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Pesticide residues in food 2012

Joint FAO/WHO Meeting on Pesticide Residues

REPORT 2012

World Health Organization

Food and Agriculture Organization of the United Nations

Pesticide residues in food 2012

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Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues
Rome, Italy, 11-20 September 2012

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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ROME, 11–20 SEPTEMBER 2012

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ABBREVIATIONS

ADI	acceptable daily intake
ai	active ingredient
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
bw	body weight
CAC	Codex Alimentarius Commission
CAS	Chemical Abstracts Service
CCN	Codex classification number (for compounds or commodities)
CCPA	4-chloro-2-carboxyphenoxyacetic acid
CCPR	Codex Committee on Pesticide Residues
C_{max}	maximum concentration
CPIA	chlorophenylisovaleric acid
CXL	Codex MRL
CYP	cytochrome P450
DAP	days after planting
DAT	days after treatment
DM	dry matter
DMA	dimethylamine
DNA	deoxyribonucleic acid
DT_{50}	time required for 50% dissipation of the initial concentration
dw	dry weight
ECD	electron capture detector
EHC	Environmental Health Criteria monograph
EHE	ethylhexyl ester
EPO	early post-emergence
EU	European Union
F_0	parental generation
F_1	first filial generation
FAO	Food and Agriculture Organization of the United Nations
fw	fresh weight

GAP	good agricultural practice
GC	gas chromatography
GC-ECD	gas chromatography with electron capture detection
GC-FPD	gas chromatography with flame photometric detection
GC/MS	gas chromatography/mass spectrometry
GC/MSD	gas chromatography/mass selective detector
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
GLC	gas liquid chromatography
GLP	good laboratory practice
GPC	gel permeation chromatography
HMCPA	4-chloro-2-hydroxymethyl phenoxyacetic acid
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
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
JP	Japan
LC	liquid chromatography
LC_{50}	median lethal concentration
LD_{50}	median lethal dose
LOAEL	lowest-observed-adverse-effect level
LOD	limit of detection
LOQ	limit of quantification
MOA	mode of action
MPA	2-methylphosphinico-acetic acid
MPB	4-methylphosphinico-butanoic acid
MPP	3-[hydroxy(methyl) phosphinoyl]propionic acid (= 3-methylphosphinico-propionic acid)

MRL	maximum residue limit
MS	mass spectrometry
MS/MS	tandem mass spectrometry
NAG	*N*-acetylglufosinate
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
PAG3	2-(2-hydroxymethylphenyl)-2-oxoacetic acid
PAM	1-methyl-3-trifluoromethyl-1H-pyrazole-4-carboxamide
PB	3-phenoxybenzoic
PBI	plant back interval
PCA	1-methyl-3-trifluoromethyl-1H-pyrazole-4-carboxylic acid; 4-chloroaniline
Pf	processing factor
PH	pre-harvest
PHI	pre-harvest interval
ppm	parts per million
PRE	pre-emergence
RAC	raw agricultural commodity
RSD	relative standard deviation
RTI	re-treatment interval
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
TAR	total administered radioactivity
TF	transfer factor
TLC	thin-layer chromatography
TMPA	2,2,3,3-tetramethylcyclopropane carboxylic acid
TRR	total radioactive residues
TTC	threshold of toxicological concern
UK	United Kingdom
USA	United States of America
US/CAN	United States and Canada
USEPA	United States Environmental Protection Agency
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 2012 JOINT FAO/WHO MEETING OF EXPERTS

1. INTRODUCTION

A Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group (JMPR) was held at FAO Headquarters, Rome (Italy), from 11 to 20 September 2012. The Panel Members of FAO met in preparatory sessions on 6–10 September.

The Meeting was opened by Dr Gavin Wall, Director, OiC, Plant Production and Protection Division (AGP), FAO. On behalf of FAO and WHO, Dr Wall welcomed and thanked the participants for providing their expertise and for the significant time and effort put into such an important activity, noting that there were 40 participants from 17 countries. He also expressed gratitude to the respective national authorities, institutes and organizations that have allowed their experts to contribute to this important work on pesticide residues.

The long history and key role played by the JMPR in the establishment of global residues standards was highlighted by Dr Wall. In particular, the importance of the JMPR pesticide risk assessments and the provision of scientific advice in helping to ensure the supply of safe food to consumers and the facilitation of fair international trade. Activities closely aligned with a fundamental principle of the UN, i.e., that all people should have access to sufficient and safe food to meet their needs via an efficient and fair food trade system.

In this context Dr Wall referred to the zero hunger campaign, recently launched by the Secretary-General of the UN at the time of the Rio+20 event. He pointed out that eradication of hunger could not be achieved without consumers having access to safe, affordable food. He highlighted that as the hungry and the sick are more vulnerable to the impacts of food contaminants there was a broader need to ensure that safe food should go hand in hand with safe water and improved sanitation, further underlining the importance of the work undertaken by the JMPR.

The issue of JMPR resourcing and its importance were also commented upon by Dr Wall. He mentioned that the issue had recently been discussed by the Codex Alimentarius Commission with member countries acknowledging their responsibility to ensure JMPR was sufficiently funded to enable the efficient provision of high quality scientific advice continued in a sustainable and timely manner. To this end Dr Wall indicated that the CAC had established a working group to identify short and longer term solutions to the current resource constraints.

Dr Selma Doyran, Chief Secretary, Codex Alimentarius Commission Joint FAO/WHO Food Standards Programme, also addressed the Meeting. She commented on the importance of scientific advice and how this had been raised at a recent the WTO SPS committee meeting. She also thanked the participants for their commitment and hard work in undertaking the activities of the JMPR.

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 residues of pesticides in foods. The reports of previous Joint Meetings (see Annex 5) contain information on acceptable daily intakes (ADIs), acute reference doses (ARfDs), MRLs and the general principles that have been used for evaluating pesticides. The supporting documents (residue and toxicological evaluations) contain detailed monographs on these pesticides and include evaluations of analytical methods.

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

The Meeting evaluated 31 pesticides, including 7 new compounds and 7 compounds that were re-evaluated within the periodic review programme of the CCPR, for toxicity or residues, or both.

The Meeting allocated ADIs and ARfDs, estimated maximum residue levels and recommended them for use by the CCPR, and estimated STMR and highest residue 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 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 of the CCPR. The rationale for methodologies for long- and short-term dietary risk assessment are described in detail in FAO Manual on the submission and evaluation of pesticide residue data for the estimation of MRLs in food and feed (2009).

The Meeting considered a number of 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 2012 JMPR had completed declaration-of-interest forms and that no conflicts had been identified.

2. GENERAL CONSIDERATIONS

2.1 FURTHER CONSIDERATION ON "COMPOUNDS NO LONGER SUPPORTED BY THE ORIGINAL SPONSOR"

The most usual reason for referring an item to the JMPR agenda is to obtain recommendations for maximum residue limits (MRLs) for plant protection products, for consideration by CCPR. These would normally be products in commerce, with a commercial sponsor (i.e. an agrochemical company) that would be expected to generate and provide the appropriate data for consideration of the establishment of health-based guidance values and MRLs.

There may be a need for use of plant protection products no longer under patent and produced by generics companies or other manufacturers, with no support from the companies that generated the original data. Sometimes, older active ingredients have changed sponsor through merger or acquisition of companies on numerous occasions. As a consequence, the raw data generated many years ago for original registration, according to now-outdated protocols and standards, may not be available or may be only partially available and of limited utility for a modern evaluation. Nevertheless, JMPR may be asked, in the context of the periodic re-evaluations by CCPR, to consider such active ingredients for recommendations of MRLs. Recent examples include dicofol, dichlorvos, propylene oxide and fenvalerate.

In formulating the problem to be addressed by the risk assessment, it is of paramount importance that a dialogue be maintained between JMPR (WHO and FAO secretariats) and the risk managers requesting advice. Among issues that will need to be resolved are:

1. Is the compound supported by the data owner?
2. Is the compound or one of its isomers registered, reviewed or likely to be registered in a country or region?
3. Is there sufficient information available to enable a meaningful evaluation?
4. What is the specific concern (duration of exposure, population exposed, source of residue in food)?
5. What form of advice would be most helpful to the risk manager?
6. If such advice cannot be provided (e.g. because of data limitations), is there alternative advice that might be of value?

In situations where the active ingredient is supported by a data owner, JMPR would expect and require all relevant study reports as described in EHC 240[1] and the FAO JMPR Manual[2] to be submitted for consideration and that these would be of an adequate quality. For situations where a company no longer sponsors the product (typically older active ingredients), the information available may not comprise a full data package. In these cases, in order to maintain consistency in the quality of its assessments, JMPR would adhere to the following principles:

- The requesting country should be responsible for providing information on the intended uses, specification of the technical active substance used in the country and a justification for assessment by JMPR.

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[1] FAO/WHO (2009). Principles and methods for the risk assessment of chemicals in food. A joint publication of the Food and Agriculture Organization of the United Nations and the World Health Organization. Geneva, Switzerland, World Health Organization (Environmental Health Criteria 240).

[2] FAO Manual (2009). Submission and evaluation of pesticide residues data for the estimation of maximum residue levels in food and feed. Rome, Italy, Food and Agriculture Organization of the United Nations (FAO Plant Production and Protection Paper 197).

- The information required would be such that it would be possible to address the key questions for the human health assessment, including establishment of an acceptable daily intake (ADI) and/or acute reference dose (ARfD), when required, and the definition of residues for enforcement of MRLs and dietary risk assessment. Furthermore, data on a sufficient number of supervised trials in or on food and feed crops reflecting the current use patterns specified on the relevant labels are required for estimation of maximum residue levels and supervised trials median residue (STMR) and highest residue (HR) values. Trial data may be complemented by relevant selective survey residue data. A complete list of information required is described in the FAO JMPR Manual.
- It is the responsibility of the requesting country to provide the available data and other relevant information, such as available assessments by supranational and national authorities and publications from a recently conducted literature search.
- If literature studies are to be relied upon, JMPR will weigh such studies for their quality and design. Because raw data will not be available, there needs to be sufficient information on methods and results to enable the study findings to be reconstructed.
- If critical data are missing, then JMPR may still determine whether an assessment is possible; in such cases, however, it is likely that conservative assumptions will be used to address the missing information. For example, in the evaluation of propylene oxide in 2011, JMPR used an additional safety factor of 10 in establishing the ADI and the ARfD, because of limitations in the database.
- If sufficient information is not available to enable the establishment of health-based guidance values, JMPR may provide alternative guidance, such as characterization of the margin of exposure, or may conclude that it is not possible to provide any guidance in the absence of additional information.

The suitability of the submitted information can be assessed only on a case-by-case basis. Three examples (see below), taken from recent JMPR evaluations, illustrate some likely situations.

Fenvalerate

Fenvalerate was re-evaluated by JMPR for toxicity and residues in 2012. One country provided access to a comprehensive data package on the toxicology of fenvalerate. Overall, the information available, including the JMPR assessment of esfenvalerate from 2002, enabled the Meeting to establish an ADI and an ARfD for fenvalerate.

The 2002 JMPR evaluation of esfenvalerate for residues was comprehensive, was based mainly on studies for fenvalerate and included all critical information on metabolism in animals and plants, animal transfer studies, etc. The evaluation in 2002 reflects current scientific knowledge, and the conclusion could be used for the re-evaluation of fenvalerate. The conduct of supervised trials and their results enabled the estimation of residue levels and calculation of dietary intake for fenvalerate.

Dicofol

Prior to its re-evaluation in 2011, dicofol was last evaluated for toxicity by JMPR in 1992. One country provided a number of original studies to JMPR, on the basis of which, together with the previous evaluation, the Meeting was able to establish an ADI and an ARfD for the compound.

In the 1994 evaluation for residues, the data presented did not contain the necessary details on the nature of plant metabolites to enable the definition of residues for risk assessment purposes. The lack of critical plant metabolism data was identified by the Meeting, and after that the required information was provided by a country. On the basis of all data, residue levels for tea could be estimated.

Dichlorvos

In the 2011 JMPR re-evaluation of dichlorvos, the data package on residues contained only limited information on plant metabolism and animal metabolism following oral administration of the compound. Furthermore, only a few supervised trials reflected the current use pattern. One country submitted additional critical information on the behaviour of residues following use according to good agricultural practice (GAP), which made possible estimation of maximum residue levels and STMR and HR values. However, the Meeting could recommend limits for only two major crops; otherwise, the upper bound of the ADI would be exceeded.

2.2 UPDATE OF THE GEMS/FOOD CLUSTER DIETS

The Global Environment Monitoring System – Food Contamination Monitoring and Assessment Programme (GEMS/Food) cluster diets are based on FAO food supply data and correspond to average per capita consumption. The clustering of countries with similar dietary patterns was performed in 1997 at the request of CCPR, and the resulting 13 cluster diets are used by the JMPR to estimate long-term intake of pesticide residues.

WHO commissioned an update of the clustering based on a more accurate statistical technique as well as on the latest available FAO data (from 2002 to 2007). The new analysis has resulted in 17 cluster diets. A project will commence in 2013 to develop an automated spreadsheet to enable the new cluster diets to be used by the JMPR within the next two years.

2.3 UPDATE OF JMPR GUIDANCE DOCUMENT

The WHO Core Assessment Group on Pesticide Residues agreed to update its guidance document to incorporate the experience gained over the years and advances in scientific knowledge and to improve the transparency and efficiency of JMPR decisions. The new guidance should be of use for industry and for Codex member states submitting dossiers as well as for experts writing or peer reviewing the JMPR reports and monographs.

Three main components were identified, relating to process and procedures, content and format of monographs and reports, and general criteria for interpretation of toxicological data. It is anticipated that the draft guidance will be discussed at the 2013 JMPR.

2.4 HAZARD ASSESSMENT IN THE 21ST CENTURY: INCORPORATING DATA FROM NEW MECHANISTIC-BASED APPROACHES IN JMPR EVALUATIONS

JMPR is not a regulatory body with specific data requirements. However, JMPR is a major user of data that are already available. The Meeting is committed to using the best information available, generated wherever by the most relevant scientific means, as long as the information is credible and addresses the needs of JMPR to evaluate the potential dietary risks of pesticides. JMPR encourages the development of more accurate, resource-effective guidance and assessment methods that are scientifically sound and, to the extent possible, internationally harmonized.

Since the publication of the United States National Research Council's report entitled *Toxicity testing in the 21st century: A vision and a strategy*[1] in 2007, there has been great interest in the development of new molecular and computer-based approaches to increase the relevance, predictability and timeliness of safety evaluations, while reducing the need for animal studies to the extent possible. JMPR is committed to reducing unnecessary animal testing, but is of the view that, at present, it is not possible to avoid the use of in vivo studies if toxicity evaluations are to be as reliable as possible. Currently, mechanistically based approaches are of most value when integrated with

[1] National Research Council (2007). Toxicity testing in the 21st century: a vision and a strategy. Washington, DC, USA, National Academies Press.

traditional test methods to enable more hypothesis-based assessments and focused evaluations on the effects of concern.

A number of proposals to achieve more effective and efficient safety assessments have been put forward by governmental agencies/organizations and international organizations. In its 2006 report, JMPR welcomed initiatives to produce more accurate assessments, while utilizing fewer resources than with the current toxicity testing and assessment paradigm.

It should be noted that the use of hypothesis-driven approaches that permit the incorporation of existing knowledge and new scientific advancements in the evaluation of toxicity have been in practice by JMPR for some time. Within the context of JMPR evaluations, assessment of data-poor compounds, such as metabolites or degradates of pesticide active ingredients, has included the use of structure–activity analysis and read-across methods. A number of JMPR evaluations have also included an assessment of the mode of action for a cancer or non-cancer end-point using the International Programme on Chemical Safety (IPCS) mode of action/human relevance framework. IPCS is currently updating this framework to incorporate current experience and in the context of new methodological developments.

A recent example of the use of data from mechanistically designed in vitro and in vivo models to evaluate the human relevance of rodent tumour and developmental toxicity responses is provided in the evaluation of sulfoxaflor (see 2011 JMPR report). The IPCS mode of action framework was employed to provide a structured, rigorous and transparent approach to support the integration of diverse types of data (i.e. in vitro, in vivo, traditional, mechanistic), including those from newer methods, through application of a weight of evidence approach using the Bradford Hill considerations to evaluate plausible causal linkages among key events at various levels of biological organization to the in vivo adverse outcomes of interest.

JMPR would rely on the demonstration that the methods used to produce toxicity data are fit for purpose and will consider such information in judgement of the suitability of data for use in its evaluations, since JMPR does not validate testing methods. It is the opinion of JMPR that scientific developments and understanding are not sufficient at this time to enable the replacement of in vivo testing with in vitro methods to predict hazards and potency for systemic toxicities. However, new approaches can be used to complement traditional testing.

The determination of when these approaches will be useful will depend not only on peer review, but on what the method predicts with respect to mode of action knowledge, including the understanding of causal linkages of key events with the adverse effects. Furthermore, to realize a paradigm shift to greater reliance on in vitro and in silico methods will require close collaboration within the scientific community, international organizations and government authorities. The transition of 21st century technologies will be a mutual learning experience.

In conclusion, it is important that methods are scientifically defensible and fit for purpose and that there is a transparent understanding of the uncertainties associated with any new method. JMPR is committed to fostering workable transitions from traditional methods to new methods within its practice. JMPR offers to evaluate data generated using new technologies as they become available, in parallel with the results of traditional toxicity testing, to determine their utility and role in pesticide evaluation.

2.5 CONSIDERATION OF ADAPTIVE AND MINOR RESPONSES TO DISCRIMINATE BETWEEN ADVERSE AND NON-ADVERSE EFFECTS

In 2006, JMPR discussed and published a guidance on the interpretation of hepatocellular hypertrophy (see 2006 JMPR report) to facilitate consistent and transparent decisions in pesticide evaluations. The purpose of that document was to provide general guidance for determining whether the observation of hepatocellular hypertrophy in different laboratory species is indicative of an adaptive or an adverse event, so that the most appropriate reference dose can be identified for the

establishment of health-based guidance values. At the 2011 Meeting, JMPR agreed that guidance on additional minor and adaptive changes was necessary and formed a small working group to define the scope of such guidance, for discussion at the 2012 Meeting.

The working group prepared a discussion document, which was considered at the Meeting in 2012, at which time it was agreed to develop this guidance further. The structure of the document was agreed and tasks were allocated, with a view to preparing draft guidance for discussion at the 2013 Meeting of JMPR.

2.6 CHANGES IN JMPR PROCEDURE

The issue of JMPR resourcing was discussed previously by both JMPR and CCPR. In parallel with the need for adequate resources for scientific advice, the need to increase JMPR capacity in coming years was recognized.

The WHO Core Assessment Group on Pesticide Residues implemented teleconferences in early July 2012 to resolve routine technical matters prior to the 2012 JMPR. These teleconferences helped to identify questions for industry that could be easily addressed by written communication before the meeting. That enabled the cancellation of the discussion with sponsors during the JMPR meeting, which consequently increased the meeting duration by more than half a day. The new procedure was considered to be efficient in terms of increasing JMPR capacity and will be implemented again for the 2013 JMPR.

The WHO Core Assessment Group also initiated the development of revised guidance for data submission and for monographers (see also section 2.3).

2.7 ASSESSMENT OF COMPOUNDS WITH VERY LOW TOXICITY

For some years, JMPR has not established an ARfD for a pesticide under consideration if the available data on acute effects indicate that the ARfD would be higher than 5 mg/kg body weight (bw). The grounds for this practice were discussed in the 2004 JMPR report (and in more detail in Solecki et al., 2005[1]) on guidance for setting ARfDs. The maximum cut-off of 5 mg/kg bw for the ARfD was based on a consideration of maximum food consumption estimates and maximum residue levels in foods. This cut-off equates to a no-observed-adverse-effect level (NOAEL) of 500 mg/kg bw, with the application of the default uncertainty factor of 100. This upper limit for the ARfD has also been adopted in Organisation for Economic Co-operation and Development (OECD) guidance on setting ARfDs[2].

With respect to toxicological effects after long-term dosing, JMPR notes that a number of pesticides developed in recent years cause no or minimal effects at limit doses in the extensive suite of repeated-dose mammalian toxicity tests required to support their regulatory approval.

One such chemical is the new fungicide ametoctradin, which was evaluated by JMPR for the first time in 2012 (see section 5.1). In the toxicology studies on this compound, no adverse effects were observed at or near the limit dose of approximately 1000 mg/kg bw per day (i.e. all individual NOAELs were well above the 500 mg/kg bw per day limit discussed above), there was no evidence of genotoxicity and there were no metabolites of any toxicological significance. Thus, the Meeting concluded that, in addition to it being unnecessary to establish an ARfD, there was also no need to establish an ADI for this compound.

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[1] Solecki R *et al*. (2005). Guidance on setting of acute reference dose (ARfD) for pesticides. Food and Chemical Toxicology, 43:1569–1593.

[2] OECD (2010). Guidance for the derivation of an acute reference dose. Paris, France, Organisation for Economic Co-operation and Development (ENV/JM/MONO(2010)15; Series on Testing and Assessment, No. 124).

This decision, taken for the first time at the 2012 JMPR, was based on a reasonable estimate of a likely maximal daily intake of residues arising from the diet. By applying a similar principle to that considered for not establishing ARfDs, the 2012 Meeting considered that it would be possible to set an extreme upper-bound limit for the ADI, noting that the long-term 24-hour dietary intake of residues of a pesticide will be less than the international estimate of short-term dietary intake (IESTI) of residues from that pesticide.

Thus, the ADI for ametoctradin was recorded as "ADI unnecessary", and the margin of exposure between the intake resulting from the proposed maximum residue levels and the highest dose tested was reported.

The Meeting noted that adoption of this practice should also help to avoid the need to conduct repeated-dose toxicity testing of low-toxicity pesticides at doses above the limit dose in order to establish an ADI.

The proposal of JMPR not to establish ADIs for pesticides with very low or no apparent mammalian toxicity when tested at limit doses will be considered further by the FAO Panel of Experts on Pesticide Residues in Food and the Environment at the 2013 JMPR. A cut-off for the ADI may be refined by the FAO Panel, taking into account long-term, high-level consumption.

2.8 UPDATE OF THE AUTOMATED SPREADSHEET APPLICATIONS FOR THE CALCULATION OF SHORT-TERM 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 by incorporating available consumption data into Excel spreadsheets and, where possible, linking this consumption data to the Codex Commodities for which HR(-P)s and STMR(-P)s are estimated. The spreadsheets are used to calculate the IESTI using the formulas as described in Chapter 7 of the 2009 FAO manual. To use the spreadsheets, estimates made by JMPR (ARfD, STMR(-P), HR(-P)) are entered according to the manual attached to the spreadsheets. Then calculations and generation of a final table are performed automatically.

In its 2010 Report, JMPR highlighted the importance of current consumption data for a reliable risk assessment (General Considerations 2.2 and 2.3). As a result of a WHO/GEMS/Food request to provide or update national large portion data for acute dietary risk assessment (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 for the JMPR 2011. As a result of the extension of the request the governments of Brazil, China, Finland, and Japan provided data for use by the current JMPR Meeting. Denmark indicated that their large portion data were already covered by the JMPR 2011 data and refrained from sending further large portion data. The government of the UK confirmed that the 2003 dataset was still valid. Large portion data already available to JMPR and provided by the governments of South Africa, and the USA were retained. Unit weight data already available to the 2003 JMPR and provided by the governments of Belgium, Sweden, and the USA were also 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 ages), women of childbearing age (14-50 yrs), and children of 6 yrs and under. Since data were available on a number of different population groups, the highest large portion (based on g/kg bw/d) for each commodity from all population groups has been used in the IESTI spreadsheet.

The 2011 JMPR Meeting accepted the large portion data without quality control. For the 2012 JMPR Meeting limited quality control of the data was conducted. The individual countries that submitted large portion data were asked for confirmation as to what their large portion data

represented. Based on this information, the data were allocated to total large portion (i.e., raw and processed commodities or unknown processed commodities converted to raw edible agricultural commodity) or to specific large portion fractions e.g., consumed as raw, consumed after household cooking/boiling, canned, dried, fruit juice). In order to compare large portions from one country to those of another country, processed commodities were expressed as processed product (i.e. commodity as such e.g., as juice, as dried). The total large portion and the large portions which represented consumption as raw were expressed as raw edible agricultural commodity (e.g., orange without peel). The countries involved confirmed that the final large portion consumption values were correct.

Every country, except the USA and South Africa, reported the number of data points the large portion data was taken from. The minimum number of datapoints is 120 for a 97.5 percentile with a significance level of 5% based on non-parametric statistics. The current Meeting considered the large portion data robust, when the large portion is derived from at least 120 datapoints.

In cases the large portion data were derived from less than 120 data points, the g/kg bw/d large portion values and/or the g/pers/d large portion values of the country in question were compared to data from other countries that had 120 datapoints. When the large portion in question was within 1.5× the large portion for a country with 120 datapoints, the large portion data were considered plausible. Large portion data derived from less than 120 data points, which were confirmed by the country in question to be plausible, were accepted. Data which were not considered plausible by the country in question, were replaced by the next highest large portion value in the JMPR 2012 database. The current Meeting therefore, considers the 2012 large portion dataset to be robust.

Since 2011, the IESTI calculations can be done 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. Aggregate large portion data differ from the large portion data for the individual raw and processed commodities because they come from different countries and/or they are expressed as a raw edible agricultural commodity.

The spreadsheet applications will be available on the WHO website. http://www.who.int/foodsafety/chem/acute_data/en/index1.html.

2.9 FURTHER CONSIDERATIONS FOR THE USE OF THE PROPORTIONALITY APPROACH

The Forty-fourth Session of the CCPR in 2012 requested JMPR to continue its exploration in the use of the proportionality approach in the evaluation of residue trial data. In addition to specific considerations related to individual compounds the Meeting noted further aspects for applying the proportionality principle.

General aspects

The Meeting noted that in the General consideration item presented in the 2010 JMPR Report, the conclusion on proportionality for spray concentrations was based on side-by-side trials conducted at comparable spray volumes. However, under practical conditions the GAP for foliar application are often expressed soley as spray concentrations without further specification of related spray volumes. The Meeting decided that proportionality based on spray concentrations can only be applied to residue trial data following careful consideration of spray concentrations and spray volumes on a case by case basis.

Since 2010 the Meeting regulary makes use of the OECD Calculator as a tool for the estimation of maximum residue levels. The Meeting points out that where application rates in supervised field trials were all within ± 25% of the GAP, the normal practice is not to scale residue data. However, if the proportionality principle is applied to give recommendations, the Meeting decided to scale residue data from all trials to avoid bias in the outcome of the OECD Calculator.

Examples from 2012 JMPR

The 2012 JMPR decided to apply the principle of proportionality in several evaluations in order to make recommendations on commodities that were without sufficient supervised field trial data conducted according to the corresponding GAP: Ametoctradin (dried hops), Chlorfenapyr (tomato), Fluopyram(dry beans, cherries, dry chick peas, dry lentils, dry lupins, peaches, peppers, sugar beets, tomatoes), Imidacloprid (celery), Glufosatinate-ammonium (sunflowers), MCPA (barley, oats, rye, triticale and wheat forage, barley, oats, rye, triticale and wheat straw and fodder), Methoxyfenozide (fruiting vegetables, cucurbits) and Spinetoram (brassica vegetables).

As in most of the above cases the only dataset available was from supervised field trials involving application rates > 125% or < 75% of the GAP, without scaling, according to the basic principles outlined by the 2010 JMPR, no recommendations could be made.

In addition to this basic approach the following examples are presented including special considerations for gluphosinate-ammonium, MCPA and spinetoram.

Glufosinate-ammonium

The GAP from Germany for the desiccation of sunflowers is an application rate of 0.5 kg ai/ha with 14 day PHI. In 2012 the Meeting received two datasets, one including four trials at 0.6 kg ai/ha and a second with five trials conducted at 0.34 kg ai/ha. The Meeting concluded that the four trials approximating GAP were not sufficient for a major crop like sunflowers and applied proportionality on the whole dataset. Although glufosinate-ammonium is a non-selective herbicide, the use as a desiccant is conducted directly before harvest and does not affect plant-growth. In the following table the scaling of residue data, including data within ± 25% of the GAP, is summarized.

Target desiccation GAP (kg ai/ha)	Field trial application rate (kg ai/ha)	Scaling factor	Total residue (mg/kg)	
			Residue field trial	Scaled residue
0.5	0.6	0.83	0.79	0.66
	0.6	0.83	0.43	0.36
	0.6	0.83	1.21	1.0
	0.6	0.83	2.3	1.9
	0.35	1.43	0.25	0.36
	0.36	1.39	0.38	0.53
	0.34	1.47	0.27	0.36
	0.34	1.47	0.46	0.68
	0.36	1.39	0.05	0.07

MCPA – Barley, oats, rye, triticale and wheat forage

The Meeting noted that only residue data from Canada on wheat provided a sufficient basis for the estimation of STMR and highest residue values for cereal forage. However, supervised field trial data were conducted at approximately 2-times the application rate reported for the Canadian GAP, leading to residues of 3.1–21 mg/kg in the forage. For the utilisation of cereal forage as a feed item the Meeting decided to apply proportionality to the data set, resulting in scaled residues of 1.6–9.5 mg/kg.

Generally, the application of proportionality in case of compounds affecting plant growth needs to be considered carefully. For MCPA the Meeting concluded that the compound is a selective herbicide against broadleaf weeds without significant impact on the growth of monocotyledonous plants such as cereals and therefore decided that proportionality could be applied.

Spinetoram

For spinetoram Australian GAP for brassica vegetables is for 4 applications of up to 48 g ai/ha each and a 3 day PHI. Supervised field trials conducted on broccoli involved treatment either first application at 35 g ai/ha, followed by three applications of 88–91 g ai/ha, or four applications at 18,

24 or 36 g ai/ha each. The Meeting decided that the field trials matching Australian GAP were insufficient for a recommendation and applied proportionality to the whole dataset.

In the following table the scaling of residue data, including data within ± 25% of the GAP, is summarized.

Target GAP (g ai/ha)	Spinetoram				Spinotoram and two metabolites			
	Field rate (g ai/ha)	Scaling factor	Residue field trial (mg/kg)	Scaled residue (mg/kg)	Field rate (g ai/ha)	Scaling factor	Residue field trial (mg/kg)	Scaled residue (mg/kg)
48	24	2	0.08	0.16	24	2	0.08	0.16
	37	1.3	0.02	0.026	25	1.9	0.03	0.058
	26	1.8	0.09	0.17	26	1.8	0.10	0.18
	91	0.52	0.09	0.045	91	0.52	0.12	0.063
	89	0.54	0.04	0.022	89	0.54	0.06	0.033
	91	0.52	0.06	0.031	91	0.52	0.10	0.052
	90	0.52	0.10	0.052	90	0.52	0.14	0.073

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. Therefore, 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 ACETAMIPRID (246)

Background

The CCPR at its Forty-fourth Session (2012) noted the concerns expressed by the Delegation of the EU regarding the acetamiprid acute dietary risk assessment for scarole based on the ARfD established by JMPR and using the European diet.

The Committee advanced the draft MRL for leafy vegetables (except spinach) to Step 5, noting the reservation of the Delegation of the EU; returned the draft MRL for spinach to Step 4 awaiting clarification of the spinach consumption data.

Evaluation of acetamiprid by JMPR

Acetamiprid is a neo-nicotinoid insecticide considered for the first time by the 2010 JMPR, where an ADI of 0–0.07 mg/kg bw/day and an ARfD of 0.1 mg/kg bw/day were established and maximum residue levels were recommended for a range of commodities, including leafy vegetables.

Based on residue information on head lettuce, leaf lettuce, spinach and mustard greens, the 2010 JMPR recommended group maximum residue level of 3 mg/kg for leafy vegetables except spinach (HR of 1.9 mg/kg) and a separate maximum residue level of 5 mg/kg for spinach (HR of 2.5 mg/kg), noting however that for spinach, the IESTI exceeded the ARfD by 180%.

For all other commodities considered by the JMPR for which consumption data were available, the IESTI represented 0–80% of the ARfD and when used in ways that have been considered by the JMPR acetamiprid is unlikely to present a public health concern.

Evaluation of acetamiprid by the EC

The present meeting received a concern form relating to the proposed maximum residue level for leafy vegetables (except spinach), together with the results of their dietary intake calculation.

Based on their risk assessment using the 0.1 mg/kg ARfD established by JMPR and using the highest reported consumption and unit body-weight information reported by EU member states (EFSA PRIMo rev 2 risk assessment model), the EU concern is that the exposure related to the CXL proposal for scarole accounts for up to 166% of the ARfD.

Comments by JMPR

The 2010 JMPR acute dietary intake estimate for acetamiprid was conducted with the best available consumption data and unit body-weight information available to the Meeting at the time and did not include the information on scarole (as provided to EFSA by EU member states).

The Meeting noted the advice to CCPR that EU member states would be invited to submit their food consumption data to JMPR as soon as possible, and looks forward to receiving this new information.

With respect to the decision by CCPR to retain the proposed spinach maximum residue level at Step 4 awaiting clarification of the spinach consumption data, the most recent version of the data base of consumption data and unit body-weight information used by the current Meeting includes revised information on a number of commodities, including spinach.

The Meeting therefore reassessed the acute intake estimate for acetamiprid on leafy vegetables (including spinach) using the new data, and concluded that for spinach and endive, the IESTI exceeded the ARfD by 110% (for children) and for lettuce, leaf and Chinese cabbages (raw pak-choi and pe-tsai) the IESTI for children exceeded the ARfD by 120%. For all other leafy vegetables for which information was available, the IESTI did not exceed the ARfD for any populations.

The Meeting agreed to revise the previous recommendation for acetamiprid for leafy vegetables (except spinach) by revising the existing footnote relating the ARfD exceedance for spinach to include pak-choi and pe-tsai cabbages and leaf lettuce, i.e.,:

"On the basis of information provided to the JMPR it was not possible to conclude from the estimate of short-term intake for acetamiprid that for children, the consumption of lettuce, leaf; Chinese cabbage, type pak-choi; Chinese cabbage, type pe-tsai; spinach and endive was less than the ARfD".

The Meeting noted the conclusions of the 2007 JMPR, that IESTI estimates above 100% of the ARfD should not necessarily be interpreted as giving rise to a health concern because of the conservatism in the derivation of the ARfD and in the estimation of intake. For example, a safety factor for inter-individual variation is included when the ARfD is established, and as such the ARfD is designed to protect those individuals at the upper-end of human susceptibility.

The Meeting confirmed the view that in cases where the ARfD is exceeded, additional considerations should be taken into account, e.g., the amount by which the ARfD is exceeded, the basis on which the ARfD had been established, likely conservatism and possible consequences and the uncertainties in the estimate of intake.

3.2 CHLORPYRIFOS-METHYL (090)

Chlorpyrifos-methyl was last evaluated for residues by the 2009 JMPR under the periodic review program, when recommendations were made for various commodities, including wheat, barley and maize, post-harvest. This recommendation was based on trials conducted on barley and wheat according to Spanish GAP for post-harvest use on wheat, barley and maize. Long-term dietary risk assessment for the compound indicated an exceedance of up to 140% of the ADI, with maize accounting for about 73% of the IEDI.

At its Forty-second Session, the CCPR agreed to return the draft MRL for the cereal grains at Step 7 to Step 6 awaiting the review of alternative GAP by the 2012 JMPR. Additionally, CXLs for cattle fat; cattle meat; cattle, edible offal of; chicken fat; chicken meat and chicken, edible offal of, were retained (ALINORM 10/33/24; par 36).

The current Meeting received a new Spanish label indicating that the post-harvest use of chlorpyrifos-methyl is no longer recommended on maize. The Meeting withdraw its previous recommendations of a maximum residue level of 3°mg/kg for chlorpyrifos-methyl on maize, post-harvest. No trials were submitted to this or previous meetings that support an estimation of a maximum residue level for maize based on pre-harvest use.

Long-term dietary risk assessment

The ADI for chlorpyrifos-methyl is 0–0.01°mg/kg bw. The International Estimated Daily Intakes (IEDI) for chlorpyrifos-methyl was estimated for the 13 GEMS/Food cluster diets using the STMR or STMR-P values estimated by the previous JMPR, excluding maize (including flour, oil and beer). The results are shown in Annex 3. The IEDI ranged from 3–60% of the maximum ADI. The Meeting

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

3.3 DICAMBA (240)

Background

Dicamba was first evaluated in 2010 by the JMPR. At the 2010 meeting the JMPR estimated maximum residue levels for 21 commodities which were later adopted as Codex MRLs at the Codex Alimentarius Commission in 2011. The 2011 JMPR evaluated the results of supervised residue trials conducted on soya beans in the USA in1994 and 1995. As the pre-harvest application rate in the trials was double the maximum GAP rate in the USA, the 2011 JMPR agreed to apply the proportionality approach to estimate a maximum residue level for soya bean (dry) at 5 mg/kg.

At its Forty-fourth Session, the CCPR advanced the proposed draft MRL for soya bean (dry) to Step 5 only due to concerns of the EU on the use of the proportionality concept. Subsequently, the Meeting received a concern form from the EU seeking clarification of the scientific basis for estimating the maximum residue level through use of the proportionality approach, with particular reference to the potential influence of pre-plant applications to the final residues.

Comments by JMPR

The 2011 JMPR evaluated the results of 23 supervised residue trials with pre-plant application of 0.56 kg ai/ha 14 days before planting and a pre-harvest foliar application of 2.24 kg ai/ha as a harvest-aid, applied 7 days before harvest. The pre-harvest application rate in the trials was double the maximum GAP rate on the new label in the USA (1.12 kg ai/ha applied 7 days prior to harvest).

In the same 23 trials mentioned above, forage and hay samples were taken prior to the pre-harvest application in order to avoid abscission, i.e, following the pre-plant application at 0.56 kg ai/ha only. Residues in those samples were mostly < 0.01 mg/kg (in 21 trials including four trials using two pre-plant applications). In the two remaining trials, quantifiable dicamba was found in forage taken 52 days after the pre-plant application at 0.05 and 0.07 mg/kg. Residues of dicamba in hay 88 or 114 days after the pre-plant application in these two trials as well as hay from other trials were all < 0.01 mg/kg. As soya beans are not mature at around 50–60 days following the pre-plant application, further decline would be anticipated by the time of the pre-harvest application. No or negligible residue of dicamba are expected to be found in leaves or seeds at the time of pre-harvest application.

The Meeting therefore confirmed that, since the contribution of pre-plant applications is negligible in this case, it was appropriate to apply the proportionality approach.

3.4 DIFLUBENZURON (130)

At the Forty-fourth Session of CCPR, the European Union (EU) raised concerns that the likely outcome of the ongoing EU evaluation of diflubenzuron was that “certain metabolites will be classified as carcinogenic and/or genotoxic”. The EU requested that JMPR assess the potential formation of metabolites or degradation products during processing of commodities treated with diflubenzuron and consider consumer exposures to such substances.

JMPR noted that since its last toxicological evaluation in 2001, new data had become available on diflubenzuron and its metabolites—in particular, genotoxicity data on the metabolite 4-chloroaniline (PCA) and in vitro metabolism data on diflubenzuron. Evaluation of these new data could be critical to the JMPR response to the EU concern form.

The Meeting requested that the EU submit the new data and the final report of the EU evaluation, for consideration at a future Meeting.

3.5 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 bw and an ARfD of 0.1 mg/kg body weight were established by the 2005 JMPR.

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

The Thirty-eighth Session of the CCPR in 2006 advanced the proposed draft MRL of 15 mg/kg for lettuce, leaf 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 Session of the CCPR in 2007.

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

In response to a request from the Fortieth Session of CCPR, the 2011 JMPR conducted an alternative GAP evaluation for leaf lettuce, based on new GAP information and concluded that the existing supervised residue trials data evaluated by the 2005 JMPR were insufficient to recommend a maximum residue level to support an alternative GAP for indoxacarb on leafy lettuce.

The Forty-fourth Session of CCPR requested JMPR to conduct a new alternative GAP evaluation based on information to be provided.

The Meeting received confirmation that the current GAP in Spain for indoxacarb on lettuce (both head and leaf lettuce) was consistent with that considered by the 2011 JMPR and that while there are no additional residue trials available, the existing data on leaf lettuce and head lettuce, when combined, were considered sufficient for the EC to support an MRL for lettuce *(i.e. head lettuce, lollo rosso (cutting lettuce), iceberg lettuce and romaine (cos) lettuce)* with extrapolation to *scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curled leave endive, sugar loaf)*.

Lettuce – Alternative GAP Re-assessment

The Meeting re-evaluated the existing lettuce residue data reported by the 2005 JMPR.

In trials from Southern Europe matching the GAP in Spain (0.038 kg ai/ha, 300–700 litres spray mix/ha, 1-day PHI), indoxacarb residues in seven trials identified as 'head lettuce' were: 0.16, 0.19, 0.25, 0.39, 0.52, 0.55 and 0.88 mg/kg and residues in three trials identified as 'leaf lettuce' were: 0.52, 0.86 and 1.6 mg/kg.

Noting that these two data sets were similar (Mann-Whitney U test) and because of the wide range of different lettuce types (crisphead/iceberg, cos/romaine, butterhead, bunching, cutting, loose leaf) available in the market place, the Meeting agreed that the data sets should be combined to give a better representation of the distribution of residues expected in the range of lettuce types in the marketplace.

The combined data set for lettuce (including leaf lettuce) matching the GAP in Spain is: 0.16, 0.19, 0.25, 0.39, 0.52, 0.52, 0.55, 0.86, 0.88 and 1.6 mg/kg (n=10).

The Meeting estimated a maximum residue level of 3 mg/kg, an STMR of 0.52 mg/kg and an HR of 1.6 mg/kg for indoxacarb on lettuce, leaf and agreed to withdraw the previous recommended maximum residue level of 15 mg/kg for indoxacarb on lettuce, leaf.

The Meeting noted that based on the new food consumption and unit weight data used by the 2012 JMPR, the leaf lettuce IESTI for the general population was up to 30% of the ARfD for the general population and up to 100% for children aged 1–6 years.

3.6 ISOPYRAZAM (249)

At the Forty-fourth Session of CCPR, the EU raised concerns that the ADI and ARfD established in its evaluation of isopyrazam differed from those established by JMPR in 2011. The ARfD of 0.2 mg/kg bw established by the EU was based on a maternal NOAEL of 20 mg/kg bw per day for reduced maternal body weight observed during the first days of dosing in a developmental toxicity study in the rat, with application of a safety factor of 100. The ADI of 0.03 mg/kg bw established by the EU was derived from the same study used by JMPR, but was based on a different end-point, for which effects were seen at the lowest dose tested. As a consequence, a higher safety factor (200) was used.

JMPR established an ARfD of 0.3 mg/kg bw on the basis of nonspecific clinical signs of toxicity (weak appearance and decreased activity) in an acute neurotoxicity study in the rat. A NOAEL of 30 mg/kg bw was identified for this effect. On this basis, and in view of the nature of the effects, a safety factor of 100 was used. In a rat developmental toxicity study, the NOAEL of 20 mg/kg bw per day for maternal toxicity was based on reduced body weight gain in dams from day 4 of treatment, accompanied by a reduction in feed consumption. In view of the magnitude and nature of this effect, the Meeting did not consider that this was an appropriate basis on which to establish an ARfD. The ARfD established by JMPR would be protective of the decreased body weight gain observed in dams at day 4.

JMPR established an ADI for isopyrazam of 0–0.06 mg/kg bw on the basis of decreased body weight gain in females and increased incidences of foci of eosinophilic hepatocytes and clinical chemistry changes (triglycerides, bilirubin) of equivocal toxicological significance in both sexes in a 104-week study in rats. A clear NOAEL of 5.5 mg/kg bw per day was identified for these effects. On this basis, and in view of the nature of the effects, a safety factor of 100 was used. Changes in liver (hepatocellular pigmentation in females, hepatocellular hypertrophy in both sexes) observed at 5.5 mg/kg bw per day were considered by the Meeting to be of minimal severity and/or adaptive and thus of no toxicological significance (as agreed at the 2006 JMPR).

3.7 OXAMYL (126)

Oxamyl was evaluated for residues and toxicology by the JMPR in 2002 under the periodic review programme, where a residue definition was established as the sum of oxamyl and oxamyl oxime, expressed as oxamyl (for both animal and plant commodities) for compliance and for dietary risk assessment. However the 2002 Meeting noted that for dietary intake estimation, this definition could result in an overestimate of the dietary intake risk because the only residue of toxicological concern was the parent compound (oxamyl).

The 2002 JMPR established an ADI of 0–0.009 mg/kg bw/day and an ARfD of 0.009 mg/kg bw/day and concluded for apple, cucumber, grapefruit, lemon, mandarin, melons, oranges, peppers and tomato the estimated short-term intakes exceeded the ARfD.

At the request of the Thirty-ninth Session of the CCPR in 2007, information on current and proposed GAPs, analytical methods and additional supervised trials data were submitted to the 2008 JMPR for an Alternative GAP evaluation for citrus fruits (orange and mandarin), cucurbits (cucumbers, courgettes, melons), peppers and tomatoes but the analytical method used in these trials reported residues of the parent compound only, and did not address the current residue definition (i.e., sum of oxamyl and oxamyl-oxime).

Although bridging studies were provided to support the extrapolation of the oxamyl results reported in the new supervised field trials to total oxamyl residues (this being the residue definition for MRL compliance), the 2008 JMPR concluded that the there was insufficient data to support alternative GAP assessments for these commodities as the new data were residues of the parent compound only while the current residue definition included the oxime metabolite.

The CCPR at its Forty-first Session agreed to retain all CXLs and draft MRLs at step 7 awaiting a review of the residue definition and analytical methods by the JMPR in 2012.

The current Meeting noted that the supervised field trials provided to the 2008 JMPR reported residues of oxamyl (i.e., parent only) following the use of oxamyl as a drip irrigation treatment on citrus (orange and mandarin) and on cucumbers, summer squash (courgettes), melons, peppers and tomatoes grown under cover and that these trials matched the 2008 GAPs in Spain and/or Greece. If the residue definition were to be changed to 'parent only', the existing data may be sufficient to support revised maximum residue levels for these commodities and the previous maximum residue levels recommended by the 2008 JMPR for these commodities (with acute intake concerns) could be replaced.

However, the Meeting also noted that for CXLs for carrots, cotton seed, peanuts and potatoes, from supervised field trials conducted in the USA and provided to the 2002 JMPR (to support the periodic review) only reported the combined residues of oxamyl plus oxamyl-oxime. If the residue definition were to be revised to 'parent only', the maximum residue levels recommended by the 2002 JMPR for these commodities would need to be withdrawn unless new residue data were available reporting 'parent only' residues.

The Meeting agreed that it was not appropriate to revise the existing residue definition until oxamyl is reconsidered under the periodic review programme or unless new GAP information and supporting data on carrots, cotton seed, peanuts and potatoes become available.

3.8 PYRACLOSTROBIN (210)

Background

Pyraclostrobin was first evaluated by JMPR in 2003 when an ADI of 0–0.03mg/kg bw and an ARfD of 0.05 mg/kg bw were established. The compound was subsequently evaluated in 2004, 2006 and 2011 for the estimation of a number of maximum residue levels. At the Forty-fourth Session of the CCPR, it was requested that JMPR re-evaluate the orange processing studies to see if the data support an MRL for citrus oil.

Comments by JMPR

The 2011 Meeting received trials conducted on grapefruits, lemon, mandarin and orange, and recommended an maximum residue level for the citrus group of 2 mg/kg for pyraclostrobin. Based on an orange processing study, the 2011 JMPR estimated a maximum residue level of 10 mg/kg for pyraclostrobin in orange oil. The 2012 JMPR agreed to extrapolate from orange oil to citrus oil, and estimated a maximum residue level of 10 mg/kg in citrus oil. The Meeting withdraws its previous recommendations of a maximum residue level of 10 mg/kg for pyraclostrobin in orange oil.

3.9 SAFLUFENACIL (251)

The Forty-fourth Session of the CCPR requested the JMPR to consider the possibility of estimating maximum residue level for saflufenacil residues in lentils.

The Meeting recalled the relevant GAP information and results of supervised trials evaluated by the 2011 JMPR, which reported that following the late season (desiccation) applications in USA according to GAP, the residues (mean of replicate samples) of parent saflufenacil were: bean, dry < 0.01 (5), 0.01, 0.045, 0.096, 0.136, and 0.155 mg/kg. The maximum residue detected in an individual sample was 0.23 mg/kg; pea, dry*:* < 0.01 (3), 0.01, 0.02, and 0.03 mg/kg; soya bean, dry: < 0.01 (14), 0.01 (2) 0.015 (2), 0.02, 0.05 mg/kg.

Conclusion:

The GAP in Canada and USA for desiccation of pulses permits the same maximum (0.05 kg ai/ha) dose with 3 and 2 day PHIs. The results of numerous trials conducted in USA indicated that the magnitude of residues of saflufenacil in pulses 2–3 days after treatment were similar. It was

confirmed with Kruskal-Wallis test (P=0.277) indicating that the residue data sets in dry beans, peas and soya beans were not significantly different.

The Meeting decided to estimate a group maximum residue level for pulses.

Based on the combined residue data (< 0.01 (22), 0.01 (4), 0.015 (2), 0.02 (2), 0.03, 0.045, 0.05, 0.096, 0.136, and 0.155 mg/kg) and taking into account the 0.23 mg/kg residue found in a bean sample, the Meeting estimated a maximum residue level of 0.3 mg/kg, and STMR of 0.01 mg/kg for pulses.

The Meeting withdrew its previous recommendations of 0.3 mg/kg for dried beans, 0.05 mg/kg for dried peas and 0.07 mg/kg for dried soya beans.

The change of recommendations does not affect the estimated long term intake of 0.1% of maximum ADI.

3.10 SPIROTETRAMAT (234)

The Forty-fourth Session of the CCPR noted the maximum residue level recommended by the 2011 JMPR for milk of 0.01 mg/kg was above the limit of analytical quantification (LOQ) of 0.005 mg/kg reported by the 2008 JMPR, even though the estimated residues were below 0.005 mg/kg, and questioned the proposal. The current Meeting re-considered the evaluation by the 2011 JMPR and acknowledged that residues in milk at the livestock dietary burden used to estimate the maximum residue level are expected to be below the LOQ. However, the Meeting also noted that finite residues occurred at the LOQ of 0.005 mg/kg in milk of cattle fed at a level slightly above the calculated maximum dietary burden for dairy cattle.

The current Meeting recommended a maximum residue level for milk of 0.005 mg/kg to replace its previous recommendation of 0.01 mg/kg.

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 13 GEMS/Food Consumption cluster diets[1]. IEDIs are expressed as a percentage of the ADI for a 55 kg or 60 kg person, depending on the cluster diet.

New evaluations

Ametoctradin, chlorfenapyr, dinotefuran, fluxapyroxad, MCPA, penthiopyrad, picoxystrobin and sedaxane were evaluated for toxicology and/or residues for the first time by the JMPR, and ADIs were established, except for ametoctradin. For this compound, an ADI was considered to be unnecessary and margins of exposure were calculated.

Long-term dietary risk assessments were not conducted for chlorfenapyr and picoxystrobin as the data available to the Meeting did not allow the definition of residues for dietary assessment purpose.

Periodic Re-evaluations

Bentazone, cycloxydim, dichlorvos, dicofol, fenpropathrin, fenvalerate and glufosinate-ammonium were evaluated for residues and/or toxicology under the Periodic Re-evaluation Programme. Long-term dietary risk assessments were conducted using ADIs established at this or previous meetings, except for bentazone and fenpropathrin. These compounds were only evaluated for toxicology and dietary assessments will be conducted during the periodic review for residues at subsequent Meetings.

Evaluations

Azoxystrobin, buprofezin, chlorothalonil, chlorpyrifos-methyl, cyfluthrin/beta cyfluthrin, cyromazine, fludioxonil, fluopyram, imidacloprid, methoxyfenozide, phorate, spinetoram and trifloxystrobin were evaluated for residues and long-term dietary risk assessments were conducted for these compounds.

The outcome of the evaluation of acetamiprid, carbofuran, dicamba, diflubenzuron, dithiocarbamates (maneb and mancozeb), fenbuconazole, indoxacarb, isopyrazam, oxamyl, pyraclostrobin, saflufenacil, thiamethoxam and spirotetramat performed at this Meeting was such that the long-term dietary assessment was not necessary or not carried out due to insufficient data.

A summary of the long-term dietary risk assessments conducted by the present meeting is shown in the Table below. 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 refined at the national level by taking into account more detailed information, as described in the Guidelines for predicting intake of pesticide residues[2].

Summary of long-term dietary of risk assessments conducted by the 2012 JMPR

CCPR code	Compound Name	ADI (mg/kg bw)	Range of IEDI, as % of maximum ADI
229	Azoxystrobin	0–0.2	2–10

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

[2] WHO. 1997. Guidelines for predicting dietary intake of pesticide residues (revised). GEMS/Food WHO, Geneva.

CCPR code	Compound Name	ADI (mg/kg bw)	Range of IEDI, as % of maximum ADI
173	Buprofezin	0–0.009	2–50
081	Chlorothalonil	0–0.02	8–50
090	Chlorpyrifos-methyl	0–0.01	10–40
179	Cycloxydim	0–0.07	6–50
157	Cyfluthrin/beta cyfluthrin	0–0.04	0–2
169	Cyromazine	0–0.06	0–4
025	Dichlorvos	0–0.004	5–30
255	Dinotefuran	0–0.2	0–3
026	Dicofol	0–0.002	1–30
119	Fenvalerate	0–0.02	0–1
211	Fludioxonil	0–0.4	0–2
243	Fluopyram	0–0.01	2–20
256	Fluxapyroxad	0–0.02	1–10
175	Glufosinate-ammonium	0–0.01[a]	6–20
206	Imidacloprid	0–0.06	2–5
257	MCPA	0–0.1	0–1
209	Methoxyfenozide	0–0.1	0–5
253	Penthiopyrad	0–0.1	1–6
112	Phorate	0–0.0007	10–40
259	Sedaxane	0–0.1	0
233	Spinetoram	0–0.05	0–1
213	Trifloxystrobin	0–0.04	1–5

[a] applies also to the metabolites N-acetyl glufosinate (NAG), glufosinate, 3-[hydroxy(methyl)phosphinoyl]propionic acid (MPP) and 2-methyl-phosphinico-acetic acid (MPA)

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 Report of the JMPR. Detailed guidance on setting ARfD is described in Section 2.1 of the 2004 Report of the JMPR[1].

Updated large portion data were provided to GEMS/Food by the governments of Australia, Brazil, China, Finland, France, Germany, Japan, Netherlands and Thailand in 2011 and 2012. Denmark indicated that their large portion data were already covered by the JMPR 2011 data and refrained from sending further large portion data. The government of the UK confirmed that the 2003 data were still valid. Large portion data already available to JMPR 2003 and provided by the governments of South Africa and the USA were retained. Large portion data have been provided for general population (all ages), women of childbearing age (14–50 yrs.) and children (6 yrs. and under). For each commodity, the highest large portion data from all different population groups was included in the spreadsheet for calculation of the IESTI.

The spreadsheet application is available at http://www.who.int/foodsafety/chem/acute_data/en/index1.html.

New evaluations

Ametoctradin, chlorfenapyr, dinotefuran, fluxapyroxad, MCPA, penthiopyrad, picoxystrobin, and sedaxane were evaluated for toxicology and/or residues for the first time by the JMPR and ARfDs were established, except for ametoctradin, where it was considered to be unnecessary.

The Meeting did not conduct a short-term dietary risk assessment for chlorfenapyr and picoxystrobin as the data available to the Meeting did not allow the definition of residues for dietary assessment purpose.

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

Periodic Re-evaluations

Cycloxydim, dichlorvos, dicofol, fenvalerate and glufosinate-ammonium were evaluated for residues and/or toxicology under the Periodic Re-evaluation Programme. ARfDs established at this or previous meetings were used for short-term dietary risk assessments.

Bentazone and fenpropathrin were only evaluated for toxicology. ARfD was considered unnecessary for bentazone and short-term dietary risk assessment for fenpropathrin will be considered during the periodic review for residues at subsequent Meetings.

Evaluations

Acetamiprid, buprofezin, carbofuran, chlorothalonil, cyfluthrin/beta cyfluthrin, cyromazine, fenbuconazole, fluopyram, imidacloprid, indoxacarb, methoxyfenozide and phorate were evaluated for residues or toxicology (fenbuconazole) and short-term dietary risk assessments were conducted for these compounds.

The outcome of the evaluation of chlorpyrifos-methyl, dicamba, isopyrazam, oxamyl, pyraclostrobin, spirotetramat and thiamethoxam performed at this Meeting was such that the short-term dietary assessment was not necessary.

Previous meetings considered unnecessary an ARfD for azoxystrobin, diflubenzuron, dithiocarbamates, fludioxonil, saflufenacil and spinetoram.

The Table below 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.

Maximum percentage of the ARfD found in the short-term dietary risk assessments conducted by the 2012 JMPR

CCPR code	**Compound Name**	**ARfD (mg/kg bw)**	**Max. percentage of the ARfD** Commodity (% ARfD)	Population
246	Acetamiprid	0.1	Chinese cabbage and lettuce (120) Endive and spinach (110)	Children, 1–6 years toddler, 8–20 m
173	Buprofezin	0.5	Tea (7)	Children, 3–6 years
96	Carbofuran	0.001	Banana (80)	Children, 1–6 years
081	Chlorothalonil	0.6	Chard (70)	Children, 2–6 years
179	Cycloxydim	2[a]	Peppers, chili, dried (10)	General population
157	Cyfluthrin/beta cyfluthrin	0.04	Cabbage head (6)	Children, 1–6 years
169	Cyromazine	0.1	Lentil, dry (20)	Children, 3–6 years
026	Dicofol	0.2	Tea (20)	All populations
025	Dichlorvos	0.1	Wheat (80)	Children, 3–6 years
255	Dinotefuran	1	Lettuce, leaf; endive; Chinese cabbage (30)	Children 1–6 years
197	Fenbuconazole	0.2	Apple (10)	toddler, 8–20 m
119	Fenvalerate	0.2	Broccoli, Chinese (40)	Children 1–6 years
243	Fluopyram	0.5	Grape (10)	Children 1–6 years
256	Fluxapyroxad	0.3	Prunes (20)	Children 2–6 years
175	Glufosinate-ammonium	0.01[b]	Cattle liver (170) Soya bean, dry (120) Lettuce and kiwi (110)	Children ≤ 6 years
206	Imidacloprid	0.4	Celery (30)	Children 1–6 years
216	Indoxacarb	0.1	Lettuce leaf (100)	Children 1–6 years
257	MCPA	0.6	Edible offal, mammalian (5)	Children 1–6 years
209	Methoxyfenozide	0.9	Orange (10)	Children 2–6 years
253	Penthiopyrad	1	Mustard greens (150)	Children 1–6 years
112	Phorate	0.003	Potato, processed (100)	Children, 1–5 years

CCPR code	Compound Name	ARfD (mg/kg bw)	Max. percentage of the ARfD Commodity (% ARfD)	Population
259	Sedaxane	0.3	All commodities (0)	All populations

[a] only for women of childbearing age;

[b] applies also to the metabolites N-acetyl glufosinate (NAG), glufosinate, 3-[hydroxy(methyl)phosphinoyl]propionic acid (MPP) and 2-methyl-phosphinico-acetic acid (MPA)

Possible risk assessment refinement when IESTI exceeds the ARfD

Glufosinate ammonium: Since the metabolite MPP represents the majority of the residue in bananas, kiwifruit, lettuce and cattle liver, and because MPP is of lower toxicity than glufosinate, these exceedances are unlikely to present a public health concern. MPP represents about 15% of the residues in soya beans, The Meeting concluded that the short-term intake of residues of glufosinate ammonium resulting from uses that have been considered by the JMPR is unlikely to present a public health concern.

When the intake assessment could not be refined, reconsideration of the ARfD might be possible based on additional studies to better characterize the acute toxicity of the compound (OECD:ENV/JM/MONO(2010)15)

6. FUTURE WORK

The items listed below are tentatively scheduled to be considered by the Meeting in 2014 and 2015. The compounds listed include those recommended as priorities by the CCPR at its Forty-fourth 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/

2014 JMPR

TOXICOLOGICAL EVALUATIONS	RESIDUE EVALUATIONS
NEW COMPOUNDS	**NEW COMPOUNDS**
Aminocyclopyrachlor [DuPont] USA	Aminocyclopyrachlor Meat, milk and edible offal
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
Fluazifop-p-butyl [Syngenta] - Switzerland	Fluazifop-p-butyl Oil seed rape, Soya bean, dry beans, cotton, Potato, Sweet potato, Sugar beets, Citrus fruits, Pome fruit, Stone fruit, Grapes, Tree nuts, Onion, Cabbage, Carrots, Vegetables, Bananas, Coffee bean, (Palm oil)
Fluensulfone Exponent	Fluensulfone
Flufenoxuron [BASF] Brazil priority 1	Flufenoxuron Soya bean, pome fruit (apple, pear), orange, melon, tomato, grape
Imazamox [BASF] Argentina	Imazamox Legume group: peas and beans (fresh), beans and beans (pulses), lentils, soybean, peanuts, cereal group (rice, wheat, maize), Oilseed group (sunflower, oilseed rape), Alfalfa
Mesotrione [Syngenta] USA	Mesotrione Asparagus, berries, Corn (grain, pop, sweet), Cranberry, Millet, Lingonberry, Oat (grain), Rhubarb, Sorghum (grain), Soybean, Sugarcane, Okra
Metrafenone [BASF] USA	Metrafenone
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, soybean, and walnut.
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
PERIODIC RE-EVALUATIONS	**PERIODIC RE-EVALUATIONS**
metalaxyl (138) [Quimicas del Vallés SCC GMBH]	metalaxyl (138) Review in 2004 for residues was for evaluation of metalaxyl-M, Support from Quimicas del Vallés - SCC GmbH , USA - Supervised trials by Thailand
triforine (116) [Sumitomo Corp]	triforine (116) Apple, Blueberries, Brussels sprouts, Cereal grains, Cherries, Common bean, Currants(Black,Rd, White), Fruiting vegetables, Cucurbits, Gooseberry, Peach, Plums(including prunes), Strawberry, Tomato
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 (Broccoli, Brussels sprouts, Cauliflower, Chinese cabbage), Pome Fruit, Fruiting Vegetables (Tomato, Pepper, Aubergine), Root and Tuber Vegetables (Carrot, Parsnip, Turnip), Cucurbit vegetables (Cucumber, Melon, Watermelon, Pumpkin, Zuchini), Berries (Blackberry, Blueberry, Blackcurrant, Gooseberry, Raspberry, Cranberry), Stone Fruit (Apricot, Cherry, Peach, Plum), Legume Vegetables (peas, beans), Nuts (Almond, Pecan, Cashew, Jujube, Pistachio, Hazelnut, Pine nut, Macadamia, Chestnut), Soya, Strawberry, Loganberry, Sugarbeet, Tobacco, Potato, Clementine, grapefruit, Nectarine, Cumquat, Mango, Gherkin, Loquat, Asparagus, Leek, Banana, Lambs Lettuce, Rocket, Chicory, Canola, Parsley, Mint, Papaya, Alfalfa, Barley, Rice, Wheat, Sweet Corn, Hops, Lentil, Persimmon, Avocado, Artichoke, Grapes, Onion, Fennel
EVALUATIONS	**EVALUATIONS**
	2,4-D (020) [Dow AgroSciences] - New GAP for soya bean
	Bifenthrin (178) [FMC] - Barley, barley (straw fodder), strawberry (alternative GAP)

	chlorothalonil (081) [Syngenta] Banana, carrot, cherry, cranberry, bulb onion, peach, sweet and chilli pepper, tomato,, common beans blueberry Apple and pear (RoK)
	dimethomorph (225) [BASF] Bulb onions (including shallots, garlic, silverskin onions), Green onions, Leek, Head cabbage, Flowerhead brassica (broccoli), Whole group leafy vegetables (excluding brassica), Celery, Globe artichokes, Oranges, Strawberry, Grapes, Ginseng
	dithiocarbamates - mancozeb (105) [Dow AgroSciences] - mandarin (ROK)
	fluopyram (243) [Bayer CropScience]- Leek, Onions, Asparagus, Lettuce heads, Herbs, Cabbage, Bush berries, Rape seed, Sunflower and Hops
	Imidacloprid (206) Pistachio (Iran)
	Phosmet (103) [Gowan] cranberry, tart cherry
	thiamethoxam (245) Pistachio (Iran), persimmon (Republic of Korea)
2015 JMPR	
NEW COMPOUNDS	**NEW COMPOUNDS**
cyazofamid [Ishihara Sangyo Kaisha]	cyazofamid Hops, Potato, tomato, grape, cucurbits, carrots, brassica vegetables, okra, spinach, other fruiting vegetables
fenazaquin [Gowan company]	fenazaquin Alfalfa, apples, apricots, berries, citrus, cotton, cucurbits (cucumbers, melons, zucchini, squash, pumpkin), eggplant, grapes, hops, nectarines, peaches, pears, peppers, pineapples, plums, prunes, strawberries, tea, tomatoes, tree nuts; zucchini.
flonicamid [Ishihara Sangyo Kaisha] USA	flonicamid cucurbit, vegetables, fruiting vegetables, leafy vegetables, pome fruit, potato, stone fruit, head/stem brassica, mustard greens, brassica leafy greens, root vegetables, radish tops, tuberous/ corm vegetables, hops, okra, cottonseed
flupyradifurone [Bayer CropScience] Germany	flupyradifurone Citrus fruit, table and wine grapes and small berries, pome fruit, tree nuts, hops, fruiting and brassica vegetables, lettuce, potatoes, sugar beets, onions, cereals, coffee, soya and cotton.
PERIODIC RE-EVALUATIONS	**PERIODIC RE-EVALUATIONS**
abamectin (177)	abamectin (177)

[Syngenta]	Pome fruits, cucurbits (edible and inedible peel), grapes, citrus fruits, stone fruits, strawberries, hops, leafy vegetables (lettuce, spinach, endive, celery), potato, almond, walnut, bean, coffee, cotton, Fruiting vegetables (tomato, aubergine, pepper, sweet pepper), avocado, papaya, mango, avocado, onion
chlormequat (15) [BASF]	chlormequat (015) Cereals, cottonseed, maize, rapeseed, maize fodder, cereals fodder/straw, meat, milk, eggs
clethodim (187) [Sumitomo - Valent USA]	clethodim (187) bean, broccoli, cabbage, carrot, cranberry, cucurbits, hops, lettuce, pea, strawberry, blueberry
ethephon (106) [Bayer CropScience]	ethephon (106) Apple, Barley, Barley straw and fodder, Blueberries, Cantaloupe, Cherries, Chili peppers (dry), Cotton seed, Dried grapes, Figs, Grapes, Hazelnuts, Peppers, Pineapple, Rye, Rye straw and fodder, Tomato, Walnuts, Wheat, Wheat straw and fodder, Chicken eggs, Edible offal of cattle, goats, horses, pigs & sheep, Meat of cattle, goats, horses, pigs & sheep, Milk of cattle, goats & sheep, Poultry meat, Poultry, edible offal. All CXLs supported
EVALUATIONS	**EVALUATIONS**

FAO TECHNICAL PAPERS

FAO PLANT PRODUCTION AND PROTECTION PAPERS

1	Horticulture: a select bibliography, 1976 (E)
2	Cotton specialists and research institutions in selected countries, 1976 (E)
3	Food legumes: distribution, adaptability and biology of yield, 1977 (E F S)
4	Soybean production in the tropics, 1977 (C E F S)
4 Rev.1	Soybean production in the tropics (first revision), 1982 (E)
5	Les systèmes pastoraux sahéliens, 1977 (F)
6	Pest resistance to pesticides and crop loss assessment – Vol. 1, 1977 (E F S)
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)
7	Rodent pest biology and control – Bibliography 1970-74, 1977 (E)
8	Tropical pasture seed production, 1979 (E F** S**)
9	Food legume crops: improvement and production, 1977 (E)
10	Pesticide residues in food, 1977 – Report, 1978 (E F S)
10 Rev.	Pesticide residues in food 1977 – Report, 1978 (E)
10 Sup.	Pesticide residues in food 1977 – Evaluations, 1978 (E)
11	Pesticide residues in food 1965-78 – Index and summary, 1978 (E F S)
12	Crop calendars, 1978 (E/F/S)
13	The use of FAO specifications for plant protection products, 1979 (E F S)
14	Guidelines for integrated control of rice insect pests, 1979 (Ar C E F S)
15	Pesticide residues in food 1978 – Report, 1979 (E F S)
15 Sup.	Pesticide residues in food 1978 – Evaluations, 1979 (E)
16	Rodenticides: analyses, specifications, formulations, 1979 (E F S)
17	Agrometeorological crop monitoring and forecasting, 1979 (C E F S)
18	Guidelines for integrated control of maize pests, 1979 (C E)
19	Elements of integrated control of sorghum pests, 1979 (E F S)
20	Pesticide residues in food 1979 – Report, 1980 (E F S)
20 Sup.	Pesticide residues in food 1979 – Evaluations, 1980 (E)
21	Recommended methods for measurement of pest resistance to pesticides, 1980 (E F)
22	China: multiple cropping and related crop production technology, 1980 (E)
23	China: development of olive production, 1980 (E)
24/1	Improvement and production of maize, sorghum and millet – Vol. 1. General principles, 1980 (E F)
24/2	Improvement and production of maize, sorghum and millet – Vol. 2. Breeding, agronomy and seed production, 1980 (E F)
25	Prosopis tamarugo: fodder tree for arid zones, 1981 (E F S)
26	Pesticide residues in food 1980 – Report, 1981 (E F S)
26 Sup.	Pesticide residues in food 1980 – Evaluations, 1981 (E)
27	Small-scale cash crop farming in South Asia, 1981 (E)
28	Second expert consultation on environmental criteria for registration of pesticides, 1981 (E F S)
29	Sesame: status and improvement, 1981 (E)
30	Palm tissue culture, 1981 (C E)
31	An eco-climatic classification of intertropical Africa, 1981 (E)
32	Weeds in tropical crops: selected abstracts, 1981 (E)
32 Sup.1	Weeds in tropical crops: review of abstracts, 1982 (E)
33	Plant collecting and herbarium development, 1981 (E)
34	Improvement of nutritional quality of food crops, 1981 (C E)
35	Date production and protection, 1982 (Ar E)
36	El cultivo y la utilización del tarwi – Lupinus mutabilis Sweet, 1982 (S)
37	Pesticide residues in food 1981 – Report, 1982 (E F S)
38	Winged bean production in the tropics, 1982 (E)
39	Seeds, 1982 (E/F/S)
40	Rodent control in agriculture, 1982 (Ar C E F S)
41	Rice development and rainfed rice production, 1982 (E)
42	Pesticide residues in food 1981 – Evaluations, 1982 (E)
43	Manual on mushroom cultivation, 1983 (E F)
44	Improving weed management, 1984 (E F S)
45	Pocket computers in agrometeorology, 1983 (E)
46	Pesticide residues in food 1982 – Report, 1983 (E F S)
47	The sago palm, 1983 (E F)
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The annual Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues was held in Rome, Italy, from 11 to 20 September 2012. The FAO Panel of Experts had met in preparatory sessions from 6 to 10 September. The Meeting was held in pursuance of recommendations made by previous Meetings and accepted by the governing bodies of FAO and WHO that studies should be undertaken jointly by experts to evaluate possible hazards to humans arising from the occurrence of pesticide residues in foods. During the meeting the FAO Panel of Experts was responsible for reviewing pesticide use patterns (use of good agricultural practices), data on the chemistry and composition of the pesticides and methods of analysis for pesticide residues and for estimating the maximum residue levels that might occur as a result of the use of the pesticides according to good agricultural use practices. The WHO Core Assessment Group was responsible for reviewing toxicological and related data and for estimating, where possible and appropriate, acceptable daily intakes (ADIs) and acute reference doses (ARfDs) of the pesticides for humans. This report contains information on ADIs, ARfDs, maximum residue levels, and general principles for the evaluation of pesticides. The recommendations of the Joint Meeting, including further research and information, are proposed for use by Member governments of the respective agencies and other interested parties.

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