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World Health Organization

Pesticide residues in food 2017

Joint FAO/WHO Meeting on Pesticide Residues

REPORT 2017

Pesticide residues in food 2017

Joint FAO/WHO Meeting on Pesticide Residues

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, 12–21 September 2017

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Contents

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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WHO Headquarters; Geneva, 12 to 21 September 2017

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ABBREVIATIONS

AChE	acetylcholinesterase
ACN	acetonitrile
ADI	acceptable daily intake
AGISAR	Advisory Group on Integrated Surveillance of Antimicrobial Resistance
ai	active ingredient
ALP	alkaline phosphatase
AMR	antimicrobial resistance
AMU	antimicrobial use
AR	applied radioactivity
ARfD	acute reference dose
as	as received
asp gr fn	aspirated grain fraction
AU	Australia
AUC	area under the plasma concentration–time curve
BBCH	**B**iologischen Bundesanstalt, **B**undessortenamt und **CH**emische Industrie
BMD	benchmark dosing
bw	body weight
CA	Chemical Abstracts
CAC	Codex Alimentarius Commission
CAR	constitutive androstane receptor
CAS	Chemical Abstracts Service
CCFA	Codex Committee on Food Additives
CCN	Codex classification number (for compounds or commodities)
CCPR	Codex Committee on Pesticide Residues
*c*GAP	Critical GAP
C_{max}	maximum concentration in blood or plasma
CSAF	chemical-specific adjustment factors
CYP	cytochrome
DAA	days after application
DALA	days after last application
DAT	days after treatment
DM	dry matter
DMCF	dimethylcarbonocyandic amide (IN-N009)
DMOA	dimethyl(oxo)acetic acid (IN-D2708)

DMTO	methyl 2-(dimethylamino)-N-hydroxy-2-oxoethanimidothioate (IN-A2213 or oxamyl oxime)
DNA	deoxyribonucleic acid
DRA	dietary risk assessment
DT_{50}	time required for 50% dissipation of the initial concentration
DT_{90}	time required for 90% dissipation of the initial concentration
dw	dry weight
ECD	electron capture detector
EFSA	European Food Safety Authority
EHC	Environmental Health Criteria monograph
ESBL	extended-spectrum beta-lactamase
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
FOB	functional observational battery
fw	fresh weight
GAP	good agricultural practice
GC	gas chromatography
GC-ECD	gas chromatography with electron capture detection
GC-FTD	gas chromatography with flame thermionic detection
GC-N-FID	gas chromatography with nitrogen selective flame ionization detection
GC/MS	gas chromatography/mass spectrometry
GC-NPD	gas chromatography coupled with nitrogen-phosphorus detector
GECDE	global estimate of chronic dietary exposure
GEMS/Food	Global Environment Monitoring System – Food Contamination Monitoring and Assessment Programme
GLASS	Global Antimicrobial Resistance Surveillance System
GLP	good laboratory practice
GPC	gel permeation chromatography
HBGV	health-based guidance values
HPLC	high performance liquid chromatography
HPLC-DAD	high performance liquid chromatography with diode array detection
HPLC-UV	high performance liquid chromatography with UV detector
HPPD	4-hydroxyphenylpyruvate dioxygenase

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
IgM	immunoglobulin M
IN-A2213	methyl 2-(dimethylamino)-*N*-hydroxy-2-oxoethanimidothioate (DMTO or oxamyl oxime)
IN-D2708	dimethyl(oxo)acetic acid (DMOA)
IN-N009	dimethylcarbonocyanidic amide (DMCF)
IPC	infection prevention and control
IPCS	International Programme on Chemical Safety
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JECFA	Joint FAO/WHO Expert Committee on Food Additives
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
JP	Japan
LC_{50}	median lethal concentration
LC-MS	Liquid chromatography with mass spectrometry
LC-UV	Liquid chromatography with UV detection
LD_{50}	median lethal dose
LLNA	local lymph node assay
LOAEC	lowest-observed-adverse-effect concentration
LOAEL	lowest-observed-adverse-effect level
LOD	limit of detection
log P_{ow}	octanol-water partition coefficient
LOQ	limit of quantification
LSC	liquid scintillation counting
MCH	mean cell haemoglobin
MCV	mean corpuscular volume
MIC	minimum inhibitory concentration
MPPZ	5-amino-1,2-dihydro-4-(*o*-tolyl)pyrazol-3-one
MRL	maximum residue limit
mRNA	messenger ribonucleic acid
MS	mass spectrometry
MS/MS	tandem mass spectrometry

m/z	mass to charge ratio (mass unit for mass spectrometry)
NOAEC	no-observed-adverse-effect concentration
NOAEL	no-observed-adverse-effect level
OECD	Organisation for Economic Co-operation and Development
4-OH	4-hydroxyquinazoline
OIE	World Organisation for Animal Health
PBI	plant back interval
PES	post extraction solids
Pf	processing factor
PHI	pre-harvest interval
ppm	parts per million
PXR	pregnane X receptor
QuEChERS	Quick Easy Cheap Effective Rugged Safe
QSAR	quantitative structure–activity relationship
RAC	raw agricultural commodity
RSD	relative standard deviation
RTI	re-treatment interval
S-2188-DC	5-amino-1,2-dihydro-2-isopropyl-4-(*o*-tolyl)pyrazol-3-one
SC	suspension concentrate
SL	soluble liquid
SPE	solid phase extraction
STMR	supervised trials median residue
STMR-P	supervised trials median residue in a processed commodity calculated by multiplying the STMR of the raw commodity by the corresponding processing factor
$t_{½}$	half-life
T_3	triiodothyronine
T_4	thyroxine
T_4-UDPGT	thyroxine-uridine glucuronosyltransferase
TAT	tyrosine aminotransferase
TBPE	tertiary butylphenylethanol
TLC	thin-layer chromatography
T_{max}	time to reach maximum concentration
TRR	total radioactive residues
TSH	thyroid-stimulating hormone
UDPGT	uridine diphosphoglucuronosyltransferase
UK	United Kingdom

USA	United States of America
US/CAN	United States and Canada
USEPA	United States Environmental Protection Agency
VICH	International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products
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 2017 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 in Geneva, Switzerland, from 12 to 21 September 2017. The FAO Panel Members met in preparatory sessions from 7–12 September.

Dr Kazuaki Miyagishima, Director, Department of Food Safety and Zoonoses – World Health Organization, WHO, warmly greeted the JMPR Meeting on behalf of WHO and FAO, and thanked FAO and WHO experts for their contributions to the 2017 JMPR.

Dr Miyagishima emphasized the need to increase public understanding of the work of JMPR and to make better known its contribution to food safety and security worldwide.

Dr Miyagishima recalled recent actions taken by WHO and FAO and in other international fora on antimicrobial resistance. To support a global action plan on antimicrobial resistance adopted in 2015, international agencies are joining forces to address issues of antibiotic use in plants, animals and humans and manage their impact on public health. Expectations are high on the ongoing work of JMPR in this regard.

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

The Meeting evaluated 39 pesticides, including nine new compounds and five compounds that were re-evaluated for toxicity or residues, or both, within the periodic review programme of the Codex Committee on Pesticide Residues (CCPR). The Meeting established ADIs and ARfDs, estimated maximum residue levels and recommended them for use by CCPR, and estimated supervised trials median residue (STMR) and highest residue (HR) levels as a basis for estimating dietary intakes.

The Meeting also estimated the dietary intakes (both short term and long term) of the pesticides reviewed and, on this basis, performed a dietary risk assessment in relation to their ADIs or ARfDs. Cases in which ADIs or ARfDs may be exceeded were clearly indicated in order to facilitate the decision-making process by CCPR.

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

2. GENERAL CONSIDERATIONS

2.1 Special studies on microbiological effects of pesticide residues in foods.

At the 2017 Joint FAO/WHO Meeting on Pesticide Residues in Food (JMPR), September 12–21, 2017 in Geneva, Switzerland, there was discussion on including, in the toxicological evaluation of pesticide residues, a microbiological assessment of the pesticide residues' adverse chronic and acute effects on the microorganisms in the human gastrointestinal tract. This is because pesticide residues in foods may have antimicrobial properties, and there is potential exposure of intestinal microbiota following ingestion of such residues in food. In this context, Joint FAO/WHO Committee on Food Additives (JECFA) routinely evaluates acute and chronic effects of veterinary drug residues in foods to determine the need to establish a microbiological acceptable daily intake (ADI). Using the same principles as JECFA, JMPR could undertake a corresponding microbiological assessment to determine the potential impact of pesticide residues on intestinal microbiota. For this purpose, the JECFA decision-tree approach, which complies with International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) GL36 and EHC 240, could be used.

The decision-tree approach initially seeks to determine if microbiologically active residues are entering the human colon. If the answer is "no", a microbiological ADI is unnecessary and the toxicological or pharmacological ADI is used. However, should potentially microbiologically active residues be present in the colon, data on the two end-points of public health concern, disruption of the colonization barrier and increase of the population(s) of resistant bacteria, would be evaluated. During the decision-tree process, it is possible to give scientific justifications for omitting testing (i.e. the need for a microbiological ADI) for either one or both end-points.

There are a number of in vitro and in vivo methodologies and databases that could be used to derive a microbiological ADI. Some examples of in vitro studies are minimum inhibitory concentration (MIC) susceptibility testing against representative predominate intestinal microbiota and continuous culture flow chemostats systems; some examples of in vivo studies are human volunteer or laboratory animal models and human microbiota–associated animals studies using a range of relevant pesticide concentrations. In addition, faecal binding of residues to determine bioavailability, bioassays and chemical methods to determine biological activity of residues in the colon, potential of the intestinal microbiota to metabolize the residue and antimicrobial resistance studies can be evaluated. Once a microbiological ADI is determined, it is compared with the toxicological ADI and the more appropriate, usually the lower, used for the compound.

References

VICH. International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products. VICH Guideline 36 (R). Studies to evaluate the safety of residues of veterinary drugs in human food: General approach to establish a microbiological ADI. Adopted at Step 7 of the VICH Process by the VICH Process by the VICH Steering Committee for implementation in February 2010. VICH. Brussels, 2010.

2.2 Use of historical control data

Following a recommendation of the 2016 JMPR, an electronic working group prepared a discussion document on "Binary data of animal toxicity studies: Recurring issues in their statistical evaluation and in the use of historical control data". The objective of is eventually to provide expanded guidance on these topics for EHC240. The present Meeting discussed the draft and agreed with the overall structure and principles elaborated. A number of recommendations were made for revision. The Meeting concluded that the electronic working group should revise the document as part of the forthcoming EHC240 update process.

2.5 Further consideration of the process for establishing group MRLs: Update on the use of the revised commodity classification for vegetables

The JMPR welcomes the activities of the CCPR in revising the commodity groups for vegetables. However, the Meeting noted that the new commodity groups contain members that do not, or are unlikely to, have similar potential for residues as the representative crop. In particular, at the current Meeting consideration was given to recommending maximum residue levels for the subgroup of tomatoes and for the subgroup of peppers.

In the subgroup of tomatoes, Tomato and Cherry tomato are the commodities for which residue trials are typically available. The JMPR has not evaluated residue data on the other members in the group but notes that differences in rate of fruit growth, fruit size (e.g., Huckleberries) and in some cases the presence of a husk (e.g., Cape Gooseberry) covering the fruit lead the JMPR to suspect that residues in tomato or cherry tomatoes may not be representative of residues in the other commodities. In the absence of data on relative residues in these crops, the Meeting decided when data are available for tomatoes to recommend maximum residue levels individually for:

VO 2700 Cherry tomato *Lycopersicon esculentum* var. cerasiforme (Dunal) A. Gray

VO 0448 Tomato *Lycopersicon esculentum* Mill.; Syn: Solanum lycopersicum L.

Similarly for the subgroup of peppers, the Meeting noted that available information suggests residues in okra differ from those in peppers. While the JMPR is not aware of trials comparing residues in peppers, roselle and martynia, differences in crop growth habit, commodity size and shape lead the Meeting to suspect that residues in Bell and non-Bell peppers may not be representative of residues in the other commodities, i.e. okra, martynia and roselle. In the absence of data on relative residues in these crops, the Meeting decided when data are available for Bell and non-Bell peppers to recommend maximum residue level for:

VO 0051 Subgroup of Peppers (except okra, martynia and roselle).

The Meeting would welcome additional information comparing residues in the various members of the crop groups.

2.4 Field use pattern anticipated residue comparison model

The JMPR evaluates residue data from supervised crop field trials to select residue levels suitable for estimating maximum residue levels and for assessing dietary exposure. When conducting these evaluations, the JMPR selects data from trials reflecting the critical GAP allowed on product labels. Frequently, there may be discrepancies in multiple field trial use pattern parameters relative to the critical GAP, such as application rate, retreatment intervals, numbers of applications, and pre-harvest interval (PHI).

Historically, the JMPR has used best judgement to discern whether these discrepancies have a meaningful impact (i.e., ±25%) on residues at harvest. In cases where residues are very short-lived or very long-lived, this decision is usually straight-forward. For other cases, the impact of these discrepancies is less clear. As an aid to help discern the impact of varying field trial use parameters on residues at harvest, the 2017 Meeting has developed a simple model that compares anticipated residues at harvest resulting from differences in application rates, retreatment intervals, and PHI. The tool incorporates dissipation kinetics to model residue decline following applications

Inputs to the model for application rates, retreatment intervals, and PHI are obtained directly from field trial reports and pesticide product labels. For dissipation kinetics, the model assumes single, first-order dissipation, and the half-life estimate needed by the model is derived from residue decline data. These half-life estimates are specific to each pesticide-crop combination, and need to be reasonably robust so as to have confidence in the model output.

The 2017 Meeting used this model only in its evaluation of cyclaniliprole, and the decision on whether to use the model was made on a crop-by-crop basis. As screening-level conditions for deriving half-life estimates, the Meeting used the following criteria:

1. At least three decline trials needed to be available,
2. Decline trials needed to include at least four time points,
3. Residues at the shortest interval after application needed to be well above the LOQ, and
4. Residues at the next harvest interval needed to be ≥ LOQ (residues at later harvest intervals could be <LOQ).

The Meeting noted that these half-life criteria should be refined as more experience is gained with using the tool. In addition, experience with the tool will help to discern limitations for input parameters (e.g., PHI ranges) and on the applicability of the tool (e.g., crop types).

Examples from the evaluation of cyclaniliprole, demonstrating output from the model and implementation decisions follow.

Table 1 Overview of GAP and trial use patterns, calculated median half-lives and comparison of the outcomes of trial and GAP use patterns

Crop group	Source	Rate g ai/ha	Max/season, g ai/ha	RTI	PHI	Total days (total of RTIs + PHI)	Half -life range, days [median] (no. of decline trials)	Trial - GAP
Pome fruit	GAP	1 × 60 + 3 × 80	300	10	7	30 + 7 = 37	4.5-21 [12] (n=15 apple +1 pear)	--
	trials	3 ×100	300	14	7	28 + 7 = 35		+2.3%
Small fruit (grapes)	GAP	1 × 60 + 3 × 80	300	7	7	21 + 7 = 28	[11] (n = 15 grapes)	--
	trials	3 × 100	300	7	7	14 + 7 = 21		+14%
Brassica's - head	GAP	4 × 60	240	5	1	15 + 1 = 16	1.0-2.0 [1.8] (n=1 cauliflower, 3 broccoli, 1 head cabbage)	--
	trials	3 × 60	240	7	1	14 + 1 = 15		-8%
	trials	3 × 100	300	7	1	14 + 1 = 15		+53%

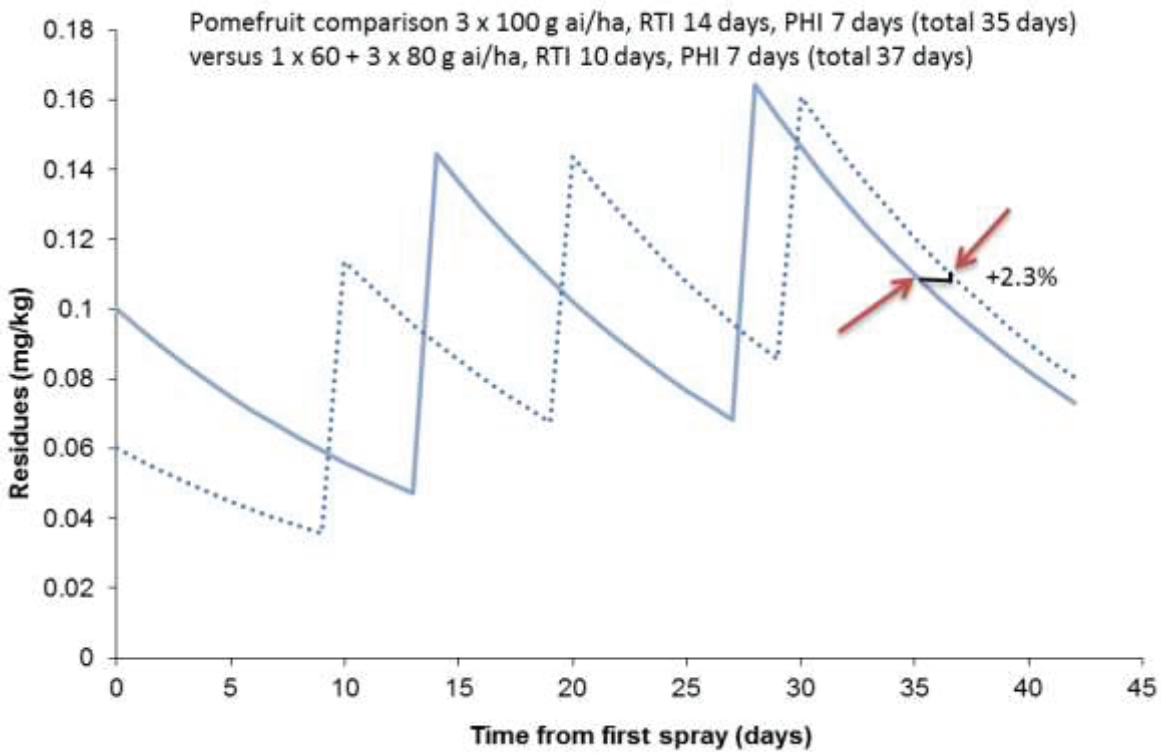

Figure 1 Estimated residue levels when following the pattern from critical GAP (———) or the pattern from field trials (.....); number of applications, dose rate and RTI vary (median half-life used was 12 days).

In Figure 1, the model indicated that the two use patterns would be expected to result in the same anticipated residues; therefore, the Meeting decided the trials were suitable for estimating maximum residues, STMRs, and HRs.

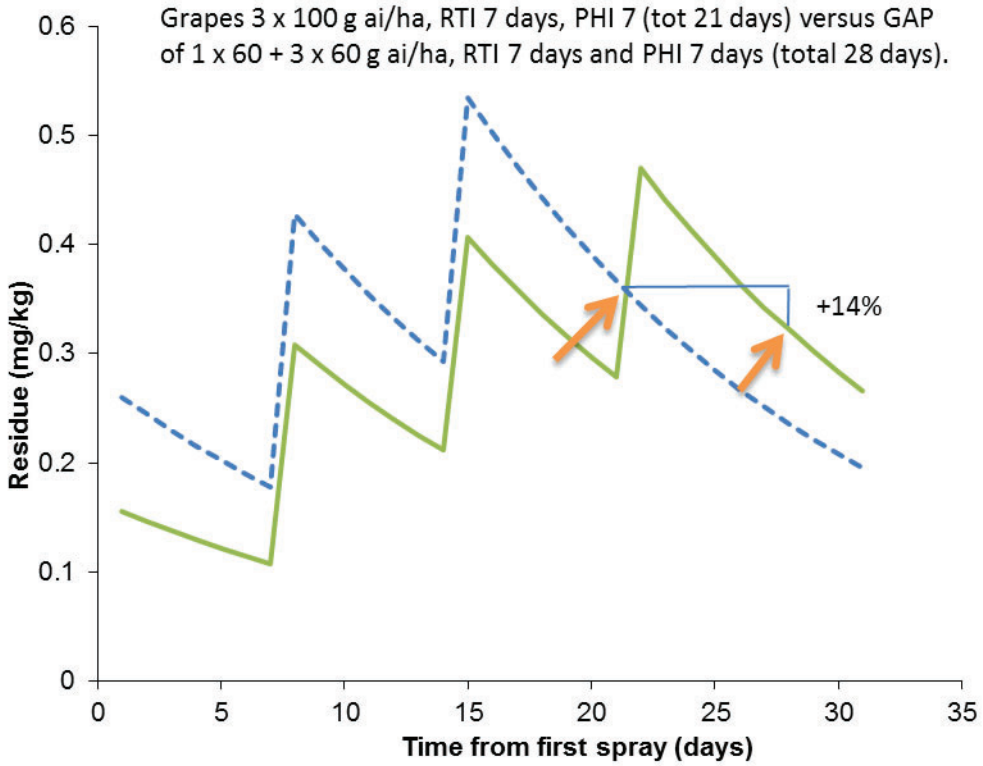

Figure 2 Estimated residue levels when following the pattern from critical GAP (———) or the pattern from field trials (– – – –); number of applications and dose rate vary, RTIs are similar (median half-life used was 11 days).

In Figure 2, the model indicates that residues from field trials might be 14% higher than those expected at GAP. As this is within the ±25% limit typically acceptable to the Meeting, the Meeting decided the trials were suitable for estimating maximum residues, STMRs, and HRs.

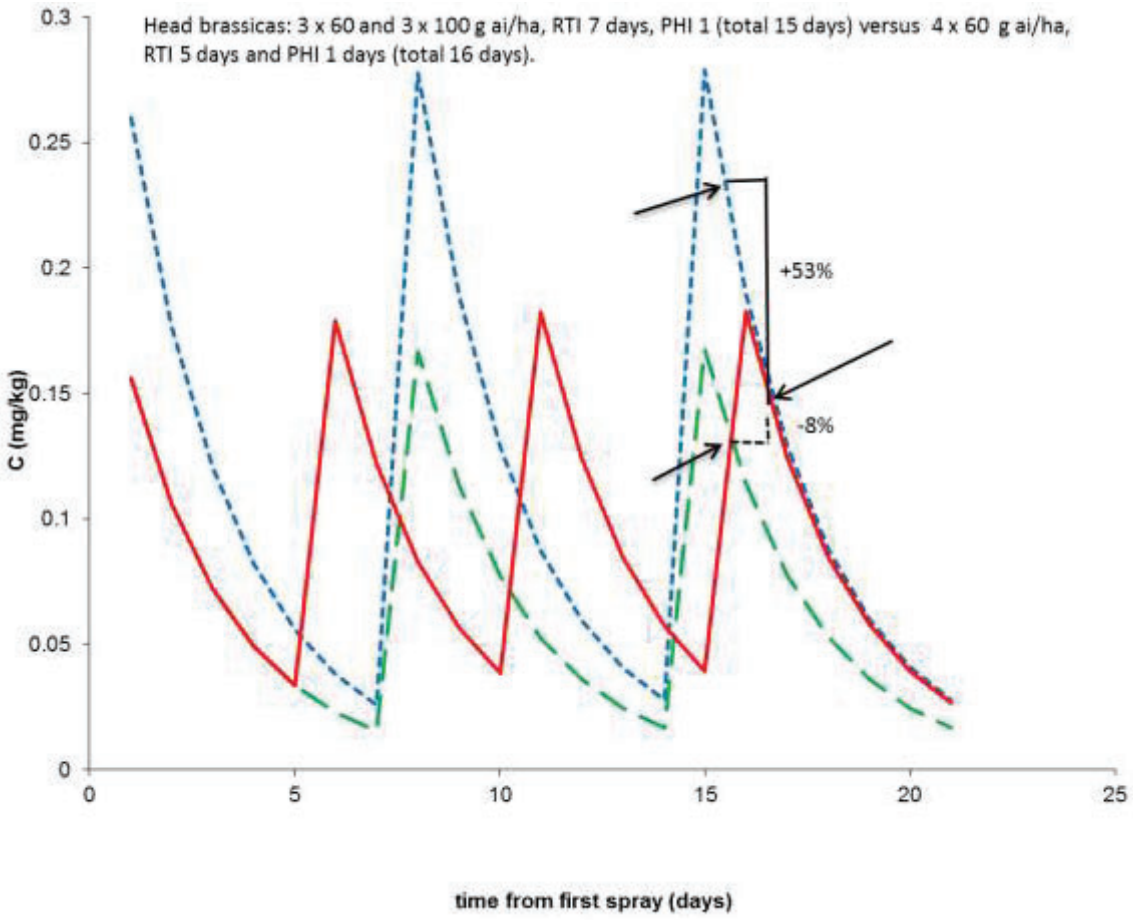

Figure 3 Estimated residue levels when following the pattern from GAP (———) or the pattern from field trials (– – – – and — — —); number of applications and RTIs differ, dose rates either higher (small dot or similar (median half-life used was 1.8 days).

In Figure 3, the model indicates that residues from field trials conducted at a similar application rate but with fewer applications at a longer retreatment interval might be 8% lower than those expected at GAP. As this is within the ±25% limit typically acceptable to the Meeting, the Meeting decided the trials were suitable for estimating maximum residues, STMRs, and HRs. However, in trials conducted at a higher rate and at the same retreatment interval, residues might be outside of the 25% limit. The Meeting did not use those trials for estimating residues.

2.5 Update of the IESTI model used for the calculation of dietary intake: New large portion data

The 2003 Meeting agreed to adopt automated spreadsheet applications for the calculation of dietary intake in order to facilitate the process. The IESTI model was constructed by RIVM (National Institute for Public Health and the Environment) of the Netherlands acting as a WHO collaborating centre. The IESTI model incorporates available consumption data in Excel spreadsheets and, where possible, links this consumption data to the Codex Commodities for which HR(-P)s and STMR(-P)s are estimated. The IESTI model calculates the IESTI using the formulas as described in Chapter 6 of the 2016 FAO manual. To use the IESTI model, estimates on ARfD, STMR(-P), HR(-P) made by JMPR are entered according to the manual in the IESTI model. Then calculations and generation of a final table, are performed automatically.

The IESTI model has been updated in 2012 to contain large portion data from more countries and to add quality controls on the large portions submitted. The IESTI model has been updated for the present Meeting to contain the more recent large portion data from USA and Canada. In addition large portions from Belgium (BE), Denmark (DK), Ireland (IE), Italy (IT), Lithuania (LT), Poland (PL), Spain (ES) and the United Kingdom (UK) available in the EFSA PRIMo model rev2 have been incorporated in the current JMPR IESTI model. The current model now contains large portion data for Australia, Brazil, Canada, China, 12 European countries, Japan, Thailand and the USA.

The IESTI model will be available on the WHO website http://www.who.int/foodsafety/areas_work/chemical-risks/gems-food/en/

3. RESPONSES TO SPECIFIC ISSUES

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

3.1.1 Quinclorac (287)

Background

Quinclorac was reviewed for the first time by the JMPR in 2015. The 2015 JMPR determined that the definition of residue for plant commodities for compliance with MRLs was quinclorac plus quinclorac conjugates.

The European Union submitted a concern form at the 49th CCPR. The EU noted that the residue definition should be reconsidered because quinclorac methyl ester, which is ten times more toxic than quinclorac, was not included in the residue definition for enforcement.

Comment by the JMPR

The 2015 JMPR evaluation noted that parent quinclorac was the major residue in examined crops and the metabolite quinclorac methyl ester while a significant residue in rape seeds was a minor residue in other primary crops and also in rotational crops. Quinclorac and its conjugates represented a significant component of the residue in all crops and is a suitable marker for compliance in all commodities.

Quinclorac methyl ester is included in the current residue definition for dietary exposure assessment.

Definition for estimating dietary intake: *Quinclorac plus quinclorac conjugates plus quinclorac methyl ester expressed as quinclorac.*

Further, the 2015 JMPR provided advice as to how the residues should be combined, taking into account the 10-fold higher toxicity of the methyl ester, that is:

Residue = (quinclorac+conjugates) + 10×quiclorac methyl ester

The calculation ensures consumer exposure is not underestimated.

The JMPR has examined the concern of the European Union that quinclorac methyl ester is included in the residue definitions for compliance established by the US EPA and Health Canada.

The definition in the USA reported in the Code of Federal Regulations is: Quinclorac (parent compound only) for barley, low growing berries, cattle commodities, cranberries, poultry commodities, goat commodities, grass, pig commodities, horse commodities, rhubarb, rice, sheep commodities, sorghum and wheat

AND

Quinclorac and its methyl ester for rapeseed

In Canada, the Health Canada MRL database lists the residue definition for quinclorac as: Quinclorac (parent compound). This residue definition applies to animal commodities as well as listed cereals

AND

Quinclorac and its methyl ester for pulses and oilseeds.

The Meeting reconfirms the residue definition established by the 2015 JMPR.

3.2 OTHER MATTERS OF INTEREST

3.2.1 Abamectin (177)

The Meeting received information on some new studies and several published papers on abamectin. However, these merely confirmed the information previously reviewed by the JMPR in 2015. The Meeting reiterated its view that the effects observed in pups in the developmental neurotoxicity studies serving as the basis of the ADI could not be attributed to the immaturity of p-glycoprotein in neonatal rats. The Meeting therefore did not find it appropriate to undertake a re-evaluation of abamectin. The previous evaluation remains unchanged.

3.2.2 Acetamiprid (246)

Following a request from CCPR, acetamiprid was on the agenda for follow up evaluation for toxicology. However, the Meeting did not receive any relevant new data regarding acetamiprid since the 2011 JMPR evaluation. Therefore, the Meeting did not find it appropriate to undertake a re-evaluation of acetamiprid and the previous evaluation is unchanged.

3.2.2 Discussion items

A number of presentations were made to the current Meeting for information and to update the JMPR on recent developments in related areas of pesticide risk assessment and management.

3.2.2.1 Update from the Joint FAO/WHO Expert Committee on Food Additives (JECFA)

Kim Petersen of the Department of Food Safety and Zoonoses, WHO, gave an overview of recent JECFA activities.

- An update on guidance on enzymes in food is due to be completed by the end of 2018.
- The development of a guidance on evaluating genotoxicity of compounds in food for human health risk assessment has been initiated.
- JECFA is also determining the best way to develop a guidance on dose–response assessment. The first step is to develop an issue paper, after which a more detailed guidance on application of BMDs will be written, likely by the end of 2018. The Core Group has been established but reviewers will be called for. A recommendation from the Meeting was to include a range of experts in the Working Group.

3.2.2.2 Harmonization of the dietary exposure methodologies for compounds used both as pesticides and veterinary drugs – Harmonizing/combining exposure from veterinary drug and pesticide use

The Agvet Residues Working Group is considering all available data as well as current approaches, that is, international estimated daily intake (IEDI) and global estimate of chronic dietary exposure (GECDE), to develop a model that harmonizes or combines exposure data from veterinary drug and pesticide use.

- The model needs to provide estimates for lifetime as well as shorter-than-lifetime exposure.
- Toxicological experts will provide information on the exposure durations on which ADIs are based and suggest the most suitable model for dietary exposure assessment.
- Residue experts are working on harmonizing the residue definition.

Currently, eight compounds used as pesticides and veterinary drugs are being assessed using national dietary estimates provided by Australia, Brazil, the People's Republic of China, Republic of Korea, New Zealand, United States and 11 European Union member states.

The Working Group is developing a description of the level of conservatism of the various international models In addition, the experts will describe the range of exposure duration covered by the various international models.

3.2.2.3 Pesticides for vector control – New Pesticide Active Ingredients Developed Initially for Vector Control: Use of JMPR WHO Core Assessment Group for Pesticides

For manufacturers developing new active ingredients for vector control, options for the independent development of human health hazard and risk assessments can be limited. Manufacturers can submit to a national regulatory authority, but countries with well-established regulatory systems often do not have a domestic need for vector control products and therefore are unlikely to accept such pesticides for review. In light of this, manufacturers can request an independent human health risk evaluation of a new public health active ingredient through the WHO Core Assessment Group for Pesticides (CAGP), part of the JMPR as it also supports the risk assessment needs of other WHO programmes including the Prequalification Team Vector Control (PQT-VC) (previously the WHO Pesticide Evaluation Scheme [WHOPES]) and programmes to do with drinking-water.

Current CAGP resources can accommodate the review of up to two additional active ingredients the Prequalification Team Vector Control (PQT-VC) (previously the WHO Pesticide Evaluation Scheme [WHOPES]) refers each year. If more than two active ingredients require review within a year, an additional CAGP meeting will be scheduled for these new active ingredients.

3.2.2.4 Other Matters of Interest: Update from the International Programme on Chemical Safety (IPCS)

Richard Brown (IPCS, WHO) delivered a presentation on recent collaborative activities of the WHO Chemical Risk Assessment Network including a recently completed review of the global use of chemical-specific adjustment factors (CSAF) since the 2005 WHO/International Programme on Chemical Safety (IPCS) guidance. The analysis focused on methodology and lessons learned with a review of the process published (Bhat *et al*., 2017).

3.2.2.5 Harmonization of the residue definition – determining the level of interest in a pilot project to achieve more harmonized residue definitions

Michael Kaethner (Bayer AG CropScience) addressed the Meeting on residue definition harmonisation between national governments and those established internationally by groups such as the JMPR.

As a way of achieving increased consistency he outlined a process in which during a review of new active substance dialogue between national regulators and FAO/WHO experts would be established to try and reach a non-binding harmonized residue definitions. With an expectation that following such discussions the proposed residue definition would be accepted by regulators and by the JMPR. He then sought feedback on the level of interest in establishing a possible pilot project to explore the issue in the future.

4. DIETARY RISK ASSESSMENT FOR PESTICIDE RESIDUES IN FOOD

4.1 CHRONIC DIETARY EXPOSURE

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

The long-term dietary risk assessment was not conducted for acetamiprid, captan, 2,4-D, fluensulfone, imidacloprid and propylene oxide as no new recommendations for maximum residue levels were made.

Thiophanate-methyl was evaluated for toxicology and an ADI was established. The evaluation for residues was unable to be completed at the current Meeting. Long-term dietary risk assessments will be conducted when the compound is evaluated for residues.

Natamycin was evaluated for toxicology but an ADI was not established. The Meeting was unable to conduct a dietary risk assessment.

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

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

Table 1 Summary of chronic dietary exposure assessments (IEDI)

CCPR code	Compound Name	ADI (mg/kg body weight)	Range of IEDI, as % of the upper bound of the ADI
229	Azoxystrobin	0–0.2	2–20%
295	Bicyclopyrone	0–0.003	3–20%
015	Chlormequat	0–0.05 as chloride 0–0.0388 as cation	1–7%
296	Cyclaniliprole	0–0.04	0–7%
207	Cyprodinil	0–0.03	8–70%
224	Difenoconazole	0–0.01	9–80%
297	Fenazaquin	0–0.05	0%
188	Fenpropimorph	0–0.004	0–10%
298	Fenpyrazamine	0–0.3	0–2%
193	Fenpyroximate	0–0.01	3–20%
282	Flonicamid	0–0.07	0–10%
243	Fluopyram	0–0.01	10–80%
285	Flupyradifurone	0–0.08	0–30%
302	Fosetyl-aluminium	0–1	1–30%
276	Imazamox	0–3	0%
267	Imazapyr	0–3	0%
299	Isoprothiolane	0–0.1	0–2%
249	Isopyrazam	0–0.06	0–1%
300	Natamycin	Not established	IEDI = 0.56 µg/kg bw/day
126	Oxamyl	0–0.009	0–1%
301	Phosphonic acid	0–1	See fosetyl-aluminium
258	Picoxystrobin	0–0.09	0–0.1%
160	Propiconazole	0–0.07	0–6%
232	Prothioconazole – ADI for prothioconazole-desthio	- 0–0.01	- 0–3%
287	Quinclorac	0–0.4	1%
251	Saflufenacil	0–0.05	20%

CCPR code	Compound Name	ADI (mg/kg body weight)	Range of IEDI, as % of the upper bound of the ADI
233	Spinetoram	0–0.05	0.3–2%
189	Tebuconazole	0–0.03	9%
213	Trifloxystrobin	0–0.04	1–7%
303	Triflumezopyrim	0–0.2	0–0.2%

4.2 ACUTE DIETARY EXPOSURE

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

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

The short-term dietary risk assessment was not conducted for acetamiprid, captan, fluensulfone, imidacloprid and propylene oxide as no new recommendations for maximum residue levels were made.

The present (or previous) Meetings agreed that ARfDs for azoxystrobin, cyclaniliprole, cyprodinil, 2,4-D, flonicamid, fosetyl-aluminium, imazapyr, isoprothiolane, phosphonic acid, saflufenacil, spinetoram, trifloxystrobin were unnecessary. For these compounds a short-term dietary exposure assessment was not undertaken.

Thiophanate-methyl was evaluated for toxicology and an ARfD was established. The evaluation for residues was unable to be completed at the current Meeting. Short-term dietary risk assessments will be conducted when the compound is evaluated for residues.

Natamycin was evaluated for toxicology and an ARfD was not established. The Meeting was unable to conduct a dietary risk assessment.

The detailed calculations of acute dietary exposure are given in Annex 4.

Table 2 Summary of acute dietary exposure assessments (IESTI)

CCPR code	Compound Name	ARfD (mg/kg bw)	Commodity (max % ARfD)	Exceeding, population, (country)
295	Bicyclopyrone	0.01 (w)	1–100%	
015	Chlormequat	0.05 as chloride; 0.0388 as cation	0–100%	
224	Difenoconazole	0.3	0–60%	
297	Fenazaquin	0.1	0–10%	
188	Fenpropimorph	0.1 (w) 0.4 (g)	0–5% 0–9%	
298	Fenpyrazamine	0.8	0–40%	
193	Fenpyroximate	0.01	Cherries total (110) Cherries raw (110) Plums raw (110) Plums dried (270) Peach total (130) Peach raw (130) Watermelon total (190) Tomato dried (310)	Child (Denmark) Child (Germany) Child (Thailand) Child (Australia) Child (Canada) Child (Japan) Child (Canada) Child (Australia)

6 FUTURE WORK

The items listed below are tentatively scheduled to be considered by the Meetings in 2019. The compounds listed include those recommended as priorities by the CCPR at its Forty-ninth and earlier Sessions and compounds scheduled for re-evaluation within the CCPR periodic review programme.

Updated calls for data are available at least ten months before each JMPR meeting from the web pages of the Joint Secretariat.

http://www.fao.org/agriculture/crops/core-themes/theme/pests/jmpr/en/

NEW COMPOUNDS

TOXICOLOGY EVALUATIONS	RESIDUE EVALUATIONS
Afidopyropen (999) (Insecticide) [USA]	Afidopyropen 999) (insecticide)
Metconazole (999) (Fungicide) Japan	Metaconazole
Orthosulfamuron (999) (Herbicide)	Orthosulfamuron
Pyflubumide (999) (Acaricide)	Pyflubumide
Pyridate (999) (Herbicide)	Pyridate
Pyrifluquinazon(999) (Insecticide) Japan	Pyrifluquinazon
SYN546330/spiropidion (999) (insecticide)	SYN546330/spiropidion (999) (insecticide)
Triflumuron (999) (Insecticide)	Triflumuron
Valifenalate (999) (Fungicide)	Valifenalate

PERIODIC RE-EVALUATIONS	
TOXICOLOGY	RESIDUE
Aldicarb (117)	Aldicarb (117)
Amitraz (122)	Amitraz (122)
Azinphos-methyl (002)	Azinphos-methyl (002)
Carbosulfan (145)/Carbofuran (096)	Carbosulfan (145)/Carbofuran (096)
Dimethoate (027)	Dimethoate (027)
Fenarimol (192)	Fenarimol (192)
Phosalone (060)	Phosalone (60)
Tolclofos-methyl (191)	Tolclofos-methyl (191)

NEW USES AND OTHER EVALUATIONS	
TOXICOLOGY	RESIDUE
	Trinexapac-ethyl (271)
	Picoxystrobin (258)
	Benzovindiflupyr (261)
	Bifenthrin(178)
	Penthiopyrad (253)
Isoprothiolane (299)	Isoprothiolane (299)
	Clofentezine (156)
	Cyclaniliprole (296)
	Cypermethrins (118)
	Fenpyroximate (193)
	Fluazifop-p-butyl (283)
	Fluensulfone (265)
	Lambda-cyhalothrin (146)
	Isoxaflutole (268)
	Pyriofenone (999)
	Pyrifluquinazon (999)
	Spirotetramat (234)
	Thiamethoxam(245)

NEW USES AND OTHER EVALUATIONS	
TOXICOLOGY	**RESIDUE**
	Tolfenpyrad (269)
XDE-777	XDE-777 (999)
	Buprofezin (173)
	Acephate (095)
	Acetamiprid (246)
	Bifenthrin (178)
	Carbendazim (72)
	Chlorpyrifos (017)
	Clofenapyr (254)
	Clothianidin (238)
	Cypermethrin (118)
	Deltamethrin (35)
	Diazinon (022)
	Dicofol (026)
	Dimethoate (027)
	Fenpropathrin (185)
	Imidacloprid (206)
	Metalaxyl (138)
	Methomyl (094)
	Parathion (059)
	Phosalone (060)
	Phorate (112)
	Profenofos (171)
	Propiconazole (160)
	Thiamethoxam (245)
	Triazophos (143)
	Spiromesifen (294)
	Lambda-cyhalothrin (146)

NEW USES AND OTHER EVALUATIONS - EXTRAORDINARY MEETING	
TOXICOLOGY	**RESIDUE**
	Chlorantraniliprole (230)
Chlorothalonil (81)	Chlorothalonil (081)
	Mesotrione (277)
	Thiabendazole (065)
	S-Methoprene (147)
	Acetochlor (280)
	Tebuconazole (189)
	Flupyradifurone (285)
Boscalid (221)	Boscalid (221)
	Mandestrobin (999)
	Pendimethalin (292)
	Fosetyl-Al (302)
	Cyantraniliprole (263)
	Cyprodinil (207)
	Azoxystrobin (229)
	Dicamba (240)
	Flonicamid (282)
	Metaflumizone (236)

7 CORRIGENDA

Pesticide Residues in Food 2016. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues. FAO Plant Production and Protection Paper, 229, 2016

Changes are shown in bold

Fipronil (202)

Recommendations Page 92
Definition of the residue (for dietary risk assessment) for animal commodities*: fipronil, fipronil-desulfinyl, fipronil-sulfone and fipronil-thioether for plant and animal commodities, expressed as fipronil*

Annex 1 Page 425

Definition of the residue (for dietary risk assessment) for animal commodities*: fipronil, fipronil-desulfinyl, fipronil-sulfone and fipronil-thioether for plant and animal commodities, expressed as fipronil*

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)
48 Guidelines for integrated control of cotton pests, 1983 (Ar E F S)
49 Pesticide residues in food 1982 – Evaluations, 1983 (E)
50 International plant quarantine treatment manual, 1983 (C E)
51 Handbook on jute, 1983 (E)
52 The palmyrah palm: potential and perspectives, 1983 (E)
53/1 Selected medicinal plants, 1983 (E)
54 Manual of fumigation for insect control, 1984 (C E F S)
55 Breeding for durable disease and pest resistance, 1984 (C E)
56 Pesticide residues in food 1983 – Report, 1984 (E F S)
57 Coconut, tree of life, 1984 (E S)
58 Economic guidelines for crop pest control, 1984 (E F S)
59 Micropropagation of selected rootcrops, palms, citrus and ornamental species, 1984 (E)
60 Minimum requirements for receiving and maintaining tissue culture propagating material, 1985 (E F S)
61 Pesticide residues in food 1983 – Evaluations, 1985 (E)
62 Pesticide residues in food 1984 – Report, 1985 (E F S)
63 Manual of pest control for food security reserve grain stocks, 1985 (C E)
64 Contribution à l'écologie des aphides africains, 1985 (F)
65 Amélioration de la culture irriguée du riz des petits fermiers, 1985 (F)
66 Sesame and safflower: status and potentials, 1985 (E)
67 Pesticide residues in food 1984 – Evaluations, 1985 (E)
68 Pesticide residus in food 1985 – Report, 1986 (E F S)
69 Breeding for horizontal resistance to wheat diseases, 1986 (E)
70 Breeding for durable resistance in perennial crops, 1986 (E)
71 Technical guideline on seed potato micropropagation and multiplication, 1986 (E)
72/1 Pesticide residues in food 1985 – Evaluations – Part I: Residues, 1986 (E)
72/2 Pesticide residues in food 1985 – Evaluations – Part II: Toxicology, 1986 (E)
73 Early agrometeorological crop yield assessment, 1986 (E F S)
74 Ecology and control of perennial weeds in Latin America, 1986 (E S)
75 Technical guidelines for field variety trials, 1993 (E F S)
76 Guidelines for seed exchange and plant introduction in tropical crops, 1986 (E)
77 Pesticide residues in food 1986 – Report, 1986 (E F S)
78 Pesticide residues in food 1986 – Evaluations – Part I: Residues, 1986 (E)
78/2 Pesticide residues in food 1986 – Evaluations – Part II: Toxicology, 1987 (E)
79 Tissue culture of selected tropical fruit plants, 1987 (E)
80 Improved weed management in the Near East, 1987 (E)
81 Weed science and weed control in Southeast Asia, 1987 (E)
82 Hybrid seed production of selected cereal, oil and vegetable crops, 1987 (E)
83 Litchi cultivation, 1989 (E S)
84 Pesticide residues in food 1987 – Report, 1987 (E F S)
85 Manual on the development and use of FAO specifications for plant protection products, 1987 (E** F S)
86/1 Pesticide residues in food 1987 – Evaluations – Part I: Residues, 1988 (E)
86/2 Pesticide residues in food 1987 – Evaluations – Part II: Toxicology, 1988 (E)

87 Root and tuber crops, plantains and bananas in developing countries – challenges and opportunities, 1988 (E)
88 Jessenia and Oenocarpus: neotropical oil palms worthy of domestication, 1988 (E S)
89 Vegetable production under arid and semi-arid conditions in tropical Africa, 1988 (E F)
90 Protected cultivation in the Mediterranean climate, 1990 (E F S)
91 Pastures and cattle under coconuts, 1988 (E S)
92 Pesticide residues in food 1988 – Report, 1988 (E F S)
93/1 Pesticide residues in food 1988 – Evaluations – Part I: Residues, 1988 (E)
93/2 Pesticide residues in food 1988 – Evaluations – Part II: Toxicology, 1989 (E)
94 Utilization of genetic resources: suitable approaches, agronomical evaluation and use, 1989 (E)
95 Rodent pests and their control in the Near East, 1989 (E)
96 Striga – Improved management in Africa, 1989 (E)
97/1 Fodders for the Near East: alfalfa, 1989 (Ar E)
97/2 Fodders for the Near East: annual medic pastures, 1989 (Ar E F)
98 An annotated bibliography on rodent research in Latin America 1960-1985, 1989 (E)
99 Pesticide residues in food 1989 – Report, 1989 (E F S)
100 Pesticide residues in food 1989 – Evaluations – Part I: Residues, 1990 (E)
100/2 Pesticide residues in food 1989 – Evaluations – Part II: Toxicology, 1990 (E)
101 Soilless culture for horticultural crop production, 1990 (E)
102 Pesticide residues in food 1990 – Report, 1990 (E F S)
103/1 Pesticide residues in food 1990 – Evaluations – Part I: Residues, 1990 (E)
104 Major weeds of the Near East, 1991 (E)
105 Fundamentos teórico-prácticos del cultivo de tejidos vegetales, 1990 (S)
106 Technical guidelines for mushroom growing in the tropics, 1990 (E)
107 Gynandropsis gynandra (L.) Briq. – a tropical leafy vegetable – its cultivation and utilization, 1991 (E)
108 Carambola cultivation, 1993 (E S)
109 Soil solarization, 1991 (E)
110 Potato production and consumption in developing countries, 1991 (E)
111 Pesticide residues in food 1991 – Report, 1991 (E)
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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, Switzerland, from 12 to 21 September 2017. The FAO Panel of Experts had met in preparatory sessions from 07 to 11 September 2017. 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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