed to deliver and rear their offspring to lactation day 4. Dams showed decreased body weight gains and feed consumption, whereas no treatment-related effects on the mean number of offspring born, offspring survival or the general physical condition of the offspring were observed.

The Meeting concluded that for the limb abnormalities and bent clavicles observed in rats, there is sufficient evidence that these effects were induced by pharmacological action of sulfoxaflor at the rat fetal muscle nAChR, whereas sulfoxaflor has no agonist activity on the equivalent human fetal nAChR or on the rat or human adult muscle nAChR. This allowed for the conclusion that these effects are not relevant to humans. Regarding the reduced neonatal survival observed in rats, the Meeting noted that the human relevance for this effect cannot be excluded, as the underlying MOA is unclear.

In an acute neurotoxicity study in rats, the NOAEL for neurotoxicity was 25 mg/kg bw, based on decreased motor activity at 75 mg/kg bw. There was no evidence for neuropathological effects up to the highest dose tested (750 mg/kg bw).

In a developmental neurotoxicity study in rats, the NOAEL for maternal and reproductive toxicity was 400 ppm (equal to 28.8 mg/kg bw per day), the highest dose tested. The NOAEL for developmental neurotoxicity was 400 ppm (equal to 28.8 mg/kg bw per day), as there were no signs of developmental neurotoxicity at any exposure level. The NOAEL for neonatal toxicity was 100 ppm (equal to 7.4 mg/kg bw per day), based on the reduction in postnatal survival and pup body weights at 400 ppm (equal to 28.8 mg/kg bw per day).

Toxicological data on metabolites

X11719474, the major soil and plant metabolite of sulfoxaflor, was of low acute oral toxicity in rats (LD_{50} > 5000 mg/kg bw) and showed no genotoxic potential in vitro in mammalian or microbial test systems. In a 90-day oral toxicity study in rats, the NOAEL was 1000 ppm (equal to 65.3 mg/kg bw per day), based on effects in the liver (vacuolization/fatty change) at 5000 ppm (equal to 327 mg/kg bw per day). In a reproduction toxicity screening study in rats, the NOAEL for reproductive and offspring performance was 5000 ppm (equal to 396 mg/kg bw per day), the highest dose tested. In a prenatal developmental toxicity study in rats, the NOAEL for developmental toxicity was 5000 ppm (equal to 368 mg/kg bw per day), the highest dose tested.

X11721061, a plant and animal (rat) metabolite of sulfoxaflor, was of low acute oral toxicity in rats (LD_{50} > 2000 mg/kg bw) and showed no genotoxic potential in vitro in mammalian or microbial test systems. In a 28-day oral toxicity study in rats, the NOAEL was 3000 ppm (equal to 236 mg/kg bw per day), based on reduced feed consumption at 8000 ppm (equal to 622 mg/kg bw per day).

X11596066, a metabolite of sulfoxaflor identified in hens and goats, was of low acute oral toxicity in rats (LD_{50} > 2000 mg/kg bw) and showed no genotoxic potential in vitro (Ames test).

X11579457, a soil metabolite of sulfoxaflor, was of low acute oral toxicity in rats (LD_{50} > 2000 mg/kg bw) and showed no genotoxic potential in vitro in mammalian or microbial test systems.

X11519540, a soil and animal (hen) metabolite of sulfoxaflor, was of moderate acute oral toxicity in rats (LD_{50} > 565 mg/kg bw) and showed no genotoxic potential in vitro in mammalian or microbial test systems. In a 28-day oral toxicity study in rats, the NOAEL was less than 100 ppm (equal to 7.7 mg/kg bw per day) in males, based on effects in liver (increased serum cholesterol), thyroid (follicular cell hypertrophy) and adrenals (increased vacuolization of the cortex).

All metabolites were less toxic than the parent compound, except for X11519540, which had higher acute and higher short-term toxicity than the parent.

There were no reports of adverse health effects in manufacturing plant personnel. Also, there were no reports of poisonings with sulfoxaflor.

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

Toxicological evaluation

The Meeting established an acceptable daily intake (ADI) for sulfoxaflor of 0–0.05 mg/kg bw, based on a NOAEL of 5.13 mg/kg bw per day for hepatocellular degeneration in female rats in a 2-year toxicity and carcinogenicity study and application of a safety factor of 100. The ADI is supported by the NOAEL of 6.07 mg/kg bw per day for systemic toxicity (increased vacuolization/fatty change of centrilobular hepatocytes in F_0 males) and offspring toxicity (reduced neonatal survival) at 24.6 mg/kg bw per day in a two-generation rat study, the NOAEL of 6.36 mg/kg bw per day, based on effects in the liver (increased serum cholesterol, vacuolization/fatty change of hepatocytes) in a 13-week study in rats, and the overall NOAEL of 6 mg/kg bw per day in the 90-day and 1-year dog studies.

The Meeting established an acute reference dose (ARfD) for sulfoxaflor of 0.3 mg/kg bw, based on the NOAEL of 25 mg/kg bw for decreased motor activity at 75 mg/kg bw in an acute neurotoxicity study in rats. A 100-fold safety factor was applied.

A toxicological monograph was prepared.

Levels relevant to risk assessment

Species	Study	Effect	NOAEL	LOAEL
Mouse	Thirteen-week study of toxicity	Toxicity	100 ppm, equal to 12.8 mg/kg bw per day	750 ppm, equal to 98 mg/kg bw per day
	Eighteen-month study of toxicity and carcinogenicity	Toxicity	100 ppm, equal to 10.4 mg/kg bw per day	750 ppm, equal to 79.6 mg/kg bw per day
		Carcinogenicity	100 ppm, equal to 10.4 mg/kg bw per day	750 ppm, equal to 79.6 mg/kg bw per day
Rat	Thirteen-week study of toxicity	Toxicity	100 ppm, equal to 6.36 mg/kg bw per day	750 ppm, equal to 47.6 mg/kg bw per day
	Two-year study of toxicity and carcinogenicity	Toxicity	100 ppm, equal to 5.13 mg/kg bw per day	750 ppm, equal to 39.0 mg/kg bw per day
		Carcinogenicity	100 ppm, equal to 4.24 mg/kg bw per day[a]	500 ppm, equal to 21.3 mg/kg bw per day
	Two-generation study of reproductive toxicity	Reproductive toxicity	400 ppm, equal to 24.6 mg/kg bw per day[b]	—
		Parental toxicity	100 ppm, equal to 6.07 mg/kg bw per day	400 ppm, equal to 24.6 mg/kg bw per day

Species	Study	Effect	NOAEL	LOAEL
		Offspring toxicity	100 ppm, equal to 6.07 mg/kg bw per day	400 ppm, equal to 24.6 mg/kg bw per day
	Developmental toxicity study	Maternal toxicity	150 ppm, equal to 11.5 mg/kg bw per day	1000 ppm, equal to 70.2 mg/kg bw per day
		Embryo and fetal toxicity	150 ppm, equal to 11.5 mg/kg bw per day	1000 ppm, equal to 70.2 mg/kg bw per day
	Acute neurotoxicity study[b]	Neurotoxicity	25 mg/kg bw	75 mg/kg bw
	Developmental neurotoxicity study	Developmental neurotoxicity	400 ppm, equal to 28.8 mg/kg bw per day[b]	—
Rabbit	Developmental toxicity study	Maternal toxicity	150 ppm, equal to 6.6 mg/kg bw per day	750 ppm, equal to 31.9 mg/kg bw per day
		Embryo and fetal toxicity	750 ppm, equal to 31.9 mg/kg bw per day[b]	—
Dog	Thirteen-week and 1-year studies of toxicity[c,d]	Toxicity	6 mg/kg bw per day	10 mg/kg bw per day

[a] Not considered relevant for human risk assessment.

[b] Highest dose tested.

[c] Gavage administration.

[d] Two studies combined.

Estimate of acceptable daily intake for humans

0–0.05 mg/kg bw

Estimate of acute reference dose

0.3 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 sulfoxaflor

Absorption, distribution, excretion and metabolism in mammals	
Rate and extent of oral absorption	Rapid; ≥ 93%
Distribution	Extensive; highest concentrations in liver, kidney and erythrocytes
Rate and extent of excretion	≥ 93% within 168 h (≥ 92% in urine; 5–9% in faeces)
Potential for accumulation	None
Metabolism in animals	Very limited, oxidative cleavage of the molecule, followed by conjugation with glucuronic acid; one metabolite identified in urine (conjugate of X11721061, 3–4% of administered dose)
Toxicologically significant compounds	Sulfoxaflor, X11519540 (soil metabolite)

(animals, plants and the environment)	
Acute toxicity	
Rat, LD_{50}, oral	1000 mg/kg bw
Rat, LD_{50}, dermal	> 5000 mg/kg bw
Rat, LC_{50}, inhalation	> 2.09 mg/L (4 h, nose-only exposure)
Rabbit, dermal irritation	Not irritating
Rabbit, eye irritation	Not irritating
Mouse, dermal sensitization (local lymph node assay)	Not sensitizing
Short-term studies of toxicity	
Target/critical effect	Liver (liver cell vacuolization/fatty change) in mice and rats; adrenals (cortical hypertrophy and vacuolation) in mice; decreased feed consumption and body weight gain in dogs
Lowest relevant oral NOAEL	6.36 mg/kg bw per day (90-day study in rats)
Lowest relevant dermal NOAEL	500 mg/kg bw per day (28-day study in rats)
Lowest relevant inhalation NOAEC	No data
Long-term toxicity and carcinogenicity	
Target/critical effect	Liver (liver cell vacuolization/fatty change) in mice and in female rats
Lowest relevant NOAEL	5.13 mg/kg bw per day (2-year study in rats)
Carcinogenicity	Unlikely to pose a carcinogenic risk to humans at levels of dietary exposure
Genotoxicity	
	Not genotoxic
Reproductive toxicity	
Reproductive target/critical effect	No effects on fertility at highest dose tested; reduced pup survival and delayed preputial separation at parentally toxic dose
Lowest relevant reproductive NOAEL	6.07 mg/kg bw per day for offspring toxicity (two-generation study in rats)
Developmental target/critical effect	Fetal abnormalities (forelimb flexure, hindlimb rotation, bent clavicle, fused sternebrae, convoluted ureter) at maternally toxic dose
Lowest relevant developmental NOAEL	11.5 mg/kg bw per day (rat)
Neurotoxicity	
Acute neurotoxicity	Decrease in motor activity; NOAEL: 25 mg/kg bw
Developmental neurotoxicity	No evidence of developmental neurotoxicity at highest dose tested
Other toxicological studies	
Mechanistic studies	Studies on liver tumorigenesis (rats, mice) demonstrate non-relevance to humans
	Studies on Leydig cell effects in rats suggested evidence for an MOA unlikely to be relevant to humans

	Studies demonstrated that limb and clavicle abnormalities are due to rat-specific agonist activity on the fetal muscle nAChR not relevant to humans
Studies on metabolites	X11719474: lower toxicity than parent compound, not genotoxic in vitro, no developmental toxicity
	X11721061, X11596066 and X11579457: lower toxicity than parent compound, not genotoxic in vitro
	X11519540: higher toxicity than parent compound, not genotoxic in vitro
Medical data	
	Limited data; no adverse health effects reported in manufacturing plant personnel

Summary

	Value	Study	Safety factor
ADI	0–0.05 mg/kg bw	Two-year study in rat (supported by two-generation study in rats, 90-day study in rats and 1-year study in dogs)	100
ARfD	0.3 mg/kg bw	Acute neurotoxicity study in rat	100

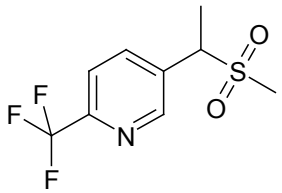
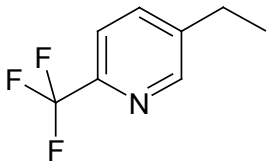
RESIDUE AND ANALYTICAL ASPECTS

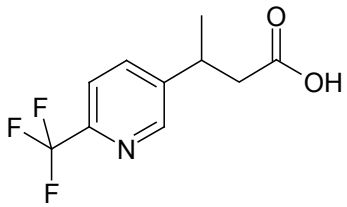
Residue, analytical, and toxicological aspects of sulfoxaflor were considered for the first time by the present meeting. The Forty-second Session of the CCPR initiated a pilot project using sulfoxaflor in which JMPR would conduct an independent, parallel review along with a joint review team from Australia, Canada, and the USA, and recommend maximum residue levels before national governments or other regional registration authorities.

Sulfoxaflor (ISO common name), a member of the novel sulfoximine class of insecticides, has broad spectrum activity against sucking and chewing insects in cereal grains (wheat and barley), soya bean, oilseed rape, cotton seed, pome fruits, stone fruits, citrus fruits, tree nuts, grapes, dried grapes, strawberries, leafy vegetables, fruiting vegetables, cucurbits, brassica vegetables, and bulb vegetables. It is currently proposed only for foliar applications.

The IUPAC name for sulfoxaflor is [methyl(oxo){1-[6-(trifluoromethyl)-3-pyridine]ethyl}-λ^6-sulfanylidene]cyanamide and the CAS name is *N*-[methyloxido[1-[6-(trifluoromethyl)-3-pyridinyl]ethyl]-λ^4-sulfanylidene]cyanamide.

Sulfoxaflor labelled in the pyridine ring was used in the metabolism and environmental fate studies. The chemical structures of sulfoxaflor and its metabolites/degradates are shown below.

Sulfoxaflor (Parent) : [1-(6-trifluoromethylpyridin-3-yl)ethyl](methyl)-oxido-λ^4-sulfanylidenecyanamide	X11719474 (Urea) 1-[methyl(oxido){1-[6-(trifluoromethyl)pyridin-3-yl]ethyl}-λ^6-sulfanylidene]urea	X11721061 (Alcohol) 1-[6-(trifluoromethyl)pyridin-3-yl]ethanol
 X11519540 (Sulfonyl) 5-[1-(methanesulfonyl)ethyl]-2-(trifluoromethyl)pyridine	 X11596066 (Ethyl) 5-ethyl-2-(trifluoromethyl)pyridine	X11579457 (Des-cyano) 5-[1-(S-methylsulfonimidoyl)ethyl]-2-(trifluoromethyl)pyridine



X11821639 (Acid)

3-[6-(trifluoromethyl) pyridin-3-yl]butanoic acid

Animal metabolism

Information was available on metabolism of sulfoxaflor in laboratory animals, lactating goats and laying hens.

When rats were orally dosed with labelled sulfoxaflor, approximately 93% of the dose was eliminated in the urine and faeces as parent sulfoxaflor. The main metabolite in urine was a glucuronide conjugate of sulfoxaflor metabolite X11721061, accounting for approximately 2–4% of the dose. Several other unidentified minor components, each less than 1% of the administered dose, were present in the urine and faecal samples. Metabolism in laboratory animals was summarized and evaluated by the WHO panel of the JMPR in 2011.

When lactating goats were orally dosed with labelled sulfoxaflor at 12.2 ppm in the diet, approximately 4% of the dose appeared in the milk and 3% in the tissues.

Residue levels in milk reached a plateau during days 3–4 of the dosing phase, at about 0.2 mg/kg eq. ^{14}C levels were highest in liver and kidney, and lowest in fat tissues. Parent sulfoxaflor was the predominant residue in all tissues, comprising over 89% TRR in milk, muscle, fat, and kidney; and approximately 60% TRR in liver. Metabolite X11519540 (sulfonyl metabolite) was found

at low levels ≤ 0.009 mg/kg eq) in several matrices; while X11596066 (ethyl metabolite) was reported only in liver samples, at 18% TRR (0.095 mg/kg eq).

Metabolite X11719474 was usually found at more than 10% TRR in plants, and consequently is considered a major plant metabolite. When lactating goats were orally dosed with labelled sulfoxaflor metabolite X11719474 at 11.4 ppm in the diet, approximately 1% of the dose appeared in the milk and 1% in the tissues.

Residue levels in milk reached a plateau during days 3–4 of the dosing phase, at about 0.2 mg/kg eq. Similar ^{14}C levels were found in liver, kidney, milk, and muscle; while lower levels were reported in fat tissues. This study demonstrated that X11719474 is not metabolized in goats: no metabolites were identified, and the radioactivity found in all tissues was from X11719474.

When laying hens were dosed with labelled sulfoxaflor at 10.9 ppm in the feed, most of the dose was excreted in the droppings. Approximately 0.5% of the dose was recovered in the combined eggs, fat, and tissues. Residue levels in eggs reached a plateau during days 6–7 of the dosing phase, at about 0.06 mg/kg eq. ^{14}C levels were highest in liver and lowest in fat tissues. Parent sulfoxaflor was the predominant residue in all tissues, comprising over 83% TRR in eggs, muscle, fat, and skin with fat; and approximately 68% TRR in liver. Metabolite X11519540 was found at low levels (≤ 0.005 mg/kg eq) in several matrices, while X11596066 was reported only in liver samples, at 14% TRR (0.020 mg/kg eq).

When laying hens were orally dosed with labelled sulfoxaflor metabolite X11719474 at 11.8 ppm in the feed, approximately 0.5% of the applied dose was recovered in the combined eggs, fat, and tissues. Similar ^{14}C levels were noted in liver, muscle, and egg; lower levels were found in fat tissues. Approximately 92% of the dose was recovered from the excreta, and 0.3% in the cage rinse. Residue levels in eggs reached a plateau by day 4 of the dosing phase, with no compounds other than X11719474 being identified. This study demonstrated that X11719474 is not metabolized in hens: no metabolites were identified and the radioactivity found in all tissues was from X11719474.

Animal metabolism summary

Metabolism studies in the laying hen and lactating goat demonstrated limited metabolism of sulfoxaflor and no metabolism of X11719474. In most hen and goat matrices, sulfoxaflor comprised approximately 80% or more of the total radioactivity when ^{14}C-sulfoxaflor was fed. Metabolites X11721061 [≤ 0.017 mg/kg eq] and X11519540 [≤ 0.009 mg/kg eq] were found at < 10% TRR in several matrices. However, more extensive metabolism occurred in liver, with metabolite X11596066 comprising up to 18% TRR (0.095 mg/kg eq). Overall, the metabolism found in livestock was qualitatively similar to that observed in laboratory animals.

Plant metabolism

Information was available on the metabolism of sulfoxaflor in tomato, lettuce, succulent peas and rice. Separate studies were reported for foliar and soil applications to all four crops.

In a foliar treatment experiment, [^{14}C-pyridine]sulfoxaflor was applied to immature tomato plants in four separate applications at 213, 202, 129, and 74 g ai/ha (1.5 × proposed GAP rate). Immature plants (after the 2nd treatment), ripe tomatoes (1, 7, and 14 DAT), and vines (14 DAT) were analysed. Parent sulfoxaflor was the most abundant residue in ripe tomatoes (0.012 mg/kg), but metabolites X11719474 (0.009 mg/kg eq) and X11721061 (in conjugated form) (0.004 mg/kg eq) were also found. In addition, low levels of free X11721061 were observed (2–3% TRR; 0.020–0.030 mg/kg eq) in the immature plants and mature vines, and a metabolite tentatively identified as X11821639 was observed at levels up to 1.2% of the TRR (0.016 mg/kg eq) in the immature plants and mature vines.

In a soil treatment experiment with tomatoes, [^{14}C- pyridine]sulfoxaflor was applied to the soil around immature tomato plants in two separate treatments at 249 and 211 g ai/ha. Metabolite

X11719474 was the primary identified component of the residue in all tomato matrices, especially in mature fruit (59–73% TRR; 0.016–0.019 mg/kg eq), while parent sulfoxaflor was present at considerably lower levels (11–17% TRR; 0.003–0.005 mg/kg eq). All other metabolites comprised less than 10% TRR in tomato matrices.

In a foliar treatment lettuce experiment, [^{14}C-pyridine]sulfoxaflor was applied to immature lettuce plants in three separate applications at 195, 199, and 205 g ai/ha (1.5 × proposed GAP rate). Immature plants were collected 14 days after the first and second applications. Mature lettuce was harvested at a 7-day PHI. While higher residue levels were found in the mature lettuce (4.4 mg/kg eq vs. 0.18 mg/kg eq), the residue distribution was essentially the same. Following three foliar applications of sulfoxaflor, major lettuce metabolites include sulfoxaflor (17% TRR; 0.031–0.73 mg/kg), and metabolite X11719474 (27–31% TRR; 0.49–1.36 mg/kg eq). The glucose conjugate of X11721061 (3–5% TRR; 0.009–0.12 mg/kg eq) and the glucose plus malonyl conjugate of X11721061 (6% TRR; 0.011–0.24 mg/kg eq) were found at lower levels. Low levels of free X11721061, X11579457, and X11519540 (each < 1% TRR) were also reported.

In a soil treatment lettuce experiment, [^{14}C- pyridine]sulfoxaflor was applied to the soil around immature lettuce plants in two separate treatments at 238 and 216 g ai/ha. Immature lettuce was collected 14 days after the first application. Mature lettuce was collected 14 days after the second application. While higher residue levels were found in the mature lettuce (1.4 mg/kg eq vs. 0.14 mg/kg eq), the residue distribution was essentially the same. X11719474 was the only major metabolite in lettuce, comprising 49–60% of the TRR (0.081-0.69 mg/kg eq). Glucose and glucose plus malonyl conjugates of X11721061 were found at ≤ 4% TRR. Sulfoxaflor, X11721061, X11579457, and X11519540 were each present at ≤ 1% TRR.

In a foliar treatment succulent pea experiment, [^{14}C-pyridine]sulfoxaflor was applied to immature pea plants in three separate applications at 197, 201, and 203 g ai/ha. Immature plants were collected 14 days after the first and second applications. Mature pods and vines were harvested at a 14-day PHI. Following three foliar applications of sulfoxaflor, significant residues of parent sulfoxaflor (59–71% TRR; 0.62–3.9 mg/kg), and X11719474 (12–13% TRR; 0.14–0.63 mg/kg eq) were found in mature pea pods and vines. The glucose conjugate of X11721061 (7–10% TRR; 0.11–0.37 mg/kg eq) and the glucose plus malonyl conjugate of X11721061 (1–3% TRR; 0.030–0.067 mg/kg eq) were found at lower levels, and free X11711061 was only found at 1% TRR in mature pea matrices. The immature pea plants demonstrated lower overall residue levels, together with relatively more of the glucose conjugate of X11721061 than found in the mature pea plants.

In a soil treatment succulent pea experiment, [^{14}C- pyridine]sulfoxaflor was applied to the soil around immature pea plants in two separate treatments at 212 and 222 g ai/ha. Immature pea plants were collected 14 days after the first application. Mature pods and vines were collected 14 days after the second soil application. For soil application of sulfoxaflor, the primary residue in mature pods and vines was metabolite X11719474 (88–90% TRR; 0.037–0.13 mg/kg eq). Parent sulfoxaflor (ND–5% TRR; < 0.001–0.002 mg/kg) and the glucose conjugate of X11721061 (2–8% TRR; 0.001–0.011 mg/kg eq) were minor metabolites in the mature pea plants.

In a rice experiment a foliar treatment of [^{14}C-pyridine]sulfoxaflor was applied to immature rice plants in three separate applications at 227, 205, and 145 g ai/ha. Immature plants were collected 14 days after the first application. Grain and straw were separated, and mature grain was separated into white rice and hulls. Following three foliar applications of sulfoxaflor, parent sulfoxaflor was the major residue in mature rice matrices (33–44% TRR; 0.086–2.5 mg/kg). Metabolite X11719474 was found at lower levels (7–10% TRR; 0.021–0.55 mg/kg eq), as was the glucose conjugate of X11721061 (5–11% TRR; 0.027–0.30 mg/kg eq). Free X11721061 (2–4% TRR; 0.005–0.23 mg/kg eq) was also found in the mature rice matrices. The immature rice plants contained mostly parent sulfoxaflor (74% TRR; 2.1 mg/kg) and correspondingly lower levels of metabolites. The glucose plus malonyl conjugate of X11721061 was only detected in mature rice straw (3% TRR; 0.16 mg/kg eq).

In a soil treatment rice experiment, one application of [^{14}C- pyridine]sulfoxaflor was made at transplant at 474 g ai/ha. Rice plants at the 3–4 leaf stage were planted immediately following soil application. Immature rice plants were collected 14 days after the first application. Following this, the plants were flooded. Immature rice plants were collected 14 and 28 days after the soil application. Mature rice was collected 138 days after the soil application. Grain and straw were separated, and mature grain was separated into white rice and hulls. After one soil application of sulfoxaflor, the major residue in the mature rice matrices was metabolite X11719474 (31–40% TRR; 0.018–0.56 mg/kg eq). No other metabolites were reported in white rice grain, and relatively low levels of metabolite X11721061 (5–6% TRR; 0.026–0.11 mg/kg eq) and its glucose conjugate (5–6% TRR; 0.024–0.098 mg/kg eq) occurred in mature rice hulls and straw. Similar residue distributions were reported in immature rice plants, although higher overall residue levels were obtained. Additionally, low levels of the metabolite X11821639 (≤ 1% TRR; ≤ 0.13 mg/kg eq) was reported in immature rice plants.

Plant metabolism summary

Metabolism studies were conducted in tomato, lettuce, succulent pea, and rice. For each metabolism study, foliar and soil application were studied separately, although currently only foliar uses are proposed. Metabolism of sulfoxaflor was similar in all four crops: oxidation of the cyano-carbon bond to form X11719474 and loss of the sulfur side chain to form X11721061. X11721061 is then conjugated with glucose, which may then be conjugated with malonic acid. Metabolism continues through natural incorporation of the radiolabelled carbon into natural plant constituents, such as lignin and starch. A very minor pathway (< 1%) included degradation of the X11719474 urea side chain to form X1159540 and X11479457, which are further reduced to give X11721061.

The primary difference noted between the foliar and soil metabolism studies was that parent sulfoxaflor, X11719474, and X11721061 conjugates commonly were found at > 10% TRR following foliar applications, while X11719474 was the only residue consistently exceeding 10% TRR following soil applications. The plant metabolism studies demonstrate that sulfoxaflor residues translocate throughout the crop matrices; thus, sulfoxaflor may be considered systemic.

Environmental fate

Aerobic Soil Metabolism

Sulfoxaflor biodegrades rapidly in laboratory soil studies, with a reported half-life of 0.3 to 0.6 days, to form X11719474. Degradation of sulfoxaflor was also very rapid under field conditions, with sulfoxaflor half-lives ranging from < 1 to 8 days observed in field dissipation studies conducted at five sites in North America.

When sulfoxaflor was applied to soil in the laboratory, the DT_{50} of resulting X11719474 ranged from 85 to 370 days. Field studies yielded half-lives of 30–277 days for X11719474.

Photolysis

No major photodegradation products of sulfoxaflor were detected in studies conducted with sterile buffered water. One minor photoproduct, X11721061, reaching a maximum concentration of 2.5% AR at 14 DAT was identified. Photodegradation of sulfoxaflor in sterile buffer and natural surface waters was slow, with estimated half–lives in excess of one year in both media. Likewise, photolytic degradation of sulfoxaflor on soil surfaces is not a significant route of degradation.

Rotational crops

Confined rotational crop study

When lettuce, radish and wheat were grown in a rotational crop situation 30, 120 and 365 days after treatment of bare ground with labelled sulfoxaflor at 0.6 kg ai/ha, significant TRR levels were found: 0.74 mg/kg eq and below for mature lettuce; 1.2 mg/kg eq and below for mature radish tops; 0.16 mg/kg eq and below for mature radish roots and 0.081 mg/kg eq and below for wheat grain. Higher TRR levels were found in wheat hay and straw: 0.71–3.8 mg/kg eq.

X11719474 was the most abundant metabolite in terms of either % of TRR or mg/kg observed in all crops at all three plant-back intervals (PBIs). X11719474 ranged from 35.3% of the TRR (1.3 mg/kg eq) in 120 DAT wheat straw to 87.8% of the TRR (0.077 mg/kg eq) in 120 DAT mature radish roots. The results of the confined rotational crop study indicate that X11719474 may be taken up by plant roots. Therefore, a limited field rotational crop study was conducted to assess the potential for accumulation in successive crops at various PBIs.

Limited field rotational crop study

Limited field rotational crop studies confirmed the general findings from the confined rotational crop study. Four foliar broadcast applications at 100 g ai/ha were applied to a primary crop of spinach, carrot, or leaf lettuce. The primary crops were harvested at a 3-day PHI. Rotational crops of radish, mustard green, sorghum, and grass were planted at PBIs of 30, 90, 120, and 365 days. Consistent with the confined rotational crop study, X11719474 was the primary residue. No parent sulfoxaflor residues were found in any plant matrix at any PBI, except for one sample [120 day radish tops], where residues were attributed to contamination. Metabolites X11721061, X11519540, and X11579457 were found in several matrices, but at significantly lower levels than X11719474.

The edible plant parts having measurable X11719474 residues in the field rotational crop study were radish root and mustard green leaves. In both cases, residues declined with PBI: from 0.031 to < 0.01mg/kg eq (31 to 124 days after planting for radish), and from 0.28 to 0.017 mg/kg eq (31 to 361 days after planting for mustard greens). These results indicate that for rotational crops planted after sulfoxaflor treatments, residues of X11719474 may be higher than indicated by the supervised residue trials. In particular, for root and tuber vegetables, residues of X11719474 may be approximately 0.03 mg/kg eq higher, and for leafy vegetables, residues of X11719474 may be approximately 0.3 mg/kg eq higher.

Analytical methods

HPLC methods with positive-ion electrospray (ESI) tandem mass spectrometry (LC/MS/MS) were developed for data collection and enforcement of sulfoxaflor residues and the two metabolites X11719474 and X11721061. Method 091116 was developed for plant commodities, and Method 091188 was developed for animal commodities. Successful validation of both methods was demonstrated for both methods. Additionally, successful radio-validation was also reported for both methods. The lowest LOQ was 0.01 mg/kg for each of sulfoxaflor, X11719474, and X11721061 in all matrices. The limit of detection (LOD) was 0.003 mg/kg for all three analytes in all matrices.

The generally good agreement between the results from the metabolism study and the proposed enforcement methods (Method 091116 for plants and 091188 for animals) demonstrated successful radio-validation of the analytical method and provides assurance that the enforcement methods are capable of extracting bio-incurred residues of interest from plant and animal commodities.

The FDA Multi-Residue Method Test guidelines in the Pesticide Analytical Manual (PAM) (Third Edition, January 1994) is not applicable for the analysis of sulfoxaflor, due to low recoveries.

Stability of residues in stored analytical samples

Results were available to evaluate the stability of sulfoxaflor and its major metabolites in oranges, peach, wheat grain, and soya bean seed stored under frozen conditions up to 680 days. Through 680 days of frozen storage, no stability problems in any crop matrix were identified.

Additional freezer storage stability studies were performed in conjunction with the poultry and bovine feeding studies to determine residue stability in frozen livestock matrices. The maximum storage interval for the poultry study was 9 weeks, while that for the bovine study was 6–8 weeks. Sulfoxaflor, X11719474, and X11721061 were stable in frozen livestock matrices over the tested intervals.

The periods of demonstrated stability cover the frozen storage intervals in the residue studies.

Definition of the residue

In animal commodities, parent sulfoxaflor was a major component of the residue in goat muscle, fat, milk and kidney, comprising 89% or more of the TRR. In goat liver, sulfoxaflor constituted approximately 60% of the residue with metabolite X11596066 at about 18% TRR (0.095 mg/kg eq). Low levels of metabolites X11721061 (0.017 mg/kg eq in liver) and X11519540 (≤ 0.009 mg/kg eq) were found in several matrices. For goats dosed with the major plant metabolite X11719474, no metabolism of X11719474 was observed.

In laying hens, the results were similar to that found in the goat study, with parent sulfoxaflor the major component in egg, muscle, skin, and fat. In hen liver, sulfoxaflor constituted approximately 68% of the residue with metabolite X11596066 at about 14% TRR (0.020 mg/kg eq). A low level (< 8% TRR) of metabolite X11519540 was found in several matrices (≤ 0.005 mg/kg eq). For hens dosed with the major plant metabolite X11719474, no metabolism of X11719474 was observed.

As sulfoxaflor was the major residue in all livestock commodities, the Meeting decided that, for animal commodities, parent sulfoxaflor is the appropriate residue of concern for MRL enforcement and dietary risk assessment. Although metabolite X11519540 is approximately two times more toxic than parent sulfoxaflor and is present in livestock commodities, however, it is present in such low levels (< 0.01 mg/kg) that it is not appropriate to include this metabolite in the residue definition.

Available studies indicate that parent sulfoxaflor is the best marker compound for plants, and is appropriate for MRL enforcement.

Metabolites X11719474 and X11721061 are commonly present in plant matrices at levels above 10% TRR. Also, limited field rotational crop studies indicate that levels of X11719474 may be up to 0.3 mg/kg higher in rotational crops than indicated by the crop field trial studies. However, the WHO Panel has confirmed that metabolites X11719474 and X11721061 are approximately seven times less toxic than parent sulfoxaflor. Taking into account this information, the Meeting decided that for plant commodities parent sulfoxaflor is the appropriate residue of concern for dietary risk assessment.

The Meeting recommended the following residue definition for sulfoxaflor.

Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities: *sulfoxaflor.*

The residue is not fat soluble.

Results of supervised trials on crops

The Meeting received supervised field trials data for sulfoxaflor uses on cereal grains (wheat and barley), soya bean, oilseed rape, cottonseed, pome fruits, stone fruits, citrus fruits, tree nuts, grapes,

dried grapes, strawberries, leafy vegetables, fruiting vegetables, cucurbits, brassica vegetables, and bulb vegetables.

The OECD calculator was used as a tool in the estimation of the maximum residue level from the selected residue data set obtained from trials conducted according to proposed GAP. As a first step, the Meeting reviewed all relevant factors related to each data set in arriving at a best estimate of the maximum residue level using expert judgement. Then, the OECD calculator was employed. If the statistical calculation spreadsheet suggested a different value from that recommended by the JMPR, a brief explanation of the deviation was provided.

Citrus fruits

Supervised trials data for citrus were available from Australia, Brazil, and the USA.

Proposed GAP for citrus fruit is for two foliar treatments at a rate of 0.2 kg ai/ha, a re-treatment interval (RTI) of 7 days, and harvest of fruit 1 day after the second application (1-day PHI).

Grapefruit

In eight trials on grapefruit in the USA matching proposed GAP, Residues of sulfoxaflor measured in whole grapefruit, in ranked order, were: < 0.01, 0.01, 0.012, 0.013, 0.016, 0.024, 0.11, and 0.13 mg/kg.

Lemon

In six trials on lemons in the USA matching proposed GAP, Residues of sulfoxaflor, in ranked order, measured in whole lemons were: < 0.010 (2), 0.040, 0.083, 0.11, and 0.29 mg/kg.

Oranges

A total of 26 trials on oranges were available from Australia (10), Brazil (4), and the USA (12).

Residues of sulfoxaflor measured in whole oranges from Australia, in ranked order, were: 0.090, 0.15 (2), 0.16, 0.28, 0.33, 0.34, 0.41, 0.43, and 0.44 mg/kg.

Residues of sulfoxaflor measured in whole oranges from Brazil, in ranked order, were: 0.096, 0.099, 0.12, and 0.28 mg/kg.

Residues of sulfoxaflor measured in whole oranges from the USA, in ranked order, were: 0.038, 0.050, 0.062, 0.074, 0.085, 0.093, 0.11, 0.12 (3), 0.16, and 0.23 mg/kg.

Summary – Citrus fruits

Residue data from trials complying with the proposed GAP were available for grapefruit, lemons, and oranges. The Meeting noted that sulfoxaflor residues were highest in orange trials from Australia and decided to estimate a citrus group maximum residue level based on this data set.

The Meeting estimated a maximum residue level of 0.9 mg/kg for residues of sulfoxaflor in citrus fruits. The Meeting estimated STMR and HR values of 0.31 and 0.44 mg/kg, respectively, for sulfoxaflor residues in citrus fruits.

Pome fruits

Supervised trials data were available for apple and pear from Australia/New Zealand, Northern and Southern Europe, and the USA.

Proposed GAP for pome fruit is for two foliar applications of sulfoxaflor at 0.2 kg ai/ha with a 7-day RTI and a 7-day PHI.

Apple

A total of 22 trials on apples were available from Australia and New Zealand (6), Northern Europe (2), Southern Europe (2), and USA (12).

Residues of sulfoxaflor measured in apples from Australia/New Zealand, in ranked order, were: 0.020, 0.065, 0.070, 0.10, 0.14, and 0.19 mg/kg.

Sulfoxaflor residue concentrations in apples from Northern Europe were: 0.078 and 0.18 mg/kg.

Sulfoxaflor residue concentrations in apples from Southern Europe were: 0.074 and 0.27 mg/kg.

Residues of sulfoxaflor measured in apples from the USA, in ranked order, were: < 0.010, 0.039, 0.040, 0.043, 0.056, 0.063, 0.064, 0.066, 0.068, 0.072, 0.10, and 0.12 mg/kg.

Pears

A total of 14 trials on pears were available from Australia (2), Northern Europe (3), Southern Europe (3) and the USA (6).

Sulfoxaflor residue concentrations in pears from Australia were: 0.11 and 0.22 mg/kg.

Residues of sulfoxaflor measured in pears from Northern Europe, in ranked order, were: 0.052, 0.058, and 0.10 mg/kg.

Residues of sulfoxaflor, in ranked order, measured in pears from Southern Europe were: 0.099 and 0.18 (2) mg/kg.

Residues of sulfoxaflor, in ranked order, measured in pears from USA were: 0.078, 0.13, 0.16, 0.18, 0.23, and 0.26 mg/kg.

Summary – Pome fruits

Residue data from trials complying with the proposed GAP were available for apples and pears. The Meeting decided to estimate pome fruit group maximum residue level based on combining the apple and pear data sets from the USA.

In 18 apple and pear trials from the USA matching the pome fruit GAP, Residues of sulfoxaflor, in ranked order, measured were: < 0.010, 0.039, 0.040, 0.043, 0.056, 0.063, 0.064, 0.066 0.068, 0.072, 0.078, 0.10, 0.12, 0.13, 0.16, 0.18, 0.23, and 0.26 mg/kg.

The Meeting estimated a maximum residue level of 0.4 mg/kg for sulfoxaflor in pome fruits. The Meeting estimated STMR and HR values of 0.07 and 0.26 mg/kg, respectively, for sulfoxaflor residues in pome fruits.

Stone fruits

Supervised trial data were available for apricot, cherries, nectarine, peach, and plums.

Proposed GAP for stone fruits is for two foliar applications of sulfoxaflor at 0.2 kg ai/ha with a 7-day RTI and a 7-day PHI.

Cherries

A total of 14 trials on cherries were available from Australia (2), Northern Europe (3), Southern Europe (3), and USA (6).

Residues of sulfoxaflor, in ranked order, measured in cherries from Australia were: 0.35 and 0.38 mg/kg.

Residues of sulfoxaflor, in ranked order, measured in cherries from Northern Europe were: 0.77, 0.90, and 1.49 mg/kg.

Residues of sulfoxaflor, in ranked order, measured in cherries from Southern Europe were: 0.54, 0.80, and 0.98 mg/kg.

Residues of sulfoxaflor, in ranked order, measured in cherries from USA were: 0.55, 0.59, 0.76, 1.05, 1.22, and 1.24 mg/kg.

Nectarines

Five nectarine trials were available from Australia and New Zealand.

In five nectarine trials matching the proposed stone fruit GAP, sulfoxaflor residues found in in nectarine pitted fruit were: 0.10, 0.11, 0.12, 0.14, and 0.18 mg/kg

Apricot

Two apricot trials from Australia/New Zealand, matching the proposed stone fruit GAP, had sulfoxaflor residues of 0.15 and 0.42 mg/kg.

Peach

A total of 20 trials on peach, matching the proposed stone fruit GAP, were available from Australia (8), Northern Europe (3), Southern Europe (3), and USA (6).

Residues of sulfoxaflor, in ranked order, measured in peach from Australia and New Zealand were: 0.012, 0.11 (2), 0.12, 0.14, 0.15, 0.24, and 0.27 mg/kg.

Residues of sulfoxaflor, in ranked order, measured in peach from Northern Europe were: 0.20, 0.36, and 0.54 mg/kg.

Residues of sulfoxaflor, in ranked order, measured in peach from Southern Europe were: 0.21, 0.27, and 0.83 mg/kg.

Residues of sulfoxaflor, in ranked order, measured in peach from USA were: 0.032, 0.054, 0.12, 0.14, 0.17, and 0.90 mg/kg.

Plums

A total of seven trials on plums were available from Australia (1) and USA (6).

The sulfoxaflor residue concentration in plums from Australia was 0.020 mg/kg.

Residues of sulfoxaflor, in ranked order, measured in plums from USA were: 0.030, 0.054, 0.066, 0.090, 0.11, and 0.36 mg/kg.

Summary – Stone fruits

Residue data from trials complying with the proposed GAP and with a sufficient number of trials were available for cherries, peaches and plums. The Meeting noted that sulfoxaflor residues were highest in the cherry trials from the USA and decided to estimate stone fruit crop group maximum residue level on this data set.

The Meeting estimated a maximum residue level of 3 mg/kg for sulfoxaflor on stone fruit. The Meeting estimated STMR and HR values of 0.91 and 1.2 mg/kg, respectively, for sulfoxaflor residues in stone fruit.

Grapes

The proposed GAP for grapes is for four foliar applications of sulfoxaflor at 0.1 kg ai/ha with a 7-day RTI and a 7-day PHI.

A total of 33 trials on grapes, complying with the proposed GAP, were available from Australia and New Zealand (12), Northern Europe (6), Southern Europe (6), and USA (9).

Residues of sulfoxaflor, in ranked order, measured in grapes from Australia/New Zealand were: 0.013, 0.034, 0.095, 0.10, 0.11, 0.13, 0.14, 0.20, 0.35, 0.45, 0.56, and 1.59 mg/kg.

Residues of sulfoxaflor, in ranked order, measured in grapes from Northern Europe were: 0.12, 0.15 (2), 0.23, 0.29, and 0.46 mg/kg.

Residues of sulfoxaflor, in ranked order, measured in grapes from Southern Europe were: 0.061, 0.080, 0.23, 0.36, 0.96, and 1.02 mg/kg.

Residues of sulfoxaflor, in ranked order, measured in grapes from the USA were: 0.042, 0.049, 0.091, 0.10 (3), 0.12, 0.14, and 0.33 mg/kg.

Based on the Australia/New Zealand trials, the Meeting estimated a maximum residue level of 2 mg/kg for sulfoxaflor in grape. The Meeting estimated STMR and HR values of 0.14 and 1.6 mg/kg, respectively, for sulfoxaflor residues in grape.

Strawberries

The proposed GAP for strawberries is for four foliar applications of sulfoxaflor at 0.1 kg ai/ha with a 7-day RTI and a 1-day PHI.

A total of 13 trials on field-grown strawberries, complying with the proposed GAP, were available from Australia and New Zealand (4) and USA (9).

Residues of sulfoxaflor, in ranked order, measured in strawberries from Australia/New Zealand were: 0.030, 0.13, 0.21, and 0.49 mg/kg.

Residues of sulfoxaflor, in ranked order, measured in strawberries from USA were: 0.065, 0.14 (2), 0.18, 0.19 (2), 0.20, and 0.21 (2) mg/kg.

Based on the USA trials, the Meeting estimated a maximum residue level of 0.5 mg/kg for sulfoxaflor in strawberry. The Meeting estimated STMR and HR values of 0.19 and 0.21 mg/kg, respectively, for sulfoxaflor residues in strawberry.

Bulb vegetables

Supervised trials data were available for bulb and spring onions from USA.

The proposed GAP for onions is for four foliar applications of sulfoxaflor at 0.1 kg ai/ha with a 7-day RTI and a 7-day PHI.

Bulb Onion

In six bulb onion trials matching the proposed foliar GAP conditions, sulfoxaflor residues in bulb onion did not exceed the LOQ (< 0.01 mg/kg) in any sample.

The Meeting estimated a maximum residue level of 0.01* mg/kg for sulfoxaflor in bulb onion. The Meeting also estimated STMR and HR values of 0.01 mg/kg, for sulfoxaflor residues in bulb onion.

The Meeting decided to extrapolate the estimated maximum residue level, STMR, and HR values for bulb onions to garlic.

Spring Onion

In six spring onion trials in USA matching the proposed GAP conditions, residues of sulfoxaflor, in ranked order, measured in spring onion were: < 0.01, 0.048, 0.09, 0.13 (2), and 0.39 mg/kg.

The Meeting estimated a maximum residue level of 0.7 mg/kg for sulfoxaflor in spring onion. The Meeting estimated STMR and HR values of 0.11 and 0.39 mg/kg, respectively, for sulfoxaflor residues in spring onion.

Brassica vegetables

Supervised trials data, matching the proposed GAP, were available for broccoli, head cabbage, and cauliflower.

Proposed GAP for head and stem *Brassica* vegetables is for four foliar applications of sulfoxaflor at 0.1 kg ai/ha, with a 7-day RTI and a 3-day PHI.

Broccoli

A total of 15 trials on broccoli were available from Australia (2), Northern Europe (5), Southern Europe (2), and USA (6).

Sulfoxaflor residue concentrations in broccoli from Australia were: 0.07 (2) mg/kg.

Residues of sulfoxaflor, in ranked order, measured in broccoli from Northern Europe were: 0.057, 0.073, 0.074, 0.32, and 1.58 mg/kg.

Residues of sulfoxaflor, in ranked order, measured in broccoli from Southern Europe were: 0.036 and 0.16 mg/kg.

Residues of sulfoxaflor, in ranked order, measured in broccoli from USA were: < 0.01, 0.029, 0.050, 0.060, 0.12, and 0.39 mg/kg.

Based on the Northern European trials, the Meeting estimated a maximum residue level of 3 mg/kg for sulfoxaflor in broccoli. The Meeting estimated STMR and HR values of 0.074 and 1.6 mg/kg, respectively, for sulfoxaflor residues in broccoli.

Head cabbage

A total of 14 trials on head cabbage were available from Australia (2), Northern Europe (3), Southern Europe (3), and USA (6).

Residues of sulfoxaflor, in ranked order, measured in head cabbage from Australia were: 0.01 and 0.15 mg/kg.

Residues of sulfoxaflor, in ranked order, measured in head cabbage from Northern Europe were: 0.034, 0.081, and 0.38 mg/kg.

Residues of sulfoxaflor, in ranked order, measured in head cabbage from Southern Europe were: 0.016, 0.019, and 0.066 mg/kg.

Residues of sulfoxaflor, in ranked order, measured in head cabbage from USA were: < 0.01, 0.040, 0.097, 0.10 (2), and 0.19 mg/kg.

Although the highest residues in head cabbage were found in the trials from Northern Europe, an insufficient number of trials were available to recommend a maximum residue level from this data set. Based on the six USA trials, the Meeting estimated a maximum residue level of 0.4 mg/kg for sulfoxaflor in head cabbage. The Meeting estimated STMR and HR values of 0.099 and 0.19 mg/kg, respectively, for sulfoxaflor residues in head cabbage.

Cauliflower

A total of ten trials on cauliflower were available from Australia (2) and Northern Europe (6), and Southern Europe (2).

Sulfoxaflor residue concentrations in cauliflower from Australia were: < 0.01 and 0.050 mg/kg.

Residues of sulfoxaflor, in ranked order, measured in cauliflower from Northern Europe were: < 0.01 (2), 0.011, 0.014 (2), and 0.021 mg/kg.

Sulfoxaflor residue concentrations in cauliflower from Southern Europe were: 0.022 and 0.029 mg/kg.

Based on the Northern European trials, the Meeting estimated a maximum residue level of 0.04 mg/kg for sulfoxaflor in cauliflower. The Meeting estimated STMR and HR values of 0.013 and 0.021 mg/kg, respectively, for sulfoxaflor residues in cauliflower.

Fruiting vegetables - Cucurbit

Supervised trials data were available for cucumbers and melons. All trials were conducted outdoors.

The proposed GAP for cucurbit vegetables is for four foliar applications of sulfoxaflor at 0.1 kg ai/ha, with a 7-day RTI and a 1-day PHI.

Cucumber

A total of 18 trials on cucumber were available from Northern Europe (6), Southern Europe (6), and USA (6).

Residues of sulfoxaflor, in ranked order, found in cucumber from Northern Europe were: 0.023, 0.029, 0.034, 0.088, 0.10, and 0.15 mg/kg. .

Residues of sulfoxaflor, in ranked order, found in cucumber from Southern Europe were: 0.031, 0.052, 0.055, 0.073, 0.083, and 0.11 mg/kg.

Residues of sulfoxaflor, in ranked order, found in cucumber from USA were: < 0.01, 0.014, 0.018, 0.025, 0.041, and 0.071 mg/kg.

Summer Squash

A total of five trials on summer squash were available from Australia (2) and USA (3).

Sulfoxaflor residue concentrations in summer squash from Australia were: 0.025 and 0.10 mg/kg.

Sulfoxaflor residue concentrations in summer squash from USA were: < 0.01 (3) mg/kg.

Cantaloupe

A total of 16 trials on cantaloupe were available from Brazil (4), Southern Europe (6) and the USA (6).

Residues of sulfoxaflor, in ranked order, found in cantaloupe from Brazil were: 0.012, 0.020, 0.027, and 0.055 mg/kg.

Residues of sulfoxaflor, in ranked order, found in cantaloupe from Southern Europe were: 0.015, 0.040, 0.045, 0.048, 0.10, and 0.13 mg/kg.

Residues of sulfoxaflor, in ranked order, found in cantaloupe from the USA were: < 0.01, 0.018, 0.025, 0.032, 0.038, and 0.27 mg/kg.

Winter Squash

Three winter squash trials were available from the USA, with the following residue levels: < 0.01, 0.011, and 0.018 mg/kg.

Summary – Fruiting vegetables, Cucurbits

The Meeting noted that sulfoxaflor residues were higher in cantaloupe than in cucumber, and decided to estimate a maximum residue level for the cucurbit vegetables group based on the USA cantaloupe data set.

The Meeting estimated a maximum residue level of 0.5 mg/kg for sulfoxaflor for fruiting vegetables, cucurbits. The Meeting estimated STMR and HR values of 0.029 and 0.27 mg/kg, respectively, for sulfoxaflor residues in fruiting vegetables, cucurbits.

Fruiting vegetables other than cucurbits

Supervised trials data were available for pepper and tomato.

Proposed GAP for fruiting vegetables other than cucurbits is for four foliar applications of sulfoxaflor at 0.1 kg ai/ha, a 7-day RTI, and a 1-day PHI.

Peppers

A total of 20 trials on field-grown peppers were available from Australia (6), Southern Europe (6), and USA (8).

Residues of sulfoxaflor, in ranked order, found in peppers from Australia were: < 0.010, 0.010, 0.08 (2), 0.40, and 0.45 mg/kg.

Residues of sulfoxaflor, in ranked order, found in peppers from Southern Europe were: 0.093 (2), 0.12, 0.18, 0.23, and 0.26 mg/kg.

Residues of sulfoxaflor, in ranked order, found in peppers from the USA were: 0.01, 0.015, 0.020, 0.055, 0.085, 0.086, 0.20, and 0.21 mg/kg.

The Meeting noted that the peppers data from Australia showed the highest sulfoxaflor residue levels and decided to estimate the peppers residue levels based on this data set.

Tomato

A total of 44 trials on tomato were available from Australia (6), Brazil (4), Northern Europe (11), Southern Europe (11) and USA (12).

Residues of sulfoxaflor, in ranked order, found in tomatoes from Australia were: 0.014, 0.015 (2), 0.025, 0.030, and 0.050 mg/kg.

Residues of sulfoxaflor, in ranked order, found in tomatoes from Brazil were: 0.015, 0.035, 0.074, and 0.096 mg/kg.

Residues of sulfoxaflor, in ranked order, found in tomatoes from Northern Europe were: 0.022, 0.024, 0.042, 0.047, 0.052, 0.054, 0.057, 0.076, 0.085, 0.095, and 0.37 mg/kg.

Residues of sulfoxaflor, in ranked order, found in tomatoes from Southern Europe were: 0.026, 0.030, 0.035, 0.054, 0.063, 0.11, 0.15, 0.31, 0.41, 0.53, and 0.60 mg/kg. Four tomato trials in Southern Europe were conducted indoors. However, residue levels in the indoor trials were not appreciably different from those in the outdoor trials.

Residues of sulfoxaflor, in ranked order, found in tomatoes from the USA were: < 0.01 (2), 0.010, 0.026, 0.030, 0.047, 0.061, 0.077, 0.082, 0.085, 0.094, and 0.15 mg/kg.

The Meeting noted that the tomato data from Southern Europe showed the highest sulfoxaflor residue levels and decided to estimate the tomato residue levels based on this data set.

Summary – Fruiting vegetables other than cucurbits

The Meeting noted that sulfoxaflor residues were higher in tomatoes than in peppers. The Meeting decided to estimate a group maximum residue level for the fruiting vegetables other than cucurbits, (except sweet corn and mushroom) based on the tomato data set.

The Meeting estimated a maximum residue level of 1.5 mg/kg for sulfoxaflor in fruiting vegetables other than cucurbits (except sweet corn and mushrooms). The Meeting estimated STMR and HR values of 0.11 and 0.60 mg/kg, respectively, for sulfoxaflor residues in fruiting vegetables other than cucurbits (except sweet corn and mushrooms).

The JMPR Manual (Section 6.9.2) indicates that a generic factor of 10 may be used for conversion of residues from fresh peppers to dried chili peppers in the estimation of maximum residue levels.

The Meeting agreed to apply the default factor of 10 for dried chili peppers to the STMR and HR values for sulfoxaflor in sweet peppers and estimated a maximum residue level, an STMR and an HR for sulfoxaflor in dried chili peppers of 15, 1.1 and 6.0 mg/kg, respectively.

Leafy vegetables

Supervised trial data were available for lettuce, mustard greens, radish tops, and spinach.

The proposed GAP for leafy vegetables is for four foliar applications of sulfoxaflor at 0.1 kg ai/ha, a 7-day RTI, and a 3-day PHI.

Head Lettuce

A total of 14 trials on field-grown head lettuce, complying with the proposed GAP, were available from Australia (4), Northern Europe (3), Southern Europe (3), and USA (4).

Residues of sulfoxaflor, in ranked order, found in head lettuce from Australia were: < 0.010, 0.035 (2), and 0.065 mg/kg.

Residues of sulfoxaflor, in ranked order, found in head lettuce from Northern Europe were: 0.015, 0.24, and 0.32 mg/kg.

Residues of sulfoxaflor, in ranked order, found in head lettuce from Southern Europe were: 0.17 and 0.49 (2) mg/kg.

Residues of sulfoxaflor, in ranked order, found in head lettuce from the USA were: < 0.01, 0.010, 0.014, and 0.18 mg/kg.

The Meeting noted that the data from Europe had the highest residue levels, and decided to combine the data from Northern and Southern Europe in mutual support. Thus, in six trials from Europe, residues of sulfoxaflor, in ranked order, found in head lettuce were: 0.015, 0.17, 0.24, 0.32, and 0.49 (2) mg/kg.

Leaf Lettuce

A total of 18 trials on field-grown leaf lettuce were available from Australia (4), Northern Europe (3), Southern Europe (3), and the USA (8). Three of the leaf lettuce trials matching the proposed foliar GAP were 'side-by-side' trials providing bridging data for the use of SC and WDG formulations at one location [Guadalupe, California trial]. Sulfoxaflor residues in lettuce leaves were 0.36, 1.10, and 0.49 mg/kg for SC; and 0.40, 0.81, and 0.58 mg/kg for WDG. The results suggest equivalence, so only one of the bridging trials (that bearing the highest residue) was included in the dataset for STMR

and maximum residue level estimation. Thus, only six of the USA trials were considered independent and used in the following analysis.

Residues of sulfoxaflor, in ranked order, found in leaf lettuce from Australia were: 0.055, 0.17, 0.23, and 0.93 mg/kg.

Residues of sulfoxaflor, in ranked order, found in leaf lettuce from Northern Europe were: 0.32, 0.42, and 0.75 mg/kg.

Residues of sulfoxaflor, in ranked order, found in leaf lettuce from Southern Europe were: 0.18, 0.42, and 1.36 mg/kg.

Residues of sulfoxaflor, in ranked order, found in leaf lettuce from the USA were: 0.41, 0.79, 1.07, 1.10, 1.59, and 2.74 mg/kg.

Mustard Greens

In eight mustard green trials from the USA matching the proposed GAP conditions for leafy vegetables, residues of sulfoxaflor, in ranked order, found in mustard greens were: 0.29, 0.50, 0.60, 0.67, 0.77, 0.82, and 0.90 (2) mg/kg.

Radish Tops

In six radish top trials from the USA matching the proposed GAP conditions for leafy vegetables, residues of sulfoxaflor, in ranked order, found were: 0.21, 0.25, 0.27, 0.42, 0.44, and 0.48 mg/kg.

Spinach

A total of seven trials on spinach were available from Australia (1) and USA (6).

The sulfoxaflor residue concentration in spinach from one Australian trial was 0.37 mg/kg.

Residues of sulfoxaflor, in ranked order, found in spinach from USA were: 0.041, 0.40, 1.04, 1.43, 1.87, and 2.86 mg/kg.

Summary – leafy vegetables

Residue data from trials complying with the proposed GAP were available for leaf lettuce, head lettuce, mustard greens, radish tops, and spinach. The Meeting noted that sulfoxaflor residues were highest in spinach and decided to estimate leafy vegetables group maximum residue levels based on this data set.

The Meeting estimated a maximum residue level of 6 mg/kg for sulfoxaflor on leafy vegetables. The STMR and HR values were 1.2 and 2.9 mg/kg, respectively.

Legume vegetables

Supervised trials data were available for common beans and succulent soya beans.

The proposed GAP for beans is for four foliar applications of sulfoxaflor with at 0.1 kg ai/ha, a 7-day RTI, and a 7-day PHI.

Common bean (pods and/or immature seeds)

A total of six trials on common bean were available from Northern Europe (3) and Southern Europe (3).

Residues of sulfoxaflor, in ranked order, found in common bean from Northern Europe were: 0.072, 0.076, and 0.31 mg/kg.

Residues of sulfoxaflor, in ranked order, found in common bean seed from Southern Europe were: 0.029, 0.12, and 1.94 mg/kg.

The Meeting concluded that no maximum residue level could be estimated for common bean due to an insufficient number of trials.

Soya bean (immature seeds)

A total of 18 trials on soya bean were available from Brazil (4) and USA (14).

Residues of sulfoxaflor, in ranked order, found in soya bean seed from Brazil were: < 0.010 (2), 0.030, and 0.039 mg/kg.

Residues of sulfoxaflor, in ranked order, found in soya bean seed from USA were: < 0.010 (6), 0.010, 0.012, 0.013, 0.017, 0.030, 0.034 (2), and 0.20 mg/kg.

The Meeting estimated a maximum residue level of 0.3 mg/kg for sulfoxaflor on soya bean (immature seeds). The STMR value was 0.011 mg/kg.

Beans, dry

Proposed GAP for beans allows the use of sulfoxaflor with four foliar applications at 0.1 kg ai/ha, a 7-day RTI, and a 7-day PHI.

A total of six trials on dry beans were available from Brazil (4) and Northern Europe (1), and Southern Europe (1).

Residues of sulfoxaflor, in ranked order, found in dry beans from Brazil were: 0.049, 0.074, 0.080, and 0.082 mg/kg.

The sulfoxaflor residue concentration in dry beans from Northern Europe was 0.10 mg/kg.

The sulfoxaflor residue concentration in dry beans from Southern Europe was 0.022 mg/kg.

The Meeting concluded that no maximum residue level could be estimated for dry beans as there were an insufficient number of trials.

Root and tuber vegetables

Supervised trials data were available for carrot, potato, radish and sugar beet.

The proposed GAP for root and tuber vegetables is for four foliar applications of sulfoxaflor at 0.1 kg ai/ha, a 7-day RTI, and a 7-day PHI.

Carrot

A total of 11 trials on carrot were available from Northern Europe (4), Southern Europe (3), and USA (4).

Residues of sulfoxaflor, in ranked order, found in carrot root from Northern Europe were: < 0.010 (2), 0.010, and 0.017 mg/kg.

Residues of sulfoxaflor, in ranked order, found in carrot root from Southern Europe were: 0.014, 0.030, and 0.031 mg/kg.

Residues of sulfoxaflor, in ranked order, found in carrot root from the USA were: < 0.010 (2), 0.010, and 0.013 mg/kg.

Four trials are considered insufficient to allow a maximum residue level estimate for carrot. Therefore, the Meeting could not make a maximum residue level estimate for carrot due to an inadequate number of trials.

Potatoes

In 18 potato trials [Canada (1), Northern Europe (4), Southern Europe (4), and USA (9)] matching the proposed GAP conditions, sulfoxaflor residues in potatoes did not exceed the LOQ (< 0.01 mg/kg) in any tuber sample.

Radish

In six radish trials from the USA, matching the proposed GAP conditions, residues of sulfoxaflor, in ranked order, in radish roots were: < 0.010 (3), 0.01, 0.012, and 0.014 mg/kg.

Sugar Beet

A total of 13 trials on sugar beet were available from Northern Europe (4), Southern Europe (4), and the USA (5).

Residues of sulfoxaflor, in ranked order, found in sugar beet roots from Northern Europe were: < 0.010 (3), and 0.012 mg/kg.

Residues of sulfoxaflor, in ranked order, found in sugar beet roots from Southern Europe were: < 0.010 (3), and 0.023 mg/kg.

None of the USA trials reported residues above the LOQ of 0.01 mg/kg in sugar beet roots.

Noting the similar residue distributions for the Northern and Southern European trials, the Meeting decided to combine these data sets in mutual support. Thus, the rank-order sulfoxaflor residues in sugar beet roots from Northern and Southern Europe were: < 0.010(6), 0.012, and 0.023 mg/kg.

Summary – Root and tuber vegetables

Sufficient residue data from trials complying with the proposed GAP were available for radish, potato, and sugar beet. Residues were highest in sugar beet and the Meeting decided to estimate a root and tuber vegetables (except carrot) group maximum residue level based on the sugar beet data.

The Meeting estimated a maximum residue level of 0.03 mg/kg for sulfoxaflor on root and tuber vegetables (except carrot). The Meeting estimated STMR and HR values of 0.010 and 0.023 mg/kg, respectively, for sulfoxaflor residues in root and tuber vegetables (except carrot).

Celery

Supervised trials data were available for celery from the USA (6).

Sulfoxaflor is proposed for use on celery as a maximum of four foliar applications at 0.1 kg ai/ha, a 7-day RTI, and a 3-day PHI.

In six celery trials matching the proposed GAP conditions, residues of sulfoxaflor, in ranked order, found in celery were: 0.10, 0.16, 0.17, 0.20, 0.69, and 0.77 mg/kg.

The Meeting estimated a maximum residue level of 1.5 mg/kg for sulfoxaflor on celery. The Meeting estimated STMR and HR values of 0.19 and 0.77 mg/kg, respectively, for sulfoxaflor residues in celery.

Barley

The proposed GAP for barley is for two foliar applications of sulfoxaflor at 0.05 kg ai/ha, a 14-day RTI, and a 14-day PHI for grain and straw [7-day PHI for forage and hay].

A total of 25 trials on barley grain were available from Australia/New Zealand (6), Northern Europe (7), Southern Europe (6), and the USA (6).

Residues of sulfoxaflor, in ranked order, found in barley grain from Australia/New Zealand were: < 0.010, 0.025, 0.050, 0.075, 0.11, and 0.32 mg/kg.

Residues of sulfoxaflor, in ranked order, found in barley grain from Northern Europe were: < 0.010, 0.050, 0.057, 0.058, 0.060, 0.079, and 0.085 mg/kg.

Residues of sulfoxaflor, in ranked order, found in barley grain from Southern Europe were: 0.015, 0.042, 0.052, 0.053, 0.055, and 0.061 mg/kg.

Residues of sulfoxaflor, in ranked order, found in barley grain from the USA were: 0.038, 0.043, 0.044, 0.047, 0.072, and 0.088 mg/kg.

The Meeting noted that sulfoxaflor residues were highest in barley trials from Australia/New Zealand, and decided to estimate maximum residue levels on this data set. The Meeting estimated a maximum residue level of 0.6 mg/kg and a STMR value of 0.063 mg/kg for sulfoxaflor residues in barley grain.

Wheat

The proposed GAP for wheat allows the use of sulfoxaflor with two foliar applications at 0.05 kg ai/ha, a 14-day RTI, and a 14-day PHI for grain and straw [7-day PHI for forage and hay].

A total of 33 trials on wheat grain were available from Australia/New Zealand (6), Brazil (4), Northern Europe (6), Southern Europe (6) and USA/Canada (11).

Residues of sulfoxaflor, in ranked order, found in wheat grain from Australia/New Zealand were: < 0.010 (2), 0.015 (2), 0.035, and 0.040 mg/kg.

Residues of sulfoxaflor, in ranked order, found in wheat grain from Brazil were: < 0.010 (3) and 0.034 mg/kg.

Residues of sulfoxaflor, in ranked order, found in wheat grain from Northern Europe were: 0.018, 0.019, 0.023, 0.027, 0.032, and 0.11 mg/kg.

Residues of sulfoxaflor, in ranked order, found in wheat grain from Southern Europe were: 0.011, 0.013, 0.014, 0.020, 0.024, and 0.056 mg/kg.

Residues of sulfoxaflor, in ranked order, found in wheat grain from USA/Canada were: < 0.010 (6), 0.012, 0.015, 0.020, 0.037, and 0.063 mg/kg.

The Meeting observed that sulfoxaflor residues were highest in wheat trials from Northern Europe, and decided to estimate maximum residue levels based on this data set. The Meeting estimated a maximum residue level of 0.2 mg/kg for sulfoxaflor on wheat grain. The Meeting estimated an STMR value of 0.025 mg/kg for sulfoxaflor residues in wheat grain.

Noting that the proposed GAP includes triticale with the same use pattern as wheat and barley, the Meeting decided to extrapolate the estimated maximum residue level and STMR value for wheat to triticale.

Tree nuts

Sulfoxaflor is proposed for use on tree nuts as two foliar applications at 0.2 kg ai/ha, a 7-day RTI, and a 7-day PHI.

Almond

In six almond trials from the USA matching the proposed GAP, residues of sulfoxaflor in almond nutmeat were less than the LOQ of 0.01 mg/kg in five trials, and 0.012 mg/kg in one trial.

Pecan

In six pecan trials from the USA matching the proposed GAP, residues of sulfoxaflor in pecan nutmeat did not exceed the LOQ (0.01 mg/kg).

Summary – tree nuts

Residue data from trials complying with the proposed GAP were available for almonds and pecans. Residues were higher in almonds and the Meeting decided to estimate a tree nut group maximum residue level based on the almond data.

The Meeting estimated a maximum residue level of 0.015 mg/kg for sulfoxaflor on tree nuts. The Meeting estimated STMR and HR values of 0.01 and 0.012 mg/kg, respectively, for sulfoxaflor residues in tree nuts.

Oilseeds

Supervised trials data were available for cotton seed and rape seed.

Cotton Seed

The proposed GAP for use of sulfoxaflor in cotton consists of a maximum of four foliar applications at 0.1 kg ai/ha, a 7-day RTI, and a 14-day PHI.

A total of 22 trials on cotton seed were available from Australia (4), Brazil (4), Southern Europe (8), and the USA (6).

Residues of sulfoxaflor, in ranked order, found in cotton seed from Australia were: < 0.010, 0.015, 0.045, and 0.080 mg/kg.

Residues of sulfoxaflor, in ranked order, found in cotton seed from Brazil were: < 0.010, 0.014, 0.039, and 0.042 mg/kg.

Residues of sulfoxaflor, in ranked order, found in cotton seed from Southern Europe were: 0.010, 0.012, 0.013, 0.018, 0.031, 0.043, 0.070, and 0.080 mg/kg.

Residues of sulfoxaflor, in ranked order, found in cotton seed from the USA were: 0.010, 0.015, 0.017, 0.023, 0.041, and 0.18 mg/kg.

The Meeting observed that sulfoxaflor residues were highest in cotton trials from the USA, and decided to estimate maximum residue levels on this data set. The Meeting estimated a maximum residue level of 0.4 mg/kg for sulfoxaflor on cotton seed. The Meeting estimated an STMR value of 0.020 mg/kg for sulfoxaflor residues in cotton seed.

Rape seed

The proposed GAP for oilseed rape allows the use of sulfoxaflor with two foliar applications at 0.05 kg ai/ha, a 14-day RTI, and a 14-day PHI.

A total of 14 trials on rape seed were available from Australia (1), Northern Europe (3), Southern Europe (2), and USA/Canada (8).

The sulfoxaflor residue concentrations in rape seed from Australian trial was 0.060 mg/kg.

Residues of sulfoxaflor, in ranked order, found in rape seed from Northern Europe were: 0.027, 0.038, and 0.057 mg/kg.

The sulfoxaflor residue concentrations in rape seed from Southern Europe were: 0.12 and 0.30 mg/kg.

Residues of sulfoxaflor, in ranked order, found in rape seed from USA/Canada were: < 0.010, 0.017, 0.035, 0.042, 0.047, 0.051, 0.072, and 0.085 mg/kg.

The Meeting observed that a sufficient number of trials were only available from USA/Canada, and decided to estimate a maximum residue level based on this data set. The Meeting estimated a maximum residue level of 0.15 mg/kg for sulfoxaflor on rape seed. The Meeting estimated an STMR value of 0.045 mg/kg for sulfoxaflor residues in rape seed.

Residues in animal feed

Straw, fodder and forage of cereal grains

Barley straw and fodder

Supervised trials data were available for barley straw and hay.

Proposed GAP for barley allows the use of sulfoxaflor for two foliar applications at 0.050 kg ai/ha, with a 14-day RTI and a 7-day PHI for hay and a 14-day PHI for straw.

Barley Straw

A total of 24 trials on barley straw were available from Australia/New Zealand (6), Northern Europe (7), Southern Europe (6), and the USA (5).

Residues of sulfoxaflor found in barley straw from Australia/New Zealand, in ranked order, were: 0.03, 0.090, 0.10, 0.22, 0.24, and 1.41 mg/kg.

Residues of sulfoxaflor found in barley straw from Northern Europe, in ranked order, were: 0.014, 0.051, 0.073, 0.11, 0.13, 0.22, and 0.26 mg/kg.

Residues of sulfoxaflor found in barley straw from Southern Europe, in ranked order, were: 0.12, 0.32, 0.37, 0.52, 0.53, and 0.58 mg/kg.

Residues of sulfoxaflor measured in barley straw from USA, in ranked order, were: 0.039, 0.19, 0.20, 0.59, and 0.70 mg/kg.

The Meeting observed that the highest sulfoxaflor residues occurred in the Australia/New Zealand trials for barley straw.

Barley Hay

A total of 20 trials on barley hay were available from Northern Europe (6), Southern Europe (8), and USA (6).

Residues of sulfoxaflor measured in barley hay, in ranked order, from Northern Europe were: 0.041, 0.086, 0.20 (2), 0.25, and 0.64 mg/kg.

Residues of sulfoxaflor, in ranked order, measured in barley hay from Southern Europe were: 0.030, 0.037, 0.21, 0.36, 0.38, 0.39, 0.41, and 0.43 mg/kg.

Residues of sulfoxaflor, in ranked order, measured in barley hay from USA were: < 0.010, 0.11, 0.12, 0.31 (2) and 0.46 mg/kg.

The Meeting observed that the highest sulfoxaflor residues occurred in the Northern European trials for barley hay.

Wheat straw, fodder, and forage

Supervised trials data were available for wheat straw, hay and forage.

The proposed GAP for wheat allows the use of sulfoxaflor for two foliar applications at 0.050 kg ai/ha, a 14-day RTI and with PHI's for hay and forage of 7-days and a PHI for straw of 14-days.

Wheat Straw

A total of 34 trials on wheat straw were available from Australia/New Zealand (6), Brazil (4), Northern Europe (7), Southern Europe (6), and USA/Canada (11).

Residues of sulfoxaflor, in ranked order, measured in wheat straw from Australia/New Zealand were: 0.060, 0.29 (2), 0.41, 0.46, and 1.38 mg/kg.

Residues of sulfoxaflor, in ranked order, measured in wheat straw from Brazil were: 0.052, 0.084, 0.24, and 1.06 mg/kg.

Residues of sulfoxaflor, in ranked order, measured in wheat straw from Northern Europe were: 0.11, 0.22, 0.23, 0.32, 0.35, 0.49, and 0.51 mg/kg.

Residues of sulfoxaflor, in ranked order, measured in wheat straw from Southern Europe were: 0.18, 0.21, 0.32, 0.62 (2), and 0.81 mg/kg.

Residues of sulfoxaflor, in ranked order, measured in wheat straw from USA/Canada were: 0.043, 0.063, 0.071, 0.11 (2), 0.12, 0.17, 0.22, 0.31, 1.34, and 1.60 mg/kg.

The Meeting observed that the highest sulfoxaflor residues occurred in the USA/Canada trials for wheat straw.

Wheat Hay

A total of 29 trials on wheat hay were available from Brazil (4), Northern Europe (7), Southern Europe (7), and USA/Canada (11).

Residues of sulfoxaflor, in ranked order, measured in wheat hay from Brazil were: 0.26, 0.42, and 0.53(2) mg/kg.

Residues of sulfoxaflor, in ranked order, measured in wheat hay from Northern Europe were: 0.074, 0.19, 0.21, 0.22, 0.34, 0.49, and 0.60 mg/kg.

Residues of sulfoxaflor, in ranked order, measured in wheat hay from Southern Europe were: 0.087, 0.10, 0.28, 0.31, 0.43, 0.57, and 0.85 mg/kg.

Residues of sulfoxaflor, in ranked order, measured in wheat hay from USA/Canada were: 0.026, 0.048, 0.082, 0.10, 0.15, 0.16, 0.19, 0.20, 0.21, 0.35, and 0.41 mg/kg.

The Meeting observed that the highest sulfoxaflor residues occurred in the Southern European trials for wheat hay.

Summary of 'barley straw and fodder' and 'wheat straw and fodder'

'Barley straw and fodder' and 'wheat straw and fodder', as commodities moving in trade, may not always be readily distinguishable from each other. Consequently, the Meeting considered it preferable that the two commodities have the same Codex MRL. For sulfoxaflor, residues in wheat straw were higher than in the barley straw, and higher than residues in hay samples. The Meeting agreed to use

the wheat straw data from USA/Canada for the maximum residue level estimation for both 'barley straw and fodder' and 'wheat straw and fodder'.

On a dry-weight basis (DM = 88%), sulfoxaflor residues in wheat straw were (n = 11): 0.049, 0.072, 0.081, 0.13 (2), 0.14, 0.19, 0.25, 0.35, 1.52, and 1.82 mg/kg.

The Meeting estimated a maximum residue level of 3 mg/kg for sulfoxaflor on wheat and barley straw and fodder, dry. The Meeting estimated median and highest residue values of 0.14 and 1.8 mg/kg, respectively, for sulfoxaflor residues in wheat and barley straw and fodder, dry.

Wheat Forage

A total of 30 trials on wheat forage were available from Australia (1), Brazil (4), Northern Europe (8), Southern Europe (6), and USA/Canada (11).

The sulfoxaflor residue concentration in wheat forage from the Australian trial was 0.92 mg/kg.

Residues of sulfoxaflor measured in wheat forage from Brazil, in ranked order, were: 0.095, 0.11 (2), and 0.39 mg/kg.

Residues of sulfoxaflor measured in wheat forage from Northern Europe, in ranked order, were: 0.020, 0.15, 0.17, 0.18, 0.19, 0.23, 0.37, and 0.44 mg/kg.

Residues of sulfoxaflor, in ranked order, measured in wheat forage from Southern Europe were: 0.033, 0.035, 0.066, 0.070, 0.10, and 0.37 mg/kg.

Residues of sulfoxaflor, in ranked order, measured in wheat forage from USA/Canada were: 0.011, 0.024, 0.042, 0.052, 0.065, 0.086, 0.092, 0.099, 0.11, 0.20, and 0.29 mg/kg.

The Meeting observed that the highest sulfoxaflor residues occurred in the wheat forage trials from Northern Europe, and based residue estimates for wheat forage on this data set.

For livestock dietary burden purposes, the Meeting estimated median and highest residue values for sulfoxaflor on wheat forage at 0.19 and 0.44 mg/kg, respectively. There is no need for a maximum residue level estimate as wheat forage is not considered a tradeable commodity.

Soya bean forage and hay (fodder)

Supervised trials data were available for soya bean forage and hay.

The proposed GAP for soya bean forage allows the use of sulfoxaflor with two foliar applications at 0.1 kg ai/ha, a 7-day RTI, and a 7-day PHI; while that for soya bean hay (fodder) allows the use of four applications at 0.1 kg ai/ha, a 7-day RTI, and a 7-day PHI.

Soya bean forage

A total of 19 trials on soya bean forage were available from Brazil (4) and USA (15).

Residues of sulfoxaflor, in ranked order, measured in soya bean forage from Brazil were: 0.11, 0.22, 0.28, and 0.37 mg/kg.

Residues of sulfoxaflor, in ranked order, measured in soya bean forage from the USA were: 0.020, 0.036, 0.11, 0.13, 0.16, 0.19, 0.21, 0.22, 0.36, 0.37, 0.40, 0.44, 0.53, 1.14, and 1.69 mg/kg.

On the basis of the soya bean forage trials from the USA, the Meeting estimated median and highest residue values of 0.22 and 1.7 mg/kg, respectively, for soya bean forage.

Soya bean hay

A total of 19 trials on soya bean hay were available from Brazil (4) and USA (15).

Residues of sulfoxaflor, in ranked order, measured in soya bean hay from Brazil were: 0.25, 0.72, 1.01, and 1.22 mg/kg.

Residues of sulfoxaflor, in ranked order, measured in soya bean hay from USA were: 0.072, 0.12, 0.13, 0.25, 0.46, 0.50, 0.56, 0.67, 0.87, 0.89, 0.94, 0.97, 1.01, 1.05, and 1.24 mg/kg.

On the basis of the soya bean hay trials from the USA, the Meeting estimated a maximum residue level of 3 mg/kg for sulfoxaflor on soya bean fodder. The median and highest residue values were 0.67 and 1.2 mg/kg, respectively.

Almond hulls

Supervised trials data were available for almond hulls. The proposed GAP for sulfoxaflor use on almond specifies two foliar applications at 0.2 kg ai/ha, a 7-day RTI, and a 7-day PHI.

In six almond trials from the USA matching GAP, Residues of sulfoxaflor, in ranked order, measured in almond hulls were: 1.22, 1.48, 1.52, 2.15, 2.25, and 3.06 mg/kg.

The Meeting estimated a median residue value of 1.8 mg/kg for sulfoxaflor residues in almond hulls.

Sugar beet leaves and tops

Supervised trials data were available for sugar beet tops from Northern Europe (4), Southern Europe (4), and the USA (5).

The proposed GAP for the use of sulfoxaflor on sugar beet specifies four foliar applications at 0.1 kg ai/ha, a 7-day RTI, and a 7-day PHI.

Residues of sulfoxaflor, in ranked order, measured in sugar beet tops from Northern Europe were: 0.84, 0.86, 0.91, and 1.61 mg/kg.

Residues of sulfoxaflor, in ranked order, measured in sugar beet tops from Southern Europe were: 0.064, 0.37, 0.53, and 0.75 mg/kg.

Residues of sulfoxaflor, in ranked order, measured in sugar beet tops from USA were: 0.15, 0.39, 0.42, 0.55, and 1.61 mg/kg.

The Meeting observed that sulfoxaflor residues were highest in sugar beet trials from Northern Europe and the USA. However, as there were five trials from the USA and only four trials from Northern Europe, the Meeting decided to use the USA data set in its estimations. The Meeting estimated median and highest residue values of 0.42 and 1.6 mg/kg for sulfoxaflor residues in sugar beet tops or leaves.

Cotton gin trash

A total of 21 trials on cotton gin trash were available from Australia (4), Brazil (4), Southern Europe (7), and the USA (6).

The proposed GAP for sulfoxaflor use on cotton specifies a maximum of four foliar applications at 0.1 kg ai/ha, a 7-day RTI, and a 14-day PHI.

Residues of sulfoxaflor measured in cotton gin trash from Australia, in ranked order, were: 0.17, 0.59, 1.60, and 3.85 mg/kg.

Residues of sulfoxaflor, in ranked order, measured in cotton gin trash from Brazil were: 0.35, 0.51, 0.93, and 1.52 mg/kg.

Residues of sulfoxaflor, in ranked order, measured in cotton gin trash from Southern Europe were: 0.19, 0.23, 0.35, 0.41, 0.49, 0.89, and 1.4 mg/kg.

Residues of sulfoxaflor, in ranked order, measured in cotton gin trash from USA were: 0.042, 0.048, 0.061, 0.23, 0.58, and 4.03 mg/kg.

The Meeting observed that the USA data set had the highest cotton gin trash residue values, and decided to estimate residue levels on this data set. The Meeting estimated median and highest residue levels of 0.15 and 4.0 mg/kg, respectively, for sulfoxaflor residues in cotton gin trash.

Fate of residues during processing

The Meeting received information on the fate of sulfoxaflor residues during the processing of apple to juice and pomace; barley to pearled barley, barley bran, barley flour, beer and malt; cabbage to sauerkraut; carrot to carrot juice; cherry to dried cherry; cotton seed to meal, hulls, and refined oil; grapes to juice, pomace, raisin, and wine; oranges to pulp, juice and oil; plums to dried prunes; potato to wet peelings, flakes, fries, chips, and dried potato; soya bean to aspirated grain fractions, meal, hulls, and refined oil; strawberry to juice and jam; sugar beet to juice, sugar, molasses, and dried pulp; tomatoes to juice, ketchup, puree, and paste; and wheat to aspirated grain fractions, bran, middlings, shorts, flour, gluten, starch, and bread.

Also information was provided on hydrolysis studies of sulfoxaflor to assist with identification of the nature of the residue during processing.

Sulfoxaflor was stable during the hydrolysis conditions simulating food processing conditions.

Calculated processing factors are summarized in the following table. Factors are indicated with a '<' (less-than) sign when the residue in the processed commodity is below the LOQ of the analytical method. The calculation is then made on the LOQ of the analytical method and the residue concentration of the RAC (raw agricultural commodity). The best estimates of the processing factors are summarized in the middle column of the table. The fourth column provides the STMR or HR of the RAC, and the last column presents the STMR-P or HR-P values obtained by multiplying the PF with the RAC STMR or HR value, as appropriate for the particular processed commodity under consideration.

Processes included in the table are those that lead to STMR-P or HR-P values useful for dietary intake estimations or for livestock dietary burden calculations.

Raw Agricultural Commodity (RAC)	Processed Commodity	Best Estimate Processing Factor (PF)	RAC STMR/HR (mg/kg)	STMR-P/HR-P (mg/kg)
Apple	Wet pomace	1.1	0.07	0.077
	Dry pomace	4.2		0.29
	Juice	0.4		0.028
	Sauce	0.6		0.042
Barley	Pearled	0.7	0.063	0.044
	Bran	1.0		0.063
	Flour	0.8		0.050
	Malt sprouts	1.3		0.082
	Beer	0.2		0.013
Cabbage	Sauerkraut	0.09	0.099	0.009
Canola (rape seed)	Meal	1.9	0.045	0.086
	Oil	0.3		0.014
Carrot	Juice	2.4	0.01	0.024
Cherry	Juice	0.8	0.91/1.2	0.73
	Jam	1.1		1.0
	Dried	5.1		4.6/6.1
Cotton	Hulls	1.8	0.02	0.036
	Meal	0.8		0.016
	Oil	< 0.1		< 0.002
Grape	Raisin	3.5	0.14/1.6	0.49/5.6
	Juice	0.7		0.098

Raw Agricultural Commodity (RAC)	Processed Commodity	Best Estimate Processing Factor (PF)	RAC STMR/HR (mg/kg)	STMR-P/HR-P (mg/kg)
	Pomace	1.0		0.14
	Wine	0.7		0.098
Orange	Juice	0.14	0.31	0.043
	Wet pulp	2.5		0.78
	Dried pulp	8.3		2.6
	Oil	< 0.2		< 0.062
	Peel	5.6		1.7
Potato	Flakes	2.5	0.01	0.025
	Chips	2.1		0.021
	Dried	3.6		0.036
	French Fries	1.6		0.016
Soya bean	Aspirated grain fractions	94	0.011	1.0
	Meal	1.3		0.014
	Hulls	1.5		0.017
	Oil	0.3		0.0033
Strawberry	Juice	0.3	0.19	0.057
	Jam	0.4		0.076
Sugar beet	Thick juice	4.7	0.014	0.066
	Raw sugar	1.8		0.025
	Molasses	10		0.14
	Dried pulp	3.0		0.042
Tomato	Juice	1.0	0.11	0.11
	Ketchup	2.1		0.29
	Puree	2.0		0.22
	Paste	4.4		0.48
Wheat	Aspirated grain fractions	21	0.025	0.53
	Bran	0.4		0.010
	Middlings	0.2		0.005
	Shorts	0.2		0.005
	Flour	0.2		0.005
	Bread	< 0.2		< 0.005
	Starch	< 0.2		< 0.005
	Gluten	< 0.2		< 0.005

In order to determine if a maximum residue level should be recommended for processed commodities, a comparison is made between the STMR-P or HR-P value and the recommended maximum residue level for the RAC from which the processed commodity was obtained. Additionally, the processed commodity must be one that is commonly traded. For sulfoxaflor, the only processed commodity for which a maximum residue level recommendation is appropriate is dried grape, at 6 mg/kg.

Residues in animal commodities

Lactating dairy cattle

The Meeting received a lactating dairy cow feeding study, which provided information on potential residues resulting in ruminant tissues and milk from sulfoxaflor residues in the animal diet.

Lactating Holstein dairy cows were dosed for 28–30 days once daily via a gelatine capsule with a mixture of sulfoxaflor, X11719474, and X11721061. The sulfoxaflor actual dosing rates were 0.45, 2.4, 6.8, and 35 ppm in the dry-weight diet. Lesser concentrations of the metabolites were dosed in proportion to the potential exposure from formation of these compounds in livestock feedstuffs.

Residues of sulfoxaflor transferred into milk, skim milk, and cream at all dose levels. Residues of sulfoxaflor reached a plateau in milk within 8 days of dosing. There was no evidence of preferential transfer of residues to skim milk or cream; in general, residues of sulfoxaflor were slightly lower in cream than in skim milk at all dose levels. In tissues, residues of sulfoxaflor transferred into muscle, fat, liver, and kidney at all dose levels. Residues were generally highest in liver and kidney and lowest in fat.

Laying hens

The Meeting also received a laying hen feeding study, which provided information on potential residues resulting in poultry tissues and egg from sulfoxaflor residues in the animal diet.

Lohman laying hens were dosed for 29 or 30 days once daily via a gelatine capsule with a mixture of sulfoxaflor, X11719474, and X11721061. The sulfoxaflor actual dosing rates were 0.15, 0.76, 2.1, and 10.7 ppm in the dry weight diet. Lesser concentrations of the metabolites were dosed in proportion to the potential exposure from formation of these compounds in the livestock feedstuffs.

In eggs, quantifiable residues of sulfoxaflor were observed at all dose levels except the lowest dose level. Residues of sulfoxaflor after plateau ranged from 0.020 to 0.59 mg/kg and were dependent on dose level. Quantifiable residues of sulfoxaflor transferred into liver at all dose levels and into muscle and fat at dose levels of 0.76 ppm and higher. In general, residues were highest in liver and lowest in fat.

Farm animal dietary burden

The Meeting estimated the dietary burden of sulfoxaflor in livestock on the basis of the diets listed in OECD Feed Table 2009[1]. Calculation from highest residue, STMR (some bulk commodities) and STMR-P values provides the levels in feed suitable for estimating maximum residue levels, while calculation from STMR and STMR-P values for feed is suitable for estimating STMR values for animal commodities.

Estimated maximum and mean dietary burdens of farm animals

Dietary burden calculations for beef cattle, dairy cattle, broilers and laying poultry are provided in Annex 6. The calculations were made according to the livestock diets from US-Canada, EU, Australia and Japan in the OECD Feed Table 2009.

		Livestock dietary burden, sulfoxaflor, ppm of dry matter diet			
		US-Canada	EU	Australia	Japan
Max	beef cattle	0.64	2.00	3.04 [a]	0.05
	dairy cattle	1.23	2.68 [c]	2.31	0.04
	poultry - broiler	0.07	0.07	0.02	0.01
	poultry - layer	0.07	0.89 [e]	0.02	0.00
Mean	beef cattle	0.18	0.60	0.91	0.05
	dairy cattle	0.57	0.77	0.90 [b d]	0.04
	poultry - broiler	0.07	0.07	0.02	0.01
	poultry - layer	0.07	0.30 [f]	0.02	0.00

[a] Highest maximum beef or dairy cattle dietary burden suitable for maximum residue level estimates for mammalian meat.

[1] Available from: http://www.fao.org/agriculture/crops/core-themes/theme/pests/pm/jmpr/jmpr-docs/en/).

[b] Highest mean beef or dairy cattle dietary burden suitable for STMR estimates for mammalian meat.

[c] Highest maximum dairy cattle dietary burden suitable for maximum residue level estimates for milk.

[d] Highest mean dairy cattle dietary burden suitable for STMR estimates for milk.

[e] Highest maximum poultry dietary burden suitable for maximum residue level estimates for poultry meat and eggs.

[f] Highest mean poultry dietary burden suitable for STMR estimates for poultry meat and eggs.

Animal commodities, maximum residue level estimation

Cattle

The sulfoxaflor maximum dietary burden for beef and dairy cattle is 3.04 and 2.68 ppm, respectively. The sulfoxaflor mean dietary burden for beef and dairy cattle is 0.91 and 0.90 ppm, respectively.

For maximum residue level estimation, the high residues in the tissues were calculated by multiplying the maximum dietary burden (3.04 ppm) by the higher tissue transfer factor (TF = maximum tissue residue divided by feeding level dose) of the two bracketing feeding levels (2.4 and 6.8 ppm) from the dairy cow feeding study.

The STMR values for the tissues were calculated by multiplying the mean dietary burden (0.91 ppm) by the higher tissue transfer factor (mean tissue residue divided by feeding level dose) of the two bracketing feeding levels (0.45 and 2.4 ppm) from the dairy cow feeding study.

For milk maximum residue level estimation, the high residues in the milk were calculated by multiplying the maximum dietary burden (2.68 ppm) by the higher tissue transfer factor (mean milk residue divided by feeding level dose) of the two bracketing feeding levels (2.4 and 6.8 ppm) from the dairy cow feeding study.

The STMR value for milk was calculated by multiplying the mean dietary burden (0.90 ppm) by the higher tissue transfer factor (mean milk residue divided by feeding level dose) of the two bracketing feeding levels (0.45 and 2.4 ppm) from the dairy cow feeding study.

This process is summarized in the table below, where the selected tissue transfer factor is indicated by shading. The estimated maximum residue levels were based on the higher of the two projected residue levels for each commodity.

Cattle commodity		Feeding level (ppm) 0.45	2.4	6.8	35	Dietary burden (ppm)	Projected residue levels (mg/kg)	Estimated maximum residue level (mg/kg)
Milk	HR (mg/kg)	0.038	0.123	0.288	1.679			
	TFHR	0.084	0.051	0.042	0.048	2.68	0.14	0.2
	STMR (mg/kg)	0.024	0.090	0.243	1.253			
	TFSTMR	0.053	0.0375	0.036	0.036	0.90	0.048	
Muscle	HR (mg/kg)	0.026	0.155	0.311	1.691			
	TFHR	0.058	0.065	0.046	0.048	3.04	0.20 a	0.3
	STMR(mg/kg)	0.020	0.105	0.271	1.453			
	TFSTMR	0.044	0.044	0.040	0.042	0.91	0.040	
Fat	HR (mg/kg)	0.014	0.057	0.139	0.915			
	TFHR	0.031	0.024	0.020	0.026	3.04	0.073 a	
	STMR (mg/kg)	0.013	0.039	0.099	0.592			
	TFSTMR	0.029	0.016	0.015	0.017	0.91	0.026	
Liver	HR (mg/kg)	0.061	0.375	0.758	4.030			
	TFHR	0.136	0.156	0.111	0.115	3.04	0.47	0.6
	STMR (mg/kg)	0.057	0.283	0.744	3.766			
	TFSTMR	0.127	0.118	0.109	0.108	0.91	0.12	
Kidney	HR (mg/kg)	0.040	0.210	0.566	2.442			

Cattle commodity		Feeding level (ppm) 0.45	2.4	6.8	35	Dietary burden (ppm)	Projected residue levels (mg/kg)	Estimated maximum residue level (mg/kg)
	TFHR	0.089	0.088	0.083	0.070	3.04	0.27	0.4
	STMR (mg/kg)	0.034	0.184	0.461	2.282			
	TFSTMR	0.076	0.077	0.068	0.065	0.91	0.070	

[a] Considered together for recommending a Meat (from mammals other than marine mammals) maximum residue level.

TF = Transfer factor.

The Meeting estimated the following STMR values: milk of 0.048 mg/kg; edible offal (based on liver) at 0.12 mg/kg; muscle at 0.040 mg/kg; and fat at 0.026 mg/kg.

The Meeting estimated the following HR values: milk, 0.14 mg/kg; edible offal (based on liver), 0.47 mg/kg; muscle, 0.20 mg/kg; and fat, 0.073 mg/kg.

The Meeting estimated the following maximum residue levels: milks, 0.2 mg/kg; edible offal (Mammalian), 0.6 mg/kg; and meat (from mammals other than marine mammals) at 0.3 mg/kg.

Poultry

The sulfoxaflor maximum dietary burden for poultry is 0.89 ppm and the mean dietary burden is 0.30 ppm.

For maximum residue level estimation, the high residues in the tissues were calculated by multiplying the maximum dietary burden (0.89 ppm) by the higher tissue transfer factor (maximum tissue residue divided by feeding level dose) of the two bracketing feeding levels (0.76 and 2.1 ppm) from the laying hen feeding study.

The STMR values for the tissues were calculated by multiplying the mean dietary burden (0.30 ppm) by the tissue transfer factor (mean tissue residue divided by feeding level dose) at the 0.76 ppm feeding level from the laying hen feeding study. The tissue transfer factor computed at the 0.15 ppm feeding level was based on < LOQ residue levels and, therefore, was not appropriate for STMR value determinations.

For egg maximum residue level estimation, the high residues in the egg were calculated by multiplying the maximum dietary burden (0.89 ppm) by the higher tissue transfer factor (mean egg residue divided by feeding level dose) of the two bracketing feeding levels (0.76 and 2.1 ppm) from the laying hen feeding study.

The STMR value for egg was calculated by multiplying the mean dietary burden (0.30 ppm) by the egg transfer factor (mean egg residue divided by feeding level dose) at the 0.76 ppm feeding level from the laying hen feeding study. The egg transfer factor computed at the 0.15 ppm feeding level was based on < LOQ residue levels and, therefore, was not appropriate for STMR value determinations.

This process is summarized in the table below, where the selected tissue transfer factor is indicated by shading. The estimated maximum residue levels were based on the higher of the two projected residue levels for each commodity.

Poultry commodity		Feeding level (ppm) 0.15	0.76	2.1	10.7	Dietary burden (ppm)	Projected residue levels (mg/kg)	Estimated maximum residue level (mg/kg)
Eggs	HR (mg/kg)	0.01	0.059	0.099	0.594			
	TF_{HR}	NC [a]	0.078	0.047	0.056	0.89	0.069	0.1
	STMR(mg/kg)	0.01	0.031	0.081	0.423			

Poultry commodity		Feeding level (ppm)				Dietary burden (ppm)	Projected residue levels (mg/kg)	Estimated maximum residue level (mg/kg)
		0.15	0.76	2.1	10.7			
	TF_{STMR}	NC [a]	0.041	0.039	0.040	0.30	0.012	
Muscle	HR (mg/kg)	0.01	0.042	0.109	0.659			
	TF_{HR}	NC [a]	0.055	0.052	0.062	0.89	0.049 [b]	0.1
	STMR (mg/kg)	0.01	0.035	0.086	0.448			
	TF_{STMR}	NC [a]	0.046	0.041	0.042	0.30	0.014	
Liver	HR (mg/kg)	0.028	0.150	0.232	1.193			
	TF_{HR}	0.193	0.198	0.111	0.111	0.89	0.18	0.3
	STMR (mg/kg)	0.015	0.110	0.171	1.118			
	TF_{STMR}	0.103	0.145	0.082	0.104	0.30	0.044	
Fat	HR (mg/kg)	0.01	0.013	0.048	0.184			
	TF_{HR}	NC [a]	0.017	0.023	0.017	0.89	0.020 [b]	
	STMR (mg/kg)	0.01	0.012	0.033	0.164			
	TF_{STMR}	NC [a]	0.016	0.016	0.015	0.30	0.005	

[a] NC - not calculated since residues were < 0.01 mg/kg (LOQ).

[b] Considered together for recommending a Poultry meat maximum residue level.

TF = Transfer factor.

The Meeting estimated the following STMR values: egg, 0.012 mg/kg; edible offal of poultry (based on liver), 0.044 mg/kg; muscle, 0.014 mg/kg; and fat, 0.005 mg/kg.

The Meeting estimated the following HR values: egg, 0.069 mg/kg; edible offal of poultry (based on liver), 0.18 mg/kg; muscle, 0.049 mg/kg; and fat, 0.020 mg/kg.

The Meeting estimated the following maximum residue levels: eggs, 0.1 mg/kg; edible offal of poultry, 0.3 mg/kg; and poultry meat, 0.1 mg/kg.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Daily Intakes (IEDI) for sulfoxaflor was estimated for the 13 GEMS/Food cluster diets using the STMR or STMR-P values estimated by the current Meeting. The results are shown in Annex 3. The IEDI ranged from 1 to 8% of the maximum ADI (0–0.05 mg/kg bw). The Meeting concluded that the long-term intake of residues of sulfoxaflor, from uses that have been considered by the JMPR, is unlikely to present a public health concern.

Short-term intake

The International Estimated Short Term Intake (IESTI) for sulfoxaflor was calculated for the plant and livestock commodities (and their processing factions) for which STMRs and HRs were estimated and for which consumption data were available. The results are shown in Annex 4.

The IESTI varied from 0 to 70% of the ARfD (0.3 mg/kg bw). The Meeting concluded that the short-term intake of residues of sulfoxaflor, from uses that have been considered by the JMPR, is unlikely to present a public health concern.

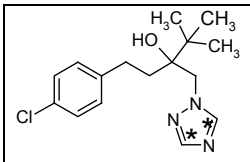
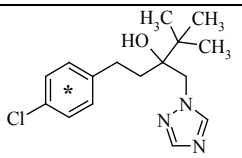
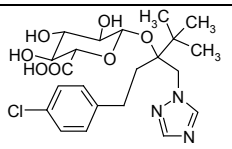
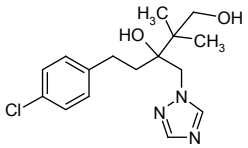
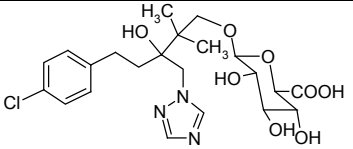
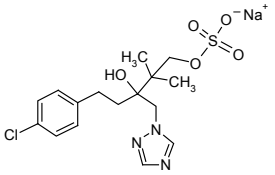
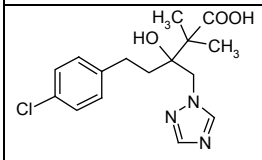
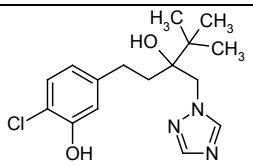
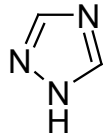
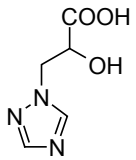
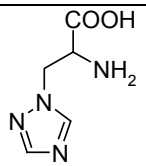
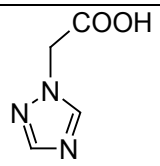
5.25 TEBUCONAZOLE (189)

RESIDUE AND ANALYTICAL ASPECTS

Tebuconazole was last evaluated for residues in 2008. In 2010, the compound was evaluated for toxicology within the periodic review program, when an ADI of 0–0.03 mg/kg bw and a ARfD of 0.3 mg/kg bw were established. The compound was scheduled for periodic review for residues at the present Meeting. Data on metabolism in livestock animals and plant, field rotational crops studies, environmental fate, methods of residue analysis, storage stability studies, GAP information, residue data on various crops, processing studies, and animal feeding studies were submitted.

Animal metabolism

Metabolism studies were conducted in rats, goats and hens. The positions of the radiolabel compounds used in the studies and the structures of the main metabolites found in animals and plants are shown below:

 [triazolyl-3,5-^{14}C]tebuconazole	 [Phenyl-UL-^{14}C]tebuconazole	 tebuconazole glucuronide
 tebuconazole-1-hydroxy	 tebuconazole-1-OH-glucuronide	 Tebuconazole-1-hydroxysulfate
 tebuconazole-carboxylic acid	 Tebuconazole-m-hydroxy	 1,2,4-Triazole (M26)
 Triazole lactic acid	 Triazole alanine	 Triazole acetic acid

The metabolism of tebuconazole in rats was evaluated by the WHO panel of the JMPR at the 2010 Meeting. In summary, the main metabolites of tebuconazole in rats were the oxidation products of one of the methyl groups of the tertiary butyl moiety (alcohol and the carboxylic acid), further conjugation with glucuronide and/or sulfate, and oxidation to triol and keto acid derivatives and cleavage of the triazole moiety (mostly in males).

In a study conducted in 1987, a lactating goat was treated orally with [phenyl-UL-^{14}C]tebuconazole at 15.0 mg/kg bw on three consecutive days. Milk was collected twice a day. The highest tebuconazole equivalents levels were found in liver (5.18 mg/kg) and kidney (3.96 mg/kg), where tebuconazole accounted for 12.4 and 2.5% TRR, respectively. Fat, muscle and milk contained 0.15, 0.05 and 0.04 mg/kg tebuconazole equiv., respectively. Over 85% of the

radioactivity in milk and tissues were recovered in the organosoluble extract. Tebuconazole was not detected in muscle and milk (< 0.01 mg/kg) and accounted for 0.01 mg/kg in fat. The predominant residues in all cases were the conjugates of tebuconazole-1-hydroxy, representing 92.8% TRR in kidney, 67.9% TRR in liver, 68.1% TRR in fat, 67.6% TRR in muscle and 49.4% TRR in milk. Tebuconazole-1-hydroxy levels corresponded to 15.3% TRR in liver, 2.3% TRR in kidney, 12.5% TRR in fat, 21.4% TRR in muscle 22.2% TRR in milk.

In a more recent goat study (2002), two animals were orally dosed with [triazolyl-3,5-^{14}C]tebuconazole at a rate of 3.0 mg/kg bw for 3 consecutive days. The highest tebuconazole equivalents levels were found in liver (1.9 mg/kg) and kidney (2.0 mg/kg). Fat, muscle and milk contained 0.095, 0.027 and 0.011 mg/kg tebuconazole equiv., respectively. Residues of unchanged parent were highest in fat and liver (18 and 15% of the total radioactive residues, TRR, respectively), and accounted for 3, 5 and 7% TRR in kidney, muscle and milk. The main metabolites were tebuconazole-1-OH-glucuronide, found in all tissues at 46 to 77% TRR, and tebuconazole-glucuronide, only found in liver and kidney (17 and 36% TRR, respectively). Milk contained also a polar component (12% TRR), which has chromatographic properties similar to 1,2,4-triazole.

In a study conducted in 1988, laying hens were orally dosed with 10 mg/kg bw [phenyl-UL-^{14}C]tebuconazole for three consecutive days. Quantification of metabolites was based on the recovered radioactivity only. The mean TRR were higher in liver and kidney (8.29 and 6.42 mg/kg tebuconazole equiv.), followed by gizzard (2.09 mg/kg), heart (1.77 mg/kg), fat (1.27 mg/kg), skin (0.5 mg/kg), muscle (0.44 mg/kg) and eggs (0.15 mg/kg). Tebuconazole amounted from 28.3 to 42.3% TRR in eggs, liver and kidney, and from 61.4 to 87.3% TRR in muscle, heart, skin, fat, and gizzard. Tebuconazole-1-hydroxy was detected in all tissues (8.4 to 29.4% TRR) and eggs (56.5% TRR). Tebuconazole-carboxylic acid and tebuconazole-1-hydroxysulfate were detected in liver and kidney (12.6 to 23.1% of the TRR).

In another study (1991), 10 mg/kg bw [phenyl-UL-^{14}C]tebuconazole (approx. 100 mg/kg feed) was administered orally to laying hens on three consecutive days. A total of 84.2% of the administered dose was recovered during the experiment, from which 80.3% in the excreta. The highest TRR were found in liver (10.86 mg/kg tebuconazole equiv.), kidney (9.05 mg/kg) and fat (5.25 mg/kg); muscle and eggs accounted for 0.9 mg/kg each and skin for 1.61 mg/kg. In liver and kidney, tebuconazole accounted for 4 and 2% TRR, respectively, with tebuconazole 1-hydroxysulfate being the main metabolite found (67 and 45.2% TRR, respectively), and tebuconazole-1-hydroxy accounting for less than 10% TRR. In muscle, tebuconazole represented 19 to 38% TRR and tebuconazole-1-hydroxy 22 to 27% TRR. In eggs, those levels were 52.9 and 31.6% TRR, respectively. Tebuconazole-carboxylic acid was present in kidney at 23.5% TRR.

In a more recent study (2002), laying hens were dosed orally for 3 days with [triazolyl-3,5-^{14}C]tebuconazole at 2.0 mg/kg bw (30 mg/kg in the feed). TRR was 3.72 mg/kg tebuconazole equ., in liver, 0.295 mg/kg in fat, 0.179 mg/kg in muscle and ranged from 0.037 to 0.162 mg/kg in eggs. Tebuconazole was the major radioactive residue in fat and muscle (65.4 and 53.4% TRR, respectively) and accounted for 16.5% TRR in liver and from 31.4 to 42.7% in eggs. Tebuconazole-1-hydroxy was present in all tissues (19 to 24.9% TRR) and in eggs (about 30% TRR). Tebuconazole-carboxylic acid and tebuconazole-1-hydroxysulfate were found in liver at 22.7 and 26.4% TRR, respectively. 1,2,4-triazole was detected only in muscle and eggs (11 to 14% of the TRR).

In summary, the metabolism of tebuconazole was extensive in goats, where the main metabolites were tebuconazole-1-hydroxy (up to 22% TRR) and its conjugates (up to 93% TRR). In hens, tebuconazole was a major component in fat and skin. Tebuconazole-1-hydroxy or its conjugates were found in all tissues (over 20% TRR in liver and muscle) and corresponded to over 50% TRR in eggs. Tebuconazole-carboxylic acid was also detected in hen liver and kidney and 1,2,4-triazole in hen muscle and eggs. The metabolic pathway of tebuconazole in livestock animals is similar to that

observed in rats, which involves mainly hydroxylation and carboxylation of the tertiary butyl moiety, followed by conjugation. Cleavage of the triazole was only observed in hens.

Plant metabolism

The metabolism of tebuconazole was investigated from 1985 to 1991 in wheat, peanuts, and grapes under simulated field conditions. In the first study conducted in wheat, [triazole-3,5-^{14}C]tebuconazole was applied to the seeds at approx. 11 g/100 kg, the seeds planted in a sandy loam soil (70 kg seed/ha) and the wheat grown in a greenhouse. Samples of green forage were taken at the boot stage and grain and straw at maturity. Straw contained the highest percentage of the applied radioactivity (17.1%). About 11% of the radioactivity was translocated to green forage and 24% to mature wheat plant. Grains contained 2.4% of the applied radioactivity. Tebuconazole accounted for 25.0% of radioactivity in straw and 76.0% in roots. Tebuconazole-1-hydroxy and its glucuronide conjugate were identified in straw (29% of the radioactivity).

In a second study, [triazole-3,5-^{14}C]tebuconazole was sprayed to wheat during the boot stage at 0.5 kg ai/ha, and plants grown in a greenhouse. In green forage, total radioactive residues (TRR) amounted 28.0 mg/kg tebuconazole equiv. at the day of the application, decreasing to 9.8 mg/kg after 21 days and increasing to 20 mg/kg at day 28; unchanged tebuconazole was the predominant residue (87.3 to 123% TRR throughout the study). At plant maturity, most of the radioactivity was found in straw (37 mg/kg), 95.1% of unchanged tebuconazole. Grain contained 0.5 mg/kg (1.2% of radioactivity in the whole plant), from which 6% was tebuconazole, 80% tebuconazole alanine and 13% triazole acetic acid. The majority of the radioactivity recovered from wheat grain was in starch (74.0%).

The metabolism of [triazole-3,5-^{14}C]tebuconazole and [phenyl-UL-^{14}C]tebuconazole were investigated in peanuts after 3 spray applications at 0.25 kg ai/ha. The plants were grown in a greenhouse and harvested at 7 weeks PHI. Foliage had the highest residue level (29.2 and 22.6 mg/kg tebuconazole equiv. in the triazole and phenyl labels, respectively), followed by the nuts (1.19 and 0.09 mg/kg) and shells (0.16 and 0.27 mg/kg). Most of the residues in foliage was tebuconazole (62% TRR) and about 15% was tebuconazole-1-hydroxy. No tebuconazole was detected in nuts, which contained mostly the cleavage product triazole alanine (54.1% TRR), triazole lactic acid and 1,2,4 triazole (10% TRR each). Peanut shells contained tebuconazole (about 15% TRR), tebuconazole-1-hydroxy and its conjugates.

In another study conducted in peanuts, [Phenyl-UL-^{14}C]tebuconazole was applied seven times to peanut plants at 0.6 kg ai/ha, the plants grown under field conditions, moved into a greenhouse in the last phase of the study and harvested 14 weeks after the last application. TRR in foliage/forage were 110 mg/kg (98% of the residues in the plant), 70% of which corresponding to tebuconazole residues; tebuconazole-1-hydroxy and tebuconazole-m-hydroxy represented < 10% TRR each. In nuts, TRR was 0.55 mg/kg and tebuconazole was the only residue identified (19% TRR); about 64% TRR remained in the lipid and aqueous fractions. Residues in the shell amounted 17.7 mg/kg, mostly as tebuconazole (58% TRR).

[Phenyl-UL-^{14}C]tebuconazole was applied once to grapes at 0.28 kg ai/ha and samples taken at 0 to 28 days PHI. TRR declined from 7.86 mg/kg at 3 days to 2.1 mg/kg at 28 days PHI, and the majority of the recovered residue (> 90% TRR) was identified as tebuconazole at any sampling time. There was evidence of small amounts of cellulose conjugation, but no metabolites were detected.

In summary, metabolism studies conducted in wheat, peanut and grapes have shown that tebuconazole was the main compound found in most samples. The main metabolite in wheat grain and peanut nut is triazole alanine. Hydroxylation of the tertiary butyl moiety of tebuconazole and conjugation also occurred. The compound was able to translocate from the treated wheat seeds to the forage and mature plant, and from foliar application to peanut plants to the peanut kernel. Although metabolism studies were not conducted in vegetables, metabolism studies showing that tebuconazole

is the main residue in cereal and peanut forage support the conclusion that the same occurs in leafy vegetables.

Environmental fate in soil

[Phenyl-UL-^{14}C]tebuconazole showed a half-life longer than 1 year in sandy loam soil treated at 10 mg/kg (13 kg ai/ha), when about 30% of the radioactivity was found bound to the organic components of the soil. In another study, [phenyl-UL-^{14}C]tebuconazole and [triazole-UL-^{14}C]tebuconazole were shown to be more stable in silt soil (Höfchen) (40% of the applied radioactivity as unchanged parent after 433 days) compared with silt loam (Nisse, manure-treated) (60%). 1,2,4-Triazole was found at higher levels in the silt soil (3.8% of the applied radioactivity). Other possible metabolites found in both soils are a mixture of tebuconazole-5-keto (or its tautomer tebuconazole-5-enol) and tebuconazole-4-hydroxy.

Soil dissipation studies with tebuconazole were carried out under field conditions in Europe (6 trials, 1989, 1997 and 2001) and North America (20 trials, 1988 to 1999) at various application rates and soil types. DT_{50} ranged from 8 to 912 days, and in most cases was over 100 days.

Thirteen long-term field studies (3 to 6 years) were conducted in various locations in Europe between 1991 to 1997 plus one in Canada (2003). In all cases, tebuconazole was shown to be stable in soil, but there is no indication of accumulation. In two trials conducted in Germany, residues in the upper 10 cm soil layer decreased from 0.16 mg/kg in the first and second year to 0.12 mg/kg in the third year. In bare soil plots, residues peaked after each application, followed by an initial rapid decline reaching a plateau, where additional decline was significantly slower.

Rotational crops

The metabolism of tebuconazole was investigated in rotational crops under confined conditions in kale, red beet, and spring wheat. [Triazole-3,5-^{14}C]tebuconazole or [phenyl-UL-^{14}C]tebuconazole were applied to the target crop (wheat) at a rate of 0.50 or 0.56 kg ai/ha at the boot stage of growth, the wheat harvested, the soil re-treated at the same rate, and after ageing for 29/30 days, the first set of rotational crops were planted (immediate planting), followed by an intermediate (122/135 days after treatment, DAT) and a final planting (273 days DAT). In soil, radioactivity was mostly due to tebuconazole at day 29/30 DAT (minimum of 83.2%); at 122 DAT, it corresponded to 31.9% TRR. At intermediate and final planting, most of the radioactivity was found in soil as bound residues (52.9 to 88% TRR). There was a significant uptake of ^{14}C-activity by the plants from the treated soil. Residues in wheat from the [triazole-3,5-^{14}C]tebuconazole treatment were mostly concentrated at in crops from the intermediate planting, mainly on wheat grain (35.4 mg/kg; 64.8% TRR of wheat plant at harvest) and from 0.8 to 2.7 mg/kg in kale, beet tops and roots. Wheat grain from the final planting period had 7.6 mg/kg. The major metabolites detected in the crops were triazole alanine (> 50% TRR in wheat grain, beet root and kale at 29 to 273 days after planting), triazole lactic acid (mainly in wheat straw and beet top; 20.5 to 52% TRR), and triazole acetic acid (wheat grain and straw, 16.2 to 42% TRR). In general, residues from the [phenyl-UL-^{14}C] tebuconazole treatment declined during the study period, and were most concentrated in wheat straw from the initial planting (0.548 mg/kg; 78.6% TRR in wheat plant at harvest). The highest residues in wheat grain and beet roots were found in plants from the intermediate planting (0.110 and 0.049 mg/kg, respectively). Tebuconazole was extensively metabolised in both studies, with low amounts detected in wheat straw, beet and kale from the initial planting (4.3 to 15% of TRR at harvest).

In another study conducted, [phenyl-UL-^{14}C]tebuconazole was incorporated into a sandy loam topsoil layer at a rate of 2.5 kg ai/ha (10x the recommended rate), spring wheat planted after 32 and 152 days, sampled for forage after 7 - 8 weeks and harvested at maturity. Residues in soil did not change significantly during the whole experiment period (around 0.8–1.2 mg/kg equ.). Wheat grain contained < 3% TRR present in the wheat plant at harvest (0.26 and 0.075 mg/kg), and most of the residues were present in straw (6.29 and 3.9 mg/kg). In grain, only the parent compound was detected,

but at very low concentration (< 0.01 mg/kg). In wheat straw, tebuconazole was the major residue (2.27 mg/kg equ., 36% TRR) and tebuconazole-1-hydroxy and its conjugates represented 7.1% TRR. Tebuconazole accounted for over 50% TRR in wheat forage.

Four field rotational crop studies were conducted with tebuconazole in winter wheat in Germany. In three trials, tebuconazole was sprayed once onto the bare soil at 0.5 kg ai/ha and wheat was sown approximately 30 days after application as a rotation crop. In the fourth trial, the product was applied at the same rate and after harvest; the field was re-planted with winter wheat. Tebuconazole residues were only detected in the upper soil layers (0–10 cm), at levels ranging from 0.09 to 0.47 mg/kg (0 to 63 days after planting). With the exception of one sample of green material (0.14 mg/kg; 240 days after planting), residues in all other samples were below the LOQ (0.05 mg/kg).

Eleven field rotational studies were conducted in the USA in 1997/1998 with spinach, wheat, sorghum and turnip planted 30 and 120 days after treatment of the soil with seven applications (7 days interval) of EC tebuconazole at 0.25 kg ai/ha. Tebuconazole residues ranged between < 0.01 and 0.05 mg/kg in plant matrices.

In twenty field trials conducted in USA in 1997/1998, wheat was treated once with tebuconazole at 0.126 kg, the wheat was destroyed after 35 days and soya beans were planted-back into the same plots. Tebuconazole residues were only detected in one hay sample (0.04 mg/kg). Residues were < 0.01 mg/kg in soya bean seed and forage and < 0.02 mg/kg in hay.

In summary, tebuconazole was the major residues in rotational crops, being metabolised to three major metabolites, triazole alanine, triazole lactic acid and triazole acetic acid. The metabolite distribution pattern showed little variation between the planting intervals, an indication that metabolite formation is influenced by the plants more than the soil. Field studies have shown that tebuconazole was generally present at levels < 0.05 mg/kg in succeeding crops.

Analytical methods

Tebuconazole can be analysed in plant commodities using the multi-residue enforcement method DFG S19. This method involves extraction with acetone/water, partition in ethyl acetate/cyclohexane and sodium chloride, clean-up by gel permeation chromatography (GPC) and analysis by GC/MSD. LOQ is 0.02 mg/kg. Various specialized methods were used in the supervised residue trials. In the methods developed in the 1980´s and early 1990´s, the plant material is extracted with organic solvent (dichloromethane, acetonitrile, acetone/water), cleaned up with SPE (C18, silica gel, aluminium oxide, diatomaceous earth) and analysed by gas chromatography using either TID, NPD or MSD. LOQ is 0.02 or 0.05 mg/kg. In all methods, inclusion of hexane extraction step for lipid removal is required for high fat content matrices. In the more recent methods, the sample is extracted with acetonitrile:water, submitted to SPE clean up or injected directly to the LC/MS/MS for quantification. LOQ ranged from 0.01 to 0.05 mg/kg. Some methods used matrix-matched standards or internal stable labelled standards for quantification.

Two methods to analyse tebuconazole and its metabolite tebuconazole-1-hydroxy in animal commodities were reported. In the Mobay method 97468, the samples are extracted with methanol, methanol/hexane or methanol/acetonitrile, the extract partitioned in dichloromethane/water or directly hydrolysed with HCl, purified by GPC and a combination of silica and florisil column or HPLC clean up. Tebuconazole is measured directly by GC/NPD and tebuconazole-1-hydroxy is derivatised to a monosilyl ether before quantitation. GC-MSD is used for confirmation. LOQ for tebuconazole and the metabolite was 0.1 mg/kg in cattle kidney, 0.05 mg/kg in cattle liver and fat, and milk. In poultry commodities, the method was satisfactory validated for tebuconazole in muscle, liver, fat and skin at 0.05 mg/kg and in eggs at 0.01 mg/kg. In Method 101316, the matrices are extracted with methanol and acetonitrile, the extract hydrolysed overnight under acidic reflux, residues separated by GPC, hexane/acetonitrile partitioning and HPLC. Tebuconazole and the t-butyldimethylsilane derivative of the 1-hydroxy metabolite were analysed by GC/NPD, and GC-MSD used for confirmation. LOQ for

tebuconazole and the metabolite was 0.1 mg/kg in cattle and poultry tissues and eggs, and 0.05 mg/kg in milk.

Stability of residues in stored analytical samples

Tebuconazole residues showed to be stable in various crops fortified at 1.0 mg/kg under frozen storage (-10 °C to -24 °C) for at least 30 months (at least 86% of the residues remained). Residues in wheat straw and forage and peanut meat showed stability for at least 63 months of storage.

Stability studies conducted with ^{14}C tebuconazole and ^{14}C tebuconazole-1-hydroxy showed that the compounds were stable for at least 5.6 months (169 days) at -24 °C in chickens and cattle tissues (from 94 to 119% remaining) and for at least 12 months in eggs and milk. The concentration of the compounds did not show a profile of decline during the period of the studies.

The periods of sample storage in the supervised trials and the feeding studies conducted with tebuconazole are considered acceptable.

Definition of the residue

Metabolism studies conducted in goat and hens show that tebuconazole was present in all animal commodities. The main metabolite was tebuconazole-1-hydroxy, free and/or in its conjugated form, represented at over 20% TRR in liver and muscle of cattle and poultry, about 50% TRR and milk and eggs and over 90% TRR in hen kidney. Tebuconazole-carboxylic acid was present in hen liver and kidney at about 20% TRR and 1,2,4-triazole at > 10% TRR in hen muscle and eggs. 1,2,4 triazole is not as specific marker for tebuconazole use as it can be formed in plants treated with other triazole compounds. Animal feeding studies have shown that residues of tebuconazole-1-hydroxy are not found in cattle and poultry meat, milk and eggs from animals exposed to tebuconazole residues at up to 4–5 times the estimated livestock dietary burden and was only found in poultry liver (0.11–0.2 mg/kg) at 2.3 times the maximum dietary burden. The metabolite is only found at the estimated dietary burden in cattle liver and kidney (< 0.2 mg/kg), two minor commodities in trade and with a low impact in the total human diet. Tebuconazole residues do not accumulate in fat.

Residue definition for animal commodities for enforcement and risk assessment purposes:

Tebuconazole

Residues of tebuconazole are not fat soluble

Tebuconazole was the major compound found in plant commodities samples, with only two exceptions. Triazole alanine, a common triazole metabolite, was the main residue in wheat grain and peanut nut (> 50% TRR) and tebuconazole-1-hydroxy and its conjugates represented about 30% TRR in wheat straw. Triazole alanine is not as specific marker for tebuconazole use as it can be formed in plants treated with other triazole compounds. The presence of tebuconazole-1-hydroxy is only found in a feed item, not relevant for human exposure.

Residue definition for plant commodities for enforcement and risk assessment purposes:

Tebuconazole

Results of supervised trials on crops

The OECD MRL calculator was used to assist in the estimation of maximum residue levels from the selected residue data set obtained from the supervised residue trials. The Meeting reviewed the trial conditions and other relevant factors related to each dataset to arrive at a best estimate of the maximum residue level using expert judgment. When the OECD calculator suggested a different value, an explanation on the discrepancy was included in the text.

Citrus fruits

In Brazil, critical GAP for tebuconazole in citrus is 2 × 0.015 kg ai/hL, 20 days PHI. Two trials conducted with 3 applications at the GAP rate gave residues of 1.3 (2) mg/kg. These trials are considered to be at GAP as the first application is unlikely to affect residues at 20 days PHI. Ten other trials did not match GAP.

In two trials conducted in oranges in South Africa at GAP (2 × 0.02 kg ai/hL), residues at 175 days PHI were < 0.01 and 0.01 mg/kg in the fruit and < 0.01 (2) in the pulp. Two trials conducted at double rate gave residues within the same range.

Data was received for eight post-harvest trials conducted in Germany in oranges and mandarins at 0.1 kg ai/hL, however there is no GAP that match these trials.

The Meeting agreed that there were an insufficient number of trials conducted according to GAP to estimate a maximum residue level for tebuconazole in citrus or any commodity within the group.

Apples and pears

In Spain, maximum GAP rate in apple and pears is 4 × 0.019 kg ai/hL, with PHI of 14 days. In six trials conducted in apples in France, Italy and Greece matching this GAP, residues were: 0.17, 0.21, 0.27, 0.39, 0.47 and 0.50 mg/kg. In four trials conducted in pears in Italy and Portugal at the same GAP, residues were: < 0.05, 0.07, 0.28 and 0.38 mg/kg.

Residues in apples and pears conducted at the same GAP belong to the same population and can be combined as < 0.05, 0.07, 0.17, 0.21, 0.27, 0.28, 0.38, 0.39, 0.47 and 0.50 mg/kg

The Meeting estimates a maximum residue level of 1 mg/kg, a HR of 0.50 mg/kg and a STMR of 0.275 mg/kg for tebuconazole in apple and pears.

The Meeting withdraws its previous recommendation of maximum residues level of 0.5 mg/kg for tebuconazole in apples and pears.

Cherries

Tebuconazole is registered in cherry in France and Italy at maximum of 2 × 0.02 kg ai/hL and 7 days PHI. In Spain, up to 3 applications of the same rate can be used. In thirteen trials conducted in France, Italy, Spain and Portugal with 2-3 applications of the GAP rate, residues at 7 days PHI were 0.06, 0.10 (2), 0.12, 0.13, 0.17, 0.18, 0.20, 0.26, 0.29, 0.30, 0.33 and 0.40 mg/kg.

In the Czech Republic, GAP consists of 2 × 0.25 kg ai/ha with a 7 day PHI. In seven trials conducted in Germany complying with this GAP, residues were: 0.32, 0.38, 0.45, 0.46, 0.48, 0.51 and 0.74 mg/kg.

In ten trials conducted in USA according to GAP (up to 6 × 0.25 kg ai/ha, 0 days PHI), residues were 0.41, 0.61, 0.64, 0.79, 0.86 (2), 0.92, 0.97, 1.4, and 3.1 mg/kg.

Using the residue data coming from the most critical GAP (USA), the Meeting estimates a maximum residue level of 4 mg/kg, a HR of 3.1 mg/kg and a STMR of 0.86 mg/kg for tebuconazole in cherries.

The Meeting withdraws its previous recommendation of maximum residues level of 5 mg/kg for tebuconazole in cherry.

Apricot, peach and nectarines

In three trials conducted in peaches in Brazil according to GAP (3 × 0.2 kg ai/ha and 7 days PHI), residues in whole fruit were 0.01, 0.02 and < 0.1 mg/kg.

Tebuconazole is registered in Italy and Spain in apricot, peach and nectarine at a maximum of 2 × 0.28 kg ai/ha and 7 days PHI. In nine trials conducted in peaches in Italy, France, Greece and Spain matching this GAP, residues were 0.09, 0.11, 0.21, 0.22 and 0.35 mg/kg in whole fruit and 0.06, 0.10, 0.11, 0.13, 0.17, 0.19, 0.23 (2) and 0.37 mg/kg in peach without stone. In the five trials, the residue ratio in whole fruit/fruit without stone was calculated (0.91, 0.94, 0.96, 0.9 and 1; mean of 0.94). When the mean ratio was applied to residues in fruit without stone, the residue population in whole fruit is 0.06, 0.09, 0.11, 0.12, 0.16, 0.18, 0.21, 0.22 and 0.35 mg/kg

In two trials conducted in nectarines in Italy according to GAP, residues were 0.06 and 0.14 mg/kg in fruit without stone and 0.05 and 0.12 (by applying a ratio of 0.83 to 0.14 mg/kg) mg/kg in whole fruit. In two trials conducted in apricots in Italy according to GAP, residues at 7 days PHI were 0.30 and 0.32 mg/kg in fruit without stone and 0.27 (by applying a ratio of 0.9 to 0.30 mg/kg) and 0.29 mg/kg in whole fruit.

In seven trials conducted in peaches in the USA according to GAP (0.25 kg ai/ha, 0 day PHI), residues in fruit without stone were 0.20, 0.21, 0.44, 0.46, 0.66, 0.97 and 1.0 mg/kg. By applying the whole fruit/fruit without stone ratio estimated previously for peaches (0.94), the estimated residues in whole fruit were 0.19, 0.20, 0.41, 0.43, 0.62, 0.91 and 0.94 mg/kg.

Based on the most critical GAP and highest residue population (USA), the Meeting estimated a maximum residue level of 2 mg/kg, a HR of 1.0 mg/kg and a STMR of 0.46 mg/kg for tebuconazole in apricot, peaches and nectarine.

The Meeting withdraws its previous recommendation of maximum residues level of 1 mg/kg for tebuconazole in peaches.

Plums

GAP for tebuconazole in plums is 3 × 0.013 kg ai/hL in the Netherlands and 3 × 0.019 kg ai/hL in Spain, with a 7 day PHI.

A total of 22 trials were conducted with tebuconazole on plums in Europe. In trials conducted in Germany matching the GAP of the Netherlands, residues in fruit were 0.06, 0.08 and 0.12 mg/kg. Trials conducted in France, Italy and Spain matching Spanish GAP were: 0.03 (3), < 0.05 (4), 0.05, 0.07, 0.07, 0.08, 0.10 (2), 0.11, 0.12, 0.24, 0.28, 0.38 and 0.40 mg/kg.

Nine trials were conducted in plums in USA at the maximum GAP rate (6 × 0.25 kg ai/ha; 0 day PHI), giving residues at in fruit of 0.02, 0.03 (2), 0.06, 0.08, 0.12, 0.13, 0.37 and 0.47 mg/kg.

Based on the most critical GAP and highest residue population (USA), the Meeting estimated a maximum residue level of 1 mg/kg, a HR of 0.47 mg/kg and a STMR of 0.08 mg/kg for tebuconazole in plums (including prunes).

The Meeting withdraws its previous recommendation of maximum residues level of 0.2 mg/kg for tebuconazole in plums (including prunes).

Elderberrries

Six trials were conducted in Austria according to the GAP rate of 3 × 0.038 kg ai/hL. Residues within the 24 days PHI were: 0.26, 0.30, 0.39, 0.70 mg/kg. In two trials, samples were harvested 14 days after the last application.

The Meeting estimated a maximum residue level of 1.5 mg/kg, a HR of 0.70 mg/kg and a STMR of 0.345 mg/kg for tebuconazole in elderberries.

The Meeting withdraws its previous recommendation of maximum residues level of 2 mg/kg for tebuconazole in elderberries

Grapes

In Brazil, the critical GAP for tebuconazole in grapes is for a maximum application rate of 0.025 kg ai/hL, maximum number of applications unspecified and a 14 day PHI. Five trials were conducted in the country with 4-6 applications of the GAP rate, with residues of 0.30 (2), 0.52, 0.60 and 0.63 mg/kg. Four trials did not match the GAP.

In France, tebuconazole can be used up to 3 times at 0.1 kg ai/ha with a PHI of 14 days. In two trials conducted in France and Germany matching this GAP, residues were 0.20 and 0.51 mg/kg.

In Italy, the GAP is 3 × 0.1 kg ai/ha with a PHI of 14 days. In five trials conducted in Italy, Portugal and Spain matching this GAP, residues were 0.03, 0.04 (2), < 0.1 and 0.14 mg/kg.

In Portugal, the GAP is 3 × 0.1 kg ai/ha with a PHI of 7 days. In eight trials conducted in Italy, Portugal and Spain matching this GAP, residues were: < 0.02, 0.08, 0.09, 0.11, 0.13, 0.14, 0.38 and 0.41 mg/kg.

Seventeen trials were conducted in the USA according to GAP (8 × 0.126 kg ai/ha). Residues at 14 days PHI were 0.09, 0.10, 0.20, 0.27, 0.33, 0.43, 0.56, 0.67, 0.72, 0.78, 0.94, 0.99, 1.0, 1.5 (2), 1.8 and 4.6 mg/kg.

Based on the most critical GAP and highest residue population (USA), the Meeting estimated a maximum residue level of 6 mg/kg, a HR of 4.6 mg/kg and a STMR of 0.72 mg/kg for tebuconazole in grapes.

The Meeting withdraws its previous recommendation of maximum residues level of 2 mg/kg for tebuconazole in grapes.

Olives

In six trials conducted with tebuconazole in olives in Greece, Italy, Spain and Portugal matching Spanish GAP (one application at 0.015 kg ai/hL before flowering), residues were: < 0.01 (2) and < 0.05 (4) mg/kg. As the application is done before flowering, no residues are expected in the olive fruit.

The Meeting estimated a maximum residue level of 0.05* mg/kg and a STMR of 0 mg/kg for tebuconazole in olives.

Bananas

Tebuconazole is registered to be used in bananas in Australia at up to 6 × 0.1 kg ai/ha with a 1 day PHI. Three trials were conducted in the country according to GAP, giving residues of 0.04, 0.16 and 0.19 mg/kg in whole fruit and 0.03, 0.10 and 0.14 mg/kg in pulp. In three trials conducted with bagged banana, residues in whole fruit and in the pulp were: < 0.01, 0.01 and < 0.02. Six other trials conducted at double rate gave residues within the same range (maximum of 0.16 mg/kg).

Thirteen trials were conducted in Brazil. In one trial conducted according to GAP (5 × 0.1 kg ai/ha, 5 days PHI), residues in the fruit were 0.02 mg/kg. Twelve trials did not match GAP.

Tebuconazole is registered in Mexico and the USA at a rate of 0.1 kg ai/ha with a 0 day PHI. In the USA, the maximum number of application is five. In three trials conducted in Puerto Rico and in four trials conducted in the USA (Hawaii) according to the US GAP rate, residues at 0 day PHI were: < 0.01 (6) and 0.03 mg/kg in fruit and < 0.01 (4) mg/kg in the pulp.

As the number of trials conducted at the most critical GAP giving rise to the highest residues (Australia) was not considered sufficient to make an estimation, the Meeting used the data from trials conducted in the USA.

The Meeting estimated a maximum residue level of 0.05 mg/kg, a HR of 0.03 mg/kg and a STMR of 0.01 mg/kg for tebuconazole in bananas.

The Meeting confirms its previous recommendation of maximum residues level of 0.05 mg/kg for tebuconazole in bananas.

Mango

A total of 18 trials were conducted with tebuconazole in mangoes in Brazil, where the critical GAP is 3 × 0.02 kg ai/hL with a 20 days PHI. In five trials matching GAP, residues in the fruit were 0.02 (2) and < 0.05 (3) mg/kg. The trials conducted at double rate or 4–6 applications gave residues at 20 days PHI from < 0.05 to < 0.1 mg/kg.

The Meeting estimated a maximum residue level of 0.05 mg/kg, a HR of 0.05 mg/kg and a STMR of 0.05 mg/kg for tebuconazole in mango.

The Meeting withdraws its previous recommendation of maximum residues level of 0.1 mg/kg for tebuconazole in mango.

Papaya

Tebuconazole is registered for papaya in Australia (6 × 0.125 kg/ha, 3 days PHI). One trial conducted in at the country at this GAP gave residues of 0.07 mg/kg; one trial at double rate gave residues < 0.01 mg/kg.

In six trials conducted in Brazil according to GAP (up to 6 × 0.2 kg ai/ha, 7 days PHI), residues in the fruit were: 0.06, 0.15, 0.17, 0.19, 0.32 and 1.2 mg/kg. Six trials were conducted at double rate.

Based on the trials conducted in Brazil, the Meeting estimated a maximum residue level of 2 mg/kg, a HR of 1.2 mg/kg and a STMR of 0.18 mg/kg for tebuconazole in papaya.

The Meeting confirms its previous recommendation of maximum residues level of 2 mg/kg for tebuconazole in papaya.

Passion fruit

Tebuconazole is registered to be used in passion fruit in Brazil at a maximum rate of 4 × 0.024 kg ai/hL and 7 days PHI. In five trials conducted in the country according to GAP, residues in the fruit were 0.02 (2) and < 0.1 (3) mg/kg. Three trials conducted at double rate gave residues < 0.1 mg/kg.

The Meeting estimated a maximum residue level of 0.1 mg/kg, a HR of 0.1 mg/kg and a STMR of 0.1 mg/kg for tebuconazole in passion fruit.

Garlic

In Brazil, the critical GAP rate for tebuconazole in garlic is 4 × 0.25 kg ai/ha; PHI is 14 days. Three trials according to GAP gave residues in the bulb of 0.02 (2) and < 0.05, mg/kg. Three trials conducted at double rate gave residues up to 0.04 mg/kg.

In five trials conducted in France according to GAP (2 × 0.25 kg ai/ha, 21 days PHI), residues were: < 0.02 (2), 0.02, 0.03 and 0.06 mg/kg.

Based on the highest residue population (France), the Meeting estimated a maximum residue level of 0.1 mg/kg, a HR of 0.06 mg/kg and a STMR of 0.02 mg/kg for tebuconazole in garlic.

The Meeting confirms its previous recommendation of maximum residues level of 0.1 mg/kg for tebuconazole in garlic.

Leek

Tebuconazole is registered in leek in Northern Europe, with a critical GAP in the Netherlands (3 × 0.30 kg ai/ha, 14 days PHI). In 12 field trials conducted in Belgium, France and Germany according to this GAP, residues were: 0.03, 0.14, 0.15 (2), 0.19 (2), 0.20, 0.22, 0.24, 0.28, 0.31 and 0.44 mg/kg.

The Meeting estimated a maximum residue level of 0.7 mg/kg, a HR of 0.44 mg/kg and a STMR of 0.195 mg/kg for tebuconazole in leek.

The Meeting withdraw its previous recommendation of maximum residues level of 1 mg/kg for tebuconazole in leek.

Onion, bulb

Twelve trials were conducted with onions in Brazil, where the critical GAP is 4 × 0.25 kg ai/ha and 14 days PHI. In six trials conducted according to GAP, residues in bulb were: < 0.02 (3), 0.02, 0.03 and 0.06 mg/kg. Six other trials conducted at higher rate gave residues up to 0.10 mg/kg.

Tebuconazole is registered in Germany and Austria at 2 × 0.25 kg ai/ha and 21 days PHI. Seventeen trials were conducted in Germany, France, Belgium, the Netherlands and the UK according to German/Austrian GAP, giving residues of < 0.01 (7), 0.01, 0.02, 0.03 and < 0.05 (7) mg/kg.

GAP in Spain is 1 application at 0.50 kg ai/ha after seeding. Seven trials conducted in Spain, Greece and Portugal did not match this GAP.

Based on the most critical GAP and the highest residue population (Brazil), the Meeting estimates a maximum residue level of 0.1 mg/kg, a HR of 0.06 mg/kg and a STMR of 0.02 mg/kg for tebuconazole in onion, bulb.

The Meeting confirms its previous recommendation of maximum residues level of 0.1 mg/kg for tebuconazole in onion, bulb.

Broccoli

Tebuconazole is registered in Germany in broccoli at 2 × 0.25 kg ai/ha with a 21 day PHI. Six trials conducted in France, Germany and the Netherlands according to this GAP gave residues of < 0.01 (3), < 0.02 (2) and 0.11 mg/kg. Nine trials conducted in Greece, Italy and Spain did not match any GAP from Southern Europe.

The Meeting estimated a maximum residue level of 0.2 mg/kg, a HR of 0.11 mg/kg and a STMR of 0.015 mg/kg for tebuconazole in broccoli.

Brussels sprout

Tebuconazole is registered in northern Europe, with the critical GAP from the Netherlands, with a maximum GAP of 3 × 0.30 kg ai/ha and 21 days PHI. In Germany, GAP is 3 × 0.25 kg ai/ha with a 21 day PHI. In four trials conducted in France, Germany, Netherlands and the UK, matching the GAP of the Netherlands, residues were: < 0.05 (2), 0.07 and 0.19 mg/kg. In 12 trials conducted in France, Germany and the UK, according to German GAP, residues were: < 0.02, 0.02, 0.05, 0.06, 0.07, 0.09, 0.10, 0.11, 0.12 (2), 0.15 and 0.17 mg/kg.

Based on the largest residue population, the Meeting estimated a maximum residue level of 0.3 mg/kg, a HR of 0.19 mg/kg and a STMR of 0.095 mg/kg for tebuconazole in Brussels sprout.

Cabbages, head

The critical GAP for tebuconazole in head cabbage in Northern Europe is 3 × 0.256 kg ai/ha, with a 21 day PHI (the Netherlands). In ten trials conducted in France, Germany and the UK matching this GAP residues were: < 0.05 (6), 0.32 (2), 0.37 and 0.56 mg/kg. Three other trials were not at GAP.

The Meeting estimated a maximum residue level of 1 mg/kg, a HR of 0.56 mg/kg and a STMR of 0.05 mg/kg for tebuconazole in head cabbage.

The Meeting withdraw its previous recommendation of maximum residues level of 1 mg/kg for tebuconazole in brassica (Cole or Cabbage) vegetables; head cabbage, flowered brassicas.

Cauliflower

Tebuconazole is registered for use in cauliflower in France and the Netherlands at a maximum GAP of 3 × 0.25-0.26 kg ai/ha, PHI is 21 days. In 21 trials conducted according to GAP in France, Germany, the Netherlands and the UK, residues in cauliflower head were: < 0.01 (6), < 0.02 (2) and < 0.05 (13) mg/kg. Three trials conducted in Italy and Spain did not match GAP.

The Meeting estimated a maximum residue level of 0.05* mg/kg, a HR of 0.05 mg/kg and a STMR of 0.05 mg/kg for tebuconazole in cauliflower

Cucumber

Tebuconazole is registered in Brazil in cucumber at a maximum of 4 × 0.2 kg ai/ha and a 5 day PHI. Three trials were conducted in the country according to GAP, giving residues of < 0.01 (2) and 0.06 mg/kg. Three other trials did not match GAP.

In Italy, the compound is registered in cucumber at a maximum rate of 4 × 0.125 kg ai/ha and a 3 day PHI. Seven trials conducted in cucumber in Italy, Greece and Spain according to this GAP gave residues of < 0.02, 0.03, 0.04, < 0.05 (2), 0.08 and 0.09 mg/kg. Six trials conducted in Spain and Greece were not at GAP. Four trials were conducted in Germany, Belgium and the Netherlands (no GAP).

Using the more extensive European data, the Meeting estimated a maximum residue level of 0.15 mg/kg, a HR of 0.09 mg/kg and a STMR of 0.05 mg/kg for tebuconazole in cucumber.

The Meeting withdraws its previous recommendation of maximum residue level of 0.2 mg/kg for tebuconazole in cucumber.

Squash, summer

In Italy, the compound is registered in zucchini at a maximum rate of 4 × 0.125 kg ai/ha and a 3 day PHI. Five trials conducted in zucchini in Italy according to GAP gave residues of < 0.05 (3), 0.08 and 0.10 mg/kg.

The Meeting estimated a maximum residue level of 0.2 mg/kg, a HR of 0.10 mg/kg and a STMR of 0.05 mg/kg for tebuconazole in squash, summer.

The Meeting withdraws its previous recommendation of maximum residues level of 0.02 mg/kg for tebuconazole in squash, summer.

Melons

The critical GAP for tebuconazole in melons in Brazil is 0.25 kg ai/ha (number of applications not specified) and a 14 day PHI. Seven trials were conducted in Brazil according to GAP, giving residues in the fruit of < 0.01, 0.03, < 0.05 (4) and 0.10 mg/kg. When applying the ratio pulp/whole fruit of 0.36 (see below) to this data, estimated residues in the pulp were: < 0.01, 0.02, < 0.02 and 0.036 mg/kg. Seven trials were not according to GAP.

In Italy, tebuconazole is registered to be used at a maximum of 4 × 0.125 kg ai/ha, with a 7 day PHI. In eight field trials conducted in France and Italy according to Italian GAP, residues in the fruit were: 0.03 (2), 0.04 (2), 0.05, 0.07 (2) and 0.09 mg/kg. In five trials residues in the pulp were: < 0.01 (2) and < 0.02 (3) mg/kg. The mean ratio of residues in pulp/fruit was < 0.36 (n = 4). In four

greenhouse trials conducted in Italy and Spain at the same GAP, residues in fruit were: < 0.02, 0.03, 0.05 and 0.06 mg/kg. When applying the ratio of 0.36 to this data, estimated residues in the pulp were: 0.007, 0.01, 0.02 and 0.02 mg/kg.

Trials conducted in Italy and France gave a higher residue population (all detectable residues) and were used for the estimations. The combined residues of tebuconazole were: < 0.02, 0.03 (2), 0.04 (2), 0.05 (3), 0.06, 0.07 (2) and 0.09 mg/kg in whole fruit and 0.007, < 0.01 (2), < 0.02 (3), 0.01, and 0.02 (2) mg/kg in the pulp

The Meeting estimates a maximum residue level of 0.15 mg/kg, a HR of 0.02 mg/kg (in the pulp) and a STMR of 0.02 mg/kg (in the pulp) for tebuconazole in melons, except watermelon.

The Meeting withdraw its previous recommendation of maximum residues level of 0.2 mg/kg for tebuconazole in melons, except watermelon.

Watermelon

The maximum rate for tebuconazole in watermelon in Brazil is 4 × 0.20 kg ai/ha with 14 days PHI. In two trials conducted according to GAP, residues in fruit were: < 0.01 and 0.01mg/kg. Two trials were conducted at double rate.

In Italy, the compound can be applied up to 4 × 0.125 kg ai/ha and 7 days PHI. In three trials conducted according to Italian GAP, residues in fruit were: < 0.02, 0.03 and 0.04 mg/kg. Residues in pulp were: < 0.02 (3) mg/kg. One trial conducted at a lower rate gave residues of 0.05 mg/kg.

The Meeting agree that three trials conducted at the same GAP were not sufficient to estimate a maximum residue level for watermelon.

The Meeting withdraws its previous recommendation of maximum residues level of 0.1 mg/kg for tebuconazole in watermelon.

Eggplant

Tebuconazole is registered in Brazil in eggplant (aubergine) at a maximum rate of 4 × 0.2 kg ai/ha and 7 days PHI. In six trials conducted in that country according to GAP, residues were 0.02, 0.03, 0.04 (2) and < 0.10 (2) mg/kg. Two other trials did not match GAP.

The Meeting estimated a maximum residue level of 0.1 mg/kg, a HR of 0.10 mg/kg and a STMR of 0.04 mg/kg for tebuconazole in eggplant.

Peppers, sweet

Tebuconazole is registered in Brazil at a maximum rate of 4 × 0.2 kg ai/ha and 7 days PHI. In three field trials conducted in that country according to GAP, residues were: < 0.10 (3) mg/kg. Three trials were conducted at double rate.

In Italy, the compound can be applied at a maximum of 4 × 0.0125 kg ai/hL and 3 days PHI. Twelve indoor trials conducted in Italy, Germany, the Netherlands, France, and Spain according to this GAP gave residues of 0.06 (2), 0.13, 0.15, 0.16, 0.20, 0.23, 0.25, 0.27, 0.33 (2) and 0.40 mg/kg.

In Spain, the maximum GAP is 3 × 0.025 kg ai/hL and 7 days PHI. Eight indoor trials conducted in the Netherlands, Germany and Spain according to this GAP gave residues of 0.10 (2), 0.15 (2), 0.24, 0.30, 0.35 and 0.62 mg/kg.

Based on the most critical GAP (Spain) and highest residue population, the Meeting estimated a maximum residue level of 1 mg/kg, an HR of 0.62 mg/kg and a STMR of 0.185 mg/kg for tebuconazole in sweet peppers.

The Meeting withdraws its previous recommendation of maximum residues level of 0.5 mg/kg for tebuconazole in sweet peppers.

By applying a concentration factor of 10, the Meeting also estimates a maximum residue level of 10 mg/kg, a HR of 6.2 mg/kg and a STMR of 1.85 mg/kg for tebuconazole in peppers, chili (dry).

The Meeting withdraws its previous recommendation of maximum residues level of 5 mg/kg for tebuconazole in peppers, chili (dry).

Sweet corn

Tebuconazole is registered in maize Brazil at a maximum rate of 3 × 0.20 kg ai/ha and 15 days PHI. In three trials conducted in Brazil with 4 applications, residues were: < 0.1 mg/kg.

Tebuconazole is registered in USA in sweet corn at a total maximum application rate of 0.756 kg ai/ha per season with a 7 day PHI. In twelve trials conducted in that country according to GAP, residues were: < 0.01 (2), 0.03, 0.04 (2), 0.05, 0.07, 0.08 (2), 0.10, 0.32 and 0.36 mg/kg.

Based on the highest residue population (USA), the Meeting estimated a maximum residue level of 0.6 mg/kg, an HR of 0.36 and a STMR of 0.06 mg/kg for tebuconazole in sweet corn (corn-on-the-cob).

The Meeting withdraws its previous recommendation of maximum residues level of 0.1 mg/kg for tebuconazole in sweet corn (corn-on-the-cob).

Tomato

Tebuconazole is registered in tomato in Brazil at 4 × 0.25 kg ai/ha with a 7 day PHI. Six trials were conducted in that country complying with this GAP, residues found were: < 0.05 (2), 0.05, 0.06, 0.10 and 0.11 mg/kg. Five trials did not match GAP.

In Spain the GAP is 3 × 0.025 kg ai/hL, 3 days PHI. Seven indoor trials conducted in Germany and Spain according to this GAP gave residues of 0.03, 0.13, 0.15, 0.19, 0.23 and 0.46 mg/kg. In two trials conducted at the same GAP in the field, residues were 0.09 and 0.15 mg/kg. Residues conducted in Europe at the Spanish GAP were: 0.03, 0.09, 0.13, 0.15 (2), 0.19, 0.23 and 0.46 mg/kg.

Based on the trials giving the highest residue levels (Europe), the Meeting estimated a maximum residue level of 0.7 mg/kg, a HR of 0.46 and a STMR of 0.15 mg/kg for tebuconazole in tomato.

The Meeting withdraws its previous maximum residue level recommendation of 0.5 mg/kg for tebuconazole in tomato.

Beans, dry

Tebuconazole is registered in Brazil in beans at up to 3 × 0.20 kg ai/ha with a 14 days PHI. In ten trials conducted in that country at this GAP, residues were: < 0.05 (5), 0.05 (2), < 0.10, 0.10 and 0.16 mg/kg. Eight trials conducted at lower or higher GAP gave residues in the same range.

In the USA, the compound can be used at a maximum of 3 × 0.189 kg ai/ha with a 14 days PHI. None of the 14 trials conducted in that country were at GAP.

Based on the Brazilian results, the Meeting estimated a maximum residue level of 0.3 mg/kg and a STMR of 0.05 mg/kg for tebuconazole in beans, dry.

Soya bean, dry

In Brazil, tebuconazole can be applied up to 3 × 0.15 kg ai/ha with a 30 days PHI. In eight trials conducted in that country within GAP, residues were: 0.02, 0.03 (3), < 0.05 (3), < 0.10 mg/kg. Six trials were conducted at double rate.

In the USA, GAP is up to 3 × 0.126 kg ai/ha and 21 days PHI. In 20 trials conducted in that country according to GAP, residues were: < 0.01 (3), 0.01 (7), 0.02 (4), 0.03 (2), 0.04 (2) and 0.05 (2) mg/kg.

Based on the largest residue data population (USA), the Meeting estimated a maximum residue level of 0.15 mg/kg, a highest residue of 0.05mg/kg and a STMR of 0.02 mg/kg for tebuconazole in soya bean, dry.

The Meeting withdraws its previous recommendation of maximum residues level of 0.1 mg/kg for tebuconazole in soya bean, dry.

Carrot

The GAP for tebuconazole in carrots in Brazil is up to 4 × 0.20 kg ai/ha and a 14 day PHI. In five trials conducted according to GAP, residues were: < 0.1 (3), 0.17 and 0.19 mg/kg. Seven other trials conducted at higher GAP gave residues up to 0.27 mg/kg.

In the Netherlands and Germany, tebuconazole can be used up to 3 × 0.258 kg ai/ha with a PHI of 21 days. In eight trials conducted in France, Germany and the UK according to this GAP, residues were 0.09, 0.10, 0.11 (2), 0.13, 0.18, 0.19 and 0.22 mg/kg.

Based on the most critical GAP and highest residue population from Europe, the Meeting estimated a maximum residue level of 0.4 mg/kg, a HR of 0.22 mg/kg and a STMR of 0.11 mg/kg for tebuconazole in carrot. The Meeting withdraws its previous of maximum residue level recommendation of 0.5 mg/kg for tebuconazole in carrots.

Artichoke, globe

The use of tebuconazole in/on artichoke is registered in Italy, with up to 4 applications at 0.12 kg ai/ha (0.0125 kg ai/hL) and 7 days PHI. Six trials were performed in Italy and Spain according to Italian GAP, with residues of < 0.05, 0.12 (2), 0.17, 0.29 and 0.32 mg/kg.

In Peru, critical GAP is 0.10 kg ai/ha with a 3 day PHI (number of applications not specified). Two trials conducted in the country did not match GAP. One trial was conducted in Mexico, where there is no GAP.

The Meeting estimated a maximum residue level of 0.6 mg/kg, a HR of 0.32 mg/kg and a STMR of 0.145 mg/kg for tebuconazole in artichoke, globe.

The Meeting withdraws its previous recommendation of 0.5 mg/kg for tebuconazole in globe artichoke.

Barley

Tebuconazole is registered in Germany at 2 × 0.31 kg ai/ha (PHI of 35 days). In 18 trials conducted in Germany, France and the UK according to this GAP, residues were: < 0.05 (11), 0.06 (2), 0.08 (2), 0.10, 0.13 and 0.21 mg/kg.

In France, GAP is 2 × 0.25 kg ai/ha and 28 days PHI. In 14 trials conducted in France, Germany, Greece, Italy, Portugal and Spain according to this GAP, residues were: < 0.05 (5), 0.07 (2), 0.10, 0.38, 0.65, 0.85, 0.93, 0.96 and 1.1 mg/kg

Based on the trials with the most critical GAP (France) and highest residue population, the Meeting estimated a maximum residue level of 2 mg/kg and a STMR of 0.085 mg/kg for tebuconazole in barley. The Meeting agrees to expand these estimations to oats

The Meeting confirms its previous recommendation for tebuconazole in barley, and withdraw its previous recommendation of 0.05* mg/kg in oats.

Maize

Tebuconazole is registered in maize Brazil at a maximum of 3 × 0.20 kg ai/ha and a 15 day PHI. In four trials conducted in Brazil according to GAP, residues were: 0.01, 0.02 and < 0.1 (2) mg/kg Three trials conducted at double rate gave similar results.

In USA, the rate is 0.189 kg ai/ha (maximum 0.757 kg ai/ha per season) with a 36 day PHI. In three trials conducted in USA according to GAP, residues were < 0.01 (3) mg/kg. Fourteen trials conducted at higher PHIs gave the same results.

The Meeting decided that four trials according to GAP were insufficient to estimate a maximum residue level for tebuconazole in maize and withdraw its previous recommendation of 0.1 mg/kg.

Rice

Tebuconazole is registered in rice in Brazil at a maximum of 2 × 0.15 kg ai/ha, and a 35 day PHI. Four trials were conducted in Brazil according to GAP, residues found were: 0.01(2), 0.02 and 0.03 mg/kg. Two trials conducted at double rate.

In Spain, GAP is 0.15 kg ai/ha (number of applications not specified) and a 35 day PHI. In eight trials conducted in Italy and Spain according to this GAP, residues in rice (with husk) were 0.11, 0.12, 0.24, 0.26, 0.29, 0.33, 0.53 and 0.97 mg/kg.

Based on trials with the highest residue population (Europe), the Meeting estimated a maximum residue level of 1.5 mg/kg and a STMR of 0.275 mg/kg for tebuconazole in rice.

The Meeting withdraws its previous recommendation of 2 mg/kg for tebuconazole in rice.

Wheat and Rye

The GAP rate for tebuconazole in wheat in Brazil is 0.187 kg ai/ha (number of applications not specified); PHI is 35 days. In eight trials conducted in that country according to GAP, residues were: 0.02 (4), 0.03 and < 0.05 (3) mg/kg

In Canada and the USA, the GAP rate for wheat a single application at 0.126 kg ai/ha, with a PHI of 36 and 30 days, respectively. In 21 trials conducted in Canada and four in USA according to GAP, residues were: < 0.01 (2), 0.01 (4), < 0.02 (8), 0.02 (4), 0.04, < 0.05 (4), 0.06 and 0.08 mg/kg.

In France, the GAP rate for wheat and rye is 2 × 0.25 kg ai/ha, with a PHI of 28 days. In ten trials conducted in France, Greece, Italy and Spain according to this GAP, residues were 0.02 mg/kg in triticale and < 0.01, 0.01 (2) and < 0.05 (4), 0.06 and 0.09 mg/kg in wheat.

In Ireland and the UK, the GAP rate is 2 × 0.25 kg ai/ha and the last application should be done before the watery ripe stage (up to BBCH 71). In 27 trials conducted in Germany, France and the UK according to this GAP residues in wheat were: < 0.01 (3), 0.02 (3), 0.03 (2), < 0.05 (18) and 0.06 mg/kg. Six trials conducted in Germany and Sweden in rye gave residues of < 0.01, < 0.05 (5) mg/kg.

In Portugal, GAP for wheat is 2 × 0.25 kg ai/ha, with a PHI of 35 days. One trial conducted in Italy according to this GAP gave residues of 0.02 mg/kg.

Based on the trials with the most critical GAP (France) and highest residue population, the Meeting estimated a maximum residue level of 0.15 mg/kg and a STMR of 0.05 mg/kg for tebuconazole in wheat. The Meeting also agreed to expand these estimations to rye and triticale.

The Meeting withdraws its previous recommendation of 0.05 mg/kg for tebuconazole in wheat.

The Meeting withdraws its previous recommendation of 0.05* mg/kg for tebuconazole in rye.

Tree nuts

In Italy, tebuconazole is registered for use on walnuts and other tree nuts (not specified) at 2 × 0.226 kg ai/ha, applied until the end of flowering. Four trials were conducted in that country in walnut according to GAP, with residues of < 0.05 (4) mg/kg

In the USA, the GAP for tree nuts is up to 4 × 0.252 kg ai/ha and a 35 day PHI. In six trials conducted in almonds, according to GAP, residues were < 0.05 (6) mg/kg. In four trials conducted in pecans at the GAP rate, samples collected 12 to 25 days after the last application gave residues of < 0.05 mg/kg.

Based on the trials with the most critical GAP (USA), the Meeting estimated a maximum residue level of 0.05* mg/kg, an HR of 0 mg/kg and a STMR of 0 mg/kg for tebuconazole in tree nuts.

Cotton seed

The GAP rate for tebuconazole in cotton in Brazil is 0.15 kg ai/ha (normally, 3 applications is enough) and 21 days PHI. Seven trials were conducted in the country with 4 or 5 applications of the GAP rate, giving residues at 21 days PHI of 0.01, 0.02 (2), 0.03 and < 0.1 (3) mg/kg.

In the USA, maximum GAP rate is 0.252 kg ai/ha (maximum of 0.756 kg ai/ha/season) and a 30 day PHI. In 17 trials conducted in that country according to GAP, residues in fuzzy (undelinted) seeds were: < 0.05 (8), 0.05, 0.10 (2), 0.12, 0.22, 0.42, 0.43, 0.69 and 1.6 mg/kg.

Based on the trials with the most critical GAP (USA) and highest residue population, the Meeting estimated a maximum residue level of 2 mg/kg and a STMR of 0.05 mg/kg for tebuconazole in cotton seed.

Peanut

In Brazil, the critical GAP for tebuconazole in peanuts is 0.125 kg ai/ha (number of applications not specified) with a 30 day PHI. In seven trials conducted according to GAP, residues were 0.01, 0.02 (2), 0.03, < 0.05 (2) and < 0.1 mg/kg. Five trials conducted at a higher rate gave residues in the same range.

In the USA, the critical GAP rate is 4 × 0.23 kg ai/ha, and a PHI of 14 days. The Meeting agreed that residues from the first 3 applications are unlikely to affect the final residues at the PHI. In 12 trials conducted with 7 applications, residues at 14 days PHI were: < 0.01 (3), 0.01, < 0.02, 0.03, 0.04, < 0.05 (4) and 0.08 mg/kg

Based on the data from the most critical GAP (USA) with the highest detected residue, the Meeting estimated a maximum residue level of 0.15 mg/kg and a STMR of 0.035 mg/kg for tebuconazole in peanut kernels.

The Meeting withdraws its previous recommendation of 0.1 mg/kg for tebuconazole in peanuts.

Rape seed

In Germany, tebuconazole is registered to be applied up to 2 × 0.375 kg ai/ha with a PHI of 56 days. In twelve trials conducted in Belgium, France, Germany, the Netherlands and the UK matching this GAP, residues were: < 0.05 (2), 0.03, 0.04, 0.06, 0.09, 0.11, 0.12 (2), 0.13, 0.17, 0.19 mg/kg.

Nineteen trials conducted in Europe did not match any GAP in the region.

The Meeting estimated a maximum residue level of 0.3 mg/kg and a STMR of 0.10 mg/kg for tebuconazole in rape seed.

The Meeting withdraws its previous recommendation of 0.5 mg/kg for tebuconazole in rape seed.

Coffee beans

The critical GAP for tebuconazole in coffee in Brazil is for 3 × 0.25 kg ai/ha, with a 30 days PHI. The Meeting agreed that residues from the first two applications are unlike to affect the final residues at the GAP PHI, as the second application was done more than 100 days before harvest. In nine trials conducted in the country in which 3 or 5 applications were made at the GAP rate, residues were: < 0.01 (2), 0.02 (2), 0.06 and < 0.10 (4) mg/kg. Six trials conducted at double GAP rate gave residues in a same range.

Four trials were conducted in Guatemala (no GAP).

The Meeting estimated a maximum residue level of 0.1 mg/kg and a STMR of 0.04 mg/kg for tebuconazole in coffee beans.

The Meeting confirms its previous recommendation of 0.1 mg/kg for tebuconazole in coffee beans.

Hops, dry

In the Czech Republic, tebuconazole can be applied to hops at up to 2 × 0.56 kg ai/ha with a 21 day PHI. In eight trials conducted in Germany within this GAP, residues in cones, kiln dried were: 5.8, 6.0, 6.3, 8.3, 11, 12, 18 and 21 mg/kg.

In the USA, the GAP rate is 0.252 kg ai/ha (maximum of 1 kg ai/ha/season) and a 14 day PHI. In three trials conducted in the country according to GAP, residues were: 0.73, 1.1 and 3.2 mg/kg.

Based on the trials with the most critical GAP (the Czech Republic) and highest residue population, the Meeting estimated a maximum residue level of 40 mg/kg and a STMR of 9.65 mg/kg for tebuconazole in hops, dry

The Meeting withdraw its previous recommendation of 30 mg/kg for tebuconazole in hops.

Animal feed commodities

Feed commodities were analysed in the studies described previously for the edible commodities. Only the trials conducted according to GAP as described before were discussed here. Maximum residue levels were not estimated for forage. Highest and/or medium residues were estimated for commodities listed in the OECD feeding table for dietary burden calculation purposes.

Barley, wheat, rye and triticale straw and/or fodder

In 16 trials conducted in barley in Germany and the UK according to German GAP (2 × 0.31 kg ai/ha 35 days PHI), residues in barley straw were: 0.14, 0.45 0.50, 0.72, 0.77, 0.86, 0.88, 1.3, 1.7 (2), 2.2, 2.5, 2.8, 3.1, 3.9 and 4.3 mg/kg.

In ten trials conducted in France, Germany, Greece, Italy, Portugal and Spain according to French GAP (2 × 0.25 kg ai/ha, 42 days PHI), residues in barley straw were: 0.29, 0.80, 1.4, 3.3, 3.8, 4.9, 5.8, 7.9, 13 and 17 mg/kg

Residues of tebuconazole in wheat straw from 25 trials conducted in Canada and USA according to GAP were: < 0.10 (3), 0.11, 0.12, 0.13, 0.14, 0.20, 0.26, 0.30, 0.34, 0.35, 0.36, 0.50, 0.52, 0.58, 0.64, 0.68, 0.87, 0.94, 1.0, 1.1, 1.4 (2) and 2.1 mg/kg.

Residues of tebuconazole in wheat and rye straw from 27 trials conducted in France, Germany, Sweden and the UK according to the GAP of the UK (2 × 0.25 kg ai/ha and the last

application up to BBCH 71) were: 0.29, 0.47, 0.68, 0.86, 0.92, 0.98, 1.1, 1.3 (3), 1.4, 1.5, 1.6, 1.8, 1.9, 2.7, 3.0, 3.3, 3.6 (2), 3.9, 4.8, 5.2, 6.0, 7.1 (2), and 7.8 mg/kg.

In 12 trials conducted in Spain, Italy and France according to French GAP (2 × 0.25 kg ai/ha, 28 day PHI) residues in wheat and rye straw were: 1.1, 1.8, 2.2, 2.3 (2), 3.2, 3.4, 3.5 (2), 4.2, 5.6 and 12 mg/kg.

Residues in 25 trials conducted in Canada and the U.S. according to GAP gave residues in wheat hay of: 0.49, 0.67, 0.71, 0.78, 0.93, 0.99, 1.0 (2), 1.1 (3), 1.4, 1.6 (3), 1.8, 2.1, 2.2 (3), 2.5 (2), 2.6, 3.5 and 4.4 mg/kg.

Based on the trials with the highest residue population (barley according to French GAP), the Meeting estimated a maximum residue level of 40 mg/kg for barley straw and fodder, dry; rye straw and fodder, dry; and wheat straw and fodder, dry (residues corrected for 88% dry matter).

The Meeting estimated a median and a highest residue of 4.35 and 17 mg/kg, respectively, for tebuconazole in barley straw and fodder.

The Meeting estimated a median and highest residues, of 3.3 and 12 mg/kg, respectively for tebuconazole in wheat and rye straw and fodder.

The Meeting estimated a median and a highest residue of 1.6 and 4.4 mg/kg, respectively, for tebuconazole in wheat hay.

The Meeting withdraws its previous recommendation of 30 mg/kg for barley straw and fodder, of 10 mg/kg for wheat straw and fodder, dry and of 5 mg/kg for rye straw and fodder, dry.

Maize fodder

The residues in maize fodder from five trials conducted in USA according to GAP were: 0.20, 0.28, 0.61, 0.83, and 2.4 mg/kg.

The Meeting estimated a median and a highest residue of 0.61 and 2.4 mg/kg, respectively, for tebuconazole in maize fodder.

The Meeting also estimated a maximum residue level of 6 mg/kg for tebuconazole in maize fodder, dry (residues corrected for 83% dry matter).

Rice straw

Four rice trials conducted in Spain and Italy according to Spanish GAP, residues found in straw 33 or 35 days after the last application (grain PHI) were: 1.1 (2), 1.6, and 1.7 mg/kg.

The Meeting agreed that there were insufficient trials according to GAP to estimate a maximum residue level for tebuconazole in rice straw.

Peanut fodder/hay/vine

In 16 trials conducted in USA considered to be at GAP, residues in hay/vine were: 1.8, 3.7, 5.0, 5.1, 5.6, 6.8, 8.6, 9.1, 9.4, 11, 13, 15, 17, 18, 20 and 23 mg/kg.

The Meeting estimated a maximum residue level of 40 mg/kg, a median residue of 9.25 mg/kg and a highest residue of 23 mg/kg for tebuconazole in peanut fodder. The Meeting withdraws its previous recommendation of 30 mg/kg.

Forage

In the trials, the forage samples (described as forage, green material or rest of the plant) were harvested at different PHIs. Whenever data was available, the 7 days PHI residue (or any day later that gave a higher residue) was chosen to represent the level of residues to which animals would be

exposed. In cases where this data point was not available, the highest value from any PHI available (up to the grain PHI) would be taken, including from 0 day PHI.

Barley forage

The residues in barley forage from 37 trials conducted according to GAP rate in Europe were: 0.29, 0.35, 0.37, 0.78, 1.0, 1.2 (2), 1.4 (2), 2.0, 3.4, 3.8, 4.3 (2), 4.7, 5.2, 5.6, 5.7, 5.8, 6.0, 6.1, 6.2, 6.5, 7.2, 7.4, 8.9, 9.0, 9.2 (2), 9.6, 10 (2), 12, 14 (2) and 18 mg/kg.

The Meeting estimates a median and highest residue of 5.8 and 18 mg/kg, respectively, for tebuconazole in barley forage.

Maize forage

The residues in maize forage from 20 trials conducted according to GAP rate in USA were: 0.09, 0.10, 0.12, 0.13, 0.19, 0.22, 0.25, 0.28, 0.30, 0.37, 0.44, 0.47 (2), 0.49 (2), 0.75 (2), 0.98 and 2.9 (2) mg/kg

The Meeting estimated a median and highest residue of 0.405 and 2.9 mg/kg, respectively, for tebuconazole in maize forage.

Wheat, rye and triticale forage

Residues of tebuconazole in wheat, rye and triticale forage from 43 trials conducted in Europe according to GAP were: 0.40, 0.49, 0.92, 1.3, 1.5, 2.2 (2), 2.3, 2.4, 2.6 (3), 2.7, 2.9, 3.3, 3.4, 3.5, 3.7 (2), 3.9, 4.1, 4.3, 4.6, 4.7, 4.8, 5.1, 5.2, 5.7 (2), 5.8 (2), 5.9, 6.1, 6.2, 6.4, 6.6 (3), 6.7, 6.8, 7.8, 8.7, 9.4, 9.5 and 12 mg/kg.

Residues in 25 trials conducted in Canada and USA according to GAP in wheat forage were: 0.01, 0.02 (3), 0.07 (2), 0.10, 0.11, 0.18 (2), 0.19, 0.20 (2), 0.22, 0.28, 0.32, 0.34, 0.47, 0.53 (2), 0.61, 0.62, 0.65, 1.0 and 1.8 mg/kg

Based on the highest residue population (Europe), the Meeting estimated a median and a highest residue of 4.6 and 12 mg/kg, respectively, for tebuconazole in wheat, rye and triticale forage.

Rape forage

From 25 trials conducted in rape in Europe according to GAP residues in forage were: 2.5 (2), 2.6, 2.7, 3.1, 3.4, 3.6, 3.7, 3.8, 3.9, 4.0, 4.2 (2), 4.3, 4.6, 4.8, 4.9, 5.1, 5.2, 5.6, 5.7, 6.3, 7.3, 7.5 and 11 mg/kg.

The Meeting estimated a median and a highest residue of 4.2 and 11 mg/kg, respectively for tebuconazole in rape forage

Almond hulls

Six trials conducted in USA according to GAP gave residues in almond hulls of 1.1, 1.2, 1.4, 2.0, 3.0 and 4.1 mg/kg. The Meeting estimated a median residue of 1.7 mg/kg for tebuconazole in almond hulls.

Cotton gin trash

Six trials conducted in USA according to GAP gave residues in cotton gin trash of 0.10, 1.5, 4.1, 7.1, 12 and 13 mg/kg. The Meeting estimated a median and a highest residue of 5.6 and 13 mg/kg, respectively, for tebuconazole in cotton gin trash.

Fate of residues during processing

A hydrolysis study conducted in buffered water (pH 4 to 6, 90 to 120 °C) simulating processing did not show degradation of tebuconazole.

A variety of processing studies were conducted with crops treated with tebuconazole. Processing factors (PF) in commodities with relevance for dietary exposure assessment and for animal dietary burden calculation are shown in the table below. The estimated PFs were multiplied by the estimated STMR of the raw commodity to estimate the STMR-P for the processed commodity.

Processing factor (PF) and estimations for processed commodities.

Commodity	Mean PF (n)*	STMR-P, mg/kg	HR-P, mg/kg	Maximum residue level, mg/kg
Apple, STMR= 0.275 mg/kg, HR=0.5 mg/kg				
Apple juice	0.23 (4)	0.063		
Apple juice, concentrated	0.33 (2)	0.091		
Apple sauce	0.34 (3)	0.094		
Apple, dried	0.61 (3)	0.168	0.305	
Apple wet pomace	2.6 (2)	0.715		
Apple dried pomace	12.7 (2)	3.5		
Plum, STMR=0.08 mg/kg, HR= 0.47 mg/kg				
Prune	2.9 (2)	0.232	1.36	3
Plum sauce	1 (1)	0.08		
Plum preserve	0.67 (1)	0.054		
Peach, STMR=0.46 mg/kg				
Peach juice	0.2 (1)	0.092		
Peach jam	0.013 (1)	0.006		
Peach preserve	0.013 (1)	0.006		
Grape, STMR=0.72mg/kg; HR= 4.6 mg/kg				
Wine	0.28 (22)	0.20		
Dried grapes	1.2 (4)	0.86	5.5	7
Cabbage, head STMR=0.05 mg/kg, HR=0.56 mg/kg				
Cabbage, cooked	0.38 (4)	0.019	0.23	
Tomato, STMR=0.15 mg/kg				
Tomato juice	0.55 (3)	0.033		
Tomato preserve	0.3 (3)	0.018		
Tomato pure	0.33 (6)	0.02		
Tomato paste	3.2 (6)	0.19		
Soya beans, STMR=0.02 mg/kg				
Soya bean oil, refined	0.07 (1)	0.001		
Soya bean aspired grain fractions	276 (1)	5.52		
Soya bean, hulls	1.1 (1)	0.022		
Soya bean meal	0.2 (1)	0.004		
Barley, STMR=0.085 mg/kg				
Barley beer	0.025 (4)	0.013		
Cotton, STMR=0.05 mg/kg				
Cotton oil, refined	0.01 (1)	0.000		
Cotton meal	0.01 (1)	0.000		
Cotton hulls	0.01 (1)	0.000		
Peanut, STMR=0.035 mg/kg				
Peanut oil, refined	0.01 (1)	0.000		
Peanut meal	0.86 (1)	0.026		

Commodity	Mean PF (n)*	STMR-P, mg/kg	HR-P, mg/kg	Maximum residue level, mg/kg
Rape seed, STMR=0.10 mg/kg				
Rape seed oil, refined	1.1 (6)	0.11		
Rape seed meal	0.83 (6)	0.08		
Coffee, STMR= 0.04 mg/kg				
Coffee, roasted	2 (1)	0.08		
Coffee, instant	0.8 (1)	0.032		
Hops, STMR=9.65 mg/kg				
Hops, beer	< 0.01 (1)	0.0965		

*n is the number of processing studies

The Meeting agreed that one processing study is not sufficient to make a recommendation for coffee, roasted and withdraws its previous recommendation of 0.5 mg/kg for coffee, roasted

Residues in animal commodities

Farm animal dietary burden

The Meeting estimated the dietary burden of tebuconazole in farm animals on the basis of the diets listed in Annex 6 of the 2009 JMPR Report (OECD Feedstuffs Derived from Field Crops), the STMR, STMR-Ps, median or highest residue levels estimated at the present Meeting. Dietary burden calculations are provided in Annex 6.

		Animal dietary burden, tebuconazole, ppm of dry matter diet			
		US-Canada	EU	Australia	Japan
Beef cattle	max	2.9	26	54[a]	0.1
	mean	1.0	8.3	18.9[c]	0.1
Dairy cattle	max	19.6	24.2	54[b]	4.0
	mean	7.4	8.1	18.9[d]	0.69
Poultry - broiler	max	0.14	0.1	0.19	0.01
	mean	0.14	0.1	0.19	0.01
Poultry - layer	max	0.14	8.5[e]	0.19	0.00
	mean	0.14	3.3[f]	0.19	0.00

[a] Highest maximum beef or dairy cattle dietary burden suitable for maximum residue level estimates for mammalian tissues

[b] Highest maximum dairy cattle dietary burden suitable for maximum residue level estimates for mammalian milk

[c] Highest mean beef or dairy cattle dietary burden suitable for STMR estimates for mammalian tissues.

[d] Highest mean dairy cattle dietary burden suitable for STMR estimates for milk.

[e] Highest maximum poultry dietary burden suitable for maximum residue level estimates for poultry tissues and eggs.

[f] Highest mean poultry dietary burden suitable for STMR estimates for poultry tissues and eggs.

The tebuconazole dietary burdens for animal commodity maximum residue level and STMR estimation (residue levels in animal feeds expressed on dry weight) reached a maximum of 54 ppm for cattle and of 8.5 ppm for poultry.

Animal feeding studies

Two dairy cattle feeding studies were submitted. The animals were fed for 28 days at 25/75/250 ppm (study 1) or 30/90/300 ppm (study 2), with 3 cows per group in each dose level. In both studies, meat and fat samples were only analysed for tebuconazole at the higher dose group (250 or 300 ppm feed), but no residues were detected (< 0.05 or < 0.1 mg/kg). Mean residues of tebuconazole at 25 and

30 ppm were 0.15 and < 0.1 mg/kg, respectively, in kidney (maximum of 0.25 and < 0.1 mg/kg) and 0.06 and < 0.1mg/kg, respectively, in liver (maximum of 0.07 and < 0.1 mg/kg). Mean residues at 75 and 90 ppm were 0.05 and < 0.1 mg/kg, respectively, in kidney (maximum of 0.05 and < 0.1 mg/kg) and 0.08 and 0.17 mg/kg, respectively, in liver (maximum of 0.12 and 0.2 mg/kg). Two poultry studies were submitted, with laying hens fed at 2, 6 and 20 ppm tebuconazole for 28 days. Residues of tebuconazole were only found in liver and eggs at the highest dose in both studies (at 0.05 mg/kg).

Animal commodity maximum residue levels

The cattle feeding studies have shown that no residues of tebuconazole are expected in muscle and milk at the maximum estimated animal dietary burden (54 ppm). At 250/300 ppm, residues were < LOQ in muscle and milk.

The Meeting estimated a maximum residue level of 0.05* mg/kg, a STMR of 0 mg/kg and a HR of 0 mg/kg for tebuconazole in meat (from mammalian other than marine mammals).

The Meeting estimated a maximum residue level of 0.01* mg/kg and a STMR of 0 mg/kg for tebuconazole in milks.

The Meeting confirms its previous recommendation of 0.05* and 0.01* for tebuconazole in meat (from mammalian other than marine mammals) and milks, respectively.

Residues in kidney and liver at the expected dietary burden are shown in the Table below. Based on the highest estimated residue in cattle liver (0.15 mg/kg), the Meeting estimates a maximum residue level of 0.2 mg/kg, a HR of 0.15 mg/kg and a STMR of 0.06 mg/kg for tebuconazole in edible offal (mammalian).

The Meeting withdraw its previous recommendation of maximum residues level of 0.5 mg/kg for tebuconazole in edible offal (mammalian).

	Feeding level (ppm) for tissue residue	Residues (mg/kg)			Feeding level (ppm) for tissue residue	Residues (mg/kg)	
		Liver	Kidney			Liver	Kidney
Maximum residue level beef or dairy cattle							
Feeding study [a]	25/75	0.10/0.12	0.25*/0.05	Feeding study [a]	30/90	< 0.1/0.2	< 0.1/< 0.1
Dietary burden and residue estimate	54	0.11	-/0.036	Dietary burden and residue estimate	54	0.15	0.05
STMR beef and dairy cattle							
Feeding study [b]	25	0.06	0.15	Feeding study [b]	30	< 0.1	< 0.1
Dietary burden and residue estimate	18.9	0.04	0.11	Dietary burden and residue estimate	18.9	0.06	

[a] highest residues for tissues;

[b] mean residues for tissue; * this value was not considered as the other 2 animals had residues < 0.05 mg/kg and the levels at 75ppm were at or <LOQ.

Poultry feeding studies have shown that no residues are expected at the dietary burden of 8.5 ppm. With exception of liver, no residues were also found at 20 ppm level.

The Meeting estimated a maximum residue level of 0.05* mg/kg, a STMR of 0 mg/kg and a HR of 0 mg/kg for tebuconazole in poultry meat

The Meeting estimated a maximum residue level of 0.05* mg/kg, a STMR of 0.05 mg/kg and a HR of 0.05 mg/kg for tebuconazole in poultry edible offal.

The Meeting estimated a maximum residue level of 0.05* mg/kg and a STMR of 0 mg/kg for tebuconazole in eggs.

The Meeting confirms its previous recommendations of 0.05* mg/kg for tebuconazole in eggs, poultry edible offal and poultry meat.

DIETARY RISK ASSESSMENT

Long-term intake

The ADI for tebuconazole is 0–0.03 mg/kg bw. The International Estimated Daily Intakes (IEDI) for tebuconazole was estimated for the 13 GEMS/Food cluster diets using the STMR or STMR-P values estimated by the current Meeting. The results are shown in Annex 3. The IEDI ranged from 3 to 10% of the maximum ADI. The Meeting concluded that the long-term intake of residues of tebuconazole from uses that have been considered by the JMPR is unlikely to present a public health concern.

Short-term intake

The ARfD for tebuconazole is 0.3 mg/kg bw. The International Estimated Short Term Intake (IESTI) for tebuconazole was calculated for the plant commodities for which STMRs/STMR-P and HRs/HR-P were estimated by the current Meeting and for which consumption data were available. The results are shown in Annex 4. The maximum% ARfD was 70%, from the consumption of grapes by children 0–6 years old. The Meeting concluded that the short-term intake of residues of tebuconazole, when used in ways that have been considered by the JMPR, is unlikely to present a public health concern.

5.26 THIAMETHOXAM (245)

RESIDUE AND ANALYTICAL ASPECTS

Thiamethoxam was evaluated as a new compound in 2010. Thiamethoxam residue data for a use on passion fruit have been provided in 2011 to support an MRL on passion fruit.

The Meeting received descriptions of the thiamethoxam analytical methods used for analysis of passion fruit samples from the trials.

The analytical methods used in the supervised trials relied on LC-MS-MS and achieved LOQs of 0.01 and 0.02 mg/kg for thiamethoxam. Metabolite CGA 322704 (*N*-(2-chlorothiazol-5-ylmethyl)-*N*'-methyl-*N*''-nitroguanidine) was not analysed with these methods.

The Meeting has not received labels or information on the registered uses of thiamethoxam on passion fruit.

The Meeting received information on supervised field trials for thiamethoxam foliar use on passion fruit in Kenya. Samples were analysed for thiamethoxam, but not for metabolite CGA 322704.

Thiamethoxam was applied at 0.1 kg ai/ha in three supervised trials in 2005 and two from 2007. The residue data from the trials in 2007 were not accepted as valid because of the aberrant procedural recoveries (> 120%) of the analytical method.

The application conditions were based on the requirement of appropriate control of diseases of passion fruit, but they were not supported by label or official declaration of approved use. Therefore, the Meeting could not estimate a maximum residue level for thiamethoxam in passion fruit.

6. RECOMMENDATIONS

6.1 The Meeting agreed that it would be beneficial to explore ways to more systematically express underlying uncertainties. For this, it was recommended that one or two JMPR experts should participate in the ongoing activity within WHO/International Programme on Chemical Safety (IPCS). The group also recommended that the Joint FAO/WHO Expert Committee on Food Additives (JECFA) should consider this approach.

7. FUTURE WORK

The items listed below are tentatively scheduled to be considered by the Meeting in 2013 and 2014. The compounds listed include those recommended as priorities by the CCPR at its Forty-third and earlier sessions and compounds scheduled for re-evaluation within the CCPR periodic review programme.

Updated calls for data are available at least ten months before each JMPR meeting from the web pages of the Joint Secretariat:

http://www.fao.org/agriculture/crops/core-themes/theme/pests/pm/jmpr/jmpr-meet/en/

http://www.who.int/ipcs/food/en/

2013 JMPR

TOXICOLOGICAL EVALUATIONS	RESIDUE EVALUATIONS
NEW COMPOUNDS	**NEW COMPOUNDS**
bixafen [Bayer CropScience] - Germany	bixafen - Cereal grains, rape seed, rape seed oil; meat from mammals and poultry, milk and eggs
cyantraniliprole [Dupont] - USA PRIORITY 1	cyantraniliprole - Pome fruit, stone fruit, brassica vegetables, cucurbit vegetables, fruiting vegetables, leafy vegetables, bulb vegetables, green/long beans, grape, potato, sweet potato, rice, cotton, canola, citrus, tree nuts
fluensulfone	fluensulfone
imazapic [BASF] - Brazil PRIORITY 1	imazapic - Peanut, sugarcane, rice, maize and soya bean, animal feed items
imazapyr BASF Brazil PRIORITY 1	imazapyr - Soya bean, sunflower, rice, corn, sugarcane, canola, animal feed items
isoxaflutole [Bayer CropScience] - Germany	isoxaflutole - Maize, maize fodder and forage, soya bean (dry), soya bean oil, sugarcane, meat from mammals and poultry, milk and eggs
mesotrione [Syngenta] - USA	mesotrione - Asparagus, berries, Corn (grain, pop, sweet), Cranberry, Millet, Lingonberry, Oat (grain), Rhubarb, Sorghum (grain), Soya bean, Sugarcane, Okra
pymetrozine [Syngenta] - USA	pymetrozine - Hops; vegetables (tuberous and corm); asparagus; vegetable (leafy, except Brassica); Brassica (head and Stem); *Brassica* (leafy greens); fruiting vegetables; cucurbit vegetables; cottonseed; pecans

TOXICOLOGICAL EVALUATIONS	RESIDUE EVALUATIONS
tolfenpyrad [Nihon Nohyaku] - Japan	tolfenpyrad - Almonds, pecans, grape (table), raisin, juice (if MRL not included under table grape), plum, peach, cherry, pear, lemon, grapefruits, oranges, cantaloupe, cucumbers, summer squash, peppers, tomatoes, cauliflower, potatoes, cotton seed, tea and corresponding animal commodity MRLs
triflumizole [Nippon Soda] - USA	triflumizole - Pome fruits, stone fruits, grape, star apple, American persimmon, mangoes, papaya, pineapple, strawberries, cucurbits, squash, melons, leafy brassica, head and stem brassica, kohlrabi, lettuce, cress, land cress, spinach, purslane, beet leaves, chervil parsley, hazelnuts, hops and animal commodities
trinexapac [Syngenta] - USA	trinexapac - Wheat, Barley, Oats, Sugarcane
SYN545192 [Syngenta] - Switzerland	SYN545192 - Wheat, barley, soya bean, corn, coffee, pome fruit, grape, sugarcane
PERIODIC RE-EVALUATIONS	**PERIODIC RE-EVALUATIONS**
	bentazone (172) – (BASF) beans (green and dried), peas (green and dried), cereals, maize, sorghum, onion, peanuts, potato, linseed, meat, milk, eggs.
diquat (031) [Syngenta] PRIORITY 1	diquat (031)) – [Syngenta] Cereal grains, Oilseeds, Legume vegetables, Head brassica, Flowering brassica, Leafy brassica, Fruiting vegetables, Root and tuber vegetables, Stalk and stem vegetable, Cucurbits (edible and inedible peel), Bulb vegetables, Citrus fruits, Lettuce, spinach, canary, lupine, mustard, apple, banana, chicory witloof, coffee, sweet corn, grape, herbs (including parsley and sage), hop, kohlrabi, lucerne, olive, peach, strawberry, clover, grass, alfalfa, sugarcane,
	dithianon (028) – [BASF] - PRIORITY 1 - pome fruit, cherry, grapes, hops, mandarin
fenbutatin oxide (109) [BASF]	fenbutatin oxide (109) Tree nuts, pome fruit, banana, cherry, citrus fruit, cucumber, grapes, raisins, stone fruit, strawberry, tomato, meat, milk, eggs

TOXICOLOGICAL EVALUATIONS	RESIDUE EVALUATIONS
fenpropathrin (185) [Sumitomo Chemical] PRIORITY 1	fenpropathrin (185) cattle meat, cattle milk, cattle edible offal, cotton seed, cotton seed oil, eggplant, eggs, gherkin, grapes, chilli pepper, sweet pepper, pome fruits, poutry meat, poutry edible offal, tea, tomato, Cherries, Stone fruit (Peach, Apricots, Nectarine, Plums), Strawberries, Bushberries, Caneberries, Tree nuts including pistachio, Olive, Citrus (Oranges, Grapefruit, Lemons), Sweet cherry
EVALUATIONS	**EVALUATIONS**
	azoxystrobin (229) [Syngenta] - Potato, coffee
	cyprodinil (207) [Syngenta] - Apple, Pear, Pistachio, Almond, Pecan
	difenoconazole (224) [Syngenta] - Grapes, raisins, citrus, Brassica vegetables, bulb vegetables, fruiting vegetables (pepper), cucurbits, potato
	fenbuconazole (197) [Dow AgroSciences] - blueberries; new GAP for citrus fruits
	fenpyroximate (193) [Nihon Nohyaku] - Avocado, bean (snap), cucumber, potato, stone fruit (cherry, peach, plum), tea strawberry
	fludioxonil (211) [Syngenta] - Tomato, Potato, Pineapple
	flutolanil (205) [Nihon Nohyaku] - leafy brassica, root vegetables, ginseng
	chlorantraniliprole (230) [DuPont] - Artichoke, globe, Berries and other Small Fruits, Citrus, Coffee, Fruiting vegetables (other than cucurbits), Hops, Legume vegetables, Oilseeds, Rice, Root and tuber vegetables, Soybean, dried
	malathion (49) [Cheminova] - Cherry
	mandipropamid (231) [Syngenta] - hops
	propiconazole (160) [Syngenta] - Oranges, grapefruit, lemon, peaches, nectarines, plum, tomato, cherry, strawberry
	spirotetramat (234)

TOXICOLOGICAL EVALUATIONS	RESIDUE EVALUATIONS
	[Bayer CropScience] – Cranberry
	triaziphos (143) (China) - Rice
2014 JMPR	
NEW COMPOUNDS	**NEW COMPOUNDS**
dichlobenil [Chemtura] USA	dichlobenil Cranberry, blackberry, blueberry, raspberry, grapes, cherry, pome fruit, hazelnut, and rhubarb
fenamidone [Bayer CropScience] Germany PRIORITY 1	fenamidone Broccoli, Brussels sprouts, Carrots, Chinese cabbage, Cauliflower, Courgettes (Summer squash), Cucumber, Eggplant, Gherkin, Grapes (Table and wine), Head cabbage, Kale, Leek, Lettuce (Head and leafy), Melon, Onion, Pepper (Bell and sweet), Potato, Pumpkin (Winter squash), Spinach, Strawberries, Sunflower seeds, Tomato, Watermelon
flufenoxuron [BASF] Brazil PRIORITY 1	flufenoxuron Soya bean, pomefruit (apple, pear), orange, melon, tomato, grape
metrafenone [BASF] USA	metrafenone Grape (table, wine, raisin), Pome fruits (apple, pears), Cherries, Fruiting vegetables (tomatoes, peppers, eggplant), Cucurbits (cucumber, squash, melon), Cereals (wheat, barley, oats, rye, triticale), Hops
norfluazuron [Syngenta] - USA	norfluazuron almond, apple, apricot, asparagus, avocado, blackberry, blueberry, cranberry, cherry (sweet and tart), citrus fruits group, cottonseed, grape, hazelnut, hops, nectarine, peach, peanut, pear, pecan, plums and prunes, raspberry, soya bean, and walnut
rotenone (R of Korea)	Rotenone
PERIODIC RE-EVALUATIONS	**PERIODIC RE-EVALUATIONS**
metalaxyl (138) [Quimicas del Vallés - SCC GmbH]	metalaxyl (138)
triforine (116) [Sumitomo Corp]	triforine (116) Apple, Blueberries, Brussels sprouts, Cereal grains, Cherries, Common bean, Currants, Fruiting vegetables, Cucurbits, Gooseberry, Peach, Plums, Strawberry, Tomato

TOXICOLOGICAL EVALUATIONS	RESIDUE EVALUATIONS
myclobutanil (181) [Dow AgroSciences]	myclobutanil (181) pome fruits, stone fruits, black currant, grapes, strawberry, banana, hops, tomato Pesticide Initiative Project – beans with pods
penconazole (182) [Syngenta]	penconazole (182) Brassica Vegetables, Pome Fruit, Fruiting Vegetables, Root and Tuber Vegetables, Cucurbit vegetables, Berries and other small fruit, Stone Fruit, Legume Vegetables, Nuts, Soya, Sugar beet, Tobacco, Clementine, grapefruit, Nectarine, Cumquat, Mango, Loquat, Asparagus, Leek, Banana, Lambs Lettuce, Rocket, Chicory, Canola, Parsley, Mint, Papaya, Alfalfa, Barley, Rice, Wheat, Sweet Corn, Hops, Lentil, Persimmon, Avocado, Artichoke, Onion, Fennel
EVALUATIONS	**EVALUATIONS**
	Bifenthrin (4 year rule) Barley, barley (straw fodder), strawberry (alternative GAP
	Chlorothalonil (4 year rule) Banana, carrot, cherry, cranberry, bulb onion, peach, sweet and chilli pepper, tomato,, common beans
	phosmet [Gowan] – USA cranberry, tart cherry

8. CORRIGENDA - CORRECTIONS TO THE REPORT OF THE 2010 MEETING

Pesticide Residues in Food—2010. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group. FAO Plant Production and Protection Paper 200, 2011

Changes are shown in bold

5.2 Bifenthrin (178)

Page 53, the table should read:

Dietary burden (ppm) Feeding level [ppm]	Milk	Milk fat	Muscle	Liver	Kidney	Fat
MRL	mean	highest	highest	highest	highest	highest
Beef cattle (8.26) [5/15]			**0.146 mg/kg** [<0.1/0.24]	**0.1 mg/kg** [<0.1/0.1]	**0.129 mg/kg** [0.1/0.19]	**1.86 mg/kg** [1.7/2.2]
Dairy cattle (7.41) [5/15]	**0.100 mg/kg** [0.082/0.15]	2.371 mg/kg [1.6/-]				
STMR	mean	mean	mean	mean	mean	mean
Beef cattle (3.4) [0/5]			<0.068 mg/kg [<0.1]	<0.068 mg/kg [<0.1]	<0.068 mg/kg [<0.1]	0.588 mg/kg [0.865]
Dairy cattle (3.21) [0/5]	0.053 mg/kg [0.082]	0.491 mg/kg [0.765]				

Page 53, paragraphs 6 and 7 should read:

The Meeting estimated STMR values of 0.07 mg/kg for mammalian muscle and 0.59 mg/kg for mammalian fat, and a maximum residue level of 3 (fat) for mammalian meat. The HRs were **0.146** and **1.86** mg/kg for muscle and fat, respectively.

The Meeting estimated an STMR value of 0.07 mg/kg and a maximum residue level of 0.2 mg/kg for mammalian edible offal, based on liver and kidney data. The HR was **0.129** mg/kg.

5.22 Thiamethoxam (245)

Page 357, paragraph 3 should read:

The processing factors for thiamethoxam residues for oranges → orange juice (0.25) and oranges → orange dry pulp (2.6) were applied to the citrus fruits STMR **for whole fruit, 0.075** mg/kg, to produce an orange juice STMR-P of **0.019** mg/kg and an orange dry pulp STMR-P of **0.195** mg/kg.

ANNEX 1: ACCEPTABLE DAILY INTAKES, SHORT-TERM DIETARY INTAKES, ACUTE REFERENCE DOSES, RECOMMENDED MAXIMUM RESIDUE LIMITS AND SUPERVISED TRIALS MEDIAN RESIDUE VALUES RECORDED BY THE 2011 MEETING

Pesticide (Codex reference number)	**CCN**	**Commodity**	**Recommended MRL mg/kg**		**STMR or STMR-P mg/kg**	**HR or HR-P mg/kg**
			New	Previous		
Acephate (095)	CM 0649	Rice, husked	1		0.405 [a] 0.535 [b] 0.055 [c]	
ADI: 0–0.03 mg/kg bw	CM 1205	Rice, polished			0.33 [a] 0.44 [b]	
ARfD: 0.1 mg/kg bw	AS 0649	Rice straw and fodder, dry	0.3		0.025 [c]	0.14 [c]
Definition of the residue for compliance with MRLS for plant and animal commodities: acephate						
Definition of the residue for estimation of dietary intake for plant and animal commodities: acephate and methamidophos						
[a] *for long term intake estimate*						
[b] *for short-term intake estimate*						
[c] *for calculation of animal dietary burden.*						
Acetamiprid (246)*	VP 0061	Beans, except broad bean and soya bean	0.4		0.01	0.18
ADI: 0–0.07 mg/kg bw	VP 0062	Beans, shelled	0.3		0.03	0.18
ARfD: 0.1 mg/kg bw	FB 0018	Berries and other small fruit (except grapes and strawberries)	2		0.64	1
	VB 0041	Cabbages, Head	0.7		0.02 0.09 [d]	0.05 0.5 [d]
	VX 0624	Celery	1.5		0.3	0.78
	FS 0013	Cherries	1.5		0.45	0.88
	FC 0001	Citrus fruits	0.8		0.25	0.45
	SO 0691	Cotton seed	0.7		0.09 [c]	
	HS 0444	Peppers Chili, dried	2		0.4	1.4
	DF 0014	Prunes	0.6		0.12	0.32
	MO 0105	Edible offal (Mammalian)	0.05		0.011 liver 0.018 kidney	0.03 liver 0.05 kidney
	PE 0112	Eggs	0.01 *		0.0	0.0
	VB 0042	Flowerhead brassicas (includes Broccoli: Broccoli, Chinese and Cauliflower)	0.4		0.02	0.22
	VC 0045	Fruiting vegetables, Cucurbits	0.2		0.05	0.11
	VO 0050	Fruiting vegetables, other than Cucurbits (except sweet corn & mushrooms)	0.2		0.04	0.14
	VA 0381	Garlic	0.02		0.01	0.01
	FB 0269	Grapes	0.5		0.085	0.25
	VL 0053	Leafy vegetables (except spinach)	3		0.64	1.9
	MF 0100	Mammalian fats (except milk fats)	0.02		0.003	0.01
	MM 0095	Meat (from mammals other than marine	0.02		0.003 fat 0.004 muscle	0.01 fat 0.01 muscle

Pesticide (Codex reference number)	**CCN**	**Commodity**	**Recommended MRL mg/kg**		**STMR or STMR-P mg/kg**	**HR or HR-P mg/kg**
			New	Previous		
		mammals)				
	ML 0106	Milks	0.02		0.004	0.009
	FS 0245	Nectarine	0.7		0.2	0.44
	VA 0385	Onion, Bulb	0.02		0.01	0.01
	FS 0247	Peach	0.7		0.2	0.44
	VP 0064	Peas, shelled (succulent seeds)	0.3		0.03	0.18
	FS 0014	Plums (including Prunes)	0.2		0.04	0.11
	FP 0009	Pome fruits	0.8		0.225	0.59
	PM 0110	Poultry meat	0.01 *		0.0	0.0
	PO 0111	Poultry, Edible offal of	0.05 *		0.01	0.0
	VL 0502	Spinach	5 [e]		0.51	2.5
	VA 0389	Spring onions	5		0.38	2
	FB 0275	Strawberry	0.5		0.1	0.24
	TN 0085	Tree nuts	0.06		0.01	0.05
	JF 0226	Apple juice				0.2
	JF 0001	Citrus juice				0.03
	OR 0001	Citrus oil				0.04
		Citrus peel				0.71
	OR 0691	Cotton seed oil, edible				0.004
	DF 0269	Dried grapes (= currants, Raisins and Sultanas)			0.23	0.08
	JF 0269	Grape juice				0.13
	VW 0448	Tomato paste				0.09
		Tomato purée				0.04

Definition of the residue (for compliance with the MRL for plant commodities and for estimation of dietary intake for plant and animal commodities): acetamiprid.

Definition of the residue (for compliance with the MRL for animal commodities and for estimation of dietary intake for plant and animal commodities): sum of acetamiprid and its desmethyl (IM-2-1) metabolite, expressed as acetamiprid

The residue is not fat-soluble.

[d] With wrapper leaves
[e] On the basis of information provided to the JMPR it was not possible to conclude from the estimate of short-term intake for Acetamiprid that the consumption of spinach was less than the ARfD

Azoxystrobin (229)	SB 0716	Coffee beans	0.02		0.01
ADI: 0–0.2 mg/kg bw	VR 0604	Ginseng	0.1		0.025
ARfD: Unnecessary		Ginseng processed products	0.5		
		Ginseng, dried			0.075
		Ginseng, red			0.05
		Ethanol extract of dried ginseng			0.13
		Water extract of dried ginseng			0.12
		Ethanol extract of red ginseng			0.12
		Water extract of red ginseng			0.05

Definition of the residue (for compliance with the MRL for plant and animal commodities and for estimation of dietary intake for plant and animal commodities): azoxystrobin.

Pesticide (Codex reference number)	**CCN**	**Commodity**	**Recommended MRL mg/kg** New	Previous	**STMR or STMR-P mg/kg**	**HR or HR-P mg/kg**
The residue is fat-soluble.						
Clothianidin (238) ADI: 0–0.1 mg/kg bw ARfD: 0.6 mg/kg bw *Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities*: clothianidin *The residue is not fat-soluble.*						
Cypermethrins (including alpha- and zeta- cypermethrin) (118) [f] ADI: 0–0.02 mg/kg bw ARfD: 0.04 mg/kg bw	VS 0621	Asparagus	0.4 *a,C*	0.01*	0.09	0.2
	FC 0001	Citrus fruits (except shaddocks or pomelos)	0.3 *a,Z*	2 [g]	0.05	0.05
	PE 0112	Eggs	0.01*	0.01*	0.0042	0.0047
	PO 0111	Poultry, Edible offal of	0.05*	0.05*	0.002	0.022
	PM 0110	Poultry meat	0.1 (fat)	0.1 (fat)	0.002 muscle 0.034 fat	0.022 muscle 0.048 fat
	PF 0111	Poultry fats	0.1		0.038	0.048
	FC 0005	Shaddocks or pomelos	0.5 a, C, z		0.05	0.05
	DT 1114	Tea, Green, Black (black, fermented and dried)	15 *C*	20 [g]	3.75	
	TN 0085	Tree nuts	0.05* *a,Z*		0.05	0.05
Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities: cypermethrin (sum of isomers). *The residue is fat soluble.* [f] Source of data supporting the proposed MRLs: *a: alpha-cypermethrin. c: cypermethrin. z: zeta-cypermethrin*. Capital letters show the source of data responsible for the MRL estimate. Small letters show the sources of other data for that commodity. [g] The Codex MRL was retained under the four year rule awaiting the evaluation of data by the 2011 Meeting of JMPR.						
Dicamba (240) ADI: 0–0.3 mg/kg bw ARfD: 0.5 mg/kg bw	VD 0541	Soya bean (dry)	5		0.335	
	OR 0541	Soya bean oil, refined			0.012	
Definition of the residue for compliance with the MRL for plant commodities: dicamba *Definition of the residue for estimation of dietary intake for plant commodities:* sum of dicamba and 5-OH dicamba expressed as dicamba *Definition of the residue for compliance with the MRL and for estimation of dietary intake for animal commodities:* sum of dicamba and 3,6-dichlorosalicylic acid (DCSA) expressed as dicamba *The residue is not fat-soluble*						
Dichlorvos (025) ** ADI: 0–0.004 mg/kg bw ARfD: 0.1 mg/kg bw						

Pesticide (Codex reference number)	**CCN**	**Commodity**	**Recommended MRL mg/kg**		**STMR or STMR-P mg/kg**	**HR or HR-P mg/kg**
			New	Previous		
Dicofol (026) **						
ADI: 0–0.002 mg/kg bw						
ARfD: 0. 2 mg/kg bw						
Diflubenzuron (130)	FS 0247	Peach	0.5		0.17	
ADI: 0–0.02 mg/kg bw	FS 0014	Plum (including Prunes)	0.5		0.17	
ARfD: Unnecessary	FS 0245	Nectarine	0.5		0.17	
	VL 0485	Mustard greens	10		1.4	
	VO 0445	Peppers, Sweet (including pimento or pimiento)	0.7		0.16	
	VO 0444	Peppers, Chili	3		0.92	
	HS 0444	Peppers Chili, dried	20		6.44	
	GC 0640	Barley	0.05*		0.05	
	GC 0654	Wheat	0.05*		0.05	
	GC 0647	Oats	0.05*		0.05	
	GC 0653	Triticale	0.05*		0.05	
	AS 0162	Hay or fodder (dry) of grasses	3		0.625	1.4
	AS 0081	Straw and fodder (dry) of cereal grain	1.5		0.29	0.90
	TN 0085	Tree nuts	0.2		0.05	
	SO 0697	Peanut	0.15		0.05	
	AL 0697	Peanut fodder	40		7.5	18.4
Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities: diflubenzuron.						
The residue is fat soluble.						
Emamectin benzoate (247)*						
ADI: 0–0.0005 mg/kg bw	VP 0061	Beans, except broad bean and soya bean	0.015		0.001	0.009
ARfD: 0.03 mg/kg bw	VL 0510	Cos lettuce	1		0.20	0.62
	SO 0691	Cotton seed	0.002*		0.002	0.002
	MO 0105	Edible offal (Mammalian)	0.08		0.006	0.072
	FB 0269	Grapes	0.03		0.0025	0.022
	VC 0045	Fruiting vegetables, Cucurbits	0.007		0.001	0.002
	VO 0050	Fruiting vegetables, other than Cucurbits (except sweet corn and mushrooms)	0.02		0.003	0.013
	VL 0482	Lettuce, Head	1		0.20	0.62
	VL 0483	Lettuce, Leaf	1		0.20	0.62
	MF 0100	Mammalian fats (except milk fats)	0.02		0.002	0.011
	MM 0095	Meat (from mammals other than marine mammals)	0.004		0.002	0.004
	ML 0106	Milks	0.002		0.0005	

Pesticide (Codex reference number)	**CCN**	**Commodity**	**Recommended MRL mg/kg**		**STMR or STMR-P mg/kg**	**HR or HR-P mg/kg**
			New	Previous		
	VL 0485	Mustard greens	0.2		0.010	0.11
	FS 0245	Nectarine	0.03		0.0095	0.015
	FS 0247	Peach	0.03		0.0095	0.015
	HS 0444	Peppers, Chili (dried)	0.2		0.03	0.13
	FP 0009	Pome fruits	0.02		0.004	0.011
	JF 0226	Apple juice			0.0028	
	OR 0691	Cotton seed oil, edible			0.00078	
Definition of the residue for compliance with the MRL and for estimation of dietary intake for plant commodities: emamectin B1a benzoate, expressed as emamectin (free base). *Definition of the residue for compliance with the MRL and for estimation of dietary intake for animal commodities*: emamectin B1a benzoate, expressed as emamectin (free base). *The residue is not fat-soluble.*						
Etofenprox (184)**	FP 0226	Apple	0.6		0.2	0.34
ADI: 0–0.03 mg/kg bw	VD 0071	Beans (dry)	0.05		0.05	
ARfD: 1 mg/kg bw	DF 0269	Dried grapes (= currants, Raisins and Sultanas)	8		1.5	5.5
	MO 0105	Edible offal (Mammalian)	0.05		0.03 liver 0.03 kidney	0.03 liver 0.03 kidney
	PE 0112	Eggs	0.01 *		0	0
	FB 0269	Grapes	4		0.73	2.6
	GC 0645	Maize	0.05 *		0.05	0.05
	MM 0095	Meat (from mammals other than marine mammals)	0.5 (fat)		0.03 muscle 0.21 fat	0.03 muscle 0.3 fat
	ML 0106	Milks	0.02		0.013	
	FS 0245	Nectarine	0.6		0.16	0.37
	FP 0230	Pear	0.6		0.2	0.34
	FS 0247	Peach	0.6		0.16	0.37
	FP 0009	Pome fruits	W	1		
	VR 0589	Potato	W	0.01 *		
	PM 0110	Poultry meat	0.01 *		0.0	0.0
	PO 0111	Poultry, Edible offal of	0.01 *		0.0	0.0
	SO 0495	Rape seed	0.01 *		0.01	0.01
	GC 0649	Rice	0.01 *		0.0	0.0
	AS 0649	Rice straw and fodder, dry	0.05		0.01	0.025
		Apple purée			0.05	
	JF 0226	Apple juice			0.012	
	JF 0269	Grape juice			0.029	
		Peach juice			0.008	
		Canned apples			0.018	
		Canned peaches			0.018	
		Wine			0.029	
Definition of the residue (for compliance with the MRL for plant and animal commodities and for estimation of dietary intake for plant and animal commodities): etofenprox *The residue is fat soluble.*						

Pesticide (Codex reference number)	**CCN**	**Commodity**	**Recommended MRL mg/kg**		**STMR or STMR-P mg/kg**	**HR or HR-P mg/kg**
			New	Previous		
Etoxazole (241) ADI: 0–0.05 mg/kg bw ARfD: Unnecessary	FP 0009	Pome fruits	0.07		0.01	
Definition of the residue (for compliance with the MRL for plant and animal commodities and for estimation of dietary intake for plant commodities): etoxazole. *The residue is fat soluble.*						
Flutriafol (248) *						
ADI: 0–0.01 mg/kg bw	FI 0327	Banana	0.3		0.05	0.09
ARfD: 0.05 mg/kg bw	SB 0716	Coffee beans	0.15		0.05	
	DF 0269	Dried grapes (= currants, Raisins and Sultanas)	2		0.59	1.7
	FB 0269	Grapes	0.8		0.21	0.61
	SO 0697	Peanut	0.15		0.02	
	AL 0697	Peanut fodder	20		2.6	8.9
	VO 0445	Peppers, Sweet (including pimento or pimiento)	1		0.28	0.41
	HS 0444	Peppers Chili, dried	10		2.7	4.1
	FP 0009	Pome fruits	0.3		0.07	0.16
	VD 0541	Soya bean (dry)	0.4		0.055	
	GC 0654	Wheat	0.15		0.015	
	CM 0654	Wheat bran, unprocessed	0.3		0.032	
	AS 0654	Wheat straw and fodder, dry	8		1.45	4.1
	JF 0226	Apple juice			0.034	
	SM 0716	Coffee beans, roasted			0.048	
	JF 0269	Grape juice			0.13	
	OR 0697	Peanut oil, edible			0.028	
		Peppers, Sweet, preserved			0.22	0.32
	OR 0541	Soya bean oil, refined			0.072	
	CF 1211	Wheat flour			0.005	
	CF 1210	Wheat germ			0.042	
Definition of the residue (for compliance with the MRL for plant and animal commodities and for estimation of dietary intake for plant and animal commodities): Flutriafol *The residue is fat-soluble.*						
Glyphosate (158)	VD 0533	Lentils (dry)	5		0.5	2.1
ADI: 0–1mg/kg bw	VR 0596	Sugar beet	15		3.4	7.3
ARfD: Unnecessary	VO 0447	Sweet corn (corn-on-the-cob)	3		0.325	2.8
	CF 1255	Maize flour			0.12	3.0
	CF 0645	Maize meal			0.12	3.0
Definition of the residue for compliance with MRL for soya bean and maize: sum of glyphosate and N-acetyl-glyphosate, expressed as glyphosate						

Pesticide (Codex reference number)	**CCN**	**Commodity**	**Recommended MRL mg/kg** New	Previous	**STMR or STMR-P mg/kg**	**HR or HR-P mg/kg**
Definition of the residue for compliance with MRL (for other plant commodities): glyphosate. *Definition of the residue for compliance with MRL (for animal commodities):* sum of glyphosate and N-acetyl-glyphosate, expressed as glyphosate *Definition of the residue for estimation of dietary intake (for plant and animal commodities):* glyphosate, N-acetyl-glyphosate, AMPA and N-acetyl AMPA, expressed as glyphosate. *The residue is not fat-soluble*						
Hexythiazox (176)	DH 1100	Hops, dry	3	2 [h]	0.79	
ADI: 0–0.03 mg/kg bw	FB 0275	Strawberry	6	0.5 [h]	0.54	
ARfD: Unnecessary	DT 1114	Tea, Green, Black (black, fermented and dried)	15		4.55	
		Beer			0.036	
		Green tea infusion			0.182	
		Fermented tea infusion			0.137	
		Strawberry, canned			0.248	
		Strawberry jam			0.359	
Definition of the residue for compliance with the MRL for plant commodities: hexythiazox. *Definition of the residue (for estimation of dietary intake) for plant commodities:* sum of hexythiazox and all metabolites containing the trans-5-(4-chlorophenyl)-4-methyl-2-oxothiazolidine-moiety (PT-1-3), expressed as hexythiazox *Definition of the residue (for compliance with MRL and for estimation of dietary intake) for animal commodities:* sum of hexythiazox and all metabolites containing the trans-5-(4-chlorophenyl)-4-methyl-2-oxothiazolidine-moiety (PT-1-3), expressed as hexythiazox *The residue is fat-soluble* [h] The Codex MRL was retained under the four year rule awaiting the evaluation of data by the 2011 Meeting of JMPR						
Isopyrazam (249)*	FI 0327	Banana	0.06		0.015	
ADI: 0–0.06 mg/kg bw	GC 0640	Barley	0.07		0.0375 0.022 [g]	
ARfD: 0.3 mg/kg bw	AS 0640	Barley straw and fodder, dry	3		0.4285 [g]	1.06 [g]
		Malt			0.022	
		Beer			0.0045	
		Pot barley			0.012	
	MO 0105	Edible offal (Mammalian)	0.02		0.0056	0.008
	MF 0100	Mammalian fats (except milk fats)	0.01*		0.0056	0.008
	MM 0095	Meat (from mammals other than marine mammals)	0.01*		0.0056 fat 0.0056 muscle	0.008
	ML 0106	Milks	0.01*		0.0042	-
	FM 0183	Milk fats	0.02		0.0042	-
	PF 0111	Poultry fats	0.01*		0.01	0.01
	PM 0110	Poultry meat	0.01*		0.01 fat 0.01 muscle	0.01
	PO 0111	Poultry, Edible offal of	0.01*		0.01	0.01
	PE 0112	Eggs	0.01*		0.01	0.01
	GC 0650	Rye	0.03		0.015	

Pesticide (Codex reference number)	**CCN**	**Commodity**	**Recommended MRL mg/kg**		**STMR or STMR-P mg/kg**	**HR or HR-P mg/kg**
			New	Previous		
					0.01 [g]	
	AS 0650	Rye straw and fodder, dry	3		0.952 [g]	1.51 [g]
	GC 0653	Triticale	0.03		0.015	
					0.01 [g]	
	AS 0653	Triticale straw and fodder, dry	3		0.952 [g]	1.51 [g]
	GC 0654	Wheat	0.03		0.015	-
					0.01 [g]	
	AS 0654	Wheat straw and fodder, dry	3		0.952 [g]	1.51 [g]
	CM 0654	Wheat bran, unprocessed	0.15		0.066	
					0.041 [g]	
		White flour			0.0035	
		Wholemeal flour			0.012	
	CP 1212	Wholemeal bread			0.0083	
	CF 1210	Wheat germ			0.0038	
Definition of the residue (for compliance with MRL) for plant commodities: isopyrazam (sum of syn-isomer and anti-isomer) *Definition of the residue for estimation of dietary intake for plant commodities:* sum of isopyrazam and 3-difluoromethyl-1-methyl-1H-pyrazole-4-carboxylic acid [9-(1-hydroxyl-1-methylethyl)-(1RS, 4RS, 9RS)-1,2,3,4-tetrahydro-1,4-methanonaphthalen-5-yl]amide expressed as isopyrazam. *Definition of the residue (for compliance with the MRL the estimation of dietary intake) for animal commodities*: isopyrazam (sum of syn-isomer and anti-isomer) *The residue is fat-soluble.* [g] for the purpose of calculating animal dietary burdens. Expressed on an "as received" basis.						
Methamidophos (100) ADI:0-0.004 mg/kg bw ARfD: 0.01 mg/kg bw	CM 0649	Rice, husked	0.6 [h]	-	0.025	-
	CM 1205	Rice, polished			0.021	-
	AS 0649	Rice straw and fodder, dry	0.1 [h]	-	0.0325 [i]	0.05 [i]
Definition of the residue for compliance with MRLs and for estimation of dietary intake for plant and animal commodities: methamidophos. *Residue is not fat-soluble.* [h] Arising from the use of acephate on rice. [i] for the calculation of animal dietary burden						
Penthiopyrad (253)* ADI: 0–0.1 mg/kg bw ARfD: 1 mg/kg bw						
Profenofos (171) ADI: 0–0.03 mg/kg bw ARfD: 1.0 mg/kg bw	VO 0444	Peppers, Chili	3	5 [l]	0.78	1.42
	HS 0444	Peppers Chili, dried	20	50 [l]	5.46	9.94
Definition of the residue (for compliance with MRL and for estimation of dietary intake) for plant and animal commodities:						

Pesticide (Codex reference number)	CCN	Commodity	Recommended MRL mg/kg		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
profenofos *The residue is not fat-soluble.* [l] The Codex MRL was retained under the four year rule awaiting evaluation of data by the 2011 Meeting of JMPR						
Propylene oxide (250)* ADI: 0–0.04 mg/kg bw ARfD: 0.04 mg/kg bw propylene chlorohydrin ADI: None established [m] ARfD: None established propylene bromohydrin ADI: None established ARfD: None established *Definition of the residue(for compliance with MRL) for plant commodities*: propylene oxide *Definition of the residue (for estimation of dietary intake) for plant commodities*: propylene oxide, propylene chlorohydrin and propylene bromohydrin. Propylene chlorohydrin and propylene bromohydrin to be considered separately from propylene oxide *The residue is not fat-soluble.* [m] The Meeting could not establish an ADI or ARfD for propylene chlorohydrin and propylene bromohydrin due to insufficient data						
Pyraclostrobin (210) ADI: 0–0.03 mg/kg bw ARfD: 0.05 mg/kg bw	AL 1020	Alfalfa fodder	30		8.38	22.28
	TN 0660	Almond	W [n]	0.02*		
	AM 0660	Almond hulls	W [o]	2		
	VS 0620	Artichoke, globe	2		0.25	1.44
	GC 0640	Barley	1	0.5	0.345	
	FB 0264	Blackberries	3		0.87	1.32
	FB 0020	Blueberries	4	1	0.78	2.08
	VC 4199	Cantaloupe	W [p]	0.2		
	FS 0013	Cherries	3		0.51	1.57
	FC 0001	Citrus fruits	2	1	0.035 (pulp)	0.1 (pulp)
	VC 0424	Cucumber	W [p]	0.5		
	VC 0045	Fruiting vegetables, Cucurbits	0.5		0.06 (edible peel) 0.052 (inedible peel)	0.41 (edible peel) 0.14 (inedible peel)
	VA 0381	Garlic	0.15	0.05*	0.02	0.09
	FS 0245	Nectarine	0.3		0.07	0.13
	GC 0647	Oats	1	0.5	0.345	
	SO 0089	Oil seed except peanut	0.4		0.055	
	VA 0385	Onion, bulb	1.5	0.2	0.06	0.62
	VA 0389	Spring onion	1.5		0.42	0.60
	FI 0350	Papaya	0.15	0.05*	0.05	0.06
	FS 0247	Peach	0.3		0.07	0.13

Pesticide (Codex reference number)	**CCN**	**Commodity**	**Recommended MRL mg/kg**		**STMR or STMR-P mg/kg**	**HR or HR-P mg/kg**
			New	Previous		
	TM 0672	Pecan	W [n]	0.02*		
	FS 0014	Plums (including Prunes)	0.8		0.09	0.40
	FB 0272	Raspberries, Red, Black	3	2	0.87	1.32
	OR 0495	Rape seed oil, edible			0.053	
	GC 0650	Rye	0.2		0.02	
	GC 0651	Sorghum	0.5		0.025	
	AS 0651	Sorghum straw and fodder, dry			0.08	0.65
	VC 0431	Squash, Summer	W [p]	0.3		
	FS 0012	Stone fruits	W	1		
	FB 0275	Strawberry	1.5	0.5	0.20	0.75
	SO 0702	Sunflower seed	W [q]	0.3		
	TN 0085	Tree nuts, except pistachio	0.02*		0	0.02
	GC 0653	Triticale	0.2		0.02	
		Beer			0.23	
		Brewing malt			0.40	
		Cherry juice			0.08	
		Cotton gin by-products			1.575	16.73
		Malt germ			0.80	
		Orange oil	10		3.03	8.17
		Pearl barley			0.23	
		Plum puree			0.17	
	DF 0014	Prunes			0.41	1.84
	OR 0541	Soya bean oil, refined			0.01	
		Strawberry jam			0.04	
	CF 0654	Wheat bran			0.018	

Definition of the residue (for compliance with MRL and for estimation of dietary intake) for plant and animal commodities: pyraclostrobin

The residue is not fat-soluble.

[n] The recommendations for almonds and pecan are withdrawn to be replaced by a recommendation for Tree nuts.
[o] The recommendation for almond hulls is withdrawn as the commodity is not traded.
[p] The recommendations for cucumber, melons and squash are withdrawn to be replaced by a recommendation for Fruiting vegetables, Cucurbits
[q] The recommendation for sunflower seed is withdrawn to be replaced by a recommendation for Oilseed except peanut.

Saflufenacil (2251)*	FI 0327	Banana	0.01		0	0
ADI: 0–0.05 mg/kg bw	AS 0640	Barley straw and fodder, dry	0.025		0.025	0.025
ARfD: Unnecessary	VD 0071	Beans (dry)	0.3		0.01	
	GC 0080	Cereal grains	0.01		0	
	FC 0001	Citrus fruits	0.01		0	0
	SB 0716	Coffee beans	0.01		0	
	SO 0691	Cotton seed	0.2		0.025	
	FB 0269	Grapes	0.01		0	0
	MO 0105	Edible offal (Mammalian)	0.3		0.14	0.26
	AS 0645	Maize fodder	0.05		0.025	0.025
	MF 0100	Mammalian fats (except milk fats)	0.01		0.01	0.01
	MM 0095	Meat (from mammals other than marine mammals)	0.01		0.01	0.01

Pesticide (Codex reference number)	CCN	Commodity	Recommended MRL mg/kg		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
	ML 0106	Milks	0.01		0.01	0.01
	VP 0063	Peas (pods and succulent = immature seeds)	0.01		0.01	
	VP 0064	Peas, shelled (succulent seeds)	0.01		0.01	
	VD 0072	Peas, dry	0.05		0.01	
	FP 0009	Pome fruits	0.01		0	
	SO 0495	Rape seed	0.6		0.054	
	AS 0651	Sorghum straw and fodder dry	0.025		0.025	0.025
	VP 0541	Soya bean (immature seeds)	0.01		0.01	
	VD 0541	Soya bean (dry)	0.07		0.01	0
	FS 0012	Stone fruits	0.01		0	
	SO 0702	Sunflower seed	0.7		0.12	
	GC 0447	Sweet corn	0.01		0	0
	TN 0085	Tree nuts	0.01		0	
	AS 0654	Wheat straw and fodder, dry	0.025		0.025	0.025
	OR 0702	Sunflower seed oil edible			0.0036	
	OR 0541	Soya bean oil, refined			0.0025	
Definition of the residue (for compliance with MRL and for estimation of dietary intake) for plant and animal commodities: saflufenacil *The residue is not fat-soluble.*						
Spinosad (203)	TN 0660	Almonds	W [r]	0.01*		
	AM 0660	Almond hulls	W [s]	2	2.2	
ADI: 0–0.02 mg/kg bw	FB 0264	Blackberries	1		0.14	
ARfD: Unnecessary	FB 0020	Blueberries	0.4		0.11	
	FB 0265	Cranberry	0.02		0.01	
	FB 0266	Dewberries (including Boysenberry and Loganberry)	1		0.14	
	VA 0385	Onion, Bulb	0.1		0.01	
	FI 0351	Passion fruit	0.7		0.23	
	FB 0272	Raspberries, Red, Black	1		0.14	
	VA 0389	Spring onion	4		0.2	
	TN 0085	Tree nuts	0.07		0.026	
Definition of the residue (for compliance with MRL and for estimation of dietary intake) for plant and animal commodities: sum of spinosyn A and spinosyn D. *The residue is fat-soluble.* *(Residues in milk should be determined in the whole milk.)* [r] The recommendation for almonds is withdrawn to be replaced by a recommendation for Tree nuts [s] The recommendation for almond hulls is withdrawn as the commodity is not traded.						
Spirotetramat (234)	SO 0691	Cotton seed	0.4		0.095	
ADI: 0–0.5 mg/kg bw	AB 1203	Cotton seed meal	1		0.12	0.36
ARfD: 1.0 mg/kg bw	MO 0105	Edible offal (Mammalian)	1	0.03	0.16	0.55

Pesticide (Codex reference number)	**CCN**	**Commodity**	**Recommended MRL mg/kg**		**STMR or STMR-P mg/kg**	**HR or HR-P mg/kg**
			New	Previous		
	PE 0112	Eggs	0.01		0.0023	0.0048
	AL 0157	Legume animal feeds	30		12	17
	VP 0060	Legume vegetables	1.5		0.505	0.84
	FI 0343	Litchi	15		1.6	6
	FI 0341	Kiwifruit	0.02 *		0.055	0.066
	FI 0345	Mango	0.3		0.16	0.25
	MM 0095	Meat (from mammals other than marine mammals)	0.05	0.01*	0.006 muscle 0.012 fat	0.019 muscle 0.043 fat
	ML 0106	Milks	0.01	0.005*	0.005	0.005
	VA 0385	Onion, Bulb	0.4		0.11	0.27
	FI 0350	Papaya	0.4		0.17	0.22
	PM 0110	Poultry meat	0.01*		0 muscle 0 fat	0.00037 muscle 0.00037 fat
	PO 0111	Poultry, Edible offal of	0.01		0.0016	0.0033
	VD 0070	Pulses [except soya bean (dry)]	2		0.21	
	VD 0541	Soya bean (dry)	4		0.45	
	OR 0691	Cotton seed oil, edible			0	0
	OR 0541	Soya bean oil, refined			0	0
		Soya bean flour (defatted)			0.46	2.7

Definition of the residue (for compliance with MRL for plant commodities: Spirotetramat and its enol metabolite, 3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]dec-3-en-2-one, expressed as spirotetramat.
Definition of the residue (for estimation of dietary intake) for plant commodities: *Spirotetramat*, *enol metabolite* 3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]dec-3-en-2-one, *ketohydroxy metabolite* 3-(2,5-dimethylphenyl)-3-hydroxy-8-methoxy-1-azaspiro[4.5]decane-2,4-dione, *monohydroxy metabolite* cis-3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]decan -2-one, and *enol glucoside* metabolite glucoside of 3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]dec-3-en-2-one, expressed as spirotetramat.
Definition of the residue (for compliance with MRL and estimation of dietary intake) for animal commodities: Spirotetramat enol metabolite, 3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]dec-3-en-2-one, expressed as spirotetramat.

The residue is not fat-soluble.

Sulfoxaflor (252)* [t]	*GC 0640*	*Barley*	*0.6*		*0.063*	
ADI: 0–0.05 mg/kg bw	*AS 0640*	*Barley straw and fodder, dry*	*3*		*0.14*	*1.8*
ARfD: 0.3 mg/kg bw	*VB 0400*	*Broccoli*	*3*		*0.074*	*1.6*
	VB 0041	*Cabbages, Head*	*0.4*		*0.099*	*0.19*
	VB 0404	*Cauliflower*	*0.04*		*0.012*	*0.021*
	VS 0624	*Celery*	*1.5*		*0.19*	*0.77*
	FC 0001	*Citrus fruits*	*0.9*		*0.31*	*0.44*
	SO 0691	*Cotton seed*	*0.4*		*0.02*	
	DF 0269	*Dried grapes (= Currants, Raisins, and Sultanas)*	*6*		*0.49*	*5.6*
	MO 0105	*Edible offal (Mammalian)*	*0.6*		*0.13*	*0.47*
	PE 0112	*Eggs*	*0.1*		*0.013*	*0.071*
	VC 0045	*Fruiting vegetables, Cucurbits*	*0.5*		*0.029*	*0.27*
	VO 0050	*Fruiting vegetables, other than Cucurbits (except sweet corn and mushrooms)*	*1.5*		*0.11*	*0.60*
	VA 0381	*Garlic*	*0.01 **		*0.01*	*0.01*
	FB 0269	*Grapes*	*2*		*0.14*	*1.6*

Pesticide (Codex reference number)	**CCN**	**Commodity**	**Recommended MRL mg/kg**		**STMR or STMR-P mg/kg**	**HR or HR-P mg/kg**
			New	Previous		
	VL 0053	*Leafy vegetables*	*6*		*1.2*	*2.9*
	MM 0095	*Meat (from mammals other than marine mammals)*	*0.3*		*0.045 muscle 0.03 fat*	*0.2 muscle 0.073 fat*
	ML 0106	*Milks*	*0.2*		*0.05*	
	VA 0385	*Onion, bulb*	*0.01**		*0*	*0*
	VA 0389	*Spring onion*	*0.7*		*0.11*	*0.39*
	HS 0444	*Peppers, Chili (dried)*	*15*		*1.1*	*6.0*
	FP 0009	*Pome fruits*	*0.4*		*0.07*	*0.26*
	PM 0110	*Poultry meat*	*0.1*		*0.015 muscle 0.005 fat*	*0.05 muscle 0.021 fat*
	PO 0111	*Poultry, Edible offal of*	*0.3*		*0.046*	*0.18*
	SO 0495	*Rape seed*	*0.15*		*0.045*	
	VR 0075	*Root and tuber vegetables*	*0.03*		*0.01*	*0.023*
	AL 0541	*Soya bean fodder*	*3*		*0.79*	*1.5*
	VP 0541	*Soya bean (immature seeds)*	*0.3*		*0.011*	
	FS 0012	*Stone fruits (except cherry)*	*2*		*0.13*	*0.9*
	FB 0275	*Strawberry*	*0.5*		*0.19*	*0.21*
	TN 0085	*Tree nuts*	*0.015*		*0.01*	*0.012*
	GC 0653	*Triticale*	*0.2*		*0.025*	
	VL 0473	*Watercress*	*6*		*1.0*	*2.9*
	GC 0654	*Wheat*	*0.2*		*0.025*	
	AS 0654	*Wheat straw and fodder, dry*	*3*		*0.14*	*1.8*
	JF 0226	*Apple juice*			*0.060*	
		Barley flour			*0.036*	
		Barley, pearled			*0.032*	
		Cherry, dried			*4.0*	*7.7*
	JF 0004	*Orange juice*			*0.022*	
	JF 0048	*Tomato juice*			*0.052*	
	VW 0448	*Tomato paste*			*0.23*	
		Tomato puree			*0.10*	
		Wine			*0.098*	
Definition of the residue (for compliance with MRL and for estimation of dietary intake) for plant and animal commodities: sulfoxaflor *The residue is not fat-soluble.* [t] Recommendations made as part of the CCPR Pilot project and are not based on official GAP.						
Tebuconazole (189)**	FP 0226	Apple	1		0.275	0.5
ADI: 0–0.03 mg/kg bw	FS 0240	Apricot	2		0.46	
	VS 0620	Artichoke, globe	0.6	0.5	0.145	0.32
ARfD: 0.3 mg/kg bw	FI 0327	Banana	0.05	0.05	0.01	
	GC 0640	Barley	2	0.2 [u]	0.85	
	AS 0640	Barley straw and fodder, dry	40	10 (30 [u])		
	VD 0071	Beans (dry)	0.3		0.05	
	VB 0400	Broccoli	0.2		0.015	0.11
	VB 0402	Brussels sprout	0.3		0.095	0.19
	VB 0041	Cabbages, Head	1		0.05	0.56

Pesticide (Codex reference number)	**CCN**	**Commodity**	**Recommended MRL mg/kg**		**STMR or STMR-P mg/kg**	**HR or HR-P mg/kg**
			New	Previous		
	VB 0404	Cauliflower	0.05*		0.05	0.05
	VR 0577	Carrot	0.4	0.5 [u]	0.11	0.22
	MO 0812	Cattle, edible offal of	W	0.05*		
	FS 0013	Cherries	4	5	0.86	3.1
	SO 0691	Cotton seed	2		0.05	
	SB 0716	Coffee beans	0.1	0.1	0.04	
	SM 0716	Coffee beans, roasted	W	0.5	0.08	
	VC 0424	Cucumber	0.15	0.2	0.05	0.09
	DF 0269	Dried grapes (=currants, Raisins and Sultanas)	7	3	0.86	5.5
	MO 0105	Edible offal (Mammalian)	0.2	0.5	0.06	0.15
	VO 0440	Egg plant	0.1		0.04	0.10
	PE 0112	Eggs	0.05*	0.05*	0	0
	FB 0267	Elderberries	1.5	2	0.345	0.70
	VA 0381	Garlic	0.1	0.1 [u]	0.02	0.06
	FB 0269	Grapes	6	2	0.72	4.6
	DH 1100	Hops, dry	40	30	9.65	
	VA 0384	Leek	0.7	1 [u]	0.195	0.44
	GC 0645	Maize	W	0.1 [u]		
	AS 0645	Maize fodder	6			
	FI 0345	Mango	0.05	0.1 [u]	0.05	0.05
	MM 0095	Meat (from mammals other than marine mammals)	0.05*	0.05*	0	0
	VC 0046	Melons, except Watermelon	0.15	0.2	0.02	0.02
	ML 0106	Milks	0.01*	0.01*	0	
	FS 0245	Nectarine	2		0.46	1
	GC 0647	Oats	2	0.05*	0.085	
	FT 0305	Olives	0.05*		0	
	VA 0385	Onion, bulb	0.1	0.1	0.02	0.06
	FI 0350	Papaya	2	2 [u]	0.18	1.2
	FI 0351	Passion fruit	0.1		0.1	0.1
	FS 0247	Peach	2	1	0.46	1
	SO 0697	Peanut	0.15	0.1 [u]	0.035	
	AL 0697	Peanut fodder	40	30		
	FP 0230	Pear	1		0.275	0.50
	HS 0444	Peppers Chili, dried	10	5	1.85	6.2
	VO 0445	Peppers, Sweet (including pimento or pimiento)	1	0.5	0.185	0.62
	FS 0014	Plums (including Prunes [except prunes]	1	0.2 [u]	0.08	0.47
		Plum preserve			0.054	
	DF 0014	Prunes	3	0.5 [u]	0.232	1.36
	PM 0110	Poultry meat	0.05*	0.05*	0	0
	PO 0111	Poultry, Edible offal of	0.05*	0.05*	0.05	0.05
	SO 0495	Rape seed	0.3	0.5	0.10	
	GC 0649	Rice	1.5	2	0.275	
	GC 0650	Rye	0.15	0.05*	0.05	
	AS 0650	Rye straw and fodder, Dry	40	5		
	VD 0541	Soya bean (dry)	0.15	0.1	0.02	
	OR 0541	Soya bean oil, refined			0.001	
	VC 0431	Squash, Summer	0.2	0.02	0.05	0.10
	VO 0447	Sweet corn (corn-on-the-cob)	0.6	0.1 [u]	0.06	0.36

Pesticide (Codex reference number)	**CCN**	**Commodity**	**Recommended MRL mg/kg**		**STMR or STMR-P mg/kg**	**HR or HR-P mg/kg**
			New	Previous		
	VO 0448	Tomato	0.7	0.2 (0.5 [u])	0.15	0.46
	GC 0653	Triticale	0.15		0.05	
	TN 0085	Tree nuts	0.05*		0	0
	VC 0432	Watermelon	W	0.1 [u]		
	GC 0654	Wheat	0.15	0.05	0.05	
	AS 0654	Wheat straw and fodder, dry	40	10		
	JF 0226	Apple juice			0.063	
		Apple sauce			0.094	
		Beer			0.002	
		Beans, cooked			0.01	
		Cabbage, cooked			0.019	0.23
	OR 0691	Cotton oil, edible			0	
		Peach juice			0.092	
		Peach jam			0.006	
		Peach preserve			0.006	
	JF 0048	Tomato juice			0.033	
	VW 0448	Tomato paste			0.19	
		Tomato preserve			0.018	
		Tomato puree			0.02	
		Wine			0.20	

Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities: tebuconazole
The residue is fat-soluble.

[q] Recommendation of the 2008 JMPR

Thiamethoxam (245)
ADI: 0–0.08 mg/kg bw
ARfD: 1 mg/kg bw

Definition of the residue (for compliance with the MRL) for plant and animal commodities: thiamethoxam.

Definition of the residue (for estimation of the dietary intake) for plant and animal commodities (except poultry): thiamethoxam and clothianidin (considered separately)

Definition of the residue for estimation of the dietary intake for poultry: sum of thiamethoxam, CGA 265307 and MU3, expressed as thiamethoxam; and clothianidin (clothianidin to be considered separately from thiamethoxam).

See also clothianidin

The residue is not 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)
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)
Acrylonitrile	1965 (T, 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)
Aminocarb (134)	1978 (T,R), 1979 (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)

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)
Beta-cyfluthrin (228)	2007 (R)
BHC (technical-grade)	1965 (T), 1968 (T,R), 1973 (T,R) (see also Lindane)
Bifenazate (219)	2006 (T, R), 2008 (R), 2010(R)
Bifenthrin (178)	1992 (T,R), 1995 (R), 1996 (R), 1997 (R), 2009 (T), 2010 (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)
Boscalid (221)	2006 (T, R), 2008 (R), 2009 (R), 2010 (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)
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 (T), 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 (acute Rf D)
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)
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)
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)
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)
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 (acute Rf D), 2000 (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)
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)
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)
Clofentezine (156)	1986 (T,R), 1987 (R), 1989 (R), 1990 (R), 1992 (R), 2005 (T), 2007 (R)
Clothianidin (238)	2010 (T, R), 2011 (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)
Cycloxydim (179)	1992 (T,R), 1993 (R), 2009 (T)
Cyfluthrin (157)	1986 (R), 1987 (T and corr. to 1986 report), 1989 (R), 1990 (R), 1992 (R), 2006 (T), 2007 (R)
Cyhalothrin (146)	1984 (T,R), 1986 (R), 1988 (R), 2007 (T), 2008 (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)
Cyproconazole (239)	2010 (T, R)
Cyprodinil (207)	2003 (T,R), 2004 (corr. to 2003 report)
Cyromazine (169)	1990 (T,R), 1991 (corr. to 1990 R evaluation), 1992 (R), 2006 (T), 2007 (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)
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)
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)
1,2-Dibromoethane (023)	1965 (T,R), 1966 (T,R), 1967 (R), 1968 (R), 1971 (R), 1979 (R), 1985 (R)
Dicamba (204)	2010 (T, R), 2011 (R)
Dicloran (083)	2003 (R)
Dichlorfluanid (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)
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)
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)
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)
Dimethomorph	2007 (T, 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)

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)
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)
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)
4,6-Dinitro-*ortho*-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)
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)
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)
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[1]), 1986 (T,R), 1987 (R), 1988 (R), 1989 (R), 1990 (R)
Famoxadone (208)	2003 (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)
Fenbuconazole (197)	1997 (T,R), 2009 (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)
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)
Fenpropathrin (185)	1993 (T,R), 2006 (R)
Fenpropimorph (188)	1994 (T), 1995 (R), 1999 (R), 2001 (T), 2004 (T)
Fenpyroximate (193)	1995 (T,R), 1996 (corr. to 1995 report.), 1999 (R), 2004 (T), 2007 (T), 2010 (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)
Ferbam See Dithiocarbamates,	1965 (T), 1967 (T,R), 1996 (T,R)
Fipronil (202)	1997 (T), 2000 (T), 2001 (R)
Fipronil-desulfinyl	1997 (T)
Flubendiamide (193)	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)
Flumethrin (195)	1996 (T, R)
Fluopicolide (235)	2009 (T, R)
Fluopyram (243)	2010 (T, R)

Flusilazole (165)	1989 (T, R), 1990 (R), 1991 (R), 1993 (R), 1995 (T), 2007 (T, R)
Flutolanil (205)	2002 (T, R)
Flutriafol (248)	2011 (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)
Glufosinate-ammonium (175)	1991 (T,R), 1992 (corr. to 1991 report, Annex I), 1994 (R), 1998 (R), 1999 (T,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)
Guazatine (114)	1978 (T.R), 1980 (R), 1997 (T,R)
Haloxyfop (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), 2011 (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)
Imidacloprid (206)	2001 (T), 2002 (R), 2006 (R), 2008 (R)
Indoxacarb (216)	2005 (T,R), 2007 (R), 2009 (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)
Isopyrazam (249)	2011 (T, R)
Kresoxim-methyl (199)	1998 (T,R), 2001 (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)
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), 2008 (R)
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)
Mandipropamid (231)	2008 (T, R)
Maneb See Dithiocarbamates, 1965 (T), 1967 (T,R), 1987 (T), 1993 (T,R)	
Mecarbam (124)	1980 (T,R), 1983 (T,R), 1985 (T,R), 1986 (T,R), 1987 (R)
Meptyldinocap (244)	2010 (T, R)
Metaflumizone (236)	2009 (T, R)
Metalaxyl (138)	1982 (T,R), 1984 (R), 1985 (R), 1986 (R), 1987 (R), 1989 (R), 1990 (R), 1992 (R), 1995 (R)
Metalaxyl –M (212)	2002 (T), 2004 (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)
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)
Methoxychlor	1965 (T), 1977 (T)
Methoxyfenozide (209)	2003 (T, R), 2004 (corr. to 2003 report), 2006 (R), 2009 (R)
Methyl bromide (052)	See Bromomethane
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)
Nabam See Dithiocarbamates,	1965 (T), 1976 (T,R)
Nitrofen (140)	1983 (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)
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)
Penthiopyrad (253)	2011 (T, 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)

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)
Phoxim (141)	1982 (T), 1983 (R), 1984 (T,R), 1986 (R), 1987 (R), 1988 (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)
Propamocarb (148)	1984 (T,R), 1986 (T,R), 1987 (R), 2005 (T), 2006 (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), 2007 (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)
Propylenethiourea (PTU, 150)	1993 (T,R), 1994 (R), 1999 (T)
Prothioconazole (232)	2008 (T, R), 2009 (R)
Pyraclostrobin (210)	2003 (T), 2004 (R), 2006 (R), 2011 (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)

Pyrimethanil	2007 (T, R)
Pyriproxyfen (200)	1999 (R,T), 2000 (R), 2001 (T)
Quinoxyfen (223)	2006 (T, 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)
Saflufenacil (251)	2011 (T, R)
Spinetoram (233)	2008 (T, R)
Spinosad (203)	2001 (T, R, 2004 (R), 2008 (R), 2011 (R)
Spirotetramat (234)	2008 (T, R), 2011 (R)
Sulfoxaflor (252)	2011 (T, 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)
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)
Temephos	2006 (T)
Terbufos (167)	1989 (T,R), 1990 (T,R), 2003 (T), 2005 (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)
Thiacloprid (223)	2006 (T, R)
Thiamethoxam (245)	2010 (T, R), 2011 (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)
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)
Tolclofos-methyl (191)	1994 (T,R) 1996 (corr. to Annex II of 1995 report)
Tolylfluanid (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)
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)
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)
Triforine (116)	1977 (T), 1978 (T, R), 1997 (T)
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 OF PESTICIDE RESIDUES

ACEPHATE (095) International Estimated Daily Intake (IEDI) ADI = 0 - 0.03 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A diet	intake	B diet	intake	C diet	intake	D diet	intake	E diet	intake	F diet	intake
FP 0226	Apple (excl juice)	0.81	0.3	0.2	56.3	45.6	18.4	14.9	38.3	31.0	40.6	32.9	28.3	22.9
JF 0226	Apple juice	0.81	0.0	0.0	2.8	2.3	0.1	0.1	1.1	0.9	6.8	5.5	7.4	6.0
VS 0620	Artichoke globe	1.55	0.0	0.0	10.0	15.5	2.1	3.3	0.1	0.2	0.8	1.2	0.1	0.2
VP 0061	Beans except broad bean & soya bean (green pods & immature seeds)	1.35	1.0	1.4	17.4	23.5	7.5	10.1	0.9	1.2	16.4	22.1	0.1	0.1
VB 0400	Broccoli	0.16	0.0	0.0	0.7	0.1	1.2	0.2	0.1	0.0	4.2	0.7	4.0	0.6
VB 0401	Broccoli, Chinese	0.16	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
VB 0404	Cauliflower	0.16	0.1	0.0	5.2	0.8	1.2	0.2	0.1	0.0	1.7	0.3	0.1	0.0
FB 0265	Cranberries	0.18	0.1	0.0	0.0	0.0	0.0	0.0	0.3	0.1	0.0	0.0	0.6	0.1
MO 0105	Edible offal (mammalian)	0.022	3.9	0.1	14.4	0.3	5.2	0.1	11.8	0.3	11.7	0.3	7.6	0.2
PE 0112	Eggs	0	2.5	0.0	29.7	0.0	25.1	0.0	24.5	0.0	37.8	0.0	27.4	0.0
FC 0003	Mandarin + mandarin-like hybrid (incl juice)	1.15	0.6	0.7	19.1	22.0	12.3	14.1	5.5	6.3	9.9	11.4	11.7	13.5
MM 0095	Meat from mammals other than marine mammals	0.022	27.7	0.6	116.5	2.6	38.5	0.8	55.1	1.2	90.2	2.0	131.3	2.9
ML 0106	Milks (excl processed products)	0.011	68.8	0.8	190.6	2.1	79.4	0.9	302.6	3.3	179.6	2.0	237.9	2.6
FS 0245	Nectarine	1.35	0.0	0.0	0.5	0.7	3.3	4.5	1.8	2.4	2.8	3.8	1.6	2.2
FS 0247	Peach	1.35	0.2	0.3	24.8	33.5	3.3	4.5	1.8	2.4	5.4	7.3	1.6	2.2
FP 0230	Pear	0.81	0.1	0.1	22.3	18.1	2.8	2.3	4.8	3.9	10.7	8.7	6.8	5.5
VO 0051	Peppers	1.9	1.4	2.7	29.9	56.8	13.0	24.7	6.3	12.0	6.2	11.8	4.0	7.6
PM 0110	Poultry meat	0	7.1	0.0	58.5	0.0	31.9	0.0	24.0	0.0	61.0	0.0	27.3	0.0
GC 0649	Rice (excl husked, incl polished)	0.33	44.7	14.8	31.3	10.3	91.2	30.1	24.2	8.0	8.4	2.8	12.2	4.0
GC 0649	Rice (incl husked, excl polished)	0.405	46.3	18.8	0.3	0.1	3.4	1.4	9.1	3.7	4.3	1.7	0.6	0.2
VD 0541	Soya bean (dry, excl oil)	0.055	0.9	0.1	0.0	0.0	0.7	0.0	0.0	0.0	0.0	0.0	0.0	0.0
OR 0541	Soya bean oil, refined	0.023	1.6	0.0	6.5	0.1	6.0	0.1	4.0	0.1	6.3	0.1	7.0	0.2
	Total intake (µg/person)=			40.4		234.4		112.2		76.9		114.5		70.9
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			1800		1800		1800		1800		1800		1800
	%ADI=			2.2%		13.0%		6.2%		4.3%		6.4%		3.9%
	Rounded %ADI=			2%		10%		6%		4%		6%		4%

Annex 3

ACEPHATE (095) International Estimated Daily Intake (IEDI) ADI = 0 - 0.03 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G diet	intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake	M diet	intake
FP 0226	Apple (excl juice)	0.81	14.3	11.5	9.4	7.6	2.1	1.7	0.0	0.0	8.8	7.1	16.6	13.4	27.8	22.5
JF 0226	Apple juice	0.81	0.1	0.1	0.5	0.4	0.1	0.1	0.0	0.0	0.7	0.6	0.9	0.7	5.7	4.6
VS 0620	Artichoke globe	1.55	0.1	0.2	0.1	0.2	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	1.6
VP 0061	Beans except broad bean & soya bean (green pods & immature seeds)	1.35	2.6	3.5	2.6	3.5	1.0	1.4	0.5	0.7	0.6	0.8	2.8	3.8	9.8	13.2
VB 0400	Broccoli	0.16	3.2	0.5	7.8	1.2	0.0	0.0	0.0	0.0	0.3	0.0	0.4	0.1	6.6	1.1
VB 0401	Broccoli, Chinese	0.16	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
VB 0404	Cauliflower	0.16	3.2	0.5	0.1	0.0	0.3	0.0	0.1	0.0	0.6	0.1	0.4	0.1	1.4	0.2
FB 0265	Cranberries	0.18	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	2.5	0.5
MO 0105	Edible offal (mammalian)	0.022	4.8	0.1	10.7	0.2	4.0	0.1	4.0	0.1	6.5	0.1	6.6	0.1	5.6	0.1
PE 0112	Eggs	0	22.1	0.0	71.5	0.0	16.6	0.0	5.1	0.0	17.6	0.0	35.2	0.0	57.4	0.0
FC 0003	Mandarin + mandarin-like hybrid (incl juice)	1.15	7.0	8.1	6.5	7.5	0.8	0.9	0.2	0.2	9.3	10.7	19.1	22.0	6.5	7.5
MM 0095	Meat from mammals other than marine mammals	0.022	54.8	1.2	89.4	2.0	30.6	0.7	28.6	0.6	82.1	1.8	61.1	1.3	158.3	3.5
ML 0106	Milks (excl processed products)	0.011	66.0	0.7	121.1	1.3	81.6	0.9	102.4	1.1	207.7	2.3	57.0	0.6	287.9	3.2
FS 0245	Nectarine	1.35	1.7	2.3	1.7	2.3	0.0	0.0	0.0	0.0	1.0	1.4	1.7	2.3	1.4	1.9
FS 0247	Peach	1.35	1.7	2.3	1.7	2.3	1.1	1.5	0.1	0.1	1.0	1.4	1.7	2.3	10.2	13.8
FP 0230	Pear	0.81	6.4	5.2	1.9	1.5	1.2	1.0	0.0	0.0	1.8	1.5	6.9	5.6	7.8	6.3
VO 0051	Peppers	1.9	8.7	16.5	22.4	42.6	8.4	16.0	9.4	17.9	3.3	6.3	5.3	10.1	8.9	16.9
PM 0110	Poultry meat	0	17.6	0.0	131.3	0.0	25.1	0.0	4.7	0.0	145.9	0.0	27.7	0.0	115.1	0.0
GC 0649	Rice (excl husked, incl polished)	0.33	375.5	123.9	63.3	20.9	35.7	11.8	44.8	14.8	146.4	48.3	372.2	122.8	34.2	11.3
GC 0649	Rice (incl husked, excl polished)	0.405	1.4	0.6	1.0	0.4	2.3	0.9	29.6	12.0	92.0	37.3	9.2	3.7	0.4	0.2
VD 0541	Soya bean (dry, excl oil)	0.055	1.8	0.1	0.0	0.0	0.0	0.0	3.2	0.2	0.1	0.0	0.0	0.0	0.0	0.0
OR 0541	Soya bean oil, refined	0.023	4.3	0.1	10.6	0.2	2.0	0.0	1.4	0.0	19.5	0.4	9.2	0.2	22.0	0.5
	Total intake (µg/person)=			177.4		94.1		36.9		47.7		120.0		189.1		108.7
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			1650		1800		1800		1800		1800		1650		1800
	%ADI=			10.8%		5.2%		2.0%		2.7%		6.7%		11.5%		6.0%
	Rounded %ADI=			10%		5%		2%		3%		7%		10%		6%

Annex 3

ACETAMIPRID (246) International Estimated Daily Intake (IEDI) ADI = 0 - 0.07 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day Intake = daily intake: µg/person											
			A		B		C		D		E		F	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
JF 0226	Apple juice	0.2	0.0	0.0	2.8	0.6	0.1	0.0	1.1	0.2	6.8	1.4	7.4	1.5
VP 0061	Beans except broad bean & soya bean (green pods & immature seeds)	0.01	1.0	0.0	17.4	0.2	7.5	0.1	0.9	0.0	16.4	0.2	0.1	0.0
VP 0062	Beans, shelled (immature seeds)	0.03	0.5	0.0	12.7	0.4	4.1	0.1	0.9	0.0	13.1	0.4	0.1	0.0
FB 0018	Berries and other small fruits (excl grapes, excl strawberries, excl cranberries)	0.64	0.0	0.0	12.3	7.9	0.0	0.0	5.9	3.8	5.6	3.6	4.3	2.8
VB 0041	Cabbage, head	0.02	1.2	0.0	14.4	0.3	2.7	0.1	16.4	0.3	15.4	0.3	18.5	0.4
MO 1280	Cattle kidney	0.018	0.4	0.0	4.4	0.1	0.0	0.0	0.9	0.0	0.0	0.0	0.6	0.0
MO 1281	Cattle liver	0.011	0.4	0.0	4.4	0.0	1.7	0.0	0.9	0.0	1.0	0.0	0.6	0.0
VS 0624	Celery	0.3	0.0	0.0	0.9	0.3	0.0	0.0	2.0	0.6	1.5	0.5	0.0	0.0
FS 0013	Cherries	0.45	0.0	0.0	6.8	3.1	0.9	0.4	6.2	2.8	3.6	1.6	0.4	0.2
FC 0001	Citrus fruit (excl lemon juice, excl mandarin juice, excl orange juice, excl grapefruit juice, excl NES juice)	0.25	15.7	3.9	86.5	21.6	52.6	13.1	24.2	6.0	16.2	4.1	12.0	3.0
SO 0691	Cotton seed (for oil processing only)	0.09	5.6	0.5	30.6	2.8	10.6	1.0	41.3	3.7	0.0	0.0	1.9	0.2
OR 0691	Cotton seed oil, edible	0.004	0.9	0.0	4.9	0.0	1.7	0.0	6.6	0.0	0.0	0.0	0.3	0.0
FB 0265	Cranberries	0.64	0.1	0.1	0.0	0.0	0.0	0.0	0.3	0.2	0.0	0.0	0.6	0.4
VB 0042	Flowerhead brassicas	0.02	0.2	0.0	11.1	0.2	3.6	0.1	0.4	0.0	7.7	0.2	4.1	0.1
VO 0050	Fruiting vegetables other than cucurbits (excl sweet corn, excl mushrooms)	0.04	18.8	0.8	233.4	9.3	148.6	5.9	68.8	2.8	38.6	1.5	45.3	1.8
VC 0045	Fruiting vegetables, cucurbits	0.05	26.6	1.3	107.5	5.4	95.9	4.8	82.2	4.1	25.4	1.3	23.2	1.2
VA 0381	Garlic	0.01	0.4	0.0	3.9	0.0	3.8	0.0	3.7	0.0	1.0	0.0	0.6	0.0
FB 0269	Grape (excl dried, excl juice, incl wine)	0.085	3.7	0.3	116.8	9.9	25.4	2.2	31.4	2.7	96.3	8.2	35.8	3.0
JF 0269	Grape juice	0.13	0.0	0.0	0.1	0.0	0.1	0.0	0.1	0.0	1.4	0.2	1.0	0.1
DF 0269	Grape, dried (= currants, raisins and sultanas)	0.08	0.0	0.0	2.9	0.2	0.4	0.0	0.4	0.0	2.3	0.2	1.7	0.1
JF 0203	Grapefruit juice	0.03	0.0	0.0	0.2	0.0	0.1	0.0	0.1	0.0	1.1	0.0	0.2	0.0
VL 0053	Leafy vegetables	0.64	5.8	3.7	45.4	29.1	10.9	7.0	26.7	17.1	17.1	10.9	38.9	24.9
-d	Lemon juice	0.03	0.0	0.0	0.9	0.0	0.1	0.0	0.0	0.0	0.2	0.0	0.4	0.0
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.003	5.5	0.0	23.3	0.1	7.7	0.0	11.0	0.0	18.0	0.1	26.3	0.1
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0.004	22.2	0.1	93.2	0.4	30.8	0.1	44.1	0.2	72.2	0.3	105.0	0.4
ML 0106	Milks (excl processed products)	0.004	68.8	0.3	190.6	0.8	79.4	0.3	302.6	1.2	179.6	0.7	237.9	1.0
FS 0245	Nectarine	0.2	0.0	0.0	0.5	0.1	3.3	0.7	1.8	0.4	2.8	0.6	1.6	0.3
-	Onion, dry	0.01	4.3	0.0	45.6	0.5	27.4	0.3	30.2	0.3	22.1	0.2	12.2	0.1

Annex 3

ACETAMIPRID (246) International Estimated Daily Intake (IEDI) ADI = 0 - 0.07 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A		B		C		D		E		F	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
JF 0004	Orange juice	0.03	0.0	0.0	2.1	0.1	4.4	0.1	1.4	0.0	16.2	0.5	22.6	0.7
FS 0247	Peach	0.2	0.2	0.0	24.8	5.0	3.3	0.7	1.8	0.4	5.4	1.1	1.6	0.3
VP 0064	Peas, shelled (immature seeds only)	0.03	0.0	0.0	0.9	0.0	6.0	0.2	0.6	0.0	9.7	0.3	3.2	0.1
FS 0014	Plum (excl dried)	0.04	0.1	0.0	5.3	0.2	2.5	0.1	7.0	0.3	5.5	0.2	0.9	0.0
DF 0014	Plum, dried (prunes)	0.12	0.0	0.0	0.2	0.0	0.0	0.0	0.1	0.0	0.5	0.1	0.6	0.1
FP 0009	Pome fruit (excl apple juice)	0.225	0.5	0.1	79.9	18.0	21.8	4.9	43.6	9.8	51.5	11.6	35.1	7.9
PO 0111	Poultry, edible offal of	0.01	0.4	0.0	0.4	0.0	1.7	0.0	0.1	0.0	0.6	0.0	0.2	0.0
MO 1288	Sheep kidney	0.018	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
MO 1289	Sheep liver	0.011	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
VL 0502	Spinach	0.51	0.0	0.0	5.0	2.6	1.1	0.6	0.1	0.1	2.6	1.3	0.1	0.1
VA 0389	Spring onion	0.38	0.3	0.1	1.0	0.4	1.4	0.5	0.3	0.1	0.3	0.1	0.6	0.2
FB 0275	Strawberry	0.1	0.0	0.0	5.0	0.5	2.0	0.2	1.7	0.2	5.2	0.5	4.1	0.4
-d	Tomato paste	0.09	0.5	0.0	1.3	0.1	3.5	0.3	1.0	0.1	3.8	0.3	4.5	0.4
TN 0085	Tree nuts	0.01	4.2	0.0	21.5	0.2	3.9	0.0	3.0	0.0	5.5	0.1	10.2	0.1
	Total intake (µg/person)=			11.2		118.0		42.9		56.1		51.6		51.1
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			4200		4200		4200		4200		4200		4200
	%ADI=			0.3%		2.8%		1.0%		1.3%		1.2%		1.2%
	Rounded %ADI=			0%		3%		1%		1%		1%		1%

ACETAMIPRID (246) International Estimated Daily Intake (IEDI) ADI = 0 - 0.07 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G		H		I		J		K		L		M	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
JF 0226	Apple juice	0.2	0.1	0.0	0.5	0.1	0.1	0.0	0.0	0.0	0.7	0.1	0.9	0.2	5.7	1.1
VP 0061	Beans except broad bean & soya bean (green pods & immature seeds)	0.01	2.6	0.0	2.6	0.0	1.0	0.0	0.5	0.0	0.6	0.0	2.8	0.0	9.8	0.1
VP 0062	Beans, shelled (immature seeds)	0.03	2.6	0.1	1.9	0.1	1.0	0.0	0.5	0.0	0.3	0.0	1.8	0.1	9.0	0.3
FB 0018	Berries and other small fruits (excl grapes, excl strawberries, excl cranberries)	0.64	0.2	0.1	0.0	0.0	0.0	0.0	0.0	0.0	1.5	1.0	0.0	0.0	2.2	1.4
VB 0041	Cabbage, head	0.02	10.0	0.2	1.0	0.0	7.2	0.1	1.0	0.0	1.4	0.0	23.9	0.5	17.0	0.3
MO 1280	Cattle kidney	0.018	0.0	0.0	0.9	0.0	0.4	0.0	0.2	0.0	0.7	0.0	0.0	0.0	0.0	0.0
MO 1281	Cattle liver	0.011	0.0	0.0	0.9	0.0	0.4	0.0	0.2	0.0	0.7	0.0	0.0	0.0	0.4	0.0
VS 0624	Celery	0.3	0.0	0.0	0.3	0.1	0.0	0.0	0.0	0.0	1.0	0.3	0.0	0.0	4.2	1.3
FS 0013	Cherries	0.45	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.3	0.1	2.5	1.1

Annex 3

ACETAMIPRID (246) International Estimated Daily Intake (IEDI) ADI = 0 - 0.07 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day Intake = daily intake: µg/person													
			G		H		I		J		K		L		M	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
FC 0001	Citrus fruit (excl lemon juice, excl mandarin juice, excl orange juice, excl grapefruit juice, excl NES juice)	0.25	15.1	3.8	153.9	38.5	3.4	0.9	41.7	10.4	218.9	54.7	23.1	5.8	18.0	4.5
SO 0691	Cotton seed (for oil processing only)	0.09	6.3	0.6	4.4	0.4	6.3	0.6	8.8	0.8	9.4	0.8	34.4	3.1	7.5	0.7
OR 0691	Cotton seed oil, edible	0.004	1.0	0.0	0.7	0.0	1.0	0.0	1.4	0.0	1.5	0.0	5.5	0.0	1.2	0.0
FB 0265	Cranberries	0.64	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	2.5	1.6
VB 0042	Flowerhead brassicas	0.02	9.6	0.2	7.9	0.2	0.6	0.0	0.2	0.0	0.9	0.0	1.1	0.0	8.0	0.2
VO 0050	Fruiting vegetables other than cucurbits (excl sweet corn, excl mushrooms)	0.04	56.4	2.3	55.2	2.2	31.0	1.2	47.8	1.9	40.5	1.6	25.4	1.0	112.8	4.5
VC 0045	Fruiting vegetables, cucurbits	0.05	69.7	3.5	25.9	1.3	14.9	1.7	18.0	0.9	18.7	0.7	39.1	2.0	44.2	2.2
VA 0381	Garlic	0.01	6.4	0.1	1.2	0.0	0.1	0.0	0.3	0.0	1.9	0.0	5.0	0.1	2.5	0.0
FB 0269	Grape (excl dried, excl juice, incl wine)	0.085	2.6	0.2	3.9	0.3	9.5	0.8	0.3	0.0	4.8	0.4	8.7	0.7	43.4	3.7
JF 0269	Grape juice	0.13	0.0	0.0	0.1	0.0	1.0	0.1	0.0	0.0	0.6	0.1	0.4	0.1	3.6	0.5
DF 0269	Grape, dried (= currants, raisins and sultanas)	0.08	0.0	0.0	0.2	0.0	0.2	0.0	0.0	0.0	0.3	0.0	0.4	0.0	2.6	0.2
JF 0203	Grapefruit juice	0.03	0.0	0.0	0.0	0.0	0.5	0.0	0.0	0.0	0.0	0.0	0.3	0.0	2.4	0.1
VL 0053	Leafy vegetables	0.64	40.8	26.1	12.0	7.7	12.5	8.0	9.5	6.1	5.4	3.5	50.0	32.0	39.1	25.0
-d	Lemon juice	0.03	0.3	0.0	0.0	0.0	1.0	0.0	0.3	0.0	0.0	0.0	0.5	0.0	2.6	0.1
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.003	11.0	0.0	17.9	0.1	6.1	0.0	5.7	0.0	16.4	0.0	12.2	0.0	31.7	0.1
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0.004	43.8	0.2	71.5	0.3	24.5	0.1	22.9	0.1	65.7	0.3	48.9	0.2	126.6	0.5
ML 0106	Milks (excl processed products)	0.004	66.0	0.3	121.1	0.5	81.6	0.3	102.4	0.4	207.7	0.8	57.0	0.2	287.9	1.2
FS 0245	Nectarine	0.2	1.7	0.3	1.7	0.3	0.0	0.0	0.0	0.0	1.0	0.2	1.7	0.3	1.4	0.3
-	Onion, dry	0.01	16.8	0.2	8.6	0.1	6.9	0.1	12.1	0.1	18.6	0.2	23.8	0.2	28.4	0.3
JF 0004	Orange juice	0.03	0.2	0.0	1.0	0.0	3.5	0.1	0.0	0.0	1.3	0.0	6.4	0.2	56.8	1.7
FS 0247	Peach	0.2	1.7	0.3	1.7	0.3	1.1	0.2	0.1	0.0	1.0	0.2	1.7	0.3	10.2	2.0
VP 0064	Peas, shelled (immature seeds only)	0.03	3.9	0.1	1.6	0.0	0.0	0.0	0.0	0.0	0.4	0.0	1.0	0.0	0.8	0.0
FS 0014	Plum (excl dried)	0.04	3.0	0.1	0.8	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.9	0.0	0.5	0.0
DF 0014	Plum, dried (prunes)	0.12	0.1	0.0	0.2	0.0	0.0	0.0	0.0	0.0	0.2	0.0	0.2	0.0	0.6	0.1
FP 0009	Pome fruit (excl apple juice)	0.225	20.8	4.7	11.6	2.6	3.3	0.7	0.1	0.0	10.7	2.4	23.6	5.3	36.9	8.3
PO 0111	Poultry, edible offal of	0.01	0.4	0.0	1.0	0.0	1.9	0.0	0.0	0.0	0.7	0.0	1.0	0.0	0.3	0.0
MO 1288	Sheep kidney	0.018	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
MO 1289	Sheep liver	0.011	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
VL 0502	Spinach	0.51	9.4	4.8	0.4	0.2	0.0	0.0	0.0	0.0	0.2	0.1	4.3	2.2	2.0	1.0
VA 0389	Spring onion	0.38	0.1	0.0	4.8	1.8	0.1	0.0	1.0	0.4	1.0	0.4	2.7	1.0	0.6	0.2
FB 0275	Strawberry	0.1	0.0	0.0	1.8	0.2	0.1	0.0	0.0	0.0	0.3	0.0	6.2	0.6	5.9	0.6
-d	Tomato paste	0.09	0.1	0.0	2.1	0.2	0.6	0.1	0.4	0.0	0.6	0.1	1.4	0.1	1.2	0.1
TN 0085	Tree nuts	0.01	16.3	0.2	15.7	0.2	9.7	0.1	1.9	0.0	19.1	0.2	29.0	0.3	5.6	0.1

Annex 3

ACETAMIPRID (246) International Estimated Daily Intake (IEDI) ADI = 0 - 0.07 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G		H		I		J		K		L		M	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
	Total intake (µg/person)=			47.6		57.5		14.2		21.1		68.2		56.4		64.4
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			3850		4200		4200		4200		4200		3850		4200
	%ADI=			1.2%		1.4%		0.3%		0.5%		1.6%		1.5%		1.5%
	Rounded %ADI=			1%		1%		0%		1%		2%		1%		2%

AZOXYSTROBIN (229) International Estimated Daily Intake (IEDI) ADI = 0–0.2 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A		B		C		D		E		F	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
TN 0660	Almond	0.01	0.0	0.0	1.9	0.0	1.0	0.0	0.0	0.0	1.0	0.0	0.8	0.0
VS 0620	Artichoke globe	1.8	0.0	0.0	10.0	18.0	2.1	3.8	0.1	0.2	0.8	1.4	0.1	0.2
VS 0621	Asparagus	0.01	0.0	0.0	1.1	0.0	0.6	0.0	0.2	0.0	1.2	0.0	0.1	0.0
FI 0327	Banana	0.03	38.8	1.2	17.4	0.5	16.0	0.5	6.6	0.2	21.5	0.6	33.8	1.0
GC 0640	Barley (incl pot, incl pearled, incl flour & grits, excl beer)	0.08	40.6	3.2	0.0	0.0	93.9	7.5	0.0	0.0	0.0	0.0	3.8	0.3
-	Barley beer	0.002	18.3	0.0	84.1	0.2	4.1	0.0	66.0	0.1	243.1	0.5	161.3	0.3
FB 0264	Blackberries	1	0.0	0.0	0.1	0.1	0.0	0.0	0.3	0.3	0.1	0.1	0.3	0.3
FB 0020	Blueberries	1	0.0	0.0	0.0	0.0	0.0	0.0	0.2	0.2	0.3	0.3	0.8	0.8
FB 4079	Boysenberry	1	0.0	0.0	0.0	0.0	0.0	0.0	0.3	0.3	0.0	0.0	0.3	0.3
TN 0662	Brazil nut	0.01	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0
VB 0402	Brussels sprouts	1.2	0.0	0.0	0.1	0.1	2.8	3.4	5.5	6.6	1.5	1.8	1.9	2.3
VA 0035	Bulb vegetables	2.2	8.5	18.7	60.3	132.7	37.7	82.9	37.2	81.8	31.8	70.0	16.7	36.7
VB 0041	Cabbage, head	1.2	1.2	1.4	14.4	17.3	2.7	3.2	16.4	19.7	15.4	18.5	18.5	22.2
TN 0295	Cashew nut	0.01	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.3	0.0	0.0	0.0
VS 0624	Celery	0.43	0.0	0.0	0.9	0.4	0.0	0.0	2.0	0.9	1.5	0.6	0.0	0.0
VC 0423	Chayote	0.17	ND	–	ND	–	ND	–	ND	–	ND	–	ND	–
TN 0664	Chestnut	0.01	0.0	0.0	1.7	0.0	0.0	0.0	0.2	0.0	0.3	0.0	0.0	0.0
FC 0001	Citrus fruit (excl lemon juice, excl mandarin juice, excl orange juice, incl grapefruit juice, incl NES juice)	4.9	15.7	76.9	91.3	447.4	53.0	259.9	24.4	119.6	21.4	104.8	13.2	64.7
TN 0665	Coconut (incl oil)	0.01	2.9	0.0	13.5	0.1	2.1	0.0	1.5	0.0	1.8	0.0	8.9	0.1
SB 0716	Coffee beans (incl green, incl extracts, incl roasted)	0.01	3.1	0.0	12.6	0.1	2.9	0.0	1.4	0.0	10.1	0.1	18.0	0.2

Annex 3

AZOXYSTROBIN (229) International Estimated Daily Intake (IEDI) ADI = 0–0.2 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day			Intake = daily intake: µg/person							
			A		B		C		D		E		F	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
SO 0691	Cotton seed (for oil processing only)	0.01	5.6	0.1	30.6	0.3	10.6	0.1	41.3	0.4	0.0	0.0	1.9	0.0
FB 0265	Cranberries	0.23	0.1	0.0	0.0	0.0	0.0	0.0	0.3	0.1	0.0	0.0	0.6	0.1
VC 0424	Cucumber	0.17	0.3	0.1	12.7	2.2	5.9	1.0	11.5	2.0	6.1	1.0	7.1	1.2
FB 0021	Currants, red, black, white	1	0.0	0.0	0.0	0.0	0.0	0.0	2.2	2.2	3.1	3.1	2.0	2.0
FB 0266	Dewberries, incl boysenberry & loganberry	1	0.0	0.0	0.0	0.0	0.0	0.0	0.3	0.3	0.0	0.0	0.3	0.3
DH 0170	Dried herbs (excl dry hops)	152	0.2	35.0	0.3	42.6	0.2	36.5	0.4	60.8	0.3	45.6	0.0	1.5
MO 0105	Edible offal (mammalian)	0.01	3.9	0.0	14.4	0.1	5.2	0.1	11.8	0.1	11.7	0.1	7.6	0.1
VO 0440	Eggplant (= aubergine)	0.35	1.7	0.6	17.5	6.1	12.3	4.3	1.7	0.6	0.8	0.3	0.4	0.1
PE 0112	Eggs	0	2.5	0.0	29.7	0.0	25.1	0.0	24.5	0.0	37.8	0.0	27.4	0.0
FB 0267	Elderberries	1	ND	–	ND	–	ND	–	ND	–	ND	–	ND	–
VB 0042	Flowerhead Brassicas	1.2	0.2	0.2	11.1	13.3	3.6	4.3	0.4	0.5	7.7	9.2	4.1	4.9
VC 0425	Gherkin	0.17	0.3	0.1	12.7	2.2	5.9	1.0	11.5	2.0	6.1	1.0	7.1	1.2
FB 0268	Gooseberries	1	0.0	0.0	12.0	12.0	0.0	0.0	0.6	0.6	1.1	1.1	0.2	0.2
FB 0269	Grape (excl dried, excl juice, excl wine)	0.53	1.9	1.0	9.2	4.9	23.8	12.6	9.8	5.2	0.0	0.0	0.0	0.0
JF 0269	Grape juice	0.19	0.0	0.0	0.1	0.0	0.1	0.0	0.1	0.0	1.4	0.3	1.0	0.2
DF 0269	Grape, dried (= currants, raisins and sultanas)	0.24	0.0	0.0	2.9	0.7	0.4	0.1	0.4	0.1	2.3	0.6	1.7	0.4
TN 0666	Hazelnut	0.01	0.0	0.0	2.1	0.0	0.0	0.0	0.1	0.0	1.3	0.0	0.3	0.0
HH 0720	Herbs	23	2.3	52.9	2.8	64.4	2.4	55.2	4.0	92.0	3.0	69.0	0.1	2.3
DH 1100	Hops, dry	11	0.1	1.1	0.1	1.1	0.1	1.1	0.1	1.1	0.3	3.3	0.1	1.1
VB 0405	Kohlrabi	1.2	0.3	0.4	0.1	0.1	0.0	0.0	5.5	6.6	12.3	14.8	1.9	2.3
VP 0060	Legume vegetables	1	6.1	6.1	23.0	23.0	18.0	18.0	12.8	12.8	26.9	26.9	5.3	5.3
VL 0482	Lettuce, head	0.28	0.1	0.0	6.2	1.7	0.7	0.2	0.1	0.0	0.1	0.0	0.0	0.0
VL 0483	Lettuce, leaf	0.28	0.0	0.0	9.2	2.6	1.0	0.3	0.1	0.0	5.4	1.5	18.0	5.0
TN 0669	Macadamia nut	0.01	ND	–	ND	–	ND	–	ND	–	ND	–	ND	–
CF 1255	Maize flour	0.01	68.9	0.7	15.4	0.2	51.3	0.5	16.6	0.2	14.7	0.1	2.0	0.0
GC 0645	Maize (excl flour, excl oil, incl beer)	0.01	0.0	0.0	1.4	0.0	51.4	0.5	11.9	0.1	0.2	0.0	0.2	0.0
OR 0645	Maize oil, edible	0.06	0.1	0.0	4.0	0.2	2.3	0.1	0.5	0.0	0.9	0.1	0.2	0.0
MF 0100	Mammalian fats (except milk fats)	0.01	0.8	0.0	10.0	0.1	0.9	0.0	6.6	0.1	11.8	0.1	3.7	0.0
FI 0345	Mango (incl juice, incl pulp)	0.05	6.3	0.3	1.0	0.1	4.6	0.2	0.2	0.0	0.7	0.0	0.3	0.0
MM 0095	Meat from mammals other than marine mammals	0.01	27.7	0.3	116.5	1.2	38.5	0.4	55.1	0.6	90.2	0.9	131.3	1.3
VC 0046	Melons, except watermelon	0.02	3.6	0.1	26.7	0.5	22.6	0.5	11.5	0.2	5.6	0.1	2.0	0.0
ML 0106	Milks (excl processed products)	0.01	68.8	0.7	190.6	1.9	79.4	0.8	302.6	3.0	179.6	1.8	237.9	2.4

Annex 3

AZOXYSTROBIN (229) International Estimated Daily Intake (IEDI) ADI = 0–0.2 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day				Intake = daily intake: µg/person							
			A		B		C		D		E		F	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
GC 0647	Oats (incl rolled)	0.08	1.4	0.1	0.6	0.0	0.2	0.0	4.2	0.3	5.7	0.5	8.9	0.7
VO 0442	Okra	0.35	3.9	1.4	1.0	0.4	5.3	1.9	0.1	0.0	0.0	0.0	0.0	0.0
JF 0004	Orange juice	0.39	0.0	0.0	2.1	0.8	4.4	1.7	1.4	0.5	16.2	6.3	22.6	8.8
FI 0350	Papaya	0.02	5.1	0.1	0.1	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0
OR 0697	Peanut oil, edible	0.03	1.7	0.1	0.8	0.0	0.5	0.0	0.1	0.0	1.4	0.0	0.4	0.0
SO 0697	Peanut, shelled (excl oil)	0.01	1.5	0.0	1.3	0.0	1.0	0.0	0.5	0.0	0.8	0.0	0.5	0.0
TN 0672	Pecan	0.01	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0
VO 0051	Peppers	0.35	1.4	0.5	29.9	10.5	13.0	4.6	6.3	2.2	6.2	2.2	4.0	1.4
TN 0673	Pine nut	0.01	ND	–	ND	–	ND	–	ND	–	ND	–	ND	–
TN 0675	Pistachio nut	0.44	0.0	0.0	0.7	0.3	0.5	0.2	0.9	0.4	0.3	0.1	0.0	0.0
FI 0354	Plantain	0.03	275.7	8.3	1.7	0.1	0.0	0.0	0.1	0.0	0.3	0.0	0.0	0.0
DF 0014	Plum, dried (prunes)	0.14	0.0	0.0	0.2	0.0	0.0	0.0	0.1	0.0	0.5	0.1	0.6	0.1
PM 0110	Poultry meat	0	7.1	0.0	58.5	0.0	31.9	0.0	24.0	0.0	61.0	0.0	27.3	0.0
PO 0111	Poultry, edible offal of	0	0.4	0.0	0.4	0.0	1.7	0.0	0.1	0.0	0.6	0.0	0.2	0.0
FB 0272	Raspberries, red, black	1	0.0	0.0	0.0	0.0	0.0	0.0	1.8	1.8	0.9	0.9	0.2	0.2
GC 0649	Rice (incl husked, excl polished)	0.68	46.3	31.5	0.3	0.2	3.4	2.3	9.1	6.2	4.3	2.9	0.6	0.4
CM 1205	Rice, polished (incl flour)	0.06	29.8	1.8	20.9	1.3	60.8	3.6	16.1	1.0	5.6	0.3	8.1	0.5
VR 0075	Root and tuber vegetables	0.23	528.2	121.5	352.8	81.1	78.5	18.0	270.3	62.2	324.1	74.5	261.3	60.1
GC 0650	Rye (incl flour)	0.01	0.1	0.0	3.7	0.0	0.3	0.0	24.3	0.2	25.8	0.3	45.8	0.5
VD 0541	Soya bean (dry, excl oil)	0.06	0.9	0.1	0.0	0.0	0.7	0.0	0.0	0.0	0.0	0.0	0.0	0.0
OR 0541	Soya bean oil, refined	0.05	1.6	0.1	6.5	0.3	6.0	0.3	4.0	0.2	6.3	0.3	7.0	0.4
VC 0431	Squash, summer (= courgette, zucchini)	0.17	0.0	0.0	8.3	1.4	11.4	1.9	7.3	1.2	3.2	0.5	0.3	0.1
FS 0012	Stone fruit (excl dried plums, incl dried apricots)	0.74	0.7	0.5	44.1	32.6	14.1	10.4	26.6	19.7	26.3	19.4	8.3	6.1
FB 0275	Strawberry	1.3	0.0	0.0	5.0	6.5	2.0	2.6	1.7	2.2	5.2	6.8	4.1	5.3
VR 0596	Sugar beet	0.08	0.0	0.0	40.7	3.3	0.0	0.0	0.1	0.0	6.0	0.5	0.1	0.0
SO 0702	Sunflower seed (excl oil)	0.04	0.0	0.0	13.1	0.5	0.0	0.0	0.1	0.0	0.1	0.0	0.1	0.0
OR 0702	Sunflower seed oil, edible	0.01	0.3	0.0	13.1	0.1	8.6	0.1	12.3	0.1	8.8	0.1	2.2	0.0
VO 0448	Tomato (excl juice, excl paste, incl canned)	0.35	3.3	1.2	179.2	62.7	103.5	36.2	54.1	18.9	7.8	2.7	3.9	1.4
JF 0448	Tomato juice	0.13	5.2	0.7	0.5	0.1	0.4	0.1	2.1	0.3	6.9	0.9	15.2	2.0
-d	Tomato paste	0.19	0.5	0.1	1.3	0.2	3.5	0.7	1.0	0.2	3.8	0.7	4.5	0.9
GC 0653	Triticale (incl flour)	0.01	0.0	0.0	115.8	1.2	0.0	0.0	0.0	0.0	0.3	0.0	0.0	0.0
TN 0678	Walnut	0.01	0.0	0.0	1.3	0.0	0.0	0.0	0.1	0.0	0.3	0.0	0.1	0.0
VC 0432	Watermelon	0.02	6.1	0.1	43.1	0.9	47.1	0.9	25.8	0.5	4.4	0.1	6.0	0.1

Annex 3

AZOXYSTROBIN (229) International Estimated Daily Intake (IEDI) ADI = 0–0.2 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day			Intake = daily intake: µg/person								
			A		B		C		D		E		F	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
GC 0654	Wheat (excl bulgur wholemeal, excl flour)	0.01	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0
CM 0654	Wheat bran, unprocessed	0.004	ND	–	ND	–	ND	–	ND	–	ND	–	ND	–
CF 1211	Wheat flour (incl macaroni, bread, pastry, starch, gluten)	0.003	63.4	0.2	296.3	0.9	327.5	1.0	300.0	0.9	181.6	0.5	166.2	0.5
CP 1211	White bread	0.001	0.0	0.0	0.1	0.0	0.0	0.0	0.1	0.0	0.1	0.0	1.0	0.0
CP 1212	Wholemeal bread	0.001	0.0	0.0	0.1	0.0	0.0	0.0	0.1	0.0	0.1	0.0	1.0	0.0
-	Wine	0.36	1.3	0.5	76.8	27.6	1.1	0.4	15.4	5.5	68.8	24.8	25.6	9.2
VC 0433	Winter squash (= pumpkin)	0.02	0.0	0.0	0.5	0.0	1.5	0.0	7.3	0.1	0.0	0.0	0.3	0.0
VS 0469	Witlof chicory (sprouts)	0.05	0.0	0.0	0.2	0.0	0.0	0.0	0.1	0.0	1.6	0.1	0.0	0.0
	Total intake (µg/person)=			369.6		1031.5		586.2		546.3		525.4		260.1
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			12000		12000		12000		12000		12000		12000
	%ADI=			3.1%		8.6%		4.9%		4.6%		4.4%		2.2%
	Rounded %ADI=			3%		9%		5%		5%		4%		2%

AZOXYSTROBIN (229) International Estimated Daily Intake (IEDI) ADI = 0–0.2 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day				Intake = daily intake: µg/person									
			G		H		I		J		K		L		M	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
TN 0660	Almond	0.01	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.3	0.0	0.3	0.0
VS 0620	Artichoke globe	1.8	0.1	0.2	0.1	0.2	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	1.8
VS 0621	Asparagus	0.01	3.7	0.0	0.3	0.0	0.2	0.0	0.0	0.0	0.0	0.0	0.5	0.0	1.1	0.0
FI 0327	Banana	0.03	21.4	0.6	36.6	1.1	11.4	0.3	9.2	0.3	70.2	2.1	40.5	1.2	32.6	1.0
GC 0640	Barley (incl pot, incl pearled, incl flour & grits, excl beer)	0.08	1.5	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.4	0.0	0.0	0.0
-	Barley beer	0.002	21.9	0.0	102.7	0.2	29.5	0.1	12.6	0.0	100.9	0.2	82.2	0.2	218.8	0.4
FB 0264	Blackberries	1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.1	0.0	0.0	0.3	0.3
FB 0020	Blueberries	1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.3	1.3
FB 4079	Boysenberry	1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.1	0.0	0.0	0.0	0.0
TN 0662	Brazil nut	0.01	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.1	0.0
VB 0402	Brussels sprouts	1.2	3.4	4.1	0.4	0.5	0.0	0.0	0.0	0.0	0.5	0.6	7.9	9.5	0.3	0.4
VA 0035	Bulb vegetables	2.2	31.6	69.5	29.6	65.1	9.7	21.3	19.6	43.1	25.7	56.5	47.2	103.8	33.1	72.8

Annex 3

AZOXYSTROBIN (229) International Estimated Daily Intake (IEDI) ADI = 0–0.2 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day				Intake = daily intake: µg/person									
			G		H		I		J		K		L		M	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
VB 0041	Cabbage, head	1.2	10.0	12.0	1.0	1.2	7.2	8.6	1.0	1.2	1.4	1.7	23.9	28.7	17.0	20.4
TN 0295	Cashew nut	0.01	0.2	0.0	0.0	0.0	0.2	0.0	0.0	0.0	0.1	0.0	0.1	0.0	0.6	0.0
VS 0624	Celery	0.43	0.0	0.0	0.3	0.1	0.0	0.0	0.0	0.0	1.0	0.4	0.0	0.0	4.2	1.8
VC 0423	Chayote	0.17	ND	–	ND	–	ND	–	ND	–	ND	–	ND	–	ND	–
TN 0664	Chestnut	0.01	0.5	0.0	0.7	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.5	0.0	0.0	0.0
FC 0001	Citrus fruit (excl lemon juice, excl mandarin juice, excl orange juice, incl grapefruit juice, incl NES juice)	4.9	15.1	73.8	153.9	754.1	5.8	28.3	41.7	204.4	218.9	1072.7	24.5	120.1	23.3	114.2
TN 0665	Coconut (incl oil)	0.01	15.3	0.2	13.4	0.1	9.3	0.1	1.6	0.0	18.9	0.2	26.7	0.3	3.4	0.0
SB 0716	Coffee beans (incl green, incl extracts, incl roasted)	0.01	0.2	0.0	7.0	0.1	0.5	0.0	0.2	0.0	5.3	0.1	5.7	0.1	12.4	0.1
SO 0691	Cotton seed (for oil processing only)	0.01	6.3	0.1	4.4	0.0	6.3	0.1	8.8	0.1	9.4	0.1	34.4	0.3	7.5	0.1
FB 0265	Cranberries	0.23	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	2.5	0.6
VC 0424	Cucumber	0.17	7.9	1.3	0.6	0.1	0.2	0.0	0.0	0.0	0.4	0.1	5.5	0.9	5.3	0.9
FB 0021	Currants, red, black, white	1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
FB 0266	Dewberries, incl boysenberry & loganberry	1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.1	0.0	0.0	0.1	0.1
DH 0170	Dried herbs (excl dry hops)	152	0.7	106.4	0.1	9.1	0.2	35.0	0.3	50.2	0.2	30.4	0.1	18.2	0.1	7.6
MO 0105	Edible offal (mammalian)	0.01	4.8	0.0	10.7	0.1	4.0	0.0	4.0	0.0	6.5	0.1	6.6	0.1	5.6	0.1
VO 0440	Egg plant (= aubergine)	0.35	20.1	7.0	0.1	0.0	0.6	0.2	6.3	2.2	0.5	0.2	6.3	2.2	0.7	0.2
PE 0112	Eggs	0	22.1	0.0	71.5	0.0	16.6	0.0	5.1	0.0	17.6	0.0	35.2	0.0	57.4	0.0
FB 0267	Elderberries	1	ND	–	ND	–	ND	–	ND	–	ND	–	ND	–	ND	–
VB 0042	Flowerhead Brassicas	1.2	9.6	11.5	7.9	9.5	0.6	0.7	0.2	0.2	0.9	1.1	1.1	1.3	8.0	9.6
VC 0425	Gherkin	0.17	7.9	1.3	0.6	0.1	0.2	0.0	0.0	0.0	0.4	0.1	5.5	0.9	5.3	0.9
FB 0268	Gooseberries	1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	1.0	0.0	0.0	0.0	0.0
FB 0269	Grape (excl dried, excl juice, excl wine)	0.53	1.2	0.6	2.6	1.4	0.0	0.0	0.2	0.1	0.0	0.0	3.7	2.0	0.0	0.0
JF 0269	Grape juice	0.19	0.0	0.0	0.1	0.0	1.0	0.2	0.0	0.0	0.6	0.1	0.4	0.1	3.6	0.7
DF 0269	Grape, dried (= currants, raisins and sultanas)	0.24	0.0	0.0	0.2	0.0	0.2	0.0	0.0	0.0	0.3	0.1	0.4	0.1	2.6	0.6
TN 0666	Hazelnut	0.01	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.0
HH 0720	Herbs	23	7.0	161.0	0.6	13.8	2.3	52.9	3.3	75.9	2.0	46.0	1.2	27.6	0.5	11.5
DH 1100	Hops, dry	11	0.0	0.0	0.1	1.1	0.1	1.1	0.1	1.1	0.1	1.1	0.1	1.1	0.6	6.6
VB 0405	Kohlrabi	1.2	3.4	4.1	0.0	0.0	0.0	0.0	0.3	0.4	0.5	0.6	7.9	9.5	0.7	0.8
VP 0060	Legume vegetables	1	19.6	19.6	6.2	6.2	6.9	6.9	6.0	6.0	1.7	1.7	29.5	29.5	26.3	26.3
VL 0482	Lettuce, head	0.28	1.2	0.3	3.5	1.0	0.1	0.0	0.3	0.1	1.0	0.3	1.2	0.3	7.9	2.2
VL 0483	Lettuce, leaf	0.28	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	2.5	0.7
TN 0669	Macadamia nut	0.01	ND	–	ND	–	ND	–	ND	–	ND	–	ND	–	ND	–
CF 1255	Maize flour	0.01	28.8	0.3	248.8	2.5	206.7	2.1	47.8	0.5	46.2	0.5	10.5	0.1	21.5	0.2
GC 0645	Maize (excl flour, excl oil, incl beer)	0.01	0.6	0.0	0.0	0.0	0.1	0.0	0.0	0.0	7.7	0.1	0.0	0.0	19.4	0.2

Annex 3

AZOXYSTROBIN (229) International Estimated Daily Intake (IEDI) ADI = 0–0.2 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day			Intake = daily intake: µg/person										
			G		H		I		J		K		L		M	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
OR 0645	Maize oil, edible	0.06	0.1	0.0	0.6	0.0	1.8	0.1	0.0	0.0	1.0	0.1	1.6	0.1	1.8	0.1
MF 0100	Mammalian fats (except milk fats)	0.01	2.2	0.0	18.6	0.2	0.5	0.0	0.8	0.0	5.7	0.1	4.5	0.0	18.2	0.2
FI 0345	Mango (incl juice, incl pulp)	0.05	12.7	0.6	26.2	1.3	6.1	0.3	12.7	0.6	9.2	0.5	8.0	0.4	1.9	0.1
MM 0095	Meat from mammals other than marine mammals	0.01	54.8	0.5	89.4	0.9	30.6	0.3	28.6	0.3	82.1	0.8	61.1	0.6	158.3	1.6
VC 0046	Melons, except watermelon	0.02	7.5	0.2	6.1	0.1	0.7	0.0	1.4	0.0	2.5	0.1	6.9	0.1	12.4	0.2
ML 0106	Milks (excl processed products)	0.01	66.0	0.7	121.1	1.2	81.6	0.8	102.4	1.0	207.7	2.1	57.0	0.6	287.9	2.9
GC 0647	Oats (incl rolled)	0.08	0.2	0.0	2.0	0.2	0.8	0.1	0.0	0.0	3.5	0.3	0.7	0.1	7.6	0.6
VO 0442	Okra	0.35	4.1	1.4	1.0	0.4	7.0	2.5	15.9	5.6	1.1	0.4	3.9	1.4	0.2	0.1
JF 0004	Orange juice	0.39	0.2	0.1	1.0	0.4	3.5	1.4	0.0	0.0	1.3	0.5	6.4	2.5	56.8	22.2
FI 0350	Papaya	0.02	1.3	0.0	11.5	0.2	1.6	0.0	13.7	0.3	14.5	0.3	1.0	0.0	0.6	0.0
OR 0697	Peanut oil, edible	0.03	3.0	0.1	0.3	0.0	1.5	0.0	7.9	0.2	0.3	0.0	0.0	0.0	0.4	0.0
SO 0697	Peanut, shelled (excl oil)	0.01	0.7	0.0	1.4	0.0	1.3	0.0	3.6	0.0	0.2	0.0	0.7	0.0	6.0	0.1
TN 0672	Pecan	0.01	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.0
VO 0051	Peppers	0.35	8.7	3.0	22.4	7.8	8.4	2.9	9.4	3.3	3.3	1.2	5.3	1.9	8.9	3.1
TN 0673	Pine nut	0.01	ND	–	ND	–	ND	–	ND	–	ND	–	ND	–	ND	–
TN 0675	Pistachio nut	0.44	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.2	0.1
FI 0354	Plantain	0.03	1.8	0.1	51.2	1.5	93.3	2.8	40.6	1.2	39.2	1.2	1.1	0.0	1.9	0.1
DF 0014	Plum, dried (prunes)	0.14	0.1	0.0	0.2	0.0	0.0	0.0	0.0	0.0	0.2	0.0	0.2	0.0	0.6	0.1
PM 0110	Poultry meat	0	17.6	0.0	131.3	0.0	25.1	0.0	4.7	0.0	145.9	0.0	27.7	0.0	115.1	0.0
PO 0111	Poultry, edible offal of	0	0.4	0.0	1.0	0.0	1.9	0.0	0.0	0.0	0.7	0.0	1.0	0.0	0.3	0.0
FB 0272	Raspberries, red, black	1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.2	0.2	0.0	0.0	0.5	0.5
GC 0649	Rice (incl husked, excl polished)	0.68	1.4	1.0	1.0	0.7	2.3	1.6	29.6	20.1	92.0	62.6	9.2	6.2	0.4	0.3
CM 1205	Rice, polished (incl flour)	0.06	250.3	15.0	42.2	2.5	23.8	1.4	29.8	1.8	97.6	5.9	248.1	14.9	22.8	1.4
VR 0075	Root and tuber vegetables	0.23	139.1	32.0	109.8	25.3	409.6	94.2	444.6	102.3	145.3	33.4	127.0	29.2	225.6	51.9
GC 0650	Rye (incl flour)	0.01	0.4	0.0	0.0	0.0	0.2	0.0	0.1	0.0	0.1	0.0	0.9	0.0	0.8	0.0
VD 0541	Soya bean (dry, excl oil)	0.06	1.8	0.1	0.0	0.0	0.0	0.0	3.2	0.2	0.1	0.0	0.0	0.0	0.0	0.0
OR 0541	Soya bean oil, refined	0.05	4.3	0.2	10.6	0.5	2.0	0.1	1.4	0.1	19.5	1.0	9.2	0.5	22.0	1.1
VC 0431	Squash, summer (= courgette, zucchini)	0.17	2.4	0.4	1.5	0.3	0.0	0.0	0.0	0.0	3.8	0.6	2.2	0.4	2.5	0.4
FS 0012	Stone fruit (excl dried plums, incl dried apricots)	0.74	6.7	5.0	4.3	3.2	1.4	1.0	0.1	0.1	4.9	3.6	4.9	3.6	17.7	13.1
FB 0275	Strawberry	1.3	0.0	0.0	1.8	2.3	0.1	0.1	0.0	0.0	0.3	0.4	6.2	8.1	5.9	7.7
VR 0596	Sugar beet	0.08	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.2	0.0	0.0	0.0	14.3	1.1
SO 0702	Sunflower seed (excl oil)	0.04	0.1	0.0	0.2	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.1	0.0	1.8	0.1
OR 0702	Sunflower seed oil, edible	0.01	1.1	0.0	3.6	0.0	5.6	0.1	0.1	0.0	1.5	0.0	0.2	0.0	3.6	0.0
VO 0448	Tomato (excl juice, excl paste, incl canned)	0.35	23.1	8.1	22.3	7.8	12.5	4.4	5.6	2.0	33.2	11.6	1.3	0.5	41.7	14.6
JF 0448	Tomato juice	0.13	0.0	0.0	0.8	0.1	0.1	0.0	7.2	0.9	0.0	0.0	2.4	0.3	45.2	5.9
-d	Tomato paste	0.19	0.1	0.0	2.1	0.4	0.6	0.1	0.4	0.1	0.6	0.1	1.4	0.3	1.2	0.2
GC 0653	Triticale (incl flour)	0.01	1.3	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0

Annex 3

AZOXYSTROBIN (229) International Estimated Daily Intake (IEDI) ADI = 0–0.2 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day				Intake = daily intake: µg/person									
			G		H		I		J		K		L		M	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
TN 0678	Walnut	0.01	0.2	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.4	0.0
VC 0432	Watermelon	0.02	39.3	0.8	14.0	0.3	2.5	0.1	13.6	0.3	8.4	0.2	14.5	0.3	13.6	0.3
GC 0654	Wheat (excl bulgur wholemeal, excl flour)	0.01	0.0	0.0	0.9	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.1	0.0
CM 0654	Wheat bran, unprocessed	0.004	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CF 1211	Wheat flour (incl macaroni, bread, pastry, starch, gluten)	0.003	133.0	0.4	60.1	0.2	52.4	0.2	32.2	0.1	87.7	0.3	79.6	0.2	180.1	0.5
CP 1211	White bread	0.001	0.0	0.0	2.2	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
CP 1212	Wholemeal bread	0.001	0.0	0.0	2.2	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
-	Wine	0.36	1.0	0.4	0.9	0.3	6.8	2.4	0.1	0.0	3.4	1.2	3.6	1.3	31.0	11.2
VC 0433	Winter squash (= pumpkin)	0.02	2.4	0.0	1.5	0.0	0.0	0.0	0.0	0.0	1.6	0.0	2.2	0.0	0.7	0.0
VS 0469	Witlof chicory (sprouts)	0.05	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.8	0.0
	Total intake (µg/person)=			544.5		926.1		275.0		526.3		1346.7		431.6		426.1
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			11000		12000		12000		12000		12000		11000		12000
	%ADI=			4.9%		7.7%		2.3%		4.4%		11.2%		3.9%		3.6%
	Rounded %ADI=			5%		8%		2%		4%		10%		4%		4%

CYPERMETHRINS (118) International Estimated Daily Intake (IEDI) ADI = 0–0.02 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day				Intake = daily intake: µg/person							
			A		B		C		D		E		F	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
VS 0620	Artichoke globe	0.025	0.0	0.0	10.0	0.3	2.1	0.1	0.1	0.0	0.8	0.0	0.1	0.0
VS 0621	Asparagus	0.09	0.0	0.0	1.1	0.1	0.6	0.1	0.2	0.0	1.2	0.1	0.1	0.0
-	Assorted (sub)tropical fruits NES (excl passion fruit)	0.495	5.2	2.6	6.5	3.2	1.2	0.6	0.0	0.0	16.8	8.3	0.0	0.0
FT 0026	Assorted tropical and subtropical fruits - edible peel	0.02	9.6	0.2	9.7	0.2	36.8	0.7	5.8	0.1	3.1	0.1	1.6	0.0
GC 0640	Barley (incl pot, incl pearled, incl flour & grits, excl beer)	1.38	40.6	56.0	0.0	0.0	93.9	129.6	0.0	0.0	0.0	0.0	3.8	5.3
-	Barley beer	0.0414	18.3	0.8	84.1	3.5	4.1	0.2	66.0	2.7	243.1	10.1	161.3	6.7
VB 0040	Brassica vegetables	0.02	1.7	0.0	25.7	0.5	9.1	0.2	27.8	0.6	36.9	0.7	26.4	0.5
GC 0641	Buckwheat (incl flour, incl bran)	0.035	0.0	0.0	0.1	0.0	0.0	0.0	1.7	0.1	1.6	0.1	0.1	0.0
FC 0001	Citrus fruit (incl lemon juice, incl mandarin	0.05	15.7	0.8	100.5	5.0	63.2	3.2	27.8	1.4	52.6	2.6	56.9	2.8

Annex 3

CYPERMETHRINS (118) International Estimated Daily Intake (IEDI) ADI = 0–0.02 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day				Intake = daily intake: µg/person							
			A diet	intake	B diet	intake	C diet	intake	D diet	intake	E diet	intake	F diet	intake
	juice, incl orange juice, incl grapefruit juice, incl NES juice)													
SB 0716	Coffee beans (incl green, incl extracts, incl roasted)	0	3.1	0.0	12.6	0.0	2.9	0.0	1.4	0.0	10.1	0.0	18.0	0.0
MO 0105	Edible offal (mammalian)	0.014	3.9	0.1	14.4	0.2	5.2	0.1	11.8	0.2	11.7	0.2	7.6	0.1
VO 0440	Egg plant (= aubergine)	0.01	1.7	0.0	17.5	0.2	12.3	0.1	1.7	0.0	0.8	0.0	0.4	0.0
PE 0112	Eggs	0.0042	2.5	0.0	29.7	0.1	25.1	0.1	24.5	0.1	37.8	0.2	27.4	0.1
VC 0045	Fruiting vegetables, cucurbits	0.01	26.6	0.3	107.5	1.1	95.9	1.0	82.2	0.8	25.4	0.3	23.2	0.2
FB 0269	Grape (excl dried, incl juice, excl wine)	0.01	1.9	0.0	9.4	0.1	24.0	0.2	9.9	0.1	2.0	0.0	1.4	0.0
DF 0269	Grape, dried (= currants, raisins and sultanas)	0.033	0.0	0.0	2.9	0.1	0.4	0.0	0.4	0.0	2.3	0.1	1.7	0.1
VL 0053	Leafy vegetables	0.07	5.8	0.4	45.4	3.2	10.9	0.8	26.7	1.9	17.1	1.2	38.9	2.7
VA 0384	Leek	0.01	0.3	0.0	5.3	0.1	0.0	0.0	0.2	0.0	4.6	0.0	1.5	0.0
VP 0060	Legume vegetables	0.22	6.1	1.3	23.0	5.1	18.0	4.0	12.8	2.8	26.9	5.9	5.3	1.2
GC 0645	Maize (incl flour, incl oil, incl beer)	0.035	82.7	2.9	148.4	5.2	135.9	4.8	31.8	1.1	33.3	1.2	7.5	0.3
MF 0100	Mammalian fats (except milk fats)	0.15	0.8	0.1	10.0	1.5	0.9	0.1	6.6	1.0	11.8	1.8	3.7	0.6
FI 0345	Mango (incl juice, incl pulp)	0.19	6.3	1.2	1.0	0.2	4.6	0.9	0.2	0.0	0.7	0.1	0.3	0.1
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.15	5.5	0.8	23.3	3.5	7.7	1.2	11.0	1.7	18.0	2.7	26.3	3.9
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0.014	22.2	0.3	93.2	1.3	30.8	0.4	44.1	0.6	72.2	1.0	105.0	1.5
ML 0106	Milks (excl processed products)	0.011	68.8	0.8	190.6	2.1	79.4	0.9	302.6	3.3	179.6	2.0	237.9	2.6
GC 0646	Millet (incl flour, incl beer)	0.035	15.8	0.6	0.1	0.0	0.8	0.0	5.6	0.2	0.2	0.0	0.1	0.0
GC 0647	Oats (incl rolled)	1.38	1.4	1.9	0.6	0.8	0.2	0.3	4.2	5.8	5.7	7.9	8.9	12.3
SO 0088	Oilseed	0.05	22.3	1.1	65.2	3.3	35.4	1.8	52.0	2.6	62.1	3.1	39.4	2.0
VO 0442	Okra	0.08	3.9	0.3	1.0	0.1	5.3	0.4	0.1	0.0	0.0	0.0	0.0	0.0
FT 0305	Olive (table olives, only)	0.05	0.0	0.0	4.8	0.2	0.8	0.0	0.4	0.0	1.0	0.1	0.8	0.0
OR 0305	Olive oil, refined	0.41	0.0	0.0	14.3	5.9	3.9	1.6	0.0	0.0	1.5	0.6	0.8	0.3
DM 0305	Olive, processed	0.065	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
VA 0385	Onion, bulb (= dry + green onion)	0.01	5.5	0.1	49.5	0.5	33.0	0.3	31.3	0.3	23.2	0.2	14.6	0.1
FI 0350	Papaya	0.135	5.1	0.7	0.1	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0
VO 0444	Peppers, chili	0.495	0.7	0.3	14.9	7.4	4.1	2.0	3.2	1.6	3.1	1.5	2.0	1.0
VO 0445	Peppers, sweet (incl. pim(i)ento)	0.05	0.7	0.0	14.9	0.7	8.8	0.4	3.2	0.2	3.1	0.2	2.0	0.1
DF 0014	Plum, dried (prunes)	1.888	0.0	0.0	0.2	0.4	0.0	0.0	0.1	0.2	0.5	0.9	0.6	1.1

Annex 3

CYPERMETHRINS (118) International Estimated Daily Intake (IEDI) ADI = 0–0.02 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day				Intake = daily intake: µg/person							
			A diet	intake	B diet	intake	C diet	intake	D diet	intake	E diet	intake	F diet	intake
FP 0009	Pome fruit (incl apple juice)	0.205	0.5	0.1	84.1	17.2	21.9	4.5	45.2	9.3	61.7	12.6	46.2	9.5
PM 0110	Poultry meat: 10% as fat	0.034	0.7	0.0	5.9	0.2	3.2	0.1	2.4	0.1	6.1	0.2	2.7	0.1
PM 0110	Poultry meat: 90% as muscle	0.002	6.4	0.0	52.7	0.1	28.7	0.1	21.6	0.0	54.9	0.1	24.6	0.0
PO 0111	Poultry, edible offal of	0.002	0.4	0.0	0.4	0.0	1.7	0.0	0.1	0.0	0.6	0.0	0.2	0.0
PF 0111	Poultry, fats	0.034	0.1	0.0	0.1	0.0	0.1	0.0	0.0	0.0	0.4	0.0	0.1	0.0
VD 0070	Pulses	0.05	54.5	2.7	62.9	3.1	51.4	2.6	36.8	1.8	49.4	2.5	47.9	2.4
OR 0495	Rape seed oil, edible	0.06	0.3	0.0	0.7	0.0	1.0	0.1	0.7	0.0	13.7	0.8	10.0	0.6
GC 0649	Rice (incl husked, incl polished)	0.57	91.0	51.9	31.6	18.0	94.6	53.9	33.2	18.9	12.7	7.2	12.7	7.2
VR 0075	Root and tuber vegetables, except sugarbeet	0.01	528.2	5.3	312.1	3.1	78.5	0.8	270.2	2.7	318.1	3.2	261.2	2.6
GC 0650	Rye (incl flour)	1.38	0.1	0.1	3.7	5.1	0.3	0.4	24.3	33.5	25.8	35.6	45.8	63.2
GC 0651	Sorghum (incl flour, incl beer)	0.035	36.9	1.3	0.0	0.0	10.2	0.4	0.0	0.0	0.0	0.0	0.0	0.0
FS 0012	Stone fruit (excl dried plums, incl dried apricots)	0.59	0.7	0.4	44.1	26.0	14.1	8.3	26.6	15.7	26.3	15.5	8.3	4.9
FB 0275	Strawberry	0.01	0.0	0.0	5.0	0.1	2.0	0.0	1.7	0.0	5.2	0.1	4.1	0.0
GS 0659	Sugar cane	0.05	30.9	1.5	43.1	2.2	51.3	2.6	0.1	0.0	5.5	0.3	0.0	0.0
VO 0447	Sweet corn (incl corn on the cob, incl frozen kernels, incl preserved kernels)	0	14.7	0.0	2.0	0.0	0.2	0.0	1.2	0.0	6.5	0.0	7.2	0.0
DT 1114	Tea, green, black (black, fermented and dried)	3.75	0.3	1.1	2.4	9.0	2.8	10.5	2.1	7.9	2.0	7.5	0.8	3.0
VO 0448	Tomato (excl juice, excl paste, excl canned)	0.05	1.3	0.1	178.4	8.9	102.8	5.1	53.4	2.7	1.6	0.1	0.0	0.0
JF 0448	Tomato juice	0.0145	5.2	0.1	0.5	0.0	0.4	0.0	2.1	0.0	6.9	0.1	15.2	0.2
-d	Tomato paste	0.05	0.5	0.0	1.3	0.1	3.5	0.2	1.0	0.1	3.8	0.2	4.5	0.2
-d	Tomato, canned	0.0055	0.1	0.0	0.4	0.0	0.5	0.0	0.4	0.0	4.9	0.0	3.2	0.0
TN 0085	Tree nuts, except coconut	0.05	1.3	0.1	8.0	0.4	1.8	0.1	1.5	0.1	3.7	0.2	1.3	0.1
GC 0653	Triticale (incl flour)	0.035	0.0	0.0	115.8	4.1	0.0	0.0	0.0	0.0	0.3	0.0	0.0	0.0
GC 0654	Wheat (incl bulgur wholemeal, excl flour)	1.38	6.0	8.3	11.1	15.3	0.8	1.0	0.2	0.3	0.2	0.3	0.0	0.0
CM 0654	Wheat bran, unprocessed	3.45	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CF 1211	Wheat flour (incl macaroni, bread, pastry, starch, gluten)	0.483	63.4	30.6	296.3	143.1	327.5	158.2	300.0	144.9	181.6	87.7	166.2	80.3
CF 1210	Wheat germ	0.7728	0.0	0.0	1.3	1.0	0.0	0.0	1.3	1.0	0.9	0.7	1.2	0.9
-	Wine	0.0008	1.3	0.0	76.8	0.1	1.1	0.0	15.4	0.0	68.8	0.1	25.6	0.0
	Total intake (µg/person)=			177.3		313.0		404.7		268.4		228.1		221.1
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			1200		1200		1200		1200		1200		1200

Annex 3

CYPERMETHRINS (118) International Estimated Daily Intake (IEDI) ADI = 0–0.02 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day A diet	intake	B diet	intake	Intake = daily intake: µg/person C diet	intake	D diet	intake	E diet	intake	F diet	intake
	%ADI=			14.8%		26.1%		33.7%		22.4%		19.0%		18.4%
	Rounded %ADI=			10%		30%		30%		20%		20%		20%

CYPERMETHRINS (118) International Estimated Daily Intake (IEDI) ADI = 0–0.02 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day G diet	intake	H diet	intake	Intake = daily intake: µg/person I diet	intake	J diet	intake	K diet	intake	L diet	intake	M diet	intake
VS 0620	Artichoke globe	0.025	0.1	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0
VS 0621	Asparagus	0.09	3.7	0.3	0.3	0.0	0.2	0.0	0.0	0.0	0.0	0.0	0.5	0.0	1.1	0.1
-	Assorted (sub)tropical fruits NES (excl passion fruit)	0.495	5.7	2.8	4.7	2.3	2.4	1.2	1.1	0.5	13.1	6.5	47.2	23.4	0.7	0.3
FT 0026	Assorted tropical and subtropical fruits - edible peel	0.02	2.8	0.1	0.6	0.0	0.2	0.0	3.9	0.1	17.3	0.3	6.7	0.1	2.3	0.0
GC 0640	Barley (incl pot, incl pearled, incl flour & grits, excl beer)	1.38	1.5	2.1	0.0	-0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.4	0.5	0.0	0.1
-	Barley beer	0.0414	21.9	0.9	102.7	4.3	29.5	1.2	12.6	0.5	100.9	4.2	82.2	3.4	218.8	9.1
VB 0040	Brassica vegetables	0.02	26.4	0.5	9.3	0.2	7.8	0.2	1.5	0.0	3.3	0.1	40.8	0.8	26.0	0.5
GC 0641	Buckwheat (incl flour, incl bran)	0.035	1.0	0.0	0.0	0.0	0.2	0.0	0.1	0.0	0.5	0.0	2.0	0.1	0.1	0.0
FC 0001	Citrus fruit (incl lemon juice, incl mandarin juice, incl orange juice, incl grapefruit juice, incl NES juice)	0.05	17.3	0.9	156.8	7.8	14.9	0.7	42.5	2.1	222.8	11.1	40.4	2.0	132.3	6.6
SB 0716	Coffee beans (incl green, incl extracts, incl roasted)	0	0.2	0.0	7.0	0.0	0.5	0.0	0.2	0.0	5.3	0.0	5.7	0.0	12.4	0.0
MO 0105	Edible offal (mammalian)	0.014	4.8	0.1	10.7	0.1	4.0	0.1	4.0	0.1	6.5	0.1	6.6	0.1	5.6	0.1
VO 0440	Egg plant (= aubergine)	0.01	20.1	0.2	0.1	0.0	0.6	0.0	6.3	0.1	0.5	0.0	6.3	0.1	0.7	0.0
PE 0112	Eggs	0.0042	22.1	0.1	71.5	0.3	16.6	0.1	5.1	0.0	17.6	0.1	35.2	0.1	57.4	0.2
VC 0045	Fruiting vegetables, cucurbits	0.01	69.7	0.7	25.9	0.3	14.9	0.1	18.0	0.2	18.7	0.2	39.1	0.4	44.2	0.4
FB 0269	Grape (excl dried, incl juice, excl wine)	0.01	1.2	0.0	2.7	0.0	1.4	0.0	0.2	0.0	0.8	0.0	4.3	0.0	5.0	0.1
DF 0269	Grape, dried (= currants, raisins and sultanas)	0.033	0.0	0.0	0.2	0.0	0.2	0.0	0.0	0.0	0.3	0.0	0.4	0.0	2.6	0.1

Annex 3

CYPERMETHRINS (118) International Estimated Daily Intake (IEDI) ADI = 0–0.02 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day Intake = daily intake: µg/person													
			G		H		I		J		K		L		M	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
VL 0053	Leafy vegetables	0.07	40.8	2.9	12.0	0.8	12.5	0.9	9.5	0.7	5.4	0.4	50.0	3.5	39.1	2.7
VA 0384	Leek	0.01	0.8	0.0	0.2	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.3	0.0	0.1	0.0
VP 0060	Legume vegetables	0.22	19.6	4.3	6.2	1.4	6.9	1.5	6.0	1.3	1.7	0.4	29.5	6.5	26.3	5.8
GC 0645	Maize (incl flour, incl oil, incl beer)	0.035	35.2	1.2	298.6	10.5	248.1	8.7	57.4	2.0	63.1	2.2	58.6	2.1	85.5	3.0
MF 0100	Mammalian fats (except milk fats)	0.15	2.2	0.3	18.6	2.8	0.5	0.1	0.8	0.1	5.7	0.9	4.5	0.7	18.2	2.7
FI 0345	Mango (incl juice, incl pulp)	0.19	12.7	2.4	26.2	5.0	6.1	1.2	12.7	2.4	9.2	1.7	8.0	1.5	1.9	0.4
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.15	11.0	1.6	17.9	2.7	6.1	0.9	5.7	0.9	16.4	2.5	12.2	1.8	31.7	4.7
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0.014	43.8	0.6	71.5	1.0	24.5	0.3	22.9	0.3	65.7	0.9	48.9	0.7	126.6	1.8
ML 0106	Milks (excl processed products)	0.011	66.0	0.7	121.1	1.3	81.6	0.9	102.4	1.1	207.7	2.3	57.0	0.6	287.9	3.2
GC 0646	Millet (incl flour, incl beer)	0.035	13.0	0.5	0.0	0.0	8.3	0.3	96.9	3.4	0.0	0.0	0.4	0.0	0.0	0.0
GC 0647	Oats (incl rolled)	1.38	0.2	0.3	2.0	2.8	0.8	1.1	0.0	0.0	3.5	4.8	0.7	1.0	7.6	10.5
SO 0088	Oilseed	0.05	26.2	1.3	19.8	1.0	24.9	1.2	39.9	2.0	7.4	0.4	62.7	3.1	29.9	1.5
VO 0442	Okra	0.08	4.1	0.3	1.0	0.1	7.0	0.6	15.9	1.3	1.1	0.1	3.9	0.3	0.2	0.0
FT 0305	Olive (table olives, only)	0.05	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.6	0.0	0.0	0.0	1.0	0.1
OR 0305	Olive oil, refined	0.41	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.3	0.1	0.3	0.1	1.6	0.7
DM 0305	Olive, processed	0.065	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
VA 0385	Onion, bulb (= dry + green onion)	0.01	17.4	0.2	27.9	0.3	7.3	0.1	16.0	0.2	22.8	0.2	34.5	0.3	30.1	0.3
FI 0350	Papaya	0.135	1.3	0.2	11.5	1.6	1.6	0.2	13.7	1.8	14.5	2.0	1.0	0.1	0.6	0.1
VO 0444	Peppers, chili	0.495	8.7	4.3	13.0	6.4	4.2	2.1	4.7	2.3	1.7	0.8	2.6	1.3	4.4	2.2
VO 0445	Peppers, sweet (incl. pim(i)ento)	0.05	0.0	0.0	9.4	0.5	4.2	0.2	4.7	0.2	1.7	0.1	2.6	0.1	4.4	0.2
DF 0014	Plum, dried (prunes)	1.888	0.1	0.2	0.2	0.4	0.0	0.0	0.0	0.0	0.2	0.4	0.2	0.4	0.6	1.1
FP 0009	Pome fruit (incl apple juice)	0.205	20.9	4.3	12.3	2.5	3.4	0.7	0.1	0.0	11.7	2.4	24.9	5.1	45.4	9.3
PM 0110	Poultry meat: 10% as fat	0.034	1.8	0.1	13.1	0.4	2.5	0.1	0.5	0.0	14.6	0.5	2.8	0.1	11.5	0.4
PM 0110	Poultry meat: 90% as muscle	0.002	15.8	0.0	118.2	0.2	22.6	0.0	4.2	0.0	131.3	0.3	24.9	0.0	103.6	0.2
PO 0111	Poultry, edible offal of	0.002	0.4	0.0	1.0	0.0	1.9	0.0	0.0	0.0	0.7	0.0	1.0	0.0	0.3	0.0
PF 0111	Poultry, fats	0.034	0.1	0.0	8.2	0.3	0.0	0.0	0.1	0.0	0.0	0.0	0.1	0.0	4.2	0.1
VD 0070	Pulses	0.05	41.9	2.1	91.8	4.6	35.9	1.8	45.2	2.3	160.0	8.0	59.5	3.0	140.1	7.0
OR 0495	Rape seed oil, edible	0.06	3.8	0.2	2.3	0.1	0.1	0.0	0.4	0.0	0.0	0.0	6.0	0.4	3.8	0.2
GC 0649	Rice (incl husked, incl polished)	0.57	376.9	214.8	64.3	36.7	38.0	21.7	74.3	42.4	238.4	135.9	381.3	217.3	34.6	19.7
VR 0075	Root and tuber vegetables, except sugarbeet	0.01	139.1	1.4	109.7	1.1	409.6	4.1	444.6	4.4	145.1	1.5	127.0	1.3	211.3	2.1

Annex 3

CYPERMETHRINS (118) International Estimated Daily Intake (IEDI) ADI = 0–0.02 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G		H		I		J		K		L		M	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
GC 0650	Rye (incl flour)	1.38	0.4	0.6	0.0	0.0	0.2	0.3	0.1	0.1	0.1	0.1	0.9	1.2	0.8	1.1
GC 0651	Sorghum (incl flour, incl beer)	0.035	9.8	0.3	19.9	0.7	18.6	0.7	112.3	3.9	0.1	0.0	3.3	0.1	3.0	0.1
FS 0012	Stone fruit (excl dried plums, incl dried apricots)	0.59	6.7	4.0	4.3	2.5	1.4	0.8	0.1	0.1	4.9	2.9	4.9	2.9	17.7	10.4
FB 0275	Strawberry	0.01	0.0	0.0	1.8	0.0	0.1	0.0	0.0	0.0	0.3	0.0	6.2	0.1	5.9	0.1
GS 0659	Sugar cane	0.05	26.2	1.3	1.5	0.1	33.8	1.7	5.5	0.3	18.6	0.9	3.0	0.2	20.2	1.0
VO 0447	Sweet corn (incl corn on the cob, incl frozen kernels, incl preserved kernels)	0	0.4	0.0	4.9	0.0	4.5	0.0	3.3	0.0	1.7	0.0	5.6	0.0	18.1	0.0
DT 1114	Tea, green, black (black, fermented and dried)	3.75	1.3	4.9	0.2	0.8	0.9	3.4	0.6	2.3	0.1	0.4	1.5	5.6	1.0	3.8
VO 0448	Tomato (excl juice, excl paste, excl canned)	0.05	22.8	1.1	4.1	0.2	12.3	0.6	1.8	0.1	32.8	1.6	0.4	0.0	27.3	1.4
JF 0448	Tomato juice	0.0145	0.0	0.0	0.8	0.0	0.1	0.0	7.2	0.1	0.0	0.0	2.4	0.0	45.2	0.7
-d	Tomato paste	0.05	0.1	0.0	2.1	0.1	0.6	0.0	0.4	0.0	0.6	0.0	1.4	0.1	1.2	0.1
-d	Tomato, canned	0.0055	0.2	0.0	14.5	0.1	0.2	0.0	0.0	0.0	0.3	0.0	0.8	0.0	1.2	0.0
TN 0085	Tree nuts, except coconut	0.05	1.0	0.1	2.3	0.1	0.4	0.0	0.3	0.0	0.2	0.0	2.3	0.1	2.2	0.1
GC 0653	Triticale (incl flour)	0.035	1.3	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
GC 0654	Wheat (incl bulgur wholemeal, excl flour)	1.38	0.0	0.0	0.9	1.2	0.0	0.0	0.0	0.1	0.1	0.1	0.0	0.0	0.1	0.1
CM 0654	Wheat bran, unprocessed	3.45	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CF 1211	Wheat flour (incl macaroni, bread, pastry, starch, gluten)	0.483	133.0	64.2	60.1	29.0	52.4	25.3	32.2	15.6	87.7	42.4	79.6	38.4	180.1	87.0
CF 1210	Wheat germ	0.7728	0.1	0.1	48.1	37.2	1.8	1.4	0.0	0.0	0.0	0.0	0.0	0.0	0.6	0.5
-	Wine	0.0008	1.0	0.0	0.9	0.0	6.8	0.0	0.1	0.0	3.4	0.0	3.6	0.0	31.0	0.0
	Total intake (µg/person)=			329.6		171.7		86.5		95.3		239.8		331.3		203.9
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			1100		1200		1200		1200		1200		1100		1200
	%ADI=			30.0%		14.3%		7.2%		7.9%		20.0%		30.1%		17.0%
	Rounded %ADI=			30%		10%		7%		8%		20%		30%		20%

Annex 3

DICAMBA (240) International Estimated Daily Intake (IEDI) ADI = 0–0.3 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A diet	intake	B diet	intake	C diet	intake	D diet	intake	E diet	intake	F diet	intake
VS 0621	Asparagus	0.87	0.0	0.0	1.1	1.0	0.6	0.5	0.2	0.2	1.2	1.0	0.1	0.1
GC 0640	Barley (incl pot, incl pearled, incl flour & grits, incl beer)	1.7	40.6	69.0	16.8	28.6	93.9	159.6	13.2	22.4	48.6	82.6	36.1	61.4
OR 0691	Cotton seed oil, edible	0.008	0.9	0.0	4.9	0.0	1.7	0.0	6.6	0.1	0.0	0.0	0.3	0.0
MO 0105	Edible offal (mammalian)	0.16	3.9	0.6	14.4	2.3	5.2	0.8	11.8	1.9	11.7	1.9	7.6	1.2
PE 0112	Eggs	0.01	2.5	0.0	29.7	0.3	25.1	0.3	24.5	0.2	37.8	0.4	27.4	0.3
GC 0645	Maize (incl flour, excl oil, incl beer)	0.02	82.7	1.7	1.4	0.0	51.4	1.0	31.8	0.6	0.2	0.0	0.2	0.0
OR 0645	Maize oil, edible	0.00116	0.1	0.0	4.0	0.0	2.3	0.0	0.5	0.0	0.9	0.0	0.2	0.0
MF 0100	Mammalian fats (except milk fats)	0.023	0.8	0.0	10.0	0.2	0.9	0.0	6.6	0.2	11.8	0.3	3.7	0.1
MM 0095	Meat from mammals other than marine mammals	0.01	27.7	0.3	116.5	1.2	38.5	0.4	55.1	0.6	90.2	0.9	131.3	1.3
ML 0106	Milks (excl processed products)	0.021	68.8	1.4	190.6	4.0	79.4	1.7	302.6	6.4	179.6	3.8	237.9	5.0
PM 0110	Poultry meat	0.01	7.1	0.1	58.5	0.6	31.9	0.3	24.0	0.2	61.0	0.6	27.3	0.3
PO 0111	Poultry, edible offal of	0.01	0.4	0.0	0.4	0.0	1.7	0.0	0.1	0.0	0.6	0.0	0.2	0.0
PF 0111	Poultry, fats	0.01	0.1	0.0	0.1	0.0	0.1	0.0	0.0	0.0	0.4	0.0	0.1	0.0
GC 0651	Sorghum (incl flour, incl beer)	2	36.9	73.8	0.0	0.0	10.2	20.4	0.0	0.0	0.0	0.0	0.0	0.0
VD 0541	Soya bean (dry, incl oil)	0.335	9.9	3.3	36.4	12.2	34.3	11.5	22.4	7.5	35.3	11.8	39.2	13.1
OR 0541	Soya bean oil, refined	0.012	1.6	0.0	6.5	0.1	6.0	0.1	4.0	0.0	6.3	0.1	7.0	0.1
GS 0659	Sugar cane	0.095	30.9	2.9	43.1	4.1	51.3	4.9	0.1	0.0	5.5	0.5	0.0	0.0
DM 0659	Sugar cane molasses	3.4	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
GC 0654	Wheat (incl bulgur wholemeal, excl flour)	0.26	6.0	1.6	11.1	2.9	0.8	0.2	0.2	0.1	0.2	0.1	0.0	0.0
CM 0654	Wheat bran, unprocessed	0.26	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CF 1211	Wheat flour (incl macaroni, bread, pastry, starch, gluten)	0.02	63.4	1.3	296.3	5.9	327.5	6.6	300.0	6.0	181.6	3.6	166.2	3.3
	Total intake (µg/person)=			156.0		63.4		208.3		46.3		107.6		86.2
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			18000		18000		18000		18000		18000		18000
	%ADI=			0.9%		0.4%		1.2%		0.3%		0.6%		0.5%
	Rounded %ADI=			1%		0%		1%		0%		1%		0%

Annex 3

DICAMBA (240) International Estimated Daily Intake (IEDI) ADI = 0 - 0.30 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day G diet	Intake = daily intake: µg/person intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake	M diet	intake
VS 0621	Asparagus	0.87	3.7	3.2	0.3	0.3	0.2	0.2	0.0	0.0	0.0	0.0	0.5	0.4	1.1	1.0
GC 0640	Barley (incl pot, incl pearled, incl flour & grits, incl beer)	1.7	5.9	10.0	20.5	34.9	5.9	10.0	2.5	4.3	20.2	34.3	16.8	28.6	43.8	74.5
OR 0691	Cotton seed oil, edible	0.008	1.0	0.0	0.7	0.0	1.0	0.0	1.4	0.0	1.5	0.0	5.5	0.0	1.2	0.0
MO 0105	Edible offal (mammalian)	0.16	4.8	0.8	10.7	1.7	4.0	0.6	4.0	0.6	6.5	1.0	6.6	1.1	5.6	0.9
PE 0112	Eggs	0.01	22.1	0.2	71.5	0.7	16.6	0.2	5.1	0.1	17.6	0.2	35.2	0.4	57.4	0.6
GC 0645	Maize (incl flour, excl oil, incl beer)	0.02	35.2	0.7	298.6	6.0	248.1	5.0	57.4	1.1	63.1	1.3	0.0	0.0	19.4	0.4
OR 0645	Maize oil, edible	0.00116	0.1	0.0	0.6	0.0	1.8	0.0	0.0	0.0	1.0	0.0	1.6	0.0	1.8	0.0
MF 0100	Mammalian fats (except milk fats)	0.023	2.2	0.1	18.6	0.4	0.5	0.0	0.8	0.0	5.7	0.1	4.5	0.1	18.2	0.4
MM 0095	Meat from mammals other than marine mammals	0.01	54.8	0.5	89.4	0.9	30.6	0.3	28.6	0.3	82.1	0.8	61.1	0.6	158.3	1.6
ML 0106	Milks (excl processed products)	0.021	66.0	1.4	121.1	2.5	81.6	1.7	102.4	2.2	207.7	4.4	57.0	1.2	287.9	6.0
PM 0110	Poultry meat	0.01	17.6	0.2	131.3	1.3	25.1	0.3	4.7	0.0	145.9	1.5	27.7	0.3	115.1	1.2
PO 0111	Poultry, edible offal of	0.01	0.4	0.0	1.0	0.0	1.9	0.0	0.0	0.0	0.7	0.0	1.0	0.0	0.3	0.0
PF 0111	Poultry, fats	0.01	0.1	0.0	8.2	0.1	0.0	0.0	0.1	0.0	0.0	0.0	0.1	0.0	4.2	0.0
GC 0651	Sorghum (incl flour, incl beer)	2	9.8	19.6	19.9	39.8	18.6	37.2	112.3	224.6	0.1	0.2	3.3	6.6	3.0	6.0
VD 0541	Soya bean (dry, incl oil)	0.335	25.9	8.7	59.4	19.9	11.2	3.8	11.0	3.7	109.3	36.6	51.5	17.3	123.2	41.3
OR 0541	Soya bean oil, refined	0.012	4.3	0.1	10.6	0.1	2.0	0.0	1.4	0.0	19.5	0.2	9.2	0.1	22.0	0.3
GS 0659	Sugar cane	0.095	26.2	2.5	1.5	0.1	33.8	3.2	5.5	0.5	18.6	1.8	3.0	0.3	20.2	1.9
DM 0659	Sugar cane molasses	3.4	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
GC 0654	Wheat (incl bulgur wholemeal, excl flour)	0.26	0.0	0.0	0.9	0.2	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.1	0.0
CM 0654	Wheat bran, unprocessed	0.26	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CF 1211	Wheat flour (incl macaroni, bread, pastry, starch, gluten)	0.02	133.0	2.7	60.1	1.2	52.4	1.0	32.2	0.6	87.7	1.8	79.6	1.6	180.1	3.6
	Total intake (µg/person)=			50.6		110.2		63.5		238.1		84.2		58.5		139.6
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			16500		18000		18000		18000		18000		16500		18000
	%ADI=			0.3%		0.6%		0.4%		1.3%		0.5%		0.4%		0.8%
	Rounded %ADI=			0%		1%		0%		1%		0%		0%		1%

Annex 3

DIFLUBENZURON (130) International Estimated Daily Intake (IEDI) ADI = 0–0.02 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A diet	intake	B diet	intake	C diet	intake	D diet	intake	E diet	intake	F diet	intake
FC 0001	Citrus fruit (incl lemon juice, incl mandarin juice, incl orange juice, incl grapefruit juice, incl NES juice)	0.26	15.7	4.1	100.5	26.1	63.2	16.4	27.8	7.2	52.6	13.7	56.9	14.8
TN 0085	Tree nuts, except coconut	0.05	1.3	0.1	8.0	0.4	1.8	0.1	1.5	0.1	3.7	0.2	1.3	0.1
FP 0009	Pome fruit (excl apple juice)	0.6	0.5	0.3	79.9	47.9	21.8	13.1	43.6	26.1	51.5	30.9	35.1	21.1
JF 0226	Apple juice	0.072	0.0	0.0	2.8	0.2	0.1	0.0	1.1	0.1	6.8	0.5	7.4	0.5
FS 0014	Plum (incl dried)	0.17	0.1	0.0	5.9	1.0	2.5	0.4	7.3	1.2	6.9	1.2	2.6	0.4
FS 0245	Nectarine	0.17	0.0	0.0	0.5	0.1	3.3	0.6	1.8	0.3	2.8	0.5	1.6	0.3
FS 0247	Peach	0.17	0.2	0.0	24.8	4.2	3.3	0.6	1.8	0.3	5.4	0.9	1.6	0.3
VO 0444	Peppers, chili	0.92	0.7	0.6	14.9	13.7	4.1	3.8	3.2	2.9	3.1	2.9	2.0	1.8
VO 0445	Peppers, sweet (incl. pim(i)ento)	0.16	0.7	0.1	14.9	2.4	8.8	1.4	3.2	0.5	3.1	0.5	2.0	0.3
VO 0450	Mushrooms	0.075	0.0	0.0	1.5	0.1	0.1	0.0	0.2	0.0	5.3	0.4	1.4	0.1
VL 0485	Mustard greens	1.4	0.3	0.4	0.3	0.4	0.0	0.0	5.5	7.7	0.0	0.0	1.9	2.7
SO 0697	Peanut, shelled (incl oil)	0.05	5.4	0.3	3.1	0.2	2.1	0.1	0.7	0.0	4.0	0.2	1.4	0.1
GC 0640	Barley (incl pot, incl pearled, incl flour & grits, incl beer)	0.05	40.6	2.0	16.8	0.8	93.9	4.7	13.2	0.7	48.6	2.4	36.1	1.8
GC 0647	Oats (incl rolled)	0.05	1.4	0.1	0.6	0.0	0.2	0.0	4.2	0.2	5.7	0.3	8.9	0.4
GC 0649	Rice (incl husked, incl polished)	0.01	91.0	0.9	31.6	0.3	94.6	0.9	33.2	0.3	12.7	0.1	12.7	0.1
GC 0653	Triticale (incl flour)	0.05	0.0	0.0	115.8	5.8	0.0	0.0	0.0	0.0	0.3	0.0	0.0	0.0
GC 0654	Wheat (incl bulgur wholemeal, incl flour)	0.05	88.4	4.4	396.3	19.8	426.5	21.3	390.2	19.5	236.3	11.8	216.0	10.8
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.1	5.5	0.6	23.3	2.3	7.7	0.8	11.0	1.1	18.0	1.8	26.3	2.6
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0.1	22.2	2.2	93.2	9.3	30.8	3.1	44.1	4.4	72.2	7.2	105.0	10.5
MO 0105	Edible offal (mammalian)	0.1	3.9	0.4	14.4	1.4	5.2	0.5	11.8	1.2	11.7	1.2	7.6	0.8
PM 0110	Poultry meat: 10% as fat	0.05	0.7	0.0	5.9	0.3	3.2	0.2	2.4	0.1	6.1	0.3	2.7	0.1
PM 0110	Poultry meat: 90% as muscle	0.05	6.4	0.3	52.7	2.6	28.7	1.4	21.6	1.1	54.9	2.7	24.6	1.2
ML 0106	Milks (excl processed products)	0.02	68.8	1.4	190.6	3.8	79.4	1.6	302.6	6.1	179.6	3.6	237.9	4.8
PE 0112	Eggs	0.05	2.5	0.1	29.7	1.5	25.1	1.3	24.5	1.2	37.8	1.9	27.4	1.4
	Total intake (µg/person)=			18.4		144.9		72.2		82.5		85.2		77.0
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			1200		1200		1200		1200		1200		1200
	%ADI=			1.5%		12.1%		6.0%		6.9%		7.1%		6.4%

Annex 3

DIFLUBENZURON (130) International Estimated Daily Intake (IEDI) ADI = 0–0.02 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A diet	intake	B diet	intake	C diet	intake	D diet	intake	E diet	intake	F diet	intake
	Rounded %ADI=			2%		10%		6%		7%		7%		6%

DIFLUBENZURON (130) International Estimated Daily Intake (IEDI) ADI = 0–0.02 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G diet	intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake	M diet	intake
FC 0001	Citrus fruit (incl lemon juice, incl mandarin juice, incl orange juice, incl grapefruit juice, incl NES juice)	0.26	17.3	4.5	156.8	40.8	14.9	3.9	42.5	11.1	222.8	57.9	40.4	10.5	132.3	34.4
TN 0085	Tree nuts, except coconut	0.05	1.0	0.1	2.3	0.1	0.4	0.0	0.3	0.0	0.2	0.0	2.3	0.1	2.2	0.1
FP 0009	Pome fruit (excl apple juice)	0.6	20.8	12.5	11.6	6.9	3.3	2.0	0.1	0.1	10.7	6.4	23.6	14.1	36.9	22.1
JF 0226	Apple juice	0.072	0.1	0.0	0.5	0.0	0.1	0.0	0.0	0.0	0.7	0.1	0.9	0.1	5.7	0.4
FS 0014	Plum (incl dried)	0.17	3.3	0.6	1.4	0.2	0.1	0.0	0.0	0.0	0.6	0.1	1.5	0.3	2.2	0.4
FS 0245	Nectarine	0.17	1.7	0.3	1.7	0.3	0.0	0.0	0.0	0.0	1.0	0.2	1.7	0.3	1.4	0.2
FS 0247	Peach	0.17	1.7	0.3	1.7	0.3	1.1	0.2	0.1	0.0	1.0	0.2	1.7	0.3	10.2	1.7
VO 0444	Peppers, chili	0.92	8.7	8.0	13.0	12.0	4.2	3.9	4.7	4.3	1.7	1.6	2.6	2.4	4.4	4.0
VO 0445	Peppers, sweet (incl. pim(i)ento)	0.16	0.0	0.0	9.4	1.5	4.2	0.7	4.7	0.8	1.7	0.3	2.6	0.4	4.4	0.7
VO 0450	Mushrooms	0.075	0.4	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.5	0.0	3.9	0.3
VL 0485	Mustard greens	1.4	3.4	4.8	0.4	0.6	2.4	3.4	0.3	0.4	0.5	0.7	7.9	11.1	0.3	0.4
SO 0697	Peanut, shelled (incl oil)	0.05	7.6	0.4	2.1	0.1	4.7	0.2	21.8	1.1	0.9	0.0	0.7	0.0	6.9	0.3
GC 0640	Barley (incl pot, incl pearled, incl flour & grits, incl beer)	0.05	5.9	0.3	20.5	1.0	5.9	0.3	2.5	0.1	20.2	1.0	16.8	0.8	43.8	2.2
GC 0647	Oats (incl rolled)	0.05	0.2	0.0	2.0	0.1	0.8	0.0	0.0	0.0	3.5	0.2	0.7	0.0	7.6	0.4
GC 0649	Rice (incl husked, incl polished)	0.01	376.9	3.8	64.3	0.6	38.0	0.4	74.3	0.7	238.4	2.4	381.3	3.8	34.6	0.3
GC 0653	Triticale (incl flour)	0.05	1.3	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
GC 0654	Wheat (incl bulgur wholemeal, incl flour)	0.05	172.9	8.6	79.0	4.0	68.1	3.4	41.9	2.1	114.1	5.7	103.4	5.2	234.2	11.7
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.1	11.0	1.1	17.9	1.8	6.1	0.6	5.7	0.6	16.4	1.6	12.2	1.2	31.7	3.2

Annex 3

DIFLUBENZURON (130) International Estimated Daily Intake (IEDI) ADI = 0–0.02 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G		H		I		J		K		L		M	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0.1	43.8	4.4	71.5	7.2	24.5	2.4	22.9	2.3	65.7	6.6	48.9	4.9	126.6	12.7
MO 0105	Edible offal (mammalian)	0.1	4.8	0.5	10.7	1.1	4.0	0.4	4.0	0.4	6.5	0.7	6.6	0.7	5.6	0.6
PM 0110	Poultry meat: 10% as fat	0.05	1.8	0.1	13.1	0.7	2.5	0.1	0.5	0.0	14.6	0.7	2.8	0.1	11.5	0.6
PM 0110	Poultry meat: 90% as muscle	0.05	15.8	0.8	118.2	5.9	22.6	1.1	4.2	0.2	131.3	6.6	24.9	1.2	103.6	5.2
ML 0106	Milks (excl processed products)	0.02	66.0	1.3	121.1	2.4	81.6	1.6	102.4	2.0	207.7	4.2	57.0	1.1	287.9	5.8
PE 0112	Eggs	0.05	22.1	1.1	71.5	3.6	16.6	0.8	5.1	0.3	17.6	0.9	35.2	1.8	57.4	2.9
	Total intake (µg/person)=			53.4		91.1		25.5		26.5		97.9		60.5		110.6
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			1100		1200		1200		1200		1200		1100		1200
	%ADI=			4.9%		7.6%		2.1%		2.2%		8.2%		5.5%		9.2%
	Rounded %ADI=			5%		8%		2%		2%		8%		6%		9%

EMAMECTIN BENZOATE (247) International Estimated Daily Intake (IEDI) ADI = 0–0.0005 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A		B		C		D		E		F	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
JF 0226	Apple juice	0.0028	0.0	0.0	2.8	0.0	0.1	0.0	1.1	0.0	6.8	0.0	7.4	0.0
VP 0061	Beans except broad bean & soybean (green pods & immature seeds)	0.001	1.0	0.0	17.4	0.0	7.5	0.0	0.9	0.0	16.4	0.0	0.1	0.0
VL 0510	Cos lettuce	0.2	0.1	0.0	6.2	1.2	0.7	0.1	0.1	0.0	0.1	0.0	0.0	0.0
SO 0691	Cotton seed (for oil processing only)	0.002	5.6	0.0	30.6	0.1	10.6	0.0	41.3	0.1	0.0	0.0	1.9	0.0
OR 0691	Cotton seed oil, edible	0.00078	0.9	0.0	4.9	0.0	1.7	0.0	6.6	0.0	0.0	0.0	0.3	0.0
MO 0105	Edible offal (mammalian)	0.006	3.9	0.0	14.4	0.1	5.2	0.0	11.8	0.1	11.7	0.1	7.6	0.0
VO 0050	Fruiting vegetables other than cucurbits (excl sweet corn, excl mushrooms)	0.003	18.8	0.1	233.4	0.7	148.6	0.4	68.8	0.2	38.6	0.1	45.3	0.1
VC 0045	Fruiting vegetables, cucurbits	0.001	26.6	0.0	107.5	0.1	95.9	0.1	82.2	0.1	25.4	0.0	23.2	0.0
FB 0269	Grape (incl dried, incl juice, incl wine)	0.0025	3.7	0.0	128.5	0.3	27.1	0.1	33.1	0.1	107.5	0.3	44.0	0.1
VL 0482	Lettuce, head	0.2	0.1	0.0	6.2	1.2	0.7	0.1	0.1	0.0	0.1	0.0	0.0	0.0
VL 0483	Lettuce, leaf	0.2	0.0	0.0	9.2	1.8	1.0	0.2	0.1	0.0	5.4	1.1	18.0	3.6

Annex 3

EMAMECTIN BENZOATE (247) International Estimated Daily Intake (IEDI) ADI = 0–0.0005 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day											
			A		B		C		D		E		F	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
MF 0100	Mammalian fats (except milk fats)	0.002	0.8	0.0	10.0	0.0	0.9	0.0	6.6	0.0	11.8	0.0	3.7	0.0
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.002	5.5	0.0	23.3	0.0	7.7	0.0	11.0	0.0	18.0	0.0	26.3	0.1
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0.002	22.2	0.0	93.2	0.2	30.8	0.1	44.1	0.1	72.2	0.1	105.0	0.2
ML 0106	Milks (excl processed products)	0.0005	68.8	0.0	190.6	0.1	79.4	0.0	302.6	0.2	179.6	0.1	237.9	0.1
VL 0485	Mustard greens	0.01	0.3	0.0	0.3	0.0	0.0	0.0	5.5	0.1	0.0	0.0	1.9	0.0
FS 0245	Nectarine	0.0095	0.0	0.0	0.5	0.0	3.3	0.0	1.8	0.0	2.8	0.0	1.6	0.0
FS 0247	Peach	0.0095	0.2	0.0	24.8	0.2	3.3	0.0	1.8	0.0	5.4	0.1	1.6	0.0
FP 0009	Pome fruit (excl apple juice)	0.004	0.5	0.0	79.9	0.3	21.8	0.1	43.6	0.2	51.5	0.2	35.1	0.1
	Total intake (µg/person) =			0.2		6.5		1.4		1.1		2.2		4.5
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			30		30		30		30		30		30
	%ADI=			0.8%		21.7%		4.7%		3.7%		7.3%		15.1%
	Rounded %ADI=			1%		20%		5%		4%		7%		20%

EMAMECTIN BENZOATE (247) International Estimated Daily Intake (IEDI) ADI = 0–0.0005 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day													
			G		H		I		J		K		L		M	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
JF 0226	Apple juice	0.0028	0.1	0.0	0.5	0.0	0.1	0.0	0.0	0.0	0.7	0.0	0.9	0.0	5.7	0.0
VP 0061	Beans except broad bean & soya bean (green pods & immature seeds)	0.001	2.6	0.0	2.6	0.0	1.0	0.0	0.5	0.0	0.6	0.0	2.8	0.0	9.8	0.0
VL 0510	Cos lettuce	0.2	1.2	0.2	3.5	0.7	0.1	0.0	0.3	0.1	1.0	0.2	1.2	0.2	7.9	1.6
SO 0691	Cotton seed (for oil processing only)	0.002	6.3	0.0	4.4	0.0	6.3	0.0	8.8	0.0	9.4	0.0	34.4	0.1	7.5	0.0
OR 0691	Cotton seed oil, edible	0.00078	1.0	0.0	0.7	0.0	1.0	0.0	1.4	0.0	1.5	0.0	5.5	0.0	1.2	0.0
MO 0105	Edible offal (mammalian)	0.006	4.8	0.0	10.7	0.1	4.0	0.0	4.0	0.0	6.5	0.0	6.6	0.0	5.6	0.0
VO 0050	Fruiting vegetables other than cucurbits (excl sweet corn, excl mushrooms)	0.003	56.4	0.2	55.2	0.2	31.0	0.1	47.8	0.1	40.5	0.1	25.4	0.1	112.8	0.3
VC 0045	Fruiting vegetables, cucurbits	0.001	69.7	0.1	25.9	0.0	14.9	0.0	18.0	0.0	18.7	0.0	39.1	0.0	44.2	0.0

Annex 3

EMAMECTIN BENZOATE (247) International Estimated Daily Intake (IEDI) ADI = 0–0.0005 mg/kg bw

		STMR or	Diets: g/person/day				Intake = daily intake: µg/person									
		STMR-P	G		H		I		J		K		L		M	
FB 0269	Grape (incl dried, incl juice, incl wine)	0.0025	2.6	0.0	4.8	0.0	11.7	0.0	0.3	0.0	6.8	0.0	10.9	0.0	58.8	0.1
VL 0482	Lettuce, head	0.2	1.2	0.2	3.5	0.7	0.1	0.0	0.3	0.1	1.0	0.2	1.2	0.2	7.9	1.6
VL 0483	Lettuce, leaf	0.2	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	2.5	0.5
MF 0100	Mammalian fats (except milk fats)	0.002	2.2	0.0	18.6	0.0	0.5	0.0	0.8	0.0	5.7	0.0	4.5	0.0	18.2	0.0
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.002	11.0	0.0	17.9	0.0	6.1	0.0	5.7	0.0	16.4	0.0	12.2	0.0	31.7	0.1
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0.002	43.8	0.1	71.5	0.1	24.5	0.0	22.9	0.0	65.7	0.1	48.9	0.1	126.6	0.3
ML 0106	Milks (excl processed products)	0.0005	66.0	0.0	121.1	0.1	81.6	0.0	102.4	0.1	207.7	0.1	57.0	0.0	287.9	0.1
VL 0485	Mustard greens	0.01	3.4	0.0	0.4	0.0	2.4	0.0	0.3	0.0	0.5	0.0	7.9	0.1	0.3	0.0
FS 0245	Nectarine	0.0095	1.7	0.0	1.7	0.0	0.0	0.0	0.0	0.0	1.0	0.0	1.7	0.0	1.4	0.0
FS 0247	Peach	0.0095	1.7	0.0	1.7	0.0	1.1	0.0	0.1	0.0	1.0	0.0	1.7	0.0	10.2	0.1
FP 0009	Pome fruit (excl apple juice)	0.004	20.8	0.1	11.6	0.0	3.3	0.0	0.1	0.0	10.7	0.0	23.6	0.1	36.9	0.1
	Total intake (µg/person)=			1.1		2.0		0.4		0.4		1.0		1.1		5.0
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			27.5		30		30		30		30		27.5		30
	%ADI=			3.9%		6.8%		1.2%		1.5%		3.2%		4.0%		16.7%
	Rounded %ADI=			4%		7%		1%		1%		3%		4%		20%

ETOFENPROX (185) International Estimated Daily Intake (IEDI) ADI = 0–0.03 mg/kg bw

		STMR or	Diets: g/person/day		Intake = daily intake: µg/person									
Codex Code	Commodity	STMR-P mg/kg	A diet	intake	B diet	intake	C diet	intake	D diet	intake	E diet	intake	F diet	intake
FP 0226	Apple (excl juice)	0.2	0.3	0.1	56.3	11.3	18.4	3.7	38.3	7.7	40.6	8.1	28.3	5.7
JF 0226	Apple juice	0.012	0.0	0.0	2.8	0.0	0.1	0.0	1.1	0.0	6.8	0.1	7.4	0.1
VD 0071	Beans (dry)	0.05	15.8	0.8	6.1	0.3	1.7	0.1	6.3	0.3	1.8	0.1	5.0	0.3
MO 0105	Edible offal (mammalian)	0.03	3.9	0.1	14.4	0.4	5.2	0.2	11.8	0.4	11.7	0.4	7.6	0.2
FB 0269	Grape (excl dried, excl juice, excl wine)	0.73	1.9	1.4	9.2	6.7	23.8	17.4	9.8	7.2	0.0	0.0	0.0	0.0
JF 0269	Grape juice	0.022	0.0	0.0	0.1	0.0	0.1	0.0	0.1	0.0	1.4	0.0	1.0	0.0
DF 0269	Grape, dried (= currants, raisins and sultanas)	1.5	0.0	0.0	2.9	4.4	0.4	0.6	0.4	0.6	2.3	3.5	1.7	2.6
GC 0645	Maize (incl flour, incl oil, incl beer)	0.05	82.7	4.1	148.4	7.4	135.9	6.8	31.8	1.6	33.3	1.7	7.5	0.4
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.21	5.5	1.2	23.3	4.9	7.7	1.6	11.0	2.3	18.0	3.8	26.3	5.5

Annex 3

ETOFENPROX (185) International Estimated Daily Intake (IEDI) ADI = 0–0.03 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A diet	intake	B diet	intake	C diet	intake	D diet	intake	E diet	intake	F diet	intake
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0.03	22.2	0.7	93.2	2.8	30.8	0.9	44.1	1.3	72.2	2.2	105.0	3.2
ML 0106	Milks (excl processed products)	0.013	68.8	0.9	190.6	2.5	79.4	1.0	302.6	3.9	179.6	2.3	237.9	3.1
FS 0245	Nectarine	0.16	0.0	0.0	0.5	0.1	3.3	0.5	1.8	0.3	2.8	0.4	1.6	0.3
FS 0247	Peach	0.16	0.2	0.0	24.8	4.0	3.3	0.5	1.8	0.3	5.4	0.9	1.6	0.3
FP 0230	Pear	0.2	0.1	0.0	22.3	4.5	2.8	0.6	4.8	1.0	10.7	2.1	6.8	1.4
SO 0495	Rape seed (incl oil)	0.01	0.9	0.0	1.8	0.0	2.5	0.0	1.9	0.0	35.7	0.4	26.1	0.3
-	Wine	0.029	1.3	0.0	76.8	2.2	1.1	0.0	15.4	0.4	68.8	2.0	25.6	0.7
	Total intake (µg/person)=			9.3		51.5		33.9		27.3		27.9		23.8
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			1800		1800		1800		1800		1800		1800
	%ADI=			0.5%		2.9%		1.9%		1.5%		1.6%		1.3%
	Rounded %ADI=			1%		3%		2%		2%		2%		1%

ETOFENPROX (185) International Estimated Daily Intake (IEDI) ADI = 0–0.03 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G diet	intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake	M diet	intake
FP 0226	Apple (excl juice)	0.2	14.3	2.9	9.4	1.9	2.1	0.4	0.0	0.0	8.8	1.8	16.6	3.3	27.8	5.6
JF 0226	Apple juice	0.012	0.1	0.0	0.5	0.0	0.1	0.0	0.0	0.0	0.7	0.0	0.9	0.0	5.7	0.1
VD 0071	Beans (dry)	0.05	3.4	0.2	25.5	1.3	7.8	0.4	2.1	0.1	44.7	2.2	5.5	0.3	7.3	0.4
MO 0105	Edible offal (mammalian)	0.03	4.8	0.1	10.7	0.3	4.0	0.1	4.0	0.1	6.5	0.2	6.6	0.2	5.6	0.2
FB 0269	Grape (excl dried, excl juice, excl wine)	0.73	1.2	0.9	2.6	1.9	0.0	0.0	0.2	0.1	0.0	0.0	3.7	2.7	0.0	0.0
JF 0269	Grape juice	0.022	0.0	0.0	0.1	0.0	1.0	0.0	0.0	0.0	0.6	0.0	0.4	0.0	3.6	0.1
DF 0269	Grape, dried (= currants, raisins and sultanas)	1.5	0.0	0.0	0.2	0.3	0.2	0.3	0.0	0.0	0.3	0.5	0.4	0.6	2.6	3.9
GC 0645	Maize (incl flour, incl oil, incl beer)	0.05	35.2	1.8	298.6	14.9	248.1	12.4	57.4	2.9	63.1	3.2	58.6	2.9	85.5	4.3
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.21	11.0	2.3	17.9	3.8	6.1	1.3	5.7	1.2	16.4	3.4	12.2	2.6	31.7	6.6
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0.03	43.8	1.3	71.5	2.1	24.5	0.7	22.9	0.7	65.7	2.0	48.9	1.5	126.6	3.8
ML 0106	Milks (excl processed products)	0.013	66.0	0.9	121.1	1.6	81.6	1.1	102.4	1.3	207.7	2.7	57.0	0.7	287.9	3.7
FS 0245	Nectarine	0.16	1.7	0.3	1.7	0.3	0.0	0.0	0.0	0.0	1.0	0.2	1.7	0.3	1.4	0.3
FS 0247	Peach	0.16	1.7	0.3	1.7	0.3	1.1	0.2	0.1	0.0	1.0	0.2	1.7	0.3	10.2	1.6
FP 0230	Pear	0.2	6.4	1.3	1.9	0.4	1.2	0.2	0.0	0.0	1.8	0.4	6.9	1.4	7.8	1.6

Annex 3

ETOFENPROX (185) International Estimated Daily Intake (IEDI) ADI = 0–0.03 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G diet	intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake	M diet	intake
SO 0495	Rape seed (incl oil)	0.01	9.9	0.1	5.9	0.1	0.3	0.0	1.0	0.0	0.0	0.0	15.5	0.2	9.9	0.1
-	Wine	0.029	1.0	0.0	0.9	0.0	6.8	0.2	0.1	0.0	3.4	0.1	3.6	0.1	31.0	0.9
	Total intake (µg/person)=			12.2		29.1		17.3		6.5		16.7		17.0		33.0
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			1650		1800		1800		1800		1800		1650		1800
	%ADI=			0.7%		1.6%		1.0%		0.4%		0.9%		1.0%		1.8%
	Rounded %ADI=			1%		2%		1%		0%		1%		1%		2%

ETOXAZOLE (241) International Estimated Daily Intake (IEDI) ADI = 0–0.05 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A diet	intake	B diet	intake	C diet	intake	D diet	intake	E diet	intake	F diet	intake
FC 0001	Citrus fruit (excl lemon juice, excl mandarin juice, excl orange juice, excl grapefruit juice, excl NES juice)	0.01	15.7	0.2	86.5	0.9	52.6	0.5	24.2	0.2	16.2	0.2	12.0	0.1
-	Citrus juice NES	0.005	0.0	0.0	1.7	0.0	0.1	0.0	0.0	0.0	1.1	0.0	0.3	0.0
TN 0085	Tree nuts	0	4.2	0.0	21.5	0.0	3.9	0.0	3.0	0.0	5.5	0.0	10.2	0.0
FP 0009	Pome fruit (incl apple juice)	0.01	0.5	0.0	84.1	0.8	21.9	0.2	45.2	0.5	61.7	0.6	46.2	0.5
FB 0269	Grape (excl dried, excl juice, incl wine)	0.04	3.7	0.1	116.8	4.7	25.4	1.0	31.4	1.3	96.3	3.9	35.8	1.4
DF 0269	Grape, dried (= currants, raisins and sultanas)	0.044	0.0	0.0	2.9	0.1	0.4	0.0	0.4	0.0	2.3	0.1	1.7	0.1
JF 0269	Grape juice	0.068	0.0	0.0	0.1	0.0	0.1	0.0	0.1	0.0	1.4	0.1	1.0	0.1
VC 0424	Cucumber	0.01	0.3	0.0	12.7	0.1	5.9	0.1	11.5	0.1	6.1	0.1	7.1	0.1
HH 0738	Mints	4.9	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
DT 1114	Tea, green, black (black, fermented and dried)	4.75	0.3	1.4	2.4	11.4	2.8	13.3	2.1	10.0	2.0	9.5	0.8	3.8
DH 1100	Hops, dry	4.2	0.1	0.4	0.1	0.4	0.1	0.4	0.1	0.4	0.3	1.3	0.1	0.4
MM 0095	Meat from mammals other than marine mammals	0.0005	27.7	0.0	116.5	0.1	38.5	0.0	55.1	0.0	90.2	0.0	131.3	0.1
MF 0100	Mammalian fats (except milk fats)	0.0005	0.8	0.0	10.0	0.0	0.9	0.0	6.6	0.0	11.8	0.0	3.7	0.0
MO 0105	Edible offal (mammalian)	0	3.9	0.0	14.4	0.0	5.2	0.0	11.8	0.0	11.7	0.0	7.6	0.0
ML 0106	Milks (excl processed products)	0	68.8	0.0	190.6	0.0	79.4	0.0	302.6	0.0	179.6	0.0	237.9	0.0

Annex 3

ETOXAZOLE (241) International Estimated Daily Intake (IEDI) ADI = 0–0.05 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A diet	intake	B diet	intake	C diet	intake	D diet	intake	E diet	intake	F diet	intake
	Total intake (µg/person)=			2.2		18.5		15.6		12.5		15.7		6.5
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			3000		3000		3000		3000		3000		3000
	%ADI=			0.1%		0.6%		0.5%		0.4%		0.5%		0.2%
	Rounded %ADI=			0%		1%		1%		0%		1%		0%

ETOXAZOLE (241) International Estimated Daily Intake (IEDI) ADI = 0–0.05 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G diet	intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake	M diet	intake
FC 0001	Citrus fruit (excl lemon juice, excl mandarin juice, excl orange juice, excl grapefruit juice, excl NES juice)	0.01	15.1	0.2	153.9	1.5	3.4	0.0	41.7	0.4	218.9	2.2	23.1	0.2	18.0	0.2
-	Citrus juice NES	0.005	0.0	0.0	0.0	0.0	0.5	0.0	0.0	0.0	0.0	0.0	0.3	0.0	0.1	0.0
TN 0085	Tree nuts	0	16.3	0.0	15.7	0.0	9.7	0.0	1.9	0.0	19.1	0.0	29.0	0.0	5.6	0.0
FP 0009	Pome fruit (incl apple juice)	0.01	20.9	0.2	12.3	0.1	3.4	0.0	0.1	0.0	11.7	0.1	24.9	0.2	45.4	0.5
FB 0269	Grape (excl dried, excl juice, incl wine)	0.04	2.6	0.1	3.9	0.2	9.5	0.4	0.3	0.0	4.8	0.2	8.7	0.3	43.4	1.7
DF 0269	Grape, dried (= currants, raisins and sultanas)	0.044	0.0	0.0	0.2	0.0	0.2	0.0	0.0	0.0	0.3	0.0	0.4	0.0	2.6	0.1
JF 0269	Grape juice	0.068	0.0	0.0	0.1	0.0	1.0	0.1	0.0	0.0	0.6	0.0	0.4	0.0	3.6	0.2
VC 0424	Cucumber	0.01	7.9	0.1	0.6	0.0	0.2	0.0	0.0	0.0	0.4	0.0	5.5	0.1	5.3	0.1
HH 0738	Mints	4.9	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
DT 1114	Tea, green, black (black, fermented and dried)	4.75	1.3	6.2	0.2	1.0	0.9	4.3	0.6	2.9	0.1	0.5	1.5	7.1	1.0	4.8
DH 1100	Hops, dry	4.2	0.0	0.0	0.1	0.4	0.1	0.4	0.1	0.4	0.1	0.4	0.1	0.4	0.6	2.5
MM 0095	Meat from mammals other than marine mammals	0.0005	54.8	0.0	89.4	0.0	30.6	0.0	28.6	0.0	82.1	0.0	61.1	0.0	158.3	0.1
MF 0100	Mammalian fats (except milk fats)	0.0005	2.2	0.0	18.6	0.0	0.5	0.0	0.8	0.0	5.7	0.0	4.5	0.0	18.2	0.0
MO 0105	Edible offal (mammalian)	0	4.8	0.0	10.7	0.0	4.0	0.0	4.0	0.0	6.5	0.0	6.6	0.0	5.6	0.0
ML 0106	Milks (excl processed products)	0	66.0	0.0	121.1	0.0	81.6	0.0	102.4	0.0	207.7	0.0	57.0	0.0	287.9	0.0

Annex 3

ETOXAZOLE (241) International Estimated Daily Intake (IEDI) ADI = 0–0.05 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G diet	intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake	M diet	intake
	Total intake (µg/person)=			6.7		3.3		5.2		3.7		3.5		8.5		10.1
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			2750		3000		3000		3000		3000		2750		3000
	%ADI=			0.2%		0.1%		0.2%		0.1%		0.1%		0.3%		0.3%
	Rounded %ADI=			0%		0%		0%		0%		0%		0%		0%

FLUTRIAFOL (248) International Estimated Daily Intake (IEDI) ADI = 0–0.01 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A diet	intake	B diet	intake	C diet	intake	D diet	intake	E diet	intake	F diet	intake
JF 0226	Apple juice	0.034	0.0	0.0	2.8	0.1	0.1	0.0	1.1	0.0	6.8	0.2	7.4	0.3
FI 0327	Banana	0.05	38.8	1.9	17.4	0.9	16.0	0.8	6.6	0.3	21.5	1.1	33.8	1.7
SB 0716	Coffee beans (incl green, incl extracts, excl roasted)	0.05	2.7	0.1	6.6	0.3	2.4	0.1	0.8	0.0	0.7	0.0	1.6	0.1
SM 0716	Coffee beans, roasted	0.048	0.4	0.0	6.0	0.3	0.5	0.0	0.6	0.0	9.4	0.5	16.4	0.8
FB 0269	Grape (excl dried, excl juice, incl wine)	0.21	3.7	0.8	116.8	24.5	25.4	5.3	31.4	6.6	96.3	20.2	35.8	7.5
JF 0269	Grape juice	0.13	0.0	0.0	0.1	0.0	0.1	0.0	0.1	0.0	1.4	0.2	1.0	0.1
DF 0269	Grape, dried (= currants, raisins and sultanas)	0.59	0.0	0.0	2.9	1.7	0.4	0.2	0.4	0.2	2.3	1.4	1.7	1.0
OR 0697	Peanut oil, edible	0.028	1.7	0.0	0.8	0.0	0.5	0.0	0.1	0.0	1.4	0.0	0.4	0.0
SO 0697	Peanut, shelled (excl oil)	0.02	1.5	0.0	1.3	0.0	1.0	0.0	0.5	0.0	0.8	0.0	0.5	0.0
VO 0445	Peppers, sweet (incl. pim(i)ento)	0.28	0.7	0.2	14.9	4.2	8.8	2.5	3.2	0.9	3.1	0.9	2.0	0.6
FP 0009	Pome fruit (excl apple juice)	0.07	0.5	0.0	79.9	5.6	21.8	1.5	43.6	3.0	51.5	3.6	35.1	2.5
VD 0541	Soya bean (dry, excl oil)	0.055	0.9	0.1	0.0	0.0	0.7	0.0	0.0	0.0	0.0	0.0	0.0	0.0
OR 0541	Soya bean oil, refined	0.072	1.6	0.1	6.5	0.5	6.0	0.4	4.0	0.3	6.3	0.5	7.0	0.5
GC 0654	Wheat (incl bulgur wholemeal, excl flour)	0.015	6.0	0.1	11.1	0.2	0.8	0.0	0.2	0.0	0.2	0.0	0.0	0.0
CM 0654	Wheat bran, unprocessed	0.032	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CF 1211	Wheat flour (incl macaroni, bread, pastry, starch, gluten)	0.005	63.4	0.3	296.3	1.5	327.5	1.6	300.0	1.5	181.6	0.9	166.2	0.8

Annex 3

FLUTRIAFOL (248) International Estimated Daily Intake (IEDI) ADI = 0–0.01 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A diet	intake	B diet	intake	C diet	intake	D diet	intake	E diet	intake	F diet	intake
CF 1210	Wheat germ	0.042	0.0	0.0	1.3	0.1	0.0	0.0	1.3	0.1	0.9	0.0	1.2	0.1
	Total intake (µg/person)=			3.8		39.8		12.7		13.1		29.5		15.9
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			600		600		600		600		600		600
	%ADI=			0.6%		6.6%		2.1%		2.2%		4.9%		2.6%
	Rounded %ADI=			1%		7%		2%		2%		5%		3%

FLUTRIAFOL (248) International Estimated Daily Intake (IEDI) ADI = 0–0.01 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G diet	intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake	M diet	intake
JF 0226	Apple juice	0.034	0.1	0.0	0.5	0.0	0.1	0.0	0.0	0.0	0.7	0.0	0.9	0.0	5.7	0.2
FI 0327	Banana	0.05	21.4	1.1	36.6	1.8	11.4	0.6	9.2	0.5	70.2	3.5	40.5	2.0	32.6	1.6
SB 0716	Coffee beans (incl green, incl extracts, excl roasted)	0.05	0.2	0.0	5.7	0.3	0.4	0.0	0.2	0.0	4.5	0.2	5.4	0.3	5.4	0.3
SM 0716	Coffee beans, roasted	0.048	0.0	0.0	1.3	0.1	0.1	0.0	0.0	0.0	0.8	0.0	0.3	0.0	7.0	0.3
FB 0269	Grape (excl dried, excl juice, incl wine)	0.21	2.6	0.5	3.9	0.8	9.5	2.0	0.3	0.1	4.8	1.0	8.7	1.8	43.4	9.1
JF 0269	Grape juice	0.13	0.0	0.0	0.1	0.0	1.0	0.1	0.0	0.0	0.6	0.1	0.4	0.1	3.6	0.5
DF 0269	Grape, dried (= currants, raisins and sultanas)	0.59	0.0	0.0	0.2	0.1	0.2	0.1	0.0	0.0	0.3	0.2	0.4	0.2	2.6	1.5
OR 0697	Peanut oil, edible	0.028	3.0	0.1	0.3	0.0	1.5	0.0	7.9	0.2	0.3	0.0	0.0	0.0	0.4	0.0
SO 0697	Peanut, shelled (excl oil)	0.02	0.7	0.0	1.4	0.0	1.3	0.0	3.6	0.1	0.2	0.0	0.7	0.0	6.0	0.1
VO 0445	Peppers, sweet (incl. pim(i)ento)	0.28	0.0	0.0	9.4	2.6	4.2	1.2	4.7	1.3	1.7	0.5	2.6	0.7	4.4	1.2
FP 0009	Pome fruit (excl apple juice)	0.07	20.8	1.5	11.6	0.8	3.3	0.2	0.1	0.0	10.7	0.7	23.6	1.6	36.9	2.6
VD 0541	Soya bean (dry, excl oil)	0.055	1.8	0.1	0.0	0.0	0.0	0.0	3.2	0.2	0.1	0.0	0.0	0.0	0.0	0.0
OR 0541	Soya bean oil, refined	0.072	4.3	0.3	10.6	0.8	2.0	0.1	1.4	0.1	19.5	1.4	9.2	0.7	22.0	1.6
GC 0654	Wheat (incl bulgur wholemeal, excl flour)	0.015	0.0	0.0	0.9	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.1	0.0
CM 0654	Wheat bran, unprocessed	0.032	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-

Annex 3

FLUTRIAFOL (248) International Estimated Daily Intake (IEDI) ADI = 0–0.01 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day Intake = daily intake: µg/person													
			G diet	intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake	M diet	intake
CF 1211	Wheat flour (incl macaroni, bread, pastry, starch, gluten)	0.005	133.0	0.7	60.1	0.3	52.4	0.3	32.2	0.2	87.7	0.4	79.6	0.4	180.1	0.9
CF 1210	Wheat germ	0.042	0.1	0.0	48.1	2.0	1.8	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.6	0.0
	Total intake (µg/person)=			4.3		9.7		4.8		2.6		8.1		7.9		20.0
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			550		600		600		600		600		550		600
	%ADI=			0.8%		1.6%		0.8%		0.4%		1.4%		1.4%		3.3%
	Rounded %ADI=			1%		2%		1%		0%		1%		1%		3%

GLYPHOSATE (158) International Estimated Daily Intake (IEDI) ADI = 0 - 1.0000 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day Intake = daily intake: µg/person											
			A diet	intake	B diet	intake	C diet	intake	D diet	intake	E diet	intake	F diet	intake
FI 0327	Banana	0.05	38.8	1.9	17.4	0.9	16.0	0.8	6.6	0.3	21.5	1.1	33.8	1.7
GC 0640	Barley (incl pot, incl pearled, incl flour & grits, incl beer)	7.65	40.6	310.6	16.8	128.5	93.9	718.3	13.2	101.0	48.6	371.8	36.1	276.2
VD 0071	Beans (dry)	0.17	15.8	2.7	6.1	1.0	1.7	0.3	6.3	1.1	1.8	0.3	5.0	0.9
GC 0641	Buckwheat (incl flour, incl bran)	3.7	0.0	0.0	0.1	0.4	0.0	0.0	1.7	6.3	1.6	5.9	0.1	0.4
OR 0691	Cotton seed oil, edible	0.04	0.9	0.0	4.9	0.2	1.7	0.1	6.6	0.3	0.0	0.0	0.3	0.0
MO 0105	Edible offal (mammalian)	2.9	3.9	11.3	14.4	41.8	5.2	15.1	11.8	34.2	11.7	33.9	7.6	22.0
PE 0112	Eggs	0	2.5	0.0	29.7	0.0	25.1	0.0	24.5	0.0	37.8	0.0	27.4	0.0
VD 0533	Lentil (dry)	0.5	0.9	0.5	5.4	2.7	3.1	1.6	1.3	0.7	0.7	0.4	0.1	0.1
CF 1255	Maize flour	0.13	68.9	9.0	15.4	2.0	51.3	6.7	16.6	2.2	14.7	1.9	2.0	0.3
GC 0645	Maize (excl flour, excl oil, incl beer)	0.12	0.0	0.0	1.4	0.2	51.4	6.2	11.9	1.4	0.2	0.0	0.2	0.0
OR 0645	Maize oil, edible	0.04	0.1	0.0	4.0	0.2	2.3	0.1	0.5	0.0	0.9	0.0	0.2	0.0
MM 0095	Meat from mammals other than marine mammals	0.05	27.7	1.4	116.5	5.8	38.5	1.9	55.1	2.8	90.2	4.5	131.3	6.6
ML 0106	Milks (excl processed products)	0	68.8	0.0	190.6	0.0	79.4	0.0	302.6	0.0	179.6	0.0	237.9	0.0
GC 0646	Millet (incl flour, incl beer)	3.7	15.8	58.5	0.1	0.4	0.8	3.0	5.6	20.7	0.2	0.7	0.1	0.4
GC 0647	Oats (incl rolled)	4.15	1.4	5.8	0.6	2.5	0.2	0.8	4.2	17.4	5.7	23.7	8.9	36.9

Annex 3

GLYPHOSATE (158) International Estimated Daily Intake (IEDI) ADI = 0 - 1.0000 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A diet	intake	B diet	intake	C diet	intake	D diet	intake	E diet	intake	F diet	intake
VD 0072	Peas (dry) (= field pea + cowpea)	0.5	6.8	3.4	1.3	0.7	1.0	0.5	2.3	1.2	4.6	2.3	3.4	1.7
GC 0656	Popcorn	3.7	0.1	0.4	0.2	0.7	0.0	0.0	0.1	0.4	0.1	0.4	0.1	0.4
PM 0110	Poultry meat	0	7.1	0.0	58.5	0.0	31.9	0.0	24.0	0.0	61.0	0.0	27.3	0.0
PO 0111	Poultry, edible offal of	0.088	0.4	0.0	0.4	0.0	1.7	0.1	0.1	0.0	0.6	0.1	0.2	0.0
SO 0495	Rape seed (excl oil)	0.93	0.1	0.1	0.0	0.0	0.0	0.0	0.1	0.1	0.1	0.1	0.1	0.1
OR 0495	Rape seed oil, edible	0.1	0.3	0.0	0.7	0.1	1.0	0.1	0.7	0.1	13.7	1.4	10.0	1.0
GC 0650	Rye (incl flour)	3.7	0.1	0.4	3.7	13.7	0.3	1.1	24.3	89.9	25.8	95.5	45.8	169.5
GC 0651	Sorghum (incl flour, incl beer)	4.8	36.9	177.1	0.0	0.0	10.2	49.0	0.0	0.0	0.0	0.0	0.0	0.0
VD 0541	Soya bean (dry, excl oil)	5	0.9	4.7	0.0	0.0	0.7	3.5	0.0	0.0	0.0	0.1	0.0	0.0
OR 0541	Soya bean oil, refined	0.1	1.6	0.2	6.5	0.7	6.0	0.6	4.0	0.4	6.3	0.6	7.0	0.7
VR 0596	Sugar beet	3.4	0.0	0.0	40.7	138.4	0.0	0.0	0.1	0.3	6.0	20.4	0.1	0.3
GS 0659	Sugar cane	0.27	30.9	8.3	43.1	11.6	51.3	13.9	0.1	0.0	5.5	1.5	0.0	0.0
DM 0659	Sugar cane molasses	2	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
SO 0702	Sunflower seed (incl oil)	0.395	0.7	0.3	44.5	17.6	20.5	8.1	29.6	11.7	21.2	8.4	5.4	2.1
VO 0447	Sweet corn (corn-on-the-cob, only)	0.325	7.3	2.4	1.0	0.3	0.1	0.0	0.5	0.2	3.3	1.1	3.6	1.2
GC 0653	Triticale (incl flour)	3.7	0.0	0.0	115.8	428.5	0.0	0.0	0.0	0.0	0.3	1.1	0.0	0.0
GC 0654	Wheat (excl bulgur wholemeal, excl flour)	3.7	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.4	0.0	0.0
CM 0654	Wheat bran, unprocessed	1.8	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
-d	Wheat bulgur wholemeal	1.05	5.5	5.8	10.2	10.7	0.7	0.7	0.2	0.2	0.1	0.1	0.0	0.0
CF 1211	Wheat flour (incl macaroni, bread, pastry, starch, gluten)	0.11	63.4	7.0	296.3	32.6	327.5	36.0	300.0	33.0	181.6	20.0	166.2	18.3
-d	Wheat macaroni	1.05	0.8	0.8	1.1	1.2	0.8	0.8	1.8	1.9	4.6	4.8	7.6	8.0
-d	Wheat pastry	1.05	0.4	0.4	1.1	1.2	0.7	0.7	2.6	2.7	1.7	1.8	5.4	5.7
	Total intake (µg/person)=			612.9		844.3		870.0		330.3		604.2		554.2
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			60000		60000		60000		60000		60000		60000
	%ADI=			1.0%		1.4%		1.5%		0.6%		1.0%		0.9%
	Rounded %ADI=			1%		1%		1%		1%		1%		1%

Annex 3

GLYPHOSATE (158) International Estimated Daily Intake (IEDI) ADI = 0 - 1.0000 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day Intake = daily intake: µg/person													
			G diet	intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake	M diet	intake
FI 0327	Banana	0.05	21.4	1.1	36.6	1.8	11.4	0.6	9.2	0.5	70.2	3.5	40.5	2.0	32.6	1.6
GC 0640	Barley (incl pot, incl pearled, incl flour & grits, incl beer)	7.65	5.9	45.1	20.5	156.8	5.9	45.1	2.5	19.1	20.2	154.5	16.8	128.5	43.8	335.1
VD 0071	Beans (dry)	0.17	3.4	0.6	25.5	4.3	7.8	1.3	2.1	0.4	44.7	7.6	5.5	0.9	7.3	1.2
GC 0641	Buckwheat (incl flour, incl bran)	3.7	1.0	3.7	0.0	0.0	0.2	0.7	0.1	0.4	0.5	1.9	2.0	7.4	0.1	0.4
OR 0691	Cotton seed oil, edible	0.04	1.0	0.0	0.7	0.0	1.0	0.0	1.4	0.1	1.5	0.1	5.5	0.2	1.2	0.0
MO 0105	Edible offal (mammalian)	2.9	4.8	13.9	10.7	31.0	4.0	11.6	4.0	11.6	6.5	18.9	6.6	19.1	5.6	16.2
PE 0112	Eggs	0	22.1	0.0	71.5	0.0	16.6	0.0	5.1	0.0	17.6	0.0	35.2	0.0	57.4	0.0
VD 0533	Lentil (dry)	0.5	1.1	0.6	1.1	0.6	0.1	0.1	0.2	0.1	1.0	0.5	0.0	0.0	1.6	0.8
CF 1255	Maize flour	0.13	28.8	3.7	248.8	32.3	206.7	26.9	47.8	6.2	46.2	6.0	10.5	1.4	21.5	2.8
GC 0645	Maize (excl flour, excl oil, incl beer)	0.12	0.6	0.1	0.0	0.0	0.1	0.0	0.0	0.0	7.7	0.9	0.0	0.0	19.4	2.3
OR 0645	Maize oil, edible	0.04	0.1	0.0	0.6	0.0	1.8	0.1	0.0	0.0	1.0	0.0	1.6	0.1	1.8	0.1
MM 0095	Meat from mammals other than marine mammals	0.05	54.8	2.7	89.4	4.5	30.6	1.5	28.6	1.4	82.1	4.1	61.1	3.1	158.3	7.9
ML 0106	Milks (excl processed products)	0	66.0	0.0	121.1	0.0	81.6	0.0	102.4	0.0	207.7	0.0	57.0	0.0	287.9	0.0
GC 0646	Millet (incl flour, incl beer)	3.7	13.0	48.1	0.0	0.0	8.3	30.7	96.9	358.5	0.0	0.0	0.4	1.5	0.0	0.0
GC 0647	Oats (incl rolled)	4.15	0.2	0.8	2.0	8.3	0.8	3.3	0.0	0.0	3.5	14.5	0.7	2.9	7.6	31.5
VD 0072	Peas (dry) (= field pea + cowpea)	0.5	1.8	0.9	2.2	1.1	3.2	1.6	26.7	13.4	1.5	0.8	1.8	0.9	1.8	0.9
GC 0656	Popcorn	3.7	0.1	0.4	0.1	0.4	0.1	0.4	0.1	0.4	0.1	0.4	0.1	0.4	1.4	5.2
PM 0110	Poultry meat	0	17.6	0.0	131.3	0.0	25.1	0.0	4.7	0.0	145.9	0.0	27.7	0.0	115.1	0.0
PO 0111	Poultry, edible offal of	0.088	0.4	0.0	1.0	0.1	1.9	0.2	0.0	0.0	0.7	0.1	1.0	0.1	0.3	0.0
SO 0495	Rape seed (excl oil)	0.93	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
OR 0495	Rape seed oil, edible	0.1	3.8	0.4	2.3	0.2	0.1	0.0	0.4	0.0	0.0	0.0	6.0	0.6	3.8	0.4
GC 0650	Rye (incl flour)	3.7	0.4	1.5	0.0	0.0	0.2	0.7	0.1	0.4	0.1	0.4	0.9	3.3	0.8	3.0
GC 0651	Sorghum (incl flour, incl beer)	4.8	9.8	47.0	19.9	95.5	18.6	89.3	112.3	539.0	0.1	0.5	3.3	15.8	3.0	14.4
VD 0541	Soya bean (dry, excl oil)	5	1.8	9.1	0.0	0.2	0.0	0.0	3.2	15.8	0.1	0.5	0.0	-0.1	0.0	0.0
OR 0541	Soya bean oil, refined	0.1	4.3	0.4	10.6	1.1	2.0	0.2	1.4	0.1	19.5	2.0	9.2	0.9	22.0	2.2
VR 0596	Sugar beet	3.4	0.0	0.0	0.1	0.3	0.0	0.0	0.0	0.0	0.2	0.7	0.0	0.0	14.3	48.6
GS 0659	Sugar cane	0.27	26.2	7.1	1.5	0.4	33.8	9.1	5.5	1.5	18.6	5.0	3.0	0.8	20.2	5.5
DM 0659	Sugar cane molasses	2	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
SO 0702	Sunflower seed (incl oil)	0.395	2.7	1.1	8.8	3.5	13.5	5.3	0.2	0.1	3.6	1.4	0.6	0.2	10.4	4.1
VO 0447	Sweet corn (corn-on-the-cob, only)	0.325	0.2	0.1	2.4	0.8	2.2	0.7	3.3	1.1	1.7	0.6	2.8	0.9	11.2	3.6
GC 0653	Triticale (incl flour)	3.7	1.3	4.8	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0

Annex 3

GLYPHOSATE (158) International Estimated Daily Intake (IEDI) ADI = 0 - 1.0000 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G diet	intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake	M diet	intake
GC 0654	Wheat (excl bulgur wholemeal, excl flour)	3.7	0.0	0.0	0.9	3.2	0.0	0.0	0.0	0.1	0.1	0.3	0.0	0.0	0.1	0.3
CM 0654	Wheat bran, unprocessed	1.8	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
-d	Wheat bulgur wholemeal	1.05	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
CF 1211	Wheat flour (incl macaroni, bread, pastry, starch, gluten)	0.11	133.0	14.6	60.1	6.6	52.4	5.8	32.2	3.5	87.7	9.6	79.6	8.8	180.1	19.8
-d	Wheat macaroni	1.05	1.7	1.8	3.6	3.8	0.5	0.5	0.2	0.2	0.3	0.3	1.7	1.8	2.0	2.1
-d	Wheat pastry	1.05	0.3	0.3	0.6	0.6	0.7	0.7	0.2	0.2	0.3	0.3	0.6	0.6	1.7	1.8
	Total intake (µg/person)=			210.0		357.5		236.6		974.1		235.3		202.2		511.9
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			55000		60000		60000		60000		60000		55000		60000
	%ADI=			0.4%		0.6%		0.4%		1.6%		0.4%		0.4%		0.9%
	Rounded %ADI=			0%		1%		0%		2%		0%		0%		1%

HEXYTHIAZOX (176) International Estimated Daily Intake (IEDI) ADI = 0 - 0.03 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A diet	intake	B diet	intake	C diet	intake	D diet	intake	E diet	intake	F diet	intake
-	Barley beer	0.036	18.3	0.7	84.1	3.0	4.1	0.1	66.0	2.4	243.1	8.8	161.3	5.8
FC 0001	Citrus fruit (incl lemon juice, incl mandarin juice, excl orange juice, incl grapefruit juice, incl NES juice)	0.074	15.7	1.2	96.7	7.2	55.3	4.1	25.3	1.9	23.4	1.7	16.2	1.2
FT 0295	Date	0.26	0.8	0.2	1.4	0.4	31.5	8.2	5.1	1.3	0.3	0.1	0.2	0.1
MO 0105	Edible offal (mammalian)	0.01	3.9	0.0	14.4	0.1	5.2	0.1	11.8	0.1	11.7	0.1	7.6	0.1
VO 0440	Egg plant (= aubergine)	0.05	1.7	0.1	17.5	0.9	12.3	0.6	1.7	0.1	0.8	0.0	0.4	0.0
PE 0112	Eggs	0.002	2.5	0.0	29.7	0.1	25.1	0.1	24.5	0.0	37.8	0.1	27.4	0.1
VC 0045	Fruiting vegetables, cucurbits (excl watermelon)	0.05	20.5	1.0	64.4	3.2	48.8	2.4	56.4	2.8	21.0	1.1	17.2	0.9
FB 0269	Grape (excl dried, excl juice, excl wine)	0.2	1.9	0.4	9.2	1.8	23.8	4.8	9.8	2.0	0.0	0.0	0.0	0.0
JF 0269	Grape juice	0.084	0.0	0.0	0.1	0.0	0.1	0.0	0.1	0.0	1.4	0.1	1.0	0.1
DF 0269	Grape, dried (= currants, raisins and sultanas)	0.32	0.0	0.0	2.9	0.9	0.4	0.1	0.4	0.1	2.3	0.7	1.7	0.5
DH 1100	Hops, dry	0.79	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.3	0.2	0.1	0.1

Annex 3

HEXYTHIAZOX (176) International Estimated Daily Intake (IEDI) ADI = 0 - 0.03 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A diet	intake	B diet	intake	C diet	intake	D diet	intake	E diet	intake	F diet	intake
MF 0100	Mammalian fats (except milk fats)	0.01	0.8	0.0	10.0	0.1	0.9	0.0	6.6	0.1	11.8	0.1	3.7	0.0
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.01	5.5	0.1	23.3	0.2	7.7	0.1	11.0	0.1	18.0	0.2	26.3	0.3
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0	22.2	0.0	93.2	0.0	30.8	0.0	44.1	0.0	72.2	0.0	105.0	0.0
ML 0106	Milks (excl processed products)	0.01	68.8	0.7	190.6	1.9	79.4	0.8	302.6	3.0	179.6	1.8	237.9	2.4
JF 0004	Orange juice	0.024	0.0	0.0	2.1	0.1	4.4	0.1	1.4	0.0	16.2	0.4	22.6	0.5
DF 0014	Plum, dried (prunes)	0.41	0.0	0.0	0.2	0.1	0.0	0.0	0.1	0.0	0.5	0.2	0.6	0.2
FP 0009	Pome fruit (incl apple juice)	0.11	0.5	0.1	84.1	9.3	21.9	2.4	45.2	5.0	61.7	6.8	46.2	5.1
PM 0110	Poultry meat: 10% as fat	0.002	0.7	0.0	5.9	0.0	3.2	0.0	2.4	0.0	6.1	0.0	2.7	0.0
PM 0110	Poultry meat: 90% as muscle	0	6.4	0.0	52.7	0.0	28.7	0.0	21.6	0.0	54.9	0.0	24.6	0.0
PO 0111	Poultry, edible offal of	0.01	0.4	0.0	0.4	0.0	1.7	0.0	0.1	0.0	0.6	0.0	0.2	0.0
FS 0012	Stone fruit (excl dried plums, incl dried apricots)	0.09	0.7	0.1	44.1	4.0	14.1	1.3	26.6	2.4	26.3	2.4	8.3	0.7
FB 0275	Strawberry	0.54	0.0	0.0	5.0	2.7	2.0	1.1	1.7	0.9	5.2	2.8	4.1	2.2
DT 1114	Tea, green, black (black, fermented and dried)	4.55	0.3	1.4	2.4	10.9	2.8	12.7	2.1	9.6	2.0	9.1	0.8	3.6
VO 0448	Tomato (incl juice, incl paste, incl canned)	0.05	11.8	0.6	185.0	9.3	118.0	5.9	60.7	3.0	31.6	1.6	40.9	2.0
-	Wine	0.01	1.3	0.0	76.8	0.8	1.1	0.0	15.4	0.2	68.8	0.7	25.6	0.3
	Total intake (µg/person)=			6.5		57.0		45.0		35.1		39.0		26.2
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			1800		1800		1800		1800		1800		1800
	%ADI=			0.4%		3.2%		2.5%		2.0%		2.2%		1.5%
	Rounded %ADI=			0%		3%		2%		2%		2%		1%

HEXYTHIAZOX (176) International Estimated Daily Intake (IEDI) ADI = 0 - 0.03 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G diet	intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake	M diet	intake
-	Barley beer	0.036	21.9	0.8	102.7	3.7	29.5	1.1	12.6	0.5	100.9	3.6	82.2	3.0	218.8	7.9
FC 0001	Citrus fruit (incl lemon juice, incl mandarin juice, excl orange juice, incl grapefruit juice, incl NES juice)	0.074	16.9	1.3	155.0	11.5	8.6	0.6	42.5	3.1	220.5	16.3	28.9	2.1	30.1	2.2

Annex 3

HEXYTHIAZOX (176) International Estimated Daily Intake (IEDI) ADI = 0 - 0.03 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day Intake = daily intake: µg/person													
			G		H		I		J		K		L		M	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
FT 0295	Date	0.26	0.9	0.2	0.1	0.0	0.1	0.0	3.8	1.0	0.0	0.0	0.0	0.0	0.2	0.1
MO 0105	Edible offal (mammalian)	0.01	4.8	0.0	10.7	0.1	4.0	0.0	4.0	0.0	6.5	0.1	6.6	0.1	5.6	0.1
VO 0440	Egg plant (= aubergine)	0.05	20.1	1.0	0.1	0.0	0.6	0.0	6.3	0.3	0.5	0.0	6.3	0.3	0.7	0.0
PE 0112	Eggs	0.002	22.1	0.0	71.5	0.1	16.6	0.0	5.1	0.0	17.6	0.0	35.2	0.1	57.4	0.1
VC 0045	Fruiting vegetables, cucurbits (excl watermelon)	0.05	30.4	1.5	11.9	0.6	12.4	0.6	4.4	0.2	10.3	0.5	24.6	1.2	30.6	1.5
FB 0269	Grape (excl dried, excl juice, excl wine)	0.2	1.2	0.2	2.6	0.5	0.0	0.0	0.2	0.0	0.0	0.0	3.7	0.7	0.0	0.0
JF 0269	Grape juice	0.084	0.0	0.0	0.1	0.0	1.0	0.1	0.0	0.0	0.6	0.1	0.4	0.0	3.6	0.3
DF 0269	Grape, dried (= currants, raisins and sultanas)	0.32	0.0	0.0	0.2	0.1	0.2	0.1	0.0	0.0	0.3	0.1	0.4	0.1	2.6	0.8
DH 1100	Hops, dry	0.79	0.0	0.0	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.6	0.5
MF 0100	Mammalian fats (except milk fats)	0.01	2.2	0.0	18.6	0.2	0.5	0.0	0.8	0.0	5.7	0.1	4.5	0.0	18.2	0.2
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.01	11.0	0.1	17.9	0.2	6.1	0.1	5.7	0.1	16.4	0.2	12.2	0.1	31.7	0.3
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0	43.8	0.0	71.5	0.0	24.5	0.0	22.9	0.0	65.7	0.0	48.9	0.0	126.6	0.0
ML 0106	Milks (excl processed products)	0.01	66.0	0.7	121.1	1.2	81.6	0.8	102.4	1.0	207.7	2.1	57.0	0.6	287.9	2.9
JF 0004	Orange juice	0.024	0.2	0.0	1.0	0.0	3.5	0.1	0.0	0.0	1.3	0.0	6.4	0.2	56.8	1.4
DF 0014	Plum, dried (prunes)	0.41	0.1	0.0	0.2	0.1	0.0	0.0	0.0	0.0	0.2	0.1	0.2	0.1	0.6	0.2
FP 0009	Pome fruit (incl apple juice)	0.11	20.9	2.3	12.3	1.4	3.4	0.4	0.1	0.0	11.7	1.3	24.9	2.7	45.4	5.0
PM 0110	Poultry meat: 10% as fat	0.002	1.8	0.0	13.1	0.0	2.5	0.0	0.5	0.0	14.6	0.0	2.8	0.0	11.5	0.0
PM 0110	Poultry meat: 90% as muscle	0	15.8	0.0	118.2	0.0	22.6	0.0	4.2	0.0	131.3	0.0	24.9	0.0	103.6	0.0
PO 0111	Poultry, edible offal of	0.01	0.4	0.0	1.0	0.0	1.9	0.0	0.0	0.0	0.7	0.0	1.0	0.0	0.3	0.0
FS 0012	Stone fruit (excl dried plums, incl dried apricots)	0.09	6.7	0.6	4.3	0.4	1.4	0.1	0.1	0.0	4.9	0.4	4.9	0.4	17.7	1.6
FB 0275	Strawberry	0.54	0.0	0.0	1.8	1.0	0.1	0.1	0.0	0.0	0.3	0.2	6.2	3.3	5.9	3.2
DT 1114	Tea, green, black (black, fermented and dried)	4.55	1.3	5.9	0.2	0.9	0.9	4.1	0.6	2.7	0.1	0.5	1.5	6.8	1.0	4.6
VO 0448	Tomato (incl juice, incl paste, incl canned)	0.05	23.5	1.2	31.7	1.6	15.0	0.8	16.2	0.8	35.6	1.8	9.9	0.5	103.0	5.2
-	Wine	0.01	1.0	0.0	0.9	0.0	6.8	0.1	0.1	0.0	3.4	0.0	3.6	0.0	31.0	0.3
	Total intake (µg/person)=			16.0		23.7		9.1		9.9		27.4		22.6		38.3
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			1650		1800		1800		1800		1800		1650		1800
	%ADI=			1.0%		1.3%		0.5%		0.6%		1.5%		1.4%		2.1%
	Rounded %ADI=			1%		1%		1%		1%		2%		1%		2%

Annex 3

ISOPYRAZAM (249) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0600 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A diet	intake	B diet	intake	C diet	intake	D diet	intake	E diet	intake	F diet	intake
FI 0327	Banana	0.15	38.8	5.8	17.4	2.6	16.0	2.4	6.6	1.0	21.5	3.2	33.8	5.1
GC 0640	Barley (excl pot, incl pearled, incl flour & grits, excl beer)	0.0375	0.0	0.0	0.0	0.0	93.9	3.5	0.0	0.0	0.0	0.0	3.8	0.1
-	Barley beer	0.0045	18.3	0.1	84.1	0.4	4.1	0.0	66.0	0.3	243.1	1.1	161.3	0.7
-	Barley, pot	0.012	29.0	0.3	0.0	0.0	11.9	0.1	4.0	0.0	2.0	0.0	12.5	0.2
MO 0105	Edible offal (mammalian)	0.0056	3.9	0.0	14.4	0.1	5.2	0.0	11.8	0.1	11.7	0.1	7.6	0.0
PE 0112	Eggs	0.01	2.5	0.0	29.7	0.3	25.1	0.3	24.5	0.2	37.8	0.4	27.4	0.3
MF 0100	Mammalian fats (except milk fats)	0.0056	0.8	0.0	10.0	0.1	0.9	0.0	6.6	0.0	11.8	0.1	3.7	0.0
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.0056	5.5	0.0	23.3	0.1	7.7	0.0	11.0	0.1	18.0	0.1	26.3	0.1
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0.0056	22.2	0.1	93.2	0.5	30.8	0.2	44.1	0.2	72.2	0.4	105.0	0.6
ML 0106	Milks (excl processed products)	0.0042	68.8	0.3	190.6	0.8	79.4	0.3	302.6	1.3	179.6	0.8	237.9	1.0
PM 0110	Poultry meat: 10% as fat	0.01	0.7	0.0	5.9	0.1	3.2	0.0	2.4	0.0	6.1	0.1	2.7	0.0
PM 0110	Poultry meat: 90% as muscle	0.01	6.4	0.1	52.7	0.5	28.7	0.3	21.6	0.2	54.9	0.5	24.6	0.2
PO 0111	Poultry, edible offal of	0.01	0.4	0.0	0.4	0.0	1.7	0.0	0.1	0.0	0.6	0.0	0.2	0.0
PF 0111	Poultry, fats	0.01	0.1	0.0	0.1	0.0	0.1	0.0	0.0	0.0	0.4	0.0	0.1	0.0
GC 0650	Rye (incl flour)	0.015	0.1	0.0	3.7	0.1	0.3	0.0	24.3	0.4	25.8	0.4	45.8	0.7
GC 0653	Triticale (incl flour)	0.015	0.0	0.0	115.8	1.7	0.0	0.0	0.0	0.0	0.3	0.0	0.0	0.0
GC 0654	Wheat (incl bulgur wholemeal, excl flour)	0.015	6.0	0.1	11.1	0.2	0.8	0.0	0.2	0.0	0.2	0.0	0.0	0.0
CM 0654	Wheat bran, unprocessed	0.066	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CF 1211	Wheat flour (incl macaroni, bread, pastry, starch, gluten)	0.0035	63.4	0.2	296.3	1.0	327.5	1.1	300.0	1.1	181.6	0.6	166.2	0.6
CF 1210	Wheat germ	0.0038	0.0	0.0	1.3	0.0	0.0	0.0	1.3	0.0	0.9	0.0	1.2	0.0
CF 1212	Wheat wholemeal	0.012	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CP 1212	Wholemeal bread	0.0083	0.0	0.0	0.1	0.0	0.0	0.0	0.1	0.0	0.1	0.0	1.0	0.0
	Total intake (µg/person)=			7.1		8.5		8.4		4.9		7.8		9.7
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			3600		3600		3600		3600		3600		3600
	%ADI=			0.2%		0.2%		0.2%		0.1%		0.2%		0.3%

Annex 3

ISOPYRAZAM (249) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0600 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A diet	intake	B diet	intake	C diet	intake	D diet	intake	E diet	intake	F diet	intake
	Rounded %ADI=			0%		0%		0%		0%		0%		0%

ISOPYRAZAM (249) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0600 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G diet	intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake	M diet	intake
FI 0327	Banana	0.15	21.4	3.2	36.6	5.5	11.4	1.7	9.2	1.4	70.2	10.5	40.5	6.1	32.6	4.9
GC 0640	Barley (excl pot, incl pearled, incl flour & grits, excl beer)	0.0375	1.5	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.4	0.0	0.0	0.0
-	Barley beer	0.0045	21.9	0.1	102.7	0.5	29.5	0.1	12.6	0.1	100.9	0.5	82.2	0.4	218.8	1.0
-	Barley, pot	0.012	0.7	0.0	0.0	0.0	0.0	0.0	0.7	0.0	2.4	0.0	4.1	0.0	0.0	0.0
MO 0105	Edible offal (mammalian)	0.0056	4.8	0.0	10.7	0.1	4.0	0.0	4.0	0.0	6.5	0.0	6.6	0.0	5.6	0.0
PE 0112	Eggs	0.01	22.1	0.2	71.5	0.7	16.6	0.2	5.1	0.1	17.6	0.2	35.2	0.4	57.4	0.6
MF 0100	Mammalian fats (except milk fats)	0.0056	2.2	0.0	18.6	0.1	0.5	0.0	0.8	0.0	5.7	0.0	4.5	0.0	18.2	0.1
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.0056	11.0	0.1	17.9	0.1	6.1	0.0	5.7	0.0	16.4	0.1	12.2	0.1	31.7	0.2
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0.0056	43.8	0.2	71.5	0.4	24.5	0.1	22.9	0.1	65.7	0.4	48.9	0.3	126.6	0.7
ML 0106	Milks (excl processed products)	0.0042	66.0	0.3	121.1	0.5	81.6	0.3	102.4	0.4	207.7	0.9	57.0	0.2	287.9	1.2
PM 0110	Poultry meat: 10% as fat	0.01	1.8	0.0	13.1	0.1	2.5	0.0	0.5	0.0	14.6	0.1	2.8	0.0	11.5	0.1
PM 0110	Poultry meat: 90% as muscle	0.01	15.8	0.2	118.2	1.2	22.6	0.2	4.2	0.0	131.3	1.3	24.9	0.2	103.6	1.0
PO 0111	Poultry, edible offal of	0.01	0.4	0.0	1.0	0.0	1.9	0.0	0.0	0.0	0.7	0.0	1.0	0.0	0.3	0.0
PF 0111	Poultry, fats	0.01	0.1	0.0	8.2	0.1	0.0	0.0	0.1	0.0	0.0	0.0	0.1	0.0	4.2	0.0
GC 0650	Rye (incl flour)	0.015	0.4	0.0	0.0	0.0	0.2	0.0	0.1	0.0	0.1	0.0	0.9	0.0	0.8	0.0
GC 0653	Triticale (incl flour)	0.015	1.3	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
GC 0654	Wheat (incl bulgur wholemeal, excl flour)	0.015	0.0	0.0	0.9	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.1	0.0
CM 0654	Wheat bran, unprocessed	0.066	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CF 1211	Wheat flour (incl macaroni, bread, pastry, starch, gluten)	0.0035	133.0	0.5	60.1	0.2	52.4	0.2	32.2	0.1	87.7	0.3	79.6	0.3	180.1	0.6

Annex 3

ISOPYRAZAM (249) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0600 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G diet	intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake	M diet	intake
CF 1210	Wheat germ	0.0038	0.1	0.0	48.1	0.2	1.8	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.6	0.0
CF 1212	Wheat wholemeal	0.012	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CP 1212	Wholemeal bread	0.0083	0.0	0.0	2.2	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Total intake (µg/person)=			4.9		9.7		3.0		2.3		14.4		8.1		10.5
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			3300		3600		3600		3600		3600		3300		3600
	%ADI=			0.1%		0.3%		0.1%		0.1%		0.4%		0.2%		0.3%
	Rounded %ADI=			0%		0%		0%		0%		0%		0%		0%

PROFENOFOS (171) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0300 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A diet	intake	B diet	intake	C diet	intake	D diet	intake	E diet	intake	F diet	intake
FI 0345	Mango (incl juice, incl pulp)	0.06	6.3	0.4	1.0	0.1	4.6	0.3	0.2	0.0	0.7	0.0	0.3	0.0
-	Assorted (sub)tropical fruits NES (excl passion fruit)	2.1	5.2	10.9	6.5	13.7	1.2	2.5	0.0	0.0	16.8	35.3	0.0	0.0
VO 0444	Peppers, chili	0.78	0.7	0.5	14.9	11.6	4.1	3.2	3.2	2.5	3.1	2.4	2.0	1.6
VO 0448	Tomato (incl juice, incl paste, incl canned)	1.3	11.8	15.3	185.0	240.5	118.0	153.4	60.7	78.9	31.6	41.1	40.9	53.2
OR 0691	Cotton seed oil, edible	0.14	0.9	0.1	4.9	0.7	1.7	0.2	6.6	0.9	0.0	0.0	0.3	0.0
MM 0095	Meat from mammals other than marine mammals	0	27.7	0.0	116.5	0.0	38.5	0.0	55.1	0.0	90.2	0.0	131.3	0.0
MF 0100	Mammalian fats (except milk fats)	0	0.8	0.0	10.0	0.0	0.9	0.0	6.6	0.0	11.8	0.0	3.7	0.0
MO 0105	Edible offal (mammalian)	0	3.9	0.0	14.4	0.0	5.2	0.0	11.8	0.0	11.7	0.0	7.6	0.0
PM 0110	Poultry meat	0	7.1	0.0	58.5	0.0	31.9	0.0	24.0	0.0	61.0	0.0	27.3	0.0
PF 0111	Poultry, fats	0	0.1	0.0	0.1	0.0	0.1	0.0	0.0	0.0	0.4	0.0	0.1	0.0
PO 0111	Poultry, edible offal of	0	0.4	0.0	0.4	0.0	1.7	0.0	0.1	0.0	0.6	0.0	0.2	0.0
ML 0106	Milks (excl processed products)	0	68.8	0.0	190.6	0.0	79.4	0.0	302.6	0.0	179.6	0.0	237.9	0.0
PE 0112	Eggs	0	2.5	0.0	29.7	0.0	25.1	0.0	24.5	0.0	37.8	0.0	27.4	0.0
	Total intake (µg/person)=			27.3		266.5		159.6		82.3		78.8		54.8

Bodyweight per region (kg bw) =		60	60	60	60	60	60				
ADI (µg/person)=		1800	1800	1800	1800	1800	1800				
%ADI=		1.5%	14.8%	8.9%	4.6%	4.4%	3.0%				
Rounded %ADI=		2%	10%	9%	5%	4%	3%				

PROFENOFOS (171) International Estimated Daily Intake (IEDI) ADI = 0–0.03 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day Intake = daily intake: µg/person													
			G diet	intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake	M diet	intake
FI 0345	Mango (incl juice, incl pulp)	0.06	12.7	0.8	26.2	1.6	6.1	0.4	12.7	0.8	9.2	0.6	8.0	0.5	1.9	0.1
-	Assorted (sub)tropical fruits NES (excl passion fruit)	2.1	5.7	12.0	4.7	9.9	2.4	5.0	1.1	2.3	13.1	27.5	47.2	99.1	0.7	1.5
VO 0444	Peppers, chili	0.78	8.7	6.8	13.0	10.1	4.2	3.3	4.7	3.7	1.7	1.3	2.6	2.0	4.4	3.4
VO 0448	Tomato (incl juice, incl paste, incl canned)	1.3	23.5	30.6	31.7	41.2	15.0	19.5	16.2	21.1	35.6	46.3	9.9	12.9	103.0	133.9
OR 0691	Cotton seed oil, edible	0.14	1.0	0.1	0.7	0.1	1.0	0.1	1.4	0.2	1.5	0.2	5.5	0.8	1.2	0.2
MM 0095	Meat from mammals other than marine mammals	0	54.8	0.0	89.4	0.0	30.6	0.0	28.6	0.0	82.1	0.0	61.1	0.0	158.3	0.0
MF 0100	Mammalian fats (except milk fats)	0	2.2	0.0	18.6	0.0	0.5	0.0	0.8	0.0	5.7	0.0	4.5	0.0	18.2	0.0
MO 0105	Edible offal (mammalian)	0	4.8	0.0	10.7	0.0	4.0	0.0	4.0	0.0	6.5	0.0	6.6	0.0	5.6	0.0
PM 0110	Poultry meat	0	17.6	0.0	131.3	0.0	25.1	0.0	4.7	0.0	145.9	0.0	27.7	0.0	115.1	0.0
PF 0111	Poultry, fats	0	0.1	0.0	8.2	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.1	0.0	4.2	0.0
PO 0111	Poultry, edible offal of	0	0.4	0.0	1.0	0.0	1.9	0.0	0.0	0.0	0.7	0.0	1.0	0.0	0.3	0.0
ML 0106	Milks (excl processed products)	0	66.0	0.0	121.1	0.0	81.6	0.0	102.4	0.0	207.7	0.0	57.0	0.0	287.9	0.0
PE 0112	Eggs	0	22.1	0.0	71.5	0.0	16.6	0.0	5.1	0.0	17.6	0.0	35.2	0.0	57.4	0.0
	Total intake (µg/person)=			50.2		62.9		28.3		28.0		75.9		115.3		139.1
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			1650		1800		1800		1800		1800		1650		1800
	%ADI=			3.0%		3.5%		1.6%		1.6%		4.2%		7.0%		7.7%
	Rounded %ADI=			3%		3%		2%		2%		4%		7%		8%

Annex 3

PYRACLOSTROBIN (210) International Estimated Daily Intake (IEDI) ADI = 0–0.03 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day Intake = daily intake: µg/person											
			A diet	intake	B diet	intake	C diet	intake	D diet	intake	E diet	intake	F diet	intake
FP 0226	Apple (incl juice)	0.104	0.3	0.0	60.5	6.3	18.5	1.9	39.9	4.1	50.8	5.3	39.4	4.1
VS 0620	Artichoke globe	0.25	0.0	0.0	10.0	2.5	2.1	0.5	0.1	0.0	0.8	0.2	0.1	0.0
FI 0327	Banana	0.02	38.8	0.8	17.4	0.3	16.0	0.3	6.6	0.1	21.5	0.4	33.8	0.7
GC 0640	Barley (incl pot, incl pearled, incl flour & grits, incl beer)	0.345	40.6	14.0	16.8	5.8	93.9	32.4	13.2	4.6	48.6	16.8	36.1	12.5
VD 0071	Beans (dry)	0.02	15.8	0.3	6.1	0.1	1.7	0.0	6.3	0.1	1.8	0.0	5.0	0.1
FB 0264	Blackberries	0.87	0.0	0.0	0.1	0.1	0.0	0.0	0.3	0.3	0.1	0.1	0.3	0.3
FB 0020	Blueberries	0.78	0.0	0.0	0.0	0.0	0.0	0.0	0.2	0.2	0.3	0.2	0.8	0.6
VB 0402	Brussels sprouts	0.03	0.0	0.0	0.1	0.0	2.8	0.1	5.5	0.2	1.5	0.0	1.9	0.1
VB 0041	Cabbage, head	0.02	1.2	0.0	14.4	0.3	2.7	0.1	16.4	0.3	15.4	0.3	18.5	0.4
VR 0577	Carrot	0.12	0.6	0.1	15.1	1.8	8.1	1.0	13.9	1.7	27.1	3.3	28.4	3.4
FS 0013	Cherries	0.51	0.0	0.0	6.8	3.5	0.9	0.5	6.2	3.2	3.6	1.8	0.4	0.2
FC 0001	Citrus fruit (incl lemon juice, incl mandarin juice, incl orange juice, incl grapefruit juice, incl NES juice)	0.035	15.7	0.5	100.5	3.5	63.2	2.2	27.8	1.0	52.6	1.8	56.9	2.0
SB 0716	Coffee beans (incl green, incl extracts, incl roasted)	0.025	3.1	0.1	12.6	0.3	2.9	0.1	1.4	0.0	10.1	0.3	18.0	0.5
-	Coffee green	0.025	2.6	0.1	6.3	0.2	2.4	0.1	0.2	0.0	0.0	0.0	0.9	0.0
FB 0021	Currants, red, black, white	0.185	0.0	0.0	0.0	0.0	0.0	0.0	2.2	0.4	3.1	0.6	2.0	0.4
MO 0105	Edible offal (mammalian)	0.008	3.9	0.0	14.4	0.1	5.2	0.0	11.8	0.1	11.7	0.1	7.6	0.1
VO 0440	Egg plant (= aubergine)	0.12	1.7	0.2	17.5	2.1	12.3	1.5	1.7	0.2	0.8	0.1	0.4	0.0
PE 0112	Eggs	0	2.5	0.0	29.7	0.0	25.1	0.0	24.5	0.0	37.8	0.0	27.4	0.0
VB 0042	Flowerhead brassicas	0.02	0.2	0.0	11.1	0.2	3.6	0.1	0.4	0.0	7.7	0.2	4.1	0.1
VC 0045	Fruiting vegetables, cucurbits	0.06	26.6	1.6	107.5	6.5	95.9	5.8	82.2	4.9	25.4	1.5	23.2	1.4
VA 0381	Garlic	0.02	0.4	0.0	3.9	0.1	3.8	0.1	3.7	0.1	1.0	0.0	0.6	0.0
FB 0269	Grape (excl dried, excl juice, excl wine)	0.44	1.9	0.8	9.2	4.1	23.8	10.5	9.8	4.3	0.0	0.0	0.0	0.0
JF 0269	Grape juice	0.005	0.0	0.0	0.1	0.0	0.1	0.0	0.1	0.0	1.4	0.0	1.0	0.0
DF 0269	Grape, dried (= currants, raisins and sultanas)	1.36	0.0	0.0	2.9	3.9	0.4	0.5	0.4	0.5	2.3	3.1	1.7	2.3
DH 1100	Hops, dry	4	0.1	0.4	0.1	0.4	0.1	0.4	0.1	0.4	0.3	1.2	0.1	0.4
VL 0480	Kale	0.175	0.0	0.0	0.0	0.0	0.0	0.0	5.5	1.0	0.6	0.1	1.9	0.3
VA 0384	Leek	0.22	0.3	0.1	5.3	1.2	0.0	0.0	0.2	0.0	4.6	1.0	1.5	0.3
VD 0533	Lentil (dry)	0.13	0.9	0.1	5.4	0.7	3.1	0.4	1.3	0.2	0.7	0.1	0.1	0.0
VL 0482	Lettuce, head	0.26	0.1	0.0	6.2	1.6	0.7	0.2	0.1	0.0	0.1	0.0	0.0	0.0
GC 0645	Maize (incl flour, incl oil, incl beer)	0.02	82.7	1.7	148.4	3.0	135.9	2.7	31.8	0.6	33.3	0.7	7.5	0.2
MF 0100	Mammalian fats (except milk fats)	0.063	0.8	0.1	10.0	0.6	0.9	0.1	6.6	0.4	11.8	0.7	3.7	0.2

Annex 3

PYRACLOSTROBIN (210) International Estimated Daily Intake (IEDI) ADI = 0–0.03 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day Intake = daily intake: µg/person											
			A diet	intake	B diet	intake	C diet	intake	D diet	intake	E diet	intake	F diet	intake
FI 0345	Mango (incl juice, incl pulp)	0.05	6.3	0.3	1.0	0.1	4.6	0.2	0.2	0.0	0.7	0.0	0.3	0.0
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.063	5.5	0.3	23.3	1.5	7.7	0.5	11.0	0.7	18.0	1.1	26.3	1.7
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0.009	22.2	0.2	93.2	0.8	30.8	0.3	44.1	0.4	72.2	0.6	105.0	0.9
ML 0106	Milks (excl processed products)	0.01	68.8	0.7	190.6	1.9	79.4	0.8	302.6	3.0	179.6	1.8	237.9	2.4
FS 0245	Nectarine	0.07	0.0	0.0	0.5	0.0	3.3	0.2	1.8	0.1	2.8	0.2	1.6	0.1
GC 0647	Oats (incl rolled)	0.345	1.4	0.5	0.6	0.2	0.2	0.1	4.2	1.4	5.7	2.0	8.9	3.1
SO 0089	Oilseed (except peanut)	0.055	16.9	0.9	62.1	3.4	33.3	1.8	51.3	2.8	58.1	3.2	38.0	2.1
-	Onion, dry	0.06	4.3	0.3	45.6	2.7	27.4	1.6	30.2	1.8	22.1	1.3	12.2	0.7
FI 0350	Papaya	0.05	5.1	0.3	0.1	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0
FS 0247	Peach	0.07	0.2	0.0	24.8	1.6	3.3	0.2	1.8	0.1	5.4	0.4	1.6	0.1
SO 0697	Peanut, shelled (incl oil)	0.02	5.4	0.1	3.1	0.1	2.1	0.0	0.7	0.0	4.0	0.1	1.4	0.0
VD 0072	Peas (dry) (= field pea + cowpea)	0.07	6.8	0.5	1.3	0.1	1.0	0.1	2.3	0.2	4.6	0.3	3.4	0.2
VP 0064	Peas, shelled (immature seeds only)	0.02	0.0	0.0	0.9	0.0	6.0	0.1	0.6	0.0	9.7	0.2	3.2	0.1
VO 0051	Peppers	0.08	1.4	0.1	29.9	2.4	13.0	1.0	6.3	0.5	6.2	0.5	4.0	0.3
TN 0675	Pistachio nut	0.22	0.0	0.0	0.7	0.2	0.5	0.1	0.9	0.2	0.3	0.1	0.0	0.0
FS 0014	Plum (excl dried)	0.09	0.1	0.0	5.3	0.5	2.5	0.2	7.0	0.6	5.5	0.5	0.9	0.1
DF 0014	Plum, dried (prunes)	0.41	0.0	0.0	0.2	0.1	0.0	0.0	0.1	0.0	0.5	0.2	0.6	0.2
VR 0589	Potato (incl flour, frozen, starch, tapioca)	0.02	19.1	0.4	160.8	3.2	61.2	1.2	243.6	4.9	230.1	4.6	204.7	4.1
PM 0110	Poultry meat	0	7.1	0.0	58.5	0.0	31.9	0.0	24.0	0.0	61.0	0.0	27.3	0.0
PO 0111	Poultry, edible offal of	0	0.4	0.0	0.4	0.0	1.7	0.0	0.1	0.0	0.6	0.0	0.2	0.0
PF 0111	Poultry, fats	0	0.1	0.0	0.1	0.0	0.1	0.0	0.0	0.0	0.4	0.0	0.1	0.0
VR 0494	Radish	0.08	0.0	0.0	1.3	0.1	0.6	0.0	2.0	0.2	1.2	0.1	0.0	0.0
FB 0272	Raspberries, red, black	0.87	0.0	0.0	0.0	0.0	0.0	0.0	1.8	1.6	0.9	0.8	0.2	0.2
GC 0650	Rye (incl flour)	0.02	0.1	0.0	3.7	0.1	0.3	0.0	24.3	0.5	25.8	0.5	45.8	0.9
GC 0651	Sorghum (incl flour, incl beer)	0.025	36.9	0.9	0.0	0.0	10.2	0.3	0.0	0.0	0.0	0.0	0.0	0.0
VD 0541	Soya bean (dry, excl oil)	0.02	0.9	0.0	0.0	0.0	0.7	0.0	0.0	0.0	0.0	0.0	0.0	0.0
OR 0541	Soya bean oil, refined	0.012	1.6	0.0	6.5	0.1	6.0	0.1	4.0	0.0	6.3	0.1	7.0	0.1
VA 0389	Spring onion	0.42	0.3	0.1	1.0	0.4	1.4	0.6	0.3	0.1	0.3	0.1	0.6	0.3
FB 0275	Strawberry	0.2	0.0	0.0	5.0	1.0	2.0	0.4	1.7	0.3	5.2	1.0	4.1	0.8
VR 0596	Sugar beet	0.04	0.0	0.0	40.7	1.6	0.0	0.0	0.1	0.0	6.0	0.2	0.1	0.0
VO 0448	Tomato (incl juice, incl paste, incl canned)	0.12	11.8	1.4	185.0	22.2	118.0	14.2	60.7	7.3	31.6	3.8	40.9	4.9

Annex 3

PYRACLOSTROBIN (210) International Estimated Daily Intake (IEDI) ADI = 0–0.03 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A diet	intake	B diet	intake	C diet	intake	D diet	intake	E diet	intake	F diet	intake
TN 0085	Tree nuts	0	4.2	0.0	21.5	0.0	3.9	0.0	3.0	0.0	5.5	0.0	10.2	0.0
GC 0653	Triticale (incl flour)	0.02	0.0	0.0	115.8	2.3	0.0	0.0	0.0	0.0	0.3	0.0	0.0	0.0
GC 0654	Wheat (incl bulgur wholemeal, excl flour)	0.02	6.0	0.1	11.1	0.2	0.8	0.0	0.2	0.0	0.2	0.0	0.0	0.0
CM 0654	Wheat bran, unprocessed	0.012	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CF 1211	Wheat flour (incl macaroni, bread, pastry, starch, gluten)	0.012	63.4	0.8	296.3	3.6	327.5	3.9	300.0	3.6	181.6	2.2	166.2	2.0
CF 1210	Wheat germ	0.016	0.0	0.0	1.3	0.0	0.0	0.0	1.3	0.0	0.9	0.0	1.2	0.0
-	Wine	0.04	1.3	0.1	76.8	3.1	1.1	0.0	15.4	0.6	68.8	2.8	25.6	1.0
	Total intake (µg/person)=			28.9		102.6		89.4		60.1		68.7		56.8
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			1800		1800		1800		1800		1800		1800
	%ADI=			1.6%		5.7%		5.0%		3.3%		3.8%		3.2%
	Rounded %ADI=			2%		6%		5%		3%		4%		3%

PYRACLOSTROBIN (210) International Estimated Daily Intake (IEDI) ADI = 0–0.03 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G diet	intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake	M diet	intake
FP 0226	Apple (incl juice)	0.104	14.4	1.5	10.1	1.1	2.2	0.2	0.0	0.0	9.8	1.0	17.9	1.9	36.3	3.8
VS 0620	Artichoke globe	0.25	0.1	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.3
FI 0327	Banana	0.02	21.4	0.4	36.6	0.7	11.4	0.2	9.2	0.2	70.2	1.4	40.5	0.8	32.6	0.7
GC 0640	Barley (incl pot, incl pearled, incl flour & grits, incl beer)	0.345	5.9	2.0	20.5	7.1	5.9	2.0	2.5	0.9	20.2	7.0	16.8	5.8	43.8	15.1
VD 0071	Beans (dry)	0.02	3.4	0.1	25.5	0.5	7.8	0.2	2.1	0.0	44.7	0.9	5.5	0.1	7.3	0.1
FB 0264	Blackberries	0.87	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.1	0.0	0.0	0.3	0.3
FB 0020	Blueberries	0.78	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.3	1.0
VB 0402	Brussels sprouts	0.03	3.4	0.1	0.4	0.0	0.0	0.0	0.0	0.0	0.5	0.0	7.9	0.2	0.3	0.0
VB 0041	Cabbage, head	0.02	10.0	0.2	1.0	0.0	7.2	0.1	1.0	0.0	1.4	0.0	23.9	0.5	17.0	0.3
VR 0577	Carrot	0.12	5.4	0.6	7.9	0.9	2.5	0.3	3.5	0.4	4.1	0.5	8.6	1.0	19.4	2.3
FS 0013	Cherries	0.51	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.3	0.2	2.5	1.3
FC 0001	Citrus fruit (incl lemon juice, incl mandarin juice, incl orange juice, incl grapefruit juice,	0.035	17.3	0.6	156.8	5.5	14.9	0.5	42.5	1.5	222.8	7.8	40.4	1.4	132.3	4.6

Annex 3

PYRACLOSTROBIN (210) International Estimated Daily Intake (IEDI) ADI = 0–0.03 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G diet	intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake	M diet	intake
	incl NES juice)															
SB 0716	Coffee beans (incl green, incl extracts, incl roasted)	0.025	0.2	0.0	7.0	0.2	0.5	0.0	0.2	0.0	5.3	0.1	5.7	0.1	12.4	0.3
-	Coffee green	0.025	0.2	0.0	5.6	0.1	0.3	0.0	0.2	0.0	4.5	0.1	5.1	0.1	5.1	0.1
FB 0021	Currants, red, black, white	0.185	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
MO 0105	Edible offal (mammalian)	0.008	4.8	0.0	10.7	0.1	4.0	0.0	4.0	0.0	6.5	0.1	6.6	0.1	5.6	0.0
VO 0440	Egg plant (= aubergine)	0.12	20.1	2.4	0.1	0.0	0.6	0.1	6.3	0.8	0.5	0.1	6.3	0.8	0.7	0.1
PE 0112	Eggs	0	22.1	0.0	71.5	0.0	16.6	0.0	5.1	0.0	17.6	0.0	35.2	0.0	57.4	0.0
VB 0042	Flowerhead brassicas	0.02	9.6	0.2	7.9	0.2	0.6	0.0	0.2	0.0	0.9	0.0	1.1	0.0	8.0	0.2
VC 0045	Fruiting vegetables, cucurbits	0.06	69.7	4.2	25.9	1.6	14.9	0.9	18.0	1.1	18.7	1.1	39.1	2.3	44.2	2.7
VA 0381	Garlic	0.02	6.4	0.1	1.2	0.0	0.1	0.0	0.3	0.0	1.9	0.0	5.0	0.1	2.5	0.1
FB 0269	Grape (excl dried, excl juice, excl wine)	0.44	1.2	0.5	2.6	1.1	0.0	0.0	0.2	0.1	0.0	0.0	3.7	1.6	0.0	0.0
JF 0269	Grape juice	0.005	0.0	0.0	0.1	0.0	1.0	0.0	0.0	0.0	0.6	0.0	0.4	0.0	3.6	0.0
DF 0269	Grape, dried (= currants, raisins and sultanas)	1.36	0.0	0.0	0.2	0.3	0.2	0.3	0.0	0.0	0.3	0.4	0.4	0.5	2.6	3.5
DH 1100	Hops, dry	4	0.0	0.0	0.1	0.4	0.1	0.4	0.1	0.4	0.1	0.4	0.1	0.4	0.6	2.4
VL 0480	Kale	0.175	0.0	0.0	0.4	0.1	0.0	0.0	0.0	0.0	0.4	0.1	0.0	0.0	0.3	0.1
VA 0384	Leek	0.22	0.8	0.2	0.2	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.3	0.1	0.1	0.0
VD 0533	Lentil (dry)	0.13	1.1	0.1	1.1	0.1	0.1	0.0	0.2	0.0	1.0	0.1	0.0	0.0	1.6	0.2
VL 0482	Lettuce, head	0.26	1.2	0.3	3.5	0.9	0.1	0.0	0.3	0.1	1.0	0.3	1.2	0.3	7.9	2.0
GC 0645	Maize (incl flour, incl oil, incl beer)	0.02	35.2	0.7	298.6	6.0	248.1	5.0	57.4	1.1	63.1	1.3	58.6	1.2	85.5	1.7
MF 0100	Mammalian fats (except milk fats)	0.063	2.2	0.1	18.6	1.2	0.5	0.0	0.8	0.1	5.7	0.4	4.5	0.3	18.2	1.1
FI 0345	Mango (incl juice, incl pulp)	0.05	12.7	0.6	26.2	1.3	6.1	0.3	12.7	0.6	9.2	0.5	8.0	0.4	1.9	0.1
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.063	11.0	0.7	17.9	1.1	6.1	0.4	5.7	0.4	16.4	1.0	12.2	0.8	31.7	2.0
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0.009	43.8	0.4	71.5	0.6	24.5	0.2	22.9	0.2	65.7	0.6	48.9	0.4	126.6	1.1
ML 0106	Milks (excl processed products)	0.01	66.0	0.7	121.1	1.2	81.6	0.8	102.4	1.0	207.7	2.1	57.0	0.6	287.9	2.9
FS 0245	Nectarine	0.07	1.7	0.1	1.7	0.1	0.0	0.0	0.0	0.0	1.0	0.1	1.7	0.1	1.4	0.1
GC 0647	Oats (incl rolled)	0.345	0.2	0.1	2.0	0.7	0.8	0.3	0.0	0.0	3.5	1.2	0.7	0.2	7.6	2.6
SO 0089	Oilseed (except peanut)	0.055	18.6	1.0	17.7	1.0	20.2	1.1	18.1	1.0	6.5	0.4	62.0	3.4	23.0	1.3
-	Onion, dry	0.06	16.8	1.0	8.6	0.5	6.9	0.4	12.1	0.7	18.6	1.1	23.8	1.4	28.4	1.7
FI 0350	Papaya	0.05	1.3	0.1	11.5	0.6	1.6	0.1	13.7	0.7	14.5	0.7	1.0	0.1	0.6	0.0
FS 0247	Peach	0.07	1.7	0.1	1.7	0.1	1.1	0.1	0.1	0.0	1.0	0.1	1.7	0.1	10.2	0.7
SO 0697	Peanut, shelled (incl oil)	0.02	7.6	0.2	2.1	0.0	4.7	0.1	21.8	0.4	0.9	0.0	0.7	0.0	6.9	0.1

Annex 3

PYRACLOSTROBIN (210) International Estimated Daily Intake (IEDI) ADI = 0–0.03 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G diet	intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake	M diet	intake
VD 0072	Peas (dry) (= field pea + cowpea)	0.07	1.8	0.1	2.2	0.2	3.2	0.2	26.7	1.9	1.5	0.1	1.8	0.1	1.8	0.1
VP 0064	Peas, shelled (immature seeds only)	0.02	3.9	0.1	1.6	0.0	0.0	0.0	0.0	0.0	0.4	0.0	1.0	0.0	0.8	0.0
VO 0051	Peppers	0.08	8.7	0.7	22.4	1.8	8.4	0.7	9.4	0.8	3.3	0.3	5.3	0.4	8.9	0.7
TN 0675	Pistachio nut	0.22	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.2	0.0
FS 0014	Plum (excl dried)	0.09	3.0	0.3	0.8	0.1	0.1	0.0	0.0	0.0	0.0	0.0	0.9	0.1	0.5	0.0
DF 0014	Plum, dried (prunes)	0.41	0.1	0.0	0.2	0.1	0.0	0.0	0.0	0.0	0.2	0.1	0.2	0.1	0.6	0.2
VR 0589	Potato (incl flour, frozen, starch, tapioca)	0.02	52.7	1.1	57.1	1.1	50.1	1.0	4.3	0.1	54.7	1.1	41.0	0.8	168.0	3.4
PM 0110	Poultry meat	0	17.6	0.0	131.3	0.0	25.1	0.0	4.7	0.0	145.9	0.0	27.7	0.0	115.1	0.0
PO 0111	Poultry, edible offal of	0	0.4	0.0	1.0	0.0	1.9	0.0	0.0	0.0	0.7	0.0	1.0	0.0	0.3	0.0
PF 0111	Poultry, fats	0	0.1	0.0	8.2	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.1	0.0	4.2	0.0
VR 0494	Radish	0.08	0.0	0.0	0.3	0.0	0.0	0.0	0.0	0.0	1.0	0.1	0.0	0.0	0.3	0.0
FB 0272	Raspberries, red, black	0.87	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.2	0.2	0.0	0.0	0.5	0.4
GC 0650	Rye (incl flour)	0.02	0.4	0.0	0.0	0.0	0.2	0.0	0.1	0.0	0.1	0.0	0.9	0.0	0.8	0.0
GC 0651	Sorghum (incl flour, incl beer)	0.025	9.8	0.2	19.9	0.5	18.6	0.5	112.3	2.8	0.1	0.0	3.3	0.1	3.0	0.1
VD 0541	Soya bean (dry, excl oil)	0.02	1.8	0.0	0.0	0.0	0.0	0.0	3.2	0.1	0.1	0.0	0.0	0.0	0.0	0.0
OR 0541	Soya bean oil, refined	0.012	4.3	0.1	10.6	0.1	2.0	0.0	1.4	0.0	19.5	0.2	9.2	0.1	22.0	0.3
VA 0389	Spring onion	0.42	0.1	0.0	4.8	2.0	0.1	0.0	1.0	0.4	1.0	0.4	2.7	1.1	0.6	0.3
FB 0275	Strawberry	0.2	0.0	0.0	1.8	0.4	0.1	0.0	0.0	0.0	0.3	0.1	6.2	1.2	5.9	1.2
VR 0596	Sugar beet	0.04	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.2	0.0	0.0	0.0	14.3	0.6
VO 0448	Tomato (incl juice, incl paste, incl canned)	0.12	23.5	2.8	31.7	3.8	15.0	1.8	16.2	1.9	35.6	4.3	9.9	1.2	103.0	12.4
TN 0085	Tree nuts	0	16.3	0.0	15.7	0.0	9.7	0.0	1.9	0.0	19.1	0.0	29.0	0.0	5.6	0.0
GC 0653	Triticale (incl flour)	0.02	1.3	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
GC 0654	Wheat (incl bulgur wholemeal, excl flour)	0.02	0.0	0.0	0.9	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.1	0.0
CM 0654	Wheat bran, unprocessed	0.012	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CF 1211	Wheat flour (incl macaroni, bread, pastry, starch, gluten)	0.012	133.0	1.6	60.1	0.7	52.4	0.6	32.2	0.4	87.7	1.1	79.6	1.0	180.1	2.2
CF 1210	Wheat germ	0.016	0.1	0.0	48.1	0.8	1.8	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.6	0.0
-	Wine	0.04	1.0	0.0	0.9	0.0	6.8	0.3	0.1	0.0	3.4	0.1	3.6	0.1	31.0	1.2
	Total intake (µg/person)=			26.6		47.1		19.3		20.1		38.8		33.8		80.1
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			1650		1800		1800		1800		1800		1650		1800
	%ADI=			1.6%		2.6%		1.1%		1.1%		2.2%		2.0%		4.4%
	Rounded %ADI=			2%		3%		1%		1%		2%		2%		4%

Annex 3

SAFLUFENACIL (251) International Estimated Daily Intake (IEDI) ADI = 0–0.0500 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A diet	intake	B diet	intake	C diet	intake	D diet	intake	E diet	intake	F diet	intake
VD 0071	Beans (dry)	0.01	15.8	0.2	6.1	0.1	1.7	0.0	6.3	0.1	1.8	0.0	5.0	0.1
OR 0691	Cotton seed oil, edible	0.025	0.9	0.0	4.9	0.1	1.7	0.0	6.6	0.2	0.0	0.0	0.3	0.0
MO 0105	Edible offal (mammalian)	0.14	3.9	0.5	14.4	2.0	5.2	0.7	11.8	1.7	11.7	1.6	7.6	1.1
MF 0100	Mammalian fats (except milk fats)	0.01	0.8	0.0	10.0	0.1	0.9	0.0	6.6	0.1	11.8	0.1	3.7	0.0
MM 0095	Meat from mammals other than marine mammals	0.01	27.7	0.3	116.5	1.2	38.5	0.4	55.1	0.6	90.2	0.9	131.3	1.3
SO 0495	Rape seed (incl oil)	0.025	0.9	0.0	1.8	0.0	2.5	0.1	1.9	0.0	35.7	0.9	26.1	0.7
VD 0541	Soya bean (dry, incl oil)	0.01	9.9	0.1	36.4	0.4	34.3	0.3	22.4	0.2	35.3	0.4	39.2	0.4
VP 0541	Soya bean (immature seeds only)	0.01	5.0	0.1	0.0	0.0	0.0	0.0	11.1	0.1	0.4	0.0	0.0	0.0
SO 0702	Sunflower seed (excl oil)	0.12	0.0	0.0	13.1	1.6	0.0	0.0	0.1	0.0	0.1	0.0	0.1	0.0
OR 0702	Sunflower seed oil, edible	0.0036	0.3	0.0	13.1	0.0	8.6	0.0	12.3	0.0	8.8	0.0	2.2	0.0
	Total intake (µg/person)=			1.2		5.5		1.6		2.9		4.0		3.5
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			3000		3000		3000		3000		3000		3000
	%ADI=			0.0%		0.2%		0.1%		0.1%		0.1%		0.1%
	Rounded %ADI=			0%		0%		0%		0%		0%		0%

SAFLUFENACIL (251) International Estimated Daily Intake (IEDI) ADI = 0–0.05 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G diet	intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake	M diet	intake
VD 0071	Beans (dry)	0.01	3.4	0.0	25.5	0.3	7.8	0.1	2.1	0.0	44.7	0.4	5.5	0.1	7.3	0.1
OR 0691	Cotton seed oil, edible	0.025	1.0	0.0	0.7	0.0	1.0	0.0	1.4	0.0	1.5	0.0	5.5	0.1	1.2	0.0
MO 0105	Edible offal (mammalian)	0.14	4.8	0.7	10.7	1.5	4.0	0.6	4.0	0.6	6.5	0.9	6.6	0.9	5.6	0.8
MF 0100	Mammalian fats (except milk fats)	0.01	2.2	0.0	18.6	0.2	0.5	0.0	0.8	0.0	5.7	0.1	4.5	0.0	18.2	0.2
MM 0095	Meat from mammals other than marine mammals	0.01	54.8	0.5	89.4	0.9	30.6	0.3	28.6	0.3	82.1	0.8	61.1	0.6	158.3	1.6
SO 0495	Rape seed (incl oil)	0.025	9.9	0.2	5.9	0.1	0.3	0.0	1.0	0.0	0.0	0.0	15.5	0.4	9.9	0.2

Annex 3

SAFLUFENACIL (251) International Estimated Daily Intake (IEDI) ADI = 0–0.05 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G diet	intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake	M diet	intake
VD 0541	Soya bean (dry, incl oil)	0.01	25.9	0.3	59.4	0.6	11.2	0.1	11.0	0.1	109.3	1.1	51.5	0.5	123.2	1.2
VP 0541	Soya bean (immature seeds only)	0.01	12.9	0.1	0.0	0.0	5.5	0.1	5.5	0.1	0.0	0.0	25.7	0.3	0.0	0.0
SO 0702	Sunflower seed (excl oil)	0.12	0.1	0.0	0.2	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.1	0.0	1.8	0.2
OR 0702	Sunflower seed oil, edible	0.0036	1.1	0.0	3.6	0.0	5.6	0.0	0.1	0.0	1.5	0.0	0.2	0.0	3.6	0.0
	Total intake (µg/person)=			1.9		3.6		1.2		1.1		3.4		2.9		4.4
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			2750		3000		3000		3000		3000		2750		3000
	%ADI=			0.1%		0.1%		0.0%		0.0%		0.1%		0.1%		0.1%
	Rounded %ADI=			0%		0%		0%		0%		0%		0%		0%

SPINOSAD (203) International Estimated Daily Intake (IEDI) ADI = 0–0.02 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A diet	intake	B diet	intake	C diet	intake	D diet	intake	E diet	intake	F diet	intake
JF 0226	Apple juice	0.0013	0.0	0.0	2.8	0.0	0.1	0.0	1.1	0.0	6.8	0.0	7.4	0.0
GC 0640	Barley (incl pot, incl pearled, incl flour & grits, incl beer)	0.7	40.6	28.4	16.8	11.8	93.9	65.7	13.2	9.2	48.6	34.0	36.1	25.3
FB 0264	Blackberries	0.14	0.0	0.0	0.1	0.0	0.0	0.0	0.3	0.0	0.1	0.0	0.3	0.0
FB 0020	Blueberries	0.11	0.0	0.0	0.0	0.0	0.0	0.0	0.2	0.0	0.3	0.0	0.8	0.1
VB 0040	Brassica vegetables	0.27	1.7	0.5	25.7	6.9	9.1	2.5	27.8	7.5	36.9	10.0	26.4	7.1
GC 0641	Buckwheat (incl flour, incl bran)	0.7	0.0	0.0	0.1	0.1	0.0	0.0	1.7	1.2	1.6	1.1	0.1	0.1
MO 1280	Cattle kidney	0.31	0.4	0.1	4.4	1.4	0.0	0.0	0.9	0.3	0.0	0.0	0.6	0.2
MO 1281	Cattle liver	0.66	0.4	0.3	4.4	2.9	1.7	1.1	0.9	0.6	1.0	0.7	0.6	0.4
MM 0812	Cattle meat (incl calf meat): 20% as fat	1.6	2.7	4.3	9.9	15.8	2.7	4.4	7.2	11.5	8.5	13.6	10.8	17.2
MM 0812	Cattle meat (incl calf meat): 80% as muscle	0.074	10.7	0.8	39.5	2.9	10.9	0.8	28.6	2.1	33.9	2.5	43.1	3.2
ML 0812	Cattle milk (excl processed products)	0.65	34.5	22.4	178.5	116.0	52.0	33.8	284.2	184.7	178.6	116.1	237.1	154.1
VS 0624	Celery	0.97	0.0	0.0	0.9	0.9	0.0	0.0	2.0	1.9	1.5	1.5	0.0	0.0
FC 0001	Citrus fruit (incl lemon juice, incl mandarin juice, excl orange juice, incl grapefruit juice, incl NES juice)	0.01	15.7	0.2	96.7	1.0	55.3	0.6	25.3	0.3	23.4	0.2	16.2	0.2
SO 0691	Cotton seed (for oil processing only)	0.0018	5.6	0.0	30.6	0.1	10.6	0.0	41.3	0.1	0.0	0.0	1.9	0.0

Annex 3

SPINOSAD (203) International Estimated Daily Intake (IEDI) ADI = 0–0.02 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day Intake = daily intake: µg/person											
			A diet	intake	B diet	intake	C diet	intake	D diet	intake	E diet	intake	F diet	intake
OR 0691	Cotton seed oil, edible	0.002	0.9	0.0	4.9	0.0	1.7	0.0	6.6	0.0	0.0	0.0	0.3	0.0
FB 0265	Cranberries	0.01	0.1	0.0	0.0	0.0	0.0	0.0	0.3	0.0	0.0	0.0	0.6	0.0
FB 0266	Dewberries, incl boysen- & loganberry	0.14	0.0	0.0	0.0	0.0	0.0	0.0	0.3	0.0	0.0	0.0	0.3	0.0
PE 0112	Eggs	0.01	2.5	0.0	29.7	0.3	25.1	0.3	24.5	0.2	37.8	0.4	27.4	0.3
VC 0045	Fruiting vegetables, cucurbits	0.046	26.6	1.2	107.5	4.9	95.9	4.4	82.2	3.8	25.4	1.2	23.2	1.1
MM 0814	Goat meat: 20% as fat	0.32	0.4	0.1	0.4	0.1	0.3	0.1	0.3	0.1	0.0	0.0	0.0	0.0
MM 0814	Goat meat: 80% as muscle	0.01	1.8	0.0	1.6	0.0	1.4	0.0	1.0	0.0	0.1	0.0	0.0	0.0
ML 0814	Goat milk (excl processed products)	0.022	8.2	0.2	7.0	0.2	4.8	0.1	5.8	0.1	0.6	0.0	0.8	0.0
MO 0814	Goat, edible offal of	0.064	0.5	0.0	0.3	0.0	0.3	0.0	0.6	0.0	0.0	0.0	0.0	0.0
FB 0269	Grape (excl dried, incl juice, excl wine)	0.084	1.9	0.2	9.4	0.8	24.0	2.0	9.9	0.8	2.0	0.2	1.4	0.1
DF 0269	Grape, dried (= currants, raisins and sultanas)	0.13	0.0	0.0	2.9	0.4	0.4	0.1	0.4	0.1	2.3	0.3	1.7	0.2
FI 0341	Kiwi fruit	0.02	0.0	0.0	2.9	0.1	0.1	0.0	0.2	0.0	2.7	0.1	1.8	0.0
VL 0053	Leafy vegetables	1.9	5.8	11.0	45.4	86.3	10.9	20.7	26.7	50.7	17.1	32.5	38.9	73.9
VP 0060	Legume vegetables	0.091	6.1	0.6	23.0	2.1	18.0	1.6	12.8	1.2	26.9	2.4	5.3	0.5
GC 0645	Maize (excl flour, excl oil, incl beer)	0.7	0.0	0.0	1.4	1.0	51.4	36.0	11.9	8.3	0.2	0.2	0.2	0.1
OR 0645	Maize oil, edible	0.77	0.1	0.1	4.0	3.1	2.3	1.8	0.5	0.4	0.9	0.7	0.2	0.2
GC 0646	Millet (incl flour, incl beer)	0.7	15.8	11.1	0.1	0.1	0.8	0.6	5.6	3.9	0.2	0.1	0.1	0.1
GC 0647	Oats (incl rolled)	0.7	1.4	1.0	0.6	0.4	0.2	0.1	4.2	2.9	5.7	4.0	8.9	6.2
-	Onion, dry	0.01	4.3	0.0	45.6	0.5	27.4	0.3	30.2	0.3	22.1	0.2	12.2	0.1
JF 0004	Orange juice	0.0072	0.0	0.0	2.1	0.0	4.4	0.0	1.4	0.0	16.2	0.1	22.6	0.2
FI 0351	Passion fruit	0.23	0.3	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
VO 0051	Peppers	0.056	1.4	0.1	29.9	1.7	13.0	0.7	6.3	0.4	6.2	0.3	4.0	0.2
MM 0818	Pig meat: 20% as fat	0.32	0.7	0.2	9.3	3.0	0.0	0.0	1.6	0.5	7.1	2.3	13.9	4.4
MM 0818	Pig meat: 80% as muscle	0.01	2.8	0.0	37.2	0.4	0.1	0.0	6.4	0.1	28.2	0.3	55.6	0.6
MO 0818	Pig, edible offal of	0.064	0.3	0.0	3.2	0.2	0.0	0.0	3.7	0.2	6.4	0.4	3.1	0.2
FP 0009	Pome fruit (excl apple juice)	0.0165	0.5	0.0	79.9	1.3	21.8	0.4	43.6	0.7	51.5	0.8	35.1	0.6
GC 0656	Popcorn	0.7	0.1	0.1	0.2	0.1	0.0	0.0	0.1	0.1	0.1	0.1	0.1	0.1
VR 0589	Potato (incl flour, frozen, starch, tapioca)	0	19.1	0.0	160.8	0.0	61.2	0.0	243.6	0.0	230.1	0.0	204.7	0.0
PM 0110	Poultry meat: 10% as fat	0.05	0.7	0.0	5.9	0.3	3.2	0.2	2.4	0.1	6.1	0.3	2.7	0.1
PM 0110	Poultry meat: 90% as muscle	0.01	6.4	0.1	52.7	0.5	28.7	0.3	21.6	0.2	54.9	0.5	24.6	0.2
PO 0111	Poultry, edible offal of	0.01	0.4	0.0	0.4	0.0	1.7	0.0	0.1	0.0	0.6	0.0	0.2	0.0
FB 0272	Raspberries, red, black	0.14	0.0	0.0	0.0	0.0	0.0	0.0	1.8	0.3	0.9	0.1	0.2	0.0
GC 0649	Rice (excl husked, excl polished)	0.7	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.1	0.0	0.0	0.0	0.0

Annex 3

SPINOSAD (203) International Estimated Daily Intake (IEDI) ADI = 0–0.02 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A diet	intake	B diet	intake	C diet	intake	D diet	intake	E diet	intake	F diet	intake
CM 1206	Rice bran, unprocessed	0.55	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CM 0649	Rice, husked (incl milled)	0.077	35.6	2.7	0.2	0.0	2.6	0.2	6.9	0.5	3.3	0.3	0.4	0.0
CM 1205	Rice, polished (incl flour)	0.015	29.8	0.4	20.9	0.3	60.8	0.9	16.1	0.2	5.6	0.1	8.1	0.1
GC 0650	Rye (incl flour)	0.7	0.1	0.1	3.7	2.6	0.3	0.2	24.3	17.0	25.8	18.1	45.8	32.1
MM 0822	Sheep meat: 20% as fat	0.32	0.4	0.1	2.2	0.7	2.1	0.7	1.3	0.4	1.3	0.4	0.9	0.3
MM 0822	Sheep meat: 80% as muscle	0.01	1.5	0.0	9.0	0.1	8.6	0.1	5.2	0.1	5.4	0.1	3.6	0.0
ML 0822	Sheep milk (excl processed products	0.022	10.0	0.2	4.0	0.1	8.9	0.2	5.6	0.1	0.4	0.0	0.0	0.0
MO 0822	Sheep, edible offal of	0.064	0.4	0.0	1.3	0.1	1.7	0.1	1.0	0.1	0.7	0.0	0.4	0.0
GC 0651	Sorghum (incl flour, incl beer)	0.7	36.9	25.8	0.0	0.0	10.2	7.1	0.0	0.0	0.0	0.0	0.0	0.0
VD 0541	Soya bean (dry, incl oil)	0	9.9	0.0	36.4	0.0	34.3	0.0	22.4	0.0	35.3	0.0	39.2	0.0
VA 0389	Spring onion	0.2	0.3	0.1	1.0	0.2	1.4	0.3	0.3	0.1	0.3	0.1	0.6	0.1
FS 0012	Stone fruit (incl dried plums, incl dried apricots)	0.0265	0.7	0.0	44.7	1.2	14.1	0.4	26.9	0.7	27.7	0.7	10.0	0.3
VO 0447	Sweet corn (incl corn on the cob, incl frozen kernels, incl preserved kernels)	0.01	14.7	0.1	2.0	0.0	0.2	0.0	1.2	0.0	6.5	0.1	7.2	0.1
VO 0448	Tomato (excl juice, excl paste, incl canned)	0.03	3.3	0.1	179.2	5.4	103.5	3.1	54.1	1.6	7.8	0.2	3.9	0.1
JF 0448	Tomato juice	0.0075	5.2	0.0	0.5	0.0	0.4	0.0	2.1	0.0	6.9	0.1	15.2	0.1
-d	Tomato paste	0.059	0.5	0.0	1.3	0.1	3.5	0.2	1.0	0.1	3.8	0.2	4.5	0.3
TN 0085	Tree nuts	0.026	4.2	0.1	21.5	0.6	3.9	0.1	3.0	0.1	5.5	0.1	10.2	0.3
GC 0653	Triticale (incl flour)	0.7	0.0	0.0	115.8	81.1	0.0	0.0	0.0	0.0	0.3	0.2	0.0	0.0
GC 0654	Wheat (excl bulgur wholemeal, excl flour)	0.7	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.1	0.0	0.0
CM 0654	Wheat bran, unprocessed	1.4	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CF 1211	Wheat flour (incl macaroni, bread, pastry, starch, gluten)	0.18	63.4	11.4	296.3	53.3	327.5	59.0	300.0	54.0	181.6	32.7	166.2	29.9
CP 1211	White bread	0.098	0.0	0.0	0.1	0.0	0.0	0.0	0.1	0.0	0.1	0.0	1.0	0.1
GC 0655	Wild rice	0.7	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
-	Wine	0.027	1.3	0.0	76.8	2.1	1.1	0.0	15.4	0.4	68.8	1.9	25.6	0.7
	Total intake (µg/person)=			124.5		415.2		251.1		370.5		282.5		361.9
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			1200		1200		1200		1200		1200		1200
	%ADI=			10.4%		34.6%		20.9%		30.9%		23.5%		30.2%
	Rounded %ADI=			10%		30%		20%		30%		20%		30%

Annex 3

SPINOSAD (203) International Estimated Daily Intake (IEDI) ADI = 0–0.02 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day G diet	Intake = daily intake: µg/person intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake
JF 0226	Apple juice	0.0013	0.1	0.0	0.5	0.0	0.1	0.0	0.0	0.0	0.7	0.0	0.9	0.0
GC 0640	Barley (incl pot, incl pearled, incl flour & grits, incl beer)	0.7	5.9	4.1	20.5	14.4	5.9	4.1	2.5	1.8	20.2	14.1	16.8	11.8
FB 0264	Blackberries	0.14	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0
FB 0020	Blueberries	0.11	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
VB 0040	Brassica vegetables	0.27	26.4	7.1	9.3	2.5	7.8	2.1	1.5	0.4	3.3	0.9	40.8	11.0
GC 0641	Buckwheat (incl flour, incl bran)	0.7	1.0	0.7	0.0	0.0	0.2	0.1	0.1	0.1	0.5	0.4	2.0	1.4
MO 1280	Cattle kidney	0.31	0.0	0.0	0.9	0.3	0.4	0.1	0.2	0.1	0.7	0.2	0.0	0.0
MO 1281	Cattle liver	0.66	0.0	0.0	0.9	0.6	0.4	0.3	0.2	0.1	0.7	0.5	0.0	0.0
MM 0812	Cattle meat (incl calf meat): 20% as fat	1.6	1.4	2.2	11.9	19.0	3.6	5.8	2.1	3.4	13.1	21.0	4.8	7.6
MM 0812	Cattle meat (incl calf meat): 80% as muscle	0.074	5.5	0.4	47.5	3.5	14.4	1.1	8.5	0.6	52.5	3.9	19.1	1.4
ML 0812	Cattle milk (excl processed products)	0.65	41.9	27.2	119.6	77.7	71.5	46.5	36.6	23.8	205.6	133.6	55.9	36.3
VS 0624	Celery	0.97	0.0	0.0	0.3	0.3	0.0	0.0	0.0	0.0	1.0	1.0	0.0	0.0
FC 0001	Citrus fruit (incl lemon juice, incl mandarin juice, excl orange juice, incl grapefruit juice, incl NES juice)	0.01	16.9	0.2	155.0	1.6	8.6	0.1	42.5	0.4	220.5	2.2	28.9	0.3
SO 0691	Cotton seed (for oil processing only)	0.0018	6.3	0.0	4.4	0.0	6.3	0.0	8.8	0.0	9.4	0.0	34.4	0.1
OR 0691	Cotton seed oil, edible	0.002	1.0	0.0	0.7	0.0	1.0	0.0	1.4	0.0	1.5	0.0	5.5	0.0
FB 0265	Cranberries	0.01	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
FB 0266	Dewberries, incl boysen- & loganberry	0.14	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0
PE 0112	Eggs	0.01	22.1	0.2	71.5	0.7	16.6	0.2	5.1	0.1	17.6	0.2	35.2	0.4
VC 0045	Fruiting vegetables, cucurbits	0.046	69.7	3.2	25.9	1.2	14.9	0.7	18.0	0.8	18.7	0.9	39.1	1.8
MM 0814	Goat meat: 20% as fat	0.32	0.4	0.1	0.2	0.1	0.4	0.1	0.9	0.3	0.1	0.0	0.1	0.0
MM 0814	Goat meat: 80% as muscle	0.01	1.6	0.0	0.7	0.0	1.7	0.0	3.6	0.0	0.5	0.0	0.3	0.0
ML 0814	Goat milk (excl processed products)	0.022	5.1	0.1	1.5	0.0	6.4	0.1	36.8	0.8	2.1	0.0	0.2	0.0
MO 0814	Goat, edible offal of	0.064	0.4	0.0	0.2	0.0	0.4	0.0	0.8	0.1	0.1	0.0	0.1	0.0
FB 0269	Grape (excl dried, incl juice, excl wine)	0.084	1.2	0.1	2.7	0.2	1.4	0.1	0.2	0.0	0.8	0.1	4.3	0.4
DF 0269	Grape, dried (= currants, raisins and sultanas)	0.13	0.0	0.0	0.2	0.0	0.2	0.0	0.0	0.0	0.3	0.0	0.4	0.1
FI 0341	Kiwi fruit	0.02	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.2	0.0	1.6	0.0
VL 0053	Leafy vegetables	1.9	40.8	77.5	12.0	22.8	12.5	23.8	9.5	18.1	5.4	10.3	50.0	95.0
VP 0060	Legume vegetables	0.091	19.6	1.8	6.2	0.6	6.9	0.6	6.0	0.5	1.7	0.2	29.5	2.7
GC 0645	Maize (excl flour, excl oil, incl beer)	0.7	0.6	0.4	0.0	0.0	0.1	0.0	0.0	0.0	7.7	5.4	0.0	0.0
OR 0645	Maize oil, edible	0.77	0.1	0.1	0.6	0.5	1.8	1.4	0.0	0.0	1.0	0.8	1.6	1.2

Annex 3

SPINOSAD (203) International Estimated Daily Intake (IEDI) ADI = 0–0.02 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			G diet	intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake
GC 0646	Millet (incl flour, incl beer)	0.7	13.0	9.1	0.0	0.0	8.3	5.8	96.9	67.8	0.0	0.0	0.4	0.3
GC 0647	Oats (incl rolled)	0.7	0.2	0.1	2.0	1.4	0.8	0.6	0.0	0.0	3.5	2.5	0.7	0.5
-	Onion, dry	0.01	16.8	0.2	8.6	0.1	6.9	0.1	12.1	0.1	18.6	0.2	23.8	0.2
JF 0004	Orange juice	0.0072	0.2	0.0	1.0	0.0	3.5	0.0	0.0	0.0	1.3	0.0	6.4	0.0
FI 0351	Passion fruit	0.23	0.0	0.0	0.3	0.1	0.1	0.0	0.1	0.0	1.3	0.3	0.0	0.0
VO 0051	Peppers	0.056	8.7	0.5	22.4	1.3	8.4	0.5	9.4	0.5	3.3	0.2	5.3	0.3
MM 0818	Pig meat: 20% as fat	0.32	8.0	2.6	5.1	1.6	0.6	0.2	0.5	0.2	2.9	0.9	6.2	2.0
MM 0818	Pig meat: 80% as muscle	0.01	32.1	0.3	20.3	0.2	2.4	0.0	2.1	0.0	11.4	0.1	24.6	0.2
MO 0818	Pig, edible offal of	0.064	2.2	0.1	3.6	0.2	0.2	0.0	0.2	0.0	1.5	0.1	3.7	0.2
FP 0009	Pome fruit (excl apple juice)	0.0165	20.8	0.3	11.6	0.2	3.3	0.1	0.1	0.0	10.7	0.2	23.6	0.4
GC 0656	Popcorn	0.7	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
VR 0589	Potato (incl flour, frozen, starch, tapioca)	0	52.7	0.0	57.1	0.0	50.1	0.0	4.3	0.0	54.7	0.0	41.0	0.0
PM 0110	Poultry meat: 10% as fat	0.05	1.8	0.1	13.1	0.7	2.5	0.1	0.5	0.0	14.6	0.7	2.8	0.1
PM 0110	Poultry meat: 90% as muscle	0.01	15.8	0.2	118.2	1.2	22.6	0.2	4.2	0.0	131.3	1.3	24.9	0.2
PO 0111	Poultry, edible offal of	0.01	0.4	0.0	1.0	0.0	1.9	0.0	0.0	0.0	0.7	0.0	1.0	0.0
FB 0272	Raspberries, red, black	0.14	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.2	0.0	0.0	0.0
GC 0649	Rice (excl husked, excl polished)	0.7	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.1	0.0	0.0	0.1	0.0
CM 1206	Rice bran, unprocessed	0.55	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CM 0649	Rice, husked (incl milled)	0.077	1.1	0.1	0.8	0.1	1.8	0.1	22.7	1.7	70.8	5.5	7.0	0.5
CM 1205	Rice, polished (incl flour)	0.015	250.3	3.8	42.2	0.6	23.8	0.4	29.8	0.4	97.6	1.5	248.1	3.7
GC 0650	Rye (incl flour)	0.7	0.4	0.3	0.0	0.0	0.2	0.1	0.1	0.1	0.1	0.1	0.9	0.6
MM 0822	Sheep meat: 20% as fat	0.32	0.4	0.1	0.3	0.1	0.6	0.2	0.7	0.2	0.2	0.1	0.2	0.1
MM 0822	Sheep meat: 80% as muscle	0.01	1.4	0.0	1.4	0.0	2.3	0.0	2.9	0.0	0.8	0.0	0.6	0.0
ML 0822	Sheep milk (excl processed products	0.022	1.0	0.0	0.0	0.0	2.9	0.1	21.3	0.5	0.0	0.0	0.0	0.0
MO 0822	Sheep, edible offal of	0.064	0.3	0.0	0.3	0.0	0.6	0.0	0.8	0.1	0.2	0.0	0.0	0.0
GC 0651	Sorghum (incl flour, incl beer)	0.7	9.8	6.9	19.9	13.9	18.6	13.0	112.3	78.6	0.1	0.1	3.3	2.3
VD 0541	Soya bean (dry, incl oil)	0	25.9	0.0	59.4	0.0	11.2	0.0	11.0	0.0	109.3	0.0	51.5	0.0
VA 0389	Spring onion	0.2	0.1	0.0	4.8	1.0	0.1	0.0	1.0	0.2	1.0	0.2	2.7	0.5
FS 0012	Stone fruit (incl dried plums, incl dried apricots)	0.0265	7.0	0.2	4.9	0.1	1.4	0.0	0.1	0.0	5.5	0.1	5.5	0.1
VO 0447	Sweet corn (incl corn on the cob, incl frozen kernels, incl preserved kernels)	0.01	0.4	0.0	4.9	0.0	4.5	0.0	3.3	0.0	1.7	0.0	5.6	0.1
VO 0448	Tomato (excl juice, excl paste, incl canned)	0.03	23.1	0.7	22.3	0.7	12.5	0.4	5.6	0.2	33.2	1.0	1.3	0.0

Annex 3

SPINOSAD (203) International Estimated Daily Intake (IEDI) ADI = 0–0.02 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			G diet	intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake
JF 0448	Tomato juice	0.0075	0.0	0.0	0.8	0.0	0.1	0.0	7.2	0.1	0.0	0.0	2.4	0.0
-d	Tomato paste	0.059	0.1	0.0	2.1	0.1	0.6	0.0	0.4	0.0	0.6	0.0	1.4	0.1
TN 0085	Tree nuts	0.026	16.3	0.4	15.7	0.4	9.7	0.3	1.9	0.0	19.1	0.5	29.0	0.8
GC 0653	Triticale (incl flour)	0.7	1.3	0.9	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
GC 0654	Wheat (excl bulgur wholemeal, excl flour)	0.7	0.0	0.0	0.9	0.6	0.0	0.0	0.0	0.0	0.1	0.1	0.0	0.0
CM 0654	Wheat bran, unprocessed	1.4	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CF 1211	Wheat flour (incl macaroni, bread, pastry, starch, gluten)	0.18	133.0	23.9	60.1	10.8	52.4	9.4	32.2	5.8	87.7	15.8	79.6	14.3
CP 1211	White bread	0.098	0.0	0.0	2.2	0.2	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0
GC 0655	Wild rice	0.7	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
-	Wine	0.027	1.0	0.0	0.9	0.0	6.8	0.2	0.1	0.0	3.4	0.1	3.6	0.1
	Total intake (µg/person)=			176.6		181.7		119.3		208.3		227.1		199.5
	Bodyweight per region (kg bw) =			55		60		60		60		60		55
	ADI (µg/person)=			1100		1200		1200		1200		1200		1100
	%ADI=			16.1%		15.1%		9.9%		17.4%		18.9%		18.1%
	Rounded %ADI=			20%		20%		10%		20%		20%		20%

SPIROTETRAMAT (234) International Estimated Daily Intake (IEDI) ADI = 0–0.05 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A diet	intake	B diet	intake	C diet	intake	D diet	intake	E diet	intake	F diet	intake
JF 0226	Apple juice	0.082	0.0	0.0	2.8	0.2	0.1	0.0	1.1	0.1	6.8	0.6	7.4	0.6
VB 0041	Cabbage, head	0.23	1.2	0.3	14.4	3.3	2.7	0.6	16.4	3.8	15.4	3.5	18.5	4.3
VS 0624	Celery	0.58	0.0	0.0	0.9	0.5	0.0	0.0	2.0	1.2	1.5	0.9	0.0	0.0
FC 0001	Citrus fruit (excl lemon juice, excl mandarin juice, incl orange juice, excl grapefruit juice, incl NES juice)	0.33	15.7	5.2	94.7	31.2	60.8	20.0	26.7	8.8	48.2	15.9	53.5	17.6
-	Citrus juice NES	0.18	0.0	0.0	1.7	0.3	0.1	0.0	0.0	0.0	1.1	0.2	0.3	0.1
OR 0691	Cotton seed oil, edible	0	0.9	0.0	4.9	0.0	1.7	0.0	6.6	0.0	0.0	0.0	0.3	0.0
MO 0105	Edible offal (mammalian)	0.16	3.9	0.6	14.4	2.3	5.2	0.8	11.8	1.9	11.7	1.9	7.6	1.2
PE 0112	Eggs	0.0023	2.5	0.0	29.7	0.1	25.1	0.1	24.5	0.1	37.8	0.1	27.4	0.1

Annex 3

SPIROTETRAMAT (234) International Estimated Daily Intake (IEDI) ADI = 0–0.05 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day A diet	Intake = daily intake: µg/person intake	B diet	intake	C diet	intake	D diet	intake	E diet	intake	F diet	intake
VB 0042	Flowerhead brassicas	0.5	0.2	0.1	11.1	5.6	3.6	1.8	0.4	0.2	7.7	3.9	4.1	2.1
VO 0050	Fruiting vegetables other than cucurbits	0.43	33.5	14.4	236.9	101.9	148.9	64.0	70.2	30.2	50.4	21.7	53.9	23.2
VC 0045	Fruiting vegetables, cucurbits	0.057	26.6	1.5	107.5	6.1	95.9	5.5	82.2	4.7	25.4	1.4	23.2	1.3
FB 0269	Grape (excl dried, excl juice, excl wine)	0.41	1.9	0.8	9.2	3.8	23.8	9.8	9.8	4.0	0.0	0.0	0.0	0.0
JF 0269	Grape juice	0.27	0.0	0.0	0.1	0.0	0.1	0.0	0.1	0.0	1.4	0.4	1.0	0.3
DF 0269	Grape, dried (= currants, raisins and sultanas)	1.1	0.0	0.0	2.9	3.2	0.4	0.4	0.4	0.4	2.3	2.5	1.7	1.9
DH 1100	Hops, dry	0.11	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.3	0.0	0.1	0.0
FI 0341	Kiwi fruit	0.055	0.0	0.0	2.9	0.2	0.1	0.0	0.2	0.0	2.7	0.1	1.8	0.1
VL 0053	Leafy vegetables	3.7	5.8	21.5	45.4	168.0	10.9	40.3	26.7	98.8	17.1	63.3	38.9	143.9
VP 0060	Legume vegetables	0.505	6.1	3.1	23.0	11.6	18.0	9.1	12.8	6.5	26.9	13.6	5.3	2.7
FI 0345	Mango (incl juice, incl pulp)	0.16	6.3	1.0	1.0	0.2	4.6	0.7	0.2	0.0	0.7	0.1	0.3	0.0
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.012	5.5	0.1	23.3	0.3	7.7	0.1	11.0	0.1	18.0	0.2	26.3	0.3
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0.006	22.2	0.1	93.2	0.6	30.8	0.2	44.1	0.3	72.2	0.4	105.0	0.6
ML 0106	Milks (excl processed products)	0.005	68.8	0.3	190.6	1.0	79.4	0.4	302.6	1.5	179.6	0.9	237.9	1.2
VA 0385	Onion, bulb (= dry + green onion)	0.11	5.5	0.6	49.5	5.4	33.0	3.6	31.3	3.4	23.2	2.6	14.6	1.6
JF 0004	Orange juice	0.18	0.0	0.0	2.1	0.4	4.4	0.8	1.4	0.3	16.2	2.9	22.6	4.1
FI 0350	Papaya	0.17	5.1	0.9	0.1	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0
VO 0444	Peppers, chili	0.95	0.7	0.7	14.9	14.2	4.1	3.9	3.2	3.0	3.1	2.9	2.0	1.9
DF 0014	Plum, dried (prunes)	3.5	0.0	0.0	0.2	0.7	0.0	0.0	0.1	0.4	0.5	1.8	0.6	2.1
FP 0009	Pome fruit (excl apple juice)	0.17	0.5	0.1	79.9	13.6	21.8	3.7	43.6	7.4	51.5	8.8	35.1	6.0
VR 0589	Potato (incl flour, frozen, starch, tapioca)	0.12	19.1	2.3	160.8	19.3	61.2	7.3	243.6	29.2	230.1	27.6	204.7	24.6
PM 0110	Poultry meat: 10% as fat	0	0.7	0.0	5.9	0.0	3.2	0.0	2.4	0.0	6.1	0.0	2.7	0.0
PM 0110	Poultry meat: 90% as muscle	0	6.4	0.0	52.7	0.0	28.7	0.0	21.6	0.0	54.9	0.0	24.6	0.0
PO 0111	Poultry, edible offal of	0.0016	0.4	0.0	0.4	0.0	1.7	0.0	0.1	0.0	0.6	0.0	0.2	0.0
VD 0070	Pulses (excl soya beans)	0.21	44.6	9.4	26.5	5.6	17.1	3.6	14.4	3.0	14.1	3.0	8.7	1.8
VD 0541	Soya bean (dry, excl oil)	0.45	0.9	0.4	0.0	0.0	0.7	0.3	0.0	0.0	0.0	0.0	0.0	0.0
OR 0541	Soya bean oil, refined	0	1.6	0.0	6.5	0.0	6.0	0.0	4.0	0.0	6.3	0.0	7.0	0.0
FS 0012	Stone fruit (excl dried plums, incl dried apricots)	1.6	0.7	1.1	44.1	70.6	14.1	22.6	26.6	42.6	26.3	42.0	8.3	13.2
TN 0085	Tree nuts	0.084	4.2	0.4	21.5	1.8	3.9	0.3	3.0	0.3	5.5	0.5	10.2	0.9
-	Wine	0.23	1.3	0.3	76.8	17.7	1.1	0.3	15.4	3.5	68.8	15.8	25.6	5.9
	Total intake (µg/person)=			65.1		489.4		200.4		255.7		239.4		263.4
	Bodyweight per region (kg bw) =			60		60		60		60		60		60

Annex 3

SPIROTETRAMAT (234) International Estimated Daily Intake (IEDI) ADI = 0–0.05 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A diet	intake	B diet	intake	C diet	intake	D diet	intake	E diet	intake	F diet	intake
	ADI (µg/person)=			3000		3000		3000		3000		3000		3000
	%ADI=			2.2%		16.3%		6.7%		8.5%		8.0%		8.8%
	Rounded %ADI=			2%		20%		7%		9%		8%		9%

SPIROTETRAMAT (234) International Estimated Daily Intake (IEDI) ADI = 0–0.05 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G diet	intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake	M diet	intake
JF 0226	Apple juice	0.082	0.1	0.0	0.5	0.0	0.1	0.0	0.0	0.0	0.7	0.1	0.9	0.1	5.7	0.5
VB 0041	Cabbage, head	0.23	10.0	2.3	1.0	0.2	7.2	1.7	1.0	0.2	1.4	0.3	23.9	5.5	17.0	3.9
VS 0624	Celery	0.58	0.0	0.0	0.3	0.2	0.0	0.0	0.0	0.0	1.0	0.6	0.0	0.0	4.2	2.4
FC 0001	Citrus fruit (excl lemon juice, excl mandarin juice, incl orange juice, excl grapefruit juice, incl NES juice)	0.33	15.4	5.1	155.7	51.4	11.0	3.6	41.7	13.8	221.3	73.0	35.4	11.7	120.5	39.8
-	Citrus juice NES	0.18	0.0	0.0	0.0	0.0	0.5	0.1	0.0	0.0	0.0	0.0	0.3	0.1	0.1	0.0
OR 0691	Cotton seed oil, edible	0	1.0	0.0	0.7	0.0	1.0	0.0	1.4	0.0	1.5	0.0	5.5	0.0	1.2	0.0
MO 0105	Edible offal (mammalian)	0.16	4.8	0.8	10.7	1.7	4.0	0.6	4.0	0.6	6.5	1.0	6.6	1.1	5.6	0.9
PE 0112	Eggs	0.0023	22.1	0.1	71.5	0.2	16.6	0.0	5.1	0.0	17.6	0.0	35.2	0.1	57.4	0.1
VB 0042	Flowerhead brassicas	0.5	9.6	4.8	7.9	4.0	0.6	0.3	0.2	0.1	0.9	0.5	1.1	0.6	8.0	4.0
VO 0050	Fruiting vegetables other than cucurbits	0.43	57.2	24.6	60.1	25.8	35.5	15.3	51.1	22.0	42.2	18.1	31.5	13.5	134.8	58.0
VC 0045	Fruiting vegetables, cucurbits	0.057	69.7	4.0	25.9	1.5	14.9	0.8	18.0	1.0	18.7	1.1	39.1	2.2	44.2	2.5
FB 0269	Grape (excl dried, excl juice, excl wine)	0.41	1.2	0.5	2.6	1.1	0.0	0.0	0.2	0.1	0.0	0.0	3.7	1.5	0.0	0.0
JF 0269	Grape juice	0.27	0.0	0.0	0.1	0.0	1.0	0.3	0.0	0.0	0.6	0.2	0.4	0.1	3.6	1.0
DF 0269	Grape, dried (= currants, raisins and sultanas)	1.1	0.0	0.0	0.2	0.2	0.2	0.2	0.0	0.0	0.3	0.3	0.4	0.4	2.6	2.9
DH 1100	Hops, dry	0.11	0.0	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.6	0.1
FI 0341	Kiwi fruit	0.055	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.2	0.0	1.6	0.1	1.0	0.1
VL 0053	Leafy vegetables	3.7	40.8	151.0	12.0	44.4	12.5	46.3	9.5	35.2	5.4	20.0	50.0	185.0	39.1	144.7
VP 0060	Legume vegetables	0.505	19.6	9.9	6.2	3.1	6.9	3.5	6.0	3.0	1.7	0.9	29.5	14.9	26.3	13.3
FI 0345	Mango (incl juice, incl pulp)	0.16	12.7	2.0	26.2	4.2	6.1	1.0	12.7	2.0	9.2	1.5	8.0	1.3	1.9	0.3

Annex 3

SPIROTETRAMAT (234) International Estimated Daily Intake (IEDI) ADI = 0–0.05 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G diet	intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake	M diet	intake
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.012	11.0	0.1	17.9	0.2	6.1	0.1	5.7	0.1	16.4	0.2	12.2	0.1	31.7	0.4
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0.006	43.8	0.3	71.5	0.4	24.5	0.1	22.9	0.1	65.7	0.4	48.9	0.3	126.6	0.8
ML 0106	Milks (excl processed products)	0.005	66.0	0.3	121.1	0.6	81.6	0.4	102.4	0.5	207.7	1.0	57.0	0.3	287.9	1.4
VA 0385	Onion, bulb (= dry + green onion)	0.11	17.4	1.9	27.9	3.1	7.3	0.8	16.0	1.8	22.8	2.5	34.5	3.8	30.1	3.3
JF 0004	Orange juice	0.18	0.2	0.0	1.0	0.2	3.5	0.6	0.0	0.0	1.3	0.2	6.4	1.2	56.8	10.2
FI 0350	Papaya	0.17	1.3	0.2	11.5	2.0	1.6	0.3	13.7	2.3	14.5	2.5	1.0	0.2	0.6	0.1
VO 0444	Peppers, chili	0.95	8.7	8.3	13.0	12.4	4.2	4.0	4.7	4.5	1.7	1.6	2.6	2.5	4.4	4.2
DF 0014	Plum, dried (prunes)	3.5	0.1	0.4	0.2	0.7	0.0	0.0	0.0	0.0	0.2	0.7	0.2	0.7	0.6	2.1
FP 0009	Pome fruit (excl apple juice)	0.17	20.8	3.5	11.6	2.0	3.3	0.6	0.1	0.0	10.7	1.8	23.6	4.0	36.9	6.3
VR 0589	Potato (incl flour, frozen, starch, tapioca)	0.12	52.7	6.3	57.1	6.9	50.1	6.0	4.3	0.5	54.7	6.6	41.0	4.9	168.0	20.2
PM 0110	Poultry meat: 10% as fat	0	1.8	0.0	13.1	0.0	2.5	0.0	0.5	0.0	14.6	0.0	2.8	0.0	11.5	0.0
PM 0110	Poultry meat: 90% as muscle	0	15.8	0.0	118.2	0.0	22.6	0.0	4.2	0.0	131.3	0.0	24.9	0.0	103.6	0.0
PO 0111	Poultry, edible offal of	0.0016	0.4	0.0	1.0	0.0	1.9	0.0	0.0	0.0	0.7	0.0	1.0	0.0	0.3	0.0
VD 0070	Pulses (excl soya beans)	0.21	16.0	3.4	32.4	6.8	24.7	5.2	34.2	7.2	50.7	10.6	8.0	1.7	16.9	3.5
VD 0541	Soya bean (dry, excl oil)	0.45	1.8	0.8	0.0	0.0	0.0	0.0	3.2	1.4	0.1	0.0	0.0	0.0	0.0	0.0
OR 0541	Soya bean oil, refined	0	4.3	0.0	10.6	0.0	2.0	0.0	1.4	0.0	19.5	0.0	9.2	0.0	22.0	0.0
FS 0012	Stone fruit (excl dried plums, incl dried apricots)	1.6	6.7	10.7	4.3	6.9	1.4	2.2	0.1	0.2	4.9	7.9	4.9	7.9	17.7	28.3
TN 0085	Tree nuts	0.084	16.3	1.4	15.7	1.3	9.7	0.8	1.9	0.2	19.1	1.6	29.0	2.4	5.6	0.5
-	Wine	0.23	1.0	0.2	0.9	0.2	6.8	1.6	0.1	0.0	3.4	0.8	3.6	0.8	31.0	7.1
	Total intake (µg/person)=			242.8		181.6		96.4		96.8		156.0		268.8		362.6
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			2750		3000		3000		3000		3000		2750		3000
	%ADI=			8.8%		6.1%		3.2%		3.2%		5.2%		9.8%		12.1%
	Rounded %ADI=			9%		6%		3%		3%		5%		10%		10%

Annex 3

SULFOXAFLOR (252) International Estimated Daily Intake (IEDI) ADI = 0–0.05 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day A diet	Intake = daily intake: µg/person intake	B diet	intake	C diet	intake	D diet	intake	E diet	intake	F diet	intake
GC 0640	Barley (incl pot, incl pearled, incl flour & grits, incl beer)	0.063	40.6	2.6	16.8	1.1	93.9	5.9	13.2	0.8	48.6	3.1	36.1	2.3
VB 0400	Broccoli	0.074	0.0	0.0	0.7	0.1	1.2	0.1	0.1	0.0	4.2	0.3	4.0	0.3
VB 0041	Cabbage, head	0.099	1.2	0.1	14.4	1.4	2.7	0.3	16.4	1.6	15.4	1.5	18.5	1.8
VB 0404	Cauliflower	0.013	0.1	0.0	5.2	0.1	1.2	0.0	0.1	0.0	1.7	0.0	0.1	0.0
VS 0624	Celery	0.19	0.0	0.0	0.9	0.2	0.0	0.0	2.0	0.4	1.5	0.3	0.0	0.0
FC 0001	Citrus fruit (incl lemon juice, incl mandarin juice, incl orange juice, incl grapefruit juice, incl NES juice)	0.31	15.7	4.9	100.5	31.2	63.2	19.6	27.8	8.6	52.6	16.3	56.9	17.6
OR 0691	Cotton seed oil, edible	0.02	0.9	0.0	4.9	0.1	1.7	0.0	6.6	0.1	0.0	0.0	0.3	0.0
MO 0105	Edible offal (mammalian)	0.12	3.9	0.5	14.4	1.7	5.2	0.6	11.8	1.4	11.7	1.4	7.6	0.9
PE 0112	Eggs	0.012	2.5	0.0	29.7	0.4	25.1	0.3	24.5	0.3	37.8	0.5	27.4	0.3
VO 0050	Fruiting vegetables other than cucurbits (excl sweet corn, excl mushrooms)	0.11	18.8	2.1	233.4	25.7	148.6	16.3	68.8	7.6	38.6	4.2	45.3	5.0
VC 0045	Fruiting vegetables, cucurbits	0.029	26.6	0.8	107.5	3.1	95.9	2.8	82.2	2.4	25.4	0.7	23.2	0.7
VA 0381	Garlic	0.01	0.4	0.0	3.9	0.0	3.8	0.0	3.7	0.0	1.0	0.0	0.6	0.0
FB 0269	Grape (excl dried, incl juice, incl wine)	0.14	3.7	0.5	116.9	16.4	25.5	3.6	31.5	4.4	98.3	13.8	37.2	5.2
DF 0269	Grape, dried (= currants, raisins and sultanas)	0.49	0.0	0.0	2.9	1.4	0.4	0.2	0.4	0.2	2.3	1.1	1.7	0.8
VL 0053	Leafy vegetables	1.2	5.8	7.0	45.4	54.5	10.9	13.1	26.7	32.0	17.1	20.5	38.9	46.7
MF 0100	Mammalian fats (except milk fats)	0.026	0.8	0.0	10.0	0.3	0.9	0.0	6.6	0.2	11.8	0.3	3.7	0.1
MM 0095	Meat from mammals other than marine mammals	0.04	27.7	1.1	116.5	4.7	38.5	1.5	55.1	2.2	90.2	3.6	131.3	5.3
ML 0106	Milks (excl processed products)	0.048	68.8	3.3	190.6	9.1	79.4	3.8	302.6	14.5	179.6	8.6	237.9	11.4
-	Onion, dry	0.01	4.3	0.0	45.6	0.5	27.4	0.3	30.2	0.3	22.1	0.2	12.2	0.1
VO 0444	Peppers, chili	1.1	0.7	0.8	14.9	16.4	4.1	4.5	3.2	3.5	3.1	3.4	2.0	2.2
FP 0009	Pome fruit (incl apple juice)	0.07	0.5	0.0	84.1	5.9	21.9	1.5	45.2	3.2	61.7	4.3	46.2	3.2
PM 0110	Poultry meat	0.014	7.1	0.1	58.5	0.8	31.9	0.4	24.0	0.3	61.0	0.9	27.3	0.4
PO 0111	Poultry, edible offal of	0.044	0.4	0.0	0.4	0.0	1.7	0.1	0.1	0.0	0.6	0.0	0.2	0.0
PF 0111	Poultry, fats	0.005	0.1	0.0	0.1	0.0	0.1	0.0	0.0	0.0	0.4	0.0	0.1	0.0
SO 0495	Rape seed (incl oil)	0.045	0.9	0.0	1.8	0.1	2.5	0.1	1.9	0.1	35.7	1.6	26.1	1.2
VR 0075	Root and tuber vegetables	0.01	528.2	5.3	352.8	3.5	78.5	0.8	270.3	2.7	324.1	3.2	261.3	2.6
VP 0541	Soya bean (immature seeds only)	0.011	5.0	0.1	0.0	0.0	0.0	0.0	11.1	0.1	0.4	0.0	0.0	0.0
VA 0389	Spring onion	0.11	0.3	0.0	1.0	0.1	1.4	0.2	0.3	0.0	0.3	0.0	0.6	0.1
FS 0012	Stone fruit (incl dried plums, incl dried apricots)	0.91	0.7	0.6	44.7	40.7	14.1	12.8	26.9	24.5	27.7	25.2	10.0	9.1
FB 0275	Strawberry	0.19	0.0	0.0	5.0	1.0	2.0	0.4	1.7	0.3	5.2	1.0	4.1	0.8
TN 0085	Tree nuts	0.01	4.2	0.0	21.5	0.2	3.9	0.0	3.0	0.0	5.5	0.1	10.2	0.1
GC 0653	Triticale (incl flour)	0.025	0.0	0.0	115.8	2.9	0.0	0.0	0.0	0.0	0.3	0.0	0.0	0.0
GC 0654	Wheat (incl bulgur wholemeal, incl flour)	0.025	88.4	2.2	396.3	9.9	426.5	10.7	390.2	9.8	236.3	5.9	216.0	5.4
	Total intake (µg/person)=			32.1		233.2		100.0		121.7		122.2		123.6

Annex 3

SULFOXAFLOR (252) International Estimated Daily Intake (IEDI) ADI = 0–0.05 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A diet	intake	B diet	intake	C diet	intake	D diet	intake	E diet	intake	F diet	intake
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			3000		3000		3000		3000		3000		3000
	%ADI=			1.1%		7.8%		3.3%		4.1%		4.1%		4.1%
	Rounded %ADI=			1%		8%		3%		4%		4%		4%

SULFOXAFLOR (252) International Estimated Daily Intake (IEDI) ADI = 0–0.05 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G diet	intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake	M diet	intake
GC 0640	Barley (incl pot, incl pearled, incl flour & grits, incl beer)	0.063	5.9	0.4	20.5	1.3	5.9	0.4	2.5	0.2	20.2	1.3	16.8	1.1	43.8	2.8
VB 0400	Broccoli	0.074	3.2	0.2	7.8	0.6	0.0	0.0	0.0	0.0	0.3	0.0	0.4	0.0	6.6	0.5
VB 0041	Cabbage, head	0.099	10.0	1.0	1.0	0.1	7.2	0.7	1.0	0.1	1.4	0.1	23.9	2.4	17.0	1.7
VB 0404	Cauliflower	0.013	3.2	0.0	0.1	0.0	0.3	0.0	0.1	0.0	0.6	0.0	0.4	0.0	1.4	0.0
VS 0624	Celery	0.19	0.0	0.0	0.3	0.1	0.0	0.0	0.0	0.0	1.0	0.2	0.0	0.0	4.2	0.8
FC 0001	Citrus fruit (incl lemon juice, incl mandarin juice, incl orange juice, incl grapefruit juice, incl NES juice)	0.31	17.3	5.4	156.8	48.6	14.9	4.6	42.5	13.2	222.8	69.1	40.4	12.5	132.3	41.0
OR 0691	Cotton seed oil, edible	0.02	1.0	0.0	0.7	0.0	1.0	0.0	1.4	0.0	1.5	0.0	5.5	0.1	1.2	0.0
MO 0105	Edible offal (mammalian)	0.12	4.8	0.6	10.7	1.3	4.0	0.5	4.0	0.5	6.5	0.8	6.6	0.8	5.6	0.7
PE 0112	Eggs	0.012	22.1	0.3	71.5	0.9	16.6	0.2	5.1	0.1	17.6	0.2	35.2	0.4	57.4	0.7
VO 0050	Fruiting vegetables other than cucurbits (excl sweet corn, excl mushrooms)	0.11	56.4	6.2	55.2	6.1	31.0	3.4	47.8	5.3	40.5	4.5	25.4	2.8	112.8	12.4
VC 0045	Fruiting vegetables, cucurbits	0.029	69.7	2.0	25.9	0.8	14.9	0.4	18.0	0.5	18.7	0.5	39.1	1.1	44.2	1.3
VA 0381	Garlic	0.01	6.4	0.1	1.2	0.0	0.1	0.0	0.3	0.0	1.9	0.0	5.0	0.1	2.5	0.0
FB 0269	Grape (excl dried, incl juice, incl wine)	0.14	2.6	0.4	4.0	0.6	10.9	1.5	0.3	0.0	5.6	0.8	9.3	1.3	48.4	6.8
DF 0269	Grape, dried (= currants, raisins and sultanas)	0.49	0.0	0.0	0.2	0.1	0.2	0.1	0.0	0.0	0.3	0.1	0.4	0.2	2.6	1.3
VL 0053	Leafy vegetables	1.2	40.8	49.0	12.0	14.4	12.5	15.0	9.5	11.4	5.4	6.5	50.0	60.0	39.1	46.9
MF 0100	Mammalian fats (except milk fats)	0.026	2.2	0.1	18.6	0.5	0.5	0.0	0.8	0.0	5.7	0.1	4.5	0.1	18.2	0.5
MM 0095	Meat from mammals other than marine mammals	0.04	54.8	2.2	89.4	3.6	30.6	1.2	28.6	1.1	82.1	3.3	61.1	2.4	158.3	6.3
ML 0106	Milks (excl processed products)	0.048	66.0	3.2	121.1	5.8	81.6	3.9	102.4	4.9	207.7	10.0	57.0	2.7	287.9	13.8
-	Onion, dry	0.01	16.8	0.2	8.6	0.1	6.9	0.1	12.1	0.1	18.6	0.2	23.8	0.2	28.4	0.3
VO 0444	Peppers, chili	1.1	8.7	9.6	13.0	14.3	4.2	4.6	4.7	5.2	1.7	1.9	2.6	2.9	4.4	4.8
FP 0009	Pome fruit (incl apple juice)	0.07	20.9	1.5	12.3	0.9	3.4	0.2	0.1	0.0	11.7	0.8	24.9	1.7	45.4	3.2

Annex 3

SULFOXAFLOR (252) International Estimated Daily Intake (IEDI) ADI = 0–0.05 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G diet	intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake	M diet	intake
PM 0110	Poultry meat	0.014	17.6	0.2	131.3	1.8	25.1	0.4	4.7	0.1	145.9	2.0	27.7	0.4	115.1	1.6
PO 0111	Poultry, edible offal of	0.044	0.4	0.0	1.0	0.0	1.9	0.1	0.0	0.0	0.7	0.0	1.0	0.0	0.3	0.0
PF 0111	Poultry, fats	0.005	0.1	0.0	8.2	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.1	0.0	4.2	0.0
SO 0495	Rape seed (incl oil)	0.045	9.9	0.4	5.9	0.3	0.3	0.0	1.0	0.0	0.0	0.0	15.5	0.7	9.9	0.4
VR 0075	Root and tuber vegetables	0.01	139.1	1.4	109.8	1.1	409.6	4.1	444.6	4.4	145.3	1.5	127.0	1.3	225.6	2.3
VP 0541	Soya bean (immature seeds only)	0.011	12.9	0.1	0.0	0.0	5.5	0.1	5.5	0.1	0.0	0.0	25.7	0.3	0.0	0.0
VA 0389	Spring onion	0.11	0.1	0.0	4.8	0.5	0.1	0.0	1.0	0.1	1.0	0.1	2.7	0.3	0.6	0.1
FS 0012	Stone fruit (incl dried plums, incl dried apricots)	0.91	7.0	6.4	4.9	4.5	1.4	1.3	0.1	0.1	5.5	5.0	5.5	5.0	19.4	17.7
FB 0275	Strawberry	0.19	0.0	0.0	1.8	0.3	0.1	0.0	0.0	0.0	0.3	0.1	6.2	1.2	5.9	1.1
TN 0085	Tree nuts	0.01	16.3	0.2	15.7	0.2	9.7	0.1	1.9	0.0	19.1	0.2	29.0	0.3	5.6	0.1
GC 0653	Triticale (incl flour)	0.025	1.3	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
GC 0654	Wheat (incl bulgur wholemeal, incl flour)	0.025	172.9	4.3	79.0	2.0	68.1	1.7	41.9	1.0	114.1	2.9	103.4	2.6	234.2	5.9
	Total intake (µg/person)=			95.2		110.6		44.7		48.5		112.2		105.0		174.9
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			2750		3000		3000		3000		3000		2750		3000
	%ADI=			3.5%		3.7%		1.5%		1.6%		3.7%		3.8%		5.8%
	Rounded %ADI=			3%		4%		1%		2%		4%		4%		6%

TEBUCONAZOLE (189) International Estimated Daily Intake (IEDI) ADI = 0–0.03 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A diet	intake	B diet	intake	C diet	intake	D diet	intake	E diet	intake	F diet	intake
FP 0226	Apple (excl juice)	0.275	0.3	0.1	56.3	15.5	18.4	5.0	38.3	10.5	40.6	11.2	28.3	7.8
JF 0226	Apple juice	0.063	0.0	0.0	2.8	0.2	0.1	0.0	1.1	0.1	6.8	0.4	7.4	0.5
FS 0240	Apricot (excl dried)	0.46	0.3	0.1	4.2	1.9	3.6	1.6	2.9	1.3	1.3	0.6	0.1	0.1
VS 0620	Artichoke globe	0.145	0.0	0.0	10.0	1.5	2.1	0.3	0.1	0.0	0.8	0.1	0.1	0.0
FI 0327	Banana	0.01	38.8	0.4	17.4	0.2	16.0	0.2	6.6	0.1	21.5	0.2	33.8	0.3
GC 0640	Barley (incl pot, excl pearled, incl flour & grits, excl beer)	0.085	40.6	3.5	0.0	0.0	0.2	0.0	0.0	0.0	0.0	0.0	3.8	0.3
-	Barley beer	0.002	18.3	0.0	84.1	0.2	4.1	0.0	66.0	0.1	243.1	0.5	161.3	0.3
VD 0071	Beans (dry)	0.05	15.8	0.8	6.1	0.3	1.7	0.1	6.3	0.3	1.8	0.1	5.0	0.3
VB 0400	Broccoli	0.015	0.0	0.0	0.7	0.0	1.2	0.0	0.1	0.0	4.2	0.1	4.0	0.1
VB 0402	Brussels sprouts	0.095	0.0	0.0	0.1	0.0	2.8	0.3	5.5	0.5	1.5	0.1	1.9	0.2
VB 0041	Cabbage, head	0.05	1.2	0.1	14.4	0.7	2.7	0.1	16.4	0.8	15.4	0.8	18.5	0.9

Annex 3

TEBUCONAZOLE (189) International Estimated Daily Intake (IEDI) ADI = 0–0.03 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day			Intake = daily intake: µg/person								
			A		B		C		D		E		F	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
VR 0577	Carrot	0.11	0.6	0.1	15.1	1.7	8.1	0.9	13.9	1.5	27.1	3.0	28.4	3.1
VB 0404	Cauliflower	0.05	0.1	0.0	5.2	0.3	1.2	0.1	0.1	0.0	1.7	0.1	0.1	0.0
FS 0013	Cherries	0.86	0.0	0.0	6.8	5.8	0.9	0.8	6.2	5.3	3.6	3.1	0.4	0.3
SB 0716	Coffee beans (incl green, incl extracts, excl roasted)	0.04	2.7	0.1	6.6	0.3	2.4	0.1	0.8	0.0	0.7	0.0	1.6	0.1
SM 0716	Coffee beans, roasted	0.08	0.4	0.0	6.0	0.5	0.5	0.0	0.6	0.0	9.4	0.8	16.4	1.3
SO 0691	Cotton seed (for oil processing only)	0.05	5.6	0.3	30.6	1.5	10.6	0.5	41.3	2.1	0.0	0.0	1.9	0.1
OR 0691	Cotton seed oil, edible	0	0.9	0.0	4.9	0.0	1.7	0.0	6.6	0.0	0.0	0.0	0.3	0.0
VC 0424	Cucumber	0.05	0.3	0.0	12.7	0.6	5.9	0.3	11.5	0.6	6.1	0.3	7.1	0.4
MO 0105	Edible offal (mammalian)	0.06	3.9	0.2	14.4	0.7	5.2	0.3	11.8	0.6	11.7	0.6	7.6	0.4
VO 0440	Eggplant (= aubergine)	0.04	1.7	0.1	17.5	0.7	12.3	0.5	1.7	0.1	0.8	0.0	0.4	0.0
PE 0112	Eggs	0	2.5	0.0	29.7	0.0	25.1	0.0	24.5	0.0	37.8	0.0	27.4	0.0
FB 0267	Elderberries	0.345	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
VA 0381	Garlic	0.02	0.4	0.0	3.9	0.1	3.8	0.1	3.7	0.1	1.0	0.0	0.6	0.0
FB 0269	Grape (excl dried, incl juice, excl wine)	0.72	1.9	1.4	9.4	6.8	24.0	17.3	9.9	7.2	2.0	1.4	1.4	1.0
DF 0269	Grape, dried (= currants, raisins and sultanas)	0.86	0.0	0.0	2.9	2.5	0.4	0.3	0.4	0.3	2.3	2.0	1.7	1.5
DH 1100	Hops, dry	9.65	0.1	1.0	0.1	1.0	0.1	1.0	0.1	1.0	0.3	2.9	0.1	1.0
VA 0384	Leek	0.195	0.3	0.1	5.3	1.0	0.0	0.0	0.2	0.0	4.6	0.9	1.5	0.3
FI 0345	Mango (incl juice, incl pulp)	0.05	6.3	0.3	1.0	0.1	4.6	0.2	0.2	0.0	0.7	0.0	0.3	0.0
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0	5.5	0.0	23.3	0.0	7.7	0.0	11.0	0.0	18.0	0.0	26.3	0.0
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0	22.2	0.0	93.2	0.0	30.8	0.0	44.1	0.0	72.2	0.0	105.0	0.0
VC 0046	Melons, except watermelon	0.02	3.6	0.1	26.7	0.5	22.6	0.5	11.5	0.2	5.6	0.1	2.0	0.0
ML 0106	Milks (excl processed products)	0	68.8	0.0	190.6	0.0	79.4	0.0	302.6	0.0	179.6	0.0	237.9	0.0
FS 0245	Nectarine	0.46	0.0	0.0	0.5	0.2	3.3	1.5	1.8	0.8	2.8	1.3	1.6	0.7
GC 0647	Oats (incl rolled)	0.085	1.4	0.1	0.6	0.1	0.2	0.0	4.2	0.4	5.7	0.5	8.9	0.8
FT 0305	Olive (table olives, only)	0	0.0	0.0	4.8	0.0	0.8	0.0	0.4	0.0	1.0	0.0	0.8	0.0
VA 0385	Onion, bulb (= dry + green onion)	0.02	5.5	0.1	49.5	1.0	33.0	0.7	31.3	0.6	23.2	0.5	14.6	0.3
FI 0350	Papaya	0.18	5.1	0.9	0.1	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0
FI 0351	Passion fruit	0.1	0.3	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
FS 0247	Peach	0.46	0.2	0.1	24.8	11.4	3.3	1.5	1.8	0.8	5.4	2.5	1.6	0.7
FP 0230	Pear	0.275	0.1	0.0	22.3	6.1	2.8	0.8	4.8	1.3	10.7	2.9	6.8	1.9
VO 0445	Peppers, sweet (incl. pim(i)ento)	0.185	0.7	0.1	14.9	2.8	8.8	1.6	3.2	0.6	3.1	0.6	2.0	0.4
FS 0014	Plum (excl dried)	0.08	0.1	0.0	5.3	0.4	2.5	0.2	7.0	0.6	5.5	0.4	0.9	0.1
DF 0014	Plum, dried (prunes)	0.232	0.0	0.0	0.2	0.0	0.0	0.0	0.1	0.0	0.5	0.1	0.6	0.1
PM 0110	Poultry meat: 10% as fat	0	0.7	0.0	5.9	0.0	3.2	0.0	2.4	0.0	6.1	0.0	2.7	0.0

Annex 3

TEBUCONAZOLE (189) International Estimated Daily Intake (IEDI) ADI = 0–0.03 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day												Intake = daily intake: µg/person	
			A		B		C		D		E		F			
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake		
PM 0110	Poultry meat: 90% as muscle	0	6.4	0.0	52.7	0.0	28.7	0.0	21.6	0.0	54.9	0.0	24.6	0.0		
PO 0111	Poultry, edible offal of	0.05	0.4	0.0	0.4	0.0	1.7	0.1	0.1	0.0	0.6	0.0	0.2	0.0		
SO 0495	Rape seed (excl oil)	0.1	0.1	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.1	0.0	0.1	0.0		
OR 0495	Rape seed oil, edible	0.11	0.3	0.0	0.7	0.1	1.0	0.1	0.7	0.1	13.7	1.5	10.0	1.1		
GC 0649	Rice (incl husked, incl polished)	0.275	91.0	25.0	31.6	8.7	94.6	26.0	33.2	9.1	12.7	3.5	12.7	3.5		
GC 0650	Rye (incl flour)	0.05	0.1	0.0	3.7	0.2	0.3	0.0	24.3	1.2	25.8	1.3	45.8	2.3		
VD 0541	Soya bean (dry, excl oil)	0.02	0.9	0.0	0.0	0.0	0.7	0.0	0.0	0.0	0.0	0.0	0.0	0.0		
OR 0541	Soya bean oil, refined	0.001	1.6	0.0	6.5	0.0	6.0	0.0	4.0	0.0	6.3	0.0	7.0	0.0		
VC 0431	Squash, summer (= courgette, zuchini)	0.05	0.0	0.0	8.3	0.4	11.4	0.6	7.3	0.4	3.2	0.2	0.3	0.0		
VO 0447	Sweet corn (incl corn on the cob, incl frozen kernels, incl preserved kernels)	0.06	14.7	0.9	2.0	0.1	0.2	0.0	1.2	0.1	6.5	0.4	7.2	0.4		
VO 0448	Tomato (excl juice, excl paste, incl canned)	0.15	3.3	0.5	179.2	26.9	103.5	15.5	54.1	8.1	7.8	1.2	3.9	0.6		
JF 0448	Tomato juice	0.033	5.2	0.2	0.5	0.0	0.4	0.0	2.1	0.1	6.9	0.2	15.2	0.5		
-d	Tomato paste	0.19	0.5	0.1	1.3	0.2	3.5	0.7	1.0	0.2	3.8	0.7	4.5	0.9		
TN 0085	Tree nuts	0	4.2	0.0	21.5	0.0	3.9	0.0	3.0	0.0	5.5	0.0	10.2	0.0		
GC 0653	Triticale (incl flour)	0.05	0.0	0.0	115.8	5.8	0.0	0.0	0.0	0.0	0.3	0.0	0.0	0.0		
GC 0654	Wheat (incl bulgur wholemeal, incl flour)	0.05	88.4	4.4	396.3	19.8	426.5	21.3	390.2	19.5	236.3	11.8	216.0	10.8		
-	Wine	0.2	1.3	0.3	76.8	15.4	1.1	0.2	15.4	3.1	68.8	13.8	25.6	5.1		
	Total intake (µg/person)=			41.8		144.5		102.4		80.2		74.1		52.4		
	Bodyweight per region (kg bw) =			60		60		60		60		60		60		
	ADI (µg/person)=			1800		1800		1800		1800		1800		1800		
	%ADI=			2.3%		8.0%		5.7%		4.5%		4.1%		2.9%		
	Rounded %ADI=			2%		8%		6%		4%		4%		3%		

TEBUCONAZOLE (189) International Estimated Daily Intake (IEDI) ADI = 0–0.03 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day												Intake = daily intake: µg/person	
			G		H		I		J		K		L		M	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
FP 0226	Apple (excl juice)	0.275	14.3	3.9	9.4	2.6	2.1	0.6	0.0	0.0	8.8	2.4	16.6	4.6	27.8	7.6
JF 0226	Apple juice	0.063	0.1	0.0	0.5	0.0	0.1	0.0	0.0	0.0	0.7	0.0	0.9	0.1	5.7	0.4
FS 0240	Apricot (excl dried)	0.46	0.2	0.1	0.1	0.0	0.2	0.1	0.0	0.0	0.0	0.0	0.1	0.0	0.4	0.2
VS 0620	Artichoke globe	0.145	0.1	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.1
FI 0327	Banana	0.01	21.4	0.2	36.6	0.4	11.4	0.1	9.2	0.1	70.2	0.7	40.5	0.4	32.6	0.3

Annex 3

TEBUCONAZOLE (189) International Estimated Daily Intake (IEDI) ADI = 0–0.03 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day G		H		I		J		K		L		M	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
GC 0640	Barley (incl pot, excl pearled, incl flour & grits, excl beer)	0.085	1.5	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.4	0.0	0.0	0.0
-	Barley beer	0.002	21.9	0.0	102.7	0.2	29.5	0.1	12.6	0.0	100.9	0.2	82.2	0.2	218.8	0.4
VD 0071	Beans (dry)	0.05	3.4	0.2	25.5	1.3	7.8	0.4	2.1	0.1	44.7	2.2	5.5	0.3	7.3	0.4
VB 0400	Broccoli	0.015	3.2	0.0	7.8	0.1	0.0	0.0	0.0	0.0	0.3	0.0	0.4	0.0	6.6	0.1
VB 0402	Brussels sprouts	0.095	3.4	0.3	0.4	0.0	0.0	0.0	0.0	0.0	0.5	0.0	7.9	0.8	0.3	0.0
VB 0041	Cabbage, head	0.05	10.0	0.5	1.0	0.1	7.2	0.4	1.0	0.1	1.4	0.1	23.9	1.2	17.0	0.9
VR 0577	Carrot	0.11	5.4	0.6	7.9	0.9	2.5	0.3	3.5	0.4	4.1	0.5	8.6	0.9	19.4	2.1
VB 0404	Cauliflower	0.05	3.2	0.2	0.1	0.0	0.3	0.0	0.1	0.0	0.6	0.0	0.4	0.0	1.4	0.1
FS 0013	Cherries	0.86	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.3	0.3	2.5	2.2
SB 0716	Coffee beans (incl green, incl extracts, excl roasted)	0.04	0.2	0.0	5.7	0.2	0.4	0.0	0.2	0.0	4.5	0.2	5.4	0.2	5.4	0.2
SM 0716	Coffee beans, roasted	0.08	0.0	0.0	1.3	0.1	0.1	0.0	0.0	0.0	0.8	0.1	0.3	0.0	7.0	0.6
SO 0691	Cotton seed (for oil processing only)	0.05	6.3	0.3	4.4	0.2	6.3	0.3	8.8	0.4	9.4	0.5	34.4	1.7	7.5	0.4
OR 0691	Cotton seed oil, edible	0	1.0	0.0	0.7	0.0	1.0	0.0	1.4	0.0	1.5	0.0	5.5	0.0	1.2	0.0
VC 0424	Cucumber	0.05	7.9	0.4	0.6	0.0	0.2	0.0	0.0	0.0	0.4	0.0	5.5	0.3	5.3	0.3
MO 0105	Edible offal (mammalian)	0.05	4.8	0.2	10.7	0.5	4.0	0.2	4.0	0.2	6.5	0.3	6.6	0.3	5.6	0.3
VO 0440	Eggplant (= aubergine)	0.04	20.1	0.8	0.1	0.0	0.6	0.0	6.3	0.3	0.5	0.0	6.3	0.3	0.7	0.0
PE 0112	Eggs	0	22.1	0.0	71.5	0.0	16.6	0.0	5.1	0.0	17.6	0.0	35.2	0.0	57.4	0.0
FB 0267	Elderberries	0.345	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
VA 0381	Garlic	0.02	6.4	0.1	1.2	0.0	0.1	0.0	0.3	0.0	1.9	0.0	5.0	0.1	2.5	0.1
FB 0269	Grape (excl dried, incl juice, excl wine)	0.72	1.2	0.9	2.7	2.0	1.4	1.0	0.2	0.1	0.8	0.6	4.3	3.1	5.0	3.6
DF 0269	Grape, dried (= currants, raisins and sultanas)	0.86	0.0	0.0	0.2	0.2	0.2	0.2	0.0	0.0	0.3	0.3	0.4	0.3	2.6	2.2
DH 1100	Hops, dry	9.65	0.0	0.0	0.1	1.0	0.1	1.0	0.1	1.0	0.1	1.0	0.1	1.0	0.6	5.8
VA 0384	Leek	0.195	0.8	0.2	0.2	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.3	0.1	0.1	0.0
FI 0345	Mango (incl juice, incl pulp)	0.05	12.7	0.6	26.2	1.3	6.1	0.3	12.7	0.6	9.2	0.5	8.0	0.4	1.9	0.1
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0	11.0	0.0	17.9	0.0	6.1	0.0	5.7	0.0	16.4	0.0	12.2	0.0	31.7	0.0
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0	43.8	0.0	71.5	0.0	24.5	0.0	22.9	0.0	65.7	0.0	48.9	0.0	126.6	0.0
VC 0046	Melons, except watermelon	0.02	7.5	0.2	6.1	0.1	0.7	0.0	1.4	0.0	2.5	0.1	6.9	0.1	12.4	0.2
ML 0106	Milks (excl processed products)	0	66.0	0.0	121.1	0.0	81.6	0.0	102.4	0.0	207.7	0.0	57.0	0.0	287.9	0.0
FS 0245	Nectarine	0.46	1.7	0.8	1.7	0.8	0.0	0.0	0.0	0.0	1.0	0.5	1.7	0.8	1.4	0.6
GC 0647	Oats (incl rolled)	0.085	0.2	0.0	2.0	0.2	0.8	0.1	0.0	0.0	3.5	0.3	0.7	0.1	7.6	0.6
FT 0305	Olive (table olives, only)	0	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.6	0.0	0.0	0.0	1.0	0.0
VA 0385	Onion, bulb (= dry + green onion)	0.02	17.4	0.3	27.9	0.6	7.3	0.1	16.0	0.3	22.8	0.5	34.5	0.7	30.1	0.6

Annex 3

TEBUCONAZOLE (189) International Estimated Daily Intake (IEDI) ADI = 0–0.03 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day; Intake = daily intake: µg/person													
			G		H		I		J		K		L		M	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
FI 0350	Papaya	0.18	1.3	0.2	11.5	2.1	1.6	0.3	13.7	2.5	14.5	2.6	1.0	0.2	0.6	0.1
FI 0351	Passion fruit	0.1	0.0	0.0	0.3	0.0	0.1	0.0	0.1	0.0	1.3	0.1	0.0	0.0	0.0	0.0
FS 0247	Peach	0.46	1.7	0.8	1.7	0.8	1.1	0.5	0.1	0.0	1.0	0.5	1.7	0.8	10.2	4.7
FP 0230	Pear	0.275	6.4	1.8	1.9	0.5	1.2	0.3	0.0	0.0	1.8	0.5	6.9	1.9	7.8	2.1
VO 0445	Peppers, sweet (incl. pim(i)ento)	0.185	0.0	0.0	9.4	1.7	4.2	0.8	4.7	0.9	1.7	0.3	2.6	0.5	4.4	0.8
FS 0014	Plum (excl dried)	0.08	3.0	0.2	0.8	0.1	0.1	0.0	0.0	0.0	0.0	0.0	0.9	0.1	0.5	0.0
DF 0014	Plum, dried (prunes)	0.232	0.1	0.0	0.2	0.0	0.0	0.0	0.0	0.0	0.2	0.0	0.2	0.0	0.6	0.1
PM 0110	Poultry meat: 10% as fat	0	1.8	0.0	13.1	0.0	2.5	0.0	0.5	0.0	14.6	0.0	2.8	0.0	11.5	0.0
PM 0110	Poultry meat: 90% as muscle	0	15.8	0.0	118.2	0.0	22.6	0.0	4.2	0.0	131.3	0.0	24.9	0.0	103.6	0.0
PO 0111	Poultry, edible offal of	0.05	0.4	0.0	1.0	0.1	1.9	0.1	0.0	0.0	0.7	0.0	1.0	0.1	0.3	0.0
SO 0495	Rape seed (excl oil)	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
OR 0495	Rape seed oil, edible	0.11	3.8	0.4	2.3	0.3	0.1	0.0	0.4	0.0	0.0	0.0	6.0	0.7	3.8	0.4
GC 0649	Rice (incl husked, incl polished)	0.275	376.9	103.6	64.3	17.7	38.0	10.5	74.3	20.4	238.4	65.6	381.3	104.9	34.6	9.5
GC 0650	Rye (incl flour)	0.05	0.4	0.0	0.0	0.0	0.2	0.0	0.1	0.0	0.1	0.0	0.9	0.0	0.8	0.0
VD 0541	Soya bean (dry, excl oil)	0.02	1.8	0.0	0.0	0.0	0.0	0.0	3.2	0.1	0.1	0.0	0.0	0.0	0.0	0.0
OR 0541	Soya bean oil, refined	0.001	4.3	0.0	10.6	0.0	2.0	0.0	1.4	0.0	19.5	0.0	9.2	0.0	22.0	0.0
VC 0431	Squash, summer (= courgette, zuchini)	0.05	2.4	0.1	1.5	0.1	0.0	0.0	0.0	0.0	3.8	0.2	2.2	0.1	2.5	0.1
VO 0447	Sweet corn (incl corn on the cob, frozen kernels, preserved kernels)	0.06	0.4	0.0	4.9	0.3	4.5	0.3	3.3	0.2	1.7	0.1	5.6	0.3	18.1	1.1
VO 0448	Tomato (excl juice, excl paste, incl canned)	0.15	23.1	3.5	22.3	3.3	12.5	1.9	5.6	0.8	33.2	5.0	1.3	0.2	41.7	6.3
JF 0448	Tomato juice	0.033	0.0	0.0	0.8	0.0	0.1	0.0	7.2	0.2	0.0	0.0	2.4	0.1	45.2	1.5
-d	Tomato paste	0.19	0.1	0.0	2.1	0.4	0.6	0.1	0.4	0.1	0.6	0.1	1.4	0.3	1.2	0.2
TN 0085	Tree nuts	0	16.3	0.0	15.7	0.0	9.7	0.0	1.9	0.0	19.1	0.0	29.0	0.0	5.6	0.0
GC 0653	Triticale (incl flour)	0.05	1.3	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
GC 0654	Wheat (incl bulgur wholemeal, incl flour)	0.05	172.9	8.6	79.0	4.0	68.1	3.4	41.9	2.1	114.1	5.7	103.4	5.2	234.2	11.7
-	Wine	0.2	1.0	0.2	0.9	0.2	6.8	1.4	0.1	0.0	3.4	0.7	3.6	0.7	31.0	6.2
	Total intake (µg/person)=			130.8		45.0		24.8		31.5		92.5		134.6		78.1
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			1650		1800		1800		1800		1800		1650		1800
	%ADI=			7.9%		2.5%		1.4%		1.8%		5.1%		8.2%		4.3%
	Rounded %ADI=			8%		2%		1%		2%		5%		8%		4%

ANNEX 4: INTERNATIONAL ESTIMATES OF SHORT-TERM DIETARY INTAKES OF PESTICIDE RESIDUES

For 2011 new large portion data became available and the IESTI as presented in this Annex is calculated using the new data. Until recently the IESTI calculations were done for aggregated large portion data (i.e., raw plus unspecified processed commodies). With the new data it is now possible to do IESTI calculations for individual raw and processed commodities (e.g., raw apples, apple juice, apple sauce, dried apples) as well as for aggregated large portion data (e.g., sum of raw apples, apple juice and dried apples). Aggregated data are indicated by "total" in the table. The large portion data for raw consumed commodities and aggregated commodities are expressed as raw edible portion (EP), while the large portion data for individual processed commodities are expressed as processed product (PP).

Generally the large portion data for the aggregated commodities will result in the highest IESTI for a certain commodity and therefore only the IESTI for the aggregated commodity is shown. When processed data were available, the IESTI for the processed data are indicated as well. In case of concentrated or highly diluted processed commodities a diet correction factor was introduced to match residues expressed as raw edible portion (EP) to large portion data expressed as processed product (PP) to avoid over- or underestimation of the IESTI. In case residue data are available for the processed commodity, both the large portion data and the residue values are expressed as processed product (PP) and a diet correction factor is not needed (i.e., is changed to a value of 1).

ACEPHATE (95) International estimate of short term intake (IESTI) Acute RfD= 0.100 mg/kg bw (100 µg/kg bw)

Maximum %ARfD: 4%

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Large portion diet				Unit weight				IESTI µg/kg bw/day	% acute RfD rounded
						Country	Population group	Expressed as	Large portion, g/person	Country	Unit weight, edible portion, g	Variability factor	Case		
GC 0649	Rice	Total	0.535		1.00	USA	Child, 1-6 yrs	EP	99.8	NLD	< 25	NR	3	3.56	4%
CM 1205	Rice	polished rice (cooked)	0.44		0.40	AUS	Child, 2-6 yrs	PP	317.8	NLD	< 25	NR	3	2.94	3%
CM 0649	Rice	husked rice (cooked)	0.535		0.40	AUS	Child, 2-6 yrs	PP	396.5	NLD	< 25	NR	3	4.47	4%

Annex 4

ACETAMIPRID (246) International estimate of short term intake (IESTI) Acute RfD= 0.100 mg/kg bw (100 µg/kg bw)

Maximum %ARfD: 180%

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Large portion diet				Unit weight				IESTI µg/kg bw/day	% acute RfD rounded
						Coun try	Population group	Expres sed as	Large portion, g/person	Coun try	Unit wt edible portion, g	Varia-bility factor	Case		
TN 0660	Almonds	Total	0.01	0.05	1.00	GER	Women, 14-50 yrs	EP	100.0	NLD	1.2	NR	1	0.07	0%
VL 0460	Amaranth	Total	0.64	1.9	1.00	AUS	Gen pop, 2+ yrs	EP	381.9	NLD	85.8	3	2a	15.69	20%
FP 0226	Apple	Total	0.225	0.59	1.00	USA	Child, 1-6 yrs	EP	624.5	USA	127.0	3	2a	34.55	30%
JF 0226	Apple	juice (pasteurised)	0.2		1.00	GER	Child, 2-4 y	PP	724.2	-	NR	NR	3	8.97	9%
VC 0421	Balsam pear	Total	005	0.11	1.00	Thai	Child, 3-6 yrs	EP	56.8	NLD	130.0	3	2b	1.10	1%
VP 0061	Beans except broad bean & soya bean (green pods & immature seeds) (Phaseolus spp)	Total	0.01	0.18	1.00	FRA	Child, 3-6 yrs	EP	213.0	NLD	19.4	NR	1	2.03	2%
-	Beans except broad bean & soya bean (green pods & immature seeds) (Phaseolus spp)	cooked/boiled	0.01	0.18	1.00	NLD	Baby, 8-20 m	PP	127.9	NLD	18.0	NR	1	2.26	2%
VP 0062	Beans, shelled (immature seeds)	Total	0.03	0.18	1.00	FRA	Child, 3-6 yrs	EP	219.6	NLD	5.8	NR	1	2.09	2%
FB 0264	Blackberries	Total	0.64	1	1.00	FRA	Gen pop, 3+ yrs	EP	407.8	NLD	2.4	NR	1	7.81	8%
FB 0020	Blueberries	Total	0.64	1	1.00	GER	Women, 14-50 yrs	EP	485.0	AUS	1.8	NR	1	7.19	7%
-	Bottle gourd	raw with skin	0.05	0.11	1.00	NLD	Gen pop, 1+ yrs	EP	68.2	NLD	325.0	3	2b	0.34	0%
TN 0662	Brazil nut	Total	0.01	0.05	1.00	AUS	Child, 2-16 yrs	EP	59.9	NLD	3.8	NR	1	0.08	0%
VB 0400	Broccoli	Total	0.02	0.22	1.00	FRA	Child, 3-6 yrs	EP	241.7	NLD	304.0	3	2b	8.44	8%
VB 0401	Broccoli, Chinese	Total	0.02	0.22	1.00	AUS	Gen pop, 2+ yrs	EP	302.9	AUS	311.0	3	2b	2.98	3%
VB 0041	Cabbage, head	Total	0.02	0.05	1.00	SAF	Child, 1-5 yrs	EP	187.1	BEL	1402.5	3	2b	1.98	2%
TN 0295	Cashew nut	Total	0.01	0.05	1.00	Thai	Child, 3-6 yrs	EP	98.8	NLD	2.1	NR	1	0.29	0%
MM 0812	Cattle meat	Total	NA	NA	1.00	FRA	Child, 3-6 yrs	EP	254.6	-	NR	NR	1	NA	0%
MM 0812	Cattle meat: 20% as fat	Total	0.003	0.01	1.00	-	-	EP	50.9	-	NR	NR	1	0.03	0%
MM 0812	Cattle meat: 80% as muscle	Total	0.004	0.01	1.00	-	-	EP	203.7	-	NR	NR	1	0.11	0%
MO 1280	Cattle, kidney	Total	0.018	0.05	1.00	USA	Child, 1-6 yrs	EP	186.6	-	NR	NR	1	0.62	1%
MO 1281	Cattle, liver	Total	0.011	0.03	1.00	USA	Child, 1-6 yrs	EP	136.1	-	NR	NR	1	0.27	0%
VB 0404	Cauliflower (head)	Total	0.02	0.22	1.00	FRA	Child, 3-6 yrs	EP	165.4	NLD	797.0	3	2b	5.78	6%
-	Cauliflower (head)	cooked/boiled	0.02	0.22	1.00	NLD	Baby, 8-20 m	PP	142.0	NLD	749.0	3	2b	9.19	9%
VS 0624	Celery (whole)	Total	0.3	0.78	1.00	FRA	Child, 3-6 yrs	EP	124.4	AUS	861.1	3	2b	15.41	20%
-	Celery (whole)	cooked/boiled	0.3	0.78	1.00	NLD	Child, 2-6 yrs	PP	126.2	NLD	607.0	3	2b	16.05	20%
VL 0464	Chard	Total	0.64	1.9	1.00	FRA	Gen pop, 3+ yrs	EP	285.5	NLD	175.0	3	2a	23.13	20%
-	Chard	cooked/boiled	0.64	1.9	1.00	NLD	Child, 2-6 yrs	PP	81.8	NLD	105.0	3	2b	25.33	30%
VC 0423	Chayote	Total	0.05	0.11	1.00	AUS	Child, 2-16 yrs	EP	140.7	AUS	197.4	3	2b	1.22	1%
FS 0013	Cherries	Total	0.45	0.88	1.00	GER	Child, 2-4 yrs	EP	187.5	NLD	7.2	NR	1	10.22	10%
VL 0465	Chervil	Total	0.64	1.9	1.00	GER	Women, 14-50 yrs	EP	9.4	NLD	< 25	NR	1	0.26	0%
-	Chervil	raw	0.64	1.9	1.00	NLD	Child, 2-6 yrs	EP	3.5	NLD	< 25	NR	1	0.36	0%
TN 0664	Chestnuts	Total	0.01	0.05	1.00	FRA	Child, 3-6 yrs	EP	195.9	NLD	20.0	NR	1	0.52	1%

Annex 4

ACETAMIPRID (246) International estimate of short term intake (IESTI) Acute RfD= 0.100 mg/kg bw (100 µg/kg bw)

Maximum %ARfD: 180%

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Large portion diet				Unit weight				IESTI µg/kg bw/day	% acute RfD rounded
						Country	Population group	Expressed as	Large portion, g/person	Country	Unit wt edible portion, g	Variability factor	Case		
VL 0469	Chicory leaves (head)	Total	0.64	1.9	1.00	GER	Child, 2-4 yrs	EP	82.4	AUS	125.0	3	2b	29.08	30%
VL 0466	Chinese cabbage, type pak-choi	Total	0.64	1.9	1.00	JPN	Child, 0-6 yrs	EP	182.7	JPN	200.0	3	2b	65.49	70%
VL 0467	Chinese cabbage, type pe-tsai	Total	0.64	1.9	1.00	JPN	Child, 0-6 yrs	EP	146.8	JPN	1500.0	3	2b	52.61	50%
TN 0665	Coconut	Total	0.01	0.05	1.00	Thai	Child, 3-6 yrs	EP	309.1	Thai	383.3	3	2b	2.71	3%
VL 0470	Corn salad	Total	0.64	1.9	1.00	GER	Child, 2-4 yrs	EP	41.2	NLD	7.8	NR	1	4.85	5%
VL 0510	Cos lettuce	Total	0.64	1.9	1.00	GER	Child, 2-4 yrs	EP	86.9	AUS	457.2	3	2b	30.67	30%
-	Cos lettuce	raw	0.64	1.9	1.00	NLD	Child, 2-6 yrs	EP	140.1	NLD	289.9	3	2b	43.40	40%
SO 0691	Cotton seed	Total	0.09		1.00	USA	Gen pop, all	EP	3.3	NLD	< 25	NR	3	0.00	0%
OR 0691	Cotton seed	Oil (refined)	0.004		1.00	USA	Child, 1-6 yrs	PP	6.2	-	NR	NR	3	0.00	0%
VL 0472	Cress, garden	Total	0.64	1.9	1.00	FRA	Gen pop, 3+ yrs	EP	47.5	NLD	15.0	NR	1	1.73	2%
VC 0424	Cucumber	Total	0.05	0.11	1.00	GER	Child, 2-4 yrs	EP	150.0	GER	458.1	3	2b	3.07	3%
FB 0021	Currants, red, black, white	Total	0.64	1	1.00	AUS	Gen pop, 2+ yrs	EP	797.6	NLD	14.9	NR	1	11.90	10%
-	Currants, red, black, white	juice (pasteurised)	0.64	1	1.00	NLD	Child, 2-6 yrs	PP	525.8	NLD	NR	NR	3	16.00	20%
VL 0474	Dandelion leaves	Total	0.64	1.9	1.00	GER	Child, 2-4 yrs	EP	16.8	NLD	35.0	3	2b	5.93	6%
MM 0813	Deer meat	Total	NA	NA	1.00	AUS	Child, 2-16 yrs	EP	364.8	-	NR	NR	1	NA	0%
MM 0813	Deer meat: 20% as fat	Total	0.003	0.01	1.00	-	-	EP	73.0	-	NR	NR	1	0.02	0%
MM 0813	Deer meat: 80% as muscle	Total	0.004	0.01	1.00	-	-	EP	291.8	-	NR	NR	1	0.08	0%
FB 0266	Dewberries, incl boysen- & loganberry	Total	0.64	1	1.00	AUS	Gen pop, 2+ yrs	EP	237.9	NLD	< 25	NR	1	3.55	4%
VO 0440	Egg plant	Total	0.04	0.14	1.00	JPN	Child, 0-6 yrs	EP	219.3	JPN	80.0	3	2a	3.34	3%
FB 0267	Elderberries	Total	0.64	1	1.00	GER	Child, 2-4 yrs	EP	7.5	NLD	29.0	3	2b	1.39	1%
VL 0476	Endive	Total	0.64	1.9	1.00	FRA	Child, 3-6 yrs	EP	197.3	NLD	375.0	3	2b	59.51	60%
-	Endive	cooked/boiled	0.64	1.9	1.00	NLD	Baby, 8-20 m	PP	135.2	NLD	251.0	3	2b	75.57	80%
VA 0381	Garlic	Total	0.01	0.01	1.00	Thai	Gen pop, 3+ yrs	EP	27.7	Thai	16.6	NR	1	0.01	0%
VC 0425	Gherkin	Total	0.05	0.11	1.00	AUS	Child, 2-6 yrs	EP	60.8	GER	54.5	3	2a	0.98	1%
-	Gherkin	pickled	0.05	0.11	1.00	NLD	Baby, 8-20 m	PP	33.5	NLD	43.0	3	2b	1.08	1%
MM 0814	Goat meat	Total	NA	NA	1.00	USA	Gen pop, all	EP	477.1	-	NR	NR	1	NA	0%
MM 0814	Goat meat: 20% as fat	Total	0.003	0.01	1.00	-	-	EP	95.4	-	NR	NR	1	0.01	0%
MM 0814	Goat meat: 80% as muscle	Total	0.004	0.01	1.00	-	-	EP	381.7	-	NR	NR	1	0.06	0%
FB 0268	Gooseberries	Total	0.64	1	1.00	GER	Child, 2-4 yrs	EP	100.0	NLD	< 25	NR	1	6.19	6%
FB 0269	Grape	Total	0.085	0.25	1.00	JPN	Child, 0-6 yrs	EP	387.8	JPN	150.0	3	2a	10.81	10%
DF 0269	Grape	dried (currants, raisins, sultanas)	0.08	0.23	1.00	USA	Child, 1-6 yrs	PP	59.3	NLD	1.0	NR	3	0.32	0%
JF 0269	Grape	juice (pasteurised)	0.13		1.00	NLD	Child, 2-6 yrs	PP	803.2	-	NR	NR	3	5.67	6%
VL 0269	Grape leaves	Total	0.64	1.9	1.00	AUS	Gen pop, 2+ yrs	EP	87.2	NLD	1.4	NR	1	2.47	2%
TN 0666	Hazelnut	Total	0.01	0.05	1.00	FRA	Child, 3-6 yrs	EP	27.2	NLD	1.2	NR	1	0.07	0%

Annex 4

ACETAMIPRID (246) International estimate of short term intake (IESTI) Acute RfD= 0.100 mg/kg bw (100 µg/kg bw)

Maximum %ARfD: 180%

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Large portion diet				Unit weight				IESTI µg/kg bw/day	% acute RfD rounded
						Country	Population group	Expressed as	Large portion, g/person	Country	Unit wt edible portion, g	Variability factor	Case		
MM 0816	Horse meat	Total	NA	NA	1.00	FRA	Child, 3-6 yrs	EP	175.5	-	NR	NR	1	NA	0%
MM 0816	Horse meat: 20% as fat	Total	0.003	0.01	1.00	-	-	EP	35.1	-	NR	NR	1	0.02	0%
MM 0816	Horse meat: 80% as muscle	Total	0.004	0.01	1.00	-	-	EP	140.4	-	NR	NR	1	0.07	0%
-	Indian mustard	raw	0.64	1.9	1.00	NLD	Gen pop, 1+ yrs	EP	49.9	NLD	250.0	3	2b	4.32	4%
VL 0480	Kale	Total	0.64	1.9	1.00	GER	Gen pop, 14-80 yrs	EP	669.8	NLD	672.0	3	2b	49.99	50%
MM 0817	Kangaroo meat	Total	NA	NA	1.00	AUS	Child, 2-16 yrs	EP	417.7	-	NR	NR	1	NA	0%
MM 0817	Kangaroo meat: 20% as fat	Total	0.003	0.01	1.00	-	-	EP	83.5	-	NR	NR	1	0.02	0%
MM 0817	Kangaroo meat: 80% as muscle	Total	0.004	0.01	1.00	-	-	EP	334.1	-	NR	NR	1	0.09	0%
VL 0507	Kangkung	Total	0.64	1.9	1.00	AUS	Child, 2-6 yrs	EP	22.6	NLD	85.8	3	2b	6.79	7%
VB 0405	Kohlrabi	Total	0.02	0.22	1.00	GER	Child, 2-4 yrs	EP	161.8	GER	175.2	3	2b	6.61	7%
FC 0204	Lemon	Total	0.25	0.45	1.00	GER	Child, 2-4 yrs	EP	125.5	AUS	108.9	3	2a	9.57	10%
-	Lemon	juice (pasteurised)	0.03		1.00	FRA	Child, 3-6 yrs	PP	90.9	-	NR	NR	3	0.14	0%
VL 0482	Lettuce, head	Total	0.64	1.9	1.00	Thai	Child, 3-6 yrs	EP	111.0	USA	512.1	3	2b	36.98	40%
-	Lettuce, head	raw	0.64	1.9	1.00	NLD	Child, 2-6 yrs	EP	140.1	NLD	338.9	3	2b	43.40	40%
VL 0483	Lettuce, leaf	Total	0.64	1.9	1.00	GER	Child, 2-4 yrs	EP	86.9	NLD	117.8	3	2b	30.67	30%
-	Lettuce, leaf	raw	0.64	1.9	1.00	NLD	Child, 2-6 yrs	EP	140.1	NLD	117.8	3	2a	38.79	40%
FC 0205	Lime	Total	0.25	0.45	1.00	AUS	Gen pop, 2+ yrs	EP	259.2	AUS	49.0	3	2a	2.40	2%
-	Lime	juice (pasteurised)	0.03		1.00	AUS	Gen pop, 2+ yrs	PP	259.2	-	NR	NR	3	0.12	0%
FP 0228	Loquat	Total	0.225	0.59	1.00	AUS	Gen pop, 2+ yrs	EP	118.5	AUS	13.0	NR	1	1.04	1%
TN 0669	Macadamia nut	Total	0.01	0.05	1.00	GER	Women, 14-50 yrs	EP	125.0	NLD	3.2	NR	1	0.09	0%
FC 0003	Mandarin + mandarin-like hybrid	Total	0.25	0.45	1.00	JPN	Child, 0-6 yrs	EP	353.3	JPN	70.0	3	2a	13.96	10%
-	Mandarin + mandarin-like hybrid	Juice (pasteurised)	0.03		1.00	GER	Gen pop, 14-80 yrs	PP	999.4	-	NR	NR	3	0.39	0%
MM 0095	Meat from mammals other than marine mammals	Total	NA	NA	1.00	AUS	Child, 2-6 yrs	EP	254.3	-	NR	NR	1	NA	0%
MM 0095	Meat from mammals other than marine mammals: 20% as fat	Total	0.003	0.01	1.00	-	-	EP	50.9	-	NR	NR	1	0.03	0%
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	Total	0.004	0.01	1.00	-	-	EP	203.5	-	NR	NR	1	0.11	0%
VC 0046	Melons, except watermelon	Total	0.05	0.11	1.00	FRA	Child, 3-6 yrs	EP	358.1	FRA	420.0	3	2b	6.25	6%
ML 0106	Milks	Total	0.004		1.00	AUS	Child, 2-6 yrs	EP	1933.6	-	NR	NR	3	0.41	0%
FB 0271	Mulberries	Total	0.64	1	1.00	AUS	Gen pop, 2+ yrs	EP	513.8	AUS	5.0	NR	1	7.67	8%
FS 0245	Nectarine	Total	0.2	0.44	1.00	FRA	Child, 3-6 yrs	EP	325.4	FRA	99.0	3	2a	12.19	10%
-	Nectarine	raw with peel	0.2	0.44	1.00	NLD	Baby, 8-20 m	EP	183.6	NLD	131.0	3	2a	19.22	20%
VO 0442	Okra	Total	0.04	0.14	1.00	USA	Child, 1-6 yrs	EP	202.5	NLD	17.0	NR	1	1.89	2%
VA 0385	Onion, bulb	Total	0.01	0.01	1.00	AUS	Child, 2-6 yrs	EP	63.7	AUS	96.8	3	2b	0.10	0%
FC 0004	Orange, sweet, sour + orange-like	Total	0.25	0.45	1.00	AUS	Child, 2-6 yrs	EP	800.8	AUS	155.8	3	2a	26.35	30%

Annex 4

ACETAMIPRID (246) International estimate of short term intake (IESTI) Acute RfD= 0.100 mg/kg bw (100 µg/kg bw)

Maximum %ARfD: 180%

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Large portion diet				Unit weight				IESTI µg/kg bw/day	% acute RfD rounded
						Coun try	Population group	Expres sed as	Large portion, g/person	Coun try	Unit wt edible portion, g	Varia-bility factor	Case		
	hybrid														
-	Orange, sweet, sour + orange-like hybrid	Juice (pasteurised)	0.03		1.00	AUS	Child, 2-6 yrs	PP	971.3	-	NR	NR	3	1.53	2%
FS 0247	Peach	Total	0.2	0.44	1.00	FRA	Child, 3-6 yrs	EP	325.4	FRA	99.0	3	2a	12.19	10%
-	Peach	raw with peel	0.2	0.44	1.00	NLD	Baby, 8-20 m	EP	183.6	NLD	131.0	3	2a	19.22	20%
FP 0230	Pear	Total	0.225	0.59	1.00	UNK	Child, 1.5-4.5 yrs	EP	253.9	UNK	170.2	3	2a	24.18	20%
-	Pear	juice (pasteurised)	0.2		1.00	NLD	Child, 2-6 yrs	PP	599.5	NLD	NR	NR	3	6.52	7%
VP 0064	Peas, shelled (immature seeds) (Pisum spp, Vigna spp)	Total	0.03	0.18	1.00	UNK	Child, 1.5-4.5 yrs	EP	174.0	NLD	< 25	NR	1	2.16	2%
TN 0672	Pecan	Total	0.01	0.05	1.00	AUS	Child, 2-16 yrs	EP	80.9	NLD	3.3	NR	1	0.11	0%
VO 0443	Pepino	Total	0.04	0.14	1.00	AUS	Gen pop, 2+ yrs	EP	73.9	AUS	1.2	3	1	0.15	0%
VO 0444	Peppers, chili	Total	0.04	0.14	1.00	USA	Gen pop, all	EP	86.7	USA	43.2	3	2a	0.37	0%
-	Peppers, chili	dried&powder	0.4	1.4	1.00	AUS	Gen Pop, 2+ yrs	PP	1.4	NLD	0.0	NR	3	0.01	0%
VO 0445	Peppers, sweet (incl. pim(i)ento)	Total	0.04	0.14	1.00	GER	Child, 2-4 yrs	EP	145.3	GER	119.3	3	2a	3.33	3%
MO 1284	Pig kidney	Total	0.018	0.05	1.00	FRA	Gen pop, 3+ yrs	EP	208.8	-	NR	NR	1	0.20	0%
MO 1285	Pig liver	Total	0.011	0.03	1.00	AUS	Gen pop, 2+ yrs	EP	430.8	-	NR	NR	1	0.19	0%
MM 0818	Pig meat	Total	NA	NA	1.00	FRA	Child, 3-6 yrs	EP	232.6	-	NR	NR	1	NA	0%
MM 0818	Pig meat: 20% as fat	Total	0.003	0.01	1.00	-	-	EP	46.5	-	NR	NR	1	0.02	0%
MM 0818	Pig meat: 80% as muscle	Total	0.004	0.01	1.00	-	-	EP	186.1	-	NR	NR	1	0.10	0%
TN 0673	Pine nut	Total	0.01	0.05	1.00	AUS	Child, 2-6 yrs	EP	17.7	NLD	0.2	NR	1	0.05	0%
TN 0675	Pistachio nut	Total	0.01	0.05	1.00	AUS	Gen pop, 2+ yrs	EP	238.2	NLD	0.9	NR	1	0.18	0%
FS 0014	Plum	Total	0.04	0.11	1.00	Thai	Child, 3-6 yrs	EP	361.8	AUS	84.0	3	2a	3.41	3%
DF 0014	Plum	dried (prunes)	0.12	0.32	1.00	AUS	Child, 2-16 yrs	PP	289.7	NLD	10.4	NR	1	2.44	2%
PO 0111	Poultry, edible offal of (includes kidney, liver and skin)	Total		0.01	1.00	FRA	Child, 3-6 yrs	EP	99.5	-	NR	NR	1	0.05	0%
VC 0429	Pumpkins	Total	0.05	0.11	1.00	SAF	Gen pop, 10+ yrs	EP	852.2	AUS	1326.0	3	2b	5.05	5%
VL 0492	Purslane	Total	0.64	1.9	1.00	GER	Women, 14-50 yrs	EP	204.1	NLD	< 25	NR	1	5.75	6%
-	Purslane	cooked/boiled	0.64	1.9	1.00	NLD	Gen pop, 1+ yrs	PP	271.2	NLD	< 25	NR	1	7.83	8%
FP 0231	Quince	Total	0.225	0.59	1.00	AUS	Gen pop, 2+ yrs	EP	209.2	AUS	282.9	3	2b	5.53	6%
MM 0819	Rabbit meat	Total	NA	NA	1.00	NLD	Gen pop, 1+ yrs	EP	411.3	NLD	NR	NR	1	NA	0%
MM 0819	Rabbit meat: 20% as fat	Total	0.003	0.01	1.00	-	-	EP	82.3	-	NR	NR	1	0.01	0%
MM 0819	Rabbit meat: 80% as muscle	Total	0.004	0.01	1.00	-	-	EP	329.0	-	NR	NR	1	0.05	0%
FB 0272	Raspberries, red, black	Total	0.64	1	1.00	FRA	Child, 3-6 yrs	EP	157.5	NLD	4.3	NR	1	8.33	8%
FB 0273	Rose hips	Total	0.64	1	1.00	GER	Child, 2-4 yrs	EP	5.5	NLD	5.7	NR	1	0.34	0%
-	Rose hips	jam (incl jelly)	0.64	1	1.00	NLD	Child, 2-6 yrs	PP	55.7	NLD	NR	NR	3	1.70	2%
VL 0496	Rucola	Total	0.64	1.9	1.00	AUS	Child, 2-16 yrs	EP	104.0	NLD	0.3	NR	1	5.20	5%

Annex 4

ACETAMIPRID (246) International estimate of short term intake (IESTI) Acute RfD= 0.100 mg/kg bw (100 µg/kg bw)

Maximum %ARfD: 180%

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Large portion diet				Unit weight				IESTI µg/kg bw/day	% acute RfD rounded
						Country	Population group	Expressed as	Large portion, g/person	Country	Unit wt edible portion, g	Variability factor	Case		
FC 0005	Shaddock or pomelo + shaddock-like hybrid	Total	0.25	0.45	1.00	GER	Child, 2-4 yrs	EP	358.6	GER	178.5	3	2a	19.94	20%
-	Shaddock or pomelo + shaddock-like hybrid	juice (pasteurised)	0.03		1.00	AUS	Gen pop, 2+ yrs	PP	1079.2	-	NR	NR	3	0.48	0%
MO 1288	Sheep kidney	Total	0.018	0.05	1.00	FRA	Gen pop, 3+ yrs	EP	82.4	-	NR	NR	1	0.08	0%
MO 1289	Sheep liver	Total	0.011	0.03	1.00	AUS	Gen pop, 2+ yrs	EP	345.6	-	NR	NR	1	0.15	0%
MM 0822	Sheep meat	Total	NA	NA	1.00	FRA	Child, 3-6 yrs	EP	204.8	-	NR	NR	1	NA	0%
MM 0822	Sheep meat: 20% as fat	Total	0.003	0.01	1.00	-	-	EP	41.0	-	NR	NR	1	0.02	0%
MM 0822	Sheep meat: 80% as muscle	Total	0.004	0.01	1.00	-	-	EP	163.8	-	NR	NR	1	0.09	0%
VL 0502	Spinach (bunch)	Total	0.51	2.5	1.00	SAF	Child, 1-5 yrs	EP	420.3	JPN	300.0	3	2a	179.63	180%
VA 0389	Spring onion	Total	0.38	2	1.00	Thai	Child, 3-6 yrs	EP	52.8	NLD	38.0	3	2a	15.07	20%
VC 0431	Squash, summer (= courgette)	Total	0.05	0.11	1.00	FRA	Child, 3-6 yrs	EP	148.8	FRA	270.0	3	2b	2.60	3%
FB 0275	Strawberry	Total	0.1	0.24	1.00	FRA	Child, 3-6 yrs	EP	339.4	FRA	13.4	NR	1	4.31	4%
-	Taro leaves	raw	0.64	1.9	1.00	NLD	Gen pop, 1+ yrs	EP	77.8	NLD	85.8	3	2b	6.74	7%
VO 0448	Tomato	Total	0.04	0.14	1.00	AUS	Child, 2-6 yrs	EP	289.3	AUS	128.7	3	2a	4.03	4%
-	Tomato	sauce/puree (single strength)	0.04		1.00	NLD	Child, 2-6 yrs	PP	175.5	-	NR	NR	3	0.38	0%
-	Tomato	paste (=concentrated sauce/puree)	0.09		1.00	AUS	Child, 2-6 yrs	PP	189.2	-	NR	NR	3	0.90	1%
VL 0506	Turnip greens	Total	0.64	1.9	1.00	USA	Child, 1-6 yrs	EP	89.9	NLD	< 25	NR	1	11.38	10%
-	Turnip greens	cooked/boiled	0.64	1.9	1.00	NLD	Baby, 8-20 m	PP	90.7	NLD	< 25	NR	1	16.90	20%
FB 0019	Vaccinium berries (incl. Bearberry)	Total	0.64	1	1.00	AUS	Child, 2-6 yrs	EP	158.2	NLD	1.8	NR	1	8.33	8%
TN 0678	Walnut	Total	0.01	0.05	1.00	GER	Child, 2-4 yrs	EP	49.4	NLD	7.0	NR	1	0.15	0%
VL 0473	Watercress	Total	0.64	1.9	1.00	AUS	Gen pop, 2+ yrs	EP	78.8	AUS	346.0	3	2b	6.71	7%
VC 0432	Watermelon	Total	0.05	0.11	1.00	AUS	Gen pop, 2+ yrs	EP	2542.2	AUS	2095.6	3	2a	11.05	10%

Annex 4

DICAMBA (240) International estimate of short term intake (IESTI) Acute RfD= 0.500 mg/kg bw (500 µg/kg bw)

Maximum %ARfD: 0%

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Large portion diet				Unit weight				IESTI µg/kg bw/day	% acute RfD rounded
						Country	Population group	Expressed as	Large portion, g/person	Country	Unit weight, edible portion, g	Variability factor	Case		
PF 0111	Poultry, fats	Total		0.02	1.00	USA	Child, 1-6 yrs	EP	15.8	-	NR	NR	1	0.02	0%
VD 0541	Soya bean (dry)	Total	0.335		1.00	JPN	Child, 0-6 yrs	EP	88.2	NLD	< 25	NR	3	1.86	0%

EMAMECTIN BENZOATE (247) International estimate of short term intake (IESTI) Acute RfD= 0.030 mg/kg bw (30 µg/kg bw)

Maximum %ARfD: 50%

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Large portion diet				Unit weight				IESTI µg/kg bw/day	% acute RfD rounded
						Country	Population group	Expressed as	Large portion, g/person	Country	Unit weight, edible portion, g	Variability factor	Case		
FP 0226	Apple	Total		0.011	1.00	USA	Child, 1–6 yrs	EP	624.5	USA	127.0	3	2a	0.64	2%
JF 0226	Apple	juice (pasteurised)	0.0028		1.00	GER	Child, 2–4 y	PP	724.2	–	NR	NR	3	0.13	0%
VC 0421	Balsam pear	Total		0.002	1.00	Thai	Child, 3–6 yrs	EP	56.8	NLD	130.0	3	2b	0.02	0%
VP 0061	Beans except broad bean & soya bean (green pods & immature seeds) (Phaseolus spp)	Total		0.009	1.00	FRA	Child, 3–6 yrs	EP	213.0	NLD	19.4	NR	1	0.10	0%
VC 0422	Bottle gourd	Total		0.002	1.00	–	–`	–	–	–	–	–	–	–	–
–	Bottle gourd	raw with skin		0.002	1.00	NLD	Gen pop, 1+ yrs	EP	68.2	NLD	325.0	3	2b	0.01	0%
VC 0423	Chayote	Total		0.002	1.00	AUS	Child, 2–16 yrs	EP	140.7	AUS	197.4	3	2b	0.02	0%
VL 0510	Cos lettuce	Total		0.62	1.00	GER	Child, 2–4 yrs	EP	86.9	AUS	457.2	3	2b	10.01	30%
–	Cos lettuce	raw		0.62	1.00	NLD	Child, 2–6 yrs	EP	140.1	NLD	289.9	3	2b	14.16	50%
SO 0691	Cotton seed	Total		0.002	1.00	USA	Gen pop, all	EP	3.3	NLD	< 25	NR	1	0.00	0%
OR 0691	Cotton seed	Oil (refined)	0.00076		1.00	USA	Child, 1–6 yrs	PP	6.2	–	NR	NR	3	0.00	0%
VC 0424	Cucumber	Total		0.002	1.00	GER	Child, 2–4 yrs	EP	150.0	GER	458.1	3	2b	0.06	0%
MO 0105	Edible offal (mammalian)	Total		0.072	1.00	USA	Child, 1–6 yrs	EP	186.6	–	NR	NR	1	0.90	3%

Annex 4

EMAMECTIN BENZOATE (247) International estimate of short term intake (IESTI) Acute RfD= 0.030 mg/kg bw (30 µg/kg bw)

Maximum %ARfD: 50%

						Large portion diet				Unit weight					
Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Country	Population group	Expressed as	Large portion, g/person	Country	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
VO 0440	Egg plant	Total		0.013	1.00	JPN	Child, 0–6 yrs	EP	219.3	JPN	80.0	3	2a	0.31	1%
VC 0425	Gherkin	Total		0.002	1.00	AUS	Child, 2–6 yrs	EP	60.8	GER	54.5	3	2a	0.02	0%
–	Gherkin	pickled		0.002	1.00	NLD	Baby, 8–20 m	PP	33.5	NLD	43.0	3	2b	0.02	0%
–	Goji berry	Total		0.013	1.00	AUS	Child, 2–16 yrs	EP	36.2	–	< 25	NR	1	0.01	0%
–	Goji berry	Dried		0.013	3.00	AUS	Child, 2–16 yrs	PP	18.9	–	< 25	NR	1	0.02	0%
FB 0269	Grape	Total		0.022	1.00	JPN	Child, 0–6 yrs	EP	387.8	JPN	150.0	3	2a	0.95	3%
VL 0482	Lettuce, head	Total		0.62	1.00	Thai	Child, 3–6 yrs	EP	111.0	USA	512.1	3	2b	12.07	40%
–	Lettuce, head	raw		0.62	1.00	NLD	Child, 2–6 yrs	EP	140.1	NLD	338.9	3	2b	14.16	50%
VL 0483	Lettuce, leaf	Total		0.62	1.00	GER	Child, 2–4 yrs	EP	86.9	NLD	117.8	3	2b	10.01	30%
–	Lettuce, leaf	raw		0.62	1.00	NLD	Child, 2–6 yrs	EP	140.1	NLD	117.8	3	2a	12.66	40%
VC 0427	Loofah, angled (= angled gourd)	Total		0.002	1.00	Thai	Child, 3–6 yrs	EP	70.0	AUS	–	–	–	–	–
FP 0228	Loquat	Total		0.011	1.00	AUS	Gen pop, 2+ yrs	EP	118.5	AUS	13.0	NR	1	0.02	0%
MF 0100	Mammalian fats (except milk fats)	Total		0.011	1.00	FRA	Child, 3–6 yrs	EP	30.2	–	NR	NR	1	0.02	0%
MM 0095	Meat from mammals other than marine mammals	Total	NA	NA	1.00	AUS	Child, 2–6 yrs	EP	254.3	–	NR	NR	1	NA	0%
MM 0095	Meat from mammals other than marine mammals: 20% as fat	Total		0.011	1.00	–	–	EP	50.9	–	NR	NR	1	0.03	0%
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	Total		0.004	1.00	–	–	EP	203.5	–	NR	NR	1	0.04	0%
FP 0229	Medlar	Total		0.011	1.00	NLD	Gen pop, 1+ yrs	EP	NC	–	–	–	–	NC	NC
VC 0046	Melons, except watermelon	Total		0.002	1.00	FRA	Child, 3–6 yrs	EP	358.1	FRA	420.0	3	2b	0.11	0%
ML 0106	Milks	Total	0.0005		1.00	AUS	Child, 2–6 yrs	EP	1933.6	–	NR	NR	3	0.05	0%
VL 0485	Mustard greens	Total		0.11	1.00	USA	Child, 1–6 yrs	EP	49.6	AUS	–	–	–	–	–
FS 0245	Nectarine	Total		0.015	1.00	FRA	Child, 3–6 yrs	EP	325.4	FRA	99.0	3	2a	0.42	1%
–	Nectarine	raw with peel		0.015	1.00	NLD	Baby, 8–20 m	EP	183.6	NLD	131.0	3	2a	0.66	2%
VO 0442	Okra	Total		0.013	1.00	USA	Child, 1–6 yrs	EP	202.5	NLD	17.0	NR	1	0.18	1%
FS 0247	Peach	Total		0.015	1.00	FRA	Child, 3–6 yrs	EP	325.4	FRA	99.0	3	2a	0.42	1%

Annex 4

EMAMECTIN BENZOATE (247) International estimate of short term intake (IESTI) Acute RfD= 0.030 mg/kg bw (30 µg/kg bw)

Maximum %ARfD: 50%

						Large portion diet				Unit weight					
Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Country	Population group	Expressed as	Large portion, g/person	Country	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
–	Peach	raw with peel		0.015	1.00	NLD	Baby, 8–20 m	EP	183.6	NLD	131.0	3	2a	0.66	2%
FP 0230	Pear	Total		0.011	1.00	UNK	Child, 1.5–4.5 yrs	EP	253.9	UNK	170.2	3	2a	0.45	2%
–	Pear	raw with peel		0.011	1.00	NLD	Baby, 8–20 m	EP	201.8	NLD	204.7	3	2b	0.65	2%
VO 0443	Pepino	Total		0.013	1.00	AUS	Gen pop, 2+ yrs	EP	73.9	AUS	1.2	3	1	0.01	0%
VO 0444	Peppers, chilli	Total		0.013	1.00	USA	Gen pop, all	EP	86.7	USA	43.2	3	2a	0.03	0%
–	Peppers, chilli	Dried & powder		0.13	1.00	AUS	Gen Pop, 2+ yrs	PP	1.4	NLD	0.0	NR	1	0.00	0%
VO 0445	Peppers, sweet (incl. pimiento)	Total		0.013	1.00	GER	Child, 2–4 yrs	EP	145.3	GER	119.3	3	2a	0.31	1%
MF 0818	Pig fat	Total		0.011	1.00	FRA	Child, 3–6 yrs	EP	64.8	–	NR	NR	1	0.04	0%
VC 0429	Pumpkins	Total		0.002	1.00	SAF	Gen pop, 10+ yrs	EP	852.2	AUS	1326.0	3	2b	0.09	0%
FP 0231	Quince	Total		0.011	1.00	AUS	Gen pop, 2+ yrs	EP	209.2	AUS	282.9	3	2b	0.10	0%
–	Seaweed	Total		0.013	1.00	AUS	Child, 2–6 yrs	EP	55.0	NLD	< 25	NR	1	0.04	0%
VC 0430	Snake gourd	Total		0.002	1.00	Thai	Child, 3–6 yrs	EP	129.6	–	–	–	–	–	–
VC 0431	Squash, summer (= courgette)	Total		0.002	1.00	FRA	Child, 3–6 yrs	EP	148.8	FRA	270.0	3	2b	0.05	0%
VO 0448	Tomato	Total		0.013	1.00	AUS	Child, 2–6 yrs	EP	289.3	AUS	128.7	3	2a	0.37	1%
VC 0432	Watermelon	Total		0.002	1.00	AUS	Gen pop, 2+ yrs	EP	2542.2	AUS	2095.6	3	2a	0.20	1%

ETOFENPROX (185) International estimate of short term intake (IESTI) Acute RfD= 1.00 mg/kg bw (1000 µg/kg bw)

Maximum %ARfD: 10%

						Large portion diet				Unit weight					
Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Country	Population group	Expressed as	Large portion, g/person	Country	Unit wt edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
FP 0226	Apple	Total	0.2	0.34	1.00	USA	Child, 1-6 yrs	EP	624.5	USA	127.0	3	2a	19.91	2%

Annex 4

ETOFENPROX (185) International estimate of short term intake (IESTI) Acute RfD= 1.00 mg/kg bw (1000 µg/kg bw)

Maximum %ARfD: 10%

						Large portion diet				Unit weight					
Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Country	Population group	Expressed as	Large portion, g/person	Country	Unit wt edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
JF 0226	Apple	juice (pasteurised)	0.012		1.00	GER	Child, 2-4 y	PP	724.2	-	NR	NR	3	0.54	0%
-	Apple	sauce/puree	0.06		1.00	NLD	Baby, 8-20 m	PP	106.6	NLD	NR	NR	3	0.63	0%
-	Apple	canned babyfood	0.018		1.00	NLD	Baby, 8-20 m	PP	348.4	NLD	NR	NR	3	0.61	0%
VD 0071	Beans (dry, Phaseolus spp)	Total	0.05		1.00	FRA	Child, 2-16 yrs	EP	145.4	NLD	0.5	NR	3	0.38	0%
ML 0810	Buffalo milk	Total	0.013		1.00	AUS	Gen pop, 2+ yrs	EP	742.3	-	NR	NR	3	0.14	0%
MM 0812	Cattle meat	Total	NA	NA	1.00	FRA	Child, 3-6 yrs	EP	254.6	-	NR	NR	1	NA	0%
MM 0812	Cattle meat: 20% as fat	Total	0.21	0.3	1.00	-	-	EP	50.9	-	NR	NR	1	0.81	0%
MM 0812	Cattle meat: 80% as muscle	Total	0.03	0.03	1.00	-	-	EP	203.7	-	NR	NR	1	0.32	0%
ML 0812	Cattle milk	Total	0.013		1.00	NLD	Baby, 8-20 m	EP	1060.7	NLD	NR	NR	3	1.35	0%
FM 0812	Cattle milk fat	Total	0.036		1.00	GER	Child, 2-4 yrs	EP	35.2	-	NR	NR	3	0.08	0%
MO 0812	Cattle, edible offal of (includes kidney and liver)	Total	0.03	0.03	1.00	SAF	Gen pop, 10+ yrs	EP	523.6	-	NR	NR	1	0.28	0%
MO 1280	Cattle, kidney	Total	0.03	0.03	1.00	USA	Child, 1-6 yrs	EP	186.6	-	NR	NR	1	0.37	0%
MO 1281	Cattle, liver	Total	0.03	0.03	1.00	USA	Child, 1-6 yrs	EP	136.1	-	NR	NR	1	0.27	0%
MM 0813	Deer meat	Total	NA	NA	1.00	AUS	Child, 2-16 yrs	EP	364.8	-	NR	NR	1	NA	0%
MM 0813	Deer meat: 20% as fat	Total	0.21	0.3	1.00	-	-	EP	73.0	-	NR	NR	1	0.58	0%
MM 0813	Deer meat: 80% as muscle	Total	0.03	0.03	1.00	-	-	EP	291.8	-	NR	NR	1	0.23	0%
MO 0105	Edible offal (mammalian)	Total	0.03	0.03	1.00	USA	Child, 1-6 yrs	EP	186.6	-	NR	NR	1	0.37	0%
MM 0814	Goat meat	Total	NA	NA	1.00	USA	Gen pop, all	EP	477.1	-	NR	NR	1	NA	0%
MM 0814	Goat meat: 20% as fat	Total	0.21	0.3	1.00	-	-	EP	95.4	-	NR	NR	1	0.44	0%
MM 0814	Goat meat: 80% as muscle	Total	0.03	0.03	1.00	-	-	EP	381.7	-	NR	NR	1	0.18	0%
ML 0814	Goat milk	Total	0.013		1.00	AUS	Child, 2-6 yrs	EP	477.9	-	NR	NR	3	0.33	0%
FB 0269	Grape	Total	0.73	2.6	1.00	JPN	Child, 0-6 yrs	EP	387.8	JPN	150.0	3	2a	112.47	10%
DF 0269	Grape	dried	1.5	5.5	3.10	USA	Child, 1-6 yrs	PP	59.3	NLD	1.0	NR	1	67.35	7%
JF 0269	Grape	juice (pasteurised)	0.022		1.00	NLD	Child, 2-6 yrs	PP	803.2	-	NR	NR	3	0.96	0%
-	Grape	red wine	0.029		1.00	FRA	Gen pop, 3+	PP	1006.5	-	NR	NR	3	0.56	0%

Annex 4

ETOFENPROX (185) International estimate of short term intake (IESTI) Acute RfD= 1.00 mg/kg bw (1000 µg/kg bw)

Maximum %ARfD: 10%

						Large portion diet				Unit weight					
Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Country	Population group	Expressed as	Large portion, g/person	Country	Unit wt edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
							yrs								
-	Grape	white wine	0.029		1.00	NLD	Gen pop, 1+ yrs	PP	622.3	NLD	NR	NR	3	0.27	0%
MM 0816	Horse meat	Total	NA	NA	1.00	FRA	Child, 3-6 yrs	EP	175.5	-	NR	NR	1	NA	0%
MM 0816	Horse meat: 20% as fat	Total	0.21	0.3	1.00	-	-	EP	35.1	-	NR	NR	1	0.56	0%
MM 0816	Horse meat: 80% as muscle	Total	0.03	0.03	1.00	-	-	EP	140.4	-	NR	NR	1	0.22	0%
MM 0817	Kangaroo meat	Total	NA	NA	1.00	AUS	Child, 2-16 yrs	EP	417.7	-	NR	NR	1	NA	0%
MM 0817	Kangaroo meat: 20% as fat	Total	0.21	0.3	1.00	-	-	EP	83.5	-	NR	NR	1	0.66	0%
MM 0817	Kangaroo meat: 80% muscle	Total	0.03	0.03	1.00	-	-	EP	334.1	-	NR	NR	1	0.26	0%
FP 0228	Loquat	Total	0.2	0.34	1.00	AUS	Gen pop, 2+ yrs	EP	118.5	AUS	13.0	NR	1	0.60	0%
GC 0645	Maize	Total	0.05	0.05	1.00	FRA	Child, 3-6 yrs	EP	116.7	NLD	< 25	NR	3	0.31	0%
MM 0095	Meat from mammals other than marine mammals	Total	NA	NA	1.00	AUS	Child, 2-6 yrs	EP	254.3	-	NR	NR	1	NA	0%
MM 0095	Meat from mammals other than marine mammals: 20% as fat	Total	0.21	0.3	1.00	-	-	EP	50.9	-	NR	NR	1	0.80	0%
MM 0095	Meat from mammals other than marine mammals: 80% muscle	Total	0.03	0.03	1.00	-	-	EP	203.5	-	NR	NR	1	0.32	0%
ML 0106	Milks	Total	0.013		1.00	AUS	Child, 2-6 yrs	EP	1933.6	-	NR	NR	3	1.32	0%
FS 0245	Nectarine	Total	0.16	0.37	1.00	FRA	Child, 3-6 yrs	EP	325.4	FRA	99.0	3	2a	10.25	1%
-	Nectarine	raw with peel	0.16	0.37	1.00	NLD	Baby, 8-20 m	EP	183.6	NLD	131.0	3	2a	16.16	2%
-	Nectarine	juice (pasteurised)	0.008		1.00	NLD	Baby, 8-20 m	PP	18.3	NLD	NR	NR	3	0.01	0%
FS 0247	Peach	Total	0.16	0.37	1.00	FRA	Child, 3-6 yrs	EP	325.4	FRA	99.0	3	2a	10.25	1%
-	Peach	raw with peel	0.16	0.37	1.00	NLD	Baby, 8-20 m	EP	183.6	NLD	131.0	3	2a	16.16	2%
-	Peach	juice (pasteurised)	0.008		1.00	NLD	Baby, 8-20 m	PP	18.3	NLD	NR	NR	3	0.01	0%
FP 0230	Pear	Total	0.2	0.34	1.00	UNK	Child, 1.5-4.5 yrs	EP	253.9	UNK	170.2	3	2a	13.93	1%
-	Pear	raw with peel	0.2	0.34	1.00	NLD	Baby, 8-20 m	EP	201.8	NLD	204.7	3	2b	20.18	2%

Annex 4

ETOFENPROX (185) International estimate of short term intake (IESTI) Acute RfD= 1.00 mg/kg bw (1000 µg/kg bw)

Maximum %ARfD: 10%

						Large portion diet				Unit weight					
Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Country	Population group	Expressed as	Large portion, g/person	Country	Unit wt edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
-	Pear	juice (pasteurised)	0.012		1.00	NLD	Child, 2-6 yrs	PP	599.5	NLD	NR	NR	3	0.39	0%
-	Pear	sauce/puree	0.06		1.00	NLD	Child, 2-6 yrs	PP	20.4	NLD	NR	NR	3	0.07	0%
-	Pear	canned babyfood	0.018		1.00	NLD	Baby, 8-20 m	PP	78.7	NLD	NR	NR	3	0.14	0%
MO 1284	Pig kidney	Total	0.03	0.03	1.00	FRA	Gen pop, 3+ yrs	EP	208.8	-	NR	NR	1	0.12	0%
MO 1285	Pig liver	Total	0.03	0.03	1.00	AUS	Gen pop, 2+ yrs	EP	430.8	-	NR	NR	1	0.19	0%
MM 0818	Pig meat	Total	NA	NA	1.00	FRA	Child, 3-6 yrs	EP	232.6	-	NR	NR	1	NA	0%
MM 0818	Pig meat: 20% as fat	Total	0.21	0.3	1.00	-	-	EP	46.5	-	NR	NR	1	0.74	0%
MM 0818	Pig meat: 80% as muscle	Total	0.03	0.03	1.00	-	-	EP	186.1	-	NR	NR	1	0.30	0%
MO 0818	Pig, edible offal (incl kidney & liver)	Total	0.03	0.03	1.00	FRA	Child, 3-6 yrs	EP	98.2	-	NR	NR	1	0.16	0%
FP 0231	Quince	Total	0.2	0.34	1.00	AUS	Gen pop, 2+ yrs	EP	209.2	AUS	282.9	3	2b	3.18	0%
MM 0819	Rabbit meat	Total	NA	NA	1.00	NLD	Gen pop, 1+ yrs	EP	411.3	NLD	NR	NR	1	NA	0%
MM 0819	Rabbit meat: 20% as fat	Total	0.21	0.3	1.00	-	-	EP	82.3	-	NR	NR	1	0.38	0%
MM 0819	Rabbit meat: 80% as muscle	Total	0.03	0.03	1.00	-	-	EP	329.0	-	NR	NR	1	0.15	0%
SO 0495	Rape seed	Total	0.01	0.01	1.00	GER	Women, 14-50 yrs	EP	18.5	NLD	< 25	NR	3	0.00	0%
-	Rape seed	sec processing	0.01	0.01	1.00	NLD	Baby, 8-20 m	PP	8.9	NLD	NR	NR	3	0.01	0%
MO 1288	Sheep kidney	Total	0.03	0.03	1.00	FRA	Gen pop, 3+ yrs	EP	82.4	-	NR	NR	1	0.05	0%
MM 0822	Sheep meat	Total	NA	NA	1.00	FRA	Child, 3-6 yrs	EP	204.8	-	NR	NR	1	NA	0%
MM 0822	Sheep meat: 20% as fat	Total	0.21	0.3	1.00	-	-	EP	41.0	-	NR	NR	1	0.65	0%
MM 0822	Sheep meat: 80% as muscle	Total	0.03	0.03	1.00	-	-	EP	163.8	-	NR	NR	1	0.26	0%
ML 0822	Sheep milk	Total	0.013		1.00	GER	Women, 14-50 yrs	EP	1848.3	-	NR	NR	3	0.36	0%

Annex 4

FLUTRIAFOL (248) International estimate of short term intake (IESTI) for Acute RfD= 0.05 mg/kg bw (50 µg/kg bw)

Maximum %ARfD: 50%

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Large portion diet				Unit weight				IESTI µg/kg bw/day	% acute RfD rounded
						Country	Population group	Expressed as	Large portion, g/person	Country	Unit weight, edible portion, g	Variability factor	Case		
FP 0226	Apple	Total		0.16	1.00	USA	Child, 1-6 yrs	EP	624.5	USA	127.0	3	2a	9.37	20%
JF 0226	Apple	juice (pasteurised)	0.034		1.00	GER	Child, 2-4 y	PP	724.2	-	NR	NR	3	1.52	3%
FI 0327	Banana	Total		0.09	1.00	FRA	Child, 3-6 yrs	EP	324.2	FRA	612.0	3	2b	4.63	9%
SB 0716	Coffee beans	Total	0.05		1.00	FRA	Child, 3-6 yrs	EP	70.3	NLD	0.1	NR	3	0.19	0%
SM 0716	Coffee beans	raw incl roasted	0.048		1.00	NLD	Gen pop, 1+ yrs	EP	NC	NLD	0.1	NR	3	NC	NC
FB 0269	Grape	Total		0.61	1.00	JPN	Child, 0-6 yrs	EP	387.8	JPN	150.0	3	2a	26.39	50%
DF 0269	Grape	dried (currants, raisins, sultanas)		1.7	1.00	USA	Child, 1-6 yrs	PP	59.3	NLD	1.0	NR	1	6.72	10%
JF 0269	Grape	juice (pasteurised)	0.13		1.00	NLD	Child, 2-6 yrs	PP	803.2	-	NR	NR	3	5.67	10%
FP 0228	Loquat	Total		0.16	1.00	AUS	Gen pop, 2+ yrs	EP	118.5	AUS	13.0	NR	1	0.28	1%
FP 0229	Medlar	Total		0.16	1.00	NLD	Gen pop, 1+ yrs	EP	NC	-	-	-	-	NC	NC
SO 0697	Peanut, shelled	Total	0.02		1.00	USA	Child, 1-6 yrs	EP	77.7	NLD	< 25	NR	3	0.10	0%
OR 0697	Peanut, shelled	Oil (refined)	0.028		1.00	FRA	Child, 3-6 yrs	PP	19.8	-	NR	NR	3	0.03	0%
FP 0230	Pear	Total		0.16	1.00	UNK	Child, 1.5-4.5 yrs	EP	253.9	UNK	170.2	3	2a	6.56	10%
-	Pear	raw with peel		0.16	1.00	NLD	Baby, 8-20 m	EP	201.8	NLD	204.7	3	2b	9.50	20%
VO 0445	Peppers, sweet (incl. pim(i)ento)	Total		0.41	1.00	GER	Child, 2-4 yrs	EP	145.3	GER	119.3	3	2a	9.74	20%
-	Peppers, sweet (incl. pim(i)ento)	canned/preserved		0.32	1.00	NLD	Child, 2-6 yrs	PP	38.3	NLD	84.0	3	2b	2.00	4%
FP 0231	Quince	Total		0.16	1.00	AUS	Gen pop, 2+ yrs	EP	209.2	AUS	282.9	3	2b	1.50	3%
VD 0541	Soya bean (dry)	Total	0.055		1.00	JPN	Child, 0-6 yrs	EP	88.2	NLD	< 25	NR	3	0.31	1%
OR 0541	Soya bean (dry)	Oil (refined)	0.072		1.00	USA	Child, 1-6 yrs	PP	35.4	-	NR	NR	3	0.17	0%
-	Soya bean (dry)	soymilk	0.055		1.00	AUS	Child, 2-6 yrs	PP	1131.2	-	NR	NR	3	3.27	7%
GC 0654	Wheat	Total	0.015		1.00	FRA	Child, 3-6 yrs	EP	384.3	NLD	< 25	NR	3	0.31	1%
CF 0654	Wheat	Bran (processed)	0.032		1.00	USA	Child, 1-6 yrs	PP	29.7	-	NR	NR	3	0.06	0%

Annex 4

FLUTRIAFOL (248) International estimate of short term intake (IESTI) for Acute RfD= 0.05 mg/kg bw (50 µg/kg bw)

Maximum %ARfD: 50%

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Large portion diet				Unit weight				IESTI µg/kg bw/day	% acute RfD rounded
						Country	Population group	Expressed as	Large portion, g/person	Country	Unit weight, edible portion, g	Variability factor	Case		
CF 1210	Wheat	Germs	0.042		1.00	FRA	Gen Pop, 3+ yrs	PP	803.1	-	NR	NR	3	0.65	1%
CF 1211	Wheat	flour (cereals)	0.005		1.00	FRA	Child, 3-6 yrs	PP	244.7	-	NR	NR	3	0.06	0%

ISOPYRAZAM (249) International estimate of short term intake (IESTI) Acute RfD= 0.300 mg/kg bw (300 µg/kg bw)

Maximum %ARfD: 0%

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Large portion diet				Unit weight				IESTI µg/kg bw/day	% acute RfD rounded
						Country	Population group	Expressed as	Large portion, g/person	Country	Unit weight, edible portion, g	Variability factor	Case		
FI 0327	Banana	Total		0.015	1.00	FRA	Child, 3-6 yrs	EP	324.2	FRA	612.0	3	2b	0.77	0%
GC 0640	Barley	Total	0.0375		1.00	AUS	Gen pop, 2+ yrs	EP	401.3	NLD	< 25	NR	3	0.22	0%
MM 0812	Cattle meat	Total	NA	NA	1.00	FRA	Child, 3-6 yrs	EP	254.6	-	NR	NR	1	NA	0%
MM 0812	Cattle meat: 20% as fat	Total		0.008	1.00	-	-	EP	50.9	-	NR	NR	1	0.02	0%
MM 0812	Cattle meat: 80% as muscle	Total		0.008	1.00	-	-	EP	203.7	-	NR	NR	1	0.09	0%
ML 0812	Cattle milk	Total	0.0042		1.00	NLD	Baby, 8-20 m	EP	1060.7	NLD	NR	NR	3	0.44	0%
FM 0812	Cattle milk fat	Total	0.0042		1.00	GER	Child, 2-4 yrs	EP	35.2	-	NR	NR	3	0.01	0%
MO 0812	Cattle, edible offal of (includes kidney and liver)	Total		0.008	1.00	SAF	Gen pop, 10+ yrs	EP	523.6	-	NR	NR	1	0.08	0%
MO 1280	Cattle, kidney	Total		0.008	1.00	USA	Child, 1-6 yrs	EP	186.6	-	NR	NR	1	0.10	0%
MO 1281	Cattle, liver	Total		0.008	1.00	USA	Child, 1-6 yrs	EP	136.1	-	NR	NR	1	0.07	0%
PE 0840	Chicken eggs	Total		0.01	1.00	FRA	Child, 3-6 yrs	EP	201.1	-	NR	NR	1	0.11	0%
PF 0840	Chicken fat	Total		0.02	1.00	USA	Child, 1-6 yrs	EP	14.3	-	NR	NR	1	0.02	0%
PM 0840	Chicken meat	Total	NA	NA	1.00	FRA	Child, 3-6 yrs	EP	305.3	-	NR	NR	1	NA	0%
PM 0840	Chicken meat: 10% as fat	Total		0.01	1.00	-	-	EP	30.5	-	NR	NR	1	0.02	0%

Annex 4

ISOPYRAZAM (249) International estimate of short term intake (IESTI) Acute RfD= 0.300 mg/kg bw (300 µg/kg bw)

Maximum %ARfD: 0%

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Large portion diet				Unit weight				IESTI µg/kg bw/day	% acute RfD rounded
						Country	Population group	Expressed as	Large portion, g/person	Country	Unit weight, edible portion, g	Variability factor	Case		
PM 0840	Chicken meat: 90% as muscle	Total		0.01	1.00	-	-	EP	274.8	-	NR	NR	1	0.15	0%
PO 0840	Chicken, edible offal of (includes kidney and liver)	Total		0.01	1.00	Thai	Child, 3-6 yrs	EP	68.4	-	NR	NR	1	0.04	0%
MO 0105	Edible offal (mammalian)	Total		0.008	1.00	USA	Child, 1-6 yrs	EP	186.6	-	NR	NR	1	0.10	0%
PE 0112	Eggs	Total		0.01	1.00	Thai	Child, 3-6 yrs	EP	109.1	-	NR	NR	1	0.06	0%
MF 0100	Mammalian fats (except milk fats)	Total		0.008	1.00	FRA	Child, 3-6 yrs	EP	30.2	-	NR	NR	1	0.01	0%
MM 0095	Meat from mammals other than marine mammals	Total	NA	NA	1.00	AUS	Child, 2-6 yrs	EP	254.3	-	NR	NR	1	NA	0%
MM 0095	Meat from mammals other than marine mammals: 20% as fat	Total		0.008	1.00	-	-	EP	50.9	-	NR	NR	1	0.02	0%
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	Total		0.008	1.00	-	-	EP	203.5	-	NR	NR	1	0.09	0%
ML 0106	Milks	Total	0.0042		1.00	AUS	Child, 2-6 yrs	EP	1933.6	-	NR	NR	3	0.43	0%
MO 1284	Pig kidney	Total		0.08	1.00	FRA	Gen pop, 3+ yrs	EP	208.8	-	NR	NR	1	0.32	0%
MO 1285	Pig liver	Total		0.08	1.00	AUS	Gen pop, 2+ yrs	EP	430.8	-	NR	NR	1	0.51	0%
MM 0818	Pig meat	Total	NA	NA	1.00	FRA	Child, 3-6 yrs	EP	232.6	-	NR	NR	1	NA	0%
MM 0818	Pig meat: 20% as fat	Total		0.008	1.00	-	-	EP	46.5	-	NR	NR	1	0.02	0%
MM 0818	Pig meat: 80% as muscle	Total		0.008	1.00	-	-	EP	186.1	-	NR	NR	1	0.08	0%
MO 0818	Pig, edible offal of (incl kidney and liver)	Total		0.08	1.00	FRA	Child, 3-6 yrs	EP	98.2	-	NR	NR	1	0.42	0%
PM 0110	Poultry meat	Total	NA	NA	1.00	AUS	Child, 2-6 yrs	EP	274.6	-	NR	NR	1	NA	0%
PM 0110	Poultry meat: 10% as fat	Total		0.01	1.00	-	-	EP	27.5	-	NR	NR	1	0.01	0%
PM 0110	Poultry meat: 90% as muscle	Total		0.01	1.00	-	-	EP	247.1	-	NR	NR	1	0.13	0%
PO 0111	Poultry, edible offal of (includes kidney, liver and skin)	Total		0.01	1.00	FRA	Child, 3-6 yrs	EP	99.5	-	NR	NR	1	0.05	0%
PF 0111	Poultry, fats	Total		0.01	1.00	USA	Child, 1-6 yrs	EP	15.8	-	NR	NR	1	0.01	0%
GC 0650	Rye	Total	0.015		1.00	FRA	Gen pop, 3+ yrs	EP	160.9	NLD	< 25	NR	3	0.05	0%
MO 1288	Sheep kidney	Total		0.08	1.00	FRA	Gen pop, 3+ yrs	EP	82.4	-	NR	NR	1	0.13	0%
MO 1289	Sheep liver	Total		0.08	1.00	AUS	Gen pop, 2+ yrs	EP	345.6	-	NR	NR	1	0.41	0%
MM 0822	Sheep meat	Total	NA	NA	1.00	FRA	Child, 3-6 yrs	EP	204.8	-	NR	NR	1	NA	0%

Annex 4

ISOPYRAZAM (249) International estimate of short term intake (IESTI) Acute RfD= 0.300 mg/kg bw (300 µg/kg bw)

Maximum %ARfD: 0%

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Large portion diet				Unit weight				IESTI µg/kg bw/day	% acute RfD rounded
						Country	Population group	Expressed as	Large portion, g/person	Country	Unit weight, edible portion, g	Variability factor	Case		
MM 0822	Sheep meat: 20% as fat	Total		0.008	1.00	-	-	EP	41.0	-	NR	NR	1	0.02	0%
MM 0822	Sheep meat: 80% as muscle	Total		0.008	1.00	-	-	EP	163.8	-	NR	NR	1	0.07	0%
FM 0822	Sheep milk fat	Total	0.0042		1.00	-	-	-	-	-	NR	NR	-	-	-
MO 0822	Sheep, edible offal of (includes kidney and liver)	Total		0.08	1.00	AUS	Child, 2-16 yrs	EP	169.8	-	NR	NR	1	0.36	0%
GC 0653	Triticale	Total	0.015		1.00	GER	Gen pop, 14-80 yrs	EP	394.7	-	< 25	NR	3	0.08	0%
GC 0654	Wheat	Total	0.015		1.00	FRA	Child, 3-6 yrs	EP	384.3	NLD	< 25	NR	3	0.31	0%

PROFENOFOS (171) International estimate of short term intake (IESTI) for Acute RfD= 1.00 mg/kg bw (1000 µg/kg bw)

Maximum %ARfD: 0%

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Large portion diet				Unit weight				IESTI µg/kg bw/day	% acute RfD rounded
						Country	Population group	Expressed as	Large portion, g/person	Country	Unit weight, edible portion, g	Variability factor	Case		
VO 0444	Peppers, chili	Total		1.42	1.00	USA	Gen pop, all	EP	86.7	USA	43.2	3	2a	3.78	0%

Annex 4

PYRACLOSTROBIN (210) International estimate of short term intake (IESTI) for Acute RfD= 0.050 mg/kg bw (50 µg/kg bw)

Maximum %ARfD: 50%

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	default PF	Large portion diet				Unit weight				IESTI µg/kg bw/day	% acute RfD rounded
						Country	Population group	Expressed as	Large portion, g/person	Country	Unit weight, edible portion, g	Variability factor	Case		
TN 0660	Almonds	Total		0	1.00	GER	Women, 14-50 yrs	EP	100.0	NLD	1.2	NR	1	0.00	0%
VS 0620	Artichoke globe	Total		1.44	1.00	FRA	Child, 3-6 yrs	EP	117.2	FRA	98.9	3	2a	24.00	50%
GC 0640	Barley	Total	0.345		1.00	AUS	Gen pop, 2+ yrs	EP	401.3	NLD	< 25	NR	3	2.07	4%
-	Barley	brewing malt	0.4		1.00	NLD	Gen pop, 1+ yrs	PP	NC	NLD	NR	NR	3	NC	NC
-	Barley	beer	0.23		1.00	AUS	Gen pop, 2+ yrs	PP	2420.8	-	NR	NR	3	8.31	20%
-	Barley	pot/pearled barley (cooked)	0.23		0.400	NLD	Child, 2-6 yrs	PP	68.7	NLD	<25	NR	1	ND	
FB 0264	Blackberries	Total		1.32	1.00	FRA	Gen pop, 3+ yrs	EP	407.8	NLD	2.4	NR	1	10.31	20%
FB 0020	Blueberries	Total		2.08	1.00	GER	Women, 14-50 yrs	EP	485.0	AUS	1.8	NR	1	14.95	30%
-	Borage seeds	Total	0.055		1.00	GER	Gen pop, 14-80 yrs	EP	42.0	NLD	< 25	NR	3	0.03	0%
TN 0662	Brazil nut	Total		0	1.00	AUS	Child, 2-16 yrs	EP	59.9	NLD	3.8	NR	1	0.00	0%
TN 0295	Cashew nut	Total		0	1.00	Thai	Child, 3-6 yrs	EP	98.8	NLD	2.1	NR	1	0.00	0%
-	Castor bean	Total	0.055		1.00	-	-	-	-	-	-	-	-	-	-
-	Castor bean	Oil (refined)	0.055		1.00	NLD	Gen pop, 1+ yrs	PP	NC	NLD	NR	NR	3	NC	NC
FS 0013	Cherries	Total		1.57	1.00	GER	Child, 2-4 yrs	EP	187.5	NLD	7.2	NR	1	18.23	40%
-	Cherries	juice (pasteurised)		0.08	0.45	NLD	Child, 2-6 yrs	PP	7.5	NLD	NR	NR	3	ND	-
TN 0664	Chestnuts	Total		0	1.00	FRA	Child, 3-6 yrs	EP	195.9	NLD	20.0	NR	1	0.00	0%
TN 0665	Coconut	Total		0	1.00	Thai	Child, 3-6 yrs	EP	309.1	Thai	383.3	3	2b	0.00	0%
SO 0691	Cotton seed	Total	0.055		1.00	USA	Gen pop, all	EP	3.3	NLD	< 25	NR	3	0.00	0%
OR 0691	Cotton seed	Oil (refined)	0.055		1.00	USA	Child, 1-6 yrs	PP	6.2	-	NR	NR	3	0.02	0%
VC 0424	Cucumber	Total		0.41	1.00	GER	Child, 2-4 yrs	EP	150.0	GER	458.1	3	2b	11.42	20%
FB 0021	Currants, red, black, white	Total		1.3	1.00	AUS	Gen pop, 2+ yrs	EP	797.6	NLD	14.9	NR	1	15.48	30%
VA 0381	Garlic	Total		0.09	1.00	Thai	Gen pop, 3+ yrs	EP	27.7	Thai	16.6	NR	1	0.05	0%
VC 0425	Gherkin	Total		0.41	1.00	AUS	Child, 2-6 yrs	EP	60.8	GER	54.5	3	2a	3.67	7%
-	Gold of pleasure seeds	Total	0.055		1.00	-	-	-	-	-	-	-	-	-	-
-	Gold of pleasure seeds	Oil (refined)	0.055		1.00	NLD	Gen pop, 1+ yrs	PP	NC	NLD	NR	NR	3	NC	NC

Annex 4

PYRACLOSTROBIN (210) International estimate of short term intake (IESTI) for Acute RfD= 0.050 mg/kg bw (50 µg/kg bw)

Maximum %ARfD: 50%

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	default PF	Large portion diet				Unit weight				IESTI µg/kg bw/day	% acute RfD rounded
						Country	Population group	Expressed as	Large portion, g/person	Country	Unit weight, edible portion, g	Variability factor	Case		
-	Grape seed	Total	0.055		1.00	-	-	-	-	-	-	-	-	-	-
-	Grape seed	Oil (refined)	0.055		1.00	AUS	Gen pop, 2+ yrs	PP	18.0	-	NR	NR	3	0.01	0%
TN 0666	Hazelnut	Total		0	1.00	FRA	Child, 3-6 yrs	EP	27.2	NLD	1.2	NR	1	0.00	0%
-	Hempseed	Total	0.055		1.00	-	-	-	-	-	-	-	-	-	-
-	Hempseed	Oil (refined)	0.055		1.00	NLD	Gen pop, 1+ yrs	PP	NC	NLD	NR	NR	3	NC	NC
SO0692	Kapok	Total	0.055		1.00	-	-	-	-	-	-	-	-	-	-
-	Kapok	Oil (refined)	0.055		1.00	NLD	Gen pop, 1+ yrs	PP	NC	NLD	NR	NR	3	NC	NC
FC 0204	Lemon	Total		0.1	1.00	GER	Child, 2-4 yrs	EP	125.5	AUS	108.9	3	2a	2.13	4%
FC 0205	Lime	Total		0.1	1.00	AUS	Gen pop, 2+ yrs	EP	259.2	AUS	49.0	3	2a	0.53	1%
SO 0693	Linseed	Total	0.055		1.00	GER	Gen pop, 14-80 yrs	EP	58.5	NLD	< 25	NR	3	0.04	0%
VC 0427	Loofah, angled (= angled gourd)	Total		0.14	1.00	Thai	Child, 3-6 yrs	EP	70.0	AUS	-	-	-	-	-
TN 0669	Macadamia nut	Total		0	1.00	GER	Women, 14-50 yrs	EP	125.0	NLD	3.2	NR	1	0.00	0%
FC 0003	Mandarin + mandarin-like hybrid	Total		0.1	1.00	JPN	Child, 0-6 yrs	EP	353.3	JPN	70.0	3	2a	3.10	6%
VC 0046	Melons, except watermelon	Total		0.14	1.00	FRA	Child, 3-6 yrs	EP	358.1	FRA	420.0	3	2b	7.96	20%
SO 0090	Mustard seed	Total	0.055		1.00	AUS	Gen pop, 2+ yrs	EP	21.4	NLD	< 25	NR	3	0.02	0%
FS 0245	Nectarine	Total		0.13	1.00	FRA	Child, 3-6 yrs	EP	325.4	FRA	99.0	3	2a	3.60	7%
GC 0647	Oats	Total	0.345		1.00	AUS	Child, 2-6 yrs	EP	82.5	NLD	< 25	NR	3	1.50	3%
VA 0385	Onion, bulb	Total		0.62	1.00	AUS	Child, 2-6 yrs	EP	63.7	AUS	96.8	3	2b	6.24	10%
-	Orange, sweet, sour + orange-like hybrid	raw, without peel		0.1	1.00	NLD	Baby, 8-12 m	EP	139.1	NLD	181.3	3	2b	4.09	8%
-	Orange, sweet, sour + orange-like hybrid	Peel		2.23	1.00	AUS	Gen pop, 2+ yrs	PP	15.1	-	-	-	-	-	-
-	Orange, sweet, sour + orange-like hybrid	Juice (pasteurised)		0.04	1.00	AUS	Child, 2-6 yrs	PP	971.3	-	NR	NR	3	ND	-
-	Orange, sweet, sour + orange-like hybrid	Oil (refined)	3.03		1.00	NLD	Gen pop, 1+ yrs	PP	NC	NLD	NR	NR	3	NC	NC

Annex 4

PYRACLOSTROBIN (210) International estimate of short term intake (IESTI) for Acute RfD= 0.050 mg/kg bw (50 µg/kg bw)

Maximum %ARfD: 50%

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	default PF	Large portion diet				Unit weight				IESTI µg/kg bw/day	% acute RfD rounded
						Country	Population group	Expressed as	Large portion, g/person	Country	Unit weight, edible portion, g	Variability factor	Case		
-	Orange, sweet, sour + orange-like hybrid	canned babyfood	0.05		1.00	NLD	Baby, 8-12 m	PP	84.3	NLD	NR	NR	3	0.41	1%
-	Palm fruit	sec processing	0.055		1.00	NLD	Child, 2-6 yrs	PP	19.2	NLD	NR	NR	3	0.06	0%
SO 0696	Palm kernels	Total	0.055		1.00	-	-	-	-	-	-	-	-	-	-
FI 0350	Papaya	Total		0.06	1.00	USA	Child, 1-6 yrs	EP	160.9	USA	203.7	3	2b	1.93	4%
FS 0247	Peach	Total		0.13	1.00	FRA	Child, 3-6 yrs	EP	325.4	FRA	99.0	3	2a	3.60	7%
SO 0697	Peanut, shelled	Total	0.055		1.00	USA	Child, 1-6 yrs	EP	77.7	NLD	< 25	NR	3	0.28	1%
TN 0672	Pecan	Total		0	1.00	AUS	Child, 2-16 yrs	EP	80.9	NLD	3.3	NR	1	0.00	0%
TN 0673	Pine nut	Total		0	1.00	AUS	Child, 2-6 yrs	EP	17.7	NLD	0.2	NR	1	0.00	0%
FS 0014	Plum	Total		0.4	1.00	Thai	Child, 3-6 yrs	EP	361.8	AUS	84.0	3	2a	12.39	20%
DF 0014	Plum	dried (prunes)		1.84	1.00	AUS	Child, 2-16 yrs	PP	288.8	NLD	10.4	NR	1	13.98	30%
-	Plum	sauce/puree	0.17		1.00	NLD	Gen pop, 1+ yrs	PP	NC	NLD	NR	NR	3	NC	NC
SO 0698	Poppy seed	Total	0.055		1.00	GER	Women, 14-50 yrs	EP	67.5	NLD	< 25	NR	3	0.06	0%
-	pumpkin seeds and other seeds of cucurbitacea	Total	0.055		1.00	GER	Child, 2-4 yrs	EP	20.2	NLD	< 25	NR	3	0.07	0%
VC 0429	Pumpkins	Total		0.14	1.00	SAF	Gen pop, 10+ yrs	EP	852.2	AUS	1326.0	3	2b	6.43	10%
SO 0495	Rape seed	Total	0.055		1.00	GER	Women, 14-50 yrs	EP	18.5	NLD	< 25	NR	3	0.02	0%
OR 0495	Rape seed	Oil (refined)	0.053		1.00	AUS	Gen pop, 2+ yrs	PP	40.7	-	NR	NR	3	0.03	0%
FB 0272	Raspberries, red, black	Total		1.32	1.00	FRA	Child, 3-6 yrs	EP	157.5	NLD	4.3	NR	1	11.00	20%
GC 0650	Rye	Total	0.02		1.00	FRA	Gen pop, 3+ yrs	EP	160.9	NLD	< 25	NR	3	0.06	0%
SO 0699	Safflower seed	Total	0.055		1.00	FRA	Gen Pop, 3+ yrs	EP	5.6	NLD	< 25	NR	3	0.01	0%
OR 0699	Safflower seed	Oil (refined)	0.055		1.00	GER	Child, 2-4 yrs	PP	15.5	-	NR	NR	3	0.05	0%
SO 0700	Sesame seed	Total	0.055		1.00	GER	Child, 2-4 yrs	EP	23.4	NLD	< 25	NR	3	0.08	0%
FC 0005	Shaddock or pomelo + shaddock-like hybrid	Total		0.1	1.00	GER	Child, 2-4 yrs	EP	358.6	GER	178.5	3	2a	4.43	9%
SO 0701	Shea nuts	Total	0.055		1.00	-	-	-	-	-	-	-	-	-	-
VC 0430	Snake gourd	Total		0.14	1.00	Thai	Child, 3-6 yrs	EP	129.6	-	-	-	-	-	-

Annex 4

PYRACLOSTROBIN (210) International estimate of short term intake (IESTI) for Acute RfD= 0.050 mg/kg bw (50 µg/kg bw)

Maximum %ARfD: 50%

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	default PF	Large portion diet				Unit weight				IESTI µg/kg bw/day	% acute RfD rounded
						Country	Population group	Expressed as	Large portion, g/person	Country	Unit weight, edible portion, g	Variability factor	Case		
GC 0651	Sorghum	Total	0.025		1.00	GER	Child, 2-4 yrs	EP	54.3	NLD	< 25	NR	3	0.08	0%
VA 0389	Spring onion	Total		0.6	1.00	Thai	Child, 3-6 yrs	EP	52.8	NLD	38.0	3	2a	4.52	9%
VC 0431	Squash, summer (= courgette)	Total		0.14	1.00	FRA	Child, 3-6 yrs	EP	148.8	FRA	270.0	3	2b	3.31	7%
FB 0275	Strawberry	Total		0.75	1.00	FRA	Child, 3-6 yrs	EP	339.4	FRA	13.4	NR	1	13.47	30%
SO 0702	Sunflower seed	Total	0.055		1.00	USA	Gen pop, all	EP	193.1	NLD	< 25	NR	3	0.16	0%
GC 0653	Triticale	Total	0.02		1.00	GER	Gen pop, 14-80 yrs	EP	394.7	-	< 25	NR	3	0.10	0%
TN 0678	Walnut	Total		0	1.00	GER	Child, 2-4 yrs	EP	49.4	NLD	7.0	NR	1	0.00	0%

SPIROTETRAMAT (234) International estimate of short term intake (IESTI) for Acute RfD= 1.00 mg/kg bw (1000 µg/kg bw)

Maximum %ARfD: 40%

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Large portion diet				Unit weight				IESTI µg/kg bw/day	% acute RfD rounded
						Country	Population group	Expressed as	Large portion, g/person	Country	Unit weight, edible portion, g	Variability factor	Case		
TN 0660	Almonds	Total	0.084	0.29	1.00	GER	Women, 14-50 yrs	EP	100.0	NLD	1.2	NR	1	0.43	0%
VL 0460	Amaranth	Total		5.5	1.00	AUS	Gen pop, 2+ yrs	EP	381.9	NLD	85.8	3	2a	45.43	5%
FP 0226	Apple	Total	0.17	0.55	1.00	USA	Child, 1-6 yrs	EP	624.5	USA	127.0	3	2a	32.21	3%
JF 0226	Apple	juice (pasteurised)	0.082		1.00	GER	Child, 2-4 y	PP	724.2	-	NR	NR	3	3.68	0%
FS 0240	Apricot	Total		2.1	1.00	GER	Child, 2-4 yrs	EP	200.0	GER	45.5	3	2a	37.84	4%
VC 0421	Balsam pear	Total		0.18	1.00	Thai	Child, 3-6 yrs	EP	56.8	NLD	130.0	3	2b	1.79	0%
VP 0520	Bambara groundnut (immature seeds)	Total		0.84	1.00	AUS	Gen pop, 2+ yrs	EP	186.1	-	-	-	-	-	-

Annex 4

SPIROTETRAMAT (234) International estimate of short term intake (IESTI) for Acute RfD= 1.00 mg/kg bw (1000 µg/kg bw)

Maximum %ARfD: 40%

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Large portion diet				Unit weight				IESTI µg/kg bw/day	% acute RfD rounded
						Country	Population group	Expressed as	Large portion, g/person	Country	Unit weight, edible portion, g	Variability factor	Case		
VD 0071	Beans (dry, Phaseolus spp)	Total	0.21		1.00	FRA	Child, 2-16 yrs	EP	145.4	NLD	0.5	NR	1	ND	-
VP 0061	Beans except broad bean & soya bean (green pods & immature seeds) (Phaseolus spp)	Total		0.84	1.00	FRA	Child, 3-6 yrs	EP	213.0	NLD	19.4	NR	1	9.47	1%
VP 0062	Beans, shelled (immature seeds)	Total		0.84	1.00	FRA	Child, 3-6 yrs	EP	219.6	NLD	5.8	NR	1	9.76	1%
TN 0662	Brazil nut	Total	0.084	0.29	1.00	AUS	Child, 2-16 yrs	EP	59.9	NLD	3.8	NR	1	0.46	0%
VD 0523	Broad bean (dry)	Total	0.21		1.00	AUS	Gen pop, 2+ yrs	EP	22.8	NLD	< 25	NR	1	ND	-
VP 0522	Broad bean (green pods & immature seeds)	Total		0.84	1.00	AUS	Gen pop, 2+ yrs	EP	153.2	-	-	-	-	-	-
VP 0523	Broad bean, shelled (immature seeds)	Total		0.84	1.00	AUS	Child, 2-16 yrs	EP	104.5	AUS	9.2	NR	1	2.31	0%
VB 0400	Broccoli	Total		0.87	1.00	FRA	Child, 3-6 yrs	EP	241.7	NLD	304.0	3	2b	33.38	3%
VB 0401	Broccoli, Chinese	Total		0.87	1.00	AUS	Gen pop, 2+ yrs	EP	302.9	AUS	311.0	3	2b	11.80	1%
VB 0041	Cabbage, head	Total		0.92	1.00	SAF	Child, 1-5 yrs	EP	187.1	BEL	1402.5	3	2b	36.36	4%
TN 0295	Cashew nut	Total	0.084	0.29	1.00	Thai	Child, 3-6 yrs	EP	98.8	NLD	2.1	NR	1	1.68	0%
VB 0404	Cauliflower (head)	Total		0.87	1.00	FRA	Child, 3-6 yrs	EP	165.4	NLD	797.0	3	2b	22.84	2%
VS 0624	Celery (whole)	Total		2.6	1.00	FRA	Child, 3-6 yrs	EP	124.4	AUS	861.1	3	2b	51.35	5%
VL 0464	Chard	Total		5.5	1.00	FRA	Gen pop, 3+ yrs	EP	285.5	NLD	175.0	3	2a	66.96	7%
FS 0013	Cherries	Total		2.1	1.00	GER	Child, 2-4 yrs	EP	187.5	NLD	7.2	NR	1	24.38	2%
VL 0465	Chervil	Total		5.5	1.00	GER	Women, 14-50 yrs	EP	9.4	NLD	< 25	NR	1	0.77	0%
TN 0664	Chestnuts	Total	0.084	0.29	1.00	FRA	Child, 3-6 yrs	EP	195.9	NLD	20.0	NR	1	3.01	0%
VD 0524	Chick-pea (dry)	Total	0.21		1.00	USA	Gen pop, all	EP	205.4	NLD	< 25	NR	1	ND	-
VL 0469	Chicory leaves (head)	Total		5.5	1.00	GER	Child, 2-4 yrs	EP	82.4	AUS	125.0	3	2b	84.19	8%
VL 0466	Chinese cabbage, type pak-choi	Total		5.5	1.00	JPN	Child, 0-6 yrs	EP	182.7	JPN	200.0	3	2b	189.59	20%
VL 0467	Chinese cabbage, type pe-tsai	Total		5.5	1.00	JPN	Child, 0-6 yrs	EP	146.8	JPN	1500.0	3	2b	152.30	20%
TN 0665	Coconut	Total	0.084	0.29	1.00	Thai	Child, 3-6 yrs	EP	309.1	Thai	383.3	3	2b	15.73	2%

Annex 4

SPIROTETRAMAT (234) International estimate of short term intake (IESTI) for Acute RfD= 1.00 mg/kg bw (1000 µg/kg bw)

Maximum %ARfD: 40%

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Large portion diet				Unit weight				IESTI µg/kg bw/day	% acute RfD rounded
						Country	Population group	Expressed as	Large portion, g/person	Country	Unit weight, edible portion, g	Variability factor	Case		
VL 0470	Corn salad	Total		5.5	1.00	GER	Child, 2-4 yrs	EP	41.2	NLD	7.8	NR	1	14.03	1%
VL 0510	Cos lettuce	Total		5.5	1.00	GER	Child, 2-4 yrs	EP	86.9	AUS	457.2	3	2b	88.78	9%
OR 0691	Cotton seed	Oil (refined)	0		1.00	USA	Child, 1-6 yrs	PP	6.2	-	NR	NR	3	0.00	0%
VL 0472	Cress, garden	Total		5.5	1.00	FRA	Gen pop, 3+ yrs	EP	47.5	NLD	15.0	NR	1	5.00	1%
VC 0424	Cucumber	Total		0.18	1.00	GER	Child, 2-4 yrs	EP	150.0	GER	458.1	3	2b	5.02	1%
VL 0474	Dandelion leaves	Total		5.5	1.00	GER	Child, 2-4 yrs	EP	16.8	NLD	35.0	3	2b	17.16	2%
MO 0105	Edible offal (mammalian)	Total		0.55	1.00	USA	Child, 1-6 yrs	EP	186.6	-	NR	NR	1	6.84	1%
VO 0440	Egg plant	Total		1.1	1.00	JPN	Child, 0-6 yrs	EP	219.3	JPN	80.0	3	2a	26.24	3%
PE 0112	Eggs	Total		0.0048	1.00	Thai	Child, 3-6 yrs	EP	109.1	-	NR	NR	1	0.03	0%
VL 0476	Endive	Total		5.5	1.00	FRA	Child, 3-6 yrs	EP	197.3	NLD	375.0	3	2b	172.26	20%
VC 0425	Gherkin	Total		0.18	1.00	AUS	Child, 2-6 yrs	EP	60.8	GER	54.5	3	2a	1.61	0%
FB 0269	Grape	Total		1.3	1.00	JPN	Child, 0-6 yrs	EP	387.8	JPN	150.0	3	2a	56.24	6%
DF 0269	Grape	dried (currants, raisins, sultanas)	1.1	3.4	3.10	USA	Child, 1-6 yrs	PP	59.3	NLD	1.0	NR	1	41.63	4%
JF 0269	Grape	juice (pasteurised)	0.27		1.00	NLD	Child, 2-6 yrs	PP	803.2	-	NR	NR	3	11.79	1%
-	Grape	red wine	0.23		1.00	FRA	Gen pop, 3+ yrs	PP	1006.5	-	NR	NR	3	4.43	0%
-	Grape	white wine	0.23		1.00	NLD	Gen pop, 1+ yrs	PP	622.3	NLD	NR	NR	3	2.18	0%
TN 0666	Hazelnut	Total	0.084	0.29	1.00	FRA	Child, 3-6 yrs	EP	27.2	NLD	1.2	NR	1	0.42	0%
-	Hops, dry	beer	0.11		0.002	NLD	Gen pop, 1+ yrs	PP	2368.8	NLD	NR	NR	3	0.01	0%
VL 0478	Indian mustard	Total		5.5	1.00	-	-	-	-	-	-	-	-	-	-
VL 0480	Kale	Total		5.5	1.00	GER	Gen pop, 14-80 yrs	EP	669.8	NLD	672.0	3	2b	144.71	10%
VL 0507	Kangkung	Total		5.5	1.00	AUS	Child, 2-6 yrs	EP	22.6	NLD	85.8	3	2b	19.65	2%
FI 0341	Kiwi fruit	Total		0.066	1.00	FRA	Child, 3-6 yrs	EP	325.1	FRA	64.5	3	2a	1.59	0%
FC 0204	Lemon	Total	0.33	0.47	1.00	GER	Child, 2-4 yrs	EP	125.5	AUS	108.9	3	2a	9.99	1%
VD 0533	Lentil (dry)	Total	0.21		1.00	FRA	Child, 3-6 yrs	EP	290.8	NLD	0.1	NR	1	ND	-
VL 0482	Lettuce, head	Total		5.5	1.00	Thai	Child, 3-6 yrs	EP	111.0	USA	512.1	3	2b	107.06	10%
VL 0483	Lettuce, leaf	Total		5.5	1.00	GER	Child, 2-4 yrs	EP	86.9	NLD	117.8	3	2b	88.78	9%
FC 0205	Lime	Total	0.33	0.47	1.00	AUS	Gen pop, 2+ yrs	EP	259.2	AUS	49.0	3	2a	2.51	0%
FI 0343	Litchi	Total		6	1.00	AUS	Gen pop, 2+ yrs	EP	517.9	AUS	13.8	NR	1	46.38	5%

Annex 4

SPIROTETRAMAT (234) International estimate of short term intake (IESTI) for Acute RfD= 1.00 mg/kg bw (1000 µg/kg bw)

Maximum %ARfD: 40%

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Large portion diet				Unit weight				IESTI µg/kg bw/day	% acute RfD rounded
						Country	Population group	Expressed as	Large portion, g/person	Country	Unit weight, edible portion, g	Variability factor	Case		
FP 0228	Loquat	Total	0.17	0.55	1.00	AUS	Gen pop, 2+ yrs	EP	118.5	AUS	13.0	NR	1	0.97	0%
VD 0545	Lupin (dry)	Total	0.21		1.00	-	-	-	-	-	-	-	-	-	-
TN 0669	Macadamia nut	Total	0.084	0.29	1.00	GER	Women, 14-50 yrs	EP	125.0	NLD	3.2	NR	1	0.54	0%
FC 0003	Mandarin + mandarin-like hybrid	Total	0.33	0.47	1.00	JPN	Child, 0-6 yrs	EP	353.3	JPN	70.0	3	2a	14.58	1%
FI 0345	Mango	Total		0.25	1.00	GER	Child, 2-4 yrs	EP	126.8	Thai	241.5	3	2b	5.89	1%
MM 0095	Meat from mammals other than marine mammals	Total	NA	NA	1.00	AUS	Child, 2-6 yrs	EP	254.3	-	NR	NR	1	NA	0%
MM 0095	Meat from mammals other than marine mammals: 20% as fat	Total		0.043	1.00	-	-	EP	50.9	-	NR	NR	1	0.12	0%
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	Total		0.019	1.00	-	-	EP	203.5	-	NR	NR	1	0.20	0%
FP 0229	Medlar	Total		0.55	1.00	NLD	Gen pop, 1+ yrs	EP	NC	-	-	-	-	NC	NC
VC 0046	Melons, except watermelon	Total		0.18	1.00	FRA	Child, 3-6 yrs	EP	358.1	FRA	420.0	3	2b	10.23	1%
ML 0106	Milks	Total	0.005	0.005	1.00	AUS	Child, 2-6 yrs	EP	1933.6	-	NR	NR	3	0.51	0%
-	Mung bean sprouts	Total	0.21		1.00	Thai	Child, 3-6 yrs	EP	47.9	NLD	< 25	NR	1	ND	-
VL 0485	Mustard greens	Total		5.5	1.00	USA	Child, 1-6 yrs	EP	49.6	AUS	-	-	-	-	-
FS 0245	Nectarine	Total		2.1	1.00	FRA	Child, 3-6 yrs	EP	325.4	FRA	99.0	3	2a	58.16	6%
VO 0442	Okra	Total		1.1	1.00	USA	Child, 1-6 yrs	EP	202.5	NLD	17.0	NR	1	14.85	1%
VA 0385	Onion, bulb	Total		0.005	1.00	AUS	Child, 2-6 yrs	EP	63.7	AUS	96.8	3	2b	0.05	0%
FC 0004	Orange, sweet, sour + orange-like hybrid	Total	0.33	0.47	1.00	AUS	Child, 2-6 yrs	EP	800.8	AUS	155.8	3	2a	27.52	3%
FI 0350	Papaya	Total		0.22	1.00	USA	Child, 1-6 yrs	EP	160.9	USA	203.7	3	2b	7.08	1%
FS 0247	Peach	Total		2.1	1.00	FRA	Child, 3-6 yrs	EP	325.4	FRA	99.0	3	2a	58.16	6%
FP 0230	Pear	Total		0.55	1.00	UNK	Child, 1.5-4.5 yrs	EP	253.9	UNK	170.2	3	2a	22.54	2%
VD 0072	Peas (dry, Pisum spp, Vigna spp)	Total	0.21		1.00	FRA	Gen pop, 3+ yrs	EP	355.9	NLD	< 25	NR	1	ND	-

Annex 4

SPIROTETRAMAT (234) International estimate of short term intake (IESTI) for Acute RfD= 1.00 mg/kg bw (1000 µg/kg bw)

Maximum %ARfD: 40%

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Large portion diet				Unit weight				IESTI µg/kg bw/day	% acute RfD rounded
						Country	Population group	Expressed as	Large portion, g/person	Country	Unit weight, edible portion, g	Variability factor	Case		
VP 0063	Peas (green pods & immature seeds) (Pisum spp, Vigna spp)	Total		0.84	1.00	USA	Child, 1-6 yrs	EP	105.0	AUS	6.2	NR	1	5.88	1%
VP 0064	Peas, shelled (immature seeds) (Pisum spp, Vigna spp)	Total		0.84	1.00	UNK	Child, 1.5-4.5 yrs	EP	174.0	NLD	< 25	NR	1	10.08	1%
TN 0672	Pecan	Total	0.084	0.29	1.00	AUS	Child, 2-16 yrs	EP	80.9	NLD	3.3	NR	1	0.62	0%
VO 0443	Pepino	Total		1.1	1.00	AUS	Gen pop, 2+ yrs	EP	73.9	AUS	1.2	3	1	1.21	0%
VO 0444	Peppers, chili	Total		1.5	1.00	USA	Gen pop, all	EP	86.7	USA	43.2	3	2a	4.00	0%
-	Peppers, chili	dried&powder		11	7.00	AUS	Gen Pop, 2+ yrs	PP	1.4	NLD	0.0	NR	1	1.57	0%
VO 0445	Peppers, sweet (incl. pim(i)ento)	Total		1.1	1.00	GER	Child, 2-4 yrs	EP	145.3	GER	119.3	3	2a	26.14	3%
VD 0537	Pigeon pea	Total	0.21		1.00	AUS	Gen pop, 2+ yrs	EP	95.8	-	< 25	NR	1	ND	-
TN 0673	Pine nut	Total	0.084	0.29	1.00	AUS	Child, 2-6 yrs	EP	17.7	NLD	0.2	NR	1	0.27	0%
TN 0675	Pistachio nut	Total	0.084	0.29	1.00	AUS	Gen pop, 2+ yrs	EP	238.2	NLD	0.9	NR	1	1.03	0%
FS 0014	Plum	Total		2.1	1.00	Thai	Child, 3-6 yrs	EP	361.8	AUS	84.0	3	2a	65.06	7%
VR 0589	Potato	Total		0.46	1.00	SAF	Child, 1-5 yrs	EP	299.6	UNK	216.0	3	2a	23.70	2%
PM 0110	Poultry meat	Total	NA	NA	1.00	AUS	Child, 2-6 yrs	EP	274.6	-	NR	NR	1	NA	0%
PM 0110	Poultry meat: 10% as fat	Total		0.00037	1.00	-	-	EP	27.5	-	NR	NR	1	0.00	0%
PM 0110	Poultry meat: 90% as muscle	Total		0.00037	1.00	-	-	EP	247.1	-	NR	NR	1	0.00	0%
PO 0111	Poultry, edible offal of (includes kidney, liver and skin)	Total		0.0033	1.00	FRA	Child, 3-6 yrs	EP	99.5	-	NR	NR	1	0.02	0%
VC 0429	Pumpkins	Total		0.18	1.00	SAF	Gen pop, 10+ yrs	EP	852.2	AUS	1326.0	3	2b	8.26	1%
VL 0492	Purslane	Total		5.5	1.00	GER	Women, 14-50 yrs	EP	204.1	NLD	< 25	NR	1	16.64	2%
FP 0231	Quince	Total		0.55	1.00	AUS	Gen pop, 2+ yrs	EP	209.2	AUS	282.9	3	2b	5.15	1%
VL 0495	Rape greens	Total		5.5	1.00	-	-	-	-	-	-	-	-	-	-
VL 0496	Rucola	Total		5.5	1.00	AUS	Child, 2-16 yrs	EP	104.0	NLD	0.3	NR	1	15.05	2%
FC 0005	Shaddock or pomelo + shaddock-like hybrid	Total	0.33	0.47	1.00	GER	Child, 2-4 yrs	EP	358.6	GER	178.5	3	2a	20.83	2%
VD 0541	Soya bean (dry)	Total	0.45		1.00	JPN	Child, 0-6 yrs	EP	88.2	NLD	< 25	NR	1	ND	-

Annex 4

SPIROTETRAMAT (234) International estimate of short term intake (IESTI) for Acute RfD= 1.00 mg/kg bw (1000 µg/kg bw)

Maximum %ARfD: 40%

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Large portion diet				Unit weight				IESTI µg/kg bw/day	% acute RfD rounded
						Country	Population group	Expressed as	Large portion, g/person	Country	Unit weight, edible portion, g	Variability factor	Case		
VP 0541	Soya bean (immature seeds)	Total		0.84	1.00	Thai	Child, 3-6 yrs	EP	66.0	-	< 25	NR	1	3.24	0%
VL 0502	Spinach (bunch)	Total		5.5	1.00	SAF	Child, 1-5 yrs	EP	420.3	JPN	300.0	3	2a	395.19	40%
VC 0431	Squash, summer (= courgette)	Total		0.18	1.00	FRA	Child, 3-6 yrs	EP	148.8	FRA	270.0	3	2b	4.25	0%
VL 0505	Taro leaves	Total		5.5	1.00	-	-	-	-	-	-	-	-	-	-
VO 0448	Tomato	Total		1.1	1.00	AUS	Child, 2-6 yrs	EP	289.3	AUS	128.7	3	2a	31.65	3%
VL 0506	Turnip greens	Total		5.5	1.00	USA	Child, 1-6 yrs	EP	89.9	NLD	< 25	NR	1	32.95	3%
TN 0678	Walnut	Total	0.084	0.29	1.00	GER	Child, 2-4 yrs	EP	49.4	NLD	7.0	NR	1	0.89	0%
VC 0432	Watermelon	Total		0.18	1.00	AUS	Gen pop, 2+ yrs	EP	2542.2	AUS	2095.6	3	2a	18.09	2%

SULFOXAFLOR (252) International estimate of short term intake (IESTI) Acute RfD= 0.3 mg/kg bw

Maximum %ARfD: 70%

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Large portion diet				Unit weight				IESTI µg/kg bw/day	% acute RfD rounded
						Country	Population group	Expressed as	Large portion g/person	Country	Unit weight, edible portion, g	Variability factor	Case		
TN 0660	Almonds	Total		0.012	1.00	GER	Women, 14-50 yrs	EP	100.0	NLD	1.2	NR	1	0.02	0%
VL 0460	Amaranth	Total		2.9	1.00	AUS	Gen pop, 2+ yrs	EP	381.9	NLD	85.8	3	2a	23.95	8%
FP 0226	Apple	Total		0.26	1.00	USA	Child, 1-6 yrs	EP	624.5	USA	127.0	3	2a	15.23	5%
JF 0226	Apple	juice (pasteurised)	0.028		1.00	GER	Child, 2-4 y	PP	724.2	-	NR	NR	3	1.26	0%
FS 0240	Apricot	Total		1.2	1.00	GER	Child, 2-4 yrs	EP	200.0	GER	45.5	3	2a	21.62	7%
VR 0573	Arrowroot	Total		0.023	1.00	AUS	Child, 2-6 yrs	EP	0.2	-	-	-	-	-	-
VC 0421	Balsam pear	Total		0.27	1.00	Thai	Child, 3-6 yrs	EP	56.8	NLD	130.0	3	2b	2.69	1%
GC 0640	Barley	Total	0.063		1.00	AUS	Gen pop, 2+ yrs	EP	401.3	NLD	< 25	NR	3	0.38	0%
VR 0574	Beetroot	Total		0.023	1.00	AUS	Child, 2-6 yrs	EP	314.1	AUS	135.5	3	2a	0.71	0%
VC 0422	Bottle gourd	Total		0.27	1.00	-	-	-	-	-	-	-	-	-	-

Annex 4

SULFOXAFLOR (252) International estimate of short term intake (IESTI) Acute RfD= 0.3 mg/kg bw
Maximum %ARfD: 70%

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Large portion diet				Unit weight				IESTI µg/kg bw/day	% acute RfD rounded
						Country	Population group	Expressed as	Large portion g/person	Country	Unit weight, edible portion, g	Variability factor	Case		
TN 0662	Brazil nut	Total		0.012	1.00	AUS	Child, 2-16 yrs	EP	59.9	NLD	3.8	NR	1	0.02	0%
VB 0400	Broccoli	Total		1.6	1.00	FRA	Child, 3-6 yrs	EP	241.7	NLD	304.0	3	2b	61.38	20%
VB 0401	Broccoli, Chinese	Total		1.6	1.00	AUS	Gen pop, 2+ yrs	EP	302.9	AUS	311.0	3	2b	21.70	7%
VB 0041	Cabbage, head	Total		0.19	1.00	SAF	Child, 1-5 yrs	EP	187.1	BEL	1402.5	3	2b	7.51	3%
TN 0295	Cashew nut	Total		0.012	1.00	Thai	Child, 3-6 yrs	EP	98.8	NLD	2.1	NR	1	0.07	0%
VR 0463	Cassava	Total		0.023	1.00	AUS	Gen pop, 2+ yrs	EP	369.7	AUS	573.4	3	2b	0.38	0%
VB 0404	Cauliflower (head)	Total		0.021	1.00	FRA	Child, 3-6 yrs	EP	165.4	NLD	797.0	3	2b	0.55	0%
VR 0578	Celeriac	Total		0.023	1.00	FRA	Child, 3-6 yrs	EP	104.0	NLD	508.2	3	2b	0.38	0%
VS 0624	Celery (whole)	Total		0.77	1.00	FRA	Child, 3-6 yrs	EP	124.4	AUS	861.1	3	2b	15.21	5%
VL 0464	Chard	Total		2.9	1.00	FRA	Gen pop, 3+ yrs	EP	285.5	NLD	175.0	3	2a	35.30	10%
VC 0423	Chayote	Total		0.27	1.00	AUS	Child, 2-16 yrs	EP	140.7	AUS	197.4	3	2b	3.00	1%
FS 0013	Cherries	Total		1.2	1.00	GER	Child, 2-4 yrs	EP	187.5	NLD	7.2	NR	1	13.93	5%
-	Cherries	dried		6.1	3.000	NLD	Gen pop, 1+ yrs	PP	25.0	NLD	< 25	NR	1	6.95	2%
VL 0465	Chervil	Total		2.9	1.00	GER	Women, 14-50 yrs	EP	9.4	NLD	< 25	NR	1	0.40	0%
TN 0664	Chestnuts	Total		0.012	1.00	FRA	Child, 3-6 yrs	EP	195.9	NLD	20.0	NR	1	0.12	0%
VL 0469	Chicory leaves (head)	Total		2.9	1.00	GER	Child, 2-4 yrs	EP	82.4	AUS	125.0	3	2b	44.39	10%
VR 0469	Chicory, roots	Total		0.023	1.00	AUS	Gen pop, 2+ yrs	EP	26.2	AUS	48.0	3	2b	0.03	0%
VL 0466	Chinese cabbage, type pak-choi	Total		2.9	1.00	JPN	Child, 0-6 yrs	EP	182.7	JPN	200.0	3	2b	99.96	30%
VL 0467	Chinese cabbage, type pe-tsai	Total		2.9	1.00	JPN	Child, 0-6 yrs	EP	146.8	JPN	1500.0	3	2b	80.30	30%
TN 0665	Coconut	Total		0.012	1.00	Thai	Child, 3-6 yrs	EP	309.1	Thai	383.3	3	2b	0.65	0%
VL 0470	Corn salad	Total		2.9	1.00	GER	Child, 2-4 yrs	EP	41.2	NLD	7.8	NR	1	7.40	2%
VL 0510	Cos lettuce	Total		2.9	1.00	GER	Child, 2-4 yrs	EP	86.9	AUS	457.2	3	2b	46.81	20%
SO 0691	Cotton seed	Total	0.02		1.00	USA	Gen pop, all	EP	3.3	NLD	< 25	NR	3	0.00	0%
VL 0472	Cress, garden	Total		2.9	1.00	FRA	Gen pop, 3+ yrs	EP	47.5	NLD	15.0	NR	1	2.64	1%
VC 0424	Cucumber	Total		0.27	1.00	GER	Child, 2-4 yrs	EP	150.0	GER	458.1	3	2b	7.52	3%
VL 0474	Dandelion leaves	Total		2.9	1.00	GER	Child, 2-4 yrs	EP	16.8	NLD	35.0	3	2b	9.05	3%
MO 0105	Edible offal (mammalian)	Total		0.47	1.00	USA	Child, 1-6 yrs	EP	186.6	-	NR	NR	1	5.85	2%
VO 0440	Egg plant	Total		0.6	1.00	JPN	Child, 0-6 yrs	EP	219.3	JPN	80.0	3	2a	14.31	5%
PE 0112	Eggs	Total		0.069	1.00	Thai	Child, 3-6 yrs	EP	109.1	-	NR	NR	1	0.44	0%
VL 0476	Endive	Total		2.9	1.00	FRA	Child, 3-6 yrs	EP	197.3	NLD	375.0	3	2b	90.83	30%
VA 0381	Garlic	Total		0.01	1.00	Thai	Gen pop, 3+ yrs	EP	27.7	Thai	16.6	NR	1	0.01	0%
VC 0425	Gherkin	Total		0.27	1.00	AUS	Child, 2-6 yrs	EP	60.8	GER	54.5	3	2a	2.41	1%
FB 0269	Grape	Total		1.6	1.00	JPN	Child, 0-6 yrs	EP	387.8	JPN	150.0	3	2a	69.21	20%
DF 0269	Grape	dried (currants,		5.6	3.100	USA	Child, 1-6 yrs	PP	59.3	NLD	1.0	NR	1	68.57	20%

Annex 4

SULFOXAFLOR (252) International estimate of short term intake (IESTI) Acute RfD= 0.3 mg/kg bw
Maximum %ARfD: 70%

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Large portion diet				Unit weight				IESTI µg/kg bw/day	% acute RfD rounded
						Country	Population group	Expressed as	Large portion g/person	Country	Unit weight, edible portion, g	Variability factor	Case		
		raisins, sultanas)													
-	Grape	red wine	0.098		1.00	FRA	Gen pop, 3+ yrs	PP	1006.5	-	NR	NR	3	1.89	1%
-	Grape	white wine	0.098		1.00	NLD	Gen pop, 1+ yrs	PP	622.3	NLD	NR	NR	3	0.93	0%
VL 0269	Grape leaves	Total		2.9	1.00	AUS	Gen pop, 2+ yrs	EP	87.2	NLD	1.4	NR	1	3.78	1%
TN 0666	Hazelnut	Total		0.012	1.00	FRA	Child, 3-6 yrs	EP	27.2	NLD	1.2	NR	1	0.02	0%
VR 0583	Horseradish	Total		0.023	1.00	USA	Child, 1-6 yrs	EP	89.0	NLD	154.0	3	2b	0.41	0%
VL 0478	Indian mustard	Total		2.9	1.00	-	-	-	-	-	-	-	-	-	-
VR 0585	Jerusalem artichoke	Total		0.023	1.00	FRA	Gen Pop, 3+ yrs	EP	126.2	AUS	356.7	3	2b	0.17	0%
VL 0480	Kale	Total		2.9	1.00	GER	Gen pop, 14-80 yrs	EP	669.8	NLD	672.0	3	2b	76.30	30%
VL 0507	Kangkung	Total		2.9	1.00	AUS	Child, 2-6 yrs	EP	22.6	NLD	85.8	3	2b	10.36	3%
FC 0204	Lemon	Total		0.44	1.00	GER	Child, 2-4 yrs	EP	125.5	AUS	108.9	3	2a	9.35	3%
VL 0482	Lettuce, head	Total		2.9	1.00	Thai	Child, 3-6 yrs	EP	111.0	USA	512.1	3	2b	56.45	20%
VL 0483	Lettuce, leaf	Total		2.9	1.00	GER	Child, 2-4 yrs	EP	86.9	NLD	117.8	3	2b	46.81	20%
FC 0205	Lime	Total		0.44	1.00	AUS	Gen pop, 2+ yrs	EP	259.2	AUS	49.0	3	2a	2.35	1%
VC 0427	Loofah, angled (= angled gourd)	Total		0.27	1.00	Thai	Child, 3-6 yrs	EP	70.0	AUS	-	-	-	-	-
FP 0228	Loquat	Total		0.26	1.00	AUS	Gen pop, 2+ yrs	EP	118.5	AUS	13.0	NR	1	0.46	0%
TN 0669	Macadamia nut	Total		0.012	1.00	GER	Women, 14-50 yrs	EP	125.0	NLD	3.2	NR	1	0.02	0%
MF 0100	Mammalian fats (except milk fats)	Total		0.073	1.00	FRA	Child, 3-6 yrs	EP	30.2	-	NR	NR	1	0.12	0%
FC 0003	Mandarin + mandarin-like hybrid	Total		0.44	1.00	JPN	Child, 0-6 yrs	EP	353.3	JPN	70.0	3	2a	13.65	5%
MM 0095	Meat from mammals other than marine mammals	Total	NA	NA	1.00	AUS	Child, 2-6 yrs	EP	254.3	-	NR	NR	1	NA	1%
MM 0095	Meat from mammals other than marine mammals: 20% as fat	Total		0.2	1.00	-	-	EP	50.9	-	NR	NR	1	0.54	0%
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	Total		0.2	1.00	-	-	EP	203.5	-	NR	NR	1	2.14	1%
FP 0229	Medlar	Total		0.26	1.00	NLD	Gen pop, 1+ yrs	EP	NC	-	-	-	-	NC	NC
VC 0046	Melons, except watermelon	Total		0.27	1.00	FRA	Child, 3-6 yrs	EP	358.1	FRA	420.0	3	2b	15.35	5%
ML 0106	Milks	Total		0.14	1.00	AUS	Child, 2-6 yrs	EP	1933.6	-	NR	NR	3	ND	-

Annex 4

SULFOXAFLOR (252) International estimate of short term intake (IESTI) Acute RfD= 0.3 mg/kg bw
Maximum %ARfD: 70%

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Large portion diet				Unit weight				IESTI µg/kg bw/day	% acute RfD rounded
						Country	Population group	Expressed as	Large portion g/person	Country	Unit weight, edible portion, g	Variability factor	Case		
VL 0485	Mustard greens	Total		2.9	1.00	USA	Child, 1-6 yrs	EP	49.6	AUS	-	-	-	-	-
FS 0245	Nectarine	Total		1.2	1.00	FRA	Child, 3-6 yrs	EP	325.4	FRA	99.0	3	2a	33.23	10%
VO 0442	Okra	Total		0.6	1.00	USA	Child, 1-6 yrs	EP	202.5	NLD	17.0	NR	1	8.10	3%
VA 0385	Onion, bulb	Total		0.01	1.00	AUS	Child, 2-6 yrs	EP	63.7	AUS	96.8	3	2b	0.10	0%
FC 0004	Orange, sweet, sour + orange-like hybrid	Total		0.44	1.00	AUS	Child, 2-6 yrs	EP	800.8	AUS	155.8	3	2a	25.76	9%
VR 0587	parsley, turnip-rooted	Total		0.023	1.00	GER	Child, 2-4 yrs	EP	4.7	GER	-	-	-	-	-
VR 0588	Parsnip	Total		0.023	1.00	UNK	Child, 1.5-4.5 yrs	EP	163.5	UNK	90.0	3	2a	0.54	0%
FS 0247	Peach	Total		1.2	1.00	FRA	Child, 3-6 yrs	EP	325.4	FRA	99.0	3	2a	33.23	10%
FP 0230	Pear	Total		0.26	1.00	UNK	Child, 1.5-4.5 yrs	EP	253.9	UNK	170.2	3	2a	10.65	4%
-	Pear	raw with peel		0.26	1.00	NLD	Baby, 8-20 m	EP	201.8	NLD	204.7	3	2b	15.43	5%
TN 0672	Pecan	Total		0.012	1.00	AUS	Child, 2-16 yrs	EP	80.9	NLD	3.3	NR	1	0.03	0%
VO 0443	Pepino	Total		0.6	1.00	AUS	Gen pop, 2+ yrs	EP	73.9	AUS	1.2	3	1	0.66	0%
VO 0444	Peppers, chili	Total		0.6	1.00	USA	Gen pop, all	EP	86.7	USA	43.2	3	2a	1.60	1%
VO 0445	Peppers, sweet (incl. pim(i)ento)	Total		0.6	1.00	GER	Child, 2-4 yrs	EP	145.3	GER	119.3	3	2a	14.26	5%
TN 0673	Pine nut	Total		0.012	1.00	AUS	Child, 2-6 yrs	EP	17.7	NLD	0.2	NR	1	0.01	0%
TN 0675	Pistachio nut	Total		0.012	1.00	AUS	Gen pop, 2+ yrs	EP	238.2	NLD	0.9	NR	1	0.04	0%
FS 0014	Plum	Total		1.2	1.00	Thai	Child, 3-6 yrs	EP	361.8	AUS	84.0	3	2a	37.18	10%
VR 0589	Potato	Total		0.023	1.00	SAF	Child, 1-5 yrs	EP	299.6	UNK	216.0	3	2a	1.19	0%
PM 0110	Poultry meat	Total	NA	NA	1.00	AUS	Child, 2-6 yrs	EP	274.6	-	NR	NR	1	NA	0%
PM 0110	Poultry meat: 10% as fat	Total		0.049	1.00	-	-	EP	27.5	-	NR	NR	1	0.07	0%
PM 0110	Poultry meat: 90% as muscle	Total		0.049	1.00	-	-	EP	247.1	-	NR	NR	1	0.64	0%
PO 0111	Poultry, edible offal of (includes kidney, liver and skin)	Total		0.18	1.00	FRA	Child, 3-6 yrs	EP	99.5	-	NR	NR	1	0.95	0%
PF 0111	Poultry, fats	Total		0.02	1.00	USA	Child, 1-6 yrs	EP	15.8	-	NR	NR	1	0.02	0%
VC 0429	Pumpkins	Total		0.27	1.00	SAF	Gen pop, 10+ yrs	EP	852.2	AUS	1326.0	3	2b	12.39	4%
VL 0492	Purslane	Total		2.9	1.00	GER	Women, 14-50 yrs	EP	204.1	NLD	< 25	NR	1	8.77	3%
FP 0231	Quince	Total		0.26	1.00	AUS	Gen pop, 2+ yrs	EP	209.2	AUS	282.9	3	2b	2.44	1%
VR 0494	Radish	Total		0.023	1.00	FRA	Child, 3-6 yrs	EP	90.5	FRA	5.7	NR	1	0.11	0%

Annex 4

SULFOXAFLOR (252) International estimate of short term intake (IESTI) Acute RfD= 0.3 mg/kg bw
Maximum %ARfD: 70%

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Large portion diet				Unit weight				IESTI µg/kg bw/day	% acute RfD rounded
						Country	Population group	Expressed as	Large portion g/person	Country	Unit weight, edible portion, g	Variability factor	Case		
VR 0590	Radish, black	Total		0.023	1.00	USA	Gen pop, all	EP	42.5	NLD	180.3	3	2b	0.05	0%
VR 0591	Radish, Japanese	Total		0.023	1.00	JPN	Child, 0-6 yrs	EP	132.4	JPN	1000.0	3	2b	0.57	0%
VL 0495	Rape greens	Total		2.9	1.00	-	-	-	-	-	-	-	-	-	-
SO 0495	Rape seed	Total	0.045		1.00	GER	Women, 14-50 yrs	EP	18.5	NLD	< 25	NR	3	0.01	0%
VL 0496	Rucola	Total		2.9	1.00	AUS	Child, 2-16 yrs	EP	104.0	NLD	0.3	NR	1	7.93	3%
VR 0498	Salsify	Total		0.023	1.00	FRA	Gen pop, 3+ yrs	EP	321.9	NLD	65.1	3	2a	0.20	0%
FC 0005	Shaddock or pomelo + shaddock-like hybrid	Total		0.44	1.00	GER	Child, 2-4 yrs	EP	358.6	GER	178.5	3	2a	19.50	6%
VC 0430	Snake gourd	Total		0.27	1.00	Thai	Child, 3-6 yrs	EP	129.6	-	-	-	-	-	-
VP 0541	Soya bean (immature seeds)	Total	0.011		1.00	Thai	Child, 3-6 yrs	EP	66.0	-	< 25	NR	1	ND	-
VL 0502	Spinach (bunch)	Total		2.9	1.00	SAF	Child, 1-5 yrs	EP	420.3	JPN	300.0	3	2a	208.38	70%
VA 0389	Spring onion	Total		0.39	1.00	Thai	Child, 3-6 yrs	EP	52.8	NLD	38.0	3	2a	2.94	1%
VC 0431	Squash, summer (= courgette)	Total		0.27	1.00	FRA	Child, 3-6 yrs	EP	148.8	FRA	270.0	3	2b	6.38	2%
FB 0275	Strawberry	Total		0.21	1.00	FRA	Child, 3-6 yrs	EP	339.4	FRA	13.4	NR	1	3.77	1%
VR 0596	Sugar beet	Total		0.023	1.00	FRA	Child, 3-6 yrs	EP	43.9	GER	-	-	-	-	-
VR 0497	Swede	Total		0.023	1.00	UNK	Child, 1.5-4.5 yrs	EP	117.2	NLD	671.2	3	2b	0.56	0%
VR 0508	Sweet potato	Total		0.023	1.00	AUS	Child, 2-6 yrs	EP	180.0	AUS	546.0	3	2b	0.65	0%
VR 0504	Tannia	Total		0.023	1.00	-	-	-	-	-	-	-	-	-	-
VR 0505	Taro	Total		0.023	1.00	Thai	Child, 3-6 yrs	EP	188.5	AUS	667.8	3	2b	0.76	0%
VL 0505	Taro leaves	Total		2.9	1.00	-	-	-	-	-	-	-	-	-	-
VO 0448	Tomato	Total		0.6	1.00	AUS	Child, 2-6 yrs	EP	289.3	AUS	128.7	3	2a	17.26	6%
GC 0653	Triticale	Total	0.025		1.00	GER	Gen pop, 14-80 yrs	EP	394.7	-	< 25	NR	3	0.13	0%
VL 0506	Turnip greens	Total		2.9	1.00	USA	Child, 1-6 yrs	EP	89.9	NLD	< 25	NR	1	17.37	6%
VR 0506	Turnip, garden	Total		0.023	1.00	JPN	Child, 0-6 yrs	EP	77.4	JPN	800.0	3	2b	0.34	0%
TN 0678	Walnut	Total		0.012	1.00	GER	Child, 2-4 yrs	EP	49.4	NLD	7.0	NR	1	0.04	0%
-	Water chestnut	Total		0.023	1.00	Thai	Child, 3-6 yrs	EP	134.2	-	-	-	-	-	-
VL 0473	Watercress	Total		2.9	1.00	AUS	Gen pop, 2+ yrs	EP	78.8	AUS	346.0	3	2b	10.23	3%
VC 0432	Watermelon	Total		0.27	1.00	AUS	Gen pop, 2+ yrs	EP	2542.2	AUS	2095.6	3	2a	27.13	9%
GC 0654	Wheat	Total	0.025		1.00	FRA	Child, 3-6 yrs	EP	384.3	NLD	< 25	NR	3	0.51	0%
VR 0600	Yams	Total		0.023	1.00	AUS	Child, 2-16 yrs	EP	41.3	-	-	-	-	-	-

Annex 4

TEBUCONAZOLE (189) International estimate of short term intake (IESTI) for Acute RfD= 0.300 mg/kg bw (300 µg/kg bw)

Maximum %ARfD: 70%

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Large portion diet				Unit weight				IESTI µg/kg bw/day	% acute RfD rounded
						Country	Population group	Expressed as	Large portion, g/person	Country	Unit weight, edible portion, g	Variability factor	Case		
TN 0660	Almonds	Total		0	1.00	GER	Women, 14-50 yrs	EP	100.0	NLD	1.2	NR	1	0.00	0%
-FP 0226?	Apple	raw with peel		0.5	1.00	NLD	Baby, 8-20 m	EP	209.4	NLD	148.3	3	2a	24.81	8%
DF 0226	Apple	dried		0.305	1.00	NLD	Child, 2-6 yrs	PP	17.4	NLD	5.7	NR	1	0.29	0%
JF 0226	Apple	juice (pasteurised)	0.063		1.00	GER	Child, 2-4 y	PP	724.2	-	NR	NR	3	2.82	1%
-	Apple	sauce/puree	0.094		1.00	NLD	Baby, 8-20 m	PP	106.6	NLD	NR	NR	3	0.98	0%
FS 0240	Apricot	Total		1	1.00	GER	Child, 2-4 yrs	EP	200.0	GER	45.5	3	2a	18.02	6%
VS 0620	Artichoke globe	Total		0.32	1.00	FRA	Child, 3-6 yrs	EP	117.2	FRA	98.9	3	2a	5.33	2%
FI 0327	Banana	Total		0.3	1.00	FRA	Child, 3-6 yrs	EP	324.2	FRA	612.0	3	2b	15.44	5%
GC 0640	Barley	Total	0.085		1.00	AUS	Gen pop, 2+ yrs	EP	401.3	NLD	< 25	NR	3	0.51	0%
-	Barley	beer	0.002		1.00	AUS	Gen pop, 2yrs	PP	2420.8	-	NR	NR	3	0.07	0%
VD 0071	Beans (dry, Phaseolus spp)	Total	0.05		1.00	FRA	Child, 2-16 yrs	EP	145.4	NLD	0.5	NR	3	0.38	0%
TN 0662	Brazil nut	Total		0	1.00	AUS	Child, 2-16 yrs	EP	59.9	NLD	3.8	NR	1	0.00	0%
VB 0400	Broccoli	Total		0.11	1.00	FRA	Child, 3-6 yrs	EP	241.7	NLD	304.0	3	2b	4.22	1%
VB 0402	Brussels sprouts	Total		0.19	1.00	FRA	Child, 3-6 yrs	EP	115.8	FRA	4.9	NR	1	1.16	0%
VB 0041	Cabbage, head	Total		0.56	1.00	SAF	Child, 1-5 yrs	EP	187.1	BEL	1402.5	3	2b	22.13	7%
-	Cabbage, head	cooked/boiled		0.23	1.00	NLD	Baby, 8-20 m	PP	129.6	NLD	833.0	3	2b	8.77	3%
VR 0577	Carrot	Total		0.22	1.00	FRA	Child, 3-6 yrs	EP	174.3	FRA	89.0	3	2a	4.10	1%
TN 0295	Cashew nut	Total		0	1.00	Thai	Child, 3-6 yrs	EP	98.8	NLD	2.1	NR	1	0.00	0%
VB 0404	Cauliflower (head)	Total		0.05	1.00	FRA	Child, 3-6 yrs	EP	165.4	NLD	797.0	3	2b	1.31	0%
FS 0013	Cherries	Total		3.1	1.00	GER	Child, 2-4 yrs	EP	187.5	NLD	7.2	NR	1	35.99	10%
TN 0664	Chestnuts	Total		0	1.00	FRA	Child, 3-6 yrs	EP	195.9	NLD	20.0	NR	1	0.00	0%
TN 0665	Coconut	Total		0	1.00	Thai	Child, 3-6 yrs	EP	309.1	Thai	383.3	3	2b	0.00	0%
SB 0716	Coffee beans	Total	0.04		1.00	FRA	Child, 3-6 yrs	EP	70.3	NLD	0.1	NR	3	0.15	0%
SO 0691	Cotton seed	Total	0.05		1.00	USA	Gen pop, all	EP	3.3	NLD	< 25	NR	3	0.00	0%
VC 0424	Cucumber	Total		0.09	1.00	GER	Child, 2-4 yrs	EP	150.0	GER	458.1	3	2b	2.51	1%
MO 0105	Edible offal (mammalian)	Total		0.15	1.00	USA	Child, 1-6 yrs	EP	186.6	-	NR	NR	1	1.49	0%
VO 0440	Egg plant	Total		0.1	1.00	JPN	Child, 0-6 yrs	EP	219.3	JPN	80.0	3	2a	2.39	1%
PE 0112	Eggs	Total	0		1.00	Thai	Child, 3-6 yrs	EP	109.1	-	NR	NR	1	ND	-

Annex 4

TEBUCONAZOLE (189) International estimate of short term intake (IESTI) for Acute RfD= 0.300 mg/kg bw (300 µg/kg bw)

Maximum %ARfD: 70%

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Large portion diet				Unit weight				IESTI µg/kg bw/day	% acute RfD rounded
						Country	Population group	Expressed as	Large portion, g/person	Country	Unit weight, edible portion, g	Variability factor	Case		
FB 0267	Elderberries	Total		0.7	1.00	GER	Child, 2-4 yrs	EP	7.5	NLD	29.0	3	2b	0.98	0%
VA 0381	Garlic	Total		0.06	1.00	Thai	Gen pop, 3+ yrs	EP	27.7	Thai	16.6	NR	1	0.03	0%
FB 0269	Grape	Total		4.6	1.00	JPN	Child, 0-6 yrs	EP	387.8	JPN	150.0	3	2a	198.99	70%
DF 0269	Grape	dried (currants, raisins, sultanas)		5.5	1.00	USA	Child, 1-6 yrs	PP	59.3	NLD	1.0	NR	1	21.73	7%
-	Grape	red wine	0.2		1.00	FRA	Gen pop, 3+ yrs	PP	1006.5	-	NR	NR	3	3.86	1%
-	Grape	white wine	0.2		1.00	NLD	Gen pop, 1+ yrs	PP	622.3	NLD	NR	NR	3	1.89	1%
TN 0666	Hazelnut	Total		0	1.00	FRA	Child, 3-6 yrs	EP	27.2	NLD	1.2	NR	1	0.00	0%
VA 0384	Leek	Total		0.44	1.00	AUS	Child, 2-16 yrs	EP	292.1	AUS	82.5	3	2a	5.29	2%
TN 0669	Macadamia nut	Total		0	1.00	GER	Women, 14-50 yrs	EP	125.0	NLD	3.2	NR	1	0.00	0%
FI 0345	Mango	Total		0.05	1.00	GER	Child, 2-4 yrs	EP	126.8	Thai	241.5	3	2b	1.18	0%
MM 0095	Meat from mammals other than marine mammals	Total	NA	NA	1.00	AUS	Child, 2-6 yrs	EP	254.3	-	NR	NR	1	NA	0%
MM 0095	Meat from mammals other than marine mammals: 20% as fat	Total		0	1.00	-	-	EP	50.9	-	NR	NR	1	0.00	0%
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	Total		0	1.00	-	-	EP	203.5	-	NR	NR	1	0.00	0%
VC 0046	Melons, except watermelon	Total		0.02	1.00	FRA	Child, 3-6 yrs	EP	358.1	FRA	420.0	3	2b	1.14	0%
ML 0106	Milks	Total	0		1.00	AUS	Child, 2-6 yrs	EP	1933.6	-	NR	NR	3	0.00	0%
FS 0245	Nectarine	Total		1	1.00	FRA	Child, 3-6 yrs	EP	325.4	FRA	99.0	3	2a	27.69	9%
GC 0647	Oats	Total	0.085		1.00	AUS	Child, 2-6 yrs	EP	82.5	NLD	< 25	NR	3	0.37	0%
FT 0305	Olive	Total	0		1.00	FRA	Child, 3-6 yrs	EP	147.2	AUS	4.4	NR	3	0.00	0%
VA 0385	Onion, bulb	Total		0.06	1.00	AUS	Child, 2-6 yrs	EP	63.7	AUS	96.8	3	2b	0.60	0%
FI 0350	Papaya	Total		1.2	1.00	USA	Child, 1-6 yrs	EP	160.9	USA	203.7	3	2b	38.62	10%
FI 0351	Passion fruit	Total		0.1	1.00	FRA	Gen pop, 3+ yrs	EP	291.8	AUS	20.5	3	1	0.56	0%
FS 0247	Peach	Total		1	1.00	FRA	Child, 3-6 yrs	EP	325.4	FRA	99.0	3	2a	27.69	9%
-	Peach	canned/preserved	0.06		1.00	NLD	Child, 2-6 yrs	PP	118.5	NLD	60.0	3	2a	ND	-
-	Peach	juice (pasteurised)	0.092		1.00	NLD	Baby, 8-20 m	PP	18.3	NLD	NR	NR	3	0.17	0%
-	Peach	jam	0.06		1.00	NLD	Child, 2-6 yrs	PP	55.7	NLD	NR	NR	3	0.18	0%
FP 0230	Pear	raw with peel		0.5	1.00	NLD	Baby, 8-20 m	EP	201.8	NLD	204.7	3	2b	29.68	10%
TN 0672	Pecan	Total		0	1.00	AUS	Child, 2-16 yrs	EP	80.9	NLD	3.3	NR	1	0.00	0%

Annex 4

TEBUCONAZOLE (189) International estimate of short term intake (IESTI) for Acute RfD= 0.300 mg/kg bw (300 µg/kg bw)

Maximum %ARfD: 70%

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Large portion diet				Unit weight				IESTI µg/kg bw/day	% acute RfD rounded
						Country	Population group	Expressed as	Large portion, g/person	Country	Unit weight, edible portion, g	Variability factor	Case		
-HS 0444?	Peppers, chili	dried&powder		6.2	1.00	AUS	Gen Pop, 2+ yrs	PP	1.4	NLD	0.0	NR	1	0.13	0%
VO 0445	Peppers, sweet (incl. pim(i)ento)	Total		0.62	1.00	GER	Child, 2-4 yrs	EP	145.3	GER	119.3	3	2a	14.74	5%
TN 0673	Pine nut	Total		0	1.00	AUS	Child, 2-6 yrs	EP	17.7	NLD	0.2	NR	1	0.00	0%
TN 0675	Pistachio nut	Total		0	1.00	AUS	Gen pop, 2+ yrs	EP	238.2	NLD	0.9	NR	1	0.00	0%
FS 0014	Plum	Total		0.47	1.00	Thai	Child, 3-6 yrs	EP	361.8	AUS	84.0	3	2a	14.56	5%
-	Plum	canned/preserved	0.054		1.00	NLD	Child, 2-6 yrs	PP	71.7	NLD	21.1	NR	1	ND	-
DF 0014	Plum	dried (prunes)		1.36	1.00	AUS	Child, 2-16 yrs	PP	289.7	NLD	10.4	NR	1	10.37	3%
PM 0110	Poultry meat	Total	NA	NA	1.00	AUS	Child, 2-6 yrs	EP	274.6	-	NR	NR	1	NA	0%
PM 0110	Poultry meat: 10% as fat	Total		0	1.00	-	-	EP	27.5	-	NR	NR	1	0.00	0%
PM 0110	Poultry meat: 90% as muscle	Total		0	1.00	-	-	EP	247.1	-	NR	NR	1	0.00	0%
PO 0111	Poultry, edible offal of (includes kidney, liver, skin)	Total		0.05	1.00	FRA	Child, 3-6 yrs	EP	99.5	-	NR	NR	1	0.26	0%
SO 0495	Rape seed	Total	0.1		1.00	GER	Women, 14-50 yrs	EP	18.5	NLD	< 25	NR	3	0.03	0%
GC 0649	Rice	Total	0.275		1.00	USA	Child, 1-6 yrs	EP	99.8	NLD	< 25	NR	3	1.83	1%
GC 0650	Rye	Total	0.05		1.00	FRA	Gen pop, 3+ yrs	EP	160.9	NLD	< 25	NR	3	0.15	0%
VD 0541	Soya bean (dry)	Total	0.02		1.00	JPN	Child, 0-6 yrs	EP	88.2	NLD	< 25	NR	3	0.11	0%
OR 0541	Soya bean (dry)	Oil (refined)	0.001		1.00	USA	Child, 1-6 yrs	PP	35.4	-	NR	NR	3	0.00	0%
VC 0431	Squash, summer (= courgette)	Total		0.1	1.00	FRA	Child, 3-6 yrs	EP	148.8	FRA	270.0	3	2b	2.36	1%
VO 0447	Sweet corn (corn-on-the-cob)	Total		0.36	1.00	Thai	Child, 3-6 yrs	EP	197.0	JPN	200.0	3	2b	12.44	4%
VO 0448	Tomato	Total		0.46	1.00	AUS	Child, 2-6 yrs	EP	289.3	AUS	128.7	3	2a	13.24	4%
-	Tomato	canned/preserved (&peeled)	0.018		1.00	AUS	Child, 2-6 yrs	PP	152.4	NLD	58.0	3	2a	ND	-
-	Tomato	paste (concentrated sauce/puree)	0.19		1.00	AUS	Child, 2-6 yrs	PP	189.2	-	NR	NR	3	1.89	1%
GC 0653	Triticale	Total	0.05		1.00	GER	Gen pop, 14-80 yrs	EP	394.7	-	< 25	NR	3	0.26	0%
TN 0678	Walnut	Total		0	1.00	GER	Child, 2-4 yrs	EP	49.4	NLD	7.0	NR	1	0.00	0%
GC 0654	Wheat	Total	0.05		1.00	FRA	Child, 3-6 yrs	EP	384.3	NLD	< 25	NR	3	1.02	0%

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

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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.

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ANNEX 6: LIVESTOCK DIETARY BURDEN

Livestock dietary burden tables

The livestock dietary burdens were estimated by considering the commodities listed in the tables below.

BEEF CATTLE		**ACEPHATE**											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	2.15	STMR	40	5.38		20	20			1.08	1.08	
Soya bean hulls	SM	0.2145	STMR	90	0.24	15	10			0.04	0.02		
Rice straw	AF/AS	0.14	HR	90	0.16		10	60	55		0.02	0.09	0.09
Rice grain	GC	0.055	STMR	88	0.06	20		20		0.01		0.01	
Soya bean seed	VD	0.03	STMR	89	0.03	5	10		15	0.00	0.00		0.01
Soya bean meal	SM	0.021	STMR	92	0.02		10		30		0.00		0.01
Total						40	60	100	100	0.05	1.12	1.18	0.10

BEEF CATTLE		**ACEPHATE**											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	2.15	STMR/ STMR-P	40	5.38		20	20			1.08	1.08	
Soya bean hulls	SM	0.2145	STMR/ STMR-P	90	0.24	15	10			0.04	0.02		
Rice grain	GC	0.055	STMR/ STMR-P	88	0.06	20		40		0.01		0.03	
Soya bean seed	VD	0.03	STMR/ STMR-P	89	0.03	5	10	20	15	0.00	0.00	0.01	0.01
Rice straw	AF/AS	0.025	STMR/ STMR-P	90	0.03		10	20	55		0.00	0.01	0.02
Soya bean meal	SM	0.021	STMR/ STMR-P	92	0.02		10		30		0.00		0.01
Total						40	60	100	100	0.05	1.11	1.11	0.03

DAIRY CATTLE		**ACEPHATE**											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	2.15	STMR	40	5.38	10	10	10		0.54	0.54	0.54	
Soya bean hulls	SM	0.2145	STMR	90	0.24		10				0.02		
Rice straw	AF/AS	0.14	HR	90	0.16		5	20	25		0.01	0.03	0.04
Rice grain	GC	0.055	STMR	88	0.06	20		20		0.01		0.01	
Soya bean seed	VD	0.03	STMR	89	0.03	10	10	20	10	0.00	0.00	0.01	0.00
Soya bean meal	SM	0.021	STMR	92	0.02	10	15	15	60	0.00	0.00	0.00	0.01
Total						50	50	85	95	0.556	0.576	0.59128	0.056

DAIRY CATTLE		**ACEPHATE**											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	2.15	STMR/ STMR-P	40	5.38	10	10	10		0.54	0.54	0.54	
Soya bean hulls	SM	0.2145	STMR/ STMR-P	90	0.24	0	10			0.00	0.02		
Rice grain	GC	0.055	STMR/ STMR-P	88	0.06	20		20		0.01		0.01	
Soya bean seed	VD	0.03	STMR/ STMR-P	89	0.03	10	10	20	10	0.00	0.00	0.01	0.00
Rice straw	AF/AS	0.025	STMR/	90	0.03	0	5	20	25	0.00	0.00	0.01	0.01

DAIRY CATTLE		**ACEPHATE**											MEAN
Commodity	CC	Residue	Basis	DM	Residue)	Diet content (%)				Residue Contribution (ppm)			
		(mg/kg)		(%)	dw (mg/kg	US- CAN	EU	AU	JP	US-CAN	EU	AU	JP
			STMR-P										
Soya bean meal	SM	0.021	STMR/ STMR-P	92	0.02	10	15	15	60	0.00	0.00	0.00	0.01
Total						50	50	85	95	0.555653	0.57	0.566	0.024

POULTRY BROILER		**ACEPHATE**											MAX
Commodity	CC	Residue	Basis	DM	Residue	Diet content (%)				Residue Contribution (ppm)			
		(mg/kg)		(%)	dw (mg/kg)	US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Soya bean hulls	SM	0.2145	STMR	90	0.24		10	5			0.02	0.01	
Rice grain	GC	0.055	STMR	88	0.06	20		50		0.01		0.03	
Soya bean seed	VD	0.03	STMR	89	0.03	20	20	15		0.01	0.01	0.01	
Soya bean meal	SM	0.021	STMR	92	0.02	25	30	20	35	0.01	0.01	0.00	0.01
Total						65	60	90	35	0.02	0.04	0.05	0.01

POULTRY BROILER		**ACEPHATE**											MEAN
Commodity	CC	Residue	Basis	DM	Residue	Diet content (%)				Residue Contribution (ppm)			
		(mg/kg)		(%)	dw (mg/kg)	US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Soya bean hulls	SM	0.2145	STMR/ STMR-P	90	0.24		10	5			0.02	0.01	
Rice grain	GC	0.055	STMR/ STMR-P	88	0.06	20		50		0.01		0.03	
Soya bean seed	VD	0.03	STMR/ STMR-P	89	0.03	20	20	15		0.01	0.01	0.01	
Soya bean meal	SM	0.021	STMR/ STMR-P	92	0.02	25	30	20	35	0.01	0.01	0.00	0.01
Total						65	60	90	35	0.02	0.04	0.05	0.01

POULTRY LAYER		**ACEPHATE**											MAX
Commodity	CC	Residue	Basis	DM	Residue	Diet content (%)				Residue Contribution (ppm)			
		(mg/kg)		(%)	dw (mg/kg)	US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Soya bean hulls	SM	0.2145	STMR	90	0.24		5	5			0.01	0.01	
Rice grain	GC	0.055	STMR	88	0.06	20		50		0.01		0.03	
Soya bean seed	VD	0.03	STMR	89	0.03	20	15	15		0.01	0.01	0.01	
Soya bean meal	SM	0.021	STMR	92	0.02	25	20	20	30	0.01	0.00	0.00	0.01
Total						65	40	90	30	0.02	0.02	0.05	0.01

POULTRY LAYER		**ACEPHATE**											MEAN
Commodity	CC	Residue	Basis	DM	Residue	Diet content (%)				Residue Contribution (ppm)			
		(mg/kg)		(%)	dw (mg/kg)	US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Soya bean hulls	SM	0.2145	STMR/ STMR-P	90	0.24		5	5			0.01	0.01	
Rice grain	GC	0.055	STMR/ STMR-P	88	0.06	20		50		0.01		0.03	
Soya bean seed	VD	0.03	STMR/ STMR-P	89	0.03	20	15	15		0.01	0.01	0.01	
Soya bean meal	SM	0.021	STMR/ STMR-P	92	0.02	25	20	20	30	0.01	0.00	0.00	0.01
Total						65	40	90	30	0.02	0.02	0.05	0.01

BEEF CATTLE		**METHAMIDOPHOS**											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	0.081	STMR	40	0.20		20	20			0.04	0.04	
Rice straw	AF/AS	0.05	HR	90	0.06		10	60	55		0.01	0.03	0.03
Soya bean hulls	SM	0.045	STMR	90	0.05	15	10			0.01	0.01		
Rice grain	GC	0.025	STMR	88	0.03	20		20		0.01		0.01	
Soya bean meal	SM	0.02	STMR	92	0.02		10		45		0.00		0.01
Soya bean seed	VD	0.01	STMR	89	0.01	5	10			0.00	0.00		
Total						40	60	100	100	0.01	0.05	0.08	0.04

BEEF CATTLE		**METHAMIDOPHOS**											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	0.081	STMR/STMR-P	40	0.20		20	20			0.04	0.04	
Soya bean hulls	SM	0.045	STMR/STMR-P	90	0.05	15	10			0.01	0.01		
Rice straw	AF/AS	0.0325	STMR/STMR-P	90	0.04		10	60	55		0.00	0.02	0.02
Rice grain	GC	0.025	STMR/STMR-P	88	0.03	20		20		0.01		0.01	
Soya bean meal	SM	0.02	STMR/STMR-P	92	0.02		10		45		0.00		0.01
Soya bean seed	VD	0.01	STMR/STMR-P	89	0.01	5	10			0.00	0.00		
Total						40	60	100	100	0.01	0.05	0.07	0.03

DAIRY CATTLE		**METHAMIDOPHOS**											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	0.081	STMR	40	0.20	10	10	10		0.02	0.02	0.02	
Rice straw	AF/AS	0.05	HR	90	0.06		5	20	25		0.00	0.01	0.01
Soya bean hulls	SM	0.045	STMR	90	0.05		10				0.01		
Rice grain	GC	0.025	STMR	88	0.03	20		20		0.01		0.01	
Soya bean meal	SM	0.02	STMR	92	0.02	10	15	15	60	0.00	0.00	0.00	0.01
Soya bean seed	VD	0.01	STMR	89	0.01	10	10	20	10	0.00	0.00	0.00	0.00
Total						50	50	85	95	0.029229	0.032	0.04255	0.028

DAIRY CATTLE		**METHAMIDOPHOS**											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	0.081	STMR/ STMR-P	40	0.20	10	10	10		0.02	0.02	0.02	
Soya bean hulls	SM	0.045	STMR/S TMR-P	90	0.05	0	10			0.00	0.01		
Rice straw	AF/AS	0.0325	STMR/ STMR-P	90	0.04	0	5	20	25	0.00	0.00	0.01	0.01
Rice grain	GC	0.025	STMR/ STMR-P	88	0.03	20		20		0.01		0.01	
Soya bean meal	SM	0.02	STMR/ STMR-P	92	0.02	10	15	15	60	0.00	0.00	0.00	0.01
Soya bean seed	VD	0.01	STMR/ STMR-P	89	0.01	10	10	20	10	0.00	0.00	0.00	0.00
Total						50	50	85	95	0.02923	0.031	0.039	0.023

POULTRY BROILER		**METHAMIDOPHOS**											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
Soya bean hulls	SM	0.045	STMR	90	0.05		10	5			0.01	0.00	
Rice grain	GC	0.025	STMR	88	0.03	20		50		0.01		0.01	
Soya bean meal	SM	0.02	STMR	92	0.02	25	30	20	35	0.01	0.01	0.00	0.01

POULTRY BROILER		**METHAMIDOPHOS**											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
Soya bean seed	VD	0.01	STMR	89	0.01	20	20	15		0.00	0.00	0.00	
Total						65	60	90	35	0.01	0.01	0.02	0.01

POULTRY BROILER		**METHAMIDOPHOS**											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
Soya bean hulls	SM	0.045	STMR/ STMR-P	90	0.05		10	5			0.01	0.00	
Rice grain	GC	0.025	STMR/ STMR-P	88	0.03	20		50		0.01		0.01	
Soya bean meal	SM	0.02	STMR/ STMR-P	92	0.02	25	30	20	35	0.01	0.01	0.00	0.01
Soya bean seed	VD	0.01	STMR/ STMR-P	89	0.01	20	20	15		0.00	0.00	0.00	
Total						65	60	90	35	0.01	0.01	0.02	0.01

POULTRY LAYER		**METHAMIDOPHOS**											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
Soya bean hulls	SM	0.045	STMR	90	0.05		5	5			0.00	0.00	
Rice grain	GC	0.025	STMR	88	0.03	20		50		0.01		0.01	
Soya bean meal	SM	0.02	STMR	92	0.02	25	20	20	30	0.01	0.00	0.00	0.01
Soya bean seed	VD	0.01	STMR	89	0.01	20	15	15		0.00	0.00	0.00	
Total						65	40	90	30	0.01	0.01	0.02	0.01

POULTRY LAYER		**METHAMIDOPHOS**											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
Soya bean hulls	SM	0.045	STMR/S TMR-P	90	0.05		5	5			0.00	0.00	
Rice grain	GC	0.025	STMR/ STMR-P	88	0.03	20		50		0.01		0.01	
Soya bean meal	SM	0.02	STMR/ STMR-P	92	0.02	25	20	20	30	0.01	0.00	0.00	0.01
Soya bean seed	VD	0.01	STMR/ STMR-P	89	0.01	20	15	15		0.00	0.00	0.00	
Total						65	40	90	30	0.01	0.01	0.02	0.01

BEEF CATTLE		**ACETAMIPRID**											MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue (mg/kg dw)	Diet content (%)				Residue Contribution (ppm)			
						US- CAN	EU	AU	JP	US-CAN	EU	AU	JP
Cotton gin byproducts	AM/AV	18	HR	90	20.00	5				1			
Cabbage heads, leaves	AM/AV	0.5	HR	15	3.33		20				0.666667		
Almond hulls	AM/AV	1.34	STMR	90	1.49			10				0.148889	
Apple pomace, wet	AB	0.32	STMR	40	0.80		20	20			0.16	0.16	
Citrus dried pulp	AB	0.7	STMR	91	0.77	10		10		0.076923		0.076923	
Cotton undelinted seed	SO	0.09	STMR	88	0.10			30				0.030682	
Cotton hulls	SM	0.07	STMR	90	0.08	10		20		0.007778		0.015556	
Cotton meal	SM	0.03	STMR	89	0.03		5	10			0.001685	0.003371	
Total						25	45	100		1.084701	0.828352	0.43542	

DAIRY CATTLE		**ACETAMIPRID**											MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue (mg/kg dw)	Diet content (%)				Residue Contribution (ppm)			
						US- CAN	EU	AU	JP	US-CAN	EU	AU	JP
Cabbage heads, leaves	AM/AV	0.5	HR	15	3.33		20				0.666667		

DAIRY CATTLE		**ACETAMIPRID**										MAX	
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue (mg/kg dw)	Diet content (%)				Residue Contribution (ppm)			
						US- CAN	EU	AU	JP	US-CAN	EU	AU	JP
Almond hulls	AM/AV	1.34	STMR	90	1.49	10		10		0.148889		0.148889	
Apple pomace, wet	AB	0.32	STMR	40	0.80	10	10	10		0.08	0.08	0.08	
Citrus dried pulp	AB	0.7	STMR	91	0.77		10	20			0.076923	0.153846	
Cotton undelinted seed	SO	0.09	STMR	88	0.10	10	10	20		0.010227	0.010227	0.020455	
Cotton hulls	SM	0.07	STMR	90	0.08			10				0.007778	
Cotton meal	SM	0.03	STMR	89	0.03	10	5	5		0.003371	0.001685	0.001685	
Total						40	55	75		0.242487	0.835502	0.412653	

POULTRY BROILER		**ACETAMIPRID**										MAX	
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue (mg/kg dw)	Diet content (%)				Residue Contribution (ppm)			
						US- CAN	EU	AU	JP	US-CAN	EU	AU	JP
Cotton meal	SM	0.03	STMR	89	0.03	20	5	10		0.006742	0.001685	0.003371	
Total						20	5	10		0.006742	0.001685	0.003371	

POULTRY LAYER		**ACETAMIPRID**										MAX	
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue (mg/kg dw)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Cabbage heads, leaves	AM/AV	0.5	HR	15	3.33		5				0.166667		
Cotton meal	SM	0.03	STMR	89	0.03	20	5	10		0.006742	0.001685	0.003371	
Total						20	10	10		0.006742	0.168352	0.003371	

BEEF CATTLE		**ACETAMIPRID**								MEAN			
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue (mg/kg dw)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Cotton gin byproducts	AM/AV	3.6	STMR/ STMR-P	90	4.00	5				0.2			
Almond hulls	AM/AV	1.34	STMR/ STMR-P	90	1.49			10				0.148889	
Apple pomace, wet	AB	0.32	STMR/ STMR-P	40	0.80		20	20			0.16	0.16	
Citrus dried pulp	AB	0.7	STMR/ STMR-P	91	0.77	10		10		0.076923		0.076923	
Cabbage heads, leaves	AM/AV	0.09	STMR/ STMR-P	15	0.60		20				0.12		
Cotton undelinted seed	SO	0.09	STMR/ STMR-P	88	0.10			30				0.030682	
Cotton hulls	SM	0.07	STMR/ STMR-P	90	0.08	10		20		0.007778		0.015556	
Cotton meal	SM	0.03	STMR/ STMR-P	89	0.03		5	10			0.001685	0.003371	
Total						25	45	100		0.284701	0.281685	0.43542	

DAIRY CATTLE		**ACETAMIPRID**								MEAN			
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue (mg/kg dw)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Almond hulls	AM/AV	1.34	STMR/ STMR-P	90	1.49	10	0	10		0.148889	0	0.148889	
Apple pomace, wet	AB	0.32	STMR/ STMR-P	40	0.80	10	10	10		0.08	0.08	0.08	
Citrus dried pulp	AB	0.7	STMR/ STMR-P	91	0.77	0	10	20		0	0.076923	0.153846	
Cabbage heads, leaves	AM/AV	0.09	STMR/ STMR-P	15	0.60	0	20			0	0.12		
Cotton undelinted seed	SO	0.09	STMR/ STMR-P	88	0.10	10	10	20		0.010227	0.010227	0.020455	
Cotton hulls	SM	0.07	STMR/ STMR-P	90	0.08	0		10		0		0.007778	
Cotton meal	SM	0.03	STMR/ STMR-P	89	0.03	10	5	5		0.003371	0.001685	0.001685	

DAIRY CATTLE		**ACETAMIPRID**											MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue (mg/kg dw)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Total						40	55	75		0.242487	0.288836	0.412653	

POULTRY BROILER		**ACETAMIPRID**											MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue (mg/kg dw)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Cotton meal	SM	0.03	STMR/ STMR-P	89	0.03	20	5	10		0.006742	0.001685	0.003371	
Total						20	5	10		0.006742	0.001685	0.003371	

POULTRY LAYER		**ACETAMIPRID**											MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue (mg/kg dw)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Cabbage heads, leaves	AM/AV	0.09	STMR/ STMR-P	15	0.60		5				0.03		
Cotton meal	SM	0.03	STMR/ STMR-P	89	0.03	20	5	10		0.006742	0.001685	0.003371	
Total						20	10	10		0.006742	0.031685	0.003371	

BEEF CATTLE		**CYPERMETHRINS**											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
Alfalfa forage	AL	11	HR	35	31.43		70	100			22.00	31.43	
Alfalfa hay	AL	20	HR	100	20.00	15			10	3.00			2.00
Beet, sugar tops	AM/AV	8.3	HR	100	8.30		20				1.66		
Barley straw	AF/AS	6.9	HR	100	6.90	10	10			0.69	0.69		
Corn, field stover	AF/AS	6.9	HR	100	6.90	5				0.35			
Wheat milled by-products	CM/CF	3.45	STMR	88	3.92	40			55	1.57			2.16
Barley grain	GC	1.38	STMR	88	1.57	30			35	0.47			0.55
Total						100	100	100	100	6.07	24.4	31.4	4.71

DAIRY CATTLE		**CYPERMETHRINS**											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
Alfalfa forage	AL	11	HR	35	31.43	20	40	60		6.29	12.57	18.86	
Alfalfa hay	AL	20	HR	100	20.00				25				5.00
Beet, sugar tops	AM/AV	8.3	HR	100	8.30		30				2.49		
Barley straw	AF/AS	6.9	HR	100	6.90	10	30	20		0.69	2.07	1.38	
Corn, field stover	AF/AS	6.9	HR	100	6.90	5		20		0.35		1.38	
Wheat forage	AF/AS	1.4	HR	25	5.60	5				0.28			
Wheat milled by-products	CM/CF	3.45	STMR	88	3.92	30			45	1.18			1.76
Almond hulls	AM/AV	2.3	STMR	90	2.56	10				0.26			
Barley grain	GC	1.38	STMR	88	1.57	20			30	0.31			0.47
Total						100	100	100	100	9.35	17.1	21.6	7.23

POULTRY BROILER		**CYPERMETHRINS**											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
Alfalfa forage	AL	11	HR	35	31.43				5				1.57
Wheat milled by-products	CM/CF	3.45	STMR	88	3.92	50	20	20	5	1.96	0.78	0.78	0.20
Barley grain	GC	1.38	STMR	88	1.57	50	70	15	10	0.78	1.10	0.24	0.16

POULTRY BROILER		**CYPERMETHRINS**											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
Rye grain	GC	1.38	STMR	88	1.57			35				0.55	
Wheat grain	GC	1.38	STMR	89	1.55			30				0.47	
Swede roots	VR	0.01	HR	10	0.10		10				0.01		
Sorghum, grain	GC	0.035	STMR	86	0.04				55				0.02
Corn, field grain	GC	0.035	STMR	88	0.04				25				0.01
Total						100	100	100	100	2.74	1.89	2.03	1.96

POULTRY LAYER		**CYPERMETHRINS**											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	8.3	HR	100	8.30		5				0.42		
Barley straw	AF/AS	6.9	HR	100	6.90		5				0.35		
Corn, field stover	AF/AS	6.9	HR	100	6.90		5				0.35		
Wheat milled by-products	CM/CF	3.45	STMR	88	3.92	50	20	20	30	1.96	0.78	0.78	1.18
Pea vines	AL	0.86	HR	25	3.44		10				0.34		
Barley grain	GC	1.38	STMR	88	1.57	50	55	15		0.78	0.86	0.24	
Rye grain	GC	1.38	STMR	88	1.57			20				0.31	
Wheat grain	GC	1.38	STMR	89	1.55			45				0.70	
Sorghum, grain	GC	0.035	STMR	86	0.04				55				0.02
Corn, field grain	GC	0.035	STMR	88	0.04				15				0.01
Total						100	100	100	100	2.74	3.10	2.03	1.20

BEEF CATTLE		**DICAMBA**											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
Soya bean asp gr fn	SM	450	STMR	85	529.41	5				26.47			
Grass forage (fresh)	AF/AS	35	HR	25	140.00		50	100	5		70.00	140.00	7.00
Barley straw	AF/AS	30	HR	89	33.71	10				3.37			
Grass hay	AF/AS	19	HR	88	21.59	5			35	1.08			7.56
Sugarcane molasses	DM	4	STMR	75	5.33	10	10			0.53	0.53		
Soya bean hulls	SM	2.6	STMR	90	2.89	10	10			0.29	0.29		
Wheat asp gr fn	CM/CF	2.3	STMR	85	2.71	5				0.14			
Barley grain	GC	1.6	STMR	88	1.82	50	30		60	0.91	0.55		1.09
Corn, field forage/silage	AF/AS	0.31	HR	40	0.78	5				0.04			
Total						100	100	100	100	32.83	71.37	140.00	15.65

BEEF CATTLE		**DICAMBA**											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
Soya bean asp gr fn	SM	450	STMR/ STMR-P	85	529.41	5				26.47			
Grass forage (fresh)	AF/AS	11	STMR/ STMR-P	25	44.00		50	100	5		22.00	44.00	2.20
Grass hay	AF/AS	6.3	STMR/ STMR-P	88	7.16	15			35	1.07			2.51
Sugarcane molasses	DM	4	STMR/ STMR-P	75	5.33	10	10			0.53	0.53		
SoyAa bean hulls	SM	2.6	STMR/ STMR-P	90	2.89	10	10			0.29	0.29		
Wheat asp gr fn	CM/C	2.3	STMR/	85	2.71	5				0.14			

BEEF CATTLE		**DICAMBA**											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
	F		STMR-P										
Barley grain	GC	1.6	STMR/ STMR-P	88	1.82	50	30		60	0.91	0.55		1.09
Sorghum, grain stover	AF/AS	1.3	STMR/ STMR-P	88	1.48	5				0.07			
Total						100	100	100	100	29.48	23.37	44.00	5.80

DAIRY CATTLE		**DICAMBA**											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
Grass forage (fresh)	AF/AS	35	HR	25	140.00	45	60	100	10	63.00	84.00	140.00	14.00
Grass hay	AF/AS	19	HR	88	21.59				60				12.95
Sugarcane molasses	DM	4	STMR	75	5.33	10	10			0.53	0.53		
Soya bean hulls	SM	2.6	STMR	90	2.89		10				0.29		
Barley grain	GC	1.6	STMR	88	1.82	45	20		30	0.82	0.36		0.55
Total						100	100	100	100	64.35	85.19	140.00	27.50

DAIRY CATTLE		**DICAMBA**											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	11	STMR/STMR-P	25	44.00	45	60	100	10	19.80	26.40	44.00	4.40
Grass hay	AF/AS	6.3	STMR/STMR-P	88	7.16	0			60	0.00			4.30
Sugarcane molasses	DM	4	STMR/STMR-P	75	5.33	10	10			0.53	0.53		
Soya bean hulls	SM	2.6	STMR/STMR-P	90	2.89	0	10			0.00	0.29		
Barley grain	GC	1.6	STMR/STMR-P	88	1.82	45	20		30	0.82	0.36		0.55
Total						100	100	100	100	21.15	27.59	44.00	9.24

POULTRY BROILER		**DICAMBA**											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
Soya bean hulls	SM	2.6	STMR	90	2.89		10	5			0.29	0.14	
Barley grain	GC	1.6	STMR	88	1.82	75	70	15	10	1.36	1.27	0.27	0.18
Sorghum, grain	GC	1	STMR	86	1.16			55	55			0.64	0.64
Soya bean seed	VD	0.67	STMR	89	0.75	20	20	15		0.15	0.15	0.11	
Wheat milled by-products	CM/CF	0.26	STMR	88	0.30	5		10	5	0.01		0.03	0.01
Corn, field grain	GC	0.01	STMR	88	0.01				30				0.00
Total						100	100	100	100	1.53	1.71	1.20	0.84

POULTRY BROILER		**DICAMBA**											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
Soya bean hulls	SM	2.6	STMR/ STMR-P	90	2.89		10	5			0.29	0.14	
Barley grain	GC	1.6	STMR/ STMR-P	88	1.82	75	70	15	10	1.36	1.27	0.27	0.18
Sorghum, grain	GC	1	STMR/ STMR-P	86	1.16			55	55			0.64	0.64
Soya bean seed	VD	0.67	STMR/ STMR-P	89	0.75	20	20	15		0.15	0.15	0.11	
Wheat milled by-products	CM/CF	0.26	STMR/ STMR-P	88	0.30	5		10	5	0.01		0.03	0.01
Corn, field grain	GC	0.01	STMR/	88	0.01				30				0.00

POULTRY BROILER		**DICAMBA**											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
			STMR-P										
Total						100	100	100	100	1.53	1.71	1.20	0.84

POULTRY LAYER		**DICAMBA**											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
Grass forage (fresh)	AF/AS	35	HR	25	140.00		10				14.00		
Soya bean hulls	SM	2.6	STMR	90	2.89		5	5			0.14	0.14	
Barley grain	GC	1.6	STMR	88	1.82	75	85	15		1.36	1.55	0.27	
Sorghum, grain	GC	1	STMR	86	1.16			55	55			0.64	0.64
Soya bean seed	VD	0.67	STMR	89	0.75	20		15		0.15		0.11	
Wheat milled by-products	CM/CF	0.26	STMR	88	0.30	5		10	30	0.01		0.03	0.09
Corn, field grain	GC	0.01	STMR	88	0.01				15				0.00
Total						100	100	100	100	1.53	15.69	1.20	0.73

POULTRY LAYER		**DICAMBA**											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	11	STMR/STMR-P	25	44.00		10				4.40		
Soya bean hulls	SM	2.6	STMR/STMR-P	90	2.89		5	5			0.14	0.14	
Barley grain	GC	1.6	STMR/STMR-P	88	1.82	75	85	15		1.36	1.55	0.27	
Sorghum, grain	GC	1	STMR/STMR-P	86	1.16			55	55			0.64	0.64
Soya bean seed	VD	0.67	STMR/STMR-P	89	0.75	20		15		0.15		0.11	
Wheat milled by-products	CM/CF	0.26	STMR/STMR-P	88	0.30	5		10	30	0.01		0.03	0.09
Corn, field grain	GC	0.01	STMR/STMR-P	88	0.01				15				0.00
Total						100	100	100	100	1.53	6.09	1.20	0.73

BEEF CATTLE		**DIFLUBENZURON**											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	18.4	HR	85	21.65			60				12.99	
Grass forage (fresh)	AF/AS	5	HR	25	20.00		50	40	5		10	8	1
Apple pomace, wet	AB	1.65	STMR	40	4.13		20				0.825		
Barley hay	AF/AS	1.4	HR	88	1.59	15				0.238636			
Rice straw	AF/AS	0.7	HR	90	0.78				50				0.389
Barley grain	GC	0.05	STMR	88	0.06	50	30		45	0.028409	0.017		0.026
Total						65	100	100	100	0.267045	10.84	20.99	1.414

DAIRY CATTLE		**DIFLUBENZURON**										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	18.4	HR	85	21.65	15		60		3.247059		12.99	
Grass forage (fresh)	AF/AS	5	HR	25	20.00	45	60	40	10	9	12	8	2
Almond hulls	AM/AV	5.2	HR	90	5.78	10				0.577778			

DAIRY CATTLE		**DIFLUBENZURON**											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	1.65	STMR	40	4.13	10	10			0.4125	0.413		
Rice straw	AF/AS	0.7	HR	90	0.78				15				0.117
Barley grain	GC	0.05	STMR	88	0.06	20	30		40	0.011364	0.017		0.023
Total						100	100	100	65	13.2487	12.43	20.99	2.139

POULTRY BROILER		**DIFLUBENZURON**											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 grain	GC	0.05	STMR	88	0.06	75	70	15	10	0.042614	0.04	0.009	0.006
Wheat grain	GC	0.05	STMR	89	0.06			55				0.031	
Rice grain	GC	0.01	STMR	88	0.01			30				0.003	
Total						75	70	100	10	0.042614	0.04	0.043	0.006

POULTRY LAYER		**DIFLUBENZURON**											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
Grass forage (fresh)	AF/AS	5	HR	25	20.00		10				2		
Barley grain	GC	0.05	STMR	88	0.06	75	90	15		0.04261	0.051	0.009	
Wheat grain	GC	0.05	STMR	89	0.06			40				0.022	
Rice grain	GC	0.01	STMR	88	0.01			45				0.005	
Total						75	100	100		0.04261	2.051	0.036	

BEEF CATTLE		**DIFLUBENZURON**											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	3	STMR/ STMR-P	25	12.00		50	100	5		6	12	0.6
Apple pomace, wet	AB	1.65	STMR/ STMR-P	40	4.13		20				0.825		
Barley hay	AF/AS	0.62	STMR/ STMR-P	88	0.70	15				0.106			
Barley grain	GC	0.05	STMR/ STMR-P	88	0.06	50	30		70	0.028	0.017		0.0398
Rice straw	AF/AS	0.02	STMR/ STMR-P	90	0.02				25				0.0056
Total						65	100	100	100	0.134	6.842	12	0.6453

DAIRY CATTLE		**DIFLUBENZURON**											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	3	STMR/ STMR-P	25	12.00	45	60	100	10	5.4	7.2	12	1.2
Peanut hay	AL	4.9	STMR/ STMR-P	85	5.76	15				0.865			
Apple pomace, wet	AB	1.65	STMR/ STMR-P	40	4.13	10	10			0.413	0.413		
Almond hulls	AM/AV	1.15	STMR/ STMR-P	90	1.28	10				0.128			
Barley grain	GC	0.05	STMR/ STMR-P	88	0.06	20	30		40	0.011	0.017		0.0227
Rice straw	AF/AS	0.02	STMR/ STMR-P	90	0.02	0			15	0			0.0033
Total						100	100	100	65	5.183	7.63	12	1.2261

POULTRY BROILER		**DIFLUBENZURON**											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 grain	GC	0.05	STMR/ STMR-P	88	0.06	75	70	15	10	0.043	0.04	0.01	0.0057
Wheat grain	GC	0.05	STMR/ STMR-P	89	0.06			55				0.03	
Rice grain	GC	0.01	STMR/ STMR-P	88	0.01			30				0	
Total						75	70	100	10	0.043	0.04	0.04	0.0057

POULTRY LAYER		**DIFLUBENZURON**											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	3	STMR/ STMR-P	25	12.00		10				1.2		
Barley grain	GC	0.05	STMR/ STMR-P	88	0.06	75	90	15		0.043	0.051	0.01	
Wheat grain	GC	0.05	STMR/ STMR-P	89	0.06			40				0.02	
Rice grain	GC	0.01	STMR/ STMR-P	88	0.01			45				0.01	
Total						75	100	100		0.043	1.251	0.04	

BEEF CATTLE		**EMAMECTIN BENZOATE**											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				0.16	
Apple pomace, wet	AB	0.0051	STMR	40	0.01		20	20			0.0026	0.0026	
Cotton undelinted seed	SO	0.002	STMR	88	0.00			20				0.00045	
Cotton hulls	SM	0.00056	STMR	90	0.00	10				0.000062			
Total						10	20	100		0.000062	0.0026	0.16	

DAIRY CATTLE		**EMAMECTIN BENZOATE**											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	0.19	
Apple pomace, wet	AB	0.0051	STMR	40	0.01	10	10	10		0.0013	0.0013	0.0013	
Cotton undelinted seed	SO	0.002	STMR	88	0.00	10	10	20		0.00023	0.00023	0.00045	
Total						20	40	100		0.0015	0.055	0.19	

BEEF CATTLE		**EMAMECTIN BENZOATE**											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	0.008	STMR/ STMR-P	35	0.02			60				0.014	
Apple pomace, wet	AB	0.0051	STMR/ STMR-P	40	0.01		20	20			0.0026	0.0026	
Cotton undelinted	SO	0.002	STMR/ STMR-P	88	0.00			20				0.00045	

BEEF CATTLE		**EMAMECTIN BENZOATE**											MEAN
Commodity	CC		Basis	DM	Residue	Diet content (%)				Residue Contribution (ppm)			
seed													
Cotton hulls	SM	0.00056	STMR/ STMR-P	90	0.00	10				0.000062			
Total						10	20	100		0.000062	0.0026	0.017	

DAIRY CATTLE		**EMAMECTIN BENZOATE**											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	0.008	STMR/ STMR-P	35	0.02		20	70			0.0046	0.016	
Apple pomace, wet	AB	0.0051	STMR/ STMR-P	40	0.01	10	10	10		0.0013	0.0013	0.0013	
Cotton, undelinted seed	SO	0.002	STMR/ STMR-P	88	0.00	10	10	20		0.00023	0.00023	0.00045	
Total						20	40	100		0.0015	0.0061	0.018	

BEEF CATTLE		ETOFENPROX											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	0.53	STMR	40	1.33		20	20			0.265	0.265	
Rice straw	AF/AS	0.025	HR	90	0.03		10	60	55		0.003	0.017	0.015
Total							30	80	55		0.268	0.282	0.015

DAIRY CATTLE		ETOFENPROX											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	0.53	STMR	40	1.33	10	10	10		0.1325	0.133	0.133	
Rice straw	AF/AS	0.025	HR	90	0.03		5	20	25		0.001	0.006	0.007
Total						10	15	30	25	0.1325	0.134	0.138	0.007

BEEF CATTLE		ETOFENPROX											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	0.53	STMR-P	40	1.33		20	20			0.265	0.265	
Rice straw	AF/AS	0.01	STMR	90	0.01		10	60	55		0.001	0.007	0.006
Total							30	80	55		0.266	0.272	0.006

DAIRY CATTLE		ETOFENPROX											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	0.53	STMR-P	40	1.33	10	10	10		0.1325	0.133	0.133	
Rice straw	AF/AS	0.01	STMR	90	0.01	0	5	20	25	0	6E-04	0.002	0.003
Total						10	15	30	25	0.1325	0.133	0.135	0.003

BEEF CATTLE		**FLUTRIAFOL**											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	19	HR	25	76.00		20	100			15.2	76	
Wheat straw	AF/AS	4.1	HR	88	4.66	10				0.465909			
Apple pomace, wet	AB	0.13	STMR	40	0.33		20				0.065		
Wheat asp gr fn	CM/CF	0.2	STMR	85	0.24	5				0.011765			
Soya bean asp gr	SM	0.094	STMR	85	0.11	5				0.005529			

BEEF CATTLE		**FLUTRIAFOL**											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
fn													
Soya bean meal	SM	0.072	STMR	92	0.08		20		65		0.016		0.0509
Soya bean seed	VD	0.055	STMR	89	0.06	5	10		15	0.00309	0.006		0.0093
Soya bean hulls	SM	0.053	STMR	90	0.06	10				0.005889			
Wheat grain	GC	0.015	STMR	89	0.02	20	30		20	0.003371	0.005		0.0034
Total						55	100	100	100	0.495553	15.29	76	0.0635

BEEF CATTLE		**FLUTRIAFOL**											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	8	STMR/ STMR-P	25	32.00		20	100			6.4	32	
Wheat straw	AF/AS	1.45	STMR/ STMR-P	88	1.65	10				0.164773			
Apple pomace, wet	AB	0.13	STMR/ STMR-P	40	0.33		20				0.065		
Wheat asp gr fn	CM/CF	0.2	STMR/ STMR-P	85	0.24	5				0.011765			
Soya bean asp gr fn	SM	0.094	STMR/ STMR-P	85	0.11	5				0.005529			
Soya bean meal	SM	0.072	STMR/ STMR-P	92	0.08		20		65		0.016		0.0509
Soya bean seed	VD	0.055	STMR/ STMR-P	89	0.06	5	10		15	0.00309	0.006		0.0093
Soya bean hulls	SM	0.053	STMR/ STMR-P	90	0.06	10				0.005889			
Wheat grain	GC	0.015	STMR/ STMR-P	89	0.02	20	30		20	0.003371	0.005		0.0034
Total						55	100	100	100	0.194416	6.492	32	0.0635

DAIRY CATTLE		**FLUTRIAFOL**											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	19	HR	25	76.00	20	20	60		15.2	15.2	45.6	
Peanut hay	AL	8.9	HR	85	10.47	15		40		1.570588		4.188	
Apple pomace, wet	AB	0.13	STMR	40	0.33	10	10			0.0325	0.033		
Soya bean meal	SM	0.072	STMR	92	0.08	10	25		60	0.007826	0.02		0.047
Soya bean seed	VD	0.055	STMR	89	0.06	10	10		10	0.00618	0.006		0.0062
Wheat grain	GC	0.015	STMR	89	0.02	20	35		10	0.003371	0.006		0.0017
Total						85	100	100	80	16.82046	15.26	49.79	0.0548

DAIRY CATTLE		**FLUTRIAFOL**											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	8	STMR/ STMR-P	25	32.00	20	20	60		6.4	6.4	19.2	
Peanut hay	AL	2.6	STMR/ STMR-P	85	3.06	15		40		0.458824		1.224	
Apple pomace, wet	AB	0.13	STMR/ STMR-P	40	0.33	10	10			0.0325	0.033		
Soya bean meal	SM	0.072	STMR/ STMR-P	92	0.08	10	25		60	0.007826	0.02		0.047
Soya bean seed	VD	0.055	STMR STMR-P	89	0.06	10	10		10	0.00618	0.006		0.0062
Wheat grain	GC	0.015	STMR/ STMR-P	89	0.02	20	35		10	0.003371	0.006		0.0017
Total						85	100	100	80	6.9087	6.464	20.42	0.0548

POULTRY BROILER		**FLUTRIAFOL**											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
Soya bean meal	SM	0.072	STMR	92	0.08	25	40	25	35	0.019565	0.031	0.02	0.0274
Soya bean seed	VD	0.055	STMR	89	0.06	20	20	15		0.01236	0.012	0.009	
Wheat grain	GC	0.015	STMR	89	0.02	55	40	60	10	0.00927	0.007	0.01	0.0017
Total						100	100	100	45	0.041194	0.05	0.039	0.0291

POULTRY BROILER		**FLUTRIAFOL**											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
Soya bean meal	SM	0.072	STMR/STMR-P	92	0.08	25	40	25	35	0.019565	0.031	0.02	0.0274
Soya bean seed	VD	0.055	STMR/STMR-P	89	0.06	20	20	15		0.01236	0.012	0.009	
Wheat grain	GC	0.015	STMR/STMR-P	89	0.02	55	40	60	10	0.00927	0.007	0.01	0.0017
Total						100	100	100	45	0.041194	0.05	0.039	0.0291

POULTRY LAYER	**FLUTRIAFOL**												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	19	HR	25	76.00		10				7.6		
Soya bean meal	SM	0.072	STMR	92	0.08	25	25	25	30	0.019565	0.02	0.02	0.0235
Soya bean seed	VD	0.055	STMR	89	0.06	20	15	15		0.01236	0.009	0.009	
Wheat grain	GC	0.015	STMR	89	0.02	55	50	55		0.00927	0.008	0.009	
Total						100	100	95	30	0.041194	7.637	0.038	0.0235

POULTRY LAYER		**FLUTRIAFOL**											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	8	STMR/STMR-P	25	32.00		10				3.2		
Soya bean meal	SM	0.072	STMR/STMR-P	92	0.08	25	25	25	30	0.019565	0.02	0.02	0.0235
Soya bean seed	VD	0.055	STMR/STMR-P	89	0.06	20	15	15		0.01236	0.009	0.009	
Wheat grain	GC	0.015	STMR/STMR-P	89	0.02	55	50	55		0.00927	0.008	0.009	
Total						100	100	95	30	0.041194	3.237	0.038	0.0235

BEEF CATTLE		**ISOPYRAZAM**											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 forage	AF/AS	3.63	HR	30	12.10		30	50			3.63	6.05	
Wheat forage	AF/AS	2.95	HR	25	11.80			50				5.90	
Rye straw	AF/AS	1.51	HR	88	1.72	10				0.17			
Wheat milled by-products	CM/CF	0.041	STMR	88	0.05	40	30		55	0.02	0.01		0.03
Barley grain	GC	0.022	STMR	88	0.03	50	40		45	0.01	0.01		0.01
Total						100	100	100	100	0.20	3.65	11.95	0.04

BEEF CATTLE	**ISOPYRAZAM**												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	2.1	STMR/ STMR-P	25	8.40		20	100			1.68	8.40	
Barley forage	AF/AS	2.45	STMR/ STMR-P	30	8.17		10				0.82		
Rye straw	AF/AS	0.952	STMR/ STMR-P	88	1.08	10				0.11			
Wheat milled by-	CM/CF	0.041	STMR/	88	0.05	40	30		55	0.02	0.01		0.03

products			STMR-P										
Barley grain	GC	0.022	STMR/ STMR-P	88	0.03	50	40		45	0.01	0.01		0.01
Total						100	100	100	100	0.14	2.52	8.40	0.04

DAIRY CATTLE	**ISOPYRAZAM**												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 forage	AF/AS	3.63	HR	30	12.10		30	50			3.63	6.05	
Wheat forage	AF/AS	2.95	HR	25	11.80	20		50		2.36		5.90	
Rye straw	AF/AS	1.51	HR	88	1.72				5				0.09
Wheat milled by-products	CM/CF	0.041	STMR	88	0.05	30	30		45	0.01	0.01		0.02
Barley grain	GC	0.022	STMR	88	0.03	45	40		40	0.01	0.01		0.01
Total						95	100	100	90	2.39	3.65	11.95	0.12

DAIRY CATTLE		**ISOPYRAZAM**											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	2.1	STMR/ STMR-P	25	8.40	20	20	60		1.68	1.68	5.04	
Barley forage	AF/AS	2.45	STMR/ STMR-P	30	8.17	0	10			0.00	0.82		
Triticale forage	AF/AS	2.1	STMR/ STMR-P	30	7.00	0		40		0.00		2.80	
Rye straw	AF/AS	0.952	STMR/ STMR-P	88	1.08	0			5	0.00			0.05
Wheat milled by-products	CM/CF	0.041	STMR/ STMR-P	88	0.05	30	30		45	0.01	0.01		0.02
Barley grain	GC	0.022	STMR/ STMR-P	88	0.03	45	40		40	0.01	0.01		0.01
Total						95	100	100	90	1.705	2.52	7.84	0.085

POULTRY BROILER		**ISOPYRAZAM**											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 by-products	CM/CF	0.041	STMR	88	0.05	50	20	20	5	0.02	0.01	0.01	0.00
Barley grain	GC	0.022	STMR	88	0.03	50	70	15	10	0.01	0.02	0.00	0.00
Rye grain	GC	0.01	STMR	88	0.01			35				0.00	
Total						100	90	70	15	0.04	0.03	0.02	0.00

POULTRY BROILER		**ISOPYRAZAM**											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 by-products	CM/CF	0.041	STMR/STMR-P	88	0.05	50	20	20	5	0.02	0.01	0.01	0.00
Barley grain	GC	0.022	STMR/STMR-P	88	0.03	50	70	15	10	0.01	0.02	0.00	0.00
Rye grain	GC	0.01	STMR/STMR-P	88	0.01			35				0.00	
Total						100	90	70	15	0.04	0.03	0.02	0.00

POULTRY LAYER	**ISOPYRAZAM**												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	2.95	HR	25	11.80		10				1.18		
Wheat milled by-products	CM/CF	0.041	STMR	88	0.05	50	20	20	30	0.02	0.01	0.01	0.01

Barley grain	GC	0.022	STMR	88	0.03	50	70	15		0.01	0.02	0.00	
Rye grain	GC	0.01	STMR	88	0.01			20				0.00	
Total						100	100	55	30	0.04	1.21	0.02	0.01

POULTRY LAYER		**ISOPYRAZAM**											MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%) US-CAN	EU	AU	JP	Residue Contribution (ppm) US-CAN	EU	AU	JP
Wheat forage	AF/AS	2.1	STMR/ STMR-P	25	8.40		10				0.84		
Wheat milled by-products	CM/ CF	0.041	STMR/ STMR-P	88	0.05	50	20	20	30	0.02	0.01	0.01	0.01
Barley grain	GC	0.022	STMR/ STMR-P	88	0.03	50	70	15		0.01	0.02	0.00	
Rye grain	GC	0.01	STMR/ STMR-P	88	0.01			20				0.00	
Total						100	100	55	30	0.04	0.87	0.02	0.01

BEEF CATTLE		**PYRCALOSTROBIN**											MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%) US-CAN	EU	AU	JP	Residue Contribution (ppm) US-CAN	EU	AU	JP
Peanut hay	AL	24	HR	85	28.24			60				16.94	
Pea vines	AL	7	HR	25	28.00		20				5.6		
Corn, field stover	AF/AS	19	HR	83	22.89	15	25	40		3.43	5.723	9.157	
Alfalfa hay	AL	19.83	HR	89	22.28	15			10	3.34			2.228
Barley straw	AF/AS	19	HR	89	21.35		5				1.067		
Pea hay	AL	18	HR	88	20.45		5				1.023		
Alfalfa forage	AL	6.61	HR	35	18.89		45				8.499		
Cotton gin by-products	AM/AV	16.73	HR	90	18.59	5				0.929			
Oat grain	GC	0.315	STMR	89	0.35				55				0.195
Barley grain	GC	0.05	STMR	88	0.06	50			35	0.028			0.02
Canola meal	SM	0.035	STMR	88	0.04	5				0.002			
Soya bean hulls	SM	0.03	STMR	90	0.03	10				0.003			
Total						100	100	100	100	7.74	21.91	26.1	2.443

DAIRY CATTLE		**PYRCALOSTROBIN**											MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%) US-CAN	EU	AU	JP	Residue Contribution (ppm) US-CAN	EU	AU	JP
Peanut hay	AL	24	HR	85	28.24	15		60		4.24		16.94	
Pea vines	AL	7	HR	25	28.00		20				5.6		
Corn, field stover	AF/AS	19	HR	83	22.89	15	20	40		3.43	4.58	9.16	
Alfalfa hay	AL	19.83	HR	89	22.28	5	20		25	1.11	4.46		5.57
Rye straw	AF/AS	19	HR	88	21.59				5				1.08
Barley straw	AF/AS	19	HR	89	21.35		10				2.135		
Oat hay	AF/AS	19	HR	90	21.11	15				3.17			
Alfalfa forage	AL	6.61	HR	35	18.89		30				5.67		
Sorghum, grain forage	AF/AS	1.33	HR	35	3.80	10			35	0.38			1.33
Almond hulls	AM/AV	1.395	STMR	90	1.55	10				0.155			
Oat grain	GC	0.315	STMR	89	0.35	20			5	0.071			0.018
Barley grain	GC	0.05	STMR	88	0.06	10			30	0.0057			0.017
Total						100	100	100	100	12.56	22.44	26.1	8.015

POULTRY BROILER		**PYRCALOSTROBIN**											MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%) US-CAN	EU	AU	JP	Residue Contribution (ppm) US-CAN	EU	AU	JP

POULTRY BROILER		**PYRCALOSTROBIN**											MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%) US-CAN	EU	AU	JP	Residue Contribution (ppm) US-CAN	EU	AU	JP
Alfalfa forage	AL	6.61	HR	35	18.89				5				0.944
Oat grain	GC	0.315	STMR	89	0.35	75	70	15		0.265	0.248	0.053	
Barley grain	GC	0.05	STMR	88	0.06				10				0.006
Canola meal	SM	0.035	STMR	88	0.04	15	18	5		0.006	0.007	0.002	
Sorghum, grain	GC	0.025	STMR	86	0.03			55	55			0.016	0.016
Rye grain	GC	0.02	STMR	88	0.02			25				0.006	
Soya bean seed	VD	0.02	STMR	89	0.02	10	12			0.002	0.003		
Soya bean meal	SM	0.01	STMR	92	0.01				30				0.003
Total						100	100	100	100	0.274	0.258	0.077	0.969

POULTRY LAYER		**PYRCALOSTROBIN**											MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%) US-CAN	EU	AU	JP	Residue Contribution (ppm) US-CAN	EU	AU	JP
Pea vines	AL	7	HR	25	28.00		10				2.8		
Corn, field stover	AF/AS	19	HR	83	22.89		10				2.289		
Beet, sugar tops	AM/AV	1.64	HR	23	7.13		5				0.357		
Oat grain	GC	0.315	STMR	89	0.35	75	70	15		0.266	0.248	0.053	
Barley grain	GC	0.05	STMR	88	0.06		5				0.003		
Canola meal	SM	0.035	STMR	88	0.04	15		5		0.006		0.002	
Sorghum, grain	GC	0.025	STMR	86	0.03			55	55			0.016	0.016
Rye grain	GC	0.02	STMR	88	0.02			25				0.006	
Soya bean seed	VD	0.02	STMR	89	0.02	10				0.0022			
Soya bean meal	SM	0.01	STMR	92	0.01				30				0.003
Total						100	100	100	85	0.273	5.696	0.077	0.019

BEEF CATTLE		**PYRCALOSTROBIN**											MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%) US-CAN	EU	AU	JP	Residue Contribution (ppm) US-CAN	EU	AU	JP
Beet, sugar tops	AM/AV	5.3	STMR/ STMR-P	23	23.04		20				4.609		
Pea vines	AL	5.1	STMR/ STMR-P	25	20.40		20	60			4.08	12.24	
Alfalfa hay	AL	7.455	STMR/ STMR-P	89	8.38	15		40	10	1.26		3.35	0.838
Pea hay	AL	6.8	STMR/ STMR-P	88	7.73		5				0.386		
Alfalfa forage	AL	1.775	STMR/ STMR-P	35	5.07		55				2.78		
Corn, field stover	AF/AS	1.5	STMR/ STMR-P	83	1.81	15				0.271			
Cotton gin by-products	AM/AV	1.575	STMR/ STMR-P	90	1.75	5				0.088			
Oat grain	GC	0.315	STMR/ STMR-P	89	0.35				55				0.195
Barley grain	GC	0.05	STMR/ TMR-P	88	0.06	50			35	0.028			0.02
Canola meal	SM	0.035	STMR/S TMR-P	88	0.04	5				0.002			
Soya bean hulls	SM	0.03	STMR/ TMR-P	90	0.03	10				0.003			
Total						100	100	100	100	1.649	11.86	15.59	1.052

DAIRY CATTLE		**PYRCALOSTROBIN**											MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%) US-CAN	EU	AU	JP	Residue Contribution (ppm) US-CAN	EU	AU	JP
Beet, sugar tops	AM/AV	5.3	STMR/ STMR-P	23	23.04		30	0			6.913	0	
Pea vines	AL	5.1	STMR/ STMR-P	25	20.40	10	20	40		2.04	4.08	8.16	
Peanut hay	AL	9	STMR/ STMR-P	85	10.59	5		20		0.529		2.118	
Alfalfa hay	AL	7.455	STMR/ STMR-P	89	8.38	5	20	40	25	0.419	1.68	3.35	2.094
Alfalfa forage	AL	1.775	STMR/ STMR-P	35	5.07	0	30			0	1.52		
Corn, field stover	AF/AS	1.5	STMR/ STMR-P	83	1.81	15				0.271			
Rye straw	AF/AS	1.5	STMR/ STMR-P	88	1.70	0			5	0			0.085
Oat hay	AF/AS	1.5	STMR/ STMR-P	90	1.67	15				0.25			
Almond hulls	AM/AV	1.395	STMR/ STMR-P	90	1.55	10				0.155			
Sorghum, grain forage	AF/AS	0.305	STMR/ STMR-P	35	0.87	10			35	0.087			0.305
Oat grain	GC	0.315	STMR/ STMR-P	89	0.35	20			5	0.071			0.018
Barley grain	GC	0.05	STMR/ STMR-P	88	0.06	10			30	0.0057			0.017
Total						100	100	100	100	3.828	14.19	13.63	2.519

POULTRY BROILER		**PYRCALOSTROBIN**											MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%) US-CAN	EU	AU	JP	Residue Contribution (ppm) US-CAN	EU	AU	JP
Alfalfa forage	AL	1.775	STMR/ STMR-P	35	5.07				5				0.254
Oat grain	GC	0.315	STMR/ STMR-P	89	0.35	75	70	15		0.265	0.248	0.053	
Barley grain	GC	0.05	STMR/ STMR-P	88	0.06				10				0.006
Canola meal	SM	0.035	STMR/S TMR-P	88	0.04	15	18	5		0.006	0.007	0.002	
Sorghum, grain	GC	0.025	STMR/ STMR-P	86	0.03			55	55			0.016	0.016
Rye grain	GC	0.02	STMR/ STMR-P	88	0.02			25				0.006	
Soya bean seed	VD	0.02	STMR/ STMR-P	89	0.02	10	12			0.0022	0.003		
Soya bean meal	SM	0.01	STMR/ STMR-P	92	0.01				30				0.003
Total						100	100	100	100	0.274	0.258	0.077	0.279

POULTRY LAYER		**PYRCALOSTROBIN**											MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%) US-CAN	EU	AU	JP	Residue Contribution (ppm) US-CAN	EU	AU	JP
Beet, sugar tops	AM/AV	5.3	STMR/ STMR-P	23	23.04		5				1.152		
Pea vines	AL	5.1	STMR/ STMR-P	25	20.40		10				2.04		
Corn, field stover	AF/AS	1.5	STMR/ STMR-P	83	1.81		10				0.181		
Oat grain	GC	0.315	STMR/ STMR-P	89	0.35	75	70	15		0.265	0.248	0.053	
Barley grain	GC	0.05	STMR/ STMR-P	88	0.06		5				0.003		

POULTRY LAYER		**PYRCALOSTROBIN**											MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%) US-CAN	EU	AU	JP	Residue Contribution (ppm) US-CAN	EU	AU	JP
Canola meal	SM	0.035	STMR/ STMR-P	88	0.04	15		5		0.006		0.002	
Sorghum, grain	GC	0.025	STMR/ STMR-P	86	0.03			55	55			0.016	0.016
Rye grain	GC	0.02	STMR/ STMR-P	88	0.02			25				0.006	
Soya bean seed	VD	0.02	STMR/ STMR-P	89	0.02	10				0.0022			
Soya bean meal	SM	0.01	STMR/ STMR-P	92	0.01				30				0.003
Total						100	100	100	85	0.274	3.623	0.077	0.019

BEEF CATTLE		**SAFLUFENACIL**											MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%) US-CAN	EU	AU	JP	Residue Contribution (ppm) US-CAN	EU	AU	JP
Cotton gin by-products	AM/AV	2.25	HR	90	2.50	5				0.125			
Sunflower meal	SM	0.096	STMR	92	0.10	5	20	30		0.005	0.021	0.031	
Wheat forage	AF/AS	0.025	HR	25	0.10		20	70			0.020	0.070	
Soya bean hulls	SM	0.079	STMR	90	0.09	10				0.009			
Sorghum, grain forage	AF/AS	0.025	HR	35	0.07	15				0.011			
Corn, field forage/silage	AF/AS	0.025	HR	40	0.06		60				0.038		
Sorghum, grain	GC	0.01	STMR	86	0.01	40			35	0.005			0.004
Barley grain	GC	0.01	STMR	88	0.01	25			65	0.003			0.007
Total						100	100	100	100	**0.157**	**0.078**	**0.101**	**0.011**

BEEF CATTLE		**SAFLUFENACIL**											MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%) US-CAN	EU	AU	JP	Residue Contribution (ppm) US-CAN	EU	AU	JP
Cotton gin by-products	AM/AV	0.2025	STMR/ STMR-P	90	0.23	5				0.011			
Sunflower meal	SM	0.096	STMR/ STMR-P	92	0.10	5	20	30		0.005	0.021	0.031	
Wheat forage	AF/AS	0.025	STMR/ STMR-P	25	0.10		20	70			0.020	0.070	
Soya bean hulls	SM	0.079	STMR/ STMR-P	90	0.09	10				0.009			
Barley forage	AF/AS	0.025	STMR/ STMR-P	30	0.08		10				0.008		
Sorghum, grain forage	AF/AS	0.025	STMR/ STMR-P	35	0.07	15				0.011			
Corn, field forage/silage	AF/AS	0.025	STMR/ STMR-P	40	0.06		50				0.031		
Sorghum, grain	GC	0.01	STMR/ STMR-P	86	0.01	40			35	0.005			0.004
Barley grain	GC	0.01	STMR/ STMR-P	88	0.01	25			65	0.003			0.007
Total						100	100	100	100	0.043	0.080	0.101	0.011

DAIRY CATTLE		**SAFLUFENACIL**											MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%) US-CAN	EU	AU	JP	Residue Contribution (ppm) US-CAN	EU	AU	JP
Sunflower meal	SM	0.096	STMR	92	0.10	10	10	15		0.010	0.010	0.016	
Wheat forage	AF/AS	0.025	HR	25	0.10	20	20	60		0.020	0.020	0.060	
Soya bean silage	AL	0.025	HR	30	0.08	20		25		0.017		0.021	
Sorghum, grain forage	AF/AS	0.025	HR	35	0.07	20			40	0.014			0.029
Corn, field forage/silage	AF/AS	0.025	HR	40	0.06	30	40		10	0.019	0.025		0.006
Sorghum, grain	GC	0.01	STMR	86	0.01		30		30		0.003		0.003

Barley grain	GC	0.01	STMR	88	0.01				20				0.002
Total						100	100	100	100	0.080	0.059	0.096	0.041

DAIRY CATTLE	**SAFLUFENACIL**												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
Sunflower meal	SM	0.096	STMR/ STMR-P	92	0.10	10	10	15		0.010	0.010	0.016	
Wheat forage	AF/AS	0.025	STMR/ STMR-P	25	0.10	20	20	60		0.020	0.020	0.060	
Barley forage	AF/AS	0.025	STMR/ STMR-P	30	0.08	0	10			0.000	0.008		
Soya bean silage	AL	0.025	STMR /STMR-P	30	0.08	20		25		0.017		0.021	
Sorghum, grain forage	AF/AS	0.025	STMR /STMR-P	35	0.07	20			40	0.014			0.029
Corn, field forage/silage	AF/AS	0.025	STMR/ STMR-P	40	0.06	30	30		10	0.019	0.019		0.006
Sorghum, grain	GC	0.01	STMR/ STMR-P	86	0.01	0	30		30	0.000	0.003		0.003
Barley grain	GC	0.01	STMR/ STMR-P	88	0.01	0			20	0.000			0.002
Total						100	100	100	100	0.080	0.061	0.096	0.041

POULTRY BROILER	**SAFLUFENACIL**												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
Sunflower meal	SM	0.096	STMR	92	0.10	25	10	15		0.026	0.010	0.016	
Sorghum, grain	GC	0.01	STMR	86	0.01	75	70	70	65	0.009	0.008	0.008	0.008
Bean seed	VD	0.01	STMR	88	0.01		20	15			0.002	0.002	
Soya bean meal	SM	0.0065	STMR	92	0.01				35				0.002
Total						100	100	100	100	0.035	0.021	0.025	0.010

POULTRY BROILER	**SAFLUFENACIL**												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
Sunflower meal	SM	0.096	STMR/ STMR-P	92	0.10	25	10	15		0.026	0.010	0.016	
Sorghum, grain	GC	0.01	STMR/ STMR-P	86	0.01	75	70	70	65	0.009	0.008	0.008	0.008
Bean seed	VD	0.01	STMR/ STMR-P	88	0.01		20	15			0.002	0.002	
Soya bean meal	SM	0.0065	STMR/ STMR-P	92	0.01				35				0.002
Total						100	100	100	100	0.035	0.021	0.025	0.010

POULTRY LAYER	**SAFLUFENACIL**												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
Sunflower meal	SM	0.096	STMR	92	0.10	25	10	15		0.026	0.010	0.016	
Wheat forage	AF/AS	0.025	HR	25	0.10		10				0.010		
Soya bean silage	AL	0.025	HR	30	0.08		10				0.008		
Sorghum, grain	GC	0.01	STMR	86	0.01	75	70	70	55	0.009	0.008	0.008	0.006
Bean seed	VD	0.01	STMR	88	0.01			15				0.002	
Soya bean meal	SM	0.0065	STMR	92	0.01				30				0.002
Total						100	100	100	85	0.035	0.037	0.025	0.009

POULTRY LAYER	**SAFLUFENACIL**												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

POULTRY LAYER	**SAFLUFENACIL**												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
Sunflower meal	SM	0.096	STMR/ STMR-P	92	0.10	25	10	15		0.026	0.010	0.016	
Wheat forage	AF/AS	0.025	STMR/ STMR-P	25	0.10		10				0.010		
Soya bean silage	AL	0.025	STMR/ STMR-P	30	0.08		10				0.008		
Sorghum, grain	GC	0.01	STMR/ STMR-P	86	0.01	75	70	70	55	0.009	0.008	0.008	0.006
Bean seed	VD	0.01	STMR/ STMR-P	88	0.01			15				0.002	
Soya bean meal	SM	0.0065	STMR /STMR-P	92	0.01				30				0.002
Total						100	100	100	85	0.035	0.037	0.025	0.009

BEEF CATTLE		**SPINOSAD**											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	VB	1.1	HR	15	7.33		20				1.467		
Maize forage	ASAF	3.1	HR	100	3.10			80				2.48	
Almond hulls	AM	2.23	STMR	90	2.48			10				0.248	
Maize fodder	ASAF	2.1	HR	100	2.10	15	25			0.315	0.525		
Barley grain	GC	0.7	STMR	88	0.80	50	55	10	70	0.3977	0.438	0.08	0.557
Maize grain	GC	0.7	STMR	88	0.80	30			5	0.2386			0.04
Apple pomace wet	AB	0.064	STMR	40	0.16								
Citrus pulp	AB	0.12	STMR	91	0.13	5				0.0066			
Soya beans	SO	0.01	HR	89	0.01				15				0.002
Total						100	100	100	90	0.958	2.429	2.807	0.598

DAIRY CATTLE		**SPINOSAD**											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	VB	1.1	HR	15	7.33		20				1.467		
Maize forage	ASAF	3.1	HR	100	3.10	45		40		1.395		1.24	
Almond hulls	AM	2.23	STMR	90	2.48	10		10		0.2478		0.248	
Barley grain	GC	0.7	STMR	88	0.80	45	40	40	40	0.358	0.318	0.318	0.318
Maize grain	GC	0.7	STMR	88	0.80				40				0.318
Wheat forage	ASAF	0.054	HR	25	0.22		20	10			0.043	0.022	
Apple pomace wet	AB	0.064	STMR	40	0.16		10				0.016		
Soya beans	SO	0.01	HR	89	0.01		10		10		0.001		0.001
Total						100	100	100	90	2.0007	1.845	1.828	0.637

BEEF CATTLE		**SPINOSAD**											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	2.23	STMR	90	2.48			10				0.248	
Cabbage	VB	0.27	STMR	15	1.80		20				0.36		
Barley grain	GC	0.7	STMR	88	0.80	50	70	80	70	0.3977	0.557	0.636	0.5568
Maize grain	GC	0.7	STMR	88	0.80	30	10		5	0.2386	0.08		0.0398
Maize forage	ASAF	0.7	STMR	100	0.70			10				0.07	
Maize fodder	ASAF	0.46	STMR	100	0.46	15				0.069			
Citrus pulp	AB	0.12	STMR	91	0.13	5				0.0066			
Soya beans	SO	0	STMR	89	0.00				15				0
Total						100	100	100	90	0.712	0.996	0.954	0.5966

DAIRY CATTLE		**SPINOSAD**											MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%) US-CAN	EU	AU	JP	Residue Contribution (ppm) US-CAN	EU	AU	JP
Almond hulls	AM	2.23	STMR	90	2.48	10		10		0.2478		0.248	
Cabbage	VB	0.27	STMR	15	1.80		20				0.36		
Barley grain	GC	0.7	STMR	88	0.80	45	40	40	40	0.358	0.318	0.318	0.3182
Maize grain	GC	0.7	STMR	88	0.80				40				0.3182
Maize forage	ASAF	0.7	STMR	100	0.70	45		40		0.315		0.28	
Sorghum	GC	0.17	STMR	86	0.20			10				0.02	
Apple pomace wet	AB	0.064	STMR	40	0.16		10				0.016		
Citrus pulp	AB	0.12	STMR	91	0.13		10				0.013		
Wheat forage	ASAF	0.01	STMR	25	0.04		20				0.008		
Soya beans	SO	0	STMR	89	0.00				10				0
Total						100	100	100	90	0.9207	0.715	0.866	0.6364

BEEF CATTLE		**SPIROTETRAMAT**											MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%) US-CAN	EU	AU	JP	Residue Contribution (ppm) US-CAN	EU	AU	JP
Soya bean forage	AL	22.4	HR	56	40.00			100				40	
Cowpea forage	AL	3.6	HR	30	12.00		35				4.2		
Cabbage heads, leaves	AM/AV	0.92	HR	15	6.13		20				1.227		
Cotton gin by-products	AM/AV	5.31	HR	90	5.90	5				0.295			
Soya bean asp gr fn	SM	1.9	STMR	85	2.24	5				0.111765			
Potato culls	VR	0.44	HR	20	2.20	30	30			0.66	0.66		
Apple pomace, wet	AB	0.44	STMR	40	1.10		15				0.165		
Soya bean meal	SM	0.62	STMR	92	0.67				65				0.438
Soya bean seed	VD	0.45	STMR	89	0.51	5			15	0.025281			0.076
Citrus dried pulp	AB	0.43	STMR	91	0.47	10				0.047253			
Soya bean hulls	SM	0.4	STMR	90	0.44	10				0.044444			
Total						65	100	100	80	1.183743	6.252	40	0.514

BEEF CATTLE		**SPIROTETRAMAT**											MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%) US-CAN	EU	AU	JP	Residue Contribution (ppm) US-CAN	EU	AU	JP
Soya bean forage	AL	10.64	STMR/ STMR-P	56	19.00			100				19	
Cowpea forage	AL	2.22	STMR /STMR-P	30	7.40		35				2.59		
Soya bean asp gr fn	SM	1.9	STMR /STMR-P	85	2.24	5				0.111765			
Cabbage heads, leaves	AM/AV	0.23	STMR /STMR-P	15	1.53		20				0.307		
Apple pomace, wet	AB	0.44	STMR/ STMR-P	40	1.10		20				0.22		
Cotton gin by-products	AM/AV	0.711	STMR/ STMR-P	90	0.79	5				0.0395			
Soya bean meal	SM	0.62	STMR/ STMR-P	92	0.67		20		65		0.135		0.438
Potato culls	VR	0.11	STMR/ STMR-P	20	0.55	30	5			0.165	0.028		
Soya bean seed	VD	0.45	STMR/ STMR-P	89	0.51	5			15	0.025281			0.076
Citrus dried pulp	AB	0.43	STMR/ STMR-P	91	0.47	10				0.047253			
Soya bean hulls	SM	0.4	STMR/ STMR-P	90	0.44	10				0.044444			
Total						65	100	100	80	0.433243	3.279	19	0.514

DAIRY CATTLE		**SPIROTETRAMAT**											MAX
Commodity	CC	Residue	Basis	DM	Residue	Diet content (%)				Residue Contribution (ppm)			
		(mg/kg)		(%)	dw (mg/kg)	US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Soya bean forage	AL	22.4	HR	56	40.00	20		40		8		16	
Cowpea forage	AL	3.6	HR	30	12.00		35	20			4.2	2.4	
Pea hay	AL	8.536	HR	88	9.70			40				3.88	
Cabbage heads, leaves	AM/AV	0.92	HR	15	6.13		20				1.227		
Almond hulls	AM/AV	4.9	STMR	90	5.44	10				0.544444			
Potato culls	VR	0.44	HR	20	2.20	10	30			0.22	0.66		
Apple pomace, wet	AB	0.44	STMR	40	1.10	10	10			0.11	0.11		
Soya bean meal	SM	0.62	STMR	92	0.67	10	5		60	0.067391	0.034		0.404
Soya bean seed	VD	0.45	STMR	89	0.51	10			10	0.050562			0.051
Cotton undelinted seed	SO	0.095	STMR	88	0.11	10				0.010795			
Total						80	100	100	70	9.003193	6.23	22.28	0.455

DAIRY CATTLE		**SPIROTETRAMAT**											MEAN
Commodity	CC	Residue	Basis	DM	Residue	Diet content (%)				Residue Contribution (ppm)			
		(mg/kg)		(%)	dw (mg/kg)	US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Soya bean forage	AL	10.64	STMR/ STMR-P	56	19.00	20	0	40		3.8	0	7.6	
Cowpea forage	AL	2.22	STMR/ STMR-P	30	7.40	0	35	20		0	2.59	1.48	
Almond hulls	AM/AV	4.9	STMR/ STMR-P	90	5.44	10		10		0.544444		0.544	
Grape pomace, wet	AB	0.74	STMR/ STMR-P	15	4.93	0		20		0		0.987	
Pea hay	AL	1.584	STMR/ STMR-P	88	1.80	0		10		0		0.18	
Cabbage heads, leaves	AM/AV	0.23	STMR/ STMR-P	15	1.53	0	20			0	0.307		
Apple pomace, wet	AB	0.44	STMR/ STMR-P	40	1.10	10	10			0.11	0.11		
Soya bean meal	SM	0.62	STMR/ STMR-P	92	0.67	10	25		60	0.067391	0.168		0.404
Potato culls	VR	0.11	STMR/ STMR-P	20	0.55	10	10			0.055	0.055		
Soya bean seed	VD	0.45	STMR/ STMR-P	89	0.51	10			10	0.050562			0.051
Cotton undelinted seed	SO	0.095	STMR/ STMR-P	88	0.11	10				0.010795			
Total						80	100	100	70	4.638193	3.23	10.79	0.455

POULTRY BROILER		**SPIROTETRAMAT**											MAX
Commodity	CC	Residue	Basis	DM	Residue	Diet content (%)				Residue Contribution (ppm)			
		(mg/kg)		(%)	dw (mg/kg)	US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Potato culls	VR	0.44	HR	20	2.20		10				0.22		
Soya bean meal	SM	0.62	STMR	92	0.67	25	40	25	35	0.168478	0.27	0.168	0.236
Soya bean seed	VD	0.45	STMR	89	0.51	20	20	15		0.101124	0.101	0.076	
Bean seed	VD	0.21	STMR	88	0.24			60				0.143	
Total						45	70	100	35	0.269602	0.591	0.388	0.236

POULTRY BROILER	**SPIROTETRAMAT**												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
Soya bean meal	SM	0.62	STMR/STMR-P	92	0.67	25	40	25	35	0.168478	0.27	0.168	0.236
Potato culls	VR	0.11	STMR/STMR-P	20	0.55		10				0.055		
Soya bean seed	VD	0.45	STMR/STMR-P	89	0.51	20	20	15		0.101124	0.101	0.076	
Bean seed	VD	0.21	STMR/STMR-P	88	0.24			60				0.143	
Total						45	70	100	35	0.269602	0.426	0.388	0.236

POULTRY LAYER		**SPIROTETRAMAT**											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
Soya bean forage	AL	22.4	HR	56	40.00		10				4		
Cabbage heads, leaves	AM/AV	0.92	HR	15	6.13		5				0.307		
Potato culls	VR	0.44	HR	20	2.20		10				0.22		
Soya bean meal	SM	0.62	STMR	92	0.67	25	25	25	30	0.168478	0.168	0.168	0.202
Soya bean seed	VD	0.45	STMR	89	0.51	20	15	15		0.101124	0.076	0.076	
Bean seed	VD	0.21	STMR	88	0.24		5	60			0.012	0.143	
Total						45	70	100	30	0.269602	4.783	0.388	0.202

POULTRY LAYER		**SPIROTETRAMAT**											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
Soya bean forage	AL	10.64	STMR/ STMR-P	56	19.00		10				1.9		
Cabbage heads, leaves	AM/AV	0.23	STMR/ STMR-P	15	1.53		5				0.077		
Soya bean meal	SM	0.62	STMR/ STMR-P	92	0.67	25	25	25	30	0.168478	0.168	0.168	0.202
Potato culls	VR	0.11	STMR/ STMR-P	20	0.55		10				0.055		
Soya bean seed	VD	0.45	STMR/ STMR-P	89	0.51	20	15	15		0.101124	0.076	0.076	
Bean seed	VD	0.21	STMR/ STMR-P	88	0.24		5	60			0.012	0.143	
Total						45	70	100	30	0.269602	2.288	0.388	0.202

BEEF CATTLE	**SULFOXAFLOR**												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				1.39		
Cotton gin by products	AM/AV	4	HR	90	4.44	5				0.22			
Soya bean forage	AL	1.7	HR	56	3.04			100				3.04	
Barley hay	AF/AS	1.8	HR	100	1.80	15				0.27			
Barley straw	AF/AS	1.8	HR	100	1.80		30				0.54		
Soya bean asp gr fn	SM	1	STMR	85	1.18	5				0.06			
Wheat asp gr fn	CM/CF	0.53	STMR	85	0.62	5				0.03			
Apple pomace, wet	AB	0.077	STMR	40	0.19		20				0.04		
Beet, sugar molasses	DM	0.14	STMR	75	0.19	10	10			0.02	0.02		
Barley grain	GC	0.063	STMR	88	0.07	50	20		70	0.04	0.01		0.05
Potato culls	VR	0.01	HR	20	0.05	10				0.01			
Soya bean meal	SM	0.014	STMR	92	0.02				30				0.00
Total						100	100	100	100	0.64	2.00	3.04	0.05

DAIRY CATTLE	**SULFOXAFLOR**												MAX
Commodity	CC	Residue	Basis	DM	Residue dw	Diet content (%)				Residue Contribution (ppm)			
		(mg/kg)		(%)	(mg/kg)	US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Beet, sugar tops	AM/AV	1.6	HR	23	6.96		30				2.09		
Soya bean forage	AL	1.7	HR	56	3.04	20		40		0.61		1.21	
Almond hulls	AM/AV	1.8	STMR	90	2.00	10		10		0.20		0.20	
Barley hay	AF/AS	1.8	HR	100	1.80	20		50		0.36		0.90	
Barley straw	AF/AS	1.8	HR	100	1.80		30				0.54		
Apple pomace, wet	AB	0.077	STMR	40	0.19	10	10			0.02	0.02		
Beet, sugar molasses	DM	0.14	STMR	75	0.19	10	10			0.02	0.02		
Canola meal	SM	0.086	STMR	88	0.10	10	10			0.01	0.01		
Barley grain	GC	0.063	STMR	88	0.07	20	10		40	0.01	0.01		0.03
Soya bean meal	SM	0.014	STMR	92	0.02				60				0.01
Total						100	100	100	100	1.23	2.68	2.31	0.04

POULTRY BROILER	**SULFOXAFLOR**												MAX
Commodity	CC	Residue	Basis	DM	Residue dw	Diet content (%)				Residue Contribution (ppm)			
		(mg/kg)		(%)	(mg/kg)	US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Canola meal	SM	0.086	STMR	88	0.10	15	18	5		0.01	0.02	0.00	
Barley grain	GC	0.063	STMR	88	0.07	75	70	15	10	0.05	0.05	0.01	0.01
Potato culls	VR	0.01	HR	20	0.05		10				0.01		
Soya bean hulls	SM	0.017	STMR	90	0.02		2				0.00		
Soya bean meal	SM	0.014	STMR	92	0.02	10		20	35	0.00		0.00	0.01
Soya bean seed	VD	0.011	STMR	89	0.01			15				0.00	
Total						100	100	55	45	0.07	0.07	0.02	0.01

POULTRY LAYER	**SULFOXAFLOR**												MAX
Commodity	CC	Residue	Basis	DM	Residue dw	Diet content (%)				Residue Contribution (ppm)			
		(mg/kg)		(%)	(mg/kg)	US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Beet, sugar tops	AM/AV	1.6	HR	23	6.96		5				0.35		
Soya bean forage	AL	1.7	HR	56	3.04		10				0.30		
Barley straw	AF/AS	1.8	HR	100	1.80		5				0.09		
Wheat forage	AF/AS	0.44	HR	25	1.76		5				0.09		
Canola meal	SM	0.086	STMR	88	0.10	15	10	5		0.01	0.01	0.00	
Barley grain	GC	0.063	STMR	88	0.07	75	65	15		0.05	0.05	0.01	
Soya bean meal	SM	0.014	STMR	92	0.02	10		20	30	0.00		0.00	0.00
Soya bean seed	VD	0.011	STMR	89	0.01			15				0.00	
Total						100	100	55	30	0.07	0.89	0.02	0.00

BEEF CATTLE	**SULFOXAFLOR**												MEAN
Commodity	CC	Residue	Basis	DM	Residue dw	Diet content (%)				Residue Contribution (ppm)			
		(mg/kg)		(%)	(mg/kg)	US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Almond hulls	AM/AV	1.8	STMR	90	2.00			10				0.20	
Beet, sugar tops	AM/AV	0.42	STMR	23	1.83		20				0.37		
Soya bean asp gr fn	SM	1	STMR	85	1.18	5				0.06			
Soya bean hay	AL	0.67	STMR	85	0.79			80				0.63	
Wheat forage	AF/AS	0.19	STMR	25	0.76		20	10			0.15	0.08	
Wheat asp gr fn	CM/CF	0.53	STMR	85	0.62	5				0.03			
Apple pomace, wet	AB	0.077	STMR-P	40	0.19		20				0.04		
Beet, sugar molasses	DM	0.14	STMR-P	75	0.19	10	10			0.02	0.02		
Cotton gin by-products	AM/AV	0.15	STMR	90	0.17	5				0.01			
Barley hay	AF/AS	0.14	STMR	100	0.14	15				0.02			
Barley straw	AF/AS	0.14	STMR	100	0.14		10				0.01		
Barley grain	GC	0.063	STMR	88	0.07	50	20		70	0.04	0.01		0.05
Potato culls	VR	0.01	STMR	20	0.05	10				0.01			
Soya bean meal	SM	0.014	STMR-P	92	0.02				30				0.00
Total						100	100	100	100	0.18	0.60	0.91	0.05

DAIRY CATTLE		**SULFOXAFLOR**											MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%) US-CAN	EU	AU	JP	Residue Contribution (ppm) US-CAN	EU	AU	JP
Almond hulls	AM/AV	1.8	STMR	90	2.00	10	0	10		0.20	0.00	0.20	
Beet, sugar tops	AM/AV	0.42	STMR	23	1.83	0	30			0.00	0.55		
Soya bean hay	AL	0.67	STMR	85	0.79	20		40		0.16		0.32	
Wheat forage	AF/AS	0.19	STMR	25	0.76	20	20	50		0.15	0.15	0.38	
Apple pomace, wet	AB	0.077	STMR-P	40	0.19	10	10			0.02	0.02		
Beet, sugar molasses	DM	0.14	STMR-P	75	0.19	10	10			0.02	0.02		
Barley straw	AF/AS	0.14	STMR	100	0.14	0	10			0.00	0.01		
Canola meal	SM	0.086	STMR-P	88	0.10	10	10			0.01	0.01		
Barley grain	GC	0.063	STMR/STMR-P	88	0.07	20	10		40	0.01	0.01		0.03
Soya bean meal	SM	0.014	STMR	92	0.02	0			60	0.00			0.01
Total						100	100	100	100	0.57	0.77	0.90	0.04

POULTRY BROILER		**SULFOXAFLOR**											MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%) US-CAN	EU	AU	JP	Residue Contribution (ppm) US-CAN	EU	AU	JP
Canola meal	SM	0.086	STMR-P	88	0.10	15	18	5		0.01	0.02	0.00	
Barley grain	GC	0.063	STMR	88	0.07	75	70	15	10	0.05	0.05	0.01	0.01
Potato culls	VR	0.01	STMR	20	0.05		10				0.01		
Soya bean hulls	SM	0.017	STMR	90	0.02		2				0.00		
Soya bean meal	SM	0.014	STMR-P	92	0.02	10		20	35	0.00		0.00	0.01
Soya bean seed	VD	0.011	STMR	89	0.01			15				0.00	
Total						100	100	55	45	0.07	0.07	0.02	0.01

POULTRY LAYER		SULFOXAFLOR											**MEAN**
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%) US-CAN	EU	AU	JP	Residue Contribution (ppm) US-CAN	EU	AU	JP
Beet, sugar tops	AM/AV	0.42	STMR	23	1.83		5				0.09		
Soya bean hay	AL	0.67	STMR	85	0.79		10				0.08		
Wheat forage	AF/AS	0.19	STMR	25	0.76		10				0.08		
Canola meal	SM	0.086	STMR-P	88	0.10	15	10	5		0.01	0.01	0.00	
Barley grain	GC	0.063	STMR	88	0.07	75	65	15		0.05	0.05	0.01	
Soya bean meal	SM	0.014	STMR-P	92	0.02	10		20	30	0.00		0.00	0.00
Soya bean seed	VD	0.011	STMR	89	0.01			15				0.00	
Total						100	100	55	30	0.07	0.30	0.02	0.00

BEEF CATTLE - MAX		**TEBUCONAZOLE**				Diet content (%)				Residue Contribution (ppm)			
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Barley forage	AF/AS	18	HR	30	60.00		30	50			18	30	
Wheat forage	AF/AS	12	HR	25	48.00			50				24	
Rape forage	AM/AV	11	HR	30	36.67		10				3.667		
Barley straw	AF/AS	17	HR	89	19.10	10				1.910			
Corn, field forage/silage	AF/AS	2.9	HR	40	7.25	5	60			0.3625	4.35		
Soya bean asp gr fn	SM	5.52	STMR	85	6.49	5				0.3247			
Cotton gin by-products	AM/AV	13	HR	90	4.56	5				0.72			
Rice grain	GC	0.275	STMR	88	0.31	20				0.062			
Barley grain	GC	0.085	STMR	88	0.10	30			70	0.029			0.068
Oat grain	GC	0.085	STMR	89	0.10				30				0.029
Soya bean hulls	SM	0.022	STMR	90	0.02	10				0.0024			

Soya bean seed	VD	0.02	STMR	89	0.02	5				0.0011			
Total						90	100	100	100	3.4	26.0	54	0.096

BEEF CATTLE - MEAN			**TEBUCONAZOLE**			Diet content (%)				Residue Contribution (ppm)			
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Barley forage	AF/AS	5.8	STMR/STMR-P	30	19.33		30	50			5.75	9.58	
Wheat forage	AF/AS	4.6	STMR/STMR-P	25	18.40			50				9.4	
Rape forage	AM/AV	4.2	STMR/STMR-P	30	14.00		10				1.4		
Soya bean asp gr fn	SM	5.52	STMR/STMR-P	85	6.49	5				0.3247			
Rye straw	AF/AS	3.3	STMR/STMR-P	88	3.75	10				0.375			
Apple pomace, dry	AB	3.5	STMR/STMR-P	100	3.50		20				0.7		
Cotton gin by-products	AM/AV	5.6	STMR/STMR-P	90	1.89	5				0.31			
Corn, field forage/silage	AF/AS	0.405	STMR/STMR-P	40	1.01	5	40			0.0506	0.405		
Rice grain	GC	0.275	STMR/STMR-P	88	0.31	20				0.0625			
Barley grain	GC	0.085	STMR/STMR-P	88	0.10	30			70	0.029			0.068
Oat grain	GC	0.085	STMR/STMR-P	89	0.10				30				0.029
Soya bean hulls	SM	0.022	STMR/STMR-P	90	0.02	10				0.0024			
Soya bean seed	VD	0.02	STMR/STMR-P	89	0.02	5				0.0011			
Total						90	100	100	100	1.2	8.3	18.9	0.097

DAIRY CATTLE - MAX		**TEBUCONAZOLE**				Diet content (%)				Residue Contribution (ppm)			
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Barley forage	AF/AS	18	HR	30	60.00		30	50			18	30	
Wheat forage	AF/AS	12	HR	25	48.00	20		50		9.6		24	
Rape forage	AM/AV	11	HR	30	36.67	10	10			3.667	3.667		
Peanut hay	AL	23	HR	85	27.06	15				4.059			
Rye straw	AF/AS	12	HR	88	13.64				5				0.682
Corn, field forage/silage	AF/AS	2.9	HR	40	7.25	25	30		45	1.812	2.175		3.263
Apple pomace, dry	AB	3.5	STMR	100	3.50	10	10			0.35	0.35		
Rice grain	GC	0.275	STMR	88	0.31	20				0.062			
Barley grain	GC	0.085	STMR	88	0.10		20		40		0.019		0.039
Rye grain	GC	0.05	STMR	88	0.06				10				0.006
Total						100	100	100	100	19.6	24.21	54	3.989

DAIRY CATTLE - MEAN		**TEBUCONAZOLE**				Diet content (%)				Residue Contribution (ppm)			
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Barley forage	AF/AS	5.8	STMR/STMR-P	30	19.33		30	50			5.8	9.667	
Wheat forage	AF/AS	4.6	STMR/STMR-P	25	18.40	20		50		3.76		9.2	
Rape forage	AM/AV	4.2	STMR/STMR-P	30	14.00	10	10			1.4	1.4		
Peanut hay	AL	9.25	STMR/STMR-P	85	10.88	15				1.632			
Rye straw	AF/AS	3.3	STMR/STMR-P	88	3.75	0			5	0			0.188
Apple pomace, dry	AB	3.5	STMR/STMR-P	100	3.50	10	10			0.35	0.35		
Corn, field forage/silage	AF/AS	0.405	STMR/STMR-P	40	1.01	25	50		45	0.2535	0.506		0.456
Rice grain	GC	0.275	STMR/STMR-P	88	0.31	20				0.0625			
Barley grain	GC	0.085	STMR/STMR-P	88	0.10	0			40	0			0.039
Rye grain	GC	0.05	STMR/STMR-P	88	0.06	0			10	0			0.006
Total						100	100	100	100	7.38	8.06	18.9	0.687

POULTRY BROILER - MAX		**TEBUCONAZOLE**				Diet content (%)				Residue Contribution (ppm)			
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Rice grain	GC	0.275	STMR	88	0.31	20		50		0.0625		0.156	
Barley grain	GC	0.085	STMR	88	0.10	55	70		10	0.053125	0.068		0.01

Oat grain	GC	0.085	STMR	89	0.10	25	30			0.023876	0.029		
Canola meal	SM	0.08	STMR	88	0.09			5				0.005	
Bean seed	VD	0.05	STMR	88	0.06			45				0.026	
Soya bean meal	SM	0.004	STMR	92	0.00				35				0.002
Total						100	100	100	45	0.14	0.096	0.186	0.011

POULTRY BROILER MEAN		**TEBUCONAZOLE**				Diet content (%)				Residue Contribution (ppm)			
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Rice grain	GC	0.275	STMR/ STMR-P	88	0.31	20		50		0.0625		0.156	
Barley grain	GC	0.085	STMR/ STMR-P	88	0.10	55	70		10	0.053125	0.068		0.01
Oat grain	GC	0.085	STMR/ STMR-P	89	0.10	25	30			0.023876	0.029		
Canola meal	SM	0.08	STMR/ STMR-P	88	0.09			5				0.005	
Bean seed	VD	0.05	STMR/ STMR-P	88	0.06			45				0.026	
Soya bean meal	SM	0.004	STMR/ STMR-P	92	0.00				35				0.002
Total						100	100	100	45	0.134	0.096	0.186	0.011

POULTRY LAYER MAX		**TEBUCONAZOLE**				Diet content (%)				Residue Contribution (ppm)			
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Wheat forage	AF/AS	12	HR	25	48.00		10				4.8		
Rape forage	AM/AV	11	HR	30	36.67		10				3.667		
Rice grain	GC	0.275	STMR	88	0.31	20		50		0.0625		0.156	
Barley grain	GC	0.085	STMR	88	0.10	55	80			0.0531	0.077		
Oat grain	GC	0.085	STMR	89	0.10	25				0.0239			
Canola meal	SM	0.08	STMR	88	0.09			5				0.005	
Bean seed	VD	0.05	STMR	88	0.06			45				0.026	
Soya bean meal	SM	0.004	STMR	92	0.00				30				0.001
Total						100	100	100	30	0.139	8.544	0.186	0.001

POULTRY LAYER MEAN	**TEBUCONAZOLE**					Diet content (%)				Residue Contribution (ppm)			
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Wheat forage	AF/AS	4.6	STMR/STMR-P	25	18.40		10				1.84		
Rape forage	AM/AV	4.2	STMR/STMR-P	30	14.00		10				1.4		
Rice grain	GC	0.275	STMR/STMR-P	88	0.31	20		50		0.0625		0.156	
Barley grain	GC	0.085	STMR/STMR-P	88	0.10	55	80			0.053125	0.077		
Oat grain	GC	0.085	STMR/STMR-P	89	0.10	25				0.023876			
Canola meal	SM	0.08	STMR/STMR-P	88	0.09			5				0.005	
Bean seed	VD	0.05	STMR/STMR-P	88	0.06			45				0.026	
Soya bean meal	SM	0.004	STMR/STMR-P	92	0.00				30				0.001
Total						100	100	100	30	0.139501	3.317	0.186	0.001

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