Food and Agriculture Organization of the United Nations

World Health Organization

ISSN 0259-2517

FAO PLANT PRODUCTION AND PROTECTION PAPER

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Pesticide residues in food 2015

Joint FAO/WHO Meeting on Pesticide Residues

REPORT 2015

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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, 15-24 September 2015

WORLD HEALTH ORGANIZATION
FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS
Rome, 2015

ISBN 978-92-5-108996-5

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* Residues

LIST OF PARTICIPANTS

2015 Joint FAO/WHO Meeting on Pesticide Residues

GENEVA, 15–24 SEPTEMBER 2015

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ABBREVIATIONS

ABCB	ATP-binding cassette subfamily B
AChE	acetylcholinesterase
AD	administered dose
ADI	acceptable daily intake
ae	acid equivalent
ai	active ingredient
AMPA	aminomethylphosphonic acid
AR	applied radioactivity
ARfD	acute reference dose
asp gr fn	aspirated grain fraction
ATP	adenosine triphosphate
AU	Australia
AUC	area under the plasma concentration–time curve
BBCH	**B**iologischen Bundesanstalt, **B**undessortenamt und **CH**emische Industrie
$BMDL_{10}$	95% lower confidence limit of the benchmark dose for a 10% response
BuChE	butyrylcholinesterase
bw	body weight
CAC	Codex Alimentarius Commission
CAS	Chemical Abstracts Service
CCBA	4-(4-chloro-2-cyanoimidazole-5-yl) benzoic acid
CCIM	4-chloro-5-*p*-tolylimidazole-2-carbonitrile
CCN	Codex classification number (for compounds or commodities)
CCPR	Codex Committee on Pesticide Residues
*c*GAP	Critical GAP
CS	capsule suspension
CXL	Codex MRL
CYP	cytochrome P450
DABQI	dialkylbenzoquinoneimine
DALA	days after last application
DAT	days after treatment
DFA	difluoroacetic acid
DM	dry matter
DMSO	dimethyl sulfoxide
DNA	deoxyribonucleic acid
DT_{50}	time required for 50% dissipation of the initial concentration

dw	dry weight
ECD	electron capture detector
EFSA	European Food Safety Authority
EHC	Environmental Health Criteria monograph
EMRL	extraneous maximum residue limit
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
fw	fresh weight
GABA	gamma-aminobutyric acid
GAP	good agricultural practice
GC	gas chromatography
GC-ECD	gas chromatography with electron capture detection
GC-FID	gas chromatography with flame ionization detection
GC-FPD	gas chromatography with flame photometric detection
GC/MS	gas chromatography/mass spectrometry
GC-NPD	gas chromatography coupled with nitrogen-phosphorus detector
GD	gestation day
GEMS/Food	Global Environment Monitoring System – Food Contamination Monitoring and Assessment Programme
GI	gastrointestinal
GLP	good laboratory practice
HCD	historical control data
HEPA	2-hydroxyethyl phosphonic acid; 2-hydroxyethephon
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
IARC	International Agency for Research on Cancer
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
LC-MS/MS	Liquid chromatography–tandem mass spectrometry
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
MDR1	multidrug resistance protein 1
MRL	maximum residue limit
MTD	maximum tolerated dose
ND	non-detect - below limit of detection
NOAEC	no-observed-adverse-effect concentration
NOAEL	no-observed-adverse-effect level
OECD	Organisation for Economic Co-operation and Development
P	parental generation
PBI	plant back interval
Pf	processing factor
PHI	pre-harvest interval
PMRA	Pest Management Regulatory Agency, Health Canada
PND	postnatal day
ppm	parts per million
PPO	protoporphyrinogen oxidase
PRE	pre-emergence
POST	post-emergent
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe–Multiresidue pesticide analysis
RAC	raw agricultural commodity
RSD	relative standard deviation
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
SUA	Supply Utilisation Account
TAR	total administered radioactivity
TFNA	4-trifluoromethylnicotinic acid

TFNA-AM	4-trifluoromethylnicotinamide
TFNA-OH	6-hydroxy-4-trifluoromethylnicotinic acid
TFNG	*N*-(4-trifluoromethylnicotinoyl) glycine
TFNG-AM	*N*-(4-trifluoromethylnicotinoyl) glycinamide
TLC	thin-layer chromatography
T_{max}	time to reach the maximum concentration in plasma/blood
TRR	total radioactive residues
TSH	thyroid stimulating hormone
TTC	threshold of toxicological concern
UDPGT	uridine diphosphate-glucuronosyltransferase
UDS	unscheduled DNA synthesis
UK	United Kingdom
USA	United States of America
US/CAN	United States and Canada
USEPA	United States Environmental Protection Agency
US-FDA	USA – Food and Drug Administration
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 2015 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 WHO Headquarters, Geneva (Switzerland), from 15 to 24 September 2015. The FAO Panel Members met in preparatory sessions on 10–14 September.

The meeting was opened by Dr Angelika Tritscher, Coordinator, Risk Assessment and Management, Department of Food Safety and Zoonoses, WHO. On behalf of WHO and FAO, Dr Tritscher welcomed and thanked the participants for providing their expertise and for devoting significant time and effort to the work of JMPR. She noted that the work of JMPR is of great importance, as it provides the scientific basis for international food safety standards as recommended by the Codex Alimentarius Commission. She emphasized that the programme is also important for other programmes within the Organizations; for example, the WHO Guidelines for Drinking-water Quality use the scientific advice provided by JMPR as the basis for the derivation of drinking-water guidelines for pesticides.

Dr Tritscher noted that further important considerations at the meeting related to methodological aspects, such as discussing the outcome of the recent workshop to review the international estimate of short-term dietary intake (IESTI) equations, in an effort to further improve and harmonize risk assessment methodology for pesticide residues. The Meeting was also asked to consider the outcome of the WHO Expert Task Force on Carcinogenicity of Diazinon, Glyphosate and Malathion, to provide recommendations to the Organizations on necessary actions in light of recent International Agency for Research on Cancer (IARC) hazard classifications. Dr Tritscher reminded the Meeting of the importance of food safety in public health; in order to raise awareness of this issue, WHO dedicated the 2015 World Health Day to food safety, with important advocacy and information material being available from the WHO website. Lastly, she reminded participants that they were invited as independent experts and not as representatives of their countries or organizations. She also reminded them of the confidential nature of the meeting, in order to allow experts to freely express their opinions.

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, supervised trials median residue (STMR) levels and highest residue (HR) levels were estimated for commodities of plant and 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 eight new compounds and four compounds that were re-evaluated within the periodic review programme of the Codex Committee on Pesticide Residues (CCPR), for toxicity or residues, or both. The original schedule of compounds to be evaluated was amended, with dicamba and methoxyfenozide not considered for residues and fluazifop-*p*-butyl not considered for toxicity or residues owing to the submission of incomplete data sets.

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

The Meeting also estimated the dietary intakes (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 residues data for the estimation of maximum residue levels in food and feed* (2009).

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 2015 JMPR had completed declaration-of-interest forms and that no conflicts had been identified.

2. GENERAL CONSIDERATIONS

2.1 EFSA WORKSHOP, COSPONSORED BY WHO AND FAO, REVISITING THE IESTI EQUATIONS

An EFSA Scientific Workshop was held in Geneva on the 8th and 9th of September 2015, concerning the Revisiting of the International Estimate of Short-Term Intake (IESTI equations) used to estimate the short-term dietary exposure to pesticide residues. The workshop was co-sponsored by WHO and FAO. The EFSA event report will be published in December 2015. A near final draft was available to the JMPR 2015 for discussion.

The overall goal of the Scientific Workshop was to evaluate the parameters within the IESTI equations as well as the equations themselves, with the aim of harmonizing the parameters and equations between different dietary risk assessment programmes. In addition, the appropriateness of the IESTI methodology in assessing residues from monitoring and enforcement programmes was considered.

Recommendations from the Scientific Workshop to EU and Codex members were:

- Replace the STMR and HR with the MRL in all cases
- Use a variability factor of 3
- Remove the unit weight from the equation
- Use conversion factors (CF) to account for differences in residue definitions and processing factors (PF) to account for residue changes during processing,
- Derive the P97.5 large-portion value from the distribution of consumption values of dietary surveys on the basis of g/kg bw (LP_{bw}), and
- Change the IESTI equations as follows
- Replace case 1 and case 3 of the current IESTI equation by

$$IESTI = LP_{bw} \times MRL \times CF \times PF$$

Replace case 2a and case 2b of the current IESTI equation by

$$IESTI = LP_{bw} \times MRL \times v \times CF \times PF$$

Food inspection services could use the IESTI equations, by replacing the MRL with the actual residue measured in a sampling lot.

In addition, it was recommended that a list of commodities be developed for which a variability factor is not needed. Furthermore, the participants of the Scientific Workshop were aware that large portion data on a per kg body weight basis are currently not available and will need to be compiled before the recommended changes could be implemented. Furthermore, conversion factors and processing factors should be compiled in a database, for use by food inspection services and other parties.

The JMPR 2015 discussed the draft EFSA event report and acknowledged that the short-term exposure estimates derived from the two IESTI equations as a whole need to be assessed. JMPR recommends that a WHO/FAO working group be established to compare the use of current and proposed equations and to present the outcome to the CCPR in due course.

2.2 SHORTER THAN LIFETIME EXPOSURES

As a follow-up of the 2014 report item 2.5, "Characterization of risk of less-than-lifetime high exposures to pesticide residues", the Meeting discussed the current JMPR practice regarding dietary risk assessment of pesticide residues.

The current long-term dietary risk assessment of pesticides consists of a comparison of the estimated chronic exposure to residues in food (international estimated daily intake, or IEDI) with the ADI. The exposure model is based on multi-annual consumption data averaged over the whole population to capture the per capita dietary pattern over a lifetime. However, no-observed-adverse-effect levels (NOAELs) derived from rodent and dog studies with exposure durations ranging from 4 to 104 weeks are often similar. This suggests that over a wide exposure duration range, the manifestation of adverse effects generally is not related to the duration of the exposure. However, the IEDI calculation does not provide information on short-term (weeks/months) or consumer-only exposures. Therefore, it is not known whether the ADI is exceeded in these situations and whether this would result in health concerns.

The development of dietary exposure assessment methods that take into account short-term toxicity (4 weeks) after less than lifetime exposures should be investigated. Special emphasis should be given to commodities for which exposures at a frequency of two or more times per week are likely. This estimate is based on the fact that most modern pesticides show little tendency to accumulate.

The Meeting recommends that the Secretariat convene an expert working group in order to develop models to cover exposures longer than 1 day but shorter than lifetime, as needed. The Meeting also recommends that the applicability of these considerations to other categories of chemicals, such as veterinary drugs and contaminants, should be investigated.

2.3 UPDATE ON THE REVISION OF PRINCIPLES AND METHODS FOR RISK ASSESSMENT OF CHEMICALS IN FOOD (EHC 240)

The Meeting discussed the implications of shorter than lifetime (more than 1 day) exposures on the risk characterization of residues of pesticides in food. It was concluded that there were occasions, such as frequent, seasonal consumers of specific commodities, where the toxicological profile of the pesticide was such that the current exposure model might not be adequately protective. The Meeting recommended that a group be convened to investigate possible exposure models to address this issue (see section 2.2). Depending on the outcome of this exercise, it might be necessary to update the relevant section of Environmental Health Criteria monograph (EHC) 240.

The Meeting discussed the report of the WHO Expert Task Force on Carcinogenicity of Diazinon, Glyphosate and Malathion (see section 3.2.2). Among the recommendations was the need to make transparent the criteria and approaches used to determine the quality, relevance and utility of all published and proprietary studies in any evaluation of the compounds. The Meeting recommended that general principles arising from this assessment should be incorporated into the relevant section of EHC 240.

The Meeting noted the published guidance by WHO on evaluating and expressing uncertainty in hazard characterization, together with related activities – for example, by the European Food Safety Authority (EFSA). The Meeting recommended that the relevant sections of EHC 240 should be reviewed and revised as necessary.

WHO and EFSA will publish their review of the threshold of toxicological concern (TTC) approach for compounds with limited or no toxicological data in the near future. The relevant section(s) of EHC 240 should be revised to reflect the outcome of this review.

The Meeting noted that the WHO Risk Assessment Network is reviewing the current status of chemical-specific adjustment factors. When complete, the relevant sections of EHC 240 should be updated.

The Meeting recommended that consideration be given to the need to include a section or revision of EHC 240 to take account of recent developments on adverse outcome pathways and their use in hazard characterization.

2.4 A REPORT ON THE JOINT FAO/WHO EXPERT MEETING ON HAZARDS ASSOCIATED WITH ANIMAL FEED CONDUCTED FROM 12 TO 15 MAY IN ROME, ITALY

An expert meeting was jointly organised by the FAO and WHO, in line with their overall aims of securing feed and food safety and ensuring fair practices in the trade of food and feed. The objective of the meeting was to provide an updated overview of the current state of knowledge on hazards associated with feed (including use of insects, former food, food processing by-products and biofuel by-products as feed). A number of recommendations were made, including some of relevance to the work of the JMPR. In particular, it was suggested that"

The Codex Committee on Pesticide Residues (CCPR) and Member Countries should establish MRLs for pesticides of concern in feed;

Member Countries, the FAO and WHO should encourage regulators to require relevant data packages from industry to support the risk assessment of pesticide residues in feed. Consider pesticide residues in feed especially as they pertain to feed ingredients, including by-products from biofuel production such as dried distillers grain soluble (DDGS).

The JMPR has been elaborating maximum residue levels for pesticides in various animal feeds relevant to international trade for many years and will continue to do so.

The Meeting welcomed the work of the expert meeting on feed and agreed that additional processing studies would be needed to estimate maximum residue levels for those by-products used as feed ingredients that are not currently considered. However, additional processing studies will only be developed if required by regulators. CCPR may wish to consider adding additional feed items to the relevant Codex Commodity Classification to facilitate establishing maximum residue levels for relevant biofuel by-products used as animal feed

2.5 MINIMUM NUMBER OF SUPERVISED FIELD TRIALS FOR MRL SETTING FOR MINOR CROPS

The Meeting noted that with the Report of the 47th Session of the CCRP (REP15/PR) an information document was introduced to be used in conjunction with guidance to facilitate the establishment of MRLs for pesticides for minor crops (APPENDIX XI to the Report). Based on their importance in consumption within the GEMS Food Cluster data three categories were proposed to classify minor crops and the minimum number of trials necessary to support the establishment of MRLs for commodities obtained thereof:

Category 1 - No data in FAO Stat and No GEMS Food Cluster data: to be considered on a case by case basis

Category 2 - < 0.5% worldwide and < 0.5% in all of the clusters: minimum of 4 trials

Category 3 - < 0.5% worldwide and > 0.5% in one or more clusters: minimum of 5 trials

The Meeting welcomed the approach to harmonise the criteria on minor crops trial data needed for MRL setting. Beginning with the 2016 JMPR Meeting, a minimum number of four independent supervised field trials reflecting the respective GAPs for Category 1 and 2 crops and five trials according to Category 3 crops will be used as the basis for recommending maximum residue levels. On a case by case basis, fewer trials may be acceptable when additional circumstances can be taken into account, e.g., undetected residues following treatment at exaggerated rates.

2.6 REVISION OF THE FAO MANUAL ON THE SUBMISSION AND EVALUATION OF PESTICIDE RESIDUES DATA FOR THE ESTIMATION OF MAXIMUM RESIDUE LEVELS IN FOOD AND FEED

The FAO Manual provides a unique source of information on the data requirements and the complex procedures applied by the JMPR in the evaluation of the information made available to the Meeting.

The JMPR continuouly develops the working principles used for the evaluation of pesticide residue data, based on its practical experience and scientific developments, so as to make best use of the available information. Since the publication of the 2nd Edition of the Manual (2009) a number of important concepts have been developed, such as the application of proportionality for adjusting pesticide use conditions to match critical GAP; the estimation of maximum residue levels based on "global GAP"; and the recommending maximum residue levels for commodity groups.

Further, the OECD Working Group on Pesticides elaborated a number of guidance documents which were adopted or considered by the JMPR. Necessitating a revision of the Manual, to ensure ist currency.

The revised FAO manual planned to be published in 2016 and will incorporate these new principles in the current working procedures to assist in their systematic application and making their applcation transparent.

3. RESPONSES TO SPECIFIC ISSUES

3.1 CONCERNS RAISED BY THE CODEX COMMITTEE ON PESTICIDE RESIDUES (CCPR)

3.1.1 BUPROFEZIN (173)

In 2015, the Forty-seventh Session of CCPR adopted the maximum residue limit (MRL) for buprofezin in coffee beans as recommended by the 2014 JMPR, noting the reservation of the Delegation of the European Union (EU) concerning the potential formation of aniline during coffee processing. This concern was due to the classification of aniline by the European Chemicals Agency as potentially mutagenic and carcinogenic.

In the 2010 JMPR monograph on buprofezin, aniline was identified as a processing metabolite, but was not found as an animal metabolite. Aniline was considered to be toxicologically relevant; however, as it can occur naturally in some foods and may also originate from many chemicals, including buprofezin, this process metabolite could not be included in the residue definition for risk assessment.

As there are different sources of exposure to aniline, aniline should be considered as a contaminant. Therefore, the Meeting recommended that the JECFA Secretariat place aniline on the agenda for an evaluation to both characterize hazard and estimate exposure from the diet, including exposure from the use of pesticides.

3.1.2 FENPROPATHRIN (185)

Fenpropathrin was evaluated by the 2014 JMPR. The Meeting could not make recommendations for raspberry because no trial matched the US GAP for caneberries (0.34 kg ai/ha with total seasonal rate of 0.67 kg/ha and a PHI of 3 days).

At the Forty-seventh Session of the CCPR the USA submitted concern in relation to the decision of the 2014 JMPR for not recommending residue levels for fenpropathrin in raspberries.

The 2015 Meeting noted that there was no decline study submitted for raspberry. However, steady declines of resides were observed in case of strawberry from day 0 to day 3, and at longer intervals (7-21 days) after last application in case of pear and peach.

The Meeting concluded that under those conditions, when two parameters (dose rate and sampling after last application) are different from GAP, the principles of proportionality cannot be applied. Consequently, recommendations cannot be made for maximum residue levels based on the residue data provided. The Meeting confirms its previous decision.

3.1.3 IMAZAMOX (276)

Concern

JMPR evaluated imazamox at the 2014 meeting. An ARfD of 3 mg/kg body weight (bw) was established based on malformations (lungs, absent intermediate lobe; cervical hemivertebra; thoracic hemivertebra) reported in a developmental toxicity study in rabbits. A concern form indicating a request for clarification was submitted by the delegation from the United States of America (USA), questioning the need for an ARfD for imazamox.

To support the concern, the following reports were submitted by the United States delegation:

- "Human-Health Assessment Scoping Document in Support of Registration Review", dated 5 June 2014;

- "Imazamox; Exemption from the Requirement of a Tolerance", Federal Register, Vol. 68, No. 31, pp. 7428–7433, dated 14 February 2003; and
- "Report of the Hazard Identification Assessment Review Committee", dated 11 July 2001.

The last report includes a summary of the developmental toxicity study in rabbits (pp. 8–9), which states, regarding the developmental findings: "There were no treatment-related effects in developmental parameters. A developmental LOAEL [lowest-observed-adverse-effect level] was not observed. The developmental NOAEL was 900 mg/kg/day." Similar conclusions are also included in the other two documents. It is possible that the increased incidence of absent intermediate lung lobe was considered not to be treatment related because it was within the range of historical control data (HCD) on a fetal basis.

Evaluation by JMPR

When the developmental toxicity study in rabbits by Hoberman (1995)[1] was evaluated by JMPR, increases in incidences of certain malformations in the groups dosed with 600 and 900 mg/kg bw per day were noted (lungs, absent intermediate lobe; cervical hemivertebra; thoracic hemivertebra) and discussed. The detailed incidences and the available HCD are given in the 2014 JMPR monograph. This is the same study that was available to the United States Environmental Protection Agency (USEPA).

Dose-dependent absence of intermediate lung lobe was reported in the 600 and 900 mg/kg bw per day dose groups at higher incidences than in the concurrent control group. It should be noted that the HCD on "lungs, one or more lobes partially or complete agenesis" also include findings in addition to the specific finding observed in fetuses in this study; hence, they may be less applicable to assessing the relevance of these findings.

Cervical hemivertebra and thoracic hemivertebra were reported in the 900 mg/kg bw per day dose group at higher incidences than in the concurrent control group and in historical controls. The same tendency was also noted for the 600 mg/kg bw per day dose group. The available HCD confirm that these malformations occur only very rarely under the conditions of the performing laboratory. Although the incidences of thoracic hemivertebra in the 600 mg/kg bw per day group reached the maximum of the HCD range, a possible dose-related increase could not be excluded.

Response to concern

In summary, the Meeting confirms that the findings at 600 and 900 mg/kg bw per day are considered to be treatment-related increases in malformations, taking into account the low background incidences reported in the HCD.

Based on current knowledge, a malformation is considered a finding that may be induced by a single dose in the absence of information to the contrary. It is consistent practice in JMPR to establish an ARfD based on malformations. Additionally, this is in line with international guidance documents on establishing ARfDs (e.g., by the OECD).

Considering that malformations were seen in the developmental toxicity study in rabbits, the 2014 Meeting established an ARfD of 3 mg/kg bw for imazamox based on these findings. This ARfD is reaffirmed by the present Meeting.

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[1] Hoberman AM (1995). An oral developmental toxicity (embryo-fetal toxicity/teratogenicity) definitive study with AC 299, 263 in rabbits. Unpublished report no. ID-432-002 from Argus Research Laboratories Inc., Horsham, PA, USA. Submitted to WHO by BASF Agro SAS, Levallois-Perret, France.

3.1.4 METHIDATHION (051)

On the basis of public health concerns raised by the EU regarding possible short-term dietary exposure above the ARfD, methidathion was moved up from the 2018 to the 2016 schedule for re-evaluation under the periodic review programme of CCPR. Methidathion was first evaluated in 1972 and evaluated for residues in subsequent years, the last being in 1994. In 1997, JMPR established an ARfD of 0.01 mg/kg bw for methidathion, on the basis of a NOAEL of 0.11 mg/kg bw (the highest dose tested) for inhibition of erythrocyte acetylcholinesterase (AChE) activity in humans and a safety factor of 10. Refinement of the current ARfD is unlikely to be possible based on available data.

The procedure for estimating short-term dietary intake was implemented by JMPR in 2001. The preliminary estimates of short-term intakes performed by the present Meeting using Codex MRLs established in a variety of crop food commodities and foods of animal origin indicate a potential exceedance of the ARfD for the general population and for children by more than an order of magnitude.

On this basis, the Meeting agreed that the inclusion of methidathion in the next JMPR call for data was appropriate. The Meeting noted that this compound is no longer supported by the manufacturer and that, at the moment, no commitment was forthcoming from Codex Member States to submit data.

3.1.5 PROPICONAZOLE (160)

Propiconazole was last evaluated by the JMPR in 2014. The residue definition for plant and animal commodities is *propiconazole* for compliance with the MRL and *propiconazole plus all metabolites convertible to 2,4-dichlorobenzoic acid, expressed as propiconazole* for the estimation of dietary intakes.

The current Meeting received a concern form from the USA regarding the lack of a maximum residue level recommendation for propiconazole for wheat, oats and barley. The Meeting re-evaluated the trials submitted in 2014 and reconsidered its previous recommendation.

In the USA, GAP for propiconazole in barley, oats and wheat, is for 2 applications at 0.125 kg ai/ha, the second being at least 14 days after an early season application and should not be performed after full head emergence, i.e., after Feekes 10.54, which corresponds to BBCH 71. Trials submitted to the 2014 JMPR and considered at GAP (last application done up to BBCH 73) are shown in Table 1.

Table 1 Residues from trials conducted with propiconazole in barely, oats and wheat in the USA following 2 applications of propiconazole (JMPR, 2014)

Region	Variety	Application		DAT (days)	Residues (mg/kg)		
		kg ai/ha	BBCH growth state		Propiconazole	Total propiconazole	Trial Ref.
Barley							
Minnesota	Spring Rawson	0.15	41 and 71	44	0.011, < 0.01 (0.01)	0.188, 0.57 (0.38)	C09-9063
N. Dakota, Northwood	Pinnacle	0.15	39 and 71	33	< 0.01	< 0.05	C13-9062
				40	< 0.01	0.0555	
				47	< 0.01 (2)	0.053, 0.066 (0.06)	
				54	< 0.01	0.0585	
N. Dakota, Carrington	Pinnacle	0.15	37 and 69	48	< 0.01 (2)	0.060, 0.072 (0.07)	C13-9065
S. Dakota,	Lacey	0.15	43-49 and 71-73	33	< 0.01 (2)	0.13 (2)	C16-9064
Nebraska	Spring, Baronesse	0.15	43 and 59	29	< 0.01 (2)	< 0.05 (2)	C33-9066
Colorado	Moravian 37	0.15	55 and 71	25	0.175, 0.21 (0.98)	0.425, 0.516 (0.47)	W12-9067

Region	Variety	Application		DAT (days)	Residues (mg/kg)		
		kg ai/ha	BBCH growth state		Propiconazole	Total propiconazole	Trial Ref.
Virginia	Nomini	0.15	55 and 71	30	0.144, 0.137 (0.14)	0.589, 0.765 (0.68)	E07-9061
California	UC937	0.15	69 and 71	49	1.3, 0.933 (1.1)	2.22, 2.02 (2.1)	W32-9068
Oat							
Minnesota	Morton	0.15	41 and 71	48	0.035, 0.044 (0.04)	0.117, 0.31 (0.11)	C09-9084
N. Dakota, Ayr	Morton	0.15	52 and 70	44	0.054, 0.067 (0.06)	0.269, 0.173 (0.22)	C12-9086
N. Dakota, Gardner	Morton	0.15	72 and 70	11	0.117	0.337	C12-9087
				18	0.252	0.688	
				25	0.311, 0.355 (0.33)	0.862, 0.968 (0.92)	
				32	0.225	0.642	
N. Dakota, Northwood	Jerry	0.15	39 and 71	33	0.017, 0.022 (0.02)	0.086, 0.089 (0.09)	C13-9083 2009
N. Dakota, Carrrington	Jerry	0.15	37 and 69	39	0.03 (2)	0.163, 0.143 (0.15)	C13-9091
S. Dakota	Stallion	0.15	43 and 71	36	0.024, 0.023 (0.02)	0.155, 0.208 (0.18)	C16-9090
Iowa	Reeves	0.15	71	32	0.086, 0.078 (0.08)	0.774, 0.91 (0.84)	C30-9085
Pensilvania	Armor	0.15	59 and 71-75	28	0.35, 0.386 (0.37)	1.32, 1.61 (1.5)	E04-9081
Colorado	Jerry	0.15	73 and 71	28	0.05 (2)	0.184, 0.206 (0.20)	W12-9092
S. Caroline	Horizon 270	0.15	43 and 55	44	< 0.01 (2)	0.26 (2)	E11-9082
Texas	BOB	0.15	60/71	35	0.252, 0.269 (0.26)	1.59, 1.52 (1.6)	W07-9089
Wheat							
N. Dakota, Gardner 2009	Durum Wheat (Maier)	0.15	52 and 55	35	< 0.01 (2)	0.052, 0.060 (0.06)	C12-9035
N. Dakota, Carrington	Spring Glenn	0.15	37 and 69	55	< 0.01 (2)	< 0.05 (2)	C13-9038
S. Dakota, Lake Andes	Spring Oxen	0.15	55 – 59 and 71	34	< 0.01 (2)	0.076, 0.075 (0.08)	C16-9037
Iowa	Hard wheat (Briggs)	0.15	71	25	< 0.01	0.055	C30-9034
				32	< 0.01	< 0.05	
				39	< 0.01 (2)	0.058, 0.053	
				46	< 0.01	0.07	
Texas, Raymondville	Caudillo	0.15	43 and 71	38	< 0.01 (2)	< 0.05, 0.06 (0.06)	W08-9036
Colorado	Winter Jagalene	0.15	53 and 71	29	< 0.01 (2)	0.054, 0.057 (0.06)	W12-9044
N. Dakota, Northwood	Winter wheat (Jerry)	0.15	45 and 71	43	< 0.01 (2)	< 0.05 (2)	C13-9033
N. Dakota, Carrington	Winter wheat (Jerry)	0.15	45 and 71	50	< 0.01 (2)	< 0.05 (2)	C13-9040
S. Dakota, Lake Andes	Winter wheat (Wendy)	0.15	43 and 67 - 69	64	< 0.01 (2)	< 0.05, 0.054 (0.05)	C16-9039
Virginia	Pioneer 26R15	0.15	65 and 75	24	< 0.01 (2)	< 0.05, 0.078 (0.06)	E07-9031
Texas, Groom	Winter Cutter	0.15	61 and 71	10	0.13	0.152	E13-9041
				17	0.0762	0.125	
				24	0.084, 0.072 (0.08)	0.165, 0.125 (0.14)	
				30	0.054	0.155	
Lousiania	Winter Terral LA841	0.15	57-59 and 73	30	< 0.01 (2)	0.063, 0.169 (0.12)	

Region	Variety	Application		DAT (days)	Residues (mg/kg)		
		kg ai/ha	BBCH growth state		Propiconazole	Total propiconazole	Trial Ref.
Idaho	Hard wheat (Klassic)	0.15	55 – 59 and 71	35	< 0.01 (2)	< 0.05 (2)	W15-9046
Texas, Levelland	TAM 112	0.15	51 and 73	35	0.011, < 0.01 (0.01)	0.125, < 0.05 (0.09)	W39-9042
Texas, Littlefield	Weathermaster	0.15	51 and 73	35	0.020, 0.023 (0.02)	0.091, 0.099 (0.10)	W39-9043

In eight trials from the USA in barley, matching US GAP, residues of propiconazole found were: < 0.01 (4), 0.01, 0.14, 0.98, 1.1 mg/kg and for total propiconazole < 0.05, 0.06, 0.07, 0.13, 0.38, 0.47, 0.68 and 2.1 mg/kg.

The Meeting estimated a maximum residue level of 2 mg/kg and a STMR of 0.255 mg/kg for propiconazole in barley. This estimate replaces the previous recommendations for propiconazole in barley.

Eleven trials conducted in the USA in oats, matching GAP, residues of propiconazole were: < 0.01, 0.02 (2), 0.03, 0.04, 0.05, 0.06, 0.08, 0.26, 0.33 and 0.37 mg/kg and of total propiconazole residue of 0.09, 0.11, 0.15, 0.18, 0.20, 0.22, 0.26, 0.84, 0.92, 1.5 and 1.6 mg/kg.

The Meeting estimated a maximum residue level of 0.7 mg/kg and a STMR of 0.22 mg/kg for propiconazole in oats.

Fifteen trials conducted in the USA in wheat, matching GAP, residues of propiconazole were: < 0.01 (12), 0.01, 0.02 and 0.08 mg/kg and a total propiconazole residue of: < 0.05 (4), 0.05, 0.06 (4), 0.07, 0.08, 0.09, 0.10, 0.12 and 0.155 mg/kg.

The Meeting estimated a maximum residue level of 0.09 mg/kg and a STMR of 0.06 mg/kg for propiconazole in wheat. The Meeting extended these estimates to rye and triticale and replaced the previous recommendations for propiconazole in wheat, rye and triticale.

Residues in animal commodities

The estimates made for barley, oat, wheat, rye and triticale did not have any significant impact on the livestock dietary burden estimated in 2014 for propiconazole, consequently no revision of the previous recommendations for animal commodities was made.

DIETARY RISK ASSESSMENT

Long-term intake

The current ADI for propiconazole is 0–0.07 mg/kg bw. The 2014 JMPR Meeting concluded that the long-term dietary intake for the 17 GEMS/Food Cluster diets of propiconazole is unlikely to present a public health concern (up to 10% of the maximum ADI). The estimations made on barley, oat, rye, triticale and wheat grain by the present Meeting does not significantly change the intake estimates or the previous conclusions made for propiconazole. As a result a new assessment was not conducted.

Short-term intake

An ARfD for propiconazole is 0.3 mg/kg bw. The International Estimated Short-Term Intake (IESTI) of propiconazole was calculated for the commodities for which STMRs and maximum residue levels was estimated by the current Meeting. The results are shown in Annex 4 to the 2015 Report. The IESTI represented a maximum of 3% of the ARfD. The Meeting concluded that the short-term intake of propiconazole residues from uses considered by the current Meeting was unlikely to present a public health concern.

3.2 OTHER MATTERS OF INTEREST

3.2.1 Comments received during review of WHO Guidelines for Drinking-water Quality background documents

3.2.1.1 Bentazone

At the 2012 JMPR, bentazone was reviewed as part of the periodic review programme of CCPR. The Meeting reaffirmed its conclusion that no ARfD was necessary, as it 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 studies that could be due to a single dose.

The WHO document *Bentazone in Drinking-water: Background document for development of WHO Guidelines for Drinking-water Quality* was based on the 2012 JMPR evaluation. During the review of this document, two comments were received that pertained to JMPR's conclusion that an ARfD for bentazone was unnecessary. The first comment, received from EFSA, referred to its evaluation of bentazone, published in 2015, which concludes that an ARfD of 1 mg/kg bw is 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 a developmental toxicity study in rats and applying an uncertainty factor of 100. This conclusion derives from the fact that developmental toxicity was observed in the absence of clear maternal toxicity.

The second comment, from Health Canada, noted two new toxicology studies that were identified in the most recent review of bentazone conducted by the USEPA in 2014. These include an acute neurotoxicity study (2012) in rats, which was used by the USEPA to set an ARfD of 0.5 mg/kg bw, and an immunotoxicity study (2012) in rats.

The Meeting recommended that bentazone be re-evaluated specifically to determine whether there is a need to establish an ARfD.

3.2.1.2 Dichlorvos

JMPR received a request from the group that prepares the WHO Guidelines for Drinking-water Quality requesting clarification on JMPR's assessment of dichlorvos and potential differences with assessments undertaken by other bodies. These clarifications related to:

- conclusions on the carcinogenicity and genotoxicity of dichlorvos;
- differences in the ADI and ARfD for dichlorvos established by JMPR compared with the EU and the USA; and
- studies not cited in the 2011 JMPR evaluation of dichlorvos.

JMPR has evaluated the carcinogenicity and genotoxicity of dichlorvos on a number of occasions, most recently in 2011. More than 10 long-term carcinogenicity studies have been evaluated, with the majority of these finding no evidence of carcinogenicity. The occurrence of a small number of forestomach lesions in mice in a United States National Toxicology Program study was attributed to the localized effect of dichlorvos administered in corn oil by gavage. These forestomach lesions were not considered relevant to humans.

JMPR has evaluated an extensive genotoxicity database on dichlorvos, covering both published and unpublished studies. Although dichlorvos tested positive for a number of in vitro genotoxicity end-points, it has consistently tested negative in in vivo studies. The 2011 Meeting concluded that the absence of an in vivo genotoxicity response is due to the rapid metabolism of dichlorvos, which limits systemic exposure to intact dichlorvos at concentrations likely to lead to direct interactions with DNA. In humans, prolonged systemic exposure to unmetabolized dichlorvos is highly unlikely.

The 1993 Meeting noted that dichlorvos methylated DNA at a rate that is 8–9 orders of magnitude lower than the rate of phosphorylation, and therefore DNA alkylation is unlikely to occur at doses lower than those inhibitory to AChE activity.

The 2011 Meeting concluded that in the absence of an in vivo genotoxic response and a carcinogenic response relevant to humans, dichlorvos is unlikely to pose a carcinogenic risk to humans.

No new data have become available since 2011 that could result in any change to previous JMPR conclusions on the carcinogenicity or genotoxicity of dichlorvos.

The toxicological end-point used to establish health-based guidance values for dichlorvos is consistent between JMPR and other risk assessment bodies: namely, the inhibition of AChE activity. Differences in the ADI and ARfD for dichlorvos established by JMPR, the USEPA and the EU (Table 1) are attributable to the use of human studies by JMPR. Whereas JMPR will evaluate and use all scientifically valid data, including those from ethically conducted human studies, other bodies do not use human data to establish ADIs and ARfDs for pesticides. Consequently, the use of NOAELs from laboratory animal studies by these bodies can result in lower reference values because of the application of a 10-fold interspecies safety factor, which is not necessary if a NOAEL from a human study is used. NOAELs for the inhibition of AChE activity from either single or short-term repeated-dose studies in humans, used by JMPR to establish the ARfD and ADI, respectively, are supported by NOAELs from laboratory animal studies. Further, laboratory animal data confirm that the duration of exposure of humans to dichlorvos in the pivotal study used as the basis for the JMPR ADI is appropriate, as no increase in the level of AChE inhibition is likely to occur following longer durations of dietary exposure.

In relation to the absence of particular studies from the 2011 JMPR evaluation, it should be noted that JMPR evaluated the study by Jolley, Stemmer & Pfitzer (1967)[1] as part of its 1993 evaluation of dichlorvos and that the study by Witherup *et al.* (1971)[2] was evaluated by WHO as part of EHC 79[3] (1988) on dichlorvos.

Table 1 Comparison of ADIs and ARfDs for dichlorvos

Jurisdiction	ARfD	Basis	ADI	Basis
JMPR (2011)	0.1 mg/kg bw	NOAEL of 1 mg/kg bw for erythrocyte AChE inhibition in the acute oral study in male volunteers (Gledhill, 1997)[b]	0–0.004 mg/kg bw	NOAEL of 0.04 mg/kg bw per day for inhibition of erythrocyte AChE activity in a 21-day study in male volunteers (Boyer et al., 1977)[d]
USEPA (2006)	0.008 mg/kg bw	$BMDL_{10}$ of 0.8 mg/kg bw in female rats for erythrocyte AChE inhibition using the acute toxicity study by Twomey (2002)[c]	0–0.000 5 mg/kg bw	NOAEL of 0.05 mg/kg bw per day in a 52-week dog study for inhibition of plasma butyrylcholinesterase and erythrocyte AChE (Markiewicz, 1990)[e]
EU[a] (2012)	0.002 mg/kg	NOAEL of 0.25 mg/kg	0.000 08 mg/kg	NOAEL of 0.008 mg/kg bw per

[1] Jolley WP, Stemmer KL, Pfitzer EA (1967). The effects exerted upon Beagle dogs during a period of two years by the introduction of Vapona insecticide into their daily diet. Unpublished report from The Kettering Laboratory, Cincinnati, OH, USA, 19 January. Prepared for Shell Chemical Company. Submitted to WHO by Bayer AG, Ciba-Geigy Ltd, Temana International Ltd.

[2] Witherup S, Jolley WJ, Stemmer K, Pfitzer EA (1971). Chronic toxicity studies with 2,2-dichlorovinyl dimethyl phosphate (DDVP) in dogs and rats including observations on rat reproduction. Toxicol Appl Pharmacol. 19:377.

[3] IPCS (1988). Dichlorvos. Geneva: World Health Organization, International Programme on Chemical Safety (Environmental Criteria Monograph 79; http://www.inchem.org/documents/ehc/ehc/ehc79.htm, accessed 28 September 2015).

Jurisdiction	ARfD	Basis	ADI	Basis
	bw	bw for erythrocyte AChE inhibition from developmental toxicity studies in rat and rabbit	bw	Day in a 2-year dog study for inhibition of erythrocyte AChE

$BMDL_{10}$: 95% lower confidence limit of the benchmark dose for a 10% response

[a] Currently, no legally adopted EU toxicological reference values are available for dichlorvos, as the EU assessment considered the toxicological data package insufficient to address the genotoxic and carcinogenic potential of dichlorvos. Considering that the setting of toxicological reference values on the basis of human studies would not be acceptable at the EU level and that the tentative values proposed during the EFSA Peer Review Co-ordination meeting are more conservative, they would be the preferred ones to be used for a provisional risk assessment.

[b] Gledhill AJ (1997). Dichlorvos: a study to investigate the effect of a single dose on erythrocyte cholinesterase inhibition in healthy male volunteers. Central Toxicology Laboratory, Macclesfield, England, United Kingdom. Unpublished report no. CTL/P/5393 (25 March 1997); AMVAC report reference 500-TOX-007.

[c] Twomey K (2002). Dichlorvos (DDVP): third acute cholinesterase inhibition study in rats. Unpublished report submitted by AMVAC Chemical Corporation and conducted by Central Toxicology Laboratory, Cheshire, England, United Kingdom. Report No. CTL/AR7138/Regulatory/Report.

[d] Boyer AC, Brown LJ, Slomka MB, Hine CH (1977). Inhibition of human plasma cholinesterase by ingested dichlorvos: effect of formulation vehicle. Toxicol Appl Pharmacol. 41:389–94.

[e] Markiewicz V (1990). A 52-week chronic toxicity study on DDVP in dogs: Lab Project Number: 2534/102. Unpublished study prepared by Hazleton Laboratories America, Inc. 431 pp. MRID 41593101.

3.2.1.3 Consideration of the report from the WHO Expert Taskforce on Diazinon, Glyphosate and Malathion

In March 2015, the International Agency for Research on Cancer (IARC) undertook a hazard identification on the carcinogenicity of some pesticides. Glyphosate, Malathion and Diazinon were classified as "probably carcinogenic to humans" (group 2A). JMPR last evaluated Diazinon, Glyphosate and Malathion in 1993, 2004 and 1997, respectively, and concluded on the absence of carcinogenicity. In May 2015, WHO created an expert task force of the WHO Core Assessment Group on Pesticide Residues, plus a representative of the IARC working group, to review the information available to IARC and determine whether new data have been generated since the last JMPR evaluations.

After consideration of the report of the expert task force, JMPR recommends the following:

- Given that the last full assessments of diazinon, glyphosate and malathion were done more than a decade ago and given the number of new studies available, JMPR recommends the re- evaluation of these compounds. This re-evaluation should consider all end-points, including carcinogenicity. Residue experts should be involved to identify possible impacts of the re-evaluation on recommended MRLs.
- Considering the importance of genotoxicity in the risk analysis process for MRL setting, experts from the field of genotoxicity and mutagenesis should be consulted.
- JMPR should make transparent in its analysis the criteria and approaches used to determine the quality, relevance and utility of all published and proprietary studies considered.
- The assessment of toxicology studies should focus on the active compounds and not on the pesticide commercial products (formulations). Information on commercial products in use (e.g. from epidemiological studies) should be included where relevant.
- In accordance with its mandate and expertise, the work of JMPR should focus on exposure from residues in food. However, consideration of other exposure routes, such as from use for vector control, is also important for public health. Relevant expertise and data should be considered when planning the assessment so that JMPR can provide recommendations regarding exposure from sources other than residues in food (e.g., indoor air).

Detailed information provided to JMPR by the Secretariat is included in Annex 7 to the 2015 Report.

4. DIETARY RISK ASSESSMENT FOR PESTICIDE RESIDUES IN FOODS

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 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 17 GEMS/Food Consumption cluster diets[1]. IEDIs are expressed as a percentage of the maximum ADI for a 55 kg or 60 kg person, depending on the cluster diet. The spreadsheet application is available at http://www.who.int/foodsafety/areas_work/chemical-risks/gems-food/en/.

New evaluations

Acetochlor, cyazofamid, flonicamid, flumioxazin, lufenuron and quinclorac 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 these compounds.

Flupyradifurone was evaluated for toxicology and an ADI was established. Long-term dietary risk assessment will be conducted when the compound is evaluated for residues in a near future.

A full evaluation of fluazifop-*p*-butyl was postponed until a complete submission of data on the fluazifop compounds and their metabolites are submitted to the Meeting.

Periodic Re-evaluations

Abamectin and ethephon were evaluated for toxicology and residues under the Periodic Re-evaluation Programme. ADIs were established at this Meeting and long-term dietary risk assessments were conducted.

Penconazole was evaluated under the Programme only for toxicological aspects and an ADI was established. Long-term dietary risk assessment will be conducted when the compound is evaluated for residues in a near future.

Evaluations

Acetamiprid, bifenthrin, chlorothalonil, cyantraniliprole, cyprodinil, difenoconazole, fluopyram, flutriafol, fluxapyroxad, imidacloprid, lambda-cyhalothrin, tebuconazole and trifloxystrobin were evaluated for residues and long-term dietary risk assessments were conducted.

The residue recommendations for imazapic, imazapyr, propiconazole, pyrimethanil and spirotetramat did not alter significantly the previous long-term dietary intake estimations and new assessments were not reported.

The residues of lindane, as an environmental contaminant (extraneous residues), in various food commodities were evaluated and a long-term dietary risk assessment was conducted.

Residues data for acetamiprid, cypermethrins, lambda-cyhalothrin, profenofos and triazophos obtained from monitoring studies in spices were evaluated. The contribution of residues of acetamiprid and lambda-cyhalothrin to the long-term-intake was addressed in the evaluation of these compounds. The estimations for cypermethrins, profenofos and triazophos do not alter significantly the previous long-term dietary intake estimations and new assessments were not reported.

The evaluations performed at this Meeting for bentazone, dichlorvos, fenpropathrin and imazamox did not impact on previous assessments.

[1] http://www.who.int/nutrition/landscape_analysis/nlis_gem_food/en/

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 to the 2015 Report. The percentages are rounded to one whole number up to 9 and to the nearest 10 above. 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 refined at the national level by taking into account more detailed information, as described in the Guidelines for predicting intake of pesticide residues[1].

Table 1 Summary of long-term dietary of risk assessments conducted by the 2015 JMPR.

CCPR code	Compound Name	ADI (mg/kg bw)	Range of IEDI, as % of the maximum ADI
177	Abamectin	0–0.001	1–5
246	Acetamiprid	0–0.07	0–4
280	Acetochlor	0–0.01	0–4
178	Bifenthrin	0–0.01	9–30
081	Chlorothalonil	0–0.02	10–50
	2,5,6-trichloro-4-hydroxyisophthalonitrile (SDS-3701)	0–0.008	4–10
263	Cyantraniliprole	0–0.03	2–20
281	Cyazofamid	0–0.2	0–4
207	Cyprodinil	0–0.03	9–70
224	Difenoconazole	0–0.01	7–70
106	Ethephon	0–0.05	0–6
282	Flonicamid	0–0.07	1–10
284	Flumioxazin	0–0.02	0–1
243	Fluopyram	0–0.01	4–30
256	Fluxapyroxad	0–0.02	4–20
248	Flutriafol	0–0.01	3–20
206	Imidacloprid	0–0.06	2–5
146	Lambda-cyhalothrin	0–0.02	2–9
048	Lindane	0–0.005	0–1
286	Lufenuron	0–0.02	0–4
287	Quinclorac	0–0.4	0
189	Tebuconazole	0–0.03	2–9
213	Trifloxystrobin	0–0.04	1–4

Assessment of risk from short-term dietary intake

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[2].

Large portion data were available to GEMS/Food for Australia, Brazil, China, Finland, France, Germany, Japan, Netherlands, South Africa, Thailand, United Kingdom and United States. Large portion data have been provided for general population (all ages), women of childbearing age (14–50 yrs), and children of various ages (6 yrs and under). For each commodity, the highest large portion data from all different population groups was included in the spreadsheet for the calculation of the IESTI. The spreadsheet application is available at http://www.who.int/foodsafety/areas_work/chemical-risks/gems-food/en/

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

2 Pesticide residues in food—2004 evaluations. Part I. Residues. FAO Plant Production and Protection Paper, 182, 2005.

New evaluations

Acetochlor, flumioxazin and quinclorac 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.

The Meeting agreed that an ARfD for flonicamid and lufenuron were unnecessary and short-term dietary intake assessments were not conducted.

An ARfD for cyazofamid was considered unnecessary, but and ARfD was established for its metabolite 4-chloro-5-p-tolymidazole-2-carbonitrile (CCIM) and a short-term dietary intake assessment was conducted.

Flupyradifurone was evaluated for toxicological effects and an ARfD was established. The compound will be evaluated for residue aspects in a near future, when the short-term-dietary assessments will be conducted.

A complete evaluation of fluazifop-*p*-butyl was postponed until a complete submission of data on the fluazifop compounds and their metabolites are submitted to the Meeting.

Periodic re-evaluations

Abamectin and ethephon were evaluated for toxicology and residues under the Periodic Re-evaluation Programme. ARfD were established and short-term dietary intake assessments were performed.

Penconazole was evaluated for toxicological effects and an ARfD was established. The compound will be evaluated for residue aspects in a near future, when the short-term-dietary assessments will be conducted.

Evaluations

Acetamiprid, bifenthrin, chlorothalonil, difenoconazole, fluopyram, fluxapyroxad, flutriafol, imidacloprid, lambda-cyhalothrin, lindane, propiconazole, spirotetramat and tebuconazole were evaluated for residues and short-term dietary risk assessments were conducted for these compounds.

The evaluations of bentazone, dichlorvos, fenpropathrin and imazamox performed at this Meeting did not impact the short-term dietary assessment performed previously.

AS, on the basis of data received by previous Meetings, ARfDs were considered unnecessary for cyantraniliprole, cyprodinil, imazapic, imazapyr, pyrimethanil and trifloxystrobin, no short-term intake assessment was conducted.

Residues of acetamiprid, cypermethrins, lambda-cyhalothrin, profenofos and triazophos obtained from monitoring studies in spices were evaluated. The short-term-intakes for acetamiprid and lambda-cyhalothrin were addressed in the evaluation of these compounds, and were performed for cypermethrins, profenofos and triazophos.

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 to the 2015 Report.

Table 2 Maximum percentage of the ARfD found in the short-term dietary risk assessments conducted by the 2015 JMPR. The crops are specified when the ARfD was exceeded,

CCPR code	Compound Name	ARfD (mg/kg bw)	Max. percentage of ARfD	
			Commodity (% ARfD)	Population, age in years (country)
177	Abamectin	0.003	Spinach (140)	Child, 1-5 (South Africa)
			Others (60)	All
246	Acetamiprid	0.1	Mustard greens (490)	Child, 1-6 (China)
			Mustard greens (200)	General population, > 1 (China)

CCPR code	Compound Name	ARfD (mg/kg bw)	Max. percentage of ARfD	
			Commodity (% ARfD)	Population, age in years (country)
			Others (10)	All
280	Acetochlor	1	All (0)	All
178	Bifenthrin	0.01	Celery (600)	Child, 1-6 (China)
			Celery (360)	General population, >1 (Netherlands)
			Head lettuce (430)	Child, 2-6 (Netherlands)
			Head lettuce (190)	General population, >1 (Netherlands)
			Others (100)	All
081	Chlorothalonil	0.6	All (30)	All
	2,5,6-trichloro-4-hydroxyisophthalonitrile (SDS-3701)	0.03	All (10)	All
281	Cyazofamid			
	4-chloro-5-p-tolymidazole-2-carbonitrile (CCIM)	0.2	All (90)	All
118	Cypermethrins	0.04	Cardamom seed (0)	All
224	Difenoconazole	0.3	All (3)	All
106	Ethephon	0.05	All (100)	All
284	Flumioxazin	0.03 [a]	All (7)	General population > 2 (Australia) [b]
243	Fluopyram	0.5	All (10)	All
248	Flutriafol	0.05	Leaf lettuce (360)	Child, 1-6 (China)
			Leaf lettuce (120)	General population, > 1 (China)
			Spinach (490)	Child, 1-5 (South Africa)
			Spinach (150)	General population, > 1 (China)
			Mustard greens (350)	Child, 1-6 (China)
			Mustard greens (140)	General population, > 1 (China)
			Others (80)	All
285	Fluxapyroxad	0.3	Spinach (190)	Child, 1-5 (South Africa)
			Others (60)	All
206	Imidacloprid	0.4	All (10)	All
146	Lambda-cyhalothrin	0.02	All (2)	All
048	Lindane	0.06	All (0)	All
112	Phorate	0.007	Fennel, seed (10)	Child, 2-4 (Germany)
171	Profenofos	1	All spices (0)	All
160	Propiconazole	0.07	All (3)	All
287	Quinclorac	2	All (1)	All
234	Spirotetramat	1	All (2)	All
189	Tebuconazole	0.3	All (5)	All
143	Triazophos	0.001	Fennel, seed (7)	Child, 2-4 (Germany)

[a] for women of child-bearing-age only;

[b] Surrogate consumption data in the absence of women of child-bearing-age consumption data.

Possible risk assessment refinement when the IESTI exceeds the ARfD

Abamectin: Spinach may be eaten without any further processing. As no alternative GAP was available to the Meeting to estimate a lower HR value, no refinement of the short-term intake is currently possible for this commodity.

The ARfD of 0.003 mg/kg bw for abamectin established by the present Meeting was based on the overall NOAEL of 0.25 mg/kg bw per day for clinical signs in dogs (mydriasis) observed in the first week of treatment at 0.5 mg/kg bw per day. Since the exact time-point for the occurrence of mydriasis in the first week of treatment was not specified in the study report, the Meeting was not able to preclude whether these effects could be attributed to a single dose. The Meeting recognized that the ARfD for abamectin may be conservative and a refinement might be possible if new data became available.

Acetamiprid: Mustard greens may be eaten without any further processing. As no alternative GAP was available to the Meeting to estimate a lower HR value, no refinement of the short-term intake is currently possible for this commodity.

The ARfD of 0.1 mg/kg bw for acetamiprid was established by the 2011 JMPR on the basis of a NOAEL of 10 mg/kg bw in an acute neurotoxicity study in rats, based on evidence of neurotoxicity, decreased locomotor activity and increased urination frequency. This ARfD was supported by the NOAEL for maternal toxicity in the developmental neurotoxicity study of 10 mg/kg bw per day, based on reduced body weight gain in dams during the first 3 days of dosing (gestation days 6–9). The present Meeting recognised that any refinement of the ARfD for acetamiprid is unlikely to result in an increase of sufficient magnitude that would alter the conclusion that the short-term-intake of acetamiprid from the consumption of mustard greens may represent a public health concern.

Bifenthrin: Celery and head lettuce may be eaten without any further processing. As no alternative GAP was available to the Meeting to estimate a lower HR value, no refinement of the short-term intake is currently possible for this commodity.

The ARfD of 0.01 mg/kg bw for bifenthrin was established in 2009 based on a threshold dose of 1.3 mg/kg bw for motor activity in a study of acute toxicity in rats treated by gavage and using a safety factor of 100. Although this study was conducted with males only, it was considered appropriate, as there was no evidence of sex-specific differences among the data on bifenthrin. This ARfD was supported by the study of developmental toxicity in rats treated by gavage in which the 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 LOAEL of 2.0 mg/kg bw per day and which thereby was also protective for developmental effects. Hence, refinement of the ARfD is unlikely since this endpoint is based on the most sensitive compound related effects measured in the study. This is supported by the fact that the LOAEL of 2 mg/kg bw in the developmental toxicity study in rats is only two-fold the NOAEL

Fluxapyroxad: Spinach may be eaten without any further processing. As no alternative GAP was available to the Meeting to estimate a lower HR value, no refinement of the short-term intake is currently possible for this commodity.

The ARfD of 0.3 mg/kg bw for fluxapyroxad was established in 2012 on the basis of the NOAEL of 25 mg/kg bw per day in the developmental toxicity study in rabbits for early resorptions and the rat developmental toxicity study based on a transient decrease in body weight gain from gestation day 6 to gestation day 8. A safety factor of 100 was applied. The present Meeting recognised that the ARfD for fluxapyroxad was conservative and a refinement might be possible if new data became available.

Flutriafol: Leaf lettuce, mustard greens and spinach may be eaten without any further processing. As no alternative GAP was available to the Meeting to estimate a lower HR value, no refinement of the short-term intake is currently possible for this commodity.

The ARfD of 0.05 mg/kg bw for flutriafol was established by the 2011 JMPR on the basis of the NOAEL of 5 mg/kg bw per day in the 90-day and 1-year toxicity studies in dogs based on reduced body weight gain (males) or body weight loss (females) after 1 week (the first time of measurement) and subsequently reduced body weight gain during the early part of the study, although feed consumption was unaffected by treatment. A safety factor of 100 was applied. This provides a margin of greater than 1000 between the ARfD and the LOAEL for cleft palate in rats (75 mg/kg bw per day). The present Meeting recognised that any refinement of the ARfD for flutriafol is unlikely to result in an increase of sufficient magnitude that would alter the conclusion that short-term-intake of flutriafol from the consumption of leaf lettuce, mustard greens and spinach may represent a public health concern.

6. RECOMMENDATIONS

The Meeting recommended that a WHO/FAO working group be established to compare the use of current and proposed IESTI equations and to present the outcome to the CCPR in due course.

The Meeting recommends that the Secretariat convene an expert working group in order to develop models to cover exposures longer than 1 day but shorter than lifetime, as needed. The Meeting also recommends that the applicability of these considerations to other categories of chemicals, such as veterinary drugs and contaminants, should be investigated.

The Meeting recommended that consideration be given to the need to include a section or revision of EHC 240 to take account of recent developments on adverse outcome pathways and their use in hazard characterization.

7. FUTURE WORK

The items listed below are tentatively scheduled to be considered by the Meetings in 2017. The compounds listed include those recommended as priorities by the CCPR at its Forty-sixth 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/

http://www.who.int/ipcs/food/en/

NEW COMPOUNDS	**NEW COMPOUNDS**
TOXICOLOGY EVALUATIONS	**RESIDUE EVALUATIONS**
Bicyclopyrone [Syngenta]	Bicyclopyrone [Syngenta]
Fenazaquin [Gowan]	Fenazaquin [Gowan]
Fenpyrazamine [Sumitomo Chemical]	Fenpyrazamine [Sumitomo Chemical]
Isoprothiolane (India)	Isoprothiolane (India)
Natamycin [DSM Food Specialties]	Natamycin [DSM Food Specialties]
Phosphorous acid & fosetyl-aluminium [Nufarm]	Phosphorous acid & fosetyl-aluminium [Nufarm]
Quinalphos (India)	Quinalphos (India)
SYN545794 [Syngenta]	SYN545794 [Syngenta]
Tricyclazole (India)	Tricyclazole (India)
Triflumezopyrim (DuPont)	Triflumezopyrim (DuPont)

PERIODIC RE-EVALUATIONS	**PERIODIC RE-EVALUATIONS**
Carbendazim [Nippon Soda Co] (72)	Carbendazim (72)
Clethodim (187) (Arysta LifeScience)	Clethodim (187)
Metalaxyl (138) (Quimicas del Vallés - SCC Gmb)	Metalaxyl (138)
Fenpyroximate (193) [Nihon Nohyaku]	Fenpyroximate (193)
Kresoxim-methyl (199) (BASF)	Kresoxim-methyl (199)
Oxamyl (126) [Dupont]	Oxamyl (126)
Tolclofos-methyl (191) [Sumitomo Chemical]	Tolclofos-methyl (191)

	EVALUATIONS (Residues)
	2,4-D (020) Dow AgroSciences]
	Acephate (95) India

	EVALUATIONS (Residues)
	Acetamiprid (246) [Syngenta]
	Azoxystrobin (229) [Syngenta]
	Bifenthrin (178) India
	Captan (7) [Arysta]
	Carbendazim (72) (India)
	Chlorpyrifos (017) (India)
	Cyprodinil (207) [Syngenta]
	Diazinon (22) (India)
	Difenoconazole (224) [Syngenta]
	Dimethoate (27) (India)
	Ethion (34) (India)
	Flonicamid (282) [Ishihara Sangyo Kaisha]
	Fluopyram (243) [Bayer CropScience]
	Flupyradifurone (285) [Bayer CropScience]
	Hexaconazole (170)
	Imidacloprid (206) India
	Imazamox (276), imazapyr (267) [BASF]
	Isopyrazam (249) [Syngenta]
	Isoxaflutole(268) [Bayer CropScience]
	Lambda-cyhalothrin (146) (India)
	Methomyl (94) (India)
	Picoxystrobin(258) [Dupont]
	Pirimicarb (101) [Syngenta]
	Profenofos (171) India
	Propiconazole (160)
	Propylene oxide [Balchem] (250)
	Prothioconazole (232) [Bayer CropScience]
	Pyraclostrobin (210)

	EVALUATIONS (Residues)
	Pyriproxyfen (200) -Costa Rica
	Sedaxane (259) [Syngenta]
	Spinetoram (233) Thailand; (Dow AgroSciences USA)
	Spiromesifen (999) India
	Tebuconazole (189) [Bayer CropScience]
	Triazophos (143) India
	Trifloxystrobin (213) [Bayer CropScience]

8. CORRIGENDA

Pesticide Residues in Food—2014. 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 221, 2014

Changes are shown in bold

5.12 Fenpropathrin (185)

Page 165, the table should read:

RAC/processed fraction	Processing factors					PF estimated	STMR-P (mg/kg)
RAC:Whole orange	-						
Juice	<0.02	<0.22				<0.02	0.007
Oil	78.7	21.56				50.1	16.5
Wet peel	0.6	0.78	2.76		2.86	2.82	0.93
Dried peel	1.6	2.67				2.1	0.70
Pulp			0.06		0.07	0.065	0.021
RAC: Plum							
Dried plum	2.56					2.56	0.639
RAC: Tomato							
Canned	0.077	0.071	0.077			<0.075	**0.014**
Wet pomace				9.9	**~~9.8~~**	9.8	**1.88**
Dry pomace				46	**~~45.0~~**	**46**	**8.74**
Tomato paste				0.78	**~~0.75~~**	**0.78**	**0.148**
Tomato juice				0.12	**~~0.1~~**	**0.12**	0.023

Page 165, paragraphs 6, 7 and 8 should read:

There is no concentration of residues in juice and molasses. Residues concentrate in oil (Pf=50.1), and dried peel (Pf=2.1). Only the peel residue data (2.76, 2.86) were taken into consideration as it was considered highly unlikely that the wet would peel contain less residue than the whole fruit, given the residue concentrates in the peel.

The Meeting estimated a maximum residue level of 100 mg/kg and STMR-P of 16.5 mg/kg for citrus oil,

Drying concentrates the residues of fenpropathrin in plums by a factor of 2.6×. The first trial where the residue in dried plum was the same as in the fresh was considered invalid. Consequently, the Meeting only considered the second trial resulting in a processing factor of 2.555. The Meeting estimated maximum residue level of 3 mg/kg, HR-P of 1.85 mg/kg and STMR-P of 0.65 mg/kg for dried plums (or prunes).

ANNEX 7: REPORT OF THE SECRETARIAT ON THE WORKOF THE WHO EXPERT TASK FORCE ON CARCINOGENICITY OF DIAZINON, GLYPHOSATE AND MALATHION FOR CONSIDERATION BY JMPR

NOTE: Extensive tables summarizing the references compiled from the relevant JMPR and IARC monographs as well as the studies submitted to EFSA for each of the three compounds were also provided to JMPR and are not included in this annex. These can be made available on request (contact: jmpr@who.int).

1 Diazinon

The full IARC monograph on diazinon was not published by September 2015 and therefore was not available to the task force. IARC has published a summary of the findings on diazinon,[1] and the full monograph will be published later as part of IARC Monograph Volume 112.[2] The IARC summary included a classification of Group 2A, probably carcinogenic to humans, for diazinon. This classification was based on:

- *limited evidence of carcinogenicity in humans* – Epidemiological studies indicated no overall increased risk of non-Hodgkin lymphoma. An increased risk of both leukaemia and lung cancer was noted in the Agricultural Health Study (a collaborative effort in the USA), but these findings were not replicated in other studies.
- *limited evidence of carcinogenicity in experimental animals* – The incidence of hepatocellular carcinoma was increased in male mice, and the combined occurrence of leukaemia and lymphoma was increased in rats, but only at the low dose (100 ppm in mice, equivalent to 15 mg/kg bw per day; 400 ppm in rats, equivalent to 20 mg/kg bw per day).
- *mechanistic evidence of genotoxicity and oxidative stress* – DNA or chromosomal damage in rodents and in human and mammalian cells in vitro.

JMPR evaluated diazinon in 1993, 2001 and 2006. The main assessment for carcinogenicity and genotoxicity was undertaken as part of the evaluation in 1993, when it was concluded that diazinon is not carcinogenic or genotoxic on the basis of no evidence of carcinogenicity in long-term studies in mice and rats and no indications of genotoxicity in an adequate series of genotoxicity assays other than the induction of chromosomal aberrations in cultured mammalian cells. JMPR has not previously evaluated any epidemiological data or considered mechanistic data on diazinon.

Subsequent to these previous JMPR evaluations, new information has become available. Therefore, it is appropriate that JMPR revisit the carcinogenicity and genotoxicity of diazinon, including an assessment of epidemiological studies and relevant mechanistic studies, as appropriate. The assessment of the relevance of the mechanistic studies should be guided by the outcome of the evaluation of the rodent bioassay data and genotoxicity assays.

Recommendation

In light of the studies that have not been previously considered by JMPR, including studies considered by IARC and national pesticide regulatory agencies, it is recommended that JMPR discuss and consider the re-evaluation of the active substance diazinon.

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[1] Guyton KZ et al., on behalf of the International Agency for Research on Cancer Monograph Working Group, IARC, Lyon, France (2015). Carcinogenicity of tetrachlorvinphos, parathion, malathion, diazinon, and glyphosate. Lancet Oncol. 16(5):490–1.

[2] IARC (2015). Some organophosphate insecticides and herbicides: diazinon, glyphosate, malathion, parathion, and tetrachlorvinphos. Lyon: International Agency for Research on Cancer (IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Volume 112).

2. Glyphosate

IARC published a summary of the findings on glyphosate in *The Lancet Oncology*,[1] and the glyphosate monograph was published on 29 July 2015[2] and provided to the task force on that date. The summary and monograph included a classification of Group 2A, probably carcinogenic to humans, for glyphosate. This classification was based on:

- *limited evidence of carcinogenicity in humans* – A positive association was observed for non-Hodgkin lymphoma.
- *sufficient evidence of carcinogenicity in experimental animals*, supported by mechanistic evidence of genotoxicity and oxidative stress.

JMPR most recently evaluated glyphosate in 2004 and 2011. The 2004 evaluation found no evidence of carcinogenicity in long-term studies in mice and rats, and negative results were obtained in an adequate range of genotoxicity studies performed in compliance with current test guidelines. The 2011 evaluation covered only the metabolites *N*-acetyl-glyphosate and *N*-acetyl-aminomethylphosphonic acid in genetically modified plants and is therefore not relevant to this exercise on the carcinogenicity of the parent compound, glyphosate.

The primary purpose of this task was to compare publications cited by IARC (2015) with those cited by JMPR (2004) and to identify those epidemiological, rodent bioassay, genotoxicity and other mechanistic studies that were not considered by JMPR in its assessment of the carcinogenic risk posed by exposure to glyphosate. In addition, the task force considered references cited in a report by EFSA (2014),[3] which was released in April 2014 for public consultation and will be finalized and published before the end of 2015. No comparison of references cited by the proposed re-evaluation decision PRVD2015-01 on glyphosate from the Pest Management Regulatory Agency (PMRA) of Health Canada (April 2015)[4] was included in this assessment, because the IARC monograph was made available only on 29 July 2015 and there was no time within the mandate of the task force to make this comparison. Any relevant study (e.g. those cited by PMRA) not identified in the current analysis because of the limited time frame should be considered in the proposed re-evaluation by JMPR.

The original reference list that IARC submitted to the task force in May 2015 included 403 studies. In the published IARC monograph (July 2015), only 263 studies were reported. The original list shared with JMPR consisted of all references "included" in the HAWC Literature Search tool (a collaborative workspace for conducting risk assessments for human health; https://hawcproject.org/) plus all references cited in the preliminary drafts. Therefore, IARC characterized the list as the literature "considered" by the IARC Working Group. The difference between the number of references included in the original list and the number of references included in the final monograph can be mainly attributed to the fact that not all identified literature must be cited in Sections 1 (epidemiology) and 4 (mechanistic and other studies).

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[1] Guyton KZ et al., on behalf of the International Agency for Research on Cancer Monograph Working Group, IARC, Lyon, France (2015). Carcinogenicity of tetrachlorvinphos, parathion, malathion, diazinon, and glyphosate. Lancet Oncol. 16(5):490–1.

[2] IARC (2015). Glyphosate. In: Some organophosphate insecticides and herbicides: diazinon, glyphosate, malathion, parathion, and tetrachlorvinphos. Lyon: International Agency for Research on Cancer (IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Volume 112; http://monographs.iarc.fr/ENG/Monographs/vol112/mono112-02.pdf, accessed 28 September 2015).

[3] The studies cited in this report, which have not yet been published, should be submitted by the European Glyphosate Task Force (a consortium of companies joining resources and efforts in order to renew the European glyphosate registration with a joint submission) for the proposed re-evaluation of glyphosate by JMPR.

[4] Summary available at http://www.hc-sc.gc.ca/cps-spc/pest/part/consultations/_prvd2015-01/prvd2015-01-eng.php.

Glyphosate References on Epidemiological Studies

Forty references for epidemiological studies were cross-checked between the relevant JMPR, IARC and EFSA publications:

- There were three studies cited by IARC (2015) and three studies cited by EFSA (2014) that were also available to and evaluated by JMPR (2004).
- There were 28 studies cited by IARC (2015) that were not available to or evaluated by JMPR (2004).
- There were 30 studies cited by EFSA (2014) that were not available to or evaluated by JMPR (2004). These studies have not yet been published by the study owner, but should be submitted by the Glyphosate Task Force for consideration by JMPR.

Glyphosate References on Rodent Cancer Bioassays

Fifteen references for carcinogenicity studies in rodents were cross-checked between the relevant JMPR, IARC and EFSA publications:

- There were two reports cited by IARC (2015) that were also available to and evaluated by JMPR (2004).
- There were five reports cited by IARC (2015) that were not available to or evaluated by JMPR (2004).
- There were six reports cited in the EFSA (2014) assessment that were not available to or evaluated by JMPR (2004) or IARC (2015), but were reviewed in the publication of Greim et al. (2015).[1] These studies have not yet been published by the study owner, but should be submitted by the Glyphosate Task Force for consideration by JMPR.

Glyphosate References on Genotoxicity Studies

Active Substance Glyphosate

There were 99 references on the genotoxicity of glyphosate, but these could not be fully cross-checked between the relevant JMPR, IARC and EFSA publications. The task force also conducted a literature search for genotoxicity references published after the IARC (2015) review:

- There were three studies cited by IARC (2015) that were also available to and evaluated by JMPR (2004). One of the three references is a review article.
- There were 49 studies cited by IARC (2015) that were not available to or evaluated by JMPR (2004).
- There were four recently published studies identified by the task force that were not evaluated by JMPR (2004).
- There were 30 studies cited by EFSA (2014) that were not available to or evaluated by IARC (2015) or JMPR (2004). These studies have not yet been published by the study owner, but should be submitted by the Glyphosate Task Force for consideration by JMPR.

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[1] Greim H, Saltmiras D, Mostert V, Strupp C (2015). Evaluation of carcinogenic potential of the herbicide glyphosate, drawing on tumor incidence data from fourteen chronic/carcinogenicity rodent studies. Crit Rev Toxicol. 45(3):185–208.

Glyphosate-containing Formulations and AMPA

There were many references relating to genotoxicity studies on glyphosate-containing formulations or aminomethylphosphonic acid (AMPA), but these could not be cross-checked between the relevant JMPR, IARC and EFSA publications within the available time frame.

Glyphosate References on Oxidative Stress and Other Mechanistic Studies

The IARC monograph includes mechanistic studies and other relevant data that might be of importance for a re-evaluation of toxicity end-points other than carcinogenicity.

Recommendations

In light of the studies identified in the publications by IARC (2015) and EFSA (2014) that were not considered by JMPR (2004), as well as the additional genotoxicity studies identified by the task force, it is recommended that JMPR discuss and consider the re-evaluation of the active substance glyphosate. In particular:

- It is recommended that Section 4.2.1 of the IARC monograph on genetic and related effects be carefully considered within the re-evaluation by JMPR, if the studies are performed with the active substance glyphosate, glyphosate-containing formulations and/or AMPA.
- It is recommended that the studies evaluated by IARC in Chapter 4 of the monograph, especially those on toxicokinetic data, receptor-mediated mechanisms, inflammation and immunomodulation, and cell proliferation and death, be considered in a full JMPR re-evaluation.

3. Malathion

The full monograph on malathion was not published by September 2015 and therefore was not available to the task force. IARC has published a summary of the findings on malathion,[1] and the full monograph will be published later as part of IARC Monograph Volume 112.[2] The IARC summary included a classification of Group 2A, probably carcinogenic to humans, for malathion based on:

- *limited evidence in humans – for non-Hodgkin lymphoma and prostate tumours.*
- *sufficient evidence in experimental animals, supported by mechanistic evidence of genotoxicity, oxidative stress, inflammation, receptor-mediated effects and cell proliferation or death.*

JMPR reviewed malathion in 1997 and summarized the animal bioassay and genotoxicity data. The 1997 Meeting concluded that malathion was not genotoxic, but did not make a concluding statement on carcinogenicity. JMPR cited the conclusion of IARC from 1983 that the available data did not provide evidence that malathion was carcinogenic in humans. New bioassays available at that time were summarized, including a mouse study that reported an increased incidence of hepatocellular adenomas at the two highest doses. JMPR also reviewed malathion in 2003, but carcinogenicity was not assessed. That Meeting focused on whether an acute reference dose was needed.

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[1] Guyton KZ et al., on behalf of the International Agency for Research on Cancer Monograph Working Group, IARC, Lyon, France (2015). Carcinogenicity of tetrachlorvinphos, parathion, malathion, diazinon, and glyphosate. Lancet Oncol. 16(5):490–1.

[2] IARC (2015). Some organophosphate insecticides and herbicides: diazinon, glyphosate, malathion, parathion, and tetrachlorvinphos. Lyon: International Agency for Research on Cancer (IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Volume 112).

Malathion References on Epidemiological Studies

None of the 47 epidemiological studies cited by IARC (2015) was available to or evaluated by JMPR (1997, 2003).

Malathion References on Rodent Cancer Bioassays

Ten references for carcinogenicity studies in rodents were cross-checked between the relevant JMPR, IARC and EFSA publications:

- Three reports cited by IARC (2015) were also available to and evaluated by JMPR (1997).
- One report cited by IARC (2015) was not available to or evaluated by JMPR (1997).
- There were four unpublished reports cited by JMPR (1997) that were not evaluated by IARC (2015) and two reports on the metabolite malaoxon (one published and one not) that were cited by JMPR (1997) but not by IARC (2015). IARC (2015) cited the USEPA, EU and PMRA evaluations of malathion, which include the majority of these reports.
- Recently, the data sponsor provided a list of references that included 16 unpublished reports not previously reviewed by JMPR (1997). It should be noted that they were all supplementary information for long-term studies that were cited by JMPR (1997). This supplementary information included statistical analysis of survivorship and pathology peer review. The USEPA review of three of these reports was cited by IARC (2015).

Malathion References on Genotoxicity Studies

There were 100 references on the genotoxicity of malathion, including two identified by the task force from a literature search for genotoxicity references published after the IARC (2015) review:

- There were 22 reports cited by IARC (2015) that were also available to and evaluated by JMPR (1997).
- There were 65 reports cited by IARC (2015) that were not available to or evaluated by JMPR (1997).
- There were six unpublished reports cited by JMPR (1997) and three unpublished reports cited by JMPR (2003) that were not cited by IARC (2015). IARC (2015) cited the USEPA, EU and PMRA evaluations of malathion, which presumably included the majority of the reports cited by JMPR.
- The data sponsor recently provided a list of references that included five unpublished reports not previously reviewed by JMPR (1997, 2003).

Recommendation

In light of the number of epidemiological and genotoxicity studies that have not been reviewed by JMPR, it is recommended that JMPR discuss and consider the re-evaluation of the active substance malathion.

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FAO PLANT PRODUCTION AND PROTECTION PAPERS

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4	Soybean production in the tropics, 1977 (C E F S)
4 Rev.1	Soybean production in the tropics (first revision), 1982 (E)
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6/2	Pest resistance to pesticides and crop loss assessment – Vol. 2, 1979 (E F S)
6/3	Pest resistance to pesticides and crop loss assessment – Vol. 3, 1981 (E F S)
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8	Tropical pasture seed production, 1979 (E F** S**)
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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 Geneva, Swizerland, from 15 to 24 September 2015. The FAO Panel of Experts had met in preparatory sessions from 10 to 14 September 2015. 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.

ISBN 978-92-5-108996-5 ISSN 0259-2517

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I5186E/1/11.15