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Pesticide residues in food 2014

Joint FAO/WHO Meeting on Pesticide Residues

REPORT 2014

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PLANT
PRODUCTION
AND PROTECTION
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221

**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, 16-25 September 2014**

WORLD HEALTH ORGANIZATION
FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS
Rome, 2014

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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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2014 JOINT FAO/WHO MEETING ON PESTICIDE RESIDUES

ROME, 16–25 SEPTEMBER 2014

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ABBREVIATIONS

ADI	acceptable daily intake
ae	acid equivalent
ai	active ingredient
AMBA	4-(methylsulfonyl)-2-aminobenzoic acid
AR	applied radioactivity
ARfD	acute reference dose
asp gr fn	aspirated grain fraction
AU	Australia
AUC	area under the plasma concentration–time curve
BAM	2,6-dichlorobenzamide
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)
CCPR	Codex Committee on Pesticide Residues
*c*GAP	Critical GAP
C_{max}	maximum concentration in plasma/blood
CPCA	cyclopropane carboxylic acid
CXL	Codex MRL
CYP	cytochrome P450
DALT	days after last treatment
DAP	days after planting
DAT	days after treatment
DC	dispersible concentrate
DM	dry matter
DNA	deoxyribonucleic acid
DT_{50}	time required for 50% dissipation of the initial concentration
dw	dry weight
ECD	electron capture detector
ETU	ethylene thiourea
EFSA	European Food Safety Authority
EHC	Environmental Health Criteria monograph
EMA	European Medicines Agency
EPO	early post-emergence

eq.	equivalent
EU	European Union
F_1	first filial generation
F_2	second filial generation
F_3	third filial generation
FAO	Food and Agriculture Organization of the United Nations
fw	fresh weight
GAP	good agricultural practice
GC	gas chromatography
GC-ECD	gas chromatography with electron capture detection
GC/MS	gas chromatography/mass spectrometry
GC/MSD	gas chromatography/mass selective detector
GC-NPD	gas chromatography coupled with nitrogen-phosphorus detector
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
HPLC	high performance liquid chromatography
HPP	4-hydroxyphenylpyruvate
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
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	liquid chromatography
LC_{50}	median lethal concentration
LD_{50}	median lethal dose
LOAEL	lowest-observed-adverse-effect level

LOD	limit of detection
log P_{ow}	octanol-water partition coefficient
LOQ	limit of quantification
MTE	Mancozeb toxicity equivalents
MNBA	2-nitro-4-(methylsulfonyl)-benzoic acid
MOA	mode of action
MRL	maximum residue limit
MS	mass spectrometry
MS/MS	tandem mass spectrometry
m/z	mass to charge ratio
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
OP	organophosphorus compound
P	parental generation
P_1	first parental generation
P_2	second parental generation
PAM	Pesticide Analytical Manual
PBI	plant back interval
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
S_f	scaling factor
SL	soluble liquid
SPE	solid phase extraction
STMR	supervised trials median residue
STMR-P	supervised trials median residue in a processed commodity calculated by multiplying the STMR of the raw commodity by the corresponding processing factor
SUA	Supply Utilisation Account

TAR	total administered radioactivity
TAT	tyrosine aminotransferase
TF	transfer factor
TLC	thin-layer chromatography
T_{max}	time to reach the maximum concentration in plasma/blood (C_{max})
TRR	total radioactive residues
TTC	threshold of toxicological concern
U	uniformly (labelled)
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 2014 JOINT FAO/WHO MEETING OF EXPERTS

1. INTRODUCTION

A Joint Meeting of the Food and Agriculture Organization of the United Nations (FAO) Panel of Experts on Pesticide Residues in Food and the Environment and the World Health Organization (WHO) Core Assessment Group on Pesticide Residues (JMPR) was held at FAO Headquarters, Rome (Italy), from 16 to 25 September 2014. The FAO Panel Members met in preparatory sessions on 11–15 September.

The Meeting was opened by Dr Clayton Campanhola, Director, Plant Production and Protection Division, FAO. On behalf of FAO and WHO, Dr Campanhola welcomed and thanked the participants for providing their expertise and for the significant time and effort devoted to such an important activity. He also expressed his sincere gratitude to the respective national authorities, institutes and organizations that have allowed their experts to contribute to the important work of the JMPR.

Dr Campanhola said that as the scientific advisory body for the Codex Committee on Pesticide Residues, the JMPR plays a central role in the establishment of global pesticide residue standards. For more than 50 years, the JMPR has been operating with two main objectives: firstly, risk assessment of pesticide residues and secondly scientific advice on the acceptable levels of pesticide residues in food and feed. Dr Campanhola further acknowledged that the deliberations of the JMPR were recognized as being authoritative, technically sound and provided an invaluable contribution to the collective efforts to provide safe food for consumers and to facilitate international trade. The growing demand for safe food and that agricultural production be sustainable underline now more than ever the continued relevance of the objectives underlying the work of the JMPR

Given the FAO's goal of eradicating hunger Dr Campanhola observed that this could not be achieved without having safe food in the hands of consumers. And that it was essential that fair practices existed in food trade allowing all producers equitable access to markets. Consequently, the work of JMPR makes an important contribution to the global fight against hunger.

Dr Campanhola also acknowledged that the demand for JMPR evaluations, in support of Codex Maximum Residue Limits, reflected the importance accorded by member countries to the scientific assessments undertaken by the JMPR, and the growth in the international trade in agricultural products. Finally, Dr Campanhola addressed his best wishes to the Meeting on behalf of the two parent organizations.

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

The Meeting evaluated 33 pesticides, including eight new compounds and three compounds that were re-evaluated within the periodic review programme of the Codex Committee on Pesticide Residues (CCPR), for toxicity or residues, or both.

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

The Meeting also estimated the dietary intakes (both short-term and long-term) of the pesticides reviewed and, on this basis, performed dietary risk assessments in relation to their ADIs or ARfDs. Cases in which ADIs or ARfDs may be exceeded were clearly indicated in order to facilitate the decision-making process of CCPR. The rationale for methodologies for long- and short-term dietary risk assessment are described in detail in the FAO manual on the submission and evaluation of pesticide residue data for the estimation of maximum residue levels in food and feed (2009).

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

1.1 Declaration of interests

The Secretariat informed the Committee that all experts participating in the 2014 JMPR had completed declaration-of-interest forms and that no conflicts had been identified.

Dr MacLachlan, as an official of the Australian Government, participated in the preparation of a concern form submitted to the Forty-Sixth CCPR on Chlorpyrifos-methyl.

The JMPR confirmed that the declaration should not be considered as a conflict of interest and that the expert should not participate in the discussion about the compound.

2. GENERAL CONSIDERATIONS

2.1 Guidance document for WHO monographers

After the 2013 JMPR, the Secretariat organized a workshop to finalize the elaboration of the new guidance document for monographers. The resulting document was agreed to by the participants of the 2013 JMPR and presented to the 79th meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in order to ensure consistency across FAO/WHO committees.

The present Meeting discussed and adopted a modified version of Chapter 7 of the guidance document on "Considerations on plant and animal metabolites". The associated assessment scheme, which includes the threshold of toxicological concern (TTC) and read-across approaches, was also modified.

The Meeting also identified minor changes to the standard phrases and templates included in the guidance document.

With these changes, the Meeting adopted the guidance document for WHO monographers and recommended that the JMPR Secretariat publish it.

2.2 Update on the revision of Principles and methods for the risk assessment of chemicals in food (EHC 240)

JMPR agreed at its meeting in 2013 that review of Environmental Health Criteria (EHC) 240, WHO's guidance on the general principles underpinning, among others, the risk assessment of pesticides, should be a standing item on its agenda, starting from the present meeting (2014), and that any chapters requiring revision would be identified.

The present Meeting adopted revised guidance for the preparation of toxicological monographs (see section 2.1), which included a new section on the assessment of the toxicological relevance of plant and animal metabolites of pesticides. The Meeting recommended that consideration should be given to updating the relevant section(s) of EHC 240 to take account of the developments included in this revised guidance.

The Meeting noted ongoing activities within WHO on the development of guidance on evaluating and expressing uncertainty in hazard characterization. This may necessitate revision of EHC 240 in the future. WHO and the European Food Safety Authority (EFSA) have commenced a review of the TTC approach for compounds with limited or no toxicological data. This, and related activities on the TTC approach, may require revision of the relevant section(s) of EHC 240. The Meeting noted that the first meeting of the WHO Risk Assessment Network will take place in Paris on 8–10 October 2014, the output of which might lead to activities necessitating revision of EHC 240.

2.3 Hazard assessment in the 21st century: Incorporating data from new mechanistic-based approaches in JMPR evaluations

At the 2012 and 2013 meetings, JMPR discussed the evaluation of data from new mechanistic-based approaches ("Tox 21") in the risk assessment of dietary exposure to pesticide residues. The Meetings concluded that it would be useful 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 the evaluation of pesticides and their metabolites. To that end, the call for data for the 2014 meeting included a request for "Data from new molecular, cell and computer-based approaches", with a note that "There has been great interest in the development of new mechanistic-based approaches. 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. In

addition, JMPR offers to evaluate without prejudice, in parallel, any data generated using emerging methods that in the view of sponsors could substitute for information obtained using conventional testing methods (see Report of 2012 JMPR)."

The Meeting was disappointed that no such data were submitted for consideration at the 2014 JMPR. There are two possible explanations for this. Either such data are not being generated or, perhaps more likely, there is a lack of confidence in their contribution to the risk assessment of pesticides at this time. The Meeting remains of the view that it would be of value to consider such data in parallel with the results of traditional toxicity testing and would welcome submission of the results of such studies for forthcoming meetings of JMPR.

2.4 Cumulative risk assessment methods used in the USA, Canada and Europe

In the report of its 46th Session, CCPR recommended that JMPR review the various approaches for assessing cumulative risk of chemicals in food that are currently under development or in use worldwide. In response, JMPR performed a review of existing guidance, assessments and proposed approaches for cumulative risk assessment related to pesticide residues in food and summarized the main principles and findings.

National approach in the USA

The United States Environmental Protection Agency (USEPA) developed a methodology for the cumulative risk assessment of pesticides that have a common mechanism of toxicity. This methodology is described in *Guidance on Cumulative Risk Assessment of Pesticide Chemicals that Have a Common Mechanism of Toxicity*.[1] "Mechanism of toxicity" is defined as "the major steps leading to a toxic effect following interaction of a pesticide with biological targets", and "common mechanism of toxicity" is defined as "pertaining to two or more pesticides or other substances that cause a common toxic effect to human health by the same, or essentially the same, sequence of major biochemical events". The preliminary grouping of substances is based upon initial screening of data related to structural similarities, mechanism of pesticidal action, understanding of general mechanisms of toxicity in mammalian systems and identification of a particular toxic effect. A detailed evaluation of all existing toxicological data on all members of the preliminary group is conducted. As cumulative risk assessment is restricted to chemicals acting by a common mechanism of toxicity, the default assumption is that the only significant type of interaction that might occur will be dose addition.

Cumulative risk assessments must be based on the end-point chosen as a direct consequence of the common mechanism, which is not necessarily the most sensitive adverse effect for all individual chemicals in the group.

Several general procedures have been considered in attempts to conduct combined or cumulative risk assessments with a group of pesticides having similar mechanisms of action:

- hazard index;
- point of departure index;
- relative potency factors;
- combined margins of exposure; and
- cumulative risk index.

[1] USEPA (2002). Guidance on cumulative risk assessment of pesticide chemicals that have a common mechanism of toxicity. Washington (DC): United States Environmental Protection Agency.

The USEPA has conducted cumulative risk assessments for the following groups of compounds:

- **Organophosphorus compounds (OPs):** OPs that inhibit acetylcholinesterase were established as the first common mechanism group, including 50 compounds. The USEPA has performed a cumulative risk assessment for OPs taking into account existing hazard and exposure data and modelling approaches. It was concluded that cumulative exposure to OPs through food was dominated by a few uses of OP pesticides on food crops and that it did not pose a concern to consumers.[1]
- **Chloroacetanilides:** A group of three compounds was considered a common mechanism group. One of these compounds was excluded from the assessment based on exposure considerations. Evaluation of the total risk from exposure to chloroacetanilides in foods indicated that the cumulative margin of exposure (13 000–53 000) did not raise concern.[2]
- **Triazines:** Three triazines and three of their metabolites were identified as a common mechanism group. The most important source of exposure was found to be drinking-water, and the determined margin of exposure was always greater than 300. It should be noted that this cumulative risk assessment is being revised, and thus the estimated margins of exposure may change.[3]
- ***N*-Methyl carbamates:** Ten *N*-methyl carbamates were identified as a common mechanism group. The USEPA concluded that a few uses of *N*-methyl carbamate pesticides on certain food crops were the major contributors to the cumulative risk. The target margin of exposure of 10 was reached at the 99.848th and 99.870th percentiles of the most exposed age groups (children 1–2 and 3–5 years old, respectively). The 99.9th percentile margins of exposure were 7.9 and 8.6 for the same age groups, whereas in the other age groups of the population, they ranged from 12 to 42.[4]
- **Pyrethroids and pyrethrins:** The most recent cumulative assessment deals with pyrethroids and pyrethrins.[5] For the pyrethroid common mechanism group, those chemicals that pose very low risk (either low toxicity or low exposure) were considered unlikely contributors to cumulative risk and were excluded from the assessment.

National approach in Canada

In Canada, the Pest Management Regulatory Agency of Health Canada adapted the USEPA's *Guidance for Identifying Pesticide Chemicals and Other Substances that Have a Common*

[1] EPA (2002). Preliminary cumulative organophosphorus risk assessment. Washington, (DC): United States Environmental Protection Agency. / USEPA (2006). Organophosphorus cumulative risk assessment. 2006 update. Washington (DC): United States Environmental Protection Agency.

[2] USEPA (2006). Cumulative risk from chloroacetanilide pesticides. Washington (DC): United States Environmental Protection Agency.

[3] USEPA (2006). Cumulative risk from triazine pesticides. Washington (DC): United States Environmental Protection Agency

[4] USEPA (2005). Estimation of cumulative risk from *N*-methyl carbamate pesticides: preliminary assessment. Washington (DC): United States Environmental Protection Agency. / USEPA (2007). Estimation of cumulative risk from *N*-methyl carbamate pesticides: preliminary assessment. Washington (DC): United States Environmental Protection Agency. / USEPA (2007). Revised *N*-methyl carbamate cumulative risk assessment. Washington (DC): United States Environmental Protection Agency.EPA (U.S. Environmental Protection Agency), 2007b. Revised N-methyl carbamate cumulative risk assessment, U.S. EPA September 24, 2007.

[5] USEPA (2011). Pyrethrins/pyrethroid cumulative risk assessment. Washington (DC): United States Environmental Protection Agency. / USEPA (2013). Common mechanism grouping for the pyrethrins and synthetic pyrethroids. Washington (DC): United States Environmental Protection Agency.

Mechanism of Toxicity and performed separate cumulative risk assessments of OPs and *N*-methylcarbamates using this guidance.[1]

Approach in the European Union

EFSA proposed a tiered approach to form cumulative assessment groups according to the following scheme: Level 1: target organ; Level 2: specific phenomenological effect; Level 3: mode of action; and Level 4: mechanism of action.[2] To date, 16 organs have been identified, forming Level 1 cumulative assessment groups; some of these cumulative assessment groups have been further evaluated to obtain Level 2 cumulative assessment groups. EFSA has not yet finalized the methodology to carry out cumulative risk assessment.

Other approaches

Several individual European countries have conducted cumulative risk assessments for OPs and carbamates, following methodology similar to that proposed by the USEPA.

On a case-by-case basis, JMPR has assessed the combined risk for active ingredients and their metabolites (e.g., fenamidone; see section 5.11).

JMPR will continue to follow the issue of cumulative risk assessment for pesticides, as it evolves, and consider its applicability to JMPR's work. The Meeting recommended that the Secretariat identify relevant developments and place them on the agenda for discussion at the next appropriate JMPR.

2.5 Characterization of risk of less-than-lifetime high exposures to pesticide residues

The current JMPR procedure for chronic dietary risk assessment for pesticide residues does not consider possible exposure scenarios where the time-weighted average exposure during less than a lifetime is greater than the lifetime average exposure. The current procedure is considered adequate as long as any toxic effects in less-than-lifetime studies occur at significantly higher levels compared with chronic studies. However, experience shows that it is not a rare finding that potency for toxicological effects is similar over a wide range of exposure durations up to chronic exposures. For example, during the current JMPR, for cyflumetofen, similar no-observed-adverse-effect levels (NOAELs) were identified in 4-week, 13-week and 104-week studies in rats (37.6, 16.5 and 16.5 mg/kg body weight [bw] per day, respectively).

The Meeting recommends that the Secretariat convene a multidisciplinary working group in order to develop criteria to identify relevant compounds and develop models to cover exposures longer than 1 day but shorter than lifetime, as needed.

2.6 Incomplete toxicological data package

During the preparation of the toxicological monographs or even at the meeting, it often appears that several toxicological studies have not been submitted to the JMPR but are publicly available or were submitted in the past to national regulatory authorities. This results in additional pressure on the scarce resources of JMPR, as the new information has to be incorporated at a late stage, which is often not feasible.

Of particular concern is when information on potentially adverse findings is not made available. The Meeting re-emphasized the importance of complete submission of data on the

[1] PMRA (2001). Guidance for identifying pesticides that have a common mechanism of toxicity for human health risk assessment. Ottawa (ON): Health Canada, Pest Management Regulatory Agency.

[2] EFSA (2013). Scientific opinion on the identification of pesticides to be included in cumulative assessment groups on the basis of their toxicological profile. EFSA J. 11(7):3293 [131 pp.].

compound and its metabolites to enable JMPR to perform state-of-knowledge risk assessments. In future, if the Meeting becomes aware of significant data that could have been submitted by the sponsor but were not, it will consider postponing the evaluation of the compound for establishing maximum residue limits (MRLs) and/or reference doses.

The Meeting recommended that the Secretariat ensure that sponsors complete a declaration that, to the best of their knowledge, all available information has been submitted for consideration by JMPR.

2.7 Maximum residue limits for pesticides for minor/specialty crops

The Meeting noted that the 46th Session of the CCPR discussed the issue of the minimum number of independent supervised residue trials required to support MRLs for minor or specialty crop[1] and while emphasising that data submitters should provide as many trials as possible to establish a robust MRL, has asked for JMPR comments on the suitability of using a tiered approach to categorise commodities according to their global or regional consumption patterns and to propose that for the elaboration of MRLs, reduced numbers of trials could be considered for commodities of lesser importance in terms of consumption.

However, rather than using a global or regional consumption-based approach to assess whether enough trials have been provided, the Meeting uses expert judgement to assess whether there are sufficient data points to adequately reflect the likely range of residues that could be expected in commodities from commercially treated crops. Ideally this should require at least 15 data points, as maximum residue level estimates become increasingly unreliable as the number of residue values decrease.

When considering the lists of commodities in the various Categories being proposed by the CCPR, the Meeting noted that in general, for those proposed in Categories 2 and 3, the suggested minimum number of trials are not too dissimilar to current JMPR procedure.

In practice, JMPR is reliant on the data provided by the data submitters, and this in turn often depends on the registration requirements of national regulatory agencies. Generally, for commodities other than those considered 'major', if the number of independent supervised trials are less than 6–8, JMPR will assess the data on a case-by-case basis, taking into account the nature of the crop, the behaviour of the pesticide, the GAP and the availability of mutually supporting data from similar commodities.

The Meeting notes that as residues in trials are inherently variable, the numbers of trials necessary to support robust maximum residue level estimates at both the national and international level may need to be increased.

2.8 Further consideration of the process for establishing group MRLs

The estimation of commodity group MRLs is common practice by the JMPR[2] with the aim to cover minor crops by a group maximum residue level. The 2013 JMPR provided additional guidance on recommending crop group MRLs[3]. The main principles were that group MRLs are only estimated if (1) the pesticide is registered for a group or sub-group of commodities as defined by the Codex Classification system and if (2) the median residue of the datasets of the commodities are within the "5 times range" to avoid an overestimation of the MRL beyond the natural variability of the data sets.

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[1] Report of the 46th Session of the Codex Committee on Pesticide Residues (REP14/PR), (para 174, Appendix XI)

[2] FAO Manual. Submission and evaluation of pesticide residues data for the estimation of maximum residue levels in food and feed. FAO plant production and protection paper 197 (ISBN 978-92-5-106436-8). FAO 2009

[3] 2013 JMPR Report, 2.9 Guidance for estimating pesticide residue levels for commodity groups.

Recently, representative commodities for each Codex Classification commodity group/subgroup were defined by the CCPR[1]. The Committee has proposed representative crops for fruits. The following principles should be used for the selection of representative commodities:

- A representative commodity is most likely to contain the highest residues.
- A representative commodity is likely to be major in terms of production and/or consumption.
- A representative commodity is most likely similar in morphology, growth habit, pest problems and edible portion to the related commodities within a group or subgroup.

The application of the three principles in the selection of representative commodities is based on the assumption that all commodities of the respective group or subgroup are treated according to a similar use pattern or GAP. It was also agreed by the Committee that, to facilitate the global use of the commodity groups for MRLs, alternative representative commodities may be selected giving flexibility for use of residue research conducted in different countries or regions that may vary due to regional differences in dietary consumption and/or areas of production for certain commodities. In the document is stated:

The JMPR may be advised to use the representative commodities adopted.

The JMPR was requested to provide to the CCPR justification for the use of any alternative representative commodities.

The JMPR welcomes the activities of the CCPR defining principles for the selection of representative crops and extrapolation to commodity groups. However, the Meeting noted that the current CCPR-principles are sometimes inconsistent and often not applicable simultaneously. For example it is not always guaranteed that a commodity, which is representative in terms of morphology, also contains the upper residue within the group. In addition, the selection of representative crops is mainly driven by production and/or consumption rather than likely residues. Therefore the Meeting stated that in some crop groups the range of residues could be significantly different to that found in the representative crop.

The Meeting took note of a review by Australia, presented at the 46th Session of CCPR on group MRLs[2]. In the review, 159 group MRLs recommended by the JMPR from 2004 to 2012 and adopted by the CAC up to 2013, were analysed. The medians of the datasets for individual commodities of the group were divided by the lowest median value. The results confirmed the approach by the 2013 JMPR and the criteria established. For illustration, the recommendations by the 2014 JMPR on group MRLs are summarized in Table 1.

The Meeting concluded that for estimating a group maximum residue level, it is necessary to have data for those representative commodities of the subgroups likely to have the highest and the lowest residues. If there are sufficient data for a subgroup according to the new Codex classification, the Meeting agreed to estimate maximum residue levels for the subgroup only. For each crop group (or sub-group) critical commodities need to be identified.

Table 1 Group MRL recommendations by the 2014 JMPR

Pesticide, registered use	Commodity, Trials (n)	Median residue	Max. ratio of Medians	Group MRL?	Data set used	Recommendation for Group/Subgroup	MRL
Chlorantraniliprole, Citrus fruits	Orange (7) Mandarin, tangelo (8)	0.22 0.22	1	Yes	Combined	Citrus fruits	0.7
Cyflumetofen,	Orange (11)	0.08	4	Yes	Combined	Citrus fruits	0.3

[1] REP12/PR-Appendix XII. Draft Principles and Guidance on the Selection of Representative Commodities for the Extrapolation of Maximum Residue Limits for Pesticides to Commodity Groups (At Step 8)

[2] CCPR 2014, 46th Session, CRD 10, Comments from Australia on Group MRLs and Commodity Groups.

Pesticide, registered use	Commodity, Trials (n)	Median residue	Max. ratio of Medians	Group MRL?	Data set used	Recommendation for Group/Subgroup	MRL
Citrus fruits	Grapefruit (6) Lemon (5)	0.04 0.02					
Cyflumetofen, Pome fruits	Apple (12) Pear (5)	0.115 0.11	1.04	Yes	Combined	Pome fruits	0.4
Fenamidone, Fruiting vegetables, cucurbits	Cucumber (9) Melons (16)	0.09 0.04	2.25	Yes	Combined	Fruiting vegetables, cucurbits	0.2
Fenamidone, Fruiting vegetables, other than cucurbits	Chili pepper (3) Tomato (17) Sweet pepper (6)	1.3 0.33 0.075	17.3a 4.4	Yes, except chili pepper	Individual based on Tomato	Fruiting vegetables, other than cucurbits, except sweet corn, mushrooms, chili pepper	1.5
Fenpropathrin, Citrus fruits	Lemon (3) Grapefruit (7) Orange (13)	0.56 0.34 0.27	2.07	Yes	Combined	Citrus fruits	2
Fenpropathrin, Pome fruits	Pear (4) Apple (4)	0.75 0.73	1.03	Yes	Combined	Pome fruits	3
Fenpropathrin, Stone fruits	Cherry (6)	1.85	7.4	No	Individual	Subgroup Cherries	7
	Peach (10)	0.705			Individual	Subgroup Peaches	3
	Plum (7)	0.25			Individual	Subgroup Plums	1
Fenpropathrin, Fruiting vegetables, other than cucurbits	Peppers (10) Tomato (9)	0.37 0.19	1.95	Yes	Combined	Fruiting vegetables other than cucurbits, except sweet corn and mushrooms	1.5
Myclobutanil, Pome fruits	Apple (6) Pear (8)	0.06 0.055	1.09	Yes	Combined	Pome fruits	0.6
Myclobutanil, Stone fruits	Cherry (8)	0.885	4.91	No	Individual	Subgroup Cherries	3
	Peach (8) Apricot (7)	0.705 0.18			Individual	Subgroup Peaches	3
	Plum (8)	0.265			Individual	Subgroup Plums	2
Myclobutanil, Fruiting vegetables, cucurbits	Melon (6) Squash (9) Cucumber (6)	0.075 0.04 0.035	2.14	Yes	Combined	Fruiting vegetables, cucurbits	0.2
Sulfoxaflor, Citrus fruits	Mandarins (4)	0.31	24.8	No	Mandarin + Orange	Subgroup Mandarin	0.8
	Oranges (6)	0.215			Mandarin + Orange	Subgroup Oranges, Sweet, Sour	0.8
	Lemons (5)	0.038			Lemons	Subgroup Lemons and Limes	0.4
	Grapefruit (6)	0.0125			Grapefruit	Subgroup Pummelos	0.15
Sulfoxaflor, Pome fruits	Apples (21) Pears (13)	0.057 0.086	1.5	Yes	Combined	Pome fruits	0.3
Sulfoxaflor, Stone fruits	Cherry (14)	0.34	8.9	No	Cherry	Subgroup Cherries	1.5
	Peach (8) Apricot (2) Nectarine (5)	0.0545 0.155 0.061			Peach + Apricot + Nectarine	Subgroup Peaches	0.4
	Plum (7)	0.038			Plums	Subgroup Plums	0.5

[a] Chili pepper

2.9 IESTI calculation for kumquat in relation to group MRLs for "Citrus fruit" and "Lemons and limes"

The Forty-sixth Session of the CCPR in 2014 considered whether it would be appropriate to remove a footnote saying "excluding kumquats" from the MRLs for "citrus fruits" and "lemons and limes" (REP 14/PR, paras 117-131).

The Committee agreed to remove the term "excluding kumquats" from the MRLs for "citrus fruits" and "lemons and limes" in the Codex Database for Pesticide Residues with the exception of the group MRLs for dimethoate, awaiting the periodic review of this pesticide by JMPR in 2019, and to forward the revised groups MRLs for "citrus fruits" and "lemons and limes" for relevant pesticides to the Codex Alimentarius Commission for adoption noting that these were consequential amendments to the revision of the fruit commodity groups in the Codex Classification (kumquats are now included in the subgroup of "lemons and limes"). These revised group MRLs were adopted by the 37th Commission (REC 14/CAC, paras 87–89).

The CCPR also agreed that, unless otherwise specified, group MRLs for "citrus fruits" and "lemons and limes" would also encompass kumquats.

The CCPR requested JMPR to:

i. calculate IESTI for kumquats when estimating MRLs for "citrus fruits" and "lemons and limes"; and
ii. consider the appropriateness to use large portion consumption data on kumquats and HR of citrus fruits in whole fruits for the estimation of the group MRLs.

As it is unlikely for JMPR to receive supervised trial data on kumquats, the Meeting concluded that it is appropriate to use the large portion consumption data on kumquats and the HR in whole fruits ("citrus fruits" or "lemons and limes") for calculating IESTI for kumquats, as the whole fruit of kumquat is edible and consumed. For calculating IESTI for other commodities in the group of "citrus fruits", the Meeting continues to use the HR in edible portion (i.e., pulp), if such data are available.

The Meeting has already conducted IESTI calculation for kumquats at the current Meeting and agreed to continue doing so in any future evaluations where maximum residue levels for "citrus fruits" or "lemons and limes" are considered.

2.10 Update of the GEMS/Food diets for the estimation of the IEDI

In 1997 the WHO introduced the GEMS/Food cluster diets. The first cluster diets were based on the 1990-1994 FAO food supply utilisation account (SUA) data. The method used cluster analysis and an iterative approach based on the use of 19 marker foods to define 13 diets representing 183 countries. The 13 cluster diets were later updated using food SUA data from 1997 to 2001. The updated 13 cluster diets were used by the JMPR to predict pesticide residue exposures in the period 2006–2013.

In 2012, WHO introduced a new methodology to cluster the FAO food SUA data into 17 diets based on statistical similarities between dietary patterns in 179 countries. The new cluster diets were based on the more recent 5-year average FAO food SUA data from 2002–2007. These average data were weighted by the population size to get average consumption in kg/person/cluster over a 5 year period.

The 2013 JMPR used the draft 17 cluster diet IEDI model on the compounds evaluated in the 2013 JMPR to gain experience in the differences in exposure that can be expected and to identify food commodities where more detailed consumption data or additional recalculations are necessary.

Following a FAO/WHO call for data in 2012 several countries submitted their national consumption data. These national consumption data were used to derive split factors for the aggregate consumption data as present in the GEMS/Food 17 cluster diet data. The aggregated data were multiplied by this split factor to get consumption data for the individual commodities.

For example, berries 'Not Elsewhere Specified' (NES) in the GEMS/food cluster diets is an aggregated food commodity including inter alia: blackberry (*Morus nigra*); loganberry; white and red mulberry (*M. alba, M. rubra*); myrtle berry (*Myrtus communis*); huckleberry; dangleberry (*Gaylussacia* spp.). In order to split the consumption data for this aggregated commodity, consumption data for adults for berries not else specified in the GEMS/food cluster diets were extracted from the national consumption database. In the national consumption database information was available for blackberries, dewberries and mulberries. For example in cluster diet G07, national consumption data were available for France and the United Kingdom. For France the fraction for blackberries was calculated based on the consumption value for blackberries, divided by the sum of the consumption values for blackberries, dewberries and mulberries (see Table 1). The fractions for France and UK were averaged and a split factor for each one was used to split the GEMS/food cluster diet G07 consumption data for berries NES into individual consumption data for blackberries, dewberries and mulberries, respectively (see Table 2). For the other berries for which no national consumption data were available (myrtle berry, huckleberry, dangleberry) a split factor of 0 was used.

National average consumption data were available for 23 countries belonging to 8 clusters. For the 9 clusters where no national consumption data were available, a split factor based on the average split factors of all other clusters was used.

Table 1 Calculation of split factors based on national consumption data

Country	Commodity	National Consumption Mean g/day	Fraction
France	Blackberries	0.0047	0.2632
	Dewberries	0.0000	0.0000
	Mulberries	0.0132	0.7368
UK	Blackberries	0.0516	0.9936
	Dewberries	0.0003	0.0064
	Mulberries	0.0000	0.0000
Average Fractions (i.e. split factors)	Blackberries	-	0.6284
	Dewberries		0.0032
	Mulberries		0.3684

Table 2 Calculation of consumption values for individual commodities within GEMS/food 17 clusters

Cluster diet G07 Consumption Mean g/day	Individual commodities	Split factors	Consumption mean g/day
0.1453 g/day Berries NES	Blackberries	0.6284	0.0913
	Dewberries	0.0032	0.0005
	Mulberries	0.3684	0.0535
	Myrtle berries	0.0000	No consumption
	Huckleberries	0.0000	No consumption
	Dangleberries	0.0000	No consumption

NES = not elsewhere specified

The consumption data of the individual commodities were incorporated in the JMPR IEDI model by RIVM[1] acting as a WHO collaborating centre. All calculations applied to the original GEMS/food data have been incorporated in the model, in order to provide transparency to the users of the IEDI model. The JMPR IEDI model is an automated Excel spreadsheet for the calculation of long term dietary intake of pesticide residues. To use the IEDI model, estimates made by JMPR (ADI, STMR(-P) and when necessary MRL values) are entered according to the manual attached to the spreadsheet. Then exposure calculations and generation of an overview table are performed automatically.

The JMPR used the new 17 cluster diet IEDI model on the compounds evaluated by the JMPR 2009-2013, where a chronic exposure of 20% ADI or higher was found. The dietary exposures obtained with the 13 cluster diet model and the new 17 cluster diet IEDI model are listed in Table 3. Since the new model is more transparent, uses more recent consumption data and clusters are more precisely defined, the JMPR 2014 Meeting decided to use the new 17 cluster diet IEDI model and considers the model final. The new 17 cluster diet IEDI model is available at http://www.who.int/foodsafety/areas_work/chemical-risks/gems-food/en/

Table 3 Comparison between the 13 cluster diet and the new 17 cluster diet IEDI model for some compounds evaluated by the JMPR 2009-2013

Codex Code	Compound	Year	No of entries	%ADI (13 clusters)	%ADI (17 clusters)
25	Dichlorvos	2012	9	5-30%	2-30%
26	Dicofol	2012	1	1-30%	4-50%
81	Chlorothalonil	2012	23	8-50%	8-50%
90	Chlorpyrifos-methyl	2013	39	20-110%	20-90%
112	Phorate	2012	18	10-40%	5-30%
118	Cypermethrins	2011	64	7-30%	7-30%
143	Triazophos	2013	3	1-40%	1-20%
173	Buprofezin	2012	28	2-50%	3-40%
179	Cycloxydim	2012	40	6-50%	6-80%
194	Haloxyfop	2009	28	20-80%	10-60%
203	Spinosad	2011	65	10-30%	6-40%
207	Cyprodinil	2013	41	5-40%	6-70%
216	Indoxacarb	2013	46	1-30%	3-40%
217	Novaluron	2010	23	7-50%	5-40%
221	Boscalid	2010	82	10-40%	10-40%
224	Difenoconazole	2013	54	4-60%	5-70%

[1] Rijksinstituut voor Volksgezondheid en Milieu (Dutch National Institute for Public Health and the Environment), Bilthoven, Netherlands

3. RESPONSES TO SPECIFIC CONCERNS

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

3.1.1 Chlorpyrifos-methyl (090)

Background

The 2013 JMPR recommended a MRL of 5 mg/kg (Po) for chlorpyrifos-methyl in cereals, except maize and rice. This recommendation was made based on post-harvest trials conducted on wheat (ten trials) and barley (nine trials) at the rate of 2.5 to 5 g ai/ton, and evaluated by the 2009 JMPR.

The 2014 JMPR received a Concern Form from the Government of Australia, which stated that the above MRL recommendation did "not accord with the commodities permitted to be treated as per the labels provided by Australia". The Australian GAP for chlorpyrifos-methyl on cereal grains excludes the use on maize, malting barley and rice, and allows one application of up to 10 g ai/ton. The 2013 JMPR erroneously interpreted the content of this label, and did not consider the highest rate allowed.

Comments by JMPR

The 2014 JMPR noted that the residue trials conducted on wheat used lower rates than the critical GAP in Australia. Currently, there is not sufficient evidence that the proportionality principle can be applied to post-harvest treatments so as to allow the scaling of residues found in the trials to the critical GAP. Therefore, the Meeting agreed to withdraw its previous recommendation of 5 mg/kg (Po) for cereals, except maize and rice.

The Meeting also withdraws its previous recommendations of 1.5 mg/kg for rice, husked and or 0.2 mg/kg for rice, polished.

Recommendation

Definition of the residue (for compliance with the MRL and for the estimation of the dietary intake) for plant and animal commodities: *chlorpyrifos-methyl*.

CCN	Commodity name	Recommended maximum residue level (mg/kg)		STMR (P) mg/kg	HR (P) mg/kg
		New	Previous		
GC 0080	Cereals, except maize and rice	W	5 (Po)		
CM 0649	Rice, husked	W	1.5 (Po)		
CM 1205	Rice, polished	W	0.2 (Po)		

3.1.2 Spirotetramat (234)

Background

Spirotetramat was first evaluated by the 2008 JMPR and most recently by the 2013 JMPR. Following the 46th Session of the CPPR a concern form was submitted by the USA relating to the 2013 JMPR not recommending maximum residue levels for pineapples and pomegranates. No recommendation was made as the whole fruits were cut in the field and transferred to the testing laboratory using freezer packs. The Concern form proposed that field cutting would not affect the validity of the analytical results

Comments by JMPR

The 2014 JMPR noted that in the trials evaluated by the 2013 JMPR, two pomegranate samples taken 1 day after the application of spirotetramat contained parent compound at 0.06 mg/kg and 0.047 mg/kg. The same samples contained residues of enol metabolites at 0.073 mg/kg and 0.07 mg/kg and enol-glycoside at concentrations of 0.022 mg/kg and 0.02 mg/kg, respectively. The presence of the enol-glycoside in these samples indicates that the enol metabolite had further decomposed during sample transportation to the testing laboratory, prior to the samples being deep-frozen. The freezing of which would assure the subsequent stability of any residues present. However, in two other samples taken 1 day post treatment, the parent compound was present at 2-3 times higher concentration than the enol metabolite, and no enol-glycoside (< 0.01 mg/kg) was detected. The results indicate that the parent compound degraded further in the first two samples, as, in addition to the enol metabolite, the enol-glycoside was detected. The enol-glycoside is not included in the residue definition for enforcement purposes.

Consequently, it cannot be excluded that degradation of the parent compound as well as the enol occurred after the fruit was cut. The sample parts were placed together in a plastic bag and cooled using freezer packs, which do not guarantee the integrity of the residues compared to being deep-frozen. The contact of the outer and inner parts of the fruit can accelerate the degradation of the parent compound resulting in an underestimation of the residues as included in the definition for MRL compliance.

Furthermore, it also needs to be noted that the requirement of avoiding cutting of whole fruits has been clearly stated in the Codex Sampling Guidelines adopted in1999.

The Meeting maintains its opinion that cutting whole fruits and vegetables in the field makes uncertain the validity of the results, unless the stability of residues has been demonstrated, utilising a method as described in section 2.6 of the 2013 JMPR Report. The Meeting therefore confirmed its previous conclusion.

Should the necessary stability tests be carried out, and the results of such studies made available to the Meeting at a later date, the Meeting could reconsider its previous conclusions based on the new results.

3.1.3 Tolfenpyrad (269)

Tolfenpyrad was evaluated by JMPR for the first time in 2013, when the Meeting established an acute reference dose (ARfD) of 0.01 mg/kg bw based on a NOAEL of 1 mg/kg bw per day for reduced body weight and feed consumption observed during the first days of treatment in a developmental toxicity study in rats at 3 mg/kg bw per day and an overall NOAEL of 1 mg/kg bw per day for vomiting and soft stools observed on the first day of treatment in 28-day, 90-day and 1-year studies in dogs at 5 mg/kg bw per day. A safety factor of 100 was applied. The Meeting considered it unlikely that the acute effects observed in rats and dogs were the result of the unpalatability of tolfenpyrad, as the effects were observed after gavage or capsule administration. The Meeting also considered it unlikely that the acute effects were secondary to local gastrointestinal irritation, as no such effects were reported in any of the studies.

The current Meeting received a concern form from the USA. The USA considers that the end-points that JMPR used for establishing the ARfD for tolfenpyrad are not appropriate, as vomiting and soft stools in dogs may be related to high concentrations following capsule administration and local (irritant) effects, and as the body weight gain decrement in the developmental toxicity study in rats may be a cumulative effect over a 3-day period and not truly representative of an acute response.

The present Meeting notes that the 2013 Meeting followed JMPR guidance on establishing an ARfD[1] in reaching its decision on the ARfD for tolfenpyrad. JMPR recognizes that although the body weight gain decrement observed in the developmental toxicity study in rats occurred during the initial 3 days of dosing, there is no information to exclude the possibility that this could have occurred after a single dose; hence, in line with normal practice, it was assumed that the body weight gain decrement could have been a single-dose effect. The 2013 Meeting discussed at some length the possibility that the effects in the dog were due to local irritation of the gastrointestinal tract. The Meeting considered this unlikely, as no local gastrointestinal irritation was reported in any of the studies. Thus, the Meeting concluded that the effects could well have been due to systemic toxicity. This was reflected in the explanation provided. The present Meeting further notes that vomiting and soft stools in dogs were observed after capsule administration of low doses of tolfenpyrad, indicating that these effects are unlikely to be the result of a high local concentration of test compound.

After reconsidering the database for tolfenpyrad, and taking into account the concerns raised by the USA, the present Meeting confirms its previous interpretation of these studies and considers that there is no basis for a revision of the ARfD for tolfenpyrad.

3.2 RESPONSES TO CONCERNS RAISED BY OTHER GROUPS

3.2.1 Emamectin benzoate (247)

Emamectin benzoate was evaluated by JMPR for the first time in 2011, when the Meeting established an ARfD of 0.03 mg/kg bw, based on a NOAEL of 5 mg/kg bw for clinical signs of neurotoxicity (tremors and irritability) observed in an acute neurotoxicity study in rats at 10 mg/kg bw. A safety factor of 200 was applied, which included a 2-fold factor based on serious histopathological observations of degeneration of neurons in brain, spinal cord and sciatic nerve at 25 mg/kg bw.

The current Meeting was made aware of a question raised by the 78th meeting of JECFA in 2013, which evaluated emamectin benzoate as a veterinary drug. JECFA considered that dogs were more sensitive than rats to the neurotoxic effects of emamectin benzoate, as in repeated-dose studies in dogs, clinical signs were first observed at doses of 1.0 and 1.5 mg/kg bw per day during week 2 of treatment. JECFA could not exclude the possibility that at higher doses, clinical signs of neurotoxicity would occur after a single dose. It therefore considered the occurrence of clinical signs in dogs as the critical effect upon which to base an ARfD. JECFA recommended that JMPR re-evaluate emamectin benzoate with respect to the ARfD.

The present Meeting re-evaluated emamectin benzoate with respect to its acute toxicity. Based on a critical review of all relevant studies in rats and dogs, a table with the overall NOAELs and lowest-observed-adverse-effect levels (LOAELS) for acute and repeated-dose toxicity studies in rats and dogs was compiled (Table 1).

[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: World Health Organization (Environmental Health Criteria 240; http://www.inchem.org/documents/ehc/ehc/ehc240_index.htm)

Table 1 Overview of overall NOAELs and LOAELs in rats and dogs

	Clinical signs of neurotoxicity		Neuropathology	
	NOAEL (mg/kg bw per day)	LOAEL (mg/kg bw per day)	NOAEL (mg/kg bw per day)	LOAEL (mg/kg bw per day)
Rat acute	5	10	10	25
Rat repeated (14-week, 1-year, 2-year studies)	2.5[a]	5.0[a]	1.0[a]	2.5[a]
Dog after 7 days of treatment (5-week, 14-week studies)	1.5	–	1.5[b]	–[b]
Dog after 13 days of treatment (5-week, 14-week, 1-year studies)	0.75[a]	1.0[a]	0.5[b,c]	1.5[b]
Dog repeated end of study (1-year study)	0.25	0.5	0.25	0.5

[a] Overall NOAELs/LOAELs.
[b] Data from a 5-week special neurotoxicity study, using a limited number of dogs.
[c] Assessed after 5 weeks of treatment.

The data on rat and dog show that in repeated-dose studies, dogs are more sensitive than rats with respect to clinical signs and neuropathological effects. Thus, it was considered likely that the NOAEL for acute toxicity in dogs will be lower than the NOAEL for acute toxicity in rats. As dogs were not treated acutely with emamectin benzoate and were treated only at doses up to 1.5 mg/kg bw per day in repeated-dose studies, an indication of the acute toxicity NOAEL may be obtained from comparison with the rat data. The data on rat show that the NOAEL and LOAEL for clinical signs in repeated-dose studies are about 2 times lower than those in the acute toxicity study. It seems reasonable to assume that a similar small difference between the acute and repeated-dose NOAELs for clinical signs exists in dogs. Thus, the Meeting agreed with JECFA that it cannot be excluded that at single doses 2–3 times above 1.5 mg/kg bw, neurotoxicity might occur in dogs.

The present Meeting concluded that as a conservative approach, it would base the ARfD on the NOAEL of 1.5 mg/kg bw per day, the highest dose at which no clinical signs or neuropathology was observed after 7 days of treatment in repeated-dose studies in the dog. Therefore, the Meeting withdrew the ARfD of 0.03 mg/kg bw, established in 2011.

The Meeting established an ARfD of 0.02 mg/kg bw for emamectin benzoate, on the basis of the absence of clinical signs of neurotoxicity after 7 days of treatment with 1.5 mg/kg bw per day in 5-week and 14-week studies in dogs, and applying a safety factor of 100. The Meeting considered that application of an additional safety factor was not necessary because clinical signs did not occur at 1.5 mg/kg bw per day given for 7 days and because in a 5-week special neurotoxicity study using a limited number of dogs, no signs of neuropathology were observed after 7 days of treatment with 1.5 mg/kg bw per day.

4. DIETARY RISK ASSESSMENT FOR PESTICIDE RESIDUES IN FOODS

4. DIETARY RISK ASSESSMENT FOR PESTICIDE RESIDUES IN FOODS

Assessment of risk from long-term dietary intake

At the present Meeting, risks associated with long-term dietary intake were assessed for compounds for which MRLs were recommended and STMRs estimated. International estimated daily intakes (IEDIs) were calculated by multiplying the concentrations of residues (STMRs and STMR-Ps) by the average daily per capita consumption estimated for each commodity on the basis of the 17 GEMS/Food Consumption cluster diets[1]. IEDIs are expressed as a percentage of the maximum ADI for a 55 kg or 60 kg person, depending on the cluster diet.

New evaluations

Aminocyclopyrachlor, cyflumetofen, dichlobenil, flufenoxuron, imazamox, mesotrione and metrafenone were evaluated for toxicology and residues for the first time by the JMPR. The Meeting established ADIs and conducted long-term dietary risk assessments for these compounds. Fenamidone, benzovindiflupyr and fluensulfone were evaluated for the first time for residues aspects and long-term dietary risk assessments were also conducted.

An ADI was established for pymetrozine. However, the data available for evaluation of this compound did not allow a conclusion on the residues definition for dietary risk assessment, and the long-term dietary risk assessment was not conducted.

Periodic Re-evaluations

Fenpropathrin, myclobutanil and triforine were evaluated for toxicology and/or residues under the Periodic Re-evaluation Programme. ADIs were established at this Meeting and long-term dietary risk assessments were conducted.

Evaluations

Buprofezin, chlorantraniliprole, clothianidin, dimethomorph, dithiocarbamate/mancozeb, emamectin benzoate, fluopyram, glufosinate-ammonium, phosmet, propamocarb, propiconazole, prothioconazole, pyraclostrobin, sedaxane, spirodiclofen, sulfoxaflor, thiamethoxam and triadimenol were evaluated for residues and long-term dietary risk assessments were conducted for these compounds.

The evaluations of chlorpyrifos-methyl, fluopicolide, glufosinate-ammonium, spirotetramat and tolfenpyrad performed at this Meeting did not lead to new or higher estimations of STMRs. Hence, a revision of the long-term dietary assessment conducted at previous Meetings was not necessary.

A summary of the long-term dietary risk assessments conducted by the present meeting is shown on Table 1. The detailed calculations of long-term dietary intakes are given in Annex 3 to the 2014 Report. 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

[1] https://extranet.who.int/sree/Reports?op=vs&path=/WHO_HQ_Reports/G7/PROD/EXT/GEMS_cluster_diets_2012

be further refined at the national level by taking into account more detailed information, as described in the Guidelines for predicting intake of pesticide residues[1].

Table 1 Summary of long-term dietary of risk assessments conducted by the 2014 JMPR

CCPR code	Compound Name	ADI (mg/kg bw)	Range of IEDI, as % of maximum ADI
272	Aminocyclopyrachlor	0-3	0
261	Benzovindiflupyr	0-0.05	0
173	Buprofezin	0-0.009	3-40
230	Chlorantraniliprole	0-2	0-1
238	Clothianidin	0-0.1	1-3
273	Cyflumetofen	0-0.1	0-1
274	Dichlobenil[a]	0-0.01	-
	2,6-dichlorobenzamide	0-0.05	0-1
225	Dimethomorph	0-0.2	0-2
105/050	Dithiocarbamates/mancozeb[b]	0-0.03 [c]	0-6
247	Emamectin benzoate	0-0.0005	1-9
264	Fenamidone	0-0.03	10-60
185	Fenpropathrin	0-0.03	1-10
265	Fluensulfone[a]	0-0.01	1-3
275	Flufenoxuron	0-0.04	0
243	Fluopyram	0-0.01	3-20
276	Imazamox	0-3	0
277	Mesotrione	0-0.5	0
278	Metrafenone	0-0.3	0
181	Myclobutanil	0-0.03	1-6
103	Phosmet	0-0.01	3-90
148	Propamocarb	0-0.4	0-2
160	Propiconazole	0-0.07	1-10
232	Prothioconazole [d]	0-0.01	0-3
210	Pyraclostrobin	0-0.03	1-6
259	Sedaxane	0-0.1	0
237	Spirodiclofen	0-0.01	1-8
252	Sulfoxaflor	0-0.05	1-7
245	Thiamethoxam	0-0.08	1-3
168	Triadimenol	0-0.03	1-3
116	Triforine	0-0.03	0-2

[a] The parent compound is not included in the residue definition for dietary intake assessment;
[b] The long-term intake was only calculated for the commodities considered at the present Meeting;
[c] for ethylene-bis-dithiocarbamates (EBDC)
[d] based on prothioconazole-desthio

Assessment of risk from short-term dietary intake

The procedures used for calculating the International estimated short-term intake (IESTI) are described in detail in Chapter 3 of the 2003 JMPR report. Detailed guidance on setting ARfD is described in Section 2.1 of the 2004 JMPR Report[2].

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.

[1] WHO (1997) Guidelines for predicting dietary intake of pesticide residues. 2nd Revised Edition, GEMS/Food Document WHO/FSF/FOS/97.7, Geneva http://www.who.int/foodsafety/publications/pesticides/en/
[2] Pesticide residues in food-2004. Report of the Joint Meeting of the Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group. FAO Plant Production and Protection Paper. 178, 2004.

Denmark indicated that their large portion data were already covered by the JMPR 2011 data. The government of the UK confirmed that the data submitted to the 2003 JMPR 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 years), and children of various ages (6 years and under). For each commodity, the highest large portion data from all different population groups was included in the spreadsheet for the calculation of the IESTI. The spreadsheet application is available at http://www.who.int/foodsafety/areas_work/chemical-risks/gems-food/en/.

New evaluations

Aminocyclopyrachlor, cyflumetofen, dichlobenil, flufenoxuron, imazamox, mesotrione, metrafenone and pymetrozine were evaluated for toxicology and residues for the first time by the JMPR. Fenamidone, benzovindiflupyr and fluensulfone were evaluated for the first time for residues aspects at the present Meeting.

The Meeting agreed that an ARfD for aminocyclopyrachlor, cyflumetofen, flufenoxuron, mesotrione and metrafenone were unnecessary and no short-term dietary intake assessments were performed for these compounds.

The data available for evaluation of pymetrozine did not allow a conclusion on the residues definition for dietary risk assessment for this compound, and the short-term dietary risk assessment was not conducted.

Periodic Re-evaluations

Fenpropathrin and myclobutanil and triforine were evaluated for toxicology and/or residues under the Periodic Re-evaluation Programme.

Evaluations

Buprofezin, chlorantraniliprole, clothianidin, dimethomorph, dithiocarbamate/mancozeb, emamectin benzoate, fluopyram, glufosinate-ammonium, phosmet, propamocarb, propiconazole, prothioconazole, pyraclostrobin, sedaxane, spirodiclofen, sulfoxaflor, thiamethoxam and triadimenol were evaluated for residues and short-term dietary risk assessments were conducted for these compounds. Emamectin benzoate was also re-evaluated for acute toxicological effects and a new ARfD was established.

The evaluations of chlorpyrifos-methyl, glufosinate-ammonium, spirotetramat and tolfenpyrad performed at this Meeting did not lead to the estimation of new or higher STMRs or HRs. Hence, a short-term dietary assessment was not conducted.

On the basis of data received by previous Meetings, the establishment of an ARfD was considered unnecessary for chlorantraniliprole, fluopicolide and spirodiclofen. Therefore, it was not necessary to estimate the short-term intakes for these compounds.

The establishment of an ARfD for dithiocarbamates has not yet been considered by the JMPR.

Table 2 shows the maximum percentage of the ARfD found in the short-term dietary risk assessments for each compound. The percentages are rounded to one whole number up to 9 and to nearest 10 above that. Percentages above 100 should not necessarily be interpreted as giving rise to a health concern because of the conservative assumptions used in the assessments. The detailed calculations of short-term dietary intakes are given in Annex 4 to the 2014 Report.

Table 2 Maximum percentage of the ARfD found in the short-term dietary risk assessments conducted by the 2014 JMPR

CCPR code	Compound Name	ARfD (mg/kg bw)	Max. percentage of ARfD	
			Commodity (% ARfD)	Population, years (country)
261	Benzovindiflupyr	0.1	All (0)	All
173	Buprofezin	0.5	Coffee beans (0)	All
238	Clothianidin	0.6	All (0)	All
274	Diclobenil [a]	0.5 [b]	-	
	2,6-dichlorobenzamide	0.3[b]	Chinese cabbage (2)	General population (China)[d]
225	Dimethomorph	0.6	Leaf lettuce (110) All others (<100)	Child, 1-6 (China) All
247	Emamectin benzoate	0.02	Lettuce (100)	Child, 1-6 (China)
264	Fenamidone	1	Mustard greens (170) Spinach (150) All others (<100)	Child, 1-6 (China) Child, 1-5 (South Africa) All
265	Fenpropathrin	0.03	Apple (390) Cherries (140) Nectarine (160) Peach (190) Pear (380) All others (<100)	Child, 1-6 (USA) Child, 2-4 (Germany) Toddler, 8-20 months (Netherlands) Child, 1-6 (Japan) Child, 1-6 (China) All
165	Fluensulfone [a]	0.3	Tomato (7)	General population (Australia)
243	Fluopyram	0.5	Leaf lettuce (100)	Child, 1-6 (China)
276	Imazamox	3	All (0)	All
181	Myclobutanil	0.3[b]	Peach (10)	General population (South Africa) [d]
103	Phosmet	0.2	Cranberry (3)	Child, 2-6 (Australia)
148	Propamocarb	2	Leek (20)	Child, 1-6 (China)
160	Propiconazole	0.3	Edible offal, mammalian (8)	Child, 1-6 (USA)
232	Prothioconazole	0.01[b,c]	Currants (100)	General population (Australia) [d]
		1[c]	All (0-1)	General population and children (all)
210	Pyraclostrobin	0.05	Cherries (40)	Child, 2-4 (Germany)
259	Sedaxane	0.3	All (0)	All
252	Sulfoxaflor	0.3	Orange (9)	Child, 2-6 (Australia)
245	Thiamethoxam	1	Avocado (1)	Child, 2-6 (Australia)
168	Triadimenol	0.08	Grapes (10)	Child, 1-6 (China)
116	Triforine	0.3	Tomato (5)	Child, 1-6 (China)

[a] The parent compound is not included in the residue definition for dietary intake assessment;
[b] for women of child-bearing-age only;
[c] for desthio-prothioconazole;
[d] Surrogate consumption data in the absence of women of child-bearing-age consumption data.

Possible risk assessment refinement when the IESTI exceeds the ARfD

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

The ARfD of 0.6 mg/kg bw for dimethomorph was established by the 2007 JMPR based on a NOAEL of 60 mg/kg bw identified on the basis of early post-implantation losses and reduced bw gain observed during days 6–10 of gestation (Days 1–5 of treatment) at the highest dose in the study of developmental toxicity in rats. The Meeting was not able to preclude whether these effects could be attributed to a single dose. The present Meeting recognised that the ARfD for dimethomorph may be conservative and a refinement might be possible if new data became available.

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

The ARfD of 1 mg/kg bw for fenamidone was established by the 2013 JMPR on the basis of a NOAEL of 125 mg/kg bw for nonspecific findings in the functional observational battery in the acute neurotoxicity study in rats. The LOAEL in this study was 500 mg/kg bw. Hence, refinement of the ARfD is unlikely.

Fenpropathrin: Apple, cherries, nectarine, peach and pear may be eaten without any further processing. As no alternative GAP was available to the Meeting to estimate a lower HR value, no refinement of the short-term intake is currently possible for these commodities.

The ARfD of 0.03 mg/kg bw for fenpropathrin was established by the 2012 JMPR on the basis of the threshold dose of 3.06 mg/kg bw from a study measuring motor activity at the time of peak effects following a single oral dose in rats. The ARfD value was supported from the results of development studies in rats. Hence, refinement of the ARfD is unlikely.

5. EVALUATION OF DATA FOR ACCEPTABLE DAILY INTAKE AND ACUTE REFERENCE DOSE FOR HUMANS, MAXIMUM RESIDUE LEVELS AND SUPERVISED TRIALS MEDIAN RESIDUE VALUES

5.1 AMINOCYCLOPYRACHLOR (272)

TOXICOLOGY

Aminocyclopyrachlor is the International Organization for Standardization (ISO)–approved common name for 6-amino-5-chloro-2-cyclopropylpyrimidine-4-carboxylic acid (International Union of Pure and Applied Chemistry [IUPAC]), with Chemical Abstracts Service (CAS) number 58956-08-8. Aminocyclopyrachlor belongs to the pyrimidine carboxylic acid chemical family and is an auxin-mimicking herbicide used for selective control of weeds, invasive species and brush in pasture. The methyl ester (CAS No. 858954-83-3) is also used as a herbicide, and information on this compound was also assessed.

Aminocyclopyrachlor has not previously been evaluated by JMPR and was reviewed by the present Meeting at the request of CCPR.

All critical studies contained statements of compliance with good laboratory practice (GLP).

Biochemical aspects

In studies conducted using [^{14}C]aminocyclopyrachlor, maximum concentrations of radioactivity in plasma (*C*max) were reached at 0.4–1 hour after a single gavage dose of 25 or 500 mg/kg bw. Gastrointestinal absorption was estimated to be 37–57%. The plasma elimination half-life was approximately 5.5 hours. More than 90% of the administered dose was excreted within 24 hours of dosing, with equal proportions recovered in urine and faeces at the low dose and a higher proportion of radioactivity detected in faeces at the high dose, suggesting a reduction in gastrointestinal absorption at the high dose. There was no evidence of tissue accumulation. Aminocyclopyrachlor was not metabolized to any great extent and was the only compound identified in plasma, urine and faeces. Low concentrations of an additional plasma metabolite, IN-LXT69, were detected only in 90-day rat and dog studies.

In studies conducted on [^{14}C]aminocyclopyrachlor-methyl using the same nominal doses of 25 or 500 mg/kg bw, radioactivity was more rapidly absorbed than for [^{14}C]aminocyclopyrachlor (up to approximately 2-fold), with C_{max} and area under the plasma concentration–time curve (AUC) values also higher (2- to 5-fold and 1.4- to 2.85-fold, respectively). Gastrointestinal absorption was estimated to be 87%. The plasma half-life values were approximately twice those of [^{14}C]aminocyclopyrachlor. The majority of the radioactivity was excreted in urine within 24 hours of dosing. There was no evidence of tissue accumulation. The main metabolite detected in plasma, urine and faeces was the free acid form of aminocyclopyrachlor. Low concentrations of aminocyclopyrachlor-methyl were detected in urine and bile shortly after dosing, but at no other times. Low concentrations of IN-LXT69 were detected in a 90-day rat study at the highest dietary concentrations.

Toxicological data

The Meeting noted that the kinetic differences between aminocyclopyrachlor-methyl and aminocyclopyrachlor do not appear to translate to any discernible difference in toxicity.

The oral and dermal median lethal dose (LD_{50}) values in rats for both aminocyclopyrachlor and aminocyclopyrachlor-methyl were greater than 5000 mg/kg bw. In rats, the median lethal concentration (LC_{50}) for aminocyclopyrachlor was greater than 5.4 mg/L. Aminocyclopyrachlor and

aminocyclopyrachlor-methyl were not skin or eye irritants in rabbits, nor were they skin sensitizers in mice (local lymph node assay).

In repeated-dose toxicity studies in rats and dogs, the main adverse effects were confined to reduced body weight, body weight gain and feed consumption. No toxicity was observed in mice up to the highest tested dietary concentration.

In a 28-day study in mice, which tested dietary concentrations of 0, 300, 3000 and 7000 parts per million (ppm) aminocyclopyrachlor (equal to 0, 45, 425 and 1056 mg/kg bw per day, respectively), the NOAEL was 7000 ppm (equal to 1056 mg/kg bw per day), the highest dietary concentration tested.

In a 90-day toxicity study in mice, which tested dietary aminocyclopyrachlor concentrations of 0, 300, 1000, 3000 and 7000 ppm (equal to 0, 47, 154, 459 and 1088 mg/kg bw per day for males and 0, 61, 230, 649 and 1629 mg/kg bw per day for females, respectively), the NOAEL was 7000 ppm (equal to 1088 mg/kg bw per day), the highest dietary concentration tested.

In a 28-day study in rats, which tested dietary aminocyclopyrachlor concentrations of 0, 600, 6000 and 18 000 ppm (equal to 0, 42, 407 and 1277 mg/kg bw per day, respectively), the NOAEL was 18 000 ppm (equal to 1277 mg/kg bw per day), the highest dietary concentration tested.

In a 3-month toxicity study in rats, which tested dietary aminocyclopyrachlor concentrations of 0, 600, 2000, 6000 and 18 000 ppm (equal to 0, 35, 114, 349 and 1045 mg/kg bw per day for males and 0, 45, 146, 448 and 1425 mg/kg bw per day for females, respectively), the NOAEL was 6000 ppm (equal to 349 mg/kg bw per day), based on reduced body weight, body weight gain and feed conversion efficiency at 18 000 ppm (equal to 1045 mg/kg bw per day).

In another 3-month toxicity study in rats, which tested dietary aminocyclopyrachlor-methyl concentrations of 0, 600, 2000, 6000 and 18 000 ppm (equal to 0, 33, 110, 326 and 961 mg acid equivalents [ae]/kg bw per day for males and 0, 40, 125, 381 and 1146 mg ae/kg bw per day for females, respectively), the NOAEL was 6000 ppm (equal to 326 mg ae/kg bw per day), based on reduced body weight, body weight gain and feed consumption at 18 000 ppm (equal to 961 mg ae/kg bw per day).

In a 90-day toxicity study in dogs, which tested dietary aminocyclopyrachlor concentrations of 0, 250, 1250, 5000 and 15 000 ppm (equal to 0, 6.5, 33, 126 and 426 mg/kg bw per day for males and 0, 7.0, 38, 124 and 388 mg/kg bw per day for females, respectively), the NOAEL was 15 000 ppm (equal to 388 mg/kg bw per day), the highest dietary concentration tested.

In a 52-week toxicity study in dogs, which tested dietary aminocyclopyrachlor concentrations of 0, 1250, 5000, 15 000 and 30 000 ppm (equal to 0, 38, 178, 465 and 1077 mg/kg bw per day for males and 0, 47, 175, 542 and 1073 mg/kg bw per day for females, respectively), the NOAEL was 30 000 ppm (equal to 1073 mg/kg bw per day), the highest dietary concentration tested.

The overall NOAEL in dogs from the 90-day and 52-week studies was 1073 mg/kg bw per day.

In an 18-month toxicity and carcinogenicity study in mice, which tested dietary aminocyclopyrachlor concentrations of 0, 300, 1000, 3000 and 7000 ppm (equal to 0, 39, 133, 393 and 876 mg/kg bw per day for males and 0, 50, 171, 527 and 1190 mg/kg bw per day for females, respectively), the NOAEL for chronic toxicity was 7000 ppm (equal to 876 mg/kg bw per day), the highest dietary concentration tested. No carcinogenicity was observed in this study.

In a 2-year study in rats, which tested dietary aminocyclopyrachlor concentrations of 0, 600, 2000, 6000 and 18 000 ppm (equal to 0, 27, 97, 279 and 892 mg/kg bw per day for males and 0, 29, 100, 309 and 957 mg/kg bw per day for females, respectively), the NOAEL for chronic toxicity was 6000 ppm (equal to 279 mg/kg bw per day), based on reduced body weight, body weight gain, feed consumption and feed conversion efficiency at 18 000 ppm (equal to 892 mg/kg bw per day). No carcinogenicity was observed in this study.

The Meeting concluded that aminocyclopyrachlor is not carcinogenic in mice or rats.

Aminocyclopyrachlor and aminocyclopyrachlor-methyl were tested for genotoxicity in an adequate range of assays, both in vitro and in vivo. No evidence of genotoxicity was found.

The Meeting concluded that aminocyclopyrachlor is unlikely to be genotoxic.

In view of the lack of genotoxicity and the absence of carcinogenicity in mice and rats, the Meeting concluded that aminocyclopyrachlor is unlikely to pose a carcinogenic risk to humans.

In a one-generation reproductive toxicity study, which tested dietary aminocyclopyrachlor-methyl concentrations of 0, 600, 5000 and 17 000 ppm (equal to 0, 36, 285 and 994 mg ae/kg bw per day for males and 0, 41, 330 and 1118 mg ae/kg bw per day for females, respectively), the NOAEL for reproductive toxicity was 17 000 ppm (equal to 994 mg ae/kg bw per day), the highest dietary concentration tested. The NOAEL for both parental toxicity and offspring toxicity was 5000 ppm (equal to 285 mg ae/kg bw per day), for reduced body weight or pup weight, body weight gain and feed consumption at 17 000 ppm (equal to 994 mg ae/kg bw per day).

In a two-generation reproductive toxicity study in rats, which tested dietary aminocyclopyrachlor concentrations of 0, 500, 1500, 5000 and 17 000 ppm (equal to 0, 30, 92, 299 and 1048 mg/kg bw per day for males and 0, 36, 110, 367 and 1243 mg/kg bw per day for females, respectively), the NOAEL for reproductive toxicity was 17 000 ppm (equal to 1048 mg/kg bw per day), the highest dietary concentration tested. The NOAEL for parental toxicity was 5000 ppm (equal to 299 mg/kg bw per day), based on reduced body weight, body weight gain and feed conversion efficiency in males at 17 000 ppm (equal to 1048 mg/kg bw per day). The NOAEL for offspring toxicity was 5000 ppm (equal to 299 mg/kg bw per day), based on reduced pup weight at 17 000 ppm (equal to 1048 mg/kg bw per day).

In a developmental toxicity study in rats, which tested aminocyclopyrachlor doses of 0, 30, 100, 300 and 1000 mg/kg bw per day, the NOAEL for both maternal toxicity and embryo/fetal toxicity was 1000 mg/kg bw per day, the highest dose tested.

In a developmental toxicity study in rabbits, which tested aminocyclopyrachlor doses of 0, 100, 300, 500 and 1000 mg/kg bw per day, the NOAEL for maternal toxicity was 500 mg/kg bw per day, based on deaths, clinical signs, reduced body weight gain, reduced feed consumption and abortions at 1000 mg/kg bw per day. The NOAEL for embryo/fetal toxicity was 1000 mg/kg bw per day, the highest dose tested.

The Meeting concluded that aminocyclopyrachlor is not teratogenic.

In an acute neurotoxicity study in rats, which tested aminocyclopyrachlor doses of 0, 200, 1000 and 2000 mg/kg bw, the NOAEL was 2000 mg/kg bw, the highest dose tested.

The Meeting concluded that aminocyclopyrachlor is not neurotoxic.

No effects on the immune system were noted in 28-day studies in mice and rats at aminocyclopyrachlor doses up to 7000 ppm (equal to 1056 mg/kg bw per day) in mice and 18 000 ppm (equal to 1277 mg/kg bw per day) in rats.

The Meeting concluded that aminocyclopyrachlor is not immunotoxic.

Toxicological data on metabolites and/or degradates

The Meeting noted the formation of a photolytic degradate of aminocyclopyrachlor, cyclopropane carboxylic acid (CPCA) (CAS No. 1759-53-1), which was not detected in rat metabolism studies. Low concentrations of this compound were detected as a possible extraction artefact in a grass metabolism study. Dietary exposure to CPCA from rotational crops and animal products is unlikely, as CPCA was not detected in aerobic or anaerobic soil metabolism studies, nor was it detected in a goat metabolism study.

In a 90-day toxicity study in rats, which tested CPCA doses of 0, 2, 10, 30 and 60 mg/kg bw per day administered by gavage, the NOAEL was 10 mg/kg bw per day, based on increased aspartate aminotransferase (females only), increased total bile acids (females only), decreased globulin with an associated decrease in total protein (males only) and adverse microscopic findings in the heart, liver (females only) and thymus (females only) at 30 mg/kg bw per day.

As CPCA appeared to be more toxic than aminocyclopyrachlor in rats following repeated oral dosing, and as it was not detected in rat metabolism studies, its toxicological relevance was assessed using JMPR's metabolite assessment scheme included in the guidance document for WHO monographers. On the basis of this assessment, the Meeting concluded that CPCA is unlikely to be a safety concern, even if not an artefact of extraction.

Human data

No information was provided on the health of workers involved in the manufacture or use of aminocyclopyrachlor or aminocyclopyrachlor-methyl. No information on accidental or intentional poisoning in humans is available.

The Meeting concluded that the existing database on aminocyclopyrachlor and aminocyclopyrachlor-methyl was adequate to characterize the potential hazards to fetuses, infants and children.

Toxicological evaluation

The Meeting established an acceptable daily intake (ADI) of 0–3 mg/kg bw per day, expressed as aminocyclopyrachlor acid equivalents, based on a NOAEL of 279 mg/kg bw per day for reduced body weight, body weight gain, feed consumption and feed conversion efficiency at 892 mg/kg bw per day in a 2-year study of toxicity in rats, with the application of a 100-fold safety factor. The ADI is supported by the NOAELs of 299 mg/kg bw per day and 285 mg ae/kg bw per day from the reproductive toxicity studies in rats conducted on aminocyclopyrachlor and aminocyclopyrachlor-methyl, respectively. The ADI is established for the sum of aminocyclopyrachlor and its methyl ester, expressed as acid equivalents.

The Meeting concluded that it is not necessary to establish an ARfD for aminocyclopyrachlor in view of its low acute oral toxicity and the absence of developmental toxicity and any other toxicological effects that would be likely to be elicited by a single dose.

A toxicological monograph was prepared.

Levels relevant to risk assessment based on studies conducted on aminocyclopyrachlor and aminocyclopyrachlor-methyl

Species	Study	Effect	NOAEL	LOAEL
Aminocyclopyrachlor				
Mouse	Eighteen-month study of toxicity and carcinogenicity[a]	Toxicity	7 000 ppm, equal to 876 mg/kg bw per day[b]	–
		Carcinogenicity	7 000 ppm, equal to 876 mg/kg bw per day[b]	–
Rat	Ninety-day study of toxicity[a]	Toxicity	6 000 ppm, equal to 349 mg/kg bw per day	18 000 ppm, equal to 1 045 mg/kg bw per day

Species	Study	Effect	NOAEL	LOAEL
	Two-year study of toxicity and carcinogenicity[a]	Toxicity	6 000 ppm, equal to 279 mg/kg bw per day	18 000, equal to 892 mg/kg bw per day
		Carcinogenicity	18 000 ppm, equal to 892 mg/kg bw per day[b]	–
	Two-generation study of reproductive toxicity[a]	Reproductive toxicity	17 000 ppm, equal to 1 048 mg/kg bw per day[b]	–
		Parental toxicity	5 000 ppm, equal to 299 mg/kg bw per day	17 000 ppm, equal to 1 048 mg/kg bw per day
		Offspring toxicity	5 000 ppm, equal to 299 mg/kg bw per day	17 000 ppm, equal to 1 048 mg/kg bw per day
	Developmental toxicity study[c]	Maternal toxicity	1 000 mg/kg bw per day[b]	–
		Embryo and fetal toxicity	1 000 mg/kg bw per day[b]	–
Rabbit	Developmental toxicity study[c]	Maternal toxicity	500 mg/kg bw per day	1 000 mg/kg bw per day
		Embryo and fetal toxicity	1 000 mg/kg bw per day[b]	–
Dog	Ninety-day and 1-year studies of toxicity[a,d]	Toxicity	30 000 ppm, equal to 1 073 mg/kg bw per day[b]	–
Aminocyclopyrachlor-methyl				
Rat	Ninety-day study of toxicity[a,e]	Toxicity	6 000 ppm, equal to 326 mg ae/kg bw per day	18 000 ppm, equal to 961 mg ae/kg bw per day
	One-generation study of reproductive toxicity[a,e]	Reproductive toxicity	17 000 ppm, equal to 994 mg ae/kg bw per day[b]	–
		Parental toxicity	5 000 ppm, equal to 285 mg ae/kg bw per day	17 000 ppm, equal to 994 mg ae/kg bw per day
		Offspring toxicity	5 000 ppm, equal to 285 mg ae/kg bw per day	17 000 ppm, equal to 994 mg ae/kg bw per day

[a] Dietary administration.
[b] Highest dose tested.
[c] Gavage administration.
[d] Two studies combined.
[e] Conducted on aminocyclopyrachlor-methyl; doses expressed as aminocyclopyrachlor acid equivalents (ae).

Estimate of acceptable daily intake (ADI)

0–3 mg/kg bw

Estimate of acute reference dose (ARfD)

Unnecessary

Information that would be useful for the continued evaluation of the compound

Results from epidemiological, occupational health and other such observational studies of human exposure

Critical end-points for setting guidance values for exposure to aminocyclopyrachlor and aminocyclopyrachlor-methyl

Absorption, distribution, excretion and metabolism in mammals	
Rate and extent of oral absorption	Rapid; 37–57% aminocyclopyrachlor; 87% aminocyclopyrachlor-methyl
Distribution	Rapid tissue distribution
Potential for accumulation	No potential for accumulation
Rate and extent of excretion	Rapid and complete
Metabolism in animals	Limited; hydrolysis of aminocyclopyrachlor-methyl to aminocyclopyrachlor
Toxicologically significant compounds in animals and plants	Aminocyclopyrachlor
Acute toxicity	
Rat, LD_{50}, oral	> 5 000 mg/kg bw
Rat, LD_{50}, dermal	> 5 000 mg/kg bw
Rat, LC_{50}, inhalation	> 5 mg/L
Rabbit, dermal irritation	Not irritating
Rabbit, ocular irritation	Not irritating
Mouse, dermal sensitization	Not sensitizing (local lymph node assay)
Short-term studies of toxicity	
Target/critical effect	Reduced body weight, body weight gain and feed consumption
Lowest relevant oral NOAEL	349 mg/kg bw per day (rat) (aminocyclopyrachlor)
	326 mg ae/kg bw per day (rat) (aminocyclopyrachlor-methyl)
Lowest relevant dermal NOAEL	No data
Lowest relevant inhalation NOAEC	No data
Long-term studies of toxicity and carcinogenicity	
Target/critical effect	Reduced body weight, body weight gain, feed consumption and feed conversion efficiency
Lowest relevant NOAEL	279 mg/kg bw per day (rat)
Carcinogenicity	Not carcinogenic
Genotoxicity	
	Unlikely to be genotoxic
Reproductive toxicity	
Target/critical effect	No evidence of reproductive toxicity (rat)
Lowest relevant parental NOAEL	299 mg/kg bw per day (two-generation study with aminocyclopyrachlor)

Lowest relevant offspring NOAEL	299 mg/kg bw per day (two-generation study with aminocyclopyrachlor)
Lowest relevant reproductive NOAEL	1 048 mg/kg bw per day, highest dose tested (two-generation study with aminocyclopyrachlor)
Developmental toxicity	
Target/critical effect	No evidence of developmental toxicity (rat and rabbit)
Lowest relevant maternal NOAEL	500 mg/kg bw per day (rabbit)
Lowest relevant embryo/fetal NOAEL	1 000 mg/kg bw per day, highest dose tested (rat and rabbit)
Neurotoxicity	
Acute neurotoxicity NOAEL	2 000 mg/kg bw per day, highest dose tested (rat)
Subchronic neurotoxicity NOAEL	No data
Developmental neurotoxicity NOAEL	No data
Other toxicological studies	
Immunotoxicity NOAEL	1 056 mg/kg bw per day, highest dose tested (mouse)
Medical data	
	No data

Summary

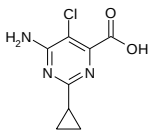
	Value	Study	Safety factor
ADI	0–3 mg/kg bw	Two-year study of toxicity (rat)	100
ARfD	Unnecessary	—	—

RESIDUE AND ANALYTICAL ASPECTS

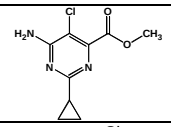
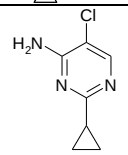
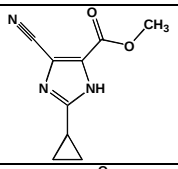
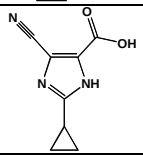
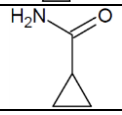
Aminocyclopyrachlor is a new pyrimidine carboxylic acid herbicide used for the control of broadleaf weeds and woody vegetation. Aminocyclopyrachlor mimics the naturally occurring phytohormone indole acetic acid (auxin) disrupting plant growth. At the Forty-fifth Session of the CCPR (2013), it was scheduled for evaluation as a new compound by the 2014 JMPR.

The Meeting received information on the metabolism of aminocyclopyrachlor and also its methyl ester (aminocyclopyrachlor-methyl, DPX-KJM44) in lactating goats and grass, methods of residue analysis, freezer storage stability, GAP information, supervised residue trials, and a cattle feeding study.

Aminocyclopyrachlor is 6-amino-5-chloro-2-cyclopropyl-4-pyrimidinecarboxylic acid (IUPAC).



Metabolites referred to in the appraisal were addressed by their codes:

DPX-KJM44	(methyl 6-amino-5-chloro-2-cyclopropyl-4-pyrimidinecarboxylic acid)	
IN-LXT69	(5-chloro-2-cyclopropyl-pyrimidin-4-ylamine)	
IN-QGC48	(5-cyano-2-cyclopropyl-3H-imidazole-4-carboxylic acid methyl ester)	
IN-QFH57	(5-cyano-2-cyclopropyl-3H-imidazole-4-carboxylic acid)	
IN-Q3007	(cyclopropane carboxamide)	

The methyl ester of aminocyclopyrachlor (DPX-KJM44) was initially explored as a potential herbicide before finally settling on aminocyclopyrachlor (free acid) as the compound to be commercialised. As DPX-KJM44 is rapidly converted to aminocyclopyrachlor in both animals and plants, studies on DPX-KJM44 were submitted to the Meeting to support the evaluation of aminocyclopyrachlor.

Animal metabolism

The current meeting evaluated laboratory animal (rat) metabolism studies of orally administered aminocyclopyrachlor-methyl (DPX-KJM44) and reported that the ester is rapidly converted to the free acid (aminocyclopyrachlor). Therefore, studies with DPX-KJM44 also serve to demonstrate the metabolism of aminocyclopyrachlor.

A lactating goat was orally dosed twice daily for five consecutive days with [pyrimidine-2-^{14}C]DPX-KJM44 at a dose equivalent to 97 ppm in the feed. Approximately 85% of the administered dose was recovered in the excreta (20% faeces, 54% urine) or gastrointestinal tract (8%). The radioactivity in the tissues ranged from 0.01 mg DPX-KJM44 equivalents/kg in fat to 1.67 mg DPX-KJM44 equivalents/kg in kidney. TRR values in milk reached 0.031 mg DPX-KJM44 equivalents/kg after five days of dosing.

With the exception of one fat sample, greater than 80% of the TRR was extracted with the solvent systems used (acetone for milk and acetonitrile/water for tissues).

No intact DPX-KJM44 was detected in tissues or milk. The major component of the ^{14}C residues were aminocyclopyrachlor (kidney 55% TRR, liver 66% TRR, muscle 43% TRR, fat 47–84% TRR, milk 16% TRR). A number of minor metabolites were unable to be identified but were generally only present at low levels (< 0.01 mg DPX-KJM44 equivalents/kg).

In summary, the metabolism of DPX-KJM44 and aminocyclopyrachlor in goats is similar to metabolism in laboratory animals in the respect that the ester is de-esterified with little further breakdown of the acid (aminocyclopyrachlor).

Plant metabolism

A study on the metabolic fate of DPX-KJM44 in grass was made available to the meeting and a number of studies were located in the literature where aminocyclopyrachlor or DPX-KJM44 were sprayed onto grass and also a variety of weed species. While the literature studies were not conducted according to the protocols developed for submission of data to regulatory authorities, they were used to contribute to the weight of evidence regarding metabolism of aminocyclopyrachlor in plants. As with animal systems, following treatment with DPX-KJM44, rapid degradation occurs with the formation of aminocyclopyrachlor, thus studies with DPX-KJM44 also provide evidence on the metabolism of aminocyclopyrachlor in plants.

Grass

The metabolic fate of [pyrimidine-2-^{14}C]DPX-KJM44 in mixed grass (30 cm high) was examined following a single foliar application at 373 g ai/ha. Absorption following spraying was rapid with only 13% of the TRR in leaves recovered in surface washes from samples collected on the day of application. DPX-KJM44 was rapidly degraded, representing 25% TRR on the day of application, 14% TRR after three days and less than 9% TRR thereafter. Aminocyclopyrachlor was the major component of the ^{14}C residue comprising 64% TRR at day 0, declining to 33% TRR at 60 days after application. Minor metabolites were IN-LXT69 (4–6% TRR), IN-QGC48 (0–4% TRR), IN-QFH57 (0–2%TRR) and IN-Q3007 (0–1% TRR). Combined, the minor metabolites accounted for no more than 6.1% TRR in individual grass samples.

In a study of [^{14}C]-aminocyclopyrachlor metabolism in tall fescue grass sprayed once at 79 g ai/ha with aminocyclopyrachlor with the addition of 0.25% non-ionic surfactant, absorption from a single leaf treated with [^{14}C]-aminocyclopyrachlor was rapid with only 37% TRR recovered in surface washes 1 day after application. At eight days after application, aminocyclopyrachlor was the only compound detected in solvent extracts of plant material.

The metabolism of DPX-KJM44 and aminocyclopyrachlor was also studied in a range of weeds (black nightshade, Canada thistle, field bindweed, large crabgrass, prickly lettuce, rush skeleton weed, yellow star thistle). In those cases where DPX-KJM44 was applied, there was rapid hydrolysis to form aminocyclopyrachlor which was translocated in the plant. There was no further transformation of aminocyclopyrachlor within the three to eight day duration of the studies.

The metabolism of aminocyclopyrachlor by plants is well understood. Following application to grass (and weeds) the major residue component consists of parent aminocyclopyrachlor.

Environmental fate

The Meeting received information on the soil aerobic metabolism, soil photolysis, aqueous hydrolysis and aqueous photolysis properties of [^{14}C]-aminocyclopyrachlor and [^{14}C]-DPX-KJM44. Studies were also received on the behaviour of [^{14}C]- DPX-KJM44 in a rotational crop situation.

In soil incubation studies under aerobic conditions in the dark at 20 °C, ^{14}C-DPX-KJM44 degraded to form aminocyclopyrachlor with a DT_{50} of 0.1 days. Subsequently aminocyclopyrachlor degraded with a DT_{50} of 275 days. In studies following the aerobic degradation of ^{14}C-aminocyclopyrachlor applied to soil, the DT_{50} for degradation ranged from 120–433 days the sandy loam, clay loam and silty clay soils studied. IN-LXT69 accounted for 4.0–6.4% of the applied radioactivity (AR) at day 0 declining to 0.2–0.4% AR by day 120 of the study. Further analysis of the unextracted portion of ^{14}C demonstrated incorporation into humin (13–20% AR), fulvic acid (11% AR) and humic acid (0.3% AR) fractions present in the soil.

In four field dissipation studies where DPX-KJM44 was applied to bare soil at two sites and to grass plots at two sites, the soil DT_{50} values were 0.4–1.6 days for DPX-KJM44 and 55 to 163 days for aminocyclopyrachlor. The DT_{50} values for grass foliage were 0.4 days for DPX-KJM44 and 4.8–8.9 days for aminocyclopyrachlor.

In a soil photolysis study with application of ^{14}C-aminocyclopyrachlor on the surface of a silt loam soil the estimated DT_{50} was 61 days suggesting photolysis will contribute to soil degradation.

Aminocyclopyrachlor was stable to hydrolysis in aqueous solutions at pH 4, 7 and 9 suggesting hydrolysis plays a negligible role in its degradation. A study on the aqueous photolysis of aminocyclopyrachlor showed it is degraded on irradiation. Aminocyclopyrachlor accounted for 28% AR after 360 hours continuous irradiation. Photodegradates formed at levels above 5% AR were IN-QFH57 (14% AR), IN-LXT69 (16% AR), IN-YY905 (8% AR), IN-Q3007 (7% AR) and IN-V0977 (12% AR).

In a confined rotational crop study with cabbage, turnip and maize, a plot of sandy loam soil was treated with [^{14}C]- DPX-KJM44 at the equivalent of 75 g ai/ha with some plots treated at 369 g ai/ha and crops sown 30, 60, 120 and 300 days after soil application for cabbage and turnip and 15, 120 and 300 days after application for maize. TRR in cabbage ranged from < LOD to 0.023 mg eq./kg with 60 to 83% of the ^{14}C accounted for by aminocyclopyrachlor. For turnips, negligible ^{14}C residues were detected in roots (maximum 0.004 mg eq./kg) while ^{14}C residues in tops ranged from 0.003 to 0.011 mg eq./kg. In the two samples with sufficient residues for identification, the major components of the ^{14}C residue in tops were aminocyclopyrachlor (41–59% TRR) and DPX-KJM44 (0–17% TRR). Radioactive residues in maize ranged from 0.011 to 0.246 mg equiv/kg for forage, 0.023–0.262 mg eq./kg for stover and 0.012–0.085 mg eq./kg for maize grain. In all cases aminocyclopyrachlor was the major component of the ^{14}C residue (46–71% TRR) with DPX-KJM44 present at ≤ 10% TRR together with small amounts of IN-LXT69 (< 2%TRR). Residues of aminocyclopyrachlor present in soil are able to be taken up the rotational crops.

In summary, aminocyclopyrachlor residues in soil may contribute to residues observed in rotational crops. A field crop rotation study is desirable.

Methods of Analysis

The Meeting received description and validation data for analytical methods suitable for residue analysis of DPX-KJM4, aminocyclopyrachlor and related metabolites IN-LXT69, IN-QFH57 and IN-QGC48 in grass and DPX-KJM4, aminocyclopyrachlor and IN-LXT69 in animal commodities.

Grass samples are homogenised with 0.15 M ammonium acetate (aq) and acetonitrile, extracted with acetonitrile/0.15 M ammonium acetate (aq) 70/30 and the extracts acidified with dilute HCL. Extracts are cleaned up using SPE cartridges before analysis by LC-MS/MS. The LOQs for all analytes are 0.01 mg/kg.

Animal commodities are analysed using a different procedure. Milk samples are extracted using acetonitrile/0.1% aqueous formic acid (90:10, v/v) with analysis by LC-MS/MS. Tissue samples are homogenised and extracted with acetonitrile/0.1% aqueous formic acid with analysis by LC-MS/MS. In the case of muscle the samples are analysed following a clean-up step using solid phase extraction. The LOQs for all analytes are 0.01 mg/kg.

QuEChERS and the US FDA pesticide multiresidue methods are not suitable for analysis of aminocyclopyrachlor.

In conclusion, suitably validated methods are available for the analysis of aminocyclopyrachlor and selected metabolites in animal and plant matrices although currently there are no multi-residue methods available for aminocyclopyrachlor.

Stability of pesticide residues in stored analytical samples

The Meeting received information on the stability of DPX-KJM-44, aminocyclopyrachlor, IN-LXT69, IN-QFH57 and IN-QGC48 in grass and hay stored frozen. The compounds were all stable in grass and hay for the duration of the stability studies; 500 days for DPX-KJM-44, aminocyclopyrachlor, IN-LXT69 and 400 days for IN-QFH57 and IN-QGC48.

In animal matrices fortified separately with DPX-KJM44, aminocyclopyrachlor and IN-LXT69, residues were stable in milk, muscle, fat and hens eggs for at least 133 days. Aminocyclopyrachlor and IN LXT69 were stable in liver and kidney for at least 147 and 88 days, respectively. DPX-KJM44 was not stable in liver and kidney, being converted to aminocyclopyrachlor either during storage or subsequent analysis.

The periods of demonstrated stability cover the frozen storage intervals used in the residue studies.

Definition of the residue

Livestock may be exposed to residues present in feeds. In a lactating goat metabolism study with DPX-KJM44, the ester was rapidly converted to aminocyclopyrachlor which was the major component of the residue in all tissues and milk (kidney 55% TRR, liver 66% TRR, muscle 43% TRR, fat 47–84% TRR, milk 16% TRR) with no individual metabolite of aminocyclopyrachlor was identified as present at levels above 0.01 mg/kg.

Residues of aminocyclopyrachlor were higher in muscle than fat in the metabolism study while in the livestock feeding study they were much higher in fat compared to muscle (2.4 to 9.0×). Levels of aminocyclopyrachlor were higher in skim milk compared to cream. The log K_{ow} for aminocyclopyrachlor is -2.48 (pH 7) suggesting the compound is not fat soluble. Taken as a whole, the Meeting considered that residues of aminocyclopyrachlor are not fat soluble.

Following foliar application of aminocyclopyrachlor (and also DPX-KJM44) to grass, the major component of the residue is aminocyclopyrachlor (33–68% TRR). All components formed from aminocyclopyrachlor were minor (<6.1% TRR).

Based on the above the Meeting decided the residue definition for compliance with MRLs and estimation of dietary intake should be as follows:

Definition of the residue for compliance with MRL and estimation of dietary intake (for animal and plant commodities): *aminocyclopyrachlor.*

The residue is not fat soluble.

Results of supervised residue trials on crops

Grass

The Meeting received supervised residue trial data for aminocyclopyrachlor on grass (including hay). GAP in the Canada is one application at up to 264 g ai/ha with a PHI of 0 days. In trials approximating critical GAP in Canada residues in grass forage were (n=6): 13, 18, 18, 22, 25, 39 mg/kg (on an as received basis) and 58, 60, 72, 77, 79 and 81 mg/kg when corrected for reported moisture contents.

The Meeting estimated a highest and median residue of 81 and 74.5 mg/kg for grass (dry weight basis).

Residues in grass hay from field trials performed in Canada and the USA approximating GAP in Canada were (n=6): 30, 35, 40, 46, 46, 48 mg/kg (on an as received basis) and 40, 45, 46, 49, 60 and 60 mg/kg when corrected for reported moisture contents.

The Meeting estimated a maximum residue limit and median and high residues of 150, 47.5 and 60 mg/kg for grass hay.

Rotational crop residues

Soil residues of aminocyclopyrachlor are moderately persistent. The use-pattern (Canadian GAP) does not specify plant-back intervals for follow-crops. In the confined rotational crop study, where DPX-KJM44 was applied to soil at the equivalent of 70 to 346 g aminocyclopyrachlor/ha, residues of aminocyclopyrachlor in cabbage and turnip from crops planted 300 days after application to soil were below practical LOQs of 0.01 mg/kg. Residues of aminocyclopyrachlor were above 0.01 mg/kg in maize commodities (forage, stover, grain). The Meeting considered the available information on residues in rotational crops to be inadequate for the purposes of estimating maximum residue levels and STMR values to cover potential residues in such crops. The Meeting also noted that the livestock dietary burden is dominated by residues in grass and hay (100% of the diet for Australia) and that any contribution from potential residues in feeds in follow crops is minor. To enable completion of the risk assessment, the Meeting noted that residues in follow crops are unlikely to average more than 0.01 mg/kg and agreed that a value of 0.01 mg/kg could be used in estimates of consumer exposure for commodities from non-permanent crops.

Residues in animal commodities

Farm animal feeding studies

The Meeting received information on the residue levels in tissues and milk of dairy cows dosed with DPX-KJM44 at the equivalent of 73, 160, 454 and 1594 ppm in the feed for 28 consecutive days.

Residues of DPX-KJM44 and IN-LXT69 in tissues and milk and aminocyclopyrachlor in muscle were < 0.01 mg/kg at all sampling intervals and doses.

Aminocyclopyrachlor residues in milk were < 0.01 mg/kg for the 73 ppm dose group and most of the samples for the 160 ppm dose group. The maximum daily mean residues were 0.024 mg/kg for the 454 ppm dose group and 0.077 mg/kg for the 1594 ppm dose group.

In kidney mean aminocyclopyrachlor residues were 0.12, 0.31, 0.34 and 0.98 mg/kg for the 73, 160, 454 and 1594 ppm dose groups respectively. Mean residues liver residues were 0.039, 0.042, 0.049 and 0.096 mg/kg and mean fat residues were < 0.01, 0.015, 0.062 and 0.46 mg/kg for the 73, 160, 454 and 1594 ppm dose groups respectively.

Animal commodity maximum residue levels

Dietary burden calculations for beef cattle and dairy cattle and poultry are provided below. The dietary burdens were estimated using the OECD diets listed in Appendix IX of the 2009 edition of the FAO Manual.

Potential cattle feed items include: grass and grass hay.

Summary of livestock dietary burden (ppm of dry matter diet)

	US-Canada		EU		Australia		Japan	
	max	mean	Max	mean	Max	Mean	Max	Mean
Beef cattle	9	7.2	41.5	37.2	81	74.5	21.2	20.4
Dairy cattle	36.4	33.5	48.6	44.7	81[a]	74.5[b]	44.3	35.6
Broilers	0	0	0	0	0	0	0	0
Layers	0	0	8.1[c]	7.4[d]	0	0	0	0

[a] Highest maximum beef or dairy cattle dietary burden suitable for MRL estimates for mammalian meat and milk
[b] Highest mean beef or dairy cattle dietary burden suitable for STMR estimates for mammalian meat and milk
[c] Highest maximum poultry dietary burden suitable for MRL estimates for poultry meat and eggs
[d] Highest mean poultry dietary burden suitable for STMR estimates for poultry meat and eggs

Animal commodity maximum residue levels

A lactating dairy cow feeding study was made available to the Meeting. A review of the laboratory animal and lactating goat metabolism studies showed that DPX-KJM44 is rapidly converted to aminocyclopyrachlor and significant differences are not expected in residues arising from dosing with DPX-KJM44 or aminocyclopyrachlor. The meeting decided the DPX-KJM44 feeding study could be used to estimate aminocyclopyrachlor residues in meat, edible offal and milk and agreed that in estimating residues levels, the feed levels should be expressed in terms of aminocyclopyrachlor acid equivalents.

The calculations used to estimate highest total residues for use in estimating maximum residue levels, STMR and HR values are shown below.

	Feed level (ppm) for milk residues	Residues (mg/kg) in milk	Feed level (ppm) for tissue residues	Residues (mg/kg) in			
				Muscle	Liver	Kidney	Fat
MRL beef or dairy cattle							
Feeding study [a]	68.5 (73)[c]	< 0.01	68.5 (73)[c]	< 0.01	0.064	0.17	0.015
	150 (160)[c]	0.012	150 (160)[c]	< 0.01	0.082	0.4	0.04
Dietary burden and high residue	81	0.01	81	< 0.01	0.067	0.21	0.019
STMR beef or dairy cattle							
Feeding study [b]	68.5 (73)[c]	< 0.01	68.5 (73)[c]	< 0.01	0.039	0.12	0.01
	150 (160)[c]	< 0.01	150 (160)[c]	< 0.01	0.042	0.31	0.015
Dietary burden and residue estimate	74.5	< 0.01	74.5	< 0.01	0.039	0.13	0.01

[a] highest residues for tissues and mean residues for milk

[b] mean residues for tissues and mean residues for milk

[c] feeding level expressed as acid equivalents = aminocyclopyrachlor, figure in brackets is feed level expressed in terms of DPX-KJM44

The Meeting estimated the following STMR values: milk 0.01 mg/kg; muscle 0.01 mg/kg; 0.039 mg/kg for liver and 0.13 mg/kg for kidney and fat 0.01 mg/kg.

The Meeting estimated the following maximum residue levels: milk 0.02 mg/kg; meat (mammalian except marine mammals) 0.01 mg/kg, fat 0.03 mg/kg and edible offal 0.3 mg/kg.

No information on residues of aminocyclopyrachlor in poultry were available to the meeting, therefore no maximum residue levels can be estimated for poultry commodities. However, Europe was the only region for which the poultry dietary burden was greater than zero. As aminocyclopyrachlor is not approved for use in Europe, the meeting considered there is no likelihood of residues in poultry commodities.

RECOMMENDATIONS

On the basis of the data obtained from supervised residue trials the Meeting concluded that the residue levels listed below are suitable for establishing maximum residue limits and for IEDI and IESTI assessment.

Definition of the residue (for compliance with MRL and estimation of dietary intake) for animal and plant commodities: *Aminocyclopyrachlor*

The residue is not fat soluble.

DIETARY RISK ASSESSMENT

Long-term intake

The WHO Panel of the 2014 JMPR established an Acceptable Daily Intake (ADI) of 0-3 mg/kg bw for aminocyclopyrachlor.

The evaluation of aminocyclopyrachlor resulted in recommendations for MRLs and STMR values for raw and processed commodities. Where data on consumption were available for the listed food commodities, dietary intakes were calculated for the 17 GEMS/Food Consumption Cluster Diets.

The IEDIs in the seventeen Cluster Diets, based on the estimated STMRs were 0% of the maximum ADI (3 mg/kg bw). The Meeting concluded that the long-term intake of residues of aminocyclopyrachlor from uses that have been considered by the JMPR is unlikely to present a public health concern.

Short-term intake

The Meeting decided that an ARfD is unnecessary. The Meeting therefore concluded that the short-term intake of residues of aminocyclopyrachlor is unlikely to present a public health concern.

5.2 BENZOVINDIFLUPYR (261)

RESIDUE AND ANALYTICAL ASPECTS

Benzovindiflupyr was scheduled for residue evaluation as a new compound by the 2014 JMPR at the Forty-fifth Session of the CCPR (2013). The toxicological review was conducted in 2013, which established an ADI of 0–0.05 mg/kg bw and an ARfD of 0.1 mg/kg bw. Additional toxicological data were provided for the metabolites SYN546039 and SYN545720. Benzovindiflupyr was defined by the WHO panel as the only toxicologically significant compound in animals, plants and the environment.

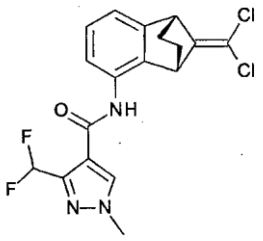
Benzovindiflupyr is a broad-spectrum fungicide belonging to the chemical class of pyrazole carboxamides. Benzovindiflupyr acts as an inhibitor of the fungal complex II respiratory chain, where it inhibits the succinate dehydrogenase enzyme (succinate dehydrogenase inhibitor, SDHI) by blocking the ubiquinone-binding sites in the mitochondrial complex.

The Meeting received information from the manufacturer on identity, metabolism, storage stability, residue analysis, use pattern, residues resulting from supervised trials on soya beans, fate of residue during processing, and livestock feeding studies.

Chemical name:

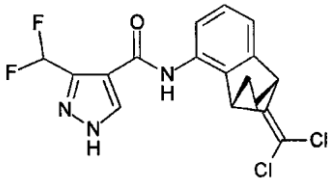
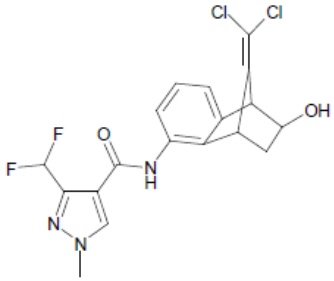
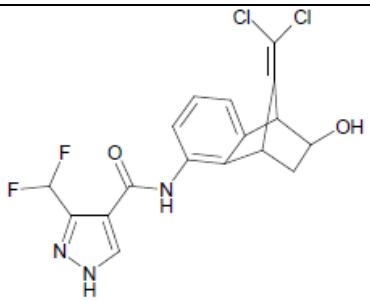
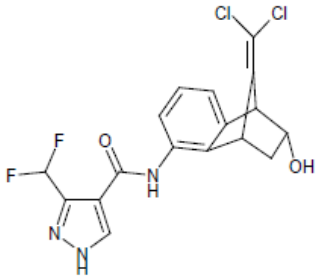
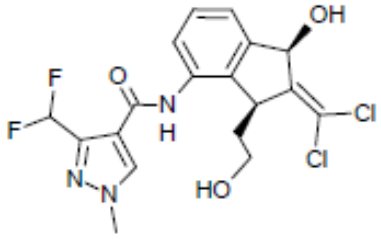
Benzovindiflupyr: N-[(1RS,4SR)-9-(dichloromethylene)-1,2,3,4-tetrahydro-1,4-methanonaphthalen-5-yl]-3-(difluoromethyl)-1-methylpyrazole-4-carboxamide (IUPAC).

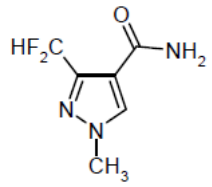
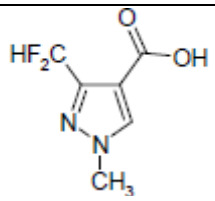
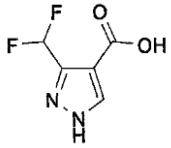
Structural formula:



Benzovindiflupyr contains chiral centres at both the bridgehead carbon atoms potentially resulting in four stereoisomeric forms. However, the bicyclic ring is a rigid structure, and therefore only two stereoisomers exist (an enantiomeric pair). Technical benzovindiflupyr consists of a racemic mixture of two enantiomers SYN546526 and SYN546527, at a ratio of 50:50. SYN546526 represents N-[(1R,4S)-9-(dichloromethylene)-1,2,3,4-tetrahydro-1,4-methanonaphthalen-5-yl]-3-(difluoromethyl)-1-methylpyrazole-4-carboxamide. SYN546527 represents N-[(1S,4R)-9-(dichloromethylene)-1,2,3,4-tetrahydro-1,4-methanonaphthalen-5-yl]-3-(difluoromethyl)-1-methylpyrazole-4-carboxamide. The enantiomers were unresolved using the chromatographic solvent systems in the reports. Both enantiomers were measured within the same single chromatographic peak and they were collectively reported as one concentration. Both enantiomers are fungicidally active. No toxicological studies were performed on the individual enantiomers.

Metabolites referred to in the appraisal by codes:

SYN546206 (N-demethyl-BVFP)	 N-demethyl-benzovindiflupyr
SYN546039 (BVFP-OH)	 hydroxy-benzovindiflupyr
SYN546041 (N-demethyl-BVFP-OH)	 N-demethyl-hydroxy-benzovindiflupyr
SYN546042 (N-demethyl-BVFP-OH)	 N-demethyl-hydroxy-benzovindiflupyr
SYN546422	 N- [(1SR,3RS)-2-(dichloromethylene)-1-hydroxy-3-(2-hydroxy-ethyl)-indan-4-yl]-3-(difluoromethyl)-1-methyl-1*H*-pyrazole-4-carboxamide

SYN508272	 3-difluoromethyl-1-methyl-1*H*-pyrazole-4-carboxylic acid amide
NOA449410	 3-difluoromethyl-1-methyl-1*H*-pyrazole-4-carboxylic acid
SYN545720	 3-difluoromethyl-1*H*-pyrazole-4-carboxylic acid

Animal metabolism

The Meeting received results of metabolism studies in laboratory animals, lactating goats and laying hens.

Metabolism in laboratory animals was summarized and evaluated by the WHO panel of the JMPR in 2013. In absorption, distribution, metabolism and excretion (ADME) studies, overnight-fasted animals showed clinical signs at doses that were non-toxic to fed animals. Therefore, most of the ADME studies were performed in fed animals. Absorption of benzovindiflupyr was approximately 80% at the low dose (1 mg/kg bw) and showed saturation at the higher dose (approximately 60% absorption at 40 mg/kg bw). In low-dose bile duct cannulated animals, 4% of the administered dose was found in urine, 17% in faeces and 69–76% in bile; in high-dose animals, 9% of the administered dose was found in urine, 32% in faeces and 47–57% in bile. At both dose levels, 86–97% of the administered dose was excreted within 48 hours after administration. The major route of excretion was by bile. For tissues, the elimination half-lives were in the range of 40–316 hours. Highest residues were identified in the liver, kidney, adrenals, thyroid and heart. After repeated daily dosing, levels of radioactivity in tissues appeared to have reached steady-state concentrations after 14 days. The predominant metabolic pathway for benzovindiflupyr is N-demethylation, phenyl and/or bicyclo hydroxylation and opening of the bicyclo system. Additionally, subsequent formation of glucuronic acid or sulfate conjugates was observed. The amide bond of benzovindiflupyr is preserved.

One lactating goat per radiolabel was dosed orally once daily for 7 consecutive days with a gelatin capsule containing [^{14}C-phenyl]-benzovindiflupyr or [^{14}C-pyrazole]-benzovindiflupyr. The equivalent actual mean daily doses in the dry feed were 41 or 32 ppm for the phenyl or pyrazole label, respectively. Goats were sacrificed 12 hours after the last dose. Total recovered radioactivity amounted to 90% and 86% of the administered dose for the phenyl and pyrazole radiolabelled forms, respectively. The majority of the radioactivity was recovered in faeces (79%/73%, phenyl/pyrazole). The remainder of the dose was recovered in urine (4.5%/5.2%, phenyl/pyrazole) and GI tract contents (6.8%/7.2%), while only low levels were found in milk and tissues (< 0.5% in total).

The highest radioactivity concentrations were found in liver (1.3/0.70 mg eq./kg) and kidney (0.28/0.18 mg eq./kg), followed by fat (0.098/0.070 mg eq./kg) and muscle (0.070/0.032 mg eq./kg).

Total radioactive residues in milk reached a plateau concentration of approximately 0.046 mg eq./kg following 96 hours dosing for the phenyl label and 0.035 mg eq./kg following 72 hours dosing for the pyrazole label.

Following solvent extraction, residue extractabilities were 78–89% TRR for liver and ≥ 94% TRR for milk and all other tissues. Liver and kidney extracts were treated with β-glucuronidase to cleave glucuronide and sulphate conjugates.

Parent was identified in milk and all goat tissues at levels of 5.5–13% TRR in milk, kidney and liver, 24–25% in muscle and 41–44% TRR in fat. Conjugated metabolites formed a significant part of the extracted residue in liver and kidney. The most significant metabolites (including conjugates) identified in all tissues and milk were the mono-hydroxylated metabolite SYN546039 (22–50% TRR) and metabolite SYN546422 (16–25% TRR in milk and kidney, 1.5–8.9% TRR in other tissues). Levels of SYN546039 in milk and tissues (except fat) or levels of SYN546422 in milk and kidney were higher than those of the parent compound. Other metabolites (including conjugates) were found at levels below 10% TRR. Post-extraction solids from liver (11–22% TRR) were shown to be associated with protein. Protease treatment of the post-extraction solids resulted in a mixture of highly polar metabolites.

Five laying hens per radiolabel were dosed orally once daily for 14 consecutive days with a gelatin capsule containing [^{14}C-phenyl]-benzovindiflupyr or [^{14}C-pyrazole]-benzovindiflupyr. The equivalent actual mean daily doses in the dry feed were 16–20 or 17–20 ppm for the phenyl or pyrazole label, respectively. Hens were sacrificed 12 hours after the last dose. Total recovered radioactivity amounted to 88% and 93% of the administered dose for the phenyl and pyrazole radiolabelled forms, respectively. The majority of the radioactivity was recovered in excreta (88%/92%, phenyl/pyrazole), while only low levels were found in eggs and tissues (< 0.2% in total).

The highest radioactivity concentrations were found in liver (0.19/0.25 mg eq./kg), followed by fat (0.033/0.045 mg eq./kg) and muscle (0.025/0.036. mg eq./kg). Total radioactive residues in egg yolks achieved a plateau concentration of 0.17-0.18 mg eq./kg after 168–240 hrs of dosing. Total radioactive residues in egg whites achieved a plateau concentration of 0.03–0.04 mg eq./kg after 120–168 hours of dosing.

Following solvent extraction, residue extractabilities were ≥ 83% TRR for egg yolk and egg white, 68–73% TRR for skin with fat, 48–49% TRR for liver and 24–37% TRR for muscle. Liver extracts were treated with β-glucuronidase to cleave glucuronide and sulphate conjugates.

Parent was identified at levels of 0.2–3.3% TRR in liver and muscle, 11–14% in eggs and 38–42% TRR in skin with fat. Benzovindiflupyr was extensively metabolised, resulting in low levels of various metabolites in tissues (< 6.0% TRR each). The most significant metabolites in eggs were the mono-hydroxylated metabolites SYN546039 (12–22% TRR in eggs, 1.3–5.1% TRR in tissues) and the mono-hydroxylated demethylated metabolites SYN546041 (10.6–12.5% TRR) and SYN546042 (6.6–12.2% TRR). Levels of SYN546039, SYN546041 and SYN546042 in eggs were in the same order of magnitude as those of the parent compound. Post-extraction solids from liver (51–52% TRR) and muscle (63–76% TRR) were shown to be associated with protein. Protease treatment of the post-extraction solids resulted in a mixture of highly polar metabolites.

In summary, metabolism observed in lactating goats and laying hens arose via hydroxylation on the alicyclic ring to form SYN546039 (all tissues, milk, eggs). In hens metabolism proceeded through N-demethylation to form SYN546041 and SYN546042 isomers (mainly in eggs), while in ruminants metabolism proceeded through an alternative pathway consisting of oxidative opening of the alicyclic ring to form SYN546422 (mainly in milk, kidney). Several other minor metabolites arose in livestock by cleavage between the pyrazole and phenyl rings and/or conjugation as glucuronide or sulphate compounds. Further metabolism involves association with proteins.

The major compounds identified in goat, hen tissues, milk or eggs are: parent, SYN546039, SYN546422, SYN546041 and SYN546042 and their conjugates. Parent and SYN546039 and its conjugates comprise a significant part of residue in tissues, milk and eggs. Significant additional

contributions are found for metabolites SYN546041 and SYN546042 in eggs and SYN546422 and its conjugates in milk and goat kidney.

In general, metabolism between goat, hen and rat is similar, with a few exceptions. Formation of SYN546422 is only found in goat. Opening of the bicyclo system as such is found in rat and metabolite SYN546422 is postulated as a plausible rat intermediate between the open bicyclo rat metabolites SYN546634 and SYN546707 (the demethylated form of SYN546422). Cleavage between the pyrazole and phenyl rings to form SYN508272 is found in the pyrazole labelled studies in hens and goats, while in the rat studies this bond is preserved.

Plant metabolism

The Meeting received plant metabolism studies for benzovindiflupyr after foliar application on fruits (tomatoes), cereals (wheat) and pulses/oilseeds (soya beans).

The metabolism of ^{14}C-phenyl-benzovindiflupyr or ^{14}C-pyrazole-benzovindflupyr in indoor grown tomatoes was studied following four foliar applications at 0.13–0.14 kg ai/ha at weekly intervals. Total radioactive residues (TRR) in mature tomato fruits at DAT=1 and 14 were 0.047 and 0.092 mg eq./kg for the phenyl label and 0.18 and 0.15 mg eq./kg for the pyrazole label, respectively. A high proportion of the residue remained on the surface of the fruit (65–79% TRR). The residues in or on the fruit could be extracted by acetonitrile/water (> 99% TRR). The principal component of the residue was the parent compound (91–95% TRR). A number of metabolites were detected, none reaching > 0.5% TRR.

The metabolism of ^{14}C-phenyl-benzovindiflupyr or ^{14}C-pyrazole-benzovindflupyr in indoor grown wheat was studied following two foliar applications at 0.14 kg ai/ha at a 35 day interval. Residue levels in wheat forage harvested 9 days after the first application and residue levels in wheat hay, wheat straw and wheat grains harvested 10, 40 and 41 days after the second application were 3.0, 4.9, 8.1, 0.12 mg eq./kg for the phenyl label and 2.1, 6.4, 9.0, 0.092 mg eq./kg for the pyrazole label, respectively. The major part of the residues (> 97% TRR) could be extracted with acetonitrile/water. The principal component of the residue was the parent compound: 84–87% TRR in grain, 81–84% TRR in straw and 89–103% in wheat forage and hay. A number of metabolites were detected, none reaching > 5.0% TRR. Several of these metabolites were present in the free and conjugated form.

The metabolism of ^{14}C-phenyl-benzovindiflypyr or ^{14}C-pyrazole-benzovindflupyr in indoor grown soya beans was studied following two foliar applications at 0.12-0.13 kg ai/ha at a 22 day interval. Residue levels in soya bean forage harvested 11 days after the first application and soya bean hay and soya bean seeds harvested at 13 and 30 days after the second application were 3.4, 14 and 0.029 mg eq./kg for the phenyl label and 4.1, 13 and 0.10 mg eq./kg for the pyrazole label, respectively. The major part of the residues (> 89% TRR) could be extracted with solvents. Parent was identified at levels of 15–31% TRR in soya bean seeds, 67–72% TRR in soya bean hay and 83–85% TRR in soya bean forage. The most significant metabolite in soya bean seeds was the cleavage product SYN545720 (47% TRR). The major part of the SYN545720 metabolite was present in the conjugated form (30% TRR), particularly as an aspartic acid conjugate or monosaccharide conjugate. The most significant metabolite in soya bean forage and hay was the mono-hydroxylated metabolite SYN546039 (9.2–12% TRR). The major part of the SYN546039 metabolite was present in the conjugated form (8.5–12% TRR), particularly as a malonyl glycoside or glycoside conjugate. A number of other metabolites were detected, none reaching > 14% TRR. One of these metabolites was NOA449410, a plant specific metabolite, which was not detected in rat. NOA449410 was present at very low levels: < 1.2% TRR or 0.012 mg eq./kg) in soya forage, 0.039 mg eq./kg in soya hay or 0.0012 mg eq./kg in soya seeds.

In summary, the degree of metabolism in crops after foliar application varied. In fruits and cereals parent compound represented the principal part of the residue in tomato fruits, wheat grain, wheat straw and wheat forage and hay. Metabolism proceeded further in pulses/oilseeds with parent

representing 15–31% TRR in soya bean seeds, 67–72% TRR in soya bean hay and 83–85% TRR in soya bean forage. Metabolism observed in pulses/oilseeds arose via hydroxylation on the alicyclic ring to form SYN546039). Metabolism proceeded through N-demethylation and cleavage between the pyrazole and phenyl rings to form SYN545720.

In general, metabolism between plants and rat is similar, except for the cleavage between the pyrazole and phenyl rings. In rat this bond is preserved. The cleavage product SYN508272 is found in the pyrazole labelled studies in hens and goats. Cleavage products NOA449410 and SYN545720 are not found in rat or in livestock.

Environmental fate in soil

The Meeting received information on photolysis in water and on soil and information on rotational crops.

All plant metabolism studies have been conducted indoors. Since the interval between the first application and harvest for the investigated commodities is long (29–111 days) and the residue is a surface residue, photolysis may form a major route of degradation. Since indoor grown plants are not subjected to the full spectrum of sunlight, degradation on field grown plants may show a different behaviour. Photolysis studies in water or on soil show a DT_{50} of 44 or 144–244 days, respectively, confirming the potential for photolysis. Photolysis in water after 15 days and on soil after 30 days demonstrated the formation of low levels of SYN546039, SYN508272, NOA449410, and SYN545720 (0.6–8.5% TAR), indicating the absence of an alternative degradation pathway under outdoor conditions. In addition, preliminary experimental work on photolysis on leaf surfaces grown under greenhouse, under artificial sunlight and outdoor conditions for 7 days, demonstrated very minor degradation in all three test conditions while the resulting minor degradates were qualitatively similar. The Meeting concluded that the indoor plant metabolism studies are considered acceptable for deriving a residue definition for plant commodities.

Metabolism of ^{14}C-phenyl-benzovindiflypyr or ^{14}C-pyrazole-benzovindflupyr was investigated in confined rotational crops following a single bare soil treatment. A sandy loam soil was treated at a rate of 0.53–0.54 kg ai/ha under indoor conditions. Rotational crops (lettuce, wheat and turnip) were sown at 30, 90 and 300 day plant back intervals (PBI). Total radioactivity in rotational crops ranged from 0.003–0.77 mg eq./kg at 30 day PBI, 0.002–0.34 mg eq./kg at 90 day PBI and 0.007–0.29 mg eq./kg at 300 day PBI. Total radioactivity levels above 0.05 mg eq./kg were found in wheat forage, hay and straw at all plant back intervals.

Wheat grain had very low residues (< 0.01–0.014 mg eq./kg) and most extracts were not amenable to chromatographic examination. In turnip roots, parent was the principal component and ranged from 81–90% TRR at the 30 day plant back interval, 69–72% TRR at the 90 day plant back interval and 64–71% at the 300 day plant back interval. In the leafy parts of crops (lettuce, turnip leaves, wheat forage, hay, straw) parent compound was the principal component of the residue at the 30 day PBI. Parent ranged from 14–37% TRR at the 30 day PBI, 13–35% TRR at the 90 day PBI and 6.5–29% TRR at the 300 day PBI. At the 90 and 300 day PBI, significant metabolites were the cleavage products NOA449410 and SYN545720, together accounting for 53–73% TRR, 34–46% TRR and 24–26% TRR in immature lettuce, mature lettuce and wheat forage, respectively. NOA449410 was mainly present in the conjugated form whereas SYN545720 was present in the free and conjugated form. Other metabolites were generally present at low levels (each < 10% TRR). In wheat forage, wheat hay and wheat straw, SYN546206 and SYN546039 were more significant, frequently occurring at > 10% TRR and occasionally approaching 20% TRR each (including conjugates). SYN546206 was mainly present in the free form; SYN546039 was mainly present in the conjugated form.

From these data the Meeting concluded that benzovindiflupyr can be taken up from the soil under confined conditions even after long plant back intervals (300–366 days). Metabolites found in confined rotational crops (SYN546206, SYN546039, NOA449410 and SYN545720) are identical to

those observed in primary crops and may have arisen from photolysis, degradation in and uptake from soil as well as from metabolism within the crop itself.

In two field rotational crop studies at four different locations in the EU benzovindiflupyr was applied onto bare soil at a single application of 0.20 kg ai/ha. Rotational crops (spinach, wheat, carrots) were sown 28–32, 60–69 or 355–366 days after application.

In another field rotational crop study at four different locations in the USA benzovindiflupyr was applied as foliar application to soya beans or peanuts at 3× 0.1 kg ai/ha with 14 day intervals. The last application was at BBCH 71–89 of the target crops. The soya bean and peanut target crops were harvested and removed from the field. Rotational crops (spinach or lettuce, radish or turnip, wheat) were sown 30 or 180 days after application.

No residues > 0.01 mg/kg of parent benzovindiflupyr or metabolites SYN546206 or SYN546039 (including conjugates) were found in any of the harvested commodities at any of the rotations, except in wheat forage and wheat straw from the 28–30 or 60 day plant back intervals. Parent and SYN546039 (including conjugates) were found in wheat forage and wheat straw at levels up to 0.012–0.022 mg/kg. Metabolites NOA449410 and SYN545720 were not analysed.

The dose rates as used in the field rotational crop studies (1× 0.2 kg ai/ha or 3×0.1 kg ai/ha) are higher than those used in the actual supervised residue trials submitted (3× 0.045 kg ai/ha for soya beans). Based on the current uses, the Meeting concluded that no residues are expected in rotational crops. Should additional uses be developed in future, rotational crop studies may need to be re-evaluated.

Methods of Analysis

The Meeting received description and validation data for analytical methods for the determination of benzovindiflupyr related residues in plant and animal commodities.

The existing multi-residue method QuEChERS was submitted as enforcement/monitoring method for the determination of parent compound in plant and animal commodities. Plant commodities were extracted with acetonitrile/water (1:1, v/v), Samples were cleaned-up by SPE prior to quantification by HPLC-MS/MS. The Meeting considers validation sufficient for plant commodities with high acid content, high water content, high starch content, high oil content and all animal commodities (meat, liver, kidney, fat, milk and eggs). The LOQ was 0.01 mg/kg for parent compound in each matrix.

Several other HPLC-MS/MS methods were submitted for the determination of parent and its metabolites SYN546206 (free), SYN545720 (including conjugates) and/or SYN546039 (including conjugates) in plant material. Crop commodities were extracted with acetonitrile/water (80/20). Parent and SYN546206 were separated off by liquid-liquid partition and the remaining extract was treated with acid at pH 2 for 6 hours at 100 ºC to cleave the SYN545720 and/or SYN546039 conjugates. Extraction efficiency for acetonitrile/water was at least 71% for parent and 81% for SYN546206 (free) as shown by a radio-validation study in wheat hay and wheat straw. Efficiency of extraction and hydrolysis was > 100% for SYN546039 (including conjugates) and SYN545720 (including conjugates) as shown by a radio-validation study in soya bean hay and soya bean seed. Most analytical methods were considered fit for purpose with LOQs of 0.01 mg/kg for individual analytes.

Another HPLC-MS/MS method was submitted for the determination of parent and its metabolites SYN546039 (including conjugates) and SYN546422 (incl conjugates) in milk, eggs or animal tissues. Animal commodities were extracted with acetonitrile/water (80/20). Parent was determined directly in the primary extract, while the remaining extract was treated with beta-glucuronidase at pH 5 for 6 hours at 37 ºC to cleave the SYN546039 and/or SYN546422 conjugates. Extraction efficiency for acetonitrile/water was > 100 % for parent, free SYN546039 and free SYN546422 as shown by a radio-validation study in milk, muscle, and egg yolk. Efficiency of

extraction and hydrolysis was > 100% for SYN546039 (including conjugates) and at least 67% for SYN546422 (including conjugates) as shown by a radio-validation study in liver. The analytical method was considered fit for purpose with LOQs of 0.01 mg/kg for individual analytes.

Stability of pesticide residues in stored analytical samples

The Meeting received information on the storage stability of parent, SYN546039, SYN546206 and SYN545720 in raw and processed plant commodities and of parent, SYN546039 and SYN546422 in animal commodities.

Storage stability studies showed that benzovindiflupyr and metabolite SYN546039 (free) were stable for at least 24 months at -18 ºC in crop commodities representative of the high water, high acid, high starch, high protein and high oil commodity groups as well as in wheat straw. Metabolite SYN546206 (free) was stable for at least 22 months at -18 ºC in crop commodities representative of the high water and high starch commodity groups as well as in wheat straw. Metabolites SYN545720 (free) and SYN508272 (free) were stable for at least 24 months at -18 ºC in crop commodities representative of the high oil, high acid and high protein commodity groups.

Benzovindiflupyr and metabolites SYN546039 (free) and SYN545720 (free) were stable for at least 24 months at -10 ºC in various processed commodities: flour (maize, soya), meal (maize), oil (maize, soya), soymilk, dried fruits (grape, apple) and fruit juice (apple).

Benzovindiflupyr and metabolites SYN546039 (free) and SYN546422 (free), at -20 ºC, were stable for at least 56–62 days in milk and eggs and at least 76–78 days in liver and muscle. According to OECD Guideline 506 storage stability in kidney and fat may be extrapolated from the other animal tissues, so The Meeting concluded that residues in kidney and fat are likely to be stable for at least 76 days.

Definition of the residue

The major compounds identified in goat, hen tissues, milk or eggs are: parent, SYN546039, SYN546422, SYN546041 and SYN546042 and their conjugates. Parent was identified at levels of 38–44% TRR (0.012–0.040 mg/kg) in goat fat and hen skin with fat, 24–25% (0.008–0.017 mg/kg) in goat muscle and 0.2–14% TRR (< 0.001–0.14 mg/kg) in milk, eggs, and all other tissues. The mono-hydroxylated metabolite SYN546039 and its conjugates was identified at levels of 22–50% TRR (0.008–0.64 mg eq./kg) in milk and goat tissues, 12–22% TRR(0.008–0.022 mg eq./kg) in eggs and < 6.0% TRR in hen tissues. Metabolite SYN546422 and its conjugates was only found in goat and was identified at levels of 16–25% TRR (0.010–0.052 mg eq./kg) in milk and goat kidney and 1.5–8.9% TRR (0.001-0.056 mg eq./kg) in other goat tissues. The mono-hydroxylated demethylated metabolite isomers SYN546041 and SYN546042 were identified at levels of 11–12% TRR (0.003–0.020 mg eq./kg) and 6.6–12% TRR (0.002-0.020 mg eq./kg) in eggs, respectively, < 5.0% TRR in hen tissues and < 10% TRR in goat tissues and milk.

Benzovindiflupyr parent is found in every animal commodity, although the levels in milk, eggs, edible offal and hen muscle are low. To be able to detect benzovindiflupyr related residues, metabolites SYN546039, SYN546422 (goat only), SYN546041 (eggs only) and SYN546042 (eggs only) could be included in the residue definition for enforcement/monitoring. Since a significant part of these metabolites is present as conjugates, a hydrolysis procedure is required to be able to measure these metabolites. Including the metabolites in the residue definition means the residue is unlikely to be measured by a multi-residue method. Since benzovindiflupyr itself can be measured by a multi-residue method and use of a multi-residue method is encouraged, the Meeting decided to define the residue for enforcement/monitoring as parent only.

The log K_{ow} for benzovindiflupyr is 4.3. The goat metabolism study and the goat feeding study did not show a clear partition of the parent compound into the fat tissues, although in the high dose cow feeding study, parent was found in cream and not in the corresponding whole milk. In a hen

metabolism study, the partitioning of the parent compound into the fatty tissues is more pronounced: highest levels of benzovindiflupyr are found in egg yolks (0.022–0.024 mg/kg) and skin with fat (0.012–0.019 mg/kg). Since benzovindiflupyr has a preference for fat in the poultry tissues as well as in high dose milk, the Meeting considers the residue fat soluble.

Apart from benzovindiflupyr, metabolites found at significant levels in livestock commodities were: SYN546039, SYN546041, SYN546042, SYN546422 and their conjugates. The toxicity of SYN546039, SYN546041, SYN546042 and SYN546422 is considered to be covered by toxicity studies on benzovindiflupyr since each of the free metabolites was actually found or agreed to be a possible intermediate in the rat. N-demethylation is regarded as neutral for toxicological potency while hydroxylation generally lowers toxicity. The JMPR 2013 received additional toxicological data for the mono-hydroxylated metabolite SYN546039, showing that this compound is at least 10 fold less toxic than parent. For metabolites SYN546041, SYN546042 and SYN546422 a read across to SYN546039 toxicity studies seems justified based on the close structural similarity and this suggests that they are also at least 10 fold less toxic than the parent. Therefore none of these metabolites is considered relevant for the residue definition for dietary risk assessment. The Meeting decided to define the residue for dietary risk assessment as parent only.

In primary crops, parent compound represented the principal part of the residue in most crop commodities: 91–95% TRR (0.004–0.16 mg/kg) in tomato fruits, 84–87% TRR (0.077–0.10 mg/kg) in wheat grain, 81–84% TRR (6.6–7.6 mg/kg) in wheat straw and 89–103% (2.1–5.9 mg/kg) in wheat forage and hay, 67–72% TRR (8.7–10 mg/kg) in soya bean hay and 83–85% TRR (2.8–3.5 mg/kg) in soya bean forage. Metabolism proceeded further in pulses/oilseeds with parent representing 15–31% TRR (0.009–0.015 mg/kg) in soya bean seeds. A significant metabolite in soya bean seeds was SYN545720 (47% TRR (0.047 mg eq./kg eq) including conjugates). A significant metabolite in soya forage and hay was SYN546039 (9.2–12% TRR (0.38–1.6 mg eq./kg) including conjugates).

In rotational crops parent was the principal component in root commodities (64–90% TRR, 0.008–0.023 mg/kg) and a significant component (6.5–37% TRR, 0.001–0.085 mg/kg) in the leafy parts of crops (lettuce, turnip leaves, wheat forage, hay, straw). Significant metabolites were the cleavage products NOA449410 and SYN545720, together accounting for 34–73% TRR (0.009–0.014 mg eq./kg) and 24–26% TRR (0.023–0.026 mg eq./kg) in lettuce and wheat forage, respectively. In wheat forage, wheat hay and wheat straw, SYN546206 and SYN546039 were frequently occurring at > 10% TRR each, and occasionally approaching 20% TRR each (0.006–0.12 mg eq./kg, including conjugates).

Benzovindiflupyr is found in every primary crop commodity, although the levels in soya bean seeds are low. Benzovindiflupyr is found in every rotational crop commodity, except cereal grains, although levels in leafy crop parts vary. To be able to detect benzovindiflupyr related residues metabolites SYN545720 and NOA449410 could be included in the residue definition for enforcement/monitoring. Since a significant part of these metabolites is present as conjugates, a hydrolysis procedure is required to be able to measure them. Including the metabolites in the residue definition means the residue is unlikely to be measured by a multi-residue method. Furthermore, SYN545720 and NOA449410 can also arise in plant commodities as a result of treatment with other pyrazole fungicides like bixafen, fluxapyroxad, isopyrazam and sedaxane. Since SYN545720 and NOA449410 cannot be seen as a marker for benzovindiflupyr, the Meeting decided to define the residue for enforcement/monitoring as parent only.

Apart from benzovindiflupyr, metabolites found at significant levels in plant commodities were: SYN546206, SYN546039, NOA449410, SYN545720 and their conjugates. The toxicity of SYN546206 and SYN546039 is considered to be covered by toxicity studies on benzovindiflupyr since each of the free metabolites was actually found in the rat. The cleavage products NOA449410 and SYN545720 are not found in rat. N-demethylation is regarded as neutral for toxicological potency, while hydroxylation generally lowers toxicity. The JMPR 2013 received additional toxicological data for the mono-hydroxylated metabolite SYN546039, showing that this compound is at least 10 fold less toxic than parent. Toxicity studies for NOA449410 (from sedaxane studies) and

SYN545720 (from isopyrazam and sedaxane studies) showed that the toxicity of these metabolites is probably 100–1000 fold less toxic than parent.. SYN546206 is the only compound which might be relevant for the residue definition for dietary risk assessment, since the toxicological potency might be similar to the parent. Metabolite SYN546206 is only found in feed commodities (wheat forage, wheat hay, wheat straw) in the confined rotational crop studies and its presence could not be confirmed in the field rotational crops studies. The Meeting decided to define the residue for dietary risk assessment as parent only.

The Meeting recommended the following residue definition for benzovindiflupyr:

Definition of the residue for compliance with the MRL and for dietary risk assessment for plant and animal commodities: *benzovindiflupyr*.

The Meeting considers the residue fat soluble.

Results of supervised residue trials on crops

Soya beans (dry)

Field trials involving soya beans were performed in Brazil.

Critical GAP for soya beans in Paraguay is for three foliar applications without adjuvant at 0.045 kg ai/ha at 14 day intervals with a PHI of 21 days. Trials from Brazil (3× 0.045 kg ai/ha, interval 19–59 and 14 days, PHI 21–28 days, adjuvant added) matched this GAP. For each plot location, replicate trials were conducted with two-three different formulations. Only the highest residue was selected from these trials. For trials, where residues at longer PHIs (28–35 days) were higher than residues at PHI 21 days, the highest residue was selected. Benzovindiflupyr residues were: < 0.01, < 0.01, < 0.01, < 0.01, 0.01, 0.03 mg/kg (n=6).

The Meeting estimated a maximum residue level of 0.05 mg/kg on soya beans (dry). The Meeting estimated an STMR of 0.01 mg/kg.

Fate of residues during processing

Information on the fate of residues during processing showed that benzovindiflupyr is stable (100% recovery) under standard conditions simulating pasteurisation, baking/brewing/boiling and sterilisation.

Processing studies were undertaken for soya beans. Processing factors based on the residue for parent only are listed in the table below. Using the $STMR_{RAC}$ obtained from benzovindiflupyr use, the Meeting estimated STMR-Ps for processed commodities to be used in the livestock dietary burden calculations and/or dietary intake calculations.

Commodity	Processing factors Residue: parent only	Processing factor (PF) (median or best estimate)	STMR-P = $STMR_{RAC}$ x PF (mg/kg)
soya aspirated grain fractions	7.4, 7.6, 7.7, 7.9, 8.3, 9.6, 11, 14	8.1	0.081
soya bean hulls	10, 11	10	0.10
soya oil, crude	0.77, 0.96	0.86	0.0086
soya oil, refined	0.65, 0.68	0.66	0.0066
soya meal, dried	< 0.38, < 0.40	< 0.4	0.004
soya fat flour	< 0.34, < 0.44	< 0.4	0.004
soya pollard	3.6, 4.8	4.2	0.042
soya okara	< 0.32, < 0.44	< 0.4	0.004
soya milk	< 0.32, < 0.44	< 0.4	0.004
soya tofu, pasteurised	0.52, 0.58	0.55	0.0055
soya sauce, pasteurised	< 0.34, < 0.36	< 0.4	0.004
soya miso, pasteurised	< 0.34, < 0.36	< 0.4	0.004

Residues in animal commodities

The Meeting estimated the dietary burden of benzovindiflupyr residues on the basis of the livestock diets listed in the FAO manual appendix IX (OECD feedstuff table). For bulk commodities like soya beans, calculation from STMR provides the levels in feed suitable for estimating maximum residue levels as well as STMR values for animal commodities. Commodities used in the dietary burden calculation are soya beans and soya bean processed commodities. Supervised residue trials on soya bean forage and fodder were not available, whereby the dietary burden for livestock might be underestimated.

Dietary burden calculations for beef cattle, dairy cattle, broilers and laying poultry are provided in Annex 6 to the 2014 Report. A mean and maximum dietary burden for livestock, based on benzovindiflupyr use, is shown in the table below.

Livestock dietary burden for benzovindiflupyr residues, expressed as ppm of dry matter diet

	US	EU	AU	JP	overall	
	Max and mean	Max and mean	Max and mean	Max and mean	Max and mean	
beef cattle	0.017	0.013	0.0022	0.011	0.017	[a]
dairy cattle	0.0016	0.013	0.0029	0.0069	0.013	[b]
poultry broiler	0.0033	0.015	0.0081	0.0015	0.015	[c]
poultry layer	0.0033	0.0081	0.0081	0.0013	0.0081	[d]

[a] Highest mean and maximum dietary burden suitable for maximum residue level and STMR estimates for mammalian meat

[b] Highest mean and maximum dietary burden suitable for maximum residue level and STMR estimates for milk

[c] Highest mean and maximum dietary burden suitable for maximum residue level and STMR estimates for poultry meat

[d] Highest mean and maximum dietary burden suitable for maximum residue level and STMR estimates for eggs

The Meeting received a feeding study on lactating cows.

Three groups of three lactating Holstein cows were dosed once daily via capsules at levels of 3.5, 16 and 32 ppm parent compound in dry weight feed for 28 consecutive days. Two control cows received a placebo. Milk was collected throughout the study and tissues were collected on day 28 within 22–24 hours after the last dose. No parent residues >º0.01 mg/kg were found in whole milk, cream, muscle, liver, kidney or fat at the 3.5 ppm dose level.

The dietary burden for beef and dairy cattle of 0.017 and 0.013 ppm, respectively, is 200 times lower than the lowest dose administered in the cow feeding study (3.5 ppm). Therefore, no parent residues > 0.01 mg/kg are expected in milk, cream and cattle tissues.

No feeding study is available for poultry. In a metabolism study laying hens were dosed at 16–20 ppm parent compound in the dry feed for 14 consecutive days. Parent residues were: 0.024 mg/kg in egg yolks, 0.0037 mg/kg in egg whites, 0.019 mg/kg in fat, in 0.00050 mg/kg in liver and 0.0012 mg/kg in muscle. The dietary burden for broiler and layer poultry of 0.015 and 0.0081 ppm, respectively, is 1000 times lower than the dose administered in the hen metabolism study (16–20 ppm). Therefore, no parent residues > 0.01 mg/kg are expected in eggs, egg yolks and hen tissues.

The Meeting estimated maximum residue levels of 0.01* mg/kg in milk, eggs and all animal commodities. The Meetings estimated an STMR and HR of 0 mg/kg in milk, eggs and all animal commodities. The residue in animal commodities is considered fat soluble.

RECOMMENDATIONS

On the basis of the data from supervised trials the Meeting concluded that the residue levels listed below are suitable for establishing maximum residue limits

Definition of the residue for compliance with the MRL and for dietary risk assessment for plant and animal commodities: *benzovindiflupyr*.

The Meeting considers the residue fat soluble.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Daily Intakes (IEDI) for benzovindiflupyr was calculated from recommendations for STMRs for raw and processed commodities in combination with consumption data for corresponding food commodities. The results are shown in Annex 3 to the 2014 Report.

The IEDI of the 17 GEMS/Food cluster diets, based on the estimated STMRs represented 0% of the maximum ADI of 0.05 mg/kg bw, expressed as benzovindiflupyr.

The Meeting concluded that the long-term intake of residues of benzovindiflupyr from uses considered by the Meeting is unlikely to present a public health concern.

Short-term intake

The International Estimated Short Term Intake (IESTI) for benzovindiflupyr was calculated from recommendations for STMRs for raw and processed commodities in combination with consumption data for corresponding food commodities. The results are shown in Annex 4 to the 2014 Report.

The IESTI for the diets submitted to the JMPR represented 0% of the ARfD (0.1 mg/kg bw, expressed as benzovindiflupyr). The Meeting concluded that the short-term intake of residues of benzovindiflupyr from uses considered by the Meeting is unlikely to present a public health concern.

5.3 BUPROFEZIN (173)

RESIDUE AND ANALYTICAL ASPECTS

Buprofezin was evaluated by JMPR in 1991 for the first time and then in 1995 and 1999. It was also reviewed under the Periodic Re-evaluation Programme in 2008 for toxicity and residues followed by residue evaluations in 2009 and 2012; and for consideration of a concern form from the USA in 2013[1].

The 2012 Meeting received information on supervised trials on coffee conducted in Brazil and the USA as well as coffee processing. These trials were conducted in accordance with GAP in the USA for coffee while employed different processing methods for producing green beans from coffee berries: wet method in Hawaii, USA; and dry method in Brazil. Due to the apparent difference in residues from different processing methods and the lack of information on processing practices for coffee berries used in the USA, the 2013 Meeting could not estimate a maximum residue level.

The current Meeting received another concern form from the USA stating that since the processing of coffee berries to green coffee followed the local practices of countries where the trials were conducted, a maximum residue levels should be estimated for coffee beans and roasted coffee beans.

During the current Meeting, new information became available about the processing practices in Hawaii, USA. According to the information, both the wet and dry methods are used for processing coffee berries to green beans. At the present time, mostly the wet method is used while the dry method is used in the small farms and some recently established large coffee farms. Based on the information, the Meeting concluded that the trials in the USA and Brazil complied with GAP in the use of pesticides for coffee and the processing practices used in the USA.

The Meeting reviewed the data provided to the 2012 Meeting. GAP in the USA for coffee allows four foliar applications (minimum interval of 14 days) at a rate of 1.12 kg ai/hL with a PHI of 0 days. The previous Meeting selected the following residue concentrations from the trials matching the above GAP:

From the trials in the USA (4): 0.08, 0.12, 0.155 and 0.24 mg/kg; and

From the trials in Brazil (3): 0.055 and 0.075 (2) mg/kg.

The combined residues were: 0.055, 0.075, 0.075, 0.08, 0.12, 0.155 and 0.24 mg/kg.

The Meeting estimated a maximum residue level and an STMR of 0.4 mg/kg and 0.08 mg/kg, respectively, for coffee beans.

Based on the STMR for coffee beans and the processing factor of 0.32 from coffee beans to roasted coffee beans and < 0.2 to freeze-dried coffee calculated in 2012 (2012 Evaluation), the Meeting estimated STMR-Ps of 0.0256 mg/kg and 0.016 mg/kg, respectively, for roasted coffee beans and freeze-dried coffee.

RECOMMENDATIONS

On the basis of the data from supervised trials, the Meeting concluded that the residue levels listed below are suitable for establishing maximum residue limits and for IEDI and IESTI assessment.

Definition of the residue for compliance with MRLs and for estimation of dietary intake (Plant commodities and animal commodities): *buprofezin*

[1] 2012 Report and Evaluation; and 2013 Report (FAO)

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Dietary Intakes (IEDIs) of buprofezin were calculated for the 17 GEMS/Food cluster diets using STMRs and STMRPs estimated by the 2008, 2009, 2012 and current Meetings (Annex 3 to the 2014 Report). The ADI is 0-0.009 mg/kg bw and the calculated IEDIs were 3–40% of the maximum ADI. The Meeting concluded that the long-term intake of residues of buprofezin resulting from the uses considered by the 2008, 2009, 2012 and current JMPR is unlikely to present a public health concern.

Short-term intake

The International Estimated Short-Term Intakes (IESTI) of buprofezin were calculated for coffee beans and their processed products commodities using STMRs/STMR-Ps estimated by the current Meeting (see Annex 4 to the 2014 Report). The ARfD is 0.5 mg/kg and the calculated IESTIs were 0–0% of the ARfD for the general population and for children. The Meeting concluded that the short-term intake of residues of buprofezin, when used in ways that have been considered by the JMPR, is unlikely to present a public health concern.

5.4 CHLORANTRANILIPROLE (230)

RESIDUE AND ANALYTICAL ASPECTS

Chlorantraniliprole was first evaluated for residues and toxicological aspects by the 2008 JMPR. The 2008 JMPR established an ADI for chlorantraniliprole of 0–2 mg/kg bw and concluded that an ARfD was unnecessary. It was also evaluated in 2010 and 2013 for additional maximum residue levels. At the Forty-fifth Session of the CCPR (2013), chlorantraniliprole was listed for consideration of further additional maximum residue levels by the 2014 JMPR.

The Meeting received information on registered use patterns, supervised residue trials and fate of residues in processing. Product labels were available from Australia, Canada, India, the Republic of South Africa and the United States of America.

The residue definition for compliance with MRL and for dietary intake for plant and animal commodities is chlorantraniliprole. The residue is considered fat soluble.

Methods of analysis

Residue trial samples were analysed using LC-MS/MS methods based on those previously evaluated by the JMPR in 2008.

Stability of pesticide residues in stored analytical samples

Samples from the submitted studies were stored for periods less than the period of stability demonstrated in studies provided to the 2008 Meeting. Since the storage stability data from the 2008 JMPR cover a diverse range of crops and demonstrated stability of chlorantraniliprole for up to 2 years, it is considered that these data should be sufficient to cover the storage stability of all commodities in this submission.

The Meeting noted that concurrent storage stability data provided with the green onion residue trials also demonstrated stability of chlorantraniliprole residues over 24 months (the period for which the samples were stored) in fresh and dried green onions.

Results of supervised residue trials on crops

The Meeting received supervised trial data for application of chlorantraniliprole on oranges, mandarins, green onions (fresh and dried), chickpeas, mung beans and soya beans, barley, grain sorghum, wheat and peanuts.

Citrus fruits

Residue trials were conducted in citrus fruits in the Republic of South Africa (RSA) in 2010 according to the critical GAP in the RSA (up to 2 applications at 3.5 g ai/100L, and a 7 day PHI).

Four trials were conducted in oranges and four trials in mandarins. In one orange trial the rate of the second application was not known, so data from this trial were not considered for estimation of a maximum residue level and STMR.

The Meeting noted that the RSA GAP is for the citrus fruit group and that a group maximum residue level of 0.5 mg/kg for chlorantraniliprole in citrus fruits was estimated at the 2010 JMPR Meeting based on 2009 South African trials in oranges (4) and mandarins/ tangelos (4). An STMR of 0.07 mg/kg was estimated.

The new citrus data were combined with the 2009 data to give a larger data set on which to base an estimation of the maximum residue level and STMR.

The ranked order of residues in oranges (whole fruit) from supervised trials in the RSA in 2009 and 2010 according to GAP was: ***0.14***, 0.15, ***0.15***, 0.22, 0.22, ***0.24*** and 0.27 mg/kg (*new data in **bold italics***).

The ranked order of residues in mandarins and tangelos (whole fruit) from supervised trials in the RSA in 2009 and 2010 according to GAP was: ***0.11***, 0.14, ***0.15***, 0.18, ***0.22***, 0.25, ***0.30*** and 0.35 mg/kg (*new data in **bold italics***).

The Meeting noted that the RSA GAP is for the citrus group and considered a group maximum residue level. To consider a group maximum residue level, residues across individual crops should not differ by more than 5×median. The Meeting noted that the median of the oranges and mandarins/ tangelos differed by less than 5-fold (only a 1.1-fold difference).

In deciding whether to combine the datasets for oranges and mandarins/ tangelos for use in the statistical calculator or to only utilise the data from the commodity with the highest residues, the Meeting recognised the similarity of the datasets (Mann-Whitney U-Test). Therefore the Meeting decided to combine the data from oranges and mandarins/ tangelos in order to estimate a maximum residue level for citrus fruit.

The ranked order of residues in oranges and mandarins/ tangelos (whole fruit) from supervised trials in the RSA in 2009 and 2010 according to GAP was: 0.11, 0.14 (2), 0.15 (3), 0.18, 0.22 (3), 0.24, 0.25, 0.27, 0.30 and 0.35 mg/kg.

The ranked order of residues in oranges and mandarins/ tangelos (edible portion - flesh) from supervised trials in the RSA in 2009 and 2010 according to GAP was: 0.02, 0.04, 0.05 (4), 0.06 (3), 0.07 (2), 0.08 (2), 0.09 and 0.11 mg/kg.

The Meeting estimated a maximum residue level of 0.7 mg/kg for residues of chlorantraniliprole in citrus fruits, together with an STMR of 0.06 mg/kg (based on the edible portion data). The Meeting estimated a median residue for whole citrus fruit of 0.22 mg/kg for use in processing calculations.

The Meeting withdrew its previous recommendation of 0.5 mg/kg for chlorantraniliprole in citrus fruits.

Bulb vegetables – green onion

The GAP for bulb vegetables in the USA is for up to 4 applications at a maximum rate of 73 g ai/ha, or a maximum of 224 g ai/ha, with a 7 day retreatment interval and a PHI of 1 day.

Residue trials were conducted in green onions in the USA (3) and Canada (2) in which two applications of chlorantraniliprole were made at 110–118 g ai/ha (223–228 g ai/ha per crop) with a 3 day retreatment interval and a PHI of 1 day.

The Meeting did not estimate a maximum residue level as the trials did not comply with the GAP.

Pulses

Chickpeas

The critical GAP in India is 2 applications at 25 g ai/ha and an 11-day PHI.

Four residue trials were conducted in chickpea (Bengal gram) in India in which two foliar applications of chlorantraniliprole were made at 25 or 50 g ai/ha. The PHI was 11–23 days.

Only one trial matches the Indian GAP. The observed residues were < 0.03 mg/kg.

The Meeting determined that a single trial was insufficient for estimation of a maximum residue level.

Three residue trials were conducted in chickpeas in Australia according to the GAP in Australia (2 applications at 24.5 g ai/ha, 7 day retreatment interval and a 14 day PHI).

The residues from supervised trials in Australia according to GAP, in ranked order, were: < 0.01, 0.015 and 0.025 mg/kg.

The Meeting decided that the number of trials available was not adequate to estimate a maximum residue level for chickpeas (dry).

Mung beans

Residue trials were conducted in mung beans in Australia according to the critical GAP in Australia (2 applications at 24.5 g ai/ha, 7 day retreatment interval and a 14 day PHI).

The residues from supervised trials in Australia according to GAP, in ranked order, were: 0.092, 0.17 and 0.26 mg/kg.

The Meeting concluded that the number of trials available was not adequate to estimate a maximum residue level for mung beans (dry).

Soya beans

The GAP for soya beans in Australia is 2 applications at 24.5 g ai/ha, 7-day retreatment interval, and a 14 day PHI.

Residue trials were conducted in soya beans in Australia.

The residues from supervised trials in Australia according to GAP, in ranked order, were: < 0.01 (3) and 0.029 mg/kg.

Residue trials conducted in soya beans in Japan, considered by the 2010 JMPR, showed that residues in dry soya beans were < 0.01 (2) mg/kg after 3 applications at 25 g ai/ha at 7 day intervals and with a 14 day PHI. These trials match the Australian GAP, with the exception of three rather than two applications being made. However, the Meeting noted that the additional application had no effect on the residues in the Japanese trials, which were below the LOQ.

The Australian and Japanese soya bean data were combined and the ranked order of residues from supervised trials in Australia and Japan according to Australian GAP were: < 0.01 (5) and 0.029 mg/kg.

The Meeting estimated a maximum residue level and an STMR value of 0.05 and 0.01 mg/kg respectively for chlorantraniliprole in soya beans.

Cereals

The Codex MRL for chlorantraniliprole in cereal grains is 0.02 mg/kg following the recommendation of the 2008 JMPR based on rotational crop data. An STMR of 0.01 mg/kg was estimated.

A study conducted on cereals in the USA in 2009–2010 (three trials in barley and sorghum and five in wheat) was submitted to the 2013 JMPR. As the compound was not registered in the USA for these crops, no estimations of maximum residue levels or STMRs were made. The study has been resubmitted, with relevant registered label use patterns in the USA and Canada for cereal grains except corn and wild rice, and is evaluated here against the critical Canadian GAP.

The GAP for cereals in Canada is 3 × 75 g ai/ha applications, with a 7-day retreatment interval and a 1-day PHI.

However, the submitted cereal trials were conducted with 2 × 111–117 g ai/ha applications (RTI 7 days, PHI 1 day). The Meeting therefore did not estimate maximum residue levels for cereal grains as the trials were not conducted in accordance with the GAP.

Peanuts

The GAP in the USA is up to 4 applications at a rate of 73g ai/ha (or a maximum of 224 g ai/ha/year) with a 3 day retreatment interval and a PHI of 1 day.

Six residues trials were conducted in peanuts in the USA in which two applications of chlorantraniliprole were made at 111–115 g ai/ha (total application rate of 224–228 g ai/ha) with a 5–6 day retreatment interval and a PHI of 1 day.

A maximum residue level and STMR were not estimated as the trials did not match the GAP.

Animal feeds

The Meeting received supervised trials data for chickpea, mung bean and soya bean forage, barley hay and straw, grain sorghum forage and stover and wheat forage, hay and straw.

Pulses forages

The GAP in Australia for chickpea, mung bean and soya bean is 2 × 24.5 g ai/ha applications with a 14-day grazing PHI.

Data for mung bean, chickpea and soya bean forage is available from the Australian trials, but does not match GAP as only one application was made, while in the chickpea trials, forage was not sampled at the correct PHI. The Meeting therefore did not estimate median and highest residues for pulse forages.

Cereals forages and fodders

Residue data for sorghum and wheat forage, barley and wheat hay, wheat straw and sorghum stover were received. The Meeting determined that the trials did not match the Canadian GAP, and maximum residue levels and median and highest residues were not estimated.

Fate of residues during processing

The Meeting received a processing study for wheat. STMR-P values were estimated for wheat grain processed commodities using the cereal grains STMR value of 0.01 mg/kg estimated by the 2008 Meeting based on rotational crop data (see table below).

A study for processing oranges into juice was considering by the 2010 Meeting (see table below).

Processing Factors for chlorantraniliprole from the processing of raw agricultural commodities (RACs)

RAC	Processed Commodity	Best Estimate Processing Factor	RAC MRL	RAC STMR	Processed Commodity STMR-P/median residue
Wheat	Aspirated Grain Fractions	33	0.02	0.01	0.34
	Bran	1.04			0.011
	Flour	0.38			0.004
	Middlings	0.28			0.003
	Shorts	0.7			0.007
	Germ	1.13			0.011
Oranges	Juice	0.17	0.7	0.22	0.037

Animal commodities

The Meeting recalculated the livestock dietary based on the uses considered by the current Meeting and by the 2008, 2010 and 2013 Meetings on the basis of diets listed in the FAO Manual Appendix IX (OECD Feedstuff Table).

The maximum dietary burdens are 36.1 ppm for beef cattle and 29.0 ppm for dairy cattle, while the mean dietary burdens are 17.4 ppm for beef cattle and 13.6 ppm for dairy cattle. These values have changed only marginally from those calculated by the 2013 Meeting (beef cattle maximum/mean of 31.7/15.7 ppm, and dairy cattle maximum/mean of 26.8/13.1 ppm). The maximum and mean dietary burdens for poultry were unchanged from those previously calculated.

The Meeting confirmed its previous recommendations for maximum residue levels and STMR values for meat from mammals other than marine mammals, milks, edible offal (mammalian), poultry meat, poultry, edible offal of, and eggs.

The Meeting noted that maximum residue levels have not previously been estimated for mammalian fats and poultry fats.

The Meeting noted that the 2010 Meeting estimated a maximum residue level of 0.2 mg/kg for meat (from mammals other than marine mammals) of 0.2 mg/kg (fat), together with STMR values of 0.049 mg/kg in fat and 0.009 mg/kg in muscle. The dietary burden has not changed significantly since. The Meeting estimated a maximum residue level of 0.2 mg/kg for mammalian fats (except milk fats), together with an STMR of 0.049 mg/kg.

The Meeting noted that the 2013 Meeting estimated a maximum residue level of 0.01* mg/kg (fat) and an STMR of 0 for poultry meat. The dietary burden has not changed significantly. The Meeting estimated a maximum residue level of 0.01* mg/kg for poultry fats, together with an STMR of 0.

RECOMMENDATIONS

On the basis of the data from supervised trials the Meeting concluded that the residue levels listed below are suitable for establishing maximum residue limits and for IEDI assessment.

Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities: *chlorantraniliprole*

The residue is fat soluble

DIETARY RISK ASSESSMENT

Long-term intake

The evaluation of chlorantraniliprole has resulted in recommendations for MRLs and STMRs for raw and processed commodities. The International Estimated Daily Intakes for the 17 GEMS/Food cluster diets, based on STMRs estimated by this Meeting and the 2008, 2010 and 2013 Meetings were in the range 0–1 % of the maximum ADI of 2 mg/kg bw (see Annex 3 to the 2014 Report).

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

Short-term intake

The 2008 JMPR decided that an ARfD was unnecessary and concluded that the short-term intake of residues of chlorantraniliprole is unlikely to present a public health concern.

5.5 CLOTHIANIDIN (238)

RESIDUE AND ANALYTICAL ASPECTS

Clothianidin is reconsidered by the Meeting because new data for thiamethoxam became available and clothianidin is a metabolite (sometimes referred to as CGA322704) of thiamethoxam.

Clothianidin was evaluated for toxicology and residues as a new compound in 2010, resulting in a number of MRL recommendations. Additional residue data were evaluated in 2011 and 2012. The residue definition for clothianidin in plant commodities for enforcement and dietary risk assessment is clothianidin.

The 2010 Meeting established an acceptable daily intake (ADI) of 0–0.1 mg/kg bw per day and established the acute reference dose (ARfD) as 0.6 mg/kg bw for clothianidin. Clothianidin residues can also arise from thiamethoxam use (metabolite CGA322704). Therefore, both compounds need to be considered if residue data in support of new uses are submitted. The residue definition in plant commodities for enforcement is thiamethoxam, while the residue definition for dietary risk assessment is thiamethoxam and the metabolite CGA322704 (clothianidin), considered separately.

At the 2014 JMPR Meeting residue data were submitted to support the use of thiamethoxam on use avocado, mango, beans, mint, hops, and persimmon.

The Meeting received analytical methods and supervised trials data for the use of thiamethoxam on avocado, mango, beans, mint, hops and persimmon as well as processing data on mango and mint. The resulting CGA322704 data relevant for maximum residue level recommendations of clothianidin are summarized below.

Combination of residues from clothianidin use and thiamethoxam use

Clothianidin residues may arise from use of clothianidin as well as from use of thiamethoxam (metabolite CGA322704).

The Meeting considered it unlikely that both pesticides are used on the same crop and therefore the maximum estimated residue levels, the maximum STMR, and the maximum HR of each use is taken as recommendation.

Summary of residue data of clothianidin following use of thiamethoxam in relation to clothianidin use reviewed by the 2014 Meeting.

CCN	Commodity name	Origin of use	MRL mg/kg	STMR or STMR-P mg/kg	HR or HR-P mg/kg
FI 0326	Avocado	thiamethoxam	0.03 T	0.01 T	0.02 T
FI 0345	Mango	thiamethoxam	0.04 T	0.02 T	0.02 T
DH 1100	Hops	thiamethoxam	0.07 T	0.026 T	0.028 T
HH 0738e	Mints	thiamethoxam	0.3 T	0.11 T	0.12 T
VP 0061	Beans with pods	thiamethoxam	0.2 T	0.07 T	0.10 T
	Bean forage	thiamethoxam		0.075 T	0.11 T

T = Thiamexthoxam use

Fate of residues during processing

Processing studies were undertaken for the use of thiamethoxam on mango and mint (no known use of clothianidin). Processing factors based on the residue for the metabolite clothianidin are listed in the table below. Using the $STMR_{RAC}$ obtained from the thiamethoxam use, the Meeting estimated STMR-Ps for processed commodities to be used in dietary intake calculations.

Commodity	PFs	PF (median or best estimate)	STMR-P = $STMR_{RAC}$ x PF (mg/kg)	HR-P = HR_{RAC} x PF (mg/kg)
	Metabolite CGA322704 (clothianidin) ($STMR_{pulp+peel}$ = 0.02 mg/kg, $HR_{pulp+peel}$= 0.02 mg/kg)			
Mango, dried flesh	5.67, 8.40, 7.00, 4.00	6.3	0.13	0.13
Mint, oil	< 0.22, < 0.19	< 0.20	n.a.	n.a.

Livestock dietary burden

The additional data on residue levels of clothianidin in bean forage from thiamethoxam use (JMPR 2014) warranted new dietary burden calculations for clothianidin.

The Meeting estimated the dietary burden of clothianidin on the basis of the livestock diets listed in the FAO manual appendix IX (OECD feedstuff table) using the OECD_Feed_Calculator_V1_4. Calculation from highest residue, STMR (some bulk commodities) and STMR-P values provides the levels in feed suitable for estimating MRLs, while calculation from STMR and STMR-P values from feed is suitable for estimating STMR values for animal commodities. The 2014 JMPR Meeting recalculated the livestock dietary burden of clothianidin through clothianidin and thiamethoxam use based on the uses presented by the 2010 Meeting and including the residue values for fresh bean forage from the 2014 JMPR Meeting on thiamethoxam.

The new dietary burdens calculations of clothianidin for beef cattle, dairy cattle, broilers and laying poultry are provided in Annex 6 to the 2014 Report. The calculations were made according to the livestock diets from US/CAN, EU, Australia and Japan in the OECD Feed Table 2009.

Livestock dietary burden, clothianidin, ppm of dry matter

	US	EU	AU	JP	overall	
	Max	Max	Max	Max	max	
Beef cattle	0.30	0.80	1.1	0.027	1.1	[a]
Dairy cattle	0.28	0.61	0.87	0.051	0.87	[b]
Poultry – broiler	0.050	0.21	0.094	0.022	0.21	
Poultry – layer	0.050	0.26	0.094	0.018	0.26	[c]
	Mean	Mean	Mean	Mean	Mean	
Beef cattle	0.088	0.17	0.75	0.024	0.75	[a]
Dairy cattle	0.12	0.17	0.61	0.033	0.61	[b]
Poultry – broiler	0.050	0.040	0.094	0.017	0.094	
Poultry – layer	0.050	0.070	0.094	0.018	0.094	[c]

[a] Highest mean and maximum beef or dairy cattle dietary burden suitable for maximum residue level and STMR estimates for mammalian meat.

[b] Highest mean and maximum dairy cattle dietary burden suitable for maximum residue level and STMR estimates for milk.

[c] Highest mean and maximum poultry dietary burden suitable for maximum residue level and STMR estimates for poultry meat and eggs.

Animal commodities maximum residue level estimation

Clothianidin residues in animal commodities from both thiamethoxam (metabolite CGA322704) and clothianidin use are considered below.

Cattle-clothianidin residues from thiamethoxam use

The residues of clothianidin were evaluated in the same way as described for thiamethoxam (see appraisal 2010) for maximum residue level estimation, the highest residue in the tissues and milk

were calculated by interpolating the maximum dietary burden (6.1 ppm) between the relevant feeding levels (6–20 ppm) from the dairy cow feeding study and using the highest tissue concentrations based on the residue definition for enforcement from individual animals within those feeding groups and using the mean milk concentration from those feeding groups (see table below).

The STMR values for the tissues and milk were calculated by interpolating the mean dietary burden (2.4 ppm) between the relevant feeding levels (2–6 ppm) from the dairy cow feeding study and using the mean tissue and milk concentrations based on the residue definition for dietary risk assessment from those feeding groups (see table below).

				Total residue (mg/kg) in			
	Feed level (ppm) for milk residues	Total residues in milk (mg/kg)	Feed level (ppm) for tissue residues	muscle	Liver	kidney	fat
Maximum residue level – beef or dairy cattle							
Feeding study	6, 20	0.013, 0.043	6, 20	< 0.01, < 0.01	0.14, 0.38	< 0.01, 0.04	< 0.01, < 0.01
Dietary burden and residue estimate	6.1	0.013	6.1	< 0.01	0.14	< 0.01	< 0.01
STMR – beef or dairy cattle							
Feeding study	2, 6	0.005, 0.013[a]	2, 6	< 0.01, < 0.01	0.049, 0.14	< 0.01, < 0.01	< 0.01, < 0.01
Dietary burden and residue estimate	2.4	0.0060	2.4	< 0.01	0.058	< 0.01	< 0.01

[a] Calculated mean (day 3-26), data retrieved from JMPR 2010 evaluation

Cattle-clothianidin residues from clothianidin use

In a feeding study where lactating cows were dosed with clothianidin at up to 2.6 ppm dry feed, no clothianidin was found in tissues (< 0.02 mg/kg). Therefore, no residues are to be expected in tissues at the mean and maximum calculated dietary burden of 0.75 and 1.1 ppm based on the new clothianidin dietary burden calculation.

For milk MRL estimation, the highest residues in the milk resulting from dietary burden based on clothianidin were calculated by interpolating the maximum dietary burden for dairy cattle (0.87 ppm) between the relevant feeding levels (0.8 and 2.6 ppm) from the dairy cow feeding study and using the mean milk concentration from those feeding groups.

For milk STMR estimation, the median residues in the milk resulting from dietary burden were calculated by interpolating the mean dietary burden for dairy cattle (0.61 ppm) between the relevant feeding levels (0.27 and 0.80 ppm) from the dairy cow feeding study and using the mean milk concentration from those feeding groups.

	Feed level (ppm) for milk residues	Total residues in milk (mg/kg)
Maximum residue level – dairy cattle		
Feeding study	0.80, 2.6	0.0020, 0.012
Dietary burden and residue estimate	0.87	0.002
STMR – dairy cattle		
Feeding study	0.27, 0.80	< 0.0020, < 0.0020
Dietary burden and residue estimate	0.61	< 0.0020

Cattle- data combined from clothianidin and thiamethoxam use

Based on the combined data, the clothianidin data from the thiamethoxam cattle feeding studies were used to support the estimation of maximum residue levels, STMR and HR values for mammalian meat and milk.

The Meeting confirmed the previous maximum residue level recommendations for clothianidin in milk, liver, muscle, fat and edible offal (except liver). The Meeting also confirmed the previous recommended STMR and HR values for meat, muscle, fat, and edible offal (except liver).

The Meeting estimated a new STMR for clothianidin in milk of 0.006 mg/kg and recommended to withdraw the previous recommendation of 0.002 mg/kg. The Meeting estimated a new STMR and HR value for clothianidin in liver of 0.058 and 0.14 mg/kg, respectively and recommended to withdraw the previous recommendations of 0.034 and 0.10 mg/kg, respectively.

Poultry-clothianidin

The new maximum and mean dietary burdens of clothianidin through clothianidin and thiamethoxam use for poultry are marginally lower or unchanged. No new estimations are required. The Meeting agreed that the previous recommendations were confirmed.

RECOMMENDATIONS

The 2011 Meeting recommended the following residue definition for clothianidin (through thiamethoxam and clothianidin use):

Definition of the residue for compliance with the MRL and for estimation of dietary intake for plant and animal commodities: *clothianidin*.

The residue is not fat soluble.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Daily Intakes (IEDI) of for clothianidin was calculated from recommendations for STMRs for raw and processed commodities in combination with consumption data for corresponding food commodities. The results are shown in Annex 3 to the 2014 Report.

The IEDI of clothianidin in the 17 food cluster diets, based on the estimated STMRs was in the range 1–3% of the maximum ADI of 0.1 mg/kg bw. The Meeting concluded that the long-term intake of residues of clothianidin arising from uses of thiamethoxam and clothianidin considered by the 2010, 2011, 2012 and the present Meeting is unlikely to present a public health concern.

Short-term intake

The International Estimated Short Term Intake (IESTI) for clothianidin was calculated from recommendations for STMRs and HRs for raw and processed commodities in combination with consumption data for corresponding food commodities. The results are shown in Annex 4 to the 2014 Report.

The IESTI for the general population represented 0% of the ARfD (0.6 mg/kg bw) and the IESTI for children represented 0–0% of the ARfD. The Meeting concluded that the short-term intake of residues of clothianidin, from uses of thiamethoxam considered by the present Meeting, is unlikely to present a public health concern.

5.6 CYFLUMETOFEN (273)

TOXICOLOGY

Cyflumetofen is the ISO-approved common name for 2-methoxyethyl (*RS*)-2-(4-*tert*-butylphenyl)-2-cyano-3-oxo-3-(α,α,α-trifluoro-*o*-tolyl)propionate (IUPAC), with CAS number 400882-07-7. It is an acaricide and interferes with energy production (inhibition of complex II in mitochondria) on contact with spider mites. Cyflumetofen is a racemic mixture.

Cyflumetofen has not been evaluated previously by JMPR and was reviewed by the present Meeting at the request of CCPR.

All critical studies contained statements of compliance with GLP.

Biochemical aspects

The specific metabolism or degradation of the individual enantiomers of the racemic mixture was not investigated.

In a pharmacokinetic study performed in mice, peak concentrations of radiolabel in plasma were reached rapidly (0.5–1 hour after dosing) and were 2.4-fold higher in females than in males. Moreover, in females, a second C_{max} was observed at 2 or 8 hours after dosing, suggesting enterohepatic recirculation. Terminal half-lives were in the range of 22–60 hours. The absorption in mice represented by the AUC was up to 2-fold higher in females than in males and increased sublinearly with increasing doses.

Absorption of cyflumetofen in rats was approximately 68–78% at the low dose (3 mg/kg bw), based on urinary and biliary excretion, with saturation at the high dose (approximately 35–46% absorption at 250 mg/kg bw). There were no remarkable differences in absorption according to sex or the position of the radiolabels used. Saturation of oral absorption was also noted after repeated daily administration at the low dose. Peak concentrations in plasma after a single high-dose application occurred after 1–4 hours. Radioactivity in plasma decreased biexponentially, with a terminal half-life of 12–22 hours. The AUC increased less than proportionally with the dose, confirming saturation in absorption. The AUC was up to 2-fold higher in females than in males at the high dose.

The major route of elimination at the low dose was the urine (58–66%), with lower amounts in faeces (25–32%). At the high dose, the major route of excretion was the faeces (68–77%), with lower amounts in urine (14–22%). Studies in bile duct–cannulated rats showed that at least 30% and 18% were excreted in bile in males and females, respectively, regardless of dose level. A decrease in urinary excretion in cannulated compared with non-cannulated rats suggests that some reabsorption from the intestinal tract after biliary excretion might occur at low doses. Within 72 hours after administration, at least 95% of the absorbed dose was excreted.

In rats, the half-lives for elimination from tissues were in the range of 9–24.5 hours at the low dose and 14–42.5 hours at the high dose, with the longest half-lives in adipose tissue, followed by bone marrow. Highest residues were identified in the liver, followed by the kidney, regardless of sex, dose, label position and time point of measurement. Levels of radioactivity in tissues appeared to have reached steady state after 4 days of repeated daily dosing. Residues in erythrocytes and skin declined relatively slowly.

Cyflumetofen was extensively metabolized. The predominant metabolic pathway was cleavage of the *tert*-butylphenyl (A-ring) and trifluorotolyl (B-ring) moieties. Major reactions on the A-ring were cleavage of the methoxyethyl group, hydroxylation at the butyl group, and decarboxylation and glucuronidation at the butyl group. Major reactions on the B-ring were glutathione conjugation at the carboxyl group and further metabolism to mercapturic acid or thiolactic acid. In addition, hydroxylation and oxidation reactions at the butyl group and cleavage of the carboxylic ester moiety were observed on the parent structure (intact A- and B-ring).

Toxicological data

The oral LD_{50} was greater than 2000 mg/kg bw in female rats. The dermal LD_{50} was greater than 5000 mg/kg bw in rats, and the LC_{50} in an inhalation study in rats was greater than 2.65 mg/L. Cyflumetofen was not irritating to the skin of rabbits and was slightly irritating to the eyes of rabbits. Skin sensitization was observed in a maximization assay in guinea-pigs.

In repeated-dose toxicity studies in mice, rats or dogs, the main effects were on the adrenals (vacuolation and hypertrophy of cortical cells) and liver (e.g. hepatocellular hypertrophy). Leydig cell adenomas occurred at the highest doses in the rat carcinogenicity study.

In a 4-week mouse feeding study with dietary concentrations of 0, 100, 500, 1000 and 5000 ppm (equal to 0, 13.1, 67.2, 135 and 663 mg/kg bw per day for males and 0, 14.5, 74.9, 150 and 763 mg/kg bw per day for females, respectively), absolute and relative adrenal weights were increased at 5000 ppm. Histopathology showed an increased incidence of diffuse vacuolation and hypertrophy of adrenocortical cells at 5000 ppm. The NOAEL was 1000 ppm (equal to 135 mg/kg bw per day), based on increased adrenal weights and histopathological changes in the adrenals at 5000 ppm (equal to 663 mg/kg bw per day).

In a 13-week mouse feeding study with dietary concentrations of 0, 300, 1000, 3000 and 10 000 ppm (equal to 0, 35.4, 117, 348 and 1200 mg/kg bw per day for males and 0, 45.0, 150, 447 and 1509 mg/kg bw per day for females, respectively), the NOAEL was 1000 ppm (equal to 117 mg/kg bw per day), based on histopathological changes in adrenocortical cells (e.g. increased incidence of diffuse vacuolation in females and of diffuse hypertrophy in males) at 3000 ppm (equal to 348 mg/kg bw per day).

In a 2-week rat feeding study with dietary concentrations of 0, 1000 and 10 000 ppm (equal to 0, 101 and 981 mg/kg bw per day for males and 0, 105 and 1000 mg/kg bw per day for females, respectively), the LOAEL was 1000 ppm (equal to 101 mg/kg bw per day), the lowest dose tested, based on changes in clinical chemistry, an increase in absolute and/or relative weight of liver and adrenals, hypertrophy of the adrenals in females and histopathological alterations, such as diffuse vacuolation of adrenocortical cells, at all doses. Moreover, all females showed vacuolation of interstitial cells in the ovary; vacuolation of corpora lutea was additionally observed at 10 000 ppm.

In a 4-week rat feeding study with dietary concentrations of 0, 100, 500, 1000 and 5000 ppm (equal to 0, 7.5, 37.6, 75.1 and 384 mg/kg bw per day for males and 0, 8.05, 40.8, 79.8 and 409 mg/kg bw per day for females, respectively), the NOAEL was 500 ppm (equal to 37.6 mg/kg bw per day), based on clinical chemistry changes (decreases in total cholesterol and triglycerides) and increases in organ weights (liver and adrenal) at 1000 ppm (equal to 75.1 mg/kg bw per day). In addition, histopathological effects, such as diffuse hypertrophy of hepatocytes (in all males at 1000 ppm and in both sexes at 5000 ppm), diffuse vacuolation of adrenocortical cells in both sexes accompanied by diffuse hypertrophy in all females and an increased incidence of vacuolation of interstitial cells in the ovaries, were observed at 1000 ppm and above. The results of lipid staining performed on the adrenals of both sexes and ovaries of females indicated that the vacuolation was due to the presence of lipid.

In a 4-week (26 days) rat feeding study with dietary concentrations of 0, 500, 1500, 4000 and 12 000 ppm (equal to 0, 43, 128, 339 and 1028 mg/kg bw per day for males and 0, 46, 132, 351 and 1039 mg/kg bw per day for females, respectively), the NOAEL was 500 ppm (equal to 43 mg/kg bw per day), based on increased adrenal weight in females and elevated incidences of adrenocortical cell vacuolation in both sexes at 1500 ppm (equal to 128 mg/kg bw per day).

In a 13-week rat feeding study with dietary concentrations of 0, 100, 300, 1000 and 3000 ppm (equal to 0, 5.4, 16.5, 54.5 and 167 mg/kg bw per day for males and 0, 6.28, 19.0, 62.8 and 193 mg/kg bw per day for females, respectively), the NOAEL was 300 ppm (equal to 16.5 mg/kg bw per day), based on increased adrenal weights and diffuse hypertrophy of adrenocortical cells in females, mild to moderate diffuse vacuolation of adrenocortical cells in males and vacuolation of ovarian interstitial cells at 1000 ppm (equal to 54.5 mg/kg bw per day).

In a 4-week dog study, cyflumetofen was administered in gelatine capsules to dogs at a dose of 0, 100, 300 or 1000 mg/kg bw per day. The NOAEL was 100 mg/kg bw per day, based on increases in adrenal weights in both sexes and increased incidences of fine vacuoles in adrenocortical cells (predominantly in the zona fasciculata and zona reticularis) at 300 mg/kg bw per day. Dark red foci (designated as capillary dilatation) on the right atrioventricular valve of the heart were observed in one female at 1000 mg/kg bw per day.

In a 13-week dog study, cyflumetofen was administered in gelatine capsules to dogs at a dose of 0, 30, 300 or 1000 mg/kg bw per day. The NOAEL was 300 mg/kg bw per day, based on a reduction in body weight gain (from day 1 to day 90), elevated absolute and relative adrenal weights in males, increased absolute and relative pituitary weights in females and an increase in absolute and relative testis weights at 1000 mg/kg bw per day. In addition, dark red foci (designated as capillary dilatation) on the right atrioventricular valve of the heart and dark red foci in the mucosa of the urinary bladder in one male and increased incidences of vacuolation of adrenocortical cells in females and males were observed at 1000 mg/kg bw per day.

In a 52-week dog study, cyflumetofen was administered in gelatine capsules at a dose of 0, 30, 300 or 1000 mg/kg bw per day. The NOAEL was 30 mg/kg bw per day, based on increased incidences of vacuolation in the adrenal cortex in both sexes, accompanied by degenerative processes (e.g. interstitial fibrosis and infiltration of brown pigment–laden macrophages) at 300 mg/kg bw per day.

In two 18-month feeding studies in mice, dietary concentrations were 0, 150, 500, 1500 and 5000 ppm (equal to 0, 15.5, 54.3, 156 and 537 mg/kg bw per day for males and 0, 14.3, 48.1, 144 and 483 mg/kg bw per day for females, respectively) in the first study and 0 and 10 000 ppm (equal to 0 and 1143 or 1132 mg/kg bw per day for males and females, respectively) in the second study. The overall NOAEL was 1500 ppm (equal to 144 mg/kg bw per day), based on increased adrenal weight (predominantly in females) and an increase in the incidence of diffuse vacuolation of adrenocortical cells in both sexes at 5000 ppm (equal to 483 mg/kg bw per day). There was no increased incidence of tumours in these studies.

In two 52-week feeding studies in rats, dietary concentrations were 0, 50, 150, 500 and 1500 ppm (equal to 0, 1.9, 5.6, 18.8 and 56.8 mg/kg bw per day for males and 0, 2.3, 6.9, 23.3 and 69.2 mg/kg bw per day for females, respectively) in the first study and 0 and 6000 ppm (equal to 0 and 250 or 319 mg/kg bw per day for males and females, respectively) in the second study. The overall NOAEL for systemic toxicity was 500 ppm (equal to 18.8 mg/kg bw per day), based on a reduction in total cholesterol and triglyceride concentrations in both sexes at several time points, increased liver weight (most pronounced early during the study period) in both sexes and increased adrenal weight in females at 1500 ppm (equal to 56.8 mg/kg bw per day). In addition, histopathology revealed an increased incidence of diffuse vacuolation of adrenocortical cells in males and an increased incidence of diffuse hypertrophy of adrenocortical cells in females at 1500 ppm. Moreover, vacuolation of interstitial gland cells in the ovaries was observed at 1500 ppm and above. In the second study, statistically significant increases in the incidence of hyperplasia of Leydig cells (19/20 versus 6/20 in controls) were observed at 6000 ppm at study termination.

In two 104-week studies in Fischer rats, dietary concentrations were 0, 150, 500 and 1500 ppm (equal to 0, 4.92, 16.5 and 49.5 mg/kg bw per day for males and 0, 6.14, 20.3 and 61.9 mg/kg bw per day for females, respectively) in the first study and 0 and 6000 ppm (equal to 0 and 220 or 287 mg/kg bw per day for males and females, respectively) in the second study. The overall NOAEL for systemic toxicity was 500 ppm (equal to 16.5 mg/kg bw per day), based on an increase in adrenal weights in both sexes, an increase in the incidence of epididymis atrophy and an increased incidence of diffuse hypertrophy and/or vacuolation of adrenocortical cells in both sexes at 1500 ppm (equal to 49.5 mg/kg bw per day). The overall NOAEL for carcinogenicity was 1500 ppm (equal to 49.5 mg/kg bw per day), the highest dose tested in the first study, based on a statistically significantly increased incidence of Leydig cell adenoma at 6000 ppm (equal to 220 mg/kg bw per day) in the second study, which was higher than the historical control incidence range. The increase in the incidence of Leydig

cell adenoma was associated with a statistically significant increase in mass of the testis, with an increase in absolute and relative testis weights at 6000 ppm. There was a slight, non-significant increase in the incidence of C-cell adenomas and adenocarcinomas of the thyroid in male rats. As these tumours are common in rats and there were no accompanying preneoplastic lesions, it was concluded that their occurrence was incidental.

The Meeting concluded that cyflumetofen is carcinogenic in male rats but not in female rats or male or female mice.

Cyflumetofen was tested for genotoxicity in an adequate range of assays, both in vitro and in vivo. A mouse lymphoma gene mutation assay was positive with and without liver enzyme activation at concentrations close to those at which precipitation occurred. Cyflumetofen was not genotoxic in an Ames test or in an in vitro chromosomal aberration assay. There was no evidence of genotoxicity in an in vivo micronucleus assay or in an in vivo unscheduled DNA synthesis assay in rat liver.

The Meeting concluded that cyflumetofen is unlikely to be genotoxic in vivo.

Five in vitro mechanistic studies were performed to identify a possible mode of action for the Leydig cell adenomas via perturbation of the estrogen or androgen system. Cyflumetofen was not a significant aromatase inhibitor in a human recombinant cell system, did not significantly interact with androgen or estrogen receptor binding using rat prostate or uterine cytosol protein preparations, respectively, and was not an agonist in a human estrogen receptor transcriptional activation system. In a steroidogenesis assay, cyflumetofen induced estrogen production at and above 5 µmol/L (maximally 1.64-fold) and inhibited testosterone production at and above 1 µmol/L (maximally 0.63-fold) in human adrenocarcinoma cells. Fischer rats are very sensitive to decreased testosterone levels, which lead to a compensatory increase in luteinizing hormone production and subsequent Leydig cell proliferation and Leydig cell adenoma progression. It cannot be excluded that this mode of action is relevant to humans. However, as an increased incidence of Leydig cell adenomas was observed only at high doses in rats, cyflumetofen can be considered as not likely to be carcinogenic to humans at levels occurring in the diet.

In view of the lack of genotoxicity, the absence of carcinogenicity in mice and the fact that only Leydig cell adenomas were observed in a particularly sensitive strain of rat at the highest dose tested, the Meeting concluded that cyflumetofen is unlikely to pose a carcinogenic risk to humans from the diet.

In a two-generation study of reproductive toxicity in rats at dietary concentrations of 0, 150, 500 and 1500 ppm (equal to 0, 10.4, 34.6 and 100.3 mg/kg bw per day for males and 0, 12, 39.7 and 121.6 mg/kg bw per day for females, respectively), the NOAEL for parental toxicity was 150 ppm (equal to 10.4 mg/kg bw per day), based on increased incidences of white/enlarged adrenals and increased adrenal weights in females and an elevated incidence of hypertrophy of adrenocortical cells in both sexes at 500 ppm (equal to 34.6 mg/kg bw per day). In addition, delayed vaginal opening and decreased follicle stimulating hormone and progesterone concentrations in serum were noted in females at 500 ppm. In offspring, the NOAEL was also 150 ppm (equal to 10.4 mg/kg bw per day), based on increased adrenal weights in both sexes and increased incidences of hypertrophy of adrenocortical cells in males at 500 ppm (equal to 34.6 mg/kg bw per day). The NOAEL for reproductive toxicity was 1500 ppm (equal to 100.3 mg/kg bw per day), the highest dose tested.

In a range-finding study on the developmental toxicity of cyflumetofen in rats administered 0, 100, 500 or 1000 mg/kg bw per day, no treatment-related developmental or maternal toxicity was observed. In the main study on the developmental toxicity of cyflumetofen in rats at dose levels of 0, 50, 250 and 1000 mg/kg bw per day, the NOAEL for maternal toxicity was 50 mg/kg bw per day, based on increased adrenal weights accompanied by an increased incidence of vacuolation of adrenocortical cells at 250 mg/kg bw per day. The NOAEL for embryo and fetal toxicity was 50 mg/kg bw per day, based on an increased incidence of incompletely ossified sternal centra at 250 mg/kg bw per day.

In a range-finding study on the developmental toxicity of cyflumetofen in rabbits at dose levels of 0, 10, 100, 500 and 1000 mg/kg bw per day, no treatment-related developmental or maternal toxicity was observed. In the main study on the developmental toxicity of cyflumetofen in rabbits at dose levels of 0, 50, 250 and 1000 mg/kg bw per day, the NOAEL for maternal toxicity was 50 mg/kg bw per day, based on slight body weight loss at gestation days 6–9 and decreased body weight gain relative to controls during the entire treatment period, which partly correlated with a decrease in feed consumption at 250 mg/kg bw per day. The NOAEL for embryo and fetal toxicity was also 50 mg/kg bw per day, based on changes in the number of ossification sites in the vertebrae, ribs and sternum at 250 mg/kg bw per day. An increased incidence of total variations (per fetus and per litter) was noted at 1000 mg/kg bw per day. Skeletal variations were confined to increased fetal and litter incidences of incompletely ossified sterna centra (above the historical control range of the laboratory) and an increase in fetal and litter incidences of angulated hyoid alae at 1000 mg/kg bw per day.

The Meeting concluded that cyflumetofen is not teratogenic.

In an acute neurotoxicity study in rats administered cyflumetofen at a dose of 0, 125, 500 or 2000 mg/kg bw, the NOAEL for acute toxicity and neurotoxicity was 2000 mg/kg bw, the highest dose tested.

In a 13-week neurotoxicity study in rats administered cyflumetofen in the diet at a concentration of 0, 500, 1500 or 5000 ppm (equal to 0, 30, 89 and 293 mg/kg bw per day for males and 0, 41, 99 and 353 mg/kg bw per day for females, respectively), the NOAEL for systemic toxicity was 500 ppm (equal to 30 mg/kg bw per day), based on an increase in adrenal weights and an increased incidence and higher degree of severity of diffuse vacuolation of the adrenocortical cells (predominantly in the zona fasciculata) in both sexes at 1500 ppm (equal to 89 mg/kg bw per day). The NOAEL for subchronic neurotoxicity was 5000 ppm (equal to 293 mg/kg bw per day), the highest dose tested.

The Meeting concluded that cyflumetofen is not neurotoxic.

In a 4-week mouse immunotoxicity study with dietary concentrations of 0, 500, 1500 and 5000 ppm (equal to 0, 33, 107 and 349 mg/kg bw per day, respectively), the NOAEL for immunotoxicity was 5000 ppm (equal to 349 mg/kg bw per day), the highest dose tested. The NOAEL for systemic toxicity was 500 ppm (equal to 33 mg/kg bw per day), based on an increase in adrenal weights correlating with discoloration and enlargement of the adrenals and microscopic changes such as vacuolation of adrenocortical cells at 1500 ppm (equal to 107 mg/kg bw per day).

The Meeting concluded that cyflumetofen is not immunotoxic.

In a mechanistic study to further elucidate the effects on adrenal gland and ovary, male and female rats were fed diets containing 0, 100 or 5000 ppm (equal to 0, 7.44 and 378 mg/kg bw per day for males and 0, 7.59 and 347 mg/kg bw per day for females, respectively) for up to 28 days. Cyflumetofen caused enlarged and discoloured adrenals with increased weights. An increase in total cholesterol concentration, predominantly cholesterylesters, in adrenals correlated with vacuolation by lipid deposition within the adrenocortical and ovarian interstitial cells at 5000 ppm in both sexes. Furthermore, a slight inhibitory effect on hormone-sensitive lipase expression, which is involved in cholesterol catabolism and therefore might result in lipid deposition, was noted at 5000 ppm in both sexes. In addition, CYP11A1 (cholesterol side-chain cleavage enzyme) expression was slightly enhanced in both sexes at 5000 ppm, probably due to the elevated supply of lipids. No effects were seen on adrenocorticotrophic hormone or corticosterone levels in serum. In conclusion, catabolism of lipids might be inhibited at cyflumetofen doses above 7.44 mg/kg bw per day, leading to the formation of lipid droplets in adrenals and ovarian cells.

In a safety pharmacology study, respiratory rate, blood pressure and heart rate (including electrocardiogram) were measured in male dogs after a single-dose application of 0 or 2000 mg/kg bw. Cyflumetofen did not cause any treatment-related adverse effects on the respiratory or cardiovascular system in dogs under the conditions of the study.

Toxicological data on metabolites and/or degradates

Acute toxicity and genotoxicity studies were performed for B-1, a goat and plant metabolite and food processing hydrolysis product. B-1 is also a major metabolite in the rat (occurring at up to 28% of the applied dose).

B-1 was of low acute oral toxicity (LD50 > 2000 mg/kg bw per day).

The potential genotoxicity of B-1 was tested in an adequate range of in vitro and in vivo assays. A mouse lymphoma gene mutation assay was positive at 1000 µg/mL without liver enzyme activation and in one of two experiments at 333 µg/mL with enzyme activation. B-1 was not mutagenic in an Ames test and was not genotoxic in an in vitro chromosomal aberration assay. There was no evidence of genotoxicity in an in vivo unscheduled DNA synthesis assay in rat liver.

The Meeting concluded that metabolite B-1 is unlikely to be genotoxic in vivo.

B-3, a soil metabolite, and AB-13, an impurity, have not been identified as food residues and are therefore not relevant for dietary risk assessment.

For AB-1, a goat metabolite and food processing hydrolysis product, no toxicological data were provided. AB-1 is an intermediate in the metabolism of rats and occurs at less than 1% of the applied dose in bile. It is further transformed to AB-3 and AB-2. In sum, AB-1, AB-2 and AB-3 and their glucuronidated derivatives account for greater than 20% of the applied dose in rats. As AB-1 is structurally similar to the parent and is transformed to metabolites, which represent a large portion of the metabolism in rats, its toxicity can therefore be considered to be covered by that of the parent.

Human data

In reports on manufacturing plant personnel, no adverse health effects were noted.

The Meeting concluded that the existing database on cyflumetofen was adequate to characterize the potential hazards to fetuses, infants and children.

Toxicological evaluation

The Meeting established an ADI of 0–0.1 mg/kg bw per day on the basis of a NOAEL of 10.4 mg/kg bw per day in the two-generation rat feeding study, based on parental and offspring toxicity at 34.6 mg/kg bw per day. A safety factor of 100 was applied. The margin between the upper bound of the ADI and the LOAEL of 220 mg/kg bw per day for Leydig cell adenomas in rats is 2200.

The Meeting concluded that it was not necessary to establish an ARfD for cyflumetofen in view of its low acute oral toxicity and the absence of developmental toxicity and any other toxicological effects that would be likely to be elicited by a single dose.

A toxicological monograph was prepared.

Levels relevant to risk assessment of cyflumetofen

Species	Study	Effect	NOAEL	LOAEL
Mice	Eighteen-month studies of toxicity and carcinogenicity[a,b]	Toxicity	1 500 ppm, equal to 144 mg/kg bw per day	5 000 ppm, equal to 483 mg/kg bw per day
		Carcinogenicity	5 000 ppm, equal to 483 mg/kg bw per day[c]	–
Rat	Ninety-day study of toxicity[a]	Toxicity	300 ppm, equal to 16.5 mg/kg bw per day	1 000 ppm, equal to 54.5 mg/kg bw per

Species	Study	Effect	NOAEL	LOAEL
				day
	Two-year studies of toxicity and carcinogenicity[a,b]	Toxicity	500 ppm, equal to 16.5 mg/kg bw per day	1 500 ppm, equal to 49.5 mg/kg bw per day
		Carcinogenicity	1 500 ppm, equal to 49.5 mg/kg bw per day	6 000 ppm, equal to 220 mg/kg bw per day
	Two-generation study of reproductive toxicity[a]	Reproductive toxicity	1 500 ppm, equal to 100.3 mg/kg bw per day[c]	–
		Parental toxicity	150 ppm, equal to 10.4 mg/kg bw per day	500 ppm, equal to 34.6 mg/kg bw per day
		Offspring toxicity	150 ppm, equal to 10.4 mg/kg bw per day	500 ppm, equal to 34.6 mg/kg bw per day
	Developmental toxicity study[d]	Maternal toxicity	50 mg/kg bw per day	250 mg/kg bw per day
		Embryo/fetal toxicity	50 mg/kg bw per day	250 mg/kg bw per day
Rabbit	Developmental toxicity study[d]	Maternal toxicity	50 mg/kg bw per day	250 mg/kg bw per day
		Embryo/fetal toxicity	50 mg/kg bw per day	250 mg/kg bw per day
Dog	One-year study of toxicity[e]	Toxicity	30 mg/kg bw per day	300 mg/kg bw per day

[a] Dietary administration.
[b] Two studies combined.
[c] Highest dose tested.
[d] Gavage application.
[e] Gelatine capsules.

Estimate of acceptable daily intake (ADI)

0–0.1 mg/kg bw

Estimate of acute reference dose (ARfD)

Unnecessary

Information that would be useful for the continued evaluation of the compound

Results from epidemiological, occupational health and other such observational studies of human exposure

Critical end-points for setting guidance values for exposure to cyflumetofen

Absorption, distribution, excretion and metabolism in mammals	
Rate and extent of oral absorption	Rapid, 68% at low dose (3 mg/kg bw), 35% at high dose (250 mg/kg bw)

Dermal absorption	20% at low concentration (0.2 g/L), 27% at high concentration (200 g/L)
Distribution	Widely distributed, highest levels in liver, followed by kidney and bone marrow
Potential for accumulation	No evidence of accumulation
Rate and extent of excretion	≥ 95% within 72 hours, mainly in urine, partly in bile
Metabolism in animals	Extensive, primarily cleavage between tolyl and phenyl moieties, hydroxylation and conjugation
Toxicologically significant compounds in animals and plants	Cyflumetofen, metabolite B-1 (goat, rat, plant and food processing hydrolysis product) and AB-1 (goat, rat and food processing hydrolysis product)
Acute toxicity	
Rat, LD_{50}, oral	> 2 000 mg/kg bw per day
Rat, LD_{50}, dermal	> 5 000 mg/kg bw per day
Rat, LC_{50}, inhalation	> 2.65 mg/L
Rabbit, dermal irritation	Not irritating
Rabbit, ocular irritation	Slightly irritating
Guinea pigs, dermal sensitization	Sensitizing (maximization test)
Short-term studies of toxicity	
Target/critical effect	Adrenals: weight and histopathological changes (rat, mouse, dog)
Lowest relevant oral NOAEL	16.5 mg/kg bw per day (rat)
Lowest relevant dermal NOAEL	1 000 mg/kg bw per day, highest dose tested
Lowest relevant inhalation NOAEC	No data
Long-term studies of toxicity and carcinogenicity	
Target/critical effect	Adrenals: weight and histopathological changes; testis: Leydig cell adenoma at highest dose (rats)
Lowest relevant NOAEL	16.5 mg/kg bw per day (rat)
Carcinogenicity	Unlikely to pose a carcinogenic risk from the diet
Genotoxicity	
	Unlikely to be genotoxic
Reproductive toxicity	
Target/critical effect	No reproductive toxicity
Lowest relevant parental NOAEL	10.4 mg/kg bw per day
Lowest relevant offspring NOAEL	10.4 mg/kg bw per day
Lowest relevant reproductive NOAEL	100.3 mg/kg bw per day, highest dose tested
Developmental toxicity	
Target/critical effect	Skeletal variations
Lowest relevant maternal NOAEL	50 mg/kg bw per day (rat and rabbit)
Lowest relevant embryo/fetal NOAEL	50 mg/kg bw per day (rat and rabbit)
Neurotoxicity	
Acute neurotoxicity NOAEL	2 000 mg/kg bw per day, highest dose tested
Subchronic neurotoxicity NOAEL	293 mg/kg bw per day, higheset dose tested
Developmental neurotoxicity NOAEL	No data

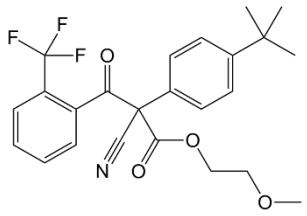
Other toxicological studies	
Mechanistic studies	Inhibition of cholesterol catabolism possibly due to a decrease in hormone-sensitive lipase expression in the adrenals of rats
	No significant effect on respiratory/cardiovascular systems in dogs
	No significant effect in vitro on the aromatase and estrogen/adrenal receptor system
	Induction of 17β-estradiol synthesis and inhibition of testosterone synthesis in an in vitro steroidogenesis assay
	Possible mode of action of Leydig cell adenoma: Testosterone level reduction and subsequent compensatory processes
Immunotoxicity NOAEL	349 mg/kg bw per day, highest dose tested
Studies on metabolites	B-1:
	LD_{50}: > 2 000 mg/kg bw
	Unlikely to be genotoxic in vivo
	Studies on B-3 and AB-13 were submitted, but these compounds are not relevant to a dietary risk assessment.
Medical reports	
	Three medical reports: No abnormal findings

Summary

	Value	Study	Safety factor
ADI	0–0.1 mg/kg bw	Two-generation reproductive toxicity study (rat)	100
ARfD	Unnecessary	–	–

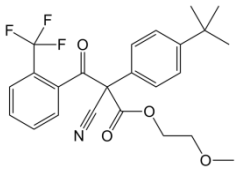
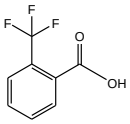
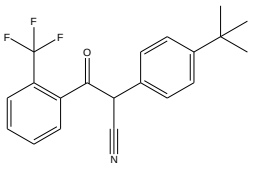
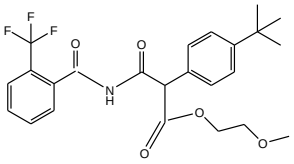
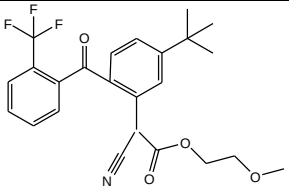
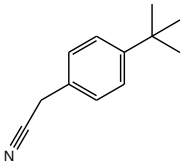
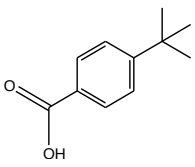
RESIDUE AND ANALYTICAL ASPECTS

Cyflumetofen (consisting of RS isomers) is a bridged diphenyl acaricide (miticide) for control of *Tetranychus* sp. and influences the mitochondrial electron transport chain by inhibiting the complex II substance in the cell. It has been registered in a number of countries.



The Meeting received information on physical and chemical properties, animal and plant metabolism, environmental fate, analytical methods, storage stability, use patterns, supervised trials, and processing. Cyflumetofen was scheduled by the Forty-fifth Session of the CCPR for review by the 2014 JMPR for the first time.

In this Appraisal, the following abbreviated names were used for referred metabolites.

Code (MW)	IUPAC name	Structure
Cyflumetofen (447.45)	2-methoxyethyl (*RS*)-2-(4-*tert*-butylphenyl)-2-cyano-3-oxo-3-(α,α,α-trifluoro-*o*-tolyl)propionate	
B-1 (190.12)	2-(trifluoromethyl)benzoic acid	
AB-1 (345.36) Syn: M9210I003	(RS)-2-(4-tert-butylphenyl) -3-oxo-3-[2-(trifluoromethyl)phenyl] propanenitrile	
AB-6 (465.45)	2-methoxyethyl-2-((*R*,*S*)-4-*tert*-butylphenyl)-3-oxo-3-({[2-(trifluoromethyl)phenyl]carbonyl}amino)propanoate	
AB-7 (447.45)	2-methoxyethyl-((R,S)-4-tert-butyl-2-{[2-(trifluoromethyl)phenyl]carbonyl}phenyl (cyano)acetate	
A-2 (173.26) Syn: M9210I001	4-tert-butylphenyl-acetonitrile	
A-12 (178.23) Syn: M9210I002	4-tert-butylbenzoic acid	

Animal metabolism

The Meeting received information on the fate of orally-dosed cyflumetofen in lactating goats.

In metabolism studies, total radioactive residues are expressed in mg eq./kg cyflumetofen equivalents unless otherwise stated.

Metabolism of cyflumetofen in rat

Metabolism studies on laboratory animals including rats were reviewed in the framework of toxicological evaluation by the current JMPR.

In a rat metabolism study, highest residues were found in the liver followed by kidney regardless of sex, dose and label position and time point of measurement. Cyflumetofen was extensively metabolized. B-1, 2-trifluoromethylbenzoic acid, was the major metabolite (occurring up to 28% of the applied dose). The predominant metabolic pathway for cyflumetofen involves cleavage of the tert-butylphenyl and trifluorotolyl moieties. Major reactions on the tert-butylphenyl ring are cleavage of the methoxyethyl group, hydroxylation at the butyl group, decarboxylation and glucuronidation at the butyl group. Major reactions on the trifluorotolyl-ring are glutathione conjugation at the carboxyl group and further changes of the glutathione group to mercapturic acid or thiolactic acid. In addition, hydroxylation and oxidation reactions at the butyl group and cleavage of the carboxylic ester moiety are observed on the parent molecule.

Metabolism of cyflumetofen in lactating goat

Two lactating goats were orally administered [benzoyl-ring-U-^{14}C]-cyflumetofen (hereafter abbreviated as benzoyl-label) for 12 consecutive days at 0.27 or 0.30 mg/kg bw (12 or 15 ppm in feed). Other two goats were orally administered [t-butylphenyl-ring-U-^{14}C]-cyflumetofen (hereafter abbreviated as butylphenyl-label) for 10 consecutive days at 0.43 or 0.48 mg/kg bw (12 or 13 ppm in feed). The goats were sacrificed 18–24 hours after the last dose.

After radio-labelled cyflumetofen was administered orally to lactating goats, it was excreted in faeces and urine (total > 78% excreted during the testing periods) and only a small portion accounting for < 0.3% of the administered radioactivity (AR) remained in body tissues/organs. Radioactive residues were the highest in liver (0.29–0.40 mg eq./kg) followed by kidney (0.17–0.19 mg eq./kg) but low in fat (0.028–0.033 mg eq./kg) and muscle (0.009–0.020 mg eq./kg). Milk of each day contained < 0.02% AR and milk collected throughout the study period contained, in total, 0.008–0.19 mg eq./kg (0.03–0.14% AR).

The parent compound, cyflumetofen, was found only in fat but at low concentration of 0.003 mg/kg accounting for 20–21% of the total radioactive residues (TRR). The predominant metabolite in all tissues/organs and milk was B-1 at around 0.1 mg eq./kg in liver (32% TRR) and kidney (54% TRR), and lower than 0.01 mg eq./kg in muscle (46–51% TRR), fat (21–40% TRR) and milk (4.5% TRR).

The metabolism of cyflumetofen in goat involves extensive hydrolysis of formic acid ester and trifluoromethylbenzoyl moiety, decarboxylation, conjugation, hydroxylation and oxidation. In principle, excretion and distribution of cyflumetofen and its metabolism in goat are similar to those in rats with some differences in metabolites identified.

Plant metabolism

Satsuma mandarin

When Satsuma mandarin trees (grown outdoor) were sprayed with benzoyl- or butylphenyl-label cyflumetofen at a rate approximating 0.60 kg ai/ha (3× GAP rate of the USA), and Satsuma mandarin fruit samples were collected 1, 7 and 30 days after the treatment, the majority of the radioactivity was

recovered from the acetonitrile surface rinse of fruits: 95–96% TRR on 1DAT; 91–93% TRR on 7DAT; and 88–89% on 30 DAT.

The predominant radioactive residue on/in mandarin fruits (total) was cyflumetofen at 0.52–0.55 mg/kg (88-90% TRR) on 1DAT, decreasing to 0.33–0.37 mg/kg (79–83% TRR) on 7 DAT and further to 0.25–0.31 mg/kg (44–54% TRR) on 30 DAT.

Other than the parent, metabolites AB-6, AB-7, A-12 and B-1 were formed. B-1 increased over time from 0.028 mg eq./kg (4.7% TRR) on 1 DAT to 0.064 mg eq./kg (11% TRR) on 30 DAT. None of AB-6, AB-7 and A-12 exceeded 10% TRR. A number of unknown peaks were observed but none of them exceeded 10% of TRR.

The radioactive residues on/in leaves showed similar profile as those on/in fruits with the majority (>87% TRR) of radioactive residues found in the surface rinse, although the TRR was >50 times that on/in fruits. A majority of radioactive residues remaining in leaves were extracted. Cyflumetofen was also the predominant identified fraction in leaves: > 73% TRR in rinse and extract together. Four metabolites were identified but none exceeded 10% TRR.

Apple

When an apple tree (grown outdoor) was sprayed with benzoyl- or butylphenyl-label cyflumetofen at a rate approximating 0.60 kg ai/ha (3× GAP rate of the USA), and apple fruit samples were collected 1, 7 and 30 days after the treatment, the majority of the radioactivity was recovered from the acetonitrile surface rinse of fruits: 95–96% TRR on 1 DAT, 82–89% TRR on 7 DAT; and 67–71% TRR on 30 DAT.

The predominant radioactive residue on/in apple fruits was cyflumetofen at 0.061–0.066 mg/kg (58–61% TRR) in rinse while pulp extract contained too little radioactivity for further analysis on 1DAT, 0.061–0.14 mg/kg (78–84% TRR) on 7 DAT and decreased to 0.037–0.042 mg/kg (53–65% TRR) on 30 DAT.

There were minor metabolites identified. However, none of them exceeded 5% TRR.

The radioactive residues on/in leaves showed similar profile as those on/in fruits with the majority (>72% TRR) of radioactive residues found in the surface rinse, although the TRR was > 50 times that on/in fruits. Cyflumetofen was also the predominant identified fraction in leaves: > 44% TRR in rinse and extract together. No metabolites exceeded 10% TRR.

Eggplant

When eggplants (grown outdoor) were sprayed with benzoyl- or butylphenyl-label cyflumetofen at a rate approximating 0.60 kg ai/ha (3× GAP rate of the USA), and eggplant samples were collected 1, 7 and 14 days after the treatment, the majority of the radioactivity was also recovered from the acetonitrile surface rinse of fruits: 87–92% TRR on 1 DAT, 79–86% TRR on 7 DAT; and 56–81% TRR on 30 DAT.

The predominant radioactive residue on/in eggplant fruits was also cyflumetofen accounting for 0.31–0.44 mg/kg (91–95% TRR) on 1 DAT, decreased to 0.25–0.39 mg/kg (67–71% TRR) on 7 DAT and then to 0.18–0.20 mg/kg (42–62% TRR) on 14 DAT.

Metabolites B-1, AB-6 and AB-7 were identified from the fruit rinse and/or extracts. B-1 was found at 0.059 mg eq./kg (11% TRR) on 7 DAT and at 0.061 mg eq./kg (15% TRR) on 14 DAT on/in fruits. AB-6 and AB-7 did not exceed 10% TRR.

The tentatively identified U1/U2 (likely to be acid labile conjugates of B-1) and U4 were also found in 7 DAT and 14 DAT fruits but not in 1 DAT fruits. U1 was present at 0.067 mg eq./kg (16% TRR) on 14 DAT but < 10% TRR on 1 DAT and 7 DAT. No other metabolites exceeded 10% TRR.

U1 and U2 were found only in the fruit extracts but not in rinse, indicating that they were formed in the fruits.

The radioactive residues on/in leaves showed similar profile as those on/in fruits with the majority (> 69% TRR) of radioactive residues found in the surface rinse, although the TRR was > 50 times that on/in fruits. Cyflumetofen was also the predominant identified fraction in leaves: > 47% TRR in rinse and extract together. No metabolites exceeded 10% TRR.

Summary of plant metabolism

The metabolism of cyflumetofen in these crops involves hydrolysis, acyl migration, oxidation and conjugation (U1 and U2 are the conjugate of B-1).

The plant metabolism studies on Satsuma mandarin, apple and eggplant showed similar pattern. Applied radioactively was mostly recovered from surface rinse with decreasing trend over time. Fruit flesh contained far less radioactivity. The predominant radioactive residue was cyflumetofen accounting for > 42% TRR at all time points. The next important radioactive residue was B-1 but at the maximum 15% TRR (around 0.06 mg eq./kg). B-1 may be present in fruits in conjugated forms.

Environmental fate

Aerobic soil metabolism

The studies on aerobic soil degradation of cyflumetofen indicate that cyflumetofen sprayed on soil was rapidly and completely degraded with DT_{50} around 1.8–4.3 days in various soils at 20–25 °C. Additionally, aerobic soil degradation of B-1 and AB-1 was studied resulting in DT50 of 6–36 days and 0.07–0.11 days respectively at 20 °C.

Photolysis on soil surface

Photolysis of cyflumetofen on soil was found to be insignificant as the degradation rates of cyflumetofen with and without light irradiation were not significantly different.

Hydrolysis in aquatic system

Cyflumetofen is susceptible to hydrolysis and was hydrolyzed faster at higher pH in aqueous buffer solutions at 25 °C. DT_{50} was calculated using first order kinetics to be 7.7 days at pH 4, 6.0 days at pH 5, 9.8 h at pH 7 and 10.3 min at pH 9.

At slightly acidic to neutral pH, a number of degradates exceeded 10% of the applied dose: A-1 (max. 14% at 8 h), A-2 (max. 44% at 720 h), A-18 (max. 36% at 120 h), B-1 (max. 53% at 48 h) and AB-1 (maximum 45%, at 120 h).

Residues in succeeding crops

A confined rotational crop study was conducted to examine the nature and level of residues of cyflumetofen in three succeeding crops (white radish, lettuce and wheat) using benzoyl- and butylphenyl-label cyflumetofen. A single application of radio-labeled cyflumetofen was made on bare soil in plastic containers at a rate of 0.40 kg ai/ha (2× GAP rate of the USA). After plant back interval (PBI) of 30, 120 and 365 days, lettuce, white radish and spring wheat were sown into the treated soil.

Following the application of cyflumetofen to soil, uptake of radioactivity from soil into rotational crops was observed, in particular, with benzoyl-label (up to 1.25 mg eq./kg in wheat chaff of 30 PBI but much lower in edible portions with the maximum of 0.17 mg eq./kg in wheat grain of 30 PBI). With butylphenyl-label, uptake of radioactivity into rotational crops were lower (maximum

of 0.11 mg eq./kg in wheat straw+chaff of 120 PBI). Uptake was, in general, less with longer plant back interval.

The only major radioactive residue identified from benzoyl-label treatment was trifluoroacetic acid in all crops (39–100% TRR). B-1, specific to this label, was detected as a minor component.

With the butylphenyl-label, a series of label-specific metabolites were observed in the extracts but all of them were less than 0.01 mg eq./kg.

No parent compound was detected from any of the crop extracts.

No significant residues of cyflumetofen, other than trifluoroacetic acid, were expected to be found in rotational crops on the basis of aerobic soil degradation studies and confined succeeding crop study.

Methods of analysis

Analytical methods for determination of residues of cyflumetofen and its metabolites B-1, AB-6 and AB-7 were developed for a wide range of matrices of plant and animal origin.

In general, the method for data generation and enforcement for plant matrices employ extraction by shaking with acetonitrile and then a mixture of acetonitrile:water (75:25, v/v) or only with acetonitrile:water, cleanup by partitioning with a mixture of ethyl acetate:cyclohexane (75:25, v/v) and determination of the analytes using LC-MS/MS.

The method for plant matrices was validated for cyflumetofen, B-1, AB-6 and AB-7 resulting in acceptable recoveries and relative standard deviations (RSDs) with the LOQ of 0.01 mg/kg for various plant matrices.

The analytical method developed for cyflumetofen and B-1 in animal matrices was similar to the one for plant matrices but employs acetonitrile:water (50:50, v/v) for extraction instead of acetonitrile:water (75:25, v/v) and different clean-up procedure. This method was validated for cyflumetofen and B-1 resulting in acceptable recoveries and RSDs with the LOQ of 0.01 mg/kg for bovine liver, and meat and 0.001 mg/kg for bovine milk. The mean recoveries for cyflumetofen in poultry eggs were low at 65–67% (RSD, 3–6%) while those for B-1 were acceptable between 86–95%.

A number of scientific papers report the validation of the QuEChERS multi-residue method with GC-MS/MS for cyflumetofen in various plant commodities with the LOQ around 0.01 mg/kg.

Stability of pesticide residues in stored analytical samples

The stability of cyflumetofen, B-1, AB-6 and AB-7 in homogenates of almond, apple (fruit, juice) kidney bean, lettuce, orange (fruit, juice, oil), radish and wheat grain at -20 to -10 °C was tested at a spike level (each analyte separately spiked) of 0.1 mg/kg for 743–910 days (24–30 months).

Cyflumetofen was stable when stored frozen for 25 months, the longest storage time tested, in almond, apple fruit, apple juice, orange fruit (24 months), orange juice, orange oil and wheat grain. However, it was stable only up to 9 months in kidney bean and lettuce, and 3 months in radish root.

B-1 was stable when stored frozen for 30 months, the longest storage time tested, in almond, kidney bean, lettuce, orange fruit, orange juice and wheat grain. It was stable up to 22 months in apple fruit, apple juice and radish root, and 6 months in orange oil.

AB-6 was stable when stored frozen for 28 months, the longest storage time tested, in almond, apple fruit, kidney bean, orange juice, orange oil, radish root, and wheat grain. It was stable up to 21 months in apple juice, lettuce and orange fruit.

AB-7 was stable when stored frozen for 26 months, the longest storage time tested, in almond, apple fruit, apple juice, kidney bean, orange juice, and orange oil. It is stable up to 19 months in orange fruit and wheat grain, 12 months in lettuce, but one month in radish root.

Definition of the residue

In goat metabolism studies, radioactive residues were highest in liver followed by kidney. Far less radioactive residues were found in fat, muscle and milk.

When benzoyl-label cyflumetofen was administered, metabolite B-1 (2-trifluoromethylbenzoic acid) was the predominant residue in all edible tissues/organs (21–54% TRR) and milk (4.5% TRR). B-1 was also found in rat metabolism and is considered to be no more toxic than the parent and, therefore, toxicologically covered by the ADI for parent compound. Cyflumetofen was detected only in fat at 0.003 mg/kg (20% TRR). No other metabolites were detected above 10% TRR.

When butylphenyl-label cyflumetofen was administered, cyflumetofen was not detected in any of edible tissues/organs or in milk. None of all the identified metabolites exceeded 0.01 mg eq./kg and 10% TRR.

There is a validated LC-MS/MS method for cyflumetofen and B-1 in bovine matrices. The Meeting considered that both cyflumetofen and B-1 were suitable residues for enforcement of MRLs and for estimating dietary intake.

LogPow of cyflumetofen is 4.3 at 25 °C and cyflumetofen was found only in the fat at < 0.01 mg/kg in the goat metabolism study. B-1 is a carboxylic acid and was present at 0.13 mg eq./kg in liver and 0.10 mg eq./kg in kidney but < 0.01 mg eq./kg in fat. The Meeting considered that, over all, residues (cyflumetofen and B-1) were not fat soluble.

In the plant metabolism studies on Satsuma mandarin, apple and eggplant, cyflumetofen was the predominant residue and accounted for > 42% TRR in the fruits of these crops at any time points. The Meeting considered that for enforcement of MRLs, cyflumetofen was a suitable residue.

The next important radioactive residue was B-1 but at the maximum 15% TRR (around 0.06 mg eq./kg). In the supervised residue trials, the concentrations of B-1 were mostly 1/10–1/2 of those of cyflumetofen. Conjugated forms of B-1 (U1 and U2) were found in the eggplant metabolism at slightly higher concentrations (in total) than B-1 itself but they were not found in the studies on Satsuma mandarin or apple. A validated LC-MS/MS method is available and used in the trials for quantification of cyflumetofen and B-1 but it determines the free form of B-1.

The Meeting considered that, for calculating dietary intake from commodities of plant origin, cyflumetofen and B-1 were suitable residues.

Based on the above, the Meeting recommended the following residue definition for plant and animal commodities:

Definition of the residue for plant commodities (for compliance with the MRL): *Cyflumetofen.*

Definition of the residue for plant commodities (for estimation of dietary intake): *Sum of cyflumetofen and 2-trifluoromethylbenzoic acid, expressed as cyflumetofen*.

Definition of the residue for animal commodities (for compliance with the MRL and estimation of dietary intake): *Sum of cyflumetofen and 2-trifluoromethylbenzoic acid, expressed as cyflumetofen*.

Residue is not fat-soluble.

Results of supervised residue trials on crops

The Meeting received supervised trial data for cyflumetofen on citrus fruits, pome fruits, grapes, strawberry, tomato, eggplant and tree nuts conducted outdoor (except trials on eggplant in Japan) using foliar spray of 20% SC formulation of cyflumetofen (except in a trial on apple in Italy).

Residues were expressed in cyflumetofen equivalents. The analytical results for B-1 were converted to cyflumetofen equivalents by multiplying the analytical results for B-1 with a factor of 2.35 based on the molecular weights of cyflumetofen (447.45) and B-1 (190.12).

For the estimation of a sum of cyflumetofen and B-1, where B-1 was below the LOQ, it was regarded as 0.02 mg eq./kg (LOQ of 0.01 mg/kg for B-1 is converted to 0.02 mg eq./kg) as B-1 was sometimes present at concentrations comparable to those of parent in trials.

Although in a number of trials conducted in the USA the water volume was smaller than the minimum water volume on the label, the Meeting agreed to use the results of these trials in estimating maximum residue levels as the purpose of the minimum requirement was for better efficacy and not for safety, and residues from lower water volume trials were not always lower than those from higher water volume trials.

Citrus fruits

A total of 23 supervised trials were conducted on orange (12), grapefruit (6) and lemon (5) in the USA in 2009 and 2010. GAP in the USA for citrus fruits allows 2 applications at a maximum rate of 0.2 kg ai/ha (at least 935 L/ha) with a PHI of 7 days.

Residues of cyflumetofen from 11 independent orange trials matching GAP for citrus fruits in the USA were: 0.01, 0.01, 0.03, 0.06, 0.06, 0.08, 0.09, 0.10, 0.10, 0.11 and 0.12 mg/kg (median 0.08 mg/kg).

The information on four trials conducted on orange in Brazil in 2007 was also provided but they did not match the GAP in Brazil (one application at a spray concentration of 0.08 kg ai/hL).

Residues of cyflumetofen from six grapefruit trials matching GAP for citrus fruits in the USA were: < 0.01, 0.02, 0.04, 0.04, 0.04 and 0.07 mg/kg (median 0.04 mg/kg).

Residues of cyflumetofen from five lemon trials matching GAP for citrus fruits in the USA were: < 0.01, 0.02, 0.02, 0.08 and 0.14 mg/kg (median 0.02 mg/kg).

As the GAP in the USA is established for the group of citrus fruits, the median values from the trials conducted in the USA on these three commodities were not different more than 5-fold, and Kruskal-Wallis test indicated that the residues of orange, grapefruits and lemon were not statistically different, the Meeting decided to estimate a group maximum residue level. The residues of orange, grapefruits and lemon were combined for estimating a maximum residue level for estimating a maximum residue level for citrus fruits (n=22): < 0.01, < 0.01, 0.01, 0.01, 0.02, 0.02, 0.02, 0.03, 0.04, 0.04,0.04, 0.06, 0.06, 0.07, 0.08, 0.08, 0.09, 0.10, 0.10, 0.11, 0.12 and 0.14 mg/kg.

The Meeting estimated a maximum residue level of 0.3 mg/kg for citrus fruit.

For the estimation of STMR, the sum of cyflumetofen and B-1 was calculated: < 0.03, < 0.03, 0.03, 0.03, 0.04, 0.04, 0.04, 0.05, 0.06, 0.06, 0.06, 0.08, 0.08, 0.09, 0.10, 0.10, 0.11, 0.12, 0.12, 0.13, 0.14 and 0.16 and mg eq./kg.

The Meeting estimated an STMR of 0.07 mg/kg expressed as cyflumetofen.

Pome fruits

A total of 17 supervised trials were conducted in the USA in 2009 and 2010 on apples (12) and pear (5). One trial was conducted in Italy in 2006 on apples. The GAP in the USA for pome fruits allows 2 applications at a maximum rate of 0.2 kg ai/ha (at least 935 L/ha) with a PHI of 7 days.

The trial from Italy was provided but did not match any GAP and was not considered.

Residues from 12 apple trials matching US GAP were: 0.01, 0.04, 0.06, 0.07, 0.10, 0.10, 0.13, 0.16, 0.18, 0.18, 0.19 and 0.20 mg/kg (median 0.115 mg/kg).

Residues from five pear trials matching US GAP were: 0.06, 0.08, 0.11, 0.12 and 0.20 mg/kg (median 0.11 mg/kg).

As the GAP in the USA is established for the group of pome fruits, and the median values from the trials conducted in the USA on the two commodities did not differ by more than 5-fold, the Meeting decided to estimate a group maximum residue level.

Man-Whitney test indicated that the residues from apple trials and those from pear trials were not statistically different. The Meeting decided to combine the data for estimating a maximum residue level. Residues were (n=17): 0.01, 0.04, 0.06, 0.06, 0.07, 0.08, 0.10, 0.10, 0.11, 0.12, 0.13, 0.16, 0.18, 0.18, 0.19, 0.20 and 0.20 mg/kg.

The Meeting estimated a maximum residue level of 0.4 mg/kg for pome fruits.

The sum of cyflumetofen and B-1 was calculated: 0.03, 0.06, 0.08, 0.08, 0.09, 0.10, 0.12, 0.12, 0.13, 0.14, 0.15, 0.18, 0.20, 0.20, 0.21, 0.22 and 0.22 mg eq./kg.

The Meeting estimated an STMR of 0.13 mg/kg expressed as cyflumetofen.

Berries and Other Small Fruits

Grapes

A total of 12 supervised trials were conducted on grapes in the USA in 2009. The GAP in the USA for grapes allows 2 applications at a maximum rate of 0.2 kg ai/ha (at least 468 L/ha) with a PHI of 14 days.

Residues from 11 independent trials matching US GAP were: 0.02, 0.09, 0.10, 0.12, 0.15, 0.16, 0.19, 0.22, 0.22, 0.27 and 0.42 mg/kg.

The Meeting estimated a maximum residue level of 0.6 mg/kg for grapes.

The sum of cyflumetofen and B-1 was calculated: 0.04, 0.12, 0.12, 0.16, 0.20, 0.22, 0.23, 0.25, 0.25, 0.33 and 0.46 mg eq./kg.

The Meeting estimated an STMR of 0.22 mg/kg expressed as cyflumetofen.

Strawberry

A total of eight supervised trials were conducted on strawberry in the USA in 2009 and 2010. The GAP in the USA for strawberry allows 2 applications at a maximum rate of 0.2 kg ai/ha (at least 468 L/ha) with a PHI of 1 day.

Residues from eight trials matching US GAP were: 0.04, 0.10, 0.14, 0.14, 0.16, 0.20, 0.23 and 0.36 mg/kg.

The Meeting estimated a maximum residue level of 0.6 mg/kg for strawberry.

The sum of cyflumetofen and B-1 was calculated: 0.06, 0.13, 0.16, 0.16, 0.20, 0.24, 0.28 and 0.40 mg eq./kg.

The Meeting estimated an STMR of 0.18 mg/kg expressed as cyflumetofen.

Fruiting Vegetables, Other Than Cucurbits

Tomato

A total of 16 supervised trials were conducted on tomato in the USA in 2009 and 2010. The GAP in the USA for tomato allows 2 applications at a maximum rate of 0.2 kg ai/ha (at least 468 L/ha) with a PHI of 3 days.

Residues from 14 independent trials matching US GAP were: 0.01, 0.02, 0.02, 0.04, 0.04, 0.04, 0.04, 0.06, 0.06, 0.06, 0.07, 0.09, 0.12 and 0.15 mg/kg.

The Meeting estimated a maximum residue level of 0.3 mg/kg for tomato.

The sum of cyflumetofen and B-1 was calculated: 0.03, 0.04, 0.06, 0.06, 0.06, 0.06, 0.06, 0.08, 0.08, 0.09, 0.09, 0.11, 0.17 and 0.18 mg eq./kg.

The Meeting estimated an STMR of 0.07 mg/kg expressed as cyflumetofen.

Eggplant

Two supervised trials were conducted on eggplant, green house grown, in Japan in 2004 with the analysis of cyflumetofen and the conjugates of B-1. The current GAP of Japan allows 2 applications at a spray concentration of 0.02 kg ai/hL with a PHI of 1 day. A spray volume of 1000–3500 L can be sprayed per ha. In the trials, spray concentration was 0.02 kg ai/hL and spray volume was 1996 L/ha, matching Japanese GAP. Residues from these trials were: 0.34 and 0.46 mg/kg.

The Meeting concluded that the data were insufficient for estimating a maximum residue level for eggplant.

Tree nuts

Five trials were conducted on almonds and five other trials were conducted on pecans in the USA in 2009. The GAP in the USA for tree nuts allows 2 application at a maximum rate of 0.2 kg ai/ha (in at least 935 L/ha) with a PHI of 7 days.

Residues in almond nutmeat from five trials matching US GAP were: < 0.01 (5) mg/kg.

Residues in pecan nutmeat from five trials matching US GAP were: < 0.01 (5) mg/kg.

As the GAP in the USA is established for the group of tree nuts and as the residues were all < 0.01 mg/kg, the Meeting agreed to estimate a maximum residue level for the tree nuts group at 0.01* mg/kg.

As the B-1 was also below the LOQ in all the trials, and the nutmeat is protected by the hull and not exposed to cyflumetofen foliar spray, the Meeting estimated an STMR to be 0.01 mg/kg expressed as cyflumetofen.

Animal feeds

Almond hulls

Five trials were conducted on almond in the USA in 2009. The GAP is the USA allows 2 application at a maximum rate of 0.2 kg ai/ha (in at least 935 L/ha) with a PHI of 7 days.

Residues in almond hull from five trials matching US GAP were: 0.35, 0.53, 0.56, 0.86 and 1.87 mg/kg.

The Meeting estimated a maximum residue level of 4 mg/kg.

The sum of cyflumetofen and B-1 was calculated: 0.38, 0.63, 0.67, 0.98 and 2.11 mg/kg. The Meeting estimated a median residue of 0.67 mg/kg.

Fate of residues during processing

High temperature hydrolysis

To simulate the degradation of cyflumetofen during pasteurization, baking, brewing, boiling and sterilization, the hydrolysis of radio-labelled cyflumetofen was investigated in sterile buffered aqueous solutions.

After incubation at 90 °C (pH 4) for 20 minutes, 100 °C (pH 5) for 60 minutes or 120 °C (pH 6) for 20 minutes, no loss of radioactivity occurred. After heating at 90 °C for 20 minutes, about 69–71% of cyflumetofen remained with 14–23% of the applied radioactivity degraded to B-1. At 100 °C for 60 minutes, only 5–18% of cyflumetofen remained with the formation of B-1 (53–59% AR) and AB-1 (32–40% AR). At 120 °C, cyflumetofen was completely hydrolyzed with the formation of B-1 (44–75% AR) and AB-1 (39–49% AR). Cyflumetofen was susceptible to hydrolysis at high temperature.

Processing

The Meeting received information on processing of orange, apple, grape and tomato.

Processing factors calculated for the processed commodities of the above raw agricultural commodities are shown in the table below. STMR-Ps were calculated for processed commodities of orange, apple and grape for which maximum residue levels were estimated.

Processed Orange Product	Cyflumetofen		Cyflumetofen and B-1*		STMR-P or median
	Processing factor	Best estimate	Processing factor	Best estimate	
Orange					0.07
Juice	< 0.02, < 0.08	0.05	< 0.04, < 0.022	0.031	0.0022
Oil	102, 137	120	88.0, 133	111	7.77
Marmalade	0.026, < 0.08	0.026	0.059, < 0.22	0.14	0.0098
Peel	2.86, 2.97	2.92	2.56, 2.67	2.6	0.18
Molasses	< 0.02, < 0.08	< 0.06	< 0.075, < 0.502	0.28	0.020
Dried pulp	0.44, 0.584	0.51	0.759, 0.958	0.86	0.060
Apple					0.13
Applesauce	2.54, 2.91	2.7	3.16, 3.73	3.4	0.44
Juice	0.197, 0.268	0.23	0.224, 0.299	0.26	0.033
Dried apples	0.17, 0.825	0.50	0.21, 0.876	0.54	0.070
Canned apples	0.035, 0.175	0.10	0.076, 0.202	0.14	0.018
Wet pomace	0.937, 1.59	1.3	0.939, 1.57	1.3	0.17
Grape					0.22
Dried grape	0.65, 0.93, 1.88, 4.64	2.0	0.86, 1.1, 2.47, 4.65	2.3	0.506
Juice	0.064,0.11, 0.2, 0.25	0.16	0.10, 0.16, 0.28, 0.32	0.22	0.0484
Wine (Young)	< 0.006, 0.029, 0.04, 0.04	0.04	0.04, 0.083,0.17, 0.2	0.12	0.0264
Must	0.02, 0.18, 0.41, 0.53	0.29	0.04, 0.22, 0.44, 0.59	0.32	0.071
Wet Pomace	1.1, 0.02, 3.39, 4.22	2.2	1.1, 3.03, 3.3, 3.97	2.9	0.638
Tomato					0.07
Juice	< 0.06, 0.2	0.2	< 0.2, 0.38	0.38	0.027
Canned Tomato	< 0.04, 0.2	0.2	< 0.1, 0.3	0.3	0.021
Puree	0.3, 0.88	0.59	0.4, 0.79	0.60	0.042
Paste	0.2, 0.4	0.3	1.2, 2.2	1.7	0.12
Wet Pomace	1.3, 5.5	3.4	1.4, 5.0	3.2	0.22

* expressed as cyflumetofen.

As the residue concentration is higher in orange oil than in fresh orange, the Meeting estimated a maximum residue level of 36 mg/kg for citrus oil by multiplying the maximum residue level of citrus fruits (0.3 mg/kg) by 120.

As the residue concentration is higher in dried grapes than in fresh grapes, the Meeting estimated a maximum residue level of 1.5 mg/kg by multiplying the maximum residue level for grapes (0.6 mg/kg) by 2.0.

In processing of foods, heating in aquatic system at high temperature may be employed, and therefore it is likely that AB-1 is present at significant concentrations after processing at slightly acidic to neutral pH (≥ 5). It may also occur from cyflumetofen during the storage of processed foods with high water content at room temperature. However, the Meeting concluded that AB-1 is covered by the ADI for the parent compound.

Residues in animal commodities

Estimation of dietary burden

The maximum and mean dietary burdens were calculated using the median residues of cyflumetofen (sum of cyflumetofen and B-1 expressed as cyflumetofen, to cover the worst case) estimated at the current Meeting on a basis of the OECD Animal Feeding Table.

Summary of livestock dietary burdens (ppm of dry matter diet)

	US-Canada		EU		Australia		Japan	
	Max	Mean	max	Mean	Max	Mean	Max	mean
Beef cattle	0.007	0.007	0.085	0.085	0.934 [a]	0.934 [b]	0	0
Dairy cattle	0.117	0.117	0.049	0.049	0.934 [a]	0.934 [b]	0	0
Broilers	0	0	0	0	0	0	0	0
Layers	0	0	0	0	0	0	0	0

[a] Suitable for estimating maximum residue levels for milk, meat, fat and edible offal of cattle.
[b] Suitable for estimating STMRs for milk, meat, fat and edible offal of cattle.

Residues in milk and cattle tissues

In the goat metabolism studies, in which goats were administered benzoyl-label cyflumetofen at a dose equivalent to 12.8 ppm in feed for 12 consecutive days and sacrificed one day later, cyflumetofen was found only in fat at 0.003 mg/kg. B-1 were found in liver, kidney, muscle, fat and milk at 0.125, 0.102, 0.005, 0.006 and 0.001 mg eq./kg respectively. The sum of cyflumetofen and B-1 in fat is 0.009 mg/kg as cyflumetofen. Neither cyflumetofen nor metabolites were found above 0.01 mg/kg or 10% TRR when butylphenyl-label cyflumetofen was administered to goats.

These concentrations were multiplied by 0.934/12.8 for estimating STMRs. The Meeting estimated STMRs of 0.010, 0.008, 0, 0 and 0 mg/kg for liver, kidney, meat, fat and milk, respectively.

The Meeting estimated maximum residue levels of 0.02, 0.01*, 0.01* and 0.01* mg/kg expressed as cyflumetofen for edible offal (mammalian), meat (from mammals other than marine mammals), mammalian fats (except milk fat) and milks, respectively.

The dietary burden for poultry was calculated to be 0 ppm of dry matter diet. No metabolism or feeding studies on laying hens were conducted.

RECOMMENDATIONS

On the basis of the data from supervised trials the Meeting concluded that the residue levels listed below are suitable for establishing maximum residue limits and for IEDI and IESTI assessment.

Definition of the residue for plant commodities (for compliance with the MRL): *Cyflumetofen.*

Definition of the residue for plant commodities (for estimation of dietary intake): *Sum of cyflumetofen and 2-trifluoromethylbenzoic acid, expressed as cyflumetofen.*

Definition of the residue for animal commodities (for compliance with the MRL and estimation of dietary intake): *Sum of cyflumetofen and 2-trifluoromethylbenzoic acid, expressed as cyflumetofen.*

Residue is not fat-soluble.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Dietary Intakes (IEDIs) of cyflumetofen were calculated for the 17 GEMS/Food cluster diets using STMRs estimated by the current Meeting (Annex 3 of the 2014 Report). The ADI is 0–0.1 mg/kg bw and the calculated IEDIs were 0–1% of the maximum ADI. The Meeting concluded that the long-term intake of residues of cyflumetofen resulting from the uses considered by the current JMPR is unlikely to present a public health concern.

Short-term intake

The 2014 JMPR decided that an ARfD was unnecessary. The Meeting therefore concluded that the short-term intake of residues of cyflumetofen is unlikely to present a public health concern.

5.7 DICHLOBENIL (274)

TOXICOLOGY

Dichlobenil is the ISO-approved common name for 2,6-dichlorobenzonitrile (IUPAC), with CAS number 1194-65-6. It belongs to the group of benzonitrile compounds, which are used as herbicides. It inhibits the germination of actively dividing meristems and acts primarily on growing points and root tips.

Dichlobenil has not previously been evaluated by JMPR and was reviewed by the present Meeting at the request of CCPR.

Some of the critical studies do not comply with GLP, as the data were generated before the implementation of GLP regulations. Overall, however, the Meeting considered that the database was adequate for the risk assessment.

Biochemical aspects

Following gavage dosing of rats at 6 mg/kg bw, dichlobenil was extensively absorbed; about 89% and 97% of the administered dose were absorbed in males and females, respectively, in 7 days, based on a comparison of urinary excretion following oral and intravenous administration. Oral absorption after repeated exposure was at least 60%, irrespective of dose and sex. Liver, kidney and kidney fat reached the highest concentrations of radioactivity; concentrations peaked 1 hour after administration in these organs and in plasma. The elimination of the radioactivity associated with [^{14}C]dichlobenil following oral administration was rapid, with most (about 80%) being eliminated within 24 hours at the low dose. About 60% was excreted in the urine and about 20% in the faeces, irrespective of sex or dose regimen, within 9–10 days after initiation of exposure. Approximately 79% of the administered dose was excreted in the bile within 24 hours in bile duct–cannulated rats, suggesting enterohepatic recirculation.

Dichlobenil was extensively metabolized, and no parent compound was detected in the urine. Most of the urinary metabolites were conjugates, such as sulfate, glutathione (and derivatives) and glucuronic acid conjugates. In faeces, three major metabolites (each representing at least 5% of the administered dose) were observed, as well as parent compound (dichlobenil). The proportion of conjugated metabolites decreased with increasing dose, whereas the amount of parent compound in faeces increased. Dichlobenil was metabolized in rats via two metabolic pathways: the first pathway involves hydroxylation at the 3 or 4 position, followed by glucuronidation or sulfation, and the second pathway involves substitution of one chlorine atom by glutathione.

Toxicological data

The acute oral and dermal LD_{50}s were greater than 2000 mg/kg bw in rats and rabbits, respectively. The acute inhalation LC_{50} in rats was greater than 3.2 mg/L. Dichlobenil was non-irritating to rabbit skin and eyes. It was not a skin sensitizer in guinea-pigs, as determined by the Magnusson and Kligman maximization test.

The liver was the primary target organ in mice, rats, hamsters and dogs in repeated-dose toxicity studies.

In a 90-day toxicity study in mice using dietary dichlobenil concentrations of 0, 25, 125, 625 and 3125 ppm (equal to 0, 3.8, 19, 91 and 447 mg/kg bw per day for males and 0, 4.8, 24, 114 and 512 mg/kg bw per day for females, respectively), the NOAEL was 625 ppm (equal to 91 mg/kg bw per day), based on transient clinical signs of toxicity, decreased body weight gains, decreased feed consumption and liver toxicity (increased liver weights, clinical chemistry, severity of centrilobular hypertrophy and glycogen storage) at 3125 ppm (equal to 447 mg/kg bw per day).

In a 90-day toxicity study in hamsters using dietary dichlobenil concentrations of 0, 41, 209, 1289 and 7500/4648 ppm (equivalent to 0, 3, 16, 79 and 395/263 mg/kg bw per day, respectively), the NOAEL was 41 ppm (equivalent to 3 mg/kg bw per day), based on decreased weight and mineralization of the prostate and decreased absolute seminal vesicle and testicular weights at 209 ppm (equivalent to 16 mg/kg bw per day).

In a 90-day toxicity study in rats, dichlobenil was administered in the diet at a concentration of 0, 100, 1000 or 3000 ppm (equivalent to 0, 10, 100 and 300 mg/kg bw per day, respectively); an additional group of males was fed 10 000 ppm (equivalent to 1000 mg/kg bw per day). The NOAEL was 100 ppm (equivalent to 10 mg/kg bw per day), based on hepatocellular necrosis and inflammation in males seen at 1000 ppm (equivalent to 100 mg/kg bw per day).

In a 90-day toxicity study in dogs using dietary dichlobenil concentrations of 0, 50, 150 and 450 ppm (equivalent to 0, 1.3, 3.8 and 11 mg/kg bw per day), the NOAEL was 150 ppm (equivalent to 3.8 mg/kg bw per day), based on increased alkaline phosphatase, alanine aminotransferase and liver and kidney weights at 450 ppm (equivalent to 11 mg/kg bw per day).

In a 52-week toxicity study in dogs administered dichlobenil by capsule at a dose of 0, 1, 6 or 36 mg/kg bw per day, the NOAEL was 1 mg/kg bw per day, based on increases in liver weights, serum cholesterol, triglycerides, phospholipids, alkaline phosphatase and gamma-glutamyltransferase and periportal hypertrophy of the hepatocytes in males at 6 mg/kg bw per day.

In a 2-year toxicity study in dogs using dietary dichlobenil concentrations of 0, 20, 50 and 350 ppm (equivalent to 0, 0.5, 1.3 and 8.8 mg/kg bw per day), the NOAEL was 50 ppm (equivalent to 1.3 mg/kg bw per day), based on increases in liver weight, serum alkaline phosphatase and serum alanine aminotransferase (females only) and liver histopathology (leukocytic infiltration around the central veins and necrosis in males) seen at 350 ppm (equivalent to 8.8 mg/kg bw per day).

The overall NOAEL for the 1- and 2-year dog studies was 50 ppm (equivalent to 1.3 mg/kg bw per day), and the overall LOAEL was 6 mg/kg bw per day.

In a first toxicity and carcinogenicity study in hamsters (91 weeks for males and 78 weeks for females) using dietary dichlobenil concentrations of 0, 675, 1500 and 3375 ppm (equal to 0, 51, 117 and 277 mg/kg bw per day for males and 0, 55, 121 and 277 mg/kg bw per day for females, respectively), decreased body weight gain in males and females and increased relative liver weight in females were observed at all doses. No NOAEL could be identified. The NOAEL for carcinogenicity in male hamsters was 1500 ppm (equal to 117 mg/kg bw per day), based on an increased incidence of hepatocellular adenoma and carcinoma at 3375 ppm (equal to 277 mg/kg bw per day). No treatment-related tumours were observed in female hamsters.

In the second toxicity and carcinogenicity study in hamsters, dichlobenil was administered at a dietary concentration of 0, 5, 26, 132 or 675 ppm (equal to 0, 0.34, 1.69, 9.39 and 45.6 mg/kg bw per day for males and 0, 0.35, 1.78, 9.20 and 48.9 mg/kg bw per day for females, respectively) for 88 weeks (males) or 80 weeks (females). The NOAEL was 26 ppm (equal to 1.69 mg/kg bw per day), based on reduced secretion of the prostate and seminal vesicles at 132 ppm (equal to 9.39 mg/kg bw per day).

In a 2-year toxicity and carcinogenicity study in rats using dietary dichlobenil concentrations of 0, 50, 400 and 3200 ppm (equal to 0, 3.2, 29 and 241 mg/kg bw per day for males and 0, 3.2, 26 and 248 mg/kg bw per day for females, respectively), the NOAEL was 50 ppm (equal to 3.2 mg/kg bw per day), based on changes in clinical chemistry (increased blood urea nitrogen, cholesterol), gross pathology (enlarged liver and kidney) and histopathology (nephrosis, parathyroid hyperplasia) in males and enlarged liver with increased liver weight and polyploidy with hepatocytic swelling in the liver in females at 400 ppm (equal to 26 mg/kg bw per day). There was an increased incidence of hepatocellular tumours at 3200 ppm in both sexes, reaching statistical significance only in females. The NOAEL for carcinogenicity was 400 ppm (equal to 26 mg/kg bw per day).

The Meeting concluded that dichlobenil is carcinogenic in rats and hamsters.

Dichlobenil was tested for genotoxicity in an adequate range of assays, both in vitro and in vivo. No evidence of genotoxicity was found.

The Meeting concluded that dichlobenil is unlikely to be genotoxic.

In view of the lack of genotoxicity and on the basis of other available toxicological information, the Meeting concluded that the mode of action for the increased incidences of hepatocellular adenomas and carcinomas in male and female rats and male hamsters, although not completely understood, is likely to involve a threshold. Therefore, the Meeting concluded that dichlobenil is unlikely to pose a carcinogenic risk to humans from the diet.

In a two-generation reproductive toxicity study in rats given diets containing dichlobenil at a concentration of 0, 60, 350 or 2000 ppm (equivalent to 0, 4, 23 and 130 mg/kg bw per day, respectively), the NOAEL for parental toxicity was 350 ppm (equivalent to 23 mg/kg bw per day), based on decreased body weight gains during premating (males and females) and gestation (females) in both generations, decreased feed consumption during premating in both generations (males and females) and a decreased number of implantations per dam in F_1 females at 2000 ppm (equivalent to 130 mg/kg bw per day). The NOAEL for offspring toxicity was 60 ppm (equivalent to 4 mg/kg bw per day), based on decreased body weight during weaning in both generations seen at 350 ppm (equivalent to 23 mg/kg bw per day). The NOAEL for reproductive toxicity was 350 ppm (equivalent to 23 mg/kg bw per day), based on a decreased number of implantations per dam in F_1 females seen at 2000 ppm (equivalent to 130 mg/kg bw per day).

In a prenatal developmental toxicity study in rats that used dichlobenil doses of 0, 20, 60 and 180 mg/kg bw per day, the NOAEL for maternal toxicity was 20 mg/kg bw per day, based on decreased body weight gain, feed consumption and feed efficiency during dosing seen at 60 mg/kg bw per day. The NOAEL for embryo and fetal toxicity was 180 mg/kg bw per day, the highest dose tested.

In a prenatal developmental toxicity study in rabbits that tested at dichlobenil doses of 0, 15, 45 and 135 mg/kg bw per day, the NOAEL for maternal toxicity was 45 mg/kg bw per day, based on decreased body weight gain and feed consumption during dosing at 135 mg/kg bw per day. The NOAEL for embryo and fetal toxicity was 45 mg/kg bw per day, based on an increased number of total resorptions per dam, increased post-implantation loss and increased incidences of external, visceral and skeletal malformations (e.g. open eyes, major fusion of sternebrae, cleft palate) seen at 135 mg/kg bw per day.

The Meeting concluded that dichlobenil is teratogenic in rabbits, but not in rats.

No evidence of immunotoxicity was observed in an immunotoxicity study in rats administered dichlobenil by gavage at a dose level of 0, 20, 60 or 180 mg/kg bw per day for 28 days.

The Meeting concluded that dichlobenil is not immunotoxic.

Dichlobenil produces harmful effects on nasal mucosa via dermal, inhalation and oral routes of exposure. These effects on nasal mucosa are reversible, and there is a threshold below which the effect was not observed.

Toxicological data on metabolites and/or degradates

The acute oral LD_{50}s for 2,6-dichlorobenzamide (BAM; a plant metabolite and soil degradate) were 1538 and 1144 mg/kg bw for male and female mice, respectively.

In a 13-week toxicity study in rats using dietary BAM concentrations of 0, 50, 180, 600 and 2300 ppm (equal to 0, 4, 14, 49 and 172 mg/kg bw per day, respectively), the NOAEL was 180 ppm (equal to 14 mg/kg bw per day), based on reduced skeletal muscle tone (males and females) and decreased body weight gain (females) seen at 600 ppm (equal to 49 mg/kg bw per day).

In a 2-year study of toxicity in dogs using dietary BAM concentrations of 0, 60, 100, 180 and 500 ppm (equivalent to 0, 1.5, 2.5, 4.5 and 12.5 mg/kg bw per day, respectively), the NOAEL was 180 ppm (equivalent to 4.5 mg/kg bw per day), based on decreased body weight and body weight gain seen at 500 ppm (equivalent to 12.5 mg/kg bw per day).

In a 2-year study of carcinogenicity in rats using dietary BAM concentrations of 0, 60, 100, 180 and 500 ppm (equal to 0, 2.2, 3.6, 6.5 and 19 mg/kg bw per day for males and 0, 2.8, 4.7, 8.5 and 25 mg/kg bw per day for females, respectively), the NOAEL was 100 ppm (equal to 4.7 mg/kg bw per day), based on decreased body weight and body weight gain and an increased incidence of hepatocellular alteration (eosinophilic foci) seen in females at 180 ppm (equal to 8.5 mg/kg bw per day). The NOAEL for carcinogenicity was 180 ppm (equal to 8.5 mg/kg bw per day), based on a marginally significant increase in the incidence of hepatocellular adenomas seen in females at 500 ppm (equal to 25 mg/kg bw per day).

The Meeting concluded that BAM is carcinogenic in rats.

BAM was tested for genotoxicity in an adequate range of assays, both in vitro and in vivo. No evidence of genotoxicity was found.

The Meeting concluded that BAM is unlikely to be genotoxic.

In view of the lack of genotoxicity and on the basis of other available toxicological information, the Meeting concluded that the mode of action for the increased incidence of hepatocellular adenomas in female rats, although not completely understood, is likely to involve a threshold. Therefore, the Meeting concluded that BAM is unlikely to pose a carcinogenic risk to humans from the diet.

In a three-generation reproductive toxicity study in rats given diets providing a BAM dose of 0, 60, 100 or 180 ppm (equivalent to 0, 4.0, 6.7 and 12 mg/kg bw per day, respectively), the NOAEL for parental toxicity, offspring toxicity and reproductive toxicity was 180 ppm (equivalent to 12 mg/kg bw per day), the highest dose tested.

In a prenatal developmental toxicity study in rabbits that administered BAM by gavage at a dose of 0, 10, 30 or 90 mg/kg bw per day, the NOAEL for maternal toxicity was 30 mg/kg bw per day, based on late abortion, thin appearance and severely decreased body weight gain and feed consumption during dosing at 90 mg/kg bw per day. The NOAEL for embryo/fetal toxicity was 30 mg/kg bw per day, based on increased incidences of late abortion and skeletal (bipartite interparietal bone) and visceral (postcaval lung lobe agenesis) malformations observed at 90 mg/kg bw per day.

The Meeting concluded that BAM is teratogenic in rabbits.

BAM produces harmful effects on nasal mucosa via intraperitoneal and oral routes of exposure. These effects on nasal mucosa are reversible, and there is a threshold below which the effect was not observed.

Human data

No information on employees working in dichlobenil manufacturing plants was provided.

The Meeting concluded that the existing database on dichlobenil was adequate to characterize the potential hazards to fetuses, infants and children.

Toxicological evaluation

Dichlobenil

The Meeting established an ADI of 0–0.01 mg/kg bw on the basis of an overall NOAEL of 1.3 mg/kg bw per day in 1- and 2-year dietary studies of toxicity in dogs, on the basis of liver toxicity (increased

liver weight, liver enzymes, cholesterol and triglycerides) at 6 mg/kg bw per day. A safety factor of 100 was applied. This ADI is supported by an overall NOAEL of 1.69 mg/kg bw per day in a dietary carcinogenicity study in hamsters, based on reduced secretion of the prostate and seminal vesicles, decreased body weight gain, and hyperplasia of the adrenal cortex, small intestine and bone marrow observed at 9.39 mg/kg bw per day. The upper bound of the ADI provides a margin of exposure of at least 24 000 relative to the LOAEL for liver tumours in hamsters and rats.

An ARfD of 0.5 mg/kg bw was established on the basis of a NOAEL of 45 mg/kg bw per day in a study of developmental toxicity in rabbits, based on increased incidences of external, visceral and skeletal malformations (e.g. open eyes, major fusion of sternebrae, cleft palate) seen at 135 mg/kg bw per day. A safety factor of 100 was applied. This ARfD applies to women of childbearing age only. The Meeting concluded that it is not necessary to establish an ARfD for the remainder of the population in view of the low acute oral toxicity of dichlobenil and the absence of any other toxicological effects that would be likely to be elicited by a single dose.

2,6-Dichlorobenzamide (BAM)

Based on a re-evaluation of the data, the Meeting withdrew the ADI and ARfD for 2,6-dichlorobenzamide (BAM) established by the 2009 JMPR as part of the evaluation of fluopicolide.

The Meeting established an ADI of 0–0.05 mg/kg bw for 2,6-dichlorobenzamide (BAM) on the basis of a NOAEL of 4.5 mg/kg bw per day in a 2-year dietary study of toxicity in dogs, based on decreased body weight and body weight gain at 12.5 mg/kg bw per day. A safety factor of 100 was applied. This ADI is supported by a NOAEL of 4.7 mg/kg bw per day in a 2-year dietary carcinogenicity study in rats, based on decreased body weight and body weight gain and an increased incidence of hepatocellular alteration (eosinophilic foci) in females observed at 8.5 mg/kg bw per day. The upper bound of the ADI provides a margin of exposure of at least 500 relative to the LOAEL for liver tumours in rats and also a 240-fold margin of exposure relative to the highest dose tested in a three-generation reproductive toxicity study in rats, at which no effects were observed.

The Meeting established an ARfD of 0.3 mg/kg bw for 2,6-dichlorobenzamide (BAM) on the basis of a NOAEL of 30 mg/kg bw per day in a developmental toxicity study in rabbits, based on increased incidences of skeletal (bipartite interparietal bone) and visceral (postcaval lung lobe agenesis) malformations seen at 90 mg/kg bw per day. A safety factor of 100 was applied. This ARfD applies to women of childbearing age only. The Meeting concluded that it is not necessary to establish an ARfD for the remainder of the population in view of the low acute oral toxicity of BAM and the absence of any other toxicological effects that would be likely to be elicited by a single dose.

Levels relevant to risk assessment of dichlobenil

Species	Study	Effect	NOAEL	LOAEL
Hamster	Eighteen-month studies of toxicity and carcinogenicity[a,b]	Toxicity	26 ppm, equal to 1.69 mg/kg bw per day	132 ppm, equal to 9.39 mg/kg bw per day
		Carcinogenicity	1 500 ppm, equal to 117 mg/kg bw per day	3 375 ppm, equal to 277 mg/kg bw per day
Rat	Two-year study of toxicity and carcinogenicity[a]	Toxicity	50 ppm, equal to 3.2 mg/kg bw per day	400 ppm, equal to 26 mg/kg bw per day
		Carcinogenicity	400 ppm, equal to 26 mg/kg bw per day	3 200 ppm, equal to 241 mg/kg bw per day
	Two-generation study of reproductive toxicity[a]	Reproductive toxicity	350 ppm, equivalent to 23 mg/kg bw per day	2 000 ppm, equivalent to 130 mg/kg bw per day
		Parental toxicity	350 ppm, equivalent to 23 mg/kg bw per day	2 000 ppm, equivalent to 130 mg/kg bw per

Species	Study	Effect	NOAEL	LOAEL
				day
		Offspring toxicity	60 ppm, equivalent to 4 mg/kg bw per day	350 ppm, equivalent to 23 mg/kg bw per day
	Developmental toxicity study[c]	Maternal toxicity	20 mg/kg bw per day	60 mg/kg bw per day
		Embryo and fetal toxicity	180 mg/kg bw per day[d]	–
Rabbit	Developmental toxicity study[c]	Maternal toxicity	45 mg/kg bw per day	135 mg/kg bw per day
		Embryo and fetal toxicity	45 mg/kg bw per day	135 mg/kg bw per day
Dog	One-[c] and 2-year studies of toxicity[a,b]	Toxicity	50 ppm, equivalent to 1.3 mg/kg bw per day	6 mg/kg bw per day

[a] Dietary administration.
[b] Two or more studies combined.
[c] Gavage administration, including capsules.
[d] Highest dose tested.

Levels relevant to risk assessment of BAM

Species	Study	Effect	NOAEL	LOAEL
Rat	Two-year study of toxicity and carcinogenicity[a]	Toxicity	100 ppm, equal to 4.7 mg/kg bw per day	180 ppm, equal to 8.5 mg/kg bw per day
		Carcinogenicity	180 ppm, equal to 8.5 mg/kg bw per day	500 ppm, equal to 25 mg/kg bw per day
	Three-generation study of reproductive toxicity[a]	Reproductive toxicity	180 ppm, equivalent to 12 mg/kg bw per day[b]	–
		Parental toxicity	180 ppm, equivalent to 12 mg/kg bw per day[b]	–
		Offspring toxicity	180 ppm, equivalent to 12 mg/kg bw per day[b]	–
Rabbit	Developmental toxicity study[c]	Maternal toxicity	30 mg/kg bw per day	90 mg/kg bw per day
		Embryo and fetal toxicity	30 mg/kg bw per day	90 mg/kg bw per day
Dog	Two-year study of toxicity[a]	Toxicity	180 ppm, equivalent to 4.5 mg/kg bw per day	500 ppm, equivalent to 12.5 mg/kg bw per day

[a] Dietary administration.
[b] Highest dose tested.
[c] Gavage administration.

Estimate of acceptable daily intake (ADI)

0–0.01 mg/kg bw

0–0.05 mg/kg bw for 2,6-dichlorobenzamide (BAM)

Estimate of acute reference dose (ARfD)

0.5 mg/kg bw (applies to women of childbearing age only)

0.3 mg/kg bw for 2,6-dichlorobenzamide (BAM) (applies to women of childbearing age only)

Information that would be useful for the continued evaluation of the compound

Results from epidemiological, occupational health and other such observational studies of human exposure

Critical end-points for setting guidance values for exposure to dichlobenil

Absorption, distribution, excretion and metabolism in mammals	
Rate and extent of oral absorption	Rapidly and completely absorbed from gastrointestinal tract (at least 89% in 24 hours)
Dermal absorption	No data
Distribution	Rapidly distributed, highest concentrations in liver, kidney, kidney fat and brown fat; concentrations peaked in 1 hour
Potential for accumulation	No evidence of accumulation
Rate and extent of excretion	Rapid; about 80% excreted within first 24 hours following single low dose
Metabolism in animals	Extensive, 10 metabolites in urine (no parent) and four metabolites and parent compound in faeces
Toxicologically significant compounds in animals and plants	Dichlobenil and 2,6-dichlorobenzamide (BAM; plant metabolite)
Acute toxicity	
Rat, LD_{50}, oral	> 2 000 mg/kg bw
Rat, LD_{50}, dermal	> 2 000 mg/kg bw
Rat, LC_{50}, inhalation	> 3.2 mg/L (4 hours)
Rabbit, dermal irritation	Not irritating
Rabbit, ocular irritation	Not irritating
Guinea-pig, dermal sensitization	Not sensitizing (maximization test)
Short-term studies of toxicity	
Target/critical effect	Liver
Lowest relevant oral NOAEL	1.3 mg/kg bw per day (dog)
Lowest relevant dermal NOAEL	≥ 1 000 mg/kg bw per day (rabbit)
Lowest relevant inhalation NOAEC	≥ 12 mg/m^3
Long-term studies of toxicity and carcinogenicity	
Target/critical effect	Liver and kidney (rat) and liver (hamster)
Lowest relevant oral NOAEL	1.69 mg/kg bw per day (hamster)
Carcinogenicity	Liver tumours (male hamster, male and female rats); unlikely to pose a carcinogenic risk to humans from the diet
Genotoxicity	
	Unlikely to be genotoxic
Reproductive toxicity	

Target/critical effect	Decreased body weights in adults and pups, decreased number of implantations per dam in F_1 females
Lowest relevant parental NOAEL	23 mg/kg bw per day
Lowest relevant offspring NOAEL	4 mg/kg bw per day
Lowest relevant reproductive NOAEL	23 mg/kg bw per day
Developmental toxicity	
Target/critical effect	Increased total resorptions, post-implantation loss and malformations (rabbit)
Lowest relevant maternal NOAEL	20 mg/kg bw per day (rat)
Lowest relevant embryo/fetal NOAEL	45 mg/kg bw per day (rabbit)
Neurotoxicity	
Acute neurotoxicity NOAEL	No data
Subchronic neurotoxicity NOAEL	No data
Developmental neurotoxicity NOAEL	No data
Other toxicological studies	
Immunotoxicity NOAEL	180 mg/kg bw per day, highest dose tested
Medical data	
	No data provided

Critical end-points for setting guidance values for exposure to BAM

Acute toxicity	
Mouse, LD_{50}, oral	1140 mg/kg bw
Short-term studies of toxicity	
Target/critical effect	Body weight and body weight gain
Lowest relevant oral NOAEL	4.5 mg/kg bw per day (dog)
Long-term studies of toxicity and carcinogenicity	
Target/critical effect	Liver and body weight
Lowest relevant oral NOAEL	4.7 mg/kg bw per day (rat)
Carcinogenicity	Hepatocellular adenomas in female rats; unlikely to pose a carcinogenic risk to humans from the diet
Genotoxicity	
	Unlikely to be genotoxic
Reproductive toxicity	
Target/critical effect	None
Lowest relevant parental NOAEL	12 mg/kg bw per day, highest dose tested
Lowest relevant offspring NOAEL	12 mg/kg bw per day, highest dose tested
Lowest relevant reproductive NOAEL	12 mg/kg bw per day, highest dose tested
Developmental toxicity	
Target/critical effect	Increased incidences of skeletal (bipartite interparietal bone) and visceral (postcaval lung lobe agenesis) anomalies
Lowest relevant maternal NOAEL	30 mg/kg bw per day (rabbit)
Lowest relevant embryo/fetal NOAEL	30 mg/kg bw per day (rabbit)
Neurotoxicity	

Acute neurotoxicity NOAEL	No data
Subchronic neurotoxicity NOAEL	No data
Developmental neurotoxicity NOAEL	No data

Summary

	Value	Study	Safety factor
Dichlobenil			
ADI	0–0.01 mg/kg bw	One-year and 2-year studies of toxicity (dog)	100
ARfD[a]	0.5 mg/kg bw	Developmental toxicity study (rabbit)	100
2,6-Dichlorobenzamide (BAM)			
ADI	0–0.05 mg/kg bw	Two-year study of toxicity (dog)	100
ARfD[a]	0.3 mg/kg bw	Developmental toxicity study (rabbit)	100

[a] Applies to women of childbearing age only.

RESIDUE AND ANALYTICAL ASPECTS

See also FLUOPICOLIDE

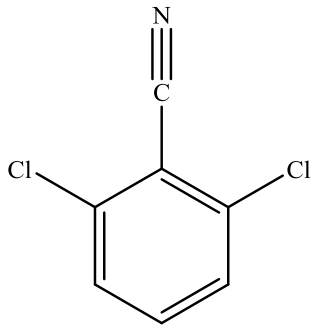
Dichlobenil is a benzonitrile herbicide for use by soil application in fruit crops, including stone fruit, grapes, and other berry crops. Dichlobenil was scheduled at the Forty-fifth Session of the CCPR in 2013 for evaluation as a new compound by the 2014 JMPR. Data was provided on physicochemical properties, metabolism in food producing animals and plants, environmental fates, methods of analysis, stability of residues in stored analytical samples, GAP information, supervised residue trials, processing studies, and animal feeding studies.

The Meeting received information on processing of oranges, strawberries, onions, lettuce head and peas.

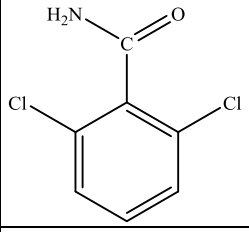
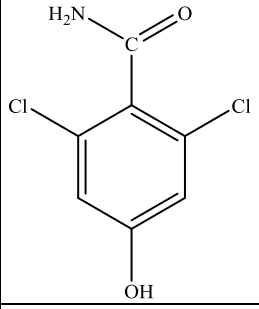
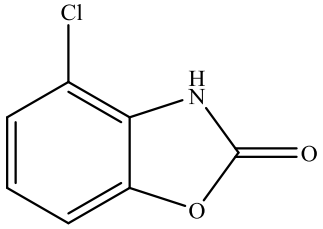
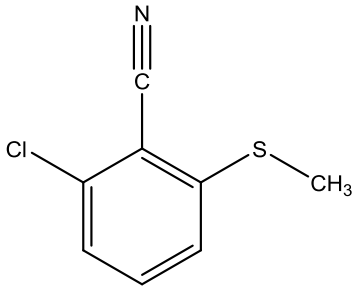
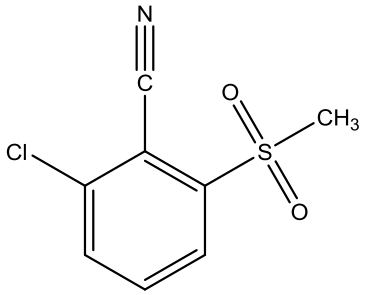
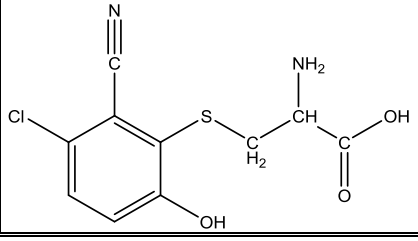
Processing factors calculated for the processed commodities for the above raw agricultural commodities, including previously estimated, are shown in the table below. STMP-Ps was calculated for processed commodities of strawberry, onion and peas for which maximum residue levels were estimated.

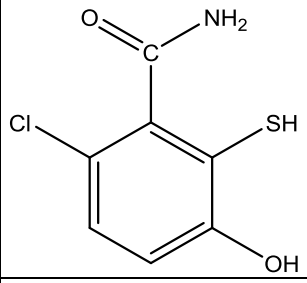
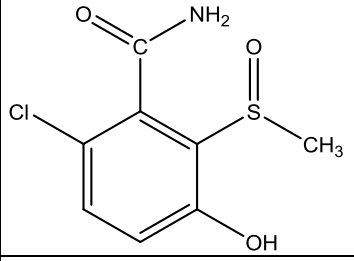
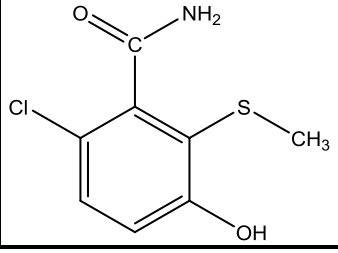
Chemical name and structure

The IUPAC name for dichlobenil is 2,6-dichlorobenzonitrile.



The following metabolites are discussed below:

2,6-Dichlorobenzamide (BAM)	
2,6-Dichloro-4-hydroxybenzamide	
4-Chloro-2(3*H*)benzoxazolone	
6-Chloro-2-methylthiobenzonitrile	
6-Chloro-2-methylsulfonylbenzonitrile	
S-(3-Chloro-2-cyano-6-hydroxyphenyl)-cysteine	

6-Chloro-3-hydroxy-2-thiobenzamide	
6-Chloro-3-hydroxy-2-methylsulfinylbenzamide	
6-Chloro-3-hydroxy-2-methylthiobenzamide	

Animal metabolism

The Meeting received information on the metabolism of ^{14}C-phenyl labelled dichlobenil in rats, lactating goats, and laying hens, and for the metabolism of ^{14}C-phenyl labelled 2,6-dichlorobenzamide (a significant plant metabolite) in lactating goats and laying hens.

Animal metabolism: dichlobenil

In rats, dichlobenil is metabolized via two metabolic pathways: hydroxylation at the 3 or 4 position followed by glucuronidation or sulphation and the second pathway includes substitution of one chlorine atom by glutathione, followed by cleavage and oxidation of the glutathione moiety to cysteine and ultimately thiol and sulfonyl derivatives.

Lactating goats were dosed orally, twice daily, with ^{14}C-phenyl dichlobenil at 10 mg/kg bw/day for three days. Milk was collected twice daily, with blood samples being collected just prior to and at various intervals after the first and fifth doses. The goats were sacrificed 15 hours after the final dose.

The majority of the administered dose was excreted (39–45% in urine, 24–31% in faeces, 2.9–4.0% in cage wash, and 0.06 to 0.33% in milk). Carcass tissue accounted for 3.2 to 3.4 % of the administered radioactivity, while 1.1–3.3% remained in GI tract tissue, and 0.4–3.3% GI tract contents.

Levels in milk peaked after about 2 days of dosing, at 1.30 mg eq./kg. At sacrifice, total residues of 27 mg eq./kg were found in liver, 4.1 mg eq./kg in kidney, 2.4 mg eq./kg in fat, and 0.42 mg eq./kg in muscle. The proportions of residue extracted were variable, at 65–70% of TRR in milk, 65% in liver, 26% in fat, 13% in muscle, and 28% in kidney.

In muscle, a metabolite tentatively identified as 2-chloro-6-methylthiobenzonitrile predominated, at 11% TRR, with smaller amounts of S-(3-chloro-2-cyano-6-hydroxyphenyl)-cysteine (0.9% TRR) and an unidentified compound (1.3% TRR).

In fat, parent comprised 60% of the identified residue (16% of TRR), with the other 40% 2-chloro-6-methylsulfonylbenzonitrile (10% TRR).

In milk, S-(3-chloro-2-cyano-6-hydroxyphenyl)-cysteine comprised 11–21% TRR, 2-chloro-6-methylsulfonylbenzonitrile 14-38% of TRR, with 3.9–12% of an unidentified component; parent was only present at ≤ 1%.

In liver, the majority of residue was present as S-(3-chloro-2-cyano-6-hydroxyphenyl)-cysteine (95% of that identified, or 62% of TRR), with a small amount of 2-chloro-6-methylsulfonylbenzonitrile (3% of TRR).

In kidney, the largest component was 2-chloro-6-methylthiobenzonitrile (23% of TRR), with smaller amounts (1.1–2.5% of TRR) of S-(3-chloro-2-cyano-6-hydroxyphenyl)-cysteine, 2-chloro-6-methylsulfonylbenzonitrile, and an unidentified component.

Laying hens were dosed orally with ^{14}C-phenyl dichlobenil at 9.8–10.2 mg/kg bw/day for three days. The dose was administered twice daily, eggs were collected twice daily, with blood samples being collected just prior to and at various intervals after the first and fifth doses. The hens were sacrificed 15 hours after the final dose.

The majority of the administered dose was excreted, with a mean of 67% recovered in excreta, 4.2% in cage washings, and 6.1% in the GI tract at sacrifice. Eggs accounted for 0.44% of the dose, with levels not reaching a plateau during the study.

The proportions of residue extracted were variable, at 60% of TRR in eggs, 90% in liver, 15% in fat, 8% in muscle, and 39% in kidney.

In fat and eggs, 100% of the extracted residue was unchanged parent compound (15% and 60% of the TRR in fat and eggs, respectively). In muscle, the largest component was the tentatively identified 2-chloro-6-methylthiobenzonitrile (6.4% of TRR), with parent compound comprising 1.6% of TRR. Similar ratios were observed for liver (2-chloro-6-methylthiobenzonitrile; 85% of TRR and parent; 5.4% of TRR). Kidney contained a number of metabolites, the cysteine conjugate of hydroxylated dichlobenil (17% of TRR), parent (9.8% of TRR), 2-chloro-6-methylsulfonylbenzonitrile (5.1% of TRR), and 2-chloro-6-methylthiobenzonitrile (4.3% of TRR), with small amounts (1.2-1.6% of TRR) of two unidentified components.

Metabolism of dichlobenil in goats and hens was similar, although the degree of metabolism appeared to be higher in goats. The chief metabolic pathway was conjugation with cysteine, replacing one of the chlorine atoms, with or without hydroxylation at an adjacent position on the ring. This was followed by cleavage and oxidation of the cysteine moiety to yield methylthio and methylsulfonyl derivatives.

There are strong similarities to the metabolism of dichlobenil in rats, with hydroxylation and glutathione conjugation followed by cleavage of the glutathione moiety taking place in rats, goats and hens.

The only residue of significance in fruit is 2,6-dichlorobenzamide, with no parent being present. Only uses in fruit crops are under consideration at this stage, therefore the Meeting considers the metabolism of dichlobenil in animals to be of secondary importance to the animal metabolism of 2,6-dichlorobenzamide.

Animal metabolism: 2,6-dichlorobenzamide

A lactating goat was dosed orally with ^{14}C-phenyl 2,6-dichlorobenzamide at 13 ppm in feed daily for five days. Milk was sampled twice daily, and the animals were sacrificed 23 hours after the final dose.

The majority of the dose was excreted. In the low dose animal, 62% of the TAR was recovered in urine, 17% in faeces, 3.4% in cage washings, and 0.26% in milk. TRRs in milk reached a plateau of 0.048 mg eq./kg on day 3 of dosing. Total residues in muscle and fat at sacrifice were 0.25 and 0.024 mg eq./kg respectively, with higher residues in the metabolic organs, 9.4 and 1.2 mg eq./kg in liver and kidney respectively.

High proportions of the residue were extracted from the matrices using column extraction methods: > 90% in all cases.

Except for liver, unchanged 2,6-dichlorobenzamide was the most significant residue component, at 0.75 mg eq./kg in kidney (63% of TRR), 0.19 mg eq./kg in muscle (77% of TRR), 0.009 mg eq./kg in fat (40% of TRR), and 0.038 mg eq./kg (80% of TRR) in 72 hour milk.

In kidney, the cysteine conjugate derivatives 6-chloro-3-hydroxy-2-thiobenzamide and 6-chloro-3-hydroxy-2-methylthiobenzamide were also found at 0.25 mg eq./kg (21% of TRR) and 0.23 mg eq./kg (19% of TRR) respectively.

In liver, the most significant residue component was 6-chloro-3-hydroxy-2-thiobenzamide at 6.6 mg eq./kg (70% of TRR), followed by 6-chloro-3-hydroxy-3-methylthiobenzamide at 1.6 mg eq./kg (17% of TRR). Much smaller amounts of 2,6-dichlorobenzamide and 6-chloro-3-hydroxy-2-methylsulfinylbenzamide (0.09–0.16 mg eq./kg, or 0.98–1.7% of TRR) were also found in liver.

Small amounts of a component postulated as dichlobenil only on the basis of retention time comparison with a standard were found in muscle and fat, at 0.01 mg eq./kg (4.4% of TRR) and 0.005 mg eq./kg (24% of TRR) respectively.

The only component found in milk apart from 2,6-dichlorobenzamide was 6-chloro-3-hydroxy-2-thiobenzamide, at 0.006 mg eq./kg (13% of TRR).

Laying hens were dosed orally with ^{14}C-phenyl 2,6-dichlorobenzamide at a mean level of 12 ppm in feed daily for five days. Eggs were sampled twice daily, and the birds were sacrificed 23 hours after the final dose.

Around half the administered dose for the low dose group was excreted, with 49% recovered from excreta and 1.5% from cage washings. In the low dose hens 3.7% of the dose was recovered in eggs, with levels not having peaked over the five day dosing period, reaching 2.4 mg eq./kg in the final day eggs. Total residues of 8.6 mg eq./kg were found in liver and 5.0 mg eq./kg in kidney. Residues were lower in fat, skin and muscle, at 1.3, 1.9 and 1.9 mg eq./kg.

Extraction was essentially quantitative, with > 95% of the TRR extracted from all matrices.

With the exception of muscle and egg, where a single additional unidentified metabolite was found at < 6% of the TRR, the extracted residue in hen matrices comprised only unchanged 2,6-dichlorobenzamide.

While 2,6-dichlorobenzamide is largely unmetabolized by hens, the metabolism of 2,6-dichlorobenzamide in goats is somewhat similar to that of dichlobenil, with the main pathway being cysteine conjugation replacing one of the chlorine atoms, followed by cleavage and oxidation of the cysteine side chain to yield metabolites such as 6-chloro-3-hydroxy-2-thiobenzamide, 6-chloro-3-hydroxy-2-methylthiobenzamide, and 6-chloro-3-hydroxy-2-methylsulfinylbenzamide.

Plant metabolism

The Meeting received information on the metabolism of ^{14}C-phenyl labelled dichlobenil in apples and grapes.

Single outdoor grown apple trees were treated in mid-February at late dormancy with a soil application of a liquid formulation of ^{14}C-phenyl dichlobenil at 6.7 kg ai/ha, the GAP for most fruit crops. Total radioactive residues were determined in soil samples collected at various intervals, as well as in immature apples collected at 77 and 107 days after soil application, and mature fruit collected at harvest (137 days after application).

Total residues in apples were low, at 0.012, 0.028, and 0.042 mg eq/kg at 77, 107, and 137 (mature harvest) days after application, respectively. The majority of the residue in mature apples, 81% of the TRR, or 0.034 mg eq./kg, could be extracted with methanol. The only residue identified in apples was 2,6-dichlorobenzamide, at 0.024 mg eq./kg, or 57% of the TRR. Unidentified components were all < 0.01 mg eq/kg.

Small plots of outdoor grown grapevines were treated in mid-February at late dormancy with a soil application of a liquid formulation of ^{14}C-phenyl dichlobenil at 6.7 kg ai/ha. Total radioactive residues were determined in soil samples collected at various intervals, as well as in immature fruit collected at 159 and 190 days after soil application, and mature grapes collected at harvest (222 days after application).

The total radioactive residues in grapes were similar at the three sampling intervals, 0.32, 0.29, and 0.39 mg eq./kg at 159, 190 and 222 days respectively. Nearly all the residue in mature grapes collected at harvest could be extracted with methanol (99% of TRR, or 0.39 mg eq./kg). The most significant residue component in grapes was by far 2,6-dichlorobenzamide, at 0.34 mg eq./kg, or 87% of the TRR. A second metabolite, 2,6-dichloro-4-hydroxybenzamide was found at < 0.01 mg eq./kg, or 2% of the TRR, while unidentified components totalled 0.06 mg eq./kg, or 15% of the TRR.

The only significant metabolic pathway for dichlobenil in fruits is hydrolysis to give 2,6-dichlorobenzamide.

Environmental fate

As all residue trials considered by the Meeting involve soil application, in accordance with the FAO Manual, data for aerobic soil metabolism, soil surface photolysis, and hydrolysis were evaluated.

Dichlobenil

In an aerobic metabolism study conducted over 50 weeks at 24 ºC in sandy loam soil, dichlobenil was principally lost through volatilization of the unchanged parent compound (57% of TAR after 50 weeks), and also by metabolism to 2,6-dichlorobenzamide (13% TAR), formation of bound residue (10% TAR), and mineralization to $^{14}CO_2$ (< 3%). The DT_{50} for dichlobenil was 13 weeks.

The Meeting noted that dichlobenil has low solubility in water, 14.6 mg/L at 20 °C. Hydrolysis of dichlobenil was insignificant, with no significant degradation in unsterilized aqueous buffer solutions over 150 days.

2,6-Dichlorobenzamide

The DT_{50} values for 2,6-dichlorobenzamide were up to 261 days (37 weeks) in soil. The Meeting noted that 2,6-dichlorobenzamide has a significantly higher water solubility than dichlobenil (2.7 g/L), and is very stable to hydrolysis.

The Meeting concluded that dichlobenil is principally lost from soil through volatilization of the parent compound, with secondary degradation pathways including metabolism to 2,6-

dichlorobenzamide, binding to soil, and mineralization to CO_2 Dichlobenil is relatively persistent, with a DT_{50} in soil of 13 weeks. Hydrolysis is not a significant pathway for degradation.

Residues in succeeding crops

No information on residues of dichlobenil in following crops was received by the Meeting, however such data is not needed given that only uses in permanent crops are under consideration.

Based on the available soil degradation data for 2,6-dichlorobenzamide in soil, the Meeting considers that there is potential for accumulation of soil residues of 2,6-dichlorobenzamide from application in multiple years. Modelling of multiple year soil accumulation using the DT_{50} value of 261 days for 2,6-dichlorobenzamide as a worst case indicates that residues of 2,6-dichlorobenzamide will reach a steady state level of 1.6× the level resulting from a single application.

Methods of analysis

The Meeting received details of analytical methods for dichlobenil and 2,6-dichlorobenzamide residues in plant and animal matrices.

Analyses of dichlobenil in plant commodities involved extraction with ethyl acetate/hexane in the presence of anhydrous sodium sulphate, with clean-up by solid phase extraction using deactivated neutral alumina as the solid phase. Residues were determined by GC-ECD or GC-MS/MS. The method LOQ is 0.01 or 0.02 mg/kg.

Analyses of 2,6-dichlorobenzamide in plant commodities involved extraction with ethyl acetate in the presence of anhydrous sodium sulphate and filter pulp or diatomaceous earth. The extracts were cleaned up by solid phase extraction (neutral alumina), followed by analysis using GC-ECD or GC-MS/MS. The method LOQ is 0.003–0.03 mg/kg.

Mean recoveries in plant matrices were generally within the acceptable range of 70–120%, with the exception of 2,6-dichlorobenzamide fortified in grape juice at 0.003 mg/kg. However, acceptable recoveries were achieved at fortifications of 0.03 and 0.30 mg/kg.

Residues of dichlobenil and 2,6-dichlorobenzamide in animal commodities were determined using a GC-MS method. Fat samples were homogenized with hexane then partitioned into acetonitrile. Kidney, muscle and liver samples were homogenized with water and extracted with ethyl acetate. Residues were transferred into hexane and partitioned into acetonitrile. Milk samples were extracted with ethyl acetate, and the residues transferred into hexane, which was cleaned up by solid phase extraction (Florisil). An LOQ of 0.01 mg/kg was achieved for both analytes in all matrices.

Mean recoveries in animal matrices were within the acceptable range of 70–120%.

Suitable methods are therefore available for determination of both dichlobenil and 2,6-dichlorobenzamide residues in plant and animal commodities with an LOQ of 0.01 mg/kg for each analyte.

Multiresidue methods were not provided to the Meeting. However, the Meeting noted that the USA FDA multiresidue method PAM I has been successfully validated for dichlobenil and 2,6-dichlorobenzamide. The Meeting also noted successful validations of the QuEChERS method for determination of both dichlobenil and 2,6-dichlorobenzamide residues.

Stability of residues in stored analytical samples

Storage stability data for residues of dichlobenil and 2,6-dichlorobenzamide in plant and animal commodities were generated as part of the residue trial and animal feeding studies.

The data showed that residues of dichlobenil and 2,6-dichlorobenzamide were stable in plant samples for at least the period for which the residue trial and animal feeding study samples were stored between collection and analysis (up to 11 months in the case of grapes and grape juice).

Storage stability of 2,6-dichlorobenzamide residues in animal matrices was acceptable over the storage period in the feeding study (up to 71 days), while dichlobenil residues were stable in muscle, fat and milk. Poor stability was observed in liver and kidney, however based on the available metabolism and feeding data, detectable residues of dichlobenil parent compound are not expected in any animal commodities.

Definition of the residue

Plant metabolism studies were available for dichlobenil in fruit crops. In metabolism studies in apples and grapes where radiolabelled compound was applied to the soil, dichlobenil was metabolised almost exclusively to 2,6-dichlorobenzamide, which comprised 57% of the TRR in mature apples, and 86% in mature grapes. No dichlobenil parent compound was found in either apples or grapes, and only one other component, 2,6-dichloro-4-hydroxybenzamide, was found, albeit at a very low level, < 0.01 mg eq./kg, or 2.1% of the TRR, in grapes only. The JMPR considered that this was not of greater toxicological concern than 2,6-dichlorobenzamide and was covered by the toxicological evaluation of 2,6-dichlorobenzamide and dichlobenil.

It is further noted that in residue trials in stone fruit, grapes, and bush berry crops, where both dichlobenil and 2,6-dichlorobenzamide were both analysed, only 2,6-dichlorobenzamide was found at quantifiable levels.

Given that dichlobenil is almost exclusively metabolised to 2,6-dichlorobenzamide in the edible portions of fruit crops, the Meeting proposes that only 2,6-dichlorobenzamide be included in the residue definition for dichlobenil in plant commodities for both compliance with MRLs and dietary risk assessment.

In considering a residue definition for animal commodities, the Meeting noted that livestock are only likely to be exposed to 2,6-dichlorobenzamide residues through feeding, as parent compound is unlikely to be found in feeds, while 2,6-dichlorobenzamide may be present in finite amounts. Therefore, only the livestock metabolism studies for 2,6-dichlorobenzamide are of significance.

In hens, 2,6-dichlorobenzamide was largely unchanged, being the only residue detected in fat, liver and kidney, and the major residue in muscle and eggs. One unidentified component was detected in muscle and eggs but at low levels (< 6% of the TRR). In goats, unchanged 2,6-dichlorobenzamide was the largest residue component in kidney, muscle, fat, and milk. In liver, 6-chloro-3-hydroxy-2-thiobenzamide was the largest component, with 2,6-dichlorobenzamide only being present at low levels. The JMPR considered that this metabolite and others found in lactating goats were not of greater toxicological concern than 2,6-dichlorobenzamide and were covered by the toxicological evaluation of 2,6-dichlorobenzamide and dichlobenil. Given that 2,6-dichlorobenzamide is not significantly metabolised in poultry, and is the most significant residue in the milk and all tissues except liver of goats dosed with the compound, the Meeting proposes that only 2,6-dichlorobenzamide will be included in the residue definition for dichlobenil in animal commodities for both compliance with MRLs and for dietary risk assessment.

The $\log_{10}P_{ow}$ of 2,6-dichlorobenzamide (0.77) indicates low fat solubility. In the goat and hen metabolism studies, residues of 2,6-dichlorobenzamide were higher in muscle than in fat. Similar observations were made in the cattle feeding study. The Meeting concluded that the residues are not fat soluble.

It is noted that 2,6-dichlorobenzamide is not uniquely a metabolite of dichlobenil, as it is also a metabolite of the fungicide fluopicolide, evaluated by JMPR in 2009. A residue definition of *fluopicolide* was established for compliance with the MRLs for plant and animal commodities, and *fluopicolide* and *2,6-dichlorobenzamide*, measured separately, for estimation of dietary intake for plant and animal commodities. Fluopicolide parent compound is the major residue resulting from use of fluopicolide. When 2,6-dichlorobenzamide is present in the absence of fluopicolide, it is most likely to have resulted from use of dichlobenil.

The Meeting considered residues of 2,6-dichlorobenzamide resulting from use of both dichlobenil and fluopicolide for establishment of MRLs and for dietary risk assessment.

The Meeting proposed the following definition of the residue (for compliance with the MRL and for dietary risk assessment, for plant and animal commodities): *2,6-dichlorobenzamide*.

The residue is not fat soluble.

Residues of supervised residue trials on crops

The Meeting received supervised trial data for soil application of dichlobenil to stone fruit (peaches, cherries and plums) and berry fruit (grapes, raspberries, blackberries, cranberries and blueberries).

The Meeting noted that residues of 2,6-dichlorobenzamide may arise from use of fluopicolide as well as from use of dichlobenil. Therefore, the Meeting has estimated maximum residue levels and STMR and HR values for 2,6-dichlorobenzamide in crops treated with fluopicolide using the data evaluated by the 2009 Meeting.

Stone fruits

Cherries

The critical GAP for dichlobenil in cherries is in the USA, where soil application at 6.7 kg ai/ha can be made in late autumn (15 November to 15 February) or early spring (up to 1 May). A harvest withholding period is not specified.

In trials on cherries conducted in the USA, 1 × 7.4–7.6 kg ai/ha soil application was made to cherry trees bearing immature fruit, with mature fruit being harvested 28 days later. Residues of 2,6-dichlorobenzamide were < 0.003 (12), and 0.004 (2) mg/kg.

The Meeting noted that most of the trials were conducted with application significantly later than specified on the label (in June or July rather than prior to 1 May), after fruit set. Insufficient trials matching GAP are available. Therefore, the Meeting did not estimate a maximum residue level for cherries.

Peaches

The GAP for dichlobenil in peaches in Canada is soil application at 7 kg ai/ha in late autumn or early spring, with no more than 7 kg ai/ha per season. A harvest withholding period is not specified.

In trials on peaches conducted in the USA, 1 × 6.8–7.7 kg ai/ha soil application was made, with fruit being harvested 20-68 days later. Residues of 2,6-dichlorobenzamide in peaches were < 0.01, 0.01, 0.02, and 0.04 mg/kg.

The Meeting determined that there were insufficient data for establishment of a maximum residue level in peaches.

Plums

The GAP for dichlobenil in plums in Canada is soil application at 7 kg ai/ha in late autumn or early spring, with no more than 7 kg ai/ha per season. A harvest withholding period is not specified.

In trials on plums conducted in the USA, 1 × 6.7–7.9 kg ai/ha soil application was made, with fruit being harvested 139-154 days later. Residues of 2,6-dichlorobenzamide in plums were < 0.01 and 0.45 mg/kg.

The Meeting determined that there were insufficient data for establishment of a maximum residue level in plums.

Berries and other small fruits

Blueberries

The GAP in the USA for blueberries involves soil application at 6.7 kg ai/ha, with application in late autumn (15 November to 15 February) or early spring (up to 1 May). No withholding period is specified.

In trials conducted on blueberries, a single soil application of dichlobenil was made in spring at 4.3 kg ai/ha. Residues of 2,6-dichlorobenzamide in blueberries at normal harvest (at a PHI of 51–58 days) were < 0.01 (3), and 0.015 mg/kg.

The Meeting determined that there were insufficient data for establishment of a maximum residue level in blueberries. Further, the Meeting noted that the trials were not conducted at the label rate, and the results were not amenable to the use of proportional scaling given that application was made at below GAP and the majority of the results were <LOQ.

Caneberries

The critical GAP for blackberries and raspberries in the USA is a soil application at 4.5 kg ai/ha made in late autumn (15 November to 15 February) or early spring (up to May 1). No withholding period is specified.

In trials conducted on blackberries and raspberries in the USA, where a single soil application was made at 4.3–4.9 kg ai/ha during spring (between mid-April and mid-May) or early summer (one trial with a mid-June application), residues of 2,6-dichlorobenzamide in mature blackberries and raspberries at normal harvest (44-89 DAT) were < 0.01 (2), 0.01, 0.02, 0.021, 0.031, 0.035, 0.056, and 0.067 mg/kg.

The Meeting noted that although a number of trials were conducted with application after 1 May, there did not appear to be a correlation between the application timing/interval and the residue level, and considered that all the trials were sufficiently robust to provide a realistic estimate of the residues.

The Meeting noted the potential for accumulation of residues of 2,6-dichlorobenzamide from application in successive years and agreed to scale the above values to account for multiple year applications by the factor of 1.6× determined from modelling of the multiple year soil accumulation. The resultant scaled data set was: < 0.016 (2), 0.016, 0.032, 0.034, 0.050, 0.056, 0.090, and 0.11 mg/kg.

Based on the above scaled data set, the Meeting estimated a maximum residue level of 0.2 mg/kg for the subgroup caneberries, along with an STMR of 0.034 mg/kg, and an HR of 0.13 mg/kg (the scaled highest residue from an individual sample).

Cranberries

The GAP for cranberries in the USA is soil application at 4.5 kg ai/ha made in late autumn or early spring (no more than 4.5 kg ai/ha in a 12-month period).

In trials conducted on cranberries in the USA, where a single soil application was made during spring at 4.8-5.7 kg ai/ha, residues of 2,6-dichlorobenzamide in cranberries at normal harvest were 0.02 (2) mg/kg.

The Meeting determined that there were insufficient data for establishment of a maximum residue level in cranberries.

Grapes

GAP for grapes in the USA involves soil application at 6.7 kg ai/ha made in early spring, with a harvest withholding period not specified.

In trials conducted in the USA on grapes, where a single soil application was made between the end of dormancy, and the beginning of fruit set, at a rate of 6.7-8.3 kg ai/ha, residues of 2,6-dichlorobenzamide in grapes at normal harvest were 0.004, 0.029, 0.033, 0.042 (2), and 0.058 mg/kg.

The Meeting determined that six trials was insufficient for estimation of a maximum residue level for grapes.

Residues of 2,6-dichlorobenzamide in grapes resulting from use of fluopicolide (2009 evaluation) were: < 0.01 (28), 0.01 (2), 0.013, 0.014, 0.015, 0.02 (2), 0.026, 0.03, 0.037, and 0.04 mg/kg.

Based on the 2,6-dichlorobenzamide residues arising from use of fluopicolide, the Meeting estimated a maximum residue level of 0.05 mg/kg for grapes, together with an STMR of 0.01 mg/kg and an HR of 0.04 mg/kg.

Crops with a fluopicolide use but no dichlobenil use

Bulb vegetables

Residues of 2,6-dichlorobenzamide in bulb onions arising from use of fluopicolide were < 0.01 mg/kg (7). The Meeting estimated a maximum residue level of 0.01* mg/kg for 2,6-dichlorobenzamide in bulb onions, together with STMR and HR values of 0.01 mg/kg.

Residues of 2,6-dichlorobenzamide in Welsh onions arising from use of fluopicolide were < 0.01 (2), and 0.01 mg/kg. The Meeting estimated a maximum residue level of 0.02 mg/kg for 2,6-dichlorobenzamide in Welsh onions, together with STMR and HR value of 0.01 mg/kg.

Brassica vegetables

In the data set for head cabbage (with wrapper leaves) used by the 2009 Meeting for fluopicolide MRL estimation and dietary risk assessment, residues of 2,6-dichlorobenzamide were < 0.01 (6), and 0.02 mg/kg.

Residues of 2,6-dichlorobenzamide in Brussels sprouts arising from use of fluopicolide were < 0.01 (8) mg/kg.

In the USA data set for broccoli used by the 2009 Meeting for MRL estimation and dietary risk assessment for Flowerhead brassicas were < 0.01 (6) mg/kg.

The Meeting noted that 2,6-dichlorobenzamide residues of < 0.01 (6), 0.02, and 0.04 mg/kg were found in head cabbage grown as a rotational crop.

The Meeting agreed to combine the head cabbage dataset for 2,6-dichlorobenzamide residues resulting from in-crop use of fluopicolide with the dataset for residues of 2,6-dichlorobenzamide in head cabbage resulting from use of fluopicolide in a preceding crop:

< 0.01 (12), 0.02 (2), and 0.04 mg/kg

Recognizing that residues of 2,6-dichlorobenzamide could occur in brassica vegetables other than cabbage grown in rotation with a crop treated with fluopicolide, the Meeting decided to estimate a group maximum residue level of 0.05 mg/kg, together with an STMR of 0.01 mg/kg and an HR of 0.04 mg/kg, based on the combined head cabbage dataset.

Fruiting vegetables, Cucurbits

In the dataset for melons used by the 2009 Meeting for estimation of a group MRL for fruiting vegetables, Cucurbits, residues of 2,6-dichlorobenzamide were not detected: < 0.01 (9) mg/kg. It is noted that residues of 2,6-dichlorobenzamide were not detected in other cucurbit crops. The Meeting estimated a group maximum residue level of 0.01* mg/kg for fruiting vegetables, Cucurbits, together an STMR and an HR of 0.01 mg/kg.

Fruiting vegetables, other than Cucurbits

In the data set in peppers, sweet and peppers, Chilli used by the 2009 Meeting to estimate a group maximum residue level for fruiting vegetables, other than Cucurbits, residues of 2,6-dichlorobenzamide were: < 0.01 (10) mg/kg. It is noted that residues of 2,6-dichlorobenzamide were not detected in other non-cucurbit fruiting vegetable crops. The Meeting estimated a group maximum residue level of 0.01* mg/kg for 2,6-dichlorobenzamide in fruiting vegetables, other than Cucurbits, together with an STMR and an HR of 0.01 mg/kg.

As residues of 2,6-dichlorobenzamide were not detected in chilli peppers treated with fluopicolide in the trials reported by the 2009 JMPR, the Meeting estimated an MRL of 0.01* mg/kg for 2,6-dichlorobenzamide in peppers, Chili, dried, together with an STMR and an HR of 0.01 mg/kg.

Leafy vegetables

The spinach data set was used by the 2009 Meeting to estimate a group MRL for leafy vegetables. Residues of 2,6-dichlorobenzamide in spinach arising from use of fluopicolide were 0.02, 0.03, 0.06, 0.07 (2), 0.09, and 0.19 mg/kg. The Meeting estimated a maximum residue level of 0.3 mg/kg for 2,6-dichlorobenzamide in leafy vegetables, together with an STMR of 0.07 mg/kg and an HR of 0.19 mg/kg.

Celery

In the dataset considered by the 2009 Meeting, residues of 2,6-dichlorobenzamide resulting from use of fluopicolide in celery were < 0.01 (4), 0.01, 0.03 and 0.04 mg/kg. The Meeting estimated a maximum residue level of 0.07 mg/kg for 2,6-dichlorobenzamide in celery, together with an STMR of 0.01 mg/kg and an HR of 0.04 mg/kg.

Rotational crops

Residues arising in rotational brassica crops are covered in the appropriate section above.

Low levels of 2,6-dichlorobenzamide residues were found in rotational pulse and cereal forages and fodders after application of fluopicolide to a preceding crop.

Residues of 2,6-dichlorobenzamide in rotational faba beans were < 0.01 (8) mg/kg.

The Meeting estimated a maximum residue level of 0.01* mg/kg for faba bean (dry), together with an STMR and an HR of 0.01 mg/kg. The Meeting agreed to extrapolate these values to establish a group maximum residue level for pulses.

Residues of 2,6-dichlorobenzamide in faba bean forage were < 0.01 (3), 0.01, 0.03, 0.06 (2), and 0.10 mg/kg (as received).

The Meeting estimated a median residue of 0.02 mg/kg, and a highest residue of 0.10 mg/kg for bean forage on an as received basis. The Meeting agreed to extrapolate these values to legume animal feeds.

Residues of 2,6-dichlorobenzamide in rotational wheat were < 0.01 (9) mg/kg.

The Meeting estimated a maximum residue level of 0.01* mg/kg for wheat, together with STMR and HR values of 0.01 mg/kg. The Meeting agreed to extrapolate these values to estimate a group maximum residue level and STMR/HR values for cereal grains.

Residues of 2,6-dichlorobenzamide in rotational wheat forage were < 0.01 (6), 0.01 (2), and 0.02 mg/kg (as received basis).

The Meeting estimated a median residue of 0.01 mg/kg and a highest residue of 0.02 mg/kg for wheat forage on an as received basis. The Meeting agreed to extrapolate these figures to cereal forage.

Residues of 2,6-dichlorobenzamide in rotational wheat hay (stalks and/or ears) were < 0.01 (6), 0.01, 0.03, and 0.06 mg/kg (as received).

As it was not clear that the samples had been dried, these values were converted to a dry weight basis assuming the 25% dry matter content for wheat forage: < 0.04 (6), 0.04, 0.12, and 0.24 mg/kg.

Residues of 2,6-dichlorobenzamide in rotational wheat straw were < 0.01 (7), 0.01, and 0.03 mg/kg on an as received basis.

Based on the hay data, the Meeting estimated a maximum residue level of 0.4 mg/kg for wheat straw and fodder, dry. The Meeting agreed to extrapolate this to straw and fodder (dry) of cereal grains.

The Meeting estimated a median residue of 0.04 mg/kg and a highest residue of 0.24 mg/kg for cereal hays based on the wheat hay data set and a median residue of 0.01 mg/kg and a highest residue of 0.03 mg/kg for cereal straws based on the wheat straw data set.

Fate of residues during processing

Plums

A processing study was provided for plums but as there was insufficient data to estimate a maximum residue level in plums, it will not be considered further.

Grapes

A processing study in grapes was provided. Grapes from a plot treated with dichlobenil at a target rate of 8.74 kg ai/ha were processed into juice and raisins, and processing factors of 1.4 and 2.8 respectively were determined for 2,6-dichlorobenzamide.

Based on the processing factor of 2.8 and the grape MRL of 0.05 mg/kg, the Meeting estimated a maximum residue level of 0.15 mg/kg for dried grapes. Based on the STMR and HR of 0.01 and 0.04 mg/kg respectively for grapes, the Meeting estimated an STMR-P of 0.028 mg/kg, and an HR-P of 0.11 mg/kg for dried grapes.

Based on the processing factor of 1.4, and the grape MRL of 0.05 mg/kg, the Meeting estimated a maximum residue level of 0.07 mg/kg for grape juice. Based on the STMR and HR values for grapes, the Meeting estimated an STMR-P of 0.014 mg/kg and an HR-P of 0.056 mg/kg.

Grape pomace is used as a feed for cattle. However, the processing study did not include results for pomace. Given that pomace consists of the dry matter remaining after manufacture of juice or wine, the Meeting estimated an STMR-P value of 0.028 mg/kg for grape pomace, dry, based on the processing data for raisins.

Tomatoes

As residues of 2,6-dichlorobenzamide were not detected in tomatoes, the Meeting confirmed the median residues and STMRs of 0.01 mg/kg estimated by the 2009 Meeting for for tomato pomace, juice, paste and ketchup.

Residues in animal commodities

Feeding studies

A feeding study for 2,6-dichlorobenzamide in lactating dairy cattle was provided to the Meeting.

Lactating Holstein dairy cow were dosed daily by capsule with 2,6-dichlorobenzamide at the equivalent of 0.6, 1.6 and 5.3 ppm in the dry weight diet for 28 consecutive days. Milk was collected throughout, and the cattle were slaughtered within 6 hours of the final dose for tissue sampling. 2,6-Dichlorobenzamide residues were found at 0.011 mg/kg in milk from the 1.6 ppm group, and at 0.031 mg/kg in milk from the 5.3 ppm group. Residues of 2,6-dichlorobenzamide were found in most tissues at all feeding levels, except for fat. The relationships between dose and residues of 2,6-dichlorobenzamide in muscle, kidney and liver were linear.

Farm animal dietary burden

Dietary burden calculations incorporating all commodities considered by the current and 2003 Meetings for beef cattle, dairy cattle, broilers and laying poultry are presented in Annex 6. The calculations are made according to the livestock diets of the USA/Canada, the European Union, Australia and Japan as laid out in the OECD table.

	US/CAN		EU		AU		Japan	
	Max.	Mean	Max.	Mean	Max.	Mean	Max.	Mean
Beef cattle	0.064	0.010	0.31	0.063	0.38	0.077	0,019	0.002
Dairy cattle	0.25	0.054	0.091	0.031	0.39	0.075	0.031	0.013
Poultry – broiler	0.009	0	0.01	0	0.012	0	0.022	0.029
Poultry – layer	0.009	0	0.096	0.017	0.012	0	0.006	0

Animal commodity maximum residue levels

The highest dietary burden for cattle is for Australia (maximum of 0.39 ppm for both beef and dairy cattle and mean values of 0.077 mg/kg for beef cattle and 0.075 mg/kg for dairy cattle).

Scaling the residues observed in milk at a feeding level of 1.6 ppm for the expected Maximum Feeding Level of 0.39 ppm shows that residues are not expected to be found above the LOQ in milk. The Meeting estimated a maximum residue level of 0.01* mg/kg for milk, together with an STMR of 0.01 mg/kg.

The calculated maximum residues for muscle, liver and kidney are tabulated below.

Tissue	Regression equation (forced through origin)	Calculated residue for 0.39 ppm residues of 2,6-dichlorobenzamide in feed (mg/kg)
Liver	y = 0.0804×	0.031
Kidney	y = 0.01×	0.004
Muscle	y = 0.0128×	0.005
Fat	Scaled from residue at LOQ (0.01 mg/kg) at 1.6 ppm feeding level	0.002

The calculated mean residues for muscle, liver and kidney are tabulated below.

Tissue	Regression equation (forced through origin)	Calculated residue for 0.075 ppm residues of 2,6-dichlorobenzamide in feed (mg/kg)
Liver	y = 0.0584×	0.004
Kidney	y = 0.0078×	0.0006
Muscle	y = 0.0114×	0.0009
Fat	Scaled from residue at LOQ (0.01 mg/kg) at 1.6 ppm feeding level	0.0004

Based on the calculated residues, the Meeting estimated a maximum residue level of 0.04 mg/kg for edible offal, mammalian, together with an STMR of 0.01 mg/kg and an HR of 0.031 mg/kg. The Meeting estimated maximum residue levels of 0.01* mg/kg for meat (mammalian, except marine mammals) and mammalian fats, together with STMR and HR values of 0.01 mg/kg.

Poultry

The highest dietary burden for poultry is for European laying hens (mean of 0.017 ppm and maximum of 0.096 ppm).

A poultry feeding study was not provided to the Meeting. In a metabolism study for 2,6-dichlorobenzamide in laying hens, after dosing at 10 ppm daily for five days, residues of 2,6-dichlorobenzamide were 8.5 mg/kg in liver, 4.8 mg/kg in kidney, 1.8 mg/kg in skin, 1.9 mg/kg in muscle, 1.3 mg/kg in fat, and 2.0 mg/kg in eggs.

Scaling the residues in hen matrices for the expected maximum and mean feeding levels in poultry, the following median and highest residues were calculated.

Tissue	Maximum residue	Median residue
Liver	0.081	0.014
Kidney	0.046	0.008
Muscle	0.018	0.003
Fat	0.012	0.002
Eggs	0.019	0.003

Based on the calculations for eggs, the Meeting estimated a maximum residue level of 0.03 mg/kg for eggs, together with an STMR of 0.01 mg/kg and an HR of 0.019 mg/kg.

Based on the calculations for liver, the Meeting estimated a maximum residue level of 0.1 mg/kg for poultry edible offal, together with an STMR of 0.014 mg/kg and an HR of 0.081 mg/kg.

Based on the calculations for muscle, the Meeting estimated an MRL of 0.03 mg/kg for poultry meat, together with an STMR of 0.01 mg/kg and an HR of 0.018 mg/kg.

Based on the calculations for fat, the Meeting estimated an MRL of 0.02 mg/kg for poultry fats, together with an STMR of 0.01 mg/kg and an HR value of 0.012 mg/kg.

RECOMMENDATIONS

Definition of the residue (for compliance with the MRL and for estimation of dietary intake for plant and animal commodities): *2,6-Dichlorobenzamide*.

The residue is not fat soluble.

DIETARY RISK ASSESSMENT

Long-term intake

The ADI for dichlobenil is 0–0.01 mg/kg bw. Finite residues of dichlobenil parent compound are not expected to be found in edible commodities, and parent compound has not been recommended for inclusion in the residue definition for dietary risk assessment. The Meeting concluded that the long-term intake of residues of dichlobenil when used in ways that have been considered by the JMPR is unlikely to present a public health concern.

The ADI for 2,6-dichlorobenzamide is 0–0.05 mg/kg bw. The International Estimated Dietary Intakes (IEDIs) for 2,6-dichlorobenzamide arising from both dichlobenil and fluopicolide were calculated for the 17 GEMS/food cluster diets using STMRs/STMR-Ps estimated by the current Meeting (see Annex 3 of the 2014 JMPR Report). The calculated IEDIs were 0–1% of the maximum ADI (0.05 mg/kg bw). The Meeting concluded that the long-term intakes of residues of 2,6-dichlorobenzamide, resulting from the uses of dichlobenil considered by the current Meeting and from the uses of fluopicolide considered by the 2009 Meeting are unlikely to present a public health concern.

Short-term intake

The ARfD for dichlobenil is 0.5 mg/kg bw (for women of childbearing age only). Finite residues of dichlobenil parent compound are not expected to be found in edible commodities, and parent compound has not been recommended for inclusion in the residue definition for dietary risk assessment. The Meeting concluded that the short-term intake of residues of dichlobenil when used in ways that have been considered by the JMPR is unlikely to present a public health concern.

The ARfD for 2,6-dichlorobenzamide is 0.3 mg/kg bw (for women of childbearing age only). The International Estimated Short-Term Intakes (IESTIs) for 2,6-dichlorobenzamide arising from dichlobenil and fluopicolide were calculated for food commodities and their processed commodities using HRs/HR-Ps or STMRs/STMR-Ps estimated by the current Meeting and by the 2009 Meeting as part of the evaluation of fluopicolide (see Annex 4 of the 2014 JMPR Report). The calculated IESTIs were 0–2% of the ARfD for all commodities. The Meeting concluded that the short-term intake of residues of 2,6-dichlorobenzamide, when dichlobenil and fluopicolide are used in ways that have been considered by the JMPR, is unlikely to present a public health concern.

5.8 DIMETHOMORPH (225)

RESIDUE AND ANALYTICAL ASPECTS

Dimethomorph is a fungicide with protective action against plant pathogenic *Phytophthora* species and a number of downy mildew diseases of fruit, vegetables and potatoes. It consists of a mixture of an E and Z isomers in approximately equal proportions. Its mode of action is through disruption of fungal cell wall formation.

Dimethomorph was evaluated for the first time by the JMPR in 2007 and the Meeting established an acceptable daily intake (ADI) of 0–0.2 mg/kg bw and an acute reference dose (ARfD) of 0.6 mg/kg bw. The residue (for compliance with the MRL and for the estimation of dietary intake) for plant and animal commodities was defined as dimethomorph (sum of isomers). Maximum residues levels for 20 commodities were proposed by the JMPR in 2007.

The current Meeting received information on supervised residue trial for dimethomorph in oranges, strawberries, grapes, papaya, bulb onions, leek, spring onions, head cabbage, broccoli, pepper, lettuce leaf, spinach, lettuce head, taro, green peas, vining peas, lima beans, artichoke, and celery. An analytical method for determination of dimethomorph in animal matrices were provided as well as validation data for an analytical method in oranges and processing studies in oranges, strawberry, onion, lettuce head, and peas.

Methods of analysis

The 2007 Meeting evaluated methods of analysis for dimethomorph in different plant and animal matrices with a LOQ of 0.01 mg/kg (LC-MS/MS or GC-NDP), LOQ of 0.02 mg/kg (GC-NDP or GC-MS) based on the multi-residue method DFG-S19.

The current Meeting received information on a new analytical method LO138/01 for dimethomorph in animal matrices. In this method dimethomorph is extracted with methanol/water/hydrochloric acid. The final determination of dimethomorph is performed by HPLC-MS/MS at two transitions. Transition m/z 388 → 301 is the target transition for quantification and transition m/z 388 →165 for confirmatory purposes. The method is suitable for measuring residues of 0.01 mg/kg for dimethomorph in milk, egg, muscle and liver.

Stability of pesticide residues in stored analytical samples

In 2007 the Meeting concluded that dimethomorph is stable (less than 10% loss of residues) under frozen conditions in stored samples in most crops and animal commodities if stored under frozen conditions at 18-24 months and 16 months, respectively.

Results of supervised residue trials on crops

Oranges

Data from supervised trials on oranges from Spain were presented to the Meeting. However, no registered GAP from Spain was available for oranges. As a result no estimation of a maximum residue level was made.

Grapes

Data from supervised trials on grapes from the USA were presented to the Meeting. The registered critical GAP in the USA is four foliar applications of 0.219 kg ai/ha and PHI of 14 days.

In twelve independent residue trials from USA matching the cGAP the residues of dimethomorph in grapes were (n=12): 0.11, 0.26, 0.41, 0.46, 0.49, 0.55, 0.65, 0.71, 0.75, 0.92, 1.77, 1.86 mg/kg.

The Meeting estimated a maximum residue level, an STMR value and an HR value for dimethomorph in grapes of 3 mg/kg, 0.60 mg/kg and 1.9 mg/kg, respectively. The Meeting replaces its previous recommendation of 2 mg/kg for a maximum residue level for grapes.

Strawberry

Data from supervised trials on strawberries were presented to the Meeting.

The critical GAP is from Belgium (protected and outdoor) with three successive root drench applications of 0.05 g ai/plant and a PHI of 35 days. No trials supporting the GAP were provided.

In Ireland the GAP (protected and outdoor) is one root drench application of 0.05 g ai/plant with a PHI of 35 days. A dataset on protected strawberries was submitted consisting of four trials with replicate plots treated either at 0.0625 g ai/plant or 0.125 g ai/plant and with four additional trials solely treated at 0.125 g ai/plant.

In four GAP compliant plots conducted at 0.0625 g ai/plant residues in strawberry fruits were (n=4): 0.03, 0.18, 0.26, 0.3 mg/kg.

In four additional trials solely conducted at 0.125 g ai/plant residues in strawberry fruits were (n=4): 0.04 (2), 0.05 and 0.21 mg/kg.

Since the four trials provided according to GAP are insufficient for an evaluation of residues in strawberries, the Meeting decided to extend the dataset by applying the proportionality approach. In accordance to the general principles outlined in the 2012 JMPR report, all residue values within and above 25% deviation from GAP were scaled to match the application rate of 0.05 g ai/plant. From replicated plots conducted at different application rates, the higher scaled residue was selected for the assessment. Scaled residues in strawberry fruits were: 0.024, 0.14, 0.21, 0.24 mg/kg (factor 0.8, based on 0.0625 g ai/plant→0.05 g ai/plant and 0.016, 0.016, 0.02, 0.084 mg/kg (factor 0.4, based on 0.125 g ai/plant→0.05 g ai/plant.

The combined scaled dataset is (n=8) 0.016, 0.016, 0.02, 0.024, 0.084, 0.14, 0.21 and 0.24 mg/kg.

Three similar outdoor trials with a PHI of 43 days from Belgium, the Netherlands and Germany were also available. The residues in these trials were for 0.125 g ai/plant (n=3) 0.01, 0.02 and 0.04 mg/kg.

For drip irrigation eight trials from Spain using 2 × 0.75 kg ai/ha with a PHI of one day were presented to the Meeting. No registered GAP from Spain was available for strawberries.

In the United Kingdom the registered GAP for outdoor is one foliar spray at 1.5 kg ai/ha applied just after planting/transplanting with a PHI of 35 days. Eight trials presented to JMPR 2007 from the Netherlands and four trials from northern Europe presented to the current Meeting match this GAP and could be combined. The residues found in these combined trials were (n=12): < 0.01mg/kg (9), 0.01, 0.02 and 0.03 mg/kg.

The highest residues came from the protected root drench treatment. Based on the combined scaled dataset from protected root drench trials for strawberries in Ireland, the Meeting estimated a maximum residue level, an STMR value and an HR value for dimethomorph for strawberries of 0.5 mg/kg, 0.05 mg/kg and 0.24 mg/kg, respectively. The Meeting replaces its previous recommendation of 0.05 mg/kg for maximum residue level for strawberry.

Papaya

Data from supervised trials on papaya from Brazil were presented to the Meeting. No registered GAP from Brazil was available for papaya. As a result no maximum residue level estimation was made.

Bulb vegetables

Bulb onion

The Meeting received results from supervised trials with dimethomorph on bulb onions. The critical GAP is for Bulb Vegetables (Garlic, Garlic great headed, Leek, Onion dry bulb, Onion green, Onion Welsh Shallot) in the USA and Canada with three foliar applications of 0.21 kg ai/ha and PHI of 0 days.

Ten independent residue trials from the USA (nine) and Canada (one) were presented on bulb onions matching the cGAP. Residues of dimethomorph in bulb onions were (n=10): 0.06, 0.08, 0.10, 0.12, 0.16, 0.18 (2), 0.23, 0.28 and 0.38 mg/kg. The highest residue of 0.40 mg/kg was measured in individual onion samples.

The Meeting estimated a maximum residue level, an STMR value and an HR value for dimethomorph in bulb onions of 0.6 mg/kg, 0.17 mg/kg and 0.40 mg/kg, respectively. The Meeting also agreed to extrapolate these estimations to shallot and garlic.

Leek

Data from supervised trials on leek were presented to the Meeting. The critical GAP is in France with two foliar applications of 0.18 kg ai/ha and a PHI of 14 days.

Eighteen independent trials from Belgium, Germany, Greece, Italy, France, the Netherlands, Spain, and the UK matching this GAP were presented. The dimethomorph residues from trials on leek in south EU were (n=4): 0.06, 0.08, 0.3 and 0.69 mg/kg and north EU (n=14): 0.01 (2), < 0.02 (2), 0.03, 0.04 (2), 0.07, 0.08 (2), 0.10 (2), 0.11, 0.13.

The combined data set is (n=18) 0.01 < 0.02 (2), 0.03 0.04 (2), 0.05, 0.06, 0.07, 0.08 (3), 0.10 (2), 0.11, 0.13, 0.30 and 0.69 mg/kg.

The Meeting estimated a maximum residue level, an STMR value and an HR value for dimethomorph in leek of 0.8 mg/kg, 0.08 mg/kg and 0.69 mg/kg, respectively.

Spring onion

Data from supervised trials on spring onion were presented to the Meeting. The critical GAP is for Bulb Vegetables (Garlic, Garlic great headed, Leek, Onion dry bulb, Onion green, Onion Welsh Shallot) in USA and Canada with three foliar applications of 0.21 kg ai/ha and a PHI of 0 days.

Six independent residue trials from the USA matched the cGAP. Residue of dimethomorph in whole plant were (n=6) 1.27, 1.56, 1.79, 2.35, 2.45 and 5.36 mg/kg. The highest residue of 6.6 mg/kg was measured in individual spring onion samples.

The Meeting estimated a maximum residue level, an STMR value and an HR value for dimethomorph in spring onion of 9 mg/kg, 2.1 mg/kg and 6.6 mg/kg, respectively. The Meeting also agreed to extrapolate this estimation to Onion, Welsh.

Brassica vegetables

Head cabbage

The Meeting received results from supervised trials with dimethomorph on head cabbage. The critical GAP is in USA with three foliar applications of 0.21 kg ai/ha and a PHI of 0 days.

Ten independent residue trials from USA matched the cGAP. Residue from dimethomorph in cabbage heads were: 0.17, 0.45, 0.46, 0.86, 1.08 (2), 1.22, 1.37 1.51 and 4.26 mg/kg (n=10). The highest residue of 4.6 mg/kg was measured in individual head cabbage samples.

The Meeting estimated a maximum residue level, an STMR value and an HR value for dimethomorph in head cabbage of 6 mg/kg, 1.1 mg/kg and 4.6 mg/kg, respectively. The Meeting replaces its previous recommendation of 2 mg/kg for maximum residue level for head cabbage.

Broccoli

Data from supervised trials on broccoli were presented to the Meeting. The critical GAP is from the USA which consists of three foliar applications of 0.21 kg ai/ha and a PHI of 0 days.

Ten independent residue trials performed in USA match the US GAP. Residues for dimethomorph in broccoli were: 0.25, 0.68, 0.74, 0.90, 0.95, 1.49, 1.62, 1.75, 1.88 and 2.33 mg/kg (n=10). The highest residue of 2.6 mg/kg was measured in an individual broccoli sample.

The Meeting estimated a maximum residue level, an STMR value and an HR value for dimethomorph in broccoli of 4 mg/kg, 1.3 mg/kg and 2.6 mg/kg, respectively. The Meeting replaces its previous recommendation of 1 mg/kg for a maximum residue level for broccoli.

Fruiting vegetables, other than cucurbits

Peppers

Data from supervised trials on pepper were presented to the Meeting. The GAP in Canada for Fruiting vegetables (tomato, eggplant, ground cherry, peppers (all varieties), pepino and tomatillo) is five foliar applications of 0.225 kg ai/ha and a PHI of 0 days.

In eleven outdoor independent residue trials in USA matching the Canadian GAP the residues of dimethomorph in peppers were: 0.04, 0.06, 0.08, 0.11, 0.13(2), 0.14, 0.25, 0.7, 0.84 and 1.05 mg/kg (n=11).

Tomato

Data from supervised trials on tomato were presented to the 2007 Meeting. The critical GAP is from Canada for Fruiting vegetable with five foliar applications of 0.225 kg ai/ha and PHI of 0 day.

In twelve outdoor independent residue **t**rials on tomato from the USA matching the cGAP the residue of dimethomorph in tomato fruit were (n=12): 0.05(2), 0.06(2), 0.07, 0.11, 0.14, 0.21, 0.3, and 0.38, 0.41 and 0.51 mg/kg.

The Meeting noted that the GAP in Canada was for fruiting vegetables, other than cucurbits, the medians of the data sets for peppers and tomatoes differed by less than 5-fold and that the residue populations were statistically similar. The Meeting therefore decided to consider recommending a crop group maximum residue level. Residue in the combined data set, matching the Canadian GAP, were: 0.04, 0.05(2) 0.06(3), 0.07, 0.08, 0.11(2), 0.13(2), 0.14(2), 0.21, 0.25, 0.30, 0.38, 0.41, 0.51 0.70, 0.84 and 1.05 mg/kg (n=23). The highest residue of 1.2 mg/kg was measured in an individual pepper sample.

The Meeting estimated a group maximum residue level, an STMR value and an HR value for dimethomorph in fruiting vegetables, other than cucurbits except mushrooms and sweet corn of 1.5 mg/kg, 0.13 mg/kg and 1.2 mg/kg, respectively.

The Meeting withdraws its previous recommendation of 1 mg/kg for fruiting vegetable, other than cucurbits except mushrooms and sweet corn.

Leafy vegetables

Lettuce, Head

Data from supervised field trials on head lettuce were presented to the Meeting. The critical GAP is from USA for Leafy vegetables, except brassica vegetables, consisting of three foliar applications at 0.19 kg/ha and a PHI of 0 days.

In fourteen independent trials from the USA matching the cGAP the residues from dimethomorph in head lettuce were: 1.08, 1.21, 1.36, 1.42, 1.46, 1.68, 1.72, 2.06, 2.3, 2.82, 3.63, 4.1, 4.37 and 6.45 mg/kg (n=14).

The Meeting noted that the US trials reported by the 2007 JMPR resulted in higher residues. The Meeting therefore, confirmed the previous recommendations made by the 2007 JMPR.

Lettuce, Leaf

Data from supervised trials on leaf lettuce were presented to the Meeting. The critical GAP is from USA for Leafy vegetables, except brassica vegetables with three foliar applications 0.19 kg/ha and a PHI of 0 days.

In nine independent trials from the USA matching the cGAP the residues from dimethomorph in lettuce leaf were: 2.09, 3.37, 3.68, 4.61, 5.19, 5.38, 5.83, 9.77 and 9.88 mg/kg (n=9). The highest residue of 10.5 mg/kg was measured in an individual lettuce sample.

The Meeting estimated a maximum residue level, an STMR value and a HR value for dimethomorph in leaf lettuce of 20 mg/kg, 5.2 mg/kg and 10.5 mg/kg.

Short-term intake assessment showed that residues in leaf lettuce exceeded the acute reference dose of 0.6 mg/kg bw by 110% for children.

Spinach

Data from supervised trials on spinach were presented to the Meeting. The critical GAP is from USA for Leafy vegetables, except brassica vegetables with three foliar applications 0.19 kg/ha and a PHI of 0 days.

In eight independent trials from the USA matching the cGAP the residues from dimethomorph in spinach leaves were: 4.69, 5.30, 5.91, 8.21, 8.35, 8.48, 10.18 and 11.26 mg/kg (n=8). The highest residue of 11.5 mg/kg was measured in individual spinach samples.

The Meeting estimated a maximum residue level, an STMR value and an HR value for dimethomorph in spinach of 30 mg/kg, 8.3 mg/kg and 11.5 mg/kg, respectively.

Taro leaves

Data from supervised trials on taro leaves from USA were presented to the Meeting. The critical GAP is five foliar applications of 0.19 kg ai/ha and PHI 7 days for use in USA except California.

Dimethomorph was applied seven times to taro at the rate of 0.225 kg ai/ha with an interval of 7–8 days. Presented residue trials from head lettuce, leaf lettuce and spinach show that residues of

dimethomorph decline significantly three days after application. The Meeting, therefore, concluded that the first two applications would not contribute significantly to the residues in leaves at harvest.

In three independent trials from USA matching the cGAP residues in taro leaves were (n=3): 1.44, 1.64 and 4.53 mg/kg. The highest residue of 5.4 mg/kg was measured in an individual taro sample.

The Meeting estimated a maximum residue level, an STMR value and an HR value for dimethomorph in taro leaves of 10 mg/kg, 1.64 mg/kg and 5.4 mg/kg, respectively.

Legume vegetable

Peas, shelled (succulent seed)

Data on supervised trials on peas were presented to the Meeting. The critical GAP is from France with two foliar applications at 0.18 kg ai/ha and a PHI of 21 days.

In twelve independent trials from north (eight) and south (four) Europe matching the cGAP residues of dimethomorph in fresh peas without pods were: < 0.01 (8), 0.016, 0.044 and 0.063 mg/kg (n=12).

The Meeting estimated a maximum residue level, an STMR value and an HR value for dimethomorph in peas without pods of 0.15 mg/kg, of 0.01 mg/kg and 0.063 mg/kg, respectively.

Lima bean

Data from supervised trials on Lima bean were presented to the Meeting. The critical GAP is from the USA with five applications at 0.19 kg ai/ha and a PHI of 0 days.

Ten independent trials matching the cGAP were conducted on Lima bean in USA. Residues of dimethomorph in beans (succulent seed without pods) (n=10) were: 0.01, 0.03(4), 0.05, 0.06, 0.08, 0.1, 0.21 and 0.47 mg/kg. The highest residue of 0.48 mg/kg was measured in an individual Lima bean sample.

The Meeting estimated a maximum residue level, an STMR value and an HR value for dimethomorph in Lima bean of 0.7 mg/kg, 0.055 mg/kg and 0.48 mg/kg, respectively.

Root and tuber vegetables

Ginseng

Data from supervised trials on ginseng were presented to the Meeting. The critical GAP from the USA, except California, is five applications of 0.19 kg ai/ha and a PHI of 14 days. Four trials were presented where dimethomorph was applied seven times at 0.225 kg ai/ha. Residue decline trials were not provided for any root and tuber vegetable to support that the first two applications did not contribute to the residues at harvest. Consequently, no maximum residue level estimation was made.

Taro root

Data on supervised trials on taro corms from Hawaii were presented to the Meeting. The critical GAP is five applications of 0.19 kg ai/ha and a PHI of 30 days in the USA, except California. Three trials were presented where dimethomorph was applied seven times at 0.225 kg ai/ha. Residue decline trials were not presented for any root and tuber vegetable to support that the first two applications not contribute to the residues at harvest. Consequently, no maximum residue level estimation was made.

Stalk and stem vegetables

Globe artichoke

Data from supervised trials on globe artichoke were presented to the Meeting. The critical GAP from France is three foliar applications of 0.18 kg ai/ha and PHI of 3 days.

In ten independent trials from Europe matching the French GAP residues of dimethomorph in artichoke heads were in North Europe (n=5) 0.11, 0.24, 0.26, 0.55 and 0.75 mg/kg and in South EU (n=5) 0.06, 0.09, 0.14, 0.32 and 1.14 mg/kg.

The combined data set was (n=10): 0.06, 0.09, 0.11, 0.14, 0.24, 0.26, 0.32, 0.55, 0.75 and 1.14 mg/kg.

The Meeting estimated a maximum residue level, an STMR value and an HR value for dimethomorph in globe artichoke of 2 mg/kg, 0.25 mg/kg and 1.14 mg/kg, respectively.

Celery

Data from supervised trials on celery were presented to the Meeting. The critical GAP is from the USA with three foliar applications of 0.21 g ai/ha and a PHI of 0 days.

In nine independent trials from Canada (two) and from USA (seven) matching the cGAP residues of dimethomorph in leaf stalks were (n=9): 1.27, 1.55, 1.85, 1.91, 2.44, 3.27, 4.02, 5.54 and 8.21 mg/kg.

The highest residue of 8.8 mg/kg was measured from an individual celery sample.

The Meeting estimated a maximum residue level, an STMR value and an HR value for dimethomorph in celery of 15 mg/kg, 2.44 mg/kg and 8.8 mg/kg, respectively.

Animal feeds

Pea forage

Data on supervised trials on peas were presented to the Meeting. The critical GAP is from France with two foliar applications at 0.18 kg ai/ha and a PHI of 21 days. However, the residues (10) 28 days after the second treatment were found to be higher and were used for animal burden calculation: 0.42, 0.59, 1.57, 1.59, 1.88, 2.40, 4.60, 4.97, 5.45 and 9.58 mg/kg.

The Meeting estimated in pea forage a median residue of 2.14 mg/kg (fresh weight) and a highest residue of 9.58 mg/kg (fresh weight).

Fate of residue during processing

The Meeting received information on processing of oranges, strawberries, onions, lettuce head and peas.

Processing factors calculated for the processed commodities for the above raw agricultural commodities, including previously estimated, are shown in the table below. STMP-Ps was calculated for processed commodities of strawberry, onion and peas for which maximum residue levels were estimated.

Processed commodity	Processing factor	PF (Best estimate)	STMR-P	HR-P
Strawberry, jam	0.24, 0.43, 0.44, 0.54	0.435	0.02	
Strawberry, canned	0.57, 1, 1.21, 1.52	1.11	0.0555	
Onions, raw without skin	0.02, 0.04, 0.12, 0.34	0.08	0.014	0.032

Processed commodity	Processing factor	PF (Best estimate)	STMR-P	HR-P
Dried onion	0.03, 0.12, 0.04, 0.34	0.13	0.022	0.053
Peas (cooked)	0.08, 0.17, 0.24, 0.26	0.21	0.002	
Peas (canned)	0.06, 0.08, 0.20, 0.24	0.14	0.0014	

*estimated by 2007JMPR Meeting
** PF =processing factor

The Meeting confirmed its previous maximum residue level estimation of 5 mg/kg for dried grapes.

Residues in animal commodities

Farm animal dietary burden

Dietary burden calculation for beef cattle, dairy cattle, broilers and laying poultry based on feed items evaluated by JMPR in 2007 and 2014 are provided in table below. The calculations were made according to the livestock diets from US-Canada, EU, Australia and Japan according to OECD feeding table. Noting that fresh forage commodities are not significant in international trade, the Meeting only included the burden contributions from the pea forages in the European dietary burden calculation, as dimethomorph is not authorised for use on peas in US-Canada, Australia or Japan.

Dietary burden calculations for beef cattle, dairy cattle, broilers and laying poultry are presented in Annex 6 and are summarised below.

Estimated maximum and mean dietary burden of farm animals Summary (ppm of dry matter diet)

	US-Canada		EU		Australia		Japan	
	max	mean	max	mean	max	mean	max	mean
Beef cattle	0.4	0.3	14.2 [a]	3.6 [c]	2.6	2.6	0.007	0.007
Dairy cow	0.1	0.1	14.1 [b]	3.5 [d]	2.6	2.6	0.01	0.01
Poultry-broiler	0.002	0.002	0.06	0.05	0.04	0.04	0.002	0.002
Poultry layer	0.002	0.002	5.4 [e g]	1.27 [f h]	0.04	0.04	0.007	0.007

[a] Highest maximum beef or dairy cattle dietary burden suitable for MRL estimates for mammalian tissues
[b] Highest maximum dairy cattle dietary burden suitable for MRL estimates for mammalian milk
[c] Highest mean beef or dairy cattle dietary burden suitable for STMR estimates for mammalian tissues.
[d] Highest mean dairy cattle dietary burden suitable for STMR estimates for milk.
[e] Highest maximum poultry dietary burden suitable for MRL estimates for poultry tissues.
[f] Highest mean poultry dietary burden suitable for STMR estimates for poultry tissues.
[g] Highest maximum poultry dietary burden suitable for MRL estimates for poultry eggs.
[h] Highest mean poultry dietary burden suitable for STMR estimates for poultry eggs

For beef and dairy cattle, the calculated maximum dietary burdens suitable for estimating maximum residue levels in mammalian tissues and milk are 14.2 and 14.1 ppm dry weight of feed respectively.

The calculated mean dietary burden, suitable for estimating STMRs in mammalian tissues and in milk is 3.6 and 3.5 ppm, dry weight of feed, respectively.

In the cattle feeding study evaluated by JMPR in 2007 where lactating cows were dosed at 37.5 ppm (approximately 40% higher than estimated maximum burden) no residues of parent dimethomorph were detected in edible tissue or milk. Therefore the Meeting concluded that no residues are to be expected at the maximum calculated dietary burden for ruminants.

The calculated maximum dietary burden suitable for estimating maximum residue levels in poultry tissues and eggs is 5.4 ppm dry weight of feed and the calculated mean dietary burden, suitable for estimating STMRs in poultry tissues and in eggs is 1 ppm dry weight of feed.

In the metabolism study where laying hens were fed the equivalent of 40 ppm in the feed for seven days, dimethomorph residues in fat and skin were < 0.02 mg/kg and were not detected in tissue or eggs. On the basis that the maximum calculated dietary burden is eight times lower than the dose rate in the metabolism study the Meeting concluded that no residues of dimethomorph are to be expected at the maximum calculated dietary burden for poultry.

The Meeting confirmed the previous recommendations for animal commodities.

RECOMMENDATIONS

On the basis of the data from supervised residue trials the Meeting concluded that the residue levels listed below are suitable for establishing maximum residue limits and for the IEDI and IESTI assessment.

Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities: dimethomorph (sum of isomers).

The residue is not fat soluble.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Daily Intakes (IEDI) of dimethomorph, based on the STMRs estimated for 30 commodities, for the 17 cluster diets were in the range of 0–2% of maximum ADI (0.2 mg/kg bw), see Annex 3 to the 2014 Report. The Meeting concluded that the long-term intake of residues of dimethomorph resulting from its uses that have been considered by JMPR is unlikely to present a health concern.

Short-term intake

The WHO Panel of the 2007 JMPR established an Acute Reference Dose (ARFD) of 0.6 mg/kg bw for dimethomorph.

The International Estimated Short Intake (IESTI) for dimethomorph was calculated for new food commodities and their processed fractions for which maximum residue levels were estimated and for which consumption data were available, see Annex 4 to the 2014 Report.

For lettuce leaf, the IESTI represented 110% of the ARfD of 0.6 mg/kg bw. On the basis of the information provided to the JMPR it was not possible to conclude that the estimate of the short-term intake of dimethomorph, from the consumption of lettuce leaf, was less than the ARfD. The Meeting noted than an alternative GAP for lettuce leaf was not available.

For the other commodities the IESTI for dimethomorph calculated on the basis of recommendations made by the JMPR represented 0–90% of the ARfD (0.6 mg/kg bw) for children and 0–30% for the general population.

The Meeting concluded that except for lettuce leaf, the short-term intake of residues of dimethomorph, when used in ways that have been considered by the JMPR is unlikely to present a public concern.

5.9 DITHIOCARBAMATES (105) / MANCOZEB (050)

RESIDUE AND ANALYTICAL ASPECTS

Mancozeb was evaluated in 1993 in the CCPR periodic review programme. Since then, in 2012, the Meeting evaluated residue data on mancozeb and maneb, however, made no recommendation for MRLs. Currently, a number of MRLs for dithiocarbamates are established based on the residue data derived from use of mancozeb, maneb, metiram, thiram, ziram and propineb.

Dithiocarbamates-Mancozeb was listed by the Forty-fifth Session of the CCPR (2013) for the evaluation of additional MRL in 2014 JMPR. The Meeting received supervised residue trial data from Thailand (chili pepper) and the Republic of Korea (ginseng and the processed products). In addition, India submitted monitoring data on spices (cardamom, coriander, cumin, fennel and black pepper).

The mancozeb residue is defined as total dithiocarbamates, determined as CS_2, evolved during acid digestion and expressed as mg CS_2/kg, for compliance with MRLs. Dithiocarbamate residues are not fat soluble.

In 1993, the JMPR established a group (or in any combination) ADI of 0–0.03 mg/kg bw for ethylene-bis-dithiocarbamates (EBDCs: mancozeb, maneb, metiram and zineb) and an ADI of 0–0.004 mg/kg bw for their metabolite ethylenethiourea (ETU). The parent EBDC and ETU are defined as the residues for evaluating dietary intake. The Meeting is assessing combined residues of mancozeb and ETU using the ratio of the ADIs (7.5) to express residues in terms of mancozeb-toxicity-equivalents (MTE).

Methods of analysis

The analytical method used for the determination of dithiocarbamates in chili pepper was considered by the JMPR in 1995. According to the method, dithiocarbamate residues in chili pepper were converted to CS_2 by treatment with hydrochloric acid in the presence of stannous chloride. The CS_2 in the head-space was determined by GC-ECD and the limit of quantification was 0.05 mg CS_2/kg. The validity of the analytical results was supported by a set of recovery test and procedural recoveries.

Mancozeb and ETU in ginseng and its processed products were directly measured using analytical method ABY0064.

The method ABY0064 is based on the direct determination, by HPLC-MS/MS, of a derivatized EBDC (EBDC-dimethyl produced by *S*-methylation). In the method, disodium EDTA and iodomethane are used for decomposing and methylating EBDC compounds, and then the extracts are cleaned up with C_{18} SPE cartridge. In the mass analysis, individual EBDCs are distinguished using compound-specific transition ions.

The method ABY0064 was fully validated with analytical matrices of orange, olive and their processed products. The recoveries of mancozeb were within an acceptable range (70–120%) at fortification levels of 0.01 mg/kg and 0.1 mg/kg. The LOQs were 0.01 mg/kg. In ginseng residue trials, procedural recoveries were acceptable and the LOQs were 0.01 mg/kg or 0.02 mg/kg.

A method developed for determination of ETU was fully validated for the same matrices used in a validation study of ABY0064. The recoveries and RSDs were within an acceptable range at fortification levels of 0.01 mg/kg and 0.1 mg/kg and the LOQs were 0.01 mg/kg. In ginseng residue trials, procedural recoveries were acceptable and the LOQs were 0.01 mg/kg.

Spectrometry was used for the analysis of dithiocarbamates in spices. Dithiocarbamate residues in spices were converted to CS_2 and two cupric complexes of N,N-bis (2-hydroxyethly) dithiocarbamic acid, which were measured at 453 nm. LOQs of dithiocarbamates in spices (cardamom, coriander, cumin, fennel and pepper) were 0.1 mg/kg. At fortification levels of 0.1–1.0 mg CS_2/kg, recoveries were 88–110% in cumin, coriander, fennel, cardamom and black pepper.

Stability of residues in stored analytical samples

Storage stability tests for ginseng samples were performed simultaneously with freezer storage of field trial samples or processed samples. Mancozeb and ETU residues were stable during the study period, 103 days until analysis of mancozeb and ETU for fresh ginseng and 11–100 days (mancozeb analysis) or 55–100 days (ETU analysis) for the processed products.

In residue trials of chili pepper, analysis of mancozeb, as CS_2, was conducted on the day the samples were harvested.

Results of supervised trials on crops

The MRLs for mancozeb are expressed as CS_2. For trials using the headspace method, residues are reported in terms of CS_2. For trials using the HPLC-MS/MS method, residues are reported as mancozeb and ETU. For those trials, maximum residue estimates are made by converting mancozeb to CS_2-equivalents.

To estimate dietary intakes, residues are expressed in terms of mancozeb toxicity-equivalents (MTE). The conversion factor for ETU to MTE is the ratio of the ADI for mancozeb to that of ETU, which is 7.5. Thus, when residues were measured as mancozeb and ETU, the total MTE was estimated by multiplying the ETU residue by 7.5 and adding the result to the measured mancozeb residue. The resulting ETU-equivalent was then converted to MTE using the 7.5 factor. The molecular weights of these compounds are CS_2=76.1 g/mol, ETU=102.2 g/mol, and mancozeb=541.0 g/mol, assuming that the 2 moles of ETU are formed from one mole of mancozeb, leading to the following conversion factors:

CS_2 mancozeb equivalent: 541.045/(4×76.139)= 1.777 × CS_2 mg/kg

Mancozeb MTE equivalent is: mancozeb mg/kg (measured as mancozeb)

MTE for ETU = 7.5×ETU mg/kg

MTE for combined residues of mancozeb measured as CS_2 mg/kg and ETU mg/kg:

$MTE_{(MCZ+ETU)}$ = 1.777× CS_2 mg/kg + 7.5× ETU mg/kg

Fruiting vegetables, other than Cucurbits

Peppers, Chili

Mancozeb is registered in Thailand for use on chili peppers at a GAP of 3 x 0.4 kg ai/hL, with 5 day intervals and a PHI of 7 days. A total of six trials were conducted in Thailand in 2005–2008, matching the GAP.

The residues, as CS_2 were (n=6): 0.31, 0.48, 0.75, 0.80, 1.2 and 1.7 mg CS_2/kg.

The Meeting estimated a maximum residue level of 3 mg CS_2/kg, an STMR of 1.4 mg MTE/kg and an HR of 3.0 mg MTE/kg for chili pepper. Using the default factor of 7 for dried chili pepper, the Meeting estimated a maximum residue level of 20 mg CS_2/kg, a STMR-P of 9.8 mg MET/kg and an HR-P of 21 mg MET/kg for dried chili pepper.

Root and tuber vegetables

Ginseng

Mancozeb is registered in the Republic of Korea for use on ginseng at a GAP of 5×0.12 kg ai/hL, with 10 day intervals and a PHI of 45 days. Four trials matching the GAP conducted in the Republic of Korea in 2013 were submitted. Two trials were conducted on the same dates of application in sites

closely located and with the same application method; therefore, the trials are not considered to be independent. Only three trials could be considered for estimation of a maximum residue level.

The measured concentrations of mancozeb in ginseng were (n=3): 0.05, 0.05 and 0.11 mg/kg, which is equivalent to 0.028, 0.028 and 0.062 mg/kg as CS_2.

The measured concentrations of ETU in ginseng were (n=3): < 0.01, 0.01 and 0.04 mg/kg.

The Meeting estimated a maximum residue level of 0.15 mg CS_2/kg.

For dietary intake, the STMR is 0.125 mg MTE/kg and the HR is 0.41 mg MTE/kg.

Results of monitoring studies on spices

Monitoring of spices was conducted for dithiocarbamates in India during 2009–2014. Residues in spices came from the use of mancozeb and other dithiocarbamates. Spice samples were analysed based on the determination of CS_2.

The numbers of samples analysed were: 383 for cumin seed, 1,037 for cardamom, 248 for coriander seed, 272 for black pepper and 286 for fennel seed.

In all of the cardamom (1,037 samples) and black pepper (272 samples), CS_2 residues were < 0.1 mg/kg.

In coriander seed, CS_2 residues were < 0.1 (247), 0.4 mg CS_2/kg.

In fennel seed, CS_2 residues were < 0.1 (283), 1.1, 2.0 and 2.8 mg CS_2/kg.

In cumin seed (383 samples), CS_2 residues ranged from 0.11 mg/kg to 17 mg CS_2/kg, with a median of 3.6 mg CS_2/kg.

For compliance, the Meeting estimated maximum residue levels of 0.1 mg CS_2/kg for black pepper, cardamom, coriander seed, and fennel seed, and 10 mg CS_2/kg for cumin seed. The Meeting noted that the maximum residue estimate covers at least 98% of the observed residues.

For dietary intake, the Meeting estimated STMRs of < 0.18 mg MTE/kg for black pepper, cardamom, coriander seed, and fennel seed, and 6.4 mg MTE/kg for cumin seed.

Fate of residues during processing

The Meeting received information on the fate of mancozeb residues during the processing of ginseng. Conversion of residues to their CS_2, mancozeb, and/or ETU equivalents was done, as needed, as described above for supervised residue trials.

RAC and processed	Pf, best estimate		STMRRAC		Median-P		HRRAC		Highest residue-P	
	mancozeb	ETU*	mancozeb (mg/ kg)	ETU (mg/kg)	mancozeb (mg /kg)	ETU equiv. (mg/kg)	mancozeb (mg/ kg)	ETU (mg/kg)	mancozeb (mg /kg)	ETU equiv. (mg/kg
Ginseng			0.05	0.01			0.11	0.04		
Ginseng, dried including red ginseng	1.5	4.2			0.075	0.1197			0.17	0.3389

* Fraction yield of ETU = $[ETU]_{proc}/([ETU]_{rac} + 0.378\times[mancozeb]_{rac})$

In dried ginseng, each processing factor for mancozeb, ETU and CS_2 residue was calculated as follows:

For mancozeb, the concentration of mancozeb in dried ginseng was divided by the concentration of mancozeb in fresh ginseng.

For ETU, the concentration of ETU in dried ginseng was divided by the sum of ETU and mancozeb (expressed as ETU equivalents) in fresh ginseng in order to account for mancozeb as a potential source of ETU during processing. The stoichiometric conversion factor for mancozeb to ETU is 0.377 (102.2 g ETU/mol ÷ 271.2 g mancozeb/mol).

For compliance, the Meeting estimated a maximum residue level of 0.3 mg CS_2/kg, based on a maximum residue level of 0.15 mg CS_2/kg for ginseng and the processing factor of dried ginseng, 1.5 (1.5×0.15=0.225 mg/kg).

For dietary intake, the Meeting estimated an STMR-P of 0.075+7.5×0.1197=0.97 mg MTE/kg and an HR-P of 0.17+7.5×0.33894=2.71 mg MTE/kg.

RECOMMENDATIONS

On the basis of the data from supervised trials the Meeting concluded that the residue levels listed below are suitable for establishing maximum residue limits and for IEDI and IESTI assessment.

The mancozeb residue is defined as total dithiocarbamates, determined as CS_2, evolved during acid digestion and expressed as mg CS_2/kg, for compliance with MRLs in plant and animal commodities.

For estimation of dietary intake in plant and animal commodities, the residue definition is mancozeb and ETU.

Dithiocarbamate residues are not fat soluble.

DIETARY RISK ASSESSMENT

Long-term intake

A group ADI (or in any combination) for ethylene-bis-dithiocarbamates (EBDCs: mancozeb, maneb, metiram and zineb) is 0–0.03 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for mancozeb were estimated based on the 17 GEMS/Food Consumption Cluster Diets using only the STMR or STMR-P values estimated by the current JMPR. The results are shown in Annex 3 of the 2014 JMPR Report. The IEDIs ranged 0-6% of the maximum ADI. The Meeting concluded that the long-term intake of residues of mancozeb from uses added by the current JMPR is unlikely to present a public health concern.

Short-term intake

The ARfD for mancozeb and its metabolite ETU is not available currently. The Meeting noted that the dithiocarbamates were last evaluated in 1993 before the ARfD established by the JMPR.

5.10 EMAMECTIN BENZOATE (247)

TOXICOLOGY

As a result of a question raised by the 78th Meeting of JECFA in 2013 (see section 3.2.1), the present Meeting re-evaluated the acute toxicity of emamectin benzoate.

Toxicological evaluation

The Meeting agreed to withdraw the ARfD of 0.03 mg/kg bw, established in 2011, and established an ARfD of 0.02 mg/kg bw, on the basis of the absence of clinical signs of neurotoxicity after 7 days of treatment with 1.5 mg/kg bw in 5-week and 14-week studies in dogs, and applying a safety factor of 100. The Meeting considered that application of an additional safety factor was not necessary because clinical signs did not occur at 1.5 mg/kg bw given for 7 days and because in a 5-week special neurotoxicity study, using a limited number of dogs, no signs of neuropathology were observed after 7 days of treatment with 1.5 mg/kg bw per day.

An addendum to the toxicological monograph was not prepared.

RESIDUE AND ANALYTICAL ASPECTS

Emamectin benzoate is a insecticide derivative of abamectin. Emamectin benzoate was first evaluated by the JMPR in 2011 for toxicology and residues. The 2011 Meeting established an ADI of 0–0.0005 mg/kg bw, expressed as emamectin benzoate. The ARfD was re-evaluated by the 2014 JMPR which reduced the ARfD to 0.02 mg/kg bw expressed as emamectin benzoate. The 2011 Meeting defined the residue as emamectin B1a benzoate for plant and animal commodities for compliance with the MRL and for estimation of dietary intake. Since the molecular weight difference between emamectin B1a benzoate and emamectin benzoate (consisting of 90% emamectin B1a benzoate and 10% emamectin B1b benzoate) is marginal, residues are not corrected for molecular weight. The 2011 Meeting considered the residue not fat soluble.

Emamectin benzoate was scheduled by the Forty-fifth Session of the CCPR (2013) for the evaluation of additional maximum residue levels by the 2014 JMPR. The manufacturer submitted additional supervised residue trials on almonds, pecans and rape, which were evaluated by the present Meeting.

Methods of Analysis

The Meeting received description and validation data for an analytical method for emamectin B1a and B1b benzoate and its 8,9-ZMa isomer in rape commodities for use in supervised residue trials. The analytical method is based on extraction with acidified acetonitrile and analysis by HPLC-MS/MS. The Meeting considered the method valid in the range 0.005–0.05 mg/kg emamectin B1a in rape seeds.

The analytical method for the determination of residues in almonds, pecans and almond hulls was considered valid by the 2011 Meeting.

Stability of pesticide residues in stored analytical samples

Storage stability studies were provided to the 2011 Meeting demonstrating the stability of emamectin B1a benzoate for at least 27 months at -20 ºC or lower in stored plant commodities with high water

content, 18 months in plant commodities with high starch content and at least 9 months in plant commodities with high oil content.

All crop commodities from supervised residue trials were analysed within the verified storage stability period. Oilseeds and rape forage were stored at -2 ºC. Since parent is shown to be stable for a long period of time, trials where temperatures during storage were raised to -2 °C, were not rejected.

Results of supervised residue trials on crops

The Meeting received supervised trials data for emamectin benzoate on rape forage, tree nuts, rape seed and almond hulls. In addition, the 2011 JMPR trials on lettuces were re-evaluated by the present Meeting because of an ARfD exceedance for leaf lettuce.

Lettuce

The International Estimated Short Term Intake (IESTI) for emamectin benzoate was recalculated as the ARfD was changed from 0.03 to 0.02 mg/kg bw and a revised IESTI calculation model was available at the 2014 Meeting. The IESTI for the diets submitted to the JMPR represented 0–190% of the ARfD (0.02 mg/kg bw, expressed as emamectin benzoate) for children. The ARfD is exceeded for leaf lettuce (total, i.e., raw and processed commodities) in the diet for children.

At the 2011 JMPR, maximum residue levels for head lettuce, leaf lettuce and Cos lettuce were recommended based on head lettuce data, of 1 mg/kg respectively. The present Meeting re-evaluated the separate datasets for head lettuce, Cos lettuce and leaf lettuce that were available to the 2011 JMPR. The leaf lettuce dataset was considered insufficient to recommend a maximum residue level (n=1–3, depending on the GAP used). The Cos lettuce dataset could however be used to propose a maximum residue level for leaf lettuce and Cos lettuce. The Meeting decided to retain the previous recommendation for head lettuce (current Codex MRL of 1 mg/kg) based on head lettuce data and to propose a new maximum residue level for Cos lettuce and leaf lettuce, based on the Cos lettuce data.

The 2011 Meeting agreed to combine the dataset for indoor and field grown Cos lettuce matching the Italian GAP (3 foliar spray applications, interval 7 days, 14.2 g ai/ha with a 3 day PHI) to represent residues in field and indoor grown Cos lettuce. This resulted in the following dataset: 0.030, 0.033, 0.042, 0.052, 0.10, 0.11, 0.30 and 0.33 mg/kg (n=8).

The present Meeting agreed that the dataset for Cos lettuce matching Italian GAP could be used to support a maximum residue level recommendation for Cos lettuce and leaf lettuce. The Meeting decided to withdraw its previous recommendations for Cos lettuce and leaf lettuce of 1 mg/kg and estimated a new maximum residue level 0.7 mg/kg for Cos lettuce and leaf lettuce. The Meeting estimated an STMR of 0.076 mg/kg and a HR of 0.33 mg/kg.

Tree nuts

The 2011 JMPR Meeting was unable to estimate a maximum residue level for almonds or pecans as the dataset was considered insufficient. Additional trials were submitted to the present Meeting and these were combined with the trials evaluated by the 2011 JMPR.

Field trials involving almonds were performed in the USA.

Critical GAP for tree nuts in the USA is for three foliar spray applications at 16.8 g ai/ha (maximum of 50.4 g ai/ha per season, interval 7 days) and a PHI of 14 days, with adjuvant. In almond trials from the USA (3 × 17 g ai/ha; interval 7 days and a 14 day PHI, applied with adjuvant) matching US GAP emamectin B1a benzoate residues in almonds (nutmeat) were: < 0.001 (4) mg/kg (including 1 value from the 2011 JMPR).

Field trials involving pecans were performed in the USA.

Critical GAP for tree nuts in the USA is for three foliar spray applications at 16.8 g ai/ha (maximum of 50.4 g ai/ha per season, interval 7 days) and a 14 day PHI, with adjuvant. In pecan trials from the USA (3 × 17 g ai/ha; interval 7 days and PHI 14 days, with adjuvant) matching US GAP emamectin B1a benzoate residues in pecans (nutmeat) were < 0.001 (5) mg/kg (including 1 value from the 2011 JMPR).

The Meeting agreed that the dataset for almonds and pecans matching USA GAP could be used to support a maximum residue level recommendation for tree nuts, and estimated a maximum residue level of 0.001* mg/kg in/on tree nuts and estimated an STMR of 0.001 mg/kg and an HR of 0.001 mg/kg.

Rape seed

Field trials involving rape were performed in Australia. Rape seeds were harvested using three different techniques: natural desiccation, herbicide desiccation, and wind-rowing. In natural desiccation seeds were collected after the plants had dried off naturally. Herbicide desiccation involves the use of a herbicide to dry off the green plant followed by seed collection up to 15 days later. Wind-rowing involves the cutting of the green crop and laying it in the rows to dry, followed by seed collection up to 15 days later. Since no residues were found in rape seeds in any of these trials, the impact of the harvest technique could not be assessed. Therefore, trials matching cGAP were selected irrespective of the harvest technique. Trials where the seeds were collected at the day of cutting (wind-rowing technique) or at the day of desiccation (herbicide desiccation technique) were excluded, since in this case the seeds were harvested from the green plant and such samples are not representative for maximum residue level derivation.

Critical GAP for rape in Australia is for two foliar spray applications at 5.1 g ai/ha with an unspecified interval and PHI 14 days. In rape trials from Australia (2 × 5.3–6.1 g ai/ha; interval 6–9 days and PHI 13–17 days, with adjuvant) matching this GAP emamectin B1a benzoate residues in rape seeds were < 0.005 (6) mg/kg. Trials at higher dose rate and shorter PHI (2× 11–13 g ai/ha, interval 5–8 days and PHI 5–8 days) confirmed the non-residue situation: < 0.005 (4) mg/kg.

The Meeting agreed that the dataset for rape matching Australian GAP could be used to support a maximum residue level recommendation for rape seeds, and estimated a maximum residue level of 0.005* mg/kg in/on rape seed and estimated an STMR of 0 mg/kg. An HR is not considered necessary, since bulking/blending of the seeds is likely for a pre-harvest application.

Almond hulls

The 2011 JMPR Meeting was unable to estimate a maximum residue level for almond hulls as the dataset was considered insufficient. Additional trials were submitted to the present Meeting and these were combined with the trials evaluated in the 2011 JMPR report.

Field trials involving almonds were performed in the USA. Three spray concentrations were tested in one trial: very concentrated (for aircraft equipment), concentrated (for airblast equipment) and dilute (for ground equipment). In this one trial, the highest residue was found for the concentrated spray concentration as used for airblast equipment: 0.088 mg/kg versus 0.057–0.059 mg/kg. Since one trial is not sufficient to conclude on the effect of spray concentration and a second trial, where a concentrate spray concentration was used, produced much lower residues (0.018 mg/kg), the Meeting decided to take the highest residue from each location irrespective of the spray concentration.

Critical GAP for tree nuts in the USA is for three foliar spray applications at 16.8 g ai/ha (maximum of 50.4 g ai/ha per season, interval 7 days) and PHI of 14 days, with adjuvant. In almond trials from the USA (3 × 17 g ai/ha; interval 7 days and PHI 14 days, with adjuvant) matching this GAP emamectin B1a benzoate residues in almond hulls were 0.018, 0.020, 0.043, 0.088 mg/kg (n=4),

as received (including 1 value from the 2011 JMPR). Since the dry weight for almond hulls is 90%, no dry weight correction is needed.

The Meeting agreed that the dataset for almond hulls matching USA GAP could be used to support a maximum residue level recommendation for almond hulls, and estimated a maximum residue level of 0.2 mg/kg in/on almond hulls and estimated a median residue of 0.0315 mg/kg. A highest residue is not considered necessary, since bulking/blending of the hulls is likely for use as feed commodity.

Rape forage

Field trials involving rape forage were performed in Australia. The only GAP available on rape is from Australia and this GAP contains a restriction not to use emamectin benzoate on rape grown as forage crop (i.e., rape forage). The Meeting decided not to use the trials.

Residues in animal commodities

The Meeting estimated the dietary burden of emamectin benzoate residues on the basis of the livestock diets listed in the FAO manual appendix IX (OECD feedstuff table). Calculation from highest residue, STMR (some bulk commodities) and STMR-P values provides the levels in feed suitable for estimating maximum residue levels, while calculation from STMR and STMR-P values from feed is suitable for estimating STMR values for animal commodities.

The 2014 JMPR Meeting recalculated the livestock dietary burden based on the uses presented by the 2011 JMPR and including the residue values for almond hulls from the 2014 JMPR Meeting. The maximum dietary burden for cattle for maximum residue level setting is not changed, while the mean dietary burden for cattle changed only marginally from 0.018 ppm in the 2011 JMPR Meeting to 0.021 ppm in the 2014 JMPR Meeting. Poultry is not exposed to emamectin benzoate through feed treated with emamectin benzoate. The Meeting therefore confirmed its previous recommendations for animal commodities.

RECOMMENDATIONS

On the basis of the data from supervised trials the Meeting concluded that the residue levels listed below are suitable for establishing maximum residue limits.

Definition of the residue for compliance with the MRL and for dietary risk assessment for plant and animal commodities: *emamectin B1a benzoate*

The Meeting considers the residue not fat soluble.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Daily Intakes (IEDI) for emamectin benzoate was calculated from recommendations for STMRs for raw and processed commodities in combination with consumption data for corresponding food commodities. The results are shown in Annex 3.

The IEDI of in the 17 GEMS/Food cluster diets, based on the estimated STMRs in the 2011 and 2014 JMPR represented 1–9% of the maximum ADI of 0.0005 mg/kg bw, expressed as emamectin benzoate. No conversion factor is needed to convert emamectin B1a benzoate residues to emamectin benzoate residues.

The Meeting concluded that the long-term intake of residues of emamectin benzoate from uses considered by the 2011 and 2014 Meeting is unlikely to present a public health concern.

Short-term intake

The International Estimated Short Term Intake (IESTI) for emamectin benzoate was recalculated due to the ARfD being changed from 0.03 to 0.02 mg/kg bw and the availability of a revised IESTI calculation model at the present Meeting. The IESTI was calculated from recommendations for STMRs and HRs for raw and processed commodities evaluated in the 2011 and 2014 JMPR Meeting in combination with consumption data for corresponding food commodities. The results are shown in Annex 4 to the 2014 Report.

The IESTI for the general population represented 0–30% of the ARfD (0.02 mg/kg bw, expressed as emamectin benzoate) and the IESTI for children represented 0–30% of the ARfD. No conversion factor is needed to convert emamectin B1a benzoate residues to emamectin benzoate residues.

The Meeting concluded that the short-term intake of residues of emamectin benzoate from uses considered by the 2011 and 2014 Meeting are unlikely to present a public health concern.

5.11 FENAMIDONE (264)

TOXICOLOGY

Fenamidone was evaluated by JMPR in 2013, when an ADI of 0–0.03 mg/kg bw and an ARfD of 1 mg/kg bw were established. The 2013 Meeting also evaluated toxicological data on the metabolites RPA 412636, RPA 410193 and RPA 412708, which are found in crops. Metabolites RPA 412636 and RPA 412708 are also present in rat urine and bile, respectively, whereas metabolite RPA 410193 is a novel plant metabolite. The 2013 Meeting concluded that these three metabolites are toxicologically significant but made no explicit statement about their respective potencies relative to fenamidone or the applicability of the ADI and ARfD for fenamidone to these metabolites.

Toxicological data on metabolites and/or degradates

Table 1 summarizes the toxicological data on fenamidone and the metabolites evaluated by the 2013 JMPR.

Table 1 Toxicological profile of fenamidone and its metabolites

Metabolite	Description	Toxicological profile
RPA 412636	Rat urine metabolite (< 1% of an administered dose)	Oral LD_{50} = 1 520 mg/kg bw (rat)
		Unlikely to be genotoxic
		14-day study of toxicity: NOAEL = 90 mg/kg bw per day (rat)
		90-day study of toxicity: NOAEL = 6.4 mg/kg bw per day (rat)
RPA 410193	Novel plant metabolite	Oral LD_{50} > 2 000 mg/kg bw (rat)
		Unlikely to be genotoxic
		14-day study of toxicity: NOAEL = 30 mg/kg bw per day (rat)
		90-day study of toxicity: NOAEL = 93.3 mg/kg bw per day (rat)
RPA 412708	Rat bile metabolite (> 10% of an administered dose)	Oral LD_{50} = 100–200 mg/kg bw (rat)
		Unlikely to be genotoxic
		14-day study of toxicity: NOAEL = 147.3 mg/kg bw per day (rat)
Fenamidone	Parent compound	Oral LD_{50} > 2 000 mg/kg bw (rat)
		30-day study of toxicity: NOAEL = 30 mg/kg bw per day (rat)
		90-day study of toxicity: NOAEL = 73.5 mg/kg bw per day (rat)
		2-year study of toxicity: NOAEL = 2.8 mg/kg bw per day (rat)

Toxicological evaluation

The current Meeting concluded that RPA 412636 is an order of magnitude more toxic than fenamidone over 90 days of dietary exposure in rats and that RPA 412708 is an order of magnitude more acutely toxic than fenamidone based on differences in LD_{50} values. The analytical method used converts RPA 412708 to RPA 412636, and both compounds are measured together as RPA 412636. On this basis, it was concluded that a 10-fold potency factor should be applied to both the acute and chronic dietary intake estimates for RPA 412636 and that these acute and chronic dietary intake estimates should be added to the acute and chronic dietary intakes of fenamidone and compared with the ARfD and ADI for fenamidone, respectively. The novel plant metabolite, RPA 410193, was concluded to have similar potency to fenamidone and would be covered by the reference doses for fenamidone.

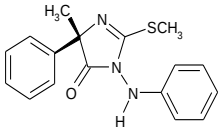
An addendum to the toxicological monograph was not prepared.

RESIDUE AND ANALYTICAL ASPECTS

Fenamidone is a broad-spectrum fungicide belonging to the imidazolinone group. The compound was evaluated the first time by the 2013 JMPR for toxicology where an ADI of 0–0.03 mg/kg bw and an ARfD of 1 mg/kg bw was allocated. The evaluation for residues was scheduled for the 2014 JMPR.

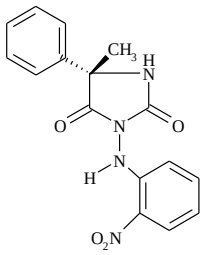
The current Meeting received information on physical and chemical properties, metabolism studies on animals and plants, environmental fate including rotational crops data, analytical methods, use pattern, supervised trials data, processing and feeding studies.

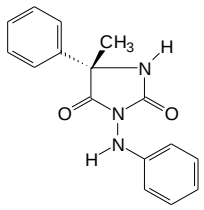
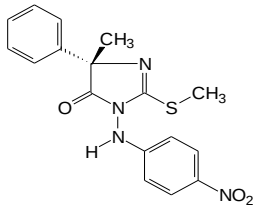
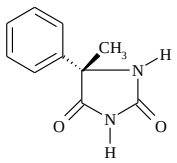
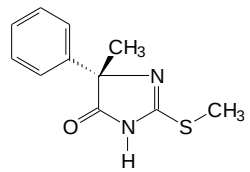
The active substance fenamidone is the S-enantiomer of a stereoisomeric molecule with the chiral centre in the 5-position of the dihydro-imidazolone ring. This S-enantiomer has been shown to be the biologically (fungicidally) active enantiomer.

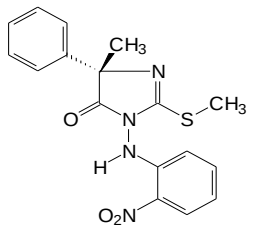
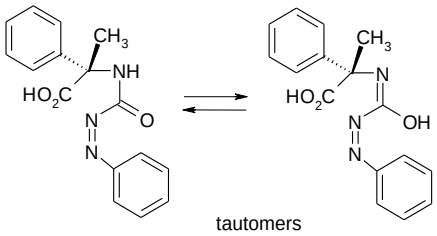


The chiral carbon atom on the 5-position of the dihydro-imidazolone ring is substituted by 4 non-hydrogen substituents, namely substituted by an amino, carbonyl, methyl and phenyl group. Prerequisite for isomerisation/racemisation of this type of centre of chirality is the presence of a hydrogen atom as a substituent that can be split off easily. In fenamidone, no hydrogen is linked to the chirality centre. Therefore, racemisation is chemically not possible and the configuration and the optical purity, respectively, established by synthesis does not change afterwards. There was also no evidence of enantiomerization or racemization of the parent substance and its metabolites during metabolic conversions in plants and animals or physical-chemical degradation in soil and water.

In this document, the code names of the S-enantiomers were used of the metabolites identified:

Name, Structure, IUPAC name, CAS name, [CAS number]	Mol. formula, molar mass Other names / codes	Occurrence, Compartment
RPA 221701  (5*S*)-5-methyl-3-[(2-nitrophenyl)amino]-5-phenyl- 2,4-imidazolidinedione (IUPAC)	$C_{16}H_{14}N_4O_4$ 326.3 g mol^{-1} S-Enantiomer: RPA 221701 AE 0591777 BCS-AX84897 2,4-imidazolidinedione, 5-methyl-3-[(2-nitrophenyl)-amino]-5-phenyl-, (5*S*)- Racemate: RPA 410995 AE 0591778	Soil, aerobic Carrot Rotational crops: Turnip, Swiss chard
RPA 410193	$C_{16}H_{15}N_3O_3$ 281.3 g mol^{-1} S-Enantiomer: RPA 410193 AE 0540049 BCS-AX71129	Soil, aerobic Soil, photolysis Hydrolysis, abiotic Photolysis, buffer Vine grapes, Lettuce,

Name, Structure, IUPAC name, CAS name, [CAS number]	Mol. formula, molar mass Other names / codes	Occurrence, Compartment
 (*S*)-5-Methyl-5-phenyl-3-(phenylamino)- 2,4-imidazolidine-dione (IUPAC)	Diketo-fenamidone (DK-Fen) Racemate: RPA 405862 AE C650488	Tomato, Potato, Carrot Hen
RPA 411639  (5*S*)-5-methyl-2-(methylthio)-3-(4-nitrophenyl)amino)-5-phenyl-3,5-dihydro-4H-imidazol-4-one (IUPAC)	$C_{17}H_{16}N_4O_3S$ 356.4 g mol^{-1} S-Enantiomer: RPA 411639 AE 0540054 BCS-AX71134 Racemate: RPA 406012 AE 0540056	Soil, aerobic Carrot Rotational crops: Turnip, Swiss chard Rat (postulated intermediate)
RPA 412636  (*S*)-5-methyl-5-phenyl-2,4-imidazolidine-dione (IUPAC) 2,4-imidazolidinedione, 5-methyl-5-phenyl-, (5*S*) (CAS)	$C_{10}H_{10}N_2O_2$ 190.2 g mol^{-1} S-Enantiomer: RPA 412636 AE 0540051 BCS-AX71131 " fenamidone-hydantoin" Desanilino-diketo-fenamidone (DADK-Fen) Racemate: RPA 717879 AE C415557	Soil, aerobic Soil, photolysis Water / sediment Lettuce, Potato, Rotational crops: Wheat, Turnip, Swiss chard Rat, Goat, Hen
RPA 412708  (5*S*)-5-methyl-2-(methylthio)-5-phenyl-3,5-dihydro- 4H-imidazol-4-one (IUPAC)	$C_{11}H_{12}N_2OS$ 220.9 g mol^{-1} S-Enantiomer: RPA 412708 AE 0540050 BCS-AX71130 Desanilino-fenamidone (DA-Fen) Racemate: RPA 408056 AE 0540057	Soil, aerobic Soil, photolysis Hydrolysis, abiotic Photolysis, buffer Photolysis, nat. water Water / sediment Lettuce, Potato Rat, Goat, Hen
RPA 413255	$C_{17}H_{16}N_4O_3S$ 356.4 g mol^{-1} S-Enantiomer: RPA 413255	Soil, aerobic Soil, photolysis

Name, Structure, IUPAC name, CAS name, [CAS number]	Mol. formula, molar mass Other names / codes	Occurrence, Compartment
 (5S)-5-methyl-2-(methylthio)-3-(2-nitrophenyl)amino)-5-phenyl-3,5-dihydro-4H-imidazol-4-one (IUPAC)	AE 0540053 BCS-AX71133 Racemate: RPA 410914 AE 0540055	Carrot Rotational crops: Turnip, Swiss chard
RPA 413350  tautomers 2-phenyl-N-{[(E)-phenyldiazenyl]carbonyl}-D-alanine (IUPAC)	$C_{16}H_{15}N3O_3$ 297.3 g mol^{-1} S-Enantiomer: RPA 413350 AE 0540052 BCS-AX71132 Racemate: RPA 409344 AE 0841910	Hydrolysis, abiotic

Animal metabolism

Metabolism studies on rats reviewed by the 2013 JMPR show that fenamidone undergoes extensive metabolism in the rat by phase I (oxidation, reduction and hydrolysis) and phase II reactions (conjugation). The plasma elimination half-life was at least 60 hours. More than 20 metabolites were detected in rat excreta, with the majority of radioactivity excreted in the faeces (up to approximately 90% of the administered dose) and the remainder in urine. Mass balance data indicated that the majority of radioactivity (> 80%) was eliminated within 48 hours of dosing. The metabolites RPA 412636 and RPA 412708 were present in rat urine and rat bile, respectively.

Metabolism studies have been conducted in lactating goats. Two dose levels were used for each label position: 1 ppm and 10.4 ppm in the diet for [C-phenyl-U-^{14}C]-fenamidone and 1.5 ppm and 11.5 ppm in the diet for [N-phenyl-U-^{14}C]-fenamidone. Dosing was performed twice daily by capsule during seven consecutive days. The total administered radioactivity (TAR) was quickly and almost completely eliminated in the excreta. In case of the C-phenyl label, the total excreted residues were 99–102% of TAR (75–80% via faeces, 17–26% via urine, 0.1% via milk). In case of the N-phenyl label, the total excreted residues were ca. 90% of TAR (45–52% via faeces, 36–40% via urine, 0.1–0.2% via milk). Neither fenamidone nor any of its metabolites accumulated in milk fat or milk proteins. At sacrifice, small amounts of radioactivity (totally 0.6 to 1.0% of TAR) were detected in edible organs/tissues and blood.

Residues in milk and edible tissues of goats were low. RPA 412708 and RPA 412636 were found, as well as hydroxylated fenamidone and hydroxylated RPA 412708. RPA 412636 was the most abundant residue in the goat, reaching after high dose administration 0.055 mg/kg (5.9% TRR) in liver, 0.018 mg/kg (15% TRR) in kidney and 0.002 mg/kg in milk (11% TRR). Fenamidone was identified in fat with 0.013 mg/kg (53% TRR), but was a minor component in milk (0.001 mg/kg, 0.7% TRR), liver (0.003 mg/kg, 0.3% TRR) and kidney (0.001 mg/kg, 0.6% TRR).

Metabolism studies have been conducted in laying hens. Two dose levels were used for each label position: 1.3 ppm and 13.8 ppm in the diet for [C-phenyl-U-^{14}C]-fenamidone and 1.0 ppm and

9.8 ppm in the diet for [N-phenyl-U-^{14}C]-fenamidone. Dosing was performed by administration of one capsule per day during fourteen consecutive days. The TAR was quickly and almost completely eliminated in excreta. The recovery of radioactivity was > 91% of the TAR. The majority of the radioactivity was in excreta (approximately 90% TAR). All of the eggs together contained 0.1% of the dose administered, most of which was retained in the yolk. At sacrifice, at both dose levels and in both labels, very minor amounts of radioactivity (0.1% of TAR) were detected in edible organs/tissues and blood.

Residues in eggs and edible tissues of hens were low. RPA 412636 was a major component in the hen, found at 0.011 mg/kg (74% TRR) in egg white, 0.014 mg/kg in egg yolk (11% TRR), 0.023 mg/kg (15% TRR) in liver and 0.002 mg/kg (16% TRR) in skin after high dose administration. RPA 412708 was the highest residue in the hen, reaching 0.028 mg/kg (25% TRR) in egg yolk but only 0.002 mg/kg (1.3% TRR) in liver. Fenamidone was identified, but was a minor component (egg yolk 0.014 mg/kg, 11% TRR; liver 0.003 mg/kg, 1.7% TRR; fat < 0.001 mg/kg, 4.6% TRR and skin 0.002 mg/kg, 14% TRR).

The Meeting concluded that, in all species investigated, the TAR was quickly and almost completely eliminated in excreta. The metabolic profiles differ quantitatively between the species, but qualitatively there are no major differences; the routes and products of metabolism in animals were consistent across the studies. Fenamidone, RPA 412708 (desanilino-fenamidone) and RPA 412636 (desanilino-diketo-fenamidone) were the components identified.

Plant metabolism

The metabolism of fenamidone has been studied in grapes, tomatoes, lettuce, carrots and potatoes.

Grapes

Following four foliar treatments of [C-phenyl-U-^{14}C]-fenamidone to a total nominal rate of the equivalent of 1.65 kg ai/ha (0.5, 0.49, 0.5 and 0.16 kg ai/ha) to field grown grape vines during the grape berry development period, the terminal residue in the mature harvest grape bunches (1.2 mg eq/kg) was shown to comprise mainly parent compound (56% TRR) and RPA 410193 (17% TRR). The interval between the last application and harvest was 24 days. The major part of the radioactivity associated with the grape bunches could be extracted by methanol/water and represented 89% of the TRR. The non-extracted radioactivity was confined mainly to the stem, skin and pips. Further extraction procedures were made including enzyme treatment followed by acid and alkali hydrolysis (100% TRR).

The metabolism of fenamidone in grapes was characterised by the formation of RPA 410193, i.e. loss of the thiomethyl group and formation of an imidazolidinedione. Some evidence was obtained to suggest that hydroxylation of parent compound (3.4% TRR) as well of RPA 410193 (4.2% TRR) also occurred. A number of other metabolites were detected, albeit polar and at very low levels.

Tomatoes

The metabolism was investigated following three foliar applications of [^{14}C]-fenamidone, each of 0.5 kg ai/ha giving a total nominal application rate of 1.5 kg ai/ha on glasshouse grown tomatoes. Both labels, C-phenyl and N-phenyl, were used separately. At final harvest, 7 days after the last treatment, the TRR in tomato fruits was less than 0.2 mg eq/kg for both labels. About 90% of the TRR was extracted and more than 75% identified.

The major component of the extracted radioactivity in both treatment regimes was unchanged parent accounting for 66–76% TRR. The next largest component was RPA 410193 accounting for 9.3–9.4% TRR. No metabolites were formed at significant levels as a result of cleavage of the two phenyl-rings.

Lettuce

The metabolism was investigated following four foliar applications of [^{14}C]-fenamidone, each of a nominal rate of 0.4 kg ai/ha on outdoor grown iceberg lettuce. Both labels, C-phenyl and N-phenyl, were used separately. At final harvest, 7 days after the last treatment, a total of 93% and 92% of the TRR for the C-phenyl-label and N-phenyl-label treated final harvest lettuces respectively, was identified. The TRR found in the lettuce wrapper leaves (12 mg eq/kg) were significantly higher than that present in the lettuce heads (0.2–0.3 mg eq/kg).

Analysis of the extracted radioactive residues showed the major components of both labels to be parent fenamidone (about 92% TRR in whole lettuce). The remaining extracted radioactivity was comprised of RPA 410193 (0.59–0.66% TRR) and multiple unidentified polar components, which comprised less than 3% TRR in total in whole lettuce. In addition, low levels of RPA 412636 (2.7% TRR) were present in the C-phenyl-label treated lettuce head leaves extracts only.

Potatoes

The metabolism was investigated following three foliar applications of [^{14}C]-fenamidone, each of nominal 0.5 kg ai/ha on outdoor grown potatoes. Both labels, C-phenyl and N-phenyl, were used separately. At final harvest, 14 days after the last treatment, the TRR in the tubers (0.038–0.087 mg eq/kg) was significantly lower than the levels detected in the leafy part of the plant (5.9–6.6 mg eq/kg) with 1.3% of the whole plant TRR being present in the root/tuber. A total of 73% TRR of the intact potato tubers and 77% TRR of the potato haulm could be extracted for C-phenyl-fenamidone treated plants at final harvest. The corresponding values for N-phenyl-fenamidone treated potatoes were 46% and 78% for intact potato tubers and potato haulm respectively.

In potato tubers, parent fenamidone accounted for 2.3 to 6% of TRR (0.002 mg/kg) and two further metabolites were formed: RPA 412708 (desanilino-fenamidone) and RPA 412636 (desanilino-diketo-fenamidone), each accounting for ca. 6% of TRR with low absolute concentrations (0.005–0.006 mg eq/kg). A large portion of the residue was polar in nature and reported to be composed by acid labile conjugates.

Carrots

The metabolism was investigated following three applications of [N-phenyl-U-^{14}C]-fenamidone, each of nominal 0.3 kg ai/ha on outdoor grown carrots. The first application was made pre-emergence followed by two foliar applications. At final harvest, 14 days after the last treatment, the TRR in leaves and roots amounted to 30.5 and 0.04 mg eq/kg, respectively. Therefore, basispetal transport of residues from the treated leaves to the roots was very limited. In leaves, 81% of the radioactivity could be extracted with acetonitrile/water using a high-speed blender and the rest by water/dichloromethane partition. In roots, 93% of the radioactivity was extracted with acetonitrile/water.

Fenamidone accounted in leaves for 89% of the TRR and in roots for 29% of the TRR. Six minor metabolites were identified. No metabolite in the roots exceeded a level of 0.01 mg/kg. Two parallel metabolic reactions were found and a combination thereof. The first reaction was an oxidative hydrolysis of the thiomethyl group at the dihydro imidazole ring to a keto substituent resulting in RPA 410193 (diketo-fenamidone). Another reaction was the nitration of the N-phenyl ring. All metabolites contained the intact basic structure with the two phenyl rings and the imidazole ring. No cleavage product, such as aniline, aminophenols or nitroanilines was detected. In addition, radiolabelled glucose was found in the leaves resulting from complete mineralization of the fenamidone in the soil and photosynthetic uptake of the formed $^{14}CO_2$ in the plant. Small amounts of a dimer of fenamidone (0.17% of TRR, 0.05 mg/kg) were also detected in leaves.

In summary, the metabolism of fenamidone in plants after foliar application was investigated in three crop categories: fruits and fruiting vegetables, leafy vegetables, root and tuber vegetables.

The metabolic pattern was shown to be similar in all these crop groups with the unchanged parent compound being the main compound of the final residue at harvest. The Meeting concluded that after foliar treatment the only significant metabolite in plants was RPA 410193 (diketo-fenamidone), formed by oxidative hydrolysis of the thiomethyl side chain of fenamidone.

Environmental fate

For fenamidone, data were received for foliar spray on permanent crops and on annual crops. A further application is on cotton seed as in furrow treatment. Therefore, according to the FAO manual, studies on the aerobic degradation in soil, photolysis, hydrolysis, rotational crops (confined, field) and field dissipation were evaluated. The fate and behaviour of fenamidone in soils was investigated using fenamidone radio-labelled in two different positions, [C-phenyl-U-^{14}C]- and [N-phenyl-U-^{14}C]-fenamidone.

Degradation in soil, photolysis and hydrolysis

Degradation of fenamidone in soil primarily proceeds by the action of aerobic soil microorganisms. In the first major pathway there is loss of the N-phenyl aniline ring to form RPA 412708, followed by loss of the S-methyl moiety and hydrolysis to form RPA 412636. Two further pathways are the concurrent formation of 2- and 4-nitro compounds by addition to parent to form RPA 413255 and RPA 411639. A further route of degradation results in the formation of numerous minor non-polar components. The rate of degradation tested in silty clay loam, sandy loam and in clay loam, is similar in both C-phenyl and N-phenyl rings with DT50s ranging from 0.9 to 9.6 days in all tested soils at 20 °C. The Meeting concluded that fenamidone was rapidly degraded in soil under aerobic conditions leading to the formation of two major metabolites RPA 412708 and RPA 412636.

Field dissipation studies undertaken at four European sites showed that the average half-lives were 5 days for fenamidone, 12 days for RPA 412708, 21 days for RPA 411639, 43 days for RPA 413255 and 47 days for RPA 412636. It can be concluded that the dissipation of fenamidone was rapid in the field.

The photolytic degradation of fenamidone was investigated on a sandy loam soil for 30 days. Artificial sunlight was provided using an artificial xenon light source for 13 hours each day. The Meeting recognized that photolytic processes do not contribute significantly to the degradation of fenamidone applied to the soil surface.

The hydrolytic degradation of fenamidone was examined in aqueous buffered solutions at pH values of 4, 5, 7 and 9 under sterile conditions at 25 °C. The Meeting recognized that fenamidone was stable at pH 5 and pH 7, but was hydrolysed at pH 4 and pH 9.

Rotational crops

One confined radiolabelled succeeding crop study was conducted in 2001 with [C-phenyl-U-^{14}C]-fenamidone. Following application to the soil at an application rate of 1.6–2.0 kg ai/ha, lettuce, turnip and barley were cultivated after three plant back intervals (30, 120/150 and 365 days). The residues in rotated plants comprised the following major metabolites: RPA 412636 and RPA 412708 and a conjugate thereof. The parent substance could not be detected. Residues of RPA 412636 were in lettuce ca. 20% of TRR at each plant back intervals, in turnip tops 3.5–11% of TRR, in turnip roots 5–8% of TRR and in barley grain 2–6% of TRR. The highest residues of RPA 412636 were found in barley straw with 2.04 mg/kg (29% TRR). RPA 412708 was found in lettuce at a maximum of 5.7% of TRR (0.04 mg/kg).

Two additional confined radiolabelled succeeding crop studies were carried out in 2013. Following application of 0.96 kg ai/ha [N-phenyl-U-^{14}C]-fenamidone and 0.97 kg ai/ha [C-phenyl-U-^{14}C]-fenamidone to the soil, wheat, turnip and Swiss chard were sown and cultivated at three plant back intervals (30, 191 and 324 days after soil treatment). Both labelled forms of fenamidone were

rapidly degraded in soil with extensive uptake of the metabolites into the plants. The parent compound was only detected in Swiss chard at 30 days plant back interval, however at a low level amounting to a maximum of 0.002 mg/kg (0.2% of TRR). It was not detected in other crops. The pathway is proposed as follows: Electrophilic nitration of the aniline ring formed fenamidone-2-nitro and fenamidone-4-nitro, most probably in the soil, with RPA 413255 (fenamidone-2-nitro) being further converted to RPA 221701 (fenamidone-desthiomethyl-2-nitro) following nucleophilic substitution and the addition of water. Conjugation with hexose and malonic acid and hydroxylation lead to the formation of fenamidone-hydroxy-nitro-malonyl-glycoside. Further conjugation with glutathione and nucleophilic substitution of methyl mercaptan also lead to the formation of fenamidone-nitro-GSH. In addition to these metabolites, the C-phenyl-labelled compound underwent further degradation of the aniline moiety of fenamidone-desthiomethyl-2-nitro to RPA 412636, again, most likely in the soil. Conjugation of RPA 412636 with glucose, hexose plus malonic acid and serine formed fenamidone-hydantoin-glucoside and fenamidone-hydantoin-serine.

The Meeting concluded that parent fenamidone is quickly degraded in soil or in the follow-on crops, not resulting in residues detected at harvest. Residues of RPA 412636, RPA 412708 and conjugates thereof were the major metabolites in commodities used as animal feed and can also occur in the edible parts of rotational crops.

Seven field succeeding crop studies were conducted, one in Europe and six in the USA. Spray applications near GAP were made to bare soil to simulate a treatment of target crops like potatoes, leafy vegetables or fruiting vegetables. Rotational crops were cereals (wheat, maize), fruiting vegetables (sweet corn) root and tuber vegetables (turnip, radish), leafy vegetables (lettuce, spinach), pulses (soya bean, dry) and strawberries.

After application of 0.9–1.2 kg ai/ha per annum to the bare soil, in the follow-on crops no parent fenamidone or its plant metabolite RPA 410193 was found at or above the LOQ of 0.02 mg/kg.

In plant parts used as human food, RPA 412636 occurred up to maximum single values of 0.04 mg/kg in radish roots, 0.04 mg/kg in radish tops and 0.12 mg/kg in spinach. Residues of RPA 412636 in wheat grain were in 22 field trials < 0.02 mg/kg and in only one trial 0.061 mg/kg.

RPA 412708 and RPA 412636 occurred in commodities that may be used as animal feeds. The sum of RPA 412708 and RPA 412636 reached up to 0.14 mg/kg in soya bean hay, 0.29 mg/kg in sweet corn stover and 0.21 mg/kg in field corn forage; RPA 412636 occurred up to 0.07 mg/kg in wheat forage, 0.27 mg/kg in wheat straw and 0.45 mg/kg in wheat hay.

In conclusion, no residues of fenamidone and RPA 410193 above the LOQ of 0.02 mg/kg would be expected in follow-on crops but residues of the metabolites RPA 412708 and RPA 412636 taken up from the soil occurred in commodities that may be used as human food and animal feed.

Methods of analysis

The Meeting received descriptions and validation data for analytical methods for residues of fenamidone and its relevant metabolites RPA 410193, RPA 412708 and RPA 412636 in plant commodities and for fenamidone, RPA 412708 and RPA 412636 in animal commodities. Residue analytical methods rely on GC with NP-detection, GC-MS or LC-MS/MS. Typical LOQs achieved for plant commodities fall in the range of 0.01–0.02 mg/kg for each analyte. The LOQ for milk was 0.01 mg/kg and for animal products (liver, kidney, muscle, eggs) 0.05 mg/kg for each analyte. Methods have been subjected to independent laboratory validation.

Fenamidone and RPA 410193 were analysed in plant material by the multi method S 19 with an LOQ of 0.01 mg/kg by GC-MS. The QuEChERS multi residue method was used for fenamidone and RPA 410193 in plant matrices as well as for fenamidone and RPA 412708 and RPA 412636 in animal matrices with LOQs of 0.01 mg/kg by LC-MS/MS for each analyte.

Stability of residues in stored analytical samples

The Meeting received storage stability studies under freezer conditions at -20 °C for fenamidone, RPA 412636, RPA 412708 and RPA 410193 for the duration of the storage of 12 months in a wide range of raw and processed crop matrices, including examples of high-water and high-starch crops and for duration of 6 months for cotton products. Furthermore, studies were conducted for fenamidone and RPA 410193 in high-water content commodities for duration of 14 months and in strawberries of 18 months.

The Meeting concluded that residues of fenamidone and RPA 410193 are stable in commodities of high-water content for at least 14 months and in strawberries for at least 18 months. Residues of fenamidone, RPA 412636, RPA 412708 and RPA 410193 are also stable for at least 6 months in high-oil content products.

Because milk and tissue samples of the ruminant feeding study were analysed within 29 days of collection, no storage stability data were submitted.

Definition of the residue

Animal metabolism studies were performed in rats, lactating goats and laying hens. The metabolic behaviour of fenamidone in the rat is summarised by the 2013 JMPR and shows pathways and major components similar to those found in ruminants and poultry. RPA 412636 and RPA 412708 are found in the rat metabolism. RPA 410193, which is a plant metabolite, was not identified in the rat ADME studies. The 2013 Meeting considered the named metabolites as toxicological relevant.

The 2014 JMPR agreed that RPA 410193 is covered by the ADI of the parent fenamidone. The toxicological relevance of RPA 412636 and its precursor RPA 412708, both detected as RPA 412636, were confirmed. RPA 412636 was considered as 10 times more toxic than the parent.

Livestock metabolism studies in goat and hen showed no major differences; the routes and products of metabolism in animals are consistent across the studies. The residues in animal products were low. Fenamidone was identified, reaching 0.013 mg/kg in ruminant fat (53% TRR) and 0.014 mg/kg in egg yolk (11% TRR). RPA 412636 was the most abundant residue in the ruminant, reaching 0.055 mg/kg in liver (5.9% TRR) and 11% TRR in milk (0.002 mg/kg). RPA 412636 was also found in the hen, at 0.011 mg/kg (74% TRR) in egg white and 0.014 mg/kg in egg yolk (11% TRR). RPA 412708 was the most abundant residue in the hen, reaching 0.028 mg/kg in egg yolk and 0.002 mg/kg in liver (25 and 1.3% TRR, respectively).

The Meeting concluded that the residue definition for MRL-setting for animal products should be parent fenamidone. For dietary intake, the residue should be defined as the sum of fenamidone, RPA 412636 and RPA 412708, expressed as fenamidone. Due to the 10-fold higher toxicity, a factor of 10 should be applied.

Fenamidone has a log P_{OW} of 2.8. No residues of fenamidone, RPA 412636 and RPA 412708 could be determined in animal products from the cattle feeding study with the exception of one milk fat sample with 0.011 mg/kg of RPA 412708. In the high dose group of the goat metabolism study, the TRR in muscle were low (0.02 mg eq/kg) and could not further identified. Fenamidone was detected in the fat (53% TRR, 0.013 mg eq/kg). In the high dose group of the egg metabolism study, fenamidone was detected in the yolk (11% TRR, 0.014 mg/kg), but not in the egg white (< 0.001 mg/kg). The Meeting decided that the residue is fat-soluble.

Plant metabolism studies for foliar spray application to the plant provide a clear understanding of the fate of the fenamidone molecule, both the C-phenyl and N-phenyl portions. The overall metabolic pathway is consistent between the different crop groups. Fenamidone forms the largest part of the residue and the only significant metabolite is RPA 410193, which reached a maximum of 17% TRR in grape. RPA 412636 and RPA 412708 reached a maximum of 6.3% TRR (0.005 mg/kg) and 6.4% TRR (0.006 mg/kg) in potato tubers. No other metabolite exceeded 5% TRR in any plant commodity.

The Meeting took into account the possibility of residues of the metabolites RPA 412708 and RPA 412636 in follow-on crops used as human food and/or animal feed. The Meeting concluded to include both metabolites in the residue definition for estimation of the dietary intake of plant commodities. Because of the10-fold higher toxicity, a factor of 10 should be applied.

The Meeting agreed the following residue definitions:

- Definition of the residue for compliance with the MRL for plant and animal commodities: *Fenamidone.*
- Definition of the residue for estimation of dietary intake for plant commodities: Sum of fenamidone, (S)-5-methyl-5-phenyl-3-(phenylamino)- 2,4-imidazolidine-dione (RPA 410193**)** plus 10 × the sum of both (S)-5-methyl-5-phenyl-2,4-imidazolidine-dione (RPA 412636) and (5S)-5-methyl-2-(methylthio)-5-phenyl-3,5-dihydro- 4H-imidazol-4-one (RPA 412708), all calculated as fenamidone.
- Residue concentration $C_{total}=C_{fenamidone} + C_{RPA\ 410193} + 10 \times (C_{RPA\ 412636} + C_{RPA\ 412708})$
- Definition of the residue for estimation of dietary intake for animal commodities: *Fenamidone plus 10 × the sum of both (S)-5-methyl-5-phenyl-2,4-imidazolidine-dione (RPA 412636) and (5S)-5-methyl-2-(methylthio)-5-phenyl-3,5-dihydro- 4H-imidazol-4-one (RPA 412708), all calculated as fenamidone.*
- Residue concentration $C_{total}=C_{fenamidone} + 10 \times (C_{RPA\ 412636} + C_{RPA\ 412708})$
- The residue is fat-soluble.

Results of supervised residue trials on crops

The Meeting received supervised residue trials data for grapes, strawberries, leek, bulb onion, spring onion, cabbage, flowerhead brassica, melons, watermelons, cucumber, summer squash, peppers, tomato, lettuce, mustard greens, spinach, carrots, potato, ginseng, Witloof chicory, celery, cotton seed, sunflower seed, common bean forage and cotton fodder. If two field samples were taken or results of two replicate plots were submitted, the mean value was calculated for estimation of maximum residue levels. For HR estimation, the highest single value of the trials according to GAP was used. From two or more trials carried out side-by-side the higher residue was chosen.

Residues are reported separately for fenamidone and RPA 410193 only because the soil metabolites RPA 412636 and RPA 412708 are not relevant for foliar treated crops. For HR and STMR estimation, the sum of fenamidone (MW 311.4 g/mol) and RPA 410193 (MW 281.3 g/mol), expressed as fenamidone (conversion factor 1.11), is needed. When residues are undetectable in a commodity, the sum of the LOQs of both components is not appropriate for all plant commodities because the days after the last treatment (DALT) differ from 2 days (e.g., lettuce) to 35 days (strawberry). The residues of RPA 410193 are found in the same order of magnitude as the parent in berries harvested 4 to 5 weeks after treatment. In other plant commodities harvested at shorter PHIs (2–21 days), the level of the metabolite is much lower than the parent in most cases. The method for calculation of the total residues of the sum of fenamidone and RPA 410193 is illustrated as follows:

- Plant commodities except grapes and strawberries

Fenamidone, mg/kg	RPA 410193, mg/kg	Total, mg/kg
< 0.02	< 0.02	< 0.02
0.05	< 0.02	0.05
0.42	0.08	0.51[a]

[a] 0.42 + (0.08 × 1.11)=0.5088

- Grapes and strawberries

Fenamidone, mg/kg	RPA 410193, mg/kg	Total, mg/kg
< 0.02	< 0.02	< 0.04
0.05	< 0.02	0.07
0.42	0.08	0.51

Trials from the USA or Canada on carrots, potatoes, fruiting—brassica, leafy and legume—as well as stalk and stem vegetables were performed with four instead of three applications and trials on bulb vegetables as well as cucurbits were performed with six instead of four applications. The Meeting accepted the trials as matching the GAP in the USA and Canada since comparative residue trials on grapes and tomatoes as well as decline studies on vegetables indicated that the contribution of two earlier applications to the terminal residue is negligible. The Meeting agreed to use the trials to estimate maximum residue levels.

Rotational crop maximum residue levels, STMRs and HRs

The Meeting noted that no residues of parent fenamidone above the LOQ of 0.02 mg/kg are expected in follow-on crops. It was concluded that the estimation of maximum residue levels is not necessary.

The Meeting recognized that, in commodities used as human food, RPA 412636 were found. The table below shows the highest and the mean residues of two plots found in follow crops as spinach, radish roots and leaves as well as wheat grain after treatment of vegetables with fenamidone at 1.2 kg ai/ha per annum. The Meeting agreed to use the proportionality approach and scaled the residues according to the US GAP of 0.9 kg ai/ha per annum for brassica vegetables, fruiting vegetables, leafy vegetables, root and tuber vegetables and celery. The values measured as RPA 412636 (MW 190.2 g/mol) were expressed as fenamidone (MW 311.4 g/mol) multiplying by 1.64.

		RPA 412636, highest residue, mg/kg			RPA 412636, mean residue, mg/kg		
Treatment, kg ai/ha	Commodity	Measured	Scaled	Calculated as fenamidone eq	Measured	Scaled	Calculated as fenamidone eq
6× 0.2	Spinach	0.12	0.09	0.15	0.096	0.072	0.12
	Radish tops	0.044	0.033	0.054	0.033	0.0275	0.045
	Radish roots	0.039	0.029	0.048	0.03	0.0225	0.037
	Wheat grain	0.061	0.046	0.075			
1× 0.2	Wheat grain				< 0.02		< 0.033 (n=22)

The Meeting concluded that the contribution of residues of RPA 412636 and RPA 412708 has to be considered for the STMR and HR estimation for annual crops like vegetables and cereals. A factor of 10 is used because of the 10-fold higher toxicity compared to parent.

For brassica vegetables, fruiting vegetables, leafy vegetables, fresh herbs as well as stalk and stem vegetables, the Meeting estimated a rotational crop STMR of 1.2 mg/kg and a rotational crop HR of 1.5 mg/kg, based on the residues analysed in spinach.

For bulb vegetables, root and tuber vegetables as well as their leaves/greens the Meeting estimated a rotational crop STMR of 0.4 mg/kg and an HR of 0.5 mg/kg, respectively.

For cereal grains, residues of RPA 412636 + RPA 412708 were in wheat of 22 field trials as well as of nine trials in maize < 0.033 mg eq/kg and in only one trial 0.075 mg eq/kg. The Meeting agreed to estimate an STMR of 0.33 mg/kg (10 times LOQ) for cereal grains except rice as follow-on crops.

No residues of RPA 412636 or RPA 412708 higher than the LOQ of 0.02 mg/kg occurred in strawberries, sweet corn kernels and soya bean seed grown as follow-on crops. The Meeting concluded that the uptake of substantial concentrations of RPA 412636 or RPA 412708 by strawberry, sweet corn, oil seeds and pulses is negligible. No STMR or HR was recommended.

Grapes

The GAP for fenamidone in Brazil on grapes is foliar spray treatment with 3× 0.13 kg ai/ha and a PHI of 7 days. Three Brazilian trials matching the GAP were submitted. The residues in grape bunches were for parent fenamidone 0.02, 0.03, 0.03 mg/kg and for the sum of fenamidone and RPA 410193 0.04, 0.05, 0.05 mg/kg.

Fenamidone is registered for foliar spray treatment on grapes in the Czech Republic with application at 3 × 0.13 kg ai/ha and a PHI of 28 days. Sixteen European trials according to GAP were conducted in 2009 and 2010 in Belgium, France, Germany, Italy, Portugal and Spain. The residues in grape bunches were for fenamidone (n=16) 0.04, 0.06, 0.08, 0.09, 0.09, 0.10, 0.13, 0.13, 0.17, 0.21, 0.22, 0.22, 0.26, 0.28, 0.30 and 0.33 mg/kg. The total residues (sum of fenamidone and RPA 410193) were 0.06, 0.09, 0.09, 0.11, 0.12, 0.13, 0.15, 0.16, 0.19, 0.25, 0.25, 0.25, 0.34, 0.34, 0.35 and 0.42 mg/kg.

Based on the European residue data, the Meeting estimated a maximum residue level of 0.6 mg/kg, an STMR of 0.175 mg/kg and an HR of 0.42 mg/kg for fenamidone residues in grapes.

Strawberry

The UK GAP for fenamidone in strawberries is one pre-transplantation treatment (0.18 kg ai/ha) followed by one post-transplantation drench or spray (0.27 kg ai/ha) and a PHI of 35 days.

Eight supervised residue trials were carried out in 2009 and 2012 in Europe in greenhouses. The plants were treated by a drip-irrigation with 0.16–0.18 kg ai/ha followed after 21/22 days by a foliar spray of 0.27 kg ai/ha. The residues were for parent fenamidone < 0.01, < 0.01, 0.01, 0.01, 0.01, 0.02, 0.02, 0.02 mg/kg and for the sum of fenamidone and RPA 410193 < 0.02, < 0.02, 0.02, 0.02, 0.02, 0.03, 0.03, 0.03 mg/kg.

Fenamidone is registered in Belgium in protected strawberries with two drench treatments of 0.45 kg ai/ha and a PHI of 35 days. Seven trials according to Belgium GAP were conducted in 2010/2011. The residues were for parent fenamidone < 0.01 (3), 0.01, 0.02 (3) mg/kg and for the sum of fenamidone and RPA 410193 < 0.02, < 0.02, 0.02, 0.02, 0.03, 0.03, 0.04 mg/kg.

The Meeting agreed to use the data set according to the Belgium GAP and estimated a maximum residue level of 0.04 mg/kg, an STMR of 0.02 mg/kg and an HR of 0.04 mg/kg for fenamidone residues in strawberries.

Bulb vegetables

Fenamidone is registered for bulb vegetables in the USA and Canada with foliar application at 4× 0.2 kg ai/ha and a PHI of 7 days. Field trials on bulb onion (8) and spring onion (4) were carried out in the USA. At each trial, six instead four spray applications of 0.2 kg ai/ha were made. The following residue data were received.

In bulb onion, the fenamidone residues as well as total residues (sum of fenamidone and RPA 410193) were < 0.02 (6), 0.02 and 0.10 mg/kg. The Meeting recognized that one duplicate field sample gave higher residues than the HR based on the mean residues and decided to use this value of 0.13 mg/kg as HR for the short-term dietary intake assessment instead. The Meeting agreed to extrapolate the residue data from bulb onions to garlic and shallots. Furthermore, the contribution in follow-on crops of 0.4 mg/kg has to be added to the STMR and 0.5 mg/kg to the HR.

The Meeting estimated a maximum residue level, an STMR and an HR of 0.15 mg/kg, 0.42 mg/kg and 0.63 mg/kg, respectively, for bulb onion, garlic and shallots.

In spring onion, the fenamidone residues were 0.24, 0.36, 0.94 and 0.94 mg/kg. The corresponding total residues were 0.24, 0.36, 0.94 and 1.1 mg/kg. The Meeting recognized that one duplicate field sample gave higher residues than the HR based on the mean residues and decided to

use this value of 1.2 mg/kg as HR for the short-term dietary intake assessment instead. The Meeting agreed to extrapolate the residue data from spring onion to welsh onion. Furthermore, the contribution in follow-on crops of 0.4 mg/kg has to be added to the STMR and 0.5 mg/kg to the HR.

The Meeting estimated a maximum residue level, an STMR and an HR of 3 mg/kg, 1.05 mg/kg and 1.7 mg/kg, respectively, for spring onion and Welsh onion.

The GAP for leek in Switzerland is 3 × 0.15 kg ai/ha and a PHI of 14 days. Four supervised residue trials (France 1, Germany 2 and the Netherlands 1) with 4 × 0.15 kg ai/ha were submitted. At a PHI of 14 days, the residues of fenamidone as well as of the sum of fenamidone and RPA 410193 were 0.02, 0.05, 0.07 and 0.13 mg/kg. Furthermore, the contribution in follow-on crops of 0.4 mg/kg has to be added to the STMR and 0.5 mg/kg to the HR.

The Meeting considered four trials on leek as sufficient and estimated a maximum residue level, an STMR and an HR of 0.3 mg/kg, 0.46 mg/kg and 0.63 mg/kg, respectively.

Brassica vegetables

Head cabbage

Fenamidone is registered in Switzerland in head cabbages as foliar spray with 3 × 0.15 kg ai/ha and a PHI of 14 days. Seven European trials (France 2, Germany 4 and Portugal 1) according to the Swiss GAP were submitted. The residues of fenamidone as well as the sum of fenamidone and RPA 410193 were < 0.01 (4), 0.01, 0.02 and 0.06 mg/kg.

The GAP for Brassica vegetables in Canada and the USA is 3 × 0.3 kg ai/ha and a PHI of 2 days. Six trials were conducted in 2003 in the USA with 4× 0.3 kg ai/ha and a PHI of 2 days. In all trials, heads with wrapper leaves were analysed. The residues were for parent fenamidone 0.10, 0.17, 0.22, 0.24, 0.35 and 0.52 mg/kg in cabbage heads with wrapper leaves. Residue data for heads without wrapper leaves were available from four of the six trials. The fenamidone residues as well as the total residues were < 0.02, < 0.02, 0.03 and 0.19 mg/kg.

The Meeting agreed to use the US residue data on cabbage heads with wrapper leaves for MRL estimation and without wrapper leaves for dietary intake purposes. Furthermore, the contribution in follow-on crops of 1.2 mg/kg has to be added to the STMR and 1.5 mg/kg to the HR.

The Meeting estimated a maximum residue level of 0.9 mg/kg, an STMR of 1.23 mg/kg and an HR of 1.69 mg/kg.

For livestock dietary burden calculation, the Meeting estimated a median residue of 0.22 mg/kg and a highest residues of 0.52 mg/kg based on the fenamidone data for head cabbage with wrapper leaves.

Flowerhead brassica

The GAP for Brassica vegetables in Canada and the USA is 3 × 0.3 kg ai/ha and a PHI of 2 days. Six trials were conducted in 2003 on broccoli in the USA with 4 × 0.3 kg ai/ha and a PHI of 2 days. The mean residues of two separate field samples were for parent fenamidone as well as the total residues 0.31, 0.51, 0.68, 1.5, 1.6 and 2.2 mg/kg.

The Meeting recognized that one duplicate field sample gave higher residues than the HR based on the mean residues and decided to use this value of 2.7 mg/kg as HR for the short-term dietary intake assessment instead. Furthermore, the contribution in follow-on crops of 1.2 mg/kg has to be added to the STMR and 1.5 mg/kg to the HR.

The Meeting estimated for fenamidone residues in flowerhead brassica a maximum residue level, an STMR and HR of 4 mg/kg, 2.29 mg/kg and 4.2 mg/kg, respectively.

Fruiting vegetables, cucurbits

The GAP for cucurbits in Canada and the USA is 4 × 0.2 kg ai/ha and a PHI of 14 days. Field trials on cucumber (9), summer squash (9) and cantaloupe melons (8) were carried out during 1999 in the USA. At each trial, six spray applications in the range of 0.19–0.21 kg ai/ha were made at intervals of 3–6 days. The following residue data were received:

- In cucumber, the residues of fenamidone as well as the total residues were < 0.02 (7), 0.02 and 0.04 mg/kg.
- In summer squash, the residues of fenamidone as well as the total residues were < 0.02 (8) and 0.06 mg/kg.
- In cantaloupe melon, the residues for fenamidone as well as the total residues were in whole fruits < 0.02, 0.02, 0.04, 0.06, 0.07, 0.08, 0.08 and 0.09 mg/kg. No data were submitted for the edible part.

The Brazilian GAP for the use of fenamidone in watermelon is 3 × 0.15 kg ai/ha and a PHI of 7 days. Three trials on watermelons were conducted in 2004 in Brazil. The residues were in whole fruits for fenamidone as well as the sum of fenamidone and RPA 410193 were 0.03, 0.04 and 0.05 mg/kg. No residue data for pulp were submitted.

Fenamidone is registered in Switzerland for cucumbers, pumpkins, melons, courgettes, patisson and rondini with three foliar spray treatments of 0.15 kg ai/ha and a PHI of 3 days. Trials on cucumber (9 indoor) and on melons (8 indoor, 8 outdoor) carried out between 2002 and 2005 in European countries according to the GAP were submitted. The following residue data were received:

- In indoor grown cucumber, the residues of fenamidone as well as the total residues were < 0.01, < 0.02, 0.04, 0.04, 0.09, 0.10, 0.10, 0.12 and 0.13 mg/kg.
- In outdoor grown melons, the residues of fenamidone in whole fruits were < 0.02, 0.03, 0.03, 0.04, 0.04, 0.05, 0.08 and 0.12 mg/kg
- In indoor grown melons, the residues of fenamidone in whole fruits were < 0.02, < 0.02, < 0.02, 0.03, 0.04, 0.07, 0.07 and 0.09 mg/kg.
- The corresponding residues of the sum of fenamidone and RPA 410193 in melon pulp were < 0.01 (6) and < 0.02 (10).

The Meeting concluded that the maximum residue level should be based on the critical Swiss GAP. It was noted, that the median of the datasets for cucumber and melons (outdoor and indoor grown) differed by less than five times and agreed to consider a group maximum residue level. In deciding on the data set to use for estimating a group maximum residue level, as a Mann-Whitney U-test indicated that the residue populations for cucumber and melons were not different, it was agreed to combine the results to give a data set for fenamidone residues in whole melons and cucumbers of (n=25) < 0.01, < 0.02 (5), 0.03 (3), 0.04 (5), 0.05, 0.07, 0.07, 0.08, 0.09, 0.09, 0.10, 0.10, 0.12, 0.12 and 0.13 mg/kg. Furthermore, the contribution in follow-on crops of 1.2 mg/kg has to be added to the STMR and 1.5 mg/kg to the HR.

The Meeting estimated for fenamidone residues in fruiting vegetables, cucurbits a maximum residue level of 0.2 mg/kg. Based on the cucumber data, an STMR of 1.29 mg/kg and an HR of 1.63 mg/kg were estimated.

Fruiting vegetables other than cucurbits

The GAP for fruiting vegetables except cucurbits in the USA is 3× 0.3 kg ai/ha and a PHI of 14 days.

Field US trials on sweet pepper (6), chilli pepper (3) and tomatoes (17) according to the US GAP were provided. At each outdoor trial, four spray treatments of about 0.3 kg ai/ha were applied. The following residue data were received:

- In sweet pepper, the residues were for fenamidone as well as for the sum of fenamidone and RPA 410193 0.03, 0.05, 0.07, 0.08, 0.08 and 0.19 mg/kg.
- In chilli pepper, the fenamidone residues and the total residues were 0.07, 1.3 and 1.5 mg/kg. The Meeting recognized that one duplicate field sample gave higher residues than the HR based on the mean residues and decided to use this value of 1.7 mg/kg as HR for the short-term dietary intake assessment instead.
- In tomatoes, the fenamidone residues were < 0.02, < 0.02, 0.07, 0.07, 0.09, 0.10, 0.11, 0.25, 0.33, 0.34, 0.38, 0.40, 0.42, 0.46, 0.47, 0.61 and 0.80 mg/kg. The total residues were (n=17) < 0.02, < 0.02, 0.07, 0.07, 0.09, 0.10, 0.11, 0.25, 0.33, 0.34, 0.38, 0.45, 0.46, 0.47, 0.40, 0.61 and 0.80 mg/kg. The Meeting recognized that one duplicate field sample gave higher residues than the HR based on the mean residues and decided to use this value of 0.82 mg/kg as HR for the short-term dietary intake assessment instead.

The Meeting noted that the GAP in the USA was for fruiting vegetables other than cucurbits and considered a group maximum residue level. Furthermore, the Meeting noted that the median of the datasets for sweet pepper and tomatoes differed by less than 5-fold but the median for chilli was 17 times higher than for sweet pepper. The Meeting agreed to consider a group maximum residue level for fruiting vegetables other than cucurbits, except sweet corn, fungi and chilli pepper. In deciding on the data set to use for estimating a group maximum residue level, as a Mann-Whitney U-test indicated that the residue populations for sweet pepper and tomatoes belong to different populations with the highest residues in tomato. Furthermore, the contribution in follow-on crops of 1.2 mg/kg has to be added to the STMR and 1.5 mg/kg to the HR.

Based on the tomato residue data, the Meeting estimated a maximum residue level of 1.5 mg/kg, an STMR of 1.53 mg/kg and an HR of 2.32 mg/kg for fruiting vegetables other than cucurbits, except sweet corn, fungi and chilli pepper.

For chilli pepper, the Meeting estimated a maximum residue level of 4 mg/kg, an STMR of 2.5 mg/kg and an HR of 3.2 mg/kg.

The Meeting also decided to estimate a maximum residue for chilli pepper (dried) of 30 mg/kg following application of a default dehydration factor of 7 to the estimated maximum residue level of 4 mg/kg for chilli pepper (7 × 4=28 mg/kg). The STMR for residues of fenamidone in chilli peppers (dry) is estimated to be 18 mg/kg (7 × 2.5=17.5 mg/kg).

Leafy vegetables

The use of fenamidone in leafy vegetables in the USA is 3 × 0.3 kg ai/ha and a PHI of 2 days and the Meeting looked at the possibility to establish a group MRL. However, the Meeting recognized that the ARfD of 1 mg/kg bw was exceeded for the single commodities, if the highest residue of 32.7 mg/kg (mustard greens) is used as HR and concluded that a group MRL cannot be recommended.

Nine outdoor US trials on head lettuce according to the US GAP were provided. At each outdoor trial, four spray treatments of about 0.3 kg ai/ha were applied. The fenamidone residues, as well as the total residues, were: 0.82, 2.3, 3.3, 3.3, 3.7, 3.9, 4.4, 8.0 and 11 mg/kg. The Meeting recognized that one single sample gave higher residues than the HR based on the mean and decided to use this value of 12 mg/kg as HR for the short-term dietary intake assessment instead. Furthermore, the contribution in follow-on crops of 1.2 mg/kg has to be added to estimate the STMR and 1.5 mg/kg the HR.

The Meeting estimated a maximum residue level of 20 mg/kg, an STMR of 4.9 mg/kg and an HR of 13.5 mg/kg for fenamidone residues in head lettuce.

Nine outdoor US trials on leaf lettuce according to the US GAP were provided. At each outdoor trial, four spray treatments of about 0.3 kg ai/ha were applied. The fenamidone residues were

1.0, 2.6, 3.4, 3.4, 6.5, 7.9, 10, 12 and 16 mg/kg. The corresponding total residues were 1.0, 2.6, 3.4, 3.4, 6.5, 8.0, 10, 12 and 16 mg/kg (residue of one duplicate field sample 17.5 mg/kg).

The Meeting noted that the ARfD of 1 mg/kg bw is exceeded for leaf lettuce by the IESTI for children (110% of ARfD) using 17.5 mg/kg as HR and decided that the US dataset is not appropriate to estimate a maximum residue level for leaf lettuce.

Alternative GAP exist for outdoor use in Switzerland with 3 × 0.15 kg ai/ha with a PHI of 14 days. Nine trials on leaf lettuce conducted in Europe were submitted. The fenamidone residues in outdoor leaf lettuce at a PHI of 14 days were < 0.02 (3), 0.02, 0.04, 0.06, 0.07, 0.42 and 0.48 mg/kg. The corresponding total residues were < 0.02 (3), 0.02, 0.04, 0.06, 0.07, 0.43 and 0.48 mg/kg. Furthermore, the contribution in follow-on crops of 1.2 mg/kg has to be added to estimate the STMR and 1.5 mg/kg the HR.

The Meeting estimated a maximum residue level of 0.9 mg/kg, an STMR of 1.24 mg/kg and an HR of 1.98 mg/kg for fenamidone residues in leaf lettuce.

Eight outdoor US trials on mustard greens and six on spinach according to the US GAP were provided. At each outdoor trial, four spray treatments of about 0.3 kg ai/ha were applied.

In mustard greens, the fenamidone residues were 11, 12, 13, 17, 24, 28, 28 and 29 mg/kg. The corresponding total residues were 11, 12, 13, 17, 24, 28, 29 and 29 mg/kg (residue of one duplicate field sample 32.7 mg/kg). In spinach, the fenamidone residues were 7.2, 7.3, 11, 21, 23 and 31 mg/kg. The corresponding total residues were 7.2, 7.4, 11, 21, 23 and 31 mg/kg (residue of one duplicate field sample 32.4 mg/kg).

The similar datasets of mustard greens and spinach were combined for mutual support. The rank order of the combined fenamidone residues in spinach and mustard greens were (n=14) 7.2, 7.3, 11, 11, 12, 13, 17, 21, 23, 24, 28, 28, 29 and 31 mg/kg. The corresponding total residues were 7.2, 7.4, 11, 11, 12, 13, 17, 21, 23, 24, 28, 29, 29 and 31 mg/kg. The Meeting recognized that one duplicate field sample gave higher residues than the HR based on the mean residues and decided to use this value of 32.7 mg/kg as HR for the short-term dietary intake assessment instead. Furthermore, the contribution in follow-on crops of 1.2 mg/kg has to be added to estimate the STMR and 1.5 mg/kg the HR.

For spinach and mustard greens, the IESTI represented 150% and 170% for children, respectively of the ARfD of 1 mg/kg bw. The Meeting noted that an alternative GAP was not available.

The Meeting estimated a maximum residue level of 60 mg/kg, an STMR of 20 mg/kg and an HR of 34 mg/kg for fenamidone residues in spinach and mustard greens.

Legume vegetables

In the USA and in Canada, fenamidone may be used as foliar spray on succulent beans with 3 × 0.3 kg ai/ha and a PHI of 3 days. Field trials using 4×0.3 kg ai/ha were carried out in the USA for lima beans (8) and seven trials on common beans (7).

In mature succulent lima beans, the fenamidone residues as well as the total residues were in seeds without pods (n=8) < 0.02 (4), 0.03, 0.04, 0.08 and 0.08 mg/kg. Furthermore, the contribution in follow-on crops of 1.2 mg/kg has to be added to estimate the STMR and 1.5 mg/kg the HR.

The Meeting estimated for fenamidone residues in beans, shelled a maximum residue level, an STMR and an HR of 0.15 mg/kg, 1.2 mg/kg and 1.58 mg/kg, respectively.

In common beans, the fenamidone residues as well as the total residues were in pods with seeds (n=7) 0.10, 0.11, 0.16, 0.19, 0.23, 0.34 and 0.46 mg/kg. Furthermore, the contribution in follow-on crops of 1.2 mg/kg has to be added to estimate the STMR and 1.5 mg/kg the HR.

The Meeting estimated for fenamidone residues in beans, except broad bean and soya bean (green pods and immature seeds) a maximum residue level, an STMR and an HR of 0.8 mg/kg, 1.39 mg/kg and 1.96 mg/kg, respectively.

Root and tuber vegetables

Fenamidone is registered in the USA on the one hand for carrots, ginseng and potatoes and on the other hand for other root and tuber vegetables (garden beet, celeriac, horseradish, parsnips, parsley root, radish, salsify, swedes and turnips) except sugar beet with 3×0.3 kg ai/ha and a PHI of 14 days. Residue data were submitted for the use of fenamidone on carrots, potatoes and ginseng, dry.

Field trials (13) on carrots using approximately 4×0.3 kg ai/ha were carried out in the USA and in Canada. The fenamidone as well as the total residues were (n=13): 0.02, 0.03, 0.03, 0.03, 0.03, 0.04, 0.05, 0.05, 0.06, 0.06, 0.07, 0.09 and 0.11 mg/kg. Furthermore, the contribution in follow-on crops of 0.4 mg/kg has to be added to estimate the STMR and 0.5 mg/kg the HR.

The Meeting estimated a maximum residue level, an STMR and an HR of 0.2 mg/kg, 0.45 mg/kg and 0.61 mg/kg respectively, for carrots.

Field trials (19) on potatoes applying approximately 4 × 0.3 kg ai/ha were carried out in the USA and in Canada. The fenamidone as well as the total residues were < 0.02 (19) mg/kg. Furthermore, the contribution in follow-on crops of 0.4 mg/kg has to be added to estimate the STMR and 0.5 mg/kg the HR.

The Meeting estimated a maximum residue level of 0.02* mg/kg for fenamidone residues in potatoes. Taking into account the uptake of RPA 412363 from the soil by rooting vegetables grown as follow-on crops, the Meeting estimated an STMR of 0.4 mg/kg and an HR of 0.5 mg/kg for fenamidone residues in potatoes.

Six supervised trials on ginseng were carried out in 2007 in the USA and Canada. Only one trial was carried according to GAP with 3 × 0.3–0.31 kg ai/ha. At five trials, nine applications with application rates in the range of 0.29–0.32 kg ai/ha were performed at intervals of 7–15 days between each foliar spray. Samples were prepared by washing the roots with water after harvest followed by drying on racks in drying chambers for 14 days at 18–46 °C. The following residue data were received:

- After a treatment with 3 × 0.3–0.31 kg ai/ha, the residue of fenamidone as well as the total residue was 0.06 mg/kg.
- After treatment with 9 × 0.29–0.32 kg ai/ha, the fenamidone residues were 0.03, 0.10, 0.17, 0.29 and 0.35 mg/kg. The corresponding total residues were 0.03, 0.10, 0.17, 0.31 and 0.37 mg/kg and the highest single value from a duplicate field sample was 0.55 mg/kg.

The Meeting noted that only one of the six trials matched the GAP and concluded that the data submitted are insufficient to estimate a separate maximum residue level for ginseng.

Stalk and stem vegetables

Fenamidone is registered in the USA for celery with 3 × 0.3 kg ai/ha and a PHI of 2 days. Six supervised trials on celery were carried out during 2003 in the USA. At each trial, fenamidone was applied by foliar spray at rates of about 0.3 kg ai/ha four times at intervals of 4–6 days. In untrimmed plants without roots, the residues of fenamidone as well as the total residues were at a 2-days PHI (n=6) 2.3, 4.4, 4.5, 8.8, 15 and 18 mg/kg. In trimmed stalks, the residues were (n=5) 0.06, 0.32, 1.1, 1.2 and 1.7 mg/kg. Furthermore, the contribution in follow-on crops of 1.2 mg/kg has to be added to estimate the STMR and 1.5 mg/kg the HR.

The Meeting estimated a maximum residue level of 40 mg/kg, an STMR of 2.3 mg/kg and an HR of 3.2 mg/kg for fenamidone residues in celery.

The GAP for Witloof chicory in Belgium is one dip treatment of 0.006 kg ai/hL followed by an irrigation treatment with 0.6 g ai/hL and a PHI of 18 days.

All in all, nine European indoor residue trials were submitted. In 2004 four hydroponic residue trials were conducted in Belgium, France and the Netherlands consisting of one application through the irrigation water system at a maximum rate of 0.6 g ai/hL of fenamidone and a water volume of 40 L/m^2, at the commencement of forcing. The fenamidone residues as well as total residues in sprouts at PHIs of 20/21 days were < 0.01 mg/kg (4).

In 2008 and 2010 five residue trials were conducted in France, Germany and the Netherlands. These trials were treated twice, one dip application for two minutes in a solution containing 6.0 g ai/hL, immediately after field sampling of the roots. After storage of the roots in a cold room for 3–8 months, a second hydroponic application was made at the commencement of forcing in the irrigation water system at a maximum rate of 0.6 g ai/hL. Sprout samples were taken on day 20/21 after the second application. The fenamidone residues as well as total residues in sprouts at PHIs of 20/21 days were < 0.01 mg/kg (5).

The Meeting estimated a maximum residue level of 0.01* mg/kg, an STMR of 0.01 mg/kg and an HR of 0.01 mg/kg for fenamidone residues in Witloof chicory.

Oilseed

Fenamidone is registered in the USA for cotton as in-furrow treatment with 1 × 0.3 kg ai/ha.

Twelve trials were conducted on cotton in the USA during 2003. In each trial, cotton plants were treated at-planting with a single in-furrow over-the-seed application at a rate of 0.3 kg ai/ha. Samples of mature cotton seed were harvested 127–190 days post treatment. The residues of fenamidone as well as the total residues were in seed < 0.02 mg/kg (12).

The Meeting estimated a maximum residue level of 0.02* mg/kg and an STMR of 0.02 mg/kg for fenamidone residues in cotton seed.

The GAP for the use of fenamidone in the USA for sunflower is seed treatment with 0.19 kg/100 kg seed. Nine trials on sunflower were conducted in 2009 in the USA. In each trial, one plot was planted with sunflower seeds treated with fenamidone at a rate of 0.19 kg ai per 100 kg seed. Two trials included an additional plot planted with seed treated at an exaggerated rate of 0.95 kg ai per 100 kg seed. Samples of mature sunflower seed were harvested 104–146 days after sowing of the treated seed. The residues of fenamidone as well as the total residues were in seed < 0.02 mg/kg (9).

The Meeting estimated a maximum residue level of 0.02* mg/kg and an STMR of zero for fenamidone residues in sunflower seed.

Legume animal feed

In the USA and Canada, fenamidone may be used as foliar spray on succulent beans with 3 × 0.3 kg ai/ha and a PHI of 3 days. Seven field trials with 4 × 0.3 kg ai/ha were carried out in the USA on common beans. The fenamidone residues were in plants with pods at a PHI of 3 days 2.3, 4.1, 5.6, 7.6, 10, 11 and 16 mg/kg (fresh weight).

For the calculation of the livestock animal dietary burden, the Meeting estimated a median residue of 7.6 mg/kg and a highest residue of 16 mg/kg bean forage (green).

Cotton fodder, dry

Fenamidone is registered in the USA for cotton as in-furrow treatment with 1 × 0.3 kg ai/ha. Trials were conducted on cotton in the USA during 2003. In each trial, cotton plants were treated at-planting with a single in-furrow over-the-seed application at a rate of 0.3 kg ai/ha. The harvest was

127–178 days post treatment. The residues of fenamidone as well as the total residues were in cotton gin by-products < 0.02 mg/kg (6).

For the calculation of the livestock animal dietary burden, the Meeting estimated 0.02 mg/kg as median residue and highest residue for cotton fodder, dry.

Fate of residues during processing

Nature of residues

To estimate the degradation behaviour of [C-phenyl-U-^{14}C]-fenamidone during industrial processing or household preparation, the processes of pasteurization (90 °C, 20 min at pH 4), baking, boiling, brewing (100 °C, 60 min at pH 5) and sterilization (120 °C, 20 min at pH 6) were simulated.

Degradation of fenamidone was limited and appeared to be dependent on the conditions. The largest extent of degradation was ca. 12% TAR under pasteurisation conditions. RPA 410193 was the only degradate under these conditions. The amounts of RPA 410193 decreased with increasing pH, to 2.5% TAR at pH 6. There was additional degradation to RPA 412708 up to 3.6% TAR at higher temperature (120 °C) and pH (6). This degradation path was not seen at the lower temperatures.

The Meeting concluded that, in addition to the parent fenamidone, the only metabolite to consider for processed products is RPA 410193.

Level of residues

The Meeting received information on the fate of fenamidone residues during the processing of raw agricultural commodities (RAC) like grapes to juice, must, wine and pomace and tomatoes into juice, paste, ketchup and canned tomatoes. Because the residues of RPA 410193 are of the same order of magnitude as the parent concentrations in processed products of grapes and tomatoes, the sum of parent and RPA 410193 is calculated as follows:

Fenamidone, mg/kg	RPA 410193, mg/kg	Total, mg/kg
< 0.02	< 0.02	< 0.04
< 0.02	0.076	0.10
0.05	< 0.02	0.07
0.53	0.13	0.67[a]

[a] 0.53 + (0.13 × 1.11) = 0.6743

Two processing studies were carried out on potatoes but were only of limited use because the residues in RAC were < LOQ. Five further studies conducted on cabbage, broccoli, peppers, mustard greens and spinach investigated the fate of fenamidone and RPA 410193 after washing and cooking. The processing factors were for washed vegetables 0.58 and for cooked vegetables 0.21.

The processing factors for the sum of fenamidone and RPA 410193 obtained in the processing studies and the estimated STMR-P values for dietary intake calculations are summarized below.

Raw agricultural commodity		Processed commodity (food)		
	STMR, mg/kg		Processing factor	STMR-P, mg/kg
Grapes	0.175	Juice	0.36 (median)	0.063
		Must	0.83 (median)	0.145
		Wine	0.71 (median)	0.124
Tomatoes	1.53	Juice	0.8 (median)	1.22
		Puree	2.1 (median)	3.21
		Ketchup	2.4 (single value)	3.67

Raw agricultural commodity		Processed commodity (food)		
	STMR, mg/kg		Processing factor	STMR-P, mg/kg
		Paste	3.65 (mean)	5.58
		Canned fruits	0.45 (median)	0.69

In some tomato processed commodities, the residues increased during processing. For parent fenamidone, the processing factors were 2.55 for paste, 1.7 for puree and 1.6 for ketchup. Based on the recommended MRL of 1.5 mg/kg in fruiting vegetables other than cucurbits, the Meeting estimated maximum residue levels of 4 mg/kg for tomato paste and of 3 mg/kg for tomato puree as well as for ketchup.

The processing factors for parent fenamidone obtained in the processing studies and the median values of fenamidone residues in the RAC (parent only) were used to calculate the residues in the feed items grape pomace, tomato pomace and potato wet peel for animal dietary burden purposes.

Raw agricultural commodity		Processed commodity (feed)		
	Median (mg/kg)		Processing factor	STMR-P (mg/kg)
Grapes	0.15	Pomace, wet	2.0 (median)	0.3
Tomatoes	0.33	Pomace, wet	4.5 (median)	1.49
Potatoes	0.02	Wet peel	> 2.3 (single value)	0.046

The Meeting noted that fenamidone concentrated during processing in grape wet pomace, tomato wet pomace and potato wet peel. Because wet pomace and wet peel are not commodities in the international trade, no maximum residue levels are estimated.

Residues in animal commodities

Farm animal feeding studies

The Meeting received information on the residue levels arising in tissues and milk when three groups of dairy cows were fed with a diet containing 0.8, 2.4 and 8 ppm fenamidone for 35 consecutive days. At the highest dose group, no residues of fenamidone or the two major metabolites RPA 412636 and RPA 412708 were found in any of the tissue or milk fat samples higher than the LOD of 0.003 mg/kg, with the exception that in one milk fat sample, RPA 412708 was detected (0.011 mg/kg).

No poultry feeding study was submitted. In two metabolism studies laying hens were dosed at 13.8 ppm (C-phenyl label) and 9.8 ppm (N-phenyl label) fenamidone in the diet. The maximum residues (sum of fenamidone, RPA 412636 and RPA 412708) were 0.012 mg/kg in egg white, 0.05 mg/kg in egg yolk, 0.028 mg/kg in liver, 0.004 mg/kg in skin and < 0.001 mg/kg in fat.

Estimated dietary burdens of farm animals

Maximum and mean dietary burden calculations for fenamidone are based on the feed items evaluated for cattle and poultry as presented in Annex 6. The calculations were made according to the livestock diets from Australia, the EU, Japan and US-Canada in the OECD feeding table. Furthermore, the Meeting estimated the maximum highest dietary burden for the main metabolites in follow-on crops.

Parent fenamidone in primary commodities

The foliar application of fenamidone to grapes, tomatoes, cabbage, root and tuber vegetables, cotton and sunflower resulted in residues of fenamidone in the following feed items: wet grape pomace, wet tomato pomace, head cabbage, carrot culls, potato culls, potato process waste, turnip roots, swede roots, cassava/tapioca roots, cotton undelinted seed, sunflower seed and cotton fodder, dry. Residue

data were also submitted for green bean forage (vines) what is listed as 60–70% of the Australian diet and for beef and dairy cattle and as 20% of the European diet for dairy cattle. Based on the named feed items, the calculated maximum animal dietary burden for dairy or beef cattle was in the USA and Canada 0.13 ppm, in the EU 10 ppm and in Australia 33 ppm. The Meeting noted that the estimated livestock dietary burden (AUS) was up to three times higher than the dose rate in the cow feeding study.

The Meeting recognized that green bean forage (vines) is not used as animal feed in the USA and in Canada but in the EU and in Australia. The Meeting was informed by an official communication of the government of Australia that no fodder crops are imported. Furthermore, the USDA Global Agricultural Trade System database indicates that no animal feed/fodder were exported from the USA to Australia and the EU in 2013. The Meeting concluded that green bean forage is not an exportable commodity and decided to make a refined calculation of the livestock dietary burden without the residues in bean vines (see Annex 6).

In the table below the estimated livestock dietary burden is presented for fenamidone after foliar treatment of plants.

	Livestock dietary burden, fenamidone, ppm of dry matter diet							
	US-Canada		EU		Australia		Japan	
	Max	Mean	Max	Mean	Max	Mean	Max	Mean
Beef cattle	0.15	0.15	1.0 [a]	0.52	1.0 [a]	0.97[b]	0	0
Dairy cattle	0.13	0.08	0.96	0.49	0.99	0.97	0	0
Poultry–broiler	0	0	0.09	0.04	0	0	0	0
Poultry–layer	0	0	0.27 [c]	0.12 [d]	0	0	0	0

[a] Suitable for MRL estimates for mammalian meat, fat, edible offal and milk.
[b] Suitable for STMR estimates for mammalian meat, edible offal and milk.
[c] Suitable for MRL estimates for eggs, meat, fat and edible offal of poultry.
[d] Suitable for STMR estimates for eggs, meat, fat and edible offal of poultry.

Metabolites in follow-on crops

Rotational crop studies showed that in the follow-on crops an uptake from the soil of the metabolites RPA 412708 and RPA 412636 occurred. Their highest concentrations found in follow-on crops as wheat, sweet corn, maize and soya beans after the treatment of bare soil with fenamidone at 1.2 kg ai/ha per annum were scaled according to the critical US GAP of 0.9 kg ai/ha per annum for brassica vegetables, fruiting vegetables, leafy vegetables, root and tuber vegetables and celery. These residues are extrapolated to similar feed items in the OECD feeding table.

The maximum livestock dietary burden for RPA 412708/RPA 412636 in follow-on crops in the USA and Canada was estimated as follows: Beef cattle 0.088 ppm (as RPA 41236), dairy cattle 0.36 ppm (as RPA 41236), poultry broiler 0 ppm and poultry layer 0 ppm. Expressed as fenamidone equivalents, the burden was for beef cattle 0.14 ppm and for dairy cattle 0.59 ppm.

The Meeting noted that RPA 412708 and RPA 412636 are not found in milk or tissues of dairy cows dosed at 8 ppm fenamidone through normal animal metabolism routes. Therefore, the two metabolites are unlikely to be present after direct administration of much lower levels (maximum livestock dietary burden 0.59 ppm).

The Meeting concluded that it is unlikely that residues of RPA 412708 and RPA 412636 in follow on crops of the uses considered by the JMPR result in residues in animal products.

Animal commodities, MRL estimation

The feeding study with fenamidone in dairy cows was performed at actual dose levels of 0.8, 2.4 and 8 ppm in the diet. At the highest dose group, no residues of fenamidone or of the two major

metabolites RPA 412636 and RPA 412708 were found in any of the tissue or milk fat samples (< 0.003 mg/kg, LOD; LOQ 0.01 mg/kg), with the exception that in one milk fat sample RPA 412708 was detected (0.011 mg/kg). The overdosing factor is calculated as about 8 (8 ppm ÷ 1 ppm). Therefore, residues of fenamidone, RPA 412636 and RPA 412708 in cattle tissues and milk arising from a burden of 1 ppm are not expected.

The Meeting estimated maximum residue levels of 0.01* mg/kg for milks, meat from mammals, other than marine mammals (fat), mammalian fat (except milk fat) and edible offal (mammalian). For milk fat, a maximum residue level of 0.02 mg/kg was estimated. The STMRs for milk and milk fat were 0.01 mg/kg and the STMR/HR values for muscle, fat and edible offal were zero.

No poultry feeding study was submitted. In two metabolism studies, laying hens were dosed at 13.8 ppm (C-phenyl label) and 9.8 ppm (N-phenyl label) fenamidone in the diet. The maximum residues (sum of fenamidone, RPA 412636 and RPA 412708) were 0.012 mg/kg in egg white, 0.05 mg/kg in egg yolk and 0.028 mg/kg in liver.

Allowing for the dose rates in the metabolism studies (overdosing factors about 40–50), it can be seen that at the maximum calculated dietary burden for poultry of 0.27 ppm, no residues of fenamidone or any of its metabolites will be found in poultry commodities at or above the LOQ of 0.01 mg/kg.

The Meeting estimated maximum residue levels of 0.01* mg/kg poultry meat, poultry fat, poultry edible offal and eggs. The STMR/HR values for poultry meat, poultry fat, poultry edible offal and eggs are zero.

RECOMMENDATIONS

On the basis of the data from supervised trials the Meeting concluded that the residue levels listed below are suitable for establishing maximum residue limits and for IEDI and IESTI assessment.

Definition of the residue for compliance with the MRL for plant and animal commodities: *Fenamidone*.

Definition of the residue for estimation of dietary intake for plant commodities: *Sum of fenamidone, (S)-5-methyl-5-phenyl-3-(phenylamino)- 2,4-imidazolidine-dione (RPA 410193) plus 10 × the sum of both (S)-5-methyl-5-phenyl-2,4-imidazolidine-dione (RPA 412636) and (5S)-5-methyl-2-(methylthio)-5-phenyl-3,5-dihydro- 4H-imidazol-4-one (RPA 412708), all calculated as fenamidone.*

Residue concentration $C_{total}=C_{fenamidone} + C_{RPA\ 410193} + 10 \times (C_{RPA\ 412636} + C_{RPA\ 412708})$

Definition of the residue for estimation of dietary intake for animal commodities: *Fenamidone plus 10 × the sum of both (S)-5-methyl-5-phenyl-2,4-imidazolidine-dione (RPA 412636) and (5S)-5-methyl-2-(methylthio)-5-phenyl-3,5-dihydro- 4H-imidazol-4-one (RPA 412708), all calculated as fenamidone*.

Residue concentration $C_{total}=C_{fenamidone} + 10 \times (C_{RPA\ 412636} + C_{RPA\ 412708})$

The residue is fat-soluble.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Dietary Intakes (IEDIs) of fenamidone were calculated for the 17 GEMS/Food cluster diets using STMRs and STMR-Ps estimated by the current Meeting (Annex 3 to

the 2014 Report). The ADI is 0–0.03 mg/kg bw and the calculated IEDIs were 10–60% of the maximum ADI. The Meeting concluded that the long-term intake of residues of fenamidone resulting from the uses considered by the current JMPR is unlikely to present a public health concern.

Short-term intake

The International Estimated Short Term Intake (IESTI) for fenamidone was calculated for food commodities and their processed fractions for which maximum residue levels were estimated and for which consumption data were available. The results are shown in Annex 4 to the 2014 Report.

The Meeting recognized that for leaf lettuce the IESTI calculated according to the maximum GAP exceeded the ARfD of 1 mg/kg bw and used an alternative GAP. For spinach and mustard greens, the IESTI represented 150% and 170%, respectively of the ARfD of 1 mg/kg bw. The Meeting noted that an alternative GAP was not available. For the other commodities considered by the JMPR, the IESTI represented 0–30% of the ARfD. The Meeting concluded that the short-term intake of residues of fenamidone, when used in ways that have been considered by the JMPR, is unlikely to present a public health concern (except mustard greens and spinach).

5.12 FENPROPATHRIN (185)

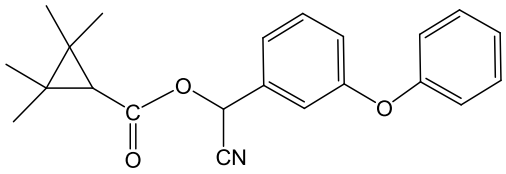
RESIDUE AND ANALYTICAL ASPECTS

Fenpropathrin is a type II pyrethroid insecticide and acaricide used for the control of a variety of arthropods including aphids, worms, moths, beetles, mites, spiders, thrips, flies, fleas and other pests in agriculture.

Fenpropathrin was first evaluated by JMPR in 1993 when an ADI of 0–0.03 mg/kg bw was established and a number of MRLs recommended. In 2006 MRL for tea was recommended. The compound was re-evaluated for toxicology within the periodic review programme in 2012 when the Meeting reaffirmed the ADI of 0–0.03 mg/kg bw and established an ARfD of 0.03 mg/kg bw.

The Forty-fifth Session of CCPR scheduled fenpropathrin for periodic re-evaluation of residues by the 2014 JMPR. Data to support proposed Codex MRLs on a number of commodities and on animal products were submitted for review.

The structural formulae and IUPAC name of fenpropathrin are:

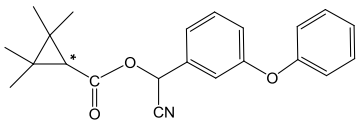


(*RS*)-α-cyano-3-phenoxybenzyl 2,2,3,3-tetramethylcyclopropanecarboxylate.

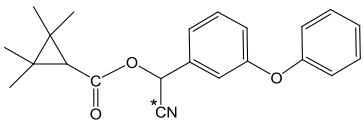
Metabolism and environmental fate

The metabolism of fenpropathrin has been investigated in apple, tomato, beans, cotton, cabbage, lactating goat and laying hens. The crops selected represent those for which supervised trials have been provided.

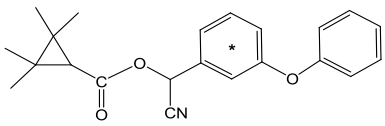
The fate and behaviour of fenpropathrin in plants, animals and soil were investigated using either [cyclopropyl-1-^{14}C]-fenpropathrin, [benzyl-^{14}C]-fenpropathrin, [phenoxyphenyl-^{14}C]-fenpropathrin or [cyano-^{14}C]-fenpropathrin (all with radiochemical purity >98%).



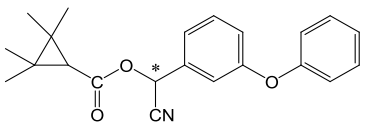
[cyclopropyl-1-^{14}C]-fenpropathrin



[cyano-^{14}C]-fenpropathrin

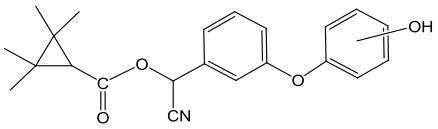
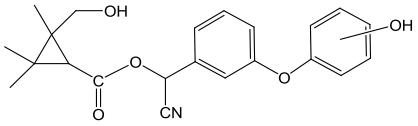
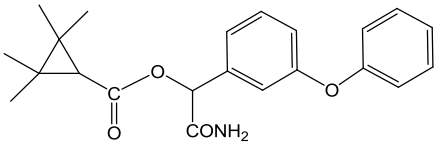
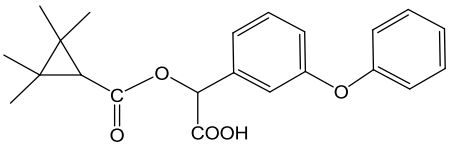
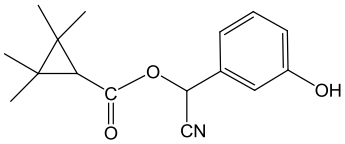
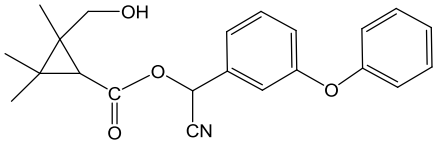
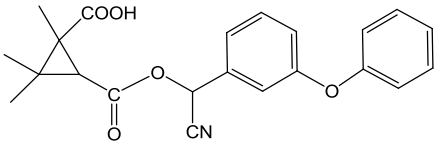
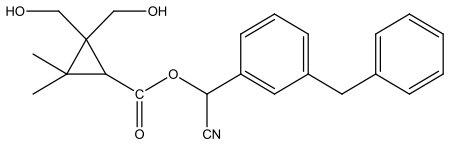
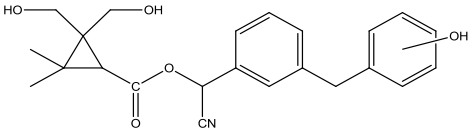
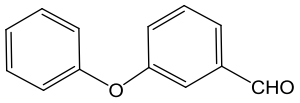
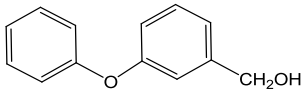
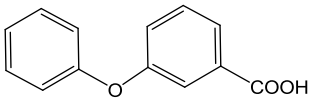


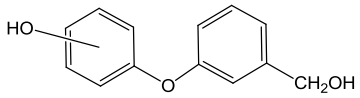
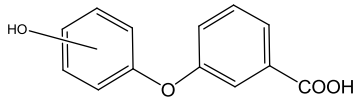
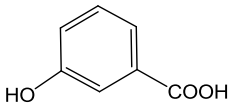
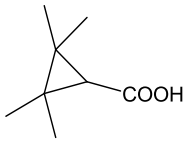
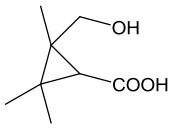
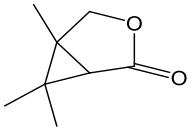
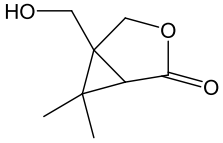
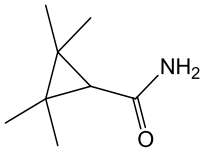
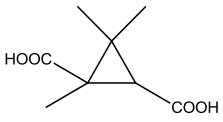
[phenoxyphenyl-^{14}C]-fenpropathrin



[benzyl-^{14}C]-fenpropathrin

The chemical and code names and structure of the major degradation compounds, referred to hereunder, are:

Compound Name	Structure	Found in:
2'-or 4'-OH-Fenpropathrin [α-cyano-3-(2'- or 4'-hydroxyphenoxy)benzyl 2,2,3,3-tetramethylcyclopropanecarboxylate]		Plant, animal, soil
2'- or 4'-OH-Fenpropathrin-CH_2OH [α-cyano-3-(2'- or 4'-hydroxyphenoxy) benzyl-2-hydroxymethyl-2,3,3-trimethylcyclopropanecarboxylate]		Plant, animal
$CONH_2$-Fenpropathrin [α-carbamoyl-3-phenoxybenzyl 2,2,3,3-tetramethylcyclopropanecarboxylate]		Soil, water plant
COOH-Fenpropathrin [α-carboxy-3-phenoxybenzyl 2,2,3,3-tetramethylcyclopropanecarboxylate]		Soil, plant
Desphenyl-Fenpropathrin [α-cyano-3-hydroxybenzyl 2,2,3,3-tetramethylcyclopropanecarboxylate]		Animal, soil, plant
Fenpropathrin-CH_2OH [α-cyano-3-phenoxybenzyl 2-hydroxymethyl-2,3,3-trimethylcyclopropanecarboxylate]		Plant, animal
Fenpropathrin-COOH [α-cyano-3-phenoxybenzyl 2-carboxy-2,3,3-trimethylcyclopropanecarboxylate]		Animal
Fenpropathrin-$(CH_2OH)_2$ [α-cyano-3-phenoxybenzyl 2,2-dihydroxymethyl-3,3-dimethylcyclopropanecarboxylate]		Plant
2'- or 4'-OH-Fenpropathrin-$(CH_2OH)_2$ [α-cyano-3-(2'- or 4'-hydroxyphenoxy)benzyl 2,2-dihydroxymethyl-3,3-dimethylcyclopropanecarboxylate]		Plant
PB aldehyde (PBald) [3-phenoxybenzaldehyde]		Plant, animal, soil
PB alcohol (PBalc) [3-phenoxybenzyl alcohol]		Plant, soil
PBacid [3-phenoxybenzoic acid]		Plant, animal, soil, water

Compound Name	Structure	Found in:
2'- or 4'-OH-PBalc [3-(2'- or 4'-hydroxyphenoxy)benzyl alcohol]		Plant
2'- or 4'-OH-PBacid [3-(2'- or 4'-hydroxyphenoxy)benzoic acid]		Plant, animal, soil
3-OH-Bacid [3-hydroxy-benzoic acid]		Animal, soil
TMPA [2,2,3,3-tetramethylcyclopropane-carboxylic acid]		Plant, animal, soil, water
TMPA-CH_2OH [2-hydroxymethyl-2,3,3-trimethylcyclopropanecarboxylic acid]		Plant, animal
TMPA-lactone [5,6,6-trimethyl-3-oxabicyclohexan-2-one]		Plant
TMPA-CH_2OH lactone [5-hydroxymethyl-6,6-dimethyl-3-oxabicyclohexan-2-one]		Plant, animal
TMPA carboxamide [2,2,3,3-tetramethylcyclopropane-carboxamide]		Water
TMPA-COOH [2-carboxy-2,3,3-trimethylcyclopropanecarboxylic acid]		Plant, animal

Animal metabolism

Laboratory animals

The toxicological evaluation fenpropathrin was carried out by the 2012 JMPR. Absorption by rats was rapid and excretion was almost complete (97%) within 48 hours. About 56% of the administered dose was found in urine and 40% in faeces after 48 hours. The amount of radioactivity excreted via expired air was 0.005%. The low residues found in blood, liver, kidney, fat, muscle and brain 24 hours after dosing depleted rapidly over the following 7 days to barely detectable levels, and less than 1.5% of the administered dose remained in the body 8 days after treatment. The highest residue was found in the fat. About 29–53% of the parent compound was detected in the faeces and no parent compound was detected in the urine. The predominant urinary metabolites derived from the acid moiety were identified as TMPA–glucuronide and TMPA-CH_2OH (*trans*). Other metabolites identified were TMPA-COOH (*trans*) and TMPA-CH_2OH-lactone in free form or as the glucuronide.

The major urinary metabolites derived from the alcohol moiety were PBacid in free form and as the glycine conjugate, 4′-OH-PBacid–sulfate and 2′-OH-PBacid–sulfate. The urinary metabolites from the alcohol moiety were similar to those from other pyrethroids. The major faecal metabolite was identified as CH_2OH *trans*-fenpropathrin, followed by COOH *trans*-fenpropathrin, 4′-OH-fenpropathrin and 4′-OH,CH_2OH *trans*-fenpropathrin. Fenpropathrin and TMPA were the major components of ^{14}C in tissues. No sex-related differences in tissue distribution were observed.

Lactating goats

Two lactating goats per group were dosed for five consecutive days via capsules with either [phenoxyphenyl-^{14}C]-fenpropathrin or [cyclopropyl-1-^{14}C]-fenpropathrin at a rate equivalent to 50 ppm. Milk samples were collected at the morning and afternoon and urine and faeces once a day.

The mean average total radioactivity recovered following dosing with both labelled compounds was about 65.8% with 40% recovered in the urine and 25% in the faeces.

Excretion via milk was a minor route with radioactivity accounting for approximately 0.15% of the applied phenoxyphenyl labelled and approximately 0.087% for the cyclopropyl labelled compound. Total radioactive residues in the milk reached a steady state by the evening milking on the third day.

Following the treatments with 50 ppm [phenoxyphenyl-^{14}C]-fenpropathrin, the maximum total residue in milk was 0.25 mg/l. The major residue components were the parent fenpropathrin 78% TRR, (0.02 mg/kg). At around the plateau, the average concentration of the parent compound was 0.05 mg/kg (29%TRR) and PBacid-glycine 0.076 mg/kg (46%TRR). The other metabolites were < 10% TRR.

At sacrifice, the average residues were: in fat: fenpropathrin (0.50 mg/kg, 78%TRR), all metabolites were present at lower than 5%TRR; in muscle: fenpropathrin (0.011 mg/kg, 45%TRR), PBacid-glycine (22.4% TRR), PBacid (10.9% TRR) the other metabolites were below 3%; in liver: fenpropathrin (0.014 mg/kg, 3.2% TRR), PBacid-glycine (20%TRR), PBacid (14% TRR), 4'-OH-PBacid (11%TRR), the other metabolites were below 10% TRR; in kidney: fenpropathrin (0.01 mg/kg, 1.24%TRR), PBacid-glycine (39%TRR), PBacid (38%TRR) and the other metabolites were below 10%.

After the goats were administered with [cyclopropyl-1-^{14}C]-fenpropathrin, the average total residue in milk was 0.11 mg/L. The parent compound in milk amounted to maximum 70% TRR (0.086 mg/kg). All metabolites amounted to maximum 4% TRR.

At sacrifice, the average residues were: in fat: fenpropathrin (0.55 mg/kg, 81% TRR), all metabolites were present at lower than 3%TRR; in muscle: fenpropathrin (0.005 mg/kg, 11.3% TRR), TMPA-CH_2OH-lactone (19.4% TRR) andTMPA-CH_2OH (11%TRR); in liver: fenpropathrin 0.011 mg/kg (2.45% TRR), TMPA (18.2%TRR), TMPA-CH_2OH (15.8%TRR) and TMPA-CH_2OH lactone (12.5% TRR); in kidney: fenpropathrin 0.0076 mg/kg (1.48% TRR), TMPA-CH_2OH-lactone (40.8% TRR) and TMPA-CH_2OH (14.5% TRR) .

The other metabolites in muscle, liver and kidney were below 5%TRR.

Laying hens

Fenpropathrin, labelled in either the cyclopropyl or the phenoxyphenyl ring was administered in capsules to laying hens daily for 10 days at a nominal rate of either 0.5 or 5 mg/kg body weight.

The recovery of total radioactivity from excreta, eggs and tissues was between 75 and 84% of the total applied dose. Between 98.9 and 99.6% of the recovered activity was found in the faeces irrespective of the label.

Approximately 0.05% of the applied phenoxyphenyl- and 0.2% of the cyclopropyl-labelled compound was found in the eggs. At about the 6th or 7th day of the study residue levels in the eggs reached a plateau of about 0.05 and 0.2 mg/kg fenpropathrin equivalent for the two doses of the phenoxyphenyl-labelled and about 0.2 and 0.5 mg/kg for those of the cyclopropyl-labelled compounds.

In case of high dose group treated with phenoxyphenyl-labelled compound, the average concentration of parent fenpropathrin amounted to 31% of TRR (0.043 mg/kg) in eggs and all identified metabolites were present at less than 10%TRR. In breast and tight muscle, the average proportions of residues (%TRR) were: parent compound 19% (0.02 mg/kg), PBacid (22%), 3-OH-BAcid (13%). In liver and kidney the average percentage distributions of TRR were, respectively: parent (0.98%, 2.11%; 0.014 mg/kg, 0.096 mg/kg), 3-OH-BAcid (29%, 35%), 4-OH-PBacid (16%, 26%) and PBacid (14.7%, 8.7%). The other metabolites were <10% TRR in all tissues.

In case of cyclopropyl label the average concentration of parent fenpropathrin amounted to 9.8% TRR (0.038 mg/kg) in eggs, and one major metabolite, TMPA-CH_2OH, was present at 11.7%n TRR. All other metabolites amounted to <10% TRR and their concentrations were < 0.03 mg/kg. In muscle, the average proportions of residues (%TRR) were: parent compound 6% (0.033 mg/kg), TMPA-CH_2OH (16%), TMPA (15.7%), TMPA-CH_2-OH-lactone (12.3%. All other metabolites amounted to <10% TRR and their concentrations were < 0.03 mg/kg. In liver and kidney the average percentage distributions of TRR were, respectively: parent (1.2%, 0.04 mg/kg; 5.1%; 0.24 mg/kg), TMPA (26.4%, 47.5%), TMPA-CH_2OH (14.7%, 7.7%), TMPA-CH_2-OH-lactone (14.8%, 5.3%), TMPA-COOH (11.4%, 15.3%). The other metabolites were present at < 1.8%TRR.

The metabolic pattern in fat was similar in case of both labels. The fat contained maximum 0.90 mg/kg total residue of which the parent compound amounted to 64%TRR (0.58 mg/kg). The most prominent metabolite was TMPA (14%nTRR), the other metabolites occurred at < 6% TRR.

In summary, the major biotransformation reactions of fenpropathrin in animals consisted of oxidation at the methyl groups of the acid moiety and at the 2'- or 4'-positions of the alcohol moiety, cleavage of the ester and ether linkages and conjugation of the resultant carboxylic acids and alcohols.

The parent compound was detected in milk, eggs and tissues, and it was the main residue in fat about 80%TRR. The major metabolites >10% TRR following the treatment with phenoxyphenyl-labelled fenpropathrin were PBacid-glycine, PBacid and 3-OH-BAcid, and after dosing with cyclopropyl-labelled compound the major metabolites were TMPA-CH_2OH, TMPA, TMPA-CH_2-OH-lactone and TMPA-COOH.

Plant metabolism

Apples

One apple tree was treated 3 times with [cyclopropyl-1-^{14}C]-fenpropathrin and [benzyl-^{14}C]-fenpropathrin at a rate equivalent to 0.45 kg ai/ha. Samples were collected 14 days after the final application. Un-extractable residues ranged from 3% (both labels in fruit) to 8% (benzyl label in leaves).

Practically, the entire residue found in the fruit (92–94% TRR) was present as the parent compound. The parent compound was also the major component in the rest of the plant (61–66%TRR). All metabolites were < 5%TRR.

Tomatoes

Greenhouse-grown tomato plants were treated four times, 7–8 days apart, with [cyclopropyl-1-^{14}C]-fenpropathrin and [benzyl-^{14}C]-fenpropathrin at rates equivalent to 0.224 kg ai/ha. Fruit and leaves were extracted at harvest 19 DALT).

The total radioactive residues were 0.1 mg/kg and 0.4 mg/kg in fruits after treatments with benzyl and cyclopropyl labelled compound and consisted of the parent compound in about 66% of the benzyl label and 28% of conjugated metabolites. Their proportion was about the opposite for cyclopropyl label. The non-extractable residues were between 5.5% and 6.7%. Because of their low level, the radioactivity could not be fully characterised.

In tomato plants, the parent compound was present in 36–39% of TRR (0.1-0.04 mg/kg). Of the identified metabolites only fenpropathrin-$(CH_2OH)_2$ was present in free form (2.7–3.1% TRR). Numerous other metabolites were in conjugated forms. Non-extractable residues amounted to 7.4–9.3%.

In another study where tomato plants were treated in greenhouse four times with [cyclopropyl1-^{14}C]-fenpropathrin and[phenoxyphenyl-^{14}C]-fenpropathrin at a rate equivalent to 0.224 kg ai/ha. Fruits and plant materials, sampled 3 days after last application, contained the parent compound in 96–98% of TRR. Polar metabolites amounted to 1.3% of TRR. The surface rinses contained 98–99% of the parent compound determined in the fruits.

Beans

Pinto bean plants grown in greenhouse were treated three times with [cyclopropyl-1-^{14}C]-fenpropathrin and [benzyl-^{14}C]-fenpropathrin at a rate equivalent to 0.224 kg ai/ha. Samples were collected 15 days after the final application. Leaves and plant parts contained 98.8%, bean pods and seeds contained 1.1% and 0.1% of the residue. In beans treated with benzyl- and cyclopropyl-labelled compound, the residue in seed was composed of the parent compound (4.1% and 0.1% of TRR), conjugated metabolites (61–51% TRR) free metabolites (17–4%TRR) and un-extractable residues 18.2%–45% TRR. The bean leaves contained 46.7% parent compound and conjugates of PBald (19.5%TRR) after treatment with benzyl labelled compound. After treatment with cyclopropyl-labelled compound the residue composed of 46.4% parent fenpropathrin and conjugates of TMPA-CH_2OH (16.7%TRR). The other metabolites were present at < 10% TRR.

Cotton

Two studies were conducted treating cotton plants with [phenoxyphenyl-^{14}C]-fenpropathrin and [cyclopropyl-1-^{14}C]-fenpropathrin.

In the first study the plants were treated in greenhouse four times with syringe applying a total of ca. 4.7–4.8 mg ^{14}C-fenpropathrin. In the leaves at harvest 66 and 111 days after treatments with phenoxyphenyl- or cyclopropyl labelled compound the total remaining radio activity included 70% TRR and 55% TRR parent compound, respectively Most of the remaining radio activity was tentatively accounted for PBacid (2.% TRR) and trans-TMPA-COOH (11%TRR) mainly in conjugated forms. All other metabolites were below 2%TRR.

Plants grown on soils treated with 0.5 kg/ha of fenpropathrin contained ^{14}C residues in very low concentration (0.002 mg/kg in leaves and 0.01 mg/kg in bolls), demonstrating limited tendency for translocation.

In the second study outdoor cotton plants were treated four times at a rate equivalent to 0.336 kg ai/ha. Seeds collected 21 day after last treatment contained total radioactivity 1.14 mg/kg and 1.59 mg/kg, while the foliage contained 78.6 mg/kg and 67.7 mg/kg fenpropathrin equivalent after treatment with phenoxyphenyl- and cyclopropyl-labelled fenpropathrin, respectively. The seed, lint and foliage contained the parent fenpropathrin in 93.8%, 96.2% and 69.2% TRR, respectively,

after treatment with phenoxyphenyl -labelled compound. The seed contained 12 metabolites each at < 0.005 mg/kg concentration. Following the application of cyclopropyl-labelled fenpropathrin the parent compound amounted to 85.6%, 100% and 67.4% TRR in seed, lint and foliage, respectively. A small number of metabolites were also detected, but not identified.

Cabbage

Cabbage plants were treated on the 3rd-4th leaves with [cyano-^{14}C]-fenpropathrin), [cyclopropyl-^{14}C]-fenpropathrin and [phenoxyphenyl-^{14}C]-fenpropathrin at a rate equivalent to about 0.09 kg ai/ha. The cabbages were sampled immediately after application and at 3, 7, 14, 21, 28, 35 and 42 days after application. The proportions of parent fenpropathrin in 28-day samples after treatment with cyano-, cyclopropyl- and phenoxphenyl-fenpropathrin were 16.9%, 15.8% and 12.9% of the applied dose, respectively, and it was present at somewhat lower proportion in 48-day samples. The major part of the residue (23-26% AD) composed of the conjugates of 2'-OH-fenpropathrin-CH_2OH, 4'-OH-fenpropathrin-CH_2OH, 2'-OH-fenpropathrin-$(CH_2OH)_2$ and 4'-OH-fenpropathrin-$(CH_2OH)_2$ and TMPA-CH_2OH-lactone-conjugate (11%). The other metabolites were present at ≤ 10% TRR after treatments with cyclopropyl- and phenoxyphenyl-labelled compounds.

Most of the recovered radiocarbon was in the treated leaves and less than 1.2% of the applied radiocarbon was found in the untreated shoots indicating that fenpropathrin and its metabolites hardly translocate from the application site to other parts of the plant.

Fate of hydrogen cyanide (HCN) and TMPA in abscised leaves

The fate of HCN and TMPA in abscised leaves of apple, kidney bean, cabbage, mandarin orange, tomato and vine was studied. Two abscised leaves from each plant were placed in 100 ml distilled water containing ^{14}C-TMPA at a concentration of 1.0 ppm. After cultivation for five days the leaves were extracted with methanol:chloroform:water (4:2:1).

TMPA was readily converted in plants to more polar products. The metabolic pathways for TMPA varied dependent upon species of plant. The glucose ester was a main product in apple and vine leaves. In orange, cabbages and bean leaves, the malonylglucoside was mainly formed.

Further on, two abscised cabbage leaves were treated for four hours with distilled water containing K^{14}CN and then transferred to K^{14}CN-free distilled water. The study demonstrated that if hydrogen cyanide were liberated during the hydrolysis of fenpropathrin, it would be rapidly converted to natural products.

Summary of plant metabolism

Metabolism of fenpropathrin has been studied in apples, tomatoes, beans, cotton and cabbage.

The general pattern of degradation in all the plant studies include break of the ester linkage to produce 3-phenoxybenzoic acid (PBacid) and the corresponding alcohol (PBalc) and aldehyde (PBald). From the acid side of the molecule, the main metabolite is TMPA which can give rise to TMPA-CH_2OH and TMPA-CH_2OH lactone. PBacid can be hydroxylated at various positions on the phenoxy ring to produce, 2'-or 4'-OH-PBacid.

The majority of radioactivity was found in leaf samples. Low levels of radioactivity were found in fruit/beans. The parent fenpropathrin amounted to the major part of the residue. Fenpropathrin and its metabolites hardly translocate from the application site to other parts of the plant.

Environmental fate

In soil

Studies on the metabolism of fenpropathrin in aerobic soil carried out with [phenoxyphenyl-^{14}C]-fenpropathrin demonstrated that fenpropathrin is degraded in the soil by a combination of photochemical and microbial processes. After 365 days, 18.4% of the dose remained as parent with accumulated volatiles accounting for 59.9% (99.8% of which was CO_2) and un-extractable residues for 17.8%. Metabolism proceeds via cleavage of the ester bonds, hydroxylation, and hydrolysis of the cyano group to $CONH_2$ and COOH groups. Metabolites included desphenyl-fenpropathrin, 4'-OH-fenpropathrin, phenoxybenzoic acid, and $CONH_2$-fenpropathrin, which was further degraded to COOH-fenpropathrin. The estimated half-life was about 4 weeks in moist soil (70–75% field capacity) and 16 weeks in a dryer soil with 16% water content.

Photodegradation studies were carried out with fenpropathrin labelled with ^{14}C in the cyano group, the phenoxyphenyl ring or C-1 position of the cyclopropyl ring. Irradiation greatly enhanced degradation of the fenpropathrin. The main degradation product under irradiation with all three labels was $CONH_2$-fenpropathrin which reached a maximum in the three soils after 5–7 days during the 14-day exposition.

Fenpropathrin is moderately stable in soil under aerobic condition. The photolysis increased the degradation of the surface residues.

Hydrolytic degradation

Fenpropathrin is stable to hydrolysis in water at pH 5 and pH 7 but it is hydrolysed at a moderate rate at pH 9.

Rotational crops

No study was submitted on rotational crops.

Methods of analysis

Analytical methods have been developed for determination of residues of fenpropathrin in plant and animal matrices. In general, the methods involve solvent extraction, clean-up by either silica gel or Florisil column, GLC using electron capture detection. Additional purification using gel permeation chromatography (GPC) was performed for oily matrices. The main variations depending on the substrates are on extraction and clean-up procedures. Fruits and vegetables may be homogenized with water, shaken with acetone, and extracted with dichloromethane, using NaCl to minimize emulsification. After drying with anhydrous sodium sulphate and clean-up by silica gel column chromatography, the solvent is evaporated at < 40 ºC and the residue dissolved in acetone before determination by gas chromatography with electron capture detection. Other extraction procedures involve direct extraction of the homogenized material suspension in water or homogenization with methanol instead of water. The methods were generally validated at 0.01 mg/kg LOQ level. The RSD of recoveries was < 20%

A multi residue method (DFG S19) was validated for the determination of fenpropathrin in plant materials of high water content and acidic plant matrices applying GC-MS detection (m/z 181 and 265 for quantification and 125, 152, 209 and 349 for confirmation).

In a supervised trial on soya bean, the residues were determined with LC-MS/MS utilising the transition of m/z 350→125. The LOQ was 0.01mg/kg.

Stability of residues in stored analytical samples

The stability of fenpropathrin residues in commodities under frozen conditions has been investigated in apples, orange, cotton, pears, grapes, tomato and its processed products as well as in products of animal origin.

Fenpropathrin was shown to be stable at least for the indicated periods (month) in: apple, orange, cotton, pears and grapes (12);cucumber (8); grape juice, dry pomace (14) wet pomace (12), hydrated raisins and raisin waste (11); melons (6); non-bell peppers (10); olives, olive oil (~7); orange oil and orange dried peel (11); raspberries (7); squash (7.5); strawberries (6); tomato (6), tomato paste (5), tomato juice (5) and wet and dry tomato pomace (5) tomato waste (5).

The residues were stable in eggs for 5 months, and milk and kidney at least for 2.5 months.

Definition of the residue

Livestock animal metabolism studies were conducted on lactating goats (50 ppm in feed) and laying hens (0.5 and 5 mg/kg body weight) applying [phenoxyphenyl-^{14}C]- and [cyclopropyl-1-^{14}C]-fenpropathrin.

In milk, at around the plateau at 3–5 days, the parent compound amounted to the major part of residues 28% TRR, (0.02 mg/kg) and 66% TRR, (0.086 mg/kg), respectively. The major metabolites were PBacid-glycine (46% TRR) from phenoxy label and all other metabolites were below 3%TRR from cyclohexyl label.

Following the treatments with 50 ppm [phenoxyphenyl-^{14}C]-fenpropathrin the average residues of the parent fenpropathrin amounted to 0.50 mg/kg (78%TRR) in fat, 0.011 mg/kg (45% TRR) in muscle, 0.14 mg/kg (3.2% TRR) in liver and 0.01 mg/kg (1.2% TRR) in kidney. The major metabolites in these tissues were PBacid-glycine (20–39% TRR), PBacid (11–38% TRR) and 4'-OH-PBacid (11% TRR). The other metabolites were present at lower than 10% TRR.

After the goats were administered with [cyclopropyl-1-^{14}C]-fenpropathrin, the average residues comprised of the parent compound 0.55 mg/kg (81% TRR) in fat, 0.005 mg/kg (11% TRR) in muscle, 0.11 mg/kg (2.5% TRR) in liver and 0.0076 mg/kg (1.5% TRR) in kidney. The major metabolites in these tissues were TMPA-CH_2OH-lactone (19–41% TRR), TMPA (18%TRR), TMPA-CH_2OH (11–16%TRR). The other metabolites were below 5%TRR.

In hens, the parent fenpropathrin was a major residue 0.043 mg/kg (31%TRR) and 0.038 mg/kg (9.7%TRR) in eggs following treatments with benzyl- and cyclopropyl-labelled compounds. The only metabolite exceeding 10% TRR was TMPA-CH_2-OH from cyclopropyl label. Following dosing with benzyl label, the average concentration of parent compound was 0.43 mg/kg (29%TRR) in fat, 0.029 mg/kg (1.6% TRR) in muscle, 0.096mg/kg (7%TRR) in kidneys and 0.014 mg/kg (1% TRR) in liver. After dosing with cyclopropyl label, the average concentration of parent compound was 0.033 mg/kg, (1.55%TRR) in muscle, 0.21 mg/kg (10% TRR) in kidneys, 0.036 mg/kg (2% TRR) in liver. The main metabolites from hens dosed with the benzyl-labelled compound were 3-OH-Bacid (4–29%TRR) or 4'-OH-PBacid (4–16% TRR and PBacid 3.2–24% TRR). While from the cyclopropyl-labelled group the TMPA (6–26% TRR) and its CH_2-OH, COOH, CH_2-OH-lactone derivatives (9–41%TRR) were the major metabolites. Several of these metabolites are also formed from other pyrethroid insecticides.

The parent fenpropathrin was the major residue in milk, meat and eggs and it was detected at low concentrations in liver and kidney. The polar metabolites listed above and the minor ones identified are of no toxicological significance.

The Meeting concluded that the parent fenpropathrin is a suitable marker for animal commodities for both enforcement and dietary risk assessment.

As the fenpropathrin residue concentrates in the fat, based on the distribution of residues in various tissues, supported by the $logP_{ow}$ of 6.0 for fenpropathrin, the Meeting concluded that the fenpropathrin residue is fat soluble.

The fate of fenpropathrin residues was studied in apples, beans, cabbages, cotton and tomatoes. The parent fenpropathrin is the major residue in apple fruits (92–94% TRR), tomato fruits (30–66% TRR), in bean leaves (46% TRR), bean seeds (up to 4.1% TRR), in cabbage leaf extract (up to 16% TRR) and cotton seed (up to 94% TRR). The major metabolites were the conjugates of 2'-OH-fenpropathrin-$(CH_2OH)_2$ and of 4'-OH-fenpropathrin-$(CH_2OH)_2$ (max 19–22% TRR in cabbage), all other metabolites (1.3–9.8%TRR) were < 10% TRR in case of all labelled compounds.

The nature of metabolites is similar to that goats and hens. The polar metabolites listed above are of no toxicological significance.

The Meeting concluded that the parent fenpropathrin is suitable marker for plant commodities for both enforcement and dietary risk assessment.

Validated analytical methods, suitable for enforcement, are available for detecting fenpropathrin in various matrices.

The Meeting agreed in the following residue definition:

Definition of residue for compliance with MRL and for estimation of dietary intake for animal and plant commodities is the parent fenpropathrin.

The residue is fat soluble.

Results of supervised residue trials on crops

The Meeting received supervised trial data on citrus fruits, pome fruits, stone fruits, berries and small fruits, fruiting vegetable, cucurbits, olives, soya beans, cotton, tree nuts, coffee beans and tea.

The HR values were estimated based on the residues measured in single samples.

Citrus fruits

A total of 31 supervised trials were conducted in the United States on citrus fruits (18 on oranges, 6 on lemons and 7 on grapefruit). The current maximum GAP for citrus in the USA consists of two applications at 0.45 kg ai/ha with a total seasonal rate of 0.90 kg ai/ha and a PHI of 1 day.

The average residues in duplicate composite samples derived from treatments corresponding to US GAP were: in oranges: 0.05, 0.07, 0.12, 0.18, 0.25, 0.26, 0.27, 0.33, 0.33, 0.46, 0.53, 0.96, 1.2 mg/kg; in lemons: 0.51, 0.56, 1.2 mg/kg; in grapefruits: 0.12, 0.18, 0.2, 0.34, 0.34, 0.37, 0.47 mg/kg.

The Meeting noted that the GAP in USA is for citrus fruits, that the residue populations were not significantly different (Kruskal-Wallis H-test) and the median residues were within the 5 times range. Furthermore, the Meeting concluded that the residue date sets for lemons, oranges and grapefruits are suitable for estimation of residue levels for the citrus group. The meeting agreed to combine the datasets which in rank order were: 0.05, 0.07, 0.12, 0.12, 0.18, 0.18, 0.2, 0.25, 0.26, 0.27, 0.33, 0.33, 0.34, 0.34, 0.37, 0.46, 0.47, 0.51, 0.53, 0.56, 0.96, 1.2, 1.2 mg/kg.

The Meeting estimated a maximum residue value of 2mg/kg and, based on the processing factor of 0.065, HR of 0.098 mg/kg and STMR values 0.02 mg/kg for citrus fruit group.

Pome fruits

Forty-seven supervised trials on pome fruit (27 in apples and 20 in pears) were conducted in the USA in 1984-1987, using a higher number of applications and total seasonal rates compared to the GAP in the USA (up to 0.9 kg ai/ha and a PHI of 14 days).

Four trials in apple and pear complied with current US GAP. The residues were: in apple: 0.48, 0.58, 0.88 and 1.1 mg/kg; and in pear:0.27, 0.3, 1.2 and 1.8 mg/kg.

The Meeting noted that the GAP in USA is for pome fruit, that the residue populations were not significantly different and that the median residues were within the 5 times range.

The Meeting concluded that the residues in apples and pears could be combined: 0.27,0.3, 0,48, 0.58, 0.88, 1.1, 1.2 and 1.8 mg/kg.

The Meeting noted that in one of the pear samples the residue was 2 mg/kg, and estimated a maximum residue level of 3 mg/kg, HR of 2 mg/kg and STMR of 0.73 mg/kg

The Meeting withdraws its previous recommendation for maximum residue levels of 5 mg/kg

The meeting noted that the short-term intakes of apples and pears for children are 390% and 280% of ARfD, respectively.

There is no alternative GAP available to be considered.

Stone fruits

Supervised trials were carried out in USA on peaches (10), cherries (6) and plums (7) according to US GAP (2 × 0.45 kg ai/ha, 3 days PHI).

The average residues in duplicate composite samples derived from treatments corresponding to US GAP were: in peach: 0.44, 0.58, 0.65, 0.66, 0.70, 0.71, 0.73, 0.92, 1.0, 1.0 mg/kg; in plums; 0.18, 0.22, 0.23, 0.25, 0.32, 0.35, 0.67 mg/kg; and in cherries: 1.4, 1.5, 1.8, 1.9, 3.3, 3.4 mg/kg.

Since the residue populations are not similar, residue levels were estimated separately for each commodity.

The meeting estimated maximum residue, HR and STMR values for subgroups of: peaches 3 mg/kg, 1.1 mg/kg and 0.71 mg/kg; plums 1 mg/kg, 0.71 mg/kg and 0.25 mg/kg; and cherries 7 mg/kg, 3.53, and 1.85 mg/kg, respectively.

The meeting noted that the short-term intakes of peaches and cherries are 190% and 140% of ARfD for children, respectively.

There is no alternative GAP to be considered.

Berries and other small fruits

Strawberry

Eleven out of 12 trials conducted on strawberry in USA matched the US GAP (applications at up to 0.45 kg ai/ha for a total of 0.9 kg ai/ha per season and a PHI of 2 days).

The average residues in duplicate composite samples derived from treatments corresponding to US GAP were: 0.26, 0.38, 0.39, 0.48, 0.48, 0.55, 0.63, 0.65, 0.69, and 1.2 mg/kg.

The Meeting estimated maximum residue level, HR and STMR values of 2 mg/kg, 1.2 mg/kg and 0.515 mg/kg, respectively.

Raspberry

Seven supervised trials on raspberries were conducted in the USA in 2005 with higher rate and shorter PHI (total 0.9 kg/ha with 2 days PHI) than the current GAP for caneberries (applications at up to 0.34 kg ai/ha for a total of 0.67 kg ai/ha per season and a PHI of 3 days).

As no trial matched the GAP, recommendation cannot be made.

Grape

Twenty five supervised trials were conducted on grapes in the USA during 1983–2001 (2 × maximum rate of 0.45 kg ai/ha, the maximum seasonal rate of 0.9 kg/ha with 21 days PHI).

The trial data did not match the critical GAP of the USA. As a result no recommendations could be made.

The Meeting withdraws its previous recommendation of 5 mg/kg.

Assorted tropical and subtropical fruits – Edible peel

Olives

Three supervised trials were conducted on olives in the USA during 2005 matching US GAP (3 × 0.34 kg ai/ha with total seasonal application rates of about 0.9 kg ai/ha and 7 days PHI).

The average residues in pitted olives from two composite samples derived from treatments corresponding to maximum application rates were in rank order: 1.9, 2.2, and 3.6 mg/kg.

Three residue values were not considered sufficient for the estimation of maximum residue levels in olives.

Fruiting Vegetables, Cucurbits

Cucumber

Six supervised trials on cucumber were conducted in the USA in 1994 and 1996, following the GAP in the USA for cucurbit vegetables (applications at the rate of up to 0.34 kg ai/ha at 7 days intervals for a total of 0.9 kg ai/ha/season; PHI is 7 days).

The Meeting noted that the trials were not conducted at maximum GAP. For multiple treatments proportionality could be applied. As a result no recommendations could be made.

Melon

Ten supervised trials on cantaloupe were conducted in the USA in 1994 following the GAP in the USA for cucurbits (applications at the rate of up to 0.34 kg ai/ha for a total of 0.9 kg ai/ha/season; PHI is 7 days).

The Meeting noted that the trials were not conducted at maximum GAP. As the number of applications and or the applied dosage rate differed from maximum GAP, the proportionality could not be applied. As a result no recommendation could be made.

Summer squash

Seven supervised trials on summer squash were conducted in the US in 1994 and 1996, following the GAP in the US for cucurbits (applications at the rate of up to 0.34 kg ai/ha for a total of 0.9 kg ai/ha/season; PHI is 7 days)

The Meeting noted that the trials were not conducted at maximum GAP. As the number of applications and or the applied dosage rate differed from maximum GAP, the proportionality could not be applied. As a result, no recommendation could be made.

Fruiting vegetables other than Cucurbits

Tomato

Nine supervised trials conducted on tomatoes in the USA in 1993 matching the US GAP for fruiting vegetables other than cucurbits (applications at the rate of 0.22-kg ai/ha at 7 days intervals but not more often than 7 days, PHI is 3 days) were received.

The average residues in two composite samples derived from treatments corresponding to maximum application rates, in ranked order, were: 0.05, 0.08, 0.11, 0.18, 0.19, 0.21, 0.27, 0.30, and 0.55 mg/kg.

Peppers

Ten supervised trials on peppers (6 on bell and 4 on non-bell) were conducted in the USA in 1996 and 1998. The application rates corresponded to US GAP (0.22 kg ai/ha up to 0.9 kg ai/ha, 3 days PHI), but samples were taken at 2 and 4 days instead of the 3 day PHI.

The average residues in two composite samples were: in Bell pepper: 0.10, 0.34, 0.37, 0.37, 0.50, 0.67 mg/kg; and Chili pepper: 0.24, 0.31, 0.38, 0.40 mg/kg

The Meeting noted that the residues obtained 2–4 days after last application were in a relatively narrow residue range (2×median) leading to lower maximum residue estimate than would be generally expected. Therefore the residue values obtained at day 2 (-33% of PHI) were considered acceptable. (Only one residue data (0.50 mg/kg) was obtained at day 3 and one at day 4 (0.10 mg/kg).

The Mann-Whitney U-test confirmed that the above data could be combined for the estimation of the maximum residue level and STMR. The ranked order of residues, from supervised trials on peppers were: 0.10, 0.24, 0.31, 0.34, 0.37, 0.37, 0.38, 0.40, 0.50, and 0.67 mg/kg.

The Meeting noted that the GAP in USA is for fruiting vegetables, other than cucurbits and the residue populations were not significantly different (Kruskal-Wallis H-test) and the median residues were within 5 times range. However, the short-term intake for eggplants would exceed the ARfD by 110% for adults. Consequently, a recommendation for the fruiting vegetables crop group could not be made.

No alternative GAP was available for fruiting vegetables other than cucurbits.

The Meeting therefore agreed to estimate residue levels for individual commodities:

Tomato: maximum residue level of 1 mg/kg, HR of 0.64 mg/kg, STMR of 0.19 mg/kg.

Peppers including chili pepper: maximum residue level of 1 mg/kg, HR of 0.70 mg/kg, STMR of 0.37 mg/kg.

Chili peppers, dried (based on concentration factor of 7): maximum residue level of 7 mg/kg, HR of 4.9 mg/kg mg/kg, STMR of 2.59 mg/kg.

The meeting confirms its previous recommendation for maximum residue level of 1 mg/kg for tomatoes.

Pulses

Soya beans

Eight supervised trials on soya beans were conducted in Brazil in 2010 and 2013, following the GAP in Brazil (one applications at the rate of 0.045 kg ai/ha and a PHI of 30 days). Residues in all samples were below the limit of quantification (< 0.01 mg/kg).

The Meeting estimated a maximum residue and STMR values of 0.01 mg/kg.

Cotton

Thirty-two supervised trials on cotton were conducted in the USA in 1983–1989 with application rates up to 0.9 kg ai/ha and a PHI of 21 days. The current US GAP is up to 0.45 kg ai/ha with a seasonal maximum rate of 0.9 kg/ha and a PHI of 21 days.

As 5–10 applications were made with low dose rates, which do not represent the critical GAP, no recommendations could be made.

The Meeting withdraws its previous recommendation of 1 mg/kg.

Tree nuts

A total of ten supervised trials on tree nuts, 5 on almonds and 5 on pecans have been conducted in the US in 2003, with application rates of 0.45 and 0.9 kg ai/ha at 7 days intervals instead of the minimum 10 days specified on the label.

The following average residue levels in two composite samples were obtained from the trials on almonds and pecans:

Almond nutmeat: < 0.01(4), 0.03 mg/kg; and in pecans: < 0.01, 0.01, 0.02, 0.05, 0.06 mg/kg.

The Meeting noted that the GAP in USA is for tree nuts and the residue populations were not significantly different (Mann-Whitney U-test) and the median residues were within 5 times range. The Meeting agreed to combine the datasets for almonds and pecans which, in ranked order, were: < 0.01(4), < 0.<u>01</u>, <u>0.01</u>, 0.02, 0.03, 0.05, and 0.06 mg/kg.

As the highest residue in an individual samples was 0.1 mg/kg, the Meeting estimated a maximum residue level of 0.15 mg/kg, HR of 0.1 mg/kg and STMR value of 0.01 mg/kg.

Coffee Beans

Six supervised trials on coffee were conducted in Brazil in 2013 following the current GAP there (two applications at a maximum rate of up to 0.12 kg ai/ha and a PHI of 14 days).

Residues in composite samples, in ranked order, were: < 0.01(4), 0.01, and 0.02 mg/kg.

The Meeting estimated a maximum residue level of 0.03 mg/kg and STMR value of 0.01 mg/kg.

Tea

All supervised trials on tea were conducted in India during 2002–2004. The compound was applied according to the GAP in India (0.05–0.06 kg ai/ha with a PHI of 7 days) and with double rate.

Six trials on black tea and in one trial green tea leaves (0.13 mg/kg) were analysed

The residues in composite samples following application at the GAP rate were: < 0.05, 0.13, <u>0.14</u>(2), 0.17, 0.18, and 1.38 mg/kg.

The Meeting estimated a maximum residue level for green and black tea of 3 mg/kg and STMR value of 0.14 mg/kg.

The Meeting withdrew its previous recommendation of 2 mg/kg for maximum residue level for tea.

Animal feeds

Almond hulls

The US GAP specifies application rates of up to 0.45 kg ai/ha with a seasonal maximum of 0.9 kg ai/ha at 10 days intervals, and a PHI of 3 days.

In almond hulls, the ranked order of residue concentrations was 2.7, 2.9, 3.1, 3.5, and 3.6 mg/kg. The Meeting estimated a maximum residue level of 10 mg/kg, the highest residue is 3.6 mg/kg and the median residue is 3.1 mg/kg.

Cottonseed hull

The trial conditions did not match US GAP (2×0.45, max seasonal rate 0.9 mg/kg, PHI 21 days), no recommendations could be made.

Fate of residues during processing

Processing studies were carried out on plums, tomato, olives, oranges, cottonseed and tea.

The processing factors calculated and STMR-P values estimated are summarized below.

Summary of selected processing factors and STMR-P values for fenpropathrin

RAC/processed fraction	Processing factors					PF estimated	STMR-P (mg/kg)
RAC: Whole orange	-						
Juice	< 0.02	< 0.22				< 0.02	0.007
Oil	78.7	21.56				50.1	16.5
Wet peel	0.6	0.78	2.76		2.86	2.82	0.93
Dried peel	1.6	2.67				2.1	0.70
Pulp			0.06		0.07	0.065	0.021
RAC: Plum							
Dried plum	2.56					2.56	0.639
RAC: Tomato							
Canned	0.077	0.071	0.077			< 0.075	0.021
Wet pomace				9.9	9.8	9.8	1.867
Dry pomace				46	45.0	45	8.618
Tomato paste				0.78	0.75	0.77	0.145
Tomato juice				0.12	0.1	0.12	0.023

Note: The residues measured in RAC samples taken at the processing plants are considered as they better reflect the residues in unprocessed commodities than these measured in field samples

There is no concentration of residues in juice and molasses. Residues concentrate in oil (Pf=50.1), and dried peel (Pf=2.1).

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

Drying concentrates the residues of fenpropathrin in plums by a factor of 2.6×; The Meeting estimated maximum residue level of 3 mg/kg, HR-P of 1.85 mg/kg and STMR-P of 0.65 mg/kg for dried plums (or prunes).

As no MRL could be estimated, the Meeting withdraws its previous recommendation of 3 mg/kg for cottonseed oil.

Residues in animal commodities

Estimation of dietary burden

The maximum and mean dietary burdens were calculated using the highest residues or median residues of fenpropathrin estimated at the current Meeting on a basis of the OECD Animal Feeding Table. Only almond hull, citrus pulp and tomato wet pomace can be used as animal feed based on recommended uses. The calculated maximum and mean animal burdens are summarised below

Summary of livestock dietary burdens (ppm of dry matter diet)

	US-Canada		EU		Australia		Japan	
	max	mean	max	Mean	max	mean	Max	mean
Beef cattle	0.09	0.09	0.045	0.045	1.46[a]	1.46[b]	0	0
Dairy cattle	0.43	0.04	0.18	0.18	1.46	1.46	0	0
Broilers	0	0	0	0	0	0	0	0
Layers	0	0	0	0	0	0	0	0

[a] Suitable for estimating maximum residue levels for milk, meat, fat and edible offal of cattle.
[b] Suitable for estimating STMRs for meat, fat and edible offal of cattle.

Farm animal feeding studies

Lactating Holstein cows were orally administered technical grade fenpropathrin (purity 92.5%) via gelatin capsules for 28 consecutive days in two equal portions at the morning and evening milkings. The treatment levels were 0, 25, 75 and 250 ppm fenpropathrin based upon the daily average food consumption.

Residues of fenpropathrin in the milk reached a plateau after three days. Average residues in the whole milk of the four cows of each group on Day 3 were 0.04, 0.17 and 0.33 mg/kg for the three dose levels. On Day 28, these levels were 0.04, 0.13 and 0.32 mg/kg. At the end of the three-day depuration period, residues had fallen to < 0.01, 0.02 and 0.04 mg/kg for the three levels. Pasteurization did not significantly reduce fenpropathrin residues in milk. The residues concentrated in milk fat by a factor of about 10 (from mean of 0.32 mg/kg in whole milk to 3.7 mg/kg in milk fat)

After 28 days of dosing, maximum and (average) residues, expressed in mg/kg, in muscle, kidney, liver and fat were 0.33 (0.2), 0.2 (0.16), 0.01 (0.01), and 4.1 (3.8) mg/kg, respectively, at the maximum 250 ppm dose level. The residues determined after feeding with 25 ppm fenpropathrin in feed, and the corresponding residues in tissues and milk resulted from the calculated mean and max dietary burden (1.46 ppm) are summarised below.

Dietary	Fat		Meat		Liver		Kidney		Milk
burden	Max	Mean	Max	Mean	Max	Mean	Max	Mean	Mean
25 ppm	0.44	0.33	0.04	0.02	< 0.01	< 0.01	0.05	0.03	0.04
1.46 ppm	0.026	0.018	0.002	0.001	< 0.0006	< 0.0006	0.003	0.002	0.002

Based on the data available the Meeting estimated maximum residue levels of 0.03 mg/kg, HR value of 0.026 mg/kg and STMR value of 0.018 mg/kg for mammalian fat except milk fat.

The Meeting estimated, at the LOQ of 0.01 mg/kg, maximum residue level of 0.01 mg/kg for mammalian meat and edible offal and 0.01 mg/kg for milk. The HR values for meat and edible offal are 0.002 mg/kg and 0.003 mg/kg, respectively

The Meeting estimated STMR values of 0.001 mg/kg for mammalian meat, 0.002 mg/kg for mammalian, edible offal of, and 0.002 mg/kg for milk.

The Meeting withdraws its previous recommendations for cattle meat, edible offal and milk.

Laying hens

Laying hens were dosed at nominal concentrations of 0, 2.5, 7.5 and 25 ppm levels for a period of 28 days. The fenpropathrin residues were below 0.01 mg/kg in case of dose groups 2.5 and 7.5 ppm over the study period. Eggs derived from 25 ppm dose contained 0.02 mg/kg fenpropathrin from day 7. Residues in muscle, gizzard and liver samples were below the LOQ of 0.01 mg/kg in all dose groups. The fenpropathrin residue in fat was 0.02, 0.05 and 0.14 mg/kg for dose groups of 2.5, 7.5 and 25 ppm. Metabolites could only be detected in liver after dosing with 25 ppm were TMPA (0.05 mg/kg) and PBA-glycin (0.03 mg/kg). The distribution of residues between white and yolk was not studied.

Taking into account that poultry feed is not treated with fenpropathrin according to the uses evaluated by the present Meeting, the Meeting estimated maximum residues levels in poultry meat , fat, edible offal and eggs of 0.01 mg/kg*.

The Meeting estimated STMR values of 0 for poultry products

The Meeting withdraws its previous recommendations for poultry products.

RECOMMENDATIONS

On the basis of the data from supervised trials, the Meeting concluded that the residue levels listed below are suitable for establishing maximum residue limits and for IEDI assessment.

Definition of residue for compliance with MRL and for estimation of dietary intake for animal and plant commodities is fenpropathrin.

The residue in fat soluble.

DIETARY RISK ASSESSMENT

Long-term intake

The evaluation of fenpropathrin resulted in recommendations for MRLs and STMR values for 24 raw and processed commodities. Where data on consumption were available for the listed food commodities, dietary intakes were calculated for the 17 GEMS/Food Consumption Cluster Diets. The results are shown in Annex 3 of the 2014 Report.

The IEDIs in the seventeen Cluster Diets, based on the estimated STMRs were 1–10% of the maximum ADI (0.03 mg/kg bw). The Meeting concluded that the long-term intake of residues of fenpropathrin from uses that have been considered by the JMPR is unlikely to present a public health concern.

Short-term intake

The International Estimated Short-term Intake (IESTI) for fenpropathrin was calculated for 24 raw and processed commodities for which maximum residue levels and STMR values were estimated. The results are shown in Annex 4 to the 2014 Report.

For cherries, peaches, and pome fruits the IESTI represented 140%, 180% and 390% of the ARfD of 0.03 mg/kg bw, respectively. No alternative GAP was available. On the basis of information provided to the JMPR it was not possible to conclude that the estimate of short-term intake of fenpropathrin, from the consumption of cherries, peaches and pome fruits, was less than the ARfD.

The other commodities considered by the JMPR were within 0–80% of ARfD. The Meeting concluded that the short-term intake of fenpropathrin when used in ways that have been considered by the MPR is unlikely to present public health concern.

5.13 FLUENSULFONE (265)

TOXICOLOGY

Fluensulfone was evaluated by JMPR in 2013, when an ADI of 0–0.01 mg/kg bw and an ARfD of 0.3 mg/kg bw were established. The 2013 Meeting also evaluated limited toxicological data on three metabolites found in plants and/or animals, characterized as thiazole sulfonic acid (M3625, TSA), methylsulfone metabolite (M3626, MeS) an

d butene sulfonic acid metabolite (M3627, BSA). The sulfonic acid metabolites have been found at low levels in rats (< 6% of the administered dose), whereas the methylsulfone metabolite is not present in rats. The 2013 Meeting did not reach any conclusions in respect of the dietary risk assessment of these metabolites based on the limited toxicological data and the fact that the residues assessment by JMPR was not scheduled until 2014.

Toxicological data on metabolites and/or degradates

Repeated-dose toxicity studies on M3625 and M3627 were submitted to the 2014 Meeting, were evaluated and are summarized below. Table 1 presents the toxicological data on the metabolites evaluated by the 2013 Meeting plus the additional information submitted to this Meeting; summary information on fluensulfone is presented for comparison purposes.

Table 1 Summary of the genotoxicity and toxicity studies on fluensulfone and metabolites

Metabolite	Description	Toxicological profile
M3625 (thiazole sulfonic acid)	Formed at low levels in rat (2–5%)	Oral LD_{50} > 2 000 mg/kg bw (rat)
		Unlikely to be genotoxic
		28-day study of toxicity: NOAEL = 113 mg/kg bw per day (rat)
		90-day study of toxicity: NOAEL = 975 mg/kg bw per day (rat)
M3626 (methylsulfone)	Not found in rat	Oral LD_{50} = 300–2 000 mg/kg bw (rat)
		Not genotoxic in vivo (micronucleus and liver unscheduled DNA synthesis)
M3627 (butene sulfonic acid)	Formed at low levels in rat (4–6%)	Oral LD_{50} > 2 000 mg/kg bw (rat)
		Unlikely to be genotoxic
		28-day study of toxicity: NOAEL = 8.6 mg/kg bw per day (rat)
Fluensulfone	Parent compound	Oral LD_{50} = 671 mg/kg bw (rat)
		Unlikely to be genotoxic
		28-day study of toxicity: NOAEL = 10 mg/kg bw per day (rat)
		90-day study of toxicity: NOAEL = 8 mg/kg bw per day (rat)

M3625 – Thiazole sulfonic acid metabolite (5-chloro-1,3-thiazole-2-sulfonic acid)

In a non-GLP-compliant, 28-day study of toxicity, groups of Wistar rats (three of each sex per dose) received M3625 at 0, 120, 500, 1200 or 12 000 ppm (equal to 0, 10, 41, 113 and 1194 mg/kg bw per day for males and 0, 12, 43, 123 and 1369 mg/kg bw per day for females, respectively). The range of in-life, haematology, clinical chemistry, gross pathology and organ weight examinations was satisfactory, but only liver, kidney, adrenal and lung were examined histopathologically. All three

top-dose males had kidney tubule basophilia (compared with one in control). The NOAEL for the study as performed was 1200 ppm (equal to 113 mg/kg bw per day).[1]

In a GLP-compliant 90-day study of toxicity, groups of Wistar rats (10 of each sex per dose) received M3625 at 0, 500, 2500 or 12 000 ppm (equal to 0, 38, 183 and 975 mg/kg bw per day for males and 0, 52, 290 and 1369 mg/kg bw per day for females, respectively). There were no adverse effects in any of the treated dose groups. Apparent alterations in white blood cell differential counts and plasma creatinine were due to individual animals with values that were outliers and are considered not to be adverse effects of treatment. The NOAEL was 12 000 ppm (equal to 975 mg/kg bw per day), the highest dose tested.[2]

M3627 – Butene sulfonic acid metabolite (3,4,4-trifluorobut-3-ene-1-sulfonic acid)

In a non-GLP-compliant, 28-day study of toxicity, groups of Wistar rats (three of each sex per dose) received M3627 at 0, 100, 500, 1000 or 10 000 ppm (equal to 0, 6.4, 30, 82 and 732 mg/kg bw per day for males and 0, 8.6, 39, 120 and 1024 mg/kg bw per day for females, respectively). The range of in-life, haematology, clinical chemistry, gross pathology and organ weight examinations was satisfactory, but only liver, kidney, adrenal and lung were examined histopathologically. There was a trend for increased kidney weights in males (105%, 106%, 111% and 114% of controls, respectively). At macroscopic examination, bilateral, dilated renal pelvis was seen at 500 ppm (two females), 1000 ppm (one male) and 10 000 ppm (two males, two females), compared with zero in controls; this was confirmed at microscopic evaluation. Although there was no dose–response relationship for the kidney effects, the small group size and limited level of histopathological investigation in the study support the treatment of this finding as potentially adverse. The NOAEL for the study as performed was 100 ppm (equal to 8.6 mg/kg bw per day), based on dilated renal pelvis in females at 500 ppm (equal to 39 mg/kg bw per day). This study indicates that M3627 is of similar repeated-dose toxicity to fluensulfone.[3]

Toxicological evaluation

The current Meeting concluded that M3625 is significantly less toxic than fluensulfone over 90 days of dietary exposure in rats and that M3627 appears to be of similar toxicity to fluensulfone over 28 days of dietary exposure in rats.

On this basis, it was concluded that residues of M3625 in plants or animals were unlikely to be of any toxicological relevance.

For M3626, in the absence of any repeated-dose toxicity data, the lack of genotoxicity in vivo supports the comparison of chronic intake estimates with the TTC value of 1.5 µg/kg bw per day for a Cramer class III compound. The international estimated daily intake (IEDI) is below this threshold value. A single-exposure TTC for Cramer class III compounds of 5 µg/kg bw has been proposed by EFSA, and the Meeting concluded that the use of this value would be conservative. The international estimate of short-term dietary intake (IESTI) is below this value. On this basis, the Meeting concluded that M3626 is considered not to be a relevant plant or animal metabolite of fluensulfone.

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[1] Takewale P (2014a). 28 day dose range finding dietary toxicity study in Wistar rats with 5-chlorothiazole-2-sulfonic acid. BSL Bioservice. Planegg, Germany; Study No. 122929. Submitted to WHO by Makteshim Chemical Works, Beer-Sheva, Israel.

[2] Takewale P (2014b). 90 day dietary toxicity study in Wistar rats with 5-chlorothiazole-2-sulfonic acid. BSL Bioservice. Planegg, Germany; Study No. 122930. Submitted to WHO by Makteshim Chemical Works, Beer-Sheva, Israel.

[3] Takewale P (2014c). 28 day dose range finding dietary toxicity study in Wistar rats with 3,4,4-trifluro-but-3-ene-1-sulfonic [*sic*] acid. BSL Bioservice. Planegg, Germany; Study No. 136081. Submitted to WHO by Makteshim Chemical Works, Beer-Sheva, Israel.

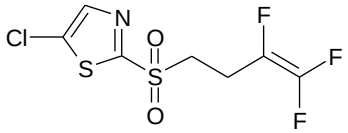
For M3627, which is of similar toxicity to fluensulfone, the ADI and ARfD for fluenesulfone could be used for an initial comparison with the IEDI and IESTI, respectively. The intake estimates showed that the margin of exposure between the IEDI for M3627 and the upper bound of the ADI for fluensulfone is 33, and the margin of exposure between the IESTI for M3627 and the ARfD for fluensulfone is 15. On this basis, the Meeting concluded that M3627 is not a relevant plant metabolite of fluensulfone.

An addendum to the toxicological monograph was not prepared.

RESIDUE AND ANALYTICAL ASPECTS

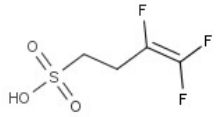
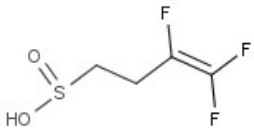
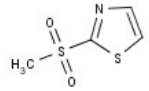
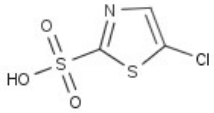
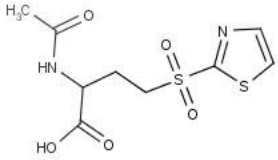
Fluensulfone is a non-fumigant nematicide in the fluoroalkenyl class of pesticides. Fluensulfone shows activity in multiple nematicide physiological systems. It was considered for the first time by the 2013 JMPR for toxicology and by the 2014 JMPR for residues. The 2013 JMPR established an ADI of 0–0.01 mg/kg bw and an ARfD of 0.3 mg/kg bw.

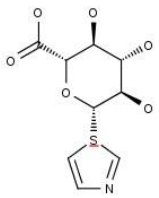
The IUPAC name for fluensulfone is 5-chloro-1,3-thiazol-2-yl 3,4,4-trifluorobut-3-en-1-yl sulfone.



Fluensulfone with ^{14}C radiolabelling in the thiazole ring or in the ethane bridge between the sulfone and trifluorobutene moieties was used in the metabolism and environmental fate studies. In this appraisal, these positions are referred to as the Th and Bu labels, respectively.

The following abbreviations, along with IUPAC names and structures, are used for the metabolites discussed in this appraisal:

BSA	3,4,4-trifluorobut-3-ene-1-sulfonic acid	
Butene sulfinic acid	3,4,4-trifluorobut-3-ene-1-sulfinic acid	
MeS	2-methylsulfonyl-1,3-thiazole	
TSA	5-chloro-1,3-thiazole-2-sulfonic acid	
Thiazole mercapturate	2-acetamido-4-(1,3-thiazole-2-sulfonyl)butanoic acid	

Thiazole glucuronides (α and ß isomers)	Name not specified	

Animal metabolism

The Meeting received studies elucidating the metabolism of fluensulfone in laboratory animals (evaluated by the 2013 Meeting), lactating goats, and laying hens.

In rats, absorption of fluensulfone administered by gavage at 5 mg/kg bw is rapid, with maximal plasma concentrations achieved within 4 hours. At 5 and 500 mg/kg bw, the extent of oral absorption is high (> 80%). Fluensulfone is widely distributed in the body. High concentrations of both butene- and thiazole-labelled material were found in the liver and kidney. The labelled material was rapidly excreted via urine (> 70%), with faecal excretion accounting for no more than 5–13%. Absorbed fluensulfone was extensively metabolized, with almost no unmetabolized parent compound detected. Other than low amounts of thiazole sulfonic acid, no other faecal metabolites were present at levels above 5% of the administered dose. The parent compound probably reacts with glutathione and cleaves, giving rise to thiazole mercapturate, thiazole glucuronide, and butene sulfinic acid, the major urinary metabolites.

In goats dosed for five consecutive days at approximately 28.8 mg/animal/day (10.5 ppm in the diet), most of the recovered radioactivity was in urine and GI tract/faeces, with only 10.7% (Th-^{14}C) or 3.5% (Bu-^{14}C) of the applied dose (AD) accounted for in tissues and body fluids. In excreta, the major identified residues were trifluorobutene sulfinic acid and the MeS metabolite. In other matrices, the highest levels of radioactivity were associated with liver (max. 2.6 mg eq./kg, 1.7% AD), kidney (maximum 1.4 mg eq./kg, 0.2% AD), and milk fat (2.0 mg eq./kg, 0.31% AD). Seventy-five to ninety percent of the radioactivity in the goat matrices was extracted with a combination of solvent extraction and alkaline digestion. No BSA, TSA, or fluensulfone was detected in any goat matrix. Radioactivity in milk and tissues was primarily associated with glucose (0.039–0.24 mg/kg; 4–17% TRR), lactose (0.036–0.21 mg/kg; 4–63% TRR), proteins/amino acids (0.015–1.2 mg/kg; 5–37% TRR), and triglycerides/fatty acids (0.009–1.1 mg/kg; 7.6–52% TRR), and the radioactivity appears to be due to incorporation of the radiolabelled carbon.

In hens dosed for seven consecutive days at 1.25 mg/animal/day (9.8 ppm in the diet), total radioactive residues (TRR) in excreta accounted for approximately 80% of the dosed material for both label positions. Total radioactivity in eggs did not plateau within the eight dosing days of the hen study. Radioactive residues in eggs were not identified. Most residues in eggs were associated with aqueous phases in the extraction schemes; however, 0.18 mg eq./kg from the butane label (27% TRR) was extracted with hexane:acetone. Fluensulfone was a major residue (0.009–0.041 mg/kg; 21–55% TRR) in poultry fat; otherwise, parent fluensulfone was not observed in any matrix. Comparison of extraction of radioactivity from liver samples treated with and without protease enzyme indicates that ca. 0.16 mg/kg (24%) of the radioactivity was associated with proteins and/or amino acids and approximately 3% (0.016 mg/kg) was identified as TSA. Incorporation of the radioactivity into triglycerides was noted in both fat matrices and in eggs. In eggs, triglyceride accounted for 7% and 27% of the TRR for the thiazole and butene labels, respectively. In fat matrices, triglycerides accounted for 7–12% and 79–87% of the TRR for the thiazole and butene labels, respectively.

Overall, the animal metabolism studies show that fluensulfone is well absorbed and that the majority (75–90%) of the dosed radioactivity is excreted. Results from rat, goat, and hen studies indicate that fluensulfone is cleaved at the sulfonyl bridge in all three animals; however, the identification of different residues in the studies suggests that there may be different metabolic pathways. In both poultry and goats, fluensulfone can be expected to break down and be incorporated

almost entirely into natural products. Based on the residue profile in poultry and the observed incorporation of radioactivity into natural components, the Meeting is of the opinion that the lack of a residue plateau in egg is not of concern.

Plant metabolism

The Meeting received studies depicting the metabolism of fluensulfone in tomato, lettuce, and potato. All of the studies were conducted with fluensulfone which was radiolabelled, separately, in the thiazole ring and the ethane bridge between the sulfonyl and trifluorobutene moieties.

To investigate the metabolism of fluensulfone on tomato, fluensulfone was applied at a rate of 4.07 kg ai/ha to soil. Later that same day, tomato seedlings were planted. Mature fruits were harvested 87 days after treatment. Total radioactive residues in tomato were higher in samples treated with Bu-^{14}C-labelled material (0.52 mg eq./kg) than those from Th-^{14}C treatment (0.27 mg eq./kg). The majority (88.7% Th-^{14}C; 91.3% Bu-^{14}C) of the radioactivity was extracted with acetonitrile:water (ACN:H_2O). TSA made up 0.12 mg/kg (45.4% TRR), with an additional 0.06 mg eq./kg (21.2% TRR) as salts/related compounds. BSA occurred at 0.22 mg/kg (41.6% TRR) with salts/related compounds making up 0.13 mg eq./kg (26.5% TRR). No other compounds, including parent fluensulfone, were identified in tomato.

Lettuce seeds were planted into soil and then fluensulfone was applied at a rate of 4.07 kg ai/ha. Samples were collected 49 days and 64 days after application to obtain immature and mature lettuce, respectively. Contrary to the results with tomato, TRR were higher from treatment with Th-^{14}C-labelled material (6.1–7.1 mg eq./kg) than with Bu-^{14}C-labelled material (1.5–2.4 mg eq./kg) and were similar in immature and mature foliage. The majority of the radioactivity was extracted with ACN:H_2O, with higher extraction efficiency from samples treated with the Th-^{14}C label. Following treatment with Th-^{14}C-labelled material, 3.57 mg/kg and 4.34 mg/kg (67.5% and 70.6% TRR) was identified as TSA in immature and mature leaves, respectively. An additional 1.39 mg eq./kg and 0.41 mg eq./kg (17.8% and 6.6% TRR) in immature and mature leaves, respectively, was determined to be salts and/or other forms of TSA. Following treatment with Bu-^{14}C-labelled material, BSA occurred at 0.49 mg/kg (23.8% TRR) in immature leaves and at 0.49 mg/kg (37.6% TRR) in mature leaves. As with TSA, salts and other forms occurred for BSA and constituted, in total, 0.75 mg eq./kg (36.0% TRR) in immature foliage and 0.29 mg eq./kg (22.1% TRR) in mature foliage. Fluensulfone occurred at trace levels (0.009 mg/kg, 0.008 mg/kg) in immature lettuce from the Th-^{14}C and Bu-^{14}C treatments, respectively. Aside from BSA and TSA, no other metabolites of fluensulfone were identified.

Potato seed pieces were planted just prior to application of fluensulfone to soil at a rate of 4.04 kg ai/ha (Th-^{14}C) or 4.13 kg ai/ha (Bu-^{14}C). Immature (70 days after treatment) and mature (106 days after treatment) tubers were harvested and analysed. For immature and mature tubers, respectively, TRR were 0.32 and 0.44 mg eq./kg from the Th-^{14}C treatment and 0.22 and 0.17 mg eq./kg from the Bu-^{14}C treatment. Extraction with ACN:H_2O efficiently released residues: 91.9% TRR (Th-^{14}C, immature tuber), 91.7% TRR (Th-^{14}C, mature tuber), 76.9% TRR (Bu-^{14}C, immature tuber), and 79.1% TRR (Bu-^{14}C, mature tuber). Fluensulfone was found at trace levels (0.005 mg/kg) from both label treatments in mature tubers only. Otherwise, the only identified residues were BSA, TSA, and their salts and/or related compounds. BSA constituted 0.069 mg/kg (30.7% TRR) and 0.042 mg/kg (25.8% TRR) in immature and mature tubers, respectively. Salts and related forms of BSA provided an additional 0.041 mg eq./kg (17.8% TRR; immature tubers) and 0.035 mg eq./kg (21.4% TRR; mature tubers). TSA occurred at 0.21 mg/kg (63.0% TRR) and 0.31 mg/kg (65.3% TRR) in immature and mature tubers, respectively. Salts and related forms of TSA gave an additional 0.028 mg eq./kg (8.4% TRR; immature tubers) and 0.025 mg eq./kg (5.3% TRR; mature tubers).

Fluensulfone was extensively metabolised in all of the studies, with the only major residues being the BSA and TSA metabolites. A few chromatographic fractions contained radioactivity in excess of 10% TRR. Investigation of these fractions indicated that the residues were associated with

the BSA or TSA metabolites, as salts of the sulfonic acids or as related forms of the metabolites. The only major residues in the harvested matrices were the BSA and TSA metabolites and, with the exception of trace levels of fluensulfone in immature lettuce and mature potato, no parent compound was detected.

Environmental fate in soil

Fluensulfone is stable to hydrolysis under accelerated conditions (50 °C, pH 4, 7, 9) but is prone to photolysis [DT_{50} of 21days (Th-^{14}C) or 35 days (Bu-^{14}C) in soil], showing first-order kinetics. In an aerobic soil metabolism study, major residues following treatment with fluensulfone were BSA, TSA, and MeS, depending on the duration of incubation. Fluensulfone had DT_{50} estimates ranging from 7 to 17 days across six soils, all following first-order kinetics. BSA formed from fluensulfone generally accumulated for the first ca. 1 month of incubation followed by dissipation (DT_{50} 18–26 days). Residues of TSA accumulated continuously over the incubation period, reaching maxima of 49–74% of the applied radioactivity at the 120-day sampling. Residues of MeS began to be observed after the first 2–4 weeks of incubation, reaching a maximum of not more than 8% of the applied radioactivity; residues of MeS declined to 0% of the applied radioactivity between the 50 and 120-day sampling times, depending on the soil. In a separate study, the DT_{50} estimates for the TSA and MeS metabolites under aerobic soil conditions are 421 and 33 days, respectively. Field dissipation studies were not provided.

Confined rotational crop studies were conducted with radish, lettuce, and wheat at plant-back intervals (PBIs) of 30, 120, and 360 or 390 days. Fluensulfone, radiolabelled as either the Th-^{14}C or Bu-^{14}C, was applied to soil at a rate of approximately 4 kg ai/ha. Lettuce was replanted at 390 days after application due to crop failure at the 360-day PBI. Following treatment with Th-^{14}C-labeled material, TRR generally declined sharply from 30 to 120 days and then remained relatively consistent between the 120 and the 360/390-day PBIs. (e.g., wheat hay: 27 mg eq./kg at 30-Day PBI, 9.4 mg eq./kg at 120-Day PBI, 10.8 mg eq./kg at 360-Day PBI) As with primary crops, the major residues were the BSA and TSA metabolites. A low level of the parent compound was observed in lettuce, radish root, radish foliage, and wheat forage, hay, and straw (but not grain). Fluensulfone, when found, was typically 1 to 2 orders of magnitude less than the BSA or TSA residue levels. In all cases, residues of fluensulfone and BSA were not quantifiable after the 120-day PBI whereas residues of TSA persisted at quantifiable levels for at least one year, ranging from 0.13 mg eq./kg (immature lettuce) to 11 mg eq./kg (wheat hay).

Overall, fluensulfone can be expected to dissipate rather rapidly in the environment, with a concomitant increase in residues of BSA, TSA, and, to a much lesser extent, MeS. BSA residues should then decline; however, TSA appears to be stable for an extended period. The Meeting concluded from the soil metabolism and confined rotational crop studies that TSA may accumulate in soils following repeated uses of fluensulfone and may occur in follow-on crops at plant-back intervals exceeding one year after treatment.

Methods of residue analysis

The Meeting received analytical methods for the analysis of fluensulfone, BSA, MeS, and TSA in plant and animal matrices. The methods are essentially identical for all samples and the LOQ for all matrices and analytes, defined as the lower limit of method validation, is 0.01 mg/kg.

Extraction of residues is accomplished with ACN:H_2O (1:1, v/v) or ACN (BSA and TSA in eggs only); the extract is then split for analysis of fluensulfone and MeS by one set of procedures and for analysis of BSA and TSA by a second set. For fluensulfone and MeS, there is no clean-up of the extract beyond filtration (except hexane partitioning for analysis of MeS in fatty/oily samples). Residues of fluensulfone and MeS are determined by reverse-phase LC-MS/MS in positive ion spray mode. For BSA and TSA, an aliquot of the initial extract is concentrated and then cleaned-up using C-18 SPE. Residues are determined by reverse-phase LC-MS/MS in negative ion spray mode.

The solvent used for extraction is the same as, or very similar to, that used in the metabolism studies and showed adequate extraction efficiency of incurred residues.

Testing of fluensulfone and the two sulfonic acid metabolites, BSA and TSA, through the FDA PAM multiresidue method protocols demonstrated that the compounds showed poor sensitivity, poor recovery, and/or poor chromatography. Overall, the results indicate that the FDA PAM multiresidue protocols are not suitable for the detection or enforcement of fluensulfone, BSA, or TSA residues in non-fatty foods.

Stability of residues in stored analytical samples

The Meeting received data depicting the stability of residues of fluensulfone, BSA, and TSA in tomato, pepper, cucumber, and melon. In addition, the stability of those analytes and MeS was investigated in frozen, stored tomato puree and paste. No dissipation of any analyte was observed during the storage periods for the various matrices. Stability was demonstrated in tomato raw agricultural commodity (RAC) for at least 469 days (approximately 15 months) and in tomato processed commodities for at least 181 days (approximately 6 months). For pepper, cucumber, and melon, residues were stable for at least 488 days (approximately 16 months).

Definition of the residue

Studies depicting the nature of the residues in animals consistently show fluensulfone to be cleaved at the sulfonyl moiety, presumably via glutathione conjugation, resulting in both halves of the molecule having a sulfonyl functional group. With the exception of poultry fat, fluensulfone was not observed in any animal commodity. In livestock, the majority of the radiolabel was excreted. Retained fluensulfone is extensively metabolized, with the radioactivity being associated primarily with sugars, amino acids, and fatty acids. MeS and butene sulfinic acid were identified in livestock studies, but were observed only in excreta. In the rats, significant residues were thiazole mercapturate, thiazole glucuronide, BSA, TSA, and butene sulfinic acid. MeS, observed in some field trial samples, was not identified in the rat metabolism study.

Based on the livestock metabolism studies, a residue definition potentially suitable for enforcement by the typical criteria is possible only for poultry fat and poultry liver, which were the only matrices in the animal metabolism studies with quantifiable residues of a fluensulfone-specific compound (fluensulfone in fat and TSA in liver). Although fluensulfone was a major residue in poultry fat (up to 55% TRR), the available residue data indicate that quantifiable residues of the parent compound are not expected in plants; thus exposure to fluensulfone via livestock diets is unlikely, making the parent compound an unsuitable marker for enforcement in any livestock commodity. The other potential marker, TSA, occurred only as a minor component in poultry liver (2.7% TRR). Based on the results of the metabolism studies and on the residue profiles observed in crop metabolism studies, confined rotational crop studies, and supervised residue trials, the Meeting determined that a residue definition for livestock commodities is not necessary.

In both plant and rotational crop metabolism studies, fluensulfone appears to follow the same glutathione-mediated pathway observed in livestock; however, in plants quantifiable residues of the BSA and TSA metabolites were consistently observed. Parent fluensulfone was identified only at trace levels in immature lettuce, mature potato, and rotational lettuce, radish foliage, and wheat hay, forage and straw at short PBIs (30 days). In target crops, BSA ranged from 0.071–1.24 mg/kg (43.6–68.1% TRR) and TSA ranged from 0.17–4.75 mg/kg (66.6–85.3% TRR). In rotational crops, BSA was detected in all matrices except wheat grain at the 30-day PBI (0.004–1.4 mg/kg) and in most matrices at the 120-day PBI (0.001–0.43 mg/kg), and was undetected (< 0.001 mg/kg) by the 360/390-day PBI, except wheat straw at 0.012 mg/kg. In contrast, TSA was detected in all rotational crop matrices at all PBIs, ranging from 0.086 mg/kg to 16 mg/kg across all samples.

In crop field trials, fluensulfone was detected in only one sample (summer squash at 0.017 mg/kg). Across all crops, residues of BSA ranged from < 0.01 to 0.27 mg/kg and TSA ranged

from < 0.01 to 0.71 mg/kg. MeS ranged from < 0.01 to 0.08 mg/kg and was less than both BSA and TSA in the corresponding sample. In all trials with only pre-plant applications (per GAP), MeS was < 0.01 mg/kg in all samples of cantaloupe, pepper, and tomato. Although MeS was not found in the plant or rotational crop metabolism studies, it was observed in supervised residue trials in cucumber (< 0.01–0.079 mg/kg) and summer squash (< 0.01–0.050 mg/kg).

The Meeting determined that fluensulfone is not a suitable marker for compliance with MRLs in crops. Both BSA and TSA are suitable markers based on results of supervised field trials. The confined rotational crop study, however, demonstrates a potential for TSA to carry over into succeeding crops. Therefore, given that quantifiable residues of fluensulfone are not expected in plant commodities, that a separate analysis is required for the analysis of fluensulfone and BSA/TSA, and that residues of TSA may occur from previous crop cycle treatments with fluensulfone, the Meeting determined that BSA is the most suitable marker for MRL compliance. A validated method exists for analysis of BSA in plant commodities. The Meeting defined the BSA metabolite as the residue definition for compliance in plants.

Regarding the toxicity of the BSA, TSA, and MeS metabolites, the JMPR has concluded that TSA is unlikely to be of any toxicological relevance; data are insufficient at this time to make a definitive toxicological determination regarding the relevancy of BSA and MeS.

For BSA, the JMPR has determined that the ADI and ARfD for fluensulfone could be used as a screening evaluation of exposure to BSA. Based on a comparison of toxicity data between BSA and fluensulfone, the evaluation may be made directly, without a correction for molecular weight. If additional uses are considered in the future, the use of the fluensulfone points of departure to evaluate exposure to BSA may need to be re-evaluated.

For MeS, the JMPR has determined that the IEDI (0.07 µg/kg bw/day) for MeS should be compared to the Cramer class III TTC value of 1.5 µg/kg bw/day and that the IESTI (3.2 µg/kg bw/day)[1] should be compared to the single-exposure TTC for Cramer class III compounds of 5 µg/kg bw proposed by EFSA. The IESTI is somewhat refined in that for melon, the specific HR (0.01 mg/kg) from melon field trials was used rather than the HR for the fruiting vegetables, Cucurbits group (0.053 mg/kg). On the basis of these comparisons, the Meeting concluded that MeS is not considered to be a relevant metabolite for the crops under consideration. If additional uses are considered in the future, this conclusion may need to be re-evaluated.

Given the residue profile in crops and taking into consideration the available information on the toxicities of the metabolites, the Meeting determined that the residue definition for dietary exposure from crops is BSA. In lieu of BSA-specific toxicological points of departure, dietary intake estimates for BSA should be compared to the ADI and ARfD for fluensulfone, with no correction for molecular weight.

Definition of the residue for compliance with the MRLs and dietary intake for plant commodities: *BSA {3,4,4-trifluorobut-3-ene-1-sulfonic acid}*.

Definition of the residue for compliance with the MRLs and for dietary intake for animal commodities: *Not necessary*

Results of supervised residue trials on crops

Fluensulfone is registered in the USA for use on cucurbit vegetables and on fruiting vegetables. For all crops, the cGAP is an application to the soil at 2.8 kg ai/ha made seven days prior to transplanting crops into the field. Application may be made by broadcast spray to the soil, by banded spray, or by

[1] The estimate of 3.2 µg/kg bw is refined, using the observed HR for melon (0.01 mg/kg) rather than the HR for the fruiting vegetables, Cucurbits group (0.053 mg/kg), which resulted in a maximum dietary intake estimate of 5.3 µg/kg bw.

drip irrigation. The applied material must be mechanically incorporated 15–20 cm into the soil profile for spray applications or by sufficient volume for drip irrigation application.

The Meeting received supervised residue trial data for cucumber, summer squash, cantaloupe, pepper, and tomato. The trials were conducted in North America (USA and Canada). All trials were conducted at a target application rate of 3.9 kg ai/ha, which reflects a nominal exaggeration of 39% relative to the cGAP. Therefore, the Meeting decided to scale residue values for all analytes from trials otherwise meeting the cGAP to an application rate of 2.8 kg ai/ha. Residues scaled to < 0.01 mg/kg were maintained at < 0.01 mg/kg. Reported values are field trial averages unless otherwise noted.

Residues of fluensulfone were < 0.01 mg/kg in all samples.

Fruiting vegetables, Cucurbits

In cucumber, mean field trial residues of BSA (unscaled) from independent field trials treated 7 days prior to transplant (n=7) were: < 0.01, 0.01 (2), 0.063, 0.07, 0.17, and 0.219 mg/kg.

Application rates for these trials ranged from 3.72 kg ai/ha to 4.11 kg ai/ha. Scaled to an application rate of 2.8 kg ai/ha, the residues of BSA are: < 0.01 (3), 0.041, 0.045, 0.114, and 0.137 mg/kg.

In summer squash, mean field trial residues of BSA (unscaled) from independent field trials treated 7 days prior to transplant (n=8) were: < 0.01, 0.05, 0.06, 0.082, 0.186, 0.196, 0.214, and 0.247 mg/kg.

Application rates for these trials ranged from 3.80 kg ai/ha to 4.14 kg ai/ha. Scaled to an application rate of 2.8 kg ai/ha, the residues of BSA are: < 0.01, 0.032, 0.038, 0.051, 0.115, 0.12, 0.133, and 0.149 mg/kg.

In melon, mean field trial residues of BSA (unscaled) from independent field trials treated 7 days prior to transplant (n=8) were: < 0.01 (3), 0.021, 0.025, 0.032, 0.049, and 0.064 mg/kg.

Application rates for these trials ranged from 3.85 kg ai/ha to 4.11 kg ai/ha. Scaled to an application rate of 2.8 kg ai/ha, the residues of BSA are: < 0.01 (3), 0.013, 0.016, 0.019, 0.030, and 0.040 mg/kg.

Noting that the GAP in the USA is for the cucurbit vegetables crop group, which is equivalent to the Codex fruiting vegetables, Cucurbit group, and that the BSA residue data from cucumbers, summer squash, and melons are not significantly different by the Kruskal-Wallis test, the Meeting determined that the residues from the trials are similar and is estimating a group maximum residue level for fruiting vegetables, Cucurbits based on the following scaled BSA residue data set (n=23): < 0.01 (7), 0.013, 0.016, 0.019, 0.030, 0.032, 0.038, 0.040, 0.041, 0.045, 0.051, 0.114, 0.115, 0.120, 0.133, 0.137, and 0.149 mg/kg.

The Meeting estimated a maximum residue level of 0.3 mg/kg for BSA on fruiting vegetables, Cucurbits; the HR is 0.16 mg/kg (from a single sample) and the STMR is 0.032 mg/kg.

Fruiting vegetables, other than Cucurbits

In chilli pepper, mean field trial residues of BSA (unscaled) from independent field trials treated 7 days prior to transplant (n=3) were: 0.040, 0.041, and 0.184 mg/kg.

Application rates for these trials ranged from 3.98 kg ai/ha to 4.10 kg ai/ha. Scaled to an application rate of 2.8 kg ai/ha, the residues of BSA are: 0.025, 0.025, 0.116 mg/kg.

In sweet peppers, mean field trial residues of BSA (unscaled) from independent field trials treated 7 days prior to transplant (n=8) were: 0.048, 0.055, 0.063, 0.070, 0.073, 0.082, 0.136, and 0.232 mg/kg.

Application rates for these trials ranged from 3.84 kg ai/ha to 410 kg ai/ha. Scaled to an application rate of 2.8 kg ai/ha, the residues of BSA are: 0.030, 0.034, 0.041, 0.045 (2), 0.050, 0.083, and 0.146 mg/kg.

In tomato, mean field trial residues of BSA (unscaled) from independent field trials treated 7 days prior to transplant (n=20) were: < 0.01 (3), 0.013, 0.023, 0.026, 0.029, 0.034, 0.042, 0.072, 0.074, 0.078, 0.087, 0.088, 0.094, 0.173, 0.198, 0.231, 0.269, and 0.273 mg/kg.

Application rates for these trials ranged from 3.64 kg ai/ha to 4.12 kg ai/ha. Scaled to an application rate of 2.8 kg ai/ha, the residues of BSA are: < 0.01 (4), 0.014, 0.016, 0.018, 0.021, 0.026, 0.045, 0.046, 0.049, 0.054, 0.055, 0.061, 0.108, 0.132, 0.140, 0.168, and 0.169 mg/kg;

Noting that the GAP in the USA is for the fruiting vegetables crop group, which is equivalent to the Codex group fruiting vegetables, other than Cucurbits except sweet corn and mushroom, and that the residue data from sweet pepper, chilli pepper, and tomato are not significantly different by the Kruskal-Wallis test, the Meeting determined that the residues from the trials are similar and is estimating a group maximum residue level for fruiting vegetables, other than Cucurbits except sweet corn and mushroom based on the following scaled BSA residue data set: (n=31): < 0.01 (4), 0.014, 0.016, 0.018, 0.021, 0.025, 0.025, 0.026, 0.030, 0.034, 0.041, 0.045 (3), 0.046, 0.049, 0.050, 0.054, 0.055, 0.061, 0.083, 0.108, 0.116, 0.132, 0.140, 0.146, 0.168, and 0.169 mg/kg.

The Meeting estimated a maximum residue level of 0.3 mg/kg for BSA on fruiting vegetables, other than Cucurbits except sweet corn and mushroom; the HR is 0.17 mg/kg (from a single sample) and the STMR is 0.045 mg/kg.

Based on the maximum residue level of fruiting vegetables, other than Cucurbits except sweet corn and mushroom (0.3 mg/kg) and a dehydration factor of 7, the Meeting estimated a maximum residue level of 2 mg/kg for BSA in chilli pepper (dry), an HR of 1.2, and an STMR of 0.32.

Fate of residues during processing

High-temperature hydrolysis

The Meeting received a study investigating the high-temperature hydrolysis of fluensulfone, BSA, MeS, and TSA. Samples of aqueous buffered solutions were spiked with fluensulfone, BSA, MeS, or TSA at ca. 1 mg/L and put under conditions simulating pasteurisation (90 °C, pH 4, 20 min.); baking, brewing, boiling (100 °C, pH 5, 60 min); and sterilisation (120 °C, pH 6, 20 min.). Solutions were analysed by HPLC-MS/MS prior to and after processing. All four analytes were shown to be stable under all three conditions, with overall recoveries ranging from 87 to 118% of the initial concentration.

Residues after processing

The Meeting received data depicting the concentration/dilution of residues during processing of tomato into canned, juice, puree, paste, wet and dry pomace, peeled, and sun-dried processed commodities. Processed commodities were derived using simulated commercial practices. Of the three studies that were submitted, two were suitable for deriving processing factors (in one study, all residues were < 0.01 mg/kg). In those two studies, residues of fluensulfone were < 0.01 mg/kg in all samples and processing factors for the parent compound could not be derived.

Crop	Processed commodity	BSA processing factors	Best processing factor estimate (average)	STMR-P, mg/kg	HR-P, mg/kg
Tomato	RAC	--	--	STMR=0.045	HR=0.17
	Canned	0.33	0.33	0.015	0.056

Crop	Processed commodity	BSA processing factors	Best processing factor estimate (average)	STMR-P, mg/kg	HR-P, mg/kg
	Dry pomace	6.6, 9.3, 17	11	0.50	1.9
	Peeled	0.33	0.33	0.015	0.056
	Sundried	1.67, 2	1.8	0.081	0.31
	Juice	0.67, 0.83	0.75	0.034	0.13
	Paste	1, 1, 3.54	1.8	0.081	0.31
	Puree	0.67, 1.38	1.0	0.045	0.17
	Wet pomace	0.66, 3, 4	2.6	0.12	0.44

Based on the maximum residue estimate for fruiting vegetables, other than Cucurbits except sweet corn and mushroom (0.3 mg/kg) and the processing factor of 1.8 for both dried tomato and tomato paste, the Meeting recommends a maximum residue level of 0.5 mg/kg for BSA in dried tomato and 0.5 mg/kg for BSA in tomato paste.

Residues in animal commodities

The Meeting has determined that residue definitions for compliance and dietary intake are not necessary for animal commodities and that residues in animal commodities are not expected.

RECOMMENDATIONS

Definition of the residue for compliance with the MRLs and dietary intake for plant commodities: *3,4,4-trifluorobut-3-ene-1-sulfonic acid (BSA)*. Note that for dietary intake, exposure estimates should be compared to the ADI and ARfD for fluensulfone, with no correction for molecular weight.

Definition of the residue for compliance with the MRLs and for dietary intake for animal commodities: *Not necessary*.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Daily Intakes (IEDIs) of BSA were calculated for the 17 GEMS/Food cluster diets using STMRs/STMR-Ps estimated by the current Meeting. The ADI for fluensulfone is 0–0.01 mg/kg bw. The calculated IEDIs for BSA were 0–3% of the maximum fluensulfone ADI. The Meeting concluded that the long-term intakes of residues of BSA, when fluensulfone is used in ways that have been considered by the JMPR, are unlikely to present a public health concern.

Short-term intake

The International Estimated Short-Term Intakes (IESTI) of BSA were calculated for food commodities and their processed commodities using HRs/HR-Ps or STMRs/STMR-Ps estimated by the current Meeting. The ARfD for fluensulfone is 0.3 mg/kg bw. The calculated maximum IESTI for BSA was 7% of the fluensulfone ARfD for all commodities. The Meeting concluded that the short-term intake of residues of BSA, when fluensulfone is used in ways that have been considered by the JMPR, is unlikely to present a public health concern.

5.14 FLUFENOXURON (275)

TOXICOLOGY

Flufenoxuron is the ISO-approved common name for *N*-{4-[2-chloro-4-(trifluoromethyl)phenoxy]-2-fluorophenyl}-*N*′-(2,6-difluorobenzoyl)urea (IUPAC), which has the CAS number 101463-69-8. Flufenoxuron is a benzoylurea insecticide and acaricide that is used on fruits, vines and ornamentals to control insects and mites. The pesticidal mode of action is the inhibition of chitin synthesis.

Flufenoxuron has not previously been evaluated by JMPR and was reviewed by the present Meeting at the request of CCPR.

All critical studies contained statements of compliance with GLP. The Meeting considered that the database was adequate for the risk assessment.

Biochemical aspects

After oral administration of flufenoxuron to rats, absorption was rapid, with a time to reach C_{max} (T_{max}) of 3–6 hours; there was evidence of saturation at higher dose levels (> 80% absorption at 3.5 mg/kg bw compared with < 15% at 350 mg/kg bw in rats). Absorption was lower in dogs than in rats (< 30% in dogs at 3.5 mg/kg bw). Absorbed flufenoxuron was widely distributed throughout the body, with highest levels in fat and bone marrow. Unchanged flufenoxuron was the major residue in all tissues, faeces and urine. Flufenoxuron is metabolized by cleavage of the bond adjacent to the 2,6-difluorobenzoyl moiety, followed by oxidation or hydroxylation. The major metabolite identified in rats was 2,6-difluorobenzoic acid, together with *N*-[4-[2-chloro-4-(trifluoromethyl)phenoxy]-2-fluorophenyl] urea and 2-amino-5-(2-chloro-4-(trifluoromethyl)phenoxy)-3-fluorophenol; 2,6-difluorobenzamide and 4-[2-chloro-4-(trifluoromethyl)phenoxy]-2-fluorobenzenamine were minor metabolites in rats. After repeated dosing, tissue radioactivity levels decreased slowly in rats (half-life 34 days, range 28–48 days) and in dogs (half-life 33 days). The routes of excretion were faecal and, to a lesser extent, urinary. Flufenoxuron was excreted in the milk of lactating rats. Flufenoxuron was shown to accumulate in body fat.

Toxicological data

The acute toxicity of flufenoxuron is low (oral LD_{50} > 3000 mg/kg bw; dermal LD_{50} > 2000 mg/kg bw; inhalation LC_{50} > 5.1 mg/L). Flufenoxuron was not irritating to the skin or the eyes of rabbits. Flufenoxuron was not a skin sensitizer in a Magnusson and Kligman test in guinea-pigs.

In repeated-dose toxicity studies with flufenoxuron in mice, rats and dogs, multiple adverse effects were observed, in particular body weight changes and toxicity to the haematological system indicative of haemolytic anaemia. Studies in dogs showed that these animals are particularly sensitive to the haematological effects of flufenoxuron. Owing to the saturation of absorption at higher doses, dose–response curves are often flat.

In a 28-day study in mice using dietary flufenoxuron concentrations of 0, 50, 500, 5000, 10 000 and 50 000 ppm (equivalent to 0, 7.1, 71, 710, 1400 and 7100 mg/kg bw per day, respectively), the NOAEL was 10 000 ppm (equivalent to 1400 mg/kg bw per day), based on reduced feed consumption observed at 50 000 ppm (equivalent to 7100 mg/kg bw per day).

In a 13-week study in mice using dietary flufenoxuron concentrations of 0, 50, 500, 5000, 10 000 and 50 000 ppm (equal to 0, 10, 103, 1069, 2139 and 11 071 mg/kg bw per day for males and 0, 12, 124, 1247, 2482 and 12 619 mg/kg bw per day for females, respectively), the NOAEL was 50 ppm (equal to 10 mg/kg bw per day), based on increased serum bilirubin concentrations in males and females at 500 ppm (equal to 103 mg/kg bw per day).

In a 28-day study in rats using dietary flufenoxuron concentrations of 0, 50, 500, 5000, 10 000 and 50 000 ppm (equal to 0, 4.8, 49, 475, 997 and 5147 mg/kg bw per day for males and 0,

5.3, 53, 534, 1067 and 5432 mg/kg bw per day for females, respectively), the NOAEL was 50 000 ppm (equal to 5147 mg/kg bw per day), the highest dose tested.

In a 13-week study in rats using dietary flufenoxuron concentrations of 0, 50, 500, 5000, 10 000 and 50 000 ppm (equal to 0, 3.5, 35, 351, 689 and 3637 mg/kg bw per day for males and 0, 4.1, 41, 399, 820 and 4151 mg/kg bw per day for females, respectively), the NOAEL was 500 ppm (equal to 41 mg/kg bw per day), based on slightly higher spleen weights and haematological changes indicative of mild anaemia observed in females at 5000 ppm (equal to 399 mg/kg bw per day).

In a 13-week study in dogs using dietary flufenoxuron concentrations of 0, 500, 5000 and 50 000 ppm (equal to 0, 18, 163 and 1961 mg/kg bw per day for males and 0, 21, 182 and 2039 mg/kg bw per day for females, respectively), the LOAEL was 500 ppm (equal to 18 mg/kg bw per day), based on haemolytic anaemia and associated changes. No NOAEL could be identified.

In a 1-year study in dogs using dietary flufenoxuron concentrations of 0, 10, 100, 500 and 50 000 ppm (equal to 0, 0.36, 3.5, 19 and 1898 mg/kg bw per day for males and 0, 0.36, 3.8, 19 and 1879 mg/kg bw per day for females, respectively), the NOAEL was 100 ppm (equal to 3.5 mg/kg bw per day), based on evidence of haemolytic anaemia and related changes at 500 ppm (equal to 19 mg/kg bw per day).

The overall NOAEL for the 13-week and 1-year dog studies was 100 ppm (equal to 3.5 mg/kg bw per day). The overall LOAEL was 500 ppm (equal to 18 mg/kg bw per day).

In a 2-year carcinogenicity study in mice using dietary flufenoxuron concentrations of 0, 100, 1000 and 10 000 ppm (equal to 0, 15.3, 152 and 1592 mg/kg bw per day for males and 0, 17.4, 187 and 1890 mg/kg bw per day for females, respectively), the NOAEL was 1000 ppm (equal to 187 mg/kg bw per day), based on decreased body weight gain in females at 10 000 ppm (equal to 1890 mg/kg bw per day). There was no evidence of carcinogenicity.

In a second 2-year carcinogenicity study in mice, using dietary flufenoxuron concentrations of 0, 500, 5000 and 50 000 ppm (equal to 0, 56, 559 and 7356 mg/kg bw per day for males and 0, 73, 739 and 7780 mg/kg bw per day for females, respectively), the NOAEL was 500 ppm (equal to 56 mg/kg bw per day), based on an increased incidence of lordotic episodes, decreased body weight gain, increased Kupffer cell aggregates in females and increased liver weight relative to brain weight in males at 5000 ppm (equal to 559 mg/kg bw per day). An increased incidence of spleen haemangiosarcomas was observed in females dosed at 50 000 ppm. However, as this finding was not accompanied by an increase in angiomas, it was not considered to be treatment related. An apparent increased incidence of hepatocellular carcinomas in treated male mice in this study was considered not treatment related because the incidence in control males was low.

The overall NOAEL for systemic toxicity in the 2-year studies in mice was 1000 ppm (equal to 187 mg/kg bw per day). The overall LOAEL was 5000 ppm (equal to 559 mg/kg bw per day).

In a 2-year toxicity and carcinogenicity study in rats using dietary flufenoxuron concentrations of 0, 1, 5, 50, 500, 5000 and 50 000 ppm (equal to 0, 0.044, 0.23, 2.2, 22, 230 and 2470 mg/kg bw per day for males and 0, 0.055, 0.28, 2.8, 28, 300 and 3210 mg/kg bw per day for females, respectively), the NOAEL was 500 ppm (equal to 22 mg/kg bw per day), based on decreased body weight gain, a small increase in non-cyanide-binding haemoglobin, considered to reflect sulfhaemoglobin, and decreased triglyceride levels in both sexes at 5000 ppm (equal to 230 mg/kg bw per day). Flufenoxuron was not carcinogenic under the conditions of the study.

In a second 2-year toxicity and carcinogenicity study in rats, using dietary flufenoxuron concentrations of 0, 500, 5000 and 50 000 ppm (equal to 0, 21.6, 218 and 2290 mg/kg bw per day for males and 0, 25.9, 276 and 2901 mg/kg bw per day for females, respectively), the NOAEL was 500 ppm (equal to 25.9 mg/kg bw per day), based on reduced body weight gain in females at 5000 ppm (equal to 276 mg/kg bw per day). No carcinogenic potential of flufenoxuron was observed.

The overall NOAEL for systemic toxicity in the 2-year studies in rats was 500 ppm (equal to 25.9 mg/kg bw per day). The overall LOAEL was 5000 ppm (equal to 230 mg/kg bw per day).

The Meeting concluded that flufenoxuron is not carcinogenic in mice or rats.

Flufenoxuron was tested for genotoxicity in an adequate range of assays, both in vitro and in vivo. There was no evidence of genotoxicity in vitro, with the exception of two assays of chromosomal aberrations in Chinese hamster ovary cells, and there was no evidence of genotoxicity in vivo. The Meeting concluded that flufenoxuron is unlikely to be genotoxic in vivo.

In view of the lack of genotoxicity in vivo and the absence of carcinogenicity in mice and rats at exposure levels that are relevant for human dietary risk assessment, the Meeting concluded that flufenoxuron is unlikely to pose a carcinogenic risk to humans from the diet.

In a two-generation reproductive toxicity study in rats using dietary flufenoxuron concentrations of 0, 50, 190, 710 and 10 000 ppm (premating dietary intakes were equal to 0, 3.8, 14.3, 53.6 and 771 mg/kg bw per day for males and 0, 4.3, 16.0, 61.0 and 907 mg/kg bw per day for females of the F_0 generation and 0, 4.2, 16.1, 62.5 and 865 mg/kg bw per day for males and 0, 4.8, 18.7, 69.2 and 956 mg/kg bw per day for females of the F_1 generation, respectively), the NOAEL for parental toxicity was 50 ppm (equal to 4.2 mg/kg bw per day), based on decreased body weight gain in males of the F_{1B} generation at 190 ppm (equal to 16.1 mg/kg bw per day). The NOAEL for offspring toxicity was 50 ppm (equal to 3.8 mg/kg bw per day), based on a reduction in average body weight gain during lactation of male and female pups of all generations at 190 ppm (equal to 14.3 mg/kg bw per day). The NOAEL for reproductive toxicity was 10 000 ppm (equal to 771 mg/kg bw per day), the highest dose tested. In this study, adverse effects on pup survival and growth were observed at 710 ppm (equal to 53.6 mg/kg bw per day). Subsequent studies, including a cross-fostering study in rats, failed to further elucidate the mechanism for the adverse effects on pup survival.

In a developmental toxicity study in rats using gavage flufenoxuron doses of 0, 7.9, 81 and 967 mg/kg bw per day, the NOAEL for maternal toxicity and for embryo and fetal toxicity was 967 mg/kg bw per day, the highest dose tested.

In a developmental toxicity study in rabbits using gavage flufenoxuron doses of 0, 7.7, 100 and 1000 mg/kg bw per day, the NOAEL for maternal toxicity and for embryo and fetal toxicity was 1000 mg/kg bw per day, the highest dose tested.

The Meeting concluded that flufenoxuron is not teratogenic.

In a 28-day neurotoxicity study in rats using dietary flufenoxuron concentrations of 0, 1000, 5000 and 20 000 ppm (equal to 0, 88, 435 and 1745 mg/kg bw per day for males and 0, 95, 475 and 1934 mg/kg bw per day for females, respectively), the NOAEL was 1000 ppm (equal to 88 mg/kg bw per day), based on reductions in body weight gain in males at 5000 ppm (equal to 435 mg/kg bw per day). No evidence of neurotoxicity was observed in this or other studies.

The Meeting concluded that flufenoxuron is not neurotoxic.

Toxicological data on metabolites and/or degradates

Acute toxicity and genotoxicity studies were performed with Reg. No. 241208 (4-[2-chloro-4-(trifluoromethyl)phenoxy]-2-fluorobenzenamine), a minor faecal (rats and dogs) and urinary (rats) metabolite and a minor residue in hens; and with Reg. No. 4064702 (*N*-[4-[2-chloro-4-(trifluoromethyl)phenoxy]-2-fluorophenyl] urea), which is a soil metabolite, a minor metabolite found in the urine of rats (at most 1% of the administered flufenoxuron dose), a water–sediment system product and a minor residue in hens.

In studies of acute oral toxicity in mice with Reg. No. 241208, the oral LD_{50} was 1937 mg/kg bw. There was no evidence of genotoxicity in a number of in vitro and in vivo studies, except for one Ames test that indicated a weak positive response.

For Reg. No. 4064702, the oral LD_{50} was 302 mg/kg bw. An Ames test was negative.

The Meeting concluded that these metabolites are not toxicologically relevant for a dietary risk assessment.

Human data

Medical surveillance of personnel at flufenoxuron manufacturing plants revealed no unusual or abnormal health effects, except for one case of skin allergy in a worker potentially exposed to flufenoxuron.

The Meeting concluded that the existing database on flufenoxuron was adequate to characterize the potential hazards to fetuses, infants and children.

Toxicological evaluation

The Meeting established an ADI of 0–0.04 mg/kg bw for flufenoxuron, on the basis of the overall NOAEL of 3.5 mg/kg bw per day for a range of effects indicative of haemolytic anaemia in 13-week and 1-year dietary studies in dogs, using a safety factor of 100. This ADI was supported by a two-generation dietary reproductive toxicity study in rats, with a NOAEL for parental toxicity of 4.2 mg/kg bw per day, based on decreased body weight gain in males, and a NOAEL for offspring toxicity of 3.8 mg/kg bw per day, based on a reduction in average body weight gain during lactation of male and female pups of all generations. An additional safety factor to extrapolate to lifetime exposure was considered unnecessary, as the LOAELs in the 13-week and 1-year studies in dogs were both 500 ppm (equal to 18–19 mg/kg bw per day), and as the concentrations of flufenoxuron in blood and fat in dogs appear to reach steady state after 3 months of treatment, indicating that effects at lower doses with more prolonged exposure are not expected.

The Meeting concluded that it was not necessary to establish an ARfD for flufenoxuron in view of its low acute toxicity, the absence of developmental toxicity and the absence of any other toxicological effects that would be likely to be elicited by a single dose.

A toxicological monograph was prepared.

Levels relevant to risk assessment of flufenoxuron

Species	Study	Effect	NOAEL	LOAEL
Mouse	Ninety-day study of toxicity[a]	Toxicity	50 ppm, equal to 10 mg/kg bw per day	500 ppm, equal to 103 mg/kg bw per day
	Two-year studies of carcinogenicity[a,b]	Toxicity	1 000 ppm, equal to 187 mg/kg bw per day	5 000 ppm, equal to 559 mg/kg bw per day
		Carcinogenicity	50 000 ppm, equal to 7 356 mg/kg bw per day[c]	–
Rat	Two-year studies of toxicity and carcinogenicity[a,b]	Toxicity	500 ppm, equal to 25.9 mg/kg bw per day	5 000 ppm, equal to 230 mg/kg bw per day
		Carcinogenicity	50 000 ppm, equal to 2 470 mg/kg bw per day[c]	–
	Two-generation study of reproductive toxicity[a]	Reproductive toxicity	10 000 ppm, equal to 771 mg/kg bw per day[c]	–
		Parental toxicity	50 ppm, equal to 4.2 mg/kg bw per day	190 ppm, equal to 16.1 mg/kg bw per

Species	Study	Effect	NOAEL	LOAEL
				day
		Offspring toxicity	50 ppm, equal to 3.8 mg/kg bw per day	190 ppm, equal to 14.3 mg/kg bw per day
	Developmental toxicity study[d]	Maternal toxicity	967 mg/kg bw per day[c]	–
		Embryo and fetal toxicity	967 mg/kg bw per day[c]	–
Rabbit	Developmental toxicity study[d]	Maternal toxicity	1 000 mg/kg bw per day[c]	–
		Embryo and fetal toxicity	1 000 mg/kg bw per day[c]	–
Dog	Ninety-day and 1-year studies of toxicity[a,b]	Toxicity	100 ppm, equal to 3.5 mg/kg bw per day	500 ppm, equal to 18 mg/kg bw per day

[a] Dietary administration.
[b] Two or more studies combined.
[c] Highest dose tested.
[d] Gavage administration.

Estimate of acceptable daily intake (ADI)

0–0.04 mg/kg bw

Estimate of acute reference dose (ARfD)

Unnecessary

Information that would be useful for the continued evaluation of the compound

Results from epidemiological, occupational health and other such observational studies of human exposure

Critical end-points for setting guidance values for exposure to flufenoxuron

Absorption, distribution, excretion and metabolism in mammals	
Rate and extent of oral absorption	Rats: Rapid; > 80% in both sexes at 3.5 mg/kg bw; > 3% in males and 12% in females at 350 mg/kg bw
	Dogs: Rapid; > 30% in both sexes at 3.5 mg/kg bw
Dermal absorption	No data
Distribution	Rats and dogs: Widespread distribution, highest concentrations found in fat and, to a lesser extent, bone marrow
	Present in milk in lactating rats
Potential for accumulation	Fat/blood residue concentration ratios were 53 (rats) and 19 (dogs) 7 days post-dosing
	Rats: Half-life in various organs after repeated administration is 20–48 days
	Dogs: Half-life in blood is 33 days
	Potential for accumulation over repeated dosing

Rate and extent of excretion	Slow, mainly via faeces (biliary excretion) and urine
Metabolism in animals	Limited metabolism; major metabolite was 2,6-difluorobenzoic acid, accounting for 10–12% of the administered dose in 0- to 48-hour urine
Toxicologically significant compounds in animals and plants	Parent
Acute toxicity	
Rat, LD_{50}, oral	> 3 000 mg/kg bw
Rat, LD_{50}, dermal	> 2 000 mg/kg bw
Rat, LC_{50}, inhalation	> 5.1 mg/L
Rabbit, dermal irritation	Not irritating
Rabbit, ocular irritation	Not irritating
Guinea-pig, dermal sensitization	Not sensitizing (maximization test)
Short-term studies of toxicity	
Target/critical effect	Haemolytic anaemia
Lowest relevant oral NOAEL	3.5 mg/kg bw per day (dogs)
Lowest relevant dermal NOAEL	No data
Lowest relevant inhalation NOAEC	No data
Long-term studies of toxicity and carcinogenicity	
Target/critical effect	Reduced body weight gain, haemolytic anaemia
Lowest relevant NOAEL	25.9 mg/kg bw per day (rats)
Carcinogenicity	Unlikely to pose a carcinogenic risk to humans from the diet
Genotoxicity	
	Unlikely to be genotoxic in vivo
Reproductive toxicity	
Target/critical effect	None
Lowest relevant parental NOAEL	4.2 mg/kg bw per day
Lowest relevant offspring NOAEL	3.8 mg/kg bw per day
Lowest relevant reproductive NOAEL	771 mg/kg bw per day, highest dose tested
Developmental toxicity	
Target/critical effect	None
Lowest relevant maternal NOAEL	967 mg/kg bw per day, highest dose tested (rat)
Lowest relevant embryo/fetal NOAEL	967 mg/kg bw per day, highest dose tested (rat)
Neurotoxicity	
Acute neurotoxicity NOAEL	No data
Subchronic neurotoxicity NOAEL	1745 mg/kg bw per day, highest dose tested
Developmental neurotoxicity NOAEL	No data
Other toxicological studies	
Studies on toxicologically relevant metabolites	Reg. No. 241208: Mouse LD_{50} oral = 1937 mg/kg bw Genotoxicity: unlikely to be genotoxic Reg. No. 406 4702: Mouse LD_{50} oral = 302 mg/kg bw Not mutagenic in Ames test

Medical data	
	One case of skin allergy possibly related to exposure to flufenoxuron

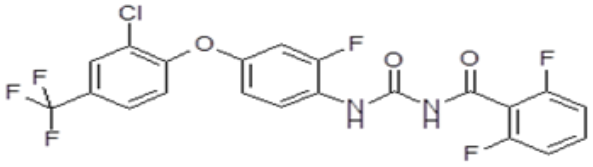
Summary

	Value	Study	Safety factor
ADI	0–0.04 mg/kg bw	Thirteen-week and 1-year studies of toxicity (dog)	100
ARfD	Unnecessary	–	–

RESIDUE AND ANALYTICAL ASPECTS

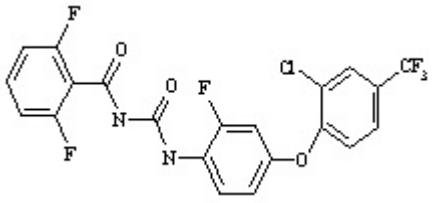
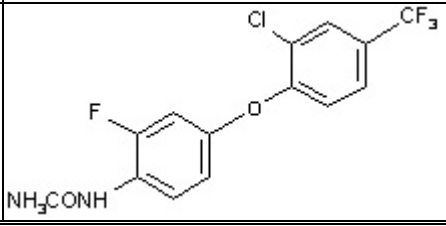
Flufenoxuron is a benzylurea insect growth regulator used to kill mites and insects, through interference with chitin production during cuticle development in mite and insect juvenile stages, on various orchard crops, fruiting vegetables and tea. It was considered for the first time by the 2014 JMPR for toxicology and residues.

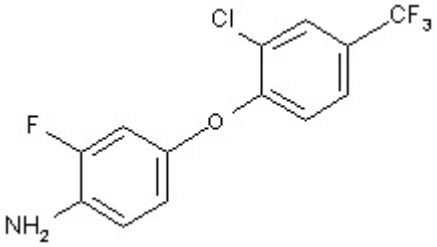
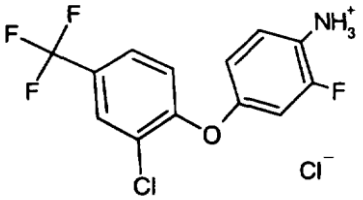
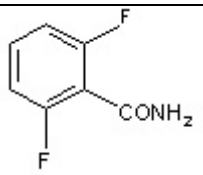
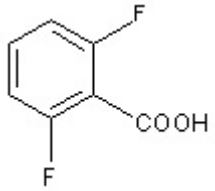
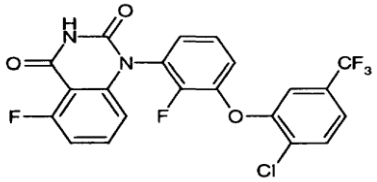
The Meeting received information on physical chemical properties, livestock and plant metabolism, environmental fate, analytical methods, storage stability, supervised residue trials, use patterns, processing and livestock feeding.



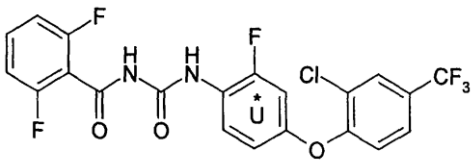
The IUPAC name of flufenoxuron is N-{4-[2-chloro-4-(trifluoromethyl)phenoxy]-2-fluorophenyl}-N'-(2,6-difluorobenzoyl)urea and the CA name is N-[[[4-[2-chloro-4-(trifluoromethyl)phenoxy]-2-fluorophenyl]amino]carbonyl]-2,6-difluorobenzamide.

Common chemical names, code names and structures of the parent and metabolites are captured below:

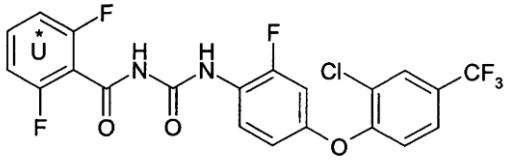
Code	Structure	Occurrence
Flufenoxuron WL 115110		Rat Lactating goat Laying hen Grape Apple Tomato Chinese cabbage Soil Hydrolysis study
Reg. No. 4064702		Rat Laying hen Soil Hydrolysis study

Code	Structure	Occurrence
Reg. No. 241208		Rat Laying hen Hydrolysis study
Reg. No. 4064703 (chloride salt of Reg. No. 241208)		Hydrolysis study
Reg. No. 102719		Rat Hydrolysis study
Reg. No. 206925		Rat Hydrolysis study
Reg. No. 4964847		Hydrolysis study

Flufenoxuron uniformly labelled in either the fluoroaniline or difluoroamide rings was used in the metabolism and environmental fate studies.



Fluoroaniline U-^{14}C



Difluoroamide U-^{14}C

Animal metabolism

Information was available on the metabolism of flufenoxuron in laboratory animals, lactating goats and laying hens.

Metabolism studies in rats demonstrated that unchanged flufenoxuron accounted for the majority of the total applied radioactivity (TAR) in faeces, with minor metabolites (less than 1% of the TAR) identified as 2-amino-5-(2-chloro-α,α,α-trifluoro-p-tolyoxy)-3-fluorophenol (Reg. No.

4110959), Reg. No. 4064702, Reg. No 241208, Reg. No 102719 and Reg. No. 206925. For organs and tissues, parent flufenoxuron was the main component observed.

In the lactating goat metabolism study, one goat received four daily doses of 2-fluoroaniline-[U-^{14}C]-ring-labelled flufenoxuron at a rate equivalent to 10 ppm in the diet (10 mg/day). The animal was sacrificed 24 hours after administration of the last dose. While the majority of the radioactivity was excreted via the faeces (18% of the TAR) and urine (2.5% of the TAR), milk and tissues accounted for ≤ 10% of the TAR. Total recovered radioactivity was low (33%). No explanation for the low recovery was evident.

The total radioactive residues (TRRs) were highest in fat (1.6 mg eq/kg), followed by liver (0.37 mg eq/kg), kidney (0.13 mg eq/kg) and muscle (0.076 to 0.1 mg eq/kg). Milk residues peaked on day 4 (average of 0.27 mg eq/L) with the highest concentrations of radioactivity detected in the cream fraction (accounting for 82–93% of the TRR in whole milk) and the lowest found in whey (1.3–5.7% of the TRR). Following solvent extraction, residue extractabilities were 66–100%.In milk and all tissues sampled, the flufenoxuron molecule remained intact with no other metabolites being detected.

Two studies on metabolism in laying hens were available. In the first study, the laying hens received 14 daily doses of flufenoxuron, uniformly labelled in the difluoroamide or fluoroaniline rings, at 13–14 ppm in the feed. The animals were sacrificed approximately 23 h after the last dose. Excreta accounted for 72–78% of the TAR. No plateau was reached in eggs during the dosing period (14 days); however, the radioactivity in eggs and tissues amounted to 1.0–1.3% and 2.6–3.6% of the TAR, respectively. Among all the tissues analysed, radioactive residues were highest in fat (5.0–5.3 mg eq/kg) followed by liver (0.6–1.1 mg eq/kg) and muscle (0.3–0.4 mg eq/kg). The total recovery of radioactivity was 82% and 77% in the groups administered the difluoroamide- and fluoroaniline-labelled flufenoxuron, respectively.

Solvent extraction released 91–102% and 88–99% of the TRRs for the difluoroamide- and fluoroaniline-label, respectively. While the lowest extractability occurred in the liver of the fluoroaniline-labelled study (88% of the TRR), microwave extraction of the liver post-extraction solid (PES) sample released another 8% of the TRR. For the difluoroamide-label, the parent was the only analyte identified in eggs, muscle, fat and liver ranging from 0.28 mg eq/kg (86.5% of the TRR, muscle) to 4.6 mg eq/kg (91.4%, fat).

For the fluoroaniline-label, the parent compound accounted for the majority of the TRRs (70–91%) in the eggs, muscle, fat and liver. The lowest level of parent was found in muscle (0.30 mg eq/kg) with the highest observed in fat (4.8 mg eq/kg). In eggs and liver, Reg. No. 4064702 was present at 0.10 mg eq/kg and 0.13 mg eq/kg (12.0% and 12.6% of the TRR, respectively) while in muscle and fat, Reg. No. 4064702 was a minor metabolite amounting to 0.02 mg eq/kg and 0.05 mg/kg, respectively (5.5% and 1.0% of the TRR). The formate derivative of Reg. No. 241208 was released from the PES of liver after microwave treatment in the presence of formic acid/acetonitrile. The radioactivity associated with this derivative amounted to 0.04 mg eq/kg (3.3% TRR). The Meeting could not confirm whether the metabolite Reg. No. 241208 is an actual in-vivo metabolite or an artefact formed during microwave treatment.

In the second study, laying hens received seven consecutive daily doses of flufenoxuron uniformly labelled in the fluoroaniline ring at a rate equivalent to 10 ppm in the diet. Hens were sacrificed 22 hours following administration of the last dose. To investigate the depuration behaviour of flufenoxuron, four groups of three laying hens each were sacrificed at 2, 9, 16, and 34 days after the last administration.

On average, 26% of the TAR was excreta-related with eggs, sampled from 0–166 h after the first administration, accounting for 5% of the TAR. At sacrifice, the highest amount of radioactive residues was detected in fat (47% of the TAR), followed by skin (12% of the TAR), muscle (4% of the TAR), liver (2% of the TAR), kidney (0.3% of the TAR), heart and gizzard (combined 0.2% TAR). The recovery of radioactivity amounted to 96% of the TAR.

Solvent extraction (including incubation of liver and kidney samples at 37 °C) released 91–102% of the TRRs). The parent compound was the predominant analyte detected in yolks, liver, kidney, muscle, gizzard and heart while it was the only compound detected in fat and skin. The metabolite Reg. No. 4064702 was detected in yolks, liver, kidney, muscle, gizzard, and heart at 6–22% of the TRR, while the minor metabolite Reg. No. 241208 was only detected in liver and kidney at ≤ 4% of the TRR, the only matrices that were incubated for 16 hours at 37 °C in 0.07M phosphate buffer at pH 7.5 prior to extraction

In the depuration study, radioactivity in egg yolks decreased steadily from a mean of 0.02 mg eq./kg, 2 days after cessation of dosing to 0.006 mg eq.kg on depuration day 34. Similarly, radioactivity in muscle decreased from 0.28 mg eg/kg to 0.06 mg eq/kg, during this same interval In kidney and liver, the decrease in radioactivity was more prominent from day 16 to day 34 of the depuration phase (kidney; 0.48 mg eq/kg to 0.17 mg eq/kg and liver; 0.89 mg eq/kg to 0.42 mg eq/kg) yet in fat, the decrease in radioactivity occurred most rapidly from day 2 to day 9 (13.18 mg eq/kg to 6.00 mg eq/kg) and from day 16 to day 34 (4.6 mg eq/kg to 1.97 mg eq/kg). These results demonstrate that radioactive residues are not retained in eggs, organs and tissues after cessation of dosing.

In both laying hen studies, the metabolic pattern was comparable with unchanged flufenoxuron accounting for the majority of the radioactivity, representing ≥ 60% of the TRRs in eggs and tissues. The minor metabolites Reg. No. 4064702 (eggs and tissues) and Reg. No. 241208 (liver and kidney), resulting from the cleavage of the benzoyl urea bond, were also observed to a limited extent (≤ 12% of the TRRs; except in the kidney where Reg. No. 4064702 represented 22% of the TRRs).

The Meeting concluded that in the lactating goat metabolism study, the parent flufenoxuron remained intact and was the only residue identified in milk and all tissues. In the laying hen metabolism studies, while flufenoxuron was the predominant residue in eggs and tissues, cleavage of the benzoyl urea bond was observed to a limited extent resulting in the formation of the metabolites Reg. No. 4064702 (eggs and tissues) and Reg. No. 241208 (liver and kidney).which were also identified in the rats.

Plant metabolism

The Meeting received metabolism studies for flufenoxuron following foliar applications of either [difluorobenzamide-U-^{14}C]- or 2-fluoroaniline-[U-^{14}C]-ring-flufenoxuron to grape, apple, tomato and Chinese cabbage.

Two foliar sprays were made to grape vines, grown outdoor and protected with plastic covers after application, during fruit development; at a rate of 0.04 kg ai/ha/application, with a 40-day retreatment interval, resulting in a total rate of 0.08 kg ai/ha. Immature leaves were collected at 15 DAT (days after last treatment) while mature leaves, stalks and fruit (from grape clusters) were harvested 28–29 DAT. TRRs in leaves declined from 2.3–2.7 mg eq/kg at 15 DAT to 1.4–1.8 mg eq/kg at 29 DAT. TRRs in mature fruit and stalks were 0.012–0.014 mg eq/kg and 0.11–0.16 mg eq/kg, respectively. Solvent extraction released approximately 95–97% of the TRR (0.012–2.6 mg eq/kg) from the grape matrices. Flufenoxuron was the only compound identified in all fruit, leaf and stalk samples (50–97% of the TRR; 0.007–2.2 mg eq/kg). Polar unknowns comprised up to 40–46% of the TRR in mature grape samples (0.005–0.006 mg eq/kg) with unextracted residues in all leaf, fruit and stalk samples accounting for ≤ 5% of the TRR (< 0.11 mg eq/kg).

Ten apple trees, maintained in glasshouses, were sprayed with flufenoxuron, uniformly labelled in the fluoroaniline ring. A single application of the dispersible concentrate was made to trees, during fruit development, at a rate of 0.01 kg ai/hL. Samples of immature fruit were harvested 0 days (4 h post-treatment) and 46 days after treatment (DAT), and mature fruit samples were collected at 99 DAT. TRRs in immature fruit were 2.6 mg eq/kg (0 DAT) and declined to 0.16 mg eq/kg (46 DAT) and 0.06 mg eq/kg (99 DAT). The radioactivity in the combined acetonitrile and hexane

surface washes decreased with increasing DAT, from 96% of the TRRs at 0 DAT to 77% of the TRRs at 99 DAT, with a corresponding increase in TRRs in fruit extracts (3.7% TRR at 0 DAT to 23% of the TRRs at 99 DAT), demonstrating limited translocation. The parent flufenoxuron accounted for the majority of the TRRs in surface washes (74–93%; 0.043–2.4 mg eq/kg) and in fruit extracts (3–16% of the TRRs; (0.01–0.08 mg eq/kg).

A single broadcast foliar application of 2-fluoroaniline-[U-^{14}C]-ring-flufenoxuron, formulated as an emulsifiable concentrate, was made to tomato plants, maintained outdoor, during fruit development at a rate of 0.125 kg ai/ha. Tomato fruit was harvested at 0 and 28 DAT. TRRs in/on tomato fruit declined from 0.38 mg eq/kg on day 0, to 0.2 mg eq/kg by day 28. The total extracted residues (ACN:water surface washes and fruit extracts) from 0 DAT to 28 DAT, accounted for 94–99% of the TRR (0.16–0.38 mg eq/kg), mainly from the surface wash (≥ 94% of the TRRs). Flufenoxuron was the only identified residue in the mature tomato sample (91% of the TRRs).

2-Fluoroaniline-[U-^{14}C]-ring-flufenoxuron, formulated as an emulsifiable concentrate, was applied once to Chinese cabbage plants, grown outdoor, during leaf development, as a foliar application, at a rate equivalent to 0.10 kg ai/ha. Cabbage plants were harvested at 0 and 28 DAT. TRRs in/on cabbage wrapper leaves declined from 6.3 mg eq/kg on day 0 to 0.35 mg eq/kg by day 28. At 0 DAT, the surface wash represented the majority of the extracted residues (84% of the TRRs; 5.3 mg eq/kg) while at the 28 DAT, the leaf extracts accounted for a greater fraction of the extractable radioactivity (76% of the TRRs; 0.27 mg eq/kg). The parent flufenoxuron was the only identified residue in mature cabbage leaves (93% of the TRRs).

The Meeting concluded that the metabolism of flufenoxuron in grape, apple, tomato and Chinese cabbage is consistent among all crops, where parent flufenoxuron remained intact. No other metabolites were identified and no other residues were characterized (other than polar unknowns). The Meeting agreed that the majority of radioactivity remained on the leaves or surface of the fruit, with limited translocation.

Environmental fate in soil

The Meeting received information on aerobic degradation in soil.

In these studies, the fluoroaniline-specific metabolite, Reg. No. 4064702, was the only metabolite identified, reaching a maximum concentration after 30 days of incubation (4.1–8.3% TAR). The predominant residue, flufenoxuron, decreased to 45.8–51.0% TAR in the soil after 119 days, resulting in a calculated DT_{50} for flufenoxuron of 115–122 days. Considering the persistence of flufenoxuron, it is desirable that confined rotational crop and field accumulation studies be submitted.

Methods of residue analysis

The Meeting received analytical methods for the analysis of flufenoxuron in plant and animal commodities. The basic principle for plant commodities employs extraction by homogenisation with dichloromethane, methanol/water/HCl or acetone followed by partitioning with water/cyclohexane. For animal matrices, flufenoxuron residues are extracted by homogenization with various non-polar organic solvents followed by liquid partitioning and/or clean-up by normal-phase or reverse-phase HPLC prior to analysis. Residues of flufenoxuron are measured by HPLC-MS/MS with two specific mass transitions or with HPLC-UV at 254–260 nm. The applicability of the proposed enforcement methods was confirmed in various independent laboratories where parent flufenoxuron was analyzed with validated LOQs of 0.05 mg/kg for plant and animal commodities and eggs, and 0.01 mg/kg for milk.

The multiresidue method DFG S-19 was tested, for the analysis of flufenoxuron in animal matrices only, and found to be unsuitable.

A number of scientific papers report the validation of the QuEChERS multi-residue method using GC-MS/MS for flufenoxuron in various plant commodities.

The Meeting concluded that the available enforcement analytical methods are suitable for determining residues of flufenoxuron in plant and animal commodities with LOQs, ranging from 0.01–0.05 mg/kg depending on the matrix.

Stability of residues in stored analytical samples

Based on the storage stability data submitted, the Meeting concluded that no significant dissipation of flufenoxuron residues was observed in cottonseed, orange, grape, and apple after 36 months of storage, in lettuce after 27 months and in watermelon (pulp and peel) after 26 months.

The Meeting agreed that no degradation of flufenoxuron residues was observed in animal matrices stored for up to 53 months of storage, except egg whites, where flufenoxuron residues were determined to be stable for up to 4 months.

Definition of the Residue

In the lactating goat metabolism study, flufenoxuron was the only residue identified in tissues and milk with no other metabolites detected. Similarly, in the laying hen metabolism studies, flufenoxuron accounted for the majority of the radioactivity in eggs, muscle, fat, liver and kidney (60–104% of the TRRs).

Therefore, the Meeting recommends the residue definition for compliance with MRL for animal commodities as flufenoxuron.

The Log K_{ow} of flufenoxuron is 4. In the goat metabolism study, highest levels of the parent compound were observed in fat and cream, while in the laying hen metabolism studies, the highest concentrations of flufenoxuron were observed in the fat (≤ 98% of the TRRs). These findings were supported by the livestock feeding studies, where the average ratio for cream/skim milk was ≥ 155 and ≥ 112 for egg yolks/egg whites. Further to this, residues in fat were 24–30-fold higher than those in muscle.

In light of this, the Meeting concluded that the residue is fat soluble.

The metabolite Reg. No. 4064702 was also identified in laying hen muscle, fat, liver, kidney and eggs (1–22% of the TRRs) with the highest levels observed in liver and kidney. The minor metabolite Reg. No. 241208 was also observed but only in liver and kidney (2.5–3.7% of the TRRs) which were the only matrices that were subject to microwave extraction (liver only) or incubation at 37 °C in 0.07M phosphate buffer at pH 7.5 prior to extraction (liver and kidney), and hence considered a potential artefact of the analytical procedure.

The toxicity of the minor metabolite Reg. No. 241208, found in laying hen matrices, was considered to be covered by toxicity studies on flufenoxuron since this metabolite was seen in the rat. The metabolite Reg. No. 4064702, also observed in eggs and tissues of laying hens, and observed in the rat, was determined to be more acutely toxic than the parent flufenoxuron based on the LD_{50}. However, according to the poultry feeding study, residues of this metabolite in liver are not expected to exceed 0.04 mg/kg at the lowest feeding level of 1 ppm. Hence, as there are no poultry feed items derived from the proposed crops, the dietary exposure to this metabolite from poultry matrices is unlikely.

The Meeting recommends the residue for dietary intake for animal commodities as parent only.

The fate of flufenoxuron in plants was investigated following foliar application to tomato, apple, grape and Chinese cabbage. In all plant commodities tested, flufenoxuron was the predominant residue accounting for > 90% of the TRR, with the exception of grape, where flufenoxuron accounted

for 50% of the TRR. No other metabolites were identified and no other residues were characterized (other than polar unknowns).

According to the hydrolysis study, simulating typical processing conditions (pH 4, 5 and 6 with 90 °C, 100 °C and 120 °C for 20, 60 and 20 minutes), flufenoxuron was degraded to various metabolites including: Reg. No. 102719 (8–32%), Reg. No. 4064702 (4%) and Reg. No. 4964847 (4–9%). All metabolites, except Reg. No. 4064702 and Reg. No. 4964847 are considered to be covered by toxicity studies on flufenoxuron, since they were seen in the rat. The absorption, distribution, metabolism and excretion studies in rat demonstrated that Reg. No. 4064702 was more acutely toxic than the parent flufenoxuron. Conversely, no toxicity information is available on metabolite Reg. No. 4964847, Reg. No. 4064702. Nevertheless, in the tomato processing study where these metabolites were measured in juice, purée and canned tomatoes, none were detected (< 0.01 mg/kg)

The Meeting recommended the following residue definition for flufenoxuron:

Definition of the residue for compliance with MRL and for estimation of dietary intake for plants and animal commodities: *flufenoxuron*

The Meeting considers the residue fat soluble.

Results of supervised residue trials on crops

The Meeting received supervised residue trials from Brazil, Europe and South Africa where flufenoxuron was applied to oranges, apples, pears, melons and tomatoes and Japanese trials on tea.

Oranges

The critical GAP in Brazil for flufenoxuron on oranges is up to two foliar applications of 0.005 kg ai/hL, with a re-treatment interval of 30 days and a PHI of 15 days. Sixteen supervised field trials were conducted in Greece, Italy, South Africa and Brazil.

Four of the trials were conducted in Brazil according to the critical GAP. Residues in whole oranges at the 15-day PHI were: 0.09, 0.11, 0.13 and 0.16 mg/kg.

Five trials in Brazil were conducted at 2× 0.002–0.003 kg ai/hL with a PHI of 15 days, representing 0.4–0.6× the critical GAP in Brazil. The residues in whole fruit were 0.03, 0.05, 0.07, 0.08 and 0.10 mg/kg. The Meeting agreed to use the proportionality approach to scale the residues at the 15-day PHI according to an application rate of 0.005 kg ai/hL. The rank order of scaled residues in whole fruit was (n=5): 0.08 (2), 0.13 (2), and 0.17 mg/kg.

When combining all the residue data, residues in whole oranges were 0.08 (2), 0.09, 0.11, 0.13 (3), 0.16 and 0.17 mg/kg and residues in pulp were 0.03, 0.04, 0.05 (3), 0.06, 0.08 (2) and 0.10 mg/kg.

The Meeting estimated a maximum residue level of 0.4 mg/kg, and a median residue of 0.13 mg/kg for residues of flufenoxuron in whole oranges. For orange pulp, the Meeting estimated an STMR of 0.05 mg/kg.

Apples

The Brazil critical GAP for flufenoxuron on apples is a single foliar application at 0.01 kg ai/hL and a PHI of 35 days.

Three trials on apples were available from Chile where trees were treated at 0.015–0.02 kg ai/hL with PHIs of 35–36 days, representing 1.5–2× the critical GAP in Brazil. The residues in the fruit were 0.17, 0.43 and 0.52 mg/kg. The Meeting agreed to use the proportionality approach to scale the residues at the PHIs of 35–36 days according to the application rate of 0.01 kg ai/hL. The scaled residues, in ranked order, were: 0.08, 0.22 and 0.35 mg/kg (n=3).

In two trials conducted in Chile in accordance with Brazilian GAP, flufenoxuron residues were 0.07 and 0.45 mg/kg.

The Meeting concluded that the number of trials available was insufficient to estimate a maximum residue level for residues of flufenoxuron in apples.

Melons

There is no GAP in Brazil for flufenoxuron on melons; therefore, the Meeting could not recommend a maximum residue level.

Tomatoes

There is no GAP in Brazil for flufenoxuron on tomatoes; therefore, the Meeting could not recommend a maximum residue level.

Tea

The critical GAP for flufenoxuron in Japan for tea is up to two foliar applications of 0.025 kg ai/hL at a re-treatment interval of 7–14 days and a PHI of 7 days.

In seven of the eleven trials conducted in Japan and matching the critical GAP, residue levels in tea (green) were: 2.37, 2.48, 3.95, 4.58, 6.02, 6.23 and 11.8 mg/kg.

The Meeting estimated a maximum residue level of 20 mg/kg and a STMR of 4.58 mg/kg for residues of flufenoxuron in tea, green, black (black, fermented and dried).

Fate of residues during processing

Nature of residues

The Meeting received information on the hydrolysis of flufenoxuron uniformly labelled in the fluoroaniline and difluoroamide rings where typical processing conditions were simulated (pH 4,5 and 6 with 90 °C, 100 °C and 120 °C for 20, 60 and 20 minutes).

In duplicate samples of sterile buffer solution flufenoxuron (accounting for 63–93% of the TAR) was seen to hydrolyse to various metabolites, however, none accounted for greater than 10%of the TAR, with the exception of Reg. No. 102719, present at 32% of the TAR, following hydrolysis conditions simulating baking, boiling and brewing procedures.

Level of residues

The Meeting also received information on the fate of flufenoxuron residues during the processing of the raw agricultural commodities like tomato to juice, pomace, puree and canned tomatoes and tea to infusion. While the magnitude of the residues of Reg. No. 102719in tea infusion was not elucidated, in the tomato processing study, the residues of flufenoxuron metabolites, including Reg. No. 102719, Reg. No. 4064702 and Reg. No. 4964847 in all processed tomato commodities were below the LOQ (0.01 mg/kg). However, in the absence of a critical GAP in Brazil for flufenoxuron on tomatoes, the tomato processing study was not relied upon to derive processing factors, STMR-P values and to estimate maximum residue levels for tomato processed commodities.

The processing factor obtained in the tea processing study and the estimated STMR-P value for the dietary intake calculation is summarized below:

Raw agricultural commodity	STMR, mg/kg	Processed commodity (food)	Processing factor	STMR-P (mg/kg)
Tea (green)	6.02	Infusion	0.0065 (median)	0.04

Residues in animal commodities

Farm animal feeding studies

The Meeting received information on the residue levels arising in animal tissues and milk when dairy cows were fed flufenoxuron for 90 days at levels equivalent of 1.75, 5.25 and 17.5 ppm in the diet. Three animals from the highest dose level group were monitored for flufenoxuron residues over a 40-day depuration phase.

At the lowest dose tested, flufenoxuron residues in milk increased steadily over the 90-day period, from 0.0243 mg/kg on day 2 to 0.64 mg/kg on day 90, however, in the mid and high dose groups, residues seemed to plateau on day 56 (at 1.6 mg/kg) and day 70 (at 5.5 mg/kg), respectively. Analysis of milk obtained from the high dose group showed that pasteurization had no effect on the levels of flufenoxuron in milk. Residues in cream were concentrated by a factor of 1.5. In skimmed milk and acid whey, residues were lower than those of raw milk.

In all tissues tested, except subcutaneous fat, residues of flufenoxuron were dose dependant, increasing with increasing dose. In subcutaneous fat, residues were 0.8 mg/kg, 9.3 mg/kg and 8.7 mg/kg, in the low, mid and high dose groups, respectively.

The residue depuration study demonstrated that flufenoxuron residues in milk decreased slowly within the 40 days of cessation of dosing, from 5.1 mg/kg on day 91 to 0.9 mg/kg on day 130. In tissues, flufenoxuron residues decreased on average by 80% by day 130.

The Meeting also received information on the residues in tissues and eggs of laying hens when dosed with flufenoxuron for 50 days at levels equivalent to 1, 3, 10 ppm in the diet. Fifteen animals from the top dose group were monitored for flufenoxuron residues over a 40-day depuration phase.

At all feeding levels, no residues of flufenoxuron in egg white exceeded 0.05 mg/kg. However, residues in egg yolks did not reach a plateau but rather increased steadily over the 50-day period.

Residues of flufenoxuron in liver, muscle, skin and fat increased with increasing feeding level.

During the depuration study, flufenoxuron residues in egg yolks decreased more rapidly than in cattle milk over the same duration, from 32.5 mg/kg on day 51 to 2.3 mg/kg on day 90.

Farm animal dietary burden

As there is no information on citrus dry pulp, the only potential cattle feed item derived from the proposed crops and there are no poultry feed items, the Meeting did not calculate farm animal dietary burdens.

Therefore, the Meeting estimated maximum residue levels of 0.05* mg/kg for flufenoxuron in meat (from mammals other than marine mammals), edible offal (mammalian), mammalian fat (except milk fats) and 0.01* mg/kg for milks. STMRs and HRs for dietary intake estimation are 0 mg/kg for meat (from mammals other than marine mammals), edible offal (mammalian), mammalian fat (except milk fats) and milks.

The Meeting did not estimate maximum residue levels, STMRs or HRs for poultry matrices.

The residue in animal commodities is considered fat soluble.

RECOMMENDATIONS

On the basis of the data from supervised trials, the Meeting concluded that the residue levels listed below are suitable for establishing maximum residue limits and for IEDI assessment.

Definition of the residue (for compliance with the MRL and for estimation of dietary intake, animal and plant commodities): *flufenoxuron*

The residue is fat soluble.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Daily Intake (IEDI) for flufenoxuron was calculated based on the recommendation for STMRs for raw and processed commodities (tea infusion) in combination with consumption data for corresponding food commodities. These results are shown in Annexe 3.

The IEDI of the 17 GEMS/Food cluster diets, based on the estimated STMRs represented 0% of the maximum ADI of 0.04 mg/kg bw, expressed as flufenoxuron. The Meeting concluded that the long-term intake of flufenoxuron residues from uses considered by the Meeting is unlikely to present a public health concern.

Short-term intake

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

5.15 FLUOPICOLIDE (235)

see also DICHLOBENIL (274)

RESIDUE AND ANALYTICAL ASPECTS

Fluopicolide was first evaluated for residues and toxicological aspects by the 2009 JMPR.

A residue definition of *fluopicolide* was established for compliance with the MRL for both plant and animal commodities, with a residue definition of *fluopicolide* and *2,6-dichlorobenzamide*, measured separately, for dietary risk assessment. A number of maximum residue levels were estimated by the 2009 Meeting.

Dichlobenil was evaluated by the present Meeting for both toxicological and residues aspects. The Meeting established an ADI of 0–0.05 mg/kg bw and ARfD of 0.3 mg/kg bw for 2,6-dichlorobenzamide. The only significant residue of dichlobenil in both plant and animal commodities was 2,6-dichlorobenzamide. The Meeting recommended a residue definition for dichlobenil of *2,6-dichlorobenzamide* in plant and animal commodities, for both compliance with the MRL and dietary risk assessment.

The Meeting noted that 2,6-dichlorobenzamide residues can arise from use of either fluopicolide or dichlobenil, and that there were a number of crops for which there are fluopicolide use, but no dichlobenil use. The Meeting noted that maximum residue levels were required to accommodate residues of 2,6-dichlorobenzamide arising from use of fluopicolide. See dichlobenil.

5.16 FLUOPYRAM (243)

RESIDUE AND ANALYTICAL ASPECTS

Fluopyram, a pyridylethylamide broad spectrum fungicide was evaluated for the first time by the 2010 JMPR, where an ADI of 0–0.01 mg/kg bw and an ARfD of 0.5 mg/kg bw were established, residue definitions were proposed and maximum residue levels were recommended for a number of uses where GAP information was available. New GAP and supporting information were evaluated by the 2012 JMPR and a number of additional maximum residue levels were recommended.

Residue definitions established by the 2010 JMPR are:

- For plant products (compliance with MRLs and dietary intake assessment): *fluopyram*
- For animal products (compliance with MRLs*): sum of fluopyram and 2-(trifluoromethyl) benzamide, expressed as fluopyram*
- For animal products (dietary intake assessment): *sum of fluopyram, 2-(trifluoromethyl)benzamide and the combined residues N-{(E)-2-[3-chloro-5-(trifluoromethyl)pyridin-2-yl]ethenyl}-2-trifluoromethyl) benzamide and N-{(Z)-2-[3-chloro-5-(trifluoromethyl)pyridin-2-yl]ethenyl}-2-trifluoromethyl) benzamide, all expressed as fluopyram.*

New GAP information and supporting residue data were provided by the manufacturer for evaluation by the Meeting.

Results of supervised residue trials in crops

The Meeting received new supervised trial data for foliar applications of fluopyram (SC formulations) on plum, peach, apricot, raspberry, onion, leek, Brussels sprouts, cabbage, cauliflower, melon, lettuce, asparagus and oilseed rape and noted that data for some of these crops had also been provided to the 2010 JMPR. New supervised trial data were also provided for watermelon and currants, but because no GAP information was available for these crops, these data were not considered by the Meeting.

The results from these new trials and those previously reported by the 2010 JMPR and either matching critical GAP or where the results can be proportionally adjusted (scaled) to reflect GAP application rates were used to estimate maximum residue levels, STMRs and HRs for a number of commodities for which GAP information was available. The proportionality approach was used to scale the results from trials where the application rates range from 0.33 × GAP to 4 × GAP and where all other parameters matched the critical GAP). Frozen sample storage times in the new trials were within the storage intervals considered acceptable by the 2010 JMPR.

Stone fruit

Results from supervised field trials on apricots, peaches and plums conducted in Europe were considered by the Meeting, including some data for peaches that were also provided to the 2010 JMPR.

Peaches (sub-group 003C)

The critical GAP for apricots is in Greece, up to two applications of 0.15 kg ai/ha, 7–14 days apart with a PHI of 3 days. No trials were available matching this GAP. In trials from Europe where apricots were treated with 2 × 0.21–0.25 kg ai/ha fluopyram, residues at 3 DALA (days after the last application) were: 0.16, 0.2, 0.33, 0.38, 0.43, 0.46, 0.58 and 0.95 mg/kg. When proportionally adjusted to the 0.15 kg ai/hL GAP application rate (scaling factors of 0.6–0.75), fluopyram residues in apricots from these trials were: 0.12, 0.14, 0.22, 0.26, 0.27, 0.28, 0.35 and 0.69 mg/kg (n=8).

For peaches, the 2012 JMPR recommended a maximum residue level of 0.4 mg/kg based trials from Southern Europe proportionally adjusted to the GAP in Turkey (0.005 kg ai/hL, PHI 3 days).

The Meeting was advised that new GAP existed in Europe, with a new critical GAP (Greece) of up to two applications of 0.15 kg ai/ha, 7–14 days apart and a PHI of 3 days. No trials were available matching this new GAP. In trials from Europe where peaches were treated with 2 × 0.21–0.25 kg ai/ha fluopyram, residues at 3 DALA were: 0.2, 0.26, 0.28, 0.28, 0.31, 0.36, 0.63 and 0.73 mg/kg. When proportionally adjusted to the 0.15 kg ai/ha GAP application rate (scaling factors of 0.6–0.75), fluopyram residues in peaches from these trials were: 0.12, 0.16, 0.17, 0.17, 0.19, 0.22, 0.45 and 0.53 mg/kg (n=8).

The Meeting noted that the medians of the data sets for apricots and peaches differed by less than 5-fold and agreed to consider a group maximum residue level for peaches (subgroup 003C) since GAP exists in Europe for all crops within this subgroup. In deciding on the data set to use for estimating a group maximum residue level, since a Mann-Whitney U-test indicated that the residue populations for apricots and peaches were not different it was agreed to combine the results to give a data set of 0.12, 0.12, 0.14, 0.16, 0.17, 0.17, 0.19, 0.22, 0.22, 0.26, 0.27, 0.28, 0.35, 0.45, 0.53 and 0.69 mg/kg (n=16)

The Meeting estimated a group maximum residue level of 1 mg/kg, an STMR of 0.22 mg/kg and an HR of 0.69 mg/kg for fluopyram on peaches (subgroup 003C) and to recommend withdrawal of the previous maximum residue level recommendation of 0.4 mg/kg for peach.

Plums (sub-group 003B)

The critical GAP for plums is in Greece, up to three applications of 0.1 kg ai/ha with a PHI of 3 days. In trials from Europe matching the GAP in Greece, residues were: 0.08, 0.1, 0.1, 0.13, 0.13, 0.14, 0.16, 0.18, 0.2, 0.2 and 0.22 mg/kg (n=11).

The Meeting estimated a sub-group maximum residue level of 0.5 mg/kg, an STMR of 0.13 mg/kg and an HR of 0.22 mg/kg for fluopyram on plums (subgroup 003B).

Berries and small fruit

Results from supervised trials on outdoor and protected raspberries conducted in Europe and outdoor raspberries were provided to the Meeting.

Cane berries

The critical GAP for small berries (including blackberries and raspberries) is in South Africa, up to two applications of 0.25 kg ai/ha, 10–14 days apart, with a PHI of 3 days. In trials from Europe where protected raspberries were treated with 2 × 0.2 kg ai/ha fluopyram, residues at 3 DAT were: 0.51, 0.69, 0.7 and 1.2 mg/kg (n=4).

Since the South African GAP does not exclude use on protected crops the Meeting agreed to use the European trial results on protected raspberries matching the GAP in South Africa to estimate a maximum residue level of 3 mg/kg, an STMR of 0.7 mg/kg and an HR of 1.2 mg/kg for fluopyram on raspberries and agreed to extrapolate these estimations to blackberries.

Bulb vegetables

Results from supervised field trials on bulb onions and leeks in Europe and bulb onions in USA were considered by the Meeting, including some data that were also provided to the 2010 JMPR.

Onion (bulb)

The critical GAP in Northern Europe for bulb onions is in Germany, a maximum of two applications of 0.1 kg ai/ha, with a PHI of 7 days. In trials in Europe matching the GAP in Germany, fluopyram residues in onion bulbs were: < 0.01 (3), < 0.01, 0.01, 0.02, 0.03 and 0.04 mg/kg (n=8).

GAP for bulb onions exists in Southern Europe (Greece and Spain), a maximum of one application of 0.2 kg ai/ha with a PHI of 7 days. In trials in Europe matching this GAP, fluopyram residues in onion bulbs were: < 0.01 (6), 0.03 and 0.04 mg/kg (n=8).

The Meeting agreed to use the results matching the GAP in Germany to estimate a maximum residue level, noting that this would accommodate the GAP in Greece and Spain.

The Meeting estimated a maximum residue level of 0.07 mg/kg, an STMR of 0.01 mg/kg and an HR of 0.04 mg/kg for fluopyram on onion (bulb).

Garlic

The Meeting noted that the GAP for onions in Greece and Spain also applied to garlic and agreed to extrapolate the results of the European onion trials matching this GAP to garlic and estimated a maximum residue level of 0.07 mg/kg, an STMR of 0.01 mg/kg and an HR of 0.04 mg/kg for fluopyram on garlic.

Leek

The critical GAP for leeks is in Germany and Switzerland, a maximum of one application of 0.2 kg ai/ha, with a PHI of 21 days. In trials in Europe matching this GAP, fluopyram residues in leeks were: < 0.01 (4),, 0.01, 0.03, 0.06 and 0.07 mg/kg.

The Meeting estimated a maximum residue level of 0.15 mg/kg, an STMR of 0.01 mg/kg and an HR of 0.07 mg/kg for fluopyram on leek.

Brassica vegetables

Results from supervised field trials on broccoli, Brussels sprouts, head cabbage and cauliflower in Europe were considered by the Meeting, including some data that were also provided to the 2010 JMPR.

Broccoli

The critical GAP for broccoli (flowerhead brassicas) is in Germany, a maximum of two foliar applications of 0.18 kg ai/ha, with a PHI of 14 days. In trials on broccoli in Europe matching this GAP, fluopyram residues in broccoli were: < 0.01, < 0.01, 0.02, 0.03, 0.05, 0.05, 0.06, 0.13 and 0.14 mg/kg (n=9).

The Meeting estimated a maximum residue level of 0.3 mg/kg, an STMR of 0.05 mg/kg and an HR of 0.14 mg/kg for fluopyram on broccoli.

Cauliflower

In trials on cauliflowers in Europe matching the GAP in Germany for cauliflower (flower head Brassicas), up to two foliar applications of 0.18 kg ai/ha, with a PHI of 14 days. fluopyram residues were: < 0.01 (4), 0.01 (5), 0.02, 0.05, 0.05 and 0.05 mg/kg (n=13).

The Meeting estimated a maximum residue level of 0.09 mg/kg, an STMR of 0.01 mg/kg and an HR of 0.05 mg/kg for fluopyram on cauliflower.

Brussels sprouts

The critical GAP for Brussels sprouts is in Germany, a maximum of two foliar applications of 0.18 kg ai/ha, with a PHI of 14 days. In trials in Europe matching this GAP, fluopyram residues in Brussels sprouts were: 0.01, 0.04, 0.04, 0.04, 0.04, 0.05, 0.07, 0.07, 0.07, 0.09, 0.14 and 0.15 mg/kg (n=12).

The Meeting estimated a maximum residue level of 0.3 mg/kg, an STMR of 0.06 mg/kg and an HR of 0.15 mg/kg for fluopyram on Brussels sprouts.

Cabbages, head

The critical GAP for head cabbages is in Germany, a maximum of two foliar applications of 0.18 kg ai/ha, with a PHI of 14 days. In trials in Europe matching this GAP, fluopyram residues in cabbage heads were: < 0.01 (4), 0.01, 0.01, 0.01, 0.02, 0.02, 0.04 and 0.08 mg/kg (n=11).

The Meeting estimated a maximum residue level of 0.15 mg/kg, an STMR of 0.01 mg/kg and an HR of 0.08 mg/kg for fluopyram on cabbage, head.

Fruiting vegetables, Cucurbits

Results from supervised field trials on protected melons and on field melons in Europe, USA and Australia were considered by the Meeting, including some data that were also provided to the 2010 JMPR.

Melons (except watermelon)

The critical GAP for melons is in South Korea, up to three applications of 0.225 kg ai/ha, 10 days apart, with a PHI of 3 days. Since this GAP does not exclude use on protected crops, the Meeting agreed to consider the data from trials on protected melons in Europe involving three applications of 0.1 kg ai/ha where residues at 3 DAT were < 0.01, 0.02, 0.07 and 0.12 mg/kg. When the results of three of these trials where residues were found above the LOQ are proportionally adjusted to the South Korean GAP (scaling factor of 2.25), fluopyram residues in these trials are: 0.05, 0.06 and 0.27 mg/kg.

The Meeting agreed that these data were not sufficient to estimate a maximum residue level for fluopyram on melons (except watermelon).

Leafy vegetables, including brassica leafy vegetables

Lettuce

The critical GAP for lettuce is in Netherlands, up to two applications of 0.25 kg ai/ha, 7 days apart, with a PHI of 7 days.

In outdoor lettuce trials in Europe matching this GAP, fluopyram residues in head lettuce were 0.12, 0.13, 0.57, and 0.63 mg/kg and in leaf lettuce were 0.18, 0.18, 0.25, 0.26, 0.27, 0.53, 0.61, 0.62 and 0.93 mg/kg.

In protected lettuce matching the GAP in Netherlands, fluopyram residues in head lettuce were 0.23, 1.4, 1.9, 2.1, 2.5 and 7.7 mg/kg and in leaf lettuce were 0.16, 0.81, 0.92, 1.2, 2.3, 2.7, 3.8, 4.4, 7.2 and 8.4 mg/kg.

The Meeting noted that highest residues were in protected lettuce and since the data sets for leaf and head lettuce were not from different populations (Mann Whitney), agreed to use the combined data set for protected head and leaf lettuce to estimate maximum residue levels for leaf and head lettuce.

The combined data set of results from the protected lettuce trials matching the GAP in Netherlands is: 0.16, 0.23, 0.81, 0.92, 1.2, 1.4, 1.9, 2.1, 2.3, 2.5, 2.7, 3.8, 4.4, 7.2, 7.7 and 8.4 mg/kg (n=16).

The Meeting estimated maximum residue levels of 15 mg/kg, STMRs of 2.2 mg/kg and HRs of 8.4 mg/kg for fluopyram on lettuce, head and lettuce, leaf.

Stalk and stem vegetables

Asparagus

The critical GAP for asparagus is in Switzerland, up to two applications of 0.2 kg ai/ha, applied to mature ferns prior to senescence, about 6 months or more before the new spears emerge. In four European trials matching this GAP, fluopyram residues in the new spears were all < 0.01 mg/kg.

The Meeting estimated a maximum residue level of 0.01* mg/kg, an STMR of 0 mg/kg and an HR of 0 mg/kg for fluopyram on asparagus.

Oilseeds

Rape seed

The critical GAP for oilseed rape is in Ukraine, up to two applications of 0.113 kg ai/ha with a PHI of 30 days. Fluopyram residues in rape seed from European trials matching this GAP were: 0.07, 0.1, 0.14, 0.25, 0.27, 0.27, 0.29, 0.33, 0.34, 0.35, 0.38, 0.38, 0.46, 0.46 and 0.61 mg/kg (n=15).

The Meeting estimated a maximum residue level of 1 mg/kg and an STMR of 0.33 mg/kg for fluopyram on rape seed.

Animal feeds

Oilseed rape, forage

The Meeting noted that the GAP for fluopyram in Europe is for use on oilseed rape over the flowering period or at early maturity (up to 30 days before harvest). The use of oilseed rape as a forage crop is normally earlier in the season, up to about BBCH 39, prior to the first application of fluopyram and the Meeting concluded that the reported GAP for fluopyram is not relevant for the use of oilseed rape as an animal forage crop.

Fate of residues during processing

The 2010 JMPR reported that fluopyram was stable under conditions simulating pasteurisation, boiling and sterilisation and also estimated processing factors and STMR-Ps for a range of commodities. Relevant processing factors and STMR-Ps for the commodities considered at this Meeting and used for dietary intake risk assessment or for estimating livestock animal burdens are summarised below.

Summary of relevant processing factors and STMR-P values for fluopyram residues

Raw agricultural commodity	Processed commodity	Processing factors [a] (mean or median)	RAC (mg/kg)		STMR-P (mg/kg)	HR-P (mg/kg)
			STMR	HR		
Cabbage			0.01	0.14		
	Cooked washed heads	< 0.36			0.004	0.05
Plums			0.13	0.22		
	Dried fruit	1.1			0.14	0.24

Raw agricultural commodity	Processed commodity	Processing factors [a] (mean or median)	RAC (mg/kg)		STMR-P (mg/kg)	HR-P (mg/kg)
			STMR	HR		
Rape seed			0.33			
	Oil (refined)	0.71			0.23	
	Meal	0.69			0.23	

[a] The processing factor is the ratio of the total residue in the processed item divided by the total residue in the RAC.

Animal commodity maximum residue levels

Cattle

The two new cattle feed commodities considered by the Meeting (rape meal and cabbage leaves) increased these dietary burdens by less than 1.5% and the Meeting agreed that the maximum residue levels, STMRs and HRs estimated by the 2012 JMPR for animal commodities did not need to be revised.

Poultry

The new poultry feed commodity considered by the Meeting (rape meal) increased the maximum dietary burden by less than 1% and increased the mean dietary burden by 11%. The Meeting agreed that the maximum residue levels and HRs estimated by the 2012 JMPR for poultry commodities did not need to be revised.

RECOMMENDATIONS

On the basis of the data from supervised trials the Meeting concluded that the residue levels listed below are suitable for establishing maximum residue limits and for IEDI assessment.

Definition of the residue for compliance with the MRL and for the estimation of dietary intake for plant commodities: *fluopyram*

Definition of the residue for compliance with the MRL for animal commodities: *Sum of fluopyram and 2-(trifluoromethyl) benzamide, expressed as fluopyram*

Definition of the residue for the estimation of dietary intake for animal commodities: *Sum of fluopyram, 2-(trifluoromethyl)benzamide and the combined residues N-{(E)-2-[3-chloro-5-(trifluoromethyl)pyridin-2-yl]ethenyl}-2-trifluoromethyl) benzamide and N-{(Z)-2-[3-chloro-5-(trifluoromethyl)pyridin-2-yl]ethenyl}-2-trifluoromethyl) benzamide, all expressed as fluopyram*.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Daily Intakes (IEDIs) for fluopyram were calculated for the food commodities for which STMRs or HRs were estimated and for which consumption data were available. The results are shown in Annex 3 to the 2014 Report.

The International Estimated Daily Intakes of fluopyram for the 17 GEMS/Food regional diets, based on estimated STMRs were 3–20% of the maximum ADI of 0.01 mg/kg bw (Annex 3). The Meeting concluded that the long-term intake of residues of fluopyram from uses that have been considered by the JMPR is unlikely to present a public health concern.

Short-term intake

The International Estimated Short-term Intakes (IESTIs) for fluopyram were calculated for the food commodities for which STMRs or HRs were estimated and for which consumption data were available (Annex 4 to the 2014 Report).

For fluopyram the IESTI varied from 0–100% of the ARfD (0.5 mg/kg bw) and the Meeting concluded that the short-term intake of residues of fluopyram from uses considered by the Meeting is unlikely to present a public health concern.

5.17 GLUFOSINATE-AMMONIUM (175)

RESIDUE AND ANALYTICAL ASPECTS

Glufosinate-ammonium is a herbicide or desiccant. It was first evaluated for residues and toxicology by the 1991 JMPR and re-evaluated (T, R) by the 2012 JMPR. The ADI of glufosinate-ammonium was 0–0.01 mg/kg bw and the ARfD was 0.0 1mg/kg bw. The compound was listed by the Forty-fifth Session of CCPR for the JMPR to consider residues in soya bean following a revision to the use-pattern.

The residue definition for compliance with MRL and for estimation of dietary intake (for animal and plant commodities) is the sum of glufosinate, 3-[hydroxy(methyl)phosphinoyl]propionic acid and N-acetyl-glufosinate, calculated as glufosinate (free acid).

For the current evaluation the Meeting received critical data required for the estimation of maximum residue levels for soya beans.

Stability of residues in stored analytical samples

The 2012 JMPR evaluated data on the storage stability of glufosinate-ammonium residues (and metabolites) in plant commodities that included soya bean. The studies concluded residues of glufosinate, NAG and MPP are stable under frozen conditions for at least 24 months in glufosinate-tolerant soya bean seed and for at least 12 months in glufosinate tolerant soya bean hay. The longest storage interval in the current trials was 5.4 months.

Results of supervised residue trials in crops

Soya beans, tolerant

The Meeting received field trials performed in the USA involving glufosinate tolerant soya beans. GAP for USA is for (1) one application pre-planting or pre-emergence at 0.59–0.74 kg ai/ha with additional applications from post-emergence to the early bloom growth stage at 0.45–0.59 kg ai/ha with a maximum seasonal rate of 1.3 kg ai/ha/year or (2) post-emergence only with applications from post-emergence to the early bloom growth stage at 0.41–0.50 kg ai/ha with a maximum seasonal rate of 0.91 kg ai/ha/year. The PHI is 70 days. Post-emergent application leads to higher residues.

The use pattern specifies both a last growth stage for application (before the bloom growth stage) and a PHI. The Meeting noted that the interval between the last application and harvest varies significantly depending on the trial location and the soya bean cultivar and that the growth stage at last application was the critical parameter in determining compliance with GAP rather than the PHI.

In trials previously reported by the 2012 JMPR and new trials made available to the current meeting approximating the revised critical GAP in the USA total residues (glyphosate+NAG+MPP) in soya bean seeds were (n=24): 0.04, 0.08, 0.08, 0.1, 0.18, 0.18, 0.19, 0.22, 0.3, 0.3, 0.32, 0.32, 0.32, 0.36, 0.39, 0.4, 0.45, 0.5, 0.51, 0.54, 0.65, 0.75, 1.09, 1.3 mg/kg. The Meeting estimated a median residue of 0.32 mg/kg for use in calculating livestock dietary burdens and a maximum residue level of 2 mg/kg for soya bean, dry to replace its previous recommendation of 3 mg/kg.

Residues for estimation of dietary intake (glufosinate + 0.1×[NAG+MPP]) residues were (n=24): 0.02, 0.02, 0.03, 0.04, 0.05, 0.05, 0.07, 0.08, 0.09, 0.09, 0.09, <u>0.09</u>, <u>0.09</u>, 0.10, 0.11, 0.11, 0.13, 0.13, 0.14, 0.14, 0.19, 0.25, 0.35 and 0.39 mg/kg. The Meeting estimated an STMR and HR of 0.09 and 0.39 mg/kg respectively for soya bean (dry) for use in calculation of dietary intake.

Fate of residues during processing

Processing factors reported by the 2012 JMPR are used to calculate median residues for aspirated grain fractions, hulls, meal and oil that are used in calculation of livestock dietary burden and also for oil used in calculation of the IEDI and IESTI for glufosinate-ammonium.

Summary of selected processing factors for glufosinate-ammonium

Raw commodity	Processed commodity	Individual PF	Best estimate PF	Median or $STMR_{RAC}$ (mg/kg)	Median or $STMR_{RAC}$ × PF (mg/kg)
Soya bean	Aspirated grain fraction	2.73 8.89	5.81	0.32	1.86
	Hulls	3.15, 11.4	7.275		2.33
	Meal	1.22	1.22		0.39
	Oil	< 0.11 < 0.12 < 0.22 < 0.9	< 0.17	0.09	< 0.015

Animal commodity maximum residue levels

The minor changes to the estimated soya bean and soya bean processed commodity levels do not result in significant differences in livestock dietary burdens. The Meeting agreed it is not necessary to make new estimates and recommendations for livestock commodities.

RECOMMENDATIONS

On the basis of the data obtained from supervised residue trials the Meeting concluded that the residue levels listed below are suitable for establishing maximum residue limits and for IEDI and IESTI assessment.

Definition of the residue for (compliance with the MRL and for estimation of dietary intake) for animal and plant commodities: *sum of glufosinate, 3-[hydroxy(methyl)phosphinoyl]propionic acid and N-acetyl-glufosinate, calculated as glufosinate (free acid)*

The residue is not fat soluble.

DIETARY RISK ASSESSMENT

Long-term intake

The Meeting noted that the reduction in the recommended maximum residue level for soya beans would result in lower IEDIs than those previously estimated for glufosinate-ammonium by the 2012 JMPR. The present meeting concluded that the long-term intake of glufosinate–ammonium resulting from the uses considered by the current JMPR is unlikely to present a public health concern.

Short-term intake

The WHO Panel of the 2012 JMPR established an Acute Reference Dose (ARfD) of 0.01 mg/kg bw for glufosinate-ammonium. The IESTI was calculated for soya bean and related commodities using STMR, STMR-P and HR values estimated by the current Meeting. The IESTIs represented 0 to 10% of the ARfD of 0.01 mg/kg bw. 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.

5.18 IMAZAMOX (276)

TOXICOLOGY

Imazamox (BAS 720 H) is the ISO-approved common name for (+)-2-(4-isopropyl-4-methyl-5-oxo-2-imidazolin-2-yl)-5-(methoxymethyl) nicotinic acid (IUPAC) (CAS No. 114311-32-9). Imazamox is an imidazolinone herbicide used pre- or post-emergence of weeds.

Imazamox has not been evaluated previously by JMPR and was reviewed by the present Meeting at the request of CCPR.

All critical studies contained statements of compliance with GLP, unless otherwise specified.

Biochemical aspects

In rats, imazamox was rapidly absorbed, and the oral absorption was approximately 75% of the administered dose. Urine was the major route of excretion (> 74%). Most of the elimination occurred within the first 24 hours after dosing, as unchanged parent compound. Smaller amounts of the test substance were excreted through faeces (> 19%). Only trace amounts of tissue residue were detected. Imazamox appears not to be metabolized. Trace levels of imazamox-related compounds detected in the urine and faeces were attributed to the presence of impurities in the dosing solution, not to rat metabolism.

A comparative in vitro metabolism study was performed in liver microsomes from mice, rats, rabbits, dogs and humans. Under the conditions of the study, no metabolites of imazamox were detected.

Toxicological data

Imazamox was of low toxicity after oral, dermal and inhalation exposure. The oral LD_{50} in rats was greater than 5000 mg/kg bw. The dermal LD_{50} in rats was greater than 4000 mg/kg bw, and the inhalation LC_{50} in rats was greater than 1.6 mg/L. Imazamox was neither a skin irritant nor an eye irritant in rabbits. In a guinea-pig maximization test, no skin sensitization occurred.

In short-term toxicity studies in rats with dietary administration of imazamox over 28 and 90 days, no adverse effects were reported up to the top dose levels, which were at least 1500 mg/kg bw per day. Similarly, in 90-day and 1-year studies, no adverse effects were reported in dogs receiving imazamox in the diet up to the top dose levels, which were at least 1100 mg/kg bw per day. In long-term toxicity and carcinogenicity studies in mice and rats, no signs of systemic toxicity or treatment-related increases in neoplastic lesions were reported up to the highest dose levels tested, which were approximately 1000 mg/kg bw per day.

The Meeting concluded that imazamox is not carcinogenic in mice or rats.

Imazamox was tested for genotoxicity in an adequate range of assays, both in vitro and in vivo. No evidence of genotoxicity was found.

The Meeting concluded that imazamox is unlikely to be genotoxic.

In view of the lack of genotoxicity and the absence of carcinogenicity in mice and rats, the Meeting concluded that imazamox is unlikely to pose a carcinogenic risk to humans.

In a two-generation study in rats, there was no evidence of adverse effects on parental animals, offspring or reproduction up to the highest tested dietary imazamox concentration of 20 000 ppm (equal to 1554 mg/kg bw per day).

In a rat developmental toxicity study that tested imazamox doses of 0, 100, 500 and 1000 mg/kg bw per day, the NOAEL for maternal toxicity was 500 mg/kg bw per day, for reduced

body weight gain and feed consumption at 1000 mg/kg bw per day. The NOAEL for embryo and fetal toxicity was 1000 mg/kg bw per day, the highest dose tested.

In a rabbit developmental toxicity study that tested imazamox doses of 0, 300, 600 and 900 mg/kg bw per day, the NOAEL for maternal toxicity was 300 mg/kg bw per day, for decreased feed intake during the dosing period at 600 mg/kg bw per day, which was of equivocal toxicological relevance. Effects on feed intake were not observed during the first days of dosing. The NOAEL for embryo and fetal toxicity was 300 mg/kg bw per day, based on an increased incidence of both absent intermediate lung lobes and hemivertebrae at 600 mg/kg bw per day.

The Meeting concluded that imazamox is teratogenic in rabbits, but not in rats.

Toxicological data on metabolites and/or degradates

The oral LD_{50}s of metabolites CL 312622 (2-(4-isopropyl-4-methyl-5-oxo-3*H*-imidazol-2-yl)pyridine-3,5-dicarboxylic acid) and CL 263284 (5-(hydroxymethyl)-2-(4-isopropyl-4-methyl-5-oxo-3*H*-imidazol-2-yl)pyridine-3-carboxylic acid) were greater than 5000 mg/kg bw in rats and mice, respectively. CL 312622 was tested for genotoxicity in an adequate range of assays in vitro. No evidence of genotoxicity was observed. CL 263284 was tested for genotoxicity in an adequate range of assays in vitro and in vivo. It gave a positive response in the in vitro micronucleus assay, but was negative in the in vivo micronucleus assay. In a 28-day repeated-dose toxicity study in rats with CL 263284, which tested dietary concentrations of 0, 1200, 4000 and 12 000 ppm (equal to 0, 102, 333 and 1004 mg/kg bw per day for males and 0, 104, 339 and 1028 mg/kg bw per day for females, respectively), the NOAEL was 4000 ppm (equal to 333 mg/kg bw per day), based on lower body weights and significantly lower body weight gains observed in males treated with 12 000 ppm. No effects were observed in females up to the highest tested dietary concentration of 12 000 ppm (equal to 1028 mg/kg bw per day). CL 189215 (2-(4-isopropyl-4-methyl-5-oxo-3*H*-imidazol-2-yl)-5-({[3,4,5-trihydroxy-6-(hydroxymethyl)oxan-2-yl]oxy}methyl)pyridine-3-carboxylic acid) was tested for genotoxicity in a range of assays in vitro, and there was no evidence of genotoxicity.

Human data

No information was provided on the health of workers involved in the manufacture or use of imazamox. No information on accidental or intentional poisoning in humans is available.

The Meeting concluded that the existing database on imazamox was adequate to characterize the potential hazards to fetuses, infants and children.

Toxicological evaluation

The Meeting established an ADI of 0–3 mg/kg bw based on the NOAEL of 300 mg/kg bw per day for reduced feed intake in dams of equivocal toxicological relevance and an increased incidence of both absent intermediate lung lobes and hemivertebrae in the developmental toxicity study in rabbits, using a safety factor of 100.

The Meeting established an ARfD of 3 mg/kg bw based on the NOAEL of 300 mg/kg bw per day for an increased incidence of both absent intermediate lung lobes and hemivertebrae in the developmental toxicity study in rabbits, using a safety factor of 100. Considering the uncertainty as to whether the observed effects on prenatal bone development are also relevant for children's bone growth (bone remodelling), the ARfD is applicable to the whole population.

The plant metabolite CL 263284 is an *O*-demethylation product of imazamox and is a common metabolite with imazapic. Although there is some indication of slightly higher toxicity of this metabolite when compared with imazamox in a 28-day toxicity study in rats, the effects observed were mild changes in body weight gain in males only. Taking into account the close structural similarity to imazamox and the effects and effect levels observed in the developmental toxicity study

in rats with imazamox, the Meeting concluded that CL 263284 is of similar toxicity to imazamox and would be covered by the ADI and ARfD for imazamox.

A toxicological monograph was prepared.

Levels relevant to risk assessment of imazamox

Species	Study	Effect	NOAEL	LOAEL
Mouse	Eighteen-month study of carcinogenicity[a]	Toxicity	7 000 ppm, equal to 1 053 mg/kg bw per day[b]	–
		Carcinogenicity	7 000 ppm, equal to 1 053 mg/kg bw per day[b]	–
Rat	Ninety-day study of toxicity[a]	Toxicity	20 000 ppm, equal to 1 550 mg/kg bw per day[b]	–
	Two-year study of toxicity and carcinogenicity[a]	Toxicity	20 000 ppm, equal to 1 068 mg/kg bw per day[b]	–
		Carcinogenicity	20 000 ppm, equal to 1 068 mg/kg bw per day[b]	–
	Two-generation reproductive toxicity study[a]	Parental toxicity	20 000 ppm, equal to 1 554 mg/kg bw per day[b]	–
		Reproductive toxicity	20 000 ppm, equal to 1 554 mg/kg bw per day[b]	–
		Offspring toxicity	20 000 ppm, equal to 1 554 mg/kg bw per day[b]	–
	Developmental toxicity study[c]	Maternal toxicity	500 mg/kg bw per day	1 000 mg/kg bw per day
		Embryo and fetal toxicity	1 000 mg/kg bw per day[b]	–
Rabbit	Developmental toxicity study[c]	Maternal toxicity	300 mg/kg bw per day	600 mg/kg bw per day
		Embryo and fetal toxicity	300 mg/kg bw per day	600 mg/kg bw per day
Dog	Ninety-day and 1-year studies of toxicity[a,d]	Toxicity	40 000 ppm, equal to 1 333 mg/kg bw per day[b]	–

[a] Dietary administration.
[b] Highest dose tested.
[c] Gavage administration.
[d] Two or more studies combined.

Estimate of acceptable daily intake (ADI)

0–3 mg/kg bw

Estimate of acute reference dose (ARfD)

3 mg/kg bw

Information that would be useful for the continued evaluation of the compound

Results from epidemiological, occupational health and other such observational studies of human exposures

Critical end-points for setting guidance values for exposure to imazamox

Absorption, distribution, excretion and metabolism in mammals	
Rate and extent of oral absorption	Rats: T_{max} = 0.5–1 hour; extensive, ~75%
Dermal absorption	No data
Distribution	Widespread tissue distribution
Potential for accumulation	No evidence of accumulation
Rate and extent of excretion	Excretion mainly via urine within 48 hours
Metabolism in animals	No metabolism
Toxicologically significant compounds in animals and plants	Parent compound
Acute toxicity	
Rat, LD_{50}, oral	> 5 000 mg/kg bw
Rat, LD_{50}, dermal	> 4 000 mg/kg bw
Rat, LC_{50}, inhalation	> 1.6 mg/L
Rabbit, dermal irritation	Not irritating
Rabbit, ocular irritation	Not irritating
Guinea-pig, dermal sensitization	Not sensitizing (maximization test)
Short-term studies of toxicity	
Target/critical effect	No adverse effects
Lowest relevant oral NOAEL	> 1 000 mg/kg bw per day, highest dose tested (rat and dog)
Lowest relevant dermal NOAEL	> 1 000 mg/kg bw per day, highest dose tested (rat)
Lowest relevant inhalation NOAEC	No data
Long-term studies of toxicity and carcinogenicity	
Target/critical effect	No adverse effects
Lowest relevant NOAEL	> ~1000 mg/kg bw per day, highest dose tested (rat and mouse)
Carcinogenicity	Unlikely to pose a carcinogenic risk to humans
Genotoxicity	
	Unlikely to be genotoxic
Reproductive toxicity	
Target/critical effect	No evidence of reproductive toxicity (rat)
Lowest relevant parental NOAEL	1 554 mg/kg bw per day, highest dose tested
Lowest relevant offspring NOAEL	1 554 mg/kg bw per day, highest dose tested
Lowest relevant reproductive NOAEL	1 554 mg/kg bw per day, highest dose tested
Developmental toxicity	
Target/critical effect	Increased incidence of both absent intermediate lung lobes and hemivertebrae at maternally toxic doses (rabbits)
Lowest relevant maternal NOAEL	300 mg/kg bw per day (rabbit)
Lowest relevant embryo/fetal NOAEL	300 mg/kg bw per day (rabbit)

Neurotoxicity	
Acute neurotoxicity NOAEL	No data
Subchronic neurotoxicity NOAEL	No data
Developmental neurotoxicity NOAEL	No data
Toxicological studies on CL 312622 (plant metabolite)	
Rat LD_{50}, oral	> 5 000 mg/kg bw
Genotoxicity	Unlikely to be genotoxic
Toxicological studies on CL 263284 (plant metabolite)	
Mouse LD_{50}, oral	> 5 000 mg/kg bw
Genotoxicity	Unlikely to be genotoxic in vivo
Twenty-eight day, rat	NOAEL: 333 mg/kg bw per day (based on reduced body weight and body weight gain in males)
Toxicological studies on CL 189215 (plant metabolite)	
Genotoxicity	Unlikely to be genotoxic
Medical data	
	No data

Summary

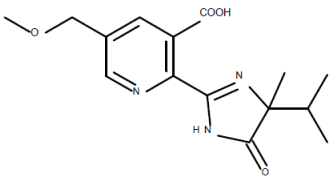
	Value	Study	Safety factor
ADI	0–3 mg/kg bw	Developmental toxicity study (rabbit)	100
ARfD	3 mg/kg bw	Developmental toxicity study (rabbit)	100

RESIDUE AND ANALYTICAL ASPECTS

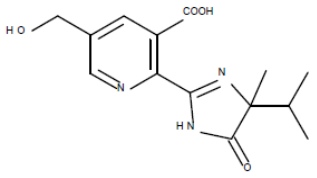
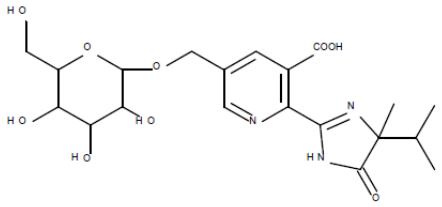
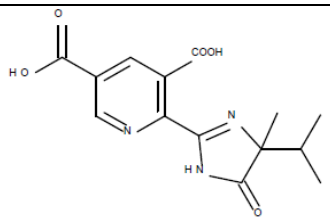
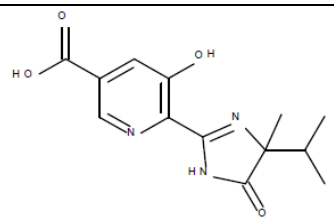
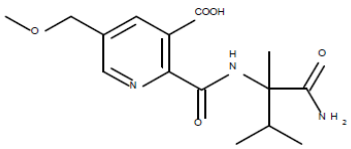
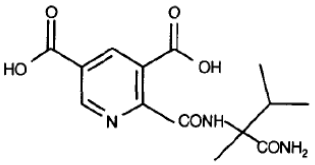
Imazamox is an imidazolinone herbicide registered in many countries to control a wide spectrum of grass and broadleaf weeds. At the Forty-fourth Session of the CCPR (2012)[1], it was scheduled for evaluation as a new compound by the 2014 JMPR.

The Meeting received information on the physical and chemical properties, animal and plant metabolism, environmental fate, analytical methods, storage stability, use patterns, supervised trials and processing studies.

The following abbreviated names were used for the metabolites discussed below.

Code (MW)	IUPAC chemical name	Structure
CL 299263 (305) Imazamox; BAS 720 H	*(RS)*-2-(4-isopropyl-4-methyl-5-oxo-2-imidazolin-2-yl)-5-methoxymethylnicotinic acid	

[1] REP12/PR-Appendix XIII

Code (MW)	IUPAC chemical name	Structure
CL 263284 (291) M715H001	5-(hydroxymethyl)-2-(4-isopropyl-4-methyl-5-oxo-2-imazazolin-2-yl) nicotinic acid	
CL 189215 (453.5) M715H002	5-[(β-glucopyranosyl oxy) methyl]-2-(4-isopropyl-4-methyl-5-oxo-2-imidazolin-2-yl) nicotinic acid	
CL 312622 (305) M720H002	2-(4-isopropyl-4-methyl-5-oxo-2-imidazolin-2-yl)-3,5-pyridine-dicarboxylic acid	
CL 354825 (277)	5-hydroxy-6-(4-isopropyl-4-methyl-5-oxo-2-imidazolin-2-yl)-nicotinic acid	
CL 336554 (323)	2-[(1-carbamoyl-1,2-dimethylpropyl) carbamoyl]-5-(methoxymethyl)-nicotinic acid	
CL 152795	2-[(1-carbamoyl-1,2-dimethylpropyl) carbamoyl]-3,5-pyridinedicarboxylic acid	

Animal metabolism

The Meeting received metabolism studies on imazamox, CL 263284 (hydroxymethyl) and CL 312622 (dicarboxylic acid) orally administered to lactating goats and laying hens.

Imazamox

Lactating goats were orally administered single daily doses of [pyridine-6-^{14}C]-imazamox, via gelatin capsules, for seven consecutive days at either 2.1 or 12 ppm. Kidney, liver, leg and loin muscle, and omental fat samples were collected approximately 20 hours after the last dosing.

In the goat the imazamox was mainly excreted in urine (92% of the low dose and 65% of the high dose) and via faeces (14.8% of the low dose and 24.0% of the high dose). Unaltered parent

accounted for most of the excreted residue. The total radioactive residues in the daily blood and milk samples and tissues (liver, leg, loin, omental fat) were less than 0.01 mg eq./kg regardless of the treatment dose levels. In the kidney, the TRR was 0.02 mg eq./kg at a dose level of 2.1 ppm and 0.06 mg eq./kg at a dose level of 12 ppm. This was mostly imazamox (89% TRR).

CL 263284

A ruminant metabolism study was conducted with [pyridine-6-^{14}C]-CL 263284. Dose levels for the goats, administered orally in gelatin capsules, were either 2.3 or 15 ppm daily for seven days. Samples of blood, milk and excreta were collected daily. After seven days of dosing, the goats were sacrificed (approximately 20 hours after the last dose) and the tissues kidney, liver, muscle and fat were collected.

Elimination of ^{14}C radioactivity via faeces accounted for 82% and 68% of the total cumulative dose at the low dose and high dose, respectively. TRR levels in most tissue samples (muscle, fat, liver) from the low and high dose treated goat and all milk samples were < 0.01 mg eq./kg. The kidney showed a residue of 0.03 mg eq./kg at the 15 ppm dose, which comprised minor component CL 263284 (9% TRR, < 0.01 mg/kg) and very labile component M1(salt or conjugate of CL 263284; 78% TRR, 0.02 mg eq./kg).

CL 312622

Lactating goats were orally treated with a mixture of [pyridine-6-^{14}C, ^{13}C]-CL 312622. The three goats were dosed for five consecutive days with either 3.1 or 33 ppm. Milk, urine and faeces samples were collected daily. Edible tissues (muscle, fat, liver and kidney) were collected at sacrifice (approximately 22 hours after the last dose).

About 90% of the total cumulative dose was excreted via the faeces. TRR levels in all tissues and milk samples were < 0.006 mg eq./kg, except kidney (0.025 mg eq./kg) and liver (0.009 mg eq./kg) of goats treated at the high dose level (33 ppm).

In the kidney sample, CL 312622 was the predominant radioactive residue (60% TRR). The impurity (CL 152795) present in the dosing solution was found at 11% of TRR. Minor polar unknowns (total 10% of TRR) and non-polar unknowns (total 12% of TRR) were also present in the kidney extract, composed with fractions of 0.003 mg eq./kg with multiple components. In the liver, CL 312622 was present at 38% of TRR (impurity, CL 152795, 19% TRR) and polar and nonpolar (31% and 11% TRR, respectively) fractions were equivalent to 0.003 mg eq./kg or lower, containing multiple components.

In summary imazamox and its metabolites (CL 263284 and CL 312622) each was mainly excreted unchanged through urine and faeces in lactating goats. There was no accumulation in any other edible goat tissue or in the milk (< 0.01 mg eq./kg) except kidney. Kidney mostly contained the unchanged administered compound.

Metabolism of imazamox in laying hens

Imazamox

Laying hens were orally dosed with [pyridine-6-^{14}C]-imazamox at a dose level of either 2.1 or 10 ppm for seven consecutive days. Eggs were collected twice daily and blood and the tissues (liver, kidney, muscle, and skin with adhering fat) were collected for analysis approximately 22 hours after the last dose. About 85% of the total dose administered at the low and high dose was in the excreta. Residues in eggs, skin with adhering fat, muscle, liver and kidney tissues were all less than 0.01 mg eq./kg.

CL 263284

A poultry metabolism study was conducted with [pyridine-6-^{14}C]-CL 263284. Hens were dosed orally at a dose level of either 2.1 or 11 ppm by gelatin capsules for seven days. Eggs and excreta were collected daily. The hens were sacrificed and the tissues (liver, kidney, muscle and skin with adhering fat) were collected approximately 22 hours after the last dose. About 87% of the total dose administered at the low and high dose was eliminated via excreta. Residues in all tissues and eggs were less than 0.01 mg eq./kg.

CL 312622

Laying hens were orally treated with a mixture of [pyridine-6-^{13}C]-CL 312622 and [pyrindine-6-^{14}C]-CL 312622. Hens were dosed for five consecutive days with a dose level of either 0.13 or 10.5 ppm. Eggs were collected twice daily and the edible tissues (muscle, liver and skin with adhering fat) were collected at sacrifice approximately 22 hours after the last dose.

About 89% of the total dose administered at the low dose and high dose was eliminated via the excreta. Residues in tissues (liver, muscle and skin with adhering fat) and eggs were all 0.006 mg eq./kg or below. There was no retention or accumulation in eggs or edible poultry tissues.

In summary, in laying hens, imazamox, its metabolites (CL 263284 and CL 312622) were mainly eliminated unchanged through excreta. No residues (< 0.01 mg eq./kg) in eggs or edible tissues were found.

Plant metabolism

The Meeting received information on the fate of imazamox in oilseed rape, soya bean, pea, maize, wheat and alfalfa.

The metabolic fate of imazamox in imidazolinone-tolerant oilseed rape was investigated in one indoor and two outdoor studies. In one of the outdoor studies, a mixture of [pyridine-6-^{14}C]-imazamox and [pyridine-6-^{13}C]-imazamox was post-emergence treated at 0.02 kg ai/ha. Residues in plant at 0 DAT and seed at 82 DAT were 2.1 mg eq./kg and < 0.002 mg eq./kg, respectively (not further identified for component in plant and seed).

In the other two studies (indoor or outdoor), either [pyridine-6-^{14}C]-imazamox or [imidazolinone-5-^{14}C, 3-^{15}N]-imazamox was applied post-emergence at rates of 0.051–0.089 kg ai/ha (outdoor) or 0.075 kg ai/ha (indoor), respectively. TRR in plant at 0 DAT were 2.2–3.9 mg eq./kg. Residues in forage (12–22 DAT) ranged from 0.04 mg eq./kg to 0.89 mg eq./kg. In straw and seed (78–90 DAT), residues were 0.088–1.1 mg eq./kg and 0.004–0.15 mg eq./kg, respectively. The majority of residues (80–99% TRR) in forage and straw samples were extracted with aqueous methanol or acidic aqueous methanol. Extractability in seeds was relatively low, 58–80% TRR.

In both labels, major components of the residues in forage were imazamox (16–42% TRR) and CL 263284 (36–54% TRR). In straw, major components were CL 263284 (44–50% TRR) and CL 312622 (up to 26% TRR); imazamox, < 2% TRR. In rape seed, major components of the residues were CL 263284 (up to 31%) or CL 189215 (up to 21%); imazamox, present at up to 13%.

The metabolic fate of [pyridine-6-^{14}C]-imazamox in soya bean under outdoor field was studied with post-emergence treatment at a rate of 0.39 kg ai/ha. TRR in plant at 0 DAT was 55 mg eq./kg. Residues in forage (29–60 DAT) ranged from 0.13 mg eq./kg to 0.56 mg eq./kg. In straw and seed (153 DAT), residues were 0.08 mg eq./kg and 0.02 mg eq./kg, respectively. The majority of residues in forage (86–97%) were extracted with aqueous methanol and dichloromethane. Acidic and/or basic digestion for straw and seed samples extracted up to 53% and 57% of residues, respectively.

A major component of the residue in soya bean forage (29–60 DAT) was CL 189215 (32–36% TRR); imazamox, CL 263284 and CL 312622 each, present at 6–11% TRR. In soya bean seed, CL 263284 was a major component, representing 12% TRR.

Field peas were treated post-emergent, under outdoor growing conditions, with [pyridine-6-^{14}C]-imazamox at a rate of 0.040 kg ai/ha. TRRs in whole plant at 0 DAT and 20 DAT were 1.1 mg eq./kg and 0.035 mg eq./kg, respectively. At 61 DAT, residues in all of the samples (pea foliage, immature peas, pea shells and pea pods) were < 0.01 mg eq./kg. In pea and pea hay (84 DAT), residues were 0.01 mg eq./kg and 0.05 mg eq./kg, respectively. The aqueous methanol extracted 61–99% of the TRR in whole plant. From the hay and peas, 58% and 39% of the TRR was extracted, respectively.

In pea hay, imazamox was present at 0.02 mg eq./kg (66% TRR) and other components (CL 263284, CL 189215) were negligible (≤ 0.01 mg eq./kg).

Alfalfa was treated, post-emergent, in plots at different ages of crop and timing of application under outdoor conditions with [pyridine-6-^{14}C]-imazamox at a rate of 0.13 kg ai/ha. TRR in alfalfa plants at 0 DAT was 6.5–15 mg eq./kg. Residues in forage (26 DAT) ranged from 0.18 mg eq./kg to 0.67 mg eq./kg. Residues in forage (1st, 2nd, 3rd cut at 26–111 DAT) and hay (1st, 2nd, 3rd cut at 28–160 DAT) were < 0.01–0.21 mg eq./kg and 0.02–0.83 mg eq./kg, respectively. The majority (65–99% TRR) of residues in forage and hay were extracted with a solvent mixture of methanol/acetone/water.

Residue components in alfalfa forage (26 DAT) were: imazamox, 3–6% TRR and CL 263284, CL 189215 and CL 312622, 14–26% TRR. For forage and hay samples, 1st, 2nd, 3rd cut, composition of the compounds were similar to those in forage at 26 DAT.

The metabolic fate of imazamox on imidazolinone-tolerant maize was investigated in two outdoor studies. Radiolabelled imazamox, either [pyridine-6-^{14}C]-imazamox or a mixture of [pyridine-6-^{14}C]-imazamox and [pyridine-6-^{13}C]-imazamox was post- or pre-emergence (one day after seedling) treated at rates of 0.13–0.14 kg ai/ha. Residues in forage (14, 30 and 62 DAT) ranged from 0.011 mg eq./kg to 0.41 mg eq./kg. In fodder and grain (100–112 DAT), TRRs were 0.012–0.047 mg eq./kg and 0.010–0.01 mg eq./kg, respectively. 40–98% of the TRR in maize samples were extracted with aqueous methanol (40% TRR in fodder).

Major components of the residues in maize forage were imazamox (18–31% TRR) and CL 263284, (12–23% TRR). In fodder, CL 263284 was present at 15% TRR, < 1–7% TRR in the other components. In grain, major components were CL 263284 (20% TRR) and CL 189215 (15% TRR) with imazamox at low level, < 5% TRR.

The metabolic fate of imazamox on imidazolinone-tolerant spring wheat was investigated under indoor and outdoor conditions. Radiolabelled imazamox, [pyridine-6-^{14}C]-imazamox or [imidazolinone-5-^{14}C, 3-^{15}N]-imazamox was post-emergence applied at rates of 0.14 or 0.76 kg ai/ha. Residues in forage (8–28 DAT) ranged from 0.10 mg eq./kg to 1.6 mg eq./kg. In straw and grain (62–70 DAT), residues were ranged in 0.16–3.2 mg eq./kg and 0.067–1.4 mg eq./kg, respectively. The 53–93% TRR in all wheat samples was extracted with methanol and water or acidic aqueous methanol (53% in straw).

Major components of the residues in spring wheat forage were imazamox (42–67% TRR) and CL 263284 (10–18% TRR). In straw, CL 263284 was most abundant (13–38% TRR). The other components, imazamox (8–10% TRR), CL 189215 (3–15% TRR) and CL 312622 (6–17% TRR) were found at lower levels. In wheat grain, imazamox was most abundant component (40–70% TRR, 0.027–1.1 mg eq./kg); CL 263284 (7–10% TRR) and CL 189215 (3–4% TRR) were present at relatively low levels and CL 312622 was not detected.

The key step of the metabolism of imazamox in plant was the cleavage of the methyl ether group (demethylation) resulting in metabolite CL 263284. Subsequently, oxidation of the hydroxyl group of CL 263284 generated the dicarboxylic acid metabolite CL 312622, while glycosylation led to the glucose conjugate CL 189215.

In conclusion, in the edible portions of most treated food crops harvested at maturity, no or a very small residue of imazamox or its metabolites are expected to be found. However, for certain crops such as wheat, it is considered that the residues may be detected in wheat grain. In animal feed crops, imazamox, CL 263284, CL 189215 and CL 312622 are expected to be found above the LOQ.

Environmental fate

The Meeting received information on aerobic soil metabolism, photodegradation on the soil surface, hydrolysis and residues in succeeding crops.

Aerobic soil metabolism

Imazamox applied in sandy loam soil degraded rapidly. In three studies, half-life of imazamox was 28–38 days in sandy loam soil treated with imazamox at 0.050–0.10 kg ai/ha. However, in another study, half-life of imazamox treated in combinations of soil type (silty clay loam and silt loam) and temperature (10 °C and 20 °C) was in a range of 12–207 days (DT_{90}, 39–687 days). Imazamox was shown to be moderately persistent in aerobic soil. In all the studies, dicarboxylic acid (CL 312622) and hydroxy acid (CL 354825) metabolites were the major residue components. The parent and both metabolites were ultimately mineralized to CO_2.

Residues in succeeding crops

In a confined rotational crop study, [pyridine-6-^{14}C]-imazamox was applied once to soya beans at the 4–6 leaf stage, in a sandy loam soil, at a rate of 0.072 kg ai/ha. One-hundred days after treatment, the soya bean crop was harvested. On the day of harvest, winter wheat was seeded into a subplot (100-day plant-back interval; PBI) of the treated field. Maize, radish, and lettuce were seeded into separate subplots at a 268-day PBI. Total radioactive residues were < 0.01 mg eq./kg in all rotational crops.

In another study, radiolabelled imazamox, either [imidazolinone-5-^{14}C, 3-^{15}N]-imazamox or [pyridine-3-^{14}C, imidazolinone-3-^{15}N]-imazamox were applied to bare sandy loam soil in plastic container followed by sowing spinach, white radish and spring wheat at PBIs of 1 month, 4 month and 1 year.

In spinach and white radish, residues were < 0.01 mg eq./kg at any PBIs. However, in spring wheat samples (forage, hay, straw, grain), total residues (TRR) were: 0.008–0.078 mg eq./kg at one month PBI (grain, 0.032–0.053 mg eq./kg), 0.004–0.132 mg eq./kg at four month PBI (grain 0.019–0.035 mg eq./kg) and < 0.001–0.052 mg eq./kg at one year PBI (grain, 0.002–0.004 mg eq./kg). In wheat grain at one month PBI, residues of imazamox and CL 263284 were 0.001–0.005 mg eq./kg.

In conclusion, residues of imazamox and the metabolites are expected to be less than 0.01 mg eq./kg in succeeding crops.

Photodegradation

Soil photolysis of [pyridine-6-^{14}C]-imazamox was studied in a sandy loam soil, surface treated at a rate equivalent to 0.10 kg ai/ha and exposed for 30 days to artificial sunlight. The 92% imazamox at time-0 decreased to 74% imazamox at the end of the 30 days irradiation. A half-life of imazamox was calculated to be 65 days. A degradate, dicarboxylic acid CL 312622 (2% TAR in dark control), was formed at about 14% of the total residues after 30 days irradiation.

Imazamox is photodegraded with a half-life of 65 days on the surface of soil. Any degradate specific for photolysis was not found.

Hydrolysis

Imazamox is used for rice production. In the hydrolysis study under different pH conditions, imazamox was stable at pH 4, pH 7 and pH 9.

Methods of analysis

The Meeting received description and validation data for analytical methods for residue analysis of imazamox and its metabolites in various plant and animal commodities.

In general, the methods involved extraction of residues with acidic methanol-water solution, clean-up procedure by mainly solvent partitioning and solid phase extraction, and determination by HPLC-UV or LC-MS/MS. In the case of milk and fat, acetonitrile in hexane is used for the extraction step. Some methods employ capillary electrophoresis-UV or GC-NPD, in case of use of GC-NPD, where combined determination for imazamox-related residues is possible by converting to a common methylated product.

A number of specific methods for plant matrices were found suitable for analysis of imazamox, CL 263284, CL 189215 and CL 312622 with LOQ ranging 0.01–0.05 mg/kg for these analytes except that it was 0.1 mg/kg for alfalfa.

For animal matrices, one method determined by LC-MS/MS was submitted and found suitable for analysis of imazamox and CL 263284 with LOQs of 0.01 mg/kg for bovine matrices and poultry egg.

No multi-residue methods were submitted.

Stability of residues in stored analytical samples

The stability of imazamox and its metabolites during frozen storage of samples was investigated in a range of plant matrices for which supervised residue trials were submitted.

Compounds tested were imazamox, CL 263284, CL 189215 and CL 312622. Each compound was spiked to matrices at 0.1 to 1 mg/kg.

All of the compounds tested were found to be stable (> 70% remaining) at least during the storage periods tested: for imazamox, 3.6 years in soya bean (seed, forage and hay), 4 years in wheat (grain, straw, forage and hay), 2 years in maize (grain, ear and immature plant), 1.5 years in rape seed and 1.5 years in alfalfa (hay, forage and seed); for CL 263284, 3.6 years in soya bean (seed, forage and hay), 10 months in processed soya bean products, 4 years in wheat (grain, straw, forage and hay), 2 years in maize (grain, ear and immature plant) and peanut (hull and nutmeat) and 1.5 years in alfalfa (hay, forage and seed); for CL 189215, 10 months in soya bean seed and processed soya bean products, 2 years in peanut (hull and nutmeat) and 1.5 years in alfalfa (hay, forage and seed); and for CL 312622, 1.5 years in alfalfa (hay, forage and seed).

Definition of the residue

In metabolism studies of imazamox and the metabolites (CL 263284, CL 312622) in goats and hens, the compounds were mostly excreted (85–106%) unchanged through urine and faeces. In hen, no detectable residues were found in eggs or edible tissue. In goat, there were no detectable residues in milk and tissues except kidney. Residue in the kidney was predominantly the administered parent. Therefore, no residues of imazamox and related compounds are expected in livestock tissues, milk or eggs at expected livestock dietary burdens of less than 3 ppm.

The log P_{ow} for imazamox is 0.73 suggesting imazamox residues are not fat soluble.

In confined crop rotation studies, any imazamox related residues in succeeding crops were not detected above more than 0.01 mg/kg.

In primary crops, imazamox is either not found or found at very low levels (< 30% TRR, < 0.01 mg eq./kg) in non-tolerant food commodities and imidazolinone-tolerant food commodities (tolerant rape seeds, soya bean seeds, pea seeds, alfalfa, tolerant maize seeds). Imidazolinone-tolerant wheat grain, is the only food commodity, where parent is found at significant levels (40–74% TRR, 0.027–1.1 mg eq./kg). Among the metabolites found, CL 263284 is the most predominant metabolite, although present at low levels in food commodities (up to 31% TRR, maximum 0.092 mg eq./kg). In supervised trials imazamox and CL 263284 are found at levels above the LOQ in food commodities (lentil seeds, sunflower seeds). In feed commodities (tolerant rape forage or straw, soya forage or straw, pea forage or hay, alfalfa forage or hay, tolerant maize forage or fodder, wheat forage, hay or straw), imazamox (1.5–67% TRR, < 0.01–5.0 mg eq./kg) and CL 263284 are more prominent (8–54% TRR, < 0.01–1.9 mg eq./kg).

Parent and CL 263284 are the only two compounds expected to be found in food commodities. Metabolite CL 263284 can also arise in plant commodities as a result of treatment with imazapic, another imidazolinone herbicide. Since CL 263284 cannot be seen as a marker for imazamox, the Meeting decided to define the residue for enforcement/monitoring as parent only.

Parent and CL 263284 are considered relevant for dietary risk assessment as the toxicity of CL 263284 is similar to that of imazamox in rat. Therefore, the Meeting decided to define the residue for dietary risk assessment as the sum of parent and CL 263284, expressed as imazamox.

The Meeting agreed the following residue definitions:

Definition of the residue for plant and animal commodities for compliance with the MRL: *imazamox.*

Definition of the residue for plant and animal commodities for the estimation of dietary intake: *sum of imazamox and 5-(hydroxymethyl)-2-(4-isopropyl-4-methyl-5-oxo-2-imazazolin-2-yl) nicotinic acid (CL 263284), expressed as imazamox.*

Residue is not fat-soluble.

Should imazamox be used on crops other than cereals, pulses and oilseeds, the residue definition may need to be revised.

Results of supervised residue trials on crops

The Meeting received supervised trial data for imazamox on legume vegetables (beans and peas), pulses (bean, pea, lentil and soya bean), cereals (rice and wheat), oil seed crops (peanut, rape and sunflower) and alfalfa.

In below, a maximum residue level was estimated based on residue concentration of imazamox. Total residue means sum of parent compound and CL 263284. Concentration of CL 263284 was expressed as parent equivalents (conversion factor, 1.048).

Legume vegetables

Beans

Residue trials on beans were performed in Denmark, Germany, France, the UK, Greece, Italy, Spain and the USA. The GAP for beans in Chile is a single early post-emergent application at 0.056 kg ai/ha with no PHI specified.

In six trials on French beans conducted in Italy (1 × 0.050 kg ai/ha at post-emergence) matching the Chile GAP, residues in bean pods with seeds were: parent < 0.05 (6) mg/kg and metabolite < 0.05 (6) mg/kg. Total residues in the bean pods with seeds were (n=6): < 0.1 (6) mg/kg.

In other six trials from USA (1 × 0.050 kg ai/ha at post-emergence) matching the Chile GAP, residue concentrations of imazamox (only measured) were < 0.05 (6) mg/kg in pods with seeds of snap beans.

Three trials conducted in France, the UK and Italy involved an earlier application timing and a higher rate (1 × 0.075 kg ai/ha at pre-emergence). Residues in pods with seeds of common bean (flageolet bean) were: parent < 0.01 (3) mg/kg, metabolite < 0.01 (3) mg/kg. Total residues in the bean pods with seeds were < 0.02 (3) mg/kg.

The Meeting considered that there was no expectation of residues above LOQ in bean pods with seeds. The Meeting estimated a maximum residue level of 0.05* mg/kg and an STMR of 0 mg/kg for beans, except broad bean and soya bean (green pods and immature seeds).

Peas

Residue trials on peas were performed in Italy, France, Spain, the UK, Germany and the USA. The GAP for peas in France is for a single pre-emergent application post sowing per every 2 years, treating on soil at 0.075 kg ai/ha with a PHI of 63 days.

In nine trials conducted in Italy and France approximating the French GAP (1 × 0.068–0.075 kg ai/ha at pre-emergence, 70–110 day PHI), residues in pea seeds were: parent < 0.05 (9) mg/kg and metabolite < 0.05 (9) mg/kg. Total residues in pea seeds were (n=9): < 0.1 (9) mg/kg.

Another ten trials were conducted in Italy and Spain with post-emergence treatments at 0.050–0.052 kg ai/ha in eight trials and 0.073–0.075 kg ai/ha in two trials. The total residues were all < 0.1 (10) mg/kg.

The Meeting estimated a maximum residue level of 0.05* mg/kg and an STMR of 0 mg/kg for peas, shelled (succulent seeds).

Pulses

Bean (dry)

Residue trials on dry beans were performed in France, Germany, Netherlands, the UK, Italy, Greece, Spain and the USA. The GAP for dry bean in the UK is a single pre-emergence application to soil at a rate of 0.075 kg ai/ha.

In four trials from France, the UK and Italy (1 × 0.075 kg ai/ha at pre-emergence, 91–108 day PHIs), approximating the UK GAP, residues in common bean seeds were: parent < 0.01 (4) mg/kg and metabolite < 0.01 (4) mg/kg. Total residues in seed of common beans were < 0.02 (4) mg/kg. In these trials, the total residues in whole plants harvested early (PHIs of 32–48 days) were < 0.02 mg/kg.

In two trials from the USA applied at a post-emergence timing and at a rate comparable to the UK GAP (1 × 0.070 kg ai/ha, 61–98 day PHIs), residue concentrations of the parent compound were also below LOQ, < 0.05 (2) mg/kg.

Pea (dry)

The GAP for dry peas in France is a single pre- or post-emergence application every 2 years at a rate of 0.075 kg ai/ha with a PHI of 63 days. A total of ten trials were conducted in France at the GAP rate (1 × 0.075 kg ai/ha at pre-emergence) but with longer PHIs (106–129 days). The residues measured for each compound or combined total residue were: parent < 0.05 (5) mg/kg, metabolite < 0.05 (5) mg/kg and total residue < 0.1(10) mg/kg.

Lentil (dry)

Residue trials for lentil were available from Canada and the USA. In Canada, imazamox is approved for use in imidazolinone-tolerant lentils with a single early post-emergent application at a rate of 0.020 kg ai/ha (plus adjuvant) with a PHI of 60 days.

In a total of fourteen trials (1 × 0.015–0.021 kg ai/ha at post- or early post-emergent timings and a 60 day, or shorter, PHI (without use of an adjuvant), residues in imidazolinone-tolerant lentils were: imazamox < 0.05 (9), 0.056, 0.060, 0.065, 0.12, 0.12 mg/kg and metabolite < 0.05 (14) mg/kg. Total residues were: < 0.1 (9), 0.11 (3), 0.17, 0.17 mg/kg.

Soya bean (dry)

Residue trials on soya bean were performed in France, Germany, Italy and Canada. The GAP for soya bean in Brazil is for a single post-emergence application at a rate of 0.049 kg ai/ha (plus adjuvant) with a PHI of 70 days.

In nine trials conducted in France, Germany and Italy (1 × 0.042–0.045 kg ai/ha at post- or early post-emergence, 69–104 days of PHI, with or without adjuvant) approximating the Brazilian GAP, residues in soya bean seeds were: imazamox < 0.01 (7) mg/kg and metabolite < 0.01 (7) mg/kg. Total residues were < 0.02 (7) mg/kg. Of which five trials showed no effect of adjuvant on the level of residue in dry seed.

In two trials conducted in Canada at an exaggerated rate of 0.070–0.071 kg ai/ha (single post-emergence application, 106–112 day PHIs), total residues were all < 0.05 (2) mg/kg.

The Meeting estimated a maximum residue level of 0.05* mg/kg and an STMR of 0 mg/kg for bean and pea in dry, respectively.

For lentil (dry), the Meeting estimated a maximum residue level of 0.2 mg/kg and an STMR of 0.1 mg/kg.

For soya bean (dry), the Meeting estimated a maximum residue level of 0.01* mg/kg and an STMR of 0 mg/kg.

Cereals

Rice

Residue trials on imidazolinone-tolerant rice were performed in Italy and Spain. The use pattern in Spain is twice post-emergence treatment at a rate of 0.035 kg ai/ha with an interval of 14–21 days and no PHI, applying on imidazolinone-tolerant rice plant in water or dry planted.

In a total of six trials on imidazolinone-tolerant rice (2 × 0.035–0.038 kg ai/ha at BBCH 13–14 and BBCH 25–31, 10–12 day interval) from Italy and Spain matching the Spain GAP, residues in rice grain were: imazamox < 0.01 (6) mg/kg and metabolite < 0.01 (3), 0.02, 0.03 (2) mg/kg. Total residues were: < 0.02 (3), 0.030, 0.040 (2) mg/kg.

The Meeting estimated a maximum residue level of 0.01* mg/kg and an STMR of 0.025 mg/kg for rice.

Wheat

Residue trials on imidazolinone-tolerant wheat were performed in France, Italy, Canada and the USA. The GAP for wheat (imidazolinone-tolerant) in Argentina is a single early post-emergence application at 0.070 kg ai/ha with no PHI.

In a total of twelve trials from France (eight trials), Italy (four trials) and USA (one trial) (1 × 0.067–0.075 kg ai/ha at post-emergence) matching the GAP, residues in imidazolinone-tolerant wheat grain were: imazamox < 0.05 (13) mg/kg and metabolite < 0.05 (13) mg/kg. Total residues were < 0.1 (13) mg/kg.

The Meeting considered that there is no expectation of residues above the LOQ for wheat grain and agreed to estimate a maximum level of 0.05* mg/kg and an STMR of 0.1 mg/kg for wheat.

Oilseeds

Peanuts

Five trials were conducted in Brazil with a single post-emergence application (BBCH 71–79) at a rate of 0.056 kg ai/ha with a PHI of 43–50 days without use of an adjuvant, matching the GAP for peanut in South Africa (1 × 0.048 kg ai/ha plus adjuvant) at post-emergence with a PHI 50 days. The residues in peanut kernels were: imazamox < 0.01 (5) mg/kg and metabolite < 0.01 (5) mg/kg. Total residues were < 0.02 (5) mg/kg.

Although only a relatively small number of trials were available, there is no expectation of residues above the LOQ in peanuts. The Meeting estimated a maximum residue level of 0.01* mg/kg and an STMR of 0 mg/kg.

Rape seed

Residue trials on imidazolinone-tolerant oilseed rape were conducted in France, Germany, the UK and Canada and Argentina. The GAP for imidazolinone-tolerant rape in Chile is a single early post-emergence application at a rate of 0.056 kg ai/ha with no PHI. In six trials from Germany, France and Argentina (1 × 0.050 kg ai/ha at post-emergence) matching the Chile GAP, residues in rape seed (imidazolinone-tolerant variety) were: imazamox < 0.01 (2), < 0.05 (4) mg/kg and metabolite < 0.01 (2), < 0.05 (4) mg/kg. Total residues were < 0.02 (2), < 0.1 (4) mg/kg.

In another eighteen trials from France, Germany and the UK, an exaggerated rate of 0.073–0.079 kg ai/ha did not lead to above LOQ (< 0.05 mg/kg) for total residues in seeds of imidazolinone-tolerant oilseed rape.

The Meeting considered that there is no expectation of residues above the LOQ in rape seeds.

The Meeting estimated a maximum residue level of 0.05* mg/kg, an STMR of 0 mg/kg for rape seed.

Sunflower seed

Residue trials on imidazolinone-tolerant sunflower were conducted in France, Germany, UK, Italy, Spain, Argentina, Canada and USA. In Canada, critical GAP for sunflower (imidazolinone-tolerant) is a single early post-emergence application at a rate of 0.015 kg ai/ha with a specified PHI of 60 days and an addition of adjuvant.

A total of six trials conducted in Canada and USA (1 × 0.015–0.019 kg ai/ha at PHIs of 58–68 days with or without adjuvant) approximated the Canadian GAP. The residues in seeds of imidazolinone-tolerant sunflower were: imazamox < 0.05 (2), 0.05 (2), 0.07, 0.14 mg/kg and metabolite < 0.05, 0.06, 0.10, 0.16, 0.17, 0.19 mg/kg. Total residues were: < 0.1, 0.13, 0.15, 0.22, 0.25, 0.30 mg/kg.

The Meeting estimated a maximum residue level of 0.3 mg/kg and an STMR of 0.19 mg/kg for sunflower seed.

Legume animal feeds

Alfalfa

Residue trials on alfalfa were performed in Greece, Spain and USA. The GAP for alfalfa in France is a single post-emergence application at a rate of 0.067 kg ai/ha with a PHI of 30 days.

In a total of seven trials from Greece, Spain and USA (1 × 0.067–0.075 kg ai/ha at PHIs of 26–30 days) matching the French GAP, residues in alfalfa forage were as received basis: imazamox < 0.1 (7) mg/kg and metabolite < 0.1 (7) mg/kg. Total residues in alfalfa forage were < 0.2 (7) mg/kg. For alfalfa hay, residues were as received basis: imazamox < 0.1 (5) mg/kg and metabolite < 0.1 (3), 0.19, 0.29 mg/kg. Total residues were < 0.2 (3), 0.32, 0.41 mg/kg in hay.

The Meeting estimated a median residue of 0 mg/kg and a highest residue of 0.2 mg/kg for alfalfa forage.

For alfalfa hay, the Meeting estimated a maximum residue level of 0.1* mg/kg, a median residue of 0.20 mg/kg and a highest residue of 0.41 mg/kg.

Pea vines (green) and pea fodder

Five trials approximating the French GAP for pea (single pre-emergence post-sowing per every 2 years at 0.075 kg ai/ha) were conducted in France with PHIs of 88–110 days. Residues in pea vines, (pods + haulm) on an as received basis, were: imazamox < 0.05 (5) mg/kg and metabolite < 0.05 (5) mg/kg. Total residues in pea vines were < 0.1 mg/kg.

Ten trials approximating the French GAP for field pea (single pre- or post-emergence application per every 2 years at a rate of 0.075 kg ai/ha) were conducted in France with PHIs of 106–120 days. Residues in pea fodder (straw or pods + haulm) on an as received basis, were: imazamox < 0.05 (5) mg/kg and metabolite < 0.05 (4), 0.17 mg/kg. Total residues were < 0.05 (5), < 0.1(4) and 0.22 mg/kg.

The Meeting estimated a median residue of 0.1 mg/kg and a highest residue of 0.1 mg/kg for pea vines. For pea fodder, the Meeting estimated a maximum residue level of 0.05* mg/kg, a median reside of 0.075 mg/kg and a highest residue of 0.22 mg/kg.

Soya bean, forage and fodder

Four trials were conducted in France and Germany approximating the Brazil GAP for soya bean (1 × 0.049 kg ai/ha). Residues in soya bean forage harvested at 27–28 PHIs were as received basis: imazamox < 0.01 (4) mg/kg and metabolite < 0.01 (4) mg/kg. Total residues were < 0.02 (4) mg/kg. For fodder, residues were as received basis: imazamox < 0.01 (4) mg/kg and metabolite < 0.01 (2), 0.01, 0.05 mg/kg. Totals residues were < 0.02 (2), 0.02, 0.06 mg/kg in soya bean fodder.

For soya bean forage, the Meeting estimated a median residue of 0.02 mg/kg and a highest residue of 0.02 mg/kg.

For soya bean fodder, the Meeting estimated a maximum residue level of 0.01* mg/kg, a median residue of 0.02 mg/kg and a highest residue of 0.06 mg/kg.

Forage and fodder of cereal grains and grasses

Rice straw and fodder

In six trials conducted in Italy and Spain matching the Spain GAP (post-emergence treatment on imidazolinone-tolerant rice plant, water or dry planted, 2× 0.035 kg ai/ha, 14–21 day interval), residues in imidazolinone-tolerant rice straw (77–90 day PHIs) were as received basis: imazamox

< 0.01 (6); metabolite < 0.01 (3), 0.01, 0.02 (2) mg/kg. Total residues were < 0.02 (3), 0.02, 0.03 (2) mg/kg in straw.

The Meeting estimated a maximum residue level of 0.01* mg/kg, a median residue of 0.02 mg/kg and a highest residue of 0.03 mg/kg in rice straw.

Wheat forage and straw

Trials on imidazolinone-tolerant wheat were conducted in Canada approximating the GAP for imidazolinone-tolerant wheat in Canada (single early post-emergence application at 0.020 kg ai/ha). In Canada, grazing and cutting for hay are not permitted within 4 days and 42 days of application, respectively. Five trials for forage (7, 14 day PHIs) and four trials (42, 56 day PHIs) for hay and five trials (72–90 PHIs) for straw matched the Canadian GAP on feedstuffs.

Residues in imidazolinone-tolerant wheat forage were as received basis: imazamox < 0.05 (2), 0.05, 0.13, 0.15 mg/kg; metabolite < 0.05 (5) mg/kg. Total residues were < 0.1 (2), 0.10, 0.20, 0.23 mg/kg.

Residues in imidazolinone-tolerant wheat hay were as received basis: imazamox < 0.05 (4) mg/kg; metabolite < 0.05 (4) mg/kg. Total residues were < 0.1 (4) mg/kg.

Residues in imidazolinone-tolerant wheat straw were as received basis: imazamox < 0.05 (5) mg/kg; metabolite < 0.05 (5) mg/kg. Total residues were < 0.1 (5) mg/kg.

For wheat forage, the Meeting estimated a median residue of 0.1 mg/kg and a highest residue of 0.23 mg/kg.

For wheat hay and straw, the Meeting estimated a maximum residue level of 0.05* mg/kg, a median residue of 0 mg/kg and a highest residue of 0.1 mg/kg.

Miscellaneous Fodder and Forage crops

Rape seed forage

In four residue trials on imidazolinone-tolerant oilseed rape conducted in France and Germany, matching the GAP of Chile for oilseed rape (imidazolinone-tolerant rape, a single early post-emergence application, 0.056 kg ai/ha), residues in whole plants without roots (12–19 day PHIs) on an as received basis were: imazamox, 0.05, 0.12, 0.14 0.19mg/kg; metabolite 0.52, < 0.05, 0.21, 0.28 mg/kg. Total residues were: 0.10, 0.33, 0.42 and 0.71, mg/kg.

The Meeting estimated a median residue of 0.38 mg/kg and a highest residue of 0.71 mg/kg for rape forage.

Fate of residues during processing

High temperature hydrolysis

The hydrolysis of [pyridine-3-^{14}C, imidazolinone-3-^{15}N]-imazamox was investigated in aqueous buffer solutions. After pasteurization (20 minutes at 90 °C, pH 4), baking/brewing/boiling (60 minutes at 100 °C, pH 5) and sterilization (20 minutes at 120 °C, pH 6), 98–104% of the applied radioactivity remained in the test solutions, where the detectable radioactive component was unchanged imazamox only. Imazamox was stable under such simulated processing conditions.

Processing

Information on processing of wheat and sunflower seed were available for an estimation of maximum residue level and STMR-P for the processed product. Estimated processing factors, maximum residue

levels and STMR-Ps are summarized below. A maximum residue level and STMR-P value for processed product were calculated with imazamox residue and STMR value (total residue of imazamox and CL 263284), respectively.

RAC and processed product	RAC		Pf, best estimate (individual Pf)		Processed product	
	Estimated maximum residue level (mg imazamox/kg)	STMR (mg total/kg)	Imazamox	Total residue	Estimated maximum residue level (mg imazamox/kg)	STMR-P total residue (mg total/kg)
Wheat	0.05*	0.1				
Wheat germ			2.7	2.2	0.1	0.22
Wheat bran, unprocessed			3.9	3.4	0.2	0.34
Wheat flour			1.2	1.2	0.06	0.12
Wheat asp. grain fraction			1.0	1.0		0.10
Wheat by products (middling, shorts)			2.4 (1.6, 3.2)	2.1 (1.5, 2.6)		0.21
Sunflower seed	0.3	0.19				
Sunflower seed meal			2.3	2.5 (1.9, 3.0)		0.48
Sunflower refined oil				< 0.5 (< 0.2, < 0.5)		0.095

The Meeting estimated maximum residue levels of 0.1 mg/kg for wheat germ and 0.2 mg/kg for wheat bran, unprocessed.

Residues in animal commodities

Farm animal feeding studies

Information on farm animal feeding studies was not submitted.

Estimation of dietary burdens

Dietary burden calculations for beef cattle and dairy cattle and poultry are provided below. The dietary burdens were estimated using the OECD diets listed in Appendix IX of the 2009 edition of the FAO Manual.

Summary of livestock dietary burden (ppm of dry matter diet)

	US-Canada		EU		Australia		Japan	
	max	mean	max	mean	max	mean	max	mean
Beef cattle	0.230	0.178	0.821	0.463	2.37[a]	1.27[c]	0.217	0.193
Dairy cattle	0.670	0.404	0.0.749	0.0433	1.50[b]	0.765[d]	0.256	0.197
Poultry broiler	0.278	0.278	0.179	0.179	0.200	0.200	0.052	0.023
Poultry layer	0.278	0.278	0.75[e]	0.478[f]	0.188	0.188	0.072	0.072

[a] Highest maximum beef cattle dietary burden suitable for MRL estimates for mammalian meat
[b] Highest maximum dairy cattle dietary burden suitable for MRL estimates for milk
[c] Highest mean beef cattle dietary burden suitable for STMR estimates for mammalian meat
[d] Highest mean dairy cattle dietary burden suitable for STMR estimates for milk
[e] Highest maximum poultry dietary burden suitable for MRL estimates for poultry meat and eggs.
[f] Highest mean poultry dietary burden suitable for STMR estimates for poultry meat and eggs

Animal commodity maximum residue levels

Maximum estimated dietary burdens for beef cattle and dairy cattle were 1.4 and 1.1 ppm, respectively. These dietary burdens were similar to the dose rates in the metabolism studies in lactating goats (< 0.01 mg eq./kg at 2.1 ppm for imazamox; < 0.01 mg eq./kg at 2.3 ppm for CL 263284). As no residues in cattle meat and milk are expected, the Meeting estimated a maximum residue level of 0.01* mg/kg and HR and STMR of 0 in each animal commodity: milk, meat (mammalian except marine mammals) and edible offal and fat.

In poultry, the maximum dietary burden, 0.75 ppm was 3 times lower than dose rates in metabolism studies in laying hens (< 0.01 mg eq./kg at 2.1 ppm for imazamox and CL 263284 each). The Meeting estimated a maximum residue level of 0.01* mg/kg and HR and STMR of 0 for poultry meat, poultry edible offal, poultry fat and eggs.

RECOMMENDATIONS

On the basis of the data from supervised trials the Meeting concluded that the residue levels listed below are suitable for establishing maximum residue limits and for IEDI and IESTI assessment.

Definition of the residue for plant and animal commodities for compliance with the MRL: *imazamox*

Definition of the residue for plant and animal commodities for estimation of dietary intake: *sum of imazamox and 5-(hydroxymethyl)-2-(4-isopropyl-4-methyl-5-oxo-2-imazazolin-2-yl) nicotinic acid (CL 263284), expressed as imazamox*

Residue is not fat soluble.

DIETARY RISK ASSESSMENT

Long-term intake

The ADI for imazamox is 0–3 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for imazamox were estimated for the 17 GEMS/Food Consumption Cluster Diets using the STMR or STMR-P values estimated by the present JMPR. The results are shown in Annex 3 of the 2014 JMPR Report. The IEDIs were 0% of the maximum ADI. The Meeting concluded that the long-term intake of residues of imazamox from uses considered by the JMPR is unlikely to present a public health concern.

Short-term intake

The ARfD for imazamox is 3 mg/kg bw. The International Estimate of Short Term Intakes (IESTIs) for imazamox were calculated for the food commodities for which STMRs or HRs were estimated by the present Meeting and for which consumption data were available. The results are shown in Annex 4. The IESTIs were 0% of the ARfD for children and the general population.

The Meeting concluded that the short-term intake of residues of imazamox from uses considered by the present Meeting are unlikely to present a public health concern.

5.19 MESOTRIONE (277)

TOXICOLOGY

Mesotrione is the ISO-approved common name for 2-(4-mesyl-2-nitrobenzoyl)cyclohexane-1,3-dione (IUPAC), with CAS number 104206-82-8. It is a new triketone herbicide with a 4-hydroxyphenylpyruvate dioxygenase (HPPD) inhibition mode of action.

Mesotrione has not been evaluated previously by JMPR and was reviewed by the present Meeting at the request of CCPR.

All critical studies contained statements of compliance with GLP or good clinical practice and the Declaration of Helsinki, as appropriate.

Biochemical aspects

Excretion and tissue retention studies were performed in mice and rats. In addition, a full set of metabolism studies was performed in rats. Radiolabelled mesotrione was administered by gavage in both species. In mice, mesotrione was extensively absorbed (> 60%) and primarily excreted in the urine, constituting 41–59% of the administered low dose (1 mg/kg bw per day) and 63–70% of the high dose (100 mg/kg bw per day). Faecal elimination comprised 21–38% of the administered dose. Elimination was essentially complete within the first 24 hours; by 72 hours following dosing, elimination comprised 91–95% of the administered dose. In rats, mesotrione is rapidly and extensively absorbed (> 60%), metabolized to a limited extent and excreted primarily in the urine after single low (54–56% at 1 mg/kg bw) or high doses (29–30% at 100 mg/kg bw) or repeated low doses (23–30% at 1 mg/kg bw per day) over 14 days to rats. Biliary excretion was minimal. Most of the radioactivity was excreted as the parent compound within the first 12 hours post-dosing. Highest levels were found in liver, kidneys and gastrointestinal tract in both species, with 10–15% present in tissues following a low dose and less than 0.3% following a high dose.

In studies performed only in rats, there was no evidence of accumulation. C_{max} values were 0.26 and 0.25 µg equiv/g in male and female rats, respectively, at the low dose (1 mg/kg bw) and 40.4 and 19.9 µg equiv/g, respectively, at the high dose (100 mg/kg bw). The T_{max} was 0.5 hour at the low dose and 1.5 hours at the high dose. Half-lives in blood were less than 2 hours, regardless of sex or dose. There were no notable differences in absorption or excretion between the sexes. Mesotrione and its metabolites were not excreted in expired air. Parent compound accounted for more than 43–64% of the administered dose in the urine and 0–8% of the administered dose in the faeces.

In rats, the metabolites produced from hydroxylation of the dione ring include 4-hydroxy-mesotrione, 5-hydroxy-mesotrione, 2-nitro-4-(methylsulfonyl)-benzoic acid (MNBA) and 4-(methylsulfonyl)-2-aminobenzoic acid (AMBA). There is also a proposed cleavage of the molecule into constituent rings and reduction by the gut microflora, resulting in a number of unidentified metabolites, accounting for a total of approximately 0–12% of the administered dose in the faeces.

Toxicological data

In the rat, mesotrione is of low acute oral toxicity (LD_{50} > 5000 mg/kg bw), low acute dermal toxicity (LD_{50} > 2000 mg/kg bw) and low acute inhalation toxicity (LC_{50} > 4.75 mg/L). In the rabbit, mesotrione was non-irritating to the skin and mildly irritating to the eyes. Mesotrione was not a dermal sensitizer in guinea-pigs (maximization test).

The primary effect of mesotrione in mammals is the inhibition of HPPD, a key enzyme of the tyrosine catabolic pathway. Inhibition of HPPD by mesotrione results in raised plasma tyrosine levels, which appear to be responsible for the critical effects observed (ocular, kidney, liver and thyroid toxicity). The plateau levels of plasma tyrosine after mesotrione administration are higher in rats (males > females) than in mice. The difference in sensitivity between male and female rats as

well as between rats and mice can be attributed to differences in tyrosine catabolism. If the activity of tyrosine aminotransferase (TAT) is low, as it is in the male rat, tyrosine cannot convert quickly to 4-hydroxyphenylpyruvate (HPP); when HPPD is inhibited, the resultant increase in plasma tyrosine levels leads to toxicity.

The critical effect (ocular toxicity) associated with the administration of mesotrione is mediated by these increased systemic levels of tyrosine and occurs only when plasma tyrosine levels exceed about 1000 nmol/mL. The ocular sensitivity of the various species to tyrosine plasma levels seems to be similar; the difference in overall toxicity of mesotrione among the species is attributable to the different levels of plasma tyrosine achieved after HPPD inhibition by mesotrione.

Although the rat is the most sensitive species for assessing tyrosine-mediated mesotrione toxicity, the mouse is a better model for such effects in humans. Humans and mice have similar TAT activities and do not experience the adverse effects associated with the same degree of HPPD inhibition in rats. The effects on the eyes, kidneys, liver and thyroid seen in the rat are unlikely to occur in humans exposed to mesotrione owing to differences in tyrosine metabolism. As all the relevant studies normally performed in the rat were also performed in the mouse, it was determined that the risk assessment would be based on toxicity in the mouse, rabbit and dog.

In a 90-day oral toxicity study in mice, animals were given diets containing mesotrione at a concentration of 0, 10, 50, 350 or 7000 ppm (equal to 0, 1.7, 8.4, 61.5 and 1212.4 mg/kg bw per day for males and 0, 2.4, 12.4, 80.1 and 1537.1 mg/kg bw per day for females, respectively). The NOAEL was 7000 ppm (equal to 1212.4 mg/kg bw per day), the highest dose tested.

In a 90-day oral toxicity study in rats, animals were given diets containing mesotrione at a concentration of 0, 1, 125, 1250 or 12 500 ppm (equal to 0, 0.09, 10.96, 112.09 and 1110.86 mg/kg bw per day for males and 0, 0.10, 12.81, 125.58 and 1212.53 mg/kg bw per day for females, respectively). At 125 ppm (equal to 10.96 mg/kg bw per day), male rats showed evidence of increased corneal opacity and vascularization and decreased body weight and feed efficiency.

In a 13-week oral toxicity study in rats, animals were given diets containing mesotrione at a concentration of 0, 2.5, 5.0, 7.5 or 150 ppm (equal to 0, 0.21, 0.41, 0.63 and 12.46 mg/kg bw per day for males and 0, 0.23, 0.47, 0.71 and 14.48 mg/kg bw per day for females, respectively). There were no non-ocular findings in either male or female rats in this study. At 7.5 and 150 ppm, males showed evidence of cloudy eyes.

In a 13-week oral capsule toxicity study in dogs, animals were exposed to 0, 100, 600 or 1000 mg/kg bw per day. At 1000 mg/kg bw per day, body weights were decreased in males compared with controls and there was an increase in minimal/slight focal mesothelial proliferation of the atrium of the heart in two males. The NOAEL was 600 mg/kg bw per day.

In a 1-year oral capsule toxicity study in dogs, animals were exposed to 0, 10, 100 or 600 mg/kg bw per day. At the high dose, body weights were decreased in females, and lenticular opacity was observed in one male and one female. In the male, the lenticular opacity was associated with unilateral keratitis and periorbital haemorrhage; in the female, it was associated with unilateral corneal erosion. The NOAEL was 100 mg/kg bw per day.

In a 1-year oral toxicity study in mice, animals were given diets containing mesotrione at a concentration of 0, 10, 50, 350 or 7000 ppm (equal to 0, 1.5, 7.8, 56.2 and 1114 mg/kg bw per day for males and 0, 2.1, 10.3, 72.4 and 1494.5 mg/kg bw per day for females, respectively). At the highest dose tested, males exhibited decreased body weight and body weight gains. There were no effects in females at the highest dose tested. The NOAEL was 350 ppm (equal to 56.2 mg/kg bw per day).

In an 18-month oral toxicity and carcinogenicity study in mice, animals were given diets containing mesotrione at a concentration of 0, 10, 350 or 3500/7000 ppm (equal to 0, 1.4, 49.7 and 897.7 mg/kg bw per day for males and 0, 1.8, 63.5 and 1102.9 mg/kg bw per day for females, respectively). As seen in the 1-year study, body weight, body weight gains and feed efficiency were decreased in males at the highest dose tested, and there were no effects in females at the highest dose

tested. There was no evidence of carcinogenicity. The NOAEL was 350 ppm (equal to 49.7 mg/kg bw per day).

In a 2-year carcinogenicity study in rats, animals were given diets containing mesotrione at a concentration of 0, 7.5, 100 or 2500 ppm (equal to 0, 0.48, 6.48 and 159.9 mg/kg bw per day for males and 0, 0.57, 7.68 and 189.5 mg/kg bw per day for females, respectively). There was no evidence of carcinogenicity. In males, changes at all doses consisted of cloudy eyes, corneal opacities, vascularization and keratitis in the clinical, ophthalmological and histopathological examinations, decreased body weights, hepatocyte fatty vacuolation in the liver and thyroid follicular cysts.

The Meeting concluded that mesotrione is not carcinogenic in mice or rats.

Mesotrione was tested for genotoxicity in an adequate range of assays, both in vitro and in vivo. There was no evidence of genotoxicity.

The Meeting concluded that mesotrione is unlikely to be genotoxic.

In view of the lack of genotoxicity and the absence of carcinogenicity in mice and rats, the Meeting concluded that mesotrione is unlikely to pose a carcinogenic risk to humans.

In a two-generation reproductive toxicity study in mice, animals were given diets containing mesotrione at a concentration of 0, 10, 50, 350, 1500 or 7000 ppm (equal to 0, 2.1, 10.2, 71.4, 311.8 and 1472 mg/kg bw per day for males and 0, 2.1, 10.0, 71.3, 301.6 and 1439 mg/kg bw per day for females, respectively). At the highest dose tested, F_1 adults and pups showed evidence of cataractous changes at clinical, gross and histopathological examination. Pups at the next lower dose also exhibited decreased body weight and body weight gain, clinical, gross and histopathological changes to the eyes (opaque/cloudy eyes, cataractous change) and increased plasma tyrosine levels. The NOAEL for parental toxicity was 1500 ppm (equal to 301.6 mg/kg bw per day). The NOAEL for reproductive toxicity was 7000 ppm (equal to 1439 mg/kg bw per day), the highest dose tested. The NOAEL for offspring toxicity was 350 ppm (equal to 71.3 mg/kg bw per day).

In a three-generation reproductive toxicity study in rats, animals were given diets containing mesotrione at a concentration of 0, 2.5, 10, 100 or 2500 ppm (equal to 0, 0.3, 1.1, 11.6 and 278.1 mg/kg bw per day for males and 0, 0.3, 1.1, 11.7 and 297.2 mg/kg bw per day for females, respectively), with an F_2 recovery group in which the dams were not treated through gestation. Effects in the parental generations consisted of ocular changes in clinical, ophthalmological, gross and histopathological examinations at dietary concentrations of 10 ppm and above, along with increased plasma tyrosine levels. In pups, cloudy/opaque eyes, keratitis and/or corneal vascularization were observed in all treated groups in males and at 100 and 2500 ppm in females in litters exposed to mesotrione in utero. Plasma tyrosine levels were measured in pups in the F_{3A} groups and were increased in all treatment groups in the continuous treatment animals; levels were comparable to those of controls in all the recovery groups. Decreased litter size, decreased survival, decreased percentage of pups born live and increased whole litter loss were observed at the highest dose tested.

A mode of action study in rats was performed to determine the link between tyrosinaemia and the changes noted in the rat reproductive toxicity study. In a modified one-generation reproductive toxicity study, animals were exposed to 0 ppm mesotrione with 0%, 0.5%, 1% or 2% tyrosine or to 2500 ppm mesotrione with 0%, 0.5%, 1% or 2% tyrosine from day 1 of gestation until termination on day 29 postpartum. Tyrosine and mesotrione increased plasma tyrosine levels and caused increases in whole litter losses, although the effect of mesotrione was greater than that of dietary tyrosine. The Meeting concluded that the reproductive effects observed in rats were likely a consequence of the elevated levels of tyrosine.

In a developmental toxicity study in mice, pregnant females were dosed at 0, 10, 60, 150 or 600 mg/kg bw per day. There were no signs of maternal or embryo/fetal toxicity up to 600 mg/kg bw per day, the highest dose tested.

In a developmental toxicity study in rats, pregnant females were dosed at 0, 100, 300 or 1000 mg/kg bw per day. Maternal body weight and feed consumption were decreased at all doses. In fetuses, delays in ossification were increased at all doses.

In a developmental toxicity study in rabbits, pregnant females were dosed at 0, 100, 250 or 500 mg/kg bw per day. At 250 and 500 mg/kg bw per day, there were increases in abortions and decreased defecation. The NOAEL for maternal toxicity was 100 mg/kg bw per day, based on increased abortions and decreased defecation at 250 mg/kg bw per day. The NOAEL for embryo/fetal toxicity was 500 mg/kg bw per day, the highest dose tested.

An investigative study was performed with pregnant female rabbits treated as follows: control (no tyrosine or mesotrione), tyrosine (1% dietary), mesotrione (500 mg/kg bw per day by gavage) and tyrosine and mesotrione (1% dietary tyrosine and 500 mg mesotrione/kg bw per day by gavage). Plasma tyrosine levels were increased in all groups treated with mesotrione, tyrosine or a combination of the two. In groups treated with both mesotrione and tyrosine, the plasma tyrosine levels were highest, followed by mesotrione-only dams and, lastly, tyrosine-only treated dams. Likewise, delays in ossification were most prevalent in the fetuses of dams treated with both mesotrione and tyrosine, followed by mesotrione-only and tyrosine-only treated dams; however, delays were prevalent in all treated groups at rates higher than those in the concurrent controls. There was only one abortion, which occurred in the group treated with both mesotrione and tyrosine. As such, the Meeting concluded that delays in ossification were related to the increase in plasma tyrosine levels. There was insufficient information to enable a conclusion to be reached with regard to abortions.

The Meeting concluded that mesotrione is not teratogenic.

In an acute neurotoxicity study in rats, no neurotoxic effects were seen at the NOAEL of 2000 mg/kg bw, the highest dose tested.

In a 13-week dietary neurotoxicity study in rats, ophthalmoscopic findings were observed at 100 ppm (equal to 8.25 mg/kg bw per day). No neurotoxicity was observed up to 5000 ppm (equal to 402.80 mg/kg bw per day), the highest dose tested.

The Meeting concluded that mesotrione is not neurotoxic.

In a 4-week dietary immunotoxicity study in mice, no effects on immunoglobulin M response to sheep red blood cells or any other signs of immunotoxicity were observed at 5000 ppm (equal to 1364 mg/kg bw per day), the highest dose tested.

The Meeting concluded that mesotrione is not immunotoxic.

Toxicological data on metabolites and/or degradates

For MNBA, a plant and livestock metabolite, studies of metabolism, HPPD inhibition, acute toxicity, short-term toxicity and genotoxicity were performed.

When given to rats as a single oral dose of 75 mg/kg bw, [^{14}C]MNBA was minimally absorbed and excreted in the urine. The majority was converted to AMBA in the gut, which was excreted unabsorbed.

MNBA was a very weak inhibitor of HPPD compared with mesotrione.

MNBA is of low acute oral toxicity, with an LD_{50} of > 5000 mg/kg bw.

In a 28-day gavage study in rats, MNBA was given in corn oil at a dose of 0, 15, 150 or 1000 mg/kg bw per day. The NOAEL was 1000 mg/kg bw per day, the highest dose tested.

In a 90-day study in rats, animals were given MNBA in the diet at a concentration of 0, 100, 650 or 3000 ppm (equal to 0, 7.7, 50.6 and 231.0 mg/kg bw per day for males and 0, 8.8, 56.9 and 263.7 mg/kg bw per day for females, respectively). At 3000 ppm, body weights were decreased

statistically significantly (by 8%) in males, and triglycerides were increased (by 36%) in females. The NOAEL was 650 ppm (equal to 50.6 mg/kg bw per day), based on equivocal effects on body weight and increased triglycerides.

MNBA was tested in an adequate range of genotoxicity assays. No evidence of genotoxicity was observed.

For AMBA, a plant and livestock metabolite, studies of HPPD inhibition, acute toxicity and genotoxicity were performed.

AMBA was a very weak inhibitor of HPPD compared with mesotrione.

AMBA is of low acute oral toxicity, with an LD_{50} of > 5000 mg/kg bw.

AMBA showed no evidence of genotoxicity in a reverse mutation assay or in a mammalian cell cytogenetic assay in the presence of metabolic activation and gave positive results in the mammalian cell cytogenetic assay in the absence of metabolic activation.

As there was insufficient information to determine the toxicological profile of MNBA and AMBA, their toxicological relevance was assessed using JMPR's metabolite assessment scheme included in the guidance document for WHO monographers. On the basis of this assessment, the Meeting concluded that these metabolites are unlikely to be a safety concern.

Human data

In a study in which human volunteers were exposed to a single oral dose of mesotrione of 0.1, 0.5 or 4 mg/kg bw in capsules, there were no symptoms, clinical signs or changes on ophthalmological examination. In volunteers given 4 mg/kg bw, plasma tyrosine levels were increased up to 48 hours following dosing, with a peak tyrosine concentration of up to 420 nmol/mL plasma; unchanged mesotrione was found in the urine.

There are no reports of poisoning cases with mesotrione.

The Meeting concluded that the existing database on mesotrione was adequate to characterize the potential hazards to fetuses, infants and children.

Toxicological evaluation

The Meeting established an ADI of 0–0.5 mg/kg bw on the basis of the NOAEL of 350 ppm (equal to 49.7 mg/kg bw per day), based on decreased body weight, body weight gain and feed efficiency in male mice in an 18-month toxicity and carcinogenicity study. A safety factor of 100 was applied.

The Meeting considered the mode of action of the HPPD-dependent effects of mesotrione and concluded that the rat was not an appropriate model on which to base the toxicological evaluation.

The Meeting concluded that it was not necessary to establish an ARfD for mesotrione in view of its low acute oral toxicity and the absence of developmental toxicity and any other toxicological effects that would be likely to be elicited by a single dose.

A toxicological monograph was prepared.

Levels relevant to risk assessment of mesotrione

Species	Study	Effect	NOAEL	LOAEL
Mouse	Eighteen-month study of toxicity and	Toxicity	350 ppm, equal to 49.7 mg/kg bw per day	7 000 ppm, equal to 897.7 mg/kg bw per

Species	Study	Effect	NOAEL	LOAEL
	carcinogenicity[a]			day
		Carcinogenicity	7 000 ppm, equal to 897.7 mg/kg bw per day[b]	–
	Two-generation study of reproductive toxicity[a]	Reproductive toxicity	7 000 ppm, equal to 1 439 mg/kg bw per day[b]	–
		Parental toxicity	1 500 ppm, equal to 301.6 mg/kg bw per day	7 000 ppm, equal to 1439 mg/kg bw per day
		Offspring toxicity	350 ppm, equal to 71.3 mg/kg bw per day	1 500 ppm, equal to 301.6 mg/kg bw per day
	Developmental toxicity study[c]	Maternal toxicity	600 mg/kg bw per day[b]	–
		Embryo and fetal toxicity	600 mg/kg bw per day[b]	–
Rat	Two-year study of toxicity and carcinogenicity[a]	Carcinogenicity	159.9 mg/kg bw per day[b]	–
Rabbit	Developmental toxicity study[c]	Maternal toxicity	100 mg/kg bw per day	250 mg/kg bw per day
		Embryo and fetal toxicity	500 mg/kg bw per day[b]	—
Dog	One-year study of toxicity[d]	Toxicity	100 mg/kg bw per day	600 mg/kg bw per day

[a] Dietary administration.
[b] Highest dose tested.
[c] Gavage administration.
[d] Capsule administration.

Estimate of acceptable daily intake (ADI)

0–0.5 mg/kg bw

Estimate of acute reference dose (ARfD)

Unnecessary

Information that would be useful for the continued evaluation of the compound

Results from epidemiological, occupational health and other such observational studies of human exposure

Critical end-points for setting guidance values for exposure to mesotrione

Absorption, distribution, excretion and metabolism in mammals	
Rate and extent of oral absorption	Rapid; extensive (> 60%)
Dermal absorption	No data
Distribution	Rapidly eliminated; highest residues in carcass, gastrointestinal tract, liver and kidneys

Potential for accumulation	No evidence of accumulation
Rate and extent of excretion	Largely complete within 24 hours; primarily via urine (41–70% in mice and 54–84% in rats), with 21–38% in faeces
Metabolism in animals	Mostly excreted unchanged
Toxicologically significant compounds in animals and plants	Mesotrione, MNBA and AMBA
Acute toxicity	
Rat, LD_{50}, oral	> 5 000 mg/kg bw
Rat, LD_{50}, dermal	> 2 000 mg/kg bw
Rat, LC_{50}, inhalation	> 4.75 mg/L
Rabbit, dermal irritation	Not irritating
Rabbit, ocular irritation	Mildly irritating
Guinea-pig, dermal sensitization	Not sensitizing (maximization test)
Short-term studies of toxicity	
Target/critical effect	Body weight
Lowest relevant oral NOAEL	100 mg/kg bw per day (dog)
Lowest relevant dermal NOAEL	1 000 mg/kg bw per day (rabbit)
Lowest relevant inhalation NOAEC	No data
Long-term studies of toxicity and carcinogenicity	
Target/critical effect	Body weight
Lowest relevant oral NOAEL	49.7 mg/kg bw per day (mouse)
Carcinogenicity	Unlikely to pose a carcinogenic risk to humans
Genotoxicity	
	Unlikely to be genotoxic
Reproductive toxicity	
Target/critical effect	Decreased body weight, clinical, gross and histopathological changes to the eye
Lowest relevant parental NOAEL	301.6 mg/kg bw per day (mouse)
Lowest relevant offspring NOAEL	71.3 mg/kg bw per day (mouse)
Lowest relevant reproductive NOAEL	1 439.1 mg/kg bw per day (mouse)
Developmental toxicity	
Target/critical effect	Abortions and decreased faecal output
Lowest relevant maternal NOAEL	100 mg/kg bw per day (rabbit)
Lowest relevant embryo/fetal NOAEL	500 mg/kg bw per day, highest dose tested (rabbit)
Neurotoxicity	
Acute neurotoxicity NOAEL	2 000 mg/kg bw, highest dose tested
Subchronic neurotoxicity NOAEL	402.80 mg/kg bw per day, highest dose tested
Developmental neurotoxicity NOAEL	No data

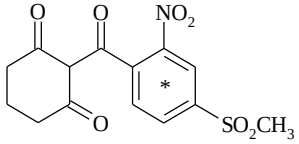
Other toxicological studies	
Studies on toxicologically relevant metabolites	MNBA:
	Metabolism: Minimally absorbed, excreted primarily in urine, majority in gut at 12 hours converted to AMBA
	HPPD inhibition: very weak compared with mesotrione
	Oral LD_{50}: > 5 000 mg/kg bw
	NOAEL: 1 000 mg/kg bw per day, highest dose tested (4-week gavage study in rats)
	NOAEL: 50.6 mg/kg bw per day, based on equivocal decreases in body weights and increased triglycerides (90-day study in rats)
	Unlikely to be genotoxic
	AMBA:
	HPPD inhibition: very weak compared with mesotrione
	Oral LD_{50}: > 5 000 mg/kg bw
	Unlikely to be genotoxic
Medical data	
	No studies submitted

Summary

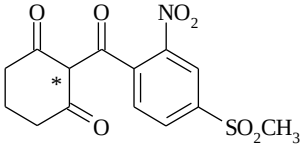
	Value	Study	Safety factor
ADI	0–0.5 mg/kg bw	Eighteen-month study of toxicity and carcinogenicity (mouse)	100
ARfD	Unnecessary	–	–

RESIDUE AND ANALYTICAL ASPECTS

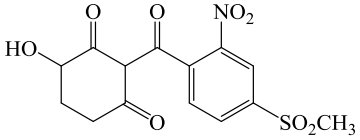
Mesotrione is a systemic pre-emergence and post-emergence herbicide for the selective contact and residual control of broadleaf weeds. The compound was scheduled for evaluation by 2014 JMPR as a new compound at the Forty-fifth Session of the CCPR (2013). Metabolism studies on animal and plants, confined rotational crops and environmental fate studies, analytical methods and residue trials on berries, okra, sweet corn, soya bean, asparagus, rhubarb maize, millet, oat, rice, sorghum, sugarcane and linseed were submitted for evaluation. The structure of mesotrione and the main metabolites found in livestock, plant tissues and soil are shown below

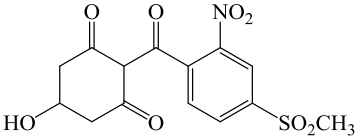


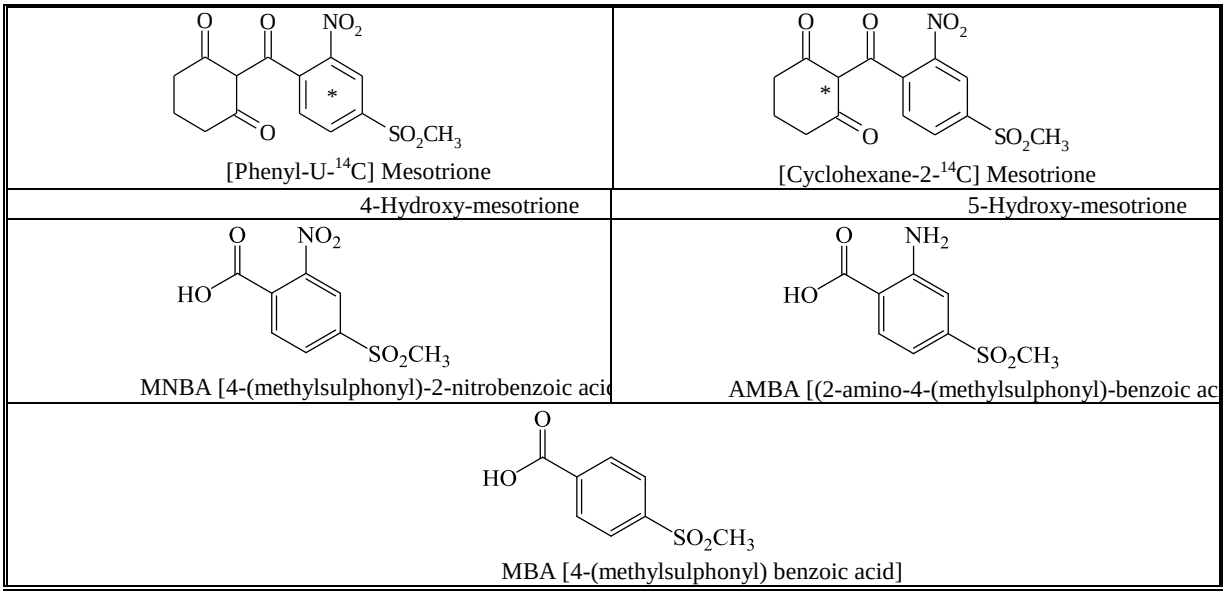
[Phenyl-U-^{14}C] Mesotrione



[Cyclohexane-2-^{14}C] Mesotrione







Animal metabolism

Rats

The metabolism of mesotrione was evaluated at the present Meeting by the JMPR WHO Panel. The compound is rapidly and extensively absorbed, minimally metabolized and excreted primarily in urine after a single or repeated dose. The majority of the radioactivity was excreted as the parent compound within 12 hours post-dose, accounting for 43–64% of the dose in urine. The metabolites found in the excreta includes 4 and 5-hydroxy mesotrione, MNBA and AMBA.

Livestock animals

Metabolism studies of mesotrione were conducted in lactating cows, swine and poultry. Additionally, the metabolism of AMBA, a plant metabolite, was investigated in the cow.

In two metabolism studies conducted in lactating cows, the animals were dosed with [phenyl-U-^{14}C-]-mesotrione or [cyclohexane-2-^{14}C]-mesotrione for 7 consecutive days at a nominal rate of 10 ppm in the diet, and sacrificed 16 hours after the final dose. Over 90% of the administered dose was found in excreta, mostly in faeces. TRR was higher in liver and kidney (0.07 to 0.11 mg eq./kg), reached 0.007 mg eq./kg in muscle, 0.013 mg/kg eq in fat and 0.08 mg eq./kg in milk (over 90% TRR in skimmed milk). Mesotrione accounted for 10–18% TRR in liver and kidney (0.01–0.02 mg eq./kg). AMBA was identified in kidney of the phenyl label experiment (0.012 mg eq./kg).

One female swine was dosed orally with [phenyl-U-^{14}C]-mesotrione for 5 consecutive days at 6 ppm, and sacrificed 23 hours after the final dose. About 90% of the administered dose was recovered in the excreta, mostly in the faeces. Highest TRR were found in liver (1.75 mg eq./kg) and kidney (0.12 mg eq./kg), with 0.01 mg eq./kg in muscle and 0.06 mg eq./kg in fat. Mesotrione was the main identified residues (90% TRR in liver, 73% TRR in kidney and 78% TRR in muscle). AMBA accounted for up to 2% TRR in tissues (up to 0.029 mg eq./kg in kidney). MNBA was only detected in liver (0.005 mg eq./kg).

Two metabolism studies were conducted in poultry, in which hens were dosed for 10 consecutive days at 11 ppm either with [phenyl-U-^{14}C]-mesotrione or [cyclohexane-2-^{14}C]-mesotrione; the hens were sacrificed 16 hours after the final dose. The radioactivity in excreta accounted for over 90% of the administered dose, and contained mesotrione (up to 55% TRR) and AMBA (18% TRR). TRRs were similar in both experiments for liver (1.1–1.2 mg eq./kg) and kidney

(0.06–0.07 mg eq./kg), but were higher in the cyclohexane experiment in muscle (up to 0.012 mg/kg eq), fat (up to 0.048 mg eq./kg), reaching 0.094 mg eq./kg in egg yolk, and 0.025 mg eq./kg in the white. Mesotrione was not detected in muscle in any experiment, and was the only compound identified in tissues and eggs in both experiments, corresponding to at least 80% TRR in the liver and fat. In egg yolk, mesotrione accounted for 81% TRR in the phenyl experiment, and 19.5% TRR in the cyclohexane experiment, in which about 15% TRR was shown to be incorporated into palmitic/oleic acid.

A lactating cow received [phenyl-U-^{14}C]-AMBA for 7 days at 12.2 ppm in the diet and was sacrificed 23 hours after the final dose. About 90% of the dose was recovered in the excreta, mostly in the faeces. Highest residues were found in kidney (0.053 mg eq./kg), with AMBA accounting for 79% TRR. Perineal fat contained 0.018 mg eq./kg, 62% identified as AMBA. TRR in liver were 0.005 mg eq./kg, and reached a maximum of 0.009 mg eq./kg in milk (day 6), but were not characterized. No radioactive residues were detected in muscle.

In summary, the biotransformation of mesotrione in livestock involves the oxidative cleavage of the parent molecule to yield MNBA, which in reduced in the nitro group to give AMBA. Highest residues were found in liver and kidney, but the levels in muscle were low, reaching a maximum of 0.012 mg eq./kg Mesotrione accounted for up to 18% TRR in cow liver and kidney, at least 70% TRR in tissues of swine and poultry, and up to 80% TRR in egg white. No single compound was detected in muscle. The metabolism of Mesotrione in rats was found to be similar of that described for livestock.

Plant metabolism

Metabolism studies were conducted in cranberries, tolerant soya bean, maize, rice and peanuts. [Phenyl-U-^{14}C]-mesotrione was applied twice to cranberry plants at 0.331 + 0.242 kg ai/ha (1×) or 0.919 + 0.642 kg ai/ha (2× rate), and samples harvested 46 days after the last treatment (DAT). TRRs in mature foliage were 16.8 mg eq./kg and 31.8 mg eq./kg for 1× and 2×, respectively. TRRs in the mature cranberry fruit were 2.57 mg eq./kg and 4.85 mg eq./kg, respectively, mostly as mesotrione (60–70% TRR) and AMBA (24–35% TRR).

Mesotrione tolerant soya bean seeds grown in sandy loam soil were treated with either [Phenyl-U-^{14}C]- or [cyclohexane-2-^{14}C]-mesotrione using three GAP application regimes: one pre-emergence at 0.225 kg ai/ha (T1), a combined pre-emergence at 0.225 kg ai/ha followed by a post-emergence at 0.125 kg ai/ha (T2), or one post-emergence at 0.225 kg ai/ha (T3). Forage was sampled at 22–28 DAT, hay at 40–42 DAT and seeds at 90–123 DAT.

Higher radioactivity was recovered from the phenyl label experiment. In forage, TRR were 0.16 to 0.5 mg eq./kg, mostly as MNBA (13 to 24% TRR; 0.04 to 0.06 mg eq./kg); mesotrione and its 4 and 5-hydroxy metabolite accounted for up to 14.3% TRR each (0.01 to 0.08 mg eq./kg). In hay, TRR ranged from 0.14 mg/kg eq (T1) to 2 mg eq./kg (T2), mostly MNBA (up to 20% TRR) and 4/5-hydroxy-mesotrione (up to 16% TRR); mesotrione accounted for up to 9% TRR. AMBA was only detected in T2 hay (0.055 mg eq./kg; 2.7% TRR). Residues in soya bean seed ranged from 0.052 to 0.104 mg eq./kg, with mesotrione and 4/5-hydroxy-mesotrione the main compounds identified (< 10% TRR). Low levels of MNBA and AMBA were found in the T1 and T2 samples (< 5% TRR, 0.005 mg eq./kg).

Results from the cyclohexane experiment showed mesotrione accounting for up to 17% TRR in forage, 8.8% TRR in hay and 5.1% TRR in seed (0.02 mg eq./kg). 4 and 5-hydroxy-mesotrione accounted for up to 19% TRR in forage and hay, and 7% TRR in seeds.

Three studies were conducted with maize, two with [Phenyl-U-^{14}C]-mesotrione and/or one with [cyclohexane-2-^{14}C]–mesotrione. In all cases, the compound was applied to the soil surface after planting the seeds at a rate of 0.3 kg ai/ha (pre-emergence; T1) or post-emergence at 0.16–0.18 kg ai/ha, 28 days after planting (T2).

Results from the phenyl label experiments showed higher total residues in fodder/stover (0.57 to 1.1 mg eq./kg) and forage (0.244 to 0.356 mg eq./kg). Over 60% of the residues in fodder were not extracted with ACN/water. In forage, MNBA and AMBA were the major residues (up to 19.7 and 13% TRR, respectively). In fodder, AMBA was the major residue (up to 28% TRR). 4-hydroxy-mesotrione was mainly present in forage (up to 8% TRR, about 50% conjugated). Mesotrione was a minor component of the residues in all cases, present at a higher level in T1 forage samples (2.2% TRR, 0.008 mg eq./kg). TRR in grain were 0.01 to 0.03 mg/kg eq, and were not further characterized.

In the cyclohexane experiment, TRR reached 0.1 mg eq./kg in forage and 0.33 mg eq./kg in fodder. In forage, the identified residues were mesotrione (up to 3% TRR) and 4-hydroxy-mesotrione (up to 10% TRR). About 18% TRR was incorporated into lignin and cellulose. Residues in grain were low (up to 0.011 mg eq./kg) and were not be further characterized.

Rice plants were treated at the 2–3 leaf stage with [phenyl-U-^{14}C]-mesotrione added directly to the paddy water at either 0.09 kg ai/ha (1×) or 0.225 kg ai/ha (2.5×). TRRs were higher in whole tops and straw (0.03 to 0.06 mg eq./kg at 1×), with 40–70% extracted by ACN/water. Residues in grain and husk (109 DAT) were 0.01 mg eq./kg, about 20% being extracted (acid released up to 75.1% TRR in grain). Immature whole tops from 1x rate contained mesotrione and 5-hydroxy-mesotrione at up to 0.01 mg/kg each (11 to 28% TRR), and traces of MNBA and AMBA (< 5% TRR from 1×). In 1× stalk and straw, mesotrione and its metabolites represented < 10% TRR each. No characterization was performed in grain. Residues from 2.5× samples were 2–5 times higher (0.02 mg eq./kg in grain).

[Phenyl-U-^{14}C] or [cyclohexane-2-^{14}C]-mesotrione were applied to the soil surface after planting peanut seed (pre-emergence) at 0.3 (T1) or 0.8 kg ai/ha (T2). Peanut foliage was harvested 90 DAT (50% maturity), mature peanuts and peanut hay at 153 DAT. Residues from [Phenyl-U-^{14}C] treatment were higher in foliage (0.028 and 0.064 mg eq./kg, in T1 and T2, respectively) and up to 0.01 mg eq./kg in hay, hull and nutmeat. Traces of MNBA, MBA, AMBA and 4-hydroxy-misotrione were found in hay (<10% TRR, ≤ 0.001 mg eq./kg), but only AMBA was found in nutmeat (up to 15% TRR, 0.002 mg eq./kg, in T1). TRR from [cyclohexane-2-^{14}C] treatment were 0.01 mg eq./kg in T1 hay and nutmeat, and 0.02 and 0.04 mg eq./kg in T2 hull and nutmeat. 4-hydroxy-mesotrione was only identified in hulls (7% TRR). The peanut oil fraction was shown to be composed primarily of ^{14}C-labelled neutral lipids.

In summary, the metabolic pathway of mesotrione following pre- and/or post-emergence foliar applications in cranberries, maize, rice, peanut and tolerant soya bean are similar. It proceeds via cleavage of the parent molecule to yield MNBA and reduction to AMBA, which either conjugated or degraded to MBA. Mesotrione is also hydroxylated in the cyclohexane-dione ring to give 4 or 5-hydroxy-mesotrione. Incorporation of radioactive residues into natural products (lignin cellulose sugar or lipid) was seen in all crops, except cranberry fruit. Residues in cranberry fruits were mostly mesotrione and AMBA (over 20% TRR each). Maize, soya and rice feed commodities contained mostly MNBA and AMBA (> 10% TRR in most cases). Residues in grains were low and mesotrione only represented higher than 10% TRR in tolerant soya bean seed.

Environment fate

The photolysis of [phenyl-^{14}C] mesotrione and [cyclohexane-^{l4}C]-mesotrione was studied in silt loam soil treated at 0.3 kg ai/ha and incubated in local sunlight (latitude 37° 56') at 20 to 24°C. About half of the radioactivity was present as mesotrione at 12–13 DAT. MNBA and AMBA accounted for 2-8% TRR at 5 DAT, increasing up to 8% TRR at 30 DAT.

The metabolism of [phenyl-2-^{14}C] or [cyclohexane-^{l4}C]-mesotrione applied to various soils at rates ranging from 0.165 to 0.85 kg ai/ha and kept under aerobic conditions in the dark at 25±1°C for 28 to 60 days was investigated. Mesotrione degrades relatively fast, with DT_{50} values ranging from 4.5 to 32 days. DT_{50} for MNBA was < 2 days in these studies.

In two water sediment systems experiments conducted with either [phenyl-2-^{14}C] or [cyclohexane-^{14}C]-mesotrione at 0.20 kg ai/ha and incubated in the dark for 101 days, showed DT_{50} were from 3 to 6 days, with mesotrione in the sediment never exceeding 4% AR. MNBA and AMBA were found in both water and sediment, starting at day 3.

The aerobic degradation of [phenyl-2-^{14}C]-AMBA was studied in soils incubated up to 60 days in the dark, showing DT_{50} ranging from 2 to 6 days.

Field studies

In six studies conducted with soils collected from different regions of Europe, mesotrione was applied at 0.15–0.2 kg ai/ha. MNBA and AMBA were detected at 6 DAT in 0–10 cm horizon (0.031 and 0.006 mg eq./kg, respectively). No residues of mesotrione or metabolites were detected in the soil below 10 cm. DT_{50} ranged from 2 to 8 days.

In one study conducted with four soils from England and USA treated with MNBA at 0.22 kg ai/ha, DT_{50} ranged from 0.6 to 10.6 days.

Confined rotational crops

Endive, radish and wheat were sown 120 days after a sandy loam soil being treated with [phenyl-U-^{14}C] or [cyclohexane-2-^{14}C]-mesotrione at 0.165 kg ai/ha. Endive was harvested at 78–63 days after planting (DAP), radish roots and leaves at 56 DAP, wheat forage at 22 DAP, wheat hay at 57 DAP and wheat grain and straw at 134–131 DAP. In the [phenyl-U-^{14}C] experiment, residues in soil declined to 34% of the applied radioactivity (AR) at 120 DAT, with the most abundant metabolites being MNBA (8% AR) and AMBA (2% AR); mesotrione accounted for only 0.1% AR. TRR were 0.02 to 0.04 mg eq./kg in wheat forage, hay and straw, mostly MNBA (0.011 mg eq./kg in forage). Residues were 0.006 mg eq./kg in wheat grain, 0.014 mg eq./kg in endive and 0.004 mg eq./kg in radish root and leaves. TRR in all cyclohexane-2-^{14}C samples were < 0.005 mg eq./kg in endive, and wheat straw, and were not further characterized.

In another study, [phenyl-U-^{14}C] or [cyclohexane-2-^{14}C]-mesotrione was applied at 0.308 kg ai/ha (T1, characteristic of pre-emergence) and 0.462 kg ai/ha (T2, characteristic of pre + post-emergence) onto a sandy loam soil, and wheat, soya, endive or radish planted at 30, 120 and/or 300 DAT. Residues in soil declined to 27% AR at 300 DAT. Residues in wheat commodities from the [phenyl-U-^{14}C] experiment were higher in straw (2.58 mg eq./kg at 30 DAT, T1). In wheat grain, residues were 0.038 mg eq./kg at 30 DAT (T1) and 0.014–0.015 mg eq./kg at 120 and 300 DAT (T2). At 30 DAT (T1), the major identified metabolite was MNBA, with residues ranging from 0.18 to 0.63 mg eq./kg in wheat forage, hay and straw and 0.003 mg eq./kg in grain. AMBA was mostly present as sulphate conjugate (total of 0.67 mg eq./kg in straw), and mesotrione and its 4-OH metabolite were only detected in forage (0.01 mg eq./kg).

At 30 DAT (T1), residues were 0.145 mg eq./kg in soya bean, and 0.46–0.64 mg eq./kg in feed. MNBA was 0.17–0.31 mg eq./kg in forage and hay and 0.014 mg eq./kg in soya bean. AMBA levels were 0.02-0.07 mg eq./kg Residues in endive and radish ranged from 0.037 to 0.053 mg eq./kg at 120 DAT, declining to 0.005 to 0.019 mg eq./kg at 300 DAT (T2). The major residue was MNBA (0.02 mg eq./kg at 120 DAT, T2).

Highest residues from [cyclohexane-2-^{14}C] experiment were found at 30 DAT, T1: 0.05 - 0.06 mg eq./kg in wheat feed, 0.01 mg eq./kg in wheat grain, and 0.02–0.03 mg eq./kg in soya bean samples. Residues in endive and radish were < 0.01 mg eq./kg Mesotrione and 4-hydroxy mesotrione were identified in wheat and soya bean feed (< 0.01 mg eq./kg) (30 DAT, T1).

In summary, mesotrione degrades quickly in soil under aerobic conditions. Although mesotrione is relatively stable to hydrolysis at pH 5–9 (less than 10% degradation after 30 days at 25 °C), it degrades rapidly in flooded systems with a half-life of approximately 4 days. Mesotrione metabolites, mainly MNBA, are expected in wheat and soya bean feed, endive and radish root when

the crops are planted up to 120 days after the soil is treated with mesotrione at 0.3 kg ai/ha rate or higher. As currently the compound is used at rates lower than 0.3 kg ai/ha, no residues arriving from the use of mesotrione are expected in rotational crops.

Methods of analysis

Mesotrione residues in vegetable crops may be analysed by LC-MS/MS (negative mode, m/z=338 → 291) after extraction with acetonitrile/water and cleaned up by SPE. Recovery data for mesotrione in maize commodities and cranberries showed good performance (84–114% recovery, 3–21% RSD, n=3–6) at the 0.01 mg/kg (LOQ) to 10 mg/kg range. The method was used in various supervised trials, with recovery data for mesotrione and MNBA within the acceptable levels at the LOQ or higher.

A modified QuEChERS LC-MS/MS multi-residue method (no clean up with primary-secondary amine (PSA) is used) was validated for mesotrione in oranges, maize and oilseed rape, with a LOQ of 0.01 mg/kg.

In a reversed-phase HPLC-fluorescence method, mesotrione and MNBA residues are extracted with acetonitrile:water (1:1) and cleaned up on silica SPE. The extract is submitted to reversed phase HPLC, the MNBA fraction collected and chemically reduced to AMBA with $SnCl_2$ in HCl, and the mesotrione fraction converted to MNBA with H_2O_2 and reduced to AMBA using acidic $SnCl_2$. Each fraction is cleaned-up by C18 SPE, and the AMBA conversion product quantified by HPLC-fluorescence. The method was validated for corn commodities with a LOQ of 0.01 mg/kg.

In a GC-MS method, mesotrione and MNBA residues are extracted from corn commodities with acetonitrile:water (1:1), acidified, partitioned with methylene chloride, which is evaporated and the residue heated with Jones Reagent (Cr^{VI} oxide acid solution) to oxidize mesotrione to MNBA. The total MNBA is extracted with ethyl acetate, evaporated to dryness, and the residue reacted with 2-iodopropane and potassium carbonate to form isopropyl ester of MNBA for analyse by GC-MS. The method determines both mesotrione and MNBA at a combined LOQ of 0.01 mg/kg.

The acetonitrile:water (1:1) extraction efficiency was radio-validated using incurred radioactive residues in forage. After extraction using a high speed homogeniser, an aliquot was partitioned three times into ethyl acetate, and residues of mesotrione and MNBA quantified by TLC with storage-phosphor autoradiography. Levels of mesotrione and MNBA in forage were similar to the results obtained after exhaustive extraction within the metabolism study.

Mesotrione and MNBA residues are extracted from milk and eggs with acetone and from animal tissues with an acetone:water, the extract acidified, partitioned into methylene chloride, and residues of mesotrione oxidised to MNBA using H_2O_2. MNBA is reduced with acidic $SnCl_2$ and AMBA determined by reversed phase HPLC-fluorescence detection. The LOQ was 0.01 mg/kg in all matrices. Mesotrione may also be determined in animal matrices using the modified QuEChERS, excluding PSA, at an LOQ of 0.01 mg/kg.

The analytical methods were considered fit for purpose to determine mesotrione alone or in combination with MNBA in plant and animal commodities at a LOQ of 0.01 mg/kg.

Stability under frozen conditions

Residues of mesotrione and/or MNBA in fortified samples of maize commodities, radish root, and soya bean seed at 0.1 mg/kg were stable under frozen conditions for at least 32 months (at least 80% of the residues remained, quantified as AMBA by HPLC-FL). Samples of blueberry, asparagus, sugarcane and okra fortified with mesotrione at 1.0 mg/kg were shown to be stable for at least 13 months when stored frozen (quantified by HPLC-MS/MS). The residue trials reports also include additional information on storage stability, and the samples were stored within the period that guaranteed the integrity of the residues at the time of analysis.

Definition of the residue

Metabolism studies conducted in cow, swine and poultry fed with ^{14}C mesotrione at 6 to 11 ppm showed higher residues in liver and kidney, and ranged from 0.01 to 0.08 mg eq./kg in muscle, milk and in eggs. When detected, mesotrione was the main residue found in animal commodities, accounting for up to 18% TRR in cow liver and kidney, at least 70% TRR in tissues of swine and poultry, and up to 80% TRR in egg white. When cow was fed with ^{14}C AMBA, residues reached a maximum of 0.05 mg eq./kg in kidney and fat, with over 60% as AMBA. Residues in other tissues and in milk were < 0.01 mg eq./kg

The Meeting agreed that the residue definition of mesotrione for enforcement and dietary exposure assessment is mesotrione.

The residues do not concentrate in fat and mesotrione has a log P_{ow} of 0.1, confirming that mesotrione is not fat soluble.

Mesotrione is a herbicide that can be applied to the soil pre and/or post emergence of the plant, with exception of cranberry, for which the use is foliar. The compound is rapidly degraded in soil. Metabolism study showed residues in cranberry fruits mostly as mesotrione (over 60% TRR) and AMBA (over 20% TRR). Metabolism studies conducted in tolerant soya bean, maize, rice and peanut showed higher residues in feed commodities, mostly as mesotrione (up to 28% TRR in rice tops), MNBA (up to 24% TRR in soya bean forage) and AMBA (up to 29% TRR in maize fodder). Total residues in edible commodities were low (≤ 0.03 mg eq./kg) and when characterized, showed mesotrione as the main residue.

The Meeting concluded that MNBA and AMBA appear to be of low toxicological concern. When the information was available, MNBA was not detected in any sample from the residue trials.

The Meeting agreed that mesotrione is an adequate marker for the uses of mesotrione in plants and is suitable for dietary intake assessment

The Meeting agreed in the following residue definition for both plant and animal commodities for enforcement and dietary risk assessment: *Mesotrione*

The residues are not fat soluble.

Residues of supervised residue trials on crops

Cranberry

GAP in USA for cranberries is 2 broadcast foliar applications at 0.28 kg ai/ha, PHI 45 days. In five trials using 2 applications, the first being at 0.388 kg ai/ha, residues were: < 0.01 mg/kg (5), indicating that no residues are expected when the product is applied at the GAP rate.

The Meeting agreed to recommend a maximum residue level of 0.01* mg/kg, and a STMR of 0 mg/kg for mesotrione in cranberries

Bush berries and cane berries

GAP in USA for bush and cane berries is 1 post-direct spray at 0.21 kg ai/ha before bloom, with no PHI specified.

In two trials conducted in blueberry in USA according to GAP (application at BBCH 59), residues were < 0.01 mg/kg (77 DAT). In four other trials where the application was done after bloom residues at 32 to 88 DAT were < 0.01 mg/kg.

In four trials conducted with raspberry at GAP, residues at 32 to 88 DAT where < 0.01 mg/kg (4) at 52 to 83 DAT.

As no residues above the LOQ were found even in the late application trials, the Meeting agreed to estimate a maximum residue level of 0.01* mg/kg and a STMR of 0 mg/kg for bush berries and cane berries

Okra

In USA, mesotrione can be applied either at pre-emergence (0.21 kg ai/ha) or post emergence (0.105 kg ai/ha). PHI in both cases is 28 days. Five post-emergence trials conducted according to GAP gave residues < 0.01 mg/kg (5).

The Meeting agreed to recommend a maximum residue level of 0.01* mg/kg, and a STMR of 0.01 mg/kg for mesotrione in okra.

Sweet corn

Mesotrione is registered in Germany for post-emergence use on sweet-corn (BBCH 12–18) at 0.15 kg ai/ha. In four trials conducted in France at this GAP rate gave residues were: < 0.01 mg/kg (4) in the kernels and in the cob at 38 to 61 DAT.

In USA, mesotrione can be used in sweet corn via three application regimes: 1) one pre-emergence application at 0.27 kg ai/ha, 2) two post emergence applications, with a maximum of 0.21 kg ai/ha; or 3) 1× pre + 1× post emergence, with a maximum of 0.27 kg ai/ha. In all cases, the PHI is 45 days. The second application should be done up to the 8 leaf stage. In one trial, conducted according to regime 2, residues in the ears were: < 0.01 mg/kg (2); other two trials conducted at the same rate residue were the same 28 to 32 DAT. In 12 trials conducted a higher rate (0.48 to 0.50 kg ai/ha; regimes 1 or 2 residues were: < 0.01 mg/kg from 23 to 36 DAT.

Although only two trials were conducted in USA according to GAP, 16 trials conducted at higher rate and/or lower PHI showed that no residues are expected in the ears of sweet corn after treatment according to GAP.

The Meeting agreed to estimate a maximum residue level of 0.01* mg/kg and a STMR of 0 mg/kg for mesotrione in sweet corn (kernels plus cob without husk).

Soya bean, dry

In USA, GAP for mesotrione in conventional soya is one pre-emergence application at 0.21 kg ai/ha, with no PHI specified. In sixteen trials conducted according to GAP, residues at 113 to 174 DAT were < 0.01 mg/kg (16). Two trials conducted at higher rates (0.6–1 kg ai/ha) gave the same results.

GAPs for mesotrione tolerant soya are 1) one pre-emergence or 2) early post-mergence (up to BBCH 13) application at 0.225 kg ai/ha, or 3) one pre + one post emergence application (BBCH 14–60) at 0.225 kg ai/ha and 0.125 kg ai/ha, respectively. Twenty seven trials were conducted with tolerant soya using application using regimes 2 or 3, residues in the mature seeds were: < 0.01 (24) and 0.02 (3) mg/kg.

Using the data from trials conducted in tolerant crops, the Meeting agreed to estimate a maximum residue level of 0.03 mg/kg and a STMR of 0.01 mg/kg for mesotrione in soya bean, dry.

Asparagus

In the USA, mesotrione can be use in asparagus either as a pre-emergence application on the soil surface at 0.27 kg ai/ha in the spring prior to spear emergence, one application after completion of harvesting directed to the weed at 0.105 kg ai/ha, or both at a maximum of 0.27 kg ai/ha. In eight trials conducted in USA using the pre-emergence GAP, residues at 8 to 18 DAT were < 0.01 mg/kg (8). In 16 other trials the application was done after emergence of the plant.

The Meeting agreed to estimate a maximum residue level of 0.01*mg/kg and a STMR of 0.01 mg/kg for mesotrione in asparagus.

Rhubarb

In USA, mesotrione can be use in rhubarb as pre-emergence application on the soil surface prior to any spring green-up at 0.21 kg ai/ha and 21 days PHI. In four trials conducted at GAP rate, residues at 28 to 42 DAT were < 0.01 mg/kg. Four trials were conducted at higher rate.

As the PHI is not relevant to a pre-emergence application, the Meeting agreed to estimate maximum residue level of 0.01* mg/kg and a STMR of 0.01 mg/kg for mesotrione in rhubarb.

Maize

Mesotrione is registered in Germany for post-emergence use on maize (BBCH 12–18) at 0.15 kg ai/ha. In two trials conducted in Germany and UK at this GAP gave results at 112 to 143 DAT of < 0.01 mg/kg (2).

In the USA, mesotrione can be used in maize in three application regimes: 1) one pre-emergence at 0.27 kg ai/ha, 2) two post emergence, with a maximum of 0.21 kg ai/ha; or 3) 1× pre + 1× post emergence, with a maximum of 0.27 kg ai/ha. The second application should be done up to the 8 leaf stage. In all cases, the PHI was 45 days. Fifty four trials were conducted in Canada and the USA using two applications, either pre-emergence, post-emergence or a combination of the two, at rates higher than USA GAP. Grain harvested at 68 to 112 DAT gave residues < 0.01 mg/kg.

The results from North American trials conducted at higher rate show that no residues are expected in maize grain after treatment according to GAP.

The Meeting agreed to estimate a maximum residue level of 0.01*mg/kg and a STMR of 0 mg/kg for mesotrione in maize grain.

Millet

Mesotrione is registered in the USA as one pre-emergence use at 0.21 kg ai/ha, and no PHI specified. In five trials conducted according to GAP residues were: < 0.01 mg/kg (5) in millet grain (84 to 132 DAT).

With the support from the data from other cereals, the Meeting agreed to estimate a maximum residue level of 0.01*mg/kg and a STMR of 0 mg/kg for mesotrione in millet grain.

Oat

Mesotrione is registered in USA either as one pre-emergence use at 0.21 kg ai/ha or as a post-emergence application at 0.105 kg ai/ha. PHI is 50 days. In sixteen post-emergence trials at GAP, residues in oat grain were < 0.01 mg/kg (16). Two trials conducted at up to 5 times the rate gave the same results.

The Meeting agreed to estimate a maximum residue level of 0.01*mg/kg and a STMR of 0 mg/kg for mesotrione in oat grain.

Rice

Mesotrione is registered in paddy rice in Republic of Korea as post-planting into the water (5–7 days after transplanting) at 1×0.09 kg ai/ha and no PHI specified. Ten trials were conducted in Republic of Korea and Japan using either a single application at higher rate, two applications at the GAP rate and/or applying latter in the season. In all cases, residues at 45 to 140 DAT were < 0.01 mg/kg.

Although the trials were not according to GAP, these results indicate that no mesotrione residues are expected when the product is used according to GAP.

The Meeting agreed to estimate a maximum residue level of 0.01*mg/kg and a STMR of 0 mg/kg for mesotrione in rice grain, husked.

Sorghum

The registered use for mesotrione in sorghum in the USA is one pre-emergence application at 0.224 kg ai/ha up to 21 days before planting. In nine trials conducted according to GAP, residues at 78 to 134 DAT were < 0.01 mg/kg (9). Twelve post-emergence trials gave the same results.

The Meeting agreed to estimate a maximum residue level of 0.01*mg/kg and a STMR of 0 mg/kg for mesotrione in sorghum.

Sugar cane

The GAP for mesotrione in sugarcane in the USA is either two post-emergence applications at 0.10 kg ai/ha to the base of the sugar cane or a combination of one pre- and one post-emergence application not exceeding a total rate of 0.36 kg ai/ha. PHI is 114 days. In twenty four trials conducted according to either of the GAPs in USA gave residues of < 0.01 mg/kg (24) from 30 to 118 DAT. Two trials conducted at 3 or 5× the rate gave the same results within 114 days PHI.

In South Africa, GAP is a single early post-emergence at 0.15 kg ai/ha, and 181 days PHI. In four trials conducted at higher rate no residues were detected.

The Meeting agreed to estimate a maximum residue level of 0.01*mg/kg and a STMR of 0 mg/kg for mesotrione in sugar cane.

Linseed

Mesotrione is registered in the USA for linseed at one pre or one post-emergence application at 0.21 kg ai/ha, and no PHI specified. Five pre-emergence trials conducted according to GAP gave residues of < 0.01 mg/kg (5). One trial at a higher rate gave the same result.

The Meeting agreed to estimate a maximum residue level of 0.01* mg/kg and a STMR of 0.01 mg/kg for mesotrione in linseed.

Animal feed

Forage

Mesotrione is registered in Germany for post-emergence use on maize (BBCH 12–18) at 0.15 kg ai/ha, and no PHI specified. In three trials conducted in maize in Europe matching German GAP, residues in stover (remaining plant) at 41 DAT were 0.01 mg/kg (3).

In the USA, mesotrione can be used in maize under three application regimes: 1) one pre-emergence at 0.27 kg ai/ha; 2) two post emergence, with a maximum of 0.21 kg ai/ha; or 3) 1× pre + 1× post emergence, with a maximum of 0.27 kg ai/ha. In all cases, PHI was 45 days for forage and stover. The second application should be made up to the 8 leaf stage (or BBCH 19).

In one trial conducted in USA according to GAP, residues in maize forage were 0.12 mg/kg.

Mesotrione is registered in USA in millet as one pre-emergence use at 0.21 kg ai/ha. In five trials conducted at GAP, residues in forage were < 0.01 mg/kg

The Meeting estimated a median residue and a highest residue of 0.01 mg/kg for mesotrione in millet forage

Mesotrione is registered in oats in USA either as one pre-emergence use at 0.21 kg ai/ha or as post-emergence application at 0.105 kg ai/ha. In 16 pre-emergence trials and 16 post-emergence US trials matching GAP, residues in oat forage were < 0.01 mg/kg (32).

The Meeting estimated a median residue and a highest residue of 0.01 mg/kg for mesotrione in oat forage.

The registered use for mesotrione in sorghum in USA is one pre-emergence application at 0.224 kg ai/ha up to 21 days before planting. In 13 trials conducted according to GAP, residues in sorghum forage were < 0.01 mg/kg (13).

The Meeting estimated a median residue and a highest residue of 0.01 mg/kg for mesotrione in sorghum forage.

Hay

In 16 pre-emergence trials and 16 post-emergence trials conducted in oats in USA, matching GAP, residues in oat hay were < 0.01 mg/kg (32). Post-emergence application trials gave the same results.

In five trials conducted in millet at GAP, residues in hay were < 0.01 mg/kg.

The Meeting estimated a median residue of 0.01 mg/kg and a highest residue of 0.01 mg/kg for mesotrione in oat hay and millet hay.

Straw

Mesotrione is registered in paddy rice in Korea as post-planting into the water (5-7 days after transplanting) at 1x0.09 kg ai/ha and no PHI specified. In eight trials conducted in Japan at this GAP gave residues in straw of < 0.002 mg/kg.

The Meeting agreed to estimate a maximum residue level of 0.01* mg/kg for mesotrione in rice straw and fodder, dry

The Meeting estimates a median residue and a highest residue of 0.01 mg/kg for mesotrione in rice straw

Fate of residues during processing

A processing study conducted with soya bean containing 0.04 mg/kg mesotrione showed residues of 0.01 mg/kg in the meal and 0.07 mg/kg in flour, with calculated processing factors of 0.25 and 1.8 mg/kg, respectively. Residues in soya oil, milk, tofu, sauce and miso were < 0.01 mg/kg, with an estimated processing factor of < 0.25. Based on a STMR of 0.01 mg/kg for soya bean, dry, the Meeting estimated a STMR-P of 0.018 mg/kg in soya bean flour, and of 0.002 mg/kg for soya oil, milk, tofu, sauce and miso.

Residue in animal commodities

Farm dietary burden

The Meeting estimated the dietary burden of mesotrione in farm animals on the basis of the OECD Animal Feed data published in the 2009 FAO Manual, and the median and highest residue levels estimated at the present Meeting for oat and sorghum forage, oat hay and rice straw.

The maximum and the mean dietary burden was 0.03 ppm for cattle, 0.01 and 0.001 ppm, for swine, respectively, and 0 ppm for poultry.

Animal commodity maximum residue level

No feeding study on mesotrione was provided to the Meeting. The metabolism study conducted with cattle at 10 ppm, gave residues of mesotrione up to 0.02 mg/kg in tissues and milk. Swine fed with radiolabeled mesotrione at 6 ppm gave residues of 1.5 mg/kg in liver, 0.09 mg/kg in kidney and 0.01 mg/kg in muscle. Interpolation of the residues found in the metabolism studies to what would be expected at the calculated dietary burden indicates that no residue will exceed 0.0025 mg/kg (in swine liver).

The Meeting agreed to estimate a maximum residue level of 0.01* mg/kg for mesotrione in milks, edible offal (mammalian) and meat (from mammals other than marine mammals).

The Meeting also estimated a STMR of 0 for mesotrione in milk and meat (from mammals other than marine mammals), and edible offal (mammalian).

Metabolism study conducted with poultry at 11 ppm showed mesotrione residues of 1.1 mg/kg in liver, 0.03 mg/kg in fat, < 0.01 mg/kg in meat and 0.02 mg/kg in eggs. As the dietary burden for poultry is 0, the Meeting agreed to estimate a maximum residue level of 0.01* mg/kg, and a STMR and a HR of 0 mg/kg for mesotrione poultry meat, poultry offal and eggs.

RECOMMENDATIONS

Definition of the residue (for compliance with the MRL and for estimation of dietary intake for plant and animal commodities): mesotrione.

The residue is not fat soluble.

DIETARY RISK ASSESSMENT

Long-term intake

The IEDI of mesotrione based on the STMRs estimated by this Meeting for the 17 GEMS/Food regional diets were 0% of the maximum ADI of 0–0.3 mg/kg bw (see Annex 3 of the 2014 Report). The Meeting concluded that the long-term dietary intake of residues of mesotrione is unlikely to present a public health concern.

Short-term intake

The 2014 JMPR decided that an ARfD is unnecessary for mesotrione. The Meeting therefore concluded that the short-term intake of residues of mesotrione is unlikely to present a public health concern.

5.20 METRAFENONE (278)

TOXICOLOGY

Metrafenone is the ISO-approved common name for (3-bromo-6-methoxy-2-methylphenyl) (2,3,4-trimethoxy-6-methylphenyl)-methanone (IUPAC), for which the CAS number is 220899-03-6.

Metrafenone is a fungicide for the control of *Erysiphe graminis* and *Pseudocercosporella herpotrichoides* (eyespot and powdery mildew) and for the control of *Uncinaria necator* (powdery mildew). It inhibits the growth of the mycelium on the leaf surface, leaf penetration, the formation of haustoria and sporulation.

Metrafenone has not been evaluated previously by JMPR and was reviewed by the present Meeting at the request of CCPR.

All critical studies contained statements of compliance with GLP.

Biochemical aspects

Following gavage dosing in rats, absorption of metrafenone was rapid and complete (> 88%) at the low dose of 10 mg/kg bw but was limited to 15–20% at the high dose of 1000 mg/kg bw, suggesting saturation of the absorption processes. Metrafenone was widely distributed in the body, with highest residue levels found mainly in the gastrointestinal tract, liver and fat. There was no evidence of accumulation. The labelled material was relatively rapidly excreted into the gastrointestinal tract via the bile (85–90%), resulting in extensive excretion via faeces. Excretion via urine was relatively low at 10 mg/kg bw (5–6%), and even lower at the high dose of 1000 mg/kg bw (~1%). Metrafenone was extensively metabolized, with most of the labelled products excreted as glucuronic acid conjugates in bile and urine. Five possible sites of conjugation with glucuronic acid were identified, following *O*-demethylation of the molecule. Residues in faeces consisted primarily of parent compound and the aglycones of bile and urine conjugates. The transformation steps included:

- *O*-demethylation of the aromatic methoxy group(s) followed by mono-*O*-glycosidation;
- hydroxylation of the bromophenyl ring; and
- hydroxylation of the methyl substituent to hydroxymethyl followed by *O*-glycosidation or further oxidation to aldehyde or lactone.

The bond between the bromophenyl ring and trimethoxyphenyl ring remained intact.

Toxicological data

Metrafenone has low acute toxicity when administered orally and dermally (LD_{50}s > 5000 mg/kg bw) and via inhalation (LC_{50} > 5 mg/L) to rats. No studies on skin and eye irritation or skin sensitization were available.

The major target organ for toxicity was the liver in short-term and long-term studies in mice and rats. Increased liver weight was the most common finding. Hepatocyte vacuolation was observed in rats, and hepatocyte hypertrophy was observed in mice. In the long-term studies, the kidneys were also a target organ in rodents, as chronic nephropathy was observed (with or without increased kidney weights). Chronic nephropathy observed only in male rats would not normally be considered relevant for a human risk assessment; however, this finding was observed in mice and both sexes of rats and therefore was considered relevant for the risk assessment.

In two 90-day studies of toxicity, mice were treated with metrafenone either at a dietary concentration of 0, 1000, 3500 or 7000 ppm (equal to 0, 163, 622 and 1206 mg/kg bw per day for males and 0, 216, 788 and 1663 mg/kg bw per day for females, respectively) or at a dietary concentration of 0, 250 or 500 ppm (equal to 0, 42 and 84 mg/kg bw per day for males and 0, 55 and 113 mg/kg bw per day for females, respectively). The overall NOAEL was 1000 ppm (equal to

163 mg/kg bw per day), on the basis of liver effects (increased total bilirubin, increased liver weight and centrilobular hepatocellular hypertrophy) observed at 3500 ppm (equal to 622 mg/kg bw per day).

In two 90-day studies of toxicity, rats were treated with metrafenone either at a dietary concentration of 0, 1000, 5000, 10 000 or 20 000 ppm (equal to 0, 79, 404, 800 and 1663 mg/kg bw per day for males and 0, 94, 486, 967 and 1938 mg/kg bw per day for females, respectively) or at a dietary concentration of 0, 250 or 500 ppm (equal to 0, 21 and 43 mg/kg bw per day for males and 0, 24 and 48 mg/kg bw per day for females, respectively). The overall NOAEL was 1000 ppm (equal to 79 mg/kg bw per day), on the basis of effects on liver (increased cholesterol and total protein, increased liver weight and periportal hepatocellular vacuolation) noted at 5000 ppm (equal to 404 mg/kg bw per day). This overall NOAEL was supported by findings in a 28-day dose range–finding study.

In 90-day and 1-year studies, dogs received metrafenone via oral capsule at 0, 50, 100 or 500 mg/kg bw per day. The overall NOAEL was 500 mg/kg bw per day, the highest dose tested, because minor changes in liver weight and/or clinical chemistry parameters were not accompanied by any microscopic abnormality and were therefore not considered adverse. This overall NOAEL was supported by findings in a 28-day dose range–finding study.

In an 18-month dietary toxicity and carcinogenicity study, mice were treated with metrafenone at 0, 250, 1000 or 7000 ppm (equal to 0, 39, 156 and 1109 mg/kg bw per day for males and 0, 53, 223 and 1492 mg/kg bw per day for females, respectively). Significant treatment-related effects were observed in the liver, kidneys and spleen at 1000 ppm (equal to 156 mg/kg bw per day) and above. Increased incidence and severity of extramedullary haematopoiesis in the spleen of female mice were recorded. Increased incidence and severity of chronic nephropathy in the kidneys (more severe in males) were recorded. Liver effects included increased weights (more severe in females) and increased incidence and severity of centrilobular and diffuse hepatocellular hypertrophy (more severe in males). The NOAEL for chronic toxicity was 250 ppm (equal to 39 mg/kg bw per day). The NOAEL for carcinogenicity was 1000 ppm (equal to 156 mg/kg bw per day), based on a treatment-related increase in hepatocellular adenomas and carcinomas in high-dose male mice at 7000 ppm (equal to 1109 mg/kg bw per day).

In a 2-year dietary study of toxicity and carcinogenicity, rats were treated with metrafenone at 0, 500, 5000 or 20 000 ppm; the dietary concentration for the high-dose females was reduced from 20 000 to 10 000 ppm beginning with study week 69 (doses equal to 0, 25, 260 and 1069 mg/kg bw per day for males and 0, 30, 320 and 1419 mg/kg bw per day [up to the end of week 68] or 593 mg/kg bw per day [weeks 72–104] for females, respectively). Body weight gains were reduced, and the liver and kidney were the target organs. Kidney effects included increased weights and increased incidence and severity of chronic nephropathy in both sexes. Effects on the liver were generally more marked in females and included increased weights, histopathological effects consistent with liver enlargement, such as centrilobular hypertrophy, and polyploidy and necrosis. The NOAEL for chronic toxicity was 500 ppm (equal to 25 mg/kg bw per day), based on effects on body weight, liver and kidney at 5000 ppm (equal to 260 mg/kg bw per day). The NOAEL for carcinogenicity was 500 ppm (equal to 30 mg/kg bw per day), based on an increased incidence of hepatocellular adenoma at the intermediate and high dose levels in females, with an equivocal response in high-dose males (LOAEL of 5000 ppm, equal to 320 mg/kg bw per day).

The Meeting concluded that metrafenone is carcinogenic in mice and rats.

Mechanistic studies in rats did not reveal tumour initiating potential in rat liver and showed that the treatment-related liver tumours identified in mice and rats were induced by a mechanism that is non-genotoxic and is expected to have a threshold. The postulated mechanism is that metrafenone induces an increased rate of hepatocyte proliferation (cytochrome P450 enzyme induction as an associated marker); continuing exposure to metrafenone leads to chronic stimulation of proliferation, which is a known mechanism that can give rise to tumours. Levels of exposure that are insufficient to

give rise to induction of liver enzymes and liver cell proliferation would not be expected to cause liver tumours following chronic exposure.

Metrafenone was tested for genotoxicity in an adequate range of assays, both in vitro and in vivo. No evidence of genotoxicity was found.

The Meeting concluded that metrafenone is unlikely to be genotoxic.

In view of the lack of genotoxicity and the fact that the observed carcinogenicity in mice and rats is expected to have a threshold, the Meeting concluded that metrafenone is unlikely to pose a carcinogenic risk to humans from the diet.

In a two-generation study of reproductive toxicity, rats were given a diet containing metrafenone at a concentration of 0, 500, 1000 or 10 000 ppm (equal to 0, 39, 79 and 811 mg/kg bw per day based on the average combined premating values for P and F_1 males and females). The NOAEL for effects on reproductive parameters was 1000 ppm (equal to 79 mg/kg bw per day), based on an increased proportion of abnormal sperm in F_1 males at 10 000 ppm (equal to 811 mg/kg bw per day), although there were no clear effects on reproductive performance at any dose. The NOAEL for parental toxicity was 500 ppm (equal to 39 mg/kg bw per day), based on effects on body weight gain in F_1 parental males at 1000 ppm (equal to 79 mg/kg bw per day). The NOAEL for effects on pups was 1000 ppm (equal to 79 mg/kg bw per day), based on adverse effects on pup weights and increased liver weights at 10 000 ppm (equal to 811 mg/kg bw per day).

In a study of prenatal developmental toxicity, rats received metrafenone via gavage at 0, 50, 500 or 1000 mg/kg bw per day. There was no evidence of either maternal or embryo/fetal toxicity. The NOAEL for both maternal and embryo/fetal toxicity was 1000 mg/kg bw per day, the highest dose tested.

In a study of prenatal developmental toxicity, rabbits received metrafenone via gavage at 0, 50, 350 or 700 mg/kg bw per day. The NOAEL for maternal toxicity was 50 mg/kg bw per day, based on lower body weight gains and feed consumption, increased liver weights and histopathological effects in the liver at 350 and 700 mg/kg bw per day. The NOAEL for embryo and fetal toxicity was 350 mg/kg bw per day, based on decreased fetal weights at 700 mg/kg bw per day.

The Meeting concluded that metrafenone is not teratogenic.

In an acute neurotoxicity study, rats received metrafenone via gavage at 0, 125, 500 or 2000 mg/kg bw per day. The NOAEL was 2000 mg/kg bw, the highest dose tested.

In a 28-day neurotoxicity study, rats were given a diet containing metrafenone at a concentration of 0, 1500, 5000 or 15 000 ppm (equal to 0, 143, 459 and 1371 mg/kg bw per day for males and 0, 152, 493 and 1371 mg/kg bw per day for females, respectively). The NOAEL for systemic toxicity was 1500 ppm (equal to 143 mg/kg bw per day), based on clinical signs (piloerection and red discoloured urine) at 5000 ppm (equal to 459 mg/kg bw per day). The NOAEL for neurotoxicity was 15 000 ppm (equal to 1371 mg/kg bw per day), the highest dose tested.

The Meeting concluded that metrafenone is not neurotoxic.

In a 28-day immunotoxicity study, female rats were given a diet containing metrafenone at a concentration of 0, 1000, 4000 or 12 000 ppm (equal to 0, 80, 315 and 1086 mg/kg bw per day, respectively). The NOAEL for immunotoxicity was 12 000 ppm (equal to 1086 mg/kg bw per day), the highest dose tested. The NOAEL for systemic toxicity was 1000 ppm (equal to 80 mg/kg bw per day), based on significantly increased absolute and relative liver weights observed at 4000 ppm (equal to 315 mg/kg bw per day).

The Meeting concluded that metrafenone is not immunotoxic.

Toxicological data on metabolites and/or degradates

No metabolites of concern were identified.

Human data

In reports on manufacturing plant personnel, no adverse health effects were noted.

The Meeting concluded that the existing database on metrafenone was adequate to characterize the potential hazards to fetuses, infants and children.

Toxicological evaluation

An ADI of 0–0.3 mg/kg bw was established, on the basis of the NOAEL of 25 mg/kg bw per day for liver and kidney effects in the 2-year dietary study in rats, using a safety factor of 100. The upper bound of the ADI provides a margin of exposure of at least 1000 relative to the LOAEL for the induction of liver tumours in rats and mice.

The Meeting concluded that it was not necessary to establish an ARfD for metrafenone in view of its low acute oral toxicity and the absence of developmental toxicity and any other toxicological effects that would be likely to be elicited by a single dose.

A toxicological monograph was prepared.

Levels relevant to risk assessment of metrafenone

Species	Study	Effect	NOAEL	LOAEL
Mouse	Eighteen-month study of toxicity and carcinogenicity[a]	Toxicity	250 ppm, equal to 39 mg/kg bw per day	1 000 ppm, equal to 156 mg/kg bw per day
		Carcinogenicity	1 000 ppm, equal to 156 mg/kg bw per day	7 000 ppm, equal to 1 109 mg/kg bw per day
Rat	Ninety-day studies of toxicity[a,b]	Toxicity	1 000 ppm, equal to 79 mg/kg bw per day	5 000 ppm, equal to 404 mg/kg bw per day
	Two-year study of toxicity and carcinogenicity[a]	Toxicity	500 ppm, equal to 25 mg/kg bw per day	5 000 ppm, equal to 260 mg/kg bw per day
		Carcinogenicity	500 ppm, equal to 30 mg/kg bw per day	5 000 ppm, equal to 320 mg/kg bw per day
	Two-generation study of reproductive toxicity[a]	Reproductive toxicity	1 000 ppm, equal to 79 mg/kg bw per day	10 000 ppm, equal to 811 mg/kg bw per day
		Parental toxicity	500 ppm, equal to 39 mg/kg bw per day	1 000 ppm, equal to 79 mg/kg bw per day
		Offspring toxicity	1 000 ppm, equal to 79 mg/kg bw per day	10 000 ppm, equal to 811 mg/kg bw per day
	Developmental toxicity study[c]	Maternal toxicity	1 000 mg/kg bw per day[d]	–
		Embryo and fetal toxicity	1 000 mg/kg bw per day[d]	–
Rabbit	Developmental toxicity study[c]	Maternal toxicity	50 mg/kg bw per day	350 mg/kg bw per day
		Embryo and fetal toxicity	350 mg/kg bw per day	700 mg/kg bw per day
Dog	Ninety-day and 1-year studies of toxicity[b,c]	Toxicity	500 mg/kg bw per day[d]	–

[a] Dietary administration.
[b] Two or more studies combined.
[c] Gavage or capsule administration.

[d] Highest dose tested.

Estimate of acceptable daily intake (ADI)

0–0.3 mg/kg bw

Estimate of acute reference dose (ARfD)

Unnecessary

Information that would be useful for the continued evaluation of the compound

Results from epidemiological, occupational health and other such observational studies of human exposures.

Critical end-points for setting guidance values for exposure to metrafenone

Absorption, distribution, excretion and metabolism in mammals	
Rate and extent of oral absorption	> 88% within 72 hours at 10 mg/kg bw; 15–20% within 72 hours at 1 000 mg/kg bw
Dermal absorption	1.8% for the concentrate and 19% for a 1/2 000 aqueous dilution
Distribution	Widely distributed; highest concentrations in gastrointestinal tract and liver
Potential for accumulation	No evidence of accumulation
Rate and extent of excretion	67–79% (mainly in faeces via bile) within 24 hours at 10 mg/kg bw
Metabolism in animals	Extensive; mostly O-demethylation and subsequent conjugation with glucuronic acid
Toxicologically significant compounds in animals and plants	Parent compound
Acute toxicity	
Rat, LD_{50}, oral	> 5 000 mg/kg bw
Rat, LD_{50}, dermal	> 5 000 mg/kg bw
Rat, LC_{50}, inhalation	> 5 mg/L
Rabbit, dermal irritation	No data
Rabbit, ocular irritation	No data
Dermal sensitization	No data
Short-term studies of toxicity	
Target/critical effect	Liver / increased weights and associated histopathological findings
Lowest relevant oral NOAEL	79 mg/kg bw per day (90-day study in rats)
Lowest relevant dermal NOAEL	1 000 mg/kg bw per day (28-day study in rats)
Lowest relevant inhalation NOAEC	No data
Long-term studies of toxicity and carcinogenicity	
Target/critical effect	Liver / hepatocyte hypertrophy and hepatocellular adenomas
Lowest relevant NOAEL	25 mg/kg bw per day (2-year study in rats)

Carcinogenicity	Hepatocellular adenomas and carcinomas in male mice (at 1 109 mg/kg bw per day) and hepatocellular adenomas in female rats (at 320 mg/kg bw per day)
	Non-genotoxic mechanism proposed (chronic induction of cell proliferation/enzyme induction)
	Unlikely to pose a carcinogenic risk to humans from the diet
Genotoxicity	
	Unlikely to be genotoxic
Reproductive toxicity	
Target/critical effect	Reduced pup weights (F_1 and F_2) and increased proportion of abnormal sperm (F_1 only) with no adverse effects on reproductive performance in the presence of parental toxicity
Lowest relevant parental NOAEL	39 mg/kg bw per day
Lowest relevant offspring NOAEL	79 mg/kg bw per day
Lowest relevant reproductive NOAEL	79 mg/kg bw per day
Developmental toxicity	
Target/critical effect	Lower fetal body weight at maternally toxic doses (rabbit)
Lowest relevant maternal NOAEL	50 mg/kg bw per day (rabbit)
Lowest relevant embryo/fetal NOAEL	350 mg/kg bw per day (rabbit)
Neurotoxicity	
Acute neurotoxicity NOAEL	2 000 mg/kg bw (highest dose tested)
Subchronic neurotoxicity NOAEL	1 371 mg/kg bw per day (highest dose tested)
Developmental neurotoxicity NOAEL	No data
Other toxicological studies	
Immunotoxicity NOAEL	1 086 mg/kg bw per day, highest dose tested
Studies on toxicologically relevant metabolites	No metabolites of concern were identified
Mechanistic studies	Reversible induction of P450 enzymes and cell proliferation in rat liver; no tumour initiating potential in rat liver
Medical data	
	No evidence of adverse effects in personnel exposed to metrafenone; no incident reports

Summary

	Value	Study	Safety factor
ADI	0–0.3 mg/kg bw	Two-year toxicity and carcinogenicity study (rat)	100
ARfD	Unnecessary	–	–

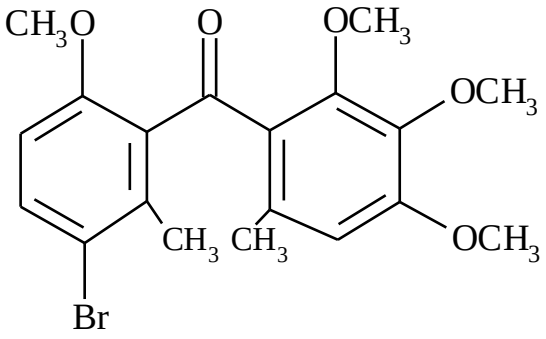
RESIDUE AND ANALYTICAL ASPECTS

Metrafenone is a benzophenone fungicide, active mainly against powdery mildews and eyespot, inhibiting mycelium growth, leaf penetration, haustoria formation and sporulation.

It was scheduled by the Forty-fifth Session of the CCPR as a new compound for consideration by the 2014 JMPR. The manufacturer submitted studies on metabolism, analytical

methods, supervised field trials, processing, freezer storage stability, environmental fate in soil and rotational crop residues.

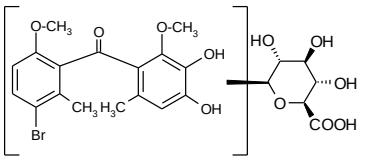
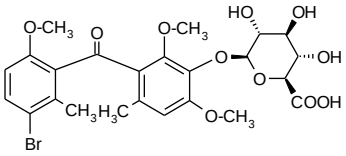
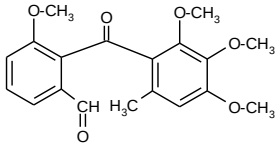
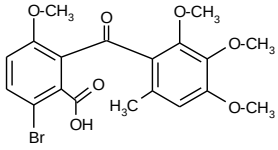
Authorisations exist for the use of metrafenone on cereals, grapes, strawberries and fruiting vegetables in over 50 countries in Europe, the Americas, Asia and the Pacific.

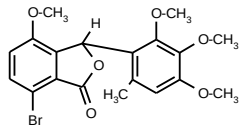
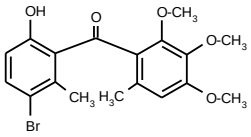
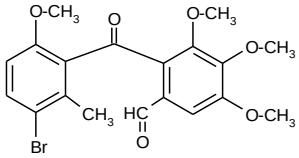
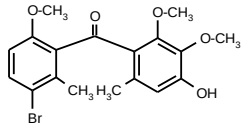
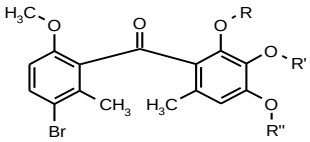


Metrafenone
(MW 409.3)

The following abbreviations are used for the major metabolites discussed below:

Table 1 Major metrafenone metabolites identified in plant, animal and soil matrices

Code	Structure	Chemical Name	Occurrence
CL 1023363		3-(3-bromo-6-methoxy-2-methylbenzoyl)-6-hydroxy-2-methoxy-4-methylphenyl β-D-glucopyranosiduronic acid Mono-O-glucuronide of Methanone, (3-bromo-6-hydroxy-2-methylphenyl)(3,4-dihydroxy-2-methoxy-6-methylphenyl-	goat
CL 1500698		3-(3-bromo-6-methoxy-2-methylbenzoyl)-2,6-dimethoxy-4-methylphenyl β-D-glucopyranosiduronic acid Methanone, (3-bromo-6-methoxy-2-methylphenyl)[3-beta-D-glucopyranuronosyloxyl)-2,4-dimethoxy-6-methylphenyl-	rat, goat
CL 1500836		3-methoxy-2-(2,3,4-trimethoxy-6-methylbenzoyl) benzaldehyde	wheat grape
CL 197675		Methanone, (3-bromo-6-methoxy-2-carboxyl)(2,3,4-trimethoxy-6-methylphenyl)-	grape

Code	Structure	Chemical Name	Occurrence
CL 3000402		7-bromo-4-methoxy-3-(2,3,4-trimethoxy-6-methylphenyl)-2-benzofuran-1(3H)-one	rat wheat grape
CL 376991		Methanone, (3-bromo-6-methoxy-2-methylphenyl)(2,3,4-trimethoxy-6-methylphenyl)-	rat wheat
CL 379395		2-(3-bromo-6-methoxy-2-methylbenzoyl)-3,4,5-trimethoxybenzaldehyde	grape
CL 434223		Methanone, (3-bromo-6-methoxy-2-methylphenyl)(4-hydroxy-2,3-dimethoxy-6-methylphenyl)-	rat wheat
M560F06	 R = H, R' and R" = CH_3 or R' = H, R and R" = CH_3 or R" = H, R and R' = CH_3	Methanone, (3-bromo-6-methoxy-2-methylphenyl)(2-hydroxy-3,4-dimethoxy-6-methylphenyl)- or Methanone, (3-bromo-6-methoxy-2-methylphenyl)(3-hydroxy-2,4-dimethoxy-6-methylphenyl)- or Methanone, (3-bromo-6-methoxy-2-methylphenyl)(4-hydroxy-2,3-dimethoxy-6-methylphenyl)-	hen

Animal metabolism

The Meeting received information on the metabolism of ^{14}C-metrafenone, separately labelled at the bromophenyl and the trimethoxyphenyl groups, in rats, lactating goats and laying hens. As no cleavage of the molecule was observed in these metabolism studies, the results for both radiolabels are reported together.

The metabolism of metrafenone in rats was evaluated by the WHO Core Assessment Group of the 2014 JMPR. Absorption of metrafenone is rapid and complete (> 88%) at the low dose of 10 mg/kg bw, limited to 15–20% at the high dose of 1000 mg/kg bw suggesting saturation of the absorption processes. Metrafenone is widely distributed in the body, with highest residue levels mainly found in the gastro-intestinal (GI) tract, liver and fat. There is no evidence of accumulation. The labelled material is relatively rapidly excreted into the GI tract via the bile (85–90%) resulting in extensive excretion via faeces. Excretion via urine is relatively low (5–6% depending on radiolabel position), and even lower at the high dose level (approximately 1%). Metrafenone is extensively metabolised, with most of the radioactivity (approximately 80%) not identified, consisting of many (11–26) different components and totalling < 0.1 ppm at the low dose and < 1 ppm at the high dose. The identified metabolites, mostly < 1.0 mg eq./kg, included metrafenone and glucuronic acid conjugates in fat, liver and kidney.

Lactating goats

Lactating goats were orally dosed with ^{14}C-metrafenone at doses equivalent to about 10 ppm (8–13 ppm) and 70 ppm (60–87 ppm) in the feed for 5 consecutive days and sacrificed 23 hours after the last dose.

The majority of the radioactivity (76–86% AR) was excreted, mainly through the faeces. The highest residue levels were found in liver (0.21-0.23 mg eq./kg at the lower dose and 0.72–1.3 mg eq./kg at the higher dose) and kidney (0.05–0.06 mg eq./kg at the low dose and 0.16–0.33 mg eq./kg at the higher dose). Residues were significantly lower in fat (0.015–0.022 mg eq./kg at the high dose rate) and were ≤ 0.01 mg eq./kg in muscle and milk regardless of the dose rate. Residues reached a plateau in milk (0.01 mg eq./kg) within 3 days.

Residue characterization and identification was conducted on samples from the high dose groups with more than 95% TRR could be extracted from liver, kidney, milk and fat. Muscle samples were not investigated further because of the low TRR levels (< 0.01 mg eq./kg).

In fat, the predominant residue was metrafenone (0.01–0.02 mg/kg), making up 60–85% TRR and no other residues above 0.005 mg eq./kg (9% TRR) were found.

In liver and kidney, metrafenone made up about 3-4% TRR. The predominant residues were the glucuronide metabolites CL 1500698 and CL 1023363, not measured individually but together represented up to 15-21% TRR (0.27 mg eq./kg) in liver and up to 26–28% TRR (max 0.09 mg eq./kg) in kidney. An additional radiolabel fraction that included the glucuronide metabolites CL 1023361, CL1023362 and CL 1500702 totalled about 9–14% of TRR (max 0.17 mg eq./kg in liver and 0.03 mg.kg in kidney). About half the TRR was made up of a number of other unidentified metabolites, each present at < 5% TRR.

In milk, residues of metrafenone (24% TRR) and numerous metabolites, including one radiolabel fraction containing CL 1500698 and CL 1023363 (11% TRR), were all < 0.005 mg eq./kg.

Laying hens

In a poultry study laying hens were orally dosed with ^{14}C-metrafenone at doses equivalent to about 14 ppm in the feed for 12 consecutive days and sacrificed 22 hours after the last dose.

The majority (86-95%) of the administered dose was excreted, with about 0.25% AR (0.1 mg eq./kg) remaining in eggs, up to 0.09% AR (0.3-0.5 mg eq./kg) found in liver, < 0.01 % AR (0.06–0.08 mg eq./kg) present skin+fat and 0.003% AR (0.01 mg eq./kg) in muscle. Residues reached a plateau in eggs after 9 days.

Extraction was able to retrieve about 80% TRR from eggs, 60% TRR from skin+fat and about 30% TRR in liver and muscle. Characterisation and identification of residues in solvent-extracted samples indicated the presence of numerous polar and non-polar components. The one identified metabolite M560F06 was found in poultry skin+fat (6-11% TRR, < 0.01 mg eq,/kg) and was identified but not quantified in eggs.

Metrafenone was found only in eggs and skin+fat, making up about 2% TRR (0.001-0.002 mg/kg) and the metabolite M560F06 was also measured in skin+fat (6–11% TRR) and identified in eggs. With the exception of one unknown component in eggs (about 14% TRR, 0.015 mg eq./kg) all other metabolites were <10% TRR (< 0.01 mg eq./kg) in all tissues and eggs.

In summary, residues were rapidly eliminated in the excreta (76–95% of the dose) with up to 0.5% of the total administered dose remaining in liver, 0.25% remaining in eggs, and TRRs were up to 0.02 mg eq./kg in fat and ≤0.01 mg eq./kg in muscle, poultry skin+fat and in milk.

The proposed metabolic pathways include hydroxylation and demethylation of the methyl groups and the phase II glucuronidation of the hydroxylated metabolites to various mono-O-glucuronides, qualitatively similar to the metabolic pathway in the rat.

Metrafenone made up about 2–4% of the TRR in liver, kidney, eggs and poultry skin+fat, was the main component in fat and was about 24% TRR in milk, but at very low levels (< 0.005 mg eq./kg). Most of the residues in liver and kidney were the glucuronide conjugates of metrafenone (CL 1500698, CL 1023363) which together made up 15–30% TRR, and numerous unidentified components, each present at < 10% TRR.

Plant metabolism

The Meeting received information on the metabolism of ^{14}C-metrafenone, separately labelled at the bromophenyl and the trimethoxyphenyl groups, in grapes, cucumber and wheat.

Grape

In outdoor grapevines treated with five foliar applications of ^{14}C-metrafenone at a rate equivalent to 0.2 kg ai/ha, 10–11 days apart, TRRs in grapes immediately after the last application were 0.6–0.77 mg eq./kg, reducing to 0.28–0.44 mg eq./kg at maturity, 35 days later. In leaves sampled immediately after the last application, TRRs were 40–42 mg eq./kg, reducing to 25–38 mg eq./kg after 35 days.

In grape juice, pomace and in leaves, 77–100% TRR was able to be sequentially extracted with acetone, methanol:water and water, with about 39–45% of the TRR in leaves being present in the acetone surface wash. Whole grapes were not analysed.

Metrafenone was not found in juice, but was the major residue in pomace (23–25% TRR, 0.06–0.11 mg/kg), and made up about 11–15% TRR in mature leave (35 days after the last application).

Characterisation of the residues in grape juice and pomace indicated the presence of several chromatographic fractions more polar than the parent, not exceeding 0.05 mg eq./kg and not more than 17% TRR. These were not identified further except for CL197675, found in juice at about 9% TRR (0.006 mg eq./kg).

Cucumber

In cucumber plants (confined) treated with two foliar applications of ^{14}C-metrafenone, applied 17 and 3 days before harvest, at a rate equivalent to 0.2 kg ai/ha, TRR in mature fruit, sampled 3 days after the second application were about 0.05 mg eq./kg (TRR), with 0.013 mg eq./kg present in pulp and 0.26 mg eq./kg in peel. More than 89% TRR was able to be extracted with methanol.

Metrafenone was the only identified residue component, making up 42% of the TRR in the mature fruit (0.02 mg/kg), and mostly in the peel (61% TRR, 0.16 mg/kg). Metrafenone also made up about 80% TRR in vines (without roots and fruit) at harvest.

Numerous polar and medium polar metabolites, characterized by their HPLC retention times and elution profiles, were present in fruit and vines at low concentrations (each less than 9% TRR).

Wheat

In outdoor wheat plants treated with 3 foliar applications of ^{14}C-metrafenone at rates equivalent to 0.3, 0.3 and 0.2 kg ai/ha, applied at 13–14 day intervals and with the last application being 35 days before harvest, highest radioactive residues (up to 9 mg eq./kg) were found in hay and straw, with the lowest residues found in the grain (0.2–0.4 mg eq./kg). The TRR in foliage, 3 days after the first application were 5–8 mg eq./kg. Methanol:water extraction was able to release about 95% TRR in foliage, 78% TRR in hay, 61% TRR in straw and 35% TRR in grain. Additional extraction with hexane and acidified methanol was able to release a further 12–14% TRR in grain.

Metrafenone was the major component in all matrices, about 59–64% TRR in foliage, 13–26% TRR in hay, 8–14% in straw and 3–8% TRR in grain.

Other characterized or identified metabolites in foliage, hay and straw each represented less than 10% TRR. In grain, no identified metabolites were found above 0.004 mg eq./kg and although only about 50% of the radioactivity was extracted, further investigation showed that residues in the PES were made up of multiple minor components.

The proposed metabolic pathway involves oxidation of the methyl groups on the bromophenyl and trimethoxyphenyl rings to yield the corresponding aldehydes. In the case of the bromophenyl ring, the aldehyde can undergo further oxidation to the carboxylic acid, cyclization to form the lactone, and/or dehalogenation to form the des-bromo aldehyde.

In summary, metrafenone is the predominant residue in crops, with numerous minor metabolites or fractions present at low concentrations and generally more polar than the parent. While these were not all identified or quantified, individual peaks were < 10% TRR or < 0.01 mg eq./kg.

Environmental fate

The Meeting received information the environmental fate and behaviour of metrafenone, including hydrolytic stability, photolysis in aqueous solutions, aerobic metabolism and rotational crop metabolism studies.

Metrafenone was stable in sterile buffered solutions at pH 4, 7, and 9 but rapidly degraded in aqueous pH 7 solutions by photolysis (DT_{50} values of 2.6–3.1 days) with the formation of multiple degradation products, all found at < 10% of the applied radioactivity. DT_{90} values were 8.5 days (natural water) and 10.2 days (sterile water).

Aerobic soil metabolism

Metrafenone degraded slowly in loamy sand, sandy loam and clay loam soils treated with the equivalent of about 0.1 kg ai/ha [bromophenyl-label]-metrafenone or [trimethoxy-label]-metrafenone and incubated for up to 210 days under aerobic laboratory conditions. Metrafenone made up about 82% AR after 120-days and 66–69% AR after 210 days. Calculated half-lives (1st order kinetics) ranged from 182–365 days.

Residues in succeeding crops

In one outdoor rotational crop metabolism study, a leafy vegetable crop (lettuce), root crop (radish) and oil crop (canola) were planted back at various time intervals (30, 60, 90 and 365 days) after a single application of [trimethoxy-label]-metrafenone or [bromophenyl-label]-metrafenone to bare soil at a rate equivalent to 0.625 kg ai/ha.

The uptake of residues in these representative rotational crops (lettuce, radish, canola) was low, with TRRs at all plant-back intervals ranging from < 0.004 to 0.048 mg eq./kg (in canola pods), generally highest in the samples from the 30-day plant back interval. In soil, radioactive residues declined by about 50% after 90 days, and were mostly found in the top 10 cm of soil samples.

Total extractable residues ranged from 64% to 88% TRR in the majority of the samples (42–86% TRR in canola seed) and comprised mostly of multiple unidentified polar components, all present at < 0.02 mg eq./kg. Metrafenone accounted for 0.004 mg/kg of the TRR in lettuce (90 DAT) and radish roots (30 DAT) and was not found in canola or radish tops.

In summary, metrafenone is stable to hydrolysis, rapidly degraded by photolysis, slowly degraded in soil under aerobic conditions (remaining mostly in the top 10 cm) and not found at significant levels in rotational crops. The Meeting concluded that residues are not expected in rotational crops following treatments according to the GAPs under consideration.

Analytical methods

Several analytical methods have been reported and validated for the analysis of metrafenone in plant and animal commodities. One method has also been validated for measuring residues of the CL 300402, CL 434223 and CL 376991 metabolites. The basic approach employs extraction with methanol/water, aqueous acetone or n-heptane/acetone, SPE or GPC clean-up and analysis by GC-ECD, GC-MS, or LC-MS/MS. In some methods, an additional partition step is included, using dichloromethane, cyclohexane, acetone, ethyl acetate, singly or sequentially.

For plant and processed plant commodities, the DFG S19 (GC-ECD or GC-MS) or the QuEChERS (LC-MS/MS) methods were used in most of the supervised residue field trials, with the RLA 12619 (LC-MS/MS) method used to measure parent and metabolites in some cereal trials. These methods were validated in a range of matrices (wheat, barley, grapes, cucumber, summer squash, melon, tomato, pepper, lemon, dry bean, oilseed rape and hops). The LOQ is 0.1 mg/kg for mushrooms and cereal forage and straws and 0.01 mg/kg for all other matrices.

For animal commodities, the DFG S19 (GC-MS) method was validated for the analysis of metrafenone in muscle, milk and eggs. After extraction with aqueous acetone, extracts are partitioned into ethyl acetate/cyclohexane before SPE clean-up and analysis. The LOQ is 0.01 mg/kg for milk and 0.05 mg/kg for muscle and eggs.

Stability of pesticide residues in stored analytical samples

Metrafenone residues were stable in analytical samples stored frozen (-18 to -20 °C) for up to 24 months in representative substrates with a high water content (lettuce, tomato), a high starch content (carrot, wheat grain), a high protein content (dry peas), a high oil content (soya bean) (grape, wine) and in , wheat forage and straw residues were stable for at least 31 months. In general, residues in the stored samples were greater than 80% of the spiked levels.

Definition of the residue

In animal commodities, metrafenone was the main identified component in goat fat (60–85% TRR) and poultry eggs and skin+fat (2% TRR) but made up about only 3–4% of the TRR in goat liver and kidney. Most of the identified residues in goat liver and kidney were in the radiolabel fraction that included CL 1500698 and CL 1023363 (totalling 15-30% TRR), with numerous unidentified minor fractions found at lower levels, each generally < 5% TRR. In muscle, TRRs were not found above 0.01 mg eq./kg in the highest dose groups of 65–87 ppm (goat) and 14 ppm (hen) and the TRR in milk was also < 0.01 mg eq./kg.

Based on the metabolism studies, a residue definition for animal commodities that includes metrafenone and the CL 1500698 and the CL 1023363 glucuronides could be considered. However the Meeting noted that these metabolites were not found in hens and only present in goats at low levels (totalling up to 0.27 mg eq./kg in liver and 0.09 mg eq./kg in kidney) following dosing at levels more than 7 times higher than the anticipated maximum livestock dietary burdens. CL 1023363 is structurally similar to rat metabolites and CL 1500698 was found in the rat metabolism study. Both metabolites are accommodated in the ADI. The Meeting therefore concluded that they need not be included in the residue definitions.

Based on the anticipated dietary exposure, the Meeting concluded that significant residues of the CL 1500698 and CL 1023363 metabolites are not expected in animal commodities and as a multi-residue method existed to measure the parent compound in animal commodities, a suitable residue definition for MRL-compliance and dietary intake estimation was metrafenone. Based on the Log P_{ow} of 4.3 and since residues of metrafenone were only found in fat and milk, the Meeting concluded that metrafenone is fat-soluble.

In plant commodities from treated crops, the metabolism studies indicated that metrafenone was the major residue in grape (up to 25% TRR in grape pomace), cucumber (up to 42% TRR) and

wheat matrices (up to 8% TRR in grain and 14-64% TRR in foliage and straw), with numerous minor metabolites or radiolabel fractions present at low concentrations and generally more polar than the parent. While these were not all identified or quantified, individual peaks were < 10% TRR or < 0.01 mg eq./kg.

Metabolite CL 3000402 was occasionally found in grain at levels up to about 10% of the parent concentration but were < 0.02 mg/kg. Metabolites CL 3000402, CL 434223 and CL 376991, found in the wheat metabolism study at up to 7% TRR in foliage and straw, were also measured in the foliage, straw and hay from a number of wheat and barley field trials, generally at levels less than 10% of the parent residue. These three metabolites were also found in the rat metabolism study and are accommodated in the ADI.

The Meeting noted that multiresidue methods exists to measure parent residues and agreed that for MRL-compliance and dietary intake estimation, the residue definition for plant commodities should be metrafenone.

Proposed definition of the residue (for compliance with the MRL and estimation of dietary intake for plant commodities): *metrafenone.*

Proposed definition of the residue (for compliance with the MRL and estimation of dietary intake for animal commodities: *metrafenone.*

Metrafenone is fat-soluble.

Results of supervised residue trials on crops

The Meeting received supervised trial data for foliar applications of metrafenone on a range of berries and other small fruits, fruiting vegetables, cereals and hops. These trials were conducted mainly in Europe and/or North America.

Where residues have been reported as ND (< LOD) the values have been considered as < LOQ (< 0.01 mg/kg) for the purposes of MRL setting. If a higher residue level was observed at a longer PHI than the GAP, the higher value has been used in MRL setting.

The Meeting noted that GAP has been authorised for the use of metrafenone in more than 50 countries in Europe, the Americas, Asia and the Pacific and that product labels were available from many of these countries. Supervised trial data were also provided for pome fruit, stone fruit and hops, but no GAP information was available to support maximum residue level estimations for these commodities.

Berries and small fruit

Results from supervised trials on grapes conducted in USA and strawberries conducted in Europe were provided to the Meeting.

Grape

The critical GAP for metrafenone on grapes is in Canada, up to 6 foliar applications of 0.225 kg ai/ha applied at least 14–21 days apart with a PHI of 14 days and with a total of 1.35 kg ai/ha/season. In trials from USA conducted at about 1.5 time higher rate than the Canadian GAP, metrafenone residues in grapes were: 0.11, 0.17, 0.18, 0.27, 0.32, 0.62, 2.1, 2.3, 2.4, 3.0, and 3.2 mg/kg. When proportionally adjusted to the Canadian GAP (scaling factors (S_f) of 0.64–0.68), metrafenone residues in these trials are: 0.08, 0.11, 0.12, 0.17, 0.22, 0.42, 1.1, 1.4, 1.5, 1.6, 2.0 and 2.2 mg/kg (n=12).

The Meeting estimated an STMR of 0.74 mg/kg and a maximum residue level of 5 mg/kg for metrafenone on grapes.

Strawberry

The critical GAP for metrafenone on strawberries is on protected crops in the Netherlands, up to 2 foliar applications of 0.15 kg ai/ha, applied at least 7 days apart with a PHI of 3 days. In trials on protected strawberries matching this GAP in Netherlands, metrafenone residues in fruit were: 0.05, 0.06, 0.08, 0.1, 0.16, 0.23, 0.28 and 0.34 mg/kg (n=8).

The Meeting estimated an STMR of 0.13 mg/kg and a maximum residue level of 0.6 mg/kg for metrafenone on strawberries.

Fruiting vegetables, Cucurbits

Results from supervised trials on cucumbers, summer squash (zucchini) and melons (cantaloupes) conducted in Europe and North America were provided to the Meeting. However no GAP information was available from North America

Cucumber

The critical GAP for metrafenone on cucumbers is in France, up to 2 foliar applications of 0.1 kg ai/ha, applied at least 7–10 days apart with a PHI of 3 days. This GAP applies to both outdoor and protected crops.

In trials on outdoor cucumbers in Europe matching this GAP in France, metrafenone residues in cucumbers were: 0.01, 0.02, 0.02, 0.02, 0.02, 0.02, 0.03 and 0.04 mg/kg (n=8).

In trials on protected cucumbers matching this GAP in France, metrafenone residues in cucumbers were: 0.02, 0.04, 0.04, 0.05, 0.05, 0.06, 0.06, 0.07 and 0.09 mg/kg (n=9).

Based on the data set for protected cucumbers, the Meeting estimated an STMR of 0.05 mg/kg and a maximum residue level of 0.2 mg/kg for metrafenone on cucumber.

The Meeting also agreed to extrapolate these estimations to gherkins.

Summer squash

The critical GAP for metrafenone on summer squash is in France, up to 2 foliar applications of 0.1 kg ai/ha, applied at least 7–10 days apart with a PHI of 3 days. In trials on summer squash in Europe matching this GAP in France, metrafenone residues in summer squash were: 0.01, 0.01, 0.01, 0.01, 0.02, 0.02, 0.02 and 0.04 mg/kg (n=8).

The Meeting estimated an STMR of 0.015 mg/kg and a maximum residue level of 0.06 mg/kg for metrafenone on summer squash.

Melons (except watermelon)

The critical GAP for metrafenone on melons is in France, up to 2 foliar applications of 0.1 kg ai/ha, applied at least 7–10 days apart with a PHI of 3 days. In trials on melons in Europe matching this GAP in France, metrafenone residues in melons were: < 0.01, 0.01, 0.01, 0.02, 0.02, 0.02, 0.02, 0.02, 0.02, 0.03, 0.05, 0.06 and 0.07 mg/kg (n=13).

However the Meeting noted that in these trials, the melons had been quartered in the field and although the subsamples had been frozen within 12 hours after sampling, no information was available on residue stability in chopped or sliced samples.

The Meeting was unable to estimate a maximum residue level for metrafenone on melons.

Fruiting vegetables, other than Cucurbits

Results from supervised trials on tomatoes and peppers (sweet, bell and non-bell) conducted in Europe and North America and from trials on mushrooms in Europe were provided to the Meeting.

Mushrooms

The critical GAP for metrafenone on mushrooms is in France, one broadcast treatment of 0.05 kg ai/15 litres water/100 square metres of compost, applied up to 10 days before harvest. In trials on mushrooms in Europe matching this GAP in France, metrafenone residues in mushrooms were: 0.1, 0.1, 0.11 and 0.19 mg/kg (n=4)

The Meeting estimated an STMR of 0.105 mg/kg and a maximum residue level of 0.5 mg/kg for metrafenone on mushrooms.

The Meeting noted that the OECD MRL-calculator proposed a maximum residue level of 0.4 mg/kg, but agreed that a higher value on 0.5 mg/kg was more appropriate due to the small data set and because the relatively close spread of results may not reflect the residue variability arising from different composts used in mushroom production.

Pepper, Sweet

The critical GAP for metrafenone on peppers is in France for protected crops, up to 2 foliar applications of 0.15 kg ai/ha, applied at least 7–10 days apart with a PHI of 3 days. In trials on protected sweet peppers matching this GAP in France, metrafenone residues in peppers were: 0.07, 0.08, 0.1, 0.11, 0.12, 0.2, 0.21 and 1.3 mg/kg (n=8).

The Meeting estimated an STMR of 0.115 mg/kg and a maximum residue level of 2.0 mg/kg for metrafenone on peppers, sweet and agreed to extrapolate these estimations to chili pepper.

For dried chili peppers, applying the default processing factor of 10 to the STMR and the maximum residue level estimated for peppers, the Meeting estimated an STMR-P of 1.15 mg/kg and a maximum residue level of 20 mg/kg for metrafenone on dried chili peppers.

Tomato

The critical GAP for metrafenone on tomatoes is in Spain, up to 2 foliar applications of 0.015 kg ai/hL with a PHI of 3 days. This GAP applies to both outdoor and protected crops.

In trials on outdoor tomatoes in Europe matching this GAP in Spain, metrafenone residues in tomatoes were: 0.02, 0.05, 0.05, 0.06, 0.06, 0.07, 0.08 and 0.15 mg/kg (n=8).

In trials on protected tomatoes matching this GAP in Spain, metrafenone residues in tomatoes were: 0.06, 0.09, 0.09, 0.1, 0.1, 0.1, 0.16 and 0.17 mg/kg (n=8).

Based on the data set for protected tomatoes, the Meeting estimated an STMR of 0.1 mg/kg and a maximum residue level of 0.4 mg/kg for metrafenone on tomato.

Cereal grains

Results from supervised trials on wheat and barley conducted in Europe were provided to the Meeting.

Wheat

The critical GAP for metrafenone on wheat is in Poland, up to 2 foliar applications of 0.15 kg ai/ha with a PHI of 35 days. In trials in Europe matching this GAP in Poland, metrafenone residues in wheat grain were: < 0.01 (9), 0.01 (4), 0.02, 0.03, 0.03, 0.04 and 0.04 mg/kg (n=18).

The Meeting estimated an STMR of 0.01 mg/kg and a maximum residue level of 0.06 mg/kg for metrafenone on wheat.

The Meeting also agreed to extrapolate these estimations to rye and triticale.

Barley

The critical GAP for metrafenone on barley is in Poland, up to 2 foliar applications of 0.15 kg ai/ha with a PHI of 35 days. In trials in Europe matching this GAP in Poland, metrafenone residues in barley grain were: < 0.01, 0.02 (3), 0.03, 0.04, 0.05 (3), 0.06, 0.06, 0.07, 0.08, 0.09, 0.11, 0.13, 0.15, 0.16, 0.23 and 0.4 mg/kg (n=20).

The Meeting estimated an STMR of 0.06 mg/kg and a maximum residue level of 0.5 mg/kg for metrafenone on barley.

The Meeting also agreed to extrapolate these estimations to oats.

Animal feeds

Cereal forages

Wheat and barley plant or foliage samples were collected in many of the European trials matching the GAP in Hungary/Poland (up to 2 foliar applications of 0.15 kg ai/ha).

Wheat forage

In wheat trials matching the GAP in Poland, metrafenone residues in plant (forage) samples taken 0-days after the last application were: 1.8, 2.0, 2.0, 2.6, 2.6, 2.6, 2.8, 3.3, 3.7, 3.8, 4.3 and 4.8 mg/kg (fresh weight).

The Meeting estimated a median residue of 2.7 mg/kg (fresh weight) and a highest residue of 4.8 mg/kg (fresh weight) for wheat forage and agreed to extrapolate these estimations to rye and triticale.

Barley forage

In barley trials matching the GAP in Poland, metrafenone residues in plant (forage) samples taken 0-days after the last application were: 1.8, 2.3, 2.5, 2.5, 3.1, 3.4, 3.7, 3.8, 4.6, 5.0, 5.8 and 5.9 mg/kg (fresh weight).

The Meeting estimated a median residue of 3.75 mg/kg (fresh weight) and a highest residue of 5.9 mg/kg (fresh weight) for barley forage and agreed to extrapolate these estimations to oats.

Cereal and grass straws and hays

Wheat and barley straw samples were collected in many of the European trials matching the GAP in Poland (up to 2 foliar applications of 0.15 kg ai/ha).

Wheat straw

In trials in Europe matching this GAP in Poland, metrafenone residues in wheat straw (fresh weight) were: 0.67, 0.67, 0.98, 1.1, 1.3, 1.4, 1.6, 1.7, 1.8, 2.0, 2.1, 2.3, 3.1, 3.1, 3.5, 3.6, 3.6 and 6.7 mg/kg (n=18). After correction for an average 88% dry matter content, residues (dry weight) were: 0.76, 0.76, 1.1, 1.3, 1.5, 1.6, 1.8, 1.9, 2.1, 2.3, 2.4, 2.6, 3.5, 3.5, 4.0, 4.1, 4.1 and 7.6 mg/kg.

The Meeting estimated a median residue of 1.9 mg/kg (fresh weight), a highest residue of 6.7 mg/kg (fresh weight) and a maximum residue level of 10 mg/kg (dry weight) for metrafenone in wheat straw.

The Meeting also agreed to extrapolate these estimations to rye and triticale.

Barley straw

In trials in Europe matching the GAP in Poland, metrafenone residues in barley straw (fresh weight) were: < 0.01, 0.24, 0.41, 0.95, 1.0, 1.1, 1.1, 1.1, 1.2, 1.3, 1.3, 1.5, 1.7, 1.8, 1.9, 1.9, 2.0, 2.1, 3.6 and 3.9 mg/kg (n=20). After correction for an average 89% dry matter content, residues (dry weight) were: < 0.01, 0.29, 0.46, 1.1, 1.1, 1.2, 1.2, 1.24 1.4, 1.5, 1.5, 1.5, 1.9, 2.0, 2.1, 2.1, 2.3, 2.4, 4.0 and 4.4 mg/kg.

The Meeting estimated a median residue of 1.3 mg/kg (fresh weight), a highest residue of 3.9 mg/kg (fresh weight) and a maximum residue level of 6 mg/kg (dry weight) for metrafenone in barley straw.

The Meeting also agreed to extrapolate these estimations to oats.

Fate of residues during processing

The effect of processing on the nature of residues was investigated using radiolabelled metrafenone in buffer solutions incubated under conditions simulating pasteurisation (in pH 4 buffer at 90 °C for 20 minutes); baking, brewing, or boiling (in pH 5 buffer at 100 °C for 60 minutes); and sterilization (in pH 6 buffer at 120 °C for 20 minutes). Metrafenone was stable under these processing conditions with no significant changes in the radio-chromatograms.

The fate of metrafenone residues has been examined in a number of studies simulating household and commercial processing of apples, grapes, strawberries, tomatoes, barley, wheat and hops. Estimated processing factors and STMR-Ps for the commodities considered at this Meeting are summarised below.

Summary of selected processing factors and STMR-P values for metrafenone

RAC	Matrix	Metrafenone [a] Calculated processing factors	PF best estimate	STMR (mg/kg)	STMR-P (mg/kg)
Grape	grapes			0.76	
	must (red wine)	0.03, 0.15, < 0.18, 0.26, 0.57, 0.77, 0.78, 0.81, 1.17, 1.29	0.67		0.51
	wet pomace	2.8, 3.6	3.2		2.4
	wine	0.03, 0.07, < 0.17, < 0.18, < 0.19, < 0.19, < 0.21, < 0.26, < 0.38, < 0.71	0.19		0.14
	juice	0.04, 0.06	0.05		0.038
	raisins	< 0.63, < 0.71, 3.63, 3.94	3.75		2.85
Tomato	fresh			0.1	
	preserved	< 0.02, < 0.02, < 0.02, 0.02	< 0.02		< 0.002
	juice (raw)	0.26, 0.33, 0.35, 0.4	0.34		0.034
	wet pomace	3.3, 4.8, 6.2, 6.3	5.5		0.55
	paste	0.27, 0.3, 0.47, 0.53	0.385		0.039
	puree	0.65, 0.79, 0.83, 1.1	0.81		0.081
Mushroom	fresh			0.105	
	canned	0.16	0.16		0.017
Barley	grain			0.06	
	pearl barley	< 0.13, 0.13, < 0.2, 0.22	0.165		0.01
	abraded fraction	2.5	2.5		0.15
	malt	0.4	0.4		0.024
	brewers grain	0.3	0.3		0.018
	beer	< 0.1, < 0.13, < 0.17, < 0.33,	< 0.15		< 0.009
Wheat	grain			0.01	
	wholemeal flour	0.94, 1.1, 1.7, 1.9	1.4		0.014
	flour type 550	0.14, 0.17, 0.21, 0.29	0.19		0.002

RAC	Matrix	Metrafenone [a] Calculated processing factors	PF best estimate	STMR (mg/kg)	STMR-P (mg/kg)
	fine bran	2.6, 3.5, 4.9, 5.3	4.2		0.042
	whole grain bread	0.6, 0.64, 0.71, 1.0	0.675		0.007

[a] Each PF value represents a separate study where residues were above the LOQ in the RAC and is the ratio of the metrafenone residues in the processed item divided by the residues in the RAC.

The Meeting noted that in the studies available, metrafenone residues did not concentrate in food commodities during processing, except in dehydrated commodities such as raisins, bran and flour. Residues also increased in wet pomace (grape and tomato), tomato peel and barley abrasion fractions.

The Meeting estimated a maximum residue level for dried grapes of 20 mg/kg based on the maximum residue level estimated for grapes (5.0 mg/kg) and the median processing factor (3.75) from the USA processing studies.

The Meeting estimated a maximum residue level for wheat bran (processed) of 0.25 mg/kg based on the maximum residue level estimated for wheat (0.06 mg/kg) and a median processing factor of 4.2.

The Meeting estimated a maximum residue level for wheat wholemeal of 0.08 mg/kg based on the maximum residue level estimated for wheat (0.06 mg/kg) and a median processing factor of 1.4.

Residues in animal commodities

Farm animal dietary burden

The Meeting estimated the dietary burden of metrafenone in farm animals on the basis of the diets listed in Appendix IX of the 2009 edition of the JMPR Manual. Noting that fresh forage commodities are not significant in international trade, the Meeting only included the burden contributions from the cereal forages in the European dietary burden calculation, as metrafenone is not authorised for use on cereals in US-Canada, Australia or Japan.

Dietary burden calculations for beef cattle, dairy cattle, broilers and laying poultry are presented in Annex 6 of the 2014 Report and are summarized below:

Estimated maximum and mean dietary burdens of farm animals

	Animal dietary burden, metrafenone, ppm of dry matter diet							
	US-Canada		EU		Australia		Japan	
	max	mean	max	mean	max	mean	max	mean
Beef cattle	0.8	0.26	5.9	3.8	9.3 [a]	4.9 [c]	0.07	0.07
Dairy cattle	0.8	0.25	5.9	3.8	9.2 [b]	4.9 [d]	0.42	0.14
Poultry – broiler	0.05	0.05	0.05	0.05	0.02	0.02	0.007	0.007
Poultry – layer	0.05	0.05	2.0 [e g]	1.3 [f h]	0.015	0.015	0.008	0.008

[a] Highest maximum beef or dairy cattle dietary burden suitable for MRL estimates for mammalian tissues
[b] Highest maximum dairy cattle dietary burden suitable for MRL estimates for mammalian milk
[c] Highest mean beef or dairy cattle dietary burden suitable for STMR estimates for mammalian tissues.
[d] Highest mean dairy cattle dietary burden suitable for STMR estimates for milk.
[e] Highest maximum poultry dietary burden suitable for MRL estimates for poultry tissues.
[f] Highest mean poultry dietary burden suitable for STMR estimates for poultry tissues.
[g] Highest maximum poultry dietary burden suitable for MRL estimates for poultry eggs.
[h] Highest mean poultry dietary burden suitable for STMR estimates for poultry eggs.

For beef and dairy cattle, the calculated maximum dietary burden is 9.3 ppm dry weight of feed and for poultry, noting that in some countries, laying hens may also be consumed, the calculated maximum dietary burden suitable is 2.0 ppm dry weight of feed.

Farm animal feeding studies

No livestock feeding studies were provided.

Animal commodity maximum residue levels

The Meeting noted that in the goat metabolism study, up to 0.014 mg/kg metrafenone was found in the kidney from the high (87 ppm) dose group animals and by extrapolation, this would equate to a maximum level of 0.0015 mg/kg in kidney from animals exposed to the calculated maximum dietary burden of 9.3 ppm.

In liver, metrafenone residues were up to 0.025 mg/kg in the high (60 ppm) dose group animals and by extrapolation, this would equate to a maximum level of 0.004 mg/kg in liver from animals exposed to the calculated maximum dietary burden of 9.3 ppm.

In animals dosed with 10 ppm in the diet (approximating the maximum calculated dietary burden for beef and dairy cattle, radiolabel residues were < 0.005 mg eq./kg in muscle, milk and fat.

The Meeting estimated maximum residue levels of 0.01* mg/kg for metrafenone in meat (from mammals other than marine mammals), 0.01 mg/kg for edible offal (mammalian), 0.01* mg/kg for mammalian fat and 0.01* mg/kg for milks. Estimated STMRs for dietary intake estimation are 0 mg/kg for meat, 0.01 mg/kg for edible offal, 0 mg/kg for fat and 0 mg/kg for milk.

In the hen metabolism study, residues of metrafenone were up to 0.002 mg/kg in eggs and up to 0.001 mg/kg in skin+fat in hens dosed with 14 ppm in the diet (about 7-fold higher than the maximum calculated dietary burden for poultry). In muscle and liver, metrafenone residues were not detected.

The Meeting estimated maximum residue levels of 0.01* mg/kg for metrafenone in poultry meat, 0.01* mg/kg for poultry offal, 0.01* mg/kg for poultry fat and 0.01* mg/kg for eggs. Estimated STMRs for dietary intake estimation are 0 mg/kg for poultry fat, 0 mg/kg for poultry meat, 0 mg/kg for poultry offal and 0 mg/kg for eggs.

RECOMMENDATIONS

On the basis of the data from supervised trials the Meeting concluded that the residue levels listed below are suitable for establishing maximum residue limits and for IEDI assessment.

Definition of the residue (for MRL-compliance and estimation of dietary intake, plant commodities): *metrafenone.*

Definition of the residue (for MRL-compliance and estimation of dietary intake, animal commodities): *metrafenone.*

The residue is fat soluble.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Daily Intake (IEDI) for metrafenone was calculated for the food commodities for which STMRs or HRs were estimated and for which consumption data were available. The results are shown in Annex 3.

The International Estimated Daily Intakes of metrafenone for the 17 GEMS/Food cluster diets, based on estimated STMRs were 0% of the maximum ADI of 0.3 mg/kg bw (Annex 3). The Meeting concluded that the long-term intake of residues of metrafenone from uses that have been considered by the JMPR is unlikely to present a public health concern.

Short-term intake

The 2014 JMPR decided that an ARfD was unnecessary. The Meeting therefore concluded that the short-term intake of metrafenone residues is unlikely to present a public health concern.

5.21 MYCLOBUTANIL (181)

TOXICOLOGY

Myclobutanil is the ISO-approved common name for (*R,S*)-2-(4-chlorophenyl-2-(1*H*-1,2,4-triazol-1-ylmethyl) hexanenitrile (IUPAC), with CAS number 88671-89-0. It is a broad-spectrum fungicide of the substituted triazole chemical class of compounds. It acts by inhibiting sterol biosynthesis in fungi.

Myclobutanil was evaluated by JMPR in 1992, when an ADI of 0–0.03 mg/kg bw was established. No ARfD was established, because the establishment of ARfDs by JMPR was not common practice in 1992. Myclobutanil was reviewed by the present Meeting as part of the periodic review programme of CCPR.

All critical studies contained statements of compliance with GLP. Several new studies on metabolites were submitted.

Biochemical aspects

Myclobutanil was rapidly and extensively absorbed in rats (> 89%). Peak plasma and tissue concentrations of radiolabelled myclobutanil were achieved within 1 hour after oral administration. Plasma elimination was biphasic; the half-lives were 5 hours for the rapid phase and 26 hours for the slow phase in rats exposed to a single dose. Myclobutanil was widely distributed, and no significant tissue accumulation was observed 96 hours post-dosing.

Metabolism was extensive and appeared to occur mainly through a variety of oxygenation reactions of the butyl group. The major unconjugated phenethyl triazole–containing metabolites were RH-9090 ((2*RS*,5*RS*)-2-(4-chlorophenyl)-5-hydroxy-2-(1*H*-1,2,4-triazol-1-ylmethyl) hexanenitrile) and RH-9089 ((2*RS*)-2-(4-chlorophenyl)-5-oxo-2-(1*H*-1,2,4-triazol-1-ylmethyl) hexanenitrile). Myclobutanil was rapidly and completely excreted in urine and faeces within 24–48 hours in rats.

Toxicological data

The oral LD_{50} for myclobutanil was greater than or equal to 1600 mg/kg bw in rats. The dermal LD_{50} was greater than 5000 mg/kg bw in rats and rabbits. The inhalation LC_{50} was greater than 5.1 mg/L in rats. Myclobutanil was not irritating to the skin but was moderately irritating to the eye of rabbits. Myclobutanil was not sensitizing in the guinea-pig maximization test or the mouse local lymph node assay and was mildly sensitizing using the Buehler method.

The liver was the interspecies target of myclobutanil in short- and long-term toxicity studies. The testis was also a target of myclobutanil in long-term toxicity studies in rats. Reductions of feed consumption and corresponding decreases in body weight gains at the beginning of treatment in short-term dietary studies in mice, rats and dogs and a reproductive toxicity study in rats are considered to be due to low palatability, rather than an adverse effect, as no similar change in feed consumption was observed in gavage studies and no effects on the gastrointestinal tract were observed.

In a 90-day toxicity study in mice administered myclobutanil in the diet at a concentration of 0, 3, 10, 30, 100, 300, 1000, 3000 or 10 000 ppm (equal to 0, 0.40, 1.54, 4.79, 14.1, 42.7, 132, 542 and 2035 mg/kg bw per day for males and 0, 0.62, 2.11, 6.94, 22.9, 65.5, 232, 710 and 2027 mg/kg bw per day for females, respectively), the NOAEL was 300 ppm (equal to 42.7 mg/kg bw per day), based on fatty changes and necrosis of hepatocytes at 1000 ppm (equal to 132 mg/kg bw per day).

In a 90-day oral toxicity study in rats, myclobutanil was administered in the diet at a concentration of 0, 5, 15, 50, 150, 500, 1500, 5000 or 15 000 ppm for weeks 1 and 2; at 0, 7, 21, 70, 210, 700, 2100, 7000 or 21 000 ppm for weeks 3 and 4; and at 0, 10, 30, 100, 300, 1000, 3000, 10 000 or 30 000 ppm for the remainder of the study. These dietary concentrations were equal to doses of 0, 0.52, 1.60, 5.22, 15.3, 51.5, 158, 585 and 1730 mg/kg bw per day for males and 0, 0.67,

2.03, 6.85, 19.7, 65.8, 195.2, 665 and 1811 mg/kg bw per day for females, respectively. The NOAEL was 500/700/1000 ppm (equal to 51.5 mg/kg bw per day), based on increased liver and kidney weights, hepatocellular hypertrophy, single-cell necrosis in the liver and pigmentation in tubular epithelium in the kidneys at 1500/2100/3000 ppm (equal to 158 mg/kg bw per day).

In a 90-day oral toxicity study in dogs administered myclobutanil in the diet at 0, 10, 200, 800 or 1600 ppm (equal to 0, 0.34, 7.26, 29.1 and 56.8 mg/kg bw per day for males and 0, 0.42, 7.88, 32.4 and 58.0 mg/kg bw per day for females, respectively), the NOAEL was 800 ppm (equal to 29.1 mg/kg bw per day), based on liver hypertrophy, increased alkaline phosphatase and increased platelets at 1600 ppm (equal to 56.8 mg/kg bw per day).

In a 1-year oral toxicity study in dogs administered myclobutanil in the diet at a concentration of 0, 10, 100, 400 or 1600 ppm (equal to 0, 0.34, 3.09, 14.3 and 54.2 mg/kg bw per day for males and 0, 0.40, 3.83, 15.9 and 58.2 mg/kg bw per day for females, respectively), the NOAEL was 400 ppm (equal to 14.3 mg/kg bw per day), based on ballooned hepatocytes, increased alkaline phosphatase and increased platelets in males at 1600 ppm (equal to 54.2 mg/kg bw per day).

The Meeting concluded that the overall NOAEL for oral toxicity in dogs was 800 ppm (equal to 29.1 mg/kg bw per day), and the overall LOAEL was 1600 ppm (equal to 54.2 mg/kg bw per day).

In a 2-year toxicity and carcinogenicity study in mice administered myclobutanil in the diet at a concentration of 0, 20, 100 or 500 ppm (equal to 0, 2.7, 13.7 and 70.2 mg/kg bw per day for males and 0, 3.2, 16.5 and 85.2 mg/kg bw per day for females, respectively), the NOAEL for toxicity was 100 ppm (equal to 13.7 mg/kg bw per day), based on histopathological signs of hepatotoxicity at 500 ppm (equal to 70.2 mg/kg bw per day). Myclobutanil was not carcinogenic in this study.

In a second 2-year carcinogenicity study conducted to confirm the absence of carcinogenicity at high doses, female mice were administered myclobutanil in the diet at a concentration of 2000 ppm (equal to 394 mg/kg bw per day), the maximum tolerated dose. No carcinogenicity was observed at this dose.

In a 2-year carcinogenicity study in rats administered myclobutanil in the diet at a concentration of 0, 50, 200 or 800 ppm (equal to 0, 2.5, 9.8 and 39.2 mg/kg bw per day for males and 0, 3.2, 12.8 and 52.3 mg/kg bw per day for females, respectively), the NOAEL for non-neoplastic effects was 50 ppm (equal to 2.5 mg/kg bw per day), based on testicular toxicity found after 12 months of treatment at 200 ppm (equal to 9.8 mg/kg bw per day). Myclobutanil was not carcinogenic in this study.

A second 2-year carcinogenicity study in rats confirmed the absence of carcinogenicity of myclobutanil at a higher dietary concentration, 2500 ppm (equal to 106 mg/kg bw per day for males and 136 mg/kg bw per day for females).

The Meeting concluded that myclobutanil is not carcinogenic in mice or rats.

Myclobutanil was tested for genotoxicity in an adequate range of assays, both in vitro and in vivo. No evidence of genotoxicity was found.

The Meeting concluded that myclobutanil is unlikely to be genotoxic.

On the basis of the lack of genotoxicity and the absence of carcinogenicity in mice and rats, the Meeting concluded that myclobutanil is unlikely to pose a carcinogenic risk to humans.

In a two-generation reproductive toxicity study in rats administered myclobutanil in the diet at a concentration of 0, 50, 200 or 1000 ppm (equal to 0, 3.67, 14.3 and 70.7 mg/kg bw per day for P_1 males, 0, 4.42, 17.2 and 85.9 mg/kg bw per day for P_1 females, 0, 3.64, 15.1 and 76.4 mg/kg bw per day for P_2 males and 0, 4.17, 17.5 and 88.0 mg/kg bw per day for P_2 females, respectively), the NOAEL for parental toxicity was 200 ppm (equal to 15.1 mg/kg bw per day), based on lower body weights, histopathological changes of vacuolation and hypertrophy of hepatocytes and testicular atrophy in P_2 males at 1000 ppm (equal to 76.4 mg/kg bw per day). The NOAEL for reproductive toxicity was 200 ppm (equal to 17.5 mg/kg bw per day), based on reduced reproductive ability,

including number of females mating, number of females giving birth, number of females weaning litters or prolonged time to mating, in P_2 females at 1000 ppm (equal to 88.0 mg/kg bw per day). The NOAEL for offspring toxicity was 200 ppm (equal to 17.2 mg/kg bw per day), based on an increased number of pups born dead for both generations at 1000 ppm (equal to 85.9 mg/kg bw per day).

In a developmental toxicity study in rats administered myclobutanil by gavage at 0, 31.3, 93.8, 313 or 469 mg/kg bw per day, the NOAEL for maternal toxicity was 93.8 mg/kg bw per day, based on clinical signs of rough hair coat, desquamation and salivation at 313 mg/kg bw per day. The NOAEL for embryo and fetal toxicity was 31.3 mg/kg bw per day, based on an increased number of early resorptions at 93.8 mg/kg bw per day.

To determine whether treatment-related early resorptions in rats were caused by chromosomal abnormalities of the spermatozoa, leading to death of conceptuses, male rats were administered a single dose of myclobutanil at 0, 10, 100 or 735 mg/kg bw and mated with untreated females. There was no evidence of treatment-related embryo death, even at a dose lethal to adults.

In a developmental toxicity study in rabbits administered myclobutanil by gavage at 0, 20, 60 or 200 mg/kg bw per day, the NOAEL for maternal toxicity was 20 mg/kg bw per day, based on decreased body weight gain on day 11 at 60 mg/kg bw per day. The NOAEL for embryo and fetal toxicity was 60 mg/kg bw per day, based on an increased number of resorptions per litter, an increased number of litters totally resorbed and lower fetal weights at 200 mg/kg bw per day.

The Meeting concluded that myclobutanil is not teratogenic.

There were no studies submitted that specifically investigated neurotoxicity or immunotoxicity.

Toxicological data on metabolites and/or degradates

The oral LD_{50} ranges for RH-9090 and RH-9089, major metabolites in plants, rats, hens and cows, were between 300 and 1000 mg/kg bw in mice.

In a 2-week oral toxicity study on myclobutanil butyric acid ((3*RS*)-3-(4-chlorophenyl)-3-cyano-4-(1*H*-1,2,4-triazol-1-yl)butanoic acid), a degradate in soil, no toxicity was observed at doses up to 1000 mg/kg bw administered by gavage to rats.

Tests of the in vitro genotoxicity of RH-9089, RH-9090 and myclobutanil butyric acid and an in vivo genotoxicity assay on myclobutanil butyric acid showed no evidence of genotoxicity.

The Meeting concluded that RH-9090 and RH-9089, which are major metabolites in rats, are covered by the reference doses for myclobutanil. Myclobutanil butyric acid is of no toxicological concern, as it is of lower toxicity than the parent.

Human data

In reports on manufacturing plant personnel, no adverse health effects were noted.

The Meeting concluded that the existing database on myclobutanil was adequate to characterize the potential hazards to fetuses, infants and children.

Toxicological evaluation

The Meeting reaffirmed the ADI of 0–0.03 mg/kg bw on the basis of the NOAEL of 2.5 mg/kg bw per day in a 2-year study in rats, based on testicular atrophy at 9.8 mg/kg bw per day. A safety factor of 100 was applied. This ADI is based on the same end-point as in 1992.

The Meeting established an ARfD of 0.3 mg/kg bw for women of childbearing age only, on the basis of the NOAEL of 31.3 mg/kg bw per day in a developmental toxicity study in rats, based on

an increased number of early resorptions at 93.8 mg/kg bw per day. A safety factor of 100 was applied. The Meeting concluded that it is not necessary to establish an ARfD for the remainder of the population in view of the low acute oral toxicity of myclobutanil and the absence of any other toxicological effects that would be likely to be elicited by a single dose.

A toxicological monograph was prepared.

Levels relevant to risk assessment of myclobutanil

Species	Study	Effect	NOAEL	LOAEL
Mouse	Two-year studies of toxicity and carcinogenicity[a,b]	Toxicity	100 ppm, equal to 13.7 mg/kg bw per day	500 ppm, equal to 70.2 mg/kg bw per day
		Carcinogenicity	2 000 ppm, equal to 394 mg/kg bw per day[c]	–
Rat	Two-year studies of toxicity and carcinogenicity[a,b]	Toxicity	50 ppm, equal to 2.5 mg/kg bw per day	200 ppm, equal to 9.8 mg/kg bw per day
		Carcinogenicity	2 500 ppm, equal to 106 mg/kg bw per day[c]	–
	Two-generation study of reproductive toxicity[a]	Reproductive toxicity	200 ppm, equal to 17.5 mg/kg bw per day	1 000 ppm, equal to 88.0 mg/kg bw per day
		Parental toxicity	200 ppm, equal to 15.1 mg/kg bw per day	1 000 ppm, equal to 76.4 mg/kg bw per day
		Offspring toxicity	200 ppm, equal to 17.2 mg/kg bw per day	1 000 ppm, equal to 85.9 mg/kg bw per day
	Developmental toxicity study[d]	Maternal toxicity	93.8 mg/kg bw per day	313 mg/kg bw per day
		Embryo and fetal toxicity	31.3 mg/kg bw per day	93.8 mg/kg bw per day
Rabbit	Developmental toxicity study[d]	Maternal toxicity	20 mg/kg bw per day	60 mg/kg bw per day
		Embryo and fetal toxicity	60 mg/kg bw per day	200 mg/kg bw per day
Dog	Thirteen-week and 1-year studies of toxicity[a,b]	Toxicity	800 ppm, equal to 29.1 mg/kg bw per day	1 600 ppm, equal to 54.2 mg/kg bw per day

[a] Dietary administration.
[d] Two or more studies combined.
[c] Highest dose tested.
[b] Gavage administration.

Estimate of acceptable daily intake (ADI)

0–0.03 mg/kg bw

Estimate of acute reference dose (ARfD)

0.3 mg/kg bw (applies to women of childbearing age only)

Information that would be useful for the continued evaluation of the compound

Results from epidemiological, occupational health and other such observational studies of human exposure

Critical end-points for setting guidance values for exposure to myclobutanil

Absorption, distribution, excretion and metabolism in mammals	
Rate and extent of oral absorption	Rapidly absorbed (> 89%)
Dermal absorption	No data
Distribution	Extensive
Potential for accumulation	No significant tissue accumulation
Rate and extent of excretion	Rapidly excreted
Metabolism in animals	Extensively metabolized, mainly through a variety of oxygenation reactions
Toxicologically significant compounds in animals and plants	Myclobutanil, unconjugated phenethyl triazole–containing metabolites (RH-9089, RH-9090) (rat, hen, cow, plants)
Acute toxicity	
Rat, LD_{50}, oral	≥ 1 600 mg/kg bw
Rat, LD_{50}, dermal	> 5 000 mg/kg bw
Rat, LC_{50}, inhalation	> 5.1 mg/L
Rabbit, dermal irritation	Not irritating to skin
Rabbit, ocular irritation	Moderately irritating to eye
Guinea-pig, dermal sensitization	Not sensitizing (maximization test and local lymph node assay); mildly sensitizing (Buehler method)
Short-term studies of toxicity	
Target/critical effect	Liver / increases in alkaline phosphatase and platelets (dog)
Lowest relevant oral NOAEL	29.1 mg/kg bw per day (dog)
Lowest relevant dermal NOAEL	100 mg/kg bw per day (rat)
Lowest relevant inhalation NOAEC	No data
Long-term studies of toxicity and carcinogenicity	
Target/critical effect	Testes/atrophy (rat)
Lowest relevant NOAEL	2.5 mg/kg bw per day (rat)
Carcinogenicity	Not carcinogenic (rat and mouse); unlikely to pose a carcinogenic risk to humans
Genotoxicity	
	Unlikely to be genotoxic
Reproductive toxicity	
Target/critical effect	Testicular atrophy, increased number of pups born dead, reduced reproductive ability
Lowest relevant parental NOAEL	15.1 mg/kg bw per day (rat)
Lowest relevant offspring NOAEL	17.2 mg/kg bw per day (rat)
Lowest relevant reproductive NOAEL	17.5 mg/kg bw per day (rat)

Developmental toxicity	
Target/critical effect	Fetal toxicity / increased number of early resorptions and lower fetal weights
Lowest relevant maternal NOAEL	20 mg/kg bw per day (rabbit)
Lowest relevant embryo/fetal NOAEL	31.3 mg/kg bw per day (rat)
Neurotoxicity	
Acute neurotoxicity NOAEL	No data
Subchronic neurotoxicity NOAEL	No data
Developmental neurotoxicity NOAEL	No data
Other toxicological studies	
Immunotoxicity	No data
Studies on toxicologically relevant metabolites	RH-9089 and RH-9090:
	Oral LD_{50}: 300–1000 mg/kg bw (mice)
	Unlikely to be genotoxic
	Myclobutanil butyric acid:
	NOAEL: 1 000 mg/kg bw, highest dose tested (2-week study in rats)
	Unlikely to be genotoxic
Studies on impurities	Studies on RH-8812 and RH-8813 not relevant for dietary risk assessment
Medical data	
	No adverse effects noted in medical surveillance reports on manufacturing plant personnel

Summary

	Value	Study	Safety factor
ADI	0–0.03 mg/kg bw	Two-year study of toxicity and carcinogenicity (rat)	100
ARfD	0.3 mg/kg bw[a]	Developmental toxicity study (rat)	100

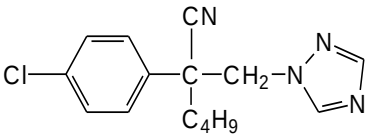
[a] Applies to women of childbearing age only.

RESIDUE AND ANALYTICAL ASPECTS

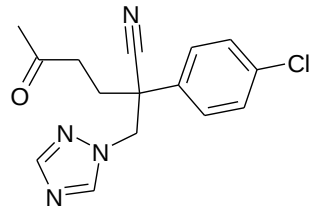
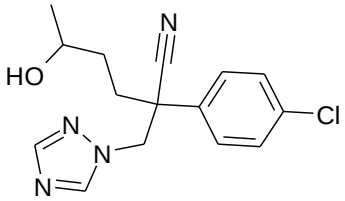
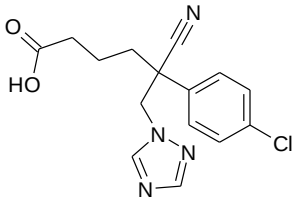
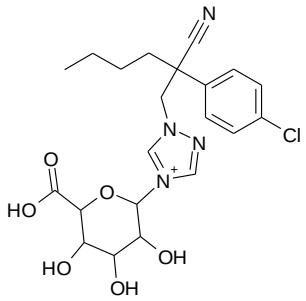
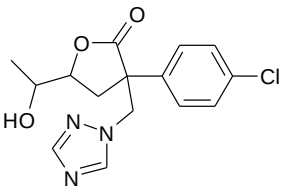
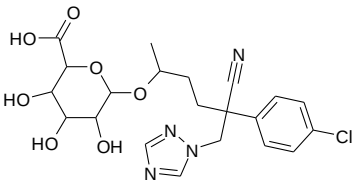
Myclobutanil was originally evaluated by the JMPR in 1992 and re-evaluated for residues in 1997 and 1998. Myclobutanil is a systemic fungicide used to control a range of economically important fungi on a variety of crops, and belongs to the steroid demethylation inhibitor (DMI) class of fungicides.

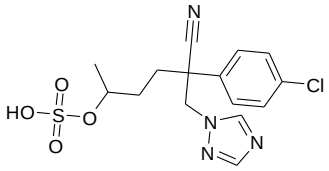
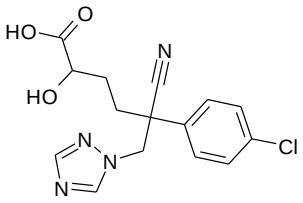
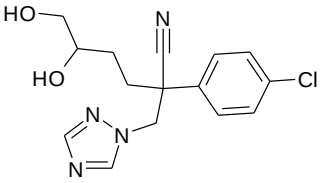
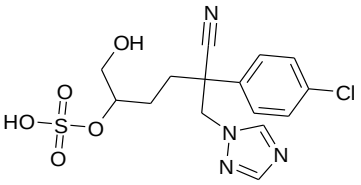
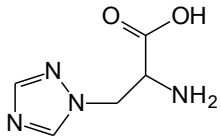
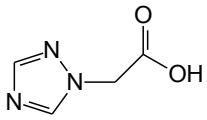
At the Forty-fifth Session of the CCPR (REP13/PR, Appendix XIV), myclobutanil was scheduled for periodic residue review by the 2014 JMPR. The Meeting received information on physical and chemical properties, metabolism, environmental fate, analytical methods and freezer storage stability, national registered use patterns, as well as supervised trials, processing studies and livestock feeding studies.

Myclobutanil is (R, S)-2-(4-chlorophenyl)-2-(1H-1, 2, 4-triazol-1-ylmethyl) hexanenitrile and exists as a racemate.



The following compound codes are used for the metabolites discussed below:

RH-9089	(2RS) -2-(4-chlorophenyl) -5-oxo-2-(1H-1,2,4-triazol-1-ylmethyl)hexanenitrile	
RH-9090	α-(4-chlorophenyl)-α-(3-hydroxybutyl)-1H-1,2,4-triazole-1-propanenitrile	
MW 318 Acid (butyl carboxylic acid of myclobutanil)	5-(4-chlorophenyl)-5-cyano-6-(1H-1,2,4-triazol-1-yl)hexanoic acid	
N-Glucuronic Acid Conjugate of Myclobutanil	1-[2-(4-chlorophenyl)-2-cyanohexyl]-4-hexopyranuronosyl-1H-1,2,4-triazol-4-ium	
Hydroxy-lactone	3-(4-chlorophenyl)-5-(1-hydroxyethyl)-3-(1H-1,2,4-triazol-1-ylmethyl)dihydrofuran-2(3H)-one	
RH-9090 Glucuronic Acid Conjugate	5-(4-chlorophenyl)-5-cyano-6-(1H-1,2,4-triazol-1-yl)hexan-2-yl hexopyranosiduronic acid	

RH-9090 Sulfate Conjugate	5-(4-chlorophenyl)-5-cyano-6-(1H-1,2,4-triazol-1-yl)hexan-2-yl hydrogen sulfate	
MW 334 Acid	5-(4-chlorophenyl)-5-cyano-2-hydroxy-6-(1H-1,2,4-triazol-1-yl)hexanoic acid	
RH-294 (Diol)	α-(-chlorophenyl)-α-(3,4-hydroxy-butyl)-1H-1,2,4-triazole-1-propane-nitrile	
RH-294 Sulfate Conjugate	5-(4-chlorophenyl)-5-cyano-1-hydroxy-6-(1H-1,2,4-triazol-1-yl)hexan-2-yl hydrogen sulfate	
RH-3968 (Triazolyl Alanine, TA)	(2*RS*)-2-amino-3-(1*H*-1,2,4-triazol-1-yl)propanoic acid	
RH-4098 (Triazolyl Acetic Acid, TAA)	1*H*-1,2,4-triazol-1-ylacetic acid	

Animal metabolism

Information was available on metabolism of myclobutanil in rats, lactating goats and laying hens.

Laboratory animals: Myclobutanil was mainly and rapidly absorbed (> 89%), extensively metabolised and rapidly and completely excreted after oral administration in rats. Peak plasma and tissue radiolabelled myclobutanil were achieved within 1 hr after oral administration and plasma elimination was biphasic. No significant tissue accumulation was observed 96 hr post-dosing. Metabolism appears to have occurred mainly through a variety of oxygenation reactions of the butyl group. The major metabolic processes involved oxygenation to the butyl group and among the metabolites formed are the RH9090 and RH9089, the major unconjugated phenethyl triazole-containing metabolites found in plants.

Lactating goats: Myclobutanil was orally dosed to lactating goats for 5 days. Individual goats were dosed separately with myclobutanil radiolabelled in either the triazole (TZ) portion or the phenyl ring (PH) at the rate of 24 ppm and 14 ppm in the diet per day, respectively. Approximately 71% and 79% of TAR was recovered in the faeces and urine for the TZ-label and PH-label dosed animal. Most of administered dose was rapidly absorbed, metabolised and rapidly eliminated via the

urine (49–58% TAR) and faeces (22% TAR). TRR levels in tissues ranged from 0.016 mg eq/kg in omental fat to 0.49 mg eq/kg in liver for the low dosed goat (PH label) and from 0.027 mg eq/kg in omental fat to 0.92 mg eq/kg in liver for the high dosed goat (TZ label). Residue levels were highest in liver and kidney and significantly lower in muscle and fat.

Milk and edible tissues were extracted with acetone, hexane and acetonitrile/water (80/20) and 78–101% radioactive residues were recovered. Unchanged parent compound was only observed in liver (2.1–6.0% TRR, 0.019–0.029 mg/kg). The metabolite RH-9090 and its sulphate and glucuronic acid conjugates were the primary residue in liver (total 59–60% TRR, 0.29–0.54 mg eq./kg), in kidney (total 58–61% TRR, 0.13–0.30 mg eq./kg), in muscle (total 47–80% TRR, 0.02–0.03 mg eq./kg) and in fat (total 44–46% TRR, 0.01–0.02 mg eq./kg). The hydroxy-lactone was the only other metabolite present in liver at levels in excess of 10% of the TRR (12–16% TRR, 0.08–0.11 mg eq./kg).

For both labels in milk, the residue levels reached a plateau within 4 days after the initiation of dosing at a level of approximately 0.033–0.079 mg eq./kg. The primary residue was RH-9090 which constituted about 28–58% of the TRR, while the only other two metabolites representing 10% or more of the TRR were RH-294 and the MW 318 carboxylic acid. No parent compound was detected in milk.

Laying hens: [^{14}C]-Myclobutanil was administered orally to groups of three laying hens once daily for 7 consecutive days at the nominal equivalent of 110 ppm in a diet. Over 95% of the dosed radioactivity was recovered in the excreta. Whole eggs and muscle were extracted with ethyl acetate, and then extracted with methanol. Fat and edible offal were extracted with n-hexane and methanol. The extracted radioactive residues accounted for 69% TRR in whole eggs, 79% TRR in fat, 83% TRR in thigh muscle, 97% TRR in breast muscle, 156% TRR in kidney (118% TRR as uncharacterized) and 72% TRR in liver (61% TRR as uncharacterized), respectively.

Total radioactive residues were observed in the liver (0.52 mg eq/kg) and the kidney (0.32 mg eq/kg), while lower residues were found in muscle (0.06 mg eq./kg) and fat (0.02 mg eq./kg). Parent myclobutanil was a main residue in fat (67% TRR) in kidney (12% TRR) in liver (4.8% TRR), and in muscle (up to 4% TRR). A band that co-chromatographed with RH-9090/RH9089 and lactone accounted for 15% TRR in kidney. The major component of the residue in muscle was RH-9089 (61–72% TRR). The major component of the residue in eggs was RH-9090 accounting for 36% TRR. No parent compound was observed in eggs.

In summary, the metabolism found in livestock was qualitatively comparable with that observed in laboratory animals. Characterization of the residues show myclobutanil together with RH-9090 and its conjugates are the major residues in the animal tissues, milk and eggs except RH-9089 as a major component in the muscle of laying hens.

Plant metabolism

The Meeting received plant metabolism studies with myclobutanil on grapes, apples, wheat, and sugar beets.

Grape seedlings in the greenhouse were placed in nutrient solution containing either ^{14}C-phenyl myclobutanil or ^{14}C-triazole myclobutanil. An average of 37% TRR remained as the parent compound. RH-9090 accounted for 6% TRR, with 11% TRR present as the RH-9090 glucoside and 14% TRR as an unknown polar component. In the 16-day uptake samples, parent compound accounted for an average of 53% TRR, RH-9090 8% TRR and RH-9090 glucoside 12% TRR.

Grape vines were sprayed five times weekly with myclobutanil, labelled with ^{14}C in the phenyl ring or the triazole ring each at a rate equivalent to 0.05 kg ai/ha. The overall recovery of identified radioactive residues ranged from 79% to 82%. TRR in whole grapes at harvest were 0.32 and 0.24 mg eq./kg for PH and TZ grapes, respectively. The major component of residue was the

parent compound accounting for 66% TRR, RH-9090 for 7–9% TRR, RH-9090 glucoside for 5–6% and RH-9089 for 1%, respectively.

Apple trees received ten approximately weekly sprays of myclobutanil, labelled with ^{14}C in the phenyl ring or the triazole ring, at 0.24 kg ai/ha. After extraction with chloroform or methanol, the overall recoveries of identified radioactive residues ranged from 84% to 86% TRR. TRR in whole grapes at harvest were 0.48 and 0.32 mg eq/kg for PH and TZ grapes, respectively. The major component of the terminal residue remained parent compound accounting for 49% of TRR. Conjugated RH-9090 accounted for 21–24% TRR. Free RH-9090 accounted for 12% TRR. A minor component was RH-9089 present at 1.9% TRR. There were no differences in the metabolic profile between the two radiolabelled experiments.

Wheat seedlings were exposed to ^{14}C-myclobutanil at either 42 mg/kg (PH label) or 64 mg/kg (TZ label) in nutrient solutions for an 11 day period placed in the greenhouse. After extraction with methanol, the overall recovery including the unextracted residue ranged from 90% to 96%. In the wheat seedlings, most of the radioactivity (62–71% TRR) remained as parent compound. The total conjugates constituted the complement of the total residues (accounting for 21–30% TRR). In the excised wheat shoots, more than 72% of TRR maintained as unchanged parent compound. In the excised heads of 13-day uptake samples, parent compound accounted for up to 75% TRR, free RH-9090 for 5% TRR, RH-9090 glucoside for up to 18% TRR for both labelling forms.

The metabolism of myclobutanil, using either PH or TZ labels, was studied in wheat under field conditions and greenhouse at a rate equivalent to 0.28 kg ai/ha. After extraction with methanol, the overall recovery of identified radioactive residues ranged between 77% and 102%. TRRs in wheat grain ranged from 0.07 to 3.6 mg eq./kg, and those in wheat straw were from 2.8–69 mg eq./kg. The main components of the residue in wheat straw were parent myclobutanil (under field: 29–47% TRR), RH-9090 and its conjugates (under field: 23–41% TRR). The main components of the residue in wheat grains were RH-9090 and its conjugates (35% TRR) and parent myclobutanil (11% TRR) treated with PH label under field conditions. However, the main components of the residue in wheat grains were RH-3968 (51% TRR) and RH-4098 (25% TRR), and RH-9090 and its conjugates (8.9% TRR) treated with TZ label under field conditions while unchanged myclobutanil was a minor component of residue treated with TZ label accounting for 0.4% TRR.

Foliar applications were made to sugar beet at application rates equivalent to 0.15 kg ai/ha and 1.50 kg ai/ha using two radiolabelled forms ([^{14}C]-phenyl-myclobutanil and [^{14}C]-triazole-myclobutanil) 30 days prior to maturity. After extracted with acetonitrile, the overall recovery ranged between 91% and 105%. The main components of the residue in roots were parent myclobutanil (27–33% TRR, 0.01–0.03 mg eq./kg), conjugated RH-9090 and free RH-9090 (total 8–14%TRR, 0.006–0.007 mg eq./kg). The main components of the residue in leaves at maturity were RH-9090 (50–62% TRR, 0.26–0.43 mg eq./kg) and parent myclobutanil (16–34% TRR, 0.11–0.18 mg/kg), respectively.

In summary, the metabolism of myclobutanil in crops is qualitatively consistent and considered comparable except in wheat treated with the TZ label. The conversion of myclobutanil to RH-9090 followed by conjugation with glucose is the major metabolic pathway. Minor amounts of RH-9089 are probably a result of oxidation of RH-9090. The presence of RH-3968 and RH-4098 in wheat treated with the TZ label indicates that the phenethyl triazole linkage in the parent was metabolically cleaved.

Environmental fate in soil

The Meeting received information on the environment fate of myclobutanil in confined and field crop rotational studies. A study on degradation of myclobutanil in aerobic soil showed that half-life values reached up to 574 days. Myclobutanil could be a persistent compound in some soils.

Confined rotational crop

The metabolism of ^{14}C-triazole-myclobutanil in succeeding crops was investigated in wheat, radish and lettuce cultivated at three different plant back intervals for all crops (30, 120 and 365 days) at 1×0.36 kg ai/ha. Lettuce, radish and wheat were planted at rotational intervals of 30, 120 and 365 days after soil treatment, TRRs ranged from 0.07 to 2.7 mg eq/kg were found in harvested crops. Radioactive residues in immature and mature lettuce and radish tops declined over time, while residues in radish roots increased. Residues in wheat hay, straw and grain did not show consistent increase or decline. The three most abundant non-polar components in crops planted 30 days after soil application were myclobutanil at 0.43 mg/kg (55% TRR) in mature lettuce, MW 309 di-acid at 0.38 mg eq./kg (14% TRR) and RH-9090 at 0.47 mg eq./kg (17% TRR), both in wheat straw. The two most abundant polar metabolites were the triazole alanine at 0.45 mg eq./kg (30% TRR) and triazole acetic acid at 0.43 mg eq./kg (29% TRR), both in 120 DAT wheat grain. Unextracted residues exceeded both 10% of the TRR and 0.05 mg eq/kg only in wheat hay, straw and grain at all plant-backs. In wheat hay and straw, the unextracted residues ranged from 11 to 23% TRR and from 0.17 to 0.53 mg eq./kg. For wheat grain, the unextracted residues ranged from 26 to 39% TRR and from 0.21 to 0.57 mg eq./kg.

The unchanged parent molecule was found as main component in samples of immature, mature lettuce (30-day PBI), radish roots (30, 120, 365-day PBI) and wheat forage (30 day PBI). Myclobutanil was detected as minor component in other samples. Metabolites were generally detected in lower concentrations. The parent compound, RH-9090 and its conjugates were found in most parts of the four crops. The other two most abundant metabolites were MW 309 di-acid (0.4–28% TRR) and butyric acid (0.9–15% TRR), were not identified in the metabolism studies of crops. This study indicates a potential uptake of residues for myclobutanil into plant commodities.

Field rotational crops

Myclobutanil was applied at 6×0.14 kg ai/ha to zucchini in the USA (California and Georgia) approximating the estimated plateau level in soil after subsequent annual application. Within 2 days after the last application, zucchini fruit were harvested and removed from the plots. The remaining plant parts were incorporated into the soil 7–10 days after harvest and then rotational crops (soya bean, radish and wheat) were planted 30 days after the last application to the target zucchini crop. Rotational crops were sampled ranging between 71 and 258 days after final treatment. The plants were soxhlet extracted with methanol and analysed for the parent compound and RH-9090. Residues of myclobutanil and RH-9090 occurred up to 0.36 and 0.15 mg/kg in soya bean forage, 0.093 and 0.19 mg/kg in soya bean hay, 0.052 and < 0.01 mg/kg in radish root, 0.044 and 0.12 mg/kg in radish tops, 0.071 and 0.11 mg/kg in wheat forage, 0.18 and 0.63 mg/kg in wheat straw, respectively. Myclobutanil and RH-9090 residues were higher in vegetative matrices (forage, hay and straw) than the respective seed or grain crop matrix. Residue values for soya bean seeds and wheat grains were all below LOQ (0.01 mg/kg).

Methods of analysis

The Meeting received descriptions and validation data for analytical methods for residues of myclobutanil and RH-9090 in plant and meat. Myclobutanil residues can be measured in most matrices to the LOQ range of 0.01 to 0.05 mg/kg. No stereo-selective methods were submitted for two myclobutanil enantiomers.

The crop and animal methods typically use an initial extraction with methanol or acetone or acetonitrile, and clean-up with partition and/or column steps. The final solution was analysed by GC-ECD, GC-MS or LC-MS/MS. If RH-9090 and its conjugates are determined, hydrolysis with concentrated acid and heating is applied after extraction. Myclobutanil residues can be measured in most matrices to an LOQ of 0.01 mg/kg. All methods are considered sufficiently validated. Multi-residue enforcement method DFG S19 and MRM-1 were provided and validated. The DFG S19 was

valid for RH-9090 in animal tissues except fat and MRM-1 was valid for myclobutanil in crops with the LOQ of 0.2 mg/kg. Analytical methods in the feeding studies were valid for determination of myclobutanil and total RH-9090 in milk, myclobutanil and free RH-9090 in muscle, fat, liver and kidney.

Stability of residues in stored analytical samples

The Meeting received information on the freezer storage stability of residues of myclobutanil in plant and animal commodities.

Storage stability studies were conducted on apples, radish root, soya bean, wheat forage, wheat grain, wheat hay, wheat straw, blueberry, cucurbits and snap beans. Analytical results demonstrated that myclobutanil and RH-9090 were stable in the different plant matrices for at least one year, the duration of the test period.

Storage stability studies on liver and muscle were carried out. Analytical results demonstrated that myclobutanil and its metabolite RH-9090 were stable for at least 80 days, the duration of the study.

Definition of the residue

The composition of the residue in the metabolism studies, the available residue data in the supervised trials, the toxicological significance of metabolites, the capabilities of enforcement analytical methods and the national residue definitions already operating all influence the decision on residue definition.

The metabolism studies of lactating goats showed that the unchanged parent compound was only observed in liver. RH-9090 and its conjugates were the primary residues in liver, kidney, muscle and fat. The primary residue was RH-9090, constituted about 28–58% of the TRR in milk and no parent compound was observed.

In laying hens studies, the highest ^{14}C levels were observed in liver and kidney, while fewer residues were found in muscle and fat. Parent was one of the main components detected in liver and in kidney. RH-9090-sulphate was another main residue detected in liver. A band that co-chromatographed with RH-9090/RH9089 and hydroxy-lactone accounted for 15% TRR in kidney. The major component of the residue in muscle extracts was RH-9089. The major component of residue in fat was parent compound. RH-9090 was the major component of the residue in eggs. No parent compound was observed in eggs.

RH-9090 and its conjugates are the main residues in the animal tissues, milk and eggs. Parent compound is also identified in most of tissues and as a major component in fat and kidney. Although RH-9090 and RH-9089 are found in tissues of animal metabolism study, no residues of parent compound and metabolites were expected above LOQ on the basis of dietary burden calculation and animal feeding studies. The Meeting recommended that, parent myclobutanil is the appropriate residues of concern for MRL enforcement and dietary risk assessment in animal commodities.

The octanol-water partition coefficient of myclobutanil (log K_{ow}=2.56) suggests that myclobutanil is not fat-soluble. Noting that myclobutanil residues in animal fat were less than those in muscle, the Meeting agreed that myclobutanil residue is not fat-soluble.

Metabolism studies on plants, and confined rotational crop showed that the main residues in food or feed of plant origin were myclobutanil and/or conjugated RH-9090 and free RH-9090. The Meeting decided that for plant commodities, parent myclobutanil is the appropriate residue of concern for MRL enforcement, and myclobutanil and RH-9090 and its conjugates for dietary risk assessment.

Definition of the residue (for compliance with the MRL) for plant and animal commodities: *myclobutanil*.

Definition of the residue (for estimation of dietary intake) for animal commodities: *myclobutanil*.

Definition of the residue (for estimation of dietary intake) for plant commodities: *sum of myclobutanil, α-(4-chlorophenyl)-α-(3-hydroxybutyl)-1H-1,2,4-triazole- 1-propanenitrile (RH-9090) and its conjugates, expressed as myclobutanil*.

The residue is considered not fat-soluble.

Results of supervised residue trials on crops

The Meeting received supervised trials data for myclobutanil formulations for apple, pear, peach, cherry, apricot, plum, currant, grapes, strawberry, banana, hops, tomato, squash, pepper, cucumber, melon, watermelon, snap beans and soya beans.

The method for calculation of the total residues is illustrated as follows (similar molecular weight, therefore sum residues of myclobutanil and RH-9090 as total residue).

RH-9090 less than LOQ (0.01 mg/kg) and more than LOD (0.0025 mg/kg)

Myclobutanil, mg/kg	RH-9090, mg/kg	Total, mg/kg
< 0.01	< 0.01	< 0.02
0.08	< 0.01	0.09

RH-9090 less LOD (0.0025 mg/kg)

Myclobutanil, mg/kg	RH-9090, mg/kg	Total, mg/kg
< 0.01	< 0.0025	< 0.01
0.08	< 0.0025	0.08

RH-9090 equal to or more than LOQ (0.01 mg/kg)

Myclobutanil, mg/kg	RH-9090, mg/kg	Total, mg/kg
0.21	0.03	0.24

Pome fruits

The critical GAP for myclobutanil on pome fruits is in Czech Republic, 3×0.09 kg ai/ha, 14-day PHI. Seven trials were available from Europe on apple against Czech GAP with myclobutanil residue of 0.03(2), 0.05, 0.07, 0.11, 0.20 and 0.34 mg/kg, with total residue of 0.03, 0.04, 0.05, 0.08, 0.12, 0.22 and 0.35 mg/kg.

Eight trials were available from Europe on pear against Czech GAP with myclobutanil residue of 0.03(2), 0.04, 0.05, 0.06, 0.10, 0.28 and 0.32 mg/kg, and with total residue of 0.05(3), 0.06, 0.07, 0.11, 0.29 and 0.35 mg/kg.

Noting the similar data population from apple and pear and medians of the datasets differed less than 5-fold, The Meeting agree to combined the residues, expressed in terms of myclobutanil, which were: 0.03(4), 0.04, 0.05(2), 0.06, 0.07, 0.10, 0.11, 0.20, 0.28, 0.32 and 0.34 mg/kg. The residues expressed in terms of total myclobutanil residues were: 0.03, 0.04, 0.05(4), 0.06, 0.07, 0.08, 0.11, 0.12, 0.22, 0.29 and 0.35(2) mg/kg. On the basis of myclobutanil residues, the Meeting estimated a maximum residue level of 0.6 mg/kg pome fruits to replace the previous recommendation of 0.5 mg/kg. The Meeting also agreed to combine two datasets to estimate an HR of 0.35 mg/kg, an STMR of 0.07 mg/kg based on the total residue.

Stone fruits

The critical GAP for myclobutanil on peach, nectarine and cherry is in the USA, 8× 0.18 kg ai/ha with PHI of 0 day. Nine trials were conducted with application number from 7 to 11 within ± 25% GAP rate in the USA. No significant contribution should be expected from the treatments more than 3 half-lives to the final residue. Myclobutanil residues with 0 day PHI on peach were: 0.34, 0.38, 0.62, 0.66, 0.75, 0.84, 0.85 and 1.23 mg/kg and the total residues were: 0.37, 0.55, 0.76, 0.82, 0.91, 1.06, 1.12 and 1.54 mg/kg.

Eight trials were available from the USA on cherries with myclobutanil residue 0.20, 0.28, 0.75, 0.85, 0.92, 1.04, 1.12 and 1.44 mg/kg, and with total residue 0.22, 0.32, 0.82, 1.05, 1.07, 1.52, 1.61 and 2.05 mg/kg.

The Meeting estimated an HR of 2.05 mg/kg, an STMR 1.06 mg/kg, and maximum residue level of 3 mg/kg for cherry.

The critical GAP for myclobutanil on apricot, plum and prune is from the USA, 7×0.18 kg ai/ha with a PHI of 0 days. Seven trials were available from the USA and Europe on apricot against US GAP, myclobutanil residues were: 0.11, 0.12, 0.17, 0.18, 0.23, 0.34 and 0.62 mg/kg, and total residues were: 0.13, 0.14, 0.21, 0.25, 0.29, 0.38 and 0.70 mg/kg.

Eight trials were available from the USA on plum against US GAP, myclobutanil residues were: 0.09, 0.13, 0.20, 0.25, 0.28, 0.59, 0.97 and 1.12 mg/kg, and total residues were: 0.11, 0.36, 0.40, 0.73 and 1.45 mg/kg.

The Meeting estimated an HR of 1.45 mg/kg, an STMR 0.40 mg/kg, and maximum residue level of 2 mg/kg and agreed to replace the previous recommendation of 0.2 mg/kg for plums.

Considering the higher residues came from peach, the Meeting decided not to combine datasets of peach and apricot, and estimated an HR of 1.54 mg/kg, STMR 0.865 mg/kg, and maximum residue level of 3 mg/kg for peach, nectarine and apricot on the basis of residues of peach. The Meeting agreed to withdraw the previous recommendation of 2 mg/kg for stone fruits (except plums) and 0.5 mg/kg for prunes.

Currants

The critical GAP for myclobutanil on currants is from the UK, 6×0.09 kg ai/ha with a PHI of 14 days. Twelve trials were available from the UK on black currants matching GAP with myclobutanil residue 0.19, 0.24(2), 0.26(2), 0.29, 0.30(2), 0.31, 0.35, 0.42 and 0.43 mg/kg, and with total residue 0.21, 0.28(2), 0.31(2), 0.34(2), 0.35, 0.37, 0.39, 0.46 and 0.47 mg/kg.

The Meeting agreed to estimate an HR 0.47 mg/kg, an STMR 0.34 mg/kg, and maximum residue level of 0.9 mg/kg for currants to replace the previous recommendation of 0.5 mg/kg on currants, black.

Grapes

The critical GAP for myclobutanil on grapes is in the USA, 5×0.15 kg ai/ha with PHI of 14 days. Nine trials were available from the USA on grapes against US GAP. Myclobutanil residues in grapes were: 0.13, 0.14(2), 0.25, 0.31, 0.32(2), 0.48 and 0.53 mg/kg, and total residues in grapes were: 0.17, 0.19(2), 0.29, 0.34, 0.40(2), 0.58 and 0.60 mg/kg.

The Meeting estimated an HR of 0.60 mg/kg, an STMR 0.34 mg/kg, and maximum residue level of 0.9 mg/kg for to replace the previous recommendation of 1 mg/kg for grapes.

Strawberry

The critical GAP for myclobutanil on strawberry is from the USA, 6×0.14 kg ai/ha with a PHI of 0 days. Seven outdoor trials from the USA against US GAP gave residues of: 0.03, 0.04, 0.10, 0.15, 0.20, 0.23 and 0.31 mg/kg.

The critical GAP for myclobutanil on strawberry is from the UK, 6×0.09 kg ai/ha with PHI of 3 days. In 19 outdoor trials from Europe at UK GAP, myclobutanil residues were 0.08, 0.10, 0.14, 0.15, 0.17, 0.18(2), 0.19(4), 0.20(2), 0.22, 0.24, 0.30, 0.48, 0.50 and 0.69 mg/kg, and total residues were 0.09, 0.10, 0.15(2), 0.17, 0.18(2), 0.19(4), 0.20(2), 0.22, 0.24, 0.31, 0.48, 0.50 and 0.69 mg/kg. Eight indoor trials were available from Europe on strawberry matching the GAP of the UK with myclobutanil residues of 0.13, 0.16, 0.18, 0.19, 0.20, 0.24, 0.37and 0.46 mg/kg, and with total residues of 0.14, 0.17, 0.19, 0.20, 0.21, 0.25, 0.38 and 0.47 mg/kg.

Considering the higher residues came from Europe, and residue populations from indoor and outdoor European trials were similar, the Meeting decided to combine the two datasets. The residues from 27 trials were: 0.08, 0.10, 0.13, 0.14, 0.15, 0.16, 0.17, 0.18(3), 0.19(5), 0.20(3), 0.22, 0.24(2), 0.30, 0.37, 0.46, 0.48, 0.50 and 0.69 mg/kg for myclobutanil and 0.09, 0.10, 0.14, 0.15(2), 0.17(2), 0.18(2), 0.19(5), 0.20(3), 0.21, 0.22, 0.24, 0.25, 0.31, 0.38, 0.47, 0.48, 0.50 and 0.69 mg/kg for myclobutanil and RH-9090 and its conjugates. The Meeting estimated a maximum residue level of 0.8 mg/kg on the basis of parent residues for strawberry to replace the previous recommendation of 1 mg/kg on strawberry. The Meeting also estimated an HR of 0.69 mg/kg and an STMR of 0.19 mg/kg on the basis of total residues.

Banana

Myclobutanil is registered in Costa Rica for use as a post-harvest run-off or dip application at 84.8 g ai/hL, application prior to the packing of fruit. Three trials from Costa Rica on banana matching GAP gave myclobutanil residues in whole fruits of 0.028(2) and 0.29 mg/kg. Total residues in banana pulp were 0.06, 0.07 and 0.09 mg/kg.

The Meeting considered three trials to be insufficient for the estimation of a maximum residue level, an STMR and an HR for banana. The Meeting agreed to withdraw the previous recommendation of 2 mg/kg for banana.

Fruiting vegetables, other than Cucurbits

Tomatoes

The critical GAP for myclobutanil on tomatoes is from the USA, 4×0.11 kg ai/ha with a PHI of 0 days. Seventeen outdoor trials were available from the USA on tomatoes matching US GAP with myclobutanil residues of 0.02, 0.03(2), 0.04(2), 0.06, 0.07(5), 0.08(2), 0.09, 0.10, 0.11 and 0.22 mg/kg, and with total residues of 0.02, 0.03, 0.04(2), 0.05, 0.06, 0.07(4), 0.08, 0.09, 0.10(2), 0.11, 0.12 and 0.25 mg/kg.

The Meeting decided to estimate an HR of 0.25 mg/kg, an STMR of 0.07 mg/kg based on total residues, and a maximum residue level of 0.3 mg/kg based on myclobutanil residues for tomatoes, confirming the previous recommendation.

Peppers

The critical GAP for myclobutanil on peppers is from the USA, 4×0.14 kg ai/ha with a PHI of 0 days. Two outdoor trials were available from the USA on sweet pepper matching US GAP with myclobutanil residue 0.03 and 0.47 mg/kg, and with total residue 0.05 and 0.64 mg/kg. Four outdoor trials were available from the USA on chilli pepper against US GAP with myclobutanil residue 0.09, 0.18, 1.19 and 2.03 mg/kg, and with total residue 0.12, 0.23, 1.39, 2.40 mg/kg.

Considering the residues from sweet and chilli peppers to be similar, the Meeting decided to combine the two datasets. The residues in six trials were 0.03, 0.09, 0.18, 0.47, 1.19 and 2.03 mg/kg for myclobutanil and 0.05, 0.12, 0.23, 0.64, 1.39, 2.40 mg/kg for myclobutanil and RH-9090 and its conjugates. The Meeting estimated an HR 2.40 mg/kg, an STMR 0.435 mg/kg based on total residues, and maximum residue level of 3 mg/kg based on myclobutanil residues for peppers.

On the basis of residues in peppers and dehydration factor of 7, the Meeting estimated an HR of 16.8 mg/kg, an STMR of 2.45 mg/kg and recommended a maximum residue level of 40 mg/kg for myclobutanil on peppers chilli, dried.

Fruiting vegetables, Cucurbits

The critical GAP for myclobutanil on cucurbits is from the USA, 5 applications at 0.14 kg ai/ha with a PHI of 0 days.

Summer Squash

Nine outdoor trials were available from the USA on summer squash matching US GAP. Myclobutanil residues in squash were: 0.01(2), 0.02(2), 0.04, 0.05, 0.06, 0.10 and 0.16 mg/kg, and with total residues of 0.01, 0.02, 0.03(2), 0.04, 0.05, 0.07, 0.11 and 0.16 mg/kg.

Cucumber

Seven outdoor trials were available from the USA on cucumbers matching US GAP. Myclobutanil residues were: 0.02, 0.03(2), 0.04(2) and 0.07 mg/kg, and with total residue of 0.03(2), 0.04 (3) and 0.07 mg/kg.

Melons

Four outdoor trials were available from the USA on melons matching US GAP with myclobutanil residues of 0.02, 0.05, 0.07 and 0.08 mg/kg, and with total residues of 0.02, 0.05, 0.07 and 0.08 mg/kg. Two outdoor trials were available from Southern Europe on melon matching US GAP with myclobutanil residues of 0.09 and 0.10 mg/kg, and total residue of 0.10 and 0.11 mg/kg.

The US GAP is the same for cucumbers, melons and squash. The Meeting considered that the residues from trials with the foliar application on cucumber, melon and squash were similar. The Meeting agreed to propose a group maximum residue level for fruiting vegetables, cucurbits. The residues expressed in terms of myclobutanil were: 0.01(2), 0.02(4), 0.03(2), 0.04(3), 0.05(2), 0.06, 0.07(2), 0.08, 0.09, 0.10(2) and 0.16 mg/kg. The residues expressed in terms of myclobutanil and RH-9090 and its conjugates were: 0.01, 0.02(2), 0.03(4), 0.04(4), 0.05(2), 0.07(3), 0.08, 0.10, 0.11(2) and 0.16 mg/kg

Based on the trials for cucumbers, melons and squash in the USA and Southern Europe, the Meeting estimated an HR of 0.16 mg/kg, an STMR of 0.04 mg/kg and a maximum residue level of 0.2 mg/kg for fruiting vegetables, cucurbits respectively.

Legume vegetables

Common bean

The critical GAP for myclobutanil on snap beans is from the USA, i.e., 4×0.14 kg ai/ha with a PHI of 0 days. Nine trials were available from the USA on snap beans matching US GAP. Myclobutanil residues found were: 0.04, 0.09, 0.14, 0.19, 0.20, 0.22, 0.30, 0.37 and 0.47 mg/kg, and total residues were: 0.06, 0.11, 0.16, 0.21, 0.22, 0.24, 0.32, 0.39 and 0.49 mg/kg.

On the basis of the trials on snap beans, the Meeting estimated an HR of 0.49 mg/kg, an STMR 0.22 mg/kg based on the total residues dataset, and a maximum residue level of 0.8 mg/kg for beans, except broad bean and soya bean (green pods and immature seeds), respectively.

Soya bean (dry)

The critical GAP for myclobutanil on soya beans is from Brazil, 2×0.125 kg ai/ha with a PHI of 24 days. Nine trials were available from Brazil on soya bean matching the Brazilian GAP with parent residues of < 0.01(5), < 0.02(2), 0.02 and 0.03 mg/kg.

Noting that total residues were not available from the Brazilian trials, the Meeting did not estimate a maximum residue level for soya bean.

Hops

The critical GAP for myclobutanil on hops is from the USA, 4×0.28 kg ai/ha with a PHI of 14 days. Ten trials were available from Germany on hops matching US GAP, myclobutanil residues in dried hops were: < 0.50, 0.53, 0.63, 0.73, 1.02, 1.06, 1.14, 1.54, 1.80 and 3.50 mg/kg, and with total residues of 0.53, < 1.00, 1.13, 1.23, 1.52, 1.56, 2.04, 3.20 and 5.60 mg/kg.

The Meeting estimated an HR of 5.60 mg/kg, a STMR 1.52 mg/kg based on the total residue dataset, and a maximum residue level of 5 mg/kg for dry hops based on myclobutanil residues to replace the previous recommendation of 2 mg/kg on dry hops.

Animal feedstuffs

The critical GAP for myclobutanil on soya bean is from the USA, 2×0.14 kg ai/ha with a PHI of 28 days.

Soya bean forage

Two trials were available from the USA on soya bean forage matching US GAP with residues of 0.67 and 1.01 mg/kg.

Two trials on soya bean forage were considered insufficient for the estimation of median and highest residues.

Soya bean hay (dry)

Noting no trials on soya bean hay were available from the USA against US GAP, the Meeting did not make recommendations for soya bean hay.

Rotational crops

The Meeting noted that myclobutanil may accumulate in soil and be taken up by following crops in significant amounts. Residues were reported in field rotational crop studies following application to zucchini at rates of 6×0.14 kg ai/ha. Since the foliage of the crop was incorporated into soil after harvest of the fruits, this application rate can be assumed to approximate the estimated soil plateau level following annual treatment according to the GAPs considered by the Meeting.

Residues for parent myclobutanil in respective field studies were < 0.003 mg/kg for soya bean seeds, 0.03 mg/kg to 0.36 mg/kg for soya bean forage and 0.017 mg/kg to 0.093 mg/kg for soya bean straw. The Meeting concluded that for pulses no significant transfer into seeds is expected. Median and highest residues were estimated at levels of 0.195 mg/kg and 0.36 mg/kg for legume forages and of 0.055 and 0.093 mg/kg for legume fodders.

Based on the average dry-matter content of 85% for soya bean hay, the Meeting estimated a maximum residue level of 0.2 mg/kg (DM) for legume animal feeds.

In leaves of radish grown as rotational crops myclobutanil residues were 0.015 mg/kg to 0.044 mg/kg. Extrapolating the residues found in radish leaves to all Brassica vegetables and leafy vegetables (including Brassica leafy vegetables), the Meeting estimated maximum residue levels of 0.05 mg/kg and HR and STMR values of 0.044 mg/kg and 0.030 mg/kg for Brassica vegetables and leafy vegetables (including leafy Brassica vegetables), respectively.

The roots of radish grown as a rotational crop contained myclobutanil residues of 0.026 mg/kg to 0.052 mg/kg. The Meeting decided to extrapolate the results to all bulb vegetables and all root and tuberous vegetables. The Meeting estimated a maximum residue level of 0.06 mg/kg and HR and STMR values of 0.039 mg/kg and 0.052 mg/kg for bulb vegetables and root and tuber vegetables, respectively.

Residues in wheat matrices obtained from field rotational crop studies contained myclobutanil residues < 0.003 mg/kg in the grain, 0.023 mg/kg to 0.071 mg/kg in forage and 0.015 mg/kg to 0.18 mg/kg in hay and straw. The Meeting concluded that for cereal grains no significant transfer of residues into seeds is expected. Median and highest residues were estimated at levels of 0.047 mg/kg and 0.071 mg/kg for cereal forages and of 0.098 and 0.18 mg/kg for cereal straw and fodder.

Based on the average dry-matter content of 88% for wheat straw, the Meeting estimated a maximum residue level of 0.3 mg/kg (DM) for straw and fodder (dry) of cereal grains.

The Meeting also concluded that the contribution of residues by uptake of myclobutanil from soil is insignificant compared to direct treatment for the uses evaluated.

Fate of residues during processing

The Meeting received information on the hydrolysis of myclobutanil as well as processing studies during the food processing of apples, grapes, tomatoes, soya beans and hops.

No degradation of myclobutanil was observed in a hydrolysis study at pH 4, 7 and 9 held at 50 °C, over a 5 day period.

In the following table all processing factors based on parent residues relevant for recommendation of maximum residue levels and estimation of animal dietary burden for processed commodities are summarized.

Portion Analysed		Median Processing Factor	Median resiudes	
			Raw commoditeis	Processed commodities
Apple			0.06	
	Wet pomace	1.61		0.097
	Dry pomace	12.1		0.726
Grapes			0.295	
	Wet pomace	0.90		0.266
	Dry pomace	3.94		1.16
	Raisin	6.31		1.86
Tomato			0.07	
	Dry pomace	20.05		1.40
	Wet pomace	4.54		0.318
Soya bean			0	
	Hulls	1.14		0
	Meal	0.43		0
	Oil, refined	2.14		0
Hops			1.04	
	Beer	0.0145		0.015

Based on the median processing factor of 6.31, the Meeting estimated a maximum residue level of 6 mg/kg for raisins.

In the following table all processing factors based on total residues relevant for the estimation of the dietary intake for processed commodities are summarized.

Raw and processed commodity		Median Processing Factor	STMR (mg/kg)	STMR-P (mg/kg)	HR (mg/kg)	HR-P (mg/kg)
Apple			0.07			
	Juice	0.17		0.012		
	Puree	0.30		0.021		
Grapes			0.34		0.60	
	Juice	0.20		0.068		
	Wine after half year	0.17		0.058		
	Wine at bottling	0.14		0.048		
	Raisin	6.29		2.14		3.77
Tomato			0.07			
	Juice	0.50		0.031		
	Purée	1.33		0.093		
	Preserve	0.29		0.020		
	Paste	3.92		0.27		
Hops	Beer	0.015	1.52	0.023		

Residues in animal commodities

Estimated maximum and mean dietary burdens of farm animals

Dietary burden calculations for beef cattle, dairy cattle, broilers and layers are provided in Annex 6 to the 2014 Report. The calculations were made according to the animal diets from US-Canada, EU, Australia and Japan in the OECD Feed Table 2009.

The calculations are then summarised and the highest dietary burdens are selected for MRL and STMR estimates on animal commodities.

	Animal dietary burden, myclobutanil, ppm of dry matter diet							
	US-Canada		EU		Australia		Japan	
	max	mean	max	mean	max	mean	max	mean
Beef cattle	0.046	0.26	1.22	0.83	1.47 [a]	0.96 [b]	0.096	0.055
Dairy cattle	0.63	0.45	0.86	0.58	1.31 [c]	0.88 [d]	0.18	0.10
Poultry-broiler	0	0	0.035	0.026	0	0	0.051	0.028
Poultry-layer	0	0	0.22 [e]	0.13 [f]	0	0	0	0

[a] Highest maximum beef or dairy cattle dietary burden suitable for MRL estimates for mammalian meat.
[b] Highest mean beef or dairy cattle dietary burden suitable for STMR estimates for mammalian meat.
[c] Highest maximum dairy cattle dietary burden suitable for MRL estimates for mammalian milk.
[d] Highest mean dairy cattle dietary burden suitable for STMR estimates for mammalian milk.
[e] Highest maximum poultry dietary burden suitable for MRL estimates for poultry meat and eggs.
[f] Highest mean poultry dietary burden suitable for STMR estimates for meat and eggs.

Lactating cows were orally administered myclobutanil equivalent to 0 ppm, 1.6 ppm, 4.8 ppm and 16 ppm in the feed, respectively. Residues of myclobutanil and RH-9090 in whole milk and tissues of the cows in all groups were < 0.01 mg/kg.

Dietary burden calculations showed the highest dietary burdens were less than the lowest feeding level. The Meeting decided to estimate maximum residue levels of 0.01*, and STMRs and HRs of 0 mg/kg for all milk, eggs and animal tissues. Confirming the previous recommendations of 0.01* mg/kg for cattle meat, milk and edible offal, and eggs, poultry meat and edible offal of the 1992 JMPR.

RECOMMENDATIONS

On the basis of the data from supervised trials, the Meeting concluded that the residue concentrations listed below are suitable for establishing MRLs and for assessing IEDIs and/or IESTIs.

Definition of the residue (for compliance with the MRL for plant and animal commodities and for estimation of dietary intake for animal commodities): *myclobutanil*.

Definition of the residue (for estimation of dietary intake for plant commodities): *sum of myclobutanil, α-(4-chlorophenyl)-α-(3-hydroxybutyl)-1H- 1,2,4-triazole-1-propanenitrile (RH-9090) and its conjugates, expressed as myclobutanil*.

DIETARY RISK ASSESSMENT

Long term intake

The evaluation of myclobutanil resulted in recommendations for MRLs and STMR values for raw and processed commodities. Data on consumption were available for 33 food commodities and were used to calculate dietary intake. The results are shown in Annex 3 to the 2014 Report.

The International Estimated Daily Intakes (IEDIs) of myclobutanil, based on the STMRs estimated, represented 1–6% of the upper bound of the maximum ADI of 0.03 mg/kg bw for the 17 GEMS/Food cluster diets. The Meeting concluded that the long-term intake of residues of myclobutanil resulting from its uses that have been considered by the JMPR was unlikely present a public health concern.

Short-term intake

The 2014 Meeting established an ARfD of 0.3 mg/kg bw for women of childbearing age only; ARfD was unnecessary for the general population.

The International Estimated Short Term Intake (IESTI) for myclobutanil was calculated for the food commodities for which STMRs, HRs and maximum residue levels were estimated by the current Meeting and for which consumption data were available. The results are shown in Annex 4 to the 2014 Report. The IESTI represented up to 10% (peach) for women of childbearing age only. The Meeting concluded that the short-term intake of residues of myclobutanil resulting from uses considered by the current Meeting was unlikely to present a public health concern.

5.22 PHOSMET (103)

RESIDUE AND ANALYTICAL ASPECTS

Phosmet is a broad-spectrum organo-phosphorus insecticide used to control a variety of insect and mite pests that attack berries, pome, stone and citrus fruit. It can also be used on field, pasture and forage crops. Phosmet is non-systemic and acts by contact and ingestion as a cholinesterase inhibitor. It is registered in a number of countries, mainly for protecting fruits and vegetables.

Phosmet was evaluated for residues several times by the JMPR between 1976 and 2007, and was evaluated under the periodic review in 1994 for toxicity and in 1997 for residues. The ADI of 0–0.01 mg/kg bw was established in 1994. The ARfD of 0.2 mg/kg bw was established in 2003. Existing residue definitions for phosmet were set at the 1997 JMPR Meeting. For plant and animal commodities, the residue definition for enforcement and dietary risk assessment is phosmet.

Results of supervised residue trials on crops

Cranberry

GAP and supervised trials data on cranberry were received and evaluated by the current Meeting. Phosmet is registered in the USA for use on cranberry at 1.1–3.1 kg ai/ha with a PHI of 14 days. Five supervised trials were conducted on cranberries in the USA in 1996. The residues of phosmet from four independent trials were: 0.13, 0.84, 0.85, 0.88 mg/kg, with the highest residue of 0.91 mg/kg from a replicate sample in one trial.

The Meeting estimated a maximum residue level of 3 mg/kg, a HR of 0.91 mg/kg, and an STMR of 0.845 mg/kg for cranberries.

RECOMMENDATIONS

On the basis of the data from independent supervised trials, the Meeting concluded that the residue concentrations listed below are suitable for establishing MRLs and for assessing IEDIs and IESTIs.

Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities: *Phosmet*.

DIETARY RISK ASSESSMENT

Long-term intake

The estimates of long-term dietary intake for phosmet (ADI 0–0.01 mg/kg bw) were calculated by the current meeting for the 17 regional diets on the basis of the STMRs estimated by the JMPR in 2002, in 2007 and in 2014. The results are shown in Annex 3 of the 2014 Report.

The International Estimated Daily Intakes (IEDI) of phosmet, based on estimated STMRs from the uses were 3–90% (rounded) of the maximum ADI (0.01 mg/kg bw). The Meeting concluded that the long-term intake of residues of phosmet from uses that have been considered by the JMPR is unlikely to present a public health concern.

Short-term intake

The International Estimated Short Term Intake (IESTI) of phosmet was calculated for cranberry. The results are shown in Annex 4 to the 2014 Report.

The IESTI of phosmet calculated on the basis of the recommendations made by current meeting represented 0-3% of the ARfD (0.2 mg/kg bw) for children, 0-2% for the general population. The Meeting concluded that the short-term intake of residues of phosmet resulting from uses in cranberry that have been considered by the JMPR is unlikely to present a public health concern.

5.23 PROPAMOCARB (148)

RESIDUE AND ANALYTICAL ASPECTS

Propamocarb is a systemic carbamate fungicide with specific activity against Oomycete species that cause seed, seedling, root, foot and stem rots and foliar diseases in a number of edible crops. The compound was first evaluated by the JMPR in 1984, and was then reviewed by JMPR in 1986, 1987 and 2005, an ADI of 0–0.4 mg/kg bw and an ARfD of 2 mg/kg bw were established in 2005. Propamocarb was evaluated within the periodic review programme for residue and analytical aspects by JMPR in 2006.

The residue definition in plant and animal products for both enforcement and dietary intake purposes is propamocarb (free base. Propamocarb is not considered fat soluble.

The meeting received information on GAP and supervised residue trials in/on onion, leek, broccoli, cauliflower, Brussels sprouts, head cabbage, kale and lima bean. A new analytical method was provided for propamocarb in animal matrices, as well as new studies in laying hen metabolism, feeding studies on lactating cow and laying hens, rotational crops and processed commodities.

Animal metabolism

Laying hen

A metabolism study with propamocarb in laying hens was received by the Meeting. Laying hens were orally dosed via capsule with [14C] propamocarb hydrochloride at a rate of approximately 19 ppm in the feed (1.0 mg/kg body weight) once daily for fourteen consecutive days. The majority of the residues (92% to 99% of the TRR) in the egg and tissues could be extracted.

The TRR in eggs increased from day-1 through too day-7 and reached a plateau, at day-8, of about 0.25 mg eq./kg. The TRR in the tissue samples were highest in liver (0.492 mg/kg) with 0.14 mg/kg in leg muscle, 0.12 mg/kg in breast muscle and 0.042 mg/kg in fat (0.065 mg/kg in renal fat).

The major residues in the eggs and tissues were parent propamocarb (2% in fat, 5% in muscle, 9% in liver and 12% in eggs) and desmethyl propamocarb (6% in fat, 22% in liver, 29% in muscle, and 45% in eggs). The minor residues found in the eggs and tissues were bis-desmethyl-propamocarb (< 1% to 7%) and propamocarb-N-oxide (< 1%).

In summary, the metabolic degradation of propamocarb is rapid and extensive in laying hens with desmethyl-propamocarb and propamocarb being the major residues in all tissues (mostly in liver, eggs and muscle). Demethylation is the main route of metabolism for the parent compound. A minor route of metabolism involves oxidation of the tertiary nitrogen to form propamocarb-N-oxide. The pathway and metabolism profile found in laying hen is consistent to that of the lactating cow metabolism study evaluated by 2006 JMPR.

Field crop rotational studies

Rotational crop studies were conducted in Germany and France during 2002/2003. Four applications of 72.2, 36.1, 3.61 and 3.61 kg ai/ha propamocarb were applied to cabbage as the primary crop, and Lamb's lettuce and wheat were grown as rotational crops with a plant-back interval (PBI) of 52–102 days. No residues of Propamocarb were found above LOQ in Lamb's lettuce, wheat grain, wheat (green material) and wheat straw.

Four rotational crop studies were conducted in the Netherlands, France, Spain and Italy from 2008 to 2010 .Three spray applications of 1.325 kg ai/ha. propamocarb with 7–13days interval were applied to lettuce as primary crop, and carrots, lettuce and wheat or barley were grown as rotational

crops, with plant-back intervals (PBI) of 26–46 days. No residues of propamocarb were found above LOQ in any of these rotational crops.

In rotational field studies with wheat, sugar beet, table beet, dry bean and soya beans conducted in USA in 1997 (four applications at rates of 1.68 kg ai/ha.), which was evaluated by 2006 JMPR, there was no residues detected in wheat grain and straw, soya bean seed, beetroot and beet tops and dry bean from a 30 day PBI, and residues were in the range of 0.229 to 0.51 mg/kg only in wheat hay and forage from a 30 day PBI.

The meeting noted that the GAP of propamocarb (3–4 applications of 1 kg ai/ha.) approximates the application rate in the new studies and was lower than in the 1997 studies. The Meeting agreed that no residue in food and feed commodities are expected from rotational crops following the registered uses.

Methods of analysis

The meeting received the information on multiresidue QuEChERS Method (BCS method ID 01205) for analysis of residues of propamocarb in meat (cattle), liver (cattle), kidney (cattle), fat (cattle), milk (cattle) and egg (chicken) (mass transitions at m/z 102 and 74). The limit of quantification (LOQ) was at 0.01 mg/kg in meat, liver, kidney, fat, milk and egg. The method was confirmed by results of an independent laboratory validation which repeated mean recovery rates of 80–88% in all matrices.

Stability of residues in stored analytical samples

The meeting received information on storage stability of propamocarb in frozen cabbage samples. Propamocarb hydrochloride was stable for a period of at least 39 months.

Results of supervised residue trials on crops

The meeting received supervised residue trial data for propamocarb in/on bulb onion, leek, broccoli, cauliflower, Brussels sprouts, head cabbage, kale and lima bean.

Bulb vegetables

Bulb onion

In 21 trials conducted in Europe according to GAP in Italy (three foliar applications of 1.0 kg ai/ha, 7days PHI), residues were < 0.01(2), 0.01, 0.02(4), 0.03, 0.04, 0.05(5), 0.07, 0.21, 0.41, 0.52, 0.86, 1.3 and 1.4 mg/kg. The Meeting estimated a maximum residue level of 2 mg/kg, a STMR of 0.05 mg/kg and a HR of 1.4 mg/kg for propamocarb in onion bulb.

Leek

In 12 trials conducted in Europe according to GAP in Albania (four foliar applications at 1.0 kg ai/ha, 14days PHI), residues were 0.24, 0.74, 0.9, 1.1(2), 2.4, 2.6, 4.0, 4.4, 5.5, 11 and 15 mg/kg. The meeting estimated a maximum residue level of 30 mg/kg, a STMR of 2.5 mg/kg and a HR of 15 mg/kg for propamocarb in leek.

Brassica vegetables

Broccoli

In ten trials conducted in Europe according to GAP in Spain (three foliar applications of 1.0 kg ai/ha, 14 days PHI), residues were 0.01, 0.16, 0.17, 0.21, 0.29(2), 0.32, 0.63, 0.97 and 1.7 mg/kg. The

meeting estimated a maximum residue level of 3 mg/kg, a STMR of 0.29 mg/kg and a HR of 1.7 mg/kg for propamocarb in broccoli.

Cauliflower

In ten trials conducted in Europe according to GAP in Greece (three foliar applications of 1.0 kg ai/ha, 14 days PHI), residues were < 0.01, 0.01, 0.02(2), 0.03, 0.04, 0.06, 0.08, 0.20 and 0.82 mg/kg. The meeting estimated a maximum residue level of 2 mg/kg, a STMR of 0.035 mg/kg and a HR of 0.82 mg/kg for propamocarb in cauliflower to replace the previous recommendation of 0.2 mg/kg.

Brussels sprouts

In eight trials conducted in Europe matching the GAP of Belgium (three foliar applications of 1.0 kg ai/ha, 14 days PHI), residues were 0.20, 0.25, 0.24, 0.46, 0.48, 0.49, 0.64 and 1.3 mg/kg. The meeting estimated a maximum residue level of 2 mg/kg, a STMR of 0.47 mg/kg and a HR of 1.3 mg/kg for propamocarb in Brussels sprouts.

Head cabbage

In 12 trials conducted in Europe matching the GAP of Spain (three foliar applications at 1.0 kg ai/ha, 14 days PHI), residue were 0.02, 0.03, 0.06, 0.08, 0.13, 0.18, 0.21, 0.23, 0.24, 0.28, 0.32 and 0.36 mg/kg. The meeting estimated a maximum residue level of 1 mg/kg, a STMR of 0.195 mg/kg and a HR of 0.36 mg/kg for propamocarb in head cabbage.

Leafy vegetables

Kale

In nine trials conducted in Europe matching the GAP of Belgium (three foliar applications of 1.0 kg ai/ha, 14 days PHI), residues were 0.33, 0.39, 0.46, 3.9, 4.0, 4.0, 5.2, 10.7 and 11.8 mg/kg. The meeting estimated a maximum residue level of 20 mg/kg, a STMR of 4.0 mg/kg and a HR of 11.8 mg/kg for propamocarb in kale.

Legume vegetables

Lima Beans

In three trials conducted in the United States according to US GAP (four foliar applications at 1.0 kg ai/ha, 0 days PHI), residues in seed without pods were 0.26, 0.42 and 0.43 mg/kg, residues in forage were 40.6, 83.6 and 47.4 mg/kg. As only three trials were conducted according to GAP the meeting could not recommend a maximum residue level for propamocarb in lima bean seed without pods.

Fate of residues during processing

The Meeting received information on the fate of propamocarb residues during the processing of tomatoes, spinach and lettuce, and a study on the nature of residues in processed commodities. Propamocarb hydrochloride was stable under all conditions of processing tested (pasteurisation, baking, brewing, boiling and sterilisation). Processing factors based on the residue of propamocarb are listed in table below. Using the STMR-RAC obtained from propamocarb use, the Meeting estimated STMR-P values for processed commodities to be used in dietary intake calculations and/or livestock dietary burden calculations.

Summary of the processing studies in tomato, spinach and lettuce

Commodity	Processed commodity	Processing factors Residue: PCB	Processing factor(PF) (Mean or best estimate)	STMR-P= STMRRAC × PF(mg/kg)
Tomato 0.515 mg/kg [a]	Juice	0.43, 0.44, 0.46, 0.53, 0.59, 0.68, 0.86	0.53	0.27
	Preserve	0.27, 0.31, 0.34, 0.40, 0.41,0.50, 0.59	0.40	0.21
	Puree	0.32, 0.40, 0.64, 0.65, 0.71, 0.83, 1.1 [a], 1.4 [a], 1.4 [a], 2.6	0.77	0.40
	Paste [a]	3.0, 3.2, 3.0	3.1	1.54
Spinach 11.2 mg/kg [a]	Leaf, cooked	0.86, 0.87, 0.88, 0.93	0.88	9.9

[a] Data from 2006 JMPR evaluation

Farm animal feeding studies

The meeting received information on feeding studies with lactating cows and laying hens.

Dairy cow feeding study

No measurable residues of propamocarb or its metabolites 2-hydroxy-propamocarb, propamocarb-N-oxide, and oxazolidine-2-one propamocarb were detected in milk or edible tissues of cattle exposed to propamocarb at levels of 0.8, 2.4 or 8 ppm administrated daily for 28 days, except for milk, where levels of up to 0.019 mg/kg of 2-hydroxy-propamocarb were found in the highest dose group (8 ppm).These residues were equally distributed between the milk fat and the skim milk. LOQs were 0.01 mg/kg (milk) and 0.05 mg/kg (tissues).

Laying hen feed study

A residue transfer study of propamocarb was conducted in laying hens. Hens were dosed orally for 35 consecutive days at the rates of 1.2 ppm (0.3×), 4.1 ppm (1×), 12.3 ppm (3×), and 41.1 ppm (10×) in the feed.

The mean (maximum) propamocarb residues in the egg samples from 1× and 0.3× feeding levels were: 0.0047 mg/kg (0.005 mg/kg) and 0.012 mg/kg (0.013 mg/kg) at Day 35.

In fat, the mean (maximum) propamocarb residues at Day 35 were < LOD (0.0014 mg/kg) in 1× and 0.3× dose groups.

In liver, the mean (maximum) propamocarb residues at Day 35 were 0.0037 mg/kg (0.0055 mg/kg) in the 1× dose group, and 0.0019 mg/kg (0.0021 mg/kg) in the 0.3× dose group.

In muscle, the mean (maximum) propamocarb residues at Day 35 were 0.0022 mg/kg (0.0028 mg/kg) in the 1× dose group, and 0.001 mg/kg (0.001 mg/kg) in the 0.3× dose group.

Animal commodity maximum residues levels

The dietary burdens were estimated using the OECD diets listed in Appendix IX of the 2009 Edition of FAO Manual. Potential cattle feed items include: cabbage, kale and potatoes (including by-products). Dietary burden calculations for beef cattle and dairy cattle and poultry are provided below.

Summary of livestock dietary burden (ppm of dry matter diet)

	US-Canada		EU		Australia		Japan	
	max	mean	max	mean	max	mean	max	mean
Beef cattle	0.38	0.20	16.16	5.58	0.11	0.05	0.00	0.00
Dairy cattle	0.13	0.07	16.11	5.53	31.55 [a, b]	10.70 [c, d]	0.00	0.00

	US-Canada		EU		Australia		Japan	
	max	mean	max	mean	max	mean	max	mean
Poultry-broiler	0.00	0.00	0.10	0.04	0.00	0.00	0.00	0.00
Poultry-layer	0.00	0.00	4.03[e]	1.37[f]	0.00	0.00	0.00	0.00

[a] Highest maximum beef or dairy cattle dietary burden suitable for MRL estimates for mammalian meat
[b] Highest maximum dairy cattle dietary burden suitable for MRL estimates for mammalian milk
[c] Highest mean beef or dairy cattle dietary burden suitable for STMR estimates for mammalian meat
[d] Highest mean dairy cattle dietary burden suitable for STMR estimates for mammalian milk
[e] Highest maximum poultry dietary burden suitable for MRL estimates for poultry meat and eggs
[f] Highest mean poultry dietary burden suitable for STMR estimates for poultry meat and eggs

The propamocarb dietary burden for animal commodity MRL and STMR estimation (residue levels in animal feed expressed on dry weight) are 31.55 and 10.7 ppm for mammalian products (based primarily on the new use on kale), and the maximum and mean dietary burdens are 4.03 and 1.37 ppm for poultry products.

Mammalian products

The Meeting noted that the maximum cattle dietary burden was about 3–4 times higher than the dose level (8 ppm) in the feeding study and the metabolism study of lactating cow (11.5 ppm), and could not estimate maximum residue levels for mammalian commodities. The Meeting agreed to withdraw the previous MRLs of 0.01* mg/kg for milk, meat from mammals other than marine mammals, and edible offal, mammalians.

Poultry products

The MRLs for poultry products were estimated using the maximum dietary burden and the highest residues obtained from the laying hen feeding study. For the estimation of the STMRs, the mean dietary burden and mean residues on poultry products from the feeding study were used.

The maximum dietary burden of 4.03 ppm DM matches the 1× dose level of the laying hen feeding study. Therefore, the residue levels reported in the feeding study were used as a direct estimate of the residue levels in poultry muscle, fat, liver and eggs resulting from the dietary burden. Similarly, the STMR of 1.37 ppm approximates the lowest dose level of the feeding study (1.2 ppm). Therefore, as an estimate for the STMR in the poultry products, the mean residue levels from the feeding study at this level were used. The estimated MRLs and STMRs are summarized in following table.

	Feed level	Residues	Feed level	Residues (mg/kg) in		
	(ppm) for egg residues	(mg/kg) in egg	(ppm) for tissue residues	Muscle	Liver	Fat
MRL poultry						
Feeding study [a]	4.1	0.005	4.1	0.0028	0.0055	< LOD [c]
Dietary burden and high residue	4.03	0.005	4.03	0.0028	0.0055	< LOD [c]
STMR poultry						
Feeding study [b]	1.2	0.0012	1.2	0.0010	0.0019	< LOD [c]
Dietary burden and residue estimate	1.37	0.0012	1.37	0.0010	0.0019	< LOD [c]

[a] Highest residues for tissues and highest residues for eggs
[b] Mean residues for tissues and mean residues for eggs
[c] LOD in fat was 0.0014 for propamocarb

The meeting estimated the following STMR values: eggs 0.001 mg/kg, muscle 0.001 mg/kg, liver 0.002 mg/kg and fat 0.001 mg/kg. The following HR values are also estimated: eggs of 0.005 mg/kg, muscles of 0.003 mg/kg, liver of 0.006 mg/kg and fat of 0.001 mg/kg.

The meeting recommended the maximum residue levels of 0.01* mg/kg for poultry fat, and confirmed it previous recommendation for maximum residue levels of 0.01* mg/kg for eggs, poultry meat, and poultry, edible offal of.

DIETARY RISK ASSESSMENT

Long-term intake

The long-term dietary intake for propamocarb (ADI 0–0.4 mg/kg bw) was calculated for the 17 regional diets on the basis of the STMRs estimated by the JMPR in 2006 and the current meeting. The results are shown in Annex 3 of the 2014 Report.

The International Estimated Daily Intakes (IEDI) of propamocarb were 0–1% of the maximum ADI (0.4 mg/kg bw). The Meeting concluded that the long-term intake of residues of propamocarb from uses that have been considered by the JMPR is unlikely to present a public health concern.

Short-term intake

The ARfD for propamocarb is 2 mg/kg bw. The International Estimated Short Term Intake (IESTI) of propamocarb was calculated for the commodities for the commodities for which residue levels were estimated. The results are shown in Annex 4 of the 2014 Report.

The IESTI of propamocarb calculated were up to 20% of the ARfD (2 mg/kg bw) for children and general population. The Meeting concluded that the short-term intake of residues of propamocarb resulting from uses that have been considered by current meeting is unlikely to present a public health concern.

5.24 PROPICONAZOLE (160)

RESIDUE AND ANALYTICAL ASPECTS

The triazole fungicide propiconazole was evaluated in the periodic review program by th 2007 JMPR, when an ADI of 0–0.07 mg/kg bw and a ARfD of 0.3 mg/kg bw were stablished, and by the 2013 JMPR for residue aspects. Propiconazole was listed by the Forty-fifth Session of the CCPR (2013) for the review of additional uses. Residue trial data on bean (dry), bean (lima), and bean (snap), mint, pineapple following post-harvest application, barley, oat and wheat were submitted to current Meeting.

Residue definition for plant and animal commodities is *propiconazole* for compliance with the MRL and *propiconazole plus all metabolites convertible to 2,4-dichlorobenzoic acid, expressed as propiconazole* for the estimation of the dietary intakes.

Methods of analysis

Methods of analysis used in the trials submitted to this Meeting were evaluated by the 2007 JMPR and were considered fit for purpose for the estimations. Methods that used LC-MS/MS analyses propiconazole, and the results are used for the estimation of maximum residue level. The common moiety method measure all residues convertible to 2,4-dichlorobenzoic (2,4-DCBA), reported as total propiconazole, and the results were used for the estimation of STMR and HR. In the residue trials, samples were stored within the period that guarantee the integrity of the residues as shown in the storage stability studies.

Results of supervised residue trials in crops

No estimations were made for lima bean, snap bean, dry beans and mint, as only the total propiconazole residue was reported in pre-harvest treatment trials. Data for these crops will not be discussed further.

Pineapple

The GAP of the USA for propiconazole in pineapple is for one post-harvest dipping treatment in a 0.015 kg ai/hL solution. Three trials were conducted using this rate, giving total residue of 1.1, 1.8 and 3.6 mg/kg of total propiconazole (highest of 4.1 mg/kg in an individual sample). As it is unlikely that propiconazole metabolites are formed between treatment and sample preparation for analysis, the results comply with both the residue definition for MRL and dietary risk assessment.

The Meeting agreed that the number of trials was not sufficient to estimate a maximum residue level for propiconazole in pineapple followingf post-harvest treatment, and did not change its previous recommendation of 0.02* mg/kg.

Cereals

In the USA, GAP for propiconazole in barley, oats and wheat, is for up to 2 applications at 0.125 kg ai/ha, the second one being at least 14 days following an early season application and should not be performed after full head emergence, which corresponds to BBCH 59.

In one trial conducted in USA in barley, matching GAP, residues of propiconazole were < 0.01 mg/kg and of total propiconazole < 0.05 mg/kg. In eight other trials the second application was made after full head emergence (BBCH 71 to 85).

In one trial conducted in USA in oats according to GAP, residues of propiconazole were < 0.01 mg/kg and of total propiconazole were 0.26 mg/kg. In eleven other trials the second application was made after full head emergence (BBCH 69 to 71).

In one trial conducted in USA in wheat according to GAP residues of propiconazole were < 0.01 mg/kg and of total propiconazole 0.06 mg/kg. In fourteen other trials, the second application was made after full head emergence (BBCH 69 to 75).

The Meeting agreed that there were not enough trials matching US GAP to estimate a maximum residue level for propiconazole in barley, oats and wheat.

The Meeting did not change its previous recommendation of 0.02 mg/kg for propiconazole in wheat, rye and triticale and of 0.2 mg/kg for propiconazole in barley.

Animal feeds

Cereals

In the USA, the GAP for propiconazole in barley, oats and wheat, is for up to 2 applications at 0.125 kg ai/ha, the second at least 14 days following an early season application and should not be performed after full head emergence, corresponding to BBCH 59. No PHI is specified for straw, and the PHI is 7 days for forage and hay.

Forage

Eleven trials were conducted in oat forage in the USA matching US GAP, with total propiconazole residues of 0.50 (2), 0.78, 1.4, 1.5 (2), 1.7, 1.8, 1.9, 2.0 and 2.4 mg/kg (2.5 mg/kg highest of individual samples).

The Meeting estimated a medium and highest residue of 1.5 and 2.5 mg/kg, respectively, for propiconazole in oat forage.

Fifteen trials were conducted in wheat forage, gave total propiconazole residues of 1.2 (2), 1.3, 1.4, 1.6, 1.9, 2.1, 2.2, 2.8, 3.0, 3.4, 3.8, 3.9, 4.8 and 9 mg/kg.

The Meeting estimates a medium and highest residue of 2.2 and 9 mg/kg, respectively, for propiconazole in wheat forage.

Hay

Nine trials were conducted in barley hay with propiconazole residues of 0.19, 0.44, 0.73, 0.78, 0.81, 1.7, 2.2, 3.0 and 4.2 mg/kg. Total propiconazole residues were: 2.1, 2.6, 2.7, 4.0, 4.3, 6.2, 10, 11 and 12 mg/kg (highest 13 mg/kg).

The Meeting estimated a maximum residue level of 8 mg/kg for propiconazole in barley straw and fodder, dry. The Meeting also estimated medium and highest residue of 4.3 and 13 mg/kg, respectively, for propiconazole in barley hay.

In the 11 trials conducted with oat hay, according to US GAP, propiconazole residues were: 0.18, 0.24, 0.35, 1.1, 1.2, 1.4, 2.0, 2.4, 3.6, 4.2 and 4.5 mg/kg. Total propiconazole were: 0.80, 0.90, 1.1, 2.7, 3.2, 3.3, 4.8 (2), 6.2, 7.7 and 8.5 mg/kg.

The Meeting estimated a maximum residue level of 8 mg/kg for propiconazole in oat straw and fodder, dry. The Meeting also estimated a medium and highest residue of 3.3 and 8.5 mg/kg, respectively, for propiconazole in oat hay.

In 15 trials conducted in wheat hay, propiconazole residues were: 0.44, 0.75, 1.1, 1.3, 1.6, 1.9, 2.0 (2), 2.2, 2.8. 3.0, 3.3, 4.2, 5.4 and 9.6 mg/kg. Total propiconazole were: 2.0, 3.2, 3.4, 4.0, 4.1, 4.3, 4.4, 5.3, 6.7, 7.9, 9.3, 10 (2),12 and 21 mg/kg (highest of 22 mg/kg).

Taking into account the trials conditions, the Meeting concluded that the residues measured in hay are applicable for sraw and fodder, and recommended a maximum residue level of 15 mg/kg for propiconazole in wheat straw and fodder, dry, and extend this estimation for rye and straw and

fodder, dry. The Meeting also estimates a medium and highest residue of 5.3 and 2.2 mg/kg, respectively, for propiconazole in wheat hay.

The Meeting withdrew its previous maximum residue level recommendation for barley, rye, triticale and wheat straw of 2 mg/kg.

Residues in animal commodities

One cow and one poultry study were evaluated by the 2007 JMPR, and only the relevant information from these studies are summarized in this appraisal.

Lactating dairy cows

Dairy cows were dosed once daily either in the feed with propiconazole at 15 ppm, 75 ppm and 150 ppm for 14–28 consecutive days. No parent propiconazole was detected in any milk (< 0.01 mg/kg), muscle and kidney samples (< 0.05 mg/kg) at all feeding levels. The maximum level in liver was 0.14 mg/kg at the 15 ppm feeding level and 0.34 mg/kg in the 75 ppm feeding level; in fat it was < 0.05 mg/kg at the 15 ppm and 75 ppm feeding levels.

No total propiconazole (< 0.01 mg eq./kg) was found in milk at 15 ppm; at 75 ppm, the average was 0.044 mg eq./kg (maximum of 0.08 mg eq./kg). In muscle, no total propiconazole (< 0.05 mg/kg) was detected at 15 ppm and the maximum level was 0.11 mg/kg at the 75 ppm (average 0.08 mg/kg). In liver, residues were 0.81 mg/kg at the 15 ppm (average 0.63 mg/kg) and 4.3 mg/kg in the 75 ppm (average 3.7 mg/kg). In kidney, it was 0.63 mg/kg at the 15 ppm (average 0.60 mg/kg) and 4.7 mg/kg in the 75 ppm (average 3.8 mg/kg). In fat it was < 0.05 mg/kg at the 15 ppm and 0.23 mg/kg at the 75 ppm feeding level (average 0.15 mg/kg).

Laying hens

Hens were fed propiconazole at 7.5, 37.5 and 75 ppm in the feed. No propiconazole residues (< 0.05 mg/kg) were found in the eggs or the tissue sample analysed, regardless of feeding level.

At 7.5 ppm, no total propiconazole was detected in eggs, muscle, fat (< 0.05 mg/kg) and liver (< 0.1 mg/kg). At 37.5 ppm, residues reached 0.18 mg/kg in eggs, 0.16 mg/kg in liver and 0.07 mg/kg in fat, but no residues were detected in muscle.

Farm animal dietary burden

The Meeting estimated the dietary burden of propiconazole (as total propiconazole) in farm animals on the basis of the OECD Animal Feed data published in the 2009 FAO Manual, the STMR, STMR-Ps or highest residue levels estimated at the present and by the 2007 JMPR. Dietary burden calculations are provided in Annex 6 of the 2014 Report.

	US-Canada		**EU**		**Australia**		Japan	
Commodity	**Max**	Mean	**Max**	Mean	**Max**	Mean	**Max**	Mean
Beef cattle	3.9	2.1	15.9	4.3	36 [a]	12 [c]	10.1	1.62
Dairy cattle	15.8	7.2	13.5	4.0	29 [b]	12 [d]	10.5	5.56
Poultry – broiler	0.5	0.51	0.1	0.11	0.005	0.005		
Poultry – layer	0.51	0.51	5.1 [e]	1.88 [f]	0.005	0.005		

[a] Highest maximum beef or dairy cattle dietary burden suitable for MRL estimates for mammalian tissues

[b] Highest maximum dairy cattle dietary burden suitable for MRL estimates for mammalian milk

[c] Highest mean beef or dairy cattle dietary burden suitable for STMR estimates for mammalian tissues.

[d] Highest mean dairy cattle dietary burden suitable for STMR estimates for milk.

[e] Highest maximum poultry dietary burden suitable for maximum residue level estimated for poultry tissues and eggs.

[f] Highest mean poultry dietary burden suitable for STMR estimated for poultry tissues and eggs

Animal commodity estimations

Propiconazole residues, for the estimation of *maximum residue level*

	Feed level for milk or egg, ppm	Residues, mg/kg	Feed level for tissues, ppm	Residues, mg/kg			
				Muscle	Liver	Kidney	Fat
Maximum residue level for cattle							
Feeding study	15 75	< 0.01 < 0.01	15 75	< 0.01 < 0.01	0.14 0.34	< 0.01 < 0.01	< 0.05 < 0.05
Dietary burden and highest residue	29	< 0.01	36	< 0.01	0.25	< 0.01	< 0.05
Maximum residue level for poultry							
Feeding study	7.5	< 0.05	7.5	< 0.05	< 0.05		< 0.05
Dietary burden and highest residue	5.1	< 0.05	4.6	< 0.05	< 0.05		< 0.05

Total propiconazole residues, for the estimation of HR and STMR

	Feed level for milk or egg, ppm	Residues, mg/kg	Feed level for tissues, ppm	Residues, mg/kg			
				Muscle	Liver	Kidney	Fat
HR for cattle							
Feeding study			15 75	< 0.05 0.11	0.81 4.3	0.63 4.7	< 0.05 0.23
Dietary burden and highest residue			36	0.085	1.97	1.9	0.115
STMR for cattle							
Feeding study	15	0.044	15	0.08	0.63	0.60	< 0.05
Dietary burden	12	0.035	12	0.064	0.504	0.50	< 0.05
HR for poultry							
Feeding study	7.5	< 0.05	7.5	< 0.05	< 0.05		< 0.05
Dietary burden and highest residue	5.1	< 0.05	4.6	< 0.05	< 0.05		< 0.05
STMR for poultry							
Feeding study	7.5	< 0.05	7.5	< 0.05	< 0.05		< 0.05
Dietary burden	1.88	< 0.05	4.6	< 0.05	< 0.05		< 0.05

The maximum dietary burden for the estimation of maximum residue levels in cattle tissue and milk were 36 and 29 ppm, respectively. The Meeting confirmed its previous recommendation of 0.01* mg/kg for propiconazole in milks and meat (from mammals other than marine mammals) and estimated a maximum residue level of 0.5 mg/kg for edible offal (mammalian) and of 0.01* mg/kg in mammalian fat (except milk fats).

The Meeting withdrew the previous recommendation of 0.01* mg/kg for propiconazole in edible offal (mammalian).

The maximum dietary burden for the estimation of HR in cattle tissues was 36 ppm. Based on the feeding levels at 15 and 75 ppm, the Meeting estimated HRs of 0.085 mg/kg in meat (from mammals other than marine mammals), of 1.97 mg/kg in edible offal (mammalian) and of 0.115 mg/kg in mammalian fat (except milk fats).

The mean dietary burden for the estimation of STMR levels in cattle tissues and milk was 12 ppm. Based on the feeding study conducted at 15 ppm, the Meeging estimated a STMR of 0.035 mg/kg in milks, 0.064 mg/kg im meat (from mammals other than marine mammals), 0.504 mg/kg in edible offal and 0.05 mg/kg in mammalian fat.

The highest calculated dietary burden for poultry was 35.1 ppm. In eggs, muscle and fat no propiconazole or total propiconazole residues were detected at the 7.5 ppm feeding level. The Meeting confirms its previous recommendation of a maximum residue level of 0.01* mg/kg for

propiconazole in poultry meat and eggs, and a STMRs and HRs of 0.05 mg/kg in eggs, muscle and fat.

RECOMMENDATIONS

Residues: For plant and animal commodities is *propiconazole* for compliance with the MRL and *propiconazole plus all metabolites convertible to 2,4-dichlorobenzoic acid, expressed as propiconazole* for the estimation of the dietary intakes.

The residue is fat soluble

DIETARY RISK ASSESSMENT

Long-term intake

The IEDI of propiconazole based on the STMRs estimated by this and previous Meetings for the 17 GEMS/Food regional diets were 1–10% of the maximum ADI of 0.07 mg/kg bw (see Annex 3 of the 2014 Report). The Meeting concluded that the long-term dietary intake of residues of propiconazole is unlikely to present a public health concern.

Short-term intake

An ARfD for propiconazole is 0.3 mg/kg bw. The International Estimated Short-Term Intake (IESTI) of propiconazole for the commodities for which STMR, HR and maximum residue levels were estimated by the current Meeting. The results are shown in Annex 4 of the 2014 Report. The IESTI represented a maximum of 8% of the ARfD. The Meeting concluded that the short-term intake of propiconazole residues from uses considered by the current Meeting was unlikely to present a public health concern.

5.25 PROTHIOCONAZOLE (232)

RESIDUE AND ANALYTICAL ASPECTS

Prothioconazole was evaluated first time by the 2008 JMPR. The residue definition for plant commodities for enforcement and dietary risk assessment was prothioconazole-desthio. The residue definition for animal commodities for enforcement was prothioconazole-desthio and for dietary risk assessment was the sum of prothioconazole-desthio, prothioconazole-desthio-3-hydroxy, prothioconazole-desthio-4-hydroxy and their conjugates, expressed as prothioconazole-desthio. The residue was considered to be not fat-soluble for the purposes of residue definition.

The 2008 JMPR established, for prothioconazole-desthio, an ADI of 0–0.01 mg/kg bw and ARfD of 0.01 mg/kg bw for women of child bearing age and 1 mg/kg bw for the general population.

The Forty-fifth Session of CCPR scheduled fenpropathrin for periodic re-evaluation of residues by the 2014 JMPR. For the 2014 Meeting data were provided on blueberry, corn, cranberry, cucurbits, potato, sweet corn peanut and soya bean together with current use recommendations and analytical methods used in supervised trials.

Methods of analysis

A number of validated analytical methods for the determination of residues in plant, animal tissue, milk and soils were evaluated by the 2007 and 2008 JMPR Meetings. The Meeting received the basic analytical methods with minor modifications which were validated to determine residues in crops that had been used in the residue trials. An analytical method was also provided for the determination of residues of prothioconazole in animal matrices.

The trials carried out in the USA/Canada used method RPA JA/03/01 or the modified method JA-001-P04-02 which involve extraction with methanol, hydrogen peroxide and sodium bicarbonate at an elevated temperature. This converts prothioconazole to a mixture of prothioconazole-sulfonic acid, while prothioconazole-desthio is extracted unchanged. After purification steps, the residues are analysed by LC-MS/MS. The LOQ of these methods is 0.02 mg/kg for prothioconazole-sulfonic acid and 0.02 mg/kg for prothioconazole-desthio.

The trials carried out in Brazil, EU and Australia used methods 01013, 00598/M001 and ATM-0053 in which residues of prothioconazole and prothioconazole-desthio are extracted with acetonitrile/water containing cysteine hydrochloride. After purification steps, dependent on the method, the analytes are analysed by LC-MS/MS. The LOQ of these methods is 0.01 mg/kg (or 0.05 mg/kg for forage and straw matrices) for prothioconazole and prothioconazole-desthio.

Storage stability under frozen conditions

Information relating to storage stability of residues in wheat, canola (seed, pod, straw), spinach (leaves), sugar beet (root, leaf with root collar), tomato (fruit) and field pea (dried) was evaluated at the 2008 JMPR Meeting. This showed that residues of prothioconazole-desthio were stable over a frozen storage period of up to 36 months in wheat and at least 24 months for the other crops. Residues of prothioconazole and prothioconazole-desthio were stable in wheat hay and straw, canola seeds, mustard greens, turnip root and tomato fruit over a frozen storage period of 36–42 months.

An additional freezer storage stability study for residues of prothioconazole and prothioconazole-desthio (JAU 6476-desthio) in wheat (forage, straw, grain, bran and flour), canola (seed and oil), mustard greens, tomato (fruit and paste) and turnip roots was performed.

No significant degradation of prothioconazole-desthio was observed in any matrix analysed over the 3-year frozen storage period.

The stability of parent prothioconazole varied from 57 days up to 378 days without showing any dependency on the sample matrix. However, metabolism studies indicated that after foliar

application prothioconazole rapidly degraded to prothioconazole-desthio and polar metabolites being converted to the sulfonic acid derivative, which is measured by the analytical method. Therefore the relative instability of parent compound does not affect the validity of the desthio residues measured in supervised trials.

Results of supervised residue trials on crops

Supervised trials have been conducted to support MRLs for the following crops or groups of crops: blueberry, cranberry, cucurbits (cucumber, summer squash and melon), sweet corn, soya bean, potato, maize (field corn, popcorn) and peanuts.

In trials conducted in the USA, Canada and Brazil, residues of prothioconazole sulfonic acid (JAU 6476 sulfonic acid), prothioconazole-desthio (JAU 6476 desthio) and total prothioconazole (JAU 6476) were determined and reported. In trials conducted in Australia, residues of prothioconazole (JAU 6476), prothioconazole-desthio (JAU 6476 desthio) and total prothioconazole (JAU 6476) were determined and reported. However, only the residues of prothioconazole-desthio have been used for calculation of MRL, HR and STMR values in accordance with the residue definition. The residues of prothioconazole-desthio are expressed as mg prothioconazole-desthio equivalents/kg.

Bush berries

Blueberry

Eleven supervised trials were conducted in 2010 in the USA and Canada matching the US GAP (2 × 200 g ai/ha nominal rate at 6–7 days intervals, 7-day PHI) for the bush berry subgroup.

Prothioconazole-desthio residues from trials on blueberries were: 0.15, 0.22, 0.26, 0.28, 0.42, 0.52, 0.56, 0.60, 0.65, 0.70 and 0.87 mg/kg.

Taking into account that blueberry is the representative commodity for the subgroup; the Meeting estimated a maximum residue level of 1.5 mg/kg, a HR of 0.87 mg/kg and a STMR of 0.52 mg/kg for prothioconazole-desthio residues for the bush berry subgroup.

Low growing berries

Cranberry

Six supervised trials were conducted in 2010 in the USA according to the US GAP (2 × 186 g ai/ha nominal rate at 7-10 days intervals, 45-day PHI)

Prothioconazole-desthio residues from trials on cranberries were: < 0.02 (3), 0.03 (2) and 0.09 mg/kg.

The Meeting estimated maximum residue level of 0.15 mg/kg, HR of 0.09 mg/kg and STMR of 0.025 mg/kg for prothioconazole-desthio residues for cranberry.

Fruiting vegetables, Cucurbits

Eight supervised trials were conducted in 2010 on *cucumber*, eight trials on *musk melon* and eight trials on *summer squash* in the USA according to US GAP (one soil +2 × 200 g ai/kg nominal rate at 7-10 days intervals, max 600 g ai/season,, 7-day PHI).

Prothioconazole-desthio residues from trials on cucumber were: 0.02, 0.02, 0.03, 0.03, 0.04, 0.05, 0.05, 0.06 mg/kg.

Prothioconazole-desthio residue concentrations from trials on musk melon were: 0.03, 0.06, 0.06, 0.06, 0.06, 0.07, 0.15, 0.15 mg/kg.

Prothioconazole-desthio residue concentrations from trials on summer squash were: < 0.02 (5), 0.03, 0.05 and 0.06 mg/kg.

The Meeting noted that the GAP in USA is for cucurbit vegetables, the residue populations were not significantly different and the median residues were within the 5 times range, and agreed to combine the datasets. Residues in the 24 trials were: < 0.02 (5), 0.02 (2), 0.03 (4), 0.04, 0.05 (3), 0.06 (6), 0.07 and 0.15 (2) mg/kg.

The Meeting noted that the ARfD would be exceeded by 150% for watermelon. As no alternative GAP for fruiting vegetables was available, watermelon was not included in the recommendation for the crop group fruiting vegetables, cucurbits.

The Meeting estimated a maximum residue level of 0.2 mg/kg, HR of 0.15 mg/kg and STMR of 0.045 mg/kg prothioconazole-desthio residues for fruiting vegetables, cucurbits (except watermelon).

Fruiting vegetables, other than Cucurbits

Sweet corn

Twelve supervised trials were conducted on sweet corn in the USA at 4 × 200 g ai/ha matching the current US GAP. The PHI for sweet corn forage and ears is 0 days and 14 days for fodder.

Prothioconazole-desthio residue concentrations in corn ears were: < 0.018 in all samples.

The Meeting estimated a maximum residue level of 0.02 mg/kg, and HR and STMR values of 0.018 mg/kg for sweet corn.

Pulses

Soya beans

Residue data on soya beans, from 19 trials conducted in the USA, were previously evaluated by the 2008 and 2009 JMPR Meetings. The current US GAP for soya beans permit 3 applications at 88–175 g ai/ha rate at 10–21 day intervals with a PHI of 21 days.

The average prothioconazole-desthio residues in soya bean samples derived from trials corresponding to the current US GAP were: < 0.05 (16), 0.051, 0.055 and 0.105 mg/kg

Ten supervised trials were conducted in 2012–2013 season on soya bean in Brazil matching the GAP for Brazil (4 × 87.5 g ai/ha, PHI 30 days). The prothioconazole-desthio residues were reported as the parent compound. Applying the conversion factor of 0.907 (312.20/344.26) the residues expressed as prothioconazole-desthio were: < 0.009 × 4, 0.009 × 2, 0.018, 0.027, 0.036 and 0.091 mg/kg.

The Meeting noted that the US trials resulted in higher residues and used those values. The meeting estimated a maximum residue level of 0.2 mg/kg and STMR value of 0.05 mg/kg.

Root and tuber vegetables

Potato

A total of twenty supervised trials were conducted in 2005 and 2010 as potato seed-piece treatments in Belgium, France, Germany, Italy, the Netherlands, Spain and the UK at maximum GAP (up to

0.64 g ai/100 kg seed, equivalent to 16 g ai/ha) or higher rate. The potatoes were harvested at maturity. The prothioconazole-desthio residues were < 0.01 mg/kg in all samples take 90–136 days after seed treatment.

Taking into account that the LOQ of the enforcement method is 0.02 mg/kg, the Meeting estimated a maximum residue level of 0.02* mg/kg, HR and STMR values of 0.01 mg/kg for potato.

Cereal grains

Maize

Twenty supervised trials were conducted in 2006 on field corn and three trials on popcorn in the USA (4 × 200 g ai/ha at 7–14 days apart, 0 day PHI for forage and 14 days for grain and fodder).

The prothioconazole-desthio residues in maze grain samples collected at 14 days after last application were: < 0.018 (17), and 0.05 mg/kg,

Ten supervised trials were conducted in 2011-2012 on corn in Brazil according to the GAP (2 × 70-87.5 g ai/ha, at minimum 15 days, 15 days PHI).

The prothioconazole-desthio residues in maize grain samples collected at 14-15 days after last application were: < 0.01 (10) mg/kg.

A total of twenty supervised trials were conducted in 2007, 2008 and 2011 on maize/corn in Europe matching the GAP of the Czech Republic (2 × 125 g ai/ha, PHI 35 days) and Italy (2 × 125 g ai/ha, retreatment at a minimum of 14 days, 35 days or non-specified PHI).

The prothioconazole-desthio residues in all of immature and mature maize grain samples collected from 17 days onward were: < 0.01 (20) mg/kg.

The Meeting considered that all maize grain/seed samples (47) contained non-detectable resides regardless of maturity and time between last application and sampling, except in one trial where residues of up to 0.05 mg/kg residue was measured.

The Meeting estimated a maximum residue level of 0.1 mg/kg and STMR value of 0.018 mg/kg for maize and popcorn.

Oilseeds

Peanuts

Residue data on peanuts from trials conducted in the USA had been evaluated by the 2009 JMPR. Residues of prothioconazole-desthio were < 0.02 mg/kg in 12 trials matching the USA GAP (4 × 200 g ai/ha, PHI 14 days).

Eight supervised trials were conducted in 2011–2012 in Australia. Four trials included plots which were treated according to the GAP for peanut in Australia (4 times 120–192 g ai/ha at 10–14 days apart, 28-day PHI), and four trials included plots which were treated with higher number of applications and a shorter PHI (up to 21 days). Samples were taken immediately before the last application and 0, 7, 14–15 and 20–21 days after.

The prothioconazole-desthio residues in all samples collected from Day 0 to day 29 days were: < 0.01 mg/kg.

The Meeting confirmed its previous recommendations of 0.01* mg/kg.

Primary feed commodities

Descriptions of trial conditions and residues are described under relevant food commodities. The residue data relevant to the feed commodities are summarized below.

Maize and sweet corn forage and fodder

Prothioconazole-desthio residue concentrations in sweet corn forage from trials conducted at 4 × 200 g ai/ha were: 1.31, 1.50, 1.89, 1.94, 1.98, 2.08, 2.12, 2.37, 2.82, 3.20, 3.75 and 4.08 mg/kg.

Prothioconazole-desthio residue concentrations in field corn forage from trials based on the USA GAP for corn are: 0.71, 1.67, 1.75, 1.84, 1.90, 1.96, 2.14, 2.15, 2.19, 2.20, 2.27, 2.41, 2.58, 2.62, 2.65, 2.99 (2), 3.06, 3.44 and 3.60 mg/kg.

The Meeting noted that the GAP in USA for sweet corn and maize is the same and that the residue populations were not significantly different, and agreed to combine the datasets.

Residues in the trials were: 0.71, 1.31, 1.50, 1.67, 1.75, 1.84, 1.89, 1.90, 1.94, 1.96, 1.98, 2.08, 2.12, 2.14, 2.15, 2.19, 2.20, 2.27, 2.37, 2.41, 2.58, 2.62, 2.65, 2.82, 2.99 (2), 3.06, 3.44, 3.60, 3.75 and 4.08 mg/kg.

Residues in forage from the European trials were much lower (< 0.2 mg/kg) than from the trials conducted according to the USA GAP, and therefore the Meeting used the US trial data for the estimation of residue levels.

The Meeting estimated highest residue of 4.08 mg/kg and median residue of 2.15 mg/kg for sweet corn and filed maize forage.

Prothioconazole-desthio residue concentrations in sweet corn stover from trials conducted at 4 × 200 g ai/ha were: 0.67 (2), 0.71, 0.82, 0.90, 0.98, 1.45, 1.68 (2), 1.70, 3.61 and 5.88 mg/kg.

Prothioconazole-desthio residue concentrations in field corn stover from trials based on the USA GAP for corn were: 0.67 (2), 0.71, 0.82, 0.90, 0.98, 0.99, 1.09, 1.45, 1.68 (2), 1.70, 2.22, 2.32, 2.35, 2.42, 2.90, 3.18, 3.22, 3.42, 3.48, 3.59, 3.61, 3.68, 3.78, 3.89, 4.05, 4.47, 4.66, 5.88, 6.16 and 6.70 mg/kg.

Prothioconazole-desthio residue concentrations in popcorn stover from trials based on the USA GAP for corn were: 2.46, 2.51 and 4.43 mg/kg.

The Meeting noted that the GAP in the USA is for sweet corn and maize is the same and the residue populations were not significantly different, and agreed to combine the datasets. Residues in the trials were: 0.99, 1.09, 2.22, 2.32, 2.35, 2.42, 2.46, 2.51, 2.90, 3.18, 3.22, 3.42, 3.48, 3.59, 3.68, 3.78, 3.89, 4.05, 4.43, 4.47, 4.66, 6.16 and 6.70 mg/kg.

The Meeting estimated a maximum residue level of 15 mg/kg (dry weight basis) highest residue of 6.7 mg/kg and median residue of 3.48 mg/kg for sweet corn and field maize stover.

Soya bean forage and hay

The Meeting received information on residues in soya bean forage and hay. However, the samples were taken at 7 days PHI, which did not correspond to the current US GAP and therefore could not be used for the estimation of residue levels.

Peanut fodder

Prothioconazole-desthio residue concentrations in peanut hay from trials based on the Australian GAP for peanuts were: 1.14, 1.15, 7.00 and 11.60 mg/kg.

The Meeting estimated highest and median residues of 11.6 mg/kg and 4.08 mg/kg, respectively, for peanut hay.

Fate of residue during processing

Processing Corn

Field corn was treated at 5× total seasonal rate. Subsamples of corn grain were removed for analysis, aspirated grain fractions were generated, and the remaining grain was used to generate the required processed commodities of starch, oil (wet and dry milled, refined, bleached, and deodorized), grits, flour, meal and bran. Processing was performed using procedures that simulated commercial practices.

The processing factors calculated from total prothioconazole residues were: starch (< 0.28), oil, wet milled (< 0.28, grits (< 0.28), flour (0.57), meal (0.43), bran (1.31), oil, dry milled (< 0.28).

The Meeting noted that the major part of the residue is prothioconazole-desthio and concluded that the results of processing study can be used for estimation of the processing factors for prothioconazole-desthio. The Meeting estimated STMR values (mg/kg) for maize starch (0.0050), maize flour (0.010), and refined maize oil (0.0050).

Processing rape seed

Rape seed was sampled following treatment with prothioconazole, 2 × 120 g/ha. The conditioned and cleaned rape seeds were pressed in a screw press, yielding screw pressed oil, and pomace. An aliquot of pomace was extracted twice with hexane. The screw pressed oil and extracted oil were combined to obtain crude oil, which was neutralized and processed to obtain refined oil.

The processing factors calculated were: screw pressed oil (1), pomace (1), meal (< 1), solvent extracted oil (2), crude oil (2), pre-clarified crude oil (2), neutralized crude oil (1) and refined oil (< 1)

The Meeting estimated STMR-P values for rape seed oil, edible of 0.02 mg/kg based on the STMR of 0.02 estimated by the 2009 JMPR

Residues in animal commodities

The following commodities evaluated by the present and previous Meetings could result in residues in animal tissues, milk, and eggs: sweet corn forage and stover, field corn forage and stover, popcorn forage and stover, soya bean hay and peanut fodder (dry), grains, straw and fodder (dry) of cereal grains.

Livestock dietary burden

The maximum and mean dietary burdens were calculated using the highest residues or median residues of prothioconazole-desthio estimated by the current Meeting on a basis of the OECD Animal Feeding Table. The calculated maximum and mean animal burdens are summarized below

Summary of livestock dietary burdens (ppm of dry matter diet)

	US-Canada		EU		Australia		Japan	
	Max	Mean	Max	Mean	Max	Mean	Max	Mean
Beef cattle	4.04	3.32	12.36	5.47	21.6[a]	5.50[c]	3.15	3.15
Dairy cattle	10.63	4.85	10.89	4.94	18.42[b]	5.50[d]	7.66	5.25
Broilers	2.86	2.86	1.17	1.17	1.18	1.18	0.29	0.29
Layers	2.86	2.86[f]	3.33[e]	1.71	1.18	1.18	1.72	1.72

[a] Highest maximum beef or dairy cattle dietary burden suitable for MRL estimates for mammalian meat

[b] Highest maximum dairy cattle dietary burden suitable for MRL estimates for mammalian milk

[c] Highest mean beef or dairy cattle dietary burden suitable for STMR estimates for mammalian meat.

[d] Highest mean dairy cattle dietary burden suitable for STMR estimates for milk.

[e] Highest maximum poultry dietary burden suitable for MRL estimates for poultry meat and eggs.

[f] Highest mean poultry dietary burden suitable for STMR estimates for poultry meat and eggs.

Animal commodity maximum residue levels

The 2009 JMPR summarized the total prothioconazole desthio residues (mg/kg) in edible tissues of dairy cattle after 28 days of dosing with prothioconazole-desthio:

Tissue	4 ppm dose		25 ppm dose		100 ppm dose	
	Range	Mean	Range	Mean	Range	Mean
Liver	0.02-0.05	0.04	0.18-0.26	0.22	0.61-1.6	0.95
Kidney	0.01-0.04	0.02	0.11-0.17	0.14	0.41-1.1	0.65
Muscle	< 0.01	< 0.01	< 0.01	< 0.01	0.01-0.03	0.02
Fat	< 0.01	< 0.01	0.01-0.02	0.01	0.03-0.14	0.07
Milk	< 0.004	< 0.004	< 0.004	< 0.004	0.013-0.02	0.017

The maximum dietary burden for beef cattle remained the same as was estimated by the 2009 JMPR. The maximum dietary burden for dairy cattle is 18.42 ppm which is smaller than the 25 ppm dose and no detectable residue can be expected in milk.

The mean dietary burden for beef and dairy cattle is 5.5 ppm, which is higher than the 4.8 ppm estimated by the 2009 JMPR. However the STMR values estimated by the 2009 JMPR cover the likely median residues.

The Meeting confirmed its previous recommendations for maximum residue levels, HR and median residues for mammalian meat, and edible offal and milk.

The 2008 Meeting concluded that the feeding study on poultry did not reflect the residue composition in feed and could not be used for estimation of residue levels.

RECOMMENDATIONS

On the basis of the data from supervised trials and farm animal feeding studies reported by the 2006 JMPR, the Meeting concluded that the residue levels listed below are appropriate for establishing maximum residue limits and for IEDI assessment.

Definition of the residue (for enforcement and dietary risk assessment) for plant commodities: *prothioconazole-desthio*.

Definition of the residue (for enforcement and dietary risk assessment) for animal commodities: *the sum of prothioconazole-desthio. (M04), prothioconazole-desthio-3-hydroxy (M14), prothioconazole-desthio-4-hydroxy (M15), expressed as prothioconazole-desthio after correction for molecular weight.*

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Daily Intake (IEDI) for prothioconazole-desthio was calculated from the recommendations for STMR-s for raw agricultural commodities in combination with consumption data for corresponding food commodities. The results are shown in Annex 3 to the 2014 Report.

The IEDI of the 17 GEMS/Food cluster diets were in the range of 0–3 % of the maximum ADI of 0.01 mg/kg bw. The Meeting concluded that the long-term intake of residues from uses of prothioconazole considered by the Meeting is unlikely to present a public health concern.

Short-term intake

The International Estimated Short-term Intake (IESTI) for prothioconazole-desthio was calculated from the recommendations for HR and STMR-s for raw agricultural commodities in combination with consumption data for corresponding food commodities. The results are shown in Annex 4 to the 2014 Report.

The IESTI for women of child bearing age is 0–100% of the ARfD of 0.01 mg/kg bw. The IESTI for children and general populations is 0–1 % of the ARfD of 1 mg/kg bw.

For watermelon the IESTI represented 150% of the ARfD of 0.01 mg-kg bw. No alternative GAP was available. On the basis of information provided to the JMPR it was not possible to conclude that the estimate of short-term intake of fenpropathrin, from the consumption of watermelon was less than the ARfD. The Meeting did not estimate MRL for watermelon.

The other commodities considered by the JMPR were within 0–100% of ARfD for women of child bearing age and 2% of general population. The Meeting concluded that the short-term intake of fenpropathrin when used in ways that have been considered by the MPR is unlikely to present public health concern.

5.26 PYMETROZINE (279)

TOXICOLOGY

Pymetrozine is the ISO-approved common name for (*E*)-4,5-dihydro-6-methyl-4-(3-pyridylmethyleneamino)-1,2,4-triazin-3(2*H*)-one (IUPAC), with CAS number 123312-89-0. Pymetrozine, which was developed under the code CGA 215944, is an insecticide that acts by inhibiting feeding, but the precise molecular targets are uncertain.

Pymetrozine has not been evaluated previously by JMPR and was reviewed by the present Meeting at the request of CCPR.

All critical studies contained statements of compliance with GLP.

Biochemical aspects

Absorption of pymetrozine (labelled with 6-14C-triazine or 5-14C-pyridine) administered to rats by gavage at 0.5 or 100 mg/kg bw was rapid, with maximal blood concentrations achieved at 15 minutes and 4 hours, respectively. The extent of oral absorption was high (> 80%) at both doses, based on urinary and biliary data. Pymetrozine was widely distributed in the body. High concentrations of both triazine- and pyridine-labelled material were found in the liver and kidney. The labelled material was rapidly excreted via urine (50–75% in 24 hours). There was a disproportionate increase in the AUC at 100 mg/kg bw, indicating a saturation of elimination.

Absorbed pymetrozine was extensively metabolized, with unmetabolized parent compound representing approximately 10% of the excreted radiolabel. Compounds containing both ring structures represented over 50% of the identified metabolites. The kinetics, excretion pattern, tissue distribution of radioactivity and metabolite profile were similar for both radiolabelled sites and both administered dose levels as well as when the administration of radiolabelled pymetrozine was preceded by 14 days of administration of the unlabelled material. A comparative study showed no notable differences in the metabolite profile in rats and mice.

Toxicological data

Pymetrozine was of low acute toxicity in rats via the oral route (LD50 = 5820 mg/kg bw) and dermal route (LD50 > 2000 mg/kg bw) and by inhalation exposure (LC50 > 1.8 mg/L air). Pymetrozine was not irritating to the skin of rabbits, but was transiently, mildly irritating to the eyes of rabbits. It was weakly sensitizing in the guinea-pig maximization test.

In all species, the liver was a target organ, with increases in weight, hepatocellular hypertrophy and necrosis. Investigations on liver enzyme activities in mice and rats revealed that pymetrozine administration resulted in significant reversible induction of the activities of some P450 enzymes and increased hepatocellular proliferation. Reduced thymus weight and thymic atrophy were also seen in all species, as were spleen and testicular effects. Reduced body weight gain, often associated with reductions in feed consumption, was also a consistent finding.

In a 90-day study of toxicity in mice, dietary pymetrozine concentrations were 0, 1000, 3000 and 7000 ppm (equal to 0, 143, 429 and 1000 mg/kg bw per day for males and 0, 252, 589 and 1240 mg/kg bw per day for females, respectively). No NOAEL was identified, as hepatocellular necrosis was observed at 1000 ppm (equal to 252 mg/kg bw per day) in female mice.

In a 28-day study of toxicity in rats, pymetrozine was administered by gavage at a dose of 0, 10, 100 or 600 mg/kg bw per day. The NOAEL was 10 mg/kg bw per day, based on thymic atrophy and hyperplasia of the splenic white pulp at 100 mg/kg bw per day.

In a 28-day study of toxicity in rats, dietary pymetrozine concentrations were 0, 100, 500, 2000 and 10 000 ppm (equal to 0, 10, 55, 203 and 691 mg/kg bw per day for males and 0, 10, 55, 212 and 699 mg/kg bw per day for females, respectively). The NOAEL was 2000 ppm (equal to

203 mg/kg bw per day), based on a range of effects on the liver, spleen, thymus, adrenals and testes at 10 000 ppm (equal to 691 mg/kg bw per day).

In a 90-day study of toxicity in rats, dietary pymetrozine concentrations were 0, 50, 500 and 5000 ppm (equal to 0, 3.4, 33 and 360 mg/kg bw per day for males and 0, 3.6, 34 and 370 mg/kg bw per day for females, respectively). The NOAEL was 500 ppm (equal to 33 mg/kg bw per day), on the basis of thymic atrophy, hepatocellular hypertrophy and renal calcification at 5000 ppm (equal to 360 mg/kg bw per day).

In a 28-day study in which dogs were administered pymetrozine in the diet at a concentration of 0, 100, 500 or 2500 ppm (equal to 0, 3.2, 15 and 55 mg/kg bw per day for males and 0, 2.8, 16 and 50 mg/kg bw per day for females, respectively), the NOAEL was 100 ppm (equal to 2.8 mg/kg bw per day), based on decreased thymus weights in females at 500 ppm (equal to 16 mg/kg bw per day).

In a 90-day study in which dogs received pymetrozine in the diet at a concentration of 0, 100, 500 or 2500 ppm (equal to 0, 3.1, 14 and 53 mg/kg bw per day for males and 0, 3.2, 15 and 60 mg/kg bw per day for females, respectively), the NOAEL was 100 ppm (equal to 3.1 mg/kg bw per day), based on thymic atrophy, testicular tubular atrophy, reduced spermatogenesis, hepatocellular necrosis and inflammatory changes in several organs at 500 ppm (equal to 14 mg/kg bw per day).

In a 1-year study in dogs in which pymetrozine was administered in the diet at a concentration of 0, 20, 200 or 1000 ppm (equal to 0, 0.57, 5.3 and 28 mg/kg bw per day for males and 0, 0.57, 5.0 and 27 mg/kg bw per day for females, respectively), the NOAEL was 20 ppm (equal to 0.57 mg/kg bw per day), on the basis of reduced testes weights, increased cholesterol and reduced haemoglobin at 200 ppm (equal to 5.0 mg/kg bw per day).

The pattern of findings in the 90-day and 1-year dog studies was similar, and the effects seen in the 1-year study at 200 and 1000 ppm were marginal. An overall NOAEL for the 90-day and 1-year studies of 100 ppm (equal to 3.1 mg/kg bw per day) was identified, with an overall LOAEL of 200 ppm (equal to 5.0 mg/kg bw per day).

In a 78-week toxicity and carcinogenicity study in mice, dietary concentrations were 0, 10, 100, 2000 and 5000 ppm (equal to 0, 1.2, 12, 254 and 678 mg/kg bw per day for males and 0, 1.2, 11, 243 and 673 mg/kg bw per day for females, respectively). The NOAEL for systemic toxicity was 100 ppm (equal to 11 mg/kg bw per day), based on liver hypertrophy, splenic haemosiderosis and haematopoiesis, and alterations in the weights of the kidneys, spleen and liver at 2000 ppm (equal to 243 mg/kg bw per day). Pymetrozine increased the incidences of hepatocellular adenomas and carcinomas in both sexes at 5000 ppm and in males at 2000 ppm; and of lung adenomas and carcinomas in females at 2000 and 5000 ppm. The NOAEL for carcinogenicity was 100 ppm (equal to 11 mg/kg bw per day), based on increased incidences of hepatocellular carcinomas in males receiving 2000 ppm (equal to 254 mg/kg bw per day) and lung adenomas and carcinomas in females receiving 2000 ppm (equal to 243 mg/kg bw per day).

In a 2-year toxicity and carcinogenicity study in rats, dietary concentrations were 0, 10, 100, 1000 and 3000 ppm (equal to 0, 0.4, 3.7, 39 and 128 mg/kg bw per day for males and 0, 0.4, 4.5, 47 and 154 mg/kg bw per day for females, respectively). The NOAEL for systemic toxicity was 100 ppm (equal to 3.7 mg/kg bw per day), on the basis of effects in both sexes (altered organ weights, foci of cellular change in the liver and thyroid hyperplasia) at 1000 ppm (equal to 39 mg/kg bw per day). Pymetrozine produced an increase in the incidence of hepatocellular adenoma in female rats given 3000 ppm in the diet. The NOAEL for carcinogenicity was 1000 ppm (equal to 47 mg/kg bw per day), based on an increase in the incidence of hepatocellular adenoma in females at 3000 ppm (equal to 154 mg/kg bw per day).

The Meeting concluded that pymetrozine is carcinogenic in male and female mice and in female but not male rats.

Pymetrozine was tested for genotoxicity in an adequate range of assays, both in vitro and in vivo. No evidence of genotoxicity was found.

The Meeting concluded that pymetrozine is unlikely to be genotoxic.

Mechanistic studies were performed to investigate the mode of action of the liver tumour findings in mice and female rats. Male mice exposed to pymetrozine exhibited moderate increases in proliferation of hepatic smooth endoplasmic reticulum and in activities of P450 enzymes, a sustained stimulation of hepatocyte proliferation and increased hepatocellular hypertrophy. These effects were reversible. A dietary level of 500 ppm was a threshold for these effects in mice. Female rats exposed to pymetrozine at 1000 ppm and above exhibited a weak and reversible induction of hepatic, xenobiotic metabolizing enzymes, most prominently uridine diphosphate–glucuronyl transferase. There were no significant effects at 100 ppm, which is considered to be the threshold. Pymetrozine at up to 1000 ppm in the diet for 18 weeks exhibited no tumour promoting potential in rats initiated with diethylnitrosamine and dihydroxy-di-*N*-propylnitrosamine.

No data were presented relating to the mode of action for the lung tumours observed in female mice exposed to pymetrozine, and it is noted that there are no preneoplastic lesions of the lungs in mice. However, there was no dose–response relationship, lung tumours are a common finding in mice and, generically, species-specific lung tumours in the mouse have been induced by a number of chemicals.

The available information and data do not permit the identification of the modes of action for the lung or liver tumours or the exclusion of their human relevance.

In view of the lack of genotoxicity and on the basis of other available toxicological information, the Meeting concluded that the modes of action for the liver tumours in mice and female rats and for the lung tumours in female mice are likely to involve a threshold. The Meeting concluded that pymetrozine is unlikely to pose a carcinogenic risk to humans from the diet.

In a two-generation study of reproductive toxicity in rats, dietary concentrations were 0, 20, 200 and 2000 ppm (equal to mean intakes of 0, 1.4, 14 and 127 mg/kg bw per day for males and 0, 1.6, 16 and 152 mg/kg bw per day for females, respectively). The NOAEL for reproductive effects was 2000 ppm (equal to 127 mg/kg bw per day), the highest dose tested. The NOAEL for parental toxicity was 200 ppm (equal to 14 mg/kg bw per day), based on reduced body weights and histopathological findings in the liver, spleen and pituitary at 2000 ppm (equal to 127 mg/kg bw per day). The NOAEL for effects on offspring was 200 ppm (equal to 14 mg/kg bw per day), based on reduced pup weight and a delay in eye opening at 2000 ppm (equal to 127 mg/kg bw per day).

In a study of developmental toxicity in rats dosed at 0, 30, 100 or 300 mg/kg bw per day, displaced pubic bones were seen in four fetuses at the top dose level; this malformation has not been recorded in contemporary historical control data. There were also increases in a number of skeletal variations at 300 mg/kg bw per day. The NOAEL for maternal toxicity was 100 mg/kg bw per day, on the basis of decreased body weight gain and initial body weight loss at 300 mg/kg bw per day. The NOAEL for embryo and fetal toxicity was 100 mg/kg bw per day, based on increases in skeletal abnormalities (including malformations) at 300 mg/kg bw per day.

In a study of developmental toxicity, rabbits were dosed at 0, 10, 75 or 125 mg/kg bw per day. Viable fetus numbers were reduced at 125 mg/kg bw per day. The NOAEL for maternal toxicity was 10 mg/kg bw per day, based on initial body weight loss with reduced feed consumption at 75 mg/kg bw per day. The NOAEL for embryo and fetal toxicity was 10 mg/kg bw per day, based on an increase in 13th ribs and reduced pubis at 75 mg/kg bw per day.

The Meeting concluded that pymetrozine is teratogenic in rats and possibly in rabbits.

The acute neurotoxicity of pymetrozine was investigated in rats at doses of 0, 125, 500 and 2000 mg/kg bw. Three males died at 2000 mg/kg bw. Dose-related reductions in locomotor activity were seen in all dose groups at 4–5 hours post-dosing, but not subsequently. There were no indications of neuropathy. No NOAEL was identified.

In a subchronic (90-day) neurotoxicity study in rats, dietary concentrations were 0, 500, 1000 and 3000 ppm (equal to 0, 35, 68 and 201 mg/kg bw per day for males and 0, 41, 68 and 204 mg/kg

bw per day for females, respectively). The NOAEL for neurotoxicity and systemic toxicity was 1000 ppm (equal to 68 mg/kg bw per day), based on altered behaviours (continuous head movements and abnormal gait) and reduced body weights at 3000 ppm (equal to 201 mg/kg bw per day). There was no evidence of neuropathy.

Pymetrozine showed some evidence of reversible, clinical signs of neurotoxicity, but with no morphological correlates.

Toxicological data on metabolites and/or degradates

The Meeting considered information on 12 metabolites of pymetrozine: 11 found in plants and one (CGA313124) found in milk.[1] No specific toxicological data were submitted on these metabolites, and therefore they were evaluated using the JMPR metabolite assessment scheme.

CGA313124 (6-hydroxymethyl-pymetrozine) is a major urinary metabolite of pymetrozine in rats, equating to approximately 30% (sum of CGA313124 and its acid metabolite) of the administered dose. The Meeting concluded that the toxicity of CGA313124 has been addressed in studies on pymetrozine and that CGA313124 is covered by the reference doses for pymetrozine.

Nicotinic acid (vitamin B_3, niacin) and nicotinamide are natural compounds and are interconverted in the body. The recommended daily intake for vitamin B_3 is approximately 200 µg/kg bw, with approximately 2.5 mg in a serving of some breakfast cereals. Intakes arising from the use of pymetrozine are significantly below these values. Nicotinic acid and nicotinamide are considered not to be relevant metabolites of pymetrozine.

CGA245342 and Ia7 have no alerts for genotoxicity and are in Cramer class III, with a chronic TTC of 1.5 µg/kg bw per day. For both compounds, the IEDIs and IESTIs are below the TTC. The Meeting concluded that CGA245342 and Ia7 are not toxicologically significant plant metabolites of pymetrozine.

Ia17 has a structural alert for genotoxicity but has not been tested for genotoxicity. On the basis of the available information, the appropriate TTC for chronic exposure is 0.0025 µg/kg bw per day. The IEDI is below 0.0025 µg/kg bw per day. For the acute exposure assessment, a single-exposure TTC of 0.2 µg/kg bw was considered appropriate by the Meeting.[2] The IESTI for Ia17 is below 0.2 µg/kg bw, and Ia17 is considered not to be a relevant plant metabolite of pymetrozine.

CGA215525 has been proposed as a rat metabolite, but the data are inconsistent, and the Meeting was unable to make use of the toxicological data on pymetrozine in evaluating this metabolite. CGA215525 has a structural alert for genotoxicity, but there was no evidence of genotoxicity in an Ames test, and it is in Cramer class III. Therefore, the relevant TTC is 1.5 µg/kg bw per day. The IEDI is below this value. A single-exposure TTC for Cramer class III compounds of 5 µg/kg bw has been proposed by EFSA, and the Meeting concluded that the use of this value would be conservative. The IESTI is below this value. The Meeting concluded that CGA215525 is not a toxicologically significant plant metabolite of pymetrozine.

CGA96956 (trigonelline) is a natural component of a range of commodities, and exposures from other sources are orders of magnitude greater than those from pymetrozine. The Meeting concluded that CGA96956 is not a toxicologically significant plant metabolite of pymetrozine.

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[1] See "Residue and analytical aspects" section below for chemical names of metabolites.

[2] This is based on the approach of the European Medicines Agency (EMA), which set a TTC of 2 µg/kg bw (120 µg/person) for single exposures to genotoxic impurities in pharmaceuticals. The chronic TTC value used by EMA is 10-fold higher than that used by WHO for potentially genotoxic compounds. Therefore, the EMA single-exposure TTC value of 2 µg/kg bw (120 µg/person) was divided by 10 to give a single-exposure TTC value of 0.2 µg/kg bw, applicable to potentially genotoxic metabolites of pesticides.

CGA23199 is a minor rat metabolite (< 3%), and its toxicity is considered not to have been adequately addressed by studies with pymetrozine. CGA23199 has no structural alerts for genotoxicity and is in Cramer class III, with a TTC of 1.5 µg/kg bw per day and a single-exposure TTC of 5 µg/kg bw. The IEDI and IESTI are below the applicable thresholds, and the Meeting concluded that CGA23199 is not a toxicologically significant plant metabolite of pymetrozine.

CGA128632 (nicotinyl alcohol) has therapeutic uses as a vasodilator. The minimal therapeutic dose is approximately 1 mg/kg bw per day. There is a margin between the minimal therapeutic dose of over 1000 relative to the IEDI and of over 50 relative to the IESTI. The Meeting concluded that CGA128632 is not a toxicologically significant plant metabolite of pymetrozine.

CGA294849 has been proposed as a rat metabolite, but the data are inconsistent, and the Meeting was unable to make use of the toxicological data on pymetrozine in evaluating this metabolite. CGA294849 has a structural alert for genotoxicity, but has not been tested for genotoxicity. The IEDI and IESTI are above the applicable chronic TTC and single-exposure TTC values, respectively. The Meeting is unable to conclude on the toxicological significance of CGA294849.

CGA300407 does not have a structural alert for genotoxicity, but the Meeting was made aware that in vitro and in vivo genotoxicity studies exist in which positive results were reported. These data were not submitted, and therefore the Meeting is unable to conclude on the toxicological significance of CGA300407.

Human data

No adverse effects have been reported during health surveillance of pymetrozine production and formulation plant workers, and no significant effects have been reported in exposed users of pymetrozine-based products.

The Meeting concluded that the existing database on pymetrozine was adequate to characterize the potential hazards to fetuses, infants and children.

Toxicological evaluation

The Meeting established an ADI for pymetrozine of 0–0.03 mg/kg bw on the basis of the overall NOAEL of 3.1 mg/kg bw per day for effects on haematology, liver, thymus and testis from the 90-day and 1-year dog studies combined. A safety factor of 100 was applied. This is supported by the NOAEL of 3.7 mg/kg bw per day in the 2-year study of toxicity in rats. There is a margin of exposure of greater than 5000 between the upper bound of the ADI and the LOAEL of 154 mg/kg bw per day for tumours in female rats.

The Meeting established an ARfD for pymetrozine of 0.1 mg/kg bw, on the basis of the NOAEL of 10 mg/kg bw per day for developmental abnormalities and maternal body weight loss at the start of dosing in the developmental toxicity study in rabbits. A safety factor of 100 was applied.

A toxicological monograph was prepared.

Levels relevant to risk assessment of pymetrozine

Species	Study	Effect	NOAEL	LOAEL
Mouse	Eighteen-month study of toxicity and carcinogenicity[a]	Toxicity	100 ppm, equal to 11 mg/kg bw per day	2 000 ppm, equal to 243 mg/kg bw per day
		Carcinogenicity	100 ppm, equal to 11 mg/kg bw per day	2 000 ppm, equal to 243 mg/kg bw per day
Rat	Two-year study of toxicity and	Toxicity	100 ppm, equal to 3.7 mg/kg bw per day	1 000 ppm, equal to 39 mg/kg bw per day

Species	Study	Effect	NOAEL	LOAEL
	carcinogenicity[a]	Carcinogenicity	1 000 ppm, equal to 47 mg/kg bw per day	3 000 ppm, equal to 154 mg/kg bw per day
	Two-generation study of reproductive toxicity[a]	Reproductive toxicity	2 000 ppm, equal to 127 mg/kg bw per day[b]	–
		Parental toxicity	200 ppm, equal to 14 mg/kg bw per day	2 000 ppm, equal to 127 mg/kg bw per day
		Offspring toxicity	200 ppm, equal to 14 mg/kg bw per day	2 000 ppm, equal to 127 mg/kg bw per day
	Developmental toxicity study[c]	Maternal toxicity	100 mg/kg bw per day	300 mg/kg bw per day
		Embryo and fetal toxicity	100 mg/kg bw per day	300 mg/kg bw per day
Rabbit	Developmental toxicity study[c]	Maternal toxicity	10 mg/kg bw per day	75 mg/kg bw per day
		Embryo and fetal toxicity	10 mg/kg bw per day	75 mg/kg bw per day
Dog	Ninety-day and 1-year studies of toxicity[a,d]	Toxicity	100 ppm, equal to 3.1 mg/kg bw per day	200 ppm, equal to 5.0 mg/kg bw per day

[a] Dietary administration.
[b] Highest dose tested.
[c] Gavage administration.
[d] Two studies combined.

Estimate of acceptable daily intake (ADI)

0–0.03 mg/kg bw

Estimate of acute reference dose (ARfD)

0.1 mg/kg bw

Information that would be useful for the continued evaluation of the compound

Results from epidemiological, occupational health and other such observational studies of human exposure; all information on the toxicity of plant and animal metabolites

Critical end-points for setting guidance values for exposure to pymetrozine

Absorption, distribution, excretion and metabolism in mammals	
Rate and extent of oral absorption	Rapid, blood T_{max} < 4 hours; > 80%
Dermal absorption	No study submitted
Distribution	Widely distributed; highest concentrations in liver and kidney
Potential for accumulation	No evidence of accumulation
Rate and extent of excretion	Largely cleared within 24 hours; primarily via urine (> 50%), bile (10–30%) and faeces (15–30%); evidence of saturation at 100 mg/kg bw
Metabolism in animals	Extensive; mainly by oxidation reactions; cleavage between the two rings is not extensive

Toxicologically significant compounds in animals and plants	Pymetrozine and CGA313124 [CGA294849 and CGA300407][1]
Acute toxicity	
Rat, LD_{50}, oral	5 820 mg/kg bw
Rat, LD_{50}, dermal	> 2 000 mg/kg bw
Rat, LC_{50}, inhalation	> 1.8 mg/L
Rabbit, dermal irritation	Not irritating
Rabbit, ocular irritation	Transiently, mildly irritating
Guinea-pig, dermal sensitization	Weakly sensitizing (maximization test)
Short-term studies of toxicity	
Target/critical effect	Haematology; liver lesions, thymus weight/atrophy and testes lesions
Lowest relevant oral NOAEL	3.1 mg/kg bw per day (dog)
Lowest relevant dermal NOAEL	1000 mg/kg bw per day (rat)
Lowest relevant inhalation NOAEC	No data
Long-term studies of toxicity and carcinogenicity	
Target/critical effect	Liver lesions, thyroid hyperplasia, liver and spleen weights
Lowest relevant NOAEL	3.7 mg/kg bw per day (rat)
Carcinogenicity	Liver tumours (rat and mouse); lung tumours (mouse)
	Unlikely to pose a carcinogenic risk to humans from the diet
Genotoxicity	
	Unlikely to be genotoxic
Reproductive toxicity	
Target/critical effect	Lower pup weight at parentally toxic dose
Lowest relevant parental NOAEL	14 mg/kg bw per day
Lowest relevant offspring NOAEL	14 mg/kg bw per day
Lowest relevant reproductive NOAEL	127 mg/kg bw per day, highest dose tested
Developmental toxicity	
Target/critical effect	Skeletal malformations (rat) and abnormalities (rabbit)
Lowest relevant maternal NOAEL	10 mg/kg bw per day (rabbit)
Lowest relevant embryo/fetal NOAEL	10 mg/kg bw per day (rabbit)
Neurotoxicity	
Acute neurotoxicity NOAEL	< 125 mg/kg bw per day, lowest dose tested (rat)
Subchronic neurotoxicity NOAEL	68 mg/kg bw per day (rat)
Developmental neurotoxicity NOAEL	No data
Other toxicological studies	
Immunotoxicity	No specific studies
Mechanistic data	Hepatocyte proliferation (mice); induction of enzymatic activities (rats and mice)

[1] Toxicological significance cannot be determined on the basis of the available information.

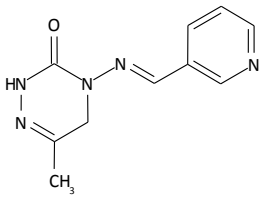
Studies on metabolites	No in vivo data submitted on individual metabolites CGA313124 – significant rat metabolite, addressed by studies with pymetrozine Nicotinic acid, nicotinamide, CGA245342, CGA215525, CGA96956, CGA23199, CGA128632, Ia7 and Ia17 were considered to be not toxicologically significant plant metabolites based on comparisons of intakes from pymetrozine uses with other types of exposure or the appropriate TTC values It was not possible to conclude on the toxicological significance of CGA294849 or CGA300407
Medical data	
	No notable adverse effects reported

Summary

	Value	Study	Safety factor
ADI	0–0.03 mg/kg bw	Ninety-day and 1-year studies of toxicity (dog)	100
ARfD	0.1 mg/kg bw	Developmental toxicity study (rabbit)	100

RESIDUE AND ANALYTICAL ASPECTS

Pymetrozine is a pyridine azomethine insecticide used to control homopteran insects (aphids and whiteflies) as well as pollen beetle selectively. Although it has no knockdown effect, pymetrozine rapidly affects the feeding behaviour of the insect pests. It was considered for the first time by the 2014 JMPR for toxicology and residues.

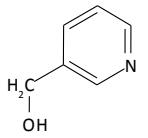
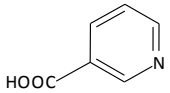
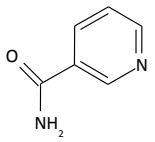
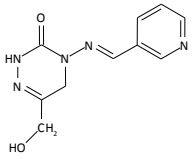
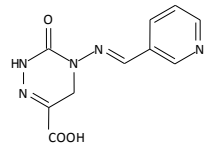
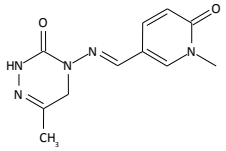
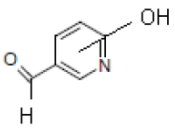
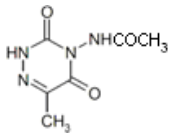
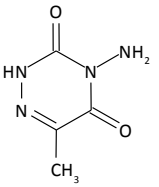
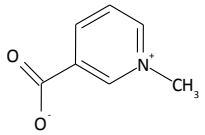


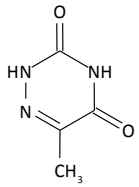
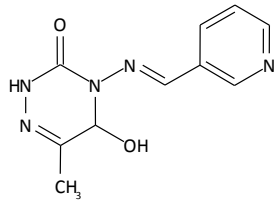
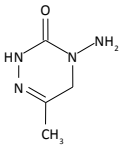
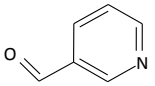
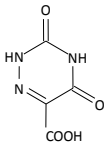
The IUPAC name of pymetrozine is (E)-4,5-dihydro-6-methyl-4-(3-pyridylmethyleneamino)-1,2,4-triazin-3(2H)-one.

The pymetrozine molecule contains a double bond about which E/Z isomerism is possible. However, pymetrozine technical material is manufactured by a process that yields almost exclusively the E isomer.

Pymetrozine labelled either in the pyridine- or triazine-moiety was used in the metabolism and environmental fate studies.

The following abbreviations are used for the metabolites discussed below:

CGA128632	3-pyridinemethanol	
CGA180777 (nicotinic acid)	3-pyridinecarboxylic acid	
CGA180778 (nicotinamide)	3-pyridinecarboxamide	
CGA313124	4,5-dihydro-6-hydroxymethyl-4-[(3-pyridinyl-methylene)amino]-1,2,4-triazine-3(2H)-one	
U5/I_{A2}	4,5-dihydro-6-carboxy-4-[(3-pyridinyl methylene)-amino]-1,2,4-triazine-3(2H)-one	
I_{A7}	4,5-dihydro-6-methyl-4-[(3-(1-methyl-6-oxo-1,6-dihydropyridinylmethylene)- amino]-1,2,4-triazine-3(2H)-one	
IA17	hydroxylated 3-pyridinecarboxaldehyde	
CGA259168	N-(4,5-dihydro-6-methyl-3,5-dioxo-1,2,4-triazine-4(2H)-yl)-acetamide	
CGA294849	4-amino-6-methyl-1,2,4-triazine-3,5(2H,4H)-dione	
CGA96956 (trigonelline)	1-methyl-3-pyridinecarboxylic acid	

GS23199	6-methyl-1,2,4-triazine-3,5(2H,4H)-dione	
CGA359009	4,5-dihydro-5-hydroxy-6-methyl-4-[(3-pyridinylmethylene)-amino]-1,2,4-triazine-3(2H)-one	
CGA215525	4-amino-6-methyl-1,2,4-triazine-3(2H)-one	
CGA300407 (nicotinealdehyde)	3-pyridinecarboxaldehyde	
CGA266591	2,3,4,5-tetrahydro-3,5-dioxo-1,2,4-triazine-6-carboxylic acid	

Animal metabolism

Information was available on metabolism of pymetrozine in laboratory animals, lactating goats and laying hens.

In the rat the extent of oral absorption is high (> 80%), based on urinary and biliary data. Pymetrozine is widely distributed in the body. High concentrations of both triazine- and pyridine-labelled material were found in the liver and kidney. The labelled material was rapidly excreted via urine (50–75% in 24 hours). Absorbed pymetrozine was extensively metabolized, with unmetabolized parent compound representing approximately 10% of the excreted radiolabel. Compounds containing both ring structures represented over 50% of the identified metabolites. The kinetics, excretion pattern, tissue distribution of radioactivity and metabolite profile were similar for both radiolabelled sites and administered dose levels as well as when the administration of radiolabelled pymetrozine was preceded by 14 days of administration of the unlabelled material (see WHO Monograph).

One study on the metabolism in lactating goats was available for each of the labels. Over four consecutive days the goats received daily doses of radiolabelled pyridine-^{14}C- or triazine-^{14}C-pymetrozine at rates equivalent to 7.5 ppm (0.39 mg/kg bw) or 10 ppm (0.54 mg/kg bw) in the diet, respectively. In both studies approximately 5-6% of the total dose was recovered from milk or tissues of the animals. Most of the administered radioactivity was recovered in faeces (15–17%) and urine (47–52%).

Following application of pyridine-^{14}C-pymetrozine highest TRR levels were found in liver (1.5 mg eq./kg), kidney (0.72 mg eq./kg) and milk (0.33 mg eq./kg). Into muscle (0.068 mg eq./kg) and fat (0.027 mg eq./kg) the overall transfer of radioactivity was minor.

Parent pymetrozine was identified in all tissues and milk, however only in muscle (11% TRR) the contribution to the TRR was more than 10 %. In tissues nicotinamide (CGA180778), which is formed by cleavage of the parent substance, was the major residue representing 44% TRR in muscle, 24% TRR in fat, 37% TRR in liver and 27% TRR in kidney.

In most tissues CGA313124 (pymetrozine-hydroxy) was also a major metabolite identified with levels of 10% TRR in muscle and 11% TRR in kidney. In milk, CGA313124 (36% TRR) and its phosphate conjugate (39% TRR) were the only major metabolites identified. In addition, I_{A17} was present in liver at 10% of the TRR.

For the triazine-^{14}C-label again highest TRR levels were found in liver (1.1 mg eq./kg), kidney (0.57 mg eq./kg) and milk (0.45 mg eq./kg). Muscle (0.047 mg eq./kg) and fat (0.098 mg eq./kg) contained lower residues.

Unchanged pymetrozine was again found in all tissues and milk, but only in muscle as a major residue representing 10% of the TRR. In tissues CGA313124 was the dominant residue found in levels of 9.5% TRR in muscle, 25% TRR in fat, 5% TRR in liver and 15% TRR in kidney. In kidney 5U/I_{A2} was another major metabolite present at 12% of the TRR. Several triazine-based cleavage products were identified, however at individual levels below 10% TRR each.

In milk, again CGA313124 (40% TRR) and its phosphate conjugate (41% TRR) were the only major metabolites identified.

For laying hens groups of hens received daily doses of [pyridine-^{14}C]-pymetrozine or [triazine-^{14}C]-pymetrozine at rates equivalent to approximately 10 ppm for four consecutive days (0.79 mg/kg bw). The animals were sacrificed ca. 6 hours after the last dose. Approximately 0.4–1.3% of the total dose in both studies was recovered from eggs or tissues of the animals. Most of the radioactivity administered was found in the excreta (76–81% AR). Total radioactive residues were 0.006–0.016 mg eq./kg in eggs, 0.021–0.043 mg eq./kg in muscle, 0.019–0.024 mg eq./kg in fat, 0.16–0.54 mg eq./kg in kidney and 0.11-0.99 mg eq./kg in liver. For both labels parent pymetrozine was found in very low levels, not exceeding 5% of the TRR. In meat, fat and eggs yolk it was below the LOQ of the method or was undetected.

Following administration of the pyridine-^{14}C-label, nicotinamide (CGA180778) was the major residue in meat (77% TRR), skin + fat (63% TRR), egg white (28% TRR) and liver (70% TRR). In kidney, nicotinic acid (CGA180777) was the major residue, representing 65% of the TRR. Further major metabolites identified were I_{A7}, present at levels of 17% TRR in skin + fat, 15% TRR in egg white and 13% TRR in kidney as well as CGA300407 with 11% TRR in egg white.

For the triazine-^{14}C-label CGA259168 was the major residue in meat (39% TRR), skin + fat (24% TRR, egg white (45% TRR), egg yolk (13% TRR) and kidney (11% TRR). I_{A7} was mainly found in kidney (49% TRR), followed by liver (27% TRR), skin + fat (22% TRR) and egg white (11% TRR). The only other major metabolite found was CGA294849 present in meat at levels of 11% of the TRR.

In summary pymetrozine is quickly degraded in goats and hens. A large quantity of the parent molecule is cleaved, resulting in formation of nicotinic acid (up to 65% TRR) and nicotinamide (up to 70% TRR) for the pyridine-moiety and several metabolites for the triazine-moiety. Another important metabolic step is the oxidation of the parent to CGA313124, which is found in most tissues and mainly in milk, including its phosphate conjugate (up to 40% and 41% TRR, respectively).

In goats, I_{A17} represented up to 10% TRR in the liver. In hen tissues, pymetrozine is also metabolised into I_{A7} (13–41% TRR in fat, egg white and kidney). Both metabolites were not identified in the rat.

Plant metabolism

The Meeting received plant metabolism studies for pymetrozine following foliar application of either [pyridine-14C]-pymetrozine or [triazine-14C]-pymetrozine to tomatoes (protected), potatoes, paddy rice and cotton (protected). For paddy rice, the metabolism following granular application was also investigated.

Following foliar application of [pyridine-^{14}C]-pymetrozine to tomatoes at rates of 2 × 0.25 kg ai/ha, total radioactive residues in the fruits declined from 1 mg eq./kg (1h) to 0.23 mg eq./kg (7 days) and finally to 0.016 mg eq./kg 27 days after the last application. In the leaves corresponding TRR levels were 14 mg eq./kg (1 hour), 7.4 mg eq./kg (7 days) and 2.4 mg eq./kg (27 days).

In the samples collected directly after treatment (1 hour), pymetrozine located in the fruit and leaf surface was the dominant residue, representing 78% TRR and 60% TRR, respectively.

After 15 days, the pymetrozine surface residues declined to 5.9% TRR in the fruits and 16% TRR in the leaves. Most of the radioactivity was recovered in the extracts. In the fruits, trigonelline (CGA96956) was the only major residue representing 70% of the TRR. In leaves, trigonelline (26% TRR) and sugar conjugates of CGA128632 (23% TRR) were major residues besides the parent.

[Triazine-^{14}C]-pymetrozine was applied to tomato plants with three foliar application with 0.47 kg ai/ha each. In the fruits collected (3, 7 and 14 days after treatment) TRR levels were 0.51–0.58 mg eq./kg. In the leaves TRR levels declined from 28 mg eq./kg (3 d) to 22 mg eq./kg (7 days) and finally to 17 mg eq./kg (14 days).

In all samples unchanged pymetrozine was the major residues, representing 32–57% TRR in the fruits and 31–50% TRR in the leaves. The only other major metabolite identified was CGA294849 present at levels of 14% TRR in fruits collected 14 days after harvest.

In the first study investigating the metabolism of pymetrozine in potatoes either [pyridine-^{14}C]- or [triazine-^{14}C]-pymetrozine were applied to potato plants with three foliar sprayings at rates of 0.15 kg ai/ha (low-dose) or 1.05 kg ai/ha (high-dose) each 61 days after planting. In the foliage samples collected after 7, 14 and 19 days TRR levels were 6.4–11.7 mg eq./kg following low-dose and 29–46 mg eq./kg following high-dose treatment. In the tubers TRR levels amounted 0.11–0.36 mg eq./kg (low-dose) and 0.34–1.1 mg eq./kg (high-dose).

For the [pyridine-^{14}C]-label, trigonelline (CGA96956) was the major residue in tubers (7, 14 and 29 days after last treatment) representing 54–75% of the TRR. In addition, nicotinic acid (CGA180777) and its glycoside represented major residues present up to 22% of the TRR. Unchanged parent pymetrozine was detected in all samples, however its levels did not exceed 2.2% of the TRR. No further major metabolites were identified in the tubers.

In the foliage, unchanged pymetrozine was present at higher levels of up to 18% TRR in day 7 samples. The only major metabolite present was CGA128632 and its glycoside, representing 1.1-3.1% TRR and 9.5–18% TRR, respectively. The major part of the radioactivity in the foliage remained unextracted (54–70% TRR).

For the [triazine-^{14}C]-label, neither parent (0.2-4.9% TRR) nor metabolites (up to 5.7% TRR) represented major residues in tubers. Most of the radioactivity was distributed into multiple minor fractions too low for identification. The foliage showed GS23199 (1.4–2.4% TRR) and its glycoside (7.6–16% TRR) as major residues. Parent pymetrozine was found in lower amounts of 6.3–10% of the TRR. Again, the amount of unextracted radioactivity in the foliage was high, representing 37–45% of the TRR.

In two additional studies either [pyridine-^{14}C]- or [triazine-^{14}C]-pymetrozine were applied to potato plants with two foliar sprayings at rates of 0.2 kg ai/ha each. In the leaves, residues declined from 9.5-11 mg eq./kg (1h after treatment) to 1.3–1.8 mg eq./kg (55 days, final harvest). Special investigation of radioactive residues in new leaves above or below the treated plant parts reveals

approximately 3–4 times higher residues on the upper leaves than in the lower leaves. In tuber collected 55 days after the final application, TRR levels were 0.051–0.072 mg eq./kg.

The identification of the radioactivity in the tubers showed no pymetrozine above the LOQ of 0.001 mg eq./kg. The only major residues identified were nicotinic acid (CGA180777) and its glycoside for the pyridine-label (22 and 29% TRR, respectively) and GS23199 (11% TRR) and its glycoside (1.7% TRR) for the triazine-label.

In the foliage pymetrozine was the dominant residue directly after treatment (42–58% TRR). In samples collected after longer intervals, the radioactivity was distributed into several minor fractions mostly too low for identification. The only identified major metabolite was conjugated CGA128632 (up to 28% TRR) for the pyridine-label. Unextracted radioactivity in potato foliage averaged at 36% TRR for both labels.

Paddy rice was treated with either [pyridine-^{14}C]- or [triazine-^{14}C]-pymetrozine with one foliar treatment of 0.25 kg ai/ha 45 days before harvest. TRR levels found were 1.7–2.1 mg eq./kg in foliage (19 days after treatment), 5.3–6.3 mg eq./kg in straw and 0.14–0.24 mg eq./kg in grain (both samples 45 days after treatment).

The identification of the radioactivity in foliage and straw showed unchanged pymetrozine as the only major residue, representing 86–89 % TRR and 63–74% TRR, respectively.

In the grain no metabolites were identified exceeding 10% TRR. The parent substance was detected in all samples, however its levels were low (0.8–2.3% TRR). In the grain 63–86% of the TRR remained unextracted.

In addition paddy rice was treated with granules of [pyridine-^{14}C]- or [triazine-^{14}C]-pymetrozine at rates corresponding to 0.6 kg ai/ha to seedling boxes. Foliage was collected 1, 41 and 69 days later, grain husks and straw at maturity after 116 days.

Total radioactive residues were highest in foliage directly after treatment with 33–42 mg eq./kg and declined to 0.72–0.82 mg eq./kg after 69 days. At harvest dry straw contained TRR levels of 2.6 mg eq./kg. In the grain the radioactivity was much lower, representing 0.21–0.52 mg eq./kg.

In the foliage parent pymetrozine was the major residue directly after treatment (1 day, 38–60% TRR), but quickly declined to < 10% TRR in all other samples collected after a longer interval. In grain, pymetrozine was not found above the LOQ of 0.001 mg eq./kg (0.2% TRR).

Major metabolites identified in foliage and straw after application of pyridine-^{14}C-pymetrozine were trigonelline (CGA96956) with 9.5–28% TRR and free and conjugated nicotinic acid (CGA180777) with a total of 17–26% TRR. For the triazine-^{14}C-label no metabolites exceeding 10% of the TRR were identified except for CGA359009 (15% TRR) and GS23199 (17% TRR) in foliage samples one day after treatment.

Grain contained very few identified metabolites. The only major metabolites were trigonelline (CGA96956, 11% TRR) and free and conjugated nicotinic acid (CGA180777, 26% TRR). Most of the radioactivity in grain remained unextracted (56-86% TRR).

The metabolism of pymetrozine in cotton was investigated by application of either [pyridine-^{14}C]- or [triazine-^{14}C]-labelled active substance under glasshouse conditions. The plants were treated with two foliar spraying at rates equivalent to 0.2 kg ai/ha each. After 93 days samples of treated leaves (0.6–5.9 mg eq./kg), new grown leaves (0.03–0.2 mg eq./kg), stem (1.6–1.7 mg eq./kg), hulls (2.7–4.8 mg eq./kg) fibres (0.065–0.17 mg eq./kg) and seeds (0.043–0.21 mg eq./kg) were collected.

For the [pyridine-^{14}C]-label unchanged pymetrozine was the major residue in all green plant parts, hulls and fibres, representing 28–83% of the TRR. The only metabolite exceeding 10% of the TRR in the plant was trigonelline (CGA96956, 0.6–23% TRR). In the seeds pymetrozine was detected at levels of 7.4–9% of the TRR. Most of the parent substance (35–58%) was found in cotton oil extracted from the seeds. The major residues in the seeds was trigonelline (CGA96956), representing 50% of the TRR.

For the [triazine-14C]-label only pymetrozine was present in major amount in the plant (28–66% TRR). Minor residues identified were CGA294849 and GS23199 (< 4% TRR each). In the seeds pymetrozine was present at TRR levels of 7.4%. On processing of seeds, 35% of the parent substance was recovered in the oil.

In summary pymetrozine is deposited on the plant surface and more or less quickly adsorbed. Unchanged parent represented 7.4–75% of the TRR in treated parts. In the plant tissue, the active substance is quickly degraded by cleavage, forming nicotinic acid, nicotinamide or trigonelline from the pyridine-moiety. Additional major metabolites found were CGA359009 (rice: 15% TRR), GS23199 including conjugates (potato tuber: 13% TRR; potato foliage: 18% TRR; rice: 17% TRR) and CGA294849 (tomato fruits: 14% TRR).

CGA128632 including its conjugates, which were major metabolites in tomato foliage (23% TRR) and potato foliage (up to 36% TRR) were not identified in the rat.

Environmental fate in soil

The Meeting received information on the fate of pymetrozine under aqueous hydrolysis. In addition, the Meeting received information on the uptake and metabolism of pymetrozine in rotational crops under confined and field conditions.

Hydrolysis in aqueous buffer solutions revealed a moderate to quick decline of the parent under acidic conditions (pH5 or less) while samples at pH 7 and pH 9 were stable (> 90% remaining). The major degradation products identified were CGA300407 for the pyridine-label and CGA215525 for the triazine-label, which are formed by direct cleavage of the parent molecule.

Confined rotational crop studies on mustard greens, radish and wheat were conducted at rates equivalent to a soil application of 0.41 kg ai/ha using either [pyridine-^{14}C]- or [triazine-^{14}C]-pymetrozine. Plantback intervals were 30, 60, 90, 120 and 360 days. Total radioactive residues in edible commodities were in the range of 0.018–0.049 mg eq./kg (wheat grain), 0.025–0.13 mg eq./kg (mustard leaves) and 0.026–0.061 mg eq./kg (radish tubers) for [triazine-6-^{14}C]-pymetrozine and of 0.036–0.11 mg eq./kg (wheat grain), 0.011–0.053 mg eq./kg (mustard leaves) and 0.014–0.042 mg eq./kg (radish tubers) for [pyridine-5-^{14}C]-pymetrozine. In potential feed items TRR levels were 0.047–0.48 mg eq./kg and 0.021–0.23 mg eq./kg in wheat forage and fodder for [triazine-6-^{14}C]- and [pyridine-5-^{14}C]-label, respectively.

In all crop samples unchanged pymetrozine was found in minor amounts not exceeding 10% of the TRR. Highest concentrations were found in wheat forage (0.011 mg/kg) while all other matrices with detected residues gave concentrations between 0.001 mg/kg and 0.01 mg/kg.

In crops planted in soil treated with [pyridine-^{14}C]-pymetrozine nicotinic acid incl. its glycoside (CGA180777, up to 24% TRR or 0.016 mg eq./kg), trigonelline (CGA96956, up to 32% TRR or 0.021 mg eq./kg), nicotinamide (CGA180778, up to 17% TRR, 0.005 mg eq./kg) and CGA-128632-glycoside (up to 11% TRR, 0.011 mg eq./kg) were found as major metabolites.

After application of [triazine-^{14}C]-pymetrozine most of the radioactivity was represented by GS23199 and its glycosides (total up to 39% TRR or 0.056 mg eq./kg in wheat forage) or CGA266591 (up to 34% TRR or 0.027 mg eq./kg).

For longer plantback intervals, unextracted radioactivity increased ranging from 19–78% TRR.

Two additional studies investigating the uptake of total radioactive residues from the soil, either [pyridine-^{14}C]- or [triazine-^{14}C]-pymetrozine were applied to bare soil at rates equivalent to 0.5 kg ai/ha. Lettuce, wheat, sugar beet and maize were cultivated as succeeding crops after plantback intervals of 63, 91 or 307 days.

TRR levels found in the various matrices were low. In edible commodities TRR levels from all plantback intervals were between 0.002–0.01 mg eq./kg. In feed commodities TRR levels ranged up to 0.061 mg eq./kg in wheat straw.

Field rotational crop studies were conducted on four locations in the USA. Pymetrozine was applied to either tomatoes, peppers, cucumbers or lettuce at rates of 4 × 0.1 kg ai/ha (7 day interval). After 30 days the crop was destroyed and wheat, turnips or lettuce were planted as rotational crops. In all samples collected (mature and immature) no pymetrozine or GS23199 above their LOQ of 0.02 mg/kg were found. However, for GS23199 no hydrolysis step was conducted to release conjugates, which posed the main part of total GS23199 identified in confined rotational crop studies.

In summary the Meeting concluded that the transfer of residues into rotational crops is low. Parent pymetrozine is quickly degraded, not resulting in significant residues at harvest.

The metabolite GS23199, mainly present as sugar-conjugate, was the major residue in most samples (up to 39% TRR). Its concentrations ranged up to a maximum of 0.056 mg eq./kg in wheat forage. In edible commodities highest residues were found in mustard leaves amounting 0.008 mg eq./kg. Approximating the maximum seasonal application rate of 0.45 kg ai/ha based on the submitted GAPs and the involved interception of the treated crop, the Meeting concluded that no residues of GS23199 (including its sugar conjugate) above 0.01 mg/kg are expected in edible commodities obtained from rotational crops.

Other potential metabolites formed are either identical to naturally occurring substances (CGA180777 and CGA180778) or also present at levels below 0.01 mg/kg under confined conditions (e.g., CGA266591).

Methods of residue analysis

The Meeting received analytical methods for the analysis of pymetrozine in plant and animal matrices. The basic principle employs extraction by homogenisation with aqueous borate buffer/methanol or n-hexane with acetonitrile/water partitioning for fatty samples. The extracts were cleaned by C18 solid-phase extraction. Residues are determined by liquid chromatography (LC) in combination with tandem mass spectroscopy (MS/MS) or UV (300 nm). The methods submitted are suitable for measuring residues with a LOQ of 0.01 mg/kg (LC-MS/MS) to 0.02 (HPLC-UV).

In addition specialised methods using LC-MS/MS methods for measuring the metabolites CGA300407 (LOQ: 0.005 mg/kg, high water and acidic matrices) and CGA313124 (LOQ: 0.01 mg/kg, animal matrices) were submitted.

The application of multi-residue methods was not tested.

In-trial validation of the analytical methods submitted was achieved at LOQs of 0.001 mg/kg up to 0.05 mg/kg, depending on the matrix.

Stability of residues in stored analytical samples

The Meeting received information on the storage stability of pymetrozine in plant and animal matrices. In addition the storage stability of GS23911 was investigated in plant matrices and the storage stability of CGA313124 in animal matrices.

Plant matrices

In fortified samples, depending on the matrix, parent pymetrozine decomposes rather quickly. In different studies the following intervals were identified, which showed at least 70% of the initial pymetrozine concentration:

Oranges	at least24 months
Peaches	up to 1 month

Tomato, fruits	up to 6 months
Tomato, paste	up to 6 months
Cucumbers	up to 2 months
Melons	at least 24 months
Lettuce	up to 1 month
Potatoes	up to 1 month
Cottonseed	at least 25 months
Cotton oil	at least 24 months
Hops, dry	at least 12 months

The Meeting noted that pymetrozine residues may degrade in stored samples, however the rate differs strongly depending on the specific commodity. No reasons for the observed degradation could be identified. Due to the inconsistency within commodity groups (e.g., like for cucurbits), specific data on the storage stability for each commodity is required.

In addition to the maximum storage intervals listed above, the Meeting noted that pymetrozine residues were stable for a period of up to one month in all fortified samples and decided that supervised field trial data analysed within one month are suitable for an estimation.

One study investigating the storage stability of incurred residues in plant commodities was submitted involving re-analysis for stored samples after 8–13 months. However, since the initial analysis of the samples was performed after 9–14 months, which is longer than the maximum storage interval identified, the data was not considered appropriate to conclude on the overall stability of the residue.

For the metabolite GS23911 no degradation was observed in stored plant matrices within 24 months (cucumber, tomato fruit + paste, cotton seed + oil, hops dry).

Animal matrices

In fortified samples of animal origin, pymetrozine showed a significant degradation after 6 months in muscle and after 12 months in liver. The metabolite CGA313124 was also tested and was stable for up to 3 months in muscle and a maximum of 6 months in liver. In milk, both analytes proved stable for at least 18 months.

Definition of the residue

Livestock animal metabolism studies were conducted on laying hens (10 ppm) and lactating goats (7.5–10 ppm).

Nicotinic acid (CGA180777) and nicotinamide (CGA180778) were identified as major residues (up to 77% TRR) in livestock animals, however due to their natural occurrence (Vitamin B group) they are not suitable as a marker substance for enforcement purposes in animal commodities. Parent pymetrozine was present in all goat tissues, most hen tissues and eggs (for eggs triazine-label only), however only in low amounts up to 11% TRR. In milk no parent pymetrozine was found. Nearly the entire residue was identified as CGA313124 and its phosphate conjugate. The Meeting recognized that pymetrozine is strongly metabolized in livestock animals. However, being the only representative analyte in most commodities, the Meeting concluded that parent pymetrozine is a suitable marker for the purpose of MRL setting in animal tissues and eggs. For milk, the residue for enforcement purposes is defined as CGA313124. Analytical methods are capable of measuring pymetrozine in animal matrices and CGA313124 in milk at LOQs of 0.01 mg/kg each.

For the estimation of the dietary intake nicotinic acid (CGA180777) and nicotinamide (CGA180778) add to natural background levels of the vitamin B group and are not considered relevant. Apart from these analytes, pymetrozine gave highest residues in goat tissues (except kidney) and CGA313124 (incl. its phosphate conjugate) in milk and kidney. CGA313124 was identified in the rat metabolism and is covered by the toxicological reference values for the parent substance. The Meeting concluded that pymetrozine is the relevant residue in mammalian tissues while CGA313124 (incl. its phosphate conjugate) is relevant for milk.

In hens tissues and eggs CGA259168 (up to 45% TRR), I_{A7} (up to 49% TRR) and CGA294849 (up to 11% TRR) were major residues present at concentrations up to 0.079 mg eq./kg at 10 ppm dose. Parent pymetrozine itself was a minor residue in all samples. CGA294849 was identified as a minor metabolite in hens muscle and liver, representing up to 9% of TRR. The Meeting concluded, that parent pymetrozine is a relevant residue for the dietary intake of poultry tissues and eggs.

The significance of the animal metabolites CGA245342, CGA294849, I_{A7} and I_{A17} was assessed with the TTC approach based on exposure levels related to the uses evaluated. Exposure to I_{A17} did not exceed the TTC value for chronic exposure of 0.0025 µg/kg bw per day (EMEA for genotoxic impurities) as well as the single-exposure TTC of 0.2 µg/kg bw. CGA245342 and I_{A7} gave estimated exposure levels below 1.5 µg/kg bw per day (Cramer Class III), respectively. Based on the assessed uses, these metabolites are not considered relevant for the dietary intake.

CGA294849 was also assessed with the TTC approach with the major part of the exposure resulting from plant commodities. CGA294849 has a structural alert for genotoxicity but has not been tested. Since the exposure assessment exceeded the applicable TTC values, no conclusion on the relevance of CGA294849 for dietary intake assessment can be made.

In all samples residue concentrations in fat tissues were in the same order of magnitude as in muscle tissues. The log P_{ow} of pymetrozine is < 0. The Meeting decided that residues of pymetrozine are not fat soluble.

In plants following foliar treatment, pymetrozine was the major residue in plant parts directly contacted, representing 28–89% of the TRR. The major degradations products in all matrices were either trigonelline (CGA96956) present at level between 9–70% of the TRR or nicotinic acid (CGA180777) present up to 26% TRR, depending on the label. The pyridine-cleavage product CGA128632 (including sugar conjugates) was a major metabolite in tomato fruits (11% TRR) and in tomato and potato foliage (up to 26% TRR). The counterpart for the triazine-moiety was identified as GS23199 (including sugar conjugates) representing 11–18% of the TRR in rice straw and potato foliage. The metabolic pattern in rotational crops was comparable to the degradation products identified in primary treated crops.

The Meeting concluded that pymetrozine is present in major amounts in most plant matrices and therefore qualifies as a marker substance for enforcement purposes. The major plant metabolites trigonelline (CGA96956) and nicotinic acid (CGA180777) occur naturally in plants and are unspecific markers for the residue. Analytical methods are capable of measuring pymetrozine in all plant matrices at a LOQ of 0.01 mg/kg.

For dietary intake purposes nicotinic acid (CGA180777) and trigonelline (CGA96956) add insignificantly to natural background levels. The Meeting noted that no metabolism study on leafy crops was submitted. In the foliage of tomatoes and potatoes used as a substitute, the cleavage products CGA128632 (up to 26% TRR) and GS23199 (up to 18% TRR) and their sugar conjugates were major residues. However, CGA128632 was not found in rats. In addition, CGA294849 was found in tomato fruit representing 7.4% TRR after 3 days increasing to 14% TRR after 14 days.

The Meeting also noted that pymetrozine may degrade under acidic food processing condition, resulting in the formation of CGA300407 (up to 42% TRR), based on hydrolysis data for pyridine-labelled active substance. The hydrolysis of triazine-labelled active substance conducted at

pH5 (25 °C and 75 °C), showed CGA215525 as the major degradation product (up to 48% TRR). No data on hydrolysis under simulated processing conditions were submitted for the triazine-label.

Besides parent pymetrozine, which is a major residue in plant commodities and should to be taken into account for dietary intake assessment, the relevance of the plant metabolites GS23199, CGA128632 and CGA294849 as well as of the degradation products formed during processing (CGA215525 and CGA300407) was assessed with the TTC approach.

Based on the exposure levels (IEDI and IESTI) estimated for the uses evaluated, GS23199 (Cramer Class III) and CGA215525 (Cramer Class III) were not considered relevant for dietary intake.

CGA128632 has therapeutic uses as a vasodilator with a minimal therapeutic dose of 1 mg/kg bw. In view of the margin compared to the estimated exposure levels (> 1000 to the IEDI and > 50 to the maximum IESTI), CGA128632 is not considered a relevant metabolite of pymetrozine for dietary intake.

CGA294849 was also assessed with the TTC approach with the major part of the exposure resulting from plant commodities. CGA294849 has a structural alert for genotoxicity but has not been tested. Since the exposure assessment exceeded the applicable TTC values, no conclusion on the relevance of CGA294849 for dietary intake assessment can be made.

The processing degradate CGA300407 does not have a structural alert for genotoxicity but the Meeting was made aware that positive genotoxicity results, in vitro and in vivo, exist for this compound. No conclusion on the relevance of CGA300407 can be made.

If future uses for pymetrozine result in changes of the dietary intake, reconsideration on the relevance of metabolites in plant and animal matrices and after processing may become necessary.

Definition of the residue for compliance with MRL for plant commodities, mammalian tissues, poultry tissues and eggs: *pymetrozine*

Definition of the residue for compliance with MRL for milk: *CGA313124 (4,5-dihydro-6-hydroxymethyl-4-[(3-pyridinyl-methylene)amino]-1,2,4-triazine-3(2H)-one)*

Definition of the residue for dietary intake in plant and animal commodities: *a conclusion could not be reached*

The residue is not fat-soluble.

Results of supervised residue trials on crops

The Meeting received supervised trial data for applications of pymetrozine on various fruit and vegetables crops as well as for oilseeds and rice conducted in China, Europe and the USA.

The Meeting recognized that pymetrozine may degrade under freezer storage conditions. All supervised field trials exceeding the maximum storage interval identified for the specific commodities are not taken into account for the evaluation of GAPs and the resulting residues. In addition residues of pymetrozine were considered stable in all plant commodities for maximum storage period of one month.

Citrus fruits

Pymetrozine is registered in Portugal for the use on citrus fruit at rates of 1 × 0.01 kg ai/hL with a PHI of 21 days. Supervised field trials conducted in the Europe according to this GAP were submitted.

In lemons (whole fruits) residues of pymetrozine were (n=4): 0.02, 0.02, 0.03, 0.07 mg/kg.

In mandarins (whole fruits) residues of pymetrozine were (n=4): < 0.02, 0.02, 0.03, 0.03 mg/kg.

In oranges (whole fruits) residues of pymetrozine were (n=13): 0.006, 0.007, 0.01, 0.012, < 0.02, 0.02(4), 0.03, 0.04, 0.05 and 0.06 mg/kg.

The Meeting noted that pymetrozine is registered in Portugal for the whole citrus group. Supervised field trials on oranges, lemons and mandarins indicated no significant difference in the datasets (Kruskal-Wallis-Testing). Therefore the Meeting decided to extend its estimations on the whole group of citrus fruits based on the combined dataset from all three commodities:

Pymetrozine residues in citrus fruits (n=21): 0.006, 0.007, 0.01, 0.012, < 0.02, < 0.02, 0.02(7), 0.03(4), 0.04, 0.05, 0.06 and 0.07 mg/kg.

In the pulp (flesh) corresponding residues were (n=21): < 0.005(4) and < 0.02(17) mg/kg.

The Meeting estimated a maximum residues level of 0.15 mg/kg for pymetrozine in citrus fruit and a median and highest residue of 0.02 mg/kg in citrus pulp.

Pome fruit

Pymetrozine is registered in Italy for the use on apples and pears at a rate of 1 × 0.25 kg ai/ha with a PHI of 14 days. Supervised field trials conducted in Italy according to this GAP were submitted.

However, the Meeting noted that for pome fruit no data on the storage stability were provided. In view of the general degradation of pymetrozine in stored commodities, specific data on the storage stability in pome fruits is required to assess the validity of the supervised field trials.

Apricot

Pymetrozine is registered in Belgium for use on apricots at the rate of 2 × 0.1 kg ai/ha with a PHI of 21 days. Supervised field trials were conducted in Europe at rates of 3 × 0.25 kg ai/ha.

The supervised field trials submitted for apricots were all conducted as decline studies. Since the active substance almost completely degraded within the 21 days investigated, the Meeting concluded that the additional treatment in comparison to the GAP from Belgium has no influence on the residue concentrations at harvest, allowing the use of the proportionality approach to adjust for the higher application rates involved.

Pymetrozine residues in apricots treated with 3 × 0.25 kg ai/ha were (n=4): < 0.01(3) and 0.01 mg/kg.

Under consideration of a proportionality factor of 0.4 (0.1 kg ai/ha divided by 0.25 kg ai/ha), scaled residues were (n=4): 0.004 and < 0.01(3) mg/kg.

Based on scaled residues from Europe, the Meeting estimated a maximum residues level of 0.01 mg/kg and a median and highest residue of 0.01 mg/kg for pymetrozine in apricots.

Peach and nectarines

Pymetrozine is registered in Spain for the use on peach and nectarines at the rate of 2 × 0.25 kg ai/ha with a PHI of 14 days. Supervised field trials were conducted in Europe at rates of 3 × 0.25 kg ai/ha.

The supervised field trials submitted for peaches were all conducted with one additional application compared to the GAP. However, taking into account low residues in samples analysed directly before the final treatment and the results from decline studies on peaches, the Meeting concluded that the additional treatment does not add significantly to the residue concentrations at harvest.

Pymetrozine residues in peach (n=6): < 0.01(4), 0.04, 0.04 mg/kg.

Based on the dataset on peach the Meeting estimated a maximum residues level of 0.07 mg/kg, a median residue of 0.01 mg/kg and a highest residue of 0.04 mg/kg for pymetrozine in peach. The Meeting decided to extrapolate the estimations also to nectarines.

Strawberries

Pymetrozine is registered in Belgium for the use on field and protected strawberries at the rate of 3 × 0.2 kg ai/ha with a PHI of 3 days. Supervised field trials conducted in United Kingdom matching the GAP were submitted.

Pymetrozine residues in field strawberries were (n=2): 0.02 and 0.06 mg/kg.

Pymetrozine residues in protected strawberries were (n=2): 0.12 mg/kg.

The Meeting concluded that the data submitted for the use of pymetrozine on strawberries was insufficient for a maximum residue level estimation.

Broccoli

Pymetrozine is registered in Belgium for the use on broccoli at rates of 3 × 0.2 kg ai/ha with a PHI of 14 days. Supervised field trials conducted in Switzerland and United Kingdom matching the GAP were submitted.

However, the Meeting noted that for broccoli no data on the storage stability were provided. In view of the general degradation of pymetrozine in stored commodities, specific data on the storage stability in broccoli is required to assess the validity of the supervised field trials.

Cauliflower

Pymetrozine is registered in Belgium for the use on cauliflower at rates of 3 × 0.2 kg ai/ha with a PHI of 14 days. Supervised field trials conducted in France and Switzerland matching the GAP were submitted, however all samples were cut into segments at harvest before storage.

In 2013 the JMPR pointed out that cutting of large commodities in the field is against the recommended Codex sampling procedure and may cause problems due to an enhanced degradation of the residue. Testing strategies to investigate the stability of the residue were outlined in the 2013 JMPR Report. However, for pymetrozine such data was not submitted. In view of the short interval of the storage stability in various matrices, the possible effect of cutting cannot be assessed.

The Meeting decided that the data on cauliflower is invalid for recommendations of maximum residue levels for pymetrozine.

Head cabbage

Pymetrozine is registered in Germany for the use on head cabbage at rates of 3 × 0.2 kg ai/ha with a PHI of 7 days. Supervised field trials conducted in Europe matching the GAP were submitted. However some of the samples were cut into segments at harvest before storage, making them invalid for the assessment (see cauliflower).

In Portugal the use of pymetrozine is registered on head cabbage at rates of 3 × 0.2 kg ai/ha with a PHI of 14 days. Supervised field trials conducted in Europe matching the GAP were submitted.

However, the Meeting noted that for cabbages no data on the storage stability were provided. In view of the general degradation of pymetrozine in stored commodities, specific data on the storage stability in head cabbage is required to assess the validity of the supervised field trials.

Cucumbers

Pymetrozine is registered in Greece for the use on protected cucumbers at rates of 2 × 0.45 kg ai/ha with a PHI of 3 days. Residue data from Europe under protected conditions matching GAP application rates were submitted.

However, the supervised field trials submitted for cucumbers were all conducted with one additional application compared to the GAP. Taking into account the low residues in samples analysed directly before the final treatment and the results from decline studies on cucumbers, the Meeting concluded that the additional treatment does not add significantly to the residue concentrations at harvest.

Pymetrozine residues in cucumbers (n=8): 0.045, 0.07, 0.08, 0.083, 0.088, 0.09, 0.11 and 0.21 mg/kg.

Four additional trials on cucumbers matching the GAP from Greece were reported, but the samples were stored 3-10 months before analysis, which is longer than the maximum storage interval of 2 month for pymetrozine in cucumbers.

The Meeting estimated a maximum residues level of 0.3 mg/kg, a median residue of 0.0855 mg/kg and a highest residue of 0.21 mg/kg for pymetrozine in cucumbers.

Melons

Pymetrozine is registered in Portugal for the use on protected melons at rates of 3 × 0.3 kg ai/ha with a PHI of 3 days. Supervised field trials conducted in Europe matching the GAP were submitted. However some of the samples were cut into segments at harvest before storage, making them invalid for the assessment (see cauliflower). Residues in the remaining trials were:

Pymetrozine residues in whole melon fruits (n=2): 0.045 and 0.16 mg/kg.

The Meeting concluded that the data submitted for the use of pymetrozine on melons was insufficient for a maximum residue level estimation.

Peppers, sweet

Pymetrozine is registered in Czech Republic for the use on protected sweet peppers at rates of 3 × 0.36 kg ai/ha with a PHI of 3 days. Supervised field trials conducted in Europe under protected conditions matching the GAP were submitted.

Pymetrozine residues in protected sweet peppers (n=8): 0.16, 0.43, 0.43, 0.54, 0.64, 0.83, 1.1 and 1.4 mg/kg.

The Meeting estimated a maximum residues level of 3 mg/kg, a median residue of 0.59 mg/kg and an highest residue of 1.4 mg/kg for pymetrozine in pepper, sweet.

Tomatoes

Pymetrozine is registered in The Netherlands for the use on protected tomatoes at rates of 3 × 0.45 kg ai/ha with a PHI of 1 day. Supervised field trials conducted in Europe under protected conditions matching the GAP were submitted.

Pymetrozine residues in protected tomato fruits (n=8): 0.08, 0.14, 0.18, 0.27, 0.3, 0.33, 0.39 and 0.77 mg/kg.

The Meeting estimated a maximum residues level of 1.5 mg/kg, a median residue of 0.285 mg/kg and a highest residue of 0.77 mg/kg for pymetrozine in tomatoes.

Leafy vegetables, except brassica leafy vegetables

Pymetrozine is registered in the USA for the use on leafy vegetables at rates of 2 × 0.1 kg ai/ha with a PHI of 7 days. Supervised field trials conducted in the USA on head lettuce, leaf lettuce and spinach matching the GAP were submitted. However, most of the trials were stored for more than 1 months, which was identified as the maximum storage interval without a significant degradation of the residues. The results from trials analysed within this interval were:

Pymetrozine residues in head lettuce (n=2): < 0.02 and 0.1 mg/kg.

The Meeting concluded that the data submitted for the use of pymetrozine on leafy vegetables, except brassica leafy vegetables, was insufficient for a maximum residue level estimation.

Potatoes

Pymetrozine is registered in the United Kingdom for the use on potatoes at rates of 2 × 0.15 kg ai/ha with a PHI of 7 days. Supervised field trials conducted in Northern Europe at a higher rate of 2 × 0.2 kg ai/ha were submitted.

Pymetrozine residues in potato tubers (n=4): < 0.01(4) mg/kg.

The Meeting concluded that the data submitted for the use of pymetrozine on potatoes was insufficient for a maximum residue level estimation.

Asparagus

Pymetrozine is registered in the USA for the use on asparagus in vegetative state at rates of 6 × 0.1 kg ai/ha to the mature ferns with a PHI of 170 days. Supervised field trials conducted in the USA on asparagus treated with rates of 3 × 0.19 kg ai/ha were submitted involving PHIs of 172-267 days. The results were:

Pymetrozine residues in asparagus (n=6): < 0.02(6) mg/kg.

Although samples of asparagus were stored longer than the maximum storage interval of 1 month for this commodity, the Meeting concluded to make estimations for the commodity. Taking into account the insignificant amounts of pymetrozine found in samples from confined rotational crop studies and the long interval between treatment and harvest without a direct application to the harvested commodity, the Meeting estimated a maximum residues level of 0.02* mg/kg and a median and highest residue of 0 mg/kg for pymetrozine in asparagus.

Celery

Pymetrozine is registered in the USA for the use on celery at rates of 2 × 0.1 kg ai/ha with a PHI of 7 days. Supervised field trials conducted in the USA matching the GAP were submitted.

However, the Meeting noted that for celery no data on the storage stability were provided. In view of the general degradation of pymetrozine in stored commodities, specific data on the storage stability in celery is required to assess the validity of the supervised field trials.

Artichoke, globe

Pymetrozine is registered in France for the use on globe artichokes at rates of 2 × 0.2 kg ai/ha with a PHI of 14 days. Supervised field trials conducted in France matching the GAP were submitted.

Pymetrozine residues in artichokes (n=3): < 0.02(3) mg/kg.

The Meeting concluded that the data submitted for the use of pymetrozine on artichoke is insufficient for a maximum residue level estimation.

Rice

Pymetrozine is registered in China for the use on rice at rates of 2 × 0.15 kg ai/ha with a PHI of 14 days. Supervised field trials conducted in China matching the GAP were submitted.

However, in the supervised field trials no data on the maximum storage interval between sampling and analysis were reported. In addition, storage stability data for cereal commodities was not provided, denying an assessment on the validity of the trials.

The Meeting concluded that the data submitted for the use of pymetrozine on rice is insufficient for a maximum residue level estimation.

Pecan

Pymetrozine is registered in the USA for the use on pecans at rates of 2 × 0.14 kg ai/ha with a PHI of 14 days. Supervised field trials conducted in the USA matching the GAP were submitted.

However, the Meeting noted that for pecan no data on the storage stability were provided. In view of the general degradation of pymetrozine in stored commodities, specific data on the storage stability in pecan is required to assess the validity of the supervised field trials.

Chestnut, hazelnut and walnut

Pymetrozine is registered in France for the use on chestnut, hazelnut and walnut at rates of 2 × 0.1 kg ai/ha with a PHI of 14 days. Supervised field trials on walnuts conducted in France matching the GAP were submitted.

However, the Meeting noted that for chestnuts, hazelnuts or walnuts no data on the storage stability were provided. In view of the general degradation of pymetrozine in stored commodities, specific data on the storage stability for respective commodities is required to assess the validity of the supervised field trials.

Rape

Pymetrozine is registered in Belgium, France and Germany for the use on oilseed rape rates of 1 × 0.075 kg ai/ha at BBCH 59 (first petals visible, flower buds still closed). The PHI is covered by the growth stage. Supervised field trials conducted in Northern and Southern Europe at slightly exaggerated rates of 1 × 0.1 kg ai/ha were submitted.

However, the Meeting noted that for rape seeds no data on the storage stability were provided. In view of the general degradation of pymetrozine in stored commodities, specific data on the storage stability in rape seeds is required to assess the validity of the supervised field trials.

Cotton

Pymetrozine is registered in Greece for the use on cotton rates of 2 × 0.2 kg ai/ha with a PHI of 35 days. Supervised field trials conducted in Southern Europe matching the registered application rate but with one additional treatment were submitted.

Pymetrozine residues in delinted seeds (n=6): < 0.<u>02</u>(6) mg/kg.

The Meeting estimated a maximum residues level of 0.02 mg/kg and a median residue of 0.02 mg/kg for pymetrozine in cotton seeds.

Animal feeds

Rice straw

Pymetrozine is registered in China for the use on rice at rates of 2 × 0.15 kg ai/ha with a PHI of 14 days. Supervised field trials conducted in China matching the GAP were submitted.

However, in the supervised field trials no data on the maximum storage interval between sampling and analysis were reported. In addition, storage stability data for cereal commodities was not provided, denying an assessment on the validity of the trials.

The Meeting concluded that the data submitted for the use of pymetrozine on rice straw is insufficient for an estimation.

Cotton seed hulls

Pymetrozine is registered in Greece for the use on cotton rates of 2 × 0.2 kg ai/ha with a PHI of 35 days. Supervised field trials conducted in Southern Europe matching the registered application rate but with one additional treatment were submitted.

Pymetrozine residues in cotton seed hulls (n=6): < 0.02(4), 0.02 and 0.02 mg/kg.

The Meeting estimated a maximum residues level of 0.04 mg/kg and a median residue of 0.02 mg/kg for pymetrozine in cotton seed hulls.

Fate of residues during processing

The Meeting received information on the hydrolysis of radio-labelled pymetrozine as well as processing studies using unlabelled material in tomatoes and sweet peppers.

In a hydrolysis study using [pyridine-^{14}C]-pymetrozine typical processing conditions were simulated (pH 4,5 and 6 with 90°C, 100°C and 120°C for 20, 60 and 20 minutes). While no degradation of the residue was observed under pH6 (120°C for 20 minutes), a significant loss of parent substance occurred at pH 4 and pH5. The cleavage product CGA300407 was identified as the primary degradation product present at 33% of the TRR at pH4 and at 42% of the TRR at pH5.

No hydrolysis study simulating processing conditions was conducted using [triazine-^{14}C]-pymetrozine. However, the hydrolysis in buffer solutions for the environmental fate was investigated showing an identical degradation of the active substance. The counterpart to CGA300407 was identified as CGA215525, which is expected to pose the remaining part of the residue in processed products.

The fate of pymetrozine residues has been examined simulating household and commercial processing of tomatoes and sweet peppers. Estimated processing factors for the commodities considered at this Meeting are summarised below.

Raw commodity	Processed commodity	Pymetrozine		
		Individual processing factors	Mean or best estimate processing factor	Median residue in mg/kg
Tomato (median: 0.285 mg/kg)	Juice, raw	0.05	0.05	0.014
	Puree	< 0.03(4), < 0.4	< 0.03	0.008
	Paste	< 0.04, < 0.4	< 0.22	0.063
	Canned/preserve	< 0.03(4), 0.07	0.03	0.008
	pomace, wet	0.08, < 0.4	0.24	0.068
Sweet pepper median: 0.59 mg/kg)	Cooked fruit	< 0.02(3)	< 0.02	0.012

The Meeting considered that maximum residue levels for processed commodities are covered by their raw agricultural commodities.

Residues in animal commodities

Farm animal feeding studies

The Meeting received feeding studies involving pymetrozine on lactating cows.

Three groups of lactating cows were dosed daily at levels of 1, 3 and 10 ppm in the diet for 28 consecutive days. Milk was collected throughout the whole study and tissues were collected on day 29 within 24 hrs after the last dose.

In milk and tissues of all dose groups no detectable residues of pymetrozine above the LOQ of 0.01 mg/kg were found.

The metabolite CGA313124 was also not found in tissues. In milk, CGA313124 was not detected for the 1ppm dose group but was present at levels of 0.02 mg/kg for the 3 ppm group and of 0.05 mg/kg for the 10 ppm group.

The Meeting noted that tissue samples were stored up to 10-13 months, which is longer than the maximum storage interval identified for pymetrozine in muscle. However, taking into account that based on goat metabolism studies liver is expected to be the tissue with highest residue concentrations, which was analysed for the parent residue within the interval supported by storage stability data, the general result of pymetrozine residues being < 0.01 mg/kg in cow tissues is accepted.

Estimated maximum and mean dietary burdens of livestock and animal commodities maximum residue levels

Dietary burden calculations for beef cattle, dairy cattle, broilers and laying poultry are presented in Annex X. The calculations were made according to the livestock diets from US-Canada, EU, Australia and Japan in the OECD Table (Annex 6 of the 2006 JMPR Report).

	Livestock dietary burden, pymetrozine, ppm of dry matter diet							
	US-Canada		EU		Australia		Japan	
	max.	mean	max.	mean	max.	mean	max.	mean
Beef cattle	< 0.01	< 0.01	none	none	0.03	0.03	none	none
Dairy cattle	< 0.01	< 0.01	none	none	0.03[a]	0.03[b]	none	none
Poultry - broiler	none	none	none	none	none	none	none	none
Poultry - layer	none	none	none	none	none	none	none	none

[a] Highest maximum beef or dairy cattle burden suitable for MRL estimates for mammalian meat and milk

[b] Highest mean beef or dairy cattle burden suitable for median estimates for mammalian meat and milk

none no relevant feed items

Animal commodity maximum residues levels

For beef and dairy cattle maximum and mean dietary burdens of 0.03 ppm were estimated, respectively. In farm animal feeding studies on lactating cows no detectable residues of pymetrozine in tissues were found for all dose groups up to 10 ppm.

The Meeting estimated median and highest residue values of 0 for mammalian meat, edible offal and fat and corresponding maximum residue levels of 0.01* mg/kg.

For milk, CGA313124 was not detected in the milk samples for the 1 ppm group. Under consideration of the maximum and mean dietary burden for dairy cattle being 33 times lower that this dose level, the Meeting estimated a maximum residue level of 0.01* mg/kg and a median residue of 0 mg/kg, respectively for milks.

For poultry no relevant feed items were identified. The Meeting estimated median and highest residue values of 0 mg/kg for poultry meat, edible offal of and fat as well as for eggs. The Meeting also estimated maximum residue levels of 0.01* mg/kg for poultry meat, edible offal of and fat as well as for eggs.

RECOMMENDATIONS

Definition of the residue for compliance with MRL for plant commodities, mammalian tissues, poultry tissues and eggs: *pymetrozine*

Definition of the residue for compliance with MRL for milk: *CGA313124 (4,5-dihydro-6-hydroxymethyl-4-[(3-pyridinyl-methylene)amino]-1,2,4-triazine-3(2H)-one)*

Definition of the residue for dietary intake in plant and animal commodities: *a conclusion could not be reached*

The residue is not fat-soluble.

FURTHER WORK OR INFORMATION

- storage stability data on more individual commodities
- supervised field trials analysed within the maximum storage periods
- stability data for pymetrozine during homogenization of field samples
- field rotational crop studies including analysis of conjugates
- applicability of multi-residue analytical methods
- a hydrolysis study simulating industrial processing using [6-triazine-^{14}C]-pymetrozine
- processing data including analysis of CGA300407 and CGA215525

DIETARY RISK ASSESSMENT

Because the Meeting was unable to conclude on the toxicological relevance of the metabolites CGA294849 and CGA300407, the Meeting could not reach a conclusion on a residue definition for the dietary intake.

As a result, long- and short-term dietary intake assessments could not be conducted.

5.27 PYRACLOSTROBIN (210)

RESIDUE AND ANALYTICAL ASPECTS

Pyraclostrobin was first evaluated for toxicology by the JMPR in 2003 where an ADI of 0–0.03 mg/kg bw per day and an ARfD of 0.05 mg/kg bw per day were established. The 2004 JMPR evaluated the residue behaviour of the fungicide and concluded that the residue definition for both, plant and animal commodities was parent pyraclostrobin for compliance with MRL values as well as for dietary risk assessments. The compound was re-evaluated for residues several times by the JMPR since 2006 and was listed by the Forty-fifth Session of the CCPR (2013) for the review of an additional MRL for apricot.

The 2011 JMPR withdraw the formerly group MRL recommendation of 1 mg/kg for stone fruits and estimated different maximum residue levels for the single commodities cherries, plums (including prunes), peach and nectarine but did no recommendation for apricot. The 2014 JMPR received GAP information and residue data of pyraclostrobin in apricot.

Results of supervised residue trials in crops

Stone fruits

The maximum GAP for the use of pyraclostrobin in stone fruits was from Canada and the USA, consisting of 5×0.13 kg ai/ha and a PHI of 0 days. Labels for alternative use patterns of pyraclostrobin in France and Italy on apricots, plums, peach and nectarine were submitted with application of 3×0.04–0.05 kg ai/ha and a PHI of 3 days.

The 2011 JMPR estimated for pyraclostrobin residues different maximum residue levels, STMRs and HRs for cherries, plums, peach and nectarine. The 2011 Meeting noted that the estimations for peach and nectarine were based on an alternative GAP (France) as the evaluation based on the maximum GAP of the USA exceeded the ARfD. The residue data on which the estimations were based are summarized as follows:

	2011 Estimation, mg/kg				Region, application
Crop	MRL	STMR	HR	Residue data, mg/kg	kg ai/ha, PHI
Cherries	3	0.51	1.57	0.03, 0.27, 0.38, 0.42, 0.47, 0.5, 0.51, 0.56, 0.63, 0.82, 1.06, 1.08, 1.57	USA, 5×0.13, 0 days
Plums	0.8	0.09	0.40	0.02, 0.02, 0.04, 0.05, 0.06, 0.07, 0.09, 0.09, 0.12, 0.19, 0.22, 0.34, 0.38, 0.40, 0.40	USA, 5 × 0.13, 0 days
Peach, nectarine	0.3	0.07	0.13	< 0.02, 0.03, 0.04, 0.05, 0.07, 0.07, 0.08, 0.11, 0.12, 0.13	South-EU, 3×0.04–0.05, 3 days

The current Meeting received information on two field trials for pyraclostrobin uses on apricots in 2013 in Italy and Spain. Three foliar sprays at rates of 0.05 kg ai/ha were made matching the French and Italian GAP. The residues were 0.08 (2) mg/kg in fruits at a 3-days PHI.

The Meeting noted that the two residue values on apricots of 0.08 mg/kg are in the same order of magnitude as the residues in peaches matching the alternative European GAP (3×0.04–0.05, PHI 3 days).

The Meeting concluded that the MRL of 0.3 mg/kg, the STMR of 0.51 mg/kg and the HR of 1.57 mg/kg established for cherries should be extrapolated to the whole Stone fruits subgroup 003A Cherries (includes all commodities in this subgroup). The meeting withdrew its previous recommendation of 0.3 mg/kg for the single commodity cherries.

The Meeting decided that the maximum residue level of 0.8 mg/kg, the STMR of 0.09 mg/kg and the HR of 0.40 mg/kg established for plums should be extrapolated to the whole stone fruit subgroup 003B for Plums. The meeting withdrew its previous recommendation of 0.8 mg/kg for the single commodity Plums (including prunes).

The Meeting decided that each maximum residue level of 0.3 mg/kg, the STMR of 0.07 mg/kg and the HR of 0.13 mg/kg established for peaches and nectarines should be extrapolated to the whole stone fruit subgroup 003 C for Peaches (including nectarines and apricots). The meeting withdrew its previous recommendation of 0.3 mg/kg for the individual commodities peaches and nectarines.

RECOMMENDATIONS

On the basis of the data from supervised trials the Meeting concluded that the residue levels listed below are suitable for establishing maximum residue limits and for dietary risk assessment.

Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities: Pyraclostrobin.

The residue is not fat-soluble.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Daily Intakes (IEDIs) of pyraclostrobin were calculated for the 17 GEMS/Food cluster diets using STMRs and STMR-Ps estimated by the JMPR in 2004, 2006, 2011, 2012 and 2014. The results are shown in Annex 3 to the 2014 Report.

The ADI is 0–0.03 mg/kg bw and the calculated IEDIs were 1–6% of the maximum ADI. The Meeting concluded that the long-term intake of residues of pyraclostrobin resulting from the uses considered by the JMPR is unlikely to present a public health concern.

Short-term intake

The International Estimated Short Term Intake (IESTI) for pyraclostrobin was calculated by the current Meeting for apricot. The results are shown in Annex 4 to the 2014 Report.

For the commodities considered by the 2014 JMPR, the IESTI represented 0–30% of the ARfD for the general population and 0–40% for children. The Meeting concluded that the short-term intake of residues of pyraclostrobin, when used in ways that have been considered by the JMPR, is unlikely to present a public health concern.

5.28 SEDAXANE (259)

RESIDUE AND ANALYTICAL ASPECTS

Sedaxane was first evaluated by the JMPR in 2012. The 2012 Meeting concluded that the residue definition for MRL compliance and estimation of dietary intake is sedaxane. An ADI of 0–0.1 mg/kg bw and an ARfD of 0.3 mg/kg bw were established. The residue was determined to be fat-soluble. The 2012 Meeting noted that none of the uses resulted in residues in human foods and that those uses are unlikely to present a public health concern.

The Forty-fifth Session of the CCPR listed sedaxane for the evaluation of additional MRLs. The 2014 Meeting received information on GAP and supervised residue trials reflecting the use of sedaxane as a seed treatment on corn/maize, pulses, potatoes, and sorghum. In addition to evaluating those crops, the Meeting was asked to consider use on rice, without residue data, on the basis of residue data supplied to the 2012 and 2014 Meetings for other grains.

Methods of analysis

Acceptable analytical methods were developed and validated for determination of sedaxane and its metabolites in plant and animal matrices. The methods were evaluated by the 2012 Meeting. The reported LOQ for the sedaxane *cis* and *trans* isomers, each, was 0.005 mg/kg, while the LOQ for all metabolites was 0.01 mg/kg in all matrices (plant and animal).

Results of supervised residue trials on crops

Supervised residue trials submitted for evaluation were as seed treatments and were conducted in Canada and/or the USA. All of the trials submitted to the 2014 Meeting are supported by storage stability data evaluated by the 2012 Meeting. Residue values listed below reflect the average for each field trial, unless otherwise noted.

Sweet corn

The critical GAP for sweet corn is from the USA at 40 g ai/100 kg seed. In 13 trials, conducted at rates ranging from 29.7 to 51.2 g ai/100 kg seed, residues of sedaxane were < 0.01 mg/kg in all samples.

Based on the results of previously evaluated metabolism data from wheat (2012 Meeting) and on the results of the submitted residue trials, the Meeting agreed that no sedaxane residues are expected in sweet corn (corn-on-the-cob).

The Meeting estimated a maximum residue level of 0.01* mg/kg for sedaxane on sweet corn (corn-on-the-cob), an HR of 0.01 mg/kg and a STMR of 0 mg/kg.

Pulses (Beans, dry and peas, dry)

The critical GAP for beans, dry and peas, dry is from Canada and the USA for use as a seed treatment at a rate of 5 g ai/100 kg seed.

Eleven trials were conducted on dry bean matching GAP in Canada (5) and the USA (6), with an additional two trials in the USA conducted at approximately a 2.5-fold exaggerated rate.

Ten trials were conducted on dry pea matching GAP in Canada (8) and the USA (2).

Sedaxane residues in harvested dry beans and dry peas from all trials (n=21), including the exaggerate-rate trials, were: < 0.01 mg/kg. Based on the results of previously evaluated metabolism data from soya beans (2012 Meeting) and on the results of the submitted residue trials, the Meeting agreed that no sedaxane residues are expected in pulses.

The Meeting estimated a maximum residue level of 0.01* mg/kg for sedaxane on pulses and an STMR of 0 mg/kg. The Meeting recommended that the individual MRL for soya bean, dry be withdrawn.

Potato

The critical GAP for potato is from Canada, as a seed-piece treatment, at a rate of 2.5 g ai/100 kg seed. Twenty-nine trials were conducted matching GAP in Canada (13) and the USA (16). Three additional trials were conducted in the USA; one at approximately a 0.4× rate and two at approximately a 2× exaggerated rate.

Sedaxane residues in harvested tubers from all at-GAP trials (n=29) were: $\underline{< 0.01}$ (28) and 0.018 mg/kg.

The Meeting estimated a maximum residue level of 0.02 mg/kg for sedaxane on potato, an STMR of 0.01 mg/kg, and an HR of 0.02 mg/kg (from a single sample).

Cereal Grains

Maize and popcorn

The critical GAPs are from Chile for maize (50 g ai/100 kg seed) and from the USA for popcorn (40 g ai/100 kg seed). No trials from Chile were provided; however, data from 15 trials with rates ranging from 40–51.2 g ai/100 kg seed were available from the USA depicting residues of sedaxane in maize. In addition, there are two trials conducted at an exaggerated rate of 120 g ai/100 kg seed.

Sedaxane residues in maize from all trials (n=15) were: < 0.01 mg/kg.

Sorghum

The critical GAP for sorghum is from Canada and the USA as a seed treatment at a rate of 5 g ai/100 kg seed. Twelve trials were conducted at an 8-fold exaggerated rate (ca. 40 g ai/100 kg seed) in the USA, of which ten were determined to be independent.

Sedaxane residues in sorghum grain from all trials (n=10) were: < 0.01 mg/kg.

The Meeting noted that while there are no GAP registrations for cereal grains as a group, there are GAPs around the world with GAPs covering the major cereal grain commodities. Based on the results of previously evaluated metabolism data from wheat (2012 Meeting) and on the results of the submitted residue trials for maize and sorghum, the Meeting agreed that no sedaxane residues are expected in cereal grains.

The Meeting estimated a maximum residue level of 0.01* mg/kg for sedaxane on cereal grains and an STMR of 0 mg/kg, and recommends that the individual MRLs for barley, oats, rye, triticale, and wheat be withdrawn.

Legume animal feeds

The critical GAP is for beans, peas, and lentils from Canada and/or the USA is as a seed treatment at a rate of 5 g ai/100 kg seed. Fifteen trials were conducted matching GAP in Canada and the USA from which forage and/or hay were harvested. An additional trial was conducted in the USA at approximately a 2.5-fold exaggerated rate.

Sedaxane residues in bean and pea forage (n=5) and hay (n=16) from all trials, including the exaggerate-rate trial, were: < 0.01 mg/kg.

The Meeting estimated a maximum residue level of 0.01* mg/kg and a median residue of 0 mg/kg for sedaxane in bean fodder and pea hay or pea fodder (dry).

The Meeting estimated a highest residue of 0.01 mg/kg and a median residue of 0 mg/kg for sedaxane in bean fodder and pea vines.

Straw, fodder, and forage of cereal grains

The critical GAP for maize is from Chile as a seed treatment at a rate of 50 g ai/100 kg seed. Nineteen trials (15 independent) were conducted at GAP in Canada and the USA from which fodder (stover) and/or forage were harvested.

Sedaxane residues in maize fodder (stover; n=15) and forage (n=15) were: < 0.01 mg/kg.

The critical GAP for sorghum is from the USA and Canada as a seed treatment at a rate of 5 g ai/100 kg seed. Twelve trials were conducted at an 8-fold exaggerated rate (ca. 40 g ai/100 kg seed) in the USA, of which ten were determined to be independent.

Sedaxane residues in sorghum forage and stover (n=10) were: < 0.01 mg/kg.

The 2014 Meeting estimates for sorghum forage (dry), a highest residue of 0.01 mg/kg, and a median residue of 0 mg/kg.

The 2012 Meeting estimated residues of sedaxane in barley, oats, rye, triticale, and wheat straw and fodder, on an as-received basis at 0.075 mg/kg (HR) and 0.01 mg/kg (STMR). In estimating those residues, the 2012 meeting noted that these commodities are not always readily distinguishable in trade and the preference for having a common MRL.

Based on the rationale of the 2012 Meeting and on the results from the maize and sorghum residue trials, the 2014 Meeting agreed to estimate residues of sedaxane in straw, fodder of cereal grains and grasses (including buckwheat fodder) (straws and fodders, dry at a maximum residue level of 0.1 mg/kg.

The Meeting estimates a highest residue of 0.075 mg/kg, and a median of 0.01 mg/kg (as received).

The Meeting withdraws its previous recommendations for straw and fodder (dry) of barley, oat, rye, triticale, and wheat.

Fate of residue during food processing

Residues of sedaxane are stable to hydrolysis (2012 JMPR).

The Meeting received processing studies for corn and potato. In the corn study, residues of sedaxane were < 0.01 mg/kg in all commodities.

Raw agricultural commodity (RAC)	STMR, mg/kg	Processed commodity	Processing factor	STMR-P, mg/kg
Potato tuber	0.01	Flakes/granules	0.83	0.0083
		Chips	0.57	0.0057
		Wet peel	4.27	0.0427

Residues in animal commodities

The 2014 Meeting evaluated sedaxane residues in animal feed items from pulses, cereal grains (corn, rice, and sorghum), and potato in addition to the feed items evaluated by the 2012 Meeting (cereal grains) as listed in the OECD feeding table.

Estimated maximum and mean dietary burdens of livestock

Estimated dietary burdens for Australia, the EU, Japan, and the US/Canada are summarized below. The livestock diets are summarized in Annex 6 to the 2014 Report.

Livestock Dietary Burdens (ppm of dry matter diet) for Sedaxane.

	Australia		EU		Japan		US/Canada	
Livestock	Max	Mean	Max	Mean	Max	Mean	Max	Mean
Cattle (beef)	0.106	0.057	0.199	0.169	0.006		0.150	0.126
Cattle (dairy)	0.090	0.039	0.168	0.136	0.014		0.080	0.054
Poultry (broiler)			0.010	0.008				
Poultry (layer)			0.023	0.012				

For all livestock, the sedaxane burdens based on the EU animal diets (bold values in the table) reflect the highest burdens for both MRL estimation (maximum diet) and STMR estimation (mean diet).

Animal commodities residue level estimation

In a cattle feeding study evaluated at the 2012 Meeting, residues in all commodities were < 0.01 mg/kg at all dose levels (0.11–2.2 ppm). The 2012 Meeting estimated a maximum residue level of 0.01* mg/kg and STMR and HR values of 0 mg/kg for mammalian commodities.

The 2014 Meeting confirms the previous recommendations.

In a poultry metabolism study evaluated by the 2012 JMPR Meting, laying hens were dosed at a rate equivalent to 20 ppm (dry matter basis) in their diet. Sedaxane was < 0.01 mg/kg in all tissues at that dose level. Based on the results of that study, the 2012 Meeting estimated a maximum residue level of 0.01* mg/kg and STMR and HR values of 0 mg/kg for poultry commodities.

The 2014 Meeting confirms the previous recommendations.

RECOMMENDATIONS

On the basis of the data from supervised trials, the Meeting concluded that the residue levels listed below are suitable for establishing maximum residue limits and for IEDI assessment.

Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities: *sedaxane*.

The residue is fat-soluble.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Daily Intakes (IEDIs) of sedaxane were calculated for the 17 GEMS/Food cluster diets using STMRs/STMR-Ps estimated by the current and previous Meetings. The ADI is 0–0.1 mg/kg bw and the calculated IEDIs were 0–0% of the maximum ADI (0.1 mg/kg bw). The Meeting concluded that the long-term intakes of residues of sedaxane, when used in ways that have been considered by the JMPR, are unlikely to present a public health concern.

Short-term intake

The International Estimated Short-Term Intakes (IESTI) of sedaxane were calculated for food commodities and their processed commodities using HRs/HR-Ps or STMRs/STMR-Ps estimated by

the current Meeting. The ARfD is 0.3 mg/kg bw and the calculated IESTIs were 0% of the ARfD for all commodities. The Meeting concluded that the short-term intake of residues of sedaxane, when used in ways that have been considered by the JMPR, is unlikely to present a public health concern.

5.29 SPIRODICLOFEN (237)

RESIDUE AND ANALYTICAL ASPECTS

Spirodiclofen, a ketoenol (tetronic acid) insecticide was evaluated for the first time by the 2009 JMPR, where an ADI of 0–0.01 mg/kg bw was established and it was agreed that an ARfD was not necessary. Residue definitions were proposed and maximum residue levels were recommended for a number of uses where GAP and supporting information were available.

Residue definitions established by the 2009 JMPR are:

- For plant products (compliance with MRLs and dietary intake estimation): *spirodiclofen*
- For animal products (compliance with MRLs): *spirodiclofen (fat soluble)*
- For animal products (dietary intake assessment): *sum of spirodiclofen and spirodiclofen-enol, expressed as spirodiclofen.*

Spirodiclofen was listed by the Forty-fifth Session of the CCPR (2013) for the review of additional MRLs for blueberries and avocados and the 2014 JMPR received GAP and residue information for these crops.

Methods of analysis

The 2009 JMPR reviewed and summarised analytical method descriptions and validation data for spirodiclofen and some of its metabolites in crop, processed commodities and animal commodities, including the HPLC-MS-MS multi-residue method 109351 (validated for the determination of parent spirodiclofen in plant commodities with high acid content, high water content and high fat content) and the HPLC/MS-MS method BA-001-P06-01 (validated for the determination of parent spirodiclofen and metabolites (3) in apples, grapes and their processed fractions).

These methods, with minor modifications were validated and used in the supervised residue trials on blueberry (Method 109351) and avocado (Method BA-001-P06-01) with an LOQ of 0.01 mg/kg.

Stability of residues in stored analytical samples

The 2009 JMPR reviewed freezer storage stability studies on a range of representative substrates and concluded that in stored frozen analytical samples, spirodiclofen was stable for at least 13 months in crops with high water content (peach), 24 months in crops with high acid content (citrus, grapes), 16 months in crops with oil content (almond nutmeat, dry hop cones), 8 months in fruit juice (apple juice, grape juice) and 10 months in dried fruit (dried apples, raisins, dried plums).

The Meeting received additional spirodiclofen storage stability studies on blueberry, showing that residues were stable in blueberry analytical samples stored frozen for at least 12 months.

Results of supervised residue trials on crops

The Meeting received new information on supervised field trials involving foliar applications of spirodiclofen to blueberries and avocados.

Blueberries

Results from supervised trials from USA and Canada on highbush and lowbush blueberries were provided to the Meeting.

The critical GAP for blueberries is in Canada, one application of 0.31 kg ai/ha with a PHI of 7 days. In trials from North America matching this GAP, spirodiclofen residues were: 0.38, 0.5, 0.51, 0.58, 0.7, 0.84, 0.99, 1.1, 1.1, 1.5, 1.5 and 2.3 mg/kg (n=12).

The Meeting estimated a maximum residue level of 4 mg/kg and an STMR of 0.92 mg/kg for spirodiclofen on blueberries.

Avocado

Results from supervised trials from USA on avocado were provided to the Meeting.

The critical GAP for avocados is in USA, one application of up to 0.35 kg ai/ha with a PHI of 2 days. In trials from USA matching this GAP, spirodiclofen residues were: 0.04, 0.07, 0.07, 0.15 and 0.47 mg/kg.

The Meeting estimated a maximum residue level of 0.9 mg/kg and an STMR of 0.07 mg/kg for spirodiclofen on avocado.

Farm animal dietary burden

As neither of these commodities are livestock feed items, the Meeting agreed that the 2009 JMPR conclusions and maximum residue level recommendations for livestock commodities did not need to be reviewed.

RECOMMENDATIONS

On the basis of the data from supervised trials the Meeting concluded that the residue levels listed below are suitable for establishing maximum residue limits and for IEDI assessment.

Definition of the residue for compliance with the MRL and for the estimation of dietary intake for plant commodities: *spirodiclofen*

Definition of the residue for compliance with the MRL for animal commodities: *spirodiclofen*

Definition of the residue for the estimation of dietary intake for animal commodities: *sum of spirodiclofen and spirodiclofen-enol, expressed as spirodiclofen.*

The residue is fat soluble

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Daily Intakes (IEDI) for spirodiclofen was calculated from recommendations for STMRs for raw commodities in combination with consumption data for corresponding food commodities. The results are shown in Annex 3 to the 2014 Report.

The International Estimated Daily Intakes (IEDI) of in the 17 GEMS/Food cluster diets, based on the estimated STMRs were in the range 1–8% of the maximum ADI of 0.01 mg/kg bw. The Meeting concluded that the long-term intake of residues of spirodiclofen from uses considered by the Meeting is unlikely to present a public health concern.

Short-term intake

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

5.30 SULFOXAFLOR (252)

RESIDUE AND ANALYTICAL ASPECTS

Sulfoxaflor was first evaluated for residues and toxicological aspects by the 2011 JMPR. The 2011 Meeting established an ADI of 0–0.05 mg/kg bw and an ARfD of 0.3 mg/kg bw. The 2011 Meeting established a residue definition of sulfoxaflor for both compliance and dietary risk assessment in both plant and animal commodities. The 2011 Meeting estimated a number of maximum residue levels prior to registration of sulfoxaflor in any country as a pilot project.

After the subsequent meeting of CCPR, the proposed MRLs for citrus fruits, pome fruits, stone fruits and tree nuts were held at Step 4 because the provisional GAP reviewed by JMPR differed from the GAP finally approved in the USA.

The 2014 Meeting received information on registered use patterns for citrus fruit, pome fruit, stone fruit and tree nuts from the manufacturer and the residue data for those crops evaluated by the 2011 Meeting are reconsidered here against the submitted GAPs.

Results of supervised residue trials on crops

Citrus fruit—Grapefruit, Lemon and Oranges

Registered use patterns from Australia and the USA were submitted. Supervised trial data for citrus were available from Australia, Brazil, and the USA.

Australian GAP for citrus fruit is for application at 9.6 g ai/100L (maximum of two applications, maximum 192 g ai/ha/single application, 1 day PHI).

USA GAP for citrus fruit is for application at 96 g ai/ha (14 day retreatment interval, maximum of four applications maximum 298 g ai/ha/ year, 1 day PHI).

None of the citrus fruit trials were conducted in accordance with the USA GAP. The majority of the Australian trials in oranges and mandarins were conducted at Australian GAP, while USA trials in oranges, grapefruit and lemons approximated Australian GAP after scaling.

The Meeting considered that US and Australian citrus fruit growing practices are similar, and noted the 2013 Meeting General Consideration item number 2.8 (Guidance for Use of Residue Trial Data from Different Geographical Locations for Estimation of Pesticide Residue Levels).

The Meeting determined that trials for all fruit will be related to Australian GAP for citrus fruit. The Meeting decided to use the concept of proportionality to estimate residue levels in citrus fruit in comparison to the Australian GAP where required. Scaled results for citrus fruit were within a range of 0.67–2.2× GAP, within the acceptable range for use of proportionality. Scaled results are indicated by an (s).

Grapefruit

Residue trials were conducted in grapefruit in the USA, approximating the critical GAP in Australia after scaling.

The results for grapefruit at a 1-day PHI after 2× 15.1–19.4 g ai/100L applications were: 0.010, 0.013, 0.016, 0.024, 0.11, and 0.13 mg/kg.

Residues in whole grapefruit after scaling to the Australian GAP were $\underline{< 0.01}$ (×3, all s), $\underline{0.015}$ (s), 0.064 (s) and 0.066 (s) mg/kg, where (s) indicates a result scaled to account for application rates outside ± 25% of GAP.

Residues in pulp of grapefruit, in ranked order after scaling, were $\underline{< 0.01}$ (×3, all s) mg/kg.

The Meeting estimated a maximum residue level of 0.15 mg/kg for the subgroup shaddocks or pomelos. The Meeting noted that sulfoxaflor has systemic properties and considered that three edible portion data points was not sufficient for estimation of STMR and HR values. Therefore, the Meeting estimated an STMR of 0.0125 mg/kg and an HR of 0.066 mg/kg for sulfoxaflor in shaddocks or pomelos, based on the whole fruit data.

Lemons and limes

Residue trials were conducted in lemons in the USA, approximating the critical GAP in Australia after scaling.

Results for whole lemons at a 1-day PHI after 2× 16.2–21.2 g ai/100L were: < 0.01 (2), 0.083, 0.11, and 0.29 mg/kg.

Residues in whole lemons after scaling to the Australian GAP where required were < 0.01 (×2, both s), 0.038 (s), 0.055 (s) and 0.17 (s) mg/kg.

The Meeting estimated a maximum residue level of 0.4 mg/kg for the subgroup lemons and limes, together with an STMR of 0.038 mg/kg, and an HR of 0.17 mg/kg.

Oranges and mandarins

Residue trials were conducted in oranges, in Australia approximating the critical GAP in Australia.

Residues of sulfoxaflor in whole oranges from the Australian trials at a 1-day PHI after 2× 6.4–20.2 g ai/100L applications were: 0.09, 0.15, 0.16, 0.33, 0.41, and 0.43 mg/kg.

Scaled residues in whole oranges from the Australian trials with scaling to the Australian GAP where necessary were 0.09, 0.15, 0.19 (s), 0.24 (s), 0.33, and 0.43 mg/kg.

Residues trials were conducted in mandarins in Australia, at GAP.

Residues in whole mandarins from the Australian trials at a 1-day PHI after 2× 7.6–9.6 g ai/100L applications were: 0.15, 0.28, 0.34, and 0.44 mg/kg.

The Meeting noted that the medians for the Australian datasets for oranges and mandarins differed by less than fivefold (medians differed by a factor of only 1.4×). The similarity of the datasets was further confirmed by the Mann-Whitney U-test. The Meeting concluded that the orange and mandarin datasets were mutually supportive and agreed to combine them for the purpose of estimation of maximum residue levels for the subgroups oranges, sweet, sour and mandarins.

The combined Australian data set for oranges and mandarins is 0.09, 0.15 (2), 0.19, 0.24, 0.28, 0.33, 0.34, 0.43, and 0.44 mg/kg.

The Meeting estimated maximum residue levels of 0.8 mg/kg for the subgroup oranges, sweet, sour and the subgroup mandarins, together with STMR values of 0.26 mg/kg and HR values of 0.44 mg/kg.

The Meeting withdrew the previous maximum residue level recommendation of 0.9 mg/kg for sulfoxaflor in citrus fruit.

Pome fruit–Apples and Pears

Registered use patterns from Australia and the USA were submitted. Supervised trials data were available for apples and pears from Australia/ New Zealand, Europe, and the USA.

Australian GAP for pome fruit is for application at 9.6 g ai/100L (maximum of two applications, maximum 192 g ai/ha/ single application, 7 day PHI).

USA GAP for pome fruit is for application at 96 g ai/ha (7 day retreatment interval, maximum of four applications maximum 298 g ai/ha/ year, 7 day PHI).

The Meeting noted that none of the trials were conducted in accordance with the USA GAP, while a number of the trials from both Australia/New Zealand and the USA matched the Australian GAP.

The Meeting considered that the US and Australian pome fruit growing practices are similar, and noted the 2013 Meeting General Consideration item number 2.8.

The Meeting determined that trials for both apples and pears will be related to Australian GAP for pome fruit. The Meeting decided to use the concept of proportionality as appropriate to estimate residue levels in pome fruit in comparison to the Australian GAP (trials for which proportionality was used were within 1.3–2.2× GAP, within the acceptable range).

Residue trials were conducted in apples and pears in Australia/ New Zealand, approximating the GAP in Australia.

Results in apples and pears from the Australia/New Zealand trials at a 7-day PHI after 2× 9.1–16.1 g ai/100L applications were 0.02, 0.065, 0.07, 0.11, 0.14, 0.19, and 0.22 mg/kg.

Residues in apples and pears from the Australia/New Zealand trials were 0.015 (s), 0.039 (s), 0.07, 0.11, 0.14, 0.19, and 0.22 mg/kg (STMR = 0.11 mg/kg), where (s) indicates a result scaled to account for application rates outside ± 25% of GAP.

Residue trials were conducted in apples and pears in the EU. Results at a 7-day PHI after 2× 10.1–21.0 g ai/100L applications were: 0.052, 0.058, 0.074, 0.078, 0.099, 0.10, 0.18 (3), and 0.27 mg/kg.

Residues in apples and pears from the European trials scaled according to the Australian GAP are: 0.025 (s), 0.028 (s), 0.036 (s), 0.048 (s), 0.071 (s), 0.078, 0.082 (s), 0.082 (s), 0.086 (s), and 0.13 (s) mg/kg (STMR = 0.075 mg/kg).

Residue trials were conducted in apples and pears in the USA.

USA apple and pear results at a 7-day PHI after 2× 7.4–19.8 g ai/100L applications were: < 0.01, 0.039, 0.040, 0.043, 0.056, 0.063, 0.064, 0.066, 0.068, 0.072, 0.075, 0.089, 0.12, 0.13, 0.16, 0.18, and 0.26 mg/kg.

Residues in apples and pears from the USA trials scaled to the Australian GAP where necessary were < 0.01 (s), 0.039, 0.040, 0.043, 0.043 (s), 0.045 (s), 0.055 (s), 0.056, 0.057 (s), 0.063, 0.066, 0.068, 0.075 (s), 0.092 (s), 0.16, 0.18, and 0.23 mg/kg (STMR = 0.057 mg/kg).

The Meeting considered that the seven data points from the Australia/New Zealand apple and pear trials were not sufficient for estimation of a group maximum residue level for pome fruit. The Meeting noted that results from Europe and the USA, relevant to the Australian GAP, were available and combined the Australian, European and USA data sets. The residue found were: < 0.01, 0.015, 0.025, 0.028, 0.036, 0.039 (2), 0.040, 0.043, 0.043, 0.045, 0.048, 0.055, 0.056, 0.057, 0.063, 0.066, 0.068, 0.07, 0.071, 0.075, 0.078, 0.082 (2), 0.086, 0.092, 0.11, 0.13, 0.14, 0.16, 0.18, 0.19, 0.22, and 0.23 mg/kg

The Meeting estimated a maximum residue level of 0.3 mg/kg for sulfoxaflor in pome fruit, together with an STMR of 0.067 mg/kg and an HR of 0.23 mg/kg.

The Meeting withdrew the previous maximum residue level recommendation of 0.4 mg/kg for sulfoxaflor in pome fruit.

Stone fruits

Registered use patterns from Australia and the USA were submitted. Supervised trial data were available for apricot (Australia and New Zealand), cherries (Australia, EU and USA), nectarine (Australia and New Zealand), peach (Australia, EU and USA) and plums (Australia and USA).

Australian GAP for stone fruit is for application at 7.2 g ai/100L (maximum of two applications, maximum 144 g ai/ha/ single application, 7-day PHI).

USA GAP for stone fruit is for application at 96 g ai/ha (7-day retreatment interval, maximum of four applications maximum 298 g ai/ha/ year, 7-day PHI).

Insufficient trials were conducted in accordance with the USA GAP, while a significantly greater number were conducted in accordance with the Australian GAP, and further trials could be related to the Australian GAP through the use of proportionality (trials for which results were scaled were within 1.3–2.9× of GAP, within the acceptable range).

The Meeting considered that the US and Australian stone fruit growing practices are similar, and noted the 2013 Meeting General Consideration item number 2.8.

Therefore trials for all stone fruit will be related to the Australian GAP for stone fruit.

Cherries subgroup

A total of 14 trials on cherries were available from Australia/ New Zealand (1 each), Europe (6), and USA (6).

Australia/New Zealand cherry results at a 7-day PHI after 2 × 9.7–16.3 g ai/100L applications were 0.35 and 0.38 mg/kg.

Residues of sulfoxaflor in cherries from Australia were: 0.17 (s) and 0.35 mg/kg (STMR = 0.26 mg/kg) where (s) indicates a result scaled to account for application rates outside ± 25% of GAP.

European cherry results at a 7-day PHI after 2× 10.1–20.1 g ai/100L applications were: 0.54, 0.77, 0.80, 0.90, 0.98 and 1.5 mg/kg.

Residues of sulfoxaflor measured in cherries from in Europe in accordance with Australian GAP (scaled where necessary) were: 0.29 (s), 0.32 (s), 0.33 (s), 0.38 (s), 0.42 (s), and 0.54 (s) mg/kg (STMR=0.355 mg/kg).

USA cherry results at a 7-day PHI after 2× 8.6–21.0 g ai/100L applications were: 0.55, 0.59, 0.76, 1.0, and 1.2 (2) mg/kg.

Residues of sulfoxaflor in cherries from USA in accordance with the Australian GAP (scaled where necessary) were: 0.24 (s), 0.26 (s), 0.26 (s), 0.42 (s), 0.46 (s) and 1.2 mg/kg (STMR=0.34 mg/kg).

The Meeting noted that there were insufficient residue trials conducted in Australia/New Zealand in accordance with the Australian GAP, and combined the Australia, American and European datasets for the purpose of estimating a maximum residue level for the cherries subgroup.

Residues in cherries from trials conducted in Australia/New Zealand, EU countries and the USA. Sulfoxaflor residues founr were: 0.17, 0.24, 0.26 (2), 0.29, 0.32, 0.33, 0.35, 0.38, 0.42 (2), 0.46, 0.54, and 1.2 mg/kg.

The Meeting estimated a maximum residue level of 1.5 mg/kg for the subgroup cherries, together with an STMR of 0.34 mg/kg, and an HR of 1.24 mg/kg (unrounded result).

Peaches subgroup

A total of five trials on nectarines were available from Australia and New Zealand. The results for nectarines at a 7-day PHI after 2× 9.8–19.7 g ai/100L applications were: 0.10, 0.11, 0.12, 0.14, and 0.18 mg/kg.

Residues of sulfoxaflor in nectarines from Australia and New Zealand were: 0.037 (s), 0.054 (s), 0.061 (s), 0.10 (s) and 0.12 (s) mg/kg (STMR=0.061 mg/kg) where (s) indicates a result scaled to account for application rates outside ± 25% of GAP.

Two trials on apricots were available from Australia and New Zealand. The results for apricots at a 7-day PHI after 2×9.5–14.8 g ai/100L applications were: 0.15 and 0.42 mg/kg.

Residues of sulfoxaflor apricots from Australia/New Zealand in accordance with the Australian GAP (scaled where necessary) were: 0.11 (s) and 0.20 (s) mg/kg (STMR=0.155 mg/kg).

Eight trials in peaches were conducted in Australia and New Zealand. The results at a 7-day PHI after 2× 9.7–19.8 g ai/100L applications were: 0.012, 0.11, 0.11, 0.12, 0.14, 0.15, 0.24, and 0.27 mg/kg.

Residues of sulfoxaflor in peaches from Australia and New Zealand (scaled to the Australian GAP where required) were: < 0.01 (s), 0.040 (s), 0.050 (s), 0.052 (s), 0.057 (s), 0.094 (s), 0.16 (s) and 0.20 (s) mg/kg (STMR=0.0545 mg/kg).

The Meeting noted that the GAP under consideration is for Australia, and that a large regional (Australia/New Zealand) data set for the peach group is available (15 trials in total for peaches, nectarines and apricots), and that the median values of these data sets are within a factor of 5× each other (the medians differed by a maximum factor of 2.8×). The Meeting agreed to combine the Australia/New Zealand peach, nectarine and apricot data for the purpose of estimating a maximum residue level for the peach subgroup. Sulfoxaflor residues found were: < 0.01, 0.037, 0.04, 0.05, 0.052, 0.054, 0.057, 0.061, 0.094, 0.10, 0.11, 0.12, 0.16, and 0.20 (2) mg/kg.

The Meeting estimated a maximum residue level of 0.4 mg/kg for the subgroup peaches, together with an STMR of 0.061 mg/kg and an HR of 0.2 mg/kg.

Plums

A total of seven trials on plums were available from Australia (1) and USA (6).

The Australian result for plums at a 7-day PHI after 2× 19.2 g ai/100L applications was: 0.020 mg/kg.

Residues of sulfoxaflor measured in plums from Australia were: < 0.01 (s) mg/kg where (s) indicates a result scaled to account for application rates outside ± 25% of GAP.

The USA results for plums at a 7-day PHI after 2× 6.9–20.9 g ai/100L applications were: 0.030, 0.054, 0.066, 0.090, 0.11, and 0.26 mg/kg.

Residues of sulfoxaflor in plums from the USA in accordance with the Australian GAP (scaled where necessary) were: 0.020 (s), 0.028 (s), 0.038 (s), 0.039 (s), 0.06 (s) and 0.26 mg/kg.

Residues in plums from trials conducted in Australia and the USA were: < 0.01, 0.020, 0.028, 0.038, 0.039, 0.06, and 0.26 mg/kg.

The Meeting estimated a maximum residue level of 0.5 mg/kg for the subgroup plums, together with an STMR of 0.038 mg/kg, and an HR of 0.26 mg/kg.

The Meeting withdrew the previous maximum residue level recommendation of 3 mg/kg for sulfoxaflor in stone fruit.

Tree nuts

USA GAP for tree nuts (Crop Group 14) including almonds, cashew, chestnut, hazelnut, macadamia, pecan and walnut is for application at 96 g ai/ha (7 day retreatment interval, maximum of four applications maximum 298 g ai/ha/ year, 7 day PHI).

Residues data from trials conducted in the USA were available for almonds and pecans. However, the trials do not match the USA GAP, with only two applications being made at a rate of 200–205 g ai/ha with a 7-day PHI. The Meeting therefore did not estimate maximum residue levels, STMRs or HRs for the tree nut group.

The Meeting agreed to withdraw the previous maximum residue level recommendation of 0.015 mg/kg for sulfoxaflor in tree nuts.

Animal feeds

Almond hulls

Residue data for sulfoxaflor in almond hulls were available to the Meeting. However, as the trials were not conducted in accordance with the USA GAP for almonds, the Meeting did not estimate a median residue value.

Fate of residues during processing

The 2011 Meeting received information on the fate of sulfoxaflor residues during the processing of apple to juice, sauce and wet and dry pomace; cherry to dried cherries, jam and juice and oranges to juice, wet and dry pulp, oil and peel.

Calculated processing factors are summarized in the following table based on the JMPR 2014 recommendations for MRLs and STMRs. Factors are indicated with a '<' (less-than) sign when the residue in the processed commodity is below the LOQ of the analytical method. The calculation is then made on the LOQ of the analytical method and the residue concentration of the RAC (raw agricultural commodity).

Processes included in the table are those that lead to STMR-P or HR-P values useful for dietary intake estimations or for livestock dietary burden calculations.

Raw Agricultural Commodity (RAC)	Processed Commodity	Best Estimate Processing Factor (PF)	RAC MRL (mg/kg)	RAC STMR (mg/kg)	RAC HR (mg/kg)	Processed commodity STMR-P (mg/kg)	Processed commodity HR-P (mg/kg)
Apple	Wet pomace	1.1	0.3	0.067	0.23	0.074	–
	Dry pomace	4.2				0.28	–
	Juice	0.4				0.027	–
	Sauce	0.6				0.040	–
Cherry	Juice	0.8	1.5	0.34	1.24	0.27	–
	Jam	1.1				0.37	–
	Dried	5.1				1.73	6.32
Orange	Juice	0.14	0.8	0.26	0.44	0.036	–
	Wet pulp	2.5				0.65	–
	Dried pulp	8.3				2.16	–
	Oil	< 0.2				< 0.052	–
	Peel	5.6				1.46	2.45

Animal commodities

The Meeting recalculated the livestock dietary burden based on the uses considered by the current Meeting and by the 2011 Meeting on the basis of diets listed in the FAO Manual Appendix IX (OECD Feedstuff Table).

The maximum dietary burden is 3.22 ppm for beef and dairy cattle, while the mean dietary burden is 1.26 ppm for beef and dairy cattle. The values calculated by the 2011 Meeting were: maximum dietary burden of 3.04 ppm for beef cattle and 2.68 ppm for dairy cattle, and a mean dietary burden of 0.91 ppm for both dairy and beef cattle. Interpolation of these values between the appropriate feeding levels in the lactating cattle feeding study considered by the 2011 Meeting showed that no changes to the maximum residue levels estimated by the 2011 Meeting for milks, edible offal (mammalian) or meat (from mammals other than marine mammals) were required.

The maximum and mean dietary burdens for poultry (both layers and broilers) are 0.93 and 0.31 ppm respectively. These have changed very little from the values determined by the 2011 Meeting (maximum and mean values of 0.89 and 0.30 ppm respectively).

The Meeting confirmed its previous recommendations for meat (from mammals other than marine mammals), edible offal (mammalian), milks, poultry meat, poultry, edible offal of, and eggs.

The Meeting noted that the 2011 Meeting did not estimate maximum residue levels for mammalian fats (except milk fats) or poultry fats.

The Meeting noted the STMR values of 0.03 mg/kg and HR value of 0.073 mg/kg estimated by the 2011 Meeting for the fat compartment of mammalian meat (from mammals other than marine mammals). Noting that the dietary burden has not significantly increased, the Meeting estimated a maximum residue level of 0.1 mg/kg for mammalian fats (except milk fats), together with an STMR of 0.03 mg/kg and an HR of 0.073 mg/kg.

The Meeting noted the STMR values of 0.005 mg/kg and HR value of 0.021 mg/kg estimated by the 2011 Meeting for the fat compartment of poultry meat. Noting that the dietary burden has not significantly increased, the Meeting estimated a maximum residue level of 0.03 mg/kg for poultry fats, together with an STMR of 0.005 mg/kg and an HR of 0.021 mg/kg.

RECOMMENDATIONS

On the basis of the data from supervised trials the Meeting concluded that the residue levels listed below are suitable for establishing maximum residue limits and for IEDI assessment.

Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities*: sulfoxaflor*

The residue is not fat soluble.

DIETARY RISK ASSESSMENT

Long-term intake

The evaluation of sulfoxaflor has resulted in recommendations for MRLs and STMRs for raw and processed commodities. The International Estimated Daily Intakes for the 17 GEMS/Food cluster diets, based on estimated STMRs were in the range 1–7% of the maximum ADI of 0.05 mg/kg bw (Annex 3 to the 2014 Report).

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

Short-term intake

The International Estimated Short Term Intake (IESTI) for sulfoxaflor was calculated for the plant and livestock commodities (and their processing fractions) for which new STMRs and HRs were estimated and for which consumption data were available. The results are shown in Annex 4 to the 2014 Report.

The IESTI varied from 0–9 % of the ARfD (0.3 mg/kg bw). The Meeting concluded that the short-term intake of residues of sulfoxaflor, from uses that have been considered by the JMPR, is unlikely to present a public health concern

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5.31 THIAMETHOXAM (245)

see also CLOTHIANIDIN (238)

RESIDUE AND ANALYTICAL ASPECTS

Thiamethoxam is a neonicotinoid compound with broad-spectrum insecticidal properties. The compound was evaluated by the JMPR in 2010 (T, R), 2011 (R) and 2012 (R).The 2010 Meeting established an ADI for Thiamethoxam of 0–0.08 mg/kg bw and an ARfD of 1 mg/kg bw. It was listed by the Forty-fifth Session of CCPR (2013) for the evaluation of 2014 JMPR for additional MRLs.

The residue definition for enforcement for thiamethoxam in plant and animal commodities is thiamethoxam. The residue for dietary risk assessment for plant and animal commodities (except poultry) is thiamethoxam and clothianidin (considered separately). The residue definition for risk assessment dietary intake for poultry is the sum of thiamethoxam, CGA 265307 and MU3, expressed as thiamethoxam and clothianidin (clothianidin to be considered separately from thiamethoxam). In the current appraisal CGA322704 is referred to as clothianidin.

At the 2014 JMPR Meeting residue data were submitted to support maximum residue level recommendations for use of thiamethoxam on several crops. Residue trials were conducted to support use avocado, mango, beans, mint and hops. In addition, trials were submitted by Republic of Korea to support the use on persimmon. Summaries of the trials have been provided to support the recommendations for thiamethoxam and clothianidin on the respective crops.

Methods of analysis

The Meeting received additional validation data for the analytical method REM 179.06 (evaluated by the 2010 Meeting) of thiamethoxam and clothianidin.

Most of the methods used in the supervised residue trials had previously been evaluated (2010 JMPR) and determined parent compound thiamethoxam and the metabolite clothianidin. Samples were extracted with methanol:water. The final residue could then be determined by HPLC-MS/MS. The Meeting considers validation of the method sufficient for the respective crops with an LOQ of 0.01 mg/kg for parent and its metabolite, respectively. The analytical methods not previously evaluated, but used in the trials for the current evaluation (LC-MS/MS Method 954/2010 and Method HPLC/DAD) were sufficiently validated.

Stability of pesticide residues in stored analytical samples

At the 2010 JMPR, thiamethoxam and clothianidin were shown to be stable for 1–2 years when stored frozen at < -18 °C or lower for a large range of commodities. The stability in the crops under evaluation in 2014 was sufficiently demonstrated in the respective residue trials.

Results of supervised residue trials on crops

The Meeting received supervised trials data for persimmon, avocado, mango, beans, mint (herbs) and hops.

Pome fruits

Residue data in support of the use of thiamethoxam and clothianidin on pome fruit (apples and pears) were previously evaluated by the 2010 JMPR. In 2010 insufficient data were submitted for the use of clothianidin on persimmons to lead to a maximum residue level recommendation (not yet categorized under pome fruit at that time). No data were previously submitted to support the use of thiamethoxam on persimmons.

The critical GAP for thiamethoxam on persimmon in Republic of Korea is for 3 foliar applications at 0.005 kg ai/hL (interval of 10 days) and a PHI of 7 days, until "leaves are dripping". The Meeting received two independent trials that were performed according to the Korean critical GAP using an application rate of 0.005 kg ai/hL.

As the GAPs for pome fruit and persimmon are different, a specific maximum residue level for persimmon would need to be estimated. However, the Meeting agreed that the dataset was insufficient for the estimation of a maximum residue level for persimmon.

The Meeting confirmed the maximum residue level, STMR and HR for thiamethoxam and clothianidin in pome fruit as recommended by the 2010 JMPR Meeting.

Assorted tropical and sub-tropical fruits – inedible peel

Supervised trials were available for avocado and mango. The use of thiamethoxam and/or clothianidin on avocados had not been previously evaluated by the JMPR. The use of thiamethoxam on mango was been evaluated by the 2010 JMPR, but there were insufficient data to support a maximum residue level recommendation. The Meeting had not previously received residue data supporting the use of clothianidin on mangoes.

Avocado

The critical GAP for use on avocado's in the USA is for 3 foliar directed applications at 0.070 kg ai/ha (minimum interval of 7 days) and no PHI.

Five field trials involving the use of thiamethoxam (3 foliar applications at approximately 70 g ai/ha, with a 6–7 day interval and PHI of 3 days) on avocados were performed in the USA (3) and in Mexico (2) in 2006 (4) and 2007 (1). Thiamethoxam residues on whole fruit (RAC) were not reported. Using a conversion factor to correct from flesh and peel to whole fruit (0.8× residue level), calculated residue levels in whole fruit were: < 0.01, 0.03, 0.06, 0.10, and 0.24 mg/kg (n=5). Converted clothianidin residues in RAC were: < 0.01, < 0.01, < 0.01, 0.016, and 0.016 mg/kg (n=5).

The Meeting agreed that the dataset for avocados matching the USA critical GAP could be used to support a maximum residue level recommendation for avocados, and estimated a maximum residue level of 0.5 mg/kg for thiamethoxam and a maximum residue level of 0.03 mg/kg for clothianidin on avocado.

The residue data for estimating the STMR and HR (flesh+peel) were: < 0.01, 0.04, 0.08, 0.12, and 0.30 mg/kg (n=5), resulting in an STMR and HR of 0.08 mg/kg and 0.30 mg/kg, respectively for thiamethoxam.

Clothianidin residues (flesh+peel) were: < 0.01, < 0.01, < 0.01, 0.02, and 0.02 mg/kg (n=5), resulting in STMR and HR estimates of 0.01 and 0.02 mg/kg, respectively.

Mango

Field trials involving the use of thiamethoxam on mango were performed in South Africa. Eight trials in 2003–2005 were evaluated by the JMPR in 2010. Trials performed 2011–2012 were submitted to the 2014 Meeting.

The critical GAP for use of thiamethoxam on mangoes in the South Africa is a single soil application at 1.44 g ai/tree poured from a jug with a PHI of 130 days. Seven residue trials (three in 2003/2005 and four in 2011/2012) matched the South African GAP, using a single soil application at a rate of 1.44 g ai/tree and a PHI of 130 days. Thiamethoxam residues (whole fruit) were: 0.01, 0.02, 0.02, 0.02, 0.036[#], 0.08[#], and 0.088[#] mg/kg. Clothianidin residues were: < 0.01, 0.01, 0.01, < 0.02[#], < 0.02[#], < 0.02[#] and 0.02 mg/kg. The values identified with [#] are residue data of flesh and peel corrected for stone using a default conversion factor of 0.8, because the weights of the different fractions of the fruit were not reported in the 2010 evaluation.

The Meeting agreed that the dataset for mangoes matching the South African critical GAP could be used to support a maximum residue level recommendation for mangoes, and estimated a maximum residue level of 0.2 mg/kg for thiamethoxam on mango. For clothianidin the Meeting estimated a maximum residue level of 0.04 mg/kg.

For the STMR and HR estimates the residue data excluding the stone are used. Thiamethoxam residues (flesh+peel) were: 0.01, 0.03, 0.03, 0.03, 0.04, 0.10, and 0.11 mg/kg, resulting in a STMR and HR of 0.03 and 0.11 mg/kg, respectively for thiamethoxam. Clothianidin residues (flesh and peel) were: 0.01, < 0.02, 0.02, 0.02, 0.02, 0.02, and 0.02 mg/kg. The Meeting estimated STMR and HR values of 0.02 and 0.02, respectively for clothianidin.

Legume vegetables

The Meeting received data on the use of thiamethoxam on fresh beans. A Portuguese label for use of thiamethoxam on fresh beans was submitted to the Meeting. The label included indoor use (foliar application and drip irrigation) and outdoor use (foliar application).

Indoor use: No data were submitted to support the indoor use (neither the foliar, nor the drip irrigation uses).

Outdoor use: The use of thiamethoxam on beans and peas had been evaluated by the 2010 Meeting. In 2010 the data reviewed covered seed treatment use; therefore the datasets could not be combined. According to the 2010 evaluation there was no GAP for clothianidin on legume vegetables. The critical GAP for outdoor use of thiamethoxam is a double foliar application of 100 g ai/ha, with an interval of 7 days and a PHI of 3 days.

Eight field trials involving fresh beans (with pods) were conducted in 2003 and 2004 in Spain. The critical GAP for outdoor use was supported with seven trials using two foliar applications of 93–113 g ai/ha (total rate of 200 g ai/ha within ±25% range), 6–8 day interval and 3 day PHI. Thiamethoxam residues were: 0.03, 0.08, 0.08, 0.08, 0.09, 0.16, and 0.18 mg/kg.

The Meeting agreed that the dataset for fresh beans matching the Portuguese critical GAP for outdoor use could be used to support a maximum residue level recommendation for fresh beans, and estimated a maximum residue level of 0.3 mg/kg for thiamethoxam in fresh beans.

The Meeting estimated STMR and HR values of 0.08 and 0.18 mg/kg, respectively for thiamethoxam in fresh beans.

The same trials were used for clothianidin. The residues were: 0.04, 0.04, 0.06, 0.07, 0.08, 0.09, and 0.10 mg/kg.

The Meeting estimated a maximum residue level of 0.2 mg/kg for clothianidin and STMR and HR values of 0.07 mg/kg and 0.10 mg/kg, respectively for clothianidin in fresh beans.

Fresh herbs

The Meeting received data on the use of thiamethoxam on mints. No uses of thiamethoxam or clothianidin on fresh herbs (mints) have previously been evaluated by the JMPR.

Mints

Field trials involving the use of thiamethoxam on mint were performed in the USA in 1999.

The critical GAP for mint in the USA is 3 foliar applications of 0.070 kg ai/ha (minimum interval 14 days, maximum total rate of 0.21 kg ai/ha per season) and PHI of 7 days. Five trials matched this GAP (3×0.072–0.074 kg/ai/ha, interval 13–15 days, PHI 6–7 days), although slightly higher applications rates were used (< 25% difference). Thiamethoxam residues were: 0.24, 0.28, 0.34, 0.36, and 0.86 mg/kg.

The Meeting agreed that the dataset on mints matching the USA GAP could be used to support a maximum residue level recommendation for mints and estimated a maximum residue level of 1.5 mg/kg for thiamethoxam on mint and STMR and HR values of 0.34 and 0.86 mg/kg, respectively for thiamethoxam.

The same trials were used to derive the residue levels for clothianidin. Residues were: 0.06, 0.07, 0.11, 0.11, and 0.12 mg/kg.

The Meeting agreed that the dataset on mints could be used to support a maximum residue level for mints and estimated a maximum residue level of 0.3 mg/kg for clothianidin and STMR and HR values of 0.11 mg/kg and 0.12 mg/kg, respectively for clothianidin.

Dried herbs

The Meeting received data on the use of thiamethoxam on hops. The use of thiamethoxam on hops was evaluated by the 2010 Meeting. No maximum residue level was recommend due to the limited dataset (n=3). The JMPR has not evaluated any uses for clothianidin on dried herbs.

Hops

Field trials involving hops were performed in the USA in 2002 (three evaluated by JMPR 2010) and 2011 (one submitted in 2014).

The critical GAP for hops in the USA is a single soil surface treatment (band application with incorporation) at a rate of 0.14 kg ai/ha and a PHI of 65 days. The trials performed in the USA matched this GAP (1×0.13–0.14 and PHI 62–66 days).

Thiamethoxam residues in hops (dried cones) were: < 0.025, 0.027, 0.029, and 0.055 mg/kg. The Meeting agreed that the dataset for hops matching the USA GAP could be used to support a maximum residue level recommendation for hop, and estimated a maximum residue level of 0.09 mg/kg for thiamethoxam on dried hops. The Meeting estimated STMR and HR values of 0.028 and 0.055 mg/kg, respectively for thiamethoxam.

Clothianidin residues were: < 0.025, 0.025, 0.027, and 0.028 mg/kg. The Meeting estimated a maximum residue level of 0.07 mg/kg for clothianidin on hops. The Meeting estimated STMR and HR values of 0.026 and 0.028 mg/kg, respectively for clothianidin, respectively.

Legume animal feeds

The Meeting received data on the outdoor use of thiamethoxam on fresh beans. The use of thiamethoxam on beans and peas has been evaluated by the 2010 Meeting, but only covered seed treatment uses and provided residue data for thiamethoxam and clothianidin in pea vines and pea hay/fodder (dry), but not for bean forage. No residue data for clothianidin in legume animal feeds was available.

Bean forage

The Portuguese outdoor GAP for use of thiamethoxam on beans is a foliar application 2×100 g ai/ha, with a PHI of 3 days and a minimum interval of 7 days.

Outdoor use

Eight field trials involving fresh beans (with pods) were conducted in 2003 and 2004 in Spain. The application rates were two foliar treatments of 69–113 g ai/ha with an interval of 6–8 days and a PHI of 3 days, matching the Portuguese GAP. Residues in bean forage were determined in four field trials. Thiamethoxam residues in bean forage (rest of plants harvested at BBCH < 80) were: 0.56,

0.82, 0.93, and 1.4 mg/kg. Clothianidin residues in bean forage were: 0.06, 0.07, 0.08, and 0.11 mg/kg.

The Meeting agreed that the dataset for fresh bean forage matching the outdoor Portuguese GAP could be used to estimate median residues of 0.87 and 0.075 mg/kg for thiamethoxam and clothianidin, respectively. The respective highest residues are 1.4 and 0.11 mg/kg.

Fate of residues during processing

Processing studies were undertaken for mango and mint. Processing factors based on the residue for parent and metabolite clothianidin are listed in the table below. Using the $STMR_{RAC}$ obtained from the thiamethoxam use, the Meeting estimated STMR-Ps for processed commodities to be used in dietary intake calculations.

Commodity	PFs	PF (median or best estimate)	STMR-P = $STMR_{pulp+peel}$ x PF (mg/kg)	HR-P = $HR_{pulp+peel}$ x PF (mg/kg)	PFs	PF (median or best estimate)	STMR-P = $STMR_{RAC}$ x PF (mg/kg)	HR-P = HR_{RAC} x PF (mg/kg)
	Parent thiamethoxam ($STMR_{pulp+peel}$ = 0.03 mg/kg $HR_{pulp+peel}$ = 0.11 mg/kg)				clothianidin ($STMR_{pulp+peel}$ = 0.02 mg/kg, $HR_{pulp+peel}$= 0.02 mg/kg)			
Mango, dried flesh	4.0, 6.7, 7.3, 5.0	5.9	0.18	0.65	5.7, 8.4, 7.00, 4.00	6.3	0.13	0.13
Mint, oil	< 0.02, < 0.03	< 0.02	n.a.	n.a.	< 0.22, < 0.19	< 0.20	n.a.	n.a.

Residues in animal commodities

The Meeting estimated the dietary burden of thiamethoxam residues (thiamethoxam only, for CGA322704 see clothianidin appraisal 2014) on the basis of the livestock diets listed in the FAO manual Appendix IX (OECD feedstuff table) using the OECD_Feed_Calculator_V1_4. Calculation from highest residue, STMR (some bulk commodities) and STMR-P values provides the levels in feed suitable for estimating MRLs, while calculation from STMR and STMR-P values from feed is suitable for estimating STMR values for animal commodities.

The Meeting recalculated the livestock dietary burden based on the uses presented by the 2010 JMPR and including the residue values for fresh bean forage from the 2014 JMPR Meeting. The maximum dietary burden for cattle for MRL (tissues) setting changed slightly from 5.2 to 6.1 ppm, and the mean dietary burden for cattle changed only marginally from 2.1 to 2.4 ppm. For residue level estimations in milk the dietary burden raised from 5.2 to 6.1 ppm (maximum) and from 1.6 to 2.4 ppm (mean). The new maximum dietary burden of thiamethoxam for poultry of 1.64 ppm is only marginally higher than the maximum dietary burden of 1.59 ppm as calculated by the Meeting in 2010, rounded both 1.6 ppm. The new mean dietary burden for poultry of 0.59 ppm is not changed since the evaluation in 2010.

The Meeting agreed that no new mean and maximum residue level estimations are needed and confirmed its previous recommendations.

Residue data for clothianidin used for the dietary burden calculation were derived from the 2010 JMPR appraisal for clothianidin, where the data from thiamethoxam and clothianidin use were combined and included the residue data on bean forage from the 2014 JMPR Meeting. For the dietary burden calculations and recommendations for animal commodities see appraisal clothianidin 2014.

RECOMMENDATIONS

Thiamethoxam

On the basis of the data from supervised residue trials the Meeting concluded that the residue levels listed below are suitable for establishing maximum residue limits and for IEDI and IESTI assessment.

The 2011 Meeting recommended the following residue definition for thiamethoxam:

Definition of the residue for animal and plant commodities (for compliance with the MRL): *thiamethoxam*.

Definition of the residue for plants and animals (except poultry), (for estimation of dietary intake): *thiamethoxam and clothianidin* (considered separately).

Definition of the residue for poultry (for estimation of dietary intake): *sum of thiamethoxam, CGA 265307 and MU3, expressed as thiamethoxam and clothianidin* (clothianidin to be considered separately from thiamethoxam).

The residue is not fat-soluble.

Note that thiamethoxam metabolite CGA322704 (N-(2-chlorothiazol-5-ylmethyl)-N'-methyl-N''-nitroguanidine) will appear as clothianidin in the analytical method and residues of CGA322704 occurring in food are included in the clothianidin MRLs.

Metabolite CGA 265307: N-(2-chlorothiazol-5-ylmethyl)-N'-nitroguanidine.

Metabolite MU3: amino-([(2-chlorothiazol-5-ylmethyl)-amino]-methylene)-hydrazide.

The recommendations for clothianidin resulting from thiamethoxam use are listed in the clothianidin appraisal 2014.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Daily Intakes (IEDI) of thiamethoxam, based on the STMRs estimated for 112 commodities, for the 17 cluster diets were in the range of 1–3% of the maximum ADI (0.08 mg/kg bw) (Annex 3 to the 2014 Report). The Meeting concluded that the long-term intake of residues of thiamethoxam resulting from its uses that have been considered by the 2010, 2011 2012 and the present Meeting is unlikely to present a public health concern.

For the International Estimated Daily Intakes (IEDI) for clothianidin resulting from thiamethoxam and clothianidin use see appraisal clothianidin 2014.

Short-term intake

The International Estimated Short Term Intake (IESTI) for thiamethoxam was calculated for food commodities and their processed fractions for which maximum residue levels were estimated and for which consumption data were available. The results are shown in Annex 4 to the 2014 Report.

The IESTI represented 0–1% of the ARfD (1.0 mg/kg bw). The Meeting concluded that the short-term intake of residues of thiamethoxam, when used in ways that have been considered by the present Meeting, is unlikely to present a public health concern.

5.32 TRIADIMENOL (168)

RESIDUE AND ANALYTICAL ASPECTS

Triadimenol is a systemic fungicide formed as the primary metabolite of triadimefon but also used as an active substance on its own. Its main mode of action is an inhibition of the ergosterol biosyntheses in fungi. Triadimenol was evaluated by JMPR several times since 1978 and the last time in 2004 for toxicology, when an ADI of 0–0.03 mg/kg bw and an ARfD of 0.08 mg/kg bw was established and in 2007 and 2009 for residues.

Definition of the residue in plant and animal commodities (for the estimation of dietary intake and for compliance with MRLs): sum of triadimefon and triadimenol

In 2007 the Meeting evaluated use patterns of triadimefon and triadimenol in grapes; however, a short-term dietary intake concern was identified without opportunity for an alternative GAP. In 2009 the 2007 evaluation on the use on grapes was repeated by the JMPR, but again no alternative GAP could be identified.

The current Meeting received new information on use patterns for triadimenol in grapes supported by new supervised residue trials on grapes from Europe.

Methods of analysis

The 2007 Meeting evaluated several methods of analyses for triadimenol in different plant and animal matrices with a LOQ of 0.05 mg/kg (GC-FID or GC-MS), based on the multi-residue method DFG-S19.

To the 2014 Meeting two new analytical methods were provided measuring triadimenol, with a LOQ of 0.01 mg/kg. Both methods involve measurement by HPLC-MS/MS for triadimenol. One of these methods measures also triadimenol including sugar conjugates and triadimenol-hydroxy including sugar conjugates in plant matrices with a LOQ of 0.01 mg/kg. For the determination of conjugates enzymatic treatment may be included in the extraction procedure.

Stability of pesticide residues in stored analytical samples

In 2007 the Meeting concluded that triadimenol is stable in stored samples of plant and animal origin for at least 24 months.

Results of supervised residue trial on crops

Grapes

For grapes, two new GAPs from France and Spain have been submitted to the Meeting.

In France, triadimenol is registered for grapes involving three applications of 0.019 kg ai/ha each with a PHI of 21 days. Supervised field trials from Europe matching the GAP were already reported in 2007 (two trials) and amended by new trial data submitted to the current Meeting (six trials).

Residues of triadimenol in grapes matching the French GAP were: < 0.01, 0.01, < 0.02(2), 0.03, 0.04, 0.08 and 0.13 mg/kg.

In Spain triadimenol is registered for grapes involving four applications of 0.063 kg ai/ha each with a PHI of 15 days for table grapes and 21 days for wine grapes. Supervised field trials from Southern Europe and Turkey matching the GAP were already reported in 2007.

Residues of triadimenol in table grapes matching the GAP were: < 0.02, < 0.02, 0.02, 0.04(3), 0.05, 0.06, 0.07, 0.08, 0.1, 0.11 mg/kg.

Residues of triadimenol in wine grapes matching the GAP were: < 0.02(4), 0.02, 0.02, 0.03, 0.04(3), 0.1 mg/kg.

Based on the French GAP, the Meeting estimated a maximum residue level of 0.3 mg/kg and HR and STMR values of 0.13 mg/kg and 0.025 mg/kg for grapes, respectively

Fate of residues during processing

The 2007 Meeting estimated processing factors for triadimenol in grapes of 0.45 for juice, 0.42 for wine, 3.1 for raisins, 3 for wet pomace and 5.7 for dry pomace. No additional data were submitted to the current Meeting.

Based on these factors and the newly estimated STMR value of 0.025 mg/kg the Meeting estimated STMR-P values for juice of 0.011 mg/kg, for dried grapes (= raisins) of 0.078 mg/kg, for wet grape pomace of 0.075 mg/kg and for dry grape pomace of 0.14 mg/kg.

Based on the newly estimated STMR value of 0.025 mg/kg for wine grapes, the Meeting estimated STMR-P value of 0.01 mg/kg for wine.

For dried grapes the Meeting estimated a HR-P of 0.4 mg/kg and a maximum residue level of 1 mg/kg to replace its previous recommendation of 10 mg/kg.

Residues in animal commodities

In the 2007 evaluation for triadimenol grape pomace (wet) was already taken into account for the livestock animal dietary burden calculation based on a residue level of 0.5 mg/kg, which is higher than the estimated residue level of 0.075 mg/kg resulting from the current GAPs.

Therefore, the Meeting concluded that the contribution of triadimenol residues in grapes after treatment according to the evaluated GAPs does not influence the overall dietary burden of livestock animals, making a re-assessment of the residue situation in animal commodities unnecessary. The Meeting confirms its previous recommendations for triadimenol in animal commodities.

RECOMMENDATIONS

Definition of the residue in plant and animal commodities (for the estimation of dietary intake and for compliance with MRLs): sum of triadimefon and triadimenol

On the basis of the additional data from supervised trials on grapes the Meeting recommends the following maximum residue levels for triadimenol.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Daily Intakes (IEDI) of triadimefon and triadimenol was calculated from previously estimated STMRs in 2007 and the new STMRs in 2014 for raw and processed commodities in combination with consumption data for corresponding food commodities. The results are shown in Annex 3.

The IEDI of the 17 GEMS/Food cluster diets, based on the estimated STMRs represented 1–3% of the maximum ADI (0.03 mg/kg bw).

The Meeting concluded that the long-term intake of residues of triadimefon and triadimenol from the uses considered by the Meeting is unlikely to represent a public health concern.

Short-term intake

The International Estimated Short-Term Intake (IESTI) of triadimenol calculated on the basis of the estimations made by the 2014 JMPR represented for children 0–10% and for the general population 0–5% of the ARfD (0.08 mg/kg bw). The Meeting concluded that the short-term intake of triadimenol from the uses considered by the 2014 JMPR is unlikely to represent a public health concern.

5.33 TRIFORINE (116)

TOXICOLOGY

Triforine is the ISO-approved common name for *N*,*N*′-[piperazine-1,4-diylbis[(trichloromethyl)methylene)] diformamide (IUPAC), with CAS number 37273-84-0. Triforine is a systemic fungicide that acts by inhibition of sterol biosynthesis in the membranes of fungi (black spot, rust, powdery mildew).

Triforine was first evaluated by JMPR in 1977, when no ADI was established. When more toxicological data were made available to the Meeting for review in 1978, an ADI of 0–0.02 mg/kg bw was established. The Meeting reviewed triforine in 1997 within the periodic review programme of CCPR and reaffirmed the ADI of 0–0.02 mg/kg bw. No ARfD was established, because the establishment of ARfDs by JMPR was not common practice in 1997. Triforine was reviewed by the present Meeting as part of the periodic review programme of CCPR.

Some of the critical studies do not comply with GLP, as the data were generated before the implementation of GLP regulations. Overall, however, the Meeting considered that the database was adequate for the risk assessment.

Biochemical aspects

In single-dose or repeated-dose studies using a dose of 10 mg/kg bw, more than 80% of administered radiolabelled triforine was rapidly absorbed by both male and female rats. In a study using a single dose of 1000 mg/kg bw, only about 10–20% was absorbed. The AUC was about 2 times greater in male rats than in female rats. Triforine was widely distributed in the body. After a single low dose (10 mg/kg bw), more than 78% was excreted in urine, 5–6% in expired air and 12–14% in faeces (9–13% in bile). After a single high dose (1000 mg/kg bw), more than 77% was excreted in faeces and 11–19% in urine. The terminal elimination half-lives at 10 mg/kg bw were 125 hours in males and 95.7 hours in females. After 168 hours, the highest residues were seen in liver, red blood cells and kidney.

Triforine was extensively metabolized by cleavage of one of the two side-chains, followed by oxidation and conjugation of the side-chain metabolites with glucuronic acid or glutathione.

Toxicological data

Triforine is of low acute toxicity, with oral LD50s greater than 5000 mg/kg bw in rats and mice. The dermal LD50 in rats was greater than 2000 mg/kg bw. The inhalation LC50 in rats was greater than 5.12 mg/L. Triforine was not irritating to the eye or skin of rabbits. It was not a dermal sensitizer in guinea-pigs (Maurer optimization test).

Administration of triforine to mice, rats and dogs in repeated-dose toxicity studies (4-week and 13-week studies in mice, 4-week, 13-week and 2-year studies in rats and 13-week and 2-year studies in dogs) resulted in haemolytic anaemia and associated effects.

In a 4-week study of toxicity in mice, triforine was administered in the diet at a concentration of 0, 200, 1000 or 5000 ppm (equal to 0, 39.0, 195.8 and 982.1 mg/kg bw per day for males and 0, 45.2, 237.0 and 1284.3 mg/kg bw per day for females, respectively). The NOAEL was 1000 ppm (equal to 195.8 mg/kg bw per day), on the basis of mild haemolytic anaemia in mice of both sexes, slightly reduced body weight gain in males and increased relative liver weight in females at 5000 ppm (equal to 982.1 mg/kg bw per day).

In a 13-week study of toxicity in mice designed solely to determine the high dose for use in longer-term studies, triforine was administered in the diet at a concentration of 0 or 7000 ppm (equal to 1354 mg/kg bw per day for males and 2239 mg/kg bw per day for females). Evidence of mild haemolytic anaemia and moderately increased spleen and liver weights were seen in treated animals.

In a 4-week study of toxicity in rats, triforine was administered in the diet at a concentration of 0, 500, 2500 or 12 500 ppm (equal to 0, 49.7, 238.2 and 1233.7 mg/kg bw per day for males and 0, 48.5, 233.2 and 1180.8 mg/kg bw per day for females, respectively). A NOAEL was not identified in this study, as the incidence and severity of haemosiderin deposition in the spleen were increased in females of all dose groups.

In a 13-week study of toxicity in rats, triforine was administered in the diet at a concentration of 0 or 20 000 ppm (equal to mean achieved doses of 1630 mg/kg bw per day for males and 1945 mg/kg bw per day for females). Treated animals showed mild haemolytic anaemia and increased spleen and liver weights.

In a 13-week study of toxicity in rats, triforine was administered in the diet at a concentration of 0, 2500, 7000 or 20 000 ppm (equal to 0, 162.7, 453.6 and 1315.3 mg/kg bw per day for males and 0, 174.1, 491.4 and 1451.4 mg/kg bw per day for females, respectively). A NOAEL was not identified, as the incidence of marked haemosiderin deposition in the spleen was increased in female rats at 2500 ppm (equal to 174.1 mg/kg bw per day), the lowest dose tested.

In a 3-month study of toxicity in rats, triforine was administered in the diet at concentrations providing doses of 0, 10, 100 and 1000 mg/kg bw per day. The NOAEL was 10 mg/kg bw per day for males and females, based on haemolytic anaemia and increased liver weight at 100 mg/kg bw per day and above.

In a 14-week study of toxicity in rats, triforine was administered in the diet at a concentration of 0, 100 or 500 ppm (equal to 0, 6.0 and 30.4 mg/kg bw per day for males and 0, 6.9 and 34.0 mg/kg bw per day for females, respectively). The NOAEL was 500 ppm (equal to 30.4 mg/kg bw per day), the highest dose tested.

In a 90-day study of toxicity and neurotoxicity in rats, triforine was administered in the diet at a concentration of 0, 200, 2000 or 20 000 ppm (equal to 0, 13, 133 and 1344 mg/kg bw per day for males and 0, 15, 150 and 1540 mg/kg bw per day for females, respectively). The NOAEL for neurotoxicity was 20 000 ppm (equal to 1334 mg/kg bw per day), the highest dose tested. The NOAEL for all other effects was 200 ppm (equal to 13 mg/kg bw per day), based on evidence of haemolytic anaemia and changes in kidney and liver at 2000 ppm (equal to 133 mg/kg bw per day) and above.

In a 13-week study of toxicity in dogs, triforine was administered in the diet at a concentration of 0, 3500, 10 000 or 30 000 ppm (equal to 0, 83, 230 and 690 mg/kg bw per day for males and 0, 85, 240 and 730 mg/kg bw per day for females, respectively). A NOAEL was not identified, as signs of haemolytic anaemia were observed at all doses.

In a further 13-week study of toxicity in dogs, triforine was administered in the diet at a concentration of 0, 100, 600 or 3500 ppm (equal to 0, 3.6, 22.6 and 121.0 mg/kg bw per day for males and 0, 3.4, 21.3 and 120.7 mg/kg bw per day for females, respectively). The NOAEL was 100 ppm (equal to 3.4 mg/kg bw per day), on the basis of increased haemosiderin deposits in the liver, spleen and bone marrow at 600 ppm (equal to 21.3 mg/kg bw per day) and above.

In a 2-year study of toxicity in dogs, triforine was administered in the diet at a concentration of 0, 10, 40, 100 or 1000 ppm (equal to 0, 0.23, 0.93, 2.39 and 22.50 mg/kg bw per day for males and 0, 0.25, 0.99, 2.56 and 23.60 mg/kg bw per day for females, respectively). The NOAEL was 100 ppm (equal to 2.39 mg/kg bw per day), based on evidence of haemolytic anaemia, increased erythropoiesis and haemosiderin deposition in the liver and bone marrow at 1000 ppm (equal to 22.50 mg/kg bw per day).

As the pattern of changes in the 13-week and 2-year dog studies was similar, the overall NOAEL was 100 ppm (equal to 3.4 mg/kg bw per day). The overall LOAEL was 600 ppm (equal to 21.3 mg/kg bw per day).

In a 105-week carcinogenicity study in mice, triforine was administered in the diet at a concentration of 0, 70, 700 or 7000 ppm (equal to 0, 11.4, 117 and 1204 mg/kg bw per day for males

and 0, 15.9, 161 and 1570 mg/kg bw per day for females, respectively). The NOAEL for systemic toxicity was 70 ppm (equal to 11.4 mg/kg bw per day), based on a slight decrease in body weight gain and changes in large intestine in males at 700 ppm (equal to 117 mg/kg bw per day) and above. In males, higher incidences of hepatocellular adenoma and carcinoma at 7000 ppm were within the historical control ranges and not associated with an increase in the incidence of preneoplastic changes. In females, incidences of alveolar/bronchiolar adenoma, carcinoma and adenoma plus carcinoma at 7000 ppm were statistically significantly increased; the incidence of adenoma was slightly higher than the historical control range, whereas the incidence of carcinoma was within the historical control range. The NOAEL for carcinogenicity was 700 ppm (equal to 161 mg/kg bw per day), based on an increased incidence of lung tumours (predominantly adenomas) in females at 7000 ppm (equal to 1570 mg/kg bw per day).

In a non-GLP-compliant 2-year study of carcinogenicity in rats, triforine was administered in the diet at a concentration of 0, 25, 125, 625 or 3125 ppm (equal to mean achieved doses of 0, 1.2, 6.2, 31.2 and 158.7 mg/kg bw per day for males and 0, 1.5, 7.8, 38.6 and 195.4 mg/kg bw per day for females, respectively). The NOAEL for toxicity was 625 ppm (equal to 31.2 mg/kg bw per day), based on evidence of haemolytic anaemia at 3125 ppm (equal to 158.7 mg/kg bw per day). Triforine was not carcinogenic in this study.

In a subsequent 2-year GLP-compliant study of toxicity and carcinogenicity in rats, triforine was administered in the diet at a concentration of 0, 200, 2000 or 20 000 ppm (equal to 0, 10.3, 101 and 1038 mg/kg bw per day for males and 0, 13.1, 136 and 1436 mg/kg bw per day for females, respectively). The NOAEL for toxicity was 200 ppm (equal to 10.3 mg/kg bw per day), based on evidence of haemolytic anaemia and related changes at 2000 ppm (equal to 101 mg/kg bw per day) and above. Triforine was not carcinogenic in this study.

The Meeting concluded that triforine is carcinogenic in female mice, but not in male mice or male or female rats.

Triforine was tested for genotoxicity in an adequate range of assays, both in vitro and in vivo. It did not induce gene mutation in bacterial and mammalian cell lines, and it did not induce unscheduled DNA synthesis or DNA repair in rat hepatocytes in vitro. Structural chromosomal aberrations were inducible in vitro, but not in vivo, in a mouse bone marrow micronucleus test.

The Meeting concluded that triforine is unlikely to be genotoxic in vivo.

In view of the lack of genotoxicity in vivo, the absence of carcinogenicity in male mice and male and female rats and the fact that an increased incidence of lung tumours (predominantly adenomas) was observed only in female mice at the highest dose tested, the Meeting concluded that triforine is unlikely to pose a carcinogenic risk to humans from the diet.

In a two-generation reproductive toxicity study in rats, triforine was administered in the diet at a concentration of 0, 500, 3000 or 20 000 ppm (equal to 0, 39.4, 252.5 and 1768.3 mg/kg bw per day for males and 0, 54.6, 323.3 and 2209.2 mg/kg bw per day for females, respectively). The NOAEL for reproductive toxicity was 20 000 ppm (equal to 1768.3 mg/kg bw per day), the highest dose tested. The NOAEL for parental toxicity was 500 ppm (equal to 39.4 mg/kg bw per day), based on reduced weight gain, increased spleen weight and haemosiderin deposition in spleen at 3000 ppm (equal to 252.5 mg/kg bw per day) and above. The NOAEL for offspring toxicity was 500 ppm (equal to 39.4 mg/kg bw per day), based on reduced preweaning body weight gain at 3000 ppm (equal to 252.5 mg/kg bw per day) and above.

In a study of developmental toxicity in rats dosed at 0, 200, 500 or 1000 mg/kg bw per day, the NOAEL for maternal and embryo/fetal toxicity was 1000 mg/kg bw per day, the highest dose tested. There was no evidence of teratogenicity.

In a developmental toxicity study in which Himalayan rabbits were dosed at 0, 5, 25 or 125 mg/kg bw per day, the NOAEL for maternal toxicity was 25 mg/kg bw per day, based on a reduction in feed consumption and body weight at 125 mg/kg bw per day during the first days of

treatment. The NOAEL for embryo and fetal toxicity was 125 mg/kg bw per day, the highest dose tested.

In a second developmental toxicity study in which New Zealand White rabbits were dosed at 0, 6, 30 or 150 mg/kg bw per day, the NOAEL for maternal toxicity was 30 mg/kg bw per day, based on reductions in feed consumption and body weight gain at 150 mg/kg bw per day. The NOAEL for embryo and fetal toxicity was 150 mg/kg bw per day, the highest dose tested.

In a third developmental toxicity study in which New Zealand White rabbits were dosed at 0 or 1000 mg/kg bw per day, a NOAEL for maternal toxicity and embryo/fetal toxicity was not identified, based on reductions in body weight gain and feed consumption in dams, a slight reduction in fetal weights and a delay in ossification in fetuses at 1000 mg/kg bw per day, the only dose tested. There was no evidence of teratogenicity.

The Meeting concluded that triforine is not teratogenic.

The Meeting concluded that triforine is not neurotoxic, based on the 90-day study in rats described previously.

In a 28-day dietary study in mice and rats, no immunotoxic effects were seen up to the highest dose tested (1115 mg/kg bw per day in both species).

The Meeting concluded that triforine is not immunotoxic.

Following a 28-day administration of triforine to mice at a dietary concentration of 7000 ppm (equal to 1555.3 mg/kg bw per day) and to rats at a dietary concentration of 20 000 ppm (equal to 1956.9 mg/kg bw per day), it was concluded that triforine does not have any marked stimulatory or inhibitory effect on hepatic xenobiotic metabolism and does not produce hepatic peroxisome proliferation in either species.

Toxicological data on metabolites and/or degradates

No metabolites or degradates have been identified in plants.

Human data

In reports on manufacturing plant personnel, no adverse health effects were noted, and no information on accidental or intentional poisoning in humans is available.

The Meeting concluded that the existing database on triforine was adequate to characterize the potential hazards to fetuses, infants and children.

Toxicological evaluation

The Meeting established an ADI of 0–0.03 mg/kg bw, derived from an overall NOAEL of 3.4 mg/kg bw per day from studies of toxicity in dogs. A safety factor of 100 was applied. The margin of exposure between the upper bound of the ADI and the LOAEL for lung tumours in female mice is greater than 50 000.

The Meeting established an ARfD of 0.3 mg/kg bw based on the NOAEL of 25 mg/kg bw per day for reduced body weight gain and reduced feed intake in dams in the first days after dosing in a rabbit developmental toxicity study. The Meeting considered the early reduction in feed intake at 25 mg/kg bw per day in this study as not relevant because it was transient, not associated with reduced body weight gain and not observed at 30 or 150 mg/kg bw per day in a second rabbit study. A safety factor of 100 was applied.

Levels relevant to risk assessment of triforine

Species	Study	Effect	NOAEL	LOAEL
Mouse	Two-year study of toxicity and carcinogenicity[a]	Toxicity	70 ppm, equal to 11.4 mg/kg bw per day	700 ppm, equal to 117 mg/kg bw per day
		Carcinogenicity	700 ppm, equal to 161 mg/kg bw per day	7 000 ppm, equal to 1 570 mg/kg bw per day
Rat	Two-year studies of toxicity and carcinogenicity[a,b]	Toxicity	200 ppm, equal to 10.3 mg/kg bw per day	2 000 ppm, equal to 101 mg/kg bw per day
		Carcinogenicity	20 000 ppm, equal to 1 038 mg/kg bw per day[c]	–
	Two-generation study of reproductive toxicity[a]	Reproductive toxicity	20 000 ppm, equal to 1 768.3 mg/kg bw per day[c]	–
		Parental toxicity	500 ppm, equal to 39.4 mg/kg bw per day	3 000 ppm, equal to 252.5 mg/kg bw per day
		Offspring toxicity	500 ppm, equal to 39.4 mg/kg bw per day	3 000 ppm, equal to 252.5 mg/kg bw per day
	Developmental toxicity study[d]	Maternal toxicity	1 000 mg/kg bw per day[c]	–
		Embryo and fetal toxicity	1 000 mg/kg bw per day[c]	–
Rabbit	Developmental toxicity study[d]	Maternal toxicity	25 mg/kg bw per day	125 mg/kg bw per day
		Embryo and fetal toxicity	125 mg/kg bw per day[c]	–
Dog	Thirteen-week and 2-year studies of toxicity[a,b]	Toxicity	100 ppm, equal to 3.4 mg/kg bw per day	600 ppm, equal to 21.3 mg/kg bw per day

[a] Dietary administration.

[b] Two or more studies combined.

[c] Highest dose tested.

[d] Gavage administration.

Estimate of acceptable daily intake (ADI)

0–0.03 mg/kg bw

Estimate of acute reference dose (ARfD)

0.3 mg/kg bw

Information that would be useful for the continued evaluation of the compound

Results from epidemiological, occupational health and other such observational studies of human exposure

Critical end-points for setting guidance values for exposure to triforine

Absorption, distribution, excretion and metabolism in mammals	
Rate and extent of oral absorption	Rapid; absorption is ~80% at low dose and 10–20% at high dose
Dermal absorption	No data
Distribution	Widely distributed
Potential for accumulation	None
Rate and extent of excretion	Rapid; at low dose, ~75% within 24 hours, mainly via urine; at high dose, 77–85% via faeces within 168 hours
Metabolism in animals	Extensively metabolized; cleavage of side-chain, followed by oxidation and conjugation with glucuronic acid or glutathione
Toxicologically significant compounds in animals and plants	Triforine
Acute toxicity	
Rat, LD_{50}, oral	> 5 000 mg/kg bw
Rat, LD_{50}, dermal	> 2 000 mg/kg bw
Rat, LC_{50}, inhalation	> 5.12 mg/L
Rabbit, dermal irritation	Not irritating
Rabbit, ocular irritation	Not irritating
Guinea-pig, dermal sensitization	Not sensitizing (Maurer optimization test)
Short-term studies of toxicity	
Target/critical effect	Haematopoietic system / haemolytic anaemia
Lowest relevant oral NOAEL	3.4 mg/kg bw (dog)
Lowest relevant dermal NOAEL	1 100 mg/kg bw, highest dose tested (rat)
Lowest relevant inhalation NOAEC	No data
Long-term studies of toxicity and carcinogenicity	
Target/critical effect	Haematopoietic system / haemolytic anaemia
Lowest relevant NOAEL	10.3 mg/kg bw per day (rat)
Carcinogenicity	Lung tumours in female mice; unlikely to pose a carcinogenic risk to humans from the diet
Genotoxicity	
	Unlikely to be genotoxic in vivo
Reproductive toxicity	
Target/critical effect	No reproductive effect
Lowest relevant parental NOAEL	39.4 mg/kg bw per day
Lowest relevant offspring NOAEL	39.4 mg/kg bw per day
Lowest relevant reproductive NOAEL	1768.3 mg/kg bw per day, highest dose tested
Developmental toxicity	
Target/critical effect	None
Lowest relevant maternal NOAEL	25 mg/kg bw per day (rabbit)
Lowest relevant embryo/fetal NOAEL	125 mg/kg bw per day, highest dose tested (rabbit)
Neurotoxicity	
Acute neurotoxicity NOAEL	No data
Subchronic neurotoxicity NOAEL	1334 mg/kg bw per day, highest dose tested

Developmental neurotoxicity NOAEL	No data
Other toxicological studies	
Immunotoxicity NOAEL	1115 mg/kg bw per day, highest dose tested
Medical data	
	No adverse health effects reported in workers at triforine manufacturing plants

Summary

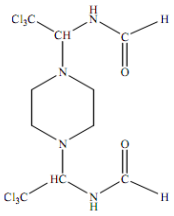
	Value	Study	Safety factor
ADI	0–0.03 mg/kg bw	Thirteen-week and 2-year studies of toxicity (dog)	100
ARfD	0.3 mg/kg bw	Developmental toxicity study (rabbit)	100

RESIDUE AND ANALYTICAL ASPECTS

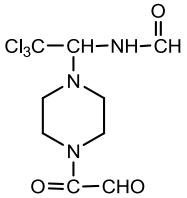
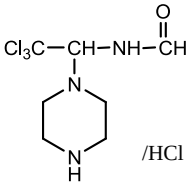
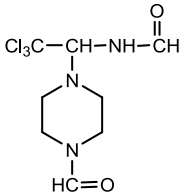
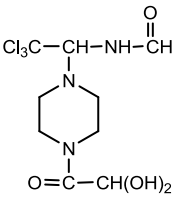
Triforine is a systemic fungicide for control of powdery mildews, rusts, scabs and rots. It was first evaluated by JMPR in 1977 (T), 1978 (T, R) and lastly in 1997 (T). The ADI for Triforine was 0–0.02 mg/kg bw and no ARfD was recommended by the previous JMPR. Triforine was scheduled at the Forty-fifth Session of the CCPR (2013) for the periodic re-evaluation of toxicity and residues by the 2014 JMPR.

The Meeting received information on identity, physical and chemical properties, animal and plant metabolism, environmental fate in soil, analytical methods, storage stability, use patterns, supervised trials, farm animal feeding studies and fates of residues in processing.

N,N'-{piperazine-1,4-diylbis[(trichloromethyl)methylene]}diformamide



In this appraisal, the following abbreviated names were used for metabolites.

WOS 2379	W 1084/W 1069	W 625	W 2379
			
N-{2,2,2-trichloro-1-[4-(2-oxoacetyl)piperazin -1-yl] ethyl}formamide	*N*-(2,2,2-trichloro-1-piperazin-1-yl-ethyl) formamide/ hydrochloride	*N*-[2,2,2-trichloro-1-(4-formyl piparazin-1-yl) ethyl]formamide	Hydrate of *N*-{2,2,2-trichloro-1-[4-(2-oxoacetyl)piperazin -1-yl] ethyl}formamide

Animal metabolism

The Meeting received animal metabolism studies with triforine in rats, lactating goat and laying hens. The metabolism and distribution of triforine in animals were investigated using the [^{14}C-piperazine] and [^{14}C-side chain]-labelled triforine.

Metabolism in rats was summarized and evaluated by the WHO panel of the JMPR in 2014.

Triforine is rapidly metabolized and excreted in rats. Highest residues were found in liver followed by kidney. Residues were lower in muscle and fat. Radioactive residues were identified in the excreta only. *N*-[2,2,2-trichloro-1-(piperazin-1-yl) ethyl]-formamide (W 1084), which is formed by the cleavage of a side chain, was the major component in urine of rats. It was excreted in urine as the glucuronide. The side-chain metabolites trichloroethanol including its glucuronide and *N*-acetylcysteine conjugate of 2,2,2-trichloroethylamine was detected in urine. W 1084 and triforine were detected in the faeces of rats.

Lactating goats were administered with [piperazine-^{14}C]-triforine as an oral dosage equivalent to a dietary level of 250 or 1000 ppm once daily for 3 consecutive days. The goats were sacrificed 4 hours or 6 days after the last treatment.

Radioactivity administered to the goats was rapidly eliminated in urine and faeces. A total of 47% and 72% of the applied radioactivity were eliminated in 24 hours, and a further 16 and 14% were excreted in the following 5 days by the 250 ppm and the 1000 ppm dose group goats, respectively.

Up to 68% of the residual radioactivity in the liver of goat sacrificed 4 hours after the last treatment was extracted. The extracted radioactivity consisted of at least five metabolite fractions. M1 and M2 represented unknown polar metabolite fractions whereas WOS 2379 and W 1084 were characterized. The fraction M1 represented 18% TRR. Triforine, WOS 2379 and W 1084 accounted for 15%, 15% and 13% TRR, respectively. Up to 14% of the residual radioactivity in the liver of goat sacrificed 6 days after the last treatment was extracted. This metabolite pattern was similar to that in the extracted radioactivity of the liver of goat sacrificed 4 hours after the last treatment.

Seventy-eight percent of the residual radioactivity in the kidneys of goats sacrificed 4 hours after the last treatment was extracted. The metabolite pattern of the extracted radioactivity was similar to that in the extracted radioactivity of the liver. The predominant fraction found in the extracted radioactivity of goat sacrificed 4 hours after the last treatment was metabolite fraction M1 (31% TRR). Triforine, WOS 2379 and W1084 represented 19%, 8.4% and 19% TRR, respectively. Analysis of the extracted radioactivity of the kidneys of a goat sacrificed 6 days after the last treatment showed a similar metabolite pattern in terms of their relative amounts in the extracts. The predominant fraction was M1 accounting for 11% TRR. Triforine represented 3.6% TRR.

Seventy-nine percent of the residual radioactivity in the muscle of goat sacrificed 4 hours after the last treatment was extracted. The predominant radioactive fraction was triforine at 41% TRR. The other metabolites accounted for 9.5% (W 1084), 13% (WOS 2379), 0.70% (M2) and 15% TRR (M1).

In one study, laying hens were orally administered with [piperazine-^{14}C]-triforine at the dietary dose equivalent to 500 or 2000 ppm in the feed once daily for 3 consecutive days. The hens were sacrificed 4 hours or 7 days after the last treatment.

The radioactivity administered to the hens was rapidly eliminated (54–84% in 56 hours after the first dose). In the following 7 days a further 10–15% of the administered radioactivity was excreted (76% excreted from 500 ppm dosed hens and 94% from 2000 ppm dosed hens).

The highest values in eggs were found about 4 to 5 days after the first treatment with [^{14}C] triforine.

In the other study, laying hens were administered with [side chain-^{14}C]-triforine for 10 consecutive days at a dose of 32 ppm in the feed. Radioactivity recovered in excreta during the 10 days accounted for about 85% of the total cumulative dose.

Total radioactivity in eggs increased steadily during the 10 days to a peak value of 1.6 mg equiv/kg (yolk) and 0.19 mg equiv/kg (white). The major components in egg white and egg yolk were the fraction A which accounted for 48% TRR (0.08 mg/kg) and the sulphate conjugate of trichloroethanol which accounted for 25% TRR (0.25 mg/kg), respectively. W 1069 was observed and accounted for 10% TRR (0.10 mg/kg) in egg yolk. Triforine accounted for 13% TRR(0.02 mg/kg) and 2.1% TRR(0.02 mg/kg) in egg white and egg yolk, respectively.

The fraction A in the protease-treated extract of liver was separated into five components each of which accounted for 0.07–0.40 mg equiv/kg (4–24% TRR). The sulphate conjugate of trichloroethanol was present in liver accounting for 9% TRR. There appeared to be a small amount of triforine in liver (2.9% TRR, 0.05 mg/kg).

The main components in muscle were the trichloroethanol sulphate conjugate and W 1069 each accounting for about 22% TRR (0.05 mg equiv/kg). Triforine was present at 8.4% TRR (0.02 mg/kg).

Triforine accounted for 18% TRR (0.02 mg/kg) and the sulphate conjugate of trichloroethanol accounted for 36% TRR (0.03 mg equiv/kg) in fat.

Triforine was also found in skin at low levels (0.01 mg/kg). The retention time of the main fraction corresponded to that of trichloroethanol sulphate (56% TRR, 0.13 mg/kg).

In animal metabolism studies, triforine, W 1084/W 1069, WOS 2379 and trichloroethanol sulphate were predominantly found in tissues of lactating goats and laying hens. The major component in milk and egg white was the polar fraction consisting of several components but they were not identified. Triforine was identified in egg white and egg yolk. Excretion, distribution and triforine and its metabolites found in excreta of lactating goats and laying hens were similar to those in rats.

Plant metabolism

The Meeting received plant metabolism studies performed on apples, tomatoes and cucumber with triforine ^{14}C-labelled in two carbons at the side chain, and on barley with triforine ^{3}H-labelled at piperazine ring ([side chain-^{14}C] and [piperazine-^{3}H]).

In an outdoor apple metabolism study, a number of fruits or leaves of apple were treated at random on the surface with [side chain-^{14}C]-triforine at a rate of 1.2 g ai/L in a series of small droplets. Treated apple fruits were harvested 2 weeks after the last of five successive applications with 8-day intervals. After five successive applications of [^{14}C] triforine, 32% (fruit) and 22% (leaf) of the applied radioactivity were recovered. On an average, 1.36 mg equiv/kg was recovered in the treated fruits.

The major component in the surface washes and extracts of fruits was identified as triforine accounted for 73–79% TRR (0.88–1.2 mg/kg) two weeks after the last application. Several minor components were observed in the extracts and each of them accounted for 1–2% TRR.

In an indoor tomato metabolism study, a number of fruits or leaves of tomato were treated at random on the surface with [side chain-^{14}C]-triforine at a rate of 1.2 g ai/L in a series of small droplets. The treated tomatoes were harvested at 2 hours and 3 days after the last of four successive applications with 8–10 days intervals. The initial surface washes of treated tomatoes at harvest contained, on an average, 92% (2 hours after the last application) and 91% (3 days after the last application) of TRR. Acetonitrile extracts of washed and homogenised tomatoes accounted for, on an average, 5.8% TRR (2 hours after the last application) and 6.2% TRR (3 days after the last

application). The TRR from the treated tomatoes accounted for, on an average, 16 (2 hours after the last application) and 9.7 (3 day after the last application) mg equiv/kg.

Triforine in the surface washes and extracts accounted for 91–93% TRR (7.6–19 mg/kg) in tomatoes taken at 2 hours and 3 days after the final application of [^{14}C] triforine. The extracts also contained several minor components each accounting for, on an average, 0.05–1.1% TRR.

In an indoor cucumber metabolism study, a number of fruits or leaves of cucumber were treated at random on the surface with [side chain-^{14}C]-triforine at a rate of 1.2 g ai/L in a series of small droplets. The treated cucumbers were harvested 3 days after the last of four successive applications at 7-day intervals. The surface washes of treated cucumbers at harvest contained, on an average, 85% of TRR. Extracts of washed and homogenised cucumber peel and flesh accounted for, on an average, 7.5% TRR (peel) and 1.4% TRR (flesh). The TRR from the treated cucumbers accounted for, on an average, 2.2 mg equiv/kg.

The major radioactive component was identified as triforine in the surface washes and extracts accounted for 87–88% TRR (1.9 mg/kg) in cucumber taken 3 days after the final application of [^{14}C] triforine. The extracts also contained several minor components each accounting for means of 0.3–2% TRR.

In the first indoor barley metabolism study, [piperazine-^{3}H]-triforine was applied to barley plants grown in plastic pots as soil drenching. The leaves were harvested at 15 and 30 days after treatment.

Triforine was identified as a major component in the barley leaves, amounting to 58% TRR at 15 days after the treatment and 43% TRR at 30 days after the treatment. W 1084 was also observed in the 0.1M HCl extract (8.4–13% TRR).

In the second indoor barley metabolism study, the leaves of barley plants root-treated with [piperazine-^{3}H]-triforine were collected 30 days after treatment. The major component was identified as triforine, accounted for 45% TRR, and W 1084 and piperazine were also observed.

In the third outdoor barley metabolism study, the plants (during the stem extension stage when the second node of the stem was formed and the next-to-last leaf was just visible) were sprayed with an aqueous emulsion of a mixture of the commercial formulation of triforine and [piperazine-^{3}H]-triforine at a rate of 0.25 kg ai/ha. Barley was harvested when ripe, and straw and grain were analysed separately.

The methanol soluble radioactive residue contained triforine and its metabolites which were free in barley straw and grain. Triforine accounted for 0.034 mg/kg (18% TRR) in straw and 0.0018 mg/kg in grain (13% TRR). W 1084 was identified as a minor component. Two other radiolabelled components were identified in straw: glycine at 0.043 mg/kg (33% TRR) and iminodiacetic acid at 0.021 mg/kg (17% TRR), respectively.

In the plant metabolism studies, triforine was the major component of the residues found in all plants studied.

Environmental fate

The Meeting received information on aerobic degradation in soil, photolysis on soil surface and hydrolytic degradation study.

In soil under the aerobic conditions, the DT_{50} ranged from 1–70 days at 20 °C. Many minor degradation products were detected in the extracts during the study. Most of the radioactivity was recovered from natural components. Mineralization was up to 45%. Minor degradates were identified as W 625, WOS 2379, piperazine and W 1069, but all of them were less than 3% TAR.

In soil photolysis study, the degradation was biphasic. The photodegradation half-life of triforine was 11 hours of artificial sunlight or 0.5 natural sunlight days for phase 1 (hours 0 to 8). For

phase 2 (hours 8 to 48), the half-life was 71 hours of artificial sunlight equivalent to 3.2 natural sunlight days.

In summary, triforine was rapidly and completely degraded in soil and is unlikely to be taken up by crops from the soil after soil treatment.

Methods of analysis

The Meeting received description of validation data on analytical methods for residues of triforine in plant and animal commodities.

In most of the methods for the determination of triforine in plant, homogenized samples were extracted with acetone, and the extract was partitioned into organic solvent and the active substance was degraded by heating with dilute sulphuric acid. Chloral hydrate thus formed was determined by GC-ECD. The methods of analysis with GC-ECD for a range of matrices were validated with acceptable recoveries with the LOQs of 0.01 mg/kg for triforine.

New methods using LC-MS or LC-MS/MS were developed for analysing triforine directly. In the methods, homogenized samples were extracted with acetone, and the extract was purified with SPE cartridge clean-ups. The methods of analysis with LC-MS or LC-MS/MS for a range of matrices were validated with acceptable recoveries with the LOQs of 0.01 mg/kg except for tomato paste for which the LOQ was 0.05 mg/kg.

In the methods for animal commodities, homogenized samples were extracted with acetone, or were diluted with water. Triforine and possible metabolites containing the Cl_3C-CH group in the acetone extract or diluted homogenate were degraded by heating with dilute sulphuric acid. Chloral hydrate thus formed was determined by GC-ECD. These methods were validated with acceptable recoveries with the LOQ of 0.001–0.003 mg/kg for milk and animal tissues, and 0.01 mg/kg for egg.

The Meeting was aware that the QuEChRS-multi residue method was validated for most plant matrices with LOQs of 0.01–0.02 mg/kg for triforine.

Stability of residues in stored analytical samples

The Meeting received information on the freezer storage stability of triforine in plant (apples, cherries, plums, peaches, blueberries and hops) and their processed (beer) commodities. Analysis was done by the common moiety method.

Using the common moiety method, storage stability results indicated that residues with common moiety including triforine were stable for at least 1 month in processed hops (beer), at least 6 months in plums and hops (dried cones), at least 12 months in apples, cherries, peaches and blueberries. However, according to the result of plant metabolism study on tomato, triforine seems stable for at least 5 months.

Definition of the residue

In the lactating goat metabolism studies, TRRs in liver and kidney were higher than those in milk, muscle and fat. Triforine, WOS 2379 and W 1084 accounted for 15%, 15% and 13% TRR in liver, and 19%, 8.4% and 19% TRR in kidney. The polar unknown fraction M1 represented 18% TRR in liver and 31% TRR in kidney. In the laying hen metabolism studies, TRR in liver was also higher than those in other tissues. In the study using [side chain-^{14}C]-triforine, the trichloroethanol sulphate conjugate and W 1069 were the main components in muscle (22% TRR) and egg yolk (10–25% TRR).

The analytical methods for animal commodities provided determine only the residues of triforine and metabolites containing the Cl_3C-CH group converted to chloral hydrate which is formed by heating in acidic condition. No method of analysis was available for quantification of triforine alone.

The Meeting decided that triforine and its metabolites containing the Cl_3C-CH group were suitable analytes for enforcement purposes and dietary risk assessment for animal commodities.

The octanol/water coefficient (log P_{ow}) of triforine was 2.2 at 20 °C. In the lactating goat and the laying hen metabolism studies, triforine and its metabolites found in muscle were 2–100 times higher than those in fat. Fractionation of whole milk showed that 32% of the radioactivity was found in cream and 76% was found in skim milk. In the lactating goat feeding study, triforine and its metabolites were detected at 0.003–0.007 mg/kg in liver, kidney and muscle but less than LOQ (< 0.003 mg/kg) in fat. The Meeting considered the residue of triforine is not fat soluble.

In plant metabolism studies, parent triforine was the major component (43–93% TRR) in apple, tomato, cucumber and barley. Several metabolites identified accounted for < 10% TRR.

In most of the analytical methods for triforine in plant, since chloral hydrate formed by heating with dilute sulphuric acid was quantified with GC-ECD, triforine and its metabolites containing piperazine ring were simultaneously measured. As the predominant residue was the parent compound in the plant metabolism study, using the common moiety method would result in only slight over-estimation of residues if PHI was short. Recently LC-MS and LC-MS/MS methods were available for determining triforine only.

The Meeting decided that parent triforine was a suitable analyte for enforcement purposes and dietary risk assessment in plant commodities.

The Meeting recommended the following residue definition:

Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant commodities: *Triforine*

Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for animal commodities: *Triforine and its metabolites determined as chloral hydrate expressed as triforine*

The residue is not fat soluble

Residue of supervised residue trials on crops

The Meeting received supervised trial data for the foliar application of triforine on apple, pear, cherry, plum, apricot, nectarine, peach, raspberry, blueberry, black currant, grape, cranberry, strawberry, cucumber, squash, melon, peppers, eggplant, tomato, common bean, barley and wheat. Residue trials were conducted in Australia, Brazil, Canada, Denmark, France, Germany, Greece, Hungary, Italy, Japan, Mexico, New Zealand, South Africa, South Korea, the United Kingdom (UK) and the USA. Most of the supervised residue trials employed the common moiety method, while the results of plant metabolism studies showed that triforine was the main component of residues in crops.

Labels were available from a number of countries in North and South America, Africa, Asia and Oceania describing the registered uses of triforine.

Pome fruits

Apple

Data were available from supervised trials conducted on apples in the USA, Canada, Australia, Germany, France and Brazil.

The GAP on apples in Canada was five foliar applications at a maximum rate of 0.475 kg ai/ha between tight cluster and petal fall stage. Trials in the USA and Canada on apples were conducted with foliar applications of EC formulation. Triforine residues in apple from the trials in Canada matching GAP of Canada were (n=1): 0.041 mg/kg.

Trials in Australia on apples were conducted with one to ten foliar applications of EC formulation (GAP: four foliar applications at a maximum spray concentration of 0.023 kg ai/hL with a PHI of 1 day). Triforine residue trials on apples in the Australia did not match the GAP of Australia.

Trials in Germany and France on apples were conducted with foliar applications of EC formulation. No GAP from European countries was available for apple.

The GAP on apples from Brazil was three foliar applications at a maximum concentration of 0.024 kg ai/hL with a PHI of 5 days. Triforine residues in apple from the trials in Brazil matching Brazilian GAP were (n=2): < 0.02 mg/kg (2).

As the data were insufficient for estimating a maximum residue level, the Meeting agreed to withdraw its previous recommendation for apple.

Pear

Data were available from a supervised trial on pears in Australia. No GAP from Australia was available for pear.

The Meeting agreed that estimation of maximum residue level was not possible for pear.

Stone fruits

Cherry

Data were available from supervised trials on cherries conducted in the USA, Canada and Germany.

The GAP on cherries in Canada was for three foliar applications at a maximum spray concentration of 0.014 kg/hL or a rate of 0.475 kg ai/ha between early and full bloom stages. Triforine residue in cherries from the trials in Canada and the USA matching GAP of Canada was (n=1): 0.007 mg/kg.

Trials in Germany on cherries were conducted with foliar applications of an EC formulation. No GAP from European countries was available for cherries.

The Meeting agreed to withdraw its previous recommendation for cherries.

Plum

Data were available from supervised trials on plums conducted in the USA, Canada, Germany, France and South Africa.

The GAP on plums in Canada is for three foliar applications at a maximum spray concentration of 0.014 kg/hL or a rate of 0.475 kg ai/ha between early and full bloom stages. No trials on plums in Canada and the USA matched the GAP of Canada.

Trials in Germany and France were conducted with foliar applications of an EC formulation. No GAP from European countries was available for plums.

The GAP on plums in South Africa was two foliar applications at a rate of 0.87 kg ai/ha with a PHI of 3 days. No trials for plums in South Africa matched the GAP of South Africa.

The Meeting agreed to withdraw its previous recommendation for plums.

Apricot

Data were available from supervised trials on apricots from the USA, France, Greece and Italy.

Trials in the USA on apricots were conducted with one to three foliar applications of an EC formulation at a spray concentration of 0.018 kg ai/hL. No GAP of the USA was available.

Trials in France, Greece and Italy on apricots were conducted with three foliar applications of DC formulation at a spray concentration of 0.038 kg ai/hL. No GAP from European countries was available for apricots.

The Meeting agreed that estimation of maximum residue level was not possible for apricots.

Nectarine

Data were available from supervised trials on nectarines from the USA.

Trials in the USA on nectarines were conducted with one to four foliar applications of an EC formulation at a spray concentration of 0.015–0.018 kg ai/hL. No GAP from the USA was available.

The Meeting agreed that the estimation of maximum residue level was not possible for nectarines.

Peach

Data were available from supervised trials on peaches from the USA, Canada, France, Greece, Japan, Brazil and South Africa.

The GAP on peaches in Canada is three foliar applications at a maximum spray concentration of 0.014 kg/hL or a rate of 0.475 kg ai/ha between early and full bloom stages. Triforine residue in peaches from trials in Canada and the USA matching GAP of Canada was (n=1): 0.02 mg/kg.

The GAP on peaches in Brazil is for three foliar applications at a maximum spray concentration of 0.024 kg ai/hL with a PHI of 3 days. Triforine residues in peaches from trials in Brazil matching GAP were (n=2): < 0.01 and 9.4 mg/kg.

Trials in France and Greece on peaches were conducted with one to eight foliar applications of a DC formulation at a rate of 0.36–0.38 kg ai/ha. No GAP from European countries was available for peaches.

The GAP on peaches in South Africa is two foliar applications at a maximum rate of 0.67 kg ai/ha with a PHI of 3 days. No trials from South Africa on peaches matched the GAP of South Africa.

The GAP on peaches in Japan is five foliar applications at a maximum spray concentration of 0.018 kg ai/hL with a PHI of 1 day. Triforine residues in peaches from the trials in Japan matching GAP of Japan were (n=2): 0.77 and 1.4 mg/kg.

The Meeting considered the data insufficient for the estimation of a maximum residue level, and agreed to withdraw its previous recommendation for peaches.

Berries and other small fruits

Raspberries, Red, black

Data were available from supervised trials on raspberries in France. No GAP from European countries was available for raspberry.

The Meeting agreed that estimation of maximum residue level was not possible for raspberry.

Blueberries

Data were available from supervised trials on blueberries in Canada.

The GAP on blueberries in Canada (except for Eastern Canada) is four foliar applications at a maximum rate of 0.570 kg ai/ha from bud break to 10–14 days after early bloom with a PHI of 60 days. Triforine residues in blueberries from the trials conducted in Canada (except for Eastern Canada) matching this GAP were (n=2): < 0.01 and 0.015 mg/kg.

The GAP for Eastern Canada (only) is three foliar applications at a maximum rate of 0.570 kg ai/ha from leaf-bud break to pink-bud stage with a PHI of 60 days. Triforine residues in blueberries from the trials conducted in Eastern Canada matching this GAP were (n=3): < 0.01(3) mg/kg.

Based on the trials on blueberries in Canada, the Meeting estimated a maximum residue level of 0.03 mg/kg to replace its previous recommendation (1 mg/kg) for blueberry. The Meeting also estimated an STMR and an HR for triforine in blueberry of 0.01 and 0.018 mg/kg, respectively. The highest residue concentration in an individual sample was selected for HR.

Currant, Black

Data were available from supervised trials on black currants in Germany and UK. No GAP from European countries was available for black currants.

The Meeting agreed to withdraw its previous recommendation for black currants.

Grapes

Data were available from supervised trials on grapes from Germany, Mexico and New Zealand.

Trials in Germany on grapes were conducted with one to three foliar applications of an EC formulation at a rate equivalent to 0.28–0.57 kg ai/ha. No GAP from European countries was available for grapes.

Trials in Mexico on grapes were conducted with one foliar application of EC formulation at a rate equivalent to 0.28 kg ai/ha. No GAP from Mexico was available for grapes.

The GAP on grapes in New Zealand is four foliar applications at a rate of at least 0.38 kg ai/ha with a PHI 14 days. No trials in New Zealand on grapes matched the GAP of New Zealand.

The Meeting agreed that estimation of maximum residue level was not possible for grapes.

Cranberry

Data were available from supervised trials on cranberries from the USA.

The GAP on cranberries in Canada was three foliar applications at a maximum rate of 0.570 kg ai/ha with a PHI of 60 days. No trials for cranberries from the USA matching the GAP of Canada were available.

The Meeting agreed that estimation of maximum residue level was not possible for cranberry.

Strawberry

Data were available from supervised trials on strawberries from Mexico, Brazil and Japan.

The GAP on strawberries in Mexico was four foliar applications at a maximum rate of 0.19 kg ai/ha with a PHI of 14 days. Triforine residue in strawberries from the trials in Mexico matching GAP of Mexico was (n=1): 0.57 mg/kg.

The GAP on strawberries in Brazil was four foliar applications at a maximum rate of 0.23 kg ai/ha with a PHI of 2 days. No trials in Brazil on strawberries matched the GAP of Brazil.

The GAP on strawberries in Japan is five foliar applications at a spray concentration equivalent to 0.009 kg ai/hL with a PHI of 1 day. Triforine residues in strawberries from the trials in Japan matching GAP of Japan were (n=4): 0.20, 0.39, 0.48 and 0.78 mg/kg.

The Meeting considered that the data was insufficient for estimating a maximum residue level, the Meeting agreed to withdraw its previous recommendation for strawberry.

Gooseberry

No supervised trials on gooseberry were available.

The Meeting agreed to withdraw its previous recommendation for gooseberry.

Brassica vegetables

Brussels sprouts

No supervised trials on Brussels sprouts were available.

The Meeting agreed to withdraw its previous recommendation for Brussels sprouts.

Fruiting vegetables, Cucurbits

Cucumber

Data were available from supervised trials on cucumbers from the USA, Canada, Mexico, Hungary, France and Germany.

Trials from the USA on cucumbers were conducted with four or five foliar applications of an EC formulation at a rate equivalent to 0.29–0.57 kg ai/ha. No GAP from the USA was available for cucumber.

One trial in Canada on cucumbers was conducted with one foliar application of an EC formulation at a rate of 0.29 kg ai/ha. No GAP from Canada was available for cucumber.

The GAP on cucumbers in Mexico is three foliar applications at a maximum rate of 0.29 kg ai/ha with a PHI of 7 days. Triforine residue in cucumber from a trial in Mexico matching the GAP of Mexico was (n=1): 0.066 mg/kg.

Trials in Hungary, France and Germany on cucumbers were conducted but no GAP from European countries were available.

The Meeting considered that the data was insufficient for estimating a maximum residue level for cucumbers.

Squash

Data were available from supervised trials on summer squash and winter squash from the USA, France and Germany. No GAP from the USA or European countries was available for squash.

The Meeting agreed that estimation of maximum residue level was not possible for squash.

Melon

Data were available from supervised trials on melon from the USA, Mexico, France, Italy and Japan.

Trials in the USA on melons were conducted with one or five foliar applications of an EC formulation at a rate of 0.23–0.46 kg ai/ha. No GAP from the USA was available for melons.

The GAP on melons in Mexico is three foliar applications at a maximum rate of 0.29 kg ai/ha with a PHI of 7 days. Triforine residue in melon from one trial in Mexico matching GAP of Mexico was (n=1): 0.039 mg/kg.

Trials from Italy and France on melon were conducted with one or four foliar applications of an EC formulation at a rate of 0.20–0.29 kg ai/ha. No GAP from European countries was available for melons.

The GAP on melon in Japan is six foliar applications at a spray concentration of 0.009 mg/hL with a PHI of 1 day. Triforine residues in melon from the trials in Japan were (n=2): < 0.005 and 0.006 mg/kg.

The Meeting considered the data was insufficient for estimating a maximum residue level for melons.

The Meeting agreed to withdraw its previous recommendation for fruiting vegetables, cucurbits.

Fruiting vegetables, other than Cucurbits

Peppers

Data were available from supervised trials on peppers from Mexico, Japan and South Korea.

The GAP on peppers in Mexico is three foliar applications at a maximum rate of 0.29 kg ai/ha with a PHI of 14 days. Triforine residue in peppers from the trials in Mexico matching GAP of Mexico was (n=1): 0.12 mg/kg.

The GAP on peppers in Japan is three foliar applications at a spray concentration of 0.018 kg ai/hL with a PHI of 14 days. Triforine residues in peppers from trials in Japan matching GAP of Japan were (n=2): 0.06 and 0.22 mg/kg.

The GAP on chili peppers in South Korea is two foliar applications at a spray concentration equivalent to 0.019 kg ai/ha with a PHI of 7 days. Tis residue in peppers from the trial in South Korea matching GAP of South Korea was (n=1): 0.35 mg/kg.

The Meeting considered that the data was insufficient for estimating a maximum residue level for peppers.

Egg plant

Data were available from supervised trials on egg plants in Mexico and Japan.

The GAP on egg plants in Mexico is three foliar applications at a maximum rate of 0.29 kg ai/ha with a PHI of 15 days. Triforine residue in egg plants from a trial in Mexico matching GAP of Mexico was (n=1): 0.066 mg/kg.

The GAP on eggplants in Japan is five foliar applications at a spray concentration of 0.018 kg ai/hL with a PHI of 1 day. Triforine residues in egg plants from the trials in Japan matching GAP of Japan were (n=5): 0.25, 0.28, 0.29, 0.38 and 0.39 mg/kg.

Based on the trials on egg plants in Japan, the Meeting estimated a maximum residue level, an STMR and an HR for triforine in egg plants of 1, 0.29 and 0.39 mg/kg, respectively.

Tomato

Data were available from supervised trials on tomatoes in the USA, Mexico, Denmark and Japan.

One trial from Denmark on tomatoes was conducted with one foliar application of EC formulation at a rate equivalent to 0.95 kg ai/ha. No GAP of European countries were available for tomatoes.

The GAP on tomatoes in Japan was three foliar applications at a spray concentration of 0.018 kg ai/hL with a PHI of 1 day. Triforine residues in tomatoes from trials in Japan matching GAP of Japan were (n=5): 0.14, 0.17, 0.26, 0.28 and 0.56 mg/kg.

The GAP on tomatoes in Mexico is four foliar applications at a maximum rate of 0.38 kg ai/ha with a PHI of 3 days. Triforine residues in tomatoes from the trials in Mexico matching GAP of Mexico were (n=5): 0.083, 0.096, 0.13, 0.27 and 0.40 mg/kg.

Trials from the USA on tomatoes were conducted with four or five foliar applications of an EC formulation at a rate of 0.18–0.41 kg ai/ha. Triforine residues in tomatoes from the trials in the USA matching GAP of Mexico were (n=3): 0.072, 0.17 and 0.28 mg/kg.

The Meeting decided to use the triforine residue data from the trials in Mexico and the USA. Triforine residues in tomatoes from the trials in Mexico and the USA matching GAP of Mexico were (n=8): 0.072, 0.083, 0.096, 0.13, 0.17, 0.27, 0.28, 0.40 mg/kg.

Based on the data, the Meeting estimated a maximum residue level of 0.7 mg/kg to replace its previous recommendation (0.5 mg/kg). The Meeting also estimated an STMR and an HR for triforine in tomato of 0.15 and 0.40 mg/kg, respectively.

Legume vegetables

Common bean

Data were available from supervised trials on common beans from Brazil and South Africa.

The GAP on beans in Brazil is three foliar applications at a maximum rate of 0.29 kg ai/ha with a PHI of 10 days. Triforine residue in bean seeds from the trials in Brazil matching GAP of Brazil was (n=1): < 0.01 mg/kg.

The GAP on beans in South Africa is for foliar application(s) with spray at a rate of 0.29 kg ai/ha with a PHI of 3 days (the maximum numbers of applications not specified). Triforine residue in beans from one trial in South Africa matching GAP of South Africa was (n=1): 0.44 mg/kg.

As the available data was insufficient for estimating a maximum residue level, the Meeting agreed to withdraw its previous recommendation for common bean (pods and immature seeds).

Cereal grains

Data were available from supervised trials on barley in France. No GAP from European countries was available for barley.

Data were available from supervised trials on wheat in Austria, France, UK and Brazil. No GAP from European countries and Brazil was available for wheat.

No other information was available for any other cereal grains.

The Meeting agreed that the estimation of maximum residue level was not possible for cereal grains.

The Meeting agreed to withdraw its previous recommendation for cereal grains.

Animal feedstuffs

Barley straw and forage

Data were available from supervised trials on barley straw and forage in France. No GAP from European countries was available for barley straw and forage.

The Meeting agreed that the estimation of a maximum residue level was not possible for barley straw and forage.

Wheat straw and forage

Data were available from supervised trials on wheat straw and forage in France and UK. No GAP from European countries was available for wheat straw and forage.

The Meeting agreed that the estimation of a maximum residue level was not possible for wheat straw and forage.

Fate of residues during processing

Residues in processed commodities

The fate of triforine residues following the processing of plums, grapes and tomatoes was made available to the Meeting. Estimated processing factors and the derived STMR-Ps are summarized in the Table below.

Processing factors, STMR-P for food

Raw agricultural commodity (RAC)	Processed commodity	Calculated processing factors [a]	PF (Mean or best estimate)	RAC STMR (mg/kg)	STMR-P (mg/kg)
Tomato	Juice	0.74 [b], 0.76 [b]	0.75	0.15	0.11
	Paste	< 0.008	< 0.008		< 0.001
	Puree	0.14, 2.3 [b], 2.6 [b]	2.3		0.35
	Wet pomace	< 0.12	< 0.12		< 0.018
	Dry pomace	1.6	1.6		0.24

[a] Each value represents a separate study.
[b] RAC was dipped in EC formulation solution.

Residues in animal commodities

Estimated maximum and mean dietary burdens of farm animals

The maximum and mean dietary burdens were calculated using the median residue of triforine in dry tomato pomace estimated at the current Meeting on a basis of the OECD Animal Feeding Table.

Summary of livestock dietary burdens (ppm of dry matter diet)

Livestock dietary burden, triforine, ppm of dry matter diet								
	US-Canada		EU		Australia		Japan	
	Max	Mean	Max	Mean	Max	Mean	Max	Mean
Beef cattle	0	0	0	0	0.027 [a]	0.027 [b]	0	0
Dairy cattle	0	0	0	0	0.027	0.027 [c]	0	0
Broilers	0	0	0	0	0	0	0	0
Layers	0	0	0	0	0	0	0	0

[a] Highest maximum beef cattle dietary burden suitable for MRL estimates for mammalian meat, fat, edible offal and milk
[b] Highest mean beef cattle dietary burden suitable for STMR estimates for mammalian meat, fat and edible offal

[c] Highest mean dairy cattle dietary burden suitable for STMR estimates for milk

Farm animal feeding studies

The Meeting received a lactating dairy goat feeding studies using triforine, which provided information on likely residues resulting in animal commodities and milk from triforine residues in the animal diet.

Lactating dairy goats

Lactating dairy goats were dosed with triforine for 30 days at doses equivalent to 5, 15 and 50 ppm in the diet. Residues of triforine were at or less than the LOQ (0.001 mg/L) in whole milk at the 5 ppm of feeding level except on sampling day 29 (< 0.001–0.003 mg/L). In the highest dose group (50 ppm feed), triforine residues in milk reached a plateau at the level of 0.002–0.010 mg/L after 3 days. In tissues, no measurable residues were found in fat, liver, kidney and muscle of the 5 ppm feed group. In the 15 ppm feed group, triforine concentration slightly exceeded the LOQ in several samples. In the 50 ppm feed group, residues were detected in all of the analysed tissues with exception of muscle in one animal and fat of all animals. The maximum values in kidney and liver were 0.009 and 0.012 ppm, respectively.

Animal commodities maximum residue levels

For MRL estimation, the residue in the animal commodities is triforine.

The maximum dietary burden for beef and dairy cattle was 0.027 ppm. The maximum dietary burden for beef and dairy cattle was 0.54% of the lowest dose of 5 ppm in feed of the lactating goat feeding study. In the lactating goat feeding study at 5 ppm, triforine was at < 0.01 mg/kg in milk and < 0.01 mg/kg in liver.

The Meeting estimated a maximum residue level of 0.01* mg/kg and an STMR of 0 mg/kg in milk.

The Meeting estimated a maximum residue level of 0.01* mg/kg, an STMR of 0 mg/kg and an HR of 0 mg/kg in mammalian meat and fat.

The Meeting estimated a maximum residue level of 0.01* mg/kg, an STMR of 0 mg/kg and an HR of 0 mg/kg in mammalian edible offal.

RECOMMENDATIONS

On the basis of the data from supervised trials, the Meeting concluded that the residue levels listed below are suitable for estimating maximum residue limits and for IEDI and IESTI assessment.

Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant commodities: *Triforine.*

Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for animal commodities: *Triforine and its metabolites determined as chloral hydrate expressed as triforine.*

The residue is not fat soluble.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Daily Intakes (IEDIs) of triforine were calculated for the 17 GEMS/Food cluster diets using STMRs/STMR-Ps estimated by the current Meeting (Annex 3 of the 2014 Report). The ADI is 0–0.03 mg/kg bw and the calculated IEDIs were 0–2% of the maximum ADI. The Meeting concluded that the long-term intakes of residues of triforine, resulting from the uses considered by current JMPR, are unlikely to present a public health concern.

Short-term intake

The ARfD for triforine is 0.3 mg/kg bw. The International Estimate of Short Term Intakes (IESTIs) for triforine were calculated for the food commodities for which STMRs or HRs were estimated by the present Meeting and for which consumption data were available. The results are shown in Annex 4 of the 2014 JMPR Report. The IESTIs were 0–5% of the ARfD for children and the general population. The Meeting concluded that the short-term intake of residues of triforine from other uses that have been considered by the present Meeting is unlikely to present a public health concern.

6. RECOMMENDATIONS

The Meeting adopted the guidance document for WHO monographers and recommended that the JMPR Secretariat publish it.

The Meeting recommended that consideration should be given to updating the relevant section(s) of EHC 240 to take account of the developments included in this revised guidance.

The Meeting recommended that the Secretariat identify relevant developments regarding cumulative risk assessment for pesticides, and place them on the agenda for discussion at the next appropriate JMPR.

The Meeting recommends that the Secretariat convene a multidisciplinary working group in order to develop criteria to identify relevant compounds and develop models to cover exposures longer than 1 day but shorter than lifetime, as needed.

The Meeting recommended that the Secretariat ensure that sponsors complete a declaration that, to the best of their knowledge, all available information has been submitted for consideration by JMPR.

7. FUTURE WORK

The items listed below are tentatively scheduled to be considered by the Meetings in 2016 and 2017. The compounds listed include those recommended as priorities by the CCPR at its Forty-sixth and earlier Sessions and compounds scheduled for re-evaluation within the CCPR periodic review programme.

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

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

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

2016 JMPR

NEW COMPOUNDS	**NEW COMPOUNDS**
TOXICOLOGY EVALUATIONS	**RESIDUE EVALUATIONS**
Acibenzolar-S methyl [Syngenta] New Zealand	Acibenzolar-S methyl Kiwifruit
	Bixafen (262) [Bayer CropScience] To be advised
Cyclaniliprole [Ishihara Sangyo Kaisha] USA	Cyclaniliprole Potato, broccoli, cabbage, mustard green, Brussels sprout, kale, cauliflower, soya bean, dried, soya bean, immature (with pods), tomato, pepper, apple, pear, cherry, peach, plum, apricot, plum, nectarine, almond hulls, almond, pecan, lettuce, head, lettuce, leaf, spinach, grape, cucumber, muskmelon, summer squash, tea
Ethiprole [Bayer CropScience] Germany	Ethiprole Coffee, corn/maize, rice, soya bean and food of animal origin
Imazethapyr BASF – USA	Imazethapyr Alfalfa, canola, clover, corn, lentils, peanut, fresh peas, dry peas, fresh beans, dry beans, rice, soya bean, sunflower, Rape seed/canola
isofetamid [Ishihara Sangyo Kaisha] USA	Isofetamid lettuce, apricot, cherry, peach, plum, grape, strawberry, almond, canola/oilseed rape
MCPB [Nufarm] – USA	MCPB Peas (fresh and dried)

NEW COMPOUNDS	**NEW COMPOUNDS**
TOXICOLOGY EVALUATIONS	**RESIDUE EVALUATIONS**
Norfluazuron – [Syngenta] – USA moved from 2014	Norfluazuron Almond, apple, apricot, asparagus, avocado, blackberry, blueberry, cranberry, cherry (sweet and tart), citrus fruits group, cottonseed, grape, hazelnut, hops, nectarine, peach, peanut, pear, pecan, plums and prunes, raspberry, soya bean, and walnut
Oxathiapiprolin [Du Pont] – USA **RESERVE (possible 2nd 2015 meeting)**	Oxathiapiprolin Grapes, potato, dry bulb onion, green onion, tomato, bell pepper, non-bell pepper, courgette, cucumber, melon, summer squash, cantaloupe, broccoli, cauliflower, head cabbage, lettuce, spinach, succulent peas, ginseng, and tobacco
Pinoxaden [Syngenta] Switzerland	Pinoxaden Wheat, barley
Pendimethalin BASF – USA	Pendimethalin Leafy Lettuce, leafy brassica (mustard greens, kale), alfalfa and grass hay, fresh legumes/dry pulses, citrus, tree nuts, carrot/other root and tuber, bulbs: onion, dry and green onion, asparagus, leeks, celery
Pyrifluquinazon [Nihon Nohyaku] Japan	Pyrifluquinazon Citrus, pome fruits, potatoes, stone fruits, grapes, tree nuts, melons, tea, grapes (table grapes, raisins, wine), fruiting vegetables, cucurbits, cotton, leafy vegetables, brassica leafy and head/stem vegetables
Spiromesifen [Bayer CropScience] – Germany **RESERVE (possible 2nd 2015 meeting)**	Spiromesifen Legume vegetables (Beans/peas (dry, succulent, edible podded) Soya bean), Leafy vegetables (Head lettuce, Leaf lettuce, Spinach, Celery), Brassica vegetables (Broccoli, Cabbage, Mustard, green), Root and tuber vegetables (Potato), Fruiting vegetables (Tomato, Bell pepper, Chili pepper), Cucurbits (Cucumber, Melon, summer squash), Cereals (Maize, sweet corn, field corn, popcorn), Oilseeds (Cotton), Berries (Strawberries), Tea, Coffee, herbal infusions and Cocoa (Tea, Coffee), Tropical fruits (Papaya, Passion fruit), Rotational crops (Alfalfa, Barley, Oat, Sugar beet, Bulb vegetables (Welsh / green onions), Wheat)

PERIODIC RE-EVALUATIONS	**PERIODIC RE-EVALUATIONS**
Fenpropimorph (188) [BASF]	Fenpropimorph Banana, cereals, sugar beet, cereals fodder/straw, meat,

PERIODIC RE-EVALUATIONS	PERIODIC RE-EVALUATIONS
	milk, eggs
Imazalil (110) [Janssen]	Imazalil (110) Nominated by EU (criteria – public health concern) To be advised
Iprodione (111) (BASF)	Iprodione (111) Tree nuts, cereals, beans, (dried), blackberry, broccoli, carrots, cheery, cucumber, grapes, kiwi, lettuce (head and leafy), onion, stone fruit, pome fruit, rapeseed, raspberry, sugar beet, sunflower, tomato, witloof
Teflubenzuron (190) [BASF]	Teflubenzuron (190) Apple, orange, coffee, field corn, soya bean, sugarcane, sunflower, tomato, melon, broccoli, cauliflower, grape, papaya

	EVALUATIONS
	Azoxystrobin (229) Pineapple (or passion fruit), guava, olive, dragon fruit
	Bixafen (262) FAO followup evaluation to consider rotational crop scenario
	Chlorantraniliprole (230) Philippines: pineapple
	Deltamethrin (135) Canada: Rapeseed/canola
	Difenoconazole (224) Pineapple (or passion fruit), guava, olive, dragon fruit
	Fipronil (202) Basil
	Fluensulfone (265) Root tuber, leafy vegetable, brassica vegetable, strawberry, cereal grain, product of animal origin, radish, legume vegetables, tree fruit
	Flutolanil (205) Carrot, potato, radish, sugar beet, ginseng
	Imazapic (266) Barley
	Isoxaflutole (268) Soya bean
	Penthiopyrad (253)

	EVALUATIONS
	Mustard greens (alternative GAP)
	Picoxystrobin (258) Fruiting vegetables, cucurbits, stone fruit, pome fruit, grapes, legume vegetables, bulb vegetables, strawberry, brassica vegetables, leafy vegetables, root and tuber vegetables, sunflower, tree nut, peanut, rice, cotton and tomato
	Propylene oxide (250) Tree nuts
	Pyriproxyfen (200) Banana, avocado, papaya, mango, pineapple
	Spinetoram (233) Mango, olive , avocado, papaya, banana, pineapple, feijoa, passionfruit, avocado, tamarillo, olives, cucurbits, pepper, strawberries, plum, cherry, apricot, potato, soya bean, corn, tangerine, sweetcorn, kiwi, passion fruit
	Spirotetramat (234) Strawberry, carrot, sugarbeet
	Sulfoxaflor (252) Corn, grain, corn, sweet, sorghum, grain, pineapple, cacao, beans, rice, grain, avocado
	Tolfenpyrad (269) Almonds, pecans, pistachio, hazelnuts, walnuts, grape (table), raisin, juice (if MRL not included under table grape), apricots, plum, prunes, peach, nectarine, cherry, pear, lemon, lime, grapefruit, tangerine (mandarin), oranges, cantaloupe, cucumbers, summer squash, pumpkin, watermelon, peppers, tomatoes, cabbage, head lettuce, leaf lettuce, celery, spinach, cauliflower, potatoes, cotton seed, and corresponding animal commodities
	Tebuconazole (189) Common beans

2017 JMPR

NEW COMPOUNDS	**NEW COMPOUNDS**
TOXICOLOGY EVALUATIONS	**RESIDUE EVALUATIONS**
Isoprothiolane India	Isoprothiolane India
Quinalphos India	Quinalphos India

NEW COMPOUNDS	**NEW COMPOUNDS**
TOXICOLOGY EVALUATIONS	**RESIDUE EVALUATIONS**
Tricyclazole India	Tricyclazole India
	Chlorfenapyr [BASF] (254)
	Prothioconazole (232) [Bayer CropScience]
	Trifloxystrobin (213) [Bayer CropScience]
	Pirimicarb (101) [Syngenta]
	Cypermethrins (118) [BASF], [FMC]

8. CORRIGENDA

CORRECTIONS TO THE REPORT OF THE 2013 MEETING

Pesticide residues in food—2013. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group. FAO Plant Production and Protection Paper 219, 2014.

Changes are shown in bold. Only significant factual errors and omissions are listed.

Under Annex 1 ***Insert*** *the following entries*

Pesticide (Codex reference number)	CCN	Commodity	Recommended MRL mg/kg		STMR or STMR-P	HR or HR-P
			New	Previous	mg/kg	mg/kg
Bentazone (172)**	A**S** 0647	Oat straw and fodder, dry	0.3	0.1	0.04	0.14
	A**S** 0650	Rye straw and fodder, dry	0.3		0.04	0.14
	A**S** 0654	Wheat straw and fodder, dry	0.3		0.04	0.14
Chlorpyrifos-methyl (090)	CM 1206	Rice bran, unprocessed				7.8
Penthiopyrad (253)	CM 0654	Wheat, bran, **unprocessed**	0.2	0.1	0.018	
Trinexapac-ethyl (271)*	CM 0654	Wheat bran, **unprocessed**	8		1.08	

ANNEX 1: ACCEPTABLE DAILY INTAKES, SHORT-TERM DIETARY INTAKES, ACUTE REFERENCE DOSES, RECOMMENDED MAXIMUM RESIDUE LIMITS AND SUPERVISED TRIALS MEDIAN RESIDUE VALUES RECORDED BY THE 2014 MEETING

Pesticide (Codex reference number)	**CCN**	**Commodity**	**Recommended Maximum residue level (mg/kg)**		**STMR or STMR-P mg/kg**	**HR or HR-P mg/kg**
			New	**Previous**		
Aminocyclopyrachlor(272) *	MO 0105	Edible offal (mammalian)	0.3		0.039 L 0.13 K	
ADI: 0-3 mg/kg bw	MF 0100	Mammalian fats (except milk fats)	0.03		0.01	
ARfD: Unnecessary	AS 0162	Hay or fodder (dry) of grasses	150			
	MM 0095	Meat (from mammals other than marine mammals)	0.01		0.01	
	ML 0106	Milks	0.02		0.01	
L- Liver; K-Kidney Definition of the residue (for compliance with MRL and estimation of dietary intake) for animal and plant commodities: *Aminocyclopyrachlor* *The residue is not fat soluble.*						
Benzovindiflupyr (261)	PE 0112	Eggs	0.01*		0	0
ADI: 0–0.05 mg/kg bw	MM 0095	Meat (from mammals other than marine mammals)	0.01*		0	0
ARfD: 0.1 mg/kg bw	MO 0105	Edible offal (mammalian)	0.01*		0	0
	MF 0100	Mammalian fats (except milk fats)	0.01*		0	0
	ML 0106	Milks	0.01*		0	0
	PO 0111	Poultry, Edible offal of	0.01*		0	0
	PF 0111	Poultry fats	0.01*		0	0
	PM 0110	Poultry meat	0.01*		0	0
	VD 0541	Soya bean (dry)	0.05		0.01	
	OC 0541	Soya bean oil, crude			0.0086	
	OR 0541	Soya bean oil, refined			0.0066	
		Soya fat flour			0.004	
		Soya milk			0.004	
		Soya tofu, pasteurised			0.0055	
		Soya sauce, pasteurised			0.004	
		Soya miso, pasteurised			0.004	
Definition of the residue (for compliance with the MRL and for dietary risk assessment) for plant and animal commodities: *benzovindiflupyr.* *The residue is fat soluble.*						
Buprofezin (173)	SB 0716	Coffee beans	0.4	-	0.08	
ADI: 0–0.009 mg/kg bw	SM 0716	Coffee beans, roasted			0.0256	
ARfD: 0.5 mg/kg bw		Freeze-dried coffee			0.016	

Pesticide (Codex reference number)	**CCN**	**Commodity**	**Recommended Maximum residue level (mg/kg)**		**STMR or STMR-P mg/kg**	**HR or HR-P mg/kg**
			New	**Previous**		
Definition of the residue (for compliance with MRLs and for estimation of dietary intake) for plant commodities and animal commodities: *buprofezin* *The residue is not fat soluble.*						
Chlorantraniliprole (230) ADI: 0–2 mg/kg bw ARfD: Unnecessary	FC 0001	Citrus fruit	0.7	0.5	0.06	
	MF 0100	Mammalian fats (except milk fats)	0.2		0.049	
	PF 0111	Poultry fats	0.01*		0	
	VD 0541	Soya bean (dry)	0.05		0.01	
	JF 0001	Citrus juice			0.037	
	CF 0654	Wheat bran, processed			0.011	
	CF 1211	Wheat flour			0.004	
	CF 1210	Wheat germ			0.012	
Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities: *chlorantraniliprole* *The residue is fat-soluble*						
Clothianidin (238) ADI: 0–0.1 mg/kg bw ARfD: 0.6 mg/kg bw	FI 0326	Avocado	0.03 T		0.01 T	0.02 T
	VP 0061	Beans, except broad bean and soya bean	0.2 T		0.07 T	0.1 T
	DH 1100	Hops, dry	0.07 T		0.026 T	0.028 T
	FI 0345	Mango	0.04 T		0.02 T	0.02 T
	HH 0738	Mints	0.3 T		0.11 T	0.12 T
	MO 0105	Edible offal (mammalian) (except liver)			0.02	0.02
	MO 0099	Liver of cattle, goats, pigs and sheep			0.058 T,c	0.14 T,c
	MF 0100	Mammalian fats (except milk fats)			0.02	0.02
		Mango pulp			0.02 T[a]	0.02 T
		Mango dried			0.13 T	0.13 T
	MM 0095	Meat (from mammals other than marine mammals)			0.02	0.02
	ML 0106	Milk			0.006 T,c	
Definition of the residue (for compliance with the MRL and for estimation of the dietary intake) for plant and animal commodities: *clothianidin* *The residue is not fat soluble* [a] Rounded from 0.016 mg/kg T = based on thiamethoxam use only; c,T or C,t = combined clothianidin and thiamethoxam use						

Pesticide (Codex reference number)	**CCN**	**Commodity**	**Recommended Maximum residue level (mg/kg)**		**STMR or STMR-P mg/kg**	**HR or HR-P mg/kg**
			New	**Previous**		
Cyflumetofen (273) *	AM 0660	Almond hulls	4		0.67 [a]	
ADI: 0-0.1 mg/kg bw	FC 0001	Citrus fruits	0.3		0.07	
ARfD: Unnecessary	OR 0001	Citrus oil, edible	36		7.77	
	DF 0269	Dried grapes (=currants, Raisins and Sultanas)	1.5		0.51	
	MO 0105	Edible offal (mammalian)	0.02		0.010 L 0.008 K	
	FB 0269	Grapes	0.6		0.22	
	MF 0100	Mammalian fats (except milk fats).	0.01*		0	
	MM 0095	Meat (from mammals other than marine mammals)	0.01*		0	
	ML 0106	Milks	0.01*		0	
	FP 0009	Pome fruits	0.4		0.13	
	FB 0275	Strawberry	0.6		0.18	
	VO 0448	Tomato	0.3		0.07	
	TN 0085	Tree nuts	0.01*		0.01	
	JF 0226	Apple juice			0.036	
		Apple sauce			0.48	
		Canned apple			0.02	
		Canned tomato			0.021	
	DF 0226	Apples, dried			0.076	
	JF 0269	Grape juice			0.048	
		Grape must			0.071	
		Grape wine			0.026	
		Marmalade			0.0098	
	JF 0004	Orange juice			0.0022	
	JF 0448	Tomato juice			0.027	
	VW 0448	Tomato paste			0.12	
		Tomato purée			0.042	

L- Liver; K-Kidney [a] Median

Definition of the residue (for compliance with the MRL) for plant commodities: c*yflumetofen*

Definition of the residue (for estimation of dietary intake) for plant commodities: *Sum of cyflumetofen and 2-trifluoromethylbenzoic acid, expressed as cyflumetofen*

Definition of the residue (for compliance with the MRL and estimation of dietary intake) for animal commodities: *Sum of cyflumetofen and 2-trifluoromethylbenzoic acid, expressed as cyflumetofen*

Residue is not fat-soluble
STMR or STMR-P expressed as cyflumetofen

Dichlobenil (274) *	VB 0040	Brassica (Cole or Cabbage) Vegetables, Head Cabbage, Flowerhead Brassicas	0.05 FL		0.01	0.04
ADI: 0-0.01 mg/kg bw	FB 2005	Cane berries	0.2 D		0.034	0.13

Pesticide (Codex reference number)	**CCN**	**Commodity**	**Recommended Maximum residue level (mg/kg)**		**STMR or STMR-P mg/kg**	**HR or HR-P mg/kg**
			New	**Previous**		
ARfD: 0.5 mg/kg bw	VS 0624	Celery	0.07 FL		0.01	0.04
BAM [a]	GC 0080	Cereal grains	0.01* FL		0.01	
ADI: 0-0.05 mg/kg bw	DF 0269	Dried grapes (= currants, Raisins and Sultanas)	0.15 FL		0.028	0.11
ARfD: 0.3 mg/kg bw	MO 0105	Edible offal (mammalian)	0.04 FL		0.01	0.031
	PE 0112	Eggs	0.03 FL		0.01	0.019
	VC 0045	Fruiting vegetables, Cucurbits	0.01* FL		0.01	0.01
Based on a re-evaluation of the data, the Meeting withdrew the ADI and ARfD established by the 2009 JMPR as part of the evaluation of fluopicolide	VO 0050	Fruiting vegetables, other than Cucurbits (except sweetcorn and mushrooms)	0.01* FL		0.01	0.01
	JF 0269	Grape juice	0.07 FL		0.014	0.056
	FB 0269	Grapes	0.05 FL		0.01	0.04
	VL 0053	Leafy vegetables	0.3 FL		0.07	0.19
	MF 0100	Mammalian fats (except milk fats)	0.01* FL		0.01	0.01
	MM 0095	Meat (from mammals other than marine mammals)	0.01* FL		0.01	0.01
	ML 0106	Milks	0.01*FL		0.01	
	VA 0385	Onion, Bulb	0.01* FL		0.01	0.01
	VA 0387	Onion, Welsh	0.02 FL		0.01	0.01
	HS 0444	Peppers Chili, dried	0.01* FL		0.01	0.01
	PO 0111	Poultry, Edible offal of	0.1FL		0.014	0.081
	PF 0111	Poultry fats	0.02 FL		0.01	0.012
	PM 0110	Poultry meat	0.03 FL		0.01	0.018
	VD 0070	Pulses	0.01* FL		0.01	
	AS 0081	Straw and fodder (dry) of cereal grains	0.4 FL			
	JF 0448	Tomato juice			0.01	
		Tomato purée			0.01	
	VW 0448	Tomato paste			0.01	
Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities: *2,6-dichlorobenzamide* *The residue is not fat soluble.* [a] BAM = *2,6-dichlorobenzamide = fluopicolide* FL = indicates values estimated to accommodate residues of 2,6-dichlorobenzamide arising from fluopicolide use. D = indicates values estimated to accommodate residues of 2,6-dichlorobenzamide arising from dichlobenil use.						
Dimethomorph (225)	VS 0620	Artichoke, Globe	2		0.25	1.14
ADI: 0-0.2 mg/kg bw	VB 0400	Broccoli	4	1	1.3	2.6
ARfD: 0.6 mg/kg bw	VB 0041	Cabbages, Head	6	2	1.1	4.6

Pesticide (Codex reference number)	CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
	VS 0624	Celery	15		2.44	8.8
	DF 0269	Dried grapes (= currants, Raisins and Sultanas)	5	5	1.17	3.4
	VO 0050	Fruiting vegetables, other than Cucurbits	1.5	1	0.13	1.2
	VA 0381	Garlic	0.6		0.17	0.4
	FB 0269	Grapes	3	2	0.60	1.9
	VA 0384	Leek	0.8		0.08	0.69
	VL 0483	Lettuce, Leaf	20[a]		5.19	10.5
	VP 0534	Lima bean (young pods and/or immature beans)	0.7		0.055	0.48
	VA 0385	Onion, Bulb	0.6		0.17	0.4
	VA 0387	Onion, Welsh	9		2.1	6.6
	VP 0064	Peas, shelled (succulent seeds)	0.15		0.01	0.63
	VA 0388	Shallots	0.6		0.17	0.4
	VL 0502	Spinach	30		8.3	11.5
	VA 0389	Spring onion	9		2.1	6.6
	FB 0275	Strawberry	0.5	0.05	0.02	0.24
	VL 0505	Taro leaves	10		1.64	5.4
		Dried onion			0.022	
		Grapes, wine			0.18	
		Onions, raw without skin			0.014	0.03
		Peas (canned)			0.0014	
		Peas (cooked)			0.002	
		Strawberry jam			0.02	
		Strawberry, canned			0.056	
	JF 0448	Tomato juice			0.065	
	VW 0448	Tomato paste			0.31	2.88
Definition of the residue (for compliance with the MRL and estimation of dietary intake) for plant and animal commodities: *Dimethomorph (sum of isomers)* *The residue is not fat soluble* [a] On the basis of information provided to the JMPR it was not possible to conclude from the estimate of short-term intake for dimethomorph, that for children the consumption of leaf lettuce was less than the ARfD.						
Dithiocarbamates (105)/Mancozeb (050) ADI: 0-0.03 mg/kg bw (Group ADI with maneb, metiram and zineb) ARfD: yet to be established	HS 0775	Cardamom seed	0.1		0.52	
	HS 0779	Coriander, seed	0.1		0.52	
	HS 0780	Cumin seed	10		19	
	HS 0731	Fennel, seed	0.1		0.52	
	VR 0604	Ginseng	0.3		0.13	0.41
	DV 0604	Ginseng, dried including red ginseng	1.5		0.71	2
	HS 0790	Pepper, Black; White	0.1		0.52	

Pesticide (Codex reference number)	**CCN**	**Commodity**	**Recommended Maximum residue level (mg/kg)**		**STMR or STMR-P mg/kg**	**HR or HR-P mg/kg**
			New	**Previous**		
	VO 0444	Peppers, Chili	3		4.1	8.9
	HS 0444	Peppers Chili, dried	20		28	60
Definition of the residue (for compliance with MRLs) in plant and animal commodities: *Total dithiocarbamates, determined as CS_2, evolved during acid digestion and expressed as mg CS_2/kg.* Definition of the residue (for the estimation of dietary intake) in plant and animal commodities: mancozeb plus ethylenethiourea (ETU) *Dithiocarbamate residues are not fat soluble*						
Emamectin benzoate (247)	VL 0510	Cos lettuce	0.7	1	0.076	0.33
ADI: 0–0.0005 mg/kg bw	VL 0483	Lettuce, Leaf	0.7	1	0.076	0.33
ARfD: 0.02 mg/kg bw	SO 0495	Rape seed	0.005*		0	
	TN 0085	Tree nuts	0.001*		0.001	0.001
Definition of the residue (for compliance with the MRL and estimation of dietary intake) for plant and animal commodities: *emamectin B1a benzoate* *The residue is not fat soluble*						
Fenamidone (264)	VP 0061	Beans, except broad bean and soya bean	0.8		1.39	1.96
ADI: 0–0.03 mg/kg bw	VP 0062	Beans, Shelled	0.15		1.2	1.58
ARfD: 1 mg/kg bw	VB 0041	Cabbages, Head	0.9		1.2	1.7
	VR 0577	Carrots	0.2		0.45	0.61
	VS 0624	Celery	40		2.3	3.2
	SO 0691	Cotton seed	0.02*		0.02	
	MO 0105	Edible offal (mammalian)	0.01*		0	0
	PE 0112	Eggs	0.01*		0	0
	VB 0042	Flowerhead brassicas (includes Broccoli: Broccoli, Chinese and Cauliflower)	4		2.3	4.2
	VC 0045	Fruiting vegetables, Cucurbits	0.2		1.29	1.63
	VO 0050	Fruiting vegetables, other than Cucurbits (except chilli pepper, fungi, sweet corn)	1.5		1.53	2.32
	VA 0381	Garlic	0.15		0.42	0.63
	FB 0269	Grapes	0.6		0.175	0.42
	VA 0384	Leek	0.3		0.46	0.63
	VL 00482	Lettuce, Head	20		4.9	13.5
	VL 00483	Lettuce, Leaf	0.9		1.24	1.98
	MM 0095	Meat (from mammals other than marine mammals)	0.01* (fat)		0	0
	FM 0183	Milk fats	0.02		0.01	0.01
	ML 0106	Milks	0.01*		0.01	0.01

Pesticide (Codex reference number)	CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
	VL 0485	Mustard greens	60 [a]		20	34
	VA 0385	Onion, Bulb	0.15		0.42	0.63
	VA 0387	Onion, Welsh	3		1.05	1.7
	VO 0444	Peppers, Chili	4		2.5	3.2
	HS 0444	Peppers, Chili, dried	30		18	
	VR 0589	Potato	0.02*		0.4	0.5
	PM 0110	Poultry meat	0.01* (fat)		0	0
	PO 0111	Poultry, Edible offal of	0.01*		0	0
	PF 0111	Poultry fats	0.01*	0	0	
	VA 0388	Shallot	0.15		0.42	0.63
	VL 0502	Spinach [a]	60 [a]		20	34
	VA 0389	Spring onion	3		1.05	1.7
	FB 0275	Strawberry	0.04		0.02	0.04
	SO 0702	Sunflower seed	0.02*		0	
		Tomato ketchup	3		3.67	
	VW 0448	Tomato paste	4		5.58	
		Tomato purée	3		3.21	
	VS 0469	Witloof chicory (sprouts)	0.01*		0.01	0.01
	JF 0269	Grape juice			0.063	
		Grape must			0.145	
		Grape wine			0.124	
		Tomato canned fruits			0.69	
	JF 0448	Tomato juice			1.22	

Definition of the residue (for compliance with the MRL) for plant and animal commodities: *Fenamidone.*

Definition of the residue (for estimation of dietary intake) for plant commodities: *Sum of fenamidone, (S)-5-methyl-5-phenyl-3-(phenylamino)- 2,4-imidazolidine-dione (RPA 410193), plus 10 x the sum of both (S)-5-methyl-5-phenyl-2,4-imidazolidine-dione (RPA 412636) and (5S)-5-methyl-2-(methylthio)-5-phenyl-3,5-dihydro- 4H-imidazol-4-one (RPA 412708), all calculated as fenamidone.*

Residue concentration $C_{total} = C_{fenamidone} + C_{RPA\ 410193} + 10 \times (C_{RPA\ 412636} + C_{RPA\ 412708})$

Definition of the residue (for the estimation of dietary intake) for animal commodities: *Sum of fenamidone plus 10 × the sum of both (S)-5-methyl-5-phenyl-2,4-imidazolidine-dione (RPA 412636) and (5S)-5-methyl-2-(methylthio)-5-phenyl-3,5-dihydro- 4H-imidazol-4-one (RPA 412708), all calculated as fenamidone.*

Residue concentration $C_{total} = C_{fenamidone} + 10 \times (C_{RPA\ 412636} + C_{RPA\ 412708})$

The residue is fat soluble

[a] On the basis of information provided to the JMPR it was not possible to conclude from the estimate of short-term intake for fenamidone that for children the consumption of mustard greens and spinach was less than the ARfD.

Fenpropathrin (185) **	AM 0660	Almond hulls	10		3.1	3.6
ADI: 0-0.03 mg/kg bw	MM 0812	Cattle meat	W	0.5 (fat)		
ARfD: 0.03 mg/kg bw	ML 0812	Cattle milk	W	0.1F		
	MO 0812	Cattle, edible offal of	W	0.05		

Pesticide (Codex reference number)	**CCN**	**Commodity**	**Recommended Maximum residue level (mg/kg)**		**STMR or STMR-P mg/kg**	**HR or HR-P mg/kg**
			New	**Previous**		
	FS 0013	Cherries	7 [a]		1.85	3.53
	HS 0444	Peppers Chili, dried	10		2.59	4.9
	FC 0001	Citrus fruits	2		0.02	0.098
	OR 0001	Citrus oil, edible	100		16.5	
	SB 0716	Coffee beans	0.03		0.01	
	SO 0691	Cotton seed	W	1		
	OC 0691	Cotton seed oil, crude	W	3		
	MO 0105	Edible offal (mammalian)	0.01		0.002	0.003
	VO 0440	Egg plant	W	0.2		
	PE 0112	Eggs	0.01*	0.01*	0	
	VC 0425	Gherkin	W			
	FB 0269	Grapes	W	5		
	MF 0100	Mammalian fats (except milk fats)	0.03		0.018	0.026
	MM 0095	Meat (from mammals other than marine mammals)	0.01		0.001 0.018 (fat)	0.002
	ML 0106	Milks	0.01		0.002	
	FS 2001	Peaches (including Nectarine and Apricots)	3 [a]		0.71	1.1
	VO 0051	Peppers	1		0.37	0.70
	FS 0014	Plums (including prunes)	1		0.25	0.71
	FP 0009	Pome fruits	3 [a]		0.73	2
	PF 0111	Poultry fats	0.01*		0	0
	PM 0110	Poultry meat	0.01* (fat)		0	0
	PO 0111	Poultry, Edible offal of	0.01*	0.01*	0	0
	DF 0014	Prunes	3		0.65	1.85
	VD 0541	Soya bean (dry)	0.01		0.01	
	FB 0275	Strawberry	2		0.515	1.2
	DT 1114	Tea, Green, Black (black, fermented and dried)	3	2	0.14	
	VO 0448	Tomato	1		0.19	0.64
	TN 0085	Tree nuts	0.15		0.01	0.1
	JF 0001	Citrus juice			0.007	
	JF 0048	Tomato juice			0.023	
		Tomato canned			0.021	
	VW 0448	Tomato paste			0.145	

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

The residue is fat soluble

[a] On the basis of information provided to the JMPR it was not possible to conclude from the estimate of short-term intake for fenpropathrin that for children the consumption of cherries, peaches and pome fruits was less than the ARfD.

Pesticide (Codex reference number)	CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
Fluensulfone (265)	VC 0045	Fruiting vegetables, Cucurbits	0.3		0.032	0.16
ADI: 0-0.01 mg/kg bw	VO 0050	Fruiting vegetables, other than Cucurbits (except sweet corn and mushrooms)	0.3		0.045	0.17
ARfD: 0.3 mg/kg bw	HS 0444	Peppers Chili, dried	2		0.32	1.2
	VW 0448	Tomato paste	0.5		0.081	0.31
	DV 0448	Tomato, dried	0.5		0.081	0.31
Definition of the residue (for compliance with the MRLs and dietary intake) for plant commodities: *BSA {3,4,4-trifluorobut-3-ene-1-sulfonic acid}* Note that for dietary intake, exposure estimates should be compared to the ADI and ARfD for fluensulfone, with no correction for molecular weight. Definition of the residue (for compliance with the MRL and for dietary risk assessment) for animal commodities Unnecessary						
Flufenoxuron (275)*	MO 0105	Edible offal (mammalian)	0.05*		0	
ADI: 0-0.04 mg/kg bw	MM 0095	Meat (from mammals other than marine mammals)	0.05*		0	
ARfD: Unnecessary	MM 0100	Mammalian fats (except milk fats)	0.05*		0	
	ML 0106	Milks	0.01*		0	
	FC 0004	Oranges, Sweet, Sour	0.4		0.05	
	DT 1114	Tea, Green, Black (black, fermented and dried)	20		6.02	
		Tea infusion			0.04	
Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for animal and plan commodities: *flufenoxuron* *The residue is fat soluble.*						
Fluopyram (243)	VS 0621	Asparagus	0.01*		0	0
ADI: 0-0.01 mg/kg bw	FB 0264	Blackberries	3.0		0.7	1.2
ARfD: 0.5 mg/kg bw	VB 0400	Broccoli	0.3		0.05	0.14
	VB 0402	Brussels sprouts	0.3		0.06	0.15
	VB 0041	Cabbages, Head	0.15		0.01	0.08
	VB 0404	Cauliflowers	0.09		0.01	0.05
	VA 0381	Garlic	0.07		0.01	0.04
	VA 0384	Leek	0.15		0.01	0.07
	VL 0482	Lettuce, Head	15		2.2	8.4
	VL 0483	Lettuce, Leaf	15		2.2	8.4
	VA 0385	Onion, Bulb	0.07		0.01	0.04
	VA 0381	Garlic	0.07		0.01	0.04
	FS 0247	Peach	W	0.4		

Pesticide (Codex reference number)	**CCN**	**Commodity**	**Recommended Maximum residue level (mg/kg)**		**STMR or STMR-P mg/kg**	**HR or HR-P mg/kg**
			New	**Previous**		
	FS 2001	Peaches (*including Nectarine and Apricots*)	1		0.22	0.69
	FS 0014	Plums (*including prunes*)	0.5		0.13	0.22
	SO 0495	Rape seed	1		0.33	
	FB 0272	Raspberries, Red, Black	3.0		0.7	1.2
		Cabbage, Washed, cooked			0.004	0.05
	DF 0014	Prunes			0.14	0.24
	OR 0495	Rape seed oil, Edible			0.23	
Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant commodities: *fluopyram.* Definition of the residue (for compliance with the MRL) for animal commodities: *Sum of fluopyram and 2-(trifluoromethyl) benzamide, expressed as fluopyram.* Definition of the residue (for estimation of dietary intake) for animal commodities: *Sum of fluopyram, 2-(trifluoromethyl)benzamide and the combined residues N-{(E)-2-[3-chloro-5-(trifluoromethyl)pyridin-2-yl]ethenyl}-2-trifluoromethyl) benzamide and N-{(Z)-2-[3-chloro-5-(trifluoromethyl)pyridin-2-yl]ethenyl}-2-trifluoromethyl) benzamide, all expressed as fluopyram* *The residue is not fat soluble*						
Glufosinate-ammonium (175) ADI: 0-0.01 mg/kg bw ARfD: 0.01 mg/kg bw	VD 0541	Soya bean (dry)	2	3	0.09	0.39
Definition of the residue (for compliance with MRL and for estimation of dietary intake) for animal and plant commodities: *sum of glufosinate, 3-[hydroxy(methyl)phosphinoyl]propionic acid and N-acetyl-glufosinate, calculated as glufosinate (free acid)* *The residue is not fat soluble*						
Imazamox (276) * ADI: 0-3 mg/kg bw ARfD: 3 mg/kg bw	AL 1020	Alfalfa fodder	0.1*		0.2	0.41
	VD 0071	Bean (dry)	0.05*		0	
	VP 0061	Beans, except broad bean and soya bean	0.05*		0	
	MO 0105	Edible offal (mammalian)	0.01*		0	0
	PE 0112	Eggs	0.01*		0	0
	VD 0533	Lentil (dry)	0.2		0.1	
	MF 0100	Mammalian fats (except milk fats)	0.01*		0	0
	MM 0095	Meat (from mammals other than marine mammals)	0.01*		0	0
	ML 0106	Milks	0.01*		0	0
	VD 0072	Peas (dry)	0.05*		0	
	AL 0072	Pea hay or pea fodder (dry)	0.05*		0.075	0.22

Pesticide (Codex reference number)	CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
	SO 0697	Peanut	0.01*		0	
	VP 0064	Peas, Shelled (succulent seeds)	0.05*		0	
	PF 0111	Poultry fats	0.01*		0	
	PM 0110	Poultry meat	0.01*		0	0
	PO 0111	Poultry, Edible offal of	0.01*		0	0
	SO 0495	Rape seed	0.05*		0	
	GC 0649	Rice	0.01*		0.025	
	AS 0649	Rice straw and fodder, dry	0.01*		0.02	0.03
	VD 0541	Soya bean (dry)	0.01*		0	
	AL 0541	Soya bean fodder	0.01*		0.02	0.06
	SO 0702	Sunflower seed	0.3		0.19	
	GC 0654	Wheat	0.05*		0	
	CM 0654	Wheat bran, unprocessed	0.2		0.34	
	CF 1210	Wheat germ	0.1		0.22	
	AS 0654	Wheat straw and fodder, dry	0.05*		0	0.1
	OR 0702	Sunflower seed oil, edible			0.095	
	CF 1211	Wheat flour			0.12	
Definition of the residue (for compliance with the MRL) for plant and animal commodities: *imazamox* Definition of the residue (for estimation of dietary intake) for plant and animal commodities: *sum of imazamox and 5-(hydroxymethyl)-2-(4-isopropyl-4-methyl-5-oxo-2-imazazolin-2-yl) nicotinic acid (CL 263284), expressed as imazamox* *Residue is not fat soluble.*						
Mesotrione (277) *	VS 0621	Asparagus	0.01*		0.01	
ADI: 0-0.5 mg/kg bw	FB 2006	Bush berries	0.01*		0	
ARfD: Unnecessary	FB 2005	Cane berries	0.01*		0	
	FB 0265	Cranberry	0.01*		0	
	MO 0105	Edible offal (mammalian)	0.01*		0	
	PE 0112	Eggs	0.01*		0	
	SO 0693	Linseed	0.01*		0.01	
	GC 0645	Maize	0.01*		0	
	MM 0095	Meat (from mammals other than marine mammals)	0.01*		0	
	GC 0646	Millet	0.01*		0	
	ML 0106	Milks	0.01*		0	
	GC 0647	Oats	0.01*		0	
	VO 0442	Okra	0.01*		0.01	
	PO 0111	Poultry, Edible offal of	0.01*		0	
	PM 0110	Poultry meat	0.01*		0	
	VS 0627	Rhubarb	0.01*		0.01	

Pesticide (Codex reference number)	**CCN**	**Commodity**	**Recommended Maximum residue level (mg/kg)**		**STMR or STMR-P mg/kg**	**HR or HR-P mg/kg**
			New	**Previous**		
	CM 0649	Rice, husked	0.01*		0	
	GC 0651	Sorghum	0.01*		0	
	VD 0541	Soya bean (dry)	0.03		0.01	
	GS 0659	Sugar cane	0.01*		0	
	VO 0447	Sweet corn (corn-on-the-cob)	0.01*		0	
		Miso			0.002	
		Soya flour			0.018	
		Soya milk			0.002	
	OR 0541	Soya bean oil, refined			0.002	
		Soya sauce			0.002	
		Tofu			0.002	
Definition of the residue (for compliance with MRL and for estimation of dietary intake) for animal and plant commodities: *Mesotrione.* *The residue is not fat soluble.*						
Metrafenone (278) *	GC 0640	Barley	0.5		0.06	
ADI: 0-0.3 mg/kg bw	AS 0640	Barley straw and fodder, dry	6 (dw)		1.3 (fw)	
ARfD: Unnecessary	VC 0424	Cucumber	0.2		0.05	
	DF 0269	Dried grapes (=currants, Raisins and Sultanas)	20		2.85	
	MO 0105	Edible offal (mammalian)	0.01		0.01	
	PE 0112	Eggs	0.01*		0	
	VC 0425	Gherkin	0.2		0.05	
	FB 0269	Grapes	5		0.76	
	MF 0100	Mammalian fats (except milk fats)	0.01*		0	
	MM 0095	Meat (from mammals other than marine mammals)	0.01*		0	
	ML 0106	Milks	0.01*		0	
	VO 0450	Mushrooms	0.5		0.105	
	AS 0647	Oat straw and fodder, dry	6 (dw)		1.3 (fw)	
	GC 0647	Oats	0.5		0.06	
	HS 0444	Peppers Chili, dried	20		1.15	
	VO 0444	Peppers, Chili	2		0.115	
	VO 0445	Peppers, Sweet (including pimento or pimiento)	2		0.115	
	PF 0111	Poultry fats	0.01*		0	
	PM 0110	Poultry meat	0.01*		0	
	PO 0111	Poultry, Edible offal of	0.01*		0	
	GC 0650	Rye	0.06		0.01	

Pesticide (Codex reference number)	CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
	AS 0650	Rye straw and fodder, dry	10 (dw)		1.9 (fw)	
	VC 0431	Squash, Summer	0.06		0.015	
	FB 0275	Strawberry	0.6		0.13	
	VO 0448	Tomato	0.4		0.1	
	GC 0653	Triticale	0.06		0.01	
	AS 0653	Triticale straw and fodder, dry	10 (dw)		1.9 (fw)	
	GC 0654	Wheat	0.06		0.01	
	CF 0654	Wheat bran, Processed	0.25		0.042	
	AS 0654	Wheat straw and fodder, dry	10 (dw)		1.9 (fw)	
	CF 1212	Wheat wholemeal	0.08		0.014	
		Beer			0.009	
		Bread (wholegrain)			0.007	
	JF 0269	Grape juice			0.038	
		Grape must			0.51	
		Malt			0.024	
		Mushrooms (canned)			0.017	
		Pearl barley			0.01	
		Tomato (canned)			0.002	
	JF 0448	Tomato juice			0.034	
	VW 0448	Tomato paste			0.039	
		Tomato purée			0.081	
	CF 1212	Wheat flour			0.002	
		Wine			0.14	
Definition of the residue (for compliance with the MRL and estimation of dietary intake) for plant and animal commodities: *Metrafenone* *The residue is fat soluble*						
Myclobutanil (181) **	FL 0327	Banana	W	2		
ADI: 0-0.03 mg/kg bw	VP 0061	Beans, except broad bean and soya bean	0.8		0.22	0.49
ARfD: 0.3 mg/kg bw	VB 0040	Brassica (Cole or Cabbage) Vegetables, Head Cabbage, Flowerhead Brassicas	0.05		0.03	0.044
	VA 0035	Bulb vegetables	0.06		0.039	0.052
	FS 0013	Cherries	3		1.05	2.05
	FB 0021	Currants, Black, Red, White	0.9	0.5	0.34	0.47
	DF 0269	Dried grapes (=currants, Raisins and Sultanas)	6		2.14	3.77
	MO 0105	Edible offal (mammalian)	0.01*		0	0.01
	PE 0112	Eggs	0.01*		0	0.01

Pesticide (Codex reference number)	**CCN**	**Commodity**	**Recommended Maximum residue level (mg/kg)**		**STMR or STMR-P mg/kg**	**HR or HR-P mg/kg**
			New	**Previous**		
	VC 0045	Fruiting vegetables, Cucurbits	0.2		0.04	0.16
	FB 0269	Grapes	0.9	1	0.34	0.6
	DH 1100	Hops, dry	5	2	1.52	5.6
	VL 0053	Leafy vegetables	0.05		0.03	0.044
	AL 0157	Legume animal feeds	0.2		0.055	0.093
	MF 0100	Mammalian fats (except milk fats)	0.01*		0	0
	MM 0095	Meat (from mammals other than marine mammals)	0.01*	0.01*	0	0.01
	ML 0106	Milks	0.01*	0.01*	0	0.01
	FS 2001	Peaches	3	-	0.865	1.54
	VO 0051	Peppers	3	-	0.435	2.4
	HS 0444	Peppers Chili, dried	20	-	3.04	16.8
	FS 0014	Plums (including prune)	2	0.2	0.38	1.45
	FP 0009	Pome fruits	0.6	0.5	0.07	0.35
	PF 0111	Poultry fats	0.01*		0	0
	PM 0110	Poultry meat	0.01*	0.01*	0	0.01
	PO 0111	Poultry, Edible offal of	0.01*	0.01*	0	0.01
	DF 0014	Prunes	W	0.5		
	VR 0075	Root and tuber vegetables leaves	0.06	-	0.039	0.052
	FS 0012	Stone fruits (except plums)	W	2		
	AS 0081	Straw and fodder (dry) of cereal grains	0.3	-	0.098	0.18
	FB 0275	Strawberry	0.8	1	0.19	0.69
	VO 0448	Tomato	0.3	0.3	0.07	0.25
	JF 0226	Apple juice			0.012	
		Beer			0.023	
	JF 0269	Grape juice			0.068	
		Grape wine			0.048	
	JF 0448	Tomato juice			0.031	
	VW 0448	Tomato paste			0.27	
		Tomato preserve			0.02	
		Tomato purée			0.093	
Definition of the residue (for compliance with the MRL for plant and animal commodities and for estimation of dietary intake for and animal commodities): *myclobutanil.* Definition of the residue (for estimation of dietary intake for plant commodities): *sum of myclobutanil, α-(4-chlorophenyl)-α-(3-hydroxybutyl)-1H-1,2,4-triazole- 1-propanenitrile (RH-9090) and its conjugates, expressed as myclobutanil* *The residue is not fat-soluble*						
Phosmet (103) ADI: 0-0.01 mg/kg bw	FB 0265	Cranberry	3		0.845	0.91

Pesticide (Codex reference number)	CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
ARfD: 0.2 mg/kg bw						
Definition of the residue for compliance with MRL and estimation of dietary intake: *Phosmet*						
Propamocarb (148)	VB 0400	Broccoli	3		0.29	1.7
ADI: 0-0.4 mg/kg bw	VB 0402	Brussels sprouts	2		0.47	1.3
ARfD: 2 mg/kg bw	VB 0041	Cabbages, Head	1		0.195	0.36
	VB 0404	Cauliflower	2	0.2	0.035	0.82
	MO 0105	Edible offal (mammalian)	W	0.01*		
	PE 0112	Eggs	0.01*	0.01*	0.001	0.005
	VL 0480	Kale (including among others: Collards, Curly kale, Scotch kale, thousand-headed kale; not including Marrow-stem kale no. AV 1052 Miscellaneous Fodder and forage crops	20		4	11.8
	VA 0384	Leek	30		2.5	15
	MM 0095	Meat (from mammals other than marine mammals)	W	0.01*		
	ML 0106	Milks	W	0.01*		
	VA 0385	Onion, Bulb	2		0.05	1.4
	PF0111	Poultry fat	0.01*		0.001	0.001
	PM 0110	Poultry meat	0.01*	0.01*	0.001	0.003
	PO 0111	Poultry, Edible offal of	0.01*	0.01*	0.002	0.006
		Spinach, cooked			9.9	
	VW 0448	Tomato paste			1.54	
	JF 0448	Tomato juice			0.27	
		Tomato preserve			0.21	
		Tomato purée			0.40	
Definition of the residue (for compliance with MRLs and estimation of dietary intake) for plant commodities: *Propamocarb*						
Propiconazole (160)	AS 0640	Barley straw and fodder, dry	8	2		
ADI: 0-0.07 mg/kg bw	MO 0105	Edible offal (mammalian)	0.5	0.01*	0.504	1.97
ARfD: 0.3 mg/kg bw	MF 0100	Mammalian fat (except milk fats)	0.01*		0.05	0.115
	MM 0095	Meat (from mammals other than marine mammals)	0.01* (fat)	0.01* (fat)	0.064	0.085
	ML 0106	Milks	0.01*	0.01*	0.035	
	AS 0647	Oat straw and fodder, dry	8	2		
	AS 0650	Rye straw and fodder, dry	15	2		
	AS 0653	Triticale straw and fodder, dry	15	2		

Pesticide (Codex reference number)	**CCN**	**Commodity**	**Recommended Maximum residue level (mg/kg)**		**STMR or STMR-P mg/kg**	**HR or HR-P mg/kg**
			New	**Previous**		
	AS 0654	Wheat straw and fodder, dry	15	2		
Definition of the residue (for compliance with the MRL) for plant and animal commodities: *propiconazole.* Definition of the residue (for the estimation of dietary intake) for plant and animal commodities: *propiconazole plus al metabolites convertible to 2,4-dichloro-benzoic acid, expressed as propiconazole.* *The residue is fat-soluble*						
Prothioconazole (232)	FB 2006	Bush berries	1.5		0.52	0.87
ADI: 0-0.05mg/kg bw	FB 0265	Cranberry	0.15		0.025	0.9
ARfD: 0.8 mg/kg bw (woman of child bearing age)	VC 0045	Fruiting vegetables, Cucurbits (except watermelon)	0.2		0.045	0.15
ARfD: Unnecessary (general population)	AL 0697	Peanut fodder	15		4.08	11.6
	GC 0656	Popcorn	0.1		0.018	
	VR 0589	Potato	0.02*		0.01	0.01
Prothioconazole-desthio	GC 0645	Maize	0.1		0.018	
ADI: 0–0.01 mg/kg bw	AS 0645	Maize fodder (dry)	15		3.48	6.7
ARfD: 0.01 mg/kg bw (woman of child bearing age)	VO 0447	Sweet corn (corn-on-the-cob)	0.02		0.018	0.018
	VD 0541	Soya bean (dry)	0.2		0.05	
ARfD: 1 mg/kg bw (general population)		Sweet corn fodder	15		3.48	6.7
	CF 1255	Maize flour			0.01	
	OR 0645	Maize oil, edible			0.005	
		Maize starch			0.005	
	OR 0495	Rape seed oil, edible			0.02	
Definition of the residue (for compliance with MRL and estimation of dietary intake) for plant commodities: *prothioconazole-desthio*. Definition of the residue (for compliance with the MRL) for animal commodities: *prothioconazole-desthio*. Definition of the residue (for the estimation of dietary intake) for animal commodities: *the sum of prothioconazole-desthio, prothioconazole-desthio-3-hydroxy, prothioconazole-desthio-4-hydroxy and their conjugates expressed as prothioconazole-desthio* *The residue is not fat soluble*						
Pymetrozine (279)* ADI: 0-0.03 mg/kg bw ARfD: 0.1 mg/kg bw						
Definition of the residue (for compliance with MRL) for plant commodities, mammalian tissues, poultry tissues and eggs: *pymetrozine* Definition of the residue (for compliance with MRL) for milks: *CGA313124 (4,5-dihydro-6-hydroxymethyl-4-[(3-pyridinyl-*						

Pesticide (Codex reference number)	CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
methylene)amino]-1,2,4-triazine-3(2H)-one) Definition of the residue for the estimation of dietary intake: *a conclusion could not be reached* *The residue is not fat soluble*						
Pyraclostrobin (210)	FS 0013	Cherries	W	3		
ADI: 0-0.03 mg/kg bw	FS 0013	Cherries (includes all commodities in this subgroup)	3		0.51	1.57
ARfD: 0.05 mg/kg bw	FS 0245	Nectarine	W	0.3		
	FS 2001	Peaches (including Nectarine and Apricots)	0.3		0.07	0.13
	FS 0247	Peach	W	0.3		
	FS 0014	Plums (includes all commodities in this subgroup)	0.8		0.09	0.40
	FS 0014	Plums (including Prunes)	W	0.8		
Definition of the residue (for compliance with MRL and for estimation of dietary intake) for plant and animal commodities: *Pyraclostrobin* *The residue is fat-soluble*						
Sedaxane (259)	GC 0640	Barley	W	0.01*		
ADI: 0-0.1 mg/kg bw	AS 0640	Barley straw and fodder, dry	W	0.01*		
ARfD: 0.3 mg/kg bw	AL 0061	Bean fodder	0.01*		0	
	GC 0080	Cereal grains	0.01*		0	
	AS 0647	Oat straw and fodder, dry	W	0.01*		
	GC 0647	Oats	W	0.01*		
	AL 0072	Pea hay or pea fodder (dry)	0.01*		0	
	VR 0589	Potato	0.02		0.01	0.018
	VD 0070	Pulses	0.01*		0	
	GC 0650	Rye	W	0.01*		
	AS 0650	Rye straw and fodder, dry	W	0.01*		
	VD 0541	Soya bean (dry)	W	0.01*		
	AS 0161	Straw, fodder (dry) and hay of cereal grains and other grass-like plants	0.1		0	
	VO 0447	Sweet corn (corn-on-the-cob)	0.01*		0	0.01
	GC 0653	Triticale	W	0.01*		
	AS 0653	Triticale straw and fodder, dry	W	0.01*		
	GC 0654	Wheat	W	0.01*		
	AS 0654	Wheat straw and fodder, dry	W	0.01*		
Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and anima						

Pesticide (Codex reference number)	**CCN**	**Commodity**	**Recommended Maximum residue level (mg/kg)**		**STMR or STMR-P mg/kg**	**HR or HR-P mg/kg**
			New	**Previous**		
commodities: *sedaxane*. *The residue is fat-soluble.*						
Spirodiclofen (237)	FI 0326	Avocado	0.9		0.07	
ADI: 0-0.01 mg/kg bw	FB 0020	Blueberries	4		0.92	
ARfD: Unnecessary						
Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant commodities: *spirodiclofen.* Definition of the residue (for compliance with the MRL) for animal commodities: *spirodiclofen.* Definition of the residue (for estimation of dietary intake) for animal commodities: *the sum of spirodiclofen and spirodiclofen-enol, expressed as spirodiclofen.* *The residue is fat soluble*						
Sulfoxaflor (252)	FS 0013	Cherries	1.5		0.34	1.24
ADI: 0-0.05 mg/kg bw	FC 0001	Citrus fruits	W	0.9		
ARfD: 0.3 mg/kg bw	FC 0002	Lemons and limes (including Citron)	0.4		0.038	0.17
	MM 0100	Mammalian fat (except milk fats)	0.1		0.03	0.073
	FC 0003	Mandarins (including Mandarin-like hybrids)	0.8		0.26	0.44
	FC 0004	Oranges, Sweet, Sour	0.8		0.26	0.44
	FS 2001	Peaches (including Nectarine and Apricots)	0.4		0.061	0.2
	FS 0014	Plums (including prunes)	0.5		0.038	0.26
	FP 0009	Pome fruits	0.3	0.4	0.067	0.23
	PF 0111	Poultry fats	0.03		0.005	0.021
	FC 0005	Pummelo and Grapefruits	0.15		0.0125	0.066
	FS0012	Stone fruits	W	3		
	TN 0085	Tree nuts	W	0.015		
	JF 0226	Apple juice			0.027	
		Apple sauce			0.040	
		Cherry juice			0.27	
		Cherry jam			0.37	
		Cherry, dried			1.73	6.32
	JF 0004	Orange juice			0.036	
	OR 0004	Orange oil, edible			< 0.052	
		Orange peel			1.46	2.46
Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities: *Sulfoxaflor* *The residue is not fat soluble*						

Pesticide (Codex reference number)	**CCN**	**Commodity**	**Recommended Maximum residue level (mg/kg)**		**STMR or STMR-P mg/kg**	**HR or HR-P mg/kg**
			New	**Previous**		
Thiamethoxam (245)	FI 0326	Avocado	0.5		0.08	0.30
ADI: 0-0.08 mg/kg bw	VP 0061	Beans, except broad bean and soya bean	0.3		0.08	0.18
ARfD: 1 mg/kg bw	DH 1100	Hops	0.09		0.028	0.55
	FI 0345	Mango	0.2		0.03	0.11
	HH 0738	Mints [a]	1.5		0.34	0.86
		Mango dried			0.18	0.65
		Mango pulp			0.02	0.07
[a] It is noted that there are several types of mints (native mints HH0764, Vietnamese mint HH0765). The reported CCN code is listed for several types of mints, including spearmint and peppermint Definition of the residue (for compliance with the MRL) for animal and plant commodities: *thiamethoxam*. Definition of the residue (for estimation of the dietary intake) for plant and animal commodities (except poultry*): thiamethoxam and clothianidin* (considered separately) Definition of the residue (for estimation of the dietary intake) for poultry: *sum of thiamethoxam, CGA 265307 and MU3, expressed as thiamethoxam; and clothianidin* (clothianidin to be considered separately from thiamethoxam). *The residue is not fat-soluble.* The recommendations for CGA322704 are listed in the clothianidin appraisal 2014						
Triadimenol (168)	FB 0269	Grapes	0.3		0.025	0.13
ADI: 0-0.03 mg/kg bw	DF 0269	Dried grapes (=currants, Raisins and Sultanas)	1 [a]	10 [b]	0.155	0.4
ARfD: 0.08 mg/kg bw						
	JF 0269	Grapes juice			0.011	
		Wine			0.01	
[a] based on uses for triadimenol [b] based on uses on triadimefon and triadimenol Definition of the residue (for the estimation of dietary intake and for compliance with MRLs) for plant and animal commodities*: sum of triadimefon and triadimenol*						
Triforine (116) **	FP 0226	Apple	W	2		
ADI: 0-0.03 mg/kg bw	FB 0020	Blueberries	0.03	1	0.01	0.018
ARfD: 0.3 mg/kg bw	VB 0402	Brussels sprouts	W	0.2		
	GC 0080	Cereal grains	W	0.1		
	FS 0013	Cherries	W	2		
	VP 0526	Common bean (pods and immature seeds)	W	1		
	FB 0021	Currants, Black, Red, White	W	1		
	MO 0105	Edible offal (mammalian)	0.01*		0	0
	VO 0440	Egg plant	1	-	0.29	0.39
	VC 0045	Fruiting vegetables, Cucurbits	W	0.5		
	FB 0268	Gooseberry	W	1		
	MM 0100	Mammalian fat (except	0.01*			

Pesticide (Codex reference number)	**CCN**	**Commodity**	**Recommended Maximum residue level (mg/kg)**		**STMR or STMR-P mg/kg**	**HR or HR-P mg/kg**
			New	**Previous**		
		milk fats)				
	MM 0095	Meat (from mammals other than marine mammals)	0.01*		0	0
	ML 0106	Milks	0.01*		0	
	FS 0247	Peach	W	5 Po		
	FS 0014	Plums (including Prunes)	W	2		
	FB 0275	Strawberry	W	1		
	VO 0448	Tomato	0.7	0.5	0.15	0.40
	JF 0448	Tomato juice			0.11	
	VW 0448	Tomato paste			<0.001	
		Tomato purée			0.35	
Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant commodities: *Triforine* Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for animal commodities: *Triforine and its metabolites determined as chloral hydrate expressed as triforine* *The residue is not fat soluble*						

ANNEX 2: INDEX OF REPORTS AND EVALUATIONS OF PESTICIDES BY THE JMPR

Numbers in parentheses after the names of pesticides are Codex classification numbers. The abbreviations used are:

T, evaluation of toxicology

R, evaluation of residue and analytical aspects

E, evaluation of effects on the environment

Abamectin (177)	1992 (T,R), 1994 (T,R), 1995 (T), 1997 (T,R), 2000 (R)
Acephate (095)	1976 (T,R), 1979 (R), 1981 (R), 1982 (T), 1984 (T,R), 1987 (T), 1988 (T), 1990 (T,R), 1991 (corr. to 1990 R evaluation), 1994 (R), 1996 (R), 2002 (T), 2003 (R), 2004 (corr. to 2003 report), 2005 (T), 2006 (R), 2011 (R)
Acetamiprid (246)	2011 (T,R)
Acrylonitrile	1965 (T,R)
Aldicarb (117)	1979 (T,R), 1982 (T,R), 1985 (R), 1988 (R), 1990 (R), 1991 (corr. to 1990 evaluation), 1992 (T), 1993 (R), 1994 (R), 1996 (R), 2001 (R), 2002 (R), 2006 (R)
Aldrin (001)	1965 (T), 1966 (T,R), 1967 (R), 1974 (R), 1975 (R), 1977 (T), 1990 (R), 1992 (R)
Allethrin	1965 (T,R)
Ametoctradin (253)	2012 (T,R)
Aminocarb (134)	1978 (T,R), 1979 (T,R)
Aminocyclopyrachlor (272)	2014 (T,R)
Aminomethylphosphonic acid (AMPA, 198)	1997 (T,R)
Aminopyralid (220)	2006 (T,R), 2007 (T,R)
Amitraz (122)	1980 (T,R), 1983 (R), 1984 (T,R), 1985 (R), 1986 (R), 1989 (R), 1990 (T,R), 1991 (R & corr. to 1990 R evaluation), 1998 (T)
Amitrole (079)	1974 (T,R), 1977 (T), 1993 (T,R), 1997 (T), 1998 (R)
Anilazine (163)	1989 (T,R), 1992 (R)
Atrazine	2007 (T)
Azinphos-ethyl (068)	1973 (T,R), 1983 (R)
Azinphos-methyl (002)	1965 (T), 1968 (T,R), 1972 (R), 1973 (T), 1974 (R), 1991 (T,R), 1992 (corr. to 1991 report), 1993 (R), 1995 (R), 2007 (T)
Azocyclotin (129)	1979 (R), 1981 (T), 1982 (R),1983 (R), 1985 (R), 1989 (T,R), 1991 (R), 1994 (T), 2005 (T,R)

Azoxystrobin (229)	2008 (T,R), 2011 (R), 2012 (R), 2013 (R)
Benalaxyl (155)	1986 (R), 1987 (T), 1988 (R), 1992 (R), 1993 (R), 2005 (T), 2009 (R)
Bendiocarb (137)	1982 (T,R), 1984 (T,R), 1989 (R), 1990 (R)
Benomyl (069)	1973 (T,R), 1975 (T,R), 1978 (T,R), 1983 (T,R), 1988 (R), 1990 (R), 1994 (R), 1995 (T,E), 1998 (R)
Bentazone (172)	1991 (T,R), 1992 (corr. to 1991 report, Annex I), 1994 (R), 1995 (R), 1998 (T,R), 1999 (corr. to 1998 report), 2004(T), 2012 (T), 2013 (R)
Benzovinfiflupyr (261)	2013 (T), 2014 (R)
BHC (technical-grade)	1965 (T), 1968 (T,R), 1973 (T,R) (see also Lindane)
Bifenazate (219)	2006 (T,R), 2008 (R), 2010 (R)
Bifenthrin (178)	1992 (T,R), 1995 (R), 1996 (R), 1997 (R), 2009 (T), 2010 (R)
Binapacryl (003)	1969 (T,R), 1974 (R), 1982 (T), 1984 (R), 1985 (T,R)
Bioresmethrin (093)	1975 (R), 1976 (T,R), 1991 (T,R)
Biphenyl	See Diphenyl
Bitertanol (144)	1983 (T), 1984 (R), 1986 (R), 1987 (T), 1988 (R), 1989 (R), 1991 (R), 1998 (T), 1999 (R), 2002 (R)
Bixafen (262)	2013 (T,R)
Boscalid (221)	2006 (T,R), 2008 (R), 2010 (R)
Bromide ion (047)	1968 (R), 1969 (T,R), 1971 (R), 1979 (R), 1981 (R), 1983 (R), 1988 (T,R), 1989 (R), 1992 (R)
Bromomethane (052)	1965 (T,R), 1966 (T,R), 1967 (R), 1968 (T,R), 1971 (R), 1979 (R), 1985 (R), 1992 (R)
Bromophos (004)	1972 (T,R), 1975 (R), 1977 (T,R), 1982 (R), 1984 (R), 1985 (R)
Bromophos-ethyl (005)	1972 (T,R), 1975 (T,R), 1977 (R)
Bromopropylate (070)	1973 (T,R), 1993 (T,R)
Butocarboxim (139)	1983 (R), 1984 (T), 1985 (T), 1986 (R)
Buprofezin (173)	1991 (T,R), 1995 (R), 1996 (corr. to 1995 report.), 1999 (R), 2008 (T,R), 2009 (R), 2012 (R), 2014 (R)
sec-Butylamine (089)	1975 (T,R), 1977 (R), 1978 (T,R), 1979 (R), 1980 (R), 1981 (T), 1984 (T,R: withdrawal of temporary ADI, but no evaluation)
Cadusafos (174)	1991 (T,R), 1992 (R), 1992 (R), 2009 (R), 2010 (R)
Campheclor (071)	1968 (T,R), 1973 (T,R)
Captafol (006)	1969 (T,R), 1973 (T,R), 1974 (R), 1976 (R), 1977 (T,R), 1982 (T), 1985 (T,R), 1986 (corr. to 1985 report), 1990 (R), 1999 (acute Rf D)

Captan (007)	1965 (T), 1969 (T,R), 1973 (T), 1974 (R), 1977 (T,R), 1978 (T,R), 1980 (R), 1982 (T), 1984 (T,R), 1986 (R), 1987 (R and corr. to 1986 R evaluation), 1990 (T,R), 1991 (corr. to 1990 R evaluation), 1994 (R), 1995 (T), 1997 (R), 2000 (R), 2004 (T), 2007 (T)
Carbaryl (008)	1965 (T), 1966 (T,R), 1967 (T,R), 1968 (R), 1969 (T,R), 1970 (R), 1973 (T,R), 1975 (R), 1976 (R), 1977 (R), 1979 (R), 1984 (R), 1996 (T), 2001 (T), 2002 (R), 2007 (R)
Carbendazim (072)	1973 (T,R), 1976 (R), 1977 (T), 1978 (R), 1983 (T,R), 1985 (T,R), 1987 (R), 1988 (R), 1990 (R), 1994 (R), 1995 (T,E), 1998 (T,R), 2003 (R), 2005 (T), 2012 (R)
Carbofuran (096)	1976 (T,R), 1979 (T,R), 1980 (T), 1982 (T), 1991 (R), 1993 (R), 1996 (T), 1997 (R), 1999 (corr. to 1997 report), 2002 (T,R), 2003 (R) (See also carbosulfan), 2004 (R), 2008 (T), 2009 (R)
Carbon disulfide (009)	1965 (T,R), 1967 (R), 1968 (R), 1971 (R), 1985 (R)
Carbon tetrachloride (010)	1965 (T,R), 1967 (R), 1968 (T,R), 1971 (R), 1979 (R), 1985 (R)
Carbophenothion (011)	1972 (T,R), 1976 (T,R), 1977 (T,R), 1979 (T,R), 1980 (T,R), 1983 (R)
Carbosulfan (145)	1984 (T,R), 1986 (T), 1991 (R), 1992 (corr. to 1991 report), 1993 (R), 1997 (R), 1999 (R), 2002 (R), 2003 (T,R), 2004 (R, corr. to 2003 report)
Cartap (097)	1976 (T,R), 1978 (T,R), 1995 (T,R)
Chinomethionat (080)	1968 (T,R) (as oxythioquinox), 1974 (T,R), 1977 (T,R), 1981 (T,R), 1983 (R), 1984 (T,R), 1987 (T)
Chlorantraniliprole (230)	2008 (T,R), 2010 (R), 2013 (R), 2014 (R)
Chlorbenside	1965 (T)
Chlordane (012)	1965 (T), 1967 (T,R), 1969 (R), 1970 (T,R), 1972 (R), 1974 (R), 1977 (T,R), 1982 (T), 1984 (T,R), 1986 (T)
Chlordimeform (013)	1971 (T,R), 1975 (T,R), 1977 (T), 1978 (T,R), 1979(T), 1980(T), 1985(T), 1986 (R), 1987 (T)
Chlorfenapyr (254)	2013 (T)
Chlorfenson	1965 (T)
Chlorfenvinphos (014)	1971 (T,R), 1984 (R), 1994 (T), 1996 (R)
Chlormequat (015)	1970 (T,R), 1972 (T,R), 1976 (R), 1985 (R), 1994 (T,R), 1997 (T), 1999 (acute Rf D), 2000 (R)
Chlorobenzilate (016)	1965 (T), 1968 (T,R), 1972 (R), 1975 (R), 1977 (R), 1980 (T)
Chloropicrin	1965 (T,R)

Chloropropylate	1968 (T,R), 1972 (R)
Chlorothalonil (081)	1974 (T,R), 1977 (T,R), 1978 (R), 1979 (T,R), 1981 (T,R), 1983 (T,R), 1984 (corr. to 1983 report and T evaluation), 1985 (T,R), 1987 (T), 1988 (R), 1990 (T,R), 1991 (corr. to 1990 evaluation), 1992 (T), 1993 (R), 1997 (R), 2009 (T), 2010 (R), 2012 (R)
Chlorpropham (201)	1965 (T), 2000 (T), 2001 (R), 2005 (T), 2008 (R)
Chlorpyrifos (017)	1972 (T,R), 1974 (R), 1975 (R), 1977 (T,R), 1981 (R), 1982 (T,R), 1983 (R), 1989 (R), 1995 (R), 1999 (T), 2000 (R), 2004 (R), 2006 (R)
Chlorpyrifos-methyl (090)	1975 (T,R), 1976 (R, Annex I only), 1979 (R), 1990, (R), 1991 (T,R), 1992 (T and corr. to 1991 report), 1993 (R), 1994 (R), 2001 (T), 2009 (R)
Chlorthion	1965 (T)
Clethodim (187)	1994 (T,R), 1997 (R), 1999 (R), 2002 (R)
Clofentezine (156)	1986 (T,R), 1987 (R), 1989 (R), 1990 (R), 1992 (R), 2005 (T), 2007 (R)
Clothianidin (238)	2010 (T,R), 2011 (R), 2014 (R)
Coumaphos (018)	1968 (T,R), 1972 (R), 1975 (R), 1978 (R), 1980 (T,R), 1983 (R), 1987 (T), 1990 (T,R)
Crufomate (019)	1968 (T,R), 1972 (R)
Cyanophenfos (091)	1975 (T,R), 1978 (T: ADI extended, but no evaluation), 1980, (T), 1982 (R), 1983 (T)
Cyantraniliprole (263)	2013 (T,R)
Cycloxydim (179)	1992 (T,R), 1993 (R), 2009 (T), 2012 (R)
Cyflumetofen (273)	2014 (T,R)
Cyfluthrin (157)	1986 (R), 1987 (T and corr. to 1986 report), 1989 (R), 1990 (R), 1992 (R), 2006 (T), 2007 (R)
Cyhalothrin (146)	1984 (T,R), 1986 (R), 1988 (R), 2007 (T), 2008 (R)
Cyhexatin (067)	1970 (T,R), 1973 (T,R), 1974 (R), 1975 (R), 1977 (T), 1978 (T,R), 1980 (T), 1981 (T), 1982 (R), 1983 (R), 1985 (R), 1988 (T), 1989 (T), 1991 (T,R), 1992 (R), 1994 (T), 2005 (T,R)
Cypermethrin (118)	1979 (T,R), 1981 (T,R), 1982 (R), 1983 (R), 1984 (R), 1985 (R), 1986 (R), 1987 (corr. to 1986 evaluation), 1988 (R), 1990 (R), 2006 (T), 2008 (R), 2009 (R), 2011 (R)
Cyproconazole (239)	2010 (T,R), 2013 (R)
Cyprodinil (207)	2003 (T,R), 2004 (corr. to 2003 report), 2013 (R)
Cyromazine (169)	1990 (T,R), 1991 (corr. to 1990 R evaluation), 1992 (R), 2006 (T), 2007 (R), 2012 (R)

2,4-D (020)	1970 (T,R), 1971 (T,R), 1974 (T,R), 1975 (T,R), 1980 (R), 1985, (R), 1986 (R), 1987 (corr. to 1986 report, Annex I), 1996 (T), 1997 (E), 1998 (R), 2001 (R)
Daminozide (104)	1977 (T,R), 1983 (T), 1989 (T,R), 1991 (T)
DDT (021)	1965 (T), 1966 (T,R), 1967 (T,R),1968 (T,R), 1969 (T,R), 1978 (R), 1979 (T), 1980 (T), 1983 (T), 1984 (T), 1993 (R), 1994 (R), 1996 (R)
Deltamethrin (135)	1980 (T,R), 1981 (T,R), 1982 (T,R), 1984 (R), 1985 (R), 1986 (R), 1987 (R), 1988 (R), 1990 (R), 1992 (R), 2000 (T), 2002 (R)
Demeton (092)	1965 (T), 1967 (R), 1975 (R), 1982 (T)
Demeton-S-methyl (073)	1973 (T,R), 1979 (R), 1982 (T), 1984 (T,R), 1989 (T,R), 1992 (R), 1998 (R)
Demeton-S-methylsulfon (164)	1973 (T,R), 1982 (T), 1984 (T,R), 1989 (T,R), 1992 (R)
Dialifos (098)	1976 (T,R), 1982 (T), 1985 (R)
Diazinon (022)	1965 (T), 1966 (T), 1967 (R), 1968 (T,R), 1970 (T,R), 1975 (R), 1979 (R), 1993 (T,R), 1994 (R), 1996 (R), 1999 (R), 2001 (T) , 2006 (T,R)
1,2-Dibromoethane (023)	1965 (T,R), 1966 (T,R), 1967 (R), 1968 (R), 1971 (R), 1979 (R), 1985 (R)
Dicamba (240)	2010 (T,R), 2011 (R), 2012 (R), 2013 (R)
Dichlobenil (274)	2014 (T,R)
Dicloran (083)	2003 (R)
Dichlorfluanid (082)	1969 (T,R), 1974 (T,R), 1977 (T,R), 1979 (T,R), 1981 (R),1982 (R), 1983 (T,R), 1985 (R)
1,2-Dichloroethane (024)	1965 (T,R), 1967 (R), 1971 (R), 1979 (R), 1985 (R)
Dichlorvos (025)	1965 (T,R), 1966 (T,R), 1967 (T,R), 1969 (R), 1970 (T,R), 1974 (R), 1977 (T), 1993 (T,R), 2011 (T), 2012 (R)
Dicloran (083)	1974 (T,R), 1977 (T,R), 1998 (T,R)
Dicofol (026)	1968 (T,R), 1970 (R), 1974 (R), 1992 (T,R), 1994 (R), 2011 (T), 2012 (R)
Dieldrin (001)	1965 (T), 1966 (T,R), 1967 (T,R), 1968 (R), 1969 (R), 1970, (T,R), 1974 (R), 1975 (R), 1977 (T), 1990 (R), 1992 (R)
Difenoconazole (224)	2007 (T,R), 2010 (R), 2013 (R)
Diflubenzuron (130)	1981 (T,R), 1983 (R), 1984 (T,R), 1985 (T,R), 1988 (R), 2001 (T), 2002 (R), 2011 (R)
Dimethenamid-P (214)	2005 (T,R)
Dimethipin (151)	1985 (T,R), 1987 (T,R), 1988 (T,R), 1999 (T), 2001 (R), 2004 (T)

Dimethoate (027)	1965 (T), 1966 (T), 1967 (T,R), 1970 (R), 1973 (R in evaluation of formothion), 1977 (R), 1978 (R), 1983 (R) 1984 (T,R) 1986 (R), 1987 (T,R), 1988 (R), 1990 (R), 1991 (corr. to 1990 evaluation), 1994 (R), 1996 (T), 1998 (R), 2003 (T,R), 2004 (corr. to 2003 report), 2006 (R), 2008 (R)
Dimethomorph (225)	2007 (T,R), 2014 (R)
Dimethrin	1965 (T)
Dinocap (087)	1969 (T,R), 1974 (T,R), 1989 (T,R), 1992 (R), 1998 (R), 1999 (R), 2000 (T), 2001 (R)
Dinotefuran (255)	2012 (T,R)
Dioxathion (028)	1968 (T,R), 1972 (R)
Diphenyl (029)	1966 (T,R), 1967 (T)
Diphenylamine (030)	1969 (T,R), 1976 (T,R), 1979 (R), 1982 (T), 1984 (T,R), 1998 (T), 2001 (R), 2003 (R), 2008 (R)
Diquat (031)	1970 (T,R), 1972 (T,R), 1976 (R), 1977 (T,R), 1978 (R), 1994 (R), 2013 (T,R)
Disulfoton (074)	1973 (T,R), 1975 (T,R), 1979 (R), 1981 (R), 1984 (R), 1991 (T,R), 1992 (corr. to 1991 report, Annex I), 1994 (R), 1996 (T), 1998 (R), 2006 (R)
Dithianon (180)	1992 (T,R), 1995 (R), 1996 (corr. to 1995 report), 2010 (T), 2013 (T,R)
Dithiocarbamates (105)	1965 (T), 1967 (T,R), 1970 (T,R), 1983 (R propineb, thiram), 1984 (R propineb), 1985 (R), 1987 (T thiram), 1988 (R thiram), 1990 (R), 1991 (corr. to 1990 evaluation), 1992 (T thiram), 1993 (T,R), 1995 (R), 1996 (T,R ferbam, ziram;, R thiram), 2004 (R), 2012 (R), 2014 (R)
4,6-Dinitro-*ortho*-cresol (DNOC)	1965 (T)
Dodine (084)	1974 (T,R), 1976 (T,R), 1977 (R), 2000 (T), 2003(R) 2004 (corr. to 2003 report)
Edifenphos (099)	1976 (T,R), 1979 (T,R), 1981 (T,R)
Emamectin benzoate (247)	2011 (T,R), 2014 (R)
Endosulfan (032)	1965 (T), 1967 (T,R), 1968 (T,R), 1971 (R), 1974 (R), 1975 (R), 1982 (T), 1985 (T,R), 1989 (T,R), 1993 (R), 1998 (T), 2006 (R), 2010 (R)
Endrin (033)	1965 (T), 1970 (T,R), 1974 (R), 1975 (R), 1990 (R), 1992 (R)
Esfenvalerate (204)	2002 (T,R)
Ethephon (106)	1977 (T,R), 1978 (T,R), 1983 (R), 1985 (R), 1993 (T), 1994 (R), 1995 (T), 1997 (T), 2002 (T)
Ethiofencarb (107)	1977 (T,R), 1978 (R), 1981 (R), 1982 (T,R), 1983 (R)

Ethion (034)	1968 (T,R), 1969 (R), 1970 (R), 1972 (T,R), 1975 (R), 1982 (T), 1983 (R), 1985 (T), 1986 (T), 1989 (T), 1990 (T), 1994 (R)
Ethoprophos (149)	1983 (T), 1984 (R), 1987 (T), 1999 (T), 2004 (R)
Ethoxyquin (035)	1969 (T,R), 1998 (T), 1999 (R). 2005 (T), 2008 (R)
Ethylene dibromide	See 1,2-Dibromoethane
Ethylene dichloride	See 1,2-Dichloroethane
Ethylene oxide	1965 (T,R), 1968 (T,R), 1971 (R)
Ethylenethiourea (ETU) (108)	1974 (R), 1977 (T,R), 1986 (T,R), 1987 (R), 1988 (T,R), 1990 (R), 1993 (T,R)
Etofenprox (184)	1993 (T,R), 2011 (T,R)
Etoxazole (241)	2010 (T,R), 2011 (R)
Etrimfos (123)	1980 (T,R), 1982 (T,R[1]), 1986 (T,R), 1987 (R), 1988 (R), 1989 (R), 1990 (R)
Famoxadone (208)	2003 (T,R)
Fenamidone (264)	2013 (T), 2014 (T,R)
Fenamiphos (085)	1974 (T,R), 1977 (R), 1978 (R), 1980 (R), 1985 (T), 1987 (T), 1997 (T), 1999 (R), 2002 (T), 2006 (R)
Fenarimol (192)	1995 (T,R, E), 1996 (R and corr. to 1995 report)
Fenbuconazole (197)	1997 (T,R), 2009 (R), 2012 (T), 2013 (R)
Fenbutatin oxide (109)	1977 (T,R), 1979 (R), 1992 (T), 1993 (R)
Fenchlorfos (036)	1968 (T,R), 1972 (R), 1983 (R)
Fenhexamid (215)	2005 (T,R)
Fenitrothion (037)	1969 (T,R), 1974 (T,R), 1976 (R), 1977 (T,R), 1979(R), 1982, (T) 1983 (R), 1984 (T,R), 1986 (T,R), 1987 (R and corr. to 1986 R evaluation), 1988 (T), 1989 (R), 2000 (T), 2003 (R), 2004 (R, corr. to 2003 report), 2007 (T,R)
Fenpropathrin (185)	1993 (T,R), 2006 (R), 2012 (T), 2014 (R)
Fenpropimorph (188)	1994 (T), 1995 (R), 1999 (R), 2001 (T), 2004 (T)
Fenpyroximate (193)	1995 (T,R), 1996 (corr. to 1995 report.), 1999 (R), 2004 (T), 2007 (T), 2010 (R), 2013 (R)
Fensulfothion (038)	1972 (T,R), 1982 (T), 1983 (R)
Fenthion (039)	1971 (T,R), 1975 (T,R), 1977 (R), 1978 (T,R), 1979 (T), 1980 (T), 1983 (R), 1989 (R), 1995 (T,R,E), 1996 (corr. to 1995 report), 1997 (T), 2000 (R)
Fentin compounds (040)	1965 (T), 1970 (T,R), 1972 (R), 1986 (R), 1991 (T,R), 1993 (R), 1994 (R)
Fenvalerate (119)	1979 (T,R), 1981 (T,R), 1982 (T), 1984 (T,R), 1985 (R), 1986 (T,R), 1987 (R and corr. to 1986

	report), 1988 (R), 1990 (R), 1991 (corr. to 1990 R evaluation), 2012 (T,R)
Ferbam See Dithiocarbamates, 1965 (T), 1967 (T,R), 1996 (T,R)	
Fipronil (202)	1997 (T), 2000 (T), 2001 (R)
Fipronil-desulfinyl	1997 (T)
Flubendiamide (242)	2010 (T,R)
Flucythrinate (152)	1985 (T,R), 1987 (R), 1988 (R), 1989 (R), 1990 (R), 1993 (R)
Fludioxonil (211)	2004 (T,R), 2006 (R), 2010 (R), 2012 (R), 2013 (R)
Fluensulfone (265)	2013 (T), 2014 (T,R)
Flufenoxuron (275)	2014 (T,R)
Flumethrin (195)	1996 (T,R)
Fluopicolide (235)	2009 (T,R), 2014 (R)
Fluopyram (243)	2010 (T,R), 2012 (R), 2014 (R)
Flusilazole (165)	1989 (T,R), 1990 (R), 1991 (R), 1993 (R), 1995 (T), 2007 (T,R)
Flutolanil (205)	2002 (T,R), 2013 (R)
Flutriafol (248)	2011 (T,R)
Fluxapyroxad (256)	2012 (T,R)
Folpet (041)	1969 (T,R), 1973 (T), 1974 (R), 1982 (T), 1984 (T,R), 1986 (T), 1987 (R), 1990 (T,R), 1991 (corr. to 1990 R evaluation), 1993 (T,R), 1994 (R), 1995 (T), 1997 (R), 1998 (R), 1999(R) , 2002 (T), 2004 (T), 2007 (T)
Formothion (042)	1969 (T,R), 1972 (R), 1973 (T,R), 1978 (R), 1998 (R)
Glufosinate-ammonium (175)	1991 (T,R), 1992 (corr. to 1991 report, Annex I), 1994 (R), 1998 (R), 1999 (T,R), 2012 (T,R), 2014 (R)
Glyphosate (158)	1986 (T,R), 1987 (R and corr. to 1986 report), 1988 (R), 1994 (R), 1997 (T,R), 2004 (T), 2005 (R), 2011 (T,R), 2013 (R)
Guazatine (114)	1978 (T.R), 1980 (R), 1997 (T,R)
Haloxyfop (194)	1995 (T,R), 1996 (R and corr. to 1995 report), 2001 (R), 2006 (T), 2009 (R)
Heptachlor (043)	1965 (T), 1966 (T,R), 1967 (R), 1968 (R), 1969 (R), 1970 (T,R), 1974 (R), 1975 (R), 1977 (R), 1987 (R), 1991 (T,R), 1992 (corr. to 1991 report, Annex I), 1993 (R), 1994 (R)
Hexachlorobenzene (044)	1969 (T,R), 1973 (T,R), 1974 (T,R), 1978(T), 1985 (R)

Hexaconazole (170)	1990 (T,R), 1991 (R and corr. to 1990 R evaluation), 1993 (R)
Hexythiazox (176)	1991 (T,R), 1994 (R), 1998 (R), 2008 (T), 2009 (R)
Hydrogen cyanide (045)	1965 (T,R)
Hydrogen phosphide (046)	1965 (T,R), 1966 (T,R), 1967 (R), 1969 (R), 1971 (R)
Imazalil (110)	1977 (T,R), 1980 (T,R), 1984 (T,R), 1985 (T,R), 1986 (T), 1988 (R), 1989 (R), 1991 (T), 1994 (R), 2000 (T), 2001 (T), 2005 (T)
Imazamox (276)	2014 (T,R)
Imazapic (266)	2013 (T,R)
Imazapyr (267)	2013 (T,R)
Imidacloprid (206)	2001 (T), 2002 (R), 2006 (R), 2008 (R), 2012 (R)
Indoxacarb (216)	2005 (T,R), 2007 (R), 2009 (R), 2012 (R), 2013 (R)
Iprodione (111)	1977 (T,R), 1980 (R), 1992 (T), 1994 (R), 1995 (T), 2001 (R)
Isofenphos (131)	1981 (T,R), 1982 (T,R), 1984 (R), 1985 (R), 1986 (T,R), 1988 (R), 1992 (R)
Isopyrazam (249)	2011 (T,R)
Isoxaflutole (268)	2013 (T,R)
Kresoxim-methyl (199)	1998 (T,R), 2001 (R)
Lead arsenate	1965 (T), 1968 (T,R)
Leptophos (088)	1974 (T,R), 1975 (T,R), 1978 (T,R)
Lindane (048)	1965 (T), 1966 (T,R), 1967 (R), 1968 (R), 1969 (R), 1970 (T,R, published as Annex VI to 1971 evaluations), 1973 (T,R), 1974 (R), 1975 (R), 1977 (T,R), 1978 (R), 1979 (R), 1989 (T,R), 1997 (T), 2002 (T), 2003 (R), 2004 (corr. to 2003 report)
Malathion (049)	1965 (T), 1966 (T,R), 1967 (corr. to 1966 R evaluation), 1968 (R), 1969 (R), 1970 (R), 1973 (R), 1975 (R), 1977 (R), 1984 (R), 1997 (T), 1999 (R), 2000 (R), 2003 (T), 2004 (R), 2005 (R), 2008 (R), 2013 (R)
Maleic hydrazide (102)	1976 (T,R), 1977 (T,R), 1980 (T), 1984 (T,R), 1996 (T), 1998 (R)
Mancozeb (050)	1967 (T,R), 1970 (T,R), 1974 (R), 1977 (R), 1980 (T,R), 1993 (T,R)
Mandipropamid (231)	2008 (T,R), 2013 (R)
Maneb See Dithiocarbamates, 1965 (T), 1967 (T,R), 1987 (T), 1993 (T,R)	
MCPA (257)	2012 (T,R)

Mecarbam (124)	1980 (T,R), 1983 (T,R), 1985 (T,R), 1986 (T,R), 1987 (R)
Meptyldinocap (244)	2010 (T,R)
Mesotrione (277)	2014 (T,R)
Metaflumizone (236)	2009 (T,R)
Metalaxyl (138)	1982 (T,R), 1984 (R), 1985 (R), 1986 (R), 1987 (R), 1989 (R), 1990 (R), 1992 (R), 1995 (R)
Metalaxyl –M (212)	2002 (T), 2004 (R)
Methacrifos (125)	1980 (T,R), 1982 (T), 1986 (T), 1988 (T), 1990 (T,R), 1992 (R)
Methamidophos (100)	1976 (T,R), 1979 (R), 1981 (R), 1982 (T,R), 1984 (R), 1985 (T), 1989 (R), 1990 (T,R), 1994 (R), 1996 (R), 1997 (R), 2002 (T), 2003 (R), 2004 (R, corr. to 2003 report)
Methidathion (051)	1972 (T,R), 1975 (T,R), 1979 (R), 1992 (T,R), 1994 (R), 1997 (T)
Methiocarb (132)	1981 (T,R), 1983 (T,R), 1984 (T), 1985 (T), 1986 (R), 1987 (T,R), 1988 (R), 1998 (T), 1999 (R), 2005 (R)
Methomyl (094)	1975 (R), 1976 (R), 1977 (R), 1978 (R), 1986 (T,R), 1987 (R), 1988 (R), 1989 (T,R), 1990 (R), 1991 (R), 2001 (T,R), 2004 (R), 2008 (R)
Methoprene (147)	1984 (T,R), 1986 (R), 1987 (T and corr. to 1986 report), 1988 (R), 1989 (R), 2001 (T), 2005 (R)
Methoxychlor	1965 (T), 1977 (T)
Methoxyfenozide (209)	2003 (T,R), 2004 (corr. to 2003 report), 2006 (R), 2009 (R), 2012 (R)
Methyl bromide (052)	See Bromomethane
Metrafenone (278)	2014 (T,R)
Metiram (186)	1993 (T), 1995 (R)
Mevinphos (053)	1965 (T), 1972 (T,R), 1996 (T), 1997 (E,R), 2000 (R)
MGK 264	1967 (T,R)
Monocrotophos (054)	1972 (T,R), 1975 (T,R), 1991 (T,R), 1993 (T), 1994 (R)
Myclobutanil (181)	1992 (T,R), 1997 (R), 1998 (R), (2001 (R)), 2014 (T,R)
Nabam See Dithiocarbamates, 1965 (T), 1976 (T,R)	
Nitrofen (140)	1983 (T,R)
Novaluron (217)	2005 (T,R), 2010 (R)
Omethoate (055)	1971 (T,R), 1975 (T,R), 1978 (T,R), 1979 (T), 1981 (T,R), 1984 (R), 1985 (T), 1986 (R), 1987 (R), 1988 (R), 1990 (R), 1998 (R)

Organomercury compounds	1965 (T), 1966 (T,R), 1967 (T,R)
Oxamyl (126)	1980 (T,R), 1983 (R), 1984 (T), 1985 (T,R), 1986 (R), 2002 (T,R)
Oxydemeton-methyl (166)	1965 (T, as demeton-*S*-methyl sulfoxide), 1967 (T), 1968 (R), 1973 (T,R), 1982 (T), 1984 (T,R), 1989 (T,R), 1992 (R), 1998 (R), 1999 (corr. to 1992 report), 2002 (T), 2004 (R)
Oxythioquinox	See Chinomethionat
Paclobutrazol (161)	1988 (T,R), 1989 (R)
Paraquat (057)	1970 (T,R), 1972 (T,R), 1976 (T,R), 1978 (R), 1981 (R), 1982 (T), 1985 (T), 1986 (T), 2003 (T), 2004 (R), 2009 (R)
Parathion (058)	1965 (T), 1967 (T,R), 1969 (R), 1970 (R), 1984 (R), 1991 (R), 1995 (T,R), 1997 (R), 2000 (R)
Parathion-methyl (059)	1965 (T), 1968 (T,R), 1972 (R), 1975 (T,R), 1978 (T,R), 1979 (T), 1980 (T), 1982 (T), 1984 (T,R), 1991 (R), 1992 (R), 1994 (R), 1995 (T), 2000 (R), 2003 (R)
Penconazole (182)	1992 (T,R), 1995 (R)
Penthiopyrad (253)	2011 (T), 2012 (R), 2013 (R)
Permethrin (120)	1979 (T,R), 1980 (R), 1981 (T,R), 1982 (R), 1983 (R), 1984 (R), 1985 (R), 1986 (T,R), 1987 (T), 1988 (R), 1989 (R), 1991 (R), 1992 (corr. to 1991 report), 1999 (T)
2-Phenylphenol (056)	1969 (T,R), 1975 (R), 1983 (T), 1985 (T,R), 1989 (T), 1990 (T,R), 1999 (T,R), 2002 (R)
Phenothrin (127)	1979 (R), 1980 (T,R), 1982 (T), 1984 (T), 1987 (R), 1988 (T,R)
Phenthoate (128)	1980 (T,R), 1981 (R), 1984 (T)
Phorate (112)	1977 (T,R), 1982 (T), 1983 (T), 1984 (R), 1985 (T), 1990 (R), 1991 (R), 1992 (R), 1993 (T), 1994 (T), 1996 (T), 2004 (T), 2005 (R), 2012 (R), 2014 (R)
Phosalone (060)	1972 (T,R), 1975 (R), 1976 (R), 1993 (T), 1994 (R), 1997 (T), 1999 (R), 2001 (T)
Phosmet (103)	1976 (R), 1977 (corr. to 1976 R evaluation), 1978 (T,R), 1979 (T,R), 1981 (R), 1984 (R), 1985 (R), 1986 (R), 1987 (R and corr. to 1986 R evaluation), 1988 (R), 1994 (T), 1997 (R), 1998 (T), 2002 (R), 2003 (R), 2007 (R)
Phosphine	See Hydrogen phosphide
Phosphamidon (061)	1965 (T), 1966 (T), 1968 (T,R), 1969 (R), 1972 (R), 1974 (R), 1982 (T), 1985 (T), 1986 (T)
Phoxim (141)	1982 (T), 1983 (R), 1984 (T,R), 1986 (R), 1987 (R), 1988 (R)

Picoxystrobin (258)	2012 (T,R), 2013 (R)
Piperonyl butoxide (062)	1965 (T,R), 1966 (T,R), 1967 (R), 1969 (R), 1972(T,R), 1992 (T,R), 1995 (T), 2001 (R), 2002 (R)
Pirimicarb (101)	1976 (T,R), 1978 (T,R), 1979 (R), 1981 (T,R), 1982 (T), 1985 (R), 2004 (T), 2006 (R)
Pirimiphos-methyl (086)	1974 (T,R), 1976 (T,R), 1977 (R), 1979 (R), 1983 (R), 1985 (R), 1992 (T), 1994 (R), 2003 (R), 2004 (R, corr. to 2003 report), 2006 (T)
Prochloraz (142)	1983 (T,R), 1985 (R), 1987 (R), 1988 (R), 1989 (R), 1990 (R), 1991 (corr. to 1990 report, Annex I, and R evaluation), 1992 (R), 2001 (T), 2004 (R), 2009 (R)
Procymidone(136)	1981 (R), 1982 (T), 1989 (T,R), 1990 (R), 1991 (corr. to 1990 Annex I), 1993 (R), 1998 (R), 2007 (T)
Profenofos (171)	1990 (T,R), 1992 (R), 1994 (R), 1995 (R), 2007 (T), 2008 (R), 2011 (R)
Propamocarb (148)	1984 (T,R), 1986 (T,R), 1987 (R), 2005 (T), 2006 (R), 2014 (R)
Propargite (113)	1977 (T,R), 1978 (R), 1979 (R), 1980 (T,R), 1982 (T,R), 1999 (T), 2002 (R), 2006 (R)
Propham (183)	1965 (T), 1992 (T,R)
Propiconazole (160)	1987 (T,R), 1991 (R), 1994 (R), 2004 (T), 2006 (R), 2007 (R), 2013 (R), 2014 (R)
Propineb	1977 (T,R), 1980 (T), 1983 (T), 1984 (R), 1985 (T,R), 1993 (T,R), 2004 (R)
Propoxur (075)	1973 (T,R), 1977 (R), 1981 (R), 1983 (R), 1989 (T), 1991 (R), 1996 (R)
Propylene oxide (250)	2011 (T,R)
Propylenethiourea (PTU, 150)	1993 (T,R), 1994 (R), 1999 (T)
Prothioconazole (232)	2008 (T,R), 2009 (R), 2014 (R)
Pymetrozine (279)	2014 (T,R)
Pyraclostrobin (210)	2003 (T), 2004 (R), 2006 (R), 2011 (R), 2012 (R), 2014 (R)
Pyrazophos (153)	1985 (T,R), 1987 (R), 1992 (T,R), 1993 (R)
Pyrethrins (063)	1965 (T), 1966 (T,R), 1967 (R), 1968 (R), 1969 (R), 1970 (T), 1972 (T,R), 1974 (R), 1999 (T), 2000 (R), 2003 (T,R), 2005 (R)
Pyrimethanil (226)	2007 (T,R), 2013 (R)
Pyriproxyfen (200)	1999 (R,T), 2000 (R), 2001 (T)
Quinoxyfen (223)	2006 (T,R)
Quintozene (064)	1969 (T,R) 1973 (T,R), 1974 (R), 1975 (T,R), 1976 (Annex I, corr. to 1975 R evaluation), 1977 (T,R), 1995 (T,R), 1998 (R)

Saflufenacil (251)	2011 (T,R)
Sedaxane (259)	2012 (T,R), 2014 (R)
Spinetoram (233)	2008 (T,R), 2012 (R)
Spinosad (203)	2001 (T,R, 2004 (R), 2008 (R), 2011 (R)
Spirodiclofen (237)	2009 (T,R)
Spirotetramat (234)	2008 (T,R), 2011 (R), 2012 (R), 2013 (R)
Sulfoxaflor (252)	2011 (T,R), 2013 (R), 2014 (R)
Sulfuryl fluoride (218)	2005 (T,R)
2,4,5-T (121)	1970 (T,R), 1979 (T,R), 1981 (T)
Tebuconazole (189)	1994 (T,R), 1996 (corr. to Annex II of 1995 report), 1997 (R), 2008 (R), 2010 (T), 2011 (R)
Tebufenozide (196)	1996 (T,R), 1997 (R), 1999 (R), 2001 (T,R), 2003(T)
Tecnazine (115)	1974 (T,R), 1978 (T,R), 1981 (R), 1983 (T), 1987 (R), 1989 (R), 1994 (T,R)
Teflubenzuron (190)	1994 (T), 1996 (R)
Temephos	2006 (T)
Terbufos (167)	1989 (T,R), 1990 (T,R), 2003 (T), 2005 (R)
Thiabendazole (065)	1970 (T,R), 1971 (R), 1972 (R), 1975 (R), 1977 (T,R), 1979 (R), 1981 (R), 1997 (R), 2000 (R), 2006 (T,R)
Thiacloprid (223)	2006 (T,R)
Thiamethoxam (245)	2010 (T,R), 2011 (R), 2012 (R), 2014 (R)
Thiodicarb (154)	1985 (T,R), 1986 (T), 1987 (R), 1988 (R), 2000 (T), 2001 (R)
Thiometon (076)	1969 (T,R), 1973 (T,R), 1976 (R), 1979 (T,R), 1988 (R)
Thiophanate-methyl (077)	1973 (T,R), 1975 (T,R), 1977 (T), 1978 (R), 1988 (R), 2002 (R), 1990 (R), 1994 (R), 1995 (T,E), 1998 (T,R), 2006 (T)
Thiram (105)	See Dithiocarbamates, 1965 (T), 1967 (T,R), 1970 (T,R), 1974 (T), 1977 (T), 1983 (R), 1984 (R), 1985 (T,R), 1987 (T), 1988 (R), 1989 (R), 1992 (T), 1996 (R)
Tolclofos-methyl (191)	1994 (T,R) 1996 (corr. to Annex II of 1995 report)
Tolfenpyrad (269)	2013 (T)
Tolylfluanid (162)	1988 (T,R), 1990 (R), 1991 (corr. to 1990 report), 2002 (T,R), 2003 (R)
Toxaphene	See Camphechlor
Triadimefon (133)	1979 (R), 1981 (T,R), 1983 (T,R), 1984 (R), 1985 (T,R), 1986 (R), 1987 (R and corr. to 1986 R

	evaluation), 1988 (R), 1989 (R), 1992 (R), 1995 (R), 2004 (T), 2007 (R)
Triadimenol (168)	1989 (T,R), 1992 (R), 1995 (R), 2004 (T), 2007 (R), 2014 (R)
Triazolylalanine	1989 (T,R)
Triazophos (143)	1982 (T), 1983 (R), 1984 (corr. to 1983 report, Annex I), 1986 (T,R), 1990 (R), 1991 (T and corr. to 1990 R evaluation), 1992 (R), 1993 (T,R), 2002 (T), 2007 (R), 2010 (R), 2013 (R)
Trichlorfon (066)	1971 (T,R), 1975 (T,R), 1978 (T,R), 1987 (R)
Trichloronat	1971 (T,R)
Trichloroethylene	1968 (R)
Tricyclohexyltin hydroxide	See Cyhexatin
Trifloxystrobin (213)	2004 (T,R), 2012 (R)
Triflumizole (270)	2013 (T,R)
Triforine (116)	1977 (T), 1978 (T,R), 1997 (T), 2004 (R), 2014 (T,R)
Trinexapac-ethyl (271)	2013 (T,R)
Triphenyltin compounds	See Fentin compounds
Vamidothion (078)	1973 (T,R), 1982 (T), 1985 (T,R), 1987 (R), 1988 (T), 1990 (R), 1992 (R)
Vinclozolin (159)	1986 (T,R), 1987 (R and corr. to 1986 report and R evaluation), 1988 (T,R), 1989 (R), 1990 (R), 1992 (R), 1995 (T)
Zineb (105)	See Dithiocarbamates, 1965 (T), 1967 (T,R), 1993 (T)
Ziram (105)	See Dithiocarbamates, 1965 (T), 1967 (T,R), 1996 (T,R)
Zoxamide (227)	2007 (T,R), 2009 (R)

ANNEX 3: INTERNATIONAL ESTIMATED DAILY INTAKES OF PESTICIDE RESIDUES

AMINOCYCLOPYRACHLOR (272) International Estimated Daily Intake (IEDI) ADI = 0 - 3.0000 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day G01 diet	Intake as µg/person/day G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
VA 0035	Bulb vegetables, raw	RAC	0.01	34.29	0.34	46.37	0.46	4.73	0.05	41.36	0.41	21.08	0.21	52.54	0.53
VB 0040	Brassica vegetables, raw: head cabbages, flowerhead brassicas, Brussels sprouts & kohlrabi	RAC	0.01	6.41	0.06	35.79	0.36	0.71	0.01	9.81	0.10	12.07	0.12	16.58	0.17
VL 0053	Leafy vegetables, raw	RAC	0.01	8.47	0.08	22.36	0.22	7.74	0.08	25.51	0.26	45.77	0.46	21.22	0.21
VP 0060	Legume vegetables, raw	RAC	0.01	7.73	0.08	1.53	0.02	0.51	0.01	2.95	0.03	5.08	0.05	12.86	0.13
VD 0070	Pulses, raw (incl processed)	RAC	0.01	85.59	0.86	64.02	0.64	34.15	0.34	88.02	0.88	89.38	0.89	96.88	0.97
VR 0075	Root and tuber vegetables, raw (incl processed)	RAC	0.01	87.83	0.88	374.04	3.74	668.92	6.69	121.64	1.22	94.20	0.94	247.11	2.47
-	Stalk and stem vegetables, raw	RAC	0.01	5.96	0.06	9.30	0.09	5.75	0.06	14.64	0.15	2.67	0.03	8.49	0.08
GC 0080	Cereal grains, raw, (incl processed)	RAC	0.01	484.29	4.84	464.63	4.65	262.36	2.62	486.81	4.87	469.62	4.70	614.04	6.14
GS 0659	Sugar cane, raw (incl sugar, incl molasses)	RAC	0.01	99.68	1.00	86.27	0.86	31.38	0.31	80.36	0.80	84.18	0.84	99.10	0.99
SO 0088	Oilseeds, raw (incl processed)	RAC	0.01	79.30	0.79	54.81	0.55	96.74	0.97	137.72	1.38	61.07	0.61	88.71	0.89
-	Seeds for beverages and seeds, raw or roasted (incl processed)	RAC	0.01	2.08	0.02	7.80	0.08	3.32	0.03	9.39	0.09	2.44	0.02	2.48	0.02
HH 0720	Herbs, raw (incl dried)	RAC	0.01	1.69	0.02	1.91	0.02	1.18	0.01	3.35	0.03	0.55	0.01	1.64	0.02
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.01	24.96	0.25	57.95	0.58	16.70	0.17	38.38	0.38	26.46	0.26	29.00	0.29
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.019	6.24	0.12	14.49	0.28	4.18	0.08	9.60	0.18	6.62	0.13	7.25	0.14
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.019	3.29	0.06	6.14	0.12	0.82	0.02	1.57	0.03	2.23	0.04	1.07	0.02
MO 0105	Edible offal (mammalian), raw	RAC	0.13	4.79	0.62	9.68	1.26	2.97	0.39	5.49	0.71	3.84	0.50	5.03	0.65
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.01	289.65	2.90	485.88	4.86	26.92	0.27	239.03	2.39	199.91	2.00	180.53	1.81
PM 0110	Poultry meat, raw (incl prepared)	RAC	0	14.63	0.00	29.76	0.00	8.04	0.00	129.68	0.00	25.04	0.00	35.66	0.00
PF 0111	Poultry fat, raw (incl rendered)	RAC	0	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.10	0.00	0.10	0.00
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0	0.12	0.00	0.12	0.00	0.11	0.00	5.37	0.00	0.24	0.00	0.10	0.00
PE 0112	Eggs, raw, (incl dried)	RAC	0	7.84	0.00	23.08	0.00	2.88	0.00	14.89	0.00	9.81	0.00	14.83	0.00
	Total intake (µg/person)=				13.0		18.8		12.1		13.9		11.8		15.5
	Bodyweight per region (kg bw) =				60		60		60		60		60		60
	ADI (µg/person)=				180000		180000		180000		180000		180000		180000
	%ADI=				0.0%		0.0%		0.0%		0.0%		0.0%		0.0%
	Rounded %ADI=				0%		0%		0%		0%		0%		0%

Annex 3

AMINOCYCLOPYRACHLOR (272) International Estimated Daily Intake (IEDI) ADI = 0 - 3.0000 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day G07 diet	Intake as µg/person/day G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
VA 0035	Bulb vegetables, raw	RAC	0.01	26.24	0.26	36.47	0.36	39.29	0.39	39.37	0.39	29.12	0.29	20.21	0.20
VB 0040	Brassica vegetables, raw: head cabbages, flowerhead brassicas, Brussels sprouts & kohlrabi	RAC	0.01	20.71	0.21	39.81	0.40	16.70	0.17	28.49	0.28	18.12	0.18	15.03	0.15
VL 0053	Leafy vegetables, raw	RAC	0.01	18.83	0.19	21.85	0.22	121.23	1.21	43.09	0.43	18.18	0.18	18.32	0.18
VP 0060	Legume vegetables, raw	RAC	0.01	18.21	0.18	8.91	0.09	7.22	0.07	10.04	0.10	23.22	0.23	0.17	0.00
VD 0070	Pulses, raw (incl processed)	RAC	0.01	112.88	1.13	123.05	1.23	47.15	0.47	204.64	2.05	227.37	2.27	109.11	1.09
VR 0075	Root and tuber vegetables, raw (incl processed)	RAC	0.01	290.31	2.90	300.35	3.00	214.25	2.14	242.72	2.43	348.67	3.49	137.52	1.38
-	Stalk and stem vegetables, raw	RAC	0.01	14.07	0.14	16.53	0.17	72.50	0.73	8.41	0.08	29.43	0.29	10.06	0.10
GC 0080	Cereal grains, raw, (incl processed)	RAC	0.01	345.63	3.46	386.16	3.86	514.33	5.14	402.72	4.03	295.30	2.95	359.97	3.60
GS 0659	Sugar cane, raw (incl sugar, incl molasses)	RAC	0.01	92.24	0.92	95.72	0.96	28.47	0.28	77.39	0.77	117.73	1.18	103.90	1.04
SO 0088	Oilseeds, raw (incl processed)	RAC	0.01	108.63	1.09	112.14	1.12	64.25	0.64	81.75	0.82	66.09	0.66	20.34	0.20
-	Seeds for beverages and seeds, raw or roasted (incl processed)	RAC	0.01	18.44	0.18	18.03	0.18	1.06	0.01	13.62	0.14	23.34	0.23	13.43	0.13
HH 0720	Herbs, raw (incl dried)	RAC	0.01	2.61	0.03	2.31	0.02	8.89	0.09	3.92	0.04	1.16	0.01	2.06	0.02
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.01	112.02	1.12	120.71	1.21	63.46	0.63	88.99	0.89	96.24	0.96	41.02	0.41
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.019	28.01	0.53	30.18	0.57	15.86	0.30	22.25	0.42	24.06	0.46	10.25	0.19
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.019	6.44	0.12	15.51	0.29	3.79	0.07	8.29	0.16	18.44	0.35	8.00	0.15
MO 0105	Edible offal (mammalian), raw	RAC	0.13	15.17	1.97	5.19	0.67	6.30	0.82	6.78	0.88	3.32	0.43	3.17	0.41
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.01	388.92	3.89	335.88	3.36	49.15	0.49	331.25	3.31	468.56	4.69	245.45	2.45
PM 0110	Poultry meat, raw (incl prepared)	RAC	0	73.76	0.00	53.86	0.00	23.98	0.00	87.12	0.00	53.38	0.00	84.45	0.00
PF 0111	Poultry fat, raw (incl rendered)	RAC	0	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.71	0.00	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0	0.33	0.00	0.72	0.00	0.27	0.00	0.35	0.00	0.80	0.00	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0	25.84	0.00	29.53	0.00	28.05	0.00	33.19	0.00	36.44	0.00	8.89	0.00
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (µg/person)=				18.3		17.7		13.7		17.2		18.9		11.7
	Bodyweight per region (kg bw) =				60		60		55		60		60		60
	ADI (µg/person)=				180000		180000		165000		180000		180000		180000
	%ADI=				0.0%		0.0%		0.0%		0.0%		0.0%		0.0%
	Rounded %ADI=				0%		0%		0%		0%		0%		0%

Annex 3

AMINOCYCLOPYRACHLOR (272) International Estimated Daily Intake (IEDI) ADI = 0 - 3.0000 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day G13 diet	Intake = daily intake: µg/person G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
VA 0035	Bulb vegetables, raw	RAC	0.01	11.28	0.11	23.80	0.24	36.11	0.36	9.66	0.10	8.69	0.09
VB 0040	Brassica vegetables, raw: head cabbages, flowerhead brassicas, Brussels sprouts & kohlrabi	RAC	0.01	4.84	0.05	3.79	0.04	58.72	0.59	0.10	0.00	NC	-
VL 0053	Leafy vegetables, raw	RAC	0.01	12.42	0.12	8.75	0.09	7.53	0.08	7.07	0.07	14.11	0.14
VP 0060	Legume vegetables, raw	RAC	0.01	0.58	0.01	3.16	0.03	10.38	0.10	0.10	0.00	NC	-
VD 0070	Pulses, raw (incl processed)	RAC	0.01	44.03	0.44	29.00	0.29	112.51	1.13	75.50	0.76	39.69	0.40
VR 0075	Root and tuber vegetables, raw (incl processed)	RAC	0.01	282.25	2.82	232.11	2.32	281.91	2.82	620.21	6.20	459.96	4.60
-	Stalk and stem vegetables, raw	RAC	0.01	8.98	0.09	6.47	0.06	7.59	0.08	6.06	0.06	12.10	0.12
GC 0080	Cereal grains, raw, (incl processed)	RAC	0.01	407.04	4.07	417.04	4.17	402.79	4.03	195.30	1.95	263.26	2.63
GS 0659	Sugar cane, raw (incl sugar, incl molasses)	RAC	0.01	33.75	0.34	106.29	1.06	78.09	0.78	29.09	0.29	45.70	0.46
SO 0088	Oilseeds, raw (incl processed)	RAC	0.01	131.71	1.32	22.49	0.22	69.33	0.69	57.68	0.58	86.74	0.87
-	Seeds for beverages and seeds, raw or roasted (incl processed)	RAC	0.01	1.61	0.02	2.21	0.02	17.92	0.18	3.14	0.03	17.04	0.17
HH 0720	Herbs, raw (incl dried)	RAC	0.01	1.85	0.02	1.67	0.02	2.80	0.03	1.24	0.01	2.75	0.03
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.01	23.34	0.23	40.71	0.41	97.15	0.97	18.06	0.18	57.71	0.58
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.019	5.84	0.11	10.18	0.19	24.29	0.46	4.52	0.09	14.43	0.27
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.019	1.05	0.02	1.14	0.02	18.69	0.36	0.94	0.02	3.12	0.06
MO 0105	Edible offal (mammalian), raw	RAC	0.13	4.64	0.60	1.97	0.26	10.01	1.30	3.27	0.43	3.98	0.52
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.01	108.75	1.09	70.31	0.70	436.11	4.36	61.55	0.62	79.09	0.79
PM 0110	Poultry meat, raw (incl prepared)	RAC	0	3.92	0.00	12.03	0.00	57.07	0.00	5.03	0.00	55.56	0.00
PF 0111	Poultry fat, raw (incl rendered)	RAC	0	NC	-	NC	-	0.32	0.00	NC	-	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0	0.10	0.00	0.70	0.00	0.97	0.00	0.10	0.00	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0	3.84	0.00	4.41	0.00	27.25	0.00	1.13	0.00	7.39	0.00
-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (µg/person)=				11.5		10.1		18.3		11.4		11.7
	Bodyweight per region (kg bw) =				60		60		60		60		60
	ADI (µg/person)=				180000		180000		180000		180000		180000
	%ADI=				0.0%		0.0%		0.0%		0.0%		0.0%
	Rounded %ADI=				0%		0%		0%		0%		0%

Annex 3

BENZOVINDIFLUPYR (261) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0500 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day	Intake as µg/person/day										
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
VD 0541	Soya bean, dry, raw (Glycine soja)	RAC	0.01	0.58	0.01	0.10	0.00	0.37	0.00	0.10	0.00	1.65	0.02	0.30	0.00
-	Soya paste (i.e. miso)	PP	0.004	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
-	Soya curd (i.e. tofu)	PP	0.0055	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
OR 0541	Soya oil, refined	PP	0.0066	12.99	0.09	10.43	0.07	3.63	0.02	13.10	0.09	10.70	0.07	13.10	0.09
-	Soya sauce	PP	0.004	0.10	0.00	0.10	0.00	0.10	0.00	0.34	0.00	0.10	0.00	0.10	0.00
-	Soya flour	PP	0.004	0.10	0.00	0.86	0.00	0.10	0.00	1.02	0.00	0.10	0.00	0.15	0.00
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)	RAC	0	31.20	0.00	72.44	0.00	20.88	0.00	47.98	0.00	33.08	0.00	36.25	0.00
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0	3.29	0.00	6.14	0.00	0.82	0.00	1.57	0.00	2.23	0.00	1.07	0.00
MO 0105	Edible offal (mammalian), raw	RAC	0	4.79	0.00	9.68	0.00	2.97	0.00	5.49	0.00	3.84	0.00	5.03	0.00
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0	289.65	0.00	485.88	0.00	26.92	0.00	239.03	0.00	199.91	0.00	180.53	0.00
PM 0110	Poultry meat, raw (incl prepared)	RAC	0	14.63	0.00	29.76	0.00	8.04	0.00	129.68	0.00	25.04	0.00	35.66	0.00
PF 0111	Poultry fat, raw (incl rendered)	RAC	0	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.10	0.00	0.10	0.00
PE 0112	Eggs, raw, (incl dried)	RAC	0	7.84	0.00	23.08	0.00	2.88	0.00	14.89	0.00	9.81	0.00	14.83	0.00
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (µg/person)=				0.1		0.1		0.0		0.1		0.1		0.1
	Bodyweight per region (kg bw) =				60		60		60		60		60		60
	ADI (µg/person)=				3000		3000		3000		3000		3000		3000
	%ADI=				0.0%		0.0%		0.0%		0.0%		0.0%		0.0%
	Rounded %ADI=				0%		0%		0%		0%		0%		0%

BENZOVINDIFLUPYR (261) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0500 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day	Intake as µg/person/day										
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
VD 0541	Soya bean, dry, raw (Glycine soja)	RAC	0.01	0.10	0.00	0.33	0.00	6.64	0.07	3.94	0.04	NC	-	5.78	0.06
-	Soya paste (i.e. miso)	PP	0.004	NC	-	NC	-	NC	-	1.87	0.01	NC	-	NC	-
-	Soya curd (i.e. tofu)	PP	0.0055	NC	-	NC	-	0.68	0.00	0.87	0.00	NC	-	NC	-
OR 0541	Soya oil, refined	PP	0.0066	19.06	0.13	21.06	0.14	5.94	0.04	33.78	0.22	40.05	0.26	13.39	0.09
-	Soya sauce	PP	0.004	0.45	0.00	0.29	0.00	2.93	0.01	4.35	0.02	0.10	0.00	0.70	0.00
-	Soya flour	PP	0.004	0.22	0.00	0.27	0.00	0.29	0.00	0.17	0.00	NC	-	NC	-
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)	RAC	0	140.03	0.00	150.89	0.00	79.32	0.00	111.24	0.00	120.30	0.00	51.27	0.00

Annex 3

BENZOVINDIFLUPYR (261) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0500 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day G07 diet	Intake as µg/person/day G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0	6.44	0.00	15.51	0.00	3.79	0.00	8.29	0.00	18.44	0.00	8.00	0.00
MO 0105	Edible offal (mammalian), raw	RAC	0	15.17	0.00	5.19	0.00	6.30	0.00	6.78	0.00	3.32	0.00	3.17	0.00
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0	388.92	0.00	335.88	0.00	49.15	0.00	331.25	0.00	468.56	0.00	245.45	0.00
PM 0110	Poultry meat, raw (incl prepared)	RAC	0	73.76	0.00	53.86	0.00	23.98	0.00	87.12	0.00	53.38	0.00	84.45	0.00
PF 0111	Poultry fat, raw (incl rendered)	RAC	0	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.71	0.00	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0	25.84	0.00	29.53	0.00	28.05	0.00	33.19	0.00	36.44	0.00	8.89	0.00
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (µg/person)=				0.1		0.1		0.1		0.3		0.3		0.1
	Bodyweight per region (kg bw) =				60		60		55		60		60		60
	ADI (µg/person)=				3000		3000		2750		3000		3000		3000
	%ADI=				0.0%		0.0%		0.0%		0.0%		0.0%		0.0%
	Rounded %ADI=				0%		0%		0%		0%		0%		0%

BENZOVINDIFLUPYR (261) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0500 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day G13 diet	Intake = daily intake: µg/person G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
VD 0541	Soya bean, dry, raw (Glycine soja)	RAC	0.01	2.76	0.03	0.10	0.00	0.33	0.00	3.16	0.03	NC	-
-	Soya paste (i.e. miso)	PP	0.004	NC	-	NC	-	NC	-	NC	-	NC	-
-	Soya curd (i.e. tofu)	PP	0.0055	NC	-	NC	-	NC	-	NC	-	NC	-
OR 0541	Soya oil, refined	PP	0.0066	2.32	0.02	2.54	0.02	18.70	0.12	2.51	0.02	6.29	0.04
-	Soya sauce	PP	0.004	0.10	0.00	0.13	0.00	0.17	0.00	0.10	0.00	0.56	0.00
-	Soya flour	PP	0.004	0.11	0.00	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)	RAC	0	29.18	0.00	50.89	0.00	121.44	0.00	22.58	0.00	72.14	0.00
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0	1.05	0.00	1.14	0.00	18.69	0.00	0.94	0.00	3.12	0.00
MO 0105	Edible offal (mammalian), raw	RAC	0	4.64	0.00	1.97	0.00	10.01	0.00	3.27	0.00	3.98	0.00
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0	108.75	0.00	70.31	0.00	436.11	0.00	61.55	0.00	79.09	0.00
PM 0110	Poultry meat, raw (incl prepared)	RAC	0	3.92	0.00	12.03	0.00	57.07	0.00	5.03	0.00	55.56	0.00
PF 0111	Poultry fat, raw (incl rendered)	RAC	0	NC	-	NC	-	0.32	0.00	NC	-	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0	3.84	0.00	4.41	0.00	27.25	0.00	1.13	0.00	7.39	0.00
-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (µg/person)=				0.0		0.0		0.1		0.0		0.0
	Bodyweight per region (kg bw) =				60		60		60		60		60
	ADI (µg/person)=				3000		3000		3000		3000		3000

Annex 3

BENZOVINDIFLUPYR (261) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0500 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day G13 diet	Intake = daily intake: µg/person G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
	%ADI=				0.0%		0.0%		0.0%		0.0%		0.0%
	Rounded %ADI=				0%		0%		0%		0%		0%

Annex 3

BUPROFEZIN (173) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0090 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day						Intake as µg/person/day					
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
TN 0660	Almonds, nutmeat	RAC	0.05	1.38	0.07	0.10	0.01	0.10	0.01	1.00	0.05	0.10	0.01	0.81	0.04
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.16	0.32	0.05	3.07	0.49	0.10	0.02	5.00	0.80	0.29	0.05	5.57	0.89
FP 0226	Apple, raw (incl cider, excl juice)	RAC	0.28	13.49	3.78	26.63	7.46	15.05	4.21	16.28	4.56	6.47	1.81	47.88	13.41
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.01	5.06	0.05	6.91	0.07	37.17	0.37	31.16	0.31	40.21	0.40	18.96	0.19
FS 0013	Cherries, raw	RAC	0.73	0.92	0.67	9.15	6.68	0.10	0.07	0.61	0.45	0.10	0.07	6.64	4.85
FC 0001	Citrus fruit, raw	RAC	0.04	32.25	1.29	11.67	0.47	16.70	0.67	76.01	3.04	33.90	1.36	92.97	3.72
-	Coffee beans, instant coffee (incl essences and concentrates)	PP	0.0016	0.10	0.00	0.94	0.00	0.10	0.00	0.70	0.00	0.10	0.00	0.29	0.00
SB 0716	Coffee beans, raw (i.e. green coffee)	RAC	0.08	0.96	0.08	0.16	0.01	0.91	0.07	0.27	0.02	1.37	0.11	0.46	0.04
SM 0716	Coffee beans, roasted	PP	0.0256	0.19	0.00	0.91	0.02	0.16	0.00	2.50	0.06	0.39	0.01	0.40	0.01
MO 0105	Edible offal (mammalian), raw	RAC	0	4.79	0.00	9.68	0.00	2.97	0.00	5.49	0.00	3.84	0.00	5.03	0.00
VC 0045	Fruiting vegetables, cucurbits, raw	RAC	0.195	53.14	10.36	86.21	16.81	6.28	1.22	92.76	18.09	15.64	3.05	155.30	30.28
JF 0269	Grape juice	PP	0.098	0.14	0.01	0.29	0.03	0.10	0.01	0.30	0.03	0.24	0.02	0.10	0.01
-	Grape wine (incl vermouths)	PP	0.15	0.67	0.10	12.53	1.88	2.01	0.30	1.21	0.18	3.53	0.53	4.01	0.60
DF 0269	Grape, dried (= currants, raisins and sultanas)	PP	0.37	0.51	0.19	0.51	0.19	0.10	0.04	1.27	0.47	0.12	0.04	2.07	0.77
FB 0269	Grape, raw (incl must, excl dried, excl juice, excl wine)	RAC	0.17	13.02	2.21	9.25	1.57	0.10	0.02	16.91	2.87	3.70	0.63	54.44	9.25
JF 0203	Grapefruits, juice (single strength, incl. concentrated)	PP	0.13	0.10	0.01	0.16	0.02	0.10	0.01	1.97	0.26	0.12	0.02	0.77	0.10
-	Lemon, juice (single strength, incl. concentrated)	PP	0.13	0.10	0.01	0.10	0.01	0.11	0.01	0.10	0.01	0.18	0.02	0.17	0.02
-	Mandarins, juice	PP	0.13	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
FI 0345	Mango, raw (incl canned mango, incl mango juice)	RAC	0.01	10.48	0.10	0.10	0.00	7.24	0.07	6.87	0.07	19.98	0.20	6.25	0.06
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)	RAC	0	31.20	0.00	72.44	0.00	20.88	0.00	47.98	0.00	33.08	0.00	36.25	0.00
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0	289.65	0.00	485.88	0.00	26.92	0.00	239.03	0.00	199.91	0.00	180.53	0.00
-	Olive oil (virgin and residue oil)	PP	3.49	2.17	7.57	0.13	0.45	0.10	0.35	1.32	4.61	0.10	0.35	2.76	9.63
JF 0004	Oranges, juice (single strength, incl. concentrated)	PP	0.13	1.27	0.17	2.20	0.29	0.10	0.01	11.81	1.54	0.46	0.06	1.69	0.22
-	Peaches and nectarines, raw	RAC	1.355	2.87	3.89	2.21	2.99	0.15	0.20	5.94	8.05	1.47	1.99	15.66	21.22
FP 0230	Pear, raw	RAC	1.09	2.16	2.35	6.24	6.80	0.10	0.11	4.07	4.44	1.16	1.26	5.34	5.82
VO 0444	Peppers, chili, raw (incl dried)	RAC	0.33	6.93	2.29	10.97	3.62	8.83	2.91	9.13	3.01	6.65	2.19	20.01	6.60
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.33	4.49	1.48	6.44	2.13	7.21	2.38	5.68	1.87	9.52	3.14	8.92	2.94
DF 0014	Plum, dried (prunes)	PP	0.465	0.10	0.05	0.10	0.05	0.10	0.05	0.18	0.08	0.10	0.05	0.10	0.05
FS 0014	Plums, raw (excl jujube)	RAC	0.155	2.40	0.37	8.60	1.33	0.10	0.02	2.52	0.39	0.58	0.09	4.16	0.64
FB 0275	Strawberry, raw	RAC	0.44	0.70	0.31	2.01	0.88	0.10	0.04	1.36	0.60	0.37	0.16	2.53	1.11
FT 0305	Table olive, raw (incl preserved)	RAC	1.125	0.70	0.79	0.32	0.36	0.10	0.11	1.53	1.72	0.17	0.19	1.85	2.08
DT 1114	Tea, green or black, fermented and dried,	RAC	9	2.28	20.52	1.98	17.82	0.46	4.14	2.43	21.87	1.29	11.61	3.04	27.36

Annex 3

BUPROFEZIN (173) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0090 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day G01 diet	Intake as µg/person/day G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
	(including concentrates)														
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.053	0.29	0.02	0.29	0.02	0.10	0.01	0.38	0.02	0.10	0.01	0.14	0.01
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.22	2.34	0.51	1.33	0.29	1.57	0.35	4.24	0.93	0.34	0.07	2.83	0.62
VO 0448	Tomato, raw (incl canned, excl juice, excl paste)	RAC	0.24	42.04	10.09	76.13	18.27	10.69	2.57	84.59	20.30	24.92	5.98	203.27	48.78
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (µg/person)=				69.4		91.0		20.4		100.7		35.5		191.3
	Bodyweight per region (kg bw) =				60		60		60		60		60		60
	ADI (µg/person)=				540		540		540		540		540		540
	%ADI=				12.9%		16.9%		3.8%		18.7%		6.6%		35.4%
	Rounded %ADI=				10%		20%		4%		20%		7%		40%

BUPROFEZIN (173) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0090 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day G07 diet	Intake as µg/person/day G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
TN 0660	Almonds, nutmeat	RAC	0.05	0.81	0.04	2.21	0.11	0.10	0.01	1.02	0.05	1.47	0.07	NC	-
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.16	14.88	2.38	11.98	1.92	0.15	0.02	9.98	1.60	30.32	4.85	3.47	0.56
FP 0226	Apple, raw (incl cider, excl juice)	RAC	0.28	41.14	11.52	56.49	15.82	26.64	7.46	31.58	8.84	51.94	14.54	3.05	0.85
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.01	25.14	0.25	23.37	0.23	23.06	0.23	23.40	0.23	18.44	0.18	39.29	0.39
FS 0013	Cherries, raw	RAC	0.73	1.40	1.02	4.21	3.07	0.10	0.07	2.93	2.14	1.50	1.10	NC	-
FC 0001	Citrus fruit, raw	RAC	0.04	38.66	1.55	54.93	2.20	26.36	1.05	51.46	2.06	51.06	2.04	466.36	18.65
-	Coffee beans, instant coffee (incl essences and concentrates)	PP	0.0016	0.75	0.00	0.30	0.00	0.10	0.00	0.67	0.00	2.43	0.00	1.43	0.00
SB 0716	Coffee beans, raw (i.e. green coffee)	RAC	0.08	0.60	0.05	NC	-	0.62	0.05	1.71	0.14	NC	-	3.51	0.28
SM 0716	Coffee beans, roasted	PP	0.0256	7.02	0.18	9.75	0.25	0.10	0.00	5.09	0.13	13.38	0.34	0.77	0.02
MO 0105	Edible offal (mammalian), raw	RAC	0	15.17	0.00	5.19	0.00	6.30	0.00	6.78	0.00	3.32	0.00	3.17	0.00
VC 0045	Fruiting vegetables, cucurbits, raw	RAC	0.195	27.81	5.42	41.93	8.18	123.30	24.04	49.47	9.65	15.95	3.11	35.99	7.02
JF 0269	Grape juice	PP	0.098	0.56	0.05	1.96	0.19	0.10	0.01	2.24	0.22	2.27	0.22	0.34	0.03
-	Grape wine (incl vermouths)	PP	0.15	88.93	13.34	62.41	9.36	1.84	0.28	25.07	3.76	61.17	9.18	5.84	0.88
DF 0269	Grape, dried (= currants, raisins and sultanas)	PP	0.37	3.09	1.14	1.51	0.56	0.10	0.04	1.38	0.51	4.26	1.58	0.42	0.16
FB 0269	Grape, raw (incl must, excl dried, excl juice, excl wine)	RAC	0.17	6.48	1.10	11.31	1.92	5.21	0.89	9.50	1.62	4.66	0.79	0.78	0.13
JF 0203	Grapefruits, juice (single strength, incl. concentrated)	PP	0.13	2.89	0.38	1.61	0.21	0.10	0.01	1.15	0.15	7.39	0.96	33.07	4.30
-	Lemon, juice (single strength, incl. concentrated)	PP	0.13	0.60	0.08	0.36	0.05	0.10	0.01	1.49	0.19	0.43	0.06	0.24	0.03
-	Mandarins, juice	PP	0.13	0.10	0.01	NC	-	0.10	0.01	0.10	0.01	NC	-	NC	-

Annex 3

BUPROFEZIN (173) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0090 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day G07 diet	Intake as µg/person/day G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
FI 0345	Mango, raw (incl canned mango, incl mango juice)	RAC	0.01	1.80	0.02	0.63	0.01	10.05	0.10	1.07	0.01	3.52	0.04	16.44	0.16
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)	RAC	0	140.03	0.00	150.89	0.00	79.32	0.00	111.24	0.00	120.30	0.00	51.27	0.00
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0	388.92	0.00	335.88	0.00	49.15	0.00	331.25	0.00	468.56	0.00	245.45	0.00
-	Olive oil (virgin and residue oil)	PP	3.49	3.40	11.87	9.49	33.12	0.10	0.35	4.28	14.94	2.74	9.56	0.48	1.68
JF 0004	Oranges, juice (single strength, incl. concentrated)	PP	0.13	33.31	4.33	1.78	0.23	0.28	0.04	18.97	2.47	14.01	1.82	13.36	1.74
-	Peaches and nectarines, raw	RAC	1.355	8.76	11.87	12.98	17.59	8.23	11.15	10.09	13.67	3.64	4.93	0.10	0.14
FP 0230	Pear, raw	RAC	1.09	8.79	9.58	8.44	9.20	12.37	13.48	9.60	10.46	10.27	11.19	0.23	0.25
VO 0444	Peppers, chili, raw (incl dried)	RAC	0.33	6.36	2.10	15.46	5.10	10.74	3.54	7.28	2.40	8.21	2.71	3.58	1.18
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.33	0.82	0.27	1.53	0.50	10.85	3.58	4.59	1.51	1.84	0.61	2.00	0.66
DF 0014	Plum, dried (prunes)	PP	0.465	0.61	0.28	0.35	0.16	0.10	0.05	0.35	0.16	0.49	0.23	0.13	0.06
FS 0014	Plums, raw (excl jujube)	RAC	0.155	3.75	0.58	3.33	0.52	5.94	0.92	2.64	0.41	2.50	0.39	0.10	0.02
FB 0275	Strawberry, raw	RAC	0.44	4.49	1.98	5.66	2.49	0.10	0.04	6.63	2.92	5.75	2.53	0.10	0.04
FT 0305	Table olive, raw (incl preserved)	RAC	1.125	2.00	2.25	2.48	2.79	0.10	0.11	1.21	1.36	1.64	1.85	0.27	0.30
DT 1114	Tea, green or black, fermented and dried, (including concentrates)	RAC	9	2.91	26.19	1.73	15.57	1.14	10.26	1.85	16.65	2.29	20.61	0.74	6.66
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.053	0.80	0.04	0.10	0.01	0.10	0.01	0.61	0.03	0.40	0.02	0.10	0.01
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.22	4.96	1.09	3.20	0.70	0.15	0.03	1.61	0.35	6.88	1.51	0.52	0.11
VO 0448	Tomato, raw (incl canned, excl juice, excl paste)	RAC	0.24	43.88	10.53	55.41	13.30	35.38	8.49	74.88	17.97	26.50	6.36	9.51	2.28
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (µg/person)=				121.5		145.4		86.3		116.6		103.4		48.6
	Bodyweight per region (kg bw) =				60		60		55		60		60		60
	ADI (µg/person)=				540		540		495		540		540		540
	%ADI=				22.5%		26.9%		17.4%		21.6%		19.2%		9.0%
	Rounded %ADI=				20%		30%		20%		20%		20%		9%

Annex 3

BUPROFEZIN (173) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0090 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day		Intake = daily intake: µg/person							
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
TN 0660	Almonds, nutmeat	RAC	0.05	0.10	0.01	0.10	0.01	0.61	0.03	0.10	0.01	NC	-
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.16	0.10	0.02	0.10	0.02	7.19	1.15	0.10	0.02	NC	-
FP 0226	Apple, raw (incl cider, excl juice)	RAC	0.28	66.67	18.67	2.06	0.58	55.83	15.63	188.29	52.72	1.38	0.39
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.01	20.88	0.21	81.15	0.81	24.58	0.25	37.92	0.38	310.23	3.10
FS 0013	Cherries, raw	RAC	0.73	0.10	0.07	0.10	0.07	5.96	4.35	0.10	0.07	NC	-
FC 0001	Citrus fruit, raw	RAC	0.04	20.93	0.84	2.35	0.09	30.71	1.23	0.15	0.01	4.45	0.18
-	Coffee beans, instant coffee (incl essences and concentrates)	PP	0.0016	0.10	0.00	0.10	0.00	0.60	0.00	0.10	0.00	5.53	0.01
SB 0716	Coffee beans, raw (i.e. green coffee)	RAC	0.08	0.83	0.07	0.69	0.06	1.09	0.09	2.91	0.23	0.82	0.07
SM 0716	Coffee beans, roasted	PP	0.0256	0.10	0.00	0.41	0.01	7.50	0.19	0.10	0.00	0.10	0.00
MO 0105	Edible offal (mammalian), raw	RAC	0	4.64	0.00	1.97	0.00	10.01	0.00	3.27	0.00	3.98	0.00
VC 0045	Fruiting vegetables, cucurbits, raw	RAC	0.195	5.96	1.16	9.74	1.90	51.82	10.10	13.61	2.65	0.10	0.02
JF 0269	Grape juice	PP	0.098	0.10	0.01	0.10	0.01	0.41	0.04	0.10	0.01	NC	-
-	Grape wine (incl vermouths)	PP	0.15	0.31	0.05	0.23	0.03	60.43	9.06	0.52	0.08	31.91	4.79
DF 0269	Grape, dried (= currants, raisins and sultanas)	PP	0.37	0.10	0.04	0.13	0.05	1.06	0.39	0.10	0.04	0.10	0.04
FB 0269	Grape, raw (incl must, excl dried, excl juice, excl wine)	RAC	0.17	0.14	0.02	0.36	0.06	15.33	2.61	0.10	0.02	0.28	0.05
JF 0203	Grapefruits, juice (single strength, incl. concentrated)	PP	0.13	0.10	0.01	0.10	0.01	0.78	0.10	0.10	0.01	NC	-
-	Lemon, juice (single strength, incl. concentrated)	PP	0.13	0.10	0.01	0.10	0.01	0.16	0.02	0.10	0.01	NC	-
-	Mandarins, juice	PP	0.13	0.10	0.01	NC	-	NC	-	NC	-	NC	-
FI 0345	Mango, raw (incl canned mango, incl mango juice)	RAC	0.01	12.25	0.12	6.83	0.07	0.76	0.01	0.10	0.00	20.12	0.20
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)	RAC	0	29.18	0.00	50.89	0.00	121.44	0.00	22.58	0.00	72.14	0.00
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0	108.75	0.00	70.31	0.00	436.11	0.00	61.55	0.00	79.09	0.00
-	Olive oil (virgin and residue oil)	PP	3.49	0.10	0.35	0.10	0.35	2.14	7.47	0.10	0.35	0.10	0.35
JF 0004	Oranges, juice (single strength, incl. concentrated)	PP	0.13	0.10	0.01	0.26	0.03	12.61	1.64	0.14	0.02	0.33	0.04
-	Peaches and nectarines, raw	RAC	1.355	0.10	0.14	0.10	0.14	7.47	10.12	0.10	0.14	NC	-
FP 0230	Pear, raw	RAC	1.09	0.10	0.11	0.14	0.15	9.45	10.30	0.10	0.11	0.14	0.15
VO 0444	Peppers, chili, raw (incl dried)	RAC	0.33	7.55	2.49	12.48	4.12	24.78	8.18	0.87	0.29	NC	-
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.33	5.49	1.81	10.57	3.49	8.84	2.92	0.91	0.30	NC	-
DF 0014	Plum, dried (prunes)	PP	0.465	0.10	0.05	0.10	0.05	0.37	0.17	0.10	0.05	NC	-
FS 0014	Plums, raw (excl jujube)	RAC	0.155	0.10	0.02	0.10	0.02	15.56	2.41	0.10	0.02	NC	-
FB 0275	Strawberry, raw	RAC	0.44	0.10	0.04	0.10	0.04	3.35	1.47	0.10	0.04	0.10	0.04
FT 0305	Table olive, raw (incl preserved)	RAC	1.125	0.10	0.11	0.10	0.11	1.75	1.97	0.10	0.11	0.24	0.27
DT 1114	Tea, green or black, fermented and dried, (including concentrates)	RAC	9	0.53	4.77	5.25	47.25	0.86	7.74	0.56	5.04	0.88	7.92
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.053	0.10	0.01	0.10	0.01	0.42	0.02	0.10	0.01	0.10	0.01

Annex 3

BUPROFEZIN (173) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0090 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day G13 diet	Intake = daily intake: µg/person G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.22	0.58	0.13	0.22	0.05	2.21	0.49	0.24	0.05	3.10	0.68
VO 0448	Tomato, raw (incl canned, excl juice, excl paste)	RAC	0.24	13.10	3.14	4.90	1.18	62.16	14.92	1.04	0.25	0.10	0.02
-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (µg/person)=				34.5		60.8		115.1		63.0		18.4
	Bodyweight per region (kg bw) =				60		60		60		60		60
	ADI (µg/person)=				540		540		540		540		540
	%ADI=				6.4%		11.3%		21.3%		11.7%		3.4%
	Rounded %ADI=				6%		10%		20%		10%		3%

Annex 3

CHLORANTRANILIPROLE (230) International Estimated Daily Intake (IEDI) ADI = 0 - 2.0000 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day											
				Intake as µg/person/day											
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
FC 0001	Citrus fruit, raw	RAC	0.06	32.25	1.94	11.67	0.70	16.70	1.00	76.01	4.56	33.90	2.03	92.97	5.58
JF 0001	Citrus fruit, juice	PP	0.037	1.30	0.05	2.37	0.09	0.22	0.01	13.88	0.51	0.75	0.03	2.63	0.10
FP 0009	Pome fruit, raw (incl cider, excl apple juice)	RAC	0.07	19.35	1.35	34.06	2.38	17.87	1.25	25.74	1.80	7.69	0.54	56.85	3.98
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.0098	0.32	0.00	3.07	0.03	0.10	0.00	5.00	0.05	0.29	0.00	5.57	0.05
FS 0012	Stone fruits, raw (incl dried plums, incl dried apricots)	RAC	0.2	11.60	2.32	23.79	4.76	0.25	0.05	11.84	2.37	2.41	0.48	33.44	6.69
FB 0018	Berries and other small fruits, raw, (incl processed), excl small fruit vine climbing (group 004D)	RAC	0.336	2.29	0.77	4.71	1.58	0.78	0.26	4.48	1.51	0.39	0.13	6.27	2.11
FB 0269	Grape, raw (incl must, excl dried, excl juice, excl wine)	RAC	0.119	13.02	1.55	9.25	1.10	0.10	0.01	16.91	2.01	3.70	0.44	54.44	6.48
DF 0269	Grape, dried (= currants, raisins and sultanas)	PP	0.411	0.51	0.21	0.51	0.21	0.10	0.04	1.27	0.52	0.12	0.05	2.07	0.85
JF 0269	Grape juice	PP	0.0869	0.14	0.01	0.29	0.03	0.10	0.01	0.30	0.03	0.24	0.02	0.10	0.01
-	Grape wine (incl vermouths)	PP	0.14	0.67	0.09	12.53	1.75	2.01	0.28	1.21	0.17	3.53	0.49	4.01	0.56
FI 0355	Pomegranate, raw, (incl processed)	RAC	0.11	3.40	0.37	2.10	0.23	2.65	0.29	10.89	1.20	NC	-	6.67	0.73
VB 0040	Brassica vegetables, raw: head cabbages, flowerhead brassicas, Brussels sprouts & kohlrabi	RAC	0.385	6.41	2.47	35.79	13.78	0.71	0.27	9.81	3.78	12.07	4.65	16.58	6.38
VC 0045	Fruiting vegetables, cucurbits, raw	RAC	0.065	53.14	3.45	86.21	5.60	6.28	0.41	92.76	6.03	15.64	1.02	155.30	10.09
VO 0440	Egg plants, raw (= aubergines)	RAC	0.066	5.58	0.37	4.31	0.28	0.89	0.06	9.31	0.61	13.64	0.90	20.12	1.33
VO 0442	Okra, raw	RAC	0.066	1.97	0.13	NC	-	3.68	0.24	3.24	0.21	5.72	0.38	1.57	0.10
VO 0443	Pepino (Melon pear, Tree melon)	RAC	0.066	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VO 0444	Peppers, chili, raw	RAC	0.066	3.99	0.26	7.30	0.48	2.93	0.19	5.62	0.37	NC	-	17.44	1.15
-	Peppers, chili, dried	PP	0.46	0.42	0.19	0.53	0.24	0.84	0.39	0.50	0.23	0.95	0.44	0.37	0.17
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.066	4.49	0.30	6.44	0.43	7.21	0.48	5.68	0.37	9.52	0.63	8.92	0.59
VO 0447	Sweet corn on the cob, raw (incl frozen, incl canned) (i.e. kernels plus cob without husks)	RAC	0.01	0.14	0.00	0.94	0.01	5.70	0.06	2.61	0.03	1.94	0.02	0.22	0.00
VO 0448	Tomato, raw (incl canned, excl juice, excl paste)	RAC	0.066	42.04	2.77	76.13	5.02	10.69	0.71	84.59	5.58	24.92	1.64	203.27	13.42
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.109	2.34	0.26	1.33	0.14	1.57	0.17	4.24	0.46	0.34	0.04	2.83	0.31
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.0589	0.29	0.02	0.29	0.02	0.10	0.01	0.38	0.02	0.10	0.01	0.14	0.01
-	Gilo (scarlet egg plant)	RAC	0.066	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
-	Goji berry	RAC	0.066	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
-	Seaweed	RAC	0.066	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VL 0269	Grape leaves, raw	RAC	7.3	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VL 0446	Roselle leaves, raw (vinagreira)	RAC	7.3	0.39	2.85	0.69	5.04	0.43	3.14	1.04	7.59	4.57	33.36	0.50	3.65
VL 0460	Amaranth leaves, raw (i.e. bledo)	RAC	7.3	1.09	7.96	1.94	14.16	1.20	8.76	2.91	21.24	NC	-	1.41	10.29

Annex 3

CHLORANTRANILIPROLE (230) International Estimated Daily Intake (IEDI) ADI = 0 - 2.0000 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day											
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
VL 0463	Cassava leaves, raw	RAC	7.3	NC	-	NC	-	0.65	4.75	0.10	0.73	NC	-	NC	-
VL 0464	Chard, raw (i.e. beet leaves)	RAC	7.3	0.40	2.92	0.70	5.11	0.44	3.21	1.06	7.74	4.66	34.02	0.51	3.72
VL 0465	Chervil, raw	RAC	7.3	0.19	1.39	0.34	2.48	0.21	1.53	0.52	3.80	NC	-	0.25	1.83
VL 0466	Chinese cabbage, type pak-choi, raw (i.e. Brassica)	RAC	7.3	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VL 0467	Chinese cabbage, type pe-tsai, raw (i.e. Brassica)	RAC	7.3	0.45	3.29	4.56	33.29	0.10	0.73	0.73	5.33	NC	-	1.67	12.19
VL 0469	Chicory leaves (sugar loaf), raw	RAC	7.3	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VL 0470	Lambs lettuce, raw (i.e. corn salad)	RAC	7.3	0.64	4.67	1.13	8.25	0.70	5.11	1.70	12.41	NC	-	0.82	5.99
VL 0472	Garden cress, raw	RAC	7.3	0.10	0.73	0.10	0.73	0.10	0.73	0.15	1.10	NC	-	0.10	0.73
VL 0473	Watercress, raw	RAC	7.3	1.21	8.83	2.15	15.70	1.33	9.71	3.24	23.65	11.36	82.93	1.56	11.39
VL 0474	Dandelion leaves, raw	RAC	7.3	0.13	0.95	0.23	1.68	0.14	1.02	0.34	2.48	1.44	10.51	0.16	1.17
VL 0476	Endive, raw (i.e. scarole)	RAC	7.3	0.10	0.73	0.10	0.73	0.10	0.73	0.40	2.92	0.10	0.73	0.39	2.85
VL 0478	Indian mustard (Amsoi) (i.e. Brassica)	RAC	7.3	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VL 0479	Japanese greens, raw (i.e. Chrysanthemum)	RAC	7.3	0.10	0.73	0.10	0.73	0.10	0.73	0.10	0.73	NC	-	0.10	0.73
VL 0480	Kale, raw (i.e. collards) (i.e. Brassica)	RAC	7.3	0.57	4.16	5.77	42.12	0.11	0.80	0.92	6.72	5.25	38.33	2.12	15.48
VL 0481	Komatsuna, raw (i.e. Brassica)	RAC	7.3	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VL 0482	Lettuce, head, raw	RAC	7.3	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VL 0483	Lettuce, leaf, raw	RAC	7.3	0.53	3.87	0.36	2.63	0.16	1.17	6.21	45.33	1.90	13.87	6.05	44.17
VL 0485	Mustard greens, raw (i.e. Brassica)	RAC	7.3	0.10	0.73	0.31	2.26	0.10	0.73	0.10	0.73	0.47	3.43	0.11	0.80
VL 0492	Purslane, raw	RAC	7.3	0.10	0.73	0.10	0.73	0.10	0.73	0.10	0.73	NC	-	0.10	0.73
VL 0494	Radish leaves, raw	RAC	10.5	0.26	2.73	0.45	4.73	0.28	2.94	0.68	7.14	NC	-	0.33	3.47
VL 0495	Rape greens, raw (i.e. Brassica)	RAC	7.3	0.10	0.73	0.31	2.26	0.10	0.73	0.10	0.73	NC	-	0.11	0.80
VL 0496	Rucola, raw (i.e. arrugula, rocket salad, roquette)	RAC	7.3	1.27	9.27	2.25	16.43	1.39	10.15	3.38	24.67	13.81	100.81	1.63	11.90
VL 0501	Sowthistle, raw	RAC	7.3	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VL 0502	Spinach, raw	RAC	7.3	0.74	5.40	0.22	1.61	0.10	0.73	0.91	6.64	0.10	0.73	2.92	21.32
VL 0503	Indian spinach, raw (i.e. vine spinach)	RAC	7.3	0.10	0.73	0.10	0.73	0.10	0.73	0.10	0.73	0.16	1.17	0.10	0.73
VL 0504	Tannia leaves, raw (i.e. taioba)	RAC	7.3	0.18	1.31	0.31	2.26	0.19	1.39	0.47	3.43	2.06	15.04	0.23	1.68
VL 0505	Taro leaves, raw	RAC	7.3	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VL 0506	Turnip greens, raw (i.e. Namenia, Tendergreen)	RAC	7.3	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VL 0507	Kang kung, raw (i.e. water spinach)	RAC	7.3	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VL 0510	Cos lettuce, raw	RAC	7.3	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
-	Perilla leaves, raw (i.e. sesame leaves)	RAC	7.3	0.15	1.10	0.27	1.97	0.17	1.24	0.40	2.92	NC	-	0.19	1.39
-	Bracken, raw (i.e. ferns)	RAC	7.3	0.10	0.73	0.19	1.39	0.12	0.88	0.28	2.04	NC	-	0.13	0.95
-	Water parsley, raw	RAC	7.3	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
-	Chinese cabbage flowering stalk, raw	RAC	7.3	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VP 0061	Beans, green, with pods, raw: beans except broad bean & soya bean (i.e. immature seeds + pods) (Phaseolus spp)	RAC	0.16	0.68	0.11	NC	-	NC	-	0.39	0.06	0.22	0.04	0.49	0.08
VP 0063	Peas green, with pods, raw (i.e. immature seeds +	RAC	0.545	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-

Annex 3

CHLORANTRANILIPROLE (230) International Estimated Daily Intake (IEDI) ADI = 0 - 2.0000 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as µg/person/day							
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
	pods) (Pisum spp)														
VP 0064	Peas, green, without pods, raw (i.e. immature seeds only) (Pisum spp)	RAC	0.025	1.97	0.05	0.51	0.01	0.10	0.00	0.79	0.02	3.68	0.09	3.80	0.10
VD 0541	Soya bean, dry, raw (incl paste, incl curd, incl oil, incl sauce)	RAC	0.01	72.79	0.73	59.05	0.59	20.55	0.21	74.20	0.74	61.12	0.61	73.24	0.73
VR 0463	Cassava raw (incl starch, incl tapioca, incl flour)	RAC	0.01	0.10	0.00	0.10	0.00	482.56	4.83	0.99	0.01	25.75	0.26	3.29	0.03
VR 0469	Chicory, roots, raw	RAC	0.01	0.10	0.00	0.20	0.00	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00
VR 0494	Radish roots, raw	RAC	0.055	2.31	0.13	4.09	0.22	2.53	0.14	6.15	0.34	5.88	0.32	2.97	0.16
VR 0497	Swede, raw (i.e. rutabaga)	RAC	0.01	1.58	0.02	2.80	0.03	1.74	0.02	4.21	0.04	NC	-	2.03	0.02
VR 0498	Salsify, raw (i.e. oysterplant)	RAC	0.01	0.21	0.00	0.37	0.00	0.23	0.00	0.55	0.01	NC	-	0.27	0.00
VR 0504	Tannia, raw (i.e. yautia)	RAC	0.01	NC	-	NC	-	NC	-	0.10	0.00	0.26	0.00	1.27	0.01
VR 0505	Taro, raw	RAC	0.01	0.10	0.00	NC	-	25.12	0.25	0.10	0.00	0.10	0.00	0.97	0.01
VR 0506	Garden turnip, raw	RAC	0.01	2.50	0.03	4.44	0.04	2.75	0.03	6.67	0.07	0.14	0.00	3.22	0.03
VR 0508	Sweet potato, raw (incl dried)	RAC	0.01	0.18	0.00	0.18	0.00	42.16	0.42	1.61	0.02	3.06	0.03	6.67	0.07
VR 0573	Arrowroot, raw	RAC	0.01	1.53	0.02	0.10	0.00	0.93	0.01	1.33	0.01	0.47	0.00	0.10	0.00
VR 0574	Beetroot, raw	RAC	0.01	3.42	0.03	6.06	0.06	3.75	0.04	9.11	0.09	NC	-	4.39	0.04
VR 0575	Burdock, greater or edible, raw	RAC	0.01	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00	NC	-	0.10	0.00
VR 0577	Carrots, raw	RAC	0.02	9.51	0.19	30.78	0.62	0.37	0.01	8.75	0.18	2.80	0.06	6.10	0.12
VR 0578	Celeriac, raw	RAC	0.01	1.70	0.02	3.01	0.03	1.87	0.02	4.53	0.05	NC	-	2.19	0.02
VR 0583	Horseradish, raw	RAC	0.01	0.51	0.01	0.91	0.01	0.56	0.01	1.37	0.01	NC	-	0.66	0.01
VR 0585	Jerusalem artichoke, raw (i.e. topinambur)	RAC	0.01	1.57	0.02	0.10	0.00	0.96	0.01	1.36	0.01	0.48	0.00	0.10	0.00
VR 0587	Parsley turnip-rooted, raw	RAC	0.01	0.32	0.00	0.57	0.01	0.35	0.00	0.85	0.01	NC	-	0.41	0.00
VR 0588	Parsnip, raw	RAC	0.01	0.59	0.01	1.05	0.01	0.65	0.01	1.58	0.02	NC	-	0.76	0.01
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.01	59.74	0.60	316.14	3.16	9.78	0.10	60.26	0.60	54.12	0.54	119.82	1.20
VR 0590	Black radish, raw	RAC	0.01	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VR 0591	Japanese radish, raw (i.e. daikon)	RAC	0.01	1.90	0.02	3.36	0.03	2.08	0.02	5.06	0.05	NC	-	2.44	0.02
VR 0600	Yams, raw (incl dried)	RAC	0.01	0.10	0.00	NC	-	90.40	0.90	6.45	0.06	0.74	0.01	0.65	0.01
-	Lotus root, raw	RAC	0.01	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
-	Water chestnut, raw	RAC	0.01	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VS 0620	Artichoke globe	RAC	0.56	0.69	0.39	0.10	0.06	0.10	0.06	0.32	0.18	0.26	0.15	1.21	0.68
VS 0624	Celery	RAC	2.1	2.14	4.49	3.79	7.96	2.35	4.94	5.69	11.95	0.10	0.21	2.75	5.78
GC 0640	Barley, raw (incl malt extract, incl pot&pearled, incl flour & grits, incl beer, incl malt)	RAC	0.01	19.91	0.20	31.16	0.31	5.04	0.05	3.10	0.03	9.77	0.10	4.31	0.04
GC 0641	Buckwheat, raw (incl flour)	RAC	0.01	NC	-	0.40	0.00	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl flour, incl oil, incl beer, incl germ, incl starch)	RAC	0.01	29.81	0.30	44.77	0.45	108.95	1.09	52.37	0.52	60.28	0.60	75.69	0.76
GC 0656	Popcorn (i.e. maize used for preparation of	RAC	0.01	-	-	-	-	-	-	-	-	-	-	-	-

Annex 3

CHLORANTRANILIPROLE (230) International Estimated Daily Intake (IEDI) ADI = 0 - 2.0000 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as µg/person/day							
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
	popcorn)														
GC 0646	Millet, raw (incl flour, incl beer)	RAC	0.01	1.46	0.01	2.32	0.02	5.84	0.06	0.89	0.01	16.17	0.16	0.10	0.00
GC 0647	Oats, raw (incl rolled)	RAC	0.01	0.10	0.00	7.05	0.07	0.10	0.00	1.71	0.02	0.96	0.01	0.10	0.00
GC 0648	Quinoa, raw	RAC	0.01	NC	-	NC	-	NC	-	NC	-	0.10	0.00	NC	-
CM 0649 (GC 0649)	Rice, husked, dry (incl flour, incl oil, incl beverages, incl starch, excl polished)	REP	0.115	1.26	0.14	1.58	0.18	31.05	3.57	5.43	0.62	0.90	0.10	2.18	0.25
CM 1205	Rice polished, dry	PP	0.013	34.21	0.44	10.39	0.14	41.72	0.54	82.38	1.07	150.24	1.95	70.47	0.92
GC 0650	Rye, raw (incl flour)	RAC	0.01	0.13	0.00	19.38	0.19	0.10	0.00	0.12	0.00	0.10	0.00	2.15	0.02
GC 0651	Sorghum, raw (incl flour, incl beer)	RAC	0.01	4.34	0.04	0.10	0.00	16.25	0.16	15.82	0.16	10.97	0.11	2.92	0.03
GC 0653	Triticale, raw (incl flour)	RAC	0.01	NC	-	NC	-	NC	-	0.10	0.00	0.39	0.00	NC	-
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, excl germ, excl wholemeal bread, excl white flour products, excl white bread)	RAC	0.01	0.10	0.00	1.12	0.01	0.10	0.00	0.10	0.00	0.61	0.01	0.10	0.00
CF 1210	Wheat, germ	PP	0.012	NC	-	NC	-	0.10	0.00	0.10	0.00	0.14	0.00	0.10	0.00
CF 0654	Wheat, bran	PP	0.011	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
CF 1212	Wheat, wholemeal flour	PP	0.004	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
CP 1212	Wheat, wholemeal bread	PP	0.01	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00
CP 1211	Wheat, white bread	PP	0.01	0.25	0.00	0.63	0.01	0.12	0.00	0.43	0.00	1.39	0.01	0.22	0.00
CF 1211	Wheat, white flour (incl white flour products: starch, gluten, macaroni, pastry)	PP	0.004	301.49	1.21	269.27	1.08	30.33	0.12	222.94	0.89	136.12	0.54	343.34	1.37
-	Fonio, raw (incl flour)	RAC	0.01	NC	-	NC	-	1.01	0.01	NC	-	NC	-	NC	-
-	Cereals, NES, raw (including processed) : canagua, quihuicha, Job's tears and wild rice	RAC	0.01	2.04	0.02	2.99	0.03	1.86	0.02	19.17	0.19	3.33	0.03	1.66	0.02
GS 0659	Sugar cane, raw (incl sugar, incl molasses)	RAC	0.145	99.68	14.45	86.27	12.51	31.38	4.55	80.36	11.65	84.18	12.21	99.10	14.37
TN 0085	Tree nuts, raw (incl processed)	RAC	0.01	4.06	0.04	3.27	0.03	7.01	0.07	13.93	0.14	14.01	0.14	9.36	0.09
SO 0495	Rape seed, raw (incl oil)	RAC	0.295	0.93	0.27	1.16	0.34	0.49	0.14	2.53	0.75	9.32	2.75	2.02	0.60
SO 0691	Cotton seed, raw	RAC	0.049	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
OR 0691	Cotton seed oil, edible	PP	0.0122	3.22	0.04	1.54	0.02	1.01	0.01	0.74	0.01	1.12	0.01	2.93	0.04
SO 0697	Peanuts, nutmeat, raw (incl roasted, incl oil, incl butter)	RAC	0.01	1.30	0.01	1.23	0.01	12.62	0.13	2.87	0.03	6.59	0.07	2.67	0.03
SO 0702	Sunflower seed, raw (incl oil)	RAC	0.185	7.40	1.37	35.86	6.63	1.15	0.21	8.76	1.62	5.45	1.01	13.62	2.52
SB 0716	Coffee beans raw (incl roasted, incl instant coffee, incl substitutes)	RAC	0.015	1.36	0.02	3.59	0.05	1.44	0.02	5.18	0.08	2.02	0.03	1.70	0.03
HH 0738	Mints, raw	RAC	4.6	0.50	2.30	0.10	0.46	NC	-	NC	-	NC	-	NC	-
DH 1100	Hops, dry	RAC	10.9	0.10	1.09	0.10	1.09	0.10	1.09	0.10	1.09	NC	-	0.10	1.09
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.009	24.96	0.22	57.95	0.52	16.70	0.15	38.38	0.35	26.46	0.24	29.00	0.26
MM 0095	MEAT FROM MAMMALS other than marine	RAC	0.05	6.24	0.31	14.49	0.72	4.18	0.21	9.60	0.48	6.62	0.33	7.25	0.36

Annex 3

CHLORANTRANILIPROLE (230) International Estimated Daily Intake (IEDI) ADI = 0 - 2.0000 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day G01 diet	Intake as µg/person/day G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
	mammals, raw (incl prepared meat) - 20% as fat														
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.05	3.29	0.16	6.14	0.31	0.82	0.04	1.57	0.08	2.23	0.11	1.07	0.05
MO 0105	Edible offal (mammalian), raw	RAC	0.047	4.79	0.23	9.68	0.45	2.97	0.14	5.49	0.26	3.84	0.18	5.03	0.24
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.006	289.65	1.74	485.88	2.92	26.92	0.16	239.03	1.43	199.91	1.20	180.53	1.08
PM 0110	Poultry meat, raw (incl prepared) - 90% as muscle	RAC	0	13.17	0.00	26.78	0.00	7.24	0.00	116.71	0.00	22.54	0.00	32.09	0.00
PM 0110	Poultry meat, raw (incl prepared) - 10% as fat	RAC	0	1.46	0.00	2.98	0.00	0.80	0.00	12.97	0.00	2.50	0.00	3.57	0.00
PF 0111	Poultry fat, raw (incl rendered)	RAC	0	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.10	0.00	0.10	0.00
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.005	0.12	0.00	0.12	0.00	0.11	0.00	5.37	0.03	0.24	0.00	0.10	0.00
PE 0112	Eggs, raw, (incl dried)	RAC	0.07	7.84	0.55	23.08	1.62	2.88	0.20	14.89	1.04	9.81	0.69	14.83	1.04
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (µg/person)=				117.5		248.9		93.3		261.1		373.8		253.0
	Bodyweight per region (kg bw) =				60		60		60		60		60		60
	ADI (µg/person)=				120000		120000		120000		120000		120000		120000
	%ADI=				0.1%		0.2%		0.1%		0.2%		0.3%		0.2%
	Rounded %ADI=				0%		0%		0%		0%		0%		0%

CHLORANTRANILIPROLE (230) International Estimated Daily Intake (IEDI) ADI = 0 - 2.0000 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day G07 diet	Intake as µg/person/day G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
FC 0001	Citrus fruit, raw	RAC	0.06	38.66	2.32	54.93	3.30	26.36	1.58	51.46	3.09	51.06	3.06	466.36	27.98
JF 0001	Citrus fruit, juice	PP	0.037	36.84	1.36	3.75	0.14	0.30	0.01	21.62	0.80	21.82	0.81	46.67	1.73
FP 0009	Pome fruit, raw (incl cider, excl apple juice)	RAC	0.07	51.09	3.58	65.40	4.58	42.71	2.99	45.29	3.17	62.51	4.38	7.74	0.54
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.0098	14.88	0.15	11.98	0.12	0.15	0.00	9.98	0.10	30.32	0.30	3.47	0.03
FS 0012	Stone fruits, raw (incl dried plums, incl dried apricots)	RAC	0.2	19.98	4.00	24.87	4.97	14.41	2.88	19.54	3.91	10.78	2.16	0.50	0.10
FB 0018	Berries and other small fruits, raw, (incl processed), excl small fruit vine climbing (group 004D)	RAC	0.336	14.68	4.93	12.74	4.28	0.23	0.08	11.77	3.95	8.01	2.69	4.08	1.37
FB 0269	Grape, raw (incl must, excl dried, excl juice, excl wine)	RAC	0.119	6.48	0.77	11.31	1.35	5.21	0.62	9.50	1.13	4.66	0.55	0.78	0.09
DF 0269	Grape, dried (= currants, raisins and sultanas)	PP	0.411	3.09	1.27	1.51	0.62	0.10	0.04	1.38	0.57	4.26	1.75	0.42	0.17
JF 0269	Grape juice	PP	0.0869	0.56	0.05	1.96	0.17	0.10	0.01	2.24	0.19	2.27	0.20	0.34	0.03

Annex 3

CHLORANTRANILIPROLE (230) International Estimated Daily Intake (IEDI) ADI = 0 - 2.0000 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day		Intake as µg/person/day									
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
-	Grape wine (incl vermouths)	PP	0.14	88.93	12.45	62.41	8.74	1.84	0.26	25.07	3.51	61.17	8.56	5.84	0.82
FI 0355	Pomegranate, raw, (incl processed)	RAC	0.11	7.91	0.87	9.72	1.07	7.67	0.84	5.26	0.58	9.04	0.99	14.43	1.59
VB 0040	Brassica vegetables, raw: head cabbages, flowerhead brassicas, Brussels sprouts & kohlrabi	RAC	0.385	20.71	7.97	39.81	15.33	16.70	6.43	28.49	10.97	18.12	6.98	15.03	5.79
VC 0045	Fruiting vegetables, cucurbits, raw	RAC	0.065	27.81	1.81	41.93	2.73	123.30	8.01	49.47	3.22	15.95	1.04	35.99	2.34
VO 0440	Egg plants, raw (= aubergines)	RAC	0.066	1.01	0.07	1.69	0.11	21.37	1.41	3.00	0.20	1.40	0.09	NC	-
VO 0442	Okra, raw	RAC	0.066	NC	-	NC	-	0.10	0.01	0.17	0.01	NC	-	0.72	0.05
VO 0443	Pepino (Melon pear, Tree melon)	RAC	0.066	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VO 0444	Peppers, chili, raw	RAC	0.066	5.57	0.37	14.00	0.92	8.25	0.54	5.77	0.38	6.44	0.43	2.53	0.17
-	Peppers, chili, dried	PP	0.46	0.11	0.05	0.21	0.10	0.36	0.17	0.21	0.10	0.25	0.12	0.15	0.07
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.066	0.82	0.05	1.53	0.10	10.85	0.72	4.59	0.30	1.84	0.12	2.00	0.13
VO 0447	Sweet corn on the cob, raw (incl frozen, incl canned) (i.e. kernels plus cob without husks)	RAC	0.01	11.43	0.11	3.71	0.04	0.74	0.01	13.63	0.14	3.07	0.03	1.50	0.02
VO 0448	Tomato, raw (incl canned, excl juice, excl paste)	RAC	0.066	43.88	2.90	55.41	3.66	35.38	2.34	74.88	4.94	26.50	1.75	9.51	0.63
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.109	4.96	0.54	3.20	0.35	0.15	0.02	1.61	0.18	6.88	0.75	0.52	0.06
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.0589	0.80	0.05	0.10	0.01	0.10	0.01	0.61	0.04	0.40	0.02	0.10	0.01
-	Gilo (scarlet egg plant)	RAC	0.066	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
-	Goji berry	RAC	0.066	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
-	Seaweed	RAC	0.066	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VL 0269	Grape leaves, raw	RAC	7.3	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VL 0446	Roselle leaves, raw (vinagreira)	RAC	7.3	NC	-	NC	-	NC	-	NC	-	NC	-	0.74	5.40
VL 0460	Amaranth leaves, raw (i.e. bledo)	RAC	7.3	NC	-	NC	-	47.45	346.39	NC	-	NC	-	2.07	15.11
VL 0463	Cassava leaves, raw	RAC	7.3	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VL 0464	Chard, raw (i.e. beet leaves)	RAC	7.3	NC	-	NC	-	NC	-	NC	-	NC	-	0.75	5.48
VL 0465	Chervil, raw	RAC	7.3	NC	-	NC	-	8.39	61.25	NC	-	NC	-	0.37	2.70
VL 0466	Chinese cabbage, type pak-choi, raw (i.e. Brassica)	RAC	7.3	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VL 0467	Chinese cabbage, type pe-tsai, raw (i.e. Brassica)	RAC	7.3	NC	-	NC	-	17.39	126.95	9.44	68.91	NC	-	1.83	13.36
VL 0469	Chicory leaves (sugar loaf), raw	RAC	7.3	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VL 0470	Lambs lettuce, raw (i.e. corn salad)	RAC	7.3	1.41	10.29	4.28	31.24	NC	-	0.10	0.73	5.11	37.30	1.20	8.76
VL 0472	Garden cress, raw	RAC	7.3	0.10	0.73	NC	-	1.27	9.27	0.13	0.95	0.21	1.53	0.10	0.73
VL 0473	Watercress, raw	RAC	7.3	0.35	2.56	3.13	22.85	0.32	2.34	NC	-	NC	-	2.30	16.79
VL 0474	Dandelion leaves, raw	RAC	7.3	0.10	0.73	0.10	0.73	NC	-	NC	-	0.10	0.73	0.24	1.75
VL 0476	Endive, raw (i.e. scarole)	RAC	7.3	0.21	1.53	0.93	6.79	NC	-	0.30	2.19	2.14	15.62	0.14	1.02
VL 0478	Indian mustard (Amsoi) (i.e. Brassica)	RAC	7.3	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VL 0479	Japanese greens, raw (i.e. Chrysanthemum)	RAC	7.3	NC	-	NC	-	NC	-	0.32	2.34	NC	-	0.10	0.73
VL 0480	Kale, raw (i.e. collards) (i.e. Brassica)	RAC	7.3	NC	-	NC	-	14.54	106.14	NC	-	NC	-	2.32	16.94
VL 0481	Komatsuna, raw (i.e. Brassica)	RAC	7.3	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VL 0482	Lettuce, head, raw	RAC	7.3	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-

Annex 3

CHLORANTRANILIPROLE (230) International Estimated Daily Intake (IEDI) ADI = 0 - 2.0000 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as µg/person/day							
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
VL 0483	Lettuce, leaf, raw	RAC	7.3	14.50	105.85	11.76	85.85	13.14	95.92	19.50	142.35	4.81	35.11	2.23	16.28
VL 0485	Mustard greens, raw (i.e. Brassica)	RAC	7.3	NC	-	NC	-	NC	-	NC	-	NC	-	0.13	0.95
VL 0492	Purslane, raw	RAC	7.3	0.10	0.73	NC	-	NC	-	NC	-	NC	-	0.10	0.73
VL 0494	Radish leaves, raw	RAC	10.5	NC	-	NC	-	NC	-	3.78	39.69	NC	-	0.48	5.04
VL 0495	Rape greens, raw (i.e. Brassica)	RAC	7.3	NC	-	NC	-	1.93	14.09	NC	-	NC	-	0.12	0.88
VL 0496	Rucola, raw (i.e. arrugula, rocket salad, roquette)	RAC	7.3	NC	-	NC	-	NC	-	1.09	7.96	0.38	2.77	2.40	17.52
VL 0501	Sowthistle, raw	RAC	7.3	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VL 0502	Spinach, raw	RAC	7.3	2.20	16.06	1.76	12.85	13.38	97.67	2.94	21.46	5.53	40.37	0.10	0.73
VL 0503	Indian spinach, raw (i.e. vine spinach)	RAC	7.3	NC	-	NC	-	NC	-	NC	-	NC	-	0.10	0.73
VL 0504	Tannia leaves, raw (i.e. taioba)	RAC	7.3	NC	-	NC	-	NC	-	NC	-	NC	-	0.33	2.41
VL 0505	Taro leaves, raw	RAC	7.3	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VL 0506	Turnip greens, raw (i.e. Namenia, Tendergreen)	RAC	7.3	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VL 0507	Kang kung, raw (i.e. water spinach)	RAC	7.3	NC	-	NC	-	3.42	24.97	NC	-	NC	-	NC	-
VL 0510	Cos lettuce, raw	RAC	7.3	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
-	Perilla leaves, raw (i.e. sesame leaves)	RAC	7.3	NC	-	NC	-	NC	-	2.23	16.28	NC	-	0.29	2.12
-	Bracken, raw (i.e. ferns)	RAC	7.3	NC	-	NC	-	NC	-	1.55	11.32	NC	-	0.20	1.46
-	Water parsley, raw	RAC	7.3	NC	-	NC	-	NC	-	1.79	13.07	NC	-	NC	-
-	Chinese cabbage flowering stalk, raw	RAC	7.3	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VP 0061	Beans, green, with pods, raw: beans except broad bean & soya bean (i.e. immature seeds + pods) (Phaseolus spp)	RAC	0.16	5.07	0.81	0.83	0.13	0.17	0.03	3.70	0.59	NC	-	NC	-
VP 0063	Peas green, with pods, raw (i.e. immature seeds + pods) (Pisum spp)	RAC	0.545	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VP 0064	Peas, green, without pods, raw (i.e. immature seeds only) (Pisum spp)	RAC	0.025	10.72	0.27	1.99	0.05	2.72	0.07	4.26	0.11	4.23	0.11	NC	-
VD 0541	Soya bean, dry, raw (incl paste, incl curd, incl oil, incl sauce)	RAC	0.01	106.33	1.06	117.78	1.18	42.12	0.42	195.70	1.96	222.52	2.23	80.47	0.80
VR 0463	Cassava raw (incl starch, incl tapioca, incl flour)	RAC	0.01	0.10	0.00	NC	-	20.96	0.21	0.14	0.00	NC	-	9.62	0.10
VR 0469	Chicory, roots, raw	RAC	0.01	0.10	0.00	0.51	0.01	0.10	0.00	0.10	0.00	21.12	0.21	NC	-
VR 0494	Radish roots, raw	RAC	0.055	3.83	0.21	11.99	0.66	NC	-	5.26	0.29	2.19	0.12	4.37	0.24
VR 0497	Swede, raw (i.e. rutabaga)	RAC	0.01	10.01	0.10	1.66	0.02	NC	-	NC	-	3.06	0.03	2.99	0.03
VR 0498	Salsify, raw (i.e. oysterplant)	RAC	0.01	1.02	0.01	0.52	0.01	NC	-	NC	-	2.08	0.02	0.39	0.00
VR 0504	Tannia, raw (i.e. yautia)	RAC	0.01	NC	-	NC	-	NC	-	0.10	0.00	NC	-	10.74	0.11
VR 0505	Taro, raw	RAC	0.01	NC	-	NC	-	1.93	0.02	0.84	0.01	NC	-	19.94	0.20
VR 0506	Garden turnip, raw	RAC	0.01	5.78	0.06	15.35	0.15	NC	-	6.54	0.07	1.95	0.02	4.73	0.05
VR 0508	Sweet potato, raw (incl dried)	RAC	0.01	0.93	0.01	0.32	0.00	64.65	0.65	5.37	0.05	0.30	0.00	3.13	0.03
VR 0573	Arrowroot, raw	RAC	0.01	0.10	0.00	0.10	0.00	2.05	0.02	0.21	0.00	NC	-	0.76	0.01
VR 0574	Beetroot, raw	RAC	0.01	9.91	0.10	6.34	0.06	NC	-	9.65	0.10	19.11	0.19	6.47	0.06
VR 0575	Burdock, greater or edible, raw	RAC	0.01	NC	-	NC	-	NC	-	0.48	0.00	NC	-	0.10	0.00

Annex 3

CHLORANTRANILIPROLE (230) International Estimated Daily Intake (IEDI) ADI = 0 - 2.0000 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day		Intake as µg/person/day									
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
VR 0577	Carrots, raw	RAC	0.02	26.26	0.53	27.13	0.54	10.07	0.20	16.49	0.33	44.69	0.89	8.75	0.18
VR 0578	Celeriac, raw	RAC	0.01	2.97	0.03	1.79	0.02	NC	-	0.10	0.00	16.91	0.17	3.22	0.03
VR 0583	Horseradish, raw	RAC	0.01	0.10	0.00	0.42	0.00	13.01	0.13	0.26	0.00	2.70	0.03	0.97	0.01
VR 0585	Jerusalem artichoke, raw (i.e. topinambur)	RAC	0.01	0.11	0.00	0.10	0.00	NC	-	0.22	0.00	NC	-	0.78	0.01
VR 0587	Parsley turnip-rooted, raw	RAC	0.01	NC	-	NC	-	NC	-	NC	-	NC	-	0.61	0.01
VR 0588	Parsnip, raw	RAC	0.01	4.42	0.04	0.10	0.00	NC	-	NC	-	NC	-	1.12	0.01
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.01	225.03	2.25	234.24	2.34	71.48	0.71	177.55	1.78	234.55	2.35	37.71	0.38
VR 0590	Black radish, raw	RAC	0.01	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VR 0591	Japanese radish, raw (i.e. daikon)	RAC	0.01	NC	-	NC	-	26.64	0.27	18.92	0.19	NC	-	3.59	0.04
VR 0600	Yams, raw (incl dried)	RAC	0.01	NC	-	NC	-	0.10	0.00	0.71	0.01	NC	-	17.57	0.18
-	Lotus root, raw	RAC	0.01	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
-	Water chestnut, raw	RAC	0.01	NC	-	NC	-	3.42	0.03	NC	-	NC	-	NC	-
VS 0620	Artichoke globe	RAC	0.56	0.98	0.55	3.65	2.04	0.10	0.06	1.67	0.94	0.26	0.15	NC	-
VS 0624	Celery	RAC	2.1	7.68	16.13	2.85	5.99	NC	-	3.34	7.01	16.83	35.34	4.04	8.48
GC 0640	Barley, raw (incl malt extract, incl pot&pearled, incl flour & grits, incl beer, incl malt)	RAC	0.01	36.18	0.36	53.45	0.53	9.39	0.09	35.25	0.35	46.68	0.47	15.92	0.16
GC 0641	Buckwheat, raw (incl flour)	RAC	0.01	0.10	0.00	0.79	0.01	0.18	0.00	0.35	0.00	NC	-	NC	-
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl flour, incl oil, incl beer, incl germ, incl starch)	RAC	0.01	18.51	0.19	26.18	0.26	26.04	0.26	39.99	0.40	7.36	0.07	64.58	0.65
GC 0656	Popcorn (i.e. maize used for preparation of popcorn)	RAC	0.01	-	-	-	-	-	-	-	-	-	-	-	-
GC 0646	Millet, raw (incl flour, incl beer)	RAC	0.01	0.10	0.00	0.16	0.00	1.75	0.02	0.69	0.01	NC	-	NC	-
GC 0647	Oats, raw (incl rolled)	RAC	0.01	7.50	0.08	6.26	0.06	0.15	0.00	4.87	0.05	3.16	0.03	2.98	0.03
GC 0648	Quinoa, raw	RAC	0.01	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
CM 0649 (GC 0649)	Rice, husked, dry (incl flour, incl oil, incl beverages, incl starch, excl polished)	REP	0.115	3.70	0.43	2.11	0.24	1.51	0.17	1.75	0.20	0.29	0.03	5.12	0.59
CM 1205	Rice polished, dry	PP	0.013	13.38	0.17	10.80	0.14	262.08	3.41	57.16	0.74	12.83	0.17	62.78	0.82
GC 0650	Rye, raw (incl flour)	RAC	0.01	3.21	0.03	35.38	0.35	0.21	0.00	6.50	0.07	1.49	0.01	NC	-
GC 0651	Sorghum, raw (incl flour, incl beer)	RAC	0.01	NC	-	NC	-	1.44	0.01	1.15	0.01	NC	-	7.12	0.07
GC 0653	Triticale, raw (incl flour)	RAC	0.01	0.10	0.00	0.17	0.00	0.29	0.00	0.10	0.00	NC	-	NC	-
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, excl germ, excl wholemeal bread, excl white flour products, excl white bread)	RAC	0.01	0.37	0.00	0.10	0.00	0.10	0.00	0.10	0.00	NC	-	0.10	0.00
CF 1210	Wheat, germ	PP	0.012	0.97	0.01	0.10	0.00	0.10	0.00	0.10	0.00	NC	-	0.10	0.00
CF 0654	Wheat, bran	PP	0.011	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
CF 1212	Wheat, wholemeal flour	PP	0.004	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
CP 1212	Wheat, wholemeal bread	PP	0.01	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00
CP 1211	Wheat, white bread	PP	0.01	1.30	0.01	0.46	0.00	0.10	0.00	0.22	0.00	2.44	0.02	0.77	0.01

Annex 3

CHLORANTRANILIPROLE (230) International Estimated Daily Intake (IEDI) ADI = 0 - 2.0000 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day			Intake as µg/person/day								
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
CF 1211	Wheat, white flour (incl white flour products: starch, gluten, macaroni, pastry)	PP	0.004	199.38	0.80	193.50	0.77	106.30	0.43	185.31	0.74	171.11	0.68	132.37	0.53
-	Fonio, raw (incl flour)	RAC	0.01	NC	-	NC	-	0.10	0.00	NC	-	NC	-	NC	-
-	Cereals, NES, raw (including processed) : canagua, quihuicha, Job's tears and wild rice	RAC	0.01	6.17	0.06	3.01	0.03	0.76	0.01	3.30	0.03	3.38	0.03	15.84	0.16
GS 0659	Sugar cane, raw (incl sugar, incl molasses)	RAC	0.145	92.24	13.37	95.72	13.88	28.47	4.13	77.39	11.22	117.73	17.07	103.90	15.07
TN 0085	Tree nuts, raw (incl processed)	RAC	0.01	8.52	0.09	8.94	0.09	15.09	0.15	9.60	0.10	14.57	0.15	26.26	0.26
SO 0495	Rape seed, raw (incl oil)	RAC	0.295	32.68	9.64	19.91	5.87	7.83	2.31	15.69	4.63	NC	-	NC	-
SO 0691	Cotton seed, raw	RAC	0.049	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
OR 0691	Cotton seed oil, edible	PP	0.0122	1.68	0.02	0.66	0.01	1.13	0.01	1.18	0.01	0.89	0.01	0.37	0.00
SO 0697	Peanuts, nutmeat, raw (incl roasted, incl oil, incl butter)	RAC	0.01	5.63	0.06	2.75	0.03	9.58	0.10	5.82	0.06	13.71	0.14	1.84	0.02
SO 0702	Sunflower seed, raw (incl oil)	RAC	0.185	23.40	4.33	29.33	5.43	1.24	0.23	13.85	2.56	6.48	1.20	6.91	1.28
SB 0716	Coffee beans raw (incl roasted, incl instant coffee, incl substitutes)	RAC	0.015	10.90	0.16	12.44	0.19	0.77	0.01	9.48	0.14	22.07	0.33	8.15	0.12
HH 0738	Mints, raw	RAC	4.6	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
DH 1100	Hops, dry	RAC	10.9	NC	-	NC	-	0.10	1.09	0.10	1.09	NC	-	NC	-
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.009	112.02	1.01	120.71	1.09	63.46	0.57	88.99	0.80	96.24	0.87	41.02	0.37
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.05	28.01	1.40	30.18	1.51	15.86	0.79	22.25	1.11	24.06	1.20	10.25	0.51
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.05	6.44	0.32	15.51	0.78	3.79	0.19	8.29	0.41	18.44	0.92	8.00	0.40
MO 0105	Edible offal (mammalian), raw	RAC	0.047	15.17	0.71	5.19	0.24	6.30	0.30	6.78	0.32	3.32	0.16	3.17	0.15
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.006	388.92	2.33	335.88	2.02	49.15	0.29	331.25	1.99	468.56	2.81	245.45	1.47
PM 0110	Poultry meat, raw (incl prepared) - 90% as muscle	RAC	0	66.38	0.00	48.47	0.00	21.58	0.00	78.41	0.00	48.04	0.00	76.01	0.00
PM 0110	Poultry meat, raw (incl prepared) - 10% as fat	RAC	0	7.38	0.00	5.39	0.00	2.40	0.00	8.71	0.00	5.34	0.00	8.45	0.00
PF 0111	Poultry fat, raw (incl rendered)	RAC	0	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.71	0.00	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.005	0.33	0.00	0.72	0.00	0.27	0.00	0.35	0.00	0.80	0.00	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0.07	25.84	1.81	29.53	2.07	28.05	1.96	33.19	2.32	36.44	2.55	8.89	0.62
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (µg/person)=				243.7		261.8		933.3		411.5		241.0		215.5
	Bodyweight per region (kg bw) =				60		60		55		60		60		60
	ADI (µg/person)=				120000		120000		110000		120000		120000		120000
	%ADI=				0.2%		0.2%		0.8%		0.3%		0.2%		0.2%
	Rounded %ADI=				0%		0%		1%		0%		0%		0%

Annex 3

CHLORANTRANILIPROLE (230) International Estimated Daily Intake (IEDI) ADI = 0 - 2.0000 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day		Intake = daily intake: µg/person							
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
FC 0001	Citrus fruit, raw	RAC	0.06	20.93	1.26	2.35	0.14	30.71	1.84	0.15	0.01	4.45	0.27
JF 0001	Citrus fruit, juice	PP	0.037	0.11	0.00	0.29	0.01	13.55	0.50	0.14	0.01	0.33	0.01
FP 0009	Pome fruit, raw (incl cider, excl apple juice)	RAC	0.07	68.85	4.82	10.93	0.77	70.82	4.96	189.78	13.28	19.56	1.37
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.0098	0.10	0.00	0.10	0.00	7.19	0.07	0.10	0.00	NC	-
FS 0012	Stone fruits, raw (incl dried plums, incl dried apricots)	RAC	0.2	0.10	0.02	0.10	0.02	33.36	6.67	0.10	0.02	NC	-
FB 0018	Berries and other small fruits, raw, (incl processed), excl small fruit vine climbing (group 004D)	RAC	0.336	1.54	0.52	18.66	6.27	11.59	3.89	0.81	0.27	4.99	1.68
FB 0269	Grape, raw (incl must, excl dried, excl juice, excl wine)	RAC	0.119	0.14	0.02	0.36	0.04	15.33	1.82	0.10	0.01	0.28	0.03
DF 0269	Grape, dried (= currants, raisins and sultanas)	PP	0.411	0.10	0.04	0.13	0.05	1.06	0.44	0.10	0.04	0.10	0.04
JF 0269	Grape juice	PP	0.0869	0.10	0.01	0.10	0.01	0.41	0.04	0.10	0.01	NC	-
-	Grape wine (incl vermouths)	PP	0.14	0.31	0.04	0.23	0.03	60.43	8.46	0.52	0.07	31.91	4.47
FI 0355	Pomegranate, raw, (incl processed)	RAC	0.11	5.49	0.60	27.17	2.99	NC	-	2.89	0.32	17.87	1.97
VB 0040	Brassica vegetables, raw: head cabbages, flowerhead brassicas, Brussels sprouts & kohlrabi	RAC	0.385	4.84	1.86	3.79	1.46	58.72	22.61	0.10	0.04	NC	-
VC 0045	Fruiting vegetables, cucurbits, raw	RAC	0.065	5.96	0.39	9.74	0.63	51.82	3.37	13.61	0.88	0.10	0.01
VO 0440	Egg plants, raw (= aubergines)	RAC	0.066	1.31	0.09	8.26	0.55	3.95	0.26	0.10	0.01	NC	-
VO 0442	Okra, raw	RAC	0.066	6.23	0.41	0.10	0.01	NC	-	NC	-	NC	-
VO 0443	Pepino (Melon pear, Tree melon)	RAC	0.066	NC	-	NC	-	NC	-	NC	-	NC	-
VO 0444	Peppers, chili, raw	RAC	0.066	3.47	0.23	3.56	0.23	16.30	1.08	0.10	0.01	NC	-
-	Peppers, chili, dried	PP	0.46	0.58	0.27	1.27	0.58	1.21	0.56	0.12	0.06	NC	-
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.066	5.49	0.36	10.57	0.70	8.84	0.58	0.91	0.06	NC	-
VO 0447	Sweet corn on the cob, raw (incl frozen, incl canned) (i.e. kernels plus cob without husks)	RAC	0.01	3.63	0.04	20.50	0.21	8.78	0.09	0.10	0.00	0.17	0.00
VO 0448	Tomato, raw (incl canned, excl juice, excl paste)	RAC	0.066	13.10	0.86	4.90	0.32	62.16	4.10	1.04	0.07	0.10	0.01
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.109	0.58	0.06	0.22	0.02	2.21	0.24	0.24	0.03	3.10	0.34
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.0589	0.10	0.01	0.10	0.01	0.42	0.02	0.10	0.01	0.10	0.01
-	Gilo (scarlet egg plant)	RAC	0.066	NC	-	NC	-	NC	-	NC	-	NC	-
-	Goji berry	RAC	0.066	NC	-	NC	-	NC	-	NC	-	NC	-
-	Seaweed	RAC	0.066	NC	-	NC	-	NC	-	NC	-	NC	-
VL 0269	Grape leaves, raw	RAC	7.3	NC	-	NC	-	NC	-	NC	-	NC	-
VL 0446	Roselle leaves, raw (vinagreira)	RAC	7.3	0.67	4.89	0.48	3.50	NC	-	0.45	3.29	0.90	6.57
VL 0460	Amaranth leaves, raw (i.e. bledo)	RAC	7.3	1.87	13.65	1.35	9.86	NC	-	1.27	9.27	2.53	18.47
VL 0463	Cassava leaves, raw	RAC	7.3	NC	-	NC	-	NC	-	NC	-	NC	-
VL 0464	Chard, raw (i.e. beet leaves)	RAC	7.3	0.68	4.96	0.49	3.58	NC	-	0.46	3.36	0.92	6.72
VL 0465	Chervil, raw	RAC	7.3	0.33	2.41	0.24	1.75	NC	-	0.22	1.61	0.45	3.29

Annex 3

CHLORANTRANILIPROLE (230) International Estimated Daily Intake (IEDI) ADI = 0 - 2.0000 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day G13 diet	Intake = daily intake: µg/person G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
VL 0466	Chinese cabbage, type pak-choi, raw (i.e. Brassica)	RAC	7.3	NC	-	NC	-	NC	-	NC	-	NC	-
VL 0467	Chinese cabbage, type pe-tsai, raw (i.e. Brassica)	RAC	7.3	0.62	4.53	0.49	3.58	NC	-	0.10	0.73	NC	-
VL 0469	Chicory leaves (sugar loaf), raw	RAC	7.3	NC	-	NC	-	NC	-	NC	-	NC	-
VL 0470	Lambs lettuce, raw (i.e. corn salad)	RAC	7.3	1.09	7.96	0.79	5.77	NC	-	0.74	5.40	1.47	10.73
VL 0472	Garden cress, raw	RAC	7.3	0.10	0.73	0.10	0.73	NC	-	0.10	0.73	0.13	0.95
VL 0473	Watercress, raw	RAC	7.3	2.08	15.18	1.50	10.95	0.10	0.73	1.41	10.29	2.81	20.51
VL 0474	Dandelion leaves, raw	RAC	7.3	0.22	1.61	0.16	1.17	NC	-	0.15	1.10	0.29	2.12
VL 0476	Endive, raw (i.e. scarole)	RAC	7.3	0.10	0.73	0.10	0.73	0.10	0.73	0.10	0.73	NC	-
VL 0478	Indian mustard (Amsoi) (i.e. Brassica)	RAC	7.3	NC	-	NC	-	NC	-	NC	-	NC	-
VL 0479	Japanese greens, raw (i.e. Chrysanthemum)	RAC	7.3	0.10	0.73	0.10	0.73	NC	-	0.10	0.73	0.10	0.73
VL 0480	Kale, raw (i.e. collards) (i.e. Brassica)	RAC	7.3	0.79	5.77	0.62	4.53	NC	-	0.10	0.73	NC	-
VL 0481	Komatsuna, raw (i.e. Brassica)	RAC	7.3	NC	-	NC	-	NC	-	NC	-	NC	-
VL 0482	Lettuce, head, raw	RAC	7.3	NC	-	NC	-	NC	-	NC	-	NC	-
VL 0483	Lettuce, leaf, raw	RAC	7.3	0.29	2.12	0.10	0.73	6.71	48.98	0.10	0.73	NC	-
VL 0485	Mustard greens, raw (i.e. Brassica)	RAC	7.3	0.10	0.73	0.10	0.73	NC	-	0.10	0.73	NC	-
VL 0492	Purslane, raw	RAC	7.3	0.10	0.73	0.10	0.73	NC	-	0.10	0.73	0.10	0.73
VL 0494	Radish leaves, raw	RAC	10.5	0.44	4.62	0.32	3.36	NC	-	0.30	3.15	0.59	6.20
VL 0495	Rape greens, raw (i.e. Brassica)	RAC	7.3	0.10	0.73	0.10	0.73	NC	-	0.10	0.73	NC	-
VL 0496	Rucola, raw (i.e. arrugula, rocket salad, roquette)	RAC	7.3	2.17	15.84	1.57	11.46	NC	-	1.47	10.73	2.93	21.39
VL 0501	Sowthistle, raw	RAC	7.3	NC	-	NC	-	NC	-	NC	-	NC	-
VL 0502	Spinach, raw	RAC	7.3	0.17	1.24	0.10	0.73	0.81	5.91	0.10	0.73	NC	-
VL 0503	Indian spinach, raw (i.e. vine spinach)	RAC	7.3	0.10	0.73	0.10	0.73	NC	-	0.10	0.73	0.10	0.73
VL 0504	Tannia leaves, raw (i.e. taioba)	RAC	7.3	0.30	2.19	0.22	1.61	NC	-	0.20	1.46	0.41	2.99
VL 0505	Taro leaves, raw	RAC	7.3	NC	-	NC	-	NC	-	NC	-	NC	-
VL 0506	Turnip greens, raw (i.e. Namenia, Tendergreen)	RAC	7.3	NC	-	NC	-	NC	-	NC	-	NC	-
VL 0507	Kang kung, raw (i.e. water spinach)	RAC	7.3	NC	-	NC	-	NC	-	NC	-	NC	-
VL 0510	Cos lettuce, raw	RAC	7.3	NC	-	NC	-	NC	-	NC	-	NC	-
-	Perilla leaves, raw (i.e. sesame leaves)	RAC	7.3	0.26	1.90	0.19	1.39	NC	-	0.18	1.31	0.35	2.56
-	Bracken, raw (i.e. ferns)	RAC	7.3	0.18	1.31	0.13	0.95	NC	-	0.12	0.88	0.24	1.75
-	Water parsley, raw	RAC	7.3	NC	-	NC	-	NC	-	NC	-	NC	-
-	Chinese cabbage flowering stalk, raw	RAC	7.3	NC	-	NC	-	NC	-	NC	-	NC	-
VP 0061	Beans, green, with pods, raw: beans except broad bean & soya bean (i.e. immature seeds + pods) (Phaseolus spp)	RAC	0.16	NC	-	NC	-	NC	-	NC	-	NC	-
VP 0063	Peas green, with pods, raw (i.e. immature seeds + pods) (Pisum spp)	RAC	0.545	NC	-	NC	-	NC	-	NC	-	NC	-
VP 0064	Peas, green, without pods, raw (i.e. immature seeds only) (Pisum spp)	RAC	0.025	0.21	0.01	0.10	0.00	5.51	0.14	0.10	0.00	NC	-
VD 0541	Soya bean, dry, raw (incl paste, incl curd, incl oil,	RAC	0.01	15.80	0.16	14.29	0.14	104.36	1.04	17.11	0.17	35.20	0.35

Annex 3

CHLORANTRANILIPROLE (230) International Estimated Daily Intake (IEDI) ADI = 0 - 2.0000 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
				Intake = daily intake: µg/person									
	incl sauce)												
VR 0463	Cassava raw (incl starch, incl tapioca, incl flour)	RAC	0.01	91.92	0.92	34.12	0.34	NC	-	259.92	2.60	45.48	0.45
VR 0469	Chicory, roots, raw	RAC	0.01	0.10	0.00	0.10	0.00	0.10	0.00	NC	-	NC	-
VR 0494	Radish roots, raw	RAC	0.055	3.96	0.22	2.86	0.16	3.30	0.18	2.67	0.15	5.34	0.29
VR 0497	Swede, raw (i.e. rutabaga)	RAC	0.01	2.71	0.03	1.96	0.02	7.80	0.08	1.83	0.02	3.66	0.04
VR 0498	Salsify, raw (i.e. oysterplant)	RAC	0.01	0.36	0.00	0.26	0.00	NC	-	0.24	0.00	0.48	0.00
VR 0504	Tannia, raw (i.e. yautia)	RAC	0.01	NC	-	NC	-	0.10	0.00	NC	-	NC	-
VR 0505	Taro, raw	RAC	0.01	6.71	0.07	31.91	0.32	NC	-	10.73	0.11	264.31	2.64
VR 0506	Garden turnip, raw	RAC	0.01	4.29	0.04	3.10	0.03	6.41	0.06	2.90	0.03	5.79	0.06
VR 0508	Sweet potato, raw (incl dried)	RAC	0.01	28.83	0.29	61.55	0.62	0.15	0.00	221.94	2.22	NC	-
VR 0573	Arrowroot, raw	RAC	0.01	13.83	0.14	18.24	0.18	0.10	0.00	0.10	0.00	19.60	0.20
VR 0574	Beetroot, raw	RAC	0.01	5.86	0.06	4.23	0.04	9.46	0.09	3.96	0.04	7.91	0.08
VR 0575	Burdock, greater or edible, raw	RAC	0.01	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.10	0.00
VR 0577	Carrots, raw	RAC	0.02	2.07	0.04	3.00	0.06	25.29	0.51	0.10	0.00	NC	-
VR 0578	Celeriac, raw	RAC	0.01	2.91	0.03	2.10	0.02	7.59	0.08	1.97	0.02	3.93	0.04
VR 0583	Horseradish, raw	RAC	0.01	0.88	0.01	0.63	0.01	0.54	0.01	0.59	0.01	1.19	0.01
VR 0585	Jerusalem artichoke, raw (i.e. topinambur)	RAC	0.01	14.22	0.14	18.75	0.19	0.10	0.00	0.10	0.00	20.14	0.20
VR 0587	Parsley turnip-rooted, raw	RAC	0.01	0.55	0.01	0.40	0.00	4.29	0.04	0.37	0.00	0.74	0.01
VR 0588	Parsnip, raw	RAC	0.01	1.02	0.01	0.74	0.01	3.50	0.04	0.69	0.01	1.37	0.01
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.01	23.96	0.24	13.56	0.14	213.41	2.13	104.35	1.04	8.56	0.09
VR 0590	Black radish, raw	RAC	0.01	NC	-	NC	-	NC	-	NC	-	NC	-
VR 0591	Japanese radish, raw (i.e. daikon)	RAC	0.01	3.25	0.03	2.35	0.02	NC	-	2.20	0.02	4.39	0.04
VR 0600	Yams, raw (incl dried)	RAC	0.01	70.93	0.71	30.62	0.31	0.10	0.00	5.65	0.06	30.85	0.31
-	Lotus root, raw	RAC	0.01	NC	-	NC	-	NC	-	NC	-	NC	-
-	Water chestnut, raw	RAC	0.01	NC	-	NC	-	NC	-	NC	-	NC	-
VS 0620	Artichoke globe	RAC	0.56	0.10	0.06	NC	-	0.10	0.06	0.10	0.06	NC	-
VS 0624	Celery	RAC	2.1	3.66	7.69	2.65	5.57	4.84	10.16	2.47	5.19	4.94	10.37
GC 0640	Barley, raw (incl malt extract, incl pot&pearled, incl flour & grits, incl beer, incl malt)	RAC	0.01	11.58	0.12	2.33	0.02	46.71	0.47	3.72	0.04	16.26	0.16
GC 0641	Buckwheat, raw (incl flour)	RAC	0.01	0.10	0.00	2.82	0.03	0.10	0.00	0.10	0.00	NC	-
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl flour, incl oil, incl beer, incl germ, incl starch)	RAC	0.01	116.66	1.17	10.52	0.11	38.46	0.38	76.60	0.77	34.44	0.34
GC 0656	Popcorn (i.e. maize used for preparation of popcorn)	RAC	0.01	-	-	-	-	-	-	-	-	-	-
GC 0646	Millet, raw (incl flour, incl beer)	RAC	0.01	61.13	0.61	0.78	0.01	NC	-	33.55	0.34	NC	-
GC 0647	Oats, raw (incl rolled)	RAC	0.01	0.37	0.00	0.10	0.00	2.79	0.03	0.10	0.00	NC	-
GC 0648	Quinoa, raw	RAC	0.01	NC	-	NC	-	NC	-	NC	-	NC	-
CM 0649 (GC 0649)	Rice, husked, dry (incl flour, incl oil, incl beverages, incl starch, excl polished)	REP	0.115	13.58	1.56	4.29	0.49	2.17	0.25	0.10	0.01	8.84	1.02

Annex 3

CHLORANTRANILIPROLE (230) International Estimated Daily Intake (IEDI) ADI = 0 - 2.0000 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
				Intake = daily intake: µg/person									
CM 1205	Rice polished, dry	PP	0.013	30.20	0.39	218.34	2.84	12.77	0.17	15.24	0.20	51.35	0.67
GC 0650	Rye, raw (incl flour)	RAC	0.01	0.10	0.00	0.10	0.00	13.95	0.14	0.10	0.00	0.88	0.01
GC 0651	Sorghum, raw (incl flour, incl beer)	RAC	0.01	89.16	0.89	2.02	0.02	NC	-	35.38	0.35	NC	-
GC 0653	Triticale, raw (incl flour)	RAC	0.01	0.10	0.00	NC	-	NC	-	NC	-	NC	-
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, excl germ, excl wholemeal bread, excl white flour products, excl white bread)	RAC	0.01	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00	0.97	0.01
CF 1210	Wheat, germ	PP	0.012	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00	NC	-
CF 0654	Wheat, bran	PP	0.011	NC	-	NC	-	NC	-	NC	-	NC	-
CF 1212	Wheat, wholemeal flour	PP	0.004	NC	-	NC	-	NC	-	NC	-	NC	-
CP 1212	Wheat, wholemeal bread	PP	0.01	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00
CP 1211	Wheat, white bread	PP	0.01	0.43	0.00	0.41	0.00	1.56	0.02	0.11	0.00	0.10	0.00
CF 1211	Wheat, white flour (incl white flour products: starch, gluten, macaroni, pastry)	PP	0.004	45.21	0.18	87.37	0.35	215.61	0.86	20.42	0.08	103.67	0.41
-	Fonio, raw (incl flour)	RAC	0.01	0.61	0.01	NC	-	NC	-	NC	-	NC	-
-	Cereals, NES, raw (including processed) : canagua, quihuicha, Job's tears and wild rice	RAC	0.01	17.71	0.18	2.00	0.02	9.61	0.10	0.45	0.00	4.55	0.05
GS 0659	Sugar cane, raw (incl sugar, incl molasses)	RAC	0.145	33.75	4.89	106.29	15.41	78.09	11.32	29.09	4.22	45.70	6.63
TN 0085	Tree nuts, raw (incl processed)	RAC	0.01	4.39	0.04	135.53	1.36	6.11	0.06	0.72	0.01	317.74	3.18
SO 0495	Rape seed, raw (incl oil)	RAC	0.295	0.19	0.06	0.10	0.03	12.07	3.56	0.10	0.03	NC	-
SO 0691	Cotton seed, raw	RAC	0.049	NC	-	NC	-	NC	-	NC	-	NC	-
OR 0691	Cotton seed oil, edible	PP	0.0122	1.28	0.02	0.10	0.00	0.45	0.01	0.42	0.01	0.15	0.00
SO 0697	Peanuts, nutmeat, raw (incl roasted, incl oil, incl butter)	RAC	0.01	18.82	0.19	0.57	0.01	2.28	0.02	6.90	0.07	0.53	0.01
SO 0702	Sunflower seed, raw (incl oil)	RAC	0.185	0.94	0.17	0.22	0.04	32.01	5.92	12.12	2.24	0.48	0.09
SB 0716	Coffee beans raw (incl roasted, incl instant coffee, incl substitutes)	RAC	0.015	0.95	0.01	1.32	0.02	11.64	0.17	2.96	0.04	14.73	0.22
HH 0738	Mints, raw	RAC	4.6	NC	-	NC	-	NC	-	NC	-	NC	-
DH 1100	Hops, dry	RAC	10.9	NC	-	NC	-	0.10	1.09	NC	-	NC	-
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.009	23.34	0.21	40.71	0.37	97.15	0.87	18.06	0.16	57.71	0.52
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.05	5.84	0.29	10.18	0.51	24.29	1.21	4.52	0.23	14.43	0.72
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.05	1.05	0.05	1.14	0.06	18.69	0.93	0.94	0.05	3.12	0.16
MO 0105	Edible offal (mammalian), raw	RAC	0.047	4.64	0.22	1.97	0.09	10.01	0.47	3.27	0.15	3.98	0.19
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.006	108.75	0.65	70.31	0.42	436.11	2.62	61.55	0.37	79.09	0.47
PM 0110	Poultry meat, raw (incl prepared) - 90% as muscle	RAC	0	3.53	0.00	10.83	0.00	51.36	0.00	4.53	0.00	50.00	0.00
PM 0110	Poultry meat, raw (incl prepared) - 10% as fat	RAC	0	0.39	0.00	1.20	0.00	5.71	0.00	0.50	0.00	5.56	0.00

Annex 3

CHLORANTRANILIPROLE (230) International Estimated Daily Intake (IEDI) ADI = 0 - 2.0000 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day G13 diet	Intake = daily intake: µg/person G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
PF 0111	Poultry fat, raw (incl rendered)	RAC	0	NC	-	NC	-	0.32	0.00	NC	-	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.005	0.10	0.00	0.70	0.00	0.97	0.00	0.10	0.00	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0.07	3.84	0.27	4.41	0.31	27.25	1.91	1.13	0.08	7.39	0.52
-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (µg/person)=				130.3		115.8		165.2		96.3		147.2
	Bodyweight per region (kg bw) =				60		60		60		60		60
	ADI (µg/person)=				120000		120000		120000		120000		120000
	%ADI=				0.1%		0.1%		0.1%		0.1%		0.1%
	Rounded %ADI=				0%		0%		0%		0%		0%

Annex 3

CLOTHIANIDIN (238) International Estimated Daily Intake (IEDI) ADI = 0 – 0.10 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day			Intake as µg/person/day								
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
FC 0001	Citrus fruit, raw (incl citrus fruit juice)	RAC	0.02	34.91	0.70	16.51	0.33	17.23	0.34	104.48	2.09	35.57	0.71	98.49	1.97
FP 0009	Pome fruits, raw (incl. apple juice, incl cider)	RAC	0.1	19.79	1.98	38.25	3.83	17.96	1.80	32.56	3.26	8.08	0.81	64.45	6.45
FP 0227	Crab-apple, raw	RAC	0.1	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
FP 0228	Loquat, raw (incl processed)	RAC	0.1	0.59	0.06	0.36	0.04	0.46	0.05	1.88	0.19	NC	-	1.15	0.12
FP 0229	Medlar, raw (incl processed)	RAC	0.1	0.47	0.05	0.29	0.03	0.36	0.04	1.49	0.15	NC	-	0.92	0.09
FP 0230	Pear, raw	RAC	0.1	2.16	0.22	6.24	0.62	0.10	0.01	4.07	0.41	1.16	0.12	5.34	0.53
FP 0307	Persimmon, Japanese, raw	RAC	0.1	1.91	0.19	0.10	0.01	1.94	0.19	1.96	0.20	NC	-	0.25	0.03
FP 0231	Quince, raw	RAC	0.1	0.73	0.07	0.54	0.05	0.10	0.01	0.10	0.01	0.10	0.01	1.31	0.13
FS 0012	Stone fruits, raw (incl dried apricots, excl dried plums)	RAC	0.04	11.33	0.45	23.62	0.94	0.24	0.01	11.32	0.45	2.28	0.09	33.26	1.33
DF 0014	Plum, dried (prunes)	PP	0.07	0.10	0.01	0.10	0.01	0.10	0.01	0.18	0.01	0.10	0.01	0.10	0.01
FB 0018	Berries and other small fruits, raw, (incl processed), excl small fruit vine climbing (group 004D)	RAC	0.01	2.29	0.02	4.71	0.05	0.78	0.01	4.48	0.04	0.39	0.00	6.27	0.06
FB 0269	Grape, raw (incl must, incl wine, excl dried, excl juice)	RAC	0.12	13.94	1.67	26.46	3.18	2.79	0.33	18.58	2.23	8.54	1.02	59.95	7.19
DF 0269	Grape, dried (= currants, raisins and sultanas)	PP	0.31	0.51	0.16	0.51	0.16	0.10	0.03	1.27	0.39	0.12	0.04	2.07	0.64
JF 0269	Grape juice	PP	0.18	0.14	0.03	0.29	0.05	0.10	0.02	0.30	0.05	0.24	0.04	0.10	0.02
FI 0326	Avocado, raw	RAC	0.01	0.13	0.00	0.10	0.00	2.05	0.02	2.54	0.03	2.34	0.02	0.12	0.00
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.02	5.06	0.10	6.91	0.14	37.17	0.74	31.16	0.62	40.21	0.80	18.96	0.38
FI 0345	Mango, raw (incl canned mango, incl mango juice)	RAC	0.02	10.48	0.21	0.10	0.00	7.24	0.14	6.87	0.14	19.98	0.40	6.25	0.13
FI 0350	Papaya, raw	RAC	0	0.35	0.00	0.10	0.00	3.05	0.00	0.80	0.00	7.28	0.00	1.00	0.00
FI 0353	Pineapple, raw (incl canned pineapple, incl pineapple juice, incl dried pineapple)	RAC	0	0.61	0.00	1.56	0.00	7.89	0.00	9.36	0.00	8.76	0.00	1.30	0.00
VB 0040	Brassica vegetables, raw: head cabbages, flowerhead brassicas, Brussels sprouts & kohlrabi	RAC	0.015	6.41	0.10	35.79	0.54	0.71	0.01	9.81	0.15	12.07	0.18	16.58	0.25
VC 0045	Fruiting vegetables, cucurbits, raw	RAC	0.02	53.14	1.06	86.21	1.72	6.28	0.13	92.76	1.86	15.64	0.31	155.30	3.11
VO 0440	Egg plants, raw (= aubergines)	RAC	0.02	5.58	0.11	4.31	0.09	0.89	0.02	9.31	0.19	13.64	0.27	20.12	0.40
VO 0442	Okra, raw	RAC	0.02	1.97	0.04	NC	-	3.68	0.07	3.24	0.06	5.72	0.11	1.57	0.03
VO 0443	Pepino (Melon pear, Tree melon)	RAC	0.02	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VO 0444	Peppers, chili, raw	RAC	0.02	3.99	0.08	7.30	0.15	2.93	0.06	5.62	0.11	NC	-	17.44	0.35
-	Peppers, chili, dried	PP	0.2	0.42	0.08	0.53	0.11	0.84	0.17	0.50	0.10	0.95	0.19	0.37	0.07
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.02	4.49	0.09	6.44	0.13	7.21	0.14	5.68	0.11	9.52	0.19	8.92	0.18

Annex 3

CLOTHIANIDIN (238) International Estimated Daily Intake (IEDI) ADI = 0 – 0.10 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day			Intake as µg/person/day								
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
VO 0447	Sweet corn on the cob, raw (incl frozen, incl canned) (i.e. kernels plus cob without husks)	RAC	0.01	0.14	0.00	0.94	0.01	5.70	0.06	2.61	0.03	1.94	0.02	0.22	0.00
VO 0448	Tomato, raw (incl juice, incl paste, incl canned)	RAC	0.02	51.75	1.04	81.80	1.64	16.99	0.34	102.02	2.04	26.32	0.53	214.77	4.30
-	Gilo (scarlet egg plant)	RAC	0.02	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
-	Goji berry	RAC	0.02	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
-	Quorn	RAC	0.02	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
-	Seaweed	RAC	0.08	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VL 0053	Leafy vegetables, raw	RAC	0.52	8.47	4.40	22.36	11.63	7.74	4.02	25.51	13.27	45.77	23.80	21.22	11.03
VP 0061	Beans, green, with pods, raw: beans except broad bean & soya bean (i.e. immature seeds + pods) (Phaseolus spp)	RAC	0.07	0.68	0.05	NC	-	NC	-	0.39	0.03	0.22	0.02	0.49	0.03
VP 0062	Beans, green, without pods, raw: beans except broad bean & soya bean (i.e. immature seeds only) (Phaseolus spp..)	RAC	0.01	1.56	0.02	0.60	0.01	0.49	0.00	1.18	0.01	0.90	0.01	7.79	0.08
VP 0063	Peas green, with pods, raw (i.e. immature seeds + pods) (Pisum spp)	RAC	0.01	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VP 0064	Peas, green, without pods, raw (i.e. immature seeds only) (Pisum spp)	RAC	0.01	1.97	0.02	0.51	0.01	0.10	0.00	0.79	0.01	3.68	0.04	3.80	0.04
VP 0520	Bambara groundnut, green, without pods (i.e. immature seeds only) (Voandzeia spp)	RAC	0.01	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VP 0522	Broad bean, green, with pods (i.e. immature seeds + pods) (Vicia spp)	RAC	0.01	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VP 0523	Broad beans, green, without pods, raw (i.e. immature seeds only) (Vicia faba)	RAC	0.01	3.51	0.04	0.43	0.00	0.10	0.00	0.60	0.01	0.29	0.00	0.78	0.01
VP 0541	Soya bean, green, without pods, raw (i.e. immature seeds only) (Glycine max)	RAC	0.01	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VP 0542	Sword bean, green, with pods (i.e. immature seeds + pods) (Canavalia spp)	RAC	0.01	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VP 0553	Lentil, green, with pods (i.e. immature seeds + pods) (Lens spp)	RAC	0.01	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VD 0070	Pulses, raw (incl processed)	RAC	0.02	85.59	1.71	64.02	1.28	34.15	0.68	88.02	1.76	89.38	1.79	96.88	1.94
VR 0075	Root and tuber vegetables, raw (incl processed)	RAC	0.02	87.83	1.76	374.04	7.48	668.92	13.38	121.64	2.43	94.20	1.88	247.11	4.94
VS 0469	Witloof chicory (sprouts)	RAC	0.01	0.10	0.00	0.10	0.00	0.10	0.00	0.36	0.00	0.10	0.00	0.35	0.00
VS 0620	Artichoke globe	RAC	0.024	0.69	0.02	0.10	0.00	0.10	0.00	0.32	0.01	0.26	0.01	1.21	0.03
VS 0621	Asparagus	RAC	0.01	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00	0.21	0.00
VS 0622	Bamboo shoots	RAC	0.01	1.72	0.02	3.05	0.03	1.89	0.02	4.59	0.05	NC	-	2.21	0.02
VS 0623	Cardoon	RAC	0.01	0.24	0.00	0.43	0.00	0.27	0.00	0.64	0.01	NC	-	0.31	0.00

Annex 3

CLOTHIANIDIN (238) International Estimated Daily Intake (IEDI) ADI = 0 – 0.10 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day			Intake as µg/person/day								
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
VS 0624	Celery	RAC	0.01	2.14	0.02	3.79	0.04	2.35	0.02	5.69	0.06	0.10	0.00	2.75	0.03
VS 0626	Palm hearts	RAC	0.01	0.39	0.00	0.70	0.01	0.43	0.00	1.05	0.01	2.27	0.02	0.51	0.01
VS 0627	Rhubarb	RAC	0.01	0.73	0.01	1.30	0.01	0.80	0.01	1.95	0.02	NC	-	0.94	0.01
GC 0640	Barley, raw (incl malt extract, incl pot&pearled, incl flour & grits, incl beer, incl malt)	RAC	0.01	19.91	0.20	31.16	0.31	5.04	0.05	3.10	0.03	9.77	0.10	4.31	0.04
GC 0640	Barley, raw (incl malt extract, incl beer, incl malt, excl pot&pearled, excl flour & grits)	RAC	0.4	3.55	1.42	19.31	7.72	4.98	1.99	3.02	1.21	7.85	3.14	3.98	1.59
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl flour, incl oil, incl beer, incl germ, incl starch)	RAC	0.02	29.81	0.60	44.77	0.90	108.95	2.18	52.37	1.05	60.28	1.21	75.69	1.51
GC 0656	Popcorn (i.e. maize used for preparation of popcorn)	RAC	0.01	-	-	-	-	-	-	-	-	-	-	-	-
CM 0649 (GC 0649)	Rice, husked, dry (incl polished, incl flour, incl starch, incl oil, incl beverages)	REP	0.145	45.40	6.58	14.99	2.17	84.88	12.31	111.73	16.20	194.75	28.24	93.12	13.50
GC 0651	Sorghum, raw (incl flour, incl beer)	RAC	0.01	4.34	0.04	0.10	0.00	16.25	0.16	15.82	0.16	10.97	0.11	2.92	0.03
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, incl germ, incl wholemeal bread, incl white flour products, incl white bread)	RAC	0.02	381.15	7.62	341.55	6.83	38.35	0.77	281.89	5.64	172.83	3.46	434.07	8.68
GS 0659	Sugar cane, raw (incl sugar, incl molasses)	RAC	0.03	99.68	2.99	86.27	2.59	31.38	0.94	80.36	2.41	84.18	2.53	99.10	2.97
TN 0672	Pecan nuts, nutmeat	RAC	0.01	0.10	0.00	0.10	0.00	0.10	0.00	0.14	0.00	0.10	0.00	0.13	0.00
SO 0088	Oilseeds, raw (incl processed)	RAC	0.02	79.30	1.59	54.81	1.10	96.74	1.93	137.72	2.75	61.07	1.22	88.71	1.77
SB 0715	Cocoa beans, raw (incl roasted, incl powder, incl butter, incl paste, incl nes products)	RAC	0.02	0.72	0.01	4.20	0.08	0.60	0.01	4.21	0.08	0.42	0.01	0.78	0.02
SB 0716	Coffee beans raw (incl roasted, incl instant coffee, incl substitutes)	RAC	0.015	1.36	0.02	3.59	0.05	1.44	0.02	5.18	0.08	2.02	0.03	1.70	0.03
HH 0624	Celery leaves, raw	RAC	0.21	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
HH 0738	Mints, raw	RAC	0.11	0.50	0.06	0.10	0.01	NC	-	NC	-	NC	-	NC	-
DH 1100	Hops, dry	RAC	0.026	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00	NC	-	0.10	0.00
DT 1114	Tea, green or black, fermented and dried	RAC	0.12	2.28	0.27	1.92	0.23	0.46	0.06	2.40	0.29	1.29	0.15	3.04	0.36
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.02	24.96	0.50	57.95	1.16	16.70	0.33	38.38	0.77	26.46	0.53	29.00	0.58
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.02	6.24	0.12	14.49	0.29	4.18	0.08	9.60	0.19	6.62	0.13	7.25	0.15
MF 0100	Mammalian fats, raw, excl milk fats (incl	RAC	0.02	3.29	0.07	6.14	0.12	0.82	0.02	1.57	0.03	2.23	0.04	1.07	0.02

Annex 3

CLOTHIANIDIN (238) International Estimated Daily Intake (IEDI) ADI = 0 – 0.10 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day			Intake as µg/person/day								
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
	rendered fats)														
MO 0105	Edible offal (mammalian), raw	RAC	0.058	4.79	0.28	9.68	0.56	2.97	0.17	5.49	0.32	3.84	0.22	5.03	0.29
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.006	289.65	1.74	485.88	2.92	26.92	0.16	239.03	1.43	199.91	1.20	180.53	1.08
PM 0110	Poultry meat, raw (incl prepared) - 90% as muscle	RAC	0.01	13.17	0.13	26.78	0.27	7.24	0.07	116.71	1.17	22.54	0.23	32.09	0.32
PM 0110	Poultry meat, raw (incl prepared) - 10% as fat	RAC	0.01	1.46	0.01	2.98	0.03	0.80	0.01	12.97	0.13	2.50	0.03	3.57	0.04
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.01	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.10	0.00	0.10	0.00
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.018	0.12	0.00	0.12	0.00	0.11	0.00	5.37	0.10	0.24	0.00	0.10	0.00
PE 0112	Eggs, raw, (incl dried)	RAC	0.01	7.84	0.08	23.08	0.23	2.88	0.03	14.89	0.15	9.81	0.10	14.83	0.15
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (µg/person)=				40.9		61.9		44.2		66.8		76.1		79.1
	Bodyweight per region (kg bw) =				60		60		60		60		60		60
	ADI (µg/person)=				6000		6000		6000		6000		6000		6000
	%ADI=				0.7%		1.0%		0.7%		1.1%		1.3%		1.3%
	Rounded %ADI=				1%		1%		1%		1%		1%		1%

CLOTHIANIDIN (238) International Estimated Daily Intake (IEDI) ADI = 0 – 0.10 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day			Intake as µg/person/day								
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
FC 0001	Citrus fruit, raw (incl citrus fruit juice)	RAC	0.02	114.42	2.29	62.91	1.26	26.97	0.54	96.72	1.93	96.22	1.92	563.19	11.26
FP 0009	Pome fruits, raw (incl. apple juice, incl cider)	RAC	0.1	71.38	7.14	81.73	8.17	42.91	4.29	58.89	5.89	103.85	10.39	12.48	1.25
FP 0227	Crab-apple, raw	RAC	0.1	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
FP 0228	Loquat, raw (incl processed)	RAC	0.1	0.96	0.10	NC	-	NC	-	3.92	0.39	NC	-	2.49	0.25
FP 0229	Medlar, raw (incl processed)	RAC	0.1	NC	-	NC	-	NC	-	NC	-	NC	-	1.98	0.20
FP 0230	Pear, raw	RAC	0.1	8.79	0.88	8.44	0.84	12.37	1.24	9.60	0.96	10.27	1.03	0.23	0.02
FP 0307	Persimmon, Japanese, raw	RAC	0.1	0.10	0.01	0.30	0.03	3.59	0.36	0.15	0.02	0.10	0.01	NC	-
FP 0231	Quince, raw	RAC	0.1	0.19	0.02	0.18	0.02	0.11	0.01	0.10	0.01	0.28	0.03	NC	-
FS 0012	Stone fruits, raw (incl dried apricots, excl dried plums)	RAC	0.04	18.18	0.73	23.83	0.95	14.27	0.57	18.52	0.74	9.35	0.37	0.11	0.00
DF 0014	Plum, dried (prunes)	PP	0.07	0.61	0.04	0.35	0.02	0.10	0.01	0.35	0.02	0.49	0.03	0.13	0.01
FB 0018	Berries and other small fruits, raw, (incl processed), excl small fruit vine climbing (group 004D)	RAC	0.01	14.68	0.15	12.74	0.13	0.23	0.00	11.77	0.12	8.01	0.08	4.08	0.04

Annex 3

CLOTHIANIDIN (238) International Estimated Daily Intake (IEDI) ADI = 0 – 0.10 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day			Intake as µg/person/day								
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
FB 0269	Grape, raw (incl must, incl wine, excl dried, excl juice)	RAC	0.12	128.64	15.44	97.04	11.64	7.74	0.93	43.94	5.27	88.68	10.64	8.80	1.06
DF 0269	Grape, dried (= currants, raisins and sultanas)	PP	0.31	3.09	0.96	1.51	0.47	0.10	0.03	1.38	0.43	4.26	1.32	0.42	0.13
JF 0269	Grape juice	PP	0.18	0.56	0.10	1.96	0.35	0.10	0.02	2.24	0.40	2.27	0.41	0.34	0.06
FI 0326	Avocado, raw	RAC	0.01	2.65	0.03	0.87	0.01	0.46	0.00	1.64	0.02	1.30	0.01	0.96	0.01
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.02	25.14	0.50	23.37	0.47	23.06	0.46	23.40	0.47	18.44	0.37	39.29	0.79
FI 0345	Mango, raw (incl canned mango, incl mango juice)	RAC	0.02	1.80	0.04	0.63	0.01	10.05	0.20	1.07	0.02	3.52	0.07	16.44	0.33
FI 0350	Papaya, raw	RAC	0	0.31	0.00	0.18	0.00	1.50	0.00	0.51	0.00	0.54	0.00	1.08	0.00
FI 0353	Pineapple, raw (incl canned pineapple, incl pineapple juice, incl dried pineapple)	RAC	0	13.13	0.00	11.13	0.00	6.94	0.00	14.36	0.00	36.74	0.00	18.81	0.00
VB 0040	Brassica vegetables, raw: head cabbages, flowerhead brassicas, Brussels sprouts & kohlrabi	RAC	0.015	20.71	0.31	39.81	0.60	16.70	0.25	28.49	0.43	18.12	0.27	15.03	0.23
VC 0045	Fruiting vegetables, cucurbits, raw	RAC	0.02	27.81	0.56	41.93	0.84	123.30	2.47	49.47	0.99	15.95	0.32	35.99	0.72
VO 0440	Egg plants, raw (= aubergines)	RAC	0.02	1.01	0.02	1.69	0.03	21.37	0.43	3.00	0.06	1.40	0.03	NC	-
VO 0442	Okra, raw	RAC	0.02	NC	-	NC	-	0.10	0.00	0.17	0.00	NC	-	0.72	0.01
VO 0443	Pepino (Melon pear, Tree melon)	RAC	0.02	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VO 0444	Peppers, chili, raw	RAC	0.02	5.57	0.11	14.00	0.28	8.25	0.17	5.77	0.12	6.44	0.13	2.53	0.05
-	Peppers, chili, dried	PP	0.2	0.11	0.02	0.21	0.04	0.36	0.07	0.21	0.04	0.25	0.05	0.15	0.03
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.02	0.82	0.02	1.53	0.03	10.85	0.22	4.59	0.09	1.84	0.04	2.00	0.04
VO 0447	Sweet corn on the cob, raw (incl frozen, incl canned) (i.e. kernels plus cob without husks)	RAC	0.01	11.43	0.11	3.71	0.04	0.74	0.01	13.63	0.14	3.07	0.03	1.50	0.02
VO 0448	Tomato, raw (incl juice, incl paste, incl canned)	RAC	0.02	64.74	1.29	68.31	1.37	36.05	0.72	82.09	1.64	54.50	1.09	11.69	0.23
-	Gilo (scarlet egg plant)	RAC	0.02	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
-	Goji berry	RAC	0.02	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
-	Quorn	RAC	0.02	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
-	Seaweed	RAC	0.08	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VL 0053	Leafy vegetables, raw	RAC	0.52	18.83	9.79	21.85	11.36	121.23	63.04	43.09	22.41	18.18	9.45	18.32	9.53
VP 0061	Beans, green, with pods, raw: beans except broad bean & soya bean (i.e. immature seeds + pods) (Phaseolus spp)	RAC	0.07	5.07	0.35	0.83	0.06	0.17	0.01	3.70	0.26	NC	-	NC	-
VP 0062	Beans, green, without pods, raw: beans except broad bean & soya bean (i.e. immature seeds only) (Phaseolus spp..)	RAC	0.01	2.21	0.02	5.25	0.05	4.17	0.04	1.61	0.02	16.95	0.17	0.17	0.00
VP 0063	Peas green, with pods, raw (i.e. immature	RAC	0.01	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-

Annex 3

CLOTHIANIDIN (238) International Estimated Daily Intake (IEDI) ADI = 0 – 0.10 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day			Intake as µg/person/day								
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
	seeds + pods) (Pisum spp)														
VP 0064	Peas, green, without pods, raw (i.e. immature seeds only) (Pisum spp)	RAC	0.01	10.72	0.11	1.99	0.02	2.72	0.03	4.26	0.04	4.23	0.04	NC	-
VP 0520	Bambara groundnut, green, without pods (i.e. immature seeds only) (Voandzeia spp)	RAC	0.01	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VP 0522	Broad bean, green, with pods (i.e. immature seeds + pods) (Vicia spp)	RAC	0.01	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VP 0523	Broad beans, green, without pods, raw (i.e. immature seeds only) (Vicia faba)	RAC	0.01	0.22	0.00	0.84	0.01	0.15	0.00	0.48	0.00	2.04	0.02	NC	-
VP 0541	Soya bean, green, without pods, raw (i.e. immature seeds only) (Glycine max)	RAC	0.01	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VP 0542	Sword bean, green, with pods (i.e. immature seeds + pods) (Canavalia spp)	RAC	0.01	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VP 0553	Lentil, green, with pods (i.e. immature seeds + pods) (Lens spp)	RAC	0.01	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VD 0070	Pulses, raw (incl processed)	RAC	0.02	112.88	2.26	123.05	2.46	47.15	0.94	204.64	4.09	227.37	4.55	109.11	2.18
VR 0075	Root and tuber vegetables, raw (incl processed)	RAC	0.02	290.31	5.81	300.35	6.01	214.25	4.29	242.72	4.85	348.67	6.97	137.52	2.75
VS 0469	Witloof chicory (sprouts)	RAC	0.01	1.50	0.02	0.95	0.01	NC	-	1.84	0.02	0.65	0.01	0.13	0.00
VS 0620	Artichoke globe	RAC	0.024	0.98	0.02	3.65	0.09	0.10	0.00	1.67	0.04	0.26	0.01	NC	-
VS 0621	Asparagus	RAC	0.01	0.84	0.01	2.08	0.02	7.11	0.07	1.01	0.01	1.69	0.02	0.10	0.00
VS 0622	Bamboo shoots	RAC	0.01	0.92	0.01	0.55	0.01	61.79	0.62	NC	-	1.72	0.02	3.26	0.03
VS 0623	Cardoon	RAC	0.01	0.10	0.00	3.49	0.03	NC	-	0.10	0.00	NC	-	0.46	0.00
VS 0624	Celery	RAC	0.01	7.68	0.08	2.85	0.03	NC	-	3.34	0.03	16.83	0.17	4.04	0.04
VS 0626	Palm hearts	RAC	0.01	0.51	0.01	0.73	0.01	3.54	0.04	0.10	0.00	0.66	0.01	0.75	0.01
VS 0627	Rhubarb	RAC	0.01	1.61	0.02	2.23	0.02	NC	-	0.52	0.01	7.63	0.08	1.39	0.01
GC 0640	Barley, raw (incl malt extract, incl pot&pearled, incl flour & grits, incl beer, incl malt)	RAC	0.01	36.18	0.36	53.45	0.53	9.39	0.09	35.25	0.35	46.68	0.47	15.92	0.16
GC 0640	Barley, raw (incl malt extract, incl beer, incl malt, excl pot&pearled, excl flour & grits)	RAC	0.4	35.17	14.07	49.45	19.78	8.86	3.54	34.31	13.72	44.87	17.95	15.82	6.33
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl flour, incl oil, incl beer, incl germ, incl starch)	RAC	0.02	18.51	0.37	26.18	0.52	26.04	0.52	39.99	0.80	7.36	0.15	64.58	1.29
GC 0656	Popcorn (i.e. maize used for preparation of popcorn)	RAC	0.01	-	-	-	-	-	-	-	-	-	-	-	-
CM 0649 (GC 0649)	Rice, husked, dry (incl polished, incl flour, incl starch, incl oil, incl beverages)	REP	0.145	20.96	3.04	16.04	2.33	339.67	49.25	75.51	10.95	16.86	2.44	86.13	12.49
GC 0651	Sorghum, raw (incl flour, incl beer)	RAC	0.01	NC	-	NC	-	1.44	0.01	1.15	0.01	NC	-	7.12	0.07

Annex 3

CLOTHIANIDIN (238) International Estimated Daily Intake (IEDI) ADI = 0 – 0.10 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day			Intake as µg/person/day								
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, incl germ, incl wholemeal bread, incl white flour products, incl white bread)	RAC	0.02	253.07	5.06	244.73	4.89	134.44	2.69	235.10	4.70	216.39	4.33	167.40	3.35
GS 0659	Sugar cane, raw (incl sugar, incl molasses)	RAC	0.03	92.24	2.77	95.72	2.87	28.47	0.85	77.39	2.32	117.73	3.53	103.90	3.12
TN 0672	Pecan nuts, nutmeat	RAC	0.01	0.38	0.00	NC	-	NC	-	0.27	0.00	NC	-	0.26	0.00
SO 0088	Oilseeds, raw (incl processed)	RAC	0.02	108.63	2.17	112.14	2.24	64.25	1.29	81.75	1.64	66.09	1.32	20.34	0.41
SB 0715	Cocoa beans, raw (incl roasted, incl powder, incl butter, incl paste, incl nes products)	RAC	0.02	7.54	0.15	5.59	0.11	0.29	0.01	4.14	0.08	1.27	0.03	5.29	0.11
SB 0716	Coffee beans raw (incl roasted, incl instant coffee, incl substitutes)	RAC	0.015	10.90	0.16	12.44	0.19	0.77	0.01	9.48	0.14	22.07	0.33	8.15	0.12
HH 0624	Celery leaves, raw	RAC	0.21	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
HH 0738	Mints, raw	RAC	0.11	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
DH 1100	Hops, dry	RAC	0.026	NC	-	NC	-	0.10	0.00	0.10	0.00	NC	-	NC	-
DT 1114	Tea, green or black, fermented and dried	RAC	0.12	2.71	0.33	0.82	0.10	1.14	0.14	1.59	0.19	1.82	0.22	0.53	0.06
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.02	112.02	2.24	120.71	2.41	63.46	1.27	88.99	1.78	96.24	1.92	41.02	0.82
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.02	28.01	0.56	30.18	0.60	15.86	0.32	22.25	0.44	24.06	0.48	10.25	0.21
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.02	6.44	0.13	15.51	0.31	3.79	0.08	8.29	0.17	18.44	0.37	8.00	0.16
MO 0105	Edible offal (mammalian), raw	RAC	0.058	15.17	0.88	5.19	0.30	6.30	0.37	6.78	0.39	3.32	0.19	3.17	0.18
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.006	388.92	2.33	335.88	2.02	49.15	0.29	331.25	1.99	468.56	2.81	245.45	1.47
PM 0110	Poultry meat, raw (incl prepared) - 90% as muscle	RAC	0.01	66.38	0.66	48.47	0.48	21.58	0.22	78.41	0.78	48.04	0.48	76.01	0.76
PM 0110	Poultry meat, raw (incl prepared) - 10% as fat	RAC	0.01	7.38	0.07	5.39	0.05	2.40	0.02	8.71	0.09	5.34	0.05	8.45	0.08
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.01	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.71	0.01	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.018	0.33	0.01	0.72	0.01	0.27	0.00	0.35	0.01	0.80	0.01	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0.01	25.84	0.26	29.53	0.30	28.05	0.28	33.19	0.33	36.44	0.36	8.89	0.09
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (µg/person)=				85.0		87.9		143.3		92.9		87.6		62.6
	Bodyweight per region (kg bw) =				60		60		55		60		60		60
	ADI (µg/person)=				6000		6000		5500		6000		6000		6000
	%ADI=				1.4%		1.5%		2.6%		1.5%		1.5%		1.0%
	Rounded %ADI=				1%		1%		3%		2%		1%		1%

Annex 3

CLOTHIANIDIN (238) International Estimated Daily Intake (IEDI) ADI = 0 – 0.10 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day			Intake = daily intake: µg/person						
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
FC 0001	Citrus fruit, raw (incl citrus fruit juice)	RAC	0.02	21.16	0.42	2.94	0.06	58.52	1.17	0.44	0.01	5.13	0.10
FP 0009	Pome fruits, raw (incl. apple juice, incl cider)	RAC	0.1	68.89	6.89	11.06	1.11	80.62	8.06	189.82	18.98	19.56	1.96
FP 0227	Crab-apple, raw	RAC	0.1	NC	-	NC	-	NC	-	NC	-	NC	-
FP 0228	Loquat, raw (incl processed)	RAC	0.1	0.94	0.09	4.68	0.47	NC	-	0.50	0.05	3.08	0.31
FP 0229	Medlar, raw (incl processed)	RAC	0.1	0.75	0.08	3.73	0.37	4.87	0.49	0.40	0.04	2.45	0.25
FP 0230	Pear, raw	RAC	0.1	0.10	0.01	0.14	0.01	9.45	0.95	0.10	0.01	0.14	0.01
FP 0307	Persimmon, Japanese, raw	RAC	0.1	0.41	0.04	0.32	0.03	0.10	0.01	0.58	0.06	12.51	1.25
FP 0231	Quince, raw	RAC	0.1	NC	-	NC	-	0.65	0.07	NC	-	NC	-
FS 0012	Stone fruits, raw (incl dried apricots, excl dried plums)	RAC	0.04	0.10	0.00	0.10	0.00	32.27	1.29	0.10	0.00	NC	-
DF 0014	Plum, dried (prunes)	PP	0.07	0.10	0.01	0.10	0.01	0.37	0.03	0.10	0.01	NC	-
FB 0018	Berries and other small fruits, raw, (incl processed), excl small fruit vine climbing (group 004D)	RAC	0.01	1.54	0.02	18.66	0.19	11.59	0.12	0.81	0.01	4.99	0.05
FB 0269	Grape, raw (incl must, incl wine, excl dried, excl juice)	RAC	0.12	0.57	0.07	0.69	0.08	98.34	11.80	0.73	0.09	44.12	5.29
DF 0269	Grape, dried (= currants, raisins and sultanas)	PP	0.31	0.10	0.03	0.13	0.04	1.06	0.33	0.10	0.03	0.10	0.03
JF 0269	Grape juice	PP	0.18	0.10	0.02	0.10	0.02	0.41	0.07	0.10	0.02	NC	-
FI 0326	Avocado, raw	RAC	0.01	1.12	0.01	0.10	0.00	0.84	0.01	0.10	0.00	6.60	0.07
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.02	20.88	0.42	81.15	1.62	24.58	0.49	37.92	0.76	310.23	6.20
FI 0345	Mango, raw (incl canned mango, incl mango juice)	RAC	0.02	12.25	0.25	6.83	0.14	0.76	0.02	0.10	0.00	20.12	0.40
FI 0350	Papaya, raw	RAC	0	6.47	0.00	0.25	0.00	0.19	0.00	0.10	0.00	26.42	0.00
FI 0353	Pineapple, raw (incl canned pineapple, incl pineapple juice, incl dried pineapple)	RAC	0	8.51	0.00	6.27	0.00	6.89	0.00	0.18	0.00	24.94	0.00
VB 0040	Brassica vegetables, raw: head cabbages, flowerhead brassicas, Brussels sprouts & kohlrabi	RAC	0.015	4.84	0.07	3.79	0.06	58.72	0.88	0.10	0.00	NC	-
VC 0045	Fruiting vegetables, cucurbits, raw	RAC	0.02	5.96	0.12	9.74	0.19	51.82	1.04	13.61	0.27	0.10	0.00
VO 0440	Egg plants, raw (= aubergines)	RAC	0.02	1.31	0.03	8.26	0.17	3.95	0.08	0.10	0.00	NC	-
VO 0442	Okra, raw	RAC	0.02	6.23	0.12	0.10	0.00	NC	-	NC	-	NC	-
VO 0443	Pepino (Melon pear, Tree melon)	RAC	0.02	NC	-	NC	-	NC	-	NC	-	NC	-
VO 0444	Peppers, chili, raw	RAC	0.02	3.47	0.07	3.56	0.07	16.30	0.33	0.10	0.00	NC	-
-	Peppers, chili, dried	PP	0.2	0.58	0.12	1.27	0.25	1.21	0.24	0.12	0.02	NC	-
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.02	5.49	0.11	10.57	0.21	8.84	0.18	0.91	0.02	NC	-
VO 0447	Sweet corn on the cob, raw (incl frozen, incl	RAC	0.01	3.63	0.04	20.50	0.21	8.78	0.09	0.10	0.00	0.17	0.00

Annex 3

CLOTHIANIDIN (238) International Estimated Daily Intake (IEDI) ADI = 0 – 0.10 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day			Intake = daily intake: µg/person						
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
	canned) (i.e. kernels plus cob without husks)												
VO 0448	Tomato, raw (incl juice, incl paste, incl canned)	RAC	0.02	15.50	0.31	5.78	0.12	71.52	1.43	2.00	0.04	12.50	0.25
-	Gilo (scarlet egg plant)	RAC	0.02	NC	-	NC	-	NC	-	NC	-	NC	-
-	Goji berry	RAC	0.02	NC	-	NC	-	NC	-	NC	-	NC	-
-	Quorn	RAC	0.02	NC	-	NC	-	NC	-	NC	-	NC	-
-	Seaweed	RAC	0.08	NC	-	NC	-	NC	-	NC	-	NC	-
VL 0053	Leafy vegetables, raw	RAC	0.52	12.42	6.46	8.75	4.55	7.53	3.92	7.07	3.68	14.11	7.34
VP 0061	Beans, green, with pods, raw: beans except broad bean & soya bean (i.e. immature seeds + pods) (Phaseolus spp)	RAC	0.07	NC	-	NC	-	NC	-	NC	-	NC	-
VP 0062	Beans, green, without pods, raw: beans except broad bean & soya bean (i.e. immature seeds only) (Phaseolus spp..)	RAC	0.01	0.30	0.00	3.13	0.03	4.11	0.04	0.10	0.00	NC	-
VP 0063	Peas green, with pods, raw (i.e. immature seeds + pods) (Pisum spp)	RAC	0.01	NC	-	NC	-	NC	-	NC	-	NC	-
VP 0064	Peas, green, without pods, raw (i.e. immature seeds only) (Pisum spp)	RAC	0.01	0.21	0.00	0.10	0.00	5.51	0.06	0.10	0.00	NC	-
VP 0520	Bambara groundnut, green, without pods (i.e. immature seeds only) (Voandzeia spp)	RAC	0.01	NC	-	NC	-	NC	-	NC	-	NC	-
VP 0522	Broad bean, green, with pods (i.e. immature seeds + pods) (Vicia spp)	RAC	0.01	NC	-	NC	-	NC	-	NC	-	NC	-
VP 0523	Broad beans, green, without pods, raw (i.e. immature seeds only) (Vicia faba)	RAC	0.01	0.10	0.00	0.10	0.00	0.76	0.01	NC	-	NC	-
VP 0541	Soya bean, green, without pods, raw (i.e. immature seeds only) (Glycine max)	RAC	0.01	NC	-	NC	-	NC	-	NC	-	NC	-
VP 0542	Sword bean, green, with pods (i.e. immature seeds + pods) (Canavalia spp)	RAC	0.01	NC	-	NC	-	NC	-	NC	-	NC	-
VP 0553	Lentil, green, with pods (i.e. immature seeds + pods) (Lens spp)	RAC	0.01	NC	-	NC	-	NC	-	NC	-	NC	-
VD 0070	Pulses, raw (incl processed)	RAC	0.02	44.03	0.88	29.00	0.58	112.51	2.25	75.50	1.51	39.69	0.79
VR 0075	Root and tuber vegetables, raw (incl processed)	RAC	0.02	282.25	5.65	232.11	4.64	281.91	5.64	620.21	12.40	459.96	9.20
VS 0469	Witloof chicory (sprouts)	RAC	0.01	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00	NC	-
VS 0620	Artichoke globe	RAC	0.024	0.10	0.00	NC	-	0.10	0.00	0.10	0.00	NC	-
VS 0621	Asparagus	RAC	0.01	0.10	0.00	0.10	0.00	0.17	0.00	0.10	0.00	NC	-
VS 0622	Bamboo shoots	RAC	0.01	2.95	0.03	2.13	0.02	1.52	0.02	2.00	0.02	3.99	0.04
VS 0623	Cardoon	RAC	0.01	0.41	0.00	0.30	0.00	NC	-	0.28	0.00	0.56	0.01
VS 0624	Celery	RAC	0.01	3.66	0.04	2.65	0.03	4.84	0.05	2.47	0.02	4.94	0.05

Annex 3

CLOTHIANIDIN (238) International Estimated Daily Intake (IEDI) ADI = 0 – 0.10 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day			Intake = daily intake: µg/person						
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
VS 0626	Palm hearts	RAC	0.01	0.67	0.01	0.49	0.00	NC	-	0.46	0.00	0.91	0.01
VS 0627	Rhubarb	RAC	0.01	1.26	0.01	0.91	0.01	0.96	0.01	0.85	0.01	1.70	0.02
GC 0640	Barley, raw (incl malt extract, incl pot&pearled, incl flour & grits, incl beer, incl malt)	RAC	0.01	11.58	0.12	2.33	0.02	46.71	0.47	3.72	0.04	16.26	0.16
GC 0640	Barley, raw (incl malt extract, incl beer, incl malt, excl pot&pearled, excl flour & grits)	RAC	0.4	3.15	1.26	2.31	0.92	43.92	17.57	3.72	1.49	16.26	6.50
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl flour, incl oil, incl beer, incl germ, incl starch)	RAC	0.02	116.66	2.33	10.52	0.21	38.46	0.77	76.60	1.53	34.44	0.69
GC 0656	Popcorn (i.e. maize used for preparation of popcorn)	RAC	0.01	-	-	-	-	-	-	-	-	-	-
CM 0649 (GC 0649)	Rice, husked, dry (incl polished, incl flour, incl starch, incl oil, incl beverages)	REP	0.145	52.55	7.62	286.02	41.47	18.64	2.70	19.67	2.85	75.09	10.89
GC 0651	Sorghum, raw (incl flour, incl beer)	RAC	0.01	89.16	0.89	2.02	0.02	NC	-	35.38	0.35	NC	-
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, incl germ, incl wholemeal bread, incl white flour products, incl white bread)	RAC	0.02	57.20	1.14	110.47	2.21	272.62	5.45	25.82	0.52	132.04	2.64
GS 0659	Sugar cane, raw (incl sugar, incl molasses)	RAC	0.03	33.75	1.01	106.29	3.19	78.09	2.34	29.09	0.87	45.70	1.37
TN 0672	Pecan nuts, nutmeat	RAC	0.01	0.15	0.00	0.22	0.00	0.31	0.00	0.10	0.00	0.10	0.00
SO 0088	Oilseeds, raw (incl processed)	RAC	0.02	131.71	2.63	22.49	0.45	69.33	1.39	57.68	1.15	86.74	1.73
SB 0715	Cocoa beans, raw (incl roasted, incl powder, incl butter, incl paste, incl nes products)	RAC	0.02	0.11	0.00	0.89	0.02	6.28	0.13	0.17	0.00	2.31	0.05
SB 0716	Coffee beans raw (incl roasted, incl instant coffee, incl substitutes)	RAC	0.015	0.95	0.01	1.32	0.02	11.64	0.17	2.96	0.04	14.73	0.22
HH 0624	Celery leaves, raw	RAC	0.21	NC	-	NC	-	NC	-	NC	-	NC	-
HH 0738	Mints, raw	RAC	0.11	NC	-	NC	-	NC	-	NC	-	NC	-
DH 1100	Hops, dry	RAC	0.026	NC	-	NC	-	0.10	0.00	NC	-	NC	-
DT 1114	Tea, green or black, fermented and dried	RAC	0.12	0.53	0.06	5.25	0.63	0.63	0.08	0.56	0.07	0.82	0.10
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 80% as muscle	RAC	0.02	23.34	0.47	40.71	0.81	97.15	1.94	18.06	0.36	57.71	1.15
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.02	5.84	0.12	10.18	0.20	24.29	0.49	4.52	0.09	14.43	0.29
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.02	1.05	0.02	1.14	0.02	18.69	0.37	0.94	0.02	3.12	0.06
MO 0105	Edible offal (mammalian), raw	RAC	0.058	4.64	0.27	1.97	0.11	10.01	0.58	3.27	0.19	3.98	0.23
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.006	108.75	0.65	70.31	0.42	436.11	2.62	61.55	0.37	79.09	0.47
PM 0110	Poultry meat, raw (incl prepared) - 90% as	RAC	0.01	3.53	0.04	10.83	0.11	51.36	0.51	4.53	0.05	50.00	0.50

Annex 3

CLOTHIANIDIN (238) International Estimated Daily Intake (IEDI) ADI = 0 – 0.10 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day			Intake = daily intake: µg/person						
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
	muscle												
PM 0110	Poultry meat, raw (incl prepared) - 10% as fat	RAC	0.01	0.39	0.00	1.20	0.01	5.71	0.06	0.50	0.01	5.56	0.06
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.01	NC	-	NC	-	0.32	0.00	NC	-	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.018	0.10	0.00	0.70	0.01	0.97	0.02	0.10	0.00	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0.01	3.84	0.04	4.41	0.04	27.25	0.27	1.13	0.01	7.39	0.07
-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (µg/person)=				41.1		66.2		79.1		48.1		60.8
	Bodyweight per region (kg bw) =				60		60		60		60		60
	ADI (µg/person)=				6000		6000		6000		6000		6000
	%ADI=				0.7%		1.1%		1.3%		0.8%		1.0%
	Rounded %ADI=				1%		1%		1%		1%		1%

Annex 3

CYFLUMETOFEN (273) International Estimated Daily Intake (IEDI) ADI = 0 - 0.1000 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day			Intake as µg/person/day								
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.031	0.32	0.01	3.07	0.10	0.10	0.00	5.00	0.16	0.29	0.01	5.57	0.17
JF 0001	Citrus fruit, juice	PP	0.0022	1.30	0.00	2.37	0.01	0.22	0.00	13.88	0.03	0.75	0.00	2.63	0.01
FC 0001	Citrus fruit, raw	RAC	0.07	32.25	2.26	11.67	0.82	16.70	1.17	76.01	5.32	33.90	2.37	92.97	6.51
MO 0105	Edible offal (mammalian), raw	RAC	0.01	4.79	0.05	9.68	0.10	2.97	0.03	5.49	0.05	3.84	0.04	5.03	0.05
JF 0269	Grape juice	PP	0.048	0.14	0.01	0.29	0.01	0.10	0.00	0.30	0.01	0.24	0.01	0.10	0.00
-	Grape must	PP	0.071	0.33	0.02	0.13	0.01	0.10	0.01	0.10	0.01	0.10	0.01	0.10	0.01
-	Grape wine (incl vermouths)	PP	0.026	0.67	0.02	12.53	0.33	2.01	0.05	1.21	0.03	3.53	0.09	4.01	0.10
DF 0269	Grape, dried (= currants, raisins and sultanas)	PP	0.51	0.51	0.26	0.51	0.26	0.10	0.05	1.27	0.65	0.12	0.06	2.07	1.06
FB 0269	Grape, raw	RAC	0.22	12.68	2.79	9.12	2.01	0.10	0.02	16.88	3.71	3.70	0.81	54.42	11.97
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0	3.29	0.00	6.14	0.00	0.82	0.00	1.57	0.00	2.23	0.00	1.07	0.00
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)	RAC	0	31.20	0.00	72.44	0.00	20.88	0.00	47.98	0.00	33.08	0.00	36.25	0.00
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0	289.65	0.00	485.88	0.00	26.92	0.00	239.03	0.00	199.91	0.00	180.53	0.00
FP 0009	Pome fruit, raw (incl cider, excl apple juice)	RAC	0.14	19.35	2.71	34.06	4.77	17.87	2.50	25.74	3.60	7.69	1.08	56.85	7.96
FB 0275	Strawberry, raw	RAC	0.18	0.70	0.13	2.01	0.36	0.10	0.02	1.36	0.24	0.37	0.07	2.53	0.46
-	Tomato, canned (& peeled)	PP	0.021	0.20	0.00	0.31	0.01	0.10	0.00	1.11	0.02	0.11	0.00	1.50	0.03
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.027	0.29	0.01	0.29	0.01	0.10	0.00	0.38	0.01	0.10	0.00	0.14	0.00
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.042	2.34	0.10	1.33	0.06	1.57	0.07	4.24	0.18	0.34	0.01	2.83	0.12
VO 0448	Tomato, raw	RAC	0.07	41.73	2.92	75.65	5.30	10.66	0.75	82.87	5.80	24.75	1.73	200.93	14.07
TN 0085	Tree nuts, raw (incl processed)	RAC	0.01	4.06	0.04	3.27	0.03	7.01	0.07	13.93	0.14	14.01	0.14	9.36	0.09
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (µg/person)=				11.3		14.2		4.7		20.0		6.4		42.6
	Bodyweight per region (kg bw) =				60		60		60		60		60		60
	ADI (µg/person)=				6000		6000		6000		6000		6000		6000
	%ADI=				0.2%		0.2%		0.1%		0.3%		0.1%		0.7%
	Rounded %ADI=				0%		0%		0%		0%		0%		1%

Annex 3

CYFLUMETOFEN (273) International Estimated Daily Intake (IEDI) ADI = 0 - 0.1 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day											
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.031	14.88	0.46	11.98	0.37	0.15	0.00	9.98	0.31	30.32	0.94	3.47	0.11
JF 0001	Citrus fruit, juice	PP	0.0022	36.84	0.08	3.75	0.01	0.30	0.00	21.62	0.05	21.82	0.05	46.67	0.10
FC 0001	Citrus fruit, raw	RAC	0.07	38.66	2.71	54.93	3.85	26.36	1.85	51.46	3.60	51.06	3.57	466.36	32.65
MO 0105	Edible offal (mammalian), raw	RAC	0.01	15.17	0.15	5.19	0.05	6.30	0.06	6.78	0.07	3.32	0.03	3.17	0.03
JF 0269	Grape juice	PP	0.048	0.56	0.03	1.96	0.09	0.10	0.00	2.24	0.11	2.27	0.11	0.34	0.02
-	Grape must	PP	0.071	0.16	0.01	0.10	0.01	0.10	0.01	0.12	0.01	0.11	0.01	NC	-
-	Grape wine (incl vermouths)	PP	0.026	88.93	2.31	62.41	1.62	1.84	0.05	25.07	0.65	61.17	1.59	5.84	0.15
DF 0269	Grape, dried (= currants, raisins and sultanas)	PP	0.51	3.09	1.58	1.51	0.77	0.10	0.05	1.38	0.70	4.26	2.17	0.42	0.21
FB 0269	Grape, raw	RAC	0.22	6.33	1.39	11.22	2.47	5.21	1.15	9.38	2.06	4.55	1.00	0.78	0.17
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0	6.44	0.00	15.51	0.00	3.79	0.00	8.29	0.00	18.44	0.00	8.00	0.00
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)	RAC	0	140.03	0.00	150.89	0.00	79.32	0.00	111.24	0.00	120.30	0.00	51.27	0.00
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0	388.92	0.00	335.88	0.00	49.15	0.00	331.25	0.00	468.56	0.00	245.45	0.00
FP 0009	Pome fruit, raw (incl cider, excl apple juice)	RAC	0.14	51.09	7.15	65.40	9.16	42.71	5.98	45.29	6.34	62.51	8.75	7.74	1.08
FB 0275	Strawberry, raw	RAC	0.18	4.49	0.81	5.66	1.02	0.10	0.02	6.63	1.19	5.75	1.04	0.10	0.02
-	Tomato, canned (& peeled)	PP	0.021	7.57	0.16	2.66	0.06	0.30	0.01	0.97	0.02	7.31	0.15	0.41	0.01
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.027	0.80	0.02	0.10	0.00	0.10	0.00	0.61	0.02	0.40	0.01	0.10	0.00
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.042	4.96	0.21	3.20	0.13	0.15	0.01	1.61	0.07	6.88	0.29	0.52	0.02
VO 0448	Tomato, raw	RAC	0.07	32.13	2.25	51.27	3.59	34.92	2.44	73.37	5.14	15.15	1.06	8.88	0.62
TN 0085	Tree nuts, raw (incl processed)	RAC	0.01	8.52	0.09	8.94	0.09	15.09	0.15	9.60	0.10	14.57	0.15	26.26	0.26
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (µg/person)=				19.4		23.3		11.8		20.4		20.9		35.5
	Bodyweight per region (kg bw) =				60		60		55		60		60		60
	ADI (µg/person)=				6000		6000		5500		6000		6000		6000
	%ADI=				0.3%		0.4%		0.2%		0.3%		0.3%		0.6%
	Rounded %ADI=				0%		0%		0%		0%		0%		1%

Annex 3

CYFLUMETOFEN (273) International Estimated Daily Intake (IEDI) ADI = 0 - 0.1 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day									
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
				Intake = daily intake: µg/person									
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.031	0.10	0.00	0.10	0.00	7.19	0.22	0.10	0.00	NC	-
JF 0001	Citrus fruit, juice	PP	0.0022	0.11	0.00	0.29	0.00	13.55	0.03	0.14	0.00	0.33	0.00
FC 0001	Citrus fruit, raw	RAC	0.07	20.93	1.47	2.35	0.16	30.71	2.15	0.15	0.01	4.45	0.31
MO 0105	Edible offal (mammalian), raw	RAC	0.01	4.64	0.05	1.97	0.02	10.01	0.10	3.27	0.03	3.98	0.04
JF 0269	Grape juice	PP	0.048	0.10	0.00	0.10	0.00	0.41	0.02	0.10	0.00	NC	-
-	Grape must	PP	0.071	0.10	0.01	0.10	0.01	0.11	0.01	0.10	0.01	0.19	0.01
-	Grape wine (incl vermouths)	PP	0.026	0.31	0.01	0.23	0.01	60.43	1.57	0.52	0.01	31.91	0.83
DF 0269	Grape, dried (= currants, raisins and sultanas)	PP	0.51	0.10	0.05	0.13	0.07	1.06	0.54	0.10	0.05	0.10	0.05
FB 0269	Grape, raw	RAC	0.22	0.14	0.03	0.36	0.08	15.22	3.35	0.10	0.02	0.10	0.02
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0	1.05	0.00	1.14	0.00	18.69	0.00	0.94	0.00	3.12	0.00
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)	RAC	0	29.18	0.00	50.89	0.00	121.44	0.00	22.58	0.00	72.14	0.00
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0	108.75	0.00	70.31	0.00	436.11	0.00	61.55	0.00	79.09	0.00
FP 0009	Pome fruit, raw (incl cider, excl apple juice)	RAC	0.14	68.85	9.64	10.93	1.53	70.82	9.91	189.78	26.57	19.56	2.74
FB 0275	Strawberry, raw	RAC	0.18	0.10	0.02	0.10	0.02	3.35	0.60	0.10	0.02	0.10	0.02
-	Tomato, canned (& peeled)	PP	0.021	0.10	0.00	0.10	0.00	2.42	0.05	0.10	0.00	NC	-
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.027	0.10	0.00	0.10	0.00	0.42	0.01	0.10	0.00	0.10	0.00
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.042	0.58	0.02	0.22	0.01	2.21	0.09	0.24	0.01	3.10	0.13
VO 0448	Tomato, raw	RAC	0.07	12.99	0.91	4.79	0.34	58.40	4.09	0.92	0.06	0.10	0.01
TN 0085	Tree nuts, raw (incl processed)	RAC	0.01	4.39	0.04	135.53	1.36	6.11	0.06	0.72	0.01	317.74	3.18
-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (µg/person)=				12.3		3.6		22.8		26.8		7.3
	Bodyweight per region (kg bw) =				60		60		60		60		60
	ADI (µg/person)=				6000		6000		6000		6000		6000
	%ADI=				0.2%		0.1%		0.4%		0.4%		0.1%
	Rounded %ADI=				0%		0%		0%		0%		0%

Annex 3

2,6-DICHLOROBENZAMIDE forDICHLOBENIL (230) International Estimated Daily Intake (IEDI) ADI = 0 - 0.05 mg/kg bw

			STMR	Diets as g/person/day			Intake as µg/person/day								
Codex Code	Commodity description	Expr as	mg/kg	G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
FB 2005	Caneberries, raw	RAC	0.034	0.42	0.01	1.05	0.04	0.10	0.00	0.10	0.00	0.10	0.00	1.24	0.04
FB 0269	Grape, raw (incl must, incl wine, excl dried, excl juice)	RAC	0.01	13.94	0.14	26.46	0.26	2.79	0.03	18.58	0.19	8.54	0.09	59.95	0.60
DF 0269	Grape, dried (= currants, raisins and sultanas)	PP	0.028	0.51	0.01	0.51	0.01	0.10	0.00	1.27	0.04	0.12	0.00	2.07	0.06
JF 0269	Grape juice	PP	0.014	0.14	0.00	0.29	0.00	0.10	0.00	0.30	0.00	0.24	0.00	0.10	0.00
-	Onions, mature bulbs, dry	RAC	0.01	29.36	0.29	37.50	0.38	3.56	0.04	34.78	0.35	18.81	0.19	43.38	0.43
-	Onions, green, raw	RAC	0.01	2.45	0.02	1.49	0.01	1.02	0.01	2.60	0.03	0.60	0.01	2.03	0.02
VB 0040	Brassica vegetables, raw: head cabbages, flowerhead brassicas, Brussels sprouts & kohlrabi	RAC	0.01	6.41	0.06	35.79	0.36	0.71	0.01	9.81	0.10	12.07	0.12	16.58	0.17
VC 0045	Fruiting vegetables, cucurbits, raw	RAC	0.01	53.14	0.53	86.21	0.86	6.28	0.06	92.76	0.93	15.64	0.16	155.30	1.55
VO 0050	Fruiting vegetables other than cucurbits, raw, (incl processed commodities), excl sweet corn commodities, excl mushroom commodities	RAC	0.01	70.72	0.71	103.53	1.04	37.61	0.38	129.38	1.29	61.87	0.62	265.39	2.65
VL 0053	Leafy vegetables, raw	RAC	0.07	8.47	0.59	22.36	1.57	7.74	0.54	25.51	1.79	45.77	3.20	21.22	1.49
VD 0070	Pulses, raw (incl processed)	RAC	0.01	85.59	0.86	64.02	0.64	34.15	0.34	88.02	0.88	89.38	0.89	96.88	0.97
VS 0624	Celery	RAC	0.01	2.14	0.02	3.79	0.04	2.35	0.02	5.69	0.06	0.10	0.00	2.75	0.03
GC 0080	Cereal grains, raw, (incl processed)	RAC	0.01	484.29	4.84	464.63	4.65	262.36	2.62	486.81	4.87	469.62	4.70	614.04	6.14
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)	RAC	0.01	31.20	0.31	72.44	0.72	20.88	0.21	47.98	0.48	33.08	0.33	36.25	0.36
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.01	3.29	0.03	6.14	0.06	0.82	0.01	1.57	0.02	2.23	0.02	1.07	0.01
MO 0105	Edible offal (mammalian), raw	RAC	0.01	4.79	0.05	9.68	0.10	2.97	0.03	5.49	0.05	3.84	0.04	5.03	0.05
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.01	289.65	2.90	485.88	4.86	26.92	0.27	239.03	2.39	199.91	2.00	180.53	1.81
PM 0110	Poultry meat, raw (incl prepared)	RAC	0.01	14.63	0.15	29.76	0.30	8.04	0.08	129.68	1.30	25.04	0.25	35.66	0.36
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.01	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.10	0.00	0.10	0.00
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.014	0.12	0.00	0.12	0.00	0.11	0.00	5.37	0.08	0.24	0.00	0.10	0.00
PE 0112	Eggs, raw, (incl dried)	RAC	0.01	7.84	0.08	23.08	0.23	2.88	0.03	14.89	0.15	9.81	0.10	14.83	0.15
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (µg/person)=				11.6		16.1		4.7		15.0		12.7		16.9
	Bodyweight per region (kg bw) =				60		60		60		60		60		60
	ADI (µg/person)=				3000		3000		3000		3000		3000		3000
	%ADI=				0.4%		0.5%		0.2%		0.5%		0.4%		0.6%
	Rounded %ADI=				0%		1%		0%		0%		0%		1%

Annex 3

2,6-DICHLOROBENZAMIDE forDICHLOBENIL (230) International Estimated Daily Intake (IEDI) ADI = 0 - 0.05 mg/kg bw

			STMR	Diets as g/person/day			Intake as µg/person/day								
Codex Code	Commodity description	Expr as	mg/kg	G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
FB 2005	Caneberries, raw	RAC	0.034	0.56	0.02	1.43	0.05	0.14	0.00	1.23	0.04	1.14	0.04	0.10	0.00
FB 0269	Grape, raw (incl must, incl wine, excl dried, excl juice)	RAC	0.01	128.64	1.29	97.04	0.97	7.74	0.08	43.94	0.44	88.68	0.89	8.80	0.09
DF 0269	Grape, dried (= currants, raisins and sultanas)	PP	0.028	3.09	0.09	1.51	0.04	0.10	0.00	1.38	0.04	4.26	0.12	0.42	0.01
JF 0269	Grape juice	PP	0.014	0.56	0.01	1.96	0.03	0.10	0.00	2.24	0.03	2.27	0.03	0.34	0.00
-	Onions, mature bulbs, dry	RAC	0.01	19.69	0.20	29.83	0.30	24.64	0.25	31.35	0.31	9.72	0.10	12.59	0.13
-	Onions, green, raw	RAC	0.01	1.55	0.02	0.74	0.01	1.05	0.01	3.74	0.04	0.94	0.01	6.45	0.06
VB 0040	Brassica vegetables, raw: head cabbages, flowerhead brassicas, Brussels sprouts & kohlrabi	RAC	0.01	20.71	0.21	39.81	0.40	16.70	0.17	28.49	0.28	18.12	0.18	15.03	0.15
VC 0045	Fruiting vegetables, cucurbits, raw	RAC	0.01	27.81	0.28	41.93	0.42	123.30	1.23	49.47	0.49	15.95	0.16	35.99	0.36
VO 0050	Fruiting vegetables other than cucurbits, raw, (incl processed commodities), excl sweet corn commodities, excl mushroom commodities	RAC	0.01	72.92	0.73	86.99	0.87	79.04	0.79	97.13	0.97	65.96	0.66	17.98	0.18
VL 0053	Leafy vegetables, raw	RAC	0.07	18.83	1.32	21.85	1.53	121.23	8.49	43.09	3.02	18.18	1.27	18.32	1.28
VD 0070	Pulses, raw (incl processed)	RAC	0.01	112.88	1.13	123.05	1.23	47.15	0.47	204.64	2.05	227.37	2.27	109.11	1.09
VS 0624	Celery	RAC	0.01	7.68	0.08	2.85	0.03	NC	-	3.34	0.03	16.83	0.17	4.04	0.04
GC 0080	Cereal grains, raw, (incl processed)	RAC	0.01	345.63	3.46	386.16	3.86	514.33	5.14	402.72	4.03	295.30	2.95	359.97	3.60
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)	RAC	0.01	140.03	1.40	150.89	1.51	79.32	0.79	111.24	1.11	120.30	1.20	51.27	0.51
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.01	6.44	0.06	15.51	0.16	3.79	0.04	8.29	0.08	18.44	0.18	8.00	0.08
MO 0105	Edible offal (mammalian), raw	RAC	0.01	15.17	0.15	5.19	0.05	6.30	0.06	6.78	0.07	3.32	0.03	3.17	0.03
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.01	388.92	3.89	335.88	3.36	49.15	0.49	331.25	3.31	468.56	4.69	245.45	2.45
PM 0110	Poultry meat, raw (incl prepared)	RAC	0.01	73.76	0.74	53.86	0.54	23.98	0.24	87.12	0.87	53.38	0.53	84.45	0.84
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.01	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.71	0.01	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.014	0.33	0.00	0.72	0.01	0.27	0.00	0.35	0.00	0.80	0.01	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0.01	25.84	0.26	29.53	0.30	28.05	0.28	33.19	0.33	36.44	0.36	8.89	0.09
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (µg/person)=				15.3		15.7		18.5		17.6		15.9		11.0
	Bodyweight per region (kg bw) =				60		60		55		60		60		60
	ADI (µg/person)=				3000		3000		2750		3000		3000		3000
	%ADI=				0.5%		0.5%		0.7%		0.6%		0.5%		0.4%
	Rounded %ADI=				1%		1%		1%		1%		1%		0%

Annex 3

2,6-DICHLOROBENZAMIDE forDICHLOBENIL (230) International Estimated Daily Intake (IEDI) ADI = 0 - 0.05 mg/kg bw

			STMR	Diets: g/person/day			Intake = daily intake: µg/person						
Codex Code	Commodity description	Expr as	mg/kg	G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
FB 2005	Caneberries, raw	RAC	0.034	0.10	0.00	7.30	0.25	2.29	0.08	0.10	0.00	NC	-
FB 0269	Grape, raw (incl must, incl wine, excl dried, excl juice)	RAC	0.01	0.57	0.01	0.69	0.01	98.34	0.98	0.73	0.01	44.12	0.44
DF 0269	Grape, dried (= currants, raisins and sultanas)	PP	0.028	0.10	0.00	0.13	0.00	1.06	0.03	0.10	0.00	0.10	0.00
JF 0269	Grape juice	PP	0.014	0.10	0.00	0.10	0.00	0.41	0.01	0.10	0.00	NC	-
-	Onions, mature bulbs, dry	RAC	0.01	9.01	0.09	20.24	0.20	30.90	0.31	9.61	0.10	2.11	0.02
-	Onions, green, raw	RAC	0.01	1.43	0.01	0.10	0.00	0.20	0.00	NC	-	6.30	0.06
VB 0040	Brassica vegetables, raw: head cabbages, flowerhead brassicas, Brussels sprouts & kohlrabi	RAC	0.01	4.84	0.05	3.79	0.04	58.72	0.59	0.10	0.00	NC	-
VC 0045	Fruiting vegetables, cucurbits, raw	RAC	0.01	5.96	0.06	9.74	0.10	51.82	0.52	13.61	0.14	0.10	0.00
VO 0050	Fruiting vegetables other than cucurbits, raw, (incl processed commodities), excl sweet corn commodities, excl mushroom commodities	RAC	0.01	36.09	0.36	37.19	0.37	109.09	1.09	3.78	0.04	12.50	0.13
VL 0053	Leafy vegetables, raw	RAC	0.07	12.42	0.87	8.75	0.61	7.53	0.53	7.07	0.49	14.11	0.99
VD 0070	Pulses, raw (incl processed)	RAC	0.01	44.03	0.44	29.00	0.29	112.51	1.13	75.50	0.76	39.69	0.40
VS 0624	Celery	RAC	0.01	3.66	0.04	2.65	0.03	4.84	0.05	2.47	0.02	4.94	0.05
GC 0080	Cereal grains, raw, (incl processed)	RAC	0.01	407.04	4.07	417.04	4.17	402.79	4.03	195.30	1.95	263.26	2.63
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)	RAC	0.01	29.18	0.29	50.89	0.51	121.44	1.21	22.58	0.23	72.14	0.72
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.01	1.05	0.01	1.14	0.01	18.69	0.19	0.94	0.01	3.12	0.03
MO 0105	Edible offal (mammalian), raw	RAC	0.01	4.64	0.05	1.97	0.02	10.01	0.10	3.27	0.03	3.98	0.04
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.01	108.75	1.09	70.31	0.70	436.11	4.36	61.55	0.62	79.09	0.79
PM 0110	Poultry meat, raw (incl prepared)	RAC	0.01	3.92	0.04	12.03	0.12	57.07	0.57	5.03	0.05	55.56	0.56
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.01	NC	-	NC	-	0.32	0.00	NC	-	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.014	0.10	0.00	0.70	0.01	0.97	0.01	0.10	0.00	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0.01	3.84	0.04	4.41	0.04	27.25	0.27	1.13	0.01	7.39	0.07
-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (µg/person)=				7.5		7.5		16.1		4.5		6.9
	Bodyweight per region (kg bw) =				60		60		60		60		60
	ADI (µg/person)=				3000		3000		3000		3000		3000
	%ADI=				0.3%		0.2%		0.5%		0.1%		0.2%
	Rounded %ADI=				0%		0%		1%		0%		0%

Annex 3

DIMETHOMOPRH (225) International Estimated Daily Intake (IEDI) ADI = 0 - 0.2 mg/kg bw

			STMR	Diets as g/person/day			Intake as µg/person/day								
Codex Code	Commodity description	Expr as	mg/kg	G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
FB 0269	Grape, raw (incl must, incl juice, excl dried, excl wine)	RAC	0.65	13.19	8.57	9.61	6.25	0.10	0.07	17,28	11,23	4,00	2,60	54,50	35,43
DF 0269	Grape, dried (= currants, raisins and sultanas)	PP	1.17	0.51	0.60	0.51	0.60	0.10	0.12	1.27	1.49	0.12	0.14	2.07	2.42
-	Grape wine (incl vermouths)	PP	0.19	0.67	0.13	12.53	2.38	2.01	0.38	1.21	0.23	3.53	0.67	4.01	0.76
FB 0275	Strawberry, raw	RAC	0.02	0.70	0.01	2.01	0.04	0.10	0.00	1.36	0.03	0.37	0.01	2.53	0.05
FI 0353	Pineapple, raw (incl canned pineapple, incl pineapple juice, incl dried pineapple)	RAC	0	0.61	0.00	1.56	0.00	7.89	0.00	9.36	0.00	8.76	0.00	1.30	0.00
VA 0381	Garlic, raw	RAC	0.17	2.29	0.39	5.78	0.98	0.11	0.02	3.69	0.63	1.65	0.28	3.91	0.66
VA 0384	Leek, raw	RAC	0.08	0.18	0.01	1.59	0.13	0.10	0.01	0.28	0.02	0.10	0.01	3.21	0.26
-	Onions, mature bulbs, dry	RAC	0.17	29.36	4.99	37.50	6.38	3.56	0.61	34.78	5.91	18.81	3.20	43.38	7.37
-	Onions, green, raw	RAC	2.1	2.45	5.15	1.49	3.13	1.02	2.14	2.60	5.46	0.60	1.26	2.03	4.26
VB 0041	Cabbages, head, raw	RAC	1.1	2.73	3.00	27.92	30.71	0.55	0.61	4.47	4.92	4.27	4.70	10.25	11.28
VB 0400	Broccoli, raw	RAC	1.3	0.88	1.14	0.17	0.22	0.10	0.13	1.25	1.63	3.00	3.90	1.09	1.42
VB 0405	Kohlrabi, raw	RAC	0.02	0.10	0.00	0.89	0.02	0.10	0.00	0.14	0.00	NC	-	0.33	0.01
VO 0440	Egg plants, raw (= aubergines)	RAC	0.13	5.58	0.73	4.31	0.56	0.89	0.12	9.31	1.21	13.64	1.77	20.12	2.62
VO 0442	Okra, raw	RAC	0.13	1.97	0.26	NC	-	3.68	0.48	3.24	0.42	5.72	0.74	1.57	0.20
VO 0443	Pepino (Melon pear, Tree melon)	RAC	0.13	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VO 0444	Peppers, chili, raw (incl dried)	RAC	0.13	6.93	0.90	10.97	1.43	8.83	1.15	9.13	1.19	6.65	0.86	20.01	2.60
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.13	4.49	0.58	6.44	0.84	7.21	0.94	5.68	0.74	9.52	1.24	8.92	1.16
VO 0448	Tomato, raw (incl canned, excl juice, excl paste)	RAC	0.13	42.04	5.47	76.13	9.90	10.69	1.39	84.59	11.00	24.92	3.24	203.27	26.43
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	1.56	2.34	3.65	1.33	2.07	1.57	2.45	4.24	6.61	0.34	0.53	2.83	4.41
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.09	0.29	0.03	0.29	0.03	0.10	0.01	0.38	0.03	0.10	0.01	0.14	0.01
VL 0470	Lambs lettuce, raw (i.e. corn salad)	RAC	3.4	0.64	2.18	1.13	3.84	0.70	2.38	1.70	5.78	NC	-	0.82	2.79
VL 0482	Lettuce, head, raw	RAC	3.6	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VL 0483	Lettuce, leaf, raw	RAC	5.2	0.53	2.76	0.36	1.87	0.16	0.83	6.21	32.29	1.90	9.88	6.05	31.46
VL 0502	Spinach, raw	RAC	8.3	0.74	6.14	0.22	1.83	0.10	0.83	0.91	7.55	0.10	0.83	2.92	24.24
VL 0505	Taro leaves, raw	RAC	1.6	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VP 0064	Peas, green, without pods, raw (i.e. immature seeds only) (Pisum spp)	RAC	0.01	1.97	0.02	0.51	0.01	0.10	0.00	0.79	0.01	3.68	0.04	3.80	0.04
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.02	59.74	1.19	316.14	6.32	9.78	0.20	60.26	1.21	54.12	1.08	119.82	2.40
VS 0620	Artichoke globe	RAC	0.25	0.69	0.17	0.10	0.03	0.10	0.03	0.32	0.08	0.26	0.07	1.21	0.30
VS 0624	Celery	RAC	2.9	2.14	6.21	3.79	10.99	2.35	6.82	5.69	16.50	0.10	0.29	2.75	7.98
DH 1100	Hops, dry	RAC	26	0.10	2.60	0.10	2.60	0.10	2.60	0.10	2.60	NC	-	0.10	2.60
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (µg/person)=				56.9		93.1		24.3		118.8		37.3		173.1

Annex 3

DIMETHOMOPRH (225) International Estimated Daily Intake (IEDI) ADI = 0 - 0.2 mg/kg bw

			STMR	Diets as g/person/day			Intake as µg/person/day								
Codex Code	Commodity description	Expr as	mg/kg	G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
	Bodyweight per region (kg bw) =				60		60		60		60		60		60
	ADI (µg/person)=				12000		12000		12000		12000		12000		12000
	%ADI=				0.5%		0.8%		0.2%		1.0%		0.3%		1.4%
	Rounded %ADI=				0%		1%		0%		1%		0%		1%

DIMETHOMOPRH (225) International Estimated Daily Intake (IEDI) ADI = 0 - 0.2 mg/kg bw

			STMR	Diets as g/person/day			Intake as µg/person/day								
Codex Code	Commodity description	Expr as	mg/kg	G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
FB 0269	Grape, raw (incl must, incl juice, excl dried, excl wine)	RAC	0.65	7.18	4.67	13.73	8.92	5.24	3.41	12.27	7.98	7.46	4.85	1.21	0.79
DF 0269	Grape, dried (= currants, raisins and sultanas)	PP	1,17	3,09	3,62	1,51	1,77	0,10	0,12	1,38	1,61	4,26	4,98	0,42	0,49
-	Grape wine (incl vermouths)	PP	0,19	88,93	16,90	62,41	11,86	1,84	0,35	25,07	4,76	61,17	11,62	5,84	1,11
FB 0275	Strawberry, raw	RAC	0,02	4,49	0,09	5,66	0,11	0,10	0,00	6,63	0,13	5,75	0,12	0,10	0,00
FI 0353	Pineapple, raw (incl canned pineapple, incl pineapple juice, incl dried pineapple)	RAC	0	13,13	0,00	11,13	0,00	6,94	0,00	14,36	0,00	36,74	0,00	18,81	0,00
VA 0381	Garlic, raw	RAC	0,17	0,98	0,17	1,49	0,25	12,88	2,19	3,74	0,64	2,05	0,35	1,14	0,19
VA 0384	Leek, raw	RAC	0,08	4,01	0,32	4,41	0,35	0,72	0,06	0,54	0,04	16,41	1,31	0,10	0,01
-	Onions, mature bulbs, dry	RAC	0,17	19,69	3,35	29,83	5,07	24,64	4,19	31,35	5,33	9,72	1,65	12,59	2,14
-	Onions, green, raw	RAC	2,1	1,55	3,26	0,74	1,55	1,05	2,21	3,74	7,85	0,94	1,97	6,45	13,55
VB 0041	Cabbages, head, raw	RAC	1,1	8,97	9,87	27,12	29,83	1,44	1,58	24,96	27,46	4,55	5,01	11,23	12,35
VB 0400	Broccoli, raw	RAC	1,3	4,24	5,51	1,76	2,29	NC	-	0,51	0,66	3,79	4,93	0,26	0,34
VB 0405	Kohlrabi, raw	RAC	0,02	NC	-	3,25	0,07	NC	-	NC	-	0,10	0,00	0,36	0,01
VO 0440	Egg plants, raw (= aubergines)	RAC	0,13	1,01	0,13	1,69	0,22	21,37	2,78	3,00	0,39	1,40	0,18	NC	-
VO 0442	Okra, raw	RAC	0,13	NC	-	NC	-	0,10	0,01	0,17	0,02	NC	-	0,72	0,09
VO 0443	Pepino (Melon pear, Tree melon)	RAC	0,13	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VO 0444	Peppers, chili, raw (incl dried)	RAC	0,13	6,36	0,83	15,46	2,01	10,74	1,40	7,28	0,95	8,21	1,07	3,58	0,47
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0,13	0,82	0,11	1,53	0,20	10,85	1,41	4,59	0,60	1,84	0,24	2,00	0,26
VO 0448	Tomato, raw (incl canned, excl juice, excl paste)	RAC	0,13	43,88	5,70	55,41	7,20	35,38	4,60	74,88	9,73	26,50	3,45	9,51	1,24
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	1,56	4,96	7,74	3,20	4,99	0,15	0,23	1,61	2,51	6,88	10,73	0,52	0,81
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0,09	0,80	0,07	0,10	0,01	0,10	0,01	0,61	0,05	0,40	0,04	0,10	0,01
VL 0470	Lambs lettuce, raw (i.e. corn salad)	RAC	3,4	1,41	4,79	4,28	14,55	NC	-	0,10	0,34	5,11	17,37	1,20	4,08
VL 0482	Lettuce, head, raw	RAC	3,6	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VL 0483	Lettuce, leaf, raw	RAC	5,2	14,50	75,40	11,76	61,15	13,14	68,33	19,50	101,40	4,81	25,01	2,23	11,60
VL 0502	Spinach, raw	RAC	8,3	2,20	18,26	1,76	14,61	13,38	111,05	2,94	24,40	5,53	45,90	0,10	0,83
VL 0505	Taro leaves, raw	RAC	1,6	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VP 0064	Peas, green, without pods, raw (i.e. immature	RAC	0,01	10,72	0,11	1,99	0,02	2,72	0,03	4,26	0,04	4,23	0,04	NC	-

Annex 3

DIMETHOMOPRH (225) International Estimated Daily Intake (IEDI) ADI = 0 - 0.2 mg/kg bw

			STMR	Diets as g/person/day			Intake as µg/person/day								
Codex Code	Commodity description	Expr as	mg/kg	G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
	seeds only) (Pisum spp)														
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0,02	225,03	4,50	234,24	4,68	71,48	1,43	177,55	3,55	234,55	4,69	37,71	0,75
VS 0620	Artichoke globe	RAC	0,25	0,98	0,25	3,65	0,91	0,10	0,03	1,67	0,42	0,26	0,07	NC	-
VS 0624	Celery	RAC	2,9	7,68	22,27	2,85	8,27	NC	-	3,34	9,69	16,83	48,81	4,04	11,72
DH 1100	Hops, dry	RAC	26	NC	-	NC	-	0,10	2,60	0,10	2,60	NC	-	NC	-
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (µg/person)=				187,9		180,9		208,0		213,2		194,4		62,8
	Bodyweight per region (kg bw) =				60		60		55		60		60		60
	ADI (µg/person)=				12000		12000		11000		12000		12000		12000
	%ADI=				1,6%		1,5%		1,9%		1,8%		1,6%		0,5%
	Rounded %ADI=				2%		2%		2%		2%		2%		1%

DIMETHOMOPRH (225) International Estimated Daily Intake (IEDI) ADI = 0 - 0.2 mg/kg bw

			STMR	Diets: g/person/day			Intake = daily intake: µg/person						
Codex Code	Commodity description	Expr as	mg/kg	G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
FB 0269	Grape, raw (incl must, incl juice, excl dried, excl wine)	RAC	0,65	0,15	0,10	0,38	0,25	15,84	10,30	0,10	0,07	0,28	0,18
DF 0269	Grape, dried (= currants, raisins and sultanas)	PP	1,17	0,10	0,12	0,13	0,15	1,06	1,24	0,10	0,12	0,10	0,12
-	Grape wine (incl vermouths)	PP	0,19	0,31	0,06	0,23	0,04	60,43	11,48	0,52	0,10	31,91	6,06
FB 0275	Strawberry, raw	RAC	0,02	0,10	0,00	0,10	0,00	3,35	0,07	0,10	0,00	0,10	0,00
FI 0353	Pineapple, raw (incl canned pineapple, incl pineapple juice, incl dried pineapple)	RAC	0	8,51	0,00	6,27	0,00	6,89	0,00	0,18	0,00	24,94	0,00
VA 0381	Garlic, raw	RAC	0,17	0,82	0,14	2,06	0,35	3,79	0,64	0,10	0,02	0,29	0,05
VA 0384	Leek, raw	RAC	0,08	0,10	0,01	1,44	0,12	1,22	0,10	0,10	0,01	NC	-
-	Onions, mature bulbs, dry	RAC	0,17	9,01	1,53	20,24	3,44	30,90	5,25	9,61	1,63	2,11	0,36
-	Onions, green, raw	RAC	2,1	1,43	3,00	0,10	0,21	0,20	0,42	NC	-	6,30	13,23
VB 0041	Cabbages, head, raw	RAC	1,1	3,82	4,20	2,99	3,29	49,16	54,08	0,10	0,11	NC	-
VB 0400	Broccoli, raw	RAC	1,3	0,10	0,13	0,10	0,13	2,13	2,77	0,10	0,13	NC	-
VB 0405	Kohlrabi, raw	RAC	0,02	0,12	0,00	0,10	0,00	1,81	0,04	0,10	0,00	NC	-
VO 0440	Egg plants, raw (= aubergines)	RAC	0,13	1,31	0,17	8,26	1,07	3,95	0,51	0,10	0,01	NC	-
VO 0442	Okra, raw	RAC	0,13	6,23	0,81	0,10	0,01	NC	-	NC	-	NC	-
VO 0443	Pepino (Melon pear, Tree melon)	RAC	0,13	NC	-	NC	-	NC	-	NC	-	NC	-
VO 0444	Peppers, chili, raw (incl dried)	RAC	0,13	7,55	0,98	12,48	1,62	24,78	3,22	0,87	0,11	NC	-
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0,13	5,49	0,71	10,57	1,37	8,84	1,15	0,91	0,12	NC	-
VO 0448	Tomato, raw (incl canned, excl juice, excl paste)	RAC	0,13	13,10	1,70	4,90	0,64	62,16	8,08	1,04	0,14	0,10	0,01

Annex 3

DIMETHOMOPRH (225) International Estimated Daily Intake (IEDI) ADI = 0 - 0.2 mg/kg bw

			STMR	Diets: g/person/day			Intake = daily intake: µg/person						
Codex Code	Commodity description	Expr as	mg/kg	G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	1,56	0,58	0,90	0,22	0,34	2,21	3,45	0,24	0,37	3,10	4,84
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0,09	0,10	0,01	0,10	0,01	0,42	0,04	0,10	0,01	0,10	0,01
VL 0470	Lambs lettuce, raw (i.e. corn salad)	RAC	3,4	1,09	3,71	0,79	2,69	NC	-	0,74	2,52	1,47	5,00
VL 0482	Lettuce, head, raw	RAC	3,6	NC	-	NC	-	NC	-	NC	-	NC	-
VL 0483	Lettuce, leaf, raw	RAC	5,2	0,29	1,51	0,10	0,52	6,71	34,89	0,10	0,52	NC	-
VL 0502	Spinach, raw	RAC	8,3	0,17	1,41	0,10	0,83	0,81	6,72	0,10	0,83	NC	-
VL 0505	Taro leaves, raw	RAC	1,6	NC	-	NC	-	NC	-	NC	-	NC	-
VP 0064	Peas, green, without pods, raw (i.e. immature seeds only) (Pisum spp)	RAC	0,01	0,21	0,00	0,10	0,00	5,51	0,06	0,10	0,00	NC	-
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0,02	23,96	0,48	13,56	0,27	213,41	4,27	104,35	2,09	8,56	0,17
VS 0620	Artichoke globe	RAC	0,25	0,10	0,03	NC	-	0,10	0,03	0,10	0,03	NC	-
VS 0624	Celery	RAC	2,9	3,66	10,61	2,65	7,69	4,84	14,04	2,47	7,16	4,94	14,33
DH 1100	Hops, dry	RAC	26	NC	-	NC	-	0,10	2,60	NC	-	NC	-
-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (µg/person)=				32,3		25,0		165,4		16,1		44,4
	Bodyweight per region (kg bw) =				60		60		60		60		60
	ADI (µg/person)=				12000		12000		12000		12000		12000
	%ADI=				0,3%		0,2%		1,4%		0,1%		0,4%
	Rounded %ADI=				0%		0%		1%		0%		0%

Annex 3

DITHIOCARBAMATES (105)/MANCOZEB (050) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0300 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day G01 diet	Intake as µg/person/day G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
VO 0444	Peppers, chili, raw	RAC	1.4	3.99	5.59	7.30	10.22	2.93	4.10	5.62	7.87	NC	-	17.44	24.42
-	Peppers, chili, dried	PP	9.8	0.42	4.12	0.53	5.19	0.84	8.23	0.50	4.90	0.95	9.31	0.37	3.63
HS 0790	Pepper (black, white)	RAC	0.18	0.10	0.02	0.13	0.02	0.10	0.02	0.36	0.06	0.17	0.03	0.13	0.02
-	Anise seeds, star anise seeds, caraway seeds, coriander seeds, cumin seeds, fennel seeds, juniper berries	RAC	6.4	0.48	3.07	0.10	0.64	0.10	0.64	1.12	7.17	0.25	1.60	0.27	1.73
-	Nutmeg, mace, cardamom, grains of paradise	RAC	0.18	0.10	0.02	0.10	0.02	0.10	0.02	0.92	0.17	0.10	0.02	0.10	0.02
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (µg/person)=				12.8		16.1		13.0		20.2		11.0		29.8
	Bodyweight per region (kg bw) =				60		60		60		60		60		60
	ADI (µg/person)=				1800		1800		1800		1800		1800		1800
	%ADI=				0.7%		0.9%		0.7%		1.1%		0.6%		1.7%
	Rounded %ADI=				1%		1%		1%		1%		1%		2%

DITHIOCARBAMATES (105)/MANCOZEB (050) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0300 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day G07 diet	Intake as µg/person/day G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
VO 0444	Peppers, chili, raw	RAC	1.4	5.57	7.80	14.00	19.60	8.25	11.55	5.77	8.08	6.44	9.02	2.53	3.54
-	Peppers, chili, dried	PP	9.8	0.11	1.08	0.21	2.06	0.36	3.53	0.21	2.06	0.25	2.45	0.15	1.47
HS 0790	Pepper (black, white)	RAC	0.18	0.31	0.06	0.41	0.07	0.12	0.02	0.34	0.06	0.70	0.13	0.89	0.16
-	Anise seeds, star anise seeds, caraway seeds, coriander seeds, cumin seeds, fennel seeds, juniper berries	RAC	6.4	0.22	1.41	0.21	1.34	0.10	0.64	0.14	0.90	0.36	2.30	0.10	0.64
-	Nutmeg, mace, cardamom, grains of paradise	RAC	0.18	0.10	0.02	0.10	0.02	0.10	0.02	0.10	0.02	0.17	0.03	0.10	0.02
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (µg/person)=				10.4		23.1		15.8		11.1		13.9		5.8
	Bodyweight per region (kg bw) =				60		60		55		60		60		60
	ADI (µg/person)=				1800		1800		1650		1800		1800		1800
	%ADI=				0.6%		1.3%		1.0%		0.6%		0.8%		0.3%
	Rounded %ADI=				1%		1%		1%		1%		1%		0%

Annex 3

DITHIOCARBAMATES (105)/MANCOZEB (050) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0300 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day G13 diet	Intake = daily intake: µg/person G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
VO 0444	Peppers, chili, raw	RAC	1.4	3.47	4.86	3.56	4.98	16.30	22.82	0.10	0.14	NC	-
-	Peppers, chili, dried	PP	9.8	0.58	5.68	1.27	12.45	1.21	11.86	0.12	1.18	NC	-
HS 0790	Pepper (black, white)	RAC	0.18	0.10	0.02	1.12	0.20	0.24	0.04	0.14	0.03	0.18	0.03
-	Anise seeds, star anise seeds, caraway seeds, coriander seeds, cumin seeds, fennel seeds, juniper berries	RAC	6.4	0.10	0.64	1.49	9.54	0.22	1.41	0.10	0.64	0.10	0.64
-	Nutmeg, mace, cardamom, grains of paradise	RAC	0.18	0.10	0.02	0.10	0.02	0.10	0.02	0.10	0.02	NC	-
-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (µg/person)=				11.2		27.2		36.1		2.0		0.7
	Bodyweight per region (kg bw) =				60		60		60		60		60
	ADI (µg/person)=				1800		1800		1800		1800		1800
	%ADI=				0.6%		1.5%		2.0%		0.1%		0.0%
	Rounded %ADI=				1%		2%		2%		0%		0%

Annex 3

EMAMECTIN BENZOATE (247) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0005 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day			Intake as µg/person/day								
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
FP 0009	Pome fruit, raw (incl cider, excl apple juice)	RAC	0.004	19.35	0.08	34.06	0.14	17.87	0.07	25.74	0.10	7.69	0.03	56.85	0.23
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.0028	0.32	0.00	3.07	0.01	0.10	0.00	5.00	0.01	0.29	0.00	5.57	0.02
-	Peaches and nectarines, raw	RAC	0.0095	2.87	0.03	2.21	0.02	0.15	0.00	5.94	0.06	1.47	0.01	15.66	0.15
FB 0269	Grape, raw (incl must, incl dried, incl juice, incl wine)	RAC	0.0025	16.25	0.04	28.96	0.07	2.87	0.01	24.22	0.06	9.33	0.02	68.64	0.17
VC 0045	Fruiting vegetables, cucurbits, raw	RAC	0.001	53.14	0.05	86.21	0.09	6.28	0.01	92.76	0.09	15.64	0.02	155.30	0.16
VO 0050	Fruiting vegetables other than cucurbits, raw, (incl processed commodities), excl sweet corn commodities, excl mushroom commodities	RAC	0.003	70.72	0.21	103.53	0.31	37.61	0.11	129.38	0.39	61.87	0.19	265.39	0.80
VL 0482	Lettuce, head, raw	RAC	0.2	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VL 0483	Lettuce, leaf, raw	RAC	0.076	0.53	0.04	0.36	0.03	0.16	0.01	6.21	0.47	1.90	0.14	6.05	0.46
VL 0485	Mustard greens, raw (i.e. Brassica)	RAC	0.01	0.10	0.00	0.31	0.00	0.10	0.00	0.10	0.00	0.47	0.00	0.11	0.00
VL 0510	Cos lettuce, raw	RAC	0.076	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VP 0061	Beans, green, with pods, raw: beans except broad bean & soya bean (i.e. immature seeds + pods) (Phaseolus spp)	RAC	0.001	0.68	0.00	NC	-	NC	-	0.39	0.00	0.22	0.00	0.49	0.00
TN 0085	Tree nuts, raw (incl processed)	RAC	0.001	4.06	0.00	3.27	0.00	7.01	0.01	13.93	0.01	14.01	0.01	9.36	0.01
SO 0495	Rape seed, raw (incl oil)	RAC	0.005	0.93	0.00	1.16	0.01	0.49	0.00	2.53	0.01	9.32	0.05	2.02	0.01
SO 0691	Cotton seed, raw	RAC	0.002	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
OR 0691	Cotton seed oil, edible	PP	0.00078	3.22	0.00	1.54	0.00	1.01	0.00	0.74	0.00	1.12	0.00	2.93	0.00
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)	RAC	0.002	31.20	0.06	72.44	0.14	20.88	0.04	47.98	0.10	33.08	0.07	36.25	0.07
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.002	3.29	0.01	6.14	0.01	0.82	0.00	1.57	0.00	2.23	0.00	1.07	0.00
MO 0105	Edible offal (mammalian), raw	RAC	0.006	4.79	0.03	9.68	0.06	2.97	0.02	5.49	0.03	3.84	0.02	5.03	0.03
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.0005	289.65	0.14	485.88	0.24	26.92	0.01	239.03	0.12	199.91	0.10	180.53	0.09
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (µg/person)=				0.7		1.1		0.3		1.5		0.7		2.2
	Bodyweight per region (kg bw) =				60		60		60		60		60		60
	ADI (µg/person)=				30		30		30		30		30		30
	%ADI=				2.4%		3.8%		1.0%		4.9%		2.2%		7.3%
	Rounded %ADI=				2%		4%		1%		5%		2%		7%

Annex 3

EMAMECTIN BENZOATE (247) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0005 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day			Intake as µg/person/day								
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
FP 0009	Pome fruit, raw (incl cider, excl apple juice)	RAC	0.004	51.09	0.20	65.40	0.26	42.71	0.17	45.29	0.18	62.51	0.25	7.74	0.03
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.0028	14.88	0.04	11.98	0.03	0.15	0.00	9.98	0.03	30.32	0.08	3.47	0.01
-	Peaches and nectarines, raw	RAC	0.0095	8.76	0.08	12.98	0.12	8.23	0.08	10.09	0.10	3.64	0.03	0.10	0.00
FB 0269	Grape, raw (incl must, incl dried, incl juice, incl wine)	RAC	0.0025	142.23	0.36	105.77	0.26	7.87	0.02	52.44	0.13	109.22	0.27	10.96	0.03
VC 0045	Fruiting vegetables, cucurbits, raw	RAC	0.001	27.81	0.03	41.93	0.04	123.30	0.12	49.47	0.05	15.95	0.02	35.99	0.04
VO 0050	Fruiting vegetables other than cucurbits, raw, (incl processed commodities), excl sweet corn commodities, excl mushroom commodities	RAC	0.003	72.92	0.22	86.99	0.26	79.04	0.24	97.13	0.29	65.96	0.20	17.98	0.05
VL 0482	Lettuce, head, raw	RAC	0.2	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VL 0483	Lettuce, leaf, raw	RAC	0.076	14.50	1.10	11.76	0.89	13.14	1.00	19.50	1.48	4.81	0.37	2.23	0.17
VL 0485	Mustard greens, raw (i.e. Brassica)	RAC	0.01	NC	-	NC	-	NC	-	NC	-	NC	-	0.13	0.00
VL 0510	Cos lettuce, raw	RAC	0.076	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VP 0061	Beans, green, with pods, raw: beans except broad bean & soya bean (i.e. immature seeds + pods) (Phaseolus spp)	RAC	0.001	5.07	0.01	0.83	0.00	0.17	0.00	3.70	0.00	NC	-	NC	-
TN 0085	Tree nuts, raw (incl processed)	RAC	0.001	8.52	0.01	8.94	0.01	15.09	0.02	9.60	0.01	14.57	0.01	26.26	0.03
SO 0495	Rape seed, raw (incl oil)	RAC	0.005	32.68	0.16	19.91	0.10	7.83	0.04	15.69	0.08	NC	-	NC	-
SO 0691	Cotton seed, raw	RAC	0.002	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
OR 0691	Cotton seed oil, edible	PP	0.00078	1.68	0.00	0.66	0.00	1.13	0.00	1.18	0.00	0.89	0.00	0.37	0.00
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)	RAC	0.002	140.03	0.28	150.89	0.30	79.32	0.16	111.24	0.22	120.30	0.24	51.27	0.10
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.002	6.44	0.01	15.51	0.03	3.79	0.01	8.29	0.02	18.44	0.04	8.00	0.02
MO 0105	Edible offal (mammalian), raw	RAC	0.006	15.17	0.09	5.19	0.03	6.30	0.04	6.78	0.04	3.32	0.02	3.17	0.02
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.0005	388.92	0.19	335.88	0.17	49.15	0.02	331.25	0.17	468.56	0.23	245.45	0.12
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (µg/person)=				2.8		2.5		1.9		2.8		1.8		0.6
	Bodyweight per region (kg bw) =				60		60		55		60		60		60
	ADI (µg/person)=				30		30		27.5		30		30		30
	%ADI=				9.3%		8.4%		7.0%		9.3%		5.9%		2.1%
	Rounded %ADI=				9%		8%		7%		9%		6%		2%

Annex 3

EMAMECTIN BENZOATE (247) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0005 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day G13 diet	Intake = daily intake: µg/person G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
FP 0009	Pome fruit, raw (incl cider, excl apple juice)	RAC	0.004	68.85	0.28	10.93	0.04	70.82	0.28	189.78	0.76	19.56	0.08
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.0028	0.10	0.00	0.10	0.00	7.19	0.02	0.10	0.00	NC	-
-	Peaches and nectarines, raw	RAC	0.0095	0.10	0.00	0.10	0.00	7.47	0.07	0.10	0.00	NC	-
FB 0269	Grape, raw (incl must, incl dried, incl juice, incl wine)	RAC	0.0025	0.60	0.00	1.26	0.00	103.25	0.26	0.74	0.00	44.23	0.11
VC 0045	Fruiting vegetables, cucurbits, raw	RAC	0.001	5.96	0.01	9.74	0.01	51.82	0.05	13.61	0.01	0.10	0.00
VO 0050	Fruiting vegetables other than cucurbits, raw, (incl processed commodities), excl sweet corn commodities, excl mushroom commodities	RAC	0.003	36.09	0.11	37.19	0.11	109.09	0.33	3.78	0.01	12.50	0.04
VL 0482	Lettuce, head, raw	RAC	0.2	NC	-	NC	-	NC	-	NC	-	NC	-
VL 0483	Lettuce, leaf, raw	RAC	0.076	0.29	0.02	0.10	0.01	6.71	0.51	0.10	0.01	NC	-
VL 0485	Mustard greens, raw (i.e. Brassica)	RAC	0.01	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	NC	-
VL 0510	Cos lettuce, raw	RAC	0.076	NC	-	NC	-	NC	-	NC	-	NC	-
VP 0061	Beans, green, with pods, raw: beans except broad bean & soya bean (i.e. immature seeds + pods) (Phaseolus spp)	RAC	0.001	NC	-	NC	-	NC	-	NC	-	NC	-
TN 0085	Tree nuts, raw (incl processed)	RAC	0.001	4.39	0.00	135.53	0.14	6.11	0.01	0.72	0.00	317.74	0.32
SO 0495	Rape seed, raw (incl oil)	RAC	0.005	0.19	0.00	0.10	0.00	12.07	0.06	0.10	0.00	NC	-
SO 0691	Cotton seed, raw	RAC	0.002	NC	-	NC	-	NC	-	NC	-	NC	-
OR 0691	Cotton seed oil, edible	PP	0.00078	1.28	0.00	0.10	0.00	0.45	0.00	0.42	0.00	0.15	0.00
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)	RAC	0.002	29.18	0.06	50.89	0.10	121.44	0.24	22.58	0.05	72.14	0.14
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.002	1.05	0.00	1.14	0.00	18.69	0.04	0.94	0.00	3.12	0.01
MO 0105	Edible offal (mammalian), raw	RAC	0.006	4.64	0.03	1.97	0.01	10.01	0.06	3.27	0.02	3.98	0.02
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.0005	108.75	0.05	70.31	0.04	436.11	0.22	61.55	0.03	79.09	0.04
-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (µg/person)=				0.6		0.5		2.1		0.9		0.8
	Bodyweight per region (kg bw) =				60		60		60		60		60
	ADI (µg/person)=				30		30		30		30		30
	%ADI=				1.9%		1.6%		7.2%		3.0%		2.5%
	Rounded %ADI=				2%		2%		7%		3%		3%

Annex 3

FENAMIDONE (264) International Estimated Daily Intake (IEDI) ADI = 0–0.03 mg/kg bw

			STMR	Diets as g/person/day			Intake as µg/person/day								
Codex Code	Commodity description	Expr as	mg/kg	G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
FB 0269	Grape, raw (incl dried, excl must, excl juice, excl wine)	RAC	0.175	14.82	2.59	11.26	1.97	0.10	0.02	22.16	3.88	4.19	0.73	63.05	11.03
–	Grape must	PP	0.145	0.33	0.05	0.13	0.02	0.10	0.01	0.10	0.01	0.10	0.01	0.10	0.01
JF 0269	Grape juice	PP	0.063	0.14	0.01	0.29	0.02	0.10	0.01	0.30	0.02	0.24	0.02	0.10	0.01
–	Grape wine (incl vermouths)	PP	0.124	0.67	0.08	12.53	1.55	2.01	0.25	1.21	0.15	3.53	0.44	4.01	0.50
FB 0275	Strawberry, raw	RAC	0.02	0.70	0.01	2.01	0.04	0.10	0.00	1.36	0.03	0.37	0.01	2.53	0.05
VA 0380	Fennel, bulb, raw	RAC	0.4	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
VA 0381	Garlic, raw	RAC	0.42	2.29	0.96	5.78	2.43	0.11	0.05	3.69	1.55	1.65	0.69	3.91	1.64
VA 0384	Leek, raw	RAC	0.46	0.18	0.08	1.59	0.73	0.10	0.05	0.28	0.13	0.10	0.05	3.21	1.48
–	Onions, mature bulbs, dry	RAC	0.42	29.36	12.33	37.50	15.75	3.56	1.50	34.78	14.61	18.81	7.90	43.38	18.22
–	Onions, green, raw	RAC	1.05	2.45	2.57	1.49	1.56	1.02	1.07	2.60	2.73	0.60	0.63	2.03	2.13
VB 0041	Cabbages, head, raw	RAC	1.23	2.73	3.36	27.92	34.34	0.55	0.68	4.47	5.50	4.27	5.25	10.25	12.61
VB 0042	Flowerhead brassicas, raw	RAC	2.29	2.96	6.78	0.57	1.31	0.10	0.23	4.17	9.55	7.79	17.84	3.64	8.34
VC 0045	Fruiting vegetables, cucurbits, raw	RAC	1.29	53.14	68.55	86.21	111.21	6.28	8.10	92.76	119.66	15.64	20.18	155.30	200.34
VO 0440	Eggplants, raw (= aubergines)	RAC	1.53	5.58	8.54	4.31	6.59	0.89	1.36	9.31	14.24	13.64	20.87	20.12	30.78
VO 0442	Okra, raw	RAC	1.53	1.97	3.01	NC	–	3.68	5.63	3.24	4.96	5.72	8.75	1.57	2.40
VO 0443	Pepino (Melon pear, Tree melon)	RAC	1.53	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
VO 0444	Peppers, chilli, raw	RAC	2.5	3.99	9.98	7.30	18.25	2.93	7.33	5.62	14.05	NC	–	17.44	43.60
–	Peppers, chilli, dried	PP	18	0.42	7.56	0.53	9.54	0.84	15.12	0.50	9.00	0.95	17.10	0.37	6.66
VO 0445	Peppers, sweet, raw (incl dried)	RAC	1.53	4.49	6.87	6.44	9.85	7.21	11.03	5.68	8.69	9.52	14.57	8.92	13.65
VO 0448	Tomato, raw	RAC	1.53	41.73	63.85	75.65	115.74	10.66	16.31	82.87	126.79	24.75	37.87	200.93	307.42
–	Tomato, canned (& peeled)	PP	0.69	0.20	0.14	0.31	0.21	0.10	0.07	1.11	0.77	0.11	0.08	1.50	1.04
–	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	5.58	2.34	13.06	1.33	7.42	1.57	8.76	4.24	23.66	0.34	1.90	2.83	15.79
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	1.22	0.29	0.35	0.29	0.35	0.10	0.12	0.38	0.46	0.10	0.12	0.14	0.17
VL 0054	Brassica leafy vegetables, raw	RAC	1.2	1.07	1.28	10.95	13.14	0.22	0.26	1.75	2.10	5.72	6.86	4.02	4.82
VL 0464	Chard, raw (i.e. beet leaves)	RAC	0.4	0.40	0.16	0.70	0.28	0.44	0.18	1.06	0.42	4.66	1.86	0.51	0.20
VL 0466	Chinese cabbage, type pak-choi, raw (i.e. Brassica)	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
VL 0467	Chinese cabbage, type pe-tsai, raw (i.e. Brassica)	RAC	1.2	0.45	0.54	4.56	5.47	0.10	0.12	0.73	0.88	NC	–	1.67	2.00
VL 0469	Chicory leaves (sugar loaf), raw	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
VL 0470	Lambs lettuce, raw (i.e. corn salad)	RAC	1.2	0.64	0.77	1.13	1.36	0.70	0.84	1.70	2.04	NC	–	0.82	0.98
VL 0472	Garden cress, raw	RAC	1.2	0.10	0.12	0.10	0.12	0.10	0.12	0.15	0.18	NC	–	0.10	0.12
VL 0473	Watercress, raw	RAC	1.2	1.21	1.45	2.15	2.58	1.33	1.60	3.24	3.89	11.36	13.63	1.56	1.87
VL 0474	Dandelion leaves, raw	RAC	1.2	1.20	1.44	0.23	0.28	0.14	0.17	0.34	0.41	1.44	1.73	0.16	0.19

Annex 3

FENAMIDONE (264) International Estimated Daily Intake (IEDI) ADI = 0–0.03 mg/kg bw

			STMR	Diets as g/person/day			Intake as µg/person/day								
Codex Code	Commodity description	Expr as	mg/kg	G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
VL 0476	Endive, raw (i.e. scarole)	RAC	1.2	0.10	0.12	0.10	0.12	0.10	0.12	0.40	0.48	0.10	0.12	0.39	0.47
VL 0478	Indian mustard (Amsoi) (i.e. Brassica)	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
VL 0479	Japanese greens, raw (i.e. Chrysanthemum)	RAC	1.2	0.10	0.12	0.10	0.12	0.10	0.12	0.10	0.12	NC	–	0.10	0.12
VL 0480	Kale, raw (i.e. collards) (i.e. Brassica)	RAC	1.2	0.57	0.68	5.77	6.92	0.11	0.13	0.92	1.10	5.25	6.30	2.12	2.54
VL 0481	Komatsuna, raw (i.e. Brassica)	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
VL 0482	Lettuce, head, raw	RAC	4.9	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
VL 0483	Lettuce, leaf, raw	RAC	1.24	0.53	0.66	0.36	0.45	0.16	0.20	6.21	7.70	1.90	2.36	6.05	7.50
VL 0485	Mustard greens, raw (i.e. Brassica)	RAC	20	0.10	2.00	0.31	6.20	0.10	2.00	0.10	2.00	0.47	9.40	0.11	2.20
VL 0492	Purslane, raw	RAC	0.4	0.10	0.04	0.10	0.04	0.10	0.04	0.10	0.04	NC	–	0.10	0.04
VL 0494	Radish leaves, raw	RAC	0.4	0.26	0.10	0.45	0.18	0.28	0.11	0.68	0.27	NC	–	0.33	0.13
VL 0495	Rape greens, raw (i.e. Brassica)	RAC	0.4	0.10	0.04	0.31	0.12	0.10	0.04	0.10	0.04	NC	–	0.11	0.04
VL 0496	Rucola, raw (i.e. arrugula, rocket salad, roquette)	RAC	1.2	1.27	1.52	2.25	2.70	1.39	1.67	3.38	4.06	13.81	16.57	1.63	1.96
VL 0501	Sowthistle, raw	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
VL 0502	Spinach, raw	RAC	20	0.74	14.80	0.22	4.40	0.10	2.00	0.91	18.20	0.10	2.00	2.92	58.40
VL 0504	Tannia leaves, raw (i.e. taioba)	RAC	0.4	0.18	0.07	0.31	0.12	0.19	0.08	0.47	0.19	2.06	0.82	0.23	0.09
VL 0505	Taro leaves, raw	RAC	0.4	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
VL 0506	Turnip greens, raw (i.e. Namenia, Tendergreen)	RAC	0.4	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
VL 0510	Cos lettuce, raw	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
–	Perilla leaves, raw (i.e. sesame leaves)	RAC	1.2	0.15	0.18	0.27	0.32	0.17	0.20	0.40	0.48	NC	–	0.19	0.23
–	Chinese cabbage flowering stalk, raw	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
VP 0061	Beans, green, with pods, raw: beans except broad bean & soya bean (i.e. immature seeds + pods) (Phaseolus spp)	RAC	1.39	0.68	0.95	NC	–	NC	–	0.39	0.54	0.22	0.31	0.49	0.68
VP 0062	Beans, green, without pods, raw: beans except broad bean & soya bean (i.e. immature seeds only) (Phaseolus spp..)	RAC	1.2	1.56	1.87	0.60	0.72	0.49	0.59	1.18	1.42	0.90	1.08	7.79	9.35
VP 0063	Peas green, with pods, raw (i.e. immature seeds + pods) (Pisum spp)	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
VP 0064	Peas, green, without pods, raw (i.e. immature seeds only) (Pisum spp)	RAC	1.2	1.97	2.36	0.51	0.61	0.10	0.12	0.79	0.95	3.68	4.42	3.80	4.56
VP 0520	Bambara groundnut, green, without pods (i.e. immature seeds only) (Voandzeia spp)	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
VP 0522	Broad bean, green, with pods (i.e. immature seeds + pods) (Vicia spp)	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
VP 0523	Broad beans, green, without pods, raw (i.e. immature seeds only) (Vicia faba)	RAC	1.2	3.51	4.21	0.43	0.52	0.10	0.12	0.60	0.72	0.29	0.35	0.78	0.94
VP 0541	Soya bean, green, without pods, raw (i.e.	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–

Annex 3

FENAMIDONE (264) International Estimated Daily Intake (IEDI) ADI = 0–0.03 mg/kg bw

			STMR	Diets as g/person/day			Intake as µg/person/day								
Codex Code	Commodity description	Expr as	mg/kg	G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
	immature seeds only) (Glycine max)														
VP 0542	Sword bean, green, with pods (i.e. immature seeds + pods) (Canavalia spp)	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
VP 0553	Lentil, green, with pods (i.e. immature seeds + pods) (Lens spp)	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
VR 0463	Cassava raw (incl starch, incl tapioca, incl flour)	RAC	0.4	0.10	0.04	0.10	0.04	482.56	193.02	0.99	0.40	25.75	10.30	3.29	1.32
VR 0494	Radish roots, raw	RAC	0.4	2.31	0.92	4.09	1.64	2.53	1.01	6.15	2.46	5.88	2.35	2.97	1.19
VR 0497	Swede, raw (i.e. rutabaga)	RAC	0.4	1.58	0.63	2.80	1.12	1.74	0.70	4.21	1.68	NC	–	2.03	0.81
VR 0498	Salsify, raw (i.e. oysterplant)	RAC	0.4	0.21	0.08	0.37	0.15	0.23	0.09	0.55	0.22	NC	–	0.27	0.11
VR 0504	Tannia, raw (i.e. yautia)	RAC	0.4	NC	–	NC	–	NC	–	0.10	0.04	0.26	0.10	1.27	0.51
VR 0505	Taro, raw	RAC	0.4	0.10	0.04	NC	–	25.12	10.05	0.10	0.04	0.10	0.04	0.97	0.39
VR 0506	Garden turnip, raw	RAC	0.4	2.50	1.00	4.44	1.78	2.75	1.10	6.67	2.67	0.14	0.06	3.22	1.29
VR 0508	Sweet potato, raw (incl dried)	RAC	0.4	0.18	0.07	0.18	0.07	42.16	16.86	1.61	0.64	3.06	1.22	6.67	2.67
VR 0573	Arrowroot, raw	RAC	0.4	1.53	0.61	0.10	0.04	0.93	0.37	1.33	0.53	0.47	0.19	0.10	0.04
VR 0574	Beetroot, raw	RAC	0.4	3.42	1.37	6.06	2.42	3.75	1.50	9.11	3.64	NC	–	4.39	1.76
VR 0575	Burdock, greater or edible, raw	RAC	0.4	0.10	0.04	0.10	0.04	0.10	0.04	0.10	0.04	NC	–	0.10	0.04
VR 0577	Carrots, raw	RAC	0.45	9.51	4.28	30.78	13.85	0.37	0.17	8.75	3.94	2.80	1.26	6.10	2.75
VR 0578	Celeriac, raw	RAC	0.4	1.70	0.68	3.01	1.20	1.87	0.75	4.53	1.81	NC	–	2.19	0.88
VR 0583	Horseradish, raw	RAC	0.4	0.51	0.20	0.91	0.36	0.56	0.22	1.37	0.55	NC	–	0.66	0.26
VR 0585	Jerusalem artichoke, raw (i.e. topinambur)	RAC	0.4	1.57	0.63	0.10	0.04	0.96	0.38	1.36	0.54	0.48	0.19	0.10	0.04
VR 0587	Parsley turnip-rooted, raw	RAC	0.4	0.32	0.13	0.57	0.23	0.35	0.14	0.85	0.34	NC	–	0.41	0.16
VR 0588	Parsnip, raw	RAC	0.4	0.59	0.24	1.05	0.42	0.65	0.26	1.58	0.63	NC	–	0.76	0.30
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.4	59.74	23.90	316.14	126.46	9.78	3.91	60.26	24.10	54.12	21.65	119.82	47.93
VR 0590	Black radish, raw	RAC	0.4	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
VR 0591	Japanese radish, raw (i.e. daikon)	RAC	0.4	1.90	0.76	3.36	1.34	2.08	0.83	5.06	2.02	NC	–	2.44	0.98
VR 0596	Sugar beet, raw (incl sugar)	RAC	0.4	0.13	0.05	NC	–	0.10	0.04	0.66	0.26	0.47	0.19	88.94	35.58
VR 0600	Yams, raw (incl dried)	RAC	0.4	0.10	0.04	NC	–	90.40	36.16	6.45	2.58	0.74	0.30	0.65	0.26
VS 0469	Witloof chicory (sprouts)	RAC	0	0.10	0.00	0.10	0.00	0.10	0.00	0.36	0.00	0.10	0.00	0.35	0.00
VS 0620	Artichoke globe	RAC	1.2	0.69	0.83	0.10	0.12	0.10	0.12	0.32	0.38	0.26	0.31	1.21	1.45
VS 0621	Asparagus	RAC	1.2	0.10	0.12	0.10	0.12	0.10	0.12	0.10	0.12	0.10	0.12	0.21	0.25
VS 0623	Cardoon	RAC	1.2	0.24	0.29	0.43	0.52	0.27	0.32	0.64	0.77	NC	–	0.31	0.37
VS 0624	Celery	RAC	2.3	2.14	4.92	3.79	8.72	2.35	5.41	5.69	13.09	0.10	0.23	2.75	6.33
VS 0627	Rhubarb	RAC	1.2	0.73	0.88	1.30	1.56	0.80	0.96	1.95	2.34	NC	–	0.94	1.13
GC 0640	Barley, raw (incl malt extract, incl pot & pearled, incl flour & grits, incl beer, incl malt)	RAC	0.33	19.91	6.57	31.16	10.28	5.04	1.66	3.10	1.02	9.77	3.22	4.31	1.42
GC 0641	Buckwheat, raw (incl flour)	RAC	0.33	NC	–	0.40	0.13	0.10	0.03	0.10	0.03	0.10	0.03	0.10	0.03

Annex 3

FENAMIDONE (264) International Estimated Daily Intake (IEDI) ADI = 0–0.03 mg/kg bw

			STMR	Diets as g/person/day			Intake as µg/person/day								
Codex Code	Commodity description	Expr as	mg/kg	G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl flour, incl oil, incl beer, incl germ, incl starch)	RAC	0.33	29.81	9.84	44.77	14.77	108.95	35.95	52.37	17.28	60.28	19.89	75.69	24.98
GC 0646	Millet, raw (incl flour, incl beer)	RAC	0.33	1.46	0.48	2.32	0.77	5.84	1.93	0.89	0.29	16.17	5.34	0.10	0.03
GC 0647	Oats, raw (incl rolled)	RAC	0.33	0.10	0.03	7.05	2.33	0.10	0.03	1.71	0.56	0.96	0.32	0.10	0.03
GC 0650	Rye, raw (incl flour)	RAC	0.33	0.13	0.04	19.38	6.40	0.10	0.03	0.12	0.04	0.10	0.03	2.15	0.71
GC 0651	Sorghum, raw (incl flour, incl beer)	RAC	0.33	4.34	1.43	0.10	0.03	16.25	5.36	15.82	5.22	10.97	3.62	2.92	0.96
GC 0653	Triticale, raw (incl flour)	RAC	0.33	NC	–	NC	–	NC	–	0.10	0.03	0.39	0.13	NC	–
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, incl germ, incl wholemeal bread, incl white flour products, incl white bread)	RAC	0.33	381.15	125.78	341.55	112.71	38.35	12.66	281.89	93.02	172.83	57.03	434.07	143.24
SO 0691	Cotton seed, raw (incl oil)	RAC	0.02	20.53	0.41	9.80	0.20	6.42	0.13	4.73	0.09	7.14	0.14	18.68	0.37
SO 0702	Sunflower seed, raw (incl oil)	RAC	0	7.40	0.00	35.86	0.00	1.15	0.00	8.76	0.00	5.45	0.00	13.62	0.00
HH 0720	Herbs, raw (incl dried)	RAC	1.2	1.69	2.03	1.91	2.29	1.18	1.42	3.35	4.02	0.55	0.66	1.64	1.97
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)	RAC	0	31.20	0.00	72.44	0.00	20.88	0.00	47.98	0.00	33.08	0.00	36.25	0.00
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0	3.29	0.00	6.14	0.00	0.82	0.00	1.57	0.00	2.23	0.00	1.07	0.00
MO 0105	Edible offal (mammalian), raw	RAC	0	4.79	0.00	9.68	0.00	2.97	0.00	5.49	0.00	3.84	0.00	5.03	0.00
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.01	289.65	2.90	485.88	4.86	26.92	0.27	239.03	2.39	199.91	2.00	180.53	1.81
PM 0110	Poultry meat, raw (incl prepared)	RAC	0	14.63	0.00	29.76	0.00	8.04	0.00	129.68	0.00	25.04	0.00	35.66	0.00
PF 0111	Poultry fat, raw (incl rendered)	RAC	0	0.10	0.00	0.10	0.00	NC	–	0.10	0.00	0.10	0.00	0.10	0.00
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0	0.12	0.00	0.12	0.00	0.11	0.00	5.37	0.00	0.24	0.00	0.10	0.00
PE 0112	Eggs, raw, (incl dried)	RAC	0	7.84	0.00	23.08	0.00	2.88	0.00	14.89	0.00	9.81	0.00	14.83	0.00
–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
	Total intake (µg/person) =				438.5		702.7		422.5		598.5		353.7		1061.7
	Bodyweight per region (kg bw) =				60		60		60		60		60		60
	ADI (µg/person) =				1800		1800		1800		1800		1800		1800
	%ADI =				24.4%		39.0%		23.5%		33.3%		19.7%		59.0%
	Rounded %ADI =				20%		40%		20%		30%		20%		60%

FENAMIDONE (264) International Estimated Daily Intake (IEDI) ADI = 0–0.03 mg/kg bw

			STMR	Diets as g/person/day			Intake as µg/person/day								
Codex Code	Commodity description	Expr as	mg/kg	G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
FB 0269	Grape, raw (incl dried, excl must, excl juice, excl	RAC	0.175	19.22	3.36	17.53	3.07	5.32	0.93	15.12	2.65	22.29	3.90	2.51	0.44

FENAMIDONE (264) International Estimated Daily Intake (IEDI) ADI = 0–0.03 mg/kg bw

			STMR	Diets as g/person/day			Intake as µg/person/day								
Codex Code	Commodity description	Expr as	mg/kg	G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
	wine)														
–	Grape must	PP	0.145	0.16	0.02	0.10	0.01	0.10	0.01	0.12	0.02	0.11	0.02	NC	–
JF 0269	Grape juice	PP	0.063	0.56	0.04	1.96	0.12	0.10	0.01	2.24	0.14	2.27	0.14	0.34	0.02
–	Grape wine (incl vermouths)	PP	0.124	88.93	11.03	62.41	7.74	1.84	0.23	25.07	3.11	61.17	7.59	5.84	0.72
FB 0275	Strawberry, raw	RAC	0.02	4.49	0.09	5.66	0.11	0.10	0.00	6.63	0.13	5.75	0.12	0.10	0.00
VA 0380	Fennel, bulb, raw	RAC	0.4	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
VA 0381	Garlic, raw	RAC	0.42	0.98	0.41	1.49	0.63	12.88	5.41	3.74	1.57	2.05	0.86	1.14	0.48
VA 0384	Leek, raw	RAC	0.46	4.01	1.84	4.41	2.03	0.72	0.33	0.54	0.25	16.41	7.55	0.10	0.05
–	Onions, mature bulbs, dry	RAC	0.42	19.69	8.27	29.83	12.53	24.64	10.35	31.35	13.17	9.72	4.08	12.59	5.29
–	Onions, green, raw	RAC	1.05	1.55	1.63	0.74	0.78	1.05	1.10	3.74	3.93	0.94	0.99	6.45	6.77
VB 0041	Cabbages, head, raw	RAC	1.23	8.97	11.03	27.12	33.36	1.44	1.77	24.96	30.70	4.55	5.60	11.23	13.81
VB 0042	Flowerhead brassicas, raw	RAC	2.29	9.50	21.76	6.77	15.50	9.03	20.68	3.21	7.35	9.36	21.43	0.87	1.99
VC 0045	Fruiting vegetables, cucurbits, raw	RAC	1.29	27.81	35.87	41.93	54.09	123.30	159.06	49.47	63.82	15.95	20.58	35.99	46.43
VO 0440	Eggplants, raw (= aubergines)	RAC	1.53	1.01	1.55	1.69	2.59	21.37	32.70	3.00	4.59	1.40	2.14	NC	–
VO 0442	Okra, raw	RAC	1.53	NC	–	NC	–	0.10	0.15	0.17	0.26	NC	–	0.72	1.10
VO 0443	Pepino (Melon pear, Tree melon)	RAC	1.53	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
VO 0444	Peppers, chilli, raw	RAC	2.5	5.57	13.93	14.00	35.00	8.25	20.63	5.77	14.43	6.44	16.10	2.53	6.33
–	Peppers, chilli, dried	PP	18	0.11	1.98	0.21	3.78	0.36	6.48	0.21	3.78	0.25	4.50	0.15	2.70
VO 0445	Peppers, sweet, raw (incl dried)	RAC	1.53	0.82	1.25	1.53	2.34	10.85	16.60	4.59	7.02	1.84	2.82	2.00	3.06
VO 0448	Tomato, raw	RAC	1.53	32.13	49.16	51.27	78.44	34.92	53.43	73.37	112.26	15.15	23.18	8.88	13.59
–	Tomato, canned (& peeled)	PP	0.69	7.57	5.22	2.66	1.84	0.30	0.21	0.97	0.67	7.31	5.04	0.41	0.28
–	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	5.58	4.96	27.68	3.20	17.86	0.15	0.84	1.61	8.98	6.88	38.39	0.52	2.90
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	1.22	0.80	0.98	0.10	0.12	0.10	0.12	0.61	0.74	0.40	0.49	0.10	0.12
VL 0054	Brassica leafy vegetables, raw	RAC	1.2	NC	–	NC	–	33.86	40.63	9.44	11.33	NC	–	4.40	5.28
VL 0464	Chard, raw (i.e. beet leaves)	RAC	0.4	NC	–	NC	–	NC	–	NC	–	NC	–	0.75	0.30
VL 0466	Chinese cabbage, type pak-choi, raw (i.e. Brassica)	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
VL 0467	Chinese cabbage, type pe-tsai, raw (i.e. Brassica)	RAC	1.2	NC	–	NC	–	17.39	20.87	9.44	11.33	NC	–	1.83	2.20
VL 0469	Chicory leaves (sugar loaf), raw	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
VL 0470	Lambs lettuce, raw (i.e. corn salad)	RAC	1.2	1.41	1.69	4.28	5.14	NC	–	0.10	0.12	5.11	6.13	1.20	1.44
VL 0472	Garden cress, raw	RAC	1.2	0.10	0.12	NC	–	1.27	1.52	0.13	0.16	0.21	0.25	0.10	0.12
VL 0473	Watercress, raw	RAC	1.2	0.35	0.42	3.13	3.76	0.32	0.38	NC	–	NC	–	2.30	2.76
VL 0474	Dandelion leaves, raw	RAC	1.2	0.10	0.12	0.10	0.12	NC	–	NC	–	0.10	0.12	0.24	0.29
VL 0476	Endive, raw (i.e. scarole)	RAC	1.2	0.21	0.25	0.93	1.12	NC	–	0.30	0.36	2.14	2.57	0.14	0.17
VL 0478	Indian mustard (Amsoi) (i.e. Brassica)	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
VL 0479	Japanese greens, raw (i.e. Chrysanthemum)	RAC	1.2	NC	–	NC	–	NC	–	0.32	0.38	NC	–	0.10	0.12
VL 0480	Kale, raw (i.e. collards) (i.e. Brassica)	RAC	1.2	NC	–	NC	–	14.54	17.45	NC	–	NC	–	2.32	2.78
VL 0481	Komatsuna, raw (i.e. Brassica)	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
VL 0482	Lettuce, head, raw	RAC	4.9	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–

Annex 3

FENAMIDONE (264) International Estimated Daily Intake (IEDI) ADI = 0–0.03 mg/kg bw

			STMR	Diets as g/person/day			Intake as µg/person/day								
Codex Code	Commodity description	Expr as	mg/kg	G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
VL 0483	Lettuce, leaf, raw	RAC	1.24	14.50	17.98	11.76	14.58	13.14	16.29	19.50	24.18	4.81	5.96	2.23	2.77
VL 0485	Mustard greens, raw (i.e. Brassica)	RAC	20	NC	–	NC	–	NC	–	NC	–	NC	–	0.13	2.60
VL 0492	Purslane, raw	RAC	0.4	0.10	0.04	NC	–	NC	–	NC	–	NC	–	0.10	0.04
VL 0494	Radish leaves, raw	RAC	0.4	NC	–	NC	–	NC	–	3.78	1.51	NC	–	0.48	0.19
VL 0495	Rape greens, raw (i.e. Brassica)	RAC	0.4	NC	–	NC	–	1.93	0.77	NC	–	NC	–	0.12	0.05
VL 0496	Rucola, raw (i.e. arrugula, rocket salad, roquette)	RAC	1.2	NC	–	NC	–	NC	–	1.09	1.31	0.38	0.46	2.40	2.88
VL 0501	Sowthistle, raw	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
VL 0502	Spinach, raw	RAC	20	2.20	44.00	1.76	35.20	13.38	267.60	2.94	58.80	5.53	110.60	0.10	2.00
VL 0504	Tannia leaves, raw (i.e. taioba)	RAC	0.4	NC	–	NC	–	NC	–	NC	–	NC	–	0.33	0.13
VL 0505	Taro leaves, raw	RAC	0.4	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
VL 0506	Turnip greens, raw (i.e. Namenia, Tendergreen)	RAC	0.4	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
VL 0510	Cos lettuce, raw	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
–	Perilla leaves, raw (i.e. sesame leaves)	RAC	1.2	NC	–	NC	–	NC	–	2.23	2.68	NC	–	0.29	0.35
–	Chinese cabbage flowering stalk, raw	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
VP 0061	Beans, green, with pods, raw: beans except broad bean & soya bean (i.e. immature seeds + pods) (Phaseolus spp)	RAC	1.39	5.07	7.05	0.83	1.15	0.17	0.24	3.70	5.14	NC	–	NC	–
VP 0062	Beans, green, without pods, raw: beans except broad bean & soya bean (i.e. immature seeds only) (Phaseolus spp..)	RAC	1.2	2.21	2.65	5.25	6.30	4.17	5.00	1.61	1.93	16.95	20.34	0.17	0.20
VP 0063	Peas green, with pods, raw (i.e. immature seeds + pods) (Pisum spp)	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
VP 0064	Peas, green, without pods, raw (i.e. immature seeds only) (Pisum spp)	RAC	1.2	10.72	12.86	1.99	2.39	2.72	3.26	4.26	5.11	4.23	5.08	NC	–
VP 0520	Bambara groundnut, green, without pods (i.e. immature seeds only) (Voandzeia spp)	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
VP 0522	Broad bean, green, with pods (i.e. immature seeds + pods) (Vicia spp)	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
VP 0523	Broad beans, green, without pods, raw (i.e. immature seeds only) (Vicia faba)	RAC	1.2	0.22	0.26	0.84	1.01	0.15	0.18	0.48	0.58	2.04	2.45	NC	–
VP 0541	Soya bean, green, without pods, raw (i.e. immature seeds only) (Glycine max)	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
VP 0542	Sword bean, green, with pods (i.e. immature seeds + pods) (Canavalia spp)	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
VP 0553	Lentil, green, with pods (i.e. immature seeds + pods) (Lens spp)	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
VR 0463	Cassava raw (incl starch, incl tapioca, incl flour)	RAC	0.4	0.10	0.04	NC	–	20.96	8.38	0.14	0.06	NC	–	9.62	3.85
VR 0494	Radish roots, raw	RAC	0.4	3.83	1.53	11.99	4.80	NC	–	5.26	2.10	2.19	0.88	4.37	1.75
VR 0497	Swede, raw (i.e. rutabaga)	RAC	0.4	10.01	4.00	1.66	0.66	NC	–	NC	–	3.06	1.22	2.99	1.20

Annex 3

FENAMIDONE (264) International Estimated Daily Intake (IEDI) ADI = 0–0.03 mg/kg bw

			STMR	Diets as g/person/day			Intake as µg/person/day								
Codex Code	Commodity description	Expr as	mg/kg	G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
VR 0498	Salsify, raw (i.e. oysterplant)	RAC	0.4	1.02	0.41	0.52	0.21	NC	–	NC	–	2.08	0.83	0.39	0.16
VR 0504	Tannia, raw (i.e. yautia)	RAC	0.4	NC	–	NC	–	NC	–	0.10	0.04	NC	–	10.74	4.30
VR 0505	Taro, raw	RAC	0.4	NC	–	NC	–	1.93	0.77	0.84	0.34	NC	–	19.94	7.98
VR 0506	Garden turnip, raw	RAC	0.4	5.78	2.31	15.35	6.14	NC	–	6.54	2.62	1.95	0.78	4.73	1.89
VR 0508	Sweet potato, raw (incl dried)	RAC	0.4	0.93	0.37	0.32	0.13	64.65	25.86	5.37	2.15	0.30	0.12	3.13	1.25
VR 0573	Arrowroot, raw	RAC	0.4	0.10	0.04	0.10	0.04	2.05	0.82	0.21	0.08	NC	–	0.76	0.30
VR 0574	Beetroot, raw	RAC	0.4	9.91	3.96	6.34	2.54	NC	–	9.65	3.86	19.11	7.64	6.47	2.59
VR 0575	Burdock, greater or edible, raw	RAC	0.4	NC	–	NC	–	NC	–	0.48	0.19	NC	–	0.10	0.04
VR 0577	Carrots, raw	RAC	0.45	26.26	11.82	27.13	12.21	10.07	4.53	16.49	7.42	44.69	20.11	8.75	3.94
VR 0578	Celeriac, raw	RAC	0.4	2.97	1.19	1.79	0.72	NC	–	0.10	0.04	16.91	6.76	3.22	1.29
VR 0583	Horseradish, raw	RAC	0.4	0.10	0.04	0.42	0.17	13.01	5.20	0.26	0.10	2.70	1.08	0.97	0.39
VR 0585	Jerusalem artichoke, raw (i.e. topinambur)	RAC	0.4	0.11	0.04	0.10	0.04	NC	–	0.22	0.09	NC	–	0.78	0.31
VR 0587	Parsley turnip-rooted, raw	RAC	0.4	NC	–	NC	–	NC	–	NC	–	NC	–	0.61	0.24
VR 0588	Parsnip, raw	RAC	0.4	4.42	1.77	0.10	0.04	NC	–	NC	–	NC	–	1.12	0.45
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.4	225.03	90.01	234.24	93.70	71.48	28.59	177.55	71.02	234.55	93.82	37.71	15.08
VR 0590	Black radish, raw	RAC	0.4	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
VR 0591	Japanese radish, raw (i.e. daikon)	RAC	0.4	NC	–	NC	–	26.64	10.66	18.92	7.57	NC	–	3.59	1.44
VR 0596	Sugar beet, raw (incl sugar)	RAC	0.4	0.10	0.04	NC	–	0.10	0.04	0.10	0.04	NC	–	NC	–
VR 0600	Yams, raw (incl dried)	RAC	0.4	NC	–	NC	–	0.10	0.04	0.71	0.28	NC	–	17.57	7.03
VS 0469	Witloof chicory (sprouts)	RAC	0	1.50	0.00	0.95	0.00	NC	–	1.84	0.00	0.65	0.00	0.13	0.00
VS 0620	Artichoke globe	RAC	1.2	0.98	1.18	3.65	4.38	0.10	0.12	1.67	2.00	0.26	0.31	NC	–
VS 0621	Asparagus	RAC	1.2	0.84	1.01	2.08	2.50	7.11	8.53	1.01	1.21	1.69	2.03	0.10	0.12
VS 0623	Cardoon	RAC	1.2	0.10	0.12	3.49	4.19	NC	–	0.10	0.12	NC	–	0.46	0.55
VS 0624	Celery	RAC	2.3	7.68	17.66	2.85	6.56	NC	–	3.34	7.68	16.83	38.71	4.04	9.29
VS 0627	Rhubarb	RAC	1.2	1.61	1.93	2.23	2.68	NC	–	0.52	0.62	7.63	9.16	1.39	1.67
GC 0640	Barley, raw (incl malt extract, incl pot & pearled, incl flour & grits, incl beer, incl malt)	RAC	0.33	36.18	11.94	53.45	17.64	9.39	3.10	35.25	11.63	46.68	15.40	15.92	5.25
GC 0641	Buckwheat, raw (incl flour)	RAC	0.33	0.10	0.03	0.79	0.26	0.18	0.06	0.35	0.12	NC	–	NC	–
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl flour, incl oil, incl beer, incl germ, incl starch)	RAC	0.33	18.51	6.11	26.18	8.64	26.04	8.59	39.99	13.20	7.36	2.43	64.58	21.31
GC 0646	Millet, raw (incl flour, incl beer)	RAC	0.33	0.10	0.03	0.16	0.05	1.75	0.58	0.69	0.23	NC	–	NC	–
GC 0647	Oats, raw (incl rolled)	RAC	0.33	7.50	2.48	6.26	2.07	0.15	0.05	4.87	1.61	3.16	1.04	2.98	0.98
GC 0650	Rye, raw (incl flour)	RAC	0.33	3.21	1.06	35.38	11.68	0.21	0.07	6.50	2.15	1.49	0.49	NC	–
GC 0651	Sorghum, raw (incl flour, incl beer)	RAC	0.33	NC	–	NC	–	1.44	0.48	1.15	0.38	NC	–	7.12	2.35
GC 0653	Triticale, raw (incl flour)	RAC	0.33	0.10	0.03	0.17	0.06	0.29	0.10	0.10	0.03	NC	–	NC	–
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, incl germ, incl wholemeal bread, incl white flour products, incl white bread)	RAC	0.33	253.07	83.51	244.73	80.76	134.44	44.37	235.10	77.58	216.39	71.41	167.40	55.24

Annex 3

FENAMIDONE (264) International Estimated Daily Intake (IEDI) ADI = 0–0.03 mg/kg bw

			STMR	Diets as g/person/day			Intake as µg/person/day								
Codex Code	Commodity description	Expr as	mg/kg	G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
SO 0691	Cotton seed, raw (incl oil)	RAC	0.02	10.71	0.21	4.23	0.08	7.19	0.14	7.54	0.15	5.66	0.11	2.38	0.05
SO 0702	Sunflower seed, raw (incl oil)	RAC	0	23.40	0.00	29.33	0.00	1.24	0.00	13.85	0.00	6.48	0.00	6.91	0.00
HH 0720	Herbs, raw (incl dried)	RAC	1.2	2.61	3.13	2.31	2.77	8.89	10.67	3.92	4.70	1.16	1.39	2.06	2.47
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)	RAC	0	140.03	0.00	150.89	0.00	79.32	0.00	111.24	0.00	120.30	0.00	51.27	0.00
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0	6.44	0.00	15.51	0.00	3.79	0.00	8.29	0.00	18.44	0.00	8.00	0.00
MO 0105	Edible offal (mammalian), raw	RAC	0	15.17	0.00	5.19	0.00	6.30	0.00	6.78	0.00	3.32	0.00	3.17	0.00
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.01	388.92	3.89	335.88	3.36	49.15	0.49	331.25	3.31	468.56	4.69	245.45	2.45
PM 0110	Poultry meat, raw (incl prepared)	RAC	0	73.76	0.00	53.86	0.00	23.98	0.00	87.12	0.00	53.38	0.00	84.45	0.00
PF 0111	Poultry fat, raw (incl rendered)	RAC	0	0.10	0.00	0.10	0.00	NC	–	0.10	0.00	0.71	0.00	NC	–
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0	0.33	0.00	0.72	0.00	0.27	0.00	0.35	0.00	0.80	0.00	NC	–
PE 0112	Eggs, raw, (incl dried)	RAC	0	25.84	0.00	29.53	0.00	28.05	0.00	33.19	0.00	36.44	0.00	8.89	0.00
–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
	Total intake (µg/person) =				536.5		611.7		867.5		629.2		599.9		290.0
	Bodyweight per region (kg bw) =				60		60		55		60		60		60
	ADI (µg/person) =				1800		1800		1650		1800		1800		1800
	%ADI =				29.8%		34.0%		52.6%		35.0%		33.3%		16.1%
	Rounded %ADI =				30%		30%		50%		30%		30%		20%

FENAMIDONE (264) International Estimated Daily Intake (IEDI) ADI = 0–0.03 mg/kg bw

			STMR	Diets: g/person/day			Intake = daily intake: µg/person						
Codex Code	Commodity description	Expr as	mg/kg	G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
FB 0269	Grape, raw (incl dried, excl must, excl juice, excl wine)	RAC	0.175	0.16	0.03	0.92	0.16	19.62	3.43	0.10	0.02	0.21	0.04
–	Grape must	PP	0.145	0.10	0.01	0.10	0.01	0.11	0.02	0.10	0.01	0.19	0.03
JF 0269	Grape juice	PP	0.063	0.10	0.01	0.10	0.01	0.41	0.03	0.10	0.01	NC	–
–	Grape wine (incl vermouths)	PP	0.124	0.31	0.04	0.23	0.03	60.43	7.49	0.52	0.06	31.91	3.96
FB 0275	Strawberry, raw	RAC	0.02	0.10	0.00	0.10	0.00	3.35	0.07	0.10	0.00	0.10	0.00
VA 0380	Fennel, bulb, raw	RAC	0.4	NC	–	NC	–	NC	–	NC	–	NC	–
VA 0381	Garlic, raw	RAC	0.42	0.82	0.34	2.06	0.87	3.79	1.59	0.10	0.04	0.29	0.12
VA 0384	Leek, raw	RAC	0.46	0.10	0.05	1.44	0.66	1.22	0.56	0.10	0.05	NC	–
–	Onions, mature bulbs, dry	RAC	0.42	9.01	3.78	20.24	8.50	30.90	12.98	9.61	4.04	2.11	0.89
–	Onions, green, raw	RAC	1.05	1.43	1.50	0.10	0.11	0.20	0.21	NC	–	6.30	6.62
VB 0041	Cabbages, head, raw	RAC	1.23	3.82	4.70	2.99	3.68	49.16	60.47	0.10	0.12	NC	–
VB 0042	Flowerhead brassicas, raw	RAC	2.29	0.10	0.23	0.10	0.23	4.86	11.13	0.10	0.23	NC	–

Annex 3

FENAMIDONE (264) International Estimated Daily Intake (IEDI) ADI = 0–0.03 mg/kg bw

			STMR	Diets: g/person/day			Intake = daily intake: µg/person						
Codex Code	Commodity description	Expr as	mg/kg	G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
VC 0045	Fruiting vegetables, cucurbits, raw	RAC	1.29	5.96	7.69	9.74	12.56	51.82	66.85	13.61	17.56	0.10	0.13
VO 0440	Eggplants, raw (= aubergines)	RAC	1.53	1.31	2.00	8.26	12.64	3.95	6.04	0.10	0.15	NC	–
VO 0442	Okra, raw	RAC	1.53	6.23	9.53	0.10	0.15	NC	–	NC	–	NC	–
VO 0443	Pepino (Melon pear, Tree melon)	RAC	1.53	NC	–	NC	–	NC	–	NC	–	NC	–
VO 0444	Peppers, chilli, raw	RAC	2.5	3.47	8.68	3.56	8.90	16.30	40.75	0.10	0.25	NC	–
–	Peppers, chilli, dried	PP	18	0.58	10.44	1.27	22.86	1.21	21.78	0.12	2.16	NC	–
VO 0445	Peppers, sweet, raw (incl dried)	RAC	1.53	5.49	8.40	10.57	16.17	8.84	13.53	0.91	1.39	NC	–
VO 0448	Tomato, raw	RAC	1.53	12.99	19.87	4.79	7.33	58.40	89.35	0.92	1.41	0.10	0.15
–	Tomato, canned (& peeled)	PP	0.69	0.10	0.07	0.10	0.07	2.42	1.67	0.10	0.07	NC	–
–	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	5.58	0.58	3.24	0.22	1.23	2.21	12.33	0.24	1.34	3.10	17.30
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	1.22	0.10	0.12	0.10	0.12	0.42	0.51	0.10	0.12	0.10	0.12
VL 0054	Brassica leafy vegetables, raw	RAC	1.2	1.50	1.80	1.17	1.40	NC	–	0.10	0.12	NC	–
VL 0464	Chard, raw (i.e. beet leaves)	RAC	0.4	0.68	0.27	0.49	0.20	NC	–	0.46	0.18	0.92	0.37
VL 0466	Chinese cabbage, type pak-choi, raw (i.e. Brassica)	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–
VL 0467	Chinese cabbage, type pe-tsai, raw (i.e. Brassica)	RAC	1.2	0.62	0.74	0.49	0.59	NC	–	0.10	0.12	NC	–
VL 0469	Chicory leaves (sugar loaf), raw	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–
VL 0470	Lambs lettuce, raw (i.e. corn salad)	RAC	1.2	1.09	1.31	0.79	0.95	NC	–	0.74	0.89	1.47	1.76
VL 0472	Garden cress, raw	RAC	1.2	0.10	0.12	0.10	0.12	NC	–	0.10	0.12	0.13	0.16
VL 0473	Watercress, raw	RAC	1.2	2.08	2.50	1.50	1.80	0.10	0.12	1.41	1.69	2.81	3.37
VL 0474	Dandelion leaves, raw	RAC	1.2	0.22	0.26	0.16	0.19	NC	–	0.15	0.18	0.29	0.35
VL 0476	Endive, raw (i.e. scarole)	RAC	1.2	0.10	0.12	0.10	0.12	0.10	0.12	0.10	0.12	NC	–
VL 0478	Indian mustard (Amsoi) (i.e. Brassica)	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–
VL 0479	Japanese greens, raw (i.e. Chrysanthemum)	RAC	1.2	0.10	0.12	0.10	0.12	NC	–	0.10	0.12	0.10	0.12
VL 0480	Kale, raw (i.e. collards) (i.e. Brassica)	RAC	1.2	0.79	0.95	0.62	0.74	NC	–	0.10	0.12	NC	–
VL 0481	Komatsuna, raw (i.e. Brassica)	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–
VL 0482	Lettuce, head, raw	RAC	4.9	NC	–	NC	–	NC	–	NC	–	NC	–
VL 0483	Lettuce, leaf, raw	RAC	1.24	0.29	0.36	0.10	0.12	6.71	8.32	0.10	0.12	NC	–
VL 0485	Mustard greens, raw (i.e. Brassica)	RAC	20	0.10	2.00	0.10	2.00	NC	–	0.10	2.00	NC	–
VL 0492	Purslane, raw	RAC	0.4	0.10	0.04	0.10	0.04	NC	–	0.10	0.04	0.10	0.04
VL 0494	Radish leaves, raw	RAC	0.4	0.44	0.18	0.32	0.13	NC	–	0.30	0.12	0.59	0.24
VL 0495	Rape greens, raw (i.e. Brassica)	RAC	0.4	0.10	0.04	0.10	0.04	NC	–	0.10	0.04	NC	–
VL 0496	Rucola, raw (i.e. arrugula, rocket salad, roquette)	RAC	1.2	2.17	2.60	1.57	1.88	NC	–	1.47	1.76	2.93	3.52
VL 0501	Sowthistle, raw	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–
VL 0502	Spinach, raw	RAC	20	0.17	3.40	0.10	2.00	0.81	16.20	0.10	2.00	NC	–
VL 0504	Tannia leaves, raw (i.e. taioba)	RAC	0.4	0.30	0.12	0.22	0.09	NC	–	0.20	0.08	0.41	0.16
VL 0505	Taro leaves, raw	RAC	0.4	NC	–	NC	–	NC	–	NC	–	NC	–
VL 0506	Turnip greens, raw (i.e. Namenia, Tendergreen)	RAC	0.4	NC	–	NC	–	NC	–	NC	–	NC	–
VL 0510	Cos lettuce, raw	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–
–	Perilla leaves, raw (i.e. sesame leaves)	RAC	1.2	0.26	0.31	0.19	0.23	NC	–	0.18	0.22	0.35	0.42

Annex 3

FENAMIDONE (264) International Estimated Daily Intake (IEDI) ADI = 0–0.03 mg/kg bw

			STMR	Diets: g/person/day			Intake = daily intake: µg/person						
Codex Code	Commodity description	Expr as	mg/kg	G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
–	Chinese cabbage flowering stalk, raw	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–
VP 0061	Beans, green, with pods, raw: beans except broad bean & soya bean (i.e. immature seeds + pods) (Phaseolus spp)	RAC	1.39	NC	–	NC	–	NC	–	NC	–	NC	–
VP 0062	Beans, green, without pods, raw: beans except broad bean & soya bean (i.e. immature seeds only) (Phaseolus spp..)	RAC	1.2	0.30	0.36	3.13	3.76	4.11	4.93	0.10	0.12	NC	–
VP 0063	Peas green, with pods, raw (i.e. immature seeds + pods) (Pisum spp)	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–
VP 0064	Peas, green, without pods, raw (i.e. immature seeds only) (Pisum spp)	RAC	1.2	0.21	0.25	0.10	0.12	5.51	6.61	0.10	0.12	NC	–
VP 0520	Bambara groundnut, green, without pods (i.e. immature seeds only) (Voandzeia spp)	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–
VP 0522	Broad bean, green, with pods (i.e. immature seeds + pods) (Vicia spp)	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–
VP 0523	Broad beans, green, without pods, raw (i.e. immature seeds only) (Vicia faba)	RAC	1.2	0.10	0.12	0.10	0.12	0.76	0.91	NC	–	NC	–
VP 0541	Soya bean, green, without pods, raw (i.e. immature seeds only) (Glycine max)	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–
VP 0542	Sword bean, green, with pods (i.e. immature seeds + pods) (Canavalia spp)	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–
VP 0553	Lentil, green, with pods (i.e. immature seeds + pods) (Lens spp)	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–
VR 0463	Cassava raw (incl starch, incl tapioca, incl flour)	RAC	0.4	91.92	36.77	34.12	13.65	NC	–	259.92	103.97	45.48	18.19
VR 0494	Radish roots, raw	RAC	0.4	3.96	1.58	2.86	1.14	3.30	1.32	2.67	1.07	5.34	2.14
VR 0497	Swede, raw (i.e. rutabaga)	RAC	0.4	2.71	1.08	1.96	0.78	7.80	3.12	1.83	0.73	3.66	1.46
VR 0498	Salsify, raw (i.e. oysterplant)	RAC	0.4	0.36	0.14	0.26	0.10	NC	–	0.24	0.10	0.48	0.19
VR 0504	Tannia, raw (i.e. yautia)	RAC	0.4	NC	–	NC	–	0.10	0.04	NC	–	NC	–
VR 0505	Taro, raw	RAC	0.4	6.71	2.68	31.91	12.76	NC	–	10.73	4.29	264.31	105.72
VR 0506	Garden turnip, raw	RAC	0.4	4.29	1.72	3.10	1.24	6.41	2.56	2.90	1.16	5.79	2.32
VR 0508	Sweet potato, raw (incl dried)	RAC	0.4	28.83	11.53	61.55	24.62	0.15	0.06	221.94	88.78	NC	–
VR 0573	Arrowroot, raw	RAC	0.4	13.83	5.53	18.24	7.30	0.10	0.04	0.10	0.04	19.60	7.84
VR 0574	Beetroot, raw	RAC	0.4	5.86	2.34	4.23	1.69	9.46	3.78	3.96	1.58	7.91	3.16
VR 0575	Burdock, greater or edible, raw	RAC	0.4	0.10	0.04	0.10	0.04	NC	–	0.10	0.04	0.10	0.04
VR 0577	Carrots, raw	RAC	0.45	2.07	0.93	3.00	1.35	25.29	11.38	0.10	0.05	NC	–
VR 0578	Celeriac, raw	RAC	0.4	2.91	1.16	2.10	0.84	7.59	3.04	1.97	0.79	3.93	1.57
VR 0583	Horseradish, raw	RAC	0.4	0.88	0.35	0.63	0.25	0.54	0.22	0.59	0.24	1.19	0.48
VR 0585	Jerusalem artichoke, raw (i.e. topinambur)	RAC	0.4	14.22	5.69	18.75	7.50	0.10	0.04	0.10	0.04	20.14	8.06
VR 0587	Parsley turnip-rooted, raw	RAC	0.4	0.55	0.22	0.40	0.16	4.29	1.72	0.37	0.15	0.74	0.30

Annex 3

FENAMIDONE (264) International Estimated Daily Intake (IEDI) ADI = 0–0.03 mg/kg bw

			STMR	Diets: g/person/day			Intake = daily intake: µg/person						
Codex Code	Commodity description	Expr as	mg/kg	G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
VR 0588	Parsnip, raw	RAC	0.4	1.02	0.41	0.74	0.30	3.50	1.40	0.69	0.28	1.37	0.55
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.4	23.96	9.58	13.56	5.42	213.41	85.36	104.35	41.74	8.56	3.42
VR 0590	Black radish, raw	RAC	0.4	NC	–	NC	–	NC	–	NC	–	NC	–
VR 0591	Japanese radish, raw (i.e. daikon)	RAC	0.4	3.25	1.30	2.35	0.94	NC	–	2.20	0.88	4.39	1.76
VR 0596	Sugar beet, raw (incl sugar)	RAC	0.4	3.93	1.57	1.68	0.67	NC	–	NC	–	36.12	14.45
VR 0600	Yams, raw (incl dried)	RAC	0.4	70.93	28.37	30.62	12.25	0.10	0.04	5.65	2.26	30.85	12.34
VS 0469	Witloof chicory (sprouts)	RAC	0	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00	NC	–
VS 0620	Artichoke globe	RAC	1.2	0.10	0.12	NC	–	0.10	0.12	0.10	0.12	NC	–
VS 0621	Asparagus	RAC	1.2	0.10	0.12	0.10	0.12	0.17	0.20	0.10	0.12	NC	–
VS 0623	Cardoon	RAC	1.2	0.41	0.49	0.30	0.36	NC	–	0.28	0.34	0.56	0.67
VS 0624	Celery	RAC	2.3	3.66	8.42	2.65	6.10	4.84	11.13	2.47	5.68	4.94	11.36
VS 0627	Rhubarb	RAC	1.2	1.26	1.51	0.91	1.09	0.96	1.15	0.85	1.02	1.70	2.04
GC 0640	Barley, raw (incl malt extract, incl pot & pearled, incl flour & grits, incl beer, incl malt)	RAC	0.33	11.58	3.82	2.33	0.77	46.71	15.41	3.72	1.23	16.26	5.37
GC 0641	Buckwheat, raw (incl flour)	RAC	0.33	0.10	0.03	2.82	0.93	0.10	0.03	0.10	0.03	NC	–
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl flour, incl oil, incl beer, incl germ, incl starch)	RAC	0.33	116.66	38.50	10.52	3.47	38.46	12.69	76.60	25.28	34.44	11.37
GC 0646	Millet, raw (incl flour, incl beer)	RAC	0.33	61.13	20.17	0.78	0.26	NC	–	33.55	11.07	NC	–
GC 0647	Oats, raw (incl rolled)	RAC	0.33	0.37	0.12	0.10	0.03	2.79	0.92	0.10	0.03	NC	–
GC 0650	Rye, raw (incl flour)	RAC	0.33	0.10	0.03	0.10	0.03	13.95	4.60	0.10	0.03	0.88	0.29
GC 0651	Sorghum, raw (incl flour, incl beer)	RAC	0.33	89.16	29.42	2.02	0.67	NC	–	35.38	11.68	NC	–
GC 0653	Triticale, raw (incl flour)	RAC	0.33	0.10	0.03	NC	–	NC	–	NC	–	NC	–
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, incl germ, incl wholemeal bread, incl white flour products, incl white bread)	RAC	0.33	57.20	18.88	110.47	36.46	272.62	89.96	25.82	8.52	132.04	43.57
SO 0691	Cotton seed, raw (incl oil)	RAC	0.02	8.14	0.16	0.32	0.01	2.84	0.06	2.69	0.05	0.97	0.02
SO 0702	Sunflower seed, raw (incl oil)	RAC	0	0.94	0.00	0.22	0.00	32.01	0.00	12.12	0.00	0.48	0.00
HH 0720	Herbs, raw (incl dried)	RAC	1.2	1.85	2.22	1.67	2.00	2.80	3.36	1.24	1.49	2.75	3.30
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)	RAC	0	29.18	0.00	50.89	0.00	121.44	0.00	22.58	0.00	72.14	0.00
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0	1.05	0.00	1.14	0.00	18.69	0.00	0.94	0.00	3.12	0.00
MO 0105	Edible offal (mammalian), raw	RAC	0	4.64	0.00	1.97	0.00	10.01	0.00	3.27	0.00	3.98	0.00
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.01	108.75	1.09	70.31	0.70	436.11	4.36	61.55	0.62	79.09	0.79
PM 0110	Poultry meat, raw (incl prepared)	RAC	0	3.92	0.00	12.03	0.00	57.07	0.00	5.03	0.00	55.56	0.00
PF 0111	Poultry fat, raw (incl rendered)	RAC	0	NC	–	NC	–	0.32	0.00	NC	–	NC	–
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0	0.10	0.00	0.70	0.00	0.97	0.00	0.10	0.00	NC	–
PE 0112	Eggs, raw, (incl dried)	RAC	0	3.84	0.00	4.41	0.00	27.25	0.00	1.13	0.00	7.39	0.00

Annex 3

FENAMIDONE (264) International Estimated Daily Intake (IEDI) ADI = 0–0.03 mg/kg bw

			STMR	Diets: g/person/day			Intake = daily intake: µg/person						
Codex Code	Commodity description	Expr as	mg/kg	G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
–	–	–	–	–	–	–	–	–	–	–	–	–	–
	Total intake (µg/person) =				336.9		259.1		646.1		354.8		302.6
	Bodyweight per region (kg bw) =				60		60		60		60		60
	ADI (µg/person) =				1800		1800		1800		1800		1800
	%ADI =				18.7%		14.4%		35.9%		19.7%		16.8%
	Rounded %ADI =				20%		10%		40%		20%		20%

Annex 3

FENPROPATHRIN (185) International Estimated Daily Intake (IEDI) ADI = 0 - 0.03 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day						Intake as µg/person/day					
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
FC 0001	Citrus fruit, raw (incl citrus fruit juice)	RAC	0.33	34.91	11.52	16.51	5.45	17.23	5.69	104.48	34.48	35.57	11.74	98.49	32.50
FP 0009	Pome fruits, raw (incl. apple juice, incl cider)	RAC	0.73	19.79	14.45	38.25	27.92	17.96	13.11	32.56	23.77	8.08	5.90	64.45	47.05
FS 0013	Cherries, raw	RAC	1.85	0.92	1.70	9.15	16.93	0.10	0.19	0.61	1.13	0.10	0.19	6.64	12.28
FS 0014	Plums, raw (excl jujube)	RAC	0.25	2.40	0.60	8.60	2.15	0.10	0.03	2.52	0.63	0.58	0.15	4.16	1.04
DF 0014	Plum, dried (prunes)	PP	0.64	0.10	0.06	0.10	0.06	0.10	0.06	0.18	0.12	0.10	0.06	0.10	0.06
FS 2001	Peaches, nectarines, apricots, raw	RAC	0.71	7.50	5.33	4.98	3.54	0.18	0.13	7.33	5.20	1.59	1.13	21.11	14.99
FB 0275	Strawberry, raw	RAC	0.515	0.70	0.36	2.01	1.04	0.10	0.05	1.36	0.70	0.37	0.19	2.53	1.30
-	Peppers, chili, dried	PP	2.59	0.42	1.09	0.53	1.37	0.84	2.18	0.50	1.30	0.95	2.46	0.37	0.96
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.37	4.49	1.66	6.44	2.38	7.21	2.67	5.68	2.10	9.52	3.52	8.92	3.30
VO 0448	Tomato, raw	RAC	0.19	41.73	7.93	75.65	14.37	10.66	2.03	82.87	15.75	24.75	4.70	200.93	38.18
-	Tomato, canned (& peeled)	PP	0.021	0.20	0.00	0.31	0.01	0.10	0.00	1.11	0.02	0.11	0.00	1.50	0.03
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.145	2.34	0.34	1.33	0.19	1.57	0.23	4.24	0.61	0.34	0.05	2.83	0.41
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.023	0.29	0.01	0.29	0.01	0.10	0.00	0.38	0.01	0.10	0.00	0.14	0.00
VD 0541	Soya bean, dry, raw (incl paste, incl curd, incl oil, incl sauce)	RAC	0.01	72.79	0.73	59.05	0.59	20.55	0.21	74.20	0.74	61.12	0.61	73.24	0.73
TN 0085	Tree nuts, raw (incl processed)	RAC	0.01	4.06	0.04	3.27	0.03	7.01	0.07	13.93	0.14	14.01	0.14	9.36	0.09
SB 0716	Coffee beans raw (incl roasted, incl instant coffee, incl substitutes)	RAC	0.01	1.36	0.01	3.59	0.04	1.44	0.01	5.18	0.05	2.02	0.02	1.70	0.02
DT 1114	Tea, green or black, fermented and dried	RAC	0.14	2.28	0.32	1.92	0.27	0.46	0.06	2.40	0.34	1.29	0.18	3.04	0.43
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.001	24.96	0.02	57.95	0.06	16.70	0.02	38.38	0.04	26.46	0.03	29.00	0.03
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.018	6.24	0.11	14.49	0.26	4.18	0.08	9.60	0.17	6.62	0.12	7.25	0.13
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.018	3.29	0.06	6.14	0.11	0.82	0.01	1.57	0.03	2.23	0.04	1.07	0.02
MO 0105	Edible offal (mammalian), raw	RAC	0.002	4.79	0.01	9.68	0.02	2.97	0.01	5.49	0.01	3.84	0.01	5.03	0.01
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.002	289.65	0.58	485.88	0.97	26.92	0.05	239.03	0.48	199.91	0.40	180.53	0.36
PM 0110	Poultry meat, raw (incl prepared) - 90% as muscle	RAC	0	13.17	0.00	26.78	0.00	7.24	0.00	116.71	0.00	22.54	0.00	32.09	0.00
PM 0110	Poultry meat, raw (incl prepared) - 10% as fat	RAC	0	1.46	0.00	2.98	0.00	0.80	0.00	12.97	0.00	2.50	0.00	3.57	0.00
PF 0111	Poultry fat, raw (incl rendered)	RAC	0	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.10	0.00	0.10	0.00
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0	0.12	0.00	0.12	0.00	0.11	0.00	5.37	0.00	0.24	0.00	0.10	0.00
PE 0112	Eggs, raw, (incl dried)	RAC	0	7.84	0.00	23.08	0.00	2.88	0.00	14.89	0.00	9.81	0.00	14.83	0.00
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (µg/person)=				46.9		77.8		26.9		87.8		31.6		153.9
	Bodyweight per region (kg bw) =				60		60		60		60		60		60

Annex 3

FENPROPATHRIN (185) International Estimated Daily Intake (IEDI) ADI = 0 - 0.03 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day G01 diet	Intake as µg/person/day G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
	ADI (µg/person)=				1800		1800		1800		1800		1800		1800
	%ADI=				2.6%		4.3%		1.5%		4.9%		1.8%		8.6%
	Rounded %ADI=				3%		4%		1%		5%		2%		9%

FENPROPATHRIN (185) International Estimated Daily Intake (IEDI) ADI = 0 - 0.03 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day G07 diet	Intake as µg/person/day G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
FC 0001	Citrus fruit, raw (incl citrus fruit juice)	RAC	0.33	114.42	37.76	62.91	20.76	26.97	8.90	96.72	31.92	96.22	31.75	563.19	185.85
FP 0009	Pome fruits, raw (incl. apple juice, incl cider)	RAC	0.73	71.38	52.11	81.73	59.66	42.91	31.32	58.89	42.99	103.85	75.81	12.48	9.11
FS 0013	Cherries, raw	RAC	1.85	1.40	2.59	4.21	7.79	0.10	0.19	2.93	5.42	1.50	2.78	NC	-
FS 0014	Plums, raw (excl jujube)	RAC	0.25	3.75	0.94	3.33	0.83	5.94	1.49	2.64	0.66	2.50	0.63	0.10	0.03
DF 0014	Plum, dried (prunes)	PP	0.64	0.61	0.39	0.35	0.22	0.10	0.06	0.35	0.22	0.49	0.31	0.13	0.08
FS 2001	Peaches, nectarines, apricots, raw	RAC	0.71	10.82	7.68	15.31	10.87	8.28	5.88	11.82	8.39	4.08	2.90	0.10	0.07
FB 0275	Strawberry, raw	RAC	0.515	4.49	2.31	5.66	2.91	0.10	0.05	6.63	3.41	5.75	2.96	0.10	0.05
-	Peppers, chili, dried	PP	2.59	0.11	0.28	0.21	0.54	0.36	0.93	0.21	0.54	0.25	0.65	0.15	0.39
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.37	0.82	0.30	1.53	0.57	10.85	4.01	4.59	1.70	1.84	0.68	2.00	0.74
VO 0448	Tomato, raw	RAC	0.19	32.13	6.10	51.27	9.74	34.92	6.63	73.37	13.94	15.15	2.88	8.88	1.69
-	Tomato, canned (& peeled)	PP	0.021	7.57	0.16	2.66	0.06	0.30	0.01	0.97	0.02	7.31	0.15	0.41	0.01
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.145	4.96	0.72	3.20	0.46	0.15	0.02	1.61	0.23	6.88	1.00	0.52	0.08
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.023	0.80	0.02	0.10	0.00	0.10	0.00	0.61	0.01	0.40	0.01	0.10	0.00
VD 0541	Soya bean, dry, raw (incl paste, incl curd, incl oil, incl sauce)	RAC	0.01	106.33	1.06	117.78	1.18	42.12	0.42	195.70	1.96	222.52	2.23	80.47	0.80
TN 0085	Tree nuts, raw (incl processed)	RAC	0.01	8.52	0.09	8.94	0.09	15.09	0.15	9.60	0.10	14.57	0.15	26.26	0.26
SB 0716	Coffee beans raw (incl roasted, incl instant coffee, incl substitutes)	RAC	0.01	10.90	0.11	12.44	0.12	0.77	0.01	9.48	0.09	22.07	0.22	8.15	0.08
DT 1114	Tea, green or black, fermented and dried	RAC	0.14	2.71	0.38	0.82	0.11	1.14	0.16	1.59	0.22	1.82	0.25	0.53	0.07
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.001	112.02	0.11	120.71	0.12	63.46	0.06	88.99	0.09	96.24	0.10	41.02	0.04
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.018	28.01	0.50	30.18	0.54	15.86	0.29	22.25	0.40	24.06	0.43	10.25	0.18
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.018	6.44	0.12	15.51	0.28	3.79	0.07	8.29	0.15	18.44	0.33	8.00	0.14
MO 0105	Edible offal (mammalian), raw	RAC	0.002	15.17	0.03	5.19	0.01	6.30	0.01	6.78	0.01	3.32	0.01	3.17	0.01

Annex 3

FENPROPATHRIN (185) International Estimated Daily Intake (IEDI) ADI = 0 - 0.03 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day G07 diet	Intake as µg/person/day G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.002	388.92	0.78	335.88	0.67	49.15	0.10	331.25	0.66	468.56	0.94	245.45	0.49
PM 0110	Poultry meat, raw (incl prepared) - 90% as muscle	RAC	0	66.38	0.00	48.47	0.00	21.58	0.00	78.41	0.00	48.04	0.00	76.01	0.00
PM 0110	Poultry meat, raw (incl prepared) - 10% as fat	RAC	0	7.38	0.00	5.39	0.00	2.40	0.00	8.71	0.00	5.34	0.00	8.45	0.00
PF 0111	Poultry fat, raw (incl rendered)	RAC	0	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.71	0.00	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0	0.33	0.00	0.72	0.00	0.27	0.00	0.35	0.00	0.80	0.00	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0	25.84	0.00	29.53	0.00	28.05	0.00	33.19	0.00	36.44	0.00	8.89	0.00
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (µg/person)=				114.5		117.6		60.8		113.2		127.2		200.2
	Bodyweight per region (kg bw) =				60		60		55		60		60		60
	ADI (µg/person)=				1800		1800		1650		1800		1800		1800
	%ADI=				6.4%		6.5%		3.7%		6.3%		7.1%		11.1%
	Rounded %ADI=				6%		7%		4%		6%		7%		10%

FENPROPATHRIN (185) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0300 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day G13 diet	Intake = daily intake: µg/person G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
FC 0001	Citrus fruit, raw (incl citrus fruit juice)	RAC	0.33	21.16	6.98	2.94	0.97	58.52	19.31	0.44	0.15	5.13	1.69
FP 0009	Pome fruits, raw (incl. apple juice, incl cider)	RAC	0.73	68.89	50.29	11.06	8.07	80.62	58.85	189.82	138.57	19.56	14.28
FS 0013	Cherries, raw	RAC	1.85	0.10	0.19	0.10	0.19	5.96	11.03	0.10	0.19	NC	-
FS 0014	Plums, raw (excl jujube)	RAC	0.25	0.10	0.03	0.10	0.03	15.56	3.89	0.10	0.03	NC	-
DF 0014	Plum, dried (prunes)	PP	0.64	0.10	0.06	0.10	0.06	0.37	0.24	0.10	0.06	NC	-
FS 2001	Peaches, nectarines, apricots, raw	RAC	0.71	0.10	0.07	0.10	0.07	9.93	7.05	0.10	0.07	NC	-
FB 0275	Strawberry, raw	RAC	0.515	0.10	0.05	0.10	0.05	3.35	1.73	0.10	0.05	0.10	0.05
-	Peppers, chili, dried	PP	2.59	0.58	1.50	1.27	3.29	1.21	3.13	0.12	0.31	NC	-
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.37	5.49	2.03	10.57	3.91	8.84	3.27	0.91	0.34	NC	-
VO 0448	Tomato, raw	RAC	0.19	12.99	2.47	4.79	0.91	58.40	11.10	0.92	0.17	0.10	0.02
-	Tomato, canned (& peeled)	PP	0.021	0.10	0.00	0.10	0.00	2.42	0.05	0.10	0.00	NC	-
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.145	0.58	0.08	0.22	0.03	2.21	0.32	0.24	0.03	3.10	0.45
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.023	0.10	0.00	0.10	0.00	0.42	0.01	0.10	0.00	0.10	0.00
VD 0541	Soya bean, dry, raw (incl paste, incl curd, incl oil, incl sauce)	RAC	0.01	15.80	0.16	14.29	0.14	104.36	1.04	17.11	0.17	35.20	0.35
TN 0085	Tree nuts, raw (incl processed)	RAC	0.01	4.39	0.04	135.53	1.36	6.11	0.06	0.72	0.01	317.74	3.18
SB 0716	Coffee beans raw (incl roasted, incl instant coffee, incl substitutes)	RAC	0.01	0.95	0.01	1.32	0.01	11.64	0.12	2.96	0.03	14.73	0.15
DT 1114	Tea, green or black, fermented and dried	RAC	0.14	0.53	0.07	5.25	0.74	0.63	0.09	0.56	0.08	0.82	0.11

Annex 3

FENPROPATHRIN (185) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0300 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day G13 diet	Intake = daily intake: µg/person G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.001	23.34	0.02	40.71	0.04	97.15	0.10	18.06	0.02	57.71	0.06
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.018	5.84	0.11	10.18	0.18	24.29	0.44	4.52	0.08	14.43	0.26
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.018	1.05	0.02	1.14	0.02	18.69	0.34	0.94	0.02	3.12	0.06
MO 0105	Edible offal (mammalian), raw	RAC	0.002	4.64	0.01	1.97	0.00	10.01	0.02	3.27	0.01	3.98	0.01
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.002	108.75	0.22	70.31	0.14	436.11	0.87	61.55	0.12	79.09	0.16
PM 0110	Poultry meat, raw (incl prepared) - 90% as muscle	RAC	0	3.53	0.00	10.83	0.00	51.36	0.00	4.53	0.00	50.00	0.00
PM 0110	Poultry meat, raw (incl prepared) - 10% as fat	RAC	0	0.39	0.00	1.20	0.00	5.71	0.00	0.50	0.00	5.56	0.00
PF 0111	Poultry fat, raw (incl rendered)	RAC	0	NC	-	NC	-	0.32	0.00	NC	-	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0	0.10	0.00	0.70	0.00	0.97	0.00	0.10	0.00	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0	3.84	0.00	4.41	0.00	27.25	0.00	1.13	0.00	7.39	0.00
-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (µg/person)=				64.4		20.2		123.0		140.5		20.8
	Bodyweight per region (kg bw) =				60		60		60		60		60
	ADI (µg/person)=				1800		1800		1800		1800		1800
	%ADI=				3.6%		1.1%		6.8%		7.8%		1.2%
	Rounded %ADI=				4%		1%		7%		8%		1%

Annex 3

BSA from FLUENSULFONE (265) International Estimated Daily Intake (IEDI) ADI = 0 - 0.01 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day G01 diet	Intake as µg/person/day G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
VC 0045	Fruiting vegetables, cucurbits, raw	RAC	0.032	53.14	1.70	86.21	2.76	6.28	0.20	92.76	2.97	15.64	0.50	155.30	4.97
VO 0050	Fruiting vegetables other than cucurbits, raw, (incl processed commodities), excl tomato commodities, excl sweet corn commodities, excl mushroom commodities	RAC	0.045	18.97	0.85	21.73	0.98	20.61	0.93	27.35	1.23	35.54	1.60	50.62	2.28
VO 0448	Tomato, raw (incl juice, incl canned, excl paste)	RAC	0.045	42.41	1.91	76.50	3.44	10.69	0.48	85.07	3.83	24.98	1.12	203.44	9.15
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.081	2.34	0.19	1.33	0.11	1.57	0.13	4.24	0.34	0.34	0.03	2.83	0.23
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (µg/person)=				4.7		7.3		1.7		8.4		3.3		16.6
	Bodyweight per region (kg bw) =				60		60		60		60		60		60
	ADI (µg/person)=				600		600		600		600		600		600
	%ADI=				0.8%		1.2%		0.3%		1.4%		0.5%		2.8%
	Rounded %ADI=				1%		1%		0%		1%		1%		3%

BSA from FLUENSULFONE (265) International Estimated Daily Intake (IEDI) ADI = 0 - 0.01 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day G07 diet	Intake as µg/person/day G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
VC 0045	Fruiting vegetables, cucurbits, raw	RAC	0.032	27.81	0.89	41.93	1.34	123.30	3.95	49.47	1.58	15.95	0.51	35.99	1.15
VO 0050	Fruiting vegetables other than cucurbits, raw, (incl processed commodities), excl tomato commodities, excl sweet corn commodities, excl mushroom commodities	RAC	0.045	8.19	0.37	18.68	0.84	42.99	1.93	15.04	0.68	11.46	0.52	6.30	0.28
VO 0448	Tomato, raw (incl juice, incl canned, excl paste)	RAC	0.045	44.88	2.02	55.49	2.50	35.44	1.59	75.65	3.40	27.00	1.22	9.61	0.43
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.081	4.96	0.40	3.20	0.26	0.15	0.01	1.61	0.13	6.88	0.56	0.52	0.04
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (µg/person)=				3.7		4.9		7.5		5.8		2.8		1.9
	Bodyweight per region (kg bw) =				60		60		55		60		60		60
	ADI (µg/person)=				600		600		550		600		600		600
	%ADI=				0.6%		0.8%		1.4%		1.0%		0.5%		0.3%
	Rounded %ADI=				1%		1%		1%		1%		0%		0%

Annex 3

BSA from FLUENSULFONE (265) International Estimated Daily Intake (IEDI) ADI = 0 - 0.01 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day	Intake = daily intake: µg/person								
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
VC 0045	Fruiting vegetables, cucurbits, raw	RAC	0.032	5.96	0.19	9.74	0.31	51.82	1.66	13.61	0.44	0.10	0.00
VO 0050	Fruiting vegetables other than cucurbits, raw, (incl processed commodities), excl tomato commodities, excl sweet corn commodities, excl mushroom commodities	RAC	0.045	20.58	0.93	31.41	1.41	37.56	1.69	1.79	0.08	NC	-
VO 0448	Tomato, raw (incl juice, incl canned, excl paste)	RAC	0.045	13.17	0.59	4.92	0.22	62.69	2.82	1.04	0.05	0.11	0.00
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.081	0.58	0.05	0.22	0.02	2.21	0.18	0.24	0.02	3.10	0.25
-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (µg/person)=				1.8		2.0		6.3		0.6		0.3
	Bodyweight per region (kg bw) =				60		60		60		60		60
	ADI (µg/person)=				600		600		600		600		600
	%ADI=				0.3%		0.3%		1.1%		0.1%		0.0%
	Rounded %ADI=				0%		0%		1%		0%		0%

Annex 3

FLUFENOXURON (275) International Estimated Daily Intake (IEDI) ADI = 0–0.04 mg/kg bw

			STMR	Diets as g/person/day			Intake as µg/person/day								
Codex Code	Commodity description	Expr as	mg/kg	G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
FC 0004	Oranges, sweet, sour, raw (incl orange juice)	RAC	0.05	23.26	1.16	9.71	0.49	12.09	0.60	62.02	3.10	22.09	1.10	59.91	3.00
DT 1114	Tea, green or black, fermented and dried, (including concentrates)	RAC	0.04	2.28	0.09	1.98	0.08	0.46	0.02	2.43	0.10	1.29	0.05	3.04	0.12
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)	RAC	0	31.20	0.00	72.44	0.00	20.88	0.00	47.98	0.00	33.08	0.00	36.25	0.00
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0	3.29	0.00	6.14	0.00	0.82	0.00	1.57	0.00	2.23	0.00	1.07	0.00
MO 0105	Edible offal (mammalian), raw	RAC	0	4.79	0.00	9.68	0.00	2.97	0.00	5.49	0.00	3.84	0.00	5.03	0.00
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0	289.65	0.00	485.88	0.00	26.92	0.00	239.03	0.00	199.91	0.00	180.53	0.00
–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
	Total intake (µg/person)=				1.3		0.6		0.6		3.2		1.2		3.1
	Bodyweight per region (kg bw) =				60		60		60		60		60		60
	ADI (µg/person)=				2400		2400		2400		2400		2400		2400
	%ADI=				0.1%		0.0%		0.0%		0.1%		0.0%		0.1%
	Rounded %ADI=				0%		0%		0%		0%		0%		0%

FLUFENOXURON (275) International Estimated Daily Intake (IEDI) ADI = 0–0.04 mg/kg bw

			STMR	Diets as g/person/day			Intake as µg/person/day								
Codex Code	Commodity description	Expr as	mg/kg	G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
FC 0004	Oranges, sweet, sour, raw (incl orange juice)	RAC	0.05	83.66	4.18	27.64	1.38	7.37	0.37	67.80	3.39	43.97	2.20	187.74	9.39
DT 1114	Tea, green or black, fermented and dried, (including concentrates)	RAC	0.04	2.91	0.12	1.73	0.07	1.14	0.05	1.85	0.07	2.29	0.09	0.74	0.03
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)	RAC	0	140.03	0.00	150.89	0.00	79.32	0.00	111.24	0.00	120.30	0.00	51.27	0.00
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0	6.44	0.00	15.51	0.00	3.79	0.00	8.29	0.00	18.44	0.00	8.00	0.00
MO 0105	Edible offal (mammalian), raw	RAC	0	15.17	0.00	5.19	0.00	6.30	0.00	6.78	0.00	3.32	0.00	3.17	0.00
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0	388.92	0.00	335.88	0.00	49.15	0.00	331.25	0.00	468.56	0.00	245.45	0.00

Annex 3

FLUFENOXURON (275) International Estimated Daily Intake (IEDI) ADI = 0–0.04 mg/kg bw

			STMR	Diets as g/person/day			Intake as µg/person/day								
Codex Code	Commodity description	Expr as	mg/kg	G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
	Total intake (µg/person)=				4.3		1.5		0.4		3.5		2.3		9.4
	Bodyweight per region (kg bw) =				60		60		55		60		60		60
	ADI (µg/person)=				2400		2400		2200		2400		2400		2400
	%ADI=				0.2%		0.1%		0.0%		0.1%		0.1%		0.4%
	Rounded %ADI=				0%		0%		0%		0%		0%		0%

FLUFENOXURON (275) International Estimated Daily Intake (IEDI) ADI = 0–0.04 mg/kg bw

			STMR	Diets: g/person/day			Intake = daily intake: µg/person						
Codex Code	Commodity description	Expr as	mg/kg	G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
FC 0004	Oranges, sweet, sour, raw (incl orange juice)	RAC	0.05	1.34	0.07	1.65	0.08	40.03	2.00	0.33	0.02	1.76	0.09
DT 1114	Tea, green or black, fermented and dried, (including concentrates)	RAC	0.04	0.53	0.02	5.25	0.21	0.86	0.03	0.56	0.02	0.88	0.04
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)	RAC	0	29.18	0.00	50.89	0.00	121.44	0.00	22.58	0.00	72.14	0.00
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0	1.05	0.00	1.14	0.00	18.69	0.00	0.94	0.00	3.12	0.00
MO 0105	Edible offal (mammalian), raw	RAC	0	4.64	0.00	1.97	0.00	10.01	0.00	3.27	0.00	3.98	0.00
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0	108.75	0.00	70.31	0.00	436.11	0.00	61.55	0.00	79.09	0.00
–	–	–	–	–	–	–	–	–	–	–	–	–	–
	Total intake (µg/person)=				0.1		0.3		2.0		0.0		0.1
	Bodyweight per region (kg bw) =				60		60		60		60		60
	ADI (µg/person)=				2400		2400		2400		2400		2400
	%ADI=				0.0%		0.0%		0.1%		0.0%		0.0%
	Rounded %ADI=				0%		0%		0%		0%		0%

Annex 3

FLUOPYRAM (243) International Estimated Daily Intake (IEDI) ADI = 0–0.01 mg/kg bw

			STMR	Diets as g/person/day			Intake as µg/person/day								
Codex Code	Commodity description	Expr as	mg/kg	G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
FP 0226	Apple, raw (incl cider, excl juice)	RAC	0.135	13.49	1.82	26.63	3.60	15.05	2.03	16.28	2.20	6.47	0.87	47.88	6.46
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.01	0.32	0.00	3.07	0.03	0.10	0.00	5.00	0.05	0.29	0.00	5.57	0.06
FP 0228	Loquat, raw (incl processed)	RAC	0.135	0.59	0.08	0.36	0.05	0.46	0.06	1.88	0.25	NC	–	1.15	0.16
FP 0229	Medlar, raw (incl processed)	RAC	0.135	0.47	0.06	0.29	0.04	0.36	0.05	1.49	0.20	NC	–	0.92	0.12
FP 0230	Pear, raw	RAC	0.135	2.16	0.29	6.24	0.84	0.10	0.01	4.07	0.55	1.16	0.16	5.34	0.72
FP 0307	Persimmon, Japanese, raw	RAC	0.135	1.91	0.26	0.10	0.01	1.94	0.26	1.96	0.26	NC	–	0.25	0.03
FP 0231	Quince, raw	RAC	0.135	0.73	0.10	0.54	0.07	0.10	0.01	0.10	0.01	0.10	0.01	1.31	0.18
FS 0013	Cherries, raw	RAC	0.205	0.92	0.19	9.15	1.88	0.10	0.02	0.61	0.13	0.10	0.02	6.64	1.36
FS 0014	Plums, raw (excl jujube)	RAC	0.13	2.40	0.31	8.60	1.12	0.10	0.01	2.52	0.33	0.58	0.08	4.16	0.54
DF 0014	Plum, dried (prunes)	PP	0.14	0.10	0.01	0.10	0.01	0.10	0.01	0.18	0.03	0.10	0.01	0.10	0.01
FS 2001	Peaches, nectarines, apricots, raw (incl dried apricots)	RAC	0.22	8.01	1.76	5.87	1.29	0.18	0.04	8.19	1.80	1.64	0.36	22.46	4.94
FB 0264	Blackberries, raw	RAC	0.7	0.35	0.25	0.11	0.08	0.10	0.07	0.10	0.07	0.10	0.07	1.23	0.86
FB 0272	Raspberries, red, black, raw	RAC	0.7	0.10	0.07	0.93	0.65	0.10	0.07	0.10	0.07	0.10	0.07	0.10	0.07
FB 0269	Grape, raw (incl must, excl dried, excl juice, excl wine)	RAC	0.58	13.02	7.55	9.25	5.37	0.10	0.06	16.91	9.81	3.70	2.15	54.44	31.58
DF 0269	Grape, dried (= currants, raisins and sultanas)	PP	1.68	0.51	0.86	0.51	0.86	0.10	0.17	1.27	2.13	0.12	0.20	2.07	3.48
JF 0269	Grape juice	PP	0.012	0.14	0.00	0.29	0.00	0.10	0.00	0.30	0.00	0.24	0.00	0.10	0.00
–	Grape wine (incl vermouths)	PP	0.1	0.67	0.07	12.53	1.25	2.01	0.20	1.21	0.12	3.53	0.35	4.01	0.40
FB 0275	Strawberry, raw	RAC	0.025	0.70	0.02	2.01	0.05	0.10	0.00	1.36	0.03	0.37	0.01	2.53	0.06
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.175	5.06	0.89	6.91	1.21	37.17	6.50	31.16	5.45	40.21	7.04	18.96	3.32
VA 0381	Garlic, raw	RAC	0.01	2.29	0.02	5.78	0.06	0.11	0.00	3.69	0.04	1.65	0.02	3.91	0.04
VA 0384	Leek, raw	RAC	0.01	0.18	0.00	1.59	0.02	0.10	0.00	0.28	0.00	0.10	0.00	3.21	0.03
–	Onions, mature bulbs, dry	RAC	0.01	29.36	0.29	37.50	0.38	3.56	0.04	34.78	0.35	18.81	0.19	43.38	0.43
VB 0041	Cabbages, head, raw	RAC	0.01	2.73	0.03	27.92	0.28	0.55	0.01	4.47	0.04	4.27	0.04	10.25	0.10
VB 0400	Broccoli, raw	RAC	0.05	0.88	0.04	0.17	0.01	0.10	0.01	1.25	0.06	3.00	0.15	1.09	0.05
VB 0402	Brussels sprouts, raw	RAC	0.06	0.63	0.04	6.41	0.38	0.13	0.01	1.03	0.06	NC	–	2.35	0.14
VB 0404	Cauliflower, raw	RAC	0.01	1.65	0.02	0.32	0.00	0.10	0.00	2.33	0.02	4.79	0.05	2.03	0.02
VC 0424	Cucumber, raw	RAC	0.11	8.01	0.88	30.66	3.37	1.45	0.16	19.84	2.18	0.27	0.03	34.92	3.84
VO 0444	Peppers, chilli, raw	RAC	0.085	3.99	0.34	7.30	0.62	2.93	0.25	5.62	0.48	NC	–	17.44	1.48
–	Peppers, chilli, dried	PP	0.85	0.42	0.36	0.53	0.45	0.84	0.71	0.50	0.43	0.95	0.81	0.37	0.31
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.085	4.49	0.38	6.44	0.55	7.21	0.61	5.68	0.48	9.52	0.81	8.92	0.76
VO 0448	Tomato, raw	RAC	0.09	41.73	3.76	75.65	6.81	10.66	0.96	82.87	7.46	24.75	2.23	200.93	18.08
–	Tomato, canned (& peeled)	PP	0.02	0.20	0.00	0.31	0.01	0.10	0.00	1.11	0.02	0.11	0.00	1.50	0.03
–	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.04	2.34	0.09	1.33	0.05	1.57	0.06	4.24	0.17	0.34	0.01	2.83	0.11
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.03	0.29	0.01	0.29	0.01	0.10	0.00	0.38	0.01	0.10	0.00	0.14	0.00

Annex 3

FLUOPYRAM (243) International Estimated Daily Intake (IEDI) ADI = 0–0.01 mg/kg bw

			STMR	Diets as g/person/day			Intake as µg/person/day								
Codex Code	Commodity description	Expr as	mg/kg	G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
VL 0482	Lettuce, head, raw	RAC	2.2	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
VL 0483	Lettuce, leaf, raw	RAC	2.2	0.53	1.17	0.36	0.79	0.16	0.35	6.21	13.66	1.90	4.18	6.05	13.31
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	0.01	2.39	0.02	1.61	0.02	10.47	0.10	1.84	0.02	12.90	0.13	7.44	0.07
VD 0524	Chick-pea, dry, raw (Cicer arietinum)	RAC	0.01	5.34	0.05	0.13	0.00	0.10	0.00	4.69	0.05	7.24	0.07	5.52	0.06
VD 0533	Lentil, dry, raw (Ervum lens)	RAC	0.01	2.12	0.02	0.10	0.00	0.10	0.00	3.21	0.03	1.60	0.02	4.90	0.05
VR 0577	Carrots, raw	RAC	0.09	9.51	0.86	30.78	2.77	0.37	0.03	8.75	0.79	2.80	0.25	6.10	0.55
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.01	59.74	0.60	316.14	3.16	9.78	0.10	60.26	0.60	54.12	0.54	119.82	1.20
VR 0596	Sugar beet, raw	RAC	0.01	NC	–	NC	–	NC	–	NC	–	0.10	0.00	NC	–
–	Sugar beet, sugar	PP	0.01	0.10	0.00	NC	–	0.10	0.00	0.10	0.00	0.10	0.00	12.63	0.13
TN 0085	Tree nuts, raw (incl processed)	RAC	0.01	4.06	0.04	3.27	0.03	7.01	0.07	13.93	0.14	14.01	0.14	9.36	0.09
SO 0495	Rape seed, raw	RAC	0.33	0.10	0.03	NC	–	NC	–	0.10	0.03	0.75	0.25	0.10	0.03
SO 0697	Peanuts, nutmeat, raw (incl roasted, excl oil, excl butter)	RAC	0.01	0.46	0.00	1.21	0.01	6.64	0.07	2.52	0.03	1.25	0.01	1.83	0.02
OR 0697	Peanut oil, edible	PP	0.0001	0.36	0.00	0.10	0.00	2.57	0.00	0.10	0.00	2.29	0.00	0.36	0.00
–	Peanut butter	PP	0.002	0.10	0.00	0.10	0.00	0.10	0.00	0.19	0.00	0.10	0.00	0.10	0.00
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)—80% as muscle	RAC	0.05	24.96	1.25	57.95	2.90	16.70	0.84	38.38	1.92	26.46	1.32	29.00	1.45
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)—20% as fat	RAC	0.06	6.24	0.37	14.49	0.87	4.18	0.25	9.60	0.58	6.62	0.40	7.25	0.44
MO 0105	Edible offal (mammalian), raw	RAC	0.58	4.79	2.78	9.68	5.61	2.97	1.72	5.49	3.18	3.84	2.23	5.03	2.92
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.05	289.65	14.48	485.88	24.29	26.92	1.35	239.03	11.95	199.91	10.00	180.53	9.03
PM 0110	Poultry meat, raw (incl prepared)—90% as muscle	RAC	0.01	13.17	0.13	26.78	0.27	7.24	0.07	116.71	1.17	22.54	0.23	32.09	0.32
PM 0110	Poultry meat, raw (incl prepared)—10% as fat	RAC	0.01	1.46	0.01	2.98	0.03	0.80	0.01	12.97	0.13	2.50	0.03	3.57	0.04
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.02	0.12	0.00	0.12	0.00	0.11	0.00	5.37	0.11	0.24	0.00	0.10	0.00
PE 0112	Eggs, raw, (incl dried)	RAC	0.008	7.84	0.06	23.08	0.18	2.88	0.02	14.89	0.12	9.81	0.08	14.83	0.12
–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
	Total intake (µg/person)=				42.7		72.3		17.4		69.8		35.6		109.6
	Bodyweight per region (kg bw) =				60		60		60		60		60		60
	ADI (µg/person)=				600		600		600		600		600		600
	%ADI=				7.1%		12.1%		2.9%		11.6%		5.9%		18.3%
	Rounded %ADI=				7%		10%		3%		10%		6%		20%

Annex 3

FLUOPYRAM (243) International Estimated Daily Intake (IEDI) ADI = 0–0.01 mg/kg bw

			STMR	Diets as g/person/day			Intake as µg/person/day								
Codex Code	Commodity description	Expr as	mg/kg	G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
FP 0226	Apple, raw (incl cider, excl juice)	RAC	0.135	41.14	5.55	56.49	7.63	26.64	3.60	31.58	4.26	51.94	7.01	3.05	0.41
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.01	14.88	0.15	11.98	0.12	0.15	0.00	9.98	0.10	30.32	0.30	3.47	0.03
FP 0228	Loquat, raw (incl processed)	RAC	0.135	0.96	0.13	NC	–	NC	–	3.92	0.53	NC	–	2.49	0.34
FP 0229	Medlar, raw (incl processed)	RAC	0.135	NC	–	NC	–	NC	–	NC	–	NC	–	1.98	0.27
FP 0230	Pear, raw	RAC	0.135	8.79	1.19	8.44	1.14	12.37	1.67	9.60	1.30	10.27	1.39	0.23	0.03
FP 0307	Persimmon, Japanese, raw	RAC	0.135	0.10	0.01	0.30	0.04	3.59	0.48	0.15	0.02	0.10	0.01	NC	–
FP 0231	Quince, raw	RAC	0.135	0.19	0.03	0.18	0.02	0.11	0.01	0.10	0.01	0.28	0.04	NC	–
FS 0013	Cherries, raw	RAC	0.205	1.40	0.29	4.21	0.86	0.10	0.02	2.93	0.60	1.50	0.31	NC	–
FS 0014	Plums, raw (excl jujube)	RAC	0.13	3.75	0.49	3.33	0.43	5.94	0.77	2.64	0.34	2.50	0.33	0.10	0.01
DF 0014	Plum, dried (prunes)	PP	0.14	0.61	0.09	0.35	0.05	0.10	0.01	0.35	0.05	0.49	0.07	0.13	0.02
FS 2001	Peaches, nectarines, apricots, raw (incl dried apricots)	RAC	0.22	13.03	2.87	16.29	3.58	8.29	1.82	12.95	2.85	5.35	1.18	0.10	0.02
FB 0264	Blackberries, raw	RAC	0.7	0.10	0.07	0.52	0.36	0.14	0.10	0.24	0.17	NC	–	0.10	0.07
FB 0272	Raspberries, red, black, raw	RAC	0.7	0.47	0.33	0.91	0.64	0.10	0.07	0.99	0.69	1.14	0.80	NC	–
FB 0269	Grape, raw (incl must, excl dried, excl juice, excl wine)	RAC	0.58	6.48	3.76	11.31	6.56	5.21	3.02	9.50	5.51	4.66	2.70	0.78	0.45
DF 0269	Grape, dried (= currants, raisins and sultanas)	PP	1.68	3.09	5.19	1.51	2.54	0.10	0.17	1.38	2.32	4.26	7.16	0.42	0.71
JF 0269	Grape juice	PP	0.012	0.56	0.01	1.96	0.02	0.10	0.00	2.24	0.03	2.27	0.03	0.34	0.00
–	Grape wine (incl vermouths)	PP	0.1	88.93	8.89	62.41	6.24	1.84	0.18	25.07	2.51	61.17	6.12	5.84	0.58
FB 0275	Strawberry, raw	RAC	0.025	4.49	0.11	5.66	0.14	0.10	0.00	6.63	0.17	5.75	0.14	0.10	0.00
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.175	25.14	4.40	23.37	4.09	23.06	4.04	23.40	4.10	18.44	3.23	39.29	6.88
VA 0381	Garlic, raw	RAC	0.01	0.98	0.01	1.49	0.01	12.88	0.13	3.74	0.04	2.05	0.02	1.14	0.01
VA 0384	Leek, raw	RAC	0.01	4.01	0.04	4.41	0.04	0.72	0.01	0.54	0.01	16.41	0.16	0.10	0.00
–	Onions, mature bulbs, dry	RAC	0.01	19.69	0.20	29.83	0.30	24.64	0.25	31.35	0.31	9.72	0.10	12.59	0.13
VB 0041	Cabbages, head, raw	RAC	0.01	8.97	0.09	27.12	0.27	1.44	0.01	24.96	0.25	4.55	0.05	11.23	0.11
VB 0400	Broccoli, raw	RAC	0.05	4.24	0.21	1.76	0.09	NC	–	0.51	0.03	3.79	0.19	0.26	0.01
VB 0402	Brussels sprouts, raw	RAC	0.06	2.24	0.13	2.67	0.16	6.23	0.37	0.32	0.02	4.19	0.25	2.58	0.15
VB 0404	Cauliflower, raw	RAC	0.01	5.27	0.05	5.01	0.05	NC	–	2.70	0.03	5.57	0.06	0.49	0.00
VC 0424	Cucumber, raw	RAC	0.11	6.72	0.74	11.03	1.21	32.10	3.53	15.10	1.66	4.05	0.45	9.57	1.05
VO 0444	Peppers, chilli, raw	RAC	0.085	5.57	0.47	14.00	1.19	8.25	0.70	5.77	0.49	6.44	0.55	2.53	0.22
–	Peppers, chilli, dried	PP	0.85	0.11	0.09	0.21	0.18	0.36	0.31	0.21	0.18	0.25	0.21	0.15	0.13
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.085	0.82	0.07	1.53	0.13	10.85	0.92	4.59	0.39	1.84	0.16	2.00	0.17
VO 0448	Tomato, raw	RAC	0.09	32.13	2.89	51.27	4.61	34.92	3.14	73.37	6.60	15.15	1.36	8.88	0.80
–	Tomato, canned (& peeled)	PP	0.02	7.57	0.15	2.66	0.05	0.30	0.01	0.97	0.02	7.31	0.15	0.41	0.01
–	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.04	4.96	0.20	3.20	0.13	0.15	0.01	1.61	0.06	6.88	0.28	0.52	0.02

Annex 3

FLUOPYRAM (243) International Estimated Daily Intake (IEDI) ADI = 0–0.01 mg/kg bw

			STMR	Diets as g/person/day			Intake as µg/person/day								
Codex Code	Commodity description	Expr as	mg/kg	G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.03	0.80	0.02	0.10	0.00	0.10	0.00	0.61	0.02	0.40	0.01	0.10	0.00
VL 0482	Lettuce, head, raw	RAC	2.2	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
VL 0483	Lettuce, leaf, raw	RAC	2.2	14.50	31.90	11.76	25.87	13.14	28.91	19.50	42.90	4.81	10.58	2.23	4.91
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	0.01	1.51	0.02	1.50	0.02	1.90	0.02	5.11	0.05	1.36	0.01	23.43	0.23
VD 0524	Chick-pea, dry, raw (Cicer arietinum)	RAC	0.01	0.27	0.00	1.33	0.01	0.32	0.00	0.15	0.00	0.10	0.00	0.10	0.00
VD 0533	Lentil, dry, raw (Ervum lens)	RAC	0.01	0.95	0.01	1.18	0.01	0.40	0.00	0.96	0.01	0.71	0.01	1.28	0.01
VR 0577	Carrots, raw	RAC	0.09	26.26	2.36	27.13	2.44	10.07	0.91	16.49	1.48	44.69	4.02	8.75	0.79
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.01	225.03	2.25	234.24	2.34	71.48	0.71	177.55	1.78	234.55	2.35	37.71	0.38
VR 0596	Sugar beet, raw	RAC	0.01	0.10	0.00	NC	–	0.10	0.00	0.10	0.00	NC	–	NC	–
–	Sugar beet, sugar	PP	0.01	0.10	0.00	NC	–	0.10	0.00	NC	–	NC	–	NC	–
TN 0085	Tree nuts, raw (incl processed)	RAC	0.01	8.52	0.09	8.94	0.09	15.09	0.15	9.60	0.10	14.57	0.15	26.26	0.26
SO 0495	Rape seed, raw	RAC	0.33	NC	–	NC	–	0.10	0.03	NC	–	NC	–	NC	–
SO 0697	Peanuts, nutmeat, raw (incl roasted, excl oil, excl butter)	RAC	0.01	3.19	0.03	2.19	0.02	5.36	0.05	4.82	0.05	1.40	0.01	1.06	0.01
OR 0697	Peanut oil, edible	PP	0.0001	1.02	0.00	0.23	0.00	1.81	0.00	0.42	0.00	5.23	0.00	0.10	0.00
–	Peanut butter	PP	0.002	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00	0.15	0.00	0.75	0.00
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)—80% as muscle	RAC	0.05	112.02	5.60	120.71	6.04	63.46	3.17	88.99	4.45	96.24	4.81	41.02	2.05
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)—20% as fat	RAC	0.06	28.01	1.68	30.18	1.81	15.86	0.95	22.25	1.33	24.06	1.44	10.25	0.62
MO 0105	Edible offal (mammalian), raw	RAC	0.58	15.17	8.80	5.19	3.01	6.30	3.65	6.78	3.93	3.32	1.93	3.17	1.84
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.05	388.92	19.45	335.88	16.79	49.15	2.46	331.25	16.56	468.56	23.43	245.45	12.27
PM 0110	Poultry meat, raw (incl prepared)–90% as muscle	RAC	0.01	66.38	0.66	48.47	0.48	21.58	0.22	78.41	0.78	48.04	0.48	76.01	0.76
PM 0110	Poultry meat, raw (incl prepared)–10% as fat	RAC	0.01	7.38	0.07	5.39	0.05	2.40	0.02	8.71	0.09	5.34	0.05	8.45	0.08
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.02	0.33	0.01	0.72	0.01	0.27	0.01	0.35	0.01	0.80	0.02	NC	–
PE 0112	Eggs, raw, (incl dried)	RAC	0.008	25.84	0.21	29.53	0.24	28.05	0.22	33.19	0.27	36.44	0.29	8.89	0.07
–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
	Total intake (µg/person)=				112.1		102.2		66.9		109.4		84.4		36.9
	Bodyweight per region (kg bw) =				60		60		55		60		60		60
	ADI (µg/person)=				600		600		550		600		600		600
	%ADI=				18.7%		17.0%		12.2%		18.2%		14.1%		6.2%
	Rounded %ADI=				20%		20%		10%		20%		10%		6%

Annex 3

FLUOPYRAM (243) International Estimated Daily Intake (IEDI) ADI = 0–0.01 mg/kg bw

			STMR	Diets: g/person/day			Intake = daily intake: µg/person						
Codex Code	Commodity description	Expr as	mg/kg	G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
FP 0226	Apple, raw (incl cider, excl juice)	RAC	0.135	66.67	9.00	2.06	0.28	55.83	7.54	188.29	25.42	1.38	0.19
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.01	0.10	0.00	0.10	0.00	7.19	0.07	0.10	0.00	NC	–
FP 0228	Loquat, raw (incl processed)	RAC	0.135	0.94	0.13	4.68	0.63	NC	–	0.50	0.07	3.08	0.42
FP 0229	Medlar, raw (incl processed)	RAC	0.135	0.75	0.10	3.73	0.50	4.87	0.66	0.40	0.05	2.45	0.33
FP 0230	Pear, raw	RAC	0.135	0.10	0.01	0.14	0.02	9.45	1.28	0.10	0.01	0.14	0.02
FP 0307	Persimmon, Japanese, raw	RAC	0.135	0.41	0.06	0.32	0.04	0.10	0.01	0.58	0.08	12.51	1.69
FP 0231	Quince, raw	RAC	0.135	NC	–	NC	–	0.65	0.09	NC	–	NC	–
FS 0013	Cherries, raw	RAC	0.205	0.10	0.02	0.10	0.02	5.96	1.22	0.10	0.02	NC	–
FS 0014	Plums, raw (excl jujube)	RAC	0.13	0.10	0.01	0.10	0.01	15.56	2.02	0.10	0.01	NC	–
DF 0014	Plum, dried (prunes)	PP	0.14	0.10	0.01	0.10	0.01	0.37	0.05	0.10	0.01	NC	–
FS 2001	Peaches, nectarines, apricots, raw (incl dried apricots)	RAC	0.22	0.10	0.02	0.10	0.02	10.76	2.37	0.10	0.02	NC	–
FB 0264	Blackberries, raw	RAC	0.7	0.10	0.07	7.29	5.10	0.25	0.18	0.10	0.07	NC	–
FB 0272	Raspberries, red, black, raw	RAC	0.7	0.10	0.07	0.10	0.07	2.04	1.43	0.10	0.07	NC	–
FB 0269	Grape, raw (incl must, excl dried, excl juice, excl wine)	RAC	0.58	0.14	0.08	0.36	0.21	15.33	8.89	0.10	0.06	0.28	0.16
DF 0269	Grape, dried (= currants, raisins and sultanas)	PP	1.68	0.10	0.17	0.13	0.22	1.06	1.78	0.10	0.17	0.10	0.17
JF 0269	Grape juice	PP	0.012	0.10	0.00	0.10	0.00	0.41	0.00	0.10	0.00	NC	–
–	Grape wine (incl vermouths)	PP	0.1	0.31	0.03	0.23	0.02	60.43	6.04	0.52	0.05	31.91	3.19
FB 0275	Strawberry, raw	RAC	0.025	0.10	0.00	0.10	0.00	3.35	0.08	0.10	0.00	0.10	0.00
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.175	20.88	3.65	81.15	14.20	24.58	4.30	37.92	6.64	310.23	54.29
VA 0381	Garlic, raw	RAC	0.01	0.82	0.01	2.06	0.02	3.79	0.04	0.10	0.00	0.29	0.00
VA 0384	Leek, raw	RAC	0.01	0.10	0.00	1.44	0.01	1.22	0.01	0.10	0.00	NC	–
–	Onions, mature bulbs, dry	RAC	0.01	9.01	0.09	20.24	0.20	30.90	0.31	9.61	0.10	2.11	0.02
VB 0041	Cabbages, head, raw	RAC	0.01	3.82	0.04	2.99	0.03	49.16	0.49	0.10	0.00	NC	–
VB 0400	Broccoli, raw	RAC	0.05	0.10	0.01	0.10	0.01	2.13	0.11	0.10	0.01	NC	–
VB 0402	Brussels sprouts, raw	RAC	0.06	0.88	0.05	0.69	0.04	2.89	0.17	0.10	0.01	NC	–
VB 0404	Cauliflower, raw	RAC	0.01	0.10	0.00	0.10	0.00	2.73	0.03	0.10	0.00	NC	–
VC 0424	Cucumber, raw	RAC	0.11	0.68	0.07	1.81	0.20	10.40	1.14	0.10	0.01	0.10	0.01
VO 0444	Peppers, chilli, raw	RAC	0.085	3.47	0.29	3.56	0.30	16.30	1.39	0.10	0.01	NC	–
–	Peppers, chilli, dried	PP	0.85	0.58	0.49	1.27	1.08	1.21	1.03	0.12	0.10	NC	–
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.085	5.49	0.47	10.57	0.90	8.84	0.75	0.91	0.08	NC	–
VO 0448	Tomato, raw	RAC	0.09	12.99	1.17	4.79	0.43	58.40	5.26	0.92	0.08	0.10	0.01
–	Tomato, canned (& peeled)	PP	0.02	0.10	0.00	0.10	0.00	2.42	0.05	0.10	0.00	NC	–
–	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.04	0.58	0.02	0.22	0.01	2.21	0.09	0.24	0.01	3.10	0.12
JF 0448	Tomato, juice (single strength, incl	PP	0.03	0.10	0.00	0.10	0.00	0.42	0.01	0.10	0.00	0.10	0.00

Annex 3

FLUOPYRAM (243) International Estimated Daily Intake (IEDI) ADI = 0–0.01 mg/kg bw

			STMR	Diets: g/person/day			Intake = daily intake: µg/person						
Codex Code	Commodity description	Expr as	mg/kg	G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
	concentrated)												
VL 0482	Lettuce, head, raw	RAC	2.2	NC	–	NC	–	NC	–	NC	–	NC	–
VL 0483	Lettuce, leaf, raw	RAC	2.2	0.29	0.64	0.10	0.22	6.71	14.76	0.10	0.22	NC	–
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	0.01	7.11	0.07	2.33	0.02	3.76	0.04	44.70	0.45	3.27	0.03
VD 0524	Chick-pea, dry, raw (Cicer arietinum)	RAC	0.01	1.09	0.01	1.56	0.02	0.33	0.00	0.18	0.00	0.47	0.00
VD 0533	Lentil, dry, raw (Ervum lens)	RAC	0.01	0.67	0.01	7.26	0.07	0.37	0.00	0.10	0.00	NC	–
VR 0577	Carrots, raw	RAC	0.09	2.07	0.19	3.00	0.27	25.29	2.28	0.10	0.01	NC	–
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.01	23.96	0.24	13.56	0.14	213.41	2.13	104.35	1.04	8.56	0.09
VR 0596	Sugar beet, raw	RAC	0.01	0.10	0.00	NC	–	NC	–	NC	–	NC	–
–	Sugar beet, sugar	PP	0.01	0.56	0.01	0.24	0.00	NC	–	NC	–	5.13	0.05
TN 0085	Tree nuts, raw (incl processed)	RAC	0.01	4.39	0.04	135.53	1.36	6.11	0.06	0.72	0.01	317.74	3.18
SO 0495	Rape seed, raw	RAC	0.33	NC	–	0.10	0.03	NC	–	NC	–	NC	–
SO 0697	Peanuts, nutmeat, raw (incl roasted, excl oil, excl butter)	RAC	0.01	7.14	0.07	0.42	0.00	1.83	0.02	6.22	0.06	0.53	0.01
OR 0697	Peanut oil, edible	PP	0.0001	5.02	0.00	0.10	0.00	0.17	0.00	0.29	0.00	NC	–
–	Peanut butter	PP	0.002	0.10	0.00	0.10	0.00	0.10	0.00	NC	–	NC	–
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)—80% as muscle	RAC	0.05	23.34	1.17	40.71	2.04	97.15	4.86	18.06	0.90	57.71	2.89
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)—20% as fat	RAC	0.06	5.84	0.35	10.18	0.61	24.29	1.46	4.52	0.27	14.43	0.87
MO 0105	Edible offal (mammalian), raw	RAC	0.58	4.64	2.69	1.97	1.14	10.01	5.81	3.27	1.90	3.98	2.31
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.05	108.75	5.44	70.31	3.52	436.11	21.81	61.55	3.08	79.09	3.95
PM 0110	Poultry meat, raw (incl prepared)—90% as muscle	RAC	0.01	3.53	0.04	10.83	0.11	51.36	0.51	4.53	0.05	50.00	0.50
PM 0110	Poultry meat, raw (incl prepared)—10% as fat	RAC	0.01	0.39	0.00	1.20	0.01	5.71	0.06	0.50	0.01	5.56	0.06
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.02	0.10	0.00	0.70	0.01	0.97	0.02	0.10	0.00	NC	–
PE 0112	Eggs, raw, (incl dried)	RAC	0.008	3.84	0.03	4.41	0.04	27.25	0.22	1.13	0.01	7.39	0.06
–	–	–	–	–	–	–	–	–	–	–	–	–	–
	Total intake (µg/person)=				27.2		34.2		102.9		41.2		74.6
	Bodyweight per region (kg bw) =				60		60		60		60		60
	ADI (µg/person)=				600		600		600		600		600
	%ADI=				4.5%		5.7%		17.2%		6.9%		12.4%
	Rounded %ADI=				5%		6%		20%		7%		10%

Annex 3

IMAZAMOX (276) International Estimated Daily Intake (IEDI) ADI = 0 - 3.0 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day			Intake as µg/person/day								
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
VP 0061	Beans, green, with pods, raw: beans except broad bean & soya bean (i.e. immature seeds + pods) (Phaseolus spp)	RAC	0	0.68	0.00	NC	-	NC	-	0.39	0.00	0.22	0.00	0.49	0.00
VP 0064	Peas, green, without pods, raw (i.e. immature seeds only) (Pisum spp)	RAC	0	1.97	0.00	0.51	0.00	0.10	0.00	0.79	0.00	3.68	0.00	3.80	0.00
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	0	2.39	0.00	1.61	0.00	10.47	0.00	1.84	0.00	12.90	0.00	7.44	0.00
VD 0071	Peas, dry, raw (Pisum spp, Vigna spp): garden peas & field peas & cow peas	RAC	0	1.67	0.00	3.22	0.00	2.66	0.00	1.51	0.00	2.91	0.00	0.24	0.00
VD 0533	Lentil, dry, raw (Ervum lens)	RAC	0.1	2.12	0.21	0.10	0.01	0.10	0.01	3.21	0.32	1.60	0.16	4.90	0.49
VD 0541	Soya bean, dry, raw (incl paste, incl curd, incl oil, incl sauce)	RAC	0	72.79	0.00	59.05	0.00	20.55	0.00	74.20	0.00	61.12	0.00	73.24	0.00
VD 0541	Soya bean, dry, raw (incl flour, incl paste, incl curd, incl oil, excl sauce)	RAC	0	72.79	0.00	59.05	0.00	20.55	0.00	74.06	0.00	61.11	0.00	73.23	0.00
CM 0649 (GC 0649)	Rice, husked, dry (incl polished, incl flour, incl starch, incl oil, incl beverages)	REP	0.025	45.40	1.14	14.99	0.37	84.88	2.12	111.73	2.79	194.75	4.87	93.12	2.33
GC 0654	Wheat, raw (incl meslin)	RAC	0.1	0.10	0.01	1.12	0.11	NC	-	0.10	0.01	0.56	0.06	NC	-
CF 1210	Wheat, germ	PP	0.22	NC	-	NC	-	0.10	0.02	0.10	0.02	0.14	0.03	0.10	0.02
CF 0654	Wheat, bran	PP	0.34	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
CF 1211	Wheat, white flour	PP	0.12	299.27	35.91	263.32	31.60	27.93	3.35	214.18	25.70	133.47	16.02	340.03	40.80
SO 0495	Rape seed, raw	RAC	0	0.10	0.00	NC	-	NC	-	0.10	0.00	0.75	0.00	0.10	0.00
SO 0697	Peanuts, nutmeat, raw (incl roasted, incl oil, incl butter)	RAC	0	1.30	0.00	1.23	0.00	12.62	0.00	2.87	0.00	6.59	0.00	2.67	0.00
SO 0702	Sunflower seed, raw	RAC	0.19	0.10	0.02	0.33	0.06	0.10	0.02	0.24	0.05	0.10	0.02	0.10	0.02
OR 0702	Sunflower seed oil, edible	PP	0.1	2.97	0.30	14.42	1.44	0.43	0.04	3.46	0.35	2.20	0.22	5.53	0.55
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)	RAC	0	31.20	0.00	72.44	0.00	20.88	0.00	47.98	0.00	33.08	0.00	36.25	0.00
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0	3.29	0.00	6.14	0.00	0.82	0.00	1.57	0.00	2.23	0.00	1.07	0.00
MO 0105	Edible offal (mammalian), raw	RAC	0	4.79	0.00	9.68	0.00	2.97	0.00	5.49	0.00	3.84	0.00	5.03	0.00
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0	289.65	0.00	485.88	0.00	26.92	0.00	239.03	0.00	199.91	0.00	180.53	0.00
PM 0110	Poultry meat, raw (incl prepared)	RAC	0	14.63	0.00	29.76	0.00	8.04	0.00	129.68	0.00	25.04	0.00	35.66	0.00
PF 0111	Poultry fat, raw (incl rendered)	RAC	0	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.10	0.00	0.10	0.00
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0	0.12	0.00	0.12	0.00	0.11	0.00	5.37	0.00	0.24	0.00	0.10	0.00
PE 0112	Eggs, raw, (incl dried)	RAC	0	7.84	0.00	23.08	0.00	2.88	0.00	14.89	0.00	9.81	0.00	14.83	0.00
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (µg/person)=				37.6		33.6		5.6		29.2		21.4		44.2
	Bodyweight per region (kg bw) =				60		60		60		60		60		60
	ADI (µg/person)=				180000		180000		180000		180000		180000		180000

Annex 3

IMAZAMOX (276) International Estimated Daily Intake (IEDI) ADI = 0 - 3.0 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day G01 diet	Intake as µg/person/day G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
	%ADI=				0.0%		0.0%		0.0%		0.0%		0.0%		0.0%
	Rounded %ADI=				0%		0%		0%		0%		0%		0%

IMAZAMOX (276) International Estimated Daily Intake (IEDI) ADI = 0 - 3.0 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day G07 diet	Intake as µg/person/day G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
VP 0061	Beans, green, with pods, raw: beans except broad bean & soya bean (i.e. immature seeds + pods) (Phaseolus spp)	RAC	0	5.07	0.00	0.83	0.00	0.17	0.00	3.70	0.00	NC	-	NC	-
VP 0064	Peas, green, without pods, raw (i.e. immature seeds only) (Pisum spp)	RAC	0	10.72	0.00	1.99	0.00	2.72	0.00	4.26	0.00	4.23	0.00	NC	-
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	0	1.51	0.00	1.50	0.00	1.90	0.00	5.11	0.00	1.36	0.00	23.43	0.00
VD 0071	Peas, dry, raw (Pisum spp, Vigna spp): garden peas & field peas & cow peas	RAC	0	3.80	0.00	1.25	0.00	1.06	0.00	2.33	0.00	2.70	0.00	3.83	0.00
VD 0533	Lentil, dry, raw (Ervum lens)	RAC	0.1	0.95	0.10	1.18	0.12	0.40	0.04	0.96	0.10	0.71	0.07	1.28	0.13
VD 0541	Soya bean, dry, raw (incl paste, incl curd, incl oil, incl sauce)	RAC	0	106.33	0.00	117.78	0.00	42.12	0.00	195.70	0.00	222.52	0.00	80.47	0.00
VD 0541	Soya bean, dry, raw (incl flour, incl paste, incl curd, incl oil, excl sauce)	RAC	0	106.15	0.00	117.67	0.00	40.94	0.00	193.94	0.00	222.48	0.00	80.19	0.00
CM 0649 (GC 0649)	Rice, husked, dry (incl polished, incl flour, incl starch, incl oil, incl beverages)	REP	0.025	20.96	0.52	16.04	0.40	339.67	8.49	75.51	1.89	16.86	0.42	86.13	2.15
GC 0654	Wheat, raw (incl meslin)	RAC	0.1	NC	-	NC	-	NC	-	0.10	0.01	NC	-	NC	-
CF 1210	Wheat, germ	PP	0.22	0.97	0.21	0.10	0.02	0.10	0.02	0.10	0.02	NC	-	0.10	0.02
CF 0654	Wheat, bran	PP	0.34	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
CF 1211	Wheat, white flour	PP	0.12	182.77	21.93	187.54	22.50	103.82	12.46	180.42	21.65	164.00	19.68	118.84	14.26
SO 0495	Rape seed, raw	RAC	0	NC	-	NC	-	0.10	0.00	NC	-	NC	-	NC	-
SO 0697	Peanuts, nutmeat, raw (incl roasted, incl oil, incl butter)	RAC	0	5.63	0.00	2.75	0.00	9.58	0.00	5.82	0.00	13.71	0.00	1.84	0.00
SO 0702	Sunflower seed, raw	RAC	0.19	0.10	0.02	1.32	0.25	0.10	0.02	1.17	0.22	NC	-	0.10	0.02
OR 0702	Sunflower seed oil, edible	PP	0.1	9.50	0.95	11.37	1.14	0.49	0.05	5.15	0.52	2.63	0.26	2.80	0.28
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)	RAC	0	140.03	0.00	150.89	0.00	79.32	0.00	111.24	0.00	120.30	0.00	51.27	0.00
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0	6.44	0.00	15.51	0.00	3.79	0.00	8.29	0.00	18.44	0.00	8.00	0.00
MO 0105	Edible offal (mammalian), raw	RAC	0	15.17	0.00	5.19	0.00	6.30	0.00	6.78	0.00	3.32	0.00	3.17	0.00

Annex 3

IMAZAMOX (276) International Estimated Daily Intake (IEDI) ADI = 0 - 3.0 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day G07 diet	Intake as µg/person/day G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0	388.92	0.00	335.88	0.00	49.15	0.00	331.25	0.00	468.56	0.00	245.45	0.00
PM 0110	Poultry meat, raw (incl prepared)	RAC	0	73.76	0.00	53.86	0.00	23.98	0.00	87.12	0.00	53.38	0.00	84.45	0.00
PF 0111	Poultry fat, raw (incl rendered)	RAC	0	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.71	0.00	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0	0.33	0.00	0.72	0.00	0.27	0.00	0.35	0.00	0.80	0.00	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0	25.84	0.00	29.53	0.00	28.05	0.00	33.19	0.00	36.44	0.00	8.89	0.00
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (µg/person)=				23.7		24.4		21.1		24.4		20.4		16.9
	Bodyweight per region (kg bw) =				60		60		55		60		60		60
	ADI (µg/person)=				180000		180000		165000		180000		180000		180000
	%ADI=				0.0%		0.0%		0.0%		0.0%		0.0%		0.0%
	Rounded %ADI=				0%		0%		0%		0%		0%		0%

IMAZAMOX (276) International Estimated Daily Intake (IEDI) ADI = 0 - 3.0 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day G13 diet	Intake = daily intake: µg/person G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
VP 0061	Beans, green, with pods, raw: beans except broad bean & soya bean (i.e. immature seeds + pods) (Phaseolus spp)	RAC	0	NC	-	NC	-	NC	-	NC	-	NC	-
VP 0064	Peas, green, without pods, raw (i.e. immature seeds only) (Pisum spp)	RAC	0	0.21	0.00	0.10	0.00	5.51	0.00	0.10	0.00	NC	-
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	0	7.11	0.00	2.33	0.00	3.76	0.00	44.70	0.00	3.27	0.00
VD 0071	Peas, dry, raw (Pisum spp, Vigna spp): garden peas & field peas & cow peas	RAC	0	14.30	0.00	3.51	0.00	3.52	0.00	7.89	0.00	0.74	0.00
VD 0533	Lentil, dry, raw (Ervum lens)	RAC	0.1	0.67	0.07	7.26	0.73	0.37	0.04	0.10	0.01	NC	-
VD 0541	Soya bean, dry, raw (incl paste, incl curd, incl oil, incl sauce)	RAC	0	15.80	0.00	14.29	0.00	104.36	0.00	17.11	0.00	35.20	0.00
VD 0541	Soya bean, dry, raw (incl flour, incl paste, incl curd, incl oil, excl sauce)	RAC	0	15.80	0.00	14.24	0.00	104.29	0.00	17.11	0.00	34.98	0.00
CM 0649 (GC 0649)	Rice, husked, dry (incl polished, incl flour, incl starch, incl oil, incl beverages)	REP	0.025	52.55	1.31	286.02	7.15	18.64	0.47	19.67	0.49	75.09	1.88
GC 0654	Wheat, raw (incl meslin)	RAC	0.1	NC	-	NC	-	NC	-	NC	-	0.97	0.10
CF 1210	Wheat, germ	PP	0.22	0.10	0.02	0.10	0.02	0.10	0.02	0.10	0.02	NC	-
CF 0654	Wheat, bran	PP	0.34	NC	-	NC	-	NC	-	NC	-	NC	-
CF 1211	Wheat, white flour	PP	0.12	43.75	5.25	85.81	10.30	206.68	24.80	19.38	2.33	92.92	11.15
SO 0495	Rape seed, raw	RAC	0	NC	-	0.10	0.00	NC	-	NC	-	NC	-

Annex 3

IMAZAMOX (276) International Estimated Daily Intake (IEDI) ADI = 0 - 3.0 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day G13 diet	Intake = daily intake: µg/person G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
SO 0697	Peanuts, nutmeat, raw (incl roasted, incl oil, incl butter)	RAC	0	18.82	0.00	0.57	0.00	2.28	0.00	6.90	0.00	0.53	0.00
SO 0702	Sunflower seed, raw	RAC	0.19	0.10	0.02	0.10	0.02	0.10	0.02	2.23	0.42	NC	-
OR 0702	Sunflower seed oil, edible	PP	0.1	0.37	0.04	0.10	0.01	12.98	1.30	4.01	0.40	0.20	0.02
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)	RAC	0	29.18	0.00	50.89	0.00	121.44	0.00	22.58	0.00	72.14	0.00
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0	1.05	0.00	1.14	0.00	18.69	0.00	0.94	0.00	3.12	0.00
MO 0105	Edible offal (mammalian), raw	RAC	0	4.64	0.00	1.97	0.00	10.01	0.00	3.27	0.00	3.98	0.00
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0	108.75	0.00	70.31	0.00	436.11	0.00	61.55	0.00	79.09	0.00
PM 0110	Poultry meat, raw (incl prepared)	RAC	0	3.92	0.00	12.03	0.00	57.07	0.00	5.03	0.00	55.56	0.00
PF 0111	Poultry fat, raw (incl rendered)	RAC	0	NC	-	NC	-	0.32	0.00	NC	-	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0	0.10	0.00	0.70	0.00	0.97	0.00	0.10	0.00	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0	3.84	0.00	4.41	0.00	27.25	0.00	1.13	0.00	7.39	0.00
-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (µg/person)=				6.7		18.2		26.6		3.7		13.1
	Bodyweight per region (kg bw) =				60		60		60		60		60
	ADI (µg/person)=				180000		180000		180000		180000		180000
	%ADI=				0.0%		0.0%		0.0%		0.0%		0.0%
	Rounded %ADI=				0%		0%		0%		0%		0%

Annex 3

MESOTRIONE (277) International Estimated Daily Intake (IEDI) ADI = 0 - 0.5 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day			Intake as µg/person/day								
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
FB 2005	Caneberries, raw	RAC	0	0.42	0.00	1.05	0.00	0.10	0.00	0.10	0.00	0.10	0.00	1.24	0.00
FB 0264	Blackberries, raw	RAC	0	0.35	0.00	0.11	0.00	0.10	0.00	0.10	0.00	0.10	0.00	1.23	0.00
FB 0265	Cranberries, raw	RAC	0	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.10	0.00	0.10	0.00
VO 0442	Okra, raw	RAC	0.01	1.97	0.02	NC	-	3.68	0.04	3.24	0.03	5.72	0.06	1.57	0.02
VD 0541	Soya bean, dry, raw (Glycine soja)	RAC	0.01	0.58	0.01	0.10	0.00	0.37	0.00	0.10	0.00	1.65	0.02	0.30	0.00
-	Soya paste (i.e. miso)	PP	0.002	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
-	Soya curd (i.e. tofu)	PP	0.002	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
OR 0541	Soya oil, refined	PP	0.002	12.99	0.03	10.43	0.02	3.63	0.01	13.10	0.03	10.70	0.02	13.10	0.03
-	Soya sauce	PP	0.002	0.10	0.00	0.10	0.00	0.10	0.00	0.34	0.00	0.10	0.00	0.10	0.00
-	Soya flour	PP	0.018	0.10	0.00	0.86	0.02	0.10	0.00	1.02	0.02	0.10	0.00	0.15	0.00
VS 0621	Asparagus	RAC	0.01	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00	0.21	0.00
VS 0627	Rhubarb	RAC	0.01	0.73	0.01	1.30	0.01	0.80	0.01	1.95	0.02	NC	-	0.94	0.01
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl flour, incl oil, incl beer, incl germ, incl starch)	RAC	0	29.81	0.00	44.77	0.00	108.95	0.00	52.37	0.00	60.28	0.00	75.69	0.00
GC 0646	Millet, raw (incl flour, incl beer)	RAC	0	1.46	0.00	2.32	0.00	5.84	0.00	0.89	0.00	16.17	0.00	0.10	0.00
GC 0647	Oats, raw (incl rolled)	RAC	0	0.10	0.00	7.05	0.00	0.10	0.00	1.71	0.00	0.96	0.00	0.10	0.00
CM 0649 (GC 0649)	Rice, husked, dry (incl polished, incl flour, incl starch, incl oil, incl beverages)	REP	0	45.40	0.00	14.99	0.00	84.88	0.00	111.73	0.00	194.75	0.00	93.12	0.00
GC 0651	Sorghum, raw (incl flour, incl beer)	RAC	0	4.34	0.00	0.10	0.00	16.25	0.00	15.82	0.00	10.97	0.00	2.92	0.00
GS 0659	Sugar cane, raw (incl sugar, incl molasses)	RAC	0	99.68	0.00	86.27	0.00	31.38	0.00	80.36	0.00	84.18	0.00	99.10	0.00
SO 0693	Linseed, raw (incl oil)	RAC	0.01	0.10	0.00	NC	-	NC	-	0.10	0.00	0.13	0.00	NC	-
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)	RAC	0	31.20	0.00	72.44	0.00	20.88	0.00	47.98	0.00	33.08	0.00	36.25	0.00
MO 0105	Edible offal (mammalian), raw	RAC	0	4.79	0.00	9.68	0.00	2.97	0.00	5.49	0.00	3.84	0.00	5.03	0.00
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0	289.65	0.00	485.88	0.00	26.92	0.00	239.03	0.00	199.91	0.00	180.53	0.00
PM 0110	Poultry meat, raw (incl prepared)	RAC	0	14.63	0.00	29.76	0.00	8.04	0.00	129.68	0.00	25.04	0.00	35.66	0.00
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0	0.12	0.00	0.12	0.00	0.11	0.00	5.37	0.00	0.24	0.00	0.10	0.00
PE 0112	Eggs, raw, (incl dried)	RAC	0	7.84	0.00	23.08	0.00	2.88	0.00	14.89	0.00	9.81	0.00	14.83	0.00
	Total intake (µg/person)=				0.1		0.1		0.1		0.1		0.1		0.1
	Bodyweight per region (kg bw) =				60		60		60		60		60		60
	ADI (µg/person)=				30000		30000		30000		30000		30000		30000
	%ADI=				0.0%		0.0%		0.0%		0.0%		0.0%		0.0%
	Rounded %ADI=				0%		0%		0%		0%		0%		0%

Annex 3

MESOTRIONE (277) International Estimated Daily Intake (IEDI) ADI = 0 - 0.5 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day											
				Intake as µg/person/day											
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
FB 2005	Caneberries, raw	RAC	0	0.56	0.00	1.43	0.00	0.14	0.00	1.23	0.00	1.14	0.00	0.10	0.00
FB 0264	Blackberries, raw	RAC	0	0.10	0.00	0.52	0.00	0.14	0.00	0.24	0.00	NC	-	0.10	0.00
FB 0265	Cranberries, raw	RAC	0	0.10	0.00	0.10	0.00	0.10	0.00	1.22	0.00	0.11	0.00	NC	-
VO 0442	Okra, raw	RAC	0.01	NC	-	NC	-	0.10	0.00	0.17	0.00	NC	-	0.72	0.01
VD 0541	Soya bean, dry, raw (Glycine soja)	RAC	0.01	0.10	0.00	0.33	0.00	6.64	0.07	3.94	0.04	NC	-	5.78	0.06
-	Soya paste (i.e. miso)	PP	0.002	NC	-	NC	-	NC	-	1.87	0.00	NC	-	NC	-
-	Soya curd (i.e. tofu)	PP	0.002	NC	-	NC	-	0.68	0.00	0.87	0.00	NC	-	NC	-
OR 0541	Soya oil, refined	PP	0.002	19.06	0.04	21.06	0.04	5.94	0.01	33.78	0.07	40.05	0.08	13.39	0.03
-	Soya sauce	PP	0.002	0.45	0.00	0.29	0.00	2.93	0.01	4.35	0.01	0.10	0.00	0.70	0.00
-	Soya flour	PP	0.018	0.22	0.00	0.27	0.00	0.29	0.01	0.17	0.00	NC	-	NC	-
VS 0621	Asparagus	RAC	0.01	0.84	0.01	2.08	0.02	7.11	0.07	1.01	0.01	1.69	0.02	0.10	0.00
VS 0627	Rhubarb	RAC	0.01	1.61	0.02	2.23	0.02	NC	-	0.52	0.01	7.63	0.08	1.39	0.01
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl flour, incl oil, incl beer, incl germ, incl starch)	RAC	0	18.51	0.00	26.18	0.00	26.04	0.00	39.99	0.00	7.36	0.00	64.58	0.00
GC 0646	Millet, raw (incl flour, incl beer)	RAC	0	0.10	0.00	0.16	0.00	1.75	0.00	0.69	0.00	NC	-	NC	-
GC 0647	Oats, raw (incl rolled)	RAC	0	7.50	0.00	6.26	0.00	0.15	0.00	4.87	0.00	3.16	0.00	2.98	0.00
CM 0649 (GC 0649)	Rice, husked, dry (incl polished, incl flour, incl starch, incl oil, incl beverages)	REP	0	20.96	0.00	16.04	0.00	339.67	0.00	75.51	0.00	16.86	0.00	86.13	0.00
GC 0651	Sorghum, raw (incl flour, incl beer)	RAC	0	NC	-	NC	-	1.44	0.00	1.15	0.00	NC	-	7.12	0.00
GS 0659	Sugar cane, raw (incl sugar, incl molasses)	RAC	0	92.24	0.00	95.72	0.00	28.47	0.00	77.39	0.00	117.73	0.00	103.90	0.00
SO 0693	Linseed, raw (incl oil)	RAC	0.01	NC	-	NC	-	0.10	0.00	0.10	0.00	NC	-	NC	-
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)	RAC	0	140.03	0.00	150.89	0.00	79.32	0.00	111.24	0.00	120.30	0.00	51.27	0.00
MO 0105	Edible offal (mammalian), raw	RAC	0	15.17	0.00	5.19	0.00	6.30	0.00	6.78	0.00	3.32	0.00	3.17	0.00
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0	388.92	0.00	335.88	0.00	49.15	0.00	331.25	0.00	468.56	0.00	245.45	0.00
PM 0110	Poultry meat, raw (incl prepared)	RAC	0	73.76	0.00	53.86	0.00	23.98	0.00	87.12	0.00	53.38	0.00	84.45	0.00
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0	0.33	0.00	0.72	0.00	0.27	0.00	0.35	0.00	0.80	0.00	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0	25.84	0.00	29.53	0.00	28.05	0.00	33.19	0.00	36.44	0.00	8.89	0.00
	Total intake (µg/person)=				0.1		0.1		0.2		0.1		0.2		0.1
	Bodyweight per region (kg bw) =				60		60		55		60		60		60
	ADI (µg/person)=				30000		30000		27500		30000		30000		30000
	%ADI=				0.0%		0.0%		0.0%		0.0%		0.0%		0.0%
	Rounded %ADI=				0%		0%		0%		0%		0%		0%

Annex 3

MESOTRIONE (277) International Estimated Daily Intake (IEDI) ADI = 0 - 0.5 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day G13 diet	Intake = daily intake: µg/person G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
FB 2005	Caneberries, raw	RAC	0	0.10	0.00	7.30	0.00	2.29	0.00	0.10	0.00	NC	-
FB 0264	Blackberries, raw	RAC	0	0.10	0.00	7.29	0.00	0.25	0.00	0.10	0.00	NC	-
FB 0265	Cranberries, raw	RAC	0	NC	-	NC	-	0.10	0.00	NC	-	NC	-
VO 0442	Okra, raw	RAC	0.01	6.23	0.06	0.10	0.00	NC	-	NC	-	NC	-
VD 0541	Soya bean, dry, raw (Glycine soja)	RAC	0.01	2.76	0.03	0.10	0.00	0.33	0.00	3.16	0.03	NC	-
-	Soya paste (i.e. miso)	PP	0.002	NC	-	NC	-	NC	-	NC	-	NC	-
-	Soya curd (i.e. tofu)	PP	0.002	NC	-	NC	-	NC	-	NC	-	NC	-
OR 0541	Soya oil, refined	PP	0.002	2.32	0.00	2.54	0.01	18.70	0.04	2.51	0.01	6.29	0.01
-	Soya sauce	PP	0.002	0.10	0.00	0.13	0.00	0.17	0.00	0.10	0.00	0.56	0.00
-	Soya flour	PP	0.018	0.11	0.00	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00
VS 0621	Asparagus	RAC	0.01	0.10	0.00	0.10	0.00	0.17	0.00	0.10	0.00	NC	-
VS 0627	Rhubarb	RAC	0.01	1.26	0.01	0.91	0.01	0.96	0.01	0.85	0.01	1.70	0.02
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl flour, incl oil, incl beer, incl germ, incl starch)	RAC	0	116.66	0.00	10.52	0.00	38.46	0.00	76.60	0.00	34.44	0.00
GC 0646	Millet, raw (incl flour, incl beer)	RAC	0	61.13	0.00	0.78	0.00	NC	-	33.55	0.00	NC	-
GC 0647	Oats, raw (incl rolled)	RAC	0	0.37	0.00	0.10	0.00	2.79	0.00	0.10	0.00	NC	-
CM 0649 (GC 0649)	Rice, husked, dry (incl polished, incl flour, incl starch, incl oil, incl beverages)	REP	0	52.55	0.00	286.02	0.00	18.64	0.00	19.67	0.00	75.09	0.00
GC 0651	Sorghum, raw (incl flour, incl beer)	RAC	0	89.16	0.00	2.02	0.00	NC	-	35.38	0.00	NC	-
GS 0659	Sugar cane, raw (incl sugar, incl molasses)	RAC	0	33.75	0.00	106.29	0.00	78.09	0.00	29.09	0.00	45.70	0.00
SO 0693	Linseed, raw (incl oil)	RAC	0.01	0.10	0.00	NC	-	0.10	0.00	NC	-	NC	-
MM 0095	Meat from mammals other than marine mammals, raw (incl prepared meat)	RAC	0	29.18	0.00	50.89	0.00	121.44	0.00	22.58	0.00	72.14	0.00
MO 0105	Edible offal (mammalian), raw	RAC	0	4.64	0.00	1.97	0.00	10.01	0.00	3.27	0.00	3.98	0.00
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0	108.75	0.00	70.31	0.00	436.11	0.00	61.55	0.00	79.09	0.00
PM 0110	Poultry meat, raw (incl prepared)	RAC	0	3.92	0.00	12.03	0.00	57.07	0.00	5.03	0.00	55.56	0.00
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0	0.10	0.00	0.70	0.00	0.97	0.00	0.10	0.00	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0	3.84	0.00	4.41	0.00	27.25	0.00	1.13	0.00	7.39	0.00
	Total intake (µg/person)=				0.1		0.0		0.1		0.0		0.0
	Bodyweight per region (kg bw) =				60		60		60		60		60
	ADI (µg/person)=				30000		30000		30000		30000		30000
	%ADI=				0.0%		0.0%		0.0%		0.0%		0.0%
	Rounded %ADI=				0%		0%		0%		0%		0%

Annex 3

METRAFENONE (278) International Estimated Daily Intake (IEDI) ADI = 0 - 0.3 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day G01 diet	Intake as µg/person/day G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
FB 0269	Grape, raw	RAC	0.76	12.68	9.64	9.12	6.93	0.10	0.08	16.88	12.83	3.70	2.81	54.42	41.36
-	Grape must	PP	0.51	0.33	0.17	0.13	0.07	0.10	0.05	0.10	0.05	0.10	0.05	0.10	0.05
DF 0269	Grape, dried (= currants, raisins and sultanas)	PP	2.85	0.51	1.45	0.51	1.45	0.10	0.29	1.27	3.62	0.12	0.34	2.07	5.90
JF 0269	Grape juice	PP	0.038	0.14	0.01	0.29	0.01	0.10	0.00	0.30	0.01	0.24	0.01	0.10	0.00
-	Grape wine (incl vermouths)	PP	0.14	0.67	0.09	12.53	1.75	2.01	0.28	1.21	0.17	3.53	0.49	4.01	0.56
FB 0275	Strawberry, raw	RAC	0.13	0.70	0.09	2.01	0.26	0.10	0.01	1.36	0.18	0.37	0.05	2.53	0.33
VC 0424	Cucumber, raw	RAC	0.05	8.01	0.40	30.66	1.53	1.45	0.07	19.84	0.99	0.27	0.01	34.92	1.75
VC 0425	Gherkin, raw	RAC	0.05	1.73	0.09	6.64	0.33	0.31	0.02	4.29	0.21	0.29	0.01	7.56	0.38
VC 0431	Squash, summer, raw (= courgette, zuchini)	RAC	0.015	0.78	0.01	2.06	0.03	0.30	0.00	1.61	0.02	2.25	0.03	2.36	0.04
VO 0444	Peppers, chili, raw	RAC	0.115	3.99	0.46	7.30	0.84	2.93	0.34	5.62	0.65	NC	-	17.44	2.01
-	Peppers, chili, dried	PP	1.15	0.42	0.48	0.53	0.61	0.84	0.97	0.50	0.58	0.95	1.09	0.37	0.43
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.115	4.49	0.52	6.44	0.74	7.21	0.83	5.68	0.65	9.52	1.09	8.92	1.03
VO 0448	Tomato, raw	RAC	0.1	41.73	4.17	75.65	7.57	10.66	1.07	82.87	8.29	24.75	2.48	200.93	20.09
-	Tomato, canned (& peeled)	PP	0.002	0.20	0.00	0.31	0.00	0.10	0.00	1.11	0.00	0.11	0.00	1.50	0.00
-	Tomato, paste (i.e. conc tomato sauce/puree)	PP	0.039	2.34	0.09	1.33	0.05	1.57	0.06	4.24	0.17	0.34	0.01	2.83	0.11
JF 0448	Tomato, juice (incl concentrated)	PP	0.034	0.29	0.01	0.29	0.01	0.10	0.00	0.38	0.01	0.10	0.00	0.14	0.00
-	Mushrooms (cultivated & wild), raw (incl dried, excl canned)	RAC	0.105	0.10	0.01	0.18	0.02	0.10	0.01	0.78	0.08	0.10	0.01	0.30	0.03
-	Mushrooms (cultivated & wild), canned	PP	0.017	0.10	0.00	0.27	0.00	0.10	0.00	1.33	0.02	0.10	0.00	0.14	0.00
GC 0640	Barley, raw	RAC	0.06	2.49	0.15	NC	-	0.10	0.01	0.10	0.01	0.18	0.01	0.38	0.02
-	Barley, pot&pearled	PP	0.01	7.12	0.07	7.34	0.07	0.10	0.00	0.10	0.00	0.67	0.01	0.20	0.00
-	Barley beer	PP	0.009	4.87	0.04	93.78	0.84	24.28	0.22	12.76	0.11	39.28	0.35	18.15	0.16
-	Barley Malt	PP	0.024	0.10	0.00	1.04	0.02	0.18	0.00	0.33	0.01	0.10	0.00	0.10	0.00
GC 0647	Oats, raw (incl rolled)	RAC	0.06	0.10	0.01	7.05	0.42	0.10	0.01	1.71	0.10	0.96	0.06	0.10	0.01
GC 0650	Rye, raw (incl flour)	RAC	0.01	0.13	0.00	19.38	0.19	0.10	0.00	0.12	0.00	0.10	0.00	2.15	0.02
GC 0653	Triticale, raw (incl flour)	RAC	0.01	NC	-	NC	-	NC	-	0.10	0.00	0.39	0.00	NC	-
GC 0654	Wheat, raw (incl meslin)	RAC	0.01	0.10	0.00	1.12	0.01	NC	-	0.10	0.00	0.56	0.01	NC	-
CF 0654	Wheat, bran	PP	0.042	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
CF 1212	Wheat, wholemeal flour	PP	0.014	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
CP 1212	Wheat, wholemeal bread	PP	0.007	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00
CF 1211	Wheat, white flour	PP	0.002	299.27	0.60	263.32	0.53	27.93	0.06	214.18	0.43	133.47	0.27	340.03	0.68
MO 0105	Edible offal (mammalian), raw	RAC	0.01	4.79	0.05	9.68	0.10	2.97	0.03	5.49	0.05	3.84	0.04	5.03	0.05
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (µg/person)=				18.6		24.4		4.4		29.3		9.3		75.0
	Bodyweight per region (kg bw) =				60		60		60		60		60		60
	ADI (µg/person)=				18000		18000		18000		18000		18000		18000

Annex 3

METRAFENONE (278) International Estimated Daily Intake (IEDI) ADI = 0 - 0.3 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day G01 diet	Intake as µg/person/day G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
	%ADI=				0.1%		0.1%		0.0%		0.2%		0.1%		0.4%
	Rounded %ADI=				0%		0%		0%		0%		0%		0%

METRAFENONE (278) International Estimated Daily Intake (IEDI) ADI = 0 - 0.3 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day G07 diet	Intake as µg/person/day G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
FB 0269	Grape, raw	RAC	0.76	6.33	4.81	11.22	8.53	5.21	3.96	9.38	7.13	4.55	3.46	0.78	0.59
-	Grape must	PP	0.51	0.16	0.08	0.10	0.05	0.10	0.05	0.12	0.06	0.11	0.06	NC	-
DF 0269	Grape, dried (= currants, raisins and sultanas)	PP	2.85	3.09	8.81	1.51	4.30	0.10	0.29	1.38	3.93	4.26	12.14	0.42	1.20
JF 0269	Grape juice	PP	0.038	0.56	0.02	1.96	0.07	0.10	0.00	2.24	0.09	2.27	0.09	0.34	0.01
-	Grape wine (incl vermouths)	PP	0.14	88.93	12.45	62.41	8.74	1.84	0.26	25.07	3.51	61.17	8.56	5.84	0.82
FB 0275	Strawberry, raw	RAC	0.13	4.49	0.58	5.66	0.74	0.10	0.01	6.63	0.86	5.75	0.75	0.10	0.01
VC 0424	Cucumber, raw	RAC	0.05	6.72	0.34	11.03	0.55	32.10	1.61	15.10	0.76	4.05	0.20	9.57	0.48
VC 0425	Gherkin, raw	RAC	0.05	0.41	0.02	5.89	0.29	NC	-	0.10	0.01	0.37	0.02	2.07	0.10
VC 0431	Squash, summer, raw (= courgette, zuchini)	RAC	0.015	NC	-	NC	-	5.48	0.08	NC	-	NC	-	1.03	0.02
VO 0444	Peppers, chili, raw	RAC	0.115	5.57	0.64	14.00	1.61	8.25	0.95	5.77	0.66	6.44	0.74	2.53	0.29
-	Peppers, chili, dried	PP	1.15	0.11	0.13	0.21	0.24	0.36	0.41	0.21	0.24	0.25	0.29	0.15	0.17
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.115	0.82	0.09	1.53	0.18	10.85	1.25	4.59	0.53	1.84	0.21	2.00	0.23
VO 0448	Tomato, raw	RAC	0.1	32.13	3.21	51.27	5.13	34.92	3.49	73.37	7.34	15.15	1.52	8.88	0.89
-	Tomato, canned (& peeled)	PP	0.002	7.57	0.02	2.66	0.01	0.30	0.00	0.97	0.00	7.31	0.01	0.41	0.00
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.039	4.96	0.19	3.20	0.12	0.15	0.01	1.61	0.06	6.88	0.27	0.52	0.02
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.034	0.80	0.03	0.10	0.00	0.10	0.00	0.61	0.02	0.40	0.01	0.10	0.00
-	Mushrooms (cultivated & wild), raw (incl dried, excl canned)	RAC	0.105	6.31	0.66	3.51	0.37	0.93	0.10	2.66	0.28	12.41	1.30	0.25	0.03
-	Mushrooms (cultivated & wild), canned	PP	0.017	0.71	0.01	1.71	0.03	0.23	0.00	0.76	0.01	1.74	0.03	0.23	0.00
GC 0640	Barley, raw	RAC	0.06	0.10	0.01	NC	-	0.10	0.01	1.36	0.08	NC	-	NC	-
-	Barley, pot&pearled	PP	0.01	0.57	0.01	2.56	0.03	0.33	0.00	0.56	0.01	0.36	0.00	NC	-
-	Barley beer	PP	0.009	180.21	1.62	259.46	2.34	45.91	0.41	172.36	1.55	234.42	2.11	65.30	0.59
-	Barley Malt	PP	0.024	0.19	0.00	NC	-	0.10	0.00	0.10	0.00	NC	-	2.14	0.05
GC 0647	Oats, raw (incl rolled)	RAC	0.06	7.50	0.45	6.26	0.38	0.15	0.01	4.87	0.29	3.16	0.19	2.98	0.18
GC 0650	Rye, raw (incl flour)	RAC	0.01	3.21	0.03	35.38	0.35	0.21	0.00	6.50	0.07	1.49	0.01	NC	-
GC 0653	Triticale, raw (incl flour)	RAC	0.01	0.10	0.00	0.17	0.00	0.29	0.00	0.10	0.00	NC	-	NC	-
GC 0654	Wheat, raw (incl meslin)	RAC	0.01	NC	-	NC	-	NC	-	0.10	0.00	NC	-	NC	-
CF 0654	Wheat, bran	PP	0.042	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
CF 1212	Wheat, wholemeal flour	PP	0.014	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
CP 1212	Wheat, wholemeal bread	PP	0.007	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00

Annex 3

METRAFENONE (278) International Estimated Daily Intake (IEDI) ADI = 0 - 0.3 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day G07 diet	Intake as µg/person/day G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
CF 1211	Wheat, white flour	PP	0.002	182.77	0.37	187.54	0.38	103.82	0.21	180.42	0.36	164.00	0.33	118.84	0.24
MO 0105	Edible offal (mammalian), raw	RAC	0.01	15.17	0.15	5.19	0.05	6.30	0.06	6.78	0.07	3.32	0.03	3.17	0.03
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (µg/person)=				34.7		34.5		13.2		27.9		32.3		6.0
	Bodyweight per region (kg bw) =				60		60		55		60		60		60
	ADI (µg/person)=				18000		18000		16500		18000		18000		18000
	%ADI=				0.2%		0.2%		0.1%		0.2%		0.2%		0.0%
	Rounded %ADI=				0%		0%		0%		0%		0%		0%

METRAFENONE (278) International Estimated Daily Intake (IEDI) ADI = 0 - 0.3 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day G13 diet	Intake = daily intake: µg/person G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
FB 0269	Grape, raw	RAC	0.76	0.14	0.11	0.36	0.27	15.22	11.57	0.10	0.08	0.10	0.08
-	Grape must	PP	0.51	0.10	0.05	0.10	0.05	0.11	0.06	0.10	0.05	0.19	0.10
DF 0269	Grape, dried (currants, raisins, sultanas)	PP	2.85	0.10	0.29	0.13	0.37	1.06	3.02	0.10	0.29	0.10	0.29
JF 0269	Grape juice	PP	0.038	0.10	0.00	0.10	0.00	0.41	0.02	0.10	0.00	NC	-
-	Grape wine (incl vermouths)	PP	0.14	0.31	0.04	0.23	0.03	60.43	8.46	0.52	0.07	31.91	4.47
FB 0275	Strawberry, raw	RAC	0.13	0.10	0.01	0.10	0.01	3.35	0.44	0.10	0.01	0.10	0.01
VC 0424	Cucumber, raw	RAC	0.05	0.68	0.03	1.81	0.09	10.40	0.52	0.10	0.01	0.10	0.01
VC 0425	Gherkin, raw	RAC	0.05	0.15	0.01	0.39	0.02	3.15	0.16	0.10	0.01	0.10	0.01
VC 0431	Squash, summer, raw (courgette, zuchini)	RAC	0.015	0.10	0.00	1.01	0.02	NC	-	1.91	0.03	NC	-
VO 0444	Peppers, chili, raw	RAC	0.115	3.47	0.40	3.56	0.41	16.30	1.87	0.10	0.01	NC	-
-	Peppers, chili, dried	PP	1.15	0.58	0.67	1.27	1.46	1.21	1.39	0.12	0.14	NC	-
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.115	5.49	0.63	10.57	1.22	8.84	1.02	0.91	0.10	NC	-
VO 0448	Tomato, raw	RAC	0.1	12.99	1.30	4.79	0.48	58.40	5.84	0.92	0.09	0.10	0.01
-	Tomato, canned (& peeled)	PP	0.002	0.10	0.00	0.10	0.00	2.42	0.00	0.10	0.00	NC	-
-	Tomato, paste (i.e. conc sauce/puree)	PP	0.039	0.58	0.02	0.22	0.01	2.21	0.09	0.24	0.01	3.10	0.12
JF 0448	Tomato, juice (incl concentrated)	PP	0.034	0.10	0.00	0.10	0.00	0.42	0.01	0.10	0.00	0.10	0.00
-	Mushrooms (cultivated & wild), raw (incl dried, excl canned)	RAC	0.105	0.10	0.01	0.10	0.01	1.92	0.20	0.10	0.01	NC	-
-	Mushrooms (cultivated & wild), canned	PP	0.017	0.10	0.00	0.10	0.00	1.29	0.02	0.10	0.00	NC	-
GC 0640	Barley, raw	RAC	0.06	0.10	0.01	0.10	0.01	0.16	0.01	NC	-	NC	-
-	Barley, pot&pearled	PP	0.01	5.46	0.05	0.10	0.00	1.44	0.01	0.10	0.00	NC	-
-	Barley beer	PP	0.009	16.25	0.15	11.36	0.10	225.21	2.03	19.49	0.18	52.17	0.47
-	Barley Malt	PP	0.024	0.10	0.00	0.11	0.00	0.67	0.02	0.10	0.00	4.61	0.11
GC 0647	Oats, raw (incl rolled)	RAC	0.06	0.37	0.02	0.10	0.01	2.79	0.17	0.10	0.01	NC	-
GC 0650	Rye, raw (incl flour)	RAC	0.01	0.10	0.00	0.10	0.00	13.95	0.14	0.10	0.00	0.88	0.01

Annex 3

METRAFENONE (278) International Estimated Daily Intake (IEDI) ADI = 0 - 0.3 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day G13 diet	Intake = daily intake: µg/person G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
GC 0653	Triticale, raw (incl flour)	RAC	0.01	0.10	0.00	NC	-	NC	-	NC	-	NC	-
GC 0654	Wheat, raw (incl meslin)	RAC	0.01	NC	-	NC	-	NC	-	NC	-	0.97	0.01
CF 0654	Wheat, bran	PP	0.042	NC	-	NC	-	NC	-	NC	-	NC	-
CF 1212	Wheat, wholemeal flour	PP	0.014	NC	-	NC	-	NC	-	NC	-	NC	-
CP 1212	Wheat, wholemeal bread	PP	0.007	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00
CF 1211	Wheat, white flour	PP	0.002	43.75	0.09	85.81	0.17	206.68	0.41	19.38	0.04	92.92	0.19
MO 0105	Edible offal (mammalian), raw	RAC	0.01	4.64	0.05	1.97	0.02	10.01	0.10	3.27	0.03	3.98	0.04
-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (µg/person)=				3.9		4.8		37.6		1.2		5.9
	Bodyweight per region (kg bw) =				60		60		60		60		60
	ADI (µg/person)=				18000		18000		18000		18000		18000
	%ADI=				0.0%		0.0%		0.2%		0.0%		0.0%
	Rounded %ADI=				0%		0%		0%		0%		0%

Annex 3

MYCLOBUTANIL (181) International Estimated Daily Intake (IEDI) ADI = 0–0.03 mg/kg bw

			STMR	Diets as g/person/day			Intake as µg/person/day								
Codex Code	Commodity description	Expr as	mg/kg	G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
FP 0009	Pome fruit, raw (incl cider, excl apple juice)	RAC	0.07	19.35	1.35	34.06	2.38	17.87	1.25	25.74	1.80	7.69	0.54	56.85	3.98
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.012	0.32	0.00	3.07	0.04	0.10	0.00	5.00	0.06	0.29	0.00	5.57	0.07
FS 0013	Cherries, raw	RAC	1.06	0.92	0.98	9.15	9.70	0.10	0.11	0.61	0.65	0.10	0.11	6.64	7.04
FS 0014	Plums, raw (incl dried plums) (excl jujube)	RAC	0.4	2.67	1.07	8.77	3.51	0.10	0.04	3.03	1.21	0.70	0.28	4.34	1.74
FS 2001	Peaches, nectarines, apricots, raw (incl dried apricots)	RAC	0.865	8.01	6.93	5.87	5.08	0.18	0.16	8.19	7.08	1.64	1.42	22.46	19.43
FB 0021	Currants, red, black, white, raw	RAC	0.34	0.10	0.03	0.74	0.25	0.10	0.03	0.10	0.03	0.10	0.03	0.10	0.03
FB 0269	Grape, raw (incl must, excl dried, excl juice, excl wine)	RAC	0.34	13.02	4.43	9.25	3.15	0.10	0.03	16.91	5.75	3.70	1.26	54.44	18.51
DF 0269	Grape, dried (= currants, raisins and sultanas)	PP	2.14	0.51	1.09	0.51	1.09	0.10	0.21	1.27	2.72	0.12	0.26	2.07	4.43
JF 0269	Grape juice	PP	0.068	0.14	0.01	0.29	0.02	0.10	0.01	0.30	0.02	0.24	0.02	0.10	0.01
–	Grape wine (incl vermouths)	PP	0.058	0.67	0.04	12.53	0.73	2.01	0.12	1.21	0.07	3.53	0.20	4.01	0.23
FB 0275	Strawberry, raw	RAC	0.19	0.70	0.13	2.01	0.38	0.10	0.02	1.36	0.26	0.37	0.07	2.53	0.48
VA 0035	Bulb vegetables, raw	RAC	0.039	34.29	1.34	46.37	1.81	4.73	0.18	41.36	1.61	21.08	0.82	52.54	2.05
VB 0040	Brassica vegetables, raw: head cabbages, flowerhead Brassicas, Brussels sprouts & kohlrabi	RAC	0.03	6.41	0.19	35.79	1.07	0.71	0.02	9.81	0.29	12.07	0.36	16.58	0.50
VC 0045	Fruiting vegetables, cucurbits, raw	RAC	0.04	53.14	2.13	86.21	3.45	6.28	0.25	92.76	3.71	15.64	0.63	155.30	6.21
VO 0444	Peppers, chilli, raw	RAC	0.435	3.99	1.74	7.30	3.18	2.93	1.27	5.62	2.44	NC	–	17.44	7.59
–	Peppers, chilli, dried	PP	4.35	0.42	1.83	0.53	2.31	0.84	3.65	0.50	2.18	0.95	4.13	0.37	1.61
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.435	4.49	1.95	6.44	2.80	7.21	3.14	5.68	2.47	9.52	4.14	8.92	3.88
VO 0448	Tomato, raw	RAC	0.07	41.73	2.92	75.65	5.30	10.66	0.75	82.87	5.80	24.75	1.73	200.93	14.07
–	Tomato, canned (& peeled)	PP	0.02	0.20	0.00	0.31	0.01	0.10	0.00	1.11	0.02	0.11	0.00	1.50	0.03
–	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.27	2.34	0.63	1.33	0.36	1.57	0.42	4.24	1.14	0.34	0.09	2.83	0.76
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.031	0.29	0.01	0.29	0.01	0.10	0.00	0.38	0.01	0.10	0.00	0.14	0.00
VL 0053	Leafy vegetables, raw	RAC	0.03	8.47	0.25	22.36	0.67	7.74	0.23	25.51	0.77	45.77	1.37	21.22	0.64
VP 0061	Beans, green, with pods, raw: beans except broad bean & soya bean (i.e. immature seeds + pods) (Phaseolus spp)	RAC	0.22	0.68	0.15	NC	–	NC	–	0.39	0.09	0.22	0.05	0.49	0.11
VR 0075	Root and tuber vegetables, raw (incl processed)	RAC	0.039	87.83	3.43	374.04	14.59	668.92	26.09	121.64	4.74	94.20	3.67	247.11	9.64
DH 1100	Hops, dry	RAC	1.52	0.10	0.15	0.10	0.15	0.10	0.15	0.10	0.15	NC	–	0.10	0.15
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)	RAC	0	31.20	0.00	72.44	0.00	20.88	0.00	47.98	0.00	33.08	0.00	36.25	0.00
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0	3.29	0.00	6.14	0.00	0.82	0.00	1.57	0.00	2.23	0.00	1.07	0.00
MO 0105	Edible offal (mammalian), raw	RAC	0	4.79	0.00	9.68	0.00	2.97	0.00	5.49	0.00	3.84	0.00	5.03	0.00
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0	289.65	0.00	485.88	0.00	26.92	0.00	239.03	0.00	199.91	0.00	180.53	0.00

Annex 3

MYCLOBUTANIL (181) International Estimated Daily Intake (IEDI) ADI = 0–0.03 mg/kg bw

			STMR	Diets as g/person/day			Intake as µg/person/day								
Codex Code	Commodity description	Expr as	mg/kg	G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
PM 0110	Poultry meat, raw (incl prepared)	RAC	0	14.63	0.00	29.76	0.00	8.04	0.00	129.68	0.00	25.04	0.00	35.66	0.00
PF 0111	Poultry fat, raw (incl rendered)	RAC	0	0.10	0.00	0.10	0.00	NC	–	0.10	0.00	0.10	0.00	0.10	0.00
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0	0.12	0.00	0.12	0.00	0.11	0.00	5.37	0.00	0.24	0.00	0.10	0.00
PE 0112	Eggs, raw, (incl dried)	RAC	0	7.84	0.00	23.08	0.00	2.88	0.00	14.89	0.00	9.81	0.00	14.83	0.00
–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
	Total intake (µg/person)=				32.8		62.0		38.1		45.1		21.2		103.2
	Bodyweight per region (kg bw) =				60		60		60		60		60		60
	ADI (µg/person)=				1800		1800		1800		1800		1800		1800
	%ADI=				1.8%		3.4%		2.1%		2.5%		1.2%		5.7%
	Rounded %ADI=				2%		3%		2%		3%		1%		6%

MYCLOBUTANIL (181) International Estimated Daily Intake (IEDI) ADI = 0–0.03 mg/kg bw

			STMR	Diets as g/person/day			Intake as µg/person/day								
Codex Code	Commodity description	Expr as	mg/kg	G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
FP 0009	Pome fruit, raw (incl cider, excl apple juice)	RAC	0.07	51.09	3.58	65.40	4.58	42.71	2.99	45.29	3.17	62.51	4.38	7.74	0.54
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.012	14.88	0.18	11.98	0.14	0.15	0.00	9.98	0.12	30.32	0.36	3.47	0.04
FS 0013	Cherries, raw	RAC	1.06	1.40	1.48	4.21	4.46	0.10	0.11	2.93	3.11	1.50	1.59	NC	–
FS 0014	Plums, raw (incl dried plums) (excl jujube)	RAC	0.4	5.55	2.22	4.37	1.75	6.08	2.43	3.66	1.46	3.93	1.57	0.46	0.18
FS 2001	Peaches, nectarines, apricots, raw (incl dried apricots)	RAC	0.865	13.03	11.27	16.29	14.09	8.29	7.17	12.95	11.20	5.35	4.63	0.10	0.09
FB 0021	Currants, red, black, white, raw	RAC	0.34	0.48	0.16	4.23	1.44	NC	–	1.51	0.51	0.49	0.17	NC	–
FB 0269	Grape, raw (incl must, excl dried, excl juice, excl wine)	RAC	0.34	6.48	2.20	11.31	3.85	5.21	1.77	9.50	3.23	4.66	1.58	0.78	0.27
DF 0269	Grape, dried (= currants, raisins and sultanas)	PP	2.14	3.09	6.61	1.51	3.23	0.10	0.21	1.38	2.95	4.26	9.12	0.42	0.90
JF 0269	Grape juice	PP	0.068	0.56	0.04	1.96	0.13	0.10	0.01	2.24	0.15	2.27	0.15	0.34	0.02
–	Grape wine (incl vermouths)	PP	0.058	88.93	5.16	62.41	3.62	1.84	0.11	25.07	1.45	61.17	3.55	5.84	0.34
FB 0275	Strawberry, raw	RAC	0.19	4.49	0.85	5.66	1.08	0.10	0.02	6.63	1.26	5.75	1.09	0.10	0.02
VA 0035	Bulb vegetables, raw	RAC	0.039	26.24	1.02	36.47	1.42	39.29	1.53	39.37	1.54	29.12	1.14	20.21	0.79
VB 0040	Brassica vegetables, raw: head cabbages, flowerhead Brassicas, Brussels sprouts & kohlrabi	RAC	0.03	20.71	0.62	39.81	1.19	16.70	0.50	28.49	0.85	18.12	0.54	15.03	0.45
VC 0045	Fruiting vegetables, cucurbits, raw	RAC	0.04	27.81	1.11	41.93	1.68	123.30	4.93	49.47	1.98	15.95	0.64	35.99	1.44
VO 0444	Peppers, chilli, raw	RAC	0.435	5.57	2.42	14.00	6.09	8.25	3.59	5.77	2.51	6.44	2.80	2.53	1.10
–	Peppers, chilli, dried	PP	4.35	0.11	0.48	0.21	0.91	0.36	1.57	0.21	0.91	0.25	1.09	0.15	0.65

Annex 3

MYCLOBUTANIL (181) International Estimated Daily Intake (IEDI) ADI = 0–0.03 mg/kg bw

			STMR	Diets as g/person/day			Intake as µg/person/day								
Codex Code	Commodity description	Expr as	mg/kg	G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.435	0.82	0.36	1.53	0.67	10.85	4.72	4.59	2.00	1.84	0.80	2.00	0.87
VO 0448	Tomato, raw	RAC	0.07	32.13	2.25	51.27	3.59	34.92	2.44	73.37	5.14	15.15	1.06	8.88	0.62
–	Tomato, canned (& peeled)	PP	0.02	7.57	0.15	2.66	0.05	0.30	0.01	0.97	0.02	7.31	0.15	0.41	0.01
–	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.27	4.96	1.34	3.20	0.86	0.15	0.04	1.61	0.43	6.88	1.86	0.52	0.14
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.031	0.80	0.02	0.10	0.00	0.10	0.00	0.61	0.02	0.40	0.01	0.10	0.00
VL 0053	Leafy vegetables, raw	RAC	0.03	18.83	0.56	21.85	0.66	121.23	3.64	43.09	1.29	18.18	0.55	18.32	0.55
VP 0061	Beans, green, with pods, raw: beans except broad bean & soya bean (i.e. immature seeds + pods) (Phaseolus spp)	RAC	0.22	5.07	1.12	0.83	0.18	0.17	0.04	3.70	0.81	NC	–	NC	–
VR 0075	Root and tuber vegetables, raw (incl processed)	RAC	0.039	290.31	11.32	300.35	11.71	214.25	8.36	242.72	9.47	348.67	13.60	137.52	5.36
DH 1100	Hops, dry	RAC	1.52	NC	–	NC	–	0.10	0.15	0.10	0.15	NC	–	NC	–
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)	RAC	0	140.03	0.00	150.89	0.00	79.32	0.00	111.24	0.00	120.30	0.00	51.27	0.00
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0	6.44	0.00	15.51	0.00	3.79	0.00	8.29	0.00	18.44	0.00	8.00	0.00
MO 0105	Edible offal (mammalian), raw	RAC	0	15.17	0.00	5.19	0.00	6.30	0.00	6.78	0.00	3.32	0.00	3.17	0.00
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0	388.92	0.00	335.88	0.00	49.15	0.00	331.25	0.00	468.56	0.00	245.45	0.00
PM 0110	Poultry meat, raw (incl prepared)	RAC	0	73.76	0.00	53.86	0.00	23.98	0.00	87.12	0.00	53.38	0.00	84.45	0.00
PF 0111	Poultry fat, raw (incl rendered)	RAC	0	0.10	0.00	0.10	0.00	NC	–	0.10	0.00	0.71	0.00	NC	–
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0	0.33	0.00	0.72	0.00	0.27	0.00	0.35	0.00	0.80	0.00	NC	–
PE 0112	Eggs, raw, (incl dried)	RAC	0	25.84	0.00	29.53	0.00	28.05	0.00	33.19	0.00	36.44	0.00	8.89	0.00
–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
	Total intake (µg/person)=				56.5		67.4		46.3		55.7		52.4		14.4
	Bodyweight per region (kg bw) =				60		60		55		60		60		60
	ADI (µg/person)=				1800		1800		1650		1800		1800		1800
	%ADI=				3.1%		3.7%		2.8%		3.1%		2.9%		0.8%
	Rounded %ADI=				3%		4%		3%		3%		3%		1%

MYCLOBUTANIL (181) International Estimated Daily Intake (IEDI) ADI = 0–0.03 mg/kg bw

			STMR	Diets: g/person/day			Intake = daily intake: µg/person						
Codex Code	Commodity description	Expr as	mg/kg	G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
FP 0009	Pome fruit, raw (incl cider, excl apple juice)	RAC	0.07	68.85	4.82	10.93	0.77	70.82	4.96	189.78	13.28	19.56	1.37

Annex 3

MYCLOBUTANIL (181) International Estimated Daily Intake (IEDI) ADI = 0–0.03 mg/kg bw

			STMR	Diets: g/person/day			Intake = daily intake: µg/person						
Codex Code	Commodity description	Expr as	mg/kg	G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.012	0.10	0.00	0.10	0.00	7.19	0.09	0.10	0.00	NC	–
FS 0013	Cherries, raw	RAC	1.06	0.10	0.11	0.10	0.11	5.96	6.32	0.10	0.11	NC	–
FS 0014	Plums, raw (incl dried plums) (excl jujube)	RAC	0.4	0.10	0.04	0.10	0.04	16.65	6.66	0.10	0.04	NC	–
FS 2001	Peaches, nectarines, apricots, raw (incl dried apricots)	RAC	0.865	0.10	0.09	0.10	0.09	10.76	9.31	0.10	0.09	NC	–
FB 0021	Currants, red, black, white, raw	RAC	0.34	0.10	0.03	NC	–	0.74	0.25	NC	–	NC	–
FB 0269	Grape, raw (incl must, excl dried, excl juice, excl wine)	RAC	0.34	0.14	0.05	0.36	0.12	15.33	5.21	0.10	0.03	0.28	0.10
DF 0269	Grape, dried (= currants, raisins and sultanas)	PP	2.14	0.10	0.21	0.13	0.28	1.06	2.27	0.10	0.21	0.10	0.21
JF 0269	Grape juice	PP	0.068	0.10	0.01	0.10	0.01	0.41	0.03	0.10	0.01	NC	–
–	Grape wine (incl vermouths)	PP	0.058	0.31	0.02	0.23	0.01	60.43	3.50	0.52	0.03	31.91	1.85
FB 0275	Strawberry, raw	RAC	0.19	0.10	0.02	0.10	0.02	3.35	0.64	0.10	0.02	0.10	0.02
VA 0035	Bulb vegetables, raw	RAC	0.039	11.28	0.44	23.80	0.93	36.11	1.41	9.66	0.38	8.69	0.34
VB 0040	Brassica vegetables, raw: head cabbages, flowerhead Brassicas, Brussels sprouts & kohlrabi	RAC	0.03	4.84	0.15	3.79	0.11	58.72	1.76	0.10	0.00	NC	–
VC 0045	Fruiting vegetables, cucurbits, raw	RAC	0.04	5.96	0.24	9.74	0.39	51.82	2.07	13.61	0.54	0.10	0.00
VO 0444	Peppers, chilli, raw	RAC	0.435	3.47	1.51	3.56	1.55	16.30	7.09	0.10	0.04	NC	–
–	Peppers, chilli, dried	PP	4.35	0.58	2.52	1.27	5.52	1.21	5.26	0.12	0.52	NC	–
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.435	5.49	2.39	10.57	4.60	8.84	3.85	0.91	0.40	NC	–
VO 0448	Tomato, raw	RAC	0.07	12.99	0.91	4.79	0.34	58.40	4.09	0.92	0.06	0.10	0.01
–	Tomato, canned (& peeled)	PP	0.02	0.10	0.00	0.10	0.00	2.42	0.05	0.10	0.00	NC	–
–	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.27	0.58	0.16	0.22	0.06	2.21	0.60	0.24	0.06	3.10	0.84
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.031	0.10	0.00	0.10	0.00	0.42	0.01	0.10	0.00	0.10	0.00
VL 0053	Leafy vegetables, raw	RAC	0.03	12.42	0.37	8.75	0.26	7.53	0.23	7.07	0.21	14.11	0.42
VP 0061	Beans, green, with pods, raw: beans except broad bean & soya bean (i.e. immature seeds + pods) (Phaseolus spp)	RAC	0.22	NC	–	NC	–	NC	–	NC	–	NC	–
VR 0075	Root and tuber vegetables, raw (incl processed)	RAC	0.039	282.25	11.01	232.11	9.05	281.91	10.99	620.21	24.19	459.96	17.94
DH 1100	Hops, dry	RAC	1.52	NC	–	NC	–	0.10	0.15	NC	–	NC	–
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)	RAC	0	29.18	0.00	50.89	0.00	121.44	0.00	22.58	0.00	72.14	0.00
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0	1.05	0.00	1.14	0.00	18.69	0.00	0.94	0.00	3.12	0.00
MO 0105	Edible offal (mammalian), raw	RAC	0	4.64	0.00	1.97	0.00	10.01	0.00	3.27	0.00	3.98	0.00
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0	108.75	0.00	70.31	0.00	436.11	0.00	61.55	0.00	79.09	0.00
PM 0110	Poultry meat, raw (incl prepared)	RAC	0	3.92	0.00	12.03	0.00	57.07	0.00	5.03	0.00	55.56	0.00
PF 0111	Poultry fat, raw (incl rendered)	RAC	0	NC	–	NC	–	0.32	0.00	NC	–	NC	–
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0	0.10	0.00	0.70	0.00	0.97	0.00	0.10	0.00	NC	–

Annex 3

MYCLOBUTANIL (181) International Estimated Daily Intake (IEDI) ADI = 0–0.03 mg/kg bw

			STMR	Diets: g/person/day			Intake = daily intake: µg/person						
Codex Code	Commodity description	Expr as	mg/kg	G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
PE 0112	Eggs, raw, (incl dried)	RAC	0	3.84	0.00	4.41	0.00	27.25	0.00	1.13	0.00	7.39	0.00
–	–	–	–	–	–	–	–	–	–	–	–	–	–
	Total intake (µg/person)=				25.1		24.3		76.8		40.2		23.1
	Bodyweight per region (kg bw) =				60		60		60		60		60
	ADI (µg/person)=				1800		1800		1800		1800		1800
	%ADI=				1.4%		1.3%		4.3%		2.2%		1.3%
	Rounded %ADI=				1%		1%		4%		2%		1%

Annex 3

PHOSMET (103) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0100 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day G01 diet	Intake as µg/person/day G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
FC 0001	Citrus fruit, raw (incl citrus fruit juice)	RAC	0.21	34.91	7.33	16.51	3.47	17.23	3.62	104.48	21.94	35.57	7.47	98.49	20.68
FP 0009	Pome fruits, raw (incl. apple juice, incl cider)	RAC	0.38	19.79	7.52	38.25	14.54	17.96	6.82	32.56	12.37	8.08	3.07	64.45	24.49
FS 0240	Apricot, raw (incl dried)	RAC	1.6	5.15	8.24	3.66	5.86	0.10	0.16	2.25	3.60	0.17	0.27	6.80	10.88
-	Peaches and nectarines, raw	RAC	1.6	2.87	4.59	2.21	3.54	0.15	0.24	5.94	9.50	1.47	2.35	15.66	25.06
FB 0020	Blueberries, raw	RAC	1	0.10	0.10	0.10	0.10	0.10	0.10	0.10	0.10	0.10	0.10	0.10	0.10
FB 0269	Grape, raw (incl must, incl dried, incl juice, incl wine)	RAC	3.1	16.25	50.38	28.96	89.78	2.87	8.90	24.22	75.08	9.33	28.92	68.64	212.78
FB 0265	Cranberries, raw	RAC	0.845	0.10	0.08	0.10	0.08	NC	-	0.10	0.08	0.10	0.08	0.10	0.08
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.05	59.74	2.99	316.14	15.81	9.78	0.49	60.26	3.01	54.12	2.71	119.82	5.99
TN 0085	Tree nuts, raw (incl processed)	RAC	0.05	4.06	0.20	3.27	0.16	7.01	0.35	13.93	0.70	14.01	0.70	9.36	0.47
SO 0691	Cotton seed, raw (incl oil)	RAC	0.05	20.53	1.03	9.80	0.49	6.42	0.32	4.73	0.24	7.14	0.36	18.68	0.93
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (µg/person)=				82.5		133.8		21.0		126.6		46.0		301.5
	Bodyweight per region (kg bw) =				60		60		60		60		60		60
	ADI (µg/person)=				600		600		600		600		600		600
	%ADI=				13.7%		22.3%		3.5%		21.1%		7.7%		50.2%
	Rounded %ADI=				10%		20%		4%		20%		8%		50%

PHOSMET (103) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0100 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day G07 diet	Intake as µg/person/day G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
FC 0001	Citrus fruit, raw (incl citrus fruit juice)	RAC	0.21	114.42	24.03	62.91	13.21	26.97	5.66	96.72	20.31	96.22	20.21	563.19	118.27
FP 0009	Pome fruits, raw (incl. apple juice, incl cider)	RAC	0.38	71.38	27.12	81.73	31.06	42.91	16.31	58.89	22.38	103.85	39.46	12.48	4.74
FS 0240	Apricot, raw (incl dried)	RAC	1.6	4.27	6.83	3.31	5.30	0.10	0.16	2.86	4.58	1.71	2.74	NC	-
-	Peaches and nectarines, raw	RAC	1.6	8.76	14.02	12.98	20.77	8.23	13.17	10.09	16.14	3.64	5.82	0.10	0.16
FB 0020	Blueberries, raw	RAC	1	0.10	0.10	0.23	0.23	0.10	0.10	0.83	0.83	0.33	0.33	NC	-
FB 0269	Grape, raw (incl must, incl dried, incl juice, incl wine)	RAC	3.1	142.23	440.91	105.77	327.89	7.87	24.40	52.44	162.56	109.22	338.58	10.96	33.98

Annex 3

PHOSMET (103) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0100 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day G07 diet	Intake as µg/person/day G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
FB 0265	Cranberries, raw	RAC	0.845	0.10	0.08	0.10	0.08	0.10	0.08	1.22	1.03	0.11	0.09	NC	-
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.05	225.03	11.25	234.24	11.71	71.48	3.57	177.55	8.88	234.55	11.73	37.71	1.89
TN 0085	Tree nuts, raw (incl processed)	RAC	0.05	8.52	0.43	8.94	0.45	15.09	0.75	9.60	0.48	14.57	0.73	26.26	1.31
SO 0691	Cotton seed, raw (incl oil)	RAC	0.05	10.71	0.54	4.23	0.21	7.19	0.36	7.54	0.38	5.66	0.28	2.38	0.12
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (µg/person)=				525.3		410.9		64.6		237.6		420.0		160.5
	Bodyweight per region (kg bw) =				60		60		55		60		60		60
	ADI (µg/person)=				600		600		550		600		600		600
	%ADI=				87.6%		68.5%		11.7%		39.6%		70.0%		26.7%
	Rounded %ADI=				90%		70%		10%		40%		70%		30%

PHOSMET (103) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0100 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day G13 diet	Intake = daily intake: µg/person G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
FC 0001	Citrus fruit, raw (incl citrus fruit juice)	RAC	0.21	21.16	4.44	2.94	0.62	58.52	12.29	0.44	0.09	5.13	1.08
FP 0009	Pome fruits, raw (incl. apple juice, incl cider)	RAC	0.38	68.89	26.18	11.06	4.20	80.62	30.64	189.82	72.13	19.56	7.43
FS 0240	Apricot, raw (incl dried)	RAC	1.6	0.10	0.16	0.10	0.16	3.29	5.26	0.10	0.16	NC	-
-	Peaches and nectarines, raw	RAC	1.6	0.10	0.16	0.10	0.16	7.47	11.95	0.10	0.16	NC	-
FB 0020	Blueberries, raw	RAC	1	NC	-	NC	-	0.20	0.20	NC	-	NC	-
FB 0269	Grape, raw (incl must, incl dried, incl juice, incl wine)	RAC	3.1	0.60	1.86	1.26	3.91	103.25	320.08	0.74	2.29	44.23	137.11
FB 0265	Cranberries, raw	RAC	0.845	NC	-	NC	-	0.10	0.08	NC	-	NC	-
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.05	23.96	1.20	13.56	0.68	213.41	10.67	104.35	5.22	8.56	0.43
TN 0085	Tree nuts, raw (incl processed)	RAC	0.05	4.39	0.22	135.53	6.78	6.11	0.31	0.72	0.04	317.74	15.89
SO 0691	Cotton seed, raw (incl oil)	RAC	0.05	8.14	0.41	0.32	0.02	2.84	0.14	2.69	0.13	0.97	0.05
-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (µg/person)=				34.6		16.5		391.6		80.2		162.0
	Bodyweight per region (kg bw) =				60		60		60		60		60
	ADI (µg/person)=				600		600		600		600		600
	%ADI=				5.8%		2.8%		65.3%		13.4%		27.0%
	Rounded %ADI=				6%		3%		70%		10%		30%

Annex 3

PROPAMOCARB (148) International Estimated Daily Intake (IEDI) ADI = 0–0.4000 mg/kg bw

			STMR	Diets as g/person/day			Intake as µg/person/day								
Codex Code	Commodity description	Expr as	mg/kg	G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
VA 0384	Leek, raw	RAC	2.5	0.18	0.45	1.59	3.98	0.10	0.25	0.28	0.70	0.10	0.25	3.21	8.03
–	Onions, mature bulbs, dry	RAC	0.05	29.36	1.47	37.50	1.88	3.56	0.18	34.78	1.74	18.81	0.94	43.38	2.17
VB 0041	Cabbages, head, raw	RAC	0.195	2.73	0.53	27.92	5.44	0.55	0.11	4.47	0.87	4.27	0.83	10.25	2.00
VB 0400	Broccoli, raw	RAC	0.29	0.88	0.26	0.17	0.05	0.10	0.03	1.25	0.36	3.00	0.87	1.09	0.32
VB 0402	Brussels sprouts, raw	RAC	0.47	0.63	0.30	6.41	3.01	0.13	0.06	1.03	0.48	NC	–	2.35	1.10
VB 0404	Cauliflower, raw	RAC	0.035	1.65	0.06	0.32	0.01	0.10	0.00	2.33	0.08	4.79	0.17	2.03	0.07
VC 0045	Fruiting vegetables, cucurbits, raw (excl melons, excl watermelons)	RAC	0.59	15.28	9.02	51.92	30.63	3.93	2.32	35.60	21.00	7.91	4.67	59.23	34.95
VC 0046	Melons, raw (excl watermelons)	RAC	0.04	8.90	0.36	8.64	0.35	0.80	0.03	17.90	0.72	2.80	0.11	29.17	1.17
VC 0432	Watermelon, raw	RAC	0.04	28.96	1.16	25.65	1.03	1.56	0.06	39.26	1.57	4.94	0.20	66.90	2.68
VO 0440	Egg plants, raw (= aubergines)	RAC	0.008	5.58	0.04	4.31	0.03	0.89	0.01	9.31	0.07	13.64	0.11	20.12	0.16
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.265	4.49	1.19	6.44	1.71	7.21	1.91	5.68	1.51	9.52	2.52	8.92	2.36
VO 0448	Tomato, raw	RAC	0.515	41.73	21.49	75.65	38.96	10.66	5.49	82.87	42.68	24.75	12.75	200.93	103.48
–	Tomato, canned (& peeled)	PP	0.21	0.20	0.04	0.31	0.07	0.10	0.02	1.11	0.23	0.11	0.02	1.50	0.32
–	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	1.54	2.34	3.60	1.33	2.05	1.57	2.42	4.24	6.53	0.34	0.52	2.83	4.36
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.27	0.29	0.08	0.29	0.08	0.10	0.03	0.38	0.10	0.10	0.03	0.14	0.04
VL 0480	Kale, raw (i.e. collards) (i.e. Brassica)	RAC	4	0.57	2.28	5.77	23.08	0.11	0.44	0.92	3.68	5.25	21.00	2.12	8.48
VL 0482	Lettuce, head, raw	RAC	9.9	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
VL 0483	Lettuce, leaf, raw	RAC	9.9	0.53	5.25	0.36	3.56	0.16	1.58	6.21	61.48	1.90	18.81	6.05	59.90
VL 0502	Spinach, raw	RAC	11.2	0.74	8.29	0.22	2.46	0.10	1.12	0.91	10.19	0.10	1.12	2.92	32.70
VR 0494	Radish roots, raw	RAC	0.33	2.31	0.76	4.09	1.35	2.53	0.83	6.15	2.03	5.88	1.94	2.97	0.98
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.05	59.74	2.99	316.14	15.81	9.78	0.49	60.26	3.01	54.12	2.71	119.82	5.99
VS 0469	Witloof chicory (sprouts)	RAC	0.6	0.10	0.06	0.10	0.06	0.10	0.06	0.36	0.22	0.10	0.06	0.35	0.21
PM 0110	Poultry meat, raw (incl prepared)	RAC	0.001	14.63	0.01	29.76	0.03	8.04	0.01	129.68	0.13	25.04	0.03	35.66	0.04
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.001	0.10	0.00	0.10	0.00	NC	–	0.10	0.00	0.10	0.00	0.10	0.00
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.002	0.12	0.00	0.12	0.00	0.11	0.00	5.37	0.01	0.24	0.00	0.10	0.00
PE 0112	Eggs, raw, (incl dried)	RAC	0.001	7.84	0.01	23.08	0.02	2.88	0.00	14.89	0.01	9.81	0.01	14.83	0.01
–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
	Total intake (µg/person)=				59.7		135.6		17.5		159.4		69.7		271.5
	Bodyweight per region (kg bw) =				60		60		60		60		60		60
	ADI (µg/person)=				24000		24000		24000		24000		24000		24000
	%ADI=				0.2%		0.6%		0.1%		0.7%		0.3%		1.1%

Annex 3

PROPAMOCARB (148) International Estimated Daily Intake (IEDI) ADI = 0–0.4000 mg/kg bw

			STMR	Diets as g/person/day			Intake as µg/person/day								
Codex Code	Commodity description	Expr as	mg/kg	G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
	Rounded %ADI=				0%		1%		0%		1%		0%		1%

PROPAMOCARB (148) International Estimated Daily Intake (IEDI) ADI = 0–0.4000 mg/kg bw

			STMR	Diets as g/person/day			Intake as µg/person/day								
Codex Code	Commodity description	Expr as	mg/kg	G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
VA 0384	Leek, raw	RAC	2.5	4.01	10.03	4.41	11.03	0.72	1.80	0.54	1.35	16.41	41.03	0.10	0.25
–	Onions, mature bulbs, dry	RAC	0.05	19.69	0.98	29.83	1.49	24.64	1.23	31.35	1.57	9.72	0.49	12.59	0.63
VB 0041	Cabbages, head, raw	RAC	0.195	8.97	1.75	27.12	5.29	1.44	0.28	24.96	4.87	4.55	0.89	11.23	2.19
VB 0400	Broccoli, raw	RAC	0.29	4.24	1.23	1.76	0.51	NC	–	0.51	0.15	3.79	1.10	0.26	0.08
VB 0402	Brussels sprouts, raw	RAC	0.47	2.24	1.05	2.67	1.25	6.23	2.93	0.32	0.15	4.19	1.97	2.58	1.21
VB 0404	Cauliflower, raw	RAC	0.035	5.27	0.18	5.01	0.18	NC	–	2.70	0.09	5.57	0.19	0.49	0.02
VC 0045	Fruiting vegetables, cucurbits, raw (excl melons, excl watermelons)	RAC	0.59	14.02	8.27	20.16	11.89	40.17	23.70	27.28	16.10	6.10	3.60	18.97	11.19
VC 0046	Melons, raw (excl watermelons)	RAC	0.04	9.20	0.37	11.95	0.48	14.63	0.59	8.99	0.36	7.86	0.31	2.46	0.10
VC 0432	Watermelon, raw	RAC	0.04	4.60	0.18	9.82	0.39	68.50	2.74	13.19	0.53	1.99	0.08	14.56	0.58
VO 0440	Egg plants, raw (= aubergines)	RAC	0.008	1.01	0.01	1.69	0.01	21.37	0.17	3.00	0.02	1.40	0.01	NC	–
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.265	0.82	0.22	1.53	0.41	10.85	2.88	4.59	1.22	1.84	0.49	2.00	0.53
VO 0448	Tomato, raw	RAC	0.515	32.13	16.55	51.27	26.40	34.92	17.98	73.37	37.79	15.15	7.80	8.88	4.57
–	Tomato, canned (& peeled)	PP	0.21	7.57	1.59	2.66	0.56	0.30	0.06	0.97	0.20	7.31	1.54	0.41	0.09
–	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	1.54	4.96	7.64	3.20	4.93	0.15	0.23	1.61	2.48	6.88	10.60	0.52	0.80
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.27	0.80	0.22	0.10	0.03	0.10	0.03	0.61	0.16	0.40	0.11	0.10	0.03
VL 0480	Kale, raw (i.e. collards) (i.e. Brassica)	RAC	4	NC	–	NC	–	14.54	58.16	NC	–	NC	–	2.32	9.28
VL 0482	Lettuce, head, raw	RAC	9.9	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
VL 0483	Lettuce, leaf, raw	RAC	9.9	14.50	143.55	11.76	116.42	13.14	130.09	19.50	193.05	4.81	47.62	2.23	22.08
VL 0502	Spinach, raw	RAC	11.2	2.20	24.64	1.76	19.71	13.38	149.86	2.94	32.93	5.53	61.94	0.10	1.12
VR 0494	Radish roots, raw	RAC	0.33	3.83	1.26	11.99	3.96	NC	–	5.26	1.74	2.19	0.72	4.37	1.44
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.05	225.03	11.25	234.24	11.71	71.48	3.57	177.55	8.88	234.55	11.73	37.71	1.89
VS 0469	Witloof chicory (sprouts)	RAC	0.6	1.50	0.90	0.95	0.57	NC	–	1.84	1.10	0.65	0.39	0.13	0.08
PM 0110	Poultry meat, raw (incl prepared)	RAC	0.001	73.76	0.07	53.86	0.05	23.98	0.02	87.12	0.09	53.38	0.05	84.45	0.08
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.001	0.10	0.00	0.10	0.00	NC	–	0.10	0.00	0.71	0.00	NC	–
PO 0111	Poultry edible offal, raw (incl	RAC	0.002	0.33	0.00	0.72	0.00	0.27	0.00	0.35	0.00	0.80	0.00	NC	–

Annex 3

PROPAMOCARB (148) International Estimated Daily Intake (IEDI) ADI = 0–0.4000 mg/kg bw

			STMR	Diets as g/person/day			Intake as µg/person/day								
Codex Code	Commodity description	Expr as	mg/kg	G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
	prepared)														
PE 0112	Eggs, raw, (incl dried)	RAC	0.001	25.84	0.03	29.53	0.03	28.05	0.03	33.19	0.03	36.44	0.04	8.89	0.01
–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
	Total intake (µg/person)=				232.0		217.3		396.3		304.9		192.7		58.2
	Bodyweight per region (kg bw) =				60		60		55		60		60		60
	ADI (µg/person)=				24000		24000		22000		24000		24000		24000
	%ADI=				1.0%		0.9%		1.8%		1.3%		0.8%		0.2%
	Rounded %ADI=				1%		1%		2%		1%		1%		0%

PROPAMOCARB (148) International Estimated Daily Intake (IEDI) ADI = 0–0.4000 mg/kg bw

			STMR	Diets: g/person/day			Intake = daily intake: µg/person						
Codex Code	Commodity description	Expr as	mg/kg	G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
VA 0384	Leek, raw	RAC	2.5	0.10	0.25	1.44	3.60	1.22	3.05	0.10	0.25	NC	–
–	Onions, mature bulbs, dry	RAC	0.05	9.01	0.45	20.24	1.01	30.90	1.55	9.61	0.48	2.11	0.11
VB 0041	Cabbages, head, raw	RAC	0.195	3.82	0.74	2.99	0.58	49.16	9.59	0.10	0.02	NC	–
VB 0400	Broccoli, raw	RAC	0.29	0.10	0.03	0.10	0.03	2.13	0.62	0.10	0.03	NC	–
VB 0402	Brussels sprouts, raw	RAC	0.47	0.88	0.41	0.69	0.32	2.89	1.36	0.10	0.05	NC	–
VB 0404	Cauliflower, raw	RAC	0.035	0.10	0.00	0.10	0.00	2.73	0.10	0.10	0.00	NC	–
VC 0045	Fruiting vegetables, cucurbits, raw (excl melons, excl watermelons)	RAC	0.59	1.48	0.87	9.35	5.52	18.15	10.71	13.61	8.03	0.10	0.06
VC 0046	Melons, raw (excl watermelons)	RAC	0.04	0.19	0.01	0.10	0.00	4.98	0.20	0.10	0.00	NC	–
VC 0432	Watermelon, raw	RAC	0.04	4.29	0.17	0.30	0.01	28.70	1.15	0.10	0.00	NC	–
VO 0440	Egg plants, raw (= aubergines)	RAC	0.008	1.31	0.01	8.26	0.07	3.95	0.03	0.10	0.00	NC	–
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.265	5.49	1.45	10.57	2.80	8.84	2.34	0.91	0.24	NC	–
VO 0448	Tomato, raw	RAC	0.515	12.99	6.69	4.79	2.47	58.40	30.08	0.92	0.47	0.10	0.05
–	Tomato, canned (& peeled)	PP	0.21	0.10	0.02	0.10	0.02	2.42	0.51	0.10	0.02	NC	–
–	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	1.54	0.58	0.89	0.22	0.34	2.21	3.40	0.24	0.37	3.10	4.77
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.27	0.10	0.03	0.10	0.03	0.42	0.11	0.10	0.03	0.10	0.03
VL 0480	Kale, raw (i.e. collards) (i.e. Brassica)	RAC	4	0.79	3.16	0.62	2.48	NC	–	0.10	0.40	NC	–
VL 0482	Lettuce, head, raw	RAC	9.9	NC	–	NC	–	NC	–	NC	–	NC	–
VL 0483	Lettuce, leaf, raw	RAC	9.9	0.29	2.87	0.10	0.99	6.71	66.43	0.10	0.99	NC	–
VL 0502	Spinach, raw	RAC	11.2	0.17	1.90	0.10	1.12	0.81	9.07	0.10	1.12	NC	–

Annex 3

PROPAMOCARB (148) International Estimated Daily Intake (IEDI) ADI = 0–0.4000 mg/kg bw

			STMR	Diets: g/person/day			Intake = daily intake: µg/person						
Codex Code	Commodity description	Expr as	mg/kg	G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
VR 0494	Radish roots, raw	RAC	0.33	3.96	1.31	2.86	0.94	3.30	1.09	2.67	0.88	5.34	1.76
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.05	23.96	1.20	13.56	0.68	213.41	10.67	104.35	5.22	8.56	0.43
VS 0469	Witloof chicory (sprouts)	RAC	0.6	0.10	0.06	0.10	0.06	0.10	0.06	0.10	0.06	NC	–
PM 0110	Poultry meat, raw (incl prepared)	RAC	0.001	3.92	0.00	12.03	0.01	57.07	0.06	5.03	0.01	55.56	0.06
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.001	NC	–	NC	–	0.32	0.00	NC	–	NC	–
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.002	0.10	0.00	0.70	0.00	0.97	0.00	0.10	0.00	NC	–
PE 0112	Eggs, raw, (incl dried)	RAC	0.001	3.84	0.00	4.41	0.00	27.25	0.03	1.13	0.00	7.39	0.01
–	–	–	–	–	–	–	–	–	–	–	–	–	–
	Total intake (µg/person)=				22.5		23.1		152.2		18.7		7.3
	Bodyweight per region (kg bw) =				60		60		60		60		60
	ADI (µg/person)=				24000		24000		24000		24000		24000
	%ADI=				0.1%		0.1%		0.6%		0.1%		0.0%
	Rounded %ADI=				0%		0%		1%		0%		0%

Annex 3

PROPICONAZOLE (160) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0700 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day			Intake as µg/person/day								
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
FC 0004	Oranges, sweet, sour, raw	RAC	2.95	20.66	60.95	5.23	15.43	11.90	35.11	37.90	111.81	21.16	62.42	56.46	166.56
JF 0004	Oranges, juice (single strength, incl. concentrated)	PP	0.02	1.27	0.03	2.20	0.04	0.10	0.00	11.81	0.24	0.46	0.01	1.69	0.03
FS 0014	Plums, raw (incl dried plums) (excl jujube)	RAC	0.185	2.67	0.49	8.77	1.62	0.10	0.02	3.03	0.56	0.70	0.13	4.34	0.80
FS 2001	Peaches, nectarines, apricots, raw	RAC	1.55	7.50	11.63	4.98	7.72	0.18	0.28	7.33	11.36	1.59	2.46	21.11	32.72
FB 0265	Cranberries, raw	RAC	0.3	0.10	0.03	0.10	0.03	NC	-	0.10	0.03	0.10	0.03	0.10	0.03
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.06	5.06	0.30	6.91	0.41	37.17	2.23	31.16	1.87	40.21	2.41	18.96	1.14
FI 0353	Pineapple, raw (incl canned pineapple, incl pineapple juice, incl dried pineapple)	RAC	0.02	0.61	0.01	1.56	0.03	7.89	0.16	9.36	0.19	8.76	0.18	1.30	0.03
VO 0447	Sweet corn on the cob, raw (incl frozen, incl canned) (i.e. kernels plus cob without husks)	RAC	0.05	0.14	0.01	0.94	0.05	5.70	0.29	2.61	0.13	1.94	0.10	0.22	0.01
VO 0448	Tomato, raw (incl juice, incl paste, incl canned)	RAC	0.8	51.75	41.40	81.80	65.44	16.99	13.59	102.02	81.62	26.32	21.06	214.77	171.82
VD 0541	Soya bean, dry, raw (incl paste, incl curd, incl oil, incl sauce)	RAC	0.03	72.79	2.18	59.05	1.77	20.55	0.62	74.20	2.23	61.12	1.83	73.24	2.20
VR 0596	Sugar beet, raw (incl sugar)	RAC	0.06	0.13	0.01	NC	-	0.10	0.01	0.66	0.04	0.47	0.03	88.94	5.34
GC 0640	Barley, raw (incl malt extract, incl pot&pearled, incl flour & grits, incl beer, incl malt)	RAC	0.0675	19.91	1.34	31.16	2.10	5.04	0.34	3.10	0.21	9.77	0.66	4.31	0.29
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl flour, incl oil, incl beer, incl germ, incl starch)	RAC	0.05	29.81	1.49	44.77	2.24	108.95	5.45	52.37	2.62	60.28	3.01	75.69	3.78
GC 0656	Popcorn (i.e. maize used for preparation of popcorn)	RAC	0.05	-	-	-	-	-	-	-	-	-	-	-	-
GC 0650	Rye, raw	RAC	0.06	NC	-	NC	-	0.10	0.01	0.10	0.01	0.10	0.01	0.10	0.01
GC 0653	Triticale, raw	RAC	0.06	NC	-	NC	-	NC	-	0.10	0.01	NC	-	NC	-
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, incl germ, incl wholemeal bread, incl white flour products, incl white bread)	RAC	0.06	381.15	22.87	341.55	20.49	38.35	2.30	281.89	16.91	172.83	10.37	434.07	26.04
GS 0659	Sugar cane, raw	RAC	0	38.16	0.00	NC	-	12.58	0.00	0.34	0.00	17.79	0.00	42.78	0.00
TN 0672	Pecan nuts, nutmeat	RAC	0.02	0.10	0.00	0.10	0.00	0.10	0.00	0.14	0.00	0.10	0.00	0.13	0.00
SO 0495	Rape seed, raw	RAC	0.06	0.10	0.01	NC	-	NC	-	0.10	0.01	0.75	0.05	0.10	0.01
MO 0105	Edible offal (mammalian), raw	RAC	0.5	4.79	2.40	9.68	4.84	2.97	1.49	5.49	2.75	3.84	1.92	5.03	2.52
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)	RAC	0,064	31,20	2,00	72,44	4,64	20,88	1,34	47,98	3,07	33,08	2,12	36,25	2,32
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.035	289.65	10.14	485.88	17.01	26.92	0.94	239.03	8.37	199.91	7.00	180.53	6.32
PM 0110	Poultry meat, raw (incl prepared) - 90% as muscle	RAC	0.05	13.17	0.66	26.78	1.34	7.24	0.36	116.71	5.84	22.54	1.13	32.09	1.60
PM 0110	Poultry meat, raw (incl prepared) - 10% as fat	RAC	0.05	1.46	0.07	2.98	0.15	0.80	0.04	12.97	0.65	2.50	0.13	3.57	0.18
PE 0112	Eggs, raw, (incl dried)	RAC	0.05	7.84	0.39	23.08	1.15	2.88	0.14	14.89	0.74	9.81	0.49	14.83	0.74
	Total intake (µg/person)=				157.8		145.0		64.3		250.2		116.8		423.7
	Bodyweight per region (kg bw) =				60		60		60		60		60		60
	ADI (µg/person)=				4200		4200		4200		4200		4200		4200

Annex 3

PROPICONAZOLE (160) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0700 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day G01 diet	Intake as µg/person/day G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
	%ADI=				3.8%		3.5%		1.5%		6.0%		2.8%		10.1%
	Rounded %ADI=				4%		3%		2%		6%		3%		10%

PROPICONAZOLE (160) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0700 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day G07 diet	Intake as µg/person/day G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
FC 0004	Oranges, sweet, sour, raw	RAC	2.95	15.68	46.26	24.00	70.80	6.80	20.06	29.09	85.82	15.39	45.40	160.47	473.39
JF 0004	Oranges, juice (single strength, incl. concentrated)	PP	0.02	33.31	0.67	1.78	0.04	0.28	0.01	18.97	0.38	14.01	0.28	13.36	0.27
FS 0014	Plums, raw (incl dried plums) (excl jujube)	RAC	0.185	5.55	1.03	4.37	0.81	6.08	1.12	3.66	0.68	3.93	0.73	0.46	0.09
FS 2001	Peaches, nectarines, apricots, raw	RAC	1.55	10.82	16.77	15.31	23.73	8.28	12.83	11.82	18.32	4.08	6.32	0.10	0.16
FB 0265	Cranberries, raw	RAC	0.3	0.10	0.03	0.10	0.03	0.10	0.03	1.22	0.37	0.11	0.03	NC	-
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.06	25.14	1.51	23.37	1.40	23.06	1.38	23.40	1.40	18.44	1.11	39.29	2.36
FI 0353	Pineapple, raw (incl canned pineapple, incl pineapple juice, incl dried pineapple)	RAC	0.02	13.13	0.26	11.13	0.22	6.94	0.14	14.36	0.29	36.74	0.73	18.81	0.38
VO 0447	Sweet corn on the cob, raw (incl frozen, incl canned) (i.e. kernels plus cob without husks)	RAC	0.05	11.43	0.57	3.71	0.19	0.74	0.04	13.63	0.68	3.07	0.15	1.50	0.08
VO 0448	Tomato, raw (incl juice, incl paste, incl canned)	RAC	0.8	64.74	51.79	68.31	54.65	36.05	28.84	82.09	65.67	54.50	43.60	11.69	9.35
VD 0541	Soya bean, dry, raw (incl paste, incl curd, incl oil, incl sauce)	RAC	0.03	106.33	3.19	117.78	3.53	42.12	1.26	195.70	5.87	222.52	6.68	80.47	2.41
VR 0596	Sugar beet, raw (incl sugar)	RAC	0.06	0.10	0.01	NC	-	0.10	0.01	0.10	0.01	NC	-	NC	-
GC 0640	Barley, raw (incl malt extract, incl pot&pearled, incl flour & grits, incl beer, incl malt)	RAC	0.0675	36.18	2.44	53.45	3.61	9.39	0.63	35.25	2.38	46.68	3.15	15.92	1.07
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl flour, incl oil, incl beer, incl germ, incl starch)	RAC	0.05	18.51	0.93	26.18	1.31	26.04	1.30	39.99	2.00	7.36	0.37	64.58	3.23
GC 0656	Popcorn (i.e. maize used for preparation of popcorn)	RAC	0.05	-	-	-	-	-	-	-	-	-	-	-	-
GC 0650	Rye, raw	RAC	0.06	0.10	0.01	NC	-	0.10	0.01	0.10	0.01	NC	-	NC	-
GC 0653	Triticale, raw	RAC	0.06	NC	-	NC	-	0.10	0.01	0.10	0.01	NC	-	NC	-
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, incl germ, incl wholemeal bread, incl white flour products, incl white bread)	RAC	0.06	253.07	15.18	244.73	14.68	134.44	8.07	235.10	14.11	216.39	12.98	167.40	10.04
GS 0659	Sugar cane, raw	RAC	0	NC	-	NC	-	4.27	0.00	0.10	0.00	NC	-	3.24	0.00
TN 0672	Pecan nuts, nutmeat	RAC	0.02	0.38	0.01	NC	-	NC	-	0.27	0.01	NC	-	0.26	0.01
SO 0495	Rape seed, raw	RAC	0.06	NC	-	NC	-	0.10	0.01	NC	-	NC	-	NC	-
MO 0105	Edible offal (mammalian), raw	RAC	0.5	15.17	7.59	5.19	2.60	6.30	3.15	6.78	3.39	3.32	1.66	3.17	1.59
MM 0095	Meat from mammals other than marine mammals, raw (incl prepared meat)	RAC	0,064	140,03	8,96	150,89	9,66	79,32	5,08	111,24	7,12	120,30	7,70	51,27	3,28
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.035	388.92	13.61	335.88	11.76	49.15	1.72	331.25	11.59	468.56	16.40	245.45	8.59
PM 0110	Poultry meat, raw (incl prepared) - 90% as muscle	RAC	0.05	66.38	3.32	48.47	2.42	21.58	1.08	78.41	3.92	48.04	2.40	76.01	3.80
PM 0110	Poultry meat, raw (incl prepared) - 10% as fat	RAC	0.05	7.38	0.37	5.39	0.27	2.40	0.12	8.71	0.44	5.34	0.27	8.45	0.42

Annex 3

PROPICONAZOLE (160) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0700 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day G07 diet	Intake as µg/person/day G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
PE 0112	Eggs, raw, (incl dried)	RAC	0.05	25.84	1.29	29.53	1.48	28.05	1.40	33.19	1.66	36.44	1.82	8.89	0.44
	Total intake (µg/person)=				172.9		200.1		86.7		223.8		149.3		519.9
	Bodyweight per region (kg bw) =				60		60		55		60		60		60
	ADI (µg/person)=				4200		4200		3850		4200		4200		4200
	%ADI=				4.1%		4.8%		2.3%		5.3%		3.6%		12.4%
	Rounded %ADI=				4%		5%		2%		5%		4%		10%

PROPICONAZOLE (160) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0700 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day G13 diet	Intake = daily intake: µg/person G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
FC 0004	Oranges, sweet, sour, raw	RAC	2.95	1.18	3.48	1.11	3.27	14.28	42.13	0.10	0.30	1.08	3.19
JF 0004	Oranges, juice (single strength, incl. concentrated)	PP	0.02	0.10	0.00	0.26	0.01	12.61	0.25	0.14	0.00	0.33	0.01
FS 0014	Plums, raw (incl dried plums) (excl jujube)	RAC	0.185	0.10	0.02	0.10	0.02	16.65	3.08	0.10	0.02	NC	-
FS 2001	Peaches, nectarines, apricots, raw	RAC	1.55	0.10	0.16	0.10	0.16	9.93	15.39	0.10	0.16	NC	-
FB 0265	Cranberries, raw	RAC	0.3	NC	-	NC	-	0.10	0.03	NC	-	NC	-
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.06	20.88	1.25	81.15	4.87	24.58	1.47	37.92	2.28	310.23	18.61
FI 0353	Pineapple, raw (incl canned pineapple, incl pineapple juice, incl dried pineapple)	RAC	0.02	8.51	0.17	6.27	0.13	6.89	0.14	0.18	0.00	24.94	0.50
VO 0447	Sweet corn on the cob, raw (incl frozen, incl canned) (i.e. kernels plus cob without husks)	RAC	0.05	3.63	0.18	20.50	1.03	8.78	0.44	0.10	0.01	0.17	0.01
VO 0448	Tomato, raw (incl juice, incl paste, incl canned)	RAC	0.8	15.50	12.40	5.78	4.62	71.52	57.22	2.00	1.60	12.50	10.00
VD 0541	Soya bean, dry, raw (incl paste, incl curd, incl oil, incl sauce)	RAC	0.03	15.80	0.47	14.29	0.43	104.36	3.13	17.11	0.51	35.20	1.06
VR 0596	Sugar beet, raw (incl sugar)	RAC	0.06	3.93	0.24	1.68	0.10	NC	-	NC	-	36.12	2.17
GC 0640	Barley, raw (incl malt extract, incl pot&pearled, incl flour & grits, incl beer, incl malt)	RAC	0.0675	11.58	0.78	2.33	0.16	46.71	3.15	3.72	0.25	16.26	1.10
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl flour, incl oil, incl beer, incl germ, incl starch)	RAC	0.05	116.66	5.83	10.52	0.53	38.46	1.92	76.60	3.83	34.44	1.72
GC 0656	Popcorn (i.e. maize used for preparation of popcorn)	RAC	0.05	-	-	-	-	-	-	-	-	-	-
GC 0650	Rye, raw	RAC	0.06	0.10	0.01	NC	-	NC	-	0.10	0.01	NC	-
GC 0653	Triticale, raw	RAC	0.06	0.10	0.01	NC	-	NC	-	NC	-	NC	-
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, incl germ, incl wholemeal bread, incl white flour products, incl white bread)	RAC	0.06	57.20	3.43	110.47	6.63	272.62	16.36	25.82	1.55	132.04	7.92
GS 0659	Sugar cane, raw	RAC	0	5.62	0.00	50.91	0.00	NC	-	11.04	0.00	0.10	0.00
TN 0672	Pecan nuts, nutmeat	RAC	0.02	0.15	0.00	0.22	0.00	0.31	0.01	0.10	0.00	0.10	0.00

Annex 3

PROPICONAZOLE (160) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0700 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day G13 diet	Intake = daily intake: µg/person G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
SO 0495	Rape seed, raw	RAC	0.06	NC	-	0.10	0.01	NC	-	NC	-	NC	-
MO 0105	Edible offal (mammalian), raw	RAC	0.5	4.64	2.32	1.97	0.99	10.01	5.01	3.27	1.64	3.98	1.99
MM 0095	Meat from mammals other than marine mammals, raw (incl prepared meat)	RAC	0,064	29,18	1,87	50,89	3,26	121,44	7,77	22,58	1,45	72,14	4,62
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.035	108.75	3.81	70.31	2.46	436.11	15.26	61.55	2.15	79.09	2.77
PM 0110	Poultry meat, raw (incl prepared) - 90% as muscle	RAC	0.05	3.53	0.18	10.83	0.54	51.36	2.57	4.53	0.23	50.00	2.50
PM 0110	Poultry meat, raw (incl prepared) - 10% as fat	RAC	0.05	0.39	0.02	1.20	0.06	5.71	0.29	0.50	0.03	5.56	0.28
PE 0112	Eggs, raw, (incl dried)	RAC	0.05	3.84	0.19	4.41	0.22	27.25	1.36	1.13	0.06	7.39	0.37
	Total intake (µg/person)=				36.2		28.4		174.5		15.6		57.3
	Bodyweight per region (kg bw) =				60		60		60		60		60
	ADI (µg/person)=				4200		4200		4200		4200		4200
	%ADI=				0.9%		0.7%		4.2%		0.4%		1.4%
	Rounded %ADI=				1%		1%		4%		0%		1%

Annex 3

PROTHIOCONAZOLE (232) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0100 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day						Intake as µg/person/day					
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
FB 0020	Blueberries, raw	RAC	0.52	0.10	0.05	0.10	0.05	0.10	0.05	0.10	0.05	0.10	0.05	0.10	0.05
FB 0021	Currants, red, black, white, raw	RAC	0.52	0.10	0.05	0.74	0.38	0.10	0.05	0.10	0.05	0.10	0.05	0.10	0.05
FB 0268	Gooseberries, raw	RAC	0.52	0.10	0.05	0.24	0.12	NC	-	0.10	0.05	0.10	0.05	NC	-
FB 0265	Cranberries, raw	RAC	0.025	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.10	0.00	0.10	0.00
VC 0045	Fruiting vegetables, cucurbits, raw	RAC	0.045	53.14	2.39	86.21	3.88	6.28	0.28	92.76	4.17	15.64	0.70	155.30	6.99
VO 0447	Sweet corn on the cob, raw (incl frozen, incl canned) (i.e. kernels plus cob without husks)	RAC	0.018	0.14	0.00	0.94	0.02	5.70	0.10	2.61	0.05	1.94	0.03	0.22	0.00
VD 0541	Soya bean, dry, raw (incl paste, incl curd, incl oil, incl sauce)	RAC	0.009	72.79	0.66	59.05	0.53	20.55	0.18	74.20	0.67	61.12	0.55	73.24	0.66
-	Pulses, NES, dry, raw: lablab or hyacinth bean, jack or sword bean, winged bean, guar bean, velvet bean, yam bean (Dolichos spp., Canavalia spp., Psophocarpus tetragonolobus, Cyamopsis tetragonoloba, Stizolobium spp., Pachyrrhizus erosus)	RAC	0.05	1.70	0.09	0.10	0.01	3.00	0.15	1.80	0.09	1.64	0.08	1.33	0.07
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.01	59.74	0.60	316.14	3.16	9.78	0.10	60.26	0.60	54.12	0.54	119.82	1.20
VR 0596	Sugar beet, raw (incl sugar)	RAC	0.05	0.13	0.01	NC	-	0.10	0.01	0.66	0.03	0.47	0.02	88.94	4.45
GC 0640	Barley, raw (incl malt extract, incl pot&pearled, incl flour & grits, incl beer, incl malt)	RAC	0.035	19.91	0.70	31.16	1.09	5.04	0.18	3.10	0.11	9.77	0.34	4.31	0.15
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl starch, excl flour, excl oil, excl beer, excl germ)	RAC	0.01	0.97	0.01	0.24	0.00	0.70	0.01	4.09	0.04	2.33	0.02	13.31	0.13
CF 1255	Maize, flour (white flour and wholemeal flour)	PP	0.0057	22.72	0.13	35.61	0.20	87.27	0.50	34.92	0.20	46.71	0.27	49.12	0.28
-	Maize starch	PP	0.0028	0.10	0.00	NC	-	0.10	0.00	2.29	0.01	0.10	0.00	0.11	0.00
OR 0645	Maize oil	PP	0.0028	0.96	0.00	0.85	0.00	0.29	0.00	5.42	0.02	0.42	0.00	2.10	0.01
GC 0647	Oats, raw (incl rolled)	RAC	0.01	0.10	0.00	7.05	0.07	0.10	0.00	1.71	0.02	0.96	0.01	0.10	0.00
GC 0650	Rye, raw (incl flour)	RAC	0.01	0.13	0.00	19.38	0.19	0.10	0.00	0.12	0.00	0.10	0.00	2.15	0.02
GC 0653	Triticale, raw (incl flour)	RAC	0.01	NC	-	NC	-	NC	-	0.10	0.00	0.39	0.00	NC	-
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, incl germ, incl wholemeal bread, incl white flour products, incl white bread)	RAC	0.01	381.15	3.81	341.55	3.42	38.35	0.38	281.89	2.82	172.83	1.73	434.07	4.34
CF 1210	Wheat, germ	PP	0.04	NC	-	NC	-	0.10	0.00	0.10	0.00	0.14	0.01	0.10	0.00
CF 0654	Wheat, bran	PP	0.048	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
SO 0495	Rape seed, raw	RAC	0.01	0.10	0.00	NC	-	NC	-	0.10	0.00	0.75	0.01	0.10	0.00
OR 0495	Rape seed oil, edible	PP	0.01	0.35	0.00	0.44	0.00	0.19	0.00	0.97	0.01	3.28	0.03	0.77	0.01
MM 0095	MEAT FROM MAMMALS other than marine	RAC	0.005	24.96	0.12	57.95	0.29	16.70	0.08	38.38	0.19	26.46	0.13	29.00	0.15

Annex 3

PROTHIOCONAZOLE (232) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0100 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day G01 diet	Intake as µg/person/day G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
	mammals, raw (incl prepared meat) -80% as muscle														
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.01	6.24	0.06	14.49	0.14	4.18	0.04	9.60	0.10	6.62	0.07	7.25	0.07
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.01	3.29	0.03	6.14	0.06	0.82	0.01	1.57	0.02	2.23	0.02	1.07	0.01
MO 0105	Edible offal (mammalian), raw	RAC	0.05	4.79	0.24	9.68	0.48	2.97	0.15	5.49	0.27	3.84	0.19	5.03	0.25
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.004	289.65	1.16	485.88	1.94	26.92	0.11	239.03	0.96	199.91	0.80	180.53	0.72
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (µg/person)=				10.2		16.1		2.4		10.5		5.7		19.6
	Bodyweight per region (kg bw) =				60		60		60		60		60		60
	ADI (µg/person)=				600		600		600		600		600		600
	%ADI=				1.7%		2.7%		0.4%		1.8%		1.0%		3.3%
	Rounded %ADI=				2%		3%		0%		2%		1%		3%

PROTHIOCONAZOLE (232) STMR Diets as g/person/day Intake as µg/person/day

Codex Code	Commodity description	Expr as	mg/kg	G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
FB 0020	Blueberries, raw	RAC	0.52	0.10	0.05	0.23	0.12	0.10	0.05	0.83	0.43	0.33	0.17	NC	-
FB 0021	Currants, red, black, white, raw	RAC	0.52	0.48	0.25	4.23	2.20	NC	-	1.51	0.79	0.49	0.25	NC	-
FB 0268	Gooseberries, raw	RAC	0.52	0.10	0.05	1.04	0.54	0.10	0.05	0.23	0.12	NC	-	NC	-
FB 0265	Cranberries, raw	RAC	0.025	0.10	0.00	0.10	0.00	0.10	0.00	1.22	0.03	0.11	0.00	NC	-
VC 0045	Fruiting vegetables, cucurbits, raw	RAC	0.045	27.81	1.25	41.93	1.89	123.30	5.55	49.47	2.23	15.95	0.72	35.99	1.62
VO 0447	Sweet corn on the cob, raw (incl frozen, incl canned) (i.e. kernels plus cob without husks)	RAC	0.018	11.43	0.21	3.71	0.07	0.74	0.01	13.63	0.25	3.07	0.06	1.50	0.03
VD 0541	Soya bean, dry, raw (incl paste, incl curd, incl oil, incl sauce)	RAC	0.009	106.33	0.96	117.78	1.06	42.12	0.38	195.70	1.76	222.52	2.00	80.47	0.72
-	Pulses, NES, dry, raw: lablab or hyacinth bean, jack or sword bean, winged bean, guar bean, velvet bean, yam bean (Dolichos spp., Canavalia spp., Psophocarpus tetragonolobus, Cyamopsis tetragonoloba, Stizolobium spp., Pachyrrhizus erosus)	RAC	0.05	0.10	0.01	NC	-	0.57	0.03	0.11	0.01	0.16	0.01	0.94	0.05
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.01	225.03	2.25	234.24	2.34	71.48	0.71	177.55	1.78	234.55	2.35	37.71	0.38
VR 0596	Sugar beet, raw (incl sugar)	RAC	0.05	0.10	0.01	NC	-	0.10	0.01	0.10	0.01	NC	-	NC	-
GC 0640	Barley, raw (incl malt extract, incl pot&pearled,	RAC	0.035	36.18	1.27	53.45	1.87	9.39	0.33	35.25	1.23	46.68	1.63	15.92	0.56

Annex 3

PROTHIOCONAZOLE (232)			STMR	Diets as g/person/day											
Codex Code	Commodity description	Expr as	mg/kg	G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
	incl flour & grits, incl beer, incl malt)														
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl starch, excl flour, excl oil, excl beer, excl germ)	RAC	0.01	0.10	0.00	9.93	0.10	1.71	0.02	21.20	0.21	0.33	0.00	0.10	0.00
CF 1255	Maize, flour (white flour and wholemeal flour)	PP	0.0057	14.27	0.08	12.86	0.07	19.71	0.11	12.55	0.07	4.21	0.02	52.30	0.30
-	Maize starch	PP	0.0028	NC	-	NC	-	0.19	0.00	7.13	0.02	NC	-	NC	-
OR 0645	Maize oil	PP	0.0028	0.90	0.00	0.47	0.00	0.15	0.00	3.01	0.01	1.86	0.01	0.36	0.00
GC 0647	Oats, raw (incl rolled)	RAC	0.01	7.50	0.08	6.26	0.06	0.15	0.00	4.87	0.05	3.16	0.03	2.98	0.03
GC 0650	Rye, raw (incl flour)	RAC	0.01	3.21	0.03	35.38	0.35	0.21	0.00	6.50	0.07	1.49	0.01	NC	-
GC 0653	Triticale, raw (incl flour)	RAC	0.01	0.10	0.00	0.17	0.00	0.29	0.00	0.10	0.00	NC	-	NC	-
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, incl germ, incl wholemeal bread, incl white flour products, incl white bread)	RAC	0.01	253.07	2.53	244.73	2.45	134.44	1.34	235.10	2.35	216.39	2.16	167.40	1.67
CF 1210	Wheat, germ	PP	0.04	0.97	0.04	0.10	0.00	0.10	0.00	0.10	0.00	NC	-	0.10	0.00
CF 0654	Wheat, bran	PP	0.048	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
SO 0495	Rape seed, raw	RAC	0.01	NC	-	NC	-	0.10	0.00	NC	-	NC	-	NC	-
OR 0495	Rape seed oil, edible	PP	0.01	12.52	0.13	7.63	0.08	3.00	0.03	6.01	0.06	NC	-	NC	-
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.005	112.02	0.56	120.71	0.60	63.46	0.32	88.99	0.44	96.24	0.48	41.02	0.21
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.01	28.01	0.28	30.18	0.30	15.86	0.16	22.25	0.22	24.06	0.24	10.25	0.10
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.01	6.44	0.06	15.51	0.16	3.79	0.04	8.29	0.08	18.44	0.18	8.00	0.08
MO 0105	Edible offal (mammalian), raw	RAC	0.05	15.17	0.76	5.19	0.26	6.30	0.32	6.78	0.34	3.32	0.17	3.17	0.16
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.004	388.92	1.56	335.88	1.34	49.15	0.20	331.25	1.33	468.56	1.87	245.45	0.98
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (µg/person)=				12.4		15.9		9.7		13.9		12.4		6.9
	Bodyweight per region (kg bw) =				60		60		55		60		60		60
	ADI (µg/person)=				600		600		550		600		600		600
	%ADI=				2.1%		2.6%		1.8%		2.3%		2.1%		1.1%
	Rounded %ADI=				2%		3%		2%		2%		2%		1%

PROTHIOCONAZOLE (232)			STMR	Diets: g/person/day										Intake = daily intake: µg/person	
Codex Code	Commodity description	Expr as	mg/kg	G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake		
FB 0020	Blueberries, raw	RAC	0.52	NC	-	NC	-	0.20	0.10	NC	-	NC	-		
FB 0021	Currants, red, black, white, raw	RAC	0.52	0.10	0.05	NC	-	0.74	0.38	NC	-	NC	-		

Annex 3

PROTHIOCONAZOLE (232)			STMR	Diets: g/person/day				Intake = daily intake: µg/person					
Codex Code	Commodity description	Expr as	mg/kg	G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
FB 0268	Gooseberries, raw	RAC	0.52	NC	-	NC	-	0.12	0.06	NC	-	NC	-
FB 0265	Cranberries, raw	RAC	0.025	NC	-	NC	-	0.10	0.00	NC	-	NC	-
VC 0045	Fruiting vegetables, cucurbits, raw	RAC	0.045	5.96	0.27	9.74	0.44	51.82	2.33	13.61	0.61	0.10	0.00
VO 0447	Sweet corn on the cob, raw (incl frozen, incl canned) (i.e. kernels plus cob without husks)	RAC	0.018	3.63	0.07	20.50	0.37	8.78	0.16	0.10	0.00	0.17	0.00
VD 0541	Soya bean, dry, raw (incl paste, incl curd, incl oil, incl sauce)	RAC	0.009	15.80	0.14	14.29	0.13	104.36	0.94	17.11	0.15	35.20	0.32
-	Pulses, NES, dry, raw: lablab or hyacinth bean, jack or sword bean, winged bean, guar bean, velvet bean, yam bean (Dolichos spp., Canavalia spp., Psophocarpus tetragonolobus, Cyamopsis tetragonoloba, Stizolobium spp., Pachyrrhizus erosus)	RAC	0.05	2.54	0.13	1.77	0.09	0.10	0.01	0.10	0.01	3.99	0.20
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.01	23.96	0.24	13.56	0.14	213.41	2.13	104.35	1.04	8.56	0.09
VR 0596	Sugar beet, raw (incl sugar)	RAC	0.05	3.93	0.20	1.68	0.08	NC	-	NC	-	36.12	1.81
GC 0640	Barley, raw (incl malt extract, incl pot&pearled, incl flour & grits, incl beer, incl malt)	RAC	0.035	11.58	0.41	2.33	0.08	46.71	1.63	3.72	0.13	16.26	0.57
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl starch, excl flour, excl oil, excl beer, excl germ)	RAC	0.01	0.37	0.00	0.52	0.01	3.26	0.03	0.18	0.00	NC	-
CF 1255	Maize, flour (white flour and wholemeal flour)	PP	0.0057	94.34	0.54	8.09	0.05	28.03	0.16	55.94	0.32	28.07	0.16
-	Maize starch	PP	0.0028	0.10	0.00	0.10	0.00	NC	-	NC	-	NC	-
OR 0645	Maize oil	PP	0.0028	0.33	0.00	0.10	0.00	0.81	0.00	0.10	0.00	NC	-
GC 0647	Oats, raw (incl rolled)	RAC	0.01	0.37	0.00	0.10	0.00	2.79	0.03	0.10	0.00	NC	-
GC 0650	Rye, raw (incl flour)	RAC	0.01	0.10	0.00	0.10	0.00	13.95	0.14	0.10	0.00	0.88	0.01
GC 0653	Triticale, raw (incl flour)	RAC	0.01	0.10	0.00	NC	-	NC	-	NC	-	NC	-
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, incl germ, incl wholemeal bread, incl white flour products, incl white bread)	RAC	0.01	57.20	0.57	110.47	1.10	272.62	2.73	25.82	0.26	132.04	1.32
CF 1210	Wheat, germ	PP	0.04	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00	NC	-
CF 0654	Wheat, bran	PP	0.048	NC	-	NC	-	NC	-	NC	-	NC	-
SO 0495	Rape seed, raw	RAC	0.01	NC	-	0.10	0.00	NC	-	NC	-	NC	-
OR 0495	Rape seed oil, edible	PP	0.01	0.10	0.00	0.10	0.00	4.62	0.05	0.10	0.00	NC	-
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.005	23.34	0.12	40.71	0.20	97.15	0.49	18.06	0.09	57.71	0.29
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.01	5.84	0.06	10.18	0.10	24.29	0.24	4.52	0.05	14.43	0.14
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.01	1.05	0.01	1.14	0.01	18.69	0.19	0.94	0.01	3.12	0.03
MO 0105	Edible offal (mammalian), raw	RAC	0.05	4.64	0.23	1.97	0.10	10.01	0.50	3.27	0.16	3.98	0.20

Annex 3

PROTHIOCONAZOLE (232)			STMR	Diets: g/person/day			Intake = daily intake: µg/person						
Codex Code	Commodity description	Expr as	mg/kg	G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.004	108.75	0.44	70.31	0.28	436.11	1.74	61.55	0.25	79.09	0.32
-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (µg/person)=				3.5		3.2		14.1		3.1		5.5
	Bodyweight per region (kg bw) =				60		60		60		60		60
	ADI (µg/person)=				600		600		600		600		600
	%ADI=				0.6%		0.5%		2.3%		0.5%		0.9%
	Rounded %ADI=				1%		1%		2%		1%		1%

Annex 3

PYRACLOSTROBIN (210) International Estimated Daily Intake (IEDI) ADI = 0 - 0.03 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day						Intake as µg/person/day					
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
FC 0001	Citrus fruit, raw (incl citrus fruit juice)	RAC	0.035	34.91	1.22	16.51	0.58	17.23	0.60	104.48	3.66	35.57	1.24	98.49	3.45
FP 0226	Apple, raw (incl juice, incl cider)	RAC	0.104	13.94	1.45	30.81	3.20	15.14	1.57	23.10	2.40	6.86	0.71	55.48	5.77
FS 0013	Cherries, raw	RAC	0.51	0.92	0.47	9.15	4.67	0.10	0.05	0.61	0.31	0.10	0.05	6.64	3.39
003B	Plums	-	0.09	-	-	-	-	-	-	-	-	-	-	-	-
FS 2001	Peaches, nectarines, apricots, raw (incl dried apricots)	RAC	0.07	8.01	0.56	5.87	0.41	0.18	0.01	8.19	0.57	1.64	0.11	22.46	1.57
FB 0264	Blackberries, raw	RAC	0.87	0.35	0.30	0.11	0.10	0.10	0.09	0.10	0.09	0.10	0.09	1.23	1.07
FB 0272	Raspberries, red, black, raw	RAC	0.87	0.10	0.09	0.93	0.81	0.10	0.09	0.10	0.09	0.10	0.09	0.10	0.09
FB 0020	Blueberries, raw	RAC	0.78	0.10	0.08	0.10	0.08	0.10	0.08	0.10	0.08	0.10	0.08	0.10	0.08
FB 0021	Currants, red, black, white, raw	RAC	0.185	0.10	0.02	0.74	0.14	0.10	0.02	0.10	0.02	0.10	0.02	0.10	0.02
FB 0269	Grape, raw (incl must, excl dried, excl juice, excl wine)	RAC	0.44	13.02	5.73	9.25	4.07	0.10	0.04	16.91	7.44	3.70	1.63	54.44	23.95
DF 0269	Grape, dried (= currants, raisins and sultanas)	PP	1.36	0.51	0.69	0.51	0.69	0.10	0.14	1.27	1.73	0.12	0.16	2.07	2.82
JF 0269	Grape juice	PP	0.005	0.14	0.00	0.29	0.00	0.10	0.00	0.30	0.00	0.24	0.00	0.10	0.00
-	Grape wine (incl vermouths)	PP	0.04	0.67	0.03	12.53	0.50	2.01	0.08	1.21	0.05	3.53	0.14	4.01	0.16
FB 0275	Strawberry, raw	RAC	0.2	0.70	0.14	2.01	0.40	0.10	0.02	1.36	0.27	0.37	0.07	2.53	0.51
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.02	5.06	0.10	6.91	0.14	37.17	0.74	31.16	0.62	40.21	0.80	18.96	0.38
FI 0345	Mango, raw (incl canned mango, incl mango juice)	RAC	0.05	10.48	0.52	0.10	0.01	7.24	0.36	6.87	0.34	19.98	1.00	6.25	0.31
FI 0350	Papaya, raw	RAC	0.05	0.35	0.02	0.10	0.01	3.05	0.15	0.80	0.04	7.28	0.36	1.00	0.05
VA 0381	Garlic, raw	RAC	0.02	2.29	0.05	5.78	0.12	0.11	0.00	3.69	0.07	1.65	0.03	3.91	0.08
VA 0384	Leek, raw	RAC	0.22	0.18	0.04	1.59	0.35	0.10	0.02	0.28	0.06	0.10	0.02	3.21	0.71
-	Onions, mature bulbs, dry	RAC	0.06	29.36	1.76	37.50	2.25	3.56	0.21	34.78	2.09	18.81	1.13	43.38	2.60
-	Onions, green, raw	RAC	0.42	2.45	1.03	1.49	0.63	1.02	0.43	2.60	1.09	0.60	0.25	2.03	0.85
VB 0041	Cabbages, head, raw	RAC	0.02	2.73	0.05	27.92	0.56	0.55	0.01	4.47	0.09	4.27	0.09	10.25	0.21
VB 0042	Flowerhead brassicas, raw	RAC	0.02	2.96	0.06	0.57	0.01	0.10	0.00	4.17	0.08	7.79	0.16	3.64	0.07
VB 0402	Brussels sprouts, raw	RAC	0.03	0.63	0.02	6.41	0.19	0.13	0.00	1.03	0.03	NC	-	2.35	0.07
VC 0045	Fruiting vegetables, cucurbits, raw	RAC	0.06	53.14	3.19	86.21	5.17	6.28	0.38	92.76	5.57	15.64	0.94	155.30	9.32
VO 0440	Egg plants, raw (= aubergines)	RAC	0.12	5.58	0.67	4.31	0.52	0.89	0.11	9.31	1.12	13.64	1.64	20.12	2.41
VO 0444	Peppers, chili, raw (incl dried)	RAC	0.08	6.93	0.55	10.97	0.88	8.83	0.71	9.13	0.73	6.65	0.53	20.01	1.60
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.08	4.49	0.36	6.44	0.52	7.21	0.58	5.68	0.45	9.52	0.76	8.92	0.71
VO 0448	Tomato, raw (incl juice, incl paste, incl canned)	RAC	0.12	51.75	6.21	81.80	9.82	16.99	2.04	102.02	12.24	26.32	3.16	214.77	25.77
VL 0480	Kale, raw (i.e. collards) (i.e. Brassica)	RAC	0.175	0.57	0.10	5.77	1.01	0.11	0.02	0.92	0.16	5.25	0.92	2.12	0.37
VL 0482	Lettuce, head, raw	RAC	0.26	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VP 0064	Peas, green, without pods, raw (i.e. immature seeds only) (Pisum spp)	RAC	0.02	1.97	0.04	0.51	0.01	0.10	0.00	0.79	0.02	3.68	0.07	3.80	0.08

Annex 3

PYRACLOSTROBIN (210) International Estimated Daily Intake (IEDI) ADI = 0 - 0.03 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day						Intake as µg/person/day					
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	0.02	2.39	0.05	1.61	0.03	10.47	0.21	1.84	0.04	12.90	0.26	7.44	0.15
VD 0071	Peas, dry, raw (Pisum spp, Vigna spp): garden peas & field peas & cow peas	RAC	0.07	1.67	0.12	3.22	0.23	2.66	0.19	1.51	0.11	2.91	0.20	0.24	0.02
VD 0533	Lentil, dry, raw (Ervum lens)	RAC	0.13	2.12	0.28	0.10	0.01	0.10	0.01	3.21	0.42	1.60	0.21	4.90	0.64
VD 0541	Soya bean, dry, raw (incl flour, incl paste, incl curd, incl sauce, excl oil)	RAC	0.02	0.63	0.01	1.09	0.02	0.40	0.01	1.40	0.03	1.68	0.03	0.48	0.01
OR 0541	Soya oil, refined	PP	0.012	12.99	0.16	10.43	0.13	3.63	0.04	13.10	0.16	10.70	0.13	13.10	0.16
VR 0494	Radish roots, raw	RAC	0.08	2.31	0.18	4.09	0.33	2.53	0.20	6.15	0.49	5.88	0.47	2.97	0.24
VR 0577	Carrots, raw	RAC	0.12	9.51	1.14	30.78	3.69	0.37	0.04	8.75	1.05	2.80	0.34	6.10	0.73
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.02	59.74	1.19	316.14	6.32	9.78	0.20	60.26	1.21	54.12	1.08	119.82	2.40
VR 0596	Sugar beet, raw (incl sugar)	RAC	0.04	0.13	0.01	NC	-	0.10	0.00	0.66	0.03	0.47	0.02	88.94	3.56
VS 0620	Artichoke globe	RAC	0.25	0.69	0.17	0.10	0.03	0.10	0.03	0.32	0.08	0.26	0.07	1.21	0.30
GC 0640	Barley, raw (incl malt extract, incl pot&pearled, incl flour & grits, incl beer, incl malt)	RAC	0.345	19.91	6.87	31.16	10.75	5.04	1.74	3.10	1.07	9.77	3.37	4.31	1.49
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl flour, incl oil, incl beer, incl germ, incl starch)	RAC	0.02	29.81	0.60	44.77	0.90	108.95	2.18	52.37	1.05	60.28	1.21	75.69	1.51
GC 0647	Oats, raw (incl rolled)	RAC	0.345	0.10	0.03	7.05	2.43	0.10	0.03	1.71	0.59	0.96	0.33	0.10	0.03
GC 0650	Rye, raw (incl flour)	RAC	0.02	0.13	0.00	19.38	0.39	0.10	0.00	0.12	0.00	0.10	0.00	2.15	0.04
GC 0651	Sorghum, raw (incl flour, incl beer)	RAC	0.025	4.34	0.11	0.10	0.00	16.25	0.41	15.82	0.40	10.97	0.27	2.92	0.07
GC 0653	Triticale, raw (incl flour)	RAC	0.02	NC	-	NC	-	NC	-	0.10	0.00	0.39	0.01	NC	-
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, excl germ, excl wholemeal bread, excl white flour products, excl white bread)	RAC	0.012	0.10	0.00	1.12	0.01	0.10	0.00	0.10	0.00	0.61	0.01	0.10	0.00
CF 1210	Wheat, germ	PP	0.016	NC	-	NC	-	0.10	0.00	0.10	0.00	0.14	0.00	0.10	0.00
CF 0654	Wheat, bran	PP	0.012	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
CF 1212	Wheat, wholemeal flour	PP	0.012	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
CP 1212	Wheat, wholemeal bread	PP	0.012	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00
CF 1211	Wheat, white flour (incl white flour products: starch, gluten, macaroni, pastry)	PP	0.012	301.49	3.62	269.27	3.23	30.33	0.36	222.94	2.68	136.12	1.63	343.34	4.12
TN 0675	Pistachio nut, nutmeat	RAC	0.22	0.41	0.09	0.10	0.02	0.10	0.02	0.85	0.19	0.10	0.02	1.08	0.24
SO 0089	Oilseeds, raw (incl processed), excl peanut commodities	RAC	0.055	78.01	4.29	53.57	2.95	84.12	4.63	134.84	7.42	54.48	3.00	86.04	4.73
SO 0697	Peanuts, nutmeat, raw (incl roasted, incl oil, incl butter)	RAC	0.02	1.30	0.03	1.23	0.02	12.62	0.25	2.87	0.06	6.59	0.13	2.67	0.05
SB 0716	Coffee beans raw (incl roasted, incl instant coffee, incl substitutes)	RAC	0.025	1.36	0.03	3.59	0.09	1.44	0.04	5.18	0.13	2.02	0.05	1.70	0.04
DH 1100	Hops, dry	RAC	4	0.10	0.40	0.10	0.40	0.10	0.40	0.10	0.40	NC	-	0.10	0.40
MM 0095	MEAT FROM MAMMALS other than marine	RAC	0.009	24.96	0.22	57.95	0.52	16.70	0.15	38.38	0.35	26.46	0.24	29.00	0.26

Annex 3

PYRACLOSTROBIN (210) International Estimated Daily Intake (IEDI) ADI = 0 - 0.03 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day G01 diet	Intake as µg/person/day G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
	mammals, raw (incl prepared meat) -80% as muscle														
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.063	6.24	0.39	14.49	0.91	4.18	0.26	9.60	0.60	6.62	0.42	7.25	0.46
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.063	3.29	0.21	6.14	0.39	0.82	0.05	1.57	0.10	2.23	0.14	1.07	0.07
MO 0105	Edible offal (mammalian), raw	RAC	0.008	4.79	0.04	9.68	0.08	2.97	0.02	5.49	0.04	3.84	0.03	5.03	0.04
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.01	289.65	2.90	485.88	4.86	26.92	0.27	239.03	2.39	199.91	2.00	180.53	1.81
PM 0110	Poultry meat, raw (incl prepared)	RAC	0	14.63	0.00	29.76	0.00	8.04	0.00	129.68	0.00	25.04	0.00	35.66	0.00
PF 0111	Poultry fat, raw (incl rendered)	RAC	0	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.10	0.00	0.10	0.00
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0	0.12	0.00	0.12	0.00	0.11	0.00	5.37	0.00	0.24	0.00	0.10	0.00
PE 0112	Eggs, raw, (incl dried)	RAC	0	7.84	0.00	23.08	0.00	2.88	0.00	14.89	0.00	9.81	0.00	14.83	0.00
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (µg/person)=				48.7		76.6		20.3		62.6		31.9		112.0
	Bodyweight per region (kg bw) =				60		60		60		60		60		60
	ADI (µg/person)=				1800		1800		1800		1800		1800		1800
	%ADI=				2.7%		4.3%		1.1%		3.5%		1.8%		6.2%
	Rounded %ADI=				3%		4%		1%		3%		2%		6%

PYRACLOSTROBIN (210) International Estimated Daily Intake (IEDI) ADI = 0 - 0.03 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day G13 diet	Intake = daily intake: µg/person G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
FC 0001	Citrus fruit, raw (incl citrus fruit juice)	RAC	0.035	21.16	0.74	2.94	0.10	58.52	2.05	0.44	0.02	5.13	0.18
FP 0226	Apple, raw (incl juice, incl cider)	RAC	0.104	66.71	6.94	2.19	0.23	65.63	6.83	188.34	19.59	1.38	0.14
FS 0013	Cherries, raw	RAC	0.51	0.10	0.05	0.10	0.05	5.96	3.04	0.10	0.05	NC	-
003B	Plums	-	0.09	-	-	-	-	-	-	-	-	-	-
FS 2001	Peaches, nectarines, apricots, raw (incl dried apricots)	RAC	0.07	0.10	0.01	0.10	0.01	10.76	0.75	0.10	0.01	NC	-
FB 0264	Blackberries, raw	RAC	0.87	0.10	0.09	7.29	6.34	0.25	0.22	0.10	0.09	NC	-
FB 0272	Raspberries, red, black, raw	RAC	0.87	0.10	0.09	0.10	0.09	2.04	1.77	0.10	0.09	NC	-
FB 0020	Blueberries, raw	RAC	0.78	NC	-	NC	-	0.20	0.16	NC	-	NC	-
FB 0021	Currants, red, black, white, raw	RAC	0.185	0.10	0.02	NC	-	0.74	0.14	NC	-	NC	-
FB 0269	Grape, raw (incl must, excl dried, excl juice, excl wine)	RAC	0.44	0.14	0.06	0.36	0.16	15.33	6.75	0.10	0.04	0.28	0.12
DF 0269	Grape, dried (= currants, raisins and sultanas)	PP	1.36	0.10	0.14	0.13	0.18	1.06	1.44	0.10	0.14	0.10	0.14
JF 0269	Grape juice	PP	0.005	0.10	0.00	0.10	0.00	0.41	0.00	0.10	0.00	NC	-
-	Grape wine (incl vermouths)	PP	0.04	0.31	0.01	0.23	0.01	60.43	2.42	0.52	0.02	31.91	1.28

Annex 3

PYRACLOSTROBIN (210) International Estimated Daily Intake (IEDI) ADI = 0 - 0.03 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day G13 diet	Intake = daily intake: µg/person G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
FB 0275	Strawberry, raw	RAC	0.2	0.10	0.02	0.10	0.02	3.35	0.67	0.10	0.02	0.10	0.02
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.02	20.88	0.42	81.15	1.62	24.58	0.49	37.92	0.76	310.23	6.20
FI 0345	Mango, raw (incl canned mango, incl mango juice)	RAC	0.05	12.25	0.61	6.83	0.34	0.76	0.04	0.10	0.01	20.12	1.01
FI 0350	Papaya, raw	RAC	0.05	6.47	0.32	0.25	0.01	0.19	0.01	0.10	0.01	26.42	1.32
VA 0381	Garlic, raw	RAC	0.02	0.82	0.02	2.06	0.04	3.79	0.08	0.10	0.00	0.29	0.01
VA 0384	Leek, raw	RAC	0.22	0.10	0.02	1.44	0.32	1.22	0.27	0.10	0.02	NC	-
-	Onions, mature bulbs, dry	RAC	0.06	9.01	0.54	20.24	1.21	30.90	1.85	9.61	0.58	2.11	0.13
-	Onions, green, raw	RAC	0.42	1.43	0.60	0.10	0.04	0.20	0.08	NC	-	6.30	2.65
VB 0041	Cabbages, head, raw	RAC	0.02	3.82	0.08	2.99	0.06	49.16	0.98	0.10	0.00	NC	-
VB 0042	Flowerhead brassicas, raw	RAC	0.02	0.10	0.00	0.10	0.00	4.86	0.10	0.10	0.00	NC	-
VB 0402	Brussels sprouts, raw	RAC	0.03	0.88	0.03	0.69	0.02	2.89	0.09	0.10	0.00	NC	-
VC 0045	Fruiting vegetables, cucurbits, raw	RAC	0.06	5.96	0.36	9.74	0.58	51.82	3.11	13.61	0.82	0.10	0.01
VO 0440	Egg plants, raw (= aubergines)	RAC	0.12	1.31	0.16	8.26	0.99	3.95	0.47	0.10	0.01	NC	-
VO 0444	Peppers, chili, raw (incl dried)	RAC	0.08	7.55	0.60	12.48	1.00	24.78	1.98	0.87	0.07	NC	-
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.08	5.49	0.44	10.57	0.85	8.84	0.71	0.91	0.07	NC	-
VO 0448	Tomato, raw (incl juice, incl paste, incl canned)	RAC	0.12	15.50	1.86	5.78	0.69	71.52	8.58	2.00	0.24	12.50	1.50
VL 0480	Kale, raw (i.e. collards) (i.e. Brassica)	RAC	0.175	0.79	0.14	0.62	0.11	NC	-	0.10	0.02	NC	-
VL 0482	Lettuce, head, raw	RAC	0.26	NC	-	NC	-	NC	-	NC	-	NC	-
VP 0064	Peas, green, without pods, raw (i.e. immature seeds only) (Pisum spp)	RAC	0.02	0.21	0.00	0.10	0.00	5.51	0.11	0.10	0.00	NC	-
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	0.02	7.11	0.14	2.33	0.05	3.76	0.08	44.70	0.89	3.27	0.07
VD 0071	Peas, dry, raw (Pisum spp, Vigna spp): garden peas & field peas & cow peas	RAC	0.07	14.30	1.00	3.51	0.25	3.52	0.25	7.89	0.55	0.74	0.05
VD 0533	Lentil, dry, raw (Ervum lens)	RAC	0.13	0.67	0.09	7.26	0.94	0.37	0.05	0.10	0.01	NC	-
VD 0541	Soya bean, dry, raw (incl flour, incl paste, incl curd, incl sauce, excl oil)	RAC	0.02	2.89	0.06	0.21	0.00	0.48	0.01	3.16	0.06	0.26	0.01
OR 0541	Soya oil, refined	PP	0.012	2.32	0.03	2.54	0.03	18.70	0.22	2.51	0.03	6.29	0.08
VR 0494	Radish roots, raw	RAC	0.08	3.96	0.32	2.86	0.23	3.30	0.26	2.67	0.21	5.34	0.43
VR 0577	Carrots, raw	RAC	0.12	2.07	0.25	3.00	0.36	25.29	3.03	0.10	0.01	NC	-
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.02	23.96	0.48	13.56	0.27	213.41	4.27	104.35	2.09	8.56	0.17
VR 0596	Sugar beet, raw (incl sugar)	RAC	0.04	3.93	0.16	1.68	0.07	NC	-	NC	-	36.12	1.44
VS 0620	Artichoke globe	RAC	0.25	0.10	0.03	NC	-	0.10	0.03	0.10	0.03	NC	-
GC 0640	Barley, raw (incl malt extract, incl pot&pearled, incl flour & grits, incl beer, incl malt)	RAC	0.345	11.58	4.00	2.33	0.80	46.71	16.11	3.72	1.28	16.26	5.61
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl flour, incl oil, incl beer, incl germ, incl starch)	RAC	0.02	116.66	2.33	10.52	0.21	38.46	0.77	76.60	1.53	34.44	0.69
GC 0647	Oats, raw (incl rolled)	RAC	0.345	0.37	0.13	0.10	0.03	2.79	0.96	0.10	0.03	NC	-
GC 0650	Rye, raw (incl flour)	RAC	0.02	0.10	0.00	0.10	0.00	13.95	0.28	0.10	0.00	0.88	0.02

Annex 3

PYRACLOSTROBIN (210) International Estimated Daily Intake (IEDI) ADI = 0 - 0.03 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day G13 diet	Intake = daily intake: µg/person G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
GC 0651	Sorghum, raw (incl flour, incl beer)	RAC	0.025	89.16	2.23	2.02	0.05	NC	-	35.38	0.88	NC	-
GC 0653	Triticale, raw (incl flour)	RAC	0.02	0.10	0.00	NC	-	NC	-	NC	-	NC	-
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, excl germ, excl wholemeal bread, excl white flour products, excl white bread)	RAC	0.012	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00	0.97	0.01
CF 1210	Wheat, germ	PP	0.016	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00	NC	-
CF 0654	Wheat, bran	PP	0.012	NC	-	NC	-	NC	-	NC	-	NC	-
CF 1212	Wheat, wholemeal flour	PP	0.012	NC	-	NC	-	NC	-	NC	-	NC	-
CP 1212	Wheat, wholemeal bread	PP	0.012	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00
CF 1211	Wheat, white flour (incl white flour products: starch, gluten, macaroni, pastry)	PP	0.012	45.21	0.54	87.37	1.05	215.61	2.59	20.42	0.25	103.67	1.24
TN 0675	Pistachio nut, nutmeat	RAC	0.22	0.10	0.02	0.10	0.02	0.15	0.03	0.10	0.02	NC	-
SO 0089	Oilseeds, raw (incl processed), excl peanut commodities	RAC	0.055	112.89	6.21	21.92	1.21	67.05	3.69	50.78	2.79	86.21	4.74
SO 0697	Peanuts, nutmeat, raw (incl roasted, incl oil, incl butter)	RAC	0.02	18.82	0.38	0.57	0.01	2.28	0.05	6.90	0.14	0.53	0.01
SB 0716	Coffee beans raw (incl roasted, incl instant coffee, incl substitutes)	RAC	0.025	0.95	0.02	1.32	0.03	11.64	0.29	2.96	0.07	14.73	0.37
DH 1100	Hops, dry	RAC	4	NC	-	NC	-	0.10	0.40	NC	-	NC	-
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.009	23.34	0.21	40.71	0.37	97.15	0.87	18.06	0.16	57.71	0.52
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.063	5.84	0.37	10.18	0.64	24.29	1.53	4.52	0.28	14.43	0.91
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.063	1.05	0.07	1.14	0.07	18.69	1.18	0.94	0.06	3.12	0.20
MO 0105	Edible offal (mammalian), raw	RAC	0.008	4.64	0.04	1.97	0.02	10.01	0.08	3.27	0.03	3.98	0.03
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.01	108.75	1.09	70.31	0.70	436.11	4.36	61.55	0.62	79.09	0.79
PM 0110	Poultry meat, raw (incl prepared)	RAC	0	3.92	0.00	12.03	0.00	57.07	0.00	5.03	0.00	55.56	0.00
PF 0111	Poultry fat, raw (incl rendered)	RAC	0	NC	-	NC	-	0.32	0.00	NC	-	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0	0.10	0.00	0.70	0.00	0.97	0.00	0.10	0.00	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0	3.84	0.00	4.41	0.00	27.25	0.00	1.13	0.00	7.39	0.00
-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (µg/person)=				34.5		22.5		86.6		34.7		32.1
	Bodyweight per region (kg bw) =				60		60		60		60		60
	ADI (µg/person)=				1800		1800		1800		1800		1800
	%ADI=				1.9%		1.3%		4.8%		1.9%		1.8%
	Rounded %ADI=				2%		1%		5%		2%		2%

Annex 3

SEDAXANE (259) International Estimated Daily Intake (IEDI) ADI = 0 - 0.100 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day G01 diet	Intake as µg/person/day G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.01	59.74	0.60	316.14	3.16	9.78	0.10	60.26	0.60	54.12	0.54	119.82	1.20
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (µg/person)=				0.6		3.2		0.1		0.6		0.5		1.2
	Bodyweight per region (kg bw) =				60		60		60		60		60		60
	ADI (µg/person)=				6600		6600		6600		6600		6600		6600
	%ADI=				0.0%		0.0%		0.0%		0.0%		0.0%		0.0%
	Rounded %ADI=				0%		0%		0%		0%		0%		0%

SEDAXANE (259) International Estimated Daily Intake (IEDI) ADI = 0 - 0.100 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day G07 diet	Intake as µg/person/day G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.01	225.03	2.25	234.24	2.34	71.48	0.71	177.55	1.78	234.55	2.35	37.71	0.38
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (µg/person)=				2.3		2.3		0.7		1.8		2.3		0.4
	Bodyweight per region (kg bw) =				60		60		55		60		60		60
	ADI (µg/person)=				6600		6600		6050		6600		6600		6600
	%ADI=				0.0%		0.0%		0.0%		0.0%		0.0%		0.0%
	Rounded %ADI=				0%		0%		0%		0%		0%		0%

SEDAXANE (259) International Estimated Daily Intake (IEDI) ADI = 0 - 0.100 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day G13 diet	Intake = daily intake: µg/person G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.01	23.96	0.24	13.56	0.14	213.41	2.13	104.35	1.04	8.56	0.09
-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (µg/person)=				0.2		0.1		2.1		1.0		0.1

Annex 3

SEDAXANE (259) International Estimated Daily Intake (IEDI) ADI = 0 - 0.100 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day G13 diet	Intake = daily intake: µg/person G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
	Bodyweight per region (kg bw) =				60		60		60		60		60
	ADI (µg/person)=				6600		6600		6600		6600		6600
	%ADI=				0.0%		0.0%		0.0%		0.0%		0.0%
	Rounded %ADI=				0%		0%		0%		0%		0%

Annex 3

SPIRODICLOFEN (237) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0100 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day						Intake as µg/person/day					
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
FC 0001	Citrus fruit, raw	RAC	0.02	32.25	0.65	11.67	0.23	16.70	0.33	76.01	1.52	33.90	0.68	92.97	1.86
JF 0001	Citrus fruit, juice	PP	0.0065	1.30	0.01	2.37	0.02	0.22	0.00	13.88	0.09	0.75	0.00	2.63	0.02
FP 0009	Pome fruit, raw (incl cider, excl apple juice)	RAC	0.2	19.35	3.87	34.06	6.81	17.87	3.57	25.74	5.15	7.69	1.54	56.85	11.37
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.004	0.32	0.00	3.07	0.01	0.10	0.00	5.00	0.02	0.29	0.00	5.57	0.02
FS 0012	Stone fruits, raw (incl dried apricots, excl dried plums)	RAC	0.315	11.33	3.57	23.62	7.44	0.24	0.08	11.32	3.57	2.28	0.72	33.26	10.48
DF 0014	Plum, dried (prunes)	PP	0.79	0.10	0.08	0.10	0.08	0.10	0.08	0.18	0.14	0.10	0.08	0.10	0.08
FB 0020	Blueberries, raw	RAC	0.92	0.10	0.09	0.10	0.09	0.10	0.09	0.10	0.09	0.10	0.09	0.10	0.09
FB 0021	Currants, red, black, white, raw	RAC	0.04	0.10	0.00	0.74	0.03	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00
FB 0269	Grape, raw (incl must, excl dried, juice, wine)	RAC	0.059	13.02	0.77	9.25	0.55	0.10	0.01	16.91	1.00	3.70	0.22	54.44	3.21
DF 0269	Grape, dried (= currants, raisins and sultanas)	PP	0.13	0.51	0.07	0.51	0.07	0.10	0.01	1.27	0.17	0.12	0.02	2.07	0.27
JF 0269	Grape juice	PP	0.0005	0.14	0.00	0.29	0.00	0.10	0.00	0.30	0.00	0.24	0.00	0.10	0.00
-	Grape wine (incl vermouths)	PP	0.018	0.67	0.01	12.53	0.23	2.01	0.04	1.21	0.02	3.53	0.06	4.01	0.07
FB 0275	Strawberry, raw	RAC	0.0615	0.70	0.04	2.01	0.12	0.10	0.01	1.36	0.08	0.37	0.02	2.53	0.16
FI 0326	Avocado, raw	RAC	0.07	0.13	0.01	0.10	0.01	2.05	0.14	2.54	0.18	2.34	0.16	0.12	0.01
FI 0350	Papaya, raw	RAC	0.03	0.35	0.01	0.10	0.00	3.05	0.09	0.80	0.02	7.28	0.22	1.00	0.03
VC 0424	Cucumber, raw	RAC	0.03	8.01	0.24	30.66	0.92	1.45	0.04	19.84	0.60	0.27	0.01	34.92	1.05
VC 0425	Gherkin, raw	RAC	0.03	1.73	0.05	6.64	0.20	0.31	0.01	4.29	0.13	0.29	0.01	7.56	0.23
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.08	4.49	0.36	6.44	0.52	7.21	0.58	5.68	0.45	9.52	0.76	8.92	0.71
VO 0448	Tomato, raw (incl juice, paste, canned)	RAC	0.08	51.75	4.14	81.80	6.54	16.99	1.36	102.02	8.16	26.32	2.11	214.77	17.18
TN 0085	Tree nuts, raw (incl processed)	RAC	0.0155	4.06	0.06	3.27	0.05	7.01	0.11	13.93	0.22	14.01	0.22	9.36	0.15
SB 0716	Coffee beans raw (incl roasted, instant, substitutes)	RAC	0.03	1.36	0.04	3.59	0.11	1.44	0.04	5.18	0.16	2.02	0.06	1.70	0.05
DH 1100	Hops, dry	RAC	11	0.10	1.10	0.10	1.10	0.10	1.10	0.10	1.10	NC	-	0.10	1.10
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.01	24.96	0.25	57.95	0.58	16.70	0.17	38.38	0.38	26.46	0.26	29.00	0.29
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.01	6.24	0.06	14.49	0.14	4.18	0.04	9.60	0.10	6.62	0.07	7.25	0.07
MO 0105	Edible offal (mammalian), raw	RAC	0.05	4.79	0.24	9.68	0.48	2.97	0.15	5.49	0.27	3.84	0.19	5.03	0.25
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.004	289.65	1.16	485.88	1.94	26.92	0.11	239.03	0.96	199.91	0.80	180.53	0.72
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (µg/person)=				16.9		28.3		8.2		24.6		8.3		49.5
	Bodyweight per region (kg bw) =				60		60		60		60		60		60
	ADI (µg/person)=				600		600		600		600		600		600
	%ADI=				2.8%		4.7%		1.4%		4.1%		1.4%		8.2%
	Rounded %ADI=				3%		5%		1%		4%		1%		8%

Annex 3

SPIRODICLOFEN (237) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0100 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day G07 diet	Intake as µg/person/day G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
FC 0001	Citrus fruit, raw	RAC	0.02	38.66	0.77	54.93	1.10	26.36	0.53	51.46	1.03	51.06	1.02	466.36	9.33
JF 0001	Citrus fruit, juice	PP	0.0065	36.84	0.24	3.75	0.02	0.30	0.00	21.62	0.14	21.82	0.14	46.67	0.30
FP 0009	Pome fruit, raw (incl cider, excl apple juice)	RAC	0.2	51.09	10.22	65.40	13.08	42.71	8.54	45.29	9.06	62.51	12.50	7.74	1.55
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.004	14.88	0.06	11.98	0.05	0.15	0.00	9.98	0.04	30.32	0.12	3.47	0.01
FS 0012	Stone fruits, raw (incl dried apricots, dried plums)	RAC	0.315	18.18	5.73	23.83	7.51	14.27	4.50	18.52	5.83	9.35	2.95	0.11	0.03
DF 0014	Plum, dried (prunes)	PP	0.79	0.61	0.48	0.35	0.28	0.10	0.08	0.35	0.28	0.49	0.39	0.13	0.10
FB 0020	Blueberries, raw	RAC	0.92	0.10	0.09	0.23	0.21	0.10	0.09	0.83	0.76	0.33	0.30	NC	-
FB 0021	Currants, red, black, white, raw	RAC	0.04	0.48	0.02	4.23	0.17	NC	-	1.51	0.06	0.49	0.02	NC	-
FB 0269	Grape, raw (incl must, excl dried, juice, wine)	RAC	0.059	6.48	0.38	11.31	0.67	5.21	0.31	9.50	0.56	4.66	0.27	0.78	0.05
DF 0269	Grape, dried (= currants, raisins and sultanas)	PP	0.13	3.09	0.40	1.51	0.20	0.10	0.01	1.38	0.18	4.26	0.55	0.42	0.05
JF 0269	Grape juice	PP	0.0005	0.56	0.00	1.96	0.00	0.10	0.00	2.24	0.00	2.27	0.00	0.34	0.00
-	Grape wine (incl vermouths)	PP	0.018	88.93	1.60	62.41	1.12	1.84	0.03	25.07	0.45	61.17	1.10	5.84	0.11
FB 0275	Strawberry, raw	RAC	0.0615	4.49	0.28	5.66	0.35	0.10	0.01	6.63	0.41	5.75	0.35	0.10	0.01
FI 0326	Avocado, raw	RAC	0.07	2.65	0.19	0.87	0.06	0.46	0.03	1.64	0.11	1.30	0.09	0.96	0.07
FI 0350	Papaya, raw	RAC	0.03	0.31	0.01	0.18	0.01	1.50	0.05	0.51	0.02	0.54	0.02	1.08	0.03
VC 0424	Cucumber, raw	RAC	0.03	6.72	0.20	11.03	0.33	32.10	0.96	15.10	0.45	4.05	0.12	9.57	0.29
VC 0425	Gherkin, raw	RAC	0.03	0.41	0.01	5.89	0.18	NC	-	0.10	0.00	0.37	0.01	2.07	0.06
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.08	0.82	0.07	1.53	0.12	10.85	0.87	4.59	0.37	1.84	0.15	2.00	0.16
VO 0448	Tomato, raw (incl juice, paste, canned)	RAC	0.08	64.74	5.18	68.31	5.46	36.05	2.88	82.09	6.57	54.50	4.36	11.69	0.94
TN 0085	Tree nuts, raw (incl processed)	RAC	0.0155	8.52	0.13	8.94	0.14	15.09	0.23	9.60	0.15	14.57	0.23	26.26	0.41
SB 0716	Coffee beans raw (incl roasted, instant,substitutes)	RAC	0.03	10.90	0.33	12.44	0.37	0.77	0.02	9.48	0.28	22.07	0.66	8.15	0.24
DH 1100	Hops, dry	RAC	11	NC	-	NC	-	0.10	1.10	0.10	1.10	NC	-	NC	-
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.01	112.02	1.12	120.71	1.21	63.46	0.63	88.99	0.89	96.24	0.96	41.02	0.41
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.01	28.01	0.28	30.18	0.30	15.86	0.16	22.25	0.22	24.06	0.24	10.25	0.10
MO 0105	Edible offal (mammalian), raw	RAC	0.05	15.17	0.76	5.19	0.26	6.30	0.32	6.78	0.34	3.32	0.17	3.17	0.16
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.004	388.92	1.56	335.88	1.34	49.15	0.20	331.25	1.33	468.56	1.87	245.45	0.98
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (µg/person)=				30.1		34.5		21.6		30.6		28.6		15.4
	Bodyweight per region (kg bw) =				60		60		55		60		60		60
	ADI (µg/person)=				600		600		550		600		600		600
	%ADI=				5.0%		5.8%		3.9%		5.1%		4.8%		2.6%
	Rounded %ADI=				5%		6%		4%		5%		5%		3%

Annex 3

SPIRODICLOFEN (237) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0100 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day G13 diet	Intake = daily intake: µg/person G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
FC 0001	Citrus fruit, raw	RAC	0.02	20.93	0.42	2.35	0.05	30.71	0.61	0.15	0.00	4.45	0.09
JF 0001	Citrus fruit, juice	PP	0.0065	0.11	0.00	0.29	0.00	13.55	0.09	0.14	0.00	0.33	0.00
FP 0009	Pome fruit, raw (incl cider, excl apple juice)	RAC	0.2	68.85	13.77	10.93	2.19	70.82	14.16	189.78	37.96	19.56	3.91
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.004	0.10	0.00	0.10	0.00	7.19	0.03	0.10	0.00	NC	-
FS 0012	Stone fruits, raw (incl dried apricots, excl dried plums)	RAC	0.315	0.10	0.03	0.10	0.03	32.27	10.17	0.10	0.03	NC	-
DF 0014	Plum, dried (prunes)	PP	0.79	0.10	0.08	0.10	0.08	0.37	0.29	0.10	0.08	NC	-
FB 0020	Blueberries, raw	RAC	0.92	NC	-	NC	-	0.20	0.18	NC	-	NC	-
FB 0021	Currants, red, black, white, raw	RAC	0.04	0.10	0.00	NC	-	0.74	0.03	NC	-	NC	-
FB 0269	Grape, raw (incl must, excl dried, excl juice, excl wine)	RAC	0.059	0.14	0.01	0.36	0.02	15.33	0.90	0.10	0.01	0.28	0.02
DF 0269	Grape, dried (= currants, raisins and sultanas)	PP	0.13	0.10	0.01	0.13	0.02	1.06	0.14	0.10	0.01	0.10	0.01
JF 0269	Grape juice	PP	0.0005	0.10	0.00	0.10	0.00	0.41	0.00	0.10	0.00	NC	-
-	Grape wine (incl vermouths)	PP	0.018	0.31	0.01	0.23	0.00	60.43	1.09	0.52	0.01	31.91	0.57
FB 0275	Strawberry, raw	RAC	0.0615	0.10	0.01	0.10	0.01	3.35	0.21	0.10	0.01	0.10	0.01
FI 0326	Avocado, raw	RAC	0.07	1.12	0.08	0.10	0.01	0.84	0.06	0.10	0.01	6.60	0.46
FI 0350	Papaya, raw	RAC	0.03	6.47	0.19	0.25	0.01	0.19	0.01	0.10	0.00	26.42	0.79
VC 0424	Cucumber, raw	RAC	0.03	0.68	0.02	1.81	0.05	10.40	0.31	0.10	0.00	0.10	0.00
VC 0425	Gherkin, raw	RAC	0.03	0.15	0.00	0.39	0.01	3.15	0.09	0.10	0.00	0.10	0.00
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.08	5.49	0.44	10.57	0.85	8.84	0.71	0.91	0.07	NC	-
VO 0448	Tomato, raw (incl juice, incl paste, incl canned)	RAC	0.08	15.50	1.24	5.78	0.46	71.52	5.72	2.00	0.16	12.50	1.00
TN 0085	Tree nuts, raw (incl processed)	RAC	0.0155	4.39	0.07	135.53	2.10	6.11	0.09	0.72	0.01	317.74	4.92
SB 0716	Coffee beans raw (incl roasted, incl instant, substitutes)	RAC	0.03	0.95	0.03	1.32	0.04	11.64	0.35	2.96	0.09	14.73	0.44
DH 1100	Hops, dry	RAC	11	NC	-	NC	-	0.10	1.10	NC	-	NC	-
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.01	23.34	0.23	40.71	0.41	97.15	0.97	18.06	0.18	57.71	0.58
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.01	5.84	0.06	10.18	0.10	24.29	0.24	4.52	0.05	14.43	0.14
MO 0105	Edible offal (mammalian), raw	RAC	0.05	4.64	0.23	1.97	0.10	10.01	0.50	3.27	0.16	3.98	0.20
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.004	108.75	0.44	70.31	0.28	436.11	1.74	61.55	0.25	79.09	0.32
-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (µg/person)=				17.4		6.8		39.8		39.1		13.5
	Bodyweight per region (kg bw) =				60		60		60		60		60
	ADI (µg/person)=				600		600		600		600		600
	%ADI=				2.9%		1.1%		6.6%		6.5%		2.2%
	Rounded %ADI=				3%		1%		7%		7%		2%

Annex 3

SULFOXAFLOR (252) International Estimated Daily Intake (IEDI) ADI = 0–0.0500 mg/kg bw

			STMR	Diets as g/person/day			Intake as µg/person/day								
Codex Code	Commodity description	Expr as	mg/kg	G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
FC 0002	Lemons and limes, raw (incl lemon juice) (incl kumquat commodities)	RAC	0.038	4.82	0.18	2.45	0.09	3.93	0.15	25.44	0.97	8.74	0.33	16.23	0.62
FC 0003	Mandarins, raw (incl mandarin juice)	RAC	0.26	6.18	1.61	3.66	0.95	0.25	0.07	6.82	1.77	3.49	0.91	19.38	5.04
FC 0004	Oranges, sweet, sour, raw	RAC	0.26	20.66	5.37	5.23	1.36	11.90	3.09	37.90	9.85	21.16	5.50	56.46	14.68
JF 0004	Oranges, juice (single strength, incl. concentrated)	PP	0.036	1.27	0.05	2.20	0.08	0.10	0.00	11.81	0.43	0.46	0.02	1.69	0.06
FC 0005	Pomelo and grapefruits, raw (incl grapefruit juice)	RAC	0.0125	0.66	0.01	0.69	0.01	0.96	0.01	10.20	0.13	1.25	0.02	2.97	0.04
FP 0009	Pome fruit, raw (incl cider, excl apple juice)	RAC	0.067	19.35	1.30	34.06	2.28	17.87	1.20	25.74	1.72	7.69	0.52	56.85	3.81
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.027	0.32	0.01	3.07	0.08	0.10	0.00	5.00	0.14	0.29	0.01	5.57	0.15
FS 0013	Cherries, raw	RAC	0.34	0.92	0.31	9.15	3.11	0.10	0.03	0.61	0.21	0.10	0.03	6.64	2.26
FS 0302	Jujube, Chinese, raw	RAC	0.038	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
FS 0014	Plums, raw (incl dried plums) (excl jujube)	RAC	0.038	2.67	0.10	8.77	0.33	0.10	0.00	3.03	0.12	0.70	0.03	4.34	0.16
FS 2001	Peaches, nectarines, apricots, raw (incl dried apricots)	RAC	0.061	8.01	0.49	5.87	0.36	0.18	0.01	8.19	0.50	1.64	0.10	22.46	1.37
FB 0269	Grape, raw (incl must, incl juice, excl dried, excl wine)	RAC	0.14	13.19	1.85	9.61	1.35	0.10	0.01	17.28	2.42	4.00	0.56	54.50	7.63
DF 0269	Grape, dried (= currants, raisins and sultanas)	PP	0.49	0.51	0.25	0.51	0.25	0.10	0.05	1.27	0.62	0.12	0.06	2.07	1.01
–	Grape wine (incl vermouths)	PP	0.098	0.67	0.07	12.53	1.23	2.01	0.20	1.21	0.12	3.53	0.35	4.01	0.39
FB 0275	Strawberry, raw	RAC	0.19	0.70	0.13	2.01	0.38	0.10	0.02	1.36	0.26	0.37	0.07	2.53	0.48
VA 0381	Garlic, raw	RAC	0.01	2.29	0.02	5.78	0.06	0.11	0.00	3.69	0.04	1.65	0.02	3.91	0.04
–	Onions, mature bulbs, dry	RAC	0	29.36	0.00	37.50	0.00	3.56	0.00	34.78	0.00	18.81	0.00	43.38	0.00
–	Onions, green, raw	RAC	0.11	2.45	0.27	1.49	0.16	1.02	0.11	2.60	0.29	0.60	0.07	2.03	0.22
VB 0041	Cabbages, head, raw	RAC	0.099	2.73	0.27	27.92	2.76	0.55	0.05	4.47	0.44	4.27	0.42	10.25	1.01
VB 0400	Broccoli, raw	RAC	0.074	0.88	0.07	0.17	0.01	0.10	0.01	1.25	0.09	3.00	0.22	1.09	0.08
VB 0404	Cauliflower, raw	RAC	0.012	1.65	0.02	0.32	0.00	0.10	0.00	2.33	0.03	4.79	0.06	2.03	0.02
VC 0045	Fruiting vegetables, cucurbits, raw	RAC	0.029	53.14	1.54	86.21	2.50	6.28	0.18	92.76	2.69	15.64	0.45	155.30	4.50
VO 0440	Egg plants, raw (= aubergines)	RAC	0.11	5.58	0.61	4.31	0.47	0.89	0.10	9.31	1.02	13.64	1.50	20.12	2.21
VO 0442	Okra, raw	RAC	0.11	1.97	0.22	NC	–	3.68	0.40	3.24	0.36	5.72	0.63	1.57	0.17
VO 0443	Pepino (Melon pear, Tree melon)	RAC	0.11	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
VO 0444	Peppers, chilli, raw	RAC	0.11	3.99	0.44	7.30	0.80	2.93	0.32	5.62	0.62	NC	–	17.44	1.92
–	Peppers, chilli, dried	PP	1.1	0.42	0.46	0.53	0.58	0.84	0.92	0.50	0.55	0.95	1.05	0.37	0.41
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.11	4.49	0.49	6.44	0.71	7.21	0.79	5.68	0.62	9.52	1.05	8.92	0.98
VO 0448	Tomato, raw (incl canned, excl juice, excl paste)	RAC	0.11	42.04	4.62	76.13	8.37	10.69	1.18	84.59	9.30	24.92	2.74	203.27	22.36
–	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.23	2.34	0.54	1.33	0.31	1.57	0.36	4.24	0.98	0.34	0.08	2.83	0.65
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.052	0.29	0.02	0.29	0.02	0.10	0.01	0.38	0.02	0.10	0.01	0.14	0.01
–	Gilo (scarlet egg plant)	RAC	0.11	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
–	Goji berry	RAC	0.11	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–

Annex 3

SULFOXAFLOR (252) International Estimated Daily Intake (IEDI) ADI = 0–0.0500 mg/kg bw

			STMR	Diets as g/person/day			Intake as µg/person/day								
Codex Code	Commodity description	Expr as	mg/kg	G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
–	Seaweed	RAC	0.11	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
VL 0269	Grape leaves, raw	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
VL 0446	Roselle leaves, raw (vinagreira)	RAC	1.2	0.39	0.47	0.69	0.83	0.43	0.52	1.04	1.25	4.57	5.48	0.50	0.60
VL 0460	Amaranth leaves, raw (i.e. bledo)	RAC	1.2	1.09	1.31	1.94	2.33	1.20	1.44	2.91	3.49	NC	–	1.41	1.69
VL 0463	Cassava leaves, raw	RAC	1.2	NC	–	NC	–	0.65	0.78	0.10	0.12	NC	–	NC	–
VL 0464	Chard, raw (i.e. beet leaves)	RAC	1.2	0.40	0.48	0.70	0.84	0.44	0.53	1.06	1.27	4.66	5.59	0.51	0.61
VL 0465	Chervil, raw	RAC	1.2	0.19	0.23	0.34	0.41	0.21	0.25	0.52	0.62	NC	–	0.25	0.30
VL 0466	Chinese cabbage, type pak-choi, raw (i.e. Brassica)	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
VL 0467	Chinese cabbage, type pe-tsai, raw (i.e. Brassica)	RAC	1.2	0.45	0.54	4.56	5.47	0.10	0.12	0.73	0.88	NC	–	1.67	2.00
VL 0469	Chicory leaves (sugar loaf), raw	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
VL 0470	Lambs lettuce, raw (i.e. corn salad)	RAC	1.2	0.64	0.77	1.13	1.36	0.70	0.84	1.70	2.04	NC	–	0.82	0.98
VL 0472	Garden cress, raw	RAC	1.2	0.10	0.12	0.10	0.12	0.10	0.12	0.15	0.18	NC	–	0.10	0.12
VL 0473	Watercress, raw	RAC	1	1.21	1.21	2.15	2.15	1.33	1.33	3.24	3.24	11.36	11.36	1.56	1.56
VL 0474	Dandelion leaves, raw	RAC	1.2	0.13	0.16	0.23	0.28	0.14	0.17	0.34	0.41	1.44	1.73	0.16	0.19
VL 0476	Endive, raw (i.e. scarole)	RAC	1.2	0.10	0.12	0.10	0.12	0.10	0.12	0.40	0.48	0.10	0.12	0.39	0.47
VL 0478	Indian mustard (Amsoi) (i.e. Brassica)	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
VL 0479	Japanese greens, raw (i.e. Chrysanthemum)	RAC	1.2	0.10	0.12	0.10	0.12	0.10	0.12	0.10	0.12	NC	–	0.10	0.12
VL 0480	Kale, raw (i.e. collards) (i.e. Brassica)	RAC	1.2	0.57	0.68	5.77	6.92	0.11	0.13	0.92	1.10	5.25	6.30	2.12	2.54
VL 0481	Komatsuna, raw (i.e. Brassica)	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
VL 0482	Lettuce, head, raw	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
VL 0483	Lettuce, leaf, raw	RAC	1.2	0.53	0.64	0.36	0.43	0.16	0.19	6.21	7.45	1.90	2.28	6.05	7.26
VL 0485	Mustard greens, raw (i.e. Brassica)	RAC	1.2	0.10	0.12	0.31	0.37	0.10	0.12	0.10	0.12	0.47	0.56	0.11	0.13
VL 0492	Purslane, raw	RAC	1.2	0.10	0.12	0.10	0.12	0.10	0.12	0.10	0.12	NC	–	0.10	0.12
VL 0494	Radish leaves, raw	RAC	1.2	0.26	0.31	0.45	0.54	0.28	0.34	0.68	0.82	NC	–	0.33	0.40
VL 0495	Rape greens, raw (i.e. Brassica)	RAC	1.2	0.10	0.12	0.31	0.37	0.10	0.12	0.10	0.12	NC	–	0.11	0.13
VL 0496	Rucola, raw (i.e. arrugula, rocket salad, roquette)	RAC	1.2	1.27	1.52	2.25	2.70	1.39	1.67	3.38	4.06	13.81	16.57	1.63	1.96
VL 0501	Sowthistle, raw	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
VL 0502	Spinach, raw	RAC	1.2	0.74	0.89	0.22	0.26	0.10	0.12	0.91	1.09	0.10	0.12	2.92	3.50
VL 0503	Indian spinach, raw (i.e. vine spinach)	RAC	1.2	0.10	0.12	0.10	0.12	0.10	0.12	0.10	0.12	0.16	0.19	0.10	0.12
VL 0504	Tannia leaves, raw (i.e. taioba)	RAC	1.2	0.18	0.22	0.31	0.37	0.19	0.23	0.47	0.56	2.06	2.47	0.23	0.28
VL 0505	Taro leaves, raw	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
VL 0506	Turnip greens, raw (i.e. Namenia, Tendergreen)	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
VL 0507	Kang kung, raw (i.e. water spinach)	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
VL 0510	Cos lettuce, raw	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
–	Perilla leaves, raw (i.e. sesame leaves)	RAC	1.2	0.15	0.18	0.27	0.32	0.17	0.20	0.40	0.48	NC	–	0.19	0.23
–	Bracken, raw (i.e. ferns)	RAC	1.2	0.10	0.12	0.19	0.23	0.12	0.14	0.28	0.34	NC	–	0.13	0.16
–	Water parsley, raw	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
–	Chinese cabbage flowering stalk, raw	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	0.075	2.39	0.18	1.61	0.12	10.47	0.79	1.84	0.14	12.90	0.97	7.44	0.56

Annex 3

SULFOXAFLOR (252) International Estimated Daily Intake (IEDI) ADI = 0–0.0500 mg/kg bw

			STMR	Diets as g/person/day			Intake as µg/person/day								
Codex Code	Commodity description	Expr as	mg/kg	G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
VD 0541	Soybean, dry, raw (incl flour, incl paste, incl curd, incl sauce, excl oil)	RAC	0.011	0.63	0.01	1.09	0.01	0.40	0.00	1.40	0.02	1.68	0.02	0.48	0.01
OR 0541	Soya oil, refined	PP	0.0033	12.99	0.04	10.43	0.03	3.63	0.01	13.10	0.04	10.70	0.04	13.10	0.04
VR 0463	Cassava raw (incl starch, incl tapioca, incl flour)	RAC	0.01	0.10	0.00	0.10	0.00	482.56	4.83	0.99	0.01	25.75	0.26	3.29	0.03
VR 0469	Chicory, roots, raw	RAC	0.01	0.10	0.00	0.20	0.00	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00
VR 0494	Radish roots, raw	RAC	0.01	2.31	0.02	4.09	0.04	2.53	0.03	6.15	0.06	5.88	0.06	2.97	0.03
VR 0497	Swede, raw (i.e. rutabaga)	RAC	0.01	1.58	0.02	2.80	0.03	1.74	0.02	4.21	0.04	NC	–	2.03	0.02
VR 0498	Salsify, raw (i.e. oysterplant)	RAC	0.01	0.21	0.00	0.37	0.00	0.23	0.00	0.55	0.01	NC	–	0.27	0.00
VR 0504	Tannia, raw (i.e. yautia)	RAC	0.01	NC	–	NC	–	NC	–	0.10	0.00	0.26	0.00	1.27	0.01
VR 0505	Taro, raw	RAC	0.01	0.10	0.00	NC	–	25.12	0.25	0.10	0.00	0.10	0.00	0.97	0.01
VR 0506	Garden turnip, raw	RAC	0.01	2.50	0.03	4.44	0.04	2.75	0.03	6.67	0.07	0.14	0.00	3.22	0.03
VR 0508	Sweet potato, raw (incl dried)	RAC	0.01	0.18	0.00	0.18	0.00	42.16	0.42	1.61	0.02	3.06	0.03	6.67	0.07
VR 0573	Arrowroot, raw	RAC	0.01	1.53	0.02	0.10	0.00	0.93	0.01	1.33	0.01	0.47	0.00	0.10	0.00
VR 0574	Beetroot, raw	RAC	0.01	3.42	0.03	6.06	0.06	3.75	0.04	9.11	0.09	NC	–	4.39	0.04
VR 0575	Burdock, greater or edible, raw	RAC	0.01	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00	NC	–	0.10	0.00
VR 0577	Carrots, raw	RAC	0.01	9.51	0.10	30.78	0.31	0.37	0.00	8.75	0.09	2.80	0.03	6.10	0.06
VR 0578	Celeriac, raw	RAC	0.01	1.70	0.02	3.01	0.03	1.87	0.02	4.53	0.05	NC	–	2.19	0.02
VR 0583	Horseradish, raw	RAC	0.01	0.51	0.01	0.91	0.01	0.56	0.01	1.37	0.01	NC	–	0.66	0.01
VR 0585	Jerusalem artichoke, raw (i.e. topinambur)	RAC	0.01	1.57	0.02	0.10	0.00	0.96	0.01	1.36	0.01	0.48	0.00	0.10	0.00
VR 0587	Parsley turnip-rooted, raw	RAC	0.01	0.32	0.00	0.57	0.01	0.35	0.00	0.85	0.01	NC	–	0.41	0.00
VR 0588	Parsnip, raw	RAC	0.01	0.59	0.01	1.05	0.01	0.65	0.01	1.58	0.02	NC	–	0.76	0.01
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.01	59.74	0.60	316.14	3.16	9.78	0.10	60.26	0.60	54.12	0.54	119.82	1.20
VR 0590	Black radish, raw	RAC	0.01	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
VR 0591	Japanese radish, raw (i.e. daikon)	RAC	0.01	1.90	0.02	3.36	0.03	2.08	0.02	5.06	0.05	NC	–	2.44	0.02
VR 0596	Sugar beet, raw	RAC	0.014	NC	–	NC	–	NC	–	NC	–	0.10	0.00	NC	–
–	Sugar beet, sugar	PP	0.025	0.10	0.00	NC	–	0.10	0.00	0.10	0.00	0.10	0.00	12.63	0.32
VR 0600	Yams, raw (incl dried)	RAC	0.01	0.10	0.00	NC	–	90.40	0.90	6.45	0.06	0.74	0.01	0.65	0.01
–	Lotus root, raw	RAC	0.01	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
–	Water chestnut, raw	RAC	0.01	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
VS 0624	Celery	RAC	0.19	2.14	0.41	3.79	0.72	2.35	0.45	5.69	1.08	0.10	0.02	2.75	0.52
GC 0640	Barley, raw (incl malt extract, incl malt, excl pot & pearled, excl flour & grits,excl beer)	RAC	0.063	2.62	0.17	1.50	0.09	0.37	0.02	0.60	0.04	0.38	0.02	0.53	0.03
–	Barley, pot & pearled	PP	0.044	7.12	0.31	7.34	0.32	0.10	0.00	0.10	0.00	0.67	0.03	0.20	0.01
–	Barley, flour (white flour and wholemeal flour)	PP	0.05	2.93	0.15	0.30	0.02	0.10	0.01	0.10	0.01	0.48	0.02	0.10	0.01
–	Barley beer	PP	0.013	4.87	0.06	93.78	1.22	24.28	0.32	12.76	0.17	39.28	0.51	18.15	0.24
GC 0653	Triticale, raw (incl flour)	RAC	0.025	NC	–	NC	–	NC	–	0.10	0.00	0.39	0.01	NC	–
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, incl germ, incl wholemeal bread, incl white flour	RAC	0.025	381.15	9.53	341.55	8.54	38.35	0.96	281.89	7.05	172.83	4.32	434.07	10.85

Annex 3

SULFOXAFLOR (252) International Estimated Daily Intake (IEDI) ADI = 0–0.0500 mg/kg bw

			STMR	Diets as g/person/day			Intake as µg/person/day								
Codex Code	Commodity description	Expr as	mg/kg	G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
	products, incl white bread)														
SO 0495	Rape seed, raw	RAC	0.045	0.10	0.00	NC	–	NC	–	0.10	0.00	0.75	0.03	0.10	0.00
OR 0495	Rape seed oil, edible	PP	0.014	0.35	0.00	0.44	0.01	0.19	0.00	0.97	0.01	3.28	0.05	0.77	0.01
SO 0691	Cotton seed, raw	RAC	0.02	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
OR 0691	Cotton seed oil, edible	PP	0.002	3.22	0.01	1.54	0.00	1.01	0.00	0.74	0.00	1.12	0.00	2.93	0.01
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)—80% as muscle	RAC	0.045	24.96	1.12	57.95	2.61	16.70	0.75	38.38	1.73	26.46	1.19	29.00	1.31
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)—20% as fat	RAC	0.03	6.24	0.19	14.49	0.43	4.18	0.13	9.60	0.29	6.62	0.20	7.25	0.22
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.03	3.29	0.10	6.14	0.18	0.82	0.02	1.57	0.05	2.23	0.07	1.07	0.03
MO 0105	Edible offal (mammalian), raw	RAC	0.13	4.79	0.62	9.68	1.26	2.97	0.39	5.49	0.71	3.84	0.50	5.03	0.65
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.05	289.65	14.48	485.88	24.29	26.92	1.35	239.03	11.95	199.91	10.00	180.53	9.03
PM 0110	Poultry meat, raw (incl prepared)—90% as muscle	RAC	0.015	13.17	0.20	26.78	0.40	7.24	0.11	116.71	1.75	22.54	0.34	32.09	0.48
PM 0110	Poultry meat, raw (incl prepared)—10% as fat	RAC	0.005	1.46	0.01	2.98	0.01	0.80	0.00	12.97	0.06	2.50	0.01	3.57	0.02
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.005	0.10	0.00	0.10	0.00	NC	–	0.10	0.00	0.10	0.00	0.10	0.00
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.046	0.12	0.01	0.12	0.01	0.11	0.01	5.37	0.25	0.24	0.01	0.10	0.00
PE 0112	Eggs, raw, (incl dried)	RAC	0.013	7.84	0.10	23.08	0.30	2.88	0.04	14.89	0.19	9.81	0.13	14.83	0.19
–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
	Total intake (µg/person)=				60.4		99.7		31.2		93.5		89.0		123.9
	Bodyweight per region (kg bw) =				60		60		60		60		60		60
	ADI (µg/person)=				3000		3000		3000		3000		3000		3000
	%ADI=				2.0%		3.3%		1.0%		3.1%		3.0%		4.1%
	Rounded %ADI=				2%		3%		1%		3%		3%		4%

SULFOXAFLOR (252) International Estimated Daily Intake (IEDI) ADI = 0–0.0500 mg/kg bw

			STMR	Diets as g/person/day			Intake as µg/person/day								
Codex Code	Commodity description	Expr as	mg/kg	G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
FC 0002	Lemons and limes, raw (incl lemon juice) (incl kumquat commodities)	RAC	0.038	10.12	0.38	15.69	0.60	2.88	0.11	12.30	0.47	22.32	0.85	6.59	0.25
FC 0003	Mandarins, raw (incl mandarin juice)	RAC	0.26	12.42	3.23	14.99	3.90	16.08	4.18	10.78	2.80	9.94	2.58	NC	–
FC 0004	Oranges, sweet, sour, raw	RAC	0.26	15.68	4.08	24.00	6.24	6.80	1.77	29.09	7.56	15.39	4.00	160.47	41.72
JF 0004	Oranges, juice (single strength, incl. concentrated)	PP	0.036	33.31	1.20	1.78	0.06	0.28	0.01	18.97	0.68	14.01	0.50	13.36	0.48
FC 0005	Pomelo and grapefruits, raw (incl grapefruit	RAC	0.0125	8.21	0.10	4.60	0.06	0.64	0.01	5.85	0.07	19.98	0.25	368.86	4.61

Annex 3

SULFOXAFLOR (252) International Estimated Daily Intake (IEDI) ADI = 0–0.0500 mg/kg bw

			STMR	Diets as g/person/day			Intake as µg/person/day								
Codex Code	Commodity description	Expr as	mg/kg	G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
	juice)														
FP 0009	Pome fruit, raw (incl cider, excl apple juice)	RAC	0.067	51.09	3.42	65.40	4.38	42.71	2.86	45.29	3.03	62.51	4.19	7.74	0.52
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.027	14.88	0.40	11.98	0.32	0.15	0.00	9.98	0.27	30.32	0.82	3.47	0.09
FS 0013	Cherries, raw	RAC	0.34	1.40	0.48	4.21	1.43	0.10	0.03	2.93	1.00	1.50	0.51	NC	–
FS 0302	Jujube, Chinese, raw	RAC	0.038	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
FS 0014	Plums, raw (incl dried plums) (excl jujube)	RAC	0.038	5.55	0.21	4.37	0.17	6.08	0.23	3.66	0.14	3.93	0.15	0.46	0.02
FS 2001	Peaches, nectarines, apricots, raw (incl dried apricots)	RAC	0.061	13.03	0.79	16.29	0.99	8.29	0.51	12.95	0.79	5.35	0.33	0.10	0.01
FB 0269	Grape, raw (incl must, incl juice, excl dried, excl wine)	RAC	0.14	7.18	1.01	13.73	1.92	5.24	0.73	12.27	1.72	7.46	1.04	1.21	0.17
DF 0269	Grape, dried (= currants, raisins and sultanas)	PP	0.49	3.09	1.51	1.51	0.74	0.10	0.05	1.38	0.68	4.26	2.09	0.42	0.21
–	Grape wine (incl vermouths)	PP	0.098	88.93	8.72	62.41	6.12	1.84	0.18	25.07	2.46	61.17	5.99	5.84	0.57
FB 0275	Strawberry, raw	RAC	0.19	4.49	0.85	5.66	1.08	0.10	0.02	6.63	1.26	5.75	1.09	0.10	0.02
VA 0381	Garlic, raw	RAC	0.01	0.98	0.01	1.49	0.01	12.88	0.13	3.74	0.04	2.05	0.02	1.14	0.01
–	Onions, mature bulbs, dry	RAC	0	19.69	0.00	29.83	0.00	24.64	0.00	31.35	0.00	9.72	0.00	12.59	0.00
–	Onions, green, raw	RAC	0.11	1.55	0.17	0.74	0.08	1.05	0.12	3.74	0.41	0.94	0.10	6.45	0.71
VB 0041	Cabbages, head, raw	RAC	0.099	8.97	0.89	27.12	2.68	1.44	0.14	24.96	2.47	4.55	0.45	11.23	1.11
VB 0400	Broccoli, raw	RAC	0.074	4.24	0.31	1.76	0.13	NC	–	0.51	0.04	3.79	0.28	0.26	0.02
VB 0404	Cauliflower, raw	RAC	0.012	5.27	0.06	5.01	0.06	NC	–	2.70	0.03	5.57	0.07	0.49	0.01
VC 0045	Fruiting vegetables, cucurbits, raw	RAC	0.029	27.81	0.81	41.93	1.22	123.30	3.58	49.47	1.43	15.95	0.46	35.99	1.04
VO 0440	Egg plants, raw (= aubergines)	RAC	0.11	1.01	0.11	1.69	0.19	21.37	2.35	3.00	0.33	1.40	0.15	NC	–
VO 0442	Okra, raw	RAC	0.11	NC	–	NC	–	0.10	0.01	0.17	0.02	NC	–	0.72	0.08
VO 0443	Pepino (Melon pear, Tree melon)	RAC	0.11	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
VO 0444	Peppers, chilli, raw	RAC	0.11	5.57	0.61	14.00	1.54	8.25	0.91	5.77	0.63	6.44	0.71	2.53	0.28
–	Peppers, chilli, dried	PP	1.1	0.11	0.12	0.21	0.23	0.36	0.40	0.21	0.23	0.25	0.28	0.15	0.17
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.11	0.82	0.09	1.53	0.17	10.85	1.19	4.59	0.50	1.84	0.20	2.00	0.22
VO 0448	Tomato, raw (incl canned, excl juice, excl paste)	RAC	0.11	43.88	4.83	55.41	6.10	35.38	3.89	74.88	8.24	26.50	2.92	9.51	1.05
–	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.23	4.96	1.14	3.20	0.74	0.15	0.03	1.61	0.37	6.88	1.58	0.52	0.12
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.052	0.80	0.04	0.10	0.01	0.10	0.01	0.61	0.03	0.40	0.02	0.10	0.01
–	Gilo (scarlet egg plant)	RAC	0.11	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
–	Goji berry	RAC	0.11	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
–	Seaweed	RAC	0.11	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
VL 0269	Grape leaves, raw	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
VL 0446	Roselle leaves, raw (vinagreira)	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–	0.74	0.89
VL 0460	Amaranth leaves, raw (i.e. bledo)	RAC	1.2	NC	–	NC	–	47.45	56.94	NC	–	NC	–	2.07	2.48
VL 0463	Cassava leaves, raw	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–

Annex 3

SULFOXAFLOR (252) International Estimated Daily Intake (IEDI) ADI = 0–0.0500 mg/kg bw

			STMR	Diets as g/person/day			Intake as µg/person/day								
Codex Code	Commodity description	Expr as	mg/kg	G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
VL 0464	Chard, raw (i.e. beet leaves)	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–	0.75	0.90
VL 0465	Chervil, raw	RAC	1.2	NC	–	NC	–	8.39	10.07	NC	–	NC	–	0.37	0.44
VL 0466	Chinese cabbage, type pak-choi, raw (i.e. Brassica)	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
VL 0467	Chinese cabbage, type pe-tsai, raw (i.e. Brassica)	RAC	1.2	NC	–	NC	–	17.39	20.87	9.44	11.33	NC	–	1.83	2.20
VL 0469	Chicory leaves (sugar loaf), raw	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
VL 0470	Lambs lettuce, raw (i.e. corn salad)	RAC	1.2	1.41	1.69	4.28	5.14	NC	–	0.10	0.12	5.11	6.13	1.20	1.44
VL 0472	Garden cress, raw	RAC	1.2	0.10	0.12	NC	–	1.27	1.52	0.13	0.16	0.21	0.25	0.10	0.12
VL 0473	Watercress, raw	RAC	1	0.35	0.35	3.13	3.13	0.32	0.32	NC	–	NC	–	2.30	2.30
VL 0474	Dandelion leaves, raw	RAC	1.2	0.10	0.12	0.10	0.12	NC	–	NC	–	0.10	0.12	0.24	0.29
VL 0476	Endive, raw (i.e. scarole)	RAC	1.2	0.21	0.25	0.93	1.12	NC	–	0.30	0.36	2.14	2.57	0.14	0.17
VL 0478	Indian mustard (Amsoi) (i.e. Brassica)	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
VL 0479	Japanese greens, raw (i.e. Chrysanthemum)	RAC	1.2	NC	–	NC	–	NC	–	0.32	0.38	NC	–	0.10	0.12
VL 0480	Kale, raw (i.e. collards) (i.e. Brassica)	RAC	1.2	NC	–	NC	–	14.54	17.45	NC	–	NC	–	2.32	2.78
VL 0481	Komatsuna, raw (i.e. Brassica)	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
VL 0482	Lettuce, head, raw	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
VL 0483	Lettuce, leaf, raw	RAC	1.2	14.50	17.40	11.76	14.11	13.14	15.77	19.50	23.40	4.81	5.77	2.23	2.68
VL 0485	Mustard greens, raw (i.e. Brassica)	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–	0.13	0.16
VL 0492	Purslane, raw	RAC	1.2	0.10	0.12	NC	–	NC	–	NC	–	NC	–	0.10	0.12
VL 0494	Radish leaves, raw	RAC	1.2	NC	–	NC	–	NC	–	3.78	4.54	NC	–	0.48	0.58
VL 0495	Rape greens, raw (i.e. Brassica)	RAC	1.2	NC	–	NC	–	1.93	2.32	NC	–	NC	–	0.12	0.14
VL 0496	Rucola, raw (i.e. arrugula, rocket salad, roquette)	RAC	1.2	NC	–	NC	–	NC	–	1.09	1.31	0.38	0.46	2.40	2.88
VL 0501	Sowthistle, raw	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
VL 0502	Spinach, raw	RAC	1.2	2.20	2.64	1.76	2.11	13.38	16.06	2.94	3.53	5.53	6.64	0.10	0.12
VL 0503	Indian spinach, raw (i.e. vine spinach)	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–	0.10	0.12
VL 0504	Tannia leaves, raw (i.e. taioba)	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–	0.33	0.40
VL 0505	Taro leaves, raw	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
VL 0506	Turnip greens, raw (i.e. Namenia, Tendergreen)	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
VL 0507	Kang kung, raw (i.e. water spinach)	RAC	1.2	NC	–	NC	–	3.42	4.10	NC	–	NC	–	NC	–
VL 0510	Cos lettuce, raw	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
–	Perilla leaves, raw (i.e. sesame leaves)	RAC	1.2	NC	–	NC	–	NC	–	2.23	2.68	NC	–	0.29	0.35
–	Bracken, raw (i.e. ferns)	RAC	1.2	NC	–	NC	–	NC	–	1.55	1.86	NC	–	0.20	0.24
–	Water parsley, raw	RAC	1.2	NC	–	NC	–	NC	–	1.79	2.15	NC	–	NC	–
–	Chinese cabbage flowering stalk, raw	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	0.075	1.51	0.11	1.50	0.11	1.90	0.14	5.11	0.38	1.36	0.10	23.43	1.76
VD 0541	Soybean, dry, raw (incl flour, incl paste, incl curd, incl sauce, excl oil)	RAC	0.011	0.47	0.01	0.77	0.01	9.12	0.10	8.05	0.09	0.10	0.00	6.06	0.07

Annex 3

SULFOXAFLOR (252) International Estimated Daily Intake (IEDI) ADI = 0–0.0500 mg/kg bw

			STMR	Diets as g/person/day			Intake as µg/person/day								
Codex Code	Commodity description	Expr as	mg/kg	G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
OR 0541	Soya oil, refined	PP	0.0033	19.06	0.06	21.06	0.07	5.94	0.02	33.78	0.11	40.05	0.13	13.39	0.04
VR 0463	Cassava raw (incl starch, incl tapioca, incl flour)	RAC	0.01	0.10	0.00	NC	–	20.96	0.21	0.14	0.00	NC	–	9.62	0.10
VR 0469	Chicory, roots, raw	RAC	0.01	0.10	0.00	0.51	0.01	0.10	0.00	0.10	0.00	21.12	0.21	NC	–
VR 0494	Radish roots, raw	RAC	0.01	3.83	0.04	11.99	0.12	NC	–	5.26	0.05	2.19	0.02	4.37	0.04
VR 0497	Swede, raw (i.e. rutabaga)	RAC	0.01	10.01	0.10	1.66	0.02	NC	–	NC	–	3.06	0.03	2.99	0.03
VR 0498	Salsify, raw (i.e. oysterplant)	RAC	0.01	1.02	0.01	0.52	0.01	NC	–	NC	–	2.08	0.02	0.39	0.00
VR 0504	Tannia, raw (i.e. yautia)	RAC	0.01	NC	–	NC	–	NC	–	0.10	0.00	NC	–	10.74	0.11
VR 0505	Taro, raw	RAC	0.01	NC	–	NC	–	1.93	0.02	0.84	0.01	NC	–	19.94	0.20
VR 0506	Garden turnip, raw	RAC	0.01	5.78	0.06	15.35	0.15	NC	–	6.54	0.07	1.95	0.02	4.73	0.05
VR 0508	Sweet potato, raw (incl dried)	RAC	0.01	0.93	0.01	0.32	0.00	64.65	0.65	5.37	0.05	0.30	0.00	3.13	0.03
VR 0573	Arrowroot, raw	RAC	0.01	0.10	0.00	0.10	0.00	2.05	0.02	0.21	0.00	NC	–	0.76	0.01
VR 0574	Beetroot, raw	RAC	0.01	9.91	0.10	6.34	0.06	NC	–	9.65	0.10	19.11	0.19	6.47	0.06
VR 0575	Burdock, greater or edible, raw	RAC	0.01	NC	–	NC	–	NC	–	0.48	0.00	NC	–	0.10	0.00
VR 0577	Carrots, raw	RAC	0.01	26.26	0.26	27.13	0.27	10.07	0.10	16.49	0.16	44.69	0.45	8.75	0.09
VR 0578	Celeriac, raw	RAC	0.01	2.97	0.03	1.79	0.02	NC	–	0.10	0.00	16.91	0.17	3.22	0.03
VR 0583	Horseradish, raw	RAC	0.01	0.10	0.00	0.42	0.00	13.01	0.13	0.26	0.00	2.70	0.03	0.97	0.01
VR 0585	Jerusalem artichoke, raw (i.e. topinambur)	RAC	0.01	0.11	0.00	0.10	0.00	NC	–	0.22	0.00	NC	–	0.78	0.01
VR 0587	Parsley turnip-rooted, raw	RAC	0.01	NC	–	NC	–	NC	–	NC	–	NC	–	0.61	0.01
VR 0588	Parsnip, raw	RAC	0.01	4.42	0.04	0.10	0.00	NC	–	NC	–	NC	–	1.12	0.01
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.01	225.03	2.25	234.24	2.34	71.48	0.71	177.55	1.78	234.55	2.35	37.71	0.38
VR 0590	Black radish, raw	RAC	0.01	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
VR 0591	Japanese radish, raw (i.e. daikon)	RAC	0.01	NC	–	NC	–	26.64	0.27	18.92	0.19	NC	–	3.59	0.04
VR 0596	Sugar beet, raw	RAC	0.014	0.10	0.00	NC	–	0.10	0.00	0.10	0.00	NC	–	NC	–
–	Sugar beet, sugar	PP	0.025	0.10	0.00	NC	–	0.10	0.00	NC	–	NC	–	NC	–
VR 0600	Yams, raw (incl dried)	RAC	0.01	NC	–	NC	–	0.10	0.00	0.71	0.01	NC	–	17.57	0.18
–	Lotus root, raw	RAC	0.01	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
–	Water chestnut, raw	RAC	0.01	NC	–	NC	–	3.42	0.03	NC	–	NC	–	NC	–
VS 0624	Celery	RAC	0.19	7.68	1.46	2.85	0.54	NC	–	3.34	0.63	16.83	3.20	4.04	0.77
GC 0640	Barley, raw (incl malt extract, incl malt, excl pot & pearled, excl flour & grits,excl beer)	RAC	0.063	0.93	0.06	0.15	0.01	0.14	0.01	1.56	0.10	0.33	0.02	3.42	0.22
–	Barley, pot & pearled	PP	0.044	0.57	0.03	2.56	0.11	0.33	0.01	0.56	0.02	0.36	0.02	NC	–
–	Barley, flour (white flour and wholemeal flour)	PP	0.05	0.10	0.01	0.10	0.01	0.10	0.01	0.10	0.01	0.68	0.03	0.10	0.01
–	Barley beer	PP	0.013	180.21	2.34	259.46	3.37	45.91	0.60	172.36	2.24	234.42	3.05	65.30	0.85
GC 0653	Triticale, raw (incl flour)	RAC	0.025	0.10	0.00	0.17	0.00	0.29	0.01	0.10	0.00	NC	–	NC	–
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, incl germ, incl wholemeal bread, incl white flour products, incl white bread)	RAC	0.025	253.07	6.33	244.73	6.12	134.44	3.36	235.10	5.88	216.39	5.41	167.40	4.19

Annex 3

SULFOXAFLOR (252) International Estimated Daily Intake (IEDI) ADI = 0–0.0500 mg/kg bw

			STMR	Diets as g/person/day			Intake as µg/person/day								
Codex Code	Commodity description	Expr as	mg/kg	G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
SO 0495	Rape seed, raw	RAC	0.045	NC	–	NC	–	0.10	0.00	NC	–	NC	–	NC	–
OR 0495	Rape seed oil, edible	PP	0.014	12.52	0.18	7.63	0.11	3.00	0.04	6.01	0.08	NC	–	NC	–
SO 0691	Cotton seed, raw	RAC	0.02	NC	–	NC	–	NC	–	NC	–	NC	–	NC	–
OR 0691	Cotton seed oil, edible	PP	0.002	1.68	0.00	0.66	0.00	1.13	0.00	1.18	0.00	0.89	0.00	0.37	0.00
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)—80% as muscle	RAC	0.045	112.02	5.04	120.71	5.43	63.46	2.86	88.99	4.00	96.24	4.33	41.02	1.85
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)—20% as fat	RAC	0.03	28.01	0.84	30.18	0.91	15.86	0.48	22.25	0.67	24.06	0.72	10.25	0.31
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.03	6.44	0.19	15.51	0.47	3.79	0.11	8.29	0.25	18.44	0.55	8.00	0.24
MO 0105	Edible offal (mammalian), raw	RAC	0.13	15.17	1.97	5.19	0.67	6.30	0.82	6.78	0.88	3.32	0.43	3.17	0.41
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.05	388.92	19.45	335.88	16.79	49.15	2.46	331.25	16.56	468.56	23.43	245.45	12.27
PM 0110	Poultry meat, raw (incl prepared)—90% as muscle	RAC	0.015	66.38	1.00	48.47	0.73	21.58	0.32	78.41	1.18	48.04	0.72	76.01	1.14
PM 0110	Poultry meat, raw (incl prepared)—10% as fat	RAC	0.005	7.38	0.04	5.39	0.03	2.40	0.01	8.71	0.04	5.34	0.03	8.45	0.04
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.005	0.10	0.00	0.10	0.00	NC	–	0.10	0.00	0.71	0.00	NC	–
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.046	0.33	0.02	0.72	0.03	0.27	0.01	0.35	0.02	0.80	0.04	NC	–
PE 0112	Eggs, raw, (incl dried)	RAC	0.013	25.84	0.34	29.53	0.38	28.05	0.36	33.19	0.43	36.44	0.47	8.89	0.12
–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
	Total intake (µg/person)=				100.6		105.8		182.7		125.5		99.8		101.0
	Bodyweight per region (kg bw) =				60		60		55		60		60		60
	ADI (µg/person)=				3000		3000		2750		3000		3000		3000
	%ADI=				3.4%		3.5%		6.6%		4.2%		3.3%		3.4%
	Rounded %ADI=				3%		4%		7%		4%		3%		3%

SULFOXAFLOR (252) International Estimated Daily Intake (IEDI) ADI = 0–0.0500 mg/kg bw

			STMR	Diets: g/person/day			Intake = daily intake: µg/person						
Codex Code	Commodity description	Expr as	mg/kg	G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
FC 0002	Lemons and limes, raw (incl lemon juice) (incl kumquat commodities)	RAC	0.038	18.97	0.72	0.97	0.04	6.23	0.24	0.10	0.00	3.35	0.13
FC 0003	Mandarins, raw (incl mandarin juice)	RAC	0.26	0.16	0.04	0.27	0.07	9.06	2.36	0.10	0.03	0.10	0.03
FC 0004	Oranges, sweet, sour, raw	RAC	0.26	1.18	0.31	1.11	0.29	14.28	3.71	0.10	0.03	1.08	0.28
JF 0004	Oranges, juice (single strength, incl. concentrated)	PP	0.036	0.10	0.00	0.26	0.01	12.61	0.45	0.14	0.01	0.33	0.01
FC 0005	Pomelo and grapefruits, raw (incl grapefruit juice)	RAC	0.0125	0.68	0.01	0.10	0.00	3.21	0.04	0.10	0.00	NC	–

Annex 3

SULFOXAFLOR (252) International Estimated Daily Intake (IEDI) ADI = 0–0.0500 mg/kg bw

			STMR	Diets: g/person/day			Intake = daily intake: µg/person						
Codex Code	Commodity description	Expr as	mg/kg	G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
FP 0009	Pome fruit, raw (incl cider, excl apple juice)	RAC	0.067	68.85	4.61	10.93	0.73	70.82	4.74	189.78	12.72	19.56	1.31
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.027	0.10	0.00	0.10	0.00	7.19	0.19	0.10	0.00	NC	–
FS 0013	Cherries, raw	RAC	0.34	0.10	0.03	0.10	0.03	5.96	2.03	0.10	0.03	NC	–
FS 0302	Jujube, Chinese, raw	RAC	0.038	NC	–	NC	–	NC	–	NC	–	NC	–
FS 0014	Plums, raw (incl dried plums) (excl jujube)	RAC	0.038	0.10	0.00	0.10	0.00	16.65	0.63	0.10	0.00	NC	–
FS 2001	Peaches, nectarines, apricots, raw (incl dried apricots)	RAC	0.061	0.10	0.01	0.10	0.01	10.76	0.66	0.10	0.01	NC	–
FB 0269	Grape, raw (incl must, incl juice, excl dried, excl wine)	RAC	0.14	0.15	0.02	0.38	0.05	15.84	2.22	0.10	0.01	0.28	0.04
DF 0269	Grape, dried (= currants, raisins and sultanas)	PP	0.49	0.10	0.05	0.13	0.06	1.06	0.52	0.10	0.05	0.10	0.05
–	Grape wine (incl vermouths)	PP	0.098	0.31	0.03	0.23	0.02	60.43	5.92	0.52	0.05	31.91	3.13
FB 0275	Strawberry, raw	RAC	0.19	0.10	0.02	0.10	0.02	3.35	0.64	0.10	0.02	0.10	0.02
VA 0381	Garlic, raw	RAC	0.01	0.82	0.01	2.06	0.02	3.79	0.04	0.10	0.00	0.29	0.00
–	Onions, mature bulbs, dry	RAC	0	9.01	0.00	20.24	0.00	30.90	0.00	9.61	0.00	2.11	0.00
–	Onions, green, raw	RAC	0.11	1.43	0.16	0.10	0.01	0.20	0.02	NC	–	6.30	0.69
VB 0041	Cabbages, head, raw	RAC	0.099	3.82	0.38	2.99	0.30	49.16	4.87	0.10	0.01	NC	–
VB 0400	Broccoli, raw	RAC	0.074	0.10	0.01	0.10	0.01	2.13	0.16	0.10	0.01	NC	–
VB 0404	Cauliflower, raw	RAC	0.012	0.10	0.00	0.10	0.00	2.73	0.03	0.10	0.00	NC	–
VC 0045	Fruiting vegetables, cucurbits, raw	RAC	0.029	5.96	0.17	9.74	0.28	51.82	1.50	13.61	0.39	0.10	0.00
VO 0440	Egg plants, raw (= aubergines)	RAC	0.11	1.31	0.14	8.26	0.91	3.95	0.43	0.10	0.01	NC	–
VO 0442	Okra, raw	RAC	0.11	6.23	0.69	0.10	0.01	NC	–	NC	–	NC	–
VO 0443	Pepino (Melon pear, Tree melon)	RAC	0.11	NC	–	NC	–	NC	–	NC	–	NC	–
VO 0444	Peppers, chilli, raw	RAC	0.11	3.47	0.38	3.56	0.39	16.30	1.79	0.10	0.01	NC	–
–	Peppers, chilli, dried	PP	1.1	0.58	0.64	1.27	1.40	1.21	1.33	0.12	0.13	NC	–
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.11	5.49	0.60	10.57	1.16	8.84	0.97	0.91	0.10	NC	–
VO 0448	Tomato, raw (incl canned, excl juice, excl paste)	RAC	0.11	13.10	1.44	4.90	0.54	62.16	6.84	1.04	0.11	0.10	0.01
–	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.23	0.58	0.13	0.22	0.05	2.21	0.51	0.24	0.06	3.10	0.71
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.052	0.10	0.01	0.10	0.01	0.42	0.02	0.10	0.01	0.10	0.01
–	Gilo (scarlet egg plant)	RAC	0.11	NC	–	NC	–	NC	–	NC	–	NC	–
–	Goji berry	RAC	0.11	NC	–	NC	–	NC	–	NC	–	NC	–
–	Seaweed	RAC	0.11	NC	–	NC	–	NC	–	NC	–	NC	–
VL 0269	Grape leaves, raw	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–
VL 0446	Roselle leaves, raw (vinagreira)	RAC	1.2	0.67	0.80	0.48	0.58	NC	–	0.45	0.54	0.90	1.08
VL 0460	Amaranth leaves, raw (i.e. bledo)	RAC	1.2	1.87	2.24	1.35	1.62	NC	–	1.27	1.52	2.53	3.04
VL 0463	Cassava leaves, raw	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–
VL 0464	Chard, raw (i.e. beet leaves)	RAC	1.2	0.68	0.82	0.49	0.59	NC	–	0.46	0.55	0.92	1.10
VL 0465	Chervil, raw	RAC	1.2	0.33	0.40	0.24	0.29	NC	–	0.22	0.26	0.45	0.54
VL 0466	Chinese cabbage, type pak-choi, raw (i.e. Brassica)	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–
VL 0467	Chinese cabbage, type pe-tsai, raw (i.e. Brassica)	RAC	1.2	0.62	0.74	0.49	0.59	NC	–	0.10	0.12	NC	–

Annex 3

SULFOXAFLOR (252) International Estimated Daily Intake (IEDI) ADI = 0–0.0500 mg/kg bw

			STMR	Diets: g/person/day			Intake = daily intake: µg/person						
Codex Code	Commodity description	Expr as	mg/kg	G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
VL 0469	Chicory leaves (sugar loaf), raw	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–
VL 0470	Lambs lettuce, raw (i.e. corn salad)	RAC	1.2	1.09	1.31	0.79	0.95	NC	–	0.74	0.89	1.47	1.76
VL 0472	Garden cress, raw	RAC	1.2	0.10	0.12	0.10	0.12	NC	–	0.10	0.12	0.13	0.16
VL 0473	Watercress, raw	RAC	1	2.08	2.08	1.50	1.50	0.10	0.10	1.41	1.41	2.81	2.81
VL 0474	Dandelion leaves, raw	RAC	1.2	0.22	0.26	0.16	0.19	NC	–	0.15	0.18	0.29	0.35
VL 0476	Endive, raw (i.e. scarole)	RAC	1.2	0.10	0.12	0.10	0.12	0.10	0.12	0.10	0.12	NC	–
VL 0478	Indian mustard (Amsoi) (i.e. Brassica)	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–
VL 0479	Japanese greens, raw (i.e. Chrysanthemum)	RAC	1.2	0.10	0.12	0.10	0.12	NC	–	0.10	0.12	0.10	0.12
VL 0480	Kale, raw (i.e. collards) (i.e. Brassica)	RAC	1.2	0.79	0.95	0.62	0.74	NC	–	0.10	0.12	NC	–
VL 0481	Komatsuna, raw (i.e. Brassica)	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–
VL 0482	Lettuce, head, raw	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–
VL 0483	Lettuce, leaf, raw	RAC	1.2	0.29	0.35	0.10	0.12	6.71	8.05	0.10	0.12	NC	–
VL 0485	Mustard greens, raw (i.e. Brassica)	RAC	1.2	0.10	0.12	0.10	0.12	NC	–	0.10	0.12	NC	–
VL 0492	Purslane, raw	RAC	1.2	0.10	0.12	0.10	0.12	NC	–	0.10	0.12	0.10	0.12
VL 0494	Radish leaves, raw	RAC	1.2	0.44	0.53	0.32	0.38	NC	–	0.30	0.36	0.59	0.71
VL 0495	Rape greens, raw (i.e. Brassica)	RAC	1.2	0.10	0.12	0.10	0.12	NC	–	0.10	0.12	NC	–
VL 0496	Rucola, raw (i.e. arrugula, rocket salad, roquette)	RAC	1.2	2.17	2.60	1.57	1.88	NC	–	1.47	1.76	2.93	3.52
VL 0501	Sowthistle, raw	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–
VL 0502	Spinach, raw	RAC	1.2	0.17	0.20	0.10	0.12	0.81	0.97	0.10	0.12	NC	–
VL 0503	Indian spinach, raw (i.e. vine spinach)	RAC	1.2	0.10	0.12	0.10	0.12	NC	–	0.10	0.12	0.10	0.12
VL 0504	Tannia leaves, raw (i.e. taioba)	RAC	1.2	0.30	0.36	0.22	0.26	NC	–	0.20	0.24	0.41	0.49
VL 0505	Taro leaves, raw	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–
VL 0506	Turnip greens, raw (i.e. Namenia, Tendergreen)	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–
VL 0507	Kang kung, raw (i.e. water spinach)	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–
VL 0510	Cos lettuce, raw	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–
–	Perilla leaves, raw (i.e. sesame leaves)	RAC	1.2	0.26	0.31	0.19	0.23	NC	–	0.18	0.22	0.35	0.42
–	Bracken, raw (i.e. ferns)	RAC	1.2	0.18	0.22	0.13	0.16	NC	–	0.12	0.14	0.24	0.29
–	Water parsley, raw	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–
–	Chinese cabbage flowering stalk, raw	RAC	1.2	NC	–	NC	–	NC	–	NC	–	NC	–
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	0.075	7.11	0.53	2.33	0.17	3.76	0.28	44.70	3.35	3.27	0.25
VD 0541	Soybean, dry, raw (incl flour, incl paste, incl curd, incl sauce, excl oil)	RAC	0.011	2.89	0.03	0.21	0.00	0.48	0.01	3.16	0.03	0.26	0.00
OR 0541	Soya oil, refined	PP	0.0033	2.32	0.01	2.54	0.01	18.70	0.06	2.51	0.01	6.29	0.02
VR 0463	Cassava raw (incl starch, incl tapioca, incl flour)	RAC	0.01	91.92	0.92	34.12	0.34	NC	–	259.92	2.60	45.48	0.45
VR 0469	Chicory, roots, raw	RAC	0.01	0.10	0.00	0.10	0.00	0.10	0.00	NC	–	NC	–
VR 0494	Radish roots, raw	RAC	0.01	3.96	0.04	2.86	0.03	3.30	0.03	2.67	0.03	5.34	0.05
VR 0497	Swede, raw (i.e. rutabaga)	RAC	0.01	2.71	0.03	1.96	0.02	7.80	0.08	1.83	0.02	3.66	0.04
VR 0498	Salsify, raw (i.e. oysterplant)	RAC	0.01	0.36	0.00	0.26	0.00	NC	–	0.24	0.00	0.48	0.00
VR 0504	Tannia, raw (i.e. yautia)	RAC	0.01	NC	–	NC	–	0.10	0.00	NC	–	NC	–

Annex 3

SULFOXAFLOR (252) International Estimated Daily Intake (IEDI) ADI = 0–0.0500 mg/kg bw

			STMR	Diets: g/person/day			Intake = daily intake: µg/person						
Codex Code	Commodity description	Expr as	mg/kg	G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
VR 0505	Taro, raw	RAC	0.01	6.71	0.07	31.91	0.32	NC	–	10.73	0.11	264.31	2.64
VR 0506	Garden turnip, raw	RAC	0.01	4.29	0.04	3.10	0.03	6.41	0.06	2.90	0.03	5.79	0.06
VR 0508	Sweet potato, raw (incl dried)	RAC	0.01	28.83	0.29	61.55	0.62	0.15	0.00	221.94	2.22	NC	–
VR 0573	Arrowroot, raw	RAC	0.01	13.83	0.14	18.24	0.18	0.10	0.00	0.10	0.00	19.60	0.20
VR 0574	Beetroot, raw	RAC	0.01	5.86	0.06	4.23	0.04	9.46	0.09	3.96	0.04	7.91	0.08
VR 0575	Burdock, greater or edible, raw	RAC	0.01	0.10	0.00	0.10	0.00	NC	–	0.10	0.00	0.10	0.00
VR 0577	Carrots, raw	RAC	0.01	2.07	0.02	3.00	0.03	25.29	0.25	0.10	0.00	NC	–
VR 0578	Celeriac, raw	RAC	0.01	2.91	0.03	2.10	0.02	7.59	0.08	1.97	0.02	3.93	0.04
VR 0583	Horseradish, raw	RAC	0.01	0.88	0.01	0.63	0.01	0.54	0.01	0.59	0.01	1.19	0.01
VR 0585	Jerusalem artichoke, raw (i.e. topinambur)	RAC	0.01	14.22	0.14	18.75	0.19	0.10	0.00	0.10	0.00	20.14	0.20
VR 0587	Parsley turnip-rooted, raw	RAC	0.01	0.55	0.01	0.40	0.00	4.29	0.04	0.37	0.00	0.74	0.01
VR 0588	Parsnip, raw	RAC	0.01	1.02	0.01	0.74	0.01	3.50	0.04	0.69	0.01	1.37	0.01
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.01	23.96	0.24	13.56	0.14	213.41	2.13	104.35	1.04	8.56	0.09
VR 0590	Black radish, raw	RAC	0.01	NC	–	NC	–	NC	–	NC	–	NC	–
VR 0591	Japanese radish, raw (i.e. daikon)	RAC	0.01	3.25	0.03	2.35	0.02	NC	–	2.20	0.02	4.39	0.04
VR 0596	Sugar beet, raw	RAC	0.014	0.10	0.00	NC	–	NC	–	NC	–	NC	–
–	Sugar beet, sugar	PP	0.025	0.56	0.01	0.24	0.01	NC	–	NC	–	5.13	0.13
VR 0600	Yams, raw (incl dried)	RAC	0.01	70.93	0.71	30.62	0.31	0.10	0.00	5.65	0.06	30.85	0.31
–	Lotus root, raw	RAC	0.01	NC	–	NC	–	NC	–	NC	–	NC	–
–	Water chestnut, raw	RAC	0.01	NC	–	NC	–	NC	–	NC	–	NC	–
VS 0624	Celery	RAC	0.19	3.66	0.70	2.65	0.50	4.84	0.92	2.47	0.47	4.94	0.94
GC 0640	Barley, raw (incl malt extract, incl malt, excl pot & pearled, excl flour & grits,excl beer)	RAC	0.063	0.10	0.01	0.15	0.01	1.13	0.07	0.10	0.01	6.34	0.40
–	Barley, pot & pearled	PP	0.044	5.46	0.24	0.10	0.00	1.44	0.06	0.10	0.00	NC	–
–	Barley, flour (white flour and wholemeal flour)	PP	0.05	0.10	0.01	NC	–	0.32	0.02	0.10	0.01	NC	–
–	Barley beer	PP	0.013	16.25	0.21	11.36	0.15	225.21	2.93	19.49	0.25	52.17	0.68
GC 0653	Triticale, raw (incl flour)	RAC	0.025	0.10	0.00	NC	–	NC	–	NC	–	NC	–
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, incl germ, incl wholemeal bread, incl white flour products, incl white bread)	RAC	0.025	57.20	1.43	110.47	2.76	272.62	6.82	25.82	0.65	132.04	3.30
SO 0495	Rape seed, raw	RAC	0.045	NC	–	0.10	0.00	NC	–	NC	–	NC	–
OR 0495	Rape seed oil, edible	PP	0.014	0.10	0.00	0.10	0.00	4.62	0.06	0.10	0.00	NC	–
SO 0691	Cotton seed, raw	RAC	0.02	NC	–	NC	–	NC	–	NC	–	NC	–
OR 0691	Cotton seed oil, edible	PP	0.002	1.28	0.00	0.10	0.00	0.45	0.00	0.42	0.00	0.15	0.00
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)—80% as muscle	RAC	0.045	23.34	1.05	40.71	1.83	97.15	4.37	18.06	0.81	57.71	2.60
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)—20% as fat	RAC	0.03	5.84	0.18	10.18	0.31	24.29	0.73	4.52	0.14	14.43	0.43

Annex 3

SULFOXAFLOR (252) International Estimated Daily Intake (IEDI) ADI = 0–0.0500 mg/kg bw

			STMR	Diets: g/person/day			Intake = daily intake: µg/person						
Codex Code	Commodity description	Expr as	mg/kg	G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.03	1.05	0.03	1.14	0.03	18.69	0.56	0.94	0.03	3.12	0.09
MO 0105	Edible offal (mammalian), raw	RAC	0.13	4.64	0.60	1.97	0.26	10.01	1.30	3.27	0.43	3.98	0.52
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.05	108.75	5.44	70.31	3.52	436.11	21.81	61.55	3.08	79.09	3.95
PM 0110	Poultry meat, raw (incl prepared)—90% as muscle	RAC	0.015	3.53	0.05	10.83	0.16	51.36	0.77	4.53	0.07	50.00	0.75
PM 0110	Poultry meat, raw (incl prepared)—10% as fat	RAC	0.005	0.39	0.00	1.20	0.01	5.71	0.03	0.50	0.00	5.56	0.03
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.005	NC	–	NC	–	0.32	0.00	NC	–	NC	–
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.046	0.10	0.00	0.70	0.03	0.97	0.04	0.10	0.00	NC	–
PE 0112	Eggs, raw, (incl dried)	RAC	0.013	3.84	0.05	4.41	0.06	27.25	0.35	1.13	0.01	7.39	0.10
–	–	–	–	–	–	–	–	–	–	–	–	–	–
	Total intake (µg/person)=				39.0		29.6		96.1		38.8		41.5
	Bodyweight per region (kg bw) =				60		60		60		60		60
	ADI (µg/person)=				3000		3000		3000		3000		3000
	%ADI=				1.3%		1.0%		3.2%		1.3%		1.4%
	Rounded %ADI=				1%		1%		3%		1%		1%

Annex 3

THIAMETHOXAM (245) International Estimated Daily Intake (IEDI) ADI = 0 – 0.080 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day			Intake as µg/person/day								
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
FC 0002	Lemons and limes, raw (incl lemon juice)	RAC	0.028	4.82	0.13	2.45	0.07	3.93	0.11	25.44	0.71	8.74	0.24	16.23	0.45
FC 0003	Mandarins, raw (incl mandarin juice)	RAC	0.028	6.18	0.17	3.66	0.10	0.25	0.01	6.82	0.19	3.49	0.10	19.38	0.54
FC 0004	Oranges, sweet, sour, raw (incl orange juice)	RAC	0.028	23.26	0.65	9.71	0.27	12.09	0.34	62.02	1.74	22.09	0.62	59.91	1.68
JF 0004	Oranges, juice (single strength, incl. concentrated)	PP	0.007	1.27	0.01	2.20	0.02	0.10	0.00	11.81	0.08	0.46	0.00	1.69	0.01
FC 0005	Pummelo and grapefruits, raw (incl grapefruit juice)	RAC	0.028	0.66	0.02	0.69	0.02	0.96	0.03	10.20	0.29	1.25	0.04	2.97	0.08
FP 0226	Apple, raw (incl cider, excl juice)	RAC	0.07	13.49	0.94	26.63	1.86	15.05	1.05	16.28	1.14	6.47	0.45	47.88	3.35
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.065	0.32	0.02	3.07	0.20	0.10	0.01	5.00	0.33	0.29	0.02	5.57	0.36
FP 0227	Crab-apple, raw	RAC	0.07	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
FP 0228	Loquat, raw (incl processed)	RAC	0.07	0.59	0.04	0.36	0.03	0.46	0.03	1.88	0.13	NC	-	1.15	0.08
FP 0229	Medlar, raw (incl processed)	RAC	0.07	0.47	0.03	0.29	0.02	0.36	0.03	1.49	0.10	NC	-	0.92	0.06
FP 0230	Pear, raw	RAC	0.07	2.16	0.15	6.24	0.44	0.10	0.01	4.07	0.28	1.16	0.08	5.34	0.37
FP 0307	Persimmon, Japanese, raw	RAC	0.07	1.91	0.13	0.10	0.01	1.94	0.14	1.96	0.14	NC	-	0.25	0.02
FP 0231	Quince, raw	RAC	0.07	0.73	0.05	0.54	0.04	0.10	0.01	0.10	0.01	0.10	0.01	1.31	0.09
FS 0012	Stone fruits, raw (incl dried apricots, excl dried plums)	RAC	0.195	11.33	2.21	23.62	4.61	0.24	0.05	11.32	2.21	2.28	0.44	33.26	6.49
DF 0014	Plum, dried (prunes)	PP	0.16	0.10	0.02	0.10	0.02	0.10	0.02	0.18	0.03	0.10	0.02	0.10	0.02
FB 2005	Caneberries, raw	RAC	0.055	0.42	0.02	1.05	0.06	0.10	0.01	0.10	0.01	0.10	0.01	1.24	0.07
FB 2006	Bush berries, raw (including processed) (i.e. blueberries, currants, gooseberries, rose hips)	RAC	0.055	0.53	0.03	1.31	0.07	0.40	0.02	1.66	0.09	0.10	0.01	0.99	0.05
FB 2007	Large shrub/tree berries, raw (including processed) (i.e. elderberries, mulberries)	RAC	0.055	0.62	0.03	0.33	0.02	0.34	0.02	1.42	0.08	0.10	0.01	1.51	0.08
FB 0269	Grape, raw (incl must, incl dried, incl juice, excl wine)	RAC	0.055	15.33	0.84	11.75	0.65	0.11	0.01	22.55	1.24	4.49	0.25	63.13	3.47
-	Grape wine (incl vermouths)	PP	0.055	0.67	0.04	12.53	0.69	2.01	0.11	1.21	0.07	3.53	0.19	4.01	0.22
FB 2009	Low growing berries, raw (i.e. cranberry and strawberry)	RAC	0.055	0.71	0.04	2.02	0.11	0.10	0.01	1.39	0.08	0.37	0.02	2.53	0.14
FI 0326	Avocado, raw	RAC	0.08	0.13	0.01	0.10	0.01	2.05	0.16	2.54	0.20	2.34	0.19	0.12	0.01
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.02	5.06	0.10	6.91	0.14	37.17	0.74	31.16	0.62	40.21	0.80	18.96	0.38
FI 0345	Mango, raw (incl canned mango, incl mango juice)	RAC	0.03	10.48	0.31	0.10	0.00	7.24	0.22	6.87	0.21	19.98	0.60	6.25	0.19
FI 0350	Papaya, raw	RAC	0	0.35	0.00	0.10	0.00	3.05	0.00	0.80	0.00	7.28	0.00	1.00	0.00
FI 0353	Pineapple, raw (incl canned pineapple, incl pineapple juice, incl dried pineapple)	RAC	0.01	0.61	0.01	1.56	0.02	7.89	0.08	9.36	0.09	8.76	0.09	1.30	0.01
VB 0040	Brassica vegetables, raw: head cabbages,	RAC	0.53	6.41	3.40	35.79	18.97	0.71	0.38	9.81	5.20	12.07	6.40	16.58	8.79

Annex 3

THIAMETHOXAM (245) International Estimated Daily Intake (IEDI) ADI = 0 – 0.080 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day			Intake as µg/person/day								
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
	flowerhead brassicas, Brussels sprouts & kohlrabi														
VC 0045	Fruiting vegetables, cucurbits, raw	RAC	0.105	53.14	5.58	86.21	9.05	6.28	0.66	92.76	9.74	15.64	1.64	155.30	16.31
VO 0440	Egg plants, raw (= aubergines)	RAC	0.08	5.58	0.45	4.31	0.34	0.89	0.07	9.31	0.74	13.64	1.09	20.12	1.61
VO 0442	Okra, raw	RAC	0.08	1.97	0.16	NC	-	3.68	0.29	3.24	0.26	5.72	0.46	1.57	0.13
VO 0443	Pepino (Melon pear, Tree melon)	RAC	0.08	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VO 0444	Peppers, chili, raw (incl dried)	RAC	0.08	6.93	0.55	10.97	0.88	8.83	0.71	9.13	0.73	6.65	0.53	20.01	1.60
-	Peppers, chili, dried	PP	0.8	0.42	0.34	0.53	0.42	0.84	0.67	0.50	0.40	0.95	0.76	0.37	0.30
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.08	4.49	0.36	6.44	0.52	7.21	0.58	5.68	0.45	9.52	0.76	8.92	0.71
VO 0447	Sweet corn on the cob, raw (incl frozen, incl canned) (i.e. kernels plus cob without husks)	RAC	0.01	0.14	0.00	0.94	0.01	5.70	0.06	2.61	0.03	1.94	0.02	0.22	0.00
VO 0448	Tomato, raw (incl canned, excl juice, excl paste)	RAC	0.08	42.04	3.36	76.13	6.09	10.69	0.86	84.59	6.77	24.92	1.99	203.27	16.26
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.24	2.34	0.56	1.33	0.32	1.57	0.38	4.24	1.02	0.34	0.08	2.83	0.68
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.054	0.29	0.02	0.29	0.02	0.10	0.01	0.38	0.02	0.10	0.01	0.14	0.01
-	Mushrooms (cultivated & wild), raw (incl canned, incl dried)	RAC	0.08	0.10	0.01	0.56	0.04	0.10	0.01	2.65	0.21	0.11	0.01	0.51	0.04
-	Gilo (scarlet egg plant)	RAC	0.08	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
-	Goji berry	RAC	0.08	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
-	Quorn	RAC	0.08	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
-	Seaweed	RAC	0.08	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VL 0053	Leafy vegetables, raw	RAC	0.54	8.47	4.57	22.36	12.07	7.74	4.18	25.51	13.78	45.77	24.72	21.22	11.46
VP 0061	Beans, green, with pods, raw: beans except broad bean & soya bean (i.e. immature seeds + pods) (Phaseolus spp)	RAC	0.08	0.68	0.05	NC	-	NC	-	0.39	0.03	0.22	0.02	0.49	0.04
VP 0062	Beans, green, without pods, raw: beans except broad bean & soya bean (i.e. immature seeds only) (Phaseolus spp..)	RAC	0.01	1.56	0.02	0.60	0.01	0.49	0.00	1.18	0.01	0.90	0.01	7.79	0.08
VP 0063	Peas green, with pods, raw (i.e. immature seeds + pods) (Pisum spp)	RAC	0.01	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VP 0064	Peas, green, without pods, raw (i.e. immature seeds only) (Pisum spp)	RAC	0.01	1.97	0.02	0.51	0.01	0.10	0.00	0.79	0.01	3.68	0.04	3.80	0.04
VP 0520	Bambara groundnut, green, without pods (i.e. immature seeds only) (Voandzeia spp)	RAC	0.01	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VP 0522	Broad bean, green, with pods (i.e. immature seeds + pods) (Vicia spp)	RAC	0.01	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VP 0523	Broad beans, green, without pods, raw (i.e.	RAC	0.01	3.51	0.04	0.43	0.00	0.10	0.00	0.60	0.01	0.29	0.00	0.78	0.01

Annex 3

THIAMETHOXAM (245) International Estimated Daily Intake (IEDI) ADI = 0 – 0.080 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day			Intake as µg/person/day								
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
	immature seeds only) (Vicia faba)														
VP 0541	Soya bean, green, without pods, raw (i.e. immature seeds only) (Glycine max)	RAC	0.01	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VP 0542	Sword bean, green, with pods (i.e. immature seeds + pods) (Canavalia spp)	RAC	0.01	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VP 0553	Lentil, green, with pods (i.e. immature seeds + pods) (Lens spp)	RAC	0.01	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VD 0070	Pulses, raw (incl processed)	RAC	0.02	85.59	1.71	64.02	1.28	34.15	0.68	88.02	1.76	89.38	1.79	96.88	1.94
VR 0075	Root and tuber vegetables, raw (incl processed)	RAC	0.01	87.83	0.88	374.04	3.74	668.92	6.69	121.64	1.22	94.20	0.94	247.11	2.47
VS 0620	Artichoke globe	RAC	0.23	0.69	0.16	0.10	0.02	0.10	0.02	0.32	0.07	0.26	0.06	1.21	0.28
GC 0640	Barley, raw (incl malt extract, incl beer, incl malt, excl pot&pearled, excl flour & grits)	RAC	0.4	3.55	1.42	19.31	7.72	4.98	1.99	3.02	1.21	7.85	3.14	3.98	1.59
-	Barley, pot&pearled	PP	0.03	7.12	0.21	7.34	0.22	0.10	0.00	0.10	0.00	0.67	0.02	0.20	0.01
-	Barley, flour (white flour and wholemeal flour)	PP	0.01	2.93	0.03	0.30	0.00	0.10	0.00	0.10	0.00	0.48	0.00	0.10	0.00
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl flour, incl oil, incl beer, incl germ, incl starch)	RAC	0.02	29.81	0.60	44.77	0.90	108.95	2.18	52.37	1.05	60.28	1.21	75.69	1.51
GC 0656	Popcorn (i.e. maize used for preparation of popcorn)	RAC	0.01	-	-	-	-	-	-	-	-	-	-	-	-
GC 0654	Wheat, raw (incl meslin)	RAC	0.02	0.10	0.00	1.12	0.02	NC	-	0.10	0.00	0.56	0.01	NC	-
-	Wheat, bulgur	PP	0.014	NC	-	NC	-	NC	-	0.10	0.00	NC	-	NC	-
CF 1210	Wheat, germ	PP	0.02	NC	-	NC	-	0.10	0.00	0.10	0.00	0.14	0.00	0.10	0.00
CF 0654	Wheat, bran	PP	0.02	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
CF 1212	Wheat, wholemeal flour	PP	0.014	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
CP 1212	Wheat, wholemeal bread	PP	0.014	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00
CF 1211	Wheat, white flour (incl white flour products: starch, gluten, macaroni, pastry)	PP	0.014	301.49	4.22	269.27	3.77	30.33	0.42	222.94	3.12	136.12	1.91	343.34	4.81
CP 1211	Wheat, white bread	PP	0.014	0.25	0.00	0.63	0.01	0.12	0.00	0.43	0.01	1.39	0.02	0.22	0.00
-	Wheat, Fermented Beverages (Korean jakju and takju)	PP	0.02	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
TN 0672	Pecan nuts, nutmeat	RAC	0.01	0.10	0.00	0.10	0.00	0.10	0.00	0.14	0.00	0.10	0.00	0.13	0.00
SO 0089	Oilseeds, raw	RAC	0.02	3.32	0.07	2.25	0.05	9.23	0.18	5.70	0.11	2.84	0.06	11.16	0.22
SO 0090	Mustard seeds, raw (incl flour, incl oil)	RAC	0.02	0.10	0.00	0.10	0.00	0.10	0.00	0.31	0.01	0.10	0.00	0.10	0.00
SO 0090	Mustard seeds, raw (incl flour, excl oil)	RAC	0.02	0.10	0.00	0.10	0.00	0.10	0.00	0.16	0.00	0.10	0.00	0.10	0.00
SO 0090	Mustard seeds, raw (incl oil, excl flour)	RAC	0.02	0.10	0.00	0.10	0.00	0.10	0.00	0.17	0.00	0.10	0.00	0.10	0.00
SO 0305	Olives for oil production, raw (incl oil)	RAC	0.02	12.61	0.25	1.35	0.03	0.27	0.01	8.04	0.16	0.58	0.01	21.80	0.44
SO 0495	Rape seed, raw (incl oil)	RAC	0.02	0.93	0.02	1.16	0.02	0.49	0.01	2.53	0.05	9.32	0.19	2.02	0.04

Annex 3

THIAMETHOXAM (245) International Estimated Daily Intake (IEDI) ADI = 0 – 0.080 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day			Intake as µg/person/day								
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
SO 0691	Cotton seed, raw	RAC	0.02	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
OR 0691	Cotton seed oil, edible	PP	0.0004	3.22	0.00	1.54	0.00	1.01	0.00	0.74	0.00	1.12	0.00	2.93	0.00
SO 0693	Linseed, raw (incl oil)	RAC	0.02	0.10	0.00	NC	-	NC	-	0.10	0.00	0.13	0.00	NC	-
SO 0696	Palm kernels, raw (incl oil)	RAC	0.02	5.81	0.12	3.77	0.08	20.07	0.40	24.53	0.49	5.94	0.12	8.99	0.18
SO 0696	Palm fruit, raw (incl oil)	RAC	0.02	28.87	0.58	1.09	0.02	53.08	1.06	80.61	1.61	24.20	0.48	17.72	0.35
SO 0697	Peanuts, nutmeat, raw (incl roasted, incl oil, incl butter)	RAC	0.02	1.30	0.03	1.23	0.02	12.62	0.25	2.87	0.06	6.59	0.13	2.67	0.05
SO 0698	Poppy seed, raw (incl oil)	RAC	0.02	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00
SO 0699	Safflower seed, raw (incl oil)	RAC	0.02	0.10	0.00	0.20	0.00	0.10	0.00	0.10	0.00	0.29	0.01	0.10	0.00
SO 0700	Sesame seed, raw (incl oil)	RAC	0.02	1.22	0.02	0.10	0.00	0.54	0.01	4.23	0.08	0.82	0.02	2.77	0.06
SO 0701	Shea nut (karite nuts), nutmeat, raw (incl butter)	RAC	0.02	NC	-	NC	-	0.34	0.01	NC	-	NC	-	NC	-
SO 0702	Sunflower seed, raw (incl oil)	RAC	0.02	7.40	0.15	35.86	0.72	1.15	0.02	8.76	0.18	5.45	0.11	13.62	0.27
-	borage seeds, raw	RAC	0.02	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
-	Castor bean, raw (incl oil)	RAC	0.02	NC	-	0.10	0.00	NC	-	NC	-	NC	-	0.10	0.00
-	Cucurbitaceae seeds, raw (melonseeds, pumpkin seeds, watermelon seeds)	RAC	0.02	0.10	0.00	NC	-	1.08	0.02	0.38	0.01	0.10	0.00	0.25	0.01
-	Oilseeds, NES, raw (including flour, incl myrtle wax, incl Japan wax): beech nut, Aleurites moluccana; Carapa guineensis; Croton tiglium; Bassia latifolia; Guizotia abyssinia; Licania rigida; Perilla frutescens; Jatropha curcas; Shorea robusta; Pongamia glabra; Astrocaryum spp., as well as tea seeds, grape seed and tomato seeds for oil extraction	RAC	0.02	0.51	0.01	0.23	0.00	0.66	0.01	0.68	0.01	0.58	0.01	0.15	0.00
SB 0715	Cocoa beans, raw (incl roasted, incl powder, incl butter, incl paste, incl nes products)	RAC	0.02	0.72	0.01	4.20	0.08	0.60	0.01	4.21	0.08	0.42	0.01	0.78	0.02
SB 0716	Coffee beans, raw (i.e. green coffee)	RAC	0.035	0.96	0.03	0.16	0.01	0.91	0.03	0.27	0.01	1.37	0.05	0.46	0.02
SM 0716	Coffee beans, roasted	PP	0.0049	0.19	0.00	0.91	0.00	0.16	0.00	2.50	0.01	0.39	0.00	0.40	0.00
-	Coffee beans, instant coffee (incl essences and concentrates)	PP	0.035	0.10	0.00	0.94	0.03	0.10	0.00	0.70	0.02	0.10	0.00	0.29	0.01
-	Coffee beans, substitutes, containing coffee	PP	0.035	0.10	0.00	0.10	0.00	0.16	0.01	0.17	0.01	0.10	0.00	0.10	0.00
HH 0624	Celery leaves, raw	RAC	0.21	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
HH 0738	Mints, raw	RAC	0.34	0.50	0.17	0.10	0.03	NC	-	NC	-	NC	-	NC	-
DH 1100	Hops, dry	RAC	0.028	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00	NC	-	0.10	0.00
DT 1114	Tea, green or black, fermented and dried, (including concentrates)	RAC	4.1	2.28	9.35	1.98	8.12	0.46	1.89	2.43	9.96	1.29	5.29	3.04	12.46
MM 0095	MEAT FROM MAMMALS other than	RAC	0.01	24.96	0.25	57.95	0.58	16.70	0.17	38.38	0.38	26.46	0.26	29.00	0.29

Annex 3

THIAMETHOXAM (245) International Estimated Daily Intake (IEDI) ADI = 0 – 0.080 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day			Intake as µg/person/day								
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
	marine mammals, raw (incl prepared meat) - 80% as muscle														
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.01	6.24	0.06	14.49	0.14	4.18	0.04	9.60	0.10	6.62	0.07	7.25	0.07
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.01	3.29	0.03	6.14	0.06	0.82	0.01	1.57	0.02	2.23	0.02	1.07	0.01
MO 0105	Edible offal (mammalian), raw	RAC	0.01	4.79	0.05	9.68	0.10	2.97	0.03	5.49	0.05	3.84	0.04	5.03	0.05
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.006	289.65	1.74	485.88	2.92	26.92	0.16	239.03	1.43	199.91	1.20	180.53	1.08
PM 0110	Poultry meat, raw (incl prepared) - 90% as muscle	RAC	0.01	13.17	0.13	26.78	0.27	7.24	0.07	116.71	1.17	22.54	0.23	32.09	0.32
PM 0110	Poultry meat, raw (incl prepared) - 10% as fat	RAC	0.01	1.46	0.01	2.98	0.03	0.80	0.01	12.97	0.13	2.50	0.03	3.57	0.04
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.01	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.10	0.00	0.10	0.00
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.016	0.12	0.00	0.12	0.00	0.11	0.00	5.37	0.09	0.24	0.00	0.10	0.00
PE 0112	Eggs, raw, (incl dried)	RAC	0.01	7.84	0.08	23.08	0.23	2.88	0.03	14.89	0.15	9.81	0.10	14.83	0.15
	Total intake (µg/person)=				47.9		89.5		28.5		74.3		60.3		105.1
	Bodyweight per region (kg bw) =				60		60		60		60		60		60
	ADI (µg/person)=				4800		4800		4800		4800		4800		4800
	%ADI=				1.0%		1.9%		0.6%		1.5%		1.3%		2.2%
	Rounded %ADI=				1%		2%		1%		2%		1%		2%

THIAMETHOXAM (245) International Estimated Daily Intake (IEDI) ADI = 0 - 0.080 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day			Intake as µg/person/day								
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
FC 0002	Lemons and limes, raw (incl lemon juice)	RAC	0.028	10.12	0.28	15.69	0.44	2.88	0.08	12.30	0.34	22.32	0.62	6.59	0.18
FC 0003	Mandarins, raw (incl mandarin juice)	RAC	0.028	12.42	0.35	14.99	0.42	16.08	0.45	10.78	0.30	9.94	0.28	NC	-
FC 0004	Oranges, sweet, sour, raw (incl orange juice)	RAC	0.028	83.66	2.34	27.64	0.77	7.37	0.21	67.80	1.90	43.97	1.23	187.74	5.26
JF 0004	Oranges, juice (single strength, incl. concentrated)	PP	0.007	33.31	0.23	1.78	0.01	0.28	0.00	18.97	0.13	14.01	0.10	13.36	0.09
FC 0005	Pummelo and grapefruits, raw (incl grapefruit juice)	RAC	0.028	8.21	0.23	4.60	0.13	0.64	0.02	5.85	0.16	19.98	0.56	368.86	10.33
FP 0226	Apple, raw (incl cider, excl juice)	RAC	0.07	41.14	2.88	56.49	3.95	26.64	1.86	31.58	2.21	51.94	3.64	3.05	0.21
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.065	14.88	0.97	11.98	0.78	0.15	0.01	9.98	0.65	30.32	1.97	3.47	0.23
FP 0227	Crab-apple, raw	RAC	0.07	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-

Annex 3

THIAMETHOXAM (245) International Estimated Daily Intake (IEDI) ADI = 0 - 0.080 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day			Intake as µg/person/day								
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
FP 0228	Loquat, raw (incl processed)	RAC	0.07	0.96	0.07	NC	-	NC	-	3.92	0.27	NC	-	2.49	0.17
FP 0229	Medlar, raw (incl processed)	RAC	0.07	NC	-	NC	-	NC	-	NC	-	NC	-	1.98	0.14
FP 0230	Pear, raw	RAC	0.07	8.79	0.62	8.44	0.59	12.37	0.87	9.60	0.67	10.27	0.72	0.23	0.02
FP 0307	Persimmon, Japanese, raw	RAC	0.07	0.10	0.01	0.30	0.02	3.59	0.25	0.15	0.01	0.10	0.01	NC	-
FP 0231	Quince, raw	RAC	0.07	0.19	0.01	0.18	0.01	0.11	0.01	0.10	0.01	0.28	0.02	NC	-
FS 0012	Stone fruits, raw (incl dried apricots, excl dried plums)	RAC	0.195	18.18	3.55	23.83	4.65	14.27	2.78	18.52	3.61	9.35	1.82	0.11	0.02
DF 0014	Plum, dried (prunes)	PP	0.16	0.61	0.10	0.35	0.06	0.10	0.02	0.35	0.06	0.49	0.08	0.13	0.02
FB 2005	Caneberries, raw	RAC	0.055	0.56	0.03	1.43	0.08	0.14	0.01	1.23	0.07	1.14	0.06	0.10	0.01
FB 2006	Bush berries, raw (including processed) (i.e. blueberries, currants, gooseberries, rose hips)	RAC	0.055	1.31	0.07	5.50	0.30	0.10	0.01	2.57	0.14	0.82	0.05	2.15	0.12
FB 2007	Large shrub/tree berries, raw (including processed) (i.e. elderberries, mulberries)	RAC	0.055	8.26	0.45	0.14	0.01	0.10	0.01	0.13	0.01	0.19	0.01	1.87	0.10
FB 0269	Grape, raw (incl must, incl dried, incl juice, excl wine)	RAC	0.055	20.07	1.10	20.04	1.10	5.35	0.29	18.01	0.99	25.20	1.39	2.94	0.16
-	Grape wine (incl vermouths)	PP	0.055	88.93	4.89	62.41	3.43	1.84	0.10	25.07	1.38	61.17	3.36	5.84	0.32
FB 2009	Low growing berries, raw (i.e. cranberry and strawberry)	RAC	0.055	4.55	0.25	5.66	0.31	0.10	0.01	7.85	0.43	5.86	0.32	0.10	0.01
FI 0326	Avocado, raw	RAC	0.08	2.65	0.21	0.87	0.07	0.46	0.04	1.64	0.13	1.30	0.10	0.96	0.08
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.02	25.14	0.50	23.37	0.47	23.06	0.46	23.40	0.47	18.44	0.37	39.29	0.79
FI 0345	Mango, raw (incl canned mango, incl mango juice)	RAC	0.03	1.80	0.05	0.63	0.02	10.05	0.30	1.07	0.03	3.52	0.11	16.44	0.49
FI 0350	Papaya, raw	RAC	0	0.31	0.00	0.18	0.00	1.50	0.00	0.51	0.00	0.54	0.00	1.08	0.00
FI 0353	Pineapple, raw (incl canned pineapple, incl pineapple juice, incl dried pineapple)	RAC	0.01	13.13	0.13	11.13	0.11	6.94	0.07	14.36	0.14	36.74	0.37	18.81	0.19
VB 0040	Brassica vegetables, raw: head cabbages, flowerhead brassicas, Brussels sprouts & kohlrabi	RAC	0.53	20.71	10.98	39.81	21.10	16.70	8.85	28.49	15.10	18.12	9.60	15.03	7.97
VC 0045	Fruiting vegetables, cucurbits, raw	RAC	0.105	27.81	2.92	41.93	4.40	123.30	12.95	49.47	5.19	15.95	1.67	35.99	3.78
VO 0440	Egg plants, raw (= aubergines)	RAC	0.08	1.01	0.08	1.69	0.14	21.37	1.71	3.00	0.24	1.40	0.11	NC	-
VO 0442	Okra, raw	RAC	0.08	NC	-	NC	-	0.10	0.01	0.17	0.01	NC	-	0.72	0.06
VO 0443	Pepino (Melon pear, Tree melon)	RAC	0.08	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VO 0444	Peppers, chili, raw (incl dried)	RAC	0.08	6.36	0.51	15.46	1.24	10.74	0.86	7.28	0.58	8.21	0.66	3.58	0.29
-	Peppers, chili, dried	PP	0.8	0.11	0.09	0.21	0.17	0.36	0.29	0.21	0.17	0.25	0.20	0.15	0.12
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.08	0.82	0.07	1.53	0.12	10.85	0.87	4.59	0.37	1.84	0.15	2.00	0.16
VO 0447	Sweet corn on the cob, raw (incl frozen, incl canned) (i.e. kernels plus cob without husks)	RAC	0.01	11.43	0.11	3.71	0.04	0.74	0.01	13.63	0.14	3.07	0.03	1.50	0.02
VO 0448	Tomato, raw (incl canned, excl juice, excl paste)	RAC	0.08	43.88	3.51	55.41	4.43	35.38	2.83	74.88	5.99	26.50	2.12	9.51	0.76

Annex 3

THIAMETHOXAM (245) International Estimated Daily Intake (IEDI) ADI = 0 - 0.080 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day			Intake as µg/person/day								
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.24	4.96	1.19	3.20	0.77	0.15	0.04	1.61	0.39	6.88	1.65	0.52	0.12
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.054	0.80	0.04	0.10	0.01	0.10	0.01	0.61	0.03	0.40	0.02	0.10	0.01
-	Mushrooms (cultivated & wild), raw (incl canned, incl dried)	RAC	0.08	7.31	0.58	5.92	0.47	1.26	0.10	3.73	0.30	14.85	1.19	0.57	0.05
-	Gilo (scarlet egg plant)	RAC	0.08	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
-	Goji berry	RAC	0.08	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
-	Quorn	RAC	0.08	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
-	Seaweed	RAC	0.08	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VL 0053	Leafy vegetables, raw	RAC	0.54	18.83	10.17	21.85	11.80	121.23	65.46	43.09	23.27	18.18	9.82	18.32	9.89
VP 0061	Beans, green, with pods, raw: beans except broad bean & soya bean (i.e. immature seeds + pods) (Phaseolus spp)	RAC	0.08	5.07	0.41	0.83	0.07	0.17	0.01	3.70	0.30	NC	-	NC	-
VP 0062	Beans, green, without pods, raw: beans except broad bean & soya bean (i.e. immature seeds only) (Phaseolus spp..)	RAC	0.01	2.21	0.02	5.25	0.05	4.17	0.04	1.61	0.02	16.95	0.17	0.17	0.00
VP 0063	Peas green, with pods, raw (i.e. immature seeds + pods) (Pisum spp)	RAC	0.01	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VP 0064	Peas, green, without pods, raw (i.e. immature seeds only) (Pisum spp)	RAC	0.01	10.72	0.11	1.99	0.02	2.72	0.03	4.26	0.04	4.23	0.04	NC	-
VP 0520	Bambara groundnut, green, without pods (i.e. immature seeds only) (Voandzeia spp)	RAC	0.01	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VP 0522	Broad bean, green, with pods (i.e. immature seeds + pods) (Vicia spp)	RAC	0.01	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VP 0523	Broad beans, green, without pods, raw (i.e. immature seeds only) (Vicia faba)	RAC	0.01	0.22	0.00	0.84	0.01	0.15	0.00	0.48	0.00	2.04	0.02	NC	-
VP 0541	Soya bean, green, without pods, raw (i.e. immature seeds only) (Glycine max)	RAC	0.01	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VP 0542	Sword bean, green, with pods (i.e. immature seeds + pods) (Canavalia spp)	RAC	0.01	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VP 0553	Lentil, green, with pods (i.e. immature seeds + pods) (Lens spp)	RAC	0.01	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VD 0070	Pulses, raw (incl processed)	RAC	0.02	112.88	2.26	123.05	2.46	47.15	0.94	204.64	4.09	227.37	4.55	109.11	2.18
VR 0075	Root and tuber vegetables, raw (incl processed)	RAC	0.01	290.31	2.90	300.35	3.00	214.25	2.14	242.72	2.43	348.67	3.49	137.52	1.38
VS 0620	Artichoke globe	RAC	0.23	0.98	0.23	3.65	0.84	0.10	0.02	1.67	0.38	0.26	0.06	NC	-
GC 0640	Barley, raw (incl malt extract, incl beer, incl malt, excl pot&pearled, excl flour & grits)	RAC	0.4	35.17	14.07	49.45	19.78	8.86	3.54	34.31	13.72	44.87	17.95	15.82	6.33
-	Barley, pot&pearled	PP	0.03	0.57	0.02	2.56	0.08	0.33	0.01	0.56	0.02	0.36	0.01	NC	-
-	Barley, flour (white flour and wholemeal flour)	PP	0.01	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00	0.68	0.01	0.10	0.00

Annex 3

THIAMETHOXAM (245) International Estimated Daily Intake (IEDI) ADI = 0 - 0.080 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day			Intake as µg/person/day								
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl flour, incl oil, incl beer, incl germ, incl starch)	RAC	0.02	18.51	0.37	26.18	0.52	26.04	0.52	39.99	0.80	7.36	0.15	64.58	1.29
GC 0656	Popcorn (i.e. maize used for preparation of popcorn)	RAC	0.01	-	-	-	-	-	-	-	-	-	-	-	-
GC 0654	Wheat, raw (incl meslin)	RAC	0.02	NC	-	NC	-	NC	-	0.10	0.00	NC	-	NC	-
-	Wheat, bulgur	PP	0.014	NC	-	NC	-	0.10	0.00	NC	-	NC	-	NC	-
CF 1210	Wheat, germ	PP	0.02	0.97	0.02	0.10	0.00	0.10	0.00	0.10	0.00	NC	-	0.10	0.00
CF 0654	Wheat, bran	PP	0.02	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
CF 1212	Wheat, wholemeal flour	PP	0.014	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
CP 1212	Wheat, wholemeal bread	PP	0.014	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00
CF 1211	Wheat, white flour (incl white flour products: starch, gluten, macaroni, pastry)	PP	0.014	199.38	2.79	193.50	2.71	106.30	1.49	185.31	2.59	171.11	2.40	132.37	1.85
CP 1211	Wheat, white bread	PP	0.014	1.30	0.02	0.46	0.01	0.10	0.00	0.22	0.00	2.44	0.03	0.77	0.01
-	Wheat, Fermented Beverages (Korean jakju and takju)	PP	0.02	NC	-	NC	-	NC	-	4.36	0.09	NC	-	NC	-
TN 0672	Pecan nuts, nutmeat	RAC	0.01	0.38	0.00	NC	-	NC	-	0.27	0.00	NC	-	0.26	0.00
SO 0089	Oilseeds, raw	RAC	0.02	2.97	0.06	4.12	0.08	5.94	0.12	7.42	0.15	1.87	0.04	0.96	0.02
SO 0090	Mustard seeds, raw (incl flour, incl oil)	RAC	0.02	0.30	0.01	0.48	0.01	0.33	0.01	0.63	0.01	1.03	0.02	0.40	0.01
SO 0090	Mustard seeds, raw (incl flour, excl oil)	RAC	0.02	0.27	0.01	0.44	0.01	0.10	0.00	0.56	0.01	1.03	0.02	0.40	0.01
SO 0090	Mustard seeds, raw (incl oil, excl flour)	RAC	0.02	0.10	0.00	0.45	0.01	0.32	0.01	0.58	0.01	0.43	0.01	NC	-
SO 0305	Olives for oil production, raw (incl oil)	RAC	0.02	17.78	0.36	48.67	0.97	0.10	0.00	22.50	0.45	14.09	0.28	2.46	0.05
SO 0495	Rape seed, raw (incl oil)	RAC	0.02	32.68	0.65	19.91	0.40	7.83	0.16	15.69	0.31	NC	-	NC	-
SO 0691	Cotton seed, raw	RAC	0.02	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
OR 0691	Cotton seed oil, edible	PP	0.0004	1.68	0.00	0.66	0.00	1.13	0.00	1.18	0.00	0.89	0.00	0.37	0.00
SO 0693	Linseed, raw (incl oil)	RAC	0.02	NC	-	NC	-	0.10	0.00	0.10	0.00	NC	-	NC	-
SO 0696	Palm kernels, raw (incl oil)	RAC	0.02	5.33	0.11	5.04	0.10	11.83	0.24	7.94	0.16	10.77	0.22	4.53	0.09
SO 0696	Palm fruit, raw (incl oil)	RAC	0.02	12.11	0.24	1.38	0.03	24.43	0.49	6.52	0.13	14.27	0.29	1.35	0.03
SO 0697	Peanuts, nutmeat, raw (incl roasted, incl oil, incl butter)	RAC	0.02	5.63	0.11	2.75	0.06	9.58	0.19	5.82	0.12	13.71	0.27	1.84	0.04
SO 0698	Poppy seed, raw (incl oil)	RAC	0.02	0.10	0.00	0.25	0.01	0.10	0.00	0.10	0.00	NC	-	NC	-
SO 0699	Safflower seed, raw (incl oil)	RAC	0.02	0.10	0.00	0.10	0.00	0.10	0.00	0.16	0.00	NC	-	NC	-
SO 0700	Sesame seed, raw (incl oil)	RAC	0.02	0.61	0.01	0.10	0.00	1.53	0.03	0.85	0.02	0.10	0.00	0.14	0.00
SO 0701	Shea nut (karite nuts), nutmeat, raw (incl butter)	RAC	0.02	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
SO 0702	Sunflower seed, raw (incl oil)	RAC	0.02	23.40	0.47	29.33	0.59	1.24	0.02	13.85	0.28	6.48	0.13	6.91	0.14
-	borage seeds, raw	RAC	0.02	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
-	Castor bean, raw (incl oil)	RAC	0.02	NC	-	NC	-	0.10	0.00	NC	-	NC	-	NC	-
-	Cucurbitaceae seeds, raw (melonseeds,	RAC	0.02	NC	-	NC	-	0.10	0.00	NC	-	NC	-	NC	-

Annex 3

THIAMETHOXAM (245) International Estimated Daily Intake (IEDI) ADI = 0 - 0.080 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day			Intake as µg/person/day								
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
	pumpkin seeds, watermelon seeds)														
-	Oilseeds, NES, raw (including flour, incl myrtle wax, incl Japan wax): beech nut, Aleurites moluccana; Carapa guineensis; Croton tiglium; Bassia latifolia; Guizotia abyssinia; Licania rigida; Perilla frutescens; Jatropha curcas; Shorea robusta; Pongamia glabra; Astrocaryum spp., as well as tea seeds, grape seed and tomato seeds for oil extraction	RAC	0.02	0.10	0.00	0.10	0.00	0.17	0.00	0.22	0.00	NC	-	0.32	0.01
SB 0715	Cocoa beans, raw (incl roasted, incl powder, incl butter, incl paste, incl nes products)	RAC	0.02	7.54	0.15	5.59	0.11	0.29	0.01	4.14	0.08	1.27	0.03	5.29	0.11
SB 0716	Coffee beans, raw (i.e. green coffee)	RAC	0.035	0.60	0.02	NC	-	0.62	0.02	1.71	0.06	NC	-	3.51	0.12
SM 0716	Coffee beans, roasted	PP	0.0049	7.02	0.03	9.75	0.05	0.10	0.00	5.09	0.02	13.38	0.07	0.77	0.00
-	Coffee beans, instant coffee (incl essences and concentrates)	PP	0.035	0.75	0.03	0.30	0.01	0.10	0.00	0.67	0.02	2.43	0.09	1.43	0.05
-	Coffee beans, substitutes, containing coffee	PP	0.035	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00	0.15	0.01
HH 0624	Celery leaves, raw	RAC	0.21	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
HH 0738	Mints, raw	RAC	0.34	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
DH 1100	Hops, dry	RAC	0.028	NC	-	NC	-	0.10	0.00	0.10	0.00	NC	-	NC	-
DT 1114	Tea, green or black, fermented and dried, (including concentrates)	RAC	4.1	2.91	11.93	1.73	7.09	1.14	4.67	1.85	7.59	2.29	9.39	0.74	3.03
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.01	112.02	1.12	120.71	1.21	63.46	0.63	88.99	0.89	96.24	0.96	41.02	0.41
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.01	28.01	0.28	30.18	0.30	15.86	0.16	22.25	0.22	24.06	0.24	10.25	0.10
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.01	6.44	0.06	15.51	0.16	3.79	0.04	8.29	0.08	18.44	0.18	8.00	0.08
MO 0105	Edible offal (mammalian), raw	RAC	0.01	15.17	0.15	5.19	0.05	6.30	0.06	6.78	0.07	3.32	0.03	3.17	0.03
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.006	388.92	2.33	335.88	2.02	49.15	0.29	331.25	1.99	468.56	2.81	245.45	1.47
PM 0110	Poultry meat, raw (incl prepared) - 90% as muscle	RAC	0.01	66.38	0.66	48.47	0.48	21.58	0.22	78.41	0.78	48.04	0.48	76.01	0.76
PM 0110	Poultry meat, raw (incl prepared) - 10% as fat	RAC	0.01	7.38	0.07	5.39	0.05	2.40	0.02	8.71	0.09	5.34	0.05	8.45	0.08
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.01	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.71	0.01	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.016	0.33	0.01	0.72	0.01	0.27	0.00	0.35	0.01	0.80	0.01	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0.01	25.84	0.26	29.53	0.30	28.05	0.28	33.19	0.33	36.44	0.36	8.89	0.09
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (µg/person)=				91.9		106.1		118.3		104.3		89.3		61.9
	Bodyweight per region (kg bw) =				60		60		55		60		60		60

Annex 3

THIAMETHOXAM (245) International Estimated Daily Intake (IEDI) ADI = 0 - 0.080 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day			Intake as µg/person/day								
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
	ADI (µg/person)=				4800		4800		4400		4800		4800		4800
	%ADI=				1.9%		2.2%		2.7%		2.2%		1.9%		1.3%
	Rounded %ADI=				2%		2%		3%		2%		2%		1%

THIAMETHOXAM (245) International Estimated Daily Intake (IEDI) ADI = 0 - 0.08 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day			Intake = daily intake: µg/person						
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
FC 0002	Lemons and limes, raw (incl lemon juice)	RAC	0.028	18.97	0.53	0.97	0.03	6.23	0.17	0.10	0.00	3.35	0.09
FC 0003	Mandarins, raw (incl mandarin juice)	RAC	0.028	0.16	0.00	0.27	0.01	9.06	0.25	0.10	0.00	0.10	0.00
FC 0004	Oranges, sweet, sour, raw (incl orange juice)	RAC	0.028	1.34	0.04	1.65	0.05	40.03	1.12	0.33	0.01	1.76	0.05
JF 0004	Oranges, juice (single strength, incl. concentrated)	PP	0.007	0.10	0.00	0.26	0.00	12.61	0.09	0.14	0.00	0.33	0.00
FC 0005	Pummelo and grapefruits, raw (incl grapefruit juice)	RAC	0.028	0.68	0.02	0.10	0.00	3.21	0.09	0.10	0.00	NC	-
FP 0226	Apple, raw (incl cider, excl juice)	RAC	0.07	66.67	4.67	2.06	0.14	55.83	3.91	188.29	13.18	1.38	0.10
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.065	0.10	0.01	0.10	0.01	7.19	0.47	0.10	0.01	NC	-
FP 0227	Crab-apple, raw	RAC	0.07	NC	-	NC	-	NC	-	NC	-	NC	-
FP 0228	Loquat, raw (incl processed)	RAC	0.07	0.94	0.07	4.68	0.33	NC	-	0.50	0.04	3.08	0.22
FP 0229	Medlar, raw (incl processed)	RAC	0.07	0.75	0.05	3.73	0.26	4.87	0.34	0.40	0.03	2.45	0.17
FP 0230	Pear, raw	RAC	0.07	0.10	0.01	0.14	0.01	9.45	0.66	0.10	0.01	0.14	0.01
FP 0307	Persimmon, Japanese, raw	RAC	0.07	0.41	0.03	0.32	0.02	0.10	0.01	0.58	0.04	12.51	0.88
FP 0231	Quince, raw	RAC	0.07	NC	-	NC	-	0.65	0.05	NC	-	NC	-
FS 0012	Stone fruits, raw (incl dried apricots, excl dried plums)	RAC	0.195	0.10	0.02	0.10	0.02	32.27	6.29	0.10	0.02	NC	-
DF 0014	Plum, dried (prunes)	PP	0.16	0.10	0.02	0.10	0.02	0.37	0.06	0.10	0.02	NC	-
FB 2005	Caneberries, raw	RAC	0.055	0.10	0.01	7.30	0.40	2.29	0.13	0.10	0.01	NC	-
FB 2006	Bush berries, raw (including processed) (i.e. blueberries, currants, gooseberries, rose hips)	RAC	0.055	0.82	0.05	4.05	0.22	5.94	0.33	0.43	0.02	2.66	0.15
FB 2007	Large shrub/tree berries, raw (including processed) (i.e. elderberries, mulberries)	RAC	0.055	0.71	0.04	7.32	0.40	NC	-	0.38	0.02	2.32	0.13
FB 0269	Grape, raw (incl must, incl dried, incl juice, excl wine)	RAC	0.055	0.17	0.01	0.94	0.05	20.24	1.11	0.10	0.01	0.40	0.02
-	Grape wine (incl vermouths)	PP	0.055	0.31	0.02	0.23	0.01	60.43	3.32	0.52	0.03	31.91	1.76
FB 2009	Low growing berries, raw (i.e. cranberry and strawberry)	RAC	0.055	0.10	0.01	0.10	0.01	3.37	0.19	0.10	0.01	0.10	0.01
FI 0326	Avocado, raw	RAC	0.08	1.12	0.09	0.10	0.01	0.84	0.07	0.10	0.01	6.60	0.53

Annex 3

THIAMETHOXAM (245) International Estimated Daily Intake (IEDI) ADI = 0 - 0.08 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day			Intake = daily intake: µg/person						
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.02	20.88	0.42	81.15	1.62	24.58	0.49	37.92	0.76	310.23	6.20
FI 0345	Mango, raw (incl canned mango, incl mango juice)	RAC	0.03	12.25	0.37	6.83	0.20	0.76	0.02	0.10	0.00	20.12	0.60
FI 0350	Papaya, raw	RAC	0	6.47	0.00	0.25	0.00	0.19	0.00	0.10	0.00	26.42	0.00
FI 0353	Pineapple, raw (incl canned pineapple, incl pineapple juice, incl dried pineapple)	RAC	0.01	8.51	0.09	6.27	0.06	6.89	0.07	0.18	0.00	24.94	0.25
VB 0040	Brassica vegetables, raw: head cabbages, flowerhead brassicas, Brussels sprouts & kohlrabi	RAC	0.53	4.84	2.57	3.79	2.01	58.72	31.12	0.10	0.05	NC	-
VC 0045	Fruiting vegetables, cucurbits, raw	RAC	0.105	5.96	0.63	9.74	1.02	51.82	5.44	13.61	1.43	0.10	0.01
VO 0440	Egg plants, raw (= aubergines)	RAC	0.08	1.31	0.10	8.26	0.66	3.95	0.32	0.10	0.01	NC	-
VO 0442	Okra, raw	RAC	0.08	6.23	0.50	0.10	0.01	NC	-	NC	-	NC	-
VO 0443	Pepino (Melon pear, Tree melon)	RAC	0.08	NC	-	NC	-	NC	-	NC	-	NC	-
VO 0444	Peppers, chili, raw (incl dried)	RAC	0.08	7.55	0.60	12.48	1.00	24.78	1.98	0.87	0.07	NC	-
-	Peppers, chili, dried	PP	0.8	0.58	0.46	1.27	1.02	1.21	0.97	0.12	0.10	NC	-
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.08	5.49	0.44	10.57	0.85	8.84	0.71	0.91	0.07	NC	-
VO 0447	Sweet corn on the cob, raw (incl frozen, incl canned) (i.e. kernels plus cob without husks)	RAC	0.01	3.63	0.04	20.50	0.21	8.78	0.09	0.10	0.00	0.17	0.00
VO 0448	Tomato, raw (incl canned, excl juice, excl paste)	RAC	0.08	13.10	1.05	4.90	0.39	62.16	4.97	1.04	0.08	0.10	0.01
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.24	0.58	0.14	0.22	0.05	2.21	0.53	0.24	0.06	3.10	0.74
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.054	0.10	0.01	0.10	0.01	0.42	0.02	0.10	0.01	0.10	0.01
-	Mushrooms (cultivated & wild), raw (incl canned, incl dried)	RAC	0.08	0.10	0.01	0.10	0.01	3.73	0.30	0.10	0.01	NC	-
-	Gilo (scarlet egg plant)	RAC	0.08	NC	-	NC	-	NC	-	NC	-	NC	-
-	Goji berry	RAC	0.08	NC	-	NC	-	NC	-	NC	-	NC	-
-	Quorn	RAC	0.08	NC	-	NC	-	NC	-	NC	-	NC	-
-	Seaweed	RAC	0.08	NC	-	NC	-	NC	-	NC	-	NC	-
VL 0053	Leafy vegetables, raw	RAC	0.54	12.42	6.71	8.75	4.73	7.53	4.07	7.07	3.82	14.11	7.62
VP 0061	Beans, green, with pods, raw: beans except broad bean & soya bean (i.e. immature seeds + pods) (Phaseolus spp)	RAC	0.08	NC	-	NC	-	NC	-	NC	-	NC	-
VP 0062	Beans, green, without pods, raw: beans except broad bean & soya bean (i.e. immature seeds only) (Phaseolus spp..)	RAC	0.01	0.30	0.00	3.13	0.03	4.11	0.04	0.10	0.00	NC	-
VP 0063	Peas green, with pods, raw (i.e. immature seeds + pods) (Pisum spp)	RAC	0.01	NC	-	NC	-	NC	-	NC	-	NC	-
VP 0064	Peas, green, without pods, raw (i.e. immature	RAC	0.01	0.21	0.00	0.10	0.00	5.51	0.06	0.10	0.00	NC	-

Annex 3

THIAMETHOXAM (245) International Estimated Daily Intake (IEDI) ADI = 0 - 0.08 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day			Intake = daily intake: µg/person						
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
	seeds only) (Pisum spp)												
VP 0520	Bambara groundnut, green, without pods (i.e. immature seeds only) (Voandzeia spp)	RAC	0.01	NC	-	NC	-	NC	-	NC	-	NC	-
VP 0522	Broad bean, green, with pods (i.e. immature seeds + pods) (Vicia spp)	RAC	0.01	NC	-	NC	-	NC	-	NC	-	NC	-
VP 0523	Broad beans, green, without pods, raw (i.e. immature seeds only) (Vicia faba)	RAC	0.01	0.10	0.00	0.10	0.00	0.76	0.01	NC	-	NC	-
VP 0541	Soya bean, green, without pods, raw (i.e. immature seeds only) (Glycine max)	RAC	0.01	NC	-	NC	-	NC	-	NC	-	NC	-
VP 0542	Sword bean, green, with pods (i.e. immature seeds + pods) (Canavalia spp)	RAC	0.01	NC	-	NC	-	NC	-	NC	-	NC	-
VP 0553	Lentil, green, with pods (i.e. immature seeds + pods) (Lens spp)	RAC	0.01	NC	-	NC	-	NC	-	NC	-	NC	-
VD 0070	Pulses, raw (incl processed)	RAC	0.02	44.03	0.88	29.00	0.58	112.51	2.25	75.50	1.51	39.69	0.79
VR 0075	Root and tuber vegetables, raw (incl processed)	RAC	0.01	282.25	2.82	232.11	2.32	281.91	2.82	620.21	6.20	459.96	4.60
VS 0620	Artichoke globe	RAC	0.23	0.10	0.02	NC	-	0.10	0.02	0.10	0.02	NC	-
GC 0640	Barley, raw (incl malt extract, incl beer, incl malt, excl pot&pearled, excl flour & grits)	RAC	0.4	3.15	1.26	2.31	0.92	43.92	17.57	3.72	1.49	16.26	6.50
-	Barley, pot&pearled	PP	0.03	5.46	0.16	0.10	0.00	1.44	0.04	0.10	0.00	NC	-
-	Barley, flour (white flour and wholemeal flour)	PP	0.01	0.10	0.00	NC	-	0.32	0.00	0.10	0.00	NC	-
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl flour, incl oil, incl beer, incl germ, incl starch)	RAC	0.02	116.66	2.33	10.52	0.21	38.46	0.77	76.60	1.53	34.44	0.69
GC 0656	Popcorn (i.e. maize used for preparation of popcorn)	RAC	0.01	-	-	-	-	-	-	-	-	-	-
GC 0654	Wheat, raw (incl meslin)	RAC	0.02	NC	-	NC	-	NC	-	NC	-	0.97	0.02
-	Wheat, bulgur	PP	0.014	0.10	0.00	NC	-	NC	-	NC	-	NC	-
CF 1210	Wheat, germ	PP	0.02	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00	NC	-
CF 0654	Wheat, bran	PP	0.02	NC	-	NC	-	NC	-	NC	-	NC	-
CF 1212	Wheat, wholemeal flour	PP	0.014	NC	-	NC	-	NC	-	NC	-	NC	-
CP 1212	Wheat, wholemeal bread	PP	0.014	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00
CF 1211	Wheat, white flour (incl white flour products: starch, gluten, macaroni, pastry)	PP	0.014	45.21	0.63	87.37	1.22	215.61	3.02	20.42	0.29	103.67	1.45
CP 1211	Wheat, white bread	PP	0.014	0.43	0.01	0.41	0.01	1.56	0.02	0.11	0.00	0.10	0.00
-	Wheat, Fermented Beverages (Korean jakju and takju)	PP	0.02	NC	-	NC	-	NC	-	NC	-	NC	-
TN 0672	Pecan nuts, nutmeat	RAC	0.01	0.15	0.00	0.22	0.00	0.31	0.00	0.10	0.00	0.10	0.00
SO 0089	Oilseeds, raw	RAC	0.02	10.97	0.22	1.26	0.03	1.75	0.04	16.04	0.32	2.96	0.06
SO 0090	Mustard seeds, raw (incl flour, incl oil)	RAC	0.02	0.10	0.00	0.19	0.00	0.32	0.01	0.10	0.00	0.10	0.00

Annex 3

THIAMETHOXAM (245) International Estimated Daily Intake (IEDI) ADI = 0 - 0.08 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day			Intake = daily intake: µg/person						
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
SO 0090	Mustard seeds, raw (incl flour, excl oil)	RAC	0.02	0.10	0.00	0.18	0.00	0.29	0.01	0.10	0.00	0.10	0.00
SO 0090	Mustard seeds, raw (incl oil, excl flour)	RAC	0.02	0.10	0.00	0.19	0.00	0.11	0.00	0.10	0.00	NC	-
SO 0305	Olives for oil production, raw (incl oil)	RAC	0.02	0.18	0.00	0.11	0.00	11.00	0.22	0.10	0.00	0.49	0.01
SO 0495	Rape seed, raw (incl oil)	RAC	0.02	0.19	0.00	0.10	0.00	12.07	0.24	0.10	0.00	NC	-
SO 0691	Cotton seed, raw	RAC	0.02	NC	-	NC	-	NC	-	NC	-	NC	-
OR 0691	Cotton seed oil, edible	PP	0.0004	1.28	0.00	0.10	0.00	0.45	0.00	0.42	0.00	0.15	0.00
SO 0693	Linseed, raw (incl oil)	RAC	0.02	0.10	0.00	NC	-	0.10	0.00	NC	-	NC	-
SO 0696	Palm kernels, raw (incl oil)	RAC	0.02	60.84	1.22	12.77	0.26	5.41	0.11	0.57	0.01	53.45	1.07
SO 0696	Palm fruit, raw (incl oil)	RAC	0.02	36.35	0.73	7.16	0.14	2.99	0.06	22.89	0.46	28.38	0.57
SO 0697	Peanuts, nutmeat, raw (incl roasted, incl oil, incl butter)	RAC	0.02	18.82	0.38	0.57	0.01	2.28	0.05	6.90	0.14	0.53	0.01
SO 0698	Poppy seed, raw (incl oil)	RAC	0.02	0.10	0.00	0.10	0.00	0.11	0.00	NC	-	NC	-
SO 0699	Safflower seed, raw (incl oil)	RAC	0.02	0.10	0.00	NC	-	NC	-	NC	-	NC	-
SO 0700	Sesame seed, raw (incl oil)	RAC	0.02	2.34	0.05	0.66	0.01	0.26	0.01	9.84	0.20	NC	-
SO 0701	Shea nut (karite nuts), nutmeat, raw (incl butter)	RAC	0.02	0.95	0.02	NC	-	NC	-	NC	-	NC	-
SO 0702	Sunflower seed, raw (incl oil)	RAC	0.02	0.94	0.02	0.22	0.00	32.01	0.64	12.12	0.24	0.48	0.01
-	borage seeds, raw	RAC	0.02	NC	-	NC	-	NC	-	NC	-	NC	-
-	Castor bean, raw (incl oil)	RAC	0.02	NC	-	NC	-	NC	-	NC	-	NC	-
-	Cucurbitaceae seeds, raw (melonseeds, pumpkin seeds, watermelon seeds)	RAC	0.02	1.81	0.04	NC	-	0.10	0.00	NC	-	NC	-
-	Oilseeds, NES, raw (including flour, incl myrtle wax, incl Japan wax): beech nut, Aleurites moluccana; Carapa guineensis; Croton tiglium; Bassia latifolia; Guizotia abyssinia; Licania rigida; Perilla frutescens; Jatropha curcas; Shorea robusta; Pongamia glabra; Astrocaryum spp., as well as tea seeds, grape seed and tomato seeds for oil extraction	RAC	0.02	1.00	0.02	0.42	0.01	NC	-	2.47	0.05	2.43	0.05
SB 0715	Cocoa beans, raw (incl roasted, incl powder, incl butter, incl paste, incl nes products)	RAC	0.02	0.11	0.00	0.89	0.02	6.28	0.13	0.17	0.00	2.31	0.05
SB 0716	Coffee beans, raw (i.e. green coffee)	RAC	0.035	0.83	0.03	0.69	0.02	1.09	0.04	2.91	0.10	0.82	0.03
SM 0716	Coffee beans, roasted	PP	0.0049	0.10	0.00	0.41	0.00	7.50	0.04	0.10	0.00	0.10	0.00
-	Coffee beans, instant coffee (incl essences and concentrates)	PP	0.035	0.10	0.00	0.10	0.00	0.60	0.02	0.10	0.00	5.53	0.19
-	Coffee beans, substitutes, containing coffee	PP	0.035	0.10	0.00	0.10	0.00	0.13	0.00	0.10	0.00	NC	-
HH 0624	Celery leaves, raw	RAC	0.21	NC	-	NC	-	NC	-	NC	-	NC	-
HH 0738	Mints, raw	RAC	0.34	NC	-	NC	-	NC	-	NC	-	NC	-
DH 1100	Hops, dry	RAC	0.028	NC	-	NC	-	0.10	0.00	NC	-	NC	-
DT 1114	Tea, green or black, fermented and dried,	RAC	4.1	0.53	2.17	5.25	21.53	0.86	3.53	0.56	2.30	0.88	3.61

Annex 3

THIAMETHOXAM (245) International Estimated Daily Intake (IEDI) ADI = 0 - 0.08 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day			Intake = daily intake: µg/person						
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
	(including concentrates)												
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.01	23.34	0.23	40.71	0.41	97.15	0.97	18.06	0.18	57.71	0.58
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.01	5.84	0.06	10.18	0.10	24.29	0.24	4.52	0.05	14.43	0.14
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.01	1.05	0.01	1.14	0.01	18.69	0.19	0.94	0.01	3.12	0.03
MO 0105	Edible offal (mammalian), raw	RAC	0.01	4.64	0.05	1.97	0.02	10.01	0.10	3.27	0.03	3.98	0.04
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.006	108.75	0.65	70.31	0.42	436.11	2.62	61.55	0.37	79.09	0.47
PM 0110	Poultry meat, raw (incl prepared) - 90% as muscle	RAC	0.01	3.53	0.04	10.83	0.11	51.36	0.51	4.53	0.05	50.00	0.50
PM 0110	Poultry meat, raw (incl prepared) - 10% as fat	RAC	0.01	0.39	0.00	1.20	0.01	5.71	0.06	0.50	0.01	5.56	0.06
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.01	NC	-	NC	-	0.32	0.00	NC	-	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.016	0.10	0.00	0.70	0.01	0.97	0.02	0.10	0.00	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0.01	3.84	0.04	4.41	0.04	27.25	0.27	1.13	0.01	7.39	0.07
-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (µg/person)=				33.9		44.3		106.5		35.5		41.2
	Bodyweight per region (kg bw) =				60		60		60		60		60
	ADI (µg/person)=				4800		4800		4800		4800		4800
	%ADI=				0.7%		0.9%		2.2%		0.7%		0.9%
	Rounded %ADI=				1%		1%		2%		1%		1%

Annex 3

TRIADIMENOL (168) International Estimated Daily Intake (IEDI) ADI = 0 - 0.03 mg/kg bw

.			STMR	Diets as g/person/day			Intake as µg/person/day								
Codex Code	Commodity description	Expr as	mg/kg	G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
FP 0226	Apple, raw (incl cider, excl juice)	RAC	0.06	13.49	0.81	26.63	1.60	15.05	0.90	16.28	0.98	6.47	0.39	47.88	2.87
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.04	0.32	0.01	3.07	0.12	0.10	0.00	5.00	0.20	0.29	0.01	5.57	0.22
FB 0021	Currants, red, black, white, raw	RAC	0.23	0.10	0.02	0.74	0.17	0.10	0.02	0.10	0.02	0.10	0.02	0.10	0.02
FB 0269	Grape, raw (incl juice, incl wine, excl must, excl dried)	RAC	0.025	13.78	0.34	26.70	0.67	2.85	0.07	18.92	0.47	8.84	0.22	59.99	1.50
DF 0269	Grape, dried (= currants, raisins and sultanas)	PP	0.155	0.51	0.08	0.51	0.08	0.10	0.02	1.27	0.20	0.12	0.02	2.07	0.32
JF 0269	Grape juice	PP	0.011	0.14	0.00	0.29	0.00	0.10	0.00	0.30	0.00	0.24	0.00	0.10	0.00
–	Grape wine (incl vermouths)	PP	0.01	0.67	0.01	12.53	0.13	2.01	0.02	1.21	0.01	3.53	0.04	4.01	0.04
FB 0275	Strawberry, raw	RAC	0.265	0.70	0.19	2.01	0.53	0.10	0.03	1.36	0.36	0.37	0.10	2.53	0.67
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.04	5.06	0.20	6.91	0.28	37.17	1.49	31.16	1.25	40.21	1.61	18.96	0.76
FI 0353	Pineapple, raw (incl canned pineapple, incl pineapple juice, incl dried pineapple)	RAC	0.11	0.61	0.07	1.56	0.17	7.89	0.87	9.36	1.03	8.76	0.96	1.30	0.14
011	FRUITING VEGETABLES, CUCURBITS	–	0.05	-	-	-	-	-	-	-	-	-	-	-	-
VO 0440	Egg plants, raw (= aubergines)	RAC	0.15	5.58	0.84	4.31	0.65	0.89	0.13	9.31	1.40	13.64	2.05	20.12	3.02
VO 0442	Okra, raw	RAC	0.15	1.97	0.30	NC	-	3.68	0.55	3.24	0.49	5.72	0.86	1.57	0.24
VO 0443	Pepino (Melon pear, Tree melon)	RAC	0.15	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VO 0444	Peppers, chilli, raw	RAC	0.15	3.99	0.60	7.30	1.10	2.93	0.44	5.62	0.84	NC	-	17.44	2.62
–	Peppers, chilli, dried	PP	2.1	0.42	0.88	0.53	1.11	0.84	1.76	0.50	1.05	0.95	2.00	0.37	0.78
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.15	4.49	0.67	6.44	0.97	7.21	1.08	5.68	0.85	9.52	1.43	8.92	1.34
VO 0448	Tomato, raw (incl canned, excl juice, excl paste)	RAC	0.15	42.04	6.31	76.13	11.42	10.69	1.60	84.59	12.69	24.92	3.74	203.27	30.49
–	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.78	2.34	1.83	1.33	1.04	1.57	1.22	4.24	3.31	0.34	0.27	2.83	2.21
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.09	0.29	0.03	0.29	0.03	0.10	0.01	0.38	0.03	0.10	0.01	0.14	0.01
VR 0596	Sugar beet, raw (incl sugar)	RAC	0.05	0.13	0.01	NC	-	0.10	0.01	0.66	0.03	0.47	0.02	88.94	4.45
VS 0620	Artichoke globe	RAC	0.14	0.69	0.10	0.10	0.01	0.10	0.01	0.32	0.04	0.26	0.04	1.21	0.17
020	CEREAL GRAINS	–	0.05	-	-	-	-	-	-	-	-	-	-	-	-
SB 0716	Coffee beans raw (incl roasted, incl instant coffee, incl substitutes)	RAC	0.05	1.36	0.07	3.59	0.18	1.44	0.07	5.18	0.26	2.02	0.10	1.70	0.09
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)	RAC	0.01	31.20	0.31	72.44	0.72	20.88	0.21	47.98	0.48	33.08	0.33	36.25	0.36
032	EDIBLE OFFAL (MAMMALIAN)	–	0	–	–	–	–	–	–	–	–	–	–	–	–
033	MILK AND MILK PRODUCTS	–	0	–	–	–	–	–	–	–	–	–	–	–	–
036	POULTRY MEAT	–	0	–	–	–	–	–	–	–	–	–	–	–	–

Annex 3

TRIADIMENOL (168) International Estimated Daily Intake (IEDI) ADI = 0 - 0.03 mg/kg bw

.			STMR	Diets as g/person/day			Intake as µg/person/day								
Codex Code	Commodity description	Expr as	mg/kg	G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
038	POULTRY, EDIBLE OFFAL OF	–	0	–	–	–	–	–	–	–	–	–	–	–	–
039	EGGS	–	0.01	–	–	–	–	–	–	–	–	–	–	–	–
–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
	Total intake (µg/person) =				13,7		21,0		10,5		26,0		14,2		52,3
	Bodyweight per region (kg bw) =				60		60		60		60		60		60
	ADI (µg/person) =				1800		1800		1800		1800		1800		1800
	%ADI =				0,8%		1,2%		0,6%		1,4%		0,8%		2,9%
	Rounded %ADI =				1%		1%		1%		1%		1%		3%

TRIADIMENOL (168) International Estimated Daily Intake (IEDI) ADI = 0 - 0.03 mg/kg bw

			STMR	Diets as g/person/day			Intake as µg/person/day								
Codex Code	Commodity description	Expr as	mg/kg	G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
FP 0226	Apple, raw (incl cider, excl juice)	RAC	0.06	41.14	2.47	56.49	3.39	26.64	1.60	31.58	1.89	51.94	3.12	3.05	0.18
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.04	14.88	0.60	11.98	0.48	0.15	0.01	9.98	0.40	30.32	1.21	3.47	0.14
FB 0021	Currants, red, black, white, raw	RAC	0.23	0.48	0.11	4.23	0.97	NC	-	1.51	0.35	0.49	0.11	NC	-
FB 0269	Grape, raw (incl juice, incl wine, excl must, excl dried)	RAC	0.025	129.18	3.23	99.38	2.48	7.75	0.19	46.58	1.16	91.37	2.28	9.23	0.23
DF 0269	Grape, dried (= currants, raisins and sultanas)	PP	0.155	3.09	0.48	1.51	0.23	0.10	0.02	1.38	0.21	4.26	0.66	0.42	0.07
JF 0269	Grape juice	PP	0.011	0.56	0.01	1.96	0.02	0.10	0.00	2.24	0.02	2.27	0.02	0.34	0.00
–	Grape wine (incl vermouths)	PP	0.01	88.93	0.89	62.41	0.62	1.84	0.02	25.07	0.25	61.17	0.61	5.84	0.06
FB 0275	Strawberry, raw	RAC	0.265	4.49	1.19	5.66	1.50	0.10	0.03	6.63	1.76	5.75	1.52	0.10	0.03
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.04	25.14	1.01	23.37	0.93	23.06	0.92	23.40	0.94	18.44	0.74	39.29	1.57
FI 0353	Pineapple, raw (incl canned pineapple, incl pineapple juice, incl dried pineapple)	RAC	0.11	13.13	1.44	11.13	1.22	6.94	0.76	14.36	1.58	36.74	4.04	18.81	2.07
011	FRUITING VEGETABLES, CUCURBITS	–	0.05	-	-	-	-	-	-	-	-	-	-	-	-
VO 0440	Egg plants, raw (= aubergines)	RAC	0.15	1.01	0.15	1.69	0.25	21.37	3.21	3.00	0.45	1.40	0.21	NC	-
VO 0442	Okra, raw	RAC	0.15	NC	-	NC	-	0.10	0.02	0.17	0.03	NC	-	0.72	0.11
VO 0443	Pepino (Melon pear, Tree melon)	RAC	0.15	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VO 0444	Peppers, chilli, raw	RAC	0.15	5.57	0.84	14.00	2.10	8.25	1.24	5.77	0.87	6.44	0.97	2.53	0.38
–	Peppers, chilli, dried	PP	2.1	0.11	0.23	0.21	0.44	0.36	0.76	0.21	0.44	0.25	0.53	0.15	0.32
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.15	0.82	0.12	1.53	0.23	10.85	1.63	4.59	0.69	1.84	0.28	2.00	0.30
VO 0448	Tomato, raw (incl canned, excl juice, excl paste)	RAC	0.15	43.88	6.58	55.41	8.31	35.38	5.31	74.88	11.23	26.50	3.98	9.51	1.43

Annex 3

TRIADIMENOL (168) International Estimated Daily Intake (IEDI) ADI = 0 - 0.03 mg/kg bw

			STMR	Diets as g/person/day			Intake as µg/person/day								
Codex Code	Commodity description	Expr as	mg/kg	G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
–	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.78	4.96	3.87	3.20	2.50	0.15	0.12	1.61	1.26	6.88	5.37	0.52	0.41
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.09	0.80	0.07	0.10	0.01	0.10	0.01	0.61	0.05	0.40	0.04	0.10	0.01
VR 0596	Sugar beet, raw (incl sugar)	RAC	0.05	0.10	0.01	NC	-	0.10	0.01	0.10	0.01	NC	-	NC	-
VS 0620	Artichoke globe	RAC	0.14	0.98	0.14	3.65	0.51	0.10	0.01	1.67	0.23	0.26	0.04	NC	-
020	CEREAL GRAINS	–	0.05	-	-	-	-	-	-	-	-	-	-	-	-
SB 0716	Coffee beans raw (incl roasted, incl instant coffee, incl substitutes)	RAC	0.05	10.90	0.55	12.44	0.62	0.77	0.04	9.48	0.47	22.07	1.10	8.15	0.41
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)	RAC	0.01	140.03	1.40	150.89	1.51	79.32	0.79	111.24	1.11	120.30	1.20	51.27	0.51
032	EDIBLE OFFAL (MAMMALIAN)	–	0	–	–	–	–	–	–	–	–	–	–	–	–
033	MILK AND MILK PRODUCTS	–	0	–	–	–	–	–	–	–	–	–	–	–	–
036	POULTRY MEAT	–	0	–	–	–	–	–	–	–	–	–	–	–	–
038	POULTRY, EDIBLE OFFAL OF	–	0	–	–	–	–	–	–	–	–	–	–	–	–
039	EGGS	–	0,01	–	–	–	–	–	–	–	–	–	–	–	–
	Total intake (µg/person) =				25,4		28,3		16,7		25,4		28,0		8,2
	Bodyweight per region (kg bw) =				60		60		55		60		60		60
	ADI (µg/person) =				1800		1800		1650		1800		1800		1800
	%ADI =				1,4%		1,6%		1,0%		1,4%		1,6%		0,5%
	Rounded %ADI =				1%		2%		1%		1%		2%		0%

TRIADIMENOL (168) International Estimated Daily Intake (IEDI) ADI = 0–0.03 mg/kg bw

			STMR	Diets: g/person/day			Intake = daily intake: µg/person						
Codex Code	Commodity description	Expr as	mg/kg	G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
FP 0226	Apple, raw (incl cider, excl juice)	RAC	0.06	66.67	4.00	2.06	0.12	55.83	3.35	188.29	11.30	1.38	0.08
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.04	0.10	0.00	0.10	0.00	7.19	0.29	0.10	0.00	NC	-
FB 0021	Currants, red, black, white, raw	RAC	0.23	0.10	0.02	NC	-	0.74	0.17	NC	-	NC	-
FB 0269	Grape, raw (incl juice, incl wine, excl must, excl dried)	RAC	0.025	0.58	0.01	0.70	0.02	98.74	2.47	0.73	0.02	43.92	1.10
DF 0269	Grape, dried (= currants, raisins and sultanas)	PP	0.155	0.10	0.02	0.13	0.02	1.06	0.16	0.10	0.02	0.10	0.02
JF 0269	Grape juice	PP	0.011	0.10	0.00	0.10	0.00	0.41	0.00	0.10	0.00	NC	-

Annex 3

TRIADIMENOL (168) International Estimated Daily Intake (IEDI) ADI = 0–0.03 mg/kg bw

			STMR	Diets: g/person/day			Intake = daily intake: µg/person						
Codex Code	Commodity description	Expr as	mg/kg	G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
–	Grape wine (incl vermouths)	PP	0.01	0.31	0.00	0.23	0.00	60.43	0.60	0.52	0.01	31.91	0.32
FB 0275	Strawberry, raw	RAC	0.265	0.10	0.03	0.10	0.03	3.35	0.89	0.10	0.03	0.10	0.03
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.04	20.88	0.84	81.15	3.25	24.58	0.98	37.92	1.52	310.23	12.41
FI 0353	Pineapple, raw (incl canned pineapple, incl pineapple juice, incl dried pineapple)	RAC	0.11	8.51	0.94	6.27	0.69	6.89	0.76	0.18	0.02	24.94	2.74
011	FRUITING VEGETABLES, CUCURBITS	–	0.05	-	-	-	-	-	-	-	-	-	-
VO 0440	Egg plants, raw (= aubergines)	RAC	0.15	1.31	0.20	8.26	1.24	3.95	0.59	0.10	0.02	NC	-
VO 0442	Okra, raw	RAC	0.15	6.23	0.93	0.10	0.02	NC	-	NC	-	NC	-
VO 0443	Pepino (Melon pear, Tree melon)	RAC	0.15	NC	-	NC	-	NC	-	NC	-	NC	-
VO 0444	Peppers, chilli, raw	RAC	0.15	3.47	0.52	3.56	0.53	16.30	2.45	0.10	0.02	NC	-
–	Peppers, chilli, dried	PP	2.1	0.58	1.22	1.27	2.67	1.21	2.54	0.12	0.25	NC	-
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.15	5.49	0.82	10.57	1.59	8.84	1.33	0.91	0.14	NC	-
VO 0448	Tomato, raw (incl canned, excl juice, excl paste)	RAC	0.15	13.10	1.97	4.90	0.74	62.16	9.32	1.04	0.16	0.10	0.02
–	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.78	0.58	0.45	0.22	0.17	2.21	1.72	0.24	0.19	3.10	2.42
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.09	0.10	0.01	0.10	0.01	0.42	0.04	0.10	0.01	0.10	0.01
VR 0596	Sugar beet, raw (incl sugar)	RAC	0.05	3.93	0.20	1.68	0.08	NC	-	NC	-	36.12	1.81
VS 0620	Artichoke globe	RAC	0.14	0.10	0.01	NC	-	0.10	0.01	0.10	0.01	NC	-
020	CEREAL GRAINS	–	0.05	-	-	-	-	-	-	-	-	-	-
SB 0716	Coffee beans raw (incl roasted, incl instant coffee, incl substitutes)	RAC	0.05	0.95	0.05	1.32	0.07	11.64	0.58	2.96	0.15	14.73	0.74
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)	RAC	0.01	29.18	0.29	50.89	0.51	121.44	1.21	22.58	0.23	72.14	0.72
032	EDIBLE OFFAL (MAMMALIAN)	–	0	–	–	–	–	–	–	–	–	–	–
033	MILK AND MILK PRODUCTS	–	0	–	–	–	–	–	–	–	–	–	–
036	POULTRY MEAT	–	0	–	–	–	–	–	–	–	–	–	–
038	POULTRY, EDIBLE OFFAL OF	–	0	–	–	–	–	–	–	–	–	–	–
039	EGGS	–	0,01	–	–	–	–	–	–	–	–	–	–
	Total intake (µg/person) =				12,5		11,7		29,5		14,1		22,4
	Bodyweight per region (kg bw) =				60		60		60		60		60
	ADI (µg/person) =				1800		1800		1800		1800		1800

Annex 3

TRIADIMENOL (168) International Estimated Daily Intake (IEDI) ADI = 0–0.03 mg/kg bw

			STMR	Diets: g/person/day			Intake = daily intake: µg/person						
Codex Code	Commodity description	Expr as	mg/kg	G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
	%ADI =				0,7%		0,7%		1,6%		0,8%		1,2%
	Rounded %ADI =				1%		1%		2%		1%		1%

Annex 3

TRIFORINE (116) International Estimated Daily Intake (IEDI) ADI = 0–0.0300 mg/kg bw

			STMR	Diets as g/person/day			Intake as µg/person/day								
Codex Code	Commodity description	Expr as	mg/kg	G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
FB 0020	Blueberries, raw	RAC	0.01	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00	0.10	0.00
VO 0440	Egg plants, raw (= aubergines)	RAC	0.29	5.58	1.62	4.31	1.25	0.89	0.26	9.31	2.70	13.64	3.96	20.12	5.83
VO 0448	Tomato, raw (incl canned, excl juice, excl paste)	RAC	0.15	42.04	6.31	76.13	11.42	10.69	1.60	84.59	12.69	24.92	3.74	203.27	30.49
–	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.35	2.34	0.82	1.33	0.47	1.57	0.55	4.24	1.48	0.34	0.12	2.83	0.99
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.11	0.29	0.03	0.29	0.03	0.10	0.01	0.38	0.04	0.10	0.01	0.14	0.02
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (µg/person)=				8.8		13.2		2.4		16.9		7.8		37.3
	Bodyweight per region (kg bw) =				60		60		60		60		60		60
	ADI (µg/person)=				1800		1800		1800		1800		1800		1800
	%ADI=				0.5%		0.7%		0.1%		0.9%		0.4%		2.1%
	Rounded %ADI=				0%		1%		0%		1%		0%		2%

TRIFORINE (116) International Estimated Daily Intake (IEDI) ADI = 0–0.0300 mg/kg bw

			STMR	Diets as g/person/day			Intake as µg/person/day								
Codex Code	Commodity description	Expr as	mg/kg	G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
FB 0020	Blueberries, raw	RAC	0.01	0.10	0.00	0.23	0.00	0.10	0.00	0.83	0.01	0.33	0.00	NC	–
VO 0440	Egg plants, raw (= aubergines)	RAC	0.29	1.01	0.29	1.69	0.49	21.37	6.20	3.00	0.87	1.40	0.41	NC	–
VO 0448	Tomato, raw (incl canned, excl juice, excl paste)	RAC	0.15	43.88	6.58	55.41	8.31	35.38	5.31	74.88	11.23	26.50	3.98	9.51	1.43
–	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.35	4.96	1.74	3.20	1.12	0.15	0.05	1.61	0.56	6.88	2.41	0.52	0.18
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.11	0.80	0.09	0.10	0.01	0.10	0.01	0.61	0.07	0.40	0.04	0.10	0.01
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (µg/person)=				8.7		9.9		11.6		12.7		6.8		1.6
	Bodyweight per region (kg bw) =				60		60		55		60		60		60
	ADI (µg/person)=				1800		1800		1650		1800		1800		1800
	%ADI=				0.5%		0.6%		0.7%		0.7%		0.4%		0.1%
	Rounded %ADI=				0%		1%		1%		1%		0%		0%

Annex 3

TRIFORINE (116) International Estimated Daily Intake (IEDI) ADI = 0–0.0300 mg/kg bw

			STMR	Diets: g/person/day			Intake = daily intake: µg/person						
Codex Code	Commodity description	Expr as	mg/kg	G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
FB 0020	Blueberries, raw	RAC	0.01	NC	–	NC	–	0.20	0.00	NC	–	NC	–
VO 0440	Egg plants, raw (= aubergines)	RAC	0.29	1.31	0.38	8.26	2.40	3.95	1.15	0.10	0.03	NC	–
VO 0448	Tomato, raw (incl canned, excl juice, excl paste)	RAC	0.15	13.10	1.97	4.90	0.74	62.16	9.32	1.04	0.16	0.10	0.02
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.35	0.58	0.20	0.22	0.08	2.21	0.77	0.24	0.08	3.10	1.09
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.11	0.10	0.01	0.10	0.01	0.42	0.05	0.10	0.01	0.10	0.01
-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (µg/person)=				2.6		3.2		11.3		0.3		1.1
	Bodyweight per region (kg bw) =				60		60		60		60		60
	ADI (µg/person)=				1800		1800		1800		1800		1800
	%ADI=				0.1%		0.2%		0.6%		0.0%		0.1%
	Rounded %ADI=				0%		0%		1%		0%		0%

ANNEX 4: INTERNATIONAL ESTIMATES OF SHORT-TERM DIETARY INTAKES OF PESTICIDE RESIDUES

BENZOVINDIFLUPYR (261)
Acute RfD= 0.1 mg/kg bw (100 µg/kg bw)

IESTI
Maximum %ARfD:

															0% gen pop	0% child
Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded	% acute RfD rounded
VD 0541	Soya bean (dry) (Glycine spp) (all commodities)	highest utilisation: soya bean milk	0.004 - 0.01	0	1.000	AU	Child, 2-6 yrs	102	1131.23	NR	NR	3	0 - 0.24	0% - 0%	0% - 0%
MM 0095	Meat from mammals other than marine mammals	Total	NA	NA	1.000	CN	Child, 1-6 yrs	302	264.84	NR	NR	1	NA	0.0%	0.0%
MM 0095	Meat from mammals other than marine mammals: 20% as fat	Total		0	1.000	CN	Child, 1-6 yrs	302	52.97	NR	NR	1	0.0000	0.0%	0.0%
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	Total		0	1.000	CN	Child, 1-6 yrs	302	211.87	NR	NR	1	0.0000	0.0%	0.0%
MF 0100	Mammalian fats (except milk fats)	Total		0	1.000	FR	Child, 3-6 yrs	0	64.80	NR	NR	1	0.0000	0.0%	0.0%
MO 0105	Edible offal (mammalian)	Total		0	1.000	US	Child, 1-6 yrs	-	186.60	NR	NR	1	0.0000	0.0%	0.0%
ML 0106	Milks	Total	0		1.000	NL	toddler, 8-20 m	1882	1060.67	NR	NR	3	0.0000	0.0%	0.0%
FM 0812	Cattle milk fat	Total	0		1.000	BR	Gen pop, > 10 yrs	441	150.00	NR	NR	3	0.0000	0.0%	0.0%
PM 0110	Poultry meat	Total	NA	NA	1.000	CN	Child, 1-6 yrs	175	347.00	NR	NR	1	NA	0.0%	0.0%
PM 0110	Poultry meat: 10% as fat	Total		0	1.000	CN	Child, 1-6 yrs	175	34.70	NR	NR	1	0.0000	0.0%	0.0%
PM 0110	Poultry meat: 90% as muscle	Total		0	1.000	CN	Child, 1-6 yrs	175	312.30	NR	NR	1	0.0000	0.0%	0.0%
PO 0111	Poultry, edible offal (includes kidney, liver and skin)	Total		0	1.000	CN	Gen pop, > 1 yrs	421	345.63	NR	NR	1	0.0000	0.0%	0.0%
PE 0112	Eggs	Total		0	1.000	CN	Child, 1-6 yrs	136	195.82	NR	NR	1	0.0000	0.0%	0.0%

Annex 4

BUPROFEZIN (173)
Acute RfD= 0.5 mg/kg bw (500 µg/kg bw)

IESTI
Maximum %ARfD:

															0% all	0% gen pop	0% child
Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
SM 0716	Coffee beans (all commodities)	highest utilisation: extract (beverage)	0.0256	0	0.040	NL	Gen pop, > 1 yrs	8366	1568.74	NR	NR	3	0.02 - 0.02	0% - 0%	0% - 0%	0% - 0%

Annex 4

CLOTHIANIDIN (238)
Acute RfD= 0.6 mg/kg bw (600 µg/kg bw)

IESTI
Maximum %ARfD:

														0% all	0% gen pop	0% child
Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion. g/person	Unit weight, edible portion, g	Varia-bility factor	Case	IESTI µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
FI 0326	Avocado (all commodities)	highest utilisation: Total	0	0.02	1.000	AU	Child, 2-6 yrs	182	229.90	171.4	3	2a	0.31 - 0.6	0% - 0%	0% - 0%	0% - 0%
FI 0345	Mango (all commodities)	highest utilisation: raw without peel	0.02 - 0.13	0.02	1.000	NL	Toddler, 8-20 m	11	160.43	288.8	3	2b	0.01 - 0.94	0% - 0%	0% - 0%	0% - 0%
VP 0061	Beans, green, with pods, raw: beans except broad bean & soya bean (i.e. immature seeds + pods) (Phaseolus spp) (all commodities)	highest utilisation: canned/preserved	0.07	0.1	1.000	NL	Toddler, 8-20 m	E	127.90	2.3	NR	1	0.11 - 1.25	0% - 0%	0% - 0%	0% - 0%
HH 0738	Mints (all commodities)	highest utilisation: raw	0.11	0.12	1.000	DE	Child, 2-4 yrs	138	11.10	<25	NR	1	0.01 - 0.08	0% - 0%	0% - 0%	0% - 0%
DH 1100	Hops, dry (all commodities)	highest utilisation: Total	0.026	0	1.000	DE	Gen pop, 14-80 yrs	5866	8.50	<25	NR	3	0 - 0	0% - 0%	0% - 0%	0% - 0%
MO 1281	Cattle, liver	Total		0.14	1.000	US	Child, 1-6 yrs	-	136.05	NR	NR	1	1.2698	0.0%	0.0%	0.0%
ML 0106	Milks	Total	0.006		1.000	NL	Toddler, 8-20 m	1882	1060.67	NR	NR	3	0.6239	0.0%	0.0%	0.0%

Annex 4

DICHLOBENIL (2,6-DICHLOROBENZAMIDE) (274)
Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

IESTI
Maximum %ARfD: 2% women

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Coun try	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Varia-bility factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
FB 0264	Blackberries (all commodities)	highest utilisation: raw with skin	0.034	0.13	1.000	DE	Gen pop, 14-80 yrs	35	460.00	2.4	NR	1	0 - 0.78	0% - 0%
FB 0266	Dewberries, incl boysen- & loganberry	Total		0.13	1.000	-	-	-	-	-	-	-	-	-
FB 0272	Raspberries, red, black (all commodities)	highest utilisation: Total	0.034	0.13	1.000	FR	gen pop, > 3 yrs	-	250.96	4.3	NR	1	0.01 - 0.63	0% - 0%
FB 0269	Grape (all commodities)	highest utilisation: Total	0.01 - 0.014	0.04 - 0.11	1.000	FR	gen pop, > 3 yrs	-	1911.18	117.5	3	2a	0.03 - 0.88	0% - 0%
VA 0385	Onion, bulb (all commodities)	highest utilisation: raw without skin	0.01	0.01	1.000	JP	Gen pop, > 1 yrs	16490	153.00	244.4	3	2b	0 - 0.08	0% - 0%
VA 0387	Onion, Welsh (Japanese bunching onion, multiplying onion) (all commodities)	highest utilisation: raw	0	0.01	1.000	JP	Gen pop, > 1 yrs	12104	76.50	97.0	3	2b	0.03 - 0.04	0% - 0%
VB 0041	Cabbage, head (all commodities)	highest utilisation: raw	0.01	0.04	1.000	CN	gen pop, > 1 yrs	6303	400.92	1402.5	3	2b	0.02 - 0.9	0% - 0%
VB 0400	Broccoli (all commodities)	highest utilisation: raw	0.01	0.04	1.000	NL	gen pop, > 1 yrs	13	424.54	304.0	3	2a	0.01 - 0.63	0% - 0%
VB 0401	Broccoli, Chinese (Kailan) (all commodities)	highest utilisation: raw	0	0.04	1.000	CN	gen pop, > 1 yrs	6965	385.09	311.0	3	2a	0.54 - 0.76	0% - 0%
VB 0402	Brussels sprouts (all commodities)	highest utilisation: frozen	0.01	0.04	1.000	NL	gen pop, > 1 yrs	5	394.80	8.0	NR	1	0 - 0.24	0% - 0%
VB 0404	Cauliflower (all commodities)	highest utilisation: cooked/boiled	0.01	0.04	1.000	NL	gen pop, > 1 yrs	644	548.31	749.0	3	2b	0 - 1	0% - 0%
VB 0405	Kohlrabi (all commodities)	highest utilisation: cooked/boiled	0	0.04	1.000	NL	gen pop, > 1 yrs	E	200.03	210.0	3	2b	0.12 - 0.36	0% - 0%
VC 0046	Melons, except watermelon (all commodities)	highest utilisation: Total	0.01	0.01	1.000	FR	gen pop, > 3 yrs	-	626.40	420.0	3	2a	0 - 0.28	0% - 0%
VC 0421	Balsam pear (Bitter cucumber, Bitter gourd, Bitter melon) (all commodities)	highest utilisation: raw without peel	0	0.01	1.000	CN	gen pop, > 1 yrs	1387	400.21	607.5	3	2b	0.07 - 0.23	0% - 0%
VC 0422	Bottle gourd (Cucuzzi) (all commodities)	highest utilisation: raw with skin	0	0.01	1.000	CN	gen pop, > 1 yrs	519	453.00	325.0	3	2a	0.21 - 0.21	0% - 0%
VC 0423	Chayote (Christophine)	highest utilisation:	0	0.01	1.000	CN	gen pop, > 1	1437	574.81	197.4	3	2a	0.07 - 0.18	0% - 0%

Annex 4

DICHLOBENIL (2,6-DICHLOROBENZAMIDE) (274) IESTI
Acute RfD= 0.3 mg/kg bw (300 µg/kg bw) Maximum %ARfD: 2% women

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Coun try	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Varia-bility factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
	(all commodities)	raw with skin					yrs							
VC 0424	Cucumber (all commodities)	highest utilisation: Total	0.01	0.01	1.000	FR	gen pop, > 3 yrs	-	313.20	360.0	3	2b	0 - 0.18	0% - 0%
VC 0425	Gherkin (all commodities)	highest utilisation: pickled&preserved	0.01	0.01	1.000	BR	Gen pop, > 10 yrs	70	500.00	54.5	3	2a	0 - 0.09	0% - 0%
VC 0427	Loofah, Angled (Sinkwa, Sinkwa towel gourd) (all commodities)	highest utilisation: raw without peel	0	0.01	1.000	TH	gen pop, > 3 yrs	8306	215.23	133.0	3	2a	0.09 - 0.09	0% - 0%
VC 0428	Loofah, Smooth (all commodities)	highest utilisation: raw without peel	0	0.01	1.000	CN	gen pop, > 1 yrs	3930	521.84	133.0	3	2a	0.15 - 0.15	0% - 0%
VC 0429	Pumpkins (all commodities)	highest utilisation: raw without peel	0.01	0.01	1.000	CN	Gen pop, > 1 yrs	10137	701.51	1851.8	3	2b	0.01 - 0.4	0% - 0%
VC 0430	Snake gourd (all commodities)	highest utilisation: raw without peel	0	0.01	1.000	TH	gen pop, > 3 yrs	8306	215.23	133.0	3	2a	0.09 - 0.09	0% - 0%
VC 0431	Squash, summer (courgette, marrow, zucchetti, zucchini) (all commodities)	highest utilisation: cooked/boiled with skin (incl consump tion without skin)	0.01	0.01	1.000	NL	gen pop, > 1 yrs	100	348.81	289.0	3	2a	0 - 0.14	0% - 0%
VC 0432	Watermelon (all commodities)	highest utilisation: Total	0.01	0.01	1.000	AU	gen pop, > 2 yrs	267	2542.18	2095.6	3	2a	0.18 - 1	0% - 0%
VO 0440	Egg plant (aubergine) (all commodities)	highest utilisation: raw with skin	0.01	0.01	1.000	CN	gen pop, > 1 yrs	19286	483.89	443.9	3	2a	0 - 0.26	0% - 0%
VO 0442	Okra (Lady's finger) (all commodities)	highest utilisation: cooked/boiled (with skin)	0	0.01	1.000	BR	Gen pop, > 10 yrs	505	320.00	16.5	NR	1	0.04 - 0.05	0% - 0%
VO 0443	Pepino (Melon pear, Tree melon)	Total		0.01	1.000	AU	gen pop, > 2 yrs	3	73.89	122.9	3	2b	0.0331	0.0%
VO 0444	Peppers, chili (all commodities)	highest utilisation: raw with skin	0.01	0.01	1.000	CN	gen pop, > 1 yrs	1743	295.71	43.2	3	2a	0 - 0.07	0% - 0%
VO 0445	Peppers, sweet (incl. pim(i)ento) (bell pepper, paprika) (all commodities)	highest utilisation: raw with skin	0.01	0.01	1.000	DE	Women, 14-50 yrs	518	191.73	119.3	3	2a	0 - 0.06	0% - 0%
VO 0448	Tomato (all commodities)	highest utilisation: dried	0.01	0.01	5.000	AU	Gen pop, > 2 yrs	61	861.10	8.0	NR	1	0.03 - 0.64	0% - 0%
-	Gilo (scarlet egg plant) (all commodities)	highest utilisation: cooked/boiled (with skin)	0	0.01	1.000	BR	Gen pop, > 10 yrs	280	360.50	28.5	3	2a	0 - 0.06	0% - 0%
VL 0269	Grape leaves (all commodities)	highest utilisation: canned/preserved	0	0.19	1.000	NL	gen pop, > 1 yrs	1	54.81	1.4	NR	1	0.15 - 0.16	0% - 0%

Annex 4

DICHLOBENIL (2,6-DICHLOROBENZAMIDE) (274) IESTI
Acute RfD= 0.3 mg/kg bw (300 µg/kg bw) Maximum %ARfD: 2% women

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Coun try	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Varia-bility factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
VL 0460	Amaranth (Bledo) (all commodities)	highest utilisation: raw	0	0.19	1.000	CN	gen pop, > 1 yrs	714	581.72	85.8	3	2a	1.57 - 2.69	1% - 1%
VL 0464	Chard (silver beet) (all commodities)	highest utilisation: cooked/boiled	0	0.19	1.000	NL	gen pop, > 1 yrs	7	193.52	105.0	3	2a	0.67 - 1.17	0% - 0%
VL 0465	Chervil (all commodities)	highest utilisation: raw	0.07	0.19	1.000	DE	Women, 14-50 yrs	1685	9.40	<25	NR	1	0 - 0.03	0% - 0%
VL 0466	Chinese cabbage, type pak-choi (all commodities)	highest utilisation: raw	0.07	0.19	1.000	CN	gen pop, > 1 yrs	38811	601.64	1548.4	3	2b	0.02 - 6.44	0% - 2%
VL 0467	Chinese cabbage, type pe-tsai (all commodities)	highest utilisation: Total	0.07	0.19	1.000	CN	gen pop, > 1 yrs	49993	668.38	1500.0	3	2b	0.02 - 7.16	0% - 2%
VL 0469	Chicory leaves (sugar loaf) (all commodities)	highest utilisation: raw	0	0.19	1.000	DE	Women, 14-50 yrs	40	113.90	280.5	3	2b	0.31 - 0.96	0% - 0%
VL 0470	Corn salad (lambs lettuce) (all commodities)	highest utilisation: Total	0	0.19	1.000	FR	gen pop, > 3 yrs	-	83.52	7.8	NR	1	0.11 - 0.3	0% - 0%
VL 0472	Cress, garden (all commodities)	highest utilisation: Total	0	0.19	1.000	AU	gen pop, > 2 yrs	1	23.42	15.0	NR	1	0.01 - 0.07	0% - 0%
VL 0473	Watercress (all commodities)	highest utilisation: raw	0	0.19	1.000	BR	gen pop, > 10 yrs	97	90.92	254.6	3	2b	0.67 - 0.8	0% - 0%
VL 0474	Dandelion leaves (all commodities)	highest utilisation: raw	0	0.19	1.000	DE	Women, 14-50 yrs	1	10.00	35.0	3	2b	0.08 - 0.08	0% - 0%
VL 0476	Endive (all commodities)	highest utilisation: Total	0.07	0.19	1.000	FR	gen pop, > 3 yrs	-	280.40	413.2	3	2b	0.04 - 3.06	0% - 1%
VL 0478	Indian mustard (Amsoi) (all commodities)	highest utilisation: raw	0	0.19	1.000	NL	gen pop, > 1 yrs	E	49.88	250.0	3	2b	0.43 - 0.43	0% - 0%
VL 0479	Japanese greens: Chrysanthemum leaves (Chrysanthemum spp) (all commodities)	highest utilisation: raw	0	0.19	1.000	CN	gen pop, > 1 yrs	993	332.67	<25	NR	1	0.41 - 1.19	0% - 0%
VL 0480	Kale (borecole, collards) (all commodities)	highest utilisation: Total	0.07	0.19	1.000	DE	Women, 14-50 yrs	31	366.40	672.0	3	2b	0.13 - 3.1	0% - 1%
VL 0481	Komatsuna	Total		0.19	1.000	JP	Gen pop, > 1 yrs	2594	147.90	<25	NR	1	0.5137	0.0%
VL 0482	Lettuce, head (all commodities)	highest utilisation: cooked/boiled	0.07	0.19	1.000	NL	gen pop, > 1 yrs	2	220.89	227.0	3	2b	0.04 - 1.91	0% - 1%
VL 0483	Lettuce, leaf	highest utilisation:	0.07	0.19	1.000	CN	gen pop, > 1	6033	451.93	305.4	3	2a	0.04 - 3.79	0% - 1%

Annex 4

DICHLOBENIL (2,6-DICHLOROBENZAMIDE) (274) IESTI
Acute RfD= 0.3 mg/kg bw (300 µg/kg bw) Maximum %ARfD: 2% women

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Coun try	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Varia-bility factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
	(all commodities)	Total					yrs							
VL 0485	Mustard greens (all commodities)	highest utilisation: raw	0.07	0.19	1.000	CN	gen pop, > 1 yrs	9701	554.45	244.8	3	2a	0.3 - 3.73	0% - 1%
VL 0492	Purslane (all commodities)	highest utilisation: cooked/boiled	0	0.19	1.000	NL	gen pop, > 1 yrs	5	271.23	<25	NR	1	0.21 - 0.78	0% - 0%
VL 0494	Radish leaves	Total		0.19	1.000	-	-	-	-	-	-	-	-	-
VL 0495	Rape greens (all commodities)	highest utilisation: cooked/boiled	0	0.19	1.000	JP	Gen pop, > 1 yrs	533	147.90	34.0	3	2a	0.74 - 0.74	0% - 0%
VL 0496	Rucola (arrugula, rocket salad, roquette) (all commodities)	highest utilisation: Total	0	0.19	1.000	AU	gen pop, > 2 yrs	10	157.33	212.8	3	2b	0.22 - 1.34	0% - 0%
VL 0501	Sowthistle (all commodities)	highest utilisation: raw	0	0.19	1.000	CN	gen pop, > 1 yrs	1187	592.49	-	-	-	0 - 0	0% - 0%
VL 0502	Spinach (all commodities)	highest utilisation: Total	0.07	0.19	1.000	DE	Women, 14-50 yrs	309	189.72	197.8	3	2b	0 - 1.6	0% - 1%
VL 0505	Taro leaves (all commodities)	highest utilisation: raw	0	0.19	1.000	NL	gen pop, > 1 yrs	E	77.78	85.8	3	2b	0.67 - 0.67	0% - 0%
VL 0506	Turnip greens (Namenia, Tendergreen) (all commodities)	highest utilisation: Total	0	0.19	1.000	US	gen pop, all ages	-	247.07	35.0	3	2a	0.26 - 0.93	0% - 0%
VL 0507	Kangkung (water spinach) (all commodities)	highest utilisation: raw	0	0.19	1.000	CN	Gen pop, > 1 yrs	3256	554.45	85.8	3	2a	2.59 - 2.59	1% - 1%
VL 0510	Cos lettuce (all commodities)	highest utilisation: Total	0.07	0.19	1.000	AU	gen pop, > 2 yrs	54	242.90	457.2	3	2b	0.04 - 2.07	0% - 1%
-	Perilla leaves (i.e. sesame leaves) (all commodities)	highest utilisation: pickled/salted	0.07	0.19	1.000	CN	gen pop, > 1 yrs	183	175.21	NR	NR	3	0.23 - 0.23	0% - 0%
VD 0071	Beans (dry) (Phaseolus spp) (all commodities)	highest utilisation: cooked/boiled	0.01	0	0.400	CN	Gen pop, > 1 yrs	722	1313.18	0.5	NR	3	0 - 0.1	0% - 0%
VD 0072	Peas (dry) (Pisum spp, Vigna spp) (all commodities)	highest utilisation: cooked/boiled	0.01	0	0.400	CN	Gen pop, > 1 yrs	268	1673.82	<25	NR	3	0.01 - 0.13	0% - 0%
VD 0520	Bambara beans, dry, raw (Voandzeia subterranea)	Total	0.01		1.000	-	-	-	-	-	-	-	-	-
VD 0523	Broad bean (dry) (Vicia spp) (all commodities)	highest utilisation: cooked/boiled	0.01	0	0.400	CN	Gen pop, > 1 yrs	737	1190.24	<25	NR	3	0 - 0.09	0% - 0%

Annex 4

DICHLOBENIL (2,6-DICHLOROBENZAMIDE) (274) IESTI
Acute RfD= 0.3 mg/kg bw (300 µg/kg bw) Maximum %ARfD: 2% women

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Coun try	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Varia-bility factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
VD 0524	Chick-pea (dry) (Cicer spp) (all commodities)	highest utilisation: canned/preserved	0.01	0	0.400	NL	gen pop, > 1 yrs	43	435.93	<25	NR	3	0.02 - 0.03	0% - 0%
VD 0531	Hyacinth bean (dry) (Lablab spp) (all commodities)	highest utilisation: cooked/boiled	0.01	0	0.400	CN	Gen pop, > 1 yrs	1219	972.42	<25	NR	3	0.07 - 0.07	0% - 0%
VD 0533	Lentil (dry) (Lens spp) (all commodities)	highest utilisation: Total	0.01	0	1.000	DE	Women, 14-50 yrs	79	138.50	0.1	NR	3	0.01 - 0.02	0% - 0%
VD 0537	Pigeon pea (dry) (Cajanus spp)	Total	0.01		1.000	AU	gen pop, > 2 yrs	129	95.83	<25	NR	3	0.0143	0.0%
VD 0541	Soya bean (dry) (Glycine spp) (all commodities)	highest utilisation: flour	0.01	0	1.000	CN	gen pop, > 1 yrs	1227	353.50	NR	NR	3	0 - 0.07	0% - 0%
-	Mung bean sprouts (all commodities)	highest utilisation: raw	0.01	0	1.000	CN	gen pop, > 1 yrs	4516	404.46	<25	NR	3	0.01 - 0.08	0% - 0%
VS 0624	Celery (all commodities)	highest utilisation: cooked/boiled	0.01	0.04	1.000	NL	gen pop, > 1 yrs	59	444.28	607.0	3	2b	0 - 0.81	0% - 0%
GC 0640	Barley (all commodities)	highest utilisation: beer	0.01	0	0.190	BR	Gen pop, > 10 yrs	1636	3600.00	NR	NR	3	0 - 0.11	0% - 0%
GC 0641	Buckwheat (all commodities)	highest utilisation: cooked/boiled	0.01	0	0.400	CN	Gen pop, > 1 yrs	198	831.68	<25	NR	3	0 - 0.06	0% - 0%
GC 0644	Job's tears (all commodities)	highest utilisation: cooked/boiled	0.01	0	0.300	TH	-	1671	135.63	<25	NR	3	0.01 - 0.01	0% - 0%
GC 0645	Maize (corn) (all commodities)	highest utilisation: Flour (cereals)	0.01	0	1.000	CN	gen pop, > 1 yrs	5654	569.28	NR	NR	3	0 - 0.11	0% - 0%
GC 0656	Popcorn (i.e. maize destined for popcorn preparation) (all commodities)	highest utilisation: popcorn	0.01	0	1.000	NL	gen pop, > 1 yrs	51	204.70	<25	NR	3	0.02 - 0.03	0% - 0%
GC 0646	Millet (all commodities)	highest utilisation: Total	0.01	0	1.000	CN	gen pop, > 1 yrs	18192	407.03	<25	NR	3	0.01 - 0.08	0% - 0%
GC 0647	Oats (all commodities)	highest utilisation: bran (processed)	0.01	0	1.000	AU	gen pop, > 2 yrs	79	109.09	NR	NR	3	0 - 0.02	0% - 0%
GC 0648	Quinoa	Total	0.01		1.000	-	-	-	-	-	-	-	-	-
GC 0649	Rice (all commodities)	highest utilisation: Total	0.01	0	1.000	DE	Women, 14-50 yrs	1506	75.18	<25	NR	3	0 - 0.01	0% - 0%
GC 0650	Rice	Rice milk	0.01		0.040	-	-	-	-	-	-	-	-	-
GC 0649	Rice (all commodities)	highest utilisation: polished rice (cooked)	0.01	0	0.400	CN	Gen pop, > 1 yrs	147565	2047.26	<25	NR	3	0.01 - 0.15	0% - 0%

Annex 4

DICHLOBENIL (2,6-DICHLOROBENZAMIDE) (274) IESTI
Acute RfD= 0.3 mg/kg bw (300 µg/kg bw) Maximum %ARfD: 2% women

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Coun try	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Varia-bility factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
GC 0650	Rye (all commodities)	highest utilisation: wholemeal bread	0.01	0	1.000	FR	gen pop, > 3 yrs	-	178.41	NR	NR	3	0 - 0.03	0% - 0%
GC 0651	Sorghum (Chicken corn, Dari seed, Durra, Feterita) (all commodities)	highest utilisation: cooked/boiled	0.01	0	0.400	CN	Gen pop, > 1 yrs	356	1348.67	<25	NR	3	0 - 0.1	0% - 0%
GC 0653	Triticale	Total	0.01		1.000	DE	Women, 14-50 yrs	8906	342.50	<25	NR	3	0.0508	0.0%
GC 0654	Wheat (all commodities)	highest utilisation: flour (cereals)	0.01	0	1.000	CN	gen pop, > 1 yrs	64028	732.96	NR	NR	3	0 - 0.14	0% - 0%
GC 0655	Wild rice (all commodities)	highest utilisation: cooked/boiled	0.01	0	0.400	CN	Gen pop, > 1 yrs	2918	1023.60	<25	NR	3	0.01 - 0.08	0% - 0%
MM 0095	Meat from mammals other than marine mammals	Total	NA	NA	1.000	BR	Gen pop, > 10 yrs	2980	665.00	NR	NR	1	NA	0.0%
MM 0095	Meat from mammals other than marine mammals: 20% as fat	Total		0.01	1.000	BR	Gen pop, > 10 yrs	2980	133.00	NR	NR	1	0.0206	0.0%
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	Total		0.01	1.000	BR	Gen pop, > 10 yrs	2980	532.00	NR	NR	1	0.0824	0.0%
MF 0100	Mammalian fats (except milk fats)	Total		0.01	1.000	AU	gen pop, > 2 yrs	3047	92.59	NR	NR	1	0.0138	0.0%
MO 0105	Edible offal (mammalian)	Total		0.031	1.000	US	gen pop, all ages	-	787.80	NR	NR	1	0.3757	0.0%
ML 0106	Milks	Total	0.01		1.000	AU	gen pop, > 2 yrs	13566	3235.19	NR	NR	3	0.4829	0.0%
PM 0110	Poultry meat	Total	NA	NA	1.000	FR	gen pop, > 3 yrs	1	576.95	NR	NR	1	NA	0.0%
PM 0110	Poultry meat: 10% as fat	Total		0.012	1.000	FR	gen pop, > 3 yrs	1	57.69	NR	NR	1	0.0133	0.0%
PM 0110	Poultry meat: 90% as muscle	Total		0.018	1.000	FR	gen pop, > 3 yrs	1	519.25	NR	NR	1	0.1791	0.0%
PF 0111	Poultry, fats (all commodities)	highest utilisation: Total	0	0.012 - 0.081	1.000	CN	gen pop, > 1 yrs	421	345.63	NR	NR	1	0 - 0.53	0% - 0%
PE 0112	Eggs	Total		0.019	1.000	FR	gen pop, > 3 yrs	1	382.80	NR	NR	1	0.1393	0.0%

Annex 4

DIMETHOMORPH (225)
Acute RfD= 0,6 mg/kg bw (600 µg/kg bw)

IESTI
Maximum %ARfD:

															110% all	30% gen pop	110% child
Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
FB 0269	Grape (all commodities)	highest utilisation: raw with skin	0,19 - 0,65	1,9 - 3,35	1,000	CN	Child, 1-6 yrs	232	366,72	636,6	3	2b	3,59 - 129,55	1% - 20%	0% - 10%	0% - 20%
FB 0275	Strawberry (all commodities)	highest utilisation: Total	0,02	0,0014 - 0,24	1,000	FR	Child, 3-6 yrs	-	339,40	13,4	NR	1	0,01 - 4,31	0% - 1%	0% - 0%	0% - 1%
VA 0381	Garlic (all commodities)	highest utilisation: raw without skin	0,17	0,4	1,000	CN	Child, 1-6 yrs	290	174,44	59,8	3	2a	0,01 - 7,29	0% - 1%	0% - 1%	0% - 1%
VA 0384	Leek (all commodities)	highest utilisation: raw	0,17 - 0,8	0,4	1,000	CN	Child, 1-6 yrs	401	149,40	175,5	3	2b	0,08 - 11,11	0% - 2%	0% - 1%	0% - 2%
VA 0385	Onion, bulb (all commodities)	highest utilisation: Total	0,022 - 0,17	0,03 - 0,4	1,000	AU	Child, 2-6 yrs	1341	63,70	96,8	3	2b	0,01 - 4,02	0% - 1%	0% - 0%	0% - 1%
VA 0387	Onion, Welsh (Japanese bunching onion, multiplying onion) (all commodities)	highest utilisation: raw	0	6,6	1,000	JP	Child, 1-6 yrs	305	35,70	97,0	3	2b	28,1 - 41,58	5% - 7%	5% - 5%	7% - 7%
VA 0388	Shallot (i.e. dry harvested small onion) (all commodities)	highest utilisation: raw without skin	0,17	0,4	1,000	CN	Child, 1-6 yrs	480	115,81	51,4	3	2a	0,14 - 5,42	0% - 1%	0% - 0%	0% - 1%
VA 0389	Spring onion (all commodities)	highest utilisation: cooked/boiled	0	6,6	1,000	NL	Child, 2-6 yrs	E	20,30	30,0	3	2b	16,82 - 21,84	3% - 4%	1% - 2%	3% - 4%
VB 0041	Cabbage, head (all commodities)	highest utilisation: raw	1,1	4,6	1,000	CN	Child, 1-6 yrs	287	255,54	1402,5	3	2b	0,79 - 218,55	0% - 40%	0% - 20%	0% - 40%
VB 0400	Broccoli (all commodities)	highest utilisation: cooked/boiled	1,3	2,6	1,000	NL	toddler, 8-20 m	125	160,73	286,0	3	2b	2,36 - 122,91	0% - 20%	0% - 7%	0% - 20%
VO 0440	Egg plant (aubergine) (all commodities)	highest utilisation: raw with skin	0,13	1,2	1,000	CN	Child, 1-6 yrs	969	253,44	443,9	3	2b	0,15 - 56,54	0% - 9%	0% - 5%	0% - 9%
VO 0442	Okra (Lady's finger) (all commodities)	highest utilisation: cooked/boiled (with skin)	0	1,2	1,000	JP	Child, 1-6 yrs	58	84,30	8,5	NR	1	4,59 - 6,4	1% - 1%	1% - 1%	1% - 1%
VO 0443	Pepino (Melon pear, Tree melon)	Total		1,2	1,000	AU	Gen pop, > 2 yrs	3	73,89	122,9	3	2b	3,9703	1,0%	1,0%	-
VO 0445	Peppers, sweet (incl. pim(i)ento) (bell pepper, paprika)	frozen	0,18		1,000	NL	Child, 2-6 yrs	4	20,07	NR	NR	3	0,1964	0,0%	0,0%	0,0%
VO 0448	Tomato (all commodities)	highest utilisation: dried	0,09 - 1,56	1,2	5,000	AU	Gen pop, > 2 yrs	61	861,10	8,0	NR	1	0,69 - 77,11	0% - 10%	0% - 10%	0% - 8%

Annex 4

DIMETHOMORPH (225)
Acute RfD= 0,6 mg/kg bw (600 µg/kg bw)

IESTI
Maximum %ARfD:

														110% all	30% gen pop	110% child
Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
VL 0482	Lettuce, head (all commodities)	highest utilisation: raw	3,6	7,2	1,000	NL	Child, 2-6 yrs	91	140,10	338,9	3	2b	2,12 - 164,46	0% - 30%	0% - 10%	0% - 30%
VL 0483	Lettuce, leaf	Total		10,5	1,000	CN	Child, 1-6 yrs	243	387,25	305,4	3	2a	649,4169	110,0%	30,0%	110,0%
VL 0483	Lettuce, leaf (all other commodities)	highest utilisation: raw	5,2	10,5	1,000	NL	Child, 2-6 yrs	91	140,10	117,8	3	2a	3,06 - 214,35	1 - 40%	1 - 10%	0 - 40%
VL 0502	Spinach (all commodities)	highest utilisation: Total	8,3	11,5	1,000	ZA	Child, 1-5 yrs	-	237,48	197,8	3	2a	0,83 - 512,63	0% - 90%	0% - 30%	0% - 90%
VL 0505	Taro leaves (all commodities)	highest utilisation: raw	0	5,4	1,000	NL	Gen pop, > 1 yrs	E	77,78	85,8	3	2b	19,15 - 19,15	3% - 3%	3% - 3%	0% - 0%
VP 0064	Peas, green, without pods, raw (i.e. immature seeds only) (Pisum spp) (all commodities)	highest utilisation: Total	0,002 - 0,01	0,71	1,000	UK	Child, 1.5-4.5 yrs	57	174,00	<25	NR	1	0,01 - 8,52	0% - 1%	0% - 1%	0% - 1%
VS 0620	Artichoke globe (all commodities)	highest utilisation: Total	0	1,1	1,000	FR	Child, 3-6 yrs	-	117,23	98,9	3	2a	4,47 - 18,34	1% - 3%	1% - 1%	0% - 3%
VS 0624	Celery (all commodities)	highest utilisation: raw	2,9	8,8	1,000	CN	Child, 1-6 yrs	454	180,29	861,1	3	2b	0,17 - 294,97	0% - 50%	0% - 30%	0% - 50%

Annex 4

EMAMECTIN BENZOATE (247)
Acute RfD= 0.02 mg/kg bw (20 µg/kg bw)

IESTI
Maximum %ARfD:

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	30% gen pop % acute RfD rounded	100% child % acute RfD rounded
FP 0226	Apple (all commodities)	highest utilisation: Total	0.0028 - 0.004	0.011	1.000	US	Child, 1-6 yrs	-	624.45	127.0	3	2a	0.01 - 0.64	0% - 1%	0% - 3%
FP 0227	Crab-apple (all commodities)	highest utilisation: raw with peel	0	0.011	1.000	CN	Gen pop, > 1 yrs	204	488.33	-	-	-	0 - 0	0% - 0%	0% - 0%
FP 0228	Loquat (Japanese medlar) (all commodities)	highest utilisation: raw without peel	0	0.011	1.000	JP	Gen pop, > 1 yrs	113	326.40	49.0	3	2a	0.02 - 0.09	0% - 0%	0% - 0%
FP 0229	Medlar	Total		0.011	1.000	-	-	-	-	-	-	-	-	-	-
FP 0230	Pear (all commodities)	highest utilisation: raw with peel (incl consumption without peel)	0.004	0.011	1.000	CN	Child, 1-6 yrs	413	418.33	255.0	3	2a	0 - 0.63	0% - 1%	0% - 3%
FT 0307	Persimmon, Japanese (all commodities)	highest utilisation: raw with peel (incl consumption without peel)	0	0.011	1.000	TH	Child, 3-6 yrs	20	264.88	227.5	3	2a	0.16 - 0.46	1% - 1%	2% - 2%
FP 0231	Quince (all commodities)	highest utilisation: Total	0.004	0.011	1.000	DE	child, 2-4 yrs	16	26.30	301.2	3	2b	0 - 0.05	0% - 0%	0% - 0%
FS 0245	Nectarine (all commodities)	highest utilisation: raw with peel (incl consumption without peel)	0.0095	0.015	1.000	NL	toddler, 8-20 m	6	183.60	131.0	3	2a	0 - 0.66	0% - 1%	0% - 3%
FS 0247	Peach (all commodities)	highest utilisation: raw with peel (incl consumption without peel)	0.0095	0.015	1.000	JP	Child, 1-6 yrs	76	306.00	255.0	3	2a	0 - 0.79	0% - 1%	0% - 4%
FB 0269	Grape (all commodities)	highest utilisation: raw with skin	0.0025	0.022	1.000	CN	Child, 1-6 yrs	232	366.72	636.6	3	2b	0.01 - 1.5	0% - 4%	0% - 8%
VC 0046	Melons, except watermelon (all commodities)	highest utilisation: Total	0.001	0.002	1.000	FR	Child, 3-6 yrs	-	358.11	420.0	3	2b	0 - 0.11	0% - 0%	0% - 1%
VC 0421	Balsam pear (Bitter cucumber, Bitter gourd, Bitter melon) (all commodities)	highest utilisation: raw without peel	0	0.002	1.000	CN	Gen pop, > 1 yrs	1387	400.21	607.5	3	2b	0.01 - 0.05	0% - 0%	0% - 0%
VC 0422	Bottle gourd (Cucuzzi) (all commodities)	highest utilisation: raw with skin	0	0.002	1.000	CN	Gen pop, > 1 yrs	519	453.00	325.0	3	2a	0.04 - 0.04	0% - 0%	0% - 0%

Annex 4

EMAMECTIN BENZOATE (247)
Acute RfD= 0.02 mg/kg bw (20 µg/kg bw)

IESTI
Maximum %ARfD:

30% gen pop

100% child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded	% acute RfD rounded
VC 0423	Chayote (Christophine) (all commodities)	highest utilisation: raw with skin	0	0.002	1.000	CN	Child, 1-6 yrs	124	284.75	197.4	3	2a	0.02 - 0.08	0% - 0%	0% - 0%
VC 0424	Cucumber (all commodities)	highest utilisation: raw with skin	0.001	0.002	1.000	CN	Child, 1-6 yrs	340	212.11	458.1	3	2b	0 - 0.08	0% - 0%	0% - 0%
VC 0425	Gherkin (all commodities)	highest utilisation: raw with skin	0.001	0.002	1.000	JP	Child, 1-6 yrs	484	91.80	54.5	3	2a	0 - 0.02	0% - 0%	0% - 0%
VC 0427	Loofah, Angled (Sinkwa, Sinkwa towel gourd) (all commodities)	highest utilisation: raw without peel	0	0.002	1.000	TH	Child, 3-6 yrs	759	129.62	133.0	3	2b	0.05 - 0.05	0% - 0%	0% - 0%
VC 0428	Loofah, Smooth (all commodities)	highest utilisation: raw without peel	0	0.002	1.000	CN	Child, 1-6 yrs	196	296.64	133.0	3	2a	0.07 - 0.07	0% - 0%	0% - 0%
VC 0429	Pumpkins (all commodities)	highest utilisation: raw without peel	0.001	0.002	1.000	CN	Child, 1-6 yrs	561	322.71	1851.8	3	2b	0 - 0.12	0% - 0%	0% - 1%
VC 0430	Snake gourd (all commodities)	highest utilisation: raw without peel	0	0.002	1.000	TH	Child, 3-6 yrs	759	129.62	133.0	3	2b	0.05 - 0.05	0% - 0%	0% - 0%
VC 0431	Squash, summer (courgette, marrow, zucchetti, zucchini) (all commodities)	highest utilisation: Total	0.001	0.002	1.000	FR	Child, 3-6 yrs	-	148.84	270.0	3	2b	0 - 0.05	0% - 0%	0% - 0%
VC 0432	Watermelon (all commodities)	highest utilisation: Total	0.001	0.002	1.000	AU	Gen pop, > 2 yrs	267	2542.18	2095.6	3	2a	0.17 - 0.2	1% - 1%	1% - 1%
VO 0440	Egg plant (aubergine) (all commodities)	highest utilisation: raw with skin	0.003	0.013	1.000	CN	Child, 1-6 yrs	969	253.44	443.9	3	2b	0 - 0.61	0% - 2%	0% - 3%
VO 0442	Okra (Lady's finger) (all commodities)	highest utilisation: cooked/boiled (with skin)	0	0.013	1.000	JP	Child, 1-6 yrs	58	84.30	8.5	NR	1	0.05 - 0.07	0% - 0%	0% - 0%
VO 0443	Pepino (Melon pear, Tree melon)	Total		0.013	1.000	AU	Gen pop, > 2 yrs	3	73.89	122.9	3	2b	0.0430	0.0%	-
VO 0444	Peppers, chili (all commodities)	highest utilisation: raw with skin	0.003	0.013 - 0.13	1.000	CN	Gen pop, > 1 yrs	1743	295.71	43.2	3	2a	0 - 0.09	0% - 0%	0% - 0%
VO 0445	Peppers, sweet (incl. pim(i)ento) (bell pepper, paprika) (all commodities)	highest utilisation: raw with skin	0.003	0.013	1.000	CN	Child, 1-6 yrs	1002	169.85	170.0	3	2b	0 - 0.41	0% - 1%	0% - 2%
VO 0448	Tomato (all commodities)	highest utilisation: dried	0.003	0.013	5.000	AU	Gen pop, > 2 yrs	61	861.10	8.0	NR	1	0.02 - 0.84	0% - 4%	0% - 3%

Annex 4

EMAMECTIN BENZOATE (247)
Acute RfD= 0.02 mg/kg bw (20 µg/kg bw)

IESTI
Maximum %ARfD: 30% gen pop 100% child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded	% acute RfD rounded
VO 0449	Fungi, edible (mainly wild, not including mushrooms) (all commodities)	highest utilisation: Total	0.003	0.013	1.000	DE	Child, 2-4 yrs	206	61.30	30.0	3	2a	0.01 - 0.1	0% - 0%	0% - 0%
-	Gilo (scarlet egg plant) (all commodities)	highest utilisation: cooked/boiled (with skin)	0	0.013	1.000	BR	Gen pop, > 10 yrs	280	360.50	28.5	3	2a	0 - 0.08	0% - 0%	0% - 0%
VL 0482	Lettuce, head (all commodities)	highest utilisation: raw	0.2	0.62	1.000	NL	Child, 2-6 yrs	91	140.10	338.9	3	2b	0.12 - 14.16	1% - 30%	0% - 70%
VL 0483	Lettuce, leaf	Total		0.33	1.000	CN	Child, 1-6 yrs	243	387.25	305.4	3	2a	20.4102	30.0%	100.0%
VL 0483	Lettuce, leaf (all other commodities)	highest utilisation: raw	0.076	0.33	1.000	NL	Child, 2-6 yrs	91	140.10	117.8	3	2a	0.04 - 6.74	0 - 10%	0 - 30%
VL 0485	Mustard greens (all commodities)	highest utilisation: raw	0.01	0.11	1.000	CN	Child, 1-6 yrs	635	299.31	244.8	3	2a	0.04 - 5.38	0% - 10%	4% - 30%
VL 0510	Cos lettuce (all commodities)	highest utilisation: raw	0.076	0.33	1.000	NL	Child, 2-6 yrs	91	140.10	289.9	3	2b	0.04 - 7.54	0% - 20%	0% - 40%
VP 0061	Beans, green, with pods, raw: beans except broad bean & soya bean (i.e. immature seeds + pods) (Phaseolus spp) (all commodities)	highest utilisation: canned/preserved	0.001	0.009	1.000	NL	toddler, 8-20 m	E	127.90	2.3	NR	1	0 - 0.11	0% - 0%	0% - 1%
TN 0295	Cashew nut (all commodities)	highest utilisation: raw incl roasted	0.001	0.001	1.000	TH	child, 3-6 yrs	374	98.84	2.5	NR	1	0 - 0.01	0% - 0%	0% - 0%
TN 0660	Almonds (all commodities)	highest utilisation: raw incl roasted	0.001	0.001	1.000	DE	Women, 14-50 yrs	24	100.00	1.2	NR	1	0 - 0	0% - 0%	0% - 0%
TN 0662	Brazil nut (all commodities)	highest utilisation: Total	0	0.001	1.000	FR	Gen pop, > 3 yrs	-	57.57	4.0	NR	1	0 - 0	0% - 0%	0% - 0%
TN 0664	Chestnuts (all commodities)	highest utilisation: Total	0	0.001	1.000	FR	child, 3-6 yrs	-	170.41	17.4	NR	1	0 - 0.01	0% - 0%	0% - 0%
TN 0665	Coconut (all commodities)	highest utilisation: raw (i.e. nutmeat)	0.001	0.001	1.000	TH	child, 3-6 yrs	826	423.40	383.0	3	2a	0 - 0.07	0% - 0%	0% - 0%
TN 0666	Hazelnut (all commodities)	highest utilisation: Total	0.001	0.001	1.000	FR	Child, 3-6 yrs	-	27.24	1.2	NR	1	0 - 0	0% - 0%	0% - 0%
TN 0669	Macadamia nut (all commodities)	highest utilisation: Total	0.001	0.001	1.000	US	Gen pop, all ages	-	106.60	3.2	NR	1	0 - 0	0% - 0%	0% - 0%

Annex 4

EMAMECTIN BENZOATE (247)
Acute RfD= 0.02 mg/kg bw (20 µg/kg bw)

IESTI
Maximum %ARfD:

														30% gen pop	100% child
Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded	% acute RfD rounded
TN 0672	Pecan (all commodities)	highest utilisation: Total	0.001	0.001	1.000	AU	Child, 2-16 yrs	52	80.87	5.0	NR	1	0 - 0	0% - 0%	0% - 0%
TN 0673	Pine nut (all commodities)	highest utilisation: Total	0	0.001	1.000	BR	Gen pop, > 10 yrs	47	200.00	0.2	NR	1	0 - 0	0% - 0%	0% - 0%
TN 0675	Pistachio nut (all commodities)	highest utilisation: Total	0.001	0.001	1.000	FR	child, 3-6 yrs	-	44.89	0.9	NR	1	0 - 0	0% - 0%	0% - 0%
TN 0678	Walnut (all commodities)	highest utilisation: raw incl roasted	0.001	0.001	1.000	DE	Child, 2-4 yrs	75	49.40	7.0	NR	1	0 - 0	0% - 0%	0% - 0%
SO 0495	Rape seed (all commodities)	highest utilisation: sec processing / composite foods	0	0	1.000	NL	toddler, 8-20 m	1882	8.93	NR	NR	3	0 - 0	0% - 0%	0% - 0%
SO 0691	Cotton seed (all commodities)	highest utilisation: Oil (refined)	0.00076 - 0.002	0	1.000	US	gen pop, all ages	-	9.10	NR	NR	3	0 - 0	0% - 0%	0% - 0%
MM 0095	Meat from mammals other than marine mammals	Total	NA	NA	1.000	CN	Child, 1-6 yrs	302	264.84	NR	NR	1	NA	0.0%	0.0%
MM 0095	Meat from mammals other than marine mammals: 20% as fat	Total		0.004	1.000	CN	Child, 1-6 yrs	302	52.97	NR	NR	1	0.0131	0.0%	0.0%
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	Total		0.004	1.000	CN	Child, 1-6 yrs	302	211.87	NR	NR	1	0.0525	0.0%	0.0%
MF 0100	Mammalian fats (except milk fats)	Total		0.011	1.000	FR	Child, 3-6 yrs	0	64.80	NR	NR	1	0.0377	0.0%	0.0%
MO 0105	Edible offal (mammalian)	Total		0.072	1.000	US	Child, 1-6 yrs	-	186.60	NR	NR	1	0.8957	4.0%	4.0%
ML 0106	Milks	Total	0.002		1.000	NL	toddler, 8-20 m	1882	1060.67	NR	NR	3	0.2080	0.0%	1.0%

Annex 4

FENAMIDONE (264)
Acute RfD= 1 mg/kg bw (1000 µg/kg bw)

IESTI
Maximum %ARfD:

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	170% all % acute RfD rounded	70% gen pop % acute RfD rounded	170% child % acute RfD rounded
FB 0269	Grape (all commodities)	highest utilisation: raw with skin		0.42	1.000	CN	Child. 1–6 yrs	232	366.72	636.6	3	2b	1.33–28.64	0–3%	0–1%	0–3%
FB 0275	Strawberry (all commodities)	highest utilisation: Total		0.04	1.000	FR	Child. 3–6 yrs	–	339.40	13.4	NR	1	0.05–0.72	0–0%	0–0%	0–0%
VA 0384	Leek (all commodities)	highest utilisation: raw		0.63	1.000	CN	Child. 1–6 yrs	401	149.40	175.5	3	2b	7.58–17.5	1–2%	0–1%	1–2%
VA 0385	Onion, bulb (all commodities)	highest utilisation: raw without skin		0.63	1.000	JP	Child. 1–6 yrs	748	102.00	244.4	3	2b	4.76–11.75	0–1%	0–1%	0–1%
VA 0387	Onion, Welsh (Japanese bunching onion, multiplying onion) (all commodities)	highest utilisation: raw		1.7	1.000	JP	Child. 1–6 yrs	305	35.70	97.0	3	2b	7.24–10.71	1–1%	1–1%	1–1%
VA 0388	Shallot (i.e. dry harvested small onion) (all commodities)	highest utilisation: raw without skin		0.63	1.000	CN	Child. 1–6 yrs	480	115.81	51.4	3	2a	1.37–8.54	0–1%	0–0%	0–1%
VA 0389	Spring onion (all commodities)	highest utilisation: cooked/boiled		1.7	1.000	NL	Child. 2–6 yrs	E	20.30	30.0	3	2b	4.33–5.63	0–1%	0–0%	0–1%
VB 0041	Cabbage, head (all commodities)	highest utilisation: raw		1.69	1.000	CN	Child. 1–6 yrs	287	255.54	1402.5	3	2b	64.44–80.29	6–8%	3–4%	6–8%
VB 0400	Broccoli (all commodities)	highest utilisation: cooked/boiled		4.2	1.000	NL	toddler. 8–20 m	125	160.73	286.0	3	2b	65.91–198.55	7–20%	6–7%	6–20%
VB 0401	Broccoli, Chinese (Kailan) (all commodities)	highest utilisation: raw		1.5	1.000	CN	Child. 1–6 yrs	334	222.48	311.0	3	2b	20.34–62.05	2–6%	2–3%	6–6%
VB 0402	Brussels sprouts	raw		1.5	1.000	NL	Gen pop. > 1 yrs	0	NC	8.3	NR	1	NC	NC	NC	NC
VB 0404	Cauliflower (all commodities)	highest utilisation: cooked/boiled		4.2	1.000	NL	toddler. 8–20 m	110	141.99	749.0	3	2b	50.73–175.4	5–20%	4–10%	5–20%
VB 0405	Kohlrabi (all commodities)	highest utilisation: Total		1.5	1.000	DE	Child. 2–4 yrs	34	161.80	175.2	3	2b	4.63–45.08	0–5%	0–1%	1–5%
VC 0046	Melons, except watermelon (all commodities)	highest utilisation: Total		1.63	1.000	FR	Child. 3–6 yrs	–	358.11	420.0	3	2b	89.95–92.65	9–9%	5–7%	9–9%
VC 0421	Balsam pear (Bitter cucumber, Bitter gourd,	highest utilisation: raw without peel		1.63	1.000	CN	Gen pop. > 1 yrs	1387	400.21	607.5	3	2b	11.83–36.77	1–4%	1–4%	1–2%

Annex 4

FENAMIDONE (264)
Acute RfD= 1 mg/kg bw (1000 µg/kg bw)

IESTI
Maximum %ARfD:

														170% all	70% gen pop	170% child
Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
	Bitter melon) (all commodities)															
VC 0422	Bottle gourd (Cucuzzi) (all commodities)	highest utilisation: raw with skin		1.63	1.000	CN	Gen pop. > 1 yrs	519	453.00	325.0	3	2a	33.78–33.78	3–3%	3–3%	0–0%
VC 0423	Chayote (Christophine) (all commodities)	highest utilisation: raw with skin		1.63	1.000	CN	Child. 1–6 yrs	124	284.75	197.4	3	2a	18.11–68.65	2–7%	1–3%	2–7%
VC 0424	Cucumber (all commodities)	highest utilisation: raw with skin		1.63	1.000	CN	Child. 1–6 yrs	340	212.11	458.1	3	2b	14.87–64.28	1–6%	1–4%	1–6%
VC 0425	Gherkin (all commodities)	highest utilisation: raw with skin		1.63	1.000	JP	Child. 1–6 yrs	484	91.80	54.5	3	2a	14.57–19.48	1–2%	0–2%	1–2%
VC 0427	Loofah, Angled (Sinkwa, Sinkwa towel gourd) (all commodities)	highest utilisation: raw without peel		1.63	1.000	TH	Child. 3–6 yrs	759	129.62	133.0	3	2b	37.07–37.07	4–4%	1–1%	4–4%
VC 0428	Loofah, Smooth (all commodities)	highest utilisation: raw without peel		1.63	1.000	CN	Child. 1–6 yrs	196	296.64	133.0	3	2a	56.84–56.84	6–6%	2–2%	6–6%
VC 0429	Pumpkins (all commodities)	highest utilisation: raw without peel		1.63	1.000	CN	Child. 1–6 yrs	561	322.71	1851.8	3	2b	26.66–97.8	3–10%	2–7%	3–10%
VC 0430	Snake gourd (all commodities)	highest utilisation: raw without peel		1.63	1.000	TH	Child. 3–6 yrs	759	129.62	133.0	3	2b	37.07–37.07	4–4%	1–1%	4–4%
VC 0431	Squash, summer (courgette, marrow, zucchetti, zucchini) (all commodities)	highest utilisation: Total		1.63	1.000	FR	Child. 3–6 yrs	–	148.84	270.0	3	2b	5.07–38.51	1–4%	1–3%	3–4%
VC 0432	Watermelon (all commodities)	highest utilisation: Total		1.63	1.000	AU	Gen pop. > 2 yrs	267	2542.18	2095.6	3	2a	140.68–163.81	10–20%	10–20%	10–10%
VO 0440	Eggplant (aubergine) (all commodities)	highest utilisation: raw with skin		2.32	1.000	CN	Child. 1–6 yrs	969	253.44	443.9	3	2b	33.14–109.32	3–10%	3–6%	3–10%
VO 0442	Okra (Lady's finger) (all commodities)	highest utilisation: cooked/boiled (with skin)		2.32	1.000	JP	Child. 1–6 yrs	58	84.30	8.5	NR	1	8.87–12.38	1–1%	1–1%	1–1%
VO 0444	Peppers, chilli (all commodities)	highest utilisation: raw with skin		3.2	1.000	CN	Gen pop. > 1 yrs	1743	295.71	43.2	3	2a	2.47–22.97	0–2%	0–2%	0–0%
VO 0445	Peppers, sweet (incl. pim(i)ento) (bell pepper, paprika) (all commodities)	highest utilisation: raw with skin		2.32	1.000	CN	Child. 1–6 yrs	1002	169.85	170.0	3	2b	13.84–73.26	1–7%	0–3%	1–7%

Annex 4

FENAMIDONE (264)
Acute RfD= 1 mg/kg bw (1000 µg/kg bw)

IESTI
Maximum %ARfD:

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	170% all % acute RfD rounded	70% gen pop % acute RfD rounded	170% child % acute RfD rounded
VO 0447	Sweet corn (corn-on-the-cob) (all commodities)	highest utilisation: cooked/boiled		1.5	1.000	TH	Child. 3–6 yrs	1383	196.99	191.1	3	2a	6.11–50.81	1–5%	0–2%	1–5%
VO 0448	Tomato (all commodities)	highest utilisation: dried		2.32	5.000	AU	Gen pop. > 2 yrs	61	861.10	8.0	NR	1	50.03–149.09	5–10%	1–10%	0–9%
VL 0460	Amaranth (Bledo) (all commodities)	highest utilisation: raw		1.5	1.000	CN	Gen pop. > 1 yrs	714	581.72	85.8	3	2a	12.39–21.23	1–2%	1–2%	0–0%
VL 0464	Chard (silver beet) (all commodities)	highest utilisation: cooked/boiled		1.5	1.000	NL	Child. 2–6 yrs	2	81.77	105.0	3	2b	5.32–20	1–2%	1–2%	1–2%
VL 0465	Chervil (all commodities)	highest utilisation: raw		1.5	1.000	NL	Child. 2–6 yrs	E	3.50	< 25	NR	1	0.29–0.29	0–0%	0–0%	0–0%
VL 0466	Chinese cabbage, type pak-choi (all commodities)	highest utilisation: raw		1.5	1.000	CN	Child. 1–6 yrs	1966	327.07	1548.4	3	2b	18.63–91.22	2–9%	2–5%	1–9%
VL 0467	Chinese cabbage, type pe-tsai (all commodities)	highest utilisation: Total		1.5	1.000	CN	Child. 1–6 yrs	2788	336.16	1500.0	3	2b	18.63–93.75	2–9%	2–6%	1–9%
VL 0469	Chicory leaves (sugar loaf) (all commodities)	highest utilisation: raw		1.5	1.000	DE	Child. 2–4 yrs	16	82.40	280.5	3	2b	5.01–22.96	1–2%	0–1%	1–2%
VL 0470	Corn salad (lambs lettuce) (all commodities)	highest utilisation: raw		1.5	1.000	DE	Child. 2–4 yrs	13	41.20	7.8	NR	1	1.27–3.83	0–0%	0–0%	0–0%
VL 0472	Cress, garden (all commodities)	highest utilisation: raw		1.5	1.000	CN	Gen pop. > 1 yrs	1443	352.50	15.0	NR	1	0.52–9.93	0–1%	0–1%	0–0%
VL 0473	Watercress (all commodities)	highest utilisation: raw		1.5	1.000	BR	gen pop. > 10 yrs	97	90.92	254.6	3	2b	5.29–6.34	1–1%	1–1%	0–0%
VL 0474	Dandelion leaves (all commodities)	highest utilisation: raw		1.5	1.000	NL	gen pop. > 1 yrs	E	49.88	35.0	3	2a	2.73–2.73	0–0%	0–0%	0–0%
VL 0476	Endive (all commodities)	highest utilisation: cooked/boiled		1.5	1.000	NL	toddler. 8–20 m	22	135.23	251.0	3	2b	24.17–59.66	2–6%	2–2%	3–6%
VL 0478	Indian mustard (Amsoi) (all commodities)	highest utilisation: raw		1.5	1.000	NL	Gen pop. > 1 yrs	E	49.88	250.0	3	2b	3.41–3.41	0–0%	0–0%	0–0%
VL 0479	Japanese greens: Chrysanthemum leaves (Chrysanthemum spp) (all commodities)	highest utilisation: raw		1.5	1.000	CN	Gen pop. > 1 yrs	993	332.67	< 25	NR	1	3.69–9.38	0–1%	0–1%	0–1%

Annex 4

FENAMIDONE (264)
Acute RfD= 1 mg/kg bw (1000 µg/kg bw)

IESTI
Maximum %ARfD:

														170% all	70% gen pop	170% child
Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
VL 0480	Kale (borecole, collards) (all commodities)	highest utilisation: Total		1.5	1.000	DE	Gen pop. 14–80 yrs	123	669.80	672.0	3	2b	24.83–39.47	2–4%	2–4%	2–4%
VL 0481	Komatsuna	Total		1.5	1.000	JP	Child. 1–6 yrs	73	71.40	< 25	NR	1	6.3750	1.0	0.0%	1.0%
VL 0482	Lettuce, head (all commodities)	highest utilisation: raw		13.5	1.000	NL	Child. 2–6 yrs	91	140.10	338.9	3	2b	126.93–308.37	10–30%	10–10%	10–30%
VL 0483	Lettuce, leaf (all commodities)	highest utilisation: Total		1.98	1.000	CN	Child. 1–6 yrs	243	387.25	305.4	3	2a	11.4–122.46	1–10%	1–4%	4–10%
VL 0485	Mustard greens (all other commodities)	highest utilisation: cooked/boiled		34	1.000	BR	Gen pop. > 10 yrs	47	288.80	244.8	3	2a	251.08–409.89	30–40%	20–40%	0.3
VL 0485	Mustard greens	raw		34	1.000	CN	Child. 1–6 yrs	635	299.31	244.8	3	2a	1662.1581	170.0%	70.0%	170.0%
VL 0492	Purslane (all commodities)	highest utilisation: cooked/boiled		1.5	1.000	NL	Gen pop. > 1 yrs	5	271.23	< 25	NR	1	1.64–6.18	0–1%	0–1%	0–0%
VL 0494	Radish leaves	Total		0.5	1.000	–	–	–	–	–	–	–	–	–	–	–
VL 0495	Rape greens (all commodities)	highest utilisation: cooked/boiled		0.5	1.000	JP	Gen pop. > 1 yrs	533	147.90	34.0	3	2a	1.94–1.94	0–0%	0–0%	0–0%
VL 0496	Rucola (arrugula, rocket salad, roquette) (all commodities)	highest utilisation: Total		1.5	1.000	AU	Gen pop. > 2 yrs	10	157.33	212.8	3	2b	1.77–10.57	0–1%	0–1%	0–0%
VL 0501	Sowthistle (all commodities)	highest utilisation: raw		1.5	1.000	CN	Gen pop. > 1 yrs	1187	592.49	–	–	–	0–0	0–0%	0–0%	0–0%
VL 0502	Spinach	Total		34	1.000	ZA	Child. 1–5 yrs	–	237.48	197.8	3	2a	1515.5878	150.0%	50.0%	150.0%
VL 0502	Spinach	raw		34	1.000	JP	Child. 1–6 yrs	229	86.70	90.0	3	2b	526.3929	50.0%	20.0%	50.0%
VL 0502	Spinach	cooked/boiled		34	1.000	NL	Gen pop. > 1 yrs	97	292.68	1.0	NR	1	151.2320	20.0%	20.0%	10.0%
VL 0505	Taro leaves (all commodities)	highest utilisation: raw		0.5	1.000	NL	Gen pop. > 1 yrs	E	77.78	85.8	3	2b	1.77–1.77	0–0%	0–0%	0–0%
VL 0506	Turnip greens (Namenia, Tendergreen) (all commodities)	highest utilisation: cooked/boiled		0.5	1.000	NL	toddler. 8–20 m	64	90.73	< 25	NR	1	0.82–4.45	0–0%	0–0%	0–0%
VL 0507	Kangkung (water spinach)	Total		1.5	1.000	AU	child. 2–6 yrs	16	22.63	85.8	3	2b	5.3599	1.0%	–	1.0%

Annex 4

FENAMIDONE (264)
Acute RfD= 1 mg/kg bw (1000 µg/kg bw)

IESTI
Maximum %ARfD:

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	170% all % acute RfD rounded	70% gen pop % acute RfD rounded	170% child % acute RfD rounded
VL 0510	Cos lettuce (all commodities)	highest utilisation: raw		1.5	1.000	NL	Child. 2–6 yrs	91	140.10	289.9	3	2b	13.88–34.26	1–3%	1–2%	1–3%
–	Perilla leaves (i.e. sesame leaves) (all commodities)	highest utilisation: Total		1.5	1.000	–	–	–	–	–	–	–	0–0	0–0%	0–0%	0–0%
VP 0061	Beans, green, with pods, raw: beans except broad bean & soya bean (i.e. immature seeds + pods) (Phaseolus spp) (all commodities)	highest utilisation: canned/preserved		1.96	1.000	NL	toddler. 8–20 m	E	127.90	2.3	NR	1	7.45–24.58	1–2%	1–2%	2–2%
VP 0062	Beans, green, without pods, raw: beans except broad bean & soya bean (i.e. immature seeds only) (Phaseolus spp.) (all commodities)	highest utilisation: Total		1.58	1.000	FR	Child. 3–6 yrs	–	219.56	5.8	NR	1	7.97–18.35	1–2%	1–1%	1–2%
VP 0063	Peas green, with pods, raw (i.e. immature seeds + pods) (Pisum spp) (all commodities)	highest utilisation: cooked/boiled		1.5	1.000	CN	Child. 1–6 yrs	1056	290.21	6.2	NR	1	10.5–26.98	1–3%	1–1%	1–3%
VP 0064	Peas, green, without pods, raw (i.e. immature seeds only) (Pisum spp) (all commodities)	highest utilisation: Total		1.5	1.000	UK	Child. 1.5–4.5 yrs	57	174.00	< 25	NR	1	5.7–18	1–2%	0–1%	1–2%
VP 0520	Bambara groundnut, green, without pods (i.e. immature seeds only) (Voandzeia spp)	Total		1.5	1.000	AU	Gen pop. > 2 yrs	22	186.07	< 25	NR	1	4.1658	0.0%	–	–
VP 0522	Broad bean, green, with pods (i.e. immature seeds + pods) (Vicia spp) (all commodities)	highest utilisation: cooked/boiled		1.5	1.000	JP	Gen pop. > 1 yrs	216	153.00	< 25	NR	1	3.43–4.14	0–0%	0–0%	0–0%
VP 0523	Broad beans, green, without pods, raw (i.e. immature seeds only)	highest utilisation: frozen		1.5	1.000	NL	Child. 2–6 yrs	E	100.00	5.8	NR	1	4.13–8.15	0–1%	1–1%	0–1%

Annex 4

FENAMIDONE (264)
Acute RfD= 1 mg/kg bw (1000 µg/kg bw)

IESTI
Maximum %ARfD:

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	170% all % acute RfD rounded	70% gen pop % acute RfD rounded	170% child % acute RfD rounded
	(Vicia faba) (all commodities)															
VP 0541	Soya bean, green, without pods, raw (i.e. immature seeds only) (Glycine max) (all commodities)	highest utilisation: cooked/boiled		1.5	1.000	CN	Child. 1–6 yrs	195	260.25	< 25	NR	1	2.56–24.19	0–2%	0–1%	2–2%
VP 0542	Sword bean, green, with pods (i.e. immature seeds + pods) (Canavalia spp) (all commodities)	highest utilisation: cooked/boiled		1.5	1.000	CN	Gen pop. > 1 yrs	891	316.83	< 25	NR	1	8.93–8.93	1–1%	1–1%	0–0%
VP 0553	Lentil, green, with pods (i.e. immature seeds + pods) (Lens spp) (all commodities)	highest utilisation: cooked/boiled		1.5	1.000	CN	Child. 1–6 yrs	371	345.76	< 25	NR	1	4.9–32.14	0–3%	0–1%	3–3%
VR 0463	Cassava (Manioc, Tapioca) (all commodities)	highest utilisation: cooked/boiled (without peel)		0.5	1.000	NL	Gen pop. > 1 yrs	E	249.97	356.0	3	2b	5.39–5.7	1–1%	1–1%	0–0%
VR 0494	Radish (all commodities)	highest utilisation: raw with skin		0.5	1.000	NL	Child. 2–6 yrs	E	64.40	172.0	3	2b	0.7–5.25	0–1%	0–0%	0–1%
VR 0497	Swede (rutabaga) (all commodities)	highest utilisation: Total		0.5	1.000	UK	Child. 1.5–4.5 yrs	147	124.70	500.0	3	2b	1.14–12.9	0–1%	0–1%	1–1%
VR 0498	Salsify (Oyster plant) (all commodities)	highest utilisation: cooked/boiled (without peel)		0.5	1.000	NL	Child. 2–6 yrs	E	133.31	57.0	3	2a	4.33–6.72	0–1%	0–0%	1–1%
VR 0504	Tannia (tanier, yautia) (all commodities)	highest utilisation: cooked/boiled (without peel)		0.5	1.000	NL	Gen pop. > 1 yrs	E	249.97	170.0	3	2a	4.48–4.48	0–0%	0–0%	0–0%
VR 0505	Taro (dasheen, eddoe) (all commodities)	highest utilisation: cooked/boiled (without peel)		0.5	1.000	CN	Child. 1–6 yrs	199	384.18	667.8	3	2b	35.71–35.71	4–4%	2–2%	4–4%
VR 0506	Turnip, garden (all commodities)	highest utilisation: cooked/boiled (without peel)		0.5	1.000	NL	Child. 2–6 yrs	E	133.31	176.0	3	2b	5.44–10.87	1–1%	0–0%	1–1%
VR 0508	Sweet potato (all commodities)	highest utilisation: Total		0.5	1.000	CN	Child. 1–6 yrs	587	376.96	546.0	3	2b	11.5–35.04	1–4%	1–2%	1–4%

Annex 4

FENAMIDONE (264)
Acute RfD= 1 mg/kg bw (1000 µg/kg bw)

IESTI
Maximum %ARfD:

														170% all	70% gen pop	170% child
Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
VR 0573	Arrowroot (all commodities)	highest utilisation: Total		0.5	1.000	AU	Child. 2–6 yrs	689	0.20	–	–	–	0–0	0–0%	0–0%	0–0%
VR 0574	Beetroot (all commodities)	highest utilisation: Total		0.5	1.000	AU	Child. 2–6 yrs	53	314.08	135.5	3	2a	1.14–15.39	0–2%	0–1%	1–2%
VR 0575	Burdock, greater or edible	Total		0.5	1.000	JP	Child. 1–6 yrs	122	35.70	–	–	–	–	–	–	–
VR 0577	Carrot (all commodities)	highest utilisation: raw with skin		0.61	1.000	CN	Child. 1–6 yrs	400	234.68	300.0	3	2b	4.98–26.62	0–3%	0–1%	0–3%
VR 0578	Celeriac (all commodities)	highest utilisation: cooked/boiled (without skin)		0.5	1.000	NL	Gen pop. > 1 yrs	23	239.12	437.0	3	2b	3.12–5.45	0–1%	0–1%	0–0%
VR 0583	Horseradish (all commodities)	highest utilisation: Total		0.5	1.000	DE	Gen pop. 14–80 yrs	47	79.50	154.0	3	2b	0.02–1.56	0–0%	0–0%	0–0%
VR 0585	Jerusalem artichoke (all commodities)	highest utilisation: cooked/boiled (without peel)		0.5	1.000	NL	Child. 2–6 yrs	E	133.33	56.0	3	2a	0.22–6.67	0–1%	0–0%	1–1%
VR 0587	parsley, turnip-rooted	Total		0.5	1.000	DE	Child. 2–4 yrs	37	4.70	–	–	–	–	–	–	–
VR 0588	Parsnip (all commodities)	highest utilisation: Total		0.5	1.000	UK	Child. 1.5–4.5 yrs	87	227.07	90.0	3	2a	1.14–14.04	0–1%	0–0%	1–1%
VR 0589	Potato (all commodities)	highest utilisation: Total		0.5	1.000	ZA	Child. 1–5 yrs	–	299.62	216.0	3	2a	2.26–25.76	0–3%	0–1%	0–3%
VR 0590	Radish, black (all commodities)	highest utilisation: raw without skin		0.5	1.000	NL	Child. 2–6 yrs	E	64.40	180.3	3	2b	0.7–5.25	0–1%	0–0%	0–1%
VR 0591	Radish, Japanese (Chinese radish, Daikon) (all commodities)	highest utilisation: raw without skin		0.5	1.000	CN	Child. 1–6 yrs	1187	293.37	1000.0	3	2b	0.7–27.27	0–3%	0–1%	0–3%
VR 0596	Sugar beet (all commodities)	highest utilisation: Total		0.5	1.000	DE	gen pop. 14–80 yrs	26295	161.79	160.0	3	2a	3.15–3.15	0–0%	0–0%	0–0%
VR 0600	Yams (all commodities)	highest utilisation: Total		0.5	1.000	CN	Gen pop. > 1 yrs	681	441.46	810.0	3	2b	3.62–12.44	0–1%	0–1%	0–1%
VS 0469	Witloof chicory (sprouts) (all commodities)	highest utilisation: cooked/boiled		0.01	1.000	NL	toddler. 8–20 m	45	160.65	124.0	3	2a	0.07–0.4	0–0%	0–0%	0–0%
VS 0620	Artichoke globe (all commodities)	highest utilisation: Total		1.5	1.000	FR	Child. 3–6 yrs	–	117.23	98.9	3	2a	6.09–25	1–3%	1–1%	0–3%

Annex 4

FENAMIDONE (264)
Acute RfD= 1 mg/kg bw (1000 µg/kg bw)

IESTI
Maximum %ARfD:

														170% all	70% gen pop	170% child
Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
VS 0621	Asparagus (all commodities)	highest utilisation: Total		1.5	1.000	US	Child. 1–6 yrs	–	142.56	42.4	3	2a	14.64–22.74	1–2%	1–1%	1–2%
VS 0622	Bamboo shoots (all commodities)	highest utilisation: cooked/boiled without peel		1.5	1.000	TH	Child. 3–6 yrs	526	150.82	47.0	3	2a	12.13–21.48	1–2%	1–1%	0–2%
VS 0623	Cardoon (all commodities)	highest utilisation: cooked/boiled		1.5	1.000	NL	Gen pop. > 1 yrs	E	200.03	607.0	3	2b	13.68–13.68	1–1%	1–1%	0–0%
VS 0624	Celery (all commodities)	highest utilisation: raw		3.2	1.000	CN	Child. 1–6 yrs	454	180.29	861.1	3	2b	63.2–107.26	6–10%	3–6%	6–10%
VS 0627	Rhubarb (all commodities)	highest utilisation: Total		1.5	1.000	AU	gen pop. > 2 yrs	58	539.42	56.7	3	2a	14.62–14.62	1–1%	1–1%	2–2%
GC 0640	Barley (all commodities)	highest utilisation: beer	0.33	0	0.190	BR	Gen pop. > 10 yrs	1636	3600.00	NR	NR	3	0.03–3.5	0–0%	0–0%	0–0%
GC 0641	Buckwheat (all commodities)	highest utilisation: cooked/boiled	0.33	0	0.400	CN	Gen pop. > 1 yrs	198	831.68	< 25	NR	3	0.03–2.06	0–0%	0–0%	0–0%
GC 0644	Job's tears (all commodities)	highest utilisation: cooked/boiled	0.33	0	0.300	TH	Child. 3–6 yrs	134	85.50	< 25	NR	3	0.5–0.5	0–0%	0–0%	0–0%
GC 0645	Maize (corn) (all commodities)	highest utilisation: Total	0.33	0	1.000	CN	Child. 1–6 yrs	166	524.69	< 25	NR	3	0.18–10.73	0–1%	0–1%	0–1%
GC 0656	Popcorn (i.e. maize destined for popcorn preparation) (all commodities)	highest utilisation: Total	0.33	0	1.000	AU	Child. 2–6 yrs	120	73.67	< 25	NR	3	1.03–1.28	0–0%	0–0%	0–0%
GC 0646	Millet (all commodities)	highest utilisation: Total	0.33	0	1.000	CN	Child. 1–6 yrs	826	219.53	< 25	NR	3	0.24–4.49	0–0%	0–0%	0–0%
GC 0647	Oats (all commodities)	highest utilisation: Total	0.33	0	1.000	CN	Gen pop. > 1 yrs	1740	330.61	< 25	NR	3	0.18–2.05	0–0%	0–0%	0–0%
GC 0648	Quinoa	Total	0.33		1.000	AU	Child. 2–16 yrs	32	78.18	< 25	NR	3	0.6789	0.0%	–	–
GC 0650	Rye (all commodities)	highest utilisation: Wholemeal	0.33	0	1.000	DE	Child. 2–4 yrs	242	95.20	NR	NR	3	0.03–1.95	0–0%	0–0%	0–0%
GC 0651	Sorghum (Chicken corn, Dari seed, Durra, Feterita) (all commodities)	highest utilisation: cooked/boiled	0.33	0	0.400	CN	Gen pop. > 1 yrs	356	1348.67	< 25	NR	3	0.08–3.34	0–0%	0–0%	0–0%
GC 0653	Triticale	Total	0.33		1.000	DE	Gen pop. 14–80 yrs	27100	394.70	< 25	NR	3	1.7055	0.0%	0.0%	0.0%

Annex 4

FENAMIDONE (264)
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IESTI
Maximum %ARfD:

														170% all	70% gen pop	170% child
Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
GC 0654	Wheat (all commodities)	highest utilisation: flour (cereals)	0.33	0	1.000	CN	Child. 1–6 yrs	3556	415.87	NR	NR	3	0.03–8.51	0–1%	0–0%	0–1%
SO 0691	Cotton seed (all commodities)	highest utilisation: Oil (refined)	0.02	0	1.000	US	gen pop. all ages	–	9.10	NR	NR	3	0–0	0–0%	0–0%	0–0%
SO 0702	Sunflower seed (all commodities)	highest utilisation: Total		0	1.000	CN	Gen pop. > 1 yrs	781	235.52	< 25	NR	3	0–0	0–0%	0–0%	0–0%
HH 0624	Celery leaves (all commodities)	highest utilisation: cooked/boiled		1.5	1.000	NL	Gen pop. > 1 yrs	291	13.69	< 25	NR	1	0.1–0.31	0–0%	0–0%	0–0%
HH 0720	Angelica, including Garden Angelica (all commodities)	highest utilisation: cooked/boiled		1.5	1.000	NL	Gen pop. > 1 yrs	291	13.69	< 25	NR	1	0.29–0.31	0–0%	0–0%	0–0%
HH 0722	Basil (all commodities)	highest utilisation: Total		1.5	1.000	AU	Child. 2–16 yrs	143	44.19	< 25	NR	1	1.03–1.74	0–0%	0–0%	0–0%
HH 0723	Bay leaves (all commodities)	highest utilisation: raw		1.5	1.000	DE	Gen pop. 14–80 yrs	50	23.10	0.0	NR	1	0.45–0.45	0–0%	0–0%	0–0%
HH 0727	Chives (all commodities)	highest utilisation: Total		1.5	1.000	DE	Child. 2–4 yrs	413	3.90	6.0	NR	1	0.29–0.36	0–0%	0–0%	0–0%
HH 0730	Dill (all commodities)	highest utilisation: cooked/boiled		1.5	1.000	NL	Gen pop. > 1 yrs	291	13.69	< 25	NR	1	0.09–0.31	0–0%	0–0%	0–0%
HH 0731	Fennel (all commodities)	highest utilisation: raw		1.5	1.000	CN	Gen pop. > 1 yrs	570	389.94	< 25	NR	1	2.55–10.99	0–1%	0–1%	0–0%
HH 0733	Hyssop (all commodities)	highest utilisation: Total		1.5	1.000	DE	Child. 2–4 yrs	27	1.10	< 25	NR	1	0.1–0.1	0–0%	0–0%	0–0%
HH 0735	Lovage (all commodities)	highest utilisation: cooked/boiled		1.5	1.000	NL	Gen pop. > 1 yrs	291	13.69	< 25	NR	1	0.1–0.31	0–0%	0–0%	0–0%
HH 0736	Marjoram (incl Oregano) (all commodities)	highest utilisation: Total		1.5	1.000	DE	Child. 2–4 yrs	70	6.10	< 25	NR	1	0.57–0.57	0–0%	0–0%	0–0%
HH 0738	Mints (all commodities)	highest utilisation: raw		1.5	1.000	DE	Child. 2–4 yrs	138	11.10	< 25	NR	1	0.52–1.03	0–0%	0–0%	0–0%
HH 0740	Parsley (all commodities)	highest utilisation: Total		1.5	1.000	DE	Child. 2–4 yrs	328	7.20	93.6	3	2b	0.27–2.01	0–0%	0–0%	0–0%
HH 0741	Rosemary (all commodities)	highest utilisation: Total		1.5	1.000	DE	Child. 2–4 yrs	23	4.90	< 25	NR	1	0.46–0.46	0–0%	0–0%	0–0%
HH 0743	Sage and related salvia species	highest utilisation: raw		1.5	1.000	DE	Gen pop. 14–80 yrs	92	20.00	< 25	NR	1	0.39–0.39	0–0%	0–0%	0–0%

Annex 4

FENAMIDONE (264)
Acute RfD= 1 mg/kg bw (1000 µg/kg bw)

IESTI
Maximum %ARfD:

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	170% all % acute RfD rounded	70% gen pop % acute RfD rounded	170% child % acute RfD rounded
	(all commodities)															
HH 0745	Savory, summer, winter (all commodities)	highest utilisation: Total		1.5	1.000	DE	Child. 2–4 yrs	34	5.10	< 25	NR	1	0.08–0.47	0–0%	0–0%	0–0%
HH 0749	Tarragon	raw		1.5	1.000	NL	Gen pop. > 1 yrs	0	NC	< 25	NR	1	NC	NC	NC	NC
HH 0750	Thyme (all commodities)	highest utilisation: Total		1.5	1.000	DE	Child. 2–4 yrs	70	6.10	< 25	NR	1	0.57–0.57	0–0%	0–0%	0–0%
HH 0751	Land cress (all commodities)	highest utilisation: raw		1.5	1.000	DE	Women. 14–50 yrs	1556	2.90	< 25	NR	1	0.06–0.06	0–0%	0–0%	0–0%
HH 0756	Cilantro/coriander leaves (all commodities)	highest utilisation: Dried		1.5	9.800	CN	gen pop. > 1 yrs	458	27.49	< 25	NR	1	1.06–7.59	0–1%	0–1%	0–0%
HH 0761	Lemongrass (all commodities)	highest utilisation: Total		1.5	1.000	AU	Child. 2–6 yrs	2	0.53	< 25	NR	1	0.04–0.04	0–0%	0–0%	0–0%
–	Toona leaves	Total		1.5	1.000	CN	Gen pop. > 1 yrs	133	313.10	–	–	–	–	–	–	–
HS 0783	Galangal, rhizomes (all commodities)	highest utilisation: cooked/boiled		0.5	1.000	NL	Gen pop. > 1 yrs	E	0.99	29.0	3	2b	0–0.02	0–0%	0–0%	0–0%
HS 0784	Ginger, root (all commodities)	highest utilisation: Total		0.5	1.000	CN	Gen pop. > 1 yrs	1652	231.42	208.0	3	2a	0.02–6.08	0–1%	0–1%	0–0%
MM 0095	Meat from mammals other than marine mammals	Total		0	1.000	CN	Child. 1–6 yrs	302	264.84	NR	NR	1	0.0000	0.0%	0.0%	0.0%
MO 0105	Edible offal (mammalian)	Total		0	1.000	US	Child. 1–6 yrs	–	186.60	NR	NR	1	0.0000	0.0%	0.0%	0.0%
ML 0106	Milks	Total	0.01		1.000	NL	toddler. 8–20 m	1882	1060.67	NR	NR	3	1.0399	0.0%	0.0%	0.0%
FM 0812	Cattle milk fat	Total	0.01		1.000	BR	Gen pop. > 10 yrs	441	150.00	NR	NR	3	0.0232	0.0%	0.0%	0.0%
PM 0110	Poultry meat	Total		0	1.000	CN	Child. 1–6 yrs	175	347.00	NR	NR	1	0.0000	0.0%	0.0%	0.0%
PF 0111	Poultry, fats (all commodities)	highest utilisation: Total		0	1.000	US	gen pop. all ages	–	42.90	NR	NR	1	0–0	0–0%	0–0%	0–0%
PE 0112	Eggs	Total		0	1.000	CN	Child. 1–6 yrs	136	195.82	NR	NR	1	0.0000	0.0%	0.0%	0.0%

Annex 4

FENPROPATHRIIN (185)
Acute RfD= 0.03 mg/kg bw (30 µg/kg bw)

IESTI
Maximum %ARfD:

														390% all	150% gen pop	390% child
Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
FC 0303	Kumquats (all commodities)	highest utilisation: raw with peel		1.5	1.000	JP	Gen pop, > 1 yrs	135	120.00	<25	NR	1	0.4 - 3.59	1% - 10%	1% - 10%	10% - 10%
FC 0204	Lemon (all commodities)	highest utilisation: Total	0.007 - 16.5	0.098	1.000	FR	child, 3-6 yrs	-	58.15	64.0	3	2b	0.01 - 0.9	0% - 3%	0% - 2%	0% - 3%
FC 0205	Lime (all commodities)	highest utilisation: Total	0.021 - 16.5	0.098	1.000	AU	Gen pop, > 2 yrs	579	259.21	49.0	3	2a	0 - 0.52	0% - 2%	0% - 2%	0% - 1%
FC 0003	Mandarins (incl mandarin-like hybrids) (all commodities)	highest utilisation: raw, without peel	0.007 - 0.02	0.098	1.000	CN	Child, 1-6 yrs	151	586.75	124.3	3	2a	0 - 5.07	0% - 20%	0% - 8%	0% - 20%
FC 0004	Oranges, sweet, sour (incl orange-like hybrids) (all commodities)	highest utilisation: Total	0.007 - 16.5	0.098	1.000	AU	Child, 2-6 yrs	1735	800.83	155.8	3	2a	0.01 - 5.74	0% - 20%	0% - 10%	0% - 20%
FC 0005	Pummelo and Grapefruits (incl Shaddock-like hybrids, among others Grapefruit) (all commodities)	highest utilisation: raw, without peel	0.021	0.098	1.000	DE	Child, 2-4 yrs	12	358.60	178.5	3	2a	0 - 4.34	0% - 10%	0% - 9%	0% - 10%
FP 0226	Apple	Total		2	1.000	US	Child, 1-6 yrs	-	624.45	127.0	3	2a	117.1160	390.0%	150.0%	390.0%
FP 0226	Apple	raw with peel (incl consumption without peel)		2	1.000	CN	Child, 1-6 yrs	1314	403.39	255.0	3	2a	113.2143	380.0%	150.0%	380.0%
FP 0226	Apple (all other commodities)	highest utilisation: canned babyfood	0.73	2	1.000	NL	toddler, 8-20 m	390	348.40	NR	NR	3	2.21 - 24.93	7 - 80%	3 - 50%	7 - 80%
JF 0226	Apple	juice (pasteurised)	0.73		1.000	DE	Child, 2-4 yrs	1605	724.15	NR	NR	3	32.7326	110.0%	80.0%	110.0%
FP 0230	Pear	Total		2	1.000	UK	Child, 1.5-4.5 yrs	169	278.98	170.2	3	2a	85.4234	280.0%	90.0%	280.0%
FP 0230	Pear	raw with peel (incl consumption without peel)	0.73	2	1.000	CN	Child, 1-6 yrs	413	418.33	255.0	3	2a	115.0661	380.0%	150.0%	380.0%
FP 0230	Pear (all other commodities)	highest utilisation: canned/preserved	0.73	2	1.000	NL	Child, 2-6 yrs	E	138.50	48.0	3	2a	0.19 - 25.49	1 - 80%	0 - 50%	1 - 80%
FP 0231	Quince (all commodities)	highest utilisation: Total	0.73	2	1.000	DE	child, 2-4 yrs	16	26.30	301.2	3	2b	0.01 - 9.77	0% - 30%	0% - 3%	0% - 30%
FS 0013	Cherries	Total		3.5	1.000	FR	Child, 3-6 yrs	-	177.06	4.5	NR	1	32.7895	110.0%	70.0%	110.0%

Annex 4

FENPROPATHRIIN (185)
Acute RfD= 0.03 mg/kg bw (30 µg/kg bw)

IESTI
Maximum %ARfD:

														390% all	150% gen pop	390% child
Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
FS 0013	Cherries	raw		3.5	1.000	DE	Child, 2-4 yrs	24	187.50	7.2	NR	1	40.6347	140.0%	120.0%	140.0%
FS 0013	Cherries (all other commodities)	highest utilisation: canned/preserved	1.85	3.5	1.000	NL	Child, 2-6 yrs	E	58.90	5.0	NR	1	0.75 - 11.2	3 - 40%	2 - 20%	2 - 40%
FS 0014	Plums (all commodities)	highest utilisation: raw with peel (incl consumption without peel)	0.25	0.71	1.000	TH	Child, 3-6 yrs	11	376.88	93.0	3	2a	0.11 - 23.37	0% - 80%	0% - 30%	0% - 80%
FS 0240	Apricot (all commodities)	highest utilisation: raw with peel (incl consumption without peel)	0.71	1.1	1.000	AU	Gen pop, > 2 yrs	77	1056.90	54.5	3	2a	0.3 - 19.14	1% - 60%	1% - 60%	1% - 70%
FS 0245	Nectarine	Total		1.1	1.000	FR	Child, 3-6 yrs	-	325.41	99.0	3	2a	30.4629	100.0%	50.0%	100.0%
FS 0245	Nectarine	raw with peel (incl consumption without peel)		1.1	1.000	NL	toddler, 8-20 m	6	183.60	131.0	3	2a	48.0441	160.0%	50.0%	160.0%
FS 0245	Nectarine (all other commodities)	highest utilisation: canned/preserved	0.71	1.1	1.000	NL	Child, 2-6 yrs	E	118.50	60.0	3	2a	0.29 - 14.26	1 - 50%	1 - 20%	1 - 50%
FS 0247	Peach	Total		1.1	1.000	FR	Child, 3-6 yrs	-	325.41	99.0	3	2a	30.4629	100.0%	70.0%	100.0%
FS 0247	Peach	raw with peel (incl consumption without peel)		1.1	1.000	JP	Child, 1-6 yrs	76	306.00	255.0	3	2a	57.9097	190.0%	50.0%	190.0%
FS 0247	Peach (all other commodities)	highest utilisation: canned/preserved	0.71	1.1	1.000	NL	Child, 2-6 yrs	E	118.50	60.0	3	2a	0.29 - 14.26	1 - 50%	1 - 20%	1 - 50%
FB 0275	Strawberry (all commodities)	highest utilisation: Total	0.515	1.2	1.000	FR	Child, 3-6 yrs	-	339.40	13.4	NR	1	0.29 - 21.55	1% - 70%	0% - 40%	1% - 70%
VO 0444	Peppers, chili (all other commodities)	highest utilisation: dried (incl powder)	2.59	4.9	7.000	CN	Gen Pop, > 1 yrs	1583	32.22	0.0	NR	1	0.05 - 20.76	0 - 70%	0 - 70%	0 - 20%
VO 0444	Peppers, chili	raw with skin		4.9	1.000	CN	Gen pop, > 1 yrs	1743	295.71	43.2	3	2a	35.1760	120.0%	120.0%	NC
VO 0444	Peppers, chili	paste (= crushed)		7	1.000	CN	Gen pop, > 1 yrs	309	142.57	43.2	3	2a	30.1126	100.0%	100.0%	-
VO 0445	Peppers, sweet (incl. pim(i)ento) (bell pepper, paprika) (all commodities)	highest utilisation: raw with skin	0.3	0.7	1.000	CN	Child, 1-6 yrs	1002	169.85	170.0	3	2b	0.05 - 22.11	0% - 70%	0% - 30%	0% - 70%
VO 0448	Tomato	highest utilisation:	0.023 -	0.64	1.000	CN	Child, 1-6	1117	263.76	180.0	3	2a	0.3 - 24.74	1 - 80%	1 - 30%	1 - 80%

Annex 4

FENPROPATHRIIN (185)
Acute RfD= 0.03 mg/kg bw (30 µg/kg bw)

IESTI
Maximum %ARfD:

														390% all	150% gen pop	390% child
Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
	(all other commodities)	raw with peel	0.19				yrs									
VO 0448	Tomato	dried		0.7	5.000	AU	Gen pop, > 2 yrs	61	861.10	8.0	NR	1	44.9829	150.0%	150.0%	5.0%
VD 0541	Soya bean (dry) (Glycine spp) (all commodities)	highest utilisation: Total	0.01		1.000	CN	Child, 1-6 yrs	179	239.05	<25	NR	3	0 - 0.15	0% - 0%	0% - 0%	0% - 0%
TN 0295	Cashew nut (all commodities)	highest utilisation: raw incl roasted	0.01	0.06	1.000	TH	child, 3-6 yrs	374	98.84	2.5	NR	1	0.13 - 0.35	0% - 1%	0% - 1%	0% - 1%
TN 0660	Almonds (all commodities)	highest utilisation: raw incl roasted	0.01	0.06	1.000	DE	Women, 14-50 yrs	24	100.00	1.2	NR	1	0 - 0.09	0% - 0%	0% - 0%	0% - 0%
TN 0664	Chestnuts (all commodities)	highest utilisation: Total		0.06	1.000	FR	child, 3-6 yrs	-	170.41	17.4	NR	1	0.15 - 0.54	0% - 2%	0% - 2%	0% - 2%
TN 0666	Hazelnut (all commodities)	highest utilisation: Total	0.01	0.06	1.000	FR	Child, 3-6 yrs	-	27.24	1.2	NR	1	0.01 - 0.09	0% - 0%	0% - 0%	0% - 0%
TN 0669	Macadamia nut (all commodities)	highest utilisation: Total	0.01	0.06	1.000	US	Gen pop, all ages	-	106.60	3.2	NR	1	0 - 0.1	0% - 0%	0% - 0%	0% - 0%
TN 0672	Pecan (all commodities)	highest utilisation: Total	0.01	0.06	1.000	AU	Child, 2-16 yrs	52	80.87	5.0	NR	1	0.04 - 0.13	0% - 0%	0% - 0%	0% - 0%
TN 0673	Pine nut (all commodities)	highest utilisation: Total		0.06	1.000	BR	Gen pop, > 10 yrs	47	200.00	0.2	NR	1	0.03 - 0.19	0% - 1%	0% - 1%	0% - 0%
TN 0675	Pistachio nut (all commodities)	highest utilisation: Total	0.01	0.06	1.000	FR	child, 3-6 yrs	-	44.89	0.9	NR	1	0 - 0.14	0% - 0%	0% - 0%	0% - 0%
TN 0678	Walnut (all commodities)	highest utilisation: raw incl roasted	0.01	0.06	1.000	DE	Child, 2-4 yrs	75	49.40	7.0	NR	1	0 - 0.18	0% - 1%	0% - 1%	0% - 1%
SB 0716	Coffee beans (all commodities)	highest utilisation: Total	0.01		1.000	FR	Child, 3-6 yrs	-	70.31	0.1	NR	3	0 - 0.04	0% - 0%	0% - 0%	0% - 0%
DT 1114	Tea, green, black (black, fermented and dried) (all commodities)	highest utilisation: raw = dried	0.14		1.000	CN	Gen pop, > 1 yrs	679	75.88	<25	NR	3	0.06 - 0.2	0% - 1%	0% - 1%	0% - 0%
MM 0095	Meat from mammals other than marine mammals	Total	NA	NA	1.000	CN	Child, 1-6 yrs	302	264.84	NR	NR	1	NA	0.0%	0.0%	0.0%
MM 0095	Meat from mammals other than marine mammals: 20% as fat	Total	0.018		1.000	CN	Child, 1-6 yrs	302	52.97	NR	NR	1	ND	-	-	-

Annex 4

FENPROPATHRIIN (185)
Acute RfD= 0.03 mg/kg bw (30 µg/kg bw)

IESTI
Maximum %ARfD:

														390% all	150% gen pop	390% child
Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	Total	0.001		1.000	CN	Child, 1-6 yrs	302	211.87	NR	NR	1	ND	-	-	-
MF 0100	Mammalian fats (except milk fats)	Total	0.018		1.000	FR	Child, 3-6 yrs	0	64.80	NR	NR	1	ND	-	-	-
MO 0105	Edible offal (mammalian)	Total		0.003	1.000	US	Child, 1-6 yrs	-	186.60	NR	NR	1	0.0373	0.0%	0.0%	0.0%
ML 0106	Milks	Total	0.002		1.000	NL	toddler, 8-20 m	1882	1060.67	NR	NR	3	0.2080	1.0%	0.0%	1.0%
FM 0812	Cattle milk fat	Total	0.018		1.000	BR	Gen pop, > 10 yrs	441	150.00	NR	NR	3	0.0418	0.0%	0.0%	0.0%
PM 0110	Poultry meat	Total	NA	NA	1.000	CN	Child, 1-6 yrs	175	347.00	NR	NR	1	NA	0.0%	0.0%	0.0%
PM 0110	Poultry meat: 10% as fat	Total	0		1.000	CN	Child, 1-6 yrs	175	34.70	NR	NR	1	ND	-	-	-
PM 0110	Poultry meat: 90% as muscle	Total	0		1.000	CN	Child, 1-6 yrs	175	312.30	NR	NR	1	ND	-	-	-
PF 0111	Poultry, fats	Total	0		1.000	US	gen pop, all ages	-	42.90	NR	NR	1	ND	-	-	-
038	POULTRY, EDIBLE OFFAL OF	-	0		-	-	-	-	-	-	-	-	-	-	-	-
039	EGGS	-	0		-	-	-	-	-	-	-	-	-	-	-	-

Annex 4

BSA from FLUENSULFONE (265)
Acute RfD = 0.3 mg/kg bw (300 µg/kg bw)

IESTI
Maximum %ARfD:

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	7% all % acute RfD rounded	7% gen pop % acute RfD rounded	4% child % acute RfD rounded
VC 0046	Melons, except watermelon (all commodities)	highest utilisation: Total	0.032	0.155	1.000	FR	Child, 3–6 yrs	–	358.11	420.0	3	2b	0–8.81	0–3%	0–2%	0–3%
VC 0421	Balsam pear (Bitter cucumber, Bitter gourd, Bitter melon) (all commodities)	highest utilisation: raw without peel	0	0.155	1.000	CN	Gen pop, > 1 yrs	1387	400.21	607.5	3	2b	1.12–3.5	0–1%	0–1%	0–1%
VC 0422	Bottle gourd (Cucuzzi) (all commodities)	highest utilisation: raw with skin	0	0.155	1.000	CN	Gen pop, > 1 yrs	519	453.00	325.0	3	2a	3.21–3.21	1–1%	1–1%	0–0%
VC 0423	Chayote (Christophine) (all commodities)	highest utilisation: raw with skin	0	0.155	1.000	CN	Child, 1–6 yrs	124	284.75	197.4	3	2a	1.72–6.53	1–2%	0–1%	1–2%
VC 0424	Cucumber (all commodities)	highest utilisation: raw with skin	0.032	0.155	1.000	CN	Child, 1–6 yrs	340	212.11	458.1	3	2b	0.01–6.11	0–2%	0–1%	0–2%
VC 0425	Gherkin (all commodities)	highest utilisation: raw with skin	0.032	0.155	1.000	JP	Child, 1–6 yrs	484	91.80	54.5	3	2a	0.02–1.85	0–1%	0–0%	0–1%
VC 0427	Loofah, Angled (Sinkwa, Sinkwa towel gourd) (all commodities)	highest utilisation: raw without peel	0	0.155	1.000	TH	Child, 3–6 yrs	759	129.62	133.0	3	2b	3.52–3.52	1–1%	0–0%	1–1%
VC 0428	Loofah, Smooth (all commodities)	highest utilisation: raw without peel	0	0.155	1.000	CN	Child, 1–6 yrs	196	296.64	133.0	3	2a	5.4–5.4	2–2%	1–1%	2–2%
VC 0429	Pumpkins (all commodities)	highest utilisation: raw without peel	0.032	0.155	1.000	CN	Child, 1–6 yrs	561	322.71	1851.8	3	2b	0.05–9.3	0–3%	0–2%	0–3%
VC 0430	Snake gourd (all commodities)	highest utilisation: raw without peel	0	0.155	1.000	TH	Child, 3–6 yrs	759	129.62	133.0	3	2b	3.52–3.52	1–1%	0–0%	1–1%
VC 0431	Squash, summer (courgette, marrow, zucchetti, zucchini) (all commodities)	highest utilisation: Total	0.032	0.155	1.000	FR	Child, 3–6 yrs	–	148.84	270.0	3	2b	0.02–3.66	0–1%	0–1%	0–1%
VC 0432	Watermelon (all commodities)	highest utilisation: Total	0.032	0.155	1.000	AU	Gen pop, > 2 yrs	267	2542.18	2095.6	3	2a	13.38–15.58	4–5%	4–5%	4–4%
VO 0440	Eggplant (aubergine) (all commodities)	highest utilisation: raw with skin	0.045	0.17	1.000	CN	Child, 1–6 yrs	969	253.44	443.9	3	2b	0.05–8.01	0–3%	0–1%	0–3%

Annex 4

			BSA from FLUENSULFONE (265) Acute RfD = 0.3 mg/kg bw (300 µg/kg bw)							IESTI Maximum %ARfD:				7% all	7% gen pop	4% child
Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
VO 0442	Okra (Lady's finger) (all commodities)	highest utilisation: cooked/boiled (with skin)	0	0.17	1.000	JP	Child, 1–6 yrs	58	84.30	8.5	NR	1	0.65–0.91	0–0%	0–0%	0–0%
VO 0443	Pepino (Melon pear, Tree melon)	Total		0.17	1.000	AU	Gen pop, > 2 yrs	3	73.89	122.9	3	2b	0.5625	0.0%	0.0%	–
VO 0444	Peppers, chilli (all commodities)	highest utilisation: raw with skin	0.045	0.17–1.2	1.000	CN	Gen pop, > 1 yrs	1743	295.71	43.2	3	2a	0–1.22	0–0%	0–0%	0–0%
VO 0445	Peppers, sweet (incl. pim(i)ento) (bell pepper, paprika) (all commodities)	highest utilisation: raw with skin	0.045	0.17	1.000	CN	Child, 1–6 yrs	1002	169.85	170.0	3	2b	0.01–5.37	0–2%	0–1%	0–2%
VO 0448	Tomato (all commodities)	highest utilisation: dried	0.045–0.081	0.17–0.31	5.000	AU	Gen pop, > 2 yrs	61	861.10	8.0	NR	1	0.24–19.92	0–7%	0–7%	0–2%
–	Gilo (scarlet eggplant) (all commodities)	highest utilisation: cooked/boiled (with skin)	0	0.17	1.000	BR	Gen pop, > 10 yrs	280	360.50	28.5	3	2a	0.16–1.1	0–0%	0–0%	0–0%

Annex 4

FLUOPYRAM (243)
Acute RfD= 0.5 mg/kg bw (500 µg/kg bw)

IESTI
Maximum %ARfD:

														100%	30%	100%
Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit wt, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
FS 0014	Plums (all commodities)	highest utilisation: raw with peel (incl consumption without peel)	0.14	0.22–0.24	1.000	TH	Child, 3–6 yrs	11	376.88	93.0	3	2a	0.06–7.24	0–1%	0–1%	0–1%
FS 0240	Apricot (all commodities)	highest utilisation: raw with peel (incl consumption without peel)	0.22	0.69	1.000	AU	Gen pop, > 2 yrs	77	1056.90	54.5	3	2a	0.09–12.01	0–2%	0–2%	0–2%
FS 2237	Japanese apricot (ume)	Total		0.69	1.000	JP	Child, 1–6 yrs	25	25.50	<25	NR	1	0.9721	0.0%	0.0%	0.0%
FS 0245	Nectarine (all commodities)	highest utilisation: raw with peel (incl consumption without peel)	0.22	0.69	1.000	NL	toddler, 8–20 m	6	183.60	131.0	3	2a	0.09–30.14	0–6%	0–2%	0–6%
FS 0247	Peach (all commodities)	highest utilisation: raw with peel (incl consumption without peel)	0.21–0.22	0.69	1.000	JP	Child, 1–6 yrs	76	306.00	255.0	3	2a	0.09–36.33	0–7%	0–3%	0–7%
FB 0264	Blackberries (all commodities)	highest utilisation: raw with skin	0.7	1.2	1.000	DE	Gen pop, 14–80 yrs	35	460.00	2.4	NR	1	0.12–7.23	0–1%	0–1%	0–1%
FB 0272	Raspberries, red, black (all commodities)	highest utilisation: Total	0.7	1.2	1.000	FR	Child, 3–6 yrs	–	157.50	4.3	NR	1	0.31–10	0–2%	0–1%	0–2%
VA 0381	Garlic (all commodities)	highest utilisation: raw without skin	0.01	0.04	1.000	CN	Child, 1–6 yrs	290	174.44	59.8	3	2a	0–0.73	0–0%	0–0%	0–0%
VA 0384	Leek (all commodities)	highest utilisation: raw	0.01	0.07	1.000	CN	Child, 1–6 yrs	401	149.40	175.5	3	2b	0–1.94	0–0%	0–0%	0–0%
VA 0385	Onion, bulb (all commodities)	highest utilisation: raw without skin	0.01	0.04	1.000	JP	Child, 1–6 yrs	748	102.00	244.4	3	2b	0–0.75	0–0%	0–0%	0–0%
VB 0041	Cabbage, head (all commodities)	highest utilisation: raw	0.01	0.08	1.000	CN	Child, 1–6 yrs	287	255.54	1402.5	3	2b	0.01–3.8	0–1%	0–0%	0–1%
VB 0400	Broccoli (all commodities)	highest utilisation: cooked/boiled	0.05	0.14	1.000	NL	toddler, 8–20 m	125	160.73	286.0	3	2b	0.09–6.62	0–1%	0–0%	0–1%
VB 0402	Brussels sprouts (all commodities)	highest utilisation: cooked/boiled	0.06	0.15	1.000	NL	toddler, 8–20 m	11	103.77	8.0	NR	1	0–1.53	0–0%	0–0%	0–0%
VB 0404	Cauliflower (all commodities)	highest utilisation: cooked/boiled	0.01	0.05	1.000	NL	toddler, 8–20 m	110	141.99	749.0	3	2b	0–2.09	0–0%	0–0%	0–0%
VL 0482	Lettuce, head (all commodities)	highest utilisation: raw	2.2	8.4	1.000	NL	Child, 2–6 yrs	91	140.10	338.9	3	2b	1.29–191.87	0–40%	0–20%	0–40%
VL 0483	Lettuce, leaf	Total		8.4	1.000	CN	Child, 1–6 yrs	243	387.25	305.4	3	2a	519.5335	100.0%	30.0%	100.0%

Annex 4

			FLUOPYRAM (243) Acute RfD= 0.5 mg/kg bw (500 µg/kg bw)										IESTI Maximum %ARfD:	100%	30%	100%
Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit wt, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
VL 0483	Lettuce, leaf (all other commodities)	highest utilisation: raw	2.2	8.4	1.000	NL	Child, 2–6 yrs	91	140.10	117.8	3	2a	1.29–171.48	0–30%	0–10%	0–30%
SO 0495	Rape seed (all commodities)	highest utilisation: Oil (refined)	0.23–0.33		1.000	AU	Gen pop, > 2 yrs	2407	40.72	NR	NR	3	0.14–0.14	0–0%	0–0%	0–0%

Annex 4

GLUFOSINATE-AMMONIUM
(158)
Acute RfD= 0.01 mg/kg bw (10 µg/kg bw)

IESTI
Maximum %ARfD:

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	10% all % acute RfD rounded	8% gen pop % acute RfD rounded	10% child % acute RfD rounded
VD 0541	Soya bean (dry) (Glycine spp) (all commodities)	highest utilisation: Total	0.09	0	1.000	CN	Child, 1-6 yrs	179	239.05	<25	NR	3	0 - 1.33	0% - 10%	0% - 8%	0% - 10%

Annex 4

IMAZAMOX (276)
Acute RfD= 3 mg/kg bw (3000 µg/kg bw)

IESTI
Maximum %ARfD:

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	0% all % acute RfD rounded	0% gen pop % acute RfD rounded	0% child % acute RfD rounded
VP 0061	Beans, green, with pods, raw: beans except broad bean & soya bean (i.e. immature seeds + pods) (Phaseolus spp) (all commodities)	highest utilisation: canned/preserved	0	0	1.000	NL	toddler, 8-20 m	E	127.90	2.3	NR	1	0 - 0	0% - 0%	0% - 0%	0% - 0%
VP 0064	Peas, green, without pods, raw (i.e. immature seeds only) (Pisum spp) (all commodities)	highest utilisation: Total	0	0	1.000	UK	Child, 1.5-4.5 yrs	57	174.00	<25	NR	1	0 - 0	0% - 0%	0% - 0%	0% - 0%
VD 0071	Beans (dry) (Phaseolus spp) (all commodities)	highest utilisation: cooked/boiled	0	0	0.400	CN	Gen pop, > 1 yrs	722	1313.18	0.5	NR	3	0 - 0	0% - 0%	0% - 0%	0% - 0%
VD 0072	Peas (dry) (Pisum spp, Vigna spp) (all commodities)	highest utilisation: cooked/boiled	0	0	0.400	CN	Gen pop, > 1 yrs	268	1673.82	<25	NR	3	0 - 0	0% - 0%	0% - 0%	0% - 0%
VD 0533	Lentil (dry) (Lens spp) (all commodities)	highest utilisation: Total	0.1	0	1.000	FR	Child, 3-6 yrs	-	290.77	0.1	NR	3	0.2 - 1.54	0% - 0%	0% - 0%	0% - 0%
VD 0541	Soya bean (dry) (Glycine spp) (all commodities)	highest utilisation: Total	0	0	1.000	CN	Child, 1-6 yrs	179	239.05	<25	NR	3	0 - 0	0% - 0%	0% - 0%	0% - 0%
GC 0649	Rice (all commodities)	highest utilisation: Total	0.025	0	1.000	US	Child, 1-6 yrs	-	99.75	<25	NR	3	0 - 0.17	0% - 0%	0% - 0%	0% - 0%
GC 0650	Rice	Rice milk	0.025		0.040	AU	Child, 2-6 yrs	25	772.50	NR	NR	3	0.0407	0.0%	-	0.0%
GC 0649	Rice (all commodities)	highest utilisation: polished rice (cooked)	0.025	0	0.400	CN	Child, 1-6 yrs	8752	1004.28	<25	NR	3	0.02 - 0.62	0% - 0%	0% - 0%	0% - 0%
GC 0654	Wheat (all commodities)	highest utilisation: flour (cereals)	0.1 - 0.34	0	1.000	CN	Child, 1-6 yrs	3556	415.87	NR	NR	3	0.01 - 3.09	0% - 0%	0% - 0%	0% - 0%
SO 0702	Sunflower seed (all commodities)	highest utilisation: Total	0.095 - 0.19	0	1.000	CN	Gen pop, > 1 yrs	781	235.52	<25	NR	3	0.1 - 0.84	0% - 0%	0% - 0%	0% - 0%
MM 0095	Meat from mammals other than marine mammals	Total	NA	NA	1.000	CN	Child, 1-6 yrs	302	264.84	NR	NR	1	NA	0.0%	0.0%	0.0%
MM 0095	Meat from mammals	Total		0	1.000	CN	Child, 1-6	302	52.97	NR	NR	1	0.0000	0.0%	0.0%	0.0%

Annex 4

IMAZAMOX (276)
Acute RfD= 3 mg/kg bw (3000 µg/kg bw)

IESTI
Maximum %ARfD:

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	0% all % acute RfD rounded	0% gen pop % acute RfD rounded	0% child % acute RfD rounded
	other than marine mammals: 20% as fat						yrs									
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	Total		0	1.000	CN	Child, 1-6 yrs	302	211.87	NR	NR	1	0.0000	0.0%	0.0%	0.0%
MF 0100	Mammalian fats (except milk fats)	Total		0	1.000	FR	Child, 3-6 yrs	0	64.80	NR	NR	1	0.0000	0.0%	0.0%	0.0%
MO 0105	Edible offal (mammalian)	Total	0		1.000	US	Child, 1-6 yrs	-	186.60	NR	NR	1	ND	-	-	-
ML 0106	Milks	Total	0		1.000	NL	toddler, 8-20 m	1882	1060.67	NR	NR	3	0.0000	0.0%	0.0%	0.0%
PM 0110	Poultry meat	Total	NA	NA	1.000	CN	Child, 1-6 yrs	175	347.00	NR	NR	1	NA	0.0%	0.0%	0.0%
PM 0110	Poultry meat: 10% as fat	Total		0	1.000	CN	Child, 1-6 yrs	175	34.70	NR	NR	1	0.0000	0.0%	0.0%	0.0%
PM 0110	Poultry meat: 90% as muscle	Total		0	1.000	CN	Child, 1-6 yrs	175	312.30	NR	NR	1	0.0000	0.0%	0.0%	0.0%
PF 0111	Poultry, fats (all commodities)	highest utilisation: Total	0	0	1.000	US	gen pop, all ages	-	42.90	NR	NR	1	0 - 0	0% - 0%	0% - 0%	0% - 0%
PE 0112	Eggs	Total	0		1.000	CN	Child, 1-6 yrs	136	195.82	NR	NR	1	ND	-	-	-

Annex 4

MYCLOBUTANIL (181)
Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

IESTI
Maximum %ARfD: 10% women

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
FP 0226	Apple (all commodities)	highest utilisation: Total	0.012–0.07	0.35	1.000	US	gen pop, all ages	–	1240.25	127.0	3	2a	0.09–8.05	0–3%
FP 0229	Medlar	Total		0.35	1.000	–	–	–	–	–	–	–	–	–
FP 0230	Pear (all commodities)	highest utilisation: Total	0.07	0.35	1.000	FR	Gen pop, > 3 yrs	–	505.57	89.0	3	2a	0.01–4.58	0–2%
FT 0307	Persimmon, Japanese (all commodities)	highest utilisation: Total	0	0.35	1.000	AU	gen pop, > 2 yrs	4	738.91	123.5	3	2a	4.67–5.15	2–2%
FS 0013	Cherries (all commodities)	highest utilisation: raw	1.06	2.05	1.000	DE	Women, 14–50 yrs	123	740.52	7.2	NR	1	0.43–22.5	0–7%
FS 0014	Plums (all commodities)	highest utilisation: Total	0.4	1.45	1.000	FR	gen pop, > 3 yrs	–	571.13	93.0	3	2a	0.18–21.03	0–7%
FS 0240	Apricot (all commodities)	highest utilisation: dried	0.865	1.54	4.110	FR	gen pop, > 3 yrs	–	176.95	6.5	NR	1	0.21–21.46	0–7%
FS 2237	Japanese apricot (ume)	Total		1.54	1.000	JP	Gen pop, > 1 yrs	2829	30.60	< 25	NR	1	0.8195	0.0%
FS 0245	Nectarine (all commodities)	highest utilisation: Total	0.865	1.54	1.000	FR	gen pop, > 3 yrs	–	543.98	99.0	3	2a	0.19–21.89	0–7%
FS 0247	Peach (all commodities)	highest utilisation: Total	0.865	1.54	1.000	ZA	gen pop, > 10 yrs	–	582.34	255.0	3	2a	0.19–30.2	0–10%
FB 0021	Currants, red, black, white (all commodities)	highest utilisation: Total	0.34	0.47	1.000	AU	Gen pop, > 2 yrs	322	797.60	14.9	NR	1	0.13–5.6	0–2%
FB 0269	Grape (all commodities)	highest utilisation: Total	0.34–2.14	0.6	1.000	FR	gen pop, > 3 yrs	–	1911.18	117.5	3	2a	0.8–13.19	0–4%
FB 0275	Strawberry (all commodities)	highest utilisation: Total	0.19	0.69	1.000	FR	gen pop, > 3 yrs	–	510.23	13.4	NR	1	0.04–6.74	0–2%
VA 0380	Fennel, bulb (all commodities)	highest utilisation: cooked/boiled	0.039	0.052	1.000	NL	gen pop, > 1 yrs	9	271.16	251.0	3	2a	0–0.61	0–0%
VA 0381	Garlic (all commodities)	highest utilisation: raw without skin	0.039	0.052	1.000	CN	gen pop, > 1 yrs	6288	288.76	59.8	3	2a	0–0.4	0–0%
VA 0384	Leek (all commodities)	highest utilisation: raw	0.039	0.052	1.000	CN	gen pop, > 1 yrs	8879	322.59	175.5	3	2a	0–0.66	0–0%
VA 0385	Onion, bulb (all commodities)	highest utilisation: raw without skin	0.039	0.052	1.000	JP	Gen pop, > 1 yrs	16490	153.00	244.4	3	2b	0.01–0.44	0–0%
VA 0386	Onion, Chinese	highest utilisation:	0	0.052	1.000	CN	gen pop, > 1	3530	289.28	–	–	–	0–0	0–0%

Annex 4

MYCLOBUTANIL (181)
Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

IESTI
Maximum %ARfD: 10% women

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
	(all commodities)	raw					yrs							
VA 0387	Onion, Welsh (Japanese bunching onion, multiplying onion) (all commodities)	highest utilisation: raw	0	0.052	1.000	JP	Gen pop, > 1 yrs	12104	76.50	97.0	3	2b	0.17–0.21	0–0%
VA 0388	Shallot (i.e. dry harvested small onion) (all commodities)	highest utilisation: raw without skin	0.039	0.052	1.000	CN	gen pop, > 1 yrs	9148	202.00	51.4	3	2a	0.04–0.3	0–0%
VA 0389	Spring onion (all commodities)	highest utilisation: cooked/boiled	0	0.052	1.000	NL	gen pop, > 1 yrs	E	30.40	30.0	3	2a	0.06–0.07	0–0%
VB 0041	Cabbage, head (all commodities)	highest utilisation: raw	0.03	0.044	1.000	CN	gen pop, > 1 yrs	6303	400.92	1402.5	3	2b	0.05–0.99	0–0%
VB 0400	Broccoli (all commodities)	highest utilisation: raw	0.03	0.044	1.000	NL	gen pop, > 1 yrs	13	424.54	304.0	3	2a	0.04–0.69	0–0%
VB 0401	Broccoli, Chinese (Kailan) (all commodities)	highest utilisation: raw	0	0.044	1.000	CN	gen pop, > 1 yrs	6965	385.09	311.0	3	2a	0.6–0.83	0–0%
VB 0402	Brussels sprouts (all commodities)	highest utilisation: frozen	0.03	0.044	1.000	NL	gen pop, > 1 yrs	5	394.80	8.0	NR	1	0–0.26	0–0%
VB 0404	Cauliflower (all commodities)	highest utilisation: cooked/boiled	0.03	0.044	1.000	NL	gen pop, > 1 yrs	644	548.31	749.0	3	2b	0–1.1	0–0%
VB 0405	Kohlrabi (all commodities)	highest utilisation: cooked/boiled	0	0.044	1.000	NL	gen pop, > 1 yrs	E	200.03	210.0	3	2b	0.14–0.4	0–0%
VC 0046	Melons, except watermelon (all commodities)	highest utilisation: Total	0.04	0.16	1.000	FR	gen pop, > 3 yrs	–	626.40	420.0	3	2a	0–4.49	0–1%
VC 0421	Balsam pear (Bitter cucumber, Bitter gourd, Bitter melon) (all commodities)	highest utilisation: raw without peel	0	0.16	1.000	CN	gen pop, > 1 yrs	1387	400.21	607.5	3	2b	1.16–3.61	0–1%
VC 0422	Bottle gourd (Cucuzzi) (all commodities)	highest utilisation: raw with skin	0	0.16	1.000	CN	gen pop, > 1 yrs	519	453.00	325.0	3	2a	3.32–3.32	1–1%
VC 0423	Chayote (Christophine) (all commodities)	highest utilisation: raw with skin	0	0.16	1.000	CN	gen pop, > 1 yrs	1437	574.81	197.4	3	2a	1.19–2.91	0–1%
VC 0424	Cucumber (all commodities)	highest utilisation: Total	0.04	0.16	1.000	FR	gen pop, > 3 yrs	–	313.20	360.0	3	2b	0.01–2.88	0–1%
VC 0425	Gherkin	highest utilisation:	0.04	0.16	1.000	BR	Gen pop, > 10	70	500.00	54.5	3	2a	0.01–1.51	0–1%

Annex 4

MYCLOBUTANIL (181)
Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

IESTI
Maximum %ARfD: 10% women

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
	(all commodities)	pickled & preserved					yrs							
VC 0427	Loofah, Angled (Sinkwa, Sinkwa towel gourd) (all commodities)	highest utilisation: raw without peel	0	0.16	1.000	TH	gen pop, > 3 yrs	8306	215.23	133.0	3	2a	1.44–1.44	0–0%
VC 0428	Loofah, Smooth (all commodities)	highest utilisation: raw without peel	0	0.16	1.000	CN	gen pop, > 1 yrs	3930	521.84	133.0	3	2a	2.37–2.37	1–1%
VC 0429	Pumpkins (all commodities)	highest utilisation: raw without peel	0.04	0.16	1.000	CN	Gen pop, > 1 yrs	10137	701.51	1851.8	3	2b	0.03–6.33	0–2%
VC 0430	Snake gourd (all commodities)	highest utilisation: raw without peel	0	0.16	1.000	TH	gen pop, > 3 yrs	8306	215.23	133.0	3	2a	1.44–1.44	0–0%
VC 0431	Squash, summer (courgette, marrow, zucchetti, zucchini) (all commodities)	highest utilisation: cooked/boiled with skin (incl consumption without skin)	0.04	0.16	1.000	NL	gen pop, > 1 yrs	100	348.81	289.0	3	2a	0.02–2.25	0–1%
VC 0432	Watermelon (all commodities)	highest utilisation: Total	0.04	0.16	1.000	AU	gen pop, > 2 yrs	267	2542.18	2095.6	3	2a	2.82–16.08	1–5%
VO 0444	Peppers, chilli (all commodities)	highest utilisation: raw with skin	0.435	2.4–24	1.000	CN	gen pop, > 1 yrs	1743	295.71	43.2	3	2a	0–17.23	0–6%
VO 0445	Peppers, sweet (incl. pim(i)ento) (bell pepper, paprika) (all commodities)	highest utilisation: raw with skin	0.435	2.4	1.000	DE	Women, 14–50 yrs	518	191.73	119.3	3	2a	0.03–15.31	0–5%
VO 0448	Tomato (all commodities)	highest utilisation: dried	0.02–0.093	0.25	5.000	AU	Gen pop, > 2 yrs	61	861.10	8.0	NR	1	0.18–16.07	0–5%
VL 0269	Grape leaves (all commodities)	highest utilisation: canned/preserved	0	0.044	1.000	NL	gen pop, > 1 yrs	1	54.81	1.4	NR	1	0.03–0.04	0–0%
VL 0460	Amaranth (Bledo) (all commodities)	highest utilisation: raw	0	0.044	1.000	CN	gen pop, > 1 yrs	714	581.72	85.8	3	2a	0.36–0.62	0–0%
VL 0464	Chard (silver beet) (all commodities)	highest utilisation: cooked/boiled	0	0.044	1.000	NL	gen pop, > 1 yrs	7	193.52	105.0	3	2a	0.16–0.27	0–0%
VL 0465	Chervil (all commodities)	highest utilisation: raw	0.03	0.044	1.000	DE	Women, 14–50 yrs	1685	9.40	< 25	NR	1	0–0.01	0–0%
VL 0466	Chinese cabbage, type pak-choi (all commodities)	highest utilisation: raw	0.03	0.044	1.000	CN	gen pop, > 1 yrs	38811	601.64	1548.4	3	2b	0.01–1.49	0–0%
VL 0467	Chinese cabbage, type pe-tsai	highest utilisation: Total	0.03	0.044	1.000	CN	gen pop, > 1 yrs	49993	668.38	1500.0	3	2b	0.01–1.66	0–1%

Annex 4

MYCLOBUTANIL (181)
Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

IESTI
Maximum %ARfD: 10% women

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
	(all commodities)													
VL 0469	Chicory leaves (sugar loaf) (all commodities)	highest utilisation: raw	0	0.044	1.000	DE	Women, 14–50 yrs	40	113.90	280.5	3	2b	0.07–0.22	0–0%
VL 0470	Corn salad (lambs lettuce) (all commodities)	highest utilisation: Total	0	0.044	1.000	FR	gen pop, > 3 yrs	–	83.52	7.8	NR	1	0.03–0.07	0–0%
VL 0472	Cress, garden (all commodities)	highest utilisation: Total	0	0.044	1.000	AU	gen pop, > 2 yrs	1	23.42	15.0	NR	1	0–0.02	0–0%
VL 0473	Watercress (all commodities)	highest utilisation: raw	0	0.044	1.000	BR	gen pop, > 10 yrs	97	90.92	254.6	3	2b	0.16–0.19	0–0%
VL 0474	Dandelion leaves (all commodities)	highest utilisation: raw	0	0.044	1.000	DE	Women, 14–50 yrs	1	10.00	35.0	3	2b	0.02–0.02	0–0%
VL 0476	Endive (all commodities)	highest utilisation: Total	0.03	0.044	1.000	FR	gen pop, > 3 yrs	–	280.40	413.2	3	2b	0.02–0.71	0–0%
VL 0478	Indian mustard (Amsoi) (all commodities)	highest utilisation: raw	0	0.044	1.000	NL	gen pop, > 1 yrs	E	49.88	250.0	3	2b	0.1–0.1	0–0%
VL 0479	Japanese greens: Chrysanthemum leaves (Chrysanthemum spp) (all commodities)	highest utilisation: raw	0	0.044	1.000	CN	gen pop, > 1 yrs	993	332.67	< 25	NR	1	0.09–0.28	0–0%
VL 0480	Kale (borecole, collards) (all commodities)	highest utilisation: Total	0.03	0.044	1.000	DE	Women, 14–50 yrs	31	366.40	672.0	3	2b	0.06–0.72	0–0%
VL 0481	Komatsuna	Total		0.044	1.000	JP	Gen pop, > 1 yrs	2594	147.90	< 25	NR	1	0.1190	0.0%
VL 0482	Lettuce, head (all commodities)	highest utilisation: cooked/boiled	0.03	0.044	1.000	NL	gen pop, > 1 yrs	2	220.89	227.0	3	2b	0.02–0.44	0–0%
VL 0483	Lettuce, leaf (all commodities)	highest utilisation: Total	0.03	0.044	1.000	CN	gen pop, > 1 yrs	6033	451.93	305.4	3	2a	0.02–0.88	0–0%
VL 0485	Mustard greens (all commodities)	highest utilisation: raw	0.03	0.044	1.000	CN	gen pop, > 1 yrs	9701	554.45	244.8	3	2a	0.13–0.86	0–0%
VL 0492	Purslane (all commodities)	highest utilisation: cooked/boiled	0	0.044	1.000	NL	gen pop, > 1 yrs	5	271.23	< 25	NR	1	0.05–0.18	0–0%
VL 0494	Radish leaves	Total		0.044	1.000	–	–	–	–	–	–	–	–	–
VL 0495	Rape greens (all commodities)	highest utilisation: cooked/boiled	0	0.044	1.000	JP	Gen pop, > 1 yrs	533	147.90	34.0	3	2a	0.17–0.17	0–0%

Annex 4

MYCLOBUTANIL (181)
Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

IESTI
Maximum %ARfD: 10% women

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
VL 0496	Rucola (arrugula, rocket salad, roquette) (all commodities)	highest utilisation: Total	0	0.044	1.000	AU	gen pop, > 2 yrs	10	157.33	212.8	3	2b	0.05–0.31	0–0%
VL 0501	Sowthistle (all commodities)	highest utilisation: raw	0	0.044	1.000	CN	gen pop, > 1 yrs	1187	592.49	–	–	–	0–0	0–0%
VL 0502	Spinach (all commodities)	highest utilisation: Total	0.03	0.044	1.000	DE	Women, 14–50 yrs	309	189.72	197.8	3	2b	0–0.37	0–0%
VL 0505	Taro leaves (all commodities)	highest utilisation: raw	0	0.044	1.000	NL	gen pop, > 1 yrs	E	77.78	85.8	3	2b	0.16–0.16	0–0%
VL 0506	Turnip greens (Namenia, Tendergreen) (all commodities)	highest utilisation: Total	0	0.044	1.000	US	gen pop, all ages	–	247.07	35.0	3	2a	0.06–0.21	0–0%
VL 0507	Kangkung (water spinach) (all commodities)	highest utilisation: raw	0	0.044	1.000	CN	Gen pop, > 1 yrs	3256	554.45	85.8	3	2a	0.6–0.6	0–0%
VL 0510	Cos lettuce (all commodities)	highest utilisation: Total	0.03	0.044	1.000	AU	gen pop, > 2 yrs	54	242.90	457.2	3	2b	0.02–0.48	0–0%
–	Perilla leaves (i.e. sesame leaves) (all commodities)	highest utilisation: pickled/salted	0.03	0.044	1.000	CN	gen pop, > 1 yrs	183	175.21	NR	NR	3	0.1–0.1	0–0%
VP 0061	Beans, green, with pods, raw: beans except broad bean & soya bean (i.e. immature seeds + pods) (Phaseolus spp) (all commodities)	highest utilisation: cooked/boiled	0.22	0.49	1.000	CN	gen pop, > 1 yrs	2695	424.46	19.4	NR	1	0.14–3.91	0–1%
VR 0463	Cassava (Manioc, Tapioca) (all commodities)	highest utilisation: cooked/boiled (without peel)	0.039	0.052	1.000	NL	gen pop, > 1 yrs	E	249.97	356.0	3	2b	0.03–0.59	0–0%
VR 0469	Chicory, roots (all commodities)	highest utilisation: Total	0.039	0.052	1.000	AU	gen pop, > 2 yrs	175	26.16	48.0	3	2b	0.01–0.06	0–0%
VR 0494	Radish (all commodities)	highest utilisation: raw with skin	0.039	0.052	1.000	DE	Women, 14–50 yrs	1665	96.22	172.0	3	2b	0–0.22	0–0%
VR 0497	Swede (rutabaga) (all commodities)	highest utilisation: cooked/boiled (without peel)	0.039	0.052	1.000	NL	gen pop, > 1 yrs	41	325.05	617.0	3	2b	0–0.77	0–0%
VR 0498	Salsify (Oyster plant)	highest utilisation:	0.039	0.052	1.000	NL	gen pop, > 1	E	200.03	57.0	3	2a	0–0.25	0–0%

Annex 4

MYCLOBUTANIL (181)
Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

IESTI
Maximum %ARfD: 10% women

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
	(all commodities)	cooked/boiled (without peel)					yrs							
VR 0504	Tannia (tanier, yautia) (all commodities)	highest utilisation: cooked/boiled (without peel)	0.039	0.052	1.000	NL	gen pop, > 1 yrs	E	249.97	170.0	3	2a	0.01–0.47	0–0%
VR 0505	Taro (dasheen, eddoe) (all commodities)	highest utilisation: cooked/boiled (without peel)	0	0.052	1.000	CN	gen pop, > 1 yrs	3948	564.91	667.8	3	2b	1.66–1.66	1–1%
VR 0506	Turnip, garden (all commodities)	highest utilisation: cooked/boiled (without peel)	0.039	0.052	1.000	NL	gen pop, > 1 yrs	E	200.03	176.0	3	2a	0.17–0.44	0–0%
VR 0508	Sweet potato (all commodities)	highest utilisation: cooked/boiled (without peel)	0.039	0.052	1.000	BR	Gen pop, > 10 yrs	880	600.00	145.4	3	2a	0.27–0.72	0–0%
VR 0573	Arrowroot (all commodities)	highest utilisation: starch	0.039	0.052	1.000	NL	gen pop, > 1 yrs	E	18.42	NR	NR	3	0.01–0.01	0–0%
VR 0574	Beetroot (all commodities)	highest utilisation: cooked/boiled (without peel)	0.039	0.052	1.000	NL	gen pop, > 1 yrs	202	365.58	182.4	3	2a	0.02–0.58	0–0%
VR 0575	Burdock, greater or edible	Total		0.052	1.000	JP	Gen pop, > 1 yrs	4146	96.90	–	–	–	–	–
VR 0577	Carrot (all commodities)	highest utilisation: cooked/boiled (with skin)	0.039	0.052	1.000	NL	gen pop, > 1 yrs	673	406.78	270.0	3	2a	0–0.75	0–0%
VR 0578	Celeriac (all commodities)	highest utilisation: cooked/boiled (without skin)	0.039	0.052	1.000	NL	gen pop, > 1 yrs	23	239.12	437.0	3	2b	0–0.57	0–0%
VR 0583	Horseradish (all commodities)	highest utilisation: Total	0	0.052	1.000	DE	Women, 14–50 yrs	9	21.20	154.0	3	2b	0–0.05	0–0%
VR 0585	Jerusalem artichoke (all commodities)	highest utilisation: cooked/boiled (without peel)	0	0.052	1.000	NL	gen pop, > 1 yrs	E	200.03	56.0	3	2a	0.02–0.25	0–0%
VR 0587	parsley, turnip-rooted (all commodities)	highest utilisation: dried (slab)	0.039	0.052	5.000	CN	gen pop, > 1 yrs	11981	38.02	NR	NR	3	0.14–0.14	0–0%
VR 0588	Parsnip (all commodities)	highest utilisation: cooked/boiled (without skin)	0.039	0.052	1.000	NL	gen pop, > 1 yrs	E	200.03	227.0	3	2b	0.12–0.47	0–0%
VR 0589	Potato	highest utilisation:	0.039	0.052	1.000	AU	gen pop, > 2	4773	649.06	123.0	3	2a	0.01–0.69	0–0%

Annex 4

MYCLOBUTANIL (181)
Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

IESTI
Maximum %ARfD: 10% women

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
	(all commodities)	boiled\microwaved (without peel)					yrs							
VR 0590	Radish, black (all commodities)	highest utilisation: raw without skin	0.039	0.052	1.000	NL	gen pop, > 1 yrs	76	96.59	180.3	3	2b	0–0.23	0–0%
VR 0591	Radish, Japanese (Chinese radish, Daikon) (all commodities)	highest utilisation: raw without skin	0.039	0.052	1.000	CN	gen pop, > 1 yrs	22418	513.04	1000.0	3	2b	0–1.5	0–1%
VR 0596	Sugar beet (all commodities)	highest utilisation: sugar	0.039	0.052	1.000	FR	Gen pop, > 3 yrs	–	495.40	NR	NR	3	0.22–0.37	0–0%
VR 0600	Yams (all commodities)	highest utilisation: Total	0	0.052	1.000	CN	Gen pop, > 1 yrs	681	441.46	810.0	3	2b	0.38–1.29	0–0%
–	Lotus root (all commodities)	highest utilisation: cooked/boiled without peel	0	0.052	1.000	TH	gen pop, > 3 yrs	2212	273.05	< 25	NR	1	0.1–0.27	0–0%
DH 1100	Hops, dry (all commodities)	highest utilisation: beer	0.023–1.52	0	1.000	NL	gen pop, > 1 yrs	E	2368.80	NR	NR	3	0.14–0.83	0–0%
MM 0095	Meat from mammals other than marine mammals	Total	NA	NA	1.000	BR	Gen pop, > 10 yrs	2980	665.00	NR	NR	1	NA	0.0%
MM 0095	Meat from mammals other than marine mammals: 20% as fat	Total		0	1.000	BR	Gen pop, > 10 yrs	2980	133.00	NR	NR	1	0.0000	0.0%
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	Total		0	1.000	BR	Gen pop, > 10 yrs	2980	532.00	NR	NR	1	0.0000	0.0%
MF 0100	Mammalian fats (except milk fats)	Total		0	1.000	AU	gen pop, > 2 yrs	3047	92.59	NR	NR	1	0.0000	0.0%
MO 0105	Edible offal (mammalian)	Total		0	1.000	US	gen pop, all ages	–	787.80	NR	NR	1	0.0000	0.0%
ML 0106	Milks	Total	0		1.000	AU	gen pop, > 2 yrs	13566	3235.19	NR	NR	3	0.0000	0.0%
PM 0110	Poultry meat	Total	NA	NA	1.000	FR	gen pop, > 3 yrs	1	576.95	NR	NR	1	NA	0.0%
PM 0110	Poultry meat: 10% as fat	Total		0	1.000	FR	gen pop, > 3 yrs	1	57.69	NR	NR	1	0.0000	0.0%
PM 0110	Poultry meat: 90% as	Total		0	1.000	FR	gen pop, > 3	1	519.25	NR	NR	1	0.0000	0.0%

Annex 4

MYCLOBUTANIL (181)
Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

IESTI
Maximum %ARfD: 10% women

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
	muscle						yrs							
PF 0111	Poultry, fats (all commodities)	highest utilisation: Total	0	0	1.000	DE	Women, 14–50 yrs	10	15.00	NR	NR	1	0–0	0–0%
PE 0112	Eggs	Total		0	1.000	FR	gen pop, > 3 yrs	1	382.80	NR	NR	1	0.0000	0.0%

Annex 4

PHOSMET (103)
Acute RfD= 0.2 mg/kg bw (200 µg/kg bw)

IESTI
Maximum %ARfD:

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Varia-bility factor	Case	IESTI µg/kg bw/day	3% all % acute RfD rounded	2% gen pop % acute RfD rounded	3% child % acute RfD rounded
FB 0265	Cranberry (all commodities)	highest utilisation: Total	.845	.91	1.000	AU	Child, 2-16 yrs	103	279.66	1.8	NR	1	.01 - 6.7	0% - 3%	0% - 2%	0% - 3%

PHOSMET (103)
Acute RfD= 0.2 mg/kg bw (200 µg/kg bw)

IESTI
Maximum %ARfD:

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	2% women % acute RfD rounded
FB 0265	Cranberry (all commodities)	highest utilisation: Total	.845	.91	1.000	US	gen pop, all ages	-	229.45	1.8	NR	1	.01 - 3.21	0% - 2%

Annex 4

PROPAMOCARB (148)
Acute RfD=0 2 mg/kg bw (2000 µg/kg bw)

IESTI
Maximum %ARfD:

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	20% all % acute RfD rounded	20% gen pop % acute RfD rounded	20% child % acute RfD rounded
VA 0384	Leek (all commodities)	highest utilisation: raw	2.5	15	1.000	CN	Child, 1–6 yrs	401	149.40	175.5	3	2b	0.26–416.67	0–20%	0–9%	0–20%
VA 0385	Onion, bulb (all commodities)	highest utilisation: raw without skin	0.05	1.4	1.000	JP	Child, 1–6 yrs	748	102.00	244.4	3	2b	0.02–26.12	0–1%	0–1%	0–1%
VB 0041	Cabbage, head (all commodities)	highest utilisation: raw	0.195	0.36	1.000	CN	Child, 1–6 yrs	287	255.54	1402.5	3	2b	0.14–17.1	0–1%	0–0%	0–1%
VB 0400	Broccoli (all commodities)	highest utilisation: cooked/boiled	0.29	1.7	1.000	NL	toddler, 8–20 m	125	160.73	286.0	3	2b	0.53–80.37	0–4%	0–1%	0–4%
VB 0402	Brussels sprouts (all commodities)	highest utilisation: cooked/boiled	0.47	1.3	1.000	NL	toddler, 8–20 m	11	103.77	8.0	NR	1	0.02–13.23	0–1%	0–0%	0–1%
VB 0404	Cauliflower (all commodities)	highest utilisation: cooked/boiled	0.035	.82	1.000	NL	toddler, 8–20 m	110	141.99	749.0	3	2b	0.01–34.25	0–2%	0–1%	0–2%
VL 0480	Kale (borecole, collards) (all commodities)	highest utilisation: Total	4	11.8	1.000	DE	Gen pop, 14–80 yrs	123	669.80	672.0	3	2b	7.6–310.47	0–20%	0–20%	2–10%
PM 0110	Poultry meat	Total	NA	NA	1.000	CN	Child, 1–6 yrs	175	347.00	NR	NR	1	NA	0.0%	0.0%	0.0%
PM 0110	Poultry meat: 10% as fat	Total		0.001	1.000	CN	Child, 1–6 yrs	175	34.70	NR	NR	1	0.0022	0.0%	0.0%	0.0%
PM 0110	Poultry meat: 90% as muscle	Total		0.003	1.000	CN	Child, 1–6 yrs	175	312.30	NR	NR	1	0.0581	0.0%	0.0%	0.0%
PF 0111	Poultry, fats (all commodities)	highest utilisation: Total	0	.001–.006	1.000	CN	Gen pop, > 1 yrs	421	345.63	NR	NR	1	0–0.04	0–0%	0–0%	0–0%
PE 0112	Eggs	Total		0.005	1.000	CN	Child, 1–6 yrs	136	195.82	NR	NR	1	0.0607	0.0%	0.0%	0.0%

Annex 4

PROPICONAZOLE (160)
Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

IESTI
Maximum %ARfD:

														8% all	8% gen pop	8% child
Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
MM 0095	Meat from mammals other than marine mammals	Total		0.085	1.000	CN	Child, 1-6 yrs	302	264.84	NR	NR	1	1.3952	0.0%	0.0%	0.0%
MF 0100	Mammalian fats (except milk fats)	Total		0.115	1.000	FR	Child, 3-6 yrs	0	64.80	NR	NR	1	0.3943	0.0%	0.0%	0.0%
MO 0105	Edible offal (mammalian)	Total		1.97	1.000	US	Child, 1-6 yrs	-	186.60	NR	NR	1	24.5068	8.0%	8.0%	8.0%
ML 0106	Milks	Total	0.035		1.000	NL	toddler, 8-20 m	1882	1060.67	NR	NR	3	3.6395	1.0%	1.0%	1.0%

Annex 4

PROTHIOCONAZOLE (232)
Acute RfD= 1 mg/kg bw (1000 µg/kg bw)

IESTI
Maximum %ARfD:

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	1% all % acute RfD rounded	1% gen pop % acute RfD rounded	1% child % acute RfD rounded
FB 0020	Blueberries (all commodities)	highest utilisation: raw with skin	0.52	0.87	1.000	DE	Gen pop, 14-80 yrs	70	388.00	1.8	NR	1	0.08 - 4.42	0% - 0%	0% - 0%	0% - 0%
FB 0021	Currants, red, black, white (all commodities)	highest utilisation: juice (pasteurised)	0.52	0.87	1.000	NL	Child, 2-6 yrs	E	525.80	NR	NR	3	0.34 - 14.86	0% - 1%	0% - 1%	0% - 1%
FB 0268	Gooseberries (all commodities)	highest utilisation: raw with skin	0.52	0.87	1.000	DE	Women, 14-50 yrs	10	338.10	<25	NR	1	0.1 - 4.36	0% - 0%	0% - 0%	0% - 0%
FB 0273	Rose hips (all commodities)	highest utilisation: jam (incl jelly)	0.52	0.87	1.000	NL	Child, 2-6 yrs	E	55.70	NR	NR	3	0.29 - 1.57	0% - 0%	0% - 0%	0% - 0%
FB 0265	Cranberry (all commodities)	highest utilisation: Total	0.025	0.9	1.000	AU	Child, 2-16 yrs	103	279.66	1.8	NR	1	0 - 6.62	0% - 1%	0% - 0%	0% - 1%
VC 0046	Melons, except watermelon (all commodities)	highest utilisation: Total	0.045	0.15	1.000	FR	Child, 3-6 yrs	-	358.11	420.0	3	2b	0 - 8.53	0% - 1%	0% - 1%	0% - 1%
VC 0421	Balsam pear (Bitter cucumber, Bitter gourd, Bitter melon) (all commodities)	highest utilisation: raw without peel		0.15	1.000	CN	Gen pop, > 1 yrs	1387	400.21	607.5	3	2b	1.09 - 3.38	0% - 0%	0% - 0%	0% - 0%
VC 0422	Bottle gourd (Cucuzzi) (all commodities)	highest utilisation: raw with skin		0.15	1.000	CN	Gen pop, > 1 yrs	519	453.00	325.0	3	2a	3.11 - 3.11	0% - 0%	0% - 0%	0% - 0%
VC 0423	Chayote (Christophine) (all commodities)	highest utilisation: raw with skin		0.15	1.000	CN	Child, 1-6 yrs	124	284.75	197.4	3	2a	1.67 - 6.32	0% - 1%	0% - 0%	0% - 1%
VC 0424	Cucumber (all commodities)	highest utilisation: raw with skin	0.045	0.15	1.000	CN	Child, 1-6 yrs	340	212.11	458.1	3	2b	0.02 - 5.92	0% - 1%	0% - 0%	0% - 1%
VC 0425	Gherkin (all commodities)	highest utilisation: raw with skin	0.045	0.15	1.000	JP	Child, 1-6 yrs	484	91.80	54.5	3	2a	0.03 - 1.79	0% - 0%	0% - 0%	0% - 0%
VC 0427	Loofah, Angled (Sinkwa, Sinkwa towel gourd) (all commodities)	highest utilisation: raw without peel		0.15	1.000	TH	Child, 3-6 yrs	759	129.62	133.0	3	2b	3.41 - 3.41	0% - 0%	0% - 0%	0% - 0%
VC 0428	Loofah, Smooth (all commodities)	highest utilisation: raw without peel		0.15	1.000	CN	Child, 1-6 yrs	196	296.64	133.0	3	2a	5.23 - 5.23	1% - 1%	0% - 0%	1% - 1%
VC 0429	Pumpkins (all commodities)	highest utilisation: raw without peel	0.045	0.15	1.000	CN	Child, 1-6 yrs	561	322.71	1851.8	3	2b	0.07 - 9	0% - 1%	0% - 1%	0% - 1%
VC 0430	Snake gourd	highest utilisation:		0.15	1.000	TH	Child, 3-6	759	129.62	133.0	3	2b	3.41 - 3.41	0% - 0%	0% - 0%	0% - 0%

Annex 4

PROTHIOCONAZOLE (232)
Acute RfD= 1 mg/kg bw (1000 µg/kg bw)

IESTI
Maximum %ARfD:

														1% all	1% gen pop	1% child
Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
	(all commodities)	raw without peel					yrs									
VC 0431	Squash, summer (courgette, marrow, zucchetti, zucchini) (all commodities)	highest utilisation: Total	0.045	0.15	1.000	FR	Child, 3-6 yrs	-	148.84	270.0	3	2b	0.03 - 3.54	0% - 0%	0% - 0%	0% - 0%
VO 0447	Sweet corn (corn-on-the-cob) (all commodities)	highest utilisation: cooked/boiled	0.018	0.018	1.000	TH	Child, 3-6 yrs	1383	196.99	191.1	3	2a	0.01 - 0.61	0% - 0%	0% - 0%	0% - 0%
VP 0541	Soya bean, green, without pods, raw (i.e. immature seeds only) (Glycine max) (all commodities)	highest utilisation: cooked/boiled	0.05	0.12	1.000	CN	Child, 1-6 yrs	195	260.25	<25	NR	1	0 - 1.94	0% - 0%	0% - 0%	0% - 0%
VR 0589	Potato (all commodities)	highest utilisation: Total	0.01	0.01	1.000	ZA	Child, 1-5 yrs	-	299.62	216.0	3	2a	0.01 - 0.52	0% - 0%	0% - 0%	0% - 0%
GC 0645	Maize (corn) (all commodities)	highest utilisation: Total	0.0028 - 0.01		1.000	CN	Child, 1-6 yrs	166	524.69	<25	NR	3	0 - 0.33	0% - 0%	0% - 0%	0% - 0%
GC 0656	Popcorn (i.e. maize destined for popcorn preparation) (all commodities)	highest utilisation: Total	0.018		1.000	AU	Child, 2-6 yrs	120	73.67	<25	NR	3	0.06 - 0.07	0% - 0%	0% - 0%	0% - 0%

Annex 4

PROTHIOCONAZOLE (232)
Acute RfD= 0.01 mg/kg bw (10 µg/kg bw)

IESTI
Maximum %ARfD: 100% women

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Coun try	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Varia-bility factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
FB 0020	Blueberries (all commodities)	highest utilisation: raw with skin	0.52	0.87	1.000	DE	Gen pop, 14-80 yrs	70	388.00	1.8	NR	1	0.03 - 4.42	0% - 40%
FB 0021	Currants, red, black, white	Total		0.87	1.000	AU	Gen pop, > 2 yrs	322	797.60	14.9	NR	1	10.3569	100.0%
FB 0021	Currants, red, black, white (all other commodities)	highest utilisation: juice (pasteurised)	0.52	0.87	1.000	NL	gen pop, > 1 yrs	34	838.95	NR	NR	3	0.23 - 6.63	2 - 70%
FB 0268	Gooseberries (all commodities)	highest utilisation: raw with skin	0.52	0.87	1.000	DE	Women, 14-50 yrs	10	338.10	<25	NR	1	0.04 - 4.36	0% - 40%
FB 0273	Rose hips (all commodities)	highest utilisation: jam (incl jelly)	0.52	0.87	1.000	NL	gen pop, > 1 yrs	E	82.32	NR	NR	3	0.15 - 0.65	2% - 7%
FB 0265	Cranberry (all commodities)	highest utilisation: Total	0.025	0.9	1.000	US	gen pop, all ages	-	229.45	1.8	NR	1	0 - 3.18	0% - 30%
VC 0046	Melons, except watermelon (all commodities)	highest utilisation: Total	0.045	0.15	1.000	FR	gen pop, > 3 yrs	-	626.40	420.0	3	2a	0 - 4.21	0% - 40%
VC 0421	Balsam pear (Bitter cucumber, Bitter gourd, Bitter melon) (all commodities)	highest utilisation: raw without peel		0.15	1.000	CN	gen pop, > 1 yrs	1387	400.21	607.5	3	2b	1.09 - 3.38	10% - 30%
VC 0422	Bottle gourd (Cucuzzi) (all commodities)	highest utilisation: raw with skin		0.15	1.000	CN	gen pop, > 1 yrs	519	453.00	325.0	3	2a	3.11 - 3.11	30% - 30%
VC 0423	Chayote (Christophine) (all commodities)	highest utilisation: raw with skin		0.15	1.000	CN	gen pop, > 1 yrs	1437	574.81	197.4	3	2a	1.11 - 2.73	10% - 30%
VC 0424	Cucumber (all commodities)	highest utilisation: Total	0.045	0.15	1.000	FR	gen pop, > 3 yrs	-	313.20	360.0	3	2b	0.01 - 2.7	0% - 30%
VC 0425	Gherkin (all commodities)	highest utilisation: pickled&preserved	0.045	0.15	1.000	BR	Gen pop, > 10 yrs	70	500.00	54.5	3	2a	0.01 - 1.41	0% - 10%
VC 0427	Loofah, Angled (Sinkwa, Sinkwa towel gourd) (all commodities)	highest utilisation: raw without peel		0.15	1.000	TH	gen pop, > 3 yrs	8306	215.23	133.0	3	2a	1.35 - 1.35	10% - 10%
VC 0428	Loofah, Smooth (all commodities)	highest utilisation: raw without peel		0.15	1.000	CN	gen pop, > 1 yrs	3930	521.84	133.0	3	2a	2.22 - 2.22	20% - 20%
VC 0429	Pumpkins (all commodities)	highest utilisation: raw without peel	0.045	0.15	1.000	CN	Gen pop, > 1 yrs	10137	701.51	1851.8	3	2b	0.03 - 5.93	0% - 60%

Annex 4

PROTHIOCONAZOLE (232) IESTI
Acute RfD= 0.01 mg/kg bw (10 µg/kg bw) Maximum %ARfD: 100% women

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Coun try	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Varia-bility factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
VC 0430	Snake gourd (all commodities)	highest utilisation: raw without peel		0.15	1.000	TH	gen pop, > 3 yrs	8306	215.23	133.0	3	2a	1.35 - 1.35	10% - 10%
VC 0431	Squash, summer (courgette, marrow, zucchetti, zucchini) (all commodities)	highest utilisation: cooked/boiled with skin (incl consump tion without skin)	0.045	0.15	1.000	NL	gen pop, > 1 yrs	100	348.81	289.0	3	2a	0.02 - 2.11	0% - 20%
VO 0447	Sweet corn (corn-on-the-cob) (all commodities)	highest utilisation: cooked/boiled	0.018	0.018	1.000	TH	Gen pop, > 3 yrs	10010	383.35	191.1	3	2a	0 - 0.26	0% - 3%
VP 0541	Soya bean, green, without pods, raw (i.e. immature seeds only) (Glycine max) (all commodities)	highest utilisation: cooked/boiled	0.05	0.12	1.000	CN	gen pop, > 1 yrs	4215	395.25	<25	NR	1	0 - 0.89	0% - 9%
VR 0589	Potato (all commodities)	highest utilisation: boiled\microwaved (without peel)	0.01	0.01	1.000	AU	gen pop, > 2 yrs	4773	649.06	123.0	3	2a	0 - 0.13	0% - 1%
GC 0645	Maize (corn) (all commodities)	highest utilisation: grits/polenta (dry)	0.0028 - 0.01		1.000	BR	Gen pop, > 10 yrs	1142	600.00	NR	NR	3	0 - 0.09	0% - 1%
GC 0656	Popcorn (i.e. maize destined for popcorn preparation) (all commodities)	highest utilisation: popcorn	0.018		1.000	NL	gen pop, > 1 yrs	51	204.70	<25	NR	3	0.03 - 0.06	0% - 1%

Annex 4

PYRACLOSTROBIN (210)

Acute RfD= 0.05 mg/kg bw (50 µg/kg bw)

IESTI Maximum %ARfD:

40% all

30% gen pop

40% child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
FS 0013	Cherries (all commodities)	highest utilisation: raw		1.57	1.000	DE	Child. 2-4 yrs	24	187.50	7.2	NR	1	1.79 - 18.23	4% - 40%	4% - 30%	10% - 40%
FS 0302	Jujube, Chinese	Total		0.4	1.000	CN	Gen pop. > 1 yrs	1328	286.17	-	-	-	-	-	-	-
FS 0014	Plums (all commodities)	highest utilisation: raw with peel (incl consumption without peel)		0.4	1.000	TH	Child. 3-6 yrs	11	376.88	93.0	3	2a	1.56 - 13.17	3% - 30%	1% - 10%	3% - 30%
FS 0240	Apricot (all commodities)	highest utilisation: raw with peel (incl consumption without peel)		0.13	1.000	AU	Gen pop. > 2 yrs	77	1056.90	54.5	3	2a	0.96 - 2.26	2% - 5%	1% - 5%	2% - 5%
FS 2237	Japanese apricot (ume)	Total		0.13	1.000	JP	Child. 1-6 yrs	25	25.50	<25	NR	1	0.1831	0.0%	0.0%	0.0%
FS 0245	Nectarine (all commodities)	highest utilisation: raw with peel (incl consumption without peel)		0.13	1.000	NL	toddler. 8-20 m	6	183.60	131.0	3	2a	0.15 - 5.68	0% - 10%	0% - 4%	3% - 10%
FS 0247	Peach (all commodities)	highest utilisation: raw with peel (incl consumption without peel)		0.13	1.000	JP	Child. 1-6 yrs	76	306.00	255.0	3	2a	0.71 - 6.84	1% - 10%	1% - 5%	1% - 10%

Annex 4

SEDAXANE (259)
Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

IESTI
Maximum %ARfD:

															0% all	0% gen pop	0% child
Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
VR 0589	Potato (all commodities)	highest utilisation: Total	0.01	0.018	1.000	ZA	Child, 1-5 yrs	-	299.62	216.0	3	2a	0.01 - 0.93	0% - 0%	0% - 0%	0% - 0%

Annex 4

SULFOXAFLOR (252)
Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

IESTI
Maximum %ARfD:

														9% all	5% gen pop	9% child
Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
FC 0303	Kumquats	Total		0.17	1.000	AU	Gen pop, > 2 yrs	2	17.95	12.0	NR	1	0.0456	0.0%	0.0%	–
FC 0204	Lemon (all commodities)	highest utilisation: Total	0.038	0.17	1.000	FR	child, 3–6 yrs	–	58.15	64.0	3	2b	0.02–1.57	0–1%	0–0%	0–1%
FC 0205	Lime (all commodities)	highest utilisation: Total	0.038	0.17	1.000	AU	Gen pop, > 2 yrs	579	259.21	49.0	3	2a	0–0.91	0–0%	0–0%	0–0%
FC 0003	Mandarins (incl mandarin-like hybrids) (all commodities)	highest utilisation: raw, without peel	0.26	0.44	1.000	CN	Child, 1–6 yrs	151	586.75	124.3	3	2a	0.02–22.78	0–8%	0–3%	0–8%
FC 0004	Oranges, sweet, sour (incl orange-like hybrids) (all commodities)	highest utilisation: Total	0.036–0.26	0.44–2.46	1.000	AU	Child, 2–6 yrs	1735	800.83	155.8	3	2a	0.17–25.76	0–9%	0–5%	0–9%
FC 0005	Pomelo and Grapefruits (incl Shaddock-like hybrids, among others Grapefruit) (all commodities)	highest utilisation: raw, without peel	0.0125	0.066	1.000	DE	Child, 2–4 yrs	12	358.60	178.5	3	2a	0–2.92	0–1%	0–1%	0–1%
FP 0226	Apple (all commodities)	highest utilisation: Total	0.027–0.067	0.23	1.000	US	Child, 1–6 yrs	–	624.45	127.0	3	2a	0.2–13.47	0–4%	0–2%	0–4%
FP 0227	Crab-apple (all commodities)	highest utilisation: raw with peel	0	0.23	1.000	CN	Gen pop, > 1 yrs	204	488.33	–	–	–	0–0	0–0%	0–0%	0–0%
FP 0228	Loquat (Japanese medlar) (all commodities)	highest utilisation: raw without peel	0	0.23	1.000	JP	Gen pop, > 1 yrs	113	326.40	49.0	3	2a	0.41–1.8	0–1%	0–1%	0–0%
FP 0229	Medlar	Total		0.23	1.000	–	–	–	–	–	–	–	–	–	–	–

Annex 4

SULFOXAFLOR (252)
Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

IESTI
Maximum %ARfD:

														9% all	5% gen pop	9% child
Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
FP 0230	Pear (all commodities)	highest utilisation: raw with peel (incl consumption without peel)	0.067	0.23	1.000	CN	Child, 1–6 yrs	413	418.33	255.0	3	2a	0.02–13.23	0–4%	0–2%	0–4%
FT 0307	Persimmon, Japanese (all commodities)	highest utilisation: raw with peel (incl consumption without peel)	0	0.23	1.000	TH	Child, 3–6 yrs	20	264.88	227.5	3	2a	3.38–9.68	1–3%	1–2%	3–3%
FP 0231	Quince (all commodities)	highest utilisation: Total	0.067	0.23	1.000	DE	child, 2–4 yrs	16	26.30	301.2	3	2b	0–1.12	0–0%	0–0%	0–0%
FS 0013	Cherries (all commodities)	highest utilisation: raw	0.27–0.37	1.24–6.32	1.000	DE	Child, 2–4 yrs	24	187.50	7.2	NR	1	0.11–14.4	0–5%	0–4%	0–5%
FS 0302	Jujube, Chinese	Total		0.26	1.000	CN	Gen pop, > 1 yrs	1328	286.17	–	–	–	–	–	–	–
FS 0014	Plums (all commodities)	highest utilisation: raw with peel (incl consumption without peel)	0.038	0.26	1.000	TH	Child, 3–6 yrs	11	376.88	93.0	3	2a	0.02–8.56	0–3%	0–1%	0–3%
FS 0240	Apricot (all commodities)	highest utilisation: raw with peel (incl consumption without peel)	0.061	0.2	1.000	AU	Gen pop, > 2 yrs	77	1056.90	54.5	3	2a	0.03–3.48	0–1%	0–1%	0–1%
FS 2237	Japanese apricot (ume)	Total		0.2	1.000	JP	Child, 1–6 yrs	25	25.50	<25	NR	1	0.2818	0.0%	0.0%	0.0%
FS 0245	Nectarine (all commodities)	highest utilisation: raw with peel (incl consumption without peel)	0.061	0.2	1.000	NL	toddler, 8–20 m	6	183.60	131.0	3	2a	0.03–8.74	0–3%	0–1%	0–3%
FS 0247	Peach (all commodities)	highest utilisation: raw with peel (incl consumption without peel)	0.061	0.2	1.000	JP	Child, 1–6 yrs	76	306.00	255.0	3	2a	0.03–10.53	0–4%	0–1%	0–4%
MF 0100	Mammalian fats (except milk fats)	Total		0.073	1.000	FR	Child, 3–6 yrs	0	64.80	NR	NR	1	0.2503	0.0%	0.0%	0.0%
PF 0111	Poultry, fats	Total		0.021	1.000	US	gen pop, all	–	42.90	NR	NR	1	0.0139	0.0%	0.0%	0.0%

Annex 4

SULFOXAFLOR (252)
Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

IESTI
Maximum %ARfD:

														9% all	5% gen pop	9% child
Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
							ages									

Annex 4

THIAMETHOXAM (245)
Acute RfD= 1 mg/kg bw (1000 µg/kg bw)

IESTI
Maximum %ARfD:

														1% all	0% gen pop	1% child
Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Coun try	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Varia-bility factor	Case	IESTI µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
FI 0326	Avocado (all commodities)	highest utilisation: Total	0	0.3	1.000	AU	Child, 2-6 yrs	182	229.90	171.4	3	2a	4.62 - 9.04	0% - 1%	0% - 0%	0% - 1%
FI 0345	Mango (all commodities)	highest utilisation: raw without peel	0.02 - 0.18	0.07 - 0.65	1.000	NL	Toddler, 8-20 m	11	160.43	288.8	3	2b	0.01 - 3.3	0% - 0%	0% - 0%	0% - 0%
VP 0061	Beans, green, with pods, raw: beans except broad bean & soya bean (i.e. immature seeds + pods) (Phaseolus spp) (all commodities)	highest utilisation: canned/preserved	0.08	0.18	1.000	NL	Toddler, 8-20 m	E	127.90	2.3	NR	1	0.12 - 2.26	0% - 0%	0% - 0%	0% - 0%
HH 0738	Mints (all commodities)	highest utilisation: raw	0.34	0.86	1.000	DE	Child, 2-4 yrs	138	11.10	<25	NR	1	0.04 - 0.59	0% - 0%	0% - 0%	0% - 0%
DH 1100	Hops, dry (all commodities)	highest utilisation: Total	0.028	0	1.000	DE	Gen pop, 14-80 yrs	5866	8.50	<25	NR	3	0 - 0	0% - 0%	0% - 0%	0% - 0%

Annex 4

TRIADIMENOL (168)
Acute RfD = 0,08 mg/kg bw (80 µg/kg bw)

IESTI
Maximum %ARfD:

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	10% all % acute RfD rounded	5% gen pop % acute RfD rounded	10% child % acute RfD rounded
FB 0269	Grapes (all commodities)	highest utilisation: raw with skin	0,01–0,011	0,13	1,000	CN	Child, 1–6 yrs	232	366,72	636,6	3	2b	0,19–8,86	0%–10%	0%–5%	0%–10%

Annex 4

TRIFORINE (116)
Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

IESTI
Maximum %ARfD:

															5% all	2% gen pop	5% child
Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
FB 0020	Blueberries	Total		0.018	1.000	FI	adult 25-74 yrs	290	206.36	1.8	NR	1	0.0504	0.0%	0.0%	0.0%
VO 0440	Egg plant (aubergine)	Total		0.39	1.000	AU	Child, 2-6 yrs	29	128.25	317.9	3	2b	7.8975	3.0%	2.0%	3.0%
VO 0448	Tomato (all commodities)	highest utilisation: raw with peel	0.001 - 0.35	0.4	1.000	CN	Child, 1-6 yrs	1117	263.76	180.0	3	2a	0.01 - 15.46	0% - 5%	0% - 2%	0% - 5%

ANNEX 5: REPORTS AND OTHER DOCUMENTS RESULTING FROM PREVIOUS JOINT MEETINGS OF THE FAO PANEL OF EXPERTS ON PESTICIDE RESIDUES IN FOOD AND THE ENVIRONMENT AND THE WHO CORE ASSESSMENT GROUP ON PESTICIDE RESIDUES

1. Principles governing consumer safety in relation to pesticide residues. Report of a meeting of a WHO Expert Committee on Pesticide Residues held jointly with the FAO Panel of Experts on the Use of Pesticides in Agriculture. FAO Plant Production and Protection Division Report, No. PL/1961/11; WHO Technical Report Series, No. 240, 1962.

2. Evaluation of the toxicity of pesticide residues in food. Report of a Joint Meeting of the FAO Committee on Pesticides in Agriculture and the WHO Expert Committee on Pesticide Residues. FAO Meeting Report, No. PL/1963/13; WHO/Food Add./23, 1964.

3. Evaluation of the toxicity of pesticide residues in food. Report of the Second Joint Meeting of the FAO Committee on Pesticides in Agriculture and the WHO Expert Committee on Pesticide Residues. FAO Meeting Report, No. PL/1965/10; WHO/Food Add./26.65, 1965.

4. Evaluation of the toxicity of pesticide residues in food. FAO Meeting Report, No. PL/1965/10/1; WHO/Food Add./27.65, 1965.

5. Evaluation of the hazards to consumers resulting from the use of fumigants in the protection of food. FAO Meeting Report, No. PL/1965/10/2; WHO/Food Add./28.65, 1965.

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ANNEX 6: LIVESTOCK DIETARY BURDEN

AMINOCYCLOPYRACHLOR (272)

ESTIMATED MAXIMUM DIETARY BURDEN														
BEEF CATTLE														MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Grass forage (fresh)	AF/AS	81	HR	100	81.00		50	100	5		40.5	81	4.05	
Grass hay	AF/AS	60	HR	100	60.00	15			35	9			21	
Total						15	50	100	40	9	40.5	81	25.05	

DAIRY CATTLE														MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Grass forage (fresh)	AF/AS	81	HR	100	81.00	45	60	100	10	36.45	48.6	81	8.1	
Grass hay	AF/AS	60	HR	100	60.00				60				36	
Total						45	60	100	70	36.45	48.6	81	44.1	

POULTRY LAYER													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Grass forage (fresh)	AF/AS	81	HR	100	81.00		10				8.1		
Total							10				8.1		

ESTIMATED MEAN DIETARY BURDEN													
BEEF CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Grass forage (fresh)	AF/AS	74.5	STMR/STMR-P	100	74.50		50	100	5		37.25	74.5	3.725
Grass hay	AF/AS	47.5	STMR/STMR-P	100	47.50	15			35	7.125			16.63
Total						15	50	100	40	7.125	37.25	74.5	20.35

DAIRY CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Grass forage (fresh)	AF/AS	74.5	STMR/STMR-P	100	74.50	45	60	100	10	33.525	44.7	74.5	7.45
Grass hay	AF/AS	47.5	STMR/STMR-P	100	47.50	0			60	0			28.5
Total						45	60	100	70	33.525	44.7	74.5	35.95

Annex 6

POULTRY LAYER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Grass forage (fresh)	AF/AS	74.5	STMR/STMR-P	100	74.50		10				7.45		
Total							10				7.45		

Annex 6

BENZOVINDIFLUPYR (261)

ESTIMATED MAXIMUM DIETARY BURDEN													
BEEF CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Soybean hulls	SM	0.1	STMR	90	0.11	15	10			0.017	0.011		
Soybean okara	SM	0.004	STMR	20	0.02				40				0.008
Soybean seed	VD	0.01	STMR	89	0.01	5	10	20	15	0.001	0.001	0.0022	0.002
Soybean meal	SM	0.004	STMR	92	0.00		10		25		0		0.001
Total						20	30	20	80	0.017	0.013	0.0022	0.011

DAIRY CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Soybean hulls	SM	0.1	STMR	90	0.11		10				0.011		
Soybean okara	SM	0.004	STMR	20	0.02				20				0.0040
Soybean seed	VD	0.01	STMR	89	0.01	10	10	20	10	0.0011	0.001	0.0022	0.0011
Soybean meal	SM	0.004	STMR	92	0.00	10	15	15	40	04	0.001	0.0007	0.0017
Total						20	35	35	70	0.0016	0.013	0.0029	0.0069

POULTRY BROILER													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Soybean hulls	SM	0.1	STMR	90	0.11		10	5			0.011	0.0056	
Soybean seed	VD	0.01	STMR	89	0.01	20	20	15		0.0022	0.002	0.0017	
Soybean meal	SM	0.004	STMR	92	0.00	25	30	20	35	0.0011	0.001	0.0009	0.0015
Total						45	60	40	35	0.0033	0.015	0.0081	0.0015

POULTRY LAYER													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Soybean hulls	SM	0.1	STMR	90	0.11		5	5			0.0056	0.0056	
Soybean seed	VD	0.01	STMR	89	0.01	20	15	15		0.0022	0.0017	0.0017	
Soybean meal	SM	0.004	STMR	92	0.00	25	20	20	30	0.0011	0.0009	0.0009	0.0013
Total						45	40	40	30	0.0033	0.0081	0.0081	0.0013

Annex 6

CHLORANTRANILIPROLE (230)

ESTIMATED MAXIMUM DIETARY BURDEN

BEEF CATTLE MAX

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Alfalfa hay	AL	38	HR	100	38.00	15		80	10	5.7		30.4	3.8
Alfalfa forage	AL	28.7	HR	100	28.70		70	20			20.09	5.74	
Corn, field stover	AF/AS	12	HR	83	14.46	15	25			2.168675	3.614		
Cotton gin byproducts	AM/AV	13	HR	90	14.44	5				0.722222			
Corn, field forage/silage	AF/AS	5.7	HR	40	14.25		5				0.713		
Corn, field asp gr fn	CM/CF	0.34	STMR	85	0.40	5				0.02			
Rice bran/pollard	CM/CF	0.196	STMR	90	0.22	10			20	0.021778			0.044
Rice grain	GC	0.115	STMR	88	0.13	20				0.026136			
Cotton hulls	SM	0.1029	STMR	90	0.11	10				0.011433			
Potato culls	VR	0.004	HR	20	0.02	20				0.004			
Barley grain	GC	0.01	STMR	88	0.01				70				0.008
Total						100	100	100	100	8.674244	24.42	36.14	3.852

DAIRY CATTLE MAX

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Alfalfa hay	AL	38	HR	100	38.00	20	40	60	25	7.6	15.2	22.8	9.5
Bean vines	AL	6.4	HR	35	18.29			10				1.829	
Corn, field stover	AF/AS	12	HR	83	14.46	15	20	30		2.168675	2.892	4.337	
Corn, field forage/silage	AF/AS	5.7	HR	40	14.25	30	40		50	4.275	5.7		7.125
Almond hulls	AM/AV	0.735	STMR	90	0.82	10				0.081667			
Apple pomace, wet	AB	0.805	STMR	100	0.81	10				0.0805			
Carrot culls	VR	0.046	HR	12	0.38	10				0.038333			
Rice bran/pollard	CM/CF	0.196	STMR	90	0.22	5			10	0.010889			0.022
Barley grain	GC	0.01	STMR	88	0.01				15				0.002
Total						100	100	100	100	14.25506	23.79	28.97	16.65

POULTRY BROILER MAX

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Alfalfa forage	AL	28.7	HR	100	28.70				5				1.435
Carrot culls	VR	0.046	HR	12	0.38		10				0.038		
Rice bran/pollard	CM/CF	0.196	STMR	90	0.22	10	10	20	5	0.021778	0.022	0.044	0.011
Rice grain	GC	0.115	STMR	88	0.13	20		50		0.026136		0.065	
Cotton meal	SM	0.0368	STMR	89	0.04	20	5	10		0.00827	0.002	0.004	
Bean seed	VD	0.02	STMR	88	0.02		20	20			0.005	0.005	
Pea seed	VD	0.02	STMR	90	0.02	20				0.004444			
Barley grain	GC	0.01	STMR	88	0.01	30	55			0.003409	0.006		
Corn, field grain	GC	0.01	STMR	88	0.01				70				0.008
Total						100	100	100	80	0.064037	0.073	0.118	1.454

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POULTRY LAYER													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Pea vines	AL	6.4	HR	25	25.60		10				2.56		
Corn, field stover	AF/AS	12	HR	83	14.46		10				1.446		
Cabbage heads, leaves	AM/AV	1.1	HR	15	7.33		5				0.367		
Carrot culls	VR	0.046	HR	12	0.38		10				0.038		
Rice bran/pollard	CM/CF	0.196	STMR	90	0.22	10	5	20	20	0.021778	0.011	0.044	0.044
Rice grain	GC	0.115	STMR	88	0.13	20		50		0.026136		0.065	
Cotton meal	SM	0.0368	STMR	89	0.04	20	5	10		0.00827	0.002	0.004	
Bean seed	VD	0.02	STMR	88	0.02		20	20			0.005	0.005	
Pea seed	VD	0.02	STMR	90	0.02	20				0.004444			
Barley grain	GC	0.01	STMR	88	0.01	30	35			0.003409	0.004		
Corn, field grain	GC	0.01	STMR	88	0.01				80				0.009
Total						100	100	100	100	0.064037	4.432	0.118	0.053

ESTIMATED MEAN DIETARY BURDEN													
BEEF CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Pea vines	AL	4.4	STMR/STMR-P	25	17.60		20	60			3.52	10.56	
Alfalfa hay	AL	17.3	STMR/STMR-P	100	17.30	15		20	10	2.595		3.46	1.73
Alfalfa forage	AL	17	STMR/STMR-P	100	17.00		50	20			8.5	3.4	
Corn, field forage/silage	AF/AS	2.4	STMR/STMR-P	40	6.00	15	30			0.9	1.8		
Cotton gin byproducts	AM/AV	4.1	STMR/STMR-P	90	4.56	5				0.227778			
Corn, field asp gr fn	CM/CF	0.34	STMR/STMR-P	85	0.40	5				0.02			
Rice bran/pollard	CM/CF	0.196	STMR/STMR-P	90	0.22	10			20	0.021778			0.0436
Rice grain	GC	0.115	STMR/STMR-P	88	0.13	20				0.026136			
Cotton hulls	SM	0.1029	STMR/STMR-P	90	0.11	10				0.011433			
Potato culls	VR	0.003	STMR/STMR-P	20	0.02	20				0.003			
Barley grain	GC	0.01	STMR/STMR-P	88	0.01				70				0.008
Total						100	100	100	100	3.805125	13.82	17.42	1.7815

DAIRY CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Pea vines	AL	4.4	STMR/STMR-P	25	17.60	10	20	40		1.76	3.52	7.04	
Alfalfa hay	AL	17.3	STMR/STMR-P	100	17.30	10	20	20	25	1.73	3.46	3.46	4.325
Bean vines	AL	4.4	STMR/STMR-P	35	12.57	0		10		0		1.257	
Corn, field forage/silage	AF/AS	2.4	STMR/STMR-P	40	6.00	45	60	30	50	2.7	3.6	1.8	3
Almond hulls	AM/AV	0.735	STMR/STMR-P	90	0.82	10				0.081667			
Apple pomace, wet	AB	0.805	STMR/STMR-P	100	0.81	10				0.0805			
Rice bran/pollard	CM/CF	0.196	STMR/STMR-P	90	0.22	15			10	0.032667			0.0218
Barley grain	GC	0.01	STMR/STMR-P	88	0.01	0			15	0			0.0017
Total						100	100	100	100	6.384833	10.58	13.56	7.3485

Annex 6

POULTRY BROILER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Alfalfa forage	AL	17	STMR/STMR-P	100	17.00				5				0.85
Rice bran/pollard	CM/CF	0.196	STMR/STMR-P	90	0.22	10	10	20	5	0.021778	0.022	0.044	0.0109
Carrot culls	VR	0.02	STMR/STMR-P	12	0.17		10				0.017		
Rice grain	GC	0.115	STMR/STMR-P	88	0.13	20		50		0.026136		0.065	
Cotton meal	SM	0.0368	STMR/STMR-P	89	0.04	20	5	10		0.00827	0.002	0.004	
Bean seed	VD	0.02	STMR/STMR-P	88	0.02		20	20			0.005	0.005	
Pea seed	VD	0.02	STMR/STMR-P	90	0.02	20				0.004444			
Barley grain	GC	0.01	STMR/STMR-P	88	0.01	30	55			0.003409	0.006		
Corn, field grain	GC	0.01	STMR/STMR-P	88	0.01				70				0.008
Total						100	100	100	80	0.064037	0.051	0.118	0.8688

POULTRY LAYER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Pea vines	AL	4.4	STMR/STMR-P	25	17.60		10				1.76		
Corn, field forage/silage	AF/AS	2.4	STMR/STMR-P	40	6.00		10				0.6		
Cabbage heads, leaves	AM/AV	0.385	STMR/STMR-P	15	2.57		5				0.128		
Rice bran/pollard	CM/CF	0.196	STMR/STMR-P	90	0.22	10	5	20	20	0.021778	0.011	0.044	0.0436
Carrot culls	VR	0.02	STMR/STMR-P	12	0.17		10				0.017		
Rice grain	GC	0.115	STMR/STMR-P	88	0.13	20		50		0.026136		0.065	
Cotton meal	SM	0.0368	STMR/STMR-P	89	0.04	20	5	10		0.00827	0.002	0.004	
Bean seed	VD	0.02	STMR/STMR-P	88	0.02		20	20			0.005	0.005	
Pea seed	VD	0.02	STMR/STMR-P	90	0.02	20				0.004444			
Barley grain	GC	0.01	STMR/STMR-P	88	0.01	30	35			0.003409	0.004		
Corn, field grain	GC	0.01	STMR/STMR-P	88	0.01				80				0.0091
Total						100	100	100	100	0.064037	2.526	0.118	0.0526

Annex 6

CLOTHIANIDIN (238)

ESTIMATED MAXIMUM DIETARY BURDEN

BEEF CATTLE MAX

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Grape pomace, wet	AB	0.23	STMR	15	1.53			20				0.31	
Swede roots	VR	0.15	HR	10	1.50		40	10			0.6	0.15	
Sugarcane tops	AM/AV	0.27	HR	25	1.08			50				0.54	
Potato culls	VR	0.15	HR	20	0.75	30				0.225			
Cabbage heads, leaves	AM/AV	0.08	HR	15	0.53		20				0.107		
Bean vines	AL	0.11	HR	35	0.31			20				0.063	
Wheat forage	AF/AS	0.06	HR	25	0.24		20				0.048		
Pea vines	AL	0.05	HR	25	0.20		20				0.04		
Rice grain	GC	0.145	STMR	88	0.16	20				0.033			
Barley hay	AF/AS	0.14	HR	88	0.16	15				0.024			
Grass forage (fresh)	AF/AS	0.025	HR	25	0.10				5				0.005
Beet, sugar molasses	DM	0.064	STMR	75	0.09	10				0.0085			
Beet, sugar dried pulp	AB	0.034	STMR	88	0.04	15			5	0.0058			0.002
Corn, field grain	GC	0.02	STMR	88	0.02	10			75	0.0023			0.017
Soybean seed	VD	0.02	STMR	89	0.02				15				0.003
Total						100	100	100	100	0.30	0.80	1.1	0.027

DAIRY CATTLE MAX

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Grape pomace, wet	AB	0.23	STMR	15	1.53			20				0.31	
Swede roots	VR	0.15	HR	10	1.50		20	10			0.3	0.15	
Carrot culls	VR	0.15	HR	12	1.25	10				0.13			
Sugarcane tops	AM/AV	0.27	HR	25	1.08			25				0.27	
Potato culls	VR	0.15	HR	20	0.75		10				0.075		
Cabbage heads, leaves	AM/AV	0.08	HR	15	0.53		20				0.11		
Bean vines	AL	0.11	HR	35	0.31		20	45			0.063	0.14	
Wheat forage	AF/AS	0.06	HR	25	0.24	20	20			0.048	0.048		
Pea vines	AL	0.05	HR	25	0.20	10				0.02			
Barley forage	AF/AS	0.05	HR	30	0.17		10				0.017		
Cowpea forage	AL	0.05	HR	30	0.17	10				0.017			
Rice grain	GC	0.145	STMR	88	0.16	20				0.033			
Lespedeza forage	AL	0.025	HR	22	0.11	20				0.023			
Grass forage (fresh)	AF/AS	0.025	HR	25	0.10	10				0.01			
Rice whole crop silage	AF/AS	0.025	HR	40	0.06				55				0.034
Beet, sugar dried pulp	AB	0.034	STMR	88	0.04				40				0.015
Corn. field grain	GC	0.02	STMR	88	0.02				5				0.001
Total						100	100	100	100	0.28	0.61	0.87	0.051

POULTRY BROILER MAX

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Swede roots	VR	0.15	HR	10	1.50		10				0.15		

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POULTRY BROILER													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Corn, field grain	GC	0.02	STMR	88	0.02	55	60		70	0.013	0.014		0.016
Pea seed	VD	0.02	STMR	90	0.02	20				0.0044			
Cotton meal	SM	0.002	STMR	89	0.00	5				0.0001			
Total						80	70		70	0.017	0.16		0.016

POULTRY LAYER													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Swede roots	VR	0.15	HR	10	1.50		10				0.15		
Rice grain	GC	0.145	STMR	88	0.16	20		50		0.033		0.082	
Rape forage	AM/AV	0.027	HR	30	0.09		5				0.005		
Bean seed	VD	0.02	STMR	88	0.02		20	50			0.005	0.011	
Corn, field grain	GC	0.02	STMR	88	0.02	55	35		80	0.013	0.008		0.018
Pea seed	VD	0.02	STMR	90	0.02	20				0.0044			
Cotton meal	SM	0.002	STMR	89	0.00	5				0.0001			
Total						100	70	100	80	0.050	0.17	0.094	0.018

ESTIMATED MEAN DIETARY BURDEN													
BEEF CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Grape pomace, wet	AB	0.23	STMR/STMR-P	15	1.53			20				0.31	
Sugarcane tops	AM/AV	0.19	STMR/STMR-P	25	0.76			50				0.38	
Bean vines	AL	0.075	STMR/STMR-P	35	0.21			30				0.064	
Cabbage heads, leaves	AM/AV	0.03	STMR/STMR-P	15	0.20		20				0.04		
Pea vines	AL	0.05	STMR/STMR-P	25	0.20		20				0.04		
Cowpea forage	AL	0.05	STMR/STMR-P	30	0.17		15				0.025		
Carrot culls	VR	0.02	STMR/STMR-P	12	0.17		15				0.025		
Rice grain	GC	0.145	STMR/STMR-P	88	0.16	20				0.0330			
Barley forage	AF/AS	0.04	STMR/STMR-P	30	0.13		30				0.04		
Potato culls	VR	0.02	STMR/STMR-P	20	0.10	30				0.0300			
Beet, sugar molasses	DM	0.064	STMR/STMR-P	75	0.09	10				0.0085			
Barley hay	AF/AS	0.05	STMR/STMR-P	88	0.06	15				0.0085			
Grass forage (fresh)	AF/AS	0.01	STMR/STMR-P	25	0.04				5				0.002
Beet, sugar dried pulp	AB	0.034	STMR/STMR-P	88	0.04	15			5	0.0058			0.002
Corn, field grain	GC	0.02	STMR/STMR-P	88	0.02	10			75	0.0023			0.017
Soybean seed	VD	0.02	STMR/STMR-P	89	0.02				15				0.003
Total						100	100	100	100	0.088	0.17	0.75	0.024

Annex 6

DAIRY CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Grape pomace, wet	AB	0.23	STMR/STMR-P	15	1.53		0	20			0	0.307	
Sugarcane tops	AM/AV	0.19	STMR/STMR-P	25	0.76	0		25		0		0.19	
Bean vines	AL	0.075	STMR/STMR-P	35	0.21	0	20	55		0	0.043	0.118	
Cabbage heads, leaves	AM/AV	0.03	STMR/STMR-P	15	0.20	0	20			0	0.04		
Pea vines	AL	0.05	STMR/STMR-P	25	0.20	10				0.02			
Cowpea forage	AL	0.05	STMR/STMR-P	30	0.17	10	15			0.0167	0.025		
Carrot culls	VR	0.02	STMR/STMR-P	12	0.17	10	15			0.0167	0.025		
Rice grain	GC	0.145	STMR/STMR-P	88	0.16	20				0.0330			
Barley forage	AF/AS	0.04	STMR/STMR-P	30	0.13	0	30			0	0.04		
Beet, sugar molasses	DM	0.064	STMR/STMR-P	75	0.09	10				0.0085			
Rape forage	AM/AV	0.02	STMR/STMR-P	30	0.07	10				0.0067			
Apple pomace, wet	AB	0.024	STMR/STMR-P	40	0.06	10				0.006			
Barley hay	AF/AS	0.05	STMR/STMR-P	88	0.06	20				0.0114			
Grass forage (fresh)	AF/AS	0.01	STMR/STMR-P	25	0.04	0			10	0			0.004
Beet, sugar dried pulp	AB	0.034	STMR/STMR-P	88	0.04	0			40	0			0.0155
Sorghum, grain forage	AF/AS	0.01	STMR/STMR-P	35	0.03	0			30	0			0.0086
Corn, field forage/silage	AF/AS	0.01	STMR/STMR-P	40	0.03	0			10	0			0.0025
Rice whole crop silage	AF/AS	0.01	STMR/STMR-P	40	0.03	0			5	0			0.0013
Corn, field grain	GC	0.02	STMR/STMR-P	88	0.02	0			5	0			0.0011
Total						100	100	100	100	0.12	0.17	0.61	0.033

POULTRY BROILER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Carrot culls	VR	0.02	STMR/STMR-P	12	0.17		10				0.017		
Corn, field grain	GC	0.02	STMR/STMR-P	88	0.02	55	60		70	0.013	0.014		0.016
Pea seed	VD	0.02	STMR/STMR-P	90	0.02	20				0.0044			
Cotton meal	SM	0.002	STMR/STMR-P	89	0.00	5				0.0001			
Total						80	70		70	0.017	0.030		0.016

POULTRY LAYER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Cabbage heads, leaves	AM/AV	0.03	STMR/STMR-P	15	0.20		5				0.01		
Barley straw	AF/AS	0.05	STMR/STMR-P	89	0.06		5				0.003		
Cassava/tapioca roots	VR	0.02	STMR/STMR-P	37	0.05		5				0.003		
Grass forage (fresh)	AF/AS	0.01	STMR/STMR-P	25	0.04		5				0.002		
Bean seed	VD	0.02	STMR/STMR-P	88	0.02		20	50			0.005	0.011	

Annex 6

POULTRY LAYER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Corn, field grain	GC	0.02	STMR/STMR-P	88	0.02	55	35		80	0.0125	0.008		0.018
Pea seed	VD	0.02	STMR/STMR-P	90	0.02	20				0.004444			
Cotton meal	SM	0.002	STMR/STMR-P	89	0.00	5				0.000112			
Total						80	75	50	80	0.017	0.03	0.011	0.018

Annex 6

CYFLUMETOFEN (273)

ESTIMATED MAXIMUM DIETARY BURDEN

BEEF CATTLE MAX

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Grape pomace, wet	AB	0.64	STMR	15	4.27			20				0.853	
Almond hulls	AM/AV	0.67	STMR	90	0.74			10				0.074	
Apple pomace, wet	AB	0.18	STMR	40	0.45		20				0.09		
Citrus dried pulp	AB	0.06	STMR	91	0.07	10		10		0.007		0.007	
Total						10	20	40		0.007	0.09	0.934	

DAIRY CATTLE MAX

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Grape pomace, wet	AB	0.64	STMR	15	4.27			20				0.853	
Almond hulls	AM/AV	0.67	STMR	90	0.74	10		10		0.074		0.074	
Apple pomace, wet	AB	0.18	STMR	40	0.45	10	10			0.045	0.045		
Citrus dried pulp	AB	0.06	STMR	91	0.07		10	10			0.007	0.007	
Total						20	20	40		0.119	0.052	0.934	

ESTIMATED MEAN DIETARY BURDEN

BEEF CATTLE MEAN

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Grape pomace, wet	AB	0.64	STMR/STMR-P	15	4.27			20				0.853	
Almond hulls	AM/AV	0.67	STMR/STMR-P	90	0.74			10				0.074	
Apple pomace, wet	AB	0.18	STMR/STMR-P	40	0.45		20				0.09		
Citrus dried pulp	AB	0.06	STMR/STMR-P	91	0.07	10		10		0.007		0.007	
Total						10	20	40		0.007	0.09	0.934	

DAIRY CATTLE MEAN

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Grape pomace, wet	AB	0.64	STMR/STMR-P	15	4.27		0	20			0	0.853	
Almond hulls	AM/AV	0.67	STMR/STMR-P	90	0.74	10		10		0.074		0.074	
Apple pomace, wet	AB	0.18	STMR/STMR-P	40	0.45	10	10			0.045	0.045		
Citrus dried pulp	AB	0.06	STMR/STMR-P	91	0.07	0	10	10		0	0.007	0.007	
Total						20	20	40		0.119	0.052	0.934	

Annex 6

DICHLOBENIL (274)

ESTIMATED MAXIMUM DIETARY BURDEN

BEEF CATTLE MAX

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Lespedeza forage	AL	0.1	HR	22	0.45			20				0.091	
Pea vines	AL	0.1	HR	25	0.40		20	40			0.08	0.16	
Clover forage	AL	0.1	HR	30	0.33		10	40			0.033	0.133	
Cowpea forage	AL	0.1	HR	30	0.33		5				0.017		
Alfalfa forage	AL	0.1	HR	35	0.29		35				0.1		
Millet hay	AF/AS	0.24	HR	85	0.28	10				0.028235			
Barley hay	AF/AS	0.24	HR	88	0.27	5				0.013636			
Triticale hay	AF/AS	0.24	HR	88	0.27		20				0.055		
Cabbage heads, leaves	AM/AV	0.04	HR	15	0.27		10				0.027		
Lespedeza hay	AL	0.1	HR	88	0.11	15				0.017045			
Alfalfa hay	AL	0.1	HR	89	0.11				10				0.011
Sorghum, grain	GC	0.01	STMR	86	0.01	40			35	0.004651			0.004
Barley grain	GC	0.01	STMR	88	0.01	10			35	0.001136			0.004
Total						**80**	100	100	80	0.064705	0.311	0.384	0.019

DAIRY CATTLE MAX

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Lespedeza forage	AL	0.1	HR	22	0.45	40		60		0.181818		0.273	
Bean vines	AL	0.1	HR	35	0.29			10				0.029	
Millet hay	AF/AS	0.24	HR	85	0.28	20		30		0.056471		0.085	
Cabbage heads, leaves	AM/AV	0.04	HR	15	0.27		20				0.053		
Barley forage	AF/AS	0.02	HR	30	0.07		30				0.02		
Sorghum, grain forage	AF/AS	0.02	HR	35	0.06	20			40	0.011429			0.023
Corn, field forage/silage	AF/AS	0.02	HR	40	0.05	5	30		10	0.0025	0.015		0.005
Sorghum, grain	GC	0.01	STMR	86	0.01	15	20		30	0.001744	0.002		0.003
Total						100	100	100	80	0.253962	0.091	0.386	0.031

POULTRY BROILER MAX

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Alfalfa forage	AL	0.1	HR	35	0.29				5				0.014
Sorghum, grain grain	GC	0.01	STMR	86	0.01	75	70	70	65	0.008721	0.008	0.008	0.008
Bean seed	VD	0.01	STMR	88	0.01		20	30			0.002	0.003	
Total						75	90	100	70	0.008721	0.01	0.012	0.022

POULTRY LAYER MAX

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Lespedeza forage	AL	0.1	HR	22	0.45		10				0.045		
Millet hay	AF/AS	0.24	HR	85	0.28		10				0.028		
Cabbage heads, leaves	AM/AV	0.04	HR	15	0.27		5				0.013		

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POULTRY LAYER													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Sorghum, grain	GC	0.01	STMR	86	0.01	75	70	70	55	0.008721	0.008	0.008	0.006
Barley grain	GC	0.01	STMR	88	0.01		5				6E-04		
Bean seed	VD	0.01	STMR	88	0.01			30				0.003	
Total						75	100	100	55	0.008721	0.096	0.012	0.006

ESTIMATED MEAN DIETARY BURDEN													
BEEF CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Lespedeza forage	AL	0.02	STMR/STMR-P	22	0.09			20				0.018	
Pea vines	AL	0.02	STMR/STMR-P	25	0.08		20	40			0.016	0.032	
Cabbage heads, leaves	AM/AV	0.01	STMR/STMR-P	15	0.07		20				0.013		
Clover forage	AL	0.02	STMR/STMR-P	30	0.07		10	40			0.007	0.027	
Alfalfa forage	AL	0.02	STMR/STMR-P	35	0.06		40				0.023		
Millet hay	AF/AS	0.04	STMR/STMR-P	85	0.05	10				0.004706			
Barley hay	AF/AS	0.04	STMR/STMR-P	88	0.05	5				0.002273			
Triticale hay	AF/AS	0.04	STMR/STMR-P	88	0.05		10				0.005		
Lespedeza hay	AL	0.02	STMR/STMR-P	88	0.02	15				0.003409			
Alfalfa hay	AL	0.02	STMR/STMR-P	89	0.02				10				0.0022
Total						30	100	100	10	0.010388	0.063	0.077	0.0022

DAIRY CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Lespedeza forage	AL	0.02	STMR/STMR-P	22	0.09	40	0	60		0.036364	0	0.055	
Cabbage heads, leaves	AM/AV	0.01	STMR/STMR-P	15	0.07	0	20			0	0.013		
Bean vines	AL	0.02	STMR/STMR-P	35	0.06	0		10		0		0.006	
Tomato pomace, wet	AB	0.01	STMR/STMR-P	20	0.05	0		10		0		0.005	
Millet hay	AF/AS	0.04	STMR/STMR-P	85	0.05	20		20		0.009412		0.009	
Oat hay	AF/AS	0.04	STMR/STMR-P	90	0.04	10				0.004444			
Barley forage	AF/AS	0.01	STMR/STMR-P	30	0.03	0	30			0	0.01		
Sorghum, grain forage	AF/AS	0.01	STMR/STMR-P	35	0.03	10			40	0.002857			0.0114
Corn, field forage/silage	AF/AS	0.01	STMR/STMR-P	40	0.03	5	30		10	0.00125	0.008		0.0025
Total						85	80	100	50	0.054327	0.031	0.075	0.0139

POULTRY BROILER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Alfalfa forage	AL	0.02	STMR/STMR-P	35	0.06				5				0.0029
Total									5				0.0029

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POULTRY LAYER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Lespedeza forage	AL	0.02	STMR/STMR-P	22	0.09		10				0.009		
Cabbage heads, leaves	AM/AV	0.01	STMR/STMR-P	15	0.07		5				0.003		
Millet hay	AF/AS	0.04	STMR/STMR-P	85	0.05		10				0.005		
Total							25				0.017		

Annex 6

DIMETHOMORPH (225)

ESTIMATED MAXIMUM DIETARY BURDEN													
BEEF CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Pea vines	AL	9.53	HR	25	38.12		20	60			7.624		
Cabbage heads, leaves	AM/AV	4.6	HR	15	30.67		20				6.133		
Grape pomace, wet	AB	1.95	STMR	15	13.00			20				2.6	
Potato process waste	AB	0.12	STMR	12	1.00	30	40			0.3	0.4		
Potato culls	VR	0.05	HR	20	0.25	30	20	10		0.075	0.05	0.025	
Bean seed	VD	0.06	STMR	88	0.07			10				0.007	
Rape meal	SM	0.04	STMR	88	0.05				15				0.007
Total						60	100	100	15	0.375	14.21	2.63	0.007

DAIRY CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Pea vines	AL	9.53	HR	25	38.12	10	20	40		3.812	7.624		
Cabbage heads, leaves	AM/AV	4.6	HR	15	30.67		20				6.133		
Grape pomace, wet	AB	1.95	STMR	15	13.00			20				2.6	
Potato process waste	AB	0.12	STMR	12	1.00	10	30			0.1	0.3		
Potato culls	VR	0.05	HR	20	0.25	10	30	10		0.025	0.075	0.025	
Bean seed	VD	0.05	STMR	88	0.06			15				0.009	
Rape meal	SM	0.04	STMR	88	0.05			15	25			0.007	0.011
Total						30	100	100	25	3.937	14.13	2.64	0.011

POULTRY BROILER													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Potato culls	VR	0.05	HR	20	0.25		10				0.025		
Potato dried pulp	AB	0.12	STMR	88	0.14		20				0.027		
Bean seed	VD	0.05	STMR	88	0.06		20	70			0.011	0.04	
Rape meal	SM	0.04	STMR	88	0.05			5	5			0.002	0.002
Pea seed	VD	0.01	STMR	90	0.01	20				0.002222			
Total						20	50	75	5	0.002222	0.064	0.042	0.002

POULTRY LAYER													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Pea vines	AL	9.53	HR	25	38.12		10				3.812		
Cabbage heads, leaves	AM/AV	4.6	HR	15	30.67		5				1.533		
Potato culls	VR	0.05	HR	20	0.25		10				0.025		
Potato dried pulp	AB	0.12	STMR	88	0.14		15				0.02		
Bean seed	VD	0.05	STMR	88	0.06		20	70			0.011	0.04	
Rape meal	SM	0.04	STMR	88	0.05		10	5	15		0.005	0.002	0.007
Pea seed	VD	0.01	STMR	90	0.01	20				0.002222			
Total						20	70	75	15	0.002222	5.407	0.042	0.007

Annex 6

ESTIMATED MEAN DIETARY BURDEN													
BEEF CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Grape pomace, wet	AB	1.95	STMR/STMR-P	15	13.00			20				2.6	
Cabbage heads, leaves	AM/AV	1.1	STMR/STMR-P	15	7.33		20				1.467		
Pea vines	AL	1.55	STMR/STMR-P	25	6.20		20	60			1.24		
Potato process waste	AB	0.12	STMR/STMR-P	12	1.00	30	40			0.3	0.4		
Potato culls	VR	0.02	STMR/STMR-P	20	0.10	30	20	10		0.03	0.02	0.01	
Bean seed	VD	0.05	STMR/STMR-P	88	0.06			10				0.006	
Rape meal	SM	0.04	STMR/STMR-P	88	0.05				15				0.007
Total						60	100	100	15	0.33	3.127	2.616	0.007

DAIRY CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Grape pomace, wet	AB	1.95	STMR/STMR-P	15	13.00		0	20			0	2.6	
Cabbage heads, leaves	AM/AV	1.1	STMR/STMR-P	15	7.33	0	20			0	1.467		
Pea vines	AL	1.55	STMR/STMR-P	25	6.20	10	20	40		0.62	1.24		
Potato process waste	AB	0.12	STMR/STMR-P	12	1.00	10	30			0.1	0.3		
Potato culls	VR	0.02	STMR/STMR-P	20	0.10	10	30	10		0.01	0.03	0.01	
Bean seed	VD	0.05	STMR/STMR-P	88	0.06	0		15		0		0.009	
Rape meal	SM	0.04	STMR/STMR-P	88	0.05	0		15	25	0		0.007	0.011
Total						30	100	100	25	0.73	3.037	2.625	0.011

POULTRY BROILER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Potato dried pulp	AB	0.12	STMR/STMR-P	88	0.14		20				0.027		
Potato culls	VR	0.02	STMR/STMR-P	20	0.10		10				0.01		
Bean seed	VD	0.05	STMR/STMR-P	88	0.06		20	70			0.011	0.04	
Rape meal	SM	0.04	STMR/STMR-P	88	0.05			5	5			0.002	0.002
Pea seed	VD	0.01	STMR/STMR-P	90	0.01	20				0.002222			
Total						20	50	75	5	0.002222	0.049	0.042	0.002

POULTRY LAYER												MEAN	
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Cabbage heads, leaves	AM/AV	1.1	STMR/STMR-P	15	7.33		5				0.367		
Pea vines	AL	1.55	STMR/STMR-P	25	6.20		10				0.62		
Potato dried pulp	AB	0.12	STMR/STMR-P	88	0.14		15				0.02		
Potato culls	VR	0.02	STMR/STMR-P	20	0.10		10				0.01		
Bean seed	VD	0.05	STMR/STMR-P	88	0.06		20	70			0.011	0.04	

Annex 6

POULTRY LAYER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Rape meal	SM	0.04	STMR/STMR-P	88	0.05		10	5	15		0.005	0.002	0.007
Pea seed	VD	0.01	STMR/STMR-P	90	0.01	20				0.0022			
Total						20	70	75	15	0.0022	1.033	0.042	0.007

Annex 6

EMAMECTIN BENZOATE (247)

ESTIMATED MAXIMUM DIETARY BURDEN

BEEF CATTLE MAX

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Bean vines	AL	0.09	HR	35	0.27			60.00				0.16	
Almond hulls	AM/AV	0.04	STMR	90	0.04			10				0.00	
Apple pomace, wet	AB	0.01	STMR	40	0.01		20	20			0.00	0.00	
Cotton undelinted seed	SO	0.00	STMR	88	0.00			10				0.00	
Cotton hulls	SM	0.00	STMR	90	0.00	10				0.00			
Total						10	20	100		0.00	0.00	0.17	

DAIRY CATTLE MAX

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Bean vines	AL	0.09	HR	35	0.27		20	70			0.05	0.19	
Almond hulls	AM/AV	0.04	STMR	90	0.04	10		10		0.00		0.00	
Apple pomace, wet	AB	0.01	STMR	40	0.01	10	10	10		0.00	0.00	0.00	
Cotton undelinted seed	SO	0.00	STMR	88	0.00	10	10	10		0.00	0.00	0.00	
Total						30.00	40	100		0.01	0.05	0.19	

ESTIMATED MEAN DIETARY BURDEN

BEEF CATTLE MEAN

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Almond hulls	AM/AV	0.04	STMR	90	0.04			10				0.00	
Bean vines	AL	0.01	STMR	35	0.02			60.00				0.01	
Apple pomace, wet	AB	0.01	STMR	40	0.01		20	20			0.00	0.00	
Cotton undelinted seed	SO	0.00	STMR	88	0.00			10				0.00	
Cotton hulls	SM	0.00	STMR	90	0.00	10				0.00			
Total						10	20	100		0.00	0.00	0.02	

DAIRY CATTLE MEAN

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Almond hulls	AM/AV	0.04	STMR	90	0.04	10	0.00	10		0.00	0.00	0.00	

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DAIRY CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Bean vines	AL	0.01	STMR	35	0.02	0.00	20	70		0.00	0.00	0.02	
Apple pomace, wet	AB	0.01	STMR	40	0.01	10	10	10		0.00	0.00	0.00	
Cotton undelinted seed	SO	0.00	STMR	88	0.00	10	10	10		0.00	0.00	0.00	
Total						30.00	40	100		0.01	0.01	0.02	

FENAMIDONE (264)

ESTIMATED MAXIMUM DIETARY BURDEN													
BEEF CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Tomato pomace, wet	AB	1.49	STMR	20	7.45			10				0.75	
Cabbage heads, leaves	AM/AV	0.52	HR	15	3.47		20				0.69		
Grape pomace, wet	AB	0.30	STMR	15	2.00			10				0.20	
Carrot culls	VR	0.11	HR	12	0.92		15	5			0.14	0.05	
Potato process waste	AB	0.05	STMR	12	0.38	30.00	40			0.12	0.15		
Potato culls	VR	0.02	HR	20	0.10	30.00	15	5		0.03	0.02	0.01	
Cotton gin byproducts	AM/AV	0.02	HR	90	0.02	5				0.00			
Total						65	90	30.00		0.15	1.00	1.00	

DAIRY CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Tomato pomace, wet	AB	1.49	STMR	20	7.45			10				0.75	
Cabbage heads, leaves	AM/AV	0.52	HR	15	3.47		20				0.69		
Grape pomace, wet	AB	0.30	STMR	15	2.00			10				0.20	
Carrot culls	VR	0.11	HR	12	0.92	10	15	5		0.09	0.14	0.05	
Potato process waste	AB	0.05	STMR	12	0.38	10	30.00			0.04	0.12		
Potato culls	VR	0.02	HR	20	0.10		15				0.02		
Total						20	80	25		0.13	0.96	0.99	

POULTRY BROILER													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Carrot culls	VR	0.11	HR	12	0.92		10				0.09		
Total							10				0.09		

Annex 6

POULTRY LAYER													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Cabbage heads, leaves	AM/AV	0.52	HR	15	3.47		5				0.17		
Carrot culls	VR	0.11	HR	12	0.92		10				0.09		
Total							15				0.27		

ESTIMATED MEAN DIETARY BURDEN													
BEEF CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Tomato pomace, wet	AB	1.49	STMR/STMR-P	20	7.45			10				0.75	
Grape pomace, wet	AB	0.30	STMR/STMR-P	15	2.00			10				0.20	
Cabbage heads, leaves	AM/AV	0.22	STMR/STMR-P	15	1.47		20				0.29		
Carrot culls	VR	0.05	STMR/STMR-P	12	0.42		15	5			0.06	0.02	
Potato process waste	AB	0.05	STMR/STMR-P	12	0.38	30.00	40			0.12	0.15		
Potato culls	VR	0.02	STMR/STMR-P	20	0.10	30.00	15	5		0.03	0.02	0.01	
Cotton gin byproducts	AM/AV	0.02	STMR/STMR-P	90	0.02	5				0.00			
Total						65	90	30.00		0.15	0.52	0.97	

DAIRY CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Tomato pomace, wet	AB	1.49	STMR/STMR-P	20	7.45		0.00	10			0.00	0.75	
Grape pomace, wet	AB	0.30	STMR/STMR-P	15	2.00	0.00		10		0.00		0.20	
Cabbage heads, leaves	AM/AV	0.22	STMR/STMR-P	15	1.47	0.00	20			0.00	0.29		
Carrot culls	VR	0.05	STMR/STMR-P	12	0.42	10	15	5		0.04	0.06	0.02	
Potato process waste	AB	0.05	STMR/STMR-P	12	0.38	10	30.00			0.04	0.12		
Potato culls	VR	0.02	STMR/STMR-P	20	0.10	0.00	15			0.00	0.02		
Total						20	80	25		0.08	0.49	0.97	

POULTRY BROILER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Carrot culls	VR	0.05	STMR/STMR-P	12	0.42		10				0.04		
Total							10				0.04		

Annex 6

POULTRY LAYER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Cabbage heads, leaves	AM/AV	0.22	STMR/STMR-P	15	1.47		5				0.07		
Carrot culls	VR	0.05	STMR/STMR-P	12	0.42		10				0.04		
Total							15				0.12		

Annex 6

FENPROPATHRIN (185)

ESTIMATED MAXIMUM DIETARY BURDEN													
BEEF CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Tomato pomace,wet	AB	1.867	STMR	20	9.335			10				0.934	
Almond hulls	AM/AV	3.100	STMR	90	3.444			10				0.344	
Citrus dried pulp	AB	0.820	STMR	91	0.901	10	5	20		0.090	0.045	0.180	
Total						10	5	40		0.090	0.045	1.458	

DAIRY CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Tomato pomace, wet	AB	1.867	STMR	20	9.335			10				0.934	
Almond hulls	AM/AV	3.100	STMR	90	3.444	10		10		0.344		0.344	
Citrus dried pulp	AB	0.820	STMR	91	0.901	10	20	20		0.090	0.180	0.180	
Total						20	20	40		0.435	0.180	1.458	

ESTIMATED MEAN DIETARY BURDEN													
BEEF CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Tomato pomace, wet	AB	1.867	STMR/STMR-P	20	9.335			10				0.934	
Almond hulls	AM/AV	3.10	STMR/STMR-P	90	3.444			10				0.344	
Citrus dried pulp	AB	0.820	STMR/STMR-P	91	0.901	10	5	20		0.090	0.045	0.180	
Total						10	5	40		0.090	0.045	1.458	

DAIRY CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Tomato pomace, wet	AB	1.867	STMR/STMR-P	20	9.335		0	10			0.000	0.934	
Almond hulls	AM/AV	3.100	STMR/STMR-P	90	3.444	10		10		0.344		0.344	
Citrus dried pulp	AB	0.820	STMR/STMR-P	91	0.901	10	20	20		0.090	0.180	0.180	
Total						20	20	40		0.435	0.180	1.458	

Annex 6

FLUOPYRAM (243)

ESTIMATED MAXIMUM DIETARY BURDEN													
BEEF CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Beet, sugar tops	AM/AV	8.30	HR	23.00	36.09		20				7.22		
Grape pomace, wet	AB	1.86	STMR	15	12.40			20				2.48	
Almond hulls	AM/AV	3.60	STMR	90	4.00			10				0.40	
Carrot culls	VR	0.19	HR	12	1.58		15	5			0.24	0.08	
Apple pomace, wet	AB	0.31	STMR	40	0.78		20				0.16		
Potato process waste	AB	0.04	STMR	12	0.33	30.00	20			0.10	0.07		
Rape meal	SM	0.23	STMR	88	0.26		20	15	15		0.05	0.04	0.04
Potato culls	VR	0.02	HR	20	0.10	30.00	5	5		0.03	0.01	0.01	
Beet, sugar molasses	DM	0.01	STMR	75	0.01	10				0.00			
Bean seed	VD	0.01	STMR	88	0.01			45				0.01	
Total						70	100	100	15	0.13	7.73	3.01	0.04

DAIRY CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Beet, sugar tops	AM/AV	8.30	HR	23.00	36.09		30.00				10.83		
Grape pomace, wet	AB	1.86	STMR	15	12.40			20				2.48	
Almond hulls	AM/AV	3.60	STMR	90	4.00	10		10		0.40		0.40	
Carrot culls	VR	0.19	HR	12	1.58	10	15	5		0.16	0.24	0.08	
Apple pomace, wet	AB	0.31	STMR	40	0.78	10	10			0.08	0.08		
Potato process waste	AB	0.04	STMR	12	0.33		20				0.07		
Rape meal	SM	0.23	STMR	88	0.26		10	15	25		0.03	0.04	0.07
Potato culls	VR	0.02	HR	20	0.10		15				0.02		
Beet, sugar molasses	DM	0.01	STMR	75	0.01	10				0.00			
Bean seed	VD	0.01	STMR	88	0.01			15				0.00	
Lupin seed	VD	0.01	STMR	88	0.01			5				0.00	
Peanut meal	SM	0.00	STMR	85	0.00	10				0.00			
Total						50	100	70	25	0.64	11.25	3.00	0.07

POULTRY BROILER													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Carrot culls	VR	0.19	HR	12	1.58		10				0.16		
Rape meal	SM	0.23	STMR	88	0.26			5	5			0.01	0.01

Annex 6

POULTRY BROILER													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Bean seed	VD	0.01	STMR	88	0.01		20	70			0.00	0.01	
Lupin seed	VD	0.01	STMR	88	0.01	10				0.00			
Peanut meal	SM	0.00	STMR	85	0.00	25	10	5		0.00	0.00	0.00	
Total						35	40	80	5	0.00	0.16	0.02	0.01

POULTRY LAYER													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Beet, sugar tops	AM/AV	8.30	HR	23.00	36.09		5				1.80		
Carrot culls	VR	0.19	HR	12	1.58		10				0.16		
Rape meal	SM	0.23	STMR	88	0.26		10	5	15		0.03	0.01	0.04
Bean seed	VD	0.01	STMR	88	0.01		20	70			0.00	0.01	
Lupin seed	VD	0.01	STMR	88	0.01	10				0.00			
Peanut meal	SM	0.00	STMR	85	0.00	25		5		0.00		0.00	
Total						35	45	80	15	0.00	1.99	0.02	0.04

ESTIMATED MEAN DIETARY BURDEN													
BEEF CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Grape pomace, wet	AB	1.86	STMR-P	15	12.40			20				2.48	
Almond hulls	AM/AV	3.60	STMR	90	4.00			10				0.40	
Beet, sugar tops	AM/AV	0.46	STMR	23.00	2.00		20				0.40		
Apple pomace, wet	AB	0.31	STMR-P	40	0.78		20				0.16		
Carrot culls	VR	0.09	STMR	12	0.75		15	5			0.11	0.04	
Potato process waste	AB	0.04	STMR-P	12	0.33	30.00	20			0.10	0.07		
Rape meal	SM	0.23	STMR-P	88	0.26		20	15	15		0.05	0.04	0.04
Potato culls	VR	0.01	STMR-P	20	0.05	30.00	5	5		0.02	0.00	0.00	
Beet, sugar molasses	DM	0.01	STMR-P	75	0.01	10				0.00			
Bean seed	VD	0.01	STMR	88	0.01			45				0.01	
Total						70	100	100	15	0.12	0.79	2.96	0.04

DAIRY CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Grape pomace, wet	AB	1.86	STMR-P	15	12.40		0.00	20			0.00	2.48	
Almond hulls	AM/AV	3.60	STMR	90	4.00	10		10		0.40		0.40	
Beet, sugar tops	AM/AV	0.46	STMR	23.00	2.00	0.00	30.00			0.00	0.60		
Apple pomace,	AB	0.31	STMR-	40	0.78	10	10			0.08	0.08		

Annex 6

DAIRY CATTLE														MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
wet			P											
Carrot culls	VR	0.09	STMR	12	0.75	10	15	5		0.08	0.11	0.04		
Potato process waste	AB	0.04	STMR-P	12	0.33	0.00	20			0.00	0.07			
Rape meal	SM	0.23	STMR-P	88	0.26	0.00	10	15	25	0.00	0.03	0.04	0.07	
Potato culls	VR	0.01	STMR	20	0.05	0.00	15			0.00	0.01			
Beet, sugar molasses	DM	0.01	STMR-P	75	0.01	10				0.00				
Bean seed	VD	0.01	STMR	88	0.01	0.00		15		0.00		0.00		
Lupin seed	VD	0.01	STMR	88	0.01	0.00		5		0.00		0.00		
Peanut meal	SM	0.00	STMR-P	85	0.00	10				0.00				
Total						50	100	70	25	0.55	0.89	2.96	0.07	

POULTRY BROILER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Carrot culls	VR	0.09	STMR	12	0.75		10				0.08		
Rape meal	SM	0.23	STMR-P	88	0.26			5	5			0.01	0.01
Bean seed	VD	0.01	STMR	88	0.01		20	70			0.00	0.01	
Lupin seed	VD	0.01	STMR	88	0.01	10				0.00			
Peanut meal	SM	0.00	STMR	85	0.00	25	10	5		0.00	0.00	0.00	
Total						35	40	80	5	0.00	0.08	0.02	0.01

POULTRY LAYER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Beet, sugar tops	AM/AV	0.46	STMR	23.00	2.00		5				0.10		
Carrot culls	VR	0.09	STMR	12	0.75		10				0.08		
Rape meal	SM	0.23	STMR-P	88	0.26		10	5	15		0.03	0.01	0.04
Bean seed	VD	0.01	STMR	88	0.01		20	70			0.00	0.01	
Lupin seed	VD	0.01	STMR	88	0.01	10				0.00			
Peanut meal	SM	0.00	STMR-P	85	0.00	25		5		0.00		0.00	
Total						35	45	80	15	0.00	0.20	0.02	0.04

Annex 6

IMAZAMOX (276)

ESTIMATED MAXIMUM DIETARY BURDEN													
BEEF CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Rape forage	AM/AV	0.71	HR	30	2.37		10	100			0.237	2.3667	
Wheat forage	AF/AS	0.23	HR	25	0.92		20				0.184		
Alfalfa forage	AL	0.2	HR	35	0.57		70				0.4		
Sunflower meal	SM	0.48	STMR	92	0.52	5				0.0261			
Alfalfa hay	AL	0.41	HR	89	0.46	15			10	0.0691			0.0461
Wheat milled bypdts	CM/CF	0.21	STMR	88	0.24	40			55	0.0955			0.1313
Wheat hay	AF/AS	0.1	HR	88	0.11	15				0.017			
Alfalfa meal	SM	0.1	STMR	89	0.11				10				0.0112
Wheat grain	GC	0.1	STMR	89	0.11	20			25	0.0225			0.0281
Total						95	100	100	100	0.2302	0.821	2.3667	0.2166

DAIRY CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Rape forage	AM/AV	0.71	HR	30	2.37	10	10	40		0.2367	0.237	0.9467	
Wheat forage	AF/AS	0.23	HR	25	0.92	20	20	60		0.184	0.184	0.552	
Alfalfa forage	AL	0.2	HR	35	0.57	20	40			0.1143	0.229		
Sunflower meal	SM	0.48	STMR	92	0.52	10	10			0.0522	0.052		
Alfalfa hay	AL	0.41	HR	89	0.46				25				0.1152
Wheat milled bypdts	CM/CF	0.21	STMR	88	0.24	30	20		45	0.0716	0.048		0.1074
Alfalfa meal	SM	0.1	STMR	89	0.11				25				0.0281
Wheat grain	GC	0.1	STMR	89	0.11	10			5	0.0112			0.0056
Total						100	100	100	100	0.67	0.749	1.4987	0.2563

POULTRY BROILER													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Alfalfa forage	AL	0.2	HR	35	0.57				5				0.0286
Sunflower meal	SM	0.48	STMR	92	0.52	25	10	15		0.1304	0.052	0.0783	
Wheat milled bypdts	CM/CF	0.21	STMR	88	0.24	50	20	20	5	0.1193	0.048	0.0477	0.0119
Wheat grain	GC	0.1	STMR	89	0.11	25	70	65	10	0.0281	0.079	0.073	0.0112
Total						100	100	100	20	0.2778	0.179	0.199	0.0517

Annex 6

POULTRY LAYER													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Rape forage	AM/AV	0.71	HR	30	2.37		10				0.237		
Rape forage	AM/AV	0.71	HR	30	2.37		10				0.237		
Wheat forage	AF/AS	0.23	HR	25	0.92		10				0.092		
Sunflower meal	SM	0.48	STMR	92	0.52	25	10	15		0.1304	0.052	0.0783	
Pea vines	AL	0.1	HR	25	0.40		10				0.04		
Wheat milled bypdts	CM/CF	0.21	STMR	88	0.24	50	20	20	30	0.1193	0.048	0.0477	0.0716
Wheat grain	GC	0.1	STMR	89	0.11	25	40	55		0.0281	0.045	0.0618	
Total						100	110	90	30	0.2778	0.75	0.1878	0.0716

ESTIMATED MEAN DIETARY BURDEN													
BEEF CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Rape forage	AM/AV	0.38	STMR/STMR-P	30	1.27		10	100			0.1267	1.267	
Sunflower meal	SM	0.48	STMR/STMR-P	92	0.52	5	20			0.0261	0.1043		
Pea vines	AL	0.1	STMR/STMR-P	25	0.40		20				0.08		
Wheat forage	AF/AS	0.1	STMR/STMR-P	25	0.40		20				0.08		
Wheat milled bypdts	CM/CF	0.21	STMR/STMR-P	88	0.24	40	30		55	0.0955	0.0716		0.131
Alfalfa hay	AL	0.2	STMR/STMR-P	89	0.22	15			10	0.0337			0.022
Alfalfa meal	SM	0.1	STMR/STMR-P	89	0.11				10				0.011
Wheat grain	GC	0.1	STMR/STMR-P	89	0.11	20			25	0.0225			0.028
Total						80	100	100	100	0.1777	0.4626	1.267	0.193

DAIRY CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Rape forage	AM/AV	0.38	STMR/STMR-P	30	1.27	10	10	40		0.1267	0.1267	0.507	
Sunflower meal	SM	0.48	STMR/STMR-P	92	0.52	10	10	15		0.0522	0.0522	0.078	
Pea vines	AL	0.1	STMR/STMR-P	25	0.40	10	20	40		0.04	0.08	0.16	
Wheat forage	AF/AS	0.1	STMR/STMR-P	25	0.40	20	20	5		0.08	0.08	0.02	
Wheat milled bypdts	CM/CF	0.21	STMR/STMR-P	88	0.24	30	30		45	0.0716	0.0716		0.107
Alfalfa hay	AL	0.2	STMR/STMR-P	89	0.22	10	10		25	0.0225	0.0225		0.056
Alfalfa meal	SM	0.1	STMR/STMR-P	89	0.11	0			25	0			0.028
Wheat grain	GC	0.1	STMR/STMR-P	89	0.11	10			5	0.0112			0.006
Total						100	100	100	100	0.4041	0.4329	0.765	0.197

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POULTRY BROILER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Sunflower meal	SM	0.48	STMR/STMR-P	92	0.52	25	10	15		0.1304	0.0522	0.078	
Wheat milled bypdts	CM/CF	0.21	STMR/STMR-P	88	0.24	50	20	20	5	0.1193	0.0477	0.048	0.012
Wheat grain	GC	0.1	STMR/STMR-P	89	0.11	25	70	65	10	0.0281	0.0787	0.073	0.011
Alfalfa forage	AL	0	STMR/STMR-P	35	0.00				5				0
Total						100	100	100	20	0.2778	0.1786	0.199	0.023

POULTRY LAYER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Rape forage	AM/AV	0.38	STMR/STMR-P	30	1.27		10				0.1267		
Rape forage	AM/AV	0.38	STMR/STMR-P	30	1.27		10				0.1267		
Sunflower meal	SM	0.48	STMR/STMR-P	92	0.52	25	10	15		0.1304	0.0522	0.078	
Pea vines	AL	0.1	STMR/STMR-P	25	0.40		10				0.04		
Wheat forage	AF/AS	0.1	STMR/STMR-P	25	0.40		10				0.04		
Wheat milled bypdts	CM/CF	0.21	STMR/STMR-P	88	0.24	50	20	20	30	0.1193	0.0477	0.048	0.072
Wheat grain	GC	0.1	STMR/STMR-P	89	0.11	25	40	55		0.0281	0.0449	0.062	
Total						100	110	90	30	0.2778	0.4782	0.188	0.072

Annex 6

MESOTRIONE (277)

ESTIMATED MAXIMUM DIETARY BURDEN

BEEF CATTLE MAX

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Millet forage	AF/AS	0.01	HR	30.00	0.03			100				0.03	
Oat forage	AF/AS	0.01	HR	30.00	0.03		20				0.01		
Millet straw	AF/AS	0.01	HR	90	0.01	10				0.00			
Oat hay	AF/AS	0.01	HR	90	0.01	5				0.00			
Total						15	20	100		0.00	0.01	0.03	

DAIRY CATTLE MAX

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Millet forage	AF/AS	0.01	HR	30.00	0.03	20	30.00	50		0.01	0.01	0.02	
Oat forage	AF/AS	0.01	HR	30.00	0.03	10		40		0.00		0.01	
Soybean forage	AL	0.01	HR	56.00	0.02	20		10		0.00		0.00	
Total						50	30.00	100		0.01	0.01	0.03	

POULTRY LAYER MAX

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Millet forage	AF/AS	0.01	HR	30.00	0.03		10				0.00		
Soybean forage	AL	0.01	HR	56.00	0.02		10				0.00		
Total							20				0.01		

ESTIMATED MEAN DIETARY BURDEN

BEEF CATTLE MEAN

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Millet forage	AF/AS	0.01	STMR/STMR-P	30.00	0.03			100				0.03	
Oat forage	AF/AS	0.01	STMR/STMR-P	30.00	0.03		20				0.01		
Millet straw	AF/AS	0.01	STMR/STMR-P	90	0.01	10				0.00			
Oat hay	AF/AS	0.01	STMR/STMR-P	90	0.01	5				0.00			
Total						15	20	100		0.00	0.01	0.03	

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DAIRY CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Millet forage	AF/AS	0.01	STMR/STMR-P	30.00	0.03	20	30.00	50		0.01	0.01	0.02	
Oat forage	AF/AS	0.01	STMR/STMR-P	30.00	0.03	10		40		0.00		0.01	
Soybean forage	AL	0.01	STMR/STMR-P	56.00	0.02	20		10		0.00		0.00	
Total						50	30.00	100		0.01	0.01	0.03	

POULTRY LAYER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Millet forage	AF/AS	0.01	STMR/STMR-P	30.00	0.03		10				0.00		
Soybean forage	AL	0.01	STMR/STMR-P	56.00	0.02		10				0.00		
Total							20				0.01		

Annex 6

METRAFENONE (278)

ESTIMATED MAXIMUM DIETARY BURDEN

BEEF CATTLE MAX

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Grape pomace, wet	AB	2.40	STMR	15	16.00			20				3.20	
Rye straw	AF/AS	6.70	HR	88	7.61	10	20	20		0.76	1.52	1.52	
Wheat straw	AF/AS	6.70	HR	88	7.61			60.00				4.57	
Barley straw	AF/AS	3.90	HR	89.00	4.38		10				0.44		
Barley bran fractions	CM/CF	0.15	STMR	90	0.17				10				0.02
Barley grain	GC	0.06	STMR	88	0.07	50	70		70	0.03	0.05		0.05
Brewer's grain dried	SM	0.02	STMR	92.00	0.02	40			20	0.01			0.00
Total						100	100	100	100	0.80	2.01	9.29	0.07

DAIRY CATTLE MAX

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Grape pomace, wet	AB	2.40	STMR	15	16.00			20				3.20	
Rye straw	AF/AS	6.70	HR	88	7.61	10	20	20	5	0.76	1.52	1.52	0.38
Triticale straw	AF/AS	6.70	HR	90	7.44			60.00				4.47	
Barley straw	AF/AS	3.90	HR	89.00	4.38		10				0.44		
Barley grain	GC	0.06	STMR	88	0.07	45	40		40	0.03	0.03		0.03
Brewer's grain dried	SM	0.02	STMR	92.00	0.02	30.00	15		40	0.01	0.00		0.01
Total						85	85	100	85	0.80	1.99	9.19	0.42

POULTRY BROILER MAX

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Barley grain	GC	0.06	STMR	88	0.07	75	70	15	10	0.05	0.05	0.01	0.01
Brewer's grain dried	SM	0.02	STMR	92.00	0.02		10				0.00		
Rye grain	GC	0.01	STMR	88	0.01			35				0.00	
Total						75	80	50	10	0.05	0.05	0.01	0.01

POULTRY LAYER MAX

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Wheat straw	AF/AS	6.70	HR	88	7.61		10				0.76		
Barley bran fractions	CM/CF	0.15	STMR	90	0.17				5				0.01
Barley grain	GC	0.06	STMR	88	0.07	75	90	15		0.05	0.06	0.01	
Rye grain	GC	0.01	STMR	88	0.01			20				0.00	
Total						75	100	35	5	0.05	0.82	0.01	0.01

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ESTIMATED MEAN DIETARY BURDEN														
BEEF CATTLE														MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Grape pomace, wet	AB	2.40	STMR/STMR-P	15	16.00			20				3.20		
Rye straw	AF/AS	1.90	STMR/STMR-P	88	2.16	10	20	20		0.22	0.43	0.43		
Wheat straw	AF/AS	1.90	STMR/STMR-P	88	2.16			60.00				1.30		
Barley straw	AF/AS	1.30	STMR/STMR-P	89.00	1.46		10				0.15			
Barley bran fractions	CM/CF	0.15	STMR/STMR-P	90	0.17				10				0.02	
Barley grain	GC	0.06	STMR/STMR-P	88	0.07	50	70		70	0.03	0.05		0.05	
Brewer's grain dried	SM	0.02	STMR/STMR-P	92.00	0.02	40			20	0.01			0.00	
Total						100	100	100	100	0.26	0.63	4.93	0.07	

DAIRY CATTLE														MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Grape pomace, wet	AB	2.40	STMR/STMR-P	15	16.00		0.00	20			0.00	3.20		
Rye straw	AF/AS	1.90	STMR/STMR-P	88	2.16	10	20	20	5	0.22	0.43	0.43	0.11	
Triticale straw	AF/AS	1.90	STMR/STMR-P	90	2.11	0.00		60.00		0.00		1.27		
Barley straw	AF/AS	1.30	STMR/STMR-P	89.00	1.46	0.00	10			0.00	0.15			
Barley grain	GC	0.06	STMR/STMR-P	88	0.07	45	40		40	0.03	0.03		0.03	
Brewer's grain dried	SM	0.02	STMR/STMR-P	92.00	0.02	30.00	15		40	0.01	0.00		0.01	
Total						85	85	100	85	0.25	0.61	4.90	0.14	

POULTRY BROILER														MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Barley grain	GC	0.06	STMR/STMR-P	88	0.07	75	70	15	10	0.05	0.05	0.01	0.01	
Brewer's grain dried	SM	0.02	STMR/STMR-P	92.00	0.02		10				0.00			
Rye grain	GC	0.01	STMR/STMR-P	88	0.01			35				0.00		
Total						75	80	50	10	0.05	0.05	0.01	0.01	

POULTRY LAYER														MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Wheat straw	AF/AS	1.90	STMR/STMR-P	88	2.16		10				0.22			
Barley bran	CM/CF	0.15	STMR/STMR-P	90	0.17				5				0.01	

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POULTRY LAYER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
fractions													
Barley grain	GC	0.06	STMR/STMR-P	88	0.07	75	90	15		0.05	0.06	0.01	
Rye grain	GC	0.01	STMR/STMR-P	88	0.01			20				0.00	
Total						75	100	35	5	0.05	0.28	0.01	0.01

Annex 6

MYCLOBUTANIL (181)

ESTIMATED MAXIMUM DIETARY BURDEN

BEEF CATTLE MAX

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Apple pomace, wet	AB	0.726	STMR	40	1.82		20	20			0.363	0.363	
Pea vines	AL	0.36	HR	25	1.44		20	60			0.288	0.864	
Clover forage	AL	0.36	HR	30	1.20		10	20			0.12	0.24	
Alfalfa forage	AL	0.36	HR	35	1.03		40				0.411		
Turnip roots	VR	0.052	HR	15	0.35		10				0.035		
Grass forage (fresh)	AF/AS	0.071	HR	25	0.28				5				0.014
Grass hay	AF/AS	0.18	HR	88	0.20	15			35	0.030682			0.072
Alfalfa hay	AL	0.093	HR	89	0.10	15			10	0.015674			0.01
Total						30	100	100	50	0.046356	1.217	1.467	0.096

DAIRY CATTLE MAX

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Apple pomace, wet	AB	0.726	STMR	40	1.82	10	10	10		0.1815	0.182	0.182	
Grape pomace, wet	AB	0.266	STMR	15	1.77			10				0.177	
Pea vines	AL	0.36	HR	25	1.44	10	20	40		0.144	0.288	0.576	
Clover forage	AL	0.36	HR	30	1.20	10	20	20		0.12	0.24	0.24	
Bean vines	AL	0.36	HR	35	1.03			10				0.103	
Turnip roots	VR	0.052	HR	15	0.35	10	20	10		0.034667	0.069	0.035	
Grass forage (fresh)	AF/AS	0.071	HR	25	0.28	45	30		10	0.1278	0.085		0.028
Grass hay	AF/AS	0.18	HR	88	0.20				60				0.123
Turnip tops (leaves)	AM/AV	0.052	HR	30	0.17	15				0.026			
Alfalfa hay	AL	0.093	HR	89	0.10				25				0.026
Total						100	100	100	95	0.633967	0.864	1.312	0.177

POULTRY BROILER MAX

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Alfalfa forage	AL	0.36	HR	35	1.03				5				0.051
Turnip roots	VR	0.052	HR	15	0.35		10				0.035		
Total							10		5		0.035		0.051

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POULTRY LAYER													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Pea vines	AL	0.36	HR	25	1.44		10				0.144		
Turnip roots	VR	0.052	HR	15	0.35		10				0.035		
Grass forage (fresh)	AF/AS	0.071	HR	25	0.28		10				0.028		
Beet, sugar tops	AM/AV	0.052	HR	23	0.23		5				0.011		
Total							35				0.218		

ESTIMATED MEAN DIETARY BURDEN													
BEEF CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Apple pomace, wet	AB	0.726	STMR/STMR-P	40	1.82		20	20			0.363	0.363	
Pea vines	AL	0.195	STMR/STMR-P	25	0.78		20	60			0.156	0.468	
Clover forage	AL	0.195	STMR/STMR-P	30	0.65		10	20			0.065	0.13	
Alfalfa forage	AL	0.195	STMR/STMR-P	35	0.56		40				0.223		
Turnip roots	VR	0.039	STMR/STMR-P	15	0.26		10				0.026		
Grass forage (fresh)	AF/AS	0.047	STMR/STMR-P	25	0.19				5				0.009
Grass hay	AF/AS	0.098	STMR/STMR-P	88	0.11	15			35	0.016705			0.039
Alfalfa hay	AL	0.055	STMR/STMR-P	89	0.06	15			10	0.00927			0.006
Total						30	100	100	50	0.025974	0.833	0.961	0.055

DAIRY CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Apple pomace, wet	AB	0.726	STMR/STMR-P	40	1.82	10	10	10		0.1815	0.182	0.182	
Grape pomace, wet	AB	0.266	STMR/STMR-P	15	1.77	0		10		0		0.177	
Pea vines	AL	0.195	STMR/STMR-P	25	0.78	10	20	40		0.078	0.156	0.312	
Clover forage	AL	0.195	STMR/STMR-P	30	0.65	10	20	20		0.065	0.13	0.13	
Bean vines	AL	0.195	STMR/STMR-P	35	0.56	0		10		0		0.056	
Turnip roots	VR	0.039	STMR/STMR-P	15	0.26	10	20	10		0.026	0.052	0.026	
Grass forage (fresh)	AF/AS	0.047	STMR/STMR-P	25	0.19	45	30		10	0.0846	0.056		0.019
Turnip tops (leaves)	AM/AV	0.039	STMR/STMR-P	30	0.13	15				0.0195			
Grass hay	AF/AS	0.098	STMR/STMR-P	88	0.11	0			60	0			0.067
Alfalfa hay	AL	0.055	STMR/STMR-P	89	0.06	0			25	0			0.015
Total						100	100	100	95	0.4546	0.576	0.883	0.101

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POULTRY BROILER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Alfalfa forage	AL	0.195	STMR/STMR-P	35	0.56				5				0.028
Turnip roots	VR	0.039	STMR/STMR-P	15	0.26		10				0.026		
Total							10		5		0.026		0.028

POULTRY LAYER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Pea vines	AL	0.195	STMR/STMR-P	25	0.78		10				0.078		
Turnip roots	VR	0.039	STMR/STMR-P	15	0.26		10				0.026		
Grass forage (fresh)	AF/AS	0.047	STMR/STMR-P	25	0.19		10				0.019		
Beet, sugar tops	AM/AV	0.039	STMR/STMR-P	23	0.17		5				0.008		
Total							35				0.131		

Annex 6

PROPAMOCARB (148)

ESTIMATED MAXIMUM DIETARY BURDEN

BEEF CATTLE MAX

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Kale leaves	AM/AV	11.8	HR	15	78.67		20				15.73		
Potato culls	VR	0.17	HR	20	0.85	30	30	10		0.255	0.255	0.085	
Potato process waste	AB	0.05	STMR	12	0.42	30	40	5		0.125	0.167	0.021	
Total						60	90	15		0.38	16.16	0.106	

DAIRY CATTLE MAX

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Kale leaves	AM/AV	11.8	HR	15	78.67		20	40			15.73	31.47	
Potato culls	VR	0.17	HR	20	0.85	10	30	10		0.085	0.255	0.085	
Potato process waste	AB	0.05	STMR	12	0.42	10	30			0.041667	0.125		
Total						20	80	50		0.126667	16.11	31.55	

POULTRY BROILER MAX

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Potato culls	VR	0.17	HR	20	0.85		10				0.085		
Potato dried pulp	AB	0.05	STMR	88	0.06		20				0.011		
Total							30				0.096		

POULTRY LAYER MAX

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Kale leaves	AM/AV	11.8	HR	15	78.67		5				3.933		
Potato culls	VR	0.17	HR	20	0.85		10				0.085		
Potato dried pulp	AB	0.05	STMR	88	0.06		15				0.009		
Total							30				4.027		

ESTIMATED MEAN DIETARY BURDEN

BEEF CATTLE MEAN

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Kale leaves	AM/AV	4	STMR/STMR-P	15	26.67		20				5.333		
Potato process waste	AB	0.05	STMR/STMR-P	12	0.42	30	40	5		0.125	0.167	0.021	
Potato culls	VR	0.05	STMR/STMR-P	20	0.25	30	30	10		0.075	0.075	0.025	
Total						60	90	15		0.2	5.575	0.046	

Annex 6

DAIRY CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Kale leaves	AM/AV	4	STMR/STMR-P	15	26.67		20	40			5.333	10.67	
Potato process waste	AB	0.05	STMR/STMR-P	12	0.42	10	30			0.041667	0.125		
Potato culls	VR	0.05	STMR/STMR-P	20	0.25	10	30	10		0.025	0.075	0.025	
Total						20	80	50		0.066667	5.533	10.69	

POULTRY BROILER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Potato culls	VR	0.05	STMR/STMR-P	20	0.25		10				0.025		
Potato dried pulp	AB	0.05	STMR/STMR-P	88	0.06		20				0.011		
Total							30				0.036		

POULTRY LAYER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Kale leaves	AM/AV	4	STMR/STMR-P	15	26.67		5				1.333		
Potato culls	VR	0.05	STMR/STMR-P	20	0.25		10				0.025		
Potato dried pulp	AB	0.05	STMR/STMR-P	88	0.06		15				0.009		
Total							30				1.367		

Annex 6

PROPICONAZOLE (160)

ESTIMATED MAXIMUM DIETARY BURDEN

BEEF CATTLE MAX

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Wheat forage	AF/AS	9	HR	25	36		20	100			7.200	36.	
Wheat hay	AF/AS	22	HR	88	25	15				3.750			
Corn, field stover	AF/AS	17	HR	83	20.482		5				1.024		
Rice straw	AF/AS	16.500	HR	90	18.333				55				10.083
Corn, field forage/silage	AF/AS	5	HR	40	12.500		55				6.875		
Beet, sugar tops	AM/AV	0.960	HR	23	4.174		20				0.835		
Triticale grain	GC	0.600	STMR	89	0.674	20				0.135			
Barley grain	GC	0.068	STMR	88	0.077	30			45	0.023			0.035
Soybean seed	VD	0.030	STMR	89	0.034	5				0.002			
Total						70	100	100	100	3.910	15.934	36	10.118

DAIRY CATTLE MAX

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Wheat forage	AF/AS	9	HR	25	36	20	20	60		7.200	7.200	21.600	
Sorghum, grain forage	AF/AS	8.100	HR	35	23.143	20		10	40	4.629		2.314	9.257
Peanut hay	AL	14	HR	85	16.471	15		30		2.471		4.941	
Corn, field forage/silage	AF/AS	5	HR	40	12.500	5	40		10	0.625	5		1.250
Soybean hay	AL	9.800	HR	85	11.529	5				0.576			
Beet, sugar tops	AM/AV	0.960	HR	23	4.174		30				1.252		
Almond hulls	AM/AV	1.400	STMR	90	1.556	10				0.156			
Triticale grain	GC	0.600	STMR	89	0.674	20	10			0.135	0.067		
Barley grain	GC	0.068	STMR	88	0.077	5			40	0.004			0.031
Soybean seed	VD	0.030	STMR	89	0.034				10				0.003
Total						100	100	100	100	15.795	13.520	28.855	10.541

POULTRY BROILER MAX

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Triticale grain	GC	0.600	STMR	89	0.674	75	15			0.506	0.101		
Soybean seed	VD	0.030	STMR	89	0.034	20	20	15		0.007	0.007	0.005	
Total						95	35	15		0.512	0.108	0.005	

Annex 6

POULTRY LAYER													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Wheat forage	AF/AS	9	HR	25	36		10				3.600		
Total							10				3.600		

ESTIMATED MEAN DIETARY BURDEN													
BEEF CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Sorghum, grain forage	AF/AS	4.650	STMR/STMR-P	35	13.286	15	20	70		1.993	2.657	9.300	
Peanut hay	AL	7.600	STMR/STMR-P	85	8.941			30				2.682	
Corn, field stover	AF/AS	3.700	STMR/STMR-P	83	4.458		5				0.223		
Barley straw	AF/AS	2.600	STMR/STMR-P	89	2.921		5				0.146		
Rice straw	AF/AS	2.600	STMR/STMR-P	90	2.889				55				1.589
Corn, field forage/silage	AF/AS	0.850	STMR/STMR-P	40	2.125		50				1.063		
Beet, sugar tops	AM/AV	0.300	STMR/STMR-P	23	1.304		20				0.261		
Triticale grain	GC	0.600	STMR/STMR-P	89	0.674	20				0.135			
Barley grain	GC	0.068	STMR/STMR-P	88	0.077	30			45	0.023			0.035
Soybean seed	VD	0.030	STMR/STMR-P	89	0.034	5				0.002			
Total						70	100	100	100	2.152	4.349	11.982	1.623

DAIRY CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Sorghum, grain forage	AF/AS	4.650	STMR/STMR-P	35	13.286	40	20	70	40	5.314	2.657	9.300	5.314
Peanut hay	AL	7.600	STMR/STMR-P	85	8.941	15		30		1.341		2.682	
Soybean forage	AL	1.875	STMR/STMR-P	56	3.348	5				0.167			
Corn, field forage/silage	AF/AS	0.850	STMR/STMR-P	40	2.125	5	40		10	0.106	0.850		0.213
Almond hulls	AM/AV	1.400	STMR/STMR-P	90	1.556	10				0.156			
Beet, sugar tops	AM/AV	0.300	STMR/STMR-P	23	1.304	0	30			0	0.391		
Triticale grain	GC	0.600	STMR/STMR-P	89	0.674	20	10			0.135	0.067		

Annex 6

DAIRY CATTLE										MEAN			
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Barley grain	GC	0.068	STMR/STMR-P	88	0.077	5			40	0.004			0.031
Soybean seed	VD	0.030	STMR/STMR-P	89	0.034	0			10	0			0.003
Total						100	100	100	100	7.223	3.966	11.982	5.561

POULTRY BROILER										MEAN			
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Triticale grain	GC	0.600	STMR/STMR-P	89	0.674	75	15			0.506	0.101		
Soybean seed	VD	0.030	STMR/STMR-P	89	0.034	20	20	15		0.007	0.007	0.005	
Total						95	35	15		0.512	0.108	0.005	

POULTRY LAYER										MEAN			
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Sorghum, grain forage	AF/AS	4.650	STMR/STMR-P	35	13.286		10				1.329		
Total							10				1.329		

Annex 6

PROTHIOCONAZOLE (232)

ESTIMATED MAXIMUM DIETARY BURDEN

BEEF CATTLE MAX

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Wheat forage	AF/AS	5.4	HR	25	21.60		20	100			4.32	21.6	
Barley forage	AF/AS	5.4	HR	30	18.00		10				1.8		
Corn, field forage/silage	AF/AS	4.08	HR	40	10.20	15	50			1.53	5.1		
Wheat milled bypdts	CM/CF	5	STMR	88	5.68	40	20		55	2.273	1.136		3.125
Soybean asp gr fn	SM	3.75	STMR	85	4.41	5				0.221			
Soybean seed	VD	0.05	STMR	89	0.06	5			15	0.003			0.008
Potato culls	VR	0.01	HR	20	0.05	30				0.015			
Barley grain	GC	0.035	STMR	88	0.04	5			30	0.002			0.012
Total						100	100	100	100	4.043	12.36	21.6	3.15

DAIRY CATTLE MAX

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Wheat forage	AF/AS	5.4	HR	25	21.60	20	20	60		4.32	4.32	12.96	
Barley forage	AF/AS	5.4	HR	30	18.00		10				1.8		
Peanut hay	AL	11.6	HR	85	13.65	15		40		2.047		5.459	
Corn, field forage/silage	AF/AS	4.08	HR	40	10.20	25	30		50	2.550	3.06		5.1
Wheat milled bypdts	CM/CF	5	STMR	88	5.68	30	30		45	1.705	1.705		2.557
Bean seed	VD	0.05	STMR	88	0.06		10				0.006		
Soybean seed	VD	0.05	STMR	89	0.06	10			5	0.006			0.003
Total						100	100	100	100	10.63	10.89	18.42	7.66

POULTRY BROILER MAX

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Wheat milled bypdts	CM/CF	5	STMR	88	5.68	50	20	20	5	2.841	1.136	1.136	0.284
Bean seed	VD	0.05	STMR	88	0.06		20	70			0.011	0.04	
Cowpea seed	VD	0.05	STMR	88	0.06	10				0.006			
Pea seed	VD	0.05	STMR	90	0.06	10				0.006			
Potato culls	VR	0.01	HR	20	0.05		10				0.005		
Barley grain	GC	0.035	STMR	88	0.04	30	50	10	10	0.012	0.02	0.004	0.004
Total						100	100	100	15	2.86	1.17	1.18	0.29

POULTRY LAYER MAX

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Wheat forage	AF/AS	5.4	HR	25	21.60		10				2.16		
Wheat milled bypdts	CM/CF	5	STMR	88	5.68	50	20	20	30	2.841	1.136	1.136	1.705
Bean seed	VD	0.05	STMR	88	0.06		20	70			0.011	0.04	
Cowpea seed	VD	0.05	STMR	88	0.06	10				0.006			
Pea seed	VD	0.05	STMR	90	0.06	10				0.006			

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POULTRY LAYER													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Potato culls	VR	0.01	HR	20	0.05		10				0.005		
Barley grain	GC	0.035	STMR	88	0.04	30	40	10		0.012	0.016	0.004	
Corn, field grain	GC	0.018	STMR	88	0.02				70				0.014
Total						100	100	100	100	2.86	3.33	1.18	1.72

ESTIMATED MEAN DIETARY BURDEN													
BEEF CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Wheat milled bypdts	CM/CF	5	STMR/STMR-P	88	5.68	40	30	40	55	2.27	1.70	2.27	3.125
Corn, field forage/silage	AF/AS	2.15	STMR/STMR-P	40	5.38	15	70	60		0.81	3.763	3.225	
Soybean asp gr fn	SM	3.75	STMR/STMR-P	85	4.41	5				0.22			
Soybean seed	VD	0.05	STMR/STMR-P	89	0.06	5			15	0.00			0.008
Potato culls	VR	0.01	STMR/STMR-P	20	0.05	30				0.02			
Barley grain	GC	0.035	STMR/STMR-P	88	0.04	5			30	0.00			0.012
Total						100	100	100	100	3.32	5.47	5.50	3.15

DAIRY CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Wheat milled bypdts	CM/CF	5	STMR/STMR-P	88	5.68	30	30	40	45	1.705	1.705	2.273	2.557
Corn, field forage/silage	AF/AS	2.15	STMR/STMR-P	40	5.38	45	60	60	50	2.419	3.225	3.225	2.688
Peanut hay	AL	4.08	STMR/STMR-P	85	4.80	15				0.720			
Bean seed	VD	0.05	STMR/STMR-P	88	0.06	0	10			0.000	0.006		
Soybean seed	VD	0.05	STMR/STMR-P	89	0.06	10			5	0.006			0.003
Total						100	100	100	100	4.85	4.94	5.50	5.25

POULTRY BROILER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Wheat milled bypdts	CM/CF	5	STMR/STMR-P	88	5.68	50	20	20	5	2.841	1.136	1.136	0.284
Bean seed	VD	0.05	STMR/STMR-P	88	0.06		20	70			0.011	0.040	
Cowpea seed	VD	0.05	STMR/STMR-P	88	0.06	10				0.006			
Pea seed	VD	0.05	STMR/STMR-P	90	0.06	10				0.006			
Potato culls	VR	0.01	STMR/STMR-P	20	0.05		10				0.005		
Barley grain	GC	0.035	STMR/STMR-P	88	0.04	30	50	10	10	0.0119	0.0199	0.0040	0.0040
Total						100	100	100	15	2.86	1.17	1.18	0.29

Annex 6

POULTRY LAYER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Wheat milled bypdts	CM/CF	5	STMR/STMR-P	88	5.68	50	20	20	30	2.841	1.136	1.136	1.705
Corn, field forage/silage	AF/AS	2.15	STMR/STMR-P	40	5.38		10				0.538		
Bean seed	VD	0.05	STMR/STMR-P	88	0.06		20	70			0.011	0.040	
Cowpea seed	VD	0.05	STMR/STMR-P	88	0.06	10				0.006			
Pea seed	VD	0.05	STMR/STMR-P	90	0.06	10				0.006			
Potato culls	VR	0.01	STMR/STMR-P	20	0.05		10				0.005		
Barley grain	GC	0.035	STMR/STMR-P	88	0.04	30	40	10		0.012	0.016	0.004	
Corn, field grain	GC	0.018	STMR/STMR-P	88	0.02				70				0.014
Total						100	100	100	100	2.86	1.71	1.18	1.72

Annex 6

PYMETROZINE (279)

ESTIMATED MAXIMUM DIETARY BURDEN

BEEF CATTLE MAX

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Cabbage heads, leaves	AM/AV	0.5	HR	15	3.33		20				0.67		
Tomato pomace, wet	AB	0.068	STMR	20	0.34			10				0.03	
Cotton hulls	SM	0.02	STMR	90	0.02	10		20		0.00		0.00	
Total						10	20	30		0.00	0.67	0.04	

DAIRY CATTLE MAX

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Cabbage heads, leaves	AM/AV	0.5	HR	15	3.33		20				0.67		
Tomato pomace, wet	AB	0.068	STMR	20	0.34			10				0.03	
Cotton hulls	SM	0.02	STMR	90	0.02			10				0.00	
Total							20	20			0.67	0.04	

POULTRY LAYER MAX

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Cabbage heads, leaves	AM/AV	0.5	HR	15	3.33		5				0.17		
Total							5				0.17		

ESTIMATED MEAN DIETARY BURDEN

BEEF CATTLE MEAN

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Tomato pomace, wet	AB	0.068	STMR/STMR-P	20	0.34			10				0.03	
Cabbage heads, leaves	AM/AV	0.03	STMR/STMR-P	15	0.20		20				0.04		
Cotton hulls	SM	0.02	STMR/STMR-P	90	0.02	10		20		0.00		0.00	
Total						10	20	30		0.00	0.04	0.04	

DAIRY CATTLE MEAN

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Tomato pomace, wet	AB	0.068	STMR/STMR-P	20	0.34		0	10			0.00	0.03	
Cabbage heads, leaves	AM/AV	0.03	STMR/STMR-P	15	0.20	0	20			0.00	0.04		
Cotton hulls	SM	0.02	STMR/STMR-	90	0.02	0		10		0.00		0.00	

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			P										
Total						0	20	20		0.00	0.04	0.04	

POULTRY LAYER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Cabbage heads, leaves	AM/AV	0.03	STMR/STMR-P	15	0.20		5				0.01		
Total							5				0.01		

Annex 6

SULFOXAFLOR (252)

ESTIMATED MAXIMUM DIETARY BURDEN

BEEF CATTLE MAX

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Beet, sugar tops	AM/AV	1.600	HR	23	6.957		20				1.391		
Cotton gin byproducts	AM/AV	4	HR	90	4.444	5				0.222			
Soybean forage	AL	1.700	HR	56	3.036			100				3.036	
Citrus dried pulp	AB	2.160	STMR	91	2.374	10	5			0.237	0.119		
Barley hay	AF/AS	1.800	HR	88	2.045	15				0.307			
Wheat hay	AF/AS	1.800	HR	88	2.045		20				0.409		
Barley straw	AF/AS	1.800	HR	89	2.022		10				0.202		
Soybean asp gr fn	SM	1	STMR	85	1.176	5				0.059			
Wheat asp gr fn	CM/CF	0.530	STMR	85	0.624	5				0.031			
Carrot culls	VR	0.030	HR	12	0.250		15				0.038		
Beet, sugar molasses	DM	0.140	STMR	75	0.187	10	10			0.019	0.019		
Apple pomace, wet	AB	0.074	STMR	40	0.185		15				0.028		
Swede roots	VR	0.010	HR	10	0.100		5				0.005		
Rape meal	SM	0.086	STMR	88	0.098				15				0.015
Barley grain	GC	0.063	STMR	88	0.072	50			70	0.036			0.050
Barley bran fractions	CM/CF	0.063	STMR	90	0.070				10				0.007
Soybean meal	SM	0.014	STMR	92	0.015				5				0.001
Total						100	100	100	100	0.911	2.210	3.036	0.073

DAIRY CATTLE MAX

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Beet, sugar tops	AM/AV	1.600	HR	23	6.957		30				2.087		
Soybean forage	AL	1.700	HR	56	3.036	20		40		0.607		1.214	
Citrus dried pulp	AB	2.160	STMR	91	2.374	10	20	30		0.237	0.475	0.712	
Barley hay	AF/AS	1.800	HR	88	2.045	20		30		0.409		0.614	
Barley straw	AF/AS	1.800	HR	89	2.022		30				0.607		
Carrot culls	VR	0.030	HR	12	0.250	10	15			0.025	0.038		
Beet, sugar molasses	DM	0.140	STMR	75	0.187	10	5			0.019	0.009		
Canola meal	SM	0.086	STMR	88	0.098	10				0.010			
Rape meal	SM	0.086	STMR	88	0.098				25				0.024
Barley grain	GC	0.063	STMR	88	0.072	20			40	0.014			0.029

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DAIRY CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Beet, sugar dried pulp	AB	0.042	STMR	88	0.048				35				0.017
Total						100	100	100	100	1.321	3.215	2.540	0.070

POULTRY BROILER													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Carrot culls	VR	0.030	HR	12	0.250		10				0.025		
Canola meal	SM	0.086	STMR	88	0.098	15	18	5		0.015	0.018	0.005	
Rape meal	SM	0.086	STMR	88	0.098				5				0.005
Bean seed	VD	0.075	STMR	88	0.085		20	70			0.017	0.060	
Barley grain	GC	0.063	STMR	88	0.072	75	52	15	10	0.054	0.037	0.011	0.007
Cotton meal	SM	0.016	STMR	89	0.018	5		5		0.001		0.001	
Soybean meal	SM	0.014	STMR	92	0.015	5		5	30	0.001		0.001	0.005
Wheat milled bypdts	CM/CF	0.010	STMR	88	0.011				5				0.001
Total						100	100	100	50	0.070	0.097	0.077	0.017

POULTRY LAYER													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Beet, sugar tops	AM/AV	1.600	HR	23	6.957		5				0.348		
Soybean forage	AL	1.700	HR	56	3.036		10				0.304		
Wheat hay	AF/AS	1.800	HR	88	2.045		10				0.205		
Carrot culls	VR	0.030	HR	12	0.250		10				0.025		
Canola meal	SM	0.086	STMR	88	0.098	15	10	5		0.015	0.010	0.005	
Rape meal	SM	0.086	STMR	88	0.098				15				0.015
Bean seed	VD	0.075	STMR	88	0.085		20	70			0.017	0.060	
Barley grain	GC	0.063	STMR	88	0.072	75	35	15		0.054	0.025	0.011	
Barley bran fractions	CM/CF	0.063	STMR	90	0.070				5				0.004
Cotton meal	SM	0.016	STMR	89	0.018	5		5		0.001		0.001	
Soybean meal	SM	0.014	STMR	92	0.015	5		5	15	0.001		0.001	0.002
Wheat milled bypdts	CM/CF	0.010	STMR	88	0.011				25				0.003
Total						100	100	100	60	0.070	0.933	0.077	0.023

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ESTIMATED MEAN DIETARY BURDEN														
BEEF CATTLE														MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Citrus dried pulp	AB	2.160	STMR/STMR-P	91	2.374	10	5	30		0.237	0.119	0.712	
Beet, sugar tops	AM/AV	0.420	STMR/STMR-P	23	1.826		20				0.365		
Soybean asp gr fn	SM	1	STMR/STMR-P	85	1.176	5				0.059			
Soybean hay	AL	0.670	STMR/STMR-P	85	0.788			70				0.552	
Wheat forage	AF/AS	0.190	STMR/STMR-P	25	0.760		20				0.152		
Wheat asp gr fn	CM/CF	0.530	STMR/STMR-P	85	0.624	5				0.031			
Beet, sugar molasses	DM	0.140	STMR/STMR-P	75	0.187	10	10			0.019	0.019		
Apple pomace, wet	AB	0.074	STMR/STMR-P	40	0.185		15				0.028		
Cotton gin byproducts	AM/AV	0.150	STMR/STMR-P	90	0.167	5				0.008			
Barley hay	AF/AS	0.140	STMR/STMR-P	88	0.159	15				0.024			
Barley straw	AF/AS	0.140	STMR/STMR-P	89	0.157		10				0.016		
Swede roots	VR	0.010	STMR/STMR-P	10	0.100		20				0.020		
Rape meal	SM	0.086	STMR/STMR-P	88	0.098				15				0.015
Barley grain	GC	0.063	STMR/STMR-P	88	0.072	50			70	0.036			0.050
Barley bran fractions	CM/CF	0.063	STMR/STMR-P	90	0.070				10				0.007
Soybean meal	SM	0.014	STMR/STMR-P	92	0.015				5				0.001
Total						100	100	100	100	0.414	0.718	1.264	0.073

DAIRY CATTLE														MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Citrus dried pulp	AB	2.160	STMR/STMR-P	91	2.374	10	20	30		0.237	0.475	0.712	
Beet, sugar tops	AM/AV	0.420	STMR/STMR-P	23	1.826	0	30			0	0.548		
Soybean hay	AL	0.670	STMR/STMR-P	85	0.788	20		40		0.158		0.315	
Wheat forage	AF/AS	0.190	STMR/STMR-P	25	0.760	20	20	30		0.152	0.152	0.228	
Beet, sugar molasses	DM	0.140	STMR/STMR-P	75	0.187	10	10			0.019	0.019		
Barley straw	AF/AS	0.140	STMR/STMR-P	89	0.157	0	10			0	0.016		
Swede	VR	0.010	STMR/STMR	10	0.100	0	10			0	0.010		

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DAIRY CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
roots			-P										
Canola meal	SM	0.086	STMR/STMR-P	88	0.098	10				0.010			
Rape meal	SM	0.086	STMR/STMR-P	88	0.098	0			25	0			0.024
Carrot culls	VR	0.010	STMR/STMR-P	12	0.083	10				0.008			
Barley grain	GC	0.063	STMR/STMR-P	88	0.072	20			40	0.014			0.029
Beet, sugar dried pulp	AB	0.042	STMR/STMR-P	88	0.048	0			35	0			0.017
Total						100	100	100	100	0.598	1.219	1.255	0.070

POULTRY BROILER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Swede roots	VR	0.010	STMR/STMR-P	10	0.100		10				0.010		
Canola meal	SM	0.086	STMR/STMR-P	88	0.098	15	18	5		0.015	0.018	0.005	
Rape meal	SM	0.086	STMR/STMR-P	88	0.098				5				0.005
Bean seed	VD	0.075	STMR/STMR-P	88	0.085		20	70			0.017	0.060	
Barley grain	GC	0.063	STMR/STMR-P	88	0.072	75	52	15	10	0.054	0.037	0.011	0.007
Cotton meal	SM	0.016	STMR/STMR-P	89	0.018	5		5		0.001		0.001	
Soybean meal	SM	0.014	STMR/STMR-P	92	0.015	5		5	30	0.001		0.001	0.005
Wheat milled bypdts	CM/CF	0.010	STMR/STMR-P	88	0.011				5				0.001
Total						100	100	100	50	0.070	0.082	0.077	0.017

POULTRY LAYER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Beet, sugar tops	AM/AV	0.420	STMR/STMR-P	23	1.826		5				0.091		
Soybean hay	AL	0.670	STMR/STMR-P	85	0.788		10				0.079		
Wheat forage	AF/AS	0.190	STMR/STMR-P	25	0.760		10				0.076		
Swede roots	VR	0.010	STMR/STMR-P	10	0.100		10				0.010		
Canola meal	SM	0.086	STMR/STMR-P	88	0.098	15	10	5		0.015	0.010	0.005	
Rape meal	SM	0.086	STMR/STMR-P	88	0.098				15				0.015

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POULTRY LAYER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Bean seed	VD	0.075	STMR/STMR-P	88	0.085		20	70			0.017	0.060	
Barley grain	GC	0.063	STMR/STMR-P	88	0.072	75	35	15		0.054	0.025	0.011	
Barley bran fractions	CM/CF	0.063	STMR/STMR-P	90	0.070				5				0.004
Cotton meal	SM	0.016	STMR/STMR-P	89	0.018	5		5		0.001		0.001	
Soybean meal	SM	0.014	STMR/STMR-P	92	0.015	5		5	15	0.001		0.001	0.002
Wheat milled bypdts	CM/CF	0.010	STMR/STMR-P	88	0.011				25				0.003
Total						100	100	100	60	0.070	0.308	0.077	0.023

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THIAMETHOXAM (245)

ESTIMATED MAXIMUM DIETARY BURDEN

BEEF CATTLE MAX

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Cabbage heads, leaves	AM/AV	3	HR	15	20		20				4		
Bean vines	AL	1.4	HR	35	4.00			60				2.4	
Wheat forage	AF/AS	0.73	HR	25	2.92		20	40			0.58	1.2	
Swede roots	VR	0.2	HR	10	2.00		40				0.8		
Barley hay	AF/AS	1.7	HR	88	1.93	15				0.29			
Barley straw	AF/AS	1.7	HR	89	1.91		10				0.19		
Potato culls	VR	0.2	HR	20	1.00	30				0.3			
Pea vines	AL	0.1	HR	25	0.40		10				0.04		
Barley grain	GC	0.12	STMR	88	0.14	50			70	0.068			0.095
Citrus dried pulp	AB	0.073	STMR	91	0.08	5				0.0040			
Corn, field grain	GC	0.02	STMR	88	0.02				5				0.0011
Soybean seed	VD	0.02	STMR	89	0.02				15				0.0034
Total						100	100	100	90	0.66	5.6	3.6	0.1

DAIRY CATTLE MAX

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Cabbage heads, leaves	AM/AV	3	HR	15	20		20				4		
Bean vines	AL	1.4	HR	35	4.00		20	70			0.8	2.8	
Wheat forage	AF/AS	0.73	HR	25	2.92	20	20	30		0.58	0.58	0.88	
Swede roots	VR	0.2	HR	10	2.00		20				0.4		
Barley straw	AF/AS	1.7	HR	89	1.91		10				0.19		
Carrot culls	VR	0.2	HR	12	1.67	10				0.17			
Potato culls	VR	0.2	HR	20	1.00		10				0.1		
Pea vines	AL	0.1	HR	25	0.40	10				0.04			
Apple pomace, wet	AB	0.11	STMR	40	0.28	10				0.028			
Clover forage	AL	0.05	HR	30	0.17	10				0.017			
Barley grain	GC	0.12	STMR	88	0.14	40			40	0.055			0.055
Corn, field forage/silage	AF/AS	0.05	HR	40	0.13				50				0.063
Corn, field grain	GC	0.02	STMR	88	0.02				10				0.0023
Total						100	100	100	100	0.89	6.1	3.7	0.12

POULTRY BROILER MAX

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Swede roots	VR	0.2	HR	10	2.00		10				0.20		
Cassava/tapioca roots	VR	0.2	HR	37	0.54		10				0.054		
Alfalfa forage	AL	0.05	HR	35	0.14				5				0.0071
Barley grain	GC	0.12	STMR	88	0.14	75	70	15	10	0.10	0.095	0.02	0.014
Bean seed	VD	0.02	STMR	88	0.02		10	70			0.0023	0.016	
Pea seed	VD	0.02	STMR	90	0.02	20				0.0044			
Cotton meal	SM	0.0054	STMR	89	0.01	5		10		03		06	
Total						100	100	95	15	0.11	0.35	0.037	0.021

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POULTRY LAYER													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Cabbage heads, leaves	AM/AV	3	HR	15	20		5				1		
Wheat forage	AF/AS	0.73	HR	25	2.92		10				0.29		
Swede roots	VR	0.2	HR	10	2.00		10				0.2		
Cassava/tapioca roots	VR	0.2	HR	37	0.54		5				0.027		
Pea vines	AL	0.1	HR	25	0.40		10				0.04		
Barley grain	GC	0.12	STMR	88	0.14	75	60	15		0.10	0.082	0.020	
Bean seed	VD	0.02	STMR	88	0.02			70				0.016	
Corn, field grain	GC	0.02	STMR	88	0.02				80				0.018
Pea seed	VD	0.02	STMR	90	0.02	20				0.0044			
Cotton meal	SM	0.0054	STMR	89	0.01	5		10		03		06	
Total						100	100	95	80	0.11	1.6	0.037	0.018

ESTIMATED MEAN DIETARY BURDEN													
BEEF CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Cabbage heads, leaves	AM/AV	0.78	STMR/STMR-P	15	5.20		20				1.0		
Bean vines	AL	0.88	STMR/STMR-P	35	2.51			60				1.5	
Wheat forage	AF/AS	0.53	STMR/STMR-P	25	2.12		20	40			0.42	0.85	
Barley hay	AF/AS	0.39	STMR/STMR-P	88	0.44	15				0.066			
Barley straw	AF/AS	0.39	STMR/STMR-P	89	0.44		10				0.04		
Apple pomace, wet	AB	0.11	STMR/STMR-P	40	0.28		20				0.055		
Pea vines	AL	0.04	STMR/STMR-P	25	0.16		20				0.032		
Barley grain	GC	0.12	STMR/STMR-P	88	0.14	50	10		70	0.068	0.014		0.095
Citrus dried pulp	AB	0.073	STMR/STMR-P	91	0.08	10				0.0080			
Potato culls	VR	0.01	STMR/STMR-P	20	0.05	25				0.013			
Corn, field grain	GC	0.02	STMR/STMR-P	88	0.02				5				0.001
Soybean seed	VD	0.02	STMR/STMR-P	89	0.02				15				0.003
Total						100	100	100	90	0.16	1.6	2.4	0.10

DAIRY CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Cabbage heads, leaves	AM/AV	0.78	STMR/STMR-P	15	5.20		20	0			1.04	0	
Bean vines	AL	0.88	STMR/STMR-P	35	2.51	0	20	70		0	0.50	1.76	
Wheat forage	AF/AS	0.53	STMR/STMR-P	25	2.12	20	20	30		0.42	0.42	0.64	
Barley straw	AF/AS	0.39	STMR/STMR-P	89	0.44	0	10			0	0.044		
Apple pomace, wet	AB	0.11	STMR/STMR-P	40	0.28	10	10			0.028	0.028		
Rape forage	AM/AV	0.05	STMR/STMR-P	30	0.17	10				0.017			
Pea vines	AL	0.04	STMR/STMR-P	25	0.16	10				0.016			
Barley grain	GC	0.12	STMR/STMR-P	88	0.14	45	20		40	0.061	0.027		0.055

Annex 6

DAIRY CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Carrot culls	VR	0.01	STMR/STMR-P	12	0.08	5				0.0042			
Corn, field forage/silage	AF/AS	0.01	STMR/STMR-P	40	0.03	0			50	0			0.013
Corn, field grain	GC	0.02	STMR/STMR-P	88	0.02	0			10	0			0.002
Total						100	100	100	100	0.55	2.1	2.4	0.069

POULTRY BROILER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Barley grain	GC	0.12	STMR/STMR-P	88	0.14	75	70	15	10	0.10	0.095	0.020	0.014
Swede roots	VR	0.01	STMR/STMR-P	10	0.10		10				0.01		
Alfalfa forage	AL	0.01	STMR/STMR-P	35	0.03				5				0.001
Cassava/tapioca roots	VR	0.01	STMR/STMR-P	37	0.03		10				0.003		
Bean seed	VD	0.02	STMR/STMR-P	88	0.02		10	70			0.002	0.016	
Pea seed	VD	0.02	STMR/STMR-P	90	0.02	20				0.0044			
Cotton meal	SM	0.0054	STMR/STMR-P	89	0.01	5		10		03		06	
Total						100	100	95	15	0.11	0.11	0.037	0.015

POULTRY LAYER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Cabbage heads, leaves	AM/AV	0.78	STMR/STMR-P	15	5.20		5				0.26		
Wheat forage	AF/AS	0.53	STMR/STMR-P	25	2.12		10				0.21		
Rape forage	AM/AV	0.05	STMR/STMR-P	30	0.17		5				0.008		
Pea vines	AL	0.04	STMR/STMR-P	25	0.16		10				0.016		
Barley grain	GC	0.12	STMR/STMR-P	88	0.14	75	70	15		0.10	0.095	0.020	
Bean seed	VD	0.02	STMR/STMR-P	88	0.02			70				0.016	
Corn, field grain	GC	0.02	STMR/STMR-P	88	0.02				80				0.018
Pea seed	VD	0.02	STMR/STMR-P	90	0.02	20				0.0044			
Cotton meal	SM	0.0054	STMR/STMR-P	89	0.01	5		10		03		06	
Total						100	100	95	80	0.11	0.59	0.037	0.018

Annex 6

TRIFORINE (116)

ESTIMATED MAXIMUM DIETARY BURDEN													
BEEF CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Tomato pomace, wet	AB	0.24	STMR	90	0.27			10				0.027	
Total								10				0.027	

DAIRY CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Tomato pomace, wet	AB	0.24	STMR	90	0.27			10				0.027	
Total								10				0.027	

ESTIMATED MEAN DIETARY BURDEN													
BEEF CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Tomato pomace, wet	AB	0.24	STMR/STMR-P	90	0.27			10				0.027	
Total								10				0.027	

DAIRY CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Tomato pomace, wet	AB	0.24	STMR/STMR-P	90	0.27		0	10			0	0.027	
Total						0		10		0		0.027	

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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 16 to 25 September 2014. The FAO Panel of Experts had met in preparatory sessions from 11 to 15 September 2014. 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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