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219

Pesticide residues in food 2013

Joint FAO/WHO Meeting on Pesticide Residues

REPORT 2013

World Health Organization

Food and Agriculture Organization of the United Nations

Pesticide residues in food 2013

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FAO PLANT PRODUCTION AND PROTECTION PAPER

219

Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues Geneva, Switzerland, From 17 to 26 September 2013

WORLD HEALTH ORGANIZATION
FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS
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CONTENTS

Table of Contents

R, residue and analytical aspects; T, toxicological evaluation

* New compound

** Evaluated within the periodic review programme of the Codex Committee on Pesticide Residues

ABBREVIATIONS

ADI	acceptable daily intake
ADME	absorption, distribution, metabolism and excretion
ai	active ingredient
ALT	alanine aminotransferase
AP	alkaline phosphatase
AR	applied radioactivity
ARfD	acute reference dose
asp gr fn	aspirated grain fraction
AST	aspartate aminotransferase
AU	Australia
AUC	area under the plasma concentration–time curve
BBCH	**B**iologischen Bundesanstalt, **B**undessortenamt und **CH**emische Industrie
$BMDL_{SD}$	the 95% lower confidence limit of the dose corresponding to a change equivalent to one standard deviation in the response for unexposed animals
BROD	benzoxyresorufin *O*-debenzylase
bw	body weight
CAC	Codex Alimentarius Commission
CAG	cumulative assessment group
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
CXL	Codex MRL
cyp	cytochrome P450
DAP	days after planting
DAT	days after treatment
DM	dry matter
DNA	deoxyribonucleic acid
DT_{50}	time required for 50% dissipation of the initial concentration
dw	dry weight
ECD	electron capture detector
EFSA	European Food Safety Authority
EHC	Environmental Health Criteria monograph

EPO	early post-emergence
EU	European Union
F_0	parental generation
F_1	first filial generation
F_2	second filial generation
FAO	Food and Agriculture Organization of the United Nations
fw	fresh weight
GA	glufosinate-ammonium
GAP	good agricultural practice
GC	gas chromatography
GC-ECD	gas chromatography with electron capture detection
GC-FPD	gas chromatography with flame photometric detection
GC/MS	gas chromatography/mass spectrometry
GC-NPD	gas chromatography coupled with nitrogen-phosphorus detector
GEMS/Food	Global Environment Monitoring System – Food Contamination Monitoring and Assessment Programme
GI	gastrointestinal
GLP	good laboratory practice
HPLC	high performance liquid chromatography
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
HRPT	hypoxanthine phosphoribosyl transferase
IEDI	international estimated daily intake
IESTI	international estimate of short-term dietary intake
IgA	immunoglobulin A
IgG	immunoglobulin G
IgM	immunoglobulin M
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JECFA	Joint FAO/WHO Expert Committee on Food Additives
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
JP	Japan
LC_{50}	median lethal concentration
LD_{50}	median lethal dose
LLNA	local lymph node assay

LOAEL	lowest-observed-adverse-effect level
LOD	limit of detection
log P_{ow}	octanol-water partition coefficient
LOQ	limit of quantification
MPA	2-methylphosphinico-acetic acid
MPP	3-[hydroxy(methyl) phosphinoyl]propionic acid (= 3-methylphosphinico-propionic acid)
MRL	maximum residue limit
mRNA	messenger ribonucleic acid
MS	mass spectrometry
MS/MS	tandem mass spectrometry
NAG	*N*-acetylglufosinate
ND	non-detect - below limit of detection
NOAEC	no-observed-adverse-effect concentration
NOAEL	no-observed-adverse-effect level
NTP	National Toxicology Program (USA)
OECD	Organisation for Economic Co-operation and Development
PAM	1-methyl-3-trifluoromethyl-1H-pyrazole-4-carboxamide
PBH	propylene bromohydrin
PBI	plant back interval
PCA	1-methyl-3-trifluoromethyl-1H-pyrazole-4-carboxylic acid; 4-chloroaniline
PCH	propylene chlorohydrin
PDC	2,3-pyridine dicarboxylic acid
Pf	processing factor
PHI	pre-harvest interval
PND	postnatal day
POD	point of departure
ppm	parts per million
PPO	propylene oxide
PRE	pre-emergence
PROD	pentoxyresorufin *O*-depentylase
RAC	raw agricultural commodity
RSD	relative standard deviation
RTI	re-treatment interval
SC	suspension concentrate
SL	soluble liquid
SPE	solid phase extraction

STMR	supervised trials median residue
STMR-P	supervised trials median residue in a processed commodity calculated by multiplying the STMR of the raw commodity by the corresponding processing factor
SUA	Supply Utilisation Account
T_3	triiodothyronine
T_4	thyroxine
TAR	total administered radioactivity
T_{max}	time to reach the maximum concentration in plasma/blood (C_{max})
TOPPS	1,2,3,4-tetrahydro-1-oxopyrido(1,2-a)-5-pyrazinium salt
TRR	total radioactive residues
TSH	thyroid stimulating hormone
TTC	threshold of toxicological concern
U	uniformly (labelled)
UDPGT	uridine diphosphate-glucuronosyltransferase
UDS	unscheduled DNA synthesis
UK	United Kingdom
USA	United States of America
US/CAN	United States and Canada
USEPA	United States Environmental Protection Agency
US-FDA	USA – Food and Drug Administration
WG	wettable granule
WHO	World Health Organization
WP	wettable powder

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GENEVA, 17–26 SEPTEMBER 2013

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PESTICIDE RESIDUES IN FOOD

REPORT OF THE 2013 JOINT FAO/WHO MEETING OF EXPERTS

1. INTRODUCTION

A Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues (JMPR) was held at World Health Organization (WHO) Headquarters, Geneva (Switzerland), from 17 to 26 September 2013. The Panel Members of the Food and Agriculture Organization of the United Nations (FAO) met in preparatory sessions on 12–16 September.

The Meeting was opened by Dr Kazuaki Miyagishima, Director, Department of Food Safety and Zoonoses, WHO. On behalf of FAO and WHO, Dr Miyagishima welcomed and thanked the participants for providing their expertise and for the significant time and effort put into such an important activity. He also expressed gratitude to the respective national authorities, institutes and organizations that have allowed their experts to contribute to this important work on pesticide residues. Dr Miyagishima said that whereas the assessment of new compounds is very important and represents the major part of the work of JMPR, it is also crucial to continue our efforts on the periodic re-evaluation of old pesticides still in use. This should allow developing countries to use old, inexpensive pesticides so that they can access international markets for their food commodities; it also should allow the removal of those compounds that are most persistent in the environment and pose the greatest risk to public health. Dr Miyagishima also noted that in order to continue using the best available science in a transparent manner, the WHO Core Assessment Group will meet during an additional day this year to update the guidance documents for experts and sponsors. Finally, JMPR is celebrating in 2013 the 50th anniversary of the first joint FAO/WHO evaluation of pesticide residues in food, and Dr Miyagishima 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 36 pesticides, including 11 new compounds and 3 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 Meeting that all experts participating in the 2013 JMPR had completed declaration of interest forms and that no conflicts had been identified. Professor Moretto declared that his hospital received a significant grant from the sponsor of benzovindiflupyr. The grant was not related to benzovindiflupyr or more generally to pesticide residues in food, and Professor Moretto was not directly involved in the funded project.

Dr Shah declared his employment as an official of the United States Environmental Protection Agency (USEPA). This institution submitted a concern form this year to JMPR regarding the health-based guidance values for propylene oxide and its metabolites. Dr Shah was not involved in the discussion and preparation of the concern form.

JMPR confirmed that these declarations should not be considered as conflicts of interest and that the considered experts could participate in the discussion about the respective compounds.

2. GENERAL CONSIDERATIONS

2.1 GUIDANCE DOCUMENT FOR WHO MONOGRAPHERS

At the 2012 JMPR, the WHO Core Assessment Group on Pesticide Residues agreed to update its guidance document to incorporate the experience gained over the years and advances in scientific knowledge and to improve the transparency and efficiency of JMPR decisions. The new guidance should be of use for industry and for Codex member states submitting dossiers, as well as for experts writing or peer reviewing the JMPR reports and monographs.

The guidance document will be discussed during a 1-day workshop of the WHO Core Assessment Group held on 26–27 September. The document describes the JMPR procedures for toxicological assessment, the content of the toxicological monographs and the interpretation of toxicological studies, with a particular focus on minor and adaptive effects.

A final version is expected by March 2014.

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

At the 2012 Meeting, JMPR discussed the incorporation of data from new mechanistic-based approaches ("Tox 21") in the risk assessment of dietary exposure to pesticide residues. JMPR offered to evaluate data generated using new technologies as they become available, in parallel with the results of traditional toxicity testing, to determine their utility and role in pesticide evaluation. Little such information was submitted for consideration by the 2013 Meeting. JMPR repeats this offer and notes that information obtained using new technologies could be of particular value in the assessment of metabolites and degradates of pesticides and in the evaluation of postulated modes of action.

The Meeting agreed that this offer should be included in the call for data, starting with the 2014 Meeting.

2.3 RISK ASSESSMENT OF METABOLITES AND DEGRADATES OF PESTICIDES

Residues of the pesticides to which consumers are exposed often comprise not just (or even) the parent compound, but also metabolites produced in treated plants, environmental degradation products and possibly other pesticide-derived compounds (e.g., during food processing). Where such a compound is also produced at significant levels in test species, it is assumed that its hazard will have been addressed in assessment of the parent compound. When this is not the case, or where levels produced in test species are low, additional assessment of the compound is necessary. With improvements in analytical sensitivity and greater awareness of the potential for exposure to metabolites and degradates, the number of compounds identified of potential concern is increasing appreciably. It is not feasible or appropriate to insist on comprehensive toxicity testing of all such compounds, a fact recognized in a recent opinion[1] of the European Food Safety Authority (EFSA).

JMPR agrees with many of the principles outlined in the EFSA opinion in determining the toxicological relevance of pesticide metabolites and degradates for the purposes of dietary risk assessment. The present Meeting agreed to produce guidance on this issue in time for it to be taken into account at the 2014 Meeting. Key elements will likely include the following:

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[1] EFSA (2012). Scientific Opinion on evaluation of the toxicological relevance of pesticide metabolites for dietary risk assessment. *EFSA Journal* 10(7):2799. [187 pp.] doi:10.2903/j.efsa.2012.2799.

- Where there is adequate exposure of test species to the compound of concern, hazard characterization will have been addressed by evaluation of the parent compound.
- Otherwise, a preliminary assessment of dietary exposure to the compound of concern should be undertaken.
- The tiered threshold of toxicological concern (TTC) approach, as recommended by EFSA (2012), should be adopted.
- Where appropriate, read-across from the parent or other metabolites/degradates with relevant toxicological information should be undertaken.
- Where adequate data are available, and when necessary, relative toxic potencies will be determined, for use in calculating an appropriate exposure estimate for comparison with the respective reference value.
- The JMPR report will clearly indicate whether it was possible to assess significant metabolites or degradates for toxicological concern.
- Three possible outcomes will be identified:
    - Evaluation was possible, and there is no concern.
    - Evaluation was possible, and there is concern.
    - No evaluation is possible. This does not necessarily mean that there is a concern, rather that it is not possible to reach such a conclusion on the basis of available data.

2.4 REVIEW OF THE NEED TO UPDATE THE PRINCIPLES AND METHODS FOR THE RISK ASSESSMENT OF CHEMICALS IN FOOD (EHC 240)

JMPR, like other expert groups advising WHO and FAO, has codified the general principles by which it evaluates pesticides for their possible risk from dietary exposure to residues. These were published in the Environmental Health Criteria (EHC) series. Since initial publication (in EHC 104, for pesticides), a number of additional principles were agreed by JMPR, which were published as general considerations in the respective meeting report. WHO sought to consolidate these evolving principles and to harmonize, to the extent possible, the approaches used by the various expert groups (the Joint FAO/WHO Expert Committee on Food Additives [JECFA], JMPR, etc.). This culminated in the publication, in 2009, of EHC 240: *Principles and Methods for the Risk Assessment of Chemicals in Food*. Even at the time of publication, it was recognized that regular updating would be necessary, and it was envisaged that this could be done by providing updates online.

The present Meeting agreed that a review of EHC 240 should be a standing item on its agenda from 2014, and that any sections of chapters requiring updating would be identified. In such cases, the Meeting would make specific recommendations on how this might be achieved.

2.5 IDENTIFICATION OF PESTICIDES TO BE INCLUDED IN CUMULATIVE ASSESSMENT GROUPS ON THE BASIS OF THEIR TOXICOLOGICAL PROFILE

The Meeting noted the request for comment on a recent opinion[1] from EFSA defining criteria and a methodology for grouping pesticides, based on their toxicological characteristics, for the purpose of taking account of cumulative effects during the setting of maximum residue levels. JMPR noted that the EFSA opinion included useful collation of information on the common effects of pesticides acting on the thyroid and nervous system. However, the Meeting was of the view that in creating cumulative assessment groups (CAGs), exposure characteristics as well as hazard and potency considerations should be used early in the process as criteria for inclusion in CAGs. Indeed, this was noted in the

[1] EFSA (2013). Scientific Opinion on the identification of pesticides to be included in cumulative assessment groups on the basis of their toxicological profile. *EFSA Journal* 11(7):3293. [131 pp.]. doi:10.2903/j.efsa.2013.3293.

EFSA opinion. JMPR looks forward to the opportunity to comment on the methodology developed by EFSA for the refinement of CAGs based on such further considerations.

The Meeting noted that the issue of cumulative risk assessment of pesticides would benefit from the engagement of interested parties, perhaps through the recently launched WHO Chemical Risk Assessment Network. JMPR agreed to explore the possible application of cumulative risk assessment to its evaluation of pesticides, for example, through conducting a case-study for the purpose, for consideration at a future meeting.

2.6 GUIDANCE FOR THE PREPARATION AND PROCESSING OF LARGE COMMODITIES FOR ANALYSIS OF PESTICIDE RESIDUES

The MRLs apply to the average residue in the laboratory sample complying with the minimum requirements of the number of primary samples and the mass of the laboratory samples[1], prepared according to the corresponding Codex Guidelines[2].

Prior experience indicated that the interaction of surface residues with the internal part of plant materials may cause very rapid degradation of the residues. Classical examples are, for instance, benomyl, captan, chlorothalonil, dithiocarbamates, etoxazole and folpet. Fifty to 90% of the parent compounds may decompose within minutes during the chopping of various plant materials at room temperature. There are many other pesticides which may decompose at various extents when the residues come into contact with plant enzymes and other liquids released from the plant cells during processing.

Since the rate of such decomposition is a function of several factors including but not limited to: chemical properties of the residues, plant matrix, temperature, and duration of the contact; without specific information on the stability of the residue the only option provided in the guidelines is to not to permit the cutting individual commodity units prior to analysis.

In order to avoid or minimize the degradation of residues as much as possible, the Codex Sampling Guidelines[9] states: "Where the bulk sample is larger than is required for a laboratory sample, it should be divided to provide a representative portion. A sampling device, quartering, or other appropriate size reduction process may be used *but units of fresh plant products or whole eggs should not be cut or broken."*

The Codex Guidelines on Good Laboratory Practice in Residue Analysis, CAC/GL 40-1993, Rev.1-2003 reiterates the same principle, stating that: "Sample processing and sub-sampling should be carried out using procedures that have been demonstrated to provide a representative analytical portion and to have no effect on the concentration of residues present."

The OECD Guideline for the Testing of Chemicals[3] states: "It is acceptable to subsample large commodities (e.g., head cabbage, melons, etc.) with procedures in the field such as quartering and collecting opposing quarters. However, if analyses are planned on matrices such as pulp and peel (e.g., for dietary risk assessment refinement), the whole commodity should be shipped to the analysis lab to avoid cross contamination of peel and pulp."

Neither the Codex Guidelines nor the OECD Guidelines provide guidance on what should be done to prove that the cutting, peeling or shelling of sampled commodities would not affect the initial residue concentration.

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[1] Recommended Methods of Sampling for the Determination of Pesticide Residues for Compliance with MRLs , *CAC/GL 33-1999.*

[2] Portion of Commodities to which Codex Maximum Residue Limits Apply and which Is Analysed, CAC/GL 41-1993

[3] OECD Guideline for the Testing of Chemicals 507 (adapted September 2009)

The Meeting recognized that cutting large bulky commodities or fruits with hard peel such as, for instance, jackfruit, watermelon, cabbage, pineapple and avocado in deep-frozen condition is very difficult. Furthermore, storing several samples of such fruits would require very large freezing capacity which is not available to many laboratories in developing countries, and consequently would limit their capacity to generate residue data to support the establishment of Codex MRLs for specific commodities of national importance.

Keeping in mind the importance of assuring that the residue levels in the laboratory samples are the same or very similar to that at the time of sampling, the Meeting recommends:

- locating trial sites at distances from which samples can be transported to the testing laboratory within 24 hours. Allowing the large commodities to be immediately sub-sampled, appropriate representative sub-sample portions further homogenised and the test portions withdrawn and stored deep-frozen prior to extraction and analysis. This procedure concurs with the allowance given by both the Codex and OECD Guidelines on transporting fresh plant materials without the need for deep-freezing; or
- Carry out a pre-test before conducting the supervised trials to verify the stability of residues in cut commodity. The test involves:
    - surface treatment of the crops with a mixture of pesticides including two of known stability and those compounds which are the intended subject of the trials,
    - performing the sub-sampling and homogenisation of the representative portions of sub-samples according to normal laboratory practice at room temperature, and analysing the residues remaining in the test portions.

If the ratio of the stable reference compounds and unknown stability residues remain the same (statistically not significantly different) taking into account the average procedural recoveries, the tested pesticides can be considered stable in the halved or quartered portions. In such cases cutting large crops is acceptable at the field site, provided that it can be done to avoid cross contamination. The applicability of the method has been extensively tested and described[1,2,3,4].

The selected sub-portions should be packed separately in suitable labelled bags for transportation to the analytical laboratory.

2.7 PRINCIPLES FOR ASSESSING THE PERFORMANCE OF ANALYTICAL METHODS BASED ON FEW RECOVERY TESTS

The JMPR considers the suitability of analytical methods used in supervised trials based on the results of method validation studies performed in the laboratory that developed the method and verified in an independent laboratory. Further, the concurrent recovery data obtained at the time of the analysis of the samples are also considered. If the method performance raises doubt about the reliability of the reported residue concentrations, the corresponding trials are not considered in estimation of residue levels.

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[1] Ambrus Á, Solymosné M.E., Korsós I., and. Estimation of Unecertainty of Sample Preparation for the Analysis of Pesticide Residues**,** J. Environ. Sci. Health. B31. No. 3 443-450, 1996.

[2] Maestroni, B., Ghods, A., El-Bidaoui M., Rathor, N., Jarju O.P., Ton, T., and Ambrus A., Testing the efficiency and uncertainty of sample processing using ^{14}C labelled Chlorpyrifos Part I in Fajgelj A., Ambrus A., eds. Principles of Method Validation pp. 49-58, Royal Society of Chemistry Cambridge UK 2000

[3] Fussell, R.J. Hetmanski, M.T. Macarthur, R. Findlay, D., Smith, F., Ambrus, Á. and Brodesser, J. P. Measurement Uncertainty Associated with Sample Processing of Oranges and Tomatoes for Pesticide Residue Analysis. J. Agric. Food Chem., 55, 1062-1070, 2007

[4] Yolci Omeroglua*, A´ . Ambrusb, D. Boyaciogluc and E. Solymosne Majzikd Uncertainty of the sample size reduction step in pesticide residue analysis of large-sized crops, Food Additives & Contaminants: Part *Part A* (30 (1): 116-126 (DOI:10.1080/19440049.2012.728720Ö

The number of recovery tests performed at various spike concentrations typically range from 3–7, occasionally higher numbers of replicates are available. The results of these studies are compared with the reference values given in the Codex Guidelines on Good Laboratory Practice in Residue Analysis [1], which agree with the general performance criteria adopted by Codex Alimentarius[2].

The Codex Guidelines specify the acceptable recovery ranges and the relative standard deviation for the within laboratory repeatability of replicate analyses. These reference values are based on large numbers of collaborative studies, as a result the range for the repeatability relative standard deviation derived from few recovery tests is not directly comparable.

Studies with n≥15 replicates, the within laboratory repeatability of analytical step (CV_A) is expected to be in the range of 0.5–0.7 of repeatability of the analysis predicted from the "Horwitz equation". However values between 0.5 and 2 may be acceptable[3].

The estimation of standard deviation based on few data points is very imprecise. The significance of differences between the experimentally obtained standard deviation or relative standard deviation (CV_{exp}) and the reference value should be verified by applying the F-test.

$$F_{calc} = \frac{CV_{exp}^2}{CV_{Ref}^2}$$

If the calculated F value is larger than the critical one, the difference is considered significant. The F_{crit} depends on the selected probability and number of replicate tests.

The reference values taken from the Codex Guidelines and the minimum experimental CV values, rounded to a whole number, which can be considered significantly different from the reference CV values at 95% confidence level depending on the number of replicate tests performed in the laboratory are summarized hereunder.

Concentration	CV_{ref} %	Significantly different CV_{exp} values from the CV_{Ref} based on replicate recovery tests (n)		
		n=3	n=5	n=7
< 1 µg/kg	35	61	54	51
> 1 µg/kg ≤0.01 mg/kg	30	52	47	44
> 0.01 mg/kg ≤ 0.1 mg/kg	20	35	31	29
> 0.1 mg/kg ≤ 1 mg/kg	15	26	24	22
> 1 mg/kg	10	18	16	15

Consequently, where the reported laboratory CV_A value is smaller than those given in the above table the repeatability of the laboratory/method is considered to be within acceptable limits.

[1] CAC/Gl 40-1993, Rev.1-2003.

[2] Codex Alimentarius Commission, Procedural Manual 21st ed. Joint FAO/WHO Food Standards Programme, FAO, Rome, 2013, p.66.

[3] Horwitz W, The potential use of quality control data to validate pesticide residue method performance, in Fajgelj A and Ambrus Á eds. Principles and practices of Method Validation, Royal Society of Chemistry pp.1-8, 2000.

2.8 GUIDANCE FOR USE OF RESIDUE TRIAL DATA FROM DIFFERENT GEOGRAPHICAL LOCATIONS FOR ESTIMATION OF PESTICIDE RESIDUE LEVELS

The best use of available residue data is always the primary objective of the JMPR when estimating maximum residue levels, therefore the Meeting regularly re-evaluates and revises its procedures. The FAO Manual notes that under practical conditions the number of trials which can be performed for a given commodity is limited. Nevertheless, a larger data set provides a more accurate estimation of the selected percentile than a small data set derived from trials representing only one critical use condition (cGAP).

As a result of evolving working principles, the proportionality approach has been elaborated to adjust residues deriving from trials conducted with different application rates to a common one. The recommended method was adopted by the Codex Alimentarius Commission [1] in 2013 for inclusion in the Procedural Manual as an Annex to the Risk Analysis Principles applied by the CCPR.

In addition, the JMPR agreed that from 2012, geographical location should not be a barrier in selecting trials for estimation of maximum residue levels[2].

The present Meeting took into account the experience gained during previous years, and decided to build on the current practice and elaborated the following principles for utilizing the globally available supervised trial residue data for estimation of residue levels, provided that the growing and processing practices to produce RAC are comparable.

Step1: Residues deriving from supervised trials reflecting the national or regional cGAP will be considered and the relevant residues selected.

- If sufficient numbers of residue data are available from the country or region representing the cGAP, that dataset is used for estimating residue levels according to the current practice of the JMPR.
- Where residue data from trials conducted in the country or region are not sufficient, then trials conducted with different application rates will be considered, and the residue values adjusted, based on the proportionality approach to obtain the largest possible residue dataset.

Step 2: Where sufficient residue data are not available from Step 1, then suitable residue data from the trials performed in other countries that meet cGAP, or can be adjusted using proportionality to the cGAP, the data can be considered with those from step 1.

The datasets obtained in Steps 1 and 2 can be combined if the residue values are within 7 times the median of the newly combined data set. As detailed analysis of the residue data sets selected by the JMPR between 1997 and 2011, for estimation of maximum residue levels, revealed that about 90% of the residues were within the seven times median range, regardless whether the residue data was derived from a single country or countries in different regions[3].

Where the spread of residues exceeds the 7 times median range, the suitability of the dataset for estimation of residue levels would then need further careful examination, taking into account all relevant information.

The JMPR will apply the above principles in further evaluations of the residue data and evaluate their applicability on a case by case basis. If the principles are considered not applicable the

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1 Thirty-sixth Session of the Codex Alimentarius Commission, Rome, Italy 1-5 July 2013, http://www.codexalimentarius.org/meetings-reports/en/?sortingDate=012013.

2 Food and Agriculture Organisation, Pesticide residues in food 2012 Report http://www.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/JMPR/Report11/JMPR_2011_Report.pdf

3 Árpád Ambrus, Zsuzsanna Horváth, Zsuzsa Farkas, István J. Szabó, Enikő Dorogházi, Mária Szeitzné-Szabó, Nature of the field-to-field distribution of pesticide residues. Submitted for publication to J. Environ Sci and Health

reason will be explained in the report. Upon gaining sufficient experience the JMPR would reconsider and further elaborate the principles if needed.

2.9 GUIDANCE FOR ESTIMATING PESTICIDE RESIDUE LEVELS FOR COMMODITY GROUPS

Aiming to cover the residues in minor commodities without separate supervised trials, the JMPR has recommended maximum residue levels, HR and STMR values for commodity groups whenever the available dataset was considered appropriate.

In order to make the data assessment process transparent and facilitate its consistent application in various situations, the JMPR considered and evaluated past experience and decided on the following basic principles in estimation of residue levels for commodity groups.

- Group maximum residue levels are only estimated if the pesticide is registered for a group or sub-group of commodities, also allowing for the differences in Codex and national commodity group classifications.
- Residue datasets reflecting cGAP will be compiled. Once the data sets have been established for individual commodities, the recommendations for residue levels for commodity groups would be considered according to the following principles.
    - The establishment of a commodity group residue level will generally be considered if the median residues of the commodities are within the 5 times range;
        i. Where the residues in individual commodities in the commodity group are statistically not different (Mann-Whitney or Kruskal-Wallis tests) the residue data can be combined for the estimation of group residue levels;
        ii. Where the residue datasets in individual commodities are statistically different then the dataset leading to the highest maximum residue level would be used for the group, provided that sufficient residue data points are available ;
        iii. If the dataset identified under (ii) does not contain sufficient data points (preferably ≥ 8) required to estimate a group maximum residue level, the commodity should be considered as an exception.
    - If the median of residues in an individual commodity dataset differs more than 5 times than those of other commodities, that commodity would not be included in the group and indicated as an exception.
    - If the medians of residues in more than one commodity of the group differ larger than five times, then recommending group residue levels may not be appropriate and would require decision based on all information available

In view of the large diversity of residue data dependant on the pesticide and other factors, the case-by-case evaluation of the available residue data is considered necessary. Where the Meeting deviates from the above principles, the rational for the divergence will be provided in the report.

Upon gaining sufficient experience the JMPR would reconsider and further elaborate the principles if needed.

2.10 UPDATE OF GEMS/FOOD DIETS FOR THE ESTIMATION OF THE IEDI

The WHO GEMS/Food diets were originally collected in 1989 to predict dietary exposure to radionuclides in food following the Chernobyl accident. They were derived from FAO food Supply Utilisation Account (SUA) data to represent five regional dietary patterns, namely Middle Eastern, Far Eastern, African, Latin American and European. These five Regional Diets were used in the

period 1989-2005 to predict the potential exposure to various chemicals occurring in food (e.g. pesticide residue exposure estimates by the JMPR). For this purpose, the need for regional grouping became less important than that of groupings based on similarities between the diets.

In 1997, the WHO introduced the GEMS/Food cluster diets. The first cluster diets were based on the 1990-1994 FAO food 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 JMPR to predict pesticide residue exposures in the period 2006 to now.

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 average 5-year FAO food supply utilisation account data from 2002–2007. These average data were weighted by the population size to get average kg/person/cluster over a 5 year period.

These 17 Cluster Diets have now been incorporated in the JMPR IEDI model by RIVM[1] in cooperation with the WHO. The JMPR IEDI model is an automated Excel spreadsheet for the calculation of chronic 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 model. Then calculations and generation of an overview table are performed automatically. The Meeting noted that the mean body weights used in the IEDI model are still 55 kg for cluster G09 and 60 kg for all others.

The main difficulty in building the IEDI model is that the FAO food SUA data does not match, one-to-one, with the Codex Classification of Foods and Animal Feeds, as used in the dietary exposure assessment for pesticide residues. These two classification systems have several incompatibilities in the definition of the commodity and in the commodity codes. The 17 cluster diets contain several food items, which need to be linked to multiple Codex commodities. In addition, the FAO food SUA data are sometimes given separately for fresh and processed commodities. In such cases, the FAO SUA data were recalculated in such a way that the IEDI model contains three types of consumption values: fresh including processed, fresh only and processed only. In this way, JMPR is able to refine the dietary intake by using processing factors.

In the 17 clusters the consumption of a food important to a certain country is now distributed together with countries where the same food is important. The main impact of the 17 cluster diet will be that for that specific country there will be an increased intake of such a food when compared with the 13 cluster diets. Furthermore, because the 17 cluster diet data are based on more aggregated food commodities as collected in the FAO database, higher exposure levels may be estimated for certain commodities. For example, FAOSTAT item code 358 (cabbages) was linked to Codex brassica leafy vegetables, head cabbages, Brussels sprouts and kohlrabi. Individual data for head cabbages, broccoli, cauliflower, Brussels sprouts, kohlrabi and leafy brassicas are not available in the FAO food SUA database. In such cases the 17 cluster diet IEDI model may overestimate the chronic dietary exposure. In the previous 13 cluster diet IEDI model consumption data for individual brassica commodities were estimated based on national consumption data.

The JMPR used the draft 17 cluster diet IEDI model on the compounds evaluated in the 2013 Meeting 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. Results are listed in the table below. For several compounds the 17 cluster diets resulted in higher exposure estimates, which are attributed to the use of aggregate consumption data.

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

For the commodities identified in the table below JMPR recommends that a questionnaire be sent to relevant countries seeking the submmission of more detailed consumption data in order to have the 17 cluster diet IEDI model ready for use at the 2014 Meeting.

Information on the FAO food SUA data is available at (http://faostat3.fao.org). The 17 Cluster diets are available at (http://www.who.int/foodsafety/chem/acute_data/en/index1.html). The 17 cluster diet IEDI model will be available on the same web address and will be updated when necessary.

Compound	No of entries in spreadsheets	Min-max %ADI (13 clusters)	Min-Max %ADI (17 clusters)	Additional consumption data (C) or recalculation (R) needed for:
azoxystrobin	88	2-10%	2-20%	C: celery, witloof R: citrus fruits (G12 high)
bentazone	17	0%	0%	C: peas with pods, peas without pods
chlorantraniliprole	65/52	0%	0%	C: peas with pods, peas without pods
cyantraniliprole	39	1-10%	4-20%	C: celery, head lettuce, summer squash, pumpkins, brassicas, brassica leafy vegs, R: root and tubers, except potato; cucurbits inedible peel; cucurbits edible peel; fruiting vegs other than cucurbits excl specified processed tomato commodities; leafy vegs except head lettuce
dicamba	21	0-1%	0-1%	C: wheat bran
difenoconazole	59	4-60%	4-80%	C: passion fruit, celeriac, summer squash, head lettuce, leaf lettuce, witloof chicory, celery, peas with pods R: potato (G02 high)
Diquat	24	0-4%	0-5%	-
dithianon	13	0-7%	0-7%	-
fenbuconazole	39	0-2%	0-3%	C: wheat bran
fenpyroximate	26	1-7%	3-5%	-
flutolanil	11	0-1%	0-1%	C: Brassica leafy vegs, rice bran
glyphosate	36	0-1%	0-1%	-
Glufosinate-ammonium	38	3-9%	3-10%	-
imazapic	14	0%	0-0.2%	-
imazapyr	14	0%	0%	-
indoxacarb	46	1-30%	1-50%	C: pumpkins, summer squash, cauliflower, head cabbage, leaf lettuce
isoxaflutole	13	0-1%	0-1%	R: Sugarcane incl sugar
malathion	none	-	-	-
mandipropamid	25	0-2%	0-3%	C: summer squash, cauliflower, head cabbage, sweet peppers, chili peppers, celery
penthiopyrad	66	0-6%	1-10%	C: mustard greens, turnip greens, celery, summer squash, pumpkins, peas without pods, radish roots, cereal brans, tomato puree
propiconazole	23/22	0-6%	0-6%	-
pyrimethanil	34	0-5%	0-10%	-
Sulfoxaflor	40	1-7%	1-6%	-
triazophos	3	1-40%	2-30%	C: Green soya beans with pods, green soya beans without pods R: Cotton seed raw excl oil, rice excl husked & excl polished.
trinexapac-ethyl	21	0.1-0.9%	0.1-0.7%	C: wheat bran

Compound	No of entries in spreadsheets	Min-max %ADI (13 clusters)	Min-Max %ADI (17 clusters)	Additional consumption data (C) or recalculation (R) needed for:
triflumizole	9/8	0-2%	0-1%	-

2.11 REVISION OF THE CODEX CLASSIFICATION OF FOODS AND ANIMAL FEEDS

The Meeting was aware of the progress being made by the CCPR on the revision of the Codex Classification of Foods and Animal Feeds and recognized that the revised classification of fruit commodities was adopted by the Codex Alimentarius Commission in 2012. The current Meeting started using the revised classification on fruit commodities in its work. As the Codex Classification has significant impacts on the estimation of maximum residue levels by the JMPR, the Meeting continues to watch the development of the revision of classification for other commodities with strong interests and looks forward to the completion of revision by the CCPR.

3. RESPONSES TO SPECIFIC CONCERNS RAISED BY THE CODEX COMMITTEE ON PESTICIDE RESIDUES (CCPR)

The Meeting noted that the information supplied on some of the concern forms submitted by CCPR Members was inadequate to permit JMPR to clearly identify the critical issues underlying the concerns. Consequently, the Meeting had great difficulty in determining the issues involved, raising the possibility that the response provided by the Meeting might not actually address the true concern. The Meeting requested that any future concerns submitted to JMPR should be accompanied by comprehensive and transparent supporting information. If such information is not provided, the Meeting might be forced to conclude that it is not able to provide a meaningful response.

3.1 BUPROFEZIN (173)

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.

The 2012 Meeting received information on supervised trials on coffee conducted in Brazil and the USA and relevant information on analytical method and storage stability. The Meeting concluded that it was not possible to estimate a maximum residue level for coffee beans as the Meeting did not have sufficient information on normal agricultural practices in coffee in Brazil or the USA to determine their similarity.

The current Meeting received a concern form from the USA along with information on the cultivation practices and field trial conditions of the trial sites in Brazil and the USA.

The Meeting considered from the information provided that their cultivation practices are sufficiently similar.

However, according to the study reports, there was a significant difference in the processing of coffee berries (cherries) to green coffee which is the raw agricultural commodity.

In the trials in Hawaii, the ripe coffee berries harvested were placed in hand-cranked pulper to separate the green beans from the berries. Beans were put in buckets with water to cover and left to ferment overnight. Pulp was then removed and the beans were dried in an oven for approximately 14–16 hours at 50 °C.

In the trials in Brazil, the collected fresh coffee berries were processed according to standard local practices to produce green coffee. The coffee berries were sun-dried during the day and moved inside each night. Once the desired moisture level was obtained, the outer part of the coffee beans was removed with a hand-held shelling device and samples were cleaned manually using sieves. The time from harvesting fresh berries in the field and obtaining the green bean sample was 17 days.

The Meeting recognized that while the cultivation practices in the trials conducted in Hawaii and those in Brazil were similar, the processing methods of harvested coffee berries to produce green coffee were significantly different. This difference may have impact on residue concentrations in green coffee. The Meeting therefore concluded that, as it is not appropriate to combine the residue populations from trials in Hawaii and those in Brazil for the reason above to estimate a maximum residue level, it was not possible to estimate a maximum residue level for coffee.

3.2 CLOTHIANIDIN (238) / THIAMETHOXAM (245)

Background

During the Forty-third Session of the CCPR meeting in 2011, the EU expressed a reservation regarding the advancement of the clothianidin MRL proposal for root and tuber vegetables. The

concern regarding the procedure used by JMPR to propose this group MRL was expressed again by the EU delegation during the Forty-fourth Session of the CCPR in 2012 (cf. REP12/PR §65). The Committee retained the proposed draft MRL for root and tuber vegetables at Step 7, noting the reservation of the Delegation of the EU; and awaiting further clarification from JMPR.

Evaluation of clothianidin and thiamethoxam by JMPR

Clothianidin is a neonictinoid insecticide and is related to the neonictinoid insecticide thiamethoxam in that clothianidin is a metabolite of thiamethoxam and thiamethoxam use may lead to clothianidin residues. Clothianidin and thiamethoxam were 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 2010 Meeting established an acceptable daily intake (ADI) of 0–0.1 mg/kg bw per day and estimated the acute reference dose (ARfD) as 0.6 mg/kg bw for clothianidin. 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 0–0.08 mg/kg bw per day and estimated the acute reference dose (ARfD as 1 mg/kg bw for thiamethoxam. The residue definition for thiamethoxam in plant commodities for enforcement is thiamethoxam, while the residue definition for dietary risk assessment is thiamethoxam and the metabolite CGA 322704 (i.e., clothianidin), considered separately.

Clothianidin residues may arise from use of clothianidin as well as from use of thiamethoxam (through metabolite CGA 322704, i.e., clothianidin). The 2010 Meeting considered it unlikely that both pesticides were used on the same crop and therefore the maximum estimated levels, the maximum STMR, and the maximum HR of each use was taken as recommendation. This is summarized in the table below.

CCN	Commodity name	Origin	Recommendation mg/kg	STMR mg/kg	HR mg/kg
VR 0075	Root and tuber vegetables	CGA 322704	0.2	0.01	0.15
VR 0577	Carrot	clothianidin	insufficient data		
VR 0469	Chicory, roots	clothianidin	insufficient data		
VR 0589	Potato	clothianidin	0.05	0.02	0.033
VR 0596	Sugar beet roots	clothianidin	0.03	0.01	0.019
VR 0075	Root and tuber vegetables	both uses	0.2 [a, b]	0.02	0.15

[a] based on clothianidin use as derived from 2010 clothianidin evaluation

[b] based on thiamethoxam use as derived from 2010 thiamethoxam evaluation (metabolite CGA 322704).

Evaluation of clothianidin by the EU

The present meeting received a concern form from the EU relating to the proposed maximum residue level of clothianidin for root and tuber vegetables.

A MRL recommendation of 0.2 mg/kg on clothianidin (CGA 322704) arising from thiamethoxam use was derived from a complete residue database on potato seed pieces (seed treatment) and was extrapolated to the root and vegetables group including sugar beet root. The EU noted that all the trials were performed at a dose rate 30% higher than the critical one.

The EU noted that the performed extrapolations were on crops with widely differing GAPs and application methods. GAPs for thiamethoxam were reported for carrots, potatoes, radishes and sugar beet. In addition, GAPs for clothianidin were reported for chicory roots, tuberous and corm

vegetable and sugar beet, but they were less critical than the use of thiamethoxam. The EU noted that the GAPs were not comparable: seed treatment for potatoes and for sugar beets, foliar application and/or soil treatment for the other crops, different application rate for carrots and radishes compared with potatoes and only GAP for clothianidin on chicory roots (not supported by sufficient trial data). An overview as made by EU is given in the table below.

Therefore the EU concluded that extrapolation of residues, found on potatoes (following treatment with thiamethoxam), to the whole group of root and tuber vegetables is not acceptable. The EU indicated that there are sufficient data to set individual MRLs for carrots, potatoes, radishes, and sugar beet root.

	origin	recommendation (mg/kg)	STMR (mg/kg)	HR (mg/kg)
Carrots Clothianidin: no GAP	clothianidin	insufficient data (trials involving seed treatments available, but no GAP)		
	CGA 322704		[≤ LOQ 0.01 mg/kg (n=8)] [≤ LOQ 0.01 mg/kg (n=6)]	
Thiamethoxam Foliar treatment at 0.070 kg ai/ha Soil treatment at sowing at 0.21 kg ai/ha				
Radish roots Thiamethoxam Foliar treatment at 0.070 kg ai/ha Soil treatment at sowing at 0.21 kg ai/ha	CGA 322704		[≤ LOQ 0.01 mg/kg (n=6)] [≤ LOQ 0.01 mg/kg (n=4)]	
Chicory roots Clothianidin Seed treatment at 0.3 mg ai/seed	clothianidin	insufficient data (only 1 trial matching GAP (< 0.01 mg/kg))		
Potato Clothianidin	clothianidin	0.05	0.02	0.033
			[< 0.02 mg/kg at exaggerated dose]	
Soil treatment (at planting) at 224 g ai/ha	CGA 322704	0.2	0.01 [30% overdosed trials]	0.15 [30% overdosed trials]
Less critical: Foliar treatment at 224 g ai/ha per season Thiamethoxam Seed treatment at 6.2 g thiamethoxam/100 kg seed) Less critical: Foliar treatment at 0.025 kg ai/ha (EU) or 0.053 kg ai/ha (USA)			[<LOQ 0.02 mg/kg (n=13)] [<LOQ 0.01 mg/kg (n=14); 100% overdosed trials]	
Sugar beet roots Clothianidin Seed treatment at 0.6 mg ai/seed Thiamethoxam Seed treatment at 60 g ai/100,000 seeds	clothianidin	0.03	0.01	0.019
	CGA 322704		[≤ LOQ 0.02 mg/kg (n=9)]	

Comments by JMPR

The current recommendation for clothianidin for the root and tuber vegetables group is based on thiamethoxam treatment of potato seed pieces. Since clothianidin residues result from clothianidin use and thiamethoxam use, clothianidin residues cannot be judged on their own. In this case thiamethoxam (parent) residues determined whether a group MRL was appropriate. Once a group MRL for thiamethoxam (parent) is set, also a group MRL for clothianidin needs to be set. Therefore, thiamethoxam data for thiamethoxam parent need to be evaluated first.

For thiamethoxam use, the 2010 Meeting received several supervised field trials on root and tuber vegetables. In trials on carrots, thiamethoxam levels were < 0.01 mg/kg (n=8) after foliar spray (0.070 kg ai/ha, PHI 7 days) and < 0.01 (2), 0.01, 0.02 (2), 0.04 mg/kg (n=6) after soil treatment (0.21 kg ai/ha, at planting). In trials on potatoes, thiamethoxam levels were < 0.02 mg/kg (n=7) or < 0.01 mg/kg (n=15, at 2× label rate) after foliar treatment. In trials on potatoes after seed treatment, thiamethoxam levels were < 0.01 (11), 0.02, 0.05, 0.14, 0.18, 0.20 mg/kg (n=16). The GAP for treatment of potato seed pieces (4.3-6.2 g ai per 100 kg pieces) resulted in higher thiamethoxam residues than the GAP for foliar treatment of potatoes (0.025 kg ai/ha with PHI 7 days or 0.053 kg ai/ha with PHI 14 days). It was noted that all the trials with seed treatments were performed at a dose rate 30% higher than the critical one. In trials on radish roots, thiamethoxam residues were < 0.01 (4), 0.01 (2) mg/kg mg/kg (n=6) after foliar spray (0.070 kg ai/ha, PHI 7 days) or < 0.01 (3), 0.02 mg/kg (n=4) after soil treatment (0.11 kg ai/ha, at planting). In trials on sugar beets, thiamethoxam did not exceed the LOQ: < 0.02 mg/kg (n=9) after seed treatment (60 g ai/100000 seeds).

The 2013 Meeting agreed that a group maximum residue level for thiamethoxam (parent) in root and tubers would normally not be considered, since the thiamethoxam GAPs for potatoes, carrots, radishes and sugar beets are different. But although the GAPs are different (soil and foliar treatments on carrots and radishes and seed treatments on potatoes and sugarbeet), the dataset for potatoes is not significantly different from those for carrots, radishes and sugarbeets (Kruskall-Wallis test). To make the best use of the available data in a complex situation with a range of crops and a range of applications, the 2013 Meeting considered it appropriate to propose a group MRL for root and tuber vegetables for thiamethoxam residues and thereby confirmed its previous recommendation 0.3 mg/kg for thiamethoxam for root and tubers. Also the EU did not have a concern regarding thiamethoxam residues for the whole group of root and tubers. When a group maximum residue level is proposed for thiamethoxam residues, also a group maximum residue level needs to be proposed for clothianidin. The Meeting therefore confirmed its previous recommendation of 0.2 mg/kg for clothianidin for roots and tubers.

3.3 GLUFOSINATE-AMMONIUM (175)

Background

Glufosinate-ammonium was last evaluated by JMPR in 2012, when an ADI of 0–0.01 mg/kg body weight (bw) was established, on the basis of an overall no-observed-adverse-effect level (NOAEL) of 1 mg/kg bw per day for reductions in glutamine synthetase activity in the brain of dogs. A safety factor of 100 was applied. The 2012 Meeting concluded that this ADI should also apply to its metabolites *N*-acetyl-glufosinate (NAG), 3-methylphosphinico-propionic acid (MPP) and 2-methylphosphinico-acetic acid (MPA). However, the 2012 Meeting noted that in view of the lower toxicity of NAG, MPP and MPA compared with glufosinate-ammonium, the application of the ADI to these metabolites is likely to be conservative.

In 2012, the Meeting also established an ARfD for glufosinate-ammonium of 0.01 mg/kg bw. This was based on the NOAEL of 1 mg/kg bw per day in a 28-day capsule study in dogs for an increase in spontaneous motor activity that occurred within a few days after the start of treatment and reductions in body weight gain and feed consumption observed during the 1st week of treatment with 8 mg/kg bw per day. A safety factor of 100 was applied. The 2012 Meeting concluded that this ARfD

should also apply to its metabolites NAG, MPP and MPA and noted that in view of the lower acute toxicity of NAG, MPP and MPA compared with glufosinate-ammonium, the application of the ARfD to these metabolites is likely to be conservative.

At the request of CCPR, the present Meeting considered the possible use of relative toxic potencies of glufosinate-ammonium and its metabolites NAG, MPP and MPA to enable refinement of the dietary risk assessment. The Meeting reviewed the previously evaluated data from the 2012 JMPR as well as newly submitted data from a one-generation study of reproductive toxicity with MPP.

Evaluation of the new reproductive toxicity study with MPP

In a one-generation dietary reproductive toxicity study not previously evaluated by JMPR[1], Wistar Crl:WI(Han) rats (25 of each sex per group) were fed MPP (purity 99.6%) at a concentration of 0, 1000, 3200 or 10 000 parts per million (ppm). The corresponding MPP intakes during the different phases of the study are presented in Table 1.

Table 1 MPP intake in parental rats and their offspring during different phases of a one-generation reproductive toxicity study

Generation	Duration of treatment (days)	Sex	Intake (mg/kg bw per day)		
			1000 ppm	3200 ppm	10 000 ppm
F0 premating	21	Male	86	276	896
F0 premating	21	Female	88	266	844
F0 gestation	22	Female	87	260	844
F0 lactation	21	Female	177	564	1678
F1 PND 21–28	7	Male	174	600	2017
F1 PND 21–28	7	Female	186	665	1989

From Milius (2011)

PND, postnatal day

Clinical examination of parental rats was performed daily. Parental body weight and feed consumption were recorded weekly during the premating and mating phases in both sexes, during the gestation period in females and on postnatal days (PNDs) 1, 4, 7, 14 and 21 in females. The rats were mated after 3 weeks of treatment. After birth, all litters were examined for number of pups, sex of pups, number of stillbirths, number of live births and pup viability. Litters were culled to eight pups per litter on PND 4. Pups were examined daily for clinical signs and weighed on PNDs 1, 4, 7, 14 and 21. In a selection of pups, body weight and feed consumption were measured on PND 28. Macroscopic examination was performed on all parental males after mating, on all parental females and about half the pups after weaning on PND 21 and on all pups kept until PND 28. Statements of adherence to quality assurance and good laboratory practice (GLP) were included.

No effect of treatment was observed on any of the parameters examined in parental rats. In male and female pups at 10 000 ppm, lower body weights compared with control pups were observed at PND 4 (4–5%), PND 7 (5–6%), PND 14 (7%), PND 21 (12–13%) and PND 28 (12%), reaching

[1] Milius AD (2011). Technical grade: AE F061517: A one-generation reproductive toxicity study in the Wistar rat. Unpublished report no. 11-P72-UI from Xenometrics, LLC, Stilwell, Kansas, USA. Submitted to WHO by Bayer CropScience, Monheim, Germany.

statistical significance from PND 14 onwards. Feed consumption from PND 21 to PND 28 was not affected by treatment of the pups.

The NOAEL for parental toxicity was 10 000 ppm (equal to 844 mg/kg bw per day), the highest dose tested.

The NOAEL for offspring toxicity was 3200 ppm (equal to 564 mg/kg bw per day, based on maternal test substance intake during lactation), on the basis of a reduced body weight gain during and after lactation at 10 000 ppm (equal to 1678 mg/kg bw per day, based on maternal test substance intake during lactation).

The NOAEL for reproductive toxicity was 10 000 ppm (equal to 844 mg/kg bw per day), the highest dose tested.

Overview of toxicity data on glufosinate-ammonium, NAG and MPP

Glufosinate-ammonium and its metabolites NAG and MPP have been tested in a number of toxicity studies of similar duration and design in mice, rats, rabbits and dogs (Table 2). It should be noted, however, that the parameters examined in the studies of similar duration are not always the same. Where the NOAEL for a certain compound is based solely on a parameter that was not investigated for the other compounds, this is indicated in the notes below the table. Short-term studies in mice were not included, as the only toxicologically relevant effect in the studies with NAG (i.e. inhibition of glutamine synthetase) was not investigated in the short-term studies with glufosinate-ammonium. Data from studies in which for all compounds the NOAEL was the highest dose tested (e.g. parental toxicity in reproductive toxicity studies) are not presented. On the basis of the comparison of NOAELs and lowest-observed-adverse-effect levels (LOAELs) in the relevant studies of these three compounds, an indication of their relative toxic potency can be obtained.

Table 2 NOAELs and LOAELs in studies of glufosinate-ammonium (GA), NAG and MPP, and relative potency based on comparison of NOAELs

Species	Study type	GA		NAG		MPP		NOAEL NAG/ NOAEL GA	NOAEL MPP/ NOAEL GA
		NOAEL (mg/kg bw per day)	LOAEL (mg/kg bw per day)	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	Thirty-eight-day neurotoxicity	1.5[a]	15	159[a]	—	—	—	106	—
Rat	Thirteen-week (neuro)toxicity	6.2[b]	63.6	63.2[b]	658	546[c]	—	10	—
Dog	Four-week toxicity	1[d]	8	—	—	—	—	—	—
Dog	Thirteen-week toxicity	2.0	7.8	20[e]	76	103	—	10	52
Dog	Fifty-two-week toxicity	4.5	10.6–13.6[f]	325	—	—	—	72	—
Mouse	Two-year toxicity	10.8	23	1188	—	—	—	110	—
Rat	Two-year toxicity	7.6	26.7	91[g]	998	—	—	12	—

Species	Study type	GA		NAG		MPP		NOAEL NAG/ NOAEL GA	NOAEL MPP/ NOAEL GA
		NOAEL (mg/kg bw per day)	LOAEL (mg/kg bw per day)	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	**One- and two-generation reproductive toxicity[h]**								
	Offspring toxicity	44	—	—	—	564	1678	—	13
	Reproductive toxicity	8.7	18	622	—	844	—	74	97
Rat	**Developmental toxicity**								
	Maternal toxicity	10	50	1000	—	300	900	100	30
	Embryo and fetal toxicity	10	50	1000	—	300	900	100	30
Rabbit	**Developmental toxicity**								
	Maternal toxicity	6.3	20	64	160	50	100	10	8
	Embryo and fetal toxicity	6.3	20	64	160	50	100	10	8

[a] GA and NAG were tested in the same 38-day neurotoxicity study. The study included measurements of glutamine synthetase activity in brain, liver and kidney.

[b] GA and NAG were tested in the same 13-week neurotoxicity study. The study included measurements of glutamine synthetase activity in brain, liver and kidney.

[c] In the 13-week neurotoxicity study with MPP, measurements of glutamine synthetase activity were not included.

[d] The 28-day study in the dog was the basis for the ADI and ARfD.

[e] In the 13-week study with NAG in the dog, the NOAEL was 500 ppm (equal to 20 mg/kg bw per day), based on reduction in brain glutamine synthetase activity (≥ 16%) at 2000 ppm (equal to 76 mg/kg bw per day). No other effects were observed at doses up to 8000 ppm (equal to 294 mg/kg bw per day). Glutamine synthetase activity was not measured in the 13-week study with glufosinate-ammonium in the dog.

[f] Doses are based on exposure to 375 ppm (equal to 10.6–13.6 mg/kg bw per day) for the first 10–17 days, after which the dose was reduced to 250 ppm (equal to 8.4 mg/kg bw per day).

[g] The NOAEL in the 2-year study with glufosinate-ammonium was, among others, based on effects on glutathione and glutathione disulfide levels and reduction of brain glutamine synthetase. These parameters were not assessed in the study with NAG.

[h] In the one- and two-generation reproductive toxicity studies with glufosinate-ammonium, NAG and MPP, the NOAELs for parental toxicity were the highest doses tested. Therefore, only data on the NOAELs and LOAELs for offspring and reproductive toxicity are presented. For glufosinate-ammonium, the overall NOAEL and LOAEL from a one- and a two-generation reproductive toxicity study are presented.

Assessment of relative toxic potencies of NAG, MPP and MPA compared with glufosinate-ammonium

Glufosinate-ammonium, NAG and MPP have been tested in a number of toxicity studies with similar designs and durations in mice, rats, rabbits and dogs. Based on these studies, an indication of the relative toxic potencies of NAG and MPP compared with the parent compound can be obtained. Table 2 shows that the NOAELs for NAG are at least 10 times higher than those for glufosinate-ammonium, and generally the NOAELs for NAG are higher than the LOAELs for glufosinate-

ammonium. The critical effect for glufosinate-ammonium, which formed the basis for its ADI and ARfD, is the inhibition of glutamine synthetase in the brain and (possibly acute) clinical signs of neurotoxicity observed in a 28-day study in dogs. NAG also caused inhibition of glutamine synthetase activity in in vivo studies and an in vitro study, at dose levels that were considerably higher than those of glufosinate-ammonium causing comparable inhibition. The inhibition of glutamine synthetase by NAG was attributed to the presence of glufosinate-ammonium as an impurity in the test substance and to the metabolic deacetylation of NAG to form free glufosinate. Biotransformation studies in rats indicate that after administration of a low dose (2.1–3.4 mg/kg bw) of NAG, up to 10% of the administered NAG may be deacetylated to glufosinate by the intestinal microflora. At higher doses, a lower percentage of NAG is converted to free glufosinate in the gut.

For NAG, the lowest NOAEL of 20 mg/kg bw per day, based on reduction in brain glutamine synthetase activity, was observed in a 13-week study in the dog. This NOAEL is 20 times higher than the NOAEL of 1 mg/kg bw per day for effects of glufosinate-ammonium in the 28-day toxicity study in dogs, which formed the basis for the ADI and ARfD.

In view of the above data, it seems reasonable to assume that after oral administration, NAG is at least 10 times less toxic than glufosinate-ammonium. Therefore, a factor of 0.1 can be applied to the dietary exposure estimate of NAG for acute and chronic dietary risk assessment of glufosinate-ammonium and its metabolites in food.

Table 2 shows that the NOAELs for MPP are at least 8 times higher than those of glufosinate-ammonium in similar studies. The lowest NOAEL for MPP was observed in a developmental toxicity study in the rabbit. This NOAEL of 50 mg/kg bw per day, for maternal and embryo/fetal toxicity, is 50 times higher than the NOAEL of 1 mg/kg bw per day for effects of glufosinate-ammonium in the 28-day toxicity study in dogs, which formed the basis for the ADI and ARfD. It is noted that the critical effect in the 28-day dog study is inhibition of glutamine synthetase activity and that MPP has no effect on this enzyme.

In view of the above data, it seems reasonable to assume that after oral administration, MPP is at least 10 times less toxic than glufosinate-ammonium. Therefore, a factor of 0.1 can be applied to the dietary exposure estimate of MPP for acute and chronic dietary risk assessment of glufosinate-ammonium and its metabolites in food.

For the metabolite MPA, only a limited toxicological database (i.e. an acute oral toxicity study, a 2-week dietary range-finding study and a 90-day dietary study in rats) is available, which in itself was considered insufficient by the Meeting to establish the toxic potency relative to that of glufosinate-ammonium. However, the Meeting noted that MPA is structurally closely related to MPP, of which it is a metabolite (see Figure 1). The Meeting considered therefore that read-across from MPP to MPA was justified and concluded that the toxicity of MPA was likely to be similar to that of MPP. This is supported by the low toxicity observed in the available studies with MPA: in the acute toxicity study, the median lethal dose (LD_{50}) was greater than 2000 mg/kg bw, with diarrhoea as the only observed adverse effect. In the repeated-dose studies, no adverse effects were observed at the highest dose tested (1128 mg/kg bw per day in the 2-week range-finding study, 684 mg/kg bw per day in the 90-day study). Therefore, the Meeting concluded that the factor of 0.1 for MPP can also be applied to the dietary exposure estimate of MPA for acute and chronic dietary risk assessment of glufosinate-ammonium and its metabolites in food.

MPP MPA

Figure 1 Chemical structures of MPP and MPA

Conclusion

The present Meeting established the relative toxic potencies of glufosinate-ammonium and the metabolites NAG, MPP and MPA on the basis of all available data.

In view of the identified differences in toxic potency of glufosinate-ammonium and its metabolites NAG, MPP and MPA, the Meeting concluded that the previously established ADI of 0–0.01 mg/kg bw, derived on the basis of an overall NOAEL of 1 mg/kg bw per day for glufosinate-ammonium for reductions in glutamine synthetase activity in the brain of dogs and application of a safety factor of 100, should be compared with the sum of the dietary exposure to glufosinate-ammonium + 0.1 × (the dietary exposure to NAG + MPP + MPA).

The Meeting concluded that the ARfD of 0.01 mg/kg bw, previously established on the basis of a NOAEL of 1 mg/kg bw per day in a 28-day capsule study of glufosinate-ammonium in dogs for an increase in spontaneous motor activity that occurred within a few days after the start of treatment and reductions in body weight gain and feed consumption observed during the 1st week of treatment with 8 mg/kg bw per day, and application of a safety factor of 100, should be compared with the sum of the dietary exposure to glufosinate-ammonium + 0.1 × (the dietary exposure to NAG + MPP + MPA).

Should new toxicological data on glufosinate-ammonium and/or its metabolites become available, the definitions of the ADI and ARfD may have to be reconsidered by a future Meeting.

Recalculation of STMR, HR, PF, STMR-P and HR-P values

The STMR and HR values as well as PFs, STMR-P and HR-P values estimated by the 2012 JMPR for foods have been recalculated using the above approach and are tabulated below.

For estimation of maximum residue levels the residues are calculated as the sum of glufosinate-ammonium, NAG, MPP and MPA without the need for adjustment for relative toxicity and as such the values used in estimating MRLs and also median and highest residues for use in livestock dietary burden do not need to be recalculated.

Table 3 Revised processing factors for glufosinate-derived residues for use in dietary intake estimation and calculated STMR-P and HR-P values

Raw commodity	Processed commodity	Individual PFs	Best estimate PF	$STMR_{RAC}$	STMP-P	HR_{RAC}	HR-P
Orange	Juice Dried peel / pulp Oil	0.96 2.1 < 0.53	0.96 2.1 < 0.53	0.05	0.048 1.05 < 0.265	0.05	0.048 1.05 < 0.265
Plum	Dried fruit	1.13	1.1	0.05	0.055	0.05	0.055
Grape	Wine	ND ND ND ND					
Olive	Oil	< 0.38	< 0.38	0.05	< 0.019	0.05	< 0.019

Raw commodity	Processed commodity	Individual PFs	Best estimate PF	$STMR_{RAC}$	STMP-P	HR_{RAC}	HR-P
Potato	Chips	2.3	2.3	0.05	0.106	0.05	0.106
	Flakes	2.0 3.0 3.0 3.8 4.0	3.0		0.15		0.15
	Crisps	1.7 1.8 1.9 2.5	1.85		0.0925		0.0925
	French fries	0.85 1.2 1.3 1.6	1.25		0.0575		0.0575
	Boiled potatoes	0.7 0.8 1.4 1.7	1.1		0.055		0.055
	Fried potatoes	1.2 2.3 4.2 5.3	3.25		0.1625		0.1625
	Baked potatoes	1.4 1.5 1.7 1.9	1.6		0.08		0.08
Sugar beet	Molasses	3.8 5.0 6.3 11	5.65	0.225	1.27		
	Raw or refined sugar	< 0.055< 0.16 < 0.18 < 0.84	< 0.17		< 0.0382 5		
Soya bean	Oil	< 0.11 < 0.12 < 0.22 < 0.9	< 0.17	0.714	< 0.121		
Rapeseed	Oil	< 0.04 < 0.79 < 0.98 < 0.98	< 0.04	0.225	< 0.009		
Cottonseed	Oil	< 0.013	< 0.013	0.677	< 0.0088		
Sunflower seed	Oil	0.023 < 0.071 < 0.074	0.023	0.47	0.0108		
Maize	Starch (wet milling)	ND ND					
	Oil (wet milling)	ND ND					
	Flour (dry milling)	ND ND					
	Oil (dry milling)	ND ND					
Rice	Bran	0.76 0.95	0.855	0.08	0.0684		
	Polished grain	< 0.86 1.15	1.15		0.092		

ND: not determined. Denotes processing trials in which no processing factor could be derived because the residues were found to be < LOQ in both the raw agricultural commodity and the processed fractions.

The revised calculation for mammalian commodities is shown below:

Table 4 Revised calculations of STMR and HR values for mammalian commodities.

Glufosinate + MPP feeding study	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
HR beef or dairy cattle							
Feeding study [a]	4.0 12	< 0.02 0.02	4.0 12	< 0.05 < 0.05	0.28 0.42	0.041 0.20	0.06 0.08
Dietary burden and high residue	4.4	< 0.02	4.7	< 0.05	0.292	0.055	0.062
STMR beef or dairy cattle							
Feeding study [b]	4.0	< 0.02	4.0	< 0.05	0.157	0.038	0.05
Dietary burden and residue estimate	2.3	< 0.012	2.4	< 0.03	0.094	0.023	0.03

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

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

Table 5 Revised STMR and HR values for use in dietary intake calculations and for calculation of STMR-P and HR-P values.

Commodity CCN	Name	STMR (mg/kg)	HR (mg/kg)
VS 0621	Asparagus	0.05	0.27
FI 0030	Assorted tropical and sub- tropical fruits - inedible peel (except banana and kiwifruit)	0.05	0.05
FT0026	Assorted tropical and sub- tropical fruits - edible peel	0.05	0.05
FI 0327	Banana	0.05	0.054
FB 0018	Berries and other small fruits (except currants)	0.03	
FB 0020	Blueberries	0.05	0.06
VR 0577	Carrot	0.05	0.05
FC 0001	Citrus fruits	0.05	0.05
VD 0526	Common bean (dry)	0.04	
SB 0716	Coffee beans	0.04	
VP 0526	Common bean (pods and/or immature seeds)	0.05	0.05
VL 0470	Corn salad	0.05	0.05
SO 0691	Cotton seed	0.677	
FB 0021	Currants, Black, Red, White	0.02	0.403
MO 0105	Edible offal (mammalian)	0.023 Kidney 0.094 Liver	0.055 Kidney 0.292 Liver
PE 0112	Eggs	0	0.02
FB 0268	Gooseberry	0.02	0.02
FB 0269	Grapes	0.02	0.12
FI 0341	Kiwifruit	0.05	0.05
VL 0482	Lettuce, Head	0.05	0.05
VL 0483	Lettuce, Leaf	0.05	0.05
GC 0645	Maize	0.05	
MM 0095	Meat (from mammals other than marine mammals)	0.03 Muscle 0.03 Fat	0.05 Muscle 0.062 Fat
ML 0106	Milks	0.01	0.02
VA 0385	Onion, Bulb	0.05	0.05
FP 0009	Pome fruits	0.05	0.05
VR 0589	Potato	0.05	0.05
PM 0110	Poultry meat	0	0.02
PO 0111	Poultry, Edible offal of	0	0.04
SO 0495	Rape seed	0.225	
FB 0272	Raspberries, Red, Black	0.03	0.03
GC 0349	Rice	0.08	
VD 0541	Soya bean (dry)	0.714	
FS 0012	Stone fruits	0.05	0.05
FB 0275	Strawberry	0.02	0.15
VR 0596	Sugar beet	0.225	
SO 0702	Sunflower seed	0.47	
TN 0085	Tree nuts	0.05	0.05

Dietary risk assessment

Long-term intake

The WHO Panel of the 2012 JMPR established an Acceptable Daily Intake (ADI) of 0–0.01 mg/kg bw for glufosinate-ammonium.

The current Meeting re-evaluated the STMR values for glufosinate-ammonium. Where data on consumption were available for the listed food commodities, dietary intakes were calculated for

the 13 GEMS/Food Consumption Cluster Diets. The results are shown in Annex 3 of the 2013 JMPR Report.

The IEDIs in the thirteen Cluster Diets, based on the estimated STMRs were 3–9% of the maximum ADI (0.01 mg/kg bw). The Meeting concluded that the long-term intake of residues of glufosinate-ammonium from uses that have been considered by the 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.

For soya bean (dry) the IESTI represented 110% of the ARfD of 0.01 mg/kg bw. For all other commodities the revised IESTI represented 0–100% of the ARfD. The Meeting concluded that, other than for soya beans, 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.

No alternative GAP was identified for soya beans (dry). Processing studies from soya bean for cooked soya bean products, including tofu, are desirable for further refinement of the exposure.

In 2012, the Meeting established an acute reference dose (ARfD) for glufosinate-ammonium of 0.01 mg/kg bw. This was based on the NOAEL of 1 mg/kg bw per day in a 28-day capsule study in dogs for an increase in spontaneous motor activity that occurred within a few days after the start of treatment and reductions in body weight gain and feed consumption observed during the 1st week of treatment with 8 mg/kg bw per day, and application of a safety factor of 100. The present Meeting concluded that it might be possible to refine the ARfD if new data became available.

3.4 PROPYLENE OXIDE (250)

Background

JMPR reviewed the toxicology data on propylene oxide (PPO) and its metabolites propylene chlorohydrin (PCH) and propylene bromohydrin (PBH) in 2011. The Meeting established an ADI of 0–0.04 mg/kg bw and an ARfD of 0.04 mg/kg bw for PPO, both based on a no-observed-adverse-effect concentration (NOAEC) of 100 ppm (equivalent to approximately 40 mg/kg bw per day orally) for systemic effects from a chronic inhalation study in rats, with the application of a 1000-fold safety factor. The additional factor of 10 was applied due to limitations in the database. The 2011 Meeting was unable to establish any reference doses for PCH or PBH due to deficiencies in the databases.

At the Forty-fourth Session of CCPR, the delegation of the United States of America (USA) informed the Committee that it would submit residue data for tree nuts for JMPR evaluation in 2014. After the Forty-fourth Session of CCPR, the delegation of the USA submitted a concern form in May 2013 requesting clarification on a number of aspects of the JMPR consideration of PPO and its metabolites. The present Meeting has considered the issues raised in the concern form and the review of PPO by the USEPA[1] and reviewed the decisions of the 2011 Meeting. The conclusions of the present Meeting are set out below, against the concerns identified by the USA in the concern form.

[1] USEPA (2006). *Reregistration Eligibility Decision for Propylene Oxide*. Washington, DC, United States Environmental Protection Agency (http://www.epa.gov/oppsrrd1/REDs/propylene_oxide_red.pdf).

Propylene oxide

Concern

"Regarding PPO, the U.S. respectfully requests that additional explanation be provided for the additional 10-fold uncertainty factor. Specifically, identification of the missing information from the relevant study(ies) is requested. As the ARfD was based on a chronic inhalation study in the rat, application of a total uncertainty factor of 1,000 to this endpoint seems excessively conservative without further explanation. Recommend consideration of a study demonstrating a single dose effect, such as the developmental study in the rat, be considered for establishment of the ARfD."

Response

The present Meeting noted that the USEPA and the 2011 JMPR agreed that there were deficiencies in the database for the toxicity of PPO and that both had used 1000-fold safety factors in establishing ADIs and ARfDs; the difference in the derived values was in the points of departure chosen. The Meeting noted that the USEPA had established an ARfD of 0.21 mg/kg bw based on a NOAEC of 300 ppm (equivalent to 209 mg/kg bw per day) from a rat developmental toxicity study, applying a 1000-fold safety factor. A poor quality developmental toxicity study in rabbits indicated that the NOAEC from such a study, which might be relevant to establishing an ARfD, could be below 75 mg/kg bw per day (oral dose equivalent). The absence of non-rodent studies and an adequate developmental toxicity study in rabbits from the database on PPO is considered important, as both these study types are used routinely in establishing ARfDs; without these studies, it was not possible to reliably assess the acute toxicity of PPO. Therefore, the present Meeting confirmed the conclusion of the 2011 JMPR that the ARfD for PPO should remain at the value of 0.04 mg/kg bw (i.e. the upper bound of the ADI).

The sponsor has the opportunity to submit additional cases or data[1] that would enable JMPR to consider if an ARfD was necessary or if the current value could be refined. However, the present Meeting believes that this might not be necessary, as it is possible that acute exposures from PPO treatment of tree nuts will be below the current JMPR ARfD. Any consideration of generating additional data relevant to refining the ARfD for PPO should therefore be delayed until the JMPR exposure assessment has been performed.

Propylene chlorohydrin

Concern

"The JMPR could not establish an ADI or ARfD for PCH due to the absence of data to characterize the hazard to fetuses. However, oral exposure is the relevant route for this metabolite, and the 1998 NTP [United States National Toxicology Program] studies identify both NOAELs and LOAELs following short-term and chronic exposure to PCH via the oral route (rats and mice) and there is a rat reproduction study. Recommend consideration of the two-generation reproduction study in the rat, along with an additional uncertainty factor of 10, for establishment of an ADI for PCH."

Response

The 2011 JMPR could not establish an ADI or ARfD for PCH in the absence of any reliable data to characterize the hazard to fetuses. The USEPA evaluation agrees that the database for PCH is incomplete in respect of developmental toxicity studies and non-rodent toxicity studies and that the chronic carcinogenicity studies in rats and mice used inadequate doses. The 2011 JMPR considered

[1] See Solecki R et al. (2005). Guidance on setting of acute reference dose (ARfD) for pesticides. *Food and Chemical Toxicology* 43:1569–1593 (http://www.who.int/foodsafety/chem/jmpr/arfd/en/).

that in the absence of key study types of adequate quality, it was not possible to reliably assess the toxicity of PCH. The present Meeting stressed that a two-generation reproductive toxicity study was not adequate for establishing the hazard to fetuses. The Meeting confirmed the conclusion of the 2011 JMPR that no ADI or ARfD could be established for PCH and that it was not possible to read across from PPO.

Propylene bromohydrin

Concern

"PCH is genotoxic in vitro. The Meeting could not establish an ADI or ARfD for PBH due to the absence of any *in vivo* data. Genotoxicity data show that PBH is genotoxic in vitro. Request citation of the study where the genotoxicity of PBH was observed."

Response

The genotoxicity data on PBH are in Leifer, Hyman & Rosenkranz (1981)[1]. Related data on the relative potency of chloro- versus bromo- short-chain hydrocarbons and alcohols are in Pfeiffer & Dunkelberg (1980)[2], Stolzenberg & Hine (1979, 1980)[3], Hooberman, Chakraborty & Sinsheimer (1993)[4] and Rosenkranz (1977)[5].

Concern

"Regulation of PPO should be protective of any toxicity from PBH based on structure activity relationship considerations. Moreover, given the trace levels of PBH in crops, reconsideration of the need to include PBH as a residue of concern for dietary risk assessment is requested."

Response

The 2011 JMPR could not establish an ADI or ARfD for PBH, as there were no in vivo data available. Submitted as part of the concern form were comparative acute oral toxicity data on PCH and PBH. These showed that PBH was approximately 3 times as potent for acute lethality as PCH (acute oral LD_{50}s in rats of 175 mg/kg bw for PBH versus 532 mg/kg bw for PCH). The present Meeting noted that acute lethality studies have no direct relationship to the critical values used to establish ADIs or ARfDs and are normally not used for this purpose. These new data do not address the potential in vivo genotoxicity of PBH. The present Meeting confirmed the conclusion of the 2011

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[1] Leifer Z, Hyman J, Rosenkranz HS (1981). Determination of genotoxic activity using DNA polymerase-deficient and -proficient *E. coli*. In: Stich HF, San RHC, eds. *Short-term tests for chemical carcinogens*. New York, Springer-Verlag, pp. 127–139.

[2] Pfeiffer EH, Dunkelberg H (1980). Mutagenicity of ethylene oxide and propylene oxide and of the glycols and halohydrins formed from them during the fumigation of foodstuffs. *Food and Cosmetics Toxicology* 18:115–118.

[3] Stolzenberg SJ, Hine CH (1979). Mutagenicity of halogenated and oxygenated three-carbon compounds. *Journal of Toxicology and Environmental Health* 5(6):1149–1158; Stolzenberg SJ, Hine CH (1980). Mutagenicity of 2- and 3-carbon halogenated compounds in the *Salmonella*/mammalian-microsome test. *Environmental Mutagenesis* 2(1):59–66.

[4] Hooberman BH, Chakraborty PK, Sinsheimer JE (1993). Quantitative structure–activity relationships for the mutagenicity of propylene oxides with *Salmonella*. *Mutation Research*, 299:85–93.

[5] Rosenkranz HS (1977). Mutagenicity of halogenated alkanes and their derivatives. *Environmental Health Perspectives* 21:79–84.

JMPR that no ADI or ARfD could be established for PBH and that as the chemical properties of PBH are different from those of PPO, it was not possible to read across from PPO.

Limited residue data for PBH were included as part of the concern form submission. These data showed that levels of PBH in almonds and walnuts were lower than the limit of quantification (LOQ). Previously evaluated data showed levels of PBH of approximately 3 ppm in nuts, cocoa powder and herbs and spices. The upper range of estimated chronic intakes of PBH, based on the previously evaluated data, is 13.5–94.3 μg/person per day.

As PBH has been shown to be genotoxic in vitro and has not been tested in vivo for genotoxic potential, a threshold of toxicological concern of 0.15 μg/person per day would apply. Estimated exposures are significantly above this; therefore, on the basis of the available data, human exposures to PBH cannot be discounted as irrelevant.

Additional, good quality residue data on PBH levels in a range of crops treated with PPO would help refine the intake estimates.

4. DIETARY RISK ASSESSMENT FOR PESTICIDE RESIDUES IN FOODS

Assessment of risk from long-term dietary intake

At the present Meeting, risks associated with long-term dietary intake were assessed for compounds for which MRLs were recommended and STMRs estimated. International estimated daily intakes (IEDIs) were calculated by multiplying the concentrations of residues (STMRs and STMR-Ps) by the average daily per capita consumption estimated for each commodity on the basis of the 13 GEMS/Food Consumption cluster diets[1]. IEDIs are expressed as a percentage of the maximum ADI for a 55 kg or 60 kg person, depending on the cluster diet.

New evaluations

Bixafen, cyantraniliprole, imazapic, imazapyr, isoxaflutole, tolfenpyrad, triflumizole and trinexapac-ethyl 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, except for bixafen. The data available for evaluation of bixafen did not allow any estimation of residues by the present Meeting, and no dietary risk assessment was performed.

Benzovindiflupyr, fenamidone and fluensulfone were evaluated only for toxicology and ADIs were established. The long-term dietary risk assessment for these compounds will be considered during the evaluation for residues at a subsequent Meeting.

Periodic Re-evaluations

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

Evaluations

Azoxystrobin, chlorantraniliprole, chlorpyrifos-methyl, cyprodinil, dicamba, difenoconazole, fenbuconazole, fenpyroximate, fludioxonil, flutolanil, glyphosate, glufosinate-ammonium, penthiopyrad, propiconazole, pyrimethanil, spirotetramat, sulfoxaflor and triazophos were evaluated for residues and long-term dietary risk assessments were conducted for these compounds.

The outcome of the evaluation of buprofezin, clothianidin/thiamethoxam, cyproconazole, indoxacarb and mandipropamid performed at this Meeting was such that the long-term dietary assessment was not necessary. Chlorfenapyr, picoxystrobin and propylene oxide were only considered for toxicological aspects and no dietary intake assessment was performed at the present Meeting.

A summary of the long-term dietary risk assessments conducted by the present meeting is shown on Table 1. The detailed calculations of long-term dietary intakes are given in Annex 3. The percentages are rounded to one whole number up to 9 and to the nearest 10 above that. Percentages above 100 should not necessarily be interpreted as giving rise to a health concern because of the conservative assumptions used in the assessments. Calculations of dietary intake can be further refined at the national level by taking into account more detailed information, as described in the Guidelines for predicting intake of pesticide residues[2].

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

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

Table 1 Summary of long-term dietary of risk assessments conducted by the 2013 JMPR

CCPR code	Compound Name	ADI (mg/kg bw)	Range of IEDI, as % of maximum ADI
229	Azoxystrobin	0-0.2	2-10
172	Bentazone	0-0.09	0
230	Chlorantraniliprole	0-2	0
090	Chlorpyrifos-methyl,	0-0.01	20-110
263	Cyantraniliprole	0-0.03	1-10
207	Cyprodinil	0-0.03	6-40
240	Dicamba	0-0.3	0-1
224	Difenoconazole	0-0.01	4-60
031	Diquat	0-0.006	0-4
028	Dithianon	0-0.01	1-9
197	Fenbuconazole	0-0.03	0-2
193	Fenpyroximate	0-0.01	1-7
211	Fludioxonil	0-0.4	2-6
205	Flutolanil	0-0.09	0-1
158	Glyphosate	0-1	0-1
175	Glufosinate-ammonium	0-0.01	3-9
266	Imazapic	0-0.7	0
267	Imazapyr	0-3	0
268	Isoxaflutole	0-0.02	0-1
049	Malathion	0-0.03	0
253	Penthiopyrad	0-0.1	0-6
160	Propiconazole	0-0.4	1-20
226	Pyrimethanil	0-0.2	0-5
252	Sulfoxaflor	0-0.05	1-7
234	Spirotetramat	0-0.05	0-20
269	Tolfenpyrad	0-0.006	0-11
143	Triazophos	0-0.001	1-40
270	Triflumizole	0-0.04	0-2
271	Trinexapac-ethyl	0-0.3	0-1

Chlorpyrifos-methyl

The highest % of the maximum ADI (110%) was found in the Cluster diet J, for which 94% of the IEDI was from the consumption of millet and sorghum (including raw grain, flour and beer for both commodities). Processing studies on other cereal grains treated with chlorpyrifos-methyl have shown that residues decrease during processing, including cooking grain in water. It is expected that the fate of residues during processing will be similar for millet and sorghum. The Meeting concluded that the long-term dietary intake of residues of chlorpyrifos-methyl is unlikely to present a public health concern.

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[1].

Updated large portion data were provided to GEMS/Food by the governments of Australia, Brazil, China, Finland, France, Germany, Japan, Netherlands and Thailand in 2011 and 2012. Denmark indicated that their large portion data were already covered by the JMPR 2011 data. 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/chem/acute_data/en/index1.html.

New evaluations

Benzovindiflupyr, bixafen, cyantraniliprole, fenamidone, fluensulfone, imazapic, imazapyr, isoxaflutole, tolfenpyrad, triflumizole and trinexapac-ethyl were evaluated for toxicology and/or residues for the first time by the JMPR.

The Meeting established ARfDs for bixafen, tolfenpyrad, triflumizole and cyantraniliprole a short-term dietary risk assessments were estimated for these compounds, except for bixafen, for which the residue data available for evaluation did not allow any estimation of residues by the present Meeting.

Benzovindiflupyr, fenamidone and fluensulfone were evaluated only for toxicology and ARfDs were established. The short-term dietary risk assessment for these compounds will be considered during the evaluation for residues at a subsequent Meeting.

The Meeting agreed that an ARfD for imazapic, imazapyr, isoxaflutole and trinexapac-ethyl were not necessary and no short-term dietary intake assessment was performed.

Periodic Re-evaluations

Bentazone, diquat and dithianon were evaluated for toxicology and/or residues under the Periodic Re-evaluation Programme. ARfD were considered not necessary for bentazone, so the short-term dietary risk assessment for this compound was not conducted.

Evaluations

Cyproconazole, chlorpyrifos-methyl, dicamba, difenoconazole, fenbuconazole, fenpyroximate, glufosinate-ammonium, indoxacarb, malathion, penthiopyrad, propiconazole, spirotetramat, sulfoxaflor and triazophos were evaluated for residues and short-term dietary risk assessments were conducted for these compounds.

The outcome of the evaluation of buprofezin and clothianidin/thiamethoxam performed at this Meeting was such that the short-term dietary assessment was not necessary. Chlorfenapyr, picoxystrobin and propylene oxide were only considered for toxicological aspects and no dietary intake assessment was performed by the present Meeting

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

On the basis of data received by the present or previous Meeting, the establishment of an ARfD was considered not necessary for azoxystrobin, chlorantraniliprole, cyprodinil, fludioxonil, flutolanil, glyphosate, mandipropamid and pyrimethanil. Therefore, it was not necessary to estimate the short-term intakes for these compounds.

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

Table 2 Maximum percentage of the ARfD found in the short-term dietary risk assessments conducted by the 2013 JMPR

CCPR code	Compound Name	ARfD (mg/kg bw)	Max. percentage of ARfD	
			Commodity (% ARfD)	Population (country)
239	Cyproconazole	0.06	Coffee (0)	General population and children (various)
090	Chlorpyrifos-methyl	0.1	Wheat (100%)	Children, 3-6 years(France)
240	Dicamba	0.5	Soya bean, dry (0)	General population and children (China)
224	Difenoconazole	0.3	Grape (30)	Children, 1-6 years (China)
			Potato (30)	Children, 1-5 years (S. Africa)
031	Diquat	0.8	All commodities (0)	General population and children (various)
028	Dithianon	0.1	Table grapes (90)	Children, 1-6 years (China)
197	Fenbuconazole	0.2	Citrus fruit (0)	General population and children (various)
193	Fenpyroximate	0.02	Peach (80)	Children, 1-6 years (Japan)
216	Indoxacarb	0.1	Tea (1)	General population and children (Various)
175	Glufosinate-ammonium	0.01	Soya bean, dry (110)	Children 1-6 years (China)
049	Malathion	2	Cherries (0)	General population and children (various)
253	Penthiopyrad	1	All (0)	General population and children (various)
258	Picoxystrobin	0.09	All (0-1)	General population and children (various)
160	Propiconazole	0.3	Oranges (100)	Children, 2-6 years (Australia)
234	Spirotetramat	1	All (0-2)	General population and children (various)
252	Sulfoxaflor	0.3	Lettuce head (60)	Children, 2-6 years (Netherlands)
269	Tolfenpyrad	0.01	Green tea (100)	General population ≥ 10 years (Brazil)
143	Triazophos	0.001	Rice, husked (130)	Children, 1-6 years (China)
270	Triflumizole	0.3	Grapes (50)	Children, under 6 years (China)

Possible risk assessment refinement when the IESTI exceeds the ARfD

Glufosinate-ammonium in soya bean

The Meeting concluded that the short-term intake of glufosinate-ammonium residues resulting from its use on soya beans (dry) might present a public health concern. There was no alternative GAP to be considered. Processing studies from soya bean for cooked soya bean products, including tofu, are desirable for further refinement of the exposure.

In 2012, the Meeting established an acute reference dose (ARfD) for glufosinate-ammonium of 0.01 mg/kg bw. This was based on the NOAEL of 1 mg/kg bw per day in a 28-day capsule study in dogs for an increase in spontaneous motor activity that occurred within a few days after the start of treatment and reductions in body weight gain and feed consumption observed during the 1st week of treatment with 8 mg/kg bw per day, and application of a safety factor of 100. The present Meeting concluded that it might be possible to refine the ARfD if new data became available.

Triazophos in rice

The Meeting concluded that the short-term intake of triazophos residues resulting from its use on rice might present a public health concern. There was no alternative GAP to be considered. Processing studies from rice (husked and polished) to cooked rice are desirable for further refinement of the exposure.

The 2002 Meeting established an ARfD of 0.001 mg/kg bw on the basis of the NOAEL of 0.0125 mg/kg bw per day in the 3-week study in humans and a safety factor of 10. Hence, further refinement is unlikely in the toxicological assessment.

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

5.1 AZOXYSTROBIN (229)

Azoxystrobin was first evaluated for toxicology and residues by the JMPR in 2008. The Meeting derived an ADI of 0–0.2 mg/kg bw per day, decided that an ARfD was unnecessary and concluded that the residue definition for plant and animal commodities for compliance with MRL values and for consumer risk assessment was parent azoxystrobin. The compound was re-evaluated for residues by the JMPR in 2011 and 2012.

Azoxystrobin was listed by the Forty-fourth Session of the CCPR for the review of additional MRLs by the JMPR in 2013. The Meeting received information on GAP and residue supervised trials data on pulses, potatoes, coffee beans, barley, oats and sorghum.

Methods of residue analysis

The Meeting received recovery data on analytical methods for coffee beans. After extraction with ethyl acetate, the residues were determined by LC-MS/MS with an LOQ of 0.01 mg/kg.

Results of supervised residue trials on crops

Most trial designs used replicate plots. If two field samples were taken or results of two replicate plots were submitted, the mean value was calculated. From two trials carried out side-by-side the higher residues was chosen.

Pulses

The 2008 JMPR estimated a maximum residue level for azoxystrobin in soya beans, dry of 0.5 mg/kg and an STMR of 0.06 mg/kg. The 2008 assessment based on the US GAP for soya beans at 6 × 0.28 kg ai/ha and a PHI of 14 days.

The use pattern in Germany for field peas, field beans and lupins is one to two applications at 0.25 kg ai/ha, with a spray interval of 14–28 days and a PHI of 35 days. The GAP in France is two foliar applications applied at 0.2–0.25 kg ai/ha with a spray interval of 14 days and a PHI of 35 days for dry peas (including chickpeas), 42 days for dry beans and lupins and 28 days for lentils.

Eight European trials (2 × UK, 4 × France, 2 × Italy) on dry beans were treated twice with 0.2–0.25 kg ai/ha. One additional French trial was treated with 0.13 + 0.2 kg ai/ha. The residues were in dry beans at PHIs of 26–36 days < 0.01 mg/kg (9).

Twenty trials were conducted on dry peas in the UK and in France matching the French and German GAPs. Azoxystrobin was applied twice at a rate of 0.2–0.25 kg ai/ha with a spray interval of 14 days. Samples of dry pea seed were collected at normal commercial harvest at PHIs of 30–45 days. If results of two replicate plots were submitted, the mean value was calculated. From two trials carried out side-by-side the higher residues were chosen for evaluation. The residues (n=20) were < 0.01 (8), 0.01 (5), 0.015, 0.015, 0.02, 0.025, 0.03, 0.03 and 0.065 mg/kg.

The Meeting estimated a maximum residue level of 0.07 mg/kg and an STMR 0.01 mg/kg for azoxystrobin residues in pulses, dry except soya beans.

Potato

The 2008 JMPR estimated a maximum residue level for azoxystrobin in root and tuber vegetables of 1 mg/kg, an STMR of 0.23 mg/kg and a highest residue of 0.45 mg/kg. The 2008 assessment based on the US GAP for root vegetables at 6 × 0.37 kg ai/ha.

Azoxystrobin is registered in the USA for one post-harvest application at 0.49 g ai/100 kg tubers. Six trials were submitted with one application of 0.44–0.50 g ai/100 kg tubers. Samples were taken directly after treatment. In three trials, stored tubers were analysed also (0–59; 0–61 and 0–231 days after treatment). The maximum residues from samples taken after treatment and after storage were 1.0, 1.5, 2.3, 2.3 and 3.8 mg/kg.

The current Meeting estimated for azoxystrobin residues in potato a maximum residue level of 7 mg/kg Po and an STMR of 2.3 mg/kg. The previous recommendation of 1 mg/kg azoxystrobin for root and tuber vegetables was withdrawn. For root and tuber vegetables, except potatoes, the Meeting confirmed the previous recommendation.

Barley and oats

The 2008 JMPR estimated a maximum residue level for azoxystrobin in barley and oats of 0.5 mg/kg and an STMR of 0.08 mg/kg based on the European GAP and residue data.

Azoxystrobin is registered in the USA in barley and oats as foliar spray with 2 × 0.15 kg ai/ha, a PHI in days for grain was not specified. The recommended use pattern is for a single early season application followed by a single application at 50% to full flag leaf emergence. New residue data were received for barley and oats.

On barley, seven independent supervised trials were conducted. In each trial, azoxystrobin was applied twice at a rate of 0.15 kg ai/ha. The residues in grains were 0.014, 0.019, 0.037, 0.05, 0.19, 0.31 and 0.99 mg/kg.

On oats, twelve supervised trials were submitted treated at a rate of 0.15 kg ai/ha. The residues in grains were 0.013, 0.028, 0.028, 0.028, 0.048, 0.049, 0.053, 0.058, 0.06, 0.12, 0.12 and 0.63 mg/kg.

The Meeting noted that the populations of azoxystrobin residues in grains of barley and oats have similar distributions and can be combined (n=19): 0.013, 0.014, 0.019, 0.028, 0.028, 0.028, 0.037, 0.048, 0.049, 0.05, 0.053, 0.058, 0.06, 0.12, 0.12, 0.19, 0.31, 0.63 and 0.99 mg/kg.

The current Meeting estimated a maximum residue level of 1.5 mg/kg for azoxystrobin residues in barley and oats to replace the previous recommendation (0.5 mg/kg). An STMR value of 0.05 mg/kg for was estimated.

Sorghum

The US GAP for sorghum is 2 × 0.28 kg ai/ha with a PHI of 14 days. Twelve independent supervised trials were conducted. In each trial, azoxystrobin was applied three times at a rate of 0.28 kg ai/ha with a 7-day application interval. The residues in grains were 0.48, 1.3, 1.4, 1.4, 1.7, 1.8, 1.9, 2.2, 2.3, 2.8, 4.5 and 8.0 mg/kg.

The Meeting estimated a maximum residue level of 10 mg/kg and an STMR of 1.85 mg/kg for azoxystrobin residues in sorghum grain.

Coffee beans

The 2011 JMPR estimated for azoxystrobin residues in coffee beans a maximum residue level of 0.02 mg/kg and an STMR of 0.01 mg/kg based on the Brazilian residue data and Brazilian GAP of 2 × 0.15 kg ai/ha (interval 90 days) or 3 × 0.1 kg ai/ha (interval 60 days) and a PHI of 30 days.

The GAP in Columbia is registered as 3 × 0.15 kg ai/ha (interval 45 days) and a PHI of 15 days. Seven new trials have been conducted in Brazil, Colombia and Guatemala in 2010/2011 to support the registered use pattern in Colombia. Azoxystrobin was applied three times at a rate of 0.15 kg ai/ha. The residues in green coffee beans were < 0.01 (4), 0.01, 0.01 and 0.015 mg/kg at a PHI of 14–15 days.

Four further Brazilian trials conducted in 2006/2007 and matching the Colombian GAP were reported by the 2011 JMPR (trials M06024, Roncato, 2008). After application of 3 × 0.15 kg ai/ha and a 14 day PHI, the azoxystrobin residues were < 0.01 mg/kg (4).

In total, the residues of azoxystrobin in green coffee beans matching Columbian GAP were, in rank order (n=11): < 0.01 (8), 0.01, 0.01 and 0.015 mg/kg.

Based on residues data matching Columbian GAP, 0.02 mg/kg were calculated as maximum residue level using the OECD MRL calculator. The Meeting noted that the calculated value is very close to the highest level of 0.015 mg/kg (mean of < 0.01 and 0.02 mg/kg from 2 replicated plots) and proposed rounding up to 0.03 mg/kg.

The current Meeting estimated a maximum residue level of 0.03 mg/kg and an STMR of 0.01 mg/kg for azoxystrobin residues in coffee beans to replace the previous recommendation.

Legume animal feeds

The use pattern in Germany for field peas, field beans and lupins is one to two applications at 0.25 kg ai/ha with a spray interval of 14–28 days. The GAP in France is for dry peas (including chickpeas), dry beans, lentils and lupins two foliar applications at 0.2–0.25 kg ai/ha with an interval of 14 days.

Pea hay or pea fodder (dry)

Twenty trials were conducted on dry peas in the UK and France matching the GAP of France and Germany. Azoxystrobin was applied twice at a rate of 0.2–0.25 kg ai/ha with a spray interval of 14 days. Samples of pea fodder were collected at normal commercial harvest, PHIs of 30–45 days.

Residues found, on fresh weight basis, were (n=20): 0.34, 0.61, 0.62, 0.63, 1.0, 1.4, 1.6, 1.8, 1.8, 2.0, 2.1, 2.3, 3.6, 3.7, 3.8, 3.9, 4.0, 4.8, 7.2 and 18 mg/kg.

The residue values, on dry weight basis, were (88% dry matter): 0.39, 0.69, 0.70, 0.72, 1.1, 1.6, 1.8, 2.0, 2.0, 2.3, 2.4, 2.6, 4.1, 4.2, 4.3, 4.4, 4.5, 5.5, 8.2 and 20 mg/kg.

The Meeting estimated a maximum residue level of 20 mg/kg for azoxystrobin residues in pea hay or fodder (dry) on dry weight basis. The estimated median and highest residue values were 1.9 mg/kg and 18 mg/kg on fresh weight basis or 2.35 mg/kg and 20 mg/kg, respectively on dry weight basis.

Pea vines (green)

Pea vines (green) aren't in international trade and an MRL is not necessary. Nevertheless, the commodity is used as animal feed and the estimation of an STMR and a highest residue values is requested.

In 18 trials conducted on peas in the UK and France matching the GAP of France and Germany for peas (dry), pea vines were sampled. Azoxystrobin was applied twice at a rate of 0.2–0.25 kg ai/ha with a spray interval of 14 days. The highest residue values of pea vines samples collected at PHIs of 2 to 30 days after treatment were selected for the evaluation. The residues were on fresh weight basis (n=18): 0.89, 1.3, 1.4, 1.5, 1.8, 2.6, 3.1, 3.1, 3.3, 3.4, 4.1, 4.5, 4.8, 4.8, 4.9, 5.6, 5.8 and 9.4 mg/kg.

The Meeting estimated a median and a highest residue of 3.35 and 9.4 mg/kg (fresh weight) equivalent to 13.4 and 37.6 mg/kg (25% dry weight basis) for azoxystrobin residues in pea vines.

Straw and fodder (dry) of cereal grains

Based on GAP and residue data for barley, oats, rice, rye, triticale and wheat straw, the 2008 JMPR estimated a maximum residue level for straw and fodder of cereal grains, except maize of 15 mg/kg, an STMR of 1.7 mg/kg and a highest residue value of 11 mg/kg on dry weight basis.

Azoxystrobin is registered in the USA in barley and oats as foliar spray with 2 × 0.15 kg ai/ha and a 7-days PHI for forage and hay. New trials are available for barley straw, oats straw, barley hay and oats hay matching the US GAP. The straw samples were taken at grain harvest 16 – 49 days after treatment. Samples of hay were taken 6 - 7 days after treatment.

The residues in barley straw on fresh weight basis (n=7) were 0.18, 0.28, 0.36, 0.70, 2.6, 3.3 and 3.5 mg/kg; this is equivalent to 0.20, 0.31, 0.40, 0.79, 2.9, 3.7 and 3.9 mg/kg (dry weight, based on 89% dry matter).

The residues in oats straw on fresh weight basis (n=12) were: 0.074, 0.075, 0.088, 0.15, 0.30, 0.31, 0.35, 0.62, 0.70, 0.73, 0.88 and 1.3 mg/kg; this is equivalent to 0.082, 0.083, 0.098, 0.17, 0.33, 0.34, 0.39, 0.69, 0.78, 0.81, 0.98 and 1.4 mg/kg (dry weight, based on 90% dry matter).

The residues in barley hay on fresh weight basis (n=7) were: 0.46, 0.69, 0.76, 0.84, 2.1, 3.2 and 3.7 mg/kg; this is equivalent to 0.52, 0.78, 0.86, 0.95, 2.4, 3.6 and 4.2 mg/kg (dry weight, based on 88% dry matter).

The residues in oats hay on fresh weight basis (n=12) were: 0.20, 0.27, 0.53, 0.66, 0.89, 1.1, 1.3, 2.2, 3.0, 3.1, 3.2 and 3.4 mg/kg; this is equivalent to 0.22, 0.30, 0.59, 0.73, 0.99, 1.2, 1.4, 2.4, 3.3, 3.4, 3.6 and 3.8 mg/kg (dry weight, based on 90% dry matter).

The Meeting noted that the residues in straw and fodder of barley and oats resulting of azoxystrobin treatment according to US GAP were covered by the MRL recommendation of the 2008 JMPR for straw and fodder of cereal grains, except maize of 15 mg/kg (90% dry matter). The estimated median residue value was 1.5 mg/kg (fresh weight) equiv. to 1.7 mg/kg (dry weight) and the highest value 9.9 mg/kg (fresh weight) equiv. to 11 mg/kg (dry weight). A new estimation of a maximum residue level, a median and a highest residue was not necessary. Because residue data on sorghum show higher residues, the commodity "straw and fodder of cereal grains, except maize" should be revised to "Straw and fodder (dry) of cereal grains, except maize and sorghum". The previous recommendation for "Straw and fodder of cereal grains, except maize" should be withdrawn.

The US GAP for sorghum is 2 × 0.28 kg ai/ha with a PHI of 14 days. Twelve trials on sorghum stover, dry, matching the US GAP were submitted. The residues on fresh weight basis (n=12) were: 0.39, 0.53, 0.71, 2.4, 2.6, 3.7, 4.0, 4.5, 4.8, 5.3, 10.5 and 14.5 mg/kg; this is equivalent to 0.44, 0.60, 0.81, 2.7, 2.95, 4.2, 4.5, 5.1, 5.5, 6.0, 12 and 16 mg/kg (dry weight, based on 88% dry matter).

The Meeting estimated maximum residue level of 30 mg/kg for azoxystrobin residues in sorghum straw and fodder, dry on dry weight basis. The estimated median residue value was 3.85 mg/kg (fresh weight) equiv. to 4.35 mg/kg (dry weight) and the highest residue 14.5 mg/kg (fresh weight) equiv. to 16 mg/kg (dry weight).

Cereal forage (green)

Residue data were received for oat and sorghum forage (green). Because these aren't commodities in international trade, MRLs are not necessary. Nevertheless, the commodities are used as animal feed and the estimation of STMRs and highest residue values is requested.

Oats forage (green)

Azoxystrobin is registered in the USA in oats as foliar spray with 2 × 0.15 kg ai/ha and a 7-days PHI for forage and hay. Twelve trials are available for oats forage matching the US GAP. The residues on fresh weight basis (n=12) were: 0.11, 0.20, 0.26, 0.44, 0.52, 0.78, 0.86, 0.95, 1.0, 1.4, 1.6 and 2.0 mg/kg.

The 2008 JMPR estimated a median residue value of 1.7 mg/kg and a highest value of 4.0 mg/kg for oats forage (fresh weight). The current Meeting noted that the residues in oats forage resulting of azoxystrobin treatment according to US GAP are covered by the estimation of the 2008 JMPR.

Sorghum forage (green)

The US GAP for sorghum is 2 × 0.28 kg ai/ha with a PHI of 14 days for grain. Supervised residue trials conducted included residue data for forage from 3 to 21 days after treatment. The residues on fresh weight basis (n=14) were: 0.25, 0.27, 0.29, 0.32, 1.5, 1.5, 1.6, 1.6, 1.7, 1.9, 5.6, 7.2, 11 and 12 mg/kg.

The Meeting estimated a median and a highest residue value of 1.6 and 12 mg/kg (fresh weight) equivalent to 4.6 and 34 mg/kg (35% dry weight basis) for azoxystrobin residues in sorghum forage (green).

Fate of residues during processing

The Meeting received information on the fate of azoxystrobin residues during the processing of potatoes to flakes, chips and wet peel, sorghum to aspirated grain fractions and green coffee to roasted and instant coffee.

The processing factors obtained in the processing studies and estimated STMR-P values are summarized below.

Raw agricultural commodity (RAC)		Processed commodity		
Name	STMR, mg/kg	Name	Processing factor	STMR-P, mg/kg
Potato	2.3	Flakes	< 0.011	0.0253
		Chips	0.012	0.0276
		Wet peel	0.904	2.08
Barley	0.05	Barley malt	0.10 [a]	0.005
		Barley spent grain	0.15 [a]	0.0075
		Beer	0.03 [a]	0.0015
Sorghum	1.85	Aspirated grain fractions	50	92.5
Coffee beans, green	0.01	Roasted coffee beans	0.625	0.006
		Instant coffee	1.06	0.0106

[a] Estimated by JMPR in 2008

Farm animal dietary burden

The 2013 JMPR evaluated residues of azoxystrobin in the following animal feed items: pulses, potato, cereal grains (barley, oats, sorghum), legume animal feeds as well as straw, fodder and forage of cereal grains which are listed in the OECD feeding table.

Estimated maximum and mean dietary burdens of farm animals

Dietary burden calculations based on the feed items evaluated by the JMPR in 2008 and 2013 for beef cattle, dairy cattle, broilers and laying poultry as presented in Annex 6. The calculations were made according to the livestock diets, in the OECD table, from Australia, the EU, Japan and US-Canada. The following table below shows the values calculated by the 2008 JMPR and by the current Meeting.

	Livestock dietary burden, azoxystrobin, ppm of dry matter diet (calculation 2008/2013)							
	Japan		US-Canada		EU		Australia	
	Max	Mean	Max	Mean	Max	Mean	Max	Mean
Beef cattle	-/0.96	-/0.96	34/17	15/12	55/61	19/25	58/72	32/51 [c]
Dairy cattle	-/16.3	-/2.97	33/30	16/12	72[a]/74	27[b]/29	39/45.5	20/20
Poultry – broiler	-/1.4	-/1.4	0.44/1.7	0.44/1.7	0.62/2.2	0.40/1.9	0.59/1.7	0.59/1.7
Poultry – layer	-/1.4	-/1.4	0.44/1.7	0.44/1.7	23[d]/21	9.1[e]/9.5	0.59/1.7	0.59/1.7

[a] Highest maximum beef or dairy cattle burden suitable for MRL estimates for mammalian meat, edible offal and milk

[b] Highest mean dairy cattle burden suitable for STMR estimates for milk

[c] Highest mean beef or dairy cattle burden suitable for STMR estimates for mammalian meat and edible offal

[d] Highest maximum poultry broiler or layer burden suitable for MRL estimates for poultry meat and eggs

[e] Highest mean poultry broiler or layer burden suitable for STMR estimates for poultry meat and eggs

Animal commodity residue levels

The Meeting noted that the new estimation did not result in a significant change of the dietary burdens of farm animals, except the mean burden for beef cattle what increased from 32 ppm in 2008 to 51 ppm in 2013 (factor 1.59).

The 2008 JMPR calculated for a dietary burden of 32 ppm mean residues of 0.013 mg/kg in liver, < 0.01 mg/kg in kidney and 0.01 mg/kg in fat. The estimated STMR values were 0.01 mg/kg for meat (fat) and edible offal from mammals other than marine mammals.

The table below shows the recalculation of the STMR values for meat (fat) and edible offal for mammals, other than marine mammals based on the results of the cattle feeding studies evaluated by the 2008 JMPR and the new dietary burden calculation.

	Mean estimated azoxystrobin concentrations (STMR, mg/kg)			
Beef cattle	Muscle	Liver	Kidney	Fat
Dietary burden (51 ppm)	< 0.01	0.02	< 0.01	0.015
Feeding level [25 ppm]	< 0.01	< 0.01	< 0.01	< 0.01
Feeding level [75 ppm]	< 0.01	0.03	0.01	0.02

The current Meeting calculated mean residues of 0.02 mg/kg in liver and < 0.01 mg/kg in kidney, < 0.01 mg/kg in muscle and 0.015 mg/kg in fat. The estimated STMR values were 0.02 mg/kg for edible offal (mammalian), 001 mg/kg for muscle and 0.015 mg/kg for fat.

The previous MRL recommendations for animal commodities and the STMRs for whole milk, milk fat, poultry meat (fat), poultry edible offal and eggs were maintained.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Daily Intakes (IEDIs) of azoxystrobin were calculated for the 13 GEMS/Food cluster diets using STMRs and STMR-Ps estimated by the JMPR in 2008, 2011, 2012 and 2013. The results are shown in Annex 3.

The ADI is 0–0.2 mg/kg bw and the calculated IEDIs were 2–10% of the maximum ADI. The Meeting concluded that the long-term intake of residues of azoxystrobin resulting from the uses considered by the JMPR is unlikely to present a public health concern.

Short-term intake

The 2008 Meeting decided that an ARfD for azoxystrobin is unnecessary and concluded that the short-term intake of residues resulting from the use of azoxystrobin is unlikely to present a public health concern.

5.2 BENTAZONE (172)

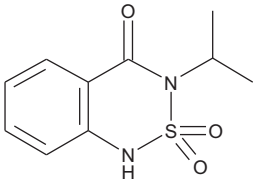
RESIDUE AND ANALYTICAL ASPECTS

Bentazone, a post-emergence herbicide, was originally evaluated by the JMPR in 1991 and re-evaluated for residues and toxicity several times up to 2004. It was reviewed as part of the periodic re-evaluation programme of CCPR on toxicity in 2012 JMPR. Bentazone is a selective herbicide applied as a post emergence treatment to control dicotyledonous weeds in agriculture, horticulture, ornamentals and amenity grasslands. The mode of action is based primarily on an irreversible blockage of photosynthetic electron transport and in further consequence the inhibition of photosynthesis at photosystem II. As a result of this reaction, CO_2 assimilation is suppressed and after a short period of growth stagnation, the plant dies.

At the Forty-third Session of the CCPR (REP 12/PR, Appendix VIII), bentazone was scheduled for periodic review of residues by the 2013 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.

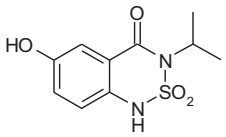
The 2012 JMPR established an ADI for bentazone of 0–0.09 mg/kg bw/day and reaffirmed its previous conclusion that no ARfD is necessary.

Bentazone is 3-isopropyl-1H-2,1,3-benzothiadiazine-4(3H)-one 2,2-dioxide.

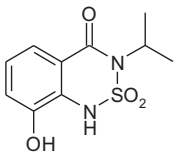


The chemical structures and names of metabolites discussed in this appraisal are:

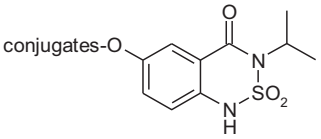
6-OH-bentazone (M351H001) 3-Isopropyl-1H-2,1,3-benzothiadiazine-4(3H)-one-6-hydroxy-2,2-dioxide



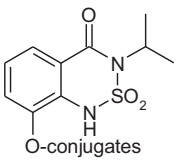
8-OH-bentazone (M351H002) 3-Isopropyl-1H-2,1,3-benzothiadiazine-4(3H)-one-8-hydroxy-2,2-dioxide



Bentazone-6-O-glucoside (M351H013)

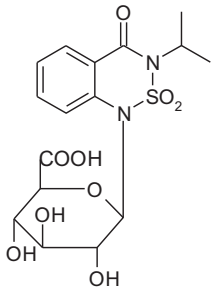


Bentazone-8-O-glucoside (M351H017)

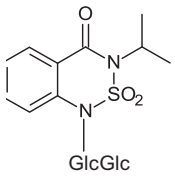


Bentazone-N-glucuronide (Metabolite A, M351H004)

3-isopropyl-1-methyl-2,2-dioxo-2,1,3-benzothiadiazin-4-one



M351H014 and isomers: M351H015-016, -018-019, -022



Animal metabolism

Information was available on metabolism of bentazone in lactating goats and laying hens.

Laboratory animals

Metabolism in laboratory animals was summarized and evaluated by JMPR in 2012. Studies on toxicokinetics showed that elimination was almost exclusively via the urine (approximately 91% within 24 hours). 5 days after dosing, less than 2% was found in faeces and less than 0.02% in expired air. Biliary excretion of radioactivity was minimal. No significant differences were found in absorption and elimination among the different species investigated (rat, rabbit and mouse). Bentazone is minimally metabolized in vivo, with the parent compound being the predominant excretion product. Only small amounts of 6-hydroxybentazone (up to approximately 6% of the dose) and minimal amounts of 8-hydroxybentazone (less than approximately 0.2% of the dose) were detected in urine.

Lactating goats

Lactating goats were administered orally with uniformly ring-labelled [^{14}C]-bentazone for 5 or 8 consecutive days at 3 and 50 mg/kg bw, 97.3% and 99.1% TAR was recovered respectively. Most of administered dose was eliminated in the urine (91.4% and 80.6% TAR). TRR levels in tissues ranged from 0.017 mg eq/kg for muscle to 0.91 mg eq/kg in fat for the low dosed goat and from 1.2 mg eq/kg in muscle to 54 mg eq/kg in kidney for the high dosed goat. The parent bentazone was the major residue component and constituted about 71–96% (0.034 mg/kg and 0.39 mg/kg) of TRR in milk, 71–97% (0.010 mg/kg and 1.2 mg/kg) in muscle, 94–98% (1.6 mg/kg and 2.8 mg/kg) in fat, 91–98% (0.55 mg/kg and 49 mg/kg) in kidney, 83–84% (0.033 mg/kg and 3.1 mg/kg) in liver. The liver in high dosed goat contained bentazone-N-glucuronide (11.1% TRR, 0.40 mg/kg) in addition to the parent compound. Two unidentified minor metabolites at a concentration of 0.002 mg/kg bentazone equivalents were found in milk from the goat dosed at 3 mg/kg bw.

The metabolism studies with [^{14}C]6-hydroxy-bentazone and [^{14}C]8-hydroxy-bentazone were conducted separately at two dose levels of 2 mg/kg bw and 40 me/kg bw for 5 or 6 consecutive days, respectively. Residue were rapidly excreted 70–86% TAR for 6-hydroxy-bentazone and 83–91% TAR for 8-hydroxy-bentazone. The major residue component in edible tissues was unchanged 6-hydroxy-bentazone constituted > 43% TRR and main metabolite was sulphate conjugate of 6-hydroxybentazone (43% of the TRR) in milk. The unchanged 8-hydroxybentazone (29–95% TRR)

was the major residue component in the milk and edible tissues. In all three studies unidentified metabolites in milk or edible tissues amounted less than 10% of the TRR.

Laying hens

[^{14}C]bentazone, [^{14}C]6-hydroxybentazone and [^{14}C]8-hydroxybentazone were each administered orally to separate groups of 10 laying hens once daily for 5 days. The doses were 10 mg/hen/day, equivalent to feed containing about 100 ppm. The excretion of radioactivity was rapid. The mean proportions of the total cumulative dose recovered 6 hours after the final dose were 94% from the bentazone group, 90% from the 6-hydroxybentazone group and 93% from the 8-hydroxybentazone group. The mean concentrations of radioactivity were highest in the kidneys in all groups (3.9, 0.66, 1.6 mg eq/kg), followed by muscle (0.39, 0.32, 0.23 mg eq/kg), and liver (1.1, 0.13, 0.23 mg eq/kg). After the administration of bentazone, the parent compound was the major radioactive component in extracts of liver (0.91 mg/kg, 84% TRR) and was exclusively found in muscle (0.29 mg/kg, 100% TRR), fat (0.056 mg/kg, 100% TRR) and eggs (0.13 mg/kg, 100% TRR).

In summary, bentazone is the major residue in the animals tissues, milk and eggs (> 70% TRR).

Plant metabolism

The Meeting received plant metabolism studies with bentazone on soya bean, rice, maize, green beans, potatoes and wheat.

Soya beans were treated with [^{14}C]bentazone once at 2.24 kg ai/ha or twice at 1.68 and 1.12 kg ai/ha. Forage at long and short pre-harvest intervals, hay and bean samples were collected. The residues from single treated forage were 19 mg eq/kg and 7.0 mg eq/kg at 9 DAT and 36 DAT and from the double treated forage were 17 mg eq/kg and 24 mg eq/kg at 9 days after the first treatment and 11 days after the second treatment. In hay, residues for the single treated forage were 21 mg eq/kg at 93 days after treatment and for the double treatment 80 mg eq/kg at 48 days after the second treatment. The residues of bentazone, 6-hydrozy and 8-hydroxy bentazone in the double treated forage, 11days after the second treatment, were 5.0 mg/kg (21% TRR), 1.8 mg/kg (3.3% TRR) and 2.3 mg/kg (9.6% TRR), respectively. The residues in seed were too low for further analysis.

Rice plants were treated by foliar application with 1 kg ai/ha of [^{14}C]bentazone and radioactive residues were determined in whole plants, grain and straw. At day 0, only bentazone (72% TRR) and 6-hydroxy-bentazone (6.5% TRR) were detected. At day 26 bentazone decreased to 24% of the TRR and 6-hydroxy- bentazone in free form increased to 17% of the TRR. At 63 days, 15% bentazone (7.8 mg/kg) and 4.0% 6-hydroxy-bentazone (2.1 mg/kg) were found in straw. In grain samples 63 days after treatment only 6.6% of the TRR was extracted and 93% remained in the insoluble fraction. It was shown that the terminal ^{14}C residue consisted predominantly of recycled fragments of bentazone and 6-hydroxy-bentazone taken up into glucose, polysaccharides and lignin. Minor residues of bentazone were observed in rice grains (1.5% TRR, 0.007 mg/kg) and were below the limit of detection (0.02 mg/kg).

The metabolism of bentazone was investigated in maize grown in outdoor plots and sprayed with an aqueous solution of the sodium salt of [^{14}C]bentazone at a rate equivalent of 1.68 kg ai/ha. In forage only bentazone and 6-hydroxy-bentazone were found in the methanol extract. The levels were 0.12 mg eq/kg and 1.2 mg eq/kg after one week and declined to < 0.05 mg eq/kg and 0.09 mg eq/kg after 9 weeks, respectively. Analysis of the final harvested grain, cobs, husk and stover showed no residues of bentazone or 6-hydroxy- or 8-hydroxy-bentazone (< 0.05mg/kg).

The magnitude of the residues in green beans were determined after one application of [^{14}C]bentazone at 2.24 kg ai/ha or two at 1.68 and 1.12 kg ai/ha. The total radioactive residues in

forage (4.1–22% TAR, 5.0–45 mg eq/kq), succulent bean (0.1–0.6% TAR, 0.13–1.9 mg eq/kg) and seed (0.02–0.04% TAR, 0.61–1.3 mg eq/kg) were not further identified.

The metabolism in potato plants was studied after two foliar spray applications of 1.12 kg ai/ha [^{14}C]bentazone. Potato tubers were harvested 41 days after the final treatment. TRR levels found in the whole tuber (0.14 mg eq/kg) were mainly located in the pulp (0.1 mg eq/kg), while the peel contained lower residues (0.037 mg eq/kg). The identified extractable residues were bentazone (3.7% TRR, 0.005 mg/kg) and conjugates of 6-hydroxy-bentazone (about 25% TRR, 0.034 mg/kg). Most of the radioactivity (56% of the TRR) was incorporated into starch.

A wheat metabolism study was performed with [^{14}C]-bentazone. The active substance was applied once at a rate of 1 kg ai/ha. Samples of wheat forage and hay were collected at BBCH 39 (20 days after application) and samples of grain, chaff and straw were sampled at BBCH 89 (83 days after application). The total radioactive residues (TRR) for wheat forage accounted for 4.46 mg eq/kg. Wheat hay showed the highest residue level of all matrices at 31 mg eq/kg, followed by wheat straw with residue levels of 17 mg eq/kg. In wheat chaff the residues amounted to 1.6 mg eq/kg while lowest residue levels were found in wheat grain at 1.1 mg eq/kg. The parent compound was found to be moderately metabolized until harvest. Portions between approximately 39% and 56% of the TRR were still present as unchanged bentazone in forage, hay and straw. The major metabolite in quantitative terms was an O-monosaccharide conjugate of a 6-hydroxylated derivative of parent compound. Other metabolites identified represented less than 4.7% of the TRR each. In the grain the major part of the radioactivity was characterized as carbohydrates (58% of the TRR).

In summary, the metabolism of bentazone in six different crops was similar and considered comparable. The main residue components were parent bentazone and 6-hydroxy-bentazone in soya bean forage and hay, rice hay and straw and grain, maize forage, potato tuber and wheat hay and straw. However, the parent compound was quite low in grains or seeds and confirmed by the supervised trials.

Environmental fate in soil

The Meeting received information on the environmental fate of bentazone in soil, including studies on aerobic soil metabolism, degradation in water/sediment system soil photolysis and crop rotational studies.

Aerobic soil metabolism

The aerobic soil metabolism of bentazone was investigated with [^{14}C-phenyl]-bentazone at a nominal rate of 2.0 and 2.7 mg per kg dry soil. The majority of radioactivity in the extracts was always unchanged compound. At the end of incubation, bentazone was detected in amounts of 2.3–19% TAR. None of metabolites exceeded 5% TAR. Metabolites were formed only in minor amounts of which the most prominent metabolite (max. 2.8% TAR) was identified as N-methyl-bentazone. The half-lives were calculated to be 31 to 45 days. Mineralization to ^{14}C-CO_2 reached a total of 9.0% to 21% TAR. No other volatile compounds were detected. In summary, bentazone was not persistent in soil.

Water/sediment dissipation

The degradation of [^{14}C]-bentazone was investigated in two different water/sediment systems (sandy loam/sand) under aerobic conditions over a period of 100 days at 0.34 mg/kg in water. The major residue component was parent bentazone which accounted for more than 60% of the TAR after 100 days. Methyl-bentazone was observed only in the water phase with the maximum concentration less than 13% of the TAR after 100 days. The half-lives in the total system were calculated to be greater than 500 days. Bentazone is stable in the water/sediment system.

Soil Photolysis

The photolytic degradation of ^{14}C-labelled bentazone was investigated on a sandy clay loam soil. The overall results for the material balances in the photolysis and the dark control samples were in the range of 95–100% TAR. Carbon dioxide was the only volatile degradation product trapped (8.1% TAR) after 15 days in the photolysis test and 1.8% TAR in the dark control. The concentration of bentazone decreased to 49% TAR in the course of the photolysis study and to 77% in the dark control samples. No degradation products of ≥ 4% TAR occurred in the photolysis samples or in the dark controls. The half-lives for bentazone in the test systems were calculated to be 13 days under continuous irradiation and 42 days in the dark.

Confined rotational crop

The metabolism of bentazone in succeeding crops was investigated in wheat, radish and lettuce cultivated at three different replant intervals for all crops (30, 120 and 365 DAT). Significant translocation of radioactive residues from soil into the plants was observed for the plant back interval of 30 DAT which decreased rapidly after longer aging periods of 120 and 365 days. The residue concentration in the top soil layer after aging and ploughing decreased slightly with increasing plant back intervals. The total radioactive residues (TRR) in lettuce (immature and mature samples) did not exceed 0.13 mg eq/kg for all plant back intervals. The TRR in white radish tops was 0.17 mg/kg at a plant back interval of 30 DAT, 0.019 mg eq/kg after 120 DAT and to 0.003 mg eq/kg (TRR combusted) after 365 DAT. The total radioactive residues in radish roots of mature crop decreased from 0.13 mg eq/kg (30 DAT), to 0.012 mg eq/kg (120 DAT) and finally to 0.001 mg eq/kg (365 DAT, TRR combusted).In spring wheat, the highest residue levels were measured in hay (declining from 1.6 to 0.07 mg eq/kg, for 30 DAT and 365 DAT, respectively) and straw (declining from 1.1 to 0.049 mg eq/kg, for 30 DAT and 365 DAT, respectively). The total radioactive residues in grain accounted 0.71 to 0.041 mg eq/kg after 30 to 365 days.

Bentazone and/or its soil metabolites were taken up and transformed in the rotational crops primarily into sugars (glucose, fructose and sucrose and further components of similar polarity) which were without exception the most abundant components in all matrices examined. The unchanged parent molecule was found as minor component in samples of immature (30 DAT) and mature lettuce (30 and 120 DAT) in concentrations of < 0.0013 mg/kg and 1.2% TRR only. Additional medium polar degradation products were detected in minor concentrations. The results of this study indicated that potential for uptake of parent bentazone residues from the soil by the succeeding crops is low.

Methods of analysis

The Meeting received descriptions and validation data for analytical methods for residues of bentazone in raw agricultural commodities, feed commodities and animal commodities.

The methods for crop and animal matrices typically use an initial extraction and hydrolysis step, either with acid, base or enzymatic treatment to hydrolyse any sugar conjugates in plant or animal matrices. After a $Ca(OH)_2$-precipitation step to remove acidic plant constituents, a reversed phase C_{18}-column clean-up is performed. The analytes are then methylated with diazomethane and their derivatives are purified using a silica gel-column. The final determination of the residues of bentazone and its OH-metabolites is performed by GC-MS or LC-MS/MS. Bentazone residues can be measured in most matrices to an LOQ of 0.01 mg/kg. All methods are considered sufficiently validated for the determination of bentazone, 6-OH-bentazone and 8-OH-bentazone including conjugates thereof. No multi-residue method was provided.

Stability of residues in stored analytical samples

The Meeting received information on the freezer storage stability of residues of bentazone in plant and animal commodities.

Storage stability studies indicated that the residues are stable over a period of two years maize (green plant, grain and straw), pea (seed), flax (seed) and potato (tuber). Analytical results demonstrated that bentazone and its metabolites 6-OH-bentazone and 8-OH-bentazone as glucoside derivatives, were stable in the different plant matrices over the test period of two years.

No storage stability study on bentazone in animal matrices was provided to the Meeting.

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 definitions.

Animal metabolism studies showed that the parent bentazone was a major component of the residue, representing 84–100% of the TRR in poultry matrices and 71–98% of the TRR in goats. No 6-hydroxy and 8-hydroxcy bentazone were found in milk and tissues in goat metabolism studies. Analytical methods are suitable for the determination of bentazone. The Meeting decided that for animal commodities, parent bentazone is the appropriate residue of concern for MRL enforcement and for dietary risk assessment.

The maximum octanol-water partition coefficient of bentazone (log K_{ow} = -0.94 at pH 7) implied that bentazone may not be fat-soluble. Noting that bentazone residues in goat fat were artificial and TRRs in poultry fat were much less than those in muscle the Meeting agreed that bentazone residue is not fat-soluble.

Metabolism studies on plants and supervised trials showed that the main residues in food or feed of plant origin were bentazone and one or both of its conjugated metabolites, 6-hydroxy- and 8-hydroxy-bentazone. However, the two hydroxy-bentazones were less toxic compared with parent bentazone and only existed in feed commodities. Therefore the Meeting decided that for plant commodities, parent bentazone is the appropriate residue of concern for MRL enforcement and for dietary risk assessment.

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

The residue is considered to be not fat-soluble.

Results of supervised residue trials on crops

The Meeting received supervised trials data in bulb onion, cucumber, sweet corn, green peas, green beans, dried beans, soya bean, potato, barley, oats, maize, rice, sorghum, wheat, linseed, peanut, herbs, alfalfa, clover, sugar beet and grass.

Onion, bulb

The critical GAP for bentazone on bulb onion was from Turkey (one foliar application at 0.96 kg ai/ha with a PHI of 30 days). Eight trials were available from southern Europe on bulb onion matching Turkish GAP from which residues were < 0.01 (7) and 0.02 mg/kg.

The Meeting estimated an STMR of 0.01 mg/kg and a maximum residue level of 0.04 mg/kg for bulb onion to replace the previous recommendation of 0.1 mg/kg.

Spring onion

The critical GAP for bentazone on spring onion was from the Netherlands (one spray application of 0.72 kg ai/ha, at least 10 cm height). Two trials were available from the Northern Europe on spring onion matching Dutch GAP with residues of < 0.01 and 0.04 mg/kg. Two trials from the Southern Europe were reported at a rate of 0.96 kg ai/ha treated at later growth stage. The residues of bentazone in spring onion from these trials were < 0.01(2) mg/kg.

Noting that the residues from the Northern and Southern Europe's trials were similar, the Meeting agreed to combine Northern and Southern Europe dataset to estimate an STMR 0.01 mg/kg, and a maximum residue level of 0.08 mg/kg for spring onion.

Cucumber

The critical GAP for bentazone on cucumber is from Sweden (one spray application of 1.0 kg ai/ha with a PHI of 42 days). Four trials were available from Canada on cucumber matching Swedish GAP from which residues were < 0.02(4) mg/kg.

Four trials from Canada on cucumber were not considered sufficient for the estimation of a maximum residue level.

Sweet corn (corn-on-the-cob)

The critical GAP for bentazone on sweet corn is from Canada (one spray application of 1.08 kg ai/ha, at 1 to 5-leaf stage) and in France (one spray application of 1.2 kg ai/ha with a PHI of 28 days). Two trials were available from Canada on sweet corn complying with Canadian GAP with residues of < 0.02 (2) mg/kg and one 2× trial treated at a later growth stage with a residue of < 0.02 mg/kg. Two trials were available from France on immature maize matching French GAP with residues of < 0.01(2) mg/kg. Eight trials were available from France on maize cobs w/o husks against French GAP with residues in immature corn of < 0.01(8) mg/kg.

As the residues from the European trials were considered similar, the Meeting decided to combine them and estimated an STMR 0.01 mg/kg, and maximum residue level of 0.01* mg/kg for sweet corn (corn-on-the-cob) respectively.

Peas (pods and succulent = immature seeds)

The critical GAP for bentazone on peas is from the USA (2 applications of 1.12 kg ai/ha with a PHI of 10 days). Ten trials were available from the USA on peas matching US GAP, residues found in peas (pods and succulent immature seeds) were < 0.05(6), 0.05, 0.0.06, 0.46 and 0.74 mg/kg.

The Meeting estimated an STMR 0.05 mg/kg, and maximum residue level of 1.5 mg/kg for peas (pods and succulent immature seeds) and agreed to withdraw the previous recommendation of 0.2 mg/kg for garden pea (young pods)(=succulent, immature seeds).

Beans, except broad bean and soya bean

The critical GAP for bentazone on beans, except broad bean and soya bean was from France (one application at 1.22 kg ai/ha with a PHI of 42 days). From eight trials in Northern Europe and six trials in Southern Europe on green beans with pods matching French GAP at a shorter PHI (35days) residues were < 0.01 (14) mg/kg.

The Meeting estimated an STMR 0.01 mg/kg, and maximum residue level of 0.01* mg/kg for beans, except broad bean and soya bean (green pods and/or immature seeds) and agreed to withdraw the previous recommendations of 0.2 mg/kg for common bean (pods and /or immature seeds) and 0.05 mg/kg for lima bean (pods and /or immature seeds).

Beans, shelled

Five trials from the Northern Europe and seven trials from the Southern Europe on green bean (immature seeds) (green beans without pods) matching French GAP at a shorter PHI (35 days) gave residues of < 0.01 (12) mg/kg.

The Meeting estimated an STMR 0 mg/kg, and maximum residue level of 0.01* mg/kg for beans, shelled (succulent= immature seeds), respectively.

Peas (dry)

The critical GAP for bentazone on peas in the USA, is two applications at 1.12 kg ai/ha with a PHI of 30 days. Two trials were available from the USA on peas matching US GAP resulting in residues of < 0.05(2) mg/kg.

Three trials on peas (dry) were not considered sufficient for the estimation of a maximum residue level. The Meeting agreed to withdraw the previous recommendation of 1 mg/kg for field pea (dry).

Beans (dry)

The critical GAP for bentazone on beans (dry) in Poland, is one application at 1.44 kg ai/ha, at 6–12 cm plant height. From seven southern European trials on beans matching Polish GAP residues were < 0.02(6) and 0.021 mg/kg. Two trials were available from northern Europe on beans matching the GAP of Poland with residues of < 0.02(2) mg/kg.

As residues from the Southern and Northern European trials were similar, the Meeting decided to combine the two datasets and estimated an STMR 0.02 mg/kg, and maximum residue level of 0.04 mg/kg for beans (dry) to replace the previous recommendation of 0.05 mg/kg.

Soya bean (dry)

The critical GAP for bentazone on soya bean (dry) is from Spain (one application of 1.0 kg ai/ha, 1st and 3rd trifoliate leaf); The GAP in Germany is for one application of 0.96 kg ai/ha, emergence to 10 cm height; and the GAP in the USA, two applications of 1.12 kg ai/ha with no PHI. Twelve trials were available from southern Europe on soya bean matching Spanish GAP with some trials treated at later growth stage. Residues found were < 0.01(12) mg/kg. Two trials were available from northern Europe on soya bean matching German GAP with one trail treated at a later growth stage with residues of < 0.01(2) mg/kg. Six trials were available from the USA on soya bean matching US GAP with residues of < 0.05(6) mg/kg. Two exaggerated rate trials from the US resulted in residues of < 0.05(2) mg/kg.

The Meeting estimated an STMR 0.01 mg/kg, and maximum residue level of 0.01* mg/kg for soya bean (dry) on the basis of European dataset replacing its previous recommendation of 0.1 mg/kg.

Potato

The GAP for bentazone on potato in Ireland is for one application of 1.44 kg ai/ha, before shoots exceed 15 cm in height. The GAP in Spain is for one application of 1.0 kg ai/ha, from post-emergence to the fourth leaf growth stage. Eight trials were available from southern Europe on potato matching Spanish GAP from which residues found were < 0.01(4), 0.01, 0.02(2) and 0.06 mg/kg. Twenty five trials were available from northern Europe on potato matching Irish GAP from which residues found were < 0.02(24) and 0.04 mg/kg.

Noting that Southern European trials resulted in higher residue, the Meeting estimated an STMR 0.01 mg/kg, and a maximum residue level of 0.1 mg/kg for potato confirming the previous recommendations.

Cereals grains

Barley, oats and wheat

The GAP for bentazone on cereal grains in Finland is for one application of 1.48 kg ai/ha, 2–3 leaf stage (BBCH 12–13). Five trials were available from southern Europe on barley matching Finnish the application rate but treated at later growth stage. Residues found were < 0.02(5) mg/kg. One trial was available from Canada on barley matching the Finnish application rate and treated at later growth stage with a residue of < 0.02 mg/kg.

The residue found from one trial on oats from Germany, at higher application rate than that of the Finnish GAP and treated at later growth stage, was below the LOQ (0.05 mg/kg).

Three trials were available from southern Europe on wheat matching the Finnish application rate and treated at later growth stage with residues of < 0.02 (3) mg/kg.

Maize

The GAP for bentazone on cereal grains in Italy is one application of 1.48 kg ai/ha with no PHI; the GAP in the Netherlands is for one application of 1.44 kg/ha, at 5-leaf stage. Thirteen trials were available from southern Europe on maize matching the Italian application rate with some trials treated at later growth stages. Residues found were < 0.01(5) and < 0.02(8) mg/kg. Seven trials were available from northern Europe on maize matching the Dutch application rate with some trials treated at later growth stages. Residues found were < 0.01(5) and < 0.02(2) mg/kg.

The ranked order of concentrations of parent compound, median underlined, was < <u>0.01</u>(10) and < <u>0.02</u>(10) mg/kg.

Rice

The GAP for bentazone on rice in China is one application of 1.44 kg ai/ha, no PHI; the GAP in Greece is one application of 1.44 kg ai/ha, BBCH 12-21; the GAP in Japan is one application of 2.8 kg ai/ha, applied up to 60 days before harvest.

Two trials were available from China on rice matching Chinese GAP with residues of < 0.02(2) mg/kg. Two trials were available from China on rice at about 1.5× maximum Chinese GAP rate with residues of < 0.02(2) mg/kg.

Two trials were available from Japan on rice matching Japanese GAP with residues of < 0.01(2) mg/kg. Two trials were available from Japan on rice at about 1.5× maximum Japanese GAP rate with residues of < 0.01(2) mg/kg.

Two trials were available from Portugal on rice matching Greek GAP with two trials treated at later growth stage with residues of < 0.02(2) mg/kg.

One trial was available from France on rice against about 1.3× maximum Greek GAP with residues of < 0.02 mg/kg.

All nine trials in Asia and Europe were treated at maximum rate or 1.3–1.6× the maximum rate and resulted in non-detectable r

esidues in rice or brown rice.

Sorghum

The critical GAP for bentazone on sorghum is from Luxembourg (one application of 1.2 kg ai/ha, from emergence to 6-leaf stage (BBCH 16)). Six trials were available from France on sorghum matching the GAP of Luxembourg with residues of < 0.05(6) mg/kg.

The Meeting noted that no residues above LOQ (0.01–0.05 mg/kg) were observed in the samples of barley, oats, wheat, maize, rice and sorghum from 45 supervised trials in various countries following treatment at early growth stages. The Meeting agreed to estimate a maximum residue level 0.01 mg/kg and an STMR 0.01 mg/kg for cereal grains and to withdraw the previous recommendations of 0.1 mg/kg for barley, oat, rice, rye, sorghum and wheat and 0.2 mg/kg for maize.

Oilseeds

Linseed

The critical GAP for bentazone on linseed in France is for one application of 1.2 kg ai/ha with a PHI of 70 days. Three trials were available from France on linseed matching the French application rate at shorter PHIs. Residues found were < 0.02(3) mg/kg. Three trials were available from Canada on linseed matching French GAP showed residues of < 0.02(3) mg/kg.

Considering residues from the French and Canadian trials were similar, the Meeting decided to combine the two dataset and estimated an STMR of 0.02 mg/kg, and maximum residue level of 0.02* mg/kg for linseed, respectively.

Peanut

The critical GAP for bentazone on peanut in the USA is for two application of 1.12 kg ai/ha, up to 28 days after ground crack stage for the second application. Six trials were available from USA on peanut matching the application rate of the US GAP with residues of < 0.05(6) mg/kg. Two trials were available from USA on peanuts with exaggerated application rates resulting in residues of < 0.05(2) mg/kg.

The Meeting estimated a maximum residue level and an STMR value for peanut of 0.05* and 0 mg/kg and replaced the previous maximum residue level recommendation of 0.05 mg/kg.

Herbs

The GAP for bentazone on herbs in Germany is for one application of 0.96 kg ai/ha with a PHI of 42 days; in France the GAP consists of one application at 1.13 kg ai/ha with a PHI of 28 days. Two trials were available from Germany on peppermint matching German GAP with residues of < 0.05(2) mg/kg. Two trials were available from France on melissa (lemon balm) matching French GAP with residues of < 0.02 and 0.037 mg/kg.

As the residues from the European trials were considered similar, the Meeting decided to combine the data and estimated a maximum residue level and an STMR value for herbs, except dry hops, of 0.1 and 0.0435 mg/kg, respectively.

Sugar beet

One trial from USA on sugar beet was received however as no associated GAP was provided the Meeting could not estimate a maximum residue level.

Animal feedstuffs

Pea vines (green)

The critical GAP for bentazone on peas in USA is 2 applications of 1.12 kg ai/ha with a PHI of 10 days. Ten trials were available from USA on peas matching US GAP from which residues found, median underlined, were: 0.11, 0.12, 0.17, 0.19, <u>0.22</u>(2), 0.31, 1.05, 7.05 and 13.1 mg/kg.

The Meeting estimated a median and highest residue for bentazone in pea vines (green) of 0.22 and 13.1 mg/kg.

Pea hay

The critical GAP for bentazone on peas in USA is for 2 applications of 1.12 kg ai/ha with a PHI of 10 days. Three trials were available from USA on peas matching US GAP from which residues found were: 0.48, 1.45 and 1.99 mg/kg.

Three trials on peas hay (dry) were considered insufficient for maximum residue level estimation.

Bean forage (green)

The critical GAP for bentazone on beans, except broad bean and soya bean in France is for one application of 1.22 kg ai/ha with a PHI of 42 days. Five trials were available from Southern Europe on green beans matching French GAP with residues found in forage of < 0.01(3), 0.01 and 0.02 mg/kg. Three trials were available from Northern Europe on green beans against French GAP with residues in forage of < 0.01 and 0.01(2) mg/kg.

As the residues from the European trials were considered similar, the Meeting decided to that the data may be combined, median underlined, < 0.01(4), <u>0.01</u>(3) and 0.02 mg/kg. The Meeting estimated median and highest residue for bentazone in green beans forage of 0.01 and 0.02 mg/kg.

Soy bean forage (green)

The GAP for bentazone on soya bean (dry) in the USA is for two applications of 1.12 kg ai/ha, with no grazing or cutting for forage or hay for at least 30 days after the last treatment. Four trials were available from USA on soya bean forage matching US GAP with residues of < 0.05(2), 0.06 and 0.15 mg/kg.

The Meeting considered four trials an insufficient number for the estimation of median and the highest residue levels for soya bean forage.

Soya bean straw and fodder

The critical GAP for bentazone on soya bean (dry) in USA, two applications of 1.12 kg ai/ha, not graze or cut for forage or hay for at least 30 days after the last treatment. Four trials were available from USA on soya bean hay against the GAP of the USA with residues of < 0.05, 0.10, 0.45 and 0.62 mg/kg.

The Meeting considered four trials an insufficient number for the estimation of median and the highest residue levels for soya bean straw and fodder.

Alfalfa forage (green)

The critical GAP for bentazone on legume animal feeds in France is one application of 0.6 kg ai/ha, BBCH 12 or 1 trifoliate leaf; in the Netherlands the GAP is one application of 1.44 kg ai/ha, 1-2 trifoliate (true) leaves. Four trials were available from Southern Europe on alfalfa forage matching French GAP with residues of 0.01(2) and 0.03(2) mg/kg. Two trials were available from Northern Europe on alfalfa forage matching French GAP with residues of 0.06 and 0.07 mg/kg.

Considering residues from European trials were comparable, the Meeting decided they could be combined. The combined residues, in rank order, were: 0.01(2), <u>0.03</u>(2), 0.06 and <u>0.07</u> mg/kg. The Meeting estimated a median of 0.03 mg/kg and the highest residue of 0.07 mg/kg, respectively.

Alfalfa fodder

The critical GAP for bentazone on legume animal feeds in France is one application of 0.6 kg ai/ha, BBCH 12 or 1 trifoliate leaf; the GAP of the Netherlands is one application of 1.44 kg ai/ha, 1–2 trifoliate (true) leaves. Four trials were available from Southern Europe on alfalfa hay matching French GAP with residues of 0.04, 0.07, 0.08 and 0.12 mg/kg. Two trials were available from Northern Europe on alfalfa hay matching French GAP with residues of 0.10 and 0.23 mg/kg.

As the residues from the European trials were considered parable, the Meeting decided to they could be combined. The residues in rank order were: 0.04, 0.07, 0.08, 0.10, 0.12 and 0.23 mg/kg. Noting the residues from European trials were consistent and based on an average dry-mass of 89% residues in alfalfa fodder (dry weight) were: 0.04, 0.08, 0.09, 0.11, 0.13 and 0.26 mg/kg. The Meeting estimated a median of 0.09 mg/kg, the highest residue of 0.23 mg/kg and a maximum residue level of 0.5 mg/kg for alfalfa fodder (dry), respectively.

Clover

The critical GAP for bentazone on clover in the US is one application of 1.12 kg ai/ha with a PHI of 50 days (for grazing of forage or hay). Two trials were available from the US on clover forage against US GAP with residues of < 0.05 and 0.06 mg/kg.

The Meeting considered two trials an insufficient number for the estimation of median and the highest residue levels for clover forage.

Clover hay or fodder

The critical GAP for bentazone on clover in US is one application of 1.12 kg ai/ha with a PHI of 50 days (for grazing of forage or hay). Two trials were available from the USA on clover forage against US GAP with residues of < 0.05 and 0.07 mg/kg.

The Meeting considered two trials an insufficient number for the estimation of STMR and a maximum residue levels for clover hay.

Peanut fodder

The critical GAP for bentazone on peanut in the US is two application of 1.12 kg ai/ha, up to 28 days after ground crack stage for the second application. Noting that no trials were in line with US GAP the Meeting agreed that the maximum residue level for peanut fodder could not be recommended.

Grass forage

The critical GAP for bentazone on grasses in Sweden is one application of 1.0 kg ai/ha with a PHI of 21 days. Thirteen trials were available from Northern Europe on grass forage matching Swedish GAP from which residues found were: < 0.02, 0.03, 0.04(2), 0.12, 0.17(2), 0.20(2), 0.22 and 0.37 mg/kg.

The Meeting estimated a median and the highest residue for bentazone in grass forage of 0.17 and 0.37 mg/kg, respectively.

Hay or fodder (dry) of grasses

The critical GAP for bentazone on grasses in Sweden is one application of 1.0 kg ai/ha with a PHI of 21 days. Ten trials were available from Northern Europe on grass hay matching Swedish GAP with residues of < 0.02, 0.03, 0.07, 0.08, 0.16, 0.22, 0.39, 0.48, 0.61 and 1.02 mg/kg.

Based on an average dry-mass of 88% residues in grass hay (dry weight) were: < 0.02, 0.03, 0.08, 0.09, 0.18, 0.25, 0.44, 0.55, 0.69 and 1.16 mg/kg.

The Meeting estimated a maximum residue level, an STMR and the highest residue for bentazone in grass hay of 2 mg/kg (DM based), 0.215 mg/kg and 1.16 mg/kg (air dry), respectively.

Straw and fodder (dry) of cereal grain

Barley, millet, oats, rye, triticale, and wheat straw and fodder, dry

The critical GAP for bentazone on cereal grains in Finland is one application of 1.48 kg ai/ha, 2–3 leaf stage Five trials were available from southern Europe on barley matching Finnish GAP with residues of 0.04(2), 0.06(2) and 0.14 mg/kg.

Residue from one German oat trial, at higher application rate than that of the Finnish GAP, was below the LOQ (0.05 mg/kg).

Three trials were available from southern Europe on wheat matching Finnish GAP with residues of 0.03(2) and 0.04 mg/kg.

As the residues from the Southern and Northern European trials were comparable, the Meeting decided to combine these datasets. The residues from the combined European residue trials in rank order, median underlined, were: 0.03(2), 0.04(3), < 0.05, 0.06(2) and 0.14 mg/kg.

Based on an average dry-mass of 88% residues in grass hay (dry weight) were: 0.03(2), 0.04(3), < 0.06, 0.07(2) and 0.16 mg/kg.

The Meeting estimated a maximum residue level, an STMR and a highest residue for bentazone in barley, millet, oats, rye, triticale, and wheat straw and fodder (dry) of 0.3 mg/kg (DM based), 0.05 mg/kg and 0.16 mg/kg (air dry), respectively.

Maize fodder

The critical GAP for bentazone on cereal grains in Italy is one application of 1.48 kg ai/ha, at the 2-4 true leaf growth stage for dicotyledonous weeds. The GAP of the Netherlands is one application of 1.44 kg/ha, (at the 5-leaf stage). Thirteen trials were available from southern Europe on maize straw matching Italian GAP with residues of < 0.01, 0.01, < 0.02(6), 0.02, 0.05, 0.13, 0.14 and 0.24 mg/kg. Seven trials were available from northern Europe on maize straw against Dutch GAP with residues of 0.01, < 0.02(2), 0.03(2), 0.06 and 0.08 mg/kg.

As the residues from the southern and northern European trials were comparable, the Meeting decided to combine the two datasets. The residues from the combined European residue trials in rank order, were: < 0.01, 0.01(2), < 0.02(8), 0.03(2), 0.04, 0.05, 0.06, 0.08, 0.13, 0.14 and 0.24 mg/kg.

Based on an average dry-mass of 83% residues in maize fodder (dry weight) were: < 0.01, 0.01(2), < 0.02(8), 0.04(2), 0.05, 0.06, 0.07, 0.10, 0.16, 0.17 and 0.29 mg/kg.

The Meeting agreed to estimate a median of 0.02 mg/kg, the highest residue 0.24 mg/kg and a maximum residue level of 0.4 mg/kg for maize fodder replacing its previous recommendation of 0.2 mg/kg.

Rice straw, dry

The critical GAP for bentazone on rice in China is one application of 1.44 kg ai/ha, no PHI; The GAP in Greece is one application of 1.44 kg ai/ha, BBCH 12-21. The GAP in Japan is one application of 2.80 kg ai/ha, up to 60 days before harvest. Two trials were available from China on rice straw against Chinese GAP with residues of < 0.02(2) mg/kg. Two trials were available from Japan on rice straw against Japanese GAP with residues of 0.06 and 0.07 mg/kg.

The Meeting considered the number of trials insufficient for the estimation of a maximum residue level for rice straw.

Fate of residues during processing

The Meeting received information on the fate of bentazone residues during the food processing of rice.

Portion Analysed		Mean Processing Factor	STMR (mg/kg)	STMR-P (mg/kg)
Rice	hulls	8.9	0.01	0.089
	bran	0.37		0.0037
	polished rice	0.08		0.0008

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. 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 summarized and the highest dietary burdens are selected for MRL and STMR estimates on animal commodities.

	Animal dietary burden, bentazone, ppm of dry matter diet							
	US-Canada		EU		Australia		Japan	
	max	mean	max	mean	max	mean	max	mean
Beef cattle	0.24	0.06	11.3	0.54	32 [a]	0.8 [b]	0.57	0.14
Dairy cattle	5.94	0.41	11.4	0.60	22 [c]	0.76 [d]	1.0	0.24
Poultry-broiler	0.0091	0.0091	0.013	0.013	0.019	0.0019	0.018	0.012
Poultry-layer	0.091	0.091	5.4 [e]	0.17 [f]	0.019	0.019	0.01	0.01

[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 goats were orally administered bentazone at the equivalent to 15 ppm and 75 ppm on the basis of an individual feed intake of 3 kg of feed per animal per day and incorporating an allowance for the difference in dry matter percentage between the type of diet offered (cereal/protein concentrate feed and hay) and fresh herbage, respectively. Residues of bentazone in the whole milk of goats in the 15 and 75 ppm groups were < 0.02 mg/kg and < 0.02 mg/kg respectively, goat tissues were not analysed.

Since no analysis of tissues was carried out in the goats feeding study, the Meeting decided that no recommendations could be made on the basis of this study.

In the animal metabolism study on lactating goats, residues in fat were significantly higher than that in muscle. However, it is not expected that bentazone, with a log P_{ow} of -0.45, would accumulate in fat. The Meeting decided not to estimate maximum residue levels for animal tissues on the basis of this study.

Residues in poultry tissues and eggs are estimated using the data from the poultry metabolism study in which the dose rate was 100 ppm and the highest and mean residues in tissues and eggs were determined.

Estimation of residues in poultry tissues and eggs

	Feed level (ppm) for egg residues	Residues (mg/kg) in egg	Feed level (ppm) for tissue residues	Residues (mg/kg) in		
				Muscle	Liver	Fat
Maximum residue level broiler or layer poultry						
Feeding study[a]	100	0.15	100	0.42	1.1	0.11
Dietary burden and residue estimate	5.4	0.008	5.4	0.023	0.059	0.006
STMR broiler or layer poultry						
Feeding study[b]	100	0.15	100	0.42	1.1	0.11
Dietary burden and residue estimate	0.17	0.0003	0.17	0.0007	0.002	0.0002

[a] Highest residue for tissues and mean residue for egg

[b] Mean residues for tissue and egg

The Meeting noted that the LOQ of the analytical method was 0.01 mg/kg, and agreed to estimate maximum residue level of 0.03 mg/kg for poultry meat (fat) and estimate maximum residue level of 0.01* for eggs and estimated a maximum residue level of 0.07 mg/kg for poultry edible offal. The Meeting estimated STMRs of 0 mg/kg for poultry meat (fat), edible offal and for eggs.

DIESTARY RISK ASSESSMENT

Long term intake

The evaluation of bentazone resulted in recommendations for MRLs and STMR values for raw and processed commodities. Data on consumption were available for 17 food commodities and were used to calculate dietary intake. The results are shown in Annex 3.

The International Estimated Daily Intakes (IEDIs) of bentazone, based on the STMRs estimated, were 0% of the maximum ADI of 0.09 mg/kg bw for the thirteen GEMS/Food cluster diets. The Meeting concluded that the long-term intake of residues of bentazone resulting from its uses that have been considered by JMPR is unlikely present a public health concern.

Short-term intake

The 2012 Meeting decided that an ARfD for bentazone is unnecessary and concluded that the short-term intake of residues resulting from the use of bentazone is unlikely to present a public health concern.

5.3 BENZOVINDIFLUPYR (261)

TOXICOLOGY

Benzovindiflupyr is the provisional International Organization for Standardization (ISO) name for *N*-[(1*RS*,4*SR*)-9-(dichloromethylidene)-1,2,3,4-tetrahydro-1,4-methanonaphthalen-5-yl]-3-(difluoromethyl)-1-methyl-1H-pyrazole-4-carboxamide (International Union of Pure and Applied Chemistry [IUPAC]) (Chemical Abstracts Service [CAS] No. 1072957-71-1). Technical benzovindiflupyr contains the enantiomers SYN546526 and SYN546527, at a ratio of 50:50. Both enantiomers are fungicidally active. No toxicological studies were performed on the individual enantiomers.

Benzovindiflupyr is a new broad-spectrum foliar fungicide of the chemical group pyrazole carboxamide. It has not been evaluated previously by JMPR and was reviewed by the present Meeting at the request of CCPR.

All pivotal studies were certified as complying with GLP.

Biochemical aspects

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). Peak levels of radiolabel occurred in plasma within 2–4 hours (1 mg/kg bw) or within 6–24 hours (40 mg/kg bw) post-dosing. Peak levels were approximately 2-fold higher in males than in females. The apparent plasma half-life of the labelled material in rats was 28–55 hours. In low-dose animals, 4% was found in urine and 17% in faeces; in high-dose animals, 9% was found in urine and 32% in faeces. However, at both dose levels, 86–97% of the absorbed dose was excreted in bile duct–cannulated rats within 48 hours after administration. 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. The major route of excretion was by bile, accounting for approximately 69–76% of the administered dose at the low dose and 47–57% at the high dose. 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.

Toxicological data

The oral LD_{50} was 55 mg/kg bw in fasted female rats. The dermal LD_{50} was greater than 2000 mg/kg bw, and the median lethal concentration (LC_{50}) in an inhalation study was 0.56 mg/L. Benzovindiflupyr was mildly irritating to the skin and moderately irritating to the eyes. Benzovindiflupyr showed no skin sensitizing potential in a mouse local lymph node assay (LLNA).

In repeated-dose toxicity studies in mice, rats and dogs, the main effects were on the liver (hepatocellular hypertrophy, increased organ weight) and body weight, with minor changes in clinical chemistry parameters.

In a 4-week mouse feeding study with dietary concentrations of 0, 100, 300 and 500 ppm (equal to 0, 15.6, 47.4 and 81.8 mg/kg bw per day for males and 0, 19.0, 57.9 and 91.5 mg/kg bw per day for females, respectively), body weight gain at 300 ppm was reduced by 7% in the absence of reduced feed consumption. Both sexes showed tubular basophilia with interstitial inflammatory cell infiltration at 500 ppm. The NOAEL was 100 ppm (equal to 15.6 mg/kg bw per day), based on reduced body weight gain at 300 ppm (equal to 47.4 mg/kg bw per day).

In a 13-week mouse feeding study with dietary concentrations of 0, 100, 300 and 500 ppm (equal to 0, 17.0, 55.6 and 97.9 mg/kg bw per day for males and 0, 20.9, 59.6 and 102.8 mg/kg bw per day for females, respectively), 3 of 13 males showing severe toxic effects, such as body weight loss, at 500 ppm were terminated early. Reduced body weight gains without reduced feed consumption were noted from the 1st day of treatment at 300 and 500 ppm. Body weights at study termination were lower compared with controls by 14% at 300 ppm and by 25% at 500 ppm in males and by 9% and 15% in females, respectively. At 300 ppm and above, some changes in clinical chemistry parameters were observed, including globulin, triglyceride, creatinine and calcium levels. The incidence of tubular basophilia in the kidney in females was increased at 500 ppm. The NOAEL was 100 ppm (equal to 17.0 mg/kg bw per day), based on reduced body weight gains and minor clinical chemistry changes at 300 ppm (equal to 55.6 mg/kg bw per day).

In a 4-week rat feeding study with dietary concentrations of 0, 100, 400 and 1200 ppm (equal to 0, 9, 36 and 107 mg/kg bw per day for males and 0, 9, 36 and 90 mg/kg bw per day for females, respectively), the NOAEL was 400 ppm (equal to 36 mg/kg bw per day), based on lower body weights in both sexes at 1200 ppm (equal to 90 mg/kg bw per day).

In a 13-week rat feeding study with dietary concentrations of 0, 100, 750 and 1500 ppm (equal to 0, 8.2, 58.8 and 108.8 mg/kg bw per day for males and 0, 9, 36 and 90 mg/kg bw per day for females, respectively), the NOAEL was 100 ppm (equal to 8.2 mg/kg bw per day), based on reduced body weight gain at 750 ppm (equal to 58.8 mg/kg bw per day).

In studies in which dogs were administered benzovindiflupyr by gelatine capsule gavage for 13 weeks (0, 30, 375 and 750 mg/kg bw per day) and 52 weeks (0, 25, 250 and 500 mg/kg bw per day), the major effects were salivation and vomiting starting at the end of the 1st week and reduced body weight gain, with an overall NOAEL of 30 mg/kg bw per day and an overall LOAEL of 250 mg/kg bw per day.

In an 18-month feeding study in mice with dietary concentrations of 0, 20, 60 and 200 ppm (equal to 0, 2.62, 7.55 and 26.18 mg/kg bw per day for males and 0, 2.89, 8.67 and 29.26 mg/kg bw per day for females, respectively), high-dose males and females had higher incidences of colon and caecum mucosal hyperplasia. There was no compound-related increase in tumours. The NOAEL was 60 ppm (equal to 7.55 mg/kg bw per day), based on colon/caecum mucosal hyperplasia at 200 ppm in both sexes (equal to 26.18 mg/kg bw per day).

The Meeting concluded that benzovindiflupyr is not carcinogenic in mice.

In a 24-month feeding study in rats with dietary concentrations of 0, 25, 100 and 600 ppm in males (equal to 0, 1.2, 4.9 and 30.2 mg/kg bw per day, respectively) and 0, 25, 100 and 400 ppm in females (equal to 0, 1.7, 6.7 and 27.4 mg/kg bw per day, respectively), body weights and feed efficiency were lower from the 1st week onwards in both sexes at the high dose level. In high-dose females, some red blood cell parameters were slightly but statistically significantly reduced in the 1st year, and prothrombin time was slightly but statistically significantly increased. The incidence of minimal hepatocellular centrilobular pigmentation was statistically significantly increased in females at 400 ppm at terminal kill. Centrilobular hepatocellular hypertrophy was increased in mid- and high-dose males and high-dose females; additionally, the incidence of eosinophilic foci of cellular alteration in liver was increased in high-dose males. In males at 600 ppm, the incidence of thyroid follicular cell adenoma was statistically significantly increased compared with the concurrent control group. The incidences were 2% at 0 ppm, 7.6% at 25 ppm, 9.6% at 100 ppm and 17.3% at 600 ppm. The incidence for males at 600 ppm was also higher than the historical control incidence range (2–11.1%). The NOAEL for systemic toxicity and carcinogenicity was 100 ppm (equal to 4.9 mg/kg bw per day), based on histological changes in the liver of males, an increased incidence of thyroid follicular cell adenoma in males and reduced body weight gain in both sexes at the high dose (600 ppm in males, equal to 30.2 mg/kg bw per day; and 400 ppm in females, equal to 27.4 mg/kg bw per day).

The Meeting concluded that benzovindiflupyr is carcinogenic in male rats at the highest dose tested.

The potential genotoxicity of benzovindiflupyr was tested in an adequate range of in vitro and in vivo studies, providing no evidence of genotoxic potential.

The Meeting concluded that benzovindiflupyr is unlikely to be genotoxic.

In a mechanistic study to investigate possible modes of action for the thyroid follicular cell adenomas, male rats were fed diets with 0, 100, 600 and 1200 ppm (equal to 0, 9.9, 57.7 and 112.8 mg/kg bw per day, respectively) for up to 14 days, and thyroxine (T_4), triiodothyronine (T_3) and thyroid stimulating hormone (TSH) levels were measured at several time points. Reversible decreases in T_3 levels were noted at the high dose from day 2 onwards, and T_4 was reduced only in the first 4 days of treatment. TSH was elevated only in the 1200 ppm group at termination. Benzovindiflupyr at 1200 ppm induced uridine diphosphate-glucuronosyltransferase (UDPGT) activity towards T_4 on days 4, 8 and 15. UDPGT activity was increased also at 600 ppm on days 4 and 15 and in the 100 ppm group on day 4. Treatment with 100, 600 or 1200 ppm also produced increases in hepatic microsomal protein content. Thyroid follicular cell proliferation was increased at 1200 ppm. In a further mechanistic study on UDPGT activity against T_4 in livers from benzovindiflupyr-treated rats, UDPGT activity was increased from the first measurement on treatment day 3 onwards at dose levels of 75 ppm and above. In an in vitro assay, benzovindiflupyr had no significant effect on rat thyroid peroxidase activity at concentrations up to 10 µmol/l.

Decreased T_4 levels, hepatocellular hypertrophy and increased thyroid follicular cell proliferation were identified in a mechanistic study as early events in male rats exposed to benzovindiflupyr. A mode of action for thyroid follicular cell adenoma based on decreased T_3/T_4 levels due to increased liver enzyme activity and a compensatory activity of the thyroid could be proposed. This would be supported by UDPGT activity, hepatocellular hypertrophy and reduced T_3/T_4, for which there was good dose concordance. However, elevated TSH levels were observed only at higher dose levels, and, apart from thyroid follicular cell adenoma, no histological changes in the thyroid were observed at 600 ppm in the rat carcinogenicity study. Therefore, this proposed mode of action is not completely supported by the data available. However, on the basis of the lack of genotoxicity, the absence of carcinogenicity in mice, and the fact that only thyroid follicular cell adenomas were observed and that these were increased only in male rats, the Meeting concluded that benzovindiflupyr 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, 25, 100 and 600 ppm (equal to 0, 1.7, 6.8 and 40.5 mg/kg bw per day, respectively) in males and 0, 25, 100 and 250 ppm (equal to 0, 1.9, 7.6 and 17.5 mg/kg bw per day, respectively) in females, body weight gain and feed consumption were reduced at 600/250 ppm in F_0 and F_1 males and females throughout premating and gestation. In the F_0 and F_1 250 ppm groups, the mean corpora lutea count at necropsy was statistically significantly lower than in controls. In the F_0 and F_1 males at 600 ppm and F_1 females at 250 ppm, the relative liver weight was higher than in controls. Centrilobular hepatocellular hypertrophy in high-dose males and hypertrophy in adrenal zona glomerulosa in high-dose females were observed. An increased number of animals in lactational diestrus was observed at 250 ppm in F_0 and F_1 females compared with controls. At 250 ppm, pup body weights at birth were lower in F_2 animals and postnatal body weight gains were lower in F_1 and F_2 animals compared with controls. The time until preputial separation and vaginal opening was statistically significantly longer in the high-dose animals. The NOAELs for parental and offspring toxicity were both 100 ppm (equal to 6.8 mg/kg bw per day), based on decreased body weight gain in parental animals and on lower postnatal body weight gain at 250 ppm (equal to 17.5 mg/kg bw per day). The reproductive NOAEL was 250 ppm (equal to 17.5 mg/kg bw per day), the highest dose tested.

In a study on the developmental toxicity of benzovindiflupyr in rats at dose levels of 0, 7.5, 15 and 30 mg/kg bw per day administered by gavage, 14 of 24 high-dose animals showed ataxia, decreased activity, hunched and prostrate posture and ruffled fur from treatment days 6 to 16. High-dose animals showed reduced feed consumption from the 1st treatment day and reduced body weights

from the 3rd treatment day onwards. High-dose litter weights were statistically significantly lower than those of controls. Five fetuses from five different high-dose litters showed soft-tissue anomalies, with no clear pattern. The incidence of renal pelvis dilatation and extra thymic tissues was statistically significantly increased on a litter basis at 30 mg/kg bw per day. At 30 mg/kg bw per day, delayed ossification was noted in cervical vertebrae, sternebrae, proximal phalanges of digits and calcanei. The NOAEL for maternal toxicity was 15 mg/kg bw per day, based on reduced body weight and clinical signs of toxicity at 30 mg/kg bw per day. The NOAEL for embryo/fetal toxicity was 15 mg/kg bw per day, based on lower litter weights, delayed ossification and increased incidences of anomalies at 30 mg/kg bw per day.

In a study on the developmental toxicity of benzovindiflupyr in rabbits at dose levels of 0, 10, 20 and 35 mg/kg bw per day, body weight gain was lower in a dose-related manner at all dose levels, statistically significantly at the middle and high doses from gestation days 13 to 21. This effect was observed from the beginning of treatment at 35 mg/kg bw per day and from the 2nd week of treatment at the lower dose levels. At gestation day 29, body weights of all groups were similar. Although the incidence of late resorptions in the 35 mg/kg bw per day group was statistically significantly higher than in the concurrent control group, it was within the range of historical control data. There were no further treatment-related effects on fetal growth and development. The NOAEL for maternal toxicity was 10 mg/kg bw per day, based on decreased body weight gain at 20 mg/kg bw per day. The NOAEL for embryo/fetal toxicity was 35 mg/kg bw per day, the highest dose tested.

The Meeting concluded that benzovindiflupyr is not teratogenic in rats or rabbits.

In an acute neurotoxicity study in rats administered benzovindiflupyr at a dose of 0, 10, 30 or 80 mg/kg bw, decreased locomotor activity was noted in females at 30 mg/kg bw and in males and females at 80 mg/kg bw at 1 hour post-dosing on the 1st day. All 80 mg/kg bw females also exhibited swaying gait, abnormal gait, collapse and ruffled fur. On days 3–14, no treatment-related daily observations were noted. On day 1 in females at 30 mg/kg bw and in males and females at 80 mg/kg bw, body temperature was statistically significantly lower than in controls. In females at 30 and 80 mg/kg bw, forelimb grip strength was reduced on day 1. The NOAEL for systemic effects was 10 mg/kg bw, based on clinical signs of toxicity at 30 mg/kg bw. The NOAEL for acute neurotoxicity was 80 mg/kg bw, the highest dose tested.

In a 13-week rat feeding study of the neurotoxicity of benzovindiflupyr with dietary concentrations of 0, 100, 400 and 800 ppm (equal to 0, 6.31, 25.95 and 50.67 mg/kg bw per day, respectively) in males and 0, 100, 250 and 500 ppm (equal to 0, 7.48, 19.17 and 37.99 mg/kg bw per day, respectively) in females, no effects were observed except for reduced feed intake and reduced body weight gain. The NOAEL for systemic toxicity was 100 ppm (equal to 6.31 mg/kg bw per day), based on decreased body weight gain in males at 400 ppm (equal to 25.95 mg/kg bw per day). The NOAELs for subchronic neurotoxicity were 800 ppm (equal to 50.67 mg/kg bw per day) in males and 500 ppm (equal to 37.99 mg/kg bw per day) in females, the highest doses tested.

The Meeting concluded that benzovindiflupyr is not neurotoxic.

In a 4-week mouse feeding study on immunotoxicity with dietary concentrations of 0, 100, 200 and 400 ppm (equal to 0, 26.4, 47.1 and 97.1 mg/kg bw per day), there were no significant effects on spleen cell number or on the humoral immune response of splenic immunoglobulin M (IgM) to the T cell–dependent antigen sheep red blood cells.

Toxicological data on metabolites and/or degradates

In studies of benzovindiflupyr, SYN546039 (CSCD695908; racemic mixture of 3-difluoromethyl-1-methyl-1H-pyrazole-4-carboxylic acid [(1*S*,2*S*,4*R*)-9-dichloromethylene-2-hydroxy-1,2,3,4-tetrahydro-1,4-methano-naphthalene-5-yl)-amide and (1*R*,2*R*,4*S*)-9-dichloromethylene-2-hydroxy-1,2,3,4-tetrahydro-1,4-methano-naphthalene-5-yl)-amide]) was found in rats, plants, soil and surface water, and SYN545720 (CSCD465008; 3-(difluoromethyl)-1H-pyrazole-4-carboxylic acid) was found in plants and soil.

SYN546039 and SYN545720 were both of low acute oral toxicity in rats, with LD_{50} values greater than 2000 mg/kg bw, and did not give any evidence of genotoxic potential.

In a 4-week rat feeding study with SYN545720 at dietary concentrations of 0, 2000, 6000 and 12 000 ppm (equal to 0, 175, 497 and 1018 mg/kg bw per day for males and 0, 176, 525 and 1107 mg/kg bw per day for females, respectively), no evidence of toxicity was observed. The NOAEL was 12 000 ppm (equal to 1018 mg/kg bw per day), the highest dose tested.

In a 13-week rat feeding study with SYN546039 at dietary concentrations yielding 0, 100, 300 and 1000 mg/kg bw per day, no evidence of toxicity was observed. The NOAEL was 1000 mg/kg bw per day, the highest dose tested.

In a study on the developmental toxicity of SYN546039 in rabbits at dose levels of 0, 100, 300 and 1000 mg/kg bw per day, the maternal NOAEL was 300 mg/kg bw per day, based on increased incidence of mortalities and abortions at 1000 mg/kg bw per day. The NOAEL for developmental toxicity was 300 mg/kg bw per day, based on the increased incidence of misshapen interparietal skull bone at 1000 mg/kg bw per day.

Human data

No information was provided on the health surveillance of workers involved in the manufacture or use of benzovindiflupyr.

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

Toxicological evaluation

The Meeting established an ADI of 0–0.05 mg/kg bw, based on the NOAEL of 4.9 mg/kg bw per day in the 2-year rat feeding study for decreased body weight gain and increased incidences of eosinophilic foci of cellular alteration in the liver at 27.4 mg/kg bw per day. A safety factor of 100 was applied. The ADI is supported by the NOAEL of 7.55 mg/kg bw per day in the mouse 80-week feeding study, based on colon/caecum mucosal hyperplasia at 26.18 mg/kg bw per day. The margin between the upper bound of the ADI and the LOAEL at 30.2 mg/kg bw per day for thyroid follicular cell adenoma in male rats is approximately 600.

The Meeting established an ARfD of 0.1 mg/kg bw, derived from the NOAEL of 10 mg/kg bw in the acute neurotoxicity study in rats, on the basis of decreased locomotor activity at 1 hour post-dosing at the LOAEL of 30 mg/kg bw per day. This ARfD is supported by the NOAEL of 15 mg/kg bw per day in a developmental toxicity study in rats with clinical signs at 30 mg/kg bw per day starting on the 1st day of treatment.

A toxicological monograph was prepared.

Levels relevant to risk assessment of benzovindiflupyr

Species	Study	Effect	NOAEL	LOAEL
Mouse	Eighteen-month study of toxicity and carcinogenicity[a]	Toxicity	60 ppm, equal to 7.55 mg/kg bw per day	200 ppm, equal to 26.18 mg/kg bw per day
		Carcinogenicity	200 ppm, equal to 26.18 mg/kg bw per day[b]	—
Rat	Acute neurotoxicity[c]	Toxicity	10 mg/kg bw	30 mg/kg bw

Species	Study	Effect	NOAEL	LOAEL
	Two-year study of toxicity and carcinogenicity[a]	Toxicity	100 ppm, equal to 4.9 mg/kg bw per day	400 ppm, equal to 27.4 mg/kg bw per day
		Carcinogenicity	100 ppm, equal to 4.9 mg/kg bw per day	600 ppm, equal to 30.2 mg/kg bw per day
	Two-generation study of reproductive toxicity[a]	Reproductive toxicity	250 ppm, equal to 17.5 mg/kg bw per day[b]	—
		Parental toxicity	100 ppm, equal to 7.6 mg/kg bw per day	250 ppm, equal to 17.5 mg/kg bw per day
		Offspring toxicity	100 ppm, equal to 7.6 mg/kg bw per day	250 ppm, equal to 17.5 mg/kg bw per day
	Developmental toxicity study[c]	Maternal toxicity	15 mg/kg bw per day	30 mg/kg bw per day
		Embryo and fetal toxicity	15 mg/kg bw per day	30 mg/kg bw per day
Rabbit	Developmental toxicity study[c]	Maternal toxicity	10 mg/kg bw per day	20 mg/kg bw per day
		Embryo and fetal toxicity	35 mg/kg bw per day[b]	—
Dog	Thirteen-week and 1-year studies of toxicity[c,d]	Toxicity	30 mg/kg bw per day	250 mg/kg bw per day
SYN545720				
Rat	Four-week study of toxicity[a]	Toxicity	12 000 ppm, equal to 1018 mg/kg bw per day[b]	—
SYN546039				
Rat	Thirteen-week study of toxicity[a]	Toxicity	1000 mg/kg bw per day[b]	—
Rabbit	Developmental toxicity study[c]	Maternal toxicity	300 mg/kg bw per day	1000 mg/kg bw per day
		Embryo and fetal toxicity	300 mg/kg bw per day	1000 mg/kg bw per day

[a] Dietary administration.

[b] Highest dose tested.

[c] Gavage administration.

[d] Two studies combined.

Estimate of acceptable daily intake

0–0.05 mg/kg bw

Estimate of acute reference dose

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 exposures

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

Absorption, distribution, excretion and metabolism in mammals	
Rate and extent of oral absorption	Rapid, 80% at low dose (1 mg/kg bw), 60% at higher dose (40 mg/kg bw)
Dermal absorption	No data (probably low, dermal LD50 high compared with oral LD50)
Distribution	Extensive, highest levels in liver
Potential for accumulation	No evidence of accumulation
Rate and extent of excretion	Rapid, 86–97% within 48 h, mainly via bile
Metabolism in animals	Extensive, primarily via hydroxylation at bicyclo and phenyl moieties
Toxicologically significant compounds in animals, plants and the environment	Benzovindiflupyr
Acute toxicity	
Rat, LD50, oral	55 mg/kg bw
Rat, LD50, dermal	> 2000 mg/kg bw
Rat, LC50, inhalation	0.56 mg/L
Rabbit, dermal irritation	Mildly irritating
Rabbit, ocular irritation	Moderately irritating
Mouse, dermal sensitization	No sensitizing potential (local lymph node assay)
Short-term studies of toxicity	
Target/critical effect	Body weight (rat)
Lowest relevant oral NOAEL	8.2 mg/kg bw per day (rat)
Lowest relevant dermal NOAEL	No data
Lowest relevant inhalation NOAEC	No data
Long-term studies of toxicity and carcinogenicity	
Target/critical effect	Liver, body weight, thyroid
Lowest relevant NOAEL	4.9 mg/kg bw per day (rat)
Carcinogenicity	Unlikely to pose a carcinogenic risk from the diet
Genotoxicity	
	Not genotoxic
Reproductive toxicity	
Target/critical effect	No reproductive toxicity
Lowest relevant parental NOAEL	7.6 mg/kg bw per day
Lowest relevant offspring NOAEL	7.6 mg/kg bw per day

Lowest relevant reproductive NOAEL	17.5 mg/kg bw per day, the highest dose tested
Developmental toxicity	
Target/critical effect	Fetal weights and anomalies at maternally toxic doses
Lowest relevant maternal NOAEL	15 mg/kg bw per day (rat)
Lowest relevant embryo/fetal NOAEL	15 mg/kg bw per day (rat)
Neurotoxicity	
Acute and subchronic neurotoxicity	Not neurotoxic
Other toxicological studies	
Immunotoxicity	Not immunotoxic
Studies on metabolites	In oral studies, SYN546039 and SYN545720 less toxic than the parent
Medical data	
	No reports submitted

Summary

	Value	Study	Safety factor
ADI	0–0.05 mg/kg bw	Two-year toxicity study in rats	100
ARfD	0.1 mg/kg bw	Acute neurotoxicity study in rats	100

5.4 BIXAFEN (262)

TOXICOLOGY

Bixafen is the ISO-approved common name for *N*-(3′,4′-dichloro-5-fluorobiphenyl-2-yl)-3-(difluoromethyl)-1-methyl-1H-pyrazole-4-carboxamide (IUPAC) (CAS No. 581809-46-3), a novel fungicide from the pyrazole-carboxamide class. Bixafen exhibits broad fungicidal activity in various crops by inhibition of succinate dehydrogenase, an enzyme of complex II within the mitochondrial respiration chain.

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

All critical studies were certified as complying with GLP.

Biochemical aspects

In rats given (dichlorophenyl-U-^{14}C)-labelled bixafen orally by gavage, absorption was rapid and accounted for at least 83% of the total administered radioactivity after a single low dose (2 mg/kg bw). The maximum plasma concentrations of radioactivity were reached approximately 2–4 and 8 hours after administration of the low and high doses (2 and 50 mg/kg bw), respectively. Radioactivity was widely distributed throughout the body. Elimination of the radioactivity was mainly via faeces (≥ 91%), whereas elimination via urine accounted for 1–3% of the administered dose. In bile duct–cannulated rats, extensive biliary excretion (up to 83%) was demonstrated. Elimination of the radioactivity from the body was rapid, with a half-life in plasma of 8–9 hours and a mean residence time of 13–19 hours (for the low dose). Residues in tissues at 72 hours after a single oral dose as well as after repeated oral dosing accounted for 0.1–3% of the administered radioactivity, with liver and kidneys containing the highest concentrations of residues.

Metabolism of bixafen in rats was extensive, and more than 30 metabolites were identified. The main metabolic routes included demethylation, hydroxylation of the parent and bixafen-desmethyl, and conjugation with glucuronic acid or glutathione. A minor metabolic reaction was the cleavage of the amide bridge of bixafen.

Toxicological data

The LD_{50} in rats treated orally or dermally with bixafen was greater than 2000 mg/kg bw, and the inhalation LC_{50} in rats was greater than 5.38 mg/L. Bixafen was not a skin irritant in rabbits, was not irritating to the eye of rabbits and was not a skin sensitizer in the local lymph node assay in mice.

Following repeated administration of bixafen, the liver was the primary target organ in mice, rats and dogs. Increased liver weights and hepatocellular hypertrophy were observed in all species tested and were considered to reflect hepatic microsomal enzyme induction. Also, in several studies, there was evidence for liver toxicity based on clinical chemistry changes (increased serum alkaline phosphatase and cholesterol, decreased serum albumin) and histopathological changes (hepatocellular pigmentation, degeneration and necrosis). In mice and rats, the thyroid was an additional target, which was considered to be secondary to the enhanced hepatic clearance of thyroid hormones. This suggestion was supported by a 14-day mechanistic study in rats in which a marked induction of phase I and II hepatic enzymes, a slight reduction of thyroid hormone (T_3, T_4) levels and a significant increase of TSH levels were observed at 150 mg/kg bw per day, the only dose tested.

In a 4-week study in mice using dietary concentrations of 0, 100, 500 and 2500 ppm (equal to 0, 17, 81 and 305 mg/kg bw per day for males and 0, 21, 103 and 424 mg/kg bw per day for females), the NOAEL was 100 ppm (equal to 17 mg/kg bw per day), based on liver toxicity (increased liver weight, clinical chemistry changes, focal coagulative necrosis) at 500 ppm (equal to 81 mg/kg bw per day) and above. In a 13-week study in mice using dietary concentrations of 0, 50, 200 and 500 ppm

(equal to 0, 8.5, 34.3 and 88 mg/kg bw per day for males and 0, 10.4, 42.9 and 110 mg/kg bw per day for females), the NOAEL was 50 ppm (equal to 8.5 mg/kg bw per day), based on liver toxicity in males (increased liver weight, clinical chemistry changes, diffuse hepatocellular vacuolation) and focal/multifocal squamous cell hyperplasia of the stomach in both sexes at 200 ppm (equal to 34.3 mg/kg bw per day) and above.

In a 4-week study in rats using dietary concentrations of 0, 50, 350 and 2000 ppm (equal to 0, 3.5, 25 and 137 mg/kg bw per day for males and 0, 4.1, 28 and 138 mg/kg bw per day for females), the NOAEL was 350 ppm (equal to 25 mg/kg bw per day), based on reduced body weight gain, reduced feed consumption, liver toxicity (increased liver weight, increased cholesterol level) and thyroid effects (hypertrophy of follicular cells) at 2000 ppm (equal to 137 mg/kg bw per day). In a 13-week study in rats using dietary concentrations of 0, 50, 200, 800 and 2000 ppm (equal to 0, 3.2, 12.9, 50.4 and 130 mg/kg bw per day for males and 0, 3.9, 15.0, 59.2 and 153 mg/kg bw per day for females), the NOAEL was 200 ppm (equal to 12.9 mg/kg bw per day), based on liver effects (enlarged liver, increased liver weight) and thyroid effects (hypertrophy of follicular cells) at 800 ppm (equal to 50.4 mg/kg bw per day) and above.

In a 13-week study in dogs testing dose levels of 0, 100, 300 and 1000 mg/kg bw per day by oral gavage, the NOAEL was 100 mg/kg bw per day, based on an increase (> 20%) in absolute and relative liver weights of females at 300 mg/kg bw per day and above. In a 1-year study in dogs testing dose levels of 0, 10, 100 and 1000 mg/kg bw per day by oral gavage, the NOAEL was 10 mg/kg bw per day, based on haematological effects (decrease in red blood cell count, haemoglobin and haematocrit) in males and liver toxicity (increased liver weight, increased alkaline phosphatase and cholesterol levels) in females at 100 mg/kg bw per day and above.

Long-term studies of toxicity and carcinogenicity were conducted in mice and rats. Due to technical problems in the production of the feed, the vitamin K_3 level of the diet (< 0.3 ppm) used in the first 5–6 months of the studies was significantly lower than the estimated requirement for mice and rats (approximately 1 ppm), with the consequence of a haemorrhagic syndrome and increased mortality, especially in the male animals from the high-dose group of mice or the mid-dose and high-dose groups of rats. After approximately 6 months of treatment, the diet was supplemented with 7–16 ppm of the synthetic vitamin K analogue menadione, and the studies were completed as scheduled, with the exception of the male rats, which were prematurely terminated after approximately 6–8 months of treatment. An additional study of chronic toxicity and carcinogenicity was therefore conducted in male rats (see below).

In the 78-week study of carcinogenicity in mice using dietary concentrations of 0, 50, 150 and 500 ppm (equal to 0, 6.7, 20.4 and 69.0 mg/kg bw per day for males and 0, 8.6, 25.5 and 85.0 mg/kg bw per day for females), there was no evidence for carcinogenicity up to the highest dose tested (500 ppm, equal to 69 mg/kg bw per day). The NOAEL for toxicity was 50 ppm (equal to 6.7 mg/kg bw per day), based on thyroid effects (follicular cell hyperplasia) in females and decreased body weights and liver toxicity (single-cell degeneration/necrosis) in males at 150 ppm (equal to 20.4 mg/kg bw per day) and above.

In the initial 24-month study of toxicity and carcinogenicity in rats, which was completed as planned for females only, dietary concentrations of 0, 50, 300 and 2000 ppm (equal to 0, 2.8, 17.4 and 117 mg/kg bw per day) were tested. There was no evidence for carcinogenicity up to the highest dose tested (2000 ppm, equal to 117 mg/kg bw per day). The NOAEL for toxicity was 50 ppm (equal to 2.8 mg/kg bw per day), based on liver effects (increased cholesterol, higher incidence and/or severity of hepatocellular brown pigments and multinucleated hepatocytes) and thyroid effects (higher incidence and/or severity of follicular cell hypertrophy and colloid alteration) at 300 ppm (equal to 17.4 mg/kg bw per day) and above. In the complementary 24-month study of toxicity and carcinogenicity in male rats using a vitamin K_3–supplemented diet (7–11 ppm) and dietary concentrations of bixafen of 0, 50, 300 and 2000 ppm (equal to 0, 2.0, 12.1 and 80.5 mg/kg bw per day), there was no evidence for carcinogenicity up to the highest dose tested (2000 ppm, equal to 80.5 mg/kg bw per day). The NOAEL for toxicity was 50 ppm (equal to 2.0 mg/kg bw per day), based

on liver effects (increased cholesterol levels, increased liver weights) and thyroid effects (higher incidence and/or severity of colloid alteration) at 300 ppm (equal to 12.1 mg/kg bw per day) and above.

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

Bixafen was tested for genotoxicity in vitro and in vivo in an adequate range of assays. There was no evidence of genotoxicity.

The Meeting concluded that bixafen is unlikely to be genotoxic.

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

In a two-generation study of reproductive toxicity in rats using dietary concentrations of 0, 50, 400 and 2500 ppm (equal to 0, 3.3, 26.4 and 169.2 mg/kg bw per day for males and 0, 3.9, 30.8 and 193.7 mg/kg bw per day for females), the NOAEL for reproductive toxicity was 2500 ppm (equal to 169.2 mg/kg bw per day), the highest dose tested. The NOAEL for parental toxicity was 400 ppm (equal to 26.4 mg/kg bw per day), based on a reduction in body weight and liver effects (liver weight increased > 20%) at 2500 ppm (equal to 169.2 mg/kg bw per day). The NOAEL for offspring toxicity was 400 ppm (equal to 26.4 mg/kg bw per day), based on a slight elevation in stillbirths and reduced pup weight/weight gain during lactation at 2500 ppm (equal to 169.2 mg/kg bw per day).

In a developmental toxicity study in rats testing dose levels of 0, 20, 75 and 250 mg/kg bw per day, the NOAEL for maternal toxicity was 20 mg/kg bw per day, based on decreased body weight gain and feed consumption at 75 mg/kg bw per day and above in the first days of treatment (i.e. gestation days 6–8). The NOAEL for embryo and fetal toxicity was 20 mg/kg bw per day, based on decreased fetal weights at 75 mg/kg bw per day and above.

In a developmental toxicity study in rabbits testing dose levels of 0, 25, 100 and 400 mg/kg bw per day, the NOAEL for maternal toxicity was 25 mg/kg bw per day, based on clinical signs (hair loss, no or reduced excreta) and a reduction in body weight gain and feed consumption at 100 mg/kg bw per day and above. The NOAEL for embryo and fetal toxicity was 25 mg/kg bw per day, based on reduced fetal body weight at 100 mg/kg bw per day and above.

The Meeting concluded that bixafen is not teratogenic in rats or rabbits.

A study using high-dose male rats from the initial 24-month study of toxicity and carcinogenicity provided evidence that the low vitamin K_3 level of the diet (< 0.3 ppm) was the cause of the haemorrhagic syndrome, as the prolonged blood coagulation time could be reversed by a vitamin K_3–supplemented diet (16 ppm). This conclusion was supported by the fact that no adverse effects on blood coagulation were observed in the multigeneration studies using diets with an adequate level of vitamin K (vitamin K_1: 0.65 ppm; vitamin K_3: 0.8 ppm).

In a 28-day study in male rats using a vitamin K_3–supplemented diet (16 ppm) and dietary concentrations of bixafen of 0, 2000, 4500 and 10 000 ppm (equal to 0, 162, 375 and 828 mg/kg bw per day), the NOAEL for effects of bixafen on blood coagulation parameters was 10 000 ppm (equal to 828 mg/kg bw per day), the highest dose tested.

Human data

In reports on manufacturing plant personnel, no adverse health effects were noted. Also, there were no reports of poisonings with bixafen.

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

Toxicological evaluation

The Meeting established an ADI for bixafen of 0–0.02 mg/kg bw, based on the NOAEL of 2 mg/kg bw per day for liver and thyroid effects observed at 12.1 mg/kg bw per day in the 24-month study of toxicity and carcinogenicity in male rats. A safety factor of 100 was applied.

The Meeting established an ARfD for bixafen of 0.2 mg/kg bw, based on the NOAEL of 20 mg/kg bw for decreased body weight gain and feed consumption observed in the first days of treatment at 75 mg/kg bw in a developmental toxicity study in rats. A safety factor of 100 was applied.

As the estimated exposures to M18, M20, M44, M45 and M47 are below the respective acute and chronic thresholds of toxicological concern for Cramer class III compounds, there is no concern for these metabolites. Bixafen-desmethyl has been tested in rodents through its formation from the parent compound and is therefore covered by the ADI for bixafen. For M25 and M26, their structural similarity to bixafen-desmethyl is such that the Meeting concluded that they would also be covered by the ADI for bixafen.

A toxicological monograph was prepared.

Levels relevant to risk assessment of bixafen

Species	Study	Effect	NOAEL	LOAEL
Mouse	Eighteen-month study of toxicity and carcinogenicity[a]	Toxicity	50 ppm, equal to 6.7 mg/kg bw per day	150 ppm, equal to 20.4 mg/kg bw per day
		Carcinogenicity	500 ppm, equal to 69 mg/kg bw per day[b]	—
Rat	Two-year studies of toxicity and carcinogenicity[a,c]	Toxicity	50 ppm, equal to 2.0 mg/kg bw per day	300 ppm, equal to 12.1 mg/kg bw per day
		Carcinogenicity	2000 ppm, equal to 80.5 mg/kg bw per day[b]	—
	Two-generation study of reproductive toxicity[a]	Reproductive toxicity	2500 ppm, equal to 169.2 mg/kg bw per day[b]	—
		Parental toxicity	400 ppm, equal to 26.4 mg/kg bw per day	2500 ppm, equal to 169.2 mg/kg bw per day
		Offspring toxicity	400 ppm, equal to 26.4 mg/kg bw per day	2500 ppm, equal to 169.2 mg/kg bw per day
	Developmental toxicity study[d]	Maternal toxicity	20 mg/kg bw per day	75 mg/kg bw per day
		Embryo and fetal toxicity	20 mg/kg bw per day	75 mg/kg bw per day
Rabbit	Developmental toxicity study[d]	Maternal toxicity	25 mg/kg bw per day	100 mg/kg bw per day
		Embryo and fetal toxicity	25 mg/kg bw per day	100 mg/kg bw per day
Dog	One-year study of toxicity[d]	Toxicity	10 mg/kg bw per day	100 mg/kg bw per day

[a] Dietary administration.

[b] Highest dose tested.

[c] Two studies combined.

[d] Gavage administration.

Estimate of acceptable daily intake

0–0.02 mg/kg bw

Estimate of acute reference dose

0.2 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 bixafen

Absorption, distribution, excretion and metabolism in mammals	
Rate and extent of oral absorption	Rapid; ≥ 83%
Dermal absorption	No data
Distribution	Widely distributed; highest concentrations in liver and kidneys
Potential for accumulation	None
Rate and extent of excretion	≥ 93% within 72 h (≥ 91% in faeces, including up to 83% in bile; 1–3% in urine)
Metabolism in animals	Extensive (> 30 metabolites identified); demethylation, hydroxylation of parent and bixafen-desmethyl; conjugation with glucuronic acid and glutathione; cleavage of the amide bridge of bixafen as a minor metabolic reaction
Toxicologically significant compounds in animals, plants and the environment	Bixafen
Acute toxicity	
Rat, LD_{50}, oral	> 2000 mg/kg bw
Rat, LD_{50}, dermal	> 2000 mg/kg bw
Rat, LC_{50}, inhalation	> 5.38 mg/L (4 h, nose-only exposure)
Rabbit, dermal irritation	Not irritating
Rabbit, ocular irritation	Not irritating
Guinea-pig, dermal sensitization	Not sensitizing (local lymph node assay)
Short-term studies of toxicity	
Target/critical effect	Liver in mice, rats and dogs; thyroid in rats
Lowest relevant oral NOAEL	8.5 mg/kg bw per day (mouse)
Lowest relevant dermal NOAEL	No data
Lowest relevant inhalation NOAEC	No data
Long-term studies of toxicity and carcinogenicity	
Target/critical effect	Liver and thyroid in mice and rats
Lowest relevant NOAEL	2.0 mg/kg bw per day (rat)

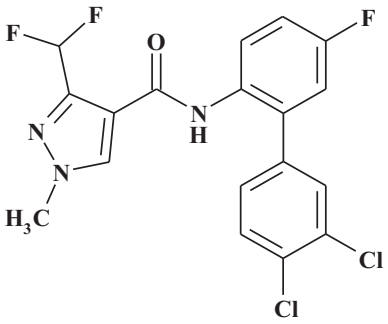
Carcinogenicity	Not carcinogenic
Genotoxicity	
	Not genotoxic
Reproductive toxicity	
Target/critical effect	No reproductive toxicity
Lowest relevant parental NOAEL	26.4 mg/kg bw per day
Lowest relevant offspring NOAEL	26.4 mg/kg bw per day
Lowest relevant reproductive NOAEL	169.2 mg/kg bw per day, the highest dose tested
Developmental toxicity	
Target/critical effect	Reduced fetal weights, visceral or skeletal variations at maternally toxic dose (rats and rabbits)
Lowest relevant maternal NOAEL	20 mg/kg bw per day (rat)
Lowest relevant embryo/fetal NOAEL	20 mg/kg bw per day (rat)
Neurotoxicity	
Acute and subchronic neurotoxicity	No specific data, but no indications from repeated-dose studies
Other toxicological studies	
Study on blood coagulation	Vitamin K_3–deficient diet contributed to prolonged blood coagulation times and haemorrhagic effects in male rats
Mechanistic study on thyroid effects	Induction of phase I and II hepatic enzymes was likely the cause of the observed thyroid hormone changes
Medical data	
	No adverse health effects reported in manufacturing plant personnel

Summary

	Value	Study	Safety factor
ADI	0–0.02 mg/kg bw	Two-year study of toxicity and carcinogenicity in rats	100
ARfD	0.2 mg/kg bw	Developmental toxicity study in rats (maternal toxicity)	100

RESIDUE AND ANALYTICAL ASPECTS

Bixafen (ISO common name) is a pyrazole-carboxamide fungicide used to control diseases on rape plants and cereals. Bixafen inhibits fungal respiration by binding to mitochondrial respiratory complex II. It was considered for the first time by the 2013 JMPR for toxicology and residues.

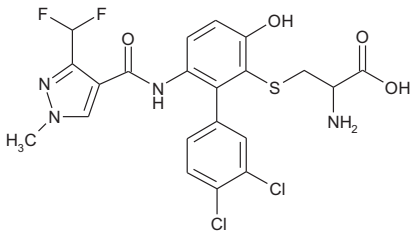


The IUPAC name of bixafen is N-(3',4'-dichloro-5-fluorobiphenyl-2-yl)-3-(difluoromethyl)-1-methyl-1H-pyrazole-4-carboxamide and the CA name is 1H-pyrazole-4-carboxamide, N-(3',4'-dichloro-5-fluoro[1,1'-biphenyl]-2-yl)-3-(difluoromethyl)-1-methyl-.

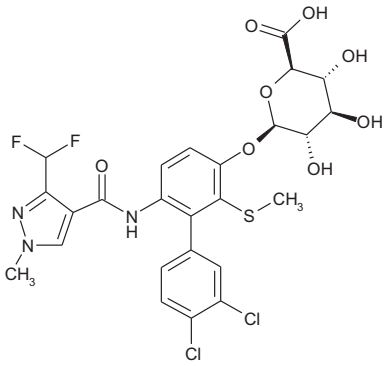
Bixafen labelled either in the pyrazole- or dichlorophenyl-moiety was used in the metabolism and environmental fate studies.

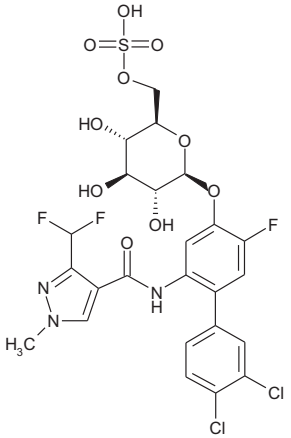
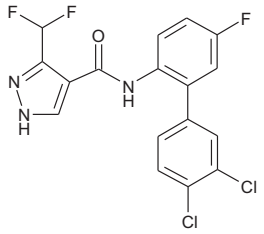
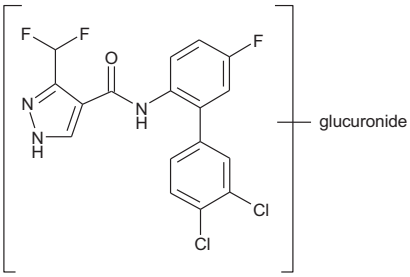
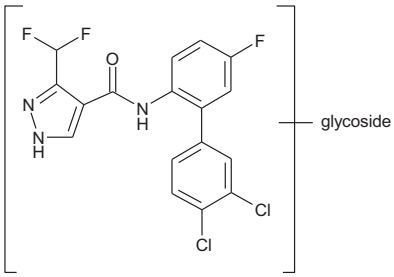
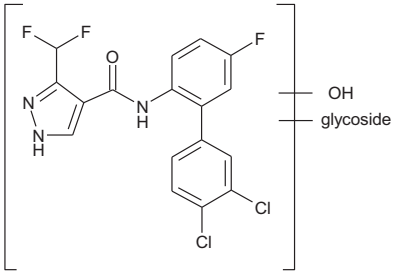
The following abbreviations are used for the metabolites discussed below:

M14 S-[3',4'-dichloro-6-({[3-(difluoromethyl)-1-methyl-1H-pyrazol-4-yl]carbonyl}amino)-3-hydroxybiphenyl-2-yl]cysteine (IUPAC)

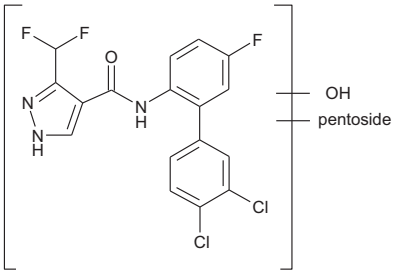


M18 3',4'-dichloro-6-({[3-(difluoromethyl)-1-methyl-1H-pyrazol-4-yl]carbonyl}amino)-2-(methylthio)biphenyl-3-yl beta-L-glucopyranosiduronic acid (IUPAC)

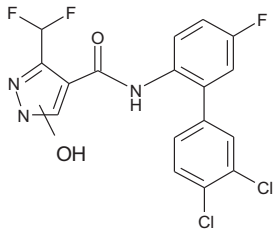


M20	not nomenclature possible - position of hydroxy group not specified	 or isomer
M21 (bixafen-desmethyl)	N-(3',4'-dichloro-5-fluorobiphenyl-2-yl)-3-(difluoromethyl)-1H-pyrazole-4-carboxamide (IUPAC)	
M23	not nomenclature possible - structure not specified	
M24	not nomenclature possible - structure not specified	
M25	not nomenclature possible - structure not specified	

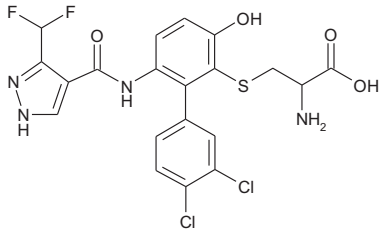
M26 not nomenclature possible - structure not specified



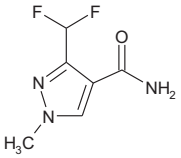
M27 not nomenclature possible - structure not specified



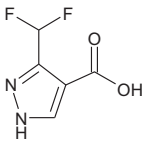
M37 S-[3',4'-dichloro-6-({[3-(difluoromethyl)-1H-pyrazol-4-yl]carbonyl}amino)-3-hydroxybiphenyl-2-yl]cysteine (IUPAC)



M43 3-(difluoromethyl)-1-methyl-1H-pyrazole-4-carboxamide (IUPAC)

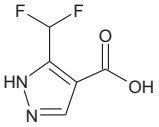


M44 3-(difluoromethyl)-1H-pyrazole-4-carboxylic acid (IUPAC)



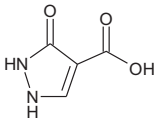
proposal for tautomer 1

M45 5-(difluoromethyl)-1H-pyrazole-4-carboxylic acid (IUPAC)



proposal for tautomer 2

M47 3-hydroxy-1H-pyrazole-4-carboxylic acid (IUPAC)



Animal metabolism

Information was available on the metabolism of bixafen in laboratory animals, lactating goats and laying hens.

In rats given (dichlorophenyl-U-^{14}C)-labelled bixafen orally by gavage, absorption was rapid and accounted for at least 83% of the total administered radioactivity after a single low dose (2 mg/kg bw). The maximum plasma concentrations of radioactivity were reached approximately 2–4 and 8 hours after administration of the low and high doses (2 and 50 mg/kg bw), respectively. Radioactivity was widely distributed throughout the body. Elimination of the radioactivity was mainly via faeces (≥ 91%), whereas elimination via urine accounted for 1–3% of the administered dose. In bile duct–cannulated rats, extensive biliary excretion (up to 83%) was demonstrated. Elimination of the radioactivity from the body was rapid, with a half-life in plasma of 8–9 hours and a mean residence time of 13–19 hours (for the low dose). Residues in tissues at 72 hours after a single oral dose as well as after repeated oral dosing accounted for 0.1–3% of the administered radioactivity, with liver and kidneys containing the highest concentrations of residues.

Metabolism of bixafen in rats was extensive, and more than 30 metabolites were identified. The main metabolic routes included demethylation, hydroxylation of the parent and bixafen-desmethyl, and conjugation with glucuronic acid or glutathione. A minor metabolic reaction was the cleavage of the amide bridge of bixafen.

Two studies on metabolism in lactating goats were available. The goats received five daily doses of [pyrazole-^{14}C]-bixafen or [dichlorophenyl-^{14}C]-bixafen at rates equivalent to 35 ppm and 46 ppm in the diet, respectively. The animals were sacrificed approximately 24 hours after the last dose. In both studies approximately 1.3% of the total dose was recovered from milk or tissues of the animals. Most of the radioactivity was excreted via faeces (74–82% AR) and urine (1.8–5.4% AR).

The metabolic pattern in both studies was comparable. In milk (TRR: 0.064–0.17 mg eq/kg), muscle (TRR: 0.047–0.057 mg eq/kg) and fat (TRR: 0.47–0.61 mg eq/kg) unchanged bixafen was the major residue, representing 74–77%, 56–66% and 89% of the total radioactivity, respectively. M21 (bixafen-desmethyl) was the only major metabolite being present at 16–18% of the TRR in milk, 34–43% in muscle and 10–11% in fat.

For kidney (TRR: 0.14–0.2 mg eq/kg) and liver (TRR: 0.74–1.2 mg eq/kg) parent bixafen was also a major residue, representing 44–46% of the total radioactivity in kidney and 18–23% in liver. Significant metabolites identified were M21 (bixafen-desmethyl), representing 37–38% of the TRR in kidney and 19–21% TRR in liver, followed by the two M23 isomers counting for a total of 9.3–15% of the TRR in kidney and 14–19% in liver.

For laying hens groups of hens received daily doses of [pyrazole-^{14}C]-bixafen or [dichlorophenyl-^{14}C]-bixafen at rates equivalent to 26 ppm and 32 ppm in the diet for 14 consecutive days. The animals were sacrificed ca. 24 hours after the last dose. Approximately 1.5% 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 (88–93% AR). Total radioactive residues were 0.53–0.9 mg eq/kg in eggs, 0.032–0.037 mg eq/kg in muscle, 0.23–0.38 mg eq/kg in fat and 0.64–0.81 mg eq/kg in liver.

Parent bixafen was a major residue in eggs and all tissues except liver, representing 51–69% of the TRR in eggs, 23–41% in muscle and 80% in fat. In hens liver, only minor amounts of bixafen were detected (4.5–6.7% TRR).

M21 (bixafen-desmethyl) was the only major metabolite found in poultry tissues and eggs. It was found at levels of 26–39% of the TRR in eggs, 35–51% in muscle, 19–20% in fat and 24–26% in liver. In liver, M14, M18, M24, M25, M26, M27 and M37 were identified as minor metabolites, representing 1.0–8.8% of the TRR (0.007–0.067 mg eq/kg) each.

In summary bixafen is the major residue in most tissues, milk and eggs. It is moderately metabolized in goats and hens mainly resulting in M21 (bixafen-desmethyl). All major metabolites

were also identified in the rat. The metabolites M18, M25 and M26, mainly found in poultry liver, were not directly identified in the rat.

Plant metabolism

The Meeting received plant metabolism studies for bixafen following foliar application of either [pyrazole-^{14}C]-bixafen or [dichlorophenyl-^{14}C]-bixafen to soya beans or wheat.

Soya beans were independently treated with both bixafen-labels with three foliar applications of 0.06 kg ai/ha each when the first flowers opened (BBCH 60), at the end of flowering (BBCH 69) and finally when approximately 80% of the pods were ripe (BBCH 88). Samples were collected containing forage (5 days after 2nd application), hay (29 days after 2nd application), straw and seed (26 days after the 3rd application). Total radioactive residues were 4.0–5.3 mg eq/kg for forage, 2.8–4.0 mg eq/kg for hay, 9.5–13 mg eq/kg for straw and 0.005–0.024 mg eq/kg for seeds.

In all plant parts directly affected by the spray solution, unchanged bixafen was the major residue representing 96–98% of the TRR in forage, 92% in hay and 90–92% in straw. The only other metabolite identified was M21 (bixafen-desmethyl), present at 0.5–2.6% of the TRR.

For soya bean seeds, only samples following application of the pyrazole-label contained sufficient total radioactive residues for further investigation. Bixafen was the major residue with 30% of the TRR. Metabolites identified were M44 and M45 (19% TRR, 0.004 mg eq/kg) and M47 (12% TRR, 0.003 mg eq/kg). M21 (bixafen-desmethyl) was not identified in soya bean seeds.

Wheat was independently treated with both bixafen-labels using one foliar application of 0.125 kg ai/ha at the end of tillering / beginning of stem elongation (BBCH 29–31) followed by a second spraying with 0.15 kg ai/ha at the end of flowering (BBCH 69). Forage was harvested 9 days after the 1st application, hay 9 days after the 2nd application and straw and grain at maturity (50 days after the 2nd application). Total radioactive residues were 1.6–1.7 mg eq/kg for forage, 6.6–7.6 mg eq/kg for hay, 23–24 mg eq/kg for straw and 0.16–0.23 mg eq/kg for seeds.

In all samples unchanged bixafen was the major residue, representing > 90% of the TRR. The only other metabolite identified was M21 (bixafen-desmethyl) at 0.8–2.4% of the TRR.

In summary the plant metabolism of bixafen in the plants investigated is very limited. In plant parts directly affected by the spray solution, unchanged bixafen was the only residue significant. M21 (bixafen-desmethyl) was present at low levels up to 2.6% of the TRR.

In soya bean seeds, which were protected by the pod during treatment, bixafen was present at lower concentrations of 0.007 mg eq/kg (30% TRR). Major metabolites in soya bean seeds were M44, M45 and M47, probably taken up from the soil and distributed systemically, however at low levels not exceeding 0.004 mg eq/kg. All three of these metabolites were not identified in the rat.

Environmental fate in soil

The Meeting received information on the fate of bixafen after aerobic degradation in soil and after photolysis on the soil surface. In addition, the Meeting received information on the uptake and metabolism of bixafen soil residues by rotational crops, its dissipation under field conditions and long-term accumulation in soil.

In soil photolysis studies degradation of bixafen was not observed.

In aerobic soil metabolism studies under laboratory conditions bixafen was highly persistent with 80–90% remaining after 120 days. The only metabolite found was M44 (maximum 2.9% of AR), while the rest of the radioactivity remained unextracted or was recovered as $^{14}CO_2$. DT_{50} values could not be calculated due to the minimal degradation observed within 120 days.

In soil samples from the confined rotational crop metabolism studies mentioned below, bixafen was also slowly degraded. The only metabolite found was identified as M21 (bixafen-

desmethyl), slowly increasing from 0.5% (day 30) to 2.3% TRR at the end of the study (day 418). M44 was not detected.

In summary it can concluded that bixafen is persistent in soil, being degraded to a very minor extent.

Confined rotational crop studies on Swiss chard, turnips and wheat were conducted at rates equivalent to 0.79 kg ai/ha (pyrazole-label) and 0.85 kg ai/ha (dichlorophenyl-label). In plant commodities bixafen (11–78% TRR) and M21 (bixafen-desmethyl, 3–73% TRR) were the major residue components found for both labels. Quantified concentrations for the sum of both analytes were 0.016–0.024 mg eq/kg for Swiss chard, 0.005–0.035 mg eq/kg in turnip roots and tops and 0.011–0.041 mg eq/kg, 0.106–0.18 mg eq/kg and 0.152–0.462 mg eq/kg for wheat forage, hay and straw, respectively. In grain TRR levels were too low for identification (0.001–< 0.01 mg eq/kg).

Following application of the pyrazole-labelled active substance, the cleavage products M43 (3–15% TRR), M44 (0.3–37% TRR) and M45 (2–23% TRR) were identified as major metabolites. Concentrations were between 0.001–0.015 mg eq/kg each.

Following treatment with the dichlorophenyl-label, M20 was found in Swiss chard only at levels of 25–38% of the TRR (0.007–0.016 mg eq/kg).

The residue concentrations of bixafen and M21 in plants declined moderately in animal feed commodities while in food commodities only a slow decline of the residue was observed over the three crop rotations investigated. In all commodities investigated, except for wheat grain, detectable residues above the LOQ of 0.01 mg/kg were found for bixafen.

Field rotational crop studies were conducted at four locations in Europe. Bixafen was either applied to bare soil to simulate crop failure (0.28 kg ai/ha) or to barley as a primary crop (0.16 kg ai/ha at BBCH 56 plus 0.125 kg ai/ha at BBCH 69). Turnip/carrots, lettuce and wheat were planted as rotational crops at three rotations. Samples analysed for residues of bixafen and M21 were below the LOQ of 0.01 mg/kg for each analyte, except for one sample of wheat straw (M21: 0.02 mg/kg) and lettuce at a pre-mature growth stage (BBCH 46; bixafen: 0.05 mg/kg).

Field dissipation studies at six locations in Europe (four in the north, two in the south) confirmed the slow degradation of bixafen in soil observed in the aerobic metabolism studies. Within the first 100 days, a significant degradation of the residue concentration in soil was observed, leaving 42–63% of the initial concentrations. However, the decline after this period up to 730 days was minimal, leaving 17–47% of the initial concentration. M21 was not found above the LOQ of the analytical method.

The Meeting observed that the degradation of bixafen in soil follows a bi-phasic kinetics, starting with a fast decline within the first 100 days. After that initial interval, bixafen is highly persistent in soil, accumulating with subsequent treatments over multiple years.

In a long-term soil accumulation study under field conditions residues of bixafen and M21 (bixafen-desmethyl) in soil were investigated involving five and seven years of annual treatment with 0.14 kg ai/ha to the ground. In the first location in France a plateau for the bixafen concentration in soil was reached after five years, resulting in concentrations of up to 0.18 mg per kg soil. In Germany, the study was terminated after 7 years, due to technical reasons, without reaching a plateau, showing a bixafen peak concentration of 0.35 mg per kg soil. Most of the residue (> 95%) was present as unchanged parent substance located in the initial 10 cm soil layer. Based on an average density of 1.5 g/cm³ for soil these concentrations are equivalent to single application rates to the bare soil of 0.27 kg ai/ha in the French trial and 0.53 kg ai/ha in the German trial.

The Meeting concluded that bixafen residues accumulate in soil after annual treatments. Under consideration of the highest annual application rate reported in the authorised GAPs of 0.25 kg ai/ha, soil residue concentrations equivalent to single application rates to bare soil of 0.9 kg ai/ha could be reached.

In summary the Meeting concluded that bixafen is persistent in soil, accumulating after subsequent years of annual treatment. Confined rotational crop studies indicate a potential uptake of residues for bixafen and M21 (bixafen-desmethyl) into plant commodities. The Meeting also recognized that field rotational crop studies involved soil treatment rates not addressing the soil concentrations expected after subsequent annual treatment.

Methods of residue analysis

The Meeting received analytical methods for the analysis of bixafen and M21 (bixafen-desmethyl) in plant and animal matrices. The basic principle employs extraction by homogenisation with acetonitrile/water (4/1, v/v) or n-hexane with acetonitrile partitioning for fatty samples. The extracts were cleaned with filtration and C18 solid-phase extraction. Residues are determined by liquid chromatography (LC) in combination with tandem mass spectroscopy (MS/MS). Mass-transitions are m/z 414→394 (m/z 414→266 for confirmation) for bixafen and m/z 398→378 (m/z 398→358 for confirmation) for M21 (bixafen-desmethyl). The methods submitted are suitable for measuring residues of bixafen and M21 in plant and animal commodities with a LOQ of 0.01 mg/kg for each analyte.

The extraction efficiency with acetonitrile/water (4/1, v/v) was tested for wheat (forage, grain straw) obtained from plant metabolism and confined rotational crop studies. Extraction rates were of > 90% for primary treated commodities and 68–73% (corresponding to 72–99% of the TTR) for commodities from rotational crops.

For the application of multi-residue methods the DFG S-19 was tested, but found to be unsuitable for analysing bixafen or M21 in plant matrices.

Stability of residues in stored analytical samples

The Meeting received information on the storage stability of bixafen and M21 (bixafen-desmethyl) in plant matrices. In wheat grain, wheat straw, wheat green material, lettuce head, potato tuber, rape seed and in soil, no significant degradation of both analytes was observed within 24 months.

For animal matrices no storage stability data were provided. Samples in livestock metabolism or feeding studies were analysed within one month of sampling.

Definition of the residue

Livestock animal metabolism studies were conducted on laying hens (36–32 ppm) and lactating goats (35–46 ppm).

In goats parent bixafen and M21 (bixafen-desmethyl) were the major residue. Bixafen represented 74–77% TRR in milk, 56–66% TRR in muscle, 44–46% TRR in kidney, 18–23% TRR in liver and 89% TRR in fat. M21 was the major metabolite present at 16–18% TRR in milk, 34–43% TRR in muscle, 37–38% TRR in kidney, 19–21% TRR in liver and 10–11% TRR in fat. In kidney and liver the two isomers of M23 were found at 9–15% of the TRR in kidney (isomer 1: 2.8–4.3%; isomer 2: 6.5–10% TRR) and of 14–19% in liver (isomer 1: 8.6–13% TRR; isomer 2: 5.2–5.8% TRR).

In laying hens again bixafen was the major residue in eggs and all tissues except liver, representing 51–69% TRR in eggs, 23–41% in muscle and 80% in fat. In liver only minor amounts of bixafen were detected (4.5–6.7% of the TRR). M21 (bixafen-desmethyl) was the major metabolite found in poultry tissues and eggs. It accounted for 26–39% of the TRR in eggs, 35–51% in muscle, 19–20% in fat and 24–26% in liver. In liver, M14, M18, M24, M25, M26, M27 and M37 were identified as minor metabolites, representing 1.0–8.8% of the TRR (0.007–0.067 mg eq/kg) each. Of these, M18, M25 and M26 were not identified in the rat, however the exposure of M18 was below the respective acute and chronic TTCs for Cramer class III while M25 and M26 have structural similarity

to bixafen-desmethyl and are covered by the ADI for bixafen. As a consequence no consideration of dietary intake is required.

M21 (bixafen-desmethyl) was identified as the major residue in rat studies, suggesting that it is covered by toxicological reference values for parent bixafen. The Meeting concluded that parent bixafen and M21 (bixafen-desmethyl) are suitable marker compounds in animal commodities and should be included into the residue definition for compliance with MRLs and for the estimation of the dietary intake. Analytical methods are capable of measuring both analytes.

In livestock feeding studies the distribution of bixafen and M21 between skim milk/cream and egg white/egg yolk was investigated. The average ratio for cream/skim milk was > 93 for bixafen and 39 for M21. Egg yolk concentrations of bixafen were three times higher than in egg white while M21 showed ratios of 12–20. For the parent substance a log P_{ow} of 3.3 was measured.

The data for milk and eggs suggests that bixafen and M21 partition in the fat portion. In addition, residues in fat tissues were about ten times higher when compared to muscle. The Meeting decided that residues of bixafen are fat-soluble.

The fate of bixafen in plants was investigated following foliar application to soya beans and wheat. In all samples unchanged bixafen was the major residue, normally representing at least 90% of the TRR. M21 was present at very low levels, not exceeding 3% of the TRR. In soya bean seeds, which were not directly exposed to the spray solution due to the pods, only 30% of the TRR (0.007 mg eq/kg) was present as bixafen. Further major metabolites in soya bean seeds were identified as the tautomers M44 and M45 (19% TRR, 0.004 mg eq/kg) and M47 (12% TRR, 0.003 mg eq/kg).

In confined rotational crop studies, plant commodities Swiss chard, wheat and turnips contained concentrations of radioactive residues as high as 0.49 mg eq/kg, in wheat straw. Bixafen (11–78% TRR) and M21 (bixafen-desmethyl, 3–73% TRR) were the major compounds identified. In addition, M43 (3–15% TRR), M44 (0.3–37% TRR) and M45 (2–23% TRR) were identified as major metabolites in all rotational crops. M20 was only found in Swiss chard (25–38% TRR, 0.007–0.016 mg eq/kg). Wheat grain did not contain TRR levels allowing further identification (0.001–< 0.01 mg eq/kg).

The Meeting concluded that parent bixafen is a suitable maker for compliance with MRLs in all plant commodities (primary treated or rotational). For the estimation of the dietary intake M21 was insignificant in wheat and soya beans directly treated, but was identified in high relative amounts in rotational crops. Therefore, the Meeting decided to include M21 (bixafen-desmethyl) into the residue definition for dietary intake with the parent substance. The metabolites M20, M44, M45 and M47, mainly found in rotational crops, were not identified in the rat. However, the estimated exposure levels based on the confined rotational crop study are below the respective acute and chronic TTCs for Cramer class III. As a result, no consideration is required for dietary intake.

Analytical methods are capable of measuring bixafen and M21 (bixafen-desmethyl) in plant matrices.

Definition of the residue for compliance with MRL for plant commodities: *bixafen*

Definition of the residue for compliance with MRL for animal commodities and (for the estimation of dietary intake) for plant and animal commodities: *sum of bixafen and N-(3',4'-dichloro-5-fluorobiphenyl-2-yl)-3-(difluoromethyl)-1H-pyrazole-4-carboxamide (bixafen-desmethyl), expressed as bixafen*

The residue is fat-soluble.

Results of supervised residue trials on crops

The Meeting received supervised European trial data for applications of bixafen to rape seed, barley and wheat.

Residue values referred to as "total" describe the sum of bixafen and M21 (bixafen-desmethyl), expressed as bixafen.

The Meeting concluded that field rotational crop studies do not address residues in soil expected after subsequent annual application of bixafen. Confined rotational crop studies available are not considered representative of field conditions. In the absence of suitable data, residue concentrations in plant commodities taken up from the soil by annual crops could not be estimated. Therefore, the Meeting decided, that no recommendations on maximum residue levels and median/highest residues could be made for bixafen in non-permanent crops.

Nevertheless, for the benefit of potential future assessments of bixafen uses, the Meeting decided to evaluate GAPs and residue data following direct application.

Rape seed

Bixafen is registered in the UK for use on rape seed at rates of 2 × 0.075 kg ai/ha with a PHI of 56 days. Supervised field trials conducted in northern Europe, according to this GAP, were submitted.

For MRL compliance purposes residues of parent bixafen in rape seeds were (n=10): < 0.01(6), 0.01(3), 0.017 mg/kg.

For dietary intake purposes the total residues in rape seeds were (n=10): < 0.02(5), 0.02(4), 0.028 mg/kg.

Barley and oats

For barley and oats the maximum GAP in northern Europe was reported from the UK involving two foliar applications of up to 0.125 kg ai/ha each. The last application is conducted at BBCH 61 and the PHI is covered by the growth between treatment and harvest. Supervised field trials conducted in northern Europe according to this GAP were submitted.

For MRL compliance purposes residues of parent bixafen in barley grain in northern Europe were (n=10): 0.02, 0.04(3), 0.05, 0.07, 0.08, 0.09, 0.09, 0.1 mg/kg.

For dietary intake purposes the total residues in barley grain in northern Europe were (n=10): 0.03, 0.05(3), 0.06, 0.08, 0.1, 0.1, 0.11, 0.11 mg/kg.

In Southern Europe a GAP for barley and oats was reported from France with one application of 0.075 kg ai/ha up to BBCH 61 with a 35 day PHI. However, no corresponding residue data were submitted.

The Meeting decided to explore the use of global residue data as outlined in the 2011 JMPR Report (2.4) for the residue data originating from southern Europe against the GAP of the UK.

For MRL compliance purposes residues of parent bixafen in barley grain in southern Europe according to the UK GAP were (n=9): 0.03, 0.04, 0.04, 0.06, 0.06, 0.08, 0.1, 0.25, 0.34 mg/kg.

For dietary intake purposes the total residues in barley grain in southern Europe according to the UK GAP were (n=9): 0.04, 0.05, 0.05, 0.08, 0.08, 0.1, 0.11, 0.29, 0.38 mg/kg.

The Meeting decided to combine that data and evaluate all European supervised field trials against the UK GAP for barley:

For MRL compliance purposes residues of parent bixafen in barley grain in whole Europe (n=19): 0.02, 0.03, 0.04(5), 0.05, 0.06, 0.06, 0.07, 0.08, 0.08, 0.09, 0.09, 0.1, 0.1, 0.25 and 0.34 mg/kg.

For dietary intake purposes the total residues in barley grain in whole Europe were (n=19): 0.03, 0.04, 0.05(5), 0.06, 0.08(3), 0.1(3), 0.11(3), 0.29 and 0.38 mg/kg.

Wheat, rye, triticale and spelt

For wheat, rye and triticale the maximum GAP in Northern Europe was reported from the UK and involved two foliar applications of up to 0.125 kg ai/ha each. The last application is conducted at BBCH 69 and the PHI is covered by the growth between treatment and harvest. Supervised field trials conducted in Northern Europe according to this GAP were submitted.

For MRL compliance purposes residues of parent bixafen in wheat grain in northern Europe were (n=10): < 0.01(6), 0.01, 0.01, 0.03, 0.03 mg/kg.

For dietary intake purposes the total residues in wheat in northern Europe were (n=10): < 0.02(6), 0.02, 0.02, 0.04, 0.04 mg/kg.

In southern Europe a GAP for wheat, rye and triticale was reported from France with one application of 0.094 kg ai/ha up to BBCH 69 with a 35 day PHI. However, no corresponding residue data were submitted.

The Meeting decided to explore the use of global residue data as outlined in the 2011 JMPR Report (2.4) for residue data from southern Europe against UK GAP:

For MRL compliance purposes residues of parent bixafen in wheat grain in Southern Europe according to the UK GAP were (n=10): < 0.01(6), 0.01, 0.02, 0.02, 0.03 mg/kg.

For dietary intake purposes the total residues in wheat grain in southern Europe according to UK GAP were (n=10): < 0.02(6), 0.02, 0.03, 0.03, 0.04 mg/kg.

The Meeting decided to combine that data and evaluate all European supervised field trials against the UK GAP for wheat:

For monitoring purposes residues of parent bixafen in wheat grain in whole Europe (n=20): < 0.01(12), 0.01(3), 0.02, 0.02, 0.03, 0.03 and 0.03 mg/kg.

For dietary intake purposes the total residues in wheat grain in whole Europe were (n=20): < 0.02(12), 0.02(3), 0.03, 0.03, 0.04, 0.04 and 0.04 mg/kg.

Animal feeds

Oilseed rape, forage

The Meeting noted that the only authorisation submitted for bixafen in rape was from UK explicitly relating to oilseed rape. This GAP involves late treatment of the crop 56 days before harvest, which is normally beyond the common timeframe for utilization of oilseed rape as a forage crop, i.e., before winter and up to BBCH 39. This is supported by supervised field trials in northern Europe, where last applications were conducted at growth stages at the end of flowering or at early maturity.

The Meeting concluded that the reported GAP for bixafen is not relevant for the utilization of oilseed rape as an animal forage crop.

Barley, oats, rye, triticale and wheat – forage of cereals

GAPs for barley and oats in the UK are for a maximum of two foliar applications up to flowering (BBCH 61) with 0.125 kg ai/ha each. The PHI is covered by the interval between treatment and harvest (covered by growth stage).

For the calculation of the livestock animal dietary burden the total residues in barley forage (fresh) in northern Europe were (n=10): 2.1, 2.5, 2.6, 2.9, 3.5, 3.9, 4.0, 4.4, 4.5, 7.3 mg/kg.

In southern Europe a GAP for barley and oats was reported from France with one application of 0.075 kg ai/ha up to BBCH 61 with a 35 day PHI. However, no corresponding residue data were submitted.

The Meeting decided to explore the use of global residue data as outlined in the 2011 JMPR Report (2.4) for residue data from southern Europe against the UK GAP:

For the calculation of the livestock animal dietary burden the total residues in barley forage (fresh) in southern Europe were (n=9): 2.7, 3.0, 3.2, 3.4, 3.4, 3.7, 3.8, 4.3, 6.0 mg/kg.

The Meeting decided to combine that data and evaluate all European supervised field trials against the UK GAP for barley and oat forage:

For the calculation of the livestock animal dietary burden the total residues in barley forage (fresh) in whole Europe were (n=19): 2.1, 2.5, 2.6, 2.7, 2.9, 3.0, 3.2, 3.4, 3.4, 3.5, 3.7, 3.8, 3.9, 4.0, 4.3, 4.4, 4.5, 6.0, 7.3 mg/kg.

For wheat, rye and triticale the maximum GAP in northern Europe was reported for the UK involving two foliar applications of up to 0.125 kg ai/ha. The last application is at BBCH 69 with the PHI covered by growth between treatment and harvest. Supervised field trials conducted in northern Europe according to this GAP were submitted.

For the calculation of the livestock animal dietary burden the total residues in wheat forage (fresh) in northern Europe were (n=10): 1.5, 2.4, 2.8, 2.9, 3.1, 3.4, 3.8, 4.7, 4.8, 7.3 mg/kg.

In southern Europe a GAP for wheat, rye and triticale was reported from France with one application of 0.094 kg ai/ha up to BBCH 69 with a 35 day PHI. However, no corresponding residue data were submitted.

The Meeting decided to explore the use of global residue data as outlined in the 2011 JMPR Report (2.4) for residue data from southern Europe against the UK GAP.

For the calculation of the livestock animal dietary burden the total residues in wheat forage (fresh) in southern Europe were (n=10): 2.6, 2.7, 2.9, 3.0, 3.6, 3.9, 4.2, 4.5, 5.2, 5.5 mg/kg.

The Meeting decided to combine that data and evaluate all European supervised field trials against the UK GAP for wheat forage.

For the calculation of the livestock animal dietary burden the total residues in barley and wheat forage (fresh) in Europe were (n=20): 1.5, 2.4, 2.6, 2.7, 2.8, 2.9, 2.9, 3.0, 3.1, 3.4, 3.6, 3.8, 3.9, 4.2, 4.5, 4.7, 4.8, 5.2, 5.5, 7.3 mg/kg.

Barley, oats, rye, triticale and wheat – straw and fodder

GAPs for barley and oats in the UK are for a maximum of two foliar applications up to flowering (BBCH 61) with 0.125 kg ai/ha each. The PHI is covered by the interval between treatment and harvest (covered by growth stage).

For MRL compliance purposes residues of parent bixafen in barley straw (fresh) in northern Europe (n=10): 0.64, 0.7, 0.77, 0.86, 1.1, 1.1, 3.7, 4.8, 5.4, 10 mg/kg.

For the calculation of the livestock animal dietary burden the total residues in barley straw (fresh) in northern Europe were (n=10): 0.72, 0.74, 0.85, 1.0, 1.2, 1.2, 3.9, 5.2, 5.6, 11 mg/kg.

In southern Europe a GAP for barley and oats was reported from France with one application of 0.075 kg ai/ha up to BBCH 61 with a 35 day PHI. However, no corresponding residue data were submitted.

The Meeting decided to explore the use of global residue data as outlined in the 2011 JMPR Report (2.4) for residue data from Southern Europe against the UK GAP.

For MRL compliance purposes residues of parent bixafen in barley straw (fresh) in southern Europe (n=9): 0.46, 0.76, 1.2, 1.5, 1.9, 3.1, 5.2, 5.7, 6.2 mg/kg.

For the calculation of the livestock animal dietary burden the total residues in barley straw (fresh) in southern Europe were (n=9): 0.5, 1.0, 1.3, 1.6, 2.1, 3.3, 5.6, 6.1, 6.7 mg/kg.

Since both datasets are not significantly different (Mann-Whitney-U-testing), the Meeting decided to combine that data and evaluate all European supervised field trials against the UK GAP for barley and oat straw.

For MRL compliance purposes residues of parent bixafen in barley straw (fresh) in whole Europe (n=19): 0.46, 0.64, 0.7, 0.76, 0.77, 0.86, 1.1, 1.1, 1.2, 1.5, 1.9, 3.1, 3.7, 4.8, 5.2, 5.4, 5.7, 6.2 and 10 mg/kg.

For the calculation of the livestock animal dietary burden the total residues in barley straw (fresh) in whole Europe were (n=19): 0.5, 0.72, 0.74, 0.85, 1.0, 1.0, 1.2, 1.2, 1.3, 1.6, 2.1, 3.3, 3.9, 5.2, 5.6, 5.6, 6.1, 6.7, 11 mg/kg.

For wheat, rye and triticale the maximum GAP in Northern Europe was reported from the UK and involved two foliar applications of up to 0.125 kg ai/ha. The last application is at BBCH 69 and the PHI is covered by growth between treatment and harvest. Supervised field trials conducted in northern Europe according to this GAP were submitted.

For MRL compliance purposes residues of parent bixafen in wheat straw (fresh) in northern Europe (n=10): 0.52, 0.93, 0.95, 1.3, 1.8, 1.9, 3.6, 4.1, 8.4 and 10 mg/kg.

For the calculation of the livestock animal dietary burden the total residues in wheat straw (fresh) in northern Europe were (n=10): 0.78, 1.2, 1.3, 1.5, 2.1, 2.5, 3.9, 4.4, 9.6 and 11 mg/kg.

In southern Europe a GAP for wheat, rye and triticale was reported from France with one application of 0.094 kg ai/ha up to BBCH 69 with a 35 day PHI. However, no corresponding residue data were submitted.

The Meeting decided to explore the use of global residue data as outlined in the 2011 JMPR Report (2.4) for residue data from southern Europe against the UK GAP:

For MRL compliance purposes residues of parent bixafen in wheat straw (fresh) in southern Europe (n=10): 0.79, 1.4, 1.7, 1.8, 2.6, 3.2, 3.3, 3.6, 5.4 and 5.7 mg/kg.

For the calculation of the livestock animal dietary burden the total residues in wheat straw (fresh) in southern Europe were (n=10): 1.2, 1.9, 1.9, 2.2, 3.2, 3.7, 3.9, 4.1, 6.0 and 6.2 mg/kg.

The Meeting decided to combine that data and evaluate all European supervised field trials against the UK GAP for wheat, rye and triticale straw:

For MRL compliance purposes residues of parent bixafen in wheat straw (fresh) in whole Europe (n=20): 0.52, 0.79, 0.93, 0.95, 1.3, 1.4, 1.7, 1.8, 1.8, 1.9, 2.6, 3.2, 3.3, 3.6, 3.6, 4.1, 5.4, 5.7, 8.4 and 10 mg/kg.

For the calculation of the livestock animal dietary burden the total residues in wheat straw (fresh) in whole Europe were (n=20): 0.78, 1.2, 1.2, 1.3, 1.5, 1.9, 1.9, 2.1, 2.2, 2.5, 3.2, 3.7, 3.9, 3.9, 41, 4.4, 6.0, 6.2, 9.6 and 11 mg/kg.

Residues in rotational crops

Bixafen is highly persistent in soil, showing accumulation over subsequent years of treatment. In field rotational crop studies conducted at rates corresponding to the highest annual application rates registered, no significant residues were found in plant commodities. However, the long-term field accumulation study submitted suggests plateau residues in soil after up to seven years of annual treatment are equivalent to 2–3 times the soil residues expected after a single treatment at the registered maximum annual application rate. In confined rotational crop studies approximating this plateau level observed in soil, residues above the LOQ of 0.01 mg/kg were found for bixafen and M21 (bixafen-desmethyl) in all plant commodities investigated except for wheat grain.

The Meeting concluded that the accumulation of bixafen in soil results in residue concentrations in follow crops which are relevant for MRL compliance, dietary intake assessment

and the estimation of livestock dietary burden. However, the Meeting recognized that the available field rotational crop studies were underdosed compared to the soil concentrations following long-term use of bixafen, while confined rotational crop studies are not considered representative for field conditions.

The Meeting decided that further information on bixafen in rotational crops under field conditions are required involving application rates approximating the plateau levels in soil after subsequent years of treatment. The estimation of maximum residue levels and median or highest residues for annual crops is not possible without considering the contribution of residues taken up from soil and will be postponed to a future meeting when new data becomes available to assess the rotational crop situation.

Fate of residues during processing

The Meeting received information on the hydrolysis of radio-labelled bixafen as well as processing studies using unlabelled material on grown residues in oilseed rape, barley and wheat.

In a hydrolysis study using radio-labelled bixafen 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 no degradation was observed.

The Meeting concluded that no recommendations on bixafen residues in plant commodities can be made (see residues in rotational crops section) and therefore no processing factors are required. For an overview of the available information on the fate of bixafen during processing please refer to the 2013 Evaluation.

Residues in animal commodities

Farm animal feeding studies

The Meeting received feeding studies involving bixafen on lactating cows and laying hens.

Three groups of lactating cows were dosed daily at levels of 4, 12 and 40 ppm in the diet (0.15, 0.45 and 1.5 mg/kg bw) for 28 consecutive days. Milk was collected throughout the whole study and tissues were collected on day 29 within 24 hours of the last dose.

In milk highest mean total residues were 0.039 mg/kg for the 4 ppm group, 0.077 mg/kg for the 12 ppm group and 0.218 mg/kg for the 40 ppm group. Investigation of the distribution of the residue in cream gave a 9.9 fold higher concentration than in whole milk (15 between whole milk and milk fat).

Total residues in muscle for the 4, 12 and 40 ppm groups were 0.039–0.065 mg/kg (mean: 0.052 mg/kg), 0.081–0.26 mg/kg (mean: 0.162 mg/kg) and 0.63–1.0 mg/kg (mean: 0.82 mg/kg), respectively. In liver residues were 0.42–0.69 mg/kg (mean: 0.57 mg/kg) for the 4 ppm group, 1.2–1.7 mg/kg (mean: 1.4 mg/kg) for the 12 ppm group and 4.8–5.4 mg/kg (mean: 5.0 mg/kg) for the 40 ppm group. Kidney contained total residues of 0.1–0.15 mg/kg (mean: 0.14 mg/kg), 0.28–0.37 mg/kg (mean: 0.34 mg/kg) and 1.0–1.3 mg/kg (mean: 1.2 mg/kg) for the for the 4, 12 and 40 ppm group.

For fat three different tissues were analysed (perirenal, mesenteric and subcutaneous fat). Highest residues were found in perirenal fat with 0.14–0.21 mg/kg (mean: 0.18 mg/kg) for the 4 ppm group, 0.33–0.48 mg/kg (mean: 0.43 mg/kg) for the 12 ppm group and 0.8–1.9 mg/kg (mean: 1.4 mg/kg) for the 40 ppm group.

For laying hens three groups of animals were dosed with rates of 1.5, 4.5 and 15 ppm in the dry weight feed (0.1, 0.3 and 1.0 mg/kg bw) for 28 consecutive days. Eggs were collected throughout the whole study and tissues were collected on day 29 after the last dose.

In eggs total residues at the plateau phase were < 0.02-0.02 mg/kg (highest daily mean: 0.02 mg/kg) for the 1.5 ppm group and ranged between 0.05 to 0.07 mg/kg (highest daily mean: 0.063 mg/kg) for the 4.5 ppm and between 0.13 to 0.22 mg/kg (highest daily mean: 0.178 mg/kg) for the 15 ppm group.

In tissues no residues above the LOQ were found in muscle. Total residues in fat for the 1.5, 4.5 and 15 ppm groups were < 0.02–0.02 mg/kg (mean: 0.02 mg/kg), 0.05–0.06 mg/kg (mean: 0.057 mg/kg) and 0.06–0.09 mg/kg (mean: 0.07 mg/kg), respectively. In liver residues were < 0.02–0.02 mg/kg (mean: 0.02 mg/kg) for the 1.5 ppm group, 0.02–0.04 mg/kg (mean: 0.03 mg/kg) for the 4.5 ppm group and 0.03–0.05 mg/kg (mean: 0.04 mg/kg) for the 15 ppm group.

Estimated maximum and mean dietary burdens of livestock and animal commodities maximum residue levels

The Meeting noted that the uptake of bixafen and M21 (bixafen-desmethyl) from soil contributes significantly to the overall residues in annual crops. Based on the information available (see residues in rotational crops), no estimation on livestock animal dietary burdens and the corresponding residue levels in animal commodities can be made.

RECOMMENDATIONS

Definition of the residue for compliance with MRL for plant commodities: *bixafen*

Definition of the residue for compliance with MRL for animal commodities and (for the estimation of dietary intake) for plant and animal commodities: *sum of bixafen and N-(3',4'-dichloro-5-fluorobiphenyl-2-yl)-3-(difluoromethyl)-1H-pyrazole-4-carboxamide (bixafen-desmethyl), expressed as bixafen*

The residue is fat-soluble.

FURTHER WORK OR INFORMATION

The Meeting considered that the currently available information on residues in rotational crops was not sufficient to make recommendations on maximum residue levels in plant and animal commodities. For future recommendations field rotational crop studies approximating plateau concentrations of bixafen in soil are required.

DIETARY RISK ASSESSMENT

The Meeting concluded that the contribution of residues in plant commodities from soil uptake cannot be estimated based on the available data. Thus no estimations on median or highest residues in food commodities of plant and animal origin could be made, precluding both long and short-term dietary risk assessments for bixafen.

Consequently, the dietary risk assessment will be undertaken at a future meeting when the residues derived from both direct application and those taken up from the soil in a rotational crop situation can be evaluated together.

5.5 CHLORANTRANILIPROLE (230)

The insecticide chlorantraniliprole was evaluated by the JMPR 2008 (T, R) and 2010 (R). The ADI for chlorantraniliprole is 0–2 mg/kg bw and an ARfD was considered unnecessary. The compound was listed by the Forty-fourth Session of the CCPR (2012) for the evaluation by the 2013 JMPR of residue data for avocadoes, pomegranates, strawberries and other berries, soya bean, radish, carrots, globe artichokes, wheat, rape seed, sunflower seed, coffee and hops.

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

Results from supervised residue trials on crops

Berries and other small fruits

Currently, there is a Codex MRL of 1 mg/kg for chlorantraniliprole in Berries and other small fruits, which replaced the previous MRL of 1 mg/kg in grapes.

In the USA, GAP for chlorantraniliprole in strawberry is for up to 4 × 0.05–0.07 kg ai/ha (7 days interval; total 0.225 kg ai/ha/season). Eight trials conducted in the USA in 2011 at 2 × 0.11 kg ai/ha (7 days interval) gave residues at 1 day PHI of 0.18, 0.21, 0.22, 0.23, 0.24 (2), 0.40 and 0.68 mg/kg. Eight indoor trials were conducted in southern Europe, where there is no approved use.

Residues of chlorantraniliprole in grapes from 17 trials in Canada and the USA evaluated by the 2008 JMPR complying with GAP of the USA (3 × 0.07–0.11 kg ai/ha and 14 days PHI) were 0.02, 0.04 (3), 0.08, 0.09 (2), 0.11, 0.12, 0.18, 0.20, 0.26, 0.32, 0.34, 0.46, 0.48 and 0.52 mg/kg.

In the USA and Canada, GAP in bushberries (include cranberry and blueberry) is 3 × 0.07–0.11 kg ai/ha and 1 day PHI, total 0.

225 kg ai/ha/season). Seventeen trials were conducted in Canada and USA in cranberry and blueberry using 2 applications of the maximum GAP rate, with residues at 1 day PHI of 0.11, 0.12 (2), 0.13 (2), 0.16, 0.18 (2), 0.21 (2), 0.23, 0.24, 0.29, 0.32, 0.46, 0.75 and 0.84 mg/kg.

Data evaluated by the 2010 JMPR on residues of chlorantraniliprole in caneberries (raspberries and blackberries) from eight trials in Canada and the USA complying with GAP of the USA were: 0.05, 0.09 (2), 0.24, 0.44, 0.48 (2) and 0.51 mg/kg

The Meeting confirms its previous recommendation of a maximum residue level of 1 mg/kg for chlorantraniliprole in berries and other small fruits.

Avocado

The GAP of chlorantraniliprole in avocado in New Zealand is 2 × 0.09 kg ai/ha (21 days interval) and a 14 day PHI. Two trials conducted in the country according to GAP gave residues in fruit of 0.03 and 0.08 mg/kg. Six other trials conducted at higher or lower GAP gave residues ranging from 0.07 to 0.31 mg/kg at 14 days DAT.

As only two trials were conducted according to GAP, the Meeting could not recommend a maximum residue level for chlorantraniliprole in avocado.

Pomegranate

The GAP of chlorantraniliprole in pomegranate in USA is 3 × 0.07–0.11 kg ai/ha (7 days interval; max. 0.2 kg ai/ha/season) and a 1 day PHI. Five trials conducted in the country according to GAP gave residues of 0.09, 0.10 (2) and 0.12 (2) mg/kg.

The Meeting recommended a maximum residue level of 0.4 mg/kg and a STMR of 0.10 mg/kg for chlorantraniliprole in pomegranate.

Radish tops

Currently, there is a Codex MRL of 20 mg/kg for chlorantraniliprole in leafy vegetables.

In the USA, chlorantraniliprole is registered in root and tuber vegetables at a maximum rate of 4 × 0.07 kg ai/ha (3 day interval; max of 0.22 kg ai/ha/season) and a 1 day PHI. In six trials conducted in radish at 2 × 0.11 kg ai/ha gave residues in radish tops at a 1 day PHI of 3.9, 7.7, 10, 11, 19 and 22 mg/kg.

The Meeting recommended a maximum residue level of 40 mg/kg and a STMR of 10.5 mg/kg for chlorantraniliprole in radish leaves (including radish tops).

The Meeting agreed to withdraw its previous recommendation of 20 mg/kg for leafy vegetables for 20 mg/kg in leafy vegetables, except radish leaves.

Legume vegetables

In Italy, chlorantraniliprole is registered in beans at up to 2 × 0.04 kg ai/ha with a 3 day PHI. In five trials conducted in France, Italy and Spain in 2008/2009, according to this GAP, residues in fresh bean pods with seeds were 0.15 0.16, 0.40 (2) and 0.41 mg/kg. Five residue trials conducted in southern Europe according to the Italian GAP and submitted to the 2010 JMPR gave residues in fresh pods with seeds of 0.08, 0.09, 0.12, 0.16 and 0.25 mg/kg.

Trials conducted in southern Europe according to GAP (n=9) gave residues in bean pods with seeds of 0.08 (2), 0.12, 0.15, 0.16 (2), 0.40 (2) and 0.41 mg/kg.

In USA, the rate for legume vegetables is up to 4 × 0.07 kg ai/ha (max. of 0.225 kg ai/ha/season) and a 1 day PHI. In nine trials conducted in the USA and Canada (2008) at 2 × 0.11 kg ai/ha, residues in bean pods with seeds were: < 0.01, 0.10, 0.12 (3), 0.14 (2), 0.16 and 0.41 mg/kg.

In Australia, GAP for legume vegetable is 3 × 0.02 kg ai/ha and a 1 day PHI. In two trials conducted according to GAP, residues in bean pods with seeds were 0.08 (2) mg/kg.

Based on the European trials, the Meeting recommended a maximum residue level of 0.8 mg/kg and a STMR of 0.16 mg/kg for chlorantraniliprole in beans, except broad bean and soya bean (green pods and immature seeds).

In four trials conducted in peas in the USA and Canada according to GAP, residues in pea pods with seeds were 0.45, 0.48, 0.61 and 0.64 mg/kg.

In three trials conducted in Australia according to the Australian GAP for legume vegetables (3 × 0.02 kg ai/ha, 1 day PHI), residues in pea pods with seeds were 0.04, 0.06 and 0.47 mg/kg.

Based on the US and Canadian trials, and with the support of the Australian trials, the Meeting recommended a maximum residue level of 2 mg/kg and a STMR of 0.545 mg/kg for chlorantraniliprole in Peas (pods and succulent = immature seeds).

In six trials conducted in the USA and Canada, according to GAP, residues in pea seed were 0.01, 0.02 (2) and 0.03 (3) mg/kg. In two trials conducted in Australia according to GAP, residues in pea seed were < 0.01 (2) mg/kg.

Based on trials conducted in Canada and the USA, and with the support of the Australian trials, the Meeting recommends a maximum residue level of 0.05 mg/kg and a STMR of 0.025 mg/kg for chlorantraniliprole in peas, shelled.

Soya bean, dry

The GAP chlorantraniliprole in soya bean in Brazil is 2 × 0.01 kg ai/ha, and a PHI of 21 days. Four trials conducted in 2010 according to GAP gave residues of < 0.01 mg/kg (4).

Four trials submitted to the 2010 JMPR used a furrow application (0.1 kg ai/ha) followed by two applications at the GAP rate gave residues at 21 days PHI of 0.10, 0.11 (2) and 0.12 mg/kg.

As only four trials according to GAP were submitted, the Meeting could not recommend a maximum residue level for chlorantraniliprole in soya beans.

Root and tuber vegetables

The current Codex MRL for chlorantraniliprole in Root and tuber vegetables is 0.02 mg/kg, following the recommendation made by the 2008 JMPR based on rotation crop data (0.01 mg/kg on radish root) and foliar trials on potatoes (< 0.01 mg/kg, n=27).

In the USA, chlorantraniliprole is registered in Root and tuber vegetables at a maximum rate of 4 × 0.07 kg ai/ha (3 days interval; max of 0.22 kg ai/ha/season) and a 1 day PHI. Six trials conducted in radish at 2 × 0.11 kg ai/ha gave residues at a 1 day PHI of 0.03, 0.04, 0.05, 0.06, 0.08 and 0.26 mg/kg in the radish root. The Meeting agreed that the contribution from previous use on the rotation regime would not significantly impact the final residues.

The Meeting estimates a maximum residue level of 0.5 mg/kg and a STMR of 0.055 mg/kg for chlorantraniliprole in radish.

Chlorantraniliprole is registered to be used in Italy in carrots at up to 2 × 0.04 kg ai/ha (7–10 days interval) and 21 days PHI. Nine trials conducted in southern Europe in 2009/2010 according to this GAP gave residues of < 0.004 (3), 0.004, 0.005 (2), 0.025, 0.03, and 0.036 mg/kg. Eight trials conducted in northern Europe at the same rate gave residues of < 0.004 (5) 0.01, 0.021, and 0.027 mg/kg. Residues in Europe can be combined as < 0.004 (8), 0.004, 0.005 (2) 0.01, 0.021, 0.025, 0.027, 0.03 and 0.036 mg/kg.

Considering the contribution from rotation crops (0.01 mg/kg), the Meeting estimated a maximum residue level of 0.08 mg/kg and a STMR of 0.02 mg/kg for chlorantraniliprole in carrots.

The Meeting agreed to replace its previous recommendation of 0.02 mg/kg for chlorantraniliprole in Root and tuber vegetables for 0.02 mg/kg in Root and tuber vegetables, except carrot and radish.

Globe artichoke

Chlorantraniliprole is registered for use in Italy in globe artichoke at 2 × 0.03kg ai/ha (14 days interval) and a 3 day PHI. Four trials conducted in southern Europe at this GAP gave residues of 0.06, 0.07, 0.08 and 0.16 mg/kg.

The product is registered in the USA at 4 × 0.05–0.11 kg ai/ha (4 days interval; max of 0.22 kg ai/ha/season) and a 3 day PHI. Four trials conducted with 2 applications of the GAP rate gave residues of 0.47, 0.53, 0.59 and 0.69 mg/kg.

Based on the US trials, the Meeting recommended a maximum residue level of 2 mg/kg and a STMR of 0.56 for chlorantraniliprole in globe artichoke.

Rice

Chlorantraniliprole is registered to be used in Brazil in rice as a foliar treatment at 1 × 0.03 kg ai/ha and a 15 day PHI. In eight trials conducted in the country according to GAP, residues were < 0.01, 0.02, 0.03, 0.10, 0.13 (2) and 0.16 (2) mg/kg.

In the USA, the product is registered as seed treatment at 0.06 mg ai/seed (0.09 kg ai/ha). Sixteen trials conducted at 0.10 mg ai/seed (0.56 kg ai/ha) gave residues ranging from 0.01 to 0.09 mg/kg. Three trials conducted within GAP gave residues in the grain of 0.01 (2) and 0.02 mg/kg.

Based on the Brazilian foliar trials conducted according to GAP, the Meeting estimated a maximum residue level of 0.4 mg/kg and a STMR of 0.115 mg/kg for chlorantraniliprole in rice grain.

Two processing studies were submitted to the Meeting. In each, two different procedures were used to produce polished rice, with processing factors of 0.07 (2), 0.15 and 0.16, median of 0.11. This PF was applied to the residue data on rice grain to derive data on polish rice.

The Meeting estimates a maximum residue level of 0.04 mg/kg and a STMR of 0.013 mg/kg for chlorantraniliprole in polished rice.

Cereals, except rice

Currently, the Codex MRL for chlorantraniliprole in cereals is 0.02 mg/kg, following the recommendation made by the 2008 JMPR based on rotation crop data.

In the USA, three trials were conducted in barley, three in sorghum and five trials were conducted in wheat using 2 × 0.11 kg ai/ha. Residues in samples harvested at 1 DAT ranged from 0.19 to 2.2 mg/kg. As the compound is not registered for use in these crops in the USA, no estimations were made.

The Meeting replaced its previous recommendation of 0.02 mg/kg for cereals for 0.02 mg/kg in cereals, except rice.

Rape and sunflower seeds

Chlorantraniliprole is registered in Canada for oilseeds, except cotton, at 3 × 0.025–0.07 kg ai/ha (max of 0.2 kg ai/ha/season) and a 1 day PHI. Twelve trials were conducted in the USA and Canada in rape seed (canola) and sunflower according to this GAP.

Six trials conducted in rape seed (canola) gave residues at of 0.14, 0.23, 0.25, 0.34, 0.83 and 1.0 mg/kg.

Six trials conducted in sunflower gave residues at of 0.03, 0.12, 0.16, 0.21, 0.79 and 0.82 mg/kg.

The Meeting estimates a maximum residue level of 2 mg/kg for chlorantraniliprole in rape seed and sunflower seed.

The Meeting estimates a STMR of 0.295 mg/kg for chlorantraniliprole in rape seed and of 0.185 mg/kg for sunflower seed.

Coffee

Chlorantraniliprole is registered in Brazil for use on coffee at 2 × 0.03 kg ai/ha with a 21 day PHI. Eight trials were conducted in Brazil matching this GAP, giving residues of < 0.01, 0.01 (3), 0.02 (3) and 0.03 mg/kg.

The Meeting recommended a maximum residue level of 0.05 mg/kg and a STMR of 0.015 mg/kg for chlorantraniliprole in coffee.

Hops

Chlorantraniliprole is registered in the USA for use in hops at 4 × 0.072 kg ai/ha (max. of 0.22 kg ai/ha/season) with a 0 day PHI. Four trials conducted at GAP (2 × 0.1 kg ai/ha) gave residues in dried cones of 7.6, 8.9, 13 and 19 mg/kg.

The Meeting estimated a maximum residue level of 40 mg/kg and a STMR of 10.9 mg/kg for chlorantraniliprole in hops, dry.

Animal feeds

Three Australian trials conducted according to GAP gave residues at a 1 day PHI in bean and pea foliage of 0.31, 0.78 and 2.2 and mg/kg. In two pea trials, residues in empty pods were 0.05 and 0.20 mg/kg.

Five trials conducted in southern Europe in beans according to Italian GAP gave residues at a 3 day PHI in bean plants without pods of 2.4, 4.3, 4.5, 6.6 and 6.8, mg/kg.

The US label has no additional information covering the grazing of legume vegetables. Nineteen trials conducted in Canada and USA according to US GAP (4 × 0.07 kg ai/ha; max. of 0.225 kg ai/ha/season gave residues at a 1 day PHI in bean or pea plants with pods of 0.01, 1.7, 2.8, 3.0, 3.4, 3.8, 3.8, 4.3, 4.4, 4.5, 4.8, 4.9, 4.9, 5.2, 5.3, 5.5, 6.0, 6.2 and 6.4 mg/kg.

Based on Canadian and US data, the Meeting estimated a median residue of 4.4 mg/kg and a highest residue of 6.4 mg/kg for chlorantraniliprole in bean forage (green) and pea vines (green).

In ten trials conducted in wheat, sorghum and barley in the USA, residues were determined in forage, hay and straw. However, as these are not registered uses for chlorantraniliprole in USA, the data was not considered further.

Sixteen trials conducted in rice after seed treatment at a higher than GAP rate in USA, residues in straw ranged from 0.05 to 0.24 mg/kg.

Fate of residues during processing

At the present Meeting, a STMR of 0.115 mg/kg was estimated for rice grain. Two studies were conducted in rice.

The best Pf estimated for rice bran (n=4) was 1.7, leading to an estimated STMR-P of 0.196 mg/kg.

The best Pf estimated for rice hull (n=4) was 3.3. For animal dietary burden purposes, a median of 0.368 mg/kg was calculated for rice hull.

Residues in animal commodities

Farm animal dietary burden

The Meeting estimated the dietary burden of chlorantraniliprole 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 previous JMPR Meetings (2008 and 2010). Dietary burden calculations are provided in Annex 6.

Livestock dietary burden for chlorantraniliprole, ppm of dry matter diet

	US-Canada		EU		Australia		Japan	
Commodity	Max	Mean	Max	Mean	Max	Mean	Max	Mean
Beef cattle	7.6	3.4	19.9	10.7	31.7[a]	15.7[c]	3.5	1.5
Dairy cattle	13.4	6.0	22.4[b]	10.1	26.8	13.1[d]	15.8	6.7
Poultry - broiler	0.06	0.06	0.06	0.032	0.11	0.11	1.06	0.55
Poultry - layer	0.06	0.06	4.42[e]	2.51[f]	0.11	0.11	0.05	0.05

[a] Highest maximum beef or dairy cattle dietary burden suitable for maximum residue level estimated for mammalian tissues

[b] Highest maximum dairy cattle dietary burden suitable for maximum residue level estimated for mammalian milk

[c] Highest mean beef or dairy cattle dietary burden suitable for STMR estimated for mammalian tissues.

[d] Highest mean dairy cattle dietary burden suitable for STMR estimated 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 maximum residue level

The dietary burden estimated by the present Meeting for cattle is similar to that estimated by the 2010 JMPR and would not impact the previous recommendations for chlorantraniliprole in edible offal (mammalian), meat (from mammals other than marine mammals) and milk fats.

The calculated maximum poultry dietary burden suitable for maximum residue level estimated for poultry tissues and eggs was 4.4 ppm, about 2.4 times higher than the previous estimation. The calculated dietary burden for STMR estimation is 0.007 ppm.

In a metabolism study evaluated by the 2008 JMPR, poultry laying hens were dosed with [^{14}C]chlorantraniliprole for 14 days at 10 ppm in the diet. Residues found in eggs, muscle, liver and skin/fat and the residues expected in poultry commodities based on the calculated animal burden are shown in the table below. The levels which the estimations were based are in bold.

	Feed level, ppm, for	Residue, mg/kg			
	Tissues and eggs residues	Eggs	Muscle	Liver	Fat
Highest residue level, hens					
Feeding study	10	0.308	0.0008	0.0196	0.009
Calculated burden	4.42	0.135	0.0004	0.008	0.004
STMR, hens					
Feeding study	10	0.282	0.0008	0.0196	0.009
Calculated burden	2.5	0.07	0.0002	0.005	0.002

The Meeting confirms its previous maximum residue level recommendation of 0.01* mg/kg for chlorantraniliprole in poultry meat (fat) and poultry edible offal, and estimated a STMR of 0 for poultry meat (fat) and 0.005 for poultry edible offal.

The Meeting estimated a maximum residue level of 0.2 mg/kg and a STMR of 0.07 for chlorantraniliprole in eggs.

The meeting withdraws its previous recommendation of 0.1 mg/kg for chlorantraniliprole in eggs.

DIETARY RISK ASSESSMENT

Long-term intake

The ADI for chlorantraniliprole is 0–2 mg/kg bw. The International Estimated Daily Intakes (IEDI) for chlorantraniliprole was estimated for the 13 GEMS/Food cluster diets using the STMR or STMR-P values estimated by the current and previous JMPR. The results are shown in Annex 3. The IEDI was 0% of the maximum ADI. 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 for chlorantraniliprole was unnecessary. The Meeting therefore concluded that the short-term intake of chlorantraniliprole is unlikely to present a public health concern.

5.6 CHLORFENAPYR (254)

TOXICOLOGY

Chlorfenapyr is the ISO-approved name for 4-bromo-2-(4-chlorophenyl)-1-ethoxymethyl-5-trifluoromethyl-1H-pyrrole-3-carbonitrile (IUPAC), with CAS No. 122453-73-0. Chlorfenapyr is a contact and stomach pyrrole insecticide that acts, following metabolic activation, as an uncoupler of oxidative phosphorylation in mitochondria. It has limited systemic activity.

Chlorfenapyr was evaluated by JMPR in 2012, when an ADI of 0–0.03 mg/kg bw was established, based on a NOAEL of 2.8 mg/kg bw per day for decreases in body weight gain and vacuolation of the white matter of the brain at 16.6 mg/kg bw per day in an 18-month mouse study and a NOAEL of 2.9 mg/kg bw per day for reduced body weight and body weight gain and increased liver weight associated with hepatocellular enlargement at 15 mg/kg bw per day in a 2-year rat study. The 2012 Meeting also established an ARfD for chlorfenapyr of 0.03 mg/kg bw, based on the NOAEL of 3 mg/kg bw for depression of grooming and reactivity and decreased spontaneous motor activity observed at 10 mg/kg bw in a pharmacological study in mice. At that meeting, it was noted that the oral LD_{50} in the rat of the livestock metabolite tralopyril, the ISO-approved name for 4-bromo-2-(4-chlorophenyl)-5-(trifluoromethyl)-1H-pyrrole-3-carbonitrile (IUPAC, CAS No. 122454-29-9, also known as AC 303,268), was an order of magnitude lower than that of the parent.

Although the sponsor had not conducted any repeated-dose studies of the toxicity of this metabolite, it became apparent during the 2012 Meeting that such information had been produced by another company to support registration of tralopyril as a biocide (molluscicide). Studies with the metabolite tralopyril on its subchronic oral and inhalational toxicity and developmental toxicity and further studies on its genotoxicity have now been provided and reviewed, allowing completion of the assessment of chlorfenapyr. Relevant parts of the most recent assessment of chlorfenapyr have been incorporated into this toxicological evaluation.

All critical studies contained certificates of compliance with GLP.

Biochemical aspects

Although tralopyril is a metabolite of chlorfenapyr in the rat, the systemic exposure to this compound cannot be quantified. This is because systemic exposure estimates are based on metabolites that could potentially have arisen from tralopyril, but which could also have arisen from an alternative pathway in which the initial step is debromination rather than dealkylation. In the absence of information on relative rates of conversion of chlorfenapyr by these two pathways, it is not possible to reach any conclusions on exposure of test species to tralopyril.

Toxicological data

Tralopyril was of high acute oral toxicity in rats (LD_{50} = 27 mg/kg bw). In contrast, the oral LD_{50} of chlorfenapyr in rats is 441 mg/kg bw.

In a 90-day study of toxicity in rats, tralopyril was administered in the diet at concentrations of 0, 80, 250 and 750 ppm (equal to 0, 5.2, 16.2 and 51.9 mg/kg bw per day for males and 0, 6.3, 20.9 and 62.0 mg/kg bw per day for females, respectively). Administration of tralopyril resulted in dose-dependent, multifocal vacuolation of the white matter in the central nervous system and multifocal intramyelinic vacuolation of the peripheral nervous system. At high doses, a variety of effects were observed, including a reduction in body weight and body weight gain and changes in a number of clinical chemistry parameters. It was not possible to identify a NOAEL in this study, as vacuolation of the central nervous system and peripheral nervous system was evident at 80 ppm in females, the lowest dose tested. Therefore, the LOAEL for this study was 80 ppm (equal to 6.3 mg/kg bw per

day). The absence of neuronal degeneration or neuronal necrosis suggests that morphological reversibility can be expected, and there is some evidence for this in a recovery group.

For comparison, the subchronic toxicity of chlorfenapyr was examined in a 90-day oral toxicity study in rats administered a dietary concentration of 0, 150, 300, 600, 900 or 1200 ppm (equal to 0, 10.9, 22.0, 44.9, 69.5 and 92.2 mg/kg bw per day for males and 0, 12.5, 26.1, 51.8, 75.4 and 102.8 mg/kg bw per day for females, respectively) and in a 13-week interim kill of males only within a 1-year oral neurotoxicity study at 0, 60, 300 and 600 ppm (equal to 0, 2.6, 13.6 and 28.2 mg/kg bw per day for males, respectively). In the 90-day study, chlorfenapyr produced vacuolation of the white matter in rats in one male at 600 ppm and in two males at 900 ppm and produced effects on relative liver weights, alkaline phosphatase (AP), blood urea nitrogen and red blood cells at 600 ppm (equal to 44.9 mg/kg bw per day for males and 51.8 mg/kg bw per day for females). In the 13-week interim kill, males exhibited swelling of the myelin sheath in the spinal roots at 600 ppm (equal to 28.2 mg/kg bw per day). By the terminal kill at 52 weeks, chlorfenapyr produced vacuolar myelinopathy, vacuolation and/or myelin sheath swelling of the brain and spinal cord at 300 ppm (equal to 13.6 and 18 mg/kg bw per day for males and females, respectively). As seen in the 90-day tralopyril study, the myelinopathic process was not associated with any evidence of myelin or axon degeneration and was not evident in the male rats terminated after the recovery period. Thus, it appears that chlorfenapyr can produce effects on white matter similar to those of tralopyril, but is neurotoxicologically less potent than tralopyril by several fold.

In a subchronic inhalation toxicity and neurotoxicity study on tralopyril in rats, animals were exposed to target levels of 0, 20, 40 or 80 mg/m^3 for 6 hours/day, 7 days/week, for 90 days. At concentrations of 40 and 80 mg/m^3, there were decreases in body weight and feed consumption in both sexes, males exhibited decreased total locomotor activity in week 3 and decreased activity throughout the study period, and females exhibited increased AP levels and increased relative lung weights. Histopathological changes consisted of ulcerations and erosions of the interior nose structures and degeneration of the respiratory and olfactory epithelium at 40 and 80 mg/m^3. At 80 mg/m^3, there were treatment-related mortalities in males.

A related study on chlorfenapyr in which rats were administered a concentration of 0, 5, 20, 40 or 80 mg/m^3 was reviewed by the 2012 JMPR. Although both were 90-day studies and the NOAECs for the end-points were numerically the same (20 mg/m^3) for the two compounds (but note that exposure duration differed: 7 days/week for tralopyril and 5 days/week for chlorfenapyr), tralopyril produced some neurotoxic effects (reduced activity and locomotor activity) as well as systemic effects in both sexes, whereas chlorfenapyr produced effects on lethality, haematological alterations and prolonged prothrombin times at 40 mg/m^3. Thus, it appears that the two chemicals are of similar potency for systemic toxicity in inhalational exposure studies, but produce different toxicological spectra. A major difference is the neurotoxicity produced by tralopyril and not by chlorfenapyr.

Tralopyril did not exhibit evidence of genotoxic activity in in vitro and in vivo assays. The Meeting noted that in the in vivo mouse micronucleus test, gavage doses of 15 mg/kg bw produced deaths, and clinical signs were seen at 12 mg/kg bw.

In a developmental toxicity study in rats on tralopyril, presumed pregnant females were dosed at 0, 5, 10 or 20 mg/kg bw per day on gestation days 6–19. The NOAEL for maternal and embryo/fetal toxicity was 5 mg/kg bw per day. At 10 mg/kg bw per day, dams exhibited an immediate increase in transient salivation after gavage, and there was a decrease in fetal weights. At 20 mg/kg bw per day, there were two treatment-related deaths comorbid with reddish salivation, tremors and convulsions and transient salivation following dosing, decreased feed consumption and decreased body weight gain in surviving dams. In the caesarean section parameters at 20 mg/kg bw per day, uterine and placental weights were decreased, and there was an increase in resorptions. Fetuses at 20 mg/kg bw per day exhibited an increased incidence of skeletal variations, although the changes were considered by the Meeting to be secondary to clear maternal toxicity. The transient salivation at

the middle and high doses was determined to be a treatment-related and adverse effect based on the neurotoxicological profile of the compound.

For the developmental toxicity study in rats on chlorfenapyr, the NOAEL for maternal toxicity was 75 mg/kg bw per day, based on decreased body weight at 225 mg/kg bw per day, and the NOAEL for embryo and fetal toxicity was 225 mg/kg bw per day, the highest dose tested. The NOAEL of 5 mg/kg bw per day for maternal and embryo/fetal toxicity in the tralopyril study was therefore 15 and 45 times lower than the NOAELs of chlorfenapyr for maternal and embryo/fetal toxicity, respectively. Importantly, the critical end-points observed in pregnant dams exposed to tralopyril (maternal salivation) differed from that with chlorfenapyr (decreased body weight and body weight gain), and there was no evidence of embryo and fetal toxicity in the chlorfenapyr study in the presence of maternal toxicity. Together, the evidence suggests that tralopyril is more potent than chlorfenapyr in developmental toxicity studies and produces more severe maternal toxicity.

In summary, after 13 weeks of oral exposure, tralopyril was several-fold more potent than chlorfenapyr in female and male rats based on a comparison of LOAELs. In developmental toxicity studies in rats, tralopyril exhibited a higher degree of toxicity than chlorfenapyr, with NOAELs for maternal and embryo/fetal toxicity 15 and 45 times lower than those for chlorfenapyr, respectively. Tralopyril produced more severe neurotoxicity in oral and inhalational studies compared with chlorfenapyr on repeated administration. The data therefore indicate that tralopyril is more toxic than chlorfenapyr following repeated oral administration.

Toxicological evaluation

In 2012, the Meeting established an ADI for chlorfenapyr of 0–0.03 mg/kg bw, based on a NOAEL of 2.8 mg/kg bw per day for decreases in body weight gain and vacuolation of the white matter of the brain at 16.6 mg/kg bw per day in an 18-month mouse study and a NOAEL of 2.9 mg/kg bw per day for reduced body weight and body weight gain and increased liver weight associated with hepatocellular enlargement at 15 mg/kg bw per day in a 2-year rat study. This was supported by a NOAEL of 2.6 mg/kg bw per day for reversible vacuolar myelinopathy, vacuolation and/or myelin sheath swelling of the brain and spinal cord in males at 13.6 mg/kg bw per day in a 1-year study of neurotoxicity in rats. A safety factor of 100 was applied. The Meeting established an ARfD for chlorfenapyr of 0.03 mg/kg bw, based on the NOAEL of 3 mg/kg bw for depression of grooming and reactivity and decreased spontaneous motor activity observed at 10 mg/kg bw in a pharmacological study in mice. Based on the available information, it was not possible for the Meeting to determine whether the ADI and ARfD would also cover tralopyril.

There is less than a 10-fold difference in potency between tralopyril and chlorfenapyr for the effects of repeated administration on vacuolation of the peripheral and central nervous systems. However, there is approximately an order of magnitude difference in some acute effects (e.g. LD_{50}s of 27 mg/kg bw for tralopyril compared with 441 mg/kg bw for chlorfenapyr), and direct comparison of the most sensitive end-point in the most sensitive species (mouse) is not possible. The Meeting therefore established a potency factor of 10 for a comparison of exposure of tralopyril with both the ADI and the ARfD:

Estimates of exposure for comparison with the ADI/ARfD = chlorfenapyr + 10 × tralopyril

The Meeting noted that it may be possible to refine this potency factor estimate with additional studies.

An addendum to the monograph was prepared.

Levels relevant to risk assessment of chlorfenapyr

Species	Study	Effect	NOAEL	LOAEL

Species	Study	Effect	NOAEL	LOAEL
Studies in metabolites: tralopyril				
Rat	Ninety-day study of toxicity[a]	Neurotoxicity	—	6.3 mg/kg bw per day[b]
	Developmental toxicity study[c]	Maternal toxicity	5 mg/kg bw per day	10 mg/kg bw per day
		Embryo and fetal toxicity	5 mg/kg bw per day	10 mg/kg bw per day

[a] Dietary administration.

[b] Lowest dose tested.

[c] Gavage administration.

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

Results from metabolism studies to determine systemic exposure to critical chlorfenapyr metabolites

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

Studies in metabolites: tralopyril	
Acute toxicity	
Rat, LD_{50}, oral	27 mg/kg bw
Short-term studies of toxicity	
Target/critical effect	Vacuolation of the central and peripheral nervous systems
Lowest relevant oral NOAEL	< 6.3 mg/kg bw per day, the lowest dose tested (rat)
Lowest relevant inhalation NOAEC	20 mg/m^3 (rat)
Genotoxicity	
	Not genotoxic
Developmental toxicity	
Target/critical effect	Maternal salivation, body weight, fetal weight
Lowest relevant maternal NOAEL	5 mg/kg bw per day
Lowest relevant embryo/fetal NOAEL	5 mg/kg bw per day

RESIDUES

To assist JMPR in finalizing a residue definition for dietary risk assessment, JMPR requires:

- Studies of the hydrolysis of chlorfenapyr under standard processing conditions (e.g., pasteurization, baking, brewing, boiling, sterilization, etc.), including identification of degradates formed;
- Results from residue trials measuring chlorfenapyr and critical metabolites.

5.7 CHLORPYRIFOS-METHYL (090)

Chlorpyrifos-methyl was evaluated for residues by the 2009 JMPR under the periodic review program, when a recommendation of 3 mg/kg for wheat, barley and maize was made based on post-harvest use. The long-term dietary risk assessment for the compound indicated an exceedance of up to 140% of the ADI of 0.01 mg/kg bw, with maize accounting for about 73% of the IEDI. This recommendation was made using an alternative Spanish GAP (2.2 g ai/ton).

The 2012 JMPR received a new Spanish label indicating that the post-harvest use of chlorpyrifos-methyl was no longer allowed on maize. The 2012 Meeting withdrew its previous recommendation of 3 mg/kg (Po) on maize, and the new long-term dietary risk assessment indicated that the highest IEDI was 60% of the ADI.

The 2013 JMPR received a request from CCPR to reconsider the current recommendation of chlorpyrifos-methyl in wheat and barley of 3 mg/kg (Po). The Meeting received a new label from Australia for post-harvest use of chlorpyrifos-methyl on cereals, except maize at up to 5 g ai/ton (for 3 to 6 months protection). Residues coming from post-harvest trials evaluated by the 2009 JMPR conducted in wheat and barley according to Australian GAP ranged from 1.6, 1.9 (2), 2.2, 2.3, 2.4, 2.6, 2.9 (2), 3.0 (2), 3.1 (2), 3.2 (3), 3.3, 3.5 and 4.7 mg/kg (n=19).

Processing studies on wheat evaluated by the 2009 JMPR gave processing factors (PF) of 0.25 for flour, 1 for whole meal, 1.9 for germ, 2.45 for bran, 0.05 for white bread, and 0.48 for whole bread. Based on a STMR of 3 mg/kg, the Meeting estimated a STMR-P of 0.75 mg/kg for wheat flour, 3 mg/kg for whole meal wheat, 5.7 mg/kg for wheat germ, 7.35 mg/kg for wheat bran, 0.15 mg/kg for white bread and 1.44 in whole meal bread. The Meeting also estimated a HR-P of 11.5 mg/kg for wheat bran, unprocessed, of 10.8 mg/kg in wheat germ, and 4.7 in wheat whole meal. These estimations were extended to triticale processed products. A processing study on barley lead to a PF of < 0.01 for beer and a STMR-P of 0.03 was estimated for beer.

As no processing studies were submitted on rice, the Meeting considered the published study conducted by Cogburn *et al*. (1990). Harvested rice grain were treated with 6 or 12 mg/kg chlorpyrifos-methyl and stored for 1, 6 and 12 weeks. After storage, treated grain was processed to brown rice (husked) or milled to produce polished rice and bran. The mean processing factors (n=6) were 0.22 for husked rice, 0.033 for polished rice, 1.7 for rice bran and 0.012 for cooked polish rice. The data are shown in the Table below.

Residues of chlorpyrifos-methyl in rice grain and processed commodities (Cogburn *et al*. (1990)

Rice grain	Husked rice		Polished rice		Rice bran		Cooked polish rice	
Residues, mg/kg	Residues, mg/kg	PF	Residues, mg/kg	PF	Residues, mg/kg	PF	Residues, mg/kg	PF
4.45	0.87	0.20	0.14	0.03	6.7	1.5	0.07	0.016
3.23	0.75	0.23	0.07	0.02	4.7	1.4		
2.3	0.58	0.25	0.15	0.06	5.7	2.5	0.06	0.026
9.9	1.85	0.19	0.25	0.02	15.3	1.5	0.08	0.008
8.3	1.99	0.24	0.18	0.02	10.3	1.2	0.04	0.004
7.43	1.61	0.22	0.28	0.04	13.3	1.8	0.04	0.005
Mean of PF		0.22		0.034		1.67		0.012

The Meeting agreed to estimate a maximum residue level of 5 mg/kg, a STMR of 3 mg/kg and a HR of 4.7 mg/kg for chlorpyrifos-methyl in cereals, except maize and rice.

Rice grain is not a trade commodity. Hence the Meeting agrees to use the residue data for wheat and barley according to Australian GAP and the processing factors estimated for husked rice and polished rice to estimate maximum residue levels, STMR-Ps and HR-Ps for these commodities.

The Meeting estimated a maximum residue level of 1.5 mg/kg for rice, husked and of 0.2 mg/kg for rice, polished.

The Meeting estimated a STMR-P of 0.661 mg/kg for husked rice, of 0.101 mg/kg for polished rice, of 5.0 mg/kg for rice bran and of 0.036 mg/kg for cooked polished rice.

The Meeting estimated a HR of 1.04 mg/kg for rice, husked of 0.15 mg/kg for rice, polished, of 7.8 mg/kg for rice bran and of 0.056 mg/kg for cooked polished rice. The Meeting recalculated the STMR and HR values for processed wheat commodities (wheat flour (0.5 mg/kg, –), wheat germ (5.7 mg/kg, 10.8 mg/kg), wheat wholemeal (3, 4.7 mg/kg), wheat bran, unprocessed (7.35 mg/kg, 11.5 mg/kg), white bread (0.15 mg/kg, –) and wholemeal bread (1.44 mg/kg, –) and barley beer (0.03 mg/kg, –), respectively, based on the new maximum residue estimate of 5 mg/kg for cereal grains.

The Meeting withdraw its previous recommendation of 3 mg/kg for chlorpyrifos-methyl in barley and wheat.

DIETARY RISK ASSESSMENT

Long-term intake

The IEDI of chlorpyrifos-methyl based on the STMRs estimated by this and previous Meetings for the 13 GEMS/Food regional diets were 0–110% of the maximum ADI of 0–0.01 mg/kg bw (see Annex 3 of this Report).

The highest % of the ADI (110%) was found in the Cluster diet J, for which 95% of the IEDI was from the consumption of millet and sorghum (include raw grain, flour and beer for both commodities). Processing studies on other cereal grains treated with chlorpyrifos-methyl have shown that residues decrease during processing, including cooking grain in water. It is expected that the fate of residues during processing will be similar for millet and sorghum. The Meeting concluded that the long-term dietary intake of residues of chlorpyrifos-methyl are unlikely to present a public health concern.

Short-term intake

An ARfD for chlorpyrifos-methyl is 0.1 mg/kg bw. The International Estimated Short-Term Intake (IESTI) for chlorpyrifos-methyl was calculated for the plant 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. The IESTI represented a maximum of 10% of the ARfD for husked rice. The Meeting concluded that the short-term intake of chlorpyrifos-methyl residues from uses considered by the current Meeting was unlikely to present a public health concern.

5.8 CYANTRANILIPROLE (263)

TOXICOLOGY

Cyantraniliprole is the ISO-approved common name for 3-bromo-1-(3-chloro-2-pyridyl)-4′-cyano-2′-methyl-6′-(methylcarbamoyl)pyrazole-5-carboxanilide (IUPAC), with CAS No. 736994-63-1. It is a new second-generation ryanodine receptor insecticide whose pesticidal mode of action is through unregulated activation of insect ryanodine receptor channels, which leads to internal calcium store depletion and impaired regulation of muscle contraction, causing paralysis and eventual death of the insect. Cyantraniliprole is used to control insect pests in fruit crops, tree nuts, oil seed crops, cotton, grapes, rice, vegetables, ornamentals and turf around the world.

Cyantraniliprole has not been evaluated previously by JMPR and is being evaluated by the present Meeting at the request of CCPR.

All critical studies were certified as complying with GLP.

Biochemical aspects

Cyantraniliprole is readily absorbed in rats, and the absorption is similar at 10 and 150 mg/kg bw. The majority of the absorption occurs during the first 24 hours (85% of the absorbed radioactivity), and the peak plasma concentration (C_{max}) is reached approximately 2 hours after dosing, regardless of the sex or dose level. The C_{max} and area under the plasma concentration–time curve (AUC) values demonstrate a 2- to 3-fold greater exposure in female rats than in male rats. Following oral dosing, the majority of the dose is extensively distributed throughout the body. The half-life is shorter in male rats than in female rats (42–53 hours in males and 117–129 hours in females). The absorbed cyantraniliprole is readily and extensively metabolized, mainly by hydroxylation of methylphenyl and *N*-methyl carbon. Further metabolism of the hydroxylated metabolites includes *N*-methylation, nitrogen-to-carbon cyclization with loss of a water molecule, oxidation of alcohols to carboxylic acids, amide bridge cleavage, amine hydrolysis and *O*-glucuronidation. The bile is found to be very rich in metabolites, and most of the metabolites are found in both urine and faeces. IN-MLA84 (2-[3-bromo-1-(3-chloro-2-pyridinyl)-1*H*-pyrazol-5-yl]-1,4-dihydro-8-methyl-4-oxo-6-quinazolinecarbonitrile) is the most abundant analyte in the blood of rats and mice of both sexes, whereas the highest concentrations in dogs are of the parent compound, cyantraniliprole.

Toxicological data

In rats, the oral LD_{50} was greater than 5000 mg/kg bw, the dermal LD_{50} was greater than 2000 mg/kg bw and the inhalation LC_{50} was greater than 5.2 mg/L. Cyantraniliprole was not a skin irritant in rabbits, an eye irritant in rabbits or a skin sensitizer.

Liver was the interspecies target of cyantraniliprole in short- and long-term studies, although dogs appeared to be more sensitive than rats. In rodents, the thyroid was also a target organ, with adverse effects on thyroid hormone metabolism.

Short-term toxicity of cyantraniliprole was examined in mice, rats and dogs. The NOAEL in a 28-day oral toxicity study in mice was 7000 ppm (equal to 1261 mg/kg bw per day), the highest dose tested. The NOAEL in a 90-day oral toxicity study in which mice were administered cyantraniliprole in the diet at a concentration of 0, 50, 300, 1000 or 7000 ppm (equal to 0, 7.2, 47.1, 150 and 1091 mg/kg bw per day for males and 0, 9.7, 58.1, 204 and 1344 mg/kg bw per day for females, respectively) was 1000 ppm (equal to 204 mg/kg bw per day), based on minimal necrosis in the liver at 7000 ppm (equal to 1344 mg/kg bw per day) in females.

In a 28-day oral toxicity study in which rats were administered cyantraniliprole in the diet at a concentration of 0, 600, 2000, 6000 or 20 000 ppm (equal to 0, 53, 175, 528 and 1776 mg/kg bw per day for males and 0, 62, 188, 595 and 1953 mg/kg bw per day for females, respectively), the NOAEL

was 600 ppm (equal to 53 mg/kg bw per day), based on liver hypertrophy and thyroid follicular cell hypertrophy observed in both sexes at 2000 ppm (equal to 175 mg/kg bw per day). In a 90-day oral toxicity study in which rats were administered a dietary concentration of 0, 100, 400, 3000 or 20 000 ppm (equal to 0, 5.7, 22, 168 and 1147 mg/kg bw per day for males and 0, 6.9, 27, 202 and 1346 mg/kg bw per day for females, respectively), the NOAEL was 100 ppm (equal to 5.7 mg/kg bw per day), based on liver hypertrophy, decreases in thyroid hormones in both sexes and histopathological changes in the thyroid in females at 400 ppm (equal to 22 mg/kg bw per day).

Three feeding studies (28 days, 90 days and 1 year) were conducted with cyantraniliprole in dogs. A NOAEL for the 28-day oral toxicity study in dogs was not determined, based on changes in body weight, nutritional parameters and clinical chemistry indicating hepatotoxicity in both sexes at 1000 ppm (equal to 35 mg/kg bw per day), the lowest dose tested. The NOAEL for the 90-day oral toxicity study in which dogs were administered cyantraniliprole at 0, 30, 10, 1000 or 10 000 ppm (equal to 0, 0.98, 3.08, 31.9 and 281 mg/kg bw per day for males and 0, 0.97, 3.48, 34.40 and 294 mg/kg bw per day for females, respectively) was 100 ppm (equal to 3.08 mg/kg bw per day), based on increased total protein, albumin and AP levels in males at 1000 ppm (equal to 31.9 mg/kg bw per day). In a 1-year dog study utilizing concentrations of 0, 40, 200, 1000 and 5000 ppm (equal to 0, 0.96, 5.67, 27.0 and 144 mg/kg bw per day for males and 0, 1.12, 6.00, 27.1 and 133 mg/kg bw per day for females, respectively), the increased levels of AP at 40 ppm were not considered adverse in view of the absence of histopathological or functional changes at this and the next higher dose (200 ppm). Therefore, the NOAEL for the 1-year oral toxicity study in dogs was 40 ppm (equal to 0.96 mg/kg bw per day), based on marginal increases in AP levels without histopathological change in the liver in both sexes, increased liver weights in males and decreased cholesterol in females at 200 ppm (equal to 5.67 mg/kg bw per day). The Meeting concluded that the overall NOAEL for oral toxicity in dogs was 100 ppm (equal to 3.08 mg/kg bw per day), and the overall LOAEL was 200 ppm (equal to 5.67 mg/kg bw per day).

Long-term toxicity studies were conducted in mice and rats. In an 18-month carcinogenicity study in which mice were administered a dietary concentration of 0, 20, 150, 1000 or 7000 ppm (equal to 0, 2.0, 15.5, 104 and 769 mg/kg bw per day for males and 0, 2.4, 18.6, 131 and 904 mg/kg bw per day for females, respectively), the NOAEL for toxicity was 1000 ppm (equal to 104 mg/kg bw per day), based on a decrease in body weight gain and increased thyroid weight in males at 7000 ppm (equal to 769 mg/kg bw per day). No increase in neoplastic incidence was observed. The NOAEL for carcinogenicity in mice was 7000 ppm (equal to 769 mg/kg bw per day), the highest dose tested.

In a 2-year toxicity and carcinogenicity feeding study in which rats were administered cyantraniliprole in the diet at 0, 20, 200, 2000 or 20 000 ppm (equal to 0, 0.8, 8.3, 84.8 and 907 mg/kg bw per day for males and 0, 1.1, 10.5, 107 and 1161 mg/kg bw per day for females, respectively), the NOAEL for toxicity was 200 ppm (equal to 8.3 mg/kg bw per day), based on increased incidences of foci of cellular alteration in the liver in males and hepatocellular vacuolation in both sexes and slight depression of body weights in females at 2000 ppm (equal to 84.8 mg/kg per day). No increase in neoplastic incidence was observed, and the NOAEL for carcinogenicity in rats was 20 000 ppm (equal to 907 mg/kg bw per day), the highest dose tested.

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

Cyantraniliprole was tested for genotoxicity in vitro and in vivo in an adequate range of assays. In these assays, there was no evidence of genotoxic potential.

The Meeting concluded that cyantraniliprole 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 cyantraniliprole is unlikely to pose a carcinogenic risk to humans.

In a multigeneration reproductive toxicity study in which rats were given cyantraniliprole at a concentration of 0, 20, 200, 2000 or 20 000 ppm (in P generation: equal, respectively, to 0, 1.1, 11.0, 110 and 1125 mg/kg bw per day for males, 0, 1.4, 13.9, 136 and 1344 mg/kg bw per day for premating females, 0, 1.4, 13.3, 135 and 1353 mg/kg bw per day for females during gestation, and 0,

2.7, 27.0, 283 and 2782 mg/kg bw per day for females during lactation; in F generation: equal, respectively, to 0, 1.4, 14.6, 150.8 and 1583 mg/kg bw per day for males, 0, 1.9, 20.1, 203 and 2125 mg/kg bw per day for premating females, 0, 1.4, 14.7, 149 and 1518 mg/kg bw per day for females during gestation and 0, 2.7, 27.4, 277 and 2769 mg/kg bw per day for females during lactation), the NOAEL for parental toxicity was 200 ppm (equal to 11.0 mg/kg bw per day), based on increased hepatocellular hypertrophy and thyroid follicular cell hypertrophy in both sexes at 2000 ppm (equal to 110 mg/kg bw per day) in the P generation. The NOAEL for reproductive toxicity was 20 000 ppm (equal to 1344 mg/kg bw per day), the highest dose tested. The NOAEL for offspring toxicity was 2000 ppm (equal to 280 mg/kg bw per day, mean value for P and F_1 parental females during lactation), based on lower body weights of F_1 and F_2 generation pups at 20 000 ppm (equal to 2780 mg/kg bw per day, mean value for P and F_1 parental females during lactation).

In a developmental toxicity study in rats administered a dose of 0, 20, 100, 300 or 1000 mg/kg bw per day, the NOAELs for both maternal and embryo/fetal toxicity in rats were 1000 mg/kg bw per day, the highest dose tested.

In a developmental toxicity study in rabbits administered a dose of 0, 25, 100, 250 or 500 mg/kg bw per day, the NOAEL for maternal toxicity was 25 mg/kg bw per day, based on mortality, increased clinical signs of toxicity, including diarrhoea, and lower body weights and feed consumption at 100 mg/kg bw per day. The NOAEL for embryo/fetal toxicity was 100 mg/kg bw per day, based on reductions in fetal weight at 250 mg/kg bw per day.

The Meeting concluded that cyantraniliprole is not teratogenic in rats or rabbits.

In an acute neurotoxicity study in rats, the NOAEL was 2000 mg/kg bw, the highest dose tested.

In a 90-day study of neurotoxicity in which rats were administered a dose of 0, 200, 2000 or 20 000 ppm (equal to 0, 11.4, 115 and 1195 mg/kg bw per day for males and 0, 14.0, 137 and 1404 mg/kg bw per day for females, respectively), the NOAEL was 20 000 ppm (equal to 1195 mg/kg bw per day), the highest dose tested.

The Meeting concluded that cyantraniliprole is not neurotoxic.

Immunotoxicity studies were conducted in mice and rats. In a 28-day immunotoxicity study in mice, the NOAEL was 7000 ppm (equal to 1065 mg/kg bw per day), the highest dose tested. In a 28-day immunotoxicity study in rats, the NOAEL was 20 000 ppm (equal to 1699 mg/kg bw per day), the highest dose tested.

Toxicological data on metabolites and/or degradates

Acute toxicity and genotoxicity studies of metabolites were conducted. 4-[[[3-Bromo-1-(3-chloro-2-pyridinyl)-1H-pyrazol-5-yl]carbonyl]amino]-3-methyl-5-[(methylamino)carbonyl]benzoic acid (IN-JSE76), 2-[3-bromo-1-(3-chloro-2-pyridinyl)-1H-pyrazol-5-yl]-1,4-dihydro-8-methyl-4-oxo-6-quinazolinecarboxylic acid (IN-PLT97), 6-chloro-4-methyl-11-oxo-11H-pyrido[2,1-*b*]quinazoline-2-carbonitrile (IN-N5M09) and 3-bromo-*N*-methyl-1H-pyrazole-5-carboxamide (IN-F6L99) were degradates in soil. All metabolites exhibited low acute toxicities and no genotoxicity. The NOAEL in a 28-day toxicity study of IN-JSE76 in rats was 20 000 ppm (equal to 1445 mg/kg bw per day), the highest dose tested.

Human data

No information on medical surveillance or poisoning incidents was available.

The Meeting concluded that the existing database on cyantraniliprole 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 on the basis of the overall NOAEL of 3.08 mg/kg bw per day in dog studies, based on liver effects at 5.67 mg/kg bw per day. A safety factor of 100 was applied.

The metabolites IN-N7B69, IN-MLA84, IN-MYX98 and IN-J9Z38 have been included in the residue definition. As the estimated exposure to IN-N7B69 is below the threshold of toxicological concern for Cramer class III compounds, there is no concern for this metabolite. For the other three metabolites, these have been tested in rodents through their formation from the parent compound and are therefore covered by the ADI for cyantraniliprole.

The Meeting concluded that it was not necessary to establish an ARfD for cyantraniliprole in view of its low acute 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 cyantraniliprole

Species	Study	Effect	NOAEL	LOAEL
Mouse	Eighteen-month study of toxicity and carcinogenicity[a]	Toxicity	1000 ppm, equal to 104 mg/kg bw per day	7000 ppm, equal to 769 mg/kg bw per day
		Carcinogenicity	7000 ppm, equal to 769 mg/kg bw per day[b]	—
Rat	Ninety-day study of toxicity[a]	Toxicity	100 ppm, equal to 5.7 mg/kg bw per day	400 ppm, equal to 22 mg/kg bw per day
	Two-year studies of toxicity and carcinogenicity[a]	Toxicity	200 ppm, equal to 8.3 mg/kg bw per day	2000 ppm, equal to 84.8 mg/kg bw per day
		Carcinogenicity	20 000 ppm, equal to 907 mg/kg bw per day[b]	—
	Multigeneration reproductive toxicity study[a,d]	Parental toxicity	200 ppm, equal to 11.0 mg/kg bw per day	2000 ppm, equal to 110 mg/kg bw per day
		Reproductive toxicity	20 000 ppm, equal to 1344 mg/kg bw per day[b]	—
		Offspring toxicity	2000 ppm, equal to 280 mg/kg bw per day	20 000 ppm, equal to 2780 mg/kg bw per day
	Developmental toxicity study[c]	Maternal toxicity	1000 mg/kg bw per day[b]	—
		Embryo and fetal toxicity	1000 mg/kg bw per day[b]	—
	Acute neurotoxicity	Toxicity	2000 mg/kg bw per day[b]	—
	Ninety-day study of neurotoxicity[a]	Neurotoxicity	20 000 ppm, equal to 1195 mg/kg bw per day[b]	—
Rabbit	Developmental	Maternal toxicity	25 mg/kg bw per day	100 mg/kg bw per day

Species	Study	Effect	NOAEL	LOAEL
	toxicity study[c]	Embryo and fetal toxicity	100 mg/kg bw per day[b]	250 mg/kg bw per day
Dog	Ninety-day and 1-year studies of toxicity[a,d]	Toxicity	100 ppm, equal to 3.08 mg/kg bw per day	200 ppm, equal to 5.67 mg/kg bw per day

[a] Dietary administration.

[b] Gavage administration.

[c] Highest dose tested.

[d] Two or more studies combined.

Estimate of acceptable daily intake

0–0.03 mg/kg bw

Estimate of acute reference dose

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 cyantraniliprole

Absorption, distribution, excretion and metabolism in mammals	
Rate and extent of oral absorption	Rapid (in 2 h) and extensive (> 85%)
Dermal absorption	No data
Distribution	Extensive; all tissues
Potential for accumulation	Low
Rate and extent of excretion	Rapid (mainly in 48 h samples) and extensive; faeces > urine
Metabolism in animals	IN-MLA84 is abundant in mice and rats, less in dogs
Toxicologically significant compounds in animals, plants and the environment	Cyantraniliprole, IN-MLA84, IN-MYX98 and IN-J9Z38
Acute toxicity	
Rat, LD_{50}, oral	> 5000 mg/kg bw
Rat, LD_{50}, dermal	> 5000 mg/kg bw
Rat, LC_{50}, inhalation	> 5.2 mg/L
Mouse, LD_{50}, oral	> 5000 mg/kg bw
Rat, dermal irritation	Non-irritating
Rabbit, ocular irritation	Non-irritating
Sensitization	Non-sensitizing (LLNA in mice; maximization test in guinea-pigs)
Short-term toxicity	

Target/critical effect	Liver and thyroid / increases in AP and liver weights (dogs)
Lowest relevant oral NOAEL	3.08 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 toxicity and carcinogenicity	
Target/critical effect	Liver and thyroid / increased incidence of altered foci of hepatocytes in the liver, decreased body weight gain in females
Lowest relevant NOAEL	8.3 mg/kg bw per day (rat)
Carcinogenicity	Not carcinogenic
Genotoxicity	
	Not genotoxic
Reproductive toxicity	
Reproduction target/critical effect	No reproductive toxicity
Lowest relevant parental NOAEL	11.0 mg/kg bw per day
Lowest relevant offspring NOAEL	280 mg/kg bw per day
Lowest relevant reproductive NOAEL	1344 mg/kg bw per day, the highest dose tested
Developmental toxicity	
Target/critical effect	Mortality, increased clinical signs, decreased body weight gain and lower feed consumption of dams
Lowest relevant maternal NOAEL	25 mg/kg bw per day (rabbit)
Lowest relevant developmental NOAEL	100 mg/kg bw per day (rabbit)
Neurotoxicity	
Acute and subchronic neurotoxicity	Not neurotoxic
Immunotoxicity	
Lowest relevant immunotoxicity NOAEL	1065 mg/kg bw per day, the highest dose tested (mouse)
Medical data	
	No information available

Summary

	Value	Study	Safety factor
ADI	0–0.03 mg/kg bw	Ninety-day and 1-year toxicity studies (dog)	100
ARfD	Unnecessary	—	—

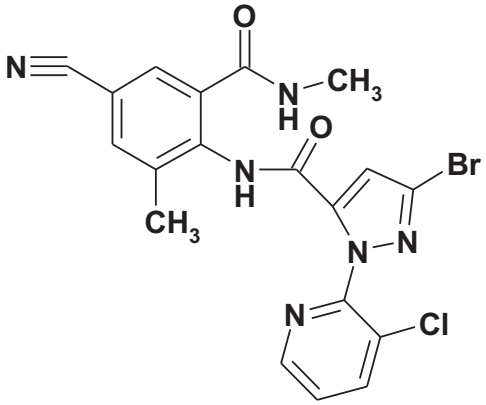
RESIDUE AND ANALYTICAL ASPECTS

Cyantraniliprole is a diamide insecticide with a mode of action (ryanodine receptor activation) similar to that of chlorantraniliprole and flubendiamide with root systemic and translaminar activity against the larval stages of lepidopteran insects; and also on thrips, aphids, and some other chewing and sucking insects.

It was scheduled by the Forty-fourth Session of the CCPR (REP12/PR) as a new compound for consideration by the 2013 JMPR. The manufacturer submitted studies on metabolism, analytical methods, supervised field trials, processing, freezer storage stability, environmental fate in soil and rotational crop residues.

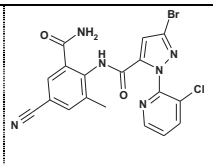
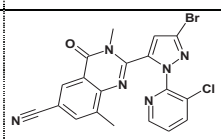
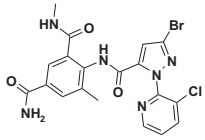
Authorisations exist for the use of cyantraniliprole in Canada, Columbia, Malaysia, New Zealand, Vietnam and in a regional grouping of countries in West Africa (CLISS).

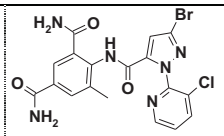
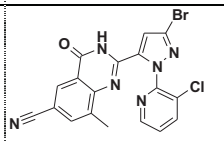
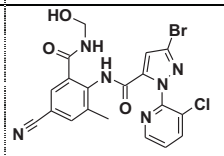
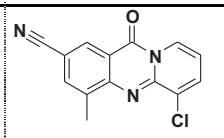
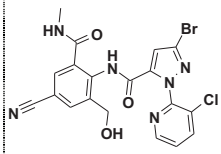
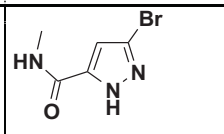
Cyantraniliprole is 3-bromo-1-(3-chloro-2-pyridyl)-4′-cyano-2′-methyl-6′-(methylcarbamoyl) pyrazole -5-carboxanilide. It is relatively insoluble in water (12 mg/L at pH 7, 6 mg/L at pH 9) and hydrolyses under alkaline conditions and at higher temperatures (above 25 °C), the major hydrolysis product being IN-J9Z38. It is not volatile (1.2×10^{-15} Pa at 20 °C), has a log P_{OW} of 1.9, its solubility in organic sovents ranges from < 1 g/L (octanol, xylene) to 5–7 g/L (methanol, dichloromethane, acetone) and is rapidly degraded by photolysis.



Cyantraniliprole (DPX-HGW86)
(MW 473.7)

The following abbreviations are used for the metabolites discussed below:

IN-HGW87		N-[2-(Aminocarbonyl)-4-cyano-6-methylphenyl]-3-bromo-1-(3-chloro-2-pyridinyl)-1*H*-pyrazole-5-carboxamide	
IN-J9Z38		2-[3-Bromo-1-(3-chloro-2-pyridinyl)-1*H*-pyrazol-5-yl]-3,4-dihydro-3,8-dimethyl-4-oxo-6-quinazolinecarbonitrile	MW 455.7
IN-JCZ38		4-[[[3-Bromo-1-(3-chloro-2-pyridinyl)-1*H*-pyrazol-5-yl]carbonyl]amino]-N′3′,5-dimethyl-1,3-benzenedicarboxamide	MW 491.7

IN-K7H19		4-[[[3-Bromo-1-(3-chloro-2-pyridinyl)-1*H*-pyrazol-5-yl]carbonyl]amino]-5-methyl-1,3-benzenedicarboxamide	MW 477.7
IN-MLA84		2-[3-Bromo-1-(3-chloro-2-pyridinyl)-1*H*-pyrazol-5-yl]-1,4-dihydro-8-methyl-4-oxo-6-quinazolinecarbonitrile	MW 441.7
IN-MYX98		3-Bromo-1-(3-chloro-2-pyridinyl)-N-[4-cyano-2[[(hydroxymethyl)amino]carbonyl]-6-methylphenyl]-1*H*-pyrazole-5-carboxamide	MW 489.7
IN-N5M09		6-Chloro-4-methyl-11-oxo-11*H*-pyrido[2,1-*b*]quinazoline-2-carbonitrile	MW 441.6
IN-N7B69		3-Bromo-1-(3-chloro-2-pyridinyl)-N-[4-cyano-2-(hydroxymethyl)-6-[(methylamino)carbonyl]phenyl]-1*H*-pyrazole-5-carboxamide	MW 489.7
IN-F6L99		3-Bromo-N-methyl-1H-pyrazole-5-carboxamide	MW 204

Animal metabolism

The Meeting received information on the metabolism of radiolabelled cyantraniliprole, separately ^{14}C-labelled at the 4-cyano (CN) and the pyrazole carbonyl (PC) groups, in rats, lactating goats and laying hens.

The WHO panel of the 2013 JMPR concluded that in rats, the majority of the dose was excreted within 24 to 48 hours, with about 1–5.5% TRR being recovered in tissues and that tissue elimination half-lives ranged from 2.6 days (fat) to about 6 days in whole blood.

The metabolic pathway was primarily through hydroxylation (to form IN-N7B69 and IN-MYX98), with IN-N7B69 being further metabolized to a glucuronide conjugate. Cyantraniliprole undergoes ring closure to generate IN-J9Z38 which is then in turn hydroxylated to form IN-NBC94, its carboxylic acid, and its glucuronide conjugate. IN-MYX98 is also metabolized to the closed-ring metabolite IN-MLA84, which, like IN-NBC94, is further oxidized to a hydroxylated metabolite, a carboxylic acid, and the glucuronide of the hydroxyl metabolite. Further, the hydroxylated metabolite IN-MYX98 can be N-dealkylated to form IN-HGW87 as well as being hydroxylated a second time to

form bis-hydroxy-cyantraniliprole. Cyantraniliprole can also be hydroxylated on the pyridine ring, followed by a ring closure analogous to the conversion of cyantraniliprole to IN-J9Z38.

Lactating goats were orally dosed with [CN-^{14}C]- or [PC-^{14}C]-cyantraniliprole at doses equivalent to approximately 13 ppm in the feed for 7 consecutive days and sacrificed 23 hours after the last dose.

The majority of the administered dose was recovered in excreta (84–88% in faeces, 7% in urine). About 1–2% (0.08–0.15 mg/kg) of the applied radioactivity was retained in milk, with 0.5 mg/kg (0.3% AR) found in liver and < 0.01% AR in other tissues. Solvent extraction was able to retrieve 99% TRR from milk, 90–98% TRR from fat, 61–81% TRR from muscle and 63–79% TRR from kidney. Solvent extractable TRR in the liver were lower (54–60% TRR) but an additional 21–27% TRR were recovered following digestion of the post extracted solids (PES) with protease.

In milk, TRR reached a plateau of 0.09 and 0.18 mg/kg after 2–3 days in the CN and PC label studies respectively. Cyantraniliprole was the major residue component, making up 40–50% (0.03–0.07 mg/kg) of the radiochemical label. Metabolite IN-MYX98 was also present at 15–18% TRR (0.01–0.03 mg/kg). Other metabolites (except IN-N7B69 at 11% TRR in the CN-label study) were found each < 0.01 mg/kg and less than 10% TRR.

In liver, TRR were 0.43–0.5 mg/kg. Cyantraniliprole (0.07–0.14 mg/kg) made up about 17–23% of the TRR and in kidney (TRR 0.14–0.21 mg/kg) with the major residue was also cyantraniliprole, accounting for 13–19% TRR (0.02–0.04 mg/kg).

In muscle, TRR were 0.03–0.04 mg/kg with the significant residue being cyantraniliprole, found at about 30% TRR and 0.01 mg/kg in the CN-label study and 15% TRR, 0.006 mg/kg in the PC-label study. The IN-MYX98 metabolite also accounted for 33% TRR (0.01 mg/kg) in the PC-label study.

TRR in fat were 0.05 and 0.12 mg/kg in the CN-label and PC-label studies respectively, with consistent results in omental, subcutaneous and renal fat. Cyantraniliprole was the major residue, averaging 31–42% TRR (0.01–0.025 mg/kg) with the IN-J9Z38 metabolite also accounted for 24–27% TRR (0.01–0.03 mg/kg).

Laying hens were orally dosed with [CN-^{14}C]- or [PC-^{14}C]-cyantraniliprole at doses equivalent to approximately 11 ppm in the feed for 14 consecutive days and sacrificed 23 hours after the last dose.

The majority of the administered dose was excreted, with 0.4–0.5% (0.20–0.26 mg/kg) remaining in egg whites, 0.07% (0.09 mg/kg) in yolks. Radioactivity in liver (0.14–0.2 mg/kg) accounted for 0.3–0.4% of the applied dose with muscle, abdominal fat and skin with fat each containing ≤ 0.1% AR (< 0.01 mg/kg).

In eggs, %TRR reached a plateau of about 0.1 mg/kg in yolks after 5–7 days. The %TRRs in egg white increased to 0.26–0.56 mg/kg over the first 2 days and decreased to a steady state of about 0.2–0.24 mg/kg after 7 days.

Solvent extraction was able to retrieve 79–99% TRR from eggs, 63–120% TRR from fat, 100% TRR from muscle and 53–72% TRR from skin with fat. Solvent extractable TRR in the liver were lower (17–23% TRR) but an additional 38% TRR were recovered following digestion of the post extracted solids (PES) with protease.

In eggs, cyantraniliprole was the major residue component, making up 33–42% TRR (0.09 mg/kg) in egg whites and 9–10% TRR (< 0.01 mg/kg) in yolks. Metabolite IN-J9Z38 made up about 17–29% TRR (0.03–0.08 mg/kg) in egg whites and 7–13% TRR (0.006–0.011 mg/kg in yolks. IN-MLA84 was also present in egg whites at about 18–19% TRR (0.04–0.05 mg/kg) and in yolks at about 12–17% TRR (0.01–0.015 mg/kg

In liver, TRR were 0.14–0.17 mg/kg. Cyantraniliprole was not found in any samples and while metabolites IN-JCZ38, IN-K5A78, IN-K5A79, IN-K7H19, IN-MLA84, IN-MYX98 and IN-N7B69 were identified, these were each present at <4% TRR (< 0.01 mg/kg).

In muscle, abdominal fat and skin with fat, no further analysis was conducted because of the low TRR (< 0.004 mg/kg) present.

In summary, the metabolism of cyantraniliprole in lactating goats (ruminant) and laying hen was consistent with that in the rat. Cyantraniliprole residues were rapidly eliminated in the excreta (94–100% of the dose) in goats and laying hens, with less than 1% of the total administered dose remaining in tissues and eggs and 1–2% found in milk). Cyantraniliprole was the predominant residue, with IN-N7B69 (milk), IN-MYX98 (muscle and milk), IN-J9Z38 (fat and eggs) and IN-MLA84 (eggs) being the principal metabolites present at more than 10% TRR or > 0.01 mg/kg.

Plant metabolism

The Meeting received plant metabolism studies on cotton, lettuce, tomato and rice seedlings following foliar and soil treatments with [^{14}C]-cyantraniliprole. A 1:1 (μCi/μCi ratio) mixture of [CN-^{14}C]-cyantraniliprole and [PC-^{14}C]-cyantraniliprole was used in the foliar treatments and separate treatments of the two radiolabels were applied as soil treatments.

Cotton

In cotton plants, treated 3 times with the equivalent of 0.15 kg ai/ha per application as foliar sprays, 7 days apart from 3 weeks after emergence, TRR in leaves immediately after the first treatment were 2.7 and 7.9 mg/kg immediately after the last application and after 13 days had decreased to 0.43 mg/kg. At harvest (124 days after the last application), TRRs in cotton gin by-products, lint and undelinted seed were 0.13, 0.01, and < 0.01 mg/kg, respectively.

Surface washing removed 56–70% TRR from immature leaves with a further 27–33% extracted into acidified aqueous acetone.

Cyantraniliprole was the major residue in leaves, decreasing from 70% TRR immediately after the first application to 20% TRR seven days later and accounted for 37% TRR (0.19 mg/kg) and 27% TRR (0.12 mg/kg), respectively, 7 and 13 days after the final application.

IN-NXX70, a photodegradate of IN-J9Z38, found predominately in the surface wash, accounted for 22% TRR seven days after the first application but decreased to 1% TRR in leaves sampled 7 days after the third application.

Surface washing of cotton gin by-products removed about 19% TRR (0.03 mg/kg) with a further 65% TRR (0.07 mg/kg) being extracted into acetone or with more aggressive extraction methods. Cyantraniliprole was the predominant residue, accounting for 34% TRR (0.04 mg/kg).

In plants from soil treatments where three applications of 0.15 kg ai/ha cyantraniliprole (SC formulation) were made to wetted soil at 7 day intervals from 7 weeks after emergence, TRRs in leaves from immature plants sampled up to 14 days after the last application were all ≤ 0.005 mg/kg. At maturity, 125 days after the last application, residues in lint and undelinted seed were < 0.001 mg/kg and TRR values in cotton gin by-products were 0.1 mg/kg (CN-label) and 0.02 mg/kg (PC-label).

Cyantraniliprole was the only significant residue in gin by-products, making up 26–47% TRR (0.01–0.03 mg/kg).

Lettuce

In lettuce plants, treated 3 times with the equivalent of 0.15 kg ai/ha per application as foliar sprays, 7 days apart from 3 weeks after emergence, TRR in leaves immediately after the first treatment was

11 mg/kg, 10 mg/kg immediately after the second application and about 8 mg/kg just after the last application. Seven days after the last application, TRRs had decreased to about 2 mg/kg and were 0.43 mg/kg at maturity, 32 days after the last application. Surface residues decreased from about 91% TRR immediately after the first application and 32 days after the last application surface residues were 13% TRR.

Cyantraniliprole was the major residue in leaves, decreasing from about 98% TRR immediately after the first application to 50% TRR in mature leaves, 32 days after the last application. The IN-J9Z38 metabolite, present in mature leaves at about 23% TRR (0.01 mg/kg) was only metabolite accounting for more than 5% TRR.

In plants from soil treatment where three applications of 0.15 kg ai/ha cyantraniliprole (SC formulation) were made to wetted soil at 7 day intervals from 7 weeks after emergence, TRRs (CN-label) in leaves from immature plants declined from 0.14 mg/kg immediately after the first application to about 0.05 mg/kg (7 days after the 2nd and 3rd applications) and were about 0.01 mg/kg at maturity. TRRs following the PC-label soil treatment were ≤ 0.06 mg/kg in immature leaves and at crop maturity.

Cyantraniliprole was the major radioactive component present in leaves, up to 77–84% TRR in young leaves and 37% TRR (0.004 mg/kg) and 69% TRR (0.04 mg/kg) in mature leaves for the CN-label and PC-labels respectively.

Tomato

In tomato plants, treated 3 times with the equivalent of 0.15 kg ai/ha per application as foliar sprays, 7 days apart from 3 weeks after emergence, TRR in leaves immediately after the first treatment were 2.5 mg/kg, 8.5 mg/kg immediately after the second application and 7.6 mg/kg just after the last application. Seven days after the last application, TRRs had decreased to about 2.2 mg/kg and were 1.3 mg/kg 14 days after the last application. Residues in fruit and leaves at harvest (132 days after the last treatment were < 0.01 mg/kg. The majority of the TRR (66–85%) were found in the surface wash with 15–34% TRR present in the extract.

Cyantraniliprole was the major residue in leaves, decreasing from about 95% TRR immediately after the first application to 61% TRR seven days later and accounted for 64 and 43% TRR respectively, 7 and 14 days after the last application. In leaves taken at maturity, residues in the surface wash were < 0.01 mg/kg and 0.01 mg/kg in the tissue extracts.

Concentrations of the unresolved radioactivity corresponding to both IN-MLA84 and IN-NXX70, (mostly in the surface wash) reached 11.5% TRR 7 days after the first application, decreasing to 4.4% TRR thereafter.

In plants from soil treatments where three applications of 0.15 kg ai/ha cyantraniliprole (SC formulation) were made to wetted soil in pots at 7 day intervals from 7 weeks after emergence, TRRs reached a maximum of 0.03 mg/kg in immature leaves 7 days after the last application and were < 0.01 mg/kg in leaves and 0.001 mg/kg in fruit at harvest (125 days after the last application).

Cyantraniliprole was the major radioactive component in leaves 7–14 days after the last application, ranging from 22–26% TRR (< 0.01 mg/kg).

Rice

Rice seedlings were treated with three foliar applications of 0.15 kg ai/ha at the 3–4 leaf stage and 7 and 14 days later and grown under flooded conditions (pots immersed in about 3 cm water) from 2 days after the initial treatment until 2–3 days before harvest.

TRRs in foliage were 2.1 mg/kg immediately after the first application, decreasing to 0.38 mg/kg after 7 days. Seven and 14 days after the last application, TRRS in leaves were 1.6 mg/kg and 1.2 mg/kg respectively. At harvest, 140 days after the last application, TRRs in straw were

0.45 mg/kg and 0.02 mg/kg in grain. In roots, TRRs increased from 0.24 mg/kg seven days after the first application to 0.68 mg/kg seven days after the last application and were 0.45 mg/kg at harvest. In immature leaves, 7 days after the last application, the surface wash contained about 75% TRR, reducing to 47% TRR in leaves sampled 14 days after the last treatment.

Cyantraniliprole was the major residue in immature leaves, making up 76–81% TRR (about 1.0 mg/kg) in samples taken 7 and 14 days after the last application. IN-J9Z38 was the predominant metabolite found at 0.6% TRR immediately after the first application and increasing to 11% TRR 14 days after the last application.

In straw, cyantraniliprole was the major component, accounting for 24.4% TRR (0.11 mg/kg) and cyantraniliprole was also the predominant residue in grain, accounting for 21% TRR (0.005 mg/kg).

Rice seedlings were also treated with a single soil application of 0.3 kg ai/ha (as surface-applied granules) at the 3–4 leaf stage and the plants were grown under flooded conditions (pots immersed in about 3 cm water) from 2 days after the initial treatment until 2–3 days before harvest, 175 days after treatment.

TRRs in foliage increased from 0.08 mg/kg (7 days after treatment) to 0.15 mg/kg (14 days after treatment) and reached 0.4 mg/kg after 56 days. Residues in roots were about 0.3 mg/kg after 56 days and at harvest (175 days after treatment). At harvest, TRRs were 0.28–0.3 mg/kg in straw and 0.01–0.03 mg/kg in grain.

Cyantraniliprole was the major residue in leaves sampled 56 days after treatment (49–57% TRR and about 0.2 mg/kg). The IN-J9Z38 metabolite was found in these samples at 16–22% TRR (about 0.08 mg/kg).

The major residue in straw was also cyantraniliprole (42–45% TRR, 0.13 mg/kg), with IN-J9Z38 (14–18% TRR) being the only significant metabolite, found at 14–18% TRR and in grain, cyantraniliprole accounted for 46–63% TRR (0.007–0.014 mg/kg).

In summary, cyantraniliprole was the predominant residue in most crop fractions at various sampling points up to crop maturity. Metabolites identified in foliar treated samples (with the exception of the photodegradate IN-NXX70) were also found in samples from plants treated with a soil drench application, indicating that the main metabolic pathways were similar. Overall, total radioactive residues were greater following foliar treatment than following soil application. A similar profile was observed in all studies.

The metabolite IN-J9Z38 was present at levels above 10% TRR only in rice foliage and lettuce (after foliar applications) and also in rice foliage and straw after soil treatment. Where present, residues were significantly lower (10–50%) than the levels of cyantraniliprole.

The metabolism of cyantraniliprole in plants was generally consistent with those in animals, except for the minor plant photodegradation pathway leading to the formation of IN-NXX70 and IN-QKV54).

Environmental fate

The Meeting received information on the environmental fate and behaviour of cyantraniliprole, including aerobic degradation in soil, photolysis on the soil surface, field soil dissipation, hydrolytic stability, soil and water/sediment degradation and confined and field rotational crop studies. Separate treatments of [CN-^{14}C]-cyantraniliprole and [PC-^{14}C]-cyantraniliprole were used in the confined studies.

Hydrolysis

Hydrolysis of cyantraniliprole was pH and temperature dependant. The rate of hydrolysis was significantly higher at high pH and temperature. The half lives at 15 °C decreased from 362 days (pH 4) to 126 days (pH 7) and was about 3 days at pH 9. A similar pattern was observed at the higher temperature of 35 °C, with the respective half-lives being 55 days, 7.5 days and < 1 day at pH 9. Under environmental conditions (pH 7, 25 °C) the half-life for cyantraniliprole was 212 days.

At all pH's, the predominant hydrolysis product was the cyclisation product IN-J9Z38 which accounted for about 28% AR (pH 4), 89% AR (pH 7) and 98% AR in the pH 9 samples.

Photolysis

In aqueous solutions, cyantraniliprole is rapidly degraded by photolysis. Half-lives in natural water and pH 4 sterile buffer exposed to continuous artificial sunlight for 15 days at 25 °C were 4–5 hours, with the formation of IN-NXX69, IN-NXX70, IN-QKV54 and IN-QKV55 as photodegradates. DT_{90s} were less than 16 hours.

In moist (non-sterile) soil (75% field capacity), treated with [^{14}C]-cyantraniliprole at the equivalent of 1 kg ai/ha parent residues decreased to about 1% AR after 30 days in the irradiated samples and to 33% AR in the non-irradiated samples. The IN-J9Z38 metabolite was the predominant residue (up to about 50% AR) with IN-RNU71 and IN-QKV54 also found at about 13–14% AR. Estimated photolysis DT_{50} and DT_{90} values for cyantraniliprole (derived from the difference in the degradation constants (k) for the irradiated and non-irraditaed samples) were 12 and 41 days respectively. Kinetic modeling suggested that nearly 34% of the cyantraniliprole in soil is degraded by photolysis and about 64% through soil degradation pathway.

Aerobic soil metabolism

Two studies were conducted in five soils (one loam soil, two silty clay loams, one silt loam and a sandy loam) with the equivalent of 0.4 kg ai/ha [CN-^{14}C]-cyantraniliprole or [PC-^{14}C]-cyantraniliprole. In these studies, the moist soils were incubated in the dark for up to a year at 20 °C or 22 °C.

Half-lives for cyantraniliprole were 9 days in the loam soil, 21–39 days in the silty clay loams, 44 days in the silty loam and 92 days in the sandy loam.

DT_{50} values for the seven major transformation products (average DT_{50} values in brackets) were: IN-JCZ38 (8 days), IN-K5A79 (64 days), IN-K5A77 (132 days), IN-J9Z38 (139 days), IN-JSE76 (410 days), IN-K5A78 (423 days) and IN-PLT97 (1032 days).

Soil dissipation

Ten field studies were conducted to investigate the degradation and mobility of cyantraniliprole under field conditions. In all of the trials a single application of 0.3 kg ai/ha or 0.45 kg ai/ha was made to bare soil in late spring or early summer and cropped soils were also treated in three of these studies. Soil samples were collected to a maximum depth of 90 cm, immediately prior to application and at pre-determined intervals over an 18 month period.

Cyantraniliprole was rapidly degraded in field soils with half-lives ranging from 17 to 51 days. While laboratory studies suggested that pH had some effect on degradation rates, degradation rate under field conditions does not appear to be pH-dependent. Downward mobility of the parent compound as well as its metabolites was limited, with residues rarely found below 15 cm. Soil metabolites formed in the bare soil treatments at levels greater than 10% of the initial soil concentration were IN-J9Z38 (max 42%), IN-K5A78 (max 17%), IN-JSE76 (max 14%), IN-JCZ38 (max 13%) and IN-K5A77 (max 11%). Lower metabolite levels were observed in soil from the cropped soil treatments, predominantly IN-J9Z38 (max 27%) and IN-JCZ38 (max 13%).

The mean temperature-normalized field DT_{50} value from all studies was 32 days, consistent with the mean laboratory derived value.

Water/sediment dissipation

Under anaerobic conditions, cyantraniliprole degraded in the water phase and also partitioned to the sediment where it was further degraded and incorporated into the sediment organic fraction. The major degradate was IN-J9Z38, present in the total system at up to 23–40% AR (0.09–0.16 ppm) during the first 28 days after treatment and declining to 5–7% AR (0.02–0.03 ppm) at the end of the study period (Day 100).

The aerobic degradation of [^{14}C]-cyantraniliprole was studied in a water/silt-loam system and a water/sand system treated with [PC-^{14}C]-cyantraniliprole at a rate of 0.5 µg ai/g and incubated outdoors for 14 days under natural sunlight at 23±2 °C.

In the water phase, cyantraniliprole residues were 1–2% AR at the end of the 14-day study period and in the sediment phase, after reaching maximum levels of 15–22% AR after 2–3 days, residues declined to 6–9% AR on Day 14.

One significant degradate, IN-J9Z38, was found in the surface water at a maximum of about 15–27% AR after 3–5 days and declining to 4.5% AR (silt-loam system) and 12% AR (sand system) at the end of the 14-day study period. In the sediment extracts residues of IN-J9Z38 increased from about 2% AR at Day 1 to about 42% AR at Day 14.

The calculated half-lives in the water/sediment systems were 3.5–4.4 days for cyantraniliprole and 40 days for the IN-J9Z38 metabolite.

Residues in succeeding crops

In two rotational crop metabolism studies using [PC-^{14}C]-cyantraniliprole or [CN-^{14}C]-cyantraniliprole, wheat, soya bean, lettuce and red beet were planted as rotational crops 25–30 and 120 days after a single bare soil application of 0.3 kg ai/ha in one study and 0.45 kg ai/ha in the second study. In the second study, after 365 days aging, a further planting of wheat was made in the 30-day rotation plots.

In the first rotation crops, total radioactive residues in food items ranged from 0.02–0.06 mg/kg in wheat grain, 0.08–0.11 mg/kg in lettuce, 0.02–0.03 mg/kg in beet roots and 0.04 mg/kg in soya bean seeds. Higher residues were seen in animal feed items; wheat hay and straw (0.97–1.6 mg/kg), soya bean foliage (0.19 mg/kg) and beet foliage (0.11 mg/kg).

The metabolic fates of cyantraniliprole in the three rotational crops were similar. Cyantraniliprole was the predominant residue in wheat straw and hay (41–53% TRR, 0.4–0.85 mg/kg), wheat grain (10–36% TRR, < 0.01–0.02 mg/kg), soya bean foliage (36% TRR, 0.07 mg/kg), red beet roots (21–27% TRR, < 0.01 mg/kg) and lettuce (60–69% TRR, 0.05–0.08 mg/kg). No cyantraniliprole was detected in soya bean seeds and parent residues in beet foliage were 3–4% TRR.

In food commodities, IN-MYX98 was the only significant metabolite present above 10% TRR, being found in 2nd rotation (120 day) lettuce leaves at 16% TRR but < 0.01 mg/kg. In animal feed commodities, IN-J9Z38 was found in wheat hay, forage and straw at up to 13% TRR (0.18 mg/kg) and IN-K7H19 was present in wheat hay and straw at 10–11% TRR (0.04–0.06 mg/kg) in the 365 day rotation crop.

Overall, the metabolism in rotational crops was consistent with metabolism seen in primary crops and in the animal studies.

Rotational crop field studies were conducted in Europe and North America to estimate residue uptake in follow crops. In two European studies, where spinach, lettuce, spring barley, oats,

soya bean and radish were planted into bare soil treated with 0.2 kg ai/ha or 0.45 kg ai/ha at plant-back intervals of 14, 30, 120, 270 and 365 days, with the exception of soya bean (seeds and forage) and radish tops, residues of cyantraniliprole and metabolites were not found in succeeding crops. In soya bean forage, residues of cyantraniliprole were 0.02–0.03 mg/kg and in soya bean seed, residues of the IN-N7B69 metabolite were < 0.01 mg/kg.

In five North American studies, bare soil was treated with 3 applications of cyantraniliprole at about 5 day intervals to achieve a total seasonal application rate of 0.45 kg ai/ha. In three of these studies, four rotational crops (lettuce/spinach, oats, radish and soya bean) were planted 14, 30, 120, and 365 days after the last application. In the other two studies, strawberries, turnip, sugar beet, garden beet, radish, carrot, bean, pea, soya bean, alfalfa, clover, field corn, sweet corn, sorghum, rice, wheat, Bermuda grass, brome grass, clover, bluegrass and peanut were planted 30 days after the last application.

Residues of cyantraniliprole and metabolites in the first rotation crops (30 day plant-back interval were below 0.05 mg/kg in commodities for human consumption (cereal grains, root crops, legumes and pulses, leafy vegetables). Higher residues were reported in animal feed commodities, up to 0.2 mg/kg in forage crops and 0.3 mg/kg in most hays and straws. Highest residues were found in soya bean hay, up to 0.63 mg/kg in one sample.

In the first rotation crops (30 day plant-back interval (PBI)), highest residues of cyantraniliprole were above 0.01 mg/kg in radish roots (0.02 mg/kg), radish and turnip tops (0.02–0.04 mg/kg), legume forages (0.02–0.14 mg/kg), legume hays (0.05–0.63 mg/kg), leafy vegetables (0.03 mg/kg), cereal forages (0.01–0.11 mg/kg), cereal hays and straws (0.07–0.21 mg/kg), forage grasses (0.01–0.09 mg/kg) and grass hays (0.02–0.23 mg/kg).

Metabolites present at more than 0.01 mg/kg were IN-J9Z38 (up to 0.03 mg/kg in cereal and legume hays and straws), IN-JZ38 (in cereal and legumes, up to 0.06 mg/kg hays and 0.03 mg/kg in forages) and IN-MLA84 (in legumes, up to 0.02 mg/kg in forage and 0.07 mg/kg in hays).

Methods of analysis

Several analytical methods have been reported for the analysis of cyantraniliprole and up to eight metabolites in plant and animal commodities. The basic approach employs extraction with acetonitrile/water and analysis by high pressure liquid chromatography with tandem mass spectrometry.

For plant and processed plant commodities, the HPLC-MS/MS method used in most of the supervised residue field trials, was validated for the analysis of cyantraniliprole and its metabolites (IN-N7B69, IN-JCZ38, IN-K7H19, IN-MYX98, IN-MLA84 and IN-J9Z38) in a range of representative matrices. The LOQ is 0.01 mg/kg for each analyte. Adequate extraction efficiencies were demonstrated in plant matrices using radiolabelled samples from metabolism and confined rotational crop studies.

For animal commodities, the HPLC-MS/MS method was validated for the analysis of cyantraniliprole, IN-HGW87, IN-N7B69, IN-K7H19, IN-JCZ38, IN-MYX98, IN-J9Z38 and IN-MLA84 in livestock tissues, milk and eggs. After extraction with acetonitrile, extracts are partitioned against hexane before SPE clean-up and analysis. The LOQ is 0.01 mg/kg for each analyte. The method was validated by an independent laboratory using kidney, muscle, and milk. The extraction efficiency was successfully demonstrated with samples of liver, muscle, milk, egg white, and egg yolk from livestock metabolism studies.

The DFG S19 multi-residue method with LC-MS/MS analysis was validated for the analysis of cyantraniliprole residues in tomato (representing high water content), orange (high acid content), wheat grain (high starch content) and almond (high oil content), and is suitable as an enforcement method for cyantraniliprole in plant commodities. It was also validated in milk, eggs, meat and liver as being a suitable enforcement method for cyantraniliprole residues in animal commodities.

The US-FDA PAM multi-residue methods were shown to be unsuitable for the detection and enforcement of cyantraniliprole and metabolites (Protocols A through F).

Stability of pesticide residues in stored analytical samples

Freezer storage stability of cyantraniliprole and metabolites IN-F6L99, IN-J9Z38, IN-JCZ38, IN-K7H19, IN-MLA84, IN-MYX98, IN-N5M09 and IN-N7B69 was investigated in five representative commodities: apples (high-water content), grapes (high-acid content), potatoes (high-starch content), dry bean seeds (high-protein content), and peanuts (high-oil content).

Residues were shown to be stable in these representative substrates for at least 24 months in frozen storage, with residues in the stored samples being greater than 80% of the spiked levels except in peanuts (high oil content), where reduced recoveries were observed at all storage intervals for the metabolites IN-JCZ38, IN-K7H19 and IN-N7B69.

Definition of the residue

In animal commodities, the predominant residues identified in the metabolism studies were cyantraniliprole, IN-J9Z38, IN-MLA84, IN-N7B69 and IN-MYX98. Where residues were found in animal tissues in the metabolism studies or the feeding studies, cyantraniliprole was the major or a significant component. Noting that a multi-residue method was available to measure cyantraniliprole in animal commodities, the Meeting agreed that for MRL-compliance, the residue definition for animal commodities should be cyantraniliprole.

The compound cyantraniliprole has a log K_{ow} of 1.9, suggesting that it is not fat soluble, and this is supported by the residue distribution in muscle and fat reported in a cow feeding study, where the residues in fat were generally only about 2-fold higher than in muscle. The Meeting therefore concluded that cyantraniliprole is not fat soluble.

For dietary intake estimation, in addition to the parent compound, metabolites found at significant levels in the animal metabolism studies were IN-N7B69 (milk), IN-MYX98 (muscle and milk), IN-J9Z38 (fat and eggs) and IN-MLA84 (eggs). In the feeding studies, at doses that reflect the expected animal burden, these individual metabolites were also found at levels ranging from about 20% to 100% of the parent concentrations in different matrices but when combined, were generally found at levels close to those of the parent.

IN-N7B69 was found in milk at a level equivalent to parent and at about half the parent concentration in kidney. IN-J9Z38 was present in eggs at about 50% parent concentration. IN-MLA84 was found in cattle liver at about 60% of the parent concentration and in eggs at about 50% parent concentration. IN-MYX98, found in eggs at about 20% parent and in poultry liver at about 135% of parent.

These metabolites also occur in rats, are not considered more toxic than the parent compound, are adequately covered in the derived toxicological reference dose and a validated HPLC-MS/MS method is available to analyse for them.

The Meeting agreed that while not all of these metabolites would occur in all tissues; these four metabolites (IN-N7B69, IN-J9Z38, IN-MLA84 and IN-MYX98) should be included in the residue definition for dietary intake estimation for animal commodities. The Meeting considered that if animal commodities were analysed only for cyantraniliprole, a conservative correction factor of 2 could be applied for the purpose of dietary intake estimation to account for these metabolites.

In plant commodities from treated crops, the metabolism studies indicated that cyantraniliprole was the major residue in rice, lettuce, cotton and tomato. In rotational crops, where residues are present, cyantraniliprole is also the main residue in food commodities. The Meeting noted that a multi-residue method exists to measure parent residues and agreed that for MRL-compliance, the residue definition for plant commodities should be cyantraniliprole.

The only metabolite identified in the plant metabolism studies at more than 10% TRR or greater than 0.01 mg/kg in commodities at harvest was IN-J9Z38, reported in leaves from foliar-treated rice (11% TRR and 0.13 mg/kg), rice straw from rice grown in treated soil (up to 18% TRR and 0.05 mg/kg) and in foliar-treated lettuce where residues of 23% TRR (0.01 mg/kg) were measured in mature leaves from seedling plants treated up to 32 days before sampling. The Meeting noted that in the supervised field trials, residues of IN-J9Z38 were also reported in some trials, but mostly < 0.01 mg/kg and rarely found at levels more than 10% of the cyantraniliprole residue.

In rotational crops, metabolite residues in food commodities did not exceed 0.01 mg/kg, with IN-J9Z38, IN-JZ38 and IN-MLA84 only present in animal feeds (cereal and legume forage, hays and straws) at up to 0.07 mg/kg.

In processed food commodities, metabolites IN-J9Z38 and to a lesser extent IN-N5M09 and IN-F6L99 were formed under conditions of heat and/or hydrolysis. In addition to cyantraniliprole, only IN-J9Z38 was observed at significant levels, being the predominant residue in cooked spinach, cottonseed oil and present at more than 50% of the parent levels in tomato paste, apple sauce and canned olives. IN-N5M09 and IN-F6L99 were only quantifiable in a few processed food commodities (e.g., cooked spinach, apple sauce) and were much lower than the levels of the parent compound and IN-J9Z38.

The main metabolite in some processed commodities (IN-J9Z38) was also observed in the animal metabolism studies and the toxicology of IN-J9Z38 is addressed in the rat studies and covered by the derived reference dose. Sufficient toxicological information is available to confirm that the IN-J9Z38 metabolite is no more toxic than cyantraniliprole and analytical methods are available to measure this metabolite.

The Meeting concluded that for dietary intake risk assessment, the residue definition for plant commodities should be cyantraniliprole but that for processed commodities, the IN-J9Z38 should also be included.

Proposed definition of the residue (for compliance with the MRL, animal and plant commodities*): cyantraniliprole*.

Proposed definition of the residue (for estimation of dietary intake for unprocessed plant commodities): *cyantraniliprole*.

Proposed definition of the residue (for estimation of dietary intake for processed plant commodities): *sum of cyantraniliprole and IN-J9Z38, expressed as cyantraniliprole*.

Proposed definition of the residue (for estimation of dietary intake for animal commodities: *sum of cyantraniliprole, 2-[3-Bromo-1-(3-chloro-2-pyridinyl)-1H-pyrazol-5-yl]-3,4-dihydro-3,8-dimethyl-4-oxo-6-quinazolinecarbonitrile [IN-J9Z38], 2-[3-Bromo-1-(3-chloro-2-pyridinyl)-1H-pyrazol-5-yl]-1,4-dihydro-8-methyl-4-oxo-6-quinazolinecarbonitrile [IN-MLA84], 3-Bromo-1-(3-chloro-2-pyridinyl)-N-[4-cyano-2-(hydroxymethyl)-6-[(methylamino)carbonyl]phenyl]-1H-pyrazole-5-carboxamide [IN- N7B69] and 3-Bromo-1-(3-chloro-2-pyridinyl)-N-[4-cyano-2[[(hydroxymethyl)amino]carbonyl]-6-methylphenyl]-1H-pyrazole-5-carboxamide [IN- MYX98], expressed a cyantraniliprole*.

The residue is not fat soluble.

Results of supervised residue trials on crops

The Meeting received supervised trial data for foliar and soil applications of cyantraniliprole on a range of fruit and vegetable crops, rice, tree nuts, oilseeds and coffee and for seed treatments (potatoes, oil-seed rape). 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 cyantraniliprole and that product labels were available from Canada, Columbia, New Zealand Malaysia, Vietnam and from a regional group of countries in West Africa. Supervised trial data were provided for citrus, grapes, olives, pomegranate, beans and sunflower, but no GAP information was available to support maximum residue level estimations for these commodities.

Pome fruits

The critical GAP for cyantraniliprole on pome fruit is in Canada, up to 4 foliar applications of 0.05–0.15 kg ai/ha applied at least 7 days apart with a PHI of 3 days and with a total of 0.45 kg ai/ha/season.

In trials on apples in North America matching the Canadian GAP (with 3 applications of 0.15 kg ai/ha, 0.45 kg ai/ha/season), cyantraniliprole residues were: 0.06, 0.07, 0.1, 0.12, 0.13, 0.13, 0.15, 0.15, 0.16, 0.17, 0.18, 0.21, 0.26, 0.26, 0.29 and 0.31 mg/kg (n=16).

In trials on pears in North America matching the Canadian GAP (with 3 applications of 0.15 kg ai/ha, 0.45 kg ai/ha/season), cyantraniliprole residues were: 0.08, 0.1, 0.12, 0.14, 0.16, 0.23, 0.42, 0.44, 0.56 and 0.58 mg/kg (n=10).

The Meeting noted that the GAP in Canada was for pome fruit and that the medians of the two data sets differed by less than 5-fold and agreed to consider a group maximum residue level. As the Mann-Whitney U-test indicated that the residue populations for apples and pears were not different it was agreed to combine the results to give a data set of: 0.06, 0.07, 0.08, 0.1, 0.1, 0.12, 0.12, 0.13, 0.13, 0.14, 0.15, 0.15, 0.16, 0.16, 0.17, 0.18, 0.21, 0.23, 0.26, 0.26, 0.29, 0.31, 0.42, 0.44, 0.56 and 0.58 mg/kg (n=26) for the pome fruit crop group.

The Meeting estimated an STMR of 0.16 mg/kg and a group maximum residue level of 0.8 mg/kg for cyantraniliprole on pome fruit.

Stone fruits

The critical GAP for cyantraniliprole on stone fruit is in Canada, up to 4 foliar applications of 0.05–0.15 kg ai/ha with a total of 0.45 kg ai/ha/season, applied at least 7 days apart with a PHI of 3 days.

In trials on cherries in North America matching the Canadian GAP (with 3 applications of 0.15 kg ai/ha, 0.45 kg ai/ha/season), cyantraniliprole residues in whole fruit were: 0.3, 0.32, 0.7, 0.8, 0.89, 0.9 and 3.4 mg/kg (n=7). In flesh residues were: 0.33, 0.36, 0.89, 0.93, 0.96, 0.98 and 3.8 mg/kg (n=7).

In trials on peaches in North America matching the Canadian GAP (with 3 applications of 0.15 kg ai/ha, 0.45 kg ai/ha/season), cyantraniliprole residues were: 0.16, 0.18, 0.19, 0.19, 0.23, 0.24, 0.28, 0.34, 0.39, 0.45, 0.51, 0.79 and 0.81 mg/kg. In flesh, residues were: 0.19, 0.19, 0.2, 0.23, 0.25, 0.27, 0.34, 0.35, 0.42, 0.49, 0.56, 0.89 and 0.94 mg/kg (n=13).

In trials on plums in North America matching the Canadian GAP (with 3 applications of 0.15 kg ai/ha, 0.45 kg ai/ha/season), cyantraniliprole residues were: 0.03, 0.05, 0.06, 0.06, 0.06, 0.07, 0.12, 0.19 and 0.28 mg/kg. In flesh, residues were: 0.03, 0.05, 0.06, 0.06, 0.07, 0.07, 0.13, 0.2 and 0.29 mg/kg (n=9).

The Meeting noted that the GAP in Canada was for stone fruit and that the medians of the data sets for cherries, peaches and plums differed more than 5-fold and agreed not to consider a group maximum residue level for stone fruit.

The Meeting estimated an STMR of 0.93 mg/kg (based on residues in flesh), and based on residues in the whole fruit, estimated a subgroup maximum residue level of 6 mg/kg for cyantraniliprole on cherries.

The Meeting estimated an STMR of 0.34 mg/kg (based on residues in flesh, and based on residues in the whole fruit, estimated a subgroup maximum residue level of 1.5 mg/kg for cyantraniliprole on peaches.

The Meeting estimated an STMR of 0.07 mg/kg (based on residues in flesh) and based on residues in the whole fruit, estimated a subgroup maximum residue level of 0.5 mg/kg for cyantraniliprole on plums.

Bush berries

The critical GAP for cyantraniliprole on bush berries is in Canada, up to 4 foliar applications of 0.05–0.15 kg ai/ha with a total of 0.45 kg ai/ha/season, applied at least 7 days apart with a PHI of 3 days.

In trials on blueberries in North America matching the Canadian GAP (with 3 applications of 0.15 kg ai/ha, 0.45 kg ai/ha/season), cyantraniliprole residues were: 0.42, 0.51, 0.52, 0.52, 0.75, 0.8, 1.5, 1.5 and 2.0 mg/kg (n=9).

The Meeting noted that blueberry can be used as a representative crop for bush berries and estimated an STMR of 0.75 mg/kg and a subgroup maximum residue level of 4.0 mg/kg for cyantraniliprole on bush berries.

Bulb vegetables

The critical GAP for cyantraniliprole on bulb vegetables is in Canada, up to 4 foliar applications of 0.1–0.15 kg ai/ha with a total of 0.45 kg ai/ha/season, applied at least 5 days apart with a PHI of 1 day.

In trials on bulb onions in North America matching the Canadian GAP (with 3 applications of 0.15 kg ai/ha, 0.45 kg ai/ha/season), cyantraniliprole residues were: < 0.01, < 0.01, < 0.01, < 0.01, 0.01, 0.02, 0.02, 0.02, 0.02 and 0.03 mg/kg (n=10).

The Meeting noted that the GAP in Canada also includes use on garlic and shallot and agreed to extrapolate the data for bulb onions to these commodities.

The Meeting estimated an STMR of 0.02 mg/kg and a maximum residue level of 0.05 mg/kg for cyantraniliprole on onion, bulb, garlic and shallot.

In trials on spring onions (green onions) in North America matching the Canadian GAP (with 3 applications of 0.15 kg ai/ha, 0.45 kg ai/ha/season), cyantraniliprole residues were: 0.38, 0.63, 1.3, 1.6 and 4.1 mg/kg (n=5).

The Meeting noted that the GAP in Canada also includes use Welsh onion and agreed to extrapolate the data for spring onions to onion, Welsh.

The Meeting estimated an STMR of 1.3 mg/kg and a maximum residue level of 8.0 mg/kg for cyantraniliprole on spring onion and onion, Welsh.

Brassica (cole or cabbage) vegetables

The critical GAP for cyantraniliprole on brassica vegetables is in Canada, up to 4 foliar applications of 0.025–0.15 kg ai/ha with a total of 0.45 kg ai/ha/season, applied at least 5–7 days apart with a PHI of 1 day.

In trials on broccoli in North America matching the critical Canadian GAP (with 3 applications of 0.15 kg ai/ha, 0.45 kg ai/ha/season), cyantraniliprole residues were: 0.22, 0.28, 0.51, 0.59, 0.61, 0.69, 0.82 and 1.1 mg/kg (n=8).

In trials on cauliflowers in North America matching the critical Canadian GAP (with 3 applications of 0.15 kg ai/ha, 0.45 kg ai/ha/season), cyantraniliprole residues in the flower heads were: 0.01 and 0.08 mg/kg (n=2).

In trials on head cabbage in North America matching the critical Canadian GAP (with 3 applications of 0.15 kg ai/ha, 0.45 kg ai/ha/season), cyantraniliprole residues in cabbages (with wrapper leaves) were: 0.29, 0.32, 0.32, 0.42, 0.47, 0.56, 0.57, 0.65, 0.71, 0.86 and 0.95 mg/kg (n=11).

The Meeting noted that the GAP in Canada was for brassica vegetables and that the medians of the data sets for broccoli and cabbage differed by less than 5-fold (insufficient data on cauliflower) and agreed to consider a group maximum residue level. 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 broccoli and cabbage were not different, it was agreed to combine the results to give a data set of: 0.01, 0.08, 0.22, 0.28, 0.29, 0.32, 0.32, 0.42, 0.47, 0.51, 0.56, 0.57, 0.59, 0.61, 0.65, 0.69, 0.71, 0.82, 0.86, 0.95 and 1.1 mg/kg (n=21) for brassica vegetables.

The Meeting estimated an STMR of 0.56 mg/kg and a group maximum residue level of 2.0 mg/kg for cyantraniliprole on brassica (cole or cabbage) vegetables. The Meeting also estimated a highest residue of 1.1 mg/kg for calculating animal dietary burdens.

Fruiting vegetables, Cucurbits

The critical GAP for cyantraniliprole on cucurbit vegetables is in Canada, up to 4 foliar applications of 0.025–0.15 kg ai/ha with a total of 0.45 kg ai/ha/season, applied at least 5–7 days apart with a PHI of 1 day.

In trials on cucumber in North America matching the GAP of Canada (with 3 applications of 0.15 kg ai/ha, 0.45 kg ai/ha/season), cyantraniliprole residues were: 0.02, 0.02, 0.02, 0.03, 0.04, 0.05, 0.05, 0.07, 0.12 and 0.16 mg/kg (n=10).

In trials on summer squash in North America matching the critical Canadian GAP (with 3 applications of 0.15 kg ai/ha, 0.45 kg ai/ha/season), cyantraniliprole residues were: 0.01, 0.03, 0.04, 0.05, 0.06, 0.07, 0.08, 0.09 and 0.11 mg/kg (n=9).

In trials on melons in North America matching the critical Canadian GAP (with 3 applications of 0.15 kg ai/ha, 0.45 kg ai/ha/season), cyantraniliprole residues were: 0.04, 0.05, 0.08, 0.09, 0.09, 0.1, 0.11, 0.15 and 0.17 mg/kg (n=9). In these trials, cyantraniliprole residues in the melon edible portion were all < 0.01 (n=9)

The Meeting noted that the GAP in Canada was for cucurbit vegetables and that the medians of the data sets for cucumber, summer squash and melons differed by less than 5-fold and agreed to consider a group maximum residue level. In deciding on the data set to use for estimating a group maximum residue level, since a Kruskal-Wallis H-test indicated that the residue populations for cucumber, summer squash and melons were not different, it was agreed to combine the results to give a data set of: 0.01, 0.02, 0.02, 0.02, 0.03, 0.03, 0.04, 0.04, 0.04, 0.05, 0.05, 0.05, 0.05, 0.06, 0.07, 0.07, 0.08, 0.08, 0.09, 0.09, 0.09, 0.1, 0.11, 0.11, 0.12, 0.15, 0.16 and 0.17 mg/kg (n=28) for cucurbit vegetables.

The Meeting estimated an STMR of 0.01 mg/kg for cucurbits with an inedible peel (based on the melon data on residues in flesh), an STMR of 0.065 mg/kg (based on the summer squash data) for cucurbits with an edible peel and a group maximum residue level of 0.3 mg/kg for cyantraniliprole on fruiting vegetables, Cucurbits.

Fruiting vegetables, other than Cucurbits

The critical GAP for cyantraniliprole on fruiting vegetables (except cucurbits) is in Canada, up to 4 foliar applications of 0.025–0.15 kg ai/ha with a total of 0.45 kg ai/ha/season, applied at least 5–7 days apart with a PHI of 1 day.

In trials on tomatoes in North America matching the critical Canadian GAP (with 3 applications of 0.15 kg ai/ha, 0.45 kg ai/ha/season), cyantraniliprole residues were: 0.04, 0.05, 0.06, 0.06, 0.07, 0.07, 0.07, 0.07, 0.08, 0.08, 0.08, 0.09, 0.09, 0.1, 0.12, 0.14, 0.14, 0.16, 0.17 and 0.26 mg/kg (n=20).

In trials on sweet peppers in North America matching the critical Canadian GAP (with 3 applications of 0.15 kg ai/ha, 0.45 kg ai/ha/season), cyantraniliprole residues were: 0.03, 0.04, 0.06, 0.07, 0.07, 0.08, 0.08, 0.15, 0.21, 0.24 and 0.28 mg/kg (n=11).

In trials on chili peppers (non-bell peppers) in North America matching the critical Canadian GAP (with 3 applications of 0.15 kg ai/ha, 0.45 kg ai/ha/season), cyantraniliprole residues were: 0.07, 0.07, 0.08, 0.09, 0.1, 0.2, 0.25, 0.31 and 0.42 mg/kg (n=9).

The Meeting noted that the GAP in Canada was for fruiting vegetables (except cucurbits) and that the medians of the data sets for sweet peppers, tomatoes and chili peppers differed by less than 5-fold and agreed to consider a group maximum residue level. In deciding on the data set to use for estimating a group maximum residue level, since a Kruskal-Wallis H-test indicated that the residue populations for sweet peppers, tomatoes and chili peppers were not different, it was agreed to combine the results to give a data set of: 0.03, 0.04, 0.04, 0.05, 0.06, 0.06, 0.06, 0.07, 0.07, 0.07, 0.07, 0.07, 0.07, 0.07, 0.07, 0.08, 0.08, 0.08, 0.08, 0.08, 0.08, 0.09, 0.09, 0.09, 0.1, 0.1, 0.12, 0.14, 0.14, 0.15, 0.16, 0.17, 0.2, 0.21, 0.24, 0.25, 0.26, 0.28, 0.31 and 0.42 mg/kg (n=40) for the non-cucurbit fruiting vegetables group.

The Meeting estimated an STMR of 0.08 mg/kg and a group maximum residue level of 0.5 mg/kg for cyantraniliprole on fruiting vegetables, other than Cucurbits (excluding sweet corn and mushrooms).

For dried chili peppers, applying the default processing factor of 7 to the data set for fresh chili peppers, the Meeting estimated an STMR-P of 0.7 mg/kg and a maximum residue level of 5 mg/kg for cyantraniliprole on dried chili peppers.

Leafy vegetables (including Brassica leafy vegetables)

The critical GAP for cyantraniliprole on leafy vegetables is in Canada, up to 4 foliar applications of 0.025–0.15 kg ai/ha with a total of 0.45 kg ai/ha/season, applied at least 5–7 days apart with a PHI of 1 day.

In trials on head lettuce in North America matching the critical Canadian GAP (with 3 applications of 0.15 kg ai/ha, 0.45 kg ai/ha/season), cyantraniliprole residues were: 0.02, 0.08, 0.16, 0.18, 0.64, 0.75, 0.83, 1.3, 1.6, 1.8, 2.1 and 2.7 mg/kg (n=12).

In trials on leaf lettuce in North America matching the critical Canadian GAP (with 3 applications of 0.15 kg ai/ha, 0.45 kg ai/ha/season), cyantraniliprole residues were: 1.1, 1.2, 2.1, 2.4, 2.4, 2.5, 3.2, 3.3, 4.0, 5.3, 6.8 and 6.8 mg/kg (n=12).

In trials on spinach in North America matching the critical Canadian GAP (with 3 applications of 0.15 kg ai/ha, 0.45 kg ai/ha/season), cyantraniliprole residues were: 3.8, 4.1, 4.2, 4.6, 4.7, 4.9, 5.8, 8.2, 10 and 13 mg/kg (n=10).

In trials on mustard greens in North America matching the critical Canadian GAP for vegetable brassicas (with 3 applications of 0.15 kg ai/ha, 0.45 kg ai/ha/season), cyantraniliprole residues were: 2.4, 3.4, 3.9, 5.5, 5.8, 6.0, 7.1, 7.2, 8.0, 13 and 19 mg/kg (n=11).

The Meeting noted that the GAP in Canada was for leafy vegetables and that the medians of the data sets for leaf lettuce, spinach and mustard greens (but not head lettuce) differed by less than 5-fold and agreed to consider a group maximum residue level for leafy vegetables except head lettuce. In deciding on the data set to use for estimating a group maximum residue level, since a Kruskal-Wallis H-test indicated that the residue populations for leaf lettuce, spinach and mustard greens were not different it was agreed to combine the results to give a data set of: 1.1, 1.2, 2.1, 2.4,

2.4, 2.4, 2.5, 3.2, 3.3, 3.4, 3.8, 3.9, 4.0, 4.1, 4.2, 4.6, 4.7, 4.9, 5.3, 5.5, 5.8, 5.8, 6.0, 6.8, 6.8, 7.1, 7.2, 8.0, 8.2, 10, 13, 13 and 19 mg/kg for leafy vegetables (n=33) except head lettuce and to use the head lettuce data to estimate a maximum residue level for head lettuce.

The Meeting estimated an STMR of 4.7 mg/kg and a group maximum residue level of 20 mg/kg for cyantraniliprole on leafy vegetables (except head lettuce).

The Meeting estimated an STMR of 0.79 mg/kg and a maximum residue level of 5 mg/kg for cyantraniliprole on head lettuce.

Root and tuber vegetables

The critical GAP for cyantraniliprole on root and tuber vegetables is in Canada, up to 4 foliar applications of 0.05–0.15 kg ai/ha with a total of 0.45 kg ai/ha/season, applied at least 5–14 days apart with a PHI of 7 days.

In trials on potatoes in North America matching the critical Canadian GAP for foliar applications to root and tuber vegetables (with 3 applications of 0.15 kg ai/ha, 0.45 kg ai/ha/season), cyantraniliprole residues were: < 0.01, < 0.01, < 0.01, < 0.01, < 0.01, < 0.01, < 0.01, < 0.01, < 0.01, < 0.01, < 0.01, < 0.01, < 0.01, < 0.01, < 0.01, < 0.01, 0.01, 0.02, 0.02 and 0.03 mg/kg (n=20).

The Meeting also noted that residues of cyantraniliprole may also arise in potatoes planted as rotational crops, and agreed to consider maximum residue level recommendations for potatoes when discussing rotational crop residues.

Stalk and stem vegetables

The critical GAP for cyantraniliprole on celery is in Canada, up to 4 foliar applications of 0.025–0.15 kg ai/ha with a total of 0.45 kg ai/ha/season, applied at least 5–7 days apart with a PHI of 1 day.

In trials on celery in North America matching the critical Canadian GAP for leafy vegetables (including celery), with 3 applications of 0.15 kg ai/ha, 0.45 kg ai/ha/season, cyantraniliprole residues were: 0.28, 0.73, 1.0, 1.1, 1.2, 2.0, 2.3, 2.5, 4.7, 5.7 and 9.1 mg/kg (n=11).

The Meeting estimated an STMR of 2.0 mg/kg and a maximum residue level of 15 mg/kg for cyantraniliprole on celery.

Rice

The critical GAP for cyantraniliprole on rice is in Vietnam, for foliar applications of 0.05–0.1 kg ai/ha with a PHI of 5 days.

Results were available from six trials on rice in China where three foliar applications of cyantraniliprole were applied up to 7 days before harvest.

The Meeting agreed that these data did not match the GAP in Vietnam in that the PHI deviated from GAP by more than 25%.

Tree nuts

The critical GAP for cyantraniliprole on tree nuts is in Canada, up to 4 foliar applications of 0.05–0.1 kg ai/ha with a total of 0.45 kg ai/ha/season, applied at least 7 days apart with a PHI of 5 days.

In six trials on almonds in USA, 3 foliar sprays of 0.15 kg ai/ha (0.45 kg ai/ha/season) were applied at 6–8 day intervals up to 5 days before harvest.

In six trials on pecans in USA, 3 foliar sprays of 0.15 kg ai/ha (0.45 kg ai/ha/season) were applied at 6–8 day intervals up to 5 days before harvest.

The Meeting noted that since both the number of applications and the treatment rates in the trials for almonds and pecans did not match the Canadian GAP, the use of the proportionality approach to estimate maximum residue levels was not appropriate.

Oilseeds

The critical GAP for cyantraniliprole on cotton is in the region of West Africa, up to 3 foliar applications of 0.05 kg ai/ha with a total of 0.15 kg ai/ha/season, applied at least 14 days apart with a PHI of 7 days.

Results were available from trials conducted in USA on cotton, where three foliar applications of 0.15 kg ai/ha cyantraniliprole were applied at 6–8 day intervals up to 7–9 days before harvest.

The Meeting noted that the application rates used in the USA trials were higher and the retreatment intervals were shorter than the GAP in West Africa and the Meeting agreed that the concept of proportionality could not be used to recommend a maximum residue level for cyantraniliprole on cotton seed.

The critical GAP for cyantraniliprole on oil seed crops (excluding cotton and peanut) is in Canada, up to 4 foliar applications of 0.025–0.1 kg ai/ha with a total of 0.11 kg ai/ha/season, applied at least 7 days apart with a PHI of 7 days.

Results were available from trials on oilseed rape and on sunflower in North America, where 3 foliar sprays of 0.15 kg ai/ha (0.45 kg ai/ha/season) were applied at 5–9 day intervals up to 7 days before harvest.

The Meeting noted that for both oilseed rape and sunflower, in addition to the application rate in the field trials differing from the Canadian GAP, the lower seasonal application rate associated with the Canadian GAP supports only a single application of the maximum recommended application rate of 0.1 kg ai/ha, compared to the three applications used in the field trials.

The Meeting concluded that these trials did not match the Canadian GAP.

Seed for beverages and sweets

The critical GAP for cyantraniliprole on coffee is in Columbia, one foliar application of 2.5–3.5 g ai/5 litres/100 trees, equivalent to 0.125–0.175 kg ai/ha with a total of 0.3 kg ai/ha/season, with a PHI of 28 days.

In two Brazilian trials matching the Columbian GAP, cyantraniliprole residues were < 0.01 and 0.02 mg/kg.

The Meeting noted that in a further six trials in Brazil involving foliar applications that matched the Columbian GAP but where two soil drenches (0.01–0.06 g ai/100 ml/plant to achieve the equivalent of 0.2 kg ai/ha/treatment) were also applied approximately 90 and approximately 120 days before harvest, cyantraniliprole residues were < 0.01 (5) and 0.01 mg/kg.

The Meeting agreed that since the early season soil drench treatments did not appear to contribute to the final residue in coffee beans, the data from these two sets of results could be combined, giving a data set of: < 0.01, < 0.01, < 0.01, < 0.01, < 0.01, < 0.01, 0.01 and 0.02 mg/kg, to recommend a maximum residue level for cyantraniliprole on coffee beans.

The Meeting estimated an STMR of 0.01 mg/kg and a maximum residue level of 0.03 mg/kg for cyantraniliprole on coffee bean.

Estimation of residues in plant commodities grown as potential succeeding crops

Residues of cyantraniliprole, while not persistent, can be taken up by following crops. In Canada, the GAP includes a maximum seasonal foliar application rate of 0.45 kg ai/ha for most crops except oil seeds where the maximum seasonal rate is 0.11 kg ai/ha. In Columbia, the maximum seasonal rate for onions and Welsh onions is 0.3 kg ai/ha and in West Africa, the total seasonal rate on cotton is 0.15 kg ai/ha.

In Canada, recommended plant-back intervals (PBIs) have been established for crops likely to be grown in rotation with treated crops. In general, for annual crops for human consumption and where MRLs have been established, there is no plant-back interval specified, but for crops likely to be used as animal feed (cereals, grasses, legumes etc) the label recommends a 30-day plant-back interval.

Field rotational crop studies conducted in USA on a range of representative crops, involving treatment rates equivalent a 0.45 kg ai/ha maximum seasonal rate to bare soil, reported cyantraniliprole residues of less than 0.05 mg/kg in representative food commodities and higher residues in animal feed commodities.

The Meeting agreed that the results of the USA field rotational crop studies, in particular the cyantraniliprole residues reported from the 30 day PBI crops, could be used to estimate residues in follow crops.

Leafy vegetables (including Brassica leafy vegetables)

Highest cyantraniliprole residues in rotational leafy vegetables were < 0.01 mg/kg in spinach and beet tops, 0.02 mg/kg in lettuce and turnip tops and 0.04 mg/kg in radish tops. These levels are adequately covered by the recommendations for leafy vegetables.

Root and tuber vegetables

Cyantraniliprole residues in rotational root and tuber vegetables ranged from < 0.01 to 0.014 mg/kg (n=29, median < 0.01 mg/kg) in beet roots, turnip roots, carrot roots and radish roots.

The Meeting agreed to use the data from 20 field trials on potatoes in North America, treated according to the Canadian GAP for root and tuber vegetables (residues in tubers ranging from < 0.01 to 0.03 mg/kg, STMR 0.01 mg/kg, n=20) and the results of the rotational crop studies on root and tuber vegetables to recommend a group maximum residue level for potatoes (to accommodate residues in follow-crop potatoes that may also be treated with cyantraniliprole).

The Meeting established a maximum residue level of 0.05 mg/kg, a highest residue of 0.044 mg/kg (for estimating animal dietary burdens) and a median residue of 0.02 mg/kg for cyantraniliprole on potato.

The Meeting also agreed to use the rotational crop studies on root and tuber vegetables to recommend a group maximum residue level for the remaining root and tuber vegetables to accommodate residues in these crops grown as follow-crops.

The Meeting established a maximum residue level of 0.05 mg/kg, a highest residue of 0.014 mg/kg and a median residue of 0.01 mg/kg for cyantraniliprole on root and tuber vegetables except potato.

Miscellaneous fodder root crops

The Meeting also agreed to use the results of the rotational crop studies on root and tuber vegetables (residues ranging from < 0.01 to 0.014 mg/kg, median < 0.01 mg/kg, n=29) to recommend maximum residue levels for turnips and fodder beet to accommodate residues in these crops grown as follow-crops.

The Meeting established a maximum residue level of 0.02 mg/kg, a highest residue of 0.014 mg/kg and a median residue of 0.01 mg/kg for cyantraniliprole on fodder beet and turnip fodder.

Legume animal feeds

Cyantraniliprole residues in legume animal feeds (forage) ranged from < 0.01 to 0.14 mg/kg (n=24, median < 0.01 mg/kg) in clover forage, bean forage, pea forage, alfalfa forage and soya bean forage. For the purpose of estimating livestock dietary burdens, the Meeting agreed to combine the data on rotational crop residues in legume animal feeds to estimate residues in legume feed crops grown as follow-crops.

Meeting estimated a median residue of 0.01 mg/kg and a highest residue of 0.14 mg/kg for cyantraniliprole in legume forages (fresh weight).

Cyantraniliprole residues in legume animal feeds (fodders) ranged from < 0.01 to 0.58 mg/kg (n=24, median 0.017 mg/kg) in peanut hay, clover hay, pea hay, bean, alfalfa hay and soya bean hay. The Meeting agreed to combine the data on rotational crop residues in legume fodder crops to recommend a group maximum residue level to accommodate residues in these crops grown as follow-crops.

The Meeting established a median residue of 0.017 mg/kg and a highest residue of 0.58 mg/kg (0.67 mg/kg DM after correction for an average dry matter content of 87%) and recommended a maximum residue level of 0.8 mg/kg (dry weight) for cyantraniliprole in legume animal feeds.

Cereal and grass forages, straws and hays

Cyantraniliprole residues in cereal and grass forage ranged from < 0.01 to 0.053 mg/kg (n=23, median < 0.01 mg/kg) in corn forage, sorghum, Bermuda grass and brome grass forages, oat forage, bluegrass forage and wheat forage. For the purpose of estimating livestock dietary burdens, the Meeting agreed to combine the data on rotational crop residues in cereal and grass forages to estimate residues in cereal and grasses grown as follow-crops.

Meeting established an STMR of 0.01 mg/kg and a highest residue of 0.053 mg/kg for cyantraniliprole in cereal and grass forages (fresh weight).

Cyantraniliprole residues in cereal and grass straws and hays ranged from < 0.01 to 0.14 mg/kg (median < 0.01 mg/kg) in sorghum stover, rice straw, corn stover, brome grass hay, Bermuda grass hay, oat straw, wheat straw, oat hay, wheat hay bluegrass hay. The Meeting agreed to combine the data on rotational crop residues in cereal and grass straws and hays to recommend a group maximum residue level to accommodate residues in these crops grown as follow-crops.

The Meeting established a median residue of 0.01 mg/kg and a highest residue of 0.14 mg/kg (0.16 mg/kg DM after correction for an average dry matter content of 89%) and recommended a maximum residue level of 0.2 mg/kg (dry weight) for cyantraniliprole in straw, fodder (dry) and hay of cereal grains and other grass-like plants.

Miscellaneous fodder leaf crops

The Meeting agreed to use the results of the rotational crop studies on beet, turnip and radish tops (residues ranging from < 0.01 to 0.021 mg/kg (n=22, median < 0.01 mg/kg) to estimate residues in fodder beet tops and the miscellaneous fodder leaf crops listed in the OECD Feedstuffs Table to accommodate residues in these commodities grown as follow-crops.

The Meeting established median residue of 0.01 mg/kg and a highest residue of 0.021 mg/kg for cyantraniliprole on sugar beet tops, fodder beet tops or leaves, kale forage, rape greens and turnip tops (fresh weight).

Fate of residues during processing

The effect of processing on the nature of residues was investigated in buffer solutions under conditions simulating pasteurisation, boiling and sterilisation. Cyantraniliprole was stable under most processing conditions. Hydrolysis to IN-J9Z38 was a significant pathway under sterilisation conditions (20 minutes at 120 °C and pH 6) making up 12–14% AR. Other degradates present were IN-F6L99 and IN-N5M09 making up a further 5–8% AR.

The fate of cyantraniliprole residues has been examined in a number of studies simulating household and commercial processing of potatoes, spinach, tomatoes, oranges, apples, plums, cottonseed, olives and grapes. Estimated processing factors and STMR-Ps for the commodities considered at this Meeting are summarized below.

Summary of selected processing factors and STMR-P values for cyantraniliprole

RAC	Commodity (RAC: STMR mg/kg [b]	Cyantraniliprole+IN-J9Z38 [a]			
		Processing factors	PF best estimate	RAC STMR (mg/kg)	STMR-P (mg/kg)
Potato	RAC: tubers			0.02	
	flakes	0.1	0.1		0.002
	waste	0.1	0.1		0.002
	peeled tubers	0.1	0.1		0.002
	chips	0.1	0.1		0.002
	wet peel	2.3	2.3		0.046 hi-res 0.1 [c]
	culls	1.0	1.0		0.02
	fries	0.1	0.1		0.002
	unpeeled, boiled	0.1	0.1		0.002
	unpeeled m'waved	< 0.33	< 0.33		0.006
Spinach	RAC: leaves			4.7	
	cooked leaves	0.81, 1.0, 1.2	1.0		4.7
Tomato	RAC: fruit (0.08 mg/kg)				
	washed	0.15, 0.17, < 0.29	0.17		0.014
	peeled	< 0.08, < 0.08, 0.1	< 0.08		0.006
	sun-dried	3.0, 3.7, 3.8	3.7		0.3
	canned	< 0.02, < 0.05, < 0.08	< 0.05		0.004
	juice	< 0.15, < 0.17, 0.19	< 0.17		0.014
	wet pomace	0.75, 1.0, 2.2	1.0		0.08
	dry pomace	1.7, 3.2, 4.0	3.2		0.26
	paste	0.62, 0.86, 1.0	0.86		0.07
	puree	0.23, 0.25, 0.43	0.25		0.02
Apple	RAC: fruit			0.16	
	washed	0.46, 0.58, 0.63	0.58		0.09
	puree	0.88, 1.0, 1.3	1.0		0.16
	canned	0.04, 0.13, 0.15	0.13		0.02
	frozen	0.62, 0.96, 1.5	0.96		0.15
	juice	0.19, 0.31, 0.38	0.31		0.05
	wet pomace	0.77, 1.0, 1.2	1.0		0.16
	dry pomace	2.0, 2.7, 3.9	2.7		0.43
	sauce	2.2, 2.4, 2.7	2.2		0.35
Plum	RAC: flesh			0.34	
	dried prunes	1.3, 1.6, 2.0	1.6		0.54

[a] Each PF value represents a separate study where residues were above the LOQ in the RAC and is the ratio of the combined cyantraniliprole+IN-J9Z38 metabolite residues in the processed item divided by the combined residues of cyantraniliprole+IN-J9Z38 in the RAC.

[b] Residues in the RAC are the sum of cyantraniliprole and IN-J9Z38

[c] Based on the highest residue in the RAC (0.044 mg/kg)

The Meeting noted that in the studies available, cyantraniliprole residues did not concentrate in food commodities during processing except in apple sauce and in dehydrated commodities such as dried prunes and sun-dried tomatoes. Residues also concentrated in dry pomace (apple and tomato).

In three plum processing studies conducted in USA, cyantraniliprole residues increased (median processing factor of 1.5) when fresh prunes (flesh) were dried to a moisture content of 15–18% (from about 85% in fresh fruit).

The Meeting estimated a maximum residue level for prunes of 0.8 mg/kg based on the maximum residue level estimated for plums of 0.5 mg/kg and a median processing factor of 1.6.

Residues in animal commodities

Farm animal dietary burden

The Meeting estimated the dietary burden of cyantraniliprole in farm animals on the basis of the diets listed in Annex 6 of the 2009 JMPR Report (OECD Feedstuffs Derived from Field Crops). Dietary burden calculations for beef cattle, dairy cattle, broilers and laying poultry are presented in Annex 6 and are summarized below.

Estimated maximum and mean dietary burdens of farm animals

	Animal dietary burden, cyantraniliprole, ppm of dry matter diet							
	US-Canada		EU		Australia		Japan	
	max	mean	max	mean	max	mean	max	mean
Beef cattle	0.34	0.2	1.9 [a]	0.98 [c]	0.68	0.14	0.13	0.004
Dairy cattle	0.45	0.1	1.9 [b]	0.95 [d]	0.67	0.11	0.29	0.02
Poultry-broiler	0.0	0.0	0.05 [e]	0.02 [f]	0.0	0.0	0.0	0.0
Poultry-layer	0.0	0.0	0.37 [g]	0.19 [h]	0.0	0.0	0.0	0.0

[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 suitable for estimating maximum residue levels in mammalian tissues and milk is 1.9 ppm dry weight of feed and the calculated mean dietary burdens, suitable for estimating STMRs in mammalian tissues and in milk are 0.98 ppm and 0.95 ppm dry weight of feed respectively.

For poultry, noting that in some countries, laying hens may also be consumed, the calculated maximum dietary burden suitable for estimating maximum residue levels in poultry tissues and eggs is 0.37 ppm dry weight of feed and the calculated mean dietary burden, suitable for estimating STMRs in poultry tissues and in eggs is 0.19 ppm dry weight of feed.

Farm animal feeding studies

The Meeting received information on the residue levels arising in animal tissues and milk when dairy cows were dosed with cyantraniliprole for 28 days at the equivalent of 3.5, 12, 35 and 112 ppm in the diet. A separate dose group (112 ppm) was used to estimate residue depuration of cyantraniliprole and its major metabolites.

In milk, residues reached a plateau after about 5 days. Average residues of cyantraniliprole were 0.03 mg/kg in the 3.5 ppm dose group and increased to 0.7 mg/kg in the highest dose group (112 ppm). In skim milk, cyantraniliprole residues were about 60% of the whole milk levels (0.016 mg/kg up to 0.47 mg/kg) and 0.066 mg/kg up to 1.8 mg/kg in cream. Residues of IN-N7B69, the predominant metabolite in milk, increased from 0.03 mg/kg to 0.28 mg/kg over the four dose groups while residues of the other metabolites (IN-MLA84, IN-J9Z38 and IN-MYX98) were present at levels at least ten-fold lower than parent.

In muscle, maximum residues of cyantraniliprole increased from 0.01 mg/kg to 0.33 mg/kg in the four dose groups, with IN-J9Z38 being the predominant metabolite, found at more than 0.01 mg/kg only in the two highest dose groups (up to 0.04 mg/kg). Other metabolites were ≤ 0.01 mg/kg at all dose levels.

In fat, maximum residues of cyantraniliprole increased from 0.015 mg/kg to 0.58 mg/kg in the four dose groups, with IN-J9Z38 being the predominant metabolite, found at 0.012 mg/kg (low dose) up to 0.45 mg/kg (highest dose). Other metabolites were found at lower levels, more than 5-fold lower that parent and only IN-N7B69 was present at more than 0.01 mg/kg, found at 0.02 mg/kg in the highest dose group.

In kidney, maximum residues of cyantraniliprole increased from 0.03 mg/kg to 0.89 mg/kg in the four dose groups, with IN-N7B69 being the predominant metabolite, found at 0.012 mg/kg (low dose) up to 0.15 mg/kg (highest dose). Other metabolites were found at levels more than 5-fold lower that parent, with residues of IN-J9Z38 and IN-MYX98 present above 0.01 mg/kg only in the two higher dose groups.

In liver, maximum residues of cyantraniliprole increased from 0.066 mg/kg to 2.1 mg/kg in the four dose groups, with IN-MLA84 being the predominant metabolite, present at 0.04 mg/kg in the lowest dose group and up to 0.57 mg/kg in the highest dose group. Metabolite IN-N7B69 residues were up to 0.01 mg/kg in the lowest dose group, increasing to 0.08 mg/kg in the highest dose group and other metabolites were all < 0.01 mg/kg except in the highest dose group where levels of < 0.03 mg/kg were found.

Residue depletion was studied in cows dosed orally for 28 days with the equivalent of 112 ppm cyantraniliprole. Parent residues depleted to < 0.01 mg/kg in muscle within 4 days after the last dose, were < 0.01 mg/kg in milk, liver and kidney within 10 days and < 0.01 mg/kg in fat within 15 days. Metabolites were all < 0.01 mg/kg in all matrices after 4 days except IN-J9Z38 (< 0.01 within 10 days in kidney and 15 days in fat), IN-MLA84 (< 0.01 mg/kg within 10 days in liver) and IN-N7B69 (< 0.01 mg/kg within 10 days in kidney).

The Meeting also received information on the residues in tissues and eggs when laying hens were dosed with cyantraniliprole for 28 days at levels equivalent to 3, 10 and 30 ppm in the diet. A separate dose group (30 ppm) was used to estimate residue depuration of cyantraniliprole and its major metabolites.

In eggs, residues reached a plateau after about 3 days. Average residues of cyantraniliprole were 0.08 mg/kg in the 3 ppm dose group and increased to 0.8 mg/kg in the highest dose group (30 ppm). In egg whites, cyantraniliprole was the predominant residue, averaging 0.08 mg/kg in the low dose group up to 0.64 mg/kg in the high dose group. Lower levels of parent were found in egg yolks, averaging 0.015 mg/kg (low dose) up to 0.1 mg/kg (high dose). Residues of IN-J9Z38, the predominant metabolite in eggs, present at levels of about 50% of parent, increased from 0.04 mg/kg to 0.4 mg/kg over the three dose groups while residues of IN-MLA84 and IN-MYX98 were present at

levels of 0.015 mg/kg in the low dose group up to 0.12 in the high dose group. In general, residues of these metabolites were about 2-fold higher in egg whites than in the yolks.

In muscle, maximum residues of cyantraniliprole increased from 0.003 mg/kg to 0.05 mg/kg in the three dose groups, with the only metabolites found at more than 0.01 mg/kg being IN-MYX98 and IN-HGW87 (up to 0.02 mg/kg in the highest dose group. Other metabolites were all ≤0.01 mg/kg at all dose levels.

In skin + fat, maximum residues of cyantraniliprole increased from 0.014 mg/kg to 0.16 mg/kg in the three dose groups, with IN-MYX98 being the predominant metabolite, found at 0.005 mg/kg (low dose) up to 0.05 mg/kg (highest dose). Other metabolites were found at lower levels, with IN-J9Z38 and IN-HGW87 present at more than 0.01 mg/kg only in the highest dose group (0.021 mg/kg and 0.023 mg/kg respectively).

In liver, maximum residues of cyantraniliprole increased from 0.03 mg/kg to 0.24 mg/kg in the three dose groups. Metabolite IN-MLA84 was present at levels similar to the parent (0.034 mg/kg in the lowest dose group and up to 0.32 mg/kg in the highest dose group). Maximum IN-MLA84, IN-HGW87 and IN-N7B69 residues were 0.01–0.02 mg/kg in the lowest dose group and 0.07–0.1 mg/kg in the highest dose group. Other metabolites were all < 0.01 mg/kg in all dose groups.

In the residue depuration dose group (30 ppm), residues depleted to < 0.01 mg/kg in all matrices within 5 days of the last dose (within 9 days in liver, when the first sample was taken).

Animal commodity maximum residue levels

The maximum dietary burden for beef and dairy cattle is 1.9 ppm. The mean dietary burdens are 0.98 ppm (beef cattle) and 0.95 ppm (dairy cattle). Residue levels of cyantraniliprole and the metabolites included in the residue definition in milk and tissues were obtained by extrapolation below the 3.5 ppm feeding level in the dairy cow feeding study.

Cyantraniliprole feeding study	Feed level (ppm) for milk residues	Residues (mg/kg) in milk	Feed level (ppm) for tissue residues	Residues [a] (mg/kg) in			
				Muscle	Liver	Kidney	Fat
MRL beef or dairy cattle							
Feeding study [b]	3.5	0.03	3.5	0.011	0.066	0.031	0.015
Dietary burden and high residue	1.9	0.016	1.9	0.006	0.036	0.017	0.008
STMR beef or dairy cattle							
Feeding study [c]	3.5	0.03	3.5	0.008	0.094	0.042	0.024
Dietary burden and residue estimate	0.95	0.016	0.98	0.002	0.026	0.012	0.007

[a] Residue values used in estimating STMRs are the sum of cyantraniliprole and metabolites IN-N7B69, IN-J9Z38, IN-MLA84 and IN-MYX98, expressed as cyantraniliprole

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

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

Residues of cyantraniliprole expected in cattle milk and tissues for use in estimating maximum residue levels are: 0.008 mg/kg (fat), 0.006 mg/kg (muscle), 0.036 mg/kg (liver) and 0.017 mg/kg (kidney) and the mean residue for milk is 0.016 mg/kg.

The Meeting estimated maximum residue levels of 0.01 mg/kg for cyantraniliprole in meat (from mammals other than marine mammals), 0.05 mg/kg for edible offal (mammalian), 0.01 mg/kg for mammalian fat and 0.02 mg/kg for milks. Estimated STMRs (parent plus metabolites) for dietary intake estimation are 0.002 mg/kg for meat, 0.026 mg/kg for edible offal, 0.007 mg/kg for fat and 0.016 mg/kg for milk.

For poultry, the maximum dietary burden is 0.37 ppm and the mean dietary burden is 0.19 ppm (based on the diet for laying hens). Residue levels of cyantraniliprole and the metabolites included in the residue definition in eggs and tissues were obtained by extrapolation below the 3.0 ppm feeding level in the dairy cow feeding study.

Cyantraniliprole feeding study	Feed level	Residues	Feed level	Residues [a] (mg/kg) in			
	(ppm) for egg residues	(mg/kg) in egg	(ppm) for tissue residues	Muscle	Liver	Skin	Fat
MRL broiler or laying hen							
Feeding study [b]	3.0	0.082	3.0	0.0055	0.03	0.014	
Dietary burden and high residue	0.37	0.01	0.37	0.0007	0.004	0.002	
STMR broiler or laying hen							
Feeding study [c]	3.0	0.082	3.0	0.007	0.062	0.016	
Dietary burden and residue estimate	0.19	0.01	0.19	0.0004	0.004	0.001	

[a] Residue values used in estimating STMRs are the sum of cyantraniliprole and metabolites IN-N7B69, IN-J9Z38, IN-MLA84 and IN-MYX98, expressed as cyantraniliprole

[b] highest residues for tissues and mean residues for egg

[c] mean residues for tissues and mean residues for egg

Residues of cyantraniliprole expected in eggs and poultry tissues for use in estimating maximum residue levels are: 0.002 mg/kg (skin plus fat), 0.0007 mg/kg (muscle), 0.004 mg/kg (liver) and the mean residue for eggs is 0.01 mg/kg.

The Meeting estimated maximum residue levels of 0.01 mg/kg for cyantraniliprole in poultry meat, 0.01 mg/kg for poultry offal, 0.01 mg/kg for poultry fat and 0.015 mg/kg for eggs. Estimated STMRs for dietary intake estimation are 0 mg/kg for poultry fat, 0 mg/kg for poultry meat, 0.004 mg/kg for poultry offal and 0.01 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 compliance with the MRL, animal and plant commodities): *cyantraniliprole*.

Definition of the residue (for estimation of dietary intake for unprocessed plant commodities): *cyantraniliprole*.

Definition of the residue (for estimation of dietary intake for processed plant commodities): *sum of cyantraniliprole and 2-[3-Bromo-1-(3-chloro-2-pyridinyl)-1H-pyrazol-5-yl]-3,4-dihydro-3,8-dimethyl-4-oxo-6-quinazolinecarbonitrile*.

Proposed definition of the residue (for estimation of dietary intake for animal commodities: sum of: *cyantraniliprole, 2-[3-Bromo-1-(3-chloro-2-pyridinyl)-1H-pyrazol-5-yl]-3,4-dihydro-3,8-dimethyl-4-oxo-6-quinazolinecarbonitrile, 2-[3-Bromo-1-(3-chloro-2-pyridinyl)-1H-pyrazol-5-yl]-1,4-dihydro-8-methyl-4-oxo-6-quinazolinecarbonitrile, 3-Bromo-1-(3-chloro-2-pyridinyl)-N-[4-cyano-2-(hydroxymethyl)-6-[(methylamino)carbonyl]phenyl]-1H-pyrazole-5-carboxamide and 3-Bromo-1-(3-chloro-2-pyridinyl)-N-[4-cyano-2[[(hydroxymethyl)amino]carbonyl]-6-methylphenyl]-1H-pyrazole-5-carboxamide*.

The residue is not fat soluble.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Daily Intake (IEDI) for cyantraniliprole 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 cyantraniliprole for the 13 GEMS/Food regional diets, based on estimated STMRs were 1–10% of the maximum ADI of 0.03 mg/kg bw (Annex 3). The Meeting concluded that the long-term intake of residues of cyantraniliprole from uses that have been considered by the JMPR is unlikely to present a public health concern.

Short-term intake

The 2013 JMPR decided that an ARfD was unnecessary. The Meeting therefore concluded that the short-term intake of cyantraniliprole residues is unlikely to present a public health concern.

5.9 CYPROCONAZOLE (239)

RESIDUE AND ANALYTICAL ASPECTS

Cyproconazole was first evaluated by the 2010 JMPR (T, R), when an ADI of 0–0.02 mg/kg bw and an ARfD of 0.06 mg/kg bw were set, and maximum residue levels were recommended for a variety of crops. Cyproconazole was scheduled at the Forty-fourth Session of the CCPR (2012) for the evaluation of residues in coffee by the 2013 JMPR. The residue definition for cyproconazole in commodities of plant and animal origin is the parent compound.

Methods of analysis

Two methods for the analysis of cyproconazole in coffee beans or roasted coffee were submitted. Residues can be extracted with acetone:water (95:5), the extract cleaned by gel permeation chromatography and the analyte analysed by LC/MS/MS (m/z 292.2 and 70.1), or extracted with methanol and analysed by LC/MS/MS after centrifugation. In both cases, satisfactory recoveries were obtained at 0.01 mg/kg (LOQ). No study was submitted to evaluate the stability of the residues in coffee samples. Studies evaluated by the 2010 JMPR on various fruits, peanuts and wheat had shown that cyproconazole residues are stable for at least 39 months under frozen conditions. The Meeting agreed that this conclusion could be extended to coffee.

Results from supervised residue trials on crops

Cyproconazole is registered in various central and South American countries. The critical GAP is found in Colombia, 3 × 0.06 kg ai/ha and 15 days PHI. A total of nine supervised residue trials were conducted on coffee from 2010 to 2012 in the region.

In two trials conducted in Brazil according to Colombian GAP, residues were 0.02 and 0.03 mg/kg. In two trials conducted in Colombia and one in Guatemala according to Colombian GAP, residues were 0.03 (2) and 0.04 mg/kg. Two declining studies conducted in Colombia according to GAP showed that residues at 10 and 14 days DAT are the same, and can be considered at GAP. Residues are 0.02 and 0.03 mg/kg.

In two other Brazilian trials, a soil drench application was applied in addition to a foliar application at 0.5 kg ai/ha, giving residues of 0.03 and 0.04 mg/kg at 23–37 DAT. Although these trials are not conducted according to GAP, they can be used as supporting information.

The Meeting agreed to combined the residues from trials conducted according to Colombian GAP (n=7) as 0.02 (2), 0.03 (4) and 0.04 mg/kg.

The Meeting estimates a maximum residue level of 0.07 mg/kg, and a STMR of 0.03 mg/kg for cyproconazole in coffee beans.

Fate of residues in processing

In one study conducted in Guatemala, green coffee beans containing 0.094 mg/kg cyproconazole were processed to roasted beans and instant coffee Residues were 0.119 mg/kg in roasted beans and 0.151 mg/kg in instant coffee, resulting in processing factors of 1.3 and 1.6, respectively.

Based on these processing factors, the Meeting recommends a maximum residue level of 0.1 mg/kg and a STMR of 0.039 mg/kg for cyproconazole in roasted coffee beans, and a STMR of 0.048 mg/kg for cyproconazole in instant coffee.

RECOMMENDATIONS

Definition of the residue for compliance with maximum residue levels and estimation of dietary intake in plant commodities: *cyproconazole*.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Daily Intakes (IEDIs) of cyproconazole calculated for the 13 GEMS/Food Consumption Cluster Diets using STMRs and STMR-Ps estimated by the 2010 Meeting ranged from 0.5 to 2% of the maximum ADI. The impact of coffee on the IEDI is unlikely to affect the previous conclusion that the long-term intake of residues of cyproconazole 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 Intakes (IESTI) of cyproconazole was calculated for coffee using STMR-P estimated by the current Meeting (Annex 4). The ARfD is 0.06 mg/kg and the calculated IESTI was 0% of the ARfD. The Meeting concluded that the short-term intake of residues of cyproconazole, when used in ways that have been considered by the JMPR, is unlikely to present a public health concern.

5.10 CYPRODINIL (207)

RESIDUE AND ANALYTICAL ASPECTS

Cyprodinil was first evaluated for residues and toxicological aspects by the 2003 JMPR. The 2003 Meeting established an ADI of 0–0.03 mg/kg bw for cyprodinil and concluded that an ARfD was not necessary. The 2003 Meeting recommended a number of maximum residue levels for cyprodinil. The residue definition was established as cyprodinil for both compliance with MRLs and dietary risk assessment, for both plant and animal commodities. The residue is fat soluble.

Cyprodinil was scheduled by the Forty-fourth CCPR meeting in 2012 for evaluation of residue data for additional crops by the 2013 JMPR.

Methods of analysis

The Meeting received two analytical methods for determination of cyprodinil residues in plant matrices which were relevant to this evaluation. The LOQ for the HPLC-UV and HPLC-MS/MS methods was 0.01 mg/kg.

Stability of residues in stored analytical samples

The Meeting received information on the storage stability of cyprodinil residues in plant matrices from trials conducted in conjunction with the residue studies submitted to the Meeting. These data and stability data from JMPR 2003 cover the maximum storage period for samples in the residue studies submitted to the Meeting.

Results of supervised residue trials on crops

The Meeting received supervised trial data for application of cyprodinil to dry beans, lima beans, common beans (snap beans), berry fruit (blueberries, caneberries and strawberries), brassica vegetables (broccoli and cabbage), cucurbit fruiting vegetables (cantaloupe, cucumber and squash), other fruiting vegetables (sweet pepper, chili pepper, and tomato), herbs (parsley, basil and chives), leafy vegetables (mustard greens, lettuce, spinach and watercress), lemons (including processing data), pome fruit (apples and pears), root vegetables (carrot and radish), and tropical fruits-inedible peel (avocado, kiwifruit and litchi).

Citrus fruits

Cyprodinil is registered in the USA for use on lemons and limes at a GAP of 1 × 0.37 kg ai/ha, and a 0-day PHI.

Three residue trials were conducted in lemons at GAP in the USA. Residues in lemons at the 0-day PHI were 0.19, 0.31 and 0.34 mg/kg.

The Meeting determined that there were insufficient data for the estimation of a maximum residue level in lemons.

Pome fruits

The 2003 JMPR estimated a maximum residue level of 0.05 mg/kg in apple based on a previous GAP in the USA of 4 × 0.26 kg ai/ha, with applications only until the end of flowering. The 2003 JMPR estimated a maximum residue level of 1 mg/kg in pear based on the European GAP of 3 × 0.38 kg ai/ha, with a 14-day PHI.

The Meeting received new residue data from the USA for both apples and pears at a different GAP from those previously considered. Cyprodinil is registered in the USA for use in apples and pears at a GAP of 6 × 0.26 kg ai/ha, and a 0-day PHI.

Nine residue trials were conducted in apples at GAP in the USA. Residues in apples at the 0-day PHI were 0.20, 0.28, 0.40, 0.50, 0.51, 0.52, 0.70, 0.94, and 1.3 mg/kg.

Five residue trials were conducted in pears at GAP in the USA. Residues in pears at the 0-day PHI were 0.17, 0.35, 0.36, 0.46, and 0.65 mg/kg.

The Meeting noted that the USA GAP is for the pome fruits group, and considered a group maximum residue level. To consider a group maximum residue level, residues in individual crops should be similar (e.g., medians should not differ by more than 5×). The Meeting agreed to estimate a maximum residue level for the crop group Pome fruits. In deciding whether to combine the datasets for apple and pear for use in the statistical calculator or to only utilize the data from the commodity with the highest residues, the Meeting recognized the similarity of the datasets (confirmed by the Mann-Whitney U test), and decided to combine the datasets for apples and pears for the purposes of determining a group maximum residue level for pome fruit. Residues found were: 0.17, 0.20, 0.28, 0.35, 0.36, 0.40, 0.46, 0.50, 0.51, 0.52, 0.65, 0.70, 0.94 and 1.3 mg/kg.

The Meeting estimated a maximum residue level of 2 mg/kg for pome fruit, and a STMR of 0.48 mg/kg. The Meeting withdrew its previous maximum residue level recommendations of 0.05 mg/kg for apple and 1 mg/kg for pear.

Berries and other small fruits

Cyprodinil is registered in the USA for use in bushberries at a GAP of 4 × 0.37 kg ai/ha with a 0-day PHI.

Five residue trials were conducted at GAP in blueberries in the USA. Residues in blueberries at the 0-day PHI were 0.50, 0.62, 1.0, 1.4 and 1.9 mg/kg.

The 2003 JMPR estimated a maximum residue level of 0.5 mg/kg in raspberries, red, black based on the Swiss GAP of 2 × 0.45 kg ai/ha, with a 14-day PHI.

The Meeting received residue data from the USA for raspberries. Cyprodinil is registered in the USA for use in caneberries at a GAP of 4 × 0.37 kg ai/ha, with a 0-day PHI.

Five residue trials were conducted in raspberries in the USA. Residues in raspberries at the 0-day PHI were 1.5, 1.6, 2.2, 2.5, and 5.9 mg/kg.

The 2003 JMPR estimated a maximum residue level of 2 mg/kg in strawberries, based on various GAPs in Europe.

The Meeting received residue data from the USA in strawberries. Cyprodinil is registered in the USA for use in strawberries at a GAP of 4 × 0.37 kg ai/ha, with a 0-day PHI.

Eight residue trials were conducted in strawberries in the USA. Residues in strawberries at the 0-day PHI were 0.10, 0.30, 0.68, 0.91, 1.1, 1.5, 1.6, and 2.0 mg/kg.

The Meeting noted that the USA GAP is the same for all berry fruit (except grapes) and considered a group maximum residue level. To consider a group maximum residue level, residues in individual crops should be similar (e.g., medians should not differ by more than 5×). The Meeting agreed to estimate a maximum residue level for the group Berry fruit (except grapes). In deciding whether to combine the datasets for blueberries, raspberries and strawberries for use in the statistical calculator or to only utilize the data from the commodity with the highest residues, the Meeting agreed not to combine the data sets (Kruskal-Wallis test). Therefore, recommendations on berry fruit will be based on raspberries, as the commodity with the highest residues. Based on the data set for raspberries, the Meeting estimated a maximum residue level of 10 mg/kg for Berries and other small fruits, except grapes, together with an STMR of 2.2 mg/kg. The Meeting withdrew its previous

maximum residue level recommendations of 0.5 mg/kg for raspberries, red, black and 2 mg/kg for strawberry.

Assorted tropical and sub-tropical fruits – inedible peel

Avocado

Cyprodinil is registered in the USA for use in avocado at a GAP of 4 × 0.37 kg ai/ha, with a 0-day PHI.

Six trials were conducted in avocados in the USA. Residues in avocados at the 0-day PHI were 0.08, 0.18, 0.23, 0.30, 0.35, and 0.60 mg/kg.

The Meeting estimated a maximum residue level of 1 mg/kg for avocados, along with an STMR of 0.265 mg/kg.

Kiwifruit

Cyprodinil is registered in the USA for use in kiwifruit at a GAP of 2 × 0.53 kg ai/ha, with a 0-day PHI.

Three residue trials were conducted in kiwifruit in the USA. Residues in kiwifruit at the 0-day PHI were 0.61, 0.99, and 1.1 mg/kg.

The Meeting determined that there were insufficient data for the estimation of a maximum residue level in kiwifruit.

Litchi (lychee)

Cyprodinil is registered in the USA for use in litchi at a GAP of 4 × 0.37 kg ai/ha, with a 0-day PHI.

One residue trial was conducted in litchi in the USA. Residues in litchi at the 0-day PHI were 1.3 mg/kg.

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

Brassica vegetables

Cabbages, Head

Cyprodinil is registered in the USA for use in brassica vegetables at a GAP of 4 × 0.37 kg ai/ha, with a 7-day PHI.

Six trials were conducted in cabbage in the USA. Residues in cabbages (with wrapper leaves) at a PHI of 6–8 days were < 0.02, 0.02 (s), 0.02, 0.04, 0.19, and 0.36 mg/kg, where (s) indicates a result scaled to account for application rates outside ± 25% of GAP. Residues in cabbages (without wrapper leaves) were < 0.02 (5), and 0.08 mg/kg.

The Meeting estimated a maximum residue level of 0.7 mg/kg for head cabbages, along with an STMR of 0.03 mg/kg.

Flowerhead Brassicas

Six trials were conducted in broccoli in the USA and Canada. Residues in broccoli at a PHI of 6–8 days were 0.02, 0.15, 0.20, 0.34, 0.43 and 1.1 mg/kg.

The Meeting estimated a maximum residue level of 2 mg/kg for broccoli, along with an STMR of 0.27 mg/kg and agreed to extend the MRL and STMR to the subgroup Flowerhead brassicas.

Fruiting vegetables, Cucurbits

The 2003 JMPR estimated maximum residue levels of 0.2 mg/kg for both cucumber and summer squash, based on data matching Spanish and Italian GAPs of 4 × 0.038 kg ai/hL with a 7-day PHI, and 3 × 0.30 kg ai/ha with a 7-day PHI respectively.

The Meeting received residue data from the USA in melon, cucumber and summer squash.

Cyprodinil is registered in the USA for use in fruiting vegetables, other than cucurbits at a GAP of 4 × 0.37 kg ai/ha, with a 1-day PHI.

Five residue trials were conducted in melons in the USA. Residues in melons at the 1-day PHI were 0.05, 0.06, 0.10, 0.17 and 0.33 mg/kg.

Seven residue trials were conducted in cucumber in the USA. Residues in cucumber at the 1-day PHI were 0.04, 0.05, 0.09 (2), 0.11, 0.15, and 0.24 mg/kg.

Five residue trials in were conducted summer squash in the USA. Residues in summer squash at the 1-day PHI were 0.02, 0.03, 0.07 (2), and 0.09 mg/kg.

The Meeting noted that the USA GAP is for all cucurbit fruiting vegetables, and considered a group maximum residue level. To consider a group maximum residue level, residues in individual crops should be similar (e.g., medians should not differ by more than 5×). The Meeting agreed to estimate a maximum residue level for the group Fruiting vegetables, Cucurbits. In deciding whether to combine the datasets for melons, cucumbers and summer squash for use in the statistical calculator or to only utilize the data from the commodity with the highest residues, the Meeting recognized the similarity of the datasets (confirmed by the Kruskal-Wallis test), and decided to combine the datasets.

Combines residues were: 0.02, 0.03, 0.04, 0.05 (2), 0.06, 0.07 (2), 0.09 (3), 0.10, 0.11, 0.15, 0.17, 0.24, and 0.33 mg/kg.

The Meeting estimated a maximum residue level of 0.5 mg/kg for Fruiting vegetables, Cucurbits, together with an STMR of 0.09 mg/kg. The Meeting withdrew the previous maximum residue level recommendations of 0.2 mg/kg for cucumber and summer squash.

Fruiting vegetables, other than Cucurbits

The 2003 JMPR estimated a maximum residue level of 0.2 mg/kg for eggplant, based on data matching the Italian GAP of 3 × 0.30 kg ai/ha, with a 7-day PHI, and the Spanish GAP of 3 × 0.038 kg ai/hL, with a 7-day PHI. Based on a combined data set from three European GAPs (Italy: 3 × 0.30 kg ai/ha, with a 7-day PHI, Spain: 3 × 0.038 kg ai/hL, with a 7-day PHI, and Switzerland: 0.30 kg ai/ha, with a 3-day PHI), the 2003 JMPR estimated a maximum residue level of 0.5 mg/kg for tomatoes. The 2003 JMPR estimated a maximum residue level of 0.5 mg/kg for peppers, sweet, based on data matching the Italian GAP of 3 × 300 g ai/ha, with a 7-day PHI, and the Spanish GAP of 3 × 38 g ai/hL, with a 7-day PHI.

The Meeting received residue data from the USA and Canada in tomatoes, sweet peppers and chili peppers. Both field and greenhouse trial data were supplied for all three crops.

Cyprodinil is registered in the USA for use in fruiting vegetables, other than cucurbits, at a GAP of 4 × 0.37 kg ai/ha, with a 0-day PHI.

Eleven residue trials were conducted in sweet pepper in the USA and Canada. Residues in sweet pepper at the 0-day PHI were 0.04, 0.10, 0.13, 0.15, 0.19, 0.21 (GH), 0.23, 0.23 (G), 0.25, 0.27 (GH), and 0.68 mg/kg. 'GH' indicates a trial conducted in a greenhouse, all other trials were conducted in the field.

Five trials were conducted in chili pepper in the USA. Residues in chili pepper at the 0-day PHI were 0.20, 0.27, 0.28, 0.59 (GH), and 0.67 mg/kg.

Sixteen trials were conducted in tomatoes in the USA. Residues in tomatoes at the 0-day PHI were 0.02, 0.03 (GH), 0.06, 0.09, 0.11, 0.13, 0.14 (2), 0.16, 0.17 (GH), 0.20, 0.22 (GH), 0.24, 0.26, 0.30, and 0.32 (GH) mg/kg.

A series of residue trials in fruiting vegetables (eggplant, sweet pepper and tomato), was considered by the 2003 JMPR. Most of the trials were conducted in greenhouse crops, and in accordance with a GAP of 3 × 0.38 kg ai/ha applications, with a 7-day PHI. The majority were conducted as decline trials and have data for the USA PHI of 0 days. The application rates from the 2003 trials are within ±25% of the USA GAP (4 × 0.37 kg ai/ha).

At a PHI of 0 days, residues of cyprodinil in greenhouse grown eggplant from trials from Italy and Spain relevant to USA GAP were 0.07, 0.14, and 0.23 (2) mg/kg.

At a PHI of 0 days, residues of cyprodinil in greenhouse grown tomato from trials from Greece, Italy, Spain, Switzerland and the UK, relevant to USA GAP were 0.08, 0.12, 0.13, 0.20, 0.21 (2), 0.22 (3), 0.23, 0.25 (3), 0.36, 0.41 mg/kg.

At a PHI of 0 days, residues of cyprodinil in field and greenhouse grown sweet pepper from Spanish and Italian trials relevant to USA GAP were 0.02, 0.26 (G), 0.27, 0.41 (GH), 0.73 (GH), 1.0 (GH), and 1.2 (GH) mg/kg. (GH) indicates a result from a greenhouse trial.

The Meeting agreed to combine the datasets for the USA (field and greenhouse) and European (greenhouse) to give a larger dataset for the purposes of estimation of dietary parameters and a maximum residue level for fruiting vegetables, other than cucurbits.

Residues in field and greenhouse grown tomatoes from trials carried out in the USA, Greece, Italy, Spain, Switzerland and the UK relevant to USA GAP were 0.02, 0.03 (G), 0.06, 0.08 (G), 0.09, 0.11, 0.12 (GH), 0.13, 0.13 (GH) , 0.14 (2), 0.16, 0.17 (G), 0.20, 0.20 (GH), 0.21 (GH) (2), 0.22 (GH) (4), 0.23 (GH), 0.24, 0.25 (GH) (3), 0.26, 0.30, 0.32 (GH), 0.36 (GH), 0.41 (GH) mg/kg.

Residues in field and greenhouse grown sweet pepper from trials carried out in the USA, Spain and Italy relevant to USA GAP were 0.02, 0.04, 0.10, 0.13, 0.15, 0.19, 0.21 (GH), 0.23, 0.23 (GH), 0.25, 0.26 (GH), 0.27, 0.27 (GH), 0.41 (GH), 0.68, 0.73 (GH), 1.0 (GH), and 1.2 (GH) mg/kg.

The Meeting considered that the USA GAP is for all fruiting vegetables, other than cucurbits, except mushroom and sweet corn, and considered a group maximum residue level. To consider a group MRL, residues in individual crops should be similar (e.g. medians should not differ by more than 5×). The Meeting agreed to estimate a maximum residue level for the group fruiting vegetables, other than cucurbits, except mushroom and sweet corn. In deciding whether to combine the datasets for sweet peppers, chili peppers, tomatoes and eggplants for use in the statistical calculator or to only utilize the data from the commodity with the highest residues, the Meeting agreed not to combine the data sets (Kruskal-Wallis test). Therefore, recommendations on fruiting vegetables, other than cucurbits, except mushroom and sweet corn will be based on the 2003 data set for sweet peppers, as the commodity with the highest residues.

Based on the combined data set for sweet pepper, the Meeting estimated a maximum residue level of 2 mg/kg for fruiting vegetables, other than cucurbits, except sweet corn and mushrooms, together with an STMR of 0.24 mg/kg. The Meeting agreed to withdraw the previous maximum residue level recommendations of 0.2 mg/kg for eggplant, 0.5 mg/kg for tomatoes, and 0.5 mg/kg for peppers, sweet.

The Meeting noted that the residues in chili pepper and other commodities within the group of fruiting vegetables differed significantly. Using the default dehydration factor of 7 for peppers, the following data set was obtained for dried chili peppers: 1.4, 1.9, 2.0, 4.1, and 4.7 mg/kg. The Meeting estimated a maximum residue level of 9 mg/kg for dried chili peppers, together with an STMR-P of 2.0 mg/kg.

Brassica leafy vegetables

Cyprodinil is registered in the USA for use in brassica leafy vegetables (including mustard greens), at a GAP of 4 × 0.37 kg ai/ha, with a 7-day PHI.

Seven trials were conducted in mustard greens in the USA in accordance with GAP. Residues in mustard green leaves at the 7-day PHI were 0.23, 0.36, 0.36 (s), 0.37, 0.71, 5.4, and 8.0 mg/kg, where (s) indicates a result scaled to account for application rates outside ±25% of GAP.

The Meeting estimated a maximum residue level of 15 mg/kg for mustard greens, together with an STMR of 0.37 mg/kg. The Meeting agreed to extrapolate to estimate a maximum residue level of 15 mg/kg for brassica leafy vegetables.

Leafy vegetables, except brassica leafy vegetables

The 2003 JMPR estimated maximum residue levels of 10 mg/kg for lettuce, head and lettuce, leaf, based on data matching GAP for France (2 × 0.19 kg ai/ha, with a 14-day PHI) and Italy (3 × 0.26 kg ai/ha, with a 14-day PHI).

The Meeting received residue data from the USA and Canada in head lettuce, leaf lettuce, spinach, and watercress.

Cyprodinil is registered in the USA for use in leafy vegetables, other than brassica leafy vegetables, at a GAP of 4 × 0.37 kg ai/ha, with a 0-day PHI.

Eight trials were conducted in lettuce, head in accordance with the USA GAP. Residues in lettuce heads, with wrapper leaves at the 0-day PHI were 1.6, 2.0, 2.2, 2.3, 2.7, 2.9, 5.1, and 21 mg/kg. Residues in lettuce head with wrapper leaves removed were 0.07, 0.15, 0.31, 0.32, 0.63, 0.69, 1.6, and 3.2 mg/kg.

Six trials were conducted in leaf lettuce, in accordance with the USA GAP. Residues in lettuce leaves at the 0-day PHI were: 8.5, 10 (2), 11, 14, and 24 mg/kg.

Ten trials were conducted in spinach in accordance with the USA GAP. Residues in spinach at the 0-day PHI were 5.6, 6.1, 6.6, 8.3, 11 (2), 12, 13, 14, and 32 mg/kg.

One trial was conducted in watercress in accordance with the USA GAP. Residues in watercress at the 0-day PHI were 12 mg/kg.

The Meeting noted that the USA GAP is the same for all leafy vegetables other than brassica leafy vegetables and considered a group maximum residue level. To consider a group maximum residue level, residues in individual crops should be similar (e.g., medians should not differ by more than 5×). However, the Meeting agreed not to combine the data sets (Kruskal-Wallis test). TAs a result recommendations on leafy vegetables other than brassica leafy vegetables were based on the spinach dataset, as the commodity with the highest residues. Based on the dataset for spinach, the Meeting estimated a maximum residue level of 50 mg/kg for leafy vegetables, except brassica leafy vegetables, together with an STMR of 11 mg/kg. The Meeting agreed to withdraw the previous maximum residue level recommendations of 10 mg/kg for lettuce, head and lettuce, leaf.

Legume vegetables

The 2003 JMPR estimated a maximum residue level of 0.5 mg/kg for beans (in pods), except broad bean and soya bean, based on data matching the GAPs of Spain (3 × 0.038 kg ai/hL, with a 14-day PHI) and (2 × 0.38 kg ai/ha, with a 14-day PHI).

The Meeting received residue data from the USA in common beans (snap beans, pods and succulent seed) and lima beans (succulent shelled seeds).

Cyprodinil is registered in the USA for use in beans (succulent), including chickpea, lupin, kidney, lima, mung, navy, pinto, snap, wax, and broad bean, asparagus bean and blackeyed pea, with a GAP of 4 × 0.37 kg ai/ha, with a 7-day PHI.

Eight trials were conducted in common beans (pods and succulent seeds) in accordance with the USA GAP. Residues in pod and seed samples at the 7-day PHI were 0.10, 0.12, 0.13, 0.16, 0.17, 0.18, 0.23, and 0.49 mg/kg.

The Meeting estimated a maximum residue level of 0.7 mg/kg in beans, except broad bean and soya bean (green pods and immature seeds), together with an STMR of 0.165 mg/kg. The Meeting agreed to withdraw the previous maximum residue level recommendation of 0.5 mg/kg for beans, except broad bean and soya bean (green pods and immature seeds).

Six trials were conducted in lima beans (seeds without pods) in accordance with the USA GAP. Residues in succulent seeds at the 7-day PHI were < 0.02 (3), 0.02, 0.03 and 0.04 mg/kg.

The Meeting estimated a maximum residue level of 0.06 mg/kg for beans, shelled, together with an STMR of 0.02 mg/kg.

Beans (dry)

Cyprodinil is registered in the USA for use in beans (dry) at a GAP of 4 × 0.37 kg ai/ha, with a 7-day PHI.

Nine trials in beans (dry) were conducted in accordance with the USA GAP. Residues in beans at the 7-day PHI were < 0.02, 0.02 (3), 0.03, 0.04 (3), and 0.15 mg/kg.

The Meeting estimated a maximum residue level of 0.2 mg/kg for beans, dry, together with an STMR of 0.03 mg/kg.

Carrots

Cyprodinil is registered in the USA for use in carrots at a GAP of 4 × 0.37 kg ai/ha, with a 7-day PHI.

Ten trials in carrots were conducted in the USA and Canada in accordance with the USA GAP. Residues in carrots at the 7-day PHI were: 0.02, 0.05 (2), 0.06 (s), 0.08 (s) 0.10, 0.12, 0.18, 0.39, and 0.40 mg/kg, where (s) indicates a result scaled to account for application rates outside ±25% of GAP.

The Meeting estimated a maximum residue level of 0.7 mg/kg for carrots, together with an STMR of 0.09 mg/kg.

The Meeting noted that the US GAP for parsnips is the same as that for carrots, and agreed to extrapolate the residue data for carrots and estimated a maximum residue level of 0.7 mg/kg for parsnips, together with an STMR of 0.09 mg/kg.

Radish

Cyprodinil is registered in the USA for use in radish at a GAP of 2 × 0.37 kg ai/ha, with a 7-day PHI.

Five trials in radish were conducted in accordance with the USA GAP. Residues in radish roots at the 7-day PHI were < 0.01 (3), 0.03, and 0.14 mg/kg.

Residues in radish tops at the 7-day PHI were 0.13, 0.17, 0.40, 0.45, and 1.3 mg/kg.

The Meeting estimated a maximum residue level of 0.3 mg/kg for radish, together with an STMR of 0.01 mg/kg.

The Meeting agreed that residues of cyprodinil arising in radish tops would be covered by the proposed maximum residue level of 15 mg/kg for brassica leafy vegetables.

Herbs

Cyprodinil is registered in the USA for use in herbs at a GAP of 4 × 0.37 kg ai/ha, with a 7-day PHI.

Three trials in basil were conducted in accordance with the USA GAP. Residues in fresh basil leaves at the 7-day PHI were 1.5, 1.7 and 2.1 mg/kg. Residues in dried basil leaves at the 7-day PHI were 8.8 mg/kg.

Three trials in chives were conducted in accordance with the USA GAP. Residues in fresh chives at the 7-day PHI were 0.62, 1.0, and 1.1 mg/kg. Residues in dried chives at the 7-day PHI were 2.9 mg/kg.

Four trials in parsley were conducted in accordance with the USA GAP. Residues in fresh parsley at the 7-day PHI were 2.9, 3.0, 7.1, and 16 mg/kg. Residues in dried parsley at the 7-day PHI were 20 (2), 30, and 112 mg/kg.

The Meeting noted that the USA GAP is for all herbs and considered a group maximum residue level. To consider a group maximum residue level, residues in individual crops should be similar (e.g., medians should not differ by more than 5×). The Meeting agreed to estimate a maximum residue level for the group herbs. In deciding whether to combine the datasets for basil, chives and parsley for use in the statistical calculator, or to only utilize the data from the commodity with the highest residues, the Meeting agreed not to combine the data sets (Kruskal-Wallis test). Therefore, recommendations on herbs were based on parsley, as the commodity with the highest residues. Based on the data set for fresh parsley, the Meeting estimated a maximum residue level of 40 mg/kg for herbs, together with an STMR of 5.05 mg/kg.

The Meeting estimated a maximum residue level of 300 mg/kg for dried herbs except hops, dry, based on the data set for dried parsley, together with an STMR of 25 mg/kg.

Processing studies

A processing study for lemons was evaluated by the current Meeting; however as the residue data set for lemons was insufficient for the estimation of a maximum residue level or STMR, STMR-P values for citrus processed products were not estimated.

Some processing data for tomatoes was generated as part of the residue trial in tomatoes provided to the Meeting. Processing studies for apples, barley, grapes, plums, tomatoes and wheat were considered by the 2003 JMPR. The studies in apples and tomatoes are relevant to the crops being considered by the current Meeting. Processing factors are tabulated below.

RAC	Processed product	PF
Apples	Wet pomace	3.5
	Juice	0.03
Tomatoes	Juice	0.17
	Purée	0.52
	Paste	0.86, 2.3

The processing factors were applied to the STMRs for the raw commodities to produce the following STMR-P values: wet apple pomace 1.8 mg/kg; apple juice 0.015 mg/kg; tomato juice 0.036 mg/kg; tomato purée 0.11 mg/kg; and tomato paste 0.48 mg/kg.

Residues in animal commodities

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	0.91	0.37	13.9	1.8	5.8	1.4	0.46	0.46
Dairy cattle	1.7	0.87	13.5	1.4	**23.3** [a]	**1.8** [b]	0.26	0.26
Poultry – broiler	0.49	0.49	0.80	0.54	0.12	0.12	0.066	0.066
Poultry – layer	0.49	0.49	**4.1** [c]	**0.76** [d]	0.12	0.12	-	-

[a] Highest maximum dairy cattle dietary burden suitable for HR and MRL estimates for mammalian milk

[b] Highest mean dairy cattle dietary burden suitable for STMR estimates for mammalian milk

[c] Highest maximum poultry dietary burden suitable for HR and 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

Mammals

A feeding study on lactating dairy cattle was considered by the 2003 JMPR.

Lactating Holstein dairy cows were dosed daily by gelatin capsule with cyprodinil at the equivalent of 5, 15 and 50 ppm in the dry-weight diet for 28 consecutive days. Milk was collected throughout and on days 28, 29, and 30, a cow from each dosing group was slaughtered for tissue collection. Cyprodinil residues were not detected (LOQ 0.01 mg/kg) in the milk (days 0, 1, 3, 7, 14, and 21), kidney, or fat of cows from the highest dose group (50 ppm), nor in milk (day 26) or muscle from any dose groups. Cyprodinil was present in liver (highest residue 0.013 mg/kg) from the highest dose group but not from the other groups.

The 2003 JMPR estimated a maximum residue level of 0.0004* mg/kg (F) for milk, together with an STMR of 0 mg/kg, based on a maximum dietary burden for dairy cattle of 8.2 ppm, and a mean dietary burden of 0.53 ppm.

The highest dietary burden for dairy cattle is for Australia (max. dietary burden of 23.3 ppm and mean dietary burden of 1.8 ppm). The Meeting noted that no residues of cyprodinil were quantified in milk above the LOQ (0.01 mg/kg) at feeding levels up to 50 ppm in cattle. The Meeting concluded that the existing maximum residue level and STMR for milk remain appropriate.

The 2003 JMPR estimated maximum residue levels of 0.01* mg/kg (fat) and STMRs of 0 mg/kg for meat (from mammals other than marine mammals), and edible offal (mammalian). These limits were based on a maximum dietary burden of 8.2 ppm, and a mean dietary burden of 0.53 ppm.

As for dairy cattle, the highest dietary burdens for calculation of meat MRLs are 23.3 ppm (max.) and 1.8 ppm (mean), considering all the use patterns evaluated by the 2003 JMPR and the present Meeting. Given that no residues of cyprodinil were found above the LOQ in muscle or fat of cattle at a feeding level of 50 ppm, the Meeting considers that the existing maximum residue level for meat (from mammals other than marine mammals), and the STMR values remain appropriate. No residues were found above the LOQ in kidney even at the highest dose of 50 ppm. In liver, no

residues were found above the LOQ in liver at feeding levels of 5 and 15 ppm, while at 50 ppm, low residues up to 0.013 mg/kg were found. The Meeting estimated a maximum residue level of 0.01 mg/kg for edible offal (mammalian), together with an STMR of 0 mg/kg. The Meeting agreed to withdraw the previous recommendation of 0.01* mg/kg for edible offal (mammalian).

Poultry

A feeding study in poultry was not presented to the 2003 JMPR or to the present Meeting.

The 2003 JMPR estimated maximum residue levels of 0.01* mg/kg for eggs and poultry, edible offal of, and 0.01* mg/kg (fat) for poultry meat and STMRs of 0 mg/kg. These limits were based on a maximum dietary burden of 2.6 ppm and a mean dietary burden of 0.50 ppm, and consideration of the laying hen metabolism study.

Based on the use patterns considered by the 2003 JMPR and the present Meeting, the Meeting noted that the highest dietary burden for poultry (both for meat and egg producing birds) was the EU diet, with a maximum dietary burden of 4.1 ppm and a mean dietary burden of 0.76 ppm.

As noted by the 2003 JMPR, cyprodinil parent compound was not detected in poultry tissues in the laying hen metabolism study (except in kidney at 0.001 mg/kg), even at feeding levels of 215 and 226 ppm. Cyprodinil was detected in eggs at 0.002-0.011 mg/kg from birds dosed at 215 and 226 ppm. Given that these feeding levels are around 50 times the maximum dietary burden of 4.1 ppm estimated for poultry, the Meeting considers that the existing maximum residue levels, and STMR values for poultry commodities remain appropriate.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Dietary Intakes (IEDIs) of cyprodinil were calculated for the 13 GEMS/food cluster diets using STMRs/STMR-Ps estimated by the current Meeting and by the 2003 JMPR. The ADI is 0–0.03 mg/kg bw and the calculated IEDIs were 5–40% of the maximum ADI (0.03 mg/kg bw). The Meeting concluded that the long-term intakes of residues of cyprodinil, resulting from the uses considered by the current Meeting and by the 2003 JMPR, are unlikely to present a public health concern.

Short-term intake

The 2003 JMPR decided that an ARfD was unnecessary and concluded that the short-term intake of cyprodinil is unlikely to present a public health concern.

5.11 DICAMBA (240)

RESIDUE AND ANALYTICAL ASPECTS

Dicamba, a systemic broad-spectrum herbicide, was first evaluated by the 2010 JMPR which estimated an ADI of 0–0.3 mg/kg bw and ARfD of 0.5 mg/kg bw, and recommended the following residue definitions for plant commodities:

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

Definition of the residue for plant commodities (for estimation of dietary intake): *Sum of dicamba and 5-OH dicamba expressed as dicamba*

Definition of the residue for animal commodities (for compliance with the MRL and for estimation of dietary intake): *Sum of dicamba and DCSA expressed as dicamba*

The 2010 Meeting reviewed metabolism, method of analysis, storage stability, supervised residue trials and processing studies of dicamba in soya beans. However, as no supervised trials matched US GAP, the Meeting could not estimate a maximum residue level for soya bean (dry). The 2011 Meeting decided to apply the concept of proportionality to the residues from these trials to recommend a maximum residue level.

The Forty-fith Session of the Codex Committee on Pesticide Residues in 2013 agreed to the Principles and Guidance for Application of the Proportionality Concept to Estimation of Maximum Residue Limits for Pesticides and further agreed that desiccants should be excluded from the application of the proportionality concept.

The current Meeting received information on new supervised trials on soya beans following the US GAP and analytical methods used for the determination of dicamba and related compounds in the new supervised trials on soya beans.

Method of analysis

The current Meeting received information on the analytical method used for the determination of dicamba, 5-OH dicamba and 3,6-dichloro-2-hydroxybenzoic acid (DCSA) arising in soya bean seeds, forage and hay in newly conducted supervised residue trials. The method analysed these compounds using LC-MS/MS, monitoring ion transitions from *m/z* 219→175 for dicamba; *m/z* 235→155 for 5-OH-dicamba; and *m/z* 205→161 for DCSA.

The method was found suitable for the determination of the three analytes in soya bean seeds, forage and hay with mean recoveries in the acceptable range of 70–110% at the fortification levels between 0.01 and 10 mg/kg.

The limit of quantitation (LOQ) is 0.01 mg/kg for the determination of dicamba, 5-OH dicamba and DCSA in soya bean seeds, forage and hay, except that this LOQ was not achievable in forage or hay for the 2010 season analysis.

Results of supervised residue trials on crops

Soya bean (dry)

A total of twelve supervised residue trials were conducted in the USA in 2010 and 2012.

The approved use of dicamba in soya bean in the USA consists of two different applications: application of up to 0.56 kg ai/ha as a broadcast application made approximately 14 days prior to planting, and/or up to 1.12 kg ai/ha applied to soya bean plants after soya bean pods have reached mature brown color and at least 75% leaf drop has occurred with a PHI of 7 days. If both pre-plant

and pre-harvest applications are used in one season, the maximum seasonal use rate must not exceed 2.24 kg ai/ha. After a pre-harvest application soya bean fodder and hay must not be fed to animals.

After one pre-plant and one pre-harvest applications using the three different salt types, residues in the seed (dry) samples were primarily the parent compound and mostly relatively low (< 0.1 mg/kg). However, residue concentrations vary hugely, due possibly to the split of pods causing seeds to come into contact with dicamba itself or dicamba residue on the outer surface of pods. Since all the trials approximated normal agricultural practices, the Meeting decided to use these trial results in estimating a maximum residue level. No significant difference or pattern was observed among the trials using these different formulations.

Residues of dicamba in soya bean (dry) from those trials matching the GAP of the USA were, in rank order (n=12): < 0.01 (2), 0.01, 0.02, 0.025 (2), 0.035, 0.06, 0.12, 0.545, 5.4 and 5.6 mg/kg.

The Meeting estimated a maximum residue level of 10 mg/kg to replace the previous recommendation of 5 mg/kg. For the purpose of calculating animal dietary burden, the Meeting estimated a median residue of 0.03 mg/kg.

Corresponding total residues (dicamba and 5-OH dicamba) of dicamba were (n=12): < 0.01, < 0.02, 0.02 (2), 0.025, 0.03, 0.035, 0.06, 0.13, 0.555, 5.635 and 6.06 mg/kg.

The Meeting estimated an STMR of 0.033 mg/kg.

Soya bean forage and hay

Soya bean forage and hay samples were collected before the second application was made to avoid abscission. Therefore, residues in these commodities came from a pre-plant application only. The US label prohibits the use of fodder or hay after a pre-harvest application.

The residues from the pre-plant application were expected to be very low as shown in the trials (mostly < 0.05 mg/kg and in one trial 0.06 mg/kg for dicamba) and, as such, residues in soya bean forage and hay from only pre-plant application would not have impacted on the livestock dietary burden. Therefore, the Meeting confirmed the decision of the 2010 and 2011 JMPR that there was no need for estimating a maximum residue level, median residue or highest residue for soya bean fodder and hay.

Fate of residues during processing

The 2010 JMPR received and reviewed information on processing of soya bean seed to oil and meal.

Processed Product	Processing factor		STMR/STMR-P
	Dicamba	Total residues	
Soya bean			0.033
Refined oil	< 0.019	< 0.036	0.001

As there is no concentration of dicamba and 5-OH dicamba observed in refined oil, the estimation of a maximum residue level is not necessary for this commodity.

On the basis of the processing factor of 0.35 for dicamba only, a median residue of 0.0105 mg/kg was calculated for soya bean meal, which may be used as a livestock feed item.

Residue concentration was observed in soya bean hulls and grain dust which may also be used as animal feeds. The processing factors of dicamba only, calculated for these commodities, were 3.9 and 676, respectively. From these factors, median residues in soya bean hulls and grain dust for the estimation of animal burden were calculated to be 0.117 and 20.3 mg/kg, respectively.

Residues in animal commodities

Soya beans and processed soya bean products may be fed to dairy cattle, beef cattle, broilers and layers. The maximum and mean dietary burdens were calculated using the highest residues and median residues of dicamba in commodities for which maximum residue levels were recommended by the 2010 JMPR and current JMPR and their processed products on a basis of the OECD Animal Feeding Table.

Residues of 5-OH dicamba was not included in the calculation of animal dietary burden as its concentrations in animal feeding items were very low and the feeding study with 5-OH dicamba resulted in very low uptake (< 0.01 mg/kg) of 5-OH dicamba into tissues, milk or blood of cattle at a dose equivalent to 59 ppm in the diet.

The resulting maximum and mean dietary burdens to be used for estimating maximum residue levels for commodities of animal origin (both mammals and poultry) were identical to those of the 2010 and 2011 JMPR.

The Meeting concluded that there was no need to re-evaluate maximum residue levels, STMRs or HRs for commodities of animal origin.

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): *Dicamba.*

Definition of the residue for plant commodities (for estimation of dietary intake): *Sum of dicamba and 5-OH dicamba expressed as dicamba*.

Definition of the residue for animal commodities (for compliance with MRLs and for estimation of dietary intake): *Dicamba and 3,6-dichlorosalicylic acid (DCSA) expressed as dicamba.*

Residue is not fat-soluble.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Dietary Intakes (IEDIs) of dicamba were calculated for the 13 GEMS/Food cluster diets using STMRs and STMRPs estimated by the 2010 and current Meeting (Annex 3). The ADI is 0–0.3 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 dicamba 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 Intakes (IESTI) of dicamba were calculated for soya bean and its processed commodity using STMRs/STMR-Ps estimated by the current Meeting (Annex 4). The ARfD is 0.5 mg/kg and the calculated IESTIs were 0% of the ARfD. The Meeting concluded that the short-term intake of residues of dicamba, when used in ways that have been considered by the JMPR, is unlikely to present a public health concern.

5.12 DIFENOCONAZOLE (224)

RESIDUE AND ANALYTICAL ASPECTS

Difenoconazole was first evaluated by the JMPR in 2007 for toxicology when an ADI of 0–0.01 mg/kg bw and an ARfD of 0.3 mg/kg bw were established. In 2007 and 2010, the JMPR evaluated for residues and recommended numerous maximum residue levels. The compound was listed by the Forty-fourth Session of the CCPR for residue evaluation for additional MRLs by the JMPR in 2013.

The residue is defined, for plant commodities, as parent difenoconazole for compliance with the MRL and for estimation of dietary intake. For animal commodities, it is defined as sum of difenoconazole and 1-[2-chloro-4-(4-chloro-phenoxy)-phenyl]-2-(1,2,4-triazol)-1-yl-ethanol (CGA 205375), expressed as difenoconazole, for compliance with the MRL and for estimation of dietary intake. The residue is fat soluble.

The present Meeting received residue trial information on citrus fruits, pome fruits, grapes, Japanese persimmon, bulb vegetables, brassica vegetables, fruiting vegetables, ginseng and post-harvest treated potato. Further, processing studies on oranges, apples, grapes, tomatoes, potatoes and ginseng were provided. According to a request from the Forty-fourth Session of the CCPR, the Meeting re-evaluated the ginseng processing studies evaluated in 2010 to estimate MRLs complying with the new classification for processed products.

Methods of analysis

The analytical methods used for the determination of difenoconazole in samples from supervised trials, had already considered by the JMPR in 2007 and 2010. The methods are based on LC-MS/MS and GC-NPD determination and the limits of quantitation were 0.01 mg/kg. The validity of the analytical results was supported by validation data on representative crops and results of concurrent recovery studies.

The methods used for ginseng and the processed products were also considered by the 2010 J MPR. The limits of quantitation for difenoconazole based on GC-ECD were between 0.003 and 0.007 mg/kg and concurrent recoveries ranged between 86% and 113% .

Difenoconazole in Japanese persimmon were extracted with acetone and partitioned with dic hloromethane. The LOQ by GC-ECD determination was 0.02 mg/kg and concurrent recoveries ranged from between 88% and 107%.

The Meeting additionally received information on analytical methods used for the determinat ion of triazole metabolites 1, 2, 4-triazole, triazole alanine and triazole acetic acid residues in the same plant commodity samples from t he supervised trials. The methods involved extraction with organic solvents, SPE clean-up and/or derivatization steps, partition with ethyl acetate and determination by LC-MS/MS. The limits of quantitation for all metabolites were 0.01 mg/kg and procedural recoveries ran ged from 70% to 115%.

Stability of residues in stored analytical samples

The 2007 JMPR concluded that difenoconazole was stable for 2 years in most plant commodities when deep frozen. This covered the stability of difenoconazole in samples from the supervised trials. New data on ginseng and Japanese persimmon were provided. The storage stability tests were conducted simultaneously with storage of field trial sample for 4–31 days in ginseng and the products and for 51 days in Japanese persimmon. The results indicated that residues in the samples were stable during the storage period.

Results of supervised residue trials on crops

Citrus fruits

Difenoconazole is registered in the USA for use on citrus fruits at a GAP of 4 × 0.14 kg ai/ha (total seasonal rate of 0.56 kg ai/ha), 7 day interval and a PHI of 0 days. Residue trials on citrus fruits were conducted in the USA, matching the critical GAP. Residue concentrations of difenoconazole in citrus fruit, determined on a whole fruit basis, were: 0.11, 0.13, 0.13, 0.14, 0.15, 0.15, 0.23, 0.26 and 0.37 mg/kg in oranges (n=9); 0.17, 0.38 mg/kg in mandarin (n=2); 0.49 mg/kg in tangerine (n=1); 0.075, 0.09, 0.11, 0.13, 0.18 and 0.18 mg/kg in grapefruit (n=6); 0.09, 0.16, 0.17, 0.19 and 0.24 mg/kg in lemons (n=5).

The Meeting noted that as the GAP in USA was for citrus fruits and that the medians of data sets for oranges, mandarins, grapefruits and lemons differed by less than 5-fold, agreed to consider a group maximum residue level. In deciding on the data set to use for estimating a group maximum residue level, given a Kruskal-Wallis H-test indicated that the residue populations were not different, it was agreed to combine the results to give a data set of: 0.075, 0.09, 0.09, 0.11, 0.11, 0.13, 0.13, 0.13, 0.14, 0.15, 0.15, 0.16, 0.17, 0.17, 0.18, 0.18, 0.19, 0.23, 0.24, 0.26, 0.37, 0.38 and 0.49 mg/kg (n=23) for citrus.

The Meeting agreed to estimate a maximum residue level of 0.6 mg/kg, an STMR of 0.16 mg/kg and an HR of 0.49 mg/kg for whole citrus fruits.

Pome fruits

Difenoconazole is registered in the USA for use on pome fruits at a GAP of 5 × 0.078 kg ai/ha (total seasonal rate of 0.37 kg ai/ha), 7 day intervals and a PHI of 14 days. Residue trials on apple and pear were conducted in the USA and complied with the US GAP.

Residues in apples were (n=13): 0.02, 0.07, 0.07, 0.08, 0.13, 0.16, 0.21, 0.25, 0.28, 0.37, 0.38, 0.39 and 0.47 mg/kg.

Residues in pears were (n=6): 0.07, 0.12, 0.12, 0.14, 0.19 and 0.27 mg/kg.

A national use pattern in the Republic of Korea permits up to five foliar applications of difenoconazole WP 10 (%, w/w) on Japanese persimmon at a rate of 0.0054 kg ai/L with 10 day intervals and a PHI of 7 days. Six trials were conducted in the Republic of Korea in 2011 (3) and 2012 (3) matching the critical GAP.

However, all trials were conducted with the same variety. In each year, three trials were performed at the same dates of application and under the same weather conditions, thus the trials were not considered as independent. As a result the Meeting considered that for this evaluation, only two residue values (0.37, 0.43 mg/kg) were available. In addition, the GAP differed from that of the US GAP for pome fruits. Consequently, the persimmon residue values could not be combined with residues from apple and pear.

The Meeting noted that the GAP in USA was for pome fruits and that the medians of the apple and pear data sets differed by less than 5-fold and agreed to consider a group maximum residue level. 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 apple and pear were not different it was agreed to combine the results to give a data set of: 0.02, 0.07 (3), 0.08, 0.12 (2), 0.13, 0.14, 0.16, 0.19, 0.21, 0.25, 0.27, 0.28, 0.37, 0.38, 0.39 and 0.47 mg/kg (n=19) for pome fruits group.

The Meeting estimated a maximum residue level of 0.8 mg/kg, an STMR of 0.16 mg/kg and an HR of 0.47 mg/kg for pome fruits. The Meeting withdrew its previous recommendation of 0.5 mg/kg for pome fruits.

Grapes

A national use pattern in the USA permits up to four foliar applications of difenoconazole EC 250 (250 g/L) on grapes at a rate of 0.13 kg ai/ha (total seasonal rate of 0.52 kg ai/ha) with 10 days interval and a PHI of 7 days. Twelve trials conducted in the USA matched the critical GAP, of which two trials were not considered independent as they were carried out on the same variety at a nearby location (experiencing the same weather conditions) and shared the same dates of application. In addition, one trial was excluded as it was carried out with a grape variety for which use was not allowed.

Residues in grapes were (n=10): 0.11, 0.17, 0.19, 0.23, 0.40, 0.64, 0.65, 0.67, 1.3 and 1.5 mg/kg.

The 2007 JMPR estimated a maximum residue level of 0.1 mg/kg for grapes, based on residu e trials conducted in southern Europe matching Italian GAP (four applications to grape vines with a s pray concentration of 0.005 kg ai/hL with a PHI of 21 days).

As the US use pattern is considered the more critical GAP than the Italian GAP, the Meeting recommended a maximum residue level of 3 mg/kg, an STMR of 0.52 mg/kg and an HR of 1.5 mg/kg for grapes, using residue data from the USA. The Meeting withdrew its previous recommendation of 0.1 mg/kg for grapes.

Bulb vegetables

Onion, bulb

A national use pattern in the USA permits up to four foliar applications of difenoconazole EC 250 (250 g/L) on bulb onions at a rate of 0.13 kg ai/ha (total seasonal rate of 0.52 kg ai/ha), with a 7 day interval and a PHI of 7 days.

Residues in onion, bulb were (n=8): < 0.01 (3), 0.01, 0.02, 0.02, 0.03 and 0.07 mg/kg.

Based on the residue values, the Meeting estimated a maximum residue level of 0.1 mg/kg, an STMR of 0.015 mg/kg and an HR of 0.07 mg/kg for onion, bulb.

Spring onion

A national use pattern in the USA permits up to three foliar applications of difenoconazole EC 250 (250 g/L) on green onions including spring onions at a rate of 0.13 kg ai/ha (total seasonal rate of 0.38 kg ai/ha), with 7 days interval and a PHI of 7 days. Three trials conducted in the USA matched the critical GAP.

Residues in whole spring onion were (n=3): 2.3, 2.8 and 3.8 mg/kg.

The Meeting estimated a maximum residue level of 9 mg/kg, an STMR of 2.8 mg/kg and an HR of 3.8 mg/kg for spring onions.

Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead cabbages

A national use pattern in the USA permits up to four foliar applications of difenoconazole EC 250 (250 g/L) on Brassica (cole) leafy vegetables at a rate of 0.13 kg ai/ha (total seasonal rate of 0.52 kg ai/ha) with 7 days interval and a PHI of 1 day. Six trials on head cabbage and broccoli each were conducted in the USA according to the critical US GAP.

Residues in head cabbage with wrapper leaves were (n=6): 0.09, 0.30, 0.34, 0.46, 0.94 and 1.3 mg/kg.

Residues in broccoli (head and stem) were (n=6): 0.15, 0.32, 0.32, 0.35, 0.37 and 0.53 mg/kg.

Based on GAPs of various European countries, the 2007 JMPR recommended a maximum residue level of 0.2 mg/kg for Brussels sprouts, head cabbage and cauliflowers, respectively, and 0.5 mg/kg for broccoli. As the USA GAP allows a shorter PHI (1 day) than the European GAP, the Meeting decided to use the US trials for maximum residue level estimation.

The Meeting noted that the GAP in USA was for Brassica vegetables and that the medians of the two data sets differed by less than 5-fold and agreed to consider a group maximum residue level. 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 head cabbage and broccoli were not different, it was agreed to combine the results to give a data set of: 0.09, 0.15, 0.3, 0.32, 0.32, 0.34, 0.35, 0.37, 0.46, 0.53, 0.94 and 1.3 mg/kg (n=12) for Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead cabbages.

The Meeting estimated a maximum residue level of 2 mg/kg, an STMR of 0.35 mg/kg and an HR of 1.3 mg/kg for the crop group, Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead cabbages. The meeting withdrew its previous recommendations for Brussels sprouts, Head cabbage and Cauliflowers of 0.2 mg/kg and for Broccoli of 0.5 mg/kg.

Fruiting vegetables, Cucurbits

Melons

A national use pattern in the USA permits up to four foliar applications of difenoconazole EC 250 (250 g/L) on cucurbit vegetables at a rate of 0.13 kg ai/ha (total seasonal rate of 0.52 kg ai/ha), 7 day interval and a PHI of 0 days. Six trials on cantaloupe conducted in the USA were provided for this Meeting. Five trials were performed according to the US critical GAP, however in one trial the harvest was made 4 days after the last application.

Residues in whole melon were (n=5): 0.06, 0.08, 0.14, 0.19 and 0.35 mg/kg.

The Meeting estimated a maximum residue level 0.7 mg/kg, an STMR of 0.14 mg/kg and an HR of 0.35 mg/kg for melons, except watermelon.

Cucumber, summer squash

A national use pattern in the USA permits up to four foliar applications of difenoconazole EC 250 (250 g/L) on cucurbit vegetables at a rate of 0.13 kg ai/ha (total seasonal rate of 0.52 kg ai/ha), 7 day interval and a PHI of 0 days. Six trials on gherkins and five trials on summer squash were provided to the Meeting. The trials were conducted in the USA complied with the critical US GAP.

Residues in gherkin were (n=6): < 0.01, 0.01, 0.03, 0.04, 0.04 and 0.15 mg/kg.

Residues in summer squash were (n=5): < 0.01, 0.02, 0.05, 0.06 and 0.06 mg/kg.

The Meeting noted that the GAP in USA is for fruiting vegetables, cucurbits with edible peel and that the medians of the two data sets differed by less than 5-fold and agreed to consider a group maximum residue level. 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 gherkin and summer squash were not different it was agreed to combine the results to give a data set of < 0.01, < 0.01, 0.01, 0.02, 0.03, 0.04, 0.04, 0.05, 0.06, 0.06 and 0.15 mg/kg (n=11) for fruiting vegetable, cucurbits with edible peel.

The Meeting estimated a maximum residue level of 0.2 mg/kg, an STMR of 0.04 mg/kg and an HR of 0.15 mg/kg for fruiting vegetables, cucurbits with edible peel (cucumber, gherkin and summer squash).

Fruiting vegetables, other than Cucurbits

A national use pattern in the USA permits up to four foliar applications of difenoconazole EC 250 (250 g/L) on fruiting vegetables (tomatoes and peppers) at a rate of 0.13 kg ai/ha (total seasonal rate of 0.52 kg ai/ha), 7 day interval and a PHI of 0 days. Trials conducted in the USA (11 trials for tomatoes, six trials for sweet peppers, three trials for chili pepper) were provided to the current Meeting. The trials were performed according to the critical US GAP.

Residues in tomato were (n=11): 0.01, 0.10, 0.11, 0.11, 0.14, 0.15, 0.16, 0.26, 0.27, 0.39 and 0.39 mg/kg.

Residues in sweet pepper were (n=6): 0.06, 0.10, 0.11, 0.14, 0.14 and 0.18 mg/kg.

Residues in chili pepper were (n=3): 0.10, 0.16 and 0.26 mg/kg.

Residue data for sweet pepper and chili pepper was combined for mutual support. Further, the Meeting noted that the GAP in USA was for fruiting vegetable other than cucurbits and that the medians of the two data sets differed by less than 5-fold 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 tomatoes and peppers were similar, it was agreed to combine the results to give a data set of 0.01, 0.06, 0.10(3), 0.11 (3), 0.14 (3), 0.15, 0.16, 0.16, 0.18, 0.26, 0.26, 0.27, 0.39 and 0.39 mg/kg (n=20) for fruiting vegetables other than cucurbits.

The 2007 JMPR recommended a maximum residue level of 0.5 mg/kg for tomato from eleven trials conducted on tomatoes in Europe (France, Greece, the UK, Spain) matching the Italian GAP (2 applications at 0.13 kg ai/ha with a PHI of 7 days). However, the GAP of the USA was considered to be the critical GAP.

Therefore, based on the combined dataset on tomato and peppers from the US trials the Meeting estimated a maximum residue level of 0.6 mg/kg, an STMR of 0.14 mg/kg and an HR of 0.39 mg/kg for fruiting vegetables other than cucurbits except sweet corn and mushrooms. The Meeting withdrew its previous recommendation for tomatoes of 0.5 mg/kg.

Furthermore, the Meeting estimated a maximum residue level of 5 mg/kg, an STMR of 1.1 mg/kg and an HR of 1.8 mg/kg for chili peppers dried.

Potato (post-harvest treatment)

A national use pattern in the USA permits a single post-harvest application of difenoconazole to potatoes at a rate of 3.19 g ai/t tubers with in an line aqueous spray application using T-jet controlled droplet applicator (CDA) or similar application system. The US GAP does not specify a withholding period.

Residue trials on potatoes involving post-harvest application were conducted at five sites in different regions of the USA. In the trials, difenoconazole FS 360 (360 g/L) was applied once to potatoes as a post-harvest treatment at a rate of 3.5–3.8 g ai/t tubers, spraying directly to tubers falling from a conveyor belt or moving along a roller table. Post-harvest treated tubers were then collected on the day of treatment (0 day) once the test substance had dried. In decline studies, tubers were stored for up to 231 days in typical storage conditions of 5–10 °C.

At one site, potato tubers were cut at the field site. At another one site, in addition to a conveyor belt treatment, three additional application methods (surface, spray chamber and brush table) were utilized. The two methods using surface spraying and spray chamber did not comply with US GAP.

Therefore, in total five trials matching US GAP were available for use in estimating a maximum residue level.

In the USA, a pre-harvest application using difenoconazole formulation is also authorized on potatoes. No residue was detected in pre-treatment samples.

Residues in potatoes from post-harvest treatment (n=5): 0.61, 0.87, 1.2, 1.3 and 1.9 mg/kg.

The Meeting estimated a maximum residue level of 4 mg/kg, an STMR of 1.2 mg/kg and an HR of 1.9 mg/kg for post-harvest treated potato. The Meeting withdrew its previous recommendation of 0.02 mg/kg for potato that had been based on the residues resulting from pre-harvest treatment.

Ginseng

The maximum GAP in the Republic of Korea allows five applications of difenoconazole SC 10 (%, w/w) on ginseng at a rate of 0.0054 kg ai/hL, with a 10 day interval and a PHI of 14 days.

Two trials, using ready to harvest ginseng plantations (5 years old), were conducted in the Republic of Korea, complying with the maximum GAP. The resulting residues were: 0.030 and 0.044 mg/kg.

Of five trials evaluated by the 2010 JMPR, four trials matched the maximum GAP of the Republic of Korea. Thus the residues were (n=6): 0.006, 0.017, < 0.02, < 0.02, 0.030 and 0.044 mg/kg.

The Meeting estimated a maximum residue level 0.08 mg/kg, an STMR of 0.02 mg/kg and an HR of 0.044 mg/kg for ginseng. The Meeting withdrew its previous recommendation of 0.5 mg/kg for ginseng.

Animal feed

Residue information on animal feeds was not provided to the current Meeting.

Fate of residues during processing

The Meeting received information on the fate of difenoconazole residues during the processing of oranges, apples, grapes, tomatoes, potatoes and ginseng. The following table summarizes processing factors, STMR-Ps and HR-Ps estimated by the Meeting.

Raw agricultural commodity	Processed commodity	Pf (best estimate)	RAC STMR/HR	STMR-P/HR-P
Citrus	Citrus juice	< 0.01	0.16	0.002
	Citrus oil	47		7.5
	Citrus dry pulp	4.0		0.64
Pome fruit	Apple juice	0.03	0.16	0.005
	Apple pomace, wet	9.5		1.5
Grape	Raisin	2.1	0.52/1.5	1.1/3.2
	Juice	0.46		0.24
Tomatoes	Paste	1.6	0.14	0.22
	Puree	0.57		0.08
Potato	Flakes	< 0.024	1.2	0.029
	Chips	0.073		0.088
	Peel, wet	3.2		3.8
Ginseng	Dried including red ginseng	2.6	0.02/0.044	0.052/0.11
	Extracts	7.0	-	0.14

For dried grapes (raisin), the Meeting estimated a maximum residue level of 6 mg/kg, based on the processing factor of 2.1 for raisins and the maximum residue level of 3 mg/kg for grapes.

The Meeting re-calculated a processing factor for dried ginseng including processing study results for red ginseng, for a processing factor of 2.6. Based on the processing factor of 2.6 and a maximum residue level of 0.08 mg/kg for the ginseng raw commodity, the Meeting recommended a maximum residue level of 0.2 mg/kg for ginseng, dried including red ginseng. For ginseng extracts, applying the calculated processing factor of 7.0, a maximum residue level of 0.6 mg/kg was estimated.

Residues in animal commodities

Estimated dietary burdens of farm animals

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 feed items include: almond hulls, apple pomace, bean forage, cabbages, head, carrot culls, citrus dried pulp, grape pomace, dry, pea vines, potato culls, potato process waste (wet peel), rape seed fodder, rape seed meal, soya bean seed, sugar beet leaves or tops, sunflower seed meal, wheat straw and fodder.

The Japanese animal diet contained only soya bean seed and rape seed meal of those commodities for which the JMPR estimated highest and median residues. The residues in the two commodities resulted in an animal dietary burden of less than 0.01 ppm on dry matter basis, therefore those values are not included in the summary table.

	Livestock dietary burden, difenoconazole, ppm of dry matter diet					
	US-Canada		EU		Australia	
	max	mean	max	mean	max	mean
Beef cattle	12.56	11.42	17.88[a]	15.30[b]	11.39	10.80
Dairy cattle	4.87	4.36	14.91[c]	12.37[d]	11.31	10.71
Poultry, broilers	0.01	0.01	0.96	0.61	0.01	0.01
Poultry, layers	0.01	0.01	1.89[e]	1.11[f]	0.01	0.01

[a] Highest maximum beef or dairy cattle dietary burden suitable for maximum residue level estimates for mammalian meat and edible offal

[b] Highest mean beef of dairy cattle dietary burden suitable for STMR estimates for mammalian meat and edible offal

[c] Highest maximum dairy cattle dietary burden suitable for maximum residue level estimates for milk

[d] Highest mean dairy cattle dietary burden suitable for STMR estimates for milk

[e] Highest maximum broiler or layer poultry dietary burden suitable for maximum residue level estimates for poultry meat, edible offal and eggs

[f] Highest mean broiler or layer poultry dietary burden suitable for STMR estimates for poultry meat, edible offal and eggs

Estimated residues in animal commodities

For MRL estimation, the residues in the animal commodities are the sum of difenoconazole and CGA 205375 (1-[2-chloro-4-(4-chloro-phenoxy)-phenyl]-2-(1, 2, 4-triazol)-1-yl-ethanol)) expressed as difenoconazole.

Cattle

The 2007 JMPR evaluated two animal transfer studies carried out with Holstein dairy cows administering difenoconazole at 1, 3, 10 ppm (study 1) or 1, 5, 15 ppm (study 2) in the dry-weight diet for 29–30 consecutive days. The Meeting concluded that the two feeding studies were generally

in good agreement of transfer factors. Thus, the present Meeting used the study with the 5 and 15 ppm feeding levels as most closely bracketing the dietary burdens.

For maximum residue level estimation, the high residues in the tissues were calculated by interpolating the maximum dietary burden of 17.88 ppm (in 2010 it was 2.42 ppm) between the relevant feeding levels (5 and 15 ppm) from the dairy cow feeding study and using the highest tissue concentrations from individual animals within those feeding groups.

The STMR values for the tissues were calculated by taking the STMR dietary burden of 15.30 ppm between the relevant feeding levels (5 and 15 ppm) from the dairy cow feeding study and using mean residue of the three animals.

The following table shows the expected residues in animal commodities.

	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
Maximum residue level beef or dairy cattle							
Feeding study [a]	5	< 0.005	5	0.012	0.29	0.046	0.058
	15	0.013	15	0.058	0.80	0.14	0.16
Dietary burden and residue estimate	14.91	0.013	17.88	0.071	0.95	0.17	0.19
STMR beef or dairy cattle							
Feeding study [b]	5	< 0.005	5	0.012	0.25	0.043	0.046
	15	0.013	15	0.046	0.70	0.13	0.14
Dietary burden and residue estimate	12.37	0.011	15.30	0.047	0.71	0.13	0.14

[a] Highest residues for tissues and mean residue for milk

[b] Mean residues for tissues and milk

For muscle, the residues arising from dietary burdens of 17.88 ppm and 15.30 ppm were 0.071 mg/kg and 0.047 mg/kg, respectively. In fat, the residues arising from dietary burdens of 17.88 ppm and 15.30 ppm were 0.19 mg/kg and 0.14 mg/kg, respectively.

The residues in milk were 0.013 mg/kg and 0.011 mg/kg from dietary burdens of 14.91 ppm and 12.37 ppm, respectively.

For liver, the residues arising from dietary burdens of 17.38 ppm and 15.30 ppm were 0.95 mg/kg and 0.71 mg/kg, respectively. In kidney, the residues arising from dietary burdens of 17.88 ppm and 15.30 ppm were 0.17 mg/kg and 0.13 mg/kg.

The Meeting estimated a maximum residue level for difenoconazole in mammalian fat of 0.2 mg/kg. STMR and HR values for mammalian muscle and fat were estimated as 0.047 and 0.071 mg/kg in muscle, 0.14 and 0.19 mg/kg in fat, respectively.

For milk, the Meeting estimated a maximum residue level of 0.02 mg/kg and an STMR value of 0.011 mg/kg. Information on fat distribution in milk was not available.

The Meeting estimated a maximum residue level, an STMR value and an HR value for difenoconazole in mammalian edible offal of 1.5, 0.71 and 0.95 mg/kg, respectively, reflecting residues in liver of higher residue level.

The Meeting withdrew its previous recommendations on commodities of mammalian origin and milks.

Poultry

The 2007 JMPR evaluated a transfer study carried out with laying white leghorn hens. Four groups of 15 laying hens were fed rations treated with difenoconazole at 0.3, 1, 3 and 10 ppm for 28 consecutive days. Eggs were collected on 10 occasions for analysis (days 0 before treatment, 1, 3, 6, 9, 13, 16, 20, and 23). Poultry tissue and egg samples from the 0.3 ppm feeding group were not analysed because residues were at or below LOQ (< 0.01 mg/kg) in the 1 ppm feeding group. For poultry tissue, residues in 1 ppm feeding level were also not analysed as the residues in 3 and 10 ppm feeding levels were at or below LOQ (< 0.01 mg/kg).

	Feed level (ppm) for egg residues	Residues (mg/kg) in egg	Feed level (ppm) for tissue residues	Residues (mg/kg) in			
				Muscle	Liver	Skin	Fat
Maximum residue level broiler or laying hen							
Feeding study [a]	1	< 0.01	3	< 0.01	< 0.01	< 0.01	< 0.01
	3	0.046	10	< 0.01	< 0.01	< 0.01	< 0.01
Dietary burden and residue estimate	1.89	0.026	1.89	< 0.01	< 0.01	< 0.01	< 0.01
STMR broiler or laying hen							
Feeding study [b]	1	< 0.01	3	< 0.01	< 0.01	< 0.01	< 0.01
	3	0.032	10	< 0.01	< 0.01	< 0.01	< 0.01
Dietary burden and residue estimate	1.11	0.011	1.11	< 0.01	< 0.01	< 0.01	< 0.01

[a] Highest residues for tissues and mean residues for egg

[b] Mean residues for tissues and mean residues for egg

For poultry tissues, residues arising from the maximum dietary burden of 1.89 ppm were below LOQ (0.01 mg/kg). The Meeting confirmed the maximum residue level recommendation of < 0.01 mg/kg for poultry tissues (fat, edible offal). Further, the Meeting estimated an STMR value and an HR value, 0.001 mg/kg and 0.002 mg/kg, respectively, for the tissues (muscle, fat and edible offal).

For eggs, residues arising from dietary burdens of 1.89 ppm and 1.11 ppm were 0.026 mg/kg and 0.011 mg/kg. The Meeting estimated a maximum residue level of 0.03 mg/kg and an STMR value 0.011 mg/kg and an HR value of 0.026 mg/kg for eggs. The Meeting withdrew its previous recommendation for eggs of 0.01* mg/kg.

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 IESTIs.

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

Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for animal commodities: *sum of difenoconazole and 1-[2-chloro-4-(4-chloro-phenoxy)-phenyl]-2-(1,2,4-triazol)-1-yl-ethanol), expressed as difenoconazole*.

The residue is fat-soluble.

DIETARY RISK ASSESSMENT

Long-term intake

The ADI for difenoconazole is 0-0.01 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for difenoconazole were estimated for the 13 GEMS/Food Consumption Cluster Diets using the STMR or STMR-P values estimated by the previous and present JMPR. The results are shown in Annex 3. The IEDIs ranged 4-60% of the maximum ADI. The Meeting concluded that the long-term intake of residues of difenoconazole from uses considered by the JMPR is unlikely to present a public health concern.

Short-term intake

The ARfD for difenoconazole is 0.3 mg/kg bw. The International Estimate of Short Term Intakes (IESTIs) for difenoconazole 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 varied from 0–30% of the ARfD for children and 0–20% for the general population.

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

5.13 DIQUAT (031)

TOXICOLOGY

Diquat is the ISO-approved name for 6,7-dihydrodipyrido[1,2-a:2′,1′-c]pyrazinediium dibromide (IUPAC), for which the CAS number is 85-00-7. The CAS number for diquat ion is 2764-72-9. Diquat is a non-selective, quick-acting contact herbicide and desiccant, causing injury only to the parts of the plant to which it is applied. Diquat interacts with the electron transfer components associated with Photosystem I, which causes inhibition of photosynthesis. It is also used as an aquatic algicide.

Diquat was previously evaluated by JMPR in 1970, 1972, 1977 and 1993. An ADI of 0–0.008 mg diquat ion/kg bw was allocated in 1977. In 1993, JMPR established an ADI of 0–0.002 mg diquat ion/kg bw based on a NOAEL of 0.19 mg diquat ion/kg bw per day identified in a 2-year study of toxicity and carcinogenicity in rats, using a safety factor of 100. Diquat was reviewed at the present Meeting as part of the periodic review programme of CCPR.

Since the last review by JMPR, the following new studies on diquat have been submitted: acute and subchronic neurotoxicity studies, an immunotoxicity study, metabolism studies and a re-evaluation of cataract observations in previous long-term studies. All dose values are expressed as diquat ion. Some of the studies do not comply with GLP, as most of the data were generated before the implementation of GLP regulations. Overall, the Meeting considered that the database was adequate for the risk assessment.

Biochemical aspects

When administered orally, [^{14}C]diquat is poorly absorbed (< 10%) from the gastrointestinal tract of rats and eliminated mainly via the faeces (about 94%) during the first 24 hours. The small amount absorbed is rapidly eliminated via the urine (about 6%). Biliary excretion represented less than 5% of the administered dose. Peak tissue and blood levels were seen at approximately 2 hours, followed by a rapid decline. Liver, kidney, gastrointestinal tract and lung had the highest residues immediately following dosing; at 96 hours, significant residues were seen primarily in the eye lens.

After oral administration of [^{14}C]diquat to rats (45 mg diquat ion/kg bw), the major excreted product was diquat in both urine (about 6% of the dose) and faeces (about 89% of the dose); diquat monopyridone was the main metabolite in the faeces (5% of dose), but a minor one in the urine. In another oral study in rats (100 mg diquat ion/kg bw), small amounts of diquat dipyridone and picolinic acid were found, in addition to the monopyridone, in urine. The biotransformation of diquat is postulated to proceed either by progressive oxidation of the pyridine rings to form diquat monopyridone and diquat dipyridone or by the cleavage of one of the pyridine rings to form picolinic acid, possibly via pyridine-2-carboxamide as an intermediary metabolite, although this was not identified.

Toxicological data

The acute oral LD_{50} in rats was 214 mg diquat ion/kg bw. There were no mortalities or clinical signs of toxicity at 100 mg/kg bw. The acute dermal LD_{50} in rats was greater than 424 mg diquat ion/kg bw. The 4-hour acute inhalation LC_{50} in rats was 0.121 mg/L. Diquat was moderately to severely irritating to rabbit skin and mildly irritating to rabbit eyes. Diquat was a skin sensitizer in the Magnusson and Kligman test.

Unlike paraquat, diquat is not actively taken up by lung slices, and lung toxicity is not characteristic of diquat poisoning. The eye was the main target organ following short-term repeated exposure in rats and dogs. In addition, effects on kidney, liver and haematological parameters were also observed.

In a 90-day toxicity study in rats using dietary concentrations of 0, 20, 100 and 500 ppm (equal to 0, 1.7, 8.5 and 39.5 mg diquat ion/kg bw per day for males and 0, 1.9, 9.2 and 41.5 mg diquat ion/kg bw per day for females, respectively), the NOAEL was 100 ppm (equal to 8.5 mg diquat ion/kg bw per day), based on decreased body weight gain, feed consumption, changes in clinical chemistry parameters, increased urine volume, decreased urinary specific gravity, minor changes in haematological values and erosion of the tongue and oral cavity and ocular changes at 500 ppm (equal to 39.5 mg/kg bw per day). An investigative 90-day toxicity study in rats was conducted at dietary concentrations of 0, 30, 60 and 300 ppm diquat ion (equal to 0, 2.4, 4.7 and 23.2 mg diquat ion/kg bw per day for males and 0, 2.7, 5.0 and 25.3 mg diquat ion/kg bw per day for females, respectively) to determine the NOAEL for cataract formation in rats. The NOAEL was 60 ppm (equal to 4.7 mg diquat ion/kg bw per day) for ocular lesions and lens opacities evident at 300 ppm (equal to 23.2 mg diquat ion/kg bw per day). The overall NOAEL in the 90-day toxicity studies in rats was 100 ppm (equal to 8.5 mg diquat ion/kg bw per day), with an overall LOAEL of 300 ppm (equal to 23.2 mg diquat ion/kg bw per day).

In a 1-year feeding study in dogs, with achieved dietary intakes of 0, 0.46, 2.42 and 11.48 mg diquat ion/kg bw per day for males and 0, 0.53, 2.53 and 13.21 mg diquat ion/kg bw per day for females, the NOAEL was 0.53 mg diquat ion/kg bw per day, based on lens opacity (cataracts) in females at 2.53 mg diquat ion/kg bw per day.

In a 2-year toxicity and carcinogenicity study in mice using dietary concentrations of 0, 30, 100 and 300 ppm (equal to 0, 3.56, 11.96 and 37.83 mg diquat ion/kg bw per day for males and 0, 4.78, 16.03 and 48.27 mg diquat ion/kg bw per day for females, respectively), the NOAEL was 30 ppm (equal to 3.56 mg diquat ion/kg bw per day), based on reduction in body weight gain, increased relative kidney weights and ocular discharges at 100 ppm (equal to 11.96 mg diquat ion/kg bw per day) and above. There was no evidence of carcinogenicity in mice at doses up to and including 300 ppm (equal to 37.83 mg diquat ion/kg bw per day), the highest dose tested.

A 2-year study of toxicity and carcinogenicity in rats was conducted using dietary concentrations of 0, 5, 15, 75 and 375 ppm (equal to 0, 0.19, 0.58, 2.91 and 14.88 mg diquat ion/kg bw per day for males and 0, 0.24, 0.72, 3.64 and 19.44 mg diquat ion/kg bw per day for females, respectively). There were no effects on survival, changes in haematology, clinical chemistry or urine analysis parameters or neoplastic changes that were considered to be of toxicological significance at any dose level. A treatment-related incidence of opacities of the lens was found in male and female animals receiving 75 and 375 ppm. Among rats receiving 375 ppm, these lesions progressed to total opacification of the lens, affecting all surviving rats receiving 375 ppm when examined at week 104. A low, but slightly higher than in controls, incidence of rats with opacities was seen in the 15 ppm group at 104 weeks only. Cataractous change was observed in the lenses of rats at 75 and 375 ppm. The NOAEL was concluded to be 5 ppm (equal to 0.19 mg diquat ion/kg bw per day) in the 1993 JMPR evaluation. Since that evaluation, the cataract data at 15 ppm have been re-evaluated by the original pathologists. Cataracts were seen in controls and all dose groups, and the incidence and severity were dose related. The present Meeting noted the conclusion of the re-evaluation of the cataract data: that, in contrast to the observations at 75 and 375 ppm, there was no evidence of progression of the disease at 15 ppm that differed from the controls. The present Meeting identified the NOAEL as 15 ppm (equal to 0.58 mg diquat ion/kg bw per day), as the incidence and severity were comparable with those of the controls. There was no evidence of carcinogenicity in this study.

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

Diquat was tested for genotoxicity in vitro and in vivo in an adequate range of assays. It gave an equivocal response in the absence of metabolic activation and a positive response in the presence of metabolic activation in the mammalian cell cytogenic assay; however, it was negative in the in vivo mouse micronucleus assay and dominant lethal assay.

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

On the basis of the lack of genotoxicity in vivo and the absence of carcinogenicity in mice and rats, the Meeting concluded that diquat is unlikely to pose a carcinogenic risk to humans from the diet.

In a two-generation study of reproductive toxicity in rats using dietary concentrations of 0, 16, 80 and 400/240 ppm (equal to 0, 1.6, 7.9 and 38.7 mg diquat ion/kg bw per day for males and 0, 1.7, 8.4 and 40.4 mg diquat ion/kg bw per day for females, respectively), the NOAEL for parental systemic toxicity was 16 ppm (equal to 1.6 mg diquat ion/kg bw per day), based on a low incidence of mouth lesions in both generations and a slightly increased incidence of cataracts at 80 ppm (equal to 7.9 mg diquat ion/kg bw per day). The NOAEL for reproductive toxicity was 400/240 ppm (equal to 38.7 mg diquat ion/kg bw per day), the highest dose tested. The NOAEL for offspring toxicity was 80 ppm (equal to 7.9 mg diquat ion/kg bw per day), based on decreased pup body weights seen in both generations at 400/240 ppm (equal to 38.7 mg diquat ion/kg bw per day).

In a developmental toxicity study in rats that tested gavage doses of 0, 12 and 40 mg diquat ion/kg bw per day, the NOAEL for maternal toxicity was 12 mg diquat ion/kg bw per day, based on reduced body weights and feed consumption seen at 40 mg diquat ion/kg bw per day. The NOAEL for embryo and fetal toxicity was 12 mg diquat ion/kg bw per day, based on reduced fetal weight, haemorrhagic kidney and increased incidence of soft tissue and minor skeletal anomalies at 40 mg diquat ion/kg bw per day.

In a developmental toxicity study in rabbits that tested gavage doses of 0, 1, 3 and 10 mg diquat ion/kg bw per day, the NOAEL for maternal toxicity was 1 mg diquat ion/kg bw per day, based on reduced weight gain and feed consumption at 3 mg diquat ion/kg bw per day. The NOAEL for embryo and fetal toxicity was 3 mg diquat ion/kg bw per day, based on skeletal anomalies at 10 mg diquat ion/kg bw per day.

The Meeting concluded that diquat is not teratogenic in rats or rabbits.

Diquat has been tested for neurotoxicity in acute and repeated-dose studies in rats. In neither study was there any indication of neurotoxicity. In an acute neurotoxicity study in rats that tested gavage doses of 0, 25, 75 and 150 mg diquat ion/kg bw per day, the NOAEL for general toxicity was 75 mg diquat ion/kg bw, based on a range of findings, including clinical signs, at 150 mg diquat ion/kg bw. In the 90-day study of neurotoxicity in rats using dietary concentrations of 0, 20, 100 and 400 ppm (equal to 0, 1.6, 7.9 and 32.4 mg/kg bw per day for males and 0, 1.9, 9.5 and 38.5 mg/kg bw per day for females, respectively), the NOAEL for systemic toxicity was 100 ppm (equal to 7.9 mg diquat ion/kg bw per day), based on evidence of eye lesions and reductions in body weight gain and feed consumption at 400 ppm (equal to 32.4 mg/kg bw per day).

The Meeting concluded that diquat is not neurotoxic.

In a 28-day study of immunotoxicity in female mice using dietary concentrations of 0, 100, 200 and 350 ppm (equal to 0, 23, 44 and 81 mg diquat ion/kg bw per day), there was no evidence of immunotoxicity at doses up to 350 ppm (equal to 81 mg diquat ion/kg bw per day).

Toxicological data on metabolites and/or degradates

Diquat monopyridone [6,7-dihydro-4-oxodipyrido(1,2-a:2′,1′-c) pyrazinium], the major metabolite following oral dosing, was less toxic than the parent compound. The oral LD_{50} for diquat monopyridone was greater than 4000 mg/kg bw. Male and female rats orally administered diquat monopyridone at a dose of 1000 mg/kg bw per day, 5 days/week, for 2 weeks showed no clinical, haematological, biochemical or histopathological abnormalities, except for a decreased number of lymphocytes in both males and females. 1,2,3,4-Tetrahydro-1-oxopyrido(1,2-a)-5-pyrazinium salt (TOPPS), a metabolite in livestock but not in rats, was less toxic than the parent compound. The acute oral LD_{50} of TOPPS in rats was 2449 mg/kg bw. There was no evidence of genotoxicity in the deoxyribonucleic acid (DNA) repair test.

Human data

No reports of adverse health effects in manufacturing plant personnel were provided. In humans, intestinal paralysis and fluid loss are prominent features of diquat intoxication and may lead to abdominal distension, tissue dehydration, hypotensive shock and severe cerebrovascular complications due to brainstem infarction and/or intracranial haemorrhage.

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

Toxicological evaluation

The Meeting established an ADI of 0–0.006 mg diquat ion/kg bw on the basis of a NOAEL of 0.58 mg diquat ion/kg bw per day in the 2-year carcinogenicity study in rats on the basis of cataracts seen at 2.9 mg diquat ion/kg bw per day. A safety factor of 100 was applied. This ADI is supported by the NOAEL of 0.46 mg diquat ion/kg bw per day observed in a 1-year toxicity study in dogs on the basis of cataracts seen at the LOAEL of 2.53 mg diquat ion/kg bw per day. The present ADI is based on the same study and end-point selected by the 1993 JMPR, but using a different NOAEL value. The current Meeting identified the NOAEL as 0.58 mg diquat ion/kg bw per day, as the incidence and progression with time and severity of cataracts at this dose were comparable to those in the controls.

An ARfD of 0.8 mg/kg bw was established on the basis of a NOAEL of 75 mg diquat ion/kg bw in an acute neurotoxicity study in rats, based on clinical signs and decreased body weight gains in the 1st week and decreased feed consumption seen at the LOAEL of 150 mg diquat ion/kg bw. A safety factor of 100 was applied. This ARfD is further supported by the acute oral toxicity study in rats (LD_{50} = 214 mg/kg bw) in which no mortality or clinical signs of toxicity were observed at 100 mg/kg bw. The Meeting considered reductions in body weight gain seen at the start of gavage dosing in several studies (e.g. developmental toxicity studies) to be secondary to gastrointestinal irritation and not relevant to establishing an ARfD. The Meeting concluded that the critical effects in the longer-term studies of eye lesions were not likely to be produced following a single dose, as the eye lesions were normally evident only after several weeks of continuous dosing.

A toxicological monograph was prepared.

Levels relevant to risk assessment of diquat

Species	Study	Effect	NOAEL	LOAEL
Mouse	Two-year study of toxicity and carcinogenicity[a]	Toxicity	30 ppm, equal to 3.6 mg diquat ion/kg bw per day	100 ppm, equal to 12.0 mg diquat ion/kg bw per day
		Carcinogenicity	300 ppm, equal to 37.8 mg diquat ion/kg bw per day[b]	—
Rat	Acute neurotoxicity study[c]	Toxicity	75 mg diquat ion/kg bw	150 mg diquat ion/kg bw
	Ninety-day studies of toxicity[a,d]	Toxicity	100 ppm, equal to 8.5 mg diquat ion/kg bw per day	300 ppm, equal to 23.2 mg diquat ion/kg bw per day
	Two-year study of toxicity and carcinogenicity[a]	Toxicity	15 ppm, equal to 0.58 mg diquat ion/kg bw per day	75 ppm, equal to 2.9 mg diquat ion/kg bw per day
		Carcinogenicity	375 ppm, equal to 14.9 mg diquat ion/kg bw per day[b]	—

Species	Study	Effect	NOAEL	LOAEL
	Two-generation study of reproductive toxicity[a]	Reproductive toxicity	400/240 ppm, equal to 38.7 mg diquat ion/kg bw per day[b]	—
		Parental toxicity	16 ppm, equal to 1.6 mg diquat ion/kg bw per day	80 ppm, equal to 7.9 mg diquat ion/kg bw per day
		Offspring toxicity	80 ppm, equal to 7.9 mg diquat ion/kg bw per day	400/240 ppm, equal to 38.7 mg diquat ion/kg bw per day
	Developmental toxicity study[c]	Maternal toxicity	12 mg diquat ion/kg bw per day	40 mg diquat ion/kg bw per day
		Embryo and fetal toxicity	12 mg diquat ion/kg bw per day	40 mg diquat ion/kg bw per day
Rabbit	Developmental toxicity study[c]	Maternal toxicity	1 mg diquat ion/kg bw per day	3 mg diquat/kg bw per day
		Embryo and fetal toxicity	3 mg diquat ion/kg bw per day	10 mg diquat ion/kg bw per day
Dog	One-year study of toxicity[a]	Toxicity	0.46 mg diquat ion/kg bw per day	2.53 mg diquat ion/kg bw per day

[a] Dietary administration.

[b] Highest dose tested.

[c] Gavage administration.

[d] Two or more studies combined.

Estimate of acceptable daily intake

0–0.006 mg/kg bw

Estimate of acute reference dose

0.8 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 diquat

Absorption, distribution, excretion and metabolism in mammals	
Rate and extent of oral absorption	Poor, ~10% in rat
Dermal absorption	About 6% in 24 h, rat skin
Distribution	Widely distributed, highest levels in eye lens
Potential for accumulation	Potential accumulation only in eye lens
Rate and extent of excretion	Rapid, absorbed dose extensively excreted (> 90%) in urine and bile within 96 h

Metabolism in animals	Metabolism was limited, with < 20% of the urinary residues (< 1% of the administered dose) consisting of metabolites
Toxicologically significant compounds in animals, plants and the environment	Diquat ion
Acute toxicity	
Rat, LD_{50}, oral	214 mg diquat ion/kg bw
Rat, LD_{50}, dermal	> 424 mg diquat ion/kg bw
Rat, LC_{50}, inhalation	0.121 mg diquat ion/l
Rabbit, dermal irritation	Moderately to severely irritating
Rabbit, ocular irritation	Mildly irritating
Dermal sensitization	Sensitizing (Magnusson and Kligman)
Short-term studies of toxicity	
Target/critical effect	Cataract, body weight (rat, dog)
Lowest relevant oral NOAEL	0.46 mg diquat ion/kg bw per day (dog)
Lowest relevant dermal NOAEL	No data
Lowest relevant inhalation NOAEC	No data
Long-term studies of toxicity and carcinogenicity	
Target/critical effect	Cataract (rat), kidney lesions (mouse)
Lowest relevant NOAEL	0.58 mg diquat ion/kg bw per day (rat)
Carcinogenicity	Unlikely to pose a carcinogenic risk to humans from the diet
Genotoxicity	
	Not genotoxic in vivo
Reproductive toxicity	
Target/critical effect	No reproductive toxicity
Lowest relevant parental NOAEL	1.6 mg diquat ion/kg bw per day
Lowest relevant offspring NOAEL	7.9 mg diquat ion/kg bw per day
Lowest relevant reproductive NOAEL	38.7 mg diquat ion/kg bw per day, the highest dose tested
Developmental toxicity	
Target/critical effect	Reduced body weight, delayed ossification; skeletal anomalies at maternally toxic doses
Lowest relevant maternal NOAEL	1 mg diquat ion/kg bw per day (rabbit)
Lowest relevant embryo and fetal NOAEL	3 mg diquat ion/kg bw per day (rabbit)
Neurotoxicity	
Acute and subchronic neurotoxicity	Not neurotoxic
Other toxicological studies	
Immunotoxicity	Not immunotoxic
Studies on metabolites	Diquat monopyridone, diquat dipyridone and TOPPS were less toxic than parent diquat
Medical data	
	No reports submitted; characteristics of intoxication

obtained from published literature

Summary

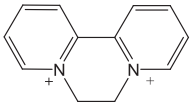
	Value	Study	Safety factor
ADI	0–0.006 mg/kg bw	Two-year study of carcinogenicity in rats	100
ARfD	0.8 mg/kg bw	Acute study of neurotoxicity in rats	100

RESIDUE AND ANALYTICAL ASPECTS

Diquat is a non-selective contact herbicide with uses on many crops. Diquat has been evaluated several times by the JMPR with the initial evaluation in 1970 and the latest in 1994. Diquat was scheduled at the 44th session of the CCPR (2012) for periodic re-evaluation of toxicology and residues by the 2013 JMPR.

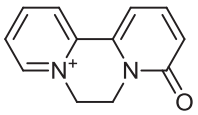
The Meeting received information on the metabolism of diquat in animals, on crops, methods of residue analysis, freezer storage stability, GAP information, supervised residue trials, fate of residue during storage and processing, and livestock feeding studies.

Diquat is 6,7-dihydrodipyrido[1,2-a:2',1'-c]pyrazinediium dibromide.

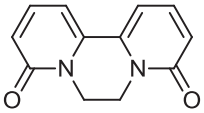


Metabolites referred to in the appraisal are addressed by their common names:

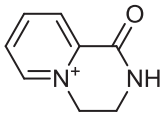
Diquat monopyridone



Diquat dipyridone



TOPPS



Animal metabolism

Metabolism of diquat in goats and hens involves formation of diquat dipyridone and diquat monopyridone. TRR are expressed in terms of diquat ion.

In a study where a lactating goat was orally treated once daily for 7 consecutive days with ring labelled [^{14}C]-diquat at a dose equivalent to 90 ppm in the feed, approximately 97% of the administered dose was recovered with the majority in the excreta (84% faeces, < 1% urine) or gastrointestinal tract (12%). The radioactivity in the tissues ranged from 0.003 in fat to 0.079 mg equiv/kg in kidney. TRR values in milk were up to 0.015 mg equiv/kg during the dosing period with levels not reaching a plateau after seven days of dosing. Major components of the ^{14}C residues were

unchanged diquat ion (liver 22% TRR), diquat dipyridone (kidney 29% TRR, liver 33% TRR, muscle 46% TRR, fat 20% TRR, milk 82% TRR) and diquat monopyridone (kidney 21% TRR, liver 13% TRR, muscle 13% TRR).

Laying hens were orally treated once daily in experiments where a single hen received a single dose at 4-5 ppm, five daily doses at 4–5 ppm or 14 doses daily doses at 0.4–0.5 ppm. By three days after administering the last dose the majority (> 94%) of the dose was recovered in the excreta. Radioactivity in tissues of hens dosed at 0.4-0.5 ppm ranged from 0.00010 mg equiv/kg in fat to 0.00045 mg equiv/kg in kidney. The ^{14}C levels in egg whites and yolks reached a plateau of 0.00003 and 0.00014 mg equiv/kg respectively by seven days of dosing. Yolk from day 9+10 eggs contained diquat ion (26% TRR), yolks from day 7 contained diquat monopyridone (85% TRR) and egg yolks from day 11 contained TOPPS (10% TRR).

In another study laying hens were each given daily doses of ^{14}C-ring labelled diquat by oral gavage for 4 days at the equivalent of 32 ppm in the diet. At sacrifice 18 hours after the last dose, radioactive residues in the muscle, fat and eggs were all < 0.01 mg equiv/kg. Levels of radioactivity in liver and kidney were 0.045 and 0.058 mg equiv/kg respectively with unchanged diquat (liver 48% TRR, kidney 12% TRR) and diquat monopyridone (liver 3.9% TRR, kidney 15% TRR) the main residue components. Minor components identified were TOPPS (liver 1.8% TRR, kidney 3.9% TRR) and diquat dipyridone (liver 3.1% TRR, kidney 6.6% TRR).

In an additional study laying hens fed a diet containing powdered grain harvested from barley plants treated with [^{14}C]-diquat, the dose was equivalent to 1 to 1.5 ppm in the feed for 11 consecutive days with hens sacrificed 4 hours or 7 days after the last exposure. The major components of the ^{14}C in the grain were diquat ion (17% TRR) and TOPPS (8.7% TRR). Most of the administered dose was recovered in the excreta (84–89%) with less than 0.1% recovered in eggs. Radioactive residues in egg white reached a plateau by day 5 of dosing with a maximum level of 0.0006 mg equiv/kg while egg yolk reached a plateau by day 8 with a maximum residue of 0.0039 mg equiv/kg. In tissues at sacrifice 4 hours after last exposure, ^{14}C residues were highest in kidney (0.014 mg equiv/kg) and much lower in muscle and fat at 0.0009 and 0.0022 mg equiv/kg respectively. Diquat ion was a minor component of the ^{14}C residues in egg yolk at 0.9% TRR with TOPPS and diquat monopyridone present at 3.5 and 3.0% TRR respectively.

Metabolism in laboratory animals (rat) was summarized and evaluated by the WHO panel of the JMPR in the present meeting. The metabolism of diquat in ruminants and laying hens is adequately understood. In both goats and hens diquat is oxidised to form diquat monopyridone and diquat dipyridone. TOPPS is found as a minor metabolite (< 10% TRR) in hens but was not detected in studies of the metabolism of diquat by goats or rats.

Plant metabolism

Diquat is used for two different situations:

- Directed sprays for weed control (crop not intentionally treated)
- Use as a crop desiccant to facilitate crop harvest (crop treated)

Plant metabolism studies were conducted with diquat to investigate these two situations.

Application prior to crop emergence

A single application of ^{14}C-diquat was made to soil into which tomato seeds had been sown prior to emergence. Residues in mature fruit and leaves harvested 112 days after application were < 0.001 and 0.002 mg equiv/kg respectively and were not analysed further.

Crop desiccation

The use of diquat as a pre-harvest desiccant was investigated in potato and rape following foliar spray application to the crop. Since the plants are senescent at the time of application or die quickly after application, metabolism is essentially stopped and translocation from the treated parts of the crops into other plant parts such as seeds and roots is reduced. Following use as a crop desiccant, diquat ion was the major component of the ^{14}C residue in the skin and flesh of potato tubers accounting for more than 70% of TRR with no other individual component comprising more than 10% TRR. The major component in rape seed harvested from crops, following pre-harvest desiccation, was diquat ion at 48% TRR with smaller amounts of TOPPS (7.8% TRR) and diquat monopyridone (2.0% TRR).

The metabolism of diquat by plants is well understood. Following directed application to weeds using shielded sprayers there is minimal contact of the crop with diquat. A portion of the spray will reach the soil, but as described later, diquat is strongly absorbed by soil components such that it is largely unavailable for uptake by plant roots.

Following use as a pre-harvest desiccant, diquat ion is the major component of the ^{14}C residue in those parts exposed to direct sprays with TOPPS and diquat monopyridone present as minor components. Only low levels of radioactivity are found in plant parts such as potato tubers that are not directly exposed to the spray (< 0.05 mg equiv/kg).

Environmental fate

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

Diquat residues are persistent in soils, however residues in soil are strongly bound to soil components and not available for uptake by plants. As such, residues in soil should not contribute significantly to the residues in succeeding crops.

In soil incubation studies under aerobic conditions in the dark, diquat disappeared with a half-life that was > 290 days. In the absence of soil, diquat was rapidly and extensively degraded by soil micro-organisms normally found in soil pore water to give a small number of non-volatile degradation products (not identified) with mineralisation to CO_2. The DT50 for degradation in solutions of soil micro-organisms is rapid at < 1 week. Addition of clay to these solutions essentially stopped further degradation confirming that sorbed diquat is not available for biological degradation.

The degradation product TOPPS is also persistent in soils. Studies on the aerobic soil degradation of the diquat metabolite TOPPS estimated DT_{50} values for degradation of 28 to 757 days.

Soil photolysis has negligible effect on degradation. In a study with application of ^{14}C-diquat on the surface of a sterilised loam soil, the DT_{50}s for photolytic degradation on dry and wet soil were 237 and 37 days respectively.

In a study of aqueous photolysis the DT_{50} for degradation was 31 hours. The major degradation product was TOPPS with smaller amounts of diquat monopyridone and 1-hydroxy-3,4-dihydro-1H-pyrido[1,2-a]pyrazine-2-carboxylic acid formed.

In a confined rotational crop study with wheat, lettuce and carrot, a plot of sandy loam soil was treated with [^{14}C]-diquat at the equivalent of 1.1 kg ai/ha and crops sown 30, 120 and 365 days. At normal commercial harvest, crops grown in soil containing ^{14}C-diquat showed negligible uptake of radioactivity (TRR up to 0.02 mg equiv/kg). Residues above the LOD of 0.008 mg equiv/kg could have been due to contamination with adhering soil. Crops grown in rotation with diquat-treated crops are not expected to contain residues of diquat ion or diquat degradation products. Diquat residues in soil should contribute little to residue levels in rotational crops.

Methods of analysis

The Meeting received description and validation data for analytical methods for residue analysis of diquat in various plant and animal commodities. Early methods used in field trials generally involved extraction of residues by reflux with sulphuric acid with clean-up on cation exchange columns. Following reduction of diquat ion with alkaline dithionite or sodium borohydride, detection was initially achieved spectrophotometrically (350–450 nm). In more recent methods the diquat ion recovered from the cation exchange column is subjected to HPLC-UV or GC-NPD for quantitation. In the case of animal commodities, trichloroacetic acid is sometimes used in place of sulphuric acid for the extraction step. LOQs were in the range 0.01 to 0.1 mg/kg.

The most recent advance in methods has been the use of LC-MS/MS which allows for the clean-up steps to be omitted with LOQs of 0.005 mg/kg for animal commodities, 0.006 mg/kg for potato and barley and 0.02 mg/kg for citrus.

The efficiency of the acid extraction step has been demonstrated during the metabolism studies where the majority of the total radioactive residue (TRR) was recovered in the acid extracts.

Multi-residue methods are currently not validated for diquat.

Stability of pesticide residues in stored analytical samples

The Meeting received information on the stability of diquat in samples of commodities from crops stored frozen.

Diquat is stable for at least 24 months in homogenised samples of spinach, wheat grain, wheat straw, rape seed, lentils, orange fruit and potato tubers fortified with diquat and stored frozen.

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

Definition of the residue

In metabolism studies of diquat in goats and hens diquat ion was a significant component of the residue in hen (48% TRR liver; 12% TRR kidney) and goat (22% TRR liver; 4.3% TRR kidney) tissues. Other major components were diquat monopyridone (13% TRR liver; 13% muscle) and diquat dipyridone (33% TRR liver; 29% kidney; 20-46% muscle and fat; > 80% milk) with small amounts of TOPPS (1.8% liver; 3.9% kidney) formed in hens. Radioactivity in egg yolks comprised mostly diquat monopyridine (up to 85% TRR) and diquat ion (up to 26% TRR) with smaller amounts of TOPPS (up to 10%TRR).

The major components of the residue in livestock are diquat ion, diquat monopyridone and diquat dipyridone and should be considered for inclusion in the residue definition for compliance with MRLs and estimation of dietary intake in animal commodities. However, at realistic livestock exposures no residues of diquat ion, diquat monopyridone or diquat dipyridone are expected. Additionally, current analytical methods for tissues have only been validated for determination of residues of diquat. Noting the above, the Meeting considered diquat ion to be a suitable as a residue definition for compliance with MRLs and estimation of dietary intake for animal commodities.

The log P_{ow} for diquat is -4.6 suggesting diquat residues are not fat soluble. There was only a small difference in residue levels in muscle and fat confirming diquat ion does not preferentially partition into fat and that the residue should not be classed as fat soluble. The Meeting decided that residues of diquat are not fat soluble.

Diquat is used on crops for two different situations:

- Directed sprays or pre-emergent application for weed control (crop not intentionally treated)
- Use as a crop desiccant to facilitate crop harvest (crop treated)

No residues are expected in situations where crops are not directly sprayed (directed sprays for weed control, pre-emergent or pre-sowing applications). The conclusion is supported by the results of confined crop rotation studies where soil residues were not taken up by crops.

Following use as a crop desiccant, diquat ion was the major component of the residue in flesh and skins of potato tubers and in rape seeds accounting for more than 70% of TRR in potatoes and 48% TRR in rape seeds. TOPPS was also detected in rape seed but represented less than 10% of the TRR. In plants, the majority of diquat-related residues in crops are accounted for in the previous residue definition; diquat ion.

Based on the above the Meeting confirmed the previous residue definition for compliance with MRLs and estimation of dietary intake for plant commodities.

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

The residue is not fat soluble.

Results of supervised residue trials on crops

The Meeting received supervised residue trial data for diquat on citrus fruits, pome fruits, strawberries, banana, tomato, pulses, carrots, potatoes, rape, sunflower and coffee as well as for some animal feed commodities.

As no data were available for alfalfa fodder, barley, maize, oats, rice, sorghum and wheat the the Meeting agreed to withdraw previous recommendations for these commodities.

A range of uses for diquat involve the application to weeds growing under trees in a variety of countries. The Meeting noted the results of soil aerobic metabolism and confined rotational crop studies that show that diquat in soil is not available for plant uptake. As application to weeds growing under trees is not expected to result in residues in harvested commodities the Meeting decided to evaluate the use on tree crops together, using the data on the crops supplied as mutual support for recommendations for those commodities with approved use-patterns. Diquat is approved for weed control in citrus fruit (Brazil, Costa Rica, Dominican Republic), pome fruit (Slovakia), banana/plantain (Belize, Costa Rica, Dominican Republic, El Salvador, Guatemala, Nicaragua, Panama), cashews (Dominican Republic), coffee (Belize, Brazil, Costa Rica, Dominican Republic, El Salvador, Guatemala, Nicaragua, Panama), stone fruit (Slovakia) and also apple and other fruit trees (Canada, USA).

Tree crops (application to weeds)

Field trials involving citrus orchards where diquat was applied to weeds were conducted in Brazil and were available to the Meeting.

The GAP for citrus in Brazil is application directed to weeds at 0.5 kg ai/ha with a PHI of 14 days. In the trials matching this GAP diquat residues in ranked order were (n=3): < 0.01 (2), < 0.02 mg/kg. Residues in trials on citrus that utilized rates higher than permitted in Brazil were < 0.01 (2) mg/kg.

Field trials involving apples were conducted in Europe were made available to the Meeting. The GAP for apples in Slovakia is application directed to weeds at 1.0 kg ai/ha with a PHI not specified (unnecessary). In twelve trials matching this GAP and with PHIs ranging from 0 to 171 days residues were (n=12): < 0.01 (10), < 0.05 (2) mg/kg.

Diquat is permitted to be used for weed control in banana plantations in various countries of central America (Belize, Costa Rica, Dominican Republic, El Salvador, Guatemala, Nicaragua, Panama) with an application rate of 0.6 kg ai/ha and no PHI required. In six trials from Costa Rica, Ecuador and Guatemala that matched GAP residues were < 0.05 mg/kg.

Diquat is approved in a range of Central and South American countries for weed control in coffee plantations including Belize, Brazil, Costa Rica, Dominican Republic, El Salvador, Guatemala, Nicaragua and Panama with maximum application rate of 0.5–0.6 kg ai/ha and a PHI typically 0 days. In trials from Costa Rica and Guatemala residues in coffee beans were < 0.05 (6) mg/kg.

The Meeting concluded that residues of diquat are not expected in harvested commodities from tree crops when application is to the weeds. The Meeting considered an LOQ of 0.02 mg/kg achievable and decided to estimate an STMR of 0 mg/kg, an HR of 0 mg/kg and a maximum residue level of 0.02 (*) mg/kg for citrus fruit, pome fruit, banana and coffee beans and to extrapolate the values to cashew apple (including cajou), cashew nuts and stone fruit.

Berries and other small fruit (application to weeds)

Strawberries

Trials were available from the UK. The GAP for strawberry in Sweden is a single application to weeds at 0.5 kg ai/ha before flowering or after harvest (use of spray shield) with no PHI required.

Residues in three trials from the UK at > 1.4 times the GAP of Sweden were: < 0.05 (3) mg/kg.

The Meeting utilized trials approximating the GAP of Sweden to estimate a maximum residue level for strawberries. Noting the exaggerated rates used in the three trials, the long interval between application and harvest and the requirement for a physical barrier when spraying, the Meeting estimated a maximum residue level of 0.05 * mg/kg, an STMR of 0 mg/kg and an HR of 0 mg/kg for strawberries.

Fruiting vegetables other than Cucurbits

Diquat is permitted to be used for weed control in row crops (includes tomatoes) in Spain with an application rate of 0.45 kg ai/ha and using spray protectors or shields, PHI 15 days.

Only one trial utilized a spray screen. The application rate was 2 times the GAP of Spain and residues were < 0.01 mg/kg. In another seven trials where the application rate was 2 times the maximum application rate of Spain and that did not use a spray shield the residues were also < 0.01 (7) mg/kg. The Meeting considered there is no expectation of residues above the LOQ for tomatoes and agreed to extrapolate the conclusion to fruiting vegetables other than cucurbits except sweet corn and fungi.

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 fruiting vegetables, other than cucurbits (except sweetcorn, fungi and mushrooms).

Pulses (pre-harvest desiccation)

Residue data from trials in common beans were made available from Germany and the USA for pre-harvest desiccation. The use pattern in Germany is 0.6 kg ai/ha with a PHI of 5 days. Analytical recoveries reported for trials from Germany on beans were low making the trials unsuitable for estimating maximum residue levels. The use pattern in Canada is for pre-harvest desiccation of beans at up to 0.41 kg ai/ha for ground application and 0.55 kg ai/ha for aerial application with a PHI of 4 days. In eight trials conducted in the USA approximating Canadian GAP residues were < 0.05 (8) mg/kg. The Meeting estimated an STMR of 0.05 mg/kg and a maximum residue level of 0.05* mg/kg for beans, dry replacing the previous recommendation of 0.2 mg/kg.

In Canada, diquat is permitted for pre-harvest desiccation of peas at up to 0.41 kg ai/ha for ground application and 0.55 kg ai/ha for aerial application with a PHI of 4 days. In five trials conducted in the USA approximating Canada GAP residues were: 0.05, 0.05, 0.09, 0.11 and 0.56 mg/kg. The Meeting considered five trials insufficient to estimate a maximum residue level for peas dry.

Pre-harvest desiccation sprays are permitted in Slovakia on peas at up to 0.8 kg ai/ha with a PHI of 6 days. In nine trials conducted in Europe, residues following a pre-harvest desiccation application at 0.6 kg ai/ha and after a 6 day PHI were: 0.03, 0.04, 0.04, 0.04, 0.05, 0.05, 0.06, 0.10, 0.15 mg/kg. The Meeting estimated an STMR of 0.05 mg/kg and a maximum residue level of 0.3 mg/kg for peas, dry confirming the previous recommendation.

In Canada, pre-harvest desiccation sprays are permitted in lentils at up to 0.41 kg ai/ha for ground application and 0.55 kg ai/ha for aerial application with a PHI of 4 days. In three trials conducted in USA with application at 0.42 kg ai/ha residues were < 0.05, 0.13 and 0.54 mg/kg at 4 days after application. The Meeting considered three trials insufficient to estimate a maximum residue level for diquat in lentils and withdrew its previous recommendation of 0.2 mg/kg.

In Canada, pre-harvest desiccation sprays are permitted in soya beans at up to 0.56 kg ai/ha with a PHI of 4 days. In seven trials conducted in USA at 0.56 kg ai/ha residues were < 0.01, 0.02, 0.03, 0.03, 0.04, 0.09, 0.16 mg/kg in samples harvested 7 to 10 days after application. The Meeting noted there was little decline in residues between 4 and 10 days and decided to use the data to estimate an STMR of 0.03 mg/kg and a maximum residue level of 0.3 mg/kg for soya beans (dry) replacing its previous recommendation of 0.2 mg/kg.

Carrots (directed application for weed control)

In Spain diquat is approved for general weed control in row crops including carrots (GAP: 0.45 kg ai/ha using spray protectors, PHI 15 days). In three trials in Germany and Italy that used spray shields and with application rates that were two times GAP of Spain residues were: 0.01, < 0.02, < 0.02 mg/kg.

The Meeting considered three trials insufficient to estimate a maximum residue level for carrots.

Potato (pre-harvest desiccation)

Diquat is approved for pre-harvest desiccation of potato crops in various countries. Pre-harvest desiccation use-patterns approved in various countries include Austria (GAP: 0.5 kg ai/ha, PHI 10 days), Brazil (GAP 0.5 kg ai/ha, PHI 7 days), Canada (GAP 2×0.84 kg ai/ha, PHI 0 days), Germany (GAP: 1 kg ai/ha, PHI 10 days), the Netherlands (GAP: 0.8 kg ai/ha, max 2 sprays and 1 kg ai/ha per crop, PHI 0 days), Spain (GAP: 0.8 kg ai/ha, PHI 15 days), the UK (GAP: 1.0 kg ai/ha, max 2 sprays and 1 kg ai/ha per crop, PHI 0 days or 14 days if storing potatoes) and the USA (GAP:0.56 kg ai/ha, PHI 7 days).

In trials in Europe approximating the GAP of the UK residues were: < 0.01 (10), 0.01, 0.01, 0.01, 0.01, 0.02, 0.02 mg/kg.

In trials conducted according to the GAP of USA residues were: < 0.05 (6), 0.06, 0.06 mg/kg.

Using the residue data from the USA, the Meeting estimated an STMR of 0.05 mg/kg, an HR of 0.06 mg/kg and a maximum residue level of 0.1 mg/kg for potato replacing the previous recommendation of 0.05 mg/kg.

Rape seed, (pre-harvest desiccation)

Diquat is approved for pre-harvest desiccation of oilseed rape in Austria (GAP: 0.6 kg ai/ha, PHI 5 days), Canada (GAP: 0.41 kg ai/ha, PHI 14 days), Germany (GAP: 0.6 kg ai/ha, PHI 5 days), the UK (GAP: 0.6 kg ai/ha, PHI 7-10 days) and the USA (GAP: 0.56 kg ai/ha, PHI 7 days).

Residues in rape seeds from trials conducted in Europe approximating German GAP were (n=12): 0.02, 0.03, 0.03, 0.05, 0.06, 0.07, 0.08, 0.10, 0.12, 0.22, 0.27, 0.33, 0.38, 0.42, 0.44, 0.45 mg/kg.

In trials approximating GAP in the USA total residues in rape seeds were (n=9): 0.06, 0.24, 0.30, 0.30, 0.46, 0.48, 0.52, 0.72, 0.82 mg/kg.

The Meeting considered the trials from the USA would lead to the higher maximum residue level and estimated an STMR of 0.49 mg/kg and a maximum residue level of 1.5 mg/kg for rape seed replacing its previous recommendation of 2 mg/kg.

Sunflower seed (pre-harvest desiccation)

Diquat is approved for pre-harvest desiccation of sunflowers in Canada (GAP: 0.41 kg ai/ha, PHI 15 days) and Slovakia (GAP: 0.6 kg ai/ha, PHI 6 days). Residues in trials from France approximating Slovakian GAP were (n=13): < 0.05, 0.06, 0.07, 0.08, 0.09, 0.10, 0.11, 0.11, 0.15, 0.19, 0.41, 0.46, 0.54 mg/kg.

The Meeting estimated an STMR of 0.11 mg/kg and a maximum residue level of 0.9 mg/kg for sunflower seed replacing its previous recommendation of 1 mg/kg.

Animal feeds

Pea fodder (pre-harvest desiccation)

Residue levels occurring in pea straw were evaluated. In four trials conducted in the UK approximating GAPs in Austria (0.6 kg ai/ha, PHI 5 days) and France (0.6 kg ai/ha, PHI 4 days) residues in pea straw were 3.6, 14, 18, 25 mg/kg all on an as received basis. The Meeting estimated median and highest residues of 16 and 25 mg/kg on an as received basis for residues of diquat in pea straw.

The Meeting estimated a median residue of 16 mg/kg, a highest residue of 25 mg/kg (both on an as received basis) and a maximum residue level of 50 mg/kg for pea fodder (on a dry weight basis).

The Meeting received two trials conducted in France that measured residues in soya bean forage. The meeting considered two trials insufficient to make recommends for soya bean forage.

Fate of residues during processing

The Meeting received information on the fate of incurred residues of diquat during the processing of soya bean, oilseed rape/canola and sunflower seeds. Studies of the hydrolysis of diquat under a range of conditions showed diquat is stable.

Summary of selected processing factors for diquat

Raw commodity	Processed commodity	Individual PF	Best estimate PF	$STMR_{RAC}$ (mg/kg)	$STMR_{RAC}$ × PF (mg/kg)
Soya bean	Hulls	2.6 3.6	3.1	0.03	0.093
	Meal	0.7 1.0	0.85		0.0255
	Oil	< 0.04 < 0.07	< 0.055		< 0.00165
Rape/canola	Meal	0.17 0.20 0.58 0.76	0.39	0.49	0.19

Raw commodity	Processed commodity	Individual PF	Best estimate PF	$STMR_{RAC}$ (mg/kg)	$STMR_{RAC}$ × PF (mg/kg)
	Oil	< 0.01 < 0.01 < 0.03 < 0.03	< 0.02		< 0.0098
Sunflower seed	Oil	< 0.1 < 0.1 < 0.1 < 0.5 < 0.6 < 0.6 < 0.7 < 0.8 < 0.8 <1	< 0.6	0.11	< 0.066
	Cake	1 1 1.2 1.2 1.2 1.2 1.3 1.3 1.3 1.3	1.2		0.132

Residues are not expected in oils obtained from treated crops.

Residues in animal commodities

Farm animal feeding studies

The Meeting received information on the residue levels arising in tissues and milk when dairy cows were fed a diet containing incurred residues of diquat at dietary levels of 18, 50 and 84 ppm for 30 consecutive days. There were no residues of diquat at or above the LOQ (0.001 mg/kg) in any of the milk samples from any of the dose groups, throughout the duration of the study. There were no residues of diquat at or above the LOQ (0.01 mg/kg) in any of the tissue samples (liver, kidney, fat and muscle) from any of the dose groups.

The Meeting also received information on the residue levels arising in tissues and eggs, when laying hens were fed a diet containing diquat at total dietary levels of 1, 5 and 10 ppm diquat for 21 or 28 consecutive days. No residues of diquat above the LOQ (< 0.01 mg/kg) were found in any of the egg, fat, muscle, skin, liver or heart samples.

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.

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	0.12	0.09	7.3	4.7	28 [a]	18 [c]	0.09	0.09
Dairy cattle	2.9	1.9	8.7	5.6	20 [b]	13 [d]	0.09	0.09
Poultry Broiler	0.06	0.06	0.11	0.10	0.08	0.08	0.04	0.04
Poultry Layer	0.06	0.06	2.9 [e]	1.9 [f g]	0.08	0.08	0.05	0.05

[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.

[g] Highest mean poultry dietary burden suitable for STMR estimates for poultry eggs.

Animal commodity maximum residue levels

The Meeting concluded that at the maximum estimated dietary burdens for cattle of 28 ppm and 2.9 ppm for poultry no residues are expected in tissues, milk and eggs.

The Meeting estimated HR and STMR values of 0 for milk, muscle, edible offal and fat. The Meeting estimated the following maximum residue levels: milk 0.001* mg/kg; meat (mammalian except marine mammals) 0.01* mg/kg and edible offal 0.01* mg/kg to replace its previous recommendations of: milk 0.01 mg/kg; meat (mammalian except marine mammals) 0.05 mg/kg and edible offal 0.05 mg/kg.

For poultry no residues are expected. The Meeting estimated the following maximum residue levels for poultry commodities: poultry meat 0.01* mg/kg; poultry edible offal 0.01* mg/kg and eggs 0.01* mg/kg to replace its previous recommendations of: eggs 0.05 mg/kg; poultry meat 0.05 mg/kg and poultry edible offal 0.05 mg/kg.

The Meeting estimated the following STMR values: poultry meat 0 mg/kg; poultry fat 0 mg/kg; poultry edible offal 0 mg/kg and eggs 0 mg/kg.

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 for estimation of dietary intake (for animal and plant commodities):

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

The residue is not fat soluble.

DIETARY RISK ASSESSMENT

Long-term intake

The WHO Panel of the 2013 JMPR established an Acceptable Daily Intake (ADI) of 0–0.006 mg/kg bw for diquat.

The evaluation of diquat resulted in recommendations for MRLs and STMR values for 30 raw and processed commodities. Where data on consumption were available for the listed food commodities, dietary intakes were calculated for the 13 GEMS/Food Consumption Cluster Diets. The results are shown in Annex 3.

The IEDIs in the thirteen Cluster Diets, based on the estimated STMRs were 0–4% of the maximum ADI (0.006 mg/kg bw). The Meeting concluded that the long-term intake of residues of diquat from uses that have been considered by the JMPR is unlikely to present a public health concern.

Short-term intake

The WHO Panel of the 2013 JMPR established an Acute Reference Dose (ARfD) of 0.8 mg/kg bw for diquat. The IESTIs represented 0% of the ARfD of 0.8 mg/kg bw.

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

5.14 DITHIANON (028)

TOXICOLOGY

Dithianon was evaluated by JMPR in 2010, when an ADI of 0–0.01 mg/kg bw and an ARfD of 0.1 mg/kg bw were established. During the 2013 Meeting, concerns were raised because of the presence of degradation products of dithianon: Reg. No. 4110904 and Reg. No. 31062. Genotoxicity studies were made available during the meeting for these two degradation products.

Reg. No. 31062 gave negative results in the Ames test and in the in vivo micronucleus assay in mice.

Reg. No. 4110904 gave negative results in the Ames test, the in vitro gene mutation (*HRPT* locus) test in Chinese hamster ovary cells and a test for chromosomal aberration in human lymphocytes. It gave positive results in a test for chromosomal aberration in V79 cells. However, the in vivo micronucleus assay in mice and the comet assay in liver and duodenum in rats gave negative results.

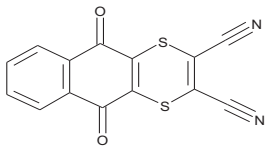
The Meeting concluded that these degradates of dithianon are unlikely to be genotoxic in vivo.

Conservative estimates of exposure were 0.08 µg/kg bw per day for chronic exposure and 1.92 µg/kg bw for acute exposure for both Reg. No. 31062 and Reg. No. 4110904. All estimates of exposure were below the threshold of toxicological concern for compounds with no evidence of genotoxicity (for Cramer class III, 1.5 µg/kg bw per day for chronic exposure; 5 µg/kg bw for acute exposure). The Meeting concluded that there is no concern for dietary exposure to these degradates.

An addendum to the toxicological monograph was prepared.

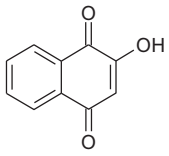
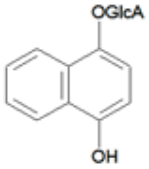
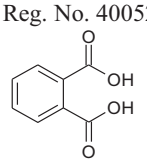
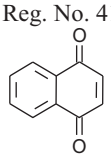
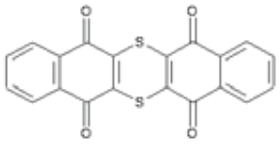
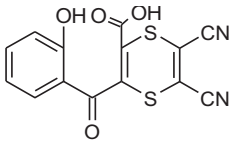
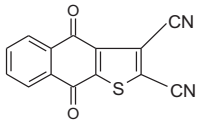
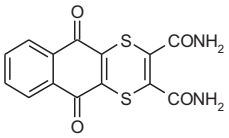
RESIDUE AND ANALYTICAL ASPECTS

The fungicide dithianon (5,10-dihydro-5,10-dioxonaphtho-[2,3-beta]-1,4-dithiine-2,3-dicarbonitrile) has been evaluated by the JMPR for the first time in 1992 (T, R). The compound was evaluated for toxicology by the 2010 JMPR where an ADI of 0.01 mg/kg bw and an ARfD of 0.1 mg/kg was allocated. The periodic review for residues was scheduled at the 39th session of the CCPR for the 2012 JMPR but postponed to evaluate in 2013.



The Meeting received information from the manufacturer on physical and chemical properties, metabolism studies on plants and animals, analytical methods, supervised residue trials data, processing studies as well as use pattern.

The metabolism and distribution of dithianon in plants and animals as well as the nature of the residue under simulated processing conditions, was investigated using the [5,6,9,10-]^{14}C-labelled compound or, in some studies, a [5,6,9,10-]^{13}C/^{14}C-labelled compound. The following abbreviations are used for the metabolites or degradation products discussed below.

CL 231509	M216F020	Reg. No. 4005234	Reg. No. 4107273
			
2-Hydroxy-1,4-napthoquinone	Glucuronic acid conjugate of 1,4-dihydroxy-naphthalene	Phthalic acid	1,4-Naphthoquinone
Reg. No. 31062	Reg. No. 4110904	Reg. No- 4110933	Reg. No. 4110934
			
Dibenzo-[*b*,*i*]-thianthrene-5,7,12,14-tetrone	5,6-Dicyano-3-(2-hydroxybenzoyl)-1,4-dithiine-2-carboxylic acid	4,9-Dihydro-4,9-dioxonaphtho[2,3–*b*]-thiophene-2,3-dicarbonitrile	5,10-Dihydro-5,10,dioxo-naphtho[2,3-*b*]-1,4-dithiin-2,3-dicarboxylic acid diamide

Animal metabolism

Metabolism studies on rats reviewed by the 2010 JMPR show that at tested doses of 10 and 50 mg/kg bw orally administered dithianon was about 40–50% absorbed in rats. The majority of the administered dose was recovered in faeces (64–72%) and in urine (27–31%). Dithianon was extensively metabolized according to the following key transformation steps: oxidation of the sulphur atoms, cleavage of the dithiine ring, reduction of the 1,4-naphthoquinone moiety and further glucuronidation, as well as substitution of the carbonitrile moieties by amino and carboxy groups. The only metabolite in rat urine at a level greater than 2% was M216F020.

Two studies were submitted on the metabolism of dithianon in lactating goats. In the first study, one lactating goat each was dosed by capsule at a daily nominal rate of 6 mg (equiv. to 2.5 ppm in the feed) and 60 mg [^{14}C] dithianon (equiv. to 28 ppm) for five days. The highest radioactive residues (TRR) of the high dose group were detected in kidney (0.49 mg/kg as dithianon equivalents) and in liver (0.17 mg/kg equiv.). Lowest TRR were found in fat (0.013 mg/kg equiv.), in milk (0.018 mg/kg equiv.) and muscle (0.013 mg/kg equiv.). Most of the [^{14}C] residue was rapidly and constantly excreted via faeces and urine—almost 80% of the applied dose was eliminated at the end of the study.

Further investigation on the nature of radioactive residues was carried out with the high dose (60 mg/day) samples. The TRR (calculated as dithianon equivalents) in muscle and fat were very low (0.013–0.014 mg/kg equiv.), and no further characterization was possible. For milk and edible tissues, the extracted radioactive residues ranged from 49% of TRR (0.08 mg/kg equiv.) in liver to 77% (0.018 mg/kg equiv.) in milk. The radioactivity in post extraction solids (PES) ranged from 20% (0.005 mg/kg equiv.) in milk to 74% (0.36 mg/kg equiv.) in kidney. Several radioactive components were detected in the extracts but not further identified. Parent dithianon was identified in liver (0.96% of TRR), kidney (2.3% of TRR) and milk (8.2% of TRR).

In the second goat study, after five consecutive daily administrations of [^{13}C/^{14}C] dithianon at a dose of 60 mg/animal and day (equivalent to 25 ppm in the feed), the highest TRR were detected in kidney (0.48 mg/kg equiv.) and in liver (0.16 mg/kg equiv.). Lower radioactive residues were found in muscle (0.013 mg/kg), in milk (0.018 mg/kg) and fat (subcutaneous 0.074 mg/kg equiv., renal 0.009 mg/kg equiv.). The major route of excretion of radioactivity was via faeces, accounting for

47% of the total administered dose. A further 18% of the total administered radioactivity was excreted via urine.

With the exception of milk, most of the radioactive residues could not be extracted. The PES in liver, kidney, muscle and fat ranged from 59.4% in kidney to 80% in muscle. Neither parent nor any corresponding metabolite was identified. However, in liver, kidney, urine and bile a very complex metabolite profile was noted. More than 20 components were found in the organic phase and at least six components were detected in the aqueous phase at low absolute residue levels (< 0.05 mg/kg) in tissues. In milk, the extracted radioactivity accounted for 78.3% of TRR (0.012 mg/kg equiv.).

The reactivity of dithianon with nucleophiles (commonly thiols in the form of proteins and peptides such as gluthathione) was demonstrated *in vitro*. Glutathione and N-acetylcysteine react very quickly with dithianon when incubated in pH 6.5 buffers at 37 °C. It was indicated that the reaction of dithianon with glutathione and protein thiol groups *in vivo* should be virtually instantaneous.

Two groups of laying hens, five hens per group, were treated orally once daily for 5 consecutive days with gelatin capsules containing dithianon. The actual doses of dithianon administered were 0.4 mg/day and 4 mg/day, equivalent to 3.6 ppm and 39 ppm in the feed, respectively.

Over the dosing period, a rapid absorption and excretion of radioactivity occurred. About 90% of the total radioactivity administered was eliminated in excreta by 6 hours after the last dose. There was no indication of accumulation of [^{14}C] dithianon in poultry tissues and eggs.

The highest TRR (in mg/kg as dithianon equiv.) were found in the kidney (0.042 and 0.34–0.38 mg/kg low and high dose, respectively), liver (0.017 and 0.17–0.19 mg/kg), skin with fat (0.005 and 0.039–0.041 mg/kg) and GI Tract (0.14 and 1.5 mg/kg). The lowest concentrations were found in muscle (0.002 and 0.022 mg/kg) and abdominal fat (< 0.002 and 0.014 mg/kg). The highest TRR in egg yolks were 0.005 and 0.075 mg/kg at the end of the study.

Solvent extraction was performed on the high dose group samples and released about of 68% of TRR in muscle (0.015 mg/kg equiv.), 76% of TRR in skin with fat (0.031 mg/kg equiv.), 72% of TRR in liver (0.13 mg/kg equiv.), 74% of TRR in kidney (0.28 mg/kg equiv.) and 47% of the TRR egg yolks (0.037 mg/kg equiv.). The majority of the extracted radioactivity was aqueous/methanol-soluble (35% in egg yolk to 67% of TRR in kidney). The chloroform-soluble radioactivity, containing less polar components, accounted for 6.6% in kidney to 16% of the TRR in liver. Radioactivity in the PES accounted for 25% in liver to 54% of the TRR in egg yolk.

Parent dithianon, detected in minor amounts in the excreta only (1.5% of TRR), was extensively metabolized to yield numerous minor metabolites. The metabolites were profiled by HPLC but were not identified as low concentrations prevented isolation. The organo-soluble metabolites accounted for ≤ 0.003 mg/kg equiv. each in the kidney and liver. One major polar component found in the aqueous/methanol extract accounted for 19% TRR (0.035 mg/kg equiv.) in liver, 11% TRR (0.042 mg/kg equiv.) in kidney, 36% TRR (0.015 mg/kg equiv.) in skin and fat, and 5.7% TRR (0.004 mg/kg equiv.) in egg yolk.

Metabolism studies performed on rats, goats and hens have shown that dithianon is rapidly and intensively metabolized by a number of degradation processes; it was only detected in trace amounts in tissues and/or excreta. As key degradation steps oxidation/reduction and reaction with nucleophiles, commonly R-SH in the form of proteins and peptides such a glutathione are assumed. These reactions result in a huge number of individual metabolites, but also incorporation into natural products. No individual metabolites had been identified; all of them were present in very minor amounts.

Plant metabolism

The metabolism of dithianon has been studied with [^{14}C] dithianon on citrus trees, apple trees, spinach and wheat. The study designs of the plant up-take parts reflect the intended use pattern with several foliar post emergence applications.

Following foliar applications, there was no translocation from the part being directly treated to other parts of the plant. When applied to fruit crops, the dithianon residues remained predominantly associated with the peel. Most of the radioactivity present (> 50% TRR) could be washed of by a surface rinse using acetonitrile/HCl. Neither parent nor any metabolite was translocated to a significant degree into flesh or pulp. Dithianon was identified as the major component of the TRR and ranged from 50.9% in wheat grain up to 96% in spinach leaves.

The parent compound is further metabolized to a large number of polar components. With the exception of spinach, these components could not be identified. None of these metabolites was found in amounts exceeding 5% of the TRR. In spinach, metabolite 4110934, a dicarboxylic acid diamide derivative, 2-hydroxynapthoquinone (CL 231509) and phthalic acid were found, indicating that the absorbed dithianon was completely metabolized by the plants. All of the individual components of the extracted residues in spinach were between 0.1 and 0.5% of the TRR (0.13–0.8 mg/kg equiv.).

The different functional groups on the dithianon molecule provide multiple sites for chemical and enzymatic attacks resulting in cleavage of the dithiine as well as the quinone ring. The primary products formed are very reactive and could be the target of quite a number of further metabolism and conjugation reactions (e.g. hydroxylation, sulphur oxidation, and reactions with naturally occurring plant constituents), but also incorporation into plant constituents. The Meeting considered parent as the only relevant residue occurring after foliar treatment of plants with dithianon.

Environmental fate

For dithianon, supervised residue trials data were received for foliar spray on permanent crops such as citrus fruits, tree nuts, pome fruits, stone fruits, grapes and hops. Therefore, neither environmental fate nor rotational crops studies are necessary.

Dithianon is not stable in aqueous media. A hydrolysis study showed DT_{50} values of 10.7 days at pH 5, 0.6 days at pH 7 and ca. 10 minutes at pH 9. The photochemical degradation at 20 °C in sterile pH 4 buffer resulted in a DT_{50} value lower than 0.05 days.

Methods of analysis

The Meeting received descriptions and validation data for analytical methods for residues of dithianon in plant and animal commodities. Residue analytical methods for dithianon rely on HPLC with UV-detection or LC-MS/MS for plants and HPLC with electrochemical detection or LC-MS/MS for animal matrices. Typical LOQs achieved for plant and animal commodities fall in the range of 0.01–0.05 mg/kg (except hops, dried, 1 mg/kg). Methods have been subjected to independent laboratory validation.

Descriptions and validation data for analytical methods for residues of the degradation product 4110904 in citrus fruit, apples, grapes, plums and grape wine were received. The analytical methods rely on LC-MS/MS. Typical LOQs achieved for plants commodities were 0.01 mg/kg.

Stability of residues in stored analytical samples

Information was received on the freezer storage stability of dithianon and 4110904 residues in plant commodities.

Older studies from 1992–1994 show that dithianon residues were not stable in spiked samples for a period longer than two months. Newer studies with incurred residues in apples (testing period 2 years) and wine grapes (testing period 14 months) show that dithianon residues were

apparently stable at freezer temperature for the intervals tested. Residues of dithianon were not stable in wine, declining on average by 86% of the original fortification after 26 weeks of frozen storage.

The storage stability studies with 4110904 demonstrate that the compound is stable under freezer conditions in plant matrices for about two years in apples, plums and wine. Residues of 4110904 were not stable in grapes, declining by ca. 65% of the fortification level after 3 months, and in lemons, declining by ca. 55% after a week.

Definition of the residue

Animal metabolism studies were performed in lactating goats and laying hens. The parent compound dithianon is rapidly and intensively metabolized and was only detected in trace amounts in tissues and excreta. There was no bioaccumulation in tissues, milk and eggs. No individual metabolites had been identified; all of them were present in very minor amounts (< 0.05 mg/kg and also < 10% TRR).

Dithianon has a log P_{OW} of 3.2. In animal metabolism studies, the TRR in muscle and fat were comparable (dithianon *per se* could not be detected). The Meeting decided that the residue of dithianon is not fat-soluble.

In plant metabolism studies performed on fruits (oranges, apples), leafy crops (spinach) and cereals (wheat) the same metabolic behaviour was observed. The parent compound dithianon is the dominant component of the residue in plant commodities and ranged from 50.9% of the TRR in wheat grain up to 96% of the TRR in spinach leaves. No individual metabolite occur at relative amounts > 10% of TRR and of absolute concentrations of > 0.05 mg/kg in the same matrix.

Therefore, from the metabolism studies on plants and animals presented, the proposed definition of the residue is parent dithianon only.

The Meeting took into account the possibility of the formation of two hydrolysis products (Reg. No. 31062 and 4110904) in significant concentrations during industrial or household processing of dithianon treated fruits. Based on their dietary risk assessment, the Meeting concluded that there is no need to include both degradates in the residue definition for estimation of the dietary intake.

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

The residue is not fat-soluble.

Results of supervised residue trials on crops

The Meeting received supervised residue trials data for citrus fruits, apple, pear, cherries, peaches, plums, grapes, currants, almonds and hops. If two field samples were taken or results of two replicate plots were submitted, the mean value was calculated. 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.

Citrus fruits

In Japan, dithianon is registered for foliar spray use on citrus fruits at a maximum application rate of 3 × 2.9 kg ai/ha with a PHI of 30 days. Supervised trials with 3 × 2.0–4.27 kg ai/ha with a PHI of 28–30 days were available from Japan: four on mandarins (four for whole fruit, six for pulp), two on pomelo, as well as one each on the small citrus fruits sudachi and kabosu (*Citrus sphaerocarpa*).

The Meeting noted that only four residue trials on mandarin, two on pomelo and two on the small citrus varieties (sudachi/kabosu) are insufficient to estimate a maximum residue level for the whole group of citrus fruits.

The Meeting considered that six residue trials were available for mandarin. It was noted that in four trials data for whole fruit and in six trials pulp data were submitted. The Meeting agreed that only four trials on mandarin (whole fruit) are insufficient to estimate a maximum residue level for the subgroup mandarins. The previous recommendations of 3 mg/kg for mandarin, shaddocks or pomelos should be withdrawn.

Pome fruits

Dithianon is registered for foliar spray treatment on pome fruit in Germany with 12 treatments per season of 0.035 kg ai/hL and 0.18 kg ai/ha per m crown height (equivalent to 0.54 kg ai/ha for 3 m crown height) and a PHI of 21 days.

During the years 1975–2000, 21 trials on apples were conducted in Germany (12), France (3), Greece (1), Italy (3) and Spain (2). Foliar applications were made from 12 to 14 times to apple trees at application rates of 0.51–0.63 kg ai/ha. At a PHI of 21 days, the residues were < 0.03, < 0.05, 0.12, 0.13, 0.20, 0.24, 0.36, 0.38, 0.43, 0.48, 0.48, 0.59, 0.62, 0.76, 0.86, 1.0, 1.3, 1.5, 1.7, 1.7 and 1.7 mg/kg.

Four trials on pears were conducted in 2004 in Germany, The Netherlands, Northern France and Denmark with foliar spray by 12 × 0.53 kg ai/ha. The dithianon residues were at a PHI of 21–22 days 0.19, 0.37, 0.39 and 0.87 mg/kg.

The rank order of the combined dithianon residues on apple and pear were (n=25): < 0.03, < 0.05, 0.12, 0.13, 0.19, 0.20, 0.24, 0.36, 0.37, 0.38, 0.39, 0.43, 0.48, 0.48, 0.59, 0.62, 0.76, 0.86, 0.87, 1.0, 1.3, 1.5, 1.7, 1.7 and 1.7 mg/kg.

The Meeting noted that the ARfD of 0.1 mg/kg bw is exceeded for apple by the IESTI for children (120% of ARfD) using 1.7 mg/kg as HR and decided that the dataset is not appropriate to estimate a maximum residue level for pome fruit.

An alternative GAP is an Italian use of 4 × 0.3 kg ai/ha on apple and of 3 × 0.3 kg ai/ha on pear with a PHI of 35 days. In Macedonia, dithianon is registered in apples with 4 × 0.24–0.30 kg ai/ha and in pear with 4 × 0.32–0.4 kg ai/ha. The PHI is 35 days also.

Five apple trials were conducted in 2003 with 4 × 0.3–0.35 kg ai/ha. The dithianon residues were 34–35 days after treatment 0.11, 0.14, 0.35, 0.39 and 0.43 mg/kg.

Eleven apples trials were carried out in 2010 in Germany (1), the UK (1), Belgium (1), the Netherlands (1), France (2), Greece (1), Italy (2) and Spain (2) with 4 × 0.36 kg ai/ha. The dithianon residues were after a PHI of 35 days < 0.01, 0.02, 0.02, 0.06, 0.10, 0.14, 0.16, 0.21, 0.27, 0.34 and 0.65 mg/kg.

The combined dithianon residue data after application of 4 × 0.3–0.36 kg ai/ha from 2003 and 2010 were (n=16): < 0.01, 0.02, 0.02, 0.06, 0.10, 0.11, 0.14, 0.14, 0.16, 0.21, 0.27, 0.34, 0.35, 0.39, 0.43 and 0.65 mg/kg.

The Meeting agreed to extrapolate from apple to the whole group and estimated a maximum residue level of 1 mg/kg for dithianon residues in pome fruits to replace the previous recommendation (5 mg/kg). An STMR and an HR value of 0.15 mg/kg and 0.65 mg/kg were estimated.

Stone fruits

The GAP for stone fruits in Hungary is 2–3 times foliar spray treatment of 0.053–0.066 kg ai/hL, 0.53 kg ai/ha and a PHI of 21 days. Supervised trials were available for cherries, peaches and plums.

On cherries, sour, seven trials were carried out in Germany from 1985 to 1995 by an application of 3 × 0.53 kg ai/ha and a PHI of 21 days. The dithianon residues were 0.17, 0.26, 0.28, 0.34, 0.41, 0.49 and 0.80 mg/kg.

Further trials on cherries (sweet and sour) were conducted in 2009/2010 in the UK (2), France (3), Germany (2), Greece (2), Italy (3), The Netherlands (2) and Spain (1) with 3 × 0.53 kg ai/ha and a PHI of 20–21 days. The dithianon residues were 0.04, 0.09, 0.19, 0.19, 0.21, 0.38, 0.43, 0.45, 0.50, 0.57, 0.59, 0.69, 0.82, 0.90 and 1.0 mg/kg.

The Meeting concluded to combine the dithianon residues on cherries from both datasets. The dithianon residues on cherries were in rank order (n=22): 0.04, 0.09, 0.17, 0.19, 0.19, 0.21, 0.26, 0.28, 0.34, 0.38, 0.41, 0.43, 0.45, 0.49, 0.50, 0.57, 0.59, 0.69, 0.80, 0.82, 0.90 and 1.0 mg/kg.

On plums, twelve trials were conducted in 2009/2010 in France (3), Belgium (1), Germany (4), Italy (2) and Spain (2) with 3 × 0.53 kg ai/ha and a PHI of 20–22 days. The dithianon residues were 0.04, 0.05, 0.06, 0.10, 0.10, 0.18, 0.21, 0.25, 0.27, 0.32, 0.40 and 0.45 mg/kg.

On peaches, twelve trials were conducted in 2009/2010 in France (4), Germany (2), Greece (2), Italy (2) and Spain (2) with 3 × 0.53 kg ai/ha and a PHI of 20–21 days. The dithianon residues were 0.17, 0.18, 0.24, 0.36, 0.38, 0.43, 0.44, 0.45, 0.56, 0.60, 1.0 and 1.6 mg/kg.

The Meeting noted that the Hungarian GAP is for the stone fruit group, and considered a group maximum residue level. To consider a group maximum residue level, residues in individual commodities should be similar (e.g., medians should not differ by more than five times). The Meeting agreed to estimate a maximum residue level for the group stone fruit.

In deciding whether to combine the datasets for the different crops for use in the statistical calculator or to only utilize the data from the commodity with the highest residues, the Meeting recognized the similarity of the datasets of cherries and peaches (confirmed by the Mann-Whitney U-test). The Meeting agreed to combine these datasets for the purposes of determining a group maximum residue level for stone fruit.

The rank order of the combined dataset of cherries and peaches is (n=34): 0.04, 0.09, 0.17, 0.17, 0.18, 0.19, 0.19, 0.21, 0.24, 0.26, 0.28, 0.34, 0.36, 0.38, 0.38, 0.41, 0.43, 0.43, 0.44, 0.45, 0.45, 0.49, 0.50, 0.56, 0.57, 0.59, 0.60, 0.69, 0.80, 0.82, 0.90, 1.0, 1.0 and 1.6 mg/kg.

The Meeting estimated a maximum residue level of 2 mg/kg, an STMR of 0.43 mg/kg and an HR of 1.6 mg/kg for dithianon residues in stone fruits. The previous recommendation of 5 mg/kg for dithianon in cherries was withdrawn.

Grapes

Dithianon is registered for foliar spray treatment on grapes in Slovenia with 1–8 × 0.35 kg ai/ha and a PHI of 42 days.

Trials on grapes were available from Germany (24). The plants were treated eight times during the growing season with 0.23–0.68 kg ai/ha; the last applications were in a range of 0.44–0.68 kg ai/ha. The Meeting agreed to use the proportionality approach to scale the residues of a PHI of 41–43 days according an application rate of 0.35 kg ai/ha. The rank order of scaled residues was (n=24): 0.15, 0.19, 0.29, 0.34, 0.36, 0.43, 0.44, 0.44, 0.48, 0.50, 0.54, 0.60, 0.61, 0.72, 0.75, 0.76, 0.80, 0.92, 1.0, 1.05, 1.2, 1.2, 1.4 and 2.5 mg/kg.

Further trials were conducted in France (3), Germany (1), Greece (1), Italy (4) and Spain (4). Grapes were treated with 8 × 0.56 kg ai/ha. The PHI was 41–42 days. The rank order of the scaled dithianon residues on the application rate of 0.35 kg ai/ha were (n=13): 0.21, 0.28, 0.33, 0.37, 0.63, 0.69, 0.69, 0.81, 0.81, 0.88, 0.94, 2.1 and 4.6 mg/kg.

The rank order of the combined scaled residue data was (n=37): 0.15, 0.19, 0.21, 0.28, 0.29, 0.33, 0.34, 0.36, 0.37, 0.43, 0.44, 0.44, 0.48, 0.50, 0.54, 0.60, 0.61, 0.63, 0.69, 0.69, 0.72, 0.75, 0.76, 0.80, 0.81, 0.81, 0.88, 0.92, 0.94, 1.0, 1.05, 1.2, 1.2, 1.4, 2.1, 2.5 and 4.6 mg/kg.

The Meeting estimated a maximum residue level of 5 mg/kg for dithianon residues in grapes. Because the ARfD of 0.1 mg/kg bw is exceeded by the IESTI of dithianon for grapes using 4.6 mg/kg

as HR (310% for children, 150% for general population), the Meeting decided that the maximum residue level of 5 mg/kg is not suitable for table grapes and should be apply to wine grapes only. For calculation of residues in processed commodities (juice, wine), a median residue level of 0.69 mg/kg was estimated.

The Meeting agreed to search for an alternative GAP to estimate a maximum residue level, an STMR and an HR for table grapes.

Another registration exists in Serbia of 3 × 0.35 kg ai/ha and a PHI of 35 days for grapes. Trials on grapes treated with 3 × 0.53 kg ai/ha and a PHI of 35 days from Germany (4), France (7), Spain (2), Italy (1) and Greece (1) were submitted. The Meeting agreed to use the proportionality approach to estimate a separate maximum residue level, an STMR and HR for table grapes. The scaled residue values according to Serbian application rate were (n=15): 0.29, 0.39, 0.48, 0.50, 0.56, 0.57, 0.59, 0.63, 0.64, 0.73, 0.86, 0.99, 1.1, 1.2 and 1.3 mg/kg.

The Meeting estimated a maximum residue level of 2 mg/kg for dithianon residues in table grapes. The Meetin agreed to withdraw the recommendation for grapes of 3 mg/kg. An STMR of 0.63 mg/kg and an HR of 1.3 mg/kg were estimated.

Currants

In France, dithianon may be used as foliar spray on currants with an application rate of 2 × 0.49 kg ai/ha and a PHI of 14 days.

Six trials on black currants according to the French GAP (2 × 0.53 kg ai/ha, PHI 14 days) were submitted. The dithianon residues were < 0.05, < 0.05, < 0.1, 0.11, 0.61 and 0.89 mg/kg.

The Meeting agreed to extrapolate from black currants to currants, black, red, white and estimated a maximum residue level of 2 mg/kg, an STMR of 0.105 mg/kg and an HR of 0.89 mg/kg for dithianon residues in currants.

Almonds

The registered use of dithianon in almonds in France is foliar spray treatment of 2 × 0.35 kg ai/ha and a PHI of 58 days. Four French trials in line with French GAP were available. The dithianon residues were in almonds (without shell) < 0.05 mg/kg (4).

The Meeting considered four trials as sufficient for the estimation of a maximum residue level in almonds because dithianon is located on the surface of the shell and no residues are to be expected in the nutmeat and estimated a maximum residue level of 0.05* mg/kg, and an STMR and an HR of 0 mg/kg.

Hops, dry

In Austria and Germany, dithianon is registered for use on hops at 10 × 0.63–1.4 kg ai/ha (depending from growth stage) and a PHI of 14 days. German trials in line with GAP (10–12 × 0.3–1.5 kg ai/ha, PHI 14 days) were submitted. The residues were in dried cones 4.1, 16, 17, 21, 22, 32, 58, 70, 82, 88, 89, 94, 96 and 242 mg/kg.

The Meeting estimated for dithianon residues in hops, dry a maximum residue level of 300 mg/kg and an STMR of 64 mg/kg. The previous recommendation of 100 mg/kg should be replaced.

Fate of residues during processing

Nature of residues

Three studies on the nature of the residue under simulated processing conditions, performed with [^{14}C] dithianon at higher temperatures, were received.

In the first study, hydrolysis was conducted in buffers solutions whereas in the second study, [^{14}C] dithianon was incubated in apple juice under the conditions of pasteurization (pH 4, incubation for 20 minutes at 90 °C). In both studies, at pH 4, the parent molecule formed the major part of the radioactivity. In addition, a multiple number of unknown degradation products was formed; each of them < 10% of the total applied radioactivity (TAR). At high temperature conditions and pH 5 (simulated processing conditions of baking, brewing and boiling) or pH 6 (simulated processing conditions of sterilization) the hydrolytic degradation of dithianon was fast and resulted in many degradation products. The degradation product 4110904 was found at pH 5 and pH 6 in concentrations exceeding the level of 10% the total applied radioactivity (TAR) accounting for 46–57% of TRR at pH 5 and for about 20% of TRR at pH 6.

A third hydrolysis study on the degradation of dithianon in apple juice at 90 °C, 100 °C and 120 °C was conducted for further characterization of the components formed. The initial high temperature hydrolysis tests with [^{14}C] dithianon in apple juice resulted in the rapid disappearance of dithianon. Between 44 and 47% of the TAR remained as dithianon after hydrolysis at 90 °C for 20 minutes, 0.9–1% of the TAR remained as dithianon after hydrolysis at 100 °C for 60 minutes and less than 1% of the TAR remained as parent after hydrolysis at 120 °C for 20 minutes. The results of the identification of the degradation products are as follows:

- The initial high temperature hydrolysis tests resulted in the formation of naphthoquinone (4107273) at greater than 10% of the TAR upon 20 minutes of hydrolysis at 120 °C. Formation of 4107273 was not observed in the lower temperature hydrolysis samples. 4107273 was also no longer found after refrigerated storage (21 days/33 days) of the apple juice sample hydrolysed at 120 °C. The compound was only found immediately after hydrolysis.
- Phthalic acid (4005234) and compound 4110933 were both observed in hydrolysed apple juice, but always at less than 5% of the TAR.
- Compounds 4110904 and 31062 were formed at 9.4% and 10.5% of TAR, respectively, upon 60 minutes of hydrolysis at 100 °C. At 20 minutes of hydrolysis at 120 °C, 4110904 was formed at 5.8% and 31062 at 10% of TAR. Both compounds appear to be stable in hydrolysed apple juice stored refrigerated.

Level of residues

The Meeting received information on the fate of dithianon residues during the processing of oranges to juice, oil and dry pulp, of apples to juice, sauce, dried apple and wet pomace, of cherries to juice, canned cherries and jam, of plums to puree and dried prunes, of grapes to juice, must, wine, raisins and wet pomace and of hops to beer.

The processing factors obtained in the processing studies and estimated STMR-P and HR-P values are summarized below.

Raw agricultural commodity (RAC)			Processed commodity			
Name	STMR (mg/kg)	HR (mg/kg)	Name	Processing factor (median or best estimate)	STMR-P (mg/kg)	HR-P (mg/kg)
Apples	0.15		Juice	< 0.03 (median)	0.0045	
			Sauce	< 0.03 (median)	0.0045	
			Syrup	< 0.04 (median)	0.006	
			Canned apple	< 0.06 (median)	0.009	
			Dried apple	0.1 (median)	0.015	

Raw agricultural commodity (RAC)			Processed commodity			
Name	STMR (mg/kg)	HR (mg/kg)	Name	Processing factor (median or best estimate)	STMR-P (mg/kg)	HR-P (mg/kg)
			Wet pomace	2.2 (median)	0.33	
Cherries	0.43		Juice	< 0.055 (median)	0.024	
			Canned cherries	< 0.055 (median)	0.024	
			Jam	< 0.055 (median)	0.024	
Plums	0.43		Puree	0.035 (median)	0.015	
			Dried prunes	0.515 (median)	0.22	
Wine-grapes	0.69		Juice	< 0.0025 (median)	0.002	
			Must	0.024 (median)	0.017	
			Wine	< 0.003 (median)	0.002	
			Wet pomace	0.93 (median)	0.64	
Table-grapes	0.63	1.3	Raisins	1.64 (median)	1.03	2.13
Hops	64		Beer	< 0.0003 (median)	0.019	

The Meeting noted that dithianon concentrated during processing in apple pomace, wet and in raisins. Because apple pomace is not a commodity in trade, no maximum residue level is estimated.

Based on the recommended MRL of 2 mg/kg for dithianon residues in table grapes and the processing factor of 1.64, the Meeting estimated a maximum residue level of 3.5 mg/kg for dried grapes (2 × 1.64 = 3.28). An STMR-P of 1.03 mg/kg and an HR-P of 2.13 mg/kg were estimated for raisins.

The Meeting discussed the relevance of the hydrolysis products 411094 and 31062 for the residue definition for industrial or household preparations of dithianon treated fruits and made the following assumptions to estimate their dietary intake:

According to the results of the hydrolysis studies, both degradation products accounted for about 10% of the TAR.

In addition to dithianon, the degradation product 4110904 was investigated in the processing studies for dithianon on apples, cherries, plums and grapes. No residues of 4110904 above the LOQ of 0.01 mg/kg were detected in the RAC. The degradate was not detected in must, wine and juice, but in raisins where the residues were lower than 1% of the dithianon residue. The Meeting agreed to use the LOQ for must, wine and juice or the highest real measured value for raisins to estimate the dietary intake of 4110904. For hops, because no data for 4110904 were available, 10% of the STMR for dithianon in hops adjusted by the molecular weight of 4110904 (330.3) was used.

Because no residue data for the degradate 31062 in RAC and the related processed products were submitted, the estimated dietary intake is based on 10% of the STMR of parent dithianon. The Meeting noted that 31062 was formed by dimerization, resulting in the doubling of the radioactivity per molecule. Therefore the stoichiometric factor to extrapolate from dithianon to 31062 residues is 0.635 [376.1 ÷ (2 × 296.3)]. The 31062 concentrations are calculated as follows:

$$RESIDUE_{31062} = STMR_{Dithianon} \times 0.635 \div 10.$$

The following concentrations of the degradates 4110904 and 31062 were estimated for chronic and acute dietary intake purposes:

Name	Name	4110904, mg/kg	Basis	31062, mg/kg	Basis
Apples,	Juice	0.01	$LOQ_{4110904}$	0.0095	$STMR_{Dithianon}$
Pears	Sauce	0.01	$LOQ_{4110904}$	0.0095	$STMR_{Dithianon}$
	Canned	0.01	$LOQ_{4110904}$	0.0095	$STMR_{Dithianon}$
	Dried	0.01	$LOQ_{4110904}$	0.0095	$STMR_{Dithianon}$
Currants	Juice	0.012	$STMR_{Dithianon}$	0.007	$STMR_{Dithianon}$
Stone fruits	Juice	0.01	$LOQ_{4110904}$	0.0273	$STMR_{Dithianon}$
	Canned	0.01	$LOQ_{4110904}$	0.0273	$STMR_{Dithianon}$

Name	Name	4110904, mg/kg	Basis	31062, mg/kg	Basis
	Jam	0.01	$LOQ_{4110904}$	0.0273	$STMR_{Dithianon}$
	Plum puree	0.01	$LOQ_{4110904}$	0.0273	$STMR_{Dithianon}$
	Dried prunes	0.01	$LOQ_{4110904}$	0.052	$HR_{Dithianon}$
Wine-grapes	Juice	0.01	$LOQ_{4110904}$	0.044	$STMR_{Dithianon}$
	Must	0.01	$LOQ_{4110904}$	0.044	$STMR_{Dithianon}$
	Wine	0.01	$LOQ_{4110904}$	0.044	$STMR_{Dithianon}$
Table-grapes	Raisins	0.11	4110904 measured value	0.135	$HR_{Dithianon}$
Hops	Beer	7.1	$STMR_{Dithianon}$	4.06	$STMR_{Dithianon}$

Conservative estimates of long-term exposure of the degradation products Reg. No. 31062 and Reg. No. 4110904 after industrial or household processing were calculated for the 13 GEMS/Food cluster diets using residue concentrations estimated above. The maximum long-term daily intake was 4.7 µg per person (0.00008 mg/kg bw). Applying this intake to the TTC approach (threshold value 0.0015 mg/kg bw, Cramer Class III), the calculated exposures were up to 5% of the TTC.

Conservative estimates of short-term exposure of the degradation products Reg. No. 31062 and Reg. No. 4110904 were calculated using the residue concentrations estimated above. The maximum short-term daily intake was 115 µg per person (0.00192 mg/kg bw). Applying this intake to the TTC approach (threshold value 0.005 mg/kg bw, Cramer Class III), the maximum calculated exposure was 40% of the TTC.

The Meeting concluded that the long-term and short-term intake of residues of Reg. No. 31062 and Reg. No. 4110904 arising of dithianon, when used in ways that have been considered by the JMPR, is unlikely to present a public health concern.

Farm animal dietary burden

The 2013 JMPR evaluated residues of dithianon in apple pomace wet and grape pomace wet which are listed under by-products in the OECD feeding table for beef and dairy cattle but not for poultry.

Estimated maximum and mean dietary burdens of farm animals

Dietary burden calculations based on the feed items evaluated for beef cattle and dairy cattle 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 Table. Because the calculation based on the STMR-P values of the processed by-products, the maximum and mean burden is identical. The table below shows the values calculated.

Because apple pomace wet and grape pomace wet are no feed items for poultry, the livestock dietary burden for broiler and layer is zero.

	Livestock dietary burden, dithianon, ppm of dry matter diet							
	US-Canada		EU		Australia		Japan	
	Max	Mean	Max	Mean	Max	Mean	Max	Mean
Beef cattle	0	0	0.165	0.165	0.853 a	0.853 a	0	0
Dairy cattle	0.083	0.083	0.090	0.090	0.853 a	0.853 a	0	0
Poultry-broiler	0	0	0	0	0	0	0	0
Poultry-layer	0	0	0	0	0	0	0	0

[a] Highest mean and maximum beef or dairy cattle dietary burden suitable for MRL and STMR estimates for mammalian meat, edible offal and milk.

Farm animal feeding and metabolism studies

No animal feeding studies of dithianon were submitted. The Meeting agreed to extrapolate the residue levels to be expected in ruminant tissues and milk from the goat metabolism studies.

The metabolism studies in lactating goats were performed at actual dose levels of 2.5 and 28 ppm in the first study and of 25 ppm in the feed of the second study. The overdosing factors are calculated as about 2.9 (2.5 ppm ÷ 0.853 ppm), 33 (28 ppm ÷ 0.853 ppm) and 29 (25 ppm ÷ 0.853 ppm), respectively.

Animal commodity maximum residue levels

The expected total residues in milk and edible tissues of ruminants can be extrapolated from the highest TRR found in the goat metabolism studies as follows:

Commodity	Feeding level, ppm	TRR from metabolism study, mg/kg	TRR extrapolated from actual dietary burden, mg/kg
Milk	2.5	< 0.01	< 0.003
Liver		0.07	0.024
Kidney		0.04	0.014
Muscle		Not detected	–
Fat		< 0.01	< 0.003
Milk	28	0.030	0.0009
Liver		0.174	0.0053
Kidney		0.489	0.0149
Muscle		0.013	0.0004
Fat		0.014	0.0004
Milk	25	0.016	0.0006
Liver		0.157	0.0054
Kidney		0.475	0.0162
Muscle		0.014	0.0005
Fat		0.074	0.0025

The extrapolated TRR are for milk, muscle and fat are lower than the LOQ of 0.01 of dithianon in animal products. In case of liver and kidney, the extrapolated TRR range from 0.005–0.02 mg/kg and 0.01–0.02 mg/kg, respectively.

The Meeting noted that the results from metabolism studies on rats, goats and hens show that dithianon is intensively metabolized. In the goat, parent dithianon was detected at low levels (≤ 0.01mg/kg) and no single metabolite in the extracts was detected > 0.05 mg/kg. Therefore, it is not expected that the calculated TRR in cattle tissues and milk arising from a burden of 0.853 ppm would account for 100% of dithianon or a related metabolite. In case of poultry, the dietary burdens for broiler and layer are zero. The Meeting concluded that the contribution of dithianon arising residues in animal products to the dietary intake is negligible.

The Meeting estimated maximum residue levels of 0.01* mg/kg for meat of mammals, other than marine mammals, edible offal (mammalian), milk, poultry meat, poultry edible offal and eggs. The STMR for milk and the STMR/HR values for mammalian and poultry meat, mammalian and poultry edible offal as well as for 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 and for estimation of dietary intake) for plant and animal commodities: *Dithianon*.

The residue is not fat-soluble.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Dietary Intakes (IEDIs) of dithianon were calculated for the 13 GEMS/Food cluster diets using STMRs and STMR-Ps estimated by the current Meeting (Annex 3). The ADI is 0–0.01 mg/kg bw and the calculated IEDIs were 1–7% of the maximum ADI. The Meeting concluded that the long-term intake of residues of dithianon 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 dithianon 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.

The Meeting noted that for apples and grapes the IESTI calculated according to the maximum GAP exceeded the ARfD of 0.1 mg/kg bw and used an alternative GAP.

For the commodities considered by the JMPR, the IESTI represented 0–40% of the ARfD for the general population and 0–90% of the ARfD for children. The Meeting concluded that the short-term intake of residues of dithianon, when used in ways that have been considered by the JMPR, is unlikely to present a public health concern.

5.15 FENAMIDONE (264)

TOXICOLOGY

Fenamidone is the ISO-approved common name for (5*S*)-5-methyl-2-(methylthio)-5-phenyl-3-(phenylamino)-3,5-dihydro-4H-imidazol-4-one (IUPAC), with CAS No. 161326-34-7. There is no conversion to the *R*-enantiomer in biological systems. Fenamidone is a foliar fungicide used on vegetables and ornamentals.

Fenamidone 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.

Biochemical aspects

In experiments conducted in rats using [^{14}C]fenamidone labelled at either the C-phenyl or N-phenyl part of the molecule, the time to reach the maximum plasma concentration of radioactivity was 2 hours after a single oral dose of 3 mg/kg bw and 26 hours after a single oral dose of 300 mg/kg bw. Gastrointestinal absorption was greater than 80%. Radioactivity distributed to most tissues, with no evidence of accumulation. Relatively high concentrations of radioactivity (approximately 400 times higher than that in plasma) were detected in the thyroid following dosing with C-phenyl- but not N-phenyl-labelled fenamidone, suggesting the distribution of a radiolabelled metabolite to the thyroid. Fenamidone undergoes extensive metabolism in the rat by phase I (oxidation, reduction and hydrolysis) and phase II reactions (conjugation). More than 20 metabolites were detected in rat excreta. The plasma elimination half-life was at least 60 hours, 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.

Toxicological data

The oral LD_{50} in rats was greater than 2000 mg/kg bw. The dermal LD_{50} in rats was greater than 2000 mg/kg bw, and the LC_{50} was greater than 2.1 mg/L. Fenamidone was neither a skin irritant nor an eye irritant in rabbits. In a guinea-pig maximization test, no skin sensitization occurred.

The target organs for fenamidone are the liver and thyroid. In rats, fenamidone was an inducer of cytochrome P450. Consistent with studies indicating a relatively high distribution of radiolabel to the rat thyroid, increased thyroid weight, follicular cell hypertrophy and hyperplasia were observed. This did not appear to be a secondary effect of liver enzyme induction, as thyroid hormone levels in plasma were not affected by treatment.

In a non-guideline 90-day toxicity study in mice that tested dietary concentrations of 0, 70, 700 and 7000 ppm (equal to 0, 11.4, 110 and 1102 mg/kg bw per day for males and 0, 14.5, 146 and 1468 mg/kg bw per day for females, respectively), the NOAEL was 700 ppm (equal to 110 mg/kg bw per day), based on clinical signs and deaths in males at 7000 ppm (equal to 1102 mg/kg bw per day). In a second 90-day study in mice that tested dietary concentrations of 0, 50, 200, 1000 and 5000 ppm (equal to 0, 11.3, 44.5, 220 and 1064 mg/kg bw per day for males and 0, 13.7, 54, 274 and 1375 mg/kg bw per day for females, respectively), the NOAEL was 1000 ppm (equal to 220 mg/kg bw per day) for equivocal histopathological findings in the liver at 5000 ppm (equal to 1064 mg/kg bw per day). The overall NOAEL for the two 90-day studies in mice was 1000 ppm (equal to 220 mg/kg bw per day), with an overall LOAEL of 5000 ppm (equal to 1064 mg/kg bw per day).

A 28-day toxicity study in rats tested dietary concentrations of 0, 500, 5000 and 15 000 ppm (equal to 0, 39, 389 and 1203 mg/kg bw per day for males and 0, 42, 405 and 1194 mg/kg bw per day for females, respectively). The NOAEL was 500 ppm (equal to 39 mg/kg bw per day) for reduced red

cell parameters and increased spleen weights coincident with hyperplasia of the germinative follicle of the white pulp at and above 5000 ppm (equal to 389 mg/kg bw per day). The NOAEL in a second 28-day study in rats, which tested dietary concentrations of 0, 60, 150, 1000 and 5000 ppm (equal to 0, 4.9, 12.3, 82.7 and 418.5 mg/kg bw per day for males and 0, 5.3, 13.9, 90.6 and 450.1 mg/kg bw per day for females, respectively), was 1000 ppm (equal to 82.7 mg/kg bw per day) for thyroid follicular cell hypertrophy in males at 5000 ppm (equal to 418.5 mg/kg bw per day).

In a 90-day toxicity study in rats, which tested dietary concentrations of 0, 50, 150, 500 and 5000 ppm (equal to 0, 3, 9, 30 and 305 mg/kg bw per day for males and 0, 3, 11, 35 and 337 mg/kg bw per day for females, respectively), the NOAEL was 500 ppm (equal to 30 mg/kg bw per day) for reduced body weight gain, reduced feed consumption and changes in red cell parameters at 5000 ppm (equal to 305 mg/kg bw per day). The NOAEL in a second 90-day rat study, which tested dietary concentrations of 0, 60, 150, 1000 and 5000 ppm (equal to 0, 4.1, 10.4, 68.3 and 344 mg/kg bw per day for males and 0, 4.8, 12, 83.3 and 381 mg/kg bw per day for females, respectively), was 1000 ppm (equal to 68.3 mg/kg bw per day) for reduced body weight gain at 5000 ppm (equal to 344 mg/kg bw per day).

In a 28-day toxicity study in dogs, which tested doses of 0, 3, 10 and 100 mg/kg bw per day given by capsule, the NOAEL was 100 mg/kg bw per day, the highest dose tested. In a 13-week study in dogs, which tested doses of 0, 10, 100 and 500 mg/kg bw per day given by capsule, the NOAEL was 500 mg/kg bw per day, the highest dose tested. In a 52-week study in dogs, which tested doses of 0, 10, 100 and 1000 mg/kg bw per day given by capsule, the NOAEL was 100 mg/kg bw per day for clinical signs (hypersalivation and vomiting), increased AP activity, increased liver weight (males) and increased bile duct hyperplasia (males) at 1000 mg/kg bw per day. The overall NOAEL for the 13 and 52-week studies was 500 mg/kg bw per day, with an overall LOAEL of 1000 mg/kg bw per day.

In a long-term study of toxicity and carcinogenicity in mice, which tested dietary concentrations of 0, 70, 350, 3500 and 7000 ppm (equal to 0, 9.5, 47.5, 525.5 and 1100 mg/kg bw per day for males and 0, 12.6, 63.8, 690.5 and 1393 mg/kg bw per day for females, respectively), the NOAEL was 350 ppm (equal to 47.5 mg/kg bw per day) for lower body weight, increased liver weight and histopathological findings in the liver at 3500 ppm (equal to 525.5 mg/kg bw per day). No treatment-related neoplastic lesions were detected at dietary concentrations up to 7000 ppm (equal to 1100 mg/kg bw per day, respectively).

In a long-term toxicity and carcinogenicity study in rats that tested dietary concentrations of 0, 60, 150, 1000 and 5000 ppm (equal to 0, 2.8, 7.1, 47.7 and 260 mg/kg bw per day for males and 0, 3.6, 9.2, 60.9 and 330 mg/kg bw per day for females, respectively), the NOAEL was 60 ppm (equal to 2.8 mg/kg bw per day) for thyroid follicular cell hypertrophy and hyperplasia at 150 ppm (equal to 7.1 mg/kg bw per day). No treatment-related neoplastic lesions were detected at dietary concentrations up to 5000 ppm (equal to 260 mg/kg bw per day).

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

Fenamidone was negative in the Ames test and in an in vitro unscheduled DNA synthesis (UDS) assay in rat hepatocytes. Fenamidone was positive in a mouse lymphoma forward mutation assay and caused chromosomal aberrations in cultured human peripheral blood lymphocytes in the presence of metabolic activation. Negative responses were obtained in vivo in the mouse micronucleus test and UDS assay in rat hepatocytes.

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

Considering the lack of in vivo genotoxicity potential and the absence of a carcinogenic response in mice and rats, the Meeting concluded that fenamidone is unlikely to pose a carcinogenic risk to humans from the diet.

In a two-generation study in rats, which tested dietary concentrations of 0, 60, 1000 and 5000 ppm (equal to 0, 3.9, 63.8 and 328.3 mg/kg bw per day for males and 0, 5.15, 84.4 and

459.6 mg/kg bw per day for females, respectively), there was no evidence of reproductive toxicity up to the highest tested dietary concentration of 5000 ppm (equal to 328.3 mg/kg bw per day). The NOAEL for parental toxicity was 60 ppm (equal to 3.9 mg/kg bw per day) for lower body weight, reduced body weight gain and reduced feed consumption at 1000 ppm (equal to 63.8 mg/kg bw per day). The NOAEL for offspring toxicity was 1000 ppm (equal to 63.8 mg/kg bw per day) for lower F_1 and F_2 pup weights at 5000 ppm (equal to 328.3 mg/kg bw per day).

In a rat developmental toxicity study that tested doses of 0, 25, 150 and 1000 mg/kg bw per day, the NOAEL for maternal toxicity was 150 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 150 mg/kg bw per day for lower fetal weight at 1000 mg/kg bw per day.

In a rabbit developmental toxicity study that tested doses of 0, 10, 30 and 100 mg/kg bw per day, the NOAEL for maternal toxicity was 30 mg/kg bw per day for decreased body weight gain at 100 mg/kg bw per day. The NOAEL for embryo and fetal toxicity was 100 mg/kg bw per day, the highest dose tested.

The Meeting concluded that fenamidone is not teratogenic in rats or rabbits.

Acute and subchronic neurotoxicity studies were conducted in rats. In the acute gavage study, which tested doses of 0, 125, 500 and 2000 mg/kg bw per day, the NOAEL was 125 mg/kg bw for nonspecific findings in the functional observational battery at 4 hours after dosing at 500 mg/kg bw per day and above. In the subchronic study, which tested dietary concentrations of 0, 150, 1000 and 5000 ppm (equal to 0, 11.2, 73.5 and 392.3 mg/kg bw per day for males and 0, 12.7, 83.4 and 414.2 mg/kg bw per day for females, respectively), the NOAEL was 1000 ppm (equal to 73.5 mg/kg bw per day) for reduced body weight gain at 5000 ppm (equal to 392.3 mg/kg bw per day).

There was no evidence of developmental neurotoxicity in a dietary study conducted in female rats, which tested dietary concentrations of 0, 60, 250, 1000 and 4700 ppm (equal to 0, 5.5, 23, 92.3 and 429 mg/kg bw per day, respectively). The NOAEL for maternal toxicity was 1000 ppm (equal to 92.3 mg/kg bw per day) for reduced body weight gain at 4700 ppm (equal to 429 mg/kg bw per day). The NOAEL for offspring toxicity was also 1000 ppm (equal to 92.3 mg/kg bw per day), for lower absolute body weight and reduced body weight gain at 4700 ppm (equal to 429 mg/kg bw per day).

The Meeting concluded that fenamidone is not neurotoxic.

Toxicological data on metabolites and/or degradates

Toxicity studies were conducted on three fenamidone metabolites: (1) (*S*)-5-methyl-5-phenyl-2,4-imidazolidine-dione (RPA 412636), which is a metabolite in rat urine present at less than 1% of an administered dose; (2) (5*S*)-5-methyl-5-phenyl-3-(phenylamino)-2,4-imidazolidine-dione (RPA 410193), which is a novel plant metabolite; and (3) (5*S*)-5-methyl-2-(methylthio)-5-phenyl-3,5-dihydro-4H-imidazol-4-one (RPA 412708), which is a metabolite in rat bile present at greater than 10% of an administered dose.

The oral LD_{50} in rats was 1520 mg/kg bw for RPA 412636, greater than 2000 mg/kg bw for RPA 410193 and greater than 100 mg/kg bw for RPA 412708.

Short-term studies of toxicity were performed on RPA 412636, RPA 410193 and RPA 412708 in rats. As with the parent compound, liver enzyme induction and liver hypertrophy occurred with RPA 412636 and RPA 410193, but not RPA 412708. In a non-guideline 14-day study on RPA 412636 that tested dietary concentrations of 0, 300, 1200 and 300 ppm (equal to 0, 23, 90 and 215 mg/kg bw per day for males and 0, 24.5, 96.7 and 233 mg/kg bw per day for females, respectively), the NOAEL was 1200 ppm (equal to 90 mg/kg bw per day) for reduced body weight gain and feed consumption at 3000 ppm (equal to 215 mg/kg bw per day). In a similar non-guideline study on RPA 410193, which tested dietary concentrations of 0, 450, 4500 and 15 000 ppm (equal to 0, 30, 299 and 1098 mg/kg bw per day for males and 0, 37, 374 and 1133 mg/kg bw per day for females, respectively), the NOAEL was 450 ppm (equal to 30 mg/kg bw per day) for histopathological

findings in the thyroid at 4500 ppm (equal to 299 mg/kg bw per day). In the non-guideline 14-day study on RPA 412708, which tested dietary concentrations of 0, 200, 500 and 2000 ppm (equal to 0, 15.1, 38.5 and 150.5 mg/kg bw per day for males and 0, 16.1, 37.8 and 147.3 mg/kg bw per day for females, respectively), the NOAEL was 2000 ppm (equal to 147.3 mg/kg bw per day), the highest dietary concentration tested.

Ninety-day dietary studies were conducted on RPA 412636 and RPA 410193 in rats. The study on RPA 412636 tested dietary concentrations of 0, 100, 500 and 2500 ppm (equal to 0, 6.4, 33 and 162 mg/kg bw per day for males and 0, 7.7, 39 and 196 mg/kg bw per day for females, respectively); the NOAEL was 100 ppm (equal to 6.4 mg/kg bw per day) for vacuolation of centrilobular hepatocytes at 500 ppm (equal to 33 mg/kg bw per day) in males. In the study conducted on RPA 410193, which tested dietary concentrations of 0, 150, 1500 and 15 000 ppm (equal to 0, 9.3, 93.3 and 978 mg/kg bw per day for males and 0, 11.5, 115 and 1090 mg/kg bw per day for females), the NOAEL was 1500 ppm (equal to 93.3 mg/kg bw per day), based on perturbations in red cell parameters at 15 000 ppm (equal to 978 mg/kg bw per day).

There was no evidence of genotoxicity in vitro and in vivo for RPA 412636, RPA 410193 and RPA 412708.

Human data

In a cohort of 15 workers involved in the processing of fenamidone over a 5-year period, no adverse medical events were reported, and there were no detectable effects following physical and biochemical examinations.

The Meeting concluded that the database on fenamidone 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 per day, based on the NOAEL of 2.8 mg/kg bw per day for a dose-related increase in thyroid follicular cell hypertrophy and hyperplasia in both sexes after 52 weeks in the 2-year rat study. A 100-fold safety factor was applied.

The Meeting established an ARfD of 1 mg/kg bw, based on the NOAEL of 125 mg/kg bw per day for nonspecific findings in the functional observational battery in the acute neurotoxicity study in rats, and using a 100-fold safety factor. The Meeting noted that decreased maternal body weight gain in the developmental toxicity study in rabbits with a lower NOAEL of 30 mg/kg bw per day was not an acute effect and was therefore not a suitable basis for establishing an ARfD for fenamidone.

A toxicological monograph was prepared.

Levels relevant to risk assessment of fenamidone

Species	Study	Effect	NOAEL	LOAEL
Mouse	Ninety-day studies of toxicity[a,b]	Toxicity	1000 ppm, equal to 220 mg/kg bw per day	5000 ppm, equal to 1064 mg/kg bw per day
	Two-year study of toxicity and carcinogenicity[a]	Toxicity	350 ppm, equal to 47.5 mg/kg bw per day	3500 ppm, equal to 525.5 mg/kg bw per day
		Carcinogenicity	7000 ppm, equal to 1100 mg/kg bw per	—

Species	Study	Effect	NOAEL	LOAEL
			day[c]	
Rat	Acute neurotoxicity study[d]	Toxicity	125 mg/kg bw per day	500 mg/kg bw per day
	Thirteen-week studies of toxicity or neurotoxicity[a,b]	Toxicity	1000 ppm, equal to 73.5 mg/kg bw per day	5000 ppm, equal to 305 mg/kg bw per day
	Two-year study of toxicity and carcinogenicity[a]	Toxicity	60 ppm, equal to 2.8 mg/kg bw per day	150 ppm, equal to 7.1 mg/kg bw per day
		Carcinogenicity	5000 ppm, equal to 260 mg/kg bw per day[c]	—
	Two-generation study of reproductive toxicity[a]	Reproductive toxicity	5000 ppm, equal to 328.3 mg/kg bw per day[c]	—
		Parental toxicity	60 ppm, equal to 3.9 mg/kg bw per day	1000 ppm, equal to 63.8 mg/kg bw per day
		Offspring toxicity	1000 ppm, equal to 63.8 mg/kg bw per day	5000 ppm, equal to 328.3 mg/kg bw per day
	Developmental toxicity study[d]	Maternal toxicity	150 mg/kg bw per day	1000 mg/kg bw per day
		Embryo and fetal toxicity	150 mg/kg bw per day	1000 mg/kg bw per day
Rabbit	Developmental toxicity study[d]	Maternal toxicity	30 mg/kg bw per day	100 mg/kg bw per day
		Embryo and fetal toxicity	100 mg/kg bw per day[c]	—
Dog	Thirteen- and 52-week studies of toxicity[b,e]	Toxicity	500 mg/kg bw per day	1000 mg/kg bw per day

[a] Dietary administration.

[b] Two or more studies combined. For the rat, two 90-day toxicity studies and a subchronic neurotoxicity study were combined.

[c] Highest dose tested.

[d] Gavage administration.

[e] Capsule administration.

Levels relevant to risk assessment of fenamidone metabolites based on studies conducted in rats

Metabolite	Study	Effect	NOAEL	LOAEL
RPA 412636[a]	Ninety-day study of toxicity[b]	Toxicity	100 ppm, equal to 6.4 mg/kg bw per day	500 ppm, equal to 33 mg/kg bw per day
RPA 410193[c]	Ninety-day study of toxicity[b]	Toxicity	1500 ppm, equal to 93.3 mg/kg bw per	15 000 ppm, equal to 978 mg/kg bw per

Metabolite	Study	Effect	NOAEL	LOAEL
			day	day
RPA 412708[d]	Fourteen-day study of toxicity[b]	Toxicity	2000 ppm, equal to 147.3 mg/kg bw per day[e]	—

[a] (*S*)-5-Methyl-5-phenyl-2,4-imidazolidine-dione.

[b] Dietary administration.

[c] (5*S*)-5-Methyl-5-phenyl-3-(phenylamino)-2,4-imidazolidine-dione.

[d] (5*S*)-5-methyl-2-(methylthio)-5-phenyl-3,5-dihydro-4H-imidazol-4-one.

[e] Highest dose tested.

Estimate of acceptable daily intake

0–0.03 mg/kg bw

Estimate of acute reference dose

1 mg/kg bw

Information that would be useful for the continued evaluation of fenamidone

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

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

Absorption, distribution, excretion and metabolism in mammals	
Rate and extent of oral absorption	Rats: T_{max} = 2–26 h; extensive, > 80%
Distribution	Widespread tissue distribution; preferential distribution of radiolabel to the thyroid
Potential for accumulation	No potential for accumulation
Rate and extent of excretion	Excretion via faeces and urine; half-life > 60 h
Metabolism in animals	Extensive
Toxicologically significant compounds in animals, plants and the environment	Fenamidone, RPA 412636, RPA 410193, RPA 412708
Acute toxicity	
Rat, LD_{50}, oral	> 2000 mg/kg bw
Rat, LD_{50}, dermal	> 2000 mg/kg bw
Rat, LC_{50}, inhalation	> 2.1 mg/L
Rabbit, dermal irritation	Non-irritating
Rabbit, ocular irritation	Non-irritating
Dermal sensitization	Non-sensitizing (guinea-pigs)
Short-term studies of toxicity	
Target/critical effect	Liver, thyroid

Lowest relevant oral NOAEL	68.3 mg/kg bw per day (rat)
Lowest relevant dermal NOAEL	No data
Lowest relevant inhalation NOAEC	No data
Long-term studies of toxicity and carcinogenicity	
Target/critical effect	Thyroid
Lowest relevant NOAEL	2.8 mg/kg bw per day (rat)
Carcinogenicity	Unlikely to pose a carcinogenic risk to humans from the diet
Genotoxicity	
	Not genotoxic in vivo
Reproductive toxicity	
Reproduction target/critical effect	No evidence of reproductive toxicity (rat)
Lowest relevant parental NOAEL	3.9 mg/kg bw per day
Lowest relevant offspring NOAEL	63.8 mg/kg bw per day
Lowest relevant reproduction NOAEL	328.3 mg/kg bw per day, the highest dose tested
Developmental toxicity	
Developmental target/critical effect	Decreased pup weights at maternally toxic doses (rat)
Lowest maternal NOAEL	30 mg/kg bw per day (rabbit)
Lowest embryo/fetal NOAEL	100 mg/kg bw per day, the highest dose tested (rabbit); 150 mg/kg bw per day (rat)
Neurotoxicity	
Neurotoxicity	Not neurotoxic
Developmental neurotoxicity	No developmental neurotoxicity
Toxicological studies on RPA 412636	
Rat, LD_{50}, oral	1520 mg/kg bw
Lowest relevant short-term oral NOAEL	6.4 mg/kg bw per day (90 days, rat)
Genotoxicity	Not genotoxic
Toxicological studies on RPA 410193	
Rat, LD_{50}, oral	> 2000 mg/kg bw
Lowest relevant short-term oral NOAEL	30 mg/kg bw per day (90 days, rat)
Genotoxicity	Not genotoxic
Toxicological studies on RPA 412708	
Rat, LD_{50}, oral	100 mg/kg bw
Lowest relevant short-term oral NOAEL	147.3 mg/kg bw per day (14 days, rat)
Genotoxicity	Not genotoxic
Medical data	
	No adverse effects in workers involved with manufacturing fenamidone

Summary

	Value	Studies	Safety factor
ADI	0–0.03 mg/kg bw	Two-year dietary study in rats	100
ARfD	1 mg/kg bw	Acute neurotoxicity study in rats	100

5.16 FENBUCONAZOLE (197)

RESIDUE AND ANALYTICAL ASPECTS

Fenbuconazole was first evaluated for residues and toxicology by the JMPR in 1997, and then evaluated for residues in 2009 and for toxicology in 2012. The 1997 JMPR allocated an ADI of 0–0.03 mg/kg bw. The 2012 JMPR established an ARfD of 0.2 mg/kg bw.

The Meeting recommended a number of maximum residue levels in 1997 and 2009. Those maximum residue levels were adopted by the Codex Alimentarius Commission in 1999, 2000 and 2013 as Codex MRLs.

The 2009 JMPR received the residue trial data on citrus fruits (grapefruit, oranges and lemons). However, it could not estimate a maximum residue level for fenbuconazole in citrus fruits as the residue trials submitted did not match the available GAP.

Fenbuconazole was scheduled by the Fourt-fourth Session of the CCPR for the residue evaluation of citrus fruits. The "Principles and guidance for application of the proportionality concept for estimation of maximum residue limits for pesticides" were adopted by the Codex Alimentarius Commission in 2013.

Results of supervised residue trials on crops

Information on GAP and supervised trial data were submitted to the 2009 JMPR for lemons and oranges and to the 1997 JMPR for grapefruit and oranges.

Citrus fruits

The GAP on citrus fruit in the USA is a maximum of three foliar applications at a rate of 0.14 kg ai/ha with a PHI of 0 day. Nine trials for grapefruit, sixteen trials for oranges and five trials for lemons were conducted in the USA (3 × 0.28 kg ai/ha, PHI 0 day). As the application rate of those trials submitted to the 1997 and 2009 JMPR was 2 times the GAP rate, the Meeting decided to use the principle of proportionality to select data for estimating a maximum residue level, an STMR value and an HR value for citrus fruit.

The Meeting considered the result from one trial on grapefruit was not appropriate for use in estimating a maximum residue level as the residue concentration in pulp was higher than in the whole fruit.

Scaled residues in the whole fruit of grapefruit were (scaling factor 0.5: 0.28➔0.14 kg ai/ha): 0.05, 0.06, 0.07, 0.08 (2), 0.10, 0.17 and 0.24 mg/kg.

Scaled residues in the whole fruit of oranges were (scaling factor 0.5: 0.28➔0.14 kg ai/ha): 0.06 (2), 0.07, 0.08, 0.09 (4), 0.10, 0.14, 0.15 (2), 0.17, 0.22, 0.26 and 0.33 mg/kg.

Scaled residues in the whole fruit in lemons were (scaling factor 0.5: 0.28➔0.14 kg ai/ha): 0.26, 0.29 (2), 0.35 and 0.42 mg/kg.

To consider a maximum residue level for a crop group, residues in individual crops should be similar (e.q., medians should not differ by more than 5×). The Meeting agreed to estimate a maximum residue level for the group of citrus fruits. In considering whether to combine data to estimate a maximum residue level, the Meeting recognized that the residue populations from trials on grapefruit, oranges and lemons were significantly different according to statistical test (Kruskal-Wallis H-test): the residue population from trials on lemons was different from those on grapefruit and oranges, while the residue populations from trials on grapefruit and oranges were not different according to statistical test (Mann-Whitney U-test). Therefore, the Meeting decided to combine the

grapefruit and oranges data sets to estimate a maximum residue level for citrus fruits (except lemons and limes).

The combined residues in the whole fruit of grapefruit and oranges, in rank order, were (n=24): 0.05, 0.06 (3), 0.07 (2), 0.08 (3), 0.09 (4), 0.10 (2), 0.14, 0.15 (2), 0.17 (2), 0.22, 0.24, 0.26 and 0.33 mg/kg.

Scaled residues in pulp of grapefruit were (scaling factor 0.5): < 0.01 (4) and 0.01 mg/kg.

Scaled residues in pulp of orange were (scaling factor 0.5): < 0.01 (5) mg/kg.

The combined residues in pulp of grapefruit and orange were in rank order (n=10): < 0.01 (9) and 0.01 mg/kg.

Based on the scaled residues in the whole fruit of grapefruit and oranges, the Meeting estimated a maximum residue level of 0.5 mg/kg and an STMR value for processing of 0.09 mg/kg for fenbuconazole in citrus fruit (except lemons and limes). Based on the scaled residues in pulp of grapefruit and orange, the Meeting estimated an STMR value of 0.01 mg/kg and an HR value of 0.01 mg/kg for fenbuconazole in citrus fruit (except lemons and limes).

Scaled residues in pulp of lemon were (scaling factor 0.5): < 0.01, 0.016, 0.018, 0.033 and 0.085 mg/kg.

Based on the scaled residues in the whole fruit of lemon, the Meeting estimated a maximum residue level of 1 mg/kg and an STMR for processing of 0.29 mg/kg for fenbuconazole in lemons and limes. Based on the scaled residues in pulp of lemon, the Meeting estimated an STMR value of 0.018 mg/kg and an HR value of 0.085 mg/kg for fenbuconazole in lemons and limes.

Fate of residues during processing

The Meeting received information on the fate of incurred residues of fenbuconazole during the processing of citrus whole fruit (grapefruit and oranges) to juice, dried pulp and cold press oil conducted in the USA in 2009. Based on processing factors for grapefruit and oranges, in combination with STMR for processing estimated for citrus fruits (except lemons and limes) and lemons and limes, the STMR-Ps for juice, dried pulp and oil were calculated as follows.

Processing factors, STMR-P and HR-P for food and feed

Processed commodity	Calculated processing factors*	PF (Mean or best estimate)	Raw agricultural commodity (RAC) STMR		STMR-P (mg/kg)
			mg/kg	RAC	
Juice	< 0.204, < 0.256	< 0.23	0.09	Citrus fruit (except lemons and limes)	0.021
			0.29	Lemons ans limes	0.067
Cold press oil	49.0, 66.7	58	0.09	Citrus fruit (except lemons and limes)	5.2
			0.29	Lemons ans limes	17
Dried pulp	6.31, 7.74	7.0	0.09	Citrus fruit (except lemons and limes)	0.63

* Processing factors were derived from the two processing studies each on grapefruit or orange. The factor is the ratio of the residue in processed commodity divided by the residue in the RAC.

The Meeting estimated the maximum residue levels of 4 mg/kg (0.5 mg/kg × 7.0 = 3.5 mg/kg) for deried citrus pulp, 30 mg/kg (0.5 mg/kg × 58 = 29 mg/kg) mg/kg for citrus oil (except lemons and limes) and 60 mg/kg (1 mg/kg × 58 = 58 mg/kg) for oil of lemons and limes based on the maximum residue levels of citrus fruit (except lemons and limes) and of lemons and limes.

Residues in animal commodities

Farm animal feeding studies

A lactating dairy cattle feeding study and a laying hen feeding study were submitted to the 1997 JMPR.

Animal commodity maximum residue levels

Dried citrus pulp may be fed to beef cattle, dairy cattle, broilers and layers. But the STMP-P of dried citrus pulp was low at 0.63 mg/kg not contributing significantly to animal dietary burden. The calculated maximum and mean dietary burdens, with addition of dried citrus pulp, to be used for estimating maximum residue levels for commodities of animal origin (both mammals and poultry) were identical to those calculated by the 2009 JMPR.

The Meeting, therefore, confirmed the previous recommendations of the maximum residue levels for fenbuconazole in 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 and for dietary intake assessment.

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

The residue is not fat soluble.

DIETARY RISK ASSESSMENT

Long-term intake

In the current evaluation STMRs were estimated for 7 food commodities. Where consumption data were available these STMRs were used in the estimates of dietary intake together with previous MRL recommendations for other food commodities. The results are shown in Annex 3.

The ADI is 0–0.03 mg/kg bw and the calculated IEDIs were 0–2% of the maximum ADI (0.03 mg/kg bw). The Meeting concluded that the long-term intake of residues of fenbuconazole, resulting from the uses considered by current JMPR, is unlikely to present a public health concern.

Short-term intake

The International Estimated Short Term Intake (IESTI) for fenbuconazole was calculated for 7 food commodities (including processed fractions) for which maximum residue levels were estimated at the present meeting and for which consumption data were available. The results are shown in Annex 4.

The ARfD is 0.2 mg/kg bw and the calculated IESTI were a maximum of 0% of the ARfD for all population groups. The Meeting concluded that the short-term intake of residues of fenbuconazole, when used in ways that have been considered by the JMPR, is unlikely to present a public health concern.

5.17 FENPYROXIMATE (193)

RESIDUE AND ANALYTICAL ASPECTS

Fenpyroximate is a pyrazole non-systemic acaricide. It was first evaluated by JMPR in 1995 and then in 1999 and 2010 for maximum residue levels, and in 2004 and 2007 for toxicology. The currently standing recommendations of JMPR are as follows:

- ADI: 0–0.01 mg/kg bw (1995)
- ARfD: 0.02 mg/kg bw (2007)
- Residue definition: Fenpyroximate for compliance with the MRL and for estimation of dietary intake (both for animal and plant commodities). The residue is fat soluble. (1999)

The current Meeting received information on the latest use pattern and the supervised residue trials on stone fruits, strawberry, avocado, cucumber, common bean (pods and/or immature seeds and bean fodder), potato and mints conducted in the USA.

Results of supervised residue trials on crops

The Meeting received supervised trial data for fenpyroximate conducted in the USA on stone fruits, strawberry, avocado, cucumber, common bean (pods and/or immature seeds; and bean fodder), potato and mints with foliar applications of the fenpyroximate emulsion concentrate (EC) formulation.

For estimating HR or highest residue, the highest individual residue concentration from the trials conducted in accordance with GAP was used.

Stone fruits

The approved use of fenpyroximate on stone fruits in the USA consists of up to two foliar spray applications with an interval of 14 days at a maximum rate of 0.117 kg ai/ha and a minimum of 748 L/ha of water, the PHI is 7 days. In supervised residue trials, various adjuvants were used with the result that there were no significant difference or trend found between the different adjuvants.

A total of eight supervised trials on cherries were conducted in the USA in 2010. The residues of fenpyroximate in cherries from six independent trials in accordance with US GAP were in rank order: 0.27, 0.34, 0.46, 0.69, 0.81 and 0.87 mg/kg.

The Meeting estimated an STMR of 0.57 mg/kg for cherries.

A total of ten supervised trials on peach were conducted in the USA in 2010. The residues from seven trials in accordance with US GAP were in rank order: 0.08, 0.08, 0.12, 0.13, 0.13, 0.15 and 0.18 mg/kg.

The Meeting estimated an STMR of 0.13 mg/kg for peach.

A total of six supervised trials on plum were conducted in the USA in 2010. The residues from five trials in accordance with US GAP were in rank order:< 0.05, 0.09, 0.13, 0.20 and 0.27 mg/kg.

The Meeting estimated an STMR of 0.13 mg/kg for plum.

The GAP in the USA covers the group of stone fruits; and the STMRs for cherries, peach and plum were within five-fold difference. However, the Meeting decided to estimate two maximum residue levels, one for cherries and the other for stone fruits except cherries, in order to avoid probability of IESTI for children calculated for peach exceeding the ARfD.

The Meeting therefore estimated a maximum residue level, STMR and HR of 2, 0.57 and 0.90 mg/kg, respectively for cherries.

As the residue populations of peach and plum were similar according to the Mann-Whitney U test, the Meeting decided to combine the data to recommend a maximum residue level for stone fruits except cherries. The combined residues were in rank order (n=12): < 0.05, 0.08, 0.08, 0.09, 0.12, 0.13, 0.13, 0.13, 0.15, 0.18, 0.20 and 0.27 mg/kg.

The Meeting estimated a maximum residue level, STMR and HR at 0.4, 0.13 and 0.29 mg/kg, respectively, for stone fruits, except cherries.

Strawberry

The approved use of fenpyroximate on strawberry in the USA consists of up to two foliar spray applications with an interval of 14 days at a maximum rate of 0.117 kg ai/ha and a minimum of 234 L/ha of water. PHI is 1 day.

A total of three supervised trials on strawberry were conducted in the USA in 2008. In a trial in Porterville, California, the water volume was less than the minimum specified in GAP. However, as the Meeting considered that difference in spray volume would have little impact on terminal residues, the Meeting used the residue data from this trial for the estimation of maximum residue level.

A total of five supervised trials on strawberry were also conducted in the USA in 2010.

The residues of fenpyroximate in strawberry from eight independent trials in accordance with US GAP were in rank order: 0.07, 0.08, 0.19, 0.19, 0.24, 0.24, 0.28 and 0.53 mg/kg.

The Meeting estimated a maximum residue level, STMR and HR at 0.8, 0.215 and 0.59 mg/kg, respectively for strawberry.

Avocado

The approved use of fenpyroximate on avocado in the USA consists of up to two foliar spray applications with an interval of 14 days at a maximum rate of 0.117 kg ai/ha and a minimum of 889 L/ha of water (for ground spray). PHI is 1 day.

A total of five supervised trials on avocado were conducted in the USA in 2008 and 2009. The residues of fenpyroximate in avocado from four independent trials in accordance with US GAP were in rank order: < 0.05 (2), 0.06 and 0.10 mg/kg.

The Meeting estimated a maximum residue level, STMR and HR at 0.2, 0.055 and 0.10 mg/kg respectively for avocado.

Cucumber

The current approved use of fenpyroximate on field grown cucumber in the USA consists of up to two foliar spray applications with an interval of 14 days at a maximum rate of 0.117 kg ai/ha and a minimum of 374 L/ha of water (for ground spray). PHI is 1 day.

A total of nine supervised trials on cucumber were conducted outdoor in the USA in 2009. The residues of fenpyroximate in cucumber from nine independent trials in accordance with US GAP were in rank order: < 0.05 (2), 0.06, 0.07, 0.07, 0.08, 0.08, 0.11 and 0.17 mg/kg.

The Meeting estimated a maximum residue level, STMR and HR at 0.3, 0.07 and 0.19 mg/kg respectively for cucumber. The new recommendation replaces that of the 2010 JMPR (maximum residue level of 0.03 mg/kg).

Common beans (pods and/or immature seeds)

The approved use of fenpyroximate on common beans (US GAP for snap beans) in the USA consists of up to two foliar spray applications with an interval of 14 days at a maximum rate of 0.117 kg ai/ha and a minimum of 281 L/ha of water (for ground spray). PHI is 1 day.

A total of eight supervised trials on common beans were conducted in the USA in 2008. The residues of fenpyroximate in common beans (pods and/or immature seeds) from seven independent trials in accordance with US GAP were in rank order: < 0.05, 0.09, 0.09, 0.09, 0.15, 0.18 and 0.19 mg/kg.

The Meeting estimated a maximum residue level, STMR and HR at 0.4, 0.09 and 0.19 mg/kg respectively for common beans (pods and/or immature seeds).

Potato

The approved use of fenpyroximate on potato in the USA consists of up to two foliar spray applications with an interval of 7 days at a maximum rate of 0.117 kg ai/ha and a minimum of 187 L/ha of water (for ground spray). PHI is 7 days.

A total of sixteen supervised trials on potato were conducted in the USA. The residues of fenpyroximate in potato from fourteen independent trials in accordance with US GAP were in rank order: < 0.05 (14) mg/kg. The residues of fenpyroximate from one trial in which the application rate was 5 times the GAP rate were also < 0.05 mg/kg.

The Meeting estimated a maximum residue level, STMR and HR at 0.05 *, 0 and 0 mg/kg respectively for potato.

Mints

The approved use of fenpyroximate on mint in the USA consists of up to two foliar spray applications with an interval of 7 days at a maximum rate of 0.117 kg ai/ha and a minimum of 234 L/ha of water (for ground spray). PHI is 1 day.

A total of six supervised trials on mint were conducted in the USA. As the method used analyses fenpyroximate and M-1 as M-1, no information was available on the concentrations of fenpyroximate alone. In general, the concentrations of M-1 in food commodities were much lower than those of fenpyroximate but the data from supervised residue trials provided to JMPR so far indicate that M-1 can be present up to 30% of fenpyroximate. The Meeting considered that the information was insufficient to estimate a maximum residue level for mints.

Legume animal feeds

Bean forage

Common bean plants with pods were sampled by cutting the whole plant at soil level.

The residues of fenpyroximate in foliage of common bean plant from seven independent trials in accordance with US GAP were in rank order: < 0.05, 0.90, 1.87, 1.92, 2.45, 3.42 and 5.80 mg/kg on a fresh weight basis.

The Meeting estimated a median residue and highest residue at 1.92 and 6.50 mg/kg respectively for bean forage (on a fresh weight basis) for the purpose calculating livestock dietary burdens.

Fate of residues during processing

The Meeting received information on the processing of plum into dried plums; potato into potato flakes, chips and wet peels; and mint into mint oils.

As concentration of fenpyroximate was observed in the processing of plums, there was a need to estimate a maximum residue level for dried plum. Using the processing factor of 1.73 shown below, a maximum residue level for dried plum was estimated to be 0.7 mg/kg.

Commodity	Fenpyroximate mg/kg	Processing factor for Fenpyroximate	STMR-(P)	HR-(P)
Fresh plum	1.84	-	0.11	0.29
Dried plum	3.18	**1.73**	**0.18**	**0.50**

As for processing of potato, no processing factors could be calculated as the residues of fenpyroximate were all below the LOQ of 0.05 mg/kg in fresh potato and processed potato products (flakes, chips and wet peels).

As for processing of mint, since no information was available for the concentration of fenpyroximate alone was available, processing factor of fenpyroximate could not be calculated. The best estimate of processing factor for the sum of fenpyroximate and M-1 in the processing of mint to mint oil was 0.20.

Residues in animal commodities

Estimation of dietary burdens

Among commodities reviewed by the 1999, 2010 and the current JMPR, apple wet pomace (STMR-P, 0.05 mg/kg), dry citrus pulp (STMR-P, 0.64 mg/kg), wet grape pomace (STMR-P, 0.06 mg/kg), wet tomato pomace (STMR-P, 0.03 mg/kg), bean forage (median residue, 1.89 mg/kg; and highest residue, 3.415 mg/kg on a fresh weight basis) and potato wet peel (STMR-P, 0.05 mg/kg) can be fed to beef and dairy cattle. There have been no feed items for poultry.

The maximum and mean dietary burdens were calculated using the highest residue and STMR/median residue of fenpyroximate in the above-mentioned commodities on a basis of the OECD Animal Feeding Table. The summary of calculated dietary burdens of fenpyroximate is shown in the following 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	0.15	0.15	0.18	0.18	11.35	3.50	-	-
Dairy cattle	0.07	0.07	3.90 [a]	1.28 [b]	13.21	4.05	-	-

[a] Suitable for estimating maximum residue levels for meat, fat, edible offal and milk of cattle (see below).

[b] Suitable for estimating STMRs for meat, fat, edible offal and milk of cattle (see below).

Residues in milk and mammalian tissues

The 1999 JMPR reviewed a cattle feeding study conducted at levels equivalent to 1, 3 and 10 ppm in the feed. In the study, fenpyroximate in milk or tissues was measured together with M-1. No information was available on the concentration of fenpyroximate alone. Nonetheless, the 1999 JMPR and 2010 JMPR used the results of this study as the dietary burdens were lower than 1 ppm and the residue concentrations in the tissues and milk were also very low.

In the animal metabolism study, residues of M-1 in tissues and milk were< 0.001 mg/kg and less than fenpyroximate except in the case of liver in which M-1 was present at much higher concentrations. In the animal feeding study, the sum of fenpyroximate and M-1 in kidney was higher

than that in liver, and as such, the residue in kidney would be the basis for a maximum residue level for edible offal. In kidney, the concentration of fenpyroximate was significantly higher than that of M-1. Therefore, the Meeting decided to use the results of animal feeding study recognizing that it would lead to some overestimate of maximum residue level.

The maximum and mean dietary burdens in cattle were 13.21 and 4.05 ppm of dry matter diet respectively. The Meeting noted that the highest maximum dietary burden in cattle, based on animal feed ration in Australia, was higher than the highest feeding level of 10 ppm in feed in the cattle feeding study by about 30%.

As fenpyroximate has not been authorized for use for common beans in Australia, and bean forage is not generally traded internationally, the Meeting decided to use the second highest maximum dietary burden based on the animal feed ration in Europe, where use of fenpyroximate for common bean has been authorized, together with residue levels in tissues and milk at 1, 3 and 10 ppm dose groups. The maximum dietary burden calculated for cattle using the feed ration in Australia without bean forage was 0.21 ppm in dry matter diet.

	Feed level (ppm) for milk residues	Fenpyroximate+M-1 (mg/kg) in milk	Feed level (ppm) for Tissue residues	Fenpyroximate+M-1 (mg/kg) in			
				Muscle	Liver	Kidney	Fat
Maximum residue level beef or dairy cattle							
Feeding study[a]	3	0.0062	3	0.017	< 0.003	< 0.01	0.073
	10	0.013	10	0.049	0.011	0.019	0.159
Dietary burden and highest residue	3.90	0.007	3.90	0.021	0.004	0.011	0.084
STMR beef or dairy cattle							
Feeding study[b]	1	-	1	< 0.01	< 0.003	< 0.003	0.015
	3	0.0062	3	0.015	< 0.003	< 0.003	0.056
Dietary burden and mean residue	1.28	< 0.005	1.28	0.011	< 0.003	< 0.003	0.021

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

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

The Meeting estimated STMR of 0.005, 0.011, 0.003, 0.003 and 0.021 mg/kg for milk, muscle, liver, kidney and fat, respectively; and HR of 0.021, 0.004, 0.011 and 0.084 mg/kg for muscle, liver, kidney and fat, respectively.

The Meeting estimated maximum residue levels of 0.01* mg/kg for milks, 0.02 mg/kg for edible offal (mammalian) and 0.2 mg/kg (fat) for meat (from mammals other than marine mammals) and withdrew the existing CXLs for cattle milk, kidney, liver and meat.

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 both plant and animal commodities (for compliance with the MRL and for estimation of dietary intake): *fenpyroximate*.

The residue is fat soluble.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Dietary Intakes (IEDIs) of fenpyroximate were calculated for the 13 GEMS/Food cluster diets using STMRs and STMRPs estimated by the 1999, 2010 and current Meetings (Annex 3). The ADI is 0–0.01 mg/kg bw and the calculated IEDIs were 1–7% of the maximum ADI. The Meeting concluded that the long-term intake of residues of fenpyroximate resulting from the uses considered by the JMPR is unlikely to present a public health concern.

Short-term intake

The International Estimated Short-Term Intakes (IESTI) of fenpyroximate were calculated for commodities and their processed commodities using STMRs/STMR-Ps estimated by the current Meeting (Annex 4). The ARfD is 0.02 mg/kg and the calculated IESTIs were 0–80% of the ARfD. The Meeting concluded that the short-term intake of residues of fenpyroximate, when used in ways that have been considered by the JMPR, is unlikely to present a public health concern.

5.18 FLUDIOXONIL (211)

RESIDUE AND ANALYTICAL ASPECTS

Fludioxonil was reviewed by the JMPR in 2004, 2006, 2010 and most recently in 2012. The ADI for fludioxonil is 0–0.4 mg/kg bw and an ARfD was considered unnecessary. Residue studies were submitted by the manufacturer for various crops, in addition to a hen feeding study and analytical method for poultry tissues and eggs.

The residue definition for fludioxonil for plant commodities for compliance with the MRL and estimation of dietary intakes is fludioxonil. For animal commodities the residue is the sum of fludioxonil and it benzopyrrole metabolites, determined as 2,2-difluoro-benzo[1,3]dioxole-4-carboxylic acid and expressed as fludioxonil. The residue is considered fat-soluble.

Methods of analysis

Method GRM025.03A, not previously evaluated by the JMPR, determines fludioxonil and its metabolites oxidisable to 2,2-difluorobenzo[1,3]dioxole-4-carboxylic acid (CGA192155) in poultry tissues and eggs. Samples of muscle, liver and kidney are homogenized, extracted by refluxing with ammonium hydroxide:acetonitrile and the aqueous phase is acidified and partitioned with toluene. Fludioxonil and its metabolites are converted to CGA192155 by heating in the presence of potassium permanganate and sodium hydroxide; the oxidation is quenched with sodium metabisulfite, the extracts are filtered, acidified, and partitioned into dichloromethane:ethyl acetate (80:20 v/v). Residues are determined as total fludioxonil by LC-MS/MS. A molecular weight correction factor of 1.23 is applied when calculating procedural recovery values and quantifying residues of CGA192155. The LOQ for fludioxonil and metabolites as CGA192155 in animal tissues was 0.01 mg/kg for fludioxonil (=0.0081 mg/kg for CGA192155). Residues of CGA192155 were shown to be stable at 0–9 °C for at least 7–9 days of storage.

Data evaluated by the 2004 JMPR showed that fludioxonil and CGA192155 are stable for at least 12 months in frozen muscle and for at least 18 months in frozen liver, milk and eggs.

Results from supervised residue trials on crops

Lemon

Five foliar supervised residue trials were conducted in the USA in lemons in 2004–2005 matching US GAP (1 × 0.245 kg ai/ha; 0 day PHI). Residues were 0.12 (3) and 0.16 (2) mg/kg.

Residues on lemons from foliar application are covered by the previous recommendation of maximum residue level of 10 mg/kg (Po) for fludioxonil on citrus

Avocado

Six supervised residue trials were conducted in USA in avocado in 2003 complying with US GAP (4 × 0.245 kg ai/ha; 0 day PHI). Residues were 0.02 (2), 0.04, 0.06, 0.11 and 0.19 mg/kg.

The Meeting estimated a maximum residue level of 0.4 mg/kg and a STMR of 0.05 mg/kg for fludioxonil in avocado.

Pineapple

Fludioxonil is registered in the USA for use in pineapple as a post-harvest high volume drench and/or directed peduncle spray at 1 × 0.06 kg ai/hL. Eight supervised residue trials were conducted in the

USA (Hawaii) in 2009 using a dip plus wax or drench application at 0.06 kg ai/hL followed by a spray directed to the peduncle at 0.87 kg ai/hL. Residues ranged from 4.8 to 6.6 mg/kg (n=8).

As no trials were conducted according to GAP, the Meeting could not estimate a maximum residue level for fludioxonil in pineapple.

Fruiting vegetables, Cucurbits

Eighteen supervised residue trials were conducted in the USA in 2004 complying with the US GAP for cucurbits (4 × 0.245 kg ai/ha; 1 day PHI).

Residues in cantaloupe were (n=6) 0.02, 0.07, 0.09, 0.13, 0.20 and 0.36 mg/kg.

Residues in cucumber were: (n=7) 0.03, 0.04 (2), 0.05, 0.06, 0.09 and 0.13 mg/kg.

Residues in summer squash were: (n=5) 0.01, 0.04 (2) and 0.08 (2) mg/kg

The median residues found in the three individual commodities were within a 5 times range, allowing a recommendation to be made for the cucurbits crop group.

As the residue populations are not statistically different, the Meeting agreed they could be combined as (n=18) 0.01, 0.02, 0.03, 0.04 (4), 0.05, 0.06, 0.07, 0.08 (2), 0.09 (2), 0.13 (2), 0.20 and 0.36 mg/kg.

The Meeting recommended a maximum residue level of 0.5 mg/kg and a STMR of 0.065 mg/kg for fludioxonil in fruiting vegetables, cucurbits.

The Meeting withdrew its previous recommendation of 0.03 mg/kg for Melons, except watermelon, and of 0.3 mg/kg for summer squash.

Tomato

Fludioxonil is registered in the USA for use on tomatoes as a post-harvest in line dip/drench at 1 × 0.06 kg ai/hL or high volume spray at 0.0044kg ai/1000 kg tomatoes (combined with propiconazole in a tank mix).

Residues in tomatoes from six trials at GAP using the dip or drench application were: 0.28, 0.43, 0.48, 0.73, 0.77 and 1.1 mg/kg (if drench and drip was used in one trial, only the highest residue was selected). Three trials conducted at GAP using spray application gave residues of 0.18, 0.66 and 1.8 mg/kg.

Residue data from the two application types were similar and could be combined for residues of 0.18, 0.28, 0.43, 0.48, 0.66, 0.73, 0.77, 1.1 and 1.8 mg/kg (n=9).

The Meeting estimated a maximum residue level of 3 mg/kg and a STMR of 0.66 mg/kg for fludioxonil in tomato (Po).

The Meeting withdrew its previous maximum residue level recommendation for fludioxonil in tomato of 0.5 mg/kg.

Peppers (Bell & Non-Bell)

Currently, there is a MRL of 1 mg/kg for fludioxonil in Peppers, sweet, based European trials matching the GAPs of Italy and Austria.

The GAP of the USA consists of 4 × 0.245 kg ai/ha; 0 day PHI. The current Meeting received 14 supervised field residue trials on bell (sweet pepper) and non-bell peppers (including chili pepper) from the USA and Canada and five greenhouse trials matching US GAP.

Residues in the field trials for sweet peppers were < 0.02 (2), 0.08, 0.09, 0.12, 0.13 (2), 0.16 (2) and 0.28 (2) mg/kg. Residues for non-bell peppers were 0.06, 0.07, 0.12 and 0.14 mg.

Residues found in the greenhouse trials were 0.10, 0.20, 0.21 and 0.22 mg/kg for sweet pepper and 0.20 mg/kg for non-bell peppers.

These data indicate that the current MRL of 1 mg/kg would accommodate the expected fludioxonil residues resulting in non-bell peppers when applied according to US GAP. The Meeting agreed to extend the previous recommendation of 1 mg/kg to peppers.

Based on the data on non-bell peppers (0.06, 0.07, 0.12, 0.14 and 0.20 mg) and a factor of 10, the Meeting estimates a maximum residue level of 4 mg/kg and a STMR of 1.2 mg/kg for dried chili peppers.

Leafy vegetables

Currently, there is a MRL of 10 mg/kg in Head lettuce, based on indoor trials matching the Italian GAP, and a MRL of 10 mg/kg in Mustard greens based on trials matching the GAP of the USA.

In the USA, GAP in leafy greens is 4 × 0.245 kg ai/ha; 0 day PHI. Twenty five trials were conducted in USA in 2001 in lettuce and spinach according to GAP were submitted to this Meeting. Additionally, trials evaluated by the 2004 JMPR according to GAP were also considered. Six trials conducted in USA in 2004 in radish tops were not at GAP.

Residue in head lettuce (with wrapper leaves) were (n=8) 0.42, 1.2, 1.4, 2.0 (2), 2.2, 2.8 and 4.6, mg/kg.

Indoor trials conducted in Europe in head lettuce at Italian GAP evaluated by the 2004 JMPR gave residues (n=11) ranging from 0.72 to 6 mg/kg, median of 2.7 mg/kg.

Residues in leafy lettuce were (n= 6) 4.8, 6.5, 6.7, 10, 16 and 22 mg/kg.

Residues in spinach were (n= 11) 1.9, 3.4, 4.6, 4.9 (2), 5.8, 7.5, 8.3, 9.8,12 and 16 mg/kg.

Residues in watercress from trials evaluated in 2004 (USA GAP) were 4.2 and 4.5 mg/kg.

Residues in mustard greens from trials evaluated in 2004 (USA GAP) ranged from 0.06 to 7.1 mg/kg, median of 1.2 mg/kg (n=9).

The median residues found in the individual commodities from trials conducted matching USA GAP were outside the 5 times range, not allowing a recommendation for leafy vegetable group.

The Meeting therefore, estimated a maximum residue level of 40 mg/kg and a STMR of 8.3 mg/kg for fludioxonil in leafy lettuce

The Meeting estimated a maximum residue level of 30 mg/kg and a STMR of 5.8 mg/kg for fludioxonil in spinach.

The Meeting agreed that there were insufficient trials to estimate a maximum residue level for watercress.

The Meeting confirmed its previous recommendation of 10 mg/kg for fludioxonil in head lettuce and mustard greens.

Potato

Currently, there is a MRL of 0.02 mg/kg for potato, based on the Australian GAP as a seed treatment.

Fludioxonil is registered in the USA for use in potatoes as a post-harvest in line spray at 0.0045 kg ai/1000 kg tubers. Five trials were conducted in the USA and Canada in 2009/2010 matching the US GAP, giving residues of 0.66, 1.1, 1.5, 1.7 and 2.9 mg/kg.

The Meeting estimated a maximum residue level of 5 mg/kg and a STMR of 1.5 mg/kg for fludioxonil in potato (Po).

The Meeting withdrew its previous recommendation for fludioxonil in potatoes of 0.02 mg/kg.

Radish

Six supervised residue trials were conducted in the USA in 2004 matching US GAP (2 × 0.245 kg ai/ha; 7 days PHI). Residues in the radish tops were: < 0.02 (2), 0.04, 0.08, and 0.10 (2) mg/kg.

The Meeting estimated a maximum residue level of .3 mg/kg and a STMR of 0.06 mg/kg for fludioxonil in radish.

Legume vegetables

Currently, there is a MRL of 0.3 mg/kg for beans, except broad beans and soya beans and for peas (pods and succulent=immature seeds), based on the GAP of France.

The GAP in USA for beans (dried and succulent, except cow beans) is 4 × 0.245 kg ai/ha; 7 days PHI). In eight trials conducted in snap beans (common beans) from the USA, matching US GAP, residues in snap beans pods were: < 0.02, 0.03 (2), 0.04 (2), 0.05 (2) and 0.38 mg/kg.

Based on the US data on snap beans, the Meeting estimated a maximum residue level of 0.6 mg/kg and a STMR of 0.04 mg/kg for fludioxonil in Beans, except broad bean and soya bean. The Meeting withdrew its previous recommendation of 0.3 mg/kg for beans, except broad bean and soya bean.

In seven trials conducted in lima beans in the USA according to US GAP, residues in succulent shelled beans were: < 0.02 (4), 0.03, 0.04 and 0.21 mg/kg.

The Meeting estimated a maximum residue level of 0.4 mg/kg and a STMR of 0.02 mg/kg for fludioxonil in Beans, Shelled. The Meeting agreed to withdraw its previous recommendation of 0.03 mg/kg for Beans, Shelled.

Fludioxonil is registered in USA to be used in peas as a seed treatment at 0.005 kg ai/100 kg seed. Five trials conducted at US GAP gave residues in mature fresh peas with pods of < 0.01 (5) mg/kg. Fifteen trials conducted at higher or lower GAP rate gave the same results.

The Meeting confirms its previous recommendation of 0.3 mg/kg for peas (pods and succulent=immature seeds).

Beans (dry)

Currently, there is a Codex MRL of 0.07 mg/kg for beans (dry) based on Spanish GAP.

Seven trials were conducted in USA in 2001 according to US GAP (4 × 0.245 kg ai/ha; 7 days PHI) gave residues in dry beans of 0.02 (2), 0.04 (2), 0.06, 0.12 and 0.23 mg/kg. In two trials harvested earlier or with 6 applications gave residues in the same range.

The Meeting estimated a maximum residue level of 0.5 mg/kg and a STMR of 0.04 mg/kg for fludioxonil in beans (dry) The Meeting withdrew its previous recommendation of 0.07 mg/kg for Baens (dry).

Herbs

Currently, there is a Codex MRL of 10 mg/kg for fludioxonil in fresh basil and chives and of 50 mg/kg for dried basil and chives.

The Meeting received four supervised residue trials in parsley from the USA matching US GAP in herbs (4 × 0.245 kg ai/ha; 7 days PHI). Residues in fresh parsley were 1.6, 2.3, 3.2 and 3.9 mg/kg and in dry parsley 8.9, 15, 18 and 23 mg/kg.

Data submitted to the 2004 JMPR matching US GAP showed residue of 1.8 and 3.9 mg/kg on fresh chives and 1.9 and 3.0 mg/kg on fresh basil, 14 and 31 mg/kg on dry chives and 15 and 24 mg/kg on dry basil.

The residues found in the individual fresh or dried commodities from trials conducted according to USA GAP are in the same range, and they are combined for allowing recommendations for herbs, fresh and dried.

The residues of fludioxonil in fresh parsley, basil and chives were considered similar and could be combined giving residues of 1.6, 1.8, 1.9, 2.3, 3.0, 3.2 and 3.9 (2) mg/kg.

The Meeting recommended a maximum residue level of 9 mg/kg and a STMR of 2.65 mg/kg for fludioxonil in herbs.

The residue data sets of fludioxonil from dried parsley, basil and chives were also considered similar and could be combined giving residues of 8.9, 14, 15 (2), 18, 22, 24 and 31 mg/kg.

The Meeting recommended a maximum residue level of 60 mg/kg and a STMR of 16.5 mg/kg for fludioxonil in dried herbs, except dried hops.

The Meeting agreed to withdraw its previous recommendations for chives and basil of 10 mg/kg and for dried chives and basil of 50 mg/kg.

Ginseng

Four supervised residue trials were conducted in the USA and Canada from 2005 to 2006 according to GAP (4 × 0.245 kg ai/ha; 14 days PHI). Residues were 0.16, 0.18, 0.40 and 1.7 mg/kg.

The Meeting recommends a maximum residue level of 4 mg/kg and a STMR of 0.29 mg/kg for fludioxonil in ginseng.

Residues in processed commodities

Pineapple fruit (5.62 mg/kg fludioxonil) processed to juice contained a residue of 5.40 mg/kg, with a processing factor (PF) of 0.96. However, as no maximum residue level recommendation on the raw commodity was made, the Meeting could not make an assessment of residues for pineapple juice.

Tomatoes containing 0.14 mg/kg of fludioxonil were processed to paste (0.15 mg/kg), giving a PF of 1.1. Processing factors estimated by the 2004 JMPR were 1.1, 1.4, 1.5 and 1.6. The best estimated processing factor for tomato paste is 1.4. Based on a STMR of 0.66 mg/kg for tomato, the Meeting estimated a of STMR-P of 0.924 mg/kg for tomato paste

Tomatoes was also processed to puree (0.05 mg/kg) giving a PF of 0.36. The Meeting estimated a STMR-P of 0.236 mg/kg for tomato puree.

The best estimate PF for tomato juice (2004 JMPR) was 0.22. The Meeting estimated a STMR-P of 0.145 mg/kg for fludioxonil.

Potato tubers containing 0.472 mg/kg fludioxonil were processed into chips. Residues were 0.797 mg/kg in wet peel (PF=1.69), 0.01 mg/kg in flakes (PF < 0.02) and 0.018 mg/kg in chips (PF of 0.04).

The Meeting estimated a STMR-P of 0.06 mg/kg for fludioxonil in potato chips (STMR in potato is 1.5 mg/kg).

Residues in animal commodities

Farm animal dietary burden

Dietary burden calculations for beef cattle, dairy cattle, broilers and laying poultry are provided in Appendix IX of the FAO manual. The calculations were made according to the animal diets from US-Canada, EU, Australia and Japan in the Table (Appendix IX of the FAO manual). The STMR, STMR-Ps were estimated at the present Meeting. Dietary burden calculations are provided in Annex 5.

Livestock dietary burden for fludioxonil, ppm of dry mater diet

	US-Canada		EU		Australia		Japan	
Commodity	Max	Mean	Max	Mean	Max	Mean	Max	Mean
Beef cattle	0.029	0.018	0.56 [a]	0.27 [c]	0.24	0.13	0.017	0.017
Dairy cattle	0.39	0.18	0.57 [a b]	0.27 [d]	0.24	0.11	0.02	0.018
Poultry - broiler	0.017	0.017	0.38 [e]	0.19 [f]	0.035	0.035	0.002	0.002
Poultry - layer	0.017	0.017	0.38	0.19	0.035	0.035	0.002	0.002

[a] Highest maximum beef or dairy cattle dietary burden suitable for maximum residue level estimated for mammalian tissues

[b] Highest maximum dairy cattle dietary burden suitable for maximum residue level estimated for mammalian milk

[c] Highest mean beef or dairy cattle dietary burden suitable for STMR estimated for mammalian tissues.

[d] Highest mean dairy cattle dietary burden suitable for STMR estimated for milk.

[e] Highest maximum poultry dietary burden suitable for maximum residue level estimated for poultry tissues

[f] Highest mean poultry dietary burden suitable for maximum residue level estimated for poultry tissues

Animal feeding study

A feeding study on poultry submitted to the current Meeting was conducted with fludioxonil at 1.54, 4.64 and 15.4 mg/kg feed on a 28-day daily dose regime via gelatine capsules.

Residues in eggs from the 15.4 ppm dose level hens were < 0.01 mg/kg 3 days after the initiation of dosing, increased to 0.024 mg/kg fludioxonil eq. (max. of 0.036 mg/kg), and reached 0.04 mg/kg at day 28. The Mean level during the study was 0.025 mg/kg and a maximum of 0.052 mg/kg fludioxonil eq. Eggs from the 4.64 ppm group had a mean and a maximum residue of 0.01 and 0.013 mg/kg fludioxonil eq., respectively. No residues were found in eggs from the 1.54 ppm dose group.

Only liver samples from the 1.54 ppm group were analysed, giving a mean of 0.05 mg/kg eq. (0.03 to 0.08 mg/kg).

In the 4.64 ppm group, residues in skin/fat (including abdominal fat) ranged from < 0.01 to 0.01 mg/kg eq. and residues in liver ranged from 0.06 to 0.21 mg/kg eq. (mean of 0.12 mg/kg).

In the 15.4 mg/kg ppm group, residues in muscle were < 0.01, from 0.01 to 0.04 mg/kg eq. in skin and fat (mean of 0.03 mg/kg) and 0.28 mg/kg eq. in liver.

A depuration study conducted at 15.4 ppm dosing level demonstrated that residues in the eggs ranged from 0.02 to 0.04 mg/kg eq. up to 3 days after termination of the study and were not detected further. Fludioxonil was not detected in any of the muscle, fat or liver samples, suggesting rapid elimination of fludioxonil following completion of dosing.

Animal commodity maximum residue levels

A feeding study in cattle evaluated by the 2004 JMPR showed that residues of fludioxonil and its metabolites found in the highest feeding level dose group (5.5 ppm) were 0.014–0.017 mg/kg in liver, 0.022–0.025 mg/kg in kidney (LOQ of 0.05 mg/kg) and none was detected in fat (< 0.05 mg/kg) or muscle (< 0.01 mg/kg). The highest and median residues in milk were 0.019 and 0.01 mg/kg, respectively (LOQ of 0.01 mg/kg). The feeding level in this study is about 10 times higher than the highest dietary burden estimated for cattle at this Meeting (0.57 ppm).

The Meeting confirmed its maximum residue level recommendation of 0.05* mg/kg for edible offal (mammalian), and 0.01* mg/kg for meat (from mammals other than marine mammals) and milks.

Based on an estimated dietary burden for poultry of 0.07 ppm and a metabolism study, the 2004 JMPR had estimated that residues of fludioxonil and metabolites were unlikely to be found in poultry commodities and recommended maximum residue levels of 0.05* mg/kg for eggs, 0.01* mg/kg for poultry meat and 0.05* mg/kg for poultry edible offal and STMRs of 0 mg/kg for eggs, poultry meat and poultry edible offal.

The highest calculated poultry dietary burden calculated by the current Meeting was 0.38 ppm. As the feeding study showed that no residues are expected at a dietary burden of 1.54 ppm (lowest dose tested), the Meeting confirmed that no residues are expected in poultry commodities.

The Meeting recommended a maximum residue level of 0.01* mg/kg and a STMR of 0 for fludioxonil in poultry edible offal and eggs.

The Meeting confirmed its previous recommendation of 0.01* mg/kg for poultry meat.

RECOMMENDATION

The residue definition: for plant commodities for compliance with the MRL and estimation of dietary intakes: *fludioxonil*.

For animal commodities the residue is the sum of fludioxonil and it benzopyrrole metabolites, determined as 2,2-difluoro-benzo[1,3]dioxole-4-carboxylic acid and expressed as fludioxonil.

The residue is fat-soluble.

DIETARY RISK ASSESSMENT

Long-term intake

The IEDI of fludioxonil based on the STMRs estimated by this and previous Meetings for the 13 GEMS/Food regional diets were 2–6% of the maximum ADI of 0–0.4 mg/kg bw (see Annex 3 of the Report). The Meeting concluded that the long-term dietary intake of residues of fludioxonil is unlikely to present a public health concern.

Short-term intake

The 2004 JMPR decided that an ARfD for fludioxonil is unnecessary. The Meeting therefore concluded that the short-term dietary intake of fludioxonil residues is unlikely to present a public health concern.

5.19 FLUENSULFONE (265)

TOXICOLOGY

Fluensulfone is the ISO-approved name for 5-chloro-2-(3,4,4-trifluorobut-3-en-1-ylsulfonyl)-1,3-thiazole (IUPAC) (CAS No. 318290-98-1). Fluensulfone is a nematicide for use on a range of vegetable crops. Target pests are root knot, root lesion and cyst nematodes. Fluensulfone's mode of pesticidal activity has not been determined.

Fluensulfone 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 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, and the butene-labelled material was also found at high concentrations in the lung. Thiazole-labelled material partitioned readily to red blood cells. Two hours after administration at both high and low doses, the thyroid had a high concentration of thiazole-labelled material relative to whole blood, although levels in thyroid were comparable to the whole blood concentrations by the subsequent time point (51 hours). The labelled material was rapidly excreted via urine (> 70%), with faecal excretion accounting for no more than 5–13%. A small proportion (< 5% of the administered dose at 5 mg/kg bw) was exhaled as carbon dioxide. 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 and butene sulfinic acid, the major urinary metabolites. The excretion pattern, tissue distribution of radioactivity and metabolite profile were essentially unaltered when the administration of thiazole-labelled substance was preceded by 14 days of administration of the unlabelled material.

Fluensulfone has a molecular weight of 272 Da and contains three fluorine atoms. If all the available fluorine is released, this means a fluensulfone dose of 100 mg/kg bw could provide about 20 mg of free fluoride ion per kilogram body weight. Approximately 50% of the administered dose is excreted as fluoride-containing compounds.

Toxicological data

Fluensulfone was of moderate acute toxicity in rats via the oral route (LD_{50} = 671 mg/kg bw), but caused no mortality at limit doses after dermal (LD_{50} > 2000 mg/kg bw) or inhalation (LC_{50} > 5.1 mg/L air) exposure. Fluensulfone was slightly irritating to the skin of rabbits, but not irritating to the eyes of rabbits. It was a skin sensitizer in guinea-pigs.

In all species, the liver was a target organ, with increases in weight and hepatocellular hypertrophy. Investigations on liver enzyme activities in all species revealed that fluensulfone administration does not result in significant induction of cytochrome P450 subfamilies, but that the (conjugating) phase II enzymes were induced to a limited extent. Effects on kidney, observed in studies in rats conducted at high doses, were most prominent in males, but some renal effects were observed in female rats treated at high doses and in dogs treated for 1 year. Reduced body weight gain, often associated with reductions in feed consumption, was a consistent, sensitive end-point. Fluorosis leading to discolouration of the teeth was reported only in the 90-day rat study at 2000 ppm (equal to 139 mg/kg bw per day), but there were no other overt signs of fluorosis. Determinations of

fluoride content of bones and teeth showed significantly increased levels of total fluoride, even at low doses of fluensulfone. Examinations of tooth colour were performed and bones were examined histopathologically, but no specific investigations of bone density, thickness or bending resistance were performed. The Meeting concluded that the dietary intake of fluoride associated with the use of fluensulfone as a nematicide should be included in an overall assessment of fluoride intake from all sources. Upper levels for fluoride intake have been proposed by a number of organizations.

In mice, rats and dogs, decreases in alanine aminotransferase (ALT) activity in both plasma and liver were recorded. Mode of action investigations were performed in dogs, the most susceptible species for this effect. It was found that direct binding of fluensulfone itself did not cause the decrease in ALT activity and that there was no significant interaction with the cofactor pyridoxal 5′-phosphate. Messenger ribonucleic acid (mRNA) levels appeared slightly induced, whereas protein expression appeared stable. No effect on the general health of the dogs accompanied the reduction of hepatic ALT activity at low doses (50 ppm, equal to 1.5 mg/kg bw per day), even when the reduction was greater than 40%. The reduced ALT activity was reversible, and alternative metabolic pathways are available. The Meeting concluded that a reduction in hepatic ALT activity per se is not adverse.

In a 28-day study of toxicity in mice, dietary concentrations were 0, 100, 500 and 2000 ppm (equal to 0, 30, 101 and 375 mg/kg bw per day for males and 0, 41, 155 and 353 mg/kg bw per day for females, respectively). The NOAEL was 500 ppm (equal to 101 mg/kg bw per day), based on body weight loss, changes in erythrocyte parameters (e.g. increased reticulocytes) and liver toxicity (altered cytoplasmic structure, single-cell necrosis, bile duct hyperplasia) at 2000 ppm (equal to 353 mg/kg bw per day).

In a 90-day study of toxicity in mice, dietary concentrations were 0, 60, 300 and 1500 ppm (equal to 0, 11, 51 and 229 mg/kg bw per day for males and 0, 18, 68 and 252 mg/kg bw per day for females, respectively). The NOAEL was 60 ppm (equal to 11 mg/kg bw per day), on the basis of haematological findings in males and hepatocyte hypertrophy observed at 300 ppm (equal to 51 mg/kg bw per day).

In a 28-day study of toxicity in rats, dietary concentrations were 0, 125, 500 and 2000 ppm (equal to 0, 10, 43 and 152 mg/kg bw per day for males and 0, 12, 37 and 166 mg/kg bw per day for females, respectively). The NOAEL was 125 ppm (equal to 10 mg/kg bw per day), based on reductions in body weight gain and kidney lesions in male rats at 500 ppm (equal to 43 mg/kg bw per day).

In a 90-day study of toxicity in rats, dietary concentrations were 0, 60, 120, 500 and 2000 ppm (equal to 0, 4, 8, 35 and 139 mg/kg bw per day for males and 0, 5, 12, 53 and 149 mg/kg bw per day for females, respectively). The NOAEL was 120 ppm (equal to 8 mg/kg bw per day), on the basis of forestomach hyperkeratosis, increased triglycerides and increased water consumption in females and decreased body weight/body weight gains in males at 500 ppm (equal to 35 mg/kg bw per day).

In a 28-day dietary study in which dogs were administered fluensulfone at 0, 50, 200 or 900 ppm (equal to 0, 1.9, 7 or 31 mg/kg bw per day for males and 0, 2, 8 or 30 mg/kg bw per day for females, respectively), the NOAEL was 200 ppm (equal to 7 mg/kg bw per day), based on reductions in feed consumption and body weight gain and increases in liver and thyroid weights at 900 ppm (equal to 30 mg/kg bw per day). In a 90-day study in which dogs received fluensulfone in the diet at 0, 5, 50 or 500 ppm (equal to 0, 0.2, 1.7 and 17 mg/kg bw per day for males and 0, 0.2, 1.8 and 18 mg/kg bw per day for females, respectively), the NOAEL was 50 ppm (equal to 1.7 mg/kg bw per day), based on increases in reticulocytes and liver weights at 500 ppm (equal to 17 mg/kg bw per day). In a 1-year study in dogs in which fluensulfone was administered in the diet at 0, 5, 50, 100 or 500 ppm (equal to 0, 0.1, 1.5, 3 and 16 mg/kg bw per day), the NOAEL was 100 ppm (equal to 3 mg/kg bw per day), on the basis of changes in erythrocyte parameters, liver weight increases and increased pigment deposition in the liver at 500 ppm (equal to 16 mg/kg bw per day). The overall NOAEL for the 90-day and 1-year studies was 100 ppm (equal to 3 mg/kg bw per day), and the overall LOAEL was 500 ppm (equal to 16 mg/kg bw per day).

In an 18-month toxicity and carcinogenicity study in mice, dietary concentrations were 0, 30, 200 and 1200 ppm (equal to 0, 4.2, 28 and 152 mg/kg bw per day for males and 0, 6.4, 39 and 188 mg/kg bw per day for females, respectively). The NOAEL was 30 ppm (equal to 4.2 mg/kg bw per day), based on decreased body weights and bronchiolization at 200 ppm (equal to 28 mg/kg bw per day). The NOAEL for tumours was 30 ppm (equal to 6.4 mg/kg bw per day), based on increased incidences of alveolar/bronchiolar adenomas and carcinomas in females receiving 200 ppm (equal to 39 mg/kg bw per day).

In a 2-year chronic toxicity and carcinogenicity study in rats, dietary concentrations were 0, 30, 200 and 1200 ppm (equal to 0, 1.4, 9.6 and 58 mg/kg bw per day for males and 0, 1.7, 12 and 69 mg/kg bw per day for females, respectively). Fluensulfone showed no carcinogenic potential in rats. The NOAEL for non-neoplastic effects was 30 ppm (equal to 1.4 mg/kg bw per day), on the basis of chronic interstitial inflammation in the lungs of females, oesophageal hyperkeratosis and decreased body weight gain in males at 200 ppm (equal to 9.6 mg/kg bw per day). Dose-related increases in plasma sodium levels were seen in both sexes from weeks 13 to 52. The sodium levels in the fluensulfone-treated groups were within the control ranges in the study, and this finding was not consistent with the results of the 90-day rat study, in which plasma sodium levels were unaltered by treatment at week 13. The Meeting concluded that the increases in plasma sodium levels were not an adverse effect of fluensulfone administration.

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

An adequate battery of in vitro and in vivo mutagenicity studies has been performed with fluensulfone. Weak positive results were seen with one strain of *Salmonella typhimurium* in one Ames test but not in two other Ames tests using the same strains. An equivocal finding was noted at high concentrations in an assay for chromosome damage. No evidence of genotoxicity was seen in an adequately performed bone marrow micronucleus assay in mice.

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

Mechanistic studies were carried out to determine the relevance for humans of the lung tumour findings in mice. Species-specific lung tumours in the mouse have been induced by a number of chemicals. The underlying cause is attributed to a high metabolic activity of the mouse lung, due to a relatively high abundance of Clara cells in the mouse compared with humans and the mouse-specific cytochrome P450 (Cyp) enzyme 2f2 in the Clara cells. The compounds are activated to reactive intermediates, leading to local cytotoxicity that promotes sustained cell proliferation, leading finally to tumour formation. Rats have lower metabolic activity in the lungs compared with mice (below the threshold needed to cause lung tumours upon lifetime exposure), and this metabolic activity in humans is reported to be significantly lower than in rats. A limited package of data specific for fluensulfone showed it to be extensively metabolized by male and female mouse lung microsomes, whereas essentially no metabolic activity was seen in human lung microsomes. Mouse-specific Cyp2f2 was shown to be a significant contributor to fluensulfone's metabolism. Administration of fluensulfone to mice led to an early increase in bronchiolar epithelial cell proliferation; however, no equivalent data are available for human or rat lung preparations. Bronchiolization indicative of a chronic inflammatory response was noted in male as well as female mice. These data do not address the fact that no increases in lung tumours were seen in male mice.

Considering the submitted mode of action, the Meeting concluded that the work undertaken is not extensive enough to conclusively identify the mode of action or to entirely exclude human relevance. However, the mode of action for mouse lung tumours in female mice administered fluensulfone is likely to be non-genotoxic and threshold dependent.

The Meeting concluded that fluensulfone is unlikely to be genotoxic in vivo and that there is a clear threshold for lung tumours in female mice. Therefore, fluensulfone 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, 30, 250 and 1800 ppm (equal to mean intakes of 0, 2.0, 16 and 122 mg/kg bw per day for males and 0, 2.8, 23 and 169 mg/kg bw per day for females, respectively). The NOAEL for reproductive effects was 1800 ppm (equal to 122 mg/kg bw per day), the highest dose tested. The parental NOAEL was 250 ppm (equal to 16 mg/kg bw per day), based on effects on body weight throughout the study in males and increased liver and kidney weights at 1800 ppm (equal to 122 mg/kg bw per day). The NOAEL for effects on offspring was 250 ppm (equal to 16 mg/kg bw per day), based on reduced pup weight at 1800 ppm (equal to 122 mg/kg bw per day).

In a study of developmental toxicity in rats dosed at 0, 7.7, 49 or 292 mg/kg bw per day, there was no evidence of teratogenicity. The Meeting noted a decrease in the incidence of some variations of the skull bones but considered that this was not toxicologically relevant. The NOAEL for maternal toxicity was 49 mg/kg bw per day, on the basis of decreased body weight gain and clinical signs at 292 mg/kg bw per day. The NOAEL for embyo and fetal toxicity was 49 mg/kg bw per day, based on four non-viable fetuses at 292 mg/kg bw per day.

In a study of developmental toxicity in rabbits dosed at 0, 2.5, 10 or 40 mg/kg bw per day, the NOAEL for maternal toxicity was 10 mg/kg bw per day, based on body weight loss, and the NOAEL for embryo and fetal toxicity was 40 mg/kg bw per day, the highest dose tested.

The Meeting concluded that fluensulfone is not teratogenic in rats or rabbits.

The acute neurotoxicity of fluensulfone was investigated in rats at dose levels of 0, 100, 400 and 1200 mg/kg bw. Clinical signs and reduced activity in a functional observational battery on day 1, but not subsequently, were seen at all dose levels, with females being more sensitive than males. Benchmark dose modelling gave reliable $BMDL_{SD}$ values ($BMDL_{SD}$ is the 95% lower confidence limit of the dose corresponding to a change equivalent to one standard deviation in the response for unexposed animals) in the range 19–33 mg/kg bw for females, and the Meeting identified 25 mg/kg bw as a reference point or point of departure (POD). There were no indications of neuropathy.

In a subchronic (90-day) neurotoxicity study in rats, dietary concentrations were 0, 100, 500 and 2500 ppm (equal to 0, 6, 31 and 153 mg/kg bw per day for males and 0, 7, 34 and 162 mg/kg bw per day for females, respectively). The NOAEL for neurotoxicity was 2500 ppm (equal to 153 mg/kg bw per day), the highest dose tested, with a NOAEL for general toxicity of 500 ppm (equal to 31 mg/kg bw per day), based on reduced body weight gain in males at 2500 ppm (equal to 153 mg/kg bw per day).

In a 28-day immunotoxicity study in female mice, dietary concentrations were 0, 100, 500 and 2500/1500 ppm (equal to 0, 17, 86 and 204 mg/kg bw per day). There were no significant effects on anti–sheep red blood cell IgM titres at any dose level. The NOAEL for general toxicity was 500 ppm (equal to 86 mg/kg bw per day), based on deaths and clinical signs at 2500/1500 ppm (equal to 204 mg/kg bw per day). Fluensulfone did not affect splenic or bone marrow cell counts or IgA, IgG or IgM titres in rats exposed at concentrations up to 2000 ppm (equal to 152 mg/kg bw per day) in the diet in the 28-day study of toxicity in rats.

Toxicological data on metabolites and/or degradates

Acute oral toxicity and genotoxicity studies were performed on the following metabolites: thiazole sulfonic acid (M-3625), methyl sulfone derivative (M-3626) and butene sulfonic acid (M-3627). Thiazole sulfonic acid and butene sulfonic acid were of low acute oral toxicity (LD_{50} > 2000 mg/kg bw) and were not genotoxic in vitro or in vivo. The methyl sulfone derivative had an acute oral LD_{50} of ≥ 300 mg/kg bw. It was weakly positive in the Ames test for test strain *S. typhimurium* TA100 at the highest concentration tested (5000 µg/plate) in the absence of metabolic activation and equivocal in a reverse mutation assay in Chinese hamster cells. Two in vivo genotoxicity studies, for bone marrow micronuclei and liver UDS, were negative.

Human data

No adverse effects have been reported in a group of over 20 individuals involved in the manufacturing, handling and testing of fluensulfone.

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

Toxicological evaluation

The Meeting established an ADI for fluensulfone of 0–0.01 mg/kg bw on the basis of the NOAEL of 1.4 mg/kg bw per day for chronic interstitial inflammation in the lungs, oesophageal hyperkeratosis and decreased body weight from the rat chronic toxicity and carcinogenicity study. A safety factor of 100 was applied. This provides a margin of exposure of 3900 between the upper bound of the ADI and the LOAEL for tumours in female mice.

The Meeting established an ARfD for fluensulfone of 0.3 mg/kg bw, on the basis of the POD of 25 mg/kg bw for changes in the functional observational battery in the acute neurotoxicity study in rats. A safety factor of 100 was applied.

A toxicological monograph was prepared.

Levels relevant to risk assessment of fluensulfone

Species	Study	Effect	NOAEL	LOAEL
Mouse	Ninety-day study of toxicity[a]	Toxicity	60 ppm, equal to 11 mg/kg bw per day	300 ppm, equal to 51 mg/kg bw per day
	Eighteen-month study of toxicity and carcinogenicity[a]	Toxicity	30 ppm, equal to 4.2 mg/kg bw per day (m)	200 ppm, equal to 28 mg/kg bw per day (m)
		Carcinogenicity	30 ppm, equal to 6.4 mg/kg bw per day (f)	200 ppm, equal to 39 mg/kg bw per day (f)
Rat	Acute neurotoxicity study[b]	Neurotoxicity	25 mg/kg bw[c]	100 mg/kg bw[d]
	Ninety-day study of toxicity[a]	Toxicity	120 ppm, equal to 8 mg/kg bw per day	500 ppm, equal to 35 mg/kg bw per day
	Two-year study of toxicity and carcinogenicity[a]	Toxicity	30 ppm, equal to 1.4 mg/kg bw per day	200 ppm, equal to 9.6 mg/kg bw per day
		Carcinogenicity	1200 ppm, equal to 69 mg/kg bw per day[e]	—
	Multigeneration reproductive toxicity study[a]	Reproductive toxicity	1800 ppm, equal to 122 mg/kg bw per day[e]	—
		Parental toxicity	250 ppm, equal to 16 mg/kg bw per day	1800 ppm, equal to 122 mg/kg bw per day
		Offspring toxicity	250 ppm, equal to 16 mg/kg bw per day	1800 ppm, equal to 122 mg/kg bw per day
	Developmental toxicity study[b]	Maternal toxicity	49 mg/kg bw per day	292 mg/kg bw per day
		Embryo and fetal toxicity	49 mg/kg bw per day	292 mg/kg bw per day

Species	Study	Effect	NOAEL	LOAEL
Rabbit	Developmental toxicity study[b]	Maternal toxicity	10 mg/kg bw per day	40 mg/kg bw per day
		Embryo and fetal toxicity	40 mg/kg bw per day[e]	—
Dog	Ninety-day and 1-year studies of toxicity[a,f]	Toxicity	100 ppm, equal to 3 mg/kg bw per day	500 ppm, equal to 16 mg/kg bw per day

f, female; m, male

[a] Dietary administration.

[b] Gavage administration.

[c] POD based on $BMDL_{SD}$ values of 19–33 mg/kg bw in females.

[d] Lowest dose tested.

[e] Highest dose tested.

[f] Two or more studies combined.

Estimate of acceptable daily intake

0–0.01 mg/kg bw

Estimate of acute reference dose

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 fluensulfone

Absorption, distribution, excretion and metabolism in mammals	
Rate and extent of oral absorption	Rapid, plasma T_{max} is 4 h; > 80%
Dermal absorption	No data
Distribution	Widely distributed; highest concentrations in liver, kidney, red blood cells and thyroid
Potential for accumulation	Potential accumulation in erythrocytes
Rate and extent of excretion	Largely cleared within 48 h at low dose; primarily via urine (> 70%) and, to a lesser extent, faeces (5–13%)
Metabolism in animals	Extensive; mainly by cleavage to yield the thiazole glutathione conjugate and butene sulfinic acid, which are further metabolized
Toxicologically significant compounds in animals, plants and the environment	Fluensulfone; fluoride ion
Acute toxicity	
Rat, LD_{50}, oral	671 mg/kg bw
Rat, LD_{50}, dermal	> 2000 mg/kg bw

Rat, LC_{50}, inhalation	> 5.1 mg/L
Rabbit, dermal irritation	Slightly irritating
Rabbit, ocular irritation	Not irritating
Guinea-pig, dermal sensitization	Sensitizing (maximization test)
Short-term studies of toxicity	
Target/critical effect	Body weight gain, haematology; liver and kidney weights
Lowest relevant oral NOAEL	3 mg/kg bw per day (dog)
Lowest relevant dermal NOAEL	No data
Lowest relevant inhalation NOAEC	No data
Long-term studies of toxicity and carcinogenicity	
Target/critical effect	Lung, oesophagus, body weight
Lowest relevant NOAEL	1.4 mg/kg bw per day (rat)
Carcinogenicity	Unlikely to be carcinogenic to humans from the diet
Genotoxicity	
	Not genotoxic in vivo
Reproductive toxicity	
Target/critical effect	Lower pup weight at parentally toxic dose
Lowest relevant parental NOAEL	16 mg/kg bw per day
Lowest relevant offspring NOAEL	16 mg/kg bw per day
Lowest relevant reproductive NOAEL	122 mg/kg bw per day, the highest dose tested
Developmental toxicity	
Target/critical effect	Pup viability at maternally toxic dose (rat)
Lowest relevant maternal NOAEL	10 mg/kg bw per day (rabbit)
Lowest relevant embryo/fetal NOAEL	40 mg/kg bw per day, the highest dose tested (rabbit); 49 mg/kg bw per day (rat)
Neurotoxicity	
Acute neurotoxicity NOAEL	POD 25 mg/kg bw (based on $BMDL_{SD}$) (rat)
Subchronic neurotoxicity NOAEL	153 mg/kg bw per day, the highest dose tested (rat)
Other toxicological studies	
Immunotoxicity	Not immunotoxic (mouse and rat)
Studies on metabolites	Thiazole sulfinic acid (M-3625): Oral LD_{50} > 2000 mg/kg bw; not genotoxic
	Methyl sulfone derivative (M-3626): Oral $LD_{50} \geq 300$ mg/kg bw; not genotoxic in vivo
	Butene sulfonic acid (M-3627): Oral LD_{50} > 2000 mg/kg bw; not genotoxic
Medical data	
	No adverse effects reported

Summary

	Value	Study	Safety factor
ADI	0–0.01 mg/kg bw	Two-year toxicity/carcinogenicity study in rats	100
ARfD	0.3 mg/kg bw	Acute neurotoxicity study in rats	100

5.20 FLUTOLANIL (205)

RESIDUE AND ANALYTICAL ASPECTS

Flutolanil was evaluated by JMPR in 2002 for the first time toxicologically and for residues. The 2002 JMPR allocated an ADI of 0–0.09 mg/kg bw and ARfD unnecessary. It also determined that the definition of residues should be flutolanil for plant commodities (for compliance with MRLs and for estimation of dietary intake) and flutolanil and transformation products containing the 2-trifluoromethylbenzoic acid moiety, expressed as flutolanil for animal commodities (for compliance with MRLs and for estimation of dietary intake) and recommended a maximum residue level for rice, husked; rice, polished; rice bran, unprocessed; rice straw and fodder, dry; tissues of cattle goats, pigs, sheep and poultry; milks; and eggs.

The current Meeting received information on analytical methods, storage stability, use patterns and supervised trials to support estimation of maximum residue levels for broccoli, cabbage and mustard greens.

Methods of analysis

The Meeting received information on the analytical method used for the determination of flutolanil. Flutolanil in broccoli or mustard green was extracted with acetone and flutolanil in cabbage was extracted with methanol:water (1:1, v/v). Acetone extract or methanol extract was partitioned with ethyl acetate:dichloromethane (1:9) and the top layer was dried down and reconstituted in acetone. Following clean up on a Florisil column, eluates were dried down, reconstituted in mobile phase. The analysis is carried out using LC-MS/MS (electro-spray ionization mode; molecular ion of 324 ($m+H^+$) m/z and product ion of 282 m/z).

This method was found to be suitable for the determination of residues of flutolanil in broccoli, cabbage and mustard greens with recoveries of 83–110%, 97–106% and 83–110%, respectively, for these matrices at fortification levels 0.05–5 mg/kg.

The LOQ was 0.05 mg/kg for broccoli, cabbage and mustard green.

Stability of pesticide residues in stored analytical samples

Storage stability studies were conducted on broccoli in conjunction with supervised trials.

Flutolanil in the frozen condition was stable up to 569 days at -22 to -4 °C (102–114% remaining) in broccoli, 297 days at -29 - -10°C (95-101% remaining) in cabbage and 519 days at -22 to -4 °C (107–114% remaining) in mustard green.

In the supervised residue trial studies, samples were stored frozen for periods shorter than the respective periods tested for the storage stability studies.

Results of supervised residue trials on crops

The Meeting considered residue data from supervised field trials conducted in the USA on broccoli, cabbage and mustard green with a flutolanil WP formulation (700 g ai/kg nominal concentration).

Brassica vegetables

The approved use of flutolanil in the USA on the crop group Brassica leafy vegetables (including Brassica vegetables) consists of one application at a rate of 0.863 kg ai/ha either as an in-furrow or directed spray (minimum of 28 L/ha) or as soil drench at planting (PHI of 45 days), or, when transplanted, as a banded application directed at plant bases immediately after transplanting (281–468 L/ha).

According to the review of information on environmental fate by the 2002 JMPR, flutolanil is strongly adsorbed to most soils and is classified as low mobility through soil.

Broccoli

A total of eleven field trials were conducted across the USA. At all the trials, a single ground application directed in a narrow band at the base of the transplants or over the seed furrow was made at the time of seeding or immediately after transplanting. The commercially mature broccoli heads (including stems, and jacket leaves) were harvested 56–106 days after the application.

Residues of flutolanil in broccoli from trials in accordance with US GAP were all < 0.05 mg/kg (9). The Meeting estimated a maximum residue level of 0.05 * mg/kg. As flutolanil is applied at the time of planting or immediately after transplanting and flutolanil is unlikely to be taken up from soil by crops, the Meeting estimated an STMR of 0 mg/kg.

Cabbages, Head

A total of nine field trials were conducted across the USA. At all the trials, a single ground application directed in a narrow band at the base of the plant or over the seed furrow was made at the time of transplanting or seeding. The commercially mature cabbage heads were harvested 62–138 days after the application.

Residues of flutolanil in head cabbages from trials in matching US GAP were all < 0.05 mg/kg (9). The Meeting estimated a maximum residue level of 0.05* mg/kg. Applying the same rational as for broccoli on soil uptake, the Meeting estimated an STMR of 0 mg/kg. The Meeting also estimated a highest residue of 0 mg/kg for the purpose of calculating livestock dietary burdens.

Leafy vegetables

Mustard greens

A total of ten field trials were conducted across the USA. At all the trials, a single ground application directed in a narrow band over the seed furrow was made at the time of seeding. The commercially mature mustard greens mustard were harvested 31–63 days after the application.

Residues of flutolanil in mustard greens from trials matching US GAP were < 0.05 (7) and 0.055 mg/kg. The Meeting estimated a maximum residue level of 0.07 mg/kg. The Meeting estimated an STMR of 0.05 mg/kg.

Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead Brassicas; and Brassica leafy vegetables

The GAP in the USA covers the crop group Brassica leafy vegetables, including head and stem Brassica, Brassica leafy vegetables and turnip greens. As this GAP involves one application at planting or immediately after transplanting, residues in commodities in this group harvested at their maturity are expected to be very low, as was observed in the trials on broccoli, cabbage and mustard greens.

Consequently, the Meeting decided to extend the recommendations for maximum residue levels of 0.05* mg/kg and STMRs of 0 mg/kg for broccoli and head cabbage to the group Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead Brassicas (VB 0040); and the recommended maximum residue level of 0.07 mg/kg and STMRs of 0.05 mg/kg for mustard greens to Brassica leafy vegetables (VL 0054).

Residues in animal commodities

Estimation of dietary burdens

The Meeting noted that in addition to rice grain, rice bran, rice hulls and rice straw from which dietary burdens were calculated by the 2002 JMPR, cabbages can also be fed to beef and dairy cattle and laying hens. Although both the STMR and highest residue of head cabbages were estimated to be 0 mg/kg and therefore not impacting on animal dietary burden, as the OECD Animal Feeding Table had been revised since the last evaluation, the maximum and mean dietary burdens were re-calculated using the highest residue and STMR/median residue of the above-mentioned commodities on a basis of the updated OECD Animal Feeding Table. The summary of calculated dietary burdens is shown in the following 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	0.372	0.372	0.822	0.411	5.83[a]	3.37 [b]	4.90	2.64
Dairy cattle	0.372	0.372	0.789	0.584	2.78 [c]	1.96 [d]	2.24	1.22
Broiler	0.278	0.278	0.189	0.189	0.599	0.599	0.094	0.094
Layer	0.278	0.278	0.094	0.094	0.599 [e]	0.599 [f]	0.378	0.378

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

[b] Suitable for estimating STMRs for meat, fat and edible offal of cattle.

[c] Suitable for estimating maximum residue level for milk of cattle.

[d] Suitable for estimating STMR for milk of cattle.

[e] Suitable for estimating maximum residue levels for meat, fat, edible offal of poultry.

[f] Suitable for estimating STMRs for meat, fat, edible offal of poultry.

Residues in milk and mammalian tissues

The 2002 JMPR reviewed a cattle feeding study conducted at levels equivalent to 39, 116 and 388 ppm in the feed.

The maximum and mean dietary burdens in cattle were 2.78 and 1.96 ppm of dry matter diet respectively for estimating a maximum residue level and STMR for milk; and 5.83 and 3.37 ppm respectively for estimating maximum residue levels and STMRs for tissues. The maximum residue levels, STMRs and highest residues for relevant commodities of animal origin were estimated using the residue levels in tissues and milk at 39 ppm feeding group.

	Feed level (ppm) for milk residues	Flutolanil* (mg/kg) in milk	Feed level (ppm) for tissue residues	Flutolanil * (mg/kg) in			
				Muscle	Liver	Kidney	Fat
Maximum residue level beef or dairy cattle							
Feeding study[a]	39	< 0.05	39	< 0.05	2.0	0.79	0.06
Dietary burden and highest residue	2.78	< 0.004	5.83	< 0.007	0.299	0.118	0.009
STMR beef or dairy cattle							
Feeding study[b]	39	< 0.05	39	< 0.05	1.7	0.42	0.05
Dietary burden and mean residue	1.96	< 0.003	3.37	< 0.004	0.147	0.036	0.004

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

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

* From the common moiety method

The Meeting estimated STMRs of 0.147 and 0.036 mg/kg for liver and kidney respectively. As the residues in meat were < 0.05 mg/kg in any of feeding groups, the Meeting confirmed the existing STMR for meat at 0 mg/kg. Since the calculated STMR for milk was less than one tenth of the LOQ, the Meeting decided to use the existing STMR of 0 mg/kg.

The Meeting confirmed the previous maximum residue level recommendations of 0.05* and 0.05* mg/kg for milks and meat (from mammals other than marine mammals), and estimated a maximum reside level of 0.5 mg/kg for edible offal (mammalian) and withdrew the previous recommendations for liver and kidney.

Residues in eggs and poultry tissues

The 2002 JMPR reviewed a chicken feeding study conducted at levels equivalent to 0.78, 2.4 and 7.8 ppm in the feed. The maximum of calculated poultry dietary burden was 0.60 ppm.

At the lowest feeding level in the feeding study, residues from the common moiety method were all < 0.05 mg/kg in the eggs and all tissues tested. As a result the Meeting confirmed the existing maximum residue levels for eggs, poultry meat and poultry, edible offal of 0.05 * mg/kg.

At all feeding levels, residues did not exceed the LOQ of 0.05 mg/kg in eggs, muscle, fat or skin. The Meeting therefore confirmed the previously estimated STMRs of 0 mg/kg for these commodities.

Residues in the liver were below 0.05 mg/kg in the lowest and middle feeding groups but were detected at 0.08, 0.10 and 0.20 mg/kg in the highest feeding group. The Meeting, therefore also confirmed the STMR of 0.05 mg/kg for poultry, edible offal of.

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 MRLs and for estimation of dietary intake): flutolanil.

Definition of the residue for animal commodities (for compliance with MRLs and for estimation of dietary intake): flutolanil and transformation products containing the 2-trifluoromethylbenzoic acid moiety, expressed as flutolanil.

The residue is not fat-soluble.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Dietary Intakes (IEDIs) of flutolanil were calculated for the 13 GEMS/Food cluster diets using STMRs estimated by the 2002 and current Meetings (Annex 3). The ADI is 0–0.09 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 flutolanil resulting from the uses considered by the current JMPR is unlikely to present a public health concern.

Short-term intake

The 2002 JMPR decided that an ARfD is unnecessary. The Meeting therefore concluded that the short-term intake of residues of flutolanil is unlikely to present a public health concern.

5.21 GLYPHOSATE (158)

RESIDUE AND ANALYTICAL ASPECTS

Glyphosate is an herbicide with uses on many crops, conventional and glyphosate tolerant. Glyphosate has been evaluated several times with the initial evaluation in 1986 and the latest in 2011 where the use of glyphosate on glyphosate tolerant crops was reviewed.

The 2011 JMPR established a residue definition for compliance with MRLs for plant commodities as the sum of glyphosate and N-acetyl-glyphosate, expressed as glyphosate in the case of soya bean and maize and glyphosate for other crops. The definition of the residue for compliance with MRL for animal commodities is the sum of glyphosate and N-acetyl-glyphosate, expressed as glyphosate. For estimation of dietary intake it is the sum of glyphosate, AMPA, N-acetyl-glyphosate and N-acetyl AMPA, expressed as glyphosate. The toxicology of glyphosate was re-evaluated by the 2011 JMPR which estimated group ADI of 0–1 mg/kg bw for the sum of glyphosate, N-acetyl-glyphosate, AMPA and N-acetyl-AMPA. The same Meeting confirmed that an ARfD was unnecessary.

For the current evaluation data have been submitted covering the use on genetically modified rape crops containing the *gat* trait (glyphosate-N-acetyl transferase or GAT gene). These crops inactivate glyphosate by converting it to *N*-acetyl-glyphosate. The Meeting received information on glyphosate metabolism in genetically modified rape containing the *gat* trait, methods of residue analysis, GAP information, supervised residue trials on *gat* rape crops and the fate of residue during storage and processing.

To assist uniform interpretation of GAP application rates have been expressed in terms of glyphosate acid equivalents (ae), unless indicated otherwise.

Metabolites referred to in the appraisal were addressed by their common names:

N-acetyl-glyphosate	*N*-acetyl-*N*-(phosphonomethyl)glycine
AMPA	aminomethyl phosphonic acid
N-acetyl-AMPA	[(acetylamino)methyl]phosphonic acid.

Plant metabolism

The metabolic fate of [^{14}C] glyphosate in *gat* rape plants was examined following a single pre-emergence soil application of 4.5 kg ae/ha, followed by three foliar applications at 1.0 kg ae/ha at three different growth stages (2 and 5 leaf stage and 1 week before harvest). Rape plants were harvested as immature foliage, immediately prior to the final application and at maturity (PHI 7 days).

N-acetyl-glyphosate was the major metabolite in immature foliage (90% TRR; 5.4 mg/kg glyphosate equivalents). Glyphosate, AMPA and *N*-acetyl-AMPA were also detected accounting for 3.0, 1.4 and 3.4% of TRR respectively. At the intermediate harvest prior to the final application the only glyphosate related compound detected in foliage and immature pods (with seeds) was N-acetyl-glyphosate representing 93% TRR in foliage and 80% TRR in immature pods (with seeds). The residue in seeds at harvest, seven days after the final application, comprised glyphosate (21% TRR; 0.45 mg/kg), N-acetyl-glyphosate (51% TRR; 1.1 mg/kg), AMPA (1.9% TRR; 0.04 mg/kg) and N-acetyl-AMPA (15% TRR; 0.32 mg/kg).

The proposed pathway of glyphosate in rape plants with the *gat* trait is deactivation to *N*-acetyl-glyphosate which can be further metabolized to *N*-acetyl-AMPA and AMPA. The metabolism is similar to that observed for maize and soya bean crops with the *gat* trait previously reviewed by the 2011 JMPR.

Methods of Analysis

The Meeting received description and validation data for analytical methods for residue analysis of glyphosate and its metabolites in various plant commodities using LC-MS/MS. The LOQs are 0.05 mg/kg.

Stability of pesticide residues in stored analytical samples

No new information was received on the stability of glyphosate and its residues in samples stored frozen. The periods of demonstrated stability reported by the 2011 JMPR for other high oil and high protein crops cover the frozen storage intervals used in the residue studies.

Definition of the residue

The 2011 JMPR reviewed glyphosate metabolism studies in tolerant maize and soya bean containing the *gat* trait. Glyphosate, AMPA, *N*-acetyl-glyphosate and *N*-acetyl-AMPA were the major components of the residue in both maize and soya bean. In seeds from *gat* rape, *N*-acetyl-glyphosate was the major component of the residue (51% TRR) followed by glyphosate (21% TRR) and N-acetyl AMPA (15% TRR). In *gat* rape forage, N-acetyl glyphosate was the major metabolite (90–93% TRR).

To accommodate the use of glyphosate on rape plants containing the *gat* trait the Meeting concluded that the previously established residue definition for enforcement in plants of "glyphosate" should be replaced by "*the sum of glyphosate and N-acetyl-glyphosate expressed as glyphosate* for soya bean, maize and rape crops and remain "*glyphosate*" for all other crops.

Based on the above the Meeting agreed to amend the previous definition for glyphosate for compliance with MRL for plant commodities as follows:

Definition of the residue for compliance with MRL (for plant commodities): for soya bean, maize and rape - *sum of glyphosate and N-acetyl-glyphosate, expressed as glyphosate*, and for other crops - *glyphosate*.

The Meeting confirmed the residue definition for estimation of dietary intake as (for plant and animal commodities: *glyphosate, N-acetyl-glyphosate, AMPA and N-acetyl AMPA, expressed as glyphosate*.

Results of supervised residue trials on crops

The Meeting received supervised residue trial data for glyphosate on glyphosate-tolerant rape (*gat* trait).

For estimation of maximum residue levels for rape crops glyphosate and *N*-acetyl glyphosate levels are summed and expressed as glyphosate equivalents.

For estimation of the residue levels for dietary risk assessment of glyphosate in *gat* crops, in general all four analytes may be present in significant amounts. In the *gat* modified rape, *N*-acetyl glyphosate is the major residue found in rape seed, followed by glyphosate and *N*-acetyl AMPA. AMPA is a minor component of the residue and is included in the sum of residues when AMPA is reported as < LOQ.

The current Meeting received field trials performed in the USA and Canada involving glyphosate tolerant rape containing the *gat* trait. GAP for Canada is for application pre-emergence at 0.68 kg ae/ha, post-emergence at the 0–6 leaf stage at 0.3–0.68 kg ae/ha followed by a pre-harvest application at 0.9 kg ae/ha (PHI 7 days).

Residues of glyphosate and N-acetyl-glyphosate in rape seed trials matching Canada GAP were: 0.775, 1.8, 1.9, 2.4, 2.85, 3.05, 3.05, 7.8, 9.2 and 15 mg/kg (n=10). The Meeting estimated a

maximum residue level of 30 mg/kg for glyphosate in rape seed to replace its previous recommendation of 20 mg/kg.

Corresponding total residues, for dietary intake estimation, were: 0.795, 1.8, 1.95, 2.4, 2.9, 3.1, 3.1, 7.8, 9.2 and 15 mg/kg. The Meeting estimated an STMR for glyphosate in rape seed of 3.0 mg/kg.

It was assumed that rape forage is plant material available from 25 days after planting. Residues in rape forage matching Canada GAP were: 0.4, 0.48, 1.0, 1.1, 1.5, 1.6, 2.1, 2.4, 2.5, 2.5, 3.3, 3.6, 4.7, 5.1, 8.0 and 16 mg/kg (dry matter basis). The Meeting estimated median and highest residues for glyphosate in rape forage of 2.25 and 16 mg/kg respectively, both on a dry-matter basis.

Fate of residues during processing

The Meeting received information on the nature of residues under simulated processing condition on the fate of incurred residues of glyphosate during the processing of rape seeds. Calculated processing factors for total glyphosate acid equivalents (combined results of the four metabolites) are summarized below.

Summary of calculated processing factors and estimated STMR-P values

Commodity	PF_{total}	Best estimate PF_{total}	$STMR_{RAC}$ (mg/kg)	$STMR_{RAC}$×PF (mg/kg)
Refined oil-cold press	< 0.0009 < 0.003 < 0.003	< 0.003	3.0	< 0.009
Refined oil-solvent extracted	< 0.0009 < 0.003 < 0.003	< 0.003		< 0.009
Meal-cold pressed	0.311 1.47 1.57	1.47		4.41
Meal-solvent extracted	0.107 1.13 1.43	1.13		3.39

The estimated STMR-P values in oil are lower than the previous values reported by the 2011 JMPR (previous 0.093 mg/kg) while the STMR-P estimated for rape seed meal is higher (previous 2.3 mg/kg).

Residues in animal commodities

Animal commodity maximum residue levels

The current evaluation has not led to recommendations that would alter the dietary burdens calculated using the livestock intake figures employed by the 2011 JMPR. The glyphosate dietary burdens for cattle (dairy and beef) were based on grass, cotton seed and barley grain while those for poultry were based on barley, soya bean grain and soya bean hulls and as such do not require a re-evaluation of animal commodity maximum residues levels.

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 assessment.

Definition of the residue for compliance with MRL (for plant commodities) for soya bean, maize and rape: *sum of glyphosate and N-acetyl-glyphosate, expressed as glyphosate*, and for other crops - *glyphosate*.

The Meeting confirmed the residue definition for estimation of dietary intake as (for plant and animal commodities: *glyphosate, N-acetyl-glyphosate, AMPA and N-acetyl AMPA, expressed as glyphosate*.

Definition of the residue for compliance with MRL (for animal commodities): *sum of glyphosate and N-acetylglyphosate, expressed as glyphosate*.

Definition of the residue for estimation of dietary intake (for plant and animal commodities): *glyphosate, N-acetylglyphosate, AMPA and N-acetyl AMPA, expressed as glyphosate*.

The residue is not fat soluble.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Daily Intakes (IEDI) of glyphosate for the 13 GEMS/Food regional diets, based on estimated STMRs were in the range 0–1% of the maximum ADI of 1 mg/kg bw for the sum of glyphosate, *N*-acetyl glyphosate, AMPA and *N*-acetyl AMPA, expressed as glyphosate. The Meeting concluded that the long-term intake of residues of glyphosate, *N*-acetyl glyphosate, AMPA and *N*-acetyl AMPA from uses that have been considered by the JMPR is unlikely to present a public health concern. The results are shown in Annex 4 of the JMPR 2013 Report.

Short-term intake

The International Estimated Short Term Intake (IESTI) of glyphosate was not calculated. The 2004 and 2005 JMPR concluded that it was unnecessary to establish an ARfD for glyphosate. The Meeting therefore concluded that short-term dietary of glyphosate residues is unlikely to present a risk to consumers.

5.22 IMAZAPIC (266)

TOXICOLOGY

Imazapic is the ISO-approved name for (*RS*)-2-(4-isopropyl-4-methyl-5-oxo-2-imidazolin-2-yl)-5-methylnicotinic acid (IUPAC), with CAS No. 104098-48-8. It is a new herbicide that belongs to the imidazolinone family. The proposed mode of action is specific to plants and involves the disruption of protein synthesis via the inhibition of acetohydroxyacid synthase, an enzyme not found in mammalian tissues.

Imazapic 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

Radiolabelled imazapic administered by oral gavage is rapidly and extensively absorbed, minimally metabolized and excreted primarily in the urine after single low (10 mg/kg bw) or high doses (1000 mg/kg bw) or repeated low doses (10 mg/kg bw per day) over 14 days to rats. Biliary excretion was minimal. The majority of radioactivity was excreted as the parent compound within the first 6 hours post-dosing. Less than 2% of the administered dose was detected in the carcass, with trace amounts detected in blood, kidneys and liver of the high-dose group at 168 hours post-dosing; however, radiolabelled test substance was not detected in any other organs. There was no evidence of accumulation. There were no notable differences in absorption or excretion between the sexes. Imazapic and its metabolites were not excreted in expired air. Parent compound accounted for more than 94% of the administered dose in the urine and 2.3% of the administered dose in the faeces. The metabolites produced from oxidation, reduction and hydrolysis, including CL 263,284 (M715H001 or 5-hydroxy methyl metabolite), CL 280,442 (no common name assigned) and several other unidentified metabolites, accounted for a total of approximately 6% of the administered dose in the urine and faeces.

Toxicological data

Imazapic is of low acute oral toxicity in the rat (LD_{50} > 5000 mg/kg bw) and low acute dermal toxicity in the rabbit (LD_{50} > 2000 mg/kg bw). Imazapic appears to be of low acute inhalation toxicity, but characterization by this route was limited due to the high median particle sizes. In the rabbit, imazapic was non-irritating to the skin and mildly irritating to the eyes. Imazapic was not a dermal sensitizer in guinea-pigs.

Overall, imazapic showed low mammalian toxicity on repeated administration. Most of the rodent studies found no adverse effects, including target organ toxicity, up to the limit dose. The dog and, to a lesser extent, the rabbit were more sensitive than the rat or mouse to imazapic-induced toxicity. The target tissues in the dog were skeletal muscle and, at higher doses, bone marrow.

In a 13-week oral toxicity study in the rat, the NOAEL was 20 000 ppm (equal to 1522 mg/kg bw per day), the highest dose tested.

In a 1-year oral toxicity study in the dog, animals were exposed to 0, 5000, 20 000 or 40 000 ppm (equal to 0, 137, 501 and 1141 mg/kg bw per day for males and 0, 180, 534 and 1092 mg/kg bw per day for females, respectively). There was an increase in lymphocyte and macrophage infiltration in the diaphragm, abdominal and thigh skeletal muscles and an increase in degeneration or necrosis of the abdominal and thigh muscles at doses greater than or equal to 5000 ppm (equal to 137 mg/kg bw per day), which was therefore the LOAEL for this study. The effects observed at the LOAEL were of minimal severity. Grade 1 lesions were seen primarily in one site per animal at the lowest dose tested, in multiple sites per animal at the middle dose and in

multiple sites at increased grades at the high dose. However, in the absence of any information on the mode of toxicological action for the effects of imazapic on the muscles of dogs, the effects were considered adverse and potentially relevant to humans.

The chronic toxicity and carcinogenicity of imazapic have been investigated in mice and rats. In the mouse study, there was no evidence of toxicity up to 7000 ppm (equal to 1134 mg/kg bw per day), the highest dose tested. In the rat study, there was no evidence of toxicity up to 20 000 ppm (equal to 1029 mg/kg bw per day), the highest dose tested.

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

Imazapic has been tested in an adequate range of genotoxicity studies in vitro and in vivo. There was no evidence of genotoxicity.

The Meeting concluded that imazapic is unlikely to be genotoxic.

Based on the lack of genotoxicity and the absence of carcinogenicity in mice and rats, the Meeting concluded that imazapic is unlikely to pose a carcinogenic risk to humans.

A multigeneration reproductive toxicity study was performed with imazapic in rats. The NOAEL for reproductive, parental and offspring toxicity was 20 000 ppm (equal to 1205 mg/kg bw per day), the highest dose tested.

In a developmental toxicity study in rats, the NOAEL for maternal and embryo and fetal toxicity was 1000 mg/kg bw per day, the highest dose tested.

In a developmental toxicity study in rabbits, pregnant females were dosed at 0, 175, 350, 500 or 700 mg/kg bw per day; however, the highest dose was not evaluated for embryo and fetal toxicity due to excessive maternal mortality. The NOAEL for maternal toxicity was 350 mg/kg bw per day, based on a loss of body weight and a decrease in body weight gain compared with controls and a decrease in feed consumption at 500 mg/kg bw per day. The NOAEL for embryo and fetal toxicity was 500 mg/kg bw per day, the highest dose at which fetuses were evaluated.

The Meeting concluded that imazapic is not teratogenic in rats or rabbits.

In an acute neurotoxicity study in rats, animals were given imazapic as a single oral gavage dose at 0, 200, 600 or 2000 mg/kg bw per day. The NOAEL was 600 mg/kg bw per day, based on increased salivation in males and females at 2000 mg/kg bw per day.

In a 13-week dietary neurotoxicity study in rats, the NOAEL was 927 mg/kg bw per day, the highest dose tested.

In a 28-day dietary immunotoxicity study in mice, no effects on IgM 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.

Human data

No specific information on the effects of impazapic on production plant workers or others was available. There are no reports of poisoning cases with imazapic.

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

Toxicological evaluation

The Meeting established an ADI of 0–0.7 mg/kg bw on the basis of the LOAEL of 5000 ppm (equal to 137 mg/kg bw per day), the lowest dose tested, for effects on skeletal muscles in a 1-year study of

toxicity in dogs. A safety factor of 200 was applied, with an additional safety factor of 2 being used to account for the use of a LOAEL instead of a NOAEL; the effects observed at the LOAEL were of minimal severity. No adverse effects were observed in chronic studies in rats or mice, up to the limit dose.

The plant metabolite CL 189,215 is the glucoside conjugate of the 5-hydroxy methyl imazapic, which occurs as a minor metabolite in rats. The Meeting concluded that this plant metabolite would be covered by the ADI for imazapic.

The Meeting concluded that it was not necessary to establish an ARfD for imazapic in view of its low acute toxicity and the absence of developmental toxicity and any other toxicological effects that would be likely to be elicited by a single dose. The effects observed in the acute neurotoxicity study occurred above 500 mg/kg bw.

A toxicological monograph was prepared.

Levels relevant to risk assessment of imazapic

Species	Study	Effect	NOAEL	LOAEL
Mouse	Two-year study of toxicity and carcinogenicity[a]	Toxicity	7000 ppm, equal to 1134 mg/kg bw per day[b]	—
		Carcinogenicity	7000 ppm, equal to 1134 mg/kg bw per day[b]	—
Rat	Thirteen-week study of toxicity[a]	Toxicity	20 000 ppm, equal to 1522 mg/kg bw per day[b]	—
	Two-year study of toxicity and carcinogenicity[a]	Toxicity	20 000 ppm, equal to 1029 mg/kg bw per day[b]	—
		Carcinogenicity	20 000 ppm, equal to 1029 mg/kg bw per day[b]	—
	Two-generation study of reproductive toxicity[a]	Reproductive toxicity	20 000 ppm, equal to 1205 mg/kg bw per day[b]	—
		Parental toxicity	20 000 ppm, equal to 1205 mg/kg bw per day[b]	—
		Offspring toxicity	20 000 ppm, equal to 1205 mg/kg bw per day[b]	—
	Developmental toxicity study[c]	Maternal toxicity	1000 mg/kg bw per day[b]	—
		Embryo and fetal toxicity	1000 mg/kg bw per day[b]	—
Rabbit	Developmental toxicity study[c]	Maternal toxicity	350 mg/kg bw per day	500 mg/kg bw per day
		Embryo and fetal toxicity	500 mg/kg bw per day[b]	—
Dog	One-year study of toxicity[a]	Toxicity	—	5000 ppm, equal to 137 mg/kg bw per day[d]

[a] Dietary administration.

[b] Highest dose tested.

[c] Gavage administration.

[d] Lowest dose tested.

Estimate of acceptable daily intake

0–0.7 mg/kg bw

Estimate of acute reference dose

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 imazapic

Absorption, distribution, excretion and metabolism in mammals	
Rate and extent of oral absorption	Rapid; extensive
Dermal absorption	No data
Distribution	Rapidly eliminated; highest residues in blood, bone, carcass and liver in males and females and fat and kidneys in females
Potential for accumulation	No evidence of accumulation
Rate and extent of excretion	Largely complete within 48 h; primarily via urine (94.50–102%) with < 5% via faeces
Metabolism in animals	Mostly excreted unchanged
Toxicologically significant compounds in animals, plants and the environment	Imazapic, 5-hydroxy methyl metabolite
Acute toxicity	
Rat, LD_{50}, oral	> 5000 mg/kg bw
Rat, LD_{50}, dermal	> 2000 mg/kg bw
Rat, LC_{50}, inhalation	No reliable data
Rabbit, dermal irritation	Non-irritating
Rabbit, ocular irritation	Mildly irritating
Guinea-pig, dermal sensitization	Not sensitizing (Buehler method)
Short-term studies of toxicity	
Target/critical effect	Skeletal muscle
Lowest relevant oral NOAEL	< 137 mg/kg bw per day, the lowest dose tested (dog)
Lowest relevant dermal NOAEL	1000 mg/kg bw per day (rabbit)
Lowest relevant inhalation NOAEC	No data
Long-term studies of toxicity and carcinogenicity	
Target/critical effect	No long-term effects up to limit dose
Lowest relevant oral NOAEL	1029 mg/kg bw per day, the highest dose tested (rat)
Carcinogenicity	Not carcinogenic
Genotoxicity	
	Not genotoxic

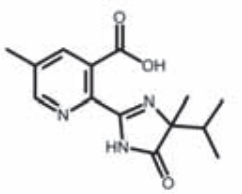
Reproductive toxicity	
Target/critical effect	No reproductive toxicity
Lowest relevant parental NOAEL	1205 mg/kg bw per day, the highest dose tested
Lowest relevant offspring NOAEL	1205 mg/kg bw per day, the highest dose tested
Lowest relevant reproductive NOAEL	1205 mg/kg bw per day, the highest dose tested
Developmental toxicity	
Target/critical effect	Body weight and feed consumption in dams
Lowest relevant maternal NOAEL	350 mg/kg bw per day (rabbit)
Lowest relevant embryo/fetal NOAEL	500 mg/kg bw per day, the highest dose tested (rabbit)
Neurotoxicity	
Acute and subchronic neurotoxicity NOAEL	Salivation: 600 mg/kg bw
Immunotoxicity	
	Not immunotoxic
Medical data	
	No studies submitted

Summary

	Value	Study	Safety factor
ADI	0–0.7 mg/kg bw	One-year oral toxicity study (dog)	200
ARfD	Unnecessary	—	—

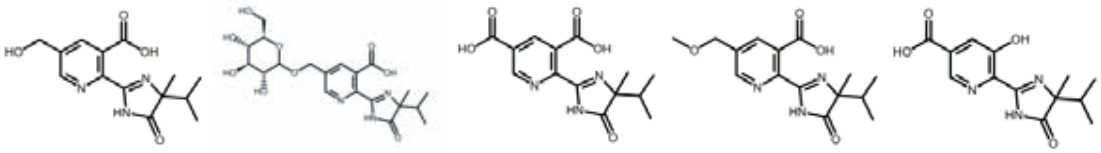
RESIDUE AND ANALYTICAL ASPECTS

Imazapic is an imidazolinone herbicide developed for the control of grass and broadleaf weeds in a variety of crops and registered in a number of countries. It was considered for the first time by the present Meeting.



Information on the physical and chemical properties, animal and plant metabolism, environmental fate, analytical methods, storage stability, use patterns, supervised trials, processing and farm animal feeding was received by the present Meeting.

The following abbreviated names were used for the metabolites discussed below.



CL263284 CL189215 CL 312622 CL 299263 CL 354825

Animal metabolism

The Meeting received information on the fate of orally-dosed imazapic in rat, lactating goats and laying hens.

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

Metabolism of imazapic in rat

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

Metabolism of imazapic in lactating goats

Imazapic

In two studies on lactating goats, [pyridine-6-^{14}C]-imazapic was orally administered at three doses via capsule (equivalent to 2.0, 11.8 and 175 ppm in feed) for 5 or 7 consecutive days. The majority was eliminated in urine (67–94% of TAR) in the form of unchanged imazapic and faeces (7–10% of TAR). Milk contained up to 0.03% of TAR and edible tissues 0.01% of TAR at the highest dose.

The TRR of daily collected milk samples were lower than the LOQ of 0.01 mg eq/kg at the two lower doses.

The goats were sacrificed 20 or 23 hours after the last dose at which time tissue samples were obtained. The highest TRR (0.275 mg eq/kg) was observed in kidney from the highest dose regime, reflecting that urinary excretion was the predominant elimination route. At the two lower doses, except that the TRR of the kidney from goat dosed at 11.8 ppm was 0.05 mg eq/kg, the TRR in milk or tissues were below the respective LOQ of 0.01 (milk) or 0.02 mg eq/kg (muscle).

The analysis of acetonitrile+methanol extract of kidney from the highest dose indicates that imazapic was the major residue at 30% TRR (0.02 mg/kg) with CL263284 at 8% of TRR (< 0.01 mg/kg). As the TRRs in milk and tissues, other than kidney, from any dose levels were too low to characterize any of radioactive residues, extraction of radioactive residues was not attempted for these tissues or milk.

CL 263284

In a study on lactating goats with oral administration of [pyridine-6-^{14}C]- CL 263284 in capsule at doses equivalent to 2.3 or 14.5 ppm in feed for 7 consecutive days, radioactivity was eliminated mostly via faeces (82% TAR for the low dose and 68% TAR for the high dose) and in a lesser amount from urine (15–18% TAR). The TRR of daily milk samples and tissues obtained 20 hours after the last dose were below the LOQ of 0.01 mg/kg except kidney from the high dose goat (0.03 mg eq/kg). About 91% of TRR in the kidney from high dose goat was extracted with methanol and CL 263284 was present at 9% (< 0.01 mg/kg) of the extracted TRR. Component M1 found at significant amounts (78% TRR, 0.02 mg eq/kg) may be an extraction artifact and was converted into CL 263284 on exposure to aqueous buffer.

Metabolism of imazapic in laying hens

In a hen study [Pyridine-6-^{14}C]-imazapic orally administered in capsule to laying hens, at a dose equivalent to 2.1 or 11.4 ppm in feed for 7 consecutive days, was mostly eliminated into excreta (91–95% of TAR). The TRR in all egg and tissue samples were less than the LOQ of 0.01 mg eq/kg.

The [Pyridine-6-^{14}C]-CL263284 orally administered to laying hens at 2.1 or 10.9 ppm in feed for 7 consecutive days was mostly eliminated into excreta and the TRR in all tissues, skin with adhering fat and eggs were below the LOQ of 0.01 mg/kg. No detectable radioactive residues were found in eggs or edible tissues obtained 22 hours after the last dose.

Metabolites of imazapic in goat were similar to those in rat. With rapid excretion, the radioactive residues in edible tissues, milk or eggs were mostly below the LOQ. In lactating goats, residues remaining in the kidney were mostly unchanged parent with a minor amount of CL263284.

Plant metabolism

The Meeting received information on the fate of imazapic in sugar cane, peanuts, Bermuda grass and transgenic soya bean.

When [pyridine-6-^{14}C]-imazapic was applied to the soil surface as a pre-emergent treatment at a rate approximating 0.15 kg ai/ha (within GAP rates) in a small test plot, no radioactive residues were detected above the LOQ of 0.005 mg/kg in the stalk of sugar cane harvested 13 months after the treatment.

When [pyridine-6-^{14}C]-imazapic was applied to the soil surface as a pre-emergent treatment at a rate approximating 0.25 kg ai/ha (within GAP rates) in a greenhouse, the TRR in the adult sugar cane stalk and leaves collected 236 DAT was 0.0039–0.048 mg eq/kg and 0.015–0.016 mg eq/kg respectively.

High percentages (63–84% TRR) of the radioactive residues in forage, leaves and stalks collected at various timings were extracted by methanol. Most of the extracted radioactive residues were water soluble.

Imazapic was found in all samples but declined with time, e.g., in stalks 0.003 mg/kg (41% TRR) at 151 DAT to 0.0005 mg/kg (11% TRR) at 236 DAT. CL263284 was found in all the samples collected at higher concentrations than the parent, but both the concentration and proportion to TRR also declined with time, e.g., in stalk 0.001 mg/kg (16% TRR) at 151 DAT to 0.0005 mg/kg (10% TRR) at 236 DAT. CL189215 was also found at lower concentrations in leaves (0.0005–0.002 mg/kg, 3–8% TRR), but not in stalks.

[Pyridine-6-^{14}C]-imazapic was applied to peanut plants at a rate of 0.072 kg ai/ha (within GAP rates) 30 days post-emergence. The TRR declined significantly from 4.2 mg eq/kg at 0 DAT to 0.094 mg eq/kg at 61 DAT in green plants and 0.22 mg eq/kg in hay collected 131 DAT. The TRR in nutmeat at 131 DAT was low at 0.022 mg eq/kg. A mixture of methanol:water:acetone (1:1:1) extracted 76–96% of the TRR in peanut samples.

The concentration of imazapic sharply declined in plants to 0.006 mg/kg at 61 DAT (2% TRR). The concentration in nutmeat, hull and hay samples collected 131 DAT were even lower (< 0.001–0.006 mg/kg, 1–3% TRR). The concentration of CL263284 also decreased over time to 0.010 mg/kg (12% TRR) at 61 DAT in plants. The concentrations of CL189215 declined over time to 0.039 mg/kg at 61 DAT (46% TRR) in plants. The concentrations of these three compounds were all less than 0.01 mg/kg in nutmeat at 131 DAT. No other component in the extracts from immature or mature samples exceeded 10% of TRR or 0.01 mg/kg.

Bermuda grass was treated post-emergence with [pyridine-6-^{14}C]-imazapic at a rate of 0.2 kg ai/ha (maximum GAP rate for grass in the USA). The TRR in plants decreased over time from 8.3 mg eq/kg at 0 DAT to 0.77 mg eq/kg at 47 DAT and was 0.92 mg eq/kg in hay (68 DAT). From forage

and hay samples, 74–100% of radioactive residues were extracted by aqueous solutions with hay sample at the lowest 74%.

The concentration of imazapic declined sharply to 0.02 mg/kg (3% TRR) at 49 DAT. CL263284 concentration showed a sharp increase in the early period to the peak concentration of 1.7 mg/kg (30% TRR) at 15 DAT and then decrease to 0.16 mg/kg (21% TRR) at 49 DAT. It was found in hay at 0.08 mg/kg (8% TRR). CL189215 also increased in concentration in the early stage to the peak concentration of 0.17 mg/kg (4% TRR) at 15 DAT then to 0.08 mg/kg (9% TRR) at 49 DAT. In the hay sample collected 68 DAT, imazapic, CL263284 and CL189215 were present at 0.02, 0.08 and 0.08 mg/kg respectively but all below 10% of TRR.

There were many minor polar components but none exceeded 10% TRR individually.

[Pyridine-3-^{14}C]-imazapic was applied to the above-ground portion of imidazolinone-tolerant soya bean plants (with mutated AtAHASL protein inserted to make the host tolerant to imidazolinone herbicide) at BBCH 65 at an application rate of 0.08 kg ai/ha. The TRR in soya bean seed and straw were 0.014 mg eq/kg and 0.092 mg eq/kg respectively. From forage, hay, seed, straw and pod samples, 78–98% of radioactive residues were extracted by aqueous solutions.

In seeds, imazapic was the most abundant residue at 20% TRR but only 0.003 mg/kg. Imazapic was the most abundant residue in straw and pods but at 0.00013 and 0.004 mg/kg respectively. CL189215 was the second most abundant compound individually but at < 0.01 mg/kg and less than 10% of TRR. CL263284 was also present but less than imazapic or CL189215. There were many minor polar components detected but none exceeded 0.01 mg/kg or 10% of TRR individually.

In the edible portions of treated food crops harvested at maturity, no or little residues of imazapic are expected to be found. In animal feed crops, such as grasses, imazapic, CL 263284 and CL 189215 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

About 70% of the applied imazapic (equivalent to 0.14 kg/ha) remained in sandy loam soils after one year of incubation in one study and about 80% remained in soil after 120 days of incubation in the other. Mineralization occurred but at very low percentage.

CL263284 applied to soil degraded to less than 1% of the applied dose in 3 days forming CL312622, CL354825 and carbon dioxide.

AC299263 and CL 312624 applied to soil degraded more gradually both transforming to CL354825 and carbon dioxide.

Degradation of these compounds was significantly less in soil under sterile conditions, indicating microbial action.

Imazapic was found to be persistent in sandy loam soils under anaerobic conditions. However, its metabolites/degradates were more readily degraded in soil.

Photodegradation

^{14}C-Labelled imazapic was applied to a sandy loam soil at a rate equivalent to 0.08 kg/ha (within GAP rates). The total radioactivity in the aqueous sodium hydroxide extract (10% AR) and unextracted fraction (3% AR) was about 7% of the applied dose after 30 days of irradiation by a xenon-arc lamp comparable to mid-autumn sunlight in New Jersey, USA.

The imazapic concentration decreased from 94% of the extracted radioactivity on day 0 to 75% after the 30-day irradiation. A diacid degradate, CL 312622, formed up to 11% of the extracted radioactivity. The DT_{50} was calculated to be 106 days.

Photolysis of imazapic (25 mg/kg) in sterilized water was rapid at pH 5, 7 and 9 under irradiation by a xenon-arc lamp comparable to mid-autumn sunlight in New Jersey, USA, with DT_{50} in a range of 6.0–7.2 hours. Six degradation products, including carbon dioxide were formed, each of which accounted for around 10%.

Imazapic is photodegraded gradually with a half-life around 100 days on the surface of soil and rapidly with half-life of about 6–7 hours in sterilized water.

Hydrolysis

As imazapic can be used in rice production, ^{14}C-Labelled imazapic was applied to water+soil at a nominal rate equivalent to about 0.14 kg/ha (within GAP rates) and kept under anaerobic conditions.

Only 0.5% of the applied dose was mineralized. No other radioactive volatile compounds were collected. No volatilization or degradation occurred.

The concentration of imazapic decreased from 92% (36% in the soil extract and 56% in water) on day 0 to 83% (54% in the soil extract and 29% in the water) of the applied dose after 366 days.

Imazapic was stable for 366 days at 25 °C in water+ soil.

Residues in succeeding crops

A confined study was conducted to examine the nature and level of residues of imazapic in succeeding crops. A single application of [pyridine-6-^{14}C]-imazapic was made on soil in field plots at a nominal rate of 0.72 kg ai/ha, higher than any GAP rates.

At each rotational interval of 90, 120, 270 and 300 days after treatment, barley, maize cotton, lettuce and carrots were sown into the treated soil and harvested at maturity.

Following the application of imazapic to soil, uptake of radioactivity into rotational crops was low (< 0.004–0.070 mg eq/kg). However, the TRR in barley and maize samples show a tendency to be higher in samples obtained from longer plant back intervals. The TRR of lettuce and carrot (both with 20 day plant back intervals (PBI)) were 0.006 and < 0.004 mg eq/kg, respectively.

In barley grain, imazapic was the most abundant residue from the 120 day PBI at 23% TRR (0.007 mg/kg) followed by the sum of CL263284 and CL189215 at 18% TRR (0.006 mg/kg). In the 270 day PBI barley grain, the most abundant residue was the sum of CL263284 and CL189215 at 37% TRR (0.021 mg/kg) followed by imazapic at 10% (0.004 mg/kg). In straw the most abundant residue was the sum of CL263284 and CL189215 at 44% TRR (0.031 mg/kg) for 120 day PBI and 44% TRR (0.031 mg/kg) for 270 day PBI. Imazapic was present in straw at 5.4–5.5% TRR (0.003–0.004 mg/kg).

In the 300 day PBI maize forage and fodder, the sum of CL263284 and CL189215 was the most abundant residue at 28% (0.005 mg/kg) and 28% (0.008 mg/kg) TRR respectively.

Radioactive residues remained mostly in the 0–8 cm depth layer of soil. High percentage (57–91% TRR) of radioactive residues in soil were extracted with aqueous methanol/acetone mixture and 2% HCl. Nine to 43% TRR remained as unextracted residues.

Following the application of imazapic to soil, uptake of radioactivity into rotational crops was low (maximum at 0.070 mg eq/kg). Among registered uses related to the current review, the highest application rate was for sugar cane or grass. In comparison, the application rate used in this confined rotational crop study was about 3 times the GAP rate in Brazil and 7.5 times the GAP rate in Australia for sugar cane or 3.5 times the GAP rate for grass in the USA. This application rate was

more than 7.5 times higher than the GAP rate for other crops used in crop rotation. Residues of imazapic in plant portions of rotational crops used as food or feed after approved application are expected to be less than one third of the residues observed in the confined rotational crop study, i.e., around or lower than the lowest LOQ of 0.01 mg/kg.

Methods of analysis

Analytical methods for the determination of residues of imazapic and its metabolites were developed for a wide range of matrices of plant and animal origin.

In general, the methods for data generation employ extraction by homogenization with a mixture of methanol:water:1M HCl (60:39:1) or, in the case of fat, acidic acetonitrile in hexane, clean-up with solid phase extraction or some other techniques, and determination of analytes using LC-MS/MS, HPLC-UV (245 nm) or capillary electrophoresis-UV (240 nm).

A number of specific methods for plant matrices were found suitable for analysis of imazapic, CL263284 and CL189215 with LOQ ranging 0.01–0.1 mg/kg for these analytes except that it was 0.5 mg/kg for grass.

Three methods for animal matrices were found suitable for analysis of imazapic and CL263284 with LOQ of 0.01 (milk and milk fat) and 0.05 (tissues) mg/kg.

No multi-residue methods were submitted.

Stability of residues in stored analytical samples

The stability of imazapic residues during storage of samples frozen at -25 to -5 °C was investigated in a range of plant and animal matrices for which supervised residue trials were submitted.

Compounds tested were imazapic, CL263284 and CL189215. Each compound was spiked to matrices at 0.5 mg/kg.

All of the compounds tested were found to be stable (> 70% remaining) at least during the storage periods tested: 2 years in wheat, sugar cane, peanut and grass matrices; 10 months in soya bean seeds; 3 months in processed soya bean products; 6 months in cattle milk; and 8 months in cattle tissues. These storage periods are longer than the longest storage conditions in trials on respective crops.

Definition of the residue

In animal metabolism, parent imazapic was the predominant residue with CL263284 a minor component at around 10% TRR in goat kidney. In other tissues, milk or eggs, TRR were below the respective LOQs. In a metabolism study in which CL 263284 was administered, TRR in milk and tissues were below the LOQ of 0.01 mg/kg. CL263284 found in goat kidney is also a metabolite in rats and, as such, is covered by the ADI. However, in the livestock feeding study using imazapic, CL 263284 was not detected above the LOQ of 0.01 mg/kg (milk and milk fat) or 0.05 mg/kg (tissues) at the highest dose of 676 ppm in the feed. Therefore, the Meeting considered that parent imazapic is a suitable residue for enforcement of MRLs and for calculating dietary intake for commodities of animal origin.

With a low $\log P_{ow}$ of 0.054 and given the distribution of residues in animal tissues from the animal metabolism studies and animal feeding study, the Meeting considered imazapic residue not fat-soluble.

The plant metabolism studies indicate that no or little residues of imazapic or its metabolites are expected to be found in the edible portions of food crops harvested at maturity. In supervised trials on soya beans, CL 263284 and CL 189215 were found at lower concentrations than the parent, when measured.

In feed crop such as grass, imazapic, CL 263284 and CL 189215 (a glucoside of CL 263284 found in plants and in a very small amount in rats) are expected to be found above the LOQ of 0.5 mg/kg (in the residue trials) as demonstrated in the metabolism study and in residue trials.

The Meeting considered that the parent imazapic was a suitable residue for enforcement of MRLs and for calculating dietary intake for commodities of plant origin.

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

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

Residue is not fat-soluble.

Results of supervised residue trials on crops

The Meeting received supervised trial data for imazapic on conventional and transgenic soya beans, maize, rice, wheat, sugar cane, peanut, grasses and transgenic rape seed.

Soya bean (dry)

A total of 16 supervised trials were conducted on imidazolinone-tolerant soya beans (conventionally bred or transgenic) in different years in Brazil. However, as no GAP for soya bean was available, it was not possible to estimate a maximum residue level.

Maize

A total of five trials were conducted on imidazolinone-tolerant maize in 2010 in Brazil.

The registered use on imidazolinone-tolerant maize in Brazil allows one application at a maximum rate of 0.0525 kg ai/ha with a PHI of 96 days.

Residues of imazapic from trials matching GAP in Brazil were: < 0.01 (4) and < 0.1 mg/kg.

Although the number of trials matching GAP is small, as the metabolism studies indicate that no residues are expected in edible portion of food crops harvested at maturity and the residue trial data on other cereal grains (rice and wheat) indicate that residues were below the respective LOQ at even exaggerated application rates, the Meeting considered that no residues would be expected in maize grain.

The Meeting therefore estimated a maximum residue level and STMR of 0.01* and 0 mg/kg, respectively, for maize.

Rice

A total of 11 trials were conducted on imidazolinone-tolerant rice in Brazil in different years.

The registered use on imidazolinone-tolerant rice in Brazil allows up to two applications at a maximum rate of 0.025 kg ai/ha with a PHI of 60 days.

Residues of imazapic from trials matching GAP in Brazil were: < 0.05 (10) mg/kg. In many trials, 2 × GAP rate was used. In these trials, residues were all < 0.05 mg/kg (9).

The Meeting estimated a maximum residue level and STMR of 0.05 * and 0 mg.kg, respectively, for rice grain.

Wheat

Four trials were conducted for imidazolinone-tolerant wheat in Australia. The registered use of imazapic on wheat in Australia allows one application at a maximum rate of 0.021 kg ai/ha (only for imidazolinone-tolerant wheat) at 4 leaf (Z14) to the commencement of the flag leaf (Z37) stage. No PHI is required. Grazing and cutting for animal feed are not allowed for 4 weeks after application.

Residues of imazapic from trials matching GAP in Australia were: < 0.05 (2) mg/kg.

Although the number of trials matching GAP is small, as residues from trials using higher rate (up to 3.5 × GAP rate) were all < 0.05 mg/kg (total of 4), and the metabolism studies indicate that no residues are expected in edible portions of food crops harvested at maturity, the Meeting considered that no residues would be expected in wheat grain.

The Meeting therefore estimated a maximum residue level and STMR of 0.05* and 0 mg/kg, respectively for wheat.

Sugar cane

A total of 14 trials were conducted on sugar cane in Argentina, Australia, Brazil, Costa Rica and Guatemala.

The registered uses on sugar cane in these countries allow one application at a maximum rate of: 0.35 kg ai/ha with a PHI of 392 days in Argentina, 0.096 kg ai/ha in Australia, 0.245 kg ai/ha with a PHI of 283 days, 0.175 kg ai/ha with a PHI of 85 days in Costa Rica and Guatemala respectively.

The trial data were evaluated against GAP in Brazil. Residues of imazapic in sugar cane from trials matching GAP in Brazil were: < 0.01 (8) and < 0.05 (5) mg/kg. With shorter PHI or at 5 × GAP rate (two trials), residues were < 0.01 mg/kg.

The Meeting estimated a maximum residue level and STMR of 0.01* and 0 mg/kg, respectively, for sugar cane.

Peanut

A total of 17 trials were conducted on peanuts in Brazil (5) and in the USA (12) in different years.

The registered uses on peanut in these countries allow one application at a maximum rate of 0.098 kg ai/ha with a PHI of 70 days in Brazil; and 0.071 kg ai/ha with a PHI of 90 days in the USA.

Residues in peanuts from trials in Brazil matching Brazilian GAP were: < 0.05 (4) and < 0.1 mg/kg. Residues in peanut nutmeat from trials in the USA matching the GAP in the USA were: < 0.1 mg/kg (7). In the 12 trials using exaggerated rates (2× or 3× GAP rate), residues in nut, hull or nutmeat were all below the LOQ (0.05 or 0.1 mg/kg) (10).

The Meeting estimated a maximum residue level and STMR of 0.05* and 0 mg/kg, respectively for peanut.

The Meeting also estimated a median residue of 0 mg/kg for peanut hulls.

Rape seed

Three trials were conducted on imidazolinone-tolerant rape seed in Australia in 1997 and 1998.

The registered use on imidazolinone-tolerant rape seed in Australia allows one application at a maximum application rate of 0.0288 kg ai/ha at the 2–6 leaf stage of the crop. No PHI is required.

Residues of imazapic in rape seed from trials within

25% of GAP in Australia were: < 0.05 mg/kg (3). Residues from trials using exaggerated application rates (up to 2.4× GAP rate) were all < 0.05 mg/kg (2).

The Meeting estimated a maximum residue level and STMR of 0.05* and 0 mg/kg, respectively for rape seed.

Animal feed

Peanut fodder

Six trials involving peanut fodder were conducted in the USA in 1995. However, according to the GAP in the USA, grazing and feeding of treated peanut hay to livestock is not allowed. Therefore, there is no need to evaluate residues in peanut hay.

Wheat straw and fodder, dry, and forage

Five trials were conducted in Australia for wheat forage (four for straw).

According to GAP in Australia, grazing and cutting for stock feed are not allowed for 4 weeks after the application.

Residues of imazapic in wheat forage from trials matching GAP in Australia 4 weeks after application were: < 0.05 (3) mg/kg. Residues in forage from trials with exaggerated rates (up to 3.5× GAP rate; five trials) were < 0.05 mg/kg and residues in forage collected 15–19 days after application at any application rate were also < 0.05 mg/kg.

A median residue and highest residue were estimated for wheat forage at 0.05 and 0.05 mg/kg, respectively.

Residues of imazapic in wheat straw from trials matching GAP in Australia were: < 0.05 mg/kg (2). Residues in wheat straw from trials with exaggerated rates (up to 3.5× GAP rate) were all < 0.05 mg/kg (4).

The Meeting estimated a maximum residue level of 0.05* mg/kg for wheat straw and fodder, dry.

A median residue and highest residue for wheat straw and fodder, dry were 0 mg/kg.

Hay or fodder (dry) of grasses

A total of 10 trials were conducted on grasses in the USA.

The registered use on grasses in the USA allows one application at a maximum rate of 0.20 kg ai/ha after grass is full (100%) green-up for spring and summer application, or grass is dormant before green-up or full green-up for winter application. According to GAP cutting treated area for hay is not allowed within 7 days after treatment. There is no restriction on grazing on the label.

Residues of imazapic in forage from trials matching GAP in the USA were: 7.3, 7.5, 8.8, 10, 12, 13, 15, 15, 22 and 24 mg/kg.

The Meeting estimated a median residue and highest residue at 12.5 and 24 mg/kg respectively for grass forage on an "as received" basis.

Residues of imazapic in hay (> 7 DALA) from trials matching GAP in the USA were: < 0.50 (8), 0.91 and 2.3 mg/kg.

The Meeting estimated a maximum residue level, median residue and highest residue at 3, 0.5 and 2.3 mg/kg for hay or fodder (dry) of grasses, respectively.

Rape seed forage

Five trials were conducted in Australia for rape seed forage.

The approved uses in Australia do not allow grazing or cutting for stock feed for 6 weeks after application. Residues in rape seed forage 42 days after application at application rates within ±25% of the GAP rate were: < 0.05 (4) mg/kg.

The Meeting estimated a median residue and highest residue of 0.05 mg/kg.

Fate of residues during processing

High temperature hydrolysis

The hydrolysis of [^{14}C]-imazapic was investigated in sterile buffered aqueous solution.

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, 101–102% of the applied radioactivity remained. At the end of the incubation periods, the detectable radioactive component was unchanged imazapic only. Imazapic was stable under conditions representing pasteurization and baking/brewing/boiling and sterilization.

Processing

The Meeting received information on processing of soya beans.

A processing factor was calculated for the processing of soya beans to oil to be 0.14.

Processing factors for meal and hulls which can be fed to animals were also calculated but not reported here as no maximum residue level was recommended for soya beans, dry.

Residues in animal commodities

Estimation of dietary burdens

The maximum and mean dietary burdens were calculated using the highest residues or median residues of imazapic 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	0.401	0.094	48.0	25.0	96.0	50.0	5.72	2.71
Dairy cattle	43.2	22.5	57.6	30.0	96.0 [a]	50.0 [b]	11.2	5.34
Broilers	0.009	0.009	0.008	0.008	0	0	0.008	0.008
Layers	0.009	0.009	9.63 [c]	5.03 [d]	0	0	0.009	0.009

[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.

[c] Suitable for estimating maximum residue levels for meat, fat and edible offal of poultry and eggs.

[d] Suitable for estimating STMRs for meat, fat and edible offal of poultry and eggs.

Residues in milk and cattle tissues

Four groups of lactating Holstein cows, each group containing three animals, were orally dosed with imazapic in gelatine capsules using a balling gun for 28 days following afternoon milking at levels equivalent to 0, 67, 223, and 676 ppm in the feed. Milk samples were collected twice daily during the

dosing period with afternoon and morning milk pooled. Within 24 hours after the last dose, the cows were sacrificed. After sacrifice, loin muscle, omental fat, liver and kidney were collected and analysed.

In the lowest dose group (67 ppm), residues of imazapic in milk reached a plateau after Day 1 and averaged 0.025 mg/kg. In milk fat and kidney, average residues were 0.013 and 0.384 mg/kg, respectively. In muscle, liver and omental fat, average residues were < 0.050 mg/kg.

In the middle dose group (223 ppm), residues of imazapic in milk averaged 0.077 mg/kg. In milk fat and omental fat, average residues were 0.037 and 0.051 mg/kg, respectively. In loin muscle, kidney and liver, average residues were 0.054, 1.57 and 0.082 mg/kg, respectively.

In the highest dose group (676 ppm), residues of imazapic in milk averaged 0.274 mg/kg. In milk fat and omental fat, average residues were 0.127 and 0.051 mg/kg, respectively. In muscle, kidney and liver, average residues were 0.079, 2.71 and 0.192 mg/kg, respectively.

Levels of CL263284 were below the respective LOQ in all matrices and at all dosing levels.

The maximum and mean dietary burdens in cattle were 96 and 50 ppm of dry matter diet respectively for estimating a maximum residue level and STMR for milk and edible tissues. The maximum residue levels, STMRs and HRs for relevant commodities of animal origin were estimated using the residue levels in tissues and milk at 67 and 223 ppm feeding group.

	Feed level (ppm) for milk residues	Imazapic (mg/kg) in milk	Feed level (ppm) for tissue residues	Imazapic (mg/kg) in			
				Muscle	Liver	Kidney	Fat
Maximum residue level beef or dairy cattle							
Feeding study [a]	67 223	0.025 0.274	67 223	< 0.05 0.063	< 0.05 0.126	0.465 2.20	< 0.05 0.054
Dietary burden and highest residue	96	0.071	96	0.052	0.064	0.788	0.051
STMR beef or dairy cattle							
Feeding study [b]	67	0.025	67	< 0.05	< 0.05	0.384	< 0.05
Dietary burden and mean residue	50	0.019	50	< 0.05	< 0.05	0.287	< 0.05

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

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

The Meeting estimated STMRs of 0.019, 0.05, 0.05, 0.287 and 0.05 mg/kg for milk, meat, liver, kidney and fat, respectively.

Based on the above, the Meeting estimated maximum residue levels of 0.1, 0.1, 1 and 0.1 mg/kg respectively for milks, meat (from mammals other than marine mammals), edible offal (mammalian) and Mammalian fats (other than milk fat).

Residues in eggs and poultry tissues

No feeding study on laying hens was conducted as expected dietary burdens for hen were low and the metabolism studies showed extremely low residues remaining in hen tissues.

In the metabolism study, the TRR in all edible tissues and eggs from hens fed orally radiolabelled imazapic at doses equivalent to 2.1 and 10.9 ppm in feed for 7 days were below the LOQ of 0.01 mg/kg.

At the maximum calculated dietary burden of 9.63 ppm in feed, the residues in eggs and edible tissues were estimated to be < 0.01 mg/kg. The Meeting therefore estimated a maximum

residue level, STMR and HR at 0.01*, 0 and 0 mg/kg respectively applicable to poultry meat, poultry 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 and for estimation of dietary intake): *Imazapic*.

Residue is not fat-soluble.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Dietary Intakes (IEDIs) of imazapic were calculated for the 13 GEMS/Food cluster diets using STMRs estimated by the current Meeting (Annex 3). The ADI is 0–0.7 mg/kg bw and the calculated IEDIs were 0% of the maximum ADI. The Meeting concluded that the long-term intake of residues of imazapic resulting from the uses considered by the current JMPR is unlikely to present a public health concern.

Short-term intake

The 2013 JMPR decided that an ARfD is unnecessary. The Meeting therefore concluded that the short-term intake of residues of imazapic is unlikely to present a public health concern.

5.23 IMAZAPYR (267)

TOXICOLOGY

Imazapyr is the ISO-approved name of 2-[(RS)-4-isopropyl-4-methyl-5-oxo-2-imidazolin-2-yl]nicotinic acid (IUPAC), with CAS No. 81334-34-1. Imazapyr is a herbicide used for the control of grasses and broadleaf weeds in a variety of crops, including major uses in soya bean, sunflower, rice, maize, sugar cane, rape, wheat and non-crop areas such as vegetation management and forestry and minor uses in tobacco and oil palm. Imazapyr kills weeds by inhibiting the activity of the plant-specific enzyme acetohydroxyacid synthase, which catalyses the production of three branched-chain amino acids (valine, leucine and isoleucine) required for protein synthesis and cell growth.

Imazapyr 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.

Biochemical aspects

Imazapyr is quickly and extensively absorbed following oral administration to rats. There were no substantial sex differences in the absorption, elimination or distribution of radioactivity in rats receiving an oral dose of radiolabelled imazapyr. The majority of the administered dose was excreted in urine (68–95%) and, to a lesser extent, in faeces (5.5–33%). Most of the elimination occurred within the first 24 hours after dosing (57–91% in urine; 3–24% in faeces). The half-life of imazapyr in the rat was less than 1 day. Imazapyr was excreted mostly unchanged. Trace levels of polar and non-polar metabolites were formed and excreted in urine and faeces. Only trace amounts of tissue residues were detected in the liver and kidneys of the high-dose group, indicating no bioaccumulation.

Toxicological data

The oral LD_{50}s were greater than or equal to 5000 mg/kg bw in rats, rabbits and dogs, but some clinical signs were noted in dogs immediately after dosing. The dermal LD_{50}s in rats and rabbits were greater than 2000 mg/kg bw. Imazapyr appears to be of low acute inhalation toxicity, but characterization by this route was limited due to the high median particle sizes. Imazapyr was irritating to the eye but not irritating to the skin in rabbits. It was not a dermal sensitizer in guinea-pigs.

Repeated-dose toxicity studies in rats and dogs indicate no effects except for reduced body weight gain in a 28-day oral toxicity study in rats, in which there was decreased body weight gain in males at the highest dose tested, 10 000 ppm (equal to 1395 mg/kg bw per day). However, in two 13-week studies in rats, no treatment-related effects were observed up to 20 000 ppm (equal to 1740 mg/kg bw per day), and in a 1-year study in dogs, up to 10 000 ppm (equal to 282.1 mg/kg bw per day).

In two long-term oral toxicity and carcinogenicity tests in mice and rats (18 months in mice, 2 years in rats), no substance-related effects were observed. In the mouse study, no treatment-related effects occurred up to the highest dose tested (10 000 ppm, equal to 1301 mg/kg bw per day). Imazapyr did not show any carcinogenic potential. In rats, the NOAEL was the highest dose tested, 10 000 ppm (equal to 503 mg/kg bw per day). No compound-related tumours were observed. Three supplementary evaluations (two histopathological and one statistical) supported the results of the 2-year rat study.

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

Imazapyr was tested for genotoxicity in an adequate range of assays, both in vitro and in vivo. It showed no evidence of genotoxicity.

The Meeting concluded that imazapyr 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 imazapyr is unlikely to pose a carcinogenic risk to humans.

In a two-generation dietary reproductive toxicity study in rats, the NOAEL for parental and offspring toxicity was 10 000 ppm (equal to about 1471.8 mg/kg bw per day), the highest dose tested. There was also no effect on reproduction at the highest dose tested.

In a study of developmental toxicity in rats treated by gavage, salivation observed in 6 of 22 gravid females at 1000 mg/kg bw per day was considered to be due to the high dose and the irritating effect of the compound. The NOAEL for embryo and fetal toxicity was 1000 mg/kg bw per day, the highest dose tested.

In a pilot study for developmental toxicity in rabbits, treatment-related maternal toxicity, including death, was observed at 1000 mg/kg bw per day and above. This toxicity appears to have been due to local effects of the compound on the gastrointestinal tract. In the main study, the NOAEL for maternal and embryo and fetal toxicity was 400 mg/kg bw per day, the highest dose tested.

The Meeting concluded that imazapyr is not teratogenic in rats or rabbits.

In acute and subchronic neurotoxicity studies with imazapyr, there was no indication of neurotoxicity (including functional observational battery and motor activity measurements), with NOAELs of 2000 mg/kg bw and 924 mg/kg bw per day, respectively. Both doses were the highest doses tested.

The Meeting concluded that imazapyr is not neurotoxic.

In a 4-week dietary study in mice, no immunotoxic effects were seen up to the highest dose tested, 1668 mg/kg bw per day.

Toxicological data on metabolites and/or degradates

2,3-Pyridine dicarboxylic acid (PDC), a minor plant metabolite of imazapyr, is of low acute toxicity by the oral (LD_{50} > 5000 mg/kg bw) and dermal (LD_{50} > 2000 mg/kg bw) routes of administration. However, a greater number of clinical signs were observed post-dosing for the metabolite than for the parent. PDC is negative in the in vivo mouse micronucleus test. In a combined repeated-dose toxicity/reproductive and developmental toxicity study, in which rats were treated by gavage from 2 weeks premating through to 1 week post-mating in males and up to day 4 of lactation in females, the NOAEL for systemic and developmental toxicity was 1000 mg/kg bw per day, the highest dose tested.

Human data

No information is available on adverse health effects or poisoning in manufacturing plant personnel or in operators and workers exposed to imazapyr.

The Meeting concluded that the existing database on imazapyr 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, derived from a NOAEL of 282 mg/kg bw per day, the highest dose tested, from the 1-year study of oral toxicity in dogs. A safety factor of 100 was applied. Although imazapyr is generally of low toxicity, the Meeting concluded that an ADI was necessary because effects were observed at high doses in the 28-day oral toxicity study in rats.

The Meeting concluded that it was not necessary to establish an ARfD for imazapyr in view of its low acute 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 imazapyr

Species	Study	Effect	NOAEL	LOAEL
Mouse	Two-year study of toxicity and carcinogenicity[a]	Toxicity	10 000 ppm, equal to 1301 mg/kg bw per day[b]	—
		Carcinogenicity	10 000 ppm, equal to 1301 mg/kg bw per day[b]	—
Rat	Short-term studies of toxicity[a,c]	Toxicity	20 000 ppm, equal to 1740 mg/kg bw per day[b]	—
	Two-year studies of toxicity and carcinogenicity[a,c]	Toxicity	10 000 ppm, equal to 503 mg/kg bw per day[b]	—
		Carcinogenicity	10 000 ppm, equal to 503 mg/kg bw per day[b]	—
	Two-generation study of reproductive toxicity[a]	Reproductive toxicity	10 000 ppm, equal to 1471.8 mg/kg bw per day[b]	—
		Parental toxicity	10 000 ppm, equal to 1471.8 mg/kg bw per day[b]	—
		Offspring toxicity	10 000 ppm, equal to 1471.8 mg/kg bw per day[b]	—
	Developmental toxicity study[d]	Maternal toxicity	1000 mg/kg bw per day[b]	—
		Embryo and fetal toxicity	1000 mg/kg bw per day[b]	—
Rabbit	Developmental toxicity study[d]	Maternal toxicity	400 mg/kg bw per day[b,e]	—
		Embryo and fetal toxicity	400 mg/kg bw per day[b]	—
Dog	One-year study of toxicity[a]	Toxicity	10 000 ppm, equal to 282.1 mg/kg bw per day[b]	—

[a] Dietary administration.

[b] Highest dose tested.

[c] Two or more studies combined.

[d] Gavage administration.

[e] Maternal deaths occurred at higher doses in the pilot study, likely due to local effects.

Estimate of acceptable daily intake

0–3 mg/kg bw

Estimate of acute reference dose

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 imazapyr

Absorption, distribution, excretion and metabolism in mammals	
Rate and extent of oral absorption	Rapid; absorption is ~80%
Dermal absorption	No data
Distribution	Widely distributed
Potential for accumulation	None
Rate and extent of excretion	Rapid, 68–90% within 24 h, mainly via urine
Metabolism in animals	Minimal
Toxicologically significant compounds in animals, plants and the environment	Imazapyr
Acute toxicity	
Rat, LD_{50}, oral	> 5000 mg/kg bw
Rat, LD_{50}, dermal	> 2000 mg/kg bw
Rat, LC_{50}, inhalation	No reliable data
Rabbit, dermal irritation	Not irritating
Rabbit, ocular irritation	Irritating
Dermal sensitization	Non-sensitizing (Magnusson and Kligman test)
Short-term studies of toxicity	
Target/critical effect	No effect at highest dose tested
Lowest relevant oral NOAEL	282 mg/kg bw per day, the highest dose tested (dog)
Lowest relevant dermal NOAEL	400 mg/kg bw per day, the highest dose tested (rabbit)
Lowest relevant inhalation NOAEC	No data
Long-term studies of toxicity and carcinogenicity	
Target/critical effect	No effects at highest dose tested
Lowest relevant NOAEL	503 mg/kg bw per day, the highest dose tested (rat)
Carcinogenicity	Not carcinogenic
Genotoxicity	
	Not genotoxic

Reproductive toxicity	
Reproduction target/critical effect	No reproductive effects
Lowest relevant parental NOAEL	1471.8 mg/kg bw per day, the highest dose tested (rat)
Lowest relevant offspring NOAEL	1471.8 mg/kg bw per day, the highest dose tested (rat)
Lowest relevant reproductive NOAEL	1471.8 mg/kg bw per day, the highest dose tested (rat)
Developmental toxicity	
Developmental target/critical effect	None (but maternal deaths observed in pilot study, likely due to local effects)
Lowest relevant maternal NOAEL	400 mg/kg bw per day, the highest dose tested (rabbit)
Lowest relevant embryo/fetal NOAEL	400 mg/kg bw per day, the highest dose tested (rabbit)
Neurotoxicity	
	Not neurotoxic
Other toxicological studies	
Immunotoxicity	Not immunotoxic
Medical data	
	No information on health effects in manufacturing personnel

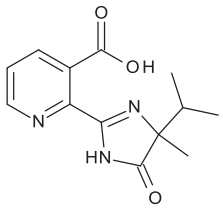
Summary

	Value	Study	Safety factor
ADI	0–3 mg/kg bw	One-year oral toxicity study (dogs)	100
ARfD	Unnecessary	—	—

RESIDUE AND ANALYTICAL ASPECTS

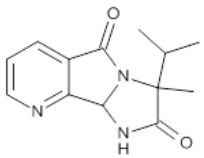
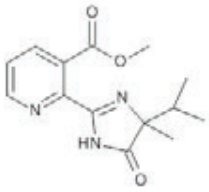
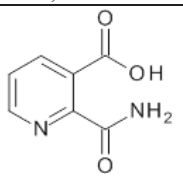
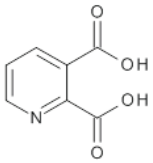
Residue and analytical aspects of imazapyr were considered for the first time by the present Meeting. The residue evaluation was scheduled for the 2013 JMPR by the Forty-fourth Session of the CCPR.

Imazapyr is a broad-spectrum herbicide in the imidazolinone family. Its primary use is as a post-emergence herbicide which is particularly effective on hard-to-control perennial grasses. It is non-selective, absorbed by foliage and rapidly translocated. The mode of action of imidazolinone herbicides is the inhibition of the enzyme acetohydroxyacid synthase (AHAS) which is a critical enzyme for the biosynthesis of branched chain amino acids necessary for cell growth and protein synthesis. The Meeting received information on identity, animal and plant metabolism, environmental fates in soil, rotational crops, analytical methods, storage stability, use patterns, supervised trials, farm animal feeding studies and fates of residues in processing.



2-[(*RS*)-4-isopropyl-4-methyl-5-oxo-2-imidazolin-2-yl] nicotinic acid. Imazapyr is a 1:1 mixture of the enantiomers.

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

CL 247, 087	CL 240,000	CL 60,032	PDC
			
5*H*-imidazo [1',2':1,2] pyrrolo [3,4-b] pyridine -2(3*H*),5-dione, 1.9b α(β)-dihydro-3α- isopropyl-3-ethyl-	2-(4-isopropyl-4-methyl-5-oxo-2-imidazolin-2-yl)-3 -carboxymethyl pyridine	2-carbamoyl-nicotinic acid	Pyridine 2,3-dicarboxylic acid

Animal metabolism

The Meeting received animal metabolism studies with imazapyr in rats, lactating goats and laying hens. The metabolism and distribution of imazapyr in animals were investigated using the [^{14}C-carboxyl], [^{14}C-6-pyridine] and [^{14}C-5-imidazole]-labelled imazapyr.

Metabolism in rats was summarized and evaluated by the WHO panel of the JMPR in 2013.

Lactating goats were dosed with [pyridine-6-^{14}C]-imazapyr as a single daily oral dosage equivalent to a dietary level of 17.7 or 42.5 ppm for 7 consecutive days. Radioactivity was mainly excreted in the urine (65.3% and 60.4%) and faeces (16.1% and 19.0%) of the dose in the 17.7 ppm and 42.5 ppm dosed goats, respectively).

The TRR levels were < 0.01–0.01 mg equiv/kg and 0.01–0.02 mg equiv/kg in the milk samples of the 17.7 and 42.5 ppm dose goats, respectively. TRR levels for leg and loin muscles, liver, and fat were all less than the LOQ (0.05 mg equiv/kg) and these tissues were not analysed further. Detectable residues were found in the kidneys at 0.08 mg equiv/kg (17.7 ppm dose) and 0.11 mg equiv/kg (42.5 ppm dose).

Kidney residues were quantitatively extractable, with the majority (95.5%) isolated in a methanol/water fraction. The extracted ^{14}C residue in the milk and kidney was identified as unchanged imazapyr.

Lactating goats received [imidazole-5-^{14}C]-imazapyr at a dose equivalent to 47 ppm in the diet once daily for 7 consecutive days. After seven days, 58.7% and 34.4% of the administered radioactive dose were excreted in the urine and faeces, respectively. The TRR levels for the dosed goat were 0.014–0.015 mg equiv/kg for milk and 0.074 mg equiv/kg for kidney.

The major component in the milk (day-7) extract (65.6% of TRR, 0.01 mg/kg) was the parent compound (imazapyr). Polar unknowns (total 14.7% of TRR) were also present in the milk extract.

Since these fractions were 0.002 mg equiv/kg and contained multiple components, no further characterization was attempted. Imazapyr was the predominant radioactive residue (81.9% of TRR, 0.061 mg/kg) in the kidney. Polar unknowns (total 11.6% of TRR) were also present in the kidney extract. The concentration of the remaining radioactive components in the kidney and the milk was below 0.01 mg equiv/kg individually.

Laying hens were orally dosed with [pyridine-6-^{14}C]-imazapyr at the actual dietary dose equivalent to 2.0 or 9.7 ppm in the feed for 7 consecutive days. The majority of the dose was rapidly eliminated in the excreta. Elimination of ^{14}C via the excreta accounted for 90.5 and 91.7% of the total dose for the low and high dose, respectively.

During treatment, TRR in the egg samples was less than the LOQ (0.01 mg equiv/kg). Residues in skin with adhering fat, muscle, liver and kidney tissues were all less than the LOQ (0.01 mg equiv/kg). Parent compound or derived residues are excreted without retention or accumulation in eggs and edible poultry tissues.

In animal metabolism studies, imazapyr was the major component in milk and kidney of lactating goat, but no residue was found in eggs and all tissues of laying hens.

Plant metabolism

Imazapyr is used in three different situations:

- Directed sprays for weed control (crop not intentionally treated)
- Use for weed control with a crop (crop treated)
- Selective use in genetically modified imidazolinone-resistant crops (crop treated)

Plant metabolism studies were conducted with imazapyr to investigate these three situations.

The Meeting received plant metabolism studies performed on soya bean, maize, sugarcane, oil palm, clover and Bermuda grass with imazapyr [^{14}C] labelled in two positions ([^{14}C-3-pyridine] and [^{14}C-6-pyridine]).

Directed sprays to weeds

In a sugar cane metabolism study, [pyridine-6-^{14}C]-imazapyr was applied to the soil surface once as a pre-emergence application at a rate equivalent to 0.28 kg ai/ha. Stalk samples were taken at maturity approximately 14 months after the pre-emergence treatment. There were no detectable residues in the treated samples.

In an oil palm metabolism study, [pyridine-6-^{14}C]-imazapyr was applied to the ground beneath an actively fruiting oil palm at an application rate of 1.0 kg ai/ha. Fruit samples were collected from the oil palm as they ripened at 0 hour, 7, 30 and 62 days after treatment. Palm oil was extracted from the fruits using a hexane: water mixture (3:1, v/v). Residual radioactivity levels were below the LOQ (0.03 mg equiv/kg) at any given time in the palm oil, aqueous phase, fruit marc, kernel shell and kernel nut. The results indicate that imazapyr derived residues will not accumulate in the palm oil of an actively fruiting oil palm after application to the ground beneath the palm.

Weed control

In a clover metabolism study, [pyridine-6-^{14}C]-imazapyr was applied to clover at a rate of 1.68 kg ai/ha. Clover foliage was collected at 0, 4, 10, 15 and 21 days after treatment (DAT). Phytotoxic effects were apparent four days after application of the test material to the clover in the test plot. The phytotoxicity remained apparent until the final collection 21 days after treatment. The TRR levels in foliage ranged from 23–49 mg equiv/kg. The majority of the radioactivity was unchanged imazapyr ranging from 68–99% of TRR. The major metabolite was CL 247,087 with CL 240,000 as a minor metabolite (their sum accounting for 0.02–18% of TRR).

In a Bermuda grass metabolism study, [pyridine-6-^{14}C]-imazapyr was applied to Bermuda grass at a rate of 1.68 kg ai/ha. Bermuda grass foliage was collected 0, 4, 10, 15 and 21 days after treatment (DAT). Phytotoxic effects were apparent four days after application of the test material to the Bermuda grass in the test plot. The phytotoxicity remained apparent until the final collection 21 days after treatment. TRR levels in foliage were the highest at 0 DAT (64 mg equiv/kg), and then were 18 mg equiv/kg (4 DAT), 22 mg equiv/kg (10 DAT), 25 mg equiv/kg (15 DAT) and 48 mg equiv/kg (21 DAT). The majority of the radioactivity was unchanged imazapyr ranging from 78–97% of TRR. Three other identified radio-components were PDC, CL 247,087 and CL 240,000. The amount of PDC increased with time to 13% of TRR at 21 DAT. The amount of CL 247,087 plus CL 240,000 ranged from 0% to 10.5% of TRR between 4 DAT and 21 DAT.

Imidazolinone-resistant crops

In a soya bean metabolism study, [pyridine-3-^{14}C]-imazapyr (SL formulation) was applied once to the above ground portion of transgenic soya bean plants at BBCH growth stage 65 at an application rate of 0.11 kg ai/ha. The forage was harvested approximately one hour after application and the hay was harvested 35 days after application. Soya bean straw, pods and seeds were harvested when mature at 98 days after treatment.

The TRR of soya bean forage was 0.66 mg equiv/kg, soya bean hay was 0.25 mg equiv/kg, soya bean seed was 0.062 mg equiv/kg, soya bean straw was 0.079 mg equiv/kg and soya bean pod was 0.15 mg equiv/kg. Imazapyr was detected in all matrices and was the most abundant component of the residue in soya bean forage (0.60 mg/kg, 93.6% TRR), hay (0.094 mg/kg, 37.3% TRR), and seed (0.024 mg/kg, 34.2% TRR). Imazapyr was present in straw at 0.006 mg/kg (8.1% TRR) and pods at 0.018 mg/kg (12.7% TRR). A polar component M3 was the most abundant component in the pods (0.041 mg equiv/kg, 28.9% TRR). This component was also present in hay (0.028 mg equiv/kg, 11.1% TRR), straw (0.009 mg equiv/kg, 12.2% TRR) and seeds (0.0161 mg equiv/kg, 23.3% TRR), but was not detected in forage. This polar peak was isolated from the soya bean seeds, and shown to consist of multiple components, each present at ≤ 0.004 mg equiv/kg. M19 was present in the straw at 0.013 mg equiv/kg (17.6% TRR) and was also found in hay at 0.022 mg equiv/kg (8.7% TRR). This component had an intermediate polarity with a retention time of about 19 minutes and was not identified.

In a maize metabolism study, [pyridine-6-^{14}C]-imazapyr was applied to imidazolinone-resistant maize at the 3 to 4 leaf growth stage at treatment rates of 0.028 and 0.080 kg ai/ha. Samples of maize plants were harvested at 0 DAT (green plant), 14 DAT (green plant), 30 DAT (early forage), and 62 DAT (late forage). At maturity (114 DAT), the stalks, husks, and cobs with grain were collected.

For the 0 DAT, 96.3% (2.37 mg equiv/kg) of the TRR was extracted. For the 114 DAT fodder, 69.9% (0.020 mg equiv/kg) of the TRR was extracted and 30.1% (0.008 mg equiv/kg) remained in the PES. For the 114 DAT grain, 0.8 to 1.5% (< 0.002 mg equiv/kg) was extracted with hexane, 80.0 to 88.8% (0.023 to 0.076 mg equiv/kg) was extracted with methanol:water:hydrochloric acid (80:18:2, v/v/v), and 10.3 to 18.5% (0.005 to 0.009 mg equiv/kg) remained in the PES. Parent imazapyr constituted the major component of the extractable residue in the green plant, forage, fodder and grain (16.8 to 84.0% of extracted TRR, 0.003 to 2.0 mg/kg). The residue levels of the minor components in the 30 DAT to 114 DAT samples were all < 0.01 mg equiv/kg.

In the plant metabolism studies on soya bean (imidazolinone-resistant), maize (imidazolinone-resistant), sugarcane, oil palm, clover and Bermuda grass, Imazapyr is the major component of the residues found in soya bean, maize, clover, and Bermuda grass. CL 247,087 and PDC were also significant components of the residues in clover and Bermuda grass.

Environmental fate

The Meeting received information on aerobic soil metabolism, soil photolysis, rotational crop and hydrolysis.

In soil under the aerobic conditions, the DT_{50} ranged from 15 months–7.5 years at 20 °C–35 °C. At 12 months after application, imazapyr remained in soil was 60.5–89.3% of the applied radioactivity. Minor degradates were identified as PDC, CL 60,032 and CL 240,000.

In soil photolysis study, there was 11% degradation of imazapyr over the 28 days of continuous irradiation. There were at least five degradation products formed, none of which accounted for > 10% of the applied dose. The photodegradation half-life of imazapyr was 149 days at 25 °C.

In confined rotational crop study, rotational crops (wheat, radish, lettuce and soya bean) were planted at 120 days after treatment (DAT) for wheat, 271 DAT for radish, lettuce and soya bean, 420 DAT for radish and lettuce. The test substance was applied as a post-emergence application to imidazolinone-resistant maize plants at the 6-leaf stage at a rate of 0.028 kg ai/ha.

The TRR in wheat forage, straw and grain; lettuce; radish foliage and root; and soya bean forage, hay, and seed were all < 0.002 mg/kg, the limit of detection of the radio assay.

A series of rotational crops, namely carrot and lettuce were planted at 330 and 540 DAT, winter wheat planted at 359 DAT, spring wheat at 520 DAT. A single application of [^{14}C] imazapyr was made to the soil at a rate of 0.885 kg ai/ha which is 10 times the highest GAP rate for crops used in rotation.

The TRR in follow crops were at < 0.01 to 0.02 mg equiv/kg at the various plant back intervals. Residue in the rotational crops included the unchanged imazapyr which ranged from < 0.001 to 0.003 mg/kg. Metabolites were not detected (< 0.001 mg/kg). The Meeting noted that residues are not expected on rotational crops.

Imazapyr is used for paddy rice. In an hydrolysis study, imazapyr was stable in water (pH 5, 7 and 9) at 25 °C.

Methods of analysis

The Meeting received description and validation data for analytical methods for residues of imazapyr in plant and animal commodities.

In most of the methods for determination of imazapyr in plants, homogenized samples were extracted with acidic aqueous methanol or acidic aqueous acetone, and the extract was cleaned up with column chromatography using solid phase extraction and/or strong cation exchange cartridges. Residues were determined by HPLC with UV or MS/MS detection. The methods of analysis for a range of substrates were validated with LOQs of the 0.05 mg/kg for imazapyr.

In the methods for animal commodities, homogenized samples were extracted with acidic solvent, and the extract was cleaned up by solvent partition and solid phase extraction. Residue of imazapyr was determined by capillary electrophoresis with UV detection. The methods of analysis were validated with the LOQ of 0.01 mg/kg for milk and milk fat, and 0.05 mg/kg for tissues of cattle.

No multi-residue method was submitted.

Stability of residues in stored analytical samples

The Meeting received information on the freezer storage stability of imazapyr in plant (maize grain, forage and fodder and soya bean seed), their processed (soya bean meal and oil) commodities and animal products.

Storage stability results indicate that imazapyr residue was stable for at least 3 months in soya bean (seed, laminated soya bean, meal and oil), at least 6 months in milk, at least 8 months in muscle and liver, and at least 27 months in maize (grain, forage and fodder).

The periods of storage stability studies generally cover the sample storage intervals of residue trials.

Definition of the residue

In the lactating goat metabolism studies, TRRs in kidney (0.074–0.11 mg equiv/kg) was higher than those in milk (< 0.01–0.02 mg equiv/kg), liver (< 0.05 mg equiv/kg), muscle (< 0.05 mg equiv/kg) and fat (< 0.05 mg equiv/kg). Imazapyr is the major component of the residue in kidney (82% TRR) and milk (67% TRR). The concentration of the remaining radioactive components in the kidney and milk were below 0.01 mg/kg.

The Meeting decided that imazapyr is suitable analytes for enforcement purposes and dietary risk assessment in animal commodities.

The octanol/water coefficient (log P_{ow}) of imazapyr is –3.96 at 20 °C (pH 7). The Meeting considered the residue of imazapyr is not fat soluble.

In plant metabolism studies, parent imazapyr was a major component (8.1–99% TRR) in soya bean (forage, hay, seed, straw and pods), maize (forage, grain and fodder), clover and Bermuda grass. Imazapyr was a major compound in conventional and tolerant crops. Though PDC was found as a significant compound in Bermuda grass (13% TRR) which is a feed commodity, it may not be necessary to consider this compound for the definition of residue for food commodities.

The Meeting decided that parent imazapyr is a suitable analyte for enforcement purposes and dietary risk assessment in plant commodities.

The Meeting recommended the following residue definition:

For plants and animals the definition of the residue (for compliance with the MRL and for estimation of dietary intake): *Imazapyr*

The residue is not fat soluble

Results of supervised residue trials on crops

The Meeting received supervised trial data for the foliar application of imazapyr on lentils, soya bean, maize, rice, wheat, sugar cane, rape and sunflower. Residue trial data was made available from Argentina, Australia, Brazil, Canada, Uruguay and the USA.

Labels were available from Australia, Canada, Latin American countries and the USA describing the registered uses of imazapyr.

Pulses

Lentil (dry)

Data were available from supervised trials on imidazolinone-tolerant lentils in Canada.

The GAP for imidazolinone-tolerant lentil in Canada is a foliar application at a maximum rate of 0.0091 kg ai/ha with a PHI of 60 days.

Imazapyr residues in lentil seeds from independent trials in Canada matching GAP were (n=4): 0.06 (2) and 0.08 (2) mg/kg.

Based on the trials for lentils in Canada, the Meeting estimated a maximum residue level and an STMR value for imazapyr in lentil seeds of 0.3 and 0.07 mg/kg respectively.

Soya bean (dry)

Data were available from supervised trials on imidazolinone-tolerant soya beans in Brazil.

No GAP of Brazil was available for imidazolinone-tolerant soya beans.

The Meeting agreed that no recommendation could be made for soya beans.

Cereal grains

Maize

Data were available from supervised trials on imidazolinone-tolerant maize in Argentina, Brazil, Australia and the USA.

The GAP for imidazolinone-tolerant maize of Argentina is for a foliar application at a maximum rate of 0.025 kg ai/ha with the application timed before reaching 6th fully developed leaf stage.

Imazapyr residues in maize grains from trials in Argentina matching GAP were (n=7): < 0.05 (7) mg/kg.

Trials from Australia on maize were reported for a foliar application of a SL formulation (GAP: a foliar application at a rate of 0.018–0.022 kg ai/ha with a PHI not required when used as directed at the application timing at the 2–6 leaf stage of the crop). Imazapyr residue in maize grain from data in Australia at an exaggerated rate of 0.032 kg ai/ha (1.5 × GAP rate) were < 0.05 (2) mg/kg and at 0.048 kg ai/ha (2.2 × GAP rate) were < 0.05 (2) mg/kg.

The GAP on imidazolinone-tolerant maize of the USA is for a foliar application at a maximum rate of 0.016 kg ai/ha with a PHI of 45 days at the application timed at before the 6 leaf stage of the crop. However, imazapyr residue trials on maize in the USA did not match the GAP of the USA.

The Meeting decided to use the data of imazapyr residues in maize grain from the trials in Argentina.

Based on the trials for maize in Argentina, the Meeting estimated a maximum residue level, an STMR value for imazapyr in maize of 0.05 (*) and 0.05 mg/kg respectively.

Rice

Data were available from supervised trials on imidazolinone-tolerant paddy rice in Brazil.

The GAP for imidazolinone-tolerant rice of Brazil is two foliar applications at a maximum rate of 0.074 kg ai/ha with a PHI of 60 days.

Trials from Brazil on rice were reported for two foliar applications at a rate of 0.12 kg ai/ha with a PHI of 60 days. Imazapyr residues in rice grains from trials at a rate of 0.12 kg ai/ha in Brazil were (n=4): < 0.05 (3) and 0.05 mg/kg. However, the trials for rice in Brazil were considered insufficient to estimate a maximum residue level for the commodity.

The Meeting could not estimate a maximum residue level for imazapyr in rice.

Wheat

Data were available from supervised trials on imidazolinone-tolerant wheat in Australia.

The GAP on imidazolinone-tolerant wheat of Australia is for a foliar application at a rate of 0.004–0.007 kg ai/ha with a PHI not required for wheat grains when used as directed.

Imazapyr residues in wheat grains from trials in Australia matching GAP were (n=3): < 0.05 (3) mg/kg. Imazapyr residues in wheat grains from data in Australia at exaggerated rate of 0.014 kg ai/ha (2 × GAP rate) were < 0.05 (5) mg/kg and at 0.028 kg ai/ha (4 × GAP rate) were < 0.05 (5) mg/kg.

Based on the trials for wheat in Australia, the Meeting estimated a maximum residue level and an STMR value for imazapyr in wheat grain of 0.05 (*) and 0 mg/kg respectively.

Grasses for sugar or syrup production

Sugar cane

Data were available from supervised trials on sugar cane in Argentina and Brazil.

The GAP on sugar cane of Argentina is two applications with a spray to weeds at a maximum rate of 0.5 kg ai/ha, 30–45 days before planting. The GAP on sugar cane of Brazil is an application with a spray to weeds of a rate of 0.13–0.5 kg ai/ha with a PHI not required when used as directed.

Imazapyr residue in sugar cane from trials in Argentina matching GAP was (n=1): < 0.05 mg/kg. However, the trial for sugar cane in Argentina was insufficient to estimate a maximum residue level for the commodity.

The Meeting could not estimate a maximum residue level for imazapyr in sugar cane.

Oilseeds

Rape seed

Data were available from supervised trials on imidazolinone-tolerant rape from Australia and Canada.

The GAP on imidazolinone-tolerant rape of Canada is a foliar application at a maximum rate of 0.0091 kg ai/ha with a PHI of 60 days.

Imazapyr residues in rape seeds from independent trials in Canada matching GAP were (n=10): < 0.05 (10) mg/kg.

Trials from Australia on rape were reported for a foliar application of a WG formulation (GAP: a foliar application at a rate of 0.0045–0.011 kg ai/ha with a PHI not required when used as directed).

Imazapyr residues in rape seeds from trials in Australia matching GAP were (n=2): < 0.05 (2) mg/kg. Imazapyr residues in rape seeds from data in Australia at an exaggerated rate of 0.028 kg ai/ha (2.3 × GAP rate) were < 0.05 (2) mg/kg.

Based on the trials for rape seeds in Canada and Australia, the Meeting estimated a maximum residue level, an STMR value for imazapyr in rape seed of 0.05 (*) and 0 mg/kg respectively.

Sunflower seed

Data were available from supervised trials on imidazolinone-tolerant sunflower in Argentina and Uruguay.

The GAP on imidazolinone-tolerant sunflowers of Argentina and Uruguay is a foliar application at a maximum rate of 0.080 kg ai/ha with the application timing of early post emergence.

Imazapyr residues in sunflower seeds from trials in Argentina and Uruguay approximating GAP were (n=15): < 0.01 (10), 0.01, 0.03 (2) and < 0.05 (2) mg/kg.

Based on the trials for sunflower in Argentina and Uruguay, the Meeting estimated a maximum residue level and an STMR value for imazapyr in sunflower seed of 0.08 and 0.01 mg/kg respectively.

Animal feedstuffs

Maize fodder and forage

Data were available from supervised trials on imidazolinone-tolerant maize in Argentina, Australia and the USA.

Trials from Argentina on maize forage were reported for the foliar application of SC or WG formulation (GAP: a foliar application of a maximum rate of 0.025 kg ai/ha, the application timing before reaching 6th fully developed leaf status).

Trials from Australia on maize forage were reported for the foliar application of a SL formulation (GAP: a foliar application of a rate of 0.018–0.022 kg ai/ha at the application timing of 2–6 leaf stage of the crop, do not graze or cut for stock food for 4 weeks after application and not required for the harvest of grain when used directed).

Trials from the USA on maize fodder and forage were reported for the foliar application of ASU or WP formulation at a rate of 0.027 kg ai/ha (GAP: a foliar application of a maximum rate of 0.016 kg ai/ha, PHI of 45 days at the application timing of before 6 leaf stage for crop).

Maize fodder

In the residue trials for imazapyr on maize fodder in the USA, no samples were collected at 45 days after application, i.e., as per GAP. The Meeting could not estimate a maximum residue level for imazapyr in maize fodder.

Maize forage

Imazapyr residues in maize forage from trials in Argentina matching GAP were (n=4): < 0.05 (4) mg/kg on an as received basis. Imazapyr residues in maize forage from data in Argentina at exaggerated rate of 0.040 kg ai/ha (1.6 × GAP rate) were < 0.05 (4) mg/kg and 0.050 kg ai/ha (2 × GAP rate) were < 0.05 (4) mg/kg.

Imazapyr residues in maize forage from data in Australia at exaggerated rate of 0.032 kg ai/ha (1.5 × GAP rate) were < 0.05 (2) mg/kg and 0.048 kg ai/ha (2.2 × GAP rate) were < 0.05 (2) mg/kg.

Imazapyr residues in maize forage from trials in the USA at exaggerated rate of 0.027 kg ai/ha (1.7 × GAP rate) were < 0.05 (18) mg/kg on an as received basis.

Based on the residues in maize forage from trials in Argentina, Australia and the USA, the Meeting estimated a median residue value and a highest residue value for imazapyr in maize forage both at 0 mg/kg.

Wheat straw and forage

Data were available from supervised trials on imidazolinone-tolerant wheat in Australia.

Trials from Australia on wheat were reported for the foliar application of a SL formulation (GAP: a foliar application of a rate of 0.004–0.007 kg ai/ha, do not graze or cut for stock food for 4 weeks after application and not required to harvest for grains when used directed).

Wheat straw

Imazapyr residues in wheat straw from trials in Australia matching GAP were (n=3): < 0.05 (3) mg/kg as received basis. Imazapyr residues in wheat straw from data in Australia at exaggerated rate of 0.014 kg ai/ha (2 × GAP rate) were < 0.05 (5) mg/kg and 0.028 kg ai/ha (4 × GAP rate) were < 0.05 (5) mg/kg.

Based on the residues in wheat straw from trials in Australia, the Meeting estimated a maximum residue level, a median residue value and a highest residue value for imazapyr in wheat straw and fodder of 0.05 (*), 0 and 0 mg/kg respectively.

Wheat forage

Imazapyr residues in wheat forage from trials in Australia matching GAP were (n=3): < 0.05 (3) mg/kg as received basis. Imazapyr residues in wheat forage from data in Australia at exaggerated rates of 0.014 kg ai/ha (2 × GAP rate) were < 0.05 (5) and 0.087 mg/kg, and 0.028 kg ai/ha (4 × GAP rate) were < 0.05 (5) and 0.11 mg/kg as received basis.

Based on the residues in wheat forage from trials in Australia, the Meeting estimated a median residue value and a highest residue value for imazapyr in wheat forage both at 0.05 mg/kg.

Rape forage

Data were available from supervised residue trials on imidazolinone-tolerant rape in Australia.

Trials from Australia on rape were reported for the foliar application of a WG formulation (GAP: a foliar application of a rate of 0.005–0.012 kg ai/ha, do not graze or cut for 5 weeks).

Imazapyr residues in rape forage from trials in Australia matching GAP were (n=1): < 0.05 mg/kg. Imazapyr residues in rape forage from data in Australia at an exaggerated rate of 0.028 kg ai/ha (2.3 × GAP rate) or at DALA 25–29 days were < 0.05 (4) mg/kg.

Based on the residues in rape forage from trials in Australia, the Meeting estimated a median residue value and a highest residue value for imazapyr in rape forage both at 0 mg/kg.

Fate of residues during processing

High temperature hydrolysis

The degradation of [^{14}C] imazapyr was studied under hydrolytic conditions at high temperatures in sterile aqueous buffers at pH 4, 5 and 6 for periods of up to 60 minutes to simulate common processing practice (pasteurization, baking/brewing/boiling, and sterilization). No degradates were detected at any of the investigated pH and temperature ranges. Imazapyr is stable under hydrolytic conditions at high temperatures.

Residues in processed commodities

The fate of imazapyr residues were examined in maize grains, rape seeds and sunflower seed processing studies. Based on the results of processing studies conducted in Canada and the USA in combination with the residues from supervised trials, the Meeting concluded that no residues are expected in processed rape and sunflower commodities. Estimated processing factors and the derived STMR-Ps are summarized in the Table below.

Processing factors, STMR-P and HR-P for food and feed

Raw agricultural commodity (RAC)	Processed commodity	Calculated processing factors*	PF (Mean or best estimate)	RAC STMR (mg/kg)	STMR-P (mg/kg)
Maize grain	Meal	1.2	1.2	0.05	0.06
	Crude oil	< 0.50	< 0.50		0.025

* Each value represents a separate study. The factor is the ratio of the residue in processed commodity divided by the residue in the RAC.

Residue in animal commodities

Farm animal dietary burden

The Meeting estimated the dietary burden of imazapyr in farm animals on the basis of the diets listed in Appendix IX of the FAO Manual 2009. Calculation from highest residue, STMR (some bulk commodities) and STMR-P values provides levels in feed suitable for estimating MRLs, while calculation from STMR and STMR-P values for feed is suitable for estimating STMR values for animal commodities. The percentage dry matter is taken as 100% when the highest residue levels and STMRs are already expressed in a dry weight basis.

Estimated maximum and mean dietary burdens of farm animals

Dietary burden calculations for beef cattle, dairy cattle, broilers and laying poultry are provided in Appendix IX of the FAO manual. The calculations were made according to the animal diets from US-Canada, EU, Australia and Japan in the Table (Appendix IX of the FAO manual).

Livestock dietary burden, imazapyr, ppm of dry matter diet

	US-Canada		EU		Australia		Japan	
	Max	Mean	Max	Mean	Max	Mean	Max	Mean
Beef cattle	0.063	0.063	0.085	0.085	0.20 [a]	0.20 [b]	0.061	0.061
Dairy cattle	0.083	0.083	0.057	0.057	0.15	0.15 [c]	0.045	0.045
Poultry—broiler	0.056d	0.056e	0.040	0.040	0.014	0.014	0.040	0.040
Poultry—layer	0.056	0.056	0.073 [d]	0.073 [e]	0.014	0.014	0.045	0.045

[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

[d] Highest maximum broiler poultry dietary burden suitable for MRL estimates for poultry meat, fat, edible offal and eggs

[e] Highest mean broiler poultry dietary burden suitable for STMR estimates for poultry meat, fat, edible offal and eggs

Farm animal feeding studies

The Meeting received a lactating dairy cow feeding study using imazapyr, which provided information on likely residues resulting in animal commodities and milk from imazapyr residues in the animals' diet.

A poultry feeding study was not submitted as the expected residues of imazapyr in poultry feed were extremely low. A poultry metabolism study at a dose rate of 9.7 ppm imazapyr in the feed

demonstrated that there was very low transfer to eggs and tissues with all residues of imazapyr less than 0.01 mg/kg.

Lactating dairy cows

Lactating dairy cows were dosed with imazapyr for 28–29 days at the dose equivalent to 58, 157, 607 and 1680 ppm in the diet. Residues of imazapyr were at or less than the LOQ (0.01 mg/kg) in whole milk at 58 ppm of feeding level. In the three higher dose groups (157, 607 and 1680 ppm feed), imazapyr residues in milk reached a plateau after 2–3 days. In kidney, imazapyr was detected as the highest concentrations among all tissues and milk in all treated groups.

Animal commodities maximum residue levels

For MRL estimation, the residue in the animal commodities is imazapyr.

The maximum dietary burden for beef and dairy cattle is 0.20 and is lower than the dose level in the lactating goat metabolism study of 18 ppm and the lactating cow feeding study of 58 ppm. In the metabolism study, in which imazapyr equivalent to 18 ppm in the diet was dosed to lactating goats for 7 consecutive days, residues of imazapyr were detected at 0.01 mg/kg in milk and 0.08 mg/kg in kidney. The maximum dietary burden for beef and dairy cattle is 1% of the dose rate in feed of the metabolism study.

The Meeting estimated a maximum residue level of 0.01 (*) mg/kg and an STMR value of 0 mg/kg in milk.

The Meeting estimated a maximum residue level of 0.05 (*) mg/kg, an STMR value of 0 mg/kg and an HR value of 0 mg/kg in mammalian meat and fat.

The Meeting estimated a maximum residue level of 0.05 (*) mg/kg, an STMR value and an HR value of 0.0008 in mammalian edible offal.

The maximum dietary burden for broiler and layer poultry is 0.073 and is lower than the dose level in the laying hen metabolism study of 9.7 ppm. In the metabolism study, in which imazapyr equivalent to 9.7 ppm in the diet was dosed to laying hens for 7 consecutive days, no residues of imazapyr exceed 0.01 mg/kg were detected in tissues and eggs.

The Meeting estimated a maximum residue level of 0.01 (*) mg/kg, an STMR value of 0 mg/kg and an HR value of 0 mg/kg in poultry meat, fat, edible offal and eggs.

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.

Plant and animal commodities:

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

The residue is not fat soluble.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Daily Intakes (IEDIs) of imazapyr were calculated for the 13 GEMS/Food cluster diets using STMRs/STMR-Ps estimated by the current Meeting (Annex 3). The ADI is 0–3 mg/kg bw and the calculated IEDIs were 0% of the maximum ADI (3 mg/kg bw). The Meeting concluded that the long-term intakes of residues of imazapyr, resulting from the uses considered by current JMPR, are unlikely to present a public health concern.

Short-term intake

The 2013 JMPR decided that an ARfD is unnecessary. The Meeting therefore concluded that the short-term intake of residues of imazapyr is unlikely to present a public health concern.

5.24 INDOXACARB (216)

RESIDUE AND ANALYTICAL ASPECTS

Indoxacarb was previously evaluated by the JMPR in 2005 (T, R), 2007 (R), 2009 (R) and 2012 (R), the Meeting established an ADI of 0–0.01 mg/kg bw and an ARfD of 0.1 mg/kg bw. At the Forty-fifth Session of the CCPR, indoxacarb was scheduled for the evaluation by the current Meeting for the additional use on tea (REP13/PR-Appendix XIV).

Definition of the residue for compliance with the MRL for all commodities and for estimation of dietary intake for plant commodities is sum of indoxacarb and its R enantiomer. Definition of the residue for estimation of dietary intake for animal commodities is sum of indoxacarb, its R enantiomer and methyl 7-chloro-2,5-dihydro-2-[[[4-(trifluoromethoxy)phenyl] amino]carbonyl]indeno[1,2-e][1,3,4]oxadiazine-4a(3H)-carboxylate, expressed as indoxacarb. The residue is fat soluble.

Methods of analysis

The Meeting received descriptions and validation data for analytical methods for residues of indoxacarb in tea and tea infusion samples.

Fresh tea leaf or tea leaf sample was extracted with water, acetonitrile and ammonia, with the addition of NaCl before centrifugation. The supernatant underwent clean-up with SPE cartridge, and centrifuged again. The supernatant was filtered and analysed by UPLC-MS/MS.

Crushed and blended tea leaves were added into boiling water, and filtered. Cool tea infusion was cleaned up with SPE cartridge and analysed with UPLC-MS/MS.

Recoveries ranged from 95.7% to 107% and validated LOQs were 0.0004 mg/kg for tea infusions, 0.01 mg/kg for fresh tea leaves and 0.02 mg/kg for tea.

Stability of residues in stored analytical samples

The Meeting received information on the stability of residues in tea.

The storage test showed that residues of indoxacarb in tea sample under -18 °C were stable for at least 6 months.

Results of supervised residue trials on tea

The Meeting received supervised trials data for indoxacarb uses on tea plants.

Eight trials were conducted on tea in China (maximum GAP: 0.050kg ai/ha, 2 applications, 10-day PHI) in 2010, 2011 and 2012. Two green tea trials and six black tea trials were available from Zhejiang, Hunan and Fujian, respectively. In the total of eight trials conducted at the maximum Chinese GAP, residues in tea leaves, median underlined, were: 0.13, 0.14, 0.33, <u>0.40</u>, <u>0.42</u>, 0.45, 1.97 and 2.60 mg/kg. The Meeting estimated a maximum residue level and an STMR value for indoxacarb in Tea, green, black (black, fermented and dried) of 5 and 0.41 mg/kg.

Fate of residues during storage and processing

The Meeting received information on the fate of indoxacarb residues during the storing and processing of tea.

Residues of indoxacarb stored under -25 ^{o}C were stable for at least 6 months.

The processing factor for tea infusion (0.062) was applied to the STMR of tea (0.41 mg/kg) to estimate an STMR-P value for tea infusion of 0.025 mg/kg.

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.

Definition of the residue for compliance with the MRL for all commodities and for estimation of dietary intake for plant commodities: *sum of indoxacarb and its R enantiomer*.

Definition of the residue for estimation of dietary intake for animal commodities: *sum of indoxacarb, its R enantiomer and methyl 7-chloro-2,5-dihydro-2-[[[4-(trifluoromethoxy)phenyl] amino]carbonyl]indeno[1,2-e][1,3,4]oxadiazine-4a(3H)-carboxylate, expressed as indoxacarb*.

The residue is fat soluble.

Dietary Risk Assessment

Long-term intake

The Meeting noted that the new estimation for tea did not result in a significant change in long-term dietary intake and concluded that the long-term intake of residues of indoxacarb resulting from the uses of indoxacarb considered by the present JMPR is unlikely to present a public health concern.

Short-term intake

The IESTI of indoxacarb calculated on the basis of the recommendations of tea made by the JMPR 1% of the ARfD (0.1 mg/kg bw) for child and general population.

The Meeting therefore concluded that the short-term intake of indoxacarb residues in tea, when used in ways that have been considered by the JMPR, is unlikely to present a public health concern.

5.25 ISOXAFLUTOLE (268)

TOXICOLOGY

Isoxaflutole is the ISO-approved name for 5-cyclopropyl-4-(2-methylsulfonyl-4-trifluoromethyl-benzoyl)-isoxazole (IUPAC), with CAS No. 141112-29-0. Isoxaflutole is an isoxazole herbicide that is used as a pre-emergent or early post-emergence broadcast treatment for the control of broadleaf and grass weeds. Its primary target in plants is the enzyme 4-hydroxyphenylpyruvate dioxygenase (HPPD); inhibition of the enzyme results in the bleaching of weeds due to the blockage of phenylquinone biosynthesis.

Isoxaflutole 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.

Biochemical aspects

Following oral gavage dosing of rats, isoxaflutole was rapidly absorbed: about 70% after low dose (1 mg/kg bw) administration and about 40% after high dose (100 mg/kg bw) administration. The maximum concentrations in blood (C_{max}) were achieved between 0.5 and 1 hour post-dosing. Only about 1.5–4.4% of the dose was recovered in the tissues (e.g. kidney, liver, blood and plasma) 7 days after dosing. The elimination of the radioactivity associated with [^{14}C]isoxaflutole following oral administration was rapid, with the majority (80%) of the radioactivity being eliminated within 48 hours at the high dose level and within 24 hours at the low dose level. The urine was the major route of elimination for the low-dose groups (about 69–74% of the dose), whereas faeces was the major route of elimination for the high-dose group (about 55–63% of the dose). Isoxaflutole and/or its metabolites have a mean β-phase elimination half-life of about 60 hours, irrespective of the dose level. Up to nine radiolabelled components were found in the urine, and up to 11 in the faeces. The major component identified in urine, faeces and liver was a diketonitrile (RPA 202248, or 3-cyclopropyl-2-[2-mesyl-4-trifluoromethylbenzoyl]-3-oxopropane nitrile), followed by RPA 203328 (2-mesyl-4-trifluoromethylbenzoic acid). Unchanged isoxaflutole was detected primarily in faeces in the high-dose animals. There were no sex differences in absorption, distribution or metabolism.

Toxicological data

The acute oral LD_{50} in rats was greater than 5000 mg/kg bw, and the acute dermal LD_{50} in both rats and rabbits was greater than 2000 mg/kg bw. The acute inhalation LC_{50} in rats was greater than the maximum achievable concentration of 5.23 mg/L air. Isoxaflutole was non-irritating to rabbit skin and minimally irritating to rabbit eyes. It was not a skin sensitizer in guinea-pigs, as determined by the Buehler method and the Magnusson and Kligman test.

The liver was the primary target organ in mice, rats and dogs in repeated-dose toxicity studies. Thyroid, kidney and the haematopoietic system were also target organs in dogs and rats. Corneal opacity was observed in repeated-dose toxicity studies in rats, but not in mice or dogs.

In a 28-day toxicity study in mice using dietary concentrations of 0, 175, 700, 2800 and 7000 ppm (equal to 0, 29.4, 120.7, 474.6 and 1140.1 mg/kg bw per day for males and 0, 34.7, 142.9, 534.4 and 1347.4 mg/kg bw per day for females, respectively), the NOAEL was 175 ppm (equal to 29 mg/kg bw per day), based on increases in liver enzymes (e.g. ALT, aspartate aminotransferase [AST] and AP), clinical chemistry changes (decreased bilirubin and creatinine levels) and increased liver weight at 700 ppm (equal to 120.7 mg/kg bw per day). In the absence of any other significant findings at 175 ppm, the increased liver weights were considered a minor adaptive change.

In a 90-day toxicity study in mice using dietary concentrations of 0, 50, 1000 and 2000 ppm (equal to 0, 7.6, 170.0 and 324.1 mg/kg bw per day for males and 0, 8.7, 181.2 and 376.2 mg/kg bw

per day for females, respectively), the NOAEL of 50 ppm (equal to 7.6 mg/kg bw per day) was based on increased ALT and AST activities, increased absolute and relative liver weights and increased incidence of periacinar hepatocytic hypertrophy at 1000 ppm (equal to 170.0 mg/kg bw per day).

In a 6-week toxicity study in rats given diets providing doses of 0, 25, 100, 400 and 1000 mg/kg bw per day, the LOAEL was 25 mg/kg bw per day, based on corneal opacities and effects on the liver observed at all doses. Most of the corneal opacities were resolved by the 2nd week of the reversibility period. In a 90-day dietary toxicity study in rats at doses of 0, 1, 3, 10 and 100 mg/kg bw per day, the NOAEL was 3 mg/kg bw per day, based on haematological changes, corneal opacity and liver toxicity observed at 10 mg/kg bw per day.

In a 1-year toxicity study in dogs using dietary concentrations of 0, 240, 1200, 12 000 and 30 000 ppm (equal to 0, 8.56, 44.81, 453 and 1265 mg/kg bw per day for males and 0, 8.41, 45.33, 498 and 1254 mg/kg bw per day for females, respectively), the NOAEL was 1200 ppm (equal to 44.81 mg/kg bw per day), based on reduced weight gains, increase liver weight, histopathological findings in the liver and changes in haemological and clinical chemistry parameters at 12 000 ppm (equal to 453 mg/kg bw per day).

In a 78-week study of toxicity and carcinogenicity in mice using dietary concentrations of 0, 25, 500 and 7000 ppm (equal to 0, 3.2, 64.4 and 977.3 mg/kg bw per day for males and 0, 4.0, 77.9 and 1161.1 mg/kg bw per day for females, respectively), the NOAEL was 25 ppm (equal to 3.2 mg/kg bw per day), based on liver effects seen at 500 ppm (equal to 64.4 mg/kg bw per day). The NOAEL for carcinogenicity was 500 ppm (equal to 64.4 mg/kg bw per day), based on an increased incidence of hepatocellular adenomas and carcinomas in both sexes at 7000 ppm (equal to 977.3 mg/kg bw per day).

In a 2-year chronic toxicity and carcinogenicity study in rats given diets providing doses of 0, 0.5, 2, 20 and 500 mg/kg bw per day, the NOAEL was 2 mg/kg bw per day, based on liver, thyroid, ocular and nervous system toxicity in males and liver toxicity in females seen at 20 mg/kg bw per day. An increased incidence of adenomas and carcinomas of the liver was found in male and female rats at 500 mg/kg bw per day. In male rats, an increase of thyroid follicular cell adenomas was also observed at 500 mg/kg bw per day.

A 14-day dietary study in mice and rats indicated a marked increase in microsomal enzyme induction (increased pentoxyresorufin *O*-dependentylase [PROD] and benzoxyresorufin *O*-debenzylase [BROD] activities) and increased liver weights. There was no peroxisome proliferation. The data were inadequate to elucidate the precursor events leading to tumour formation and dose concordance for hepatocellular adenomas and carcinomas in mice and rats. In a 14-day oral gavage study in rats, isoxaflutole was found to decrease T_4 levels, with little or no change in T_3 levels, and an increased systemic clearance of ^{125}I-labelled T_4 was observed. The results of these mechanistic studies were suggestive of the induction of microsomal enzymes and tumour formation, but failed to establish the mode of action.

The Meeting concluded that isoxaflutole is carcinogenic in mice and rats.

Special studies conducted to evaluate the corneal opacity seen in rats suggest that the lesion may be linked to the inhibition of the enzyme HPPD in the catabolic pathway of tyrosine. The studies have shown that if HPPD is inhibited, alternative pathways may be utilized to remove excess tyrosine, and species specificity may be linked to the differences in activity of these alternative pathways. The results of the comparative metabolism study in mice and rats suggest that the elimination of tyrosine as 4-hydroxyphenyl lactate and 4-hydroxyphenyl acetate is more efficient in the mouse than in the rat, with twice as much of the administered dose of [^{14}C]tyrosine observed in mouse urine as in rat urine. The results of special studies indicate that rats are more sensitive than mice, dogs and humans to tyrosinaemia.

Isoxaflutole was tested for genotoxicity in vitro and in vivo in an adequate range of assays. No genotoxicity was observed.

The Meeting concluded that isoxaflutole is unlikely to be genotoxic.

On the basis of the absence of genotoxicity and other available toxicological information, the Meeting concluded that the mode of action for the increased incidences of hepatocellular adenomas and carcinomas in both male and female mice and rats and the increased incidence of thyroid follicular cell adenomas in male rats, while not completely understood, is likely to involve a threshold. Therefore, the Meeting concluded that isoxaflutole is unlikely to pose a carcinogenic risk to humans from the diet.

In a two-generation reproductive toxicity study in rats given diets providing doses of 0, 0.5, 2, 20 and 500 mg/kg bw per day, the NOAEL for parental systemic toxicity and offspring toxicity was 2 mg/kg bw per day. The NOAEL for reproductive toxicity was 500 mg/kg bw per day, the highest dose tested. The parental systemic toxicity LOAEL of 20 mg/kg bw per day was based on increased liver weights, liver hypertrophy and vacuolation. The offspring toxicity LOAEL of 20 mg/kg bw per day was based on decreased pup weights and reduced pup viability.

In a developmental toxicity study in rats that tested doses of 0, 10, 100 and 500 mg/kg bw per day, the maternal NOAEL was 100 mg/kg bw per day, based on decreased body weight gain observed at 500 mg/kg bw per day. The NOAEL for embryo and fetal toxicity was 10 mg/kg bw per day, based on decreased fetal weight and delayed ossification observed at 100 mg/kg bw per day.

In a developmental toxicity study in rabbits that tested doses of 0, 5, 20 and 100 mg/kg bw per day, the NOAEL for maternal toxicity was 20 mg/kg bw per day, based on decreased maternal body weight, decreased feed consumption and increased numbers of resorptions seen at 100 mg/kg bw per day. The NOAEL for embryo and fetal toxicity was 20 mg/kg bw per day, based on slightly delayed development of the fetuses, decreased fetal weights and delayed ossification at 100 mg/kg bw per day.

The Meeting concluded that isoxaflutole is not teratogenic in rats or rabbits.

In an oral acute neurotoxicity study in rats that tested doses of 0, 125, 500 and 2000 mg/kg bw, no evidence of neurotoxicity or systemic toxicity was observed at doses up to 2000 mg/kg bw. In a 90-day neurotoxicity study in rats given diets providing doses of 0, 25, 250 and 750 mg/kg bw per day, no neurotoxicity was observed at doses up to 750 mg/kg bw per day. A NOAEL for systemic toxicity was not identified, as only limited parameters were evaluated in this study.

In a developmental neurotoxicity study in rats that tested gavage doses of 0, 5, 25 and 250 mg/kg bw per day, the maternal NOAEL was 25 mg/kg bw per day, based on decreased maternal body weight, body weight gain and feed consumption at 250 mg/kg bw per day. The offspring toxicity NOAEL was 25 mg/kg bw per day, due to decreased pup survival, body weight and body weight gain at 250 mg/kg bw per day. In the absence of any neurotoxic findings, the NOAEL for neurotoxicity in the rat was 250 mg/kg bw per day, the highest dose tested.

The Meeting concluded that isoxaflutole is not neurotoxic.

Toxicological data on metabolites and/or degradates

The acute oral LD_{50} of metabolite RPA 202248, a major metabolite of urine, faeces and liver, was greater than 5000 mg/kg bw. The metabolite was not genotoxic in the Ames test.

Metabolite RPA 203328, detected in urine and faeces, was extensively studied. The acute oral LD_{50} in rats was greater than 5000 mg/kg bw. RPA 203328 was not genotoxic in a range of in vivo and in vitro genotoxicity assays. In a 14-day gavage toxicity study in rats, the NOAEL for RPA 203328 was 30 mg/kg bw per day, based on increased salivation, slightly decreased body weight gains and changes in the haematology and clinical chemistry parameters seen at 300 mg/kg bw per day. Dietary 28-day and 90-day toxicity studies in rats were conducted for RPA 203328 at doses up to 15 000 ppm (equal to 1178 mg/kg bw per day) and 12 000 ppm (equal to 769 mg/kg bw per day), respectively. No evidence of systemic toxicity was observed in these studies. No evidence of

teratogenicity or developmental toxicity in rats was observed in a developmental toxicity study for RPA 203328 at doses up to 750 mg/kg bw per day.

Human data

In reports on employees working in isoxaflutole manufacturing plants, no adverse health effects were reported.

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

Toxicological evaluation

The Meeting established an ADI of 0–0.02 mg/kg bw on the basis of a NOAEL of 2 mg/kg bw per day in a 2-year dietary study of toxicity and carcinogenicity in rats, on the basis of liver, thyroid and nervous system toxicity in males and liver toxicity in females at 20 mg/kg bw per day. A safety factor of 100 was applied. This ADI is supported by a NOAEL of 2 mg/kg bw per day in a dietary two-generation reproductive toxicity study in rats, based on increased liver weights, liver hypertrophy, vacuolation, decreased pup weights and pup viability observed at 20 mg/kg bw per day. The ADI provides a margin of exposure of at least 25 000 relative to the LOAEL for liver and thyroid tumours in rats and at least 48 000 relative to the LOAEL for the liver tumour response in mice. Thus, the Meeting considered that isoxaflutole is not likely to pose a carcinogenic risk to humans from the diet.

The Meeting concluded that it was not necessary to establish an ARfD for isoxaflutole in view of its low acute 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 isoxaflutole

Species	Study	Effect	NOAEL	LOAEL
Mouse	Ninety-day study of toxicity[a]	Toxicity	50 ppm, equal to 7.6 mg/kg bw per day	1000 ppm, equal to 170 mg/kg bw per day
	Eighteen-month study of toxicity and carcinogenicity[a]	Toxicity	25 ppm, equal to 3.2 mg/kg bw per day	500 ppm, equal to 64.4 mg/kg bw per day
		Carcinogenicity	500 ppm, equal to 64.4 mg/kg bw per day	7000 ppm, equal to 977 mg/kg bw per day
Rat	Acute neurotoxicity study[b]	Toxicity	2000 mg/kg bw[c]	—
	Ninety-day study of toxicity[a]	Toxicity	3 mg/kg bw per day	10 mg/kg bw per day
	Two-year study of toxicity and carcinogenicity[a]	Toxicity	2 mg/kg bw per day	20 mg/kg bw per day
		Carcinogenicity	20 mg/kg bw per day	500 mg/kg bw per day
	Two-generation study of reproductive toxicity[a]	Reproductive toxicity	500 mg/kg bw per day[c]	—
		Parental toxicity	2 mg/kg bw per day	20 mg/kg bw per day
		Offspring toxicity	2 mg/kg bw per day	20 mg/kg bw per day

Species	Study	Effect	NOAEL	LOAEL
	Developmental toxicity study[b]	Maternal toxicity	100 mg/kg bw per day	500 mg/kg bw per day
		Embryo and fetal toxicity	10 mg/kg bw per day	100 mg/kg bw per day
Rabbit	Developmental toxicity study[b]	Maternal toxicity	20 mg/kg bw per day	100 mg/kg bw per day
		Embryo and fetal toxicity	20 mg/kg bw per day	100 mg/kg bw per day
Dog	One-year study of toxicity[a]	Toxicity	1200 ppm, equal to 44.8 mg/kg bw per day	12 000 ppm, equal to 453 mg/kg bw per day

[a] Dietary administration.

[b] Gavage administration.

[c] Highest dose tested.

Estimate of acceptable daily intake

0–0.02 mg/kg bw

Estimate of acute reference dose

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 isoxaflutole

Absorption, distribution, excretion and metabolism in mammals	
Rate and extent of oral absorption	Rapid, at least 70%
Dermal absorption	Low, < 4.5%
Distribution	Widely distributed (highest levels in kidney and liver)
Potential for accumulation	None
Rate and extent of excretion	Rapid and complete, about 80% in urine and faeces in 24 h in rats
Metabolism in animals	Extensive; saturated at high doses
Toxicologically significant compounds in animals, plants and the environment	Isoxaflutole, RPA 202248[a], RPA 205834[a], RPA 207048[a]
Acute toxicity	
Rat, LD_{50}, oral	> 5000 mg/kg bw
Rat, LD_{50}, dermal	> 2000 mg/kg bw
Rat, LC_{50}, inhalation	> 5.23 mg/L (whole-body exposure)
Rabbit, dermal irritation	Non-irritating
Rabbit, ocular irritation	Minimally irritating

Dermal sensitization	Non-sensitizing (Buehler method and Magnusson-Kligman test)
Short-term studies of toxicity	
Target/critical effect	Eye, liver and red blood cells
Lowest relevant oral NOAEL	3 mg/kg bw per day (rat)
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 and thyroid
Lowest relevant oral NOAEL	2 mg/kg bw per day (rat)
Carcinogenicity	Unlikely to pose a carcinogenic risk to humans from the diet
Genotoxicity	
	Not genotoxic
Reproductive toxicity	
Target/critical effect	Pup viability and pup weights
Lowest relevant parental NOAEL	2 mg/kg bw per day
Lowest relevant offspring NOAEL	2 mg/kg bw per day
Lowest relevant reproductive NOAEL	500 mg/kg bw per day, the highest dose tested
Developmental toxicity	
Developmental target/critical effect	Delayed ossification, decreased fetal weights
Lowest maternal NOAEL	20 mg/kg bw per day (rabbit)
Lowest embryo/fetal NOAEL	10 mg/kg bw per day (rat)
Neurotoxicity	
Acute and subchronic neurotoxicity	Not neurotoxic
Other toxicological studies	
Studies on metabolites	Rat, LD_{50}, oral: > 5000 mg/kg bw (RPA 203348 and RPA 203328)
	Lowest relevant short-term NOAEL: 769 mg/kg bw per day (RPA 203328)
	Not genotoxic (RPA 202248 and RPA 203328)
Medical data	
	No adverse effects

[a] Based on structural similarity to the parent compound.

Summary

	Value	Study	Safety factor
ADI	0–0.02 mg/kg bw	Two-year study of toxicity and carcinogenicity in rats	100
ARfD	Unnecessary	—	—

RESIDUE AND ANALYTICAL ASPECTS

Isoxaflutole was scheduled for the evaluation as a new compound by 2013 JMPR at the Forty-fourth Session of the CCPR (2012). Isoxaflutole is a synthetic compound of the isoxazole group of chemicals used as a herbicide. The mode of action of isoxaflutole is the inhibition of the enzyme 4-hydroxyphenylpyruvate dioxygenase (HPPD), which inhibits pigment formation, causing bleaching of the developing tissues of the target plants. Isoxaflutole controls a wide spectrum of grasses and broadleaf weeds by bleaching emerging or emerged weeds following herbicide uptake via the root system.

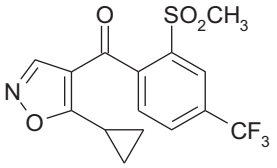
The Meeting received information from the manufacturer on identity, metabolism, storage stability, residue analysis, use patterns, residues resulting from supervised trials on sweet corn, chickpeas, glyphosate/HPPD tolerant soya beans, maize, sugar cane and poppy seed, fates of residue during processing, and livestock feeding studies.

Chemical name:

Isoxaflutole

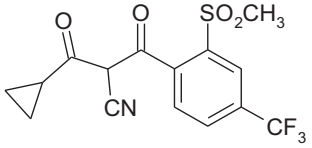
IUPAC: 5-cyclopropyl-4-(2-methylsulfonyl-4-trifluoromethylbenzoyl)-isoxazole

Structural formula:

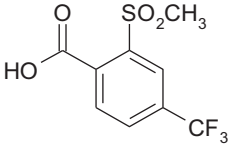


Metabolites referred to in the appraisal by codes:

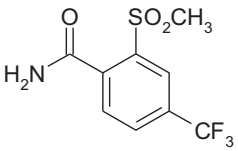
IFT-DKN
RPA 202248
Isoxaflutole diketonitrile;
IUPAC: 3-cyclopropyl-2-[2-mesyl-4-(trifluoromethyl)benzoyl]-3-oxopropanenitrile;



IFT-BA
RPA 203328
Isoxaflutole benzoic acid
IUPAC: 2-mesyl-4-trifluoromethylbenzoic acid;

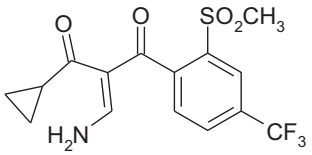


IFT-amide
(no code)
Isoxaflutole benzamide

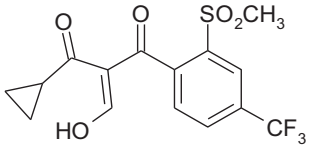


IUPAC: 2-mesyl-4-trifluoromethyl benzamide

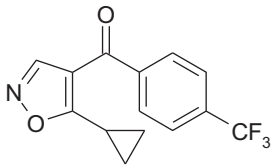
RPA 205834
2-aminomethylene-l-cyclopropyl-3-(2-mesyl-4-trifluoromethylphenyl)-propane-1,3-dione



RPA 207048 1-cyclopropyl-2-hydroxymethylene-3-(2-mesyl-4-trifluoromethylphenyl)-propane-1,3-dione



RPA 205568 5-cyclopropyl-1,2-oxazol-4-yl-α,α,α-trifluoro-p-tolyl ketone



No code 4-trifluoromethyl benzoic acid
CH_3-C_6H_4-COOH

Animal metabolism

The Meeting received results of animal metabolism studies in lactating goats and laying hens. Experiments were carried out with [U-^{14}C-phenyl]-isoxaflutole.

Metabolism in laboratory animals was summarized and evaluated by the WHO panel of the JMPR in 2013. Following oral administration in rats, [U-^{14}C-phenyl]-isoxaflutole was rapidly and extensively metabolized yielding nine radioactive fractions in the urine and up to eleven in the faeces. There were no indications of any metabolites resulting from phase II (conjugation) reaction. Parent isoxaflutole was only found in the faeces of the single 100 mg/kg bw high dose group and to a lesser extent also in the urine of this group (together 5.7–8.2% of the administered dose). The major radioactive component (70–85% of the administered dose) in both urine and faeces, as well as in solvent fractions of liver was IFT-DKN for all three dose groups (single 1 mg/kg bw low dose, single 100 mg/kg bw high dose, repeated 1 mg/kg bw low dose).

The parent compound metabolized to IFT-DKN (major pathway) or RPA 205834 and subsequently further oxidized, respectively to IFT-BA (most polar, 0.6–3.5% of the administered dose) or RPA 207048. A third minor metabolic pathway includes the cleavage of the sulfonic acid group to metabolite RPA 205568 (only 1.3–2.0% of the administered dose).

Four lactating goats, orally treated twice daily for 7 consecutive days with [U-^{14}C-phenyl]-isoxaflutole, were sacrificed 23 hours after the last dose. The four goats received low, medium (2) and high actual doses equivalent to 1.1 (goat 1), 10 (goat 2), 13 (goat 3) and 64 (goat 4) ppm dry feed (2.0, 20, 20 and 100 mg ai/kg bw, respectively). Total recovered radioactivity amounted to 97, 88, 78, and 73% of the administered dose in goat 1 to 4, respectively. Radioactivity recovered from urine and faeces ranged from 56% of the administered dose in the high dosed goat (27% in urine, 29% in faeces) to 85% in the low dosed goat (54% in urine, 31% in faeces). Radioactivity in edible tissues and organs ranged from 5.3% of the administered dose in the high dose goat to 11% in the low dose goat. Radioactivity in milk ranged from not detectable in the low dose goat to 0.54–0.60% of the administered dose in the medium to high dosed goats. Radioactivity levels in milk peaked at 0.093–0.095 mg/kg eq in goat 3 at day 4–5, 0.059–0.060 mg/kg eq in goat 2 at day 6–7 and 0.33–0.35 mg/kg eq in goat 4 at day 5–7.

Tissues (goat 3) and milk (goat 2) were subjected to further analysis. The total radioactive residues (TRR) were 2.1 mg/kg eq (liver), 0.90 mg/kg eq (kidney), 0.26 mg/kg eq (muscle), 0.069 mg/kg eq (renal fat), 0.062 mg/kg eq (omental fat) and 0.060 mg/kg eq (milk). Radioactive residues could be extracted with methanol (milk), phosphate buffer pH 7.5 (liver, kidney and fat) or phosphate buffer pH 7.5 in combination with protease treatment (muscle). The extracted radioactive residues in the medium dosed goats amounted to 95% TRR for milk, 98% TRR for liver, 94% TRR for kidney, 76% TRR for muscle, 98% TRR for omental fat and 93%TRR for renal fat.

Parent compound was not found in any of the goat commodities. In goat milk, and all tissues the metabolite IFT-DKN was the most abundant component of the residues in the primary extracts (18–86% TRR or 0.015–1.8 mg/kg eq), followed by the metabolite RPA 207048 (9.1–26% TRR or 0.10–0.016 mg/kg eq, respectively). Muscle contained 18.3% TRR free and 23% conjugated IFT-DKN as well as 9.1% free and 3.4% conjugated RPA 207048; (released as free metabolites by protease treatment). Metabolite RPA 205834 (8.1–18% TRR or 0.005–0.011 mg/kg eq) was only found in milk and fat.

Ten laying hens, orally treated once daily for 14 consecutive days with [U-^{14}C-phenyl]-isoxaflutole, were sacrificed 23 hours after the last dose. Hens were treated at an actual dose rate of 1.1 (group A) or 11 (group B) ppm dry feed. Total recovered radioactivity amounted to 117% and 92% of the administered dose in group A and B, respectively. Radioactivity from the excreta amounted to 112% and 88% of the administered dose for group A and B, respectively. Low levels of radioactivity were recovered in the eggs (0.12–0.15% of the administered dose) or tissues (1.7% in group A and 0.20% in group B).

In the low dose group (A) the concentrations of radioactivity in egg whites were below 0.002 mg/kg eq at all-time points. The levels of radioactivity in egg yolk reached a steady state within 7 days after the first dose (0.022–0.028 mg/kg eq). In the high dose group (B) the concentration of radioactivity in egg whites reached a steady state (0.010–0.015 mg/kg eq) within 4 days. The levels of radioactivity in egg yolk were up to 16 times higher, with a steady state concentration of 0.14–0.15 mg/kg eq within 7 days of exposure.

The highest radioactivity concentrations in edible tissues were found in the liver (0.84 and 0.95 mg/kg eq for dose group A and B, respectively) and kidney (0.055 and 0.16 mg/kg eq, respectively for A and B). Radioactivity in fat and muscle was only observed in the high (B) dose group, being 0.028 and 0.035 mg/kg eq, respectively. Some radioactivity was found in skin (0.008 and 0.068 mg/kg eq in dose group A and B, respectively).

Radioactivity was characterized in tissues and eggs from the high dose group B. Radioactive residues were extracted sequentially by exhaustive extractions using hexane, methanol, acetonitrile, ethyl acetate, acidified methanol and/or water. The primary extractable residues amounted to 97% TRR for liver, 74% TRR for kidney, 54% TRR for muscle, 93% TRR for fat, 53% TRR for skin, 66% TRR for egg yolk and 50% TRR for egg white. After treatment with protease, another 16%, 29%, 21%, 46% and 20% TRR could be released from kidney, muscle, skin, egg yolk and egg white, respectively. After extensive acid hydrolysis (6 M HCl at 95 ºC for 7 days) another 1.9%, 43%, 7.4% and 20% TRR could be released from kidney, muscle, skin and egg white, respectively.

In egg yolk (0.137 mg/kg eq), the major compounds in the primary extracts represented IFT-DKN (26% TRR) and RPA 205834 (28% TRR). Parent, IFT-BA and RPA 207048 were not found. Exhaustive acid hydrolysis released additional IFT-DKN (17% TRR) from egg yolk. Residues in egg white (0.010 mg/kg eq) and the remaining fractions from egg yolk could not be identified, although two fractions in egg yolk contained considerable radioactivity (10% TRR or 0.014 mg/kg eq in the primary extract and 18% TRR or 0.025 mg/kg eq in the acid hydrolysate).

In hen liver (0.953 mg/kg eq), kidney (0.155 mg/kg eq) and skin (0.068 mg/kg eq), the major compound in the primary extracts represented IFT-DKN (93%, 74% and 37% TRR, respectively). Parent, RPA 207048 and RPA 205834 were not found. IFT-BA was found as minor metabolite in

liver and kidney (3.5% TRR and 0.65% TRR, respectively). Protease digestion and exhaustive acid hydrolysis released additional IFT-DKN (18% and 7.4% TRR, respectively) from skin.

In hen muscle (0.035 mg/kg eq) the only compound identified in the primary extracts was RPA 207048 (31%TRR). Parent and RPA 205834 were not found. Exhaustive acid hydrolysis released additional RPA 207048 (17% TRR) as well low levels of IFT-DKN and IFT-BA (5.7% and 5.7% TRR, respectively) from muscle.

In hen fat (0.028 mg/kg eq) the major compounds in the primary extracts were IFT-DKN (29% TRR) and RPA 207048 (21% TRR).

The metabolic pathway of isoxaflutole in livestock involves the opening of the oxazole ring and the formation of the diketo-nitrile derivative (IFT-DKN) or the diketo-amine derivative (RPA 205834). Further degradation occurs through deamination to form the diketo-hydroxy derivative (RPA 207048) or through further cleavage to form the benzoic acid derivative (IFT-BA). Further metabolism involves conjugation of IFT-DKN, RPA 207048 and/or IFT-BA with proteins or acid cleavable compounds.

Parent compound was not found in milk, eggs, goat tissues or hen tissues. This may represent rapid metabolism within the animal or it may represent degradation during frozen storage of the samples or degradation during extraction.

The major compounds identified in goat, hen tissues, milk or eggs are: IFT-DKN, RPA 207048, RPA 205834, conjugated IFT-DKN and conjugated RPA 207048. In goats, metabolites IFT-DKN (18–86% TRR) and RPA 207048 (9.1–26% TRR) were found in all tissues and milk. Metabolite RPA 205834 (8.1–18% TRR) was only found in milk and fat. Conjugated forms of IFT-DKN (23% TRR) and RPA 207048 (3.4% TRR) were only found in goat muscle and free metabolites could be released by protease digestion. In hens, metabolite IFT-DKN (26–93% TRR) was found in eggs and all tissues, except muscle. Metabolite RPA 207048 (21–31% TRR) was only found in muscle and fat. Metabolite RPA 205834 was only found in eggs (28% TRR in egg yolk). Conjugated forms of IFT-DKN (5.7–25% TRR) were found in hen muscle, skin and eggs and free metabolites could be released by protease (skin only) or exhaustive acid hydrolysis. Conjugated forms of RPA 207048 were found in hen muscle only and free metabolites could be released by exhaustive acid hydrolysis. IFT-BA was only found as a minor metabolite in hen liver and kidney (3.5% TRR and 0.65% TRR, respectively) and as conjugate form in hen muscle (5.7% TRR).

The metabolic pathway in ruminants and poultry is identical to the metabolic pathway in rats, although in rats an additional minor pathway to RPA 205568 is found, which is not found in ruminant or poultry. All metabolites identified in livestock are also found in rats.

Plant metabolism

The Meeting received plant metabolism studies for isoxaflutole on cereals (maize and wheat), pulses/oilseeds (soya beans and poppy seeds) and sugar cane after a pre-plant, crop pre-emergence, crop post-emergence or crop foliar application.

The metabolism of [U-^{14}C-phenyl]-isoxaflutole in outdoor grown maize was studied following pre-plant soil incorporated and pre-emergent applications. Maize forage, grains and fodder were harvested at DAT = 41, 122 and 122/138. Residue levels in maize forage, grains and fodder were 0.20–0.044–0.15 mg/kg eq, respectively, for pre-plant incorporated treatment at 0.21 kg ai/ha and 0.23–0.039–0.12 mg/kg eq, respectively, for pre-emergence treatment after 0.23 kg ai/ha. Residue levels were 0.80–0.15–0.66 mg/kg eq for pre-plant incorporated treatment at 0.66 kg ai/ha and 0.49–0.12–0.53 mg/kg eq for pre-emergence treatment at 1.1 kg ai/ha. Residue levels in maize forage, grains and fodder after pre-plant incorporated treatment were higher than those after pre-emergence treatment at the high dose rate; they were similar at the low dose rates. Exaggerated dose rates exhibited greater phytotoxicity. Radioactivity was characterized in maize from the low dose treatments. The major part of the residues could be extracted with an exhaustive range of solvents:

hexane/ethyl acetate, acetonitrile, water pH 5.5, and acidified acetonitrile: 91–99% TRR in forage, 83–87% TRR in grains and 75–79% TRR in fodder. Additional residues could be released by cellulase digestion (3.0–6.5% TRR). Parent isoxaflutole was not found in any of the maize commodities. The major compound identified was free IFT-BA (61–89% TRR) in all maize commodities. Minor metabolites represented conjugated IFT-DKN (0.49–0.53% TRR in forage only) and conjugated IFT-BA (1.1–2.7% TRR in forage and fodder).

In a second study, the metabolism of [U-^{14}C-phenyl]-isoxaflutole was studied in outdoor grown maize following post-emergent application at 0.21 kg ai/ha in the presence of the safener cyprosulfamide. Maize forage and sweet corn were harvested at DAT 75; maize grains and fodder were harvested at DAT = 106. Residue levels in maize forage, sweet corn, maize grains and fodder were 0.13–0.010–0.015–0.10 mg/kg eq, respectively after pre-plant incorporated treatment. These residue levels were similar to those from the pre-plant incorporated and pre-emergence treatments in the previous study. The major part of the residues could be extracted with acetonitrile and water: 93% TRR in forage, 97% TRR in sweet corn, 77% TRR in grains and 88% TRR in fodder. Aqueous fractions underwent base hydrolysis. Parent isoxaflutole was not found in any of the maize commodities. The major compound identified was free IFT-BA (52–63% TRR) in all maize commodities. Other identified metabolites represented free IFT-DKN (4.0–9.8% TRR in sweet corn, fodder and grain) and conjugated IFT-BA (4.1–15% TRR in forage and fodder).

The metabolism of [U-^{14}C-phenyl]-isoxaflutole in outdoor grown wheat was studied following a post-emergent application at 0.055 kg ai/ha onto immature plants (Zadoks 30). Residue levels in wheat hay, straw and grains harvested at DAT 41, 93 and 93/99 were 0.172–0.107–0.058 mg/kg eq, respectively. The major part of the residues (86–96% TRR) could be extracted with acetonitrile/water. Parent isoxaflutole was only found in wheat hay (6.5% TRR). Major metabolites identified were free IFT-BA (65–96% TRR) in all wheat commodities and free IFT-DKN (9.9–21% TRR in forage and straw only). A small fraction of the metabolites in straw might be attributed to conjugates because 3% TRR was released through acid reflux.

The metabolism of [U-^{14}C-phenyl]-isoxaflutole in indoor grown glyphosate/HPPD-tolerant soya was studied following a pre-plant application or a foliar application to plants in full bloom (BBCH 65, 57 days after planting) at 0.331 kg ai/ha. Soya bean forage, hay and seeds were harvested at DAT 74/17, 189/132 and 189/132, respectively, for pre-plant/foliar treatment. Residue levels in soya bean forage, hay and seeds were 0.27–0.49–0.15 mg/kg eq after pre-plant treatment and 13–1.8–0.26 mg/kg eq after foliar treatment. The major part of the residues could be extracted with acetonitrile/water: 91–100% TRR in all soya commodities. The foliar application of isoxaflutole had a significant effect on the metabolic profile. Major compounds identified in the pre-plant application were free IFT-amide (53%, 13% and 8% TRR in forage, hay and seeds, respectively), free IFT-BA (66%, 56% and 27% TRR in seeds, hay and forage, respectively) and free IFT-DKN (13–17% TRR in all soya commodities). Major compounds identified in the foliar application were parent (72% and 25% TRR in forage and hay, respectively), free IFT-BA (62%, 38% and 6% TRR in seeds, hay and forage, respectively) and free IFT-DKN (18–24% TRR in all soya commodities). Minor metabolites identified in the foliar application were free IFT-amide (3–8% TRR in hay and seeds).

FG 72 soya beans express the hppdPfW336 gene from *Pseudomonas fluorescens* and the 2mepsps gene derived from maize. These genes confer tolerance to the herbicide isoxaflutole and glyphosate-containing herbicides, respectively, via a modification of the target enzyme which makes the modified enzymes insensitive against the herbicide. Since in the FG72 soya bean variety the tolerance against glyphosate and isoxaflutole is not based on detoxification of the pesticides, the tolerance to glyphosate is not expected to modify the nature and levels of isoxaflutole-derived residues in treated soya beans. Similarly the tolerance to isoxaflutole is not expected to modify the nature and levels of glyphosate residues.

The metabolism of [U-^{14}C-phenyl]-isoxaflutole in outdoor grown poppies was studied following a pre-emergent application (3 days after planting) at 0.11 kg ai/ha in the presence of the safener cyprosulfamide. Residue levels in poppy seeds, seed bolls and straw harvested at DAT 110

were 0.056, 0.78 and 0.72 mg/kg eq, respectively. Most of the radioactivity (92–98% TRR) could be extracted with acetonitrile/water. Parent isoxaflutole was not found in any of the samples. The major compound identified was free IFT-BA (66–94% TRR) in all commodities. Free IFT-DKN was found in low levels (2.1–3.5% TRR) in seed bolls and straw, but not in poppy seeds.

The metabolism of [U-^{14}C-phenyl]-isoxaflutole in outdoor grown sugarcane was studied following a pre-emergent application at 0.210 kg ai/ha or a foliar application (47 days after planting) at 0.133 kg ai/ha. Residue levels in sugarcane plants harvested at DAT 81, 95 and 365 were 0.12–0.15–< 0.01 mg/kg eq, respectively, for pre-emergence treatment and 0.18, < 0.01 and < 0.01 mg/kg eq at DAT 40, 95 and 365, respectively, for foliar treatment. Radioactivity in samples with residues > 0.01 mg/kg eq was characterized. Most of the radioactivity could be extracted with acetonitrile: 66%, 79% and 84% TRR in DAT 40, 81 and 95 samples, respectively. Additional residues (9.5–24% TRR) could be released by exhaustive extraction procedures including reflux with acetonitrile, reflux with 0.1 M HCl and reflux with 0.1 M ammonia. The major compound identified in immature sugarcane (DAT 40, 81 and 95) was IFT-BA (66–93% TRR). Parent isoxaflutole (11% TRR) and IFT-DKN (2.2% TRR) were only found in the foliar treated crop harvested at DAT 40. Since initial acetonitrile extracts were combined with more exhaustive extracts, it is not clear whether the identified compounds are free or conjugated.

The effect of the safener cyprosulfamide on the metabolism of isoxaflutole was investigated in 3 day old maize seedlings grown in nutrient solution. Roots were exposed for 24 h to [U-^{14}C-phenyl]-isoxaflutole alone or in combination with cyprosulfamide. After this period the plants were grown in blank nutrient solution for 3 days. Shoots, seeds and roots were collected and extracted with acetonitrile/water. The effect of the safener cyprosulfamide is a clear reduction of leaf damage (bleaching) and a lower ratio of IFT-DKN to IFT-BA in the shoots.

From these data it is concluded that in cereal grains, seeds of pulses/oilseeds, sugarcanes, forage and fodder of cereals or pulses/oilseeds, metabolite IFT-BA is the only residue identified at significant quantities (52–99% TRR). Parent isoxaflutole (6.5–11% TRR) is only found after post-emergent or foliar treatments in wheat hay or immature sugarcane. Minor metabolites identified were IFT-DKN (2.1–21% TRR in sweet corn, maize grain, immature sugarcane, cereal forage, cereal fodder and poppy straw), conjugated IFT-DKN (0.49–0.53% TRR in maize forage) and conjugated IFT-BA (1.1–15% TRR in maize forage and maize fodder).

Glyphosate/HPPD-tolerant soya has a somewhat different metabolic profile. Major compounds identified in the pre-plant application were free IFT-amide (53%, 13% and 8% TRR in forage, hay and seeds, respectively), free IFT-BA (66%, 56% and 27% TRR in seeds, hay and forage, respectively) and free IFT-DKN (13–17% TRR in all soya commodities). Major compounds identified in the foliar application were parent (72% and 25% TRR in forage and hay, respectively), free IFT-BA (62%, 38% and 6% TRR in seeds, hay and forage, respectively) and free IFT-DKN (18–24% TRR in all soya commodities).

The first hydrolytic step in the degradation in plants is the opening of the isoxazole ring to form IFT-DKN. Further hydrolytical cleavage of the carbonyl bridge and loss of the complete isoxazole moiety leads to the corresponding benzoic acid derivative (IFT-BA). In glyphosate/HPPD tolerant soya beans loss of the complete isoxazole moiety may also lead to the benzamide derivative (IFT-amide).

Metabolites IFT-DKN and IFT-BA are also found in rat. Metabolite IFT-amide (8–53% TRR) seems to be formed in glyphosate/HPPD tolerant soya beans only. This metabolite was not found in rat.

Environmental fate in soil

The Meeting received information on aerobic degradation in soil, soil photolysis and fate in rotational crops.

Aerobic degradation of [U-^{14}C-phenyl]-isoxaflutole under laboratory conditions was studied at 20 °C in various soil types treated at 0.2 mg ai/kg dry soil (0.20 kg ai/ha). The half-life for isoxaflutole was estimated at 7.6–11 h in clay loam and loamy sand soils, 1.3–2.5 days for sandy loam and clay soils and 4 days for loamy soils. The major metabolites identified were IFT-DKN (max. 52–96% TAR during a period 3–10 days after treatment) and IFT-BA (max. 30–90% TAR during a period of 1–12 months after treatment). IFT-BA levels in clay loam soil were very low (max 7.1% TRR at 7 days). Carbon dioxide was formed from day 1 onwards and these levels increased with time (up to 1.8–37% TRR after 1 year). These study results show that parent isoxaflutole is unlikely to be taken up by crops (and weeds) when applied onto bare soil as pre-plant or pre-emergent application.

Using the data from these soil degradation studies, the half-life for the metabolite IFT-DKN were estimated at 20 days in a sandy loam soil, 25 days in a loam soil, 37 days in a clay soil, 41 days in a clay loam soil and 56 days in a loamy sand soil. The half-life for IFT-BA was estimated at 290 days in clay soil and 980 days in a sandy loam soil. These studies show that metabolites IFT-DKN and IFT-BA are available for take-up by the plants for a considerable period after pre-plant or pre-emergence application depending on the soil type.

Soil photolysis of [U-^{14}C-phenyl]-isoxaflutole was studied in a sandy loam soil, surface treated at 0.645 kg ai/ha and exposed for 31 days to artificial sunlight. The half-life for isoxaflutole (DT_{50} 23 hours) was similar to the one for the dark control (DT_{50} 20 hours). The formation of transformation products specific for photolytic processes was insignificant. The study shows that light has no effect on the degradation of isoxaflutole on soil.

Metabolism of [U-^{14}C-phenyl]-isoxaflutole was investigated in confined rotational crops following pre-plant incorporated soil treatment or pre-emergence treatment. A sandy loam soil was treated at a rate of 0.213 kg ai/ha under outdoor conditions. Rotational crops (radish, lettuce, mustard greens, sorghum and wheat) were sown 34, 123 and 365–375 days after application, representing first, second and third rotation. Total radioactivity for pre-plant incorporated soil treatment ranged from 0.003–0.24 mg/kg eq after first rotation, 0.001–0.030 mg/kg eq after second rotation and 0.001–0.051 mg/kg eq after third rotation. Total radioactivity for pre-emergence application ranged from 0.010–0.126 mg/kg eq after first rotation, < 0.001–0.042 mg/kg eq after second rotation and 0.001–0.030 mg/kg eq after third rotation. Total radioactivity levels above 0.05 mg/kg eq were only found in immature lettuce and sorghum commodities after the first rotation (0.126–0.24 mg/kg eq in sorghum forage, 0.13 mg/kg eq in sorghum fodder, 0.12 mg/kg in sorghum grain, 0.056 mg/kg eq in immature lettuce) and after the third rotation (0.051 mg/kg eq in sorghum forage). Parent isoxaflutole was not found in any of the rotational crops. IFT-BA represented the major compound and was present in the commodities of the first, second and third rotation at levels between < 0.001–0.11 mg/kg eq (6.9–100% TRR). IFT-DKN was only found in radish leaves and sorghum grain at levels up 0.005 mg/kg eq (0.8–27.3% TRR) in the first rotation. RPA 205834 was detected by HPLC-MS-MS in trace amounts (< 0.001 mg/kg eq) in mature lettuce of the first rotation. A fourth metabolite (U1) was found in the commodities of the first, second and third rotation at levels between < 0.001–0.022 mg/kg eq (10–100% TRR). The polarity of this compound and the molecular weight of 192, as determined by HPLC-MS-MS, suggests it is a carboxylic acid degradation product of IFT-BA with the structural formula CF_3-C_6H_4-COOH (4-trifluoromethyl benzoic acid).

In a field rotational crop study at two different locations in the USA isoxaflutole was applied as pre-plant or pre-emergent application to maize at 0.154–0.161 kg ai/ha. Rotational crops (soya beans, sugar beets, radishes, turnips, mustard greens, wheat and sorghum) were sown 29/30, 104, 119/120, 151, 166, 180, 365 days after application, representing various rotations of maize. No residues (< 0.01 mg/kg) of parent isoxaflutole, metabolites IFT-DKN or metabolite IFT-BA were found in any of the crops at any of the rotations. Metabolite 4-trifluoromethyl benzoic acid was not analysed, but since its levels are expected to be in the same order of magnitude as IFT-BA, based on the confined rotational crop study, it is not expected to be found at levels > 0.01 mg/kg.

From these data it is concluded that the first hydrolytic step in the aerobic degradation in soil is the opening of the isoxazole ring to form IFT-DKN, which is responsible for the mode of action. Further hydrolytical cleavage of the carbonyl bridge and loss of the complete isoxazole moiety leads to the corresponding benzoic acid derivative (IFT-BA). Light has no effect on the degradation of isoxaflutole on soil. Isoxaflutole has a very short half-life of 8 h to 4 days in soil, and consequently is not found in rotational crops after pre-plant or crop pre-emergence applications. Metabolites IFT-DKN and IFT-BA have long half-lives of 20–56 and 290–980 days, respectively, in soil and consequently are the main metabolites found in plants after pre-plant, crop pre-emergence or crop post-emergence applications. Since metabolites IFT-DKN and IFT-BA were also found after foliar treatments of sugarcane and glyphosate/HPPD tolerant soya beans, it is likely that metabolites IFT-DKN and IFT-BA are also formed in plants. In confined rotational crop studies, a third metabolite (4-trifluoromethyl benzoic acid (CF_3-C_6H_4-COOH)) was found (10–100% TRR), formed by the loss of the methylsulfonyl moiety of IFT-BA. It is not clear whether this metabolite is formed exclusively in the plants or is formed in the soil and taken up by the plants. Metabolite 4-trifluoromethyl benzoic acid was not found in rat.

Methods of Analysis

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

For plants, a HPLC-MS-MS method was submitted as enforcement/monitoring method for the individual determination of parent and its metabolite IFT-DKN. Plant material was extracted with acidified methanol/water followed by filtration. The Meeting considers validation sufficient for commodities with high acid content, high water content, high starch content and high oil content. The LOQ was 0.01 mg/kg for each analyte.

Several other HPLC-MS-MS methods were submitted for the determination of parent and its metabolites IFT-DKN and IFT-BA in plant material. In some trials a GC-MS method was used, where residues were extracted with methanol and converted into a common moiety IFT-methylbenzoate by hydrolysis and methylation. Most analytical methods were considered fit for purpose with LOQs ranging from 0.01 mg/kg eq for total residues or 0.01–0.03 mg/kg for individual analytes.

For animal commodities, the existing multi-residue method QuEChERS was submitted as enforcement/monitoring method. The Meeting considers this method valid for the individual determination of parent and its metabolite IFT-DKN in all animal commodities. The LOQ was 0.01 mg/kg for milk, eggs, meat, fat, liver and kidney for each analyte.

Three other analytical methods were submitted for the determination of isoxaflutole related residues in milk, eggs or animal tissues. HPLC-UV methods were used for milk and eggs. A HPLC-MS-MS method was used for tissues. Conjugates of IFT-DKN and RPA 207048 were not analysed by these methods. The reported LOQ of 0.05 mg/kg for each analyte in meat, fat, liver and kidney needs to be substantiated by additional data, since only 1–2 recoveries per matrix were provided at this level. Parent is degraded during extraction and is measured as increased IFT-DKN in these methods. Based on the validation data available, the methods are considered suitable for determination of parent, IFT-DKN, RPA 205834 and RPA 207048 in milk at 0.02–2.0 mg/kg and 0.05–0.25 mg/kg in eggs and tissues.

Solvents used in the analytical methods were different from the extraction methods used in the metabolism studies. Extraction efficiency, using radiolabelled samples from the metabolism studies, was not verified for any of the analytical methods.

Stability of pesticide residues in stored analytical samples

The Meeting received information on the stability of isoxaflutole, IFT-DKN and IFT-BA in plant commodities or isoxaflutole, IFT-DKN, IFT-BA, RPA 205834 and RPA 207048 in animal commodities in animal commodities stored frozen.

Storage stability studies at -10 ºC and -20 ºC showed that total isoxaflutole residues (sum of parent, IFT-DKN and IFT-BA, measured as common moiety) were stable for at least 11 months in commodities with high protein content (chickpea seeds), 15 months in commodities with high starch content (maize grains) and straw (maize fodder) and at least 20 months in commodities with high water content (sugar canes).

Storage stability studies showed that isoxaflutole converts to IFT-DKN after 3–6 months of storage at -10 ºC in commodities with high acid content (oranges), high water content (sugar canes), high protein content (dry pinto beans) and high oil content (dry soya beans). The metabolite IFT-DKN remained stable for at least 12 months at -10 ºC in commodities with high acid content (oranges), high water content (sugar canes), high protein content (dry pinto beans) and at least 16 months in commodities with high oil content (poppy seeds and dry soya bean seeds). Metabolite IFT-DKN converts to IFT-BA within a period of 23 months at -20 ºC in commodities with high water content (sorghum forage, lettuce and radish leaves), high starch content (radish roots), high protein content (sorghum grain) and straw (sorghum fodder).

Based on storage stability studies at -20 °C in fortified samples of animal commodities the Meeting noted that isoxaflutole was not stable. Isoxaflutole degraded rapidly to IFT-DKN in eggs and degraded after a period of 85 days in milk and muscle. Parent isoxaflutole also degrades to IFT-DKN by the extraction method used for tissue analysis in the feeding studies. Metabolite IFT-DKN is stable for a period of at least 113–130 days in liver, kidney, muscle, fat, milk and eggs. If metabolite IFT-DKN is included in the residue definition, any degradation from isoxaflutole to IFT-DKN is covered by the total residues measured.

Metabolite RPA 205834 is stable for a period of 113–131 days in kidney, muscle, fat and milk. Metabolite RPA 205834 is stable for a maximum storage period of 94 days in liver and degrades significantly thereafter (36% remaining after 130 days). Storage stability of RPA 205834 was not investigated in eggs.

Metabolite RPA 207048 is not stable in any animal commodity. RPA 207048 degrades rapidly in kidney to a level of about 45% which is maintained from 13–115 days. RPA 207048 is stable for a maximum storage period of 28 days in muscle, 40 days in liver and 84 days in fat and thereafter remains stable at a level of about 50% of the original residue level for a period up to 85–113 days. Storage stability of RPA 207048 has not been investigated in milk and eggs. Precautions need to be taken when analysing this metabolite. Besides storage conditions, also extraction conditions are critical.

In case quantitative levels of total residues based on parent, IFT-DKN, RPA 205834 and RPA 207048 are needed, samples of animal origin need to be analysed within 30 days. And even then, metabolite RPA 207048 will be underestimated in kidney.

Definition of the residue

Parent compound isoxaflutole was not found in milk, eggs or livestock tissues. Metabolites found at significant levels in livestock commodities were: IFT-DKN, conjugated IFT-DKN, RPA 205834, RPA 207048, and conjugated RPA 207048. Metabolite IFT-DKN (18–93% TRR) was found in milk, eggs, all goat and hen tissues, except hen muscle. Conjugated forms of IFT-DKN (5.7–25% TRR) were only found in goat muscle, hen muscle, hen skin and eggs and the free metabolite could be released by protease digestion (goat muscle and hen skin) and/or exhaustive acid hydrolysis (hen muscle and eggs). Metabolite RPA 205834 (8.1–28% TRR) was found in milk, eggs (yolk) and goat fat in the metabolism studies on goat and hen, but it was also found in milk, bovine liver and bovine

kidney in cow feeding study. Metabolite RPA 207048 (9.1–31% TRR) was found in milk, all goat tissues, hen muscle and hen fat. Conjugated forms of RPA 207048 (3.4% TRR) were only found in goat and hen muscle and could be released by protease digestion (goat muscle) or exhaustive acid hydrolysis (hen muscle). Further there seems to be a metabolic shift between RPA 205834 and RPA 207048 between goat and cow. In goat, RPA 207048 seems to be present in all goat tissues and at higher levels than RPA 205834, while in cow RPA 207048 is not found. This metabolic shift might be related to the shorter period between last application and slaughter time for cows (7.5 h) compared to goats (23 h).

Isoxaflutole is easily converted to IFT-DKN. Since no discrimination can be made whether isoxaflutole is metabolized within the animal, or whether it is degraded because of its sensitivity to physical chemical conditions, isoxaflutole needs to be included in the residue definition for enforcement. Any isoxaflutole degraded because of storage or extraction conditions will be measured as IFT-DKN. The sum of IFT and IFT-DKN can therefore serve as the marker residue for enforcement.

The log K_{ow} for isoxaflutole is 2.34. Isoxaflutole and its metabolite IFT-DKN are extracted with acidified aqueous solvents and highest levels of these metabolites are found in the organs kidney and liver. The sum of parent and IFT-DKN is considered not fat soluble.

Apart from isoxaflutole and IFT-DKN other metabolites found at significant levels in livestock commodities were conjugated IFT-DKN, RPA 205834, RPA 207048, and conjugated RPA 207048.

Toxicity of the free IFT-DKN, RPA 205834 and RPA 207048 is considered to be covered by toxicity studies on isoxaflutole since each of the free metabolites was found in the rat high dose group. Free IFT-DKN is the major compound found in rat urine, faeces and solvent fractions of liver, and its toxicity is considered to be similar to that of the parent compound. Since metabolites RPA 205834 and RPA 207048 have similar structures as IFT-DKN and no data are available to conclude that they are of less toxicological significance, each metabolite is considered relevant for the residue definition for dietary risk assessment. Conjugated forms of IFT-DKN and RPA 207048 are considered relevant for dietary exposure, since the free metabolites can be released during the metabolic process in humans. The Meeting proposed to include parent, IFT-DKN, conjugated IFT-DKN, RPA 205834, RPA 207048, and conjugated RPA 207048 in the residue definition for dietary risk assessment of animal commodities.

The analytical method used in the feeding study cannot determine the conjugated forms of IFT-DKN and RPA 207048. For goat muscle, conjugates represent 26.62% TRR and free compounds (IFT-DKN + RPA 205834 + RPA 207048) represent 27.43% TRR. For hen muscle, conjugates represent 22.81% TRR and free compounds represent 31.4% TRR. For hen eggs, conjugates represent 16.8% TRR and free compounds represent 54% TRR. A multiplication factor 2 for goat and hen muscle and 1.3 for hen eggs could be used on the total residues to compensate for this underestimation of dietary exposure.

In primary crops, metabolite IFT-BA is the only residue identified at significant quantities (52–99% TRR). Parent isoxaflutole is only found after post-emergent or foliar treatments in livestock feed commodities: major amounts in glyphosate/HPPD-tolerant soya bean forage and hay (25–72% TRR) and minor amounts (6.5–11% TRR) in wheat hay or immature sugarcane. Minor metabolites identified were IFT-DKN (2.1–21% TRR), conjugated IFT-DKN (0.49–0.53% TRR) and conjugated IFT-BA (1.1–15% TRR). Metabolite IFT-amide (8–53% TRR) seems only to be formed in glyphosate/HPPD tolerant soya bean (seeds, forage, hay).

Metabolite IFT-BA is the major residue and is relevant for consideration in the residue definition for enforcement. However, IFT-BA can also arise in plant commodities as a result of treatment with pyrasulfotole. For this reason IFT-BA cannot be used as a marker for isoxaflutole.

The only other compounds relevant for the residue definition for enforcement are the parent and IFT-DKN. The sum of IFT and IFT-DKN can therefore serve as the marker residue for enforcement.

Apart from isoxaflutole and IFT-DKN, other metabolites found at significant levels in plant commodities are IFT-BA (feed commodities and tolerant soya beans) and IFT-amide (tolerant soya beans only). Assessment of additional toxicological data on IFT-BA demonstrated that metabolite IFT-BA is considerably less toxic then the parent compound. Thus, from a toxicological point of view it is not necessary to include IFT-BA in the residue definition. Metabolite IFT-amide is not found in rat. But since IFT-amide is present at lower levels than IFT-BA in soya bean seeds and because of its structural similarity with IFT-BA, IFT-amide is considered not relevant for the residue definition.

The Meeting recommended the following residue definition for isoxaflutole:

Definition of the residue for compliance with the MRL and for dietary risk assessment for plant commodities: *sum of isoxaflutole and isoxaflutole diketonitrile, expressed as isoxaflutole.*

Definition of the residue for compliance with the MRL for animal commodities: *sum of isoxaflutole and isoxaflutole diketonitrile, expressed as isoxaflutole.*

The Meeting considers the residue not fat soluble.

Definition of the residue for dietary risk assessment for animal commodities: *sum of isoxaflutole, isoxaflutole diketonitrile, RPA 205834 (2-aminomethylene-l-cyclopropyl-3-(2-mesyl-4-trifluoromethylphenyl)-propane-1,3-dione) and RPA 207048 (1-cyclopropyl-2-hydroxymethylene-3-(2-mesyl-4-trifluoromethylphenyl)-propane-1,3-dione), including their conjugates, expressed as isoxaflutole.*

Results of supervised residue trials on crops

The total residue values selected for maximum residue level recommendations and dietary intake are based on the sum of isoxaflutole and IFT-DKN. In case a common moiety method is used for analysis also the IFT-BA metabolite is included. Since the relative molecular weight of IFT-DKN is identical to that of isoxaflutole, no molecular weight conversion is needed. Soil type and the addition of the safener cyprosulfamide affect the residue levels in plant commodities. Residue trials were conducted in a range of soil types, which included those with the longest half-lives.

Since IFT-DKN is included in the residue definition, any degradation from isoxaflutole to IFT-DKN is covered by the total residues measured. Since IFT-BA is not part of the residue definition, any degradation from IFT-DKN to IFT-BA means an underestimation of the original residue present in the sample. Therefore, the Meeting takes only those trials into account, where samples have been stored for a maximum of 16 months (commodities with high oil content) or 12 months (all other commodities). Also trials where IFT-BA is below LOQ can be taken into account, because it indicates that no degradation of IFT or IFT-DKN to IFT-BA occurred.

Sweet corn (corn-on-the-cob)

Field trials involving sweet corn were performed in Spain, Italy, Greece, Portugal, Germany, France, Netherlands and the United Kingdom.

Critical GAP for sweet corn in France is for a single post sowing pre-emergence treatment (BBCH 00–08) at 0.099 kg ai/ha, where the safener cyprosulfamide is added. Trials from Spain, Italy, Germany, France, Netherlands and the UK (0.099–0.10 kg ai/ha, growth stage BBCH 0–06, cyprosulfamide added) matched this GAP. For sweet corn harvested at BBCH 79, total residues were: < 0.02 (10) mg/kg (n=10).

Several trials, where isoxaflutole was applied at the same dose rate at a later growth stage (BBCH 13–14), as well as a metabolism study in sweet corn following a post-emergence treatment at 0.21 kg ai/ha, confirmed the non-residue situation.

The Meeting estimated a maximum residue level of 0.02* mg/kg on sweet corn (corn-on-the-cob). The Meeting estimated an STMR of 0 mg/kg.

Pulses

Field trials involving chick-peas (dry) were performed in Australia.

Critical GAP for chick-peas in Australia is a single post plant crop, pre-emergence application at 0.075 kg ai/ha. In trials from Australia (1× 0.075 kg ai/ha post planting pre-emergent) matching this GAP, total residues were: < 0.01 (3) and < 0.01[a] mg/kg (n=4) with a common moiety method (including IFT-BA). The superscript (a) indicates the addition of an adjuvant. The addition of which did not result in a difference in total residue levels.

An additional four trials at the same locations using a single post-plant crop emergence application at a higher application rate of 0.15 kg ai/ha, as well as a metabolism study in poppy seeds after post-plant crop pre-emergence treatment at 0.11 kg ai/ha, confirmed the no residue situation.

The Meeting estimated a maximum residue level of 0.01* mg/kg on chickpea, dry and an STMR of 0 mg/kg.

Field trials involving glyphosate/HPPD tolerant soya beans (FG72) (dry) were performed in the USA and Canada.

No authorised uses were available for glyphosate/HPPD tolerant soya beans (FG72). The Meeting agreed that no recommendations could be set for soya beans.

Maize

Field trials involving maize were performed in Spain, Italy, Greece, Portugal, Germany, France, Netherlands, the United Kingdom, the USA and Canada.

Critical GAP for maize in France is a single early post emergence treatment up to 3 leaf stage of the crop (BBCH 13) at 0.099 kg ai/ha with the addition of the safener cyprosulfamide. In field trials from Spain, Italy, Greece, Portugal, Germany, France, the Netherlands and the United Kingdom (1× 0.10 kg ai/ha, BBCH 13, with cyprosulfamide) matching this GAP, total residues for maize grain harvested at BBCH 89 were: < 0.02 (14) mg/kg.

The GAP for maize in the USA is a single pre-emergence treatment at 0.16 kg ai/ha without the addition of the safener cyprosulfamide or a single early post-emergence treatment at 0.105 kg ai/ha up to 2 leaf-collar growth stage of the crop (GS 12) with the addition of the safener cyprosulfamide. In field trials from the USA (1× 0.15–0.17 kg ai/ha, pre-emergent, no adjuvants) matching the first GAP, total residues for maize grains harvested at maturity were < 0.02 (17) mg/kg. In field trials from the USA (1× 0.13 kg ai/ha, post-emergent GS 12, with safener cyprosulfamide, no adjuvants) matching the second GAP, total residues for maize grains harvested at maturity were < 0.03 (17) mg/kg.

A metabolism study with mature maize grains at 0.21 kg ai/ha after pre plant or post-emergence application did not confirm the non-residue situation.

The Meeting estimated a maximum residue level of 0.02* mg/kg and an STMR of 0.02 mg/kg.

Sugar cane

Supervised residue trials on sugar cane were conducted in Australia, Mexico and Brazil.

There were no authorised uses available for Mexico and Brazil.

Critical GAP for sugar cane in Australia is a single soil directed application at 0.15 kg ai/ha when the sugar cane was at least 0.75 m high and with a PHI of 19 weeks without adjuvant. In field trials from Australia (1× 0.150 kg ai/ha, PHI 133–166 days) matching this GAP, total residues were < 0.01 (2) mg/kg with a common moiety method (including IFT-BA).

Two additional trials, at the same locations, at 1× 0.225 kg ai/ha and a PHI of 133–166 days, two trials in Brazil using two applications at 0.150 kg ai/ha and a PHI of 92–95 days and a metabolism study in mature sugar cane after soil directed application to emerged plants at 0.133 kg ai/ha, confirmed the no residue situation.

The Meeting estimated a maximum residue level of 0.01* mg/kg on sugar cane and an STMR of 0 mg/kg.

Poppy seed

Field trials involving poppy seed were performed in France, Spain, Germany, Netherlands and Hungary.

Critical GAP for poppy seed in Spain is for a single pre-emergence application at 0.060 kg ai/ha without the safener cyprosulfamide. There were no trials matching this GAP.

Critical GAP for poppy seed in Hungary is for a single pre-emergence application at 0.11 kg ai/ha with the safener cyprosulfamide. In field trials from Germany, the Netherlands and Northern France (1× 0.10 kg ai/ha, pre-emergence, with cyprosulfamide) matching this GAP, total residues poppy seeds were < 0.02 (3) mg/kg.

A metabolism study in poppy following post-plant crop pre-emergence treatment at 0.11 kg ai/ha confirmed the no residue situation.

The Meeting estimated a maximum residue level of 0.02* mg/kg in poppy seeds and an STMR of 0 mg/kg.

Legume animal feeds

Field trials involving chick-pea forage were performed in Australia.

Critical GAP for chickpeas in Australia is a single post plant crop pre-emergence application at 0.075 kg ai/ha with a PHI of 6 weeks for use as forage. There were no trials matching this GAP.

Field trials involving chick-pea fodder were performed in Australia.

Critical GAP for chick-peas in Australia is a single post plant crop pre-emergence application at 0.075 kg ai/ha. In trials from Australia (1× 0.075 kg ai/ha, post planting pre-emergent) matching this GAP, total residues were: < 0.01 (3) and < 0.01[a] mg/kg (n=4) with a common moiety method (including IFT-BA). The superscript (a) indicates the addition of adjuvant. The addition of which did not result in a difference in total residue levels.

An additional trial at the same location using a single post-plant pre-emergence application at a higher application rate of 0.20 kg ai/ha did not confirm the non-residue situation.

The Meeting estimated a maximum residue level of 0.01* mg/kg on chickpea fodder, a median residue of 0.01 mg/kg and a highest residue of 0.01 mg/kg for livestock dietary burden calculations.

Forage and fodder of cereal grains and grasses

Field trials involving maize forage were performed in Spain, Italy, Greece, Portugal, Germany, France, the Netherlands, the United Kingdom, the USA and Canada.

Critical GAP for maize in France is a single early post-emergence treatment up to 3 leaf stage of the crop (BBCH 13) at 0.099 kg ai/ha with the addition of the safener cyprosulfamide. No PHI is mentioned. High total residues ranging from 1.3–16 mg/kg eq were found immediately after treatment (DAT=0). However, the Meeting considers DAT=0 irrelevant for maize forage harvest and considers growth stage BBCH 16 or 33 (3 nodes with 6 leaves) the earliest grazing time for maize forage. In field trials from Spain, Italy, Greece, Portugal, Germany, France, Netherlands and the United Kingdom (1× 0.099–0.10 kg ai/ha, BBCH 13, with cyprosulfamide) matching the French GAP, total residues for maize forage harvested at BBCH 19 or 33–35 (DAT 40–41) were < 0.02 (11) and 0.34 mg/kg (n=12).

Critical GAP for maize in the USA is a single early post-emergence treatment at 0.105 kg ai/ha up to 2 leaf-collar growth stage of the crop (BBCH 14 or 32) with the addition of the safener cyprosulfamide, with or without the addition of an adjuvant. The pre-harvest interval is 45 days. In field trials from the USA (1× 0.13 kg ai/ha, PHI 43–45 days, with safener cyprosulfamide, no adjuvants) matching this GAP, total residues for early maize forage were < 0.03 (15) mg/kg.

The Meeting agreed that the dataset matching French GAP could be used to estimate a median residue of 0.02 mg/kg and a highest residue of 0.34 mg/kg for livestock dietary burden calculations.

Field trials involving maize fodder were performed in Spain, Italy, Greece, Portugal, Germany, France, Netherlands, the United Kingdom, the USA and Canada.

Critical GAP for maize in France is a single early post emergence treatment up to 3 leaf stage of the crop (BBCH 13) at 0.099 kg ai/ha with the addition of the safener cyprosulfamide. In field trials from Spain, Italy, Greece, Portugal, Germany, France, Netherlands and the United Kingdom (1× 0.099–0.10 kg ai/ha, BBCH 13, with cyprosulfamide) matching this GAP total residues for maize fodder harvested at BBCH 79 (sweet corn fodder) were < 0.02 (13) mg/kg.

Critical GAP for maize in the USA is a single pre-emergence treatment at 0.16 kg ai/ha without the addition of the safener cyprosulfamide or a single early post-emergence treatment at 0.105 kg ai/ha up to 2 leaf-collar growth stage of the crop (i.e. GS 12) with the addition of the safener cyprosulfamide, each with or without the addition of an adjuvant. In field trials from the USA (1× 0.15–0.17 kg ai/ha, pre-emergent, no adjuvants) matching the first GAP, total residues for maize fodder harvested at dent stage to maturity were < 0.02 (17) mg/kg. In field trials from the USA (1× 0.13 kg ai/ha, post-emergent GS 12, with safener cyprosulfamide, no adjuvants) matching the second GAP, total residues for maize fodder harvested at maturity were < 0.03 (14) mg/kg.

A metabolism study with mature maize fodder at 0.21 kg ai/ha after post-emergence application did not confirm the non-residue situation.

The Meeting estimated a maximum residue level of 0.02* mg/kg, a median residue of 0.02 mg/kg and a highest residue of 0.02 mg/kg for livestock dietary burden calculations.

Miscellaneous forage and fodder crops

Supervised residue trials on sugar cane tops/fodder were conducted in Australia.

The Meeting estimated a maximum residue level of 0.01* mg/kg on sugar cane fodder, a median residue of 0 mg/kg and a highest residue of 0.01 mg/kg for livestock dietary burden calculations.

Residues from rotational crops

Total residues above 0.01 mg/kg eq are not expected in rotational crops.

Fate of residues during processing

Processing studies with isoxaflutole were undertaken for soya beans. However, since no MRLs could be set for soya beans, no processing factors are needed.

Residues in animal commodities

The Meeting estimated the dietary burden of isoxaflutole residues on the basis of the livestock diets listed in the FAO manual appendix IX (OECD feedstuff table). Calculation from highest residue and STMR (some bulk commodities) provides the levels in feed suitable for estimating maximum residue levels, while calculation from STMR values from feed is suitable for estimating STMR values for animal commodities. Commodities used in the dietary burden calculation are maize grains, maize forage, chickpea fodder, maize forage, maize fodder and sugar cane tops.

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

Animal dietary burden for isoxaflutole total residues, expressed as ppm of dry matter diet

	US	EU	AU	JP	overall
	max	max	max	max	max
beef cattle	0.146	0.685	0.688	0.017	0.688
dairy cattle	0.394	0.518	0.688	0.436	0.688 [a, b]
poultry broiler	0.017	0.016	–	0.016	0.017
poultry layer	0.017	0.102	–	0.018	0.102 [c, d]
	mean	mean	mean	mean	mean
beef cattle	0.026	0.045	0.048	0.017	0.048
dairy cattle	0.034	0.038	0.048	0.036	0.048 [a, b]
poultry broiler	0.017	0.016	–	0.016	0.017
poultry layer	0.017	0.022	–	0.018	0.022 [c, 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

Livestock feeding studies

The Meeting received a feeding study on lactating cows and laying hens. Total residues in animal commodities for enforcement are defined as the sum of isoxaflutole and IFT-DKN, expressed as isoxaflutole equivalents. Total residues for dietary risk assessment are defined as the sum of isoxaflutole, IFT-DKN, RPA 205834 and RPA 207048, and their conjugates, expressed as isoxaflutole equivalents.

Four groups of four lactating Holstein cows were dosed once daily via capsules at levels of 0.0, 4.7, 14.4 and 45.5 ppm parent compound in dry weight feed for 42 consecutive days. Milk was collected throughout the study and tissues were collected on day 42 within 7.5 h after the last dose. Milk was not analysed for RPA 207048, but the level of RPA 207048 has been estimated based on relative levels to the other metabolites in the metabolism study. Residues found at the 4.7 ppm dose level are summarized in the residues section below.

Four groups of 15 laying hens were dosed once daily via capsules at levels of 0.0, 0.18, 0.54 and 1.8 ppm parent compound in dry weight feed for 42 consecutive days. Eggs were collected throughout the study and tissues were collected on day 42 within 3 h after the last dose. Eggs and hen

tissues were not analysed for RPA 205834 and RPA 207048, but the level of these metabolites has been estimated based on relative levels to the other metabolites in the metabolism study. Residues found at the 0.18 ppm dose level are summarized in the residue section below.

Residues in animal commodities

Cattle

For maximum residue level estimation, the highest residue in the tissues and milk were calculated by interpolating the maximum dietary burden (0.688 ppm) between the relevant feeding levels (0–4.7 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 (0.048 ppm) between the relevant feeding levels (0–4.7 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 residues (mg/kg eq) in			
	Feed level (ppm) for milk residues	Total residues (mg/kg eq) in milk	Feed level (ppm) for tissue residues	Muscle	Liver	Kidney	Fat
Maximum residue level—beef or dairy cattle (residue definition for enforcement)							
Feeding study [a]	4.7	NA	4.7	NA	0.82	0.22	NA
Dietary burden and residue estimate	0.688	0	0.688	0	< 0.1	< 0.1	0
STMR—beef or dairy cattle (residue definition for dietary risk assessment)							
Feeding study [b]	4.7	NA	4.7	NA	0.81	0.29	NA
Dietary burden and residue estimate	0.048	0	0.048	0	< 0.2	< 0.2	0

NA not analysed, because highest dose level of 45.5 ppm showed residues below or just above the LOQ

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

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

The Meeting estimated a maximum residue level for total isoxaflutole residues of 0.01* mg/kg in meat (from mammals other than marine mammals), mammalian fats (except milk fats), milks, and 0.1 mg/kg in mammalian edible offal. The residue in animal commodities is considered not fat soluble.

The Meeting estimated an STMR for total isoxaflutole residues of 0 mg/kg in meat (from mammals other than marine mammals), mammalian fats (except milk fats) and milks, and 0.2 mg/kg in mammalian edible offal.

Poultry

For maximum residue level estimation, the high residue in the tissues and eggs were calculated by interpolating the maximum dietary burden (0.102 ppm) between the relevant feeding levels (0–0.18 ppm) from the laying hen feeding study and using the highest tissue and egg concentrations based on the residue definition for enforcement from individual animals within those feeding groups (see table below).

The STMR values for the tissues and eggs were calculated by interpolating the mean dietary burden (0.022 ppm) between the relevant feeding levels (0–0.18 ppm) from the laying hen feeding study and using the mean tissue and egg concentrations based on the residue definition for dietary risk assessment from those feeding groups (see table below).

				Total residues (mg/kg eq) in			
	Feed level (ppm) for egg residues	Total residues (mg/kg eq) in egg	Feed level (ppm) for tissue residues	Muscle	Liver	Kidney	Fat
Maximum residue level—poultry broilers or layers (residue definition for enforcement)							
Feeding study [a]	0.18	NA	0.18	NA	0.21	–	NA
Dietary burden and residue estimate	0.102	0	0.102	0	0.12	–	0
STMR—poultry broilers or layers (residue definition for dietary risk assessment)							
Feeding study [b]	0.18	NA	0.18	NA	0.19	–	NA
Dietary burden and residue estimate	0.022	0	0.022	0	< 0.1	–	0

NA not analysed, because highest (1.8 ppm) and medium (0.54 ppm) dose level did not show residues

[a] highest residues for tissues and eggs

[b] mean residues for tissues and eggs

The Meeting estimated a maximum residue level for isoxaflutole total residues of 0.2 mg/kg in poultry edible offal, 0.01* mg/kg in poultry meat, poultry fats and poultry eggs. The residue in animal commodities is considered not fat soluble.

The Meeting estimated an STMR for isoxaflutole total residues of 0.1 mg/kg in poultry edible offal, 0 mg/kg in poultry meat and poultry fats, 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.

Definition of the residue for compliance with the MRL and for dietary risk assessment for plant commodities: *sum of isoxaflutole and isoxaflutole diketonitrile, expressed as isoxaflutole.*

Definition of the residue for compliance with the MRL for animal commodities: *sum of isoxaflutole and isoxaflutole diketonitrile, expressed as isoxaflutole.*

The Meeting considers the residue not fat soluble.

Definition of the residue for dietary risk assessment for animal commodities: *sum of isoxaflutole, isoxaflutole diketonitrile, RPA 205834 (2-aminomethylene-l-cyclopropyl-3-(2-mesyl-4-trifluoromethylphenyl)-propane-1,3-dione) and RPA 207048 (1-cyclopropyl-2-hydroxymethylene-3-(2-mesyl-4-trifluoromethylphenyl)-propane-1,3-dione), including their conjugates, expressed as isoxaflutole.*

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Daily Intakes (IEDI) of for isoxaflutole 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 13 GEMS/Food cluster diets, based on the estimated STMRs were in the range 0–1% of the maximum ADI of 0.02 mg/kg bw. The Meeting concluded that the long-term intake of residues of isoxaflutole from uses considered by the Meeting is unlikely to present a public health concern.

Short-term intake

Since no ARfD is considered necessary, no short-term intake assessment is considered necessary. The Meeting concluded that the short-term intake of residues of isoxaflutole from uses considered by the Meeting is unlikely to present a public health concern.

5.26 MALATHION (49)

RESIDUE AND ANALYTICAL ASPECTS

The JMPR evaluated malathion residues for the first time in 1966, and several times thereafter. The compound was evaluated within the periodic review programme in 1999, and the residue was defined as malathion for compliance with MRL values as well as for consumer dietary intake assessment. An ADI of 0–0.03 mg/kg bw and an ARfD of 2 mg/kg bw were established by the 1999 and 2005 JMPRs, respectively.

The manufacturer provided current US labels for ground and aerial application of malathion on sweet and tart cherries, and resubmitted the reports of supervised trials conducted in 1993 in the USA at higher rates than permitted by the present US GAP, to be evaluated applying the proportionality concept adopted by the Thirty-sixth Session of CAC. No new information was provided.

Results of supervised residue trials on crops

The present US GAP specifies a maximum 4 ground treatments of cherries at 3 day intervals, a maximum dose rate of 1.96 kg/ha with a PHI of 3 days. The compound may be used for aerial application four times at seven days intervals on sweet cherries and six times on tart cherries at a maximum dose rate of 1.37 kg ai/ha with a PHI of 1 day.

Supervised trials were conducted in USA in 1993. The sweet and tart cherry plots were treated 6 or 7 times with an EC formulation at 4.2 kg ai/ha rate by foliar ground application 7 days apart. Samples were collected at 3, 7 and 14 days after the last application.

The residues in whole sweet cherries at a 3-day PHI were: 0.26, 0.45 and 1.2 mg/kg.

The residues in whole tart cherries at a 3-day PHI were: 1.1, 1.6 and 2.6 mg/kg

At the same geographical locations the cherry trees were aerially treated 6 times with an ULV formulation at a rate of 1.37 kg ai/ha 7 days apart. Samples were collected at 1, 4, 7 and 14 days after the final application.

The residues in whole sweet cherries at a 1-day PHI were: 0.02, 0.17 and 0.19mg/kg.

The residues in whole tart cherries at a 1-day PHI were: 0.03, 0.34, 0.47 mg/kg.

The Meeting noted that the last 3 ground treatments were carried out at 4.2 kg/ha rate in all trials and the early applications with 8.96 kg ai/ha did not affect the residues in harvested fruits, as the residues derived from these trials were within the residue ranges observed in other trials. As a result the Meeting agreed to apply the proportionality approach to the data set.

The residues following ground treatments were adjusted with the proportionality factor of 1.96/4.2=0.467. This resulted in residues in sweet cherries of 0.12, 0.21 and 0.56 mg/kg, and in tart cherries of 0.51, 0.75 and 1.21mg/kg.

The Meeting noted that the aerial treatment resulted in lower residues in both commodities then the ground application, and that tart cherries contained higher residues than the sweet cherries. Since the highest and lowest residue values in the datasets overlapped the Meeting decided to use the residue data derived from ground application to estimate maximum, median and high residues.

The combined residue data in cherries in rank order were: 0.12, 0.21, , 0.51, 0.56, 0.75 and 1.21 mg/kg.

The Meeting considered that residues in sweet and tart cherries properly represent various cherry fruits and estimated a median residue of 0.535 mg/kg, a HR of 1.21 mg/kg and a maximum residue level of 3 mg/kg for cherries.

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: *malathion.*

The residue is fat soluble

DIETARY RISK ASSESSMENT

Long-term intake

The evaluation of malathion resulted in recommendations for MRL and STMR values for cherries. The results are shown in Annex 3. The International Estimated Daily Intake for the 13 GEMS/Food diet based on estimated STMR value was up to 0% of the maximum ADI of 0.03 mg/kg bw. The Meeting concluded that the long-term intake of residues of malathion from cherries is unlikely to present a public health concern.

Short-term intake

The International Estimated Short-term Intake (IESTI) for malathion was calculated for cherries for which maximum residue levels and STMR values were estimated. The results are shown in Annex 4. The IESTI was 0% of the ARfD (2 mg/kg bw).

Meeting concluded that the short-term intake of residues of malathion resulting from its use on cherries is unlikely to present a public health concern.

5.27 MANDIPROPAMID (231)

RESIDUE AND ANALYTICAL ASPECTS

Mandipropamid was first evaluated by JMPR in 2008 when an ADI of 0–0.2 mg/kg bw was established and decided that an ARfD was unnecessary. At the Forty-fourth Session of the CCPR, mandipropamid was scheduled for the evaluation of 2013 JMPR for additional uses on hops.

Methods of analysis

The Meeting received descriptions and validation data for analytical methods for residues of mandipropamid in hops and processed hop samples.

Hop samples were extracted with acetonitrile:water (80:20 v/v). Extracts are centrifuged and aliquots diluted with water prior to being cleaned-up using polymeric solid-phase extraction cartridges. Residues of mandipropamid were quantified with HPLC-MS/MS. Validated LOQs was 0.01 mg/kg.

Stability of residues in stored analytical samples

The Meeting received information on the stability of residues in crop commodities in tomatoes, grapes, potatoes, lettuce, cucumbers, wheat and soya beans for two years.

The commodities in which stability was tested were both raw agricultural commodities and processed, such as tomatoes (fruit and paste), grapes (fruit and juice), potatoes (tubers and granules/flakes), lettuce, cucumbers, wheat (forage, grain and straw), and soya beans (beans, hulls, meal and oil). There was no significant change in the mandipropamid residue levels in any commodity during the 24 months of storage at -20 °C with any apparent losses being < 30%. These commodities contained representatives of the four crop types, i.e., predominantly water, oil, protein, and starch containing materials. Therefore, residues of mandipropamid are expected to be stable in all crop commodities including hops stored under these conditions for at least two years.

Results of supervised residue trials on crops

The Meeting received supervised trials data for mandipropamid uses on hops.

Hops

Ten trials were conducted on hops in Europe (maximum German GAP: 0.40 kg ai/ha, two applications, 14-day PHI) in 2005 and 2006 and in the USA (maximum USA GAP: 0.145 kg ai/ha, three applications, 7-day PHI). In eight trials conducted at the maximum German GAP, the ranked order of concentrations in dry cone, median underlined, were: 14, 20, 26(2), 31, 32 and 34(2) mg/kg. In three trials conducted at the maximum US GAP, the ranked order of concentration in the dry cones was: 4.3, 5.4 and 10.6 mg/kg.

Noting that European trials resulted in higher residues in dry cones, the Meeting estimated a maximum residue level and an STMR value for mandipropamid in hops, dry of 90 and 28.5 mg/kg on the basis of European dataset.

Fate of residues during processing

The Meeting received information on the fate of mandipropamid residues during the food processing of hops.

The processing factor for beer (0.002) was applied to the estimated STMR for dry cone (28.5 mg/kg) to produce an STMR-P value for beer (0.057 mg/kg).

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.

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

DIETARY RISK ASSESSMENT

Long-term intake

The Meeting noted that the new estimation of dry hops did not result in a significant change of the long term dietary intake and concluded that the long-term intake of residues of mandipropamid resulting from its uses that have been considered by JMPR is unlikely to present a public health concern.

Short-term intake

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

5.28 PENTHIOPYRAD (253)

RESIDUE AND ANALYTICAL ASPECTS

Penthiopyrad (ISO common name) is a carboxamide fungicide used to control a broad spectrum of diseases on a large variety of crops. Penthiopyrad inhibits fungal respiration by binding to mitochondrial respiratory complex II. It was considered for the first time by the 2011 JMPR for toxicology, establishing an acceptable daily intake (ADI) of 0–0.1 mg/kg bw and an acute reference dose (ARfD) of 1 mg/kg bw. In 2012, the Meeting evaluated uses from the USA for residues, resulting in the recommendation of various maximum residue levels for plant and poultry commodities.

However, the Meeting estimated a maximum and mean dietary burden for beef and dairy cattle above the highest dose level administered in livestock animal feeding studies on cows and concluded, that no recommendations on mammalian animal products and milk could be made based on the available data. The maximum and mean dietary burden was calculated based on the Australian diet for beef and dairy cattle (main contributor: soya bean hay).

The Forty-fifth Session of the CCPR scheduled penthiopyrad for the evaluation of additional labels from Australia, Ireland, Italy, New Zealand, United Kingdom and the USA. In addition, following official communication from Australia that no fodder crops are imported, a re-evaluation of the dietary burden for livestock animals was requested. No additional residue data were provided to the 2013 Meeting.

Results of supervised residue trials on crops

As indicated the present Meeting did not receive additional supervised trial data for penthiopyrad. New European GAPs residue data was previously presented in the 2012 Evaluation for penthiopyrad, which at the time could not be taken into account as label authorisations had not been finalised.

For the new labels registered for penthiopyrad in Australia, New Zealand and the USA the Meeting noted that none of the GAPs involves higher application rates or shorter PHIs than evaluated in 2012. Since no additional supervised field trial data were submitted, no re-evaluation of these uses was conducted by the 2013 JMPR.

For dietary intake assessment the residue is defined as the sum of penthiopyrad and PAM, expressed as penthiopyrad (referred to as "total"). Since residue data were expressed in mg of the specific analyte per kg sample, PAM needs to be converted into penthiopyrad equivalents. The corresponding factor is: PAM → penthiopyrad = 359.42 g/mol ÷ 193.13 g/mol = 1.86. In supervised field trials PAM residues were normally found at much lower levels than parent penthiopyrad. As a result, no adjustment of PAM or addition of LOQs was conducted, if both analytes were below the LOQ. For all other purposes of calculation < LOQ values were handled as their numeric value (e.g., < 0.01 mg/kg as 0.01 mg/kg).

This is illustrated below:

Penthiopyrad [mg/kg]	PAM [mg/kg]	Total [mg/kg]* (Sum of penthiopyrad and PAM, expressed as penthiopyrad equivalents)
< 0.01	< 0.01	< 0.01
0.1	< 0.01	0.12 (0.1 + 1.86 × 0.01)
< 0.01	0.1	0.2 (0.01 + 1.86 × 0.1)
0.1	0.1	0.29 (0.1 + 1.86 × 0.1)

* rounded to two significant figures above the LOQ

Cucurbits with edible peel

In Italy penthiopyrad is registered for the use on cucumber and summer squash (zucchini) with one foliar application of 0.04 kg ai/hL with a 3 day PHI. Supervised field trial data on courgettes (zucchini) and cucumbers involving two treatments at the registered spray concentration were available for glasshouse use (Belgium, France, Greece, Italy and Spain) and field application (France, Greece, Italy and Spain). The analysis of samples collected directly before the second treatment indicates a contribution by the previous application of < 25% to the final residue, making these trials acceptable for evaluation.

For the purposes of MRL estimation penthiopyrad residues in protected summer squash were (n=2): 0.13 and 0.23 mg/kg.

For the dietary intake purposes the total residues in protected summer squash were (n=2): 0.15 and 0.25 mg/kg.

For the purposes of MRL estimations penthiopyrad residues in field summer squash were (n=2): 0.075, 0.12 mg/kg.

For the dietary intake purposes the total residues in field summer squash were (n=2): 0.095 0.14 mg/kg.

For the purposes of MRL estimations penthiopyrad residues in protected cucumber were (n=4): 0.031, 0.041, 0.053, 0.058 mg/kg.

For the dietary intake purposes the total residues in protected cucumber were (n=4): 0.051, 0.061, 0.073, 0.078 mg/kg.

For the purposes of MRL estimations penthiopyrad residues in field cucumber were (n=5): 0.013, 0.019, 0.082, 0.13, 0.3 mg/kg.

For the dietary intake purposes the total residues in field cucumber were (n=5): 0.033, 0.039, 0.1, 0.15, 0.32 mg/kg.

The Meeting decided that the previous recommendation for a maximum residue level of 0.5 mg/kg for penthiopyrad in fruiting vegetables, cucurbits also covered residues in cucumber and summer squash resulting from the new uses considered.

Tomato and eggplants

In Italy penthiopyrad is registered for the use on tomato and eggplants with one foliar application of 0.04 kg ai/hL with a 3 day PHI. Supervised field trial data on tomato involving two treatments at the registered spray concentration were available for glasshouse (Belgium, France, Greece, Italy, Spain) and field application (France, Greece, Italy, Spain). The analysis of samples collected directly before the second treatment indicates a contribution by the previous application of < 25% to the final residue, making these trials acceptable for evaluation.

For the purposes of MRL estimations penthiopyrad residues in protected tomato were (n=7): 0.15, 0.24, 0.31, 0.38, 0.55, 0.76, 0.76 mg/kg.

For the dietary intake purposes the total residues in protected tomato were (n=7): 0.17, 0.26, 0.33, 0.4, 0.57, 0.78, 0.78 mg/kg.

For the purposes of MRL estimations penthiopyrad residues in field tomato were (n=5): 0.11, 0.18, 0.22, 0.29, 0.32 mg/kg.

For the dietary intake purposes the total residues in field tomato were (n=5): 0.13, 0.2, 0.24, 0.31, 0.34 mg/kg.

The Meeting recognized that residue data on tomato can also be extrapolated to eggplants.

The Meeting decided that the previous recommendation for a maximum residue level of 2 mg/kg for penthiopyrad in fruiting vegetables, other than cucurbits, except sweet corn and mushrooms also covers residues in tomatoes and eggplants resulting from the new uses considered.

Barley and oats

In Ireland and the UK penthiopyrad is registered for the use on barley and oats with two foliar application up to 0.3 kg ai/ha each. The PHI is covered by a specified growth stage (BBCH 61). Supervised residue trials approximating this GAP were submitted to the 2012 Meeting from France, Germany, Hungary and the UK.

For the purposes of MRL estimations penthiopyrad residues in barley grain were (n=14): < 0.01(3), 0.01, 0.01, 0.039, 0.057, 0.063, 0.069, 0.071, 0.076, 0.1, 0.12 mg/kg.

For the dietary intake purposes the total residues in barley grain were (n=14): < 0.01(3), 0.03, 0.03, 0.059, 0.083, 0.089, 0.091, 0.096, 0.1, 0.12, 0.14 mg/kg.

The Meeting recognized that barley and oats share an identical GAP and decided to extrapolate residue data from barley to oats.

The Meeting estimated a maximum residue level and an STMR of 0.2 mg/kg and 0.086 mg/kg for penthiopyrad in barley and oats, respectively, replacing its previous recommendation of a maximum residue level of 0.15 mg/kg for barley and oats.

Wheat, rye and triticale

In Ireland and the UK penthiopyrad is registered for the use on rye, triticale and wheat with two foliar application up to 0.3 kg ai/ha each. The PHI is covered by a specified growth stage (BBCH 71). Supervised residue trials approximating this GAP were submitted to the 2012 Meeting from France, Germany, Hungary and UK.

For the purposes of MRL estimations penthiopyrad residues in wheat grain were (n=13): < 0.01(9), 0.013, 0.015, 0.015, 0.081 mg/kg.

For the dietary intake purposes the total residues in wheat grain were (n=13): < 0.01(9), 0.033, 0.035, 0.035, 0.1 mg/kg.

The Meeting recognized that wheat, rye and triticale share an identical GAP and decided to extrapolate residue data from wheat to rye and triticale.

The Meeting estimated a maximum residue level of 0.1 mg/kg and confirmed its previous estimate of an STMR of 0.01 mg/kg for penthiopyrad in wheat, rye and triticale, respectively, replacing its previous recommendation of a maximum residue level of 0.04 mg/kg for wheat, rye and triticale.

Animal feeds

Barley, oats, rye, triticale and wheat forage

In Ireland and the UK penthiopyrad is registered for the use on barley, oats, rye, triticale and wheat with two foliar application up to 0.3 kg ai/ha each. The PHI is covered by specified growth stages (BBCH 61 & 71). Supervised residue trials approximating this GAP were submitted to the 2012 Meeting from France, Germany, Hungary and the UK.

For the calculation of the livestock animal dietary burden total residues in barley forage (fresh) were (n=6): 2.0, 3.5, 3.9, 3.9, 4.0 and 4.5 mg/kg.

For the calculation of the livestock animal dietary burden total residues in wheat forage (fresh) were (n=6): 2.2, 3.0, 3.8, 4.3, 5.3 and 5.7 mg/kg.

The Meeting decided that the previously estimated median and highest residues in barley, oats, rye, triticale and wheat forage (fresh) of 10 mg/kg and 17 mg/kg, respectively, covered residues resulting from the new uses considered by the present Meeting.

Barley, oats, rye, triticale and wheat straw and fodder of cereals

In Ireland and the UK penthiopyrad is registered for the use on barley, oats, rye, triticale and wheat with two foliar application up 0.3 kg ai/ha each. The PHI is covered by specified growth stages (BBCH 61 & 71). Supervised residue trials approximating this GAP were submitted to the 2012 Meeting from France, Germany, Hungary and the UK.

For the purposes of MRL estimations penthiopyrad residues in barley straw (fresh) were (n=12): < 0.05, 0.051, 0.11, 0.13, 0.15, 0.2, 0.25, 0.28, 0.28, 0.36, 0.57 and 0.68 mg/kg.

For the calculation of the livestock animal dietary burden total residues in barley straw (fresh) were (n=12): < 0.05, 0.15, 0.21, 0.23, 0.25, 0.3, 0.35, 0.38, 0.38, 0.46, 0.67, 0.78 and 1.0 mg/kg.

For the purposes of MRL estimations penthiopyrad residues in wheat straw (fresh) were (n=13): 0.05, 0.052, 0.059, 0.067, 0.077, 0.12, 0.13, 0.16, 0.21, 0.26, 0.75, 1.1 and 2.3 mg/kg.

For the calculation of the livestock animal dietary burden total residues in wheat straw (fresh) were (n=13): 0.15, 0.16, 0.16, 0.17, 0.18, 0.22, 0.23, 0.26, 0.31, 0.36, 0.85, 1.2 and 2.6 mg/kg.

The Meeting decided that the previously estimated maximum residue level, median and highest residue in barley, oats, rye, triticale and wheat straw of 80 mg/kg (DM based), 21 mg/kg and 54 mg/kg, respectively, covered residues resulting from the new uses considered by the present Meeting.

Fate of residues during processing

The Meeting estimated new maximum residue levels for barley, oats, rye, triticale and wheat and a new STMR for barley and oats.

The estimation of maximum residue levels is based on the parent substance only, whereas for the dietary intake assessment the total residue needs to be taken into account. Based on the processing factors derived by the 2012 Meeting the following residues in processed products were estimated:

Commodity	Processing factor	Processing factor (median or best estimate)	MRL / STMR (mg/kg)	MRL, STMR-P (mg/kg)
Barley beer	Total: < 0.11, < 0.36	Total: < 0.24	STMR: 0.086	STMR- P: 0.021
Pot barley	Total: 0.67, 0.68	Total: 0.68	STMR: 0.086	STMR-P: 0.058
Wheat bran	Penthiopyrad: 1.8	Penthiopyrad: 1.8	MRL: 0.1	MRL: 0.2
Wheat germ	Penthiopyrad: 2.1	Penthiopyrad: 2.1	MRL: 0.1	MRL: 0.2

For wheat processed into wheat bran and wheat germ the Meeting estimated maximum residue levels of 0.2 mg/kg, respectively, and agreed to withdraw its previous recommendations of 0.1 mg/kg.

Residues in animal commodities

Livestock dietary burden

Livestock feeding studies involving administration of penthiopyrad to lactating cows and laying hens were reported in the 2012 JMPR Report.

Estimated maximum and mean dietary burdens of livestock

Dietary burden calculations for beef cattle, dairy cattle, broilers and laying poultry are presented in Annex 6.

The Meeting received official communication from Australia that no fodder crops are imported. The Meeting therefore decided to make a refined calculation of the livestock dietary burden based using the following parameters:

For the Australian diet only feed commodities corresponding to Australian authorisations plus globally traded non-fodder commodities are taken into account (e.g., grains and seeds).

For US-Canada, EU and Japan the calculation was conducted according to the usual procedure described in FAO Manual and amended by the new estimated median residue of 0.086 mg/kg for barley and oats. However, in contrast to 2012, forage crops were only included in the dietary burden for regions with corresponding labels (e.g. barley, oats, rye, triticale and wheat forage for Europe).

The dietary burdens were estimated using the OECD diets listed in Appendix IX of the 2009 edition of the FAO Manual.

	Livestock dietary burden, total residue*, ppm of dry matter diet							
	US-Canada		EU		Australia		Japan	
	max.	mean	max.	mean	max.	mean	max.	mean
Beef cattle	12	4.5	23	12	1.3	1.3	1.9	0.46
Dairy cattle	55 [a c]	26 [b d]	30	13	1.1	1.1	4.6	0.9
Poultry - broiler	0.2	0.2	0.19	0.19	0.19	0.19	0.17	0.17
Poultry - layer	0.2	0.2	22 [e]	11 [f]	0.19	0.19	0.14	0.14

[a] Highest maximum beef or dairy cattle burden suitable for MRL estimates for mammalian meat

[b] Highest mean beef or dairy cattle burden suitable for STMR estimates for mammalian meat

[c] Highest maximum dairy cattle burden suitable for MRL estimates for milk

[d] Highest mean dairy cattle burden suitable for STMR estimates for milk

[e] Highest maximum broiler or laying hen burden suitable for MRL estimates for poultry products and eggs

[f] Highest mean broiler or laying hen burden suitable for STMR estimates for poultry products and eggs

* total residue: sum of penthiopyrad and PAM, expressed as penthiopyrad

Animal commodities, MRL estimation

For beef and dairy cattle maximum and mean dietary burdens of 55 ppm and 26 ppm were estimated, respectively. The calculation to estimate highest total residues for use in estimating maximum residue levels, STMR and HR values were shown below.

Penthiopyrad feeding study	Feed level	Total residue				
	(ppm)	(mg/kg) in milk	(mg/kg) in muscle	(mg/kg) in kidney	(mg/kg) in liver	(mg/kg) in fat
Maximum residue level: dairy cattle						
Feeding study	21.4 74.6	< 0.01 0.042	< 0.01 0.036	0.03 0.07	0.04 0.08	0.03 0.04
Dietary burden and residue estimate	55	0.03	0.026	0.055	0.065	0.036
STMR dairy cattle						
Feeding study	21.4 74.6	< 0.01 0.042	< 0.01 0.036	0.03 0.07	0.04 0.08	0.03 0.04
Dietary burden and residue estimate	26	0.013	0.012	0.033	0.043	0.031

For beef and dairy cattle the Meeting estimated HR values for penthiopyrad (total residue) of 0.026 mg/kg in muscle, of 0.065 mg/kg in edible offal (based on liver) and of 0.036 mg/kg in fat. STMR values were estimated at levels of 0.013 mg/kg for milk, 0.012 mg/kg for meat, 0.043 mg/kg for edible offal (based on liver) and 0.031 mg/kg for fat.

The Meeting also estimated the following maximum residue levels: milk 0.04 mg/kg, meat (mammalian except marine mammals) 0.04 mg/kg, mammalian fat 0.05 mg/kg and edible offal 0.08 mg/kg.

For poultry the mean and maximum dietary burden differed insignificantly compared to the calculation by the 2012 Meeting (Max/Mean; 2012: 22ppm/10ppm; 2013: 22ppm/11ppm). The previous recommendations for penthiopyrad in poultry tissues and eggs are confirmed.

RECOMMENDATIONS

The Meeting estimated the STMR, HR and MRL values shown below.

Definition of the residue for compliance with MRL for plant commodities: *penthiopyrad*

Definition of the residue for compliance with MRL for animal commodities and for the estimation of dietary intake for plant and animal commodities: *sum of penthiopyrad and 1-methyl-3-trifluoromethyl-1H-pyrazole-4-carboxamide (PAM), expressed as penthiopyrad*

The residue is not fat-soluble.

DIESTARY RISK ASSESSMENT

Long-term intake

The WHO Panel of the 2011 JMPR established an Acceptable Daily Intake (ADI) of 0-0.1 mg/kg bw/day for penthiopyrad.

The 2013 evaluation of penthiopyrad resulted in new recommendations for MRLs and STMR values for barley, oats, rye, triticale, wheat and mammalian animal products. Where data on consumption were available for the listed food commodities evaluated in 2012 or 2013, dietary intakes were calculated for the 13 GEMS/Food Consumption Cluster Diets. The results are shown in Annex 3.

The IEDIs in the thirteen Cluster Diets, based on the estimated STMRs were 0-6% of the maximum ADI (0.1 mg/kg bw). The Meeting concluded that the long-term intake of residues of penthiopyrad from uses that have been considered by the JMPR is unlikely to present a public health concern.

Short-term intake

The WHO Panel of the 2011 JMPR established an Acute Reference Dose (ARfD) of 1 mg/kg bw for penthiopyrad.

The International Estimated Short-Term Intake (IESTI) for penthiopyrad was 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 IESTI for children and for the general population was 0% of the ARfD.

The Meeting concluded that the short-term intake of residues of penthiopyrad resulting from uses that have been considered by the 2013 JMPR is unlikely to present a public health concern.

5.29 PICOXYSTROBIN (258)

TOXICOLOGY

Picoxystrobin was evaluated by JMPR in 2012, when an ADI of 0–0.09 mg/kg bw and an ARfD of 0.09 mg/kg bw were established. However, the Meeting was unable to conclude on the toxicological relevance of estimated intakes of picoxystrobin metabolite IN-H8612 due to equivocal data in an in vitro assay for chromosomal aberrations. The Meeting was also unable to conclude on the toxicological relevance of estimated intakes of 2-(2-formylphenyl)-2-oxoacetic acid due to a lack of toxicological studies and a structural alert identified for genotoxicity.

During the 2013 JMPR, a new in vivo mouse micronucleus study[1] for IN H8612 was submitted. The protocol used for this study is consistent with international guidelines (Organisation for Economic Co-operation and Development Test Guideline No. 474). This in vivo study was evaluated by the Meeting and showed no evidence of genotoxicity. This allayed the concern from the in vitro study evaluated previously.

Conservative estimates of exposure were 0.2 µg/kg bw per day for chronic exposure and 0.6 µg/kg bw for acute exposure. Both estimates of exposure were below the threshold of toxicological concern for compounds with no evidence of genotoxicity (for Cramer class III, 1.5 µg/kg bw per day for chronic exposure; 5 µg/kg bw for acute exposure). The Meeting concluded that there is no concern for dietary exposure to IN-H8612.

No new data were submitted for 2-(2-formylphenyl)-2-oxoacetic acid. The company informed the Meeting that it was unable to synthesize the compound in sufficient amounts to perform an in vivo mouse micronucleus study, but that residues in soya beans were expected to be exceedingly low and therefore dietary exposure would be expected to be insignificant. The Meeting concluded that additional genotoxicity testing (e.g., an Ames test) and/or information on residues would be required in order to facilitate the further evaluation of this metabolite.

An addendum to the toxicological monograph was not prepared.

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[1] Myhre A (2013). IN-H8612: Mouse bone marrow micronucleus test. Performed by DuPont Haskell Global Centers for Health and Environmental Sciences, Newark, Delaware, USA. DuPont Project No. 36929. Submitted to WHO by E.I. DuPont de Nemours, Wilmington, Delaware, USA.

5.30 PROPICONAZOLE (160)

RESIDUE AND ANALYTICAL ASPECTS

Propiconazole was evaluated by the JMPR for residues in 1987, 1991, 1994, and within the periodic review program in 2007, when a number of maximum residue levels were recommended. Propiconazole has an ADI of 0–0.07 mg/kg bw and an ARfD of 0.3 mg/kg bw. Information and residue trial data on citrus, stone fruits and tomato following post-harvest applications of propiconazole were submitted to current Meeting.

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

Methods of analysis

Methods of analysis evaluated by the 2007 JMPR are divided into two groups. Methods where only propiconazole is analysed involves mostly LC-MS/MS detection, with LOQ of 0.01 mg/kg for citrus and tomato and of 0.05 mg/kg for stone fruits. The common moiety method measure all residues convertible to 2,4-dichlorobenzoic (2,4-DCBA) and are performed using mostly GC-MSD (after derivatisation of 2,4-DCBA to its methyl ester) with an LOQ of 0.05 mg/kg.

Stability of residues in stored analytical samples

A study to investigate the stability of residues in analytical samples in peach submitted to the 2007 JMPR showed that residues of propiconazole in peach samples are stable up to 36 months after frozen storage. New studies evaluated by the present Meeting have shown that propiconazole residues were stable for up to 207 days in orange, 154 days in juice and dried pulp, and 224 days in orange oil and 189 days in cherries. Propiconazole residues measured using the common moiety method in tomato (fortified with propiconazole at 0.5 mg/kg level) were stable up to 160 days, and the samples in the residue trials were analysed within this period. No storage stability study for total residues was performed in stone fruits (samples were stored for at least 560 days).

Results from supervised residue trials on crops

The 2007 JMPR agreed that, based on metabolism study, a factor of 3 needs to be applied to convert parent residues to total residues (all residues convertible to 2,4-DCBA and expressed as propiconazole). Data evaluated by the present Meeting are from post harvested uses, and it is unlikely that propiconazole metabolites are formed between treatment and sample preparation for analysis. Furthermore, residues of propiconazole will be used for dietary exposure assessment, without using the factor of 3.

Citrus fruits

In USA, propiconazole can be applied twice as post-harvest treatment as in line dip/drench twice at up to 0.054 kg ai/hL or in-line aqueous or fruit coating spray at up to 1.8 g ai/1000 kg fruit. Seventeen post-harvest trials on citrus were conducted in 2006 in USA according to GAP rate, but in eight trials the samples were washed before the second application.

In four trials conducted in orange using dip application conducted according to GAP, residues of propiconazole were 2.2, 2.5, 3.4 and 3.7 mg/kg (highest level of duplicate sample was 4.9 mg/kg).

The Meeting estimates a maximum residue level of 9 mg/kg, a STMR of 2.95 mg/kg and a HR of 4.9 mg/kg for propiconazole in oranges.

Stone fruits

In USA, propiconazole can be applied once as post-harvest treatment in stone fruits using in line dip/drench twice at up to 0.014 kg ai/hL or in-line aqueous or fruit coating spray at up to 0.56 g ai/1000 kg fruit. Nine post-harvest trials on stone fruits were conducted in 2007 in USA according to GAP. In all trials, fruits without stone was analysed, but the Meeting agreed that the residues found in whole fruit is within 10% (higher) of that found in the fruits withouth the stones and consider the data appropriate.

Residues of propiconazole from trials conducted using dip application were 1.2, 1.4, 1.7 and 2.1 mg/kg in peaches (highest value of duplicate samples of 2.2 mg/kg), 0.18 and 0.20 mg/kg in plums (highest value of duplicate samples of 0.22 mg/kg) and 0.67 and 0.85 mg/kg in cherry.

Residue of propiconazole in fruits without stone from trials conducted using in-line aqueous application were 0.14, 0.20, 0.49 and 0.50 mg/kg in peaches, 0.16 and 0.19 mg/kg in plum and 0.17 mg/kg in cherry.

The Meeting agreed that trials conducted using dip application in peach gave the highest residues and recommends a maximum residue level of 5 mg/kg (Po), a STMR of 1.55 mg/kg and a HR of 2.2 mg/kg for propiconazole in peaches.

Residues in plums from dip and spray application are similar and can be grouped as 0.16, 0.18, 0.19 and 0.20 mg/kg. The Meeting recommends a maximum residue level of 0.6 mg/kg, a STMR of 0.185 mg/kg and a HR of 0.22 mg/kg for propiconazole in plums.

The Meeting agreed that there is not enough trials to estimate a maximum residue level for cherry.

Tomato

In USA, propiconazole can be used in tomato as a post-harvest treatment in line dip or drench at up to 0.27 kg ai/hL or high volume spray application at 4.5 g ai/1000 kg fruit. Nine post-harvest trials on tomato were conducted in 2009 in USA according to GAP.

In six trials using dip or drench application, residues of propiconazole in tomatoes were 0.47 (2), 0.80 (2), 0.87 and 1.4 mg/kg. In three trials using in-line spray, residues were 0.37, 0.74 and 1.5 mg/kg.

The Meeting agreed that the dip/drench and the in-line spray trials gave similar results that can be grouped as (n=9) 0.37, 0.47 (2), 0.74, 0.80 (2), 0.87 and 1.4 and 1.5 mg/kg (highest level among the samples was 1.5 mg/kg)

The Meeting estimates a maximum residue level of 3 mg/kg, a STMR of 0.80 mg/kg and a HR of 1.5 mg/kg for propiconazole in tomato.

Fate of residues in storage and processing

Effect on the nature of the residues during processing

The hydrolytic stability of [triazolyl-U-^{14}C]-propiconazole was investigated in aqueous buffer solutions at three pH values and temperatures to simulate processing practices The study was performed at pH 4 and 90 ºC for 20 minuts to simulate pasteurisation, pH 5 and 100 ºC for 60 min to simulate baking/brewing/boiling, and at pH 6 and 120 ºC for 20 min to simulate sterilisation. Only the parent compound was detected in the buffer solutions throughout the study, indicating that propiconazole is hydrolytically stable under the conditions of the tests.

Residues in processed commodities

In one study, orange were processed to oil, juice and dried pomace using procedures simulating commercial practice. Residues of propiconazole in oranges were 0.94 mg/kg, not detected in juice (< 0.01 mg/kg), 1.29 mg/kg in dried pulp and 174 mg/kg in oil, giving processing factors of < 0.011 for orange juice and of 184 for orange oil.

Based on a STMR of 1.95 mg/kg in oranges, the Meeting estimated a STMR-P of 0.02 mg/kg in orange juice.

Residues in animal commodities

Dried orange fruit can contribute to animal diets and is listed on the OECD animal diet. However, in commercial practice, post-harvest treatment is normally reserved for high value commodities and is unlikely that dried fruit from treated fruits would be fed to livestock. The Meeting considered that the esitmations for propiconazole in orange will not change the dietary burden calculated by the 2007 JMPR meeting, and confirms its previous recommendations for animal commodities

RECOMMENDATION

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.

DIETARY RISK ASSESSMENT

Long-term intake

The IEDI of propiconazole based on the STMRs estimated by this and previous Meetings for the 13 GEMS/Food regional diets were 1–20% of the maximum ADI of 0-0.07 mg/kg bw (see Annex 3 of the 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

The ARfD for propiconazole is 0.3 mg/kg bw. The International Estimated Short-Term Intake (IESTI) for propiconazole was calculated for the plant 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. The IESTI represented a maximum of 100% of the ARfD for oranges (children 2–6 years). The Meeting concluded that the short-term intake of propiconazole residues from uses considered by the current Meeting were unlikely to present a public health concern.

5.31 PYRIMETHANIL (226)

RESIDUE AND ANALYTICAL ASPECTS

Pyrimethanil was most recently evaluated for toxicology and residues by the JMPR in 2007. The Meeting derived an ADI of 0.2 mg/kg bw per day and decided that an ARfD is unnecessary.

In 2007 the Meeting agreed that the residue definition for both enforcement and dietary intake for plant commodities is parent pyrimethanil. The Meeting further concluded that the residue definition for both enforcement and dietary exposure considerations for milk is the sum of pyrimethanil and 2-anilino-4,6-dimethylpyrimidin-5-ol, expressed as pyrimethanil; and for livestock tissues (excluding poultry) is the sum of pyrimethanil and 2-(4-hydroxyanilino)-4,6-dimethylpyrimidine, expressed as pyrimethanil.

The compound was listed by the Forty-fourth Session of the CCPR for the evaluation of additional MRLs. The 2013 JMPR received residue data for pome fruit, stone fruit, lemons and ginseng.

Methods of analysis

The Meeting received information on the analytical methods used for determination of pyrimethanil residues in samples obtained from supervised trials on pome fruit, stone fruit, lemon, and ginseng. The residues were measured using GC/MS or HPLC/UV with LOQs of 0.05 mg/kg. The methods were reviewed by the JMPR in 2007, which concluded that adequate analytical methods for pyrimethanil exist for both data collection and enforcement purposes. The methods used in the trials submitted to the 2013 Meeting are essentially identical to those accepted at the 2007 Meeting.

Stability of residues in stored analytical samples

Detailed information from the 2007 JMPR showed that pyrimethanil residues are stable (> 70% remaining) in frozen storage for at least 12 months in the tested commodities, i.e., apple, grape, tomato, lettuce, carrot, pea, peach, and plum. Concurrent storage stability studies were submitted with the ginseng trials and demonstrated residue stability for at least 259 days.

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

Results of supervised residue trials on crops

The 2007 JMPR received supervised trials for many crops, including pre- and post-harvest uses of pome and stone fruit. However, due to incomplete GAP information, pome fruit thermofog data were not included in the pome fruit MRL recommendation. The 2013 JMPR received complete GAP information for pome and stone fruits, as well as expanded post-harvest residue data. For completeness, all relevant pome and stone fruit supervised trial data for pyrimethanil are considered in the following sections. The USA GAP allows for pre- and post-harvest applications of pyrimethanil to pome and stone fruit; however, few trials reflect residues from the combined pre- and post-harvest applications.

Lemon

In the USA, pyrimethanil is registered for use on lemons for up to 4 treatments at a rate of 1.7 kg ai/ha, with a PHI and a retreatment interval of 7 days. Five supervised field trials are available at this GAP from the USA.

Rank-order pyrimethanil residues in lemon were (n=5): 0.18, 0.21, <u>0.27</u> (2), and 0.82 mg/kg.

The Meeting noted that there is a current MRL for citrus fruit at 7 mg/kg based on post-harvest uses and concluded that the current MRL for citrus is adequate to cover the submitted pre-harvest-use lemon data. Therefore, the Meeting confirms its previous recommendation.

Pome fruits

In 2007, the Meeting reviewed residue values on pome fruits from pre-harvest and post-harvest trials according to Belgium, France, Germany, Greece, Italy, Netherlands, United Kingdom, and USA GAPs. Residues from post-harvest GAPs were higher and served as the basis for the previous recommendations for maximum residue level, STMR, and HR estimates of 7(Po), 0.7, and 3.8 mg/kg, respectively.

The 2013 Meeting has evaluated data from the USA and Europe matching a new GAP for uses of pyrimethanil as a post-harvest thermofog treatment. Although the GAP for thermofog uses in the US has a higher application rate than the GAPs in European countries (one application at 9.6 kg ai/1000 kg fruits vs. one application at the rate of 5.6 to 8 kg ai/1000 kg fruits), the residues resulting from the trials conducted according to the GAP in Europe were approximately 10-fold higher than the trial conducted according to the US GAP; therefore, the meeting selected data according to GAP in Europe.

Residues from post-harvest trials in apples (n=8, new data in bold) were: 1.1, 1.4 (2), 1.5, 1.6, **4.9**, **6.4**, and **7.1** mg/kg.

Residues from post-harvest trials in pears (n=4) were: 1.0, 1.6, 1.8, and 3.5 mg/kg.

As the residue data from apples and pears are from the same population, they were combined to give the following residues (n=12, median underlined): 1.0, 1.1, 1.4 (2), 1.5, 1.6 (2), 1.8, 3.5, 4.9, 6.4, and 7.1 mg/kg. The Meeting agreed to replace its previous maximum residue level recommendation of 7 mg/kg with a new estimated STMR of 1.6 mg/kg and a maximum residue level of 15 (Po) mg/kg for pome fruit.

Stone fruits

In 2007, the Meeting recommended an STMR of 1.3 mg/kg and a maximum residue level of 4 (Po) for cherries based on the post-harvest GAP for Chile. The 2013 Meeting received new information on the post-harvest GAP in the USA. Post-harvest trials were conducted at 2× the USA GAP. Since post-harvest data may not be adjusted via proportionality, there are no new data for the Meeting to use for a recommendation. Therefore, the Meeting confirmed its prior recommendations.

Berries and other small fruits

From the 2007 JMPR:

"Eight trial were conducted on the foliar application of pyrimethanil to strawberries in theUSA, where the GAP is 600 g/L SC, 0.8 kg ai/ha, 2.4 kg ai/ha/season, 1 day PHI. All trials were at maximum GAP, and the residues in ranked order (median underlined) were: 0.79, 0.93, 0.99, 1.1, 1.2, 1.3(2), and 2.3 mg/kg. The Meeting estimated an STMR of 1.2 mg/kg and a maximum residue level of 3 mg/kg for strawberries."

The current Meeting was asked to extrapolate the strawberry field trial data to Berries and Other Small Fruits [Subgroup 004E, Low Growing Berries (including Bakeapple; Cranberry (FB 0265); Cloudberry (FB 0277); Muntries (FB 0283); Partridge berry; Squaw vine; Strawberry (FB 0275); Strawberries, wild (FB 0276); Strawberry, Musky)], reflecting the USA label allowing use on the Low Growing Berry Crop Subgroup 13-07G.

Taking into account the available historic data showing that pesticide residues in strawberry are generally comparable to or higher than residues in other low-growing berries, the Meeting agreed to extrapolate the residue estimates for strawberry to commodities comprising the low-growing

berries subgroup. Therefore, for the low-growing berries subgroup (Subgroup 004E, FB 2009) the Meeting recommended a maximum residue level of 3 mg/kg and estimated an STMR of 1.2 mg/kg. The Meeting agreed to withdraw its previous recommendation of 3 mg/kg for strawberry.

Ginseng

In the USA, pyrimethanil is registered for use on ginseng for up to 3 treatments at a rate of 0.78 kg ai/ha, with a PHI of 30 days and a retreatment interval of 7 days. Three supervised field trials were available at this GAP from the USA.

Rank-order pyrimethanil residues in dried ginseng were (n=3): 0.099, 0.41, and 0.59 mg/kg.

The Meeting estimated an STMR value of 0.41 mg/kg and a maximum residue level value of 1.5 mg/kg for ginseng, dried.

Fate of residue during processing

In 2007, the Meeting estimated the following STMR-Ps for citrus juice, citrus pulp (dried) and citrus oil, respectively: 0.028 mg/kg; 1.3 mg/kg; 56 mg/kg. As these estimates adequately cover residues in lemon, the Meeting confirmed its prior recommendations for citrus.

The 2007 Meeting estimated a processing factor of 0.45 for apple juice, 0.37 for apple puree, and 4.1 for wet apple pomace. Applying these processing factors to the estimated STMR for pome fruit (1.6 mg/kg) resulted in STMR-P estimates of 0.72 mg/kg for apple juice, 0.59 mg/kg for apple puree, and 6.6 mg/kg for wet apple pomace. The Meeting agreed these values should replace the estimates made in 2007.

Residues in animal commodities

Dietary burden calculations for beef cattle and dairy cattle 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: apple pomace, almond hulls, carrot culls, citrus pulp, grape pomace, pea seed and pea straw. Pyrimethanil residues in all these feed items were as estimated by the 2007 JMPR except for apple pomace, which has a revised STMR-P of 6.6 mg/kg (the previous estimate was 2.9 mg/kg).

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	0.14	0.14	4.3	3.6	4.6[a]	3.9[c]	0.0	0.0
Dairy cattle	2.5	2.1	2.8	2.1	4.1[b]	3.4[d]	0.0	0.0

[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.

Animal commodity maximum residue levels

The calculations used to estimate residues in animal commodities based on comparisons of the dietary burden to results of the bovine feeding study, for use in estimating maximum residue levels, STMR and HR values, are shown below.

Pyrimethanil feeding study	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]	3 10	< 0.01 0.017	3 10	< 0.05 < 0.05	< 0.05 < 0.05	0.08 0.13	< 0.05 < 0.05
Dietary burden and high residue	4.1	< 0.01	4.6	< 0.05	< 0.05	0.09	< 0.05
STMR beef or dairy cattle							
Feeding study [b]	3 10	< 0.01 0.017	3 10	< 0.05 < 0.05	< 0.05 < 0.05	0.066 0.12	< 0.05 < 0.05
Dietary burden and residue estimate	3.4	< 0.01	3.9	< 0.05	< 0.05	0.07	< 0.05

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

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

Residue estimates in animal commodities are unchanged relative to those recommended in 2007; therefore, the Meeting confirmed its prior recommendations: an STMR of 0.01 mg/kg for milk and estimated a maximum residue level of 0.01 mg/kg for milk. The Meeting estimated STMRs of 0.0 mg/kg for each of meat and fat and maximum residue levels of 0.05 (*) mg/kg for meat. The Meeting estimated an STMR of 0.07 mg/kg for edible offal based on the STMR value for beef cattle kidney.

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 MRL and dietary intake) for plant commodities: *pyrimethanil.*

The residue is not fat-soluble.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Daily Intakes (IEDIs) of pyrimethanil were calculated for the 13 GEMS/Food cluster diets using STMRs/STMR-Ps estimated by the current Meeting. The ADI is 0–0.2 mg/kg bw and the calculated IEDIs were 0–5% of the maximum ADI (0.2 mg/kg bw). The Meeting concluded that the long-term intakes of residues of pyrimethanil, resulting from the uses considered by the current Meeting, are unlikely to present a public health concern.

Short-term intake

The 2007 JMPR decided that an ARfD was unnecessary and concluded that the short-term intake of pyrimethanil residues is unlikely to present a public health concern.

5.32 SPIROTETRAMAT (234)

RESIDUE AND ANALYTICAL ASPECTS

Spirotetramat was evaluated for the first time by the JMPR in 2008 for toxicology and residues. The Meeting derived an ADI of 0–0.05 mg/kg bw and an ARfD of 1.0 mg/kg bw and recommended maximum residue levels for a range of crops. In 2011 and 2012, the JMPR recommended additional maximum residue levels. The residue is defined as follows.

For compliance with the MRL for plant commodities: *spirotetramat plus spirotetramat enol, expressed as spirotetramat.*

For dietary intake estimation for plant commodities: *spirotetramat plus the metabolites enol, ketohydroxy, enol glucoside, and monohydroxy, expressed as spirotetramat*.

For compliance with the MRL and for dietary intake estimation for animal commodities: *spirotetramat enol, expressed as spirotetramat*.

The residue is not fat soluble.

The present Meeting evaluated supervised field trial data for various crops including their analytical methods, stability of frozen sample and stability tests, and processing studies.

Methods of analysis

Analytical methods used in raw agricultural commodities from field trials were suitable for quantifyin g spirotetramat residues including the metabolites spirotetramat enol, spirotetramat ketohydroxy, spir otetramat monohydroxy and spirotetramat enol glucoside in the various plant commodities. The meth ods were based on LC-MS/MS and the reference method used was evaluated by the Meeting in 2008 and 2011. The limits of quantitation for the raw commodities are 0.01 mg/kg (parent equivalents) for each analyte and 0.05 mg/kg for total spirotetramat equivalents.

For the processed products of pineapple and coffee bean, overall, the method performance wa s not acceptable. In pineapple juice and processing by-products, average recoveries of enol glucoside (0.01 mg/kg as parent equivalents) were not in the allo wable range.

In roasted coffee bean, a limit of quantitation for enol glucoside was as high as 0.05 mg/kg. F or freeze-dried coffee, the LOQ levels for spirotetramat enol, -ketohydroxy and - monohydroxy were 0.1 mg/kg, i.e., the fortification levels were not sufficiently low enough, further, some recoveries of parent and enol glucoside at the indicated LOQ level were outside the acceptable r ange, as a result the method performance was not considered satisfactory.

Stability of residues in stored analytical samples

Storage stability studies were performed with banana with peel, peeled banana, green coffee bean, roasted coffee bean and freeze-dried coffee. They indicated that the residues were stable during the frozen storage intervals of field trial samples. Stabilities of residues in commodities not assessed by the present Meeting are covered by the storage stability data evaluated by the 2008 JMPR, which demonstrated stability of all analytes for up to 2 years for a diverse range of commodities.

Results of supervised residue trials on crops

The Meeting received supervised residue trial data for the foliar application of spirotetramat as a suspension concentrate formulation (SC) to a variety of crops, i.e., blueberries, cranberry, banana, pineapple, pomegranate, blub onion, spring onion, watercress, globe artichoke and coffee.

In the discussions below, spirotetramat plus enol residues considered first for the estimation of maximum residue levels followed by total residues (spirotetramat plus the metabolites enol, ketohydroxy, monohydroxy, and enol glucoside, expressed as spirotetramat) for estimation of STMR and HR values for the dietary risk assessments.

Berries and other small fruits

Blueberries

In Canada, spirotetramat is registered at a rate of 0.20 kg ai/ha, a 7-day retreatment interval, a total seasonal rate of 0.44 kg, and a 7-day PHI. Eleven residue trials were conducted in the USA (7) and Canada (4) with three applications at a rate of 0.17–0.19 kg ai/ha, total seasonal rate of 0.52–0.56 kg ai/ha, 5–8 days retreatment intervals and 6–8 days PHIs. Of the trials, two were not considered independent as they were conducted at the same site, with the same variety at very close dates of application.

Residues of spirotetramat plus enol from the trials were (n=10): 0.14, 0.17, 0.21, 0.31, 0.37, 0.39, 0.53, 0.53, 0.68 and 0.69 mg/kg.

Total residues of spirotetramat from the trials were (n=10): 0.38, 0.44, 0.45, 0.49, 0.60, 0.66, 0.69, 1.1, 1.2 and 1.6 mg/kg.

The Meeting estimated a maximum residue level of 1.5 mg/kg and an STMR of 0.63 mg/kg and an HR of 1.6 mg/kg for bush berries as blueberry is a representative crop of the subgroup.

Cranberry

In Canada, spirotetramat is registered for the use on cranberry at a rate of 0.20 kg ai/ha, a 7-day retreatment interval, a total seasonal rate of 0.44 kg, and a 7-day PHI. Six residue trials were conducted in the USA and Canada with three applications at a rate of 0.17-0.19 kg ai/ha, total seasonal rate of 0.52–0.55 kg ai/ha, 6–8 days retreatment intervals and 7–8 days PHIs, approximating the Canadian GAP.

Residues of spirotetramat plus enol from the trials were (n=6): < 0.02, 0.023, 0.025, 0.046, 0.058 and 0.12 mg/kg.

Total residues of spirotetramat from the trials were (n=6): < 0.05, 0.054, 0.055, 0.076, 0.088 and 0.15 mg/kg.

The Meeting estimated a maximum residue level of 0.2 mg/kg and an STMR of 0.066 mg/kg and an HR of 0.15 mg/kg for cranberry.

Assorted tropical and sub-tropical fruits-inedible peel

Banana

Five residue trials were conducted using five applications in Hawaii, USA, according to the USA GAP (rate of 0.28 kg ai/ha, 14-day retreatment interval, total seasonal rate of 1.4 kg ai/ha, and 1-day PHI). In one trial, application was made on bagged banana. For the other four trials, banana bunches were not bagged, however, residues in pulp were not analysed, except one trial.

From the trials, residues of spirotetramat plus enol in unbagged whole banana were (n=4): 0.16 0.55, 1.0, 1.4 and 1.7 mg/kg.

From the trials, total residues of spirotetramat in unbagged whole banana were (n=4): 0.2, 0.62, 1.2, 1.4 and 1.8 mg/kg.

In the one trial, residues in pulp were 0.14 mg/kg (0.55 mg/kg for whole) for spirotetramat plus enol and 0.19 mg/kg (0.62 mg/kg for whole) for total spirotetramat.

The Meeting could not estimate a maximum residue level for banana as the number of trials was considered insufficient.

Pineapple

Five trials were conducted in Hawaii, USA with two applications, according to the USA GAP (rate of 0.18 kg ai/ha, 14-day retreatment interval, total seasonal rate of 0.36 kg ai/ha, and 1-day PHI). In these trials the preparation of samples did not comply with the relevant FAO guidelines, i.e., samples underwent cutting/quartering at the field site.

As the handling of samples did not comply with the relevant FAO guidelines on sample preparation, the Meeting decided that residue data could not be used for the estimation of a maximum residue level.

Pomegranate

Four trials were conducted in the USA with two applications, complying with the GAP of the USA (rate of 0.18 kg ai/ha, 14-day retreatment interval, 0.36 kg ai/ha/12-month, and a 1-day PHI). In these trials the preparation of samples did not comply with the relevant FAO guidelines, i.e., samples underwent cutting/quartering at the field site. As a result the residue data could not be used in estimating a maximum residue level.

Bulb vegetables,

Onion, bulb

Twelve trials were performed in Canada and USA with two applications, according to the USA GAP (rate of 0.09 kg ai/ha, 7-day retreatment interval, total seasonal rate of 0.18 kg ai/ha, and 3-day PHI). Two trials were not independent as they were conducted at the same site with the same variety with the same dates of application.

Residues of spirotetramat plus enol from the trials were (n=11): < 0.02, < 0.02, < 0.02, 0.026, 0.046, 0.051, 0.057, 0.058, 0.075, 0.095 and 0.28 mg/kg.

Total residues of spirotetramat from the trials were (n=11): < 0.05, < 0.05, < 0.05, 0.056, 0.076, 0.081, 0.087, 0.088, 0.11, 0.13 and 0.32 mg/kg.

Based on the residue values, the Meeting estimated a maximum residue level of 0.4 mg/kg.

The 2011 JMPR recommended a maximum residue level of 0.4 mg/kg, an STMR of 0.11 mg/kg and an HR of 0.27 mg/kg, based on the residues from trials in Australia matching GAP (2 applications at 0.048 kg ai/ha with a PHI of 7 days).

The Meeting therefore confirmed its previous maximum residue level recommendation of 0.4 mg/kg for onion, bulb.

Spring onion

Two trials were performed in Canada with two applications, matching the USA GAP (rate of 0.09 kg ai/ha, 7-day retreatment interval, total seasonal rate of 0.18 kg ai/ha, and 7-day PHI). The residues were 0.093 and 0.24 mg/kg as spirotetramat plus enol, 0.16 and 0.32 mg/kg as total residues.

The Meeting considered the number of trials insufficient to estimate a maximum residue level.

Watercress

Three trials were performed in the USA with two applications, according to GAP of the country (rate of 0.22 kg ai/ha, 7-day retreatment interval, total seasonal rate of 0.45 kg ai/ha, and 3-day PHI).

Two trials were not independent as they were conducted at the same site with the same variety, with dates of application 13 days apart. In addition, in one trial, two methods of application were utilized, i.e., using a backpack sprayer and overhead mini-sprinkler in a separate plot. These treatments were considered replicates of the trial. As a result one residue value was selected from each of the trials.

Residues from the trials were 0.26 and 0.32 mg/kg for spirotetramat plus enol, 0.51 and 0.56 mg/kg for total residues. The Meeting could not estimate a maximum residue level due to insufficient residue data.

The Meeting noted that the residues from the trials were covered by the previously recommended maximum residue level for leafy vegetables.

Artichoke, globe

Five trials were conducted in Canada and the USA with four applications, according to the USA GAP (rate of 0.15 kg ai/ha, 7-day retreatment interval, total seasonal rate of 0.56 kg ai/ha, and 3-day PHI).

Residues of spirotetramat plus enol from the trials were (n=5): 0.13, 0.20, 0.27, 0.47 and 0.49 mg/kg.

Total residues of spirotetramat from the trials were (n=5): 0.23, 0.34, 0.41, 0.60 and 0.70 mg/kg.

The Meeting estimated a maximum residue level of 1 mg/kg and an STMR of 0.41 mg/kg and an HR of 0.70 mg/kg for artichoke, globe.

Coffee beans

Five trials were conducted in Hawaii, USA with three applications, according to the GAP of that country (rate of 0.18 kg ai/ha, 21-day retreatment interval, total seasonal rate of 0.53 kg ai/ha, and 14-day PHI). Exceptionally, in one trial, a retreatment interval between the second and third application was 7 days due to an earlier ripening of coffee beans. The Meeting considered such a divergence from GAP would have little impact on the final residue level. Two trials were not considered independent as they were carried out at geographically close sites on the same variety within the same growing season.

Residues of spirotetramat plus enol from the four trials available were: 0.020, 0.028, 0.031 and 0.038 mg/kg; and 0.050, 0.059, 0.062 and 0.072 mg/kg for total residues of spirotetramat.

The Meeting considered the number of trials insufficient to estimate a maximum residue level.

Animal feeds

Residue information on animal feeds was not available for this Meeting.

Fate of residues during processing

One processing study for pineapple juice and pineapples processing by-products, roasted coffee bean and freeze-dried coffee were made available. However, the estimation of processing factors was not required as maximum residue levels could not be recommended for pineapple and coffee beans.

Residues in animal commodities

From the evaluations by the present Meeting, no feed items were added to the feed list evaluated by the 2011 JMPR. The Meeting retained the residue levels for animal commodities estimated by the 2011 and 2012 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 IESTIs.

Definition of the residue (for compliance with MRL for plant commodities: Spirotetramat and its enol metabolite, 3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]dec-3-en-2-one, expressed as spirotetramat.

Definition of the residue (for estimation of dietary intake)for plant commodities: Spirotetramat, enol metabolite 3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]dec-3-en-2-one, ketohydroxy metabolite 3-(2,5-dimethylphenyl)-3-hydroxy-8-methyoxy-1-azaspiro[4.5]decane-2,4-dione, monohydroxy metabolite cis-3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]decan-2-one, and enol glucoside metabolite glucoside of 3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]dec-3-en-2-one, expressed as spirotetramat.

Definition of the residue (for compliance with MRL and estimation of dietary intake) for animal commodities: Spirotetramat enol metabolite, 3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]dec-3-en-2-one, expressed as spirotetramat.

The residue is not fat-soluble.

DIETARY RISK ASSESSMENT

Long–term intake

The ADI for spirotetramat is 0–0.05 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for spirotetramat were estimated for the 13 GEMS/Food Consumption Cluster Diets using the STMR or STMR-P values estimated by the previous and present JMPR. The results are shown in Annex 3. The IEDIs ranged 2–20% of the maximum ADI. The Meeting concluded that the long-term intake of residues of spirotetramat from uses considered by the JMPR is unlikely to present a public health concern.

Short-term intake

The ARfD for spirotetramat is 1.0 mg/kg bw. The International Estimate Short Term Intakes (IESTIs) for difenoconazole 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 varied from 0–2% of the ARfD for children and 0–1% for general population.

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

5.33 SULFOXAFLOR (252)

RESIDUE AND ANALYTICAL ASPECTS

At the Forty-fifth Session of the Codex Committee on Pesticide Residues (2013) concern was raised by the USA regarding MRL recommendations by the 2011 JMPR for sulfoxaflor in/on bean (dry), common bean and carrots which were based on a regional approach to the selection of residue trial data for use in MRL estimation, as opposed to a global approach.

The 2011 JMPR evaluated sulfoxaflor as part of the CCPR pilot project in which JMPR would conduct an evaluation and recommend maximum residue levels prior to registration by national governments. At the same Meeting, the JMPR considered a change in its practices for selection of residue trials for estimating maximum residue levels and agreed to consider residue data from all geographic regions in selecting residue trials matching a particular GAP (global approach). The 2011 meeting prepared a general consideration item to communicate the planned change to CCPR and provided notification that the change would be introduced at its 2012 meeting. The aim was to allow the CCPR time to consider the change prior to its implementation. The general consideration item also listed MRL recommendations that would have been made if a global approach had been taken allowing CCPR as the risk managers the option of utilising these recommendations.

The Forty-fourth Session of CCPR (2012) indicated their support for the change and suggested JMPR develop clear guidance and criteria on identifying and combining comparable data sets from different geographical regions.

The current Meeting prepared a general consideration item providing guidance on the use of the global approach (General considerations item 2.8) and agreed to the request to re-evaluate the residue data for bean (dry), Common bean and carrots using the global approach to data selection.

Beans (dry)

Sulfoxaflur is registered in the USA for use on beans (GAP: 4 × 0.08 kg ai/ha, a 14 day RTI, and a 7 day PHI).

In 2011 the JMPR reported that six trials on dry beans were available from Brazil (4) and Northern Europe (1), and Southern Europe (1).

Residues of sulfoxaflor, in ranked order, found in dry beans from:

Brazil: 0.05, 0.07, 0.08, and 0.10 mg/kg.

Germany: 0.10 mg/kg.

Spain: 0.022 mg/kg.

Using the global dataset the Meeting estimated a maximum residue level of 0.3 mg/kg and an STMR of 0.075 mg/kg.

Common bean (pods and/or immature seeds)

The registered use pattern in the USA for sulfoxaflor on common beans is 4 × 0.1 kg ai/ha, a 7 day RTI, and a 7 day PHI.

The 2011 JMPR reported six trials on common bean that matched the GAP of the USA, one each from Germany, Greece, Hungary, Italy, Poland and Spain. Residues were: 0.03, 0.07, 0.08, 0.12, 0.31, 1.9 mg/kg. No reason was found for the large difference between the highest and other residue values. The Meeting suggested additional residue trial data are required to estimate an appropriate maximum residue level.

Carrots

In the USA sulfoxaflor is registered for use on carrots at 4 × 0.1 kg ai/ha with a 7 day RTI and a 7 day PHI. Seven trials from Europe and four from the USA matched the GAP of the USA with residues of: < 0.01, < 0.01, 0.01, 0.01, 0.02, 0.03, 0.03 mg/kg from Europe and < 0.01, < 0.01, 0.01, 0.01 mg/kg from the USA.

The Meeting estimated a maximum residue level of 0.05 mg/kg for carrots, an STMR of 0.01 mg/kg and an HR of 0.03 mg/kg.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Daily Intakes (IEDI) for sulfoxaflor was estimated for the 13 GEMS/Food cluster diets using the STMR or STMR-P values estimated by the current Meeting. The results are shown in Annex 3 of the 2013 JMPR Report. The IEDI ranged from 1 to 7% of the ADI (0–0.05 mg/kg bw). 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 factions) for which STMRs and HRs were estimated and for which consumption data were available. The results are shown in Annex 4 of the 2013 JMPR Report.

The IESTI varied from 0 to 60% 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.

5.34 TOLFENPYRAD (269)

TOXICOLOGY

Tolfenpyrad, a pyrazole insecticide, is the ISO-approved name for 4-chloro-3-ethyl-1-methyl-*N*-[4-(*p*-tolyloxy)benzyl]pyrazole-5-carboxamide (IUPAC), which has the CAS number 129558-76-5. Tolfenpyrad has broad insecticidal activity against a variety of pests on egg, larval, nymphal and adult stages and is used on a variety of crops. The pesticidal mode of action is thought to be the inhibition of complex I of the respiratory electron transport chain in the mitochondria.

Tolfenpyrad has not previously been evaluated by JMPR and is being reviewed by the present Meeting at the request of CCPR.

All critical studies contained statements of compliance with GLP unless otherwise specified.

Biochemical aspects

After administration of a single oral dose of radiolabelled tolfenpyrad to rats, maximum concentrations in blood and plasma were reached 2–8 hours after a low dose (1 mg/kg bw) and 4–12 hours after a high dose (20 mg/kg bw). Excretion of radioactivity in urine (2–3%) and bile (51–70%) and residual radioactivity in the carcass (5–11%) 48 hours after dosing indicate that absorption was at least 58% of the dose. Plasma half-lives were 11–28 hours. Radioactivity was widely distributed to the tissues, higher concentrations being found in liver, kidney, bone marrow and brown fat. Seven days after dosing, 88–93% and 2–3% of the radioactivity were excreted in faeces and urine, respectively. In faeces, 4–15% of the radioactivity represented tolfenpyrad, and 24–49% of the radioactivity represented the metabolite PT-CA (see Table 1 for names of metabolites). In plasma, liver and kidney, 91–100% of the radioactivity represented PT-CA, indicating extensive metabolism of tolfenpyrad. In bile, 50–67% of the administered dose was excreted within 48 hours, the major part as PT-CA-TA, PT-CA-glucuronide and PT-CA, whereas low levels of Sul-OH-PT-CA and CO-PT and other, unidentified metabolites were also detected. These data indicate extensive conjugation of PT-CA in the liver and subsequent excretion into the bile. Only 0.1–0.4% of the administered dose was present in bile as unchanged tolfenpyrad. In bile duct–cannulated rats, only 3–8% of the administered dose was excreted into faeces, predominantly as tolfenpyrad (up to 6%) and PT-CA (up to 1%). PT-CA is deconjugated following its biliary excretion and excreted in faeces. In urine, no intact tolfenpyrad was detected. Various individual metabolites (including OH-PAM and CA-T-CA) were present in urine at less than 0.5% of the administered dose, with the exception of PT-CA and PT-CA-TA (these metabolites could not be further separated), which were present at up to 1.9% of the administered dose. Observed differences in metabolite levels between sexes, doses and position of radiolabel were minor. Following repeated dosing of [^{14}C]tolfenpyrad, plasma concentrations of radioactivity stabilized after two or three administrations at 1.5–3 times the plasma concentration found after the first dose. Tissue distribution, excretion and metabolism were similar following the single low and high doses and following single and repeated dosing.

List of abbreviations and chemical names of metabolites used in the report

Abbreviation	Chemical name
OH-PT	4-Chloro-3-(1-hydroxyethyl)-1-methyl-*N*-[4-(*p*-tolyloxy) benzyl]pyrazole-5-carboxamide
CO-PT	3-Acetyl-4-chloro-1-methyl-*N*-[4-(*p*-tolyloxy)benzyl]pyrazole-5-carboxamide
PT-CA	4-[4-[(4-Chloro-3-ethyl-1-methylpyrazol-5-yl)carbonylaminomethyl]phenoxy]benzoic acid
OH-PT-CA	4-[4-[(4-Chloro-3-(1-hydroxyethyl)-1-methylpyrazol-5-yl)carbonylaminomethyl]phenoxy]benzoic acid
T-CA	4-(*p*-Tolyloxy)benzoic acid

Abbreviation	Chemical name
CA-T-CA	4,4′-Oxydibenzoic acid
PAM	4-Chloro-3-ethy1-1-methylpyrazole-5-carboxamide
OH-PAM	4-Chloro-3-(1-hydroxyethyl)-1-methylpyrazole-5-carboxamide
Sul-OH-PT-CA	4-[4-[(4-Chloro-1-methyl-3-(1-sulfoxyethyl)pyrazol-5-yl)carbonylaminomethyl]phenoxy]benzoic acid
PT-CA-TA	2-[4-[4-[(4-Chloro-3-ethyl-1-methylpyrazol-5-yl)carbonylaminomethyl]phenoxy]phenylcarbonylamino]ethane-1-sulfonic acid
PT(A)-4OH	4-Chloro-3-ethyl-*N*-(4-hydroxybenzyl)-1-methylpyrazole-5-carboxamide
T-AM	4-(4-Tolyloxy)benzamide
PCA	4-Chloro-3-ethyl-1-methylpyrazole-5-carboxylic acid
OH-T-CA	4-[4-(Hydroxymethyl)phenoxy] benzoic acid

Toxicological data

The oral LD_{50} values for tolfenpyrad dissolved in aqueous carboxymethylcellulose were greater than or equal to 113 mg/kg bw in two rat studies, and the oral LD_{50} for tolfenpyrad dissolved in olive oil was greater than or equal to 75 mg/kg bw in one rat study. The LD_{50} for dermal toxicity was greater than 2000 mg/kg bw in rats. The acute inhalation LC_{50} was 1.5–2.21 mg/L. Tolfenpyrad was not irritating to the skin and slightly irritating to the eye of rabbits. Tolfenpyrad was not a skin sensitizer in a Magnusson and Kligman test in guinea-pigs.

In repeated-dose toxicity studies with tolfenpyrad, multiple adverse effects were observed. In a 90-day toxicity study in mice using dietary concentrations of 0, 15, 100 and 300 ppm (equal to 0, 2.4, 15.9 and 46.2 mg/kg bw per day for males and 0, 3.0, 20.2 and 57.9 mg/kg bw per day for females, respectively), the NOAEL was 100 ppm (equal to 15.9 mg/kg bw per day), based on increased AST activity, increased relative heart weight in males and increased relative liver weight in both sexes at 300 ppm (equal to 46.2 mg/kg bw per day). In a 90-day toxicity study in rats using dietary concentrations of 0, 15, 80 and 160 ppm (equal to 0, 0.906, 4.78 and 9.33 mg/kg bw per day for males and 0, 1.01, 5.17 and 9.32 mg/kg bw per day for females, respectively), the NOAEL was 15 ppm (equal to 0.906 mg/kg bw per day), based on changes in clinical chemistry, a reduced white blood cell count, dark brown change of the liver, hypertrophy of the proximal renal tubular epithelium and the acinar cells in the mandibular glands in females and an increase in mast cells in the mesenteric lymph nodes, diffuse hypertrophy of hepatocytes and hypertrophy of the pancreatic acinar cells in both sexes at 80 ppm (equal to 4.78 mg/kg bw per day).

In a 28-day as well as a 90-day capsule study in dogs using doses of 0, 1, 5 and 10 mg/kg bw per day, the NOAEL was 1 mg/kg bw per day, based on the increased incidence of vomiting at 5 mg/kg bw per day. In a second 90-day capsule study in dogs with administration of tolfenpyrad at doses of 0, 10, 30 and 100 mg/kg bw per day, mild toxicity (i.e. vomiting, soft and mucous faeces) was observed at 10 mg/kg bw per day, the lowest dose tested. Severe toxicity including mortality was observed at doses of 30 and 100 mg/kg bw per day. In a 1-year capsule study in dogs using doses of 0, 1, 5 and 20/10 mg/kg bw per day, the NOAEL was 1 mg/kg bw per day, based on increased incidences of vomiting, soft or mucous stool and salivation and increased ALT level at 5 mg/kg bw per day. In all the studies in dogs, vomiting and soft stool were observed as early as the 1st day of dosing. Therefore, the overall NOAEL for these effects was 1 mg/kg bw per day, with an overall LOAEL of 5 mg/kg bw per day.

In a 78-week toxicity study in mice using dietary concentrations of 0, 15, 150 and 500/400/300 ppm (equal to 0, 2.2, 20.8 and 60.9 mg/kg bw per day for males and 0, 2.8, 27.1 and

75.9 mg/kg bw per day for females, respectively), the NOAEL was 15 ppm (equal to 2.2 mg/kg bw per day), based on decreased body weight gain and feed consumption and changes in organ weights observed in males and females at 150 ppm (equal to 20.8 mg/kg bw per day). No increased incidences of tumours were observed at doses up to 500/400/300 ppm (equal to 60.9 mg/kg bw per day), the highest concentration tested.

In a 2-year toxicity and carcinogenicity study in rats using dietary concentrations of 0, 15, 40 and 80 ppm (equal to 0, 0.561, 1.5 and 3.1 mg/kg bw per day for males and 0, 0.686, 1.9 and 3.8 mg/kg bw per day for females, respectively), the NOAEL was 15 ppm (equal to 0.561 mg/kg bw per day), based on reduced feed intake, increased severity of basophilic foci of altered hepatocytes, sinus histiocytosis of the mesenteric lymph nodes and hypertrophy of the proximal renal tubule epithelia in females at 40 ppm (equal to 1.5 mg/kg bw per day). There was no compound-related increase in the incidence of tumours.

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

Tolfenpyrad was tested for genotoxicity in an adequate range of in vitro and in vivo assays. These assays provided no evidence of genotoxic potential.

The Meeting concluded that tolfenpyrad 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 tolfenpyrad is unlikely to pose a carcinogenic risk to humans.

A standard two-generation reproductive toxicity study in rats was performed in which dietary concentrations were adjusted to maintain the desired dose levels of 0, 0.75, 1.5 and 3 mg/kg bw per day. This was followed by a modified non-GLP two-generation reproductive toxicity study focusing on the effects of tolfenpyrad on immune function, in which the dietary concentrations were adjusted to maintain target dose levels of 0, 0.75 and 3 mg/kg bw per day. The overall NOAEL for parental toxicity from these two studies was 1.5 mg/kg bw per day, based on moribundity, decreased body weight gain and decreased feed consumption at 3 mg/kg bw per day observed in the first study. The overall NOAEL for offspring toxicity was 0.75 mg/kg bw per day, based on a reduction in absolute and relative thymus weights in males and females of the F_2 generation at 1.5 mg/kg bw per day, observed in the first study, and on reduced body weight gain during lactation and a reduced number of F_1 pups at PND 4, black change in the peritoneal cavity after birth in F_1 and F_2 pups, lower thymus and spleen weights soon after birth in F_1 pups and in F_2 male pups, reduced thymus and spleen cellularity, and changes in immune cell ratios in the spleen in F_2 male pups at 3 mg/kg bw per day, observed in the second study. The Meeting concluded that the small reductions in absolute and relative thymus weights observed at 0.75 mg/kg bw per day, in the absence of other relevant effects, were not toxicologically significant. In the second study, humoral immunity and cellular immune function were normal in adult F_1 and F_2 rats. The overall NOAEL for reproductive toxicity was 1.5 mg/kg bw per day, based on a range of effects occurring late in gestation resulting in a reduced number of live offspring, observed in the first but not in the second study, at 3 mg/kg bw per day.

In a developmental toxicity study in rats using doses of 0, 1, 3 and 4.5 mg/kg bw per day, the NOAEL for maternal toxicity was 1 mg/kg bw per day, based on reduced body weight gain and feed consumption at 3 mg/kg bw per day, observed during the first days of treatment. The NOAEL for embryo and fetal toxicity was 3 mg/kg bw per day, based on decreased fetal weight, increased incidence of skeletal variations and delayed ossification observed at 4.5 mg/kg bw per day. No evidence of a teratogenic effect was observed.

In a developmental toxicity study in rabbits using doses of 0, 1, 3 and 6 mg/kg bw per day, the NOAEL for maternal toxicity was 1 mg/kg bw per day, based on one mortality observed at 3 mg/kg bw per day. The NOAEL for embryo and fetal toxicity was 6 mg/kg bw per day, the highest dose tested. No evidence of a teratogenic effect was observed.

The Meeting concluded that tolfenpyrad is not teratogenic in rats or rabbits.

In an acute oral (gavage) neurotoxicity study in rats using doses of 0, 20, 40 and 60 mg/kg bw in males and 0, 10, 20 and 40 mg/kg bw in females, the LOAEL was 10 mg/kg bw, the lowest dose tested, based on reductions in body weight and feed consumption observed in females on the day of dosing. Clinical signs were observed at 40 mg/kg bw in females and at 60 mg/kg bw in males. No neurotoxicity was observed.

In a 90-day neurotoxicity study in rats using dietary concentrations of 0, 15, 40 and 80 ppm (equal to 0, 1.0, 2.7 and 5.4 mg/kg bw per day for males and 0, 1.2, 3.2 and 6.0 mg/kg bw per day for females, respectively), the NOAEL was 40 ppm (equal to 3.2 mg/kg bw per day), based on reductions in body weight gain and feed consumption in females at 80 ppm (equal to 6.0 mg/kg bw per day). No clinical, functional or histological signs of neurotoxicity were observed at doses up to 80 ppm (equal to 5.4 mg/kg bw per day), the highest dose tested.

The Meeting concluded that tolfenpyrad is not neurotoxic.

In the modified two-generation reproductive toxicity study focusing on effects of tolfenpyrad on immune function (see above), tolfenpyrad caused changes in the immune system in rat pups but did not affect normal humoral immunity or cellular immune function in adult rats.

Toxicological data on metabolites and/or degradates

Studies of acute oral toxicity were performed with the tolfenpyrad metabolites OH-PT, PT-CA, PT(A)-4OH, T-CA, T-AM, CA-T-CA, OH-T-CA, PAM, OH-PAM and PCA dissolved in aqueous carboxymethylcellulose. In general, the metabolites had low acute toxicity, except for OH-PT ($LD_{50} \geq 35.5$ mg/kg bw) and PT-CA ($LD_{50} \geq 15.4$ mg/kg bw), which were slightly more toxic than tolfenpyrad. All these metabolites showed negative results in tests for reverse mutation induction in bacteria (Note: PT(A)-4OH and PAM were not tested). OH-PT and PT-CA were also tested in a chromosomal aberration test in vitro and a micronucleus test in vivo. No genotoxicity was observed. In a 4-week dietary study in rats, the toxicity of tolfenpyrad at dietary concentrations of 0, 10, 30 and 100 ppm was compared with the toxicities of PT-CA and OH-PT at dietary concentrations of 0, 3, 10, 30 and 100 ppm. The NOAEL for tolfenpyrad was 30 ppm (equal to 2.5 mg/kg bw per day), based on a mild reduction in feed consumption in males and females, a mild reduction in body weight gain observed in males and increased incidences and severity of hypertrophy of acinar cells in pancreas in females at 100 ppm (equal to 8 mg/kg bw per day). The NOAEL for PT-CA was 100 ppm (equal to 8.1 mg/kg bw per day), the highest dose tested, and the NOAEL for OH-PT was 100 ppm (equal to 8.4 mg/kg bw per day), the highest dose tested. In view of the lower LD_{50} values for the metabolites PT-CA and OH-PT compared with tolfenpyrad, the Meeting considered these two compounds to be toxicologically relevant.

In the absence of any toxicological information on the livestock metabolite OH-PT-CA, but on consideration of the similarity of its structure to that of tolfenpyrad, it was assumed that OH-PT-CA was of similar toxic potency to tolfenpyrad. No data were available on the toxicity of the livestock metabolites, PT-CA conjugates and OH-PT-CA conjugates. However, as these are likely to be hydrolysed to PT-CA and OH-PT-CA, respectively, the Meeting concluded that their toxicities should be considered equivalent to those of PT-CA and OH-PT-CA.

Human data

No information on adverse health effects or poisoning in manufacturing plant personnel or in operators and workers exposed to tolfenpyrad was available.

The Meeting concluded that the existing database on tolfenpyrad is sufficient to characterize the potential hazards to fetuses, infants and children.

Toxicological evaluation

The Meeting established an ADI for tolfenpyrad of 0–0.006 mg/kg bw on the basis of a NOAEL of 0.561 mg/kg bw per day in a 2-year rat study with tolfenpyrad, for reduced feed intake, increased severity of basophilic foci of altered hepatocytes, sinus histiocytosis of the mesenteric lymph nodes and hypertrophy of the proximal tubule epithelia in females at 1.5 mg/kg bw per day, using a safety factor of 100.

The Meeting established an ARfD of 0.01 mg/kg bw for tolfenpyrad 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 with tolfenpyrad in rats at 3 mg/kg bw and an overall NOAEL of 1 mg/kg bw per day for vomiting and soft stool observed on the 1st day of treatment in 28-day, 90-day and 1-year studies with tolfenpyrad in dogs at 5 mg/kg bw per day. A safety factor of 100 was applied. The ARfD provides a margin of exposure of 1000 over the LOAEL in the acute neurotoxicity study in rats. The Meeting considered it unlikely that the acute effects observed in rats and dogs are 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 Meeting considered that the ADI and ARfD are also applicable to the metabolites PT-CA and OH-PT, which showed similar toxicity to tolfenpyrad in LD_{50} studies but lower toxicity in a 4-week dietary study. In addition, the Meeting considered the ADI and ARfD applicable to all the livestock metabolites: OH-PT-CA, PT-CA conjugates and OH-PT-CA conjugates. The Meeting noted that in the absence of data on the effects of these metabolites in long-term and developmental toxicity studies in rats and capsule studies in dogs (i.e. studies that formed the basis of the ADI and ARfD), it would not be possible to establish the relative potency of the metabolites to tolfenpyrad in order to refine the dietary exposure assessment.

A toxicological monograph was prepared.

Levels relevant for risk assessment of tolfenpyrad

Species	Study	Effect	NOAEL	LOAEL
Mouse	Eighteen-month study of toxicity and carcinogenicity[a]	Toxicity	15 ppm, equal to 2.2 mg/kg bw per day	150 ppm, equal to 20.8 mg/kg bw per day
		Carcinogenicity	500/400/300 ppm, equal to 60.9 mg/kg bw per day[b]	—
Rat	Thirteen-week study of toxicity[a]	Toxicity	15 ppm, equal to 0.906 mg/kg bw per day	80 ppm, equal to 4.78 mg/kg bw per day
	Two-year study of toxicity and carcinogenicity[a]	Toxicity	15 ppm, equal to 0.561 mg/kg bw per day	40 ppm, equal to 1.5 mg/kg bw per day
		Carcinogenicity	80 ppm, equal to 3.1 mg/kg bw per day[b]	—
	Two-generation studies of reproductive toxicity[a,c,d]	Parental toxicity	1.5 mg/kg bw per day	3 mg/kg bw per day
		Offspring toxicity	0.75 mg/kg bw per day	1.5 mg/kg bw per day
		Reproductive toxicity	1.5 mg/kg bw per day	3 mg/kg bw per day
	Developmental toxicity study[d]	Maternal toxicity	1 mg/kg bw per day	3 mg/kg bw per day
		Embryo and fetal toxicity	3 mg/kg bw per day	4.5 mg/kg bw per day
	Acute neurotoxicity	Neurotoxicity	40 mg/kg bw[b]	—

Species	Study	Effect	NOAEL	LOAEL
	study[e]	Toxicity	—	10 mg/kg bw[f]
	Ninety-day neurotoxicity study[a]	Neurotoxicity	80 ppm, equal to 5.4 mg/kg bw per day	—
Rabbit	Developmental toxicity study[e]	Maternal toxicity	1 mg/kg bw per day	3 mg/kg bw per day
		Embryo and fetal toxicity	6 mg/kg bw per day[b]	—
Dog	Four-week, 13-week and 1-year studies of toxicity[c,g,h]	Toxicity	1 mg/kg bw per day	5 mg/kg bw per day

[a] Dietary administration.

[b] Highest dose tested.

[c] Two or more studies combined.

[d] Dietary concentrations of tolfenpyrad were adjusted over the course of the study in order to obtain the required daily doses (mg/kg bw per day) for the different dose groups and sexes. Therefore, ppm values are not presented.

[e] Gavage administration.

[f] Lowest dose tested.

[g] Identical NOAELs and LOAELs were observed in all three dog studies. In all studies, vomiting and soft stool were observed on the 1st day of testing.

[h] Capsule administration.

Estimate of acceptable daily intake

0–0.006 mg/kg bw

Estimate of acute reference dose

0.01 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 tolfenpyrad

Absorption, distribution, excretion and metabolism in mammals	
Rate and extent of oral absorption	Rapid (T_{max} 2–8 h); ≥ 58% (rats)
Dermal absorption	No data available (probably relatively low in view of data from LD_{50} and short-term studies with oral and dermal dosing)
Distribution	Widely distributed (rats)
Potential for accumulation	Low
Rate and extent of excretion	88–93% in faeces and 2–3% in urine; plasma half-lives at 1 and 20 mg/kg bw: 11–28 h
Metabolism in animals	Extensive, rapidly metabolized in the liver and subsequently

	conjugated and then excreted into bile
Toxicologically significant compounds in animals, plants and the environment	Tolfenpyrad, PT-CA, PT-CA conjugates, OH-PT, OH-PT-CA, OH-PT-CA conjugates
Acute toxicity	
Rat, LD_{50}, oral	Dissolved in aqueous carboxymethylcellulose: ≥ 113 mg/kg bw
	Dissolved in olive oil: ≥ 75 mg/kg bw
Rat, LD_{50}, dermal	> 2000 mg/kg bw
Rat, LC_{50}, inhalation	≥ 1.5 mg/L
Rabbit, dermal irritation	Not irritating
Rabbit, ocular irritation	Slightly irritating
Guinea pig, dermal sensitization	Not sensitizing (Magnusson and Kligman)
Short-term studies of toxicity	
Target/critical effect	Many end-points affected
Lowest relevant oral NOAEL	0.906 mg/kg bw per day (rat)
Lowest relevant dermal NOAEL	200 mg/kg bw per day, the highest dose tested (rat)
Lowest relevant inhalatory NOAEC	2 mg/m^3 (rat)
Long-term studies of toxicity and carcinogenicity	
Target/critical effect	Feed intake, liver, kidneys, mesenteric lymph nodes (rats)
Lowest relevant NOAEL	0.561 mg/kg bw per day (rat)
Carcinogenicity	Not carcinogenic
Genotoxicity	
	Not genotoxic
Reproductive toxicity	
Target/critical effect	Reduced number of live offspring at parentally toxic doses
Lowest relevant parental NOAEL	1.5 mg/kg bw per day
Lowest relevant offspring NOAEL	0.75 mg/kg bw per day
Lowest relevant reproductive NOAEL	1.5 mg/kg bw per day
Developmental toxicity	
Target/critical effect	Decreased fetal weight, increased skeletal variations at maternally toxic doses
Lowest relevant maternal NOAEL	1 mg/kg bw per day (rat, rabbit)
Lowest relevant embryo/fetal NOAEL	3 mg/kg bw per day (rat)
Neurotoxicity	
Acute and subchronic neurotoxicity	Not neurotoxic
Other toxicological studies	
Immunotoxicity	Increased thymus and spleen weights and changed immune cell ratios in pups but not in adults
Studies with PT-CA	
Acute toxicity	LD_{50} ≥ 15.4 mg/kg bw

4-week dietary toxicity	8.1 mg/kg bw per day, the highest dose tested
Genotoxicity	Not genotoxic
Studies with OH-PT	
Acute toxicity	$LD_{50} \geq 35.5$ mg/kg bw
4-week dietary toxicity	8.4 mg/kg bw per day, the highest dose tested
Genotoxicity	Not genotoxic
Medical data	
	No data

Summary

	Value	Study	Safety factor
ADI	0–0.006 mg/kg bw	Two-year study of toxicity in rats	100
ARfD	0.01 mg/kg bw	Developmental toxicity study in rats; 28-day, 90-day and 1-year toxicity studies in dogs	100

RESIDUE AND ANALYTICAL ASPECTS

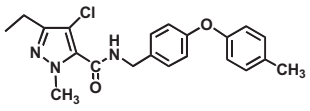
The toxicological and residue evaluation of tolfenpyrad was scheduled for the 2013 JMPR by the Forty-fourth Session of the CCPR.

Tolfenpyrad is a broad spectrum insecticide and a miticide, with contact activity against target pests on eggs, larvae, nymphs, and adults. It also has anti-feeding activity on larvae of lepidopteran insects. It belongs to the pyrazole class of insecticides. It has activity against several economically important insect pests of vegetables, fruits, nuts, vines and row crops.

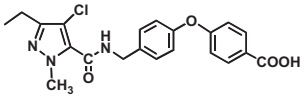
The Meeting received information from the manufacturer on identity, the animal and plant metabolism, environmental fate analytical methods, storage stability, effect of processing, animal feeding studies, and results of supervised trials on almonds, cantaloupe,, cauliflower, cherries, cucumbers, cotton seed, grapes (table), grapefruits, lemons, oranges, peaches, pears, pecans, peppers, plums, potatoes, summer squash, tea and tomatoes.

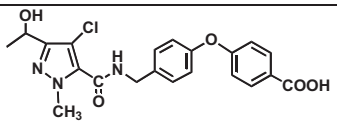
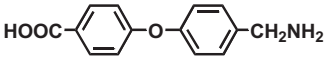
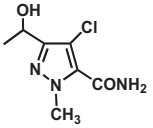
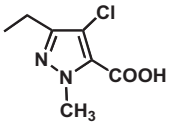
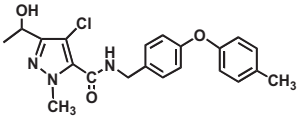
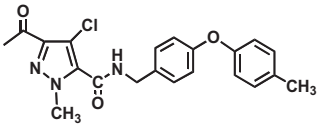
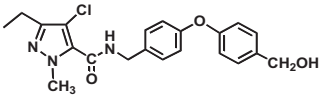
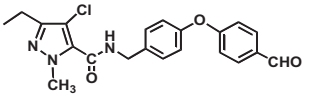
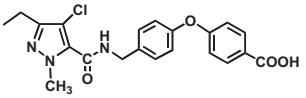
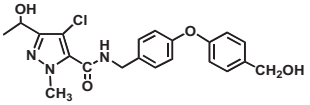
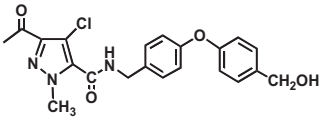
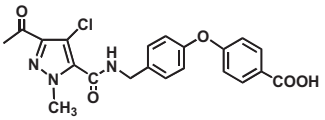
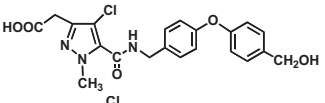
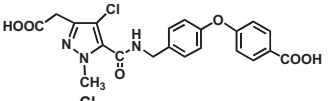
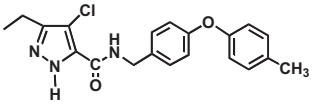
Chemical name and structure

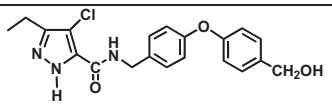
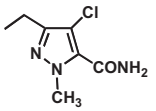
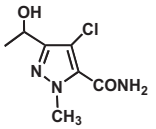
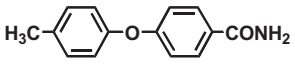
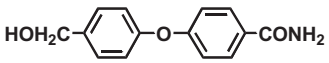
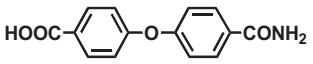
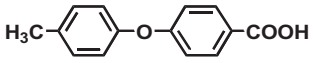
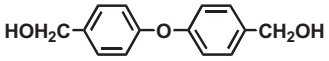
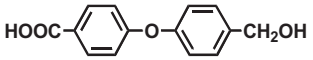
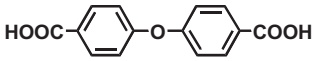
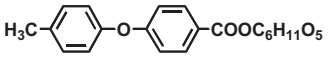
4-chloro-3-ethyl-1-methyl-*N*-[4-(*p*-tolyloxy)benzyl]pyrazole-5-carboxamide



Chemical names and structures of metabolites referred to in the appraisal by codes:

Code Name	Chemical name	Structure	Matrices
PT-CA	4-[4-[(4-chloro-3-ethyl-1-methylpyrazol-5-yl)carbonylaminomethyl]phenoxy]benzoic acid		rat, plant, soil animal commodities

Code Name	Chemical name	Structure	Matrices
OH-PT-CA	4-[4-[[4-chloro-3-(1-hydroxyethyl) -1-methylpyrazol-5-yl]carbonylamino-methyl]phenoxy] benzoic acid		rat, plant, animal
CA-T-NH_2	4-[4-(aminomethyl)phenoxy]benzoic acid		Photodecompositio n, animal
OH-PAM	4-chloro-3-(1-hydroxyethyl)-1-methylpyrazole-5-carboxamide		rat, plant, soil, eggs
PCA	4-chloro-3-ethyl-1-methylpyrazole-5-carboxylic acid		Plant, soil, eggs
OH-PT	4-chloro-3-(1-hydroxyethyl)-1-methyl-*N*-[4-(p-tolyloxy)benzyl] pyrazole-5-carboxamide		rat, plant
CO-PT	3-acetyl-4-chloro-1-methyl-*N*-[4-(*p*-tolyloxy)benzyl] pyrazole-5-carboxamide		plant
PT-OH	4-chloro-3-ethyl-*N*-[4-[4-(hydroxymethyl)phenoxy]benzyl]-1-methylpyrazole-5-carboxamide		rat, plant, soil, photodecomposition
PT-CHO	4-chloro-3-ethyl-*N*-[4-(4-formylphenoxy)benzyl]-1-methylpyrazole-5-carboxamide		rat, plant, soil, photodecomposition
PT-CA	4-[4-[(4-chloro-3-ethyl-1-methylpyrazol-5-yl)carbonylaminomethyl]phenoxy]benzoic acid		rat, plant, soil animal commodities
OH-PT-OH	4-chloro-3-(1-hydroxyethyl)-*N*-[4-[4-(hydroxymethyl)phenoxy]benzyl]-1-methylpyrazole-5-carboxamide		rat, plant, animal commodities
CO-PT-OH	3-acetyl-4-chloro-*N*-[4-[4-(hydroxymethyl)phenoxy]benzyl]-1-methylpyrazole-5-carboxamide		plant
CO-PT-CA	4-[4-[(3-acetyl-4-chloro-1-methylpyrazol-5-yl) carbonyl-aminomethyl]phenoxy]benzoic acid		plant
CA-PT-OH	[4-chloro-5-[N-[4-(4-hydroxymethyl) phenoxy]benzylcarbamoyl]-1-methylpyrazol-3-yl]acetic acid		rat, plant
CA-PT-CA	4-[4-[3-(carboxymethyl-4-chloro-1-methylpyrazol-5-yl]carbonyl-aminomethyl]phenoxy]benzoic acid		rat, plant
DM-PT	4-chloro-3-ethyl-*N*-[4-(*p*-tolyloxy) benzyl]pyrazole-5-carboxamide		plant

Code Name	Chemical name	Structure	Matrices
DM-PT-OH	4-chloro-3-ethyl-*N*-[4-[4-(hydroxymethyl)phenyl]benzyl] pyrazole-5-carboxami		plant
PAM	4-chloro-3-ethyl-1-methylpyrazole-5-carboxamide		rat, plant, soil
OH-PAM	4-chloro-3-(1-hydroxyethyl)-1-methylpyrazole-5-carboxamide		rat, plant, soil, eggs
T-AM	[4-(*p*-tolyloxy)benzamide		plant
OH-T-AM	4-[4-(hydroxymethyl)phenoxy] benzamide		plant
CA-T-AM	4-(4-carbamoylphenoxy)benzoic acid		plant
T-CA	4-(*p*-tolyloxy)benzoic acid		rat, plant
OH-T-OH	*bis*[4-(hydroxymethyl)phenyl]ether		pant
OH-T-CA	4-[4-(hydroxymethyl)phenoxy] benzoic acid		rat, plant
CA-T-CA	4,4'-oxydibenzoic acid		rat, plant
T-CA-Glu	glucose conjugate of 4-(*p*-tolyloxy) benzoic acid		plant

Animal metabolism

The Meeting received reports of animal metabolism studies in lactating goats and laying hens. The studies were conducted with [^{14}C] tolfenpyrad labelled on the pyrazole and tolyl rings.

Metabolism in laboratory animals is summarized under toxicology.

Lactating goats

[Pyrazole-^{14}C]-tolfenpyrad and [tolyl-^{14}C]-tolfenpyrad were administered orally (12.3–12.5 mg/kg feed/day) to two lactating goats once daily for five consecutive days. Milk was collected twice daily and excreta were collected once daily. The total recovery of radiolabel was 76.1% and 96.3% of the administered dose (AD) for the pyrazole- and tolyl-labels, respectively. Most of the administered dose was recovered in the excreta (46.8–49.8%) and gastrointestinal tracts (19.2–32.6%) at sacrifice.

Administration of [tolyl-^{14}C]-tolfenpyrad resulted in consistently higher residues in tissues than the administration of [pyrazole-^{14}C]-tolfenpyrad. The total radioactive residues (TRR) expressed

as tolfenpyrad mg equivalents/kg were in liver (25 mg/kg, 12%AD) and kidney (6.93 mg/kg, 0.7%AD) and substantially lower in the fat (0.36 mg/kg, 0.4%AD), milk (0.17 mg/kg, 19% AD) and muscle (0.14 mg/kg, 0.1–0.2%AD). No free metabolite unique to only one of the radiolabels was found.

The parent tolfenpyrad was present up to 4.1% TRR (< 0.01 mg/kg) in milk, 10% TRR (0.01 mg/kg) in muscle, 17.3%TRR (0.06 mg/kg) in fat, and was not detected in liver and kidney.

Following the administration of pyrazole- and tolyl- labelled tolfenpyrad, the predominant residues were PT-CA in free and its conjugated form. The free and conjugated PT-CA, respectively, amounted up to 7.6% and 48% of TRR (0.01–0.08 mg/kg) in milk, 68% TRR (0.09 mg/kg) (its conjugate was not detected (nd) in muscle from the tolyl label), 52% and 9.0% of TRR (13–1.74 mg/kg) in liver, 63% and 3.5% of TRR (4.33–0.21 mg/kg) in kidney and nd–34.1% of TRR(nd–0.09 mg/kg) in fat. PT-CA is rapidly conjugated in the liver. But in the gastrointestinal tract it is deconjugated.

OH-PT-CA was present in free form 17% TRR (0.03 mg/kg), in milk, 8.9%TRR (< 0.01 mg/kg,) in muscle, 27% TRR (6.69 mg/kg,) in liver, 19.3% TRR (1.34 mg/kg)in kidney, and in conjugated from 1.2%TRR (0.21 mg/kg) in liver and 0.3%TRR in kidney (0.02 mg/kg,). It was not detected in fat.

In addition, CA-T-NH_2 could be released by hydrolysis from milk (19.4%TRR) and fat (5.3%TRR).

In summary, tolfenpyrad is oxidized at the tolyl-methyl group to PT-CA. Further oxidation at the pyrazole ethyl group of PT-CA produces OH-PT-CA. Both PT-CA and OH-PT-CA occur as free metabolites in milk, liver, kidney, and muscle. PT-CA and its hydrolysis metabolites (PCA and CA-T-NH_2) are converted into nonpolar lipids in milk and fat. Saponification of the lipid conjugates releases PT-CA, PCA, and CA-T-NH_2.

Laying hens

[Pyrazole-^{14}C]-tolfenpyrad and [tolyl-^{14}C]-tolfenpyrad were administered orally (in gelatine capsules) to two separate groups of hens once daily for seven consecutive days. The administered daily dose was 12.6–13.5 mg/kg feed/day. Eggs were collected twice daily and excreta were collected once daily. Hens were sacrificed approximately 22–23 hours after the last dose administration. Liver, muscle, fat and gastrointestinal tracts with contents were collected for analysis.

The total recovery of radiolabel was 85.4% and 91.4% of the administered dose (AD) for the pyrazole- and tolyl-labels, respectively. Of the total dose 2.3–2.4% remained in the gastrointestinal tract one day after the last dose. The total identified residues were 66–78% in eggs, 85–89% in muscle, 84–96% in liver and 62–73% in fat. In tissues, the total radioactive residue (TRR) was highest in liver (up to 1.94 mg/kg; 0.8% AD) and lower in eggs (0.3% AD), fat (0.1% AD) and muscle (0.1% AD).

The parent tolfenpyrad was only present at 0.06 mg/kg concentration in fat (15% TRR) and < 0.01 mg/kg concentration in eggs (2.4%TRR), muscle (1.8% TR) and liver (0.2% TRR).

Following the administration of pyrazole- and tolyl-labelled tolfenpyrad, the predominant residues were PT-CA in free and its conjugated form. The free PT-CA amounted up to 40.5% TRR (0.07 mg/kg) in eggs, 85%TRR (0.1 mg/kg) in muscle and conjugated PT-CA, respectively, amounted up to 40.5–29% TRR (0.07–0.04 mg/kg) in eggs, 79% TRR (1.3 mg/kg) in liver, and 15% TRR ((0.07 mg/kg) in fat. The conjugated PT-CA was present in eggs, liver and fat at 29, 11.4, and 34.5% of TRR, respectively.

OH-PAM was present in free form at 12.6% TRR (0.02 mg/kg) in eggs, and 12.4% TRR (0.02 mg/kg) in muscle. It was not detected in liver and fat.

OH-PT-CA was detected at 2.7% TRR (< 0.01 mg/kg) in muscle, 5.2% TRR (0.09 mg/kg) in liver. It was not detected in eggs and fat.

In summary, the initial metabolite of tolfenpyrad is PT-CA occurring as a major residue in eggs, liver, kidney, muscle, and fat. Further oxidation at the pyrazole-ethyl group of PT-CA produces OH-PT-CA that occurs in liver and muscle. OH-PAM occurs as a free metabolite in eggs and muscle. Tolfenpyrad is a trace residue in eggs, liver, and muscle but was more abundant in fat. PT-CA and its hydrolysis product (PCA) are incorporated into non-polar lipid conjugates occurring in eggs and fat.

Plant metabolism

Cabbage

[Tolyl-^{14}C]-tolfenpyrad was applied to individual cabbage plants in a spray chamber. One application was made at a rate corresponding to 750 g ai/ha. Samples were taken at day 0 (immediately after the spray dried) and at 7, 14 and 28 days.

Twenty eight days after application 99.7% of the TRR (8.39 mg tolfenpyrad equivalent/kg) was on the outer leaves, 78.7% in the organo-soluble fraction and 15.9% in the water-soluble fraction, and only 0.3% of the TRR (0.03 mg equiv./kg) was in the heads, distributed between the water soluble (0.2%) and organo soluble fraction (0.1%).

Tolfenpyrad was found in the outer leaves at levels of 12.6 mg/kg (89% of TRR) immediately after application decreasing to 4.6 mg/kg (55.0% of TRR) after 28 days. In samples taken 28 days after application, OH-PT, OH-T-CA, OH-T-OH, and CA-T-AM were present at 0.54 mg/kg (6.4% of TRR, 0.33 mg/kg (3.9% of TRR), 0.31 mg/kg (3.7% of TRR), and 0.20 mg/kg (2.4% of TRR), respectively. Other metabolites were present at lower proportions. In cabbage head without outer leaves neither the parent compound nor any of the identified metabolite were detected (< 0.01 mg/kg).

In a second cabbage study, [pyrazole-^{14}C]-tolfenpyrad was applied once to individual cabbage in a spray chamber at a rate corresponding to 750 g ai/ha. Cabbage samples were collected at 28 days after application. At that time 97.2% of the AD (9.22 mg/kg) was distributed on the outer leaves and 2.8% (0.23 mg/kg) in the heads.

Tolfenpyrad was found in the outer leaves at levels of 4.7 mg/kg (49.8% of TRR). The identified metabolites, expresses as TRR, were 7.9% OH-PT (0.75 mg/kg), 3.4% OH-PT-OH and 2.9% OH-PT-CA. Other metabolites were detected at levels of ≤ 0.20 mg/kg (≤ 2.1% of AD). In the head, levels of metabolites did not exceed 0.1% of TRR.

Peach

[Tolyl-^{14}C]-tolfenpyrad was applied to individual peach plants in a spray chamber. One branch and one fruit were treated on each plant. One application was made at a rate corresponding to 750 g ai/ha.

Immediately after application, 83.5% of the AD was distributed on the leaves with 11.8% on the stem and 4.7% on the fruit. There was no significant change in distribution 56 days after application; TRRs remained were 83.1%, 7.5% and 9.3%, respectively.

In the fruit, parent tolfenpyrad was found at 3.0 mg/kg (100% of AD) immediately after application decreasing to 0.79 mg/kg (77% of TRR) by day 56. The majority of residues (8.4% TRR) were in the peel while only 0.4% TRR in the pulp. The metabolites did not exceed 2.8% TRR throughout the study period, except the glucose conjugate of T-CA at 6.1%TRR.

In the second peach study [pyrazole-^{14}C]-tolfenpyrad was applied to individual peach plants in a spray chamber. One branch and one fruit were treated on each plant. One application was made at a rate corresponding to 750 g ai/ha. Peach fruits were collected 53 days after application. At that

time, 86.1% of the AD was distributed on the leaves, 7.3% on the stem and 6.6% (0.77 mg/kg) on the fruit concentrated mainly in the peel (11 mg/kg) with low concentration (0.12 mg/kg) in the pulp.

In the fruit, parent tolfenpyrad was found at levels of 0.53 mg/kg (65% of TRR) 53 days after application. The only identified metabolite, OH-PAM, was found in the pulp at 0.03 mg/kg (4.0% of TRR).

In the leaves, parent tolfenpyrad was found at levels of 21.1 mg/kg (32.7% of TRR) after 56 days. Free PT-CA was the main metabolite found at 10.0 mg/kg (15.5% of TRR) with a contribution of glucose-conjugated PT-CA at 0.94 mg/kg (1.5% of TRR) followed by other metabolites present at less than 10% TRR.

The studies indicated that the translocation of unchanged tolfenpyrad was very limited. The predominant part of the TRR was located in the peel (86.4–94.6%) of the fruit residue.

Radish

[Tolyl-U-^{14}C]-tolfenpyrad or [pyrazole-^{14}C]-tolfenpyrad were applied to radish located outdoors. Each plot received two applications, 14 days apart, at a nominal rate of 230 g ai/ha. Radish plants were sampled 1 day after the second application and separated into root and foliage samples.

Labelled tolfenpyrad distributed into the roots (0.44–0.59 mg/kg, 4.9–5.2% of AD) and the foliage (7.0–11 mg/kg, 94.8–95.1% of TRR).

The major residues in radish roots were tolfenpyrad (0.24 mg/kg, 54.0% of TRR), PT-CA (0.11 mg/kg, 21.5% of TRR). Other metabolites amounted to less than 10%TRR except conjugated OH-PAM and PAM which were the major metabolite found in radish roots at 32.2% and 26.7% TRR respectively.

The major residue in foliage was tolfenpyrad (9.31 mg/kg, 85.0% of TRR) with a much lesser amount of metabolites amounting to less than 4% of TRR.

In summary, the metabolic pathways of tolfenpyrad in three different crops were considered comparable. In each case, unchanged parent accounted for a very significant proportion of the residue. All three crops contain the identified metabolites OH-PT (not observed but assumed in radish as an intermediate to OH-PAM), OH-PAM, PAM and PT-CA.

Environmental fate

The Meeting received information on photolysis on soil, aerobic degradation in soil, aqueous photolysis and confined and field rotational crop studies.

Soil photolysis

A photolysis study of [^{14}C] tolfenpyrad was conducted in sandy loam soil exposed to artificial light (290 nm) for 13 days. In the light exposed samples, unextracted radiocarbon increased slowly reaching an average of 3.2% (pyrazole label) and 10.7% (tolyl label) of applied radioactivity (AR) by day 313. Only minimal radiocarbon was recovered (0.3%) in traps of organic volatiles for light exposed samples, and none in dark control samples. Photoproducts consisted mainly of PT-CHO, PAM and OH-PAM present at a maximum of 6.6%, 11.3% and 3.5% AD, respectively in both labels. Tolfenpyrad showed negligible degradation in dark control samples with an average of 90% still present as parent in both labels at the end of the study. The PT-CA was the major degradate (2.0% in pyrazole labelled material and 4.7% in tolyloxy labelled material). The calculated half-life of tolfenpyrad was 444 days from tolyl label and 624 days from pyrazole label. The results indicate that photolysis is a very minor route of the degradation of tolfenpyrad

Aerobic soil metabolism

An aerobic soil metabolism study was conducted on a California sandy loam soil using [^{14}C] tolfenpyrad. The treated samples were incubated in the dark at 25 °C for periods up to 365 days. Tolfenpyrad degraded rapidly in soil under aerobic conditions and represented an average of 30.0% AR by day 21, declining to an average of 1.6% at the end of the incubation period. The primary degradates observed in the study were CO_2, PT-Cam PCA and soil bound residues. The soil bound residues were completely mineralised within one year. The calculated DT_{50} and DT_{90} values were maximum 14 and 78 days, respectively, indicating that tolfenpyrad is not persistent.

Confined rotational crop study

Tolfenpyrad radiolabelled in two positions (pyrazole- and tolyl-rings) was applied to test plots at a target application rate of 350 g ai/ha. Lettuce, radish and wheat were planted at intervals of 30, 120 and 365 days after single bare soil application. Samples were taken at appropriate harvest times and analysed for residues.

Metabolites at ≥ 0.01 mg/kg were OH-PAM (free and conjugated), OH-PCA (free and conjugated), and PAM (radish foliage and root only). A number of other metabolites were detected in combined extracts, but each was < 0.01 mg/kg or < 10% of TRR. Conjugates of OH-PAM and OH-PCA were liberated by acid hydrolysis.

Following pyrazole labelled tolfenpyrad application the detected metabolites in lettuce amounted up to 0.02 mg tolfenpyrad equivalent. The free and conjugated OH-PAM, OH-PCA and PAM were the major metabolites, each was less than 26% TRR No other single metabolite represented more than 2.5% TRR (< 0.01 mg/kg).

In radish foliage the detected metabolites (at 0.02–0.03 mg tolfenpyrad equivalent/kg) were the OH–PAM conjugates (20%TRR) the OH-PCA conjugates (24% TRR) as well as free OH-PAM and PAM with lesser amounts of OH-PCA and PT-CA.

In radish roots, the only detected metabolites were the OH-PCA conjugates (27% TRR) as well as free OH-PAM (8.5%TRR) and PAM (24.5%TRR).

In wheat grain, none of the metabolites were detected (< 0.01 mg/kg).

In wheat forage the predominant metabolites were the OH-PAM conjugates (≤ 0.16 mg eq/kg, 29.7% TR at 30 days PBI) the OH-PCA conjugates (0.17 mg eq/kg) as well as free OH-PCA (0.09) with lesser amounts of OH-PAM, PAM and PCA. No other single metabolite represented more than 5.2% TRR (0.01 mg/kg).

In wheat hay and straw the maximum concentrations were for OH-PAM conjugates (0.4 mg eq/kg, 32%TR) and OH-PCA conjugates (0.17 mg eq/kg). With exception of OH-PAM conjugates in wheat hay, all identified metabolites show a decrease with increasing aging of the soil.

Following the treatment with tolyl- labelled compound no relevant concentration of any individual compounds were found in lettuce, radish, wheat forage, hay, straw and grain at any plant-back interval. Only trace amounts of PT-CA were found in radish (120-day) and wheat hay (30-day) samples. In summary, tolfenpyrad is a minor residue (< 0.01 mg/kg) in confined rotational crops (lettuce, radish, and wheat). Most radiolabelled residues derived from cleavage of the amide bond, resulting in pyrazole and diphenyl ether fragments.

Field rotational crop studies

Two field trials were carried on mustard greens as the primary crop treated at about maximum seasonal rate of 0.598 kg ai/ha. The primary crop was removed from the trials at normal harvest with a PHI of one day after last application. Rotational crops (radish, lettuce and sorghum) were planted at intervals of 14, 28–30 and 58–60 days after last application.

At normal harvest of the rotational crops, no residues of tolfenpyrad, OH-PAM, OH-PCA and PAM were found above the LOQ in radish roots, lettuce and sorghum forage, grain and stover. Residues of OH-PAM and OH-PCA at the LOQ (0.01 mg/kg) were found at rotational intervals of 14 and 30 days after last application only in radish tops from one trial site.

Methods of analysis

The HPLC methods for determining the parent compound and OH-PT metabolite residues in plant matrices are based on three repeated extractions with methanol, followed by various solid phase extraction clean-up(s). The cleaned samples either concentrated or diluted to known volume before determination with HPLC-MS/MS. The LOQ for both compounds in all matrices is 0.01 mg/kg, except tea (0.05 mg/kg). The specificity of the detection was assured with two mass transitions. Average recoveries were all within the acceptable range of 70–120%, with relative standard deviations (RSD) below 20%.

For the rotational crop study the method used was validated for the determination of tolfenpyrad, OH-PAM, PAM and OH-PCA. Recovery data were generated from three samples fortified at the LOQ and three samples fortified at 10 × LOQ for each matrix. The mean percentage recoveries at 0.01 mg/kg and 0.1 mg/ kg were generally between 70–110% with RSD < 20%. There were some deviations especially when the extracts were hydrolysed. The mean recoveries and RSD values were in some cases outside the nominal ranges, but the differences were not significant taking into account the limited number of tests.

The HPLC-MS/MS methods were developed for determination of tolfenpyrad and its metabolites PT-CA, OH-PT-CA and PCA in animal commodities with an LOQ of 0.01 mg/kg. The milk samples were extracted with methanol, the tissues with methanol/water (5/1). The extracts were partitioned into ethyl acetate after adding either citric acid (milk and fat) or sodium chloride (muscle, liver and kidney). After evaporation to dryness the extracts were taken up in methanol or hexane and partly subjected to SPE clean-up. The other part of the milk, liver and fat extracts was hydrolysed. The final extracts were analysed by HPLC/MS/MS. The specificity of the detection was assured by two mass transitions for tolfenpyrad and three transitions for the metabolites. Repeatability data was generated from three samples fortified at the LOQ and three samples fortified at 10 × LOQ for each matrix. The mean percentage recoveries at each fortification level were within 70–110, except PT-CA in liver with hydrolysis (65% at 0.01 mg/kg), fat with hydrolysis (60% at 0.1 mg/kg) and OH-PT-CA in fat with hydrolysis (64% at 0.01 and 69% at 0.1 mg/kg). In spite of some deviations, the methods applied in the studies are considered suitable for the intended purpose.

Stability of residues in stored analytical samples

In plant matrices, freezer storage stability (at about -20 ± 5 °C) of tolfenpyrad and OH-PT has been demonstrated in tomatoes, apples, lettuce, grapes, oranges, almonds (nutmeat and hulls), cottonseed oil and potato flakes (18 months), peaches (4 months), prunes (dried) (5 months), cucumbers (5.5 months), cauliflower (6 months), and tea (12 months).

Freezer storage stability of tolfenpyrad, OH-PAM, OH-PCA and PAM has also been demonstrated in radish (roots) (112 days), lettuce (150 days) and sorghum forage (114 days), stover (87 days) and grain (109 days). This covers high acid, high water, high starch and high oil content crops.

When stored < 0 ºC tolfenpyrad, PT-CA and OH-PT-CA were stable in bovine muscle (85 days), kidney (85 days), fat (99 days) and milk (177 days). The average OH-PT-CA residue remained in liver was 39% after 111 days storage, but the procedural recoveries (41%) were similar. PCA was stable in fat and milk.

Definition of the residue

In goat, the parent tolfenpyrad was not detected in liver, and kidney, but it was found at < 0.01 mg/kg in milk (2.9–4.1% of TRR) and muscle (10% TRR) and at 0.04–0.06 mg/kg in fat (13.6–17.3% TRR).

The major radioactive residue derived from the administration of pyrazole and tolyl labelled tolfenpyrad was PT-CA being present up to 0.03 mg/kg (16.9% TRR) in milk, 0.09 mg/kg (63.% TRR) in muscle, 13.1 mg/kg (51.8% TRR) in liver, 4.33 mg/kg (62.6% TRR) in kidney, and 0.06 mg/kg (16.3% TRR) in fat.

The concentration and % proportion of TRR of OH-TP-PCA derived from administration of pyrazole- or tolyl-labelled tolfenpyrad was up to 0.03 mg/kg (16.9%) in milk, < 0.01 mg/kg (8.9%) in muscle, 6.8 mg/kg (26.9%) in liver, 1.3 mg/kg (19.3%) in kidney, and it was not detected in fat. The other metabolites identified were present at substantially lower concentrations.

Dairy cattle feeding study revealed that in milk, the only detected residue (> 0.01 mg/kg) is PT-CA which can be recovered after hydrolysis with maximum concentration of 0.27 mg/kg. In cream derived from 2.5 and 25 ppm dose groups the parent tolfenpyrad was present in about 0.01–0.02 mg/kg, respectively, and PT-CA were present at approximately 25 times higher concentration in conjugated form than in free form. In muscle, fat, liver and kidney the PT-CA is the major residue. Hydrolysis of samples revealed that only free PT-CA is present in the liver.

In the study with laying hens administered with labelled tolfenpyrad the parent tolfenpyrad was found at low concentrations < 0.01 mg/kg, (1.2–1.8% TRR) in eggs, muscle and liver, but it was present at 0.06 mg/kg (14–15%TRR) in fat.

The PT-CA occurs as a major residue up to 0.07 mg/kg (41%TRR) in eggs, 0.10 mg/kg (85%TRR) in muscle, 1.4 mg/kg (79%TRR) in liver, and 0.07 mg/kg 15% TRR) in fat. PT-CA is converted to OH-PT-CA, which was found up to 0.09 mg/kg (5.2% TRR) in liver and < 0.01 mg/kg (2.7%TRR) muscle.

Analytical methods are available for the simultaneous determination of tolfenpyrad, and free PT-CA, OH-PT-CA and PCA in one step and the conjugates can be released in a separate step after alkaline hydrolysis. However, the latter procedure could be carried out with sometimes low and varying recovery and it is not considered suitable for routine analyses.

Taking into account the relative proportions and concentration of the parent tolfenpyrad and its metabolites, and the availability suitable analytical method, the sum of tolfenpyrad and the free PT-CA are considered suitable marker compounds for enforcement purposes. For dietary risk assessment the free and the conjugated PT-CA, OH-PT-CA should be considered, because they have a toxic potency similar to PT-CA and OH-PT-CA.

PT-CA, the major residue component is present in higher concentration in muscle than in fat. OH-PT-CA was not present in fat. The Meeting concluded that the residue is not fat soluble.

The parent tolfenpyrad was present in outer leaves of cabbage at 4.71 mg/kg 28 days after treatment while the concentrations of all the identified metabolites were below 0.3 mg/kg

The concentrations of parent tolfenpyrad were 3.95 mg/kg (89.4%TRR) and 0.37 mg/kg (70% TRR) in peach fruits 14 and 28 days after treatment. In the same samples and sampling time T-AM, PT-OH, PT-CA were present at 0.12 and< 0.02 mg/kg, 0.06 and nd mg/kg, and 0.06 and nd mg/kg, respectively.

Radish leaves and roots on day 1 after the 2nd application contained 5.7 mg/kg and 0.24 mg/kg parent residue respectively, while any of the identified metabolites were present at less than 10% and 20% of the parent compound, respectively.

No residue is expected above 0.01 mg/kg in any rotational crops.

The Meeting noted that the parent tolfenpyrad is the major residue in plant commodities and it is a good marker for compliance with GAP.

The Meeting recommended the following residue definitions for tolfenpyrad:

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

Definition of the residue for compliance with the MRL and estimation of dietary intake for animal commodities: *sum of tolfenpyrad, and free and conjugated PT-CA (4-[4-[(4-chloro-3-ethyl-1-methylpyrazol-5-yl)carbonylaminomethyl]phenoxy]benzoic acid and OH-PT-CA (4-[4-[[4-chloro-3-(1-hydroxyethyl) -1-methylpyrazol-5-yl]carbonylaminomethyl]phenoxy] benzoic acid) (released with alkaline hydrolysis) expressed as tolfenpyrad*.

The residue is not fat soluble.

Results of supervised residue trials on crops

The Meeting received supervised trials for a number of commodities from the USA for which there were no authorised uses. Trials were received from Japan where tolfenpyrad is authorised for use on tea. The residues obtained from supervised trials not supported by GAP are summarized in the JMPR Monograph but were not used for the estimation of STMR, HR and maximum residue levels.

Tea

Four residue trials were conducted on green tea in 1997–98 in Japan. One foliar application of tolfenpyrad was made with spray solutions of 0.0015 kg/hL following the design of reverse decline trials. The treated plots of each trial were harvested at a PHI of 7, 14, 21 and 30 days after treatment and the samples were analysed twice at intervals of about 1 year.

The GAP in Japan permits one foliar application of 15% EC formulation in 1000 times dilution using 2000–4000 L/ha water. The PHI is 14 days.

The average residues obtained in replicate samples taken at 14 days were: 3.77, 4.29, 7.05 and 12.1 mg/kg.

The Meeting estimated a maximum residue level of 30 mg/kg, an STMR value of 5.65 mg/kg and 13.8 mg/kg of STMR and HR values for green tea, respectively

Fate of residues during processing

Following one application of tolfenpyrad at rates of 0.30 kg ai/ha or 0.45 kg ai/ha, mean residues of tolfenpyrad were substantially reduced in tea infusion to the levels of 0.20 mg/kg, 0.06–0.08 mg/kg, 0.01 mg/kg and < 0.01 mg/kg, respectively, at PHIs of 7, 14, 21 and 30 days.

In a second study tolfenpyrad was applied at a rate of 0.6 kg ai/ha. Tolfenpyrad residues were substantially reduced in tea infusion to the levels of 1.12–2.21 mg/kg, 0.14–0.49 mg/kg and < 0.01 mg/kg, respectively, at PHIs of 7, 14 and 28 days. The two sets of trials gave about four times different average processing factors, therefore the larger factor (0.043) is used for dietary intake assessment.

The Meeting estimated for green tea infusion an STMR value of 0.24 mg/kg.

Residues in animal commodities

Farm animal dietary burden

As there are no registered uses on animal feed, the animal burden cannot be calculated.

Farm animal feeding studies

In a dairy cattle feeding study, tolfenpyrad was administered orally by gelatine capsules for 28 consecutive days to 3 groups of 3 cows at dose levels equivalent to 2.5 (2×), 7.5 (6×) and 25 (20×) ppm in feed. Residues of tolfenpyrad and its metabolites PT-CA, OH-PT-CA or PCA were determined in milk and tissues. Neither the parent compound nor any of the metabolites were detected in any samples derived from control animals.

Residues in milk

No quantifiable residues of tolfenpyrad, PT-CA, OH-PT-CA or PCA were detected in milk from cows treated with tolfenpyrad at the 2× and 6× dose levels, except PT-CA (0.02 mg/kg and 0.08 mg/kg, respectively) released by hydrolysis. In milk samples of the 6× dose group, no quantifiable free or conjugated residues were detected for tolfenpyrad, OH-PT-CA or PCA, whereas free or conjugated residues of PT-CA were present with maximums of 0.01 mg/kg and 0.27 mg/kg. In general the free metabolite corresponds to approximately 5–10% of the conjugated metabolite.

In milk samples of the 20× dose group, no free PCA and only trace levels of tolfenpyrad and OH-PT-CA averaging below LOQ were detected. Free PT-CA close to the LOQ was found after day 13. Conjugated PT-CA was found at significantly higher concentrations, reaching a plateau near 0.25 mg/kg by day 16. During two weeks of depuration no metabolites were detected in milk with the exception of a residue of 0.07 mg/kg PT-CA in the 31 days milk sample of the 20× dose group.

Residues in cream and skim milk

In cream samples from the 2× dose group, only conjugated PT-CA residues were detected averaging 0.02 mg/kg and 0.01 mg/kg for days 13 and 28, respectively. No quantifiable residues were found in skimmed milk samples from the 2× dose group. In cream samples from the 20× dose group, comparable levels were found for free and conjugated tolfenpyrad corresponding to approximately 0.02 mg/kg for both 13 and 28 days. Conjugated PT-CA in cream was approximately 25 times higher than free PT-CA being present at a level of about 0.02 mg/kg. In skimmed milk only PT-CA was found in samples of the 20× dose group at levels of 0.01 mg/kg for free and 0.04–0.05 mg/kg for the conjugated form.

Residues in muscle

Tolfenpyrad and OH-PT-CA residues were not present in quantifiable concentrations in the samples of every dose groups. The average PT-CA residues were present at 0.01 mg/kg, 0.02 mg/kg and 0.05–0.09 mg/kg in samples of dose groups of 2.5 ppm, 7.5 ppm and 25 ppm.

Residues in liver

No parent tolfenpyrad residues were found in any treated liver sample. Residues of PT-CA were found in all dose levels in approximate proportion to the level of dosing. Free PT-CA residues after 28 days of dosing averaged for 0.65 mg/kg for the 2× dose level, 2.0 mg/kg for the 6× dose level, and 4.8 mg/kg for the 20× dose level. Conjugated residues of PT-CA were at a similar level, suggesting that only free PT-CA is present in the liver. After fourteen days of depuration, PT-CA residues (0.03 mg/kg) were reduced by a factor > 100 compared to the 28 days level (4.8 mg/kg). Also OH–PT-CA was found at a lesser extent than PT-CA. Residues of free OH-PT-CA averaged at 0.03 mg/kg, 0.07 mg/kg and 0.27 mg/kg for the 2×, 6× and 20× dose levels, respectively. Conjugated residues were less than or equal to residues of free OH-PT-CA, suggesting that only free metabolite is present in liver.

Residues in kidney

No parent tolfenpyrad residues were found in kidney samples of the 2× and 6× dose groups. In the 20× dose group tolfenpyrad was present at the LOQ (0.01 mg/kg). Residues of PT-CA were found in all dose levels in approximate proportion to the level of dosing. PT-CA residues after 28 days of dosing were averaged for 0.13 mg/kg for the 2× dose level, 0.49 mg/kg for the 6× dose level, and 1.3 mg/kg for the 20× dose level. Residues of OH-PT-CA were less than the LOQ (< 0.01 mg/kg) for the 2× dose level and averaged at 0.02 mg/kg and 0.09 mg/kg for the 6× and 20× dose level, respectively. After fourteen days of depuration, residues of tolfenpyrad were below the LOD, and residues of PT-CA and OH-PT-CA were below the LOQ (< 0.01 mg/kg).

Residues in fat

For the 2× dose level, no residues of tolfenpyrad, OH-PT-CA or PCA were found. Residues of free tolfenpyrad in the 6× and 20× dose levels averaged for 0.01 mg/kg and 0.065 mg/kg, respectively. Residues of free PT-CA in fat were below the LOQ (< 0.01 mg/kg) for the 2× dose level and averaged at 0.01 mg/kg and 0.04 mg/kg for the 6× dose level and the 20× dose level, respectively. Residues of OH-PT-CA and PCA were only detected in the 20× dose group samples at levels below the LOQ (< 0.01 mg/kg). Residues after sample hydrolysis were in a similar order indicating that no conjugated residues were present in fat. The depuration period showed a steady decline in residues with no determinable residues present by day 14 after last dosing.

Considering the residues in samples derived from the highest (20×) dose group, the free and conjugated PT-CA released with hydrolysis were the major residues in muscle (0.09 mg/kg), liver (6.9 mg/kg) kidney (1.8 mg/kg), and fat (0.04 mg/kg)

Parent tolfenpyrad was only present in milk cream and fat in the highest dose group.

PT-CA concentration rapidly decreased during depuration.

Animal commodity maximum residue levels

Without calculated animal burden no residue levels can be calculated 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 and for IEDI assessment.

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

Definition of the residue for compliance with the MRL and estimation of dietary intake for animal commodities: sum of tolfenpyrad, and free and conjugated PT-CA (4-[4-[(4-chloro-3-ethyl-1-methylpyrazol-5-yl)carbonylaminomethyl]phenoxy]benzoic acid and OH-PT-CA (4-[4-[[4-chloro-3-(1-hydroxyethyl) -1-methylpyrazol-5-yl]carbonylaminomethyl]phenoxy] benzoic acid) (released with alkaline hydrolysis) expressed as tolfenpyrad.

The residue is not fat soluble.

DIETARY RISK ASSESSMENT

Long-term intake

The evaluation of tolfenpyrad resulted in recommendations for STMR-P value for green tea infusion which was used for the calculation. The results are shown in Annex 3. The International Estimated Daily Intake for the 13 GEMS/Food diet based on estimated STMR value was up to 0–11% of maximum ADI of 0.006 mg/kg bw. The Meeting concluded that the long-term intake of residues of tolfenpyrad from green tea is unlikely to present a public health concern.

Short-term intake

The International Estimated Short-term Intake (IESTI) for tolfenpyrad was calculated for green tea infusion for which STMR-P value was estimated. The results are shown in Annex 4. The IESTI was 50 to 100% of the ARfD (0.01 mg/kg bw) for the general population.

Meeting concluded that the short-term intake of residues of tolfenpyrad resulting from its use on green tea is unlikely to present a public health concern.

5.35 TRIAZOPHOS (143)

RESIDUE AND ANALYTICAL ASPECTS

Triazophos is an organophosphates insecticide and acaricide and shows broad-spectrum activity against a wide range of insect pests via soil or foliar treatment of crops. Triazophos was first evaluated by the JMPR in 1982 for toxicology and in 1983 for residues and has been evaluated several times since. Triazophos was evaluated within the periodic review programme by the 2002 JMPR for toxicology and by the 2007 JMPR for residues. The 2002 Meeting established an ADI of 0–0.001 mg/kg bw and an ARfD of 0.001 mg/kg bw. The 2007 JMPR confirmed its previous residue definition: *triazophos* (for compliance with the MRL and for estimation of dietary intake). The 2007 JMPR evaluated the triazophos residues in food and withdrew its previous recommendations except for cotton seed, cotton seed oil and soya bean (immature seeds). The 2010 JMPR evaluated additional residue data on rice and soya bean (immature seeds).

The 2010 JMPR Meeting estimated a maximum residue level of 2 mg/kg in/on husked rice (brown rice), and a median residue of 0.421 mg/kg based on 15 trials conducted in China in 2008 and 2009. Triazophos was applied at the target rate of either 3–4 × 0.506 kg ai/ha (ME formulation) or 3–4× 0.45 kg ai/ha (EC formulation) both with PHIs of 28 days. No maximum residue level recommendation could be made because the estimated short-term intake from residues in rice was 260% of the ARfD for children and general population. There was no alternative GAP available. The 2010 JMPR considered that studies on the effect of processing (polishing, cooking, frying) to be desirable as they would enable a more realistic estimation of residue levels in food actually consumed. Triazophos was listed by the Forty-fourth Session of CCPR for the 2013 JMPR for reconsideration of residues in rice.

China submitted processing data for rice, which were evaluated by the present Meeting.

Methods of analysis

The Meeting received a description and validation data for an analytical method of triazophos on processed commodities of rice. The analytical method was based on extraction with acetone and determination of triazophos with GC-FPD. The Meeting considered the method valid in the range 0.003–3.0 mg/kg triazophos in rice grains, husked rice, polished rice and rice bran.

Stability of residues in stored analytical samples

No storage stability data were received for rice or its processed commodities. Storage stability studies were provided to the 2007 Meeting which demonstrated stability of residues in stored samples of cotton fibre, cotton seed, oranges, carrots and soil for a period of up to 24 months. The Meeting agreed that these studies covered storage stability for rice commodities.

Results of supervised residue trials on crops

The 2010 JMPR Meeting estimated a maximum residue level of 2 mg/kg in/on husked rice (brown rice), and a median residue of 0.421 mg/kg based on 15 trials in/on paddy rice conducted in China in 2008 and 2009.

An additional two trials on paddy rice were submitted to the present Meeting. The trials were conducted in China with 2 applications at 0.45 kg ai/ha instead of 3 applications at 0.45 kg ai/ha (cGAP in China). Since the residues were higher compared to the JMPR 2010 data, the Meeting decided to include the mean value per location (3.7 and 4.9 mg/kg) from these trials with the JMPR 2010 data. This resulted in the following dataset: 0.059, 0.059, 0.060, 0.087, 0.13, 0.34, 0.35, 0.42, 0.51, 0.68, 0.76, 0.81, 0.89, 1.0, 1.2, 3.7, 4.9 mg/kg (n=17).

Based on the 17 trials conducted in China, the Meeting estimated a maximum residue level of 7 mg/kg in/on rice grain and a median residue of 0.51 mg/kg. As rice grains (i.e., rice with hulls) are not traded, the Meeting agreed that a maximum residue level recommendation for rice was not appropriate and decided to use the residue values for rice, to estimate maximum residue levels for husked rice and polished rice.

Fate of residues during processing

Information on the fate of triazophos during processing was provided for rice. In the table below, relevant processing factors for this commodity are summarized based on the residue definition of *triazophos*. Hydrolysis studies under cooking conditions or processing studies for cooking of rice were not submitted to the present or previous Meetings.

Using the $STMR_{RAC}$ obtained from triazophos use, the Meeting estimated STMR-Ps for processed commodities as listed below. An HR-P is not required for processed rice commodities.

Commodity	Processing factors (triazophos)	Max level = Max_{RAC}xPF	STMR-P = $STMR_{RAC}$xPF mg/kg
rice grains – husked, dry	0.24 (n=15, mean)	7 × 0.24 = 1.68	0.51 × 0.24 = 0.12
rice grains – polished, dry	0.080 (n=6, median)	7 × 0.080 = 0.56	0.51 × 0.080 = 0.041

The Meeting confirmed its previous recommendation of 2 mg/kg in/on husked rice, and estimated an STMR-P of 0.12 mg/kg.

The Meeting estimated a maximum residue level of 0.6 mg/kg in polished rice and an STMR-P of 0.041 mg/kg.

Residues in animal commodities

The 2007 JMPR concluded that because of the lack of appropriate animal livestock metabolism study, a residue definition for animal products could not be determined and therefore the Meeting could not make use of the results of the feeding studies. Consequently, the residues in animal products derived from the use of triazophos on rice and its processed commodities were not considered by the present Meeting.

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 use in dietary risk assessment.

Definition of residue (for compliance with the MRL and for estimation of dietary intake): *triazophos*.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Daily Intakes (IEDI) of for triazophos was calculated from recommendations for STMRs for raw and processed commodities in combination with consumption data for corresponding food commodities by the 2007, 2010 and 2013 JMPR. The IEDI of in the 13 GEMS/Food cluster diets, based on the estimated STMRs were in the range 1–40% of the maximum ADI of 0.001 mg/kg bw. The 2013 Meeting concluded that the long-term intake of residues of triazophos from uses considered by the 2007, 2010 and 2013 Meeting is unlikely to present a public health concern.

Short-term intake

The International Estimated Short Term Intake (IESTI) for triazophos was calculated for rice and its processed commodities for which maximum residue levels were estimated and for which consumption data were available. For those processed commodities, where no processing data were available, the STMR-P for polished rice was used for rice flour, rice beer and rice wine, while the STMR-P for husked rice was used on all other processed commodities. Since husked rice and polished rice are not consumed raw, but in cooked form and consumption data are available for the cooked form, a default dilution factor of 0.4 was used to compensate for the swelling during cooking. A default dilution factor of 0.04, 0.19 and 0.15 was used on rice milk, rice beer, and rice wine respectively. The results are shown in Annex 4.

The IESTI for rice and its processed commodities and based on the 2012 consumption data and an ARfD of 0.001 mg/kg bw represents 0–130% of the ARfD for cooked husked rice consumption of children of 1–6 years in Japan, and 0–100% of the ARfD for all other processed rice commodities by children or general population.

The Meeting concluded that the short-term intake of residues of triazophos resulting from its uses that have been considered by JMPR might present a public health concern. There was no alternative GAP to be considered and refinement of the dietary risk assessment by using processing factors for husked rice still showed a potential public health concern. Processing studies from rice (husked and polished) are desirable for further refinement of the exposure.

The 2002 Meeting established an ARfD of 0.001 mg/kg bw on the basis of the NOAEL of 0.0125 mg/kg bw per day in the 3-week study in humans and a safety factor of 10. Hence, further refinement is unlikely in the toxicological assessment.

5.36 TRIFLUMIZOLE (270)

TOXICOLOGY

Triflumizole is the common name provisionally approved by ISO for (*E*)-4-chloro-α,α,α-trifluoro-*N*-(1-imidazol-1-yl-2-propoxyethylidene)-*o*-toluidine (IUPAC), for which the CAS number is 68694-11-1. Triflumizole is a fungicide used for the control of powdery mildew. As a consequence of ergosterol biosynthesis inhibition, spore germination, mycelial growth and the spread of the fungi within the plants are inhibited.

Triflumizole 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

The absorption of (phenyl-U-^{14}C)-labelled triflumizole in rats was about 72% of the administered single dose at 10 and 300 mg/kg bw and about 80% of the applied repeated dose at 10 mg/kg bw. Absorption was considerably slower after the high dose than after the low dose, as evidenced by the much longer time to reach C_{max} (T_{max}). The radioactivity detected in tissues was generally low (~2%), with highest concentrations found in the liver. Excretion of triflumizole occurred rapidly and independently of sex. Most of the administered low dose (~90%) was recovered within 24 hours. At the single high dose of 300 mg/kg bw, 45–35% of the administered dose was excreted by 24 hours, increasing to 99–92% at 96 hours. The majority of the radiolabel was excreted via the urinary route (~75% of the administered dose compared with ~20% excreted via the faeces).

Triflumizole is extensively metabolized. A few differences in metabolite pattern were observed between males and females after repeated low and single high doses, but not after a single low dose. The major urinary metabolites are the sulfate conjugates of *N*-(4-chloro-2-trifluoromethyl-phenyl)-2-hydroxy-acetamidine (FM-8-1) and 2-amino-5-chloro-3-trifluoromethylphenol (FA-1-5). In faeces, *N*-(4-chloro-2-trifluoromethylphenyl)-2-hydroxy-acetamide (FD-2-1) is a major metabolite. Differences between dose regimens exist with respect to other major metabolites. 2-(4-Chloro-2-trifluoromethylphenylimino)-2-imidazol-1-yl-ethanol (FM-2-1) is the major metabolite after a single oral low dose. 4-Chloro-2-trifluoromethylphenylamine (FA-1-1) is a major metabolite after single and repeated low dosing, whereas *N*-(4-chloro-2-trifluoromethylphenyl)-2-propoxy-acetamide (FD-1-1) is the major metabolite after a single high dose The presence of the metabolite *N*-(4-chloro-2-trifluoromethylphenyl)-2-propoxy-acetamidine (FM-6-1) was confirmed in rat faeces and urine.

Toxicological data

Triflumizole has an oral LD_{50} of 1057 mg/kg bw in rats. The dermal LD_{50} is greater than 5000 mg/kg bw, and the inhalation LC_{50} is greater than 3.6 mg/L. No skin irritation and only mild eye irritation were observed. Based on a maximization test in guinea-pigs, triflumizole is considered a skin sensitizer. These studies were conducted prior to GLP, except for the acute inhalation study, but they were conducted to an acceptable standard.

In all short-term studies, decreased body weight gain combined with increased feed consumption and increased liver weights were observed. In a non-GLP 90-day dietary toxicity study, mice were exposed to 0, 20, 200 or 2000 ppm (equal to 0, 3.2, 33 and 381 mg/kg bw per day for males and 0, 4.2, 43 and 466 mg/kg bw per day for females, respectively). The NOAEL was 200 ppm (equal to 33 mg/kg bw per day), based on decreased body weight gain, increased feed consumption and liver effects (increased liver weight, swelling of cytoplasm) observed at 2000 ppm (equal to 381 mg/kg bw per day).

In a second non-GLP 90-day dietary toxicity study, rats were exposed to 0, 20, 200 or 2000 ppm (equal to 0, 1.4, 15 and 177 mg/kg bw per day for males and 0, 1.8, 17 and 218 mg/kg bw per day for females, respectively). Decreased body weight gain, increased feed consumption, liver effects (increased liver weight, fatty changes) and increased kidney weights were also observed at 2000 ppm in both sexes. Based on these effects at 2000 ppm (equal to 177 mg/kg bw per day), the NOAEL was 200 ppm (equal to 15 mg/kg bw per day).

In a 1-year oral toxicity study with dogs exposed to 0, 100, 300 or 1000 ppm (equal to 0, 3, 10 and 34 mg/kg bw per day for males and 0, 3, 11 and 35 mg/kg bw per day for females, respectively), the NOAEL was 300 ppm (equal to 10 mg/kg bw per day), based on liver effects (increased weights, macroscopic changes) and increased AP levels at 1000 ppm (equal to 34 mg/kg bw per day).

In a combined chronic toxicity and carcinogenicity study in mice, animals were exposed through the diet to triflumizole at a concentration of 0, 100, 400 or 1600 ppm (equal to 0, 16, 67 and 296 mg/kg bw per day for males and 0, 22, 88 and 362 mg/kg bw per day for females, respectively). At 400 ppm (equal to 67 mg/kg bw per day) and above, liver effects were observed, as demonstrated by increased organ weight and histopathological findings (nodules and fatty changes in both sexes as well as granulomatous inflammation, cytological alterations, pigmentation and necrosis in some males). Based on these liver effects, the NOAEL was 100 ppm (equal to 16 mg/kg bw per day).

In a combined chronic toxicity and carcinogenicity study in which rats were exposed through the diet to triflumizole at a concentration of 0, 100, 400 or 1600 ppm (equal to 0, 3.5, 14 and 59 mg/kg bw per day for males and 0, 4.5, 18 and 77 mg/kg bw per day for females, respectively), the liver was an important target organ, as demonstrated by increased organ weight and a wide range of histopathological findings at 400 ppm (equal to 14 mg/kg bw per day) and above. The highest dose group of females also showed an increased incidence of convulsive episodes and an increased incidence of ovarian follicular cysts. Based on the liver effects observed, the NOAEL was 100 ppm (equal to 3.5 mg/kg bw per day).

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

The genotoxic potential of triflumizole was tested in an adequate range of in vitro and in vivo studies. Triflumizole showed no evidence of genotoxicity in any assays.

The Meeting concluded that triflumizole is unlikely to be genotoxic.

Based on the lack of genotoxicity and the absence of carcinogenicity in mice and rats, the Meeting concluded that triflumizole is unlikely to be carcinogenic in humans.

In a three-generation reproductive toxicity study, rats were exposed through the diet to triflumizole at a concentration of 0, 30, 70 or 170 ppm (equal to 0, 2.1, 4.8 and 12 mg/kg bw per day for males and 0, 2.5, 5.8 and 14 mg/kg bw per day for females, respectively). The NOAEL for parental toxicity was 70 ppm (equal to 4.8 mg/kg bw per day), based on increased placental weights and increased liver and kidney weights at the high dose (170 ppm, equal to 12 mg/kg bw per day). The NOAEL for reproductive toxicity was 70 ppm (equal to 4.8 mg/kg bw per day), based on reduced mating, fertility and litter size. The NOAEL for offspring toxicity was 170 ppm (equal to 12 mg/kg bw per day), the highest dose tested.

Two developmental toxicity studies were conducted in rats. In a non-GLP study, rats were exposed by gavage to 0, 10, 35 or 120 mg/kg bw per day, and in a GLP study, the dose levels were 0, 3, 7 and 35 mg/kg bw per day. Maternal toxic effects were similar in the two studies and comprised reduced body weight gain and feed consumption and increased placental weight at 35 mg/kg bw per day as well as increased liver and spleen weights at the same dose in the non-GLP study. Based on these effects, the overall NOAEL for maternal toxicity was 10 mg/kg bw per day, and the overall LOAEL was 35 mg/kg bw per day. The observed developmental effects were a reduction in the number of viable fetuses, a reduction in fetal weight and an increase in the number of late resorptions

at 35 mg/kg bw per day. The overall NOAEL for embryo and fetal toxicity was 10 mg/kg bw per day, with an overall LOAEL of 35 mg/kg bw per day.

Two developmental toxicity studies were conducted in rabbits. In a non-GLP study, rabbits were exposed by gavage to 0, 50, 100 or 200 mg/kg bw per day, and in a GLP study, the dose levels were 0, 5, 25 and 50 mg/kg bw per day. Maternal toxic effects were reduced body weight gain and feed consumption, increased liver weights, decreased ovary weights and decreased placental weight at 200 mg/kg bw per day. The overall NOAEL for maternal toxicity was 100 mg/kg bw per day, with an overall LOAEL of 200 mg/kg bw per day. The observed developmental effects were a lower 24-hour pup survival rate and decreased pup weight at 200 mg/kg bw per day. Based on these effects, the overall NOAEL for embryo and fetal toxicity was 100 mg/kg bw per day, with an overall LOAEL of 200 mg/kg bw per day.

The Meeting concluded that triflumizole is not teratogenic in rats or rabbits.

The Meeting was aware of several mechanistic studies and unpublished reports that have been submitted to a regulatory authority. These studies aimed to clarify the effects seen in the reproductive and developmental toxicity studies in rats. These studies were not made available to the Meeting.

In an acute neurotoxicity study, rats were administered triflumizole by gavage at 0, 25, 100 or 400 (males)/200 (females) mg/kg bw. Based on the clinical findings and the functional and motor activity effects observed at the next higher dose (100 mg/kg bw), the NOAEL was 25 mg/kg bw.

In a 13-week neurotoxicity study, rats were exposed to triflumizole at 0, 70, 700 or 2000 ppm (equal to 0, 4.1, 41 and 117 mg/kg bw per day for males and 0, 4.9, 48 and 133 mg/kg bw per day for females, respectively). The systemic findings were similar to those obtained in the 90-day repeated-dose toxicity study, the liver clearly being the main target organ. Based on the liver effects at 700 ppm (equal to 41 mg/kg bw per day), the NOAEL for non-neurotoxic effects was 70 ppm (equal to 4.1 mg/kg bw per day). Observed effects on motor activity were considered not adverse because there was no dose-response relationship, there were no effects in females and the locomotor changes were within the normal range of behaviour. The NOAEL for neurotoxicity was 2000 ppm (equal to 117 mg/kg bw per day), the highest dose tested.

In an immunotoxicity study, triflumizole was administered for 28 days to female mice in diet containing concentrations of 0, 20, 200 and 2000 ppm (equal to 0, 4.4, 43 and 413 mg/kg bw per day, respectively). The NOAEL for systemic toxicity was 200 ppm (equal to 43 mg/kg bw per day), based on significantly reduced body weight gain at 2000 ppm (equal to 413 mg/kg bw per day). The NOAEL for immunotoxicity was 200 ppm (equal to 43 mg/kg bw per day), based on a significant reduction in anti–sheep red blood cell IgM in mice immunized with sheep red blood cells at 2000 ppm (equal to 413 mg/kg bw per day).

Toxicological data on metabolites and/or degradates

Acute oral toxicity studies were performed with a number of triflumizole metabolites. For metabolites FD-1-1, FD-2-1, FD-6-1, FM-2-1, FM-5-1, FM-6-1, FM-8-1 and FA-1-5, the oral LD_{50}s were similar to or higher than that of the parent (1057 mg/kg bw). Only metabolites FA-1-1 and FD-7-1 were slightly more toxic than the parent (LD_{50} = 771 mg/kg bw and ~1000 mg/kg bw, respectively).

Human data

A report on the health examination of production workers in the period May 1996 – May 2002 did not reveal any adverse health effects. No cases of acute poisoning or skin/eye irritation were observed in the same period.

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

Toxicological evaluation

An ADI of 0–0.04 mg/kg bw was established on the basis of the NOAEL of 3.5 mg/kg bw per day for hepatotoxicity (increased liver weight, macroscopic and microscopic hepatic changes) in the chronic toxicity study in the rat. A safety factor of 100 was applied. This is supported by the NOAEL of 4.8 mg/kg bw per day in the multigeneration study of reproductive toxicity in rats.

An ARfD of 0.3 mg/kg bw was established on the basis of the NOAEL of 25 mg/kg bw in the acute neurotoxicity study in the rat, based on clinical findings and effects on function and motor activity at 100 mg/kg bw. A safety factor of 100 was applied. The effects observed in developmental toxicity studies in rats were not considered to be a consequence of a single dose.

The ADI and the ARfD are also applicable to the metabolites containing the 4-chloro-2-(trifluoromethyl)phenyl group.

A toxicological monograph was prepared.

Levels relevant to risk assessment of triflumizole

Species	Study	Effect	NOAEL	LOAEL
Mouse	Ninety-day study of toxicity[a]	Toxicity	200 ppm, equal to 33 mg/kg bw per day	2000 ppm, equal to 381 mg/kg bw per day
	Two-year study of toxicity and carcinogenicity[a]	Toxicity	100 ppm, equal to 16 mg/kg bw per day	400 ppm, equal to 67 mg/kg bw per day
		Carcinogenicity	1600 ppm, equal to 296 mg/kg bw per day[b]	—
Rat	Acute neurotoxicity study[c]	Neurotoxicity	25 mg/kg bw	100 mg/kg bw
	Ninety-day studies of toxicity[a,d]	Toxicity	200 ppm, equal to 15 mg/kg bw per day	700 ppm, equal to 41 mg/kg bw per day[d]
	Two-year study of toxicity and carcinogenicity[a]	Toxicity	100 ppm, equal to 3.5 mg/kg bw per day	400 ppm, equal to 14 mg/kg bw per day
		Carcinogenicity	1600 ppm, equal to 59 mg/kg bw per day[b]	—
	Three-generation study of reproductive toxicity[a]	Parental toxicity	70 ppm, equal to 4.8 mg/kg bw per day	170 ppm, equal to 12 mg/kg bw per day
		Offspring toxicity	170 ppm, equal to 12 mg/kg bw per day[b]	—
		Reproductive toxicity	70 ppm, equal to 4.8 mg/kg bw per day	170 ppm, equal to 12 mg/kg bw per day

Species	Study	Effect	NOAEL	LOAEL
	Developmental toxicity studies[c,d]	Maternal toxicity	10 mg/kg bw per day	35 mg/kg bw per day
		Embryo and fetal toxicity	10 mg/kg bw per day	35 mg/kg bw per day
Rabbit	Developmental toxicity studies[c,d]	Maternal toxicity	100 mg/kg bw per day	200 mg/kg bw per day
		Embryo and fetal toxicity	100 mg/kg bw per day	200 mg/kg bw per day
Dog	One-year study of toxicity[a]	Toxicity	300 ppm, equal to 10 mg/kg bw per day	1000 ppm, equal to 34 mg/kg bw per day

[a] Dietary administration.

[b] Highest dose tested.

[c] Gavage administration.

[d] Two or more studies combined.

Estimate of acceptable daily intake

0–0.04 mg/kg bw

Estimate of acute reference dose

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 triflumizole

Absorption, distribution, excretion and metabolism in mammals	
Rate and extent of oral absorption	Rapid and extensive, 72–79%; 2-fold slower at 24 h at high dose than at low dose
Dermal absorption	No data
Distribution	Widely distributed
Potential for accumulation	No evidence for accumulation
Rate and extent of excretion	Rapid, ~90% excreted within first 24 h, mainly via urine (~75%)
Metabolism in animals	Extensively metabolized, less than 2% excreted as parent compound
Toxicologically significant compounds in animals, plants and the environment	Triflumizole and metabolites containing the 4-chloro-2-(trifluoromethyl)phenyl group
Acute toxicity	
Rat, LD_{50}, oral	1057 mg/kg bw

Rat, LD_{50}, dermal	> 5000 mg/kg bw
Rat, LC_{50}, inhalation	> 3.6 mg/L (4 h, nose only)
Rabbit, dermal irritation	Not a skin irritant
Rabbit, ocular irritation	Mild eye irritant
Guinea-pig, dermal sensitization	Sensitizer (maximization test)
Short-term studies of toxicity	
Target/critical effect	Liver
Lowest relevant oral NOAEL	15 mg/kg bw per day (rat)
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
Lowest relevant NOAEL	3.5 mg/kg bw per day (rat)
Carcinogenicity	Not carcinogenic
Genotoxicity	
	Not genotoxic
Reproductive toxicity	
Reproduction target/critical effect	Reduced fertility and litter size at parentally toxic doses
Lowest relevant parental NOAEL	4.8 mg/kg bw per day
Lowest relevant offspring NOAEL	12 mg/kg bw per day, the highest dose tested
Lowest relevant reproductive NOAEL	4.8 mg/kg bw per day
Developmental toxicity	
Developmental target/critical effect	Placenta, fetal viability and weight, number of late resorptions at maternally toxic doses
Lowest relevant maternal NOAEL	10 mg/kg bw per day (rat)
Lowest relevant embryo/fetal NOAEL	10 mg/kg bw per day (rat)
Neurotoxicity	
Acute neurotoxicity NOAEL	25 mg/kg bw per day (rat)
Subchronic neurotoxicity	177 mg/kg bw per day, the highest dose tested (rat)[a]
Other toxicological studies	
Immunotoxicity NOAEL	43 mg/kg bw per day (mouse)
Studies on metabolites	FD-1-1, FD-2-1, FD-6-1, FD-7-1FM-2-1, FM-5-1, FM-6-1, FM-8-1, FA-1-1, FA-1-5: oral LD_{50}s similar to or higher than that of parent
Medical data	
	No effects in manufacturing personnel, no cases of poisoning

[a] In the chronic study, possible neurotoxicity (convulsive periods) were observed in female rats from week 30 onwards.

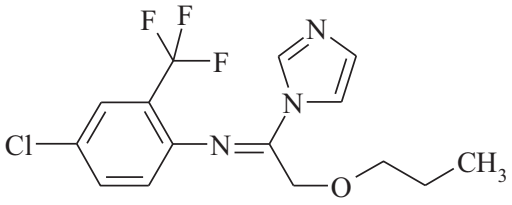
Summary

	Value	Study	Safety factor
ADI	0–0.04 mg/kg bw	Two-year study in rats	100
ARfD	0.3 mg/kg bw	Acute neurotoxicity study in rats	100

RESIDUE AND ANALYTICAL ASPECTS

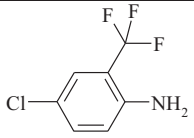
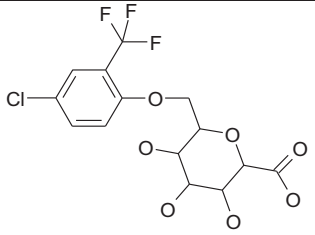
Residue and analytical aspects of triflumizole were considered for the first time by the present Meeting. The residue evaluation was scheduled for the 2013 JMPR by the Forty-fourth Session of the CCPR.

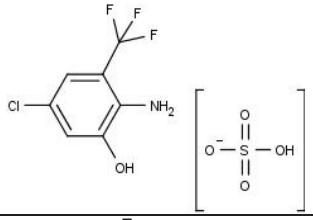
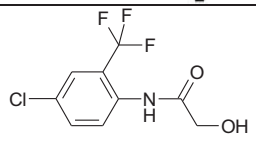
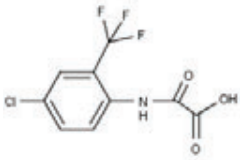
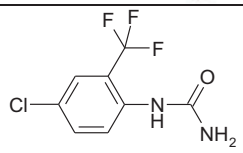
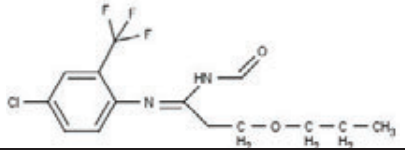
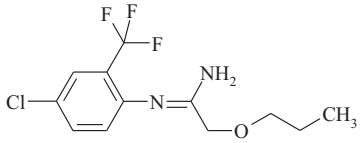
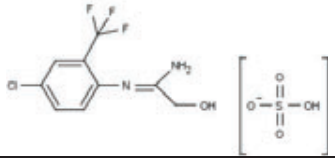
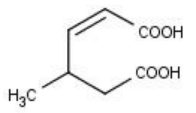
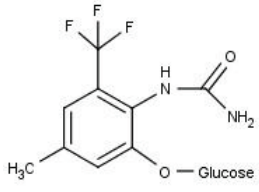
Triflumizole is a broad-spectrum foliar fungicide that controls a variety of fungal diseases in fruits and vegetables. It acts as a protectant and as an eradicant by preventing disease symptoms after infection has occurred. Triflumizole has anti-sporulant activity which reduces spores after lesions become visible. Triflumizole belongs to the demethylation inhibitor (DMI) group of fungicides classified as Group 3 by the Fungicide Resistance Action Committee (FRAC). Triflumizole has protective and curative action, and acts as an inhibitor of chitin biosynthesis. The product is mixed with water and applied as a foliar spray using ground equipment equipped for conventional spraying on crops. The Meeting received information on identity, animal and plant metabolism, environmental fates in soil, rotational crops, analytical methods, storage stability, use patterns, supervised trials, dairy cattle feeding studies, and fates of residues in processing.



(E)-4-chloro-α,α,α-trifluoro-N-(1-imidazol-1-yl-2-propoxyethylidene)-o-toluidine

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

Identifier	Chemical Structure
FA-1-1	
FA-1-glucuronide	

Identifier	Chemical Structure
FA-1-5 (Free and sulphate conjugate)	
FD-2-1	
FD-7-1	
FD-9-1	
FM-5-1	
FM-6-1	
FM-8-1 (Free and sulphate conjugate)	
XIV	
XXVI	

Animal metabolism

The Meeting received animal metabolism studies with triflumizole in rats, lactating goat and laying hens. The metabolism and distribution of triflumizole in animals were investigated using triflumizole universally labelled in the phenyl ring.

In the metabolism studies, rats were dosed at 10 mg/kg bw per day (single and multiple dose studies) or at 300 mg/kg bw per day (single dose study). Metabolite identification in tissues was not provided. The metabolite profile indicates that triflumizole is extensively metabolized in rats: less than 2% of the radiolabel recovered from urine or faeces was identified as parent compound. A few differences in metabolite pattern were observed between males and females after repeated low and single high doses, but not after a single low dose. The major urinary metabolites are the sulphate conjugates of N-(4-chloro-2-trifluoromethylphenyl)-2-hydroxy-acetamidine (FM-8-1) and 2-amino-5-chloro-3-trifluoromethylphenol (FA-1-5). In faeces, N-(4-chloro-2-trifluoromethylphenyl)-2-hydroxy-acetamide (FD-2-1) is a major metabolite. Differences between dose regimens exist with respect to other major metabolites. 2-(4-Chloro-2- trifluoromethylphenylimino)- 2-imidazol- 1-yl-ethanol (FM-2-1) is the major metabolite after a single oral low dose, 4-Chloro-2-trifluoromethylphenylamine (FA-1-1) is a major metabolite after single and repeated low dosing, whereas N-(4-chloro-2-trifluoromethylphenyl)-2-propoxy-acetamide (FD-1-1) is the major metabolite after a single high dose. The presence of the metabolite N-(4-chloro-2-trifluoromethylphenyl)- 2-propoxy-acetamidine (FM-6-1) was confirmed in rat faeces and urine.

Lactating goat was dosed with [^{14}C]triflumizole at a dose equivalent to approximately 280 ppm in the diet twice daily for 5 consecutive days. Gelatine capsules containing [^{14}C]triflumizole were administered orally via a balling gun. The majority of the dose was rapidly excreted in urine (56% of the TAR) and faeces (19.9% TAR).

Total radioactive residues (TRR) in the milk accounted for 0.18% TAR. Tissues contained approximately 0.65% TAR. Total material balance was 76.7% TAR, with an additional 5–12% TAR estimated to be in the bladder, digestive tract and carcass; $^{14}CO_2$ was not monitored.

Levels of radiolabel material reached a plateau in milk within approximately 24 hours and account for approximately 0.16% TAR. TRR was highest in liver and kidney (11.3 and 3.4 mg eq/kg, respectively) and approximately an order of magnitude lower in muscle (0.3 mg eq/kg) and fat (0.66 mg eq/kg). The residue in liver accounted for 0.4% TAR.

Triflumizole was not detected in any matrix. Major residues in liver were FA-1-1 (79.2% TRR, of which 54.8% TRR was bound) and FA-1-5-sulphate (12.4% TRR). In milk, major residues were FA-1-5-sulphate (29.1% TRR), FA-1-5-glucuronide (11.8% TRR), FD-2-1 (10.4% TRR), and FM-8-1-sulphate (12.6% TRR). No other individual compounds accounted for more than 10% of the TRR. The study noted that residues in other matrices were not identified due to low radioactivity; however, it is unclear why further characterization/identification was not done in muscle and liver given the level of residues in those tissues (0.3 and 0.66 mg eq/kg, respectively).

Laying hens were orally dosed with [^{14}C]triflumizole at a dose equivalent to 39 (3 hens) or 53 (2 hens) ppm in the diet twice daily for 5 consecutive days. The majority of the dose was rapidly eliminated in the excreta. Average radioactive residues in the excreta and cage wash accounted for 85.3% of the total administered dose.

Total ^{14}C residues in eggs did not plateau during the dosing period. Egg yolk and white were assayed separately for the eggs from hens treated at 53 ppm. Initially, TRR levels were greater in egg white than in the yolk; however, by Day 3 of dosing residues in yolk were much greater than in the egg white. On Day 5, residues in whole eggs from hens treated at 39 ppm ranged from 0.215 to 0.431 mg eq/kg. Residues ranged from 0.899 to 2.312 mg eq/kg in egg yolk and from 0.074 to 0.408 mg eq/kg in egg white. Residues in tissues from hens treated at the lower rate were consistently lower than those from hens treated at the higher rate. At the lower rate, residue ranges (mg eq/kg) were 0.989–1.232 in liver, 0.537–0.677 in kidney, 0.050–0.067 in fat, 0.017–0.047 in leg muscle, and 0.026–0.049 in breast muscle. At the higher rate, residues (mg eq/kg) were 0.781 and 1.115 in kidney,

0.312 and 0.358 in fat, 0.066 and 0.073 in leg muscle, and 0.054 and 0.087 in breast muscle; liver samples were used for metabolite identification and were not assayed for total radioactivity.

Major residues identified in egg white/yolk consisted of triflumizole (13.4/3.7% TRR), FD-6-1 or FD-4-1 (12.6/3.0% TRR), and FA-1-1 (35.3/22.1% TRR). Volatility of FA-1-1 resulted in some evaporative losses of that analyte. Unextracted residues accounted for 17.2 and 39.8% TRR in egg white and yolk, respectively. All other identified or characterized residues were less than approximately 4% TRR. Analysis of the liver samples indicated that the only metabolite was FA-1-1 or a compound convertible to FA-1-1 during proteolytic digestion.

In animal metabolism studies, triflumizole was metabolized to several compounds. The majority of the dosed radioactivity was excreted and radioactive residues in tissues were generally low. Triflumizole was identified as a residue in egg whites only. Metabolite FA-1-1 was the most prominent component in liver and egg. Sulphur- and glucuronide-conjugated FA-1-5 was the most prominent residue in milk.

Plant metabolism

The Meeting received plant metabolism studies performed on apple, pear, grape, and cucumber with triflumizole universally labelled in the phenyl ring.

In the apple metabolism study, trees were grown in a greenhouse and treated by spotting clusters of leaves with the test substance (approximately 0.127 mg/4-leaf cluster). Branches were harvested at 0, 1, 3, 7, 14, 21, 31, 60, and 90 DAT; fruits were not harvested.

Over the 90-day time span, the overall residue decreased from 51.65 mg eq/kg to 3.03 mg eq/kg, with an initial half-life of approximately 4 days, and was associated primarily with the treated leaves. Radioactive residue in the surface wash of treated leaves accounted for the majority of the residue until 14-DAT sampling. By the 14-DAT sampling, over half of the radioactivity in treated leaves was accounted for as extracted residues or associated with the post-extraction solids (PES). Radioactivity in untreated leaves above the treatment location remained relatively constant throughout the study, ranging from 0.04–0.07 mg eq/kg. Residues in untreated leaves below the treatment location showed a small increase in levels with time, with a maximum of 0.24 mg eq/kg at the 21-DAT sampling. In treated leaves, the only major (> 10% TRR) identified compounds that appeared consistently in the residue profile were triflumizole (0.02–0.12 mg eq/kg) and FM-6-1 (1.2–31% TRR, 0.01–0.02 mg eq/kg); FD-2-1 accounted for 12.6% TRR (< 0.01 mg eq/kg) at the 90-DAT sampling. As overall residues of radiocarbon declined with increasing time after treatment FD-2-1, unidentified metabolites and the contribution from PES became more prominent in the residue profile in terms of %TRR.

In the pear metabolism study, pear trees grown in a greenhouse were treated with test substance by spotting leaves (approximately 1 mg/4-leaf cluster) or the surface of pear fruits (approximately 0.166 mg/fruit) with radiolabelled test substance. Branches from leaf-treated trees were harvested at 0, 1, 3, 7, 14, 21, 31, 60, and 90 DAT and were divided into treated leaves, untreated leaves, and fruit. Treated fruits were harvested 0, 1, 3, 7, and 14 DAT.

Data from the leaf-treatment samples showed very little movement of radioactivity away from the treated leaves. Radioactivity reached maxima of 0.98% TAR in untreated leaves and 0.18% TAR in untreated fruit. In treated leaves, the majority of the radioactivity was associated with the surface wash through the 31-DAT sampling, at which point extractable residues and PES-associated residues, combined, constitute more than half of the TRR (56% TRR, 5.6 mg eq/kg). As with the apple study, the data show a rapid decline in radiocarbon residues, with an initial half-life of approximately 4 days.

For treated fruit, the vast majority (> 95%) of the radioactive residue was confined to the peel, with very little movement into the flesh or core of the pear. For peel, residues in surface wash were the majority at the 0- and 1-DAT sampling times, after which extractable residues became the

most prominent. The data also show a rapid decline in radiocarbon residues, with an initial half-life of between 1 and 3 days, and a slower rate of decline between 3 and 14 DAT.

In leaves, triflumizole and FM-6-1 were the only residues > 10% TRR. After 3 days and for the remainder of the study, FM-6-1 occurred at levels greater than triflumizole, peaking at 0.25 mg eq/kg at 3 DAT. In fruit, major residues were triflumizole (maximum = 93.56% TRR, 1.11 mg eq/kg, 0 DAT), FM-6-1 (maximum = 30.0% TRR, 0.14 mg eq/kg, 7 DAT) and FD-1-1 (10.51% TRR, 0.06 mg eq/kg, 3 DAT).

In the grape metabolism study, grape vines were grown in a greenhouse. Treatments were with triflumizole, uniformly labelled with ^{14}C in the phenyl ring, applied either to a branch of approximately 10 leaves and blossoms approximately 67 days prior to harvesting mature fruit, or to a bunch of young fruits 35 days before harvesting mature fruit. For both treatments, the rate was equivalent to 0.280 kg ai/ha. Treated branches were harvested 0, 3, 7, 14, 31, and 67 DAT and were divided into treated leaves and fruit; treated fruits were harvested 0, 3, 7, 14, and 35 DAT.

Following treatment of leaves, the % TAR decreased from 99% TAR to 15% TAR at 67 DAT. Most of the radioactivity in leaves was recovered from the surface wash, with < 2% TAR being translocated to fruits. Triflumizole was the major residue out to 31 DAT (51% TRR, 8.8 mg eq/kg). The only other major residue was FM-6-1 (11.1% TRR, 0.76 mg eq/kg at 67 DAT). Post-extraction residues in leaves gradually increased from 3.1% TRR (1.73 mg eq/kg) to 26.02% TRR (1.79 mg eq/kg) over the course of the study. Minor metabolites and those remaining at the origin increased to 39% TRR at 67 DAT, with no individual component exceeding 8% TRR.

In treated fruit over the 35-day period of the study, overall radioactivity decreased from 100% TAR (7.79 mg eq/kg) to 24.8% TAR (1.93 mg eq/kg). The majority of the radioactivity in treated fruit was recovered from the surface wash for the 0-, 3-, and 7-DAT samples; at the 14- and 35-DAT sampling points. More of the total residue was associated with extracted and bound residues. At all of the sampling times, the only major residue was triflumizole. FM-6-1 reached a maximum of 7.59% TRR (0.07 mg eq/kg) at 35 DAT, at which point triflumizole constituted 31% TRR (0.31 mg eq/kg).

The cucumber study was conducted under greenhouse conditions. Three types of treatment were made: Foliar treatment to investigate metabolism (0.13 mg/plant), fruit treatment to investigate metabolism (0.041 mg/plant), and foliar treatment to investigate translocation (0.16 mg/plant). In the case of the foliar treatment for metabolism, whole plants were harvested 1, 3, 7, 14, 21, and 45 days after treatment (DAT). For the fruit metabolism and translocation investigations, fruits were harvested 1 (metabolism only), 3, 7, and 14 DAT.

Results from all three lines of investigation demonstrated that the majority of the radioactivity (65–76% of applied) remained on the surface of the harvested material and that there was very little movement of radioactivity within the cucumber plants. Triflumizole accounted for most of the radioactivity through 14 DAT; at 21 DAT and 45 DAT, FM-6-1 residues were approximately equal to those of triflumizole and at 45 DAT, residues of F-8-1 were greater than either triflumizole or FM-6-1 on a % TRR basis. No metabolite exceeded 10% of the TRR except for FM-6-1approximately 12% TRR, < 0.01 mg eq/kg) at the 7- and 14-DAT sampling times in the cucumber fruit study. In those samples, FM-6-1 was associated with the peel and flesh of the fruit and not the surface wash.

The metabolic profile observed in these studies was similar across all four crops. Over the time course of the studies, triflumizole and FM-6-1 account for the majority of the radioactivity. Generally triflumizole decreased rather rapidly (half-life on the order of 3 days), with the exception of grapes where metabolism was slower (half-life approximately 14 days). Loss of triflumizole was accompanied by an increase in the FM-6-1 metabolite, which was the only metabolite to consistently occur at $\geqslant$ 10% TRR.

Environmental fate in soil

The Meeting received information on soil-surface photolysis, soil dissipation, aerobic soil metabolism, and confined and field rotational crop studies.

Under aerobic conditions in soil, the imidazole ring of triflumizole is opened to yield FM-5-1, FD-1-1, and FM-6-1. The resulting amide or amine moiety is then hydrolysed to form the FA-1-1 metabolite, which then becomes associated with bound residues or is oxidized to CO_2. The DT_{50} was 16–22 days at 20 °C with indoor studies and 7.1–22 days with outdoor studies.

In the soil photolysis study, triflumizole degraded significantly. On average after 11 days of exposure, triflumizole had declined to 30.0% of the AD. This was accompanied by formation of FM-6-1, which reached a maximum of 21.8% TAR after 7 days of exposure to simulated sunlight and then dissipated to 15.6% TAR at Day 11. The metabolites FD-1-1 (3.6% TAR at Day 11), FM-8-1 (1.8% TAR, Day 11), FD-7-1 (8.6% TAR, Day 11), and CO_2 (3.5% TAR, Day 11) were also observed. Bound residues increased over the time course of the study and averaged 18.7% TAR by the end of the 11-day period.

The results of both the aerobic soil and soil photolysis study indicate that triflumizole is not likely to be persistent in the environment.

In the confined rotational crop study, radiolabelled triflumizole was applied to bare soil at approximately 1.4 kg ai/ha (1× GAP; 6 plots) or approximately 12.7 kg ai/ha (10× GAP; 2 plots) and rotational crops of lettuce, radish, and wheat were planted into each. Plant-back intervals (PBIs) were 30, 120, and 365 days for the 1× plots and 30 days for the 10× plots. Radish was sampled for roots and tops, and wheat was sampled for forage, grain, hay, and straw. The 1X plots were used to determine % TRR only and the 10× plots were used to make metabolite identifications (except for 1× samples for wheat forage).

Quantifiable levels of TRR occurred for all crop matrices at all PBIs. Highest values were for wheat straw, starting at 1.65 mg eq/kg at the 30-day PBI and declining to 0.478 mg eq/kg at the 365-day PBI. The lowest values were for lettuce (0.086 to 0.021 mg eq/kg at the 120- and 365-day PBI, respectively). For each crop matrix, the TRR declined when going from shorter to longer PBIs with the exception of lettuce which had a maximum at the 120-day PBI (0.086 mg eq/kg) and wheat grain for which the 365-day PBI TRR (0.067 mg eq/kg) was greater than the 120-day PBI TRR (0.055 mg eq/kg).

Triflumizole underwent extensive metabolism in the confined rotational crop study. Forty-nine metabolites were identified, four of which were > 10% TRR and > 0.01 mg eq/kg in at least one matrix. No triflumizole was identified in any crop and no single metabolite was consistently the predominant residue. Two of the major metabolites were identified as glucose conjugates of FM-6-1 and FM-8-1, which constituted 22.9% TRR in lettuce and 16.1% TRR in wheat forage, respectively. The other major metabolites in the confined rotational crop study (XIV and XXVI) were not significant residues in either the crop or livestock metabolism profiles.

Field rotational crop studies were conducted with lettuce, turnip, cabbage, cotton, onion, tomato and wheat. Triflumizole was applied to squash at approximately 30 days prior to harvest or to cucumbers at the vining stage. In both studies, the initial application was followed by four subsequent applications at 7 ± 1 day intervals. All applications were 0.28 kg ai/ha for a total rate of 1.4 kg ai/ha. For all commodities except wheat fodder, forage, and hay, residues of triflumizole, analysed by the common-moiety method, were < 0.01 mg/kg, or in a few cases slightly above 0.01 mg/kg, at plant-back intervals (PBIs) of 30, 60, 90, 120, 180, and 270 days (not all crops were sampled at all intervals). In wheat animal forage, hay, and straw, quantifiable residues persisted throughout all of the plant-back intervals with no particular trend related to PBI. Residue ranges were < 0.01–0.20 mg/kg in wheat forage, < 0.01–0.144 mg/kg in wheat hay, and < 0.01–0.134 mg/kg in wheat straw.

The field rotational crop study indicates that residues are generally not expected (< 0.01 mg/kg) in food crops planted in rotation following treatment to the previous crop. When residues do occur, they are not expected to be much above 0.01 mg/kg. In contrast, readily quantifiable residues in forage/fodder, hay, and straw commodities from cereal grains are expected when such crops are planted in rotation following a treated.

Methods of analysis

The Meeting received description and validation data for analytical methods for residues of total triflumizole (all residues convertible to the FA-1-1 metabolite, expressed as triflumizole) as well as methods for specific residues (e.g., triflumizole, FM-6-1, FA-1-5). Recovery data were provided for raw and processed agricultural commodities as well as animal commodities.

Methods that analyse total triflumizole in crops involve an initial extraction with water. Hydrolysis is accomplished by refluxing in concentrated acetic acid and sodium acetate followed by distillation in the presence of sodium hydroxide into hexane. Residues are cleaned up by column chromatography, and analysed by GC-NPD, GC-MSD, or HPLC-UV.

Methods for the analysis of specific residues in crops use solvent extraction (methanol or acetonitrile), clean-up by solid-phase partitioning and liquid/liquid partitioning, and analysis by GC-NPD, GC-MSD, HPLC-UV, or LC-MS/MS.

Recoveries for the common-moiety method averaged 80.8% and recoveries for the specific-residue method averaged 86.5%. Recoveries for both methods were generally within the range of 70–120%. Limits of quantitation are reported as being of 0.01 mg/kg for most matrices, 0.02 mg/kg for hops, and 0.05 mg/kg for nutmeats.

Data describing multi-residue method testing for residues of triflumizole were not provided.

In animals, the common-moiety method uses 20% NaOH and a Bleidner extractor to digest/distil/extract residues into hexane. The terminal residue is the FA-1-1 metabolite and analysis is by GC-NPD. Recoveries for this method ranged from 78 to 92%.

In the procedure for determining residues containing FA-1-5, the sample was extracted using an acidic digestion followed by clean up and concentration using solid phase extraction (SPE) on reversed phase C18 columns. Final separation and quantification was conducted by HPLC on a C18 column and electrochemical detection. Recoveries for this method averaged 85%.

All of the submitted methods are adequate for the analysis of triflumizole residues.

Stability of residues in stored analytical samples

The Meeting received data on the stability of residues of triflumizole and its metabolites in crops (apple, grape, strawberry, cucumber, cherry, muskmelon, squash, lettuce, and wheat forage) and livestock. The test compound was added to homogenized test matrix. Samples were placed into frozen storage and analysed by the common-moiety or analyte-specific method(s) used in the supervised residue trial.

For the following commodities, stability of residues during storage was demonstrated for at least 3 months in hazelnut, 4 months in wheat forage, 6 months in animal commodities, 12 months in cherries and grapes, and 18 months in papaya.

For the following commodities, stability of residues during storage was demonstrated for no longer than 2 months in lettuce, 3 months in muskmelon and summer squash, and 6 months in apple, cucumber, and strawberry.

For the following commodities, stability of residues during storage was not demonstrated for any time period: cabbage, mustard greens, Swiss chard, and tomato.

Definition of the residue

In the lactating goat metabolism study, TRR were significantly higher in liver than in any other matrix, including milk. Triflumizole was not detected in liver or milk. In liver, free and conjugated FA-1-1 constituted nearly 80% of the residue, with FA-1-5-sulphate making up an additional 12%. In milk, sulphate and glucuronide conjugates of FA-1-5 account for 40% of the residue; the only other major residues were FD-2-1 (10.4% TRR) and FM-8-1-sulphate (12.6% TRR).

In the laying hen metabolism study, TRR were highest in liver, kidney, and egg. Liver contained only FA-1-1 (or a metabolite converted to FA-1-1 during proteolytic digestion). In egg, major residues were triflumizole (13.4% TRR in whites), FD-6-1 or FD-4-1 (12.6% TRR in white), and FA-1-1 (up to 35% TRR in white and 22% TRR in yolk). Hen kidney was not subjected to analysis for residue identification.

In the lactating cattle feeding study, samples were analysed using a common-moiety method, which would have captured all of the major residues observed in the lactating goat and laying hen metabolism studies except for FA-1-5-sulphate, which was the major metabolite in milk observed in the metabolism study. However, in the feeding study, residues of FA-1-5-sulphate were < 0.01 mg/kg in milk and < 0.03 mg/kg in liver and kidney.

Analytical methods for animal matrices are available for the analysis of residues convertible to FA-1-1 or for analysis of FA-1-5-sulphate.

The Meeting agreed that residues converted to 4-chloro-2-(trifluoromethyl)aniline (FA-1-1) and expressed as parent triflumizole are suitable for enforcement and dietary risk purposes in animal commodities.

The log P_{OW} of the residues in animal commodities will be determined by the composition and relative amounts of the metabolite residues in the various matrices. In the lactating cattle feeding study, total residues of triflumizole in fat were, on average, approximately 3.5 times greater than those in muscle.

The Meeting concluded that the residue is fat soluble.

In metabolism studies with apple (leaves only), pear, cucumber, and grape, triflumizole and FM-6-1 constitute the vast majority of the identified residues, and no other residues consistently occur at greater than 10% TRR. The FM-6-1 metabolite was observed in the rat.

The analytical method for plant matrices is a common-moiety method that quantifies all residues convertible to FA-1-1, including FM-6-1.

The Meeting agreed that residues converted to 4-chloro-2-(trifluoromethyl)aniline (FA-1-1) and expressed as parent triflumizole are suitable for enforcement and dietary risk purposes in plant commodities.

The Meeting recommended the following residue definition:

For plants and animals:

Definition of the residue (for compliance with the MRL and for estimation of dietary intake):

Residues analysed as 4-chloro-2-(trifluoromethyl)aniline and expressed as parent triflumizole.

Results from supervised residue trials on crops

The Meeting received supervised trial data for the foliar application of triflumizole on apple, pear, cherry, grape, strawberry, papaya, broccoli, cabbage, cucumber, muskmelon, squash, tomato, lettuce (head and leaf), mustard green, Swiss chard, turnip green, hazelnuts and hops. Residue trial data were made available from the USA for all crops as well as Japan (cucumber, apple and pear), Netherlands (cucumber and tomato), and Belgium (tomato).

Labels for end-use products containing triflumizole were available from the USA and the Netherlands (glasshouse use on tomato and cucumber only) describing the registered uses of triflumizole.

For most crops, the residues were determined by the common-moiety method and reflect the sum of all residues convertible to the aniline moiety, expressed as triflumizole. For the trials in Japan (cucumber), the Netherlands (cucumber and tomato) and Belgium (tomato), the reported residues are the sum of triflumizole and FM-6-1. Side-by-side data reflecting analysis by both common-moiety and residue-specific (triflumizole + FM-6-1) methods are available for hops. In those samples, residues from the common-moiety method were considerably greater than those from the residue-specific method. As the residue definition is for residues convertible to the FA-1-1 metabolite, only residues determined as total triflumizole are suitable for making residue estimates.

Pome fruits

The GAP in the USA on pome fruit is foliar application at a maximum rate of 0.56 kg ai/ha and a PHI of 14 days. Applications may be made at a 7- to 10-day interval with a maximum seasonal rate of 2.24 kg ai/ha.

Apple

Data were available from supervised trials on apple in the USA. Data were also provided from Japan; however, there is no GAP in Japan.

Eighteen supervised trials were conducted in the USA at GAP and residues were obtained by the common-moiety method. Using trials with a supported storage interval, the Meeting selected the following data for consideration (n=3): < 0.02, 0.26, 0.30 mg/kg.

The meeting agreed that the data for apple were insufficient to make a recommendation.

Pear

Data were available from supervised trials on pear in the USA. Data were also provided from Japan; however, there is no GAP in Japan.

Seven supervised trials were conducted in the USA at GAP and residues were obtained by the common-moiety method. Using trials with a supported storage interval, the Meeting selected to following datum for consideration (n=1): 0.28 mg/kg.

The Meeting agreed that the data for pear were insufficient to make a recommendation.

Cherry

The GAP in the USA on cherry is foliar application at a maximum rate of 0.56 kg ai/ha and a PHI of 1 day. Applications may be made at a 7- to 14-day interval with a maximum seasonal rate of 3.36 kg ai/ha.

Eight supervised trials were conducted in the USA at GAP and residues were obtained by the common-moiety method. The residue results are supported by the available storage stability data. The

trials resulted in the following eight independent residue values: 0.59, 0.96, 1.1, 1.1, 1.2 (2), 1.3, 1.5 mg/kg.

The Meeting estimated a maximum residue level, STMR, and HR for triflumizole residues in cherries (Subgroup 003A) of 4 mg/kg, 1.2 mg/kg, and 1.5 mg/kg, respectively.

Berries and other small fruits

The GAP in the USA on grapes and strawberries is foliar application at a maximum rate of 0.28 kg ai/ha and a PHI of 7 days for grapes and 1 day for strawberry. Applications may be made at a minimum interval of 14 days, with a maximum seasonal rate of 1.12 kg ai/ha.

Grape

Nineteen supervised trials were conducted in the USA at GAP for grapes and residues were obtained by the common-moiety method. The residue results are supported by the available storage stability data. The trials resulted in the following ten independent residue values: 0.09, 0.1, 0.15, 0.16, 0.18, 0.21, 0.31, 0.50, 0.90, 0.94, 1.4, and 2.0 mg/kg.

Based on these data, the Meeting estimated a maximum residue level, STMR, and HR for triflumizole residues in grapes of 3 mg/kg, 0.26 mg/kg, and 2.0 mg/kg, respectively.

Strawberry

Eight supervised trials were conducted in the USA. The residue data for strawberry are not supported by the available storage stability data.

The Meeting agreed not to make a recommendation for strawberry.

Papaya

The GAP in the USA on papaya is foliar application at a maximum rate of 0.35 kg ai/ha on a 14-day interval, with a PHI of 0 days. The maximum seasonal rate is 0.84 kg ai/ha.

Four supervised trials were conducted in the USA. Each treated plot received five applications at approximately 0.42 kg ai/ha on a 12- to14-day interval for a total rate of approximately 2.1 kg ai/ha. Papaya were harvested 0 DAT.

The Meeting agreed that although application in the papaya field trials reflects an over dosing relative to GAP due to the number of applications, the retreatment interval (12 to14 days) combined with residue decline and the rapid growth of the papaya fruit which would be occurring during the first two applications, the early applications are unlikely to have contributed significantly to the residue level at harvest. Therefore, the available trials are suitable for estimation of residue levels resulting from GAP applications. The residue data (n=4) are: 0.22, 0.53, 0.88, and 0.89 mg/kg.

Based on the trials for papaya in the USA, the Meeting estimated a maximum residue level, STMR, and HR for triflumizole residues in papaya of 2 mg/kg, 0.71 mg/kg, and 0.89 mg/kg, respectively.

Brassica (Cole or Cabbage) Vegetables, Head Cabbages, Flowerhead Cabbages

The GAP in the USA on Brassica vegetables is foliar application at a maximum rate of 0.28 kg ai/ha, at a 14-day interval, and a PHI of 1 day. The maximum seasonal rate is 0.63 kg ai/ha.

Broccoli

Ten supervised trials were conducted in the USA. The residue data for broccoli are not supported by the available storage stability data.

The Meeting agreed not to make a recommendation for broccoli.

Cabbage

Nine supervised trials were conducted in the USA. The residue data for cabbage are not supported by the available storage stability data.

The Meeting agreed not to make a recommendation for cabbage.

Fruiting vegetables, Cucurbits

The GAP in the USA on cucurbit vegetables is foliar application at a maximum rate of 0.28 kg ai/ha at a 7- to 14-day interval, and a PHI of 0 days. The maximum seasonal rate is 1.4 kg ai/ha.

The GAP in the Netherlands on cucumber and summer squash is foliar application at a maximum rate of 0.225 kg ai/ha and a PHI of 1 day. One to six applications may be made per season at a 7-day interval.

Cucumber-Outdoor Crops

Six supervised trials were conducted in the USA at GAP and residues were obtained by the common-moiety method. The residue results supported by the available storage stability data are as follows (n=4): 0.13 (2), 0.17, and 0.18 mg/kg.

The Meeting agreed that the data from field-grown cucumber were insufficient to make a recommendation.

Cucumber-Indoor Crops

Four supervised trials were conducted in the USA at GAP and residues were obtained by the common-moiety method. The residue results supported by the available storage stability data are as follows (n=3): 0.10, 0.11, and 0.21 mg/kg.

An additional four trials were conducted in the Netherlands according to the Netherlands GAP. The trials measured only triflumizole and FM-6-1; therefore the residues did not match the residue definition.

The Meeting agreed that the data from indoor-grown cucumber were insufficient to make a recommendation.

Residues from the indoor and outdoor trials on cucumbers from the USA matching the USA GAP are from the same population (Mann-Whitney U test). Using the combined data set (n=7): 0.10, 0.11, 0.13 (2), 0.17, 0.18 and 0.21 mg/kg, the Meeting estimated a maximum residue level, STMR, and HR for triflumizole residues in cucumber of 0.5 mg/kg, 0.13 mg/kg, and 0.21 mg/kg, respectively.

Melon

Six supervised trials were conducted on muskmelon in the USA at GAP. The residue data for muskmelon are not supported by the available storage stability data.

The Meeting agreed not to make a recommendation for muskmelon.

Summer squash

Five supervised trials were conducted in the USA at GAP at GAP and residues were obtained by the common-moiety method. The residue data for summer squash are not supported by the available storage stability data.

The Meeting chose not to make a recommendation for summer squash.

Tomato

The GAP in the USA on tomato is foliar application at a maximum rate of 0.28 kg ai/ha at a 7- to 14-day interval and a PHI of 0 days. The maximum seasonal rate is 1.4 kg ai/ha. The USA GAP is the Critical GAP.

Four supervised trials were conducted in the USA at GAP and residues were obtained by the common-moiety method. The residue data for tomato are marginally supported by the storage stability data and are as follows (n=4): < 0.5 (2), 0.59, and 0.76 mg/kg.

The Meeting agreed that the data for tomato from the USA were insufficient to make a recommendation.

The GAP in the Netherlands on tomato is foliar application at a maximum rate of 0.015 kg ai/hL and a PHI of 1 day. One to five applications may be made per season at a 7-day interval.

Four supervised trials were conducted in each of the Netherlands and Belgium. Treated plot received three applications each at 0.016 kg ai/hL on a 7-day interval and fruits were harvested 3 DAT.

The trials in the Netherlands and Belgium were conducted according to the Netherlands GAP. The Netherlands trials measured only triflumizole and FM-6-1; therefore the residues do not reflect the residue definition.

The Meeting agreed not to make a recommendation for tomato.

Leafy vegetables (including Brassica leafy vegetables)

The GAP in the USA on leafy vegetables is foliar application at a maximum rate of 0.28 kg ai/ha at a 14-day interval and a PHI of 0 days. The maximum seasonal rate is 0.63 kg ai/ha.

Lettuce

Data were available from supervised trials on lettuce in the USA.

Seventeen supervised trials were conducted in the USA on lettuce (head lettuce = seven field trials; leaf lettuce = seven field trials + two greenhouse trials; unspecified = one field trial). In 16 trials, treated plot received four applications each at approximately 0.28 kg ai/ha on a 6- to 9-day interval. The total application rate was approximately 1.12 kg ai/ha. In the remaining trial on the unspecified lettuce variety, five applications were made at approximately 0.57 kg ai/ha, for a total rate of approximately 2.85 kg ai/ha. Lettuce was harvested 0 DAT.

The Meeting agreed that in both the number and interval of applications, the residue trials for lettuce did not match the GAP for lettuce in the USA, and that the proportionality concept could not be used.

The Meeting agreed not to make a recommendation for lettuce.

Mustard greens

Ten supervised trials were conducted in the USA on mustard greens at GAP. The residue trials are not supported by the available storage stability data.

The Meeting agreed not to make a recommendation for mustard greens.

Swiss chard

Data were available from supervised trials on Swiss chard in the USA at GAP. The residue trials are not supported by the available storage stability data.

The meeting agreed not to make a recommendation for Swiss chard.

Turnip greens

The GAP in the USA for triflumizole on turnip greens is foliar application at a maximum rate of 0.28 kg ai/ha and a PHI of 1 day. Two to three applications may be made per season at a 14-day interval with a maximum seasonal rate of 0.63 kg ai/ha.

In one trial conducted in USA, where five applications of 0.27–0.3 kg ai/ha triflumizole were made on a 7-day schedule, total residues in turnip greens 1 day after the last application were 7.1 mg/kg.

The Meeting agreed that the supporting data for turnip greens did not match the GAP in USA and are of insufficient quantity. The Meeting agreed not to make a recommendation for turnip greens.

Hazelnuts/Filberts

The GAP in the USA on hazelnut is foliar application at a maximum rate of 0.21 kg ai/ha and a PHI of 18 days. Four to six applications may be made per season at a 10- to 14-day interval with a maximum seasonal rate of 0.84 kg ai/ha.

All of the field trials in the USA (n=3) were conducted at an exaggerated rate of 6.25× GAP. Per-trial average triflumizole residues (via common moiety) were < 0.05 mg/kg for all samples. The Meeting noted that all three trials were conducted in the same year and in the same orchard complex.

The Meeting noted that the trials are not independent and agreed not to make a recommendation for hazelnuts.

Hops

The GAP in the USA on hops is foliar application at a maximum rate of 0.42 kg ai/ha and a PHI of 7 days. Three applications may be made per season at a 14-day interval with a maximum seasonal rate of 1.26 kg ai/ha.

Data were available from supervised trials on hops in the USA.

Four supervised trials were conducted in the USA at GAP and residues were obtained by the common-moiety method. The residue results are supported by the available storage stability data. The trials resulted in the following 4 independent residue values for dried hops: 7.0, 7.8, 10, and 11 mg/kg.

Based on the trials for hops in the USA, the Meeting estimated a maximum residue level, STMR, and HR for triflumizole residues in hops, dried of 30 mg/kg, 8.9 mg/kg, and 11 mg/kg, respectively.

Fate of residues during processing

The Meeting received data depicting the effects of processing on residue levels in apple (juice, sauce, and wet/dry pomace) and grape (juice, raisins (and related commodities), stems, and wet/dry pomace). The estimated processing factors for grape commodities are 0.42 for juice; 0.22 for grape, dried; and 4.3 for wet pomace.

The Meeting estimated an STMR and HR for grapes of 0.41 mg/kg and 2.0 mg/kg, respectively. Application of the estimated processing factors results in an estimated STMR-P and HR-P, respectively, of 0.09 mg/kg and 0.44 mg/kg for grape, dried; an STMR-P of 0.17 mg/kg for grape juice; and an STMR-P of 1.2 mg/kg for wet grape pomace.

Residue in animal commodities

Farm animal dietary burden

The Meeting estimated the dietary burden of triflumizole in farm animals on the basis of the diets listed in Appendix IX of the FAO Manual 2009. Calculation from highest residue, STMR (some bulk commodities) and STMR-P values provides levels in feed suitable for estimating MRLs, while calculation from STMR and STMR-P values for feed is suitable for estimating STMR values for animal commodities.

Estimated maximum and mean dietary burdens of farm animals

Dietary burden calculations for beef cattle, dairy cattle, broilers and laying poultry are provided in Appendix IX of the FAO manual. The calculations were made according to the animal diets from US-Canada, EU, Australia and Japan in the Table (Appendix IX of the FAO manual). The diets are based on residues in wet grape pomace.

Livestock dietary burden, triflumizole, ppm of dry matter diet [a]								
	US-Canada		EU		Australia		Japan	
	Max	Mean	Max	Mean	Max	Mean	Max	Mean
Beef cattle	–	–	–	–	1.49 [a]	1.49 [c]	–	–
Dairy cattle	–	–	–	–	1.49 [b]	1.49 [d]	–	–
Poultry—broiler	–	–	–	–	–	–	–	–
Poultry—layer	–	–	–	–	–	–	–	–

[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.

Farm animal feeding studies

The Meeting received lactating dairy cow feeding studies, which provided information on likely residues resulting in animal commodities and milk from triflumizole residues in the animal diet.

Lactating dairy cows

Lactating dairy cows were dosed with triflumizole for 28 days at the equivalent of 10 or 50 ppm in the diet. Analysis was for residues convertible to FA-1-1 and FA-1-5 (high-dose group only). Residues for all analyses and tissues were < 0.02 for control animals.

From the high-dose group, milk samples from even-numbered treatment days (except Day 24) were analysed. Residues of FA-1-5 were < 0.01 mg/kg in all milk samples and < 0.03 mg/kg in liver and kidney, which were the only tissue analysed for this compound. Total triflumizole residues were < 0.02 mg/kg in milk on Day 0 and were then rather consistent, ranging from, on average, 0.03 to 0.06 mg/kg. In the low- and high-dose tissue samples, respectively, average residues were 0.06 to 0.33 mg/kg in fat, 0.31 to 1.55 mg/kg in kidney, 0.48 to 4.25 mg/kg in liver, < 0.02 to 0.94 in muscle, and < 0.02 to 0.04 mg/kg in milk.

Animal commodities maximum residue levels

For MRL estimation, the residue in the animal commodities is residues analysed as 4-chloro-2-(trifluoromethyl)aniline and expressed as parent triflumizole.

Residues in tissues and milk at the expected dietary burden for beef cattle in Australia are shown in the Table below. The residue in milk was relatively consistent from Day 2 through Day 28 and the mean estimated residue in milk was calculated using the residue values from Day 4 to the final day.

Triflumizole feeding study	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]	10 50	< 0.02 0.041	10 50	< 0.02 0.106	0.496 4.602	0.460 1.717	0.115 0.478
Dietary burden and high residue	1.49	< 0.02	1.49	< 0.02	0.07	0.69	0.03
STMR beef or dairy cattle							
Feeding study [b]	10 50	< 0.02 0.041	10 50	< 0.02 0.094	0.484 4.248	0.307 1.552	0.056 0.330
Dietary burden and residue estimate	1.49	< 0.02	1.49	< 0.02	0.072	0.046	0.008

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

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

The Meeting estimated the following maximum residue levels: Milk = 0.02(*) mg/kg, meat = 0.03 (fat) mg/kg and edible offal = 0.1 mg/kg.

The Meeting estimated the following STMR levels: Milk = 0 mg/kg, meat = 0 mg/kg, fat = 0.008 mg/kg and edible offal = 0.072 mg/kg.

The Meeting estimated the following HR levels: Milk = 0mg/kg, meat = 0 mg/kg, fat = 0.017 mg/kg and edible offal = 0.074 mg/kg.

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 assessments.

Plant and animal commodities:

Definition of the residue for plant and animal commodities (for compliance with the MRL and for estimation of dietary intake): *Residues analysed as 4-chloro-2-(trifluoromethyl)aniline and expressed as parent triflumizole.*

The residue is fat soluble

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Daily Intakes (IEDIs) of triflumizole were calculated for the 13 GEMS/Food cluster diets using STMRs/STMR-Ps estimated by the current Meeting. The ADI is 0–0.04 mg/kg bw and the calculated IEDIs were 0–2% of the maximum ADI (0.04 mg/kg bw). The Meeting concluded that the long-term intakes of residues of triflumizole, resulting from the uses considered by the current JMPR, are unlikely to present a public health concern.

Short-term intake

The International Estimated Short-Term Intakes (IESTI) of triflumizole 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 ≤ 100% of the ARfD for all commodities. The Meeting concluded that the short-term intake of residues of triflumizole, when used in ways that have been considered by the JMPR, is unlikely to present a public health concern.

5.37 TRINEXAPAC-ETHYL (271)

TOXICOLOGY

Trinexapac-ethyl is the ISO-approved common name for 4-(cyclopropyl-α-hydroxymethylene)-3,5-dioxo-cyclohexanecarboxylic acid ethyl ester (IUPAC), with CAS No. 95266-40-3. Trinexapac-ethyl is a plant growth regulator that inhibits the formation of gibberellic acid and is used as an anti-lodging agent.

Trinexapac-ethyl 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.

Biochemical aspects

In studies conducted in rats using [^{14}C]trinexapac-ethyl, the time to reach the maximum plasma and tissue concentration of radioactivity was 15 minutes following a single gavage dose of 1 or 200 mg/kg bw. Gastrointestinal absorption was at least 96%. The plasma elimination half-life of radioactivity was less than 1 hour. Radioactivity was rapidly eliminated from tissues; mean first-phase tissue half-lives ranged from 0.2 to 0.5 hour at 1 mg/kg bw and from 0.5 to 0.9 hour at 200 mg/kg bw, whereas the slower second-phase elimination ranged from 1.6 to 3.2 hours at 1 mg/kg bw and from 3.2 to 11.7 hours at 200 mg/kg bw. There was no evidence of accumulation of radioactivity in any tissue. Excretion of radioactivity was predominantly via the urine (≥ 90% of the administered dose), with the majority of this occurring within 24 hours of dosing. Low levels of radioactivity were detected in faeces and bile (up to approximately 2.4% and 3.3% of the administered dose, respectively). Trinexapac-ethyl undergoes limited metabolism in the rat, involving predominantly ester hydrolysis of trinexapac-ethyl to trinexapac acid. The predominant urinary metabolite was trinexapac acid (up to 100% of total urinary radioactivity), with low levels of a conjugated derivative of trinexapac acid detected only in the urine of bile duct–cannulated rats (6.3% of the administered dose). In faeces, the parent compound accounted for 5–22% of total faecal radioactivity (1–2.5% of the administered dose), with the balance comprising trinexapac acid. Bile contained mainly a conjugated derivative of trinexapac acid (2.9% of the administered dose), with low levels of the parent compound also detected (0.2% of the administered dose).

Toxicological data

The oral LD_{50} in rats was greater than 2000 mg/kg bw. In rats, the dermal LD_{50} was greater than 4000 mg/kg bw, and the LC_{50} was greater than 5.3 mg/L. Trinexapac-ethyl was neither a skin nor an eye irritant in rabbits. In a guinea-pig maximization test, no skin sensitization occurred.

In repeated-dose toxicity studies in rats and dogs, the main target organ was the kidneys. In rats, increased kidney weight and accompanying histopathological changes (focal tubular basophilia, tubular hyaline droplets and pigment depositon) occurred. Additional treatment-related effects in the brain were observed in dog studies.

In a 4-week gavage study in rats, which tested doses of 0, 10, 100 and 1000 mg/kg bw per day, the NOAEL was 100 mg/kg bw per day for effects on the liver and kidneys at 1000 mg/kg bw per day.

In a 13-week dietary toxicity study in rats, which tested concentrations of 0, 50, 500, 5000 and 20 000 ppm (equal to 0, 3, 34, 346 and 1350 mg/kg bw per day for males and 0, 4, 38, 395 and 1551 mg/kg bw per day for females, respectively), the NOAEL was 500 ppm (equal to 34 mg/kg bw per day) for histopathological findings in the kidney in males at 5000 ppm (equal to 346 mg/kg bw per day).

In a 7-week, non-guideline study in dogs that tested dietary concentrations of 0, 500, 5000, 15 000, 30 000 and 50 000 ppm (equal to an average of 0, 23, 217, 683, 734 and 965 mg/kg bw per day in both sexes, respectively), the NOAEL was 15 000 ppm (equal to 683 mg/kg bw per day), based on a range of effects that occurred at 30 000 ppm (equal to 734 mg/kg bw per day), including body weight loss, lower feed consumption, increased serum cholesterol, increased kidney weight and histopathological findings in the kidney.

In a 13-week study in dogs, which tested dietary concentrations of 0, 50, 1000, 15 000 and 30 000 ppm (equal to 0, 2, 35, 516 and 927 mg/kg bw per day for males and 0, 2, 40, 582 and 891 mg/kg bw per day for females, respectively), the NOAEL was 15 000 ppm (equal to 516 mg/kg bw per day) for reduced body weight gain and feed consumption at 30 000 ppm (equal to 927 mg/kg bw per day). Reduced blood glucose and focal vacuolation in the brain occurred in one male dog at 30 000 ppm.

In a 52-week toxicity study in dogs, which tested dietary concentrations of 0, 40, 1000, 10 000 and 20 000 ppm (equal to 0, 1.6, 32, 366 and 727 mg/kg bw per day for males and 0, 1.4, 40, 357 and 793 mg/kg bw per day for females, respectively), the NOAEL was 1000 ppm (equal to 32 mg/kg bw per day) for cerebral vacuolation at 10 000 ppm (equal to 357 mg/kg bw per day) in the absence of neurodegenerative or inflammatory histopathological changes or neurological signs.

In a 78-week study in mice, which tested dietary concentrations of 0, 7, 70, 1000, 3500 and 7000 ppm (equal to 0, 0.9, 9, 131, 451 and 912 mg/kg bw per day for males and 0, 1.1, 11, 154, 539 and 1073 mg/kg bw per day for females, respectively), the NOAEL for chronic toxicity and carcinogenicity was 7000 ppm (equal to 912 mg/kg bw per day), the highest tested dietary concentration.

In a 104-week study in rats, which tested dietary concentrations of 0, 10, 100, 3000, 10 000 and 20 000 ppm (equal to 0, 0.4, 4, 116, 393 and 806 mg/kg bw per day for males and 0, 0.5, 5, 147, 494 and 1054 mg/kg bw per day for females, respectively), the NOAEL for chronic toxicity was 3000 ppm (equal to 116 mg/kg bw per day) for histopathological lesions in the kidneys at 10 000 ppm (equal to 393 mg/kg bw per day). The NOAEL for carcinogenicity was 20 000 ppm (equal to 806 mg/kg bw per day), the highest tested dietary concentration.

The Meeting concluded that trinexapac-ethyl is not carcinogenic in mice or rats.

Trinexapac-ethyl was tested in an adequate range of in vitro and in vivo genotoxicity tests. No evidence of genotoxicity was found.

The Meeting concluded that trinexapac-ethyl is unlikely to be genotoxic.

Given the lack of genotoxicity and the absence of carcinogenicity in mice and rats, the Meeting concluded that trinexapac-ethyl is unlikely to pose a carcinogenic risk to humans.

In a two-generation reproductive toxicity study in rats, which tested dietary concentrations of 0, 10, 1000, 10 000 and 20 000 ppm (equal to 0, 0.57, 58.6, 570.5 and 1166 mg/kg bw per day for males and 0, 0.73, 73, 721.5 and 1427 mg/kg bw per day for females, respectively), there was no evidence of reproductive toxicity up to the highest tested dietary concentration of 20 000 ppm (equal to 1166 mg/kg bw per day). The NOAEL for parental toxicity was 1000 ppm (equal to 58.6 mg/kg bw per day) for reduced body weight gain and feed consumption at 10 000 ppm (equal to 570.5 mg/kg bw per day). The NOAEL for offspring toxicity was 10 000 ppm (equal to 570.5 mg/kg bw per day) for reduced survival and body weight in the F_1 and F_2 generations at 20 000 ppm (equal to 1166 mg/kg bw per day).

In a rat developmental toxicity study, which tested doses of 0, 20, 200 and 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.

In a rabbit developmental toxicity study, which tested doses of 0, 10, 60 and 360 mg/kg bw per day, the NOAEL for maternal toxicity was 60 mg/kg bw per day for deaths of several dams at

360 mg/kg bw per day. The NOAEL for embryo and fetal toxicity was also 60 mg/kg bw per day for increased post-implantation losses and a reduction in mean number of live fetuses at 360 mg/kg bw per day.

The Meeting concluded that trinexapac-ethyl is not teratogenic in rats or rabbits.

In an acute neurotoxicity study in rats that tested doses of 0, 500, 1000 and 2000 mg/kg bw per day, the NOAEL was 2000 mg/kg bw, the highest dose tested.

In a subchronic neurotoxicity study in rats that tested dietary concentrations of 0, 3750, 7500 and 15 000 ppm (equal to 0, 233, 464 and 948 mg/kg bw per day for males and 0, 294, 588 and 1171 mg/kg bw per day for females, respectively), the NOAEL was 15 000 ppm (equal to 948 mg/kg bw per day), the highest tested dietary concentration.

Toxicological data on metabolites and/or degradates

The Meeting noted the formation of two processing degradates of trinexapac acid, CGA 113745 and CGA 313458, not detected in rat metabolism studies. Based on a structural assessment of these degradates and an estimate of the levels of chronic dietary intake, the Meeting concluded that they are unlikely to pose a dietary risk.

Human data

There were no reports submitted on adverse health effects in workers involved in the manufacture or use of trinexapac-ethyl. No cases of human poisonings have been reported.

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

Toxicological evaluation

The Meeting established an ADI of 0–0.3 mg/kg bw per day, expressed as trinexapac acid equivalents[1], based on a NOAEL of 32 mg/kg bw per day for trinexapac-ethyl (equivalent to 29 mg/kg bw per day expressed as trinexapac acid equivalents) for cerebral vacuolation in male and female dogs following 52 weeks of dietary exposure, with the application of a 100-fold safety factor. In the absence of information to the contrary, including mechanistic data, the cerebral vacuolation observed in dogs was considered relevant to humans.

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

A toxicological monograph was prepared.

[1] To cover the possible dietary exposure to a range of salts, esters and conjugates of trinexapac, it is appropriate to express the ADI as trinexapac acid equivalents using a conversion factor of 0.9 based on differences in molecular weight between trinexapac-ethyl and trinexapac acid.

Levels relevant to risk assessment of trinexapac-ethyl

Species	Study	Effect	NOAEL	LOAEL
Mouse	Two-year study of toxicity and carcinogenicity[a]	Toxicity	7000 ppm, equal to 912 mg/kg bw per day[b]	—
		Carcinogenicity	7000 ppm, equal to 912 mg/kg bw per day[b]	—
Rat	Thirteen-week study of toxicity[a]	Toxicity	500 ppm, equal to 34 mg/kg bw per day	5000 ppm, equal to 346 mg/kg bw per day
	Two-year study of toxicity and carcinogenicity[a]	Toxicity	3000 ppm, equal to 116 mg/kg bw per day	10 000, equal to 393 mg/kg bw per day
		Carcinogenicity	30 000 ppm, equal to 806 mg/kg bw per day[b]	—
	Two-generation study of reproductive toxicity[a]	Reproductive toxicity	20 000 ppm, equal to 1166 mg/kg bw per day[b]	—
		Parental toxicity	1000 ppm, equal to 59 mg/kg bw per day	10 000 ppm, equal to 571 mg/kg bw per day
		Offspring toxicity	10 000 ppm, equal to 571 mg/kg bw per day	20 000 ppm, equal to 1166 mg/kg bw per day
	Developmental toxicity study[c]	Maternal toxicity	1000 mg/kg bw per day[b]	—
		Embryo and fetal toxicity	1000 mg/kg bw per day[b]	—
Rabbit	Developmental toxicity study[c]	Maternal toxicity	60 mg/kg bw per day	360 mg/kg bw per day
		Embryo and fetal toxicity	60 mg/kg bw per day	360 mg/kg bw per day
Dog	One-year study of toxicity[a]	Toxicity	1000 ppm, equal to 32 mg/kg bw per day	10 000 ppm, equal to 357 mg/kg bw per day

[a] Dietary administration.

[b] Highest dose tested.

[c] Gavage administration.

Estimate of acceptable daily intake

0–0.3 mg/kg bw per day

Estimate of acute reference dose

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 trinexapac-ethyl

Absorption, distribution, excretion and metabolism in mammals	
Rate and extent of oral absorption	Rapid and complete
Distribution	Widespread tissue distribution
Potential for accumulation	No potential for accumulation
Rate and extent of excretion	Rapid and complete
Metabolism in animals	Limited; mainly hydrolysis to trinexapac acid
Toxicologically significant compounds in animals, plants and the environment	Trinexapac-ethyl, trinexapac acid
Acute toxicity	
Rat, LD_{50}, oral	> 2000 mg/kg bw
Rat, LD_{50}, dermal	> 4000 mg/kg bw
Rat, LC_{50}, inhalation	> 5.3 mg/L
Rabbit, dermal irritation	Non-irritating
Rabbit, ocular irritation	Non-irritating
Dermal sensitization	Non-sensitizing (maximization test)
Short-term studies of toxicity	
Target/critical effect	Kidney and brain
Lowest relevant oral NOAEL	32 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	Kidney
Lowest relevant NOAEL	116 mg/kg bw per day (rat)
Carcinogenicity	Not carcinogenic
Genotoxicity	
	Not genotoxic
Reproductive toxicity	
Reproduction target/critical effect	No evidence of reproductive toxicity
Lowest relevant parental NOAEL	59 mg/kg bw per day
Lowest relevant offspring NOAEL	571 mg/kg bw per day
Lowest relevant reproduction NOAEL	1166 mg/kg bw per day, the highest dose tested
Developmental toxicity	

Developmental target/critical effect	Post-implantation losses at maternally toxic doses (rabbit)
Lowest maternal NOAEL	60 mg/kg bw per day (rabbit)
Lowest embryo/fetal NOAEL	60 mg/kg bw per day (rabbit)
Neurotoxicity	
Acute and subchronic neurotoxicity	Not neurotoxic
Medical data	
	No data

Summary

	Value	Studies	Safety factor
ADI	0–0.3 mg/kg bw	One-year toxicity study in dogs	100
ARfD	Unnecessary	—	—

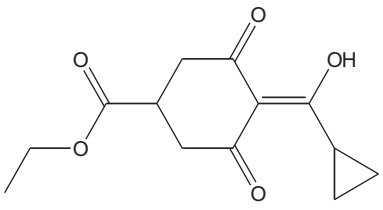
RESIDUES AND ANALYTICAL ASPECTS

At the 44th session of the CCPR (2012), trinexapac-ethyl was scheduled for evaluation as a new compound by 2013 JMPR.

Trinexapac-ethyl is a synthetic plant growth regulator that is derived from cyclohexanecarboxylate. It is applied as a foliar spray, post-emergence and is approved for use on cereal crops such as barley, durum wheat, oats, rye, triticale and wheat, oilseed rape and sugarcane as well as on grassland pastures.

The manufacturer supplied information on identity, metabolism, methods of residue analysis, freezer storage stability, registered use patterns, supervised residue trials, fates of residues in processing and farm animal feeding studies.

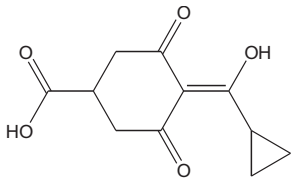
The IUPAC name is 4-(cyclopropyl-hydroxy-methylene)-3,5-dioxo-cyclohexanecarboxylic acid ethyl ester.



Trinexapac-ethyl

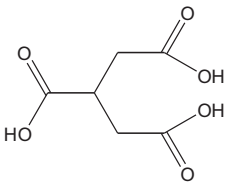
The 2013 JMPR established an ADI for trinexapac-ethyl of 0–0.3 mg/kg bw trinexapac acid equivalents.

The structures of the key metabolites discussed are shown below:



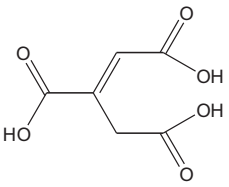
CGA 179500

Trinexapac acid



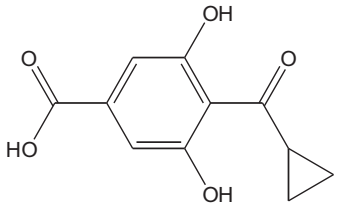
CGA 275537

Tricarballylic acid

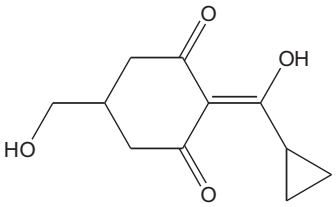


CGA 312753

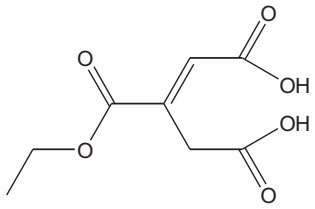
Trans aconitic acid



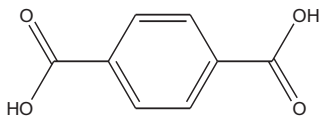
CGA 329773



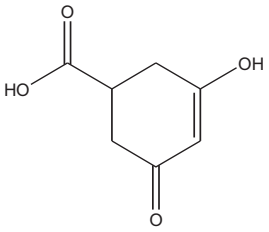
CGA 351210



CGA 312753 mono-ethyl ester



Terephthalic acid



CGA113745

Animal metabolism

The Meeting received animal metabolism studies with trinexapac-ethyl in rats, hens and goats.

Rats

Evaluation of the metabolism studies in rats was carried out by the WHO Core Assessment Group.

Trinexapac-ethyl undergoes limited metabolism in the rat, involving predominantly ester hydrolysis of trinexapac-ethyl to trinexapac acid. The predominant urinary metabolite was trinexapac acid (up to 100% of total urinary radioactivity), with low levels of a conjugated derivative of trinexapac acid detected only in the urine of bile-duct cannulated rats (6.3% of the administered dose). In faeces, the parent compound accounted for 5–22% of total faecal radioactivity (1–2.5% of the administered dose), with the balance comprising trinexapac acid. Bile contained mainly a conjugated derivative of trinexapac acid (2.9% of the administered dose), with low levels of the parent compound also detected (0.2% of the administered dose).

Goats

[1, 2-^{14}C-cyclohexyl] trinexapac-ethyl was orally administered via capsule to lactating goats at 7.2 ppm or 694 ppm in the feed (or 0.20 or 19.9 mg/kg bw/day respectively) for 4 consecutive days. Milk was sampled twice daily, in the morning and afternoon. Animals were sacrificed approximately 4 hours after the last dose.

The low dose goat eliminated 16% and 50% via faeces and urine of the total administered dose respectively at 76 hours in the study, while the corresponding values of the high dosed goat were 19% and 62%. In milk, 0.02% of the administered dose was recovered at both dose levels. A plateau was reached after 2 days (low dose-0.002 mg/kg equiv (am) and 0.007 mg/kg equiv. (pm)) or 3 days (high dose-0.22 mg/kg equiv (am) and 0.83 mg/kg equiv. (pm)) after administration.

The tissue residues of the low dosed goat were 0.035–0.043 mg/kg equiv. in muscles, 0.017–0.094 mg/kg equiv. in fat, 0.25 mg/kg equiv. in liver and 0.50 mg/kg equiv. in kidney. In the high dosed goat the residues were correspondingly higher, i.e., 1.90–2.49 mg/kg equiv. in muscles, 1.20–1.55 mg/kg equiv. in fat, 12.1 mg/kg equiv. in liver and 41.9 mg/kg equiv. in kidney.

Residues in muscle and kidney were mostly trinexapac acid (81–90% TRR). In milk, trinexapac acid accounted for 46–76% TRR. In liver and fat trinexapac acid was 31–67% TRR, although for fat this represented 87–96% of the extracted radioactivity. For liver this represented only 34–47% of the extracted radioactivity.

In another study [1, 2, 6-^{14}C-cyclohexyl] trinexapac-ethyl was orally administered by gelatine capsule to two lactating goats at 100 ppm in the feed (or 3.1 mg/kg bw/day) for 4 consecutive days. Milk was sampled twice daily. Animals were sacrificed approximately 6 hours after the last dose.

The goats had eliminated 3% and 81% via faeces and urine of the total administered dose respectively at 78 hours in the study while 0.05% of the administered dose was recovered in milk. Residues in the Day 2 pm sample of milk were 0.076 mg/kg equiv.

The tissue residues were 0.28 mg/kg equiv. in muscles, 0.11 mg/kg equiv. in fat, 0.80 mg/kg equiv. in liver and 5.90 mg/kg equiv. in kidney.

No parent was observed in tissues or milk. Residues in liver, kidney, muscle and fat were mostly trinexapac acid (CGA179500) (66–97% TRR). In milk, trinexapac acid accounted for 85% TRR. In liver, kidney and fat the metabolite CGA113745 accounted for 6–16% TRR. This metabolite was not detected in either muscle or milk.

Hens

[1, 2-^{14}C-cyclohexyl] trinexapac-ethyl was orally administered daily to laying hens using gelatine capsules at a low dose level (2 hens, 0.4 mg/kg body weight equivalent to 3.8 ppm in feed) or a high dose level (4 hens, 20.3 mg/kg body weight equivalent to 180 ppm in feed) for 4 consecutive days. Eggs were collected throughout the day and in the morning before subsequent administration. Animals were sacrificed approximately 4 hours after the last dose.

Over the period of the experiment (76 hours), 85–89% (high and low doses respectively) of the total administered dose was eliminated in excreta. Transfer of radioactivity into eggs accounted for only 0.01% and 0.02% of the total administered dose for the low and high dosed hens, respectively. A plateau was reached at Day 2 of the dosing period. Concentrations of radioactivity in egg yolk were generally less than in egg whites. Concentrations of radioactivity in egg white and egg yolk in the low-dosed hens did not exceed 0.007 and 0.002 mg/kg equiv., respectively. In the high dosed hens the corresponding values were 0.33 and 0.055 mg/kg equiv.

Mean radioactive residues in tissues of the low-dosed hens were 0.002 mg/kg equiv. in lean meat (0.12 mg/kg equiv. high dose), 0.011 mg/kg equiv. in skin (including attached fat) (0.37 mg/kg equiv.), 0.003 mg/kg equiv. in peritoneal fat (0.18 mg/kg equiv.), 0.013 mg/kg equiv. in liver (0.60 mg/kg equiv.) and 0.043 mg/kg in kidney (1.77 mg/kg equiv.).

Radioactive residues in muscle (lean meat), liver, kidney and fat samples of low and high-dosed hens were predominantly trinexapac acid (44–84% TRR). In skin including attached fat in which the extractability was low, trinexapac acid was again the major metabolite accounting for 64–80% of the extracted radioactivity.

In the yolk the major metabolite was trinexapac acid accounting for 57–76% of the extracted radioactivity (0.0003–0.011 mg/kg equiv.), while parent trinexapac-ethyl was present at only 10–25% (< 0.0001–0.005 mg/kg equiv.). In egg white the major residue was parent accounting for 64–78% of the extractable TRR (0.0017–0.124 mg/kg equiv.). Trinexapac acid was either not detected (high dose) or accounted for only 13% (0.0003 mg/kg equiv.) of the extractable TRR (low dose).

In another hen metabolism study [1, 2, 6-^{14}C-cyclohexyl] trinexapac-ethyl was orally administered daily to 5 laying hens by gelatine capsule at 8.1–10.4 ppm in feed for 10 consecutive days. Eggs were collected at 24 hour intervals throughout the morning before subsequent administration. Animals were sacrificed approximately 22 hours after the last dose.

Of the administered dose 89% was recovered in the excreta. Residue levels in the various tissue samples were all < 0.01 mg/kg equiv. Residue levels in egg yolk were very low, ranging from < 0.003–0.009 mg/kg equiv. Egg white residues ranged from 0.005–0.031 mg/kg equiv. The maximum residue levels of 0.009 and 0.031 mg/kg equiv. were reached by Day 8 of the dosing period. Overall retention of the radioactivity in eggs was < 0.1% of the administered dose.

TRR values for edible tissues and egg yolks were below 0.01 mg/kg equiv., so no further analysis was undertaken. The major metabolites identified in the organosoluble residue of the composite egg white sample were parent trinexapac-ethyl and trinexapac acid which accounted for 31% TRR and 20% TRR respectively.

Summary of animal metabolism

The metabolic pathways of trinexapac-ethyl observed in rats, goats and poultry are similar. Animal metabolism studies showed that parent was rapidly absorbed and almost completely hydrolysed to trinexapac acid before excretion. No accumulation of residues was observed in any organ, tissue or animal commodity.

Plant metabolism

Paddy rice, spring wheat, spring rape and grass (foliar treatment) metabolism studies were carried out with [1, 2-^{14}C-cyclohexyl] trinexapac-ethyl or [1, 2, 6-^{14}C-cyclohexyl] trinexapac-ethyl.

[1, 2, 6-^{14}C-cyclohexyl] trinexapac-ethyl was applied by foliar methods to rice at rates of 40 and 160 g ai/ha. TRRs in samples taken at maturity (60 days after treatment at 160 g ai/ha) were 1.58 mg/kg equiv. for straw, 2.22 mg/kg equiv. for husks and 1.07 mg/kg equiv. for grain. Trinexapac acid was the only identified compound present in rice grain at greater than 10% TRR (36% TRR) and was the major identified component of rice husks (30% TRR). It was present in rice straw at 9% TRR. Tricarballylic acid (CGA 275537) was present at 14% TRR in straw. Some parent compound was observed in grain, husks and straw (all < 10% TRR). Metabolite CGA 329773 was a minor metabolite in grain, husks and straw (< 3% TRR).

[1, 2-^{14}C-cyclohexyl] trinexapac-ethyl was applied to spring wheat by foliar spraying at a rate of 150 g ai/ha. Trinexapac acid was the only identified component in wheat grain (24% TRR) and was the only identified component of both wheat husks and wheat straw observed at > 10% of the TRR (15 and 21% TRR respectively).

A stem-injection experiment was conducted on six week old wheat plants grown under greenhouse conditions. Trinexapac acid was the major identified component of wheat grain (27.9% TRR, 0.129 mg/kg equiv.) and was the only identified component of both wheat husks and wheat straw observed at > 10% of the TRR (17% (0.073 mg/kg equiv.) and 13% TRR (0.069 mg/kg equiv.) respectively). Metabolites CGA329773 and CGA275537 were present in grain at 11% (0.050 mg/kg equiv.) and 3% TRR (0.014 mg/kg equiv.) respectively and in straw at 3 and 2% TRR respectively.

[1, 2, 6-^{14}C-cyclohexyl] trinexapac-ethyl was applied to spring rape under greenhouse conditions in plastic containers filled with soil. Trinexapac acid (free and conjugated) was the major metabolite observed in rape meal (31% TRR, 0.647 mg/kg equiv.), rape whole seeds (30% TRR, 0.431 mg/kg equiv.), pods (19% TRR, 1.06 mg/kg equiv.) and stalks (10% TRR, 0.304 mg/kg equiv.) and was also observed in oil (4% TRR, 0.004 mg/kg equiv.). Metabolite CGA 351210 was observed in oil at 16% TRR but at only 0.02 mg/kg equiv. This metabolite, only observed in rape, accounted for 16–28% TRR in pods and stalks (0.918 mg/kg equiv. and 0.869 mg/kg equiv. respectively).

[1, 2, 6-^{14}C-cyclohexyl] trinexapac-ethyl was applied by foliar methods to tall fescue grass at 560 g ai/ha. TRRs of 5.45 mg/kg equiv., 7.13 mg/kg equiv. and 4.78 mg/kg equiv. were observed for seeds, seed screenings and for straw respectively. TRRs of 2.03 mg/kg equiv. and 0.054 mg/kg equiv. were observed for 22 day forage and 105 day forage respectively. In grass, trinexapac acid was the major identified component of 22 day forage (16% TRR), straw (22% TRR) and regrowth forage (10% TRR) and was also a major component of seeds (15% TRR) and seed screenings (13% TRR). Also observed in all matrices were CGA 275537 (9-17% TRR) and terephthalic acid (7–12% TRR) the latter metabolite only observed in grass.

Summary of plant metabolism

Parent compound was completely degraded and was not detectable (< 0.001/< 0.002 mg/kg) in any plant part of wheat, rapeseed and grass at harvest time. In rice only traces (0.001 and 0.003 mg/kg) were observed in straw and husks respectively.

Trinexapac acid was therefore the major metabolite which was present in all species and all plant parts at harvest. Sugar conjugates of trinexapac acid were hydrolysed in some crop parts to yield free acid which, in some cases, significantly increased the levels of trinexapac acid recovered. Trinexapac acid sugar conjugates accounted for an increase in trinexapac acid of 11.6% TRR in rice grain and 10% and 14% TRR in grass forage and straw, respectively.

Rotational Crops

Studies of residues in confined rotational crops have been submitted in which soil was treated at 350 g ai/ha, followed by soil aging at 30, 120 and 270 days. Representative succeeding crops of lettuce (leafy vegetable), radish (root vegetable) and wheat (cereal grain) were planted at the above intervals to determine whether trinexapac-ethyl residues or degradates appear in follow crops.

The uptake of residues by the rotational crops lettuce, radish and wheat planted or sown after several intervals after application of trinexapac-ethyl to bare ground was very low. No accumulation was observed. Residues of trinexapac-ethyl in the rotational crop RACs were below the LOQ (< 0.001 mg/kg). The residues of trinexapac acid and CGA 312753 (trans aconitic acid) were very close to or below the LOQ (< 0.001–0.002 mg/kg). The very limited uptake of radioactive material in succeeding crops clearly indicates the lack of systemic behaviour of trinexapac-ethyl. It was concluded that residues in rotational crops are negligible.

The Meeting received information on field rotational crop studies for trinexapac-ethyl which were conducted in both the USA and Switzerland.

In a study conducted in the USA in the 2004–2005 growing season, a 250 g/L EC formulation of trinexapac-ethyl was applied once as a broadcast spray to wheat at 203 g ai/ha. Radish, wheat and spinach were planted after three different plant back intervals (14, 30 and 45 days). The results showed that rotational crops sown 14, 30 and 45 days after application of trinexapac-ethyl to the target crop, are very unlikely to contain residues of trinexapac-ethyl as its main metabolite trinexapac acid, above the LOQ of 0.05 mg/kg.

A trial was conducted in Switzerland during 1989 to investigate residues of trinexapac-ethyl in succeeding crops, grown in soil previously treated with [14C]cyclohexyl trinexapac-ethyl. A 250 g/L EC formulation of trinexapac-ethyl was applied once to bare soil at a rate of 150 g ai/ha.

Treated plots were planted after four different time intervals (69, 119, 299 and 338 days after treatment). The crops investigated were lettuce, winter wheat, sugar beet and maize (corn).

The uptake of residues by the rotational crops lettuce, winter wheat, sugar beet and maize planted or sown after several intervals after application of trinexapac-ethyl to bare ground was therefore very low. No accumulation was observed. Residues of trinexapac-ethyl in the rotational crop RACs were below the LOQ (< 0.001 mg/kg) so no characterization was possible. The very limited uptake of radioactive material in succeeding crops clearly indicates the lack of systemic behaviour of trinexapac-ethyl. It was concluded that the residues situation in rotational crops is negligible.

The confined and field rotational crop studies suggest that residues of trinexapac acid are unlikely to occur in succeeding crops.

Methods of analysis

The Meeting received information on analytical methods suitable for the determination of residues of trinexapac acid in plant matrices and animal matrices. The methodology involves quantification of free trinexapac acid (plant and animal matrices) or quantification of both free and conjugated trinexapac acid with the inclusion of an acid hydrolysis step (plant matrices). The methods used are based on HPLC-MS/MS (LOQs of 0.01 or 0.05 mg/kg for trinexapac acid in plant matrices and 0.02 mg/kg for animal matrices (0.01 mg/kg for milk)) and HPLC-UV (LOQs of 0.02 mg/kg for trinexapac acid in plant matrices or 0.01 mg/kg in animal matrices (0.005 mg/kg for milk)).

Details of HPLC-UV methods for determining residues of parent trinexapac-ethyl have also been submitted (LOQs of 0.02 or 0.04 mg/kg).

Stability of pesticide residues in stored analytical samples

The Meeting received information on the freezer storage stability of trinexapac acid in plant and animal commodities.

Freezer storage stability studies indicate that trinexapac acid is stable for at least 24 months in wheat grain and rapeseed and up to 24 months in wheat straw and for at least 12 months in wheat processed fractions. The stability of trinexapac acid in extracts of animal matrices was tested in the dairy cattle and laying hen feeding studies. No significant degradation of residues of trinexapac acid was observed in cattle matrices (83–121 days) or in poultry matrices (31–82 days).

The periods of storage stability studies cover the sample storage intervals of residue trials.

Definition of the residue

Animals

In the goat metabolism studies, no parent was observed in tissues and milk. Trinexapac acid accounted for 81–97% of the total residues in muscle and kidney, 31–84% of the TRRs in liver and fat and 46–85% of the TRRs in milk. In one study the metabolite CGA 113745 accounted for 6–16% TRR in liver, kidney and fat, but was not detected in either muscle or milk.

In the hen metabolism studies residues in muscle (lean meat), liver, kidney and fat samples of low and high-dosed hens were dominated by trinexapac acid (44–84% of TRR). Only in the skin (with subcutaneous fat) was the major portion of the total radioactivity (70–86%) not extractable. However trinexapac acid was the dominant metabolite in the extract (64–80% of the extractable radioactivity). The major metabolites identified in the organosoluble residue of egg whites were parent trinexapac-ethyl and trinexapac acid which accounted for 31% TRR and 20% TRR respectively.

The observed metabolic pathway of trinexapac-ethyl in livestock is comparable to that observed for the rat in which trinexapac acid is the major and only residue component of significance.

The ratio of trinexapac acid residues in muscle and fat observed in the livestock metabolism and feeding studies support the conclusion that trinexapac is not fat soluble. There is no evidence to suggest that there is significant potential for bioaccumulation in fat tissues.

It is considered that a residue definition of "Trinexapac (acid)" is appropriate for commodities of animal origin for compliance with MRLs (enforcement) and for risk assessment.

Plants

In the rice study trinexapac acid was the major identified component in rice grain (36% TRR) and rice husks (30% TRR). In the spring wheat study, trinexapac acid was the major identified component of wheat grain (28% TRR) and was the only identified component of both wheat husks and wheat straw observed at > 10% of the TRR. It was the major metabolite observed in rape meal, rape whole seeds and pods (19–31% TRR) and was also observed in oil and stalks (4–10% TRR). In grass, trinexapac acid was the major identified component of 22 day forage, straw, straw and regrowth forage (10–22% TRR) and was also a major component of seed screenings and seeds (13–15% TRR). Sugar conjugates of trinexapac acid were hydrolysed in some crop parts to yield free acid.

Trinexapac acid was present in all species and all plants parts at harvest and was generally the main component of the TRR. A definition of trinexapac acid is therefore considered suitable as the residue definition for compliance. Since conjugates of trinexapac acid were sometimes significant in edible commodities and are supposed to be of similar toxicity, the Meeting decided to include conjugates of trinexapac acid in the residue definition for risk to the acid assessment. A suitable method is available for determining residues of free and conjugated trinexapac acid.

It is therefore considered that a residue definition of "Trinexapac (acid)" is appropriate for plant commodities for compliance with MRLs (enforcement). It is considered that a residue definition of "Trinexapac and its conjugates, expressed as trinexapac acid" is appropriate for plant commodities for risk assessment.

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

Definition of the residue (for estimation of dietary intake for plant commodities): Trinexapac and its conjugates, expressed as trinexapac acid

The residue is considered not fat soluble.

Results of supervised residue trials on crops

Supervised trials were available for the use of trinexapac on barley, wheat, oilseed rape and sugarcane.

In some studies (barley, wheat and sugarcane) residues have been determined as total trinexapac (includes free trinexapac acid and conjugates of trinexapac acid) while in other studies (wheat, sugarcane and rape seed) residues have been determined as trinexapac (free trinexapac acid only). In both cases trinexapac means trinexapac acid. For dietary intake assessment (risk assessment) residues expressed as total trinexapac acid, where available, have been considered. For maximum residue level estimation (compliance) residues expressed as trinexapac acid, where available, have been considered.

Product labels were available from Belgium, France, Germany and the United States of America.

Cereals - wheat (free trinexapac acid)

Residue trials were conducted in wheat in the USA according to the critical GAP in the USA (1 application at 0.123 kg ai/ha, 45-day PHI).

For the estimation of maximum residue levels the ranked order of residues of trinexapac acid in wheat grain from supervised trials according to the GAP in the USA was 0.10, 0.25, 0.32, 0.34, 0.35, 0.46, 0.49, 0.55, 0.55, 0.57, 0.77, 0.88, 0.91, 0.98, 0.99, 1.05, 1.35 and 1.95 mg/kg.

The Meeting estimated a maximum residue level for trinexapac acid in wheat of 3 mg/kg.

The Meeting recognized that wheat (spring wheat, winter wheat and durum wheat) and triticale, barley and oats have similar GAPs and normally show comparable residues after early treatment. As application was before flowering, the Meeting decided to extrapolate the MRL estimated for wheat grain to barley, oats and triticale.

Cereals - barley

Residue trials were conducted in barley in the USA according to the GAP in the USA (1 application at 0.123 kg ai/ha, 45-day PHI).

For dietary intake purposes the ranked order of total residues of trinexapac acid in barley grain from supervised trials according to the GAP in the USA was 0.03, 0.08, 0.44, 0.50, 0.52, 0.53, 0.60, 0.72, 0.76, 0.83, 1.0 and 1.2 mg/kg.

Cereals - wheat (total residues of trinexapac acid)

Residue trials were conducted in wheat in the USA according to the GAP in the USA (1 application at 0.123 kg ai/ha, 45-day PHI).

For dietary intake purposes the ranked order of total residues of trinexapac acid in wheat grain from supervised trials according to the GAP in the USA was 0.07, 0.15, 0.27, 0.31, 0.32, 0.40, 0.45, 0.47, 0.53, 0.77, 0.78, 0.82, 0.85, 0.99, 1.01, 1.14, 1.64 and 3.32 mg/kg.

The Meeting noted that the USA GAP is the same for barley and wheat. The Meeting noted that the populations of residues data for barley and wheat matching USA GAP resulted in similar distributions of residues for barley and wheat (e.g. medians do not differ by more than 5×). Given the similarity of the datasets (confirmed by the Mann-Whitney U test), the Meeting decided to combine the datasets for barley and wheat to give a larger dataset for estimation of dietary parameters for the purposes of determining an STMR residue level for barley grain and wheat grain.

For dietary intake purposes residues were 0.03, 0.07, 0.08, 0.15, 0.27, 0.31, 0.32, 0.40, 0.44, 0.45, 0.47, 0.50, 0.52, 0.53, 0.53, 0.60, 0.72, 0.76, 0.77, 0.78, 0.82, 0.83, 0.85, 0.99, 1.0, 1.01, 1.14, 1.2, 1.64 and 3.32 mg/kg.

The Meeting estimated an STMR of 0.57 mg/kg.

The Meeting recognized that wheat (spring wheat, winter wheat and durum wheat), triticale, barley and oats have similar GAPs and normally show comparable residues after early treatment. As application was before flowering, the Meeting decided to extrapolate the STMR estimated for barley grain and wheat grain to oats and triticale.

Grasses for sugar or syrup production - sugarcane (free trinexapac acid)

Residue trials were conducted in sugarcane in the USA according to the critical GAP in the USA (1 application at 0.347 kg ai/ha, 28-day PHI).

For the estimation of maximum residue levels the ranked order of residues of trinexapac acid in sugar cane from supervised trials according to the GAP in the USA was < 0.05, 0.06, 0.09, 0.12, 0.22, 0.23 and 0.25 mg/kg.

The Meeting estimated a maximum residue level for trinexapac acid in sugarcane of 0.5 mg/kg.

Grasses for sugar or syrup production—sugarcane (total residues of trinexapac acid)

Residue trials were conducted in sugarcane in the USA according to the critical GAP in the USA (1 application at 0.347 kg ai/ha, 28-day PHI).

For dietary intake purposes the ranked order of total residues of trinexapac acid in sugar cane from supervised trials according to the GAP in the USA was < 0.01, 0.04, 0.06, 0.08, 0.17 and 0.42 mg/kg.

The Meeting estimated an STMR value for trinexapac acid in sugarcane of 0.07 mg/kg.

Oilseeds - Rape

As conjugates of trinexapac acid were not significant in the submitted rape metabolism studies, residue levels from the submitted rape seed studies, which were determined as trinexapac only, have been considered suitable for estimation of a maximum residue level and also for estimation of dietary intake parameters.

Residue trials were conducted in winter rape (canola) in Germany according to the critical GAP in Germany for winter rape (1 application at 0.375 kg ai/ha).

For the estimation of maximum residue levels and for dietary purposes the ranked order of residues of trinexapac acid in winter rape seed from supervised trials according to GAP was 0.04, 0.10, 0.10, 0.13, 0.15, 0.15, 0.16, 0.24, 0.24, 0.26, 0.29, 0.31, 0.64, 0.64, 0.90 and 1.0 mg/kg.

The Meeting estimated maximum residue level and STMR values for trinexapac acid in rape seed of 1.5 and 0.24 mg/kg respectively.

Animal feeds

The Meeting received supervised trials data for barley hay and straw, wheat forage, hay and straw and rape seed forage.

Moisture content percentages for animal feeds have not been determined. The values from the FAO Manual on the Submission and Evaluation of Pesticides Residues Data for the feeds, have been used to convert wet weight or 'as received' residues values to dry weight residues values.

Forage - Wheat (residues of free and conjugated trinexapac acid)

Wheat forage was collected in the trials carried out in the USA according to GAP in the USA (1 application at 0.123 kg ai/ha).

For the calculation of the livestock animal dietary burden the ranked order of total residues in wheat forage samples collected 30 days after application (wet weight) at the GAP application rate was 0.02, 0.03, 0.04, 0.06, 0.07, 0.08, 0.08, 0.09, 0.10, 0.10, 0.12, 0.17, 0.17, 0.22, 0.23, 0.33, 0.38 and 0.94 mg/kg.

For the calculation of the livestock animal dietary burden the ranked order of total residues in wheat forage samples collected 30 days after application (dry weight) at the GAP application rate was 0.08, 0.12, 0.16, 0.24, 0.28, 0.32, 0.32, 0.36, 0.40, 0.40, 0.48, 0.68, 0.68, 0.88, 0.92, 1.32, 1.52 and 3.76 mg/kg.

The Meeting estimated median and highest residue values for trinexapac acid in wheat forage (dry weight) of 0.40 and 3.76 mg/kg respectively.

The Meeting recognized that wheat (spring wheat, winter wheat and durum wheat) and triticale, barley and oats have similar GAPs and normally show comparable residues after early treatment. The Meeting decided to extrapolate the dietary parameters estimated for wheat forage to barley, oats and triticale.

Hay and Straw - Barley and Wheat

Data for wheat hay and straw were collected in the trials carried out in the USA which approximate USA GAP (1 application at 0.123 kg ai/ha).

For the estimation of maximum residue levels the ranked order of residues in wheat hay samples collected 30 days after application (wet weight) at the GAP application rate was < 0.05, < 0.05, < 0.05, 0.05, 0.06, 0.07, 0.07, 0.08, 0.08, 0.09, 0.11, 0.11, 0.13, 0.15, 0.18, 0.19, 0.19 and 0.75 mg/kg.

The ranked order of residues in wheat hay samples converted to dry weight basis at the GAP application rate was < 0.06, < 0.06, < 0.06, 0.06, 0.07, 0.08, 0.08, 0.09, 0.09, 0.10, 0.13, 0.13, 0.15, 0.17, 0.20, 0.22, 0.22 and 0.85 mg/kg.

For the estimation of maximum residue levels the ranked order of residues in wheat straw samples collected 45 days after application (wet weight) at the GAP application rate was < 0.05, < 0.05, < 0.05, < 0.05, < 0.05, < 0.05, < 0.05, < 0.05, < 0.05, < 0.05, 0.06, 0.06, 0.07, 0.07, 0.08, 0.10, 0.11 and 0.12 mg/kg.

The ranked order of residues in wheat straw samples (dry weight) at the GAP application rate was < 0.06, < 0.06, < 0.06, < 0.06, < 0.06, < 0.06, < 0.06, < 0.06, < 0.06, < 0.06, 0.07, 0.07, 0.08, 0.08, 0.09, 0.11, 0.13 and 0.14 mg/kg.

The Meeting used the wheat hay data for the free trinexapac acid to estimate a maximum residue level in wheat straw and fodder (dry) of 0.9 mg/kg. The Meeting recognized that wheat (spring wheat, winter wheat and durum wheat), triticale, barley and oats have similar GAPs and normally show comparable residues after early treatment. It was therefore decided to apply the maximum residue level recommended for trinexapac acid on wheat straw and fodder (dry) to barley, oats and triticale.

For the calculation of the livestock animal dietary burden the ranked order of total residues in barley hay samples collected 30 days after application (wet weight) at the GAP application rate was < 0.01, 0.03, 0.05, 0.10, 0.13, 0.15, 0.17, 0.18, 0.25, 0.33, 0.40 and 0.48 mg/kg.

The ranked order of total residues in barley hay samples converted to a dry weight basis at the GAP application rate was < 0.011, 0.03, 0.06, 0.11, 0.15, 0.17, 0.19, 0.20, 0.28, 0.38, 0.45 and 0.55 mg/kg.

For the calculation of the livestock animal dietary burden the ranked order of total residues in barley straw samples collected 45 days after application (wet weight) at the GAP application rate was < 0.01, 0.02, 0.07, 0.08, 0.08, 0.09, 0.11, 0.12, 0.14, 0.17, 0.20 and 0.24 mg/kg.

The ranked order of total residues in barley straw samples converted to a dry weight basis at the GAP application rate was 0.01, 0.02, 0.08, 0.09, 0.09, 0.10, 0.12, 0.13, 0.16, 0.19, 0.22 and 0.27 mg/kg.

For the calculation of the livestock animal dietary burden the ranked order of total residues in wheat hay samples collected 30 days after application (wet weight) at the GAP application rate was 0.03, 0.04, 0.04, 0.06, 0.09, 0.11, 0.11, 0.14, 0.17, 0.19, 0.24, 0.30, 0.31, 0.41, 0.50, 0.59, 0.78 and 1.18 mg/kg.

The ranked order of total residues in wheat hay samples collected 30 days after application (dry weight) at the GAP application rate was 0.03, 0.05, 0.05, 0.07, 0.10, 0.13, 0.13, 0.16, 0.19, 0.22, 0.27, 0.34, 0.35, 0.47, 0.57, 0.67, 0.89 and 1.34 mg/kg.

For the calculation of the livestock animal dietary burden the ranked order of total residues in wheat straw samples collected 45 days after application (wet weight) at the GAP application rate was 0.01, 0.03, 0.04, 0.04, 0.06, 0.09, 0.11, 0.11, 0.15, 0.15, 0.17, 0.20, 0.23, 0.28, 0.33, 0.46, 0.59 and 0.60 mg/kg.

The ranked order of total residues in wheat straw samples collected 45 days after application (dry weight) at the GAP application rate was 0.01, 0.03, 0.05, 0.05, 0.07, 0.10, 0.13, 0.13, 0.17, 0.17, 0.19, 0.23, 0.26, 0.32, 0.38, 0.52, 0.67 and 0.68 mg/kg.

The Meeting noted that the USA GAP is the same for barley and wheat. The Meeting also noted that the populations of residues data for barley and wheat hay matching USA GAP gave higher residues than the straw and resulted in similar distributions of residues (e.g., medians do not differ by more than 5×). Given the similarity of the datasets (confirmed by the Mann-Whitney U test), the Meeting decided to combine the datasets for barley and wheat hay (dry weight) to give a larger dataset for estimation of dietary parameters for the purposes of determining median and highest residue levels for barley straw and fodder (dry) and wheat straw and fodder (dry).

For the calculation of the livestock animal dietary burden the ranked order of total residues of trinexapac acid in barley and wheat hay (dry weight) collected 30 days after application (dry weight) from supervised trials according to the GAP in the USA was < 0.011, 0.03, 0.03, 0.05, 0.05, 0.06, 0.07, 0.10, 0.11, 0.13, 0.13, 0.15, 0.16, 0.17, 0.19, 0.19, 0.20, 0.22, 0.27, 0.28, 0.34, 0.35, 0.38, 0.45, 0.47, 0.55, 0.57, 0.67, 0.89 and 1.34 mg/kg.

The Meeting used the barley and wheat hay data to estimate median and highest residue values for trinexapac acid in barley straw and fodder (dry) and wheat straw and fodder (dry) of 0.19 and 1.34 mg/kg respectively, based on the combined dataset for barley and wheat hay.

The Meeting recognized that wheat (spring wheat, winter wheat and durum wheat) and barley have similar GAPs to oats and triticale and normally show comparable residues after early treatment. The Meeting decided to extrapolate the dietary parameters estimated for wheat and barley to oats and triticale.

Rape seed forage

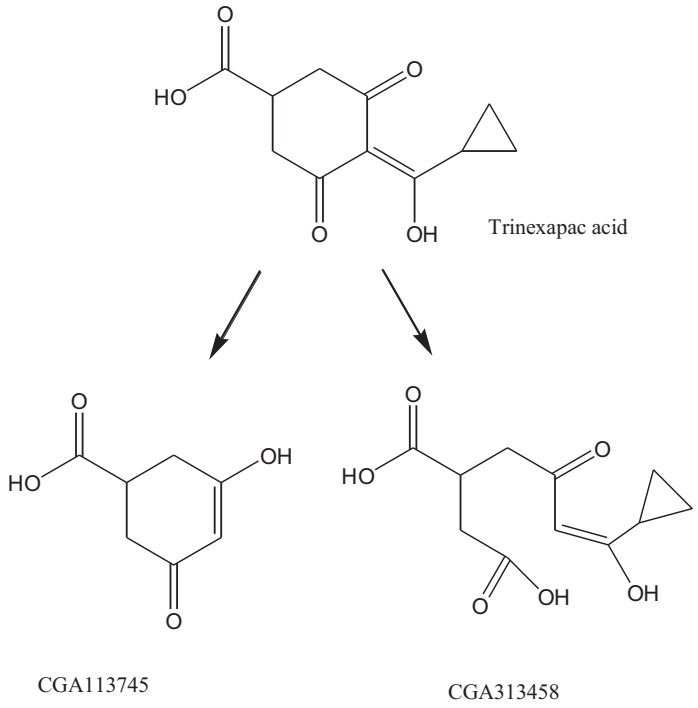
In four trials conducted according to GAP in Germany, residues in rape remaining plant type (forage) at PHIs from 49–68 days were < 0.04, < 0.04, < 0.04 and 0.04 mg/kg.

The Meeting agreed that four trials according to GAP were not sufficient to estimate a highest residue for trinexapac in rape forage.

Fate of residues during processing

High temperature hydrolysis of residues of trinexapac-ethyl and trinexapac acid under varying conditions have been reported. The [^{14}C]-labelled compounds were dissolved in aqueous buffer; at pH 4 and heated for 20 or 25 minutes at 90 ºC to simulate pasteurisation, at pH 5 and refluxed at 100 ºC for 60 minutes to simulate baking, brewing and boiling and at pH 6 at about 120 ºC in an autoclave for 20 minutes to simulate sterilisation. Trinexapac-ethyl was not degraded. Trinexapac acid underwent limited degradation and was the major component of the radioactive material at the end of the hydrolysis reactions (51–59%). It degraded into the compounds CGA113745 (10–12%) and CGA313458 (16–21%).

CGA113745 was observed as a goat metabolite in one metabolism study, while CGA313458 was observed as a rapeseed and rice metabolite. Based on a structural assessment of CGA 113745 and CGA 313458 and the estimated levels of chronic dietary intake, the Meeting concluded that these metabolites are unlikely to pose a dietary risk.



Hydrolysis of trinexapac acid under processing conditions

The Meeting also received processing studies for barley, wheat, sugarcane and rape seed. The table below summarizes STMR-P values calculated on the determined processing factors. In addition the following maximum residue levels were estimated.

Barley

Based on the total trinexapac processing factor of 1.9 for barley bran (in the absence of a trinexapac processing factor) and the barley grain MRL of 3 mg/kg, the calculated expected highest residues in barley bran are 5.7 mg/kg. The Meeting estimated an MRL for trinexapac in barley bran of 6 mg/kg.

Wheat

Based on the trinexapac processing factor of 2.3 for wheat bran and the wheat grain MRL of 3 mg/kg the calculated expected highest residues in wheat bran are 6.9 mg/kg. The Meeting estimated an MRL for trinexapac in wheat bran of 8 mg/kg.

The processing factors derived from the processing studies and the resulting recommendations for STMR-Ps (and maximum residue levels) are summarized in the table below.

Processing Factors from the Processing of Raw Agricultural Commodities (RACs) with Field-Incurred Residues from Foliar Treatment with Trinexapac-ethyl

RAC	Processed Commodity	Best Estimate Processing Factor	RAC MRL	RAC STMR	Processed Commodity STMR-P
Barley	Pearled barley	1.2	3	0.57	0.68
	Bran	1.9			1.08
	Flour	0.43			0.25
Wheat	Aspirated Grain Fractions	0.55	3	0.57	0.31

RAC	Processed Commodity	Best Estimate Processing Factor	RAC MRL	RAC STMR	Processed Commodity STMR-P
	Bran	1.9			1.08
	Flour	0.43			0.25
	Middlings	0.55			0.31
	Shorts	0.46			0.26
	Germ	1.1			0.63
Sugarcane	Molasses	5.8	0.5	0.07	0.40
	Refined sugar	0.15			0.01
Rapeseed	Press cake	1.2	1.5	0.24	0.32
	Refined oil	0.05			0.01

Except for the rapeseed study (in which processing factors were determined based on residues of trinexapac), processed commodity STMR-Ps were calculated on the basis of the total trinexapac acid processing factors.

Residues in animal commodities

Estimated maximum and mean dietary burdens of farm animals

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: wheat, barley, oat and triticale grain, straw, forage, hay and silage, wheat milled by-products (bran), wheat aspirated grain fractions, barley bran fractions, sugarcane molasses and bagasse and rape forage and rape seed meal.

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

	US-Canada		EU		Australia		Japan	
	max	mean	max	mean	max	mean	max	mean
Beef cattle	0.98	0.87	1.76	0.82	3.76 [a]	0.88	0.97	0.97 [c]
Dairy cattle	1.76	0.77	1.76	0.76	3.76 [b]	0.86 [d]	1.00	0.83

[a] Highest maximum beef or dairy cattle dietary burden suitable for HR and MRL estimates for mammalian meat

[b] Highest maximum dairy cattle dietary burden suitable for HR and 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

Potential poultry feed items include: wheat, barley, oat and triticale grain, straw, forage, hay and silage, wheat milled by-products (bran), wheat aspirated grain fractions, barley bran fractions, sugarcane molasses and bagasse and rape forage and rape seed meal.

Summary of poultry dietary burden for trinexapac (ppm of dry matter diet)

	US-Canada		EU		Australia		Japan	
	max	mean	max	mean	max	mean	max	mean
Poultry Broiler	0.94	0.94	0.70	0.70	0.34	0.34	0.13	0.13
Poultry Layer	0.94	0.94 [b]	1.08 [a]	0.76	0.34	0.34	0.37	0.37

[a] Highest maximum poultry dietary burden suitable for HR and MRL estimates for poultry meat and eggs

[b] Highest maximum poultry dietary burden suitable for STMR estimates for poultry meat and eggs

Farm Animal Dietary Burden

The Meeting received a lactating dairy cow feeding study which provided information on residues of trinexapac acid arising in tissues and milk when dairy cows were dosed for 29–30 days, at target feeding levels equivalent to 0, 2, 6 and 20 ppm trinexapac acid in the diet.

No quantifiable residues of trinexapac acid were observed in milk at the 0, 2 and 6 ppm dose groups. Residues in the 20 ppm dose group ranged from < 0.005–0.011 mg/kg. Residues reached a plateau after one day.

No quantifiable residues of trinexapac acid were observed in the tissues of the control cow. In the lowest and mid-range dose groups (2 and 6 ppm), no quantifiable residues were detected in muscle, liver and fat, although residues slightly above LOQ (0.02 mg/kg) were observed in kidney (highest (mean in brackets) were 0.03 (0.03) and 0.05 (0.04) mg/kg respectively). No quantifiable residues were detected in muscle in the 20 ppm dose group while the highest residues (mean in brackets) observed in liver, kidney and fat in the 20 ppm dose group were 0.03 (0.03), 0.29 (0.17) and 0.02 (< 0.02) mg/kg respectively.

The Meeting also received information on the residue levels arising in tissues and eggs when laying hens were dosed with trinexapac acid for 28 days, at feeding levels equivalent to 3.7, 10 and 37 ppm in the diet.

No quantifiable residues of trinexapac acid were observed in eggs at any feeding level except in the 37 ppm dose group at 28 days (highest and mean residues were 0.01 mg/kg).

No residues of trinexapac acid above LOQ (0.01 mg/kg) were detected in any muscle (breast and thigh muscle) sample from any treatment group. No residues of trinexapac acid above LOQ were detected in any liver sample from any treatment group apart from the highest dose group (highest and mean residues were 0.02 mg/kg). No residues of trinexapac acid above LOQ were detected in any fat sample from any treatment group apart from the highest dose group (highest and mean residues were 0.03 mg/kg). Highest (mean) residues of trinexapac acid in kidney were 0.08 (0.06), 0.05 (0.04) and 0.54 (0.45) mg/kg in the lowest to highest dose groups respectively.

Animal commodity maximum residue levels

Cattle- STMR, HR and MRLs

For highest residue level estimation, the high residues in the cattle tissues were calculated by interpolating the maximum dietary burden for beef cattle (3.76 ppm) between the relevant feeding levels (2 and 6 ppm) in the dairy cow feeding study and using the highest tissue concentrations from individual animals within those feeding groups. For highest residue level estimation, the high residues in the cattle milk were calculated by interpolating the maximum dietary burden for dairy cattle (3.76 ppm) with the lowest feeding level (2 and 6 ppm) in the dairy cow feeding study and using the highest mean milk concentrations from those feeding groups.

The STMR values for the tissues were calculated by extrapolating the mean dietary burden for beef cattle (0.97 ppm) with the 2 ppm feeding level from the dairy cow feeding study and using the mean tissue concentrations from that feeding group. The STMR values for the milk were calculated by extrapolating the mean dietary burden for dairy cattle (0.86 ppm) with the 2 ppm feeding level from the dairy cow feeding study and using the mean milk concentrations from that feeding group.

Trinexapac Feeding Study	Feed Level (ppm) for milk residues	Residues (mg/kg) in milk	Feed Level (ppm) for tissue residues	Residues (mg/kg)			
				Muscle	Liver	Kidney	Fat
HR Determination (beef or dairy cattle)							
Feeding Study	2	< 0.005	2	< 0.02	< 0.02	0.03	< 0.02
	6	< 0.005	6	< 0.02	< 0.02	0.05	< 0.02
Dietary burden and estimate of highest residue	3.76	< 0.005	3.76	< 0.02	< 0.02	0.04	< 0.02
STMR Determination (beef or dairy cattle)							
Feeding Study	2	< 0.005	2	< 0.02	< 0.02	0.03	< 0.02
Dietary burden and estimate of highest residue	0.86	< 0.0022	0.97	< 0.010	< 0.010	0.015	< 0.010

The Meeting estimated the following STMR values: milk 0 mg/kg; muscle 0 mg/kg; edible offal (based on kidney) 0.015 mg/kg and fat 0 mg/kg.

The Meeting estimated the following maximum residue levels: milk 0.005(*) mg/kg; meat (mammalian except marine mammals) 0.01(*) mg/kg, edible offal (based on kidney) 0.1 mg/kg and mammalian fats (except milk fats) 0.01(*) mg/kg.

Poultry - STMR, HR and MRLs

For highest residue level estimation, the high residues in the hen tissues and eggs were calculated by extrapolating the maximum dietary burden (1.08 ppm) with the lowest feeding level (3.7 ppm) in the laying hen feeding study and using the highest tissue concentrations from individual animals within that feeding group and using the highest mean egg concentration from that feeding group.

The STMR values for the tissues and eggs were calculated by extrapolating the mean dietary burden (0.94 ppm) with the lowest feeding level (3.7 ppm) from the poultry feeding study and using the mean tissue and egg concentrations from that feeding group.

Trinexapac Feeding Study	Feed Level (ppm) for egg residues	Residues (mg/kg) in egg	Feed Level (ppm) for tissue residues	Residues (mg/kg)			
				Muscle	Liver	Kidney	Fat
HR Determination (poultry broiler or layer)							
Feeding Study	3.7	< 0.01	3.7	< 0.01	< 0.01	0.08	< 0.01
Dietary burden and estimate of highest residue	1.08	< 0.003	1.08	< 0.003	< 0.003	0.023	< 0.003
STMR Determination (poultry broiler or layer)							
Feeding Study	3.7	< 0.01	3.7	< 0.01	< 0.01	0.06	< 0.01
Dietary burden and estimate of highest residue	0.94	< 0.0025	0.94	< 0.0025	< 0.0025	0.015	< 0.0025

The Meeting estimated the following STMR values: egg 0 mg/kg; muscle 0 mg/kg; edible offal (based on kidney) 0.015 mg/kg and fat 0 mg/kg.

The Meeting estimated the following maximum residue levels: eggs 0.01(*) mg/kg; poultry meat 0.01(*) mg/kg, poultry edible offal (based on kidney) 0.05 mg/kg and poultry fats 0.01(*) mg/kg.

RECOMMENDATIONS

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

Definition of the residue (for estimation of dietary intake for plant commodities): *Trinexapac and its conjugates, expressed as trinexapac acid.*

The Meeting estimated the maximum residue levels and STMR values shown below.

DIETARY RISK ASSESSMENT

Long-term intake

The evaluation of trinexapac has resulted in recommendations for MRLs and STMRs for raw and processed commodities. Consumption data were available for 36 food commodities and were used in the dietary intake calculation. The results are shown in Annex 3. The International Estimated Daily Intakes for the 13 GEMS/Food regional diets, based on estimated STMRs were in the range 0–1% of the maximum ADI of 0.3 mg/kg bw (Annex 3).

The Meeting concluded that the long-term intake of residues of trinexapac 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 trinexapac was not calculated, as it was not considered necessary to establish an ARfD.

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

6. RECOMMENDATIONS

The Meeting considered that the currently available information on residues in rotational crops was not sufficient to make recommendations on maximum residue levels in plant and animal commodities for bixafen. For future recommendations field rotational crop studies approximating plateau concentrations of bixafen in soil are required.

7. FUTURE WORK

The items listed below are tentatively scheduled to be considered by the Meeting in 2015 and 2016. The compounds listed include those recommended as priorities by the CCPR at its Forty-fifth 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/

2015 JMPR

TOXICOLOGICAL EVALUATIONS	RESIDUE EVALUATIONS
NEW COMPOUNDS	**NEW COMPOUNDS**
Acetochlor USA	Acetochlor Corn, field, forage; corn, field, grain; corn, field, stover; corn, pop, grain; corn, pop, stover; corn, sweet, forage; corn, sweet, kernels plus cob with husks removed; corn, sweet, stover; cotton, gin by-products; cotton, undelinted seed; sorghum, grain forage; sorghum, grain, grain; sorghum, grain, stover; soya bean, meal; soya bean, seed; beet, sugar, dried pulp; beet, sugar, molasses; beet, sugar, roots; beet, sugar, tops; peanut; peanut, hay; peanut, meal For crops planted in rotation which are included in a crop group tolerance or which have a stand-alone tolerance in the USA: rice, grain; rice, straw; wheat, forage; wheat, hay; wheat, straw; wheat, grain; alfalfa, forage; alfalfa, hay; clover; potatoes; sunflower seed
Cyazofamid [Ishihara Sangyo Kaisha] USA	Cyazofamid Hops; potato; tomato; grape; cucurbits; carrots; brassica vegetables; okra; spinach; other fruiting vegetables
Fenazaquin [Gowan company] USA	Fenazaquin Alfalfa; apples; apricots; berries; citrus; cotton; cucurbits (cucumbers, melons, zucchini, squash, pumpkin); eggplant; grapes; hops; nectarines; peaches; pears; peppers; pineapples; plums; prunes; strawberries; tea; tomatoes; tree nuts; zucchini
Flonicamid [Ishihara Sangyo Kaisha] USA	Flonicamid Cucurbit, vegetables; fruiting vegetables; leafy vegetables; pome fruit; potato; stone fruit; head/stem brassica; mustard greens; brassica leafy greens; root vegetables; radish tops; tuberous/corm vegetables; hops; okra; cottonseed
Fluazifop-p-butyl [Syngenta]	Fluazifop-p-butyl Oil seed rape; soya bean; dry beans; cotton; potato;

TOXICOLOGICAL EVALUATIONS	RESIDUE EVALUATIONS
NEW COMPOUNDS	**NEW COMPOUNDS**
	sweet potato; sugar beets; citrus fruits; pome fruit; stone fruit; grapes; tree nuts; onion (could include bulb veg); cabbage; carrots; vegetables; bananas; coffee bean; (palm oil) IR-4 Add-On: lettuce; rhubarb; caneberry; blueberry; onion, green Animal feeding study data to support MRLs in animal commodities given use of cotton seed, rape seed and soya beans or their by-products as animal feeds
Flupyradifurone [Bayer CropScience] Germany	Flupyradifurone Citrus fruit; table and wine grapes and small berries; pome fruit; tree nuts; hops; fruiting and brassica vegetables; lettuce; potatoes; sugar beets; onions; cereals; coffee; soya and cotton
Flumioxazin [Sumitomo] USA	Flumioxazin Alfalfa; artichoke; asparagus; bushberry subgroup; cabbage and Chinese cabbage; cactus; corn; cotton; fish, freshwater; fruit, pome; fruit, stone; garlic; grape; hop; leaf petiole subgroup 4B; nut, tree; okra; olive; onion, bulb; pea and bean; dried shelled, except soya bean; peanut; peppermint; pistachio; pomegranate; rapeseed subgroup 20A; shallot bulb; soya bean; spearmint; strawberry; sugarcane; sunflower (subgroup 20B); vegetable; cucurbit; group 9; vegetable, fruiting; group 8; vegetable, tuberous and corm subgroup 1C (potato); wheat
Lufenuron Brasil [Syngenta]	Lufenuron Soya bean, citrus, pome fruit, stone fruit, grapes, fruiting vegetables, melon, cucumber/squash, flowering brassica, head brassica, leafy vegetables, cotton, potato, sunflower, sugarcane, corn, wheat, rice, coffee
Phosphorous acid [manufacturer] Australia	Phosphorous acid Grapes
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
Quinclorac [BASF] USA	Quinclorac Barley; canola; cranberry; rhubarb; rice; sorghum; wheat; and animal feed items

	PERIODIC RE-EVALUATIONS
Abamectin (177) [Syngenta]	Abamectin (177) Pome fruits; cucurbits (edible and inedible peel); grapes; citrus fruits; stone fruits; strawberries; hops; leafy vegetables (lettuce, spinach, endive, celery); potato; almond; walnut; bean; coffee; cotton; fruiting vegetables (tomato, aubergine, pepper, sweet pepper); avocado; papaya; mango; avocado; onion Chili peppers (Thailand) tomato; mango; papaya (Indonesia REP12/PR, CRD 26) (appears to be no support for animal product CXLs)
Chlormequat (15) [BASF]	Chlormequat (15) Cereals; cottonseed; maize; rapeseed; maize fodder; cereals fodder/straw; meat; milk; eggs
Clethodim (187) Arysta LifeScience – USA	Clethodim (187) Bean; broccoli; cabbage; carrot; cranberry; cucurbits; hops; lettuce; pea; strawberry; blueberry
Ethephon (106) [Bayer CropScience]	Ethephon (106) Apple; barley; barley straw and fodder; blueberries; cantaloupe; cherries; chili peppers (dry); cotton seed; dried grapes; figs; grapes; hazelnuts; peppers; pineapple; rye; rye straw and fodder; tomato; walnuts; wheat; wheat straw and fodder; chicken eggs; edible offal of cattle; goats; horses; pigs & sheep; meat of cattle; goats; horses; pigs & sheep; milk of cattle; goats & sheep; poultry meat; poultry; edible offal All CXLs supported
Penconazole (182)	Penconazole (182) Pome fruit, Stone Fruit, Grapes, Cane Berries
Metalaxyl (138) Quimicas del Vallés - SCC GmbH postponed on request	Metalaxyl (138) Review in 2004 for residues was for evaluation of metalaxyl-M; support from Quimicas del Vallés - SCC GmbH; USA - supervised trials by Thailand – pineapples Ginseng (RoK)

	EVALUATIONS
	Acetamiprid (246) [Nippon Soda] Fruiting vegetables other than cucurbits China (tomatoes and cucumbers) seed spices [HS 190]; fruit and berry spices [HS 191] (India) Pistachio (Iran);
	Bifenthrin [FMC] (178) Barley; barley (straw fodder); strawberry; papaya; okra; mango
	Chlorothalonil [Syngenta] (81) (4 year rule) Carrot; cherry; cranberry; bulb onion; peach; sweet and chili pepper; tomato; common beans; asparagus Blueberry USA Apple and pear (RoK) IR-4 Add-On: radish (root veg); ginseng; horseradish; rhubarb; mustard greens; pepper (bell); pepper (NB); orange; lemon; grapefruit (citrus fruit); almond; pistachio; mushroom; guava; lychee; mango; papaya; persimmon
	Imidacloprid (206) [Bayer CropScience] Stone fruit, olive, tea, chinese cabbage, kale Pistachio (Iran) Seed spices [HS 190]; fruit and berry spices [HS 191] (India)
	Lambda-cyhalothrin (146) [Syngenta] Basil (Thailand)
	Carbofuran (145) FMC Seed spices [HS 190]; fruit and berry spices [HS 191] (India)
	Dicamba (240) USA [Monsanto] Cotton – undelinted seed, cotton – gin by-products
	Difenoconazole (224) [Syngenta] USA Papaya (Kenya)
	Fipronil (202) [BASF] Basil (Thailand)
	Fluopyram (243) [Bayer CropScience] Grapes; berries and small fruits; artichoke; tuber vegetables; leek; plum; tomato/aubergine; onion; peppers; cucumber; melon; chicory; beans); peas;

	EVALUATIONS
	maize; wheat & barley Soya bean; cotton; alfalfa
	Flutriafol (248) USA [Cheminova] Pears; peach/nectarine; plum; cherry; sugar beet; rice; strawberry; almond; pecan; tomato; cucumber; muskmelon; summer squash
	Fluxapyroxad (256) USA [BASF] Tree nuts; berries and small fruit; grape; strawberry; bulb vegetables; brassica, leafy and head and stem, cucurbits; leafy vegetables (lettuce, spinach, celery); root and tuber vegetables (radish, carrot); cereal grains; grasses for sugar production (sugar cane); sorghum
	Methoxyfenozide (209) [Dow AgroScience] Fruiting vegetables / cucurbits, spring onion
	Picoxystrobin(258)– [Dupont] –USA 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
	Pyrimethanil (226) [Bayer CropScience] Blueberry
	Spirotetramat(234) [Bayer CropScience] Sweet corn
	Tebuconazole (189) [Bayer CropScience] China (banana and cucumber); Kenya (common beans) Lettuce head
	Trifloxystrobin (213) [Bayer CropScience] Lentils; chick pea; beans; peas; soya beans
	Spices [India] Cardamon – cypermethrin (118), lambda-cyhalothrin (146), profenofos (171), quinalphos, triazophos (143) Black Pepper – profenofos (171), quinalphos, ethion (34), triazophos (143) Cumin – phorate (112), profenofos (171), dithiocarbamates (50 and 105), quinalphos Curry leaves – profenofos (171), chorpyrifos (17), cypermethrin (118), methyl parathion (59), triazophos (143), ethion (34), quinalphos.

2016 JMPR	
NEW COMPOUNDS	**NEW COMPOUNDS**
Acibenzolar-S methyl [Syngenta] New Zealand	Acibenzolar-S methyl Kiwifruit
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
Spiromesifen [Bayer CropScience] – Germany	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; milk; eggs All CXLs supported
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 (All CXLs appear to be supported)
Teflubenzuron (190) [BASF]	Teflubenzuron (190) Apple; orange; coffee; field corn; soya bean; sugarcane; sunflower; tomato; melon; broccoli; cauliflower; grape; papaya (no support for plum, potato, cabbage and Brussels sprout CXLs)

	EVALUATIONS
	Pyriproxyfen (200) Costa Rica: banana, Peru: avocado, Philippines: papaya, Malaysia/Singapore: mango, Panama: pineapple
	Spinetoram (233) Thailand: mango, Egypt or Morocco: olive , Colombia: avocado, Costa Rica: papaya, Bolivia and Ghana: banana, Senegal: pineapple NZ – feijoa, passionfruit, avocado, tamarillo
	Azoxystrobin (229) [Syngenta] Uganda: pineapple (or passion fruit), Tanzania: guava, Egypt or Morocco: olive , Indonesia: dragon fruit (this needs to be moved from 2013 to 2016)
	Difenoconazole (224) [Syngenta] Uganda: pineapple (or passion fruit), Tanzania: guava, Egypt or Morocco: olive , Indonesia: dragon fruit (this needs to be moved from 2013 to 2016)
	Fluensulfone [Makhteshim] Root tuber, leafy vegetable, brassica vegetable, strawberry, cereal grain, product of animal origin, radish, legume vegetables, tree fruit
	Chlorantraniliprole (230) Philippines – pineapple, Thailand

8. CORRIGENDA

CORRECTIONS TO THE REPORT OF THE 2012 MEETING

Pesticide residues in food—2012. 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 215, 2012.

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**
Cycloxydim (179)	VP 0526	Common bean (pods and/or immature seeds)	W	1		
Sedaxane (259)	VD 0541	Soya bean (dry)	0.01*		0	

Under Annex 1 ***Replace*** *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**
Cycloxydim (179)	AS 0645	Maize fodder (dry)	**3**		0.105	1.1

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 2013 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		
Azoxystrobin (229)	GC 0640	Barley	1.5	0.5	0.05	
ADI: 0–0.2 mg/kg bw		Barley malt			0.005	
ARfD: Unnecessary		Barley spent grain			0.0075	
		Beer			0.0015	
	SB 0716	Coffee beans	0.03	0.02	0.01	
	SM 0716	Coffee beans, roasted			0.006	
	MO 0105	Edible offal (Mammalian)			0.02	
		Instant coffee			0.0106	
	MF 0100	Mammalian fats (except milk fats)			0.015	
	MM 0095	Meat (from mammals other than marine mammals)			0.01 (muscle) 0.015 (fat)	
	GC 0647	Oats	1.5	0.5	0.05	
	AL 0072	Pea hay or fodder (dry) a	20 [a]		1.9 [b]	18 [b c]
	AL 0528	Pea vines (green)			3.35 [b]	9.4 [b c]
	VR 0589	Potato	7 Po		2.3 Po	
		Potato chips			0.0276	
		Potato flakes			0.0253	
		Potato wet peel			2.08	
	VD 0070	Pulses, dry, except soya beans	0.07		0.01	
	VR 0075	Root and tuber vegetables	W	1		
	VR 0075	Root and tuber vegetables, except potato	1		0.23	
	GC 0651	Sorghum	10		1.85	
	AF 0651	Sorghum forage (green)			1.6 [b]	12 [b c]
	AS 0651	Sorghum straw and fodder, dry	30 [a]		3.85 [b]	14.5 [b c]
		Sorghum, aspirated grain fractions			92.5	
	AS 0081	Straw and fodder of cereal grains, except maize	W	15		
	AS 0081	Straw and fodder of cereal grains, except maize and sorghum	15 [a]		1.5 [b]	

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

The residue is fat-soluble.

[a] Dry weight basis
[b] Fresh weight basis
[c] Highest residue for the purpose of estimating animal dietary burdens

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		
Bentazone (172)**	AL 1020	Alfalfa fodder	0.5		0.09	
ADI: 0–0.09 mg/kg bw	AF 1020	Alfalfa forage (green)			0.03	0.07 [a]
ARfD: Unnecessary	GC 0640	Barley	W	0.1		
	AS 0640	Barley straw and fodder, dry	0.3		0.04	
	VD 0071	Beans (dry)	0.04	0.05*	0.02	
	VP 0061	Beans, except broad bean and soya beans (green pods and immature seeds)	0.01*		0.01	
	AL 1030	Bean forage (green)			0.01	0.02 [a]
	VP 0062	Beans, shelled (succulent=immature seeds)	0.01*		0.01	
	GC 0080	Cereal grains	0.01*		0.01	
	VP 0526	Common bean (pods and/or immature seeds)	W	0.2		
	PE 0112	Eggs	0.01*	0.05*	0	
	VD 0561	Field pea (dry)	W	1		
	VP 0528	Garden pea (young pods)(=succulent, immature seeds)	W	0.2		
	AS 0162	Hay of fodder (dry) of grass	2		0.215	1.16 [a]
		Grass forage			0.22	0.37 [a]
	HH 0092	Herbs	0.1		0.05	
	VP 0534	Lima bean (young pods and /or immature beans)	W	0.05		
	SO 0693	Linseed	0.02*	0.1	0.02	
	GC 0645	Maize	W	0.2		
	AS 0645	Maize fodder	0.4	0.2	0.02	
	MM 0095	Meat (from mammals other than marine mammals)	W	0.05*	0	
	ML 0106	Milks	0.01*	0.05*	0	
	AS 0646	Millet fodder, dry	0.3		0.04	0.14 [a]
	GC 0647	Oats	W	0.1		
	AF 0647	Oat straw and fodder, dry	0.3	0.1	0.04	0.14 [a]
	VA 0385	Onion, Bulb	0.04	0.1	0.01	
	SO 0697	Peanut	0.05*	0.05	0	
	VP 0063	Peas (pods and succulent = immature seeds)	1.5		0.05	
	AL 0528	Pea vines (green)			0.22	13.1 [a]
	VR 0589	Potato	0.1	0.1	0.01	
	PM 0110	Poultry meat (fat)	0.03		0	
	PO 0111	Poultry, Edible offal of	0.07		0	
	GC 0649	Rice	W	0.1		
	CM 1207	Rice hulls			0.089	
	CF 0649	Rice bran, processed			0.0037	
	GC 0650	Rye	W	0.1		
	AS 0650	Rye straw and fodder, dry	0.3		0.04	0.14 [a]
	GC 0651	Sorghum	W	0.1	0.01	
	VD 0541	Soya bean (dry)	0.01*	0.1	0.01	
	VA 0389	Spring onion	0.08		0.01	
	VO 0447	Sweet corn (corn-on-the-cob)	0.01*		0.01	
	AS 0653	Triticale straw and fodder, dry	0.3		0.04	0.14 [a]
	GC 0654	Wheat	W	0.1	0.01	
	AS 0654	Wheat straw and fodder, dry	0.3		0.04	0.14 [a]

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

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		
The residue is not fat-soluble. [a] Highest residue for the purpose of estimating animal dietary burdens.						
Benzovindiflupyr (261)* ADI: 0–0.05 mg/kg bw ARfD: 0.1 mg/kg bw						
Bixafen (262)* ADI: 0–0.02 mg/kg bw ARfD: 0.2 mg/kg bw Definition of the residue for compliance with MRL for plant commodities: *bixafen* Definition of the residue for compliance with MRL for animal commodities and (for the estimation of dietary intake) for plant and animal commodities: *sum of bixafen and N-(3',4'-dichloro-5-fluorobiphenyl-2-yl)-3-(difluoromethyl)-1H-pyrazole-4-carboxamide (bixafen-desmethyl), expressed as bixafen* The residue is fat-soluble. The currently available information on residues in rotational crops was not sufficient to make recommendations on maximum residue levels in plant and animal commodities.						
Chlorantraniliprole (230) ADI: 0–2 mg/kg bw ARfD: Unnecessary	VS 0620	Artichoke, Globe	2		0.56	
	VP 0061	Beans, except broad bean and soya bean (green pods and immature seeds)	0.8		0.16	
	VR 0577	Carrot	0.08		0.02	
	GC 0080	Cereal grains	W	0.02		
	GC 0080	Cereal grains, except rice	0.02		0.01	
	SB 0716	Coffee beans	0.05		0.015	
	PE 0112	Eggs	0.2	0.1	0.07	
	DH 1100	Hops, dry	40		10.9	
	VL 0053	Leafy vegetables	W	20		
	VL 0053	Leafy vegetables, except radish leaves	20			
	VP 0063	Peas (pods and succulent = immature seeds)	2		0.545	
	VP 0064	Peas, shelled (succulent seeds)	0.05		0.025	
	FI 0355	Pomegranate	0.4		0.11	
	PM 0110	Poultry meat	0.01 *	0.01*	0	
	PO 0111	Poultry, Edible offal of	0.01 *	0.01*	0.005	
	VR 0494	Radish	0.5		0.055	
	VL 0494	Radish leaves, including radish tops	40		10.5	
	SO 0495	Rape seed	2		0.295	
	GC 0649	Rice	0.4		0.115	
	CF 0649	Rice bran, processed			0.196	
		Rice, polished	0.04		0.013	
	VR 0075	Root and tuber vegetables	W	0.02		
	VR 0075	Root and tuber vegetables, except carrot and radish	0.02		0.01	
	SO 0702	Sunflower seed	2		0.185	
Definition of the residue (for compliance with MRL and for estimation of dietary intake) for plant and animal commodities:						

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		
chlorantraniliprole The residue is fat-soluble						
Chlorfenapyr (254) ADI: 0–0.03 mg/kg bw ARfD: 0.03 mg/kg bw						
Chlorpyrifos-methyl (090)	GC 0640	Barley	W	3		
ADI: 0–0.01 mg/kg bw	GC 0080	Cereals, except maize and rice	5 Po		3	4.7
ARfD: 0.1 mg/kg bw	CM 0649	Rice, husked	1.5 Po		0.66	1.04
	CM 1205	Rice, polished	0.2 Po		0.101	0.15
	CM 1206	Rice bran, unprocessed				7.8
	GC 0654	Wheat	W	3		
For compliance with MRLs and estimation of dietary intake in plant and animal commodities: *Chlorpyrifos-methyl.* The residue is fat soluble						
Cyantraniliprole (263)*	JF 0226	Apple juice			0.05	
ADI: 0–0.03 mg/kg bw	VB 0040	Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead brassicas	2		0.56	
ARfD: Unnecessary	FB 2006	Bush berries	4		0.68	
	VX 0624	Celery	15		2	
		Cereal & grass forages (follow crop)			0.01	
	FS 0013	Cherries	6		0.93	
	SB 0716	Coffee beans	0.03		0.01	
	MO 0105	Edible offal (Mammalian)	0.05		0.025	
	PE 0112	Eggs	0.015		0.01	
	AM 1051	Fodder beet	0.02		0.01	
	VC 0045	Fruiting vegetables, Cucurbits	0.3		0.065 [a] 0.01 [b]	
	VO 0050	Fruiting vegetables, other than Cucurbits (except mushrooms & sweet corn)	0.5		0.08	
	VA 0381	Garlic	0.05		0.02	
	VL 0053	Leafy vegetables (except Lettuce, Head)	20		4.7	
	AL 0157	Legume animal feeds	0.8 [c]		0.17	
		Legume forages (follow-crop)			0.01	
	VL 0482	Lettuce, Head	5		0.79	
	ML 0106	Milks	0.02		0.015	
	VA 0385	Onion, Bulb	0.05		0.02	
	VA 0387	Onion, Welsh	8		1.3	
	FS 0247	Peach	1.5		0.34	
	HS 0444	Peppers Chili, dried	5		0.7	
	FS 0014	Plums (including prunes)	0.5		0.07	
	FP 0009	Pome fruits	0.8		0.16	
	VR 0589	Potato	0.05		0.02	
	PF 0111	Poultry fat	0.01		0	
	PM 0110	Poultry meat	0.01		0	
	PO 0111	Poultry, Edible offal of	0.01		0.072	

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		
	DF 0014	Prunes	0.8		0.54	
	VR 0075	Root and tuber vegetables except potato	0.05		0.01	
	VA 0388	Shallot	0.05		0.02	
		Spinach (cooked)			5.3	
	VA 0389	Spring onion	8		1.3	
	AS 0161	Straw, fodder (dry) & hay of cereal grains and other grass like plants	0.2 [c]		0.05	
		Tomato (canned)			0.004	
	JF 0048	Tomato juice			0.014	
	VW 0448	Tomato paste			0.07	
	AM 0506	Turnip fodder	0.02		0.01	
		Turnip leaves or tops			0.01	
Definition of the residue (for compliance with the MRL, animal and plant commodities)*: cyantraniliprole.* Definition of the residue (for estimation of dietary intake for unprocessed plant commodities): *cyantraniliprole.* Definition of the residue (for estimation of dietary intake for processed plant commodities): *sum of cyantraniliprole and 2-[3-Bromo-1-(3-chloro-2-pyridinyl)-1H-pyrazol-5-yl]-3,4-dihydro-3,8-dimethyl-4-oxo-6-quinazolinecarbonitrile.* Proposed definition of the residue (for estimation of dietary intake for animal commodities*: sum of:-* *cyantraniliprole* *2-[3-Bromo-1-(3-chloro-2-pyridinyl)-1H-pyrazol-5-yl]-3,4-dihydro-3,8-dimethyl-4-oxo-6-quinazolinecarbonitrile* *2-[3-Bromo-1-(3-chloro-2-pyridinyl)-1H-pyrazol-5-yl]-1,4-dihydro-8-methyl-4-oxo-6-quinazolinecarbonitrile* *3-Bromo-1-(3-chloro-2-pyridinyl)-N-[4-cyano-2-(hydroxymethyl)-6-[(methylamino)carbonyl]phenyl]-1H-pyrazole-5-carboxamide* *3-Bromo-1-(3-chloro-2-pyridinyl)-N-[4-cyano-2[[(hydroxymethyl)amino]carbonyl]-6-methylphenyl]-1H-pyrazole-5-carboxamide expressed as cyantraniliprole* The residue is not fat soluble [a] edible peel [b] inedible peel [c] Dry weight basis						
Cyproconazole (239) ADI: 0–0.02 mg/kg bw ARfD: 0.06 mg/kg bw	SB 0761	Coffee beans	0.07		0.03	
	SM 0716	Coffee beans roasted	0.1		0.039	
		Instant coffee			0.048	
Definition of the residue (for compliance with the MRL, animal and plant commodities)*: cyproconazole.* Definition of the residue (for estimation of dietary intake for plant commodities): *cyproconazole.* Definition of the residue (for estimation of dietary intake for animal commodities): *cyproconazole, free and conjugated.* The residue is fat-soluble.						
Cyprodinil (207) ADI:0–0.03 mg/kg bw ARfD: Unnecessary	FP 0226	Apple	W	0.05		
	JF 0226	Apple juice			0.015	
		Apple pomace, wet			1.8	
	FI 0326	Avocado	1		0.265	
	VD 0071	Beans (dry)	0.2		0.03	
	VP 0061	Beans, except broad bean and soya bean (green pods and immature seeds)	0.7	0.5	0.165	
	VP 0062	Beans, shelled	0.06		0.02	
	FB 0018	Berries and other small fruits, except grapes	10		2.2	

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		
	VL 0054	Brassica leafy vegetables	15		0.37	
	VB 0041	Cabbages, Head	0.7		0.03	
	VR 0577	Carrot	0.7		0.09	
	VC 0424	Cucumber	W	0.2		
	DH 0170	Dried herbs, except hops, dry	300		25	
	MO 0105	Edible offal (Mammalian)	0.01	0.01*	0	
	VO 0440	Egg plant	W	0.2		
	VB 0042	Flowerhead Brassicas (includes Broccoli: Broccoli , Chinese and Cauliflower)	2		0.27	
	VC 0045	Fruiting vegetables, Cucurbits	0.5		0.09	
	VO 0050	Fruiting vegetables, other than Cucurbits, except sweet corn and mushroom	2		0.24	
	HH 0092	Herbs	40		5.05	
	VL 0053	Leafy vegetables, except brassica leafy vegetables	50		11	
	VL 0482	Lettuce, Head	W	10		
	VL 0483	Lettuce, Leaf	W	10		
	VR 0588	Parsnip	0.7		0.09	
	FP 0230	Pear	W	1		
	HS 0444	Peppers Chili, dried	9		2.0	
	VO 0445	Peppers, Sweet (including Pimento or pimiento)	W	0.5		
	FP 0009	Pome fruits	2		0.48	
	VR 0494	Radish	0.3		0.01	
	FB 0272	Raspberries, Red, Black	W	0.5		
	VC 0431	Squash, Summer	W	0.2		
	FB 0275	Strawberry	W	2		
	VO 0448	Tomato	W	0.5		
	JF 0448	Tomato juice			0.036	
		Tomato purée			0.11	
	VW 0448	Tomato paste			0.48	
Definition of the residue for plant and animal commodities (for compliance with MRLs and for estimation of dietary intake): *cyprodinil.* The residue is fat soluble.						
Dicamba (240) ADI: 0–0.3 mg/kg bw ARfD: 0.5 mg/kg bw	VD 0541 OR 0541	Soya bean (dry) Soya bean oil, refined Soya bean meal Soya bean hull Soya bean grain dust	10	5	0.033 0.001 0.0105 0.117 20.3	
Definition of the residue for plant commodities (for compliance with the MRL): *Dicamba* Definition of the residue for plant commodities (for estimation of dietary intake): *Sum of dicamba and 5-OH dicamba expressed as dicamba* Definition of the residue for animal commodities (for compliance with the MRL and for estimation of dietary intake): *Sum of dicamba and DCSA expressed as dicamba* 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		
Difenoconazole (224)	JF 0226	Apple juice			0.005	
ADI: 0–0.01 mg/kg bw	VB 0040	Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead brassicas	2		0.35	1.3
ARfD: 0.3 mg/kg bw	VB 0400	Broccoli	W	0.5		
	VB 0402	Brussels sprouts	W	0.2		
	VB 0041	Cabbages, Head	W	0.2		
	VB 0404	Cauliflowers	W	0.2		
	FC 0001	Citrus fruits	0.6		0.16	0.49
	JF 0001	Citrus juice			0.002	
	OR 0001	Citrus oil, Edible			7.5	
		Citrus pulp dry			0.64	
	VC 0424	Cucumber	0.2		0.04	0.15
	DF 0269	Dried grapes (=currants, Raisins and Sultanas)	6		1.1	3.2
	MO 0105	Edible offal (Mammalian)	1.5	0.2	0.71	0.95
	PE 0112	Eggs	0.03	0.01*	0.011	0.026
	VO 0050	Fruiting vegetables , other than Cucurbits, except sweet corn and mushroom	0.6		0.14	0.39
	VO 0448	Tomato	W	0.5		
	VC 0425	Gherkin	0.2		0.04	0.15
	VR 0604	Ginseng	0.08	0.5	0.02	0.044
	DV 0604	Ginseng, dried including red ginseng	0.2		0.052	0.11
	DM 0604	Ginseng, extracts	0.6		0.14	
	FB 0269	Grapes	3	0.1	0.52	1.5
	JF 0269	Grape juice			0.24	
		Grape pomace, dry			6.2	
	MM 0095	Meat (from mammals other than marine mammals)	0.2 (fat)	0.05 (fat)	0.047 (muscle) 014 (fat)	0.071 (muscle) 0.19 (fat)
	VC 0046	Melons, except Watermelon	0.7		0.14	0.35
	ML 0106	Milks	0.02	0.005*	0.011	
	VA 0385	Onion, Bulb	0.1		0.015	0.07
	HS 0444	Peppers, Chili, dried	5		1.1	1.8
	FP 0009	Pome fruits	0.8	0.5	0.16	0.47
	VR 0589	Potato	4 Po	0.02	1.2	1.9
		Potato chips			0.088	
		Potato flakes			0.029	
		Potato, wet peel			3.8	
	VA 0389	Spring Onion	9		2.8	3.8
	VC 0431	Squash, Summer	0.2		0.04	0.15
	VW 0448	Tomato paste			0.22	
		Tomato purée			0.08	
	JF 0048	Tomato juice			0.031	
		Tomato canned			0.01	
		Wine			0.094	

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

Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for animal commodities: *sum of difenoconazole and 1-[2-chloro-4-(4-chloro-phenoxy)-phenyl]-2-(1,2,4-triazol)-1-yl-ethanol), expressed as difenoconazole*.

The residue is 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		
Diquat (031)**	AL 1020	Alfalfa fodder	W	100		
ADI: 0–0.006 mg/kg bw	FI 0327	Banana	0.02*		0	0
ARfD: 0.8 mg/kg bw	GC 0640	Barley	W	5		
	VD 0071	Beans (dry)	0.05	0.2	0.05	
	FT 2352	Cajou (pseudofruit)	0.02 *		0	0
	FT 0292	Cashew apple	0.02 *		0	0
	TN 0292	Cashew nut	0.02 *		0	0
	FC 0001	Citrus fruits	0.02 *		0	0
	SB 0716	Coffee beans	0.02 *		0	
	MO 0105	Edible offal (Mammalian)	0.01 *	0.05	0	0
	PE 0112	Eggs	0.01 *	0.05	0	0
	VO 0050	Fruiting vegetables, other than cucurbits (except sweetcorn, fungi and mushrooms)	0.01*		0	0
	VD 0533	Lentil (dry)	W	0.2		
	GC 0645	Maize	W	0.05		
	MM 0095	Meat (from mammals other than marine mammals)	0.01 *	0.05	0	0
	ML 0106	Milks	0.001 *	0.01	0	0
	GC 0647	Oats	W	2		
	VD 0072	Peas (dry)	0.3	0.2	0.05	
	AL 0072	Pea fodder	50		16	25
	FP 0009	Pome fruits	0.02 *		0	0
	VR 0589	Potato	0.1	0.05	0.05	0.06
	PM 0110	Poultry meat	0.01 *	0.05	0	0
	PO 0111	Poultry, Edible offal of	0.01 *	0.05	0	0
	SO 0495	Rape seed	1.5	2	0.49	
		Rape seed meal			0.19	
	OR 0495	Rape seed oil, edible			0.0098	
	GC 0649	Rice	W	10		
	CM 0649	Rice, husked	W	1		
	CM 1205	Rice, polished	W	0.2		
	GC 0651	Sorghum	W	2		
	VD 0541	Soya bean (dry)	0.3	0.2	0.03	
		Soya bean meal			0.0255	
	OR 0541	Soya bean oil, refined			0.00165	
	FS 0012	Stone fruits	0.02 *		0	
	FB 0275	Strawberry	0.05 *		0	
	SO 0702	Sunflower seed	0.9	1	0.11	
		Sunflower seed cake/meal			0.132	
	OR 0702	Sunflower seed oil, edible			0.066	
	OC 0172	Vegetable oils, Crude	W	0.05		
		Vegetables (except as otherwise listed)	W	0.05		
	GC 0654	Wheat	W	2		
	CM 0654	Wheat bran, unprocessed	W	2		
	CF 1211	Wheat flour	W	0.5		
	CF 1212	Wheat wholemeal	W	2		
Definition of the residue for compliance with MRL and for estimation of dietary intake (for animal and plant commodities): *Diquat* The residue is not fat soluble.						
Dithianon (180)**		Apples, canned			0.009	
ADI: 0–0.01 mg/kg bw	DF 0226	Apples, dried			0.015	

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: 0.1 mg/kg bw		Apples, canned			0.009	
	JF 0226	Apple juice			0.0045	
		Apple sauce			0.0045	
		Apple syrup			0.006	
		Apple wet pomace			0.33	
	TN 0660	Almonds	0.05*		0	0
	FS 0013	Cherries	W	5[a]		
		Beer			0.019	
		Cherries, canned			0.024	
		Cherry jam			0.024	
		Cherry juice			0.024	
	FB 0021	Currants, Black, Red, White	2		0.105	0.89
	DF 0269	Dried grapes (= currants, Raisins and Sultanas)	3.5		1.03	2.13
	MO 0105	Edible offal (Mammalian)	0.01*		0	0
	PE 0112	Eggs	0.01*		0	0
	FB 0269	Grapes	W	3 [b]		
	JF 0269	Grape juice			0.002 [d]	
		Grape must			0.017 [d]	
		Grape wine			0.002 [d]	
		Grape wet pomace			0.64 [d]	
	DH 1100	Hops, dry	300	100	64	
	FC 0206	Mandarin	W	3		
	MM 0095	Meat (from mammals other than marine mammals)	0.01*		0	0
	ML 0106	Milks	0.01*		0	0
		Plum puree			0.015	
	FP 0009	Pome fruits	1	5	0.15	0.65
	PM 0110	Poultry meat	0.01*		0	0
	PO 0110	Poultry, Edible offal of	0.01*		0	0
	DF 0014	Prunes			0.22	0.82
	FC 0005	Shaddocks or pomelos (including Shaddock-like hybrids, among others than grapefruit)	W	3		
	FS 0012	Stone fruits	2		0.43	1.6
	FB 1235	Table-grapes	2		0.63	1.3
	FB 1236	Wine-grapes	5		0.69[c]	
Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities: *Dithianon.* The residue is not fat-soluble. [a] The recommendation for cherries is withdrawn and replaced by a recommendation for stone fruit. [b] The recommendation for grapes is withdrawn and replaced by separate recommendations for table grapes and wine grapes. [c] Median value for calculation of STMR-P for wine, juice and must. [d] STMR-P based on median residue of wine grapes						
Fenamidone (264)* ADI: 0–0.03 mg/kg bw ARfD: 1 mg/kg bw						
Fenbuconazole (197)	FC 0001	Citrus fruit (except Lemons and Limes)	0.5	-	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		
ADI: 0–0.03 mg/kg bw	OR 0001	Citrus oil, edible (except Lemons and Limes)	30	-	5.2	-
ARfD: 0.2 mg/kg bw	AB 0001	Citrus pulp, dry	4	-	0.63	-
	JF 0001	Citrus juice (except lemons and limes)			0.021	
		Juice of lemons and limes			0.067	
	FC 0002	Lemons and Limes (including Citron)	1	-	0.018	0.085
Definition of the residue (for compliance with the MRL and for estimation of dietary intake, for plant and animal commodities): *fenbuconazole* The residue is not fat soluble						
Fenpyroximate (193)	FI 0326	Avocado	0.2	-	0.055	0.10
ADI: 0–0.01 mg/kg bw	AL 1030	Bean forage			1.92 [a]	5.80 [a]
ARfD: 0.02 mg/kg bw	MO 1280	Cattle kidney	W	0.01*		
	MO 1281	Cattle liver	W	0.01*		
	MM 0812	Cattle meat	W	0.02 (fat)		
	ML 0812	Cattle milk	W	0.005* F		
	FS 0013	Cherries	2	-	0.57	0.90
	VP 0526	Common bean (pods and/or immature seeds)	0.4	-	0.09	0.19
	VC 0424	Cucumber	0.3	0.03	0.07	0.19
	MO 0105	Edible offal (Mammalian)	0.02		0.003 Liver 0.003 Kidney	0.004 Liver 0.011 Kidney
	MM 0095	Meat (from mammals other than marine mammals)	0.2 (fat)		0.011 (muscle) 0.021(fat)	0.021 (muscle) 0.084 (fat)
	ML 0106	Milks	0.01*		0.005	
	VR 0589	Potato	0.05	-	0	0
	DF 0014	Prunes	0.7	-	0.18	0.50
	FS 0012	Stone fruits (except cherries)	0.4	-	0.13	0.29
	FB 0275	Strawberry	0.8	-	0.215	0.59
Definition of the residue for both plant and animal commodities (for compliance with the MRL and for estimation of dietary intake): *fenpyroximate.* The residue is fat soluble [a] for the purpose of calculating animal dietary burdens. Expressed on an "as received" basis						
Fludioxonil (211)	FI 0326	Avocado	0.4		0.05	
ADI: 0–0.4 mg/kg bw	HH 0772	Basil, sweet	W	10		
ARfD: Unnecessary	DH 0772	Basil, dry	W	50		
	VP 0061	Beans, except broad bean and soya bean (green pods and immature seeds)	0.6	0.3	0.04	
	VP 0062	Beans (shelled)	0.4		0.02	
	VD 0071	Beans (dry)	0.5	0.07	0.04	
	VC 4199	Melons	W	0.03		
	HH 0727	Chives	W	10		
	DH 0727	Chives, dry	W	50		
	HS 0444	Peppers Chili, dried	4		1.2	
	DH 0092	Dried herbs	60		16.5	
	PE 0112	Eggs	0.01*	0.05*	0	

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	0.5		0.065	
	VR 0604	Ginseng	4		0.29	
	HH 0092	Herbs	9		2.65	
	VL 0483	Lettuce, leaf	40		8.3	
	VO 0051	Peppers	1		0.18	
	VO 0445	Peppers, sweet (including pimento or pimiento)	W	1		
	VR 0589	Potato	5 Po	0.02	1.4	
		Potato chips			0.056	
	PM 0110	Poultry meat	0.01*	0.01*	0	
	PO 0111	Poultry, Edible offal of	0.05*	0.05*	0	
	VR 0494	Radish	0.3		0.06	
	VL 0494	Radish leaves (including Radish tops)	20		3.8	
	VP 4453	Snap beans (young pods)	0.6		0.04	
	VL 0502	Spinach	30		5.8	
	VC 0431	Squash, Summer	W	0.3		
	VO 0448	Tomato	2	0.5	0.605	
		Tomato purée			0.028	
	JF 0048	Tomato juice			0.026	
For compliance with the MRL and for estimation of dietary intake for plant commodities: *fludioxonil*. For compliance with the MRL and for estimation of dietary intake for animal commodities: *fludioxonil and its benzopyrrole metabolites, determined as 2,2-difluoro-1,3-benzodioxole-4-carboxylic acid and expressed as fludioxonil.* The residue is fat-soluble.						
Fluensulfone (265)* ADI: 0–0.01 mg/kg bw ARfD: 0.3 mg/kg bw						
Flutolanil (205) ADI: 0–0.09 mg/kg bw ARfD: Unnecessary	VL 0054	Brassica leafy vegetables	0.07		0.05	
	VB 0040	Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead brassicas	0.05*		0	
	MO 0105	Edible offal	0.5		0.147 Liver 0.036 Kidney	
	MO 0098	Kidney of cattle, goats, pigs and sheep	W	0.1		
	MO 0099	Liver of cattle, goats, pigs and sheep	W	0.2		
Definition of the residue for plant commodities (for compliance with MRLs and for estimation of dietary intake): *flutolanil.* Definition of the residue for animal commodities (for compliance with MRLs and for estimation of dietary intake): *flutolanil and transformation products containing the 2-trifluoromethylbenzoic acid moiety, expressed as flutolanil.* The residue is not fat-soluble						
Glyphosate (158) ADI: 0–1 mg/kg bw ARfD: Unnecessary	SO 0495	Rape seed	30	20	3.0	
		Rape forage			2.25 (16 [a])	
		Rape seed meal			4.41	
	OR 0495	Rape seed oil, edible			0.009	

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 MRL (for plant commodities): *for soya bean, maize and rape: sum of glyphosate and N-acetylglyphosate, expressed as glyphosatefor other crops: glyphosate.* Definition of the residue for compliance with MRL (for animal commodities): *sum of glyphosate and N-acetylglyphosate, expressed as glyphosate* Definition of the residue for estimation of dietary intake (for plant and animal commodities): *glyphosate, N-acetylglyphosate, AMPA and N-acetyl AMPA, expressed as glyphosate*. The residue is not fat soluble. [a] highest residue						
Imazapic (266)*	MO 0105	Edible offal (Mammalian)	1		0.05 Liver 0.287 Kidney	
ADI: 0–0.7 mg/kg bw	PE 0112	Eggs	0.01*		0	
ARfD: Unnecessary		Grass forage			12.5	24 [a]
	AS 0162	Hay or fodder (dry) of grasses	3		0.5 [a]	2.3 [a]
	GC 0645	Maize	0.01*		0.01	
	MF 0100	Mammalian fats (except milk fats)	0.1		0.05	
	MM 0095	Meat (from mammals other than marine mammals)	0.1		0.05	
	ML 0106	Milks	0.1		0.019	
	SO 0697	Peanut	0.05*		0	
	PF 0111	Poultry fats	0.01*		0	
		Peanut hulls			0	
	PM 0110	Poultry meat	0.01*		0	
	PO 0111	Poultry, edible offal of	0.01*		0	
	SO 0495	Rape seed	0.05*		0	
		Rape seed forage			0.05	0.05 [a]
	GC 0649	Rice	0.05*		0	
	GC 0654	Wheat	0.05*		0	
	GS 0659	Sugar cane	0.01*		0	
	AS 0654	Wheat straw and fodder, dry	0.05*		0	0 [a]
Definition of the residue for plant and animal commodities (for compliance with the MRL and for estimation of dietary intake): *Imazapic* Residue is not fat-soluble. [a] Highest residue for the purpose of estimating animal dietary burdens.						
Imazapyr (267)*	MO 0105	Edible offal (Mammalian)	0.05*		0.0008	
ADI: 0–3 mg/kg bw	PE 0112	Eggs	0.01*		0	
ARfD: Unnecessary	VD 0533	Lentil (dry)	0.3		0.07	
	GC 0645	Maize	0.05*		0.05	
	AF 0645	Maize forage			0	0
	CF 0645	Maize meal			0.06	
	OR 0645	Maize oil, edible			0.025	
	MF 0100	Mammalian fats (except milk fats)	0.05*		0	
	MM 0095	Meat (from mammals other than marine mammals)	0.05*		0	
	ML 0106	Milks	0.01*		0	

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		
	PO 0111	Poultry, Edible offal of	0.01*		0	
	PF 0111	Poultry fats	0.01*		0	
	PM 0110	Poultry meat	0.01*		0	
	SO 0495	Rape seed	0.05*		0	
		Rape seed forage			0	0
	SO 0702	Sunflower seed	0.08		0.01	
	GC 0654	Wheat	0.05*		0	
		Wheat forage			0.05	0.05 [a]
	AS 0654	Wheat straw and fodder, dry	0.05*		0	
Definition of the residue for plant commodities (for compliance with the MRL and for estimation of dietary intake): *Imazapyr* The residue is not fat soluble. [a] Highest residue for the purpose of estimating animal dietary burdens						
Indoxacarb (216) ADI: 0–0.01 mg/kg bw ARfD: 0.1 mg/kg bw	DT1114	Tea, green, black (black, fermented and dried)	5		0.41	
		Tea infusion			0.025	
Definition of the residue for compliance with the MRL for all commodities and for estimation of dietary intake for plant commodities: *sum of indoxacarb and its R enantiomer.* Definition of the residue for estimation of dietary intake for animal commodities: sum of indoxacarb, its R enantiomer and methyl 7-chloro-2,5-dihydro-2-[[[4-(trifluoromethoxy)phenyl] amino]carbonyl]indeno[1,2-e][1,3,4]oxadiazine-4a(3H)-carboxylate, expressed as indoxacarb. The residue is fat soluble.						
Isoxaflutole (268)*	VD 0524	Chick-pea (dry)	0.01*		0	
ADI: 0–0.02 mg/kg bw	AL 0524	Chick-pea fodder	0.01*		0.01	0.01 [a]
ARfD: Unnecessary	MO 0105	Edible offal (Mammalian)	0.1		0.2	
	PE 0112	Eggs	0.01*		0	
	GC 0645	Maize	0.02*		0.02	
	AS 0645	Maize fodder	0.02*		0.02	0.02 [a]
	AF 0645	Maize forage			0.02	0.34 [a]
		Maize stover			0.02	0.02 [a]
	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	
	SO 0698	Poppy seed	0.02*		0	
	PM 0110	Poultry meat	0.01*		0	
	PF 0111	Poultry fats	0.01*		0	
	PO 0111	Poultry, Edible offal of	0.2		0.1	
	GS 0659	Sugar cane	0.01*		0	
	AV 0659	Sugar cane fodder	0.01*		0	0.01 [a]
	VO 0447	Sweet corn (corn-on-the-cob)	0.02*		0	
		Sweet corn forage			0.02	0.34 [a]
		Sweet corn stover			0.02	0.02 [a]
Definition of the residue for compliance with the MRL and for dietary risk assessment for plant commodities: *sum of isoxaflutole and isoxaflutole diketonitrile, expressed as isoxaflutole.* Definition of the residue for compliance with the MRL for animal commodities: *sum of isoxaflutole and isoxaflutole diketonitrile, expressed as isoxaflutole.* Definition of the residue for dietary risk assessment for animal commodities: *sum of isoxaflutole, isoxaflutole diketonitrile, RPA*						

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		
205834 (2-aminomethylene-1-cyclopropyl-3-(2-mesyl-4-trifluoromethylphenyl)-propane-1,3-dione) and RPA 207048 (1-cyclopropyl-2-hydroxymethylene-3-(2-mesyl-4-trifluoromethylphenyl)-propane-1,3-dione), including their conjugates, expressed as isoxaflutole. The residue not fat soluble. [a] Highest residue, for the purpose of estimating animal dietary burdens.						
Malathion (049) ADI: 0–0.3 mg/kg bw ARfD: 2 mg/kg bw	FS0013	Cherries	3		0.535	1.21
Definition of the residue (for compliance with the MRL and for estimation of dietary intake for plant and animal commodities): *malathion* The residue is fat soluble						
Mandipropamid (231) ADI: 0–0.2 mg/kg bw ARfD: Unnecessary	DH 1100	Hops, dry	90		28.5	
	-	Beer			0.057	
Definition of the residue (for compliance with the MRL and for estimation of dietary intake for plant and animal commodities)*: mandipropamid.* The residue not fat soluble.						
Penthiopyrad (253) ADI: 0–0.1 mg/kg bw ARfD: 1 mg/kg bw	GC 0640	Barley	0.2	0.15	0.086	
		Barley, beer			0.021	
		Barley, pearl			0.058	
	MO 0105	Edible offal (Mammalian)	0.08		0.043	0.065
	MF 0100	Mammalian fats (except milk fats)	0.05		0.031	0.036
	MM 0095	Meat (from mammals other than marine mammals)	0.04		0.012	0.026
	ML 0106	Milks	0.04		0.013	
	GC 0647	Oats	0.2	0.15	0.086	
	GC 0650	Rye	0.1	0.04	0.01	
	GC 0653	Triticale	0.1	0.04	0.01	
	GC 0654	Wheat	0.1	0.04	0.01	
	CM 0654	Wheat bran, unprocessed	0.2	0.1	0.018	
	CF 1210	Wheat, germ	0.2	0.1	0.019	
Definition of the residue for compliance with MRL for plant commodities: *penthiopyrad* Definition of the residue for compliance with MRL for animal commodities and for the estimation of dietary intake for plant and animal commodities: *sum of penthiopyrad and 1-methyl-3-trifluoromethyl-1H-pyrazole-4-carboxamide (PAM), expressed as penthiopyrad* The residue is not fat-soluble						
Propiconazole (160) ADI: 0–0.07 mg/kg bw ARfD: 0.3 mg/kg bw	JF 0004	Orange juice			0.02	
	FS 0247	Peach	5 Po		1.55	2.2
	FS 0014	Plums (including prunes)	0.6 Po		0.185	0.22
	FC 0004	Oranges, Sweet, Sour (including Orange-like hybrids): several cultivars	9 Po		2.95	4.9

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 0448	Tomato	3		0.8	1.5
Definition of the residue for compliance with MRL (for plant and animal commodities): *propiconazole* Definition of the residue for estimation of dietary intake (for plant and animal commodities): *propiconazole plus all metabolites convertible to 2.4-dichlorobenzoic acid, expressed as Propiconazole* The residue is fat soluble						
Pyrimethanil (226) ADI: 0–0.2 mg/kg bw ARfD: Unnecessary	JF 0226	Apple, Juice			0.72	
	FP 0009	Pome Fruits	15 Po	7	1.6	
	DV 0604	Ginseng, dried including red ginseng	1.5		0.41	
	FB 2009	Low growing berries	3		1.2	
	FB 0275	Strawberry	W	3		
Definition of the residue (for compliance with MRL and dietary intake) for plant commodities: *pyrimethanil* The residue is not fat-soluble						
Spirotetramat (234) ADI: 0–0.05 mg/kg bw ARfD: 1.0 mg/kg bw	VS 0620	Artichoke, Globe	1		0.41	0.70
	FB 2006	Bush berries	1.5		0.63	1.6
	FB 0265	Cranberry	0.2		0.066	0.15
Definition of the residue (for compliance with MRL for plant commodities: *Spirotetramat and its enol metabolite, 3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]dec-3-en-2-one, expressed as spirotetramat*. Definition of the residue (for estimation of dietary intake)for plant commodities: *Spirotetramat, enol metabolite 3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]dec-3-en-2-one, ketohydroxy metabolite 3-(2,5-dimethylphenyl)-3-hydroxy-8-methyoxy-1-azaspiro[4.5]decane-2,4-dione, monohydroxy metabolite cis-3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]decan-2-one, and enol glucoside metabolite glucoside of 3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]dec-3-en-2-one, expressed as spirotetramat.* Definition of the residue (for compliance with MRL and estimation of dietary intake) for animal commodities: *Spirotetramat enol metabolite, 3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]dec-3-en-2-one, expressed as spirotetramat*. The residue is not fat-soluble.						
Sulfoxaflor (252) ADI: 0–0.05 mg/kg bw ARfD: 0.3 mg/kg bw	VD 0071	Beans (dry)	0.3		0.075	
	VR 0577	Carrots	0.05		0.01	0.03
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.						
Tolfenpyrad (269)* ADI: 0–0.006 mg/kg bw ARfD: 0.01 mg/kg bw		Tea, green	30		5.65	
		Green tea infusion			0.24	
Definition of the residue for compliance with the MRL and estimation of dietary intake for plant commodities: *tolfenpyrad.* Definition of the residue for compliance with the MRL for animal commodities tolfenpyrad and free PT-CA (and conjugated *PT-CA and OH-PT-CA) expressed as tolfenpyrad*. Definition of the residue for estimation of dietary intake for animal commodities: *sum of tolfenpyrad, and free and conjugated*						

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		
PT-CA (and OH-PT-CA) expressed as tolfenpyrad. The residue is not fat soluble.						
Triazophos (143) ADI: 0–0.001 mg/kg bw ARfD: 0.001 mg/kg bw	CM 0649 CM 1205	Rice, husked Rice, polished	2 0.6		0.12 0.041	
Definition of residue (for compliance with the MRL and for estimation of dietary intake): *triazophos*.						
Triflumizole (270)* ADI: 0–0.04 mg/kg bw ARfD: 0.3 mg/kg bw	FS 0013 VC 0424 DF 0269 MO 0105 FB 0269 JF 0269 DH 1100 MF 0100 ML 0106 MM 0095 FI 0350	Cherries Cucumber Dried grapes (=currants, Raisins and Sultanas) Edible Offal (Mammalian) Grapes Grape juice Hops, dry Mammalian fats (except milk fat) Milks Meat (from mammals other than marine mammals) Papaya	4 0.5 0.2 4 30 0.02 0.02 * 0.05 (fat) 2		1.17 0.13 0.06 0.072 0.41 0.11 8.9 0.01 0 (Muscle) 0.008 (Fat) 0.71	1.5 0.21 0.072 2.0 11 0.02 0 (Muscle) 0.017 (Fat) 0.89
Definition of the residue for plant and animal commodities (for compliance with the MRL and for estimation of dietary intake): *Residues analysed as 4-chloro-2-(trifluoromethyl)aniline and expressed as parent triflumizole.* The residue is fat soluble						
Trinexapac-ethyl (271)* ADI: 0–0.3 mg/kg bw ARfD: Unnecessary	GC 0640 AS 0640 MO 0105 PE 0112 MF 0100 MM 0095 ML 0106 GC 0647 AF 0647 AS 0647 PF 0111 PM 0110 PO 0111 SO 0495 OR 0495 GS 0659	Barley Barley bran Barley flour Barley pearled Barley forage Barley straw and fodder, dry Edible offal (Mammalian) Eggs Mammalian fats (except milk fats) Meat (from mammals other than marine mammals) Milks Oats Oat forage (green) Oat straw and fodder, dry Poultry fats Poultry meat Poultry, Edible offal of Rape seed Rape seed oil, edible Sugar cane	3 6 0.9 [a] 0.1 0.01* 0.01 * 0.01 * 0.005 * 3 0.9 [a] 0.01 * 0.01 * 0.05 1.5 0.5		0.57 1.08 0.25 0.68 0.40 0.19 0.015 0 0 0 0 0.57 0.40 0.19 0 0 0.015 0.24 0.01 0.07	 3.76 1.34 [b] 3.76 1.34 [b]

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		
	DM 0659	Sugar cane molasses			0.40	
	GC 0653	Triticale	3		0.57	
		Triticale forage			0.40	3.76
	AS 0653	Triticale straw and fodder, dry	0.9 [a]		0.19	1.34 [b]
	GC 0654	Wheat	3		0.57	
	CM 0654	Wheat bran, unprocessed	8		1.08	
	AS 0654	Wheat straw and fodder, dry	0.9 [a]		0.19	1.34 [b]
	CF 1211	Wheat flour			0.25	
		Wheat forage			0.40	3.76
	CF 1210	Wheat germ			0.63	

Definition of the residue (for compliance with the MRL for plant and animal commodities and for estimation of dietary intake for animal commodities): *Trinexapac (acid)*
Definition of the residue (for estimation of dietary intake for plant commodities): *Trinexapac and its conjugates, expressed as trinexapac acid*
The residue is not fat soluble

[a] Dry weight basis
[b] for the purpose of estimating animal dietary burdens.

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), 2012 (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 (260)	2012 (T, R)
Aminocarb (134)	1978 (T, R), 1979 (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)
Beta-cyfluthrin (228)	2007 (R)
Benzovindiflupyr (261)	2013 (T)
BHC (technical-grade)	1965 (T), 1968 (T, R), 1973 (T, R) (see also Lindane)
Bifenazate (219)	2006 (T, R), 2007 (R), 2008 (R), 2010(R)
Bifenthrin (178)	1992 (T, R), 1995 (R), 1996 (R), 1997 (R), 2009 (T), 2010 (T,R), 2011 (T,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), 2009 (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), 2013 (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 (T), 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), 2008 (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), 2007 (T)
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 (T,R), 2012 (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), 2009 (R), 2010 (R), 2013 (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)	2012 (T, R), 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), 2012 (R), 2013 (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), 2013 (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)
Cyfluthrin (157)	1986 (R), 1987 (T and corr. to 1986 report), 1989 (R), 1990 (R), 1992 (R), 2006 (T), 2007 (R), 2009 (R), 2012 (R)
Cyhalothrin (146)	1984 (T, R), 1986 (R), 1988 (R), 2007 (T), 2008 (T, 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), 3010 (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 (204)	2010 (T, R), 2011 (R), 2012 (R), 2013 (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), 2003 (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), 2012 (T)
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	2007 (T, 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 (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 maneb, mancozeb)
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)
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)
Fenamidone (264)	2013 (T)
Famoxadone (208)	2003 (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)
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 (193)	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)
Flumethrin (195)	1996 (T, R)
Fluopicolide (235)	2009 (T, R), 2010 (T)
Fluopyram (243)	2010 (T, R), 2012 (R)
Flusilazole (165)	1989 (T, R), 1990 (R), 1991 (R), 1993 (R), 1995 (T), 2007 (T, R), 2008 (T)
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), 2013 (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), 2011 (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)
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), 2011 (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), 2012 (T)
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), 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)
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), 2009 (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
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)
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 (R), 2008 (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), 2010 (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), 2009 (R), 2012 (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 (T)

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), 2009 (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)
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), 2007 (R), 2013 (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), 2013 (T)
Propylenethiourea (PTU, 150)	1993 (T, R), 1994 (R), 1999 (T)
Prothioconazole (232)	2008 (T, R), 2009 (R)
Pyraclostrobin (210)	2003 (T), 2004 (R), 2006 (R), 2011 (R), 2012 (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	2007 (T, R), 2013 (R)
Pyriproxyfen (200)	1999 (R,T), 2000 (R), 2001 (T)
Quinoxyfen (223)	2006 (T, R), 2007 (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), 2012 (R)
Sedaxane (259)	2012 (T, 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), 2009 (R), 2011 (R), 2012 (R), 2013 (R)
Sulfoxaflor (252)	2011 (T, R), 2013 (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), 2007 (R)
Thiacloprid (223)	2006 (T, R)
Thiamethoxam (245)	2010 (T, R), 2011 (R), 2012 (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, R)
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), 2009 (R)
Triadimenol (168)	1989 (T, R), 1992 (R), 1995 (R), 2004 (T), 2007 (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)
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

AZOXYSTROBIN (229) International Estimated Daily Intake (IEDI) ADI = 0 - 0.2 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day A diet	Intake = daily intake: µg/person intake	B diet	intake	C diet	intake	D Diet	intake	E diet	intake	F diet	intake
TN 0660	Almond	0.01	0.0	0.0	1.9	0.0	1.0	0.0	0.0	0.0	1.0	0.0	0.8	0.0
VS 0620	Artichoke globe	1.8	0.0	0.0	10.0	18.0	2.1	3.8	0.1	0.2	0.8	1.4	0.1	0.2
VS 0621	Asparagus	0.01	0.0	0.0	1.1	0.0	0.6	0.0	0.2	0.0	1.2	0.0	0.1	0.0
FI 0327	Banana	0.03	38.8	1.2	17.4	0.5	16.0	0.5	6.6	0.2	21.5	0.6	33.8	1.0
GC 0640	Barley (incl pot, incl pearled, incl flour & grits, excl beer)	0.05	40.6	2.0	0.0	0.0	93.9	4.7	0.0	0.0	0.0	0.0	3.8	0.2
-	Barley beer	0.0015	18.3	0.0	84.1	0.1	4.1	0.0	66.0	0.1	243.1	0.4	161.3	0.2
VR 0574	Beetroot	0.23	0.0	0.0	40.7	9.4	0.0	0.0	0.1	0.0	6.0	1.4	0.1	0.0
FB 0264	Blackberries	1	0.0	0.0	0.1	0.1	0.0	0.0	0.3	0.3	0.1	0.1	0.3	0.3
FB 0020	Blueberries	1	0.0	0.0	0.0	0.0	0.0	0.0	0.2	0.2	0.3	0.3	0.8	0.8
FB 4079	Boysenberry	1	0.0	0.0	0.0	0.0	0.0	0.0	0.3	0.3	0.0	0.0	0.3	0.3
TN 0662	Brazil nut	0.01	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0
VB 0402	Brussels sprouts	1.2	0.0	0.0	0.1	0.1	2.8	3.4	5.5	6.6	1.5	1.8	1.9	2.3
VA 0035	Bulb vegetables	2.2	8.5	18.7	60.3	132.7	37.7	82.9	37.2	81.8	31.8	70.0	16.7	36.7
VB 0041	Cabbage, head	1.2	1.2	1.4	14.4	17.3	2.7	3.2	16.4	19.7	15.4	18.5	18.5	22.2
FT 0289	Carambola	0.023	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
VR 0577	Carrot	0.23	0.6	0.1	15.1	3.5	8.1	1.9	13.9	3.2	27.1	6.2	28.4	6.5
TN 0295	Cashew nut	0.01	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.3	0.0	0.0	0.0
VR 0463	Cassava (incl flour, incl tapioca)	0.23	242.8	55.8	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
VR 0578	Celeriac	0.23	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
VS 0624	Celery	0.43	0.0	0.0	0.9	0.4	0.0	0.0	2.0	0.9	1.5	0.6	0.0	0.0
VC 0423	Chayote	0.17	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
TN 0664	Chestnut	0.01	0.0	0.0	1.7	0.0	0.0	0.0	0.2	0.0	0.3	0.0	0.0	0.0
VR 0469	Chicory, roots	0.23	0.0	0.0	0.2	0.0	0.0	0.0	0.6	0.1	4.5	1.0	0.0	0.0
FC 0001	Citrus fruit (incl lemon juice, incl mandarin juice, excl orange juice, incl grapefruit juice, incl NES juice)	4.9	15.7	76.9	96.7	473.9	55.3	270.9	25.3	123.9	23.4	114.9	16.2	79.5
TN 0665	Coconut (incl oil)	0.01	2.9	0.0	13.5	0.1	2.1	0.0	1.5	0.0	1.8	0.0	8.9	0.1
SB 0716	Coffee beans (incl green, incl extracts, excl roasted)	0.01	2.7	0.0	6.6	0.1	2.4	0.0	0.8	0.0	0.7	0.0	1.6	0.0
SM 0716	Coffee beans, roasted	0.006	0.4	0.0	6.0	0.0	0.5	0.0	0.6	0.0	9.4	0.1	16.4	0.1
SO 0691	Cotton seed (for oil processing only)	0.01	5.6	0.1	30.6	0.3	10.6	0.1	41.3	0.4	0.0	0.0	1.9	0.0

Annex 3

AZOXYSTROBIN (229) International Estimated Daily Intake (IEDI) ADI = 0 - 0.2 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day; Intake = daily intake: µg/person											
			A diet	intake	B diet	intake	C diet	intake	D Diet	intake	E diet	intake	F diet	intake
FB 0265	Cranberries	0.23	0.1	0.0	0.0	0.0	0.0	0.0	0.3	0.1	0.0	0.0	0.6	0.1
VC 0424	Cucumber	0.17	0.3	0.1	12.7	2.2	5.9	1.0	11.5	2.0	6.1	1.0	7.1	1.2
FB 0021	Currants, red, black, white	1	0.0	0.0	0.0	0.0	0.0	0.0	2.2	2.2	3.1	3.1	2.0	2.0
FB 0266	Dewberries, incl boysen- & loganberry	1	0.0	0.0	0.0	0.0	0.0	0.0	0.3	0.3	0.0	0.0	0.3	0.3
DH 0170	Dried herbs (excl dry hops)	152	0.2	35.0	0.3	42.6	0.2	36.5	0.4	60.8	0.3	45.6	0.0	1.5
MO 0105	Edible offal (mammalian)	0.02	3.9	0.1	14.4	0.3	5.2	0.1	11.8	0.2	11.7	0.2	7.6	0.2
VO 0440	Egg plant (= aubergine)	0.35	1.7	0.6	17.5	6.1	12.3	4.3	1.7	0.6	0.8	0.3	0.4	0.1
PE 0112	Eggs	0	2.5	0.0	29.7	0.0	25.1	0.0	24.5	0.0	37.8	0.0	27.4	0.0
FB 0267	Elderberries	1	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
VB 0042	Flowerhead brassicas	1.2	0.2	0.2	11.1	13.3	3.6	4.3	0.4	0.5	7.7	9.2	4.1	4.9
VC 0425	Gherkin	0.17	0.3	0.1	12.7	2.2	5.9	1.0	11.5	2.0	6.1	1.0	7.1	1.2
FB 0268	Gooseberries	1	0.0	0.0	12.0	12.0	0.0	0.0	0.6	0.6	1.1	1.1	0.2	0.2
FB 0269	Grape (excl dried, excl juice, excl wine)	0.53	1.9	1.0	9.2	4.9	23.8	12.6	9.8	5.2	0.0	0.0	0.0	0.0
JF 0269	Grape juice	0.19	0.0	0.0	0.1	0.0	0.1	0.0	0.1	0.0	1.4	0.3	1.0	0.2
DF 0269	Grape, dried (= currants, raisins and sultanas)	0.24	0.0	0.0	2.9	0.7	0.4	0.1	0.4	0.1	2.3	0.6	1.7	0.4
TN 0666	Hazelnut	0.01	0.0	0.0	2.1	0.0	0.0	0.0	0.1	0.0	1.3	0.0	0.3	0.0
HH 0720	Herbs	23	2.3	52.9	2.8	64.4	2.4	55.2	4.0	92.0	3.0	69.0	0.1	2.3
DH 1100	Hops, dry	11	0.1	1.1	0.1	1.1	0.1	1.1	0.1	1.1	0.3	3.3	0.1	1.1
VR 0583	Horseradish	0.23	0.0	0.0	2.2	0.5	0.0	0.0	2.0	0.5	0.0	0.0	0.0	0.0
VR 0585	Jerusalem artichoke	0.23	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
VB 0405	Kohlrabi	1.2	0.3	0.4	0.1	0.1	0.0	0.0	5.5	6.6	12.3	14.8	1.9	2.3
VP 0060	Legume vegetables	1	6.1	6.1	23.0	23.0	18.0	18.0	12.8	12.8	26.9	26.9	5.3	5.3
VL 0482	Lettuce, head	0.28	0.1	0.0	6.2	1.7	0.7	0.2	0.1	0.0	0.1	0.0	0.0	0.0
VL 0483	Lettuce, leaf	0.28	0.0	0.0	9.2	2.6	1.0	0.3	0.1	0.0	5.4	1.5	18.0	5.0
TN 0669	Macadamia nut	0.01	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CF 1255	Maize flour	0.01	68.9	0.7	15.4	0.2	51.3	0.5	16.6	0.2	14.7	0.1	2.0	0.0
GC 0645	Maize (excl flour, excl oil, incl beer)	0.01	0.0	0.0	1.4	0.0	51.4	0.5	11.9	0.1	0.2	0.0	0.2	0.0
OR 0645	Maize oil, edible	0.06	0.1	0.0	4.0	0.2	2.3	0.1	0.5	0.0	0.9	0.1	0.2	0.0
MF 0100	Mammalian fats (except milk fats)	0.015	0.8	0.0	10.0	0.2	0.9	0.0	6.6	0.1	11.8	0.2	3.7	0.1
FI 0345	Mango (incl juice, incl pulp)	0.05	6.3	0.3	1.0	0.1	4.6	0.2	0.2	0.0	0.7	0.0	0.3	0.0
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.015	5.5	0.1	23.3	0.3	7.7	0.1	11.0	0.2	18.0	0.3	26.3	0.4
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0.01	22.2	0.2	93.2	0.9	30.8	0.3	44.1	0.4	72.2	0.7	105.0	1.1
VC 0046	Melons, except watermelon	0.02	3.6	0.1	26.7	0.5	22.6	0.5	11.5	0.2	5.6	0.1	2.0	0.0

Annex 3

AZOXYSTROBIN (229) International Estimated Daily Intake (IEDI) ADI = 0 - 0.2 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day A diet	Intake = daily intake: µg/person intake	B diet	intake	C diet	intake	D Diet	intake	E diet	intake	F diet	intake
ML 0106	Milks (excl processed products)	0.01	68.8	0.7	190.6	1.9	79.4	0.8	302.6	3.0	179.6	1.8	237.9	2.4
GC 0647	Oats (incl rolled)	0.05	1.4	0.1	0.6	0.0	0.2	0.0	4.2	0.2	5.7	0.3	8.9	0.4
VO 0442	Okra	0.35	3.9	1.4	1.0	0.4	5.3	1.9	0.1	0.0	0.0	0.0	0.0	0.0
JF 0004	Orange juice	0.39	0.0	0.0	2.1	0.8	4.4	1.7	1.4	0.5	16.2	6.3	22.6	8.8
FI 0350	Papaya	0.02	5.1	0.1	0.1	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0
VR 0588	Parsnip	0.23	0.0	0.0	6.8	1.6	0.0	0.0	2.0	0.5	0.5	0.1	0.0	0.0
OR 0697	Peanut oil, edible	0.03	1.7	0.1	0.8	0.0	0.5	0.0	0.1	0.0	1.4	0.0	0.4	0.0
SO 0697	Peanut, shelled (excl oil)	0.01	1.5	0.0	1.3	0.0	1.0	0.0	0.5	0.0	0.8	0.0	0.5	0.0
TN 0672	Pecan	0.01	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0
VO 0051	Peppers	0.35	1.4	0.5	29.9	10.5	13.0	4.6	6.3	2.2	6.2	2.2	4.0	1.4
TN 0673	Pine nut	0.01	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
TN 0675	Pistachio nut	0.44	0.0	0.0	0.7	0.3	0.5	0.2	0.9	0.4	0.3	0.1	0.0	0.0
FI 0354	Plantain	0.03	275.7	8.3	1.7	0.1	0.0	0.0	0.1	0.0	0.3	0.0	0.0	0.0
DF 0014	Plum, dried (prunes)	0.14	0.0	0.0	0.2	0.0	0.0	0.0	0.1	0.0	0.5	0.1	0.6	0.1
VR 0589	Potato (incl flour, frozen, starch, tapioca)	2.3	19.1	43.9	160.8	369.8	61.2	140.8	243.6	560.3	230.1	529.2	204.7	470.8
PM 0110	Poultry meat	0	7.1	0.0	58.5	0.0	31.9	0.0	24.0	0.0	61.0	0.0	27.3	0.0
PO 0111	Poultry, edible offal of	0	0.4	0.0	0.4	0.0	1.7	0.0	0.1	0.0	0.6	0.0	0.2	0.0
VD 0070	Pulses (excl soya beans)	0.01	44.6	0.4	26.5	0.3	17.1	0.2	14.4	0.1	14.1	0.1	8.7	0.1
VR 0494	Radish	0.23	0.0	0.0	1.3	0.3	0.6	0.1	2.0	0.5	1.2	0.3	0.0	0.0
VR 0590	Radish, black	0.23	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
VR 0591	Radish, Japanese	0.23	2.3	0.5	0.0	0.0	0.0	0.0	2.0	0.5	0.0	0.0	0.0	0.0
FB 0272	Raspberries, red, black	1	0.0	0.0	0.0	0.0	0.0	0.0	1.8	1.8	0.9	0.9	0.2	0.2
GC 0649	Rice (incl husked, excl polished)	0.68	46.3	31.5	0.3	0.2	3.4	2.3	9.1	6.2	4.3	2.9	0.6	0.4
CM 1205	Rice, polished (incl flour)	0.06	29.8	1.8	20.9	1.3	60.8	3.6	16.1	1.0	5.6	0.3	8.1	0.5
-	Roots and tubers NES	0.23	110.0	25.3	84.1	19.3	0.1	0.0	0.0	0.0	47.3	10.9	0.0	0.0
GC 0650	Rye (incl flour)	0.01	0.1	0.0	3.7	0.0	0.3	0.0	24.3	0.2	25.8	0.3	45.8	0.5
VR 0498	Salsify	0.23	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
GC 0651	Sorghum (incl flour, incl beer)	1.85	36.9	68.3	0.0	0.0	10.2	18.9	0.0	0.0	0.0	0.0	0.0	0.0
VD 0541	Soya bean (dry, excl oil)	0.06	0.9	0.1	0.0	0.0	0.7	0.0	0.0	0.0	0.0	0.0	0.0	0.0
OR 0541	Soya bean oil, refined	0.05	1.6	0.1	6.5	0.3	6.0	0.3	4.0	0.2	6.3	0.3	7.0	0.4
VC 0431	Squash, summer (= courgette, zuchini)	0.17	0.0	0.0	8.3	1.4	11.4	1.9	7.3	1.2	3.2	0.5	0.3	0.1
FS 0012	Stone fruit (excl dried plums, incl dried apricots)	0.74	0.7	0.5	44.1	32.6	14.1	10.4	26.6	19.7	26.3	19.4	8.3	6.1
FB 0275	Strawberry	1.3	0.0	0.0	5.0	6.5	2.0	2.6	1.7	2.2	5.2	6.8	4.1	5.3
VR 0596	Sugar beet	0.08	0.0	0.0	40.7	3.3	0.0	0.0	0.1	0.0	6.0	0.5	0.1	0.0

Annex 3

AZOXYSTROBIN (229) International Estimated Daily Intake (IEDI) ADI = 0 - 0.2 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A diet	intake	B diet	intake	C diet	intake	D Diet	intake	E diet	intake	F diet	intake
SO 0702	Sunflower seed (excl oil)	0.04	0.0	0.0	13.1	0.5	0.0	0.0	0.1	0.0	0.1	0.0	0.1	0.0
OR 0702	Sunflower seed oil, edible	0.01	0.3	0.0	13.1	0.1	8.6	0.1	12.3	0.1	8.8	0.1	2.2	0.0
VR 0497	Swede	0.23	0.0	0.0	0.0	0.0	0.0	0.0	2.0	0.5	0.8	0.2	14.0	3.2
VR 0508	Sweet potato	0.23	60.5	13.9	0.6	0.1	5.2	1.2	0.0	0.0	0.0	0.0	0.0	0.0
VR 0504	Tannia	0.23	0.1	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
VR 0505	Taro	0.23	29.6	6.8	0.1	0.0	1.5	0.3	0.0	0.0	0.0	0.0	0.0	0.0
VO 0448	Tomato (excl juice, excl paste, incl canned)	0.35	3.3	1.2	179.2	62.7	103.5	36.2	54.1	18.9	7.8	2.7	3.9	1.4
JF 0448	Tomato juice	0.13	5.2	0.7	0.5	0.1	0.4	0.1	2.1	0.3	6.9	0.9	15.2	2.0
-d	Tomato paste	0.19	0.5	0.1	1.3	0.2	3.5	0.7	1.0	0.2	3.8	0.7	4.5	0.9
GC 0653	Triticale (incl flour)	0.01	0.0	0.0	115.8	1.2	0.0	0.0	0.0	0.0	0.3	0.0	0.0	0.0
VR 0506	Turnip, garden	0.23	0.0	0.0	0.1	0.0	0.8	0.2	2.0	0.5	0.6	0.1	14.0	3.2
FB 0019	Vaccinium berries (incl. bearberry)	1	0.1	0.1	0.0	0.0	0.0	0.0	0.5	0.5	0.3	0.3	1.4	1.4
TN 0678	Walnut	0.01	0.0	0.0	1.3	0.0	0.0	0.0	0.1	0.0	0.3	0.0	0.1	0.0
VC 0432	Watermelon	0.02	6.1	0.1	43.1	0.9	47.1	0.9	25.8	0.5	4.4	0.1	6.0	0.1
GC 0654	Wheat (incl bulgur wholemeal, excl flour)	0.01	6.0	0.1	11.1	0.1	0.8	0.0	0.2	0.0	0.2	0.0	0.0	0.0
CM 0654	Wheat bran, unprocessed	0.004	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CF 1211	Wheat flour (incl macaroni, bread, pastry, starch, gluten)	0.003	63.4	0.2	296.3	0.9	327.5	1.0	300.0	0.9	181.6	0.5	166.2	0.5
CP 1211	White bread	0.001	0.0	0.0	0.1	0.0	0.0	0.0	0.1	0.0	0.1	0.0	1.0	0.0
CP 1212	Wholemeal bread	0.001	0.0	0.0	0.1	0.0	0.0	0.0	0.1	0.0	0.1	0.0	1.0	0.0
-	Wine	0.36	1.3	0.5	76.8	27.6	1.1	0.4	15.4	5.5	68.8	24.8	25.6	9.2
VC 0433	Winter squash (= pumpkin)	0.02	0.0	0.0	0.5	0.0	1.5	0.0	7.3	0.1	0.0	0.0	0.3	0.0
VS 0469	Witloof chicory (sprouts)	0.05	0.0	0.0	0.2	0.0	0.0	0.0	0.1	0.0	1.6	0.1	0.0	0.0
VR 0600	Yams	0.23	63.2	14.5	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Total intake (µg/person)=			476.9		1382.2		739.9		1055.5		1010.8		699.8
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			12000		12000		12000		12000		12000		12000
	%ADI=			4.0%		11.5%		6.2%		8.8%		8.4%		5.8%
	Rounded %ADI=			4%		10%		6%		9%		8%		6%

Annex 3

AZOXYSTROBIN (229) International Estimated Daily Intake (IEDI) ADI = 0 - 0.2 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day		Intake = daily intake: µg/person											
			G		H		I		J		K		L		M	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
TN 0660	Almond	0.01	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.3	0.0	0.3	0.0
VS 0620	Artichoke globe	1.8	0.1	0.2	0.1	0.2	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	1.8
VS 0621	Asparagus	0.01	3.7	0.0	0.3	0.0	0.2	0.0	0.0	0.0	0.0	0.0	0.5	0.0	1.1	0.0
FI 0327	Banana	0.03	21.4	0.6	36.6	1.1	11.4	0.3	9.2	0.3	70.2	2.1	40.5	1.2	32.6	1.0
GC 0640	Barley (incl pot, incl pearled, incl flour & grits, excl beer)	0.05	1.5	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.4	0.0	0.0	0.0
-	Barley beer	0.0015	21.9	0.0	102.7	0.2	29.5	0.0	12.6	0.0	100.9	0.2	82.2	0.1	218.8	0.3
VR 0574	Beetroot	0.23	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.2	0.0	0.0	0.0	14.3	3.3
FB 0264	Blackberries	1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.1	0.0	0.0	0.3	0.3
FB 0020	Blueberries	1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.3	1.3
FB 4079	Boysenberry	1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.1	0.0	0.0	0.0	0.0
TN 0662	Brazil nut	0.01	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.1	0.0
VB 0402	Brussels sprouts	1.2	3.4	4.1	0.4	0.5	0.0	0.0	0.0	0.0	0.5	0.6	7.9	9.5	0.3	0.4
VA 0035	Bulb vegetables	2.2	31.6	69.5	29.6	65.1	9.7	21.3	19.6	43.1	25.7	56.5	47.2	103.8	33.1	72.8
VB 0041	Cabbage, head	1.2	10.0	12.0	1.0	1.2	7.2	8.6	1.0	1.2	1.4	1.7	23.9	28.7	17.0	20.4
FT 0289	Carambola	0.023	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
VR 0577	Carrot	0.23	5.4	1.2	7.9	1.8	2.5	0.6	3.5	0.8	4.1	0.9	8.6	2.0	19.4	4.5
TN 0295	Cashew nut	0.01	0.2	0.0	0.0	0.0	0.2	0.0	0.0	0.0	0.1	0.0	0.1	0.0	0.6	0.0
VR 0463	Cassava (incl flour, incl tapioca)	0.23	15.6	3.6	23.9	5.5	171.3	39.4	282.2	64.9	57.7	13.3	20.0	4.6	0.8	0.2
VR 0578	Celeriac	0.23	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
VS 0624	Celery	0.43	0.0	0.0	0.3	0.1	0.0	0.0	0.0	0.0	1.0	0.4	0.0	0.0	4.2	1.8
VC 0423	Chayote	0.17	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
TN 0664	Chestnut	0.01	0.5	0.0	0.7	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.5	0.0	0.0	0.0
VR 0469	Chicory, roots	0.23	0.0	0.0	0.0	0.0	1.1	0.3	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
FC 0001	Citrus fruit (incl lemon juice, incl mandarin juice, excl orange juice, incl grapefruit juice, incl NES juice)	4.9	16.9	83.0	155.0	759.5	8.6	42.1	42.5	208.3	220.5	1080.3	28.9	141.5	30.1	147.3
TN 0665	Coconut (incl oil)	0.01	15.3	0.2	13.4	0.1	9.3	0.1	1.6	0.0	18.9	0.2	26.7	0.3	3.4	0.0
SB 0716	Coffee beans (incl green, incl extracts, excl roasted)	0.01	0.2	0.0	5.7	0.1	0.4	0.0	0.2	0.0	4.5	0.0	5.4	0.1	5.4	0.1
SM 0716	Coffee beans, roasted	0.006	0.0	0.0	1.3	0.0	0.1	0.0	0.0	0.0	0.8	0.0	0.3	0.0	7.0	0.0
SO 0691	Cotton seed (for oil processing only)	0.01	6.3	0.1	4.4	0.0	6.3	0.1	8.8	0.1	9.4	0.1	34.4	0.3	7.5	0.1
FB 0265	Cranberries	0.23	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	2.5	0.6

Annex 3

AZOXYSTROBIN (229) International Estimated Daily Intake (IEDI) ADI = 0 - 0.2 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G		H		I		J		K		L		M	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
VC 0424	Cucumber	0.17	7.9	1.3	0.6	0.1	0.2	0.0	0.0	0.0	0.4	0.1	5.5	0.9	5.3	0.9
FB 0021	Currants, red, black, white	1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
FB 0266	Dewberries, incl boysen- & loganberry	1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.1	0.0	0.0	0.1	0.1
DH 0170	Dried herbs (excl dry hops)	152	0.7	106.4	0.1	9.1	0.2	35.0	0.3	50.2	0.2	30.4	0.1	18.2	0.1	7.6
MO 0105	Edible offal (mammalian)	0.02	4.8	0.1	10.7	0.2	4.0	0.1	4.0	0.1	6.5	0.1	6.6	0.1	5.6	0.1
VO 0440	Egg plant (= aubergine)	0.35	20.1	7.0	0.1	0.0	0.6	0.2	6.3	2.2	0.5	0.2	6.3	2.2	0.7	0.2
PE 0112	Eggs	0	22.1	0.0	71.5	0.0	16.6	0.0	5.1	0.0	17.6	0.0	35.2	0.0	57.4	0.0
FB 0267	Elderberries	1	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
VB 0042	Flowerhead brassicas	1.2	9.6	11.5	7.9	9.5	0.6	0.7	0.2	0.2	0.9	1.1	1.1	1.3	8.0	9.6
VC 0425	Gherkin	0.17	7.9	1.3	0.6	0.1	0.2	0.0	0.0	0.0	0.4	0.1	5.5	0.9	5.3	0.9
FB 0268	Gooseberries	1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	1.0	0.0	0.0	0.0	0.0
FB 0269	Grape (excl dried, excl juice, excl wine)	0.53	1.2	0.6	2.6	1.4	0.0	0.0	0.2	0.1	0.0	0.0	3.7	2.0	0.0	0.0
JF 0269	Grape juice	0.19	0.0	0.0	0.1	0.0	1.0	0.2	0.0	0.0	0.6	0.1	0.4	0.1	3.6	0.7
DF 0269	Grape, dried (= currants, raisins and sultanas)	0.24	0.0	0.0	0.2	0.0	0.2	0.0	0.0	0.0	0.3	0.1	0.4	0.1	2.6	0.6
TN 0666	Hazelnut	0.01	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.0
HH 0720	Herbs	23	7.0	161.0	0.6	13.8	2.3	52.9	3.3	75.9	2.0	46.0	1.2	27.6	0.5	11.5
DH 1100	Hops, dry	11	0.0	0.0	0.1	1.1	0.1	1.1	0.1	1.1	0.1	1.1	0.1	1.1	0.6	6.6
VR 0583	Horseradish	0.23	7.0	1.6	0.3	0.1	0.0	0.0	0.0	0.0	1.0	0.2	7.4	1.7	0.0	0.0
VR 0585	Jerusalem artichoke	0.23	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
VB 0405	Kohlrabi	1.2	3.4	4.1	0.0	0.0	0.0	0.0	0.3	0.4	0.5	0.6	7.9	9.5	0.7	0.8
VP 0060	Legume vegetables	1	19.6	19.6	6.2	6.2	6.9	6.9	6.0	6.0	1.7	1.7	29.5	29.5	26.3	26.3
VL 0482	Lettuce, head	0.28	1.2	0.3	3.5	1.0	0.1	0.0	0.3	0.1	1.0	0.3	1.2	0.3	7.9	2.2
VL 0483	Lettuce, leaf	0.28	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	2.5	0.7
TN 0669	Macadamia nut	0.01	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CF 1255	Maize flour	0.01	28.8	0.3	248.8	2.5	206.7	2.1	47.8	0.5	46.2	0.5	10.5	0.1	21.5	0.2
GC 0645	Maize (excl flour, excl oil, incl beer)	0.01	0.6	0.0	0.0	0.0	0.1	0.0	0.0	0.0	7.7	0.1	0.0	0.0	19.4	0.2
OR 0645	Maize oil, edible	0.06	0.1	0.0	0.6	0.0	1.8	0.1	0.0	0.0	1.0	0.1	1.6	0.1	1.8	0.1
MF 0100	Mammalian fats (except milk fats)	0.015	2.2	0.0	18.6	0.3	0.5	0.0	0.8	0.0	5.7	0.1	4.5	0.1	18.2	0.3
FI 0345	Mango (incl juice, incl pulp)	0.05	12.7	0.6	26.2	1.3	6.1	0.3	12.7	0.6	9.2	0.5	8.0	0.4	1.9	0.1
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.015	11.0	0.2	17.9	0.3	6.1	0.1	5.7	0.1	16.4	0.2	12.2	0.2	31.7	0.5
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0.01	43.8	0.4	71.5	0.7	24.5	0.2	22.9	0.2	65.7	0.7	48.9	0.5	126.6	1.3
VC 0046	Melons, except watermelon	0.02	7.5	0.2	6.1	0.1	0.7	0.0	1.4	0.0	2.5	0.1	6.9	0.1	12.4	0.2
ML 0106	Milks (excl processed products)	0.01	66.0	0.7	121.1	1.2	81.6	0.8	102.4	1.0	207.7	2.1	57.0	0.6	287.9	2.9

Annex 3

AZOXYSTROBIN (229) International Estimated Daily Intake (IEDI) ADI = 0 - 0.2 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day; Intake = daily intake: µg/person													
			G		H		I		J		K		L		M	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
GC 0647	Oats (incl rolled)	0.05	0.2	0.0	2.0	0.1	0.8	0.0	0.0	0.0	3.5	0.2	0.7	0.0	7.6	0.4
VO 0442	Okra	0.35	4.1	1.4	1.0	0.4	7.0	2.5	15.9	5.6	1.1	0.4	3.9	1.4	0.2	0.1
JF 0004	Orange juice	0.39	0.2	0.1	1.0	0.4	3.5	1.4	0.0	0.0	1.3	0.5	6.4	2.5	56.8	22.2
FI 0350	Papaya	0.02	1.3	0.0	11.5	0.2	1.6	0.0	13.7	0.3	14.5	0.3	1.0	0.0	0.6	0.0
VR 0588	Parsnip	0.23	0.0	0.0	0.3	0.1	0.0	0.0	0.0	0.0	1.0	0.2	0.0	0.0	0.1	0.0
OR 0697	Peanut oil, edible	0.03	3.0	0.1	0.3	0.0	1.5	0.0	7.9	0.2	0.3	0.0	0.0	0.0	0.4	0.0
SO 0697	Peanut, shelled (excl oil)	0.01	0.7	0.0	1.4	0.0	1.3	0.0	3.6	0.0	0.2	0.0	0.7	0.0	6.0	0.1
TN 0672	Pecan	0.01	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.0
VO 0051	Peppers	0.35	8.7	3.0	22.4	7.8	8.4	2.9	9.4	3.3	3.3	1.2	5.3	1.9	8.9	3.1
TN 0673	Pine nut	0.01	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
TN 0675	Pistachio nut	0.44	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.2	0.1
FI 0354	Plantain	0.03	1.8	0.1	51.2	1.5	93.3	2.8	40.6	1.2	39.2	1.2	1.1	0.0	1.9	0.1
DF 0014	Plum, dried (prunes)	0.14	0.1	0.0	0.2	0.0	0.0	0.0	0.0	0.0	0.2	0.0	0.2	0.0	0.6	0.1
VR 0589	Potato (incl flour, frozen, starch, tapioca)	2.3	52.7	121.2	57.1	131.3	50.1	115.2	4.3	9.9	54.7	125.8	41.0	94.3	168.0	386.4
PM 0110	Poultry meat	0	17.6	0.0	131.3	0.0	25.1	0.0	4.7	0.0	145.9	0.0	27.7	0.0	115.1	0.0
PO 0111	Poultry, edible offal of	0	0.4	0.0	1.0	0.0	1.9	0.0	0.0	0.0	0.7	0.0	1.0	0.0	0.3	0.0
VD 0070	Pulses (excl soya beans)	0.01	16.0	0.2	32.4	0.3	24.7	0.2	34.2	0.3	50.7	0.5	8.0	0.1	16.9	0.2
VR 0494	Radish	0.23	0.0	0.0	0.3	0.1	0.0	0.0	0.0	0.0	1.0	0.2	0.0	0.0	0.3	0.1
VR 0590	Radish, black	0.23	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
VR 0591	Radish, Japanese	0.23	7.0	1.6	0.3	0.1	2.3	0.5	3.3	0.8	1.0	0.2	7.4	1.7	0.0	0.0
FB 0272	Raspberries, red, black	1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.2	0.2	0.0	0.0	0.5	0.5
GC 0649	Rice (incl husked, excl polished)	0.68	1.4	1.0	1.0	0.7	2.3	1.6	29.6	20.1	92.0	62.6	9.2	6.2	0.4	0.3
CM 1205	Rice, polished (incl flour)	0.06	250.3	15.0	42.2	2.5	23.8	1.4	29.8	1.8	97.6	5.9	248.1	14.9	22.8	1.4
-	Roots and tubers NES	0.23	1.0	0.2	5.6	1.3	3.8	0.9	1.8	0.4	2.0	0.5	3.3	0.8	0.1	0.0
GC 0650	Rye (incl flour)	0.01	0.4	0.0	0.0	0.0	0.2	0.0	0.1	0.0	0.1	0.0	0.9	0.0	0.8	0.0
VR 0498	Salsify	0.23	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
GC 0651	Sorghum (incl flour, incl beer)	1.85	9.8	18.1	19.9	36.8	18.6	34.4	112.3	207.8	0.1	0.2	3.3	6.1	3.0	5.6
VD 0541	Soya bean (dry, excl oil)	0.06	1.8	0.1	0.0	0.0	0.0	0.0	3.2	0.2	0.1	0.0	0.0	0.0	0.0	0.0
OR 0541	Soya bean oil, refined	0.05	4.3	0.2	10.6	0.5	2.0	0.1	1.4	0.1	19.5	1.0	9.2	0.5	22.0	1.1
VC 0431	Squash, summer (= courgette, zuchini)	0.17	2.4	0.4	1.5	0.3	0.0	0.0	0.0	0.0	3.8	0.6	2.2	0.4	2.5	0.4
FS 0012	Stone fruit (excl dried plums, incl dried apricots)	0.74	6.7	5.0	4.3	3.2	1.4	1.0	0.1	0.1	4.9	3.6	4.9	3.6	17.7	13.1
FB 0275	Strawberry	1.3	0.0	0.0	1.8	2.3	0.1	0.1	0.0	0.0	0.3	0.4	6.2	8.1	5.9	7.7
VR 0596	Sugar beet	0.08	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.2	0.0	0.0	0.0	14.3	1.1
SO 0702	Sunflower seed (excl oil)	0.04	0.1	0.0	0.2	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.1	0.0	1.8	0.1

Annex 3

AZOXYSTROBIN (229) International Estimated Daily Intake (IEDI) ADI = 0 - 0.2 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G		H		I		J		K		L		M	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
OR 0702	Sunflower seed oil, edible	0.01	1.1	0.0	3.6	0.0	5.6	0.1	0.1	0.0	1.5	0.0	0.2	0.0	3.6	0.0
VR 0497	Swede	0.23	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.2	0.0	0.0	1.1	0.3
VR 0508	Sweet potato	0.23	47.4	10.9	7.8	1.8	22.0	5.1	20.9	4.8	5.5	1.3	20.8	4.8	6.1	1.4
VR 0504	Tannia	0.23	0.1	0.0	1.6	0.4	0.1	0.0	0.1	0.0	7.5	1.7	0.1	0.0	0.1	0.0
VR 0505	Taro	0.23	2.7	0.6	0.0	0.0	50.3	11.6	12.7	2.9	1.5	0.3	6.7	1.5	0.3	0.1
VO 0448	Tomato (excl juice, excl paste, incl canned)	0.35	23.1	8.1	22.3	7.8	12.5	4.4	5.6	2.0	33.2	11.6	1.3	0.5	41.7	14.6
JF 0448	Tomato juice	0.13	0.0	0.0	0.8	0.1	0.1	0.0	7.2	0.9	0.0	0.0	2.4	0.3	45.2	5.9
-d	Tomato paste	0.19	0.1	0.0	2.1	0.4	0.6	0.1	0.4	0.1	0.6	0.1	1.4	0.3	1.2	0.2
GC 0653	Triticale (incl flour)	0.01	1.3	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
VR 0506	Turnip, garden	0.23	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.2	0.0	0.0	0.4	0.1
FB 0019	Vaccinium berries (incl. bearberry)	1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	3.8	3.8
TN 0678	Walnut	0.01	0.2	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.4	0.0
VC 0432	Watermelon	0.02	39.3	0.8	14.0	0.3	2.5	0.1	13.6	0.3	8.4	0.2	14.5	0.3	13.6	0.3
GC 0654	Wheat (incl bulgur wholemeal, excl flour)	0.01	0.0	0.0	0.9	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.1	0.0
CM 0654	Wheat bran, unprocessed	0.004	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CF 1211	Wheat flour (incl macaroni, bread, pastry, starch, gluten)	0.003	133.0	0.4	60.1	0.2	52.4	0.2	32.2	0.1	87.7	0.3	79.6	0.2	180.1	0.5
CP 1211	White bread	0.001	0.0	0.0	2.2	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
CP 1212	Wholemeal bread	0.001	0.0	0.0	2.2	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
-	Wine	0.36	1.0	0.4	0.9	0.3	6.8	2.4	0.1	0.0	3.4	1.2	3.6	1.3	31.0	11.2
VC 0433	Winter squash (= pumpkin)	0.02	2.4	0.0	1.5	0.0	0.0	0.0	0.0	0.0	1.6	0.0	2.2	0.0	0.7	0.0
VS 0469	Witloof chicory (sprouts)	0.05	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.8	0.0
VR 0600	Yams	0.23	0.0	0.0	4.5	1.0	87.5	20.1	111.7	25.7	5.9	1.4	5.2	1.2	0.3	0.1
	Total intake (µg/person)=			681.1		1087.0		423.0		746.2		1468.1		542.7		813.1
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			11000		12000		12000		12000		12000		11000		12000
	%ADI=			6.2%		9.1%		3.5%		6.2%		12.2%		4.9%		6.8%
	Rounded %ADI=			6%		9%		4%		6%		10%		5%		7%

Annex 3

BENTAZONE (172) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0900 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A		B		C		D		E		F	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
VR 0589	Potato (incl flour, frozen, starch, tapioca)	0.01	19.1	0.2	160.8	1.6	61.2	0.6	243.6	2.4	230.1	2.3	204.7	2.0
-	Onion, dry	0.01	4.3	0.0	45.6	0.5	27.4	0.3	30.2	0.3	22.1	0.2	12.2	0.1
VA 0389	Spring onion	0.01	0.3	0.0	1.0	0.0	1.4	0.0	0.3	0.0	0.3	0.0	0.6	0.0
VO 0447	Sweet corn (corn-on-the-cob, only)	0.01	7.3	0.1	1.0	0.0	0.1	0.0	0.5	0.0	3.3	0.0	3.6	0.0
HH 0720	Herbs	0.0435	2.3	0.1	2.8	0.1	2.4	0.1	4.0	0.2	3.0	0.1	0.1	0.0
VP 0061	Beans except broad bean & soya bean (green pods & immature seeds)	0.01	1.0	0.0	17.4	0.2	7.5	0.1	0.9	0.0	16.4	0.2	0.1	0.0
VP 0062	Beans, shelled (immature seeds)	0.01	0.5	0.0	12.7	0.1	4.1	0.0	0.9	0.0	13.1	0.1	0.1	0.0
VP 0063	Peas (green pods and/or immature seeds)	0.05	0.1	0.0	2.9	0.1	6.0	0.3	0.6	0.0	9.7	0.5	5.2	0.3
VD 0071	Beans (dry)	0.02	15.8	0.3	6.1	0.1	1.7	0.0	6.3	0.1	1.8	0.0	5.0	0.1
VD 0541	Soya bean (dry, incl oil)	0.01	9.9	0.1	36.4	0.4	34.3	0.3	22.4	0.2	35.3	0.4	39.2	0.4
SO 0693	Linseed (incl oil)	0.02	2.6	0.1	14.2	0.3	5.7	0.1	19.2	0.4	0.0	0.0	1.3	0.0
SO 0697	Peanut, shelled (incl oil)	0	5.4	0.0	3.1	0.0	2.1	0.0	0.7	0.0	4.0	0.0	1.4	0.0
GC 0080	Cereal grains	0.01	356.9	3.6	713.9	7.1	763.0	7.6	504.5	5.0	365.2	3.7	328.7	3.3
PM 0110	Poultry meat	0	7.1	0.0	58.5	0.0	31.9	0.0	24.0	0.0	61.0	0.0	27.3	0.0
PO 0111	Poultry, edible offal of	0	0.4	0.0	0.4	0.0	1.7	0.0	0.1	0.0	0.6	0.0	0.2	0.0
ML 0106	Milks (excl processed products)	0	68.8	0.0	190.6	0.0	79.4	0.0	302.6	0.0	179.6	0.0	237.9	0.0
PE 0112	Eggs	0	2.5	0.0	29.7	0.0	25.1	0.0	24.5	0.0	37.8	0.0	27.4	0.0
	Total intake (µg/person)=			4.5		10.6		9.5		8.7		7.5		6.3
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			5400		5400		5400		5400		5400		5400
	%ADI=			0.1%		0.2%		0.2%		0.2%		0.1%		0.1%
	Rounded %ADI=			0%		0%		0%		0%		0%		0%

Annex 3

BENTAZONE (172) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0900 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G		H		I		J		K		L		M	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
VR 0589	Potato (incl flour, frozen, starch, tapioca)	0.01	52.7	0.5	57.1	0.6	50.1	0.5	4.3	0.0	54.7	0.5	41.0	0.4	168.0	1.7
-	Onion, dry	0.01	16.8	0.2	8.6	0.1	6.9	0.1	12.1	0.1	18.6	0.2	23.8	0.2	28.4	0.3
VA 0389	Spring onion	0.01	0.1	0.0	4.8	0.0	0.1	0.0	1.0	0.0	1.0	0.0	2.7	0.0	0.6	0.0
VO 0447	Sweet corn (corn-on-the-cob, only)	0.01	0.2	0.0	2.4	0.0	2.2	0.0	3.3	0.0	1.7	0.0	2.8	0.0	11.2	0.1
HH 0720	Herbs	0.0435	7.0	0.3	0.6	0.0	2.3	0.1	3.3	0.1	2.0	0.1	1.2	0.1	0.5	0.0
VP 0061	Beans except broad bean & soya bean (green pods & immature seeds)	0.01	2.6	0.0	2.6	0.0	1.0	0.0	0.5	0.0	0.6	0.0	2.8	0.0	9.8	0.1
VP 0062	Beans, shelled (immature seeds)	0.01	2.6	0.0	1.9	0.0	1.0	0.0	0.5	0.0	0.3	0.0	1.8	0.0	9.0	0.1
VP 0063	Peas (green pods and/or immature seeds)	0.05	3.9	0.2	1.6	0.1	0.4	0.0	0.0	0.0	0.9	0.0	1.0	0.1	8.6	0.4
VD 0071	Beans (dry)	0.02	3.4	0.1	25.5	0.5	7.8	0.2	2.1	0.0	44.7	0.9	5.5	0.1	7.3	0.1
VD 0541	Soya bean (dry, incl oil)	0.01	25.9	0.3	59.4	0.6	11.2	0.1	11.0	0.1	109.3	1.1	51.5	0.5	123.2	1.2
SO 0693	Linseed (incl oil)	0.02	3.9	0.1	1.9	0.0	3.0	0.1	4.0	0.1	0.0	0.0	43.3	0.9	0.9	0.0
SO 0697	Peanut, shelled (incl oil)	0	7.6	0.0	2.1	0.0	4.7	0.0	21.8	0.0	0.9	0.0	0.7	0.0	6.9	0.0
GC 0080	Cereal grains	0.01	617.0	6.2	487.1	4.9	389.4	3.9	385.7	3.9	440.2	4.4	567.7	5.7	409.9	4.1
PM 0110	Poultry meat	0	17.6	0.0	131.3	0.0	25.1	0.0	4.7	0.0	145.9	0.0	27.7	0.0	115.1	0.0
PO 0111	Poultry, edible offal of	0	0.4	0.0	1.0	0.0	1.9	0.0	0.0	0.0	0.7	0.0	1.0	0.0	0.3	0.0
ML 0106	Milks (excl processed products)	0	66.0	0.0	121.1	0.0	81.6	0.0	102.4	0.0	207.7	0.0	57.0	0.0	287.9	0.0
PE 0112	Eggs	0	22.1	0.0	71.5	0.0	16.6	0.0	5.1	0.0	17.6	0.0	35.2	0.0	57.4	0.0
	Total intake (µg/person)=			7.8		6.9		5.0		4.4		7.3		8.0		8.2
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			4950		5400		5400		5400		5400		4950		5400
	%ADI=			0.2%		0.1%		0.1%		0.1%		0.1%		0.2%		0.2%
	Rounded %ADI=			0%		0%		0%		0%		0%		0%		0%

Annex 3

CHLORANTRANILIPROLE (230) International Estimated Daily Intake (IEDI) ADI = 0 - 2.0000 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A		B		C		D		E		F	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
JF 0226	Apple juice	0	0.0	0.0	2.8	0.0	0.1	0.0	1.1	0.0	6.8	0.0	7.4	0.0
FS 0240	Apricot (excl dried)	0.13	0.3	0.0	4.2	0.5	3.6	0.5	2.9	0.4	1.3	0.2	0.1	0.0
VP 0061	Beans except broad bean & soya bean (green pods & immature seeds)	0.16	1.0	0.2	17.4	2.8	7.5	1.2	0.9	0.1	16.4	2.6	0.1	0.0
VR 0574	Beetroot	0.01	0.0	0.0	40.7	0.4	0.0	0.0	0.1	0.0	6.0	0.1	0.1	0.0
FB 0018	Berries and other small fruits	0.336	3.8	1.3	145.8	49.0	29.1	9.8	41.0	13.8	118.3	39.7	53.0	17.8
VB 0040	Brassica vegetables	0.385	1.7	0.7	25.7	9.9	9.1	3.5	27.8	10.7	36.9	14.2	26.4	10.2
VR 0577	Carrot	0.02	0.6	0.0	15.1	0.3	8.1	0.2	13.9	0.3	27.1	0.5	28.4	0.6
VR 0463	Cassava (incl flour, incl tapioca)	0.01	242.8	2.4	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
MO 1280	Cattle kidney	0.03	0.4	0.0	4.4	0.1	0.0	0.0	0.9	0.0	0.0	0.0	0.6	0.0
MO 1281	Cattle liver	0.047	0.4	0.0	4.4	0.2	1.7	0.1	0.9	0.0	1.0	0.0	0.6	0.0
VR 0578	Celeriac	0.01	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
VS 0624	Celery	2.1	0.0	0.0	0.9	1.9	0.0	0.0	2.0	4.2	1.5	3.2	0.0	0.0
-	Cereal grains (excl rice)	0.01	265.9	2.7	682.3	6.8	668.4	6.7	471.3	4.7	352.5	3.5	316.0	3.2
FS 0013	Cherries	0.2	0.0	0.0	6.8	1.4	0.9	0.2	6.2	1.2	3.6	0.7	0.4	0.1
VR 0469	Chicory, roots	0.01	0.0	0.0	0.2	0.0	0.0	0.0	0.6	0.0	4.5	0.0	0.0	0.0
FC 0001	Citrus fruit (excl lemon juice, excl mandarin juice, excl orange juice, excl grapefruit juice, excl NES juice)	0.07	15.7	1.1	86.5	6.1	52.6	3.7	24.2	1.7	16.2	1.1	12.0	0.8
-	Citrus juice NES	0.037	0.0	0.0	1.7	0.1	0.1	0.0	0.0	0.0	1.1	0.0	0.3	0.0
SB 0716	Coffee beans (incl green, incl extracts, incl roasted)	0.015	3.1	0.0	12.6	0.2	2.9	0.0	1.4	0.0	10.1	0.2	18.0	0.3
PE 0112	Eggs	0.07	2.5	0.2	29.7	2.1	25.1	1.8	24.5	1.7	37.8	2.6	27.4	1.9
VO 0050	Fruiting vegetables other than cucurbits (excl sweet corn, excl mushrooms)	0.066	18.8	1.2	233.4	15.4	148.6	9.8	68.8	4.5	38.6	2.5	45.3	3.0
VC 0045	Fruiting vegetables, cucurbits	0.065	26.6	1.7	107.5	7.0	95.9	6.2	82.2	5.3	25.4	1.7	23.2	1.5
JF 0269	Grape juice	0.0869	0.0	0.0	0.1	0.0	0.1	0.0	0.1	0.0	1.4	0.1	1.0	0.1
JF 0203	Grapefruit juice	0.037	0.0	0.0	0.2	0.0	0.1	0.0	0.1	0.0	1.1	0.0	0.2	0.0
DH 1100	Hops, dry	10.9	0.1	1.1	0.1	1.1	0.1	1.1	0.1	1.1	0.3	3.3	0.1	1.1
VR 0583	Horseradish	0.01	0.0	0.0	2.2	0.0	0.0	0.0	2.0	0.0	0.0	0.0	0.0	0.0
VR 0585	Jerusalem artichoke	0.01	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
VL 0053	Leafy vegetables	7.3	5.8	42.3	45.4	331.4	10.9	79.6	26.7	194.9	17.1	124.8	38.9	284.0
-d	Lemon juice	0.037	0.0	0.0	0.9	0.0	0.1	0.0	0.0	0.0	0.2	0.0	0.4	0.0
MF 0100	Mammalian fats (except milk fats)	0.049	0.8	0.0	10.0	0.5	0.9	0.0	6.6	0.3	11.8	0.6	3.7	0.2

Annex 3

CHLORANTRANILIPROLE (230) International Estimated Daily Intake (IEDI) ADI = 0 - 2.0000 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A		B		C		D		E		F	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.00018	5.5	0.0	23.3	0.0	7.7	0.0	11.0	0.0	18.0	0.0	26.3	0.0
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0.0072	22.2	0.2	93.2	0.7	30.8	0.2	44.1	0.3	72.2	0.5	105.0	0.8
ML 0106	Milks (excl processed products)	0.006	68.8	0.4	190.6	1.1	79.4	0.5	302.6	1.8	179.6	1.1	237.9	1.4
FS 0245	Nectarine	0.13	0.0	0.0	0.5	0.1	3.3	0.4	1.8	0.2	2.8	0.4	1.6	0.2
JF 0004	Orange juice	0.037	0.0	0.0	2.1	0.1	4.4	0.2	1.4	0.1	16.2	0.6	22.6	0.8
VR 0588	Parsnip	0.01	0.0	0.0	6.8	0.1	0.0	0.0	2.0	0.0	0.5	0.0	0.0	0.0
FS 0247	Peach	0.13	0.2	0.0	24.8	3.2	3.3	0.4	1.8	0.2	5.4	0.7	1.6	0.2
VP 0063	Peas (green pods and/or immature seeds)	0.545	0.1	0.1	2.9	1.6	6.0	3.3	0.6	0.3	9.7	5.3	5.2	2.8
VP 0064	Peas, shelled (immature seeds only)	0.025	0.0	0.0	0.9	0.0	6.0	0.2	0.6	0.0	9.7	0.2	3.2	0.1
FS 0014	Plum (excl dried)	0.015	0.1	0.0	5.3	0.1	2.5	0.0	7.0	0.1	5.5	0.1	0.9	0.0
DF 0014	Plum, dried (prunes)	0.0285	0.0	0.0	0.2	0.0	0.0	0.0	0.1	0.0	0.5	0.0	0.6	0.0
FP 0009	Pome fruit (excl apple juice)	0.07	0.5	0.0	79.9	5.6	21.8	1.5	43.6	3.0	51.5	3.6	35.1	2.5
VR 0589	Potato (incl flour, frozen, starch, tapioca)	0.01	19.1	0.2	160.8	1.6	61.2	0.6	243.6	2.4	230.1	2.3	204.7	2.0
PM 0110	Poultry meat	0	7.1	0.0	58.5	0.0	31.9	0.0	24.0	0.0	61.0	0.0	27.3	0.0
PO 0111	Poultry, edible offal of	0.005	0.4	0.0	0.4	0.0	1.7	0.0	0.1	0.0	0.6	0.0	0.2	0.0
VR 0494	Radish	0.05	0.0	0.0	1.3	0.1	0.6	0.0	2.0	0.1	1.2	0.1	0.0	0.0
VR 0590	Radish, black	0.01	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
VR 0591	Radish, Japanese	0.01	2.3	0.0	0.0	0.0	0.0	0.0	2.0	0.0	0.0	0.0	0.0	0.0
SO 0495	Rape seed (incl oil)	0.295	0.9	0.3	1.8	0.5	2.5	0.7	1.9	0.6	35.7	10.5	26.1	7.7
GC 0649	Rice (incl husked, excl polished)	0.115	46.3	5.3	0.3	0.0	3.4	0.4	9.1	1.0	4.3	0.5	0.6	0.1
CM 1206	Rice bran, unprocessed	0.196	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CM 1205	Rice, polished (incl flour)	0.013	29.8	0.4	20.9	0.3	60.8	0.8	16.1	0.2	5.6	0.1	8.1	0.1
-	Roots and tubers NES	0.01	110.0	1.1	84.1	0.8	0.1	0.0	0.0	0.0	47.3	0.5	0.0	0.0
VR 0498	Salsify	0.01	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
MO 1288	Sheep kidney	0.03	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
MO 1289	Sheep liver	0.047	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
VR 0596	Sugar beet	0.01	0.0	0.0	40.7	0.4	0.0	0.0	0.1	0.0	6.0	0.1	0.1	0.0
SO 0702	Sunflower seed (incl oil)	0.185	0.7	0.1	44.5	8.2	20.5	3.8	29.6	5.5	21.2	3.9	5.4	1.0
VR 0497	Swede	0.01	0.0	0.0	0.0	0.0	0.0	0.0	2.0	0.0	0.8	0.0	14.0	0.1
VO 0447	Sweet corn (corn-on-the-cob, only)	0.01	7.3	0.1	1.0	0.0	0.1	0.0	0.5	0.0	3.3	0.0	3.6	0.0
VR 0508	Sweet potato	0.01	60.5	0.6	0.6	0.0	5.2	0.1	0.0	0.0	0.0	0.0	0.0	0.0
VR 0504	Tannia	0.01	0.1	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
VR 0505	Taro	0.01	29.6	0.3	0.1	0.0	1.5	0.0	0.0	0.0	0.0	0.0	0.0	0.0

Annex 3

CHLORANTRANILIPROLE (230) International Estimated Daily Intake (IEDI) ADI = 0 - 2.0000 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A		B		C		D		E		F	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
TN 0085	Tree nuts	0.01	4.2	0.0	21.5	0.2	3.9	0.0	3.0	0.0	5.5	0.1	10.2	0.1
VR 0506	Turnip, garden	0.01	0.0	0.0	0.1	0.0	0.8	0.0	2.0	0.0	0.6	0.0	14.0	0.1
VR 0600	Yams	0.01	63.2	0.6	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Total intake (µg/person)=			64.8		461.9		137.5		261.3		232.4		344.9
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			120000		120000		120000		120000		120000		120000
	%ADI=			0.1%		0.4%		0.1%		0.2%		0.2%		0.3%
	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	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G		H		I		J		K		L		M	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
JF 0226	Apple juice	0	0.1	0.0	0.5	0.0	0.1	0.0	0.0	0.0	0.7	0.0	0.9	0.0	5.7	0.0
FS 0240	Apricot (excl dried)	0.13	0.2	0.0	0.1	0.0	0.2	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.4	0.1
VP 0061	Beans except broad bean & soya bean (green pods & immature seeds)	0.16	2.6	0.4	2.6	0.4	1.0	0.2	0.5	0.1	0.6	0.1	2.8	0.4	9.8	1.6
VR 0574	Beetroot	0.01	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.2	0.0	0.0	0.0	14.3	0.1
FB 0018	Berries and other small fruits	0.336	2.8	0.9	6.6	2.2	11.8	4.0	0.3	0.1	8.6	2.9	17.1	5.7	69.4	23.3
VB 0040	Brassica vegetables	0.385	26.4	10.2	9.3	3.6	7.8	3.0	1.5	0.6	3.3	1.3	40.8	15.7	26.0	10.0
VR 0577	Carrot	0.02	5.4	0.1	7.9	0.2	2.5	0.1	3.5	0.1	4.1	0.1	8.6	0.2	19.4	0.4
VR 0463	Cassava (incl flour, incl tapioca)	0.01	15.6	0.2	23.9	0.2	171.3	1.7	282.2	2.8	57.7	0.6	20.0	0.2	0.8	0.0
MO 1280	Cattle kidney	0.03	0.0	0.0	0.9	0.0	0.4	0.0	0.2	0.0	0.7	0.0	0.0	0.0	0.0	0.0
MO 1281	Cattle liver	0.047	0.0	0.0	0.9	0.0	0.4	0.0	0.2	0.0	0.7	0.0	0.0	0.0	0.4	0.0
VR 0578	Celeriac	0.01	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
VS 0624	Celery	2.1	0.0	0.0	0.3	0.6	0.0	0.0	0.0	0.0	1.0	2.1	0.0	0.0	4.2	8.8
-	Cereal grains (excl rice)	0.01	240.1	2.4	422.8	4.2	351.4	3.5	311.4	3.1	201.8	2.0	186.4	1.9	375.3	3.8
FS 0013	Cherries	0.2	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.3	0.1	2.5	0.5
VR 0469	Chicory, roots	0.01	0.0	0.0	0.0	0.0	1.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
FC 0001	Citrus fruit (excl lemon juice, excl mandarin	0.07	15.1	1.1	153.9	10.8	3.4	0.2	41.7	2.9	218.9	15.3	23.1	1.6	18.0	1.3

Annex 3

CHLORANTRANILIPROLE (230) International Estimated Daily Intake (IEDI) ADI = 0 - 2.0000 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day Intake = daily intake: µg/person G diet	G intake	H diet	H intake	I diet	I intake	J diet	J intake	K diet	K intake	L diet	L intake	M diet	M intake
	juice, excl orange juice, excl grapefruit juice, excl NES juice)															
-	Citrus juice NES	0.037	0.0	0.0	0.0	0.0	0.5	0.0	0.0	0.0	0.0	0.0	0.3	0.0	0.1	0.0
SB 0716	Coffee beans (incl green, incl extracts, incl roasted)	0.015	0.2	0.0	7.0	0.1	0.5	0.0	0.2	0.0	5.3	0.1	5.7	0.1	12.4	0.2
PE 0112	Eggs	0.07	22.1	1.5	71.5	5.0	16.6	1.2	5.1	0.4	17.6	1.2	35.2	2.5	57.4	4.0
VO 0050	Fruiting vegetables other than cucurbits (excl sweet corn, excl mushrooms)	0.066	56.4	3.7	55.2	3.6	31.0	2.0	47.8	3.2	40.5	2.7	25.4	1.7	112.8	7.4
VC 0045	Fruiting vegetables, cucurbits	0.065	69.7	4.5	25.9	1.7	14.9	1.0	18.0	1.2	18.7	1.2	39.1	2.5	44.2	2.9
JF 0269	Grape juice	0.0869	0.0	0.0	0.1	0.0	1.0	0.1	0.0	0.0	0.6	0.1	0.4	0.0	3.6	0.3
JF 0203	Grapefruit juice	0.037	0.0	0.0	0.0	0.0	0.5	0.0	0.0	0.0	0.0	0.0	0.3	0.0	2.4	0.1
DH 1100	Hops, dry	10.9	0.0	0.0	0.1	1.1	0.1	1.1	0.1	1.1	0.1	1.1	0.1	1.1	0.6	6.5
VR 0583	Horseradish	0.01	7.0	0.1	0.3	0.0	0.0	0.0	0.0	0.0	1.0	0.0	7.4	0.1	0.0	0.0
VR 0585	Jerusalem artichoke	0.01	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
VL 0053	Leafy vegetables	7.3	40.8	297.8	12.0	87.6	12.5	91.3	9.5	69.4	5.4	39.4	50.0	365.0	39.1	285.4
-d	Lemon juice	0.037	0.3	0.0	0.0	0.0	1.0	0.0	0.3	0.0	0.0	0.0	0.5	0.0	2.6	0.1
MF 0100	Mammalian fats (except milk fats)	0.049	2.2	0.1	18.6	0.9	0.5	0.0	0.8	0.0	5.7	0.3	4.5	0.2	18.2	0.9
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.00018	11.0	0.0	17.9	0.0	6.1	0.0	5.7	0.0	16.4	0.0	12.2	0.0	31.7	0.0
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0.0072	43.8	0.3	71.5	0.5	24.5	0.2	22.9	0.2	65.7	0.5	48.9	0.4	126.6	0.9
ML 0106	Milks (excl processed products)	0.006	66.0	0.4	121.1	0.7	81.6	0.5	102.4	0.6	207.7	1.2	57.0	0.3	287.9	1.7
FS 0245	Nectarine	0.13	1.7	0.2	1.7	0.2	0.0	0.0	0.0	0.0	1.0	0.1	1.7	0.2	1.4	0.2
JF 0004	Orange juice	0.037	0.2	0.0	1.0	0.0	3.5	0.1	0.0	0.0	1.3	0.0	6.4	0.2	56.8	2.1
VR 0588	Parsnip	0.01	0.0	0.0	0.3	0.0	0.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0	0.1	0.0
FS 0247	Peach	0.13	1.7	0.2	1.7	0.2	1.1	0.1	0.1	0.0	1.0	0.1	1.7	0.2	10.2	1.3
VP 0063	Peas (green pods and/or immature seeds)	0.545	3.9	2.1	1.6	0.9	0.4	0.2	0.0	0.0	0.9	0.5	1.0	0.5	8.6	4.7
VP 0064	Peas, shelled (immature seeds only)	0.025	3.9	0.1	1.6	0.0	0.0	0.0	0.0	0.0	0.4	0.0	1.0	0.0	0.8	0.0
FS 0014	Plum (excl dried)	0.015	3.0	0.0	0.8	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.9	0.0	0.5	0.0
DF 0014	Plum, dried (prunes)	0.0285	0.1	0.0	0.2	0.0	0.0	0.0	0.0	0.0	0.2	0.0	0.2	0.0	0.6	0.0
FP 0009	Pome fruit (excl apple juice)	0.07	20.8	1.5	11.6	0.8	3.3	0.2	0.1	0.0	10.7	0.7	23.6	1.6	36.9	2.6
VR 0589	Potato (incl flour, frozen, starch, tapioca)	0.01	52.7	0.5	57.1	0.6	50.1	0.5	4.3	0.0	54.7	0.5	41.0	0.4	168.0	1.7
PM 0110	Poultry meat	0	17.6	0.0	131.3	0.0	25.1	0.0	4.7	0.0	145.9	0.0	27.7	0.0	115.1	0.0
PO 0111	Poultry, edible offal of	0.005	0.4	0.0	1.0	0.0	1.9	0.0	0.0	0.0	0.7	0.0	1.0	0.0	0.3	0.0
VR 0494	Radish	0.05	0.0	0.0	0.3	0.0	0.0	0.0	0.0	0.0	1.0	0.1	0.0	0.0	0.3	0.0

Annex 3

CHLORANTRANILIPROLE (230) International Estimated Daily Intake (IEDI) ADI = 0 - 2.0000 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G		H		I		J		K		L		M	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
VR 0590	Radish, black	0.01	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
VR 0591	Radish, Japanese	0.01	7.0	0.1	0.3	0.0	2.3	0.0	3.3	0.0	1.0	0.0	7.4	0.1	0.0	0.0
SO 0495	Rape seed (incl oil)	0.295	9.9	2.9	5.9	1.7	0.3	0.1	1.0	0.3	0.0	0.0	15.5	4.6	9.9	2.9
GC 0649	Rice (incl husked, excl polished)	0.115	1.4	0.2	1.0	0.1	2.3	0.3	29.6	3.4	92.0	10.6	9.2	1.1	0.4	0.0
CM 1206	Rice bran, unprocessed	0.196	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CM 1205	Rice, polished (incl flour)	0.013	250.3	3.3	42.2	0.5	23.8	0.3	29.8	0.4	97.6	1.3	248.1	3.2	22.8	0.3
-	Roots and tubers NES	0.01	1.0	0.0	5.6	0.1	3.8	0.0	1.8	0.0	2.0	0.0	3.3	0.0	0.1	0.0
VR 0498	Salsify	0.01	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
MO 1288	Sheep kidney	0.03	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
MO 1289	Sheep liver	0.047	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
VR 0596	Sugar beet	0.01	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.2	0.0	0.0	0.0	14.3	0.1
SO 0702	Sunflower seed (incl oil)	0.185	2.7	0.5	8.8	1.6	13.5	2.5	0.2	0.0	3.6	0.7	0.6	0.1	10.4	1.9
VR 0497	Swede	0.01	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0	1.1	0.0
VO 0447	Sweet corn (corn-on-the-cob, only)	0.01	0.2	0.0	2.4	0.0	2.2	0.0	3.3	0.0	1.7	0.0	2.8	0.0	11.2	0.1
VR 0508	Sweet potato	0.01	47.4	0.5	7.8	0.1	22.0	0.2	20.9	0.2	5.5	0.1	20.8	0.2	6.1	0.1
VR 0504	Tannia	0.01	0.1	0.0	1.6	0.0	0.1	0.0	0.1	0.0	7.5	0.1	0.1	0.0	0.1	0.0
VR 0505	Taro	0.01	2.7	0.0	0.0	0.0	50.3	0.5	12.7	0.1	1.5	0.0	6.7	0.1	0.3	0.0
TN 0085	Tree nuts	0.01	16.3	0.2	15.7	0.2	9.7	0.1	1.9	0.0	19.1	0.2	29.0	0.3	5.6	0.1
VR 0506	Turnip, garden	0.01	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0	0.4	0.0
VR 0600	Yams	0.01	0.0	0.0	4.5	0.0	87.5	0.9	111.7	1.1	5.9	0.1	5.2	0.1	0.3	0.0
	Total intake (µg/person)=			336.1		130.8		116.3		91.4		87.3		412.8		378.6
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			110000		120000		120000		120000		120000		110000		120000
	%ADI=			0.3%		0.1%		0.1%		0.1%		0.1%		0.4%		0.3%
	Rounded %ADI=			0%		0%		0%		0%		0%		0%		0%

Annex 3

CHLOPYRIFOS METHYL (090) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0100 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A		B		C		D		E		F	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
JF 0226	Apple juice	0.005	0.0	0.0	2.8	0.0	0.1	0.0	1.1	0.0	6.8	0.0	7.4	0.0
GC 0640	Barley (incl pot, incl pearled, incl flour & grits, excl beer)	3	40.6	121.8	0.0	-0.1	93.9	281.7	0.0	0.0	0.0	-0.1	3.8	11.5
-	Barley beer	0.003	18.3	0.1	84.1	0.3	4.1	0.0	66.0	0.2	243.1	0.7	161.3	0.5
GC 0641	Buckwheat (incl flour, incl bran)	3	0.0	0.0	0.1	0.3	0.0	0.0	1.7	5.1	1.6	4.8	0.1	0.3
FC 0001	Citrus fruit (incl lemon juice, incl mandarin juice, incl orange juice, incl grapefruit juice, incl NES juice)	0.01	15.7	0.2	100.5	1.0	63.2	0.6	27.8	0.3	52.6	0.5	56.9	0.6
MO 0105	Edible offal (mammalian)	0	3.9	0.0	14.4	0.0	5.2	0.0	11.8	0.0	11.7	0.0	7.6	0.0
VO 0440	Egg plant (= aubergine)	0.06	1.7	0.1	17.5	1.1	12.3	0.7	1.7	0.1	0.8	0.0	0.4	0.0
PE 0112	Eggs	0	2.5	0.0	29.7	0.0	25.1	0.0	24.5	0.0	37.8	0.0	27.4	0.0
FB 0269	Grape (excl dried, incl juice, excl wine)	0.02	1.9	0.0	9.4	0.2	24.0	0.5	9.9	0.2	2.0	0.0	1.4	0.0
DF 0269	Grape, dried (= currants, raisins and sultanas)	0.001	0.0	0.0	2.9	0.0	0.4	0.0	0.4	0.0	2.3	0.0	1.7	0.0
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.03	5.5	0.2	23.3	0.7	7.7	0.2	11.0	0.3	18.0	0.5	26.3	0.8
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0	22.2	0.0	93.2	0.0	30.8	0.0	44.1	0.0	72.2	0.0	105.0	0.0
ML 0106	Milks (excl processed products)	0.0006	68.8	0.0	190.6	0.1	79.4	0.0	302.6	0.2	179.6	0.1	237.9	0.1
GC 0646	Millet (incl flour, incl beer)	3	15.8	47.4	0.1	0.3	0.8	2.4	5.6	16.8	0.2	0.6	0.1	0.3
GC 0647	Oats (incl rolled)	3	1.4	4.2	0.6	1.8	0.2	0.6	4.2	12.6	5.7	17.1	8.9	26.7
VO 0051	Peppers	0.06	1.4	0.1	29.9	1.8	13.0	0.8	6.3	0.4	6.2	0.4	4.0	0.2
FP 0009	Pome fruit (excl apple juice)	0.06	0.5	0.0	79.9	4.8	21.8	1.3	43.6	2.6	51.5	3.1	35.1	2.1
VR 0589	Potato (incl flour, frozen, starch, tapioca)	0	19.1	0.0	160.8	0.0	61.2	0.0	243.6	0.0	230.1	0.0	204.7	0.0
PM 0110	Poultry meat: 10% as fat	0.004	0.7	0.0	5.9	0.0	3.2	0.0	2.4	0.0	6.1	0.0	2.7	0.0
PM 0110	Poultry meat: 90% as muscle	0	6.4	0.0	52.7	0.0	28.7	0.0	21.6	0.0	54.9	0.0	24.6	0.0
PO 0111	Poultry, edible offal of	0	0.4	0.0	0.4	0.0	1.7	0.0	0.1	0.0	0.6	0.0	0.2	0.0
GC 0649	Rice (excl husked, excl polished)	3	0.0	0.1	0.0	0.0	0.0	0.1	0.1	0.2	0.0	0.0	0.0	0.1
CM 0649	Rice, husked (incl milled)	0.66	35.6	23.5	0.2	0.1	2.6	1.7	6.9	4.6	3.3	2.2	0.4	0.3
CM 1205	Rice, polished (incl flour)	0.101	29.8	3.0	20.9	2.1	60.8	6.1	16.1	1.6	5.6	0.6	8.1	0.8
GC 0651	Sorghum (incl flour, incl beer)	3	36.9	110.7	0.0	0.0	10.2	30.6	0.0	0.0	0.0	0.0	0.0	0.0
FS 0012	Stone fruit (incl dried plums, incl dried apricots)	0.02	0.7	0.0	44.7	0.9	14.1	0.3	26.9	0.5	27.7	0.6	10.0	0.2
FB 0275	Strawberry	0.01	0.0	0.0	5.0	0.1	2.0	0.0	1.7	0.0	5.2	0.1	4.1	0.0
VO 0448	Tomato (excl juice, incl paste, incl peeled)	0.06	5.3	0.3	184.4	11.1	117.5	7.1	58.1	3.5	23.0	1.4	21.9	1.3
JF 0448	Tomato juice	0.002	5.2	0.0	0.5	0.0	0.4	0.0	2.1	0.0	6.9	0.0	15.2	0.0

Annex 3

CHLOPRYRIFOS METHYL (090) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0100 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A		B		C		D		E		F	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
GC 0653	Triticale (excl flour)	3	0.0	0.0	0.0	-0.1	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0
-	Triticale flour	0.75	0.0	0.0	89.1	66.8	0.0	0.0	0.0	0.0	0.2	0.2	0.0	0.0
GC 0654	Wheat (excl bulgur wholemeal, excl flour)	3	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.3	0.0	0.0
CM 0654	Wheat bran, unprocessed	7.35	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CF 1211	Wheat flour (incl macaroni, bread, pastry, starch, gluten)	0.75	63.4	47.6	296.3	222.2	327.5	245.6	300.0	225.0	181.6	136.2	166.2	124.7
CF 1210	Wheat germ	5.7	0.0	0.0	1.3	7.4	0.0	0.0	1.3	7.4	0.9	5.1	1.2	6.8
CF 1212	Wheat wholemeal	3	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CP 1211	White bread	0.15	0.0	0.0	0.1	0.0	0.0	0.0	0.1	0.0	0.1	0.0	1.0	0.2
CP 1212	Wholemeal bread	1.44	0.0	0.0	0.1	0.1	0.0	0.0	0.1	0.1	0.1	0.1	1.0	1.4
-	Wine	0.002	1.3	0.0	76.8	0.2	1.1	0.0	15.4	0.0	68.8	0.1	25.6	0.1
	Total intake (µg/person)=			359.2		323.2		580.4		281.9		175.0		179.1
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			600		600		600		600		600		600
	%ADI=			59.9%		53.9%		96.7%		47.0%		29.2%		29.9%
	Rounded %ADI=			60%		50%		100%		50%		30%		30%

CHLOPRYRIFOS METHYL (090) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0100 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G		H		I		J		K		L		M	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
JF 0226	Apple juice	0.005	0.1	0.0	0.5	0.0	0.1	0.0	0.0	0.0	0.7	0.0	0.9	0.0	5.7	0.0
GC 0640	Barley (incl pot, incl pearled, incl flour & grits, excl beer)	3	1.5	4.6	0.0	-0.1	0.0	0.0	0.0	-0.1	0.0	0.1	0.4	1.1	0.0	0.1
-	Barley beer	0.003	21.9	0.1	102.7	0.3	29.5	0.1	12.6	0.0	100.9	0.3	82.2	0.2	218.8	0.7
GC 0641	Buckwheat (incl flour, incl bran)	3	1.0	3.0	0.0	0.0	0.2	0.6	0.1	0.3	0.5	1.5	2.0	6.0	0.1	0.3
FC 0001	Citrus fruit (incl lemon juice, incl mandarin juice, incl orange juice, incl grapefruit juice, incl NES juice)	0.01	17.3	0.2	156.8	1.6	14.9	0.1	42.5	0.4	222.8	2.2	40.4	0.4	132.3	1.3

Annex 3

CHLOPRYRIFOS METHYL (090) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0100 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day Intake = daily intake: µg/person G diet	G intake	H diet	H intake	I diet	I intake	J diet	J intake	K diet	K intake	L diet	L intake	M diet	M intake
MO 0105	Edible offal (mammalian)	0	4.8	0.0	10.7	0.0	4.0	0.0	4.0	0.0	6.5	0.0	6.6	0.0	5.6	0.0
VO 0440	Egg plant (= aubergine)	0.06	20.1	1.2	0.1	0.0	0.6	0.0	6.3	0.4	0.5	0.0	6.3	0.4	0.7	0.0
PE 0112	Eggs	0	22.1	0.0	71.5	0.0	16.6	0.0	5.1	0.0	17.6	0.0	35.2	0.0	57.4	0.0
FB 0269	Grape (excl dried, incl juice, excl wine)	0.02	1.2	0.0	2.7	0.1	1.4	0.0	0.2	0.0	0.8	0.0	4.3	0.1	5.0	0.1
DF 0269	Grape, dried (= currants, raisins and sultanas)	0.001	0.0	0.0	0.2	0.0	0.2	0.0	0.0	0.0	0.3	0.0	0.4	0.0	2.6	0.0
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.03	11.0	0.3	17.9	0.5	6.1	0.2	5.7	0.2	16.4	0.5	12.2	0.4	31.7	0.9
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0	43.8	0.0	71.5	0.0	24.5	0.0	22.9	0.0	65.7	0.0	48.9	0.0	126.6	0.0
ML 0106	Milks (excl processed products)	0.0006	66.0	0.0	121.1	0.1	81.6	0.0	102.4	0.1	207.7	0.1	57.0	0.0	287.9	0.2
GC 0646	Millet (incl flour, incl beer)	3	13.0	39.0	0.0	0.0	8.3	24.9	96.9	290.7	0.0	0.0	0.4	1.2	0.0	0.0
GC 0647	Oats (incl rolled)	3	0.2	0.6	2.0	6.0	0.8	2.4	0.0	0.0	3.5	10.5	0.7	2.1	7.6	22.8
VO 0051	Peppers	0.06	8.7	0.5	22.4	1.3	8.4	0.5	9.4	0.6	3.3	0.2	5.3	0.3	8.9	0.5
FP 0009	Pome fruit (excl apple juice)	0.06	20.8	1.2	11.6	0.7	3.3	0.2	0.1	0.0	10.7	0.6	23.6	1.4	36.9	2.2
VR 0589	Potato (incl flour, frozen, starch, tapioca)	0	52.7	0.0	57.1	0.0	50.1	0.0	4.3	0.0	54.7	0.0	41.0	0.0	168.0	0.0
PM 0110	Poultry meat: 10% as fat	0.004	1.8	0.0	13.1	0.1	2.5	0.0	0.5	0.0	14.6	0.1	2.8	0.0	11.5	0.0
PM 0110	Poultry meat: 90% as muscle	0	15.8	0.0	118.2	0.0	22.6	0.0	4.2	0.0	131.3	0.0	24.9	0.0	103.6	0.0
PO 0111	Poultry, edible offal of	0	0.4	0.0	1.0	0.0	1.9	0.0	0.0	0.0	0.7	0.0	1.0	0.0	0.3	0.0
GC 0649	Rice (excl husked, excl polished)	3	0.0	0.1	0.0	-0.1	0.0	-0.1	0.1	0.3	0.0	-0.1	0.1	0.2	0.0	0.0
CM 0649	Rice, husked (incl milled)	0.66	1.1	0.7	0.8	0.5	1.8	1.2	22.7	15.0	70.8	46.7	7.0	4.6	0.3	0.2
CM 1205	Rice, polished (incl flour)	0.101	250.3	25.3	42.2	4.3	23.8	2.4	29.8	3.0	97.6	9.9	248.1	25.1	22.8	2.3
GC 0651	Sorghum (incl flour, incl beer)	3	9.8	29.4	19.9	59.7	18.6	55.8	112.3	336.9	0.1	0.3	3.3	9.9	3.0	9.0
FS 0012	Stone fruit (incl dried plums, incl dried apricots)	0.02	7.0	0.1	4.9	0.1	1.4	0.0	0.1	0.0	5.5	0.1	5.5	0.1	19.4	0.4
FB 0275	Strawberry	0.01	0.0	0.0	1.8	0.0	0.1	0.0	0.0	0.0	0.3	0.0	6.2	0.1	5.9	0.1
VO 0448	Tomato (excl juice, incl paste, incl peeled)	0.06	23.5	1.4	30.7	1.8	14.9	0.9	7.2	0.4	35.6	2.1	6.9	0.4	46.5	2.8
JF 0448	Tomato juice	0.002	0.0	0.0	0.8	0.0	0.1	0.0	7.2	0.0	0.0	0.0	2.4	0.0	45.2	0.1
GC 0653	Triticale (excl flour)	3	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
-	Triticale flour	0.75	1.0	0.8	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
GC 0654	Wheat (excl bulgur wholemeal, excl flour)	3	0.0	0.0	0.9	2.6	0.0	0.0	0.0	0.1	0.1	0.3	0.0	0.0	0.1	0.2
CM 0654	Wheat bran, unprocessed	7.35	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-

Annex 3

CHLOPRYRIFOS METHYL (090) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0100 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day Intake = daily intake: µg/person													
			G		H		I		J		K		L		M	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
CF 1211	Wheat flour (incl macaroni, bread, pastry, starch, gluten)	0.75	133.0	99.8	60.1	45.1	52.4	39.3	32.2	24.2	87.7	65.8	79.6	59.7	180.1	135.1
CF 1210	Wheat germ	5.7	0.1	0.6	48.1	274.2	1.8	10.3	0.0	0.0	0.0	0.0	0.0	0.0	0.6	3.4
CF 1212	Wheat wholemeal	3	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CP 1211	White bread	0.15	0.0	0.0	2.2	0.3	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
CP 1212	Wholemeal bread	1.44	0.0	0.0	2.2	3.2	0.1	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
-	Wine	0.002	1.0	0.0	0.9	0.0	6.8	0.0	0.1	0.0	3.4	0.0	3.6	0.0	31.0	0.1
	Total intake (µg/person)=			208.9		402.2		139.1		672.5		141.2		113.7		182.9
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			550		600		600		600		600		550		600
	%ADI=			38.0%		67.0%		23.2%		112.1%		23.5%		20.7%		30.5%
	Rounded %ADI=			40%		70%		20%		110%		20%		20%		30%

Annex 3

CYANTRANILIPROLE (263) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0300 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A		B		C		D		E		F	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
JF 0226	Apple juice	0.05	0.0	0.0	2.8	0.1	0.1	0.0	1.1	0.1	6.8	0.3	7.4	0.4
FS 0240	Apricot (incl dried)	0.34	0.3	0.1	6.2	2.1	3.9	1.3	3.2	1.1	2.0	0.7	0.8	0.3
VR 0574	Beetroot	0.01	0.0	0.0	40.7	0.4	0.0	0.0	0.1	0.0	6.0	0.1	0.1	0.0
FB 0020	Blueberries	0.75	0.0	0.0	0.0	0.0	0.0	0.0	0.2	0.2	0.3	0.2	0.8	0.6
VL 0054	Brassica leafy vegetables	4.7	1.0	4.7	5.5	25.9	2.8	13.2	22.1	103.9	0.7	3.3	7.7	36.2
VB 0040	Brassica vegetables	0.56	1.7	1.0	25.7	14.4	9.1	5.1	27.8	15.6	36.9	20.7	26.4	14.8
VR 0577	Carrot	0.01	0.6	0.0	15.1	0.2	8.1	0.1	13.9	0.1	27.1	0.3	28.4	0.3
VR 0463	Cassava (incl flour, incl tapioca)	0.01	242.8	2.4	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
VR 0578	Celeriac	0.01	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
VS 0624	Celery	2	0.0	0.0	0.9	1.8	0.0	0.0	2.0	4.0	1.5	3.0	0.0	0.0
VC 0423	Chayote	0.065	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
FS 0013	Cherries	0.93	0.0	0.0	6.8	6.3	0.9	0.8	6.2	5.8	3.6	3.3	0.4	0.4
VL 0469	Chicory leaves (green and red)	4.7	0.1	0.5	1.2	5.6	0.1	0.5	0.1	0.5	1.6	7.5	0.0	0.0
VR 0469	Chicory, roots	0.01	0.0	0.0	0.2	0.0	0.0	0.0	0.6	0.0	4.5	0.0	0.0	0.0
SB 0716	Coffee beans (incl green, incl extracts, incl roasted)	0.01	3.1	0.0	12.6	0.1	2.9	0.0	1.4	0.0	10.1	0.1	18.0	0.2
VL 0470	Corn salad	4.7	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
VL 0510	Cos lettuce	4.7	0.1	0.2	6.2	28.9	0.7	3.1	0.1	0.2	0.1	0.2	0.0	0.0
VL 0472	Cress, garden	4.7	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
VC 0424	Cucumber	0.065	0.3	0.0	12.7	0.8	5.9	0.4	11.5	0.7	6.1	0.4	7.1	0.5
FB 0021	Currants, red, black, white	0.75	0.0	0.0	0.0	0.0	0.0	0.0	2.2	1.7	3.1	2.3	2.0	1.5
MO 0105	Edible offal (mammalian)	0.026	3.9	0.1	14.4	0.4	5.2	0.1	11.8	0.3	11.7	0.3	7.6	0.2
VO 0440	Egg plant (= aubergine)	0.08	1.7	0.1	17.5	1.4	12.3	1.0	1.7	0.1	0.8	0.1	0.4	0.0
PE 0112	Eggs	0.01	2.5	0.0	29.7	0.3	25.1	0.3	24.5	0.2	37.8	0.4	27.4	0.3
VL 0476	Endive	4.7	0.0	0.0	0.9	4.2	0.0	0.0	0.1	0.5	1.6	7.5	0.0	0.0
VA 0381	Garlic	0.02	0.4	0.0	3.9	0.1	3.8	0.1	3.7	0.1	1.0	0.0	0.6	0.0
VC 0425	Gherkin	0.065	0.3	0.0	12.7	0.8	5.9	0.4	11.5	0.7	6.1	0.4	7.1	0.5
FB 0268	Gooseberries	0.75	0.0	0.0	12.0	9.0	0.0	0.0	0.6	0.5	1.1	0.8	0.2	0.2
VR 0583	Horseradish	0.01	0.0	0.0	2.2	0.0	0.0	0.0	2.0	0.0	0.0	0.0	0.0	0.0
VR 0585	Jerusalem artichoke	0.01	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
VL 0482	Lettuce, head	0.79	0.1	0.0	6.2	4.9	0.7	0.5	0.1	0.0	0.1	0.0	0.0	0.0
VL 0483	Lettuce, leaf	4.7	0.0	0.0	9.2	43.2	1.0	4.7	0.1	0.5	5.4	25.4	18.0	84.6
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.007	5.5	0.0	23.3	0.2	7.7	0.1	11.0	0.1	18.0	0.1	26.3	0.2
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0.002	22.2	0.0	93.2	0.2	30.8	0.1	44.1	0.1	72.2	0.1	105.0	0.2

Annex 3

CYANTRANILIPROLE (263) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0300 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A		B		C		D		E		F	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
VC 0046	Melons, except watermelon	0.01	3.6	0.0	26.7	0.3	22.6	0.2	11.5	0.1	5.6	0.1	2.0	0.0
ML 0106	Milks (excl processed products)	0.016	68.8	1.1	190.6	3.0	79.4	1.3	302.6	4.8	179.6	2.9	237.9	3.8
FS 0245	Nectarine	0.34	0.0	0.0	0.5	0.2	3.3	1.1	1.8	0.6	2.8	1.0	1.6	0.5
VO 0442	Okra	0.08	3.9	0.3	1.0	0.1	5.3	0.4	0.1	0.0	0.0	0.0	0.0	0.0
-	Onion, dry	0.02	4.3	0.1	45.6	0.9	27.4	0.5	30.2	0.6	22.1	0.4	12.2	0.2
VA 0387	Onion, Welsh	1.3	0.3	0.4	1.0	1.3	1.4	1.8	0.3	0.4	0.3	0.4	0.6	0.8
VR 0588	Parsnip	0.01	0.0	0.0	6.8	0.1	0.0	0.0	2.0	0.0	0.5	0.0	0.0	0.0
FS 0247	Peach	0.34	0.2	0.1	24.8	8.4	3.3	1.1	1.8	0.6	5.4	1.8	1.6	0.5
VO 0051	Peppers	0.08	1.4	0.1	29.9	2.4	13.0	1.0	6.3	0.5	6.2	0.5	4.0	0.3
FS 0014	Plum (excl dried)	0.07	0.1	0.0	5.3	0.4	2.5	0.2	7.0	0.5	5.5	0.4	0.9	0.1
DF 0014	Plum, dried (prunes)	0.54	0.0	0.0	0.2	0.1	0.0	0.0	0.1	0.1	0.5	0.3	0.6	0.3
FP 0009	Pome fruit (excl apple juice)	0.16	0.5	0.1	79.9	12.8	21.8	3.5	43.6	7.0	51.5	8.2	35.1	5.6
VR 0589	Potato (incl flour, frozen, starch, tapioca)	0.02	19.1	0.4	160.8	3.2	61.2	1.2	243.6	4.9	230.1	4.6	204.7	4.1
PO 0111	Poultry, edible offal of	0.004	0.4	0.0	0.4	0.0	1.7	0.0	0.1	0.0	0.6	0.0	0.2	0.0
VL 0492	Purslane	4.7	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
VR 0494	Radish	0.01	0.0	0.0	1.3	0.0	0.6	0.0	2.0	0.0	1.2	0.0	0.0	0.0
VR 0590	Radish, black	0.01	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
VR 0591	Radish, Japanese	0.01	2.3	0.0	0.0	0.0	0.0	0.0	2.0	0.0	0.0	0.0	0.0	0.0
-	Roots and tubers NES	0.01	110.0	1.1	84.1	0.8	0.1	0.0	0.0	0.0	47.3	0.5	0.0	0.0
VR 0498	Salsify	0.01	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
VA 0388	Shallot	0.02	0.3	0.0	1.0	0.0	1.4	0.0	0.3	0.0	0.3	0.0	0.6	0.0
VL 0502	Spinach	4.7	0.0	0.0	5.0	23.5	1.1	5.2	0.1	0.5	2.6	12.2	0.1	0.5
VA 0389	Spring onion	1.3	0.3	0.4	1.0	1.3	1.4	1.8	0.3	0.4	0.3	0.4	0.6	0.8
VC 0431	Squash, summer (= courgette, zuchini)	0.065	0.0	0.0	8.3	0.5	11.4	0.7	7.3	0.5	3.2	0.2	0.3	0.0
-d	Squashes & pumpkins & gourds	0.01	16.3	0.2	12.3	0.1	14.4	0.1	21.9	0.2	3.2	0.0	1.0	0.0
VR 0596	Sugar beet	0.01	0.0	0.0	40.7	0.4	0.0	0.0	0.1	0.0	6.0	0.1	0.1	0.0
VR 0497	Swede	0.01	0.0	0.0	0.0	0.0	0.0	0.0	2.0	0.0	0.8	0.0	14.0	0.1
VR 0508	Sweet potato	0.01	60.5	0.6	0.6	0.0	5.2	0.1	0.0	0.0	0.0	0.0	0.0	0.0
VR 0504	Tannia	0.01	0.1	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
VR 0505	Taro	0.01	29.6	0.3	0.1	0.0	1.5	0.0	0.0	0.0	0.0	0.0	0.0	0.0
VO 0448	Tomato (excl juice, excl paste, excl canned)	0.08	1.3	0.1	178.4	14.3	102.8	8.2	53.4	4.3	1.6	0.1	0.0	0.0
JF 0448	Tomato juice	0.014	5.2	0.1	0.5	0.0	0.4	0.0	2.1	0.0	6.9	0.1	15.2	0.2
-d	Tomato paste	0.07	0.5	0.0	1.3	0.1	3.5	0.2	1.0	0.1	3.8	0.3	4.5	0.3
-d	Tomato, canned	0.004	0.1	0.0	0.4	0.0	0.5	0.0	0.4	0.0	4.9	0.0	3.2	0.0
VR 0506	Turnip, garden	0.01	0.0	0.0	0.1	0.0	0.8	0.0	2.0	0.0	0.6	0.0	14.0	0.1

Annex 3

CYANTRANILIPROLE (263) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0300 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A		B		C		D		E		F	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
FB 0019	Vaccinium berries (incl. bearberry)	0.75	0.1	0.1	0.0	0.0	0.0	0.0	0.5	0.4	0.3	0.2	1.4	1.1
VL 0473	Watercress	4.7	2.3	10.8	0.0	0.0	3.3	15.5	2.0	9.4	0.1	0.5	0.0	0.0
VC 0432	Watermelon	0.01	6.1	0.1	43.1	0.4	47.1	0.5	25.8	0.3	4.4	0.0	6.0	0.1
VR 0600	Yams	0.01	63.2	0.6	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Total intake (µg/person)=			26.3		226.1		76.5		173.0		112.9		160.7
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			1800		1800		1800		1800		1800		1800
	%ADI=			1.5%		12.6%		4.3%		9.6%		6.3%		8.9%
	Rounded %ADI=			1%		10%		4%		10%		6%		9%

CYANTRANILIPROLE (263) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0300 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G		H		I		J		K		L		M	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
JF 0226	Apple juice	0.05	0.1	0.0	0.5	0.0	0.1	0.0	0.0	0.0	0.7	0.0	0.9	0.0	5.7	0.3
FS 0240	Apricot (incl dried)	0.34	0.2	0.1	0.1	0.0	0.2	0.1	0.0	0.0	0.0	0.0	0.1	0.0	1.1	0.4
VR 0574	Beetroot	0.01	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.2	0.0	0.0	0.0	14.3	0.1
FB 0020	Blueberries	0.75	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.3	1.0
VL 0054	Brassica leafy vegetables	4.7	10.3	48.4	4.0	18.8	7.3	34.3	1.0	4.7	2.0	9.4	23.8	111.9	1.7	8.0
VB 0040	Brassica vegetables	0.56	26.4	14.8	9.3	5.2	7.8	4.4	1.5	0.8	3.3	1.8	40.8	22.8	26.0	14.6
VR 0577	Carrot	0.01	5.4	0.1	7.9	0.1	2.5	0.0	3.5	0.0	4.1	0.0	8.6	0.1	19.4	0.2
VR 0463	Cassava (incl flour, incl tapioca)	0.01	15.6	0.2	23.9	0.2	171.3	1.7	282.2	2.8	57.7	0.6	20.0	0.2	0.8	0.0
VR 0578	Celeriac	0.01	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
VS 0624	Celery	2	0.0	0.0	0.3	0.6	0.0	0.0	0.0	0.0	1.0	2.0	0.0	0.0	4.2	8.4
VC 0423	Chayote	0.065	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
FS 0013	Cherries	0.93	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.3	0.3	2.5	2.3
VL 0469	Chicory leaves (green and red)	4.7	2.4	11.3	0.0	0.0	0.2	0.9	0.6	2.8	0.0	0.0	2.4	11.3	0.1	0.5
VR 0469	Chicory, roots	0.01	0.0	0.0	0.0	0.0	1.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
SB 0716	Coffee beans (incl green, incl extracts, incl roasted)	0.01	0.2	0.0	7.0	0.1	0.5	0.0	0.2	0.0	5.3	0.1	5.7	0.1	12.4	0.1
VL 0470	Corn salad	4.7	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-

Annex 3

CYANTRANILIPROLE (263) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0300 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G		H		I		J		K		L		M	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
VL 0510	Cos lettuce	4.7	1.2	5.6	3.5	16.5	0.1	0.5	0.3	1.4	1.0	4.7	1.2	5.6	7.9	36.9
VL 0472	Cress, garden	4.7	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
VC 0424	Cucumber	0.065	7.9	0.5	0.6	0.0	0.2	0.0	0.0	0.0	0.4	0.0	5.5	0.4	5.3	0.3
FB 0021	Currants, red, black, white	0.75	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
MO 0105	Edible offal (mammalian)	0.026	4.8	0.1	10.7	0.3	4.0	0.1	4.0	0.1	6.5	0.2	6.6	0.2	5.6	0.1
VO 0440	Egg plant (= aubergine)	0.08	20.1	1.6	0.1	0.0	0.6	0.0	6.3	0.5	0.5	0.0	6.3	0.5	0.7	0.1
PE 0112	Eggs	0.01	22.1	0.2	71.5	0.7	16.6	0.2	5.1	0.1	17.6	0.2	35.2	0.4	57.4	0.6
VL 0476	Endive	4.7	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.2	0.9
VA 0381	Garlic	0.02	6.4	0.1	1.2	0.0	0.1	0.0	0.3	0.0	1.9	0.0	5.0	0.1	2.5	0.1
VC 0425	Gherkin	0.065	7.9	0.5	0.6	0.0	0.2	0.0	0.0	0.0	0.4	0.0	5.5	0.4	5.3	0.3
FB 0268	Gooseberries	0.75	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.8	0.0	0.0	0.0	0.0
VR 0583	Horseradish	0.01	7.0	0.1	0.3	0.0	0.0	0.0	0.0	0.0	1.0	0.0	7.4	0.1	0.0	0.0
VR 0585	Jerusalem artichoke	0.01	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
VL 0482	Lettuce, head	0.79	1.2	0.9	3.5	2.8	0.1	0.1	0.3	0.2	1.0	0.8	1.2	0.9	7.9	6.2
VL 0483	Lettuce, leaf	4.7	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	2.5	11.8
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.007	11.0	0.1	17.9	0.1	6.1	0.0	5.7	0.0	16.4	0.1	12.2	0.1	31.7	0.2
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0.002	43.8	0.1	71.5	0.1	24.5	0.0	22.9	0.0	65.7	0.1	48.9	0.1	126.6	0.3
VC 0046	Melons, except watermelon	0.01	7.5	0.1	6.1	0.1	0.7	0.0	1.4	0.0	2.5	0.0	6.9	0.1	12.4	0.1
ML 0106	Milks (excl processed products)	0.016	66.0	1.1	121.1	1.9	81.6	1.3	102.4	1.6	207.7	3.3	57.0	0.9	287.9	4.6
FS 0245	Nectarine	0.34	1.7	0.6	1.7	0.6	0.0	0.0	0.0	0.0	1.0	0.3	1.7	0.6	1.4	0.5
VO 0442	Okra	0.08	4.1	0.3	1.0	0.1	7.0	0.6	15.9	1.3	1.1	0.1	3.9	0.3	0.2	0.0
-	Onion, dry	0.02	16.8	0.3	8.6	0.2	6.9	0.1	12.1	0.2	18.6	0.4	23.8	0.5	28.4	0.6
VA 0387	Onion, Welsh	1.3	0.1	0.1	4.8	6.2	0.1	0.1	1.0	1.3	1.0	1.3	2.7	3.5	0.6	0.8
VR 0588	Parsnip	0.01	0.0	0.0	0.3	0.0	0.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0	0.1	0.0
FS 0247	Peach	0.34	1.7	0.6	1.7	0.6	1.1	0.4	0.1	0.0	1.0	0.3	1.7	0.6	10.2	3.5
VO 0051	Peppers	0.08	8.7	0.7	22.4	1.8	8.4	0.7	9.4	0.8	3.3	0.3	5.3	0.4	8.9	0.7
FS 0014	Plum (excl dried)	0.07	3.0	0.2	0.8	0.1	0.1	0.0	0.0	0.0	0.0	0.0	0.9	0.1	0.5	0.0
DF 0014	Plum, dried (prunes)	0.54	0.1	0.1	0.2	0.1	0.0	0.0	0.0	0.0	0.2	0.1	0.2	0.1	0.6	0.3
FP 0009	Pome fruit (excl apple juice)	0.16	20.8	3.3	11.6	1.8	3.3	0.5	0.1	0.0	10.7	1.7	23.6	3.8	36.9	5.9
VR 0589	Potato (incl flour, frozen, starch, tapioca)	0.02	52.7	1.1	57.1	1.1	50.1	1.0	4.3	0.1	54.7	1.1	41.0	0.8	168.0	3.4
PO 0111	Poultry, edible offal of	0.004	0.4	0.0	1.0	0.0	1.9	0.0	0.0	0.0	0.7	0.0	1.0	0.0	0.3	0.0
VL 0492	Purslane	4.7	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
VR 0494	Radish	0.01	0.0	0.0	0.3	0.0	0.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0	0.3	0.0

Annex 3

CYANTRANILIPROLE (263) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0300 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G		H		I		J		K		L		M	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
VR 0590	Radish, black	0.01	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
VR 0591	Radish, Japanese	0.01	7.0	0.1	0.3	0.0	2.3	0.0	3.3	0.0	1.0	0.0	7.4	0.1	0.0	0.0
-	Roots and tubers NES	0.01	1.0	0.0	5.6	0.1	3.8	0.0	1.8	0.0	2.0	0.0	3.3	0.0	0.1	0.0
VR 0498	Salsify	0.01	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
VA 0388	Shallot	0.02	0.1	0.0	4.8	0.1	0.1	0.0	1.0	0.0	1.0	0.0	2.7	0.1	0.0	0.0
VL 0502	Spinach	4.7	9.4	44.2	0.4	1.9	0.0	0.0	0.0	0.0	0.2	0.9	4.3	20.2	2.0	9.4
VA 0389	Spring onion	1.3	0.1	0.1	4.8	6.2	0.1	0.1	1.0	1.3	1.0	1.3	2.7	3.5	0.6	0.8
VC 0431	Squash, summer (= courgette, zuchini)	0.065	2.4	0.2	1.5	0.1	0.0	0.0	0.0	0.0	3.8	0.2	2.2	0.1	2.5	0.2
-d	Squashes & pumpkins & gourds	0.01	7.1	0.1	4.6	0.0	11.3	0.1	3.0	0.0	7.0	0.1	6.7	0.1	7.6	0.1
VR 0596	Sugar beet	0.01	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.2	0.0	0.0	0.0	14.3	0.1
VR 0497	Swede	0.01	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0	1.1	0.0
VR 0508	Sweet potato	0.01	47.4	0.5	7.8	0.1	22.0	0.2	20.9	0.2	5.5	0.1	20.8	0.2	6.1	0.1
VR 0504	Tannia	0.01	0.1	0.0	1.6	0.0	0.1	0.0	0.1	0.0	7.5	0.1	0.1	0.0	0.1	0.0
VR 0505	Taro	0.01	2.7	0.0	0.0	0.0	50.3	0.5	12.7	0.1	1.5	0.0	6.7	0.1	0.3	0.0
VO 0448	Tomato (excl juice, excl paste, excl canned)	0.08	22.8	1.8	4.1	0.3	12.3	1.0	1.8	0.1	32.8	2.6	0.4	0.0	27.3	2.2
JF 0448	Tomato juice	0.014	0.0	0.0	0.8	0.0	0.1	0.0	7.2	0.1	0.0	0.0	2.4	0.0	45.2	0.6
-d	Tomato paste	0.07	0.1	0.0	2.1	0.1	0.6	0.0	0.4	0.0	0.6	0.0	1.4	0.1	1.2	0.1
-d	Tomato, canned	0.004	0.2	0.0	14.5	0.1	0.2	0.0	0.0	0.0	0.3	0.0	0.8	0.0	1.2	0.0
VR 0506	Turnip, garden	0.01	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0	0.4	0.0
FB 0019	Vaccinium berries (incl. bearberry)	0.75	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	3.8	2.9
VL 0473	Watercress	4.7	7.0	32.9	0.3	1.4	2.3	10.8	3.3	15.5	0.3	1.4	7.4	34.8	0.0	0.0
VC 0432	Watermelon	0.01	39.3	0.4	14.0	0.1	2.5	0.0	13.6	0.1	8.4	0.1	14.5	0.1	13.6	0.1
VR 0600	Yams	0.01	0.0	0.0	4.5	0.0	87.5	0.9	111.7	1.1	5.9	0.1	5.2	0.1	0.3	0.0
	Total intake (µg/person)=			173.4		70.9		60.9		37.7		36.9		226.5		130.5
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			1650		1800		1800		1800		1800		1650		1800
	%ADI=			10.5%		3.9%		3.4%		2.1%		2.1%		13.7%		7.3%
	Rounded %ADI=			10%		4%		3%		2%		2%		10%		7%

Annex 3

CYPRODINIL (207) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0300 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A		B		C		D		E		F	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
TN 0660	Almond	0.02	0.0	0.0	1.9	0.0	1.0	0.0	0.0	0.0	1.0	0.0	0.8	0.0
JF 0226	Apple juice	0.015	0.0	0.0	2.8	0.0	0.1	0.0	1.1	0.0	6.8	0.1	7.4	0.1
FI 0326	Avocado	0.265	3.7	1.0	1.0	0.3	0.2	0.1	0.0	0.0	0.9	0.2	0.8	0.2
GC 0640	Barley (incl pot, incl pearled, incl flour & grits, excl beer)	0.58	40.6	23.5	0.0	0.0	93.9	54.5	0.0	0.0	0.0	0.0	3.8	2.2
-	Barley beer	0.0058	18.3	0.1	84.1	0.5	4.1	0.0	66.0	0.4	243.1	1.4	161.3	0.9
VD 0071	Beans (dry)	0.03	15.8	0.5	6.1	0.2	1.7	0.1	6.3	0.2	1.8	0.1	5.0	0.2
VP 0061	Beans except broad bean & soya bean (green pods & immature seeds)	0.165	1.0	0.2	17.4	2.9	7.5	1.2	0.9	0.1	16.4	2.7	0.1	0.0
VP 0062	Beans, shelled (immature seeds)	0.02	0.5	0.0	12.7	0.3	4.1	0.1	0.9	0.0	13.1	0.3	0.1	0.0
FB 0018	Berries and other small fruits (excl grapes)	2.2	0.1	0.2	17.3	38.1	2.0	4.4	7.9	17.4	10.8	23.8	9.0	19.8
VL 0054	Brassica leafy vegetables	0.37	1.0	0.4	5.5	2.0	2.8	1.0	22.1	8.2	0.7	0.3	7.7	2.8
VB 0041	Cabbage, head	0.03	1.2	0.0	14.4	0.4	2.7	0.1	16.4	0.5	15.4	0.5	18.5	0.6
VR 0577	Carrot	0.09	0.6	0.1	15.1	1.4	8.1	0.7	13.9	1.3	27.1	2.4	28.4	2.6
DH 0170	Dried herbs (excl dry hops)	25	0.2	5.8	0.3	7.0	0.2	6.0	0.4	10.0	0.3	7.5	0.0	0.3
MO 0105	Edible offal (mammalian)	0	3.9	0.0	14.4	0.0	5.2	0.0	11.8	0.0	11.7	0.0	7.6	0.0
PE 0112	Eggs	0	2.5	0.0	29.7	0.0	25.1	0.0	24.5	0.0	37.8	0.0	27.4	0.0
VB 0042	Flowerhead brassicas	0.27	0.2	0.1	11.1	3.0	3.6	1.0	0.4	0.1	7.7	2.1	4.1	1.1
VO 0050	Fruiting vegetables other than cucurbits (excl sweet corn, excl mushrooms)	0.24	18.8	4.5	233.4	56.0	148.6	35.7	68.8	16.5	38.6	9.3	45.3	10.9
VC 0045	Fruiting vegetables, cucurbits	0.09	26.6	2.4	107.5	9.7	95.9	8.6	82.2	7.4	25.4	2.3	23.2	2.1
FB 0269	Grape (excl dried, excl juice, excl wine)	0.79	1.9	1.5	9.2	7.3	23.8	18.8	9.8	7.7	0.0	0.0	0.0	0.0
JF 0269	Grape juice	0.12	0.0	0.0	0.1	0.0	0.1	0.0	0.1	0.0	1.4	0.2	1.0	0.1
DF 0269	Grape, dried (= currants, raisins and sultanas)	1.7	0.0	0.0	2.9	4.9	0.4	0.7	0.4	0.7	2.3	3.9	1.7	2.9
HH 0720	Herbs	5.05	2.3	11.6	2.8	14.1	2.4	12.1	4.0	20.2	3.0	15.2	0.1	0.5
VL 0053	Leafy vegetables (excl brassica leafy vegetables)	11	4.8	52.8	39.9	438.9	8.1	89.1	4.6	50.6	16.4	180.4	31.2	343.2
MM 0095	Meat from mammals other than marine mammals	0	27.7	0.0	116.5	0.0	38.5	0.0	55.1	0.0	90.2	0.0	131.3	0.0
ML 0106	Milks (excl processed products)	0	68.8	0.0	190.6	0.0	79.4	0.0	302.6	0.0	179.6	0.0	237.9	0.0
VA 0385	Onion, bulb (= dry + green onion)	0.065	5.5	0.4	49.5	3.2	33.0	2.1	31.3	2.0	23.2	1.5	14.6	0.9
VR 0588	Parsnip	0.09	0.0	0.0	6.8	0.6	0.0	0.0	2.0	0.2	0.5	0.0	0.0	0.0
DF 0014	Plum, dried (prunes)	1.2	0.0	0.0	0.2	0.2	0.0	0.0	0.1	0.1	0.5	0.6	0.6	0.7

Annex 3

CYPRODINIL (207) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0300 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day											
			A		B		C		D		E		F	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
FP 0009	Pome fruit (excl apple juice)	0.48	0.5	0.2	79.9	38.4	21.8	10.4	43.6	20.9	51.5	24.7	35.1	16.8
PM 0110	Poultry meat	0	7.1	0.0	58.5	0.0	31.9	0.0	24.0	0.0	61.0	0.0	27.3	0.0
PO 0111	Poultry, edible offal of	0	0.4	0.0	0.4	0.0	1.7	0.0	0.1	0.0	0.6	0.0	0.2	0.0
VR 0494	Radish	0.01	0.0	0.0	1.3	0.0	0.6	0.0	2.0	0.0	1.2	0.0	0.0	0.0
HS 0093	Spices	2	2.8	5.6	1.0	2.0	2.5	5.0	0.8	1.6	1.6	3.2	1.1	2.2
FS 0012	Stone fruit (excl dried plums, incl dried apricots)	0.68	0.7	0.5	44.1	30.0	14.1	9.6	26.6	18.1	26.3	17.9	8.3	5.6
JF 0448	Tomato juice	0.036	5.2	0.2	0.5	0.0	0.4	0.0	2.1	0.1	6.9	0.2	15.2	0.5
-d	Tomato paste	0.48	0.5	0.2	1.3	0.6	3.5	1.7	1.0	0.5	3.8	1.8	4.5	2.2
GC 0654	Wheat (incl bulgur wholemeal, excl flour)	0.07	6.0	0.4	11.1	0.8	0.8	0.1	0.2	0.0	0.2	0.0	0.0	0.0
CM 0654	Wheat bran, unprocessed	0.21	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CF 1211	Wheat flour (incl macaroni, bread, pastry, starch, gluten)	0.019	63.4	1.2	296.3	5.6	327.5	6.2	300.0	5.7	181.6	3.5	166.2	3.2
CF 1212	Wheat wholemeal	0.064	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CP 1212	Wholemeal bread	0.036	0.0	0.0	0.1	0.0	0.0	0.0	0.1	0.0	0.1	0.0	1.0	0.0
-	Wine	0.062	1.3	0.1	76.8	4.8	1.1	0.1	15.4	1.0	68.8	4.3	25.6	1.6
	Total intake (µg/person)=			113.4		673.2		269.4		191.5		310.2		424.3
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			1800		1800		1800		1800		1800		1800
	%ADI=			6.3%		37.4%		15.0%		10.6%		17.2%		23.6%
	Rounded %ADI=			6%		40%		10%		10%		20%		20%

CYPRODINIL (207) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0300 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day													
			G		H		I		J		K		L		M	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
TN 0660	Almond	0.02	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.3	0.0	0.3	0.0
JF 0226	Apple juice	0.015	0.1	0.0	0.5	0.0	0.1	0.0	0.0	0.0	0.7	0.0	0.9	0.0	5.7	0.1
FI 0326	Avocado	0.265	0.2	0.1	13.9	3.7	1.0	0.3	1.7	0.5	3.4	0.9	0.5	0.1	2.1	0.6
GC 0640	Barley (incl pot, incl pearled, incl flour & grits, excl beer)	0.58	1.5	0.9	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.4	0.2	0.0	0.0
-	Barley beer	0.0058	21.9	0.1	102.7	0.6	29.5	0.2	12.6	0.1	100.9	0.6	82.2	0.5	218.8	1.3

Annex 3

CYPRODINIL (207) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0300 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day; Intake = daily intake: µg/person													
			G		H		I		J		K		L		M	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
VD 0071	Beans (dry)	0.03	3.4	0.1	25.5	0.8	7.8	0.2	2.1	0.1	44.7	1.3	5.5	0.2	7.3	0.2
VP 0061	Beans except broad bean & soya bean (green pods & immature seeds)	0.165	2.6	0.4	2.6	0.4	1.0	0.2	0.5	0.1	0.6	0.1	2.8	0.5	9.8	1.6
VP 0062	Beans, shelled (immature seeds)	0.02	2.6	0.1	1.9	0.0	1.0	0.0	0.5	0.0	0.3	0.0	1.8	0.0	9.0	0.2
FB 0018	Berries and other small fruits (excl grapes)	2.2	0.2	0.4	1.8	4.0	0.1	0.2	0.0	0.0	1.8	4.0	6.2	13.6	10.6	23.3
VL 0054	Brassica leafy vegetables	0.37	10.3	3.8	4.0	1.5	7.3	2.7	1.0	0.4	2.0	0.7	23.8	8.8	1.7	0.6
VB 0041	Cabbage, head	0.03	10.0	0.3	1.0	0.0	7.2	0.2	1.0	0.0	1.4	0.0	23.9	0.7	17.0	0.5
VR 0577	Carrot	0.09	5.4	0.5	7.9	0.7	2.5	0.2	3.5	0.3	4.1	0.4	8.6	0.8	19.4	1.7
DH 0170	Dried herbs (excl dry hops)	25	0.7	17.5	0.1	1.5	0.2	5.8	0.3	8.3	0.2	5.0	0.1	3.0	0.1	1.3
MO 0105	Edible offal (mammalian)	0	4.8	0.0	10.7	0.0	4.0	0.0	4.0	0.0	6.5	0.0	6.6	0.0	5.6	0.0
PE 0112	Eggs	0	22.1	0.0	71.5	0.0	16.6	0.0	5.1	0.0	17.6	0.0	35.2	0.0	57.4	0.0
VB 0042	Flowerhead brassicas	0.27	9.6	2.6	7.9	2.1	0.6	0.2	0.2	0.1	0.9	0.2	1.1	0.3	8.0	2.2
VO 0050	Fruiting vegetables other than cucurbits (excl sweet corn, excl mushrooms)	0.24	56.4	13.5	55.2	13.2	31.0	7.4	47.8	11.5	40.5	9.7	25.4	6.1	112.8	27.1
VC 0045	Fruiting vegetables, cucurbits	0.09	69.7	6.3	25.9	2.3	14.9	1.3	18.0	1.6	18.7	1.7	39.1	3.5	44.2	4.0
FB 0269	Grape (excl dried, excl juice, excl wine)	0.79	1.2	0.9	2.6	2.1	0.0	0.0	0.2	0.1	0.0	0.0	3.7	2.9	0.0	0.0
JF 0269	Grape juice	0.12	0.0	0.0	0.1	0.0	1.0	0.1	0.0	0.0	0.6	0.1	0.4	0.0	3.6	0.4
DF 0269	Grape, dried (= currants, raisins and sultanas)	1.7	0.0	0.0	0.2	0.3	0.2	0.3	0.0	0.0	0.3	0.5	0.4	0.7	2.6	4.4
HH 0720	Herbs	5.05	7.0	35.4	0.6	3.0	2.3	11.6	3.3	16.7	2.0	10.1	1.2	6.1	0.5	2.5
VL 0053	Leafy vegetables (excl brassica leafy vegetables)	11	30.5	335.5	8.0	88.0	5.2	57.2	8.5	93.5	3.4	37.4	26.2	288.2	37.4	411.4
MM 0095	Meat from mammals other than marine mammals	0	54.8	0.0	89.4	0.0	30.6	0.0	28.6	0.0	82.1	0.0	61.1	0.0	158.3	0.0
ML 0106	Milks (excl processed products)	0	66.0	0.0	121.1	0.0	81.6	0.0	102.4	0.0	207.7	0.0	57.0	0.0	287.9	0.0
VA 0385	Onion, bulb (= dry + green onion)	0.065	17.4	1.1	27.9	1.8	7.3	0.5	16.0	1.0	22.8	1.5	34.5	2.2	30.1	2.0
VR 0588	Parsnip	0.09	0.0	0.0	0.3	0.0	0.0	0.0	0.0	0.0	1.0	0.1	0.0	0.0	0.1	0.0
DF 0014	Plum, dried (prunes)	1.2	0.1	0.1	0.2	0.2	0.0	0.0	0.0	0.0	0.2	0.2	0.2	0.2	0.6	0.7
FP 0009	Pome fruit (excl apple juice)	0.48	20.8	10.0	11.6	5.5	3.3	1.6	0.1	0.0	10.7	5.1	23.6	11.3	36.9	17.7
PM 0110	Poultry meat	0	17.6	0.0	131.3	0.0	25.1	0.0	4.7	0.0	145.9	0.0	27.7	0.0	115.1	0.0
PO 0111	Poultry, edible offal of	0	0.4	0.0	1.0	0.0	1.9	0.0	0.0	0.0	0.7	0.0	1.0	0.0	0.3	0.0
VR 0494	Radish	0.01	0.0	0.0	0.3	0.0	0.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0	0.3	0.0
HS 0093	Spices	2	2.9	5.8	1.8	3.6	1.3	2.6	2.6	5.2	0.5	1.0	2.0	4.0	1.3	2.6
FS 0012	Stone fruit (excl dried plums, incl dried apricots)	0.68	6.7	4.6	4.3	2.9	1.4	1.0	0.1	0.1	4.9	3.3	4.9	3.3	17.7	12.0
JF 0448	Tomato juice	0.036	0.0	0.0	0.8	0.0	0.1	0.0	7.2	0.3	0.0	0.0	2.4	0.1	45.2	1.6
-d	Tomato paste	0.48	0.1	0.0	2.1	1.0	0.6	0.3	0.4	0.2	0.6	0.3	1.4	0.7	1.2	0.6
GC 0654	Wheat (incl bulgur wholemeal, excl flour)	0.07	0.0	0.0	0.9	0.1	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.1	0.0
CM 0654	Wheat bran, unprocessed	0.21	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-

Annex 3

CYPRODINIL (207) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0300 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G		H		I		J		K		L		M	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
CF 1211	Wheat flour (incl macaroni, bread, pastry, starch, gluten)	0.019	133.0	2.5	60.1	1.1	52.4	1.0	32.2	0.6	87.7	1.7	79.6	1.5	180.1	3.4
CF 1212	Wheat wholemeal	0.064	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CP 1212	Wholemeal bread	0.036	0.0	0.0	2.2	0.1	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
-	Wine	0.062	1.0	0.1	0.9	0.1	6.8	0.4	0.1	0.0	3.4	0.2	3.6	0.2	31.0	1.9
	Total intake (µg/person)=			442.6		140.9		95.5		140.5		86.2		359.9		525.9
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			1650		1800		1800		1800		1800		1650		1800
	%ADI=			26.8%		7.8%		5.3%		7.8%		4.8%		21.8%		29.2%
	Rounded %ADI=			30%		8%		5%		8%		5%		20%		30%

DICAMBA (240) International Estimated Daily Intake (IEDI) ADI = 0 - 0.3000 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A		B		C		D		E		F	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
VS 0621	Asparagus	0.87	0.0	0.0	1.1	1.0	0.6	0.5	0.2	0.2	1.2	1.0	0.1	0.1
GC 0640	Barley (incl pot, incl pearled, incl flour & grits, incl beer)	1.7	40.6	69.0	16.8	28.6	93.9	159.6	13.2	22.4	48.6	82.6	36.1	61.4
OR 0691	Cotton seed oil, edible	0.008	0.9	0.0	4.9	0.0	1.7	0.0	6.6	0.1	0.0	0.0	0.3	0.0
MO 0105	Edible offal (mammalian)	0.16	3.9	0.6	14.4	2.3	5.2	0.8	11.8	1.9	11.7	1.9	7.6	1.2
PE 0112	Eggs	0.01	2.5	0.0	29.7	0.3	25.1	0.3	24.5	0.2	37.8	0.4	27.4	0.3
GC 0645	Maize (incl flour, excl oil, incl beer)	0.02	82.7	1.7	1.4	0.0	51.4	1.0	31.8	0.6	0.2	0.0	0.2	0.0
OR 0645	Maize oil, edible	0.00116	0.1	0.0	4.0	0.0	2.3	0.0	0.5	0.0	0.9	0.0	0.2	0.0
MF 0100	Mammalian fats (except milk fats)	0.023	0.8	0.0	10.0	0.2	0.9	0.0	6.6	0.2	11.8	0.3	3.7	0.1
MM 0095	Meat from mammals other than marine mammals	0.01	27.7	0.3	116.5	1.2	38.5	0.4	55.1	0.6	90.2	0.9	131.3	1.3
ML 0106	Milks (excl processed products)	0.021	68.8	1.4	190.6	4.0	79.4	1.7	302.6	6.4	179.6	3.8	237.9	5.0
PM 0110	Poultry meat	0.01	7.1	0.1	58.5	0.6	31.9	0.3	24.0	0.2	61.0	0.6	27.3	0.3
PO 0111	Poultry, edible offal of	0.01	0.4	0.0	0.4	0.0	1.7	0.0	0.1	0.0	0.6	0.0	0.2	0.0
PF 0111	Poultry, fats	0.01	0.1	0.0	0.1	0.0	0.1	0.0	0.0	0.0	0.4	0.0	0.1	0.0
GC 0651	Sorghum (incl flour, incl beer)	2	36.9	73.8	0.0	0.0	10.2	20.4	0.0	0.0	0.0	0.0	0.0	0.0

Annex 3

DICAMBA (240) International Estimated Daily Intake (IEDI) ADI = 0 - 0.3000 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A		B		C		D		E		F	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
VD 0541	Soya bean (dry, excl oil)	0.033	0.9	0.0	0.0	0.0	0.7	0.0	0.0	0.0	0.0	0.0	0.0	0.0
OR 0541	Soya bean oil, refined	0.001	1.6	0.0	6.5	0.0	6.0	0.0	4.0	0.0	6.3	0.0	7.0	0.0
GS 0659	Sugar cane	0.095	30.9	2.9	43.1	4.1	51.3	4.9	0.1	0.0	5.5	0.5	0.0	0.0
DM 0659	Sugar cane molasses	3.4	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
GC 0654	Wheat (incl bulgur wholemeal, excl flour)	0.26	6.0	1.6	11.1	2.9	0.8	0.2	0.2	0.1	0.2	0.1	0.0	0.0
CM 0654	Wheat bran, unprocessed	0.26	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CF 1211	Wheat flour (incl macaroni, bread, pastry, starch, gluten)	0.02	63.4	1.3	296.3	5.9	327.5	6.6	300.0	6.0	181.6	3.6	166.2	3.3
	Total intake (µg/person)=			152.7		51.1		196.7		38.8		95.7		73.0
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			18000		18000		18000		18000		18000		18000
	%ADI=			0.8%		0.3%		1.1%		0.2%		0.5%		0.4%
	Rounded %ADI=			1%		0%		1%		0%		1%		0%

DICAMBA (240) International Estimated Daily Intake (IEDI) ADI = 0 - 0.3000 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G		H		I		J		K		L		M	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
VS 0621	Asparagus	0.87	3.7	3.2	0.3	0.3	0.2	0.2	0.0	0.0	0.0	0.0	0.5	0.4	1.1	1.0
GC 0640	Barley (incl pot, incl pearled, incl flour & grits, incl beer)	1.7	5.9	10.0	20.5	34.9	5.9	10.0	2.5	4.3	20.2	34.3	16.8	28.6	43.8	74.5
OR 0691	Cotton seed oil, edible	0.008	1.0	0.0	0.7	0.0	1.0	0.0	1.4	0.0	1.5	0.0	5.5	0.0	1.2	0.0
MO 0105	Edible offal (mammalian)	0.16	4.8	0.8	10.7	1.7	4.0	0.6	4.0	0.6	6.5	1.0	6.6	1.1	5.6	0.9
PE 0112	Eggs	0.01	22.1	0.2	71.5	0.7	16.6	0.2	5.1	0.1	17.6	0.2	35.2	0.4	57.4	0.6
GC 0645	Maize (incl flour, excl oil, incl beer)	0.02	35.2	0.7	298.6	6.0	248.1	5.0	57.4	1.1	63.1	1.3	0.0	0.0	19.4	0.4
OR 0645	Maize oil, edible	0.00116	0.1	0.0	0.6	0.0	1.8	0.0	0.0	0.0	1.0	0.0	1.6	0.0	1.8	0.0
MF 0100	Mammalian fats (except milk fats)	0.023	2.2	0.1	18.6	0.4	0.5	0.0	0.8	0.0	5.7	0.1	4.5	0.1	18.2	0.4
MM 0095	Meat from mammals other than marine mammals	0.01	54.8	0.5	89.4	0.9	30.6	0.3	28.6	0.3	82.1	0.8	61.1	0.6	158.3	1.6
ML 0106	Milks (excl processed products)	0.021	66.0	1.4	121.1	2.5	81.6	1.7	102.4	2.2	207.7	4.4	57.0	1.2	287.9	6.0

Annex 3

DICAMBA (240) International Estimated Daily Intake (IEDI) ADI = 0 - 0.3000 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G		H		I		J		K		L		M	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
PM 0110	Poultry meat	0.01	17.6	0.2	131.3	1.3	25.1	0.3	4.7	0.0	145.9	1.5	27.7	0.3	115.1	1.2
PO 0111	Poultry, edible offal of	0.01	0.4	0.0	1.0	0.0	1.9	0.0	0.0	0.0	0.7	0.0	1.0	0.0	0.3	0.0
PF 0111	Poultry, fats	0.01	0.1	0.0	8.2	0.1	0.0	0.0	0.1	0.0	0.0	0.0	0.1	0.0	4.2	0.0
GC 0651	Sorghum (incl flour, incl beer)	2	9.8	19.6	19.9	39.8	18.6	37.2	112.3	224.6	0.1	0.2	3.3	6.6	3.0	6.0
VD 0541	Soya bean (dry, excl oil)	0.033	1.8	0.1	0.0	0.0	0.0	0.0	3.2	0.1	0.1	0.0	0.0	0.0	0.0	0.0
OR 0541	Soya bean oil, refined	0.001	4.3	0.0	10.6	0.0	2.0	0.0	1.4	0.0	19.5	0.0	9.2	0.0	22.0	0.0
GS 0659	Sugar cane	0.095	26.2	2.5	1.5	0.1	33.8	3.2	5.5	0.5	18.6	1.8	3.0	0.3	20.2	1.9
DM 0659	Sugar cane molasses	3.4	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
GC 0654	Wheat (incl bulgur wholemeal, excl flour)	0.26	0.0	0.0	0.9	0.2	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.1	0.0
CM 0654	Wheat bran, unprocessed	0.26	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CF 1211	Wheat flour (incl macaroni, bread, pastry, starch, gluten)	0.02	133.0	2.7	60.1	1.2	52.4	1.0	32.2	0.6	87.7	1.8	79.6	1.6	180.1	3.6
	Total intake (µg/person)=			41.9		90.2		59.7		234.5		47.4		41.1		98.1
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			16500		18000		18000		18000		18000		16500		18000
	%ADI=			0.3%		0.5%		0.3%		1.3%		0.3%		0.2%		0.5%
	Rounded %ADI=			0%		1%		0%		1%		0%		0%		1%

DIFENOCONAZOLE (224) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0100 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A		B		C		D		E		F	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
FC 0001	Citrus fruit (excl lemon juice, excl mandarin juice, excl orange juice, excl grapefruit juice, excl NES juice)	0.16	15.7	1.8	86.5	9.7	52.6	5.9	24.2	2.7	16.2	1.8	12.0	1.3
-d	Lemon juice	0.002	0.0	0.0	0.9	0.0	0.1	0.0	0.0	0.0	0.2	0.0	0.4	0.0
-	Citrus juice NES	0.002	0.0	0.0	1.7	0.0	0.1	0.0	0.0	0.0	1.1	0.0	0.3	0.0
JF 0004	Orange juice	0.002	0.0	0.0	2.1	0.0	4.4	0.0	1.4	0.0	16.2	0.0	22.6	0.0
JF 0203	Grapefruit juice	0.002	0.0	0.0	0.2	0.0	0.1	0.0	0.1	0.0	1.1	0.0	0.2	0.0
TN 0085	Tree nuts	0.01	4.2	0.0	21.5	0.2	3.9	0.0	3.0	0.0	5.5	0.1	10.2	0.1

Annex 3

DIFENOCONAZOLE (224) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0100 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day; Intake = daily intake: µg/person											
			A		B		C		D		E		F	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
FP 0009	Pome fruit (excl apple juice)	0.16	0.5	0.1	79.9	12.8	21.8	3.5	43.6	7.0	51.5	8.2	35.1	5.6
JF 0226	Apple juice	0.005	0.0	0.0	2.8	0.0	0.1	0.0	1.1	0.0	6.8	0.0	7.4	0.0
FS 0013	Cherries	0.04	0.0	0.0	6.8	0.3	0.9	0.0	6.2	0.2	3.6	0.1	0.4	0.0
FS 0014	Plum (incl dried)	0.04	0.1	0.0	5.9	0.2	2.5	0.1	7.3	0.3	6.9	0.3	2.6	0.1
FS 0245	Nectarine	0.15	0.0	0.0	0.5	0.1	3.3	0.5	1.8	0.3	2.8	0.4	1.6	0.2
FS 0247	Peach	0.15	0.2	0.0	24.8	3.7	3.3	0.5	1.8	0.3	5.4	0.8	1.6	0.2
FB 0269	Grape (excl dried, excl juice, excl wine)	0.52	1.9	1.0	9.2	4.8	23.8	12.4	9.8	5.1	0.0	0.0	0.0	0.0
DF 0269	Grape, dried (= currants, raisins and sultanas)	1.1	0.0	0.0	2.9	3.2	0.4	0.4	0.4	0.4	2.3	2.5	1.7	1.9
JF 0269	Grape juice	0.24	0.0	0.0	0.1	0.0	0.1	0.0	0.1	0.0	1.4	0.3	1.0	0.2
-	Wine	0.094	1.3	0.1	76.8	7.2	1.1	0.1	15.4	1.4	68.8	6.5	25.6	2.4
FT 0305	Olive (table olives, only)	0.465	0.0	0.0	4.8	2.2	0.8	0.4	0.4	0.2	1.0	0.5	0.8	0.4
OR 0305	Olive oil, refined	0.65	0.0	0.0	14.3	9.3	3.9	2.5	0.0	0.0	1.5	1.0	0.8	0.5
FI 0327	Banana	0.02	38.8	0.5	17.4	0.2	16.0	0.2	6.6	0.1	21.5	0.3	33.8	0.5
FI 0345	Mango (incl juice, incl pulp)	0.03	6.3	0.2	1.0	0.0	4.6	0.1	0.2	0.0	0.7	0.0	0.3	0.0
FI 0350	Papaya	0.065	5.1	0.3	0.1	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0
FI 0351	Passion fruit	0.01	0.3	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
VR 0577	Carrot	0.05	0.6	0.0	15.1	0.8	8.1	0.4	13.9	0.7	27.1	1.4	28.4	1.4
VR 0578	Celeriac	0.12	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
VR 0589	Potato (incl flour, frozen, starch, tapioca)	1.2	19.1	22.9	160.8	193.0	61.2	73.4	243.6	292.3	230.1	276.1	204.7	245.6
VR 0596	Sugar beet	0.02	0.0	0.0	40.7	0.8	0.0	0.0	0.1	0.0	6.0	0.1	0.1	0.0
VA 0384	Leek	0.08	0.3	0.0	5.3	0.4	0.0	0.0	0.2	0.0	4.6	0.4	1.5	0.1
-	Onion, dry	0.015	4.3	0.1	45.6	0.7	27.4	0.4	30.2	0.5	22.1	0.3	12.2	0.2
VA 0389	Spring onion	2.8	0.3	0.8	1.0	2.8	1.4	3.9	0.3	0.8	0.3	0.8	0.6	1.7
VC 0046	Melons, except watermelon	0.14	3.6	0.5	26.7	3.7	22.6	3.2	11.5	1.6	5.6	0.8	2.0	0.3
VC 0424	Cucumber	0.04	0.3	0.0	12.7	0.5	5.9	0.2	11.5	0.5	6.1	0.2	7.1	0.3
VC 0425	Gherkin	0.04	0.3	0.0	12.7	0.5	5.9	0.2	11.5	0.5	6.1	0.2	7.1	0.3
VC 0431	Squash, summer (= courgette, zuchini)	0.04	0.0	0.0	8.3	0.3	11.4	0.5	7.3	0.3	3.2	0.1	0.3	0.0
VO 0051	Peppers	0.14	1.4	0.2	29.9	4.2	13.0	1.8	6.3	0.9	6.2	0.9	4.0	0.6
VO 0440	Egg plant (= aubergine)	0.14	1.7	0.2	17.5	2.5	12.3	1.7	1.7	0.2	0.8	0.1	0.4	0.1
VO 0442	Okra	0.14	3.9	0.5	1.0	0.1	5.3	0.7	0.1	0.0	0.0	0.0	0.0	0.0
VO 0448	Tomato (excl juice, excl paste, excl canned)	0.14	1.3	0.2	178.4	25.0	102.8	14.4	53.4	7.5	1.6	0.2	0.0	0.0
JF 0448	Tomato juice	0.031	5.2	0.2	0.5	0.0	0.4	0.0	2.1	0.1	6.9	0.2	15.2	0.5
-d	Tomato paste	0.22	0.5	0.1	1.3	0.3	3.5	0.8	1.0	0.2	3.8	0.8	4.5	1.0
-d	Tomato, canned	0.01	0.1	0.0	0.4	0.0	0.5	0.0	0.4	0.0	4.9	0.0	3.2	0.0

Annex 3

DIFENOCONAZOLE (224) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0100 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A		B		C		D		E		F	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
VB 0040	Brassica vegetables	0.35	1.7	0.6	25.7	9.0	9.1	3.2	27.8	9.7	36.9	12.9	26.4	9.2
VL 0482	Lettuce, head	0.41	0.1	0.0	6.2	2.5	0.7	0.3	0.1	0.0	0.1	0.0	0.0	0.0
VL 0483	Lettuce, leaf	0.41	0.0	0.0	9.2	3.8	1.0	0.4	0.1	0.0	5.4	2.2	18.0	7.4
VP 0061	Beans except broad bean & soya bean (green pods & immature seeds)	0.07	1.0	0.1	17.4	1.2	7.5	0.5	0.9	0.1	16.4	1.1	0.1	0.0
VP 0063	Peas (green pods and/or immature seeds)	0.07	0.1	0.0	2.9	0.2	6.0	0.4	0.6	0.0	9.7	0.7	5.2	0.4
VS 0621	Asparagus	0.02	0.0	0.0	1.1	0.0	0.6	0.0	0.2	0.0	1.2	0.0	0.1	0.0
VS 0624	Celery	0.14	0.0	0.0	0.9	0.1	0.0	0.0	2.0	0.3	1.5	0.2	0.0	0.0
VD 0541	Soya bean (dry, incl oil)	0.02	9.9	0.2	36.4	0.7	34.3	0.7	22.4	0.4	35.3	0.7	39.2	0.8
SO 0495	Rape seed (incl oil)	0.02	0.9	0.0	1.8	0.0	2.5	0.1	1.9	0.0	35.7	0.7	26.1	0.5
SO 0702	Sunflower seed (incl oil)	0.01	0.7	0.0	44.5	0.4	20.5	0.2	29.6	0.3	21.2	0.2	5.4	0.1
GC 0654	Wheat (incl bulgur wholemeal, incl flour)	0	88.4	0.0	396.3	0.0	426.5	0.0	390.2	0.0	236.3	0.0	216.0	0.0
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.14	5.5	0.8	23.3	3.3	7.7	1.1	11.0	1.5	18.0	2.5	26.3	3.7
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0.047	22.2	1.0	93.2	4.4	30.8	1.4	44.1	2.1	72.2	3.4	105.0	4.9
MO 0105	Edible offal (mammalian)	0.71	3.9	2.8	14.4	10.2	5.2	3.7	11.8	8.4	11.7	8.3	7.6	5.4
PM 0110	Poultry meat: 10% as fat	0.001	0.7	0.0	5.9	0.0	3.2	0.0	2.4	0.0	6.1	0.0	2.7	0.0
PM 0110	Poultry meat: 90% as muscle	0.001	6.4	0.0	52.7	0.1	28.7	0.0	21.6	0.0	54.9	0.1	24.6	0.0
PO 0111	Poultry, edible offal of	0.001	0.4	0.0	0.4	0.0	1.7	0.0	0.1	0.0	0.6	0.0	0.2	0.0
ML 0106	Milks (excl processed products)	0.011	68.8	0.8	190.6	2.1	79.4	0.9	302.6	3.3	179.6	2.0	237.9	2.6
PE 0112	Eggs	0.011	2.5	0.0	29.7	0.3	25.1	0.3	24.5	0.3	37.8	0.4	27.4	0.3
	Total intake (µg/person)=			36.2		328.1		141.7		350.7		341.3		300.9
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			600		600		600		600		600		600
	%ADI=			6.0%		54.7%		23.6%		58.5%		56.9%		50.2%
	Rounded %ADI=			6%		50%		20%		60%		60%		50%

Annex 3

DIFENOCONAZOLE (224) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0100 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day; Intake = daily intake: µg/person													
			G		H		I		J		K		L		M	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
FC 0001	Citrus fruit (excl lemon juice, excl mandarin juice, excl orange juice, excl grapefruit juice, excl NES juice)	0.16	15.1	1.7	153.9	17.2	3.4	0.4	41.7	4.7	218.9	24.5	23.1	2.6	18.0	2.0
-d	Lemon juice	0.002	0.3	0.0	0.0	0.0	1.0	0.0	0.3	0.0	0.0	0.0	0.5	0.0	2.6	0.0
-	Citrus juice NES	0.002	0.0	0.0	0.0	0.0	0.5	0.0	0.0	0.0	0.0	0.0	0.3	0.0	0.1	0.0
JF 0004	Orange juice	0.002	0.2	0.0	1.0	0.0	3.5	0.0	0.0	0.0	1.3	0.0	6.4	0.0	56.8	0.1
JF 0203	Grapefruit juice	0.002	0.0	0.0	0.0	0.0	0.5	0.0	0.0	0.0	0.0	0.0	0.3	0.0	2.4	0.0
TN 0085	Tree nuts	0.01	16.3	0.2	15.7	0.2	9.7	0.1	1.9	0.0	19.1	0.2	29.0	0.3	5.6	0.1
FP 0009	Pome fruit (excl apple juice)	0.16	20.8	3.3	11.6	1.8	3.3	0.5	0.1	0.0	10.7	1.7	23.6	3.8	36.9	5.9
JF 0226	Apple juice	0.005	0.1	0.0	0.5	0.0	0.1	0.0	0.0	0.0	0.7	0.0	0.9	0.0	5.7	0.0
FS 0013	Cherries	0.04	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.3	0.0	2.5	0.1
FS 0014	Plum (incl dried)	0.04	3.3	0.1	1.4	0.1	0.1	0.0	0.0	0.0	0.6	0.0	1.5	0.1	2.2	0.1
FS 0245	Nectarine	0.15	1.7	0.3	1.7	0.3	0.0	0.0	0.0	0.0	1.0	0.2	1.7	0.3	1.4	0.2
FS 0247	Peach	0.15	1.7	0.3	1.7	0.3	1.1	0.2	0.1	0.0	1.0	0.2	1.7	0.3	10.2	1.5
FB 0269	Grape (excl dried, excl juice, excl wine)	0.52	1.2	0.6	2.6	1.4	0.0	0.0	0.2	0.1	0.0	0.0	3.7	1.9	0.0	0.0
DF 0269	Grape, dried (= currants, raisins and sultanas)	1.1	0.0	0.0	0.2	0.2	0.2	0.2	0.0	0.0	0.3	0.3	0.4	0.4	2.6	2.9
JF 0269	Grape juice	0.24	0.0	0.0	0.1	0.0	1.0	0.2	0.0	0.0	0.6	0.1	0.4	0.1	3.6	0.9
-	Wine	0.094	1.0	0.1	0.9	0.1	6.8	0.6	0.1	0.0	3.4	0.3	3.6	0.3	31.0	2.9
FT 0305	Olive (table olives, only)	0.465	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.6	0.3	0.0	0.0	1.0	0.5
OR 0305	Olive oil, refined	0.65	0.0	0.0	0.1	0.1	0.0	0.0	0.0	0.0	0.3	0.2	0.3	0.2	1.6	1.0
FI 0327	Banana	0.02	21.4	0.3	36.6	0.5	11.4	0.2	9.2	0.1	70.2	1.0	40.5	0.6	32.6	0.5
FI 0345	Mango (incl juice, incl pulp)	0.03	12.7	0.4	26.2	0.8	6.1	0.2	12.7	0.4	9.2	0.3	8.0	0.2	1.9	0.1
FI 0350	Papaya	0.065	1.3	0.1	11.5	0.7	1.6	0.1	13.7	0.9	14.5	0.9	1.0	0.1	0.6	0.0
FI 0351	Passion fruit	0.01	0.0	0.0	0.3	0.0	0.1	0.0	0.1	0.0	1.3	0.0	0.0	0.0	0.0	0.0
VR 0577	Carrot	0.05	5.4	0.3	7.9	0.4	2.5	0.1	3.5	0.2	4.1	0.2	8.6	0.4	19.4	1.0
VR 0578	Celeriac	0.12	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
VR 0589	Potato (incl flour, frozen, starch, tapioca)	1.2	52.7	63.2	57.1	68.5	50.1	60.1	4.3	5.2	54.7	65.6	41.0	49.2	168.0	201.6
VR 0596	Sugar beet	0.02	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.2	0.0	0.0	0.0	14.3	0.3
VA 0384	Leek	0.08	0.8	0.1	0.2	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.3	0.0	0.1	0.0
-	Onion, dry	0.015	16.8	0.3	8.6	0.1	6.9	0.1	12.1	0.2	18.6	0.3	23.8	0.4	28.4	0.4
VA 0389	Spring onion	2.8	0.1	0.3	4.8	13.4	0.1	0.3	1.0	2.8	1.0	2.8	2.7	7.6	0.6	1.7
VC 0046	Melons, except watermelon	0.14	7.5	1.1	6.1	0.9	0.7	0.1	1.4	0.2	2.5	0.4	6.9	1.0	12.4	1.7
VC 0424	Cucumber	0.04	7.9	0.3	0.6	0.0	0.2	0.0	0.0	0.0	0.4	0.0	5.5	0.2	5.3	0.2
VC 0425	Gherkin	0.04	7.9	0.3	0.6	0.0	0.2	0.0	0.0	0.0	0.4	0.0	5.5	0.2	5.3	0.2
VC 0431	Squash, summer (= courgette, zuchini)	0.04	2.4	0.1	1.5	0.1	0.0	0.0	0.0	0.0	3.8	0.2	2.2	0.1	2.5	0.1

Annex 3

DIFENOCONAZOLE (224) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0100 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G		H		I		J		K		L		M	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
VO 0051	Peppers	0.14	8.7	1.2	22.4	3.1	8.4	1.2	9.4	1.3	3.3	0.5	5.3	0.7	8.9	1.2
VO 0440	Egg plant (= aubergine)	0.14	20.1	2.8	0.1	0.0	0.6	0.1	6.3	0.9	0.5	0.1	6.3	0.9	0.7	0.1
VO 0442	Okra	0.14	4.1	0.6	1.0	0.1	7.0	1.0	15.9	2.2	1.1	0.2	3.9	0.5	0.2	0.0
VO 0448	Tomato (excl juice, excl paste, excl canned)	0.14	22.8	3.2	4.1	0.6	12.3	1.7	1.8	0.3	32.8	4.6	0.4	0.1	27.3	3.8
JF 0448	Tomato juice	0.031	0.0	0.0	0.8	0.0	0.1	0.0	7.2	0.2	0.0	0.0	2.4	0.1	45.2	1.4
-d	Tomato paste	0.22	0.1	0.0	2.1	0.5	0.6	0.1	0.4	0.1	0.6	0.1	1.4	0.3	1.2	0.3
-d	Tomato, canned	0.01	0.2	0.0	14.5	0.1	0.2	0.0	0.0	0.0	0.3	0.0	0.8	0.0	1.2	0.0
VB 0040	Brassica vegetables	0.35	26.4	9.2	9.3	3.3	7.8	2.7	1.5	0.5	3.3	1.2	40.8	14.3	26.0	9.1
VL 0482	Lettuce, head	0.41	1.2	0.5	3.5	1.4	0.1	0.0	0.3	0.1	1.0	0.4	1.2	0.5	7.9	3.2
VL 0483	Lettuce, leaf	0.41	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	2.5	1.0
VP 0061	Beans except broad bean & soya bean (green pods & immature seeds)	0.07	2.6	0.2	2.6	0.2	1.0	0.1	0.5	0.0	0.6	0.0	2.8	0.2	9.8	0.7
VP 0063	Peas (green pods and/or immature seeds)	0.07	3.9	0.3	1.6	0.1	0.4	0.0	0.0	0.0	0.9	0.1	1.0	0.1	8.6	0.6
VS 0621	Asparagus	0.02	3.7	0.1	0.3	0.0	0.2	0.0	0.0	0.0	0.0	0.0	0.5	0.0	1.1	0.0
VS 0624	Celery	0.14	0.0	0.0	0.3	0.0	0.0	0.0	0.0	0.0	1.0	0.1	0.0	0.0	4.2	0.6
VD 0541	Soya bean (dry, incl oil)	0.02	25.9	0.5	59.4	1.2	11.2	0.2	11.0	0.2	109.3	2.2	51.5	1.0	123.2	2.5
SO 0495	Rape seed (incl oil)	0.02	9.9	0.2	5.9	0.1	0.3	0.0	1.0	0.0	0.0	0.0	15.5	0.3	9.9	0.2
SO 0702	Sunflower seed (incl oil)	0.01	2.7	0.0	8.8	0.1	13.5	0.1	0.2	0.0	3.6	0.0	0.6	0.0	10.4	0.1
GC 0654	Wheat (incl bulgur wholemeal, incl flour)	0	172.9	0.0	79.0	0.0	68.1	0.0	41.9	0.0	114.1	0.0	103.4	0.0	234.2	0.0
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.14	11.0	1.5	17.9	2.5	6.1	0.9	5.7	0.8	16.4	2.3	12.2	1.7	31.7	4.4
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0.047	43.8	2.1	71.5	3.4	24.5	1.2	22.9	1.1	65.7	3.1	48.9	2.3	126.6	6.0
MO 0105	Edible offal (mammalian)	0.71	4.8	3.4	10.7	7.6	4.0	2.8	4.0	2.8	6.5	4.6	6.6	4.7	5.6	4.0
PM 0110	Poultry meat: 10% as fat	0.001	1.8	0.0	13.1	0.0	2.5	0.0	0.5	0.0	14.6	0.0	2.8	0.0	11.5	0.0
PM 0110	Poultry meat: 90% as muscle	0.001	15.8	0.0	118.2	0.1	22.6	0.0	4.2	0.0	131.3	0.1	24.9	0.0	103.6	0.1
PO 0111	Poultry, edible offal of	0.001	0.4	0.0	1.0	0.0	1.9	0.0	0.0	0.0	0.7	0.0	1.0	0.0	0.3	0.0
ML 0106	Milks (excl processed products)	0.011	66.0	0.7	121.1	1.3	81.6	0.9	102.4	1.1	207.7	2.3	57.0	0.6	287.9	3.2
PE 0112	Eggs	0.011	22.1	0.2	71.5	0.8	16.6	0.2	5.1	0.1	17.6	0.2	35.2	0.4	57.4	0.6
	Total intake (µg/person)=			100.0		133.8		76.8		26.5		121.8		98.9		269.1
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			550		600		600		600		600		550		600
	%ADI=			18.2%		22.3%		12.8%		4.4%		20.3%		18.0%		44.9%
	Rounded %ADI=			20%		20%		10%		4%		20%		20%		40%

Annex 3

DIQUAT (32) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0060 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A		B		C		D		E		F	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
FI 0327	Banana	0	38.8	0.0	17.4	0.0	16.0	0.0	6.6	0.0	21.5	0.0	33.8	0.0
VD 0071	Beans (dry)	0.05	15.8	0.8	6.1	0.3	1.7	0.1	6.3	0.3	1.8	0.1	5.0	0.3
FT 0292	Cashew apple	0	8.4	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
FC 0001	Citrus fruit (incl lemon juice, incl mandarin juice, incl orange juice, incl grapefruit juice, incl NES juice)	0	15.7	0.0	100.5	0.0	63.2	0.0	27.8	0.0	52.6	0.0	56.9	0.0
SB 0716	Coffee beans (incl green, incl extracts, incl roasted)	0	3.1	0.0	12.6	0.0	2.9	0.0	1.4	0.0	10.1	0.0	18.0	0.0
MO 0105	Edible offal (mammalian)	0	3.9	0.0	14.4	0.0	5.2	0.0	11.8	0.0	11.7	0.0	7.6	0.0
PE 0112	Eggs	0	2.5	0.0	29.7	0.0	25.1	0.0	24.5	0.0	37.8	0.0	27.4	0.0
VO 0050	Fruiting vegetables other than cucurbits (excl sweet corn, excl mushrooms)	0	18.8	0.0	233.4	0.0	148.6	0.0	68.8	0.0	38.6	0.0	45.3	0.0
MF 0100	Mammalian fats (except milk fats)	0	0.8	0.0	10.0	0.0	0.9	0.0	6.6	0.0	11.8	0.0	3.7	0.0
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0	5.5	0.0	23.3	0.0	7.7	0.0	11.0	0.0	18.0	0.0	26.3	0.0
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0	22.2	0.0	93.2	0.0	30.8	0.0	44.1	0.0	72.2	0.0	105.0	0.0
ML 0106	Milks (excl processed products)	0	68.8	0.0	190.6	0.0	79.4	0.0	302.6	0.0	179.6	0.0	237.9	0.0
VD 0072	Peas (dry) (= field pea + cowpea)	0.05	6.8	0.3	1.3	0.1	1.0	0.1	2.3	0.1	4.6	0.2	3.4	0.2
VR 0589	Potato (incl flour, frozen, starch, tapioca)	0.05	19.1	1.0	160.8	8.0	61.2	3.1	243.6	12.2	230.1	11.5	204.7	10.2
PM 0110	Poultry meat: 10% as fat	0	0.7	0.0	5.9	0.0	3.2	0.0	2.4	0.0	6.1	0.0	2.7	0.0
PM 0110	Poultry meat: 90% as muscle	0	6.4	0.0	52.7	0.0	28.7	0.0	21.6	0.0	54.9	0.0	24.6	0.0
PO 0111	Poultry, edible offal of	0	0.4	0.0	0.4	0.0	1.7	0.0	0.1	0.0	0.6	0.0	0.2	0.0
SO 0495	Rape seed (excl oil)	0.49	0.1	0.1	0.0	0.0	0.0	0.0	0.1	0.0	0.1	0.0	0.1	0.0
OR 0495	Rape seed oil, edible	0.0098	0.3	0.0	0.7	0.0	1.0	0.0	0.7	0.0	13.7	0.1	10.0	0.1
VD 0541	Soya bean (dry, excl oil)	0.03	0.9	0.0	0.0	0.0	0.7	0.0	0.0	0.0	0.0	0.0	0.0	0.0
OR 0541	Soya bean oil, refined	0.00165	1.6	0.0	6.5	0.0	6.0	0.0	4.0	0.0	6.3	0.0	7.0	0.0
FS 0012	Stone fruit (incl dried plums, incl dried apricots)	0	0.7	0.0	44.7	0.0	14.1	0.0	26.9	0.0	27.7	0.0	10.0	0.0
FB 0275	Strawberry	0	0.0	0.0	5.0	0.0	2.0	0.0	1.7	0.0	5.2	0.0	4.1	0.0
SO 0702	Sunflower seed (excl oil)	0.11	0.0	0.0	13.1	1.4	0.0	0.0	0.1	0.0	0.1	0.0	0.1	0.0
OR 0702	Sunflower seed oil, edible	0.066	0.3	0.0	13.1	0.9	8.6	0.6	12.3	0.8	8.8	0.6	2.2	0.1
	Total intake (µg/person)=			2.2		10.7		3.8		13.5		12.6		11.0
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			360		360		360		360		360		360
	%ADI=			0.6%		3.0%		1.1%		3.7%		3.5%		3.0%
	Rounded %ADI=			1%		3%		1%		4%		3%		3%

DIQUAT (32) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0060 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G		H		I		J		K		L		M	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
FI 0327	Banana	0	21.4	0.0	36.6	0.0	11.4	0.0	9.2	0.0	70.2	0.0	40.5	0.0	32.6	0.0
VD 0071	Beans (dry)	0.05	3.4	0.2	25.5	1.3	7.8	0.4	2.1	0.1	44.7	2.2	5.5	0.3	7.3	0.4
FT 0292	Cashew apple	0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	15.3	0.0	0.0	0.0	0.0	0.0
FC 0001	Citrus fruit (incl lemon juice, incl mandarin juice, incl orange juice, incl grapefruit juice, incl NES juice)	0	17.3	0.0	156.8	0.0	14.9	0.0	42.5	0.0	222.8	0.0	40.4	0.0	132.3	0.0
SB 0716	Coffee beans (incl green, incl extracts, incl roasted)	0	0.2	0.0	7.0	0.0	0.5	0.0	0.2	0.0	5.3	0.0	5.7	0.0	12.4	0.0
MO 0105	Edible offal (mammalian)	0	4.8	0.0	10.7	0.0	4.0	0.0	4.0	0.0	6.5	0.0	6.6	0.0	5.6	0.0
PE 0112	Eggs	0	22.1	0.0	71.5	0.0	16.6	0.0	5.1	0.0	17.6	0.0	35.2	0.0	57.4	0.0
VO 0050	Fruiting vegetables other than cucurbits (excl sweet corn, excl mushrooms)	0	56.4	0.0	55.2	0.0	31.0	0.0	47.8	0.0	40.5	0.0	25.4	0.0	112.8	0.0
MF 0100	Mammalian fats (except milk fats)	0	2.2	0.0	18.6	0.0	0.5	0.0	0.8	0.0	5.7	0.0	4.5	0.0	18.2	0.0
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0	11.0	0.0	17.9	0.0	6.1	0.0	5.7	0.0	16.4	0.0	12.2	0.0	31.7	0.0
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0	43.8	0.0	71.5	0.0	24.5	0.0	22.9	0.0	65.7	0.0	48.9	0.0	126.6	0.0
ML 0106	Milks (excl processed products)	0	66.0	0.0	121.1	0.0	81.6	0.0	102.4	0.0	207.7	0.0	57.0	0.0	287.9	0.0
VD 0072	Peas (dry) (= field pea + cowpea)	0.05	1.8	0.1	2.2	0.1	3.2	0.2	26.7	1.3	1.5	0.1	1.8	0.1	1.8	0.1
VR 0589	Potato (incl flour, frozen, starch, tapioca)	0.05	52.7	2.6	57.1	2.9	50.1	2.5	4.3	0.2	54.7	2.7	41.0	2.1	168.0	8.4
PM 0110	Poultry meat: 10% as fat	0	1.8	0.0	13.1	0.0	2.5	0.0	0.5	0.0	14.6	0.0	2.8	0.0	11.5	0.0
PM 0110	Poultry meat: 90% as muscle	0	15.8	0.0	118.2	0.0	22.6	0.0	4.2	0.0	131.3	0.0	24.9	0.0	103.6	0.0
PO 0111	Poultry, edible offal of	0	0.4	0.0	1.0	0.0	1.9	0.0	0.0	0.0	0.7	0.0	1.0	0.0	0.3	0.0
SO 0495	Rape seed (excl oil)	0.49	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
OR 0495	Rape seed oil, edible	0.0098	3.8	0.0	2.3	0.0	0.1	0.0	0.4	0.0	0.0	0.0	6.0	0.1	3.8	0.0
VD 0541	Soya bean (dry, excl oil)	0.03	1.8	0.1	0.0	0.0	0.0	0.0	3.2	0.1	0.1	0.0	0.0	0.0	0.0	0.0
OR 0541	Soya bean oil, refined	0.00165	4.3	0.0	10.6	0.0	2.0	0.0	1.4	0.0	19.5	0.0	9.2	0.0	22.0	0.0
FS 0012	Stone fruit (incl dried plums, incl dried apricots)	0	7.0	0.0	4.9	0.0	1.4	0.0	0.1	0.0	5.5	0.0	5.5	0.0	19.4	0.0
FB 0275	Strawberry	0	0.0	0.0	1.8	0.0	0.1	0.0	0.0	0.0	0.3	0.0	6.2	0.0	5.9	0.0
SO 0702	Sunflower seed (excl oil)	0.11	0.1	0.0	0.2	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.1	0.0	1.8	0.2
OR 0702	Sunflower seed oil, edible	0.066	1.1	0.1	3.6	0.2	5.6	0.4	0.1	0.0	1.5	0.1	0.2	0.0	3.6	0.2

Annex 3

DIQUAT (32) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0060 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day G diet	Intake = daily intake: µg/person G intake	H diet	H intake	I diet	I intake	J diet	J intake	K diet	K intake	L diet	L intake	M diet	M intake
	Total intake (µg/person)=			3.1		4.5		3.5		1.8		5.2		2.5		9.4
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			330		360		360		360		360		330		360
	%ADI=			0.9%		1.3%		1.0%		0.5%		1.4%		0.8%		2.6%
	Rounded %ADI=			1%		1%		1%		0%		1%		1%		3%

DITHIANON (180) International Estimated Daily Intake (IEDI) ADI = 0–0.01 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day A diet	Intake = daily intake: µg/person A intake	B diet	B intake	C diet	C intake	D diet	D intake	E diet	E intake	F Diet	F intake
TN 0660	Almond	0	0.0	0.0	1.9	0.0	1.0	0.0	0.0	0.0	1.0	0.0	0.8	0.0
JF 0226	Apple juice	0.0045	0.0	0.0	2.8	0.0	0.1	0.0	1.1	0.0	6.8	0.0	7.4	0.0
DF 0226	Apple, dried	0.015	ND	–	ND	–	ND	–	ND	–	ND	–	ND	–
FB 0021	Currants, red, black, white	0.105	0.0	0.0	0.0	0.0	0.0	0.0	2.2	0.2	3.1	0.3	2.0	0.2
MO 0105	Edible offal (mammalian)	0	3.9	0.0	14.4	0.0	5.2	0.0	11.8	0.0	11.7	0.0	7.6	0.0
PE 0112	Eggs	0	2.5	0.0	29.7	0.0	25.1	0.0	24.5	0.0	37.8	0.0	27.4	0.0
FB 0269	Grape (excl dried, excl juice, excl wine)	0.63	1.9	1.2	9.2	5.8	23.8	15.0	9.8	6.2	0.0	0.0	0.0	0.0
JF 0269	Grape juice	0.002	0.0	0.0	0.1	0.0	0.1	0.0	0.1	0.0	1.4	0.0	1.0	0.0
DF 0269	Grape, dried (= currants, raisins and sultanas)	1.03	0.0	0.0	2.9	3.0	0.4	0.4	0.4	0.4	2.3	2.4	1.7	1.8
MF 0100	Mammalian fats (except milk fats)	0	0.8	0.0	10.0	0.0	0.9	0.0	6.6	0.0	11.8	0.0	3.7	0.0
MM 0095	Meat from mammals other than marine mammals	0	27.7	0.0	116.5	0.0	38.5	0.0	55.1	0.0	90.2	0.0	131.3	0.0
ML 0106	Milks (excl processed products)	0	68.8	0.0	190.6	0.0	79.4	0.0	302.6	0.0	179.6	0.0	237.9	0.0
DF 0014	Plum, dried (prunes)	0.22	0.0	0.0	0.2	0.0	0.0	0.0	0.1	0.0	0.5	0.1	0.6	0.1
FP 0009	Pome fruit (excl apple juice)	0.15	0.5	0.1	79.9	12.0	21.8	3.3	43.6	6.5	51.5	7.7	35.1	5.3
PM 0110	Poultry meat	0	7.1	0.0	58.5	0.0	31.9	0.0	24.0	0.0	61.0	0.0	27.3	0.0
PO 0111	Poultry, edible offal of	0	0.4	0.0	0.4	0.0	1.7	0.0	0.1	0.0	0.6	0.0	0.2	0.0
PF 0111	Poultry, fats	0	0.1	0.0	0.1	0.0	0.1	0.0	0.0	0.0	0.4	0.0	0.1	0.0

Annex 3

DITHIANON (180) International Estimated Daily Intake (IEDI) ADI = 0–0.01 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day		Intake = daily intake: µg/person									
			A		B		C		D		E		F	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	Diet	intake
FS 0012	Stone fruit (excl dried plums, incl dried apricots)	0.43	0.7	0.3	44.1	19.0	14.1	6.1	26.6	11.4	26.3	11.3	8.3	3.6
–	Wine	0.002	1.3	0.0	76.8	0.2	1.1	0.0	15.4	0.0	68.8	0.1	25.6	0.1
	Total intake (µg/person)=			1.6		40.0		24.7		24.8		22.0		11.0
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			600		600		600		600		600		600
	%ADI=			0.3%		6.7%		4.1%		4.1%		3.7%		1.8%
	Rounded % ADI=			0%		7%		4%		4%		4%		2%

DITHIANON (180) International Estimated Daily Intake (IEDI) ADI = 0–0.01 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day		Intake = daily intake: µg/person											
			G		H		I		J		K		L		M	
			Diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	Intake
TN 0660	Almond	0	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.3	0.0	0.3	0.0
JF 0226	Apple juice	0.0045	0.1	0.0	0.5	0.0	0.1	0.0	0.0	0.0	0.7	0.0	0.9	0.0	5.7	0.0
DF 0226	Apple, dried	0.015	ND	–	ND	–	ND	–	ND	–	ND	–	ND	–	ND	–
FB 0021	Currants, red, black, white	0.105	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
MO 0105	Edible offal (mammalian)	0	4.8	0.0	10.7	0.0	4.0	0.0	4.0	0.0	6.5	0.0	6.6	0.0	5.6	0.0
PE 0112	Eggs	0	22.1	0.0	71.5	0.0	16.6	0.0	5.1	0.0	17.6	0.0	35.2	0.0	57.4	0.0
FB 0269	Grape (excl dried, excl juice, excl wine)	0.63	1.2	0.8	2.6	1.6	0.0	0.0	0.2	0.1	0.0	0.0	3.7	2.3	0.0	0.0
JF 0269	Grape juice	0.002	0.0	0.0	0.1	0.0	1.0	0.0	0.0	0.0	0.6	0.0	0.4	0.0	3.6	0.0
DF 0269	Grape, dried (= currants, raisins and sultanas)	1.03	0.0	0.0	0.2	0.2	0.2	0.2	0.0	0.0	0.3	0.3	0.4	0.4	2.6	2.7
MF 0100	Mammalian fats (except milk fats)	0	2.2	0.0	18.6	0.0	0.5	0.0	0.8	0.0	5.7	0.0	4.5	0.0	18.2	0.0
MM 0095	Meat from mammals other than marine mammals	0	54.8	0.0	89.4	0.0	30.6	0.0	28.6	0.0	82.1	0.0	61.1	0.0	158.3	0.0
ML 0106	Milks (excl processed products)	0	66.0	0.0	121.1	0.0	81.6	0.0	102.4	0.0	207.7	0.0	57.0	0.0	287.9	0.0
DF 0014	Plum, dried (prunes)	0.22	0.1	0.0	0.2	0.0	0.0	0.0	0.0	0.0	0.2	0.0	0.2	0.0	0.6	0.1
FP 0009	Pome fruit (excl apple juice)	0.15	20.8	3.1	11.6	1.7	3.3	0.5	0.1	0.0	10.7	1.6	23.6	3.5	36.9	5.5
PM 0110	Poultry meat	0	17.6	0.0	131.3	0.0	25.1	0.0	4.7	0.0	145.9	0.0	27.7	0.0	115.1	0.0

Annex 3

DITHIANON (180) International Estimated Daily Intake (IEDI) ADI = 0–0.01 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G		H		I		J		K		L		M	
			Diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	Intake
PO 0111	Poultry, edible offal of	0	0.4	0.0	1.0	0.0	1.9	0.0	0.0	0.0	0.7	0.0	1.0	0.0	0.3	0.0
PF 0111	Poultry, fats	0	0.1	0.0	8.2	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.1	0.0	4.2	0.0
FS 0012	Stone fruit (excl dried plums, incl dried apricots)	0.43	6.7	2.9	4.3	1.9	1.4	0.6	0.1	0.0	4.9	2.1	4.9	2.1	17.7	7.6
–	Wine	0.002	1.0	0.0	0.9	0.0	6.8	0.0	0.1	0.0	3.4	0.0	3.6	0.0	31.0	0.1
	Total intake (µg/person)=			6.8		5.5		1.3		0.2		4.1		8.4		16.0
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			550		600		600		600		600		550		600
	%ADI=			1.2%		0.9%		0.2%		0.0%		0.7%		1.5%		2.7%
	Rounded % ADI=			1%		1%		0%		0%		1%		2%		3%

FENBUCONAZOLE (197) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0300 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A		B		C		D		E		F	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
JF 0226	Apple juice	0.01	0.0	0.0	2.8	0.0	0.1	0.0	1.1	0.0	6.8	0.1	7.4	0.1
DF 0226	Apple, dried	0.3	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
FS 0240	Apricot (incl dried)	0.25	0.3	0.1	6.2	1.6	3.9	1.0	3.2	0.8	2.0	0.5	0.8	0.2
FI 0327	Banana	0.01	38.8	0.4	17.4	0.2	16.0	0.2	6.6	0.1	21.5	0.2	33.8	0.3
GC 0640	Barley (incl pot, incl pearled, incl flour & grits, incl beer)	0.03	40.6	1.2	16.8	0.5	93.9	2.8	13.2	0.4	48.6	1.5	36.1	1.1
FB 0020	Blueberries	0.06	0.0	0.0	0.0	0.0	0.0	0.0	0.2	0.0	0.3	0.0	0.8	0.0
FS 0013	Cherries	0.36	0.0	0.0	6.8	2.4	0.9	0.3	6.2	2.2	3.6	1.3	0.4	0.1
-	Citrus juice NES	0.021	0.0	0.0	1.7	0.0	0.1	0.0	0.0	0.0	1.1	0.0	0.3	0.0
FB 0265	Cranberries	0.13	0.1	0.0	0.0	0.0	0.0	0.0	0.3	0.0	0.0	0.0	0.6	0.1
VC 0424	Cucumber	0.025	0.3	0.0	12.7	0.3	5.9	0.1	11.5	0.3	6.1	0.2	7.1	0.2
MO 0105	Edible offal (mammalian)	0.02	3.9	0.1	14.4	0.3	5.2	0.1	11.8	0.2	11.7	0.2	7.6	0.2
PE 0112	Eggs	0	2.5	0.0	29.7	0.0	25.1	0.0	24.5	0.0	37.8	0.0	27.4	0.0
FB 0269	Grape (incl dried, excl juice, excl wine)	0.3	1.9	0.6	20.8	6.3	25.4	7.6	11.4	3.4	9.2	2.8	6.8	2.0
JF 0269	Grape juice	0.03	0.0	0.0	0.1	0.0	0.1	0.0	0.1	0.0	1.4	0.0	1.0	0.0

Annex 3

FENBUCONAZOLE (197) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0300 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A		B		C		D		E		F	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
JF 0203	Grapefruit juice	0.021	0.0	0.0	0.2	0.0	0.1	0.0	0.1	0.0	1.1	0.0	0.2	0.0
FC 0002	Lemon + lime + citrus fruit NES (excl lemon juice, excl NES juice)	0.018	10.4	0.2	11.4	0.2	11.5	0.2	7.4	0.1	0.8	0.0	0.8	0.0
-d	Lemon juice	0.067	0.0	0.0	0.9	0.1	0.1	0.0	0.0	0.0	0.2	0.0	0.4	0.0
FC 0003	Mandarin + mandarin-like hybrid (excl juice)	0.01	0.6	0.0	16.0	0.2	10.3	0.1	4.6	0.0	8.4	0.1	9.7	0.1
-	Mandarin + mandarin-like hybrid juice	0.021	0.0	0.0	1.4	0.0	0.9	0.0	0.4	0.0	0.7	0.0	0.9	0.0
MM 0095	Meat from mammals other than marine mammals	0.003	27.7	0.1	116.5	0.3	38.5	0.1	55.1	0.2	90.2	0.3	131.3	0.4
VC 0046	Melons, except watermelon	0.025	3.6	0.1	26.7	0.7	22.6	0.6	11.5	0.3	5.6	0.1	2.0	0.1
ML 0106	Milks (excl processed products)	0	68.8	0.0	190.6	0.0	79.4	0.0	302.6	0.0	179.6	0.0	237.9	0.0
JF 0004	Orange juice	0.021	0.0	0.0	2.1	0.0	4.4	0.1	1.4	0.0	16.2	0.3	22.6	0.5
FC 0004	Orange, sweet, sour + orange-like hybrid (excl juice)	0.01	4.2	0.0	54.1	0.5	30.1	0.3	11.9	0.1	0.2	0.0	0.5	0.0
FS 0247	Peach	0.25	0.2	0.1	24.8	6.2	3.3	0.8	1.8	0.5	5.4	1.4	1.6	0.4
OR 0697	Peanut oil, edible	0.04	1.7	0.1	0.8	0.0	0.5	0.0	0.1	0.0	1.4	0.1	0.4	0.0
SO 0697	Peanut, shelled (excl oil)	0.03	1.5	0.0	1.3	0.0	1.0	0.0	0.5	0.0	0.8	0.0	0.5	0.0
VO 0051	Peppers	0.15	1.4	0.2	29.9	4.5	13.0	2.0	6.3	0.9	6.2	0.9	4.0	0.6
FS 0014	Plum (incl dried)	0.08	0.1	0.0	5.9	0.5	2.5	0.2	7.3	0.6	6.9	0.6	2.6	0.2
FP 0009	Pome fruit (excl apple juice)	0.12	0.5	0.1	79.9	9.6	21.8	2.6	43.6	5.2	51.5	6.2	35.1	4.2
PM 0110	Poultry meat	0	7.1	0.0	58.5	0.0	31.9	0.0	24.0	0.0	61.0	0.0	27.3	0.0
PO 0111	Poultry, edible offal of	0	0.4	0.0	0.4	0.0	1.7	0.0	0.1	0.0	0.6	0.0	0.2	0.0
SO 0495	Rape seed (incl oil)	0.05	0.9	0.0	1.8	0.1	2.5	0.1	1.9	0.1	35.7	1.8	26.1	1.3
GC 0650	Rye (incl flour)	0.02	0.1	0.0	3.7	0.1	0.3	0.0	24.3	0.5	25.8	0.5	45.8	0.9
FC 0005	Shaddock or pomelo + shaddock-like hybrid (excl juice)	0.01	0.5	0.0	4.9	0.0	0.7	0.0	0.3	0.0	6.8	0.1	1.0	0.0
VC 0431	Squash, summer (= courgette, zuchini)	0.02	0.0	0.0	8.3	0.2	11.4	0.2	7.3	0.1	3.2	0.1	0.3	0.0
SO 0702	Sunflower seed (incl oil)	0.02	0.7	0.0	44.5	0.9	20.5	0.4	29.6	0.6	21.2	0.4	5.4	0.1
FC 4031	Tangelo	0.01	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
TN 0085	Tree nuts	0	4.2	0.0	21.5	0.0	3.9	0.0	3.0	0.0	5.5	0.0	10.2	0.0
GC 0654	Wheat (incl bulgur wholemeal, excl flour)	0.02	6.0	0.1	11.1	0.2	0.8	0.0	0.2	0.0	0.2	0.0	0.0	0.0
CM 0654	Wheat bran, unprocessed	0.26	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CF 1211	Wheat flour (incl macaroni, bread, pastry, starch, gluten)	0.025	63.4	1.6	296.3	7.4	327.5	8.2	300.0	7.5	181.6	4.5	166.2	4.2
CP 1212	Wholemeal bread	0.046	0.0	0.0	0.1	0.0	0.0	0.0	0.1	0.0	0.1	0.0	1.0	0.0
-	Wine	0.018	1.3	0.0	76.8	1.4	1.1	0.0	15.4	0.3	68.8	1.2	25.6	0.5
	Total intake (µg/person)=			5.0		44.8		28.2		24.6		25.4		17.9
	Bodyweight per region (kg bw) =			60		60		60		60		60		60

Annex 3

FENBUCONAZOLE (197) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0300 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A		B		C		D		E		F	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
	ADI (µg/person)=			1800		1800		1800		1800		1800		1800
	%ADI=			0.3%		2.5%		1.6%		1.4%		1.4%		1.0%
	Rounded %ADI=			0%		2%		2%		1%		1%		1%

FENBUCONAZOLE (197) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0300 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G		H		I		J		K		L		M	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
JF 0226	Apple juice	0.01	0.1	0.0	0.5	0.0	0.1	0.0	0.0	0.0	0.7	0.0	0.9	0.0	5.7	0.1
DF 0226	Apple, dried	0.3	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
FS 0240	Apricot (incl dried)	0.25	0.2	0.1	0.1	0.0	0.2	0.1	0.0	0.0	0.0	0.0	0.1	0.0	1.1	0.3
FI 0327	Banana	0.01	21.4	0.2	36.6	0.4	11.4	0.1	9.2	0.1	70.2	0.7	40.5	0.4	32.6	0.3
GC 0640	Barley (incl pot, incl pearled, incl flour & grits, incl beer)	0.03	5.9	0.2	20.5	0.6	5.9	0.2	2.5	0.1	20.2	0.6	16.8	0.5	43.8	1.3
FB 0020	Blueberries	0.06	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.3	0.1
FS 0013	Cherries	0.36	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.3	0.1	2.5	0.9
-	Citrus juice NES	0.021	0.0	0.0	0.0	0.0	0.5	0.0	0.0	0.0	0.0	0.0	0.3	0.0	0.1	0.0
FB 0265	Cranberries	0.13	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	2.5	0.3
VC 0424	Cucumber	0.025	7.9	0.2	0.6	0.0	0.2	0.0	0.0	0.0	0.4	0.0	5.5	0.1	5.3	0.1
MO 0105	Edible offal (mammalian)	0.02	4.8	0.1	10.7	0.2	4.0	0.1	4.0	0.1	6.5	0.1	6.6	0.1	5.6	0.1
PE 0112	Eggs	0	22.1	0.0	71.5	0.0	16.6	0.0	5.1	0.0	17.6	0.0	35.2	0.0	57.4	0.0
FB 0269	Grape (incl dried, excl juice, excl wine)	0.3	1.2	0.4	3.4	1.0	0.8	0.2	0.2	0.0	1.2	0.4	5.3	1.6	10.4	3.1
JF 0269	Grape juice	0.03	0.0	0.0	0.1	0.0	1.0	0.0	0.0	0.0	0.6	0.0	0.4	0.0	3.6	0.1
JF 0203	Grapefruit juice	0.021	0.0	0.0	0.0	0.0	0.5	0.0	0.0	0.0	0.0	0.0	0.3	0.0	2.4	0.1
FC 0002	Lemon + lime + citrus fruit NES (excl lemon juice, excl NES juice)	0.018	1.7	0.0	22.8	0.4	0.6	0.0	38.3	0.7	6.3	0.1	2.4	0.0	3.3	0.1
-d	Lemon juice	0.067	0.3	0.0	0.0	0.0	1.0	0.1	0.3	0.0	0.0	0.0	0.5	0.0	2.6	0.2
FC 0003	Mandarin + mandarin-like hybrid (excl juice)	0.01	5.9	0.1	5.4	0.1	0.6	0.0	0.2	0.0	7.8	0.1	16.0	0.2	6.5	0.1
-	Mandarin + mandarin-like hybrid juice	0.021	0.5	0.0	0.5	0.0	0.1	0.0	0.0	0.0	0.7	0.0	1.4	0.0	0.0	0.0
MM 0095	Meat from mammals other than marine	0.003	54.8	0.2	89.4	0.3	30.6	0.1	28.6	0.1	82.1	0.2	61.1	0.2	158.3	0.5

Annex 3

FENBUCONAZOLE (197) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0300 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G		H		I		J		K		L		M	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
	mammals															
VC 0046	Melons, except watermelon	0.025	7.5	0.2	6.1	0.2	0.7	0.0	1.4	0.0	2.5	0.1	6.9	0.2	12.4	0.3
ML 0106	Milks (excl processed products)	0	66.0	0.0	121.1	0.0	81.6	0.0	102.4	0.0	207.7	0.0	57.0	0.0	287.9	0.0
JF 0004	Orange juice	0.021	0.2	0.0	1.0	0.0	3.5	0.1	0.0	0.0	1.3	0.0	6.4	0.1	56.8	1.2
FC 0004	Orange, sweet, sour + orange-like hybrid (excl juice)	0.01	7.0	0.1	117.1	1.2	2.0	0.0	2.4	0.0	200.7	2.0	0.5	0.0	0.2	0.0
FS 0247	Peach	0.25	1.7	0.4	1.7	0.4	1.1	0.3	0.1	0.0	1.0	0.3	1.7	0.4	10.2	2.6
OR 0697	Peanut oil, edible	0.04	3.0	0.1	0.3	0.0	1.5	0.1	7.9	0.3	0.3	0.0	0.0	0.0	0.4	0.0
SO 0697	Peanut, shelled (excl oil)	0.03	0.7	0.0	1.4	0.0	1.3	0.0	3.6	0.1	0.2	0.0	0.7	0.0	6.0	0.2
VO 0051	Peppers	0.15	8.7	1.3	22.4	3.4	8.4	1.3	9.4	1.4	3.3	0.5	5.3	0.8	8.9	1.3
FS 0014	Plum (incl dried)	0.08	3.3	0.3	1.4	0.1	0.1	0.0	0.0	0.0	0.6	0.0	1.5	0.1	2.2	0.2
FP 0009	Pome fruit (excl apple juice)	0.12	20.8	2.5	11.6	1.4	3.3	0.4	0.1	0.0	10.7	1.3	23.6	2.8	36.9	4.4
PM 0110	Poultry meat	0	17.6	0.0	131.3	0.0	25.1	0.0	4.7	0.0	145.9	0.0	27.7	0.0	115.1	0.0
PO 0111	Poultry, edible offal of	0	0.4	0.0	1.0	0.0	1.9	0.0	0.0	0.0	0.7	0.0	1.0	0.0	0.3	0.0
SO 0495	Rape seed (incl oil)	0.05	9.9	0.5	5.9	0.3	0.3	0.0	1.0	0.1	0.0	0.0	15.5	0.8	9.9	0.5
GC 0650	Rye (incl flour)	0.02	0.4	0.0	0.0	0.0	0.2	0.0	0.1	0.0	0.1	0.0	0.9	0.0	0.8	0.0
FC 0005	Shaddock or pomelo + shaddock-like hybrid (excl juice)	0.01	0.4	0.0	8.6	0.1	0.3	0.0	0.8	0.0	4.2	0.0	4.2	0.0	8.1	0.1
VC 0431	Squash, summer (= courgette, zuchini)	0.02	2.4	0.0	1.5	0.0	0.0	0.0	0.0	0.0	3.8	0.1	2.2	0.0	2.5	0.1
SO 0702	Sunflower seed (incl oil)	0.02	2.7	0.1	8.8	0.2	13.5	0.3	0.2	0.0	3.6	0.1	0.6	0.0	10.4	0.2
FC 4031	Tangelo	0.01	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
TN 0085	Tree nuts	0	16.3	0.0	15.7	0.0	9.7	0.0	1.9	0.0	19.1	0.0	29.0	0.0	5.6	0.0
GC 0654	Wheat (incl bulgur wholemeal, excl flour)	0.02	0.0	0.0	0.9	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.1	0.0
CM 0654	Wheat bran, unprocessed	0.26	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CF 1211	Wheat flour (incl macaroni, bread, pastry, starch, gluten)	0.025	133.0	3.3	60.1	1.5	52.4	1.3	32.2	0.8	87.7	2.2	79.6	2.0	180.1	4.5
CP 1212	Wholemeal bread	0.046	0.0	0.0	2.2	0.1	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
-	Wine	0.018	1.0	0.0	0.9	0.0	6.8	0.1	0.1	0.0	3.4	0.1	3.6	0.1	31.0	0.6
	Total intake (µg/person)=			10.2		11.9		4.8		3.9		8.9		10.8		23.7
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			1650		1800		1800		1800		1800		1650		1800
	%ADI=			0.6%		0.7%		0.3%		0.2%		0.5%		0.7%		1.3%
	Rounded %ADI=			1%		1%		0%		0%		0%		1%		1%

Annex 3

FENPYROXIMATE (193) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0100 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A		B		C		D		E		F	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
JF 0226	Apple juice	0.04	0.0	0.0	2.8	0.1	0.1	0.0	1.1	0.0	6.8	0.3	7.4	0.3
FS 0240	Apricot (incl dried)	0.13	0.3	0.0	6.2	0.8	3.9	0.5	3.2	0.4	2.0	0.3	0.8	0.1
FI 0326	Avocado	0.055	3.7	0.2	1.0	0.1	0.2	0.0	0.0	0.0	0.9	0.0	0.8	0.0
-	Barley beer	0.005	18.3	0.1	84.1	0.4	4.1	0.0	66.0	0.3	243.1	1.2	161.3	0.8
FS 0013	Cherries	0.57	0.0	0.0	6.8	3.9	0.9	0.5	6.2	3.5	3.6	2.1	0.4	0.2
FC 0001	Citrus fruit (incl lemon juice, incl mandarin juice, incl orange juice, incl grapefruit juice, incl NES juice)	0.034	15.7	0.5	100.5	3.4	63.2	2.1	27.8	0.9	52.6	1.8	56.9	1.9
VP 0526	Common bean (green pods and/or immature seeds)	0.09	0.5	0.0	4.7	0.4	4.1	0.4	0.0	0.0	13.1	1.2	0.0	0.0
VC 0424	Cucumber	0.06	0.3	0.0	12.7	0.8	5.9	0.4	11.5	0.7	6.1	0.4	7.1	0.4
MO 0105	Edible offal (mammalian)	0.003	3.9	0.0	14.4	0.0	5.2	0.0	11.8	0.0	11.7	0.0	7.6	0.0
VO 0050	Fruiting vegetables other than cucurbits (excl sweet corn, excl mushrooms)	0.06	18.8	1.1	233.4	14.0	148.6	8.9	68.8	4.1	38.6	2.3	45.3	2.7
FE 0269	Grape (incl dried, incl juice, excl wine)	0.02	1.9	0.0	21.0	0.4	25.6	0.5	11.5	0.2	11.2	0.2	8.2	0.2
DF 0269	Grape, dried (= currants, raisins and sultanas)	0.06	0.0	0.0	2.9	0.2	0.4	0.0	0.4	0.0	2.3	0.1	1.7	0.1
DH 1100	Hops, dry	4.4	0.1	0.4	0.1	0.4	0.1	0.4	0.1	0.4	0.3	1.3	0.1	0.4
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.021	5.5	0.1	23.3	0.5	7.7	0.2	11.0	0.2	18.0	0.4	26.3	0.6
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0.011	22.2	0.2	93.2	1.0	30.8	0.3	44.1	0.5	72.2	0.8	105.0	1.2
VC 0046	Melons, except watermelon	0.05	3.6	0.2	26.7	1.3	22.6	1.1	11.5	0.6	5.6	0.3	2.0	0.1
ML 0106	Milks (excl processed products)	0.005	68.8	0.3	190.6	1.0	79.4	0.4	302.6	1.5	179.6	0.9	237.9	1.2
FS 0245	Nectarine	0.13	0.0	0.0	0.5	0.1	3.3	0.4	1.8	0.2	2.8	0.4	1.6	0.2
FS 0247	Peach	0.13	0.2	0.0	24.8	3.2	3.3	0.4	1.8	0.2	5.4	0.7	1.6	0.2
FS 0014	Plum (excl dried)	0.13	0.1	0.0	5.3	0.7	2.5	0.3	7.0	0.9	5.5	0.7	0.9	0.1
DF 0014	Plum, dried (prunes)	0.18	0.0	0.0	0.2	0.0	0.0	0.0	0.1	0.0	0.5	0.1	0.6	0.1
FP 0009	Pome fruit (excl apple juice)	0.09	0.5	0.0	79.9	7.2	21.8	2.0	43.6	3.9	51.5	4.6	35.1	3.2
VR 0589	Potato (incl flour, frozen, starch, tapioca)	0	19.1	0.0	160.8	0.0	61.2	0.0	243.6	0.0	230.1	0.0	204.7	0.0
-	Stone fruit NES	0.13	0.1	0.0	0.5	0.1	0.2	0.0	6.6	0.9	7.0	0.9	3.0	0.4
FB 0275	Strawberry	0.215	0.0	0.0	5.0	1.1	2.0	0.4	1.7	0.4	5.2	1.1	4.1	0.9
TN 0085	Tree nuts	0.05	4.2	0.2	21.5	1.1	3.9	0.2	3.0	0.2	5.5	0.3	10.2	0.5
-	Wine	0.0004	1.3	0.0	76.8	0.0	1.1	0.0	15.4	0.0	68.8	0.0	25.6	0.0
	Total intake (µg/person)=			3.7		42.2		19.7		20.3		22.4		15.9
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			600		600		600		600		600		600
	%ADI=			0.6%		7.0%		3.3%		3.4%		3.7%		2.6%
	Rounded %ADI=			1%		7%		3%		3%		4%		3%

Annex 3

FENPYROXIMATE (193) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0100 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day Intake = daily intake: µg/person G diet	G intake	H diet	H intake	I diet	I intake	J diet	J intake	K diet	K intake	L diet	L intake	M diet	M intake
JF 0226	Apple juice	0.04	0.1	0.0	0.5	0.0	0.1	0.0	0.0	0.0	0.7	0.0	0.9	0.0	5.7	0.2
FS 0240	Apricot (incl dried)	0.13	0.2	0.0	0.1	0.0	0.2	0.0	0.0	0.0	0.0	0.0	0.1	0.0	1.1	0.1
FI 0326	Avocado	0.055	0.2	0.0	13.9	0.8	1.0	0.1	1.7	0.1	3.4	0.2	0.5	0.0	2.1	0.1
-	Barley beer	0.005	21.9	0.1	102.7	0.5	29.5	0.1	12.6	0.1	100.9	0.5	82.2	0.4	218.8	1.1
FS 0013	Cherries	0.57	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.3	0.2	2.5	1.4
FC 0001	Citrus fruit (incl lemon juice, incl mandarin juice, incl orange juice, incl grapefruit juice, incl NES juice)	0.034	17.3	0.6	156.8	5.3	14.9	0.5	42.5	1.4	222.8	7.6	40.4	1.4	132.3	4.5
VP 0526	Common bean (green pods and/or immature seeds)	0.09	0.0	0.0	1.9	0.2	0.0	0.0	0.0	0.0	0.3	0.0	1.8	0.2	8.0	0.7
VC 0424	Cucumber	0.06	7.9	0.5	0.6	0.0	0.2	0.0	0.0	0.0	0.4	0.0	5.5	0.3	5.3	0.3
MO 0105	Edible offal (mammalian)	0.003	4.8	0.0	10.7	0.0	4.0	0.0	4.0	0.0	6.5	0.0	6.6	0.0	5.6	0.0
VO 0050	Fruiting vegetables other than cucurbits (excl sweet corn, excl mushrooms)	0.06	56.4	3.4	55.2	3.3	31.0	1.9	47.8	2.9	40.5	2.4	25.4	1.5	112.8	6.8
FE 0269	Grape (incl dried, incl juice, excl wine)	0.02	1.2	0.0	3.5	0.1	2.2	0.0	0.2	0.0	2.0	0.0	5.9	0.1	15.4	0.3
DF 0269	Grape, dried (= currants, raisins and sultanas)	0.06	0.0	0.0	0.2	0.0	0.2	0.0	0.0	0.0	0.3	0.0	0.4	0.0	2.6	0.2
DH 1100	Hops, dry	4.4	0.0	0.0	0.1	0.4	0.1	0.4	0.1	0.4	0.1	0.4	0.1	0.4	0.6	2.6
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.021	11.0	0.2	17.9	0.4	6.1	0.1	5.7	0.1	16.4	0.3	12.2	0.3	31.7	0.7
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0.011	43.8	0.5	71.5	0.8	24.5	0.3	22.9	0.3	65.7	0.7	48.9	0.5	126.6	1.4
VC 0046	Melons, except watermelon	0.05	7.5	0.4	6.1	0.3	0.7	0.0	1.4	0.1	2.5	0.1	6.9	0.3	12.4	0.6
ML 0106	Milks (excl processed products)	0.005	66.0	0.3	121.1	0.6	81.6	0.4	102.4	0.5	207.7	1.0	57.0	0.3	287.9	1.4
FS 0245	Nectarine	0.13	1.7	0.2	1.7	0.2	0.0	0.0	0.0	0.0	1.0	0.1	1.7	0.2	1.4	0.2
FS 0247	Peach	0.13	1.7	0.2	1.7	0.2	1.1	0.1	0.1	0.0	1.0	0.1	1.7	0.2	10.2	1.3
FS 0014	Plum (excl dried)	0.13	3.0	0.4	0.8	0.1	0.1	0.0	0.0	0.0	0.0	0.0	0.9	0.1	0.5	0.1
DF 0014	Plum, dried (prunes)	0.18	0.1	0.0	0.2	0.0	0.0	0.0	0.0	0.0	0.2	0.0	0.2	0.0	0.6	0.1
FP 0009	Pome fruit (excl apple juice)	0.09	20.8	1.9	11.6	1.0	3.3	0.3	0.1	0.0	10.7	1.0	23.6	2.1	36.9	3.3
VR 0589	Potato (incl flour, frozen, starch, tapioca)	0	52.7	0.0	57.1	0.0	50.1	0.0	4.3	0.0	54.7	0.0	41.0	0.0	168.0	0.0
-	Stone fruit NES	0.13	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	2.9	0.4	0.2	0.0	2.0	0.3
FB 0275	Strawberry	0.215	0.0	0.0	1.8	0.4	0.1	0.0	0.0	0.0	0.3	0.1	6.2	1.3	5.9	1.3
TN 0085	Tree nuts	0.05	16.3	0.8	15.7	0.8	9.7	0.5	1.9	0.1	19.1	1.0	29.0	1.5	5.6	0.3
-	Wine	0.0004	1.0	0.0	0.9	0.0	6.8	0.0	0.1	0.0	3.4	0.0	3.6	0.0	31.0	0.0

Annex 3

FENPYROXIMATE (193) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0100 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G		H		I		J		K		L		M	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
	Total intake (µg/person)=			9.6		15.6		4.9		6.0		16.2		11.6		29.4
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			550		600		600		600		600		550		600
	%ADI=			1.7%		2.6%		0.8%		1.0%		2.7%		2.1%		4.9%
	Rounded %ADI=			2%		3%		1%		1%		3%		2%		5%

FLUDIOXONIL (211) International Estimated Daily Intake (IEDI) ADI = 0 - 0.4000 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			A		B		C		D		E		F			
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake		
JF 0226	Apple juice	0.17	0.0	0.0	2.8	0.5	0.1	0.0	1.1	0.2	6.8	1.2	7.4	1.3		
FI 0326	Avocado	0.05	3.7	0.2	1.0	0.1	0.2	0.0	0.0	0.0	0.9	0.0	0.8	0.0		
VD 0071	Beans (dry)	0.04	15.8	0.6	6.1	0.2	1.7	0.1	6.3	0.3	1.8	0.1	5.0	0.2		
VP 0061	Beans except broad bean & soya bean (green pods & immature seeds)	0.04	1.0	0.0	17.4	0.7	7.5	0.3	0.9	0.0	16.4	0.7	0.1	0.0		
VP 0062	Beans, shelled (immature seeds)	0.02	0.5	0.0	12.7	0.3	4.1	0.1	0.9	0.0	13.1	0.3	0.1	0.0		
FB 0264	Blackberries	1	0.0	0.0	0.1	0.1	0.0	0.0	0.3	0.3	0.1	0.1	0.3	0.3		
FB 0020	Blueberries	0.6	0.0	0.0	0.0	0.0	0.0	0.0	0.2	0.1	0.3	0.2	0.8	0.5		
VB 0400	Broccoli	0.23	0.0	0.0	0.7	0.2	1.2	0.3	0.1	0.0	4.2	1.0	4.0	0.9		
VB 0041	Cabbage, head	0.24	1.2	0.3	14.4	3.5	2.7	0.6	16.4	3.9	15.4	3.7	18.5	4.4		
VR 0577	Carrot	0.2	0.6	0.1	15.1	3.0	8.1	1.6	13.9	2.8	27.1	5.4	28.4	5.7		
GC 0080	Cereal grains	0.02	356.9	7.1	####	14.3	763.0	15.3	504.5	10.1	365.2	7.3	328.7	6.6		
FC 0001	Citrus fruit (excl lemon juice, excl mandarin juice, excl orange juice, excl grapefruit juice, excl NES juice)	5.8	15.7	91.1	86.5	501.5	52.6	304.9	24.2	140.3	16.2	94.0	12.0	69.6		
-	Citrus juice NES	0.64	0.0	0.0	1.7	1.1	0.1	0.1	0.0	0.0	1.1	0.7	0.3	0.2		
OR 0691	Cotton seed oil, edible	0.05	0.9	0.0	4.9	0.2	1.7	0.1	6.6	0.3	0.0	0.0	0.3	0.0		
VC 0424	Cucumber	0.06	0.3	0.0	12.7	0.8	5.9	0.4	11.5	0.7	6.1	0.4	7.1	0.4		
FB 0266	Dewberries, incl boysen- & loganberry	1	0.0	0.0	0.0	0.0	0.0	0.0	0.3	0.3	0.0	0.0	0.3	0.3		
DH 0170	Dried herbs (excl dry hops)	16.5	0.2	3.8	0.3	4.6	0.2	4.0	0.4	6.6	0.3	5.0	0.0	0.2		
MO 0105	Edible offal (mammalian)	0	3.9	0.0	14.4	0.0	5.2	0.0	11.8	0.0	11.7	0.0	7.6	0.0		
VO 0440	Egg plant (= aubergine)	0.06	1.7	0.1	17.5	1.1	12.3	0.7	1.7	0.1	0.8	0.0	0.4	0.0		
PE 0112	Eggs	0	2.5	0.0	29.7	0.0	25.1	0.0	24.5	0.0	37.8	0.0	27.4	0.0		

Annex 3

FLUDIOXONIL (211) International Estimated Daily Intake (IEDI) ADI = 0 - 0.4000 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A		B		C		D		E		F	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
VC 0045	Fruiting vegetables, cucurbits (excl watermelon)	0.07	20.5	1.3	64.4	4.2	48.8	3.2	56.4	3.7	21.0	1.4	17.2	1.1
FB 0269	Grape (incl dried, excl juice, incl wine)	0.28	3.7	1.0	####	35.9	27.0	7.5	33.0	9.2	105.5	29.6	42.6	11.9
JF 0269	Grape juice	0.26	0.0	0.0	0.1	0.0	0.1	0.0	0.1	0.0	1.4	0.4	1.0	0.3
JF 0203	Grapefruit juice	0.64	0.0	0.0	0.2	0.1	0.1	0.1	0.1	0.1	1.1	0.7	0.2	0.1
HH 0720	Herbs	2.65	2.3	6.1	2.8	7.4	2.4	6.4	4.0	10.6	3.0	8.0	0.1	0.3
FI 0341	Kiwi fruit	7.2	0.0	0.0	2.9	20.9	0.1	0.7	0.2	1.4	2.7	19.4	1.8	13.0
-d	Lemon juice	0.64	0.0	0.0	0.9	0.6	0.1	0.1	0.0	0.0	0.2	0.1	0.4	0.3
VL 0482	Lettuce, head	2.7	0.1	0.1	6.2	16.6	0.7	1.8	0.1	0.1	0.1	0.1	0.0	0.0
VL 0483	Lettuce, leaf	8.3	0.0	0.0	9.2	76.4	1.0	8.3	0.1	0.8	5.4	44.8	18.0	149.4
FI 0345	Mango (incl juice, incl pulp)	0.02	6.3	0.1	1.0	0.0	4.6	0.1	0.2	0.0	0.7	0.0	0.3	0.0
MM 0095	Meat from mammals other than marine mammals	0	27.7	0.0	####	0.0	38.5	0.0	55.1	0.0	90.2	0.0	131.3	0.0
ML 0106	Milks (excl processed products)	0	68.8	0.0	####	0.0	79.4	0.0	302.6	0.0	179.6	0.0	237.9	0.0
VL 0485	Mustard greens	1.2	0.3	0.4	0.3	0.4	0.0	0.0	5.5	6.6	0.0	0.0	1.9	2.3
VA 0385	Onion, bulb (= dry + green onion)	0.04	5.5	0.2	49.5	2.0	33.0	1.3	31.3	1.3	23.2	0.9	14.6	0.6
JF 0004	Orange juice	0.64	0.0	0.0	2.1	1.3	4.4	2.8	1.4	0.9	16.2	10.4	22.6	14.5
VD 0072	Peas (dry) (= field pea + cowpea)	0.02	6.8	0.1	1.3	0.0	1.0	0.0	2.3	0.0	4.6	0.1	3.4	0.1
VP 0063	Peas (green pods and/or immature seeds)	0.04	0.1	0.0	2.9	0.1	6.0	0.2	0.6	0.0	9.7	0.4	5.2	0.2
VO 0051	Peppers	0.18	1.4	0.3	29.9	5.4	13.0	2.3	6.3	1.1	6.2	1.1	4.0	0.7
FS 0014	Plum (incl dried)	0.96	0.1	0.1	5.9	5.7	2.5	2.4	7.3	7.0	6.9	6.6	2.6	2.5
FP 0009	Pome fruit (excl apple juice)	2.1	0.5	1.1	79.9	167.8	21.8	45.7	43.6	91.5	51.5	108.2	35.1	73.7
VR 0589	Potato (excl flour, excl frozen, excl starch, excl tapioca)	1.5	19.1	28.7	####	218.3	58.5	87.7	242.3	363.5	203.4	305.2	168.0	252.0
PM 0110	Poultry meat	0	7.1	0.0	58.5	0.0	31.9	0.0	24.0	0.0	61.0	0.0	27.3	0.0
PO 0111	Poultry, edible offal of	0	0.4	0.0	0.4	0.0	1.7	0.0	0.1	0.0	0.6	0.0	0.2	0.0
SO 0495	Rape seed (incl oil)	0.02	0.9	0.0	1.8	0.0	2.5	0.1	1.9	0.0	35.7	0.7	26.1	0.5
FB 0272	Raspberries, red, black	1	0.0	0.0	0.0	0.0	0.0	0.0	1.8	1.8	0.9	0.9	0.2	0.2
VL 0502	Spinach	5.8	0.0	0.0	5.0	29.0	1.1	6.4	0.1	0.6	2.6	15.1	0.1	0.6
VA 0389	Spring onion	0.59	0.3	0.2	1.0	0.6	1.4	0.8	0.3	0.2	0.3	0.2	0.6	0.4
VC 0431	Squash, summer (= courgette, zuchini)	0.06	0.0	0.0	8.3	0.5	11.4	0.7	7.3	0.4	3.2	0.2	0.3	0.0
FS 0012	Stone fruit (excl dried plums, excl dried apricots)	0.8	0.7	0.6	42.1	33.7	13.8	11.0	26.3	21.0	25.6	20.5	7.6	6.1
FB 0275	Strawberry	0.27	0.0	0.0	5.0	1.4	2.0	0.5	1.7	0.5	5.2	1.4	4.1	1.1
VO 0447	Sweet corn (corn-on-the-cob, only)	0.01	7.3	0.1	1.0	0.0	0.1	0.0	0.5	0.0	3.3	0.0	3.6	0.0
VR 0508	Sweet potato	3.5	60.5	211.8	0.6	2.1	5.2	18.2	0.0	0.0	0.0	0.0	0.0	0.0
VO 0448	Tomato (excl juice, excl paste, incl canned)	0.66	3.3	2.2	####	118.3	103.5	68.3	54.1	35.7	7.8	5.1	3.9	2.6

Annex 3

FLUDIOXONIL (211) International Estimated Daily Intake (IEDI) ADI = 0 - 0.4000 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A		B		C		D		E		F	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
JF 0448	Tomato juice	0.15	5.2	0.8	0.5	0.1	0.4	0.1	2.1	0.3	6.9	1.0	15.2	2.2
-d	Tomato paste	0.92	0.5	0.5	1.3	1.2	3.5	3.2	1.0	0.9	3.8	3.5	4.5	4.2
VL 0473	Watercress	1.2	2.3	2.8	0.0	0.0	3.3	4.0	2.0	2.4	0.1	0.1	0.0	0.0
-	Wine	0.01	1.3	0.0	76.8	0.8	1.1	0.0	15.4	0.2	68.8	0.7	25.6	0.3
VR 0600	Yams	3.5	63.2	221.2	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Total intake (µg/person)=			582.9		1282.6		612.3		727.9		706.6		631.6
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			24000		24000		24000		24000		24000		24000
	%ADI=			2.4%		5.3%		2.6%		3.0%		2.9%		2.6%
	Rounded %ADI=			2%		5%		3%		3%		3%		3%

FLUDIOXONIL (211) International Estimated Daily Intake (IEDI) ADI = 0 - 0.4000 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			G		H		I		J		K		L		M	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
JF 0226	Apple juice	0.17														
FI 0326	Avocado	0.05	0.1	0.0	0.5	0.1	0.1	0.0	0.0	0.0	0.7	0.1	0.9	0.2	5.7	1.0
VD 0071	Beans (dry)	0.04	0.2	0.0	13.9	0.7	1.0	0.1	1.7	0.1	3.4	0.2	0.5	0.0	2.1	0.1
VP 0061	Beans except broad bean & soya bean (green pods & immature seeds)	0.04	3.4	0.1	25.5	1.0	7.8	0.3	2.1	0.1	44.7	1.8	5.5	0.2	7.3	0.3
VP 0062	Beans, shelled (immature seeds)	0.02	2.6	0.1	2.6	0.1	1.0	0.0	0.5	0.0	0.6	0.0	2.8	0.1	9.8	0.4
FB 0264	Blackberries	1	2.6	0.1	1.9	0.0	1.0	0.0	0.5	0.0	0.3	0.0	1.8	0.0	9.0	0.2
FB 0020	Blueberries	0.6	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.1	0.0	0.0	0.3	0.3
VB 0400	Broccoli	0.23	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.3	0.8
VB 0041	Cabbage, head	0.24	3.2	0.7	7.8	1.8	0.0	0.0	0.0	0.0	0.3	0.1	0.4	0.1	6.6	1.5
VR 0577	Carrot	0.2	10.0	2.4	1.0	0.2	7.2	1.7	1.0	0.2	1.4	0.3	23.9	5.7	17.0	4.1
GC 0080	Cereal grains	0.02	5.4	1.1	7.9	1.6	2.5	0.5	3.5	0.7	4.1	0.8	8.6	1.7	19.4	3.9
FC 0001	Citrus fruit (excl lemon juice, excl	5.8	617.0	12.3	487.1	9.7	389.4	7.8	385.7	7.7	440.2	8.8	####	11.4	409.9	8.2

Annex 3

FLUDIOXONIL (211) International Estimated Daily Intake (IEDI) ADI = 0 - 0.4000 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G		H		I		J		K		L		M	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
	mandarin juice, excl orange juice, excl grapefruit juice, excl NES juice)															
-	Citrus juice NES	0.64	15.1	87.3	153.9	892.6	3.4	19.9	41.7	242.0	218.9	1269.7	23.1	133.9	18.0	104.4
OR 0691	Cotton seed oil, edible	0.05	0.0	0.0	0.0	0.0	0.5	0.3	0.0	0.0	0.0	0.0	0.3	0.2	0.1	0.1
VC 0424	Cucumber	0.06	1.0	0.1	0.7	0.0	1.0	0.1	1.4	0.1	1.5	0.1	5.5	0.3	1.2	0.1
FB 0266	Dewberries, incl boysen- & loganberry	1	7.9	0.5	0.6	0.0	0.2	0.0	0.0	0.0	0.4	0.0	5.5	0.3	5.3	0.3
DH 0170	Dried herbs (excl dry hops)	16.5	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.1	0.0	0.0	0.1	0.1
MO 0105	Edible offal (mammalian)	0	0.7	11.6	0.1	1.0	0.2	3.8	0.3	5.4	0.2	3.3	0.1	2.0	0.1	0.8
VO 0440	Egg plant (= aubergine)	0.06	4.8	0.0	10.7	0.0	4.0	0.0	4.0	0.0	6.5	0.0	6.6	0.0	5.6	0.0
PE 0112	Eggs	0	20.1	1.2	0.1	0.0	0.6	0.0	6.3	0.4	0.5	0.0	6.3	0.4	0.7	0.0
VC 0045	Fruiting vegetables, cucurbits (excl watermelon)	0.07	22.1	0.0	71.5	0.0	16.6	0.0	5.1	0.0	17.6	0.0	35.2	0.0	57.4	0.0
FB 0269	Grape (incl dried, excl juice, incl wine)	0.28	30.4	2.0	11.9	0.8	12.4	0.8	4.4	0.3	10.3	0.7	24.6	1.6	30.6	2.0
JF 0269	Grape juice	0.26	2.6	0.7	4.7	1.3	10.3	2.9	0.3	0.1	6.0	1.7	10.3	2.9	53.8	15.1
JF 0203	Grapefruit juice	0.64	0.0	0.0	0.1	0.0	1.0	0.3	0.0	0.0	0.6	0.2	0.4	0.1	3.6	0.9
HH 0720	Herbs	2.65	0.0	0.0	0.0	0.0	0.5	0.3	0.0	0.0	0.0	0.0	0.3	0.2	2.4	1.5
FI 0341	Kiwi fruit	7.2	7.0	18.6	0.6	1.6	2.3	6.1	3.3	8.7	2.0	5.3	1.2	3.2	0.5	1.3
-d	Lemon juice	0.64	0.0	0.0	0.1	0.7	0.0	0.0	0.0	0.0	0.2	1.4	1.6	11.5	1.0	7.2
VL 0482	Lettuce, head	2.7	0.3	0.2	0.0	0.0	1.0	0.6	0.3	0.2	0.0	0.0	0.5	0.3	2.6	1.7
VL 0483	Lettuce, leaf	8.3	1.2	3.2	3.5	9.5	0.1	0.3	0.3	0.8	1.0	2.7	1.2	3.2	7.9	21.2
		STMR or	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	2.5	20.8
MM 0095	Meat from mammals other than marine mammals	0	12.7	0.3	26.2	0.5	6.1	0.1	12.7	0.3	9.2	0.2	8.0	0.2	1.9	0.0
ML 0106	Milks (excl processed products)	0	54.8	0.0	89.4	0.0	30.6	0.0	28.6	0.0	82.1	0.0	61.1	0.0	158.3	0.0
VL 0485	Mustard greens	1.2	66.0	0.0	121.1	0.0	81.6	0.0	102.4	0.0	207.7	0.0	57.0	0.0	287.9	0.0
VA 0385	Onion, bulb (= dry +	0.04	3.4	4.1	0.4	0.5	2.4	2.9	0.3	0.4	0.5	0.6	7.9	9.5	0.3	0.4

Annex 3

FLUDIOXONIL (211) International Estimated Daily Intake (IEDI) ADI = 0 - 0.4000 mg/kg bw

		STMR or STMR-P	Diets: g/person/day Intake = daily intake: µg/person													
Codex Code	Commodity	mg/kg	G		H		I		J		K		L		M	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
	green onion)															
JF 0004	Orange juice	0.64	17.4	0.7	27.9	1.1	7.3	0.3	16.0	0.6	22.8	0.9	34.5	1.4	30.1	1.2
VD 0072	Peas (dry) (= field pea + cowpea)	0.02	0.2	0.1	1.0	0.6	3.5	2.2	0.0	0.0	1.3	0.8	6.4	4.1	56.8	36.4
VP 0063	Peas (green pods and/or immature seeds)	0.04	1.8	0.0	2.2	0.0	3.2	0.1	26.7	0.5	1.5	0.0	1.8	0.0	1.8	0.0
VO 0051	Peppers	0.18	3.9	0.2	1.6	0.1	0.4	0.0	0.0	0.0	0.9	0.0	1.0	0.0	8.6	0.3
FS 0014	Plum (incl dried)	0.96	8.7	1.6	22.4	4.0	8.4	1.5	9.4	1.7	3.3	0.6	5.3	1.0	8.9	1.6
FP 0009	Pome fruit (excl apple juice)	2.1	3.3	3.2	1.4	1.3	0.1	0.1	0.0	0.0	0.6	0.6	1.5	1.4	2.2	2.1
VR 0589	Potato (excl flour, excl frozen, excl starch, excl tapioca)	1.5	20.8	43.6	11.6	24.3	3.3	6.8	0.1	0.2	10.7	22.4	23.6	49.5	36.9	77.4
PM 0110	Poultry meat	0	51.3	76.9	45.1	67.6	37.8	56.7	3.3	4.9	43.3	64.9	0.0	0.0	162.6	243.9
PO 0111	Poultry, edible offal of	0	17.6	0.0	131.3	0.0	25.1	0.0	4.7	0.0	145.9	0.0	27.7	0.0	115.1	0.0
SO 0495	Rape seed (incl oil)	0.02	0.4	0.0	1.0	0.0	1.9	0.0	0.0	0.0	0.7	0.0	1.0	0.0	0.3	0.0
FB 0272	Raspberries, red, black	1	9.9	0.2	5.9	0.1	0.3	0.0	1.0	0.0	0.0	0.0	15.5	0.3	9.9	0.2
VL 0502	Spinach	5.8	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.2	0.2	0.0	0.0	0.5	0.5
VA 0389	Spring onion	0.59	9.4	54.5	0.4	2.3	0.0	0.0	0.0	0.0	0.2	1.2	4.3	24.9	2.0	11.6
VC 0431	Squash, summer (= courgette, zuchini)	0.06	0.1	0.1	4.8	2.8	0.1	0.1	1.0	0.6	1.0	0.6	2.7	1.6	0.6	0.4
FS 0012	Stone fruit (excl dried plums, excl dried apricots)	0.8	2.4	0.1	1.5	0.1	0.0	0.0	0.0	0.0	3.8	0.2	2.2	0.1	2.5	0.2
FB 0275	Strawberry	0.27	6.7	5.4	4.3	3.5	1.4	1.1	0.1	0.1	4.9	3.9	4.9	3.9	17.0	13.6
VO 0447	Sweet corn (corn-on-the-cob, only)	0.01	0.0	0.0	1.8	0.5	0.1	0.0	0.0	0.0	0.3	0.1	6.2	1.7	5.9	1.6
VR 0508	Sweet potato	3.5	0.2	0.0	2.4	0.0	2.2	0.0	3.3	0.0	1.7	0.0	2.8	0.0	11.2	0.1
VO 0448	Tomato (excl juice, excl paste, incl canned)	0.66	47.4	165.9	7.8	27.3	22.0	77.0	20.9	73.2	5.5	19.3	20.8	72.8	6.1	21.4
JF 0448	Tomato juice	0.15	23.1	15.2	22.3	14.7	12.5	8.2	5.6	3.7	33.2	21.9	1.3	0.9	41.7	27.5
-d	Tomato paste	0.92	0.0	0.0	0.8	0.1	0.1	0.0	7.2	1.0	0.0	0.0	2.4	0.3	45.2	6.6
VL 0473	Watercress	1.2	0.1	0.1	2.1	1.9	0.6	0.6	0.4	0.4	0.6	0.6	1.4	1.3	1.2	1.1
-	Wine	0.01	7.0	8.4	0.3	0.4	2.3	2.8	3.3	4.0	0.3	0.4	7.4	8.9	0.0	0.0

Annex 3

FLUDIOXONIL (211) International Estimated Daily Intake (IEDI) ADI = 0 - 0.4000 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G		H		I		J		K		L		M	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
	Total intake (µg/person)=		0.0	0.0	4.5	15.8	87.5	306.3	111.7	391.0	5.9	20.7	5.2	18.2	0.3	1.1
	Bodyweight per region (kg bw) =			522.7		1092.5		512.7		749.3		1457.5		381.7		647.5
	ADI (µg/person)=			55		60		60		60		60		55		60
	%ADI=			22000		24000		24000		24000		24000		22000		24000
	Rounded %ADI=			2.4%		4.6%		2.1%		3.1%		6.1%		1.7%		2.7%
				2%		5%		2%		3%		6%		2%		3%

FLUTOLANIL (205) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0900 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A		B		C		D		E		F	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
VL 0054	Brassica leafy vegetables	0.05	1.0	0.1	5.5	0.3	2.8	0.1	22.1	1.1	0.7	0.0	7.7	0.4
VB 0040	Brassica vegetables	0	1.7	0.0	25.7	0.0	9.1	0.0	27.8	0.0	36.9	0.0	26.4	0.0
MO 0105	Edible offal (mammalian)	0.147	3.9	0.6	14.4	2.1	5.2	0.8	11.8	1.7	11.7	1.7	7.6	1.1
PE 0112	Eggs	0	2.5	0.0	29.7	0.0	25.1	0.0	24.5	0.0	37.8	0.0	27.4	0.0
MM 0095	Meat from mammals other than marine mammals	0	27.7	0.0	116.5	0.0	38.5	0.0	55.1	0.0	90.2	0.0	131.3	0.0
ML 0106	Milks (excl processed products)	0	68.8	0.0	190.6	0.0	79.4	0.0	302.6	0.0	179.6	0.0	237.9	0.0
PM 0110	Poultry meat	0	7.1	0.0	58.5	0.0	31.9	0.0	24.0	0.0	61.0	0.0	27.3	0.0
PO 0111	Poultry, edible offal of	0.05	0.4	0.0	0.4	0.0	1.7	0.1	0.1	0.0	0.6	0.0	0.2	0.0
CM 1206	Rice bran, unprocessed	1.7	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CM 0649	Rice, husked (incl milled)	0.39	35.6	13.9	0.2	0.1	2.6	1.0	6.9	2.7	3.3	1.3	0.4	0.2
CM 1205	Rice, polished (incl flour)	0.195	29.8	5.8	20.9	4.1	60.8	11.9	16.1	3.1	5.6	1.1	8.1	1.6
	Total intake (µg/person)=			20.3		6.6		13.9		8.7		4.2		3.2
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			5400		5400		5400		5400		5400		5400
	%ADI=			0.4%		0.1%		0.3%		0.2%		0.1%		0.1%
	Rounded %ADI=			0%		0%		0%		0%		0%		0%

Annex 3

FLUTOLANIL (205) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0900 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G		H		I		J		K		L		M	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
VL 0054	Brassica leafy vegetables	0.05	10.3	0.5	4.0	0.2	7.3	0.4	1.0	0.1	2.0	0.1	23.8	1.2	1.7	0.1
VB 0040	Brassica vegetables	0	26.4	0.0	9.3	0.0	7.8	0.0	1.5	0.0	3.3	0.0	40.8	0.0	26.0	0.0
MO 0105	Edible offal (mammalian)	0.147	4.8	0.7	10.7	1.6	4.0	0.6	4.0	0.6	6.5	1.0	6.6	1.0	5.6	0.8
PE 0112	Eggs	0	22.1	0.0	71.5	0.0	16.6	0.0	5.1	0.0	17.6	0.0	35.2	0.0	57.4	0.0
MM 0095	Meat from mammals other than marine mammals	0	54.8	0.0	89.4	0.0	30.6	0.0	28.6	0.0	82.1	0.0	61.1	0.0	158.3	0.0
ML 0106	Milks (excl processed products)	0	66.0	0.0	121.1	0.0	81.6	0.0	102.4	0.0	207.7	0.0	57.0	0.0	287.9	0.0
PM 0110	Poultry meat	0	17.6	0.0	131.3	0.0	25.1	0.0	4.7	0.0	145.9	0.0	27.7	0.0	115.1	0.0
PO 0111	Poultry, edible offal of	0.05	0.4	0.0	1.0	0.1	1.9	0.1	0.0	0.0	0.7	0.0	1.0	0.1	0.3	0.0
CM 1206	Rice bran, unprocessed	1.7	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CM 0649	Rice, husked (incl milled)	0.39	1.1	0.4	0.8	0.3	1.8	0.7	22.7	8.9	70.8	27.6	7.0	2.7	0.3	0.1
CM 1205	Rice, polished (incl flour)	0.195	250.3	48.8	42.2	8.2	23.8	4.6	29.8	5.8	97.6	19.0	248.1	48.4	22.8	4.4
	Total intake (µg/person)=			50.5		10.4		6.4		15.3		47.7		53.3		5.5
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			4950		5400		5400		5400		5400		4950		5400
	%ADI=			1.0%		0.2%		0.1%		0.3%		0.9%		1.1%		0.1%
	Rounded %ADI=			1%		0%		0%		0%		1%		1%		0%

Annex 3

GLYPHOSATE (158) International Estimated Daily Intake (IEDI) ADI = 0–1.0000 mg/kg bw

		STMR or	Diets: g/person/day						Intake = daily intake: µg/person					
		STMR-P	A		B		C		D		E		F	
Codex Code	Commodity	mg/kg	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
FI 0327	Banana	0.05	38.8	1.9	17.4	0.9	16.0	0.8	6.6	0.3	21.5	1.1	33.8	1.7
GC 0640	Barley (incl pot, incl pearled, incl flour & grits, incl beer)	3.7	40.6	150.2	16.8	62.2	93.9	347.4	13.2	48.8	48.6	179.8	36.1	133.6
VD 0071	Beans (dry)	0.17	15.8	2.7	6.1	1.0	1.7	0.3	6.3	1.1	1.8	0.3	5.0	0.9
GC 0641	Buckwheat (incl flour, incl bran)	3.7	0.0	0.0	0.1	0.4	0.0	0.0	1.7	6.3	1.6	5.9	0.1	0.4
OR 0691	Cotton seed oil, edible	0.52	0.9	0.5	4.9	2.5	1.7	0.9	6.6	3.4	0.0	0.0	0.3	0.2
MO 0105	Edible offal (mammalian)	2.9	3.9	11.3	14.4	41.8	5.2	15.1	11.8	34.2	11.7	33.9	7.6	22.0
PE 0112	Eggs	0	2.5	0.0	29.7	0.0	25.1	0.0	24.5	0.0	37.8	0.0	27.4	0.0
VD 0533	Lentil (dry)	0.5	0.9	0.5	5.4	2.7	3.1	1.6	1.3	0.7	0.7	0.4	0.1	0.1
CF 1255	Maize flour	0.13	68.9	9.0	15.4	2.0	51.3	6.7	16.6	2.2	14.7	1.9	2.0	0.3
GC 0645	Maize (excl flour, excl oil, incl beer)	0.12	0.0	0.0	1.4	0.2	51.4	6.2	11.9	1.4	0.2	0.0	0.2	0.0
OR 0645	Maize oil, edible	0.04	0.1	0.0	4.0	0.2	2.3	0.1	0.5	0.0	0.9	0.0	0.2	0.0
MM 0095	Meat from mammals other than marine mammals	0.05	27.7	1.4	116.5	5.8	38.5	1.9	55.1	2.8	90.2	4.5	131.3	6.6
ML 0106	Milks (excl processed products)	0	68.8	0.0	190.6	0.0	79.4	0.0	302.6	0.0	179.6	0.0	237.9	0.0
GC 0646	Millet (incl flour, incl beer)	3.7	15.8	58.5	0.1	0.4	0.8	3.0	5.6	20.7	0.2	0.7	0.1	0.4
GC 0647	Oats (excl rolled)	3.7	0.1	0.3	0.0	0.1	0.0	0.0	0.0	0.1	0.0	0.0	0.0	–0.1
–	Oats, rolled	0.95	0.7	0.7	0.3	0.3	0.1	0.1	2.2	2.1	3.0	2.9	4.7	4.5
VD 0072	Peas (dry) (= field pea + cowpea)	0.5	6.8	3.4	1.3	0.7	1.0	0.5	2.3	1.2	4.6	2.3	3.4	1.7
GC 0656	Popcorn	3.7	0.1	0.4	0.2	0.7	0.0	0.0	0.1	0.4	0.1	0.4	0.1	0.4
PM 0110	Poultry meat	0	7.1	0.0	58.5	0.0	31.9	0.0	24.0	0.0	61.0	0.0	27.3	0.0
PO 0111	Poultry, edible offal of	0.088	0.4	0.0	0.4	0.0	1.7	0.1	0.1	0.0	0.6	0.1	0.2	0.0
SO 0495	Rape seed (excl oil)	3	0.1	0.4	0.0	0.0	0.0	0.0	0.1	0.2	0.1	0.2	0.1	0.3
OR 0495	Rape seed oil, edible	0.009	0.3	0.0	0.7	0.0	1.0	0.0	0.7	0.0	13.7	0.1	10.0	0.1
GC 0650	Rye (incl flour)	3.7	0.1	0.4	3.7	13.7	0.3	1.1	24.3	89.9	25.8	95.5	45.8	169.5
GC 0651	Sorghum (excl flour, incl beer)	3.7	0.0	0.2	0.0	0.0	0.0	–0.1	0.0	0.0	0.0	0.0	0.0	0.0
–	Sorghum flour	1.5	33.5	50.3	0.0	0.0	9.3	14.0	0.0	0.0	0.0	0.0	0.0	0.0
VD 0541	Soya bean (dry, excl oil)	5	0.9	4.7	0.0	0.0	0.7	3.5	0.0	0.0	0.0	0.1	0.0	0.0
OR 0541	Soya bean oil, refined	0.1	1.6	0.2	6.5	0.7	6.0	0.6	4.0	0.4	6.3	0.6	7.0	0.7
VR 0596	Sugar beet	3.4	0.0	0.0	40.7	138.4	0.0	0.0	0.1	0.3	6.0	20.4	0.1	0.3
GS 0659	Sugar cane	0.065	30.9	2.0	43.1	2.8	51.3	3.3	0.1	0.0	5.5	0.4	0.0	0.0
SO 0702	Sunflower seed (incl oil)	0.395	0.7	0.3	44.5	17.6	20.5	8.1	29.6	11.7	21.2	8.4	5.4	2.1

Annex 3

GLYPHOSATE (158) International Estimated Daily Intake (IEDI) ADI = 0–1.0000 mg/kg bw

		STMR or	Diets: g/person/day				Intake = daily intake: µg/person							
		STMR-P	A		B		C		D		E		F	
Codex Code	Commodity	mg/kg	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
VO 0447	Sweet corn (incl corn on the cob, incl frozen kernels, incl preserved kernels)	0.325	14.7	4.8	2.0	0.7	0.2	0.1	1.2	0.4	6.5	2.1	7.2	2.3
GC 0653	Triticale (incl flour)	3.7	0.0	0.0	115.8	428.5	0.0	0.0	0.0	0.0	0.3	1.1	0.0	0.0
GC 0654	Wheat (excl bulgur wholemeal, excl flour)	3.7	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.4	0.0	0.0
–d	Wheat bulgur wholemeal	0.48	5.5	2.6	10.2	4.9	0.7	0.3	0.2	0.1	0.1	0.0	0.0	0.0
CF 1211	Wheat flour (incl macaroni, bread, pastry, starch, gluten)	0.11	63.4	7.0	296.3	32.6	327.5	36.0	300.0	33.0	181.6	20.0	166.2	18.3
GC 0655	Wild rice	3.7	ND	–	ND	–	ND	–	ND	–	ND	–	ND	–
	Total intake (µg/person)=			313.3		761.5		451.5		261.7		383.5		366.0
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			60000		60000		60000		60000		60000		60000
	%ADI=			0.5%		1.3%		0.8%		0.4%		0.6%		0.6%
	Rounded %ADI=			1%		1%		1%		0%		1%		1%

GLYPHOSATE (158) International Estimated Daily Intake (IEDI) ADI = 0–1.0000 mg/kg bw

		STMR or	Diets: g/person/day				Intake = daily intake: µg/person									
		STMR-P	G		H		I		J		K		L		M	
Codex Code	Commodity	mg/kg	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
FI 0327	Banana	0.05	21.4	1.1	36.6	1.8	11.4	0.6	9.2	0.5	70.2	3.5	40.5	2.0	32.6	1.6
GC 0640	Barley (incl pot, incl pearled, incl flour & grits, incl beer)	3.7	5.9	21.8	20.5	75.9	5.9	21.8	2.5	9.3	20.2	74.7	16.8	62.2	43.8	162.1
VD 0071	Beans (dry)	0.17	3.4	0.6	25.5	4.3	7.8	1.3	2.1	0.4	44.7	7.6	5.5	0.9	7.3	1.2
GC 0641	Buckwheat (incl flour, incl bran)	3.7	1.0	3.7	0.0	0.0	0.2	0.7	0.1	0.4	0.5	1.9	2.0	7.4	0.1	0.4
OR 0691	Cotton seed oil, edible	0.52	1.0	0.5	0.7	0.4	1.0	0.5	1.4	0.7	1.5	0.8	5.5	2.9	1.2	0.6
MO 0105	Edible offal (mammalian)	2.9	4.8	13.9	10.7	31.0	4.0	11.6	4.0	11.6	6.5	18.9	6.6	19.1	5.6	16.2
PE 0112	Eggs	0	22.1	0.0	71.5	0.0	16.6	0.0	5.1	0.0	17.6	0.0	35.2	0.0	57.4	0.0
VD 0533	Lentil (dry)	0.5	1.1	0.6	1.1	0.6	0.1	0.1	0.2	0.1	1.0	0.5	0.0	0.0	1.6	0.8
CF 1255	Maize flour	0.13	28.8	3.7	248.8	32.3	206.7	26.9	47.8	6.2	46.2	6.0	10.5	1.4	21.5	2.8
GC 0645	Maize (excl flour, excl oil, incl beer)	0.12	0.6	0.1	0.0	0.0	0.1	0.0	0.0	0.0	7.7	0.9	0.0	0.0	19.4	2.3

Annex 3

GLYPHOSATE (158) International Estimated Daily Intake (IEDI) ADI = 0–1.0000 mg/kg bw

		STMR or STMR-P	Diets: g/person/day			Intake = daily intake: µg/person									
			G		H		I		J		K		L		M	
OR 0645	Maize oil, edible	0.04	0.1	0.0	0.6	0.0	1.8	0.1	0.0	0.0	1.0	0.0	1.6	0.1	1.8	0.1
MM 0095	Meat from mammals other than marine mammals	0.05	54.8	2.7	89.4	4.5	30.6	1.5	28.6	1.4	82.1	4.1	61.1	3.1	158.3	7.9
ML 0106	Milks (excl processed products)	0	66.0	0.0	121.1	0.0	81.6	0.0	102.4	0.0	207.7	0.0	57.0	0.0	287.9	0.0
GC 0646	Millet (incl flour, incl beer)	3.7	13.0	48.1	0.0	0.0	8.3	30.7	96.9	358.5	0.0	0.0	0.4	1.5	0.0	0.0
GC 0647	Oats (excl rolled)	3.7	0.0	0.0	0.7	2.5	0.0	0.1	0.0	0.0	0.5	1.7	0.5	1.9	0.0	0.0
–	Oats, rolled	0.95	0.1	0.1	0.7	0.7	0.4	0.4	0.0	0.0	1.6	1.5	0.1	0.1	4.0	3.8
VD 0072	Peas (dry) (= field pea + cowpea)	0.5	1.8	0.9	2.2	1.1	3.2	1.6	26.7	13.4	1.5	0.8	1.8	0.9	1.8	0.9
GC 0656	Popcorn	3.7	0.1	0.4	0.1	0.4	0.1	0.4	0.1	0.4	0.1	0.4	0.1	0.4	1.4	5.2
PM 0110	Poultry meat	0	17.6	0.0	131.3	0.0	25.1	0.0	4.7	0.0	145.9	0.0	27.7	0.0	115.1	0.0
PO 0111	Poultry, edible offal of	0.088	0.4	0.0	1.0	0.1	1.9	0.2	0.0	0.0	0.7	0.1	1.0	0.1	0.3	0.0
SO 0495	Rape seed (excl oil)	3	0.0	0.1	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1
OR 0495	Rape seed oil, edible	0.009	3.8	0.0	2.3	0.0	0.1	0.0	0.4	0.0	0.0	0.0	6.0	0.1	3.8	0.0
GC 0650	Rye (incl flour)	3.7	0.4	1.5	0.0	0.0	0.2	0.7	0.1	0.4	0.1	0.4	0.9	3.3	0.8	3.0
GC 0651	Sorghum (excl flour, incl beer)	3.7	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.4	0.0	0.0	2.2	8.3
–	Sorghum flour	1.5	8.9	13.4	18.1	27.2	16.9	25.4	102.1	153.2	0.0	0.0	3.0	4.5	0.7	1.1
VD 0541	Soya bean (dry, excl oil)	5	1.8	9.1	0.0	0.2	0.0	0.0	3.2	15.8	0.1	0.5	0.0	–0.1	0.0	0.0
OR 0541	Soya bean oil, refined	0.1	4.3	0.4	10.6	1.1	2.0	0.2	1.4	0.1	19.5	2.0	9.2	0.9	22.0	2.2
VR 0596	Sugar beet	3.4	0.0	0.0	0.1	0.3	0.0	0.0	0.0	0.0	0.2	0.7	0.0	0.0	14.3	48.6
GS 0659	Sugar cane	0.065	26.2	1.7	1.5	0.1	33.8	2.2	5.5	0.4	18.6	1.2	3.0	0.2	20.2	1.3
SO 0702	Sunflower seed (incl oil)	0.395	2.7	1.1	8.8	3.5	13.5	5.3	0.2	0.1	3.6	1.4	0.6	0.2	10.4	4.1
VO 0447	Sweet corn (incl corn on the cob, incl frozen kernels, incl preserved kernels)	0.325	0.4	0.1	4.9	1.6	4.5	1.5	3.3	1.1	1.7	0.6	5.6	1.8	18.1	5.9
GC 0653	Triticale (incl flour)	3.7	1.3	4.8	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
GC 0654	Wheat (excl bulgur wholemeal, excl flour)	3.7	0.0	0.0	0.9	3.2	0.0	0.0	0.0	0.1	0.1	0.3	0.0	0.0	0.1	0.3
–d	Wheat bulgur wholemeal	0.48	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
CF 1211	Wheat flour (incl macaroni, bread, pastry, starch, gluten)	0.11	133.0	14.6	60.1	6.6	52.4	5.8	32.2	3.5	87.7	9.6	79.6	8.8	180.1	19.8
GC 0655	Wild rice	3.7	ND	–	ND	–	ND	–	ND	–	ND	–	ND	–	ND	–
	Total intake (µg/person)=			145.1		199.2		139.7		577.4		140.3		123.5		300.5
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			55000		60000		60000		60000		60000		55000		60000
	%ADI=			0.3%		0.3%		0.2%		1.0%		0.2%		0.2%		0.5%
	Rounded %ADI=			0%		0%		0%		1%		0%		0%		1%

Annex 3

IMAZAPIC (266) International Estimated Daily Intake (IEDI) ADI = 0 - 0.7000 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A		B		C		D		E		F	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
MO 0105	Edible offal (mammalian)	0.287	3.9	1.1	14.4	4.1	5.2	1.5	11.8	3.4	11.7	3.4	7.6	2.2
PE 0112	Eggs	0	2.5	0.0	29.7	0.0	25.1	0.0	24.5	0.0	37.8	0.0	27.4	0.0
GC 0645	Maize (incl flour, incl oil, incl beer)	0	82.7	0.0	148.4	0.0	135.9	0.0	31.8	0.0	33.3	0.0	7.5	0.0
MF 0100	Mammalian fats (except milk fats)	0.05	0.8	0.0	10.0	0.5	0.9	0.0	6.6	0.3	11.8	0.6	3.7	0.2
MM 0095	Meat from mammals other than marine mammals	0.05	27.7	1.4	116.5	5.8	38.5	1.9	55.1	2.8	90.2	4.5	131.3	6.6
ML 0106	Milks (excl processed products)	0.019	68.8	1.3	190.6	3.6	79.4	1.5	302.6	5.7	179.6	3.4	237.9	4.5
SO 0697	Peanut, shelled (incl oil)	0	5.4	0.0	3.1	0.0	2.1	0.0	0.7	0.0	4.0	0.0	1.4	0.0
PM 0110	Poultry meat	0	7.1	0.0	58.5	0.0	31.9	0.0	24.0	0.0	61.0	0.0	27.3	0.0
PO 0111	Poultry, edible offal of	0	0.4	0.0	0.4	0.0	1.7	0.0	0.1	0.0	0.6	0.0	0.2	0.0
PF 0111	Poultry, fats	0	0.1	0.0	0.1	0.0	0.1	0.0	0.0	0.0	0.4	0.0	0.1	0.0
SO 0495	Rape seed (incl oil)	0	0.9	0.0	1.8	0.0	2.5	0.0	1.9	0.0	35.7	0.0	26.1	0.0
GC 0649	Rice (incl husked, incl polished)	0	91.0	0.0	31.6	0.0	94.6	0.0	33.2	0.0	12.7	0.0	12.7	0.0
GS 0659	Sugar cane	0	30.9	0.0	43.1	0.0	51.3	0.0	0.1	0.0	5.5	0.0	0.0	0.0
GC 0654	Wheat (incl bulgur wholemeal, incl flour)	0	88.4	0.0	396.3	0.0	426.5	0.0	390.2	0.0	236.3	0.0	216.0	0.0
	Total intake (µg/person)=			3.9		14.1		5.0		12.2		11.9		13.5
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			42000		42000		42000		42000		42000		42000
	%ADI=			0.0%		0.0%		0.0%		0.0%		0.0%		0.0%
	Rounded %ADI=			0%		0%		0%		0%		0%		0%

IMAZAPIC (266) International Estimated Daily Intake (IEDI) ADI = 0 - 0.7000 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G		H		I		J		K		L		M	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
MO 0105	Edible offal (mammalian)		4.8	1.4	10.7	3.1	4.0	1.1	4.0	1.1	6.5	1.9	6.6	1.9	5.6	1.6
PE 0112	Eggs	0	22.1	0.0	71.5	0.0	16.6	0.0	5.1	0.0	17.6	0.0	35.2	0.0	57.4	0.0
GC 0645	Maize (incl flour, incl oil, incl beer)	0	35.2	0.0	298.6	0.0	248.1	0.0	57.4	0.0	63.1	0.0	58.6	0.0	85.5	0.0

Annex 3

IMAZAPIC (266) International Estimated Daily Intake (IEDI) ADI = 0 - 0.7000 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G		H		I		J		K		L		M	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
MF 0100	Mammalian fats (except milk fats)	0.05	2.2	0.1	18.6	0.9	0.5	0.0	0.8	0.0	5.7	0.3	4.5	0.2	18.2	0.9
MM 0095	Meat from mammals other than marine mammals	0.05	54.8	2.7	89.4	4.5	30.6	1.5	28.6	1.4	82.1	4.1	61.1	3.1	158.3	7.9
ML 0106	Milks (excl processed products)	0.019	66.0	1.3	121.1	2.3	81.6	1.6	102.4	1.9	207.7	3.9	57.0	1.1	287.9	5.5
SO 0697	Peanut, shelled (incl oil)	0	7.6	0.0	2.1	0.0	4.7	0.0	21.8	0.0	0.9	0.0	0.7	0.0	6.9	0.0
PM 0110	Poultry meat	0	17.6	0.0	131.3	0.0	25.1	0.0	4.7	0.0	145.9	0.0	27.7	0.0	115.1	0.0
PO 0111	Poultry, edible offal of	0	0.4	0.0	1.0	0.0	1.9	0.0	0.0	0.0	0.7	0.0	1.0	0.0	0.3	0.0
PF 0111	Poultry, fats	0	0.1	0.0	8.2	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.1	0.0	4.2	0.0
SO 0495	Rape seed (incl oil)	0	9.9	0.0	5.9	0.0	0.3	0.0	1.0	0.0	0.0	0.0	15.5	0.0	9.9	0.0
GC 0649	Rice (incl husked, incl polished)	0	376.9	0.0	64.3	0.0	38.0	0.0	74.3	0.0	238.4	0.0	381.3	0.0	34.6	0.0
GS 0659	Sugar cane	0	26.2	0.0	1.5	0.0	33.8	0.0	5.5	0.0	18.6	0.0	3.0	0.0	20.2	0.0
GC 0654	Wheat (incl bulgur wholemeal, incl flour)	0	172.9	0.0	79.0	0.0	68.1	0.0	41.9	0.0	114.1	0.0	103.4	0.0	234.2	0.0
	Total intake (µg/person)=			5.5		10.8		4.3		4.6		10.2		6.3		15.9
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			38500		42000		42000		42000		42000		38500		42000
	%ADI=			0.0%		0.0%		0.0%		0.0%		0.0%		0.0%		0.0%
	Rounded %ADI=			0%		0%		0%		0%		0%		0%		0%

Annex 3

IMAZAPYR (267) International Estimated Daily Intake (IEDI) ADI = 0–3.0000 mg/kg bw

		STMR or	Diets: g/person/day			Intake = daily intake: µg/person								
		STMR-P	A		B		C		D		E		F	
Codex Code	Commodity	mg/kg	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
MO 0105	Edible offal (mammalian)	0.0008	3.9	0.0	14.4	0.0	5.2	0.0	11.8	0.0	11.7	0.0	7.6	0.0
PE 0112	Eggs	0	2.5	0.0	29.7	0.0	25.1	0.0	24.5	0.0	37.8	0.0	27.4	0.0
VD 0533	Lentil (dry)	0.07	0.9	0.1	5.4	0.4	3.1	0.2	1.3	0.1	0.7	0.0	0.1	0.0
GC 0645	Maize (incl flour, excl oil, incl beer)	0.05	82.7	4.1	1.4	0.1	51.4	2.6	31.8	1.6	0.2	0.0	0.2	0.0
OR 0645	Maize oil, edible	0.025	0.1	0.0	4.0	0.1	2.3	0.1	0.5	0.0	0.9	0.0	0.2	0.0
MF 0100	Mammalian fats (except milk fats)	0	0.8	0.0	10.0	0.0	0.9	0.0	6.6	0.0	11.8	0.0	3.7	0.0
MM 0095	Meat from mammals other than marine mammals	0	27.7	0.0	116.5	0.0	38.5	0.0	55.1	0.0	90.2	0.0	131.3	0.0
ML 0106	Milks (excl processed products)	0	68.8	0.0	190.6	0.0	79.4	0.0	302.6	0.0	179.6	0.0	237.9	0.0
PM 0110	Poultry meat	0	7.1	0.0	58.5	0.0	31.9	0.0	24.0	0.0	61.0	0.0	27.3	0.0
PO 0111	Poultry, edible offal of	0	0.4	0.0	0.4	0.0	1.7	0.0	0.1	0.0	0.6	0.0	0.2	0.0
PF 0111	Poultry, fats	0	0.1	0.0	0.1	0.0	0.1	0.0	0.0	0.0	0.4	0.0	0.1	0.0
SO 0495	Rape seed (incl oil)	0	0.9	0.0	1.8	0.0	2.5	0.0	1.9	0.0	35.7	0.0	26.1	0.0
SO 0702	Sunflower seed (incl oil)	0.01	0.7	0.0	44.5	0.4	20.5	0.2	29.6	0.3	21.2	0.2	5.4	0.1
GC 0654	Wheat (incl bulgur wholemeal, incl flour)	0	88.4	0.0	396.3	0.0	426.5	0.0	390.2	0.0	236.3	0.0	216.0	0.0
	Total intake (µg/person) =			4.2		1.0		3.1		2.0		0.3		0.1
	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

IMAZAPYR (267) International Estimated Daily Intake (IEDI) ADI = 0–3.0000 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day G diet	Intake = daily intake: µg/person G intake	H diet	H intake	I diet	I intake	J diet	J intake	K diet	K intake	L diet	L intake	M diet	M intake
MO 0105	Edible offal (mammalian)	0.0008	4.8	0.0	10.7	0.0	4.0	0.0	4.0	0.0	6.5	0.0	6.6	0.0	5.6	0.0
PE 0112	Eggs	0	22.1	0.0	71.5	0.0	16.6	0.0	5.1	0.0	17.6	0.0	35.2	0.0	57.4	0.0
VD 0533	Lentil (dry)	0.07	1.1	0.1	1.1	0.1	0.1	0.0	0.2	0.0	1.0	0.1	0.0	0.0	1.6	0.1
GC 0645	Maize (incl flour, excl oil, incl beer)	0.05	35.2	1.8	298.6	14.9	248.1	12.4	57.4	2.9	63.1	3.2	0.0	0.0	19.4	1.0
OR 0645	Maize oil, edible	0.025	0.1	0.0	0.6	0.0	1.8	0.0	0.0	0.0	1.0	0.0	1.6	0.0	1.8	0.0
MF 0100	Mammalian fats (except milk fats)	0	2.2	0.0	18.6	0.0	0.5	0.0	0.8	0.0	5.7	0.0	4.5	0.0	18.2	0.0
MM 0095	Meat from mammals other than marine mammals	0	54.8	0.0	89.4	0.0	30.6	0.0	28.6	0.0	82.1	0.0	61.1	0.0	158.3	0.0
ML 0106	Milks (excl processed products)	0	66.0	0.0	121.1	0.0	81.6	0.0	102.4	0.0	207.7	0.0	57.0	0.0	287.9	0.0
PM 0110	Poultry meat	0	17.6	0.0	131.3	0.0	25.1	0.0	4.7	0.0	145.9	0.0	27.7	0.0	115.1	0.0
PO 0111	Poultry, edible offal of	0	0.4	0.0	1.0	0.0	1.9	0.0	0.0	0.0	0.7	0.0	1.0	0.0	0.3	0.0
PF 0111	Poultry, fats	0	0.1	0.0	8.2	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.1	0.0	4.2	0.0
SO 0495	Rape seed (incl oil)	0	9.9	0.0	5.9	0.0	0.3	0.0	1.0	0.0	0.0	0.0	15.5	0.0	9.9	0.0
SO 0702	Sunflower seed (incl oil)	0.01	2.7	0.0	8.8	0.1	13.5	0.1	0.2	0.0	3.6	0.0	0.6	0.0	10.4	0.1
GC 0654	Wheat (incl bulgur wholemeal, incl flour)	0	172.9	0.0	79.0	0.0	68.1	0.0	41.9	0.0	114.1	0.0	103.4	0.0	234.2	0.0
	Total intake (µg/person) =			1.9		15.1		12.6		2.9		3.3		0.1		1.2
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person) =			165000		180000		180000		180000		180000		165000		180000
	%ADI =			0.0%		0.0%		0.0%		0.0%		0.0%		0.0%		0.0%
	Rounded %ADI =			0%		0%		0%		0%		0%		0%		0%

Annex 3

ISOXAFLUTOLE (268) International Estimated Daily Intake (IEDI) ADI = 0–0.0200 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A		B		C		D		E		F	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
VD 0524	Chick-pea (dry)	0	3.3	0.0	5.8	0.0	3.2	0.0	3.1	0.0	0.2	0.0	0.1	0.0
MO 0105	Edible offal (mammalian)	0.2	3.9	0.8	14.4	2.9	5.2	1.0	11.8	2.4	11.7	2.3	7.6	1.5
PE 0112	Eggs	0	2.5	0.0	29.7	0.0	25.1	0.0	24.5	0.0	37.8	0.0	27.4	0.0
GC 0645	Maize (incl flour, incl oil, incl beer)	0.02	82.7	1.7	148.4	3.0	135.9	2.7	31.8	0.6	33.3	0.7	7.5	0.2
MF 0100	Mammalian fats (except milk fats)	0	0.8	0.0	10.0	0.0	0.9	0.0	6.6	0.0	11.8	0.0	3.7	0.0
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0	5.5	0.0	23.3	0.0	7.7	0.0	11.0	0.0	18.0	0.0	26.3	0.0
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0	22.2	0.0	93.2	0.0	30.8	0.0	44.1	0.0	72.2	0.0	105.0	0.0
ML 0106	Milks (excl processed products)	0	68.8	0.0	190.6	0.0	79.4	0.0	302.6	0.0	179.6	0.0	237.9	0.0
SO 0698	Poppy seed (incl oil)	0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.2	0.0	0.1	0.0
PM 0110	Poultry meat: 10% as fat	0	0.7	0.0	5.9	0.0	3.2	0.0	2.4	0.0	6.1	0.0	2.7	0.0
PM 0110	Poultry meat: 90% as muscle	0	6.4	0.0	52.7	0.0	28.7	0.0	21.6	0.0	54.9	0.0	24.6	0.0
PO 0111	Poultry, edible offal of	0.1	0.4	0.0	0.4	0.0	1.7	0.2	0.1	0.0	0.6	0.1	0.2	0.0
PF 0111	Poultry, fats	0	0.1	0.0	0.1	0.0	0.1	0.0	0.0	0.0	0.4	0.0	0.1	0.0
GS 0659	Sugar cane	0	30.9	0.0	43.1	0.0	51.3	0.0	0.1	0.0	5.5	0.0	0.0	0.0
VO 0447	Sweet corn (incl corn on the cob, incl frozen kernels, incl preserved kernels)	0	14.7	0.0	2.0	0.0	0.2	0.0	1.2	0.0	6.5	0.0	7.2	0.0
	Total intake (µg/person)=			2.5		5.9		3.9		3.0		3.1		1.7
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			1200		1200		1200		1200		1200		1200
	%ADI=			0.2%		0.5%		0.3%		0.3%		0.3%		0.1%
	Rounded %ADI=			0%		0%		0%		0%		0%		0%

Annex 3

ISOXAFLUTOLE (268) International Estimated Daily Intake (IEDI) ADI = 0–0.0200 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G		H		I		J		K		L		M	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
VD 0524	Chick-pea (dry)	0	5.0	0.0	0.5	0.0	0.6	0.0	0.2	0.0	0.2	0.0	0.0	0.0	0.6	0.0
MO 0105	Edible offal (mammalian)	0.2	4.8	1.0	10.7	2.1	4.0	0.8	4.0	0.8	6.5	1.3	6.6	1.3	5.6	1.1
PE 0112	Eggs	0	22.1	0.0	71.5	0.0	16.6	0.0	5.1	0.0	17.6	0.0	35.2	0.0	57.4	0.0
GC 0645	Maize (incl flour, incl oil, incl beer)	0.02	35.2	0.7	298.6	6.0	248.1	5.0	57.4	1.1	63.1	1.3	58.6	1.2	85.5	1.7
MF 0100	Mammalian fats (except milk fats)	0	2.2	0.0	18.6	0.0	0.5	0.0	0.8	0.0	5.7	0.0	4.5	0.0	18.2	0.0
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0	11.0	0.0	17.9	0.0	6.1	0.0	5.7	0.0	16.4	0.0	12.2	0.0	31.7	0.0
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0	43.8	0.0	71.5	0.0	24.5	0.0	22.9	0.0	65.7	0.0	48.9	0.0	126.6	0.0
ML 0106	Milks (excl processed products)	0	66.0	0.0	121.1	0.0	81.6	0.0	102.4	0.0	207.7	0.0	57.0	0.0	287.9	0.0
SO 0698	Poppy seed (incl oil)	0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.1	0.0	0.1	0.0
PM 0110	Poultry meat: 10% as fat	0	1.8	0.0	13.1	0.0	2.5	0.0	0.5	0.0	14.6	0.0	2.8	0.0	11.5	0.0
PM 0110	Poultry meat: 90% as muscle	0	15.8	0.0	118.2	0.0	22.6	0.0	4.2	0.0	131.3	0.0	24.9	0.0	103.6	0.0
PO 0111	Poultry, edible offal of	0.1	0.4	0.0	1.0	0.1	1.9	0.2	0.0	0.0	0.7	0.1	1.0	0.1	0.3	0.0
PF 0111	Poultry, fats	0	0.1	0.0	8.2	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.1	0.0	4.2	0.0
GS 0659	Sugar cane	0	26.2	0.0	1.5	0.0	33.8	0.0	5.5	0.0	18.6	0.0	3.0	0.0	20.2	0.0
VO 0447	Sweet corn (incl corn on the cob, incl frozen kernels, incl preserved kernels)	0	0.4	0.0	4.9	0.0	4.5	0.0	3.3	0.0	1.7	0.0	5.6	0.0	18.1	0.0
	Total intake (µg/person)=			1.7		8.2		6.0		1.9		2.6		2.6		2.9
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			1100		1200		1200		1200		1200		1100		1200
	%ADI=			0.2%		0.7%		0.5%		0.2%		0.2%		0.2%		0.2%
	Rounded %ADI=			0%		1%		0%		0%		0%		0%		0%

Annex 3

MALATHION (049) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0300 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day		Intake = daily intake: µg/person									
			A		B		C		D		E		F	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
FS 0013	Cherries	0.275	0.0	0.0	6.8	1.9	0.9	0.2	6.2	1.7	3.6	1.0	0.4	0.1
	Total intake (µg/person)=			0.0		1.9		0.2		1.7		1.0		0.1
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			1800		1800		1800		1800		1800		1800
	%ADI=			0.0%		0.1%		0.0%		0.1%		0.1%		0.0%
	Rounded %ADI=			0%		0%		0%		0%		0%		0%

MALATHION (049) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0300 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day		Intake = daily intake: µg/person									
			G		H		I		J		K		L		M	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
FS 0013	Cherries	0.275	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.3	0.1	2.5	0.7
	Total intake (µg/person)=			0.0		0.0		0.0		0.0		0.0		0.1		0.7
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			1650		1800		1800		1800		1800		1650		1800
	%ADI=			0.0%		0.0%		0.0%		0.0%		0.0%		0.0%		0.0%
	Rounded %ADI=			0%		0%		0%		0%		0%		0%		0%

Annex 3

MANDIPROPAMID (231) International Estimated Daily Intake (IEDI) ADI = 0 - 0.2000 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A		B		C		D		E		F	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
FB 0269	Grape (excl dried, excl juice, excl wine)	0.43	1.9	0.8	9.2	4.0	23.8	10.2	9.8	4.2	0.0	0.0	0.0	0.0
DF 0269	Grape, dried (= currants, raisins and sultanas)	1.68	0.0	0.0	2.9	4.9	0.4	0.7	0.4	0.7	2.3	3.9	1.7	2.9
JF 0269	Grape juice	0.14	0.0	0.0	0.1	0.0	0.1	0.0	0.1	0.0	1.4	0.2	1.0	0.1
-	Wine	0.366	1.3	0.5	76.8	28.1	1.1	0.4	15.4	5.6	68.8	25.2	25.6	9.4
VR 0589	Potato (incl flour, frozen, starch, tapioca)	0.01	19.1	0.2	160.8	1.6	61.2	0.6	243.6	2.4	230.1	2.3	204.7	2.0
-	Onion, dry	0.01	4.3	0.0	45.6	0.5	27.4	0.3	30.2	0.3	22.1	0.2	12.2	0.1
VA 0389	Spring onion	0.48	0.3	0.1	1.0	0.5	1.4	0.7	0.3	0.1	0.3	0.1	0.6	0.3
VC 0046	Melons, except watermelon	0.115	3.6	0.4	26.7	3.1	22.6	2.6	11.5	1.3	5.6	0.6	2.0	0.2
VC 0424	Cucumber	0.02	0.3	0.0	12.7	0.3	5.9	0.1	11.5	0.2	6.1	0.1	7.1	0.1
VC 0431	Squash, summer (= courgette, zuchini)	0.04	0.0	0.0	8.3	0.3	11.4	0.5	7.3	0.3	3.2	0.1	0.3	0.0
VO 0051	Peppers	0.12	1.4	0.2	29.9	3.6	13.0	1.6	6.3	0.8	6.2	0.7	4.0	0.5
VO 0444	Peppers, chili	0.84	0.7	0.6	14.9	12.5	4.1	3.4	3.2	2.7	3.1	2.6	2.0	1.7
VO 0448	Tomato (excl juice, incl paste, excl canned)	0.06	5.2	0.3	183.9	11.0	116.9	7.0	57.6	3.5	16.9	1.0	17.9	1.1
JF 0448	Tomato juice	0.059	5.2	0.3	0.5	0.0	0.4	0.0	2.1	0.1	6.9	0.4	15.2	0.9
-d	Tomato, canned	0.022	0.1	0.0	0.4	0.0	0.5	0.0	0.4	0.0	4.9	0.1	3.2	0.1
VB 0041	Cabbage, head	0.01	1.2	0.0	14.4	0.1	2.7	0.0	16.4	0.2	15.4	0.2	18.5	0.2
VB 0400	Broccoli	0.435	0.0	0.0	0.7	0.3	1.2	0.5	0.1	0.0	4.2	1.8	4.0	1.7
VL 0054	Brassica leafy vegetables	5.65	1.0	5.7	5.5	31.1	2.8	15.8	22.1	124.9	0.7	4.0	7.7	43.5
VL 0502	Spinach	5.65	0.0	0.0	5.0	28.3	1.1	6.2	0.1	0.6	2.6	14.7	0.1	0.6
VS 0624	Celery	2.7	0.0	0.0	0.9	2.4	0.0	0.0	2.0	5.4	1.5	4.1	0.0	0.0
DH 1100	Hops, dry	28.5	0.1	2.9	0.1	2.9	0.1	2.9	0.1	2.9	0.3	8.6	0.1	2.9
-	Barley beer	0.057	18.3	1.0	84.1	4.8	4.1	0.2	66.0	3.8	243.1	13.9	161.3	9.2
-	Maize beer	0.057	39.1	2.2	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0
-	Millet beer	0.057	14.0	0.8	0.0	0.0	0.0	0.0	0.0	0.0	0.5	0.0	0.0	0.0
-	Sorghum beer	0.057	62.3	3.6	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Total intake (µg/person)=			19.6		140.2		53.8		159.9		84.8		77.4
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			12000		12000		12000		12000		12000		12000
	%ADI=			0.2%		1.2%		0.4%		1.3%		0.7%		0.6%
	Rounded %ADI=			0%		1%		0%		1%		1%		1%

Annex 3

MANDIPROPAMID (231) International Estimated Daily Intake (IEDI) ADI = 0 - 0.2000 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G		H		I		J		K		L		M	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
FB 0269	Grape (excl dried, excl juice, excl wine)	0.43	1.2	0.5	2.6	1.1	0.0	0.0	0.2	0.1	0.0	0.0	3.7	1.6	0.0	0.0
DF 0269	Grape, dried (= currants, raisins and sultanas)	1.68	0.0	0.0	0.2	0.3	0.2	0.3	0.0	0.0	0.3	0.5	0.4	0.7	2.6	4.4
JF 0269	Grape juice	0.14	0.0	0.0	0.1	0.0	1.0	0.1	0.0	0.0	0.6	0.1	0.4	0.1	3.6	0.5
-	Wine	0.366	1.0	0.4	0.9	0.3	6.8	2.5	0.1	0.0	3.4	1.2	3.6	1.3	31.0	11.3
VR 0589	Potato (incl flour, frozen, starch, tapioca)	0.01	52.7	0.5	57.1	0.6	50.1	0.5	4.3	0.0	54.7	0.5	41.0	0.4	168.0	1.7
-	Onion, dry	0.01	16.8	0.2	8.6	0.1	6.9	0.1	12.1	0.1	18.6	0.2	23.8	0.2	28.4	0.3
VA 0389	Spring onion	0.48	0.1	0.0	4.8	2.3	0.1	0.0	1.0	0.5	1.0	0.5	2.7	1.3	0.6	0.3
VC 0046	Melons, except watermelon	0.115	7.5	0.9	6.1	0.7	0.7	0.1	1.4	0.2	2.5	0.3	6.9	0.8	12.4	1.4
VC 0424	Cucumber	0.02	7.9	0.2	0.6	0.0	0.2	0.0	0.0	0.0	0.4	0.0	5.5	0.1	5.3	0.1
VC 0431	Squash, summer (= courgette, zuchini)	0.04	2.4	0.1	1.5	0.1	0.0	0.0	0.0	0.0	3.8	0.2	2.2	0.1	2.5	0.1
VO 0051	Peppers	0.12	8.7	1.0	22.4	2.7	8.4	1.0	9.4	1.1	3.3	0.4	5.3	0.6	8.9	1.1
VO 0444	Peppers, chili	0.84	8.7	7.3	13.0	10.9	4.2	3.5	4.7	3.9	1.7	1.4	2.6	2.2	4.4	3.7
VO 0448	Tomato (excl juice, incl paste, excl canned)	0.06	23.3	1.4	12.6	0.8	14.6	0.9	7.2	0.4	35.2	2.1	5.9	0.4	45.0	2.7
JF 0448	Tomato juice	0.059	0.0	0.0	0.8	0.0	0.1	0.0	7.2	0.4	0.0	0.0	2.4	0.1	45.2	2.7
-d	Tomato, canned	0.022	0.2	0.0	14.5	0.3	0.2	0.0	0.0	0.0	0.3	0.0	0.8	0.0	1.2	0.0
VB 0041	Cabbage, head	0.01	10.0	0.1	1.0	0.0	7.2	0.1	1.0	0.0	1.4	0.0	23.9	0.2	17.0	0.2
VB 0400	Broccoli	0.435	3.2	1.4	7.8	3.4	0.0	0.0	0.0	0.0	0.3	0.1	0.4	0.2	6.6	2.9
VL 0054	Brassica leafy vegetables	5.65	10.3	58.2	4.0	22.6	7.3	41.2	1.0	5.7	2.0	11.3	23.8	134.5	1.7	9.6
VL 0502	Spinach	5.65	9.4	53.1	0.4	2.3	0.0	0.0	0.0	0.0	0.2	1.1	4.3	24.3	2.0	11.3
VS 0624	Celery	2.7	0.0	0.0	0.3	0.8	0.0	0.0	0.0	0.0	1.0	2.7	0.0	0.0	4.2	11.3
DH 1100	Hops, dry	28.5	0.0	0.0	0.1	2.9	0.1	2.9	0.1	2.9	0.1	2.9	0.1	2.9	0.6	17.1
-	Barley beer	0.057	21.9	1.2	102.7	5.9	29.5	1.7	12.6	0.7	100.9	5.8	82.2	4.7	218.8	12.5
-	Maize beer	0.057	0.1	0.0	0.1	0.0	23.5	1.3	9.0	0.5	0.0	0.0	0.1	0.0	45.5	2.6
-	Millet beer	0.057	0.0	0.0	0.0	0.0	22.5	1.3	8.8	0.5	0.0	0.0	0.0	0.0	0.0	0.0
-	Sorghum beer	0.057	0.0	0.0	0.0	0.0	35.1	2.0	28.6	1.6	0.1	0.0	0.0	0.0	3.3	0.2
	Total intake (µg/person)=			126.5		58.0		59.6		18.7		31.3		176.6		97.9
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			11000		12000		12000		12000		12000		11000		12000
	%ADI=			1.2%		0.5%		0.5%		0.2%		0.3%		1.6%		0.8%
	Rounded %ADI=			1%		0%		0%		0%		0%		2%		1%

Annex 3

PENTHIOPYRAD (253) International Estimated Daily Intake (IEDI) ADI = 0 - 0.1000 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A		B		C		D		E		F	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
JF 0226	Apple juice	0.021	0.0	0.0	2.8	0.1	0.1	0.0	1.1	0.0	6.8	0.1	7.4	0.2
GC 0640	Barley (incl pot, excl pearled, incl flour & grits, excl beer)	0.086	40.6	3.5	0.0	0.0	0.2	0.0	0.0	0.0	0.0	0.0	3.8	0.3
-	Barley beer	0.021	18.3	0.4	84.1	1.8	4.1	0.1	66.0	1.4	243.1	5.1	161.3	3.4
-	Barley, pearled	0.058	0.0	0.0	0.4	0.0	27.9	1.6	0.4	0.0	0.4	0.0	0.9	0.1
VP 0061	Beans except broad bean & soya bean (green pods & immature seeds)	0.9	1.0	0.9	17.4	15.7	7.5	6.8	0.9	0.8	16.4	14.8	0.1	0.1
VP 0062	Beans, shelled (immature seeds)	0.0685	0.5	0.0	12.7	0.9	4.1	0.3	0.9	0.1	13.1	0.9	0.1	0.0
VB 0041	Cabbage, head	0.4	1.2	0.5	14.4	5.8	2.7	1.1	16.4	6.6	15.4	6.2	18.5	7.4
VR 0577	Carrot	0.09	0.6	0.1	15.1	1.4	8.1	0.7	13.9	1.3	27.1	2.4	28.4	2.6
VS 0624	Celery	3.1	0.0	0.0	0.9	2.8	0.0	0.0	2.0	6.2	1.5	4.7	0.0	0.0
VC 0423	Chayote	0.13	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
SO 0691	Cotton seed (for oil processing only)	0.17	5.6	1.0	30.6	5.2	10.6	1.8	41.3	7.0	0.0	0.0	1.9	0.3
VC 0424	Cucumber	0.13	0.3	0.0	12.7	1.7	5.9	0.8	11.5	1.5	6.1	0.8	7.1	0.9
MO 0105	Edible offal (mammalian)	0.043	3.9	0.2	14.4	0.6	5.2	0.2	11.8	0.5	11.7	0.5	7.6	0.3
VO 0440	Egg plant (= aubergine)	0.27	1.7	0.5	17.5	4.7	12.3	3.3	1.7	0.5	0.8	0.2	0.4	0.1
PE 0112	Eggs	0.02	2.5	0.1	29.7	0.6	25.1	0.5	24.5	0.5	37.8	0.8	27.4	0.5
VB 0042	Flowerhead brassicas	1.4	0.2	0.3	11.1	15.5	3.6	5.0	0.4	0.6	7.7	10.8	4.1	5.7
VC 0425	Gherkin	0.13	0.3	0.0	12.7	1.7	5.9	0.8	11.5	1.5	6.1	0.8	7.1	0.9
VL 0053	Leafy vegetables (excl brassica leafy vegetables)	3.15	4.8	15.1	39.9	125.7	8.1	25.5	4.6	14.5	16.4	51.7	31.2	98.3
CF 1255	Maize flour	0.014	68.9	1.0	15.4	0.2	51.3	0.7	16.6	0.2	14.7	0.2	2.0	0.0
GC 0645	Maize (excl flour, excl oil, incl beer)	0.01	0.0	0.0	1.4	0.0	51.4	0.5	11.9	0.1	0.2	0.0	0.2	0.0
OR 0645	Maize oil, edible	0.027	0.1	0.0	4.0	0.1	2.3	0.1	0.5	0.0	0.9	0.0	0.2	0.0
MF 0100	Mammalian fats (except milk fats)	0.031	0.8	0.0	10.0	0.3	0.9	0.0	6.6	0.2	11.8	0.4	3.7	0.1
MM 0095	Meat from mammals other than marine mammals	0.012	27.7	0.3	116.5	1.4	38.5	0.5	55.1	0.7	90.2	1.1	131.3	1.6
ML 0106	Milks (excl processed products)	0.013	68.8	0.9	190.6	2.5	79.4	1.0	302.6	3.9	179.6	2.3	237.9	3.1
GC 0646	Millet (incl flour, incl beer)	0.22	15.8	3.5	0.1	0.0	0.8	0.2	5.6	1.2	0.2	0.0	0.1	0.0
VL 0485	Mustard greens	11	0.3	3.3	0.3	3.3	0.0	0.0	5.5	60.5	0.0	0.0	1.9	20.9
GC 0647	Oats (incl rolled)	0.086	1.4	0.1	0.6	0.1	0.2	0.0	4.2	0.4	5.7	0.5	8.9	0.8
VO 0442	Okra	0.27	3.9	1.1	1.0	0.3	5.3	1.4	0.1	0.0	0.0	0.0	0.0	0.0
-	Onion, dry	0.074	4.3	0.3	45.6	3.4	27.4	2.0	30.2	2.2	22.1	1.6	12.2	0.9
-	Onion, green (= shallot, Welsh, spring onion, others)	0.89	1.2	1.1	3.9	3.5	5.6	5.0	1.1	1.0	1.1	1.0	2.4	2.1
OR 0697	Peanut oil, edible	0.04	1.7	0.1	0.8	0.0	0.5	0.0	0.1	0.0	1.4	0.1	0.4	0.0

Annex 3

PENTHIOPYRAD (253) International Estimated Daily Intake (IEDI) ADI = 0 - 0.1000 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day A		B		C		D		E		F	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
SO 0697	Peanut, shelled (excl oil)	0.01	1.5	0.0	1.3	0.0	1.0	0.0	0.5	0.0	0.8	0.0	0.5	0.0
VP 0063	Peas (green pods and/or immature seeds)	0.9	0.1	0.1	2.9	2.6	6.0	5.4	0.6	0.5	9.7	8.7	5.2	4.7
VP 0064	Peas, shelled (immature seeds only)	0.0685	0.0	0.0	0.9	0.1	6.0	0.4	0.6	0.0	9.7	0.7	3.2	0.2
VO 0051	Peppers	0.27	1.4	0.4	29.9	8.1	13.0	3.5	6.3	1.7	6.2	1.7	4.0	1.1
DF 0014	Plum, dried (prunes)	0.032	0.0	0.0	0.2	0.0	0.0	0.0	0.1	0.0	0.5	0.0	0.6	0.0
FP 0009	Pome fruit (excl apple juice)	0.15	0.5	0.1	79.9	12.0	21.8	3.3	43.6	6.5	51.5	7.7	35.1	5.3
VR 0589	Potato (incl flour, frozen, starch, tapioca)	0.01	19.1	0.2	160.8	1.6	61.2	0.6	243.6	2.4	230.1	2.3	204.7	2.0
PM 0110	Poultry meat	0.02	7.1	0.1	58.5	1.2	31.9	0.6	24.0	0.5	61.0	1.2	27.3	0.5
PO 0111	Poultry, edible offal of	0.02	0.4	0.0	0.4	0.0	1.7	0.0	0.1	0.0	0.6	0.0	0.2	0.0
PF 0111	Poultry, fats	0.02	0.1	0.0	0.1	0.0	0.1	0.0	0.0	0.0	0.4	0.0	0.1	0.0
VD 0070	Pulses (excl soya beans)	0.01	44.6	0.4	26.5	0.3	17.1	0.2	14.4	0.1	14.1	0.1	8.7	0.1
VR 0494	Radish	0.305	0.0	0.0	1.3	0.4	0.6	0.2	2.0	0.6	1.2	0.4	0.0	0.0
SO 0495	Rape seed (excl oil)	0.084	0.1	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.1	0.0	0.1	0.0
OR 0495	Rape seed oil, edible	0.11	0.3	0.0	0.7	0.1	1.0	0.1	0.7	0.1	13.7	1.5	10.0	1.1
GC 0650	Rye (incl flour)	0.01	0.1	0.0	3.7	0.0	0.3	0.0	24.3	0.2	25.8	0.3	45.8	0.5
GC 0651	Sorghum (incl flour, incl beer)	0.22	36.9	8.1	0.0	0.0	10.2	2.2	0.0	0.0	0.0	0.0	0.0	0.0
VD 0541	Soya bean (dry, incl oil)	0.032	9.9	0.3	36.4	1.2	34.3	1.1	22.4	0.7	35.3	1.1	39.2	1.3
VC 0431	Squash, summer (= courgette, zuchini)	0.13	0.0	0.0	8.3	1.1	11.4	1.5	7.3	0.9	3.2	0.4	0.3	0.0
-d	Squashes & pumpkins & gourds	0.01	16.3	0.2	12.3	0.1	14.4	0.1	21.9	0.2	3.2	0.0	1.0	0.0
FS 0012	Stone fruit (excl dried plums, incl dried apricots)	1.3	0.7	0.9	44.1	57.4	14.1	18.3	26.6	34.6	26.3	34.1	8.3	10.7
FB 0275	Strawberry	0.8	0.0	0.0	5.0	4.0	2.0	1.6	1.7	1.4	5.2	4.2	4.1	3.3
VR 0596	Sugar beet	0.033	0.0	0.0	40.7	1.3	0.0	0.0	0.1	0.0	6.0	0.2	0.1	0.0
SO 0702	Sunflower seed (incl oil)	0.12	0.7	0.1	44.5	5.3	20.5	2.5	29.6	3.6	21.2	2.5	5.4	0.6
VO 0447	Sweet corn (incl corn on the cob, incl frozen kernels, incl preserved kernels)	0.01	14.7	0.1	2.0	0.0	0.2	0.0	1.2	0.0	6.5	0.1	7.2	0.1
VO 0448	Tomato (excl juice, excl paste, excl canned)	0.27	1.3	0.4	178.4	48.2	102.8	27.8	53.4	14.4	1.6	0.4	0.0	0.0
JF 0448	Tomato juice	0.092	5.2	0.5	0.5	0.0	0.4	0.0	2.1	0.2	6.9	0.6	15.2	1.4
-d	Tomato paste	0.92	0.5	0.5	1.3	1.2	3.5	3.2	1.0	0.9	3.8	3.5	4.5	4.1
-d	Tomato, canned	0.54	0.1	0.1	0.4	0.2	0.5	0.3	0.4	0.2	4.9	2.6	3.2	1.7
TN 0085	Tree nuts	0.01	4.2	0.0	21.5	0.2	3.9	0.0	3.0	0.0	5.5	0.1	10.2	0.1
GC 0653	Triticale (incl flour)	0.01	0.0	0.0	115.8	1.2	0.0	0.0	0.0	0.0	0.3	0.0	0.0	0.0
VL 0506	Turnip greens	9.4	0.1	0.9	0.0	0.0	0.0	0.0	0.1	0.9	0.0	0.0	0.1	0.9
VC 0432	Watermelon	0.01	6.1	0.1	43.1	0.4	47.1	0.5	25.8	0.3	4.4	0.0	6.0	0.1
GC 0654	Wheat (incl bulgur wholemeal, excl flour)	0.01	6.0	0.1	11.1	0.1	0.8	0.0	0.2	0.0	0.2	0.0	0.0	0.0

Annex 3

PENTHIOPYRAD (253) International Estimated Daily Intake (IEDI) ADI = 0 - 0.1000 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A		B		C		D		E		F	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
CM 0654	Wheat bran, unprocessed	0.018	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CF 1211	Wheat flour (incl macaroni, bread, pastry, starch, gluten)	0.004	63.4	0.3	296.3	1.2	327.5	1.3	300.0	1.2	181.6	0.7	166.2	0.7
CF 1210	Wheat germ	0.019	0.0	0.0	1.3	0.0	0.0	0.0	1.3	0.0	0.9	0.0	1.2	0.0
	Total intake (µg/person)=			47.9		348.5		134.8		185.8		182.3		191.3
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			6000		6000		6000		6000		6000		6000
	%ADI=			0.8%		5.8%		2.2%		3.1%		3.0%		3.2%
	Rounded %ADI=			1%		6%		2%		3%		3%		3%

PENTHIOPYRAD (253) International Estimated Daily Intake (IEDI) ADI = 0 - 0.1000 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G		H		I		J		K		L		M	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
JF 0226	Apple juice	0.021	0.1	0.0	0.5	0.0	0.1	0.0	0.0	0.0	0.7	0.0	0.9	0.0	5.7	0.1
GC 0640	Barley (incl pot, excl pearled, incl flour & grits, excl beer)	0.086	1.5	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.4	0.0	0.0	0.0
-	Barley beer	0.021	21.9	0.5	102.7	2.2	29.5	0.6	12.6	0.3	100.9	2.1	82.2	1.7	218.8	4.6
-	Barley, pearled	0.058	0.5	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.7	0.0	0.0	0.0	0.1	0.0
VP 0061	Beans except broad bean & soya bean (green pods & immature seeds)	0.9	2.6	2.3	2.6	2.3	1.0	0.9	0.5	0.5	0.6	0.5	2.8	2.5	9.8	8.8
VP 0062	Beans, shelled (immature seeds)	0.0685	2.6	0.2	1.9	0.1	1.0	0.1	0.5	0.0	0.3	0.0	1.8	0.1	9.0	0.6
VB 0041	Cabbage, head	0.4	10.0	4.0	1.0	0.4	7.2	2.9	1.0	0.4	1.4	0.6	23.9	9.6	17.0	6.8
VR 0577	Carrot	0.09	5.4	0.5	7.9	0.7	2.5	0.2	3.5	0.3	4.1	0.4	8.6	0.8	19.4	1.7
VS 0624	Celery	3.1	0.0	0.0	0.3	0.9	0.0	0.0	0.0	0.0	1.0	3.1	0.0	0.0	4.2	13.0
VC 0423	Chayote	0.13	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
SO 0691	Cotton seed (for oil processing only)	0.17	6.3	1.1	4.4	0.7	6.3	1.1	8.8	1.5	9.4	1.6	34.4	5.8	7.5	1.3
VC 0424	Cucumber	0.13	7.9	1.0	0.6	0.1	0.2	0.0	0.0	0.0	0.4	0.1	5.5	0.7	5.3	0.7
MO 0105	Edible offal (mammalian)	0.043	4.8	0.2	10.7	0.5	4.0	0.2	4.0	0.2	6.5	0.3	6.6	0.3	5.6	0.2
VO 0440	Egg plant (= aubergine)	0.27	20.1	5.4	0.1	0.0	0.6	0.2	6.3	1.7	0.5	0.1	6.3	1.7	0.7	0.2

Annex 3

PENTHIOPYRAD (253) International Estimated Daily Intake (IEDI) ADI = 0 - 0.1000 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G		H		I		J		K		L		M	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
PE 0112	Eggs	0.02	22.1	0.4	71.5	1.4	16.6	0.3	5.1	0.1	17.6	0.4	35.2	0.7	57.4	1.1
VB 0042	Flowerhead brassicas	1.4	9.6	13.4	7.9	11.1	0.6	0.8	0.2	0.3	0.9	1.3	1.1	1.5	8.0	11.2
VC 0425	Gherkin	0.13	7.9	1.0	0.6	0.1	0.2	0.0	0.0	0.0	0.4	0.1	5.5	0.7	5.3	0.7
VL 0053	Leafy vegetables (excl brassica leafy vegetables)	3.15	30.5	96.1	8.0	25.2	5.2	16.4	8.5	26.8	3.4	10.7	26.2	82.5	37.4	117.8
CF 1255	Maize flour	0.014	28.8	0.4	248.8	3.5	206.7	2.9	47.8	0.7	46.2	0.6	10.5	0.1	21.5	0.3
GC 0645	Maize (excl flour, excl oil, incl beer)	0.01	0.6	0.0	0.0	0.0	0.1	0.0	0.0	0.0	7.7	0.1	0.0	0.0	19.4	0.2
OR 0645	Maize oil, edible	0.027	0.1	0.0	0.6	0.0	1.8	0.0	0.0	0.0	1.0	0.0	1.6	0.0	1.8	0.0
MF 0100	Mammalian fats (except milk fats)	0.031	2.2	0.1	18.6	0.6	0.5	0.0	0.8	0.0	5.7	0.2	4.5	0.1	18.2	0.6
MM 0095	Meat from mammals other than marine mammals	0.012	54.8	0.7	89.4	1.1	30.6	0.4	28.6	0.3	82.1	1.0	61.1	0.7	158.3	1.9
ML 0106	Milks (excl processed products)	0.013	66.0	0.9	121.1	1.6	81.6	1.1	102.4	1.3	207.7	2.7	57.0	0.7	287.9	3.7
GC 0646	Millet (incl flour, incl beer)	0.22	13.0	2.9	0.0	0.0	8.3	1.8	96.9	21.3	0.0	0.0	0.4	0.1	0.0	0.0
VL 0485	Mustard greens	11	3.4	37.4	0.4	4.4	2.4	26.4	0.3	3.3	0.5	5.5	7.9	86.9	0.3	3.3
GC 0647	Oats (incl rolled)	0.086	0.2	0.0	2.0	0.2	0.8	0.1	0.0	0.0	3.5	0.3	0.7	0.1	7.6	0.7
VO 0442	Okra	0.27	4.1	1.1	1.0	0.3	7.0	1.9	15.9	4.3	1.1	0.3	3.9	1.1	0.2	0.1
-	Onion, dry	0.074	16.8	1.2	8.6	0.6	6.9	0.5	12.1	0.9	18.6	1.4	23.8	1.8	28.4	2.1
-	Onion, green (= shallot, Welsh, spring onion, others)	0.89	0.6	0.5	19.3	17.2	0.4	0.4	3.9	3.5	4.2	3.7	10.7	9.5	1.7	1.5
OR 0697	Peanut oil, edible	0.04	3.0	0.1	0.3	0.0	1.5	0.1	7.9	0.3	0.3	0.0	0.0	0.0	0.4	0.0
SO 0697	Peanut, shelled (excl oil)	0.01	0.7	0.0	1.4	0.0	1.3	0.0	3.6	0.0	0.2	0.0	0.7	0.0	6.0	0.1
VP 0063	Peas (green pods and/or immature seeds)	0.9	3.9	3.5	1.6	1.4	0.4	0.4	0.0	0.0	0.9	0.8	1.0	0.9	8.6	7.7
VP 0064	Peas, shelled (immature seeds only)	0.0685	3.9	0.3	1.6	0.1	0.0	0.0	0.0	0.0	0.4	0.0	1.0	0.1	0.8	0.1
VO 0051	Peppers	0.27	8.7	2.3	22.4	6.0	8.4	2.3	9.4	2.5	3.3	0.9	5.3	1.4	8.9	2.4
DF 0014	Plum, dried (prunes)	0.032	0.1	0.0	0.2	0.0	0.0	0.0	0.0	0.0	0.2	0.0	0.2	0.0	0.6	0.0
FP 0009	Pome fruit (excl apple juice)	0.15	20.8	3.1	11.6	1.7	3.3	0.5	0.1	0.0	10.7	1.6	23.6	3.5	36.9	5.5
VR 0589	Potato (incl flour, frozen, starch, tapioca)	0.01	52.7	0.5	57.1	0.6	50.1	0.5	4.3	0.0	54.7	0.5	41.0	0.4	168.0	1.7
PM 0110	Poultry meat	0.02	17.6	0.4	131.3	2.6	25.1	0.5	4.7	0.1	145.9	2.9	27.7	0.6	115.1	2.3
PO 0111	Poultry, edible offal of	0.02	0.4	0.0	1.0	0.0	1.9	0.0	0.0	0.0	0.7	0.0	1.0	0.0	0.3	0.0
PF 0111	Poultry, fats	0.02	0.1	0.0	8.2	0.2	0.0	0.0	0.1	0.0	0.0	0.0	0.1	0.0	4.2	0.1
VD 0070	Pulses (excl soya beans)	0.01	16.0	0.2	32.4	0.3	24.7	0.2	34.2	0.3	50.7	0.5	8.0	0.1	16.9	0.2
VR 0494	Radish	0.305	0.0	0.0	0.3	0.1	0.0	0.0	0.0	0.0	1.0	0.3	0.0	0.0	0.3	0.1
SO 0495	Rape seed (excl oil)	0.084	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
OR 0495	Rape seed oil, edible	0.11	3.8	0.4	2.3	0.3	0.1	0.0	0.4	0.0	0.0	0.0	6.0	0.7	3.8	0.4
GC 0650	Rye (incl flour)	0.01	0.4	0.0	0.0	0.0	0.2	0.0	0.1	0.0	0.1	0.0	0.9	0.0	0.8	0.0
GC 0651	Sorghum (incl flour, incl beer)	0.22	9.8	2.2	19.9	4.4	18.6	4.1	112.3	24.7	0.1	0.0	3.3	0.7	3.0	0.7

Annex 3

PENTHIOPYRAD (253) International Estimated Daily Intake (IEDI) ADI = 0 - 0.1000 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G		H		I		J		K		L		M	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
VD 0541	Soya bean (dry, incl oil)	0.032	25.9	0.8	59.4	1.9	11.2	0.4	11.0	0.4	109.3	3.5	51.5	1.6	123.2	3.9
VC 0431	Squash, summer (= courgette, zuchini)	0.13	2.4	0.3	1.5	0.2	0.0	0.0	0.0	0.0	3.8	0.5	2.2	0.3	2.5	0.3
-d	Squashes & pumpkins & gourds	0.01	7.1	0.1	4.6	0.0	11.3	0.1	3.0	0.0	7.0	0.1	6.7	0.1	7.6	0.1
FS 0012	Stone fruit (excl dried plums, incl dried apricots)	1.3	6.7	8.7	4.3	5.6	1.4	1.8	0.1	0.1	4.9	6.4	4.9	6.4	17.7	23.0
FB 0275	Strawberry	0.8	0.0	0.0	1.8	1.4	0.1	0.1	0.0	0.0	0.3	0.2	6.2	5.0	5.9	4.7
VR 0596	Sugar beet	0.033	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.2	0.0	0.0	0.0	14.3	0.5
SO 0702	Sunflower seed (incl oil)	0.12	2.7	0.3	8.8	1.1	13.5	1.6	0.2	0.0	3.6	0.4	0.6	0.1	10.4	1.2
VO 0447	Sweet corn (incl corn on the cob, incl frozen kernels, incl preserved kernels)	0.01	0.4	0.0	4.9	0.0	4.5	0.0	3.3	0.0	1.7	0.0	5.6	0.1	18.1	0.2
VO 0448	Tomato (excl juice, excl paste, excl canned)	0.27	22.8	6.2	4.1	1.1	12.3	3.3	1.8	0.5	32.8	8.9	0.4	0.1	27.3	7.4
JF 0448	Tomato juice	0.092	0.0	0.0	0.8	0.1	0.1	0.0	7.2	0.7	0.0	0.0	2.4	0.2	45.2	4.2
-d	Tomato paste	0.92	0.1	0.1	2.1	1.9	0.6	0.6	0.4	0.4	0.6	0.6	1.4	1.3	1.2	1.1
-d	Tomato, canned	0.54	0.2	0.1	14.5	7.8	0.2	0.1	0.0	0.0	0.3	0.2	0.8	0.4	1.2	0.6
TN 0085	Tree nuts	0.01	16.3	0.2	15.7	0.2	9.7	0.1	1.9	0.0	19.1	0.2	29.0	0.3	5.6	0.1
GC 0653	Triticale (incl flour)	0.01	1.3	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
VL 0506	Turnip greens	9.4	0.1	0.9	0.0	0.0	0.1	0.9	0.1	0.9	0.1	0.9	0.1	0.9	0.5	4.7
VC 0432	Watermelon	0.01	39.3	0.4	14.0	0.1	2.5	0.0	13.6	0.1	8.4	0.1	14.5	0.1	13.6	0.1
GC 0654	Wheat (incl bulgur wholemeal, excl flour)	0.01	0.0	0.0	0.9	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.1	0.0
CM 0654	Wheat bran, unprocessed	0.018	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CF 1211	Wheat flour (incl macaroni, bread, pastry, starch, gluten)	0.004	133.0	0.5	60.1	0.2	52.4	0.2	32.2	0.1	87.7	0.4	79.6	0.3	180.1	0.7
CF 1210	Wheat germ	0.019	0.1	0.0	48.1	0.9	1.8	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.6	0.0
	Total intake (µg/person)=			203.1		115.6		77.1		99.1		67.0		235.6		257.4
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			5500		6000		6000		6000		6000		5500		6000
	%ADI=			3.7%		1.9%		1.3%		1.7%		1.1%		4.3%		4.3%
	Rounded %ADI=			4%		2%		1%		2%		1%		4%		4%

Annex 3

PROPICONAZOLE (160) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0700 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day											
			A		B		C		D		E		F	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
FI 0327	Banana	0.06	38.8	2.3	17.4	1.0	16.0	1.0	6.6	0.4	21.5	1.3	33.8	2.0
GC 0640	Barley (incl pot, incl pearled, incl flour & grits, incl beer)	0.0675	40.6	2.7	16.8	1.1	93.9	6.3	13.2	0.9	48.6	3.3	36.1	2.4
SB 0716	Coffee beans (incl green, incl extracts, incl roasted)	0.06	3.1	0.2	12.6	0.8	2.9	0.2	1.4	0.1	10.1	0.6	18.0	1.1
MO 0105	Edible offal (mammalian)	0.06	3.9	0.2	14.4	0.9	5.2	0.3	11.8	0.7	11.7	0.7	7.6	0.5
PE 0112	Eggs	0.05	2.5	0.1	29.7	1.5	25.1	1.3	24.5	1.2	37.8	1.9	27.4	1.4
GC 0645	Maize (incl flour, incl oil, incl beer)	0.05	82.7	4.1	148.4	7.4	135.9	6.8	31.8	1.6	33.3	1.7	7.5	0.4
MF 0100	Mammalian fats (except milk fats)	0.05	0.8	0.0	10.0	0.5	0.9	0.0	6.6	0.3	11.8	0.6	3.7	0.2
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.01	5.5	0.1	23.3	0.2	7.7	0.1	11.0	0.1	18.0	0.2	26.3	0.3
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0.04	22.2	0.9	93.2	3.7	30.8	1.2	44.1	1.8	72.2	2.9	105.0	4.2
ML 0106	Milks (excl processed products)	0.01	68.8	0.7	190.6	1.9	79.4	0.8	302.6	3.0	179.6	1.8	237.9	2.4
FC 0208	Orange, sweet (incl juice)	0.02	2.1	0.0	28.4	0.6	19.0	0.4	7.2	0.1	8.8	0.2	29.0	0.6
FC 0004	Orange, sweet, sour + orange-like hybrid (excl juice)	2.95	4.2	12.4	54.1	159.7	30.1	88.7	11.9	35.0	0.2	0.7	0.5	1.5
FS 0247	Peach	1.55	0.2	0.3	24.8	38.4	3.3	5.1	1.8	2.8	5.4	8.4	1.6	2.5
TN 0672	Pecan	0.02	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0
FI 0353	Pineapple (incl canned, incl juice)	0.02	3.8	0.1	6.2	0.1	0.6	0.0	0.9	0.0	7.7	0.2	8.2	0.2
FS 0014	Plum (incl dried)	0.185	0.1	0.0	5.9	1.1	2.5	0.5	7.3	1.4	6.9	1.3	2.6	0.5
PM 0110	Poultry meat: 10% as fat	0.005	0.7	0.0	5.9	0.0	3.2	0.0	2.4	0.0	6.1	0.0	2.7	0.0
PM 0110	Poultry meat: 90% as muscle	0.045	6.4	0.3	52.7	2.4	28.7	1.3	21.6	1.0	54.9	2.5	24.6	1.1
PF 0111	Poultry, fats	0.05	0.1	0.0	0.1	0.0	0.1	0.0	0.0	0.0	0.4	0.0	0.1	0.0
SO 0495	Rape seed (incl oil)	0.06	0.9	0.1	1.8	0.1	2.5	0.2	1.9	0.1	35.7	2.1	26.1	1.6
GC 0650	Rye (incl flour)	0.06	0.1	0.0	3.7	0.2	0.3	0.0	24.3	1.5	25.8	1.5	45.8	2.7
VD 0541	Soya bean (dry, incl oil)	0.03	9.9	0.3	36.4	1.1	34.3	1.0	22.4	0.7	35.3	1.1	39.2	1.2
SO 0702	Sunflower seed (incl oil)	0.06	0.7	0.0	44.5	2.7	20.5	1.2	29.6	1.8	21.2	1.3	5.4	0.3
VO 0448	Tomato (incl juice, incl paste, incl canned)	0.8	11.8	9.4	185.0	148.0	118.0	94.4	60.7	48.6	31.6	25.3	40.9	32.7
GC 0653	Triticale (incl flour)	0.06	0.0	0.0	115.8	6.9	0.0	0.0	0.0	0.0	0.3	0.0	0.0	0.0
GC 0654	Wheat (incl bulgur wholemeal, incl flour)	0.06	88.4	5.3	396.3	23.8	426.5	25.6	390.2	23.4	236.3	14.2	216.0	13.0
	Total intake (µg/person)=			39.7		404.2		236.4		126.4		73.6		72.6
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			4200		4200		4200		4200		4200		4200
	%ADI=			0.9%		9.6%		5.6%		3.0%		1.8%		1.7%
	Rounded %ADI=			1%		10%		6%		3%		2%		2%

Annex 3

PROPICONAZOLE (160) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0700 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G		H		I		J		K		L		M	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
FI 0327	Banana	0.06	21.4	1.3	36.6	2.2	11.4	0.7	9.2	0.6	70.2	4.2	40.5	2.4	32.6	2.0
GC 0640	Barley (incl pot, incl pearled, incl flour & grits, incl beer)	0.0675	5.9	0.4	20.5	1.4	5.9	0.4	2.5	0.2	20.2	1.4	16.8	1.1	43.8	3.0
SB 0716	Coffee beans (incl green, incl extracts, incl roasted)	0.06	0.2	0.0	7.0	0.4	0.5	0.0	0.2	0.0	5.3	0.3	5.7	0.3	12.4	0.7
MO 0105	Edible offal (mammalian)	0.06	4.8	0.3	10.7	0.6	4.0	0.2	4.0	0.2	6.5	0.4	6.6	0.4	5.6	0.3
PE 0112	Eggs	0.05	22.1	1.1	71.5	3.6	16.6	0.8	5.1	0.3	17.6	0.9	35.2	1.8	57.4	2.9
GC 0645	Maize (incl flour, incl oil, incl beer)	0.05	35.2	1.8	298.6	14.9	248.1	12.4	57.4	2.9	63.1	3.2	58.6	2.9	85.5	4.3
MF 0100	Mammalian fats (except milk fats)	0.05	2.2	0.1	18.6	0.9	0.5	0.0	0.8	0.0	5.7	0.3	4.5	0.2	18.2	0.9
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.01	11.0	0.1	17.9	0.2	6.1	0.1	5.7	0.1	16.4	0.2	12.2	0.1	31.7	0.3
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0.04	43.8	1.8	71.5	2.9	24.5	1.0	22.9	0.9	65.7	2.6	48.9	2.0	126.6	5.1
ML 0106	Milks (excl processed products)	0.01	66.0	0.7	121.1	1.2	81.6	0.8	102.4	1.0	207.7	2.1	57.0	0.6	287.9	2.9
FC 0208	Orange, sweet (incl juice)	0.02	3.7	0.1	118.9	2.4	4.1	0.1	1.2	0.0	203.0	4.1	3.3	0.1	70.0	1.4
FC 0004	Orange, sweet, sour + orange-like hybrid (excl juice)	2.95	7.0	20.8	117.1	345.4	2.0	5.9	2.4	7.1	200.7	591.9	0.5	1.4	0.2	0.5
FS 0247	Peach	1.55	1.7	2.6	1.7	2.6	1.1	1.7	0.1	0.2	1.0	1.6	1.7	2.6	10.2	15.8
TN 0672	Pecan	0.02	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.0
FI 0353	Pineapple (incl canned, incl juice)	0.02	3.9	0.1	11.7	0.2	12.6	0.3	11.1	0.2	16.6	0.3	21.4	0.4	22.6	0.5
FS 0014	Plum (incl dried)	0.185	3.3	0.6	1.4	0.3	0.1	0.0	0.0	0.0	0.6	0.1	1.5	0.3	2.2	0.4
PM 0110	Poultry meat: 10% as fat	0.005	1.8	0.0	13.1	0.1	2.5	0.0	0.5	0.0	14.6	0.1	2.8	0.0	11.5	0.1
PM 0110	Poultry meat: 90% as muscle	0.045	15.8	0.7	118.2	5.3	22.6	1.0	4.2	0.2	131.3	5.9	24.9	1.1	103.6	4.7
PF 0111	Poultry, fats	0.05	0.1	0.0	8.2	0.4	0.0	0.0	0.1	0.0	0.0	0.0	0.1	0.0	4.2	0.2
SO 0495	Rape seed (incl oil)	0.06	9.9	0.6	5.9	0.4	0.3	0.0	1.0	0.1	0.0	0.0	15.5	0.9	9.9	0.6
GC 0650	Rye (incl flour)	0.06	0.4	0.0	0.0	0.0	0.2	0.0	0.1	0.0	0.1	0.0	0.9	0.1	0.8	0.0
VD 0541	Soya bean (dry, incl oil)	0.03	25.9	0.8	59.4	1.8	11.2	0.3	11.0	0.3	109.3	3.3	51.5	1.5	123.2	3.7
SO 0702	Sunflower seed (incl oil)	0.06	2.7	0.2	8.8	0.5	13.5	0.8	0.2	0.0	3.6	0.2	0.6	0.0	10.4	0.6
VO 0448	Tomato (incl juice, incl paste, incl canned)	0.8	23.5	18.8	31.7	25.4	15.0	12.0	16.2	13.0	35.6	28.5	9.9	7.9	103.0	82.4
GC 0653	Triticale (incl flour)	0.06	1.3	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
GC 0654	Wheat (incl bulgur wholemeal, incl flour)	0.06	172.9	10.4	79.0	4.7	68.1	4.1	41.9	2.5	114.1	6.8	103.4	6.2	234.2	14.1
	Total intake (µg/person)=			63.2		417.8		42.7		29.7		658.3		34.5		147.2
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60

Annex 3

PROPICONAZOLE (160) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0700 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G		H		I		J		K		L		M	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
	ADI (µg/person)=		3850		4200		4200		4200		4200		3850		4200	
	%ADI=		1.6%		9.9%		1.0%		0.7%		15.7%		0.9%		3.5%	
	Rounded %ADI=		2%		10%		1%		1%		20%		1%		4%	

Annex 3

PYRIMETHANIL (226) International Estimated Daily Intake (IEDI) ADI = 0 - 0.2000 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A		B		C		D		E		F	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
TN 0660	Almond	0.05	0.0	0.0	1.9	0.1	1.0	0.1	0.0	0.0	1.0	0.1	0.8	0.0
JF 0226	Apple juice	0.59	0.0	0.0	2.8	1.7	0.1	0.1	1.1	0.6	6.8	4.0	7.4	4.4
FS 0240	Apricot (incl dried)	1.2	0.3	0.4	6.2	7.4	3.9	4.7	3.2	3.8	2.0	2.4	0.8	1.0
FI 0327	Banana	0.05	38.8	1.9	17.4	0.9	16.0	0.8	6.6	0.3	21.5	1.1	33.8	1.7
VR 0577	Carrot	0.14	0.6	0.1	15.1	2.1	8.1	1.1	13.9	1.9	27.1	3.8	28.4	4.0
FS 0013	Cherries	1.3	0.0	0.0	6.8	8.8	0.9	1.2	6.2	8.1	3.6	4.7	0.4	0.5
FC 0001	Citrus fruit (excl lemon juice, excl mandarin juice, excl orange juice, excl grapefruit juice, excl NES juice)	2.8	15.7	44.0	86.5	242.1	52.6	147.2	24.2	67.7	16.2	45.4	12.0	33.6
-	Citrus juice NES	0.028	0.0	0.0	1.7	0.0	0.1	0.0	0.0	0.0	1.1	0.0	0.3	0.0
VP 0526	Common bean (green pods and/or immature seeds)	0.22	0.5	0.1	4.7	1.0	4.1	0.9	0.0	0.0	13.1	2.9	0.0	0.0
FB 0265	Cranberries	1.2	0.1	0.1	0.0	0.0	0.0	0.0	0.3	0.4	0.0	0.0	0.6	0.7
MO 0105	Edible offal (mammalian)	0.065	3.9	0.3	14.4	0.9	5.2	0.3	11.8	0.8	11.7	0.8	7.6	0.5
VD 0561	Field pea (dry)	0.09	2.9	0.3	1.3	0.1	0.8	0.1	2.3	0.2	4.6	0.4	3.4	0.3
FB 0269	Grape (excl dried, excl juice, excl wine)	0.71	1.9	1.3	9.2	6.6	23.8	16.9	9.8	7.0	0.0	0.0	0.0	0.0
JF 0269	Grape juice	0.5	0.0	0.0	0.1	0.1	0.1	0.1	0.1	0.1	1.4	0.7	1.0	0.5
DF 0269	Grape, dried (= currants, raisins and sultanas)	1.1	0.0	0.0	2.9	3.2	0.4	0.4	0.4	0.4	2.3	2.5	1.7	1.9
JF 0203	Grapefruit juice	0.028	0.0	0.0	0.2	0.0	0.1	0.0	0.1	0.0	1.1	0.0	0.2	0.0
-d	Lemon juice	0.028	0.0	0.0	0.9	0.0	0.1	0.0	0.0	0.0	0.2	0.0	0.4	0.0
VL 0482	Lettuce, head	0.85	0.1	0.0	6.2	5.2	0.7	0.6	0.1	0.0	0.1	0.0	0.0	0.0
MF 0100	Mammalian fats (except milk fats)	0	0.8	0.0	10.0	0.0	0.9	0.0	6.6	0.0	11.8	0.0	3.7	0.0
MM 0095	Meat from mammals other than marine mammals	0	27.7	0.0	116.5	0.0	38.5	0.0	55.1	0.0	90.2	0.0	131.3	0.0
ML 0106	Milks (excl processed products)	0.01	68.8	0.7	190.6	1.9	79.4	0.8	302.6	3.0	179.6	1.8	237.9	2.4
FS 0245	Nectarine	1.3	0.0	0.0	0.5	0.7	3.3	4.3	1.8	2.3	2.8	3.6	1.6	2.1
-	Onion, dry	0.062	4.3	0.3	45.6	2.8	27.4	1.7	30.2	1.9	22.1	1.4	12.2	0.8
JF 0004	Orange juice	0.028	0.0	0.0	2.1	0.1	4.4	0.1	1.4	0.0	16.2	0.5	22.6	0.6
FS 0247	Peach	1.3	0.2	0.3	24.8	32.2	3.3	4.3	1.8	2.3	5.4	7.0	1.6	2.1
FS 0014	Plum (excl dried)	0.59	0.1	0.1	5.3	3.1	2.5	1.5	7.0	4.1	5.5	3.2	0.9	0.5
DF 0014	Plum, dried (prunes)	0.48	0.0	0.0	0.2	0.1	0.0	0.0	0.1	0.0	0.5	0.2	0.6	0.3
FP 0009	Pome fruit (excl apple juice)	1.6	0.5	0.8	79.9	127.8	21.8	34.8	43.6	69.7	51.5	82.4	35.1	56.2
VR 0589	Potato (incl flour, frozen, starch, tapioca)	0.05	19.1	1.0	160.8	8.0	61.2	3.1	243.6	12.2	230.1	11.5	204.7	10.2
VA 0389	Spring onion	0.38	0.3	0.1	1.0	0.4	1.4	0.5	0.3	0.1	0.3	0.1	0.6	0.2
FB 0275	Strawberry	1.2	0.0	0.0	5.0	6.0	2.0	2.4	1.7	2.0	5.2	6.2	4.1	4.9

Annex 3

PYRIMETHANIL (226) International Estimated Daily Intake (IEDI) ADI = 0 - 0.2000 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day; Intake = daily intake: µg/person											
			A		B		C		D		E		F	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
VO 0448	Tomato (incl juice, excl paste, incl canned)	0.32	9.8	3.1	179.8	57.5	104.0	33.3	56.7	18.1	16.4	5.2	22.9	7.3
-d	Tomato paste	0.35	0.5	0.2	1.3	0.5	3.5	1.2	1.0	0.4	3.8	1.3	4.5	1.6
-	Wine	0.34	1.3	0.4	76.8	26.1	1.1	0.4	15.4	5.2	68.8	23.4	25.6	8.7
	Total intake (µg/person)=			55.4		547.6		262.7		212.9		216.8		146.9
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			12000		12000		12000		12000		12000		12000
	%ADI=			0.5%		4.6%		2.2%		1.8%		1.8%		1.2%
	Rounded %ADI=			0%		5%		2%		2%		2%		1%

PYRIMETHANIL (226) International Estimated Daily Intake (IEDI) ADI = 0 - 0.2000 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day; Intake = daily intake: µg/person													
			G		H		I		J		K		L		M	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
TN 0660	Almond	0.05	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.3	0.0	0.3	0.0
JF 0226	Apple juice	0.59	0.1	0.1	0.5	0.3	0.1	0.1	0.0	0.0	0.7	0.4	0.9	0.5	5.7	3.4
FS 0240	Apricot (incl dried)	1.2	0.2	0.2	0.1	0.1	0.2	0.2	0.0	0.0	0.0	0.0	0.1	0.1	1.1	1.3
FI 0327	Banana	0.05	21.4	1.1	36.6	1.8	11.4	0.6	9.2	0.5	70.2	3.5	40.5	2.0	32.6	1.6
VR 0577	Carrot	0.14	5.4	0.8	7.9	1.1	2.5	0.4	3.5	0.5	4.1	0.6	8.6	1.2	19.4	2.7
FS 0013	Cherries	1.3	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.3	0.4	2.5	3.3
FC 0001	Citrus fruit (excl lemon juice, excl mandarin juice, excl orange juice, excl grapefruit juice, excl NES juice)	2.8	15.1	42.2	153.9	430.9	3.4	9.6	41.7	116.8	218.9	613.0	23.1	64.7	18.0	50.4
-	Citrus juice NES	0.028	0.0	0.0	0.0	0.0	0.5	0.0	0.0	0.0	0.0	0.0	0.3	0.0	0.1	0.0
VP 0526	Common bean (green pods and/or immature seeds)	0.22	0.0	0.0	1.9	0.4	0.0	0.0	0.0	0.0	0.3	0.1	1.8	0.4	8.0	1.8
FB 0265	Cranberries	1.2	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	2.5	3.0
MO 0105	Edible offal (mammalian)	0.065	4.8	0.3	10.7	0.7	4.0	0.3	4.0	0.3	6.5	0.4	6.6	0.4	5.6	0.4
VD 0561	Field pea (dry)	0.09	1.6	0.1	1.4	0.1	0.7	0.1	0.8	0.1	1.3	0.1	0.6	0.1	1.7	0.2
FB 0269	Grape (excl dried, excl juice, excl wine)	0.71	1.2	0.9	2.6	1.8	0.0	0.0	0.2	0.1	0.0	0.0	3.7	2.6	0.0	0.0
JF 0269	Grape juice	0.5	0.0	0.0	0.1	0.1	1.0	0.5	0.0	0.0	0.6	0.3	0.4	0.2	3.6	1.8

Annex 3

PYRIMETHANIL (226) International Estimated Daily Intake (IEDI) ADI = 0 - 0.2000 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G		H		I		J		K		L		M	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
DF 0269	Grape, dried (= currants, raisins and sultanas)	1.1	0.0	0.0	0.2	0.2	0.2	0.2	0.0	0.0	0.3	0.3	0.4	0.4	2.6	2.9
JF 0203	Grapefruit juice	0.028	0.0	0.0	0.0	0.0	0.5	0.0	0.0	0.0	0.0	0.0	0.3	0.0	2.4	0.1
-d	Lemon juice	0.028	0.3	0.0	0.0	0.0	1.0	0.0	0.3	0.0	0.0	0.0	0.5	0.0	2.6	0.1
VL 0482	Lettuce, head	0.85	1.2	1.0	3.5	3.0	0.1	0.1	0.3	0.3	1.0	0.9	1.2	1.0	7.9	6.7
MF 0100	Mammalian fats (except milk fats)	0	2.2	0.0	18.6	0.0	0.5	0.0	0.8	0.0	5.7	0.0	4.5	0.0	18.2	0.0
MM 0095	Meat from mammals other than marine mammals	0	54.8	0.0	89.4	0.0	30.6	0.0	28.6	0.0	82.1	0.0	61.1	0.0	158.3	0.0
ML 0106	Milks (excl processed products)	0.01	66.0	0.7	121.1	1.2	81.6	0.8	102.4	1.0	207.7	2.1	57.0	0.6	287.9	2.9
FS 0245	Nectarine	1.3	1.7	2.2	1.7	2.2	0.0	0.0	0.0	0.0	1.0	1.3	1.7	2.2	1.4	1.8
-	Onion, dry	0.062	16.8	1.0	8.6	0.5	6.9	0.4	12.1	0.8	18.6	1.2	23.8	1.5	28.4	1.8
JF 0004	Orange juice	0.028	0.2	0.0	1.0	0.0	3.5	0.1	0.0	0.0	1.3	0.0	6.4	0.2	56.8	1.6
FS 0247	Peach	1.3	1.7	2.2	1.7	2.2	1.1	1.4	0.1	0.1	1.0	1.3	1.7	2.2	10.2	13.3
FS 0014	Plum (excl dried)	0.59	3.0	1.8	0.8	0.5	0.1	0.1	0.0	0.0	0.0	0.0	0.9	0.5	0.5	0.3
DF 0014	Plum, dried (prunes)	0.48	0.1	0.0	0.2	0.1	0.0	0.0	0.0	0.0	0.2	0.1	0.2	0.1	0.6	0.3
FP 0009	Pome fruit (excl apple juice)	1.6	20.8	33.2	11.6	18.5	3.3	5.2	0.1	0.2	10.7	17.0	23.6	37.7	36.9	59.0
VR 0589	Potato (incl flour, frozen, starch, tapioca)	0.05	52.7	2.6	57.1	2.9	50.1	2.5	4.3	0.2	54.7	2.7	41.0	2.1	168.0	8.4
VA 0389	Spring onion	0.38	0.1	0.0	4.8	1.8	0.1	0.0	1.0	0.4	1.0	0.4	2.7	1.0	0.6	0.2
FB 0275	Strawberry	1.2	0.0	0.0	1.8	2.2	0.1	0.1	0.0	0.0	0.3	0.4	6.2	7.4	5.9	7.1
VO 0448	Tomato (incl juice, excl paste, incl canned)	0.32	23.1	7.4	23.3	7.5	12.6	4.0	14.6	4.7	33.2	10.6	4.3	1.4	98.2	31.4
-d	Tomato paste	0.35	0.1	0.0	2.1	0.7	0.6	0.2	0.4	0.1	0.6	0.2	1.4	0.5	1.2	0.4
-	Wine	0.34	1.0	0.3	0.9	0.3	6.8	2.3	0.1	0.0	3.4	1.2	3.6	1.2	31.0	10.5
	Total intake (µg/person)=			98.2		481.2		29.2		126.0		658.0		132.7		218.3
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			11000		12000		12000		12000		12000		11000		12000
	%ADI=			0.9%		4.0%		0.2%		1.0%		5.5%		1.2%		1.8%
	Rounded %ADI=			1%		4%		0%		1%		5%		1%		2%

Annex 3

SPIROTETRAMAT (234) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0500 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A		B		C		D		E		F	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
FC 0001	Citrus fruit (incl lemon juice, incl mandarin juice, incl orange juice, incl grapefruit juice, incl NES juice)	0.33	15.7	5.2	100.5	33.2	63.2	20.9	27.8	9.2	52.6	17.4	56.9	18.8
TN 0085	Tree nuts	0.084	4.2	0.4	21.5	1.8	3.9	0.3	3.0	0.3	5.5	0.5	10.2	0.9
FP 0009	Pome fruit (excl apple juice)	0.17	0.5	0.1	79.9	13.6	21.8	3.7	43.6	7.4	51.5	8.8	35.1	6.0
JF 0226	Apple juice	0.082	0.0	0.0	2.8	0.2	0.1	0.0	1.1	0.1	6.8	0.6	7.4	0.6
FS 0012	Stone fruit (excl dried plums, incl dried apricots)	1.6	0.7	1.1	44.1	70.6	14.1	22.6	26.6	42.6	26.3	42.0	8.3	13.2
DF 0014	Plum, dried (prunes)	3.5	0.0	0.0	0.2	0.7	0.0	0.0	0.1	0.4	0.5	1.8	0.6	2.1
FB 0020	Blueberries	0.63	0.0	0.0	0.0	0.0	0.0	0.0	0.2	0.1	0.3	0.2	0.8	0.5
FB 0265	Cranberries	0.066	0.1	0.0	0.0	0.0	0.0	0.0	0.3	0.0	0.0	0.0	0.6	0.0
FB 0021	Currants, red, black, white	0.63	0.0	0.0	0.0	0.0	0.0	0.0	2.2	1.4	3.1	2.0	2.0	1.3
FB 0278	Currants, black	0.63	0.0	0.0	0.0	0.0	0.0	0.0	1.1	0.7	1.6	1.0	1.0	0.6
FB 0279	Currants, red, white	0.63	0.0	0.0	0.0	0.0	0.0	0.0	1.1	0.7	1.6	1.0	1.0	0.6
FB 0268	Gooseberries	0.63	0.0	0.0	12.0	7.6	0.0	0.0	0.6	0.4	1.1	0.7	0.2	0.1
FB 0269	Grape (excl dried, excl juice, excl wine)	0.41	1.9	0.8	9.2	3.8	23.8	9.8	9.8	4.0	0.0	0.0	0.0	0.0
DF 0269	Grape, dried (= currants, raisins and sultanas)	1.1	0.0	0.0	2.9	3.2	0.4	0.4	0.4	0.4	2.3	2.5	1.7	1.9
JF 0269	Grape juice	0.27	0.0	0.0	0.1	0.0	0.1	0.0	0.1	0.0	1.4	0.4	1.0	0.3
-	Wine	0.23	1.3	0.3	76.8	17.7	1.1	0.3	15.4	3.5	68.8	15.8	25.6	5.9
FI 0341	Kiwi fruit	0.055	0.0	0.0	2.9	0.2	0.1	0.0	0.2	0.0	2.7	0.1	1.8	0.1
FI 0345	Mango (incl juice, incl pulp)	0.16	6.3	1.0	1.0	0.2	4.6	0.7	0.2	0.0	0.7	0.1	0.3	0.0
FI 0350	Papaya	0.17	5.1	0.9	0.1	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0
VR 0589	Potato (incl flour, frozen, starch, tapioca)	0.12	19.1	2.3	160.8	19.3	61.2	7.3	243.6	29.2	230.1	27.6	204.7	24.6
VA 0385	Onion, bulb (= dry + green onion)	0.11	5.5	0.6	49.5	5.4	33.0	3.6	31.3	3.4	23.2	2.6	14.6	1.6
VC 0045	Fruiting vegetables, cucurbits	0.057	26.6	1.5	107.5	6.1	95.9	5.5	82.2	4.7	25.4	1.4	23.2	1.3
VO 0050	Fruiting vegetables other than cucurbits	0.43	33.5	14.4	236.9	101.9	148.9	64.0	70.2	30.2	50.4	21.7	53.9	23.2
VO 0444	Peppers, chili	0.95	0.7	0.7	14.9	14.2	4.1	3.9	3.2	3.0	3.1	2.9	2.0	1.9
VB 0041	Cabbage, head	0.23	1.2	0.3	14.4	3.3	2.7	0.6	16.4	3.8	15.4	3.5	18.5	4.3
VB 0042	Flowerhead brassicas	0.5	0.2	0.1	11.1	5.6	3.6	1.8	0.4	0.2	7.7	3.9	4.1	2.1
VL 0053	Leafy vegetables	3.7	5.8	21.5	45.4	168.0	10.9	40.3	26.7	98.8	17.1	63.3	38.9	143.9
VP 0060	Legume vegetables	0.505	6.1	3.1	23.0	11.6	18.0	9.1	12.8	6.5	26.9	13.6	5.3	2.7
VS 0620	Artichoke globe	0.41	0.0	0.0	10.0	4.1	2.1	0.9	0.1	0.0	0.8	0.3	0.1	0.0
VS 0624	Celery	0.58	0.0	0.0	0.9	0.5	0.0	0.0	2.0	1.2	1.5	0.9	0.0	0.0
VD 0070	Pulses (excl soya beans)	0.21	44.6	9.4	26.5	5.6	17.1	3.6	14.4	3.0	14.1	3.0	8.7	1.8

Annex 3

SPIROTETRAMAT (234) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0500 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A		B		C		D		E		F	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
VD 0541	Soya bean (dry, excl oil)	0.45	0.9	0.4	0.0	0.0	0.7	0.3	0.0	0.0	0.0	0.0	0.0	0.0
OR 0541	Soya bean oil, refined	0	1.6	0.0	6.5	0.0	6.0	0.0	4.0	0.0	6.3	0.0	7.0	0.0
OR 0691	Cotton seed oil, edible	0	0.9	0.0	4.9	0.0	1.7	0.0	6.6	0.0	0.0	0.0	0.3	0.0
DH 1100	Hops, dry	5.2	0.1	0.5	0.1	0.5	0.1	0.5	0.1	0.5	0.3	1.6	0.1	0.5
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.012	5.5	0.1	23.3	0.3	7.7	0.1	11.0	0.1	18.0	0.2	26.3	0.3
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0.006	22.2	0.1	93.2	0.6	30.8	0.2	44.1	0.3	72.2	0.4	105.0	0.6
MO 0105	Edible offal (mammalian)	0.16	3.9	0.6	14.4	2.3	5.2	0.8	11.8	1.9	11.7	1.9	7.6	1.2
PM 0110	Poultry meat: 10% as fat	0	0.7	0.0	5.9	0.0	3.2	0.0	2.4	0.0	6.1	0.0	2.7	0.0
PM 0110	Poultry meat: 90% as muscle	0	6.4	0.0	52.7	0.0	28.7	0.0	21.6	0.0	54.9	0.0	24.6	0.0
PO 0111	Poultry, edible offal of	0.0016	0.4	0.0	0.4	0.0	1.7	0.0	0.1	0.0	0.6	0.0	0.2	0.0
ML 0106	Milks (excl processed products)	0	68.8	0.0	190.6	0.0	79.4	0.0	302.6	0.0	179.6	0.0	237.9	0.0
PE 0112	Eggs	0.0023	2.5	0.0	29.7	0.1	25.1	0.1	24.5	0.1	37.8	0.1	27.4	0.1
	Total intake (µg/person)=			65.2		501.9		201.3		258.1		243.6		263.0
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			3000		3000		3000		3000		3000		3000
	%ADI=			2.2%		16.7%		6.7%		8.6%		8.1%		8.8%
	Rounded %ADI=			2%		20%		7%		9%		8%		9%

SPIROTETRAMAT (234) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0500 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G		H		I		J		K		L		M	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
FC 0001	Citrus fruit (incl lemon juice, incl mandarin juice, incl orange juice, incl grapefruit juice, incl NES juice)	0.33	17.3	5.7	156.8	51.7	14.9	4.9	42.5	14.0	222.8	73.5	40.4	13.3	132.3	43.7
TN 0085	Tree nuts	0.084	16.3	1.4	15.7	1.3	9.7	0.8	1.9	0.2	19.1	1.6	29.0	2.4	5.6	0.5
FP 0009	Pome fruit (excl apple juice)	0.17	20.8	3.5	11.6	2.0	3.3	0.6	0.1	0.0	10.7	1.8	23.6	4.0	36.9	6.3
JF 0226	Apple juice	0.082	0.1	0.0	0.5	0.0	0.1	0.0	0.0	0.0	0.7	0.1	0.9	0.1	5.7	0.5

Annex 3

SPIROTETRAMAT (234) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0500 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G		H		I		J		K		L		M	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
FS 0012	Stone fruit (excl dried plums, incl dried apricots)	1.6	6.7	10.7	4.3	6.9	1.4	2.2	0.1	0.2	4.9	7.9	4.9	7.9	17.7	28.3
DF 0014	Plum, dried (prunes)	3.5	0.1	0.4	0.2	0.7	0.0	0.0	0.0	0.0	0.2	0.7	0.2	0.7	0.6	2.1
FB 0020	Blueberries	0.63	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.3	0.8
FB 0265	Cranberries	0.066	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	2.5	0.2
FB 0021	Currants, red, black, white	0.63	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
FB 0278	Currants, black	0.63	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
FB 0279	Currants, red, white	0.63	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
FB 0268	Gooseberries	0.63	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.6	0.0	0.0	0.0	0.0
FB 0269	Grape (excl dried, excl juice, excl wine)	0.41	1.2	0.5	2.6	1.1	0.0	0.0	0.2	0.1	0.0	0.0	3.7	1.5	0.0	0.0
DF 0269	Grape, dried (= currants, raisins and sultanas)	1.1	0.0	0.0	0.2	0.2	0.2	0.2	0.0	0.0	0.3	0.3	0.4	0.4	2.6	2.9
JF 0269	Grape juice	0.27	0.0	0.0	0.1	0.0	1.0	0.3	0.0	0.0	0.6	0.2	0.4	0.1	3.6	1.0
-	Wine	0.23	1.0	0.2	0.9	0.2	6.8	1.6	0.1	0.0	3.4	0.8	3.6	0.8	31.0	7.1
FI 0341	Kiwi fruit	0.055	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.2	0.0	1.6	0.1	1.0	0.1
FI 0345	Mango (incl juice, incl pulp)	0.16	12.7	2.0	26.2	4.2	6.1	1.0	12.7	2.0	9.2	1.5	8.0	1.3	1.9	0.3
FI 0350	Papaya	0.17	1.3	0.2	11.5	2.0	1.6	0.3	13.7	2.3	14.5	2.5	1.0	0.2	0.6	0.1
VR 0589	Potato (incl flour, frozen, starch, tapioca)	0.12	52.7	6.3	57.1	6.9	50.1	6.0	4.3	0.5	54.7	6.6	41.0	4.9	168.0	20.2
VA 0385	Onion, bulb (= dry + green onion)	0.11	17.4	1.9	27.9	3.1	7.3	0.8	16.0	1.8	22.8	2.5	34.5	3.8	30.1	3.3
VC 0045	Fruiting vegetables, cucurbits	0.057	69.7	4.0	25.9	1.5	14.9	0.8	18.0	1.0	18.7	1.1	39.1	2.2	44.2	2.5
VO 0050	Fruiting vegetables other than cucurbits	0.43	57.2	24.6	60.1	25.8	35.5	15.3	51.1	22.0	42.2	18.1	31.5	13.5	134.8	58.0
VO 0444	Peppers, chili	0.95	8.7	8.3	13.0	12.4	4.2	4.0	4.7	4.5	1.7	1.6	2.6	2.5	4.4	4.2
VB 0041	Cabbage, head	0.23	10.0	2.3	1.0	0.2	7.2	1.7	1.0	0.2	1.4	0.3	23.9	5.5	17.0	3.9
VB 0042	Flowerhead brassicas	0.5	9.6	4.8	7.9	4.0	0.6	0.3	0.2	0.1	0.9	0.5	1.1	0.6	8.0	4.0
VL 0053	Leafy vegetables	3.7	40.8	151.0	12.0	44.4	12.5	46.3	9.5	35.2	5.4	20.0	50.0	185.0	39.1	144.7
VP 0060	Legume vegetables	0.505	19.6	9.9	6.2	3.1	6.9	3.5	6.0	3.0	1.7	0.9	29.5	14.9	26.3	13.3
VS 0620	Artichoke globe	0.41	0.1	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.4
VS 0624	Celery	0.58	0.0	0.0	0.3	0.2	0.0	0.0	0.0	0.0	1.0	0.6	0.0	0.0	4.2	2.4
VD 0070	Pulses (excl soya beans)	0.21	16.0	3.4	32.4	6.8	24.7	5.2	34.2	7.2	50.7	10.6	8.0	1.7	16.9	3.5
VD 0541	Soya bean (dry, excl oil)	0.45	1.8	0.8	0.0	0.0	0.0	0.0	3.2	1.4	0.1	0.0	0.0	0.0	0.0	0.0
OR 0541	Soya bean oil, refined	0	4.3	0.0	10.6	0.0	2.0	0.0	1.4	0.0	19.5	0.0	9.2	0.0	22.0	0.0
OR 0691	Cotton seed oil, edible	0	1.0	0.0	0.7	0.0	1.0	0.0	1.4	0.0	1.5	0.0	5.5	0.0	1.2	0.0
DH 1100	Hops, dry	5.2	0.0	0.0	0.1	0.5	0.1	0.5	0.1	0.5	0.1	0.5	0.1	0.5	0.6	3.1
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.012	11.0	0.1	17.9	0.2	6.1	0.1	5.7	0.1	16.4	0.2	12.2	0.1	31.7	0.4
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0.006	43.8	0.3	71.5	0.4	24.5	0.1	22.9	0.1	65.7	0.4	48.9	0.3	126.6	0.8

Annex 3

SPIROTETRAMAT (234) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0500 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G		H		I		J		K		L		M	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
MO 0105	Edible offal (mammalian)	0.16	4.8	0.8	10.7	1.7	4.0	0.6	4.0	0.6	6.5	1.0	6.6	1.1	5.6	0.9
PM 0110	Poultry meat: 10% as fat	0	1.8	0.0	13.1	0.0	2.5	0.0	0.5	0.0	14.6	0.0	2.8	0.0	11.5	0.0
PM 0110	Poultry meat: 90% as muscle	0	15.8	0.0	118.2	0.0	22.6	0.0	4.2	0.0	131.3	0.0	24.9	0.0	103.6	0.0
PO 0111	Poultry, edible offal of	0.0016	0.4	0.0	1.0	0.0	1.9	0.0	0.0	0.0	0.7	0.0	1.0	0.0	0.3	0.0
ML 0106	Milks (excl processed products)	0	66.0	0.0	121.1	0.0	81.6	0.0	102.4	0.0	207.7	0.0	57.0	0.0	287.9	0.0
PE 0112	Eggs	0.0023	22.1	0.1	71.5	0.2	16.6	0.0	5.1	0.0	17.6	0.0	35.2	0.1	57.4	0.1
	Total intake (µg/person)=			243.1		181.7		97.0		97.0		156.4		269.5		359.3
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			2750		3000		3000		3000		3000		2750		3000
	%ADI=			8.8%		6.1%		3.2%		3.2%		5.2%		9.8%		12.0%
	Rounded %ADI=			9%		6%		3%		3%		5%		10%		10%

Annex 3

SULFOXAFLOR (252) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0500 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A		B		C		D		E		F	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
JF 0226	Apple juice	0.028	0.0	0.0	2.8	0.1	0.1	0.0	1.1	0.0	6.8	0.2	7.4	0.2
GC 0640	Barley (incl pot, excl pearled, excl flour & grits, excl beer)	0.063	40.6	2.6	0.0	0.0	0.2	0.0	0.0	0.0	0.0	0.0	3.8	0.2
-	Barley beer	0.013	18.3	0.2	84.1	1.1	4.1	0.1	66.0	0.9	243.1	3.2	161.3	2.1
-	Barley flour and grits	0.05	0.0	0.0	0.3	0.0	10.8	0.5	0.3	0.0	0.5	0.0	0.9	0.0
-	Barley, pearled	0.044	0.0	0.0	0.4	0.0	27.9	1.2	0.4	0.0	0.4	0.0	0.9	0.0
VD 0071	Beans (dry)	0.075	15.8	1.2	6.1	0.5	1.7	0.1	6.3	0.5	1.8	0.1	5.0	0.4
VB 0400	Broccoli	0.074	0.0	0.0	0.7	0.1	1.2	0.1	0.1	0.0	4.2	0.3	4.0	0.3
VB 0041	Cabbage, head	0.099	1.2	0.1	14.4	1.4	2.7	0.3	16.4	1.6	15.4	1.5	18.5	1.8
VB 0404	Cauliflower	0.013	0.1	0.0	5.2	0.1	1.2	0.0	0.1	0.0	1.7	0.0	0.1	0.0
VS 0624	Celery	0.19	0.0	0.0	0.9	0.2	0.0	0.0	2.0	0.4	1.5	0.3	0.0	0.0
FC 0001	Citrus fruit (incl lemon juice, incl mandarin juice, excl orange juice, incl grapefruit juice, incl NES juice)	0.31	15.7	4.9	96.7	30.0	55.3	17.1	25.3	7.8	23.4	7.3	16.2	5.0
OR 0691	Cotton seed oil, edible	0.002	0.9	0.0	4.9	0.0	1.7	0.0	6.6	0.0	0.0	0.0	0.3	0.0
MO 0105	Edible offal (mammalian)	0.12	3.9	0.5	14.4	1.7	5.2	0.6	11.8	1.4	11.7	1.4	7.6	0.9
PE 0112	Eggs	0.012	2.5	0.0	29.7	0.4	25.1	0.3	24.5	0.3	37.8	0.5	27.4	0.3
VO 0050	Fruiting vegetables other than cucurbits (excl sweet corn, excl mushrooms)	0.11	18.8	2.1	233.4	25.7	148.6	16.3	68.8	7.6	38.6	4.2	45.3	5.0
VC 0045	Fruiting vegetables, cucurbits	0.029	26.6	0.8	107.5	3.1	95.9	2.8	82.2	2.4	25.4	0.7	23.2	0.7
VA 0381	Garlic	0.01	0.4	0.0	3.9	0.0	3.8	0.0	3.7	0.0	1.0	0.0	0.6	0.0
FB 0269	Grape (incl dried, incl juice, incl wine)	0.14	3.7	0.5	128.5	18.0	27.1	3.8	33.1	4.6	107.5	15.1	44.0	6.2
VL 0053	Leafy vegetables	1.2	5.8	7.0	45.4	54.5	10.9	13.1	26.7	32.0	17.1	20.5	38.9	46.7
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.026	5.5	0.1	23.3	0.6	7.7	0.2	11.0	0.3	18.0	0.5	26.3	0.7
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0.04	22.2	0.9	93.2	3.7	30.8	1.2	44.1	1.8	72.2	2.9	105.0	4.2
ML 0106	Milks (excl processed products)	0.048	68.8	3.3	190.6	9.1	79.4	3.8	302.6	14.5	179.6	8.6	237.9	11.4
-	Onion, dry	0.01	4.3	0.0	45.6	0.5	27.4	0.3	30.2	0.3	22.1	0.2	12.2	0.1
JF 0004	Orange juice	0.043	0.0	0.0	2.1	0.1	4.4	0.2	1.4	0.1	16.2	0.7	22.6	1.0
FP 0009	Pome fruit (excl apple juice)	0.07	0.5	0.0	79.9	5.6	21.8	1.5	43.6	3.0	51.5	3.6	35.1	2.5
PM 0110	Poultry meat: 10% as fat	0.014	0.7	0.0	5.9	0.1	3.2	0.0	2.4	0.0	6.1	0.1	2.7	0.0
PM 0110	Poultry meat: 90% as muscle	0.005	6.4	0.0	52.7	0.3	28.7	0.1	21.6	0.1	54.9	0.3	24.6	0.1
PO 0111	Poultry, edible offal of	0.044	0.4	0.0	0.4	0.0	1.7	0.1	0.1	0.0	0.6	0.0	0.2	0.0

Annex 3

SULFOXAFLOR (252) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0500 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A		B		C		D		E		F	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
SO 0495	Rape seed (excl oil)	0.045	0.1	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.1	0.0	0.1	0.0
OR 0495	Rape seed oil, edible	0.014	0.3	0.0	0.7	0.0	1.0	0.0	0.7	0.0	13.7	0.2	10.0	0.1
VR 0075	Root and tuber vegetables	0.01	528.2	5.3	352.8	3.5	78.5	0.8	270.3	2.7	324.1	3.2	261.3	2.6
VP 0541	Soya bean (immature seeds only)	0.011	5.0	0.1	0.0	0.0	0.0	0.0	11.1	0.1	0.4	0.0	0.0	0.0
FS 0012	Stone fruit (incl dried plums, incl dried apricots)	0.91	0.7	0.6	44.7	40.7	14.1	12.8	26.9	24.5	27.7	25.2	10.0	9.1
FB 0275	Strawberry	0.19	0.0	0.0	5.0	1.0	2.0	0.4	1.7	0.3	5.2	1.0	4.1	0.8
TN 0085	Tree nuts	0.01	4.2	0.0	21.5	0.2	3.9	0.0	3.0	0.0	5.5	0.1	10.2	0.1
GC 0653	Triticale (incl flour)	0.025	0.0	0.0	115.8	2.9	0.0	0.0	0.0	0.0	0.3	0.0	0.0	0.0
GC 0654	Wheat (incl bulgur wholemeal, excl flour)	0.025	6.0	0.1	11.1	0.3	0.8	0.0	0.2	0.0	0.2	0.0	0.0	0.0
CM 0654	Wheat bran, unprocessed	0.01	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CF 1211	Wheat flour (incl macaroni, bread, pastry, starch, gluten)	0.005	63.4	0.3	296.3	1.5	327.5	1.6	300.0	1.5	181.6	0.9	166.2	0.8
	Total intake (µg/person)=			30.8		206.8		79.6		108.9		102.9		103.5
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			3000		3000		3000		3000		3000		3000
	%ADI=			1.0%		6.9%		2.7%		3.6%		3.4%		3.4%
	Rounded %ADI=			1%		7%		3%		4%		3%		3%

SULFOXAFLOR (252) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0500 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G		H		I		J		K		L		M	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
JF 0226	Apple juice	0.028	0.1	0.0	0.5	0.0	0.1	0.0	0.0	0.0	0.7	0.0	0.9	0.0	5.7	0.2
GC 0640	Barley (incl pot, excl pearled, excl flour & grits, excl beer)	0.063	1.5	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.4	0.0	0.0	0.0
-	Barley beer	0.013	21.9	0.3	102.7	1.3	29.5	0.4	12.6	0.2	100.9	1.3	82.2	1.1	218.8	2.8
-	Barley flour and grits	0.05	0.4	0.0	0.0	0.0	0.1	0.0	0.0	0.0	1.0	0.1	0.8	0.0	0.0	0.0
-	Barley, pearled	0.044	0.5	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.7	0.0	0.0	0.0	0.1	0.0
VD 0071	Beans (dry)	0.075	3.4	0.3	25.5	1.9	7.8	0.6	2.1	0.2	44.7	3.4	5.5	0.4	7.3	0.5
VB 0400	Broccoli	0.074	3.2	0.2	7.8	0.6	0.0	0.0	0.0	0.0	0.3	0.0	0.4	0.0	6.6	0.5

Annex 3

SULFOXAFLOR (252) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0500 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day; Intake = daily intake: µg/person													
			G		H		I		J		K		L		M	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
VB 0041	Cabbage, head	0.099	10.0	1.0	1.0	0.1	7.2	0.7	1.0	0.1	1.4	0.1	23.9	2.4	17.0	1.7
VB 0404	Cauliflower	0.013	3.2	0.0	0.1	0.0	0.3	0.0	0.1	0.0	0.6	0.0	0.4	0.0	1.4	0.0
VS 0624	Celery	0.19	0.0	0.0	0.3	0.1	0.0	0.0	0.0	0.0	1.0	0.2	0.0	0.0	4.2	0.8
FC 0001	Citrus fruit (incl lemon juice, incl mandarin juice, excl orange juice, incl grapefruit juice, incl NES juice)	0.31	16.9	5.3	155.0	48.1	8.6	2.7	42.5	13.2	220.5	68.3	28.9	9.0	30.1	9.3
OR 0691	Cotton seed oil, edible	0.002	1.0	0.0	0.7	0.0	1.0	0.0	1.4	0.0	1.5	0.0	5.5	0.0	1.2	0.0
MO 0105	Edible offal (mammalian)	0.12	4.8	0.6	10.7	1.3	4.0	0.5	4.0	0.5	6.5	0.8	6.6	0.8	5.6	0.7
PE 0112	Eggs	0.012	22.1	0.3	71.5	0.9	16.6	0.2	5.1	0.1	17.6	0.2	35.2	0.4	57.4	0.7
VO 0050	Fruiting vegetables other than cucurbits (excl sweet corn, excl mushrooms)	0.11	56.4	6.2	55.2	6.1	31.0	3.4	47.8	5.3	40.5	4.5	25.4	2.8	112.8	12.4
VC 0045	Fruiting vegetables, cucurbits	0.029	69.7	2.0	25.9	0.8	14.9	0.4	18.0	0.5	18.7	0.5	39.1	1.1	44.2	1.3
VA 0381	Garlic	0.01	6.4	0.1	1.2	0.0	0.1	0.0	0.3	0.0	1.9	0.0	5.0	0.1	2.5	0.0
FB 0269	Grape (incl dried, incl juice, incl wine)	0.14	2.6	0.4	4.8	0.7	11.7	1.6	0.3	0.0	6.8	1.0	10.9	1.5	58.8	8.2
VL 0053	Leafy vegetables	1.2	40.8	49.0	12.0	14.4	12.5	15.0	9.5	11.4	5.4	6.5	50.0	60.0	39.1	46.9
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.026	11.0	0.3	17.9	0.5	6.1	0.2	5.7	0.1	16.4	0.4	12.2	0.3	31.7	0.8
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0.04	43.8	1.8	71.5	2.9	24.5	1.0	22.9	0.9	65.7	2.6	48.9	2.0	126.6	5.1
ML 0106	Milks (excl processed products)	0.048	66.0	3.2	121.1	5.8	81.6	3.9	102.4	4.9	207.7	10.0	57.0	2.7	287.9	13.8
-	Onion, dry	0.01	16.8	0.2	8.6	0.1	6.9	0.1	12.1	0.1	18.6	0.2	23.8	0.2	28.4	0.3
JF 0004	Orange juice	0.043	0.2	0.0	1.0	0.0	3.5	0.2	0.0	0.0	1.3	0.1	6.4	0.3	56.8	2.4
FP 0009	Pome fruit (excl apple juice)	0.07	20.8	1.5	11.6	0.8	3.3	0.2	0.1	0.0	10.7	0.7	23.6	1.6	36.9	2.6
PM 0110	Poultry meat: 10% as fat	0.014	1.8	0.0	13.1	0.2	2.5	0.0	0.5	0.0	14.6	0.2	2.8	0.0	11.5	0.2
PM 0110	Poultry meat: 90% as muscle	0.005	15.8	0.1	118.2	0.6	22.6	0.1	4.2	0.0	131.3	0.7	24.9	0.1	103.6	0.5
PO 0111	Poultry, edible offal of	0.044	0.4	0.0	1.0	0.0	1.9	0.1	0.0	0.0	0.7	0.0	1.0	0.0	0.3	0.0
SO 0495	Rape seed (excl oil)	0.045	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
OR 0495	Rape seed oil, edible	0.014	3.8	0.1	2.3	0.0	0.1	0.0	0.4	0.0	0.0	0.0	6.0	0.1	3.8	0.1
VR 0075	Root and tuber vegetables	0.01	139.1	1.4	109.8	1.1	409.6	4.1	444.6	4.4	145.3	1.5	127.0	1.3	225.6	2.3
VP 0541	Soya bean (immature seeds only)	0.011	12.9	0.1	0.0	0.0	5.5	0.1	5.5	0.1	0.0	0.0	25.7	0.3	0.0	0.0
FS 0012	Stone fruit (incl dried plums, incl dried apricots)	0.91	7.0	6.4	4.9	4.5	1.4	1.3	0.1	0.1	5.5	5.0	5.5	5.0	19.4	17.7
FB 0275	Strawberry	0.19	0.0	0.0	1.8	0.3	0.1	0.0	0.0	0.0	0.3	0.1	6.2	1.2	5.9	1.1
TN 0085	Tree nuts	0.01	16.3	0.2	15.7	0.2	9.7	0.1	1.9	0.0	19.1	0.2	29.0	0.3	5.6	0.1
GC 0653	Triticale (incl flour)	0.025	1.3	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
GC 0654	Wheat (incl bulgur wholemeal, excl flour)	0.025	0.0	0.0	0.9	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.1	0.0

Annex 3

SULFOXAFLOR (252) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0500 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day G	Intake = daily intake: µg/person G	H	H	I	I	J	J	K	K	L	L	M	M
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
CM 0654	Wheat bran, unprocessed	0.01	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CF 1211	Wheat flour (incl macaroni, bread, pastry, starch, gluten)	0.005	133.0	0.7	60.1	0.3	52.4	0.3	32.2	0.2	87.7	0.4	79.6	0.4	180.1	0.9
	Total intake (µg/person)=			81.4		93.4		37.1		42.3		109.0		95.5		133.8
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			2750		3000		3000		3000		3000		2750		3000
	%ADI=			3.0%		3.1%		1.2%		1.4%		3.6%		3.5%		4.5%
	Rounded %ADI=			3%		3%		1%		1%		4%		3%		4%

Annex 3

TOLFENPYRAD (269) International Estimated Daily Intake (IEDI) ADI = 0–0.0060 mg/kg bw

		STMR or	Diets: g/person/day											
		STMR-P	A		B		C		D		E		F	
Codex Code	Commodity	mg/kg	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
DT 1114	Tea, green, black (black, fermented and dried)	0.24	0.3	4.3	2.4	34.6	2.8	40.3	2.1	30.2	2.0	28.8	0.8	11.5
	Total intake (µg/person)=			4.3		34.6		40.3		30.2		28.8		11.5
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			360		360		360		360		360		360
	%ADI=			1.2%		9.6%		11.2%		8.4%		8.0%		3.2%
	Rounded %ADI=			1%		10%		10%		8%		8%		3%

TOLFENPYRAD (269) International Estimated Daily Intake (IEDI) ADI = 0–0.0060 mg/kg bw

		STMR or	Diets: g/person/day											
		STMR-P	G		H		I		J		K		L		M	
Codex Code	Commodity	mg/kg	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
DT 1114	Tea, green, black (black, fermented and dried)	0.24	1.3	18.7	0.2	2.9	0.9	13.0	0.6	8.6	0.1	1.4	1.5	21.6	1.0	14.4
	Total intake (µg/person)=			18.7		2.9		13.0		8.6		1.4		21.6		14.4
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			330		360		360		360		360		330		360
	%ADI=			5.7%		0.8%		3.6%		2.4%		0.4%		6.5%		4.0%
	Rounded %ADI=			6%		1%		4%		2%		0%		7%		4%

Annex 3

TRIAZOPHOS (143) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0010 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A		B		C		D		E		F	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
OR 0691	Cotton seed oil, edible	0.13	0.9	0.1	4.9	0.6	1.7	0.2	6.6	0.9	0.0	0.0	0.3	0.0
GC 0649	Rice (excl husked, excl polished)	0.51	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.0
CM 0649	Rice, husked (incl milled)	0.12	35.6	4.3	0.2	0.0	2.6	0.3	6.9	0.8	3.3	0.4	0.4	0.0
CM 1205	Rice, polished (incl flour)	0.041	29.8	1.2	20.9	0.9	60.8	2.5	16.1	0.7	5.6	0.2	8.1	0.3
VP 0541	Soya bean (immature seeds only)	0.37	5.0	1.9	0.0	0.0	0.0	0.0	11.1	4.1	0.4	0.1	0.0	0.0
	Total intake (µg/person)=			7.5		1.5		3.0		6.5		0.8		0.4
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			60		60		60		60		60		60
	%ADI=			12.5%		2.5%		5.1%		10.8%		1.3%		0.7%
	Rounded %ADI=			10%		3%		5%		10%		1%		1%

TRIAZOPHOS (143) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0010 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G		H		I		J		K		L		M	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
OR 0691	Cotton seed oil, edible	0.13	1.0	0.1	0.7	0.1	1.0	0.1	1.4	0.2	1.5	0.2	5.5	0.7	1.2	0.2
GC 0649	Rice (excl husked, excl polished)	0.51	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.1	0.0	0.0	0.0
CM 0649	Rice, husked (incl milled)	0.12	1.1	0.1	0.8	0.1	1.8	0.2	22.7	2.7	70.8	8.5	7.0	0.8	0.3	0.0
CM 1205	Rice, polished (incl flour)	0.041	250.3	10.3	42.2	1.7	23.8	1.0	29.8	1.2	97.6	4.0	248.1	10.2	22.8	0.9
VP 0541	Soya bean (immature seeds only)	0.37	12.9	4.8	0.0	0.0	5.5	2.0	5.5	2.0	0.0	0.0	25.7	9.5	0.0	0.0
	Total intake (µg/person)=			15.3		1.9		3.3		6.2		12.7		21.3		1.1
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			55		60		60		60		60		55		60
	%ADI=			27.8%		3.2%		5.6%		10.3%		21.1%		38.7%		1.9%
	Rounded %ADI=			30%		3%		6%		10%		20%		40%		2%

Annex 3

TRIFLUMIZOLE (270) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0400 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day A diet	Intake = daily intake: µg/person A intake	B diet	B intake	C diet	C intake	D diet	D intake	E diet	E intake	F diet	F intake
FS 0013	Cherries	1.17	0.0	0.0	6.8	8.0	0.9	1.1	6.2	7.3	3.6	4.2	0.4	0.5
VC 0424	Cucumber	0.13	0.3	0.0	12.7	1.7	5.9	0.8	11.5	1.5	6.1	0.8	7.1	0.9
MO 0105	Edible offal (mammalian)	0.072	3.9	0.3	14.4	1.0	5.2	0.4	11.8	0.8	11.7	0.8	7.6	0.5
FB 0269	Grape (excl dried, excl juice, incl wine)	0.26	3.7	1.0	116.8	30.4	25.4	6.6	31.4	8.2	96.3	25.0	35.8	9.3
JF 0269	Grape juice	0.11	0.0	0.0	0.1	0.0	0.1	0.0	0.1	0.0	1.4	0.2	1.0	0.1
DF 0269	Grape, dried (= currants, raisins and sultanas)	0.06	0.0	0.0	2.9	0.2	0.4	0.0	0.4	0.0	2.3	0.1	1.7	0.1
DH 1100	Hops, dry	8.9	0.1	0.9	0.1	0.9	0.1	0.9	0.1	0.9	0.3	2.7	0.1	0.9
MF 0100	Mammalian fats (except milk fats)	0.008	0.8	0.0	10.0	0.1	0.9	0.0	6.6	0.1	11.8	0.1	3.7	0.0
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.008	5.5	0.0	23.3	0.2	7.7	0.1	11.0	0.1	18.0	0.1	26.3	0.2
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0	22.2	0.0	93.2	0.0	30.8	0.0	44.1	0.0	72.2	0.0	105.0	0.0
ML 0106	Milks (excl processed products)	0	68.8	0.0	190.6	0.0	79.4	0.0	302.6	0.0	179.6	0.0	237.9	0.0
FI 0350	Papaya	0.71	5.1	3.6	0.1	0.1	0.0	0.0	0.0	0.0	0.1	0.1	0.0	0.0
	Total intake (µg/person)=			5.8		42.4		9.8		18.8		34.2		12.6
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			2400		2400		2400		2400		2400		2400
	%ADI=			0.2%		1.8%		0.4%		0.8%		1.4%		0.5%
	Rounded %ADI=			0%		2%		0%		1%		1%		1%

TRIFLUMIZOLE (270) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0400 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day G diet	Intake = daily intake: µg/person G intake	H diet	H intake	I diet	I intake	J diet	J intake	K diet	K intake	L diet	L intake	M diet	M intake
FS 0013	Cherries	1.17	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.3	0.4	2.5	2.9
VC 0424	Cucumber	0.13	7.9	1.0	0.6	0.1	0.2	0.0	0.0	0.0	0.4	0.1	5.5	0.7	5.3	0.7
MO 0105	Edible offal (mammalian)	0.072	4.8	0.3	10.7	0.8	4.0	0.3	4.0	0.3	6.5	0.5	6.6	0.5	5.6	0.4
FB 0269	Grape (excl dried, excl juice, incl wine)	0.26	2.6	0.7	3.9	1.0	9.5	2.5	0.3	0.1	4.8	1.2	8.7	2.3	43.4	11.3
JF 0269	Grape juice	0.11	0.0	0.0	0.1	0.0	1.0	0.1	0.0	0.0	0.6	0.1	0.4	0.0	3.6	0.4
DF 0269	Grape, dried (= currants, raisins and sultanas)	0.06	0.0	0.0	0.2	0.0	0.2	0.0	0.0	0.0	0.3	0.0	0.4	0.0	2.6	0.2

Annex 3

TRIFLUMIZOLE (270) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0400 mg/kg bw

		STMR or	Diets: g/person/day								Intake = daily intake: µg/person					
		STMR-P	G		H		I		J		K		L		M	
Codex Code	Commodity	mg/kg	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
DH 1100	Hops, dry	8.9	0.0	0.0	0.1	0.9	0.1	0.9	0.1	0.9	0.1	0.9	0.1	0.9	0.6	5.3
MF 0100	Mammalian fats (except milk fats)	0.008	2.2	0.0	18.6	0.1	0.5	0.0	0.8	0.0	5.7	0.0	4.5	0.0	18.2	0.1
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.008	11.0	0.1	17.9	0.1	6.1	0.0	5.7	0.0	16.4	0.1	12.2	0.1	31.7	0.3
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0	43.8	0.0	71.5	0.0	24.5	0.0	22.9	0.0	65.7	0.0	48.9	0.0	126.6	0.0
ML 0106	Milks (excl processed products)	0	66.0	0.0	121.1	0.0	81.6	0.0	102.4	0.0	207.7	0.0	57.0	0.0	287.9	0.0
FI 0350	Papaya	0.71	1.3	0.9	11.5	8.2	1.6	1.1	13.7	9.7	14.5	10.3	1.0	0.7	0.6	0.4
	Total intake (µg/person)=			3.1		11.2		5.0		11.0		13.2		5.6		22.0
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			2200		2400		2400		2400		2400		2200		2400
	%ADI=			0.1%		0.5%		0.2%		0.5%		0.6%		0.3%		0.9%
	Rounded %ADI=			0%		0%		0%		0%		1%		0%		1%

Annex 3

TRINEXAPAC-ETHYL International Estimated Daily Intake (IEDI) ADI = 0 - 0.3000 mg/kg bw

Codex Code	Commodity	STMR or STMR-P	Diets: g/person/day			Intake = daily intake: µg/person								
			A		B		C		D		E		F	
		mg/kg	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
GC 0640	Barley (incl pot, excl pearled, excl flour & grits, incl beer)	0.57	40.6	23.1	16.8	9.6	0.2	0.1	13.2	7.5	48.6	27.7	36.1	20.6
-	Barley flour and grits	0.25	0.0	0.0	0.3	0.1	10.8	2.7	0.3	0.1	0.5	0.1	0.9	0.2
-	Barley, pearled	0.68	0.0	0.0	0.4	0.3	27.9	19.0	0.4	0.3	0.4	0.3	0.9	0.6
MO 0105	Edible offal (mammalian)	0.015	3.9	0.1	14.4	0.2	5.2	0.1	11.8	0.2	11.7	0.2	7.6	0.1
PE 0112	Eggs	0	2.5	0.0	29.7	0.0	25.1	0.0	24.5	0.0	37.8	0.0	27.4	0.0
MF 0100	Mammalian fats (except milk fats)	0	0.8	0.0	10.0	0.0	0.9	0.0	6.6	0.0	11.8	0.0	3.7	0.0
MM 0095	Meat from mammals other than marine mammals	0	27.7	0.0	116.5	0.0	38.5	0.0	55.1	0.0	90.2	0.0	131.3	0.0
ML 0106	Milks (excl processed products)	0	68.8	0.0	190.6	0.0	79.4	0.0	302.6	0.0	179.6	0.0	237.9	0.0
GC 0647	Oats (incl rolled)	0.57	1.4	0.8	0.6	0.3	0.2	0.1	4.2	2.4	5.7	3.2	8.9	5.1
PM 0110	Poultry meat	0	7.1	0.0	58.5	0.0	31.9	0.0	24.0	0.0	61.0	0.0	27.3	0.0
PO 0111	Poultry, edible offal of	0.015	0.4	0.0	0.4	0.0	1.7	0.0	0.1	0.0	0.6	0.0	0.2	0.0
PF 0111	Poultry, fats	0	0.1	0.0	0.1	0.0	0.1	0.0	0.0	0.0	0.4	0.0	0.1	0.0
SO 0495	Rape seed (excl oil)	0.24	0.1	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.1	0.0	0.1	0.0
OR 0495	Rape seed oil, edible	0.01	0.3	0.0	0.7	0.0	1.0	0.0	0.7	0.0	13.7	0.1	10.0	0.1
GS 0659	Sugar cane	0.07	30.9	2.2	43.1	3.0	51.3	3.6	0.1	0.0	5.5	0.4	0.0	0.0
DM 0659	Sugar cane molasses	0.40	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
GC 0653	Triticale (incl flour)	0.57	0.0	0.0	115.8	66.0	0.0	0.0	0.0	0.0	0.3	0.2	0.0	0.0
GC 0654	Wheat (incl bulgur wholemeal, excl flour)	0.57	6.0	3.4	11.1	6.3	0.8	0.4	0.2	0.1	0.2	0.1	0.0	0.0
CM 0654	Wheat bran, unprocessed	1.08	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CF 1211	Wheat flour (incl macaroni, bread, pastry, starch, gluten)	0.25	63.4	15.9	296.3	74.1	327.5	81.9	300.0	75.0	181.6	45.4	166.2	41.6
CF 1210	Wheat germ	0.63	0.0	0.0	1.3	0.8	0.0	0.0	1.3	0.8	0.9	0.6	1.2	0.8
	Total intake (µg/person)=			45.5		160.7		107.9		86.4		78.3		69.0
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			18000		18000		18000		18000		18000		18000
	%ADI=			0.3%		0.9%		0.6%		0.5%		0.4%		0.4%
	Rounded %ADI=			0%		1%		1%		0%		0%		0%

Annex 3

TRINEXAPAC-ETHYL International Estimated Daily Intake (IEDI) ADI = 0 - 0.3000 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day	Intake = daily intake: µg/person											
			G		H		I		J		K		L		M	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
GC 0640	Barley (incl pot, excl pearled, excl flour & grits, incl beer)	0.57	5.9	3.4	20.5	11.7	5.9	3.4	2.5	1.4	20.2	11.5	16.8	9.6	43.8	25.0
-	Barley flour and grits	0.25	0.4	0.1	0.0	0.0	0.1	0.0	0.0	0.0	1.0	0.3	0.8	0.2	0.0	0.0
-	Barley, pearled	0.68	0.5	0.3	0.1	0.1	0.0	0.0	0.0	0.0	0.7	0.5	0.0	0.0	0.1	0.1
MO 0105	Edible offal (mammalian)	0.015	4.8	0.1	10.7	0.2	4.0	0.1	4.0	0.1	6.5	0.1	6.6	0.1	5.6	0.1
PE 0112	Eggs	0	22.1	0.0	71.5	0.0	16.6	0.0	5.1	0.0	17.6	0.0	35.2	0.0	57.4	0.0
MF 0100	Mammalian fats (except milk fats)	0	2.2	0.0	18.6	0.0	0.5	0.0	0.8	0.0	5.7	0.0	4.5	0.0	18.2	0.0
MM 0095	Meat from mammals other than marine mammals	0	54.8	0.0	89.4	0.0	30.6	0.0	28.6	0.0	82.1	0.0	61.1	0.0	158.3	0.0
ML 0106	Milks (excl processed products)	0	66.0	0.0	121.1	0.0	81.6	0.0	102.4	0.0	207.7	0.0	57.0	0.0	287.9	0.0
GC 0647	Oats (incl rolled)	0.57	0.2	0.1	2.0	1.1	0.8	0.5	0.0	0.0	3.5	2.0	0.7	0.4	7.6	4.3
PM 0110	Poultry meat	0	17.6	0.0	131.3	0.0	25.1	0.0	4.7	0.0	145.9	0.0	27.7	0.0	115.1	0.0
PO 0111	Poultry, edible offal of	0.015	0.4	0.0	1.0	0.0	1.9	0.0	0.0	0.0	0.7	0.0	1.0	0.0	0.3	0.0
PF 0111	Poultry, fats	0	0.1	0.0	8.2	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.1	0.0	4.2	0.0
SO 0495	Rape seed (excl oil)	0.24	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
OR 0495	Rape seed oil, edible	0.01	3.8	0.0	2.3	0.0	0.1	0.0	0.4	0.0	0.0	0.0	6.0	0.1	3.8	0.0
GS 0659	Sugar cane	0.07	26.2	1.8	1.5	0.1	33.8	2.4	5.5	0.4	18.6	1.3	3.0	0.2	20.2	1.4
DM 0659	Sugar cane molasses	0.41	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
GC 0653	Triticale (incl flour)	0.57	1.3	0.7	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
GC 0654	Wheat (incl bulgur wholemeal, excl flour)	0.57	0.0	0.0	0.9	0.5	0.0	0.0	0.0	0.0	0.1	0.1	0.0	0.0	0.1	0.0
CM 0654	Wheat bran, unprocessed	1.08	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CF 1211	Wheat flour (incl macaroni, bread, pastry, starch, gluten)	0.25	133.0	33.3	60.1	15.0	52.4	13.1	32.2	8.1	87.7	21.9	79.6	19.9	180.1	45.0
CF 1210	Wheat germ	0.63	0.1	0.1	48.1	30.3	1.8	1.1	0.0	0.0	0.0	0.0	0.0	0.0	0.6	0.4
	Total intake (µg/person)=			39.9		59.0		20.5		9.9		37.6		30.5		76.4
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			16500		18000		18000		18000		18000		16500		18000
	%ADI=			0.2%		0.3%		0.1%		0.1%		0.2%		0.2%		0.4%
	Rounded %ADI=			0%		0%		0%		0%		0%		0%		0%

ANNEX 4: INTERNATIONAL ESTIMATES OF SHORT-TERM DIETARY INTAKES OF PESTICIDE RESIDUES

CHLORPYRIFOS-METHYL (090)

Acute RfD= 0.1 mg/kg bw (100 µg/kg bw)

Maximum %ARfD: 100% all; 60% gen pop; 100% child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
GC 0640	Barley (all commodities)	highest utilisation: Total	0.03	4.7	1.000	NL	Gen pop, > 1 yrs	1873	437.6	<25	NR	1	0% - 30%	0% - 30%	0% - 20%
GC 0646	Millet (all commodities)	highest utilisation: Total	0	4.7	1.000	CN	Child, 1-6 yrs	826	219.5	<25	NR	1	30% - 60%	30% - 40%	20% - 60%
GC 0648	Quinoa	Total		4.7	1.000	AU	Child, 2-16 yrs	32	78.2	<25	NR	1	10%	-	-
GC 0649	Rice (all commodities)	highest utilisation: Total	0	0.056 - 1.04	1.000	US	Child, 1-6 yrs	-	99.8	<25	NR	1	1% - 20%	1% - 10%	1% - 20%
GC 0651	Sorghum (Chicken corn, Dari seed, Durra, Feterita)	Total		4.7	1.000	DE	Gen pop, 14-80 yrs	5509	17.6	<25	NR	1	1%	1%	-
GC 0654	Wheat (all commodities)	highest utilisation: Total	0.15 - 1.44	4.7 - 11.5	1.000	FR	Child, 3-6 yrs	100.0%	384.3	<25	NR	1	3% - 100%	2% - 60%	3% - 100%
GC 0655	Wild rice	cooked/boiled		0.056	0.400	CN	Child, 1-6 yrs	129	552.6	<25	NR	1	1%	0%	1%

Annex 4

CYPROCONAZOLE (239)
Acute RfD= 0.06 mg/kg bw (60 µg/kg bw)

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	diet corr fact	Coun try	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Varia-bility factor	Case	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
SB 0716	Coffee beans (all commodities)	highest utilisation: Total	0.03	0	1.000	FR	Child, 3-6 yrs	6.5%	70.3	0.1	NR	3	0% - 0%	0% - 0%	0% - 0%

DICAMBA (240)
Acute RfD= 0.5 mg/kg bw (500 µg/kg bw)

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	diet corr fact	Coun try	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Varia-bility factor	Case	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
VD 0541	Soya bean (dry) (Glycine spp) (all commodities)	highest utilisation: silken tofu (soft soya bean curd)	0.001 - 0.033		1.000	CN	Child, 1-6 yrs	1491	248.2	NR	NR	3	0% - 0%	0% - 0%	0% - 0%

DICAMBA (240)
Acute RfD= 0.5 mg/kg bw (500 µg/kg bw)

Maximum %ARfD: 0% women

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Coun try	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Varia-bility factor	Case	% acute RfD rounded
VD 0541	Soya bean (dry) (Glycine spp) (all commodities)	highest utilisation: silken tofu (soft soya bean curd)	0.001 - 0.033		1.000	CN	gen pop, > 1 yrs	31091	431.2	NR	NR	3	0% - 0%

Annex 4

DIFENOCONAZOLE (224)
Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

Maximum %ARfD:

															30% all	20% gen pop	30% child
Codex Code	Commodity	Pr	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
TN 0660	Almonds (all commodities)		highest utilisation: raw incl roasted	0.01	0.02	1.000	DE	Women, 14-50 yrs	24	100.0	1.2	NR	1	0% - 0%	0% - 0%	0% - 0%
FP 0226	Apple (all commodities)		highest utilisation: raw with peel (incl consumption without peel)	0.005 - 0.16	0.47	1.000	CN	Child, 1-6 yrs	1314	403.4	255.0	3	2a	0% - 9%	0% - 4%	0% - 9%
VS 0621	Asparagus	0	Total	0.02	0.02	1.000	US	Child, 1-6 yrs	-	142.6	42.4	3	2a	0%	0%	0%
FI 0327	Banana	1	raw without peel	0.02	0.02	1.000	CN	Child, 1-6 yrs	286	455.8	767.3	3	2b	1%	0%	1%
VP 0061	Beans except broad bean & soya bean (green pods & immature seeds) (Phaseolus spp)	0	Total	0.07	0.5	1.000	NL	toddler, 8-20 m	218	140.5	19.4	NR	1	2%	1%	2%
VB 0401	Broccoli, Chinese (Kailan) (all commodities)		highest utilisation: raw	0.35	1.3	1.000	CN	Child, 1-6 yrs	334	222.5	311.0	3	2b	4% - 20%	2% - 8%	4% - 20%
VB 0041	Cabbage, head (all commodities)		highest utilisation: raw	0.35	1.3	1.000	CN	Child, 1-6 yrs	287	255.5	1402.5	3	2b	20% - 20%	7% - 10%	20% - 20%
VR 0577	Carrot (all commodities)		highest utilisation: raw with skin	0.05	0.13	1.000	CN	Child, 1-6 yrs	400	234.7	300.0	3	2b	1% - 2%	1% - 1%	0% - 2%
TN 0295	Cashew nut	1	raw incl roasted	0.01	0.02	1.000	TH	child, 3-6 yrs	374	98.8	2.5	NR	1	0%	0%	0%
MM 0812	Cattle meat: 20% as fat	0	Total	0.14	0.19	1.000	FR	Child, 3-6 yrs	98.8%	50.9	NR	NR	1	0%	0%	0%
MM 0812	Cattle meat: 80% as muscle	0	Total	0.047	0.071	1.000	FR	Child, 3-6 yrs	98.8%	203.7	NR	NR	1	0%	0%	0%
ML 0812	Cattle milk	0	Total	0.011	0.014	1.000	NL	toddler, 8-20 m	1882	1060.7	NR	NR	3	0%	0%	0%
VB 0404	Cauliflower (all commodities)		highest utilisation: Total	0.35	1.3	1.000	NL	toddler, 8-20 m	173	148.1	797.0	3	2b	10% - 20%	3% - 10%	10% - 20%
VS 0624	Celery	1	raw	0.14	2	1.000	CN	Child, 1-6 yrs	454	180.3	861.1	3	2b	20%	10%	20%

Annex 4

DIFENOCONAZOLE (224)

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

Maximum %ARfD: 30% all | 20% gen pop | 30% child

Codex Code	Commodity	Pr	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
FS 0013	Cherries	1	raw	0.04	0.1	1.000	DE	Child, 2-4 yrs	24	187.5	7.2	NR	1	0%	0%	0%
TN 0664	Chestnuts	0	Total	0.01	0.02	1.000	FR	child, 3-6 yrs	4.1%	170.4	17.4	NR	1	0%	0%	0%
PE 0840	Chicken eggs	0	Total	0.011	0.026	1.000	CN	Child, 1-6 yrs	3025	194.7	NR	NR	1	0%	0%	0%
TN 0665	Coconut (all commodities)		highest utilisation: raw incl copra (incl coconut juice)	0.01	0.02	1.000	TH	child, 3-6 yrs	826	423.4	383.0	3	2a	0% - 0%	0% - 0%	0% - 0%
VC 0424	Cucumber	1	raw with skin	0.04	0.15	1.000	CN	Child, 1-6 yrs	340	212.1	458.1	3	2b	2%	1%	2%
PO 0841	Duck, edible offal of (includes kidney and liver)	0	Total	0.001	0.002	1.000	CN	Gen pop, > 1 yrs	421	345.6	NR	NR	1	0%	0%	-
MO 0105	Edible offal (mammalian)	0	Total	0.71	0.95	1.000	US	Child, 1-6 yrs	-	186.6	NR	NR	1	4%	4%	4%
VO 0440	Egg plant (aubergine)	1	raw with skin	0.14	0.39	1.000	CN	Child, 1-6 yrs	969	253.4	443.9	3	2b	6%	3%	6%
VA 0381	Garlic (all commodities)		highest utilisation: raw without skin	0.015	0.07	1.000	CN	Child, 1-6 yrs	290	174.4	59.8	3	2a	0% - 3%	0% - 1%	0% - 3%
VC 0425	Gherkin	1	raw with skin	0.04	0.15	1.000	JP	Child, 1-6 yrs	484	91.8	54.5	3	2a	1%	0%	1%
-	Gilo (scarlet egg plant)	1	cooked/boiled (with skin)	0.14	0.39	1.000	BR	Gen pop, > 10 yrs	280	360.5	28.5	3	2a	1%	1%	-
FB 0269	Grape	1	raw with skin	0.52	1.5	1.000	CN	Child, 1-6 yrs	232	366.7	636.6	3	2b	30%	20%	30%
FC 0204	Lemon (all commodities)		highest utilisation: Total	0	0.49	1.000	FR	child, 3-6 yrs	16.1%	58.2	64.0	3	2b	1% - 2%	1% - 1%	1% - 2%
VL 0482	Lettuce, head (all commodities)		highest utilisation: raw	0.41	1	1.000	NL	Child, 2-6 yrs	91	140.1	338.9	3	2b	8% - 20%	2% - 7%	8% - 20%
TN 0669	Macadamia nut (all commodities)		highest utilisation: Total	0.01	0.02	1.000	US	Gen pop, all ages	-	106.6	3.2	NR	1	0% - 0%	0% - 0%	0% - 0%
FC 0003	Mandarin + mandarin-like hybrid (all commodities)		highest utilisation: raw, without peel	0.16	0.49	1.000	CN	Child, 1-6 yrs	151	586.7	124.3	3	2a	8% - 10%	4% - 5%	8% - 10%

Annex 4

DIFENOCONAZOLE (224)
Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

Maximum %ARfD:

														30% all	20% gen pop	30% child
Codex Code	Commodity	Pr	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
FI 0345	Mango	1	raw without peel	0.03	0.04	1.000	NL	toddler, 8-20 m	11	160.4	288.8	3	2b	1%	0%	1%
VC 0046	Melons, except watermelon	0	Total	0.14	0.35	1.000	FR	Child, 3-6 yrs	16.4%	358.1	420.0	3	2b	7%	3%	7%
FS 0245	Nectarine	1	raw with peel (incl consumption without peel)	0.15	0.26	1.000	NL	toddler, 8-20 m	6	183.6	131.0	3	2a	4%	1%	4%
VO 0442	Okra (Lady's finger)	3	cooked/boiled (with skin)	0.14	0.39	1.000	JP	Child, 1-6 yrs	58	84.3	8.5	NR	1	1%	1%	1%
FT 0305	Olive (all commodities)		highest utilisation: Total	0.465 - 0.65	1.2	1.000	AU	Child, 2-6 yrs	77	66.4	4.4	NR	1	0% - 1%	0% - 1%	0% - 1%
VA 0385	Onion, bulb	1	raw without skin	0.015	0.07	1.000	JP	Child, 1-6 yrs	748	102.0	244.4	3	2b	0%	0%	0%
FI 0350	Papaya	1	raw without peel	0.065	0.13	1.000	CN	Gen pop, > 1 yrs	350	733.9	526.4	3	2a	1%	1%	1%
FI 0351	Passion fruit	9	juice (pasteurised)	0.01	0.04	1.000	BR	Gen pop, > 10 yrs	2624	720.0	NR	NR	3	0%	0%	0%
FS 0247	Peach	1	raw with peel (incl consumption without peel)	0.15	0.26	1.000	JP	Child, 1-6 yrs	76	306.0	255.0	3	2a	5%	1%	5%
FP 0230	Pear (all commodities)		highest utilisation: raw with peel (incl consumption without peel)	0.16	0.47	1.000	CN	Child, 1-6 yrs	413	418.3	255.0	3	2a	1% - 9%	0% - 4%	1% - 9%
VP 0063	Peas (green pods & immature seeds) (Pisum spp, Vigna spp)	3	cooked/boiled	0.07	0.5	1.000	CN	Child, 1-6 yrs	1056	290.2	6.2	NR	1	3%	2%	3%
VO 0444	Peppers, chili (all commodities)		highest utilisation: raw with skin	0.14 - 1.1	0.39 - 1.8	1.000	CN	Gen pop, > 1 yrs	1743	295.7	43.2	3	2a	0% - 1%	0% - 1%	0% - 0%
VO 0445	Peppers, sweet (incl.	1	raw with skin	0.14	0.39	1.000	CN	Child, 1-6 yrs	1002	169.8	170.0	3	2b	4%	2%	4%

Annex 4

DIFENOCONAZOLE (224)
Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

Maximum %ARfD: 30% all | 20% gen pop | 30% child

Codex Code	Commodity	Pr	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
	pim(i)ento) (bell pepper, paprika)															
TN 0673	Pine nut	0	Total	0.01	0.02	1.000	BR	Gen pop, > 10 yrs	47	200.0	0.2	NR	1	0%	0%	0%
FS 0014	Plum	1	raw with peel (incl consumption without peel)	0.04	0.1	1.000	TH	Child, 3-6 yrs	11	376.9	93.0	3	2a	1%	0%	1%
VR 0589	Potato (all commodities)	0	highest utilisation: Total	0.088-1.2	1.9	1.000	ZA	Child, 1-5 yrs	-	299.6	216.0	3	2a	8%-30%	5%-9%	8%-30%
PM 0110	Poultry meat: 10% as fat	0	Total	0.001	0.002	1.000	AU	Child, 2-6 yrs	1563	27.5	NR	NR	1	0%	0%	0%
PM 0110	Poultry meat: 90% as muscle	0	Total	0.001	0.002	1.000	AU	Child, 2-6 yrs	1563	247.1	NR	NR	1	0%	0%	0%
SO 0495	Rape seed	0	Total	0.02		1.000	NL	toddler, 8-20 m	1882	21.3	<25	NR	3	0%	0%	0%
VD 0541	Soya bean (dry) (Glycine spp)	58	silken tofu (soft soya bean curd)	0.02		1.000	CN	Child, 1-6 yrs	1491	248.2	NR	NR	3	0%	0%	0%
VA 0389	Spring onion	3	cooked/boiled	2.8	3.8	1.000	NL	Child, 2-6 yrs	E	20.3	30.0	3	2b	4%	2%	4%
VC 0431	Squash, summer (courgette, marrow, zucchetti, zucchini)	0	Total	0.04	0.15	1.000	NL	toddler, 8-20 m	11	82.1	328.3	3	2b	1%	1%	1%
VR 0596	Sugar beet	52	sugar	0.02		1.000	FR	Child, 3-6 yrs	100.0%	274.7	NR	NR	3	0%	0%	0%
SO 0702	Sunflower seed	0	Total	0.01		1.000	CN	Gen pop, > 1 yrs	781	235.5	<25	NR	3	0%	0%	0%
VO 0448	Tomato (all commodities)		highest utilisation: raw with peel	0.01 - 0.22	0.39	1.000	CN	Child, 1-6 yrs	1117	263.8	180.0	3	2a	0% - 5%	0% - 2%	0% - 5%
TN 0678	Walnut	1	raw incl roasted	0.01	0.02	1.000	DE	Child, 2-4 yrs	75	49.4	7.0	NR	1	0%	0%	0%
CF 1211	Wheat	39	flour (cereals)	0		1.000	CN	Child, 1-6 yrs	3556	415.9	NR	NR	3	0%	0%	0%

Annex 4

DIQUAT (31)

Acute RfD= 0.8 mg/kg bw (800 µg/kg bw)

Maximum %ARfD: 0% all 0% gen pop

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	% acute RfD rounded	% acute RfD rounded
FP 0226	Apple (all commodities)	highest utilisation: Total	0	0	1.000	NL	toddler, 8-20 m	1314	443.7	148.3	3	2a	0% - 0%	0% - 0%
FS 0240	Apricot (all commodities)	highest utilisation: raw with peel (incl consumption without peel)	0	0	1.000	AU	Gen pop, > 2 yrs	77	1056.9	54.5	3	2a	0% - 0%	0% - 0%
FI 0327	Banana (all commodities)	highest utilisation: raw without peel	0	0	1.000	CN	Child, 1-6 yrs	286	455.8	767.3	3	2b	0% - 0%	0% - 0%
VD 0071	Beans (dry) (Phaseolus spp) (all commodities)	highest utilisation: cooked/boiled	0.05	0	0.400	CN	Gen pop, > 1 yrs	72200.0%	1313.2	0.5	NR	3	0% - 0%	0% - 0%
FT 0292	Cashew apple (all commodities)	highest utilisation: raw	0	0	1.000	BR	Gen pop, > 10 yrs	179	1088.8	72.6	3	2a	0% - 0%	0% - 0%
FS 0013	Cherries (all commodities)	highest utilisation: raw	0	0	1.000	DE	Child, 2-4 yrs	2400.0%	187.5	7.2	NR	1	0% - 0%	0% - 0%
SB 0716	Coffee beans (all commodities)	highest utilisation: Total	0	0	1.000	FR	Child, 3-6 yrs	6.5%	70.3	0.1	NR	3	0% - 0%	0% - 0%
MO 0105	Edible offal (mammalian)	Total		0	1.000	US	Child, 1-6 yrs	-	186.6	NR	NR	1	0%	0%
PE 0112	Eggs	Total		0	1.000	TH	Child, 3-6 yrs	2171	109.1	NR	NR	1	0%	0%
FC 0204	Lemon (all commodities)	highest utilisation: raw without peel	0	0	1.000	BR	Gen pop, > 10 yrs	165	69.1	22.6	3	1	0% - 0%	0% - 0%
FC 0205	Lime (all commodities)	highest utilisation: raw, without peel	0	0	1.000	DE	Gen pop, 14-80 yrs	13	64.7	67.9	3	2b	0% - 0%	0% - 0%
FP 0228	Loquat (Japanese medlar) (all commodities)	highest utilisation: raw without peel	0	0	1.000	JP	Gen pop, > 1 yrs	113	326.4	49.0	3	2a	0% - 0%	0% - 0%
MF 0100	Mammalian fats (except milk fats)	Total		0	1.000	FR	Child, 3-6 yrs	39.9%	30.2	NR	NR	1	0%	0%
FC 0003	Mandarin + mandarin-like hybrid (all commodities)	highest utilisation: raw, without peel	0	0	1.000	CN	Child, 1-6 yrs	151	586.7	124.3	3	2a	0% - 0%	0% - 0%
MM 0095	Meat from mammals other than marine mammals	Total	NA	NA	1.000	AU	Child, 2-6 yrs	2269	254.3	NR	NR	1	0%	0%
MM 0095	Meat from mammals other than marine mammals: 20% as fat	Total		0	1.000	AU	Child, 2-6 yrs	2269	50.9	NR	NR	1	0%	0%
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	Total		0	1.000	AU	Child, 2-6 yrs	2269	203.5	NR	NR	1	0%	0%

Annex 4

DIQUAT (31)

Acute RfD= 0.8 mg/kg bw (800 µg/kg bw)

Maximum %ARfD: 0% all 0% gen pop

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	% acute RfD rounded	% acute RfD rounded
FS 0245	Nectarine (all commodities)	highest utilisation: raw with peel (incl consumption without peel)	0	0	1.000	NL	toddler, 8-20 m	6	183.6	131.0	3	2a	0% - 0%	0% - 0%
FC 0004	Orange, sweet, sour + orange-like hybrid (all commodities)	highest utilisation: Peel	0	0	1.000	AU	Gen pop, > 2 yrs	698	15.1	-	-	-	0% - 0%	0% - 0%
FS 0247	Peach (all commodities)	highest utilisation: raw with peel (incl consumption without peel)	0	0	1.000	JP	Child, 1-6 yrs	76	306.0	255.0	3	2a	0% - 0%	0% - 0%
FP 0230	Pear (all commodities)	highest utilisation: raw with peel (incl consumption without peel)	0	0	1.000	CN	Child, 1-6 yrs	413	418.3	255.0	3	2a	0% - 0%	0% - 0%
VD 0072	Peas (dry) (Pisum spp, Vigna spp) (all commodities)	highest utilisation: cooked/boiled	0.05	0	0.400	CN	Gen pop, > 1 yrs	268	1673.8	<25	NR	3	0% - 0%	0% - 0%
FS 0014	Plum (all commodities)	highest utilisation: raw with peel (incl consumption without peel)	0	0	1.000	TH	Child, 3-6 yrs	11	376.9	93.0	3	2a	0% - 0%	0% - 0%
VR 0589	Potato (all commodities)	highest utilisation: Total	0.05	0.06	1.000	ZA	Child, 1-5 yrs	-	299.6	216.0	3	2a	0% - 0%	0% - 0%
PM 0110	Poultry meat	Total	NA	NA	1.000	AU	Child, 2-6 yrs	1563	274.6	NR	NR	1	0%	0%
PM 0110	Poultry meat: 10% as fat	Total		0	1.000	AU	Child, 2-6 yrs	1563	27.5	NR	NR	1	0%	0%
PM 0110	Poultry meat: 90% as muscle	Total		0	1.000	AU	Child, 2-6 yrs	1563	247.1	NR	NR	1	0%	0%
PO 0111	Poultry, edible offal of (includes kidney, liver and skin)	Total		0	1.000	FR	Child, 3-6 yrs	7.3%	99.5	NR	NR	1	0%	0%
PF 0111	Poultry, fats	Total		0	1.000	US	gen pop, all ages	-	42.9	NR	NR	1	0%	0%
FP 0231	Quince (all commodities)	highest utilisation: jam (incl jelly)	0	0	1.000	NL	Child, 2-6 yrs	E	55.7	NR	NR	3	0% - 0%	0% - 0%
SO 0495	Rape seed (all commodities)	highest utilisation: Total	0.0098 - 0.49	0	1.000	NL	toddler, 8-20 m	1882	21.3	<25	NR	3	0% - 0%	0% - 0%
FC 0005	Shaddock or pomelo + shaddock-like hybrid (all commodities)	highest utilisation: raw, without peel	0	0	1.000	DE	Child, 2-4 yrs	12	358.6	178.5	3	2a	0% - 0%	0% - 0%
VD 0541	Soya bean (dry) (Glycine	highest utilisation:	0.00165 -	0	1.000	CN	Child, 1-6 yrs	1491	248.2	NR	NR	3	0% - 0%	0% - 0%

Annex 4

DIQUAT (31)
Acute RfD= 0.8 mg/kg bw (800 µg/kg bw)

Maximum %ARfD: 0% all 0% gen pop

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	% acute RfD rounded	% acute RfD rounded
	spp) (all commodities)	silken tofu (soft soya bean curd)	0.03											
FB 0275	Strawberry (all commodities)	highest utilisation: Total	0	0	1.000	FR	Child, 3-6 yrs	32.3%	339.4	13.4	NR	1	0% - 0%	0% - 0%
SO 0702	Sunflower seed (all commodities)	highest utilisation: Total	0.066 - 0.11	0	1.000	CN	Gen pop, > 1 yrs	781	235.5	<25	NR	3	0% - 0%	0% - 0%

DITHIANON (180)
Acute RfD= 0.1 mg/kg bw (100 µg/kg bw)

Maximum % ARfD: 90% all 40% gen pop 90% child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
TN 0660	Almonds (all commodities)	highest utilisation: raw incl roasted	0	0	1.000	DE	Women. 14–50 yrs	24	100.0	1.2	NR	1	0–0%	0–0%	0–0%
FP 0226	Apple (all commodities)	highest utilisation: Total	0.0045	0.015–0.65	1.000	NL	toddler 8–20 m	1314	443.7	148.3	3	2a	0–50%	0–10%	0–50%
FS 0240	Apricot (all commodities)	highest utilisation: raw with peel (incl consumption without peel)	0.024	0.024–1.6	1.000	AU	Gen pop. > 2 yrs	77	1056.9	54.5	3	2a	0–40%	0–30%	0–40%
FS 0013	Cherries (all commodities)	highest utilisation: raw	0.024	0.024–1.6	1.000	DE	Child. 2–4 yrs	2400.0%	187.5	7.2	NR	1	0–30%	0–20%	0–30%
FB 0021	Currants, red, black, white (all commodities)	highest utilisation: Total	0.105	0.89	1.000	NL	toddler 8–20 m	3	262.9	14.9	NR	1	0–20%	0–10%	0–20%
MO 0105	Edible offal (mammalian)	Total		0	1.000	US	Child. 1–6 yrs	-	186.6	NR	NR	1	0%	0%	0
PE 0112	Eggs	Total		0	1.000	TH	Child. 3–6 yrs	2171	109.1	NR	NR	1	0%	0%	0
FB 0269	Grape	highest utilisation:	0.002–0.63	1.3–2.13	1.000	CN	Child. 1–6 yrs	23200.0%	366.7	636.6	3	2b	0–90%	0–40%	0–90%

Annex 4

DITHIANON (180)
Acute RfD= 0.1 mg/kg bw (100 µg/kg bw)

Maximum % ARfD:

													90% all	40% gen pop	90% child
Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
	(all commodities)	raw with skin													
DH 1100	Hops, dry (all commodities)	highest utilisation: Total	0.019–64	0	1.000	DE	Gen pop. 14–80 yrs	5866	8.5	<25	NR	3	1–7%	1–7%	0–0%
FP 0228	Loquat (Japanese medlar) (all commodities)	highest utilisation: raw without peel		0.65	1.000	JP	Gen pop. > 1 yrs	113	326.4	49.0	3	2a	1–5%	1–5%	0–0%
MM 0095	Meat from mammals other than marine mammals	Total		0	1.000	AU	Child. 2–6 yrs	2269	254.3	NR	NR	1	0%	0%	0%
MM 0095	Meat from mammals other than marine mammals: 20% as fat	Total		0	1.000	AU	Child. 2–6 yrs	2269	50.9	NR	NR	1	0%	0%	0%
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	Total		0	1.000	AU	Child. 2–6 yrs	2269	203.5	NR	NR	1	0%	0%	0%
ML 0106	Milks	Total	0		1.000	AU	Child. 2–6 yrs	2923	1933.6	NR	NR	3	0%	0%	0%
FS 0245	Nectarine (all commodities)	highest utilisation: raw with peel (incl consumption without peel)	0.024	0.024–1.6	1.000	NL	toddler 8–20 m	6	183.6	131.0	3	2a	0–70%	0–30%	0–70%
FS 0247	Peach (all commodities)	highest utilisation: raw with peel (incl consumption without peel)	0.024	0.024–1.6	1.000	JP	Child 1–6 yrs	76	306.0	255.0	3	2a	0–80%	0–20%	0–80%
FP 0230	Pear (all commodities)	highest utilisation: raw with peel (incl consumption without peel)	0.0045	0.009–0.65	1.000	CN	Child 1–6 yrs	413	418.3	255.0	3	2a	0%–40%	0–10%	0–40%
FS 0014	Plum (all commodities)	highest utilisation: raw with peel (incl consumption without peel)	0.024	0.024–1.6	1.000	TH	Child 3–6 yrs	11	376.9	93.0	3	2a	0%–50%	0–20%	0–50%

Annex 4

DITHIANON (180)
Acute RfD= 0.1 mg/kg bw (100 µg/kg bw)

Maximum % ARfD: 90% all | 40% gen pop | 90% child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
PM 0110	Poultry meat	Total		0	1.000	AU	Child 2–6 yrs	1563	274.6	NR	NR	1	0%	0%	0%
PM 0110	Poultry meat: 10% as fat	Total		0	1.000	AU	Child 2–6 yrs	1563	27.5	NR	NR	1	0%	0%	0%
PM 0110	Poultry meat: 90% as muscle	Total		0	1.000	AU	Child 2–6 yrs	1563	247.1	NR	NR	1	0%	0%	0%
PO 0111	Poultry, edible offal of (includes kidney, liver and skin)	Total		0	1.000	FR	Child 3–6 yrs	7.3%	99.5	NR	NR	1	0%	0%	0%

FENBUCONAZOLE (197)
Acute RfD= 0.2 mg/kg bw (200 µg/kg bw)

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	diet corr fact	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Varia-bility factor	Case	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
FC 0204	Lemon (all commodities)	highest utilisation: juice (pasteurised)	0.018 - 17	0.085	1.000	FR	Child, 3-6 yrs	0.15836	90.9	NR	NR	3	0% - 0%	0% - 0%	0% - 0%
FC 0205	Lime (all commodities)	highest utilisation: raw, without peel	0.018 - 17	0.085	1.000	DE	Gen pop, 14-80 yrs	13	64.7	67.9	3	2b	0% - 0%	0% - 0%	0% - 0%
FC 0003	Mandarin + mandarin-like hybrid (all commodities)	highest utilisation: raw, without peel	0.01 - 0.021	0.01	1.000	CN	Child, 1-6 yrs	151	586.7	124.3	3	2a	0% - 0%	0% - 0%	0% - 0%
FC 0004	Orange, sweet, sour + orange-like hybrid (all commodities)	highest utilisation: Juice (pasteurised)	0.01 - 5.2	0.01	1.000	NL	Child, 2-6 yrs	224	537.2	NR	NR	3	0% - 0%	0% - 0%	0% - 0%
FC 0005	Shaddock or pomelo + shaddock-like hybrid (all commodities)	highest utilisation: raw, without peel	0.01 - 5.2	0.01	1.000	DE	Child, 2-4 yrs	12	358.6	178.5	3	2a	0% - 0%	0% - 0%	0% - 0%

Annex 4

FENPYROXIMATE (193)

Acute RfD= 0.02 mg/kg bw (20 µg/kg bw)

Maximum %ARfD: 80% all; 50% gen pop; 80% child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
FS 0240	Apricot (all commodities)	highest utilisation: raw with peel (incl consumption without peel)	0.13	0.29	1.000	AU	Gen pop, > 2 yrs	77	1056.9	54.5	3	2a	0% - 40%	0% - 30%	0% - 40%
FI 0326	Avocado (all commodities)	highest utilisation: Total		0.1	1.000	AU	Child, 2-6 yrs	182	229.9	171.4	3	2a	8% - 20%	6% - 8%	7% - 20%
VP 0061	Beans except broad bean & soya bean (green pods & immature seeds) (Phaseolus spp) (all commodities)	highest utilisation: Total	0.09	0.19	1.000	NL	toddler, 8-20 m	218	140.5	19.4	NR	1	1% - 10%	0% - 8%	1% - 10%
FS 0013	Cherries (all commodities)	highest utilisation: raw	0.57	0.9	1.000	DE	Child, 2-4 yrs	2400.0%	187.5	7.2	NR	1	1% - 50%	1% - 50%	1% - 50%
VC 0424	Cucumber (all commodities)	highest utilisation: raw with skin	0.06	0.19	1.000	CN	Child, 1-6 yrs	340	212.1	458.1	3	2b	0% - 40%	0% - 20%	0% - 40%
MO 0105	Edible offal (mammalian)	Total		0.011	1.000	US	Child, 1-6 yrs	-	186.6	NR	NR	1	1%	1%	1%
MM 0095	Meat from mammals other than marine mammals	Total	NA	NA	1.000	AU	Child, 2-6 yrs	2269	254.3	NR	NR	1	2%	1%	2%
MM 0095	Meat from mammals other than marine mammals: 20% as fat	Total		0.084	1.000	AU	Child, 2-6 yrs	2269	50.9	NR	NR	1	1%	1%	1%
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	Total		0.021	1.000	AU	Child, 2-6 yrs	2269	203.5	NR	NR	1	1%	1%	1%
FS 0245	Nectarine (all commodities)	highest utilisation: raw with peel (incl consumption without peel)	0.13	0.29	1.000	NL	toddler, 8-20 m	6	183.6	131.0	3	2a	0% - 60%	0% - 30%	0% - 60%
FS 0247	Peach (all commodities)	highest utilisation: raw with peel (incl consumption without peel)	0.13	0.29	1.000	JP	Child, 1-6 yrs	76	306.0	255.0	3	2a	0% - 80%	0% - 20%	0% - 80%
FS 0014	Plum (all commodities)	highest utilisation: dried (prunes)	0.13	0.29 - 0.5	3.090	JP	Child, 1-6 yrs	11	127.5	10.4	NR	1	0% - 70%	0% - 40%	0% - 70%
VR 0589	Potato	highest utilisation:	0	0	1.000	ZA	Child, 1-5	-	299.6	216.0	3	2a	0% - 0%	0% - 0%	0% - 0%

Annex 4

FENPYROXIMATE (193)

Acute RfD= 0.02 mg/kg bw (20 µg/kg bw)

Maximum %ARfD: 80% all, 50% gen pop, 80% child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
	(all commodities)	Total					yrs								
FB 0275	Strawberry (all commodities)	highest utilisation: Total	0.215	0.59	1.000	FR	Child, 3-6 yrs	32.3%	339.4	13.4	NR	1	1% - 50%	0% - 30%	0% - 50%

INDOXACARB (216)

Acute RfD= 0.1 mg/kg bw (100 µg/kg bw)

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	diet corr fact	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
DT 1114	Tea, green, black (black, fermented and dried) (all commodities)	highest utilisation: infusion (brew/beverage)	.025 - .41	0	1.000	BR	Gen pop, > 10 yrs	3534	2640.0	NR	NR	3	1% - 1%	1% - 1%	0% - 1%

Annex 4

MALATHION (69)

Acute RfD= 2 mg/kg bw (2000 µg/kg bw)

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	diet corr fact	Coun try	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Varia-bility factor	Case	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
FS 0013	Cherries (all commodities)	highest utilisation: jam	0.53		1.000	NL	Child, 2-6 yrs	E	55.7	NR	NR	3	0% - 0%	0% - 0%	0% - 0%

PENTHIOPYRAD (253)

Acute RfD= 1 mg/kg bw (1000 µg/kg bw)

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	diet corr fact	Coun try	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Varia-bility factor	Case	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
GC 0640	Barley (all commodities)	highest utilisation: Total	0,021 - 0,086	0	1.000	NL	Gen pop, > 1 yrs	1873	437.6	<25	NR	3	0% - 0%	0% - 0%	0% - 0%
MO 0105	Edible offal (mammalian)	Total		0.065	1.000	US	Child, 1-6 yrs	-	186.6	NR	NR	1	0%	0%	0%
MF 0100	Mammalian fats (except milk fats)	Total		0.036	1.000	FR	Child, 3-6 yrs	39.9%	30.2	NR	NR	1	0%	0%	0%
MM 0095	Meat from mammals other than marine mammals	Total	NA	NA	1.000	AU	Child, 2-6 yrs	2269	254.3	NR	NR	1	0%	0%	0%
MM 0095	Meat from mammals other than marine mammals: 20% as fat	Total		0.026	1.000	AU	Child, 2-6 yrs	2269	50.9	NR	NR	1	0%	0%	0%
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	Total		0.026	1.000	AU	Child, 2-6 yrs	2269	203.5	NR	NR	1	0%	0%	0%
ML 0106	Milks	Total	0.013		1.000	AU	Child, 2-6 yrs	2923	1933.6	NR	NR	3	0%	0%	0%
GC 0647	Oats (all commodities)	highest utilisation: Total	0,086	0	1.000	CN	Gen pop, > 1 yrs	1740	330.6	<25	NR	3	0% - 0%	0% - 0%	0% - 0%

Annex 4

PROPICONAZOLE (160)
Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

Maximum %ARfD: 100% all; 50% gen pop; 100% child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
FC 0004	Orange, sweet, sour + orange-like hybrid (all commodities)	highest utilisation: Total	0.02	4.9	1.000	AU	Child, 2-6 yrs	1735	800.8	155.8	3	2a	0% - 100%	0% - 50%	0% - 100%
FS 0247	Peach (all commodities)	highest utilisation: raw with peel (incl consumption without peel)	0	1.55	1.000	JP	Child, 1-6 yrs	7600.0%	306.0	255.0	3	2a	3% - 30%	1% - 10%	3% - 30%
FS 0014	Plum (all commodities)	highest utilisation: raw with peel (incl consumption without peel)	0	0.185	1.000	TH	Child, 3-6 yrs	1100.0%	376.9	93.0	3	2a	0% - 2%	0% - 1%	0% - 2%
VO 0448	Tomato (all commodities)	highest utilisation: dried	0	0.8	5.000	AU	Gen pop, > 2 yrs	61	861.1	8.0	NR	1	6% - 20%	2% - 20%	1% - 10%

SPIROTETRAMAT (234)
Acute RfD= 1 mg/kg bw (1000 µg/kg bw)

Maximum %ARfD: 2% all; 1% gen pop; 2% child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
VS 0620	Artichoke globe	Total	0.41	0.7	1.000	FR	Child, 3-6 yrs	39.3%	117.2	98.9	3	2a	1%	1%	1%
FB 0020	Blueberries	sauce/puree	0.63	1.6	1.000	NL	Child, 2-6 yrs	E	109.7	NR	NR	3	0%	0%	0%
FB 0021	Currants, red, black, white	juice (pasteurised)	0.63	1.6	1.000	NL	Child, 2-6 yrs	E	525.8	NR	NR	3	2%	1%	2%
FB 0268	Gooseberries	raw with skin	0.63	1.6	1.000	DE	Women, 14-50 yrs	10	338.1	<25	NR	1	1%	1%	0%

Annex 4

SULFOXAFLOR (252)
Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

Maximum %ARfD: 60% all | 40% gen pop | 60% child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
TN 0660	Almonds (all commodities)	highest utilisation: raw incl roasted	0.01	0.012	1.000	DE	Women, 14-50 yrs	24	100.0	1.2	NR	1	0% - 0%	0% - 0%	0% - 0%
VL 0460	Amaranth (Bledo)	raw		2.9	1.000	CN	Gen pop, > 1 yrs	714	581.7	85.8	3	2a	10%	10%	NC
FP 0226	Apple (all commodities)	highest utilisation: Total	0.028 - 0.07	0.26	1.000	NL	toddler, 8-20 m	1314	443.7	148.3	3	2a	0% - 6%	0% - 2%	0% - 6%
FS 0240	Apricot (all commodities)	highest utilisation: raw with peel (incl consumption without peel)	0.91	1.2	1.000	AU	Gen pop, > 2 yrs	77	1056.9	54.5	3	2a	0% - 10%	0% - 7%	0% - 10%
VR 0573	Arrowroot (all commodities)	highest utilisation: starch	0.01	0.023	1.000	NL	Child, 2-6 yrs	E	12.4	NR	NR	3	0% - 0%	0% - 0%	0% - 0%
VC 0421	Balsam pear (Bitter cucumber, Bitter gourd, Bitter melon) (all commodities)	highest utilisation: raw without peel	0	0.27	1.000	CN	Gen pop, > 1 yrs	1387	400.2	607.5	3	2b	1% - 2%	1% - 2%	1% - 1%
GC 0640	Barley (all commodities)	highest utilisation: Total	0.013 - 0.063	0	1.000	NL	Gen pop, > 1 yrs	1873	437.6	<25	NR	3	0% - 0%	0% - 0%	0% - 0%
VD 0071	Beans (dry) (Phaseolus spp) (all commodities)	highest utilisation: cooked/boiled	0.075	0	0.400	CN	Gen pop, > 1 yrs	72200	1313.2	0.5	NR	3	0% - 0%	0% - 0%	0% - 0%
VR 0574	Beetroot (all commodities)	highest utilisation: cooked/boiled (without peel)	0.01	0.023	1.000	NL	toddler, 8-20 m	26	64.6	182.4	3	2b	0% - 0%	0% - 0%	0% - 0%
VC 0422	Bottle gourd (Cucuzzi)	raw with skin		0.27	1.000	CN	Gen pop, > 1 yrs	519	453.0	325.0	3	2a	2%	2%	NC
TN 0662	Brazil nut	raw incl roasted		0.012	1.000	BR	Gen pop, > 10 yrs	47	48.5	4.0	NR	1	0%	0%	0%
VB 0400	Broccoli (all commodities)	highest utilisation: cooked/boiled	0.074	1.6	1.000	NL	toddler, 8-20 m	125	160.7	286.0	3	2b	0% - 30%	0% - 8%	0% - 30%
VB 0041	Cabbage, head (all commodities)	highest utilisation: raw	0.009 - 0.099	0.17	1.000	CN	Child, 1-6 yrs	287	255.5	1402.5	3	2b	0% - 30%	0% - 9%	0% - 30%
VR 0577	Carrot (all commodities)	highest utilisation: raw with skin	0.01 - 0.024	0.03	1.000	CN	Child, 1-6 yrs	400	234.7	300.0	3	2b	0% - 0%	0% - 0%	0% - 0%
TN 0295	Cashew nut	highest utilisation:	0.01	0.012	1.000	TH	child, 3-6 yrs	374	98.8	2.5	NR	1	0% - 0%	0% - 0%	0% - 0%

Annex 4

SULFOXAFLOR (252)
Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

Maximum %ARfD: 60% all | 40% gen pop | 60% child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
	(all commodities)	raw incl roasted													
VR 0463	Cassava (Manioc, Tapioca) (all commodities)	highest utilisation: cooked/boiled (without peel)	0.01	0.023	1.000	NL	Gen pop, > 1 yrs	E	250.0	356.0	3	2b	0% - 0%	0% - 0%	0% - 0%
VB 0404	Cauliflower (all commodities)	highest utilisation: Total	0.013	0.021	1.000	NL	toddler, 8-20 m	173	148.1	797.0	3	2b	0% - 0%	0% - 0%	0% - 0%
VR 0578	Celeriac (all commodities)	highest utilisation: cooked/boiled (without skin)	0.01	0.03	1.000	NL	Gen pop, > 1 yrs	23	239.1	437.0	3	2b	0% - 0%	0% - 0%	0% - 0%
VS 0624	Celery (all commodities)	highest utilisation: raw	0.19	0.77	1.000	CN	Child, 1-6 yrs	45400	180.3	861.1	3	2b	0% - 9%	0% - 5%	0% - 9%
VL 0464	Chard (silver beet) (all commodities)	highest utilisation: Total	0	2.9	1.000	NL	Child, 2-6 yrs	2	136.2	175.0	3	2b	3% - 20%	3% - 10%	10% - 20%
VC 0423	Chayote (Christophine) (all commodities)	highest utilisation: raw with skin	0	0.27	1.000	CN	Child, 1-6 yrs	124	284.7	197.4	3	2a	1% - 4%	1% - 2%	1% - 4%
FS 0013	Cherries (all commodities)	highest utilisation: raw	0.73 - 1	1.2	1.000	DE	Child, 2-4 yrs	2400.0%	187.5	7.2	NR	1	0% - 9%	0% - 6%	0% - 9%
VL 0465	Chervil (all commodities)	highest utilisation: raw	1.2	2.9	1.000	NL	Child, 2-6 yrs	E	3.5	<25	NR	1	0% - 20%	0% - 20%	0% - 10%
TN 0664	Chestnuts (all commodities)	highest utilisation: Total	0	0.012	1.000	FR	child, 3-6 yrs	4.1%	170.4	17.4	NR	1	0% - 0%	0% - 0%	0% - 0%
VL 0469	Chicory leaves (sugar loaf)	raw		2.9	1.000	DE	Child, 2-4 yrs	16	82.4	280.5	3	2b	10%	5%	10%
VR 0469	Chicory, roots (all commodities)	highest utilisation: sec processing / composite foods	0.01	0.023	1.000	NL	Child, 2-6 yrs	E	13.3	NR	NR	3	0% - 0%	0% - 0%	0% - 0%
VL 0466	Chinese cabbage, type pak-choi (all commodities)	highest utilisation: raw	1.2	2.9	1.000	CN	Child, 1-6 yrs	1966	327.1	1548.4	3	2b	0% - 60%	0% - 40%	0% - 60%
VL 0467	Chinese cabbage, type pe-tsai (all commodities)	highest utilisation: raw	1.2	2.9	1.000	JP	Child, 1-6 yrs	186	86.7	2162.0	3	2b	0% - 20%	0% - 10%	0% - 20%
TN 0665	Coconut (young coconut) (all commodities)	highest utilisation: raw incl copra (incl coconut juice)	0.01	0.012	1.000	TH	child, 3-6 yrs	826	423.4	383.0	3	2a	0% - 0%	0% - 0%	0% - 0%
VL 0470	Corn salad (lambs lettuce)	highest utilisation:	0	2.9	1.000	DE	Child, 2-4	13	41.2	7.8	NR	1	0% - 2%	0% - 2%	0% - 2%

Annex 4

SULFOXAFLOR (252)
Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

Maximum %ARfD: 60% all; 40% gen pop; 60% child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
	(all commodities)	raw					yrs								
VL 0510	Cos lettuce (all commodities)	highest utilisation: raw	1.2	2.9	1.000	NL	Child, 2-6 yrs	91	140.1	289.9	3	2b	0% - 20%	0% - 10%	0% - 20%
SO 0691	Cotton seed (all commodities)	highest utilisation: Oil (refined)	0.002 - 0.02	0	1.000	US	gen pop, all ages	-	9.1	NR	NR	3	0% - 0%	0% - 0%	0% - 0%
VL 0472	Cress, garden	raw		2.9	1.000	CN	Gen pop, > 1 yrs	1443	352.5	15.0	NR	1	6%	6%	0%
VC 0424	Cucumber (all commodities)	highest utilisation: raw with skin	0.029	0.27	1.000	CN	Child, 1-6 yrs	340	212.1	458.1	3	2b	0% - 4%	0% - 2%	0% - 4%
VL 0474	Dandelion leaves	raw		2.9	1.000	NL	gen pop, > 1 yrs	E	49.9	35.0	3	2a	2%	2%	-
MO 0105	Edible offal (mammalian)	Total		0.47	1.000	US	Child, 1-6 yrs	-	186.6	NR	NR	1	2%	2%	2%
VO 0440	Egg plant (aubergine) (all commodities)	highest utilisation: raw with skin	0.11	0.6	1.000	CN	Child, 1-6 yrs	969	253.4	443.9	3	2b	0% - 9%	0% - 5%	0% - 9%
PE 0112	Eggs	Total		0.069	1.000	TH	Child, 3-6 yrs	2171	109.1	NR	NR	1	0%	0%	0%
VL 0476	Endive (all commodities)	highest utilisation: Total	1.2	2.9	1.000	NL	toddler, 8-20 m	54	201.9	375.0	3	2b	2% - 60%	0% - 20%	2% - 60%
VA 0381	Garlic (all commodities)	highest utilisation: raw without skin	0.01	0.01	1.000	CN	Child, 1-6 yrs	290	174.4	59.8	3	2a	0% - 0%	0% - 0%	0% - 0%
VC 0425	Gherkin (all commodities)	highest utilisation: raw with skin	0.029	0.27	1.000	JP	Child, 1-6 yrs	484	91.8	54.5	3	2a	0% - 1%	0% - 1%	0% - 1%
-	Gilo (scarlet egg plant) (all commodities)	highest utilisation: Total	0.11	0.6	1.000	AU	Child, 2-16 yrs	1.67836	36.2	<25	NR	1	0% - 0%	0% - 0%	0% - 0%
VL 0269	Grape leaves (all commodities)	highest utilisation: canned/preserved	0	2.9	1.000	NL	Gen pop, > 1 yrs	1	54.8	1.4	NR	1	1% - 8%	1% - 8%	0% - 3%
FB 0269	Grape (all commodities)	highest utilisation: raw with skin	0.098 - 0.14	1.6 - 5.6	1.000	CN	Child, 1-6 yrs	23200	366.7	636.6	3	2b	0% - 40%	0% - 20%	0% - 40%
TN 0666	Hazelnut (all commodities)	highest utilisation: raw incl roasted	0.01	0.012	1.000	DE	Gen pop, 14-80 yrs	79	100.0	1.2	NR	1	0% - 0%	0% - 0%	0% - 0%
VR 0583	Horseradish	raw		0.03	1.000	NL	Gen pop, > 1 yrs	E	1.0	154.0	3	2b	0%	0%	NC
VL 0478	Indian mustard (Amsoi)	raw		2.9	1.000	NL	Gen pop, > 1 yrs	E	49.9	250.0	3	2b	2%	2%	NC
VL 0479a	Japanese greens:	highest utilisation:	0	2.9	1.000	CN	Gen pop, > 1	993	332.7	<25	NR	1	2% - 6%	2% - 6%	2% - 3%

Annex 4

SULFOXAFLOR (252)
Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

Maximum %ARfD: 60% all | 40% gen pop | 60% child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
	Chrysanthemum leaves (Chrysanthemum spp) (all commodities)	raw					yrs								
VR 0585	Jerusalem artichoke (all commodities)	highest utilisation: cooked/boiled (without peel)	0	0.03	1.000	NL	Child, 2-6 yrs	E	133.3	56.0	3	2a	0% - 0%	0% - 0%	0% - 0%
VL 0480	Kale (borecole, collards) (all commodities)	highest utilisation: Total	1.2	2.9	1.000	NL	toddler, 8-20 m	33	100.6	672.0	3	2b	1% - 30%	1% - 30%	3% - 30%
VL 0507	Kangkung (water spinach)	raw		2.9	1.000	CN	Child, 1-6 yrs	183	270.7	85.8	3	2a	30%	10%	30%
FC 0204	Lemon (all commodities)	highest utilisation: juice (pasteurised)	0.31	0.44	1.000	FR	Child, 3-6 yrs	0.15836	90.9	NR	NR	3	0% - 1%	0% - 1%	0% - 1%
VL 0482	Lettuce, head (all commodities)	highest utilisation: raw	1.2	2.9	1.000	NL	Child, 2-6 yrs	91	140.1	338.9	3	2b	0% - 60%	0% - 20%	0% - 60%
VL 0483	Lettuce, leaf (all commodities)	highest utilisation: raw	1.2	2.9	1.000	NL	Child, 2-6 yrs	91	140.1	117.8	3	2a	0% - 20%	0% - 7%	0% - 20%
FC 0205	Lime (all commodities)	highest utilisation: raw, without peel	0.31	0.44	1.000	DE	Gen pop, 14-80 yrs	13	64.7	67.9	3	2b	0% - 0%	0% - 0%	0% - 0%
FP 0228	Loquat (Japanese medlar) (all commodities)	highest utilisation: raw without peel	0	0.44	1.000	JP	Gen pop, > 1 yrs	113	326.4	49.0	3	2a	0% - 1%	0% - 1%	0% - 0%
TN 0669	Macadamia nut (all commodities)	highest utilisation: raw incl roasted	0.01	0.012	1.000	DE	Gen pop, 14-80 yrs	16	50.1	3.2	NR	1	0% - 0%	0% - 0%	0% - 0%
FC 0003	Mandarin + mandarin-like hybrid (all commodities)	highest utilisation: raw, without peel	0.31	0.44	1.000	CN	Child, 1-6 yrs	151	586.7	124.3	3	2a	0% - 9%	0% - 5%	0% - 9%
MM 0095	Meat from mammals other than marine mammals	Total	NA	NA	1.000	AU	Child, 2-6 yrs	2269	254.3	NR	NR	1	1%	0%	1%
MM 0095	Meat from mammals other than marine mammals: 20% as fat	Total		0.073	1.000	AU	Child, 2-6 yrs	2269	50.9	NR	NR	1	0%	0%	0%
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	Total		0.2	1.000	AU	Child, 2-6 yrs	2269	203.5	NR	NR	1	1%	0%	1%
VC 0046	Melons, except watermelon (all commodities)	highest utilisation: Total	0.029	0.27	1.000	FR	Child, 3-6 yrs	16.4%	358.1	420.0	3	2b	0% - 5%	0% - 4%	0% - 5%

Annex 4

SULFOXAFLOR (252)
Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

Maximum %ARfD: 60% all; 40% gen pop; 60% child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
VL 0485	Mustard greens (all commodities)	highest utilisation: raw	1.2	2.9	1.000	CN	Child, 1-6 yrs	635	299.3	244.8	3	2a	2% - 50%	2% - 20%	50% - 50%
FS 0245	Nectarine (all commodities)	highest utilisation: raw with peel (incl consumption without peel)	0.91	1.2	1.000	NL	toddler, 8-20 m	6	183.6	131.0	3	2a	0% - 20%	0% - 8%	0% - 20%
VO 0442	Okra (Lady's finger) (all commodities)	highest utilisation: cooked/boiled (with skin)	0	0.6	1.000	JP	Child, 1-6 yrs	58	84.3	8.5	NR	1	1% - 1%	1% - 1%	1% - 1%
VA 0385	Onion, bulb (all commodities)	highest utilisation: raw without skin	0.01	0.01	1.000	JP	Child, 1-6 yrs	748	102.0	244.4	3	2b	0% - 0%	0% - 0%	0% - 0%
FC 0004	Orange, sweet, sour + orange-like hybrid (all commodities)	highest utilisation: raw, without peel	0.043 - 0.31	0.44	1.000	DE	Child, 2-4 yrs	92	238.4	121.3	3	2a	0% - 4%	0% - 3%	0% - 4%
VR 0587	parsley, turnip-rooted	dried (slab)	0.01		5.000	CN	Child, 1-6 yrs	427	22.8	NR	NR	3	0%	0%	0%
VR 0588	Parsnip (all commodities)	highest utilisation: Total	0.01	0.03	1.000	UK	Child, 1.5-4.5 yrs	87	227.1	90.0	3	2a	0% - 1%	0% - 0%	0% - 1%
FS 0247	Peach (all commodities)	highest utilisation: raw with peel (incl consumption without peel)	0.91	1.2	1.000	JP	Child, 1-6 yrs	76	306.0	255.0	3	2a	0% - 20%	0% - 6%	0% - 20%
FP 0230	Pear (all commodities)	highest utilisation: raw with peel (incl consumption without peel)	0.31	0.44	1.000	CN	Child, 1-6 yrs	413	418.3	255.0	3	2a	0% - 8%	0% - 3%	0% - 8%
TN 0672	Pecan (all commodities)	highest utilisation: raw incl roasted	0.01	0.012	1.000	BR	Gen pop, > 10 yrs	9	39.0	5.0	NR	1	0% - 0%	0% - 0%	0% - 0%
VO 0444	Peppers, chili (all commodities)	highest utilisation: dried (incl powder)	0.11	0.6 - 6	7.000	CN	Gen Pop, > 1 yrs	1583	32.2	0.0	NR	1	0% - 8%	0% - 8%	0% - 2%
VO 0445	Peppers, sweet (incl. pim(i)ento) (bell pepper, paprika) (all commodities)	highest utilisation: raw with skin	0.11	0.6	1.000	CN	Child, 1-6 yrs	1002	169.8	170.0	3	2b	0% - 6%	0% - 3%	0% - 6%
TN 0673	Pine nut	raw incl roasted		0.012	1.000	NL	Child, 2-6 yrs	E	10.1	0.2	NR	1	0%	0%	0%
TN 0675	Pistachio nut (all commodities)	highest utilisation: Total	0.01	0.012	1.000	FR	child, 3-6 yrs	2.6%	44.9	0.9	NR	1	0% - 0%	0% - 0%	0% - 0%
FS 0014	Plum (all commodities)	highest utilisation: raw with peel (incl	0.91	1.2	1.000	TH	Child, 3-6 yrs	11	376.9	93.0	3	2a	0% - 10%	0% - 6%	0% - 10%

Annex 4

SULFOXAFLOR (252)
Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

Maximum %ARfD: 60% all | 40% gen pop | 60% child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
		consumption without peel)													
VR 0589	Potato (all commodities)	highest utilisation: fried (without peel)	0.01 - 0.036	0.03	1.000	NL	toddler, 8-20 m	49	148.5	134.0	3	2a	0% - 0%	0% - 0%	0% - 0%
PM 0110	Poultry meat	Total	NA	NA	1.000	AU	Child, 2-6 yrs	1563	274.6	NR	NR	1	0%	0%	0%
PM 0110	Poultry meat: 10% as fat	Total		0.02	1.000	AU	Child, 2-6 yrs	1563	27.5	NR	NR	1	0%	0%	0%
PM 0110	Poultry meat: 90% as muscle	Total		0.049	1.000	AU	Child, 2-6 yrs	1563	247.1	NR	NR	1	0%	0%	0%
PO 0111	Poultry, edible offal of (includes kidney, liver and skin)	Total		0.18	1.000	FR	Child, 3-6 yrs	7.3%	99.5	NR	NR	1	0%	0%	0%
VC 0429	Pumpkins (all commodities)	highest utilisation: raw without peel	0.029	0.27	1.000	CN	Child, 1-6 yrs	561	322.7	1851.8	3	2b	0% - 5%	0% - 4%	0% - 5%
VL 0492	Purslane (all commodities)	highest utilisation: cooked/boiled	0	2.9	1.000	NL	Gen pop, > 1 yrs	5	271.2	<25	NR	1	1% - 4%	1% - 4%	0% - 0%
FP 0231	Quince (all commodities)	highest utilisation: jam (incl jelly)	0.31	0.44	1.000	NL	Child, 2-6 yrs	E	55.7	NR	NR	3	0% - 0%	0% - 0%	0% - 0%
VR 0494	Radish (all commodities)	highest utilisation: raw with skin	0.01	0.023	1.000	NL	Child, 2-6 yrs	E	64.4	172.0	3	2b	0% - 0%	0% - 0%	0% - 0%
VR 0590	Radish, black (all commodities)	highest utilisation: raw without skin	0.01	0.03	1.000	NL	Child, 2-6 yrs	E	64.4	180.3	3	2b	0% - 0%	0% - 0%	0% - 0%
VR 0591	Radish, Japanese (Chinese radish, Daikon) (all commodities)	highest utilisation: raw without skin	0.01	0.03	1.000	CN	Child, 1-6 yrs	1187	293.4	1000.0	3	2b	0% - 1%	0% - 0%	0% - 1%
VL 0495	Rape greens (all commodities)	highest utilisation: cooked/boiled	0	2.9	1.000	JP	Gen pop, > 1 yrs	533	147.9	34.0	3	2a	4% - 7%	4% - 7%	5% - 5%
SO 0495	Rape seed (all commodities)	highest utilisation: Total	0.014 - 0.045	0	1.000	NL	toddler, 8-20 m	1882	21.3	<25	NR	3	0% - 0%	0% - 0%	0% - 0%
VL 0496	Rucola (arrugula, rocket salad, roquette)	raw		2.9	1.000	NL	Gen pop, > 1 yrs	E	77.8	0.3	NR	1	1%	1%	NC
VR 0498	Salsify (Oyster plant) (all commodities)	highest utilisation: cooked/boiled (without peel)	0.01	0.023	1.000	NL	Child, 2-6 yrs	E	133.3	57.0	3	2a	0% - 0%	0% - 0%	0% - 0%
FC 0005	Shaddock or pomelo + shaddock-like hybrid	highest utilisation: raw, without peel	0	0.44	1.000	DE	Child, 2-4 yrs	12	358.6	178.5	3	2a	1% - 6%	1% - 4%	1% - 6%

Annex 4

SULFOXAFLOR (252)
Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

Maximum %ARfD: 60% all; 40% gen pop; 60% child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
	(all commodities)														
VL 0502	Spinach (all commodities)	highest utilisation: Total	1.2	2.9	1.000	ZA	Child, 1-5 yrs	-	237.5	197.8	3	2a	0% - 40%	0% - 10%	0% - 40%
VA 0389	Spring onion (all commodities)	highest utilisation: cooked/boiled	0	0.39	1.000	NL	Child, 2-6 yrs	E	20.3	30.0	3	2b	0% - 0%	0% - 0%	0% - 0%
VC 0431	Squash, summer (courgette, marrow, zucchetti, zucchini) (all commodities)	highest utilisation: Total	0.029	0.27	1.000	NL	toddler, 8-20 m	11	82.1	328.3	3	2b	0% - 9%	0% - 9%	0% - 8%
FB 0275	Strawberry (all commodities)	highest utilisation: Total	0.057 - 0.19	0.21	1.000	FR	Child, 3-6 yrs	32.3%	339.4	13.4	NR	1	0% - 1%	0% - 1%	0% - 1%
VR 0596	Sugar beet (all commodities)	highest utilisation: sugar	0.014	0	1.000	FR	Child, 3-6 yrs	1	274.7	NR	NR	3	0% - 0%	0% - 0%	0% - 0%
VR 0497	Swede (rutabaga) (all commodities)	highest utilisation: cooked/boiled (without peel)	0.01	0.023	1.000	NL	Child, 2-6 yrs	4	102.8	617.0	3	2b	0% - 0%	0% - 0%	0% - 0%
VR 0508	Sweet potato (all commodities)	highest utilisation: cooked/boiled (without peel)	0.01	0.023	1.000	NL	Child, 2-6 yrs	E	171.1	126.0	3	2a	0% - 0%	0% - 0%	0% - 0%
VR 0504	Tannia (tanier, yautia) (all commodities)	highest utilisation: cooked/boiled (without peel)	0.01	0.023	1.000	NL	Gen pop, > 1 yrs	E	250.0	170.0	3	2a	0% - 0%	0% - 0%	0% - 0%
VR 0505	Taro (dasheen, eddoe) (all commodities)	highest utilisation: cooked/boiled (without peel)	0	0.023	1.000	CN	Child, 1-6 yrs	199	384.2	667.8	3	2b	0% - 1%	0% - 0%	0% - 1%
VL 0505	Taro leaves	raw		2.9	1.000	NL	Gen pop, > 1 yrs	E	77.8	85.8	3	2b	3%	3%	NC
VO 0448	Tomato (all commodities)	highest utilisation: dried	0.11	0.6	5.000	AU	Gen pop, > 2 yrs	61	861.1	8.0	NR	1	0% - 10%	0% - 10%	0% - 8%
GC 0653	Triticale	Total	0.025		1.000	DE	Gen pop, 14-80 yrs	27100	394.7	<25	NR	3	0%	0%	0%
VL 0506	Turnip greens (Namenia, Tendergreen) (all commodities)	highest utilisation: Total	0	2.9	1.000	NL	toddler, 8-20 m	110	322.0	<25	NR	1	2% - 30%	1% - 10%	2% - 30%
VR 0506	Turnip, garden (all commodities)	highest utilisation: cooked/boiled (without	0.01	0.023	1.000	NL	Child, 2-6 yrs	E	133.3	176.0	3	2b	0% - 1%	0% - 0%	0% - 1%

Annex 4

SULFOXAFLOR (252)
Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

Maximum %ARfD: 60% all, 40% gen pop, 60% child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
		peel)													
TN 0678	Walnut (all commodities)	highest utilisation: raw incl roasted	0.01	0.012	1.000	DE	Child, 2-4 yrs	75	49.4	7.0	NR	1	0% - 0%	0% - 0%	0% - 0%
-	Water chestnut	Total		0.03	1.000	AU	Gen pop, > 2 yrs	16	127.1	<25	NR	1	0%	0%	-
VL 0473	Watercress (all commodities)	highest utilisation: raw	0	2.9	1.000	BR	gen pop, > 10 yrs	97	90.9	254.6	3	2b	3% - 4%	3% - 4%	1% - 1%
VC 0432	Watermelon (all commodities)	highest utilisation: raw without peel	0.029	0.27	1.000	JP	Child, 1-6 yrs	56	448.8	3000.0	3	2b	8% - 8%	8% - 8%	8% - 8%
GC 0654	Wheat (all commodities)	highest utilisation: Total	0.005 - 0.1	0	1.000	FR	Child, 3-6 yrs	100.0%	384.3	<25	NR	3	0% - 0%	0% - 0%	0% - 0%
VR 0600	Yams (all commodities)	highest utilisation: raw without peel	0	0.03	1.000	JP	Child, 1-6 yrs	22	102.0	810.0	3	2b	0% - 0%	0% - 0%	0% - 0%

TOLFENPYRAD (269)
Acute RfD= 0.01 mg/kg bw (10 µg/kg bw)

Maximum %ARfD: 100% all, 100% gen pop, 80% child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
DT 1114	Tea, green, black (black, fermented and dried) (all commodities)	highest utilisation: infusion (brew/beverage)	0.24–5.65		1.000	BR	Gen pop, > 10 yrs	3534	2640.0	NR	NR	3	50–100%	80–100%	50–80%

Annex 4

TRIAZOPHOS (143)

Acute RfD= 0.001 mg/kg bw (1 µg/kg bw)

Maximum %ARfD: 130% all; 80% gen pop; 130% child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Varia-bility factor	Case	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
CM 0649	Rice	husked rice (cooked)	0.12		0.400	JP	Child, 1-6 yrs	991	446.3	<25	NR	3	130%	80%	130%
GC 0649	Rice (all other commodities)	highest utilisation: Wholemeal (milled husked rice)	0.041 - 0.12		1.000	AU	Child, 2-6 yrs	117.712	158.6	NR	NR	3	1 - 100%	1 - 60%	3 - 100%

TRIFLUMIZOLE (270)

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

Maximum %ARfD: 50% all; 20% gen pop; 50% child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Varia-bility factor	Case	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
FS 0013	Cherries (all commodities)	highest utilisation: raw	1.17	1.5	1.000	DE	Child, 2-4 yrs	2400.0%	187.5	7.2	NR	1	0% - 6%	0% - 5%	0% - 6%
SB 0716	Coffee beans (all commodities)	highest utilisation: Total	0.03		1.000	FR	Child, 3-6 yrs	6.5%	70.3	0.1	NR	3	0% - 0%	0% - 0%	0% - 0%
VC 0424	Cucumber (all commodities)	highest utilisation: raw with skin	0.13	0.21	1.000	CN	Child, 1-6 yrs	340	212.1	458.1	3	2b	0% - 3%	0% - 2%	0% - 3%
MO 0105	Edible offal (mammalian)	Total		0.12	1.000	US	Child, 1-6 yrs	-	186.6	NR	NR	1	0%	0%	0%
FB 0269	Grape (all commodities)	highest utilisation: raw with skin	0.17 - 0.41	0.44 - 2	1.000	CN	Child, 1-6 yrs	23200	366.7	636.6	3	2b	1% - 50%	0% - 20%	0% - 50%
DH 1100	Hops, dry (all commodities)	highest utilisation: Total	8.9		1.000	DE	Gen pop, 14-80 yrs	5866	8.5	<25	NR	3	0% - 0%	0% - 0%	0% - 0%
MF 0100	Mammalian fats (except milk fats)	Total		0.017	1.000	FR	Child, 3-6 yrs	39.9%	30.2	NR	NR	1	0%	0%	0%
MM 0095	Meat from mammals other than marine mammals	Total	NA	NA	1.000	AU	Child, 2-6 yrs	2269	254.3	NR	NR	1	0%	0%	0%

Annex 4

TRIFLUMIZOLE (270)

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

Maximum %ARfD: 50% all; 20% gen pop; 50% child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Varia-bility factor	Case	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
MM 0095	Meat from mammals other than marine mammals: 20% as fat	Total		0.017	1.000	AU	Child, 2-6 yrs	2269	50.9	NR	NR	1	0%	0%	0%
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	Total		0	1.000	AU	Child, 2-6 yrs	2269	203.5	NR	NR	1	0%	0%	0%
ML 0106	Milks	Total	0		1.000	AU	Child, 2-6 yrs	2923	1933.6	NR	NR	3	0%	0%	0%
FI 0350	Papaya (all commodities)	highest utilisation: raw without peel	0.71	0.89	1.000	CN	Gen pop, > 1 yrs	350	733.9	526.4	3	2a	0% - 10%	0% - 10%	1% - 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.

6. Pesticide residues in food. Joint report of the FAO Working Party on Pesticide Residues and the WHO Expert Committee on Pesticide Residues. FAO Agricultural Studies, No. 73; WHO Technical Report Series, No. 370, 1967.

7. Evaluation of some pesticide residues in food. FAO/PL:CP/15; WHO/Food Add./67.32, 1967.

8. Pesticide residues. Report of the 1967 Joint Meeting of the FAO Working Party and the WHO Expert Committee. FAO Meeting Report, No. PL:1967/M/11; WHO Technical Report Series, No. 391, 1968.

9. 1967 Evaluations of some pesticide residues in food. FAO/PL:1967/M/11/1; WHO/Food Add./68.30, 1968.

10. Pesticide residues in food. Report of the 1968 Joint Meeting of the FAO Working Party of Experts on Pesticide Residues and the WHO Expert Committee on Pesticide Residues. FAO Agricultural Studies, No. 78; WHO Technical Report Series, No. 417, 1968.

11. 1968 Evaluations of some pesticide residues in food. FAO/PL:1968/M/9/1; WHO/Food Add./69.35, 1969.

12. Pesticide residues in food. Report of the 1969 Joint Meeting of the FAO Working Party of Experts on Pesticide Residues and the WHO Expert Group on Pesticide Residues. FAO Agricultural Studies, No. 84; WHO Technical Report Series, No. 458, 1970.

13. 1969 Evaluations of some pesticide residues in food. FAO/PL:1969/M/17/1; WHO/Food Add./70.38, 1970.

14. Pesticide residues in food. Report of the 1970 Joint Meeting of the FAO Working Party of Experts on Pesticide Residues and the WHO Expert Committee on Pesticide Residues. FAO Agricultural Studies, No. 87; WHO Technical Report Series, No. 4574, 1971.

15. 1970 Evaluations of some pesticide residues in food. AGP:1970/M/12/1; WHO/Food Add./71.42, 1971.

16. Pesticide residues in food. Report of the 1971 Joint Meeting of the FAO Working Party of Experts on Pesticide Residues and the WHO Expert Committee on Pesticide Residues. FAO Agricultural Studies, No. 88; WHO Technical Report Series, No. 502, 1972.

17. 1971 Evaluations of some pesticide residues in food. AGP:1971/M/9/1; WHO Pesticide Residue Series, No. 1, 1972.

18. Pesticide residues in food. Report of the 1972 Joint Meeting of the FAO Working Party of Experts on Pesticide Residues and the WHO Expert Committee on Pesticide Residues. FAO Agricultural Studies, No. 90; WHO Technical Report Series, No. 525, 1973.

19. 1972 Evaluations of some pesticide residues in food. AGP:1972/M/9/1; WHO Pesticide Residue Series, No. 2, 1973.

20. Pesticide residues in food. Report of the 1973 Joint Meeting of the FAO Working Party of Experts on Pesticide Residues and the WHO Expert Committee on Pesticide Residues. FAO Agricultural Studies, No. 92; WHO Technical Report Series, No. 545, 1974.

21. 1973 Evaluations of some pesticide residues in food. FAO/AGP/1973/M/9/1; WHO Pesticide Residue Series, No. 3, 1974.

22. 22. Pesticide residues in food. Report of the 1974 Joint Meeting of the FAO Working Party of Experts on Pesticide Residues and the WHO Expert Committee on Pesticide Residues. FAO Agricultural Studies, No. 97; WHO Technical Report Series, No. 574, 1975.

23. 1974 Evaluations of some pesticide residues in food. FAO/AGP/1974/M/11; WHO Pesticide Residue Series, No. 4, 1975.

24. Pesticide residues in food. Report of the 1975 Joint Meeting of the FAO Working Party of Experts on Pesticide Residues and the WHO Expert Committee on Pesticide Residues. FAO Plant Production and Protection Series, No. 1; WHO Technical Report Series, No. 592, 1976.

25. 1975 Evaluations of some pesticide residues in food. AGP:1975/M/13; WHO Pesticide Residue Series, No. 5, 1976.

26. Pesticide residues in food. Report of the 1976 Joint Meeting of the FAO Panel of Experts on Pesticide Residues and the Environment and the WHO Expert Group on Pesticide Residues. FAO Food and Nutrition Series, No. 9; FAO Plant Production and Protection Series, No. 8; WHO Technical Report Series, No. 612, 1977.

27. 1976 Evaluations of some pesticide residues in food. AGP:1976/M/14, 1977.

28. Pesticide residues in food—1977. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues and Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 10 Rev, 1978.

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31. Pesticide residues in food: 1978 evaluations. FAO Plant Production and Protection Paper 15 Suppl., 1979.

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35. Pesticide residues in food: 1980 evaluations. FAO Plant Production and Protection Paper 26 Suppl., 1981.

36. Pesticide residues in food—1981. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 37, 1982.

37. Pesticide residues in food: 1981 evaluations. FAO Plant Production and Protection Paper 42, 1982.

38. Pesticide residues in food—1982. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 46, 1982.

39. Pesticide residues in food: 1982 evaluations. FAO Plant Production and Protection Paper 49, 1983.

40. Pesticide residues in food—1983. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 56, 1985.

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42. Pesticide residues in food—1984. Report of the Joint Meeting on Pesticide Residues. FAO Plant Production and Protection Paper 62, 1985.

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53. Pesticide residues in food—1988. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and a WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 92, 1988.

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ANNEX 6: LIVESTOCK DIETARY BURDEN

AZOXYSTROBIN - 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	44	HR	23	191.30		20				38.26		
Sorghum, asp. grain fraction	CM/CF	92.5	STMR	85	108.82	5		20		5.44		21.76	
Soya bean hay	AL	53	HR	85	62.35			80				49.88	
Pea vines	AL	9.4	HR	25	37.60		20				7.52		
Sorghum, grain forage	AF/AS	12	HR	35	34.29	15	20			5.14	6.86		
Corn, field stover	AF/AS	21	HR	83	25.30		5				1.27		
Cowpea hay	AL	18	HR	86	20.93		15				3.14		
Corn, field forage/silage	AF/AS	7.2	HR	40	18.00		20				3.6		
Potato process waste	AB	2.08	STMR	12	17.33	30				5.2			
Sorghum, grain grain	GC	1.85	STMR	86	2.15	40			35	0.86			0.75
Rice bran/pollard	CM/CF	0.82	STMR	90	0.91	10			20	0.09			0.18
Soya bean seed	VD	0.06	STMR	89	0.07				15				0.01
Barley grain	GC	0.05	STMR	88	0.06				30				0.017
Total						100	100	100	100	16.7	60.6	71.6	0.96

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	44	HR	23	191.3		30				57.39		
Soya bean hay	AL	53	HR	85	62.35	20		40		12.47		24.94	
Sorghum, grain forage	AF/AS	12	HR	35	34.29	40	20	60	40	13.71	6.86	20.57	13.7
Cowpea hay	AL	18	HR	86	20.93		35				7.33		
Corn, field forage/silage	AF/AS	7.2	HR	40	18.00	5	15		10	0.9	2.7		1.8
Potato process waste	AB	2.08	STMR	12	17.33	10				1.73			
Carrot culls	VR	0.45	HR	12	3.75	10				0.38			
Sorghum, grain grain	GC	1.85	STMR	86	2.15	15			30	0.32			0.65
Rice bran/pollard	CM/CF	0.82	STMR	90	0.91				10				0.09
Soya bean seed	VD	0.06	STMR	89	0.07				10				0.007
Total						100	100	100	100	29.5	74.3	45.5	16.3

POULTRY BROILER MAX

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%) US-CAN	EU	AU	JP	Residue Contribution (ppm) US-CAN	EU	AU	JP
Swede roots	VR	0.45	HR	10	4.50		10				0.45		
Sorghum, grain grain	GC	1.85	STMR	86	2.15	75	70	70	65	1.61	1.51	1.51	1.398
Cassava/tapioca roots	VR	0.45	HR	37	1.22		10				0.12		
Rice bran/pollard	CM/CF	0.82	STMR	90	0.91	10	10	20	5	0.09	0.09	0.18	0.046
Soya bean hulls	SM	0.13	STMR	90	0.14			5				0.007	
Soya bean seed	VD	0.06	STMR	89	0.07	15		5		0.01		0.003	
Total						100	100	100	70	1.71	2.17	1.7	1.4

POULTRY LAYER **MAX**

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%) US- CAN	EU	AU	JP	Residue Contribution (ppm) US-CAN	EU	AU	JP
Beet, sugar tops	AM/AV	44	HR	23	191.30		5				9.57		
Soya bean hay	AL	53	HR	85	62.35		10				6.24		
Sorghum, grain forage	AF/AS	12	HR	35	34.29		10				3.43		
Swede roots	VR	0.45	HR	10	4.50		10				0.45		
Sorghum, grain grain	GC	1.85	STMR	86	2.15	75	65	70	55	1.61	1.4	1.51	1.18
Rice bran/pollard	CM/CF	0.82	STMR	90	0.91	10		20	20	0.09		0.182	0.18
Soya bean hulls	SM	0.13	STMR	90	0.14			5				0.007	
Soya bean seed	VD	0.06	STMR	89	0.07	15		5		0.01		0.0034	
Corn, field grain	GC	0.01	STMR	88	0.01				25				0.0028
Total						100	100	100	100	1.7	21.1	1.7	1.4

AZOXYSTROBIN - ESTIMATED MEAN DIETARY BURDEN

BEEF CATTLE MEAN

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%) US-CAN	EU	AU	JP	Residue Contribution (ppm) US-CAN	EU	AU	JP
Sorghum, grain asp gr fn	CM/CF	92.5	STMR/STMR-P	85	108.82	5		20		5.44		21.77	
Beet, sugar tops	AM/AV	16	STMR/STMR-P	23	69.57		20				13.91		
Soya bean hay	AL	31	STMR/STMR-P	85	36.47			80				29.18	
Potato process waste	AB	2.08	STMR/STMR-P	12	17.33	30	40			5.2	6.93		
Pea vines	AL	3.35	STMR/STMR-P	25	13.40		20				2.68		
Wheat forage	AF/AS	1.9	STMR/STMR-P	25	7.60		20				1.52		
Corn, field stover	AF/AS	4.2	STMR/STMR-P	83	5.06	15				0.76			
Sorghum, grain grain	GC	1.85	STMR/STMR-P	86	2.15	40			35	0.86			0.75
Rice bran/pollard	CM/CF	0.82	STMR/STMR-P	90	0.91	10			20	0.091			0.18
Soya bean seed	VD	0.06	STMR/STMR-P	89	0.07				15				0.01
Barley grain	GC	0.05	STMR/STMR-P	88	0.06				30				0.017
Total						100	100	100	100	12.35	25.05	50.9	0.96

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
Beet, sugar tops	AM/AV	16	STMR/STMR-P	23	69.57		30	0			20.87	0	
Soya bean hay	AL	31	STMR/STMR-P	85	36.47	20		40		7.29		14.59	
Potato process waste	AB	2.08	STMR/STMR-P	12	17.33	10	30			1.73	5.2		
Grape pomace, wet	AB	1.6	STMR/STMR-P	15	10.67	0		20		0		2.13	
Citrus dried pulp	AB	9.3	STMR/STMR-P	91	10.22	0		10		0		1.02	
Wheat forage	AF/AS	1.9	STMR/STMR-P	25	7.60	20	20	30		1.52	1.52	2.28	
Barley forage	AF/AS	1.7	STMR/STMR-P	30	5.67	0	10			0	0.57		
Oat forage	AF/AS	1.7	STMR/STMR-P	30	5.67	10				0.57			
Sorghum, grain forage	AF/AS	1.6	STMR/STMR-P	35	4.57	10			40	0.46			1.83
Corn, field forage/silage	AF/AS	1.6	STMR/STMR-P	40	4.00	5	10		10	0.2	0.4		0.4
Sorghum, grain grain	GC	1.85	STMR/STMR-P	86	2.15	25			30	0.54			0.645
Rice bran/pollard	CM/CF	0.82	STMR/STMR-P	90	0.91	0			10	0			0.09
Soya bean seed	VD	0.06	STMR/STMR-P	89	0.07	0			10	0			0.0067
Total						100	100	100	100	12.3	28.6	20.0	2.97

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
Swede roots	VR	0.23	STMR/STMR-P	10	2.30		10				0.23		
Sorghum, grain grain	GC	1.85	STMR/STMR-P	86	2.15	75	70	70	65	1.61	1.51	1.51	1.4
Rice bran/pollard	CM/CF	0.82	STMR/STMR-P	90	0.91	10	10	20	5	0.09	0.09	0.18	0.046
Cassava/tapioca roots	VR	0.23	STMR/STMR-P	37	0.62		10				0.06		
Soya bean hulls	SM	0.13	STMR/STMR-P	90	0.14			5				0.007	
Soya bean seed	VD	0.06	STMR/STMR-P	89	0.07	15		5		0.01		0.003	
Total						100	100	100	70	1.7	1.9	1.7	1.4

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	16	STMR/STMR-P	23	69.57		5				3.48		
Soya bean hay	AL	31	STMR/STMR-P	85	36.47		10				3.65		
Wheat forage	AF/AS	1.9	STMR/STMR-P	25	7.60		10				0.76		
Swede roots	VR	0.23	STMR/STMR-P	10	2.30		10				0.23		
Sorghum, grain grain	GC	1.85	STMR/STMR-P	86	2.15	75	65	70	55	1.61	1.4	1.51	1.18
Rice bran/pollard	CM/CF	0.82	STMR/STMR-P	90	0.91	10		20	20	0.09		0.18	0.18
Soya bean hulls	SM	0.13	STMR/STMR-P	90	0.14			5				0.007	
Soya bean seed	VD	0.06	STMR/STMR-P	89	0.07	15		5		0.01		0.003	
Corn, field grain	GC	0.01	STMR/STMR-P	88	0.01				25				0.003
Total						100	100	100	100	1.7	9.5	1.7	1.4

BENTAZONE - 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	13.1	HR	25	52.40		20	60			10.48	31.44	
Grass forage (fresh)	AF/AS	0.37	HR	25	1.48		50	40	5		0.74	0.592	0.074
Grass hay	AF/AS	1.16	HR	88	1.32	15			35	0.197727			0.461
Alfalfa hay	AL	0.23	HR	89	0.26	15			10	0.038764			0.026
Alfalfa forage	AL	0.07	HR	35	0.20		30				0.06		
Sorghum, grain grain	GC	0.01	STMR	86	0.01	40			35	0.004651			0.004
Barley grain	GC	0.01	STMR	88	0.01	10			15	0.001136			0.002
Corn, field grain	GC	0.01	STMR	88	0.01	20				0.002273			
Total						100	100	100	100	0.244552	11.28	32.03	0.567

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	13.1	HR	25	52.40	10	20	40		5.24	10.48	20.96	
Grass forage (fresh)	AF/AS	0.37	HR	25	1.48	45	60	60	10	0.666	0.888	0.888	0.148
Grass hay	AF/AS	1.16	HR	88	1.32				60				0.791
Alfalfa hay	AL	0.23	HR	89	0.26	10	20		25	0.025843	0.052		0.065
Sorghum, grain grain	GC	0.01	STMR	86	0.01	35			5	0.00407			6E-04
Total						100	100	100	100	5.935912	11.42	21.85	1.004

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	0.07	HR	35	0.20				5				0.01
Bean seed	VD	0.02	STMR	88	0.02		20	70			0.005	0.016	
Sorghum, grain grain	GC	0.01	STMR	86	0.01	75	70	30	65	0.008721	0.008	0.003	0.008
Rice bran/pollard	CM/CF	0.0037	STMR	90	0.00	10	10		5	0.000411	4E-04		2E-04
Total						85	100	100	75	0.009132	0.013	0.019	0.018

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	13.1	HR	25	52.40		10				5.24		
Grass forage (fresh)	AF/AS	0.37	HR	25	1.48		10				0.148		
Bean seed	VD	0.02	STMR	88	0.02		20	70			0.005	0.016	
Sorghum, grain grain	GC	0.01	STMR	86	0.01	75	60	30	55	0.008721	0.007	0.003	0.006
Corn, field grain	GC	0.01	STMR	88	0.01				25				0.003
Rice bran/pollard	CM/CF	0.0037	STMR	90	0.00	10			20	0.000411			8E-04
Total						85	100	100	100	0.009132	5.4	0.019	0.01

BENTAZONE - 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	0.22	STMR/STMR-P	25	0.88		20	60			0.176	0.528	
Grass forage (fresh)	AF/AS	0.17	STMR/STMR-P	25	0.68		50	40	5		0.34	0.272	0.034
Grass hay	AF/AS	0.215	STMR/STMR-P	88	0.24	15			35	0.036648			0.086
Alfalfa hay	AL	0.09	STMR/STMR-P	89	0.10	15			10	0.015169			0.01
Alfalfa forage	AL	0.03	STMR/STMR-P	35	0.09		30				0.026		
Sorghum, grain grain	GC	0.01	STMR/STMR-P	86	0.01	40			35	0.004651			0.004
Barley grain	GC	0.01	STMR/STMR-P	88	0.01	10			15	0.001136			0.002
Corn, field grain	GC	0.01	STMR/STMR-P	88	0.01	20				0.002273			
Total						100	100	100	100	0.059877	0.542	0.8	0.135

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	0.22	STMR/STMR-P	25	0.88	10	20	40		0.088	0.176	0.352	
Grass forage (fresh)	AF/AS	0.17	STMR/STMR-P	25	0.68	45	60	60	10	0.306	0.408	0.408	0.068
Grass hay	AF/AS	0.215	STMR/STMR-P	88	0.24	0			60	0			0.147
Alfalfa hay	AL	0.09	STMR/STMR-P	89	0.10	10	20		25	0.010112	0.02		0.025
Sorghum, grain grain	GC	0.01	STMR/STMR-P	86	0.01	35			5	0.00407			6E-04
Total						100	100	100	100	0.408182	0.604	0.76	0.24

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	0.03	STMR/STMR-P	35	0.09				5				0.004
Bean seed	VD	0.02	STMR/STMR-P	88	0.02		20	70			0.005	0.016	
Sorghum, grain grain	GC	0.01	STMR/STMR-P	86	0.01	75	70	30	65	0.008721	0.008	0.003	0.008
Rice bran/pollard	CM/CF	0.0037	STMR/STMR-P	90	0.00	10	10		5	0.000411	4E-04		2E-04
Total						85	100	100	75	0.009132	0.013	0.019	0.012

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	0.22	STMR/STMR-P	25	0.88		10				0.088		
Grass forage (fresh)	AF/AS	0.17	STMR/STMR-P	25	0.68		10				0.068		
Bean seed	VD	0.02	STMR/STMR-P	88	0.02		20	70			0.005	0.016	
Sorghum, grain grain	GC	0.01	STMR/STMR-P	86	0.01	75	60	30	55	0.008721	0.007	0.003	0.006
Corn, field grain	GC	0.01	STMR/STMR-P	88	0.01				25				0.003
Rice bran/pollard	CM/CF	0.0037	STMR/STMR-P	90	0.00	10			20	0.000411			8E-04
Total						85	100	100	100	0.009132	0.168	0.019	0.01

CHLORANTRANILIPROLE - 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	30.67	HR	89	34.46	15		80	10	5.169101		27.57	3.446
Pea vines	AL	6.4	HR	25	25.60		20				5.12		
Alfalfa forage	AL	7.3	HR	35	20.86		50	20			10.43	4.171	
Corn, field stover	AF/AS	12	HR	83	14.46	15	25			2.168675	3.614		
Corn, field forage/silage	AF/AS	5.7	HR	40	14.25		5				0.713		
Cotton gin byproducts	AM/AV	4.1	HR	90	4.56	5				0.227778			
Rice bran/pollard	CM/CF	0.196	STMR	90	0.22	15			20	0.032667			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	0.004	STMR	88	0.00				70				0.003
Total						100	100	100	100	7.63979	19.88	31.74	3.493

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	30.67	HR	89	34.46	20	40	60	25	6.892135	13.78	20.68	8.615
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
Apple pomace, wet	AB	0.154	STMR	40	0.39	10				0.0385			
Carrot culls	VR	0.04	HR	12	0.33	10				0.033333			
Rice bran/pollard	CM/CF	0.196	STMR	90	0.22	15			10	0.032667			0.022
Barley grain	GC	0.004	STMR	88	0.00				15				7E-04
Total						100	100	100	100	13.44031	22.38	26.84	15.76

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	7.3	HR	35	20.86				5				1.043
Carrot culls	VR	0.04	HR	12	0.33		10				0.033		
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	
Barley grain	GC	0.004	STMR	88	0.00	50	70			0.002273	0.003		
Corn, field grain	GC	0.004	STMR	88	0.00				70				0.003
Total						100	95	80	80	0.058457	0.06	0.113	1.057

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	0.04	HR	12	0.33		10				0.033		
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	
Barley grain	GC	0.004	STMR	88	0.00	50	55			0.002273	0.003		
Corn, field grain	GC	0.004	STMR	88	0.00				80				0.004
Total						100	100	80	100	0.058457	4.421	0.113	0.047

CHLORANTRANILIPROLE - 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	13.3	STMR/STMR-P	89	14.94	15		20	10	2.241573		2.989	1.494
Alfalfa forage	AL	3.8	STMR/STMR-P	35	10.86		50	20			5.429	2.171	
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			
Rice bran/pollard	CM/CF	0.196	STMR/STMR-P	90	0.22	15			20	0.032667			0.044
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			
Barley grain	GC	0.004	STMR/STMR-P	88	0.00	20			70	0.000909			0.003
Total						100	100	100	100	3.440496	10.75	15.72	1.541

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	13.3	STMR/STMR-P	89	14.94	10	20	20	25	1.494382	2.989	2.989	3.736
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
Apple pomace, wet	AB	0.154	STMR/STMR-P	40	0.39	10				0.0385			
Rice bran/pollard	CM/CF	0.196	STMR/STMR-P	90	0.22	15			10	0.032667			0.022
Rice grain	GC	0.115	STMR/STMR-P	88	0.13	10				0.013068			
Barley grain	GC	0.004	STMR/STMR-P	88	0.00	0			15	0			7E-04
Total						100	100	100	100	6.038617	10.11	13.09	6.758

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	3.8	STMR/STMR-P	35	10.86				5				0.543
Rice bran/pollard	CM/CF	0.196	STMR/STMR-P	90	0.22	10	10	20	5	0.021778	0.022	0.044	0.011
Rice grain	GC	0.115	STMR/STMR-P	88	0.13	20		50		0.026136		0.065	
Carrot culls	VR	0.01	STMR/STMR-P	12	0.08		10				0.008		
Cotton meal	SM	0.0368	STMR/STMR-P	89	0.04	20	5	10		0.00827	0.002	0.004	
Barley grain	GC	0.004	STMR/STMR-P	88	0.00	50	70			0.002273	0.003		
Corn, field grain	GC	0.004	STMR/STMR-P	88	0.00				70				0.003
Total						100	95	80	80	0.058457	0.035	0.113	0.557

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	0.044
Rice grain	GC	0.115	STMR/STMR-P	88	0.13	20		50		0.026136		0.065	
Carrot culls	VR	0.01	STMR/STMR-P	12	0.08		10				0.008		
Cotton meal	SM	0.0368	STMR/STMR-P	89	0.04	20	5	10		0.00827	0.002	0.004	
Barley grain	GC	0.004	STMR/STMR-P	88	0.00	50	55			0.002273	0.003		
Corn, field grain	GC	0.004	STMR/STMR-P	88	0.00				80				0.004
Total						100	100	80	100	0.058457	2.512	0.113	0.047

CHLORPYRIFOS-METHYL - 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 milled bypdts	CM/CF	5.14	STMR	88	5.84	40	30	40	55	2.336364	1.752	2.336	3.213
Sorghum, grain grain	GC	3	STMR	86	3.49	40	40	60	35	1.395349	1.395	2.093	1.221
Barley grain	GC	3	STMR	88	3.41	10	30		10	0.340909	1.023		0.341
Total						90	100	100	100	4.072622	4.17	4.429	4.774

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 milled bypdts	CM/CF	5.14	STMR	88	5.84	30	30	40	45	1.752273	1.752	2.336	2.628
Sorghum, grain grain	GC	3	STMR	86	3.49	45	40	50	30	1.569767	1.395	1.744	1.047
Total						75	70	90	75	3.32204	3.148	4.081	3.675

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	5.14	STMR	88	5.84	50	20	20	5	2.920455	1.168	1.168	0.292
Sorghum, grain grain	GC	3	STMR	86	3.49	50	70	70	65	1.744186	2.442	2.442	2.267
Total						100	90	90	70	4.664641	3.61	3.61	2.559

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 milled bypdts	CM/CF	5.14	STMR	88	5.84	50	20	20	30	2.920455	1.168	1.168	1.752
Sorghum, grain grain	GC	3	STMR	86	3.49	50	70	70	55	1.744186	2.442	2.442	1.919
Barley grain	GC	3	STMR	88	3.41		10				0.341		
Total						100	100	90	85	4.664641	3.951	3.61	3.671

CHLORPYRIFOS-METHYL - 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	5.14	STMR/STMR-P	88	5.84	40	30	40	55	2.336364	1.752	2.336	3.213
Sorghum, grain grain	GC	3	STMR/STMR-P	86	3.49	40	40	60	35	1.395349	1.395	2.093	1.221
Barley grain	GC	3	STMR/STMR-P	88	3.41	10	30		10	0.340909	1.023		0.341
Total						90	100	100	100	4.072622	4.17	4.429	4.774

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	5.14	STMR/STMR-P	88	5.84	30	30	40	45	1.752273	1.752	2.336	2.628
Sorghum, grain grain	GC	3	STMR/STMR-P	86	3.49	45	40	50	30	1.569767	1.395	1.744	1.047
Total						75	70	90	75	3.32204	3.148	4.081	3.675

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	5.14	STMR/STMR-P	88	5.84	50	20	20	5	2.920455	1.168	1.168	0.292
Sorghum, grain grain	GC	3	STMR/STMR-P	86	3.49	50	70	70	65	1.744186	2.442	2.442	2.267
Total						100	90	90	70	4.664641	3.61	3.61	2.559

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	5.14	STMR/STMR-P	88	5.84	50	20	20	30	2.920455	1.168	1.168	1.752
Sorghum, grain grain	GC	3	STMR/STMR-P	86	3.49	50	70	70	55	1.744186	2.442	2.442	1.919
Barley grain	GC	3	STMR/STMR-P	88	3.41		10				0.341		
Total						100	100	90	85	4.664641	3.951	3.61	3.671

CYANTRANILIPROLE - ESTIMATED MAXIMUM DIETARY BURDEN

BEEF CATTLE — MAX

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						USCAN	EU	AU	JP	US-CAN	EU	AU	JP
Cabbage heads, leaves	AM/AV	1.1	HR	15	7.33		20				1.467		
Peanut hay	AL	0.58	HR	85	0.68			60				0.409	
Soya bean hay	AL	0.58	HR	85	0.68			40				0.273	
Cowpea hay	AL	0.58	HR	86	0.67		35				0.236		
Lespedeza hay	AL	0.58	HR	88	0.66	15				0.098864			
Alfalfa hay	AL	0.58	HR	89	0.65				10				0.065
Potato culls	VR	0.1	HR	20	0.50	30	30			0.15	0.15		
Clover forage	AL	0.14	HR	30	0.47		15				0.07		
Potato process waste	AB	0.046	STMR	12	0.38	30				0.115			
Corn, field stover	AF/AS	0.23	HR	83	0.28	15				0.041566			
Grass forage (fresh)	AF/AS	0.053	HR	25	0.21				5				0.011
Grass hay	AF/AS	0.14	HR	88	0.16				35				0.056
Total						90	100	100	50	0.40543	1.923	0.682	0.131

DAIRY CATTLE MAX

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						USCAN	EU	AU	JP	US-CAN	EU	AU	JP
Cabbage heads, leaves	AM/AV	1.1	HR	15	7.33		20				1.467		
Peanut hay	AL	0.58	HR	85	0.68	15		60		0.102353		0.409	
Soya bean hay	AL	0.58	HR	85	0.68	5				0.034118			
Cowpea hay	AL	0.58	HR	86	0.67		35				0.236		
Lespedeza hay	AL	0.58	HR	88	0.66	20				0.131818			
Pea hay	AL	0.58	HR	88	0.66			40				0.264	
Alfalfa hay	AL	0.58	HR	89	0.65		5		25		0.033		0.163
Potato culls	VR	0.1	HR	20	0.50	10	30			0.05	0.15		
Clover forage	AL	0.14	HR	30	0.47		10				0.047		
Potato process waste	AB	0.046	STMR	12	0.38	10				0.038333			
Corn, field stover	AF/AS	0.23	HR	83	0.28	15				0.041566			
Sorghum, grain stover	AF/AS	0.23	HR	88	0.26				5				0.013
Grass forage (fresh)	AF/AS	0.053	HR	25	0.21	25			5	0.053			0.011
Grass hay	AF/AS	0.14	HR	88	0.16				65				0.103
Total						100	100	100	100	0.451188	1.932	0.673	0.29

POULTRY BROILER MAX

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						USCAN	EU	AU	JP	US-CAN	EU	AU	JP
Potato culls	VR	0.1	HR	20	0.50		10				0.05		
Total							10				0.05		

POULTRY LAYER MAX

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						USCAN	EU	AU	JP	US-CAN	EU	AU	JP
Cabbage heads, leaves	AM/AV	1.1	HR	15	7.33		5				0.367		
Total							5				0.367		

CYANTRANILIPROLE - ESTIMATED MEAN DIETARY BURDEN

BEEF CATTLE MEAN

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						USCAN	EU	AU	JP	US-CAN	EU	AU	JP
Cabbage heads, leaves	AM/AV	0.56	STMR	15	3.73		20				0.747		
Apple pomace, wet	AB	0.16	STMR-P	40	0.40		20	20			0.08	0.08	
Potato process waste	AB	0.046	STMR-P	12	0.38	30	20			0.115	0.077		
Potato culls	VR	0.046	STMR-P	20	0.23	30	30	10		0.069	0.069	0.023	
Swede roots	VR	0.01	STMR	10	0.10		10				0.01		
Corn, field stover	AF/AS	0.05	STMR	83	0.06	15		40		0.009036		0.024	
Sorghum, grain stover	AF/AS	0.05	STMR	88	0.06			30				0.017	
Grass forage (fresh)	AF/AS	0.01	STMR	25	0.04				5				0.002
Alfalfa hay	AL	0.017	STMR	89	0.02	15			10	0.002865			0.002
Clover hay	AL	0.017	STMR	89	0.02	10				0.00191			
Total						100	100	100	15	0.197811	0.982	0.144	0.004

DAIRY CATTLE — MEAN

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						USCAN	EU	AU	JP	US-CAN	EU	AU	JP
Cabbage heads, leaves	AM/AV	0.56	STMR	15	3.73		20	0			0.747	0	
Apple pomace, wet	AB	0.16	STMR-P	40	0.40	10	10	10		0.04	0.04	0.04	
Potato process waste	AB	0.046	STMR-P	12	0.38	0	20			0	0.077		
Potato culls	VR	0.046	STMR-P	20	0.23	10	30	10		0.023	0.069	0.023	
Beet, mangel fodder	AM/AV	0.01	STMR	15	0.07	0	20			0	0.013		
Kale leaves	AM/AV	0.01	STMR	15	0.07	0		40		0		0.027	
Corn, field stover	AF/AS	0.05	STMR	83	0.06	15		40		0.009036		0.024	
Sorghum, grain stover	AF/AS	0.05	STMR	88	0.06	0			5	0			0.003
Lespedeza forage	AL	0.01	STMR	22	0.05	40				0.018182			
Grass forage (fresh)	AF/AS	0.01	STMR	25	0.04	25			5	0.01			0.002
Corn, field forage/silage	AF/AS	0.01	STMR	40	0.03	0			40	0			0.01
Alfalfa hay	AL	0.017	STMR	89	0.02	0			25	0			0.005
Total						100	100	100	75	0.100218	0.946	0.114	0.02

POULTRY BROILER — MEAN

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						USCAN	EU	AU	JP	US-CAN	EU	AU	JP
Potato culls	VR	0.046	STMR-P	20	0.23		10				0.023		
Total							10				0.023		

POULTRY LAYER — MEAN

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						USCAN	EU	AU	JP	US-CAN	EU	AU	JP
Cabbage heads, leaves	AM/AV	0.56	STMR	15	3.73		5				0.187		
Total							5				0.187		

CYPRODINIL - 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	8	HR	15	53.33		20				10.667		
Barley straw	AF/AS	5.8	HR	100	5.80	10	30	100		0.58	1.74	5.8	
Apple pomace, wet	AB	1.8	STMR	40	4.50		20				0.9		
Carrot culls	VR	0.4	HR	12	3.33		15				0.5		
Barley grain	GC	0.58	STMR	88	0.66	50	15		70	0.3296	0.0989		0.4613
Total						60	100	100	70	0.9096	13.905	5.8	0.4614

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	1.8	STMR/STMR-P	40	4.50		20	20			0.9	0.9	
Kale leaves	AM/AV	0.37	STMR/STMR-P	15	2.47		20				0.493		
Carrot culls	VR	0.09	STMR/STMR-P	12	0.75		15	5			0.113	0.038	
Barley grain	GC	0.58	STMR/STMR-P	88	0.66	50	45	75	70	0.330	0.297	0.494	0.461
Barley straw	AF/AS	0.395	STMR/STMR-P	100	0.40	10				0.040			
Total						60	100	100	70	0.369	1.802	1.432	0.461

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	8	HR	15	53.33		20	40			10.667	21.333	
Barley straw	AF/AS	5.8	HR	100	5.80	10	30	20		0.580	1.740	1.160	
Apple pomace, wet	AB	1.8	STMR	40	4.50	10	10	10		0.450	0.450	0.450	
Carrot culls	VR	0.4	HR	12	3.33	10	15	5		0.333	0.500	0.167	
Barley grain	GC	0.58	STMR	88	0.66	45	25	25	40	0.297	0.165	0.165	0.264
Almond hulls	AM/AV	0.05	STMR	90	0.06	10				0.006			
Total						85	100	100	40	1.665	13.521	23.275	0.264

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	1.8	STMR/STMR-P	40	4.50	10	10	10		0.45	0.45	0.45	
Kale leaves	AM/AV	0.37	STMR/STMR-P	15	2.47	0	20	40		0	0.493	0.987	
Carrot culls	VR	0.09	STMR/STMR-P	12	0.75	10	15	5		0.075	0.113	0.038	
Barley grain	GC	0.58	STMR/STMR-P	88	0.66	45	40	40	40	0.297	0.264	0.264	0.264
Barley straw	AF/AS	0.395	STMR/STMR-P	100	0.40	10	15	5		0.040	0.059	0.020	
Almond hulls	AM/AV	0.05	STMR/STMR-P	90	0.06	10				0.006			
Total						85	100	100	40	0.867	1.379	1.758	0.264

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	0.4	HR	12	3.33		10				0.333		
Barley grain	GC	0.58	STMR	88	0.66	75	70	15	10	0.494	0.461	0.099	0.066
Bean seed	VD	0.03	STMR	88	0.03		20	70			0.007	0.024	
Total						75	100	85	10	0.494	0.802	0.123	0.066

CYPRODINIL - ESTIMATED MEAN DIETARY BURDEN

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/STMR-P	12	0.75		10				0.075		
Barley grain	GC	0.58	STMR/STMR-P	88	0.66	75	70	15	10	0.494	0.461	0.099	0.066
Bean seed	VD	0.03	STMR/STMR-P	88	0.03		20	70			0.007	0.024	
Total						75	100	85	10	0.494	0.543	0.123	0.066

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	8	HR	15	53.33		5				2.667		
Barley straw	AF/AS	5.8	HR	100	5.80		5				0.290		
Wheat straw	AF/AS	5.8	HR	100	5.80		5				0.290		
Carrot culls	VR	0.4	HR	12	3.33		10				0.333		
Barley grain	GC	0.58	STMR	88	0.66	75	75	15		0.494	0.494	0.099	
Bean seed	VD	0.03	STMR	88	0.03			70				0.024	
Total						75	100	85		0.494	4.074	0.123	

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	0.37	STMR/STMR-P	15	2.47		5				0.123		
Carrot culls	VR	0.09	STMR/STMR-P	12	0.75		10				0.075		
Barley grain	GC	0.58	STMR/STMR-P	88	0.66	75	85	15		0.494	0.560	0.099	
Bean seed	VD	0.03	STMR/STMR-P	88	0.03			70				0.024	
Total						75	100	85		0.494	0.759	0.123	

DIFENOCONAZOLE - 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	6.2	STMR	15	41.33			20				8.267	
Potato process waste	AB	3.8	STMR	12	31.67	30	40			9.5	12.67		
Potato culls	VR	1.9	HR	20	9.50	30	30	10		2.85	2.85	0.95	
Cabbage heads, leaves	AM/AV	1.3	HR	15	8.67		20				1.733		
Beet, mangel fodder	AM/AV	0.95	HR	15	6.33		10				0.633		
Pea vines	AL	0.85	HR	25	3.40			60				2.04	
Almond hulls	AM/AV	1.24	STMR	90	1.38			10				0.138	
Wheat hay	AF/AS	1.2	HR	88	1.36	15				0.205			
Canola meal	SM	0.02	STMR	88	0.02	5				0.001			
Rape meal	SM	0.02	STMR	88	0.02				15				0.003
Soya bean seed	VD	0.02	STMR	89	0.02	5			15	0.001			0.003
Total						85	100	100	30	12.56	17.88	11.39	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
Grape pomace, wet	AB	6.2	STMR	15	41.33			20				8.267	
Potato process waste	AB	3.8	STMR	12	31.67	10	30			3.17	9.5		
Potato culls	VR	1.9	HR	20	9.50	10	30	10		0.95	2.85	0.95	
Cabbage heads, leaves	AM/AV	1.3	HR	15	8.67		20				1.733		
Beet, mangel fodder	AM/AV	0.95	HR	15	6.33		5				0.317		
Pea vines	AL	0.85	HR	25	3.40	10	15	40		0.34	0.51	1.36	
Bean vines	AL	0.85	HR	35	2.43			30				0.729	
Almond hulls	AM/AV	1.24	STMR	90	1.38	10				0.14			
Wheat hay	AF/AS	1.2	HR	88	1.36	20				0.27			
Canola meal	SM	0.02	STMR	88	0.02	10				0			
Rape meal	SM	0.02	STMR	88	0.02				25				0.006
Soya bean seed	VD	0.02	STMR	89	0.02	10			10	0			0.002
Total						80	100	100	35	4.87	14.91	11.31	0.008

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	1.9	HR	20	9.50		10				0.95		
Canola meal	SM	0.02	STMR	88	0.02	15	18	5		0	0.004	0.001	
Soya bean seed	VD	0.02	STMR	89	0.02	20	20	15		0	0.004	0.003	
Sunflower meal	SM	0.01	STMR	92	0.01	10				0			
Total						45	48	20		0.01	0.959	0.005	

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	1.9	HR	20	9.50		10				0.95		
Cabbage heads, leaves	AM/AV	1.3	HR	15	8.67		5				0.43		
Pea vines	AL	0.85	HR	25	3.40		10				0.34		
Wheat hay	AF/AS	1.2	HR	88	1.36		10				0.14		
Rape forage	AM/AV	0.14	HR	30	0.47		5				0.02		
Canola meal	SM	0.02	STMR	88	0.02	15	10	5		0	0	0.001	
Soya bean seed	VD	0.02	STMR	89	0.02	20	15	15		0	0	0.003	
Sunflower meal	SM	0.01	STMR	92	0.01	10				0			
Total						45	65	20		0.01	1.89	0.005	

DIFENOCONAZOLE - 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	6.2	STMR /STMR-P	15	41.33			20				8.2667	
Potato process waste	AB	3.8	STMR /STMR-P	12	31.67	30	40			9.5	12.667		
Potato culls	VR	1.2	STMR /STMR-P	20	6.00	30	30	10		1.8	1.8	0.6	
Pea vines	AL	0.75	STMR /STMR-P	25	3.00		20	60			0.6	1.8	
Cabbage heads, leaves	AM/AV	0.35	STMR/STMR-P	15	2.33		10				0.2333		
Almond hulls	AM/AV	1.24	STMR /STMR-P	90	1.38			10				0.1378	
Wheat hay	AF/AS	0.685	STMR /STMR-P	88	0.78	15				0.117			
Canola meal	SM	0.02	STMR/ STMR-P	88	0.02	5				0.001			
Rape meal	SM	0.02	STMR/ STMR-P	88	0.02				15				0.003
Soya bean seed	VD	0.02	STMR/ STMR-P	89	0.02	5			15	0.001			0.003
Total						85	100	100	30	11.42	15.3	10.80	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	6.2	STMR /STMR-P	15	41.33		0	20			0	8.2667	
Potato process waste	AB	3.8	STMR /STMR-P	12	31.67	10	30			3.17	9.5		
Potato culls	VR	1.2	STMR /STMR-P	20	6.00	10	30	10		0.6	1.8	0.6	
Pea vines	AL	0.75	STMR /STMR-P	25	3.00	10	20	40		0.3	0.6	1.2	
Cabbage heads, leaves	AM/AV	0.35	STMR /STMR-P	15	2.33	0	20			0	0.467		
Bean vines	AL	0.75	STMR /STMR-P	35	2.14	0		30		0		0.64	
Almond hulls	AM/AV	1.24	STMR /STMR-P	90	1.38	10				0.14			
Wheat hay	AF/AS	0.685	STMR /STMR-P	88	0.78	20				0.16			
Canola meal	SM	0.02	STMR /STMR-P	88	0.02	10				0			
Rape meal	SM	0.02	STMR /STMR-P	88	0.02	0			25	0			0.006
Soya bean seed	VD	0.02	STMR /STMR-P	89	0.02	10			10	0			0.002
Total						80	100	100	35	4.36	12.37	10.71	0.008

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	1.2	STMR/ STMR-P	20	6.00		10				0.6		
Canola meal	SM	0.02	STMR/ STMR-P	88	0.02	15	18	5		0	0.004	0.0011	
Soya bean seed	VD	0.02	STMR/ STMR-P	89	0.02	20	20	15		0	0.004	0.0034	
Sunflower meal	SM	0.01	STMR/ STMR-P	92	0.01	10				0			
Total						45	48	20		0.01	0.609	0.0045	

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
Potato culls	VR	1.2	STMR/ STMR-P	20	6.00		10				0.6		
Pea vines	AL	0.75	STMR/ STMR-P	25	3.00		10				0.3		
Cabbage heads, leaves	AM/AV	0.35	STMR/ STMR-P	15	2.33		5				0.117		
Wheat hay	AF/AS	0.685	STMR/ STMR-P	88	0.78		10				0.078		
Rape forage	AM/AV	0.06	STMR/ STMR-P	30	0.20		5				0.01		
Canola meal	SM	0.02	STMR/ STMR-P	88	0.02	15	10	5		0	0.002	0.0011	
Soya bean seed	VD	0.02	STMR/ STMR-P	89	0.02	20	15	15		0	0.003	0.0034	
Sunflower meal	SM	0.01	STMR/ STMR-P	92	0.01	10				0			
Total						45	65	20		0.01	1.11	0.0045	

DIQUAT - 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 hay	AL	25	HR	88	28.41		25	100			7.10	28.41	
Potato culls	VR	0.07	HR	20	0.35	30	30			0.11	0.11		
Canola meal	SM	0.19	STMR	88	0.22	5				0.01			
Rape meal	SM	0.19	STMR	88	0.22		20		15		0.04		0.03
Soya bean meal	SM	0.093	STMR	92	0.10				50				0.05
Pea seed	VD	0.05	STMR	90	0.06		20				0.01		
Soya bean seed	VD	0.03	STMR	89	0.03	5			15	0.00			0.01
Soya bean hulls	SM	0.0255	STMR	90	0.03	10	5			0.00	0.00		
Total						50	100	100	80	0.12	7.27	28.41	0.09

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 hay	AL	25	HR	88	28.41	10	30	70		2.84	8.52	19.89	
Potato culls	VR	0.07	HR	20	0.35	10	30	10		0.04	0.11	0.04	
Canola meal	SM	0.19	STMR	88	0.22	10	10	15		0.02	0.02	0.03	
Rape meal	SM	0.19	STMR	88	0.22				25				0.05
Soya bean meal	SM	0.093	STMR	92	0.10		15		35		0.02		0.04
Pea seed	VD	0.05	STMR	90	0.06		15	5			0.01	0.00	
Soya bean seed	VD	0.03	STMR	89	0.03	10			10	0.00			0.00
Total						40	100	100	70	2.90	8.67	19.96	0.09

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	0.07	HR	20	0.35		10				0.04		
Canola meal	SM	0.19	STMR	88	0.22	15	18	5		0.03	0.04	0.01	
Rape meal	SM	0.19	STMR	88	0.22				5				0.01
Sunflower meal	SM	0.132	STMR	92	0.14	10		10		0.01		0.01	
Soya bean meal	SM	0.093	STMR	92	0.10		22	10	30		0.02	0.01	0.03
Pea seed	VD	0.05	STMR	90	0.06	20	20	5		0.01	0.01	0.00	
Bean seed	VD	0.05	STMR	88	0.06			65				0.04	
Soya bean seed	VD	0.03	STMR	89	0.03			5				0.00	
Total						45	70	100	35	0.06	0.11	0.08	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
Pea hay	AL	25	HR	88	28.41		10				2.84		
Potato culls	VR	0.07	HR	20	0.35		10				0.04		
Canola meal	SM	0.19	STMR	88	0.22	15	10	5		0.03	0.02	0.01	
Rape meal	SM	0.19	STMR	88	0.22				15				0.03
Sunflower meal	SM	0.132	STMR	92	0.14	10		10		0.01		0.01	
Soya bean meal	SM	0.093	STMR	92	0.10		15	10	15		0.02	0.01	0.02
Pea seed	VD	0.05	STMR	90	0.06	20	20	5		0.01	0.01	0.00	
Bean seed	VD	0.05	STMR	88	0.06			65				0.04	
Soya bean seed	VD	0.03	STMR	89	0.03			5				0.00	
Total						45	65	100	30	0.06	2.93	0.08	0.05

DIQUAT - 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 hay	AL	16	STMR/STMR-P	88	18.18		25	100			4.55	18.18	
Potato culls	VR	0.05	STMR/STMR-P	20	0.25	30	30			0.08	0.08		
Canola meal	SM	0.19	STMR/STMR-P	88	0.22	5				0.01			
Rape meal	SM	0.19	STMR/STMR-P	88	0.22		20		15		0.04		0.03
Soya bean meal	SM	0.093	STMR/STMR-P	92	0.10				50				0.05
Pea seed	VD	0.05	STMR/STMR-P	90	0.06		20				0.01		
Soya bean seed	VD	0.03	STMR/STMR-P	89	0.03	5			15	0.00			0.01
Soya bean hulls	SM	0.0255	STMR/STMR-P	90	0.03	10	5			0.00	0.00		
Total						50	100	100	80	0.09	4.68	18.18	0.09

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 hay	AL	16	STMR/STMR-P	88	18.18	10	30	70		1.82	5.45	12.73	
Potato culls	VR	0.05	STMR/STMR-P	20	0.25	10	30	10		0.03	0.08	0.03	
Canola meal	SM	0.19	STMR/STMR-P	88	0.22	10	10	15		0.02	0.02	0.03	
Rape meal	SM	0.19	STMR/STMR-P	88	0.22	0			25	0.00			0.05
Soya bean meal	SM	0.093	STMR/STMR-P	92	0.10	0	15		35	0.00	0.02		0.04
Pea seed	VD	0.05	STMR/STMR-P	90	0.06	0	15	5		0.00	0.01	0.00	
Soya bean seed	VD	0.03	STMR/STMR-P	89	0.03	10			10	0.00			0.00
Total						40	100	100	70	1.87	5.58	12.79	0.09

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				0.03		
Canola meal	SM	0.19	STMR/STMR-P	88	0.22	15	18	5		0.03	0.04	0.01	
Rape meal	SM	0.19	STMR/STMR-P	88	0.22				5				0.01
Sunflower meal	SM	0.132	STMR/STMR-P	92	0.14	10		10		0.01		0.01	
Soya bean meal	SM	0.093	STMR/STMR-P	92	0.10		22	10	30		0.02	0.01	0.03
Pea seed	VD	0.05	STMR/STMR-P	90	0.06	20	20	5		0.01	0.01	0.00	
Bean seed	VD	0.05	STMR/STMR-P	88	0.06			65				0.04	
Soya bean seed	VD	0.03	STMR/STMR-P	89	0.03			5				0.00	
Total						45	70	100	35	0.06	0.10	0.08	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
Pea hay	AL	16	STMR/STMR-P	88	18.18		10				1.82		

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
Potato culls	VR	0.05	STMR/STMR-P	20	0.25		10				0.03		
Canola meal	SM	0.19	STMR/STMR-P	88	0.22	15	10	5		0.03	0.02	0.01	
Rape meal	SM	0.19	STMR/STMR-P	88	0.22				15				0.03
Sunflower meal	SM	0.132	STMR/STMR-P	92	0.14	10		10		0.01		0.01	
Soya bean meal	SM	0.093	STMR/STMR-P	92	0.10		15	10	15		0.02	0.01	0.02
Pea seed	VD	0.05	STMR/STMR-P	90	0.06	20	20	5		0.01	0.01	0.00	
Bean seed	VD	0.05	STMR/STMR-P	88	0.06			65				0.04	
Soya bean seed	VD	0.03	STMR/STMR-P	89	0.03			5				0.00	
Total						45	65	100	30	0.06	1.89	0.08	0.05

DITHIANON - ESTIMATED DIETARY BURDEN

BEEF CATTLE MEAN/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-P	15	4.27			20				0.853	
Apple pomace, wet	AB	0.33	STMR-P	40	0.83		20				0.165		
Total							20	20			0.165	0.853	

DAIRY CATTLE MEAN/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-P	15	4.27			20				0.853	
Apple pomace, wet	AB	0.33	STMR-P	40	0.83	10	10			0.083	0.083		
Total						10	20	20		0.083	0.083	0.853	

FENBUCONAZOLE - 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
Peanut hay	AL	7.1	HR	85	8.35			60				5.012	
Wheat straw	AF/AS	2.5	HR	88	2.84	10	20	40		0.284091	0.568	1.136	
Barley straw	AF/AS	2.4	HR	89	2.70		10				0.27		
Citrus dried pulp	AB	1.1	STMR	91	1.21	10	5			0.120879	0.06		
Apple pomace, wet	AB	0.3	STMR	40	0.75		15				0.113		
Barley grain	GC	0.03	STMR	88	0.03	50	50		70	0.017045	0.017		0.024
Total						70	100	100	70	0.422015	1.028	6.148	0.024

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
Peanut hay	AL	7.1	HR	85	8.35	15		60		1.252941		5.012	
Wheat straw	AF/AS	2.5	HR	88	2.84	10	20	20		0.284091	0.568	0.568	
Barley straw	AF/AS	2.4	HR	89	2.70		10				0.27		
Citrus dried pulp	AB	1.1	STMR	91	1.21	10	20	20		0.120879	0.242	0.242	
Almond hulls	AM/AV	0.45	STMR	90	0.50	10				0.05			
Barley grain	GC	0.03	STMR	88	0.03	45	40		40	0.015341	0.014		0.014
Peanut meal	SM	0.015	STMR	85	0.02	10	10			0.001765	0.002		
Total						100	100	100	40	1.725017	1.095	5.822	0.014

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	0.03	STMR	88	0.03	75	70	15	10	0.025568	0.024	0.005	0.003
Peanut meal	SM	0.015	STMR	85	0.02	25	10	10		0.004412	0.002	0.002	
Total						100	80	25	10	0.02998	0.026	0.007	0.003

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	2.5	HR	88	2.84		10				0.284		
Barley grain	GC	0.03	STMR	88	0.03	75	90	15		0.025568	0.031	0.005	
Peanut meal	SM	0.015	STMR	85	0.02	25		10		0.004412		0.002	
Total						100	100	25		0.02998	0.315	0.007	

FENBUCONAZOLE - 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
Peanut hay	AL	2.3	STMR/STMR-P	85	2.71			60				1.624	
Citrus dried pulp	AB	1.1	STMR/STMR-P	91	1.21	10	5	30		0.120879	0.06	0.363	
Barley straw	AF/AS	0.94	STMR/STMR-P	89	1.06	10	30	10		0.105618	0.317	0.106	
Apple pomace, wet	AB	0.3	STMR/STMR-P	40	0.75		15				0.113		
Barley grain	GC	0.03	STMR/STMR-P	88	0.03	50	50		70	0.017045	0.017		0.024
Total						70	100	100	70	0.243543	0.507	2.092	0.024

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
Peanut hay	AL	2.3	STMR/STMR-P	85	2.71	15	0	60		0.405882	0	1.624	
Citrus dried pulp	AB	1.1	STMR/STMR-P	91	1.21	10	20	30		0.120879	0.242	0.363	
Barley straw	AF/AS	0.94	STMR/STMR-P	89	1.06	10	30	10		0.105618	0.317	0.106	
Almond hulls	AM/AV	0.45	STMR/STMR-P	90	0.50	10				0.05			
Barley grain	GC	0.03	STMR/STMR-P	88	0.03	45	40		40	0.015341	0.014		0.014
Peanut meal	SM	0.015	STMR/STMR-P	85	0.02	10	10			0.001765	0.002		
Total						100	100	100	40	0.699485	0.574	2.092	0.014

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	0.03	STMR/STMR-P	88	0.03	75	70	15	10	0.025568	0.024	0.005	0.003
Peanut meal	SM	0.015	STMR/STMR-P	85	0.02	25	10	10		0.004412	0.002	0.002	
Total						100	80	25	10	0.02998	0.026	0.007	0.003

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
Barley straw	AF/AS	0.94	STMR/STMR-P	89	1.06		5				0.053		
Wheat straw	AF/AS	0.79	STMR/STMR-P	88	0.90		5				0.045		
Barley grain	GC	0.03	STMR/STMR-P	88	0.03	75	90	15		0.025568	0.031	0.005	
Peanut meal	SM	0.015	STMR/STMR-P	85	0.02	25		10		0.004412		0.002	
Total						100	100	25		0.02998	0.128	0.007	

FENPYROXIMATE - 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	6.5	HR	35	18.57			60				11.14	
Citrus dried pulp	AB	0.64	STMR	91	0.70	10	5	30		0.070	0.035	0.211	
Potato process waste	AB	0.05	STMR	12	0.42	20	35			0.083	0.146		
Total						30	40	90		0.154	0.181	11.35	

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	6.5	HR	35	18.57		20	70			3.71	13	
Citrus dried pulp	AB	0.64	STMR	91	0.70	10	20	30		0.070	0.14	0.21	
Potato process waste	AB	0.05	STMR	12	0.42		10				0.042		
Total						10	50	100		0.070	3.90	13.21	

FENPYROXIMATE - 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
Bean vines	AL	1.92	STMR/STMR-P	35	5.49			60				3.29	
Citrus dried pulp	AB	0.64	STMR/STMR-P	91	0.70	10	5	30		0.070	0.035	0.21	
Potato process waste	AB	0.05	STMR/STMR-P	12	0.42	20	35			0.083	0.146		
Total						30	40	90		0.154	0.181	3.50	

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	1.92	STMR/STMR-P	35	5.49		20	70			1.10	3.84	
Citrus dried pulp	AB	0.64	STMR/STMR-P	91	0.70	10	20	30		0.070	0.14	0.21	
Potato process waste	AB	0.05	STMR/STMR-P	12	0.42	0	10			0.000	0.042		
Total						10	50	100		0.070	1.28	4.05	

FLUDIOXONIL - 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
Carrot culls	VR	0.42	HR	12	3.50		15	5			0.525	0.175	
Corn, field stover	AF/AS	0.06	HR	83	0.07	15	25	40		0.010843	0.018	0.029	
Barley hay	AF/AS	0.06	HR	88	0.07			55				0.038	
Barley straw	AF/AS	0.06	HR	89	0.07		5				0.003		
Bean seed	VD	0.04	STMR	88	0.05		20				0.009		
Barley grain	GC	0.02	STMR	88	0.02	50	35		70	0.011364	0.008		0.016
Corn, field grain	GC	0.02	STMR	88	0.02	30			5	0.006818			0.001
Total						95	100	100	75	0.029025	0.563	0.241	0.017

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
Carrot culls	VR	0.42	HR	12	3.50	10	15	5		0.35	0.525	0.175	
Corn, field stover	AF/AS	0.06	HR	83	0.07	15	20	40		0.010843	0.014	0.029	
Barley hay	AF/AS	0.06	HR	88	0.07	5		10		0.003409		0.007	
Barley straw	AF/AS	0.06	HR	89	0.07		10				0.007		
Oat hay	AF/AS	0.06	HR	90	0.07	10		40		0.006667		0.027	
Cotton undelinted seed	SO	0.05	STMR	88	0.06	10	10	5		0.005682	0.006	0.003	
Bean seed	VD	0.04	STMR	88	0.05		20				0.009		
Barley grain	GC	0.02	STMR	88	0.02	45	25		40	0.010227	0.006		0.009
Corn, field grain	GC	0.02	STMR	88	0.02				40				0.009
Total						95	100	100	80	0.386828	0.567	0.24	0.018

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	0.42	HR	12	3.50		10				0.35		
Bean seed	VD	0.04	STMR	88	0.05		20	70			0.009	0.032	
Barley grain	GC	0.02	STMR	88	0.02	75	70	15	10	0.017045	0.016	0.003	0.002
Total						75	100	85	10	0.017045	0.375	0.035	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
Carrot culls	VR	0.42	HR	12	3.50		10				0.35		
Corn, field stover	AF/AS	0.06	HR	83	0.07		10				0.007		
Bean seed	VD	0.04	STMR	88	0.05		20	70			0.009	0.032	
Barley grain	GC	0.02	STMR	88	0.02	75	60	15		0.017045	0.014	0.003	
Corn, field grain	GC	0.02	STMR	88	0.02				80				0.018
Total						75	100	85	80	0.017045	0.38	0.035	0.018

FLUDIOXONIL - 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
Carrot culls	VR	0.2	STMR/STMR-P	12	1.67		15	5			0.25	0.083	
Cotton undelinted seed	SO	0.05	STMR/STMR-P	88	0.06			30				0.017	
Bean seed	VD	0.04	STMR/STMR-P	88	0.05		20	50			0.009	0.023	
Barley grain	GC	0.02	STMR/STMR-P	88	0.02	50	65	15	70	0.011364	0.015	0.003	0.016
Corn, field grain	GC	0.02	STMR/STMR-P	88	0.02	30			5	0.006818			0.001
Total						80	100	100	75	0.018182	0.274	0.127	0.017

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	0.2	STMR/STMR-P	12	1.67	10	15	5		0.166667	0.25	0.083	
Cotton undelinted seed	SO	0.05	STMR/STMR-P	88	0.06	10	10	20		0.005682	0.006	0.011	
Bean seed	VD	0.04	STMR/STMR-P	88	0.05	0	20	15		0	0.009	0.007	
Barley grain	GC	0.02	STMR/STMR-P	88	0.02	45	40	40	40	0.010227	0.009	0.009	0.009
Corn, field grain	GC	0.02	STMR/STMR-P	88	0.02	0			40	0			0.009
Total						65	85	80	80	0.182576	0.274	0.111	0.018

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	0.2	STMR/STMR-P	12	1.67		10				0.167		
Bean seed	VD	0.04	STMR/STMR-P	88	0.05		20	70			0.009	0.032	
Barley grain	GC	0.02	STMR/STMR-P	88	0.02	75	70	15	10	0.017045	0.016	0.003	0.002
Total						75	100	85	10	0.017045	0.192	0.035	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
Carrot culls	VR	0.2	STMR/STMR-P	12	1.67		10				0.167		
Bean seed	VD	0.04	STMR/STMR-P	88	0.05		20	70			0.009	0.032	
Barley grain	GC	0.02	STMR/STMR-P	88	0.02	75	70	15		0.017045	0.016	0.003	
Corn, field grain	GC	0.02	STMR/STMR-P	88	0.02				80				0.018
Total						75	100	85	80		0.192	0.035	0.018

FLUTOLANIL - 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
Rice straw	AF/AS	7.4	HR	90	8.22		10	60	55		0.822	4.93	4.52
Rice hulls	CM/CF	4.3	STMR	90	4.78			5				0.24	
Rice bran/pollard	CM/CF	1.7	STMR	90	1.89	15		35	20	0.283		0.66	0.38
Rice grain	GC	0.39	STMR	88	0.44	20				0.089			
Total						35	30	100	75	0.372	0.822	5.83	4.90

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
Rice straw	AF/AS	7.4	HR	90	8.22		5	20	25		0.411	1.64	2.06
Rice hulls	CM/CF	4.3	STMR	90	4.78			10				0.48	
Rice bran/pollard	CM/CF	1.7	STMR	90	1.89	15	20	30	10	0.283	0.378	0.57	0.19
Rice grain	GC	0.39	STMR	88	0.44	20		20		0.089		0.09	
Total						35	45	80	35	0.372	0.789	2.78	2.24

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
Rice bran/pollard	CM/CF	1.7	STMR	90	1.89	10	10	20	5	0.189	0.189	0.378	0.094
Rice grain	GC	0.39	STMR	88	0.44	20		50		0.089		0.222	
Total						30	10	70	5	0.278	0.189	0.599	0.094

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
Rice bran/pollard	CM/CF	1.7	STMR	90	1.89	10	5	20	20	0.189	0.094	0.378	0.378
Rice grain	GC	0.39	STMR	88	0.44	20		50		0.089		0.222	
Total						30	10	70	20	0.278	0.094	0.599	0.378

FLUTOLANIL - 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
Rice hulls	CM/CF	4.3	STMR/STMR-P	90	4.78			5				0.239	
Rice straw	AF/AS	3.7	STMR/STMR-P	90	4.11		10	60	55		0.411	2.47	2.26
Rice bran/pollard	CM/CF	1.7	STMR/STMR-P	90	1.89	15		35	20	0.283		0.66	0.38
Rice grain	GC	0.39	STMR/STMR-P	88	0.44	20				0.089			
Total						35	30	100	75	0.372	0.411	3.37	2.64

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
Rice hulls	CM/CF	4.3	STMR/STMR-P	90	4.78		0	10			0	0.478	
Rice straw	AF/AS	3.7	STMR/STMR-P	90	4.11	0	5	20	25	0	0.206	0.822	1.03
Rice bran/pollard	CM/CF	1.7	STMR/STMR-P	90	1.89	15	20	30	10	0.283	0.378	0.567	0.189
Rice grain	GC	0.39	STMR/STMR-P	88	0.44	20		20		0.089		0.089	
Total						35	45	80	35	0.372	0.584	1.96	1.22

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
Rice bran/pollard	CM/CF	1.7	STMR/STMR-P	90	1.89	10	10	20	5	0.189	0.189	0.378	0.094
Rice grain	GC	0.39	STMR/STMR-P	88	0.44	20		50		0.089		0.222	
Total						30	10	70	5	0.278	0.189	0.599	0.094

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
Rice bran/pollard	CM/CF	1.7	STMR/STMR-P	90	1.89	10	5	20	20	0.189	0.094	0.378	0.378
Rice grain	GC	0.39	STMR/STMR-P	88	0.44	20		50		0.089		0.222	
Total						30	10	70	20	0.278	0.094	0.599	0.378

IMAZAPIC - 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	24	HR	25	96.00		50	100	5		48	96	4.8
Grass hay	AF/AS	2.3	HR	88	2.61	15			35	0.392			0.915
Rape forage	AM/AV	0.05	HR	30	0.17		10				0.017		
Corn, field grain	GC	0.01	STMR	88	0.01	80	40		60	0.009	0.005		0.007
Total						95	100	100	100	0.401	48.0	96	5.722

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	24	HR	25	96.00	45	60	100	10	43.2	57.6	96	9.6
Grass hay	AF/AS	2.3	HR	88	2.61				60				1.568
Rape forage	AM/AV	0.05	HR	30	0.17	10	10			0.017	0.017		
Corn, field grain	GC	0.01	STMR	88	0.01	45	30		30	0.005	0.003		0.003
Total						100	100	100	100	43.2	57.6	96	11.2

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	0.01	STMR	88	0.01	75	70		70	0.009	0.008		0.008
Total						75	70		70	0.009	0.008		0.008

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	24	HR	25	96.00		10				9.6		
Rape forage	AM/AV	0.05	HR	30	0.17		10				0.017		
Corn, field grain	GC	0.01	STMR	88	0.01	75	70		80	0.009	0.008		0.009
Total						75	90		80	0.009	9.63		0.009

IMAZAPIC - 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	12.5	STMR/STMR-P	25	50.00		50	100	5		25	50	2.5
Grass hay	AF/AS	0.5	STMR/STMR-P	88	0.57	15			35	0.085			0.199
Rape forage	AM/AV	0.05	STMR/STMR-P	30	0.17		10				0.017		
Corn, field grain	GC	0.01	STMR/STMR-P	88	0.01	80	40		60	0.009	0.005		0.007
Total						95	100	100	100	0.094	25.0	50	2.71

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	12.5	STMR/STMR-P	25	50.00	45	60	100	10	22.5	30	50	5
Grass hay	AF/AS	0.5	STMR/STMR-P	88	0.57	0			60	0.000			0.341
Rape forage	AM/AV	0.05	STMR/STMR-P	30	0.17	10	10			0.017	0.017		
Corn, field grain	GC	0.01	STMR/STMR-P	88	0.01	45	30		30	0.005	0.003		0.003
Total						100	100	100	100	22.5	30.02	50	5.34

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
Corn, field grain	GC	0.01	STMR/STMR-P	88	0.01	75	70		70	0.009	0.008		0.008
Total						75	70		70	0.009	0.008		0.008

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	12.5	STMR/STMR-P	25	50.00		10				5		
Rape forage	AM/AV	0.05	STMR/STMR-P	30	0.17		10				0.017		
Corn, field grain	GC	0.01	STMR/STMR-P	88	0.01	75	70		80	0.009	0.008		0.009
Total						75	90		80	0.009	5.03		0.009

IMAZAPYR - 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	0.05	HR	25	0.20		20	100			0.04	0.2	
Corn, field hominy meal	CM/CF	0.06	STMR	88	0.07	50			35	0.034091			0.024
Corn, field grain	GC	0.05	STMR	88	0.06	50	80		65	0.028409	0.045		0.037
Total						100	100	100	100	0.0625	0.085	0.2	0.061

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	0.05	HR	25	0.20	20	20	60		0.04	0.04	0.12	
Corn, field hominy meal	CM/CF	0.06	STMR	88	0.07	25		40		0.017045		0.027	
Corn, field grain	GC	0.05	STMR	88	0.06	45	30		80	0.025568	0.017		0.045
Total						90	50	100	80	0.082614	0.057	0.147	0.045

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 hominy meal	CM/CF	0.06	STMR	88	0.07	20		20		0.013636		0.014	
Corn, field grain	GC	0.05	STMR	88	0.06	75	70		70	0.042614	0.04		0.04
Total						95	70	20	70	0.05625	0.04	0.014	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
Wheat forage	AF/AS	0.05	HR	25	0.20		10				0.02		
Corn, field hominy meal	CM/CF	0.06	STMR	88	0.07	20	20	20		0.013636	0.014	0.014	
Corn, field grain	GC	0.05	STMR	88	0.06	75	70		80	0.042614	0.04		0.045
Total						95	100	20	80	0.05625	0.073	0.014	0.045

IMAZAPYR - 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 forage	AF/AS	0.05	STMR/STMR-P	25	0.20		20	100			0.04	0.2	
Corn, field hominy meal	CM/CF	0.06	STMR/STMR-P	88	0.07	50			35	0.034091			0.024
Corn, field grain	GC	0.05	STMR/STMR-P	88	0.06	50	80		65	0.028409	0.045		0.037
Total						100	100	100	100	0.0625	0.085	0.2	0.061

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 forage	AF/AS	0.05	STMR/STMR-P	25	0.20	20	20	60		0.04	0.04	0.12	
Corn, field hominy meal	CM/CF	0.06	STMR/STMR-P	88	0.07	25		40		0.017045		0.027	
Corn, field grain	GC	0.05	STMR/STMR-P	88	0.06	45	30		80	0.025568	0.017		0.045
Total						90	50	100	80	0.082614	0.057	0.147	0.045

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
Corn, field hominy meal	CM/CF	0.06	STMR/STMR-P	88	0.07	20		20		0.013636		0.014	
Corn, field grain	GC	0.05	STMR/STMR-P	88	0.06	75	70		70	0.042614	0.04		0.04
Total						95	70	20	70	0.05625	0.04	0.014	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
Wheat forage	AF/AS	0.05	STMR/STMR-P	25	0.20		10				0.02		
Corn, field hominy meal	CM/CF	0.06	STMR/STMR-P	88	0.07	20	20	20		0.013636	0.014	0.014	
Corn, field grain	GC	0.05	STMR/STMR-P	88	0.06	75	70		80	0.042614	0.04		0.045
Total						95	100	20	80	0.05625	0.073	0.014	0.045

ISOXAFLUTOLE - 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
Corn, field forage/silage	AF/AS	0.34	HR	40	0.85	15	80	80		0.128	0.680	0.680	
Sugarcane tops	AM/AV	0.01	HR	25	0.04			20				0.008	
Corn, field grain	GC	0.02	STMR	88	0.02	80	20		75	0.018	0.005		0.017
Total						95	100	100	75	0.146	0.685	0.688	0.017

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
Corn, field forage/silage	AF/AS	0.34	HR	40	0.85	45	60	80	50	0.383	0.510	0.680	0.425
Sugarcane tops	AM/AV	0.01	HR	25	0.04			20				0.008	
Corn, field grain	GC	0.02	STMR	88	0.02	45	30		50	0.010	0.007		0.011
Pea hay	AL	0.01	HR	88	0.01	10	10			0.001	0.001		
Total						100	100	100	100	0.394	0.518	0.688	0.436

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	75	70		70	0.017	0.016		0.016
Total						75	70		70	0.017	0.016		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
Corn, field forage/silage	AF/AS	0.34	HR	40	0.85		10				0.085		
Corn, field grain	GC	0.02	STMR	88	0.02	75	70		80	0.017	0.016		0.018
Pea hay	AL	0.01	HR	88	0.01		10				0.001		
Total						75	90		80	0.017	0.102		0.018

ISOXAFLUTOLE - 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
Corn, field forage/silage	AF/AS	0.02	STMR/STMR-P	40	0.05	15	80	80		0.008	0.04	0.04	
Sugarcane tops	AM/AV	0.01	STMR/STMR-P	25	0.04			20				0.008	
Corn, field grain	GC	0.02	STMR/STMR-P	88	0.02	80	20		75	0.018	0.005		0.017
Total						95	100	100	75	0.026	0.045	0.048	0.017

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
Corn, field forage/silage	AF/AS	0.02	STMR/STMR-P	40	0.05	45	60	80	50	0.023	0.030	0.040	0.025
Sugarcane tops	AM/AV	0.01	STMR/STMR-P	25	0.04	0		20		0.000		0.008	
Corn, field grain	GC	0.02	STMR/STMR-P	88	0.02	45	30		50	0.010	0.007		0.011
Pea hay	AL	0.01	STMR/STMR-P	88	0.01	10	10			0.001	0.001		
Total						100	100	100	100	0.034	0.038	0.048	0.036

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
Corn, field grain	GC	0.02	STMR/STMR-P	88	0.02	75	70		70	0.017	0.016		0.016
Total						75	70		70	0.017	0.016		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
Corn, field forage/silage	AF/AS	0.02	STMR/STMR-P	40	0.05		10				0.005		
Corn, field grain	GC	0.02	STMR/STMR-P	88	0.02	75	70		80	0.017	0.016		0.018
Pea hay	AL	0.01	STMR/STMR-P	88	0.01		10				0.001		
Total						75	90		80	0.017	0.022		0.018

PENTHIOPYRAD – 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	17	HR	25	68.00		20				13.60		
Barley hay	AF/AS	54	HR	88	61.36	15				9.20			
Barley straw	AF/AS	54	HR	89	60.67		10				6.07		
Alfalfa hay	AL	16	HR	89	17.98	15			10	2.70			1.80
Cabbage heads, leaves	AM/AV	2.4	HR	15	16.00		20				3.20		
Tomato pomace,wet	AB	1.4	STMR	20	7.00			10				0.70	
Almond hulls	AM/AV	2.4	STMR	90	2.67			10				0.27	
Apple pomace, wet	AB	0.69	STMR	40	1.73		20	10				0.17	
Sorghum, grain	GC	0.22	STMR	86	0.26	40	40	70	35	0.10	0.10	0.18	0.09
Millet grain	GC	0.22	STMR	88	0.25	10				0.03			
Barley grain	GC	0.086	STMR	88	0.10		10		35		0.01		0.03
Soya bean seed	VD	0.032	STMR	89	0.04	5			15	0.00			0.01
Corn, field grain	GC	0.01	STMR	88	0.01	15			5	0.00			0.00
Total						100	100	100	100	12.03	22.98	1.32	1.93

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
Soya bean hay	AL	125	HR	85	147.06	20				29.41			
Wheat forage	AF/AS	17	HR	25	68.00	20	20			13.60	13.60		
Barley straw	AF/AS	54	HR	89	60.67		10				6.07		
Oat hay	AF/AS	54	HR	90	60.00	10				6.00			
Sorghum, grain forage	AF/AS	14	HR	35	40.00	10				4.00			
Corn, field forage/silage	AF/AS	14	HR	40	35.00	5				1.75			
Alfalfa hay	AL	16	HR	89	17.98		40		25		7.19		4.49
Cabbage heads, leaves	AM/AV	2.4	HR	15	16.00		20				3.20		
Tomato pomace,wet	AB	1.4	STMR	20	7.00			10				0.70	
Almond hulls	AM/AV	2.4	STMR	90	2.67	10		10		0.27		0.27	
Apple pomace, wet	AB	0.69	STMR	40	1.73	10				0.17			
Beet, sugar dried pulp	AB	0.56	STMR	88	0.64	5				0.03			
Sorghum, grain	GC	0.22	STMR	86	0.26	10	10	50	30	0.03	0.03	0.13	0.08
Soya bean seed	VD	0.032	STMR	89	0.04			20	10			0.01	0.00
Corn, field grain	GC	0.01	STMR	88	0.01				35				0.00
Total						100	100	90	100	55.26	30.08	1.10	4.58

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
Soya bean hay	AL	125	HR	85	147.06		10				14.71		
Wheat forage	AF/AS	17	HR	25	68.00		10				6.80		
Cabbage heads, leaves	AM/AV	2.4	HR	15	16.00		5				0.80		
Sorghum, grain grain	GC	0.22	STMR	86	0.26	75	70	70	55	0.19	0.18	0.18	0.14
Barley grain	GC	0.086	STMR	88	0.10		5				0.00		
Soya bean seed	VD	0.032	STMR	89	0.04	20		15		0.01		0.01	
Bean seed	VD	0.01	STMR	88	0.01			15				0.00	
Corn, field grain	GC	0.01	STMR	88	0.01				25				0.00
Total						95	100	100	80	0.20	22.49	0.19	0.14

PENTHIOPYRAD – 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 forage	AF/AS	10	STMR/STMR-P	25	40.00		20				8.00		
Barley forage	AF/AS	10	STMR/STMR-P	30	33.33		10				3.33		
Barley hay	AF/AS	21	STMR/STMR-P	88	23.86	15				3.58			
Tomato pomace,wet	AB	1.4	STMR/STMR-P	20	7.00			10				0.70	
Cotton gin byproducts	AM/AV	4.55	STMR/STMR-P	90	5.06	5				0.25			
Alfalfa hay	AL	2.9	STMR/STMR-P	89	3.26	15			10	0.49			0.33
Almond hulls	AM/AV	2.4	STMR/STMR-P	90	2.67			10				0.27	
Cabbage heads, leaves	AM/AV	0.4	STMR/STMR-P	15	2.67		20				0.53		
Apple pomace, wet	AB	0.69	STMR/STMR-P	40	1.73			10				0.17	
Sorghum, grain	GC	0.22	STMR/STMR-P	86	0.26	40	40	70	35	0.10	0.10	0.18	0.09
Millet grain	GC	0.22	STMR/STMR-P	88	0.25	10				0.03			
Barley grain	GC	0.086	STMR/STMR-P	88	0.10		10		35		0.01		0.03
Soya bean seed	VD	0.032	STMR/STMR-P	89	0.04	5			15	0.00			0.01
Corn, field grain	GC	0.01	STMR/STMR-P	88	0.01	10			5	0.00			0.00
Total						100	100	100	100	4.45	11.98	1.32	0.46

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
Soya bean hay	AL	52.5	STMR/STMR-P	85	61.76	20	0			12.35	0.00		
Wheat forage	AF/AS	10	STMR/STMR-P	25	40.00	20	20			8.00	8.00		
Barley forage	AF/AS	10	STMR/STMR-P	30	33.33		10				3.33		
Oat forage	AF/AS	10	STMR/STMR-P	30	33.33	10				3.33			
Sorghum, grain forage	AF/AS	5	STMR/STMR-P	35	14.29	10				1.43			
Corn, field forage/silage	AF/AS	5	STMR	40	12.5	5				0.63			
Tomato pomace,wet	AB	1.4	STMR/STMR-P	20	7.00		0	10			0.00	0.70	
Alfalfa hay	AL	2.9	STMR/STMR-P	89	3.26		40		25		1.30		0.81
Cabbage heads, leaves	AM/AV	0.4	STMR/STMR-P	15	2.67	0	20			0.00	0.53		
Almond hulls	AM/AV	2.4	STMR/STMR-P	90	2.67	10		10		0.27		0.27	
Apple pomace, wet	AB	0.69	STMR	40	1.73	10				0.17			
Beet, sugar dried pulp	AB	0.56	STMR	88	0.64	5				0.03			
Sorghum, grain	GC	0.22	STMR/STMR-P	86	0.26	10	10	50	30	0.03	0.03	0.13	0.08
Soya bean seed	VD	0.032	STMR/STMR-P	89	0.04	0		20	10	0.00		0.01	0.00
Corn, field grain	GC	0.01	STMR/STMR-P	88	0.01	0			35	0.00			0.00
Total						100	100	100	100	26.24	13.20	1.10	0.90

POULTRY BROILER — MAX & 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 grain	GC	0.22	STMR	86	0.26	75	70	70	65	0.19	0.18	0.18	0.17
Soya bean seed	VD	0.032	STMR	89	0.04	20	20	15		0.01	0.01	0.01	
Bean seed	VD	0.01	STMR	88	0.01			15				0.00	
Total						95	90	100	65	0.20	0.19	0.19	0.17

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
Soya bean hay	AL	52.5	STMR/STMR-P	85	61.76		10				6.18		
Wheat forage	AF/AS	10	STMR/STMR-P	25	40.00		10				4.00		
Cabbage heads, leaves	AM/AV	0.4	STMR/STMR-P	15	2.67		5				0.13		
Sorghum, grain grain	GC	0.22	STMR/STMR-P	86	0.26	75	70	70	55	0.19	0.18	0.18	0.14
Barley grain	GC	0.086	STMR/STMR-P	88	0.10		5				0.00		
Soya bean seed	VD	0.032	STMR/STMR-P	89	0.04	20		15		0.01		0.01	
Bean seed	VD	0.01	STMR/STMR-P	88	0.01			15				0.00	
Corn, field grain	GC	0.01	STMR/STMR-P	88	0.01				25				0.00
Total						95	100	100	80	0.20	10.49	0.19	0.14

PYRIMETHANIL - 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	6.6	STMR	40	16.50		20	20			3.3	3.3	
Carrot culls	VR	0.54	HR	12	4.50		15	5			0.675	0.225	
Almond hulls	AM/AV	2.6	STMR	90	2.89			10				0.289	
Citrus dried pulp	AB	1.3	STMR	91	1.43	10		10		0.143		0.143	
Pea hay	AL	1	HR	88	1.14		25	55			0.284	0.625	
Pea seed	VD	0.09	STMR	90	0.10		20				0.02		
Total						10	80	100		0.143	4.279	4.582	

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	6.6	STMR	40	16.50	10	10	10		1.650	1.65	1.65	
Grape pomace, wet	AB	1.7	STMR	15	11.33			10				1.133	
Carrot culls	VR	0.54	HR	12	4.50	10	15	5		0.450	0.675	0.225	
Almond hulls	AM/AV	2.6	STMR	90	2.89	10		10		0.289		0.289	
Citrus dried pulp	AB	1.3	STMR	91	1.43		10	10			0.143	0.143	
Pea hay	AL	1	HR	88	1.14	10	30	55		0.114	0.341	0.625	
Pea seed	VD	0.09	STMR	90	0.10		20				0.02		
Total						40	85	100		2.503	2.829	4.065	

PYRIMETHANIL - 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	6.6	STMR/STMR-P	40	16.50		20	20			3.3	3.3	
Almond hulls	AM/AV	2.6	STMR/STMR-P	90	2.89			10				0.289	
Citrus dried pulp	AB	1.3	STMR/STMR-P	91	1.43	10		10		0.143		0.143	
Carrot culls	VR	0.14	STMR/STMR-P	12	1.17		15	5			0.175	0.058	
Pea hay	AL	0.2	STMR/STMR-P	88	0.23		25	55			0.057	0.125	
Pea seed	VD	0.09	STMR/STMR-P	90	0.10		20				0.02		
Total						10	80	100		0.143	3.552	3.915	

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	6.6	STMR/STMR-P	40	16.50	10	10	10		1.650	1.65	1.65	
Grape pomace, wet	AB	1.7	STMR/STMR-P	15	11.33	0		10		0.000		1.133	
Almond hulls	AM/AV	2.6	STMR/STMR-P	90	2.89	10		10		0.289		0.289	
Citrus dried pulp	AB	1.3	STMR/STMR-P	91	1.43	0	10	10		0.000	0.143	0.143	
Carrot culls	VR	0.14	STMR/STMR-P	12	1.17	10	15	5		0.117	0.175	0.058	
Pea hay	AL	0.2	STMR/STMR-P	88	0.23	10	30	55		0.023	0.068	0.125	
Pea seed	VD	0.09	STMR/STMR-P	90	0.10	0	20			0.000	0.02		
Total						40	85	100		2.078	2.056	3.398	

SPIROTETRAMAT - 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
Soya bean forage	AL	22.4	HR	56	40.00			100				40	
Cowpea forage	AL	3.6	HR	30	12.00		35				4.2		
Cabbage heads, leaves	AM/AV	0.92	HR	15	6.13		20				1.227		
Cotton gin byproducts	AM/AV	5.31	HR	90	5.90	5				0.295			
Soya bean asp gr fn	SM	1.9	STMR	85	2.24	5				0.112			
Potato culls	VR	0.44	HR	20	2.20	30	30			0.66	0.66		
Apple pomace, wet	AB	0.44	STMR	40	1.10		15				0.165		
Soya bean meal	SM	0.62	STMR	92	0.67				65				0.438
Soya bean seed	VD	0.45	STMR	89	0.51	5			15	0.025			0.076
Citrus dried pulp	AB	0.43	STMR	91	0.47	10				0.047			
Soya bean hulls	SM	0.4	STMR	90	0.44	10				0.044			
Total						65	100	100	80	1.184	6.252	40	0.514

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
Soya bean forage	AL	22.4	HR	56	40.00	20		40		8		16	
Cowpea forage	AL	3.6	HR	30	12.00		35	20			4.2	2.4	
Pea hay	AL	8.536	HR	88	9.70			10				0.97	
Cabbage heads, leaves	AM/AV	0.92	HR	15	6.13		20				1.227		
Almond hulls	AM/AV	4.9	STMR	90	5.44	10		10		0.544		0.544	
Grape pomace, wet	AB	0.74	STMR	15	4.93			20				0.987	
Potato culls	VR	0.44	HR	20	2.20	10	30			0.22	0.66		
Apple pomace, wet	AB	0.44	STMR	40	1.10	10	10			0.11	0.11		
Soya bean meal	SM	0.62	STMR	92	0.67	10	5		60	0.067	0.034		0.404
Soya bean seed	VD	0.45	STMR	89	0.51	10			10	0.051			0.051
Cotton undelinted seed	SO	0.095	STMR	88	0.11	10				0.011			
Total						80	100	100	70	9.003	6.23	20.9	0.455

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	0.44	HR	20	2.20		10				0.22		
Soya bean meal	SM	0.62	STMR	92	0.67	25	40	25	35	0.168	0.27	0.168	0.236
Soya bean seed	VD	0.45	STMR	89	0.51	20	20	15		0.101	0.101	0.076	
Bean seed	VD	0.21	STMR	88	0.24			55				0.131	
Total						45	70	95	35	0.27	0.591	0.376	0.236

SPIROTETRAMAT - ESTIMATED 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
Soya bean forage	AL	22.4	HR	56	40.00			100				40	
Cowpea forage	AL	3.6	HR	30	12.00		35				4.2		
Cabbage heads, leaves	AM/AV	0.92	HR	15	6.13		20				1.227		
Cotton gin byproducts	AM/AV	5.31	HR	90	5.90	5				0.295			
Soya bean asp gr fn	SM	1.9	STMR	85	2.24	5				0.1118			
Potato culls	VR	0.44	HR	20	2.20	30	30			0.66	0.66		
Apple pomace, wet	AB	0.44	STMR	40	1.10		15				0.165		
Soya bean meal	SM	0.62	STMR	92	0.67				65				0.438
Soya bean seed	VD	0.45	STMR	89	0.51	5			15	0.0253			0.076
Citrus dried pulp	AB	0.43	STMR	91	0.47	10				0.0473			
Soya bean hulls	SM	0.4	STMR	90	0.44	10				0.0444			
Total						65	100	100	80	1.1837	6.252	40	0.514

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
Soya bean forage	AL	22.4	HR	56	40.00	20		40		8		16	
Cowpea forage	AL	3.6	HR	30	12.00		35	20			4.2	2.4	
Pea hay	AL	8.536	HR	88	9.70			10				0.97	
Cabbage heads, leaves	AM/AV	0.92	HR	15	6.13		20				1.227		
Almond hulls	AM/AV	4.9	STMR	90	5.44	10		10		0.5444		0.544	
Grape pomace, wet	AB	0.74	STMR	15	4.93			20				0.987	
Potato culls	VR	0.44	HR	20	2.20	10	30			0.22	0.66		
Apple pomace, wet	AB	0.44	STMR	40	1.10	10	10			0.11	0.11		
Soya bean meal	SM	0.62	STMR	92	0.67	10	5		60	0.0674	0.034		0.404
Soya bean seed	VD	0.45	STMR	89	0.51	10			10	0.0506			0.051
Cotton undelinted seed	SO	0.095	STMR	88	0.11	10				0.0108			
Total						80	100	100	70	9.0032	6.23	20.9	0.455

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	0.44	HR	20	2.20		10				0.22		
Soya bean meal	SM	0.62	STMR	92	0.67	25	40	25	35	0.1685	0.27	0.168	0.236
Soya bean seed	VD	0.45	STMR	89	0.51	20	20	15		0.1011	0.101	0.076	
Bean seed	VD	0.21	STMR	88	0.24			55				0.131	
Total						45	70	95	35	0.2696	0.591	0.376	0.236

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
Soya bean forage	AL	22.4	HR	56	40.00		10				4		
Cabbage heads, leaves	AM/AV	0.92	HR	15	6.13		5				0.307		
Potato culls	VR	0.44	HR	20	2.20		10				0.22		
Soya bean meal	SM	0.62	STMR	92	0.67	25	25	25	30	0.1685	0.168	0.168	0.202
Soya bean seed	VD	0.45	STMR	89	0.51	20	15	15		0.1011	0.076	0.076	
Bean seed	VD	0.21	STMR	88	0.24			55				0.131	
Total						45	65	95	30	0.2696	4.771	0.376	0.202

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
Soya bean forage	AL	10.64	STMR/ STMR-P	56	19.00			100				19	
Cowpea forage	AL	2.22	STMR/ STMR-P	30	7.40		35				2.59		
Soya bean asp gr fn	SM	1.9	STMR/ STMR-P	85	2.24	5				0.1118			
Cabbage heads, leaves	AM/AV	0.23	STMR/ STMR-P	15	1.53		20				0.307		
Apple pomace, wet	AB	0.44	STMR/ STMR-P	40	1.10		20				0.22		
Cotton gin byproducts	AM/AV	0.711	STMR/ STMR-P	90	0.79	5				0.0395			
Soya bean meal	SM	0.62	STMR/ STMR-P	92	0.67		20		65		0.135		0.438
Potato culls	VR	0.11	STMR/ STMR-P	20	0.55	30	5			0.165	0.028		
Soya bean seed	VD	0.45	STMR/ STMR-P	89	0.51	5			15	0.0253			0.076
Citrus dried pulp	AB	0.43	STMR/ STMR-P	91	0.47	10				0.0473			
Soya bean hulls	SM	0.4	STMR/ STMR-P	90	0.44	10				0.0444			
Total						65	100	100	80	0.4332	3.279	19	0.514

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
Soya bean forage	AL	10.64	STMR/ STMR-P	56	19.00	20	0	40		3.8	0	7.6	
Cowpea forage	AL	2.22	STMR/ STMR-P	30	7.40	0	35	20		0	2.59	1.48	
Almond hulls	AM/AV	4.9	STMR/ STMR-P	90	5.44	10		10		0.544		0.544	
Grape pomace, wet	AB	0.74	STMR/ STMR-P	15	4.93	0		20		0		0.987	
Pea hay	AL	1.584	STMR/ STMR-P	88	1.80	0		10		0		0.18	
Cabbage heads, leaves	AM/AV	0.23	STMR/ STMR-P	15	1.53	0	20			0	0.307		
Apple pomace, wet	AB	0.44	STMR/ STMR-P	40	1.10	10	10			0.11	0.11		
Soya bean meal	SM	0.62	STMR/ STMR-P	92	0.67	10	25		60	0.067	0.168		0.404
Potato culls	VR	0.11	STMR/ STMR-P	20	0.55	10	10			0.055	0.055		
Soya bean seed	VD	0.45	STMR/ STMR-P	89	0.51	10			10	0.051			0.051
Cotton undelinted seed	SO	0.095	STMR/ STMR-P	88	0.11	10				0.011			
Total						80	100	100	70	4.638	3.23	10.79	0.455

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
Soya bean meal	SM	0.62	STMR/ STMR-P	92	0.67	25	40	25	35	0.168	0.27	0.168	0.236
Potato culls	VR	0.11	STMR/ STMR-P	20	0.55		10				0.055		
Soya bean seed	VD	0.45	STMR/ STMR-P	89	0.51	20	20	15		0.101	0.101	0.076	
Bean seed	VD	0.21	STMR/ STMR-P	88	0.24			55				0.131	
Total						45	70	95	35	0.27	0.426	0.376	0.236

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
Soya bean forage	AL	10.64	STMR/ STMR-P	56	19.00		10				1.9		
Cabbage heads, leaves	AM/AV	0.23	STMR/ STMR-P	15	1.53		5				0.077		
Soya bean meal	SM	0.62	STMR/ STMR-P	92	0.67	25	25	25	30	0.168	0.168	0.168	0.202
Potato culls	VR	0.11	STMR/ STMR-P	20	0.55		10				0.055		
Soya bean seed	VD	0.45	STMR/ STMR-P	89	0.51	20	15	15		0.101	0.076	0.076	
Bean seed	VD	0.21	STMR/STMR-P	88	0.24			55				0.131	
Total						45	65	95	30	0.27	2.276	0.376	0.202

TRIFLUMIZOLE - 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	1.76	STMR	15	11.73			20				2.347	
Total								20				2.347	

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	1.76	STMR	15	11.73			20				2.347	
Total								20				2.347	

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	1.76	STMR/STMR-P	15	11.73			20				2.347	
Total								20				2.347	

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	1.76	STMR/STMR-P	15	11.73		0	20			0	2.347	
Total						0		20		0.000		2.347	

POULTRY BROILER/LAYER

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
No feed items applicable!													

TRINEXAPAC-ETHYL - 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
Barley forage	AF/AS	3.76	HR	100	3.76		30	50			1.128	1.88	
Oat forage	AF/AS	3.76	HR	100	3.76			50				1.88	
Barley hay	AF/AS	1.34	HR	100	1.34	15				0.201			
Wheat milled bypdts	CM/CF	1.08	STMR	88	1.23	40	30		55	0.491	0.368		0.675
Barley grain	GC	0.57	STMR	88	0.65	45	40		45	0.291	0.259		0.291
Total						100	100	100	100	0.983	1.755	3.76	0.966

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
Barley forage	AF/AS	3.76	HR	100	3.76		30	50			1.128	1.88	
Oat forage	AF/AS	3.76	HR	100	3.76	30		50	5	1.128		1.88	0.188
Wheat milled bypdts	CM/CF	1.08	STMR	88	1.23	30	30		45	0.368	0.368		0.552
Barley grain	GC	0.57	STMR	88	0.65	40	40		40	0.259	0.259		0.259
Total						100	100	100	90	1.755	1.755	3.76	0.999

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
Oat forage	AF/AS	3.76	HR	100	3.76		10				0.376		
Wheat milled bypdts	CM/CF	1.08	STMR	88	1.23	50	20	20	30	0.614	0.245	0.245	0.368
Barley grain	GC	0.57	STMR	88	0.65	50	70	15		0.324	0.453	0.097	
Total						100	100	35	30	0.938	1.075	0.343	0.368

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	1.08	STMR	88	1.23	50	20	20	5	0.614	0.245	0.245	0.061
Barley grain	GC	0.57	STMR	88	0.65	50	70	15	10	0.324	0.453	0.097	0.065
Total						100	90	35	15	0.938	0.699	0.343	0.126

TRINEXAPAC-ETHYL - 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	1.08	STMR/STMR-P	88	1.23	40	30	40	55	0.491	0.368	0.491	0.675
Barley grain	GC	0.57	STMR/STMR-P	88	0.65	50	70	60	45	0.324	0.453	0.389	0.291
Sugarcane molasses	DM	0.4	STMR/STMR-P	75	0.53	10				0.053			
Total						100	100	100	100	0.868	0.822	0.88	0.966

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 forage	AF/AS	3.76	HR	100	3.76		30	50			1.128	1.88	
Oat forage	AF/AS	3.76	HR	100	3.76	30		50	5	1.128		1.88	0.188
Wheat milled bypdts	CM/CF	1.08	STMR	88	1.23	30	30		45	0.368	0.368		0.552
Barley grain	GC	0.57	STMR	88	0.65	40	40		40	0.259	0.259		0.259
Total						100	100	100	90	1.755	1.755	3.76	0.999

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	1.08	STMR/STMR-P	88	1.23	50	20	20	5	0.614	0.245	0.245	0.061
Barley grain	GC	0.57	STMR/STMR-P	88	0.65	50	70	15	10	0.324	0.453	0.097	0.065
Total						100	90	35	15	0.938	0.699	0.343	0.126

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	1.08	STMR/STMR-P	88	1.23	50	20	20	30	0.614	0.245	0.245	0.368
Barley grain	GC	0.57	STMR/STMR-P	88	0.65	50	80	15		0.324	0.518	0.097	
Total						100	100	35	30	0.938	0.764	0.343	0.368

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The annual Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues was held in Geneva, Switzerland, from 17 to 26 September 2013. The FAO Panel of Experts had met in preparatory sessions from 6 to 10 September. The Meeting was held in pursuance of recommendations made by previous Meetings and accepted by the governing bodies of FAO and WHO that studies should be undertaken jointly by experts to evaluate possible hazards to humans arising from the occurrence of pesticide residues in foods. During the meeting the FAO Panel of Experts was responsible for reviewing pesticide use patterns (use of good agricultural practices), data on the chemistry and composition of the pesticides and methods of analysis for pesticide residues and for estimating the maximum residue levels that might occur as a result of the use of the pesticides according to good agricultural use practices. The WHO Core Assessment Group was responsible for reviewing toxicological and related data and for estimating, where possible and appropriate, acceptable daily intakes (ADIs) and acute reference doses (ARfDs) of the pesticides for humans. This report contains information on ADIs, ARfDs, maximum residue levels, and general principles for the evaluation of pesticides. The recommendations of the Joint Meeting, including further research and information, are proposed for use by Member governments of the respective agencies and other interested parties.

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