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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

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GENEVA, 20–29 SEPTEMBER 2011

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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-term and short-term dietary risk assessment is described in detail in the reports of the 1997 JMPR (Annex 5, reference *80*, section 2.3) and 1999 JMPR (Annex 5, reference *86*, section 2.2). Additional considerations are described in the report of the 2000 JMPR (Annex 5, reference *89*, sections 2.1–2.3).

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	Residue data (mg/kg)		Maximum residue level (mg/kg)	
GAP, country (1)	Rate, kg ai/ha (2)	(3)	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**

[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)**
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**
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.

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.

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