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Pesticide residues in food 2016

Joint FAO/WHO Meeting
on Pesticide Residues

REPORT 2016

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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
Rome, Italy, 13–22 September 2016

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R, residue and analytical aspects; T, toxicological evaluation

* New compound

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

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ABBREVIATIONS

ADI	acceptable daily intake
AHS	Agricultural Health Study
ai	active ingredient
AIC	Akaike Information Criterion
AR	applied radioactivity
ARfD	acute reference dose
as	as received
asp gr fn	aspirated grain fraction
AU	Australia
AUC	area under the plasma concentration–time curve
BBCH	B iologischen B undesanstalt, B undessortenamt und C hemische Industrie
BMD	benchmark dose
BMD ₁₀	benchmark dose for a 10% response
BMDL	lower 95% confidence limit on the benchmark dose
BMDL ₁₀	lower 95% confidence limit on the benchmark dose for a 10% response
BMDS	Benchmark Dose Software
BSA	3,4,4-trifluorobut-3-ene-1-sulfonic acid
bw	body weight
CA	Chemical Abstracts
CAC	Codex Alimentarius Commission
CAS	Chemical Abstracts Service
CCN	Codex classification number (for compounds or commodities)
CCPR	Codex Committee on Pesticide Residues
cGAP	Critical GAP
C _{max}	maximum concentration in plasma
CSAF	chemical-specific adjustment factor
CYP/Cyp	cytochrome P450
DAA	days after application
DALA	days after last application
DAT	days after treatment
DM	dry matter
DNA	deoxyribonucleic acid
DT ₅₀	time required for 50% dissipation of the initial concentration
DT ₉₀	time required for 90% dissipation of the initial concentration

dw	dry weight
ECD	electron capture detector
EFSA	European Food Safety Authority
EHC	Environmental Health Criteria monograph
EU	European Union
¹⁹ F-NMR	Fluorine-19 nuclear magnetic resonance
F ₀	parental generation
F ₁	first filial generation
F ₂	second filial generation
FAO	Food and Agriculture Organization of the United Nations
fw	fresh weight
GAP	good agricultural practice
GC	gas chromatography
GC-ECD	gas chromatography with electron capture detection
GC/MS	gas chromatography/mass spectrometry
GC-NPD	gas chromatography coupled with nitrogen-phosphorus detector
GEMS/Food	Global Environment Monitoring System – Food Contamination Monitoring and Assessment Programme
GGT	gamma-glutamyltransferase
GI	gastrointestinal
GLP	good laboratory practice
GPC	gel permeation chromatography
HPLC	high performance liquid chromatography
HPLC-UV	high performance liquid chromatography with UV detector
HPRT	hypoxanthine–guanine phosphoribosyltransferase
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
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
JP	Japan
LC ₅₀	median lethal concentration

LD ₅₀	median lethal dose
LOAEL	lowest-observed-adverse-effect level
LOD	limit of detection
log P _{ow}	octanol-water partition coefficient
LOQ	limit of quantification
MeS	2-methylsulfonyl-1,3-thiazole
MRL	maximum residue limit
MS	mass spectrometry
MS/MS	tandem mass spectrometry
NOAEC	no-observed-adverse-effect concentration
NOAEL	no-observed-adverse-effect level
OECD	Organisation for Economic Co-operation and Development
PBI	plant back interval
PES	post extraction solids
Pf	processing factor
PHI	pre-harvest interval
ppm	parts per million
QSAR	quantitative structure–activity relationship
RAC	raw agricultural commodity
RSD	relative standard deviation
RTI	re-treatment interval
S9	9000 × g supernatant fraction from rat liver homogenate
SC	suspension concentrate
SL	soluble liquid
SPE	solid phase extraction
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 the maximum concentration in plasma/blood
TRR	total radioactive residues
TSA	5-chloro-1,3-thiazole-2-sulfonic acid
TSH	thyroid stimulating hormone
TTC	threshold of toxicological concern
UK	United Kingdom

USA	United States of America
US/CAN	United States and Canada
USEPA	United States Environmental Protection Agency
WG	wettable granule
WHO	World Health Organization
WP	wettable powder

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 2016 JOINT FAO/WHO MEETING OF EXPERTS

1. INTRODUCTION

A Joint Meeting of the Food and Agriculture Organization of the United Nations (FAO) Panel of Experts on Pesticide Residues in Food and the Environment and the World Health Organization (WHO) Core Assessment Group on Pesticide Residues (JMPR) was held at FAO Head-quarters, Rome (Italy), from 13 to 23 September 2016. The FAO Panel Members met in preparatory sessions from 8–12 September.

The Meeting was opened by Mr Bill Murray, Deputy Director, Plant Production and Protection Division (AGP), FAO. On behalf of FAO and WHO, Mr Murray welcomed and thanked the participants for providing their expertise and for devoting significant time and effort to the work of the JMPR. Mr Murray noted the important contribution of the JMPRs work in trade facilitation through the establishment of global standards for pesticide residues in food and feed, and in food safety via the published pesticide risk assessments, further underscoring the continued relevance of the JMPRs work.

Mr Murray also acknowledged the progress made by the JMPR in recent years in improving the transparency of its procedures and operational efficiencies while at the same time continuing to consider and incorporate new scientific principles and methodologies. He suggested the success of these efforts was demonstrated by the increasing importance and impact of the JMPRs work internationally. He highlighted recent examples such as the incorporation of JMPR Evaluations by national and regional regulatory authorities into their assessments; the increasing level of adoption by member countries of CODEX MRLs as recommended by JMPR; and the contribution of the JMPRs recent assessment of glyphosate to the global discussion on its continued use.

Mr Murray then suggested that perhaps the most significant example of JMPRs success was the continued and growing demand for JMPR assessments, with the number of compound nominations from member countries, through the Codex Committee on Pesticide Residues (CCPR), having increased by 70% from 2010 to 2015, while noting the constraints under which the JMPR operates.

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

The Meeting evaluated 29 pesticides, including nine new compounds and three compounds that were re-evaluated within the periodic review programme of the CCPR, for toxicity or residues, or both.

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

The Meeting also estimated the dietary exposures (both short-term and long-term) of the pesticides reviewed and, on this basis, performed dietary risk assessments 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 of 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 maximum residue levels in food and feed (2016).

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

1.1 Declaration of Interests

The Secretariat informed the Meeting that all experts participating in the 2016 JMPR had completed declaration-of-interest forms and that no conflicts had been identified.

2. GENERAL CONSIDERATIONS

2.1 Update on the revision of *Principles and Methods for Risk Assessment of Chemicals in Food* (EHC 240)

2.1.1 Benchmark dose

The present Meeting utilized the results of benchmark dose (BMD) modelling in its assessment of teflubenzuron (see section 5.24). Although Environmental Health Criteria (EHC) 239 (*Principles for modelling dose–response for the risk assessment of chemicals*; <http://www.inchem.org/documents/ehc/ehc/ehc239.pdf>) and EHC 240 (<http://www.who.int/foodsafety/publications/chemical-food/en/>) provide guidance on the application, performance and interpretation of dose–response modelling, the Meeting felt that a number of additional points had emerged since publication of these guidance documents that need to be considered or emphasized.

In the BMD approach, criteria for judging model relevance using biological understanding are paramount. This includes the judgement of which types of data (e.g. external versus internal doses) should be put into the model. Biological considerations should take precedence over mathematical analysis when a clear way forward is not obvious. The results should be assessed for model fit using criteria described, for example, in the United States Environmental Protection Agency's (USEPA) Benchmark Dose Software (BMDS) guidance document (https://www.epa.gov/sites/production/files/2015-01/documents/benchmark_dose_guidance.pdf). The criteria consist of adequacy determinations of *P*-value, scaled residual, visual fit, determining whether the remaining models reflect no particular influence of the individual models (e.g. ratio between BMD and lower 95% confidence limit on the BMD, or BMDL), Akaike Information Criterion (AIC) and expert judgement. Each of these criteria needs to be addressed and also weighed in the sequence suggested, in order to make choices that are most biologically reasonable.

As this is a general item, the Meeting recommended that EHC 240 be updated to reflect experience gained in the application of dose–response modelling since the guidance was published.

2.1.2 Chemical-specific adjustment factors (CSAFs)

The Meeting received an overview of the CSAF approach. Dr Richard Brown of WHO then updated the Meeting on an ongoing activity within the WHO Risk Assessment Network, in which experience, progress and obstacles in the application of the CSAF approach since its introduction in 2005 were being evaluated. Following compilation of CSAFs both successfully and unsuccessfully applied in risk assessment, a review workshop was held, and the outcome will be published in the peer-reviewed literature. The need for clear terminology, templates for common reporting format and updated guidance was identified and will be the subject of further activity. Once complete, this may necessitate an update to the relevant section of EHC 240.

2.1.3 Guidance on the use and interpretation of statistical evaluations and historical control data

In EHC 240, some guidance is given on the use and interpretation of statistical evaluations and historical control data within the evaluation of toxicological data of compounds. Further details are provided in the JMPR guidance document for WHO monographers and reviewers (<http://www.who.int/foodsafety/publications/JMPR-guidance-document/en/>). However, the Meeting noted that some aspects of the use of statistics and the use of historical control data need elaboration or clarification. For example, this Meeting discussed the issues of multiple comparisons (e.g. pendimethalin; see section 5.19) and the use of historical control data (e.g. pinoxaden; see section 5.20).

In view of the relevance of these issues, the Meeting recommended that a joint JMPR/Joint FAO/WHO Expert Committee on Food Additives (JECFA) electronic working group be convened to consider possible amendments to EHC 240.

2.2 JMPR guidance documents for WHO monographers and reviewers

The Meeting recommended that the JMPR guidance document for WHO monographers and reviewers (<http://www.who.int/foodsafety/publications/JMPR-guidance-document/en/>) be updated, as appropriate, with the results of discussions on the issues raised in section 2.1.

2.3 Evaluation of genotoxicity data

The Meeting considered a number of issues related to genotoxicity evaluations, including a weight of evidence approach. The Meeting noted the intention of WHO to establish a working group to update the EHC 240 guidance on genotoxicity and expressed the need for specific considerations on pesticide residues. The Meeting raised in particular the need for guidance to balance data from regulatory dossiers and from published studies, the former usually providing more detailed information on the methodology and findings.

2.4 Update of the OECD Livestock Animal Burden Feed Table

The Meeting noted that the OECD Livestock animal dietary burden feed table, used for the estimation of livestock animal dietary burden, has been updated (Guidance Document on Residues in Livestock, Series on Pesticides No. 73, ENV/JM/MONO(2013)8; [http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono\(2013\)8&doclanguage=en](http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2013)8&doclanguage=en)).

The Meeting decided to incorporate this update, using the consolidated feed compositions for USA/Canada, the EU, Australia and Japan, beginning with the 2017 Meeting.

3. RESPONSES TO SPECIFIC ISSUES

3.1 Concerns raised by the the Codex Committee on Pesticide Residues (CCPR)

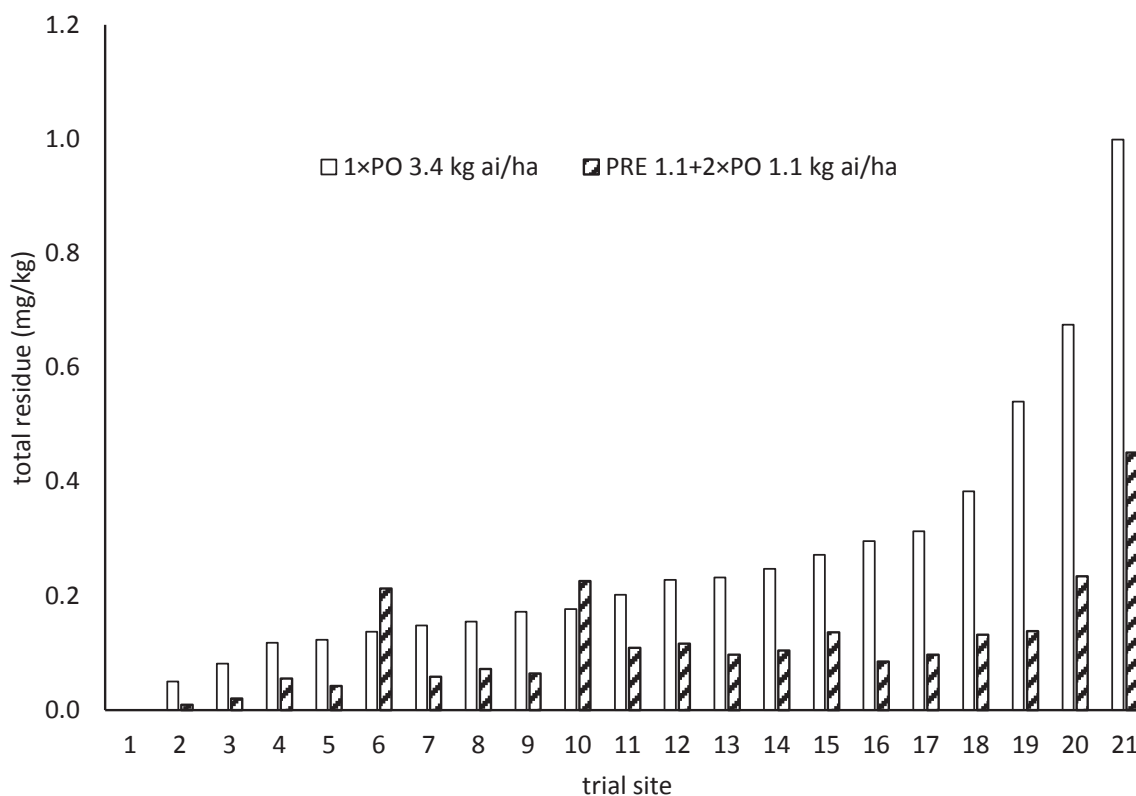
3.1.1 Acetochlor (280)

Background

Acetochlor was first evaluated by the JMPR in 2015. Following the 48th Session of the CPPR a concern form was submitted by the USA relating to the 2015 JMPR not recommending a maximum residue level for soya beans. In the USA acetochlor is approved for use on soya beans. GAP in the USA is applications pre-plant, pre-emergence or post-emergence but before the R2 growth stage (full flowering) at up to 1.7 kg ai/ha with a PHI not required. The maximum rate per year is 3.4 kg ai/ha.

No recommendation was made as the 2015 Meeting considered none of the trials as matching critical GAP (2×1.7 kg ai/ha post-emergence applications) as they included a pre-plant/pre-emergent application and that none were deemed suitable for application of the proportionality approach. The concern form proposed that the proportionality approach could be used for the soya bean trials and noted that:

- In the acetochlor soya bean metabolism study, total radioactive residues (TRR) in the soya beans resulting from a single 3.4 kg ai/ha pre-plant application were low. Scaled to an application rate of 1.12 kg ai/ha, the 45-day pre-plant application would result in TRR of 0.06 mg equiv/kg in soya bean seed at harvest.
- In the confined rotational crop study where soya beans were planted 30-days after a 3.1 kg ai/ha application of acetochlor to bare ground, TRR in the harvested soya beans were low. Scaled to an application rate of 1.12 kg ai/ha, the TRR in soya bean seed were 0.03 mg equiv/kg.
- A comparison of residues following a single application of 3.4 kg ai/ha at growth stage R1/R2 with those following a pre-plant and two post-emergence applications of 1.12 kg ai/ha each shows the post-emergence application at growth stage R1/R2 accounts for most of the residues at harvest, see figure below. Although the total applied acetochlor is (3.4 kg ai/ha) is the same for the two treatments, the application rate at growth stage R1/R2 for the single spray at 3.4 kg ai/ha is $3 \times$ the application rate at growth stage R1/R2 for three applications at 1.12 kg ai/ha. If all residues in seed at harvest were due to the R1/R2 application alone, the residues following the three applications should be $3 \times$ those following the single application. On average, the ratio of residues in seed at each site is 2.5, indicating that the last post-emergence application contributes most to the residues in seed.



- The pre-plant application (included in the residue study treatment but not in the cGAP) makes a negligible contribution to residues at harvest, compared to the two subsequent post-emergence applications at growth stages V3 and R1/R2.

Comments by JMPR

The Meeting noted that the trials submitted to the 2015 JMPR either involved a single post-emergent application at a nominal rate of 3.4 kg ai/ha at growth stage R1-R2 (beginning flowering to full flowering) or three applications, one pre-plant (45 days prior to planting), and two post-emergence (3rd trifoliolate leaf and R1-R2), each nominally at 1.12 kg ai/ha to give a seasonal application rate of 3.4 kg ai/ha.

The CCPR developed “Principles and guidance for application of the proportionality concept for estimation of maximum residue limits for pesticides” that restrict the use of the proportionality approach. Principle 4 states “*Scaling is only acceptable if the application rate is the only deviation from critical GAP (cGAP). In agreement with JMPR practice, additional use of the ±25% rule for other parameters such as PHI is not acceptable. For additional uncertainties introduced, e.g. use of global residue data, these need to be considered on a case-by-case basis so that the overall uncertainty of the residue estimate is not increased*”.

The available trials utilised three applications compared to critical GAP which is two post-emergent applications, each at 1.7 kg ai/ha with the last prior to full flowering (R2 growth stage). The 2015 JMPR considered trials with three applications could be considered for use of the proportionality approach if the initial pre-emergent application did not contribute to the final residue. However, pre-plant and pre-emergence applications give rise to residues in soya beans at harvest as noted above. In a rotational crop study residues in soya bean follow crops were planted 253-425 days after application to a primary maize crop at 2.2 kg ai/ha, residues in grain ranged from < 0.02 to

0.1 mg/kg suggesting the pre-plant application might contribute < 0.02 to 0.05 mg/kg to the terminal residue.

The Meeting confirmed its previous conclusion that, based on the CCPR principles and guidance, the data are not suitable for the application of the proportionality approach. With regards to maize, application of the proportionality approach by the 2015 JMPR was possible as in that case, residues at harvest from the pre-plant applications were <LOQ.

3.1.2 Chlorothalonil (081)

se of chlorothalonil on cranberries were evaluated by the 2015 JMPR, concluding storage stability data for both parent chlorothalonil and its metabolite SDS-3701 indicated a potential degradation within 10 months, which was the only interval tested. Samples from supervised field trials have been stored for such an interval and were therefore considered invalid by the Meeting.

At the 48th Session of the CCPR, the USA raised a concern to this decision, pointing out that under consideration of the procedural recovery data correction for the degradation could be made and that a dietary intake concern does not arise from residues of chlorothalonil in cranberries.

The Meeting reviewed the data submitted in 2015. In the respective storage stability study residues recovered in cranberry samples were generally below 70% for both analytes (55–70% for chlorothalonil, 38–39% for SDS-3701). In addition, procedural recoveries were also below 70% for both analytes (58–64% for chlorothalonil, 66–74% for SDS-3701). Since both, fortified sample recoveries and procedural recoveries were below 70%, the study is generally unsuitable to draw conclusions on the stability of chlorothalonil and SDS-3701 residues in cranberries. The Meeting therefore confirms its previous conclusion on the invalidity of the study.

3.1.3 Flonicamid (282)

Background

At the 48th Meeting of the Codex Committee on Pesticide Residues (CCPR), the JMPR Secretariat advised the Committee that the livestock dietary burden for flonicamid would be reviewed by the 2016 JMPR and the Committee agreed to hold the proposed draft MRLs for commodities of animal origin and for animal feed (and associated) commodities at Step 4 and to advance all other proposed draft MRLs to Step 5/8.

The Committee noted that the USA had submitted a concern form requesting a review of the JMPR decision on MRLs for cucurbits based upon the greenhouse cucumber data. The JMPR Secretariat clarified that with the current principle JMPR was not able to make an estimation on MRLs for cucurbits but that the 2016 JMPR would provide a reply to the concern form for consideration by CCPR49.

JMPR responses

Fruiting vegetables, Cucurbits

The label from the USA allows foliar or soil/growth media applications to greenhouse cucumbers. Based on the supervised residue trials on greenhouse cucumbers reviewed by the 2015 Meeting, the foliar application was determined to be the method which resulted in the highest residues (0.54 mg/kg). Due to there being only four trials matching the critical GAP of the USA, the Meeting considered these trials insufficient to recommend a maximum residue level for greenhouse cucumbers. The Meeting confirms its previous recommendation of a maximum residue level of 0.2 mg/kg and an STMR of 0.04 mg/kg for Fruiting Vegetables, Cucurbits.

Residues in animal commodities

The estimated dietary burdens of farm animals and the estimated maximum residue levels for animal commodities were recalculated by the current Meeting to incorporate livestock feeds from the *Brassica* leafy vegetables subgroup (e.g., kale, turnip tops/greens, etc.), as recommended by the 2015 JMPR, using the estimated HR of 8.31 mg/kg and STMR of 4.59 mg/kg for mustard greens.

Estimated dietary burdens of farm animals

Maximum and mean dietary burden calculations for flonicamid are based on the feed items evaluated for cattle and poultry as presented in Annex 6. The calculations were made according to the livestock diets from Australia, the EU, Japan and US-Canada in the OECD feeding table.

	Livestock dietary burden, flonicamid, ppm of dry matter							
	US-Canada		EU		Australia		Japan	
	Max	Mean	Max	Mean	Max	Mean	Max	Mean
Beef cattle	0.27	0.13	17.6	10.1	27.7 ^A	15.3 ^B	0.005	0.005
Dairy cattle	0.12	0.12	11.2	6.2	22.2 ^C	12.2 ^D	0.003	0.003
Poultry - broiler	0.03	0.03	0.008	0.008	0.02	0.02	0	0
Poultry-layer	0	0	2.8 ^E	1.5 ^F	0	0	0	0

^A Suitable for MRL estimates for mammalian meat, fat and edible offal

^B. Suitable for STMR estimates for mammalian meat, edible offal

^C. Suitable for MRL estimates for milks

^D. Suitable for STMR estimates for milks

^E Suitable for MRL estimates for eggs, meat, fat and edible offal of poultry

^F Suitable for STMR estimates for eggs, meat, fat and edible offal of poultry

Animal commodities maximum residue level estimation

	Feed level (ppm) for milk residues	Total flonicamid and TFNA-AM residues in milk (mg/kg)	Feed level for tissue residues (ppm)	Flonicamid and TFNA-AM Residues			
				Muscle	Liver	Kidney	Fat
Maximum residue level - beef or dairy cattle							
Feeding study	6.89	0.03	6.89	0.06	0.07	0.06	<0.02
	23.69	0.11	23.69	0.11	0.15	0.15	0.03
Dietary burden and residue estimate	22.2	0.10	27.7	0.12	0.17	0.17	0.03
STMR - beef or dairy cattle							
Feeding study	6.89	0.03	6.89	0.05	0.06	0.06	0.02
	23.69	0.10	23.69	0.08	0.14	0.13	0.02
Dietary burden and residue estimate	12.2	0.05	15.3	0.06	0.10	0.10	0.02

	Feed level (ppm) for egg residues	Total flonicamid and TFNA-AM residues in eggs (mg/kg)	Feed level for tissue residues (ppm)	Flonicamid and TFNA-AM Residues		
				Muscle	Liver	Fat
Maximum residue level – poultry broiler or layer						
Feeding study	2.51	0.11	2.51	0.07	0.08	0.04
	7.47	0.38	7.47	0.20	0.20	0.09
Dietary burden and residue estimate	2.8	0.12	2.8	0.08	0.09	0.04
STMR – poultry broiler or layer						
Feeding study	0.26	0.02	0.26	<0.02	<0.02	<0.02
	2.51	0.10	2.51	0.06	0.06	0.03
Dietary burden and residue estimate	1.5	0.06	1.5	0.04	0.04	0.04

The Meeting recommends the maximum residue levels of 0.05 mg/kg for mammalian fats and 0.15 mg/kg for each, meat from mammals other than marine mammals and milks and 0.20 mg/kg for edible offal (mammalian), to replace those estimated at the 2015 Meeting. The STMRs for mammalian fats, milks, meat from mammals other than marine mammals and edible offal (mammalian) are 0.02 mg/kg, 0.05 mg/kg, 0.06 mg/kg and 0.10 mg/kg, respectively.

In addition, the Meeting recommends maximum residue levels of 0.15 mg/kg for eggs, 0.05 mg/kg for poultry fats and 0.10 mg/kg for each, edible offal and meat of poultry, to replace those estimated at the 2015 Meeting. The STMR is 0.06 mg/kg for eggs and 0.04 mg/kg for each meat, edible offal and fat.

Dietary risk assessment

Long-term dietary exposure

The International Estimated Dietary Intakes (IEDIs) of flonicamid were re-calculated for the 17 GEMS/Food cluster diets using revised STMRs for animal commodities estimated by the current Meeting (Annex 3). The ADI is 0–0.07 mg/kg bw and the calculated IEDIs were 0–10% of the maximum ADI. The Meeting concluded that the long-term exposure to residues of flonicamid, resulting from the revised dietary burdens is unlikely to present a public health concern.

Short-term dietary exposure

No ARfD was considered necessary. The Meeting concluded that the short-term dietary exposure to flonicamid residues from uses considered by the present Meeting is unlikely to present a public health concern.

3.1.4 Penthiopyrad (253)

The Meeting received confirmative GAP information from Australia for consideration, since maximum residue levels for penthiopyrad are currently retained at Step 4 awaiting JMPR assessment of an animal dietary burden that excludes forage and fodder crops from the Australian diet. In addition, consideration of an alternative GAP for mustard greens should be explored since an exceedance of the ARfD (150%) was identified for this commodity based on US GAP. No study data were submitted to the current Meeting.

The Meeting noted that the confirmative Australian GAP information submitted for penthiopyrad is identical to the Australian GAP already considered by the 2013 Meeting. It was also noted, that the maximum and mean dietary burdens of livestock animals estimated by the 2013

Meeting already considered the registered Australian uses. In 2013 it was decided to exclude feed and fodder commodities (e.g., soya bean forage and fodder) from the calculation for the Australian livestock animal dietary burden, as penthiopyrad is not registered for such uses in Australia and respective feed items are not imported due to quarantine constraints. Thus the maximum and mean livestock animal dietary burdens for ruminants and poultry were estimated for the US-Canadian and EU region, respectively, which were also the basis for the estimation of maximum residue levels, STMR and HR values in animal commodities.

Since both the US-Canadian and the EU livestock animal dietary burdens are unaffected by the confirmative Australian GAP information sent to this Meeting, the 2013 recommendations for penthiopyrad in animal commodities are confirmed. The Meeting points out, that the maximum residue levels recommended in 2013 for penthiopyrad are already based on a refined estimation of the livestock animal dietary burden and that residues in animal commodities were derived using interpolation between dose levels of the feeding studies available.

GAP information provided by Australia allowed no consideration for an alternative GAP for mustard greens. Supervised field trial data on mustard greens are available from Canada and the USA (see 2012 Evaluation), but did not match the newly submitted GAP information from Australia.

3.2 OTHER MATTERS OF INTEREST

3.2.1 Bentazone (172)

Background

Bentazone is the International Organization for Standardization (ISO)-approved common name for 3-isopropyl-1*H*-2,1,3-benzothiadiazin-4(3*H*)-one-2,2-dioxide (International Union of Pure and Applied Chemistry), with the Chemical Abstracts Service (CAS) number 25057-89-0. Bentazone is a post-emergence herbicide that acts by interfering with photosynthesis.

Bentazone was evaluated by JMPR in 2012, as part of the periodic review programme of the Codex Committee on Pesticide Residues (CCPR). The 2012 Meeting established an acceptable daily intake (ADI) of 0–0.09 mg/kg body weight (bw), based on a no-observed-adverse-effect level (NOAEL) of 9 mg/kg bw per day from a 2-year study of toxicity and carcinogenicity in rats for prolonged blood coagulation and clinical chemistry changes indicative of effects on liver and kidney at 35 mg/kg bw per day and application of a safety factor of 100. The 2012 Meeting also reaffirmed its previous conclusion that no acute reference dose (ARfD) was necessary, as the Meeting considered that the post-implantation loss seen in the rat developmental toxicity study was not caused by a single dose and that no other effects were observed in repeated-dose toxicity studies that could be due to a single dose.

During the review of the background document on bentazone for the development of the WHO Guidelines for Drinking-water Quality, which was based on the 2012 JMPR evaluation, two comments were received that pertained to JMPR's conclusion that an ARfD for bentazone was unnecessary. The first comment, received from the European Food Safety Authority (EFSA), referred to its evaluation of bentazone, published in 2015, which concluded that an ARfD of 1 mg/kg bw was required based on the NOAEL of 100 mg/kg bw per day for increased post-implantation loss, reduced number of live fetuses and retarded fetal development observed in the developmental toxicity study in rats and application of an uncertainty factor of 100. The second comment, from Health Canada, identified an acute neurotoxicity study in rats, published in 2012, that was used by the USEPA in 2014 to set an ARfD of 0.5 mg/kg bw.

JMPR, at its meeting in 2015, recommended that bentazone be re-evaluated specifically to determine whether there is a need to establish an ARfD.

Biochemical and toxicological data

Several new biochemical and toxicological studies were made available to the present Meeting. The Meeting evaluated these studies and concluded that only the acute neurotoxicity study would have an impact on the consideration of the need to establish an ARfD for bentazone.

In an acute neurotoxicity study in which rats were administered bentazone by gavage at a single dose of 0, 50, 150 or 400 mg/kg bw, the NOAEL was 50 mg/kg bw, based on decreased motor activity in males observed on day 0 at 150 mg/kg bw.

Toxicological evaluation

Owing to the availability of new data, the Meeting established an ARfD of 0.5 mg/kg bw, based on a NOAEL of 50 mg/kg bw for decreased motor activity in males observed on day 0 in an acute neurotoxicity study in rats, using a safety factor of 100.

An addendum to the toxicological monograph was prepared.

Residue and analytical aspects

Bentazone, a post-emergence herbicide to control dicotyledonous weeds, it was originally evaluated by the JMPR in 1991 and re-evaluated under the periodic review program for toxicology in 2012 and for residues in 2013. The 2012 JMPR established an ADI for bentazone of 0-0.09 mg/kg bw and concluded that no ARfD was necessary. In the present Meeting, the WHO Core Assessment Group reviewed new data and established an ARfD for bentazone of 0.5 mg/kg bw.

Based on the uses assessed by the 2013 Meeting, the short-term dietary exposure for bentazone was estimated by the present Meeting. In the 2013 Meeting, the following residue definition was derived by the Meeting:

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

The residue is not fat soluble.

Dietary risk assessment

In 2013 no HR values were derived for bentazone by the Meeting. Based on the highest residues from datasets used for recommendations, the following HR values were estimated for the short-term dietary exposure calculation, if required: onion, bulb (0.02 mg/kg); spring onions (0.04 mg/kg); sweet corn on the cob (0.01 mg/kg); peas (pods and succulent = immature seeds) (0.74 mg/kg); beans except broad beans and soya beans (0.01 mg/kg); beans, shelled (0); potato (0.06 mg/kg); peanuts (0); herbs, except dry hops (0.05 mg/kg); poultry meat (0); poultry fats (0); poultry edible offal (0) and eggs (0).

Long-term dietary exposure

No changes to the established ADI of 0-0.09 mg/kg bw or additional GAPs were considered by the current Meeting. The previous conclusion, that the long-term exposure to residues of bentazone, resulting from the uses that have been considered by JMPR, is unlikely to present a public health concern, is confirmed.

Short-term dietary exposure

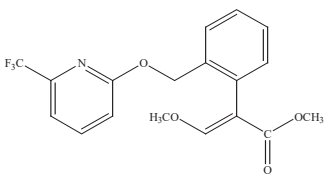
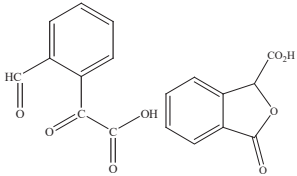
The International Estimated Short term Intake (IESTI) for bentazone was calculated for all food commodities (and their processed fractions) for which recommendations were made by the 2013 Meeting and for which consumption data were available. The results are shown in Annex 4 of the 2016 Report.

For bentazone the IESTI represented 0-1% of the ARfD (0.5 mg/kg bw) for the general population and 0-3% of the ARfD for children. On the basis of information provided to the Meeting it was concluded that the short-term exposure to residues of bentazone, when used in ways that have been considered by the JMPR, is unlikely to present a public health concern.

3.2.2 Picoxystrobin (258)***Background***

Picoxystrobin was evaluated as a new compound by the 2012 JMPR for toxicology and residues. The 2012 JMPR established an ADI of 0-0.09 mg/kg bw for picoxystrobin and an ARfD of 0.09 mg/kg bw.

The 2012 JMPR proposed a residue definition for enforcement of picoxystrobin and estimated a number of maximum residue levels. However, the 2012 JMPR was unable to conclude on the toxicological relevance of two metabolites IN-H8612 and 2-(2-formylphenyl)-2-oxoacetic acid tentatively identified in plant metabolism studies, for which IEDIs were above the threshold of toxicological concern of 0.15 µg/person/day for compounds with alerts for genotoxicity. As a result, it was not possible to propose a residue definition for dietary risk assessment or calculate dietary intakes, and maximum residue levels were not recommended.

Common names	Chemical name	Structure
Picoxystrobin, ZA 1963, DPX-YT669	Methyl (E)-3-methoxy-2-[2-(6-trifluoromethyl-2-pyridyloxymethyl)-phenyl]acrylate	
IN-H8612	1,3-Dihydro-3-oxoisobenzofuran-1-carboxylic acid	
	2-(2-Formylphenyl)-2-oxoacetic acid	

The 2013 JMPR received additional toxicological data (a mouse micronucleus study) for IN-H8612 which showed no evidence of genotoxicity. Conservative estimates for chronic and acute exposure to IN-H8612 were both below the relevant TTC values for Cramer class III compounds with no evidence of genotoxicity. The 2013 JMPR concluded that there was no concern for dietary exposure to IN-H8612. However, no toxicological data were submitted for 2-(2-formylphenyl)-2-oxoacetic acid, as the compound was unable to be synthesised in sufficient amounts. Although argument was provided that levels in soya beans were likely to be extremely low, the 2013 JMPR concluded that genotoxicity data or additional residues information would be required to allow further evaluation of 2-(2-formylphenyl)-2-oxoacetic acid.

Assessment of new data

During the current Meeting, the FAO panel received a new metabolism study for picoxystrobin in soya bean intended to address the concerns regarding 2-(2-formylphenyl)-2-oxoacetic acid, which was reported as a metabolite in mature seed in the soya bean metabolism study considered by the 2012 JMPR.

A preliminary evaluation of the new study indicates that the metabolic pathway for picoxystrobin in soya beans is broadly similar to that observed in the earlier study. Metabolites identified in the new soya bean study were mostly also identified in the plant metabolism studies provided to the 2012 JMPR (for wheat, canola, soya bean and rotational crops).

The 2-(2-formylphenyl)-2-oxoacetic acid metabolite was not identified in the new soya bean study. The Meeting noted that IN-H8612 was a significant metabolite in soya bean matrices in the new study, particularly mature seed. Further, IN-H8612 is a structural isomer of 2-(2-formylphenyl)-2-oxo-acetic acid, and in chromatography conducted for the new metabolism study, IN-H8612 was reported as eluting as two peaks.

Conclusion

The Meeting concluded that further information was required on the possible interconversion of IN-H8612 and 2-(2-formylphenyl)-2-oxoacetic acid, possibly through ring-chain tautomerism.

4. DIETARY RISK ASSESSMENT FOR PESTICIDE RESIDUES IN FOOD

4.1 Long-term dietary exposure

At the present Meeting, an International Estimated Daily Intake (IEDI) was calculated for each compound for which an ADI was established, by multiplying the median concentrations of residues (STMRs and/or STMR-Ps) for each commodity for which maximum residue levels were recommended by the average daily per capita consumption estimated on the basis of the 17 GEMS/Food Consumption cluster diets¹. Detailed description of the method is in the Environment Health Criteria 240 (EHC 240)².

The long-term dietary risk assessment was not conducted for sulfoxaflor as no new recommendations for maximum residue levels were made.

Fenpropimorph was evaluated for toxicology and an ADI and ARfD were established. Long-term and short-term dietary risk assessments will be conducted when the compound is evaluated for residues.

These IEDIs are expressed as a percentage of the upper bound of the ADIs for a 55 kg or 60 kg person, depending on the cluster diet (Table 1). The spreadsheet application is available at http://www.who.int/foodsafety/areas_work/chemical-risks/gems-food/en/.

The detailed calculations of chronic dietary exposure assessments are given in Annex 3.

Table 1: Summary of chronic dietary exposure assessments (IEDI)

CCPR code	Compound name	ADI (mg/kg body weight)	Range of IEDI, as % of the upper bound of the ADI
288	Acibenzolar-S-methyl	0–0.08	0–1
261	Benzovindiflupyr	0–0.05	0–2
172	Bentazone	0–0.09	0
262	Bixafen	0–0.02	1–9
173	Buprofezin	0–0.009	0–40
230	Chlorantraniliprole	0–2	0–1
135	Deltamethrin	0–0.01	0–50
225	Dimethomorph	0–0.2	0–2
202	Fipronil	0–0.0002	20–90
282	Flonicamid	0–0.07	0–10
283	Fluazifop-P-butyl	0–0.004	40–160
265	Fluensulfone	0–0.01	1–3
285	Flupyradiflurone	0–0.08	7–20
289	Imazethapyr	0–0.6	0
290	Isofetamid	0–0.05	0–1
147	Methoprene assessed as S-methoprene (see below)	0–0.09	
147	S-Methoprene	0–0.05	10–60
278	Metrafenone	0–0.3	0–10
291	Oxathiapiprolin	0–4	0
182	Penconazole	0–0.03	0–3
292	Pendimethalin	0–0.1	0

¹https://extranet.who.int/sree/Reports?op=vs&path=/WHO_HQ_Reports/G7/PROD/EXT/GEMS_cluster_diets_2012&userid=G7_ro&password=inetsoft123

² http://apps.who.int/iris/bitstream/10665/44065/9/WHO_EHC_240_9_eng_Chapter6.pdf

CCPR code	Compound name	ADI (mg/kg body weight)	Range of IEDI, as % of the upper bound of the ADI
293	Pinoxaden	0–0.1	0–1
251	Saflufenacil	0–0.05	2–20
294	Spiromesifen	0–0.03	2–20
190	Teflubenzuron	0–0.005	1–30
269	Tolfenpyrad	0–0.006	0–8

4.2 Short-term dietary exposure

At the present Meeting, an International Estimated Short-Term Intake (IESTI) was calculated for compounds for which an Acute Reference Dose was established. For each relevant food commodity, the highest expected residue (HR or HR-P) and the highest large portion data for general population (all ages), women of childbearing age (14–50 years), and children (6 years and under) were used for the calculation of the IESTI. Detailed description of the method is in the Environment Health Criteria 240 (EHC 240)¹.

These IESTI results are expressed as a percentage of the ARfD (Table 2). The spreadsheet application is available at: http://www.who.int/foodsafety/areas_work/chemical-risks/gems-food/en/

The Meeting agreed that an ARfD for imazethapyr, oxathiapiprolin, spiromesifen and teflubenzuron were unnecessary and short-term dietary exposure assessments were not conducted.

The detailed calculations of acute dietary exposure are given in Annex 4 to the 2016 Report.

Table 2 Summary of acute dietary exposure assessments (IESTI)

CCPR code	Compound name	ARfD (mg/kg bw)	Max. percentage of ARfD and exceedances	
				For exceedances, population, age in years (country)
288	Acibenzolar- <i>S</i> -methyl	0.5	10	
261	Benzovindiflupyr	0.1	70	
172	Bentazone	0.5	3	
262	Bixafen	0.2	20	
173	Buprofezin	0.5	0	
135	Deltamethrin	0.05	0	
225	Dimethomorph	0.6	60	
202	Fipronil	0.003	20	
283	Fluazifop- <i>P</i> -butyl	0.4	40	
265	Fluensulfone	0.3	9	
285	Flupyradiflurone	0.2	Spinach (130) Spinach (420) Leaf lettuce (250) Mustard greens (250) Mustard greens (610) Celery (120) Others (80)	General population (South Africa) Children (South Africa) Children (China) General population (China) Children (China) Children (China)
290	Isofetamid	3	10	
182	Penconazole	0.8	10	
292	Pendimethalin	1	10	

¹ http://apps.who.int/iris/bitstream/10665/44065/9/WHO_EHC_240_9_eng_Chapter6.pdf

6. FUTURE WORK

The items listed below are tentatively scheduled to be considered by the Meetings in 2018. The compounds listed include those recommended as priorities by the CCPR at its Forty-seventh 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/jmpr/en/>

NEW COMPOUNDS

TOXICOLOGY EVALUATIONS	RESIDUE EVALUATIONS
	Chlorfenapyr [BASF] (254)
Ethiprole [Bayer CropScience]	Ethiprole
Mandestrobin [Sumitomo Chemical]	Mandestrobin
Norflurazon [Tessenderlo Kerley Inc.]	Norflurazon
Pyrifluquinazon [Nihon Nohyaku]	Pyrifluquinazon
Pydiflumetofen - SYN545794 [Syngenta]	Pydiflumetofen - SYN545794
XDE-777 [Dow AgroSciences]	XDE-777
Metconazole [Valent USA Corporation, on behalf of Kureha Corporation]	Metconazole
Fluazinam [ISK Biosciences; Ishihara Sangyo Kaisha]	Fluazinam
Pyriofenone [IshiharaSangyoKaisha/ISK Biosciences]	Pyriofenone
Quinalphos [India]	Quinalphos
Tricyclazole [India]	Tricyclazole India
Tioxazafen [Monsanto]	Tioxazafen and its metabolite benzamidine
Ethion (034) [India ¹]	Ethion (034)
Hexaconazole (170) ² India	Hexaconazole (170)

PERIODIC RE-EVALUATIONS

Iprodione (111) [FMC]	Iprodione (111) [FMC]
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¹ This compound was previously been removed from the Pesticide List and all CXLs revoked.

² This compound was previously been removed from the Pesticide List and all CXLs revoked.

TOXICOLOGY EVALUATIONS	RESIDUE EVALUATIONS
Flumethrin (195) [Bayer CropSciences]	Flumethrin (195) [Bayer CropSciences]
Metalaxyl (138) [Quimicas del Vallés - SCC GmbH]	Metalaxyl (138) [Quimicas del Vallés - SCC GmbH]
Dithiocarbamates (105) [Taminco]	Dithiocarbamates (105) [Taminco]
Tolclofos-methyl (191) [Sumitomo Chemical]	Tolclofos-methyl (191) [Sumitomo Chemical]
Imazalil (110) [Janssen] First reserve for 2017	Imazalil (110) [Janssen] First reserve for 2017
Bromopropylate (070) No manufacturer support	Bromopropylate (070) No manufacturer support
Permethrin (120) No manufacturer support	Permethrin (120) No manufacturer support

NEW USES AND OTHER EVALUATIONS

TOXICOLOGY EVALUATIONS	RESIDUE EVALUATIONS
	Abamectin (177) [Syngenta]
	Acephate (095) India
	Acetamiprid (246) [Nippon Soda]
	Bentazone [BASF] (172)
	Benzovindiflupyr (261) [Syngenta]
	Bifenthrin (178) [FMC]
	Chlorpyrifos (017) India
	Chlorothalonil (081); (fungicide) [Syngenta]
	Cyantraniliprole (263) [DuPont]
	Cyazofamid (281) [ISK Biosciences]
	Diquat (031) [Syngenta]
	Diazinon (22) India
	Fluazifop-p-butyl (283) ([Syngenta]
	Fludioxonil (211) [Syngenta]
	Fluensulfone (265) [Adama]
	Imidacloprid (206) India
	Isofetamid (290) [Ishihara Sangyo Kaisha]

TOXICOLOGY EVALUATIONS	RESIDUE EVALUATIONS
Isoprothiolane LATAM	Isoprothiolane LATAM
	Lufenuron (286) [Syngenta]
	Mesotrione (277) [Syngenta]
	Metalaxyl-M [Syngenta] (212)
	Methomyl (094) India
	Penthiopyrad (253)
	Pyriproxyfen (200) [Valent USA Corporation; subsidiary of Sumitomo Chemical Co., Ltd.]
	Profenofos (171) India
	Propamocarb (148) [Bayer CropSciences]
Spiromesifen (294) [India]	Spiromesifen (294) [India]
Sulfoxaflor [Dow AgroSciences]	Sulfoxaflor (252) [Dow AgroSciences]
	Thiabendazole (065) [Syngenta]
	Triazophos (143) India
	Trinexapac (271) [Syngenta]

7. CORRIGENDA

Pesticide Residues in Food 2015. 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. FAO Plant Production and Protection Paper, 223, 2015.

Changes are shown in bold

Abamectin (177)

Annex 1 Page 347 entries for Blackberries and Raspberry red, black should read

Pesticide (Codex reference number)	CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
Abamectin (177)**	FB 0264	Blackberries	0.05		0.02	0.03
ADI: 0–0.001 mg/kg bw ARfD: 0.003 mg/kg bw	FB 0272	Raspberry, red, black	0.05		0.02	0.03

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The annual 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 was held in Rome, Italy, from 13 to 22 September 2016. The FAO Panel of Experts had met in preparatory sessions from 08 to 12 September 2016. The Meeting was held in pursuance of recommendations made by previous Meetings and accepted by the governing bodies of FAO and WHO that studies should be undertaken jointly by experts to evaluate possible hazards to humans arising from the occurrence of pesticide residues in foods. During the meeting the FAO Panel of Experts was responsible for reviewing pesticide use patterns (use of good agricultural practices), data on the chemistry and composition of the pesticides and methods of analysis for pesticide residues and for estimating the maximum residue levels that might occur as a result of the use of the pesticides according to good agricultural use practices. The WHO Core Assessment Group was responsible for reviewing toxicological and related data and for estimating, where possible and appropriate, acceptable daily intakes (ADIs) and acute reference doses (ARfDs) of the pesticides for humans. This report contains information on ADIs, ARfDs, maximum residue levels, and general principles for the evaluation of pesticides. The recommendations of the Joint Meeting, including further research and information, are proposed for use by Member governments of the respective agencies and other interested parties.

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215	Pesticide residues in food 2012 – Report, 2011 (E)		The FAO Technical Papers are available through the authorized FAO Sales Agents or directly from Sales and Marketing Group, FAO, Viale delle Terme di Caracalla, 00153 Rome, Italy.
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The annual 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 was held in Rome, Italy, from 13 to 22 September 2016. The FAO Panel of Experts had met in preparatory sessions from 08 to 12 September 2016. The Meeting was held in pursuance of recommendations made by previous Meetings and accepted by the governing bodies of FAO and WHO that studies should be undertaken jointly by experts to evaluate possible hazards to humans arising from the occurrence of pesticide residues in foods. During the meeting the FAO Panel of Experts was responsible for reviewing pesticide use patterns (use of good agricultural practices), data on the chemistry and composition of the pesticides and methods of analysis for pesticide residues and for estimating the maximum residue levels that might occur as a result of the use of the pesticides according to good agricultural use practices. The WHO Core Assessment Group was responsible for reviewing toxicological and related data and for estimating, where possible and appropriate, acceptable daily intakes (ADIs) and acute reference doses (ARfDs) of the pesticides for humans. This report contains information on ADIs, ARfDs, maximum residue levels, and general principles for the evaluation of pesticides. The recommendations of the Joint Meeting, including further research and information, are proposed for use by Member governments of the respective agencies and other interested parties.

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