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Pesticide residues in food 2012

Joint FAO/WHO Meeting on Pesticide Residues

REPORT 2012

World Health Organization

Food and Agriculture Organization of the United Nations

Pesticide residues in food 2012

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

WORLD HEALTH ORGANIZATION
FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS
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R, residue and analytical aspects; T, toxicological evaluation

* New compound

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

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ROME, 11–20 SEPTEMBER 2012

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ABBREVIATIONS

ADI	acceptable daily intake
ai	active ingredient
AR	applied radioactivity
ARfD	acute reference dose
asp gr fn	aspirated grain fraction
ATP	adenosine triphosphate
AU	Australia
AUC	area under the plasma concentration–time curve
BBCH	**B**iologischen Bundesanstalt, **B**undessortenamt und **CH**emische Industrie
bw	body weight
CAC	Codex Alimentarius Commission
CAS	Chemical Abstracts Service
CCN	Codex classification number (for compounds or commodities)
CCPA	4-chloro-2-carboxyphenoxyacetic acid
CCPR	Codex Committee on Pesticide Residues
C_{max}	maximum concentration
CPIA	chlorophenylisovaleric acid
CXL	Codex MRL
CYP	cytochrome P450
DAP	days after planting
DAT	days after treatment
DM	dry matter
DMA	dimethylamine
DNA	deoxyribonucleic acid
DT_{50}	time required for 50% dissipation of the initial concentration
dw	dry weight
ECD	electron capture detector
EHC	Environmental Health Criteria monograph
EHE	ethylhexyl ester
EPO	early post-emergence
EU	European Union
F_0	parental generation
F_1	first filial generation
FAO	Food and Agriculture Organization of the United Nations
fw	fresh weight

GAP	good agricultural practice
GC	gas chromatography
GC-ECD	gas chromatography with electron capture detection
GC-FPD	gas chromatography with flame photometric detection
GC/MS	gas chromatography/mass spectrometry
GC/MSD	gas chromatography/mass selective detector
GC-NPD	gas chromatography coupled with nitrogen-phosphorus detector
GD	gestation day
GEMS/Food	Global Environment Monitoring System – Food Contamination Monitoring and Assessment Programme
GI	gastrointestinal
GLC	gas liquid chromatography
GLP	good laboratory practice
GPC	gel permeation chromatography
HMCPA	4-chloro-2-hydroxymethyl phenoxyacetic acid
HPLC	high performance liquid chromatography
HR	highest residue in the edible portion of a commodity found in trials used to estimate a maximum residue level in the commodity
HR-P	highest residue in a processed commodity calculated by multiplying the HR of the raw commodity by the corresponding processing factor
IEDI	international estimated daily intake
IESTI	international estimate of short-term dietary intake
IPCS	International Programme on Chemical Safety
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
JP	Japan
LC	liquid chromatography
LC_{50}	median lethal concentration
LD_{50}	median lethal dose
LOAEL	lowest-observed-adverse-effect level
LOD	limit of detection
LOQ	limit of quantification
MOA	mode of action
MPA	2-methylphosphinico-acetic acid
MPB	4-methylphosphinico-butanoic acid
MPP	3-[hydroxy(methyl) phosphinoyl]propionic acid (= 3-methylphosphinico-propionic acid)

MRL	maximum residue limit
MS	mass spectrometry
MS/MS	tandem mass spectrometry
NAG	*N*-acetylglufosinate
ND	non-detect - below limit of detection
NOAEC	no-observed-adverse-effect concentration
NOAEL	no-observed-adverse-effect level
OECD	Organisation for Economic Co-operation and Development
PAG3	2-(2-hydroxymethylphenyl)-2-oxoacetic acid
PAM	1-methyl-3-trifluoromethyl-1H-pyrazole-4-carboxamide
PB	3-phenoxybenzoic
PBI	plant back interval
PCA	1-methyl-3-trifluoromethyl-1H-pyrazole-4-carboxylic acid; 4-chloroaniline
Pf	processing factor
PH	pre-harvest
PHI	pre-harvest interval
ppm	parts per million
PRE	pre-emergence
RAC	raw agricultural commodity
RSD	relative standard deviation
RTI	re-treatment interval
SC	suspension concentrate
SL	soluble liquid
SPE	solid phase extraction
STMR	supervised trials median residue
STMR-P	supervised trials median residue in a processed commodity calculated by multiplying the STMR of the raw commodity by the corresponding processing factor
TAR	total administered radioactivity
TF	transfer factor
TLC	thin-layer chromatography
TMPA	2,2,3,3-tetramethylcyclopropane carboxylic acid
TRR	total radioactive residues
TTC	threshold of toxicological concern
UK	United Kingdom
USA	United States of America
US/CAN	United States and Canada
USEPA	United States Environmental Protection Agency
US-FDA	USA – Food and Drug Administration

WG	wettable granule
WHO	World Health Organization
WP	wettable powder

USE OF JMPR REPORTS AND EVALUATIONS BY REGISTRATION AUTHORITIES

Most of the summaries and evaluations contained in this report are based on unpublished proprietary data submitted for use by JMPR in making its assessments. A registration authority should not grant a registration on the basis of an evaluation unless it has first received authorization for such use from the owner of the data submitted for the JMPR review or has received the data on which the summaries are based, either from the owner of the data or from a second party that has obtained permission from the owner of the data for this purpose.

PESTICIDE RESIDUES IN FOOD
REPORT OF THE 2012 JOINT FAO/WHO MEETING OF EXPERTS

1. INTRODUCTION

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

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

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

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

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

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

The Meeting was held in pursuance of recommendations made by previous Meetings and accepted by the governing bodies of FAO and WHO that studies should be undertaken jointly by experts to evaluate possible hazards to humans arising from the occurrence of residues of pesticides in foods. The reports of previous Joint Meetings (see Annex 5) contain information on acceptable daily intakes (ADIs), acute reference doses (ARfDs), MRLs and the general principles that have been used for evaluating pesticides. The supporting documents (residue and toxicological evaluations) contain detailed monographs on these pesticides and include evaluations of analytical methods.

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

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

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

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

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

1.1 DECLARATION OF INTERESTS

The Secretariat informed the Meeting that all experts participating in the 2012 JMPR had completed declaration-of-interest forms and that no conflicts had been identified.

2. GENERAL CONSIDERATIONS

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

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

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

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

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

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

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

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

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

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

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

Fenvalerate

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

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

Dicofol

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

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

Dichlorvos

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

2.2 UPDATE OF THE GEMS/FOOD CLUSTER DIETS

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

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

2.3 UPDATE OF JMPR GUIDANCE DOCUMENT

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

2.6 CHANGES IN JMPR PROCEDURE

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

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

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

2.7 ASSESSMENT OF COMPOUNDS WITH VERY LOW TOXICITY

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

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

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

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

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

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

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

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

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

2.8 UPDATE OF THE AUTOMATED SPREADSHEET APPLICATIONS FOR THE CALCULATION OF SHORT-TERM DIETARY INTAKE: NEW LARGE PORTION DATA

The 2003 Meeting of the JMPR agreed to adopt automated spreadsheet applications for the calculation of dietary intake, in order to harmonize and facilitate the estimation process. The spreadsheet applications were constructed by RIVM (National Institute for Public Health and the Environment), of the Netherlands in cooperation with WHO/GEMS/Food by incorporating available consumption data into Excel spreadsheets and, where possible, linking this consumption data to the Codex Commodities for which HR(-P)s and STMR(-P)s are estimated. The spreadsheets are used to calculate the IESTI using the formulas as described in Chapter 7 of the 2009 FAO manual. To use the spreadsheets, estimates made by JMPR (ARfD, STMR(-P), HR(-P)) are entered according to the manual attached to the spreadsheets. Then calculations and generation of a final table are performed automatically.

In its 2010 Report, JMPR highlighted the importance of current consumption data for a reliable risk assessment (General Considerations 2.2 and 2.3). As a result of a WHO/GEMS/Food request to provide or update national large portion data for acute dietary risk assessment (March 2011), the governments of Australia, France, Germany, Netherlands and Thailand provided new or updated information on large portion data and/or commodity unit weights and percent edible portions for the JMPR 2011. As a result of the extension of the request the governments of Brazil, China, Finland, and Japan provided data for use by the current JMPR Meeting. Denmark indicated that their large portion data were already covered by the JMPR 2011 data and refrained from sending further large portion data. The government of the UK confirmed that the 2003 dataset was still valid. Large portion data already available to JMPR and provided by the governments of South Africa, and the USA were retained. Unit weight data already available to the 2003 JMPR and provided by the governments of Belgium, Sweden, and the USA were also retained.

The population age groups for which large portion data have been provided differed between countries. Large portion data are now available for general population (all ages), women of childbearing age (14-50 yrs), and children of 6 yrs and under. Since data were available on a number of different population groups, the highest large portion (based on g/kg bw/d) for each commodity from all population groups has been used in the IESTI spreadsheet.

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

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

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

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

Since 2011, the IESTI calculations can be done for individual raw and processed commodities (e.g., raw apples, apple juice, apple sauce, dried apples) as well as for aggregated large portion data (e.g., sum of raw apples, apple juice and dried apples). Large portion data for individual raw and individual processed commodities are listed separately from aggregate large portion data in the spreadsheet. Aggregate large portion data differ from the large portion data for the individual raw and processed commodities because they come from different countries and/or they are expressed as a raw edible agricultural commodity.

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

2.9 FURTHER CONSIDERATIONS FOR THE USE OF THE PROPORTIONALITY APPROACH

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

General aspects

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

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

Examples from 2012 JMPR

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

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

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

Glufosinate-ammonium

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

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

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

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

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

Spinetoram

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

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

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

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

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

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

3.1 ACETAMIPRID (246)

Background

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

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

Evaluation of acetamiprid by JMPR

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

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

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

Evaluation of acetamiprid by the EC

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

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

Comments by JMPR

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

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

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

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

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

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

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

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

3.2 CHLORPYRIFOS-METHYL (090)

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

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

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

Long-term dietary risk assessment

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

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

3.3 DICAMBA (240)

Background

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

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

Comments by JMPR

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

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

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

3.4 DIFLUBENZURON (130)

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

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

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

3.5 INDOXACARB (216)

Indoxacarb, an indeno-oxadiazine insecticide used for control of Lepidoptera and other pests, was first evaluated by the 2005 JMPR, with additional commodities and commodity groups being considered at the 2007 and 2009 JMPR Meetings. An ADI of 0–0.01 mg/kg bw and an ARfD of 0.1 mg/kg body weight were established by the 2005 JMPR.

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

The Thirty-eighth Session of the CCPR in 2006 advanced the proposed draft MRL of 15 mg/kg for lettuce, leaf to Step 5, noting the acute dietary intake concerns for children expressed by the EC [Alinorm 06/29/24 - para 135]. This draft MRL was subsequently advanced to Step 8 by the Thirty-ninth Session of the CCPR in 2007.

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

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

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

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

Lettuce – Alternative GAP Re-assessment

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

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

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

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

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

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

3.6 ISOPYRAZAM (249)

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

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

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

3.7 OXAMYL (126)

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

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

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

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

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

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

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

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

3.8 PYRACLOSTROBIN (210)

Background

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

Comments by JMPR

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

3.9 SAFLUFENACIL (251)

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

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

Conclusion:

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

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

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

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

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

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

3.10 SPIROTETRAMAT (234)

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

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

4. DIETARY RISK ASSESSMENT FOR PESTICIDE RESIDUES IN FOODS

Assessment of risk from long-term dietary intake

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

New evaluations

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

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

Periodic Re-evaluations

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

Evaluations

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

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

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

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

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

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

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

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

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

Assessment of risk from short-term dietary intake

The procedures used for calculating the International Estimated Short-Term Intake (IESTI) are described in detail in Chapter 3 of the 2003 Report of the JMPR. Detailed guidance on setting ARfD is described in Section 2.1 of the 2004 Report of the JMPR[1].

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

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

New evaluations

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

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

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

Periodic Re-evaluations

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

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

Evaluations

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

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

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

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

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

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

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

[a] only for women of childbearing age;

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

Possible risk assessment refinement when IESTI exceeds the ARfD

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

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

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 AMETOCTRADIN (253)

TOXICOLOGY

Ametoctradin is the common name provisionally approved by the International Organization for Standardization (ISO) for 5-ethyl-6-octyl[1,2,4]triazolo[1,5-a]pyrimidin-7-amine, for which the Chemical Abstracts Service (CAS) number is 865318-97-4. Ametoctradin is a fungicide that inhibits zoospore differentiation within the zoosporangium, the release of zoospores from the zoosporangium, the motility of any released zoospores and the germination of encysted zoospores. It acts by reducing the adenosine triphosphate (ATP) content in these stages of development by binding to and inhibiting complex III of the respiratory chain in mitochondria of oomycetes.

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

All studies evaluated were performed by good laboratory practice (GLP)–certified laboratories and complied with the relevant OECD and/or United States Environmental Protection Agency (USEPA) test guidelines.

Biochemical aspects

Following oral administration, ^{14}C-labelled ametoctradin underwent limited and saturable absorption from the gastrointestinal tract, but was quite widely distributed. Maximum plasma concentrations (C_{max}) were observed within 1–2 hours after administration, and initial half-lives ranged from 2 to 3 hours. The area under the plasma concentration–time curve (AUC) values indicate that internal exposure was not different in males and females. Excretion of ametoctradin occurred rapidly and independently of sex. Most of the administered dose (91–110%) was recovered within 168 hours after a single low or high dose and repeated high doses, with faeces as the main elimination route. Based on the amount of radioactivity excreted via bile and urine, the bioavailability of ametoctradin in rats was calculated to be about 40% of the administered dose at 50 mg/kg bw and about 20% of the applied dose at 500 mg/kg bw. The parent compound is metabolized by terminal oxidation of the octyl side-chain to the respective carboxylic acid (M650F09), with subsequent degradation of the carboxylic side-chain to give M650F06 and M650F01. In addition, conjugation of the respective oxidized side-chain with taurine and/or glucuronic acid occurs, leading to metabolites M650F10 (taurine conjugate of M650F09), M650F11 (glucuronic acid conjugate of M650F06) and M650F12 (taurine conjugate of M650F06). Also, a minor metabolic step leads to the formation of M650F05 (ω-hetarylpentanoic acid). Several metabolites of ametoctradin were found in liver, kidneys, plasma and bile, with metabolite M650F06 being the most abundant.

Toxicological data

Ametoctradin has low acute oral and dermal toxicity (median lethal doses [LD_{50}s] > 2000 mg/kg bw) and low toxicity by inhalation (median lethal concentration [LC_{50}] > 5.5 mg/L). No skin or eye irritation was observed after ametoctradin exposure. Ametoctradin was not a sensitizer in a Magnusson & Kligman maximization test or in the murine local lymph node assay.

In repeated-dose toxicity studies in mice, rats and dogs, no consistent toxicological findings were evident in any of the species at any dose tested up to the limit dose (around 1000 mg/kg bw per day) or after any study duration. Ametoctradin was extensively tested in a comprehensive set of current guideline studies, including short-term studies of toxicity, long-term studies of toxicity and carcinogenicity, studies of reproductive and developmental toxicity, neurotoxicity studies and an immunotoxicity study.

In the long-term studies of toxicity and carcinogenicity, no treatment-related changes in tumour incidence were observed.

The Meeting concluded that ametoctradin was not carcinogenic in mice or rats.

Ametoctradin was tested for genotoxicity in an adequate range of in vitro and in vivo studies. No evidence for genotoxicity was observed in any of these tests.

The Meeting concluded that ametoctradin was not genotoxic.

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

The toxicity of several soil metabolites of ametoctradin was examined. Ninety-day dietary toxicity studies in rats were performed with metabolites M650F03 and M650F04, metabolites that were not found in the rat. In the 90-day dietary toxicity studies, no adverse effects were observed after exposure to either M650F03 or M650F04 up to the limit dose (i.e. 15 000 parts per million [ppm], equivalent to about 1000 mg/kg bw per day). The genotoxic potential of three soil metabolites, M650F02, M650F03 and M650F04, was tested in several in vitro and in vivo studies. All were negative for genotoxicity.

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

Toxicological evaluation

From the animal studies with ametoctradin, no adverse effects were observed at or near the limit dose of approximately 1000 mg/kg bw per day. The Meeting concluded that it was not necessary to establish an ADI for ametoctradin. This was based on a reasonable estimate of a likely maximal intake of the residues of a pesticide arising from the daily diet. In the 2004 JMPR report and in more detail in the 2005 publication by Solecki et al. on guidance on setting ARfDs[1], a maximum cut-off of 5 mg/kg bw for the ARfD was suggested, based on food consumption estimates and maximum residue levels in foods. This cut-off would equate to a NOAEL of 500 mg/kg bw per day in an animal study, with the application of the default uncertainty factor of 100. A similar principle was considered by the Meeting to be applicable in setting an extreme upper bound for the ADI, noting that the long-term daily dietary exposure for the residues of a particular pesticide will be less than the IESTI for the residues of that pesticide. A cut-off for the ADI could be refined, taking into account long-term high-level consumption.

The Meeting concluded that it was not necessary to establish an ARfD for ametoctradin in view of the absence of acute toxicity or any other effect that could be elicited by a single dose.

A toxicological monograph was prepared.

Levels relevant to risk assessment

Species	Study	Effect	NOAEL	LOAEL
Mouse	Eighteen-month study of toxicity and carcinogenicity[a]	Toxicity	6000 ppm, equal to 1099 mg/kg bw per day[b]	—
		Carcinogenicity	6000 ppm, equal to 1099 mg/kg bw per day[b]	—
Rat	Two-year study of toxicity and carcinogenicity[a]	Toxicity	15 000–22 500 ppm, equal to 871 mg/kg bw per day[b]	—
		Carcinogenicity	15 000–22 500 ppm,	—

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

Species	Study	Effect	NOAEL	LOAEL
			equal to 871 mg/kg bw per day[b]	
	Two-generation study of reproductive toxicity[a]	Parental toxicity	939 mg/kg bw per day[b]	—
		Offspring toxicity	939 mg/kg bw per day[b]	—
		Reproductive toxicity	939 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]	—
	Acute neurotoxicity study[c]	Neurotoxicity	2000 mg/kg bw per day[b]	—
Rabbit	Developmental toxicity study[c]	Maternal toxicity	1000 mg/kg bw per day[b]	—
		Embryo and fetal toxicity	1000 mg/kg bw per day[b]	—
Dog	One-year study of toxicity[a]	Toxicity	30 000 ppm, equal to 848 mg/kg bw per day[b]	—

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

Estimate of acceptable daily intake for humans

Unnecessary

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 ametoctradin

Absorption, distribution, excretion and metabolism in mammals	
Rate and extent of oral absorption	Approximately 20% at high dose (500 mg/kg bw) and 40% at low dose (50 mg/kg bw)
Dermal absorption	No information on the pure active substance
Distribution	Widely distributed
Potential for accumulation	None
Rate and extent of excretion	Rapid and complete
Metabolism in animals	Limited; several metabolites, with M650F06 being most abundant
Toxicologically significant compounds in animals, plants and the environment	None
Acute toxicity	
Rat, LD_{50}, oral	> 2000 mg/kg bw per day
Rat, LD_{50}, dermal	> 2000 mg/kg bw per day
Rat, LC_{50}, inhalation	> 5.5 mg/L air (4 h, nose only)
Rabbit, dermal irritation	Non-irritant
Rabbit, ocular irritation	Non-irritant
Dermal sensitization	Not sensitizing (Magnusson & Kligman and local lymph node assay)
Short-term studies of toxicity	
Target/critical effect	No adverse effects at the limit dose
Long-term studies of toxicity and carcinogenicity	
Target/critical effect	No adverse effects at the limit dose
Carcinogenicity	No carcinogenic potential

Genotoxicity	
	No genotoxic potential
Reproductive toxicity	
Target/critical effect	No adverse effects at the limit dose
Developmental toxicity	
Target/critical effect	No adverse effects at the limit dose
Neurotoxicity	
Acute neurotoxicity	No neurotoxicity at the limit dose
Other toxicological studies	
Immunotoxicity studies	No immunotoxicity at the limit dose
Studies performed on metabolites or impurities	M650F02: Not genotoxic M650F03: Not genotoxic; no effects at the limit dose in 90-day rat study M650F04: Not genotoxic; no effects at the limit dose in 90-day rat study
Medical data	
	Limited information; new compound

Summary

	Value	Study	Safety factor
ADI	Unnecessary	—	—
ARfD	Unnecessary	—	—

RESIDUE AND ANALYTICAL ASPECTS

Residue and analytical aspects of ametoctradin were considered for the first time by the present Meeting. The residue evaluation was scheduled for the 2012 JMPR by the Forty-third Session of the CCPR.

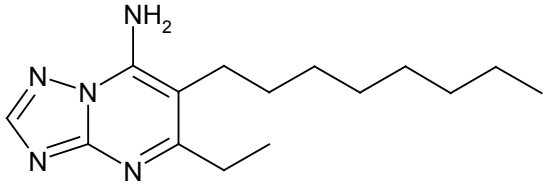
Ametoctradin is a fungicide of the chemical class triazolo-pyrimidylamines. Ametoctradin strongly inhibits zoospore differentiation within the zoosporangium, the release of zoospores from the zoosporangium, the motility of any released zoospores and the germination of encysted zoospores. The inhibition caused by ametoctradin reduces the ATP content in these stages of development by binding to and inhibiting complex III of the respiratory chain in mitochondria of Oomycetes.

The Meeting received information from the manufacturer on identity, metabolism, storage stability, residue analysis, use pattern, residues resulting from supervised trials on grapes, bulb vegetables, Brassica vegetables, fruiting vegetables, leafy vegetables, celery, potatoes and hops, fate of residue during processing, and livestock feeding studies.

Chemical name:

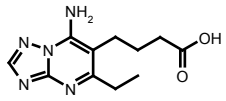
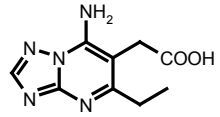
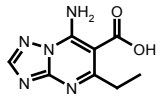
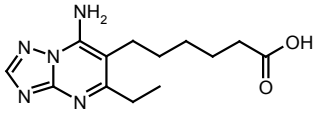
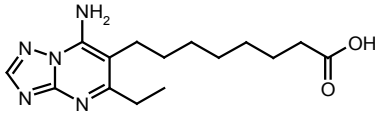
Ametoctradin or IUPAC: 5-ethyl-6-octyl[1,2,4]triazolo[1,5-a]pyrimidin-7-amine

Structural formula:



Metabolites referred to in the appraisal by codes:

M650F01	4-(7-amino-5-ethyl[1,2,4]triazolo[1,5-a]pyrimidin-6-yl)butanoic acid or ω-hetarylbutanoic acid

	
M650F03	(7-amino-5-ethyl [1,2,4]triazolo [1,5-a]pyrimidin-6-yl) acetic acid or hetarylacetic acid 
M650F04	7-amino-5-ethyl [1,2,4]triazolo [1,5-a]pyrimidine-6-carboxylic acid or hetarylcarboxylic acid 
M650F06	6-(7-amino-5-ethyl[1,2,4]triazolo[1,5-a]pyrimidin-6-yl)hexanoic acid or ω-hetarylhexanoic acid 
M650F09	8-(7-amino-5-ethyl[1,2,4]triazolo[1,5-a]pyrimidin-6-yl)octanoic acid or ω-hetaryloctanoic acid 

Animal metabolism

The Meeting received results of animal metabolism studies in lactating goats and laying hens. Experiments were carried out with [2,7-^{14}C]-ametoctradin.

Metabolism in laboratory animals was summarized and evaluated by the WHO panel of the JMPR in 2012. Oral administration of radiolabelled ametoctradin in rats results in a rapid absorption and high degree of biotransformation, as indicated by low amounts of parent compound found in urine and bile. A considerable part of the applied ametoctradin was excreted unchanged via faeces. In liver, kidneys, plasma and bile, several metabolites of ametoctradin were found, with metabolite M650F06 being the most abundant. The parent compound is metabolized by terminal oxidation of the octyl side chain to the respective carboxylic acid (M650F09) with subsequent degradation of the carboxylic side chain (M650F06 and M650F01). In addition, conjugation of the respective oxidised side chain with taurine and/or glucuronic acid occurs, leading to metabolites M650F10 (taurine conjugate of M650F09), M650F11 (glucuronic acid conjugate of M650F06), and M650F12 (taurine conjugate of M650F06), respectively. Also a minor metabolic step leads to the formation of M650F05 (ω-hetarylpentanoic acid).

Two lactating goats, orally treated once daily for 10 consecutive days with [2,7-^{14}C]-ametoctradin, were sacrificed 23 hours after the last dose. The two goats received an actual dose rate of 13 and 12 ppm dry feed (0.51 and 0.49 mg ai/kg bw, respectively). Total recovered radioactivity amounted to 64% of the administered dose in goat 1 and 88% in goat 2. Radioactivity recovered from urine, faeces and cage wash amounted to 61% of the administered dose in goat 1 (24% in urine; 36%

in faeces) and 84% in goat 2 (26% in urine, 58% in faeces). In both animals, radioactivity amounted to 0.15–0.19% of the applied dose in milk and 0.05% in edible tissues and organs.

The total radioactive residues (TRR) in tissues and milk were 0.10 mg/kg eq (liver), 0.036 mg/kg eq (kidney), 0.016 mg/kg eq (fat), 0.010 mg/kg eq (muscle) and 0.028 mg/kg eq (pooled milk). Radioactivity levels in afternoon milk were higher than residue levels in morning milk (just before the next dosing). Radioactivity levels in milk did not reach a clear plateau, although a flattening of the curve started by day 5–8 (0.026–0.048 mg/kg eq).

Methanol and water extracted 98% TRR for milk, 53% TRR for liver, 63% TRR for kidney, 72% TRR for muscle and 82% TRR for fat. The parent compound was not found in any of the goat commodities. In goat milk, liver, kidney and fat, the metabolite M650F06 (ω-hetarylhexanoic acid) was the most abundant component of the residues (22–47% TRR or 0.006–0.021 mg/kg eq), followed by the metabolite M650F01 (ω-hetarylbutanoic acid, 14–26% TRR or 0.003–0.014 mg/kg eq) and the metabolite M650F09 (ω-hetaryloctanoic acid, 7.7–9.4% TRR or 0.002–0.003 mg/kg eq; not detected in liver). A total of 91% (milk), 36% (liver), 46% (kidney), and 57% (fat) of the TRR could be identified in the initial extracts. No metabolite was identified in muscle (total extractable residues: 0.002 mg/kg eq). The solids remaining after initial extraction in liver and kidney were treated with protease and microwave, resulting in a release of most of the radioactivity (38% TRR in liver and 30% TRR in kidney). This radioactivity could not be attributed to any of the known metabolites.

Nine laying hens, orally treated once daily for 10 consecutive days with [2,7-^{14}C]-ametoctradin, were sacrificed 23 hours after the last dose. Hens were treated at an actual dose rate of 12 ppm dry feed (equivalent to 0.81 mg ai/kg bw). The total recovery of the applied dose was 93%. Radioactivity from the excreta and cage wash amounted to 92.4% of the administered dose, while 0.03% was found in liver, 0.06% in muscle, 0.00% in fat and 0.09% in eggs.

Concentrations in eggs increased within the first 6 application days and reached a plateau from day 6 onwards (0.037–0.040 mg/kg eq). The highest radioactivity concentrations in edible tissues were found in liver (0.11 mg/kg eq), followed by muscle (0.026 mg/kg eq) and fat (0.014 mg/kg eq).

Radioactivity was characterized in liver, muscle, fat and eggs. Methanol and water extracted 82% TRR for eggs, 52% TRR for liver, 44% TRR for muscle, and 66% TRR for fat. In hens, only low levels of residues were identified (each compound < 0.01 mg/kg eq). The major compounds were metabolite M650F01 (ω-hetarylbutanoic acid) with 28%, 8.7%, 1.9% TRR in fat, liver, muscle, respectively and parent compound with 22%, 11% TRR in eggs and fat, respectively. Metabolite M650F06 (ω-hetarylhexanoic acid) was only identified in liver and muscle at trace amounts (1.1–1.3% TRR) and metabolite M650F09 was not detected. A total of 22% (eggs), 10% (liver), 39% (fat) and 3.0% (muscle) of the TRR could be identified in the initial extracts. Other peaks and fractions individually ranged up to 12% TRR and 0.0083 mg/kg eq. All individual identified or characterized residues were at low levels (< 0.01 mg/kg eq). The solids remaining after initial extraction from eggs, liver, muscle and fat were subjected to sequential solubilisation procedures, resulting in a release of most of the radioactivity in eggs, liver and muscle (16%, 47%, 55% TRR respectively). This radioactivity could not be attributed to any of the known metabolites. In fat 33% TRR could not be solubilized.

Metabolism of ametoctradin in livestock involves oxidation of the aliphatic side chain to the respective terminal carboxylic acid (forming metabolite M650F09, ω-hetaryloctanoic acid) and subsequent stepwise oxidative cleavage of the side chain (loss of C_2H_4-units) analogous to the β-oxidation of fatty acids to form the metabolites M650F06 (ω-hetarylhexanoic acid) and M650F01 (ω-hetarylbutanoic acid). In goats metabolite M650F06 was the major metabolite found (22–47% TRR) in all tissues and milk, followed by M650F01 (14–26% TRR) and M650F09 (7.7–9.4% TRR). No parent compound was detected in goat tissues and milk. In hens, only low levels of residues were found (each < 0.01 mg/kg eq). The major compounds were metabolite M650F01 (1.9–28% TRR in liver, fat, muscle) and parent compound (22% in eggs and 11% in fat). Metabolite M650F06 was only identified in liver and muscle in trace amounts (1.1–1.3% TRR) and metabolite M650F09 was not detected.

The metabolic pathway in livestock is identical to the metabolic pathway in rats, although in rats more conjugation products are found.

Plant metabolism

The Meeting received plant metabolism studies for ametoctradin in/on fruits (tomatoes), leafy crops (lettuce) and root and tuber vegetables (potato) after foliar treatment.

Uptake and translocation studies with ^{14}C-labelled ametoctradin on leaves from tomato plants showed low uptake (5% TRR) and essentially no translocation of ametoctradin.

Uptake and translocation studies with tomato plants in nutrient solutions containing ^{14}C-labelled M650F03 or ^{14}C-labelled M650F04 soil metabolites showed that both soil metabolites are taken up by tomato plants via the root system concurrently with the stream of water. Both soil metabolites are equally distributed over the whole plants.

Indoor grown tomato plants were sprayed three times with an SC formulation of 2,7-^{14}C-radio labelled ametoctradin at an actual application rate of 3 × 0.30 kg ai/ha. Tomato plants were sampled at maturity 1 day after the last application (1DAT) and separated into leaves and fruit. Total radioactive residues (TRR) in tomato fruit and leaves at 1DAT were 0.36 mg/kg eq and 9.2 mg/kg eq. Residues could be extracted with methanol (99% TRR). The parent compound ametoctradin accounted for 99% TRR (0.036 mg/kg eq) in fruits and 99% TRR (9.0 mg/kg eq) in leaves. No other compounds were detected. The Meeting noted that since the plants were sampled only 1 day after the last application, it is to be expected that parent compound dominates the residue.

Indoor grown lettuce was sprayed three times with an SC formulation of 2,7-^{14}C-labelled ametoctradin at a concentration of 3 × 0.22 kg ai/ha. Plants were sampled at maturity at 7DAT. TRR in lettuce leaves were 8.5 mg/kg eq. Residues could be extracted with methanol (99% TRR). The parent compound accounted for 99% TRR (8.4 mg/kg eq). No other compounds were detected.

Indoor grown potato plants were sprayed three times with an SC formulation of 2,7-^{14}C-radio labelled ametoctradin at an actual concentration of 3 × 0.44 kg ai/ha. Immature plants were taken 14 days prior to the second application and mature plants 7 day after the last application. Plants were separated in tubers and leaves.

TRR in immature and mature tubers was 0.025 and 0.041 mg/kg eq, respectively. Residues in the tubers could be extracted with methanol (81–83% TRR) and water (4.1–7.7%) with 1.0–11% TRR remaining as solids. Ametoctradin was the main compound in immature tubers (0.017 mg/kg eq, 67% TRR), but represented only 3.6% TRR (0.001 mg/kg eq) in mature tubers. Identified metabolites were M650F03 (hetarylacetic acid, 13% and 40% TRR in immature and mature tubers, respectively, 0.003 and 0.016 mg/kg eq) and M650F04 (hetarylcarboxylic acid, 27% TRR in mature tubers only, 0.011 mg/kg eq).

TRR in immature and mature leaves was, respectively, 22 and 45 mg/kg eq. Residues in the leaves could be extracted with methanol (98% TRR). The parent ametoctradin was the main compound (95 and 85% TRR in immature and mature leaves, respectively). All metabolites detected were each ≤ 0.81 mg/kg eq (≤ 1.9% TRR) and in total < 5.0% TRR and thus of minor importance.

From these data it is concluded that in leafy vegetables and fruits parent ametoctradin is the only residue identified at significant quantities (99% TRR). In root and tuber vegetables (potatoes) considerable amounts of residues are found in/on leaves (22 or 45 mg/kg eq), while only low amounts of residues are found in the tubers (0.025 or 0.041 mg/kg eq). Parent compound is the major compound found in/on leaves (85–95% TRR), while varying amounts of parent compound are found in the tubers (67% in immature tubers and 3.6% TRR in mature tubers). In potato tubers two major metabolites are identified: M650F03 (13% and 40% TRR, respectively in immature and mature tubers) and M650F04 (27% TRR in mature tubers only).

Ametoctradin is hardly taken up, is not translocated via the leaves or fruits of plants and is hardly metabolized when sprayed on the leaves of fruits of plants. Since parent compound is found in potato tubers, it seems likely that the parent compound is taken up and translocated via the roots of the

plants. The presence of small amounts of metabolites in potato leaves (total < 5.0% TRR) indicates that once the parent compound is inside the plant it can be metabolized.

The two major metabolites found in potato tubers, M650F03 and M650F04, were not found in rat or in livestock. Metabolites M650F03 and M650F04 were identified in soil degradation studies of ametoctradin, and were the only metabolites taken up by rotational crops (see environmental fate in soil). Metabolites M650F03 and M650F04 were also seen in a variety of supervised field trials after foliar application. In most instances these levels were too low to quantitate but in some supervised field trials, the residues exceeded the LOQ and were reported. Since the ametoctradin formulation was applied 3–4 times with intervals of 5–14 days in the supervised field trials, it seems likely that the spray from the early application(s) reached the soil because of incomplete soil coverage by the plants. It is likely that parent present in these early applications is degraded in the soil to the metabolites M650F03 and M650F04 and these metabolites are taken up by the plants in low levels and can be detected at harvest (7–35 days after the first application). Therefore it seems likely that metabolites M650F03 and M650F04 are the result of uptake from soil via the roots and translocation within the plant, although small amounts may be formed by degradation of the parent compound within the plant. However, since the contribution of the total identified metabolites in leaves is very low (total 3.3–4.4% TRR) and identified residue levels in potato tubers are very low (0.020–0.026 mg/kg eq), uptake from soil and subsequent metabolism within the plant is considered of minor importance in primary crops.

Environmental fate in soil

The Meeting received information on aerobic degradation in soil, soil photolysis and fate in rotational crops.

The half life for 2,7-^{14}C-labelled-ametoctradin ranged from 1.5 to 3.2 days at 20 °C and 6.3 days at 10 °C in a study where three soils (sandy loam and loamy sand) were treated at 1.1 mg ai/kg dry soil (0.40 kg ai/ha). In a second study the half-life was 1.3 days in one sandy loam soil, treated at 1.9 mg ai/kg dry soil (0.72 kg ai/ha). The major metabolites in both studies were M650F01 (max. 54% TAR on day 10), M650F02 (max. 13% TAR on day 3), M650F03 (max. 57% TAR on day 10) and M650F04 (max. 55% TAR on day 120). A number of other degradation products were formed, but all < 5.5% TAR.

Using the data from these two soil degradation studies, the half-lives for the metabolites were estimated at 1–10 days for M650F01, 5–22 days for M650F02, 28–88 days for M650F03 and > 226 days for M650F04. Additional soil studies were performed with metabolites M650F03 and M650F04.

The half life for [pyrimidine-5-^{14}C]-M650F03 ranged from 29–43 days at 20 °C in a study where three soils (loamy sand, sandy loam, sand) were treated at 0.51–0.55 mg ai/kg dry soil (0.20 kg ai/ha). The amount of the major metabolite M650F04 continuously increased in the course of the study with 31–44% TAR present at 120 days. A number of other degradation products were formed, but all < 6.1% TAR.

The half life for [pyrimidine-5-^{14}C]-M650F04 was 228 days at 20 °C in a study where loamy sand was treated at an equivalent rate of 0.20 kg ai/ha. Two minor degradation products were formed (total < 7.0% TAR).

The half life for [2,7-^{14}C] ametoctradin in non-sterile sandy loam soil treated with 2.7 mg ai/kg dry soil (0.40 kg ai/ha) during a 15 days exposure to artificial sunlight (DT_{50} 23 days) was longer than in the dark control (DT_{50} 7 days). Despite the expectation that photolysis contributes to the degradation of ametoctradin based on its significant absorption at 295 nm and moderate photolysis in sterile water, the study results showed that light has no effect on the degradation of ametoctradin in soil, probably because the degradation in aerobic soil is already very fast.

In a confined rotational crop study, [2,7-^{14}C]-ametoctradin was sprayed on a loamy sand soil at a rate of 1.44 kg ai/ha under greenhouse conditions. Rotational crops were sown 30, 120 and 365 days after application, representing first, second and third rotations. Total radioactivity was 0.080–1.2–0.030 mg/kg eq in immature lettuce leaves after first-second-third rotations, 0.060–0.064–

0.016 mg/kg eq in mature lettuce leaves, 2.4–0.28–0.062 mg/kg eq in radish tops, 0.66–0.062–0.018 mg/kg eq in radish roots, 6.0–3.8–1.2 mg/kg in wheat straw, 5.2–2.7–1.7 mg/kg eq in wheat hay, and 1.8–1.2–0.84 mg/kg eq in wheat grain. Total radioactivity in wheat forage was only determined after second and third rotation, being 1.7 an 0.36 mg/kg eq. Except for radish root (second rotation) and mature lettuce leaves (first rotation) no significant amount of parent compound was detected in the various crop samples. Metabolite M650F03 was the major compound in lettuce leaves (30–42% TRR) at first rotation. At second and third rotation the major compound in lettuce leaves was the metabolite M650F04 (26–32% TRR). In radish roots and tops metabolite M650F03 remained the major compound (100 and 96% TRR, respectively) after first rotation followed by 67%TRR and 46% TRR, respectively at second and 39%TRR and 23% TRR, respectively at third rotation. Apart from wheat straw, where the metabolite M650F03 was the major compound (43% TRR) at first rotation, the metabolite M650F04 was the major component in all the wheat samples, 25% TRR in straw at first rotation and 44–98% TRR in all other fractions and different plant back intervals.

In a field rotational crop study at four different locations in Europe significant residues were found in rotational crop wheat after a single treatment of the bare soil with 0.96 kg ai/ha and a plant back interval of 120 days. The parent ametoctradin was not detected in wheat commodities. Metabolite M650F03 was detected between < 0.01 and 0.092 mg/kg and M650F04 between < 0.01 and 0.30 mg/kg in wheat forage and grain. Relatively high metabolite residues were found in wheat straw: 0.016–0.14 mg/kg for M650F03 and 0.040–1.0 mg/kg for M650F04.

In a second field rotational crop study at four different locations in Europe significant residues were found in rotational crops wheat, carrot, cauliflower and head lettuce after a single treatment of the bare ground with 0.96 kg ai/ha at plant back intervals of 30, 120 and 365 days. The parent compound ametoctradin was found in only two samples at the 30 day plant back interval; 0.038 mg/kg in wheat straw and 0.020 mg/kg in cauliflower inflorescence. The two soil metabolites M650F03 and M650F04 formed the majority of the residues in rotational crops. Residues were highest in the animal feed commodities immature carrot plants, carrot tops, wheat forage and wheat straw, moderate in the edible food commodities wheat grain and carrot root and low in lettuce and cauliflower inflorescence. Residues were highest after a plant back interval of approximately 30 days and decreased at longer plant back intervals.

- After a plant back interval of 30 days, metabolite M650F03 and M650F04 were found between < 0.01–0.92 mg/kg eq and < 0.01–0.35 mg/kg eq in animal feedstuff and between < 0.01–0.056 mg/kg eq and < 0.01–0.12 mg/kg eq in wheat grain, carrot roots, cauliflower inflorescence and head lettuce, respectively. Residues were found in all commodities.
- After a plant back interval of 120 days, metabolites M650F03 and M650F04 were found between < 0.01 – 0.054 mg/kg eq and < 0.01 mg/kg eq in animal feedstuff, respectively. No residues above the LOQ were found in wheat grain, carrot roots, cauliflower inflorescence and head lettuce.
- After a plant back interval of 365 days, metabolites M650F03 and M650F04 were found between < 0.01–0.038 mg/kg eq and < 0.01–0.056 mg/kg eq in animal feedstuff and between < 0.01–0.015 mg/kg eq and < 0.01–0.016 mg/kg eq in wheat grain and cauliflower inflorescence, respectively. No residues above the LOQ were found in carrot roots and head lettuce.

In a third field rotational crop study undertaken at two different locations in the USA, bare soil was treated with ametoctradin at a rate of 3 × 0.30 kg ai/ha with a 5 (± 1) day interval . Radish, lettuce and winter wheat were planted at 4 different plant back intervals (PBI: 1, 2, 3 and 4 months). No quantifiable residues (< 0.01 mg/kg) of the parent ametoctradin were observed in any of the rotational crops. Quantifiable residues of the metabolite M650F03 were observed in all rotational crops planted up to 4 months after the last application, with the exception of radish root, where M650F03 residues (0.01 mg/kg) were last observed at the 3 month PBI and lettuce leaves, with non–quantifiable residues at all PBIs. In wheat samples from the 4 month PBI maximum residue levels of M650F03 were 0.07 mg/kg (forage), 0.07 mg/kg (hay), 0.02 mg/kg (grain) and 0.33 mg/kg (straw). Quantifiable residues of the metabolite M650F04 were also observed in all rotational crops planted up to 4 months after the last application, with the exception of radish root and lettuce leaves, were

M650F03 residues were non-quantifiable throughout the study. In wheat samples from the 4 month PBI, the maximum M650F04 residues were 0.13 mg/kg (forage), 0.12 mg/kg (hay), 0.19 mg/kg (grain) and 0.29 mg/kg (straw).

From these data it is concluded that the aerobic degradation in soil proceeds primarily via stepwise oxidative cleavage of the n-octyl side chain. Ametoctradin is transformed to M650F01 (ω-hetarylbutanoic acid), M650F02 (ω-hetarylpropanoic acid) and subsequently to M650F03 (hetarylacetic acid) and M650F04 (hetarylcarboxylic acid) by oxidation. Metabolites underwent further metabolisation by mineralisation to CO_2 or incorporation in humins, humic acids or fulvic acids. Metabolite M650F04 has a very long dissipation time in soil and metabolites M650F03 and M650F04 can be taken up by primary crops and rotational crops.

Methods of residue analysis

The Meeting received description and validation data for analytical methods of ametoctradin, M650F03 and M650F04 in plant commodities or ametoctradin, M650F01 and M650F06 in animal commodities.

As ametoctradin and its soil metabolites M650F03 and M650F04 were shown not to be compatible with existing GC or HPLC-fluorescence multiresidue methods, only single residue methods were submitted to the Meeting. Three single residue analytical methods were proposed to the Meeting.

Macerated samples were extracted with methanol/water. The extract was cleaned up by solvent partition and/or solid phase extraction, if necessary. The final residue could then be determined by HPLC-MS-MS. The Meeting considers validation sufficient for commodities with high water, high acid content, high starch content, dried hops and animal commodities. LOQs were in the 0.01–0.1 mg/kg range for parent and its metabolites in plant and animal commodities.

Methanol/water extraction on samples with incurred radioactive residues from metabolism studies on goat (liver and kidney), wheat (forage, grain), potato leaves and tomato fruits showed that the methanol/water mixture extracted similar amounts of total radioactive residues as the combined methanol extracts in the metabolism studies and resulted in comparable HPLC patterns. Therefore the extraction solvent used in the HPLC-MS-MS methods is sufficiently able to extract the analytes defined.

Stability of pesticide residues in stored analytical samples

The Meeting received information on the stability of ametoctradin, M650F03 and M650F04 in plant commodities as well as ametoctradin, M650F01 and M650F06 in animal commodities stored frozen.

Storage stability studies in plant commodities had variable results. In a study where plant commodities were fortified with a mixture of parent, M650F03 and M650F04 and samples were stored at -20 °C, degradation of parent was found for some commodities (tomatoes) but not in others. In a second study where tomatoes and lettuce with incurred residues from a metabolism study were stored at -18 °C it was shown that parent was stable for at least 3 and 2 years.

Considering both storage stability studies on plant commodities, the Meeting considers parent, M650F03, M650F04 stable for at least 2 years in all plant commodities investigated: commodities with high water content, high acid content, high starch content, high protein content and straw.

Based on storage stability studies at -18 °C in fortified milk samples, the Meeting considers parent and metabolite M650F01 stable for at least 41 days and M650F06 for at least 34 days in milk. Milk samples within the feeding study were analysed within this period. Storage stability studies in animal tissues are not available. Since the tissue samples from the animal feeding study were analysed within 30 days after slaughter and ametoctradin and its metabolites were shown to be stable in various other commodities, storage stability studies are not considered necessary for the purpose of this evaluation.

Definition of the residue

The parent compound ametoctradin was only present in egg and fat of hen (22% and 11% TRR or 0.008 and 0.001 mg/kg eq), and in hen fat it was the only compound identified. Metabolites M650F01, M650F06 were found in significant quantities in other animal tissues in varying amounts. In goat milk, liver, kidney and fat, the metabolite M650F06 (ω-hetarylhexanoic acid) is the most abundant component of the residues (22–47% TRR or 0.006–0.021 mg/kg eq), followed by the metabolite M650F01 (ω-hetarylbutanoic acid, 14%–26% TRR or 0.003–0.014 mg/kg eq). The major metabolite in hens was M650F01 (ω-hetarylbutanoic acid) with 28%, 8.7%, 1.9% TRR in fat, liver, muscle, respectively. For this reason, parent and the metabolites M650F01 and M650F06 are the candidate compounds for inclusion in the residue definition for animal commodities.

Metabolites M650F01 and M650F06 are found in the rat and are therefore covered by the toxicity studies on parent. Since M650F01 and M650F06 are major components of the residue and valid analytical methods are available to quantitate parent and its metabolites in animal commodities, the Meeting decided to include the metabolites M650F01 and M650F06 in the residue definition for animal commodities.

Fat solubility of the parent compound is indicated by the log Kow of 4.18–4.40 and its presence in hen fat and eggs only. Metabolites M650F01 and M650F06 are amphoteric compounds and they are not fat-soluble. Since the metabolites M650F01 and M650F06 are the major components of the residue, the sum of parent, M650F01 and M650F06 is considered not fat-soluble.

In primary crops, parent compound ametoctradin is the only compound found in significant quantities (> 95% TRR). Therefore parent should be included in the residue definition for plant commodities. However, in rotational crops uptake of residues proceeds via the soil and the main metabolites taken up from the soil are M650F03 (30–100% TRR) and M650F04 (26–98% TRR), while parent is found in trace amounts. The level of the metabolites found in the various rotational crops is significant, even after a plant back interval of 365 days (up to 0.056 mg/kg eq for M650F04).

Metabolites M650F03 and M650F04 are not found in the rat. In 90 day dietary toxicity studies, no adverse effects were observed after exposure to either M650F03 or M650F04 up to the limit dose (about 1000 mg/kg bw per day). This is comparable to ametoctradin which showed no adverse effects were observed at or near the limit dose of approximately 1000 mg/kg bw per day in an extensive set of repeated-dose toxicity studies.

The Meeting noted that the parent compound alone is a good marker for compliance with GAP. Although metabolites M650F03 and M650F04 have a similar lack of toxicity and the same core structure as the parent compound, the metabolites M650F03 and M650F04 are only found at significant levels in rotational crops. Since an ADI or ARfD is not considered necessary for the parent compound, there is no dietary intake concern for parent compound or metabolites M650F03 and M650F04. For these reasons, the Meeting decided not to include the metabolites M650F03 and M650F04 in the residue definition and to refrain from setting a residue definition for estimation of the dietary intake of ametoctradin.

The Meeting recommended the following residue definition for ametoctradin:

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

Definition of the residue for compliance with the MRL for animal commodities: *sum of ametoctradin, ω-hetarylbutanoic acid (M650F01) and ω-hetarylhexanoic acid (M650F06), expressed as ametoctradin.*

The Meeting considers the residue is not fat-soluble

Results of supervised residue trials on crops

The Meeting received supervised trials data for ametoctradin on grapes, bulb onions, green onions, broccoli, head cabbage, cucumbers, melons, pumpkins, summer squash, sweet peppers, chili peppers, tomatoes, head lettuce, leaf lettuce, mustard greens, spinach, potatoes, celery, and dried hops.

All plant commodities from supervised residue trials were analysed within 4–24 months, although storage temperatures varied. Since ametoctradin, M650F03 and M650F04 are shown to be stable for a long period of time, trials where samples were stored for a few days at +5 °C before being frozen and trials where temperatures of frozen samples increased to -1 °C were considered acceptable.

Trials conducted at the same location and at the same kg ai/ha dose rate, where only the spray concentration was different, were not considered as independent trials. Trials conducted at the same location, where only the crop variety was different, were not considered as independent trials. The maximum value from each location was selected for maximum residue level recommendations.

As an ADI and ARfD were considered not necessary, no STMR and no HR values are reported as a long and short term exposure assessment is not needed.

The OECD MRL calculator was used as a tool in the estimation of the maximum residue level from the selected residue data set obtained from supervised field trials conducted according to the critical GAP. For those trials where the outcome of the OECD MRL calculator was different from the recommendation made by the Meeting, a rationale is provided for this deviation.

Grapes

Field trials involving grapes were performed in Canada, USA, Germany, France, Spain, Italy and Greece.

Critical GAP for grapes in the USA is for 4 foliar spray applications (interval 7 days) at 0.31 kg ai/ha and PHI 14 days with adjuvant recommended. Trials from USA and Canada (4 × 0.29–0.32 kg ai/ha, interval 6–8 days, PHI 14–15 days, adjuvant added) matched this GAP. Trials from USA and Canada were conducted at two spray concentrations per location (0.0086–0.032 and 0.042–0.065 kg ai/hL); both far lower than indicated in the GAP (0.13–0.16 kg ai/hL). The highest residue value from each location was selected: 0.21, 0.33, 0.34, 0.87, 0.89, 0.92, 0.97, 1.3, 1.4, 1.4, 1.9 and 2.2 mg/kg (n=12).

Critical GAP for grapes in the Former Yugoslav Republic of Macedonia is for 3 foliar spray applications (interval 10 days) at 0.075 kg ai/hL and PHI 35 days. In trials performed in Southern France, Spain, Italy and Greece (3 × 0.060 kg ai/hL, interval 10 days, PHI 34–36 days) matching this GAP parent residues were: 0.15, 0.22, 0.37, 0.72, 1.1, 1.1, 2.7 and 3.1 (n=8).

The Meeting noted that the US and Southern European dataset for grapes resulted in similar residues (Mann-Whitney U test). However, since the GAPs are different, the Meeting agreed that the Southern European dataset for grapes matching Former Yugoslav Republic of Macedonia GAP could be used to support a grape maximum residue level recommendation and estimated a maximum residue level of 6 mg/kg on grapes. For the purpose of livestock dietary burden calculation, the Meeting estimated an STMR of 0.605 mg/kg.

Bulb vegetables

Field trials involving bulb onions were performed in Canada and the USA.

Critical GAP for bulb vegetables (includes bulb onions) in the USA is for 3 foliar spray applications (interval 5 days) at 0.31 kg ai/ha and PHI 0 days with adjuvant recommended. In trials from USA and Canada (3 × 0.29–0.34 kg ai/ha, interval 4–8 days, PHI 0 days, adjuvant added) matching this GAP parent residues were: 0.095, 0.095, 0.14, 0.19, 0.21, 0.22, 0.25, 0.43, 0.46, 0.84 mg/kg (n=10).

The Meeting agreed that the USA and Canadian datasets for bulb onions matching USA GAP could be used to support a bulb onion maximum residue level recommendation and estimated a maximum residue level of 1.5 mg/kg on bulb onions and decided to extrapolate the recommendation for bulb onions to garlic and shallots.

Field trials involving spring onions were performed in the USA.

Critical GAP for bulb vegetables (includes green onions) in the USA is for 3 foliar spray applications (interval 5 days) at 0.31 kg ai/ha and PHI 0 days with adjuvant recommended. In field trials from USA and Canada (3 × 0.29–0.34 kg ai/ha, interval 4–8 days, PHI 0 days, adjuvant added) matching this GAP parent residues were: 3.4, 4.3, 9.1 mg/kg (n=3).

The Meeting agreed that the USA and Canadian datasets for spring onions matching USA GAP could be used to support a green onion maximum residue level recommendation and estimated a maximum residue level of 20 mg/kg on spring onions.

Brassica vegetables

Field trials involving broccoli were performed in Canada and the USA.

Critical GAP for brassica vegetables (includes broccoli) in the USA is for 3 foliar spray applications (interval 7 days) at 0.31 kg ai/ha and PHI 0 days with adjuvant recommended. In field trials from USA and Canada (3 × 0.29–0.31 kg ai/ha, interval 6–9 days, PHI 0 days, adjuvant added) matching this GAP parent residues in broccoli heads and stems were 1.2, 1.2, 1.3, 1.6, 1.7, 2.5, 2.9, 3.2 mg/kg (n=8).

Field trials involving head cabbage were performed in Canada and USA.

Critical GAP for brassica vegetables (includes head cabbage) in the USA is for 3 foliar spray applications (interval 7 days) at 0.31 kg ai/ha and PHI 0 days with adjuvant recommended. In field trials from USA and Canada (3 × 0.29–0.31 kg ai/ha, interval 5–9 days, PHI 0 days, adjuvant added) matching this GAP parent residues in head cabbage with wrapper leaves (as marketed) were 0.35, 1.1, 1.4, 1.6, 1.8, 2.2, 3.1, 3.2, 3.3, 7.5 mg/kg (n=10).

The Meeting noted that the datasets for broccoli and head cabbage resulted in similar residues (Mann-Whitney U test). Since the GAPs are the same and there is a GAP for brassica vegetables, the Meeting agreed to combine the data to propose a group maximum residue level for brassicas. This resulting in the following residues: 0.35, 1.1, 1.2, 1.2, 1.3, 1.4, 1.6, 1.6, 1.7, 1.8, 2.2, 2.5, 2.9, 3.1, 3.2, 3.2, 3.3, 7.5 (n=18).

The Meeting agreed that the combined datasets for broccoli and head cabbage matching USA GAP could be used to support a maximum residue level recommendation for brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead cabbages and estimated a maximum residue level of 9 mg/kg. For the purpose of livestock dietary burden calculations the Meeting estimated a highest residue of 7.5 mg/kg for brassicas.

Fruiting vegetables, Cucurbits

Supervised residue trials on outdoor and indoor grown cucumbers were conducted in Canada, USA, the UK, the Netherlands, France, Greece and Spain.

Critical GAP for fruiting vegetables, cucurbits in the USA is for 3 foliar spray applications (interval 5 days) at 0.31 kg ai/ha and a PHI of 0 days, with adjuvant recommended. In field trials from USA and Canada (3 × 0.29–0.30 kg ai/ha, interval 6–8 days, PHI 0 days, adjuvant added) matching this GAP parent residues in cucumber were: 0.060, 0.08, 0.090, 0.12, 0.12, 0.16, 0.16, 0.24 mg/kg (n=8).

Critical GAP for cucumbers in the Former Yugoslav Republic of Macedonia (Southern Europe) is for 4 foliar spray applications (interval 10 days) at 0.30 kg ai/ha and PHI 1 days. In field trials from Southern France and Greece and greenhouse trials from Europe (3 × 0.24 kg ai/ha, interval 7 days, PHI 1 day) matching this GAP parent residues in cucumber were 0.038, 0.09, 0.11 and 0.17 mg/kg (n=4) for field trials and 0.024, 0.037, 0.15 and 0.18 mg/kg (n=4) for greenhouse trials. As the datasets for outdoor and indoor grown cucumbers resulted in similar residues (Mann-Whitney U test), the datasets were combined: 0.024, 0.037, 0.038, 0.09, 0.11, 0.15, 0.17 and 0.18 mg/kg (n=8) for outdoor and indoor grown cucumbers.

The Meeting noted that datasets for USA and Former Yugoslav Republic of Macedonia resulted in similar datasets (Mann-Whitney U test). However, since the GAPs are different, the Meeting decided to take only the USA dataset into account in making estimations.

Field trials involving melons were performed in the USA.

Critical GAP for fruiting vegetables, cucurbits in the USA is for 3 foliar spray applications (interval 5 days) at 0.31 kg ai/ha and PHI 0 days with adjuvant recommended. In field trials from USA (3 × 0.29–0.31 kg ai/ha, interval 6–8 days, PHI 0 days, adjuvant added) matching this GAP, parent residues in melons with peel were: 0.18, 0.49, 0.59, 0.60, 0.72, 0.80, 1.3, 1.7 mg/kg (n=8).

Field trials involving pumpkins were performed in the USA.

Critical GAP for fruiting vegetables cucurbits in the USA is for 3 foliar spray applications (interval 5 days) at 0.31 kg ai/ha and PHI 0 days with adjuvant recommended. In field trials from the USA (3 × 0.29–0.30 kg ai/ha, interval 7 days, PHI 0 days, adjuvant added) matching this GAP, parent residues in pumpkins with peel were: 0.10, 0.14, 0.34, 0.47, 1.3 mg/kg (n=5).

Field trials involving summer squash (i.e., courgette/zucchini) were performed in the USA.

Critical GAP for fruiting vegetables cucurbits in the USA is for 3 foliar spray applications (interval 5 days) at 0.31 kg ai/ha and PHI 0 days with adjuvant recommended. In field trials from the USA (3 × 0.28–0.31 kg ai/ha, interval 6–8 days, PHI 0 days, adjuvant added) matching this GAP, parent residues in summer squash with peel were: 0.13, 0.22, 0.36, 0.98, 1.1 mg/kg (n=5).

The Meeting noted that the datasets for melons, pumpkins and summer squash were similar (Kruskal-Wallis test). Since the GAP is the same for each of these commodities, the Meeting agreed to propose a group maximum residue level for cucurbits, except cucumbers, based on the combined residue data for melons, pumpkins and summer squash and agreed to propose a separate maximum residue level for cucumbers.

The combined dataset for melons, pumpkins and summer squash resulted in the following residues: 0.10, 0.13, 0.14, 0.18, 0.22, 0.34, 0.36, 0.47, 0.49, 0.59, 0.60, 0.72, 0.80, 0.98, 1.1, 1.3, 1.3, 1.7 mg/kg (n=18). The Meeting agreed that the combined dataset matching the GAP of the USA could be used to support a maximum residue level recommendation for cucurbits, except cucumber, and estimated a maximum residue level of 3 mg/kg in/on cucurbits, except cucumber, based on the combined data.

The Meeting agreed that the dataset for cucumbers matching the US GAP could be used to support a maximum residue level recommendation for cucumbers, and estimated a maximum residue level of 0.4 mg/kg for cucumbers.

Fruiting vegetables other than cucurbits

Field trials involving sweet peppers were performed in Canada, the USA, Greece, Italy, Spain, France, Germany, the Netherlands and Belgium.

Critical GAP for fruiting vegetables other than cucurbits (includes sweet peppers) in the USA is for 3 foliar spray applications (interval 5 days) at 0.31 kg ai/ha and PHI 4 days with adjuvant recommended. In field trials from the USA and Canada (3 × 0.29–0.32 kg ai/ha, interval 6–8 days, PHI 4 days, adjuvant added) matching this GAP, parent residues in sweet peppers were: 0.050, 0.080, 0.085, 0.14, 0.16, 0.22, 0.84 mg/kg (n=7).

The GAP for peppers in Former Yugoslav Republic of Macedonia (Southern Europe) is for 4 foliar spray applications (interval 10 days) at 0.30 kg ai/ha and a 1 day PHI. In greenhouse trials from Europe (3 × 0.23–0.25 kg ai/ha, interval 7 days, PHI 1 day) matching this GAP, parent residues in sweet peppers were: 0.20, 0.21, 0.28, 0.34, 0.37, 0.47, 0.79, 0.90 mg/kg (n=8).

Field trials involving chili peppers were performed in USA.

The GAP for fruiting vegetables, other than cucurbits (includes chili peppers), in the USA is for 3 foliar spray applications (interval 5 days) at 0.31 kg ai/ha and PHI 4 days with adjuvant

recommended. In field trials from the USA (3 × 0.29–0.31 kg ai/ha, interval 7 days, PHI 4 days, adjuvant added) matching this GAP none of the residue values could be selected, as the laboratory was unable to show adequate performance of the analytical method.

Field trials involving tomatoes were performed in Canada and the USA.

Critical GAP for fruiting vegetables other than cucurbits (includes tomatoes) in the USA is for 3 foliar spray applications (interval 5 days) at 0.31 kg ai/ha and PHI 4 days with adjuvant recommended. In field trials from the USA and Canada (3 × 0.28–0.32 kg ai/ha, interval 6–8 days, PHI 4 days, adjuvant added) matching this GAP, parent residues in tomatoes (including two trials on cherry tomatoes) were: 0.050, 0.10, 0.11, 0.12, 0.15, 0.16, 0.16, 0.18, 0.20, 0.20, 0.22, 0.22, 0.25, 0.32, 0.60, 0.70, 0.76 mg/kg (n=17).

The Meeting noted that the sweet pepper dataset corresponding to the GAP of the Former Yugoslav Republic of Macedonian (3 × 0.30 kg ai/ha PHI 1 days) resulted in higher residues than the dataset corresponding to the US GAP (3 × 0.30 kg ai/ha, PHI 4 days) (Mann-Whitney U test). However, both datasets would result in the same maximum residue level recommendation (1.5 mg/kg). The sweet pepper dataset, matching USA GAP, resulted in similar residues as the tomato dataset, matching USA GAP, (Mann-Whitney U test). The Meeting concluded that these datasets could be combined to allow a commodity group recommendation for fruiting vegetables other than cucurbits. This resulted in the following dataset: 0.050, 0.050, 0.080, 0.085, 0.10, 0.11, 0.12, 0.14, 0.15, 0.16, 0.16, 0.16, 0.18, 0.20, 0.20, 0.22, 0.22, 0.22, 0.25, 0.32, 0.60, 0.70, 0.76 and 0.84 mg/kg (n=24).

The Meeting estimated a maximum residue level of 1.5 mg/kg fruiting vegetables other than cucurbits, except sweet corn and mushrooms, based on the combined dataset. For the purpose of livestock dietary burden calculations, the Meeting estimated an STMR of 0.16 mg/kg in/on fruiting vegetables other than cucurbits.

The FAO Manual (section 6.9.2) describes how a generic concentration factor may be used for conversion of HR residue values from fresh peppers to dried chili peppers. A concentration factor of 10 is used for the estimation of parent residue levels of pesticides in dried chili peppers.

The Meeting agreed to apply the concentration factor of 10 for dried chili peppers to the maximum residue level for sweet peppers (1.5 mg/kg) and estimated a maximum residue level in peppers, chili, dried of 15 mg/kg.

Leafy vegetables

Field trials involving head lettuce were performed in Canada and the USA.

Critical GAP for leafy vegetables (includes head lettuce) in the USA is for 3 foliar spray applications (interval 5 days) at 0.31 kg ai/ha and PHI 0 days with adjuvant recommended. In field trials from the USA and Canada (3 × 0.29–0.32 kg ai/ha, interval 4–7 days, PHI 0 days, adjuvant added) matching this GAP none of the residue values could be selected as the analytical laboratory could not demonstrate adequate performance of the analytical method.

Field trials involving leaf lettuce were performed in Canada and the USA.

Critical GAP for leafy vegetables (includes leaf lettuce) in the USA is for 3 foliar spray applications (interval 5 days) at 0.31 kg ai/ha and PHI 0 days with adjuvant recommended. In field trials from the USA and Canada (3 × 0.30–0.31 kg ai/ha, interval 4–6 days, PHI 0 days, adjuvant added) matching this GAP none of the residue values could be selected as the laboratory could not demonstrate adequate performance of the analytical method.

Field trials involving mustard greens were performed in USA.

Critical GAP for leafy vegetables (includes mustard greens) in the USA is for 3 foliar spray applications (interval 5 days) at 0.31 kg ai/ha and PHI 0 days with adjuvant recommended. In field trials from the USA (3 × 0.28–0.31 kg ai/ha, interval 6–8 days, PHI 0 days, adjuvant added) matching this GAP, parent residues in mustard greens were: 9.2, 13, 13, 16, 19, 24, 28 mg/kg (n=7).

Field trials involving spinach were performed in Canada and the USA.

Critical GAP for leafy vegetables (includes spinach) in the USA is for 3 foliar spray applications (interval 5 days) at 0.31 kg ai/ha and PHI 0 days with adjuvant recommended. In field trials from USA and Canada (3 × 0.29–0.33 kg ai/ha, interval 4–8 days, PHI 0 days, adjuvant added) matching this GAP in spinach were: 6.0, 11, 12, 13, 13, 20, 21, 35 mg/kg (n=8).

The Meeting noted that the datasets for mustard greens and spinach are similar (Mann-Whitney U-test), confirming the experience of the JMPR that residues in leafy vegetables at DAT=0 are similar. Since the GAPs are the same for mustard greens and spinach, the Meeting agreed to combine the data to propose a group maximum residue level for leafy vegetables, based on the combined residue dataset for mustard greens and spinach. The combination of the two datasets resulted in the following residues: 6.0, 9.2, 11, 12, 13, 13, 13, 13, 16, 19, 20, 21, 24, 28 and 35 mg/kg (n=15).

The Meeting agreed that the combined dataset for mustard greens and spinach, matching US GAP, could be used to support a maximum residue level recommendation for leafy vegetables and estimated a maximum residue level of 50 mg/kg in/on leafy vegetables based on the combined dataset. For the purpose of livestock dietary burden calculations, the Meeting estimated a highest residue of 35 mg/kg for leafy vegetables, based on the combined residue dataset.

Potatoes

Field trials involving potatoes were performed in Canada and the USA.

Critical GAP for root and tuber vegetables (includes potatoes) in the USA is for 3 foliar spray applications (interval 5 days) at 0.31 kg ai/ha and PHI 4 days with adjuvant recommended. In field trials from the USA (3–4 × 0.28–0.31 kg ai/ha, interval 4–8 days, PHI 4 days, adjuvant added) matching this GAP parent residues in potato tubers were: < 0.01 (12), 0.010 (5), 0.020, 0.025 (2), 0.035 mg/kg (n=21).

The Meeting agreed that the dataset for potatoes matching US GAP could be used to support a maximum residue level recommendation for potatoes, and estimated a maximum residue level of 0.05 mg/kg in/on potatoes. For the purpose of livestock dietary burden calculations the Meeting estimated a highest residue of 0.035 mg/kg for potatoes.

Celery

Field trials involving celery were performed in Canada and the USA.

Critical GAP for leafy vegetables (includes celery) in the USA is for 3 foliar spray applications (interval 5 days) at 0.31 kg ai/ha and PHI 0 days with adjuvant recommended. In field trials from the USA and Canada (3 × 0.29–0.32 kg ai/ha, interval 4–6 days, PHI 0 days, adjuvant added) matching this GAP were: 4.2, 4.7, 5.1, 5.5, 6.2, 6.7, 7.0, 11 mg/kg (n=8).

The Meeting agreed that the dataset for celery matching US GAP could be used to support a maximum residue level recommendation for celery, and estimated a maximum residue level of 20 mg/kg in/on celery.

Hops, dry

Field trials involving dried hops were performed in Germany and the USA.

Critical GAP for hops in the USA is for 3 foliar spray applications (interval 7 days) at 0.31 kg ai/ha and PHI 7 days with adjuvant recommended. Trials from USA (3x 0.30–0.31 kg ai/ha, interval 10–11 days, PHI 7 days, adjuvant added) matched this GAP. Trials from the USA were conducted at two spray concentrations per location (0.015–0.021 and 0.037–0.043 kg ai/hL); both far lower than indicated in the GAP (0.13–0.16 kg ai/hL). The highest residue from each location could be selected: 0.96, 2.4, 6.7 mg/kg (n=3). The Meeting agreed that 3 trials were insufficient to estimate a maximum residue level recommendation for dried hops.

Additional trials performed in the USA at higher dose rate (0.53–0.54 kg ai/ha, interval 10–11 days, PHI 6–8 days) could be matched to the USA GAP by using the proportionality approach by multiplying by 0.31/0.54=0.57. Parent residues in dried hops were 0.57 × (9.3, 18, 29) mg/kg (n=3). After applying the proportionality factor this results in the following dataset: 5.3, 10, 17 mg/kg (n=3). When combining the two datasets this resulted in the following dataset: 0.96, 2.4, 5.3, 6.7, 10, 17 mg/kg (n=6).

The Meeting agreed that the normal and scaled dataset for dried hops matching US GAP could be used to support a maximum residue level recommendation for dried hops, and estimated a maximum residue level of 30 mg/kg in/on dried hops.

Residues from rotational crops

Parent residues above 0.01 mg/kg are not expected in rotational crops.

Fate of residues during processing

Information on the fate of residues during processing by radioactivity studies showed that ametoctradin is stable (96–109%) under standard conditions used to simulate food processing operations (pH 4 and 90 °C, pH 5 and 100 °C, pH 6 and 120 °C).

Processing studies with ametoctradin were undertaken for grapes, bulb onions, gherkins, tomatoes and hops. Since no long or short term exposure assessments are considered necessary, only the processing factors that lead to maximum residue level proposals or the processing factors that are needed for livestock dietary burden calculations are listed in the table below.

Using the $STMR_{RAC}$ obtained from ametoctradin use, the Meeting estimated STMR-Ps for processed commodities as listed below. The Meeting considered the appropriate STMR-P to be used in the livestock dietary burden calculation or dietary intake calculation.

Commodity	Processing factors (parent only)	Processing factor (median or best estimate) (parent only)	STMR-P = $STMR_{RAC}$xPF mg/kg
grape raisin	1.9, 2.0, 4.8, 6.2 (n=4)	3.4	not necessary
grape wet pomace	1.8, 2.5, 2.7, 2.9, 3.9, 4.2, 4.8, 5.1 (n=8)	3.4	0.605 × 3.4 = 2.1
tomato wet pomace	1.1, 1.2, 1.4, 1.4 (n=4)	1.3	0.16 × 1.3=0.21 (based on fruiting vegetables other than cucurbits)

Based on a maximum residue level of 6 mg/kg for grapes and a processing factor of 3.4, the Meeting estimated a maximum residue level of 20 mg/kg for raisins.

Residues in animal commodities

The Meeting estimated the dietary burden of ametoctradin residues on the basis of the livestock diets listed in the FAO manual Appendix IX (OECD feedstuff table). Calculation from highest residue, STMR (some bulk commodities) and STMR-P values provides the levels in feed suitable for estimating MRLs. Since no long or acute dietary exposure assessment is needed, STMR values for animal commodities are not needed and therefore no mean dietary burden is calculated.

All plant commodities used in the dietary burden calculation are listed below. Residues in plant commodities were based on parent only.

Crop	Feedstuff	Highest Residue	STMR or STMR-P	DM (%)
Forages				

Crop	Feedstuff	Highest Residue	STMR or STMR-P	DM (%)
Cabbage	heads, leaves	7.5	not needed	15
Kale	leaves	35	not needed	15
Rape	forage	35	not needed	30
Roots & Tubers				
Potato	culls	0.035	not needed	20
Byproducts				
Grape	pomace, wet		2.1	15
Tomato	pomace, wet		0.21	20

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 ametoctradin use, is shown in the table below.

Animal dietary burden for ametoctradin parent, expressed as ppm of dry matter diet

	US	EU	AU	JP	overall
	max	max	max	max	max
beef cattle	0.053	46.72	116.7	-	116.7 [a]
dairy cattle	11.68	46.72	96.15	-	96.15 [b]
poultry broiler		0.018			0.018
poultry layer		17.52			17.52 [c d]

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

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

[c] Highest maximum poultry broiler or poultry layer dietary burden suitable for maximum residue level for poultry meat.

[d] Highest maximum poultry layer suitable for maximum residue level for eggs.

Livestock feeding studies

The Meeting received a feeding study on lactating cows.

Four groups of three lactating Holstein-Friesian cows were dosed once daily via capsules at levels of 0.0, 2.5, 7.5 and 25 ppm parent compound in dry weight feed for 28 consecutive days. Milk was collected throughout the study and tissues were collected on day 28 within 25 hours after the last dose. Parent was not found in milk or any of the tissues (< 0.01 mg/kg). Metabolites M650F01 and M650F06 were only found in liver and kidney samples. Mean and maximum total residues (parent + 1.10 × M650F01 + 0.993 × M650F06), expressed as parent equivalents, are shown in the table below.

Animal commodity	Dose level (ppm feed)	Mean Residue (mg/kg)	Highest Residue (mg/kg)
Liver	2.5	< 0.031	< 0.031
	7.5	0.033	0.036
	25	0.073	0.096
Kidney	2.5	< 0.031	< 0.031
	7.5	< 0.031	< 0.031
	25	0.039	0.048
Fat	2.5	< 0.031	< 0.031
	7.5	< 0.031	< 0.031
	25	< 0.031	< 0.031
Muscle	2.5	< 0.031	< 0.031
	7.5	< 0.031	< 0.031
	25	< 0.031	< 0.031
Milk	2.5	< 0.031	< 0.031
	7.5	< 0.031	< 0.031
	25	< 0.031	< 0.031

Residues in animal commodities

In a feeding study where lactating cows were dosed at 25 ppm ametoctradin in the dry feed, total residues (sum of parent, M650F01 and M650F06) were 0.073–0.096 mg/kg eq in liver and 0.039–0.048 mg/kg eq in kidney. No residues were found in muscle, fat and milk (each < 0.031 mg/kg eq). However, since the estimated maximum dietary burden in ruminants is much higher (116.7 ppm in beef cattle and 96.15 ppm in dairy cattle, based on parent only in feed commodities), the feeding study cannot be used to estimate residues in ruminant commodities. Therefore the data are insufficient to propose maximum residue levels in ruminants.

No feeding study is available for poultry. In a metabolism study, where laying hens were dosed at 12 ppm ametoctradin in the dry feed, total residues were 0.0088 mg/kg eq in eggs (22% × 0.040 mg/kg), 0.0055 mg/kg eq in fat (11% + 28% × 0.014 mg/kg), in 0.011 mg/kg eq in liver (8.7% + 1.3% × 0.11 mg/kg) and 0.00078 mg/kg in muscle (1.9% + 1.1% × 0.026 mg/kg). Since the estimated maximum dietary burden in poultry is in the same order of magnitude (17.52 ppm in poultry, based on parent only in feed commodities), the metabolism study can be used to estimate residues in poultry commodities. After extrapolation to a dietary burden of 17.52 ppm, residues in poultry commodities all lie below the limit of quantification of 0.031 mg/kg eq (total residues) of the available analytical method.

The Meeting was unable to estimate maximum residue levels in ruminant commodities, because of insufficient data. The Meeting estimated a maximum residue level for ametoctradin total residues of 0.03* mg/kg for eggs, poultry meat and poultry edible offal. The total residue in animal commodities is not considered fat-soluble.

DIETARY RISK ASSESSMENT

Since no ADI and no ARfD is considered necessary, no long-term or short-term intake assessment is considered necessary. However, to get an impression of the margins of exposure, the International Estimated Daily Intake (IEDI) for ametoctradin was calculated. The results are shown in Annex 3 of the 2012 report of the JMPR.

As a conservative approach, the crop with the highest residues (leafy vegetables) was used to estimate the total median residue of ametoctradin of individual crops. When the highest median residue for leafy vegetables from the presented field trials (i.e., 13 mg/kg) is used for all possible plant commodities and the highest median residue for animal commodities from the presented feed studies (i.e., 0.031 mg/kg for poultry commodities) is used for all possible animal commodities, the IEDI was in the range of 0.232–0.477 mg/kg bw/d. This IEDI also accommodates possible contributions from metabolites M650F03 and M650F04 in rotational crops. Considering the absence of adverse effects at or near the limit dose of approximately 1000 mg/kg bw/day in an extensive set of repeated-dose toxicity studies, the margins of exposure ranged between 2100–4300.

When the highest maximum residue level proposed for plant commodities (i.e., 50 mg/kg for leafy vegetables) is used for all possible plant commodities and the highest maximum residue level proposed for animal commodities (i.e., 0.031 mg/kg for poultry commodities), the IEDI was in the range of 0.893–1.836 mg/kg bw/d. The margins of exposure ranged between 540–1100.

The Meeting concluded that the long-term and short-term intake of residues of ametoctradin from uses considered by the Meeting, or from possible future uses is unlikely to present a public health concern.

5.2 AZOXYSTROBIN (229)

RESIDUE AND ANALYTICAL ASPECTS

Azoxystrobin (methyl (E)-2-[2-[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl]-3-methoxyacrylate) 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 commodities for compliance with MRL values and for consumer risk assessments was parent azoxystrobin. The compound was listed by the Forty-second Session of the CCPR for the review of additional MRLs by the JMPR in 2011.

The Forty-fourth Session of the CCPR requested the 2012 JMPR to re-evaluate the processing studies for ginseng processed products to estimate MRLs for ginseng extracts. Furthermore, the Meeting received information on GAP and residue data for carambola from Malaysia.

Methods of residue analysis

The Meeting received summarized information on an analytical method for azoxystrobin residues in carambola. The samples were extracted with ethyl acetate. After clean-up, the residues were determined by GC-ECD with an LOQ of 0.005 mg/kg. The recoveries were reported as 104% (0.005 mg/kg), 93% (0.01 mg/kg) and 96% (0.1 mg/kg).

No new information on storage stability was submitted but the studies reported by the 2008 JMPR for fruits and vegetables cover the sample material evaluated by the present Meeting.

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.

Results of supervised residue trials on crops

The OECD calculator was used as a tool in the estimation of the maximum residue level from the selected residue data set obtained from trials conducted according to GAP. As a first step, the Meeting reviewed all relevant factors related to each data set in arriving at a best estimate of the maximum residue level using expert judgment. Then, the OECD calculator was employed. If the statistical calculation spreadsheet suggested a different value from that recommended by the JMPR, a brief explanation of the deviation was provided.

Carambola

Azoxystrobin is registered in Malaysia as foliar spray treatment with 2 × 0.0115 kg ai/hL (2 × 0.115 kg ai/ha) with a 1-day PHI. Four trials matching the Malaysian GAP were carried out in Malaysia in 2005 (LOQ 0.05 mg/kg) and in 2010 (LOQ 0.005 mg/kg). The residues were: 0.007, 0.011, 0.034 and < 0.05 mg/kg. Using the OECD MRL calculator, 0.15 mg/kg were calculated as maximum residue level. The Meeting noted that the highest residue value was lower than the LOQ of 0.05 mg/kg and concluded that 0.1 mg/kg would be more appropriate as MRL.

The Meeting estimated for azoxystrobin residues in carambola a maximum residue level of 0.1 mg/kg and an STMR 0.023 mg/kg.

Ginseng processed products

The 2011 JMPR estimated a maximum residue level of 0.1 mg/kg and an STMR of 0.025 mg/kg for azoxystrobin in ginseng.

The 2011 JMPR evaluated ginseng processing studies. The following median processing factors were calculated: 3 for dried ginseng, 2 for red ginseng, 5.2 for ethanol extract of dried ginseng, 4.8 for water extract of dried ginseng, 4.9 for ethanol extract of red ginseng and 2 for water extract of red ginseng.

The 2011 JMPR estimated 0.5 mg/kg as maximum residue level for ginseng, processed products (dried, red, ethanol and water extracts).

Based on the STMR of 0.025 mg/kg for fresh ginseng roots, the 2011 Meeting estimated the following STMR-P-values: 0.075 mg/kg for dried ginseng, 0.05 mg/kg for red ginseng, 0.13 mg/kg for ethanol extract of dried ginseng, 0.12 mg/kg for the water extract of dried ginseng, 0.12 mg/kg for the ethanol extract of red ginseng and 0.05 mg/kg for the water extract of red ginseng.

At the Forty-fourth CCPR, the Committee decided to separate the commodity "ginseng, processed products" into "ginseng, dried including red ginseng" and "ginseng, extracts". The Forty-fourth CCPR requested the 2012 JMPR to re-evaluate the processing studies on ginseng to estimate separate maximum residue levels for the two commodities.

The 2012 JMPR agreed to estimate separate maximum residue levels and STMR-P values for the above mentioned commodities. Based on the data evaluated by the 2011 JMPR, the individual processing factors were combined according to the new commodity groups. Median processing factors of 2.75 for dried ginseng (incl. red ginseng) and of 4.8 for ginseng extracts were estimated.

The Meeting estimated a maximum residue level of 0.3 mg/kg and an STMR-P of 0.069 mg/kg for ginseng, dried including red ginseng.

The Meeting estimated a maximum residue level of 0.5 mg/kg and an STMR-P of 0.12 for ginseng, extracts.

The former recommendation of 0.5 mg/kg for ginseng processed products (dried, red, ethanol and water extracts) should be withdrawn.

DIETARY RISK ASSESSMENT

Long-term intake

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

The ADI is 0–0.2 mg/kg bw and the calculated IEDI 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.

5.3 BENTAZONE (172)

TOXICOLOGY

Bentazone is the ISO-approved common name for 3-isopropyl-1H-2,1,3-benzothiadiazin-4(3H)-one-2,2-dioxide (International Union of Pure and Applied Chemistry [IUPAC]), with CAS number 25057-89-0. Bentazone is a post-emergence herbicide used for selective control of broadleaf weeds and sedges in beans, rice, corn, peanuts, mint and others. It acts by interfering with photosynthesis.

Bentazone was first evaluated by JMPR in 1991, when an ADI of 0–0.1 mg/kg bw was established on the basis of a NOAEL of 9 mg/kg bw per day (for increased clotting times and increased output of urine with decreased specific gravity) in a long-term study of toxicity in rats and using a safety factor of 100. In 1998, the Meeting re-evaluated bentazone and data on 6-hydroxybentazone, a metabolite of bentazone. The Meeting concluded that 6-hydroxybentazone was less toxic than bentazone and reaffirmed the ADI of 0–0.1 mg/kg bw. Because data were not evaluated to establish an ARfD, the Meeting in 2004 re-evaluated bentazone and concluded that the establishment of an ARfD was not necessary.

Bentazone is being reviewed at the present meeting as part of the periodic re-evaluation programme of CCPR.

Since the 2004 JMPR review, no relevant new studies have been provided. Two published literature studies on the effects of bentazone on spermatogenesis in mice and on litter size and postnatal growth in rats were submitted. Most of the studies do not comply with GLP, as they were generated before implementation of GLP.

Biochemical aspects

Toxicokinetic studies performed on mice, rats and rabbits indicate that bentazone is rapidly and almost completely absorbed via the oral route (> 99%), and maximum blood concentrations of radioactivity are achieved in approximately 15 minutes at low doses (4 mg/kg bw) and by 1 hour at high doses (200 mg/kg bw). Administration of bentazone either as the sodium salt or as the free acid did not result in any significant differences in absorption. There was no evidence of penetration into the central nervous system or spinal cord, and elimination from other tissues was rapid, with no indication of bioaccumulation.

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, 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.

Toxicological data

Bentazone has moderate acute toxicity when administered orally to rats, guinea-pigs and rabbits and low toxicity when administered dermally or by inhalation to rats. In rats, the oral LD_{50} was greater than or equal to 850 mg/kg bw. The dermal LD_{50} in rats was greater than 5000 mg/kg bw. The inhalation LC_{50} was greater than 5.1 mg/L of air (4-hour exposure; nose only). Bentazone was moderately irritating to the eye but not irritating to the skin in rabbits. It was a dermal sensitizer in the Magnusson & Kligman maximization test and the Buehler test in guinea-pigs.

Repeated-dose toxicity studies (subchronic and chronic) in mice, rats and dogs indicate that effects on haematology and blood coagulation (e.g. prolongation of prothrombin time and partial thromboplastin time) were consistently observed.

Three short-term oral rat studies demonstrated an overall NOAEL of 400 ppm (equal to 25.3 mg/kg bw per day), with a lowest-observed-adverse-effect level (LOAEL) of 800 ppm (equal to 40 mg/kg bw per day) for decreased body weight gain, decreased feed consumption, increased serum total cholesterol levels, increased urine output and prolonged prothrombin time and partial thromboplastin time.

In 90-day and 1-year dog studies, clinical signs, anaemia and effects on blood coagulation were noted. In the 90-day study, the NOAEL was 300 ppm (equal to 12.0 mg/kg bw per day), on the basis of sedation and ulceration and alopecia on the leg of one dog at 1000 ppm (equal to 39.6 mg/kg bw per day). The NOAEL for the 1-year study was 400 ppm (equal to 13.1 mg/kg bw per day), on the basis of anaemia, altered blood coagulation parameters, clinical signs and weight loss at the highest dietary concentration of 1600 ppm (equal to 52.3 mg/kg bw per day).

In a 2-year dietary toxicity and carcinogenicity study in mice, the NOAEL was 100 ppm (equal to 12 mg/kg bw per day), based on prolongation of prothrombin time and an increased incidence of calcification of the testicular tunica albuginea and deferent canals in the males at 400 ppm (equal to 47 mg/kg bw per day). No carcinogenic effects were observed in this study.

In a 2-year combined toxicity and carcinogenicity study in rats, the NOAEL was 200 ppm (equal to 9 mg/kg bw per day), based on clinical chemistry changes indicative of effects on liver and kidney and effects on blood coagulation parameters at 800 ppm (equal to 35 mg/kg bw per day). No carcinogenic effects were observed in this study.

The Meeting concluded that bentazone was not carcinogenic in rats or mice.

Bentazone 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 bentazone 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 bentazone is unlikely to pose a carcinogenic risk to humans.

In a two-generation dietary reproduction study in rats, the NOAEL for parental and offspring toxicity was 200 ppm (equal to 14 mg/kg bw per day), on the basis of reduced parental feed consumption and body weight gain and reduced pup body weight resulting from parental toxicity at 800 ppm (equal to 59 mg/kg bw per day). There were no effects on reproduction at 3200 ppm (240 mg/kg bw per day), the highest dose tested.

In two studies of developmental toxicity in rats treated by gavage, the overall NOAEL for maternal toxicity was 250 mg/kg bw per day, the highest dose tested. The developmental NOAEL was 200 mg/kg bw per day, on the basis of increased post-implantation loss, reduced weight of fetuses surviving to day 21 and skeletal anomalies at the next higher dose of 250 mg/kg bw per day.

In a third study of developmental toxicity, in which rats were given diets containing bentazone from day 0 to day 21, the NOAEL for maternal toxicity was 2000 ppm (equal to 162 mg/kg bw per day), on the basis of increased water consumption at 4000 ppm (equal to 324 mg/kg bw per day). The developmental NOAEL was 4000 ppm (equal to 324 mg/kg bw per day), on the basis of decreased fetal weight gain and reduced ossification of cervical vertebrae at 8000 ppm (equal to 631 mg/kg bw per day).

In two gavage studies of developmental toxicity in rabbits, the overall NOAEL for maternal and developmental toxicity was 150 mg/kg bw per day, on the basis of a reduction in maternal feed consumption and increased post-implantation losses at 375 mg/kg bw per day.

The Meeting concluded that bentazone was not teratogenic in rats or rabbits.

In a subchronic neurotoxicity study, there was no indication of neurotoxicity at doses up to 3500 ppm (equal to 258 mg/kg bw per day), the highest dose tested.

6-Hydroxybentazone and 8-hydroxybentazone are major plant metabolites of bentazone. Both were less acutely toxic than the parent compound. Neither of the metabolites induced mutations in

bacterial tests, and 8-hydroxybentazone was also not genotoxic in an in vitro mammalian forward mutation test and an in vivo mouse micronucleus test. In a subchronic dietary toxicity study and a developmental toxicity study in rats with 8-hydroxybentazone, the NOAEL was approximately 250 mg/kg bw per day, the highest dose tested.

No adverse health effects or poisoning in manufacturing plant personnel or in operators and workers exposed to bentazone have been reported.

Several case reports of suicide attempts due to ingestion of bentazone formulations have been reported in the literature, including four cases resulting in death. The range of doses ingested that resulted in death was 35–250 g of bentazone. The poisoning symptoms and signs included nausea, vomiting, abdominal pain, rhabdomyolysis, hepatorenal damage and cardiac failure.

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

Toxicological evaluation

The Meeting established an ADI of 0–0.09 mg/kg bw derived from a NOAEL of 9 mg/kg bw per day from the 2-year study of toxicity and carcinogenicity in rats, on the basis of prolonged blood coagulation and clinical chemistry changes indicative of effects on liver and kidney at 35 mg/kg bw per day. A safety factor of 100 was applied. This ADI was supported by the NOAEL of 13.1 mg/kg bw per day observed in the 1-year study in dogs for anaemia, altered blood coagulation parameters, clinical signs and weight loss seen at the highest dose of 52.3 mg/kg bw per day; by the NOAEL of 14 mg/kg bw per day in the two-generation study in rats, on the basis of reduced parental feed consumption and body weight gain and reduced pup body weight resulting from parental toxicity at 59 mg/kg bw per day; and by the NOAEL of 12 mg/kg bw per day in a 2-year toxicity and carcinogenicity study in mice, based on prolongation of prothrombin time and an increased incidence of testicular calcification at 47 mg/kg bw per day.

The Meeting reaffirmed its previous conclusion that no ARfD is necessary. It considered that the post-implantation loss seen in the rat developmental study was not caused by a single dose and that no other effects were observed in repeated-dose studies that could be due to a single dose.

A toxicological monograph was prepared.

Levels relevant to risk assessment

Species	Study	Effect	NOAEL	LOAEL
Mouse	Two-year study of toxicity and carcinogenicity[a]	Toxicity	100 ppm, equal to 12 mg/kg bw per day	400 ppm, equal to 47 mg/kg bw per day
		Carcinogenicity	2000 ppm, equal to 275 mg/kg bw per day[b]	—
Rat	Short-term studies of toxicity[c]	Toxicity	400 ppm, equal to 25.3 mg/kg bw per day	800 ppm, equal to 40 mg/kg bw per day
	Two-year studies of toxicity and carcinogenicity[a,c]	Toxicity	200 ppm, equal to 9 mg/kg bw per day	800 ppm, equal to 35 mg/kg bw per day
		Carcinogenicity	4000 ppm, equal to 274 mg/kg bw per day[b]	—
	Two-generation study of reproductive toxicity[a]	Reproductive toxicity	3200 ppm, equal to 240 mg/kg bw per day[b]	—
		Parental toxicity	200 ppm, equal to 14 mg/kg bw per day	800 ppm, equal to 59 mg/kg bw per day

Species	Study	Effect	NOAEL	LOAEL
		Offspring toxicity	200 ppm, equal to 14 mg/kg bw per day	800 ppm, equal to 59 mg/kg bw per day
	Developmental toxicity study[c,d]	Maternal toxicity	250 mg/kg bw per day[b]	—
		Embryo and fetal toxicity	200 mg/kg bw per day	250 mg/kg bw per day
Rabbit	Developmental toxicity study[d]	Maternal toxicity	150 mg/kg bw per day	375 mg/kg bw per day
		Embryo and fetal toxicity	150 mg/kg bw per day	375 mg/kg bw per day
Dog	Ninety-day and 1-year studies of toxicity[a,c]	Toxicity	400 ppm, equal to 13.1 mg/kg bw per day	1000 ppm, equal to 39.6 mg/kg bw per day

[a] Dietary administration.

[b] Highest dose tested.

[c] Two or more studies combined.

[d] Gavage administration.

Estimate of acceptable daily intake for humans

0–0.09 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 bentazone

Absorption, distribution, excretion and metabolism in mammals	
Rate and extent of oral absorption	Rapid and almost completely absorbed (> 90%)
Dermal absorption	Poorly absorbed (1–2%)
Distribution	Widely distributed
Potential for accumulation	None
Rate and extent of excretion	Rapid, more than 90% within 24 h, mainly via urine
Metabolism in animals	Minimal
Toxicologically significant compounds in animals, plants and the environment	Parent compound
Acute toxicity	
Rat, LD_{50}, oral	≥ 850 mg/kg bw
Rat, LD_{50}, dermal	> 5000 mg/kg bw
Rat, LC_{50}, inhalation	> 5.1 mg/L of air
Rabbit, dermal irritation	Not irritating
Rabbit, ocular irritation	Irritating
Dermal sensitization	Sensitizer (Magnusson & Kligman test)
Short-term studies of toxicity	
Target/critical effect	Blood coagulation
Lowest relevant oral NOAEL	12 mg/kg bw per day (dogs)
Lowest relevant dermal NOAEL	1000 mg/kg bw per day (highest dose tested) (rabbits)
Lowest relevant inhalation NOAEC	No data
Long-term studies of toxicity and carcinogenicity	
Target/critical effect	Blood coagulation, liver and kidney effects
Lowest relevant NOAEL	9 mg/kg bw per day (rats)
Carcinogenicity	Not carcinogenic in rats or mice

Genotoxicity	
	Not genotoxic
Reproductive toxicity	
Target/critical effect	No reproductive effects
Lowest relevant parental NOAEL	14 mg/kg bw per day (rat)
Lowest relevant offspring NOAEL	14 mg/kg bw per day (rat)
Lowest relevant reproductive NOAEL	240 mg/kg bw per day (highest dose tested) (rat)
Developmental toxicity	
Target/critical effect	Post-implantation loss, reduced fetal weight and skeletal anomalies
Lowest relevant maternal NOAEL	150 mg/kg bw per day (rabbit)
Lowest relevant embryo/fetal NOAEL	150 mg/kg bw per day (rabbit)
Neurotoxicity	
Subchronic neurotoxicity	No effect up to 258 mg/kg bw per day (highest dose tested)
Medical data	
	No significant health effects in manufacturing personnel. Three cases of intentional poisoning have been reported with various critical symptoms.

Summary

	Value	**Study**	**Safety factor**
ADI	0–0.09 mg/kg bw	2-year chronic toxicity and carcinogenicity study (rats)	100
ARfD	Unnecessary	—	—

5.4 BUPROFEZIN (173)

RESIDUE AND ANALYTICAL ASPECTS

Buprofezin, insecticide, 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. The 2008 JMPR allocated an ADI of 0–0.009 mg/kg bw and ARfD of 0.5 mg/kg bw. It concluded that the residue definition for compliance with the MRL and for estimation of dietary intake, both for animal and plant commodities, should be buprofezin. Buprofezin was further evaluated for additional maximum residue levels in 2009.

At the Forty-third Session, the CCPR included buprofezin in the Priority List for review by the current JMPR for additional MRLs.

The current Meeting received information on supervised trials on banana, coffee and tea. The Meeting also received information on method validation and storage stability studies additional to those submitted to the 2008 and 2009 JMPR.

Methods of analysis

The Meeting received information on validation of analytical methods used in the supervised field trial studies for determination of buprofezin in banana, coffee bean or crude green tea.

A number of CG-NPD methods and HPLC-MS-MS methods were validated for determination of buprofezin in banana (pulp and peel), coffee or green tea. Mean recoveries were within the acceptable range of 70–110% with RSDs less than 20%. The reported LOQ was 0.01 mg/kg for the methods used for determination of buprofezin in banana pulp and peel and coffee. For the two GC-NPD methods for determining buprofezin in green tea, reported limit of detection was 0.01–0.05 mg/kg.

Stability of residues in stored analytical samples

The current Meeting received information on the storage stability studies on banana, coffee and tea to determine the stability of buprofezin following frozen storage.

Buprofezin was demonstrated to be stable when stored frozen at -20 °C for at least the longest storing periods in studies: 70 days in whole banana (0.01 mg/kg), 656 days in green coffee beans (0.50 mg/kg), 658 days in roasted coffee beans (0.50 mg/kg) and 680 days in freeze-dried coffee (0.50 mg/kg) and 75 days in crude green tea (2 mg/kg). The storage duration of samples in supervised trials was within the above mentioned period for each commodity.

Results of supervised residue trials on crops

The Meeting received supervised trial data for buprofezin on banana, coffee and tea.

The OECD MRL calculator was used as a tool to assist in the estimation of maximum residue levels from the selected residue data set obtained from the supervised residue trials. As a first step, the Meeting reviewed trial conditions and other relevant factors related to each data set to arrive at a best estimate of the maximum residue level using expert judgement. Then, the OECD calculator was employed. If the statistical calculation spreadsheet suggested a different value, a brief explanation of the derivation was supplied.

Banana

Six supervised trials were conducted in the USA: one in Puerto Rico and four in Hawaii in 1996 and one in Florida in 2003. Four applications were made at around 0.34 kg ai/ha with an exception that in the trial in Puerto Rico the first application rate was 0.84 kg ai/ha. The registered use on banana in the USA allows the maximum of 4 foliar spray applications at the maximum rate of 0.34 kg ai/ha with PHI of 1 day. The maximum spray concentration is 0.24 kg ai/hL.

The Meeting decided that as about three times higher rate applied at the first application (42 days before the last application) in one trial did not seem to contribute significantly to residues in fruits at harvest, it was appropriate to use the residue data from this trial.

In five trials banana fruit was either bagged or unbagged and one half of each sample of bagged or unbagged banana was peeled and analysed with the rest unpeeled and analysed. No residues were found in pulp portion of both bagged and unbagged banana, or in bagged whole banana fruit. Therefore, the Meeting decided to use data set from unbagged banana. Residues in unbagged whole banana from trials conducted in USA following US GAP were in rank order: 0.02, 0.04, 0.05, 0.06, 0.07, and 0.18 mg/kg.

Corresponding residues in pulp were in rank order: < 0.01 mg/kg (5). In the trial in Florida, only whole fruits were analysed.

Additionally four trials were conducted in Spain: two in 2009 and two other in 2010. The registered use on banana in Spain allows the maximum spray concentration of 0.01–0.02 kg ai/hL with PHI of 7 days. The spray concentrations in trials were 0.025–0.04 kg ai/hL.

Residues in unbagged whole banana from trials conducted in Spain following Spanish GAP were: 0.32 mg/kg.

The GAP of the USA and that of Spain are significantly different and the data from trials in Spain were not sufficient for estimating a maximum residue level, the Meeting decided to use the results of S trials as a basis of estimating a maximum residue level, STMR and HR.

The Meeting estimated a maximum residue level of 0.3 mg/kg, an STMR of 0.01 mg/kg and HR of 0.01 mg/kg on a basis of US trials.

Coffee bean

Supervised trials were conducted on coffee in Hawaii in the USA in 2004 with four applications at 1.12–1.23 kg ai/ha. The 2009 JMPR reviewed these data and concluded that data were insufficient to recommend a maximum residue level.

Residues of buprofezin in green coffee beans from trials in the USA conducted following US GAP for coffee (1.12 kg ai/ha × 4, PHI 0 day) were re-evaluated by the current Meeting. These were in rank order: 0.08, 0.12, 0.16 and 0.24 mg/kg.

Additionally three trials were conducted in Brazil in 2011 with four applications at 1.12–1.14 kg ai/ha. These trials were in accordance with US GAP.

As the Meeting does not have sufficient information on normal agricultural practices in coffee cultivation in Brazil or the USA to determine their similarity, it concluded that it was not possible to estimate a maximum residue level for coffee bean.

Green tea

Supervised trials were conducted on tea in five Prefectures in Japan in 1981 and 1996 with two foliar applications at the spray concentration rate of 0.02 (SC) or 0.025(WP) kg ai/hL. The registered use in Japan allows maximum of two applications at the maximum spray concentration of 0.020 (in case of SC) or 0.025 (in case of WP) kg ai/hL. No maximum rate per ha is specified.

Residues of buprofezin in crude (unblended) green tea from trials in accordance with GAP in Japan were in rank order: 6.9, 7.1, 8.2, 9.8, 11 and 12 mg/kg.

The Meeting estimated a maximum residue level of 30 mg/kg and STMR of 9.0 mg/kg for tea, green.

As the processing of green tea is significantly different from that of black tea, the Meeting concluded that the estimated maximum residue level should be applicable only to green tea.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Daily Intakes (IEDIs) of buprofezin were calculated for the 13 GEMS/Food cluster diets using STMRs and STMRPs estimated by the 2004, 2006, 2010 and current Meetings (Annex 3). The ADI is 0–0.009 mg/kg bw and the calculated IEDIs were 2–50% of the maximum ADI. The Meeting concluded that the long-term intake of residues of buprofezin resulting from the uses considered by the 2008, 2009 and current JMPR is unlikely to present a public health concern.

Short-term intake

The International Estimated Short-Term Intakes (IESTI) of buprofezin were calculated for food commodities and their processed commodities using HRs/HR-Ps or STMRs/STMR-Ps estimated by the current Meeting (see Annex 4). The ARfD is 0.5 mg/kg and the calculated IESTIs were 0–7 % of the ARfD. The Meeting concluded that the short-term intake of residues of buprofezin, when used in ways that have been considered by the JMPR, is unlikely to present a public health concern.

5.5 CARBOFURAN (096)

RESIDUE ANDF ANALYTICAL ASPECTS

The insecticide, nematicide and acaricide carbofuran has been evaluated numerous times by the JMPR since 1976, the most recent being in 2008 for toxicology and 2009 for residues. The 2008 Meeting estimated an acceptable daily intake (ADI) for humans of 0–0.001°mg/kg bw and an acute reference dose (ARfD) of 0.001°mg/kg bw. The residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities was defined as the sum of carbofuran and 3-OH carbofuran expressed as carbofuran. The information provided in 2009 to the JMPR did not preclude that the IESTI of carbofuran in bananas will be below the ARfD. However the 2009 Meeting also noted that the short-term dietary risk assessment of bananas could be refined, if a metabolism study on banana or residue trials employing a very sensitive analytical method were available.

The current Meeting received new information on residue analysis, use pattern and residues resulting from supervised residue trials on bananas.

Methods of analysis

The Meeting previously evaluated several methods of analyses for carbofuran and 3-OH carbofuran in different vegetable matrices each with varying LOQs and LODs ranging from 0.005–0.1 mg/kg for both analytes.

The method reported to the current Meeting and used in the supervised residue trials determined carbofuran and 3-OH-carbofuran. The limit of quantification (LOQ) for bananas was 0.01 mg/kg for both carbofuran and 3-OH carbofuran. The limit of detection (LOD) of 0.003 mg/kg for carbofuran and for 3- OH carbofuran was assumed to be thirty percent of the LOQ.

Results of supervised residue trial on crops

Bananas

In bananas, carbofuran residues may arise from ground treatment use against nematodes. The 2009 Meeting noted that in eight Central and South American trials, no residues of carbofuran or 3-OH carbofuran were detected in any sample (whole fruit, peel or pulp). The LOQ and LOD were 0.05 mg/kg and 0.01 mg/kg, respectively, both for carbofuran and 3-OH carbofuran. In an additional Brazilian trial (LOQ: 0.1 mg/kg) and in a Spanish trial (LOQ: 0.05 mg/kg, LOD: 0.02 mg/kg) no residues were detected in pulp or peel either.

Monitoring data from the United States Department of Agriculture (USDA) reviewed in 2009 showed that in almost 4000 banana samples no carbofuran or 3-OH carbofuran residues above the LODs (0.002–0.076 mg/kg for carbofuran and 0.004–0.076 mg/kg for 3-OH carbofuran) have been detected.

Based on the overall findings, the 2009 Meeting concluded that in the case of bananas, a zero-residue situation seemed plausible. However, the Meeting decided to use the LODs for carbofuran and 3-OH carbofuran as reported in the eight Central and South American trials (0.01 mg/kg for each of them) for the estimation of an STMR and HR of 0.02 mg/kg each for carbofuran in bananas.

For the present evaluation new supervised field trials involving bananas were performed in Central America (Costa Rica, Honduras and Equador). The maximum GAP for carbofuran on bananas in these countries is 2 × 3.1 g ai per plant and year with an interval of 4–5 months and no specified PHI.

In four trials matching the GAP no carbofuran and 3-OH carbofuran residues in bananas (whole fruit) were detected following DATs ranging from 0–124 days:

Carbofuran: < 0.01 mg/kg (n=4) and not detected (LOD: 0.003 mg/kg)

3-hydroxy-carbofuran: < 0.01 mg/kg (n=4) and not detected (LOD: 0.003 mg/kg).

The Meeting noted that the use of carbofuran according to the GAPs submitted lead to a very low residue situation in bananas, in which with no detectable residues in the fruits and concluded that the sum of both analytes would be unlikely to exceed 0.01 mg/kg.

The Meeting estimated a maximum residue level, an STMR and an HR of 0.01* mg/kg, 0.01 mg/kg and 0.01 mg/kg, respectively, for the sum of carbofuran and 3-OH carbofuran, expressed as carbofuran in bananas.

The Meeting withdraws its previous recommendation of 0.02* mg/kg for bananas.

DIETARY RISK ASSESSMENT

Long-term intake

The Meeting of 2009 concluded that the long-term intake of residues of carbofuran from uses that have been considered by the JMPR is unlikely to present a public health concern. As the current Meetings estimated STMR for bananas is lower than that estimated in 2009, no new long-term intake calculations were performed.

Short-term intake

The ARfD for carbofuran is 0.001 mg/kg bw. The International Estimated Short-term Intake (IESTI) was calculated for banana using an HR of 0.01 mg/kg for bananas. The IESTI was 90% of the ARfD for bananas. The short-term intake of residues of carbofuran from uses of carbosulfan on banana 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) (CAS No. 122453-73-0). Chlorfenapyr is a contact and stomach insecticide that acts, following metabolic activation, as an uncoupler of oxidative phosphorylation in mitochondria. It has limited systemic activity.

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

All critical studies with chlorfenapyr were certified to be compliant with GLP, unless otherwise specified.

Biochemical aspects

In two metabolism studies, one of which was not certified to be compliant with GLP, chlorfenapyr labelled with ^{14}C in either the pyrrole or the phenyl ring was administered by oral gavage to intact and bile duct–cannulated rats. The radiolabel was relatively slowly absorbed, the extent varying from 80% at 2 mg/kg bw to 65% at 20 mg/kg bw. The maximum concentration of radiolabel in plasma was achieved after about 8–12 hours, was dose proportional (at 2–20 mg/kg bw) and did not differ between males and females. Absorbed radiolabel was slowly distributed throughout the body, with concentrations in fat, liver and adrenals being greater than those in plasma. In general, tissue radiolabel concentration increased with dose. Blood and tissue concentrations of radiolabel were 2- to 3-fold higher in female rats than in male rats. Excretion was relatively rapid, mainly via the faeces, ranging from 80% to 106% of the administered dose in 7 days. There was little or no potential for accumulation, with 70% of the dose excreted in 24 hours and approximately 90% within 48 hours. The elimination half-life for plasma radiolabel was approximately 56 hours. Most of the chlorfenapyr in faeces was present as the unchanged compound, comprising material that was not absorbed together with material excreted via the bile, which was the main route of elimination. Faeces also contained minor amounts of *N*-dealkylated, debrominated and hydroxylated oxidation products of chlorfenapyr. Excretion via the urine was minor, representing only 5–11% of the administered dose over 7 days. There was no elimination of chlorfenapyr-related radioactivity via respiration.

The major routes of metabolism are *N*-dealkylation, dehalogenation, hydroxylation and conjugation, but not with sulfate or glucuronide. There is no cleavage of the bond between the pyrrole and phenyl rings of chlorfenapyr during its biotransformation.

Toxicological data

Chlorfenapyr technical is moderately toxic via the oral route, with LD_{50}s of 441 mg/kg bw in rats and 45 mg/kg bw in mice, and via the inhalation route, with an LC_{50} of 0.83 mg/L in rats. Chlorfenapyr was of low toxicity after dermal exposure in rabbits (LD_{50} > 2000 mg/kg bw). It is not irritating to the skin or eye of rabbits and is not a dermal sensitizer in the guinea-pig maximization test.

Following repeated administration of chlorfenapyr to mice, rats and dogs, decreased feed consumption and body weight gains were observed in all three species. Increased liver weights, associated with hepatocellular hypertrophy, and vacuolation in the brain and spinal cord were also noted in rats and mice.

In a 28-day study in mice, the NOAEL was 160 ppm (equal to 30.1 mg/kg bw per day), based on decreased body weight gain, mortality and increased relative liver weight at 240 ppm (equal to 43.6 mg/kg bw per day). In a 90-day study in mice, the NOAEL was 80 ppm (equal to 14.8 mg/kg bw per day), based on increased relative spleen weight and myelopathy in brain and spinal cord in males at 160 ppm (equal to 27.6 mg/kg bw per day).

In a 28-day study in rats, the NOAEL was 600 ppm (equal to 68.3 mg/kg bw per day), based on increases in relative liver weights and alanine aminotransferase activity at 900 ppm (equal to 106.3 mg/kg bw per day). In a 90-day study in rats, the NOAEL was 300 ppm (equal to 22 mg/kg bw per day), based on increases in relative liver weight, alkaline phosphatase activity and blood urea nitrogen and, in females, changes in red cell parameters (haemoglobin) at 600 ppm (equal to 44.9 mg/kg bw per day). Vacuolation of the brain and spinal cord was seen at higher doses (900 ppm, equal to 106.3 mg/kg bw per day, and above).

In a 90-day dietary study in dogs, the NOAEL was 120 ppm (equal to 4.0 mg/kg bw per day), based on decreased body weight gain at 200 ppm (equal to 7.1 mg/kg bw per day). In a 1-year dietary study in dogs, the NOAEL was 120 ppm (equal to 4.0 mg/kg bw per day), based on reduced body weight and body weight gain at 240 ppm (equal to 8.7 mg/kg bw per day). The overall NOAEL for these two studies in the dog was 4 mg/kg bw per day.

Long-term studies of toxicity and carcinogenicity were performed in mice and rats, with similar NOAELs in the two species. In an 18-month dietary study in mice, the NOAEL for non-neoplastic effects was 20 ppm (equal to 2.8 mg/kg bw per day), based on decreases in body weight gain and vacuolation of the white matter of the brain at 120 ppm (equal to 16.6 mg/kg bw per day). No evidence of carcinogenicity was found.

In a 24-month dietary study in rats, the NOAEL for non-neoplastic effects was 60 ppm (equal to 2.9 mg/kg bw per day), based on reduced body weight and body weight gain and increased liver weight associated with hepatocellular hypertrophy at 300 ppm (equal to 15 mg/kg bw per day). No evidence of carcinogenicity was found.

The Meeting concluded that chlorfenapyr was not carcinogenic in rats and mice.

The potential genotoxicity of chlorfenapyr was tested in an adequate range of in vitro and in vivo studies. Chlorfenapyr showed no evidence of genotoxicity.

The Meeting concluded that chlorfenapyr was unlikely to be genotoxic in vivo.

On the basis of the lack of genotoxicity and the absence of carcinogenicity in the rat and the mouse, the Meeting concluded that chlorfenapyr is unlikely to be carcinogenic in humans.

In a two-generation reproductive toxicity study in rats, the NOAEL for effects on fertility was 600 ppm (equal to 44 mg/kg bw per day), the highest dose tested. The NOAEL for parental toxicity was 60 ppm (equal to 5 mg/kg bw per day), based on decreased body weight and body weight gain at 300 ppm (equal to 22 mg/kg bw per day). The NOAEL for offspring toxicity was 60 ppm (equal to 5 mg/kg bw per day), based on decreased body weight of pups at 300 ppm (equal to 22 mg/kg bw per day).

In a developmental toxicity study in rats, the NOAEL for maternal toxicity was 75 mg/kg bw per day, based on decreased body weight at 225 mg/kg bw per day. The NOAEL for developmental toxicity was 225 mg/kg bw per day, the highest dose tested.

In a developmental toxicity study in rabbits, the NOAEL for maternal toxicity was 5 mg/kg bw per day, based on decreased body weight gain at 15 mg/kg bw per day. The NOAEL for developmental toxicity was 30 mg/kg bw per day, the highest dose tested.

The Meeting concluded that chlorfenapyr was not teratogenic.

In an acute neurotoxicity study in rats, the NOAEL for systemic toxicity was 45 mg/kg bw, based on clinical signs of toxicity (2 lethargic animals out of 20) at 90 mg/kg bw and above. Lethality (20%) was observed at 180 mg/kg bw. There was no evidence for neuropathological effects or neurotoxicity up to the highest dose tested (180 mg/kg bw).

In a 1-year neurotoxicity study in rats, the NOAEL for neurotoxicity was 60 ppm (equal to 2.6 mg/kg bw per day), based on vacuolar myelinopathy, vacuolation and/or myelin sheath swelling of the brain and spinal cord in males at 300 ppm (equal to 13.6 mg/kg bw per day). There was no change in motor activity or other behavioural activity. The effects observed were reversible within 16 weeks.

In a developmental neurotoxicity study in rats, the NOAEL for maternal toxicity was 15 mg/kg bw per day, the highest dose tested. The NOAEL for developmental neurotoxicity was 10 mg/kg bw per day, based on an increased incidence of multifocal vacuolation (minimal to moderate severity) of the white matter of the brain on postnatal day 22 at 15 mg/kg bw per day. This effect appears to be reversible (i.e. 38 days after end of treatment), as no adverse effects on either behaviour or neuropathology were evident in rats on postnatal day 60.

Single-dose studies on the pharmacological action of MK-242 were performed in mice, rats and rabbits to evaluate effects on the central nervous system, autonomic nervous system, respiratory and cardiovascular systems, gastrointestinal system, skeletal muscle and blood coagulation. The only relevant pharmacological effects were observed on the central nervous system, such as changes in general behaviour and an increase in body temperature. Convulsions due to stimulation of the central nervous system were thought to be the cause of death observed in rats and mice after acute intoxication. No changes in the electroencephalogram were observed at non-lethal doses in rabbits. NOAELs were 3 mg/kg bw in mice, 10 mg/kg bw in rats and 30 mg/kg bw (the highest dose tested) in rabbits, based on depression of grooming behaviour and reactivity, a decrease in spontaneous motor activity and prone position in mice and rats.

The acute oral toxicity of four chlorfenapyr animal metabolites (AC 312,094, AC 303,268, AC 322,250 and AC 325,195) was tested in Sprague-Dawley rats.

AC 312,094 was of low acute oral toxicity in rats (LD_{50} > 5000 mg/kg bw) and showed no mutagenic potential in microbial test systems.

AC 303,268 was of high acute oral toxicity in rats (LD_{50} = 27 mg/kg bw). This metabolite showed no mutagenic potential in microbial test systems. It is present at significant levels in livestock.

AC 322,250 was of slight acute oral toxicity in rats (LD_{50} = 2500 mg/kg bw) and showed no mutagenic potential in microbial test systems.

AC 325,195 was of moderate acute oral toxicity in rats (LD_{50} = 776 mg/kg bw) and showed no mutagenic potential in microbial test systems.

There were no reports of adverse health effects of chlorfenapyr in manufacturing plant personnel.

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

Toxicological evaluation

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. A 100-fold safety factor was applied.

Based on available information, it was not possible for the Meeting to determine whether the ADI and ARfD would also cover the metabolite AC 303,268.

A toxicological monograph was prepared.

Levels relevant to risk assessment

Species	Study	Effect	NOAEL	LOAEL
Mouse	Eighteen-month study of toxicity and carcinogenicity[a]	Toxicity	20 ppm, equal to 2.8 mg/kg bw per day	120 ppm, equal to 16.6 mg/kg bw per day
		Carcinogenicity	240 ppm, equal to 34.5 mg/kg bw per day[b]	—
	Pharmacological study[c]	Toxicity	3 mg/kg bw	10 mg/kg bw
Rat	Two-year study of toxicity and carcinogenicity[a]	Toxicity	60 ppm, equal to 2.9 mg/kg bw per day	300 ppm, equal to 15 mg/kg bw per day
		Carcinogenicity	600 ppm, equal to 30.8 mg/kg bw per day[b]	—
	Two-generation study of reproductive toxicity[a]	Reproductive toxicity	600 ppm, equal to 44 mg/kg bw per day[b]	—
		Parental toxicity	60 ppm, equal to 5 mg/kg bw per day	300 ppm, equal to 22 mg/kg bw per day
		Offspring toxicity	60 ppm, equal to 5 mg/kg bw per day	300 ppm, equal to 22 mg/kg bw per day
	Developmental toxicity study[c]	Maternal toxicity	75 mg/kg bw per day	225 mg/kg bw per day
		Embryo and fetal toxicity	225 mg/kg bw per day[b]	—
	Acute neurotoxicity study[c]	Toxicity Neurotoxicity	45 mg/kg bw 180 mg/kg bw[b]	90 mg/kg bw —
	One-year neurotoxicity study[a]	Neurotoxicity	60 ppm, equal to 2.6 mg/kg bw per day	300 ppm, equal to 13.6 mg/kg bw per day
	Developmental neurotoxicity study[c]	Maternal toxicity	15 mg/kg bw per day[b]	—
		Offspring neurotoxicity	10 mg/kg bw per day	15 mg/kg bw per day
Rabbit	Developmental toxicity study[c]	Maternal toxicity	5 mg/kg bw per day	15 mg/kg bw per day
		Embryo and fetal toxicity	30 mg/kg bw per day[b]	—
Dog	Thirteen-week and 1-year studies of toxicity[a,d]	Toxicity	120 ppm, equal to 4 mg/kg bw per day	240 ppm, equal to 8.7 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 for humans

0–0.03 mg/kg bw

Estimate of acute reference dose

0.03 mg/kg bw

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

Additional studies on the toxicity of AC 303,268 to enable adequate characterization of the dietary risk from this metabolite. The Meeting was aware that additional studies on the compound have been performed but did not have access to sufficiently detailed reports to enable their evaluation.

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

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

Absorption, distribution, excretion and metabolism in mammals	
Rate and extent of oral absorption	Slow, approximately 80% and 65% in the low-dose and high-dose groups, respectively
Dermal absorption	No data
Distribution	Extensive
Potential for accumulation	No evidence of accumulation
Rate and extent of excretion	Rapid and almost complete in 168 h in urine and faeces
Metabolism in animals	Absorbed dose metabolized by *N*-dealkylation, debromination, ring hydroxylation and conjugation
Toxicologically significant compounds in animals, plants and the environment	Chlorfenapyr , AC 303,268
Acute toxicity	
Rat, LD_{50}, oral	441 mg/kg bw
Rabbit, LD_{50}, dermal	> 2000 mg/kg bw
Rat, LC_{50}, inhalation	0.83 mg/L (4 h aerosol, whole-body exposure)
Rabbit, dermal irritation	Not irritating
Rabbit, ocular irritation	Not irritating
Dermal sensitization	Not sensitizing (Magnusson & Kligman)
Short-term studies of toxicity	
Target/critical effect	Decreased body weights and weight gain, increased liver weights, vacuolation of the white matter (rat and mouse)
Lowest relevant oral NOAEL	4 mg/kg bw per day (dog)
Lowest relevant dermal NOAEL	100 mg/kg bw per day (rabbit)
Lowest relevant inhalation NOAEC	20 mg/m^3 (rat)
Long-term studies of toxicity and carcinogenicity	
Target/critical effect	Reduced growth rate and feed intake, vacuolation of the white matter (mice), haematological changes (rat)
Lowest relevant NOAEL	2.8 mg/kg bw per day (mouse carcinogenicity study)
Carcinogenicity	Not carcinogenic
Genotoxicity	
	Not genotoxic
Reproductive toxicity	
Target/critical effect	Reductions in pup body weights at parentally toxic doses
Lowest relevant parental NOAEL	5 mg/kg bw per day
Lowest relevant reproductive NOAEL	44 mg/kg bw per day (highest dose tested)
Lowest relevant offspring NOAEL	5 mg/kg bw per day
Developmental toxicity	
Target/critical effect	Not teratogenic, no developmental toxicity
Lowest relevant maternal NOAEL	5 mg/kg bw per day (rabbit)
Lowest relevant developmental NOAEL	30 mg/kg bw per day (highest dose tested) (rabbit)
Neurotoxicity	
Acute neurotoxicity target/critical effect	Not acutely neurotoxic
One-year neurotoxicity target/critical effect	Vacuolation of the white matter (reversible) (rat)
Lowest relevant NOAEL	2.6 mg/kg bw per day (rat)
Neurodevelopmental toxicity target/critical effect	Vacuolation of white matter of the brain (reversible) (rat)
Lowest relevant NOAEL	10 mg/kg bw per day

Other toxicological studies	
Acute toxicity of metabolites	AC 312,094: rat LD_{50} > 5000 mg/kg bw AC 303,268: rat LD_{50} = 27 mg/kg bw AC 322,250: rat LD_{50} = 2500 mg/kg bw AC 325,195: rat LD_{50} = 776 mg/kg bw
Genotoxicity of metabolites	Not genotoxic
Medical data	
	No data available

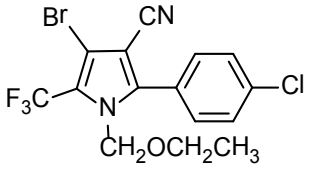
Summary

	Value	Study	Safety factor
ADI	0–0.03 mg/kg bw	Eighteen-month (mouse) and 2-year (rat) studies of toxicity; 1-year neurotoxicity study (rat)	100
ARfD	0.03 mg/kg bw	Pharmacological study (mouse)	100

RESIDUE AND ANALYTICAL ASPECTS

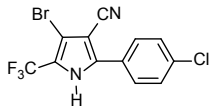
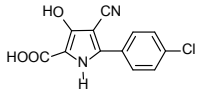
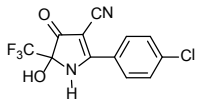
The chlorfenapyr is a pro-insecticide-miticide. Its biological activity depends upon its activation to another chemical (CL303268). Oxidative removal of the N-ethoxymethyl group of chlorfenapyr by mixed function oxidases forms CL303268. This compound uncouples oxidative phosphorylation at the mitochondria, resulting in the disruption of ATP production, cellular death, and ultimately organism mortality. It is considered for the first time by the 2012 JMPR.

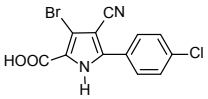
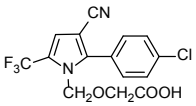
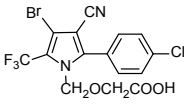
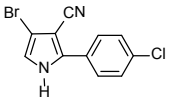
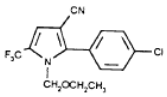
The chemical name of chlorfenapyr is: 4-bromo-2-(4-chlorophenyl)-1-(ethoxymethyl)-5-(trifluoromethyl)-pyrrole-3-carbonitrile. Its structural formula is shown in the following figure:



The Meeting received information on identity, metabolism, storage stability, residue analysis, use patterns, residues (resulting from supervised trials on citrus fruit, papaya, bulb vegetable, fruiting vegetables (melon, squash, cucumber), tomato, eggplant, pepper, potato, carrot and tea, and fates of residues during processing, and livestock feeding studies.

Metabolites codes and names used in the discussion that follows are detailed below:

	Chlorfenapyr	4-bromo-2-(4-chlorophenyl)-1-(ethoxymethyl)-5-(trifluoromethyl)-pyrrole-3-carbonitrile
	CL303268	4-bromo-2-(p-chlorophenyl)-5-(trifluoromethyl)-pyrrole-3-carbonitrile
	CL152837	4-hydroxy-2-(p-chlorophenyl)-5-(carboxylic)- pyrrole-3-carbonitrile a hydroxylated CL303268 metabolite
	CL325195	2-(4-chlorophenyl)-5-hydroxyl-4-oxo-5-(trifluoromethyl)-3-pyrrole-3-carbonitrile

	CL322250	4-bromo-2-(p-chlorophenyl)-5-(carboxylic)- pyrrole-3-carbonitrile
	CL152835	desbromo-N-carboxymethylmethoxy BAS 306 I
	CL325157	{[3-bromo-5-(p-chlorophenyl)-4-cyano-2-(trifluoromethyl) pyrrol-1-yl]methyl}- acetic acid
	CL152832	destrifluoromethyl CL303268
	CL312094	2-(4-chlorophenyl)-1-(ethoxymethyl)-5-(trifluoromethyl) -1H-pyrrole-3-carbonitrile

Animal metabolism

The Meeting received information on the fate of orally dosed chlorfenapyr in laying hens and lactating goats. Studies were carried out with ^{14}C-chlorfenapyr, labelled at the phenyl (U) and pyrrole ring. The bond between the pyrrole ring and the phenyl ring was not cleaved in metabolism studies.

Metabolism in laboratory animals (rat) was summarized and evaluated by the WHO panel of the JMPR in the present meeting.

Lactating goats, were dosed via capsules with ^{14}C-chlorfenapyr for seven consecutive days at low dose diets (3.0–3.2 ppm feed) and high dose diets (16–25 ppm feed) to determine the fate of chlorfenapyr in milk and tissues.

The major route of elimination of the radioactivity was via the faeces which accounted for 67 to 76% of the administered dose; urine accounted for 6.3 to 15% of the administered dose. The distribution of the TRR in milk and tissues from both labels was similar. In the high dose group, the TRR in milk increased from 0.03 to 0.07 mg eq/kg by day 7 while ^{14}C residues in tissues ranged from 0.03–0.05 mg eq/kg in muscle to 1.4–1.5 mg eq/kg in liver.

Chlorfenapyr was the major component of the ^{14}C residues in milk (25–68% TRR), fat (47–78% TRR) and muscle (29–52% TRR). Other major ^{14}C residue components were CL303268 in fat (4.5–19% TRR) Metabolism was more extensive in liver and kidney and in these tissues chlorfenapyr represented less than 7 and 10% TRR respectively. The major components of the ^{14}C residue in liver and kidney released following pepsin hydrolysis were CL325195 and its conjugates which accounted for somewhere between 12 and 48% of TRR as well as CL152837 and its conjugates which accounted for 7 to 24% TRR. Lack of separation of some of the components made it difficult to estimate proportions of the different components.

Chlorfenapyr undergoes extensive metabolism in the goat involving modification of the phenyl ring and the substituents of the pyrrole ring. The metabolic pathways of chlorfenapyr include N-dealkylation, dehalogenation and hydroxylation of both the phenyl and the pyrrole ring, hydroxylation and oxidation of the N-alkyl group and conjugation to endogenous components.

Laying hens were orally treated with ^{14}C-chlorfenapyr once daily for 7 consecutive days via capsule, at nominal doses of 3.0 or 15 ppm feed of [phenyl (U)-^{14}C] chlorfenapyr and 3.1 or 14 ppm of (pyrrole-^{14}C) chlorfenapyr. Analyses of the excreta of dosed animals over the 7-day testing period

showed that 78 to 94% of the administered doses were excreted. Radioactive residues were highest in liver followed by kidney, skin/fat, eggs and lowest in muscle.

The ^{14}C residues in skin with fat were predominantly parent chlorfenapyr (71–84% TRR), whereas in eggs the ^{14}C residues were mainly chlorfenapyr (33–42% TRR) and the N-dealkylation product (CL303268, 28–34% TRR). The ^{14}C residues in muscle comprised mainly chlorfenapyr (25–31% TRR) and CL152832 (11–23% TRR). In liver and kidney major ^{14}C residue components were chlorfenapyr (liver 2–3% TRR, kidney 7–17% TRR) and CL303268 (liver 3–17% TRR; kidney 14–25% TRR), however extractability of ^{14}C with the solvent system used was low at 14–32% for liver and 69–79% for kidney. When liver and kidneys from additional groups of birds dosed at the equivalent of 16–17 ppm were subjected to a more extreme extraction scheme, major metabolites were CL152835 (23–28% TRR in liver; 25–26% TRR in kidney) and CL325157 (23–35% TRR in liver; 44–51% in kidney). Chlorfenapyr was present at 5.6–8.2% TRR in liver and 5.7–7.9% TRR in kidney. Other components were CL303268 (6.9–8.9% liver; 3.8–3.9% kidney), CL152837 (3.8–6.3% liver; 1.7–2.3% kidney) and CL312094 (1.6–3.2% liver).

Metabolism of chlorfenapyr in the hen takes place at the phenyl ring and the substituents of the pyrrole ring. Fragmentation between the two rings is not evident. The metabolic processes comprised of N-dealkylation, dehalogenation, ring hydroxylation, and oxidation of the terminal N-alkyl group

The metabolism of chlorfenapyr in goats and hens is qualitatively the same as for rats.

Plant metabolism

The Meeting received plant metabolism studies for chlorfenapyr on cotton, citrus fruit, tomato, head lettuce and potato. Studies were made with ^{14}C-chlorfenapyr labelled at either the phenyl (U) or pyrrole ring.

Orange trees were sprayed with ^{14}C-chlorfenapyr at 3 × 0.74 kg ai/ha. The TRR in fruit harvested one week before the third treatment and 7 to 28 days after the last ranged from 0.10 to 0.35 mg eq/kg. TRR in oranges was nearly all located in the peel (91–96%). Chlorfenapyr was the major component of ^{14}C residues accounting for 55–77% of the TRR in fruit. Other metabolites identified were CL303268 (1.4–3.3% TRR), CL222250 (0.9–1.1% TRR) and CL325195 (1.0–2.3% TRR). Numerous unidentified compounds were present but at levels that individually did not exceed 0.01 mg eq/kg.

Tomato plants were treated with 5 × 0.22 kg ai/ha sprays of ^{14}C-chlorfenapyr. TRR in fruits harvested at 7 to 14 days after the last application ranged from 0.03 to 0.05 mg eq/kg. Chlorfenapyr was the major ^{14}C residue component and accounted for 38–50% of the TRR in tomato fruit. Numerous unidentified components were individually present at level that did not exceed 0.01 mg eq/kg.

Head lettuce was treated with ^{14}C-chlorfenapyr as five sprays at 0.22 kg ai/ha. Solvent extracted ^{14}C accounted for 90–98% of the TRR in head lettuce. Chlorfenapyr was the predominant ^{14}C residue component and accounted for 75–77% of the TRR in lettuce. Other metabolites identified were CL303268 (1.1–1.3% TRR), CL312094 (0.8–1.4% TRR) and CL325194 (1.2–1.8% TRR). Numerous unidentified compounds were present but at levels that individually did not exceed 0.01 mg eq/kg.

Potato plants were sprayed with ^{14}C-chlorfenapyr a rate of 0.22 kg ai/ha once a week for four weeks. TRR in the potato tubers was below the detection limit. There was no translocation of ^{14}C-chlorfenapyr from foliage to tubers.

Cotton plants were sprayed with ^{14}C-chlorfenapyr at a rate of 0.45 kg ai/ha as 5 applications at 7 day intervals. The cotton was harvested near 28 days after the last application. TRR in cottonseed (seed meal plus linters) was 0.27–31 mg eq/kg. Chlorfenapyr was the major ^{14}C residue and accounted for 59% to 68% of the TRR in cottonseed.

The metabolism of chlorfenapyr in the various plants studies is qualitatively similar. Generally chlorfenapyr is the major portion of the residue. There were a large number of unidentified metabolites; however, each accounted for equal to or less than 0.01 mg eq/kg.

Environmental fate in soil

The Meeting received information on the fate of chlorfenapyr on confined rotational crops, field crop rotation, aerobic degradation in soil, photo-degradation on soil, aqueous hydrolysis and photolysis. Studies were carried out with ^{14}C-chlorfenapyr, labelled at the phenyl (U) and pyrrole ring.

Chlorfenapyr was persistent in studies on aerobic soil degradation with DT_{50} values in a range of soils ranging from 241 to over 1000 days in laboratory studies and 157 to 418 days in field studies.

In a confined rotational crop study, the ^{14}C-chlorfenapyr was sprayed on the bare sandy loam soil in the treatment plot at weekly intervals for five consecutive weeks at a rate of 0.45 kg ai/ha. Rotational crops of leaf lettuce, carrot, barley and soya bean were planted at 31, 60, 119 and 364 days after treatment.

The radioactivity in rotational crops was attributed to chlorfenapyr and metabolites CL325195 and CL312094. At the 31-day plant back interval, the concentration of chlorfenapyr, in rotational crops ranged from ≤ 0.01 (crops other than carrots) to 0.13 (carrot, immature roots) mg eq/kg, CL325195 was present at ≤ 0.01 mg eq/kg and CL312094 at < 0.01 to 0.03 mg eq/kg. At a plant back interval of 60 days or later, all residue components were ≤ 0.01 mg eq/kg. There were many minor unidentified metabolites in each rotational crop that were individually present at less than or equal to 0.01 mg eq/kg. The metabolite profile in rotational crops was similar for both labels.

The Meeting concluded that residues of chlorfenapyr in rotational crop with minimum plant back interval of 31 days may be possible, but residues would be at or near the limit of quantification of the analytical method, 0.01 mg/kg.

Methods of analysis

Adequate analytical methods exist for the determination of chlorfenapyr residues in both plant and animal matrices. The basic approach for plant matrices employs extraction by homogenisation with methanol:water, and column clean-up using SPE. The extraction solvent system used for animal matrices depends on the tissue and is typically acetone for milk, methanol for muscle and acetonitrile for fat, liver and kidney. Residues are determined by gas chromatography (GC) with an electron capture detector (ECD), nitrogen phosphorous detector (NPD) or mass spectra detection (MS) or by liquid chromatography with mass spectra detection (MS). The limit of quantification was usually 0.01–0.05 mg/kg.

Stability of residues in stored analytical samples

The Meeting received information on the stability of chlorfenapyr in plant commodities during two years freezer storage and milk stored frozen for three months. The chlorfenapyr residues were stable in all the crop matrices (orange, tomato, tomato process fractions, cabbage, lettuce, potato, peach, pear, strawberry and grape) for at least two years. The chlorfenapyr residues in milk were stable for at least three months.

Definition of the residue

Parent chlorfenapyr was a major component of ^{14}C residues in goat's milk (25–68%), fat (47–78%) and muscle (9–52%) and in hens eggs (40%), muscles (31%) and skin/fat (84%). Other major ^{14}C residue components were CL303268 in eggs (31%) and goat fat (4.5–19%) and CL152832 in chicken muscle (11–23% TRR) and chicken kidney (2–11% TRR). Parent chlorfenapyr was extensively metabolised in livestock liver and kidney. CL152835 and CL325157 were major components of the ^{14}C residue in hen liver (23% and 35%) and kidney (28% and 51%). Major components of the ^{14}C residue in goat liver and kidney were CL325195 and its conjugates (about 12–48% TRR) and CL152837 and its conjugates (about 7 to 24% TRR). Chlorfenapyr was present in goat and chicken

liver and kidney at 0.5–17% TRR. As chlorfenapyr is a major component of the residue in most tissues and is present in all tissues, milk and eggs, chlorfenapyr is an adequate residue definition for compliance purposes.

Negligible residues of chlorfenapyr and metabolites are expected in poultry tissues and eggs as the dietary burden for chickens is about 600 times less than the dosing level used in the poultry metabolism studies. It is not necessary to include CL152832, CL152835 and CL325157 in the residue definition for dietary risk assessment for animal commodities.

Available analytical methods only measure parent chlorfenapyr.

The major metabolites found in animal commodities are considered to have comparable or lower toxicity compared to the parent compound. The exception to this is CL303268 which is more acutely toxic than the parent compound (20–30×). As there was no other information on the toxicological properties of this compound it was not possible to determine whether the parent and this metabolite should be evaluated individually or together in assessing risk associated with dietary exposure. The Meeting could not reach a conclusion on a residue definition for dietary risk assessment associated with exposure to residues in animal commodities.

In the lactating cow feeding study residues of chlorfenapyr in fat were at least 16× higher than in muscle. The log Kow for chlorfenapyr 5.28 suggested fat solubility. Residues of chlorfenapyr are fat-soluble.

For plants, chlorfenapyr was the major component of the ^{14}C residue in oranges (55–77%), tomatoes (38–50%), lettuce (75–77%) and cottonseed (59–68%), and often the only compound present in plants at levels above 0.01 mg/kg. CL303268 was sometimes present but at low levels, <5% TRR. The residue definition for plant commodities for compliance purposes should be chlorfenapyr. As the toxicological database available to the Meeting did not allow for conclusions to be made regarding an appropriate health-based guidance values for CL303268 the Meeting could not reach a conclusion on a residue definition for dietary risk assessment associated with exposure to residues in plant commodities.

The Meeting recommended the following residue definition for chlorfenapyr.

Definition of the residue for compliance with the MRL for animal and plant commodities: *chlorfenapyr.*

Definition of the residue for estimation of dietary intake for animal and plant commodities*: a conclusion could not be reached*

The residue is fat soluble.

Results of supervised residue trials on crops

The Meeting received supervised trials data for chlorfenapyr on citrus fruit, papaya, garlic, bulb onion, melons, peppers, eggplants, tomatoes, potatoes and tea. Where the available data permit, the Meeting decided to estimate maximum residue levels. However, as the Meeting could not determine a residue definition for estimation of dietary intake, STMR and HR values are not estimated.

The OECD calculator was used as a tool in the estimation of the maximum residue level from the selected residue dataset obtained from trials conducted according to GAP. First, the Meeting reviewed all relevant factors related to each data set in arriving at a best estimate of the maximum residue level using expert judgment. Then, the OECD calculator was employed. If the statistical calculation spreadsheet suggested a different value from that recommended by the JMPR, a brief explanation of the deviation was provided.

Citrus fruits

Supervised residue trials on orange and lime conducted in Brazil were provided to the Meeting. GAP for citrus in Brazil allows three foliar spray applications at 15 g ai/hL with a PHI 14 days.

In oranges, chlorfenapyr residues in whole fruit from trials in Brazil, matching the GAP in Brazil were (n=7): 0.14, 0.18, 0.39, 0.44, 0.53, 0.54 and 0.87 mg/kg.

In limes, chlorfenapyr residues in whole fruit from trials in Brazil, matching the GAP in Brazil were (n=8): 0.05, 0.08, 0.13, 0.15, 0.17, 0.28, 0.31 and 0.49 mg/kg.

To consider a maximum residue level for a group, 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 Citrus fruit. In deciding whether to combine the datasets for orange and limes for use in the statistical calculator or to only utilize the data from the commodity with the highest residues, the Meeting noted that the populations of residues in oranges and limes are sufficiently different (Mann-Whitney U-test) and decided to use the data from oranges to estimate a maximum residue level of 1.5 mg/kg for citrus fruit.

The median residue in whole orange fruit for use in estimating residues in processed orange commodities was 0.44 mg/kg.

Assorted tropical and sub-tropical fruits – edible peel

Papaya

In five supervised residue trials in papaya conducted in Brazil and matching the Brazilian GAP (3 foliar applications at 12 g ai/hL, PHI 14 days) chlorfenapyr residues were (n=5): < 0.01, 0.03, 0.05, 0.11 and 0.12 mg/kg.

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

Bulb vegetables

Garlic

The GAP in Brazil allows for up to 3 foliar applications of 24 g ai/hL with a 14 day PHI. The Meeting noted the instructions for use suggest a spray volume of 800–1000 L/ha. One trial matched GAP with residues of < 0.01 mg/kg. In a further four trials the application rate was expressed in terms of g ai/ha and as the spray volume was not reported the equivalent spray concentration was not available. Using a figure of 800 L/ha the estimated spray concentration would approximate GAP of Brazil with residues of chlorfenapyr in garlic bulbs of < 0.01 (4) mg/kg.

The Meeting estimated a maximum residue level of 0.01 mg/kg (*) for garlic.

Onion, Bulb

In nine supervised residue trials in bulb onion conducted in Brazil and approximating the Brazilian GAP (up to three foliar applications of 180 g ai/ha with a PHI of 14 days), chlorfenapyr residues in onion bulbs were (n=9): < 0.01 mg/kg.

The Meeting estimated a maximum residue level of 0.01 mg/kg (*) for onion, bulb.

Fruiting vegetables, Cucurbits

Melons, except Watermelon

In supervised residue trials in melons, conducted in Brazil and matching the Brazilian GAP (24 g ai/hL, PHI 14 days), chlorfenapyr residues in whole fruit were (n=9): < 0.01, < 0.01, 0.01, 0.02, 0.02, 0.06, 0.06, 0.17 and 0.17 mg/kg. Where residues in pulp were measured they were: < 0.01 (4) and 0.01 mg/kg.

The Meeting estimated a maximum residue level of 0.4 mg/kg melons (except watermelon).

Fruiting vegetables, other than Cucurbits

Peppers (including pepper, chili and pepper sweet)

The GAP in the USA is for use on glasshouse grown peppers (up to 3 foliar applications of 224 g ai/ha and a 0-day PHI). Two indoor trials on peppers from the USA were available but these did not match the US GAP.

In field trials on peppers conducted in Brazil and matching the Brazilian GAP of up to three applications of 7.2 g ai/hL with a PHI of 14 days, chlorfenapyr residues were (n=7): < 0.01, 0.01, 0.04, 0.05, 0.06, 0.13 and 0.15 mg/kg.

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

Based on the estimated maximum residue level for peppers and a default dehydration factor of 10, the Meeting recommended a maximum residue level of 3 mg/kg for chili peppers (dry).

Egg plant

Four supervised trials were conducted in Mexico according to the Mexico GAP for outdoor crops (up to 96 g ai/ha, PHI 0 days). In trials matching this GAP, chlorfenapyr residues were (n=4): 0.08, 0.09, 0.1 and 0.2 mg/kg.

The Meeting agreed to estimate a maximum residue level of 0.4 mg/kg for eggplant.

Tomato

The GAP in USA is for use on glasshouse grown tomatoes (up to 3 foliar applications of 224 g ai/ha and a 0-day PHI, do not use on varieties with mature fruit of < 2.5 cm diameter). Two indoor tomato trials from the USA were available but these did not match the GAP of the USA.

The GAP in Mexico for field grown tomatoes is for applications at 96 g ai/ha with a 0-day PHI. No trials were available that matched the Mexican GAP.

The residue data from Brazil and Argentina can be assessed against the GAP of Brazil by employing proportionality.

The GAP for field tomatoes in Brazil is for a maximum rate of 12 g ai/hL with a PHI 7 days. While none of the field trials conducted in Brazil and Argentina matched this GAP, chlorfenapyr residues in trials involving a higher (2×) rate of 24 g ai/hL (PHI 7 days) with a spray volume of 1000 L/ha were (n=8): 0.03, 0.09, 0.10, 0.11 0.14, 0.21, 0.37 and 0.37 mg/kg.

When proportionally adjusted by dividing the residues above by two to reflect the 12 g ai/hL GAP application rate in Brazil, the scaled residues (after rounding) were: 0.02, 0.05, 0.05, 0.06, 0.07, 0.11, 0.19 and 0.19 mg/kg.

The Meeting agreed to use the data from Brazil and Argentina, proportionally adjusted to reflect the Brazilian GAP and estimated a maximum residue level of 0.4 mg/kg for tomatoes.

Root and tuber vegetables

Potato

In supervised residue trials on potatoes conducted in Brazil and matching the Brazilian GAP (180 g ai/ha, PHI 7 days), chlorfenapyr residues in tubers were (n=9): < 0.01(9).

The Meeting estimated a maximum residue level of 0.01 mg/kg (*) for potato.

Tea, Green

Critical GAP in Japan for chlorfenapyr on tea is for up to 2 foliar spray applications of 5 g ai/hL, 7 days apart, with a PHI of 7 days. In four trials from Japan matching this GAP, chlorfenapyr residues

in green tea were (n=4): 4.2, 4.5, 16 and 28 mg/kg. In two trials involving only one spray application residues were 20 and 29 mg/kg.

The Meeting noted that compared with black tea, green tea is a minor commodity in trade and agreed four trials would be sufficient to estimate a maximum residue level. The Meeting estimated a maximum residue level of 60 mg/kg for green tea.

Fate of residues during processing

Studies were received on the distribution of chlorfenapyr residues in the skin and flesh of citrus and melons and the fate of residues in the processed fractions of citrus (oranges, limes), tomatoes, potatoes, and tea under conditions simulating commercial processing practices.

Estimated processing factors for the commodities considered at this Meeting and used for dietary intake estimation or for estimating livestock dietary burdens are summarized below.

Commodities	Processing factors (PF)	Best estimate PF
Citrus pulp (wet)	1.08, 0.99	1.0 (mean)
Citrus pulp (dry)	0.55, 0.87, 2.3, 2.4	1.6 (median)
Orange oil	3.1, 17, 23, 70	70
Tomato pomace (wet)	63	63
Tomato pomace (dry)	157	157

Processing factors are based on residues of parent chlorfenapyr, processing studies did not measure residues of CL303268

The Meeting estimated a maximum residue level for citrus oil of 30 mg/kg based on a median residue of 0.44 mg/kg in orange fruit (whole) and a processing factor of 70.

Residues in animal commodities

Farm animal dietary burden

The Meeting estimated the dietary burden of chlorfenapyr in farm animals on the basis of the diets listed in Annex 6 of the 2009 JMPR Report (OECD Feedstuffs Derived from Field Crops), median or highest residue levels estimated at the present Meeting. Dietary burden calculations are provided in Annex 6.

Dietary burden calculations for beef cattle and dairy cattle and poultry are provided below. Potential cattle feed items include: citrus pulp, tomato pomace and potato culls. Potential poultry feed items were: potato culls.

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

	US-Canada	EU	Australia	Japan
Beef cattle	0.09	0.05	2.2	-
Dairy cattle	0.08	0.17	2.2 [a, b]	-
Poultry Broiler	-	0.005	-	-
Poultry Layer	-	0.005 [c]	-	-

[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 maximum poultry dietary burden suitable for MRL estimates for poultry meat and eggs.

Farm animal feeding studies

The Meeting received a feeding study on lactating dairy cows. Animals were dosed orally for 28 consecutive days equivalent to 0.66, 2.2 and 6.8 ppm dry matter in the feed.

Residues of chlorfenapyr in whole milk of animals in the 0.66, 2.2 and 6.8 ppm groups were < 0.01 mg/kg, < 0.01–0.035 and < 0.01–0.042 mg/kg respectively. In muscle and for the same groups,

residues were < 0.01, < 0.01–0.017 and < 0.01–0.022 mg/kg respectively. Residues of chlorfenapyr in fat were 0.031–0.067, 0.17–0.43 and 0.15–0.60 mg/kg respectively. Residues in liver were < 0.05, < 0.05 and < 0.05–0.054 mg/kg respectively for the 0.66, 2.2 and 6.8 ppm feeding groups. Residues of chlorfenapyr in kidney were < 0.05 mg/kg (LOQ) at all the doses studied.

Animal commodity maximum residue levels

Cattle

For maximum residue estimation, the high residues of chlorfenapyr were obtained for the maximum dietary burden (2.2 ppm) directly using the 2.2 ppm feeding level in the dairy cow feeding study and using the highest tissue concentrations of chlorfenapyr from individual animals within those feeding groups and for milk using the mean residues.

	Feed level	Residues	Feed level	Residues (mg/kg) in			
	(ppm) for milk residues	(mg/kg) in milk	(ppm) for tissue residues	Muscle	Liver	Kidney	Fat
Maximum residue level beef or dairy cattle							
Feeding study [a]	2.2	0.017	2.2	0.017	< 0.05	< 0.05	0.43
Estimated highest chlorfenapyr	2.2	0.017	2.2	0.017	< 0.05	< 0.05	0.43

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

The Meeting estimated maximum residue levels of 0.6 (fat) mg/kg for chlorfenapyr in meat (from mammals other than marine mammals), 0.05 (*) mg/kg for edible offal (mammalian) and 0.03 mg/kg for milks.

No feeding study on poultry was available however the estimated dietary burden for poultry is 0.005 ppm, about 600 times less than the level used in the poultry metabolism studies. No residues of chlorfenapyr are expected in poultry tissues and eggs. The Meeting estimated maximum residue levels of 0.01(*) mg/kg for eggs, poultry meat (fat) and poultry edible offal.

DIETARY RISK ASSESSMENT

No maximum residue levels are recommended, nor are levels estimated for use for long- and short-term dietary intake assessments as the Meeting could not reach a conclusion on a residue definition for dietary risk assessment.

5.7 CHLOROTHALONIL (081)

RESIDUE AND ANALYTICAL ASPECTS

Chlorothalonil (tetrachloroisophthalonitrile) was most recently evaluated by the JMPR in 2009 for toxicology and in 2010 for residues. For the parent compound, an ADI of 0–0.02 mg/kg bw and an ARfD of 0.6 mg/kg bw were established. In addition, the Meeting set an ADI of 0–0.008 mg/kg bw and an ARfD of 0.03 mg/kg bw for the metabolite SDS-3701.

The 2010 JMPR recommended the following residue definition for chlorothalonil:

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

Definition of the residue for estimation of dietary intake for plant commodities:

chlorothalonil

SDS-3701 (2,5,6-trichloro-4-hydroxyisophthalonitrile), all considered separately.

Definition of the residue for compliance with MRL and for estimation of dietary intake for animal commodities: *SDS-3701 (2,5,6-trichloro-4-hydroxyisophthalonitrile).*

The 2010 JMPR estimated maximum residue levels for numerous commodities, which were adopted as Codex MRLs by the Codex Alimentarius Commission in 2011. The compound was listed by the Forty-third Session of the CCPR for the review of additional MRLs. The 2012 JMPR received residue data for banana, chard, chicory, endive, spring onion, spinach, and peas.

Methods of residue analysis

The Meeting received information on the analytical methods used in the chlorothalonil field trials for bananas and vegetables. For banana, the samples were extracted with acidified acetone. After clean up, the residues were determined by GC-ECD with a resulting LOQ of 0.1 mg/kg in the trials from 2005. The trials conducted in 2008 made use of similar extraction and sample clean-up, together with GC/MSD analysis to obtain a LOQ of 0.01 mg/kg. Mean recoveries of 74–104% were reported in banana whole fruit and pulp samples spiked at the following levels: 0.01, 0.1, 4.0, and 10 mg/kg. Similar methods were used in the analysis of vegetables, with reported LOQs ranging from 0.01 to 0.05 mg/kg. Analytical methods used in the reported studies made appropriate use of sulphuric acid during sample homogenization to avoid degradation of chlorothalonil residues.

Stability of residues in stored analytical samples

No new information on storage stability was submitted. Detailed information from the 2010 JMPR showed that chlorothalonil residues are stable (> 70% remaining) in frozen storage for up to 12 months in most commodities: peaches, strawberries, oranges, potatoes, carrots, onions, cabbages, leeks, lentils, tomatoes, melons, sugar beet and barley forage.

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

Results of supervised residue trials on crops

The 2010 JMPR noted that metabolite SDS-3701 is found at negligible levels following direct crop treatments. In follow crops or after processing, the contribution of SDS-3701 should be accounted for in a separate dietary intake analysis, reflecting its different toxicological endpoint from chlorothalonil. Neither banana nor chard have processed commodities or are livestock feedstuffs. These commodities are not expected to increase the contribution of SDS-3701 included in the analysis conducted in 2010.

The OECD calculator was used as a tool in the estimation of the maximum residue level from the selected residue data set obtained from trials conducted according to proposed GAP. As a first step, the Meeting reviewed all relevant factors related to each data set in arriving at a best estimate of the maximum residue level using expert judgement. Then, the OECD calculator was employed. If the

statistical calculation spreadsheet suggested a different value from that recommended by the JMPR, a brief explanation of the deviation was provided.

Bananas

In Brazil, chlorothalonil is registered for the use on banana at a rate of 1 kg ai/ha, a retreatment interval of 15 days, and a PHI of 0 days. Eight supervised field trials were conducted in Brazil. In four trials, whole fruit and pulp data were collected following 4 and 6 applications at the GAP rate. In the four other trials, only whole fruit data were collected after 6 applications at the GAP rate.

Chlorothalonil residues in whole fruits were (n=8): 0.11, 0.24, 0.28, 0.34, 0.59, 1.4, 1.8, and 10 mg/kg. In the pulp, residues were (n=4): 0.05, 0.07 (2), and 0.13 mg/kg. The mean of the ratios of the residue levels between the pulp and whole fruit in trials where both values were determined, was 0.071 (n=40).

Based on the data for whole fruits treated according to Brazilian GAP, the Meeting estimated a maximum residue level of 15 mg/kg for chlorothalonil in banana (whole fruit). Using the pulp/whole fruit ratio, the Meeting estimated an STMR value of 0.033 mg/kg (0.47 × 0.071) and an HR value of 0.71 mg/kg (10 × 0.071) for chlorothalonil in banana pulp.

Spring onion

Supervised trials data were available for spring onion from Australia.

In Australia, GAP for spring onion allows the use of chlorothalonil at 1.7 kg ai/ha with a 14-day retreatment interval and a 14-day PHI.

In five spring onion trials in Australia matching GAP, chlorothalonil residues in spring onion were (n=5): 0.13, 0.44, 0.95, 1.2, and 2.8 mg/kg.

Following recommendations from the 2010 JMPR, there is an existing spring onion MRL of 10 mg/kg, based on two applications at a rate of 1 kg ai/ha and a 14-day PHI, and four trials from the United Kingdom. The Meeting agreed that the existing MRL accommodates the GAP used in Australia.

Leafy vegetables

Supervised trial data were available for chard, chicory, endive, and spinach.

Chard (Silverbeet)

In Australia, chlorothalonil is registered for use on chard for up to 4 treatments at a rate of 1.7 kg ai/ha, with a PHI and a retreatment interval of 7 days. Three supervised field trials are available at this GAP from Australia.

Rank-order chlorothalonil residues in Swiss chard were (n=3): 8.5, 16, and 19 mg/kg.

The Meeting estimated a maximum residue level of 50 mg/kg for chlorothalonil in/on chard, an STMR value of 16 mg/kg, and an HR value of 19 mg/kg.

Chicory

In Australia, GAP for chicory specifies the use of chlorothalonil with a maximum of two foliar applications at 0.75 kg ai/ha, a 7-day retreatment interval, and a 7-day PHI.

One trial matching GAP from Australia was submitted, showing a residue of 4.4 mg/kg chlorothalonil.

The Meeting agreed that one trial is insufficient to base maximum residue estimates for chicory.

Endive

In Australia, GAP for endive specifies the use of chlorothalonil with a maximum of two foliar applications at 0.75 kg ai/ha, a 7-day retreatment interval, and a 7-day PHI.

One trial matching GAP from Australia was submitted, showing a residue of 6.6 mg/kg chlorothalonil.

The Meeting agreed that one trial is insufficient to base maximum residue estimates for endive.

Spinach

In Australia, GAP for spinach allows the use of chlorothalonil with a maximum of four foliar applications at 1.7 kg ai/ha, a 7-day retreatment interval, and a 7-day PHI.

Four trials matching GAP were available from Australia.

Rank-order chlorothalonil residue concentrations in spinach were: 2.8, 38, 42, and 66 mg/kg.

The Meeting agreed that 4 trials are insufficient to base maximum residue estimates for spinach.

Peas (pods and succulent = immature seeds)

Supervised trials data were available for garden and snow peas.

In Australia, GAP for peas allows the use of chlorothalonil with four foliar applications at 1.3 kg ai/ha, a 7-day retreatment interval, and a 7-day PHI.

A total of four trials on garden peas and two trials on snow peas were submitted from Australia. However, the Meeting noted that the garden pea trials were not independent; hence, only two trials match GAP for garden peas and snow peas, respectively.

Chlorothalonil residue concentrations in garden peas were: 5.4 and 7.3 mg/kg.

Chlorothalonil residue concentrations in snow peas were: 2.5 and 5.1 mg/kg.

The Meeting determined that insufficient trials were available to support maximum residue estimates for peas.

Beetroot

In Australia, chlorothalonil is registered for use on beetroot for up to 4 treatments at a rate of 1.7 kg ai/ha, with a PHI and retreatment interval of 7 days. Supervised field trials are available at this GAP.

A total of three trials on beetroot were conducted in Australia according to GAP.

Rank-order chlorothalonil residues in beetroot were (n=3): < 0.05 (2), and 2.1 mg/kg.

The Meeting determined that insufficient trials were available to support maximum residue estimates for beetroot.

DIETARY RISK ASSESSMENT

Long-term intake

The ADI for chlorothalonil is 0–0.02 mg/kg bw. The International Estimated Daily Intakes (IEDI) for chlorothalonil was estimated for the 13 GEMS/Food cluster diets using the STMR or STMR-P values estimated by the current Meeting in addition to those determined by the 2010 JMPR. The results are shown in Annex 3. The IEDI ranged from 8–50% of the maximum ADI. The Meeting concluded that the long-term intake of residues of chlorothalonil, from uses that have been considered by the JMPR, is unlikely to present a public health concern.

Short-term intake

The ARfD for chlorothalonil is 0.6 mg/kg bw. The International Estimated Short Term Intake (IESTI) for chlorothalonil was calculated for the plant commodities for which STMRs and HRs were estimated (banana and chard). The results are shown in Annex 4. The IESTI calculated for chlorothalonil represented 7–70% of the ARfD. The Meeting concluded that the short-term intake of residues of chlorothalonil, from uses that have been considered by the JMPR, is unlikely to present a public health concern.

5.8 CYCLOXYDIM (179)

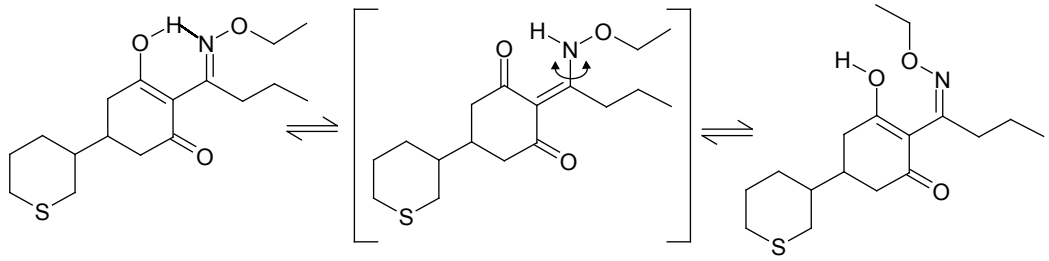
RESIDUE AND ANALYTICAL ASPECTS

Cycloxydim is a post-emergence cyclohexene oxime herbicide that inhibits the acetylcoenzyme A carboxylase (ACCase) in chloroplasts of sensitive weeds. Cycloxydim was firstly evaluated by JMPR in 1992 (T, R). In 2009, an ADI of 0–0.07 mg/kg bw and an ARfD of 2 mg/kg bw for women of childbearing age were established; an ARfD was unnecessary for the general population. Cycloxydim was scheduled at the 43rd session of the CCPR (2011) for the periodic re-evaluation of residues by the 2012 JMPR.

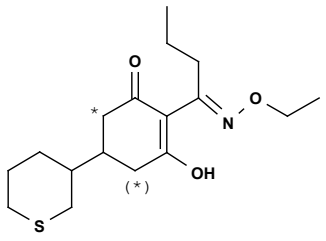
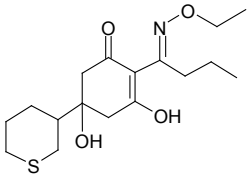
Data on physical and chemical properties, metabolism in plants and livestock animals, environmental fate and analytical methods, animal feeding studies and processing studies were submitted. Residue supervised trials were submitted on pome fruits, stone fruits, grapes, strawberries, potatoes, carrots, celeriac, onions, tomatoes, peppers, cauliflower, Brussels sprouts, head cabbage, curly kale, lettuce, spinach, green beans and peas, leek, sugar beet roots, sugar beet tops, dry beans and peas, oilseed rape, sunflower, soya bean, rice and maize.

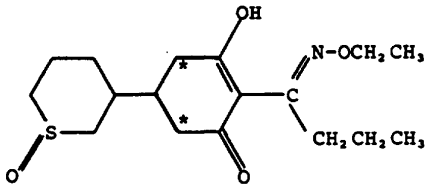
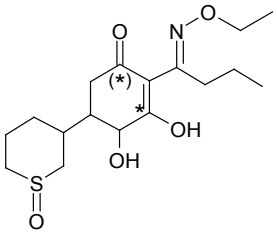
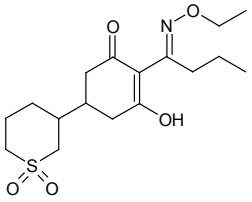
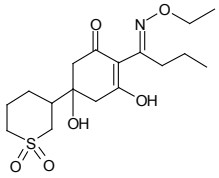
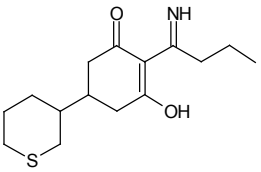
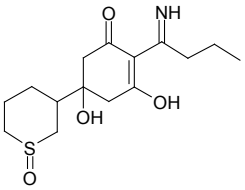
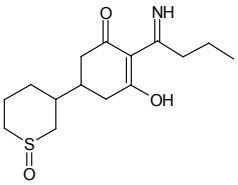
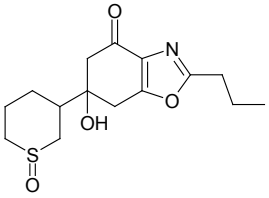
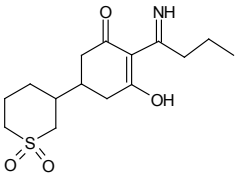
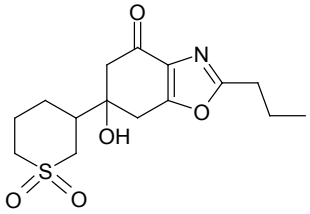
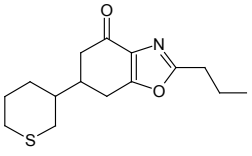
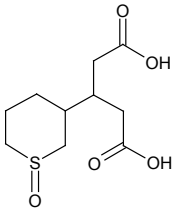
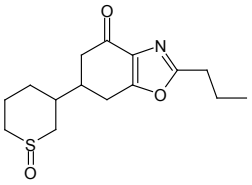
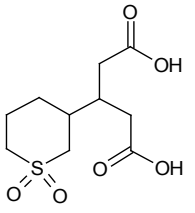
Metabolism studies

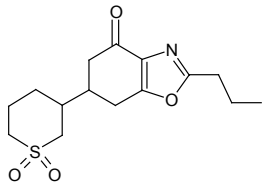
Cycloxydim is a racemic mixture. In the [^{14}C]labelled cycloxydim stored in toluene, the compound is almost exclusively present as E-isomer, but E/Z isomerisation in the ethoxyimino group may occurs on in plants and in solution depending on solvent polarity, temperature and pH. In all metabolism studies, residues were reported as the sum of the two isomers.



The positions of the radiolabel compounds used in the metabolism studies and the structures of the main metabolites found in animals and plants are shown next.

Name	Structure	Name	Structure
^{14}C-Cycloxydim		Cycloxydim-5-OH-TS	

Name	Structure	Name	Structure
^{14}C-Cycloxydim-TSO		^{14}C-Cycloxydim-5-OH-TSO	
Cycloxydim-TSO2		Cycloxydim-5-OH-TSO2	
Cycloxydim-T1S		Cycloxydim-5-OH-T1SO	
Cycloxydim-T1SO		Cycloxydim-6-OH-T2SO	
Cycloxydim-T1SO2		Cycloxydim-6-OH-T2SO2	
Cycloxydim-T2S		Cycloxydim-TGSO	
Cycloxydim-T2SO		Cycloxydim-TGSO2	

Name	Structure	Name	Structure
Cycloxydim-T2SO2			

Animal metabolism

Rats

Metabolism studies conducted in rats were evaluated by the JMPR 2009. The studies were conducted after oral administration of the vinylogus acid [^{14}C]cycloxydim-TS and its sodium salt and after intravenous administration of the sodium salt, at a nominal dose of 10 mg/kg bw (no-effect level) or 300 mg/kg bw (toxic effect level). The major metabolite found in urine was cycloxydim-TSO, followed by cycloxydim-T1SO and cycloxydim-TSO. In addition to unchanged parent, other metabolites were cycloxydim-T1SO2, cycloxydim-T2SO, and the metabolite hydroxylated at the 5-position of the cyclohexene ring of the parent. Patterns of metabolites in the bile were similar after the administration of either the free acid or the sodium salt of cycloxydim.

Lactating goats

[^{14}C]cycloxydim was administrated for 7 days to goats at 15 ppm feed. About 85% of the dose was recovered at the end of the experiment, mainly in urine (72%) and faeces (12%), and 0.09% in milk. Radioactivity in milk was constant during the 7 days dosing period (mean of 0.023 mg/kg). Total radioactive residue (TRR) was 0.005–0.006 mg/kg eq. in fat and muscle, and fat to 0.062–0.076 mg/kg eq. in liver and kidney, respectively. Non-extracted residues accounted for up to 64.1%TRR in liver, most of it solubilised by pronase. The major metabolite identified in milk was cycloxydim-T1SO (16%TRR). Cycloxydim-TSO represented 15%TRR in milk, 8%TRR in liver and 12%TRR in kidney. Parent compound was only detected in liver (10.8%TRR, 0.008 mg/kg). Minor metabolites found are cycloxydim-T1S, cycloxydim-TSO2 in liver (up to 2%TRR, 0.001 mg/kg) and cycloxydim-T2SO2 in milk (up to 2%TRR, < 0.001 to < 0.001 mg/kg).

A lactating goat was dosed with [^{14}C]cycloxydim-TSO at 100 ppm feed for five days. At sacrifice, 89.1% of the administered dose was recovered, mostly in urine (78%) and faeces (10%). TRR in milk accounted for 0.11% of the dose (0.09–0.12 mg/kg). Liver and kidney had the highest residues, 0.46, 0.52 and, 0.52 mg/kg eq., respectively. Concentrations in fat and muscle were 0.04 mg/kg, and were not further identified. Cycloxydim-TSO and cyclodixim-T1SO were the major components in milk (about 23%TRR, 0.06 mg/kg and the only residues identified in liver (22%TRR, 0.10 mg/kg; and 10%TRR, 0.05 mg/kg, respectively). Cycloxydim-T2SO cycloxydim-T1SO2 (5%TRR, 0.01 mg/kg) and cycloxydim-TSO2 (2.7%TRR, < 0.01 mg/kg) were also found in milk. Residues in kidney were not characterized.

The [^{14}C]cycloxydim-5-OH-TSO was administrated to goats at a dose level of 12 ppm feed on nine consecutive days. In average, 97% of the administered dose was recovered in the experiment, of which 75% was in urine and 15.7% in faeces. TRR was about 0.02 mg/kg eq. in milk, 0.024 in fat and 0.025 in muscle, 0.203 in liver and 0.26 mg/kg eq. in kidney. Non-extracted residues accounted for up to 10.2% TRR in muscle. Cycloxydim-5-OH-TSO was the main residue in milk, muscle, kidney and fat (31 to 38%TRR; 0.007 to 0.10 mg/kg). In liver, the main residue was cycloxydim-5-OH-TS (17.4%TRR, 0.03 mg/kg), followed by cycloxydim-5-OH-TSO (11%TRR, 0.02 mg/kg). Cycloxydim-5-OH-TS was also a significant residue in kidney (25%TRR, 0.06 mg/kg) and fat (11%TRR, 0.003 mg/kg). Cycloxydim-6-OH-T2SO residues reached 13%TRR in muscle and cycloxydim-5-OH-T1SO represented < 10%TRR in all matrices.

Laying hens

The metabolism and distribution of [^{14}C]cycloxydim was investigated in laying hens following oral administration at 12 ppm feed for 10 days. About 80% of the administered dose was recovered at the end of the experiment, mostly in the excreta (78.0%), 0.33% in eggs. 0.11 % in muscle, 0.07 % in liver and 0.02% in fat. TRR in eggs ranged from 0.05 mg/kg eq. at day 1 to 0.14 mg/kg at day 10 (mean of 0.12 mg/kg eq.), starting to plateau at day 8. In tissues, TRR was 0.051–0.053 mg/kg eq. in fat and muscle and 0.28 mg/kg eq. in liver. Unextracted residues in muscle accounted for 4.5% TRR. Residues in eggs were mostly cycloxydim-TSO (0.04 mg/kg eq., 30.9%TRR), followed by cycloxydim-TSO2 (0.008 mg/kg eq., 6.4%TRR) and the parent compound (0.004 mg/kg eq., 3.4%TRR). In muscle, only cycloxydim-TSO2 was detected (0.001 mg/kg eq., 0.9%TRR) and in fat only cycloxydim-TSO (0.008 mg/kg, 18%TRR). In liver, the main residue detected was also cycloxydim-TSO (0.02 mg/kg eq., 7.4%TRR), followed by cycloxydim (0.005 mg/kg eq., 1.7%TRR) and cycloxydim-TSO2 (0.002 mg/kg eq., 0.6%TRR).

The [^{14}C]cycloxydim-TSO was administered to laying hens at a dose level of 50 ppm feed for 7 days. Treated animals were sacrificed 6 (group 2), 24 (group 3) and 48 hours (group 4) after the last dose. About 94% of the administered dose was recovered in group 4, mostly (92.3%) in the excreta, and 0.08% in eggs. In this group, TRR in eggs increased rapidly to an apparent plateau of 0.08–0.10 mg/kg after day 2. TRR from group 2 ranged from 0.10 mg/kg eq. in muscle to 0.99 mg/kg eq. in kidney, and were < 0.1 mg/kg in all tissues from group 4. Residues were only identified in eggs and liver. In eggs, cycloxydim-TSO (0.12 mg/kg, 41.4%TRR) was the major residue, followed by cycloxydim-TSO2 (0.03 mg/kg, 8.8 %TRR) and cycloxydim-T2SO (0.02 mg/kg, 5.5%TRR). In liver, cycloxydim-TSO was the major residue (0.19 mg/kg, 33%TRR), followed by cycloxydim-T2SO (0.14 mg/kg, 24%TRR) and cycloxydim-T1SO (0.10 mg/kg, 17%TRR).

The [^{14}C]cycloxydim-5-OH-TSO was administered to hens at a dose of 12 ppm feed for 11 days. The radioactivity was rapidly excreted within 24 hours after the last dose, with 93% of the applied dose recovered, mainly on excreta (89.7%). In eggs, mean residues were 0.066 mg/kg eq. (0.21% of the applied dose). In tissues, the highest radioactivity was found in liver (0.11 mg/kg eq.), followed by muscle (0.028 mg/kg eq.), and fat (0.02 mg/kg eq.). Non-extracted residues ranged from 24.1%TRR in fat to 38% TRR in muscle, with over 80% being released by protease. Cycloxydim-5-OH-TSO accounted for 15% TRR in eggs (0.01 mg/kg) to 29%TRR in fat (0.005 mg/kg). Cycloxydim-5-OH-TS accounted for about 19–22%TRR in muscle, fat and liver (0.004–0.021 mg/kg) and 50.7%TRR in eggs (0.034 mg/kg).

In summary, studies conducted with cycloxydim or its metabolites cycloxydim-TSO and cycloxydim-5-OH-TSO showed that the primary metabolic pathway of cycloxydim in animals involves two main routes: 1) oxidation to cycloxydim-TSO and subsequently to cycloxydim-TSO2, and 2) Beckmann re-arrangement with subsequent ring closure to form the oxazol cycloxydim-T2S, which can be oxidized further to cycloxydim-T2SO and cycloxydim-T2SO2. Cycloxydim was a minor component in eggs and tissues from dosed hens and was only detected in goat liver (11%TRR).

Plant metabolism

Soya beans, cotton and sugar beet

The metabolism of [^{14}C]cycloxydim was studied in soya beans, cotton and sugar beet using two different treatments. To evaluate root uptake, the plants were cultivated in a nutrient solution containing 5 mg/L [^{14}C]cycloxydim. To evaluate the uptake by the leaf, 10 µg [^{14}C]cycloxydim was applied to the upper leaf surface (soya bean, sugar beet) or one cotyledon (cotton). Samples were taken 3 and 7 days (soya bean and cotton) or 4 and 8 days (sugar beets) after the application, respectively. [^{14}C] cycloxydim was taken up by the roots and transported acropetally to the cotyledons, stem and the remaining leaves. The highest radioactivity was detected in the primary leaves and roots (25–26 µg [^{14}C]cycloxydim/[^{14}C]equiv at 7 DAT in soya beans). After leaf application, about 30% of the total radioactivity is translocated to the untreated soya bean plant parts at 7 days DAT, 8.3% to untreated cotton parts and 11.8% to untreated sugar beet parts.

In another study conducted with sugar beet at the 3-leaves stage, the seedlings were treated with [^{14}C]cycloxydim at 0.2 kg ai/ha. Immediately after application, TRR was 8.48 mg/kg eq.in the tops. At harvest (119 DAT), TRR was 0.13 mg/kg eq. in the tops and 0.015 mg/kg eq. in roots. At 22 DAT, cycloxydim-TSO2 and cycloxydim-T2SO were found in the tops at 0.18 mg/kg eq. (13.9% TRR) and 0.14 mg/kg eq. (11% TRR), respectively. At 46 DAT, various metabolites were found in the tops at low levels (0.0026 to 0.023 mg/kg eq., up to 4%TRR). No hydroxylated metabolites where detected in any sample.

In a third study on sugar beet, [^{14}C]cycloxydim was applied at 0.65 kg ai/ha 2 months after sowing and samples taken 1 day after treatment and at crop maturity (94 DAT). At 1 DAT, TRR were 23 and 4 mg/kg eq. in leaves and roots, respectively, mostly extracted in methanol and dichloromethane. At harvest, residues were 2.2 and 0.16 mg/kg eq. in tops and roots, respectively. Cycloxydim was not detected in any of the top and root samples taken. At 1 DAT, residues mainly of cycloxydim-TSO, with 7.6 mg/kg(31.6%) in the tops and 2.4 mg/kg (60.1%) in roots. Cycloxydim-TSO2 accounted for 16–18%TRR. At harvest, both metabolites were still present (< 10%TRR), but cycloxydim-T1SO was the predominant metabolite (0.42–0.02 mg/kg, 19–14%TRR in tops and roots, respectively). Only cycloxydim-T2S was present in amounts greater than 10%TRR (13.7%). No hydroxylated metabolite was observed.

[^{14}C]cycloxydim was applied to soya beans at 0.2 kg ai/ha two to eight weeks after sowing (three trials, group 1) or at 1 kg ai/ha two months after sowing (one trial, group 2). TRR were 20, 2.3 and 0.46 mg/kg eq. at 45, 71 and 82 DAT in seeds from the group 1 and 12.5, 0.76 and 0.31 mg/kg eq. in straw and stalk. TRR in straw and seed from group 2 were 91 and 38.4 mg/kg eq., respectively. In most plant samples, more than 85% of the TRR were extracted with aqueous methanol and at later sampling intervals, considerable amounts of radioactivity were detected in the aqueous phase. The parent molecule was detected only at the day of application in all trials. The major metabolites found in seed samples were cycloxydim-TSO (0.078 to 0.42 mg/kg, 11.9 to 18.3%TRR), cycloxydim-T2SO (0.11 to 3.7 mg/kg, 4.8 to 18%TRR), cycloxydim-5-OH-TSO (0.2 to 1.3 mg/kg, 6.4 to 8.7% TRR) and cycloxydim-5-OH-TSO2 (0.06 to 0.90 mg/kg, 4.5 to 12%TRR). In straw the hydroxylated metabolites were detected at low levels (up to 3.4%TRR).

Maize

In two studies conducted in tolerant maize, [^{14}C]cycloxydim was applied at 0.4 kg ai/ha (normal rate) at BBCH growth stage 22–23 or at 0.8 kg ai/ha during flowering (BBCH 61-67). In the normal use rate, TRR at harvest (96 DAT) were 0.123 mg/kg eq. in grain, 0.06 mg/kg eq.in cobs, 0.118 mg/kg eq.in husks and 0.17 mg/kg in straw; residues in forage at 72 DAT were 31 mg/kg eq. In the exaggerated rate samples, the TRRs ranged from 4.9 mg/kg eq. in grain to 13 mg/kg in straw eq.. Cycloxydim was not detected in any sample from any trial. In the normal rate trials, metabolite levels accounted for up to 1%TRR in grain, up to 8.7%TRR in straw (0.015 mg/kg cycloxydim-TGS + cycloxydim-TGSO2) and up to 11%TRR in forage (3.6 mg/kg cycloxydim-T1SO). In grain from the exaggerated rate trial, cycloxydim-TSO (0.53 mg/kg, 10.6%TRR), cycloxydim-T1S0 + cycloxydim-T2SO2 and cycloxydim-T2S02 + cycloxydim-T1SO2 (0.71 mg/kg, 14%TRR each) were the major metabolites. Only cycloxydim-T2SO accounted for higher than 10%TRR in straw, husks and cobs. In all normal use rate samples except forage, the most prominent peak was very polar and eluted with the void volume from the HPLC column. The metabolites formed were further degraded and radioactivity incorporated into the carbohydrate pool.

In summary, cycloxydim is metabolized in plants mainly by four steps: 1) oxidation at the sulphur of the thiopyrane ring to the sulfoxide and to the sulphone, 2) cleavage of the oxime ether group (loss of the alkyl side chain), 3) hydroxylation at the 5-position of the cyclohexenone ring system and 4) oxidative cleavage of the cyclohexenone ring resulting in substituted glutaric acid derivatives. Cycloxydim was not present in any of the samples from treated crops at harvest, with the main metabolites being cycloxydim-TSO, cycloxydim-T2SO, cycloxydim-T1SO (sugar beet root) and cycloxydim-5-OH-TSO (soya bean).

Environmental fate in soil

The aerobic degradation and metabolism of [^{14}C]cycloxydim was studied in a loamy sand soil treated with 10 mg/kg dry soil, equivalent to a maximum single application rate of about 7.5 kg ai/ha, and to a multiple dose of 0.6 kg ai/ha. The soil was incubated at 22 ± 2 °C for 90 day. About 14% TRR was detected as cycloxydim at day 0, decreasing to 0.9%TRR after 14 days. Cycloxydim-TSO/cycloxydim-T1SO/cycloxydim-T2SO represented 16% TRR at 56 DAT and cycloxydim-T1S/cycloxydim-T2S/cycloxydim-TSO2 represented 2.7% TRR at 28 DAT. After three months, bound residues accounted for about 40% TRR and CO_2 to 38% TRR. In another study conducted under the same conditions with loamy sand and a loam soils, cycloxydim accounted for over 90% TRR at day 0, decreasing to 4.6 and 0%TRR at day 21, respectively. Cycloxydim-TSO was the major metabolite found in soils (up to 39.5%TRR at 21 DAT and to 11% TRR at 90 DAT). In another study conducted with seven batches of sandy loam and loam sandy soils treated at 0.8 mg/kg, the soils were incubated for 119 days in the dark at 20 °C and 40% maximum water holding capacity. The degradation of cycloxydim was very fast in the soils (DT_{50} < 9 hours), with up to 18% of the applied radioactivity (TAR) found at 0 DAT. Cycloxydim-TSO (5–6%TAR), cycloxydim-TSO2 (1.5–2.8%TAR) and cycloxydim-T2SO (about 1%TAR) were the major metabolites at 60 DAT, with DT_{50} of 9.3–1.6 days, 8.8–13 days and 19–291 days, respectively.

The photolytic degradation of cycloxydim was studied on loamy sand soil treated with 10 mg/kg dry and incubated at 30 ± 5 °C for 8 hours. Bound residues were similar with and without irradiation (maximum about 8–15% TAR). Polar degradation products did not accumulate in the course of the study. Cycloxydim residues dropped to 2% TAR at 8 hours. Cycloxydim-TSO/cycloxydim-T2SO accounted to 77–81% TAR after 3 to 8 hours of incubation.

Confined rotational studies were conducted with [^{14}C]cycloxydim applied to soils at 0.65 kg ai/ha. The treated soils were aged for 30 days (radish and lettuce), 80 days (wheat), 120 days and 365 days. Residues in soil were 4.84 mg/kg eq. at day 0 and 0.034 to 0.136 mg/kg eq. after aging and harvesting in all cases. At 30 DAT, TRRs in lettuce (67 days after planting, DAP) and radish root and top (86 DAP) ranged from 0.032 to 0.051 mg/kg eq. At 120 and 365 DAT they ranged from 0.003 to 0.011 mg/kg. At 80, 120 and 365 DAT (118 to 169 DAP) residues ranged from 0.014 to 0.098 mg/kg eq. in wheat grain, from 0.07 to 0.14 mg/kg in straw and from 0.05 to 0.14 mg/kg in chaff. In wheat forage (57 to 70 DAP), they ranged from 0.008 to 0.031 mg/kg. At 30 DAT, cycloxydim-TSO and cycloxydim-TSO2 were the major metabolites in lettuce (0.008 mg/kg, 16%TRR), radish root (0.002 mg/kg, 6.3% TRR) and top (0.006 mg/kg, 12% TRR). At 120 DAT, only cycloxydim-TSO2 could be detected as a single compound (in radish, 10%TRR, 0.001 mg/kg). At 80 DAT, cycloxydim-TGSO2 was the major metabolite in wheat forage (0.008 mg/kg, 26% TRR), and cycloxydim-T2SO (0.03 mg/kg, 20% TRR) and cycloxydim-T1SO (0.02 mg/kg, 16% TRR) in straw. No single residues > 10%TRR were found in wheat commodities at 120 and 365 DAT.

In summary, cycloxydim is extensively and rapidly degraded in soil (DT_{50} < 9 hours), mainly to cycloxydim-TSO, cycloxydim-T1SO and cycloxydim-T2SO. Cycloxydim-TSO and cycloxydim-TSO2 were found in lettuce and radish planted on aged treated soil. Cycloxydim-TGSO2 (cycloxydim-1-dicarboxylic acid) was the main residue in succeeding wheat forage, and cycloxydim-T1S0 and cycloxydim-T2SO in wheat straw (80 DAT). No single residues were detected in wheat grain planted in aged treated soil.

Methods of analysis

Two common moiety analytical methods were developed, allowing the determination of cycloxydim, cycloxydim-5-OH-TSO2 and all metabolites that can be oxidized to cycloxydim-TGSO2 or cycloxydim-5-OH-TGSO2 with H_2O_2 under alkaline conditions in various plant matrices. In the LC-MS/MS method, the residues are extracted with isopropanol/water and hydrogen peroxide to form the corresponding pentane acids, the acids removed by precipitation with $Ca(OH)_2$, the excess of oxidizing agent eliminated using a C_{18}-column and, after a NH_2-column clean-up, cycloxydim-TGSO2 and cycloxydim-5-OH-TGSO2 are analysed. In the GC method, the acids are converted into the dimethyl esters cycloxydim-TDME and cycloxydim-OH-TDME, cleaned up in silica gel and

analysed by GC/FPD or GC/MS. [^{14}C]cycloxydim studies showed that extraction with isopropanol/water released from 66 to 94%TRR. Both GC and LC methods were satisfactorily validated at 0.05 mg/kg (LOQ) or higher levels (up to 5 mg/kg), using cycloxydim and cycloxydim-OH-SO2 as representative analytes for the non-hydroxylated and hydroxylated compounds, respectively, or with different metabolites.

Cycloxydim-TSO can be selectively analysed in plant matrices after extraction with methanol/water buffer, saturation with NaCl-solution and partitioned with dichloromethane. The aqueous phase is acidified, residues extracted with isooctane/dichloromethane, the extract washed with saturated NaCl-solution, re-extracted with NaCl-solution, the aqueous phase purified by C_{18}SPE and residues determined by HPLC/UV. LOQ was 0.05 mg/kg.

Common moiety methods were also validated in matrices of animal origin, with an LOQ of 0.05 mg/kg for tissues and eggs and 0.01 mg/kg for milk (GC method) or 0.01 mg/kg (tissues and eggs) and 0.003 mg/kg (milk) in the LC methods. Efficiency of the acetonitrile/hexane extraction was comparable with the results from hen metabolism studies (methanol extraction) for eggs and muscle, but not for liver, where acetonitrile/hexane only extracts about 50–70% of the radioactivity. The efficiency of the acetonitrile/hexane extraction of liver, kidney and milk was also comparable with the results obtained in the goat metabolism studies.

Stability of residues in stored analytical samples

The stability of cycloxydim, cycloxydim-TSO + cycloxydim-T2SO2 and/or cycloxydim-5-OH-TSO2 residues was investigated in various plant matrices fortified at 0.4 to 0.5 mg/kg levels stored at -20 °C over a period of up to 2 years. Samples were analysed immediately after spiking and after different storing intervals using the common moiety methods. The results showed that the residues were stable (70–110% remaining) for at least 2 years of storage in most cases.

Liver and milk samples from animal metabolism studies with [^{14}C]cycloxydim or [^{14}C]cycloxydim-5-OH-TSO were re-extracted with methanol or acetonitrile/hexane (4:3) in order to investigate their stability in animal matrices stored for a period of 78–89 month at –20 ºC. The results showed that cycloxydim levels decreased over time while its metabolites increased (cycloxydim-T1SO and cycloxydim-5-OH-T2SO). This degradation is not relevant when the common moiety method is used to analyse the samples in the trials.

Residue definition

Metabolism studies conducted in hens and goats with cycloxydim showed that the parent compound was only detected in liver (0.008 mg/kg, 10.8%TRR). The main metabolites found were cycloxydim-TSO, cycloxydim-TSO2 (hens and goats) and cycloxydim-T1SO (up to 14.8%TRR in milk). Residues were present in fat and muscle at about the same level.

Metabolism studies conducted in soya bean, cotton, sugar beet and maize with cycloxydim have showed that the parent compound was not present in any of the samples at harvest, with the main metabolites being cycloxydim-TSO, cycloxydim-T2SO, cycloxydim-TSO2, cycloxydim-T1SO and cycloxydim-5-OH-TSO.

In all the supervised trials and animal feeding studies submitted to the Meeting, residues were measured using one of the common moiety methods, where residues present in the samples are oxidized to cycloxydim-TGSO2 (including cycloxydim-TSO, cycloxydim-T2SO, cycloxydim-TSO2, cycloxydim-T1SO) and/or cycloxydim-5-OH-TGSO2 (including cycloxydim-5-OH-TSO) and analysed by LC-MS/MS or further methylated to cycloxydim-TMDE and/or cycloxydim-5-OH-TMDE for analysis by GC/FPD or GC/MS.

The Meeting agreed that the common moiety analytical methods analyse all the relevant residues formed when cycloxydim is applied on the field or when residues present in feed are ingested by farm animals.

The residue definition for animal and plant commodities for enforcement and risk assessment purposes is: *Cycloxydim, metabolites and degradation products which can be oxidized to 3-(3-thianyl) glutaric acid S-dioxide and 3-hydroxy-3-(3-thianyl) glutaric acid S-dioxide, expressed as cycloxydim*.

The residue is not fat-soluble

Results of supervised residue trials on crops

In some countries, cycloxydim label does not specify the PHI, indicating that the product should be applied when the weeds are actively growing. When a GAP with no specified PHI was used to support the trials, the highest residue found in the trials at any DAT, except the 0 day, was selected for the estimation.

The OECD MRL calculator was used to assist in the estimation of maximum residue levels from the selected residue data set obtained from the supervised residue trials. The Meeting reviewed the trial conditions and other relevant factors related to each dataset to arrive at a best estimate of the maximum residue level using expert judgment. When the OECD calculator suggested a different value, an explanation on the discrepancy was included in the text.

Pome fruits and stone fruits

Cycloxydim is registered to be used by direct spraying to control weeds in apple and pear orchards in Portugal using one application at 0.4 kg ai/ha and 28 days PHI. Two trials were conducted with apples and two with pears in Italy and Spain, matching the GAP of Portugal, gave residues of cycloxydim < 0.09 mg/kg (4).

Cycloxydim is registered to be used by direct spraying to control weeds in Italy in apricot and peach orchards up to 0.6 kg ai/ha with a 30 day PHI. In three trials in peaches and two in apricots conducted in Italy, at GAP, residues were < 0.09 mg/kg (5).

The Meeting concluded that on the basis of the data from these nine trials that the application of cycloxydim to the orchard floor, matching GAP, does not result in residues in the fruit.

The Meeting estimated a maximum residue level of 0.09* mg/kg, a HR of 0.09 mg/kg and a STMR of 0.09 mg/kg for cycloxydim in pome fruits and stone fruits

Grapes

The critical application rate of cycloxydim used for directed spraying to control weeds in grapes is a single application at 0.4 kg ai/ha in Spain and 0.6 kg ai/ha in Switzerland, with no specified PHI.

Eight trials were conducted in northern/central France and Germany, matching the GAP of Switzerland, gave residues of (n=8) < 0.09 (4), 0.13 (2) and 0.18 (2) mg/kg.

In eight trials conducted in Italy, Greece and Spain according to Spanish GAP, residues were < 0.09 mg/kg (8).

Based on the residue data from trials conducted in northern Europe, the Meeting estimated a maximum residue level of 0.3 mg/kg, a HR of 0.18 mg/kg and a STMR of 0.11 mg/kg for cycloxydim in grape.

The Meeting withdrew its previous recommendation of 0.5 mg/kg for cycloxydim in grape.

Strawberry

Cycloxydim is registered for use in strawberries in Switzerland at 1 × 0.6 kg ai/ha with a 42 day PHI and in Slovakia at 1 × 0.4 kg ai/ha and no PHI specified. The product is also registered in Romania at 1 × 0.4 kg ai/ha with no PHI specified.

Seven trials conducted according to Slovakian GAP in France (north), the Netherlands, Germany and the UK, gave total cycloxydim residues of 0.19, 0.22, 0.29, 0.33, 0.34 0.47 and

0.61 mg/kg. One trial conducted in Sweden according to the GAP of Switzerland gave residues of 0.63 mg/kg.

Eight trials were conducted in southern France, Greece, Italy and Spain matching Romanian GAP, gave residues of 0.29, 0.33, 0.35, 0.49, 0.57, 0.74, 1.2 1.4 and 1.4 mg/kg

Based on the residue data from trials conducted in southern Europe, the Meeting estimated a maximum residue level of 3 mg/kg, a HR of 1.4 mg/kg and a STMR of 0.53 mg/kg for cycloxydim in strawberries.

The Meeting withdrew its previous recommendation of 0.5 mg/kg for cycloxydim in strawberries.

Onion, Bulb

Cycloxydim is registered in the Netherlands at up to 2 × 0.6 kg ai/ha with a 21 day PHI. In Belgium, the GAP is for 1 × 0.6 kg ai/ha and a 28 day PHI. In Italy, the GAP is for 1 × 0.6 kg ai/ha and a 60 day PHI. In Spain, it is 1 × 0.4 kg ai/ha with no PHI specified.

In four trials conducted in the UK matching the GAP of the Netherlands, residues were < 0.09 (4).

In seven trials conducted in France, the Netherlands, Sweden and the UK, complying with Belgian GAP, residues were: < 0.09 (3), 0.21, 0.25, 0.31 and 0.39 mg/kg.

In four trials conducted in Greece, Spain and Italy matching Italian GAP, residues were < 0.09 (2), 0.19 and 0.24 mg/kg.

In four trials conducted in France (south), Italy, Greece and Spain according to Spanish GAP residues were: 0.17, 0.25, 0.32 0.98, and 1.3 mg/kg

Based on the residue trials conducted according to GAP in Spain, and with the results from the other trials conducted in Europe used as supporting data, the Meeting estimated a maximum residue level of 3 mg/kg, a HR 1.3 mg/kg and a STMR of 0.285 mg/kg for cycloxydim in bulb onions.

Leek

Cycloxydim is registered for use in leeks in Portugal with a GAP of 1 × 0.4 kg ai/ha and a 42 day PHI. In Ireland, the rate is the same but no PHI is specified. In Switzerland, GAP consists of 1 × 0.6 kg ai/ha and a 56 day PHI

In six trials conducted in Belgium, Denmark, Germany and the UK matching Irish GAP, residues were 0.13, 0.28, 0.33, 0.39, 0.62 and 2.3 mg/kg.

In four trials conducted in the Netherlands according to the GAP of Switzerland, residues were 0.11, 0.12, 0.21 and 0.24 mg/kg.

In three trials conducted in southern France, Italy and Spain according to Portuguese GAP, residues were < 0.09 (2) and 0.09 mg/kg.

Based on the residue trials conducted according to the GAP in Ireland, the Meeting estimated a maximum residue level of 4 mg/kg, a HR of 2.3 mg/kg and a STMR of 0.36 mg/kg for cycloxydim in leek.

Brassica vegetables

Cycloxydim is registered in Brassica vegetables in Switzerland at 1 × 0.6 kg ai/ha and a 28 day PHI, and in Spain at 1 × 0.4 kg ai/ha with no specified PHI.

Twelve trials were conducted in Brussels sprouts in Europe at 0.5 kg ai/ha. Residues from seven trials conducted in Belgium, France (north), Germany, the Netherlands and the UK according to the GAP in Switzerland were: 1.0, 1.1, 1.8 (2), 2.0, 2.9 and 3.6 mg/kg.

Four trials conducted in France (south), Italy, Spain and Greece according to Spanish GAP gave residues of 1.9, 2.6, 3.5 and 6.0 mg/kg.

Residues in Brussels sprouts from trials matching comparable GAP in northern and southern Europe were considered similar and could be combined, were (n=12): 1.0 (2), 1.1, 1.8 (2), 1.9, 2.0, 2.6, 2.9, 3.5, 3.6 and 6.0 mg/kg.

Fourteen trials were conducted in cabbages at 0.5–0.6 kg ai/ha. In nine trials conducted in France (north), Germany, Sweden, Belgium and the UK according to the GAP of Switzerland, residues were: < 0.09, 0.40, 0.50 (2), 0.63, 0.74, 1.0, 1.3 and 3.0 mg/kg. In five trials conducted in Spain, France (south), Greece and Italy according to Spanish GAP (sample taken at 28 days after application), residues were: 0.88, 1.0, 1.2, 1.4 and 1.7 mg/kg.

Twelve trials were conducted in Europe in cauliflower at 0.5–0.6 kg ai/ha. In eight trials conducted in Belgium, France (north), Sweden and the UK according to the GAP of Switzerland, residues were: 0.27, 0.59, 1.5 (2), 1.7, 1.9, 2.1 and 2.3 mg/kg. Four trials conducted in southern Europe did not match the GAP.

Based on the residue data for Brussels sprouts the Meeting estimated a maximum residue level of 9 mg/kg, a HR of 6 mg/kg and a STMR of 5 mg/kg for cycloxydim in Brassica (Cole or Cabbage) Vegetables, Head Cabbage and Flowerhead Brassicas

The Meeting withdrew its previous recommendations.

Peppers

Cycloxydim is registered in peppers (chili and sweet) in Italy at 1 × 0.60 kg ai/ha and a 20 day PHI. In eight trials conducted peppers in southern Europe according to this GAP, residues were: 0.68, 0.78, 1.2, 1.5, 1.6, 3.0, 3.1, and 5.3 mg/kg.

The Meeting estimated a maximum residue level of 9 mg/kg, a HR of 5.3 mg/kg and a STMR of 1.55 mg/kg for cycloxydim in peppers.

The Meeting also estimated a maximum residue level of 90 mg/kg, a HR-P of 53 mg/kg and a STMR-P of 15.5 mg/kg for cycloxydim in dried chili peppers, by applying a factor of 10 to the MRL, HR and STMR values estimated for peppers.

Tomatoes

Cycloxydim is registered in tomatoes at 1 × 0.4 kg ai/ha and a 35 day PHI in Greece, and at 0.6 kg ai/ha and a 56 day PHI in Switzerland.

In eight trials conducted in southern Europe according to Greek GAP, residues were: 0.12, 0.17, 0.25, 0.26, 0.31, 0.39, 0.43 and 0.55 mg/kg.

In eight trials conducted in northern Europe according to the GAP of Switzerland, residues were: 0.21, 0.39 (2), 0.44, 0.45, 0.46, 0.50 and 0.84 mg/kg.

Based on the residue trial population in North of Europe, the Meeting estimated a maximum residue level of 1.5 mg/kg, a HR of 0.84 mg/kg and a STMR of 0.445 mg/kg for cycloxydim in tomatoes.

Chinese cabbage

Cycloxydim is registered for brassica vegetables in Spain at 1 × 0.4 kg ai/ha with no specified PHI.

In two trials conducted in Greece and Italy according to this GAP, residues were < 0.09 and 0.23 mg/kg

The Meeting agreed that there were insufficient data complying with GAP with which to estimate a maximum residue level for cycloxydim in Chinese cabbage.

Kale

Cycloxydim is registered for brassica vegetables in Switzerland at 1 × 0.6 and a 28 day PHI and in Spain at 1 × 0.4 kg ai/ha with no specified PHI.

In four trials conducted in kale, curly in France (north), Germany and the Netherlands according to the GAP of Switzerland, residues were: 0.77, 0.90 and 1.8 mg/kg.

In four trials conducted in France (south), Greece, Italy and Spain according to Spanish GAP, residues were: < 0.09, 0.23, 0.98 and 1.1 mg/kg.

Based on the residue data from trials conducted in south of Europe, the Meeting estimated a maximum residue level of 3 mg/kg, a HR of 1.1 mg/kg and a STMR of 0.65 mg/kg for cycloxydim in kale.

Lettuce

Cycloxydim is registered in lettuce (leaf and head) in Austria at 1 × 0.5 kg ai/ha and a 14 day PHI, in France at 0.4 kg ai/ha and a 21 day PHI and in Slovenia at 0.4 kg ai/ha with a 14 day PHI. Twenty two trials were conducted in lettuce in Europe at 0.5 kg ai/ha, matching GAP rate in northern and southern Europe.

Six trials were conducted in northern Europe according to Austrian GAP, giving residues of 0.18, 0.28, 0.48, 0.65, 0.69 and 0.71 mg/kg.

Six trials were conducted in northern Europe according to French GAP, giving residues of 0.11, 0.12, 0.21, 0.28 and 0.34 (2) mg/kg.

In ten trials conducted in southern Europe according to Slovenian GAP, residues were: 0.09, 0.11, 0.24, 0.31 (2), 0.36, 0.38, 0.41 (2) and 1.0 mg/kg

Based on the residue trial population in southern Europe, the Meeting estimated a maximum residue level of 1.5 mg/kg, a HR of 1 mg/kg and a STMR of 0.335 mg/kg for cycloxydim in lettuce, head and lettuce, leaf.

The Meeting withdrew its previous recommendation of 0.2 mg/kg for cycloxydim in lettuce, head and lettuce, leaf.

Spinach

Cycloxydim is registered in spinach at 1 × 0.4 kg ai/ha in Slovenia and in France, with PHIs of 28 days and 42 days, respectively. Eight trials were conducted in Europe at 0.5 kg ai/ha.

In four trials conducted in north of Europe according to French GAP, residues were: < 0.09 (3) and 0.10 mg/kg

In four trials conducted in south of Europe according to Slovenian GAP, residues were: < 0.09, 0.19, 0.20 and 2.4 mg/kg.

The Meeting agreed that there were insufficient trials according to GAP to estimate a maximum residue level of cycloxydim in spinach.

Green beans with pods

Cycloxydim is registered in green beans at 1 × 0.6 kg ai/ha in Belgium with a 28 day PHI. In Spain, the rate is 0.4 kg ai/ha with no PHI specified.

In ten trials conducted in northern Europe according to Belgian GAP, residues were: < 0.09, 0.21, 0.22, 0.26, 0.30, 0.40, 0.64, 0.73, 1.2 and 1.3 mg/kg

In eleven trials conducted in southern Europe according to Spanish GAP, residues were: < 0.05, 0.20 (2), 0.24, 0.29, 0.35, 0.41, 0.52, 0.56, 4.4 and 11 mg/kg.

Based on the residue trial population from southern Europe (statistically higher), the Meeting estimated a maximum residue level of 15 mg/kg, a HR of 11 mg/kg and a STMR of 0.35 mg/kg for cycloxydim in beans except broad bean & soya bean (green pods & immature seeds).

The Meeting withdrew its previous recommendation of 1 mg/kg for cycloxydim in common bean (pods and/or immature seeds).

Peas, Shelled (succulent seeds)

Cycloxydim is registered in green peas at 1 × 0.5 kg ai/ha in Germany with a 35 day PHI. In Spain, the rate is up to 0.4 kg ai/ha and no PHI is specified.

In seven trials conducted in northern Europe according to German GAP, residues in peas (seeds) were: 0.80, 1.2, 1.8, 2.5, 3.2, 4.4 and 4.7 mg/kg.

In eight trials conducted in south of Europe according to Spanish GAP rate (PHI from 28 to 49 days) were: 0.45, 0.84, 2.1, 2.3, 3.1, 5.3, 5.9 and 8.5 mg/kg.

Based on the residue trials in southern Europe, the Meeting estimated a maximum residue level of 15 mg/kg, and a STMR of 2.7 mg/kg for cycloxydim in peas, shelled (succulent seeds). The Meeting withdrew its previous recommendation of 2 mg/kg for cycloxydim in peas, shelled (succulent seeds) and of 1 mg/kg in peas (pods and succulent = immature seeds).

Dry beans

Cycloxydim is registered in dry beans at 1 × 0.45 kg ai/ha in France, with no PHI specified. Twenty one trials were conducted in Europe matching this GAP.

In eight trials conducted in northern Europe, residues were: 0.51, 1.5, 2.8, 4.4 (2), 7.9, 9.8 and 15 mg/kg.

In thirteen trials conducted in southern Europe, residues were: 0.20, 0.31, 0.57, 0.70, 1.1, 2.0, 2.4, 3.0, 3.5, 3.6, 4.0, 4.5 and 6.1 mg/kg

Based on the trials conducted in northern Europe the Meeting estimated a maximum residue level of 30 mg/kg, and a STMR of 4.4 mg/kg for cycloxydim in beans, dry.

The Meeting withdrew its previous recommendation of 2 mg/kg for cycloxydim in beans (dry).

Dry peas

Cycloxydim is registered in peas at 1 × 0.60 kg ai/ha in Sweden with no PHI specified. In Italy, the rate is the same with a 60 day PHI.

In four trials conducted in the Netherlands and the UK matching the GAP rate in Sweden, residues at 55 days PHI were: 1.2, 3.4, 5.9 and 12 mg/kg.

In ten trials conducted in south of Europe according to Italian GAP, residues were: 0.30, 0.69, 0.84, 1.6 (2), 3.2 (2), 3.6, 5.5 and 5.9 mg/kg.

The Meeting estimated a maximum residue level of 30 mg/kg, and a STMR of 5.6 mg/kg for cycloxydim in peas, dry.

Soya beans

Cycloxydim is registered in soya beans at 1 × 0.40 kg ai/ha in France with a 56 day PHI. In Spain, the rate is the same, with no PHI specified,

In thirteen trials conducted in Europe at 0.5 kg ai/ha and PHI of 49–63, matching GAP in France and Spain, residues were: 0.23, 0.83, 1.2, 2.8, 3.4, 9.2, 13, 14, 26, 30 (2), 33 and 40 mg/kg.

The Meeting estimated a maximum residue level of 80 mg/kg, and a STMR of 13 mg/kg for cycloxydim in soya bean, dry.

The Meeting withdrew its previous recommendation of 2 mg/kg for cycloxydim in soya beans.

Carrots

Cycloxydim is registered in carrots in Belgium at a single application up to 0.60 kg ai/ha and in Portugal at 0.40 kg ai/ha, with a PHI of 28 days. Eleven trials were conducted in Europe at 0.50 kg ai/ha, matching both the GAP rates of Belgium and Portugal.

Residues, at the 28 day PHI, from northern European trials according to Belgian GAP were: 0.32, 0.42, 0.44 and 0.64 mg/kg.

Trials from southern Europe, according to Portuguese GAP at the 28 day PHI, gave residues of: 0.18, 0.29, 0.33, 0.44, 0.47, 1.1 and 3.0 mg/kg.

Based on the residue trials from southern Europe, the Meeting estimated a maximum residue level of 5 mg/kg, a HR of 3 mg/kg and a STMR of 0.44 mg/kg for cycloxydim in carrots.

The Meeting withdrew its previous recommendation of 0.5 mg/kg for cycloxydim in carrots.

Celeriac

Cycloxydim is registered in celeriac in France at 1× 0.60 kg ai/ha and a 48 day PHI.

In eight trials conducted in Europe according to this GAP, residues were: 0.10, 0.12, 0.13 (3), 0.14, 0.19 and 0.64 mg/kg.

The Meeting estimated a maximum residue level of 1 mg/kg, a HR of 0.64 mg/kg and a STMR of 0.13 mg/kg for cycloxydim in celeriac.

Potatoes

Cycloxydim is registered in potatoes at 1 × 0.60 kg ai/ha in Belgium and the Netherlands with a 56 day PHI. In Italy, the rate is the same with a 100 day PHI. In ten trials conducted in northern Europe according to Belgian GAP, residues were: 0.31, 0.41, 0.55, 0.65, 0.72, 0.75, 0.79, 1.0, 1.2 and 1.6 mg/kg.

Seven trials conducted in southern Europe, according to Italian GAP, residues were: < 0.09 (2), 0.10, 0.21, 0.27, 0.44 and 0.46 mg/kg.

Based on the residue trials in north of Europe, the Meeting estimated a maximum residue level of 3 mg/kg, a HR of 1.6 mg/kg and a STMR of 0.735 mg/kg for cycloxydim in potatoes.

The Meeting withdrew its previous recommendation of 2 mg/kg for cycloxydim in potatoes.

Turnips

From six trials on turnips conducted in Norway at a rate of 0.6 kg ai/ha residues in turnip roots 77 to 103 days post application were: < 0.09 to 0.13 mg/kg. The GAP rate in Europe is up to 0.4 kg ai/ha.

As no trials were conducted according to GAP, the Meeting did not estimate a maximum residue level for cycloxydim in turnips.

Sugar beet

Cycloxydim is registered in sugar beet at 1 × 0.50 and 0.60 kg ai/ha in Germany and the Netherlands, respectively, no PHI specified. In Italy, the rate is 0.60 kg ai/ha and 100 days PHI. GAP for swede in THE UK is 0.45 kg ai/ha with 56 days PHI and for beetroot in Switzerland is 0.60 kg ai/ha with 56 days PHI.

In ten trials conducted in north of Europe according to German GAP, residues were < 0.09 (9) and 0.10 mg/kg.

In eight trials conducted in south of Europe according to Italian GAP, residues were < 0.09 (8) mg/kg.

Based on the residue trials in north of Europe, the Meeting estimated a maximum residue level of 0.2 mg/kg, a HR of 0.1 mg/kg and a STMR of 0.09 mg/kg for cycloxydim in sugar beet.

The Meeting agreed to extrapolate these estimations to beetroot and swede.

The Meeting confirms its previous recommendation of 0.2 mg/kg for cycloxydim in sugar beet.

Maize

Cycloxydim is registered in Germany for use in maize at 1 × 0.40 kg ai/ha (no PHI specified) and France (90 days PHI).

In six trials conducted in northern Europe, matching German GAP, residues were: < 0.09 (5) and 0.12 mg/kg.

In eight trials conducted in southern Europe, according to French GAP, residues were: < 0.09 (8) mg/kg.

Based on trials conducted in northern Europe, the Meeting estimated a maximum residue level of 0.2 mg/kg, and a STMR of 0.09 mg/kg for cycloxydim in maize grain.

Rice

Cycloxydim is registered in rice in Italy at 1 × 0.40 two days before sowing, with no PHI specified. In 11 trials conducted in the country according to GAP, residues found in grain, 133 to 162 days after treatment, were: < 0.09 (11) mg/kg.

The Meeting estimated a maximum residue level of 0.09* mg/kg, and a STMR of 0.09 mg/kg for cycloxydim in rice.

Rape seed

Cycloxydim is registered in rape seed at 1 × 0.60 kg ai/ha in Italy, with a PHI of 100 days. In Germany the rate is 0.50 kg ai/ha with no PHI specified.

In nine trials conducted in northern Europe, according to German GAP, residues at PHIs from 85 to 100 days PHI were: 0.77, 1.0, 1.5, 1.6, 1.8, 1.9, 2.2, 2.5 and 5.3 mg/kg

In six trials conducted in southern Europe, according to Italian GAP residues were: 0.54, 1.6, 1.8, 2.8, 3.1 and 4.0 mg/kg

The fifteen trials conducted according to the same GAP in the south and north of Europe belonged to the same residue population and were combined: 0.54, 0.77, 1.0, 1.5, 1.6 (2), 1.8, 1.9, 2.2, 2.5, 2.8 (2), 3.1, 4.0 and 5.3 mg/kg.

The Meeting estimated a maximum residue level of 7 mg/kg, and a STMR of 1.9 mg/kg for cycloxydim in rape seed.

The GAP for linseed in Sweden is 0.6 kg ai/ha with no PHI specified. The Meeting agreed to extrapolate the rape seed estimates to linseed.

The Meeting withdrew its previous recommendation of 2 mg/kg for cycloxydim in rape seed.

Sunflower

Cycloxydim is registered in sunflower at 1 × 0.60 kg ai/ha in Italy, with a PHI of 80 days. In Germany the rate is 0.50 kg ai/ha with a 100 day PHI.

In four trials conducted in northern Europe according to German GAP, residues were: < 0.09, 0.37, 0.38 and 2.8 mg/kg.

In 15 trials conducted in southern Europe, according to Italian GAP, residues were: < 0.09 (4), 0.09, 0.12, 0.14, 0.25, 0.28, 0.37, 0.38, 0.39, 0.50, 0.94 and 1.8 mg/kg.

Based on the data coming from northern Europe, and with the support of the other trials conducted in Europe, the Meeting estimated a maximum residue level of 6 mg/kg, and a STMR of 0.375 mg/kg for cycloxydim in sunflower seed.

Feed commodities

Maximum residue levels will not be estimated for forage commodities as it is understood that the international trade of such commodities is unlikely. Highest residue and/or STMR will be estimated for commodities listed in the OECD feeding table for animal dietary burden calculation purposes.

Bean vines

Residues of cycloxydim in bean vine (whole plant or rest of the plant) from trials conducted in northern Europe, according to GAP (0.4–0.45 kg ai/ha, no PHI specified), were (n=7): 0.3, 0.84, 0.9, 0.99, 1.2, 1.4 and 1.5 mg/kg.

Residues of cycloxydim in bean vine from trials conducted in southern Europe, according to GAP, were (n=9): 0.34, 0.43, 0.67, 0.71, 0.77, 1.2 (2), 1.3 and 2.0 mg/kg.

Based on the southern European trials, which gave the highest residues, the Meeting estimated a highest residue of 2 mg/kg and a STMR of 0.77 mg/kg for cycloxydim in bean vines.

Pea vines

Residues of cycloxydim in pea vine (whole plant or without the seed, or rest of the plant) from trials conducted in northern Europe, according to GAP (0.6 kg ai/ha, no PHI specified) were (n=8): 0.8, 0.93, 2.4, 2.5, 2.6, 3.5, 3.6 and 3.9 mg/kg.

Residues of cycloxydim in pea vine from trials conducted in southern Europe, according to GAP (0.6 kg ai/ha, 60 day PHI or 0.4 kg ai/ha no PHI specified), were (n=17): 0.14, 0.16, 0.21, 0.24, 0.27, 0.45, 1.1, 1.8 (2), 2.1, 2.2, 2.3, 5.5, 5.9, 6.1, 8.4 and 9.0 mg/kg.

Based on the southern European trials, which gave the highest residues, the Meeting estimated a highest residue of 9 mg/kg and a STMR of 1.48 mg/kg for cycloxydim in pea vines.

The Meeting also recommends a maximum residue level of 60 mg/kg for pea vines (dry) (25% DM).

Sugar beet leaves or tops

In ten trials conducted in northern Europe, according to GAP (0.5 kg ai/ha, no PHI specified), residues in the leaves (tops) were: < 0.09 (6), 0.09, 0.16, 0.33 and 0.50 mg/kg.

In six trials conducted in southern Europe according to GAP (0.6 kg ai/ha, 100 day PHI), residues were: < 0.09 (6) mg/kg.

Based on the northern European trials, the Meeting estimated a highest residue of 0.50 mg/kg and a STMR of 0.09 mg/kg for cycloxydim in sugar beet leaves or tops.

Maize fodder

In ten trials conducted with cycloxydim in northern Europe according to GAP (0.4 kg ai/ha, no PHI specified), residues in fodder were: < 0.09 (7), 0.11, 0.3 and 0.41 mg/kg.

In four trials conducted in south of Europe according to GAP (0.4 kg a.i./ha, 90 days PHI), residues were 0.10, 0.11, 0.29 and 1.1 mg/kg

Based on the trials conducted in southern Europe and with the support of the trials conducted in northern Europe the Meeting estimated a highest residue of 1.1 mg/kg and a STMR of 0.247 mg/kg for cycloxydim in maize fodder.

The Meeting also estimated a maximum residue level of 2 mg/kg in maize fodder, dry (85% DM).

Rice straw and fodder

In eight trials conducted with cycloxydim in Italy, according to GAP, residues in rice straw were: < 0.09 (8) mg/kg.

The Meeting estimated a maximum residue level of 0.09* mg/kg, a HR of 0.09 mg/kg and a STMR of 0.09 mg/kg for cycloxydim rice straw (DM=90%).

Rape forage

In three trials conducted in Norway according to GAP, residues in rape seed forage were 0.24, 0.25 and 0.26 mg/kg.

The Meeting agreed that three trials according to GAP was sufficient to estimate a highest residue for cycloxydim in rape forage.

Fate of residues in processing

The [^{14}C]-cycloxydim was dissolved in aqueous buffer solution at pH 4 and heated for 20 minutes at 90 °C to simulate pasteurization, at pH 5 and refluxed at 100 °C for 60 minutes to simulate baking, brewing and boiling, and at pH 6 at about 120 °C in an autoclave for 20 minutes to simulate pasteurization. Cycloxydim degraded mainly to cycloxydim-T2S, which accounted for 93.5, 86.8 and 75% of the total applied radioactivity (TAR), respectively. T2SO accounted for up to 11% TAR (at pH 6).

A variety of processing studies were conducted with crops treated with cycloxydim. Processing factors (PF) in commodities with relevance for dietary exposure assessment and for animal dietary burden calculation are shown in the Table below. The estimated PFs were multiplied by the estimated HR and STMR of the raw commodity to estimate the HR-P and STMR-P for the processed commodity.

Processing factor (PF) and estimations for processed commodities

Commodity	Best estimate PF (n)*	STMR-P, mg/kg	HR-P, mg/kg
Strawberry, STMR= 0.53 mg/kg, HR=1.4 mg/kg			
Strawberry jam	0.55 (4)	0.291	
Strawberry canned	0.90 (4)	0.447	1.26
Onion, STMR=0.285 mg/kg, HR= 1.3 mg/kg			
Onion, peeled	1.1 (2)	0.31	1.43
Cabbage, STMR=1.95 mg/k, HR= 9.0 mg/kg			
Cabbage, cooked	0.56 (4)	1.09	5.04
Pasteurized sauerkraut	0.78 (4)	1.17	
Tomato, STMR=0.445mg/kg , HR= 0.89 mg/kg			
Tomato, canned	0.57 (4)	0.254	0.51
Tomato juice	1.1 (4)	0.49	
Ketchup	1.8 (4)	0.801	
Tomato pure, pasteurized	3.7 (4)	1.65	
Pea, STMR=5.6 mg/kg			
Pea, cooked	0.7 (4)	3.92	
Pea, canned	0.2 (4)	1.12	
Carrot, STMR= 0.44 mg/k, HR= 3.0 mg/kg			
Carrot, cooked	0.77 (4)	0.339	2.31
Carrot, juice	0.50 (4)	0.22	
Carrot, canned	0.36 (4)	0.158	1.08

Commodity	Best estimate PF (n)*	STMR-P, mg/kg	HR-P, mg/kg
Potato, STMR= 0.735 mg/kg, HR= 1.6 mg/kg			
Potato, peeled	1.3 (4)	0.960	2.08
Potato, boiled	1.5 (4)	1.10	2.4
Potato, steamed	1 (4)	0.735	1.6
French fries	1.3 (4)	0.956	2.08
Rape seed, STMR= 1.9 mg/kg			
Rape oil, refined	< 0.05 (4)	0.095	
Rape oil meal	1.5 (6)	2.85	
Sunflower, STMR=0.05 mg/kg			
Sunflower oil	0.1 (2)	0.00	

[a] number of processing studies

Residues in animal commodities

Farm animal dietary burden

The Meeting estimated the dietary burden of cycloxydim in farm animals on the basis of the diets listed in Annex 6 of the 2006 JMPR Report (OECD Feedstuffs Derived from Field Crops), the STMR, STMR-Ps or highest residue levels estimated at the present Meeting (see Table below). Dietary burden calculations are provided in Annex 6.

Livestock dietary burden for cycloxydim, ppm of dry matter diet

	US-Canada		EU		Australia		Japan	
	Max	Mean	Max	Mean	Max	Mean	Max	Mean
Beef cattle	3.54	2.09	22.4	7.26	26.8[a]	8.5 [c]	2.28	2.28
Dairy cattle	8.1	2.96	22.6[b]	7.55[d]	20.4	7.0	1.55	1.55
Poultry - broiler	3.47	3.47	6.06	3.92	5.1	5.1	0.07	0.07
Poultry - layer	3.47	3.47	10.89 [e]	4.32	5.1[f]	5.1	0.08	0.08

[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 feeding studies

Cattle

A mixture of cycloxydim and cycloxydim-5-OH-TSO (2:1) was administered orally to cattle for 28 days at 5.1, 15.2 and 50.2 ppm feed levels. Residues (sum of non-hydroxylated and hydroxylated metabolites; expressed as parent equivalents) in milk was only detected at the highest dose, with a mean of 0.044 mg/kg. Mean residues in skim milk and cream (from day 21) were similar (0.044 and 0.033 mg/kg, respectively).

In muscle, residues were not detected at the lowest dose. Mean and highest residues were 15.2 ppm of 0.023 and 0.026 mg/kg, respectively. Mean and highest residues at 50.2 ppm were 0.073 and 0.088 mg/kg, respectively

In liver, mean residues were 0.043, 0.128 and 0.336 mg/kg were at feeding levels of 5.1, 15.2 and 50.2 ppm, respectively, with the highest residues of 0.045, 0.151 and 0.381 mg/kg, respectively. Residue 2 days after the dose withdrawal was 0.079 mg/kg.

In kidney, mean residues were 0.068, 0.202 and 0.593 mg/kg at feeding levels of 5.1, 15.2 and 50.2 ppm, respectively, with the highest residues of 0.073, 0.239 and 0.727 mg/kg, respectively. The residue 2 days after dose withdrawal was 0.057 mg/kg.

In fat, mean residues were < 0.019, 0.025 and 0.119 mg/kg at feeding levels of 5.1, 15.2 and 50.2 ppm, respectively, with the highest residues of < 0.019, 0.030 and 0.138 mg/kg, respectively. The residue 2 days after dose withdrawal was 0.020 mg/kg.

In another study conducted at the same dose levels, residues in milk (total, skin and cream), muscle and fat were only detected at the highest dose: mean of 0.020 mg/kg in milk and skim milk and 0.016 mg/kg in cream; mean and highest in muscle of 0.06 and 0.07 mg/kg, respectively and in fat of 0.10 and 0.12 mg/kg.

In liver, mean residues were 0.03, 0.12 and 0.29 mg/kg at 5, 15 and 50 mg/kg dose levels, respectively, with the highest residues of 0.04, 0.15 and 0.31 kg/kg, respectively. The residue 2 days after dose withdrawal was 0.06 mg/kg.

In kidney, mean residues were 0.05, 0.14 and 0.44 mg/kg at 5, 15 and 50 mg/kg dose levels, respectively, with the highest residues of 0.06, 0.18 and 0.51 kg/kg, respectively. The residue 2 days after dose withdrawal was 0.05 mg/kg.

Poultry

A mixture of cycloxydim and cycloxydim-OH-TSO (1:1) was administered orally to groups of hens for 28 days at doses of 2.29, 6.71 and 23.2 ppm in the feed. Mean and highest residues in eggs detected at 6.71 ppm dose were 0.022 and 0.058 mg/kg, respectively (n=9). At the highest dose, mean and highest values were 0.065 and 0.102 mg/kg, respectively (n=9). Residues were < 0.02 mg/kg during the depuration phase (between 29 and 33 days). Residues were not detected above the LOQ in muscle and fat in any dose group. In liver, residues were detected only at the highest dose group (mean of 0.022 mg/kg and highest of 0.03 mg/kg).

In another study, cycloxydim and cycloxydim-OH-TSO (1:1) was administered to laying hens at a target dose level of 2.5, 7.5 and 25 ppm. Residues were not detected in muscle, liver and fat at any dose level. In eggs, residues were detected at the 7.5 ppm (mean of < 0.03 mg/kg, highest of 0.041 mg/kg) and at the 25 mg/kg dose (mean of 0.046 mg/kg, highest of 0.069 mg/kg). Residues during the depuration phase (3–7 days) were < 0.03 mg/kg.

Animal commodity maximum residue levels

The residues expected in animal commodities based on the calculated animal burden and the feeding studies are shown in Table 3. The levels which the estimations were based are in bold.

Residues in kidney and liver at the expected dietary burden are outlined below.

	Feed level, ppm, for		Residue, mg/kg					
	Milk residues	Tissues and eggs residues	Milk	Muscle	Liver	Kidney	Fat	Eggs
Highest residue level, cattle								
Feeding study	50	15 50	0.032	0.026 0.088	0.151 0.381	0.239 0.727	0.030 0.138	
Burden and residue	22.6	26.8	0.014	0.047	0.228	0.40	0.066	
STMR, cattle								
Feeding study	50	5 15	0.032	< 0.019 0.026	0.036 0.124	0.059 0.171	< 0.019 0.027	
Burden and residue	7.55	8.5	0.0054	0.021	0.067	0.0984	0.022	
Highest residue level, hens								
Feeding study		6.7/7.5 23.2		< 0.02	0.03		< 0.02/< 0.03	0.058/0.041

	Feed level, ppm, for		Residue, mg/kg					
	Milk residues	Tissues and eggs residues	Milk	Muscle	Liver	Kidney	Fat	Eggs
Burden and residue		10.8		< 0.03	0.014		< 0.03	0.092/0.023
STMR, hens								
Feeding study		6.7/7.5 23.5		< 0.02	0.022		< 0.03	0.022/0.03
Burden and residue		5.1		0	0.0054		0	0.02/0.017

Based on the results obtained for cattle, the Meeting estimated for cycloxydim a maximum residue level of 0.02 mg/kg and a STMR of 0.005 mg/kg in milks; a maximum residue level of 0.06 mg/kg, a HR of 0.047 mg/kg and a STMR of 0.021 mg/kg in meat (from mammalian other than marine mammals); a maximum residue of 0.1 mg/kg, a HR of 0.066 mg/kg and a STMR of 0.021 mg/kg for mammalian fats (except milk fats); and a maximum residue level of 0.5 mg/kg, a HR of 0.403 mg/kg and a STMR of 0.098 mg/kg in edible offal (mammalian).

Based on the results obtained for hens, the Meeting estimated for cycloxydim a maximum residue level of 0.15 mg/kg, a HR of 0.092 mg/kg, and a STMR of 0.018 mg/kg in eggs; a maximum residue level of 0.03* mg/kg, a HR of 0.03 mg/kg and a STMR of 0 mg/kg in poultry meat and poultry fats; and a maximum residue level of 0.02 mg/kg, a HR of 0.014 mg/kg and a STMR of 0.005 mg/kg for cycloxydim in poultry edible offal

DIETARY RISK ASSESSMENT

Long-term intake

The ADI for cycloxydim is 0–0.07 mg/kg bw. The International Estimated Daily Intakes (IEDI) for cycloxydim was estimated for the 13 GEMS/Food cluster diets using the STMR or STMR-P values estimated by the current JMPR. The results are shown in Annex 3. The IEDI ranged from 7–50% of the maximum ADI. The Meeting concluded that the long-term intake of residues of cycloxydim from uses that have been considered by the JMPR is unlikely to present a public health concern.

Short-term intake

An ARfD for cycloxydim for women of childbearing age is 2 mg/kg bw; ARfD was unnecessary for the general population. The International Estimated Short-Term Intake (IESTI) for cycloxydim 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 peppers, chili dried. The Meeting concluded that the short-term intake of cycloxydim residues from uses considered by the current Meeting was unlikely to present a public health concern.

5.9 CYFLUTHRIN/BETA-CYFLUTHRIN (157)

RESIDUE AND ANALYTICAL ASPECTS

Cyfluthrin and beta-cyfluthrin were evaluated for toxicology (JMPR 2006) and residues (JMPR 2007) under the periodic review programme, and maximum residue levels for cyfluthrin, arising from the use of either cyfluthrin or beta-cyfluthrin on a number of commodities, were recommended.

The definition of the residue (for compliance with MRL and for estimation of dietary intake) for plant and animal commodities is: cyfluthrin (sum of isomers). The residue is fat-soluble.

The 2007 JMPR estimated short-term intakes for children that exceeded the ARfD for cyfluthrin and beta-cyfluthrin of 0.04 mg/kg bw for broccoli and head cabbage and noted that there was insufficient data to support an estimation of lower maximum residue levels based on alternative GAPs for these commodities.

At the Forty-first Session of the CCPR in 2009, the Committee agreed that if no data were available to support lower maximum residue level estimates for broccoli and head cabbage (based on alternative GAP), the draft MRLs would be considered for withdrawal at the 2010 session (ALINORM 09/32/24, para 106–107). While additional information on head cabbage was provided to the 2011 JMPR, this information was deemed insufficient to support an Alternative GAP evaluation and the Forty-second Session of the CCPR agreed to retain the draft MRL of 4 mg/kg on Cabbages, Head awaiting the evaluation of additional data by JMPR in 2012.

The Meeting received additional supervised trials data from Indonesia for beta-cyfluthrin on head cabbages and also received information from the manufacturer to support a new GAP in the USA for beta-cyfluthrin on soya beans.

Methods of residue analysis

Analytical methods for residues of cyfluthrin and beta-cyfluthrin in plant and animal matrices, including the methods used in the new soya bean studies, have been evaluated by the 2007 JMPR and generally involve extraction by homogenization with an organic solvent mixture (with varying proportions of polar and non-polar solvents) and liquid–liquid partition and column clean-up before GC-ECD or GC-MSD analysis. Validated LOQs ranged from 0.01 to 0.05 mg/kg. Validation data were provided for soya bean and its processed commodities, including procedural recoveries carried out during the residue trials and during the processing study.

The analytical method used in the supervised trials from Indonesia was based a multi-residue method with the modified clean-up method for chlorophyll and sulfuric compound co-extractants. The validation and procedural recovery rates support an LOQ of 0.01 mg/kg.

Results of supervised residue trials on crops

Cabbage, Head—beta-cyfluthrin

Based on US GAP and residue data for cyfluthrin, the 2007 JMPR estimated a maximum residue level of 4 mg/kg, an STMR of 0.25 mg/kg and an HR of 2.1 mg/kg for cyfluthrin in cabbage (head) but estimated that the short-term intake for children was 240% of the ARfD (0.04 mg/kg bw).

Critical GAP in Indonesia is 15 g ai/ha with a PHI of 7 days. In three trials with beta-cyfluthrin evaluated by the 2007 JMPR and in four more recent trials, all matching the GAP in Indonesia, residues were: < 0.01, < 0.01, < 0.01, 0.01, 0.01, 0.02 and 0.05 mg/kg (n=7).

The Meeting estimated a maximum residue level of 0.08 mg/kg, an STMR of 0.01 mg/kg and an HR of 0.05 mg/kg for cyfluthrin on head cabbage to support the Alternative GAP in Indonesia and agreed to withdraw the previous maximum residue level recommendation of 4 mg/kg.

Soya bean—beta-cyfluthrin

Revised GAP in USA for beta-cyfluthrin on soya bean is a maximum of four applications/season of up to 25 g ai/ha, PHI 21 days.

In trials from USA, matching this GAP, residues in soya bean seed were: < 0.01 (12), 0.01 (3), 0.02, 0.02, 0.02 and 0.02 mg/kg (n=19)

The Meeting estimated a maximum residue level of 0.03 mg/kg and an STMR of 0.01 mg/kg for cyfluthrin on soya bean (dry).

Animal feeds

Soya bean forage—beta-cyfluthrin

Revised GAP in USA for beta-cyfluthrin on soya bean is a maximum of four applications/season of up to 25 g ai/ha with a 15-day livestock withholding period for hay and forage.

In trials from USA, matching this GAP, residues in soya bean forage (fresh weight) were: 0.1, 0.13, 0.25, 0.29, 0.29, 0.32, 0.33, 0.34, 0.34, 0.38, 0.42, 0.42, 0.43, 0.47, 0.5, 0.66, 0.7, 0.8, 0.8 and 1.0 mg/kg (n=20).

The Meeting estimated a median residue of 0.4 mg/kg and a highest residue of 1.0 mg/kg for cyfluthrin on soya bean forage (fresh weight).

Soya bean hay—beta-cyfluthrin

Revised GAP in USA for beta-cyfluthrin on soya bean is a maximum of four applications/season of up to 25°g°ai/ha, PHI 21 days and with a 15-day livestock withholding period for hay and forage.

In trials from USA, matching this GAP, residues in soya bean hay (fresh weight) were: 0.3, 0.49, 0.73, 0.74, 0.83, 0.88, 0.95, 1.1, 1.1, 1.1, 1.2, 1.2, 1.2, 1.4, 1.5, 1.5, 1.5, 1.7 and 2.2 mg/kg (n=20).

The Meeting estimated a maximum residue level of 4 mg/kg for soya bean hay (after correcting for 85% dry matter) and estimated a median residue of 1.15 mg/kg (fresh weight) and a highest residue of 2.2 mg/kg (fresh weight).

Fate of residues during processing

The 2007 JMPR reviewed the results of processing studies and estimated processing factors and STMR-Ps for cyfluthrin in a range of commodities and a new beta-cyfluthrin processing study on soya beans was provided to the Meeting. The only processed commodity of relevance to the commodities considered at the Meeting is soya bean aspirated grain fraction. The Meeting estimated a processing factor of 2218 for cyfluthrin in soya bean aspirated grain fraction and based on the STMR of 0.01 mg/kg established for soya bean (dry) the Meeting estimated an STMR-P of 22 mg/kg.

Residues in animal commodities

Livestock dietary burdens

The Meeting estimated the dietary burden of cyfluthrin in farm animals on the basis of the diets listed in Annex 6 of the 2009 JMPR Report (OECD Feedstuffs Derived from Field Crops) and using information on cyfluthrin residues in animal feedstuffs reported by the 2007 JMPR.

Dietary burden calculations for beef and dairy cattle, calculated using the animal diets from US-Canada, EU and Australia in the OECD Table (Annex 6 of the 2006 JMPR Report) are summarized below.

	Animal dietary burden, cyfluthrin, ppm of dry matter diet							
	US-Canada		EU		Australia		Japan	
	Max	Mean	Max	Mean	Max	Mean	Max	Mean
Beef cattle	1.35	1.35	0.16	0.11	2.43[a]	1.22[c]	0.002	0.002
Dairy cattle	0.69	0.39	0.21	0.16	1.55[b]	0.88[d]	0.001	0.001
Poultry – broiler	0.011	0.011	0.017[e]	0.017[f]	0.005	0.005	–	–
Poultry – layer	0.011	0.011	0.39[f]	0.22[g]	0.005	0.005	–	–

[a] Highest maximum beef or dairy cattle dietary burden suitable for MRL estimates for mammalian tissues

[b] Highest maximum dairy cattle dietary burden suitable for MRL estimates for mammalian milk

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

[d] Highest mean dairy cattle dietary burden suitable for STMR estimates for milk.

[e] Highest maximum poultry dietary burden suitable for 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.

Livestock feeding studies

The 2007 JMPR reviewed feeding studies with cyfluthrin on lactating dairy cows and laying hens and the conclusions from these residue transfer studies were used to estimate residue levels of fluopyram and its metabolites in milk, eggs and livestock tissues, based on the above dietary burdens. The maximum and mean residues identified by the 2007 JMPR in milk, fat and muscle following 28 daily doses of cyfluthrin corresponding to 4.5 ppm in the diet and in liver and kidney from animals in the 40 ppm dose group (where samples were subjected to strong extraction required to release the majority of cyfluthrin residues) were used to estimate transfer of residues to livestock tissues and milk.

Animal commodity maximum residue levels

Cattle

Maximum and mean residues expected in milk and tissues were obtained by using the residue transfer factors estimated by the 2007 JMPR.

For maximum residue estimation, the high residues of cyfluthrin were calculated by extrapolating the maximum dietary burden (2.43 ppm) from the 4.5 ppm feeding level (40 ppm for liver and kidney) in the dairy cow feeding study and using the highest tissue concentrations of cyfluthrin from individual animals within those feeding groups.

The STMR values for the tissues were calculated by extrapolating the STMR dietary burden (1.22 ppm from the same feeding levels (4.5 ppm for muscle and fat, 40 ppm for liver and kidney) and using the mean tissue concentrations of cyfluthrin from those feeding groups.

For milk MRL estimation, the high residues in the milk were calculated by extrapolating the maximum dietary burden for dairy cattle (1.55 ppm) from the feeding level (4.5 ppm) in the dairy cow feeding study and using the mean milk concentrations of cyfluthrin from this feeding group.

The STMR value for milk was calculated by extrapolating the mean dietary burden for dairy cows (0.88 ppm) from the 4.5 ppm feeding level and using the mean milk concentrations of cyfluthrin from this feeding group.

	Feed level (mg/kg) for milk residues	Residues (mg/kg) in milk	Feed level (mg/kg) for tissue residues	Residues (mg/kg)			
				Muscle	Liver	Kidney	Fat
Maximum residue level beef or dairy cattle							
Feeding study [a]	4.5	0.02	4.5 40	< 0.01	 0.14[c]	 0.18c	0.3
Dietary burden and residue estimate	1.55[b]	0.007	2.43[a]	< 0.01	0.009	0.011	0.16
STMR beef or dairy cattle							
Feeding study [b]	4.5	0.02	4.5 40	< 0.01	 0.14[c]	 0.18[c]	0.25
Dietary burden and residue estimate	0.88[d]	0.004	1.22[c]	< 0.01	0.004	0.005	0.067

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

[b] Mean residues for tissues and for milk

[c] Residue values for kidney and liver were obtained from the dosing level equivalent to 40 ppm in the feed as only these samples were subject to reanalysis using a stronger extraction process

Residues of cyfluthrin expected in cattle milk and tissues for use in estimating maximum residue levels are: 0.16 mg/kg (fat), < 0.01 mg/kg (muscle), 0.009 mg/kg (liver) and 0.011 mg/kg (kidney) and the mean residue for milk is 0.007 mg/kg.

The Meeting estimated maximum residue levels of 0.2 mg/kg (fat) for cyfluthrin in meat (from mammals other than marine mammals), 0.02 mg/kg for edible offal (mammalian) and 0.01 mg/kg for milks.

Estimated HRs for cyfluthrin are 0.16 mg/kg for mammalian fat, 0.01 mg/kg for mammalian muscle, 0.01 mg/kg for edible offal and STMRs are 0.07 mg/kg for mammalian fat, 0.01 mg/kg for mammalian muscle, 0.005 mg/kg for edible offal and 0.004 mg/kg for milks.

The Meeting also agreed to withdraw the previous recommended maximum residue levels of 1 mg/kg (fat) for meat (from mammals other than marine mammals), 0.05 mg/kg for liver of cattle, goats, pigs and sheep, 0.05 mg/kg for kidney of cattle, goats, pigs and sheep and 0.04 mg/kg for milks.

Poultry

The highest maximum and the mean dietary burdens for poultry are 0.39 ppm and 0.22 ppm respectively. No residues above the LOQ of the analytical method used were observed in the feeding study for laying hens at the lowest dose level equivalent to 2 ppm in the diet (about five times higher than the maximum burden in poultry). Maximum residues expected in muscle, fat, liver, kidney and eggs are all < 0.01 mg/kg.

The Meeting confirmed the 2007 JMPR recommended maximum residue levels for poultry meat of 0.01* mg/kg (fat); poultry offal 0.01* and eggs 0.01* mg/kg.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Daily Intake (IEDI) for cyfluthrin 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 cyfluthrin for the 13 GEMS/Food regional diets, based on estimated STMRs were 0–2% of the maximum ADI of 0.04 mg/kg bw (Annex 3). The

Meeting concluded that the long-term intake of residues of cyfluthrin 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 cyfluthrin was calculated for the food commodities for which STMRs or HRs were estimated and for which consumption data were available (Annex 4).

For cyfluthrin the IESTI varied from 0–6% of the ARfD (0.04 mg/kg bw) and the Meeting concluded that the short-term intake of residues of cyfluthrin from uses considered by the Meeting is unlikely to present a public health concern.

5.10 CYROMAZINE (169)

RESIDUE AND ANALYTICAL ASPECTS

Cyromazine was first evaluated by JMPR in 1990 and subsequently in 1991 and 1992 for residues and in 2006 for toxicity when an ADI of 0–0.06 mg/kg bw and an ARfD of 0.1 mg/kg bw were established. It was again evaluated by JMPR in 2007 under the periodic review programme. The 2007 JMPR recommended cyromazine as the residue definition for plant and animal commodities both for compliance with the MRL and for estimation of dietary intake.

At its Forty-third Session, the CCPR included cyromazine in the Priority List to be evaluated by the current Meeting for additional maximum residue levels.

The current Meeting received information on methods of analysis, storage stability and supervised trials to support additional maximum residue levels for cyromazine. The current Meeting also received a request to consider extending the Codex MRL for beans (dry) to chick pea and lentil.

Methods of analysis

The Meeting received information on the analytical methods used in the supervised residue trials submitted to the current Meeting. These methods used were either GC/NPD, HPLC/MS or HPLC/MS/MS. They were validated successfully for determining cyromazine in snap bean (pods and immature seeds), French bean and lima bean with mean recoveries in the acceptable range of 70–110% with RDSs less than 20%.

Stability of pesticide residues in stored analytical samples

The 2007 JMPR concluded that cyromazine at the fortification level of 1 mg/kg was stable in haricot beans for at least two years when stored at ≤ -18 °C. Samples from the US supervised trials were stored frozen no longer than one year and French bean samples from the supervised trials in Senegal and Kenya were stored no longer than four months.

Results of supervised residue trials on crops

The Meeting received information on supervised on supervised trials of cyromazine on common bean (pods and/or immature seeds), lima bean (immature seeds) and beans (dry).

The OECD MRL calculator was used as a tool to assist in the estimation of maximum residue levels from the selected residue data set obtained from the supervised residue trials. As a first step, the Meeting reviewed trial conditions and other relevant factors related to each data set to arrive at a best estimate of the maximum residue level using expert judgement. Then, the OECD calculator was employed. If the statistical calculation spreadsheet suggested a different value, a brief explanation of the derivation was supplied.

Legume vegetables

Common bean (pods and/or immature seeds)

The Meeting received information on supervised residue trials conducted in the USA, Senegal and Kenya.

Trials were conducted on common bean (snap bean) in four locations in the USA. However, the dates of last application and harvest were either the same or only slightly different at the same locations, and as the variability between varieties is not considered significant for snap beans, the Meeting considered that there were only four valid trials in accordance with US GAP (6 applications at 140 g ai/ha, PHI 7 days). Residues of cyromazine in snap beans (pods and seeds) from these trials were: 0.80, 1.2, 1.3 and 1.3 mg/kg.

A total of three trials were conducted in Senegal (1) and Kenya (3) on common bean (French bean). Residues from the trials according to GAP in Kenya (maximum of three applications with 10-14 day interval, maximum rate of 225 g ai/ha for 200-800 L/ha, a PHI of 14 days) in ranked order, were: 0.24, 0.28 and 0.56 mg/kg.

As the GAP in the USA and that in Kenya are significantly different from each other, the Meeting concluded that data available were insufficient to estimate a maximum residue level for common beans.

Lima bean

Another three trials were reported for lima beans from the USA. Residues of cyromazine in lima bean (immature beans) from trials according to US GAP were: < 0.05, 0.11 and 0.24 mg/kg.

The 2004 JMPR estimated a maximum residue level of 1 mg/kg, STMR of 0.23 mg/kg and HR of 0.58 mg/kg for lima beans (young pods and/or immature beans) based on the six trials from the USA on lima beans in pods. The current Meeting considered that the previous recommendation for lima beans (young pods and/or immature beans) was sufficiently high to cover lima bean immature beans.

Pulses

The Meeting received information on nine trials from a number of states in the USA conducted in 1998 on various kinds of dry beans. Eight of these trials had been provided to the 2004 JMPR which estimated, on the basis of these eight trials and one additional trial in the USA, a maximum residue level of 3 mg/kg for beans (dry), which were adopted as Codex MRL. An STMR of 1.0 mg/kg was also estimated.

Trials were conducted in the USA in 1998 on black-eyed pea (cow pea), pinto bean, navy bean, kidney bean and great northern bean with comparable residue results and US GAP is for all "*dried varieties of beans except cow peas and soya beans*". The current Meeting therefore concluded that it was appropriate to extend the previous recommendation for beans (dry) to chick-pea (dry), lentil (dry) and lupin (dry).

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Daily Intakes (IEDIs) of cyromazine were calculated for the 13 GEMS/Food cluster diets using STMRs estimated by the current Meeting (Annex 3). The ADI is 0–0.06 mg/kg bw and the calculated IEDIs were 0-4 % of the maximum ADI. The Meeting concluded that the long-term intake of residues of cyromazine resulting from the uses considered by the 2007 and current JMPR is unlikely to present a public health concern.

Short-term intake

The International Estimated Short-Term Intakes (IESTI) of cyromazine were calculated for food commodities and their processed commodities using HRs/HR-Ps or STMRs/STMR-Ps estimated by the current Meeting (see Annex 4). The ARfD is 0.1 mg/kg and the calculated IESTIs were 3–20 % of the ARfD. The Meeting concluded that the short-term intake of residues of cyromazine, when used in ways that have been considered by the JMPR, is unlikely to present a public health concern.

5.11 DICHLORVOS (025)

RESIDUE AND ANALYTICAL ASPECTS

Dichlorvos is an organophosphate insecticide. It is effective against a broad spectrum of insect pests in stored products. It is also used in public health vector control and in animal health for the control of ectoparasites. It was evaluated by JMPR 1965 (T,R), 1970 (T,R), 1993 (T,R), and in 2011 (T) as part of the periodic review programme. The ADI and acute reference dose for dichlorvos were established as 0–0.004 mg/kg bw and 0.1 mg/kg bw, respectively. Dichlorvos was scheduled at the Forty-third Session of the CCPR (2011) for the periodic re-evaluation of residues by the 2012 JMPR.

Animal metabolism

Information on the metabolism of dichlorvos has been evaluated in goats following dermal and oral dosing, in swine and laying hens after dermal application of dichlorvos. The latter information was obtained from studies published in scientific literature.

Dermal treatment

Two lactating goats were treated dermally twice daily for three consecutive days with vinyl-^{14}C-dichlorvos at the target dose rate of 10 mg/kg body weight/day. To dose at an exaggerated rate, the application site of one goat was shaved and occluded with a Teflon patch immediately after each treatment ("occluded goat"). The other treated goat was treated normally, that is, the application site was not shaved nor occluded ("non-occluded"). Treated goats were sacrificed 16–18 hours after the final dose.

The following TRR levels (mg/kg) were found in various tissues of occluded and non-occluded goat, respectively: distal and proximal muscle 2.30 mg/kg (3.6%)–2.56 mg/kg (0.1%) and 0.65 (0.8)–0.55 mg/kg (0.0%); liver 36.1 mg/kg (2.8%)– 9.13 mg/kg (0.5%); kidney 13.5 mg/kg (0.1%) and 3.23mg/kg (0.0%); distal and proximal fat 0.69 mg/kg (0.1%)–0.64 mg/kg (0.0%), and 0.13 mg/kg (0.0%)–0.43 mg/kg (0.0%). The cumulate TRR found in the tissues accounted for 6.7% and 1.3% of the administered dose, for the occluded and non-occluded goats, respectively.

TRR levels found in milk from the occluded goat ranged from 6.09 to 10.76 mg/kg and accounted for 3.5% of the administered dose. The TRR levels found in milk from the non-occluded goat ranged from 0.618 to 1.821 mg/kg and accounted for 0.6% of the administered dose.

Comparison of the TRR levels in proximal and distal muscle and fat samples from both treated animals demonstrated that residue levels were not any higher in the proximal samples, suggesting that dermally absorbed residues were quantitatively distributed throughout the animal's body by the circulatory system.

Material balance for this study, including residues in urine and faeces, accounted for 52.1% and 42.2% of the administered dose for the occluded and non-occluded goats, respectively.

The metabolic fate of vinyl-1-^{14}C-dichlorvos in the occluded goat was examined in the edible tissues and milk. Solvent extraction of tissues and milk removed between 30.7 and 70.5 percent of the TRR. Subsequent acid and/or base hydrolyses of the post-extracted solids quantitatively solubilized the "bound" residues.

Chromatographic analysis of the aqueous extracts demonstrated that neither dichlorvos nor desmethyl dichlorvos, 2,2-dichloroacetic acid, 2,2 dichloro acetaldehyde and 2,2-dichloroethanol were present. Mass spectral analyses of the water-soluble residues suggested that the polar residues found in the tissues represented incorporation of the dechlorinated vinyl portion of dichlorvos into relatively high-molecular weight natural products.

Milk aqueous extract was shown to contain a single radioactive residue which was identified as ^{14}C-lactose.

The organo-soluble residues were further characterized by saponification. Analysis of the saponified-aqueous fractions from milk, liver and fat revealed that ^{14}C-glycerol accounted for 100%, 28.6% and 23.1% of the radiocarbon present in the fraction, respectively.

The "non-saponifiable" (lipid) fraction accounted for approximately 30–50% of radioactivity. These "bound" residues were quantitatively solubilised after acid and/or base hydrolysis resulting in compounds similar to amino acids.

Results from this study showed that vinyl-l-^{14}C-dichlorvos was extensively metabolized in the goat so that the vinyl portion of the molecule was incorporated into various natural products. Natural products identified in this study were lactose (in skim milk) and glycerol, resulting from the saponification of triglycerides present in milk, muscle and fat organo-soluble fractions. Although structural assignments were not made for the water-soluble residues extracted from tissues, five relatively high molecular weight polar compounds, which lacked chlorine atoms, were confirmed by mass spectral analysis. Bound residues solubilised by acid hydrolysis were tentatively identified as amino acids.

Laying hens

The metabolism of dichlorvos was studied on laying hens treated dermally twice daily for three consecutive days with vinyl-1-^{14}C-dichlorvos at the dose rate of 18.7 mg/kg body weight/day.

To maximize absorption of the applied dose, the feathers and down on the application site (vent and fluff area) were clipped-off prior to the first treatment. Treated hens were sacrificed approximately 20–21 hours after the final dose and the total radioactive residue (TRR) levels in selected tissues, were determined by combustion analysis.

The TRRs were 1.48 mg/kg in liver, 0.39 mg/kg in breast muscle, 0.49 mg/kg in fat, 0.88 mg/kg in egg white and 0.86 mg/kg egg yolk. Radioactivity found in the internal tissues and on the proximal and distal skin accounted for 0.3%, 20.0% and 0.8% of the administered dose, respectively.

Solvent extraction of tissues and eggs recovered between 8.6% and 93.5% of the TRR. Subsequent acid and base hydrolysis of the post-extracted solids quantitatively solubilised the "bound" residues.

The parent dichlorvos (0.004 mg/kg, 1.1% of TRR) and des-methyl dichlorvos (0.039 mg/kg, 7.8% of TRR) were identified in breast muscle and fat.

Results from this study showed that vinyl-1-^{14}C-dichlorvos was extensively metabolized in poultry. Majority of the radioactivity was incorporated into water-soluble natural products, amino acids and glycerol (fats), resulting from the saponification of triglycerides present in the organic extracts of liver, fat, and egg yolk.

Oral application of dichlorvos

Cows

In an early non GLP study four cows were treated with ^{32}P-labelled dichlorvos on the first day with 1 mg/kg bw dose in capsule and followed after 7 days by a 20 mg/kg bw dose. Following the 1 and 20 mg/kg bw oral doses the total radioactivity in milk reached an approximate plateau (0.6 mg/kg dichlorvos equivalent) between 12 and 24 hours and 10.5–11.1 mg/kg between 8 and 12 hours, respectively. The radioactive residues in milk declined continuously to 1.3 mg/kg dichlorvos equivalent after 6 days. The organosoluble residues in milk were much lower reaching the maximum of 0.077 mg/kg after one hour of administration of 20 mg/kg bw dose.

In another experiment cows were administered ^{32}P-dichlorvos at 1 mg/kg bw and 20 mg/kg bw. Following oral administration, the majority (68–100%) of radioactivity was eliminated in urine and faeces within a week of administration. The majority of radioactivity in urine was present as mono- or di-methyl phosphates (70–98%) and desmethyl dichlorvos (0–30%). Radioactivity

eliminated in milk of cows peaked at 0.61 mg/kg and 11.1 mg/kg dichlorvos equivalent approximately 12 hours after administration of 1 mg/kg and 20 mg/kg dose, respectively. It was concluded that dichlorvos was rapidly metabolized *in vivo* predominantly *via* cleavage of the P-O (vinyl) bond.

Swine

The Metabolic fate of dichlorvos in swine was studied by short and long-term oral and inhalation exposure utilising ^{32}P-, ^{36}Cl- and ^{14}C-labelled dichlorvos. Pregnant sows were administered, in the form of slow release polyvinylchloride pellets, a nominal dose of 4 mg/kg bw per day of ^{14}C-dichlorvos for up to 4 weeks before birth of piglets. Radioactivity was retained in tissues of both sows and piglets (levels not specified), but analysis showed that dichlorvos, demethyl dichlorvos, dichloroacetaldehyde or dichloroacetic acid were absent. Metabolites in liver and muscle tissues were identified as ^{14}C-carbon dioxide, glycine and serine, and a number of intermediates derived from these, including glucose, fatty acids, choline, ribonucleic acid and cholesterol. Similar experiments using ^{36}Cl-dichlorvos demonstrated that radioactivity was present as chloride ion and not as organochlorine compounds directly related to dichlorvos.

In three separate trials pregnant sows were fed non-labelled, and ^{14}C- and ^{36}Cl-labelled dichlorvos separately and in combination during the last third of the sows' gestation period at a rate of 4 mg of dichlorvos per kg of body weight per day. Samples of brain, kidney, liver, quadriceps muscle, and mesenteric fat from the sows, and muscle and liver from the piglets were analysed with GC method. No residues of dichlorvos, demethyl dichlorvos, dichloroacetaldehyde, dichloroacetic acid, or dichloroethanol were found in the tissues of the sows and piglets (LOQ was not given), although the tissues contained ^{l4}C and ^{36}Cl residues ranging from 0.3 to 18.0 mg/kg equivalents. The ^{14}C and ^{36}Cl residues in the tissues were assumed to be due to degradation of the vinyl group in dichlorvos into ^{36}Cl ions and the incorporation of the ^{14}C into normal tissue constituents such as glycine, serine, creatine, glucose, glycogen, fatty acids, cholesterol, choline, lecithin, and ribonucleic acid.

In summary, vinyl-l-^{14}C-dichlorvos was extensively metabolized. Neither dichlorvos nor desmethyl dichlorvos, 2,2-dichloroacetic acid, 2,2 dichloro acetaldehyde and 2,2-dichloroethanol were present in detectable concentrations in tissues, milk and eggs, except dichlorvos (0.004 mg/kg, 1.1% of TRR) and des-methyl dichlorvos (0.039 mg/kg, 7.8% of TRR) in poultry breast muscle and fat following extremely high dose. The phosphorus moiety of the molecule was excreted via urine and faeces as mono- or di-methyl phosphates and desmethyl dichlorvos. The dechlorinated vinyl portion of dichlorvos was incorporated into various natural products such as amino acids and glycerol (fats). Organochlorine compounds deriving from the vinyl moiety were not present.

Plant metabolism

Wheat grains were topically treated with ^{14}C-dichlorvos. Some of the grains were dissected manually into pericarp, endosperm, and germ, and the total radioactivity in each fraction was determined. Other part of grain was crushed and extracted with (a) chloroform, (b) acetone, (c) saline. The saline extract and remaining part of the grains extracts were digested with protease and assayed for ^{14}C. The results show that dichlorvos rapidly diminished after the grains saturated and the protein was phosphorylated. Dichlorvos amounted to 24%, 8% and 3% of radioactivity in chloroform 2, 7 and 14 days after treatment. The protease extract did not contain dichlorvos. The dichlorvos degraded to dimethyl phosphate and fairly stable phosphorylated protein derivatives.

^{32}P-labelled trichlorfon and ^{36}Cl-dichlorvos were applied to cotton leaves by petiole injection. Leaf samples were collected after application then residues extracted by partitioning into chloroform and water. Dichlorvos was present in low concentrations amounting to 0.8%, 0.9% and 0.1% of applied dose 1, 24 and 48 hours after trichlorfon administration.

Following dichlorvos application, more than 80% of the applied radioactivity was lost within 48 hours of treatment, presumably due to volatilisation. Dichlorvos was the predominant residue immediately after application (37% of applied radioactivity), but declined to less than 0.1% of applied radioactivity after 48 hours. Dimethyl phosphate was detected at up to *ca.* 13% of applied radioactivity after 24–48 hours.

The half-lives of dichlorvos degradation were determined in cotton, bean, tomato and potato plants following treatment with ^{32}P-labelled dichlorvos. The plants, with or without roots, were placed in a formulated 0.1–0.2% ^{32}P-dichlorvos solution or given a foliar application by dipping the whole plants into solutions of the labelled material. Between 60–80% of radioactivity was lost from the plants by volatilisation. In cotton, dichlorvos was degraded with a half-life of 4.6 hours, while half-lives of dichlorvos degradation of 6.8, 4.6 and 6.8 hours were determined for beans, tomatoes and potatoes, respectively. It was stated, without giving full details of characterization, that dimethyl phosphate was the predominant radioactive species identified.

Faba and soya beans were treated with ^{14}C-labelled dichlorvos at 12 mg/kg and 24 mg/kg dose rate. The treated grains were stored for 30 weeks under simulated local storage conditions. The residues on the seed coat (external extract) were removed with a mixture of water and acetone (3:1). Washed beans were then crushed in a mortar and Soxhlet extracted with 95% methanol for 24 hours.

The surface residues decreased with storage time and amounted to 15–21% of the actual applied dose for both beans by the end of the experiment. The radioactivity in the internal extract increased from 20% to 57% for faba beans and from 36% to 62% for soya beans in relation to the actual doses of 12 and 24 mg/kg applied, respectively. Non-extractable residues slowly increased with time, and amounted to 8–10% and 9–11% of the actual applied doses in faba beans and soya beans after 30 weeks. The total recovered radioactivity was over 81% of the applied doses.

Dichlorvos alone was present in the external extracts. Desmethyl-dichlorvos, dimethylphosphate and monomethylphosphate were the main degradation products of ^{14}C-dichlorvos in the internal extract. Desmethyl-dichlorvos could only be extracted after acid hydrolysis indicating that it was present in conjugated form. The isolated metabolites suggested that dichlorvos is degraded in both stored faba and soya beans via two main pathways to give a number of metabolites. The major degradation pathway is cleavage of the P-O-CH_3 bond to give desmethyl dichlorvos. Hydrolysis of desmethyl dichlorvos gave monomethyl phosphate. The minor pathway is the hydrolysis of the P-O-vinyl ester linkage to give dimethyl phosphate.

In summary dichlorvos is rapidly metabolized, with a half-life in cotton, beans, potato and tomato of about 4.6–6.8 hours and in cereals of 27–54 hours. Most of the radioactivity was lost by volatilization. The main routes of degradation of dichlorvos in plants were found to be: (i) hydrolysis to form the major metabolite dimethyl phosphate and dichloroacetaldehyde; (ii) demethylation of dimethyl phosphate to monomethyl phosphate and inorganic phosphates; (iii) conversion of dichloroacetaldehyde to 2,2-dichloroethanol, which is then conjugated and/or incorporated into naturally occurring plant components; and (iv) loss by volatilization.

Methods of residue analysis

The methods used in the studies carried out with stored plant commodities were similar and based on extraction with a 4:1 mixture of acetonitrile: water followed by partitioning into dichloromethane, the concentrated extract was purified by gel permeation chromatography and analysed by GC-FPD (flame photometric detection).

Milk samples were extracted with a mixture of ethanol, diethyl ether and petroleum ether in the presence of sodium oxalate. The dried concentrated extract was cleaned up on GPC column. The dichlorvos residues were determined with GC-FPD.

Animal tissue samples were extracted with dichloromethane, cleaned up on GPC and analysed by GC-FPD.

The validated LOQ was 0.01 in all matrices, and the recoveries ranged between 70–120%.

Some of the studies published in scientific papers employed colorimetric method based on enzyme inhibition and spectrophotometric detection. The LOQ of the methods for plant materials was 0.1 mg/kg. The recovery varied but was in the acceptable range of 70–110%

Dichlorvos residues may also be quantitatively determined with several multi residue methods used currently by regulatory laboratories.

Stability of residues in stored analytical samples

Peanut samples were obtained from a facility which was treated for 9 months at the daily rate of 18 g ai/1000 m^3) air space. The samples stored at -20 ºC were analysed on days 0, 39, 74, and 136 days after storage. The remaining residues were ≥ 70% in all samples demonstrating that residues of dichlorvos in peanuts are stable up to 136 days under frozen conditions. The maximum period of storage prior to analysis of all the bulk peanut samples in the facility was 134 days.

Winter wheat of about 12% moisture content was treated at a 15 mg/kg calculated deposit rate. Samples were stored for 8 weeks at -18 °C. The residues remaining in wheat grain varied in the range of 57% and 144% with an average of 90%.

Wheat grains of 9, 11, 13 and 14% moisture content were treated with dichlorvos at 50 mg/kg and stored for 11 months at -15 °C. At the end of the storage period, the samples contained 49, 43, 34 and 34 mg/kg of dichlorvos residues, respectively, corresponding to losses of 2%, 14%, 32 and 32% of initial dichlorvos.

It is apparent from the results that the disappearance of dichlorvos on wheat is dependent on both moisture content and temperature, which are affecting the stability of the residues. The stability of residues in commodities for which residue levels could be estimated was supported by the reported storage stability tests.

Definition of the residue

Biotransformation studies indicated that dichlorvos is rapidly absorbed by all routes of exposure and rapidly metabolized.

In lactating goats treated dermally the following TRR levels (mg/kg) were found in various tissues of occluded and non-occluded goat, respectively: distal and proximal muscle 2.30–2.56, 0.65–0.55; liver 36.1; 9.13; kidney 13.5; 3.23 distal and proximal fat 0.69–0.64, 0.13–0.43. The aggregated TRR found in the tissues accounted for 6.7% and 1.3% of the administered dose, for the occluded and non-occluded goats, respectively. The phosphorous moiety was mainly excreted as phosphates via urine.

Neither dichlorvos nor desmethyl dichlorvos, 2,2-dichloroacetic acid, 2,2 dichloroacetaldehyde and 2,2-dichloroethanol were present in tissues and milk. The dechlorinated vinyl portion of dichlorvos was incorporated into natural products such as glycerol, lactose and amino acids.

In dermally dosed laying hens TRR levels found in egg yolks ranged from < 0.014 to 0.863 mg/kg, and in egg whites ranged from 0.015 to 0.876 mg/kg., The parent dichlorvos (0.004 mg/kg, 1.1% of TRR) and des-methyl dichlorvos (0.039 mg/kg, 7.8% of TRR) were only present in breast muscle and fat following dermal treatment with grossly exaggerated dose (18.7 mg/kg bw) Consequently, these compounds would not be detectable under practical use conditions.

Animal transfer studies with exaggerated oral dose resulted in non-detectable residues in meat, liver, kidney and fat of cows, similarly no residue was detectable in poultry meat, fat, liver, kidney and eggs.

Dichlorvos concentration in/on treated plants declined rapidly partly by evaporation due to its high vapour pressure. The parent compound was the predominant residue immediately after application and degraded rapidly via (i) hydrolysis to form the major metabolite dimethyl phosphate and dichloroacetaldehyde; (ii) demethylation of dimethyl phosphate to monomethyl phosphate and inorganic phosphates; (iii) conversion of dichloroacetaldehyde to 2,2-dichloroethanol. The metabolites are conjugated and/or incorporated into naturally occurring plant components such as phosphorylated protein derivatives. The dimethyl phosphate is a common metabolite of several other pesticides.

Analytical methods are available for determining dichlorvos residues in plant and animal tissues, milk and eggs. In supervised trials on plant commodities the parent dichlorvos was the only residue component measured.

Dichlorvos residues are present in muscle at about 4 times higher concentration than in fat and are about equally distributed between egg yolk and egg white, Further, the parent dichlorvos has high water solubility (245 g/L) and log P_{ow} value of 2.

Based on the metabolism studies on plants and animals and availability of analytical methods, the Meeting recommended the following residue definition for dichlorvos.

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

The residue is not fat-soluble.

Residues deriving from post-harvest use of dichlorvos

Treatment of bagged, packed or covered commodities according to US GAP

The US GAP specifies a minimum of 7 day intervals between applications at 15–70 g ai/1000 m^3 except on cocoa beans and whole peanuts where daily applications should not exceed 18 g ai/1000 m^3 of head space. Bulk unpacked food and feed should be removed or covered before the treatment begins. The US GAP does not specify a withholding period. Therefore, the residues measured in bagged, packed and covered commodities can only be considered for estimating maximum residue levels when the trial conditions are compared to US GAP. The residues deriving from dichlorvos application according to US GAP are summarized below.

Following multiple treatments the residue levels generally increased with the number of dichlorvos applications and they were typically the highest in the samples taken from top boxes followed by those from the side and interior of the piles. Consequently, for estimating maximum residue levels only the highest residue was considered from each trial which included sequential sampling or sampling from different positions of the treated commodities.

Study 1: In a simulated warehouse experiment in USA four applications were made at one week intervals at the nominal maximum GAP rate of 70 g ai/1000 m^3 for each application. Thirteen commodities (breakfast cereal, cocoa beans, coffee beans, cookies, crackers, dried beans, field corn, flour, oats, peanuts, soya beans, sugar and walnuts) were selected for evaluation to provide data on typical residues to be expected following storage in the facility.

The commodities were kept in their commercial packing and were placed on pallets in three to five tiers with four to five bags per tier. Two replicate samples were taken from the top tier, opposite sides of the pallet and from the interior of the pallets about 6 hours after the pesticide application.

The highest average residues detected in bagged commodities after sequential treatments 1–4 were: breakfast cereals: 0.02 mg/kg; cocoa beans: < 0.01 mg/kg; coffee beans: 0.43 mg/kg; cookies: 0.06 mg/kg; crackers: 0.29 mg/kg; dried beans: 0.12 mg/kg; field corn: 0.66 mg/kg; flour: 0.45 mg/kg; oat: 0.65 mg/kg; peanut: 3.49 mg/kg; peanut nutmeat: 0.28 mg/kg; soya beans: 0.13 mg/kg; sugar: 0.04 mg/kg; walnut meat: < 0.01 mg/kg;

No residue was detectable in pre-treatment samples.

Study 2: Dichlorvos was applied weekly in USA for 21 weeks at a rate of about 53 g/1000 m^3 (0.76 × max GAP). Samples were collected before applications 2, 8 and 16 (1 week after last application) and 6 hours after applications 1, 3, 5, 9, 13, 17 and 21. The residues were determined with an enzyme inhibition method (LOQ 0.1 mg/kg). Though the surface of the bags contained relatively high dichlorvos residues, no residue (< 0.1 mg/kg) was determined in any samples of beans, flour, noodles, raisins, rice and sugar.

Detectable residues were present in wheat flour (0.1 mg/kg) and in peanut (1.6 mg/kg).

Study 3: Bulk commodities including cocoa beans, coffee beans, dried beans, field corn, flour, oats, soya beans, sugar, tree nuts (walnuts) and wheat were treated without cover in a simulated warehouse experiment at the maximum US GAP rate of 70 g ai/1000 m^3. Some of the commodities were covered with plastic sheet. Post-application samples were collected within a day of application.

The average residues measured in duplicate samples taken from tote bins covered with plastic sheets were: cocoa beans: < 0.01 mg/kg; coffee beans: 0.02 mg/kg; field corn: < 0.01 mg/kg; flour: 0.02 mg/kg; soya beans: < 0.01 mg/kg and sugar: < 0.01 mg/kg;

The samples taken before dichlorvos treatment did not contain detectable residues.

Studies conducted according to Australian GAP

In Australia, dichlorvos can be used as surface spray or fumigant for protection of stored grains, applying EC formulation at 6 g ai /t grain or 12 g ai/t grain with withholding periods of 7 and 28 days respectively. It can also be applied as fog at 70 g ai/1000 m^3 or 3.5 g ai/50 m^2.

Study 4: In laboratory scale experiments wheat (*ca.* 1 kg samples) was treated with dichlorvos at rates equivalent to 6 and 12 g ai/t and then the stored at 20 °C or 30 °C for up to 8 weeks in closed screw cap jars. The residues in stored wheat were 0.7 mg/kg, 2.8 mg/kg and 4.1 mg/kg 7 days after treatment at 6 g ai/t. The residues were 2.2 and 1.4 mg/kg four weeks after treatment at 12 g ai/t rate.

Study 5: Residues on stored paddy rice was studied at commercial rice storage facilities and laboratory scale experiments in Australia. Dichlorvos was applied to paddy rice at 6 or 12 g ai/t rate then paddy rice was stored for up to 28 days after application. Seven days after treatment at 6 g ai/t rate the residue was 2.9 mg/kg in paddy rice, while following 12 g ai/t treatment the residues were 1.9, 2.8 and 5.2 mg/kg 28 days after application.

Study 6: Dichlorvos was applied as a direct spray application with diluted EC formulation at 5, 10 and 15 g/t paddy rice in a jar and small bin tests. 30 days after the treatment with dichlorvos at 15 mg/kg rate, the paddy rice contained 0.87 mg/kg residue.

In summary, residues in commodities treated according to US GAP were

	Covered	Packed or bagged
Cocoa beans:	< 0.01 mg/kg	< 0.01 mg/kg
Coffee beans:	0.02 mg/kg	0.43 mg/kg
Dried beans:		0.12 mg/kg
Peanut		3.5 mg/kg 1.6 mg/kg
Soya beans:	< 0.01 mg/kg	0.13 mg/kg
Oats:		0.65 mg/kg
Field corn:	< 0.01 mg/kg	0.66 mg/kg
Walnuts:	< 0.01 mg/kg	< 0.01 mg/kg
Flour:	0.02 mg/kg	0.45 mg/kg
Sugar:	< 0.01 mg/kg	0.04 mg/kg

Because only one or two independent residue data are available for each commodity treated according to US GAP, the database is considered insufficient for the estimation of maximum residue levels.

The Meeting considered that the residues in wheat 7 and 28 days after treatments with 6 g ai/t and 12 g ai/t, respectively, were not different and could be combined.

In wheat treated according to Australian GAP the residues were: 0.7, 1.4, 2.2, 2.8 and 4.1 mg/kg.

The residues in paddy rice following treatments according to Australian use pattern were: 0.87, 1.9, 2.8, 2.9 and 5.2 mg/kg.

The residues in other cereal commodities can be expected to be in the same range because the decline of dichlorvos is mainly influenced by the moisture content of the grains and the temperature

of storage. Therefore, the residues in wheat should cover the expected residues in other cereal products except rice.

However, the Meeting noted that including cereal grains excluding rice would result in long-term intake of 220% of maximum ADI of 0.004 mg/kg. Therefore the Meeting recommends maximum residue levels, STMR and HR values wheat only and for rice and resulting processed products.

The Meeting estimated a maximum residue level of 7 mg/kg, HR of 4.1 and STMR of 2.2 mg/kg for wheat.

The Meeting estimated a maximum residue level of 7 mg/kg, HR of 5.2 and STMR of 2.8 mg/kg for rice.

The Meeting withdraws its previous recommendations for maximum residue levels of 5 mg/kg for cereal grains.

Fate of residues during processing

The effect of processing was studied on peanut, corn, wheat, rice, cotton seed and soya bean following treatment with dichlorvos at recommended or exaggerated rates.

Study P1: As part of the study on residues in bulk peanut an exaggerated 40× rate was used (843 g ai/1000 m^3). The whole peanut samples were processed into fractions of meal, crude oil, refined oil, and soapstock.

Study P2: Field corn, wheat, rice, cotton seed, and soya beans were treated with dichlorvos at an exaggerated 12× rate of 842 g ai/1000 m^3 in a simulated warehouse. The treated commodities were processed in a pilot scale facility applying methods representing the industrial practice as close as possible.

Study P3: Residues in various wheat grain and milled products were determined in pilot scale trials (2 tonnes of grain treated at each rate). Wheat was treated with dichlorvos at rates of 6, 12 and 20 g ai/t. From the milled products noodles and breads were prepared.

Study P4: Winter wheat was treated at a 15 g ai/t calculated deposit rate. Samples were collected after 0, 0.5, 1, 2, 3, 4, 5, 6, 8, 12, and 16 weeks of storage. The dichlorvos residues were determined in the milling fractions and in bread made from the patent flour fraction.

Study P5: Rice was treated at 12 g ai/t in 2 commercial scale trials and 6 or 12 g ai/t in laboratory scale trials. Dichlorvos residues were determined in paddy rice, brown rice, white rice, hulls and bran by GC.

*Study P6***:** Soya beans were treated with water emulsion of dichlorvos at an intended rate of 20 g ai/t. After 7 days the treated beans were milled and the meal extracted for oil with large-scale laboratory equipment representing the industrial process.

Study 7: Potatoes were sprayed with a mixed solution containing dichlorvos. Initial residues in unwashed potatoes were 0.92 mg/kg. Washing for 1 minute in water removed > 96% of residues. No dichlorvos residues (< 0.001 mg/kg) were detected in wet or dry starch.

The processing factors (P_f) calculated from the studies are summarized in the following table. Factors are indicated with a "<" (less than) sign when the residue in the processed commodity is below the LOQ of the analytical method. The calculation is then made with the LOQ of the analytical method and the residue concentration of the RAC (raw agricultural commodity).

Treated commodity (RAC)	Processed commodity	P_f Median or best estimate	RAC STMR/HR	STMR-P/HR-P	
Whole wheat (Study P3)	Bran	1.73	2.2, 4.1	3.81	7.09
	Germ	1.02		2.24	4.18
	Flour	0.10		0.22	0.41

	Whole meal flour	0.40		0.88	1.64
Whole wheat (Study P4)	Bran	1.78	2.2, 4.1	3.92	7.30
	Flour low grade	0.10		0.23	0.42
	Patent flour	0.09		0.20	0.38
	Bread	1.00		0.88	1.64
White flour (Study 3)	White bread	0.33	2.2 4.1	0.073	0.14
	White noodles	0.6		0.132	0.25
Whole meal flour	Whole meal bread	0.14		0.123	0.23
	Flat bread	2.25		1.98	3.69
Whole rice (Study 2 and Study 5)	Polished rice	0.005	2.8, 5.2	0.014	0.03
	Brown rice	0.16		0.448	0.83
	Hulls	5.47		15.3	28.4
	Bran	1.05		2.94	5.46

Based on the residues measured in cereal grains and taking into account the best estimates for the processing factors, the Meeting estimated maximum residue levels for: rice polished 0.15 mg/kg, rice husked: 1.5 mg/kg and rice bran: 15 mg/kg,

The Meeting withdraws its previous recommendations for maximum residue levels of 1 mg/kg for wheat flour, 10 mg/kg for wheat germ and 2 mg/kg for wheat wholemeal.

Residues in animal commodities

Farm animal dietary burden

The Meeting estimated the dietary burden of dichlorvos in livestock on the basis of the diets listed in OECD Feed Table 2009 (available from the FAO website: http//www.fao.org/agriculture/crops/core-themes/theme/pests/pm/jmpr/jmpr-docs/en/). Calculation from highest residue, STMR and STMP-P values provides the 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 layer are provided in Annex 6 and summarized below.

	Animal dietary burden, dichlorvos, ppm of dry matter diet							
	US-Canada		EU		Australia		Japan	
	Max	Mean	Max	Mean	Max	Mean	Max	Mean
Beef cattle	2.40	2.40	2.31	2.31	4.16[a]	4.16[b]	3.04	3.04
Dairy cattle	1.96	1.96	2.31	2.31	3.66[c]	3.66	1.98	2.23
Poultry - broiler	3.58[d]	3.58	2.61	2.61	2.96	2.96	0.22	0.47
Poultry - layer	3.58	3.58[e]	2.61	2.61	2.59	2.59	1.32	1.32

[a] Highest maximum beef or dairy cattle dietary burden suitable for MRL estimates for mammalian meat and mammalian milk.

[b] Highest mean beef or dairy cattle dietary burden suitable for STMR estimates for mammalian meat and mammalian milk.

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

[d] Highest maximum poultry dietary burden suitable for MRL estimates for poultry meat and eggs.

[e] Highest mean poultry dietary burden suitable for STMR estimates for poultry meat and eggs.

Farm animal feeding studies

Dairy cows

Nine Holstein cows were orally dosed with encapsulated test material for 28 days at 2, 6, and 20 ppm levels based on dry matters.

Milk samples were collected in the morning and in the evening daily for 28 days. Equal portions of morning and evening milk were composited and then analysed.

Within 15 hours after administering the last dose, all cows were sacrificed muscle, perirenal and omental fat, liver, and kidneys samples were collected.

The LOQ of the method was 0.01 mg/kg for all matrices. No detectable dichlorvos residue was present in any of the samples.

Laying hens

Thirty two white leghorn laying hens were orally dosed with encapsulated dichlorvos for 42 days at nominal dose rates of 0, 2.0, 6.0 and 20 ppm for 42 days. Each capsule contained half a dose and each hen received two capsules per day, one in the morning and one in the evening. Nominal dose concentrations were 0.0 ppm (controls), 2.0 ppm, 6.0 ppm and 20.0 ppm.

Eggs were sampled from 1 to 42 days. Whole eggs (yolks and albumin) were collected as one sample and egg shells were discarded. Eggs within each group were pooled to form one composite sample and weighed.

All hens were sacrificed on day 43, and muscle (breast and thigh), liver, peritoneal fat, and kidneys tissues were collected from each hen.

None of the egg or tissue samples contained detectable residues. The LOQ of the methods was 0.01 mg/kg.

Animal commodity maximum residue levels

Animal feeding studies indicated that there was no detectable residue in milk, meat, eggs and edible offal even at exaggerated continuous dose of 20 ppm in feed on dry weight basis, which was about 5 times higher than the calculated maximum animal burden. The Meeting noted that the metabolism study following dermal application at extreme dose rate revealed that dichlorvos residues may occur at trace levels in poultry tissues. However, it was concluded that dichlorvos residues would not be present under practical conditions.

The Meeting estimated maximum residue level of 0.01* mg/kg for meet, fat and edible offal of mammals and poultry, and mammalian milks and eggs. The estimated HR and STMR values for animal commodities are 0 mg/kg.

DIETARY RISK ASSESSMENT

Long-term intake

The evaluation of dichlorvos resulted in recommendations for MRLs and STMR values for raw and processed commodities. The residue data were used to calculate dietary intake. The results are shown in Annex 3.

The International Estimated Daily Intakes (IEDIs) of dichlorvos, based on the STMRs estimated, were 5–30% of the maximum ADI of 0.004 mg/kg bw for the thirteen GEMS/Food cluster diets. The Meeting concluded that the long-term intake of residues of dichlorvos resulting from its uses that have been considered by JMPR unlikely to present a public health concern.

Short-term intake

The IESTI of dichlorvos calculated on the basis of the recommendations made by the JMPR was from 80% of the ARfD (0.1 mg/kg bw) for children and 60% of the general population.

The Meeting concluded that the short-term intake of residues of dichlorvos resulting from its uses that have been considered by JMPR unlikely to present a public health concern.

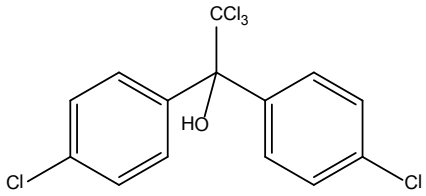
5.12 DICOFOL (026)

RESIDUE AND ANALYTICAL ASPECTS

Dicofol is an organochlorine acaricide. It was evaluated by JMPR 1968 (T, R), 1992 (T,R), 1994 (R), 2011(T). It was evaluated for toxicological review by JMPR in 2011 as a periodic re-evaluation chemical. The ADI for dicofol was established as 0–0.002 mg/kg.bw and acute reference dose was 0.2 mg/kg bw. Dicofol was scheduled at the Forty-third Session of the CCPR for the periodic re-evaluation of residues by the 2012 Meeting of the JMPR.

Structure

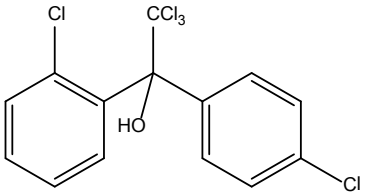
Common name: Chemical name



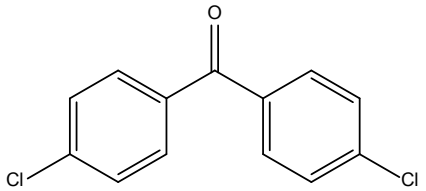
p,p′-dicofol: 1,1-bis(4-chlorophenyl)-2,2,2-trichloroethanol

Structure

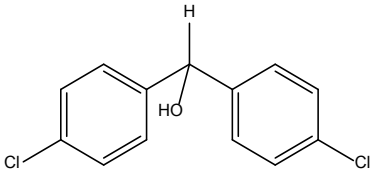
Common name: Chemical name



o,p′-dicofol: 1-(2-chlorophenyl)-1-(4-chlorophenyl)-2,2,2-trichloroethanol



DCBP: Dichlorobenzophenone



DCBH: Dichlorobenzhydrol

Technical dicofol is a 80:20 mixture of p,p'-dicofol and o,p'-dicofol. The major impurities are DDT and related contaminants. No information was provided regarding the level of these impurities.

Plant Metabolism

Information on plant metabolism was taken from the 1992 JMPR evaluation, supplemented by the original plant metabolism study reports. Translocation studies were provided for bean and grapefruit, and metabolism studies were provided for tomato and cotton. The studies indicate that dicofol is primarily a surface residue that does not translocate in plants, and that parent is the predominant residue, comprising 50% TRR in grapefruit five months after treatment.

The tomato metabolism study involved treatment of ^{14}C-labeled p,p′-dicofol and o,p′-dicofol in separate experiments. The metabolites DCBP and DCBH were detected in tomatoes 21 days after treatment, but less was formed from the major dicofol isomer, p,p′-dicofol, than from o,p′-dicofol. Less than 1% TRR was comprised on DCBP and DCBH in the p,p′-dicofol experiment, while the sum of DCBP and DCBH totaled about 11% TRR in the o,p′-dicofol experiment.

Similar results were obtained in the cotton metabolism studies, although these experiments involved sampling 72 days after treatment and demonstrated relatively more conversion of dicofol into its DCBP and DCBH metabolites than observed in the tomato metabolism studies.

Methods of residue analysis

The method involves re-hydration of the dry tea leaves with distilled water and extraction with a 4:1 v/v mixture of n-hexane and acetone. Residues were partitioned into hexane and extracts cleaned with alumina. Quantitation of the cleaned extracts was by GLC-ECD using a fused silica open tubular wide bore capillary column coated with DB-5. The limit of quantitation was 0.02 mg/kg. Method validation was demonstrated up to 5 mg/kg.

Stability of residues in stored analytical samples

Residues in stored samples were demonstrated to be stable over the storage intervals involved in the magnitude of the residue studies.

Definition of the residue

The available plant metabolism and translocation studies demonstrate that dicofol is primarily a surface residue that does not translocate. Dicofol comprised the major portion of the residue, with some conversion to the metabolites DCBP and DCBH over time. In tomato experiments with a 21 day PHI, < 1% TRR was found as DCBP and DCBH in the p,p'-dicofol experiment, while DCBP and DCBH comprised approximately 11% TRR in the o,p'-dicofol experiment. As the GAP for tea in India lists a 7 day PHI, less conversion to the dicofol metabolites is expected in tea than observed in the tomato metabolism studies. The Meeting agreed that parent dicofol is the appropriate residue for enforcement and dietary risk assessment.

Dicofol has a log K_{ow} of 4.3.

No animal metabolism data were submitted. As tea is not a livestock feedstuff, the Meeting agreed that a residue definition for animals is not currently required. However, for future uses on plant commodities that are livestock feedstuffs, animal metabolism studies will be necessary.

The Meeting recommended the following residue definition for dicofol

For plants: Definition of the residue (for compliance with the MRL and for estimation of dietary intake): *dicofol (sum of o,p′ and p,p′ isomers)*

Results of supervised residue trials on crops

The Meeting received supervised field trial data for dicofol uses on tea from India; and tea monitoring data from Morocco. The Meeting noted that no information regarding the levels of DDT in tea, as a result of its possible presence as a contaminant in the technical grade dicofol, was provided in the residue trials.

The OECD MRL calculator was used as a tool in the estimation of the maximum residue level from the selected residue data set obtained from trials conducted according to proposed GAP. As a first step, the Meeting reviewed all relevant factors related to each data set in arriving at a best estimate of the maximum residue level using expert judgement. Then, the OECD calculator was employed. If the statistical calculation spreadsheet suggested a different value from that recommended by the JMPR, a brief explanation of the deviation was provided.

Tea

The GAP in India for tea allows the use of dicofol as one foliar treatment at a rate of 0.19 kg ai/ha, and harvest of fruit 7 days after application (7-day PHI). Trials were conducted at four sites in India during both the dry and wet seasons.

Rank-order dicofol residue concentrations in tea from dry season Indian trials were: 9.7, 13, 15.5, and 15.6 mg/kg.

Rank-order dicofol residue concentrations in tea from wet season Indian trials were: 1.9, 4.1, 9.2, and 14.4 mg/kg.

Residue data with suitable GAP were available for tea. Noting the overlap between the residue levels in tea samples, the Meeting decided to combine the results for the purposes of estimating dicofol residue levels in tea. Thus, the rank-order dicofol residue concentrations in tea were: 1.9, 4.1, 9.2, 9.7, 12.6, 14.4, 15.5, and 15.6 mg/kg.

The Meeting estimated a maximum residue level of 40 mg/kg for residues of dicofol in tea, green and black. The Meeting estimated STMR and HR values of 11.2 and 15.6 mg/kg, respectively, for dicofol residues in tea. The Meeting withdraws its previous maximum residue level recommendation of 50 mg/kg for dicofol in tea, green and black.

Green Tea Monitoring Data from Morocco

The highest dicofol level found in green tea samples from Morocco over the years 2000–2011 was 6.7 mg/kg.

Fate of residues during processing

The transfer of dicofol residues from made tea to tea brew was studied. The tea brew processing factor was 0.016.

DIETARY RISK ASSESSMENT

Long-term intake

The ADI for dicofol is 0–0.002 mg/kg bw. The International Estimated Daily Intake (IEDI) for dicofol was estimated for the 13 GEMS/Food cluster diets using the STMR values estimated by the current Meeting. The results are shown in Annex 3. The IEDI ranged from 1–30% of the maximum ADI. The Meeting concluded that the long-term intake of residues of dicofol, from uses that have been considered by the JMPR, is unlikely to present a public health concern.

Short-term intake

The ARfD for dicofol is 0.2 mg/kg bw. The International Estimated Short Term Intake (IESTI) for dicofol was calculated for the plant commodities for which STMRs and HRs were estimated and for which consumption data were available. The results are shown in Annex 4. The IESTI calculated for dicofol represented 0 and 20% of the ARfD for brewed tea and tea leaf, respectively. The Meeting concluded that the short-term intake of residues of dicofol, from uses that have been considered by the JMPR, is unlikely to present a public health concern.

5.13 DINOTEFURAN (255)

TOXICOLOGY

Dinotefuran is the ISO-approved common name for (*EZ*)-(*RS*)-1-methyl-2-nitro-3-(tetrahydro-3-furylmethyl)guanidine (IUPAC) (CAS No. 165252-70-0), a novel neonicotinic insecticide used in various crops. Dinotefuran acts as an agonist at the insect nicotinic acetylcholine receptor and exhibits broad insecticidal activity via ingestion and contact. Dinotefuran has not been evaluated previously by JMPR and was reviewed at the present Meeting at the request of CCPR.

All critical studies were certified as complying with GLP.

Biochemical aspects

In rats given ^{14}C-tetrahydrofuran-labelled or ^{14}C-guanidine-labelled dinotefuran orally by gavage, absorption was rapid and accounted for at least 88% of the total administered radioactivity after a single low dose (50 mg/kg bw) or high dose (1000 mg/kg bw). The maximum plasma concentrations of radioactivity were reached after approximately 0.5 and 2 hours after administration of the low and high doses, respectively, whereas the half-lives in plasma ranged from 4 to 15 hours for the low and high doses, respectively. Radioactivity was widely distributed throughout the body. Elimination of the radioactivity was mainly via urine (≥ 88% of the administered dose), whereas elimination via faeces accounted for 1–3% after oral administration and 1% after intravenous administration. Residues in tissues 168 hours after a single oral or intravenous dose as well as after repeated oral dosing accounted for less than 0.5% of the administered radioactivity, and the concentrations in most tissues were below the limit of detection (0.001 ppm).

Metabolism of dinotefuran in rats was limited, with more than 90% of the dose being eliminated as unchanged parent molecule, which was also the major component in plasma, milk, bile and most tissues collected 4–8 hours after administration. About 20 metabolites were identified; the metabolic routes included hydroxylation on the tetrahydrofuran ring, followed by further oxidation, reduction and acetylation. Other routes of metabolism involved desmethylation, nitro-reduction and hydrolysis.

Toxicological data

The LD_{50} in rats treated orally with dinotefuran was 2450 mg/kg bw. The dermal LD_{50} in rats was greater than 2000 mg/kg bw, and the inhalation LC_{50} in rats was greater than 4.09 mg/L. Dinotefuran was not a skin irritant in rabbits, was slightly irritating to the eye of rabbits and was not a skin sensitizer in the maximization test in guinea-pigs.

Although dinotefuran is neurotoxic in insects, neurotoxicity in mammals was not a critical effect after repeated exposure. No specific target organs were clearly identified in any species following short-term or long-term oral exposure, despite the administration of very high doses of up to 10 635, 3156 and 862 mg/kg bw per day for 13 weeks in mice, rats and dogs, respectively. In all species, the NOAELs were based on decreases in body weight and/or body weight gain as the critical effect. At higher dose levels, a number of minor effects on clinical chemistry parameters, without histopathological correlates, occurred in all species and comprised increased serum albumin concentration and reduced urinary pH in mice, increased serum cholesterol and urea nitrogen concentrations and reduced serum glucose and protein concentrations in rats, and reduced urinary pH in dogs.

In a 4-week study in mice, the NOAEL was 5000 ppm (equal to 901 mg/kg bw per day), based on reduced body weight gain at 25 000 ppm (equal to 4612 mg/kg bw per day) and above. In a 13-week study in mice, the NOAEL was 25 000 ppm (equal to 4442 mg/kg bw per day), based on reduced body weight and body weight gain at 50 000 ppm (equal to 10 635 mg/kg bw per day).

In a 4-week study in rats, the NOAEL was 5000 ppm (equal to 390 mg/kg bw per day), based on reduced body weight gain and increased serum cholesterol in males at 25 000 ppm (equal to

1814 mg/kg bw per day) and above. In a 13-week study in rats, the NOAEL was 500 ppm (equal to 38 mg/kg bw per day), based on reduced body weight and body weight gain at 5000 ppm (equal to 384 mg/kg bw per day) and above in females.

In a 13-week feeding study in dogs, a NOAEL could not be identified; the LOAEL was 1600 ppm (equal to 58 mg/kg bw per day) in females, based on a reduction in feed consumption, body weight and body weight gain at all doses administered. In males, the NOAEL was 8000 ppm (equal to 307 mg/kg bw per day), based on a reduction in feed and water consumption, body weight and body weight gain at 24 000–40 000 ppm (equal to an average dose of 862 mg/kg bw per day). In a 1-year feeding study in dogs, the NOAEL was 640 ppm (equal to 22 mg/kg bw per day) in females, based on a reduction in feed consumption, body weight and body weight gain at 3200 ppm (equal to 108 mg/kg bw per day) and above. In males, the NOAEL was 3200 ppm (equal to 111 mg/kg bw per day), based on a reduction in body weight gain at 16 000 ppm (equal to 559 mg/kg bw per day).

Long-term studies of toxicity and carcinogenicity were conducted in mice and rats. In a 78-week study of carcinogenicity in mice, there was no evidence for carcinogenicity up to the highest dose tested (25 000 ppm, equal to 3694 mg/kg bw per day). The NOAEL for toxicity was 2500 ppm (equal to 345 mg/kg bw per day), based on reduced body weight and body weight gain at 25 000 ppm.

In a 104-week study of toxicity and carcinogenicity in rats, there was no evidence for carcinogenicity up to the highest dose tested (20 000 ppm, equal to 991 mg/kg bw per day). The NOAEL for toxicity was 2000 ppm (equal to 100 mg/kg bw per day), based on a reduction in body weight, body weight gain and feed consumption at 20 000 ppm.

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

Dinotefuran was tested for genotoxicity in vitro and in vivo in an adequate range of assays. It was not found to be genotoxic.

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

In a two-generation study of reproductive toxicity in rats, the NOAEL for reproductive toxicity was 10 000 ppm (equal to 822 mg/kg bw per day), the highest dose tested, whereas a reduced number of implantations, increased post-implantation loss and reduced litter size were observed in a range-finding study at 20 000 ppm (equal to 1340 mg/kg bw per day). The NOAEL for parental toxicity was 3000 ppm (equal to 241 mg/kg bw per day), based on a reduction in feed consumption, body weight and spleen weight at 10 000 ppm. The NOAEL for offspring toxicity was 3000 ppm, based on reduced pup weight gain during lactation and reduced spleen weight at 10 000 ppm.

In a developmental toxicity study in rats, the NOAEL for maternal toxicity was 300 mg/kg bw per day, based on decreased weight gain and feed consumption and increased water consumption at 1000 mg/kg bw per day. The NOAEL for developmental toxicity was 1000 mg/kg bw per day, the highest dose tested.

In a developmental toxicity study in rabbits, acute clinical signs (hypoactivity, prone position, panting, erythema, tremor) were observed in dams at 300 mg/kg bw per day from the start of treatment at gestation day 6 until gestation day 13; the NOAEL was 125 mg/kg bw per day. Also in dams, a reduction in body weight gain was noted at 125 mg/kg bw per day and above, with a NOAEL of 52 mg/kg bw per day. The NOAEL for developmental toxicity was 300 mg/kg bw per day, the highest dose tested.

The Meeting concluded that dinotefuran was not teratogenic in rats or rabbits.

In an acute neurotoxicity study in rats, the NOAEL was 750 mg/kg bw, based on a transient decrease in motor activity at 1500 mg/kg bw. There was no evidence for neuropathological effects up to the highest dose tested (1500 mg/kg bw).

In a 13-week neurotoxicity study in rats, a transient decrease in motor activity was observed in females at 50 000 ppm (equal to 3806 mg/kg bw per day), which is well above the limit dose. The

NOAEL for the study was 5000 ppm (equal to 327 mg/kg bw per day), based on reduced body weight gain and feed consumption at 50 000 ppm.

In a dose range–finding developmental neurotoxicity and immunotoxicity study in rats, there was no evidence for developmental neurotoxicity or immunotoxicity up to the highest dose tested (10 000 ppm, equal to 1043 mg/kg bw per day). The NOAEL for maternal toxicity was 10 000 ppm (equal to 670 mg/kg bw per day), the highest dose tested, whereas the NOAEL for offspring toxicity was 3000 ppm (equal to 311 mg/kg bw per day), based on reduced body weight and body weight gain at 10 000 ppm.

In a developmental neurotoxicity study in rats, there was no evidence for developmental neurotoxicity up to the highest dose tested (10 000 ppm, equal to 784 mg/kg bw per day). The NOAEL for maternal toxicity was 3000 ppm (equal to 237 mg/kg bw per day), based on reduced body weight gain at 10 000 ppm.

In 4-week immunotoxicity studies in mice and rats, there was no evidence for immunotoxicity up to the highest dose tested (7000 ppm in mice, equal to 1053 mg/kg bw per day; 14 000 ppm in rats, equal to 992 mg/kg bw per day). The NOAELs for systemic toxicity were 2800 and 5600 ppm (equal to 405 and 425 mg/kg bw per day, respectively) in mice and rats, respectively, based on decreased body weight gain at 7000 and 14 000 ppm, respectively.

There were no reports of adverse health effects in manufacturing plant personnel. Also, there were no reports of poisonings with dinotefuran.

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

Toxicological evaluation

The Meeting established an ADI for dinotefuran of 0–0.2 mg/kg bw, based on the NOAEL of 22 mg/kg bw per day for reduced body weight/body weight gain in female dogs in a 1-year toxicity study and application of a safety factor of 100.

The Meeting established an ARfD for dinotefuran of 1 mg/kg bw, based on the NOAEL of 125 mg/kg bw for acute clinical signs observed in dams after a single dose of 300 mg/kg bw in a developmental toxicity study in rabbits. A 100-fold safety factor was applied.

A toxicological monograph was prepared.

Levels relevant to risk assessment

Species	Study	Effect	NOAEL	LOAEL
Mouse	Eighteen-month study of toxicity and carcinogenicity[a]	Toxicity	2500 ppm, equal to 345 mg/kg bw per day	25 000 ppm, equal to 3694 mg/kg bw per day
		Carcinogenicity	25 000 ppm, equal to 3694 mg/kg bw per day[b]	—
Rat	Two-year study of toxicity and carcinogenicity[a]	Toxicity	2000 ppm, equal to 100 mg/kg bw per day	20 000 ppm, equal to 991 mg/kg bw per day
		Carcinogenicity	20 000 ppm, equal to 991 mg/kg bw per day[b]	—
	Two-generation study of reproductive toxicity[a]	Reproductive toxicity	10 000 ppm, equal to 822 mg/kg bw per day[b]	—
		Parental toxicity	3000 ppm, equal to 241 mg/kg bw per day	10 000 ppm, equal to 822 mg/kg bw per day
		Offspring toxicity	3000 ppm, equal to 241 mg/kg bw per day	10 000 ppm, equal to 822 mg/kg bw per day
	Developmental toxicity study[c]	Maternal toxicity	300 mg/kg bw per day	1000 mg/kg bw per day
		Embryo and fetal toxicity	1000 mg/kg bw per day[b]	—
Rabbit	Developmental toxicity study[c]	Maternal toxicity	125 mg/kg bw per day[d] 52 mg/kg bw per day[e]	300 mg/kg bw per day 125 mg/kg bw per day

Species	Study	Effect	NOAEL	LOAEL
		Embryo and fetal toxicity	300 mg/kg bw per day[b]	—
Dog	Thirteen-week and 1-year studies of toxicity[a,f]	Toxicity	640 ppm, equal to 22 mg/kg bw per day	1600 ppm, equal to 58 mg/kg bw per day

[a] Dietary administration.
[b] Highest dose tested.
[c] Gavage administration.
[d] NOAEL for acute clinical signs.
[e] NOAEL for maternal toxicity.
[f] Two studies combined.

Estimate of acceptable daily intake for humans

0–0.2 mg/kg bw

Estimate of acute reference dose

1 mg/kg bw

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

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

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

Absorption, distribution, excretion and metabolism in mammals	
Rate and extent of oral absorption	Rapid; ≥ 88%
Dermal absorption	No data
Distribution	Widely distributed; highest concentrations in kidney and urine
Potential for accumulation	None
Rate and extent of excretion	≥ 93% within 168 h (≥ 88% in urine; 1–3% in faeces; 1–6% in cage rinse)
Metabolism in animals	Limited (> 90% eliminated as parent); hydroxylation on the tetrahydrofuran ring, followed by oxidation, reduction and acetylation; other routes include desmethylation, nitro-reduction and hydrolysis
Toxicologically significant compounds in animals, plants and the environment	Dinotefuran
Acute toxicity	
Rat, LD_{50}, oral	2450 mg/kg bw
Rat, LD_{50}, dermal	> 2000 mg/kg bw
Rat, LC_{50}, inhalation	> 4.09 mg/L (4 h, nose-only exposure)
Rabbit, dermal irritation	Not irritating
Rabbit, ocular irritation	Slightly irritating
Dermal sensitization	Not sensitizing (maximization test)
Short-term studies of toxicity	
Target/critical effect	Reduced body weight gain
Lowest relevant oral NOAEL	22 mg/kg bw per day (1-year study in dogs)
Lowest relevant dermal NOAEL	1000 mg/kg bw per day (28-day study in rats)
Lowest relevant inhalation NOAEC	0.22 mg/L (28-day study in rats)
Long-term studies of toxicity and carcinogenicity	
Target/critical effect	Reduced body weight gain
Lowest relevant NOAEL	100 mg/kg bw per day (2-year study in rats)
Carcinogenicity	Not carcinogenic in mice or rats
Genotoxicity	
	Not genotoxic

Reproductive toxicity	
Target/critical effect	No reproductive toxicity; reduced pup weight gain and reduced spleen weight at parentally toxic dose
Lowest relevant reproductive NOAEL	822 mg/kg bw per day (highest dose tested)
Lowest relevant parental NOAEL	241 mg/kg bw per day
Lowest relevant offspring NOAEL	241 mg/kg bw per day
Developmental toxicity	
Target/critical effect	No evidence for developmental toxicity (rats and rabbits)
Lowest relevant maternal NOAEL	52 mg/kg bw per day (rabbits)
Lowest relevant embryo/fetal NOAEL	300 mg/kg bw per day (rabbits) (highest dose tested)
Neurotoxicity	
Acute and subchronic neurotoxicity	No specific signs of acute or subchronic neurotoxicity at highest dose tested (acute: 1500 mg/kg bw; subchronic: 3806 mg/kg bw per day)
Developmental neurotoxicity	No evidence for developmental neurotoxicity at highest dose tested (784 mg/kg bw per day)
Other toxicological studies	
Immunotoxicity	No evidence for immunotoxicity at highest dose tested (1053 mg/kg bw per day in mice; 992 mg/kg bw per day in rats)
Developmental immunotoxicity	No evidence for developmental immunotoxicity at highest dose tested (670 mg/kg bw per day)
Medical data	
	No adverse health effects reported in manufacturing plant personnel

Summary

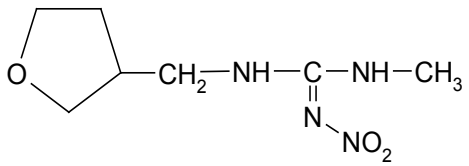
	Value	Study	Safety factor
ADI	0–0.2 mg/kg bw	One-year study of toxicity in dogs	100
ARfD	1 mg/kg bw	Developmental toxicity study in rabbits (acute clinical signs in dams)	100

RESIDUE AND ANALYTICAL ASPECTS

Residue and analytical aspects of dinotefuran were considered for the first time by the present Meeting. The residue evaluation was scheduled for the 2012 JMPR by the Forty-third Session of the CCPR (ALINORM 11/34/24)

Dinotefuran is an insecticide used for the control a range of sucking insects, such as whiteflies, plant bugs, leafhoppers and mealybugs, in vegetables, fruit, paddy rice and turf. The formulated products can be applied to foliage, soil, nursery boxes and to paddy water by spray, drench, broadcast and 'pricking-in-hole' treatment. The Meeting received information on identity, animal and plant metabolism, environmental fate in soil, rotational crops, analytical methods, storage stability, use patterns, supervised trials, farm animal feeding studies and fate of residues in processing.

(*RS*)-1-methyl-2-nitro-3-(tetrahydro-3-furylmethyl) guanidine



Dinotefuran is a 1:1 mixture of the enantiomers.

In this appraisal, the following abbreviated names were used for the various metabolites.

UF	1-methyl-3-(tetrahydro-3-furylmethyl) urea
DN	1-methyl-3-(tetrahydro-3- furylmethyl) guanidium dihydrogen
446-DO	1-[4-hydroxy-2-(hydroxymethyl) butyl]-3-methyl-2-nitroguanidine
FNG	2-nitro-1-(tetrahydro-3-furylmethyl) guanidine
PHP	6-hydroxy-5-(2-hydroxyethyl)-1-methyl-1, 3-diazinane-2-ylidene-N-nitroamine
MNG	1-methyl-2-nitroguanidine
NG	Nitroguanidine
MG	1-methylguanidine
BCDN	3-(methylamino)-9-oxa-2-aza-4-azoniabicyclo [4.3.0] non-3-ene hydrogen
UF-DO	1-[4-hydroxy-2-(hydroxymethyl) butyl]-3-methylurea
DN-OH	1-(2-hydroxytetrahydro-3-furylmethyl)-3-methylguanidine (DN-2-OH) or 1-(3-hydroxytetrahydro-3-furylmethyl)-3-methylguanidine (DN-3-OH)

Animal metabolism

The Meeting received animal metabolism studies with dinotefuran in rats, lactating goats and laying hens. The metabolism and distribution of dinotefuran in animals were investigated using the [^{14}C-furanyl] and [^{14}C-guanidine]-labelled dinotefuran.

Metabolism in rats was summarized and evaluated by the WHO panel of the JMPR in 2012.

Lactating goats were dosed with ^{14}C-furanyl and ^{14}C-guanidine dinotefuran at a dose equivalent to approximately 10 ppm in the diet once daily for 5 consecutive days. Gelatin capsules containing ^{14}C-furanyl and ^{14}C-guanidine dinotefuran were administered orally via a balling gun. The majority of the dose was rapidly excreted in urine and faeces. Radioactive residues in the faeces, cage wash and urine accounted for 81.9% of the total administered dose.

Total ^{14}C residues in the milk accounted for 0.3% of the administered dose. Tissues contained approximately 1.1% of the administered dose. The remaining 16.6% of the administered radioactivity resided in the gastrointestinal tract and its contents.

The total radioactive residue (TRR) levels in milk reached a steady state of approximately 0.045 mg eq./kg by Day 2 of dosing. The residue levels detected in milk, liver, kidney, fat, muscle, blood and heart were 0.012–0.27 mg eq./kg and accounted for 0.01–0.73% of the administered dose.

Dinotefuran was the major component in milk (40.1% TRR, 0.018 mg/kg) with a number of minor metabolites (PHP, 446-DO, UF and FNG) detected but all were < 10% TRR and < 0.005 mg eq./kg. Bound residues were accounted for only 0.001 mg eq./kg in the post extraction solids (PES).

Dinotefuran was present as the major residue in muscle (0.018 mg/kg, 41.3% TRR), fat (0.002 mg/kg, 20.0% TRR), liver (0.017 mg/kg, 12.1% TRR) and kidney (0.035 mg/kg, 12.7% TRR). UF was also a major metabolite in muscle (0.006 mg eq./kg, 14.6% TRR). FNG was the major metabolite detected in the kidney (0.055 mg eq./kg, 20.1% TRR). No other individual compounds accounted for more than 10% of TRR in the tissues.

Laying hens were orally dosed with ^{14}C-furanyl and ^{14}C-guanidine dinotefuran at a dose equivalent to 10 ppm in the feed for 5 consecutive days. The majority of the dose was rapidly eliminated in the excreta. Radioactive residues in the excreta and cage wash accounted for 88.9% of the total administered dose.

Total ^{14}C residues in the eggs accounted for 0.07% (0.02% in the yolk and 0.05% in the white) of the administered dose. Tissues contained approximately 0.23% of the administered dose. The gastrointestinal tract and its contents accounted for 1.31% of the administered radioactivity residues. The residue levels detected in egg white, egg yolk, liver, fat, muscle and blood were 0.007–0.13 mg eq./kg and accounted for 0.01–0.12% of the administered dose.

Dinotefuran was the major residue component at 57.0% TRR (0.013 mg/kg) in egg white and 44.2% TRR (0.0071 mg/kg) in egg yolk. FNG was only metabolite in egg white (0.0030 mg eq./kg, 13.1% TRR) and egg yolk (0.0013 mg eq./kg, 8.0% TRR). All other components were detected at < 0.003 mg eq./kg in egg white and egg yolk. Bound residues were accounted for only 0.0012–0.0028 mg eq./kg in the post-extraction solids (PES).

Dinotefuran was detected at 9.1% TRR (0.0049 mg/kg) in muscle, 10.8% TRR (0.0012 mg/kg) in fat and 9.3% TRR (0.011 mg/kg) in liver. Minor metabolites FNG, UF and DN were identified at 2.2–7.4% TRR (0.0006–0.0080 mg eq./kg) in muscle, fat and liver (DN was not detected in fat). All other components were also detected at < 0.01 mg eq./kg in those tissues.

In animal metabolism studies, dinotefuran was metabolized to several compounds. Dinotefuran was the most important component in milk and muscle for lactating goat, and in eggs for laying hens.

Plant metabolism

The Meeting received plant metabolism studies performed on apples, lettuce, rice and oilseed rape with dinotefuran ^{14}C-labeled in two positions (^{14}C-furanyl and ^{14}C-guanidine).

In an apple metabolism study under field conditions, apple trees were treated with a foliar spray using a 20% SG formulation at a nominal rate of 200 g ai/ha (1× rate) on one tree and at an exaggerated rate treatment at 2000 g ai/ha (10× rate) on the second tree to generate metabolites for identification. The trees were treated 21 days before mature fruit harvest.

The overall residue levels (TRR) in the harvested apples were 0.15 mg/kg for fruits from the apple tree treated at the nominal application rate (1×) and 1.9 mg/kg in apples from exaggerated rate (10×) treatment. Dinotefuran was one of the major ^{14}C residues present and accounted for approximately 29–33% (0.044–0.63 mg/kg) of the total radioactivity in the harvested apples. UF was identified as the major metabolite, accounted for 0.031 mg/kg, 20.0% TRR at 1× rate and 0.40 mg/kg, 20.9% TRR at 10× rate. DN was also identified at a concentration ranging from 0.016 mg/kg, 10.4% TRR at 1× rate and 0.13 mg/kg, 6.9% TRR at 10× rate. PHP was also present at > 10% TRR (0.021 mg/kg, 13.5% TRR from 1×; 0.25 mg/kg, 13.2% TRR from 10×). NG, MNG, 446-DO, BCDN, UF-DO and FNG were identified in the apple fruit as minor metabolites (< 5% TRR).

In a lettuce metabolism study, under greenhouse conditions was carried out to generate metabolites for identification. The test substance was applied as a foliar spray using a 20% SG formulation at a nominal rate equivalent to 150 g ai/ha and at an exaggerated rate equivalent to 1500 g ai/ha. Lettuce plants were treated 14 days before mature harvest (approximately 8 weeks from seeding).

Residue levels in the mature lettuce were 1.8 and 11 mg/kg for the 150 and 1500 g ai/ha applications, respectively. The extracted radioactivity from the mature lettuce accounted for 97.6 and 98.0% TRR for the 150 and 1500 g ai/ha applications, respectively. Dinotefuran was the major residue in the mature lettuce, accounted for 1.1 mg/kg (61.6% TRR) and 6.9 mg/kg (64.7% TRR) for the 150 and 1500 g ai/ha applications, respectively. PHP, 446-DO, UF, DN-OH, BCDN, DN, NG and MNG were detected as metabolites in the mature lettuce, but none of these metabolites were present at greater than 5% TRR level. Among these metabolites, relatively higher amounts of PHP, UF and DN were detected as compared to the other minor metabolites, approaching 4–5% of the TRR level.

In a potato metabolism study under field conditions, the application of test item was performed by foliar spray at rates equivalent to 100 g ai/ha, 200 g ai/ha (six plants each), or 1000 g ai/ha (exaggerated dose; one plant) at the BBCH stage 50–59 (just before flowering). One

potato plant at each of the two lower application rates was harvested 54 days after treatment. The remaining five plants per dosage as well as the plant of exaggerated dose were harvested at maturity (75 days after treatment).

The TRR in peel and pulp (peeled potato tubers) was determined. The TRR in the whole potato was very low for the 100 and 200 g ai/ha treatment rates, even at the first harvest interval. The majority of the radioactive residue was extracted with acetonitrile/water followed by water (94.5% to 97.7% of TRR for all samples). In the first harvest, dinotefuran accounted for 13.1% TRR (0.004 mg/kg) at 100 g ai/ha and 8.5% (0.003 mg/kg) at 200 g ai/ha application rate. One very polar fraction (M3) was determined with 61.7% TRR (0.019 mg/kg) and 57.1% TRR (0.021 mg/kg) at application rates of 100 and 200 g ai/ha, respectively. This fraction could be characterised to consist of traces of NG and at least six further unknown fractions each being less than 10% of the TRR. MNG was found at 7.6% TRR (0.002 mg/kg) and 9.6% TRR (0.003 mg/kg) at both application rates. Four other metabolites characterized as UF, PHP, 446-DO and FNG were all less than 7% TRR. The metabolic pattern of the mature potatoes was qualitatively similar to that of the first harvest, but the concentrations of dinotefuran and metabolites were even lower.

In a rice metabolism study under greenhouse conditions, simulating rice-paddy application of dinotefuran were performed to quantify total ^{14}C levels in rice plant tissue and grain and identify major components of the residue and their distribution in the plant.

There were two application times (5 and 20 days after bolting, DAB) and two application methods (soil and foliar spray application). Extracts of whole rice grain, brown rice, polished rice, chaff, bran, straw, root and soil were analysed to determine the nature of metabolites and their relative distribution in the samples. The results were similar for both application times (5 and 20 DAB).

Residue levels in whole grain from the soil applications were 0.35–0.40 mg/kg. Residues were greatly reduced when the chaff was removed from the whole grain and further reduced upon polishing of the brown rice to produce polished rice. The residue levels were 0.052–0.055 mg/kg in brown rice, and 0.033–0.039 mg/kg in polished rice. Dinotefuran was the major residue in whole rice grain and brown rice from the soil applications. The level of dinotefuran residues ranged from 0.23 mg/kg (66.0% TRR) to 0.24 mg/kg (60.5% TRR) in the whole grain, and 0.014 mg/kg (26.2% TRR) to 0.015 mg/kg (26.3% TRR) in the brown rice. After polishing of the brown rice, to produce polished rice, the residues of dinotefuran decreased to 0.008–0.010 mg/kg (21.2–29.9% TRR). PHP, 446-DO, UF, DN-OH, BCDN and DN were detected as the minor metabolites in whole grain and brown rice (< 10% TRR). PHP, 446-DO, UF and DN were also detected in polished rice at the level of less than 8% TRR.

The TRR in rice straw were 1.3–1.8 mg/kg for the soil applications. Dinotefuran was the major residue in straw, accounting for 0.70– 0.97 mg/kg (51.6–53.0% TRR). UF and DN were observed as the major metabolites in straw. UF accounted for 0.18–0.22 mg/kg (13.4–11.8% TRR), while DN accounted for 0.089–0.091 mg/kg (6.6–5.0% TRR). PHP, 446-DO, DN-OH and BCDN were detected as the minor metabolites (< 5% TRR).

The TRR in the whole rice grain for the foliar spray applications accounted for 5.1–5.8 mg/kg. Residues were greatly reduced during processing to produce the brown rice and polished rice fractions, similar to what was observed for the soil application. The residue levels in brown rice were 0.34–0.61 mg/kg, while the residue levels in polished rice were 0.15–0.34 mg/kg. Dinotefuran was the major residue in whole rice grain and brown rice. The level of dinotefuran ranged from 2.1 mg/kg (35.9% TRR) to 2.7 mg/kg (52.7% TRR) in the whole grain, and 0.18 mg/kg (53.6% TRR) to 0.20 mg/kg (33.4% TRR) in the brown rice. The residues of dinotefuran were further reduced to 0.073 mg/kg (48.4% TRR) to 0.14 mg/kg (41.7% TRR) in the polished rice. UF were observed as the major metabolite, accounting for 0.70–1.0 mg/kg (13.7–17.2% TRR) in whole grain, 0.048–0.1 mg/kg (14.1–17.2% TRR) in brown rice, and 0.021–0.076 mg/kg (14.2–22.8% TRR) in polished rice. PHP, 446-DO, DN-OH, BCDN and DN were detected as the minor metabolites in whole grain, brown rice and polished rice (< 8% TRR).

The TRR in rice straw were 7.6–8.1 mg/kg for the foliar spray applications. Dinotefuran was the major residue in straw, accounting for 4.0–5.6 mg/kg (53.3–69.0% TRR). UF and DN were observed as the major metabolites in straw. UF accounted for 0.72–1.2 mg/kg (8.8–15.9% TRR), while DN accounted for 0.47–0.65 mg/kg (5.7–8.5% TRR). PHP, 446-DO, DN-OH and BCDN were detected as the metabolites in straw (< 5% TRR).

In an oilseed rape metabolism study under natural conditions, oilseed rape plants were treated at pre-flowering (growth stage 50–59) by foliar application with formulated ^{14}C-dinotefuran at doses of 100 g ai/ha (low dose), 200 g ai/ha (high dose) and 1000 g ai/ha (exaggerated dose, plant pot). Planting, cultivation and harvesting of the mature winter rape plants was carried out according to common agricultural practice.

The TRR in the whole rape plant was 0.21, 0.49 and 2.1 mg/kg for the 100, 200 and 1000 g ai/ha treatment rates, respectively. For seeds, the residue levels for the 100, 200 and 1000 g ai/ha doses were determined to be 0.055, 0.13 and 0.70 mg/kg, respectively. Accordingly, residue levels for foliage were determined to be 0.26, 0.65 and 2.4 mg/kg, respectively.

In seeds dinotefuran was found at levels of 0.006 mg/kg (14.8% TRR), 0.016 mg/kg (18.7% TRR) and 0.095 mg/kg (18.0% TRR) for doses 100, 200 and 1000 g ai/ha, respectively. MNG was found as the most significant fraction, amounting to 0.005 mg/kg (12.4% TRR), 0.004 mg/kg (4.8% TRR) and 0.071 mg/kg (13.4% TRR) in seeds for the three application rates respectively. None of the other radioactive fractions exceeded 8.2% of TRR. UF, PHP, FNG, MG, DN and BCDN were found at low concentrations not exceeding 0.003 mg/kg for the low or high dosed plants with the exception of PHP amounting to 0.006 mg/kg.

In foliage dinotefuran was found at levels of 0.025 mg/kg (11.3% TRR), 0.094 mg/kg (16.9% TRR) and 0.22 mg/kg (10.6% TRR) for doses 100, 200 and 1000 g ai/ha, respectively. Radioactive fractions M3 (at least 8 compounds), MG and DN were found as significant metabolite fractions. M3 amounted to 0.12 mg/kg (53.4% TRR), 0.27 mg/kg (48.8% TRR) and 0.62 mg/kg (29.5% TRR) for the three application rates respectively. MG was found at 0.007 mg/kg (8.7% TRR), 0.010 mg/kg (4.9% TRR) and 0.088 mg/kg (11.5% TRR) for the three application rates respectively. DN was 0.037 mg/kg (13.2% TRR), 0.11 mg/kg (15.0% TRR) and 0.46 mg/kg (17.4% TRR) for the three application rates respectively. Furthermore detected in foliage at a dose of 1000 g ai/ha were UF, MNG (one of the compounds in M3) and BCDN amounting to 0.14 mg/kg (8.7% TRR), 0.14 mg/kg (6.5% TRR) and 0.043 mg/kg (2.7% TRR), respectively.

In the plant metabolism studies on apples, lettuce, potato, rice and oilseed rape, dinotefuran was the major component of the residues found in apples, lettuce, potato, rice (grain and straw) and oilseed rape (seed). UF and DN were significant components (> 10% TRR) in apples, rice (grain and straw) and foliage of oilseed rape. MNG was present at more than 10% TRR in seeds of oilseed rape but its concentration was less than 0.01 mg/kg at a normal rate. UF-DO and NG were only found in plants but the contributions were insignificant (< 5% TRR).

Environmental fate in soil

The Meeting received information on aerobic soil metabolism, soil photolysis and rotational crop study.

Dinotefuran degraded in soil under the aerobic conditions employed, principally via cleavage of tetrahydromethyl portion of the molecule to MNG and demethylation of MNG to NG. The DT_{50} was 10–52 days at 20 to 25 °C.

The photolysis study indicated that photolysis was not a significant degradation pathway for dinotefuran in soil incubated at 20 °C.

In confined rotational crop study, rotational crops (radish, lettuce, sorghum and wheat) were planted at 30 and 120 days after treatment. The test substance was applied as one broadcast spray application at a rate of 0.60 kg ai/ha in a volume of 1062 L/ha.

The TRR found in each of the plant fractions amounted to as much as 1.3 mg/kg in 30 day immature radish leaves to as little as 0.003 mg/kg in 120 day lettuce (mature and immature). The TRR was less than 0.01 mg/kg in all of the 120 day plant sample fractions except for the radish leaf samples where it was 0.035 mg/kg in the immature samples and 0.026 mg/kg in the mature samples.

For the 30 day after the application, in the immature radish samples, dinotefuran was present as the highest concentration of any individual components in the leaf and root samples (0.33 and 0.019 mg/kg, respectively). In the immature lettuce samples, BCDN and UF metabolites were found at the highest concentration (0.027 mg/kg for both). In the immature sorghum, the highest residue level was for dinotefuran followed by BCDN, DN, PHP, 446-DO, UF and MNG (0.20, 0.19, 0.14, 0.13, 0.080, 0.069 and 0.017 mg/kg, respectively).

In the mature radish samples (leaf and root), DN was present at the highest concentration (0.074 and 0.007 mg/kg, respectively). In the mature lettuce samples, PHP was found to be present at the highest concentration (0.083 mg/kg) followed by dinotefuran, BCDN and DN (0.064, 0.061 and 0.033 mg/kg, respectively). The mature sorghum samples analyses indicated extracted residues of 0.15, 0.12 and 0.034 mg/kg in forage, chaff and grain. The extracted residues consisted of BCDN and DN in forage and chaff as well as an unidentified component known as M16.

There were no individual components seen at concentrations above 0.006 mg/kg in any matrix in the 120 day samples.

Methods of residue analysis

The Meeting received description and validation data for analytical methods for residues of parent dinotefuran and its metabolites (DN and UF) in raw agricultural commodities, processed commodities, feed commodities and animal commodities. In most of the methods for determination of dinotefuran, UF and DN, homogenized samples were extracted with acetonitrile/water, and the extract was cleaned up with liquid –liquid partition followed by column chromatography using SPE 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 0.01 mg/kg for dinotefuran, UF and DN.

The multiresidue method with GC employing NPD or ECD detection was validated for dinotefuran in plant materials (non-fatty and fatty). LOQs were 0.01 mg/kg for dinotefuran.

Stability of residues in stored analytical samples

The Meeting received information on the freezer storage stability of dinotefuran and its metabolites (DN and UF) in plant (apple, peach, grape, cranberry, bulb onion, green onion, broccoli, melon, tomato, lettuce, watercress, potato, rice grain and cotton seed), their processed (rice bran, cotton meal and refined oil) commodities and animal products.

Storage stability results indicate that dinotefuran and its metabolites (DN and UF) residues were stable for at least 4 days in milk and eggs, for at least 2 months in bovine tissues, for at least 3 months in rice bran, for at least 4 months in grape and broccoli, for at least 5 months in melon, for at least 9 months in cranberry, for at least 12 months in apple, tomato, lettuce, potato and cotton (seeds, meal and oil), for at least 14 months in rice grain, for at least 20 months in watercress, for at least 22 months in green onion, for at least 24 months in bulb onion, and for at least 26 months in peach.

The periods of storage stability studies cover the sample storage intervals of residue trials.

Definition of the residue

In the lactating goat metabolism study, TRRs in kidney (0.27 mg/kg) and liver (0.14 mg/kg) were higher than those in milk (0.04–0.05 mg/kg), heart (0.05 mg/kg), muscle (0.04 mg/kg) and fat (0.01 mg/kg). Dinotefuran is the major component of the residue in muscle (41% TRR), milk (40% TRR), fat (20% TRR), kidney (13% TRR) and liver (12% TRR). FNG is the major component of the residue in kidney (20% TRR) but less than 7% TRR in all other tissues and milk.

In the lactating cow feeding study, the mixture of dinotefuran, UF and DN (3:1:1) was administered. Livestock are expected to be exposed to a mixture of dinotefuran, UF and DN at approximately 3:1:1 ratio from animal feedstuffs such as rice straw or cotton gin trash. UF was the predominant residue in tissues and milk. No detectable residues of dinotefuran occurred in any tissue samples and low concentrations of dinotefuran occurred in milk at the highest dose group (10×) only. Low concentrations of DN (0.02–0.04 mg/kg) were detected in liver, kidney and muscle from animals in the highest dose group only (10×). DN was occasionally found at very low concentrations (0.01 mg/kg) in whole milk. The concentrations of UF in tissues and milk are at least 10 times higher than those of dinotefuran at a highest dose. The concentrations of UF in tissues are approximately 10 times higher than those of DN at a highest dose.

In the laying hen metabolism study, TRRs were the highest for liver (0.13 mg/kg), followed by muscle (0.05 mg/kg), eggs (0.01–0.02 mg/kg for egg white, < 0.002–0.02 mg/kg for egg yolk) and fat (0.01 mg/kg). Dinotefuran is the major residue component in eggs (57% TRR for egg white, 44% TRR for egg yolk). FNG is present in egg white (13% TRR) but its concentration is very low (0.003 mg/kg). In other tissues (muscle, liver and fat), dinotefuran is detected at 9.1–11% TRR. However, all components were detected at ≤0.01 mg/kg (< 10% TRR) in all tissues and eggs.

The analytical methods for animal products submitted to the Meeting can quantify dinotefuran, UF and DN individually using the same analytical method.

The Meeting decided that parent dinotefuran and metabolite UF are suitable analytes for enforcement purposes and dietary risk assessment in animal commodities.

The octanol/water coefficient (log P_{ow}) of dinotefuran is -0.6 at 25 °C (pH 7). In the lactating goat and laying hen metabolism study, dinotefuran residues in muscle were at least 4 times higher than those in fat. In the lactating cow feeding study, dinotefuran residues in skimmed milk were at least twice higher than those in cream. The Meeting considered the residue of dinotefuran is not fat-soluble.

Parent dinotefuran was a major component (11–66% TRR) in apple, lettuce, potato, rice grains, rape seeds and foliage. UF, DN and MNG were detected as major metabolites in some matrices. UF was present in apple (21% TRR), rice grains (17% TRR for the spray application) and rice straw (16% TRR for the spray application, 13% TRR for the soil application,). DN was present in apple (10% TRR) and rape foliage (17% TRR). MNG was found in rape seeds (12%) but at very low concentration at a normal rate (< 0.01 mg/kg). No other radioactive components in the extracts from plant matrices were individually present at more than 10% TRR.

The results of the trials indicated that UF and DN residues were generally less than 10% of parent dinotefuran residue in food commodity matrices. These findings agree with the information obtained from the metabolism studies. The Meeting assumed the toxicity of UF and DN was comparable to that of dinotefuran.

The Meeting decided that parent dinotefuran is a suitable analyte for enforcement purposes and dinotefuran, UF and DN are suitable analytes for dietary risk assessment in plant commodities.

The Meeting recommended the following residue definition:

For plants: Definition of the residue (for compliance with the MRL): *Dinotefuran*

Definition of the residue (for estimation of dietary intake): *Sum of dinotefuran, 1-methyl-3-(tetrahydro-3-furylmethyl) urea (UF) and 1-methyl-3-(tetrahydro-3-furylmethyl) guanidium dihydrogen (DN) expressed as dinotefuran.*

For animalS: Definition of the residue (for compliance with the MRL and for estimation of dietary intake): *Sum of Dinotefuran and 1-methyl-3-(tetrahydro-3-furylmethyl) urea (UF) expressed as dinotefuran*

The residue is not fat-soluble

Results of supervised residue trials on crops

The Meeting received supervised trial data for the foliar application and soil application (irrigation) of dinotefuran on peaches, grapes, cranberries, bulb onions, green onions, broccoli, cauliflowers, cabbages, cucumbers, melons, summer squashes, zucchinis, peppers, tomatoes, lettuces, spinach, watercress, potatoes, celery, rice and cotton. Residue trial data was made available from Japan and the USA.

Labels were available from Japan, Korea and the USA describing the registered uses of dinotefuran.

The OECD calculator was used as a tool to assist in the estimation of maximum residue levels from the selected residue data set obtained from the supervised residue trials. As a first step, the Meeting reviewed the trial conditions and other relevant factors related to each data set to arrive at a best estimate of the maximum residue level using expert judgement. Then the OECD calculator was employed. If the statistical calculation spreadsheet suggested a different value, a brief explanation of the deviation was supplied.

The residue concentrations are reported for dinotefuran, UF and DN. Total residues for estimation of STMRs are calculated by summing up the concentrations of dinotefuran, UF and DN.

In case that the residues of dinotefuran were found at high levels, UF and DN were also detected and the residue levels of both metabolites depend on the commodity.

Since the residue values were expressed as mg of the analyte/kg sample, UF and DN need to be converted into dinotefuran equivalent. The conversion factors are 1.3 (202.21/158.20=1.28) for UF and 1.3 (202.21/157.22=1.29) for DN. Residues of < LOQ for both analytes are not converted.

The method for calculation of the total residues for plant commodities is illustrated below.

Dinotefuran	UF	DN	Total
< 0.01	< 0.01	< 0.01	< 0.03 (0.01 + 0.01 + 0.01)
0.051	< 0.01	< 0.01	0.071 (0.051 + 0.01 + 0.01)
0.056	0.011	< 0.01	0.080 (0.056 + 0.011 × 1.3 + 0.01)
0.14	0.016	0.010	0.17 (0.14 + 0.016 × 1.3 + 0.010 × 1.3)

Stone fruits

Peach

Data were available from supervised trials on peaches in the USA.

The US GAP on peach and nectarine is for a soil application at a maximum rate of 0.30 kg ai/ha with a PHI of 21 days and a foliar application at a maximum rate of 0.20 kg ai/ha with a PHI of 3 days. The maximum seasonal rate is 0.30 kg ai/ha for soil application and 0.30 kg ai/ha for foliar application. The seasonal rate for foliar application of the trials was slightly higher (33%) than the US GAP. The Meeting agreed to use the residue data for foliar application because the contribution of the first foliar spray to the final residue was less than 20% based on the decline study.

Dinotefuran residues in peaches from trials in the USA approximating GAP were (n=7): 0.09, 0.21 (2), 0.24, 0.31, 0.35 and 0.47 mg/kg.

Total residues in peaches were (n=7): 0.11, 0.23, 0.25, 0.28, 0.35, 0.37 and 0.57 mg/kg.

Based on the trials for peaches in the USA, the Meeting estimated a maximum residue level, an STMR value and an HR value for dinotefuran in peach of 0.8, 0.28 and 0.57 mg/kg respectively.

The Meeting agreed to extrapolate these recommendations to nectarine.

Berries and other small fruits

Grape

Data were available from supervised trials on grapes in the USA.

The US GAP on Berry and Small fruit (Small fruit vine climbing, except fuzzy kiwifruit) is for a soil application at a maximum rate of 0.38 kg ai/ha with a PHI of 28 days and two foliar applications at a maximum rate of 0.15 kg ai/ha (at a maximum seasonal rate of 0.30 kg ai/ha for foliar application) with a PHI of 1 day.

Dinotefuran residues in grapes from trials in the USA matching GAP were (n=13): 0.087, 0.10, 0.11, 0.12, 0.16, 0.17, 0.20, 0.22, 0.27 (2), 0.40, 0.52 and 0.55 mg/kg.

Total residues in grapes were (n=13): 0.11, 0.12, 0.13, 0.14, 0.18, 0.19, 0.22, 0.24, 0.29 (2), 0.47, 0.57 and 0.67 mg/kg.

Based on the trials for grapes in the USA, the Meeting estimated a maximum residue level, an STMR value and an HR value for dinotefuran in grape of 0.9, 0.22 and 0.67 mg/kg respectively.

Cranberry

Data were available from supervised trials on cranberries in the USA.

The GAP on Berry and Small fruit (Low growing berry subgroup, except strawberry) of the USA is a foliar application at a maximum rate of 0.20 kg ai/ha (at a maximum seasonal rate of 0.40 kg ai/ha) with a PHI of 7 days.

Dinotefuran residues in cranberries from trials in the USA matching GAP were (n=4): 0.01, 0.04, 0.05 and 0.06 mg/kg.

Total residues in cranberries were (n=4): 0.03, 0.06, 0.07 and 0.10 mg/kg.

Based on the trials for cranberries in the USA, the Meeting estimated a maximum residue level, an STMR value and an HR value for dinotefuran in cranberry of 0.15, 0.065 and 0.10 mg/kg respectively.

Bulb vegetables

Onion, bulb

Data were available from supervised trials on bulb onions in the USA.

The GAP on Onion, bulb and green of the USA is a soil application at a maximum rate of 0.30 kg ai/ha at planting and a foliar application at a maximum rate of 0.20 kg ai/ha with a PHI of 1 day. The maximum seasonal rate is 0.30 kg ai/ha for each application. The maximum seasonal rate is 0.43 kg ai/ha regardless of application method. The seasonal rate for foliar application of the trials was slightly higher (33%) than the US GAP. The Meeting accepted the residue data because it would accommodate the residue from potential combination from soil and foliar applications.

Dinotefuran residues in bulb onions from trials in the USA approximating GAP were (n=8): < 0.01 (2), 0.01, 0.02 (3), 0.04 and 0.06 mg/kg.

Total residues in bulb onions were (n=8): < 0.03 (2), 0.03, 0.04 (3), 0.06 and 0.09 mg/kg.

Based on the trials for bulb onions in the USA, the Meeting estimated a maximum residue level, an STMR value and an HR value for dinotefuran in onion, bulb of 0.1, 0.04 and 0.09 mg/kg respectively.

Onion, green

Data were available from supervised trials on green onions in the USA.

The GAP on Onion, bulb and green of the USA is a soil application at a maximum rate of 0.30 kg ai/ha at planting and a foliar application at a maximum rate of 0.20 kg ai/ha with a PHI of 1 day. The maximum seasonal rates are 0.30 kg ai/ha for each application. The residues from the trial for the soil application are insignificant, compared those for the foliar application. The Meeting decided to estimate a maximum residue level, an STMR and an HR based on the residue data for the foliar application.

Dinotefuran residues in green onions from trials in the USA matching GAP were (n=5): 0.086, 0.22, 0.52, 1.3 and 1.9 mg/kg.

Total residues in green onions were (n=5): 0.12, 0.59, 0.91, 1.5 and 2.3 mg/kg.

Based on the trials for green onions in the USA, the Meeting estimated a maximum residue level, an STMR value and an HR value for dinotefuran in spring onion of 4, 0.91 and 2.3 mg/kg respectively.

Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead cabbages

Broccoli and Cauliflower

Data were available from supervised trials on broccoli and cauliflowers in the USA.

The GAP of the USA for Head and stem brassica is for a soil application at a maximum rate of 0.37 kg ai/ha with a PHI of 21 days (at a maximum seasonal rate of 0.60 kg ai/ha for soil application) or a foliar application at a maximum rate of 0.20 kg ai/ha (at a maximum seasonal rate of 0.30 kg ai/ha for foliar application) with a PHI of 1 day. Only one application method can be used.

Dinotefuran residues in broccoli and cauliflowers from trials for the foliar application in the USA, matching GAP were (n=6): 0.49 and 1.0 (2) mg/kg for broccoli, and 0.086, 0.20 and 0.36 mg/kg for cauliflowers. Dinotefuran residues in broccoli from trials for the soil application in the USA matching GAP were (n=2): < 0.01 and 0.059 mg/kg.

Total residues in broccoli and cauliflowers for the foliar application were (n=6): 0.56, 1.0 and 1.1 mg/kg for broccoli, and 0.11, 0.22 and 0.41 mg/kg for cauliflowers. Total residues in broccoli for the soil application were (n=2): < 0.03 and 0.079 mg/kg.

Cabbage, head

Data were available from supervised trials on head cabbages in the USA.

The GAP on Head and stem brassica of the USA is a soil application at a maximum rate of 0.37 kg ai/ha with a PHI of 21 days (at a maximum seasonal rate of 0.60 kg ai/ha for soil application) or a foliar application at a maximum rate of 0.20 kg ai/ha (at a maximum seasonal rate of 0.30 kg ai/ha for foliar application) with a PHI of 1 day. Only one application method can be used.

Dinotefuran residues in head cabbages from trials for the foliar application in the USA matching GAP were (n=6): 0.013, 0.036, 0.22, 0.25, 0.78 and 0.85 mg/kg. Dinotefuran residue in cabbages from trials for the soil application in the USA matching GAP was 0.17 mg/kg.

Total residues in head cabbages for the foliar application were (n=6): 0.033, 0.056, 0.28, 0.38, 0.90 and 1.1 mg/kg. Total residue in head cabbages for the soil application was 0.34 mg/kg.

The GAP is the same for broccoli, cauliflower and head cabbage. The Meeting considered that the residues from trials with the foliar application on broccoli/cauliflowers and head cabbages were similar. The Meeting agreed to explore a group maximum residue level for brassica (cole or cabbage) vegetables, head cabbages, flowerhead cabbages.

Since the residue populations from trials on broccoli/cauliflowers and head cabbages were not significantly different (Mann-Whitney U-test), the Meeting agreed that they could be combined. The residues of dinotefuran in those brassica vegetables for the foliar application were (n=12): 0.013, 0.036, 0.086, 0.20, 0.22, 0.25, 0.36, 0.49, 0.78, 0.85 and 1.0 (2) mg/kg. Total residues for the foliar application were (n=12): 0.033, 0.056, 0.11, 0.22, 0.28, 0.38, 0.41, 0.56, 0.90, 1.0 and 1.1 (2) mg/kg

Based on the trials for broccoli/cauliflowers and head cabbages in the USA, the Meeting estimated a maximum residue level, an STMR value and an HR value for dinotefuran in brassica (cole or cabbage) vegetables, head cabbages, flowerhead cabbages of 2, 0.40 and 1.1 mg/kg respectively.

Fruiting vegetables, Cucurbits

Cucumber

Data were available from supervised trials on cucumbers in the USA.

The GAP on Cucurbits of the USA is a soil application at a maximum rate of 0.37 kg ai/ha with a PHI of 21 days (at a maximum seasonal rate of 0.60 kg ai/ha for soil application) or a foliar application at a maximum rate of 0.20 kg ai/ha (at a maximum seasonal rate of 0.30 kg ai/ha for foliar application) with a PHI of 1 day. Only one application method can be used.

Dinotefuran residues in cucumbers from trials for the foliar application in the USA matching GAP were (n=7): 0.13, 0.14, 0.17, 0.18 (2), 0.20 and 0.21 mg/kg. Dinotefuran residue in cucumbers from trials for the soil application in the USA matching GAP was 0.053 mg/kg.

Total residues in cucumbers for the foliar application were (n=7): 0.18, 0.26 (3), 0.28 (2) and 0.33 mg/kg. Total residue in cucumbers for the soil application was 0.073 mg/kg.

Melon

Data were available from supervised trials on melons in the USA.

The GAP on Cucurbits of the USA is a soil application at a maximum rate of 0.37 kg ai/ha with a PHI of 21 days (at a maximum seasonal rate of 0.60 kg ai/ha for soil application) or a foliar application at a maximum rate of 0.20 kg ai/ha (at a maximum seasonal rate of 0.30 kg ai/ha for foliar application) with a PHI of 1 day. Only one application method can be used.

Dinotefuran residues in melons from trials for the foliar application in the USA matching GAP were (n=6): 0.042, 0.054, 0.082, 0.15, 0.18 and 0.20 mg/kg. Dinotefuran residue in melons from trials for the soil application in the USA matching GAP was 0.040 mg/kg.

Total residues in melons for the foliar application were (n=6): 0.073, 0.11, 0.16, 0.23, 0.24 and 0.32 mg/kg. Total residue in melons for the soil application was 0.060 mg/kg.

Summer squash and Zucchini

Data were available from supervised trials on summer squashes and zucchinis in the USA.

The GAP on Cucurbits of the USA is a soil application at a maximum rate of 0.37 kg ai/ha with a PHI of 21 days (at a maximum seasonal rate of 0.60 kg ai/ha for soil application) or a foliar application at a maximum rate of 0.20 kg ai/ha (at a maximum seasonal rate of 0.30 kg ai/ha for foliar application) with a PHI of 1 day. Only one application method can be used.

Dinotefuran residues in summer squashes and zucchini from trials for the foliar application in the USA matching GAP were (n=5): 0.092, 0.15 and 0.18 mg/kg for summer squashes, and 0.10 and 0.15 mg/kg for zucchini. Dinotefuran residues in summer squashes from trials for the soil application in the USA matching GAP were (n=2): 0.041 and 0.087 mg/kg.

Total residues in summer squashes and zucchini for the foliar application were (n=5): 0.19, 0.30 and 0.32 mg/kg for summer squashes, and 0.14 and 0.22 mg/kg for zucchini. Total residues in summer squashes for the soil application were (n=2): 0.065 and 0.11 mg/kg.

The GAP is the same for cucumber, melon, summer squash and zucchini. The Meeting considered that the residues from trials with the foliar application on cucumber, melon, summer squash and zucchini were similar. The Meeting agreed to propose a group maximum residue level for fruiting vegetables, cucurbits.

Since the residue populations from trials on cucumbers, melons, summer squashes and zucchinis for foliar application were not significantly different (Kruskal-Wallis H-test), the Meeting agreed that they could be combined. The residues of dinotefuran in those cucurbits for the foliar application were (n=18): 0.042, 0.054, 0.082, 0.092, 0.10, 0.13, 0.14, 0.15 (3), 0.17, 0.18 (4), 0.20 (2) and 0.21 mg/kg. Total residues for the foliar application were (n=18): 0.073, 0.11, 0.14, 0.16, 0.18, 0.19, 0.22, 0.23, 0.24, 0.26 (3), 0.28 (2), 0.30, 0.32 (2) and 0.33 mg/kg.

Based on the trials for cucumbers, melons, summer squashes and zucchinis in the USA, the Meeting estimated a maximum residue level, an STMR value and an HR value for dinotefuran in fruiting vegetables, cucurbits of 0.5, 0.25 and 0.33 mg/kg respectively.

Fruiting vegetables, other than Cucurbits

Peppers

Data were available from supervised trials on sweet peppers and chili peppers in Japan and the USA.

In Japan, dinotefuran is registered for use on sweet pepper and chili pepper at two foliar applications of 0.0067–0.010 kg ai/hL with a PHI of 1 day. Residues in green peppers from trials matching GAP of Japan were (n=2): 0.43 and 1.2 mg/kg. However, the trials for green peppers matching GAP of Japan were insufficient to estimate a maximum residue level for the commodity.

The GAP on Fruiting vegetables of the USA is a soil application at a maximum rate of 0.37 kg ai/ha with a PHI of 21 days (at a maximum seasonal rate of 0.60 kg ai/ha for soil application) or a foliar application at a maximum rate of 0.20 kg ai/ha (at a maximum seasonal rate of 0.30 kg ai/ha for foliar application) with a PHI of 1 day. Only one application method can be used.

Dinotefuran residues in sweet peppers and chili peppers from trials for the foliar application in the USA matching GAP were (n=8): 0.030, 0.042, 0.14 (2), 0.25 and 0.27 mg/kg for sweet peppers, and 0.23 and 0.41 mg/kg for chili peppers. Dinotefuran residues in sweet peppers from trials for the soil application in the USA matching GAP were (n=2): 0.024 and 0.094 mg/kg.

Total residues in sweet peppers and chili peppers for the foliar application were (n=8): 0.050, 0.062, 0.17, 0.18, 0.29 and 0.50 mg/kg for sweet peppers, and 0.26 and 0.55 mg/kg for chili peppers. Total residues in sweet peppers for the soil application were (n=2): 0.044 and 0.11 mg/kg.

Tomato

Data were available from supervised trials on tomatoes in Japan and the USA.

In Japan, dinotefuran is registered for use on tomato at an irrigation treatment to nursery box of 0.20 kg ai/hL at planting and two foliar applications of 0.0067–0.010 kg ai/hL with a PHI of 1 day. Residues in tomatoes from trials matching GAP of Japan were (n=2): 0.094 and 0.35 mg/kg. However, the trials for tomatoes matching GAP of Japan were insufficient to estimate a maximum residue level for the commodity.

The GAP on Fruiting vegetables (except varieties of tomato which are less than 2 inches in size) of the USA is a soil application at a maximum rate of 0.37 kg ai/ha with a PHI of 21 days (at a maximum seasonal rate of 0.60 kg ai/ha for soil application) or a foliar application at a maximum rate of 0.20 kg ai/ha (at a maximum seasonal rate of 0.30 kg ai/ha for foliar application) with a PHI of 1 day. Only one application method can be used.

Dinotefuran residues in tomatoes from trials for the foliar application in the USA matching GAP were (n=15): 0.039, 0.051, 0.056, 0.060, 0.069 (2), 0.071, 0.084, 0.097, 0.13 (2), 0.14, 0.15, 0.16 (2) mg/kg. Dinotefuran residues in tomatoes from trials for the soil application in the USA matching GAP were (n=2): 0.015 and 0.045 mg/kg.

Total residues in tomatoes for the foliar application were (n=15): 0.059, 0.071, 0.080 (2), 0.089, 0.091, 0.10 (2), 0.12, 0.15 (2), 0.18, 0.19 (2) and 0.20 mg/kg. Total residues in tomatoes for the soil application were (n=2): 0.035 and 0.065 mg/kg.

The GAP is the same for peppers and tomato and the residues of these commodities are similar. The Meeting agreed to propose a group maximum residue level for fruiting vegetables, other than cucurbits except sweet corn and mushrooms.

Since the residue populations from trials on peppers and tomatoes from foliar applications were not significantly different (Mann-Whitney U-test), the Meeting agreed that they could be combined. The residues of dinotefuran in those fruiting vegetables for the foliar application were (n=23): 0.030, 0.039, 0.042, 0.051, 0.056, 0.060, 0.069 (2), 0.071, 0.084, 0.097, 0.13 (2), 0.14 (3), 0.15, 0.16 (2), 0.23, 0.25, 0.27 and 0.41 mg/kg. Total residues for the foliar application were (n=23): 0.050, 0.059, 0.062, 0.071, 0.080 (2), 0.089, 0.091, 0.10 (2), 0.12, 0.15 (2), 0.17, 0.18 (2), 0.19 (2), 0.20, 0.26, 0.29, 0.50 and 0.55 mg/kg.

Based on the trials for peppers and tomatoes in the USA, the Meeting estimated a maximum residue level, an STMR value and an HR value for dinotefuran in fruiting vegetables, other than cucurbits except sweet corn and mushrooms of 0.5, 0.15 and 0.55 mg/kg respectively.

Leafy vegetables (including Brassica leafy vegetables)

Lettuce, leaf

Data were available from supervised trials on leaf lettuce in the USA.

The GAP on Leafy vegetables from the USA is a soil application at a maximum rate of 0.37 kg ai/ha with a PHI of 21 days (at a maximum seasonal rate of 0.60 kg ai/ha for soil application) or a foliar application at a maximum rate of 0.15 kg ai/ha (at a maximum seasonal rate of 0.30 kg ai/ha for foliar application) with a PHI of 7 day. Only one application method can be used.

Dinotefuran residues in leaf lettuce from trials for the foliar application in the USA matching GAP were (n=8): 0.15, 0.20, 0.21, 0.29, 0.32, 0.91, 1.1 and 2.4 mg/kg. Dinotefuran residues in leaf lettuce from trials for the soil application in the USA matching GAP were (n=2): 0.016 and 0.11 mg/kg.

Total residues in leaf lettuce for the foliar application were (n=8): 0.33, 0.63, 0.66, 0.73, 0.81, 1.7, 2.0 and 3.3 mg/kg. Total residues in leaf lettuce for the soil application were (n=2): 0.039 and 0.20 mg/kg.

Lettuce, head

Data were available from supervised trials on head lettuce in the USA.

The GAP on Leafy vegetables of the USA is a soil application at a maximum rate of 0.37 kg ai/ha with a PHI of 21 days (at a maximum seasonal rate of 0.60 kg ai/ha for soil application) or a foliar application at a maximum rate of 0.15 kg ai/ha (at a maximum seasonal rate of 0.30 kg ai/ha for foliar application) with a PHI of 7 day. Only one application method can be used.

Dinotefuran residues in head lettuce from trials for the foliar application in the USA matching GAP were (n=7): 0.08, 0.12, 0.16 (2), 0.18, 0.19 and 0.53 mg/kg. Dinotefuran residue in head lettuce from trials for the soil application in the USA matching GAP was 0.016 mg/kg.

Total residues in head lettuce for the foliar application were (n=7): 0.25, 0.29 (2), 0.46, 0.49, 0.83 and 1.4 mg/kg. Total residue in head lettuce for the soil application was 0.049 mg/kg.

Spinach

Data were available from supervised trials on spinach in the USA.

The GAP on Leafy vegetables of the USA is a soil application at a maximum rate of 0.37 kg ai/ha with a PHI of 21 days (at a maximum seasonal rate of 0.60 kg ai/ha for soil application) or a foliar application at a maximum rate of 0.15 kg ai/ha (at a maximum seasonal rate of 0.30 kg ai/ha for foliar application) with a PHI of 7 day. Only one application method can be used.

Dinotefuran residues in spinach from trials for the foliar application in the USA matching GAP were (n=7): 0.43, 0.48, 0.56, 0.62, 1.2, 2.0 and 3.3 mg/kg. Dinotefuran residue in spinach from trials for the soil application in the USA matching GAP was 0.65 mg/kg.

Total residues in spinach for the foliar application were (n=7): 0.63, 0.68, 0.89, 1.2, 2.3, 2.6 and 4.4 mg/kg. Total residue in spinach for the soil application was 0.73 mg/kg.

The GAP is the same for leaf lettuce, head lettuce and spinach. The median residue in leaf lettuce (0.305 mg/kg), head lettuce (0.16 mg/kg) and spinach (0.62 mg/kg) are similar. The Meeting agreed to propose a group maximum residue level for leafy vegetables except watercress.

The Meeting recognized that the residue populations from trials on leaf lettuce, head lettuce and spinach were significantly different according to statistical test. The therefore Meeting decided to use the crop with the highest residue, i.e., spinach, to estimate a maximum residue level for leafy vegetables.

Based on the trials in spinach from the USA, the Meeting estimated a maximum residue level, an STMR value and an HR value for dinotefuran in leafy vegetables of 6, 1.2 and 4.4 mg/kg, respectively.

Watercress

Data were available from supervised trials on watercress in the USA.

The GAP on watercress of the USA is a foliar application at a maximum rate of 0.20 kg ai/ha (at a maximum seasonal rate of 0.40 kg ai/ha for foliar application) with a PHI of 1 day.

Dinotefuran residues in watercress from trials in the USA matching GAP were (n=3): 1.6, 2.1 and 3.4 mg/kg.

Total residues in watercress were (n=3): 2.0, 2.9 and 3.8 mg/kg.

Based on the trials for watercress in the USA, the Meeting estimated a maximum residue level, an STMR value and an HR value for dinotefuran in watercress of 7, 2.9 and 3.8 mg/kg respectively.

Potato

Data were available from supervised trials on potatoes in the USA.

The GAP on tuberous and corm vegetables from the USA is as a pre-plant soil application at a maximum rate of 0.38 kg ai/ha (at a maximum seasonal rate of 0.38 kg ai/ha for soil application) or a foliar application at a maximum rate of 0.076 kg ai/ha (at a maximum seasonal rate of 0.23 kg ai/ha for foliar application) with a PHI of 7 day. Only one application method can be used.

The trials on potatoes in the USA did not match the GAP. Consequently, the Meeting could not estimate a maximum residue level for dinotefuran in potatoes.

Celery

Data were available from supervised trials on celery from the USA.

The GAP from the USA is for a soil application at a maximum rate of 0.37 kg ai/ha with a PHI of 21 days (at a maximum seasonal rate of 0.60 kg ai/ha for soil application) or a foliar application at a maximum rate of 0.15 kg ai/ha (at a maximum seasonal rate of 0.30 kg ai/ha for foliar application) with a PHI of 7 day. Only one application method can be used.

Dinotefuran residues in celery from the foliar application matching US GAP were (n=6): 0.06, 0.10, 0.18, 0.22, 0.24 and 0.28 mg/kg.

Total residues in celery following the foliar application were (n=6): 0.08, 0.20, 0.36, 0.51, 0.58 and 0.67 mg/kg.

Based on the trials for celery in the USA, the Meeting estimated a maximum residue level, an STMR value and an HR value for dinotefuran in celery of 0.6, 0.435 and 0.67 mg/kg respectively.

Rice

Data were available from supervised trials on rice in the USA.

Trials from the USA on rice were reported for the foliar application of a SG formulation (GAP: two foliar applications of a maximum rate of 0.15 kg ai/ha, PHI of 7 days).

Dinotefuran residues in rice grains from trials in the USA matching GAP were (n=9): 1.4, 1.8, 1.9 (2), 2.4, 2.5, 2.9 (2) and 4.0 mg/kg.

Total residues in rice grains were (n=9): 1.9, 2.4, 2.7, 2.9, 3.3, 3.8, 4.4, 4.6 and 8.1 mg/kg.

Based on the trials for rice in the USA, the Meeting estimated a maximum residue level, an STMR value for dinotefuran in rice of 8 and 3.3 mg/kg respectively.

Cotton seed

Data were available from supervised trials on cotton in the USA.

Trials from the USA on cotton were reported for a foliar application of a SG formulation (GAP: a foliar application of a maximum rate of 0.15 kg ai/ha with a seasonal maximum rate of 0.30 kg ai/ha, PHI of 14 days).

Dinotefuran residues in cotton seeds from trials in the USA matching GAP were (n=12): < 0.05 (5), 0.05 (3), 0.07 (2), 0.10 and 0.16mg/kg.

Total residues in cotton seeds were (n=12): < 0.15 (5), 0.15 (3), 0.17 (2), 0.20 and 0.33 mg/kg.

Based on the trials for cotton in the USA, the Meeting estimated a maximum residue level and an STMR value for dinotefuran in cotton seeds of 0.2 and 0.15 mg/kg respectively.

Animal feedstuffs

Rice straw

Data were available from supervised trials on rice in the USA.

Trials from the USA on rice were reported for the foliar application of a SG formulation (GAP: two foliar applications of a maximum rate of 0.15 kg ai/ha, PHI of 7 days).

Dinotefuran residues in rice straw from trials in the USA matching GAP were (n=9): 0.61, 0.82, 0.87, 0.90, 1.2, 1.3, 1.4, 2.6 and 3.8 mg/kg.

Total residues in rice straw were (n=9): 1.1 (2), 1.2, 1.3, 1.6, 1.7, 1.8, 3.7 and 4.3 mg/kg.

Based on the residues in rice straw from trials in the USA, the Meeting estimated a maximum residue level, a median residue value and a highest residue value for dinotefuran in rice straw and fodder, dry of 6, 1.6 and 4.3 mg/kg respectively.

Cotton gin trash

Data were available from supervised residue trials on cotton in the USA.

Trials from the USA on cotton were reported for the foliar application of a SG formulation (GAP: a foliar application of a maximum rate of 0.15 kg ai/ha at a seasonal maximum rate of 0.30 kg ai/ha, PHI of 14 days).

Total residues in cotton gin trash from trials in the USA matching GAP were (n=7): 1.5, 3.3 (2), 3.8, 4.9, 5.6 and 7.1 mg/kg.

Based on the trials for cotton in the USA, the Meeting estimated a median residue value and a highest residue value for dinotefuran in cotton gin trash of 3.8 and 7.1 mg/kg respectively.

Rotational crops

The US GAP shows that for all crops other than berry and small fruit (subgroup small fruit vine climbing except fuzzy kiwifruit and low growing berry except strawberry), cotton, head and stem brassica, leafy brassica greens (including turnip greens), cucurbits, fruiting vegetables, leafy vegetables, bulb onion, green onion, peach and nectarine, tuberous and corm vegetables, and watercress, a 120-day plant-back interval must be observed. The Meeting noted that residues were not expected on rotational crops.

Fate of residues during processing

The fate of dinotefuran residues has been examined in grapes, tomatoes, potatoes, rice grains and cotton seeds processing studies. Based on the results of processing studies conducted in the USA, processing factors were calculated for grapes, tomatoes, potatoes, rice grains and cotton seeds. 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)	RAC HR (mg/kg)	HR-P (mg/kg)
Grape	Juice	0.95, 1.4	1.2	0.22	0.264	0.67	
	Raisin	3.1, 4.2	3.7		0.814		2.479
Tomato	Puree	1.1, 1.6, 2.1	1.6	0.10	0.16		
	Paste	3.3, 4.6, 5.2	4.6		0.46		
Potato	Granules	3.0, 2.3	2.7				
	Chips	2.1, 1.5	1.9				
Rice	Polished rice	0.02, 0.05	0.04	3.3	0.132		
	Bran	0.42, 0.85	0.64		2.112		
	Hulls	3.8, 5.4	4.6		15.18		
Cotton	Meal	0.27, 0.47	0.37	0.15	0.0555		
	Hulls	0.29, 0.72	0.51		0.0765		
	Refined oil	< 0.05, < 0.09	< 0.07		0.0105		

* Each value represents a separate study. The factor is the ratio of the residue in processed commodity divided by the residue in the RAC.

The Meeting estimated a maximum residue level of 3 mg/kg (0.9 × 3.7 = 3.33 mg/kg) for dried grape and 0.3 mg/kg (8 × 0.04 = 0.32 mg/kg) for polished rice.

On the basis of the STMR and HR for sweet peppers and default dehydration factor of 10, the Meeting estimated at an STMR value and an HR value for dried chili peppers of 1.75 and 5.0 mg/kg respectively. Based on the maximum residue level of fruiting vegetables, other than cucurbits, the Meeting recommended a maximum residue level of 5 mg/kg for chili peppers (dry).

Residue in animal commodities

Farm animal dietary burden

The Meeting estimated the dietary burden of dinotefuran 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, dinotefuran, ppm of dry matter diet								
	US-Canada		EU		Australia		Japan	
	Max	Mean	Max	Mean	Max	Mean	Max	Mean
Beef cattle	1.5	1.3	9.3	2.6	13	4.6	3.1	1.4
Dairy cattle	5.5	2.3	6.6	2.2	**15**[a]	**6.3**[bc]	1.4	0.68
Poultry–broiler	1.0	1.0	0.24	0.24	2.4	2.4	0.12	0.12
Poultry–layer	1.0	1.0	1.6	0.52	**2.4**[d]	**2.4**[e]	0.47	0.47

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

[b] Highest mean beef or dairy cattle dietary burden suitable for STMR estimates for mammalian meat

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

[d] Highest maximum poultry dietary burden suitable for MRL estimates for poultry meat and eggs

[e] Highest mean poultry dietary burden suitable for STMR estimates for poultry meat and eggs

Farm animal feeding studies

The Meeting received a lactating dairy cow feeding studies, which provided information on likely residues resulting in animal commodities and milk from dinotefuran residues in the animal diet.

A poultry feeding study was not submitted as the expected residues of dinotefuran in poultry feed were very low. A poultry metabolism study at a dose rate of 10 ppm dinotefuran in feed demonstrated that there was very low transfer to eggs and tissues with all residues of dinotefuran and metabolites less than 0.01 mg/kg.

Lactating dairy cows

Lactating dairy cows were dosed with the mixture of dinotefuran, UF and DN (3:1:1) for 29–30 days at the equivalent of 5, 15 and 50 ppm in the diet. Residues of dinotefuran were below the LOQ (0.01 mg/kg) in whole milk with some exceptions at all feeding levels. UF was the predominant residue found in milk from all treated animals. No detectable residues of dinotefuran occurred in any tissue samples. UF was again the predominant residue in all tissues.

Animal commodities maximum residue levels

For MRL estimation, the residue in the animal commodities is dinotefuran and UF.

Residues in tissues and milk at the expected dietary burden for dairy cattle are shown in the Table below. The total residue of dinotefuran and UF in milk reached a plateau at Day 4. The mean estimated residue in milk was calculated using the residue values of Day 4 to the final day.

	Feed level (ppm) for milk residues	Residues (mg/kg) in milk [a]	Feed level (ppm) for tissue residues	Residues (mg/kg) in[a]			
				Muscle	Liver	Kidney	Fat
Maximum residue level beef or dairy cattle							
Feeding study	15	0.082	15	0.062	0.066	0.076	0.065
Dietary burden and residue estimate	15	0.082	15	0.062	0.066	0.076	0.065
STMR beef or dairy cattle							
Feeding study	5 15	0.033 0.082	5 15	0.026 0.058	0.024 0.061	0.023 0.072	< 0.02 0.044
Dietary burden and residue estimate	6.3	0.039	6.3	0.030	0.030	0.030	0.025

[a]: Sum of dinotefuran and UF expressed as dinotefuran (using a molecular weight conversion factor of 1.3 for UF)

Based on the highest estimated residue in milk (0.082 mg/kg), the Meeting estimated a maximum residue level of 0.1 mg/kg in milk.

Based on the highest estimated residue in muscle (0.062 mg/kg), the Meeting estimated a maximum residue level of 0.1 mg/kg, an HR value of 0.062 mg/kg in mammalian meat.

Based on the highest estimated residue in kidney (0.076 mg/kg), the Meeting estimated a maximum residue level of 0.1 mg/kg, an HR value of 0.076 mg/kg in mammalian edible offal.

Based on the mean estimated residues in tissues and milk, the Meeting estimated STMR values of 0.039 mg/kg in milk, 0.030 mg/kg in meat and 0.030 mg/kg in edible offal.

The maximum dietary burden for broiler and layer poultry is 2.4 and is lower than the dose level in the laying hen metabolism study of 10 ppm. In the metabolism study, in which dinotefuran equivalent to 10 ppm in the diet was dosed to laying hens for 5 consecutive days, no residues of dinotefuran, UF and DN exceed 0.01 mg/kg were detected in tissues and egg yolk. Dinotefuran was only detected at 0.013 mg/kg in egg white.

The Meeting estimated a maximum residue level of 0.02* mg/kg, an STMR value of 0 mg/kg and an HR value of 0 mg/kg in poultry meat, poultry edible offal and eggs.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Daily Intakes (IEDIs) of dinotefuran were calculated for the 13 GEMS/Food cluster diets using STMRs/STMR-Ps estimated by the current Meeting (Annex 3). The ADI is 0–0.2 mg/kg bw and the calculated IEDIs were 0–3% of the maximum ADI (0.2 mg/kg bw). The Meeting concluded that the long-term intakes of residues of dinotefuran, resulting from the uses considered by current JMPR, are unlikely to present a public health concern.

Short-term intake

The International Estimated Short-Term Intakes (IESTI) of dinotefuran were calculated for food commodities and their processed commodities using HRs/HR-Ps or STMRs/STMR-Ps estimated by the current Meeting (Annex 4). The ARfD is 1 mg/kg bw and the calculated IESTIs were a maximum of 30% of the ARfD. The Meeting concluded that the short-term intake of residues of dinotefuran, when used in ways that have been considered by the JMPR, is unlikely to present a public health concern.

5.14 DITHIOCARBAMATES (105)

RESIDUE AND ANALYTICAL ASPECTS

Ethylene-bis-dithiocarbamate fungicides were evaluated several times by the JMPR for toxicology and residues. In 1993, the JMPR estimated a group ADI of 0–0.03 mg/kg bw for mancozeb, maneb, metiram and zineb.

Dithiocarbamate pesticides were listed by the Forty-third Session of the CCPR for evaluation of additional commodities by the 2012 JMPR. The Meeting received information on residue analysis and supervised trials with mancozeb and maneb on okra.

Methods of analysis

The analytical method used in the supervised trials of mancozeb and maneb in okra relied on CS_2 evolution using GC-MSD with a reporting limit for of quantification of dithiocarbamates of 0.05 mg/kg.

Results of supervised residue trials on crops

The Meeting received supervised trial data for mancozeb and maneb on okra in Côte d'Ivoire. As part of the field trials conducted within the Pesticide Initiative Programme aiming to provide data for establishing import MRLs in the European Union, maneb and mancozeb were applied in combination with other pesticides as foliar spray treatment with up to three times at about 2 kg ai/ha in six trials carried out in Côte d'Ivoire. The residues 7 days after one to three applications of mancozeb were: < 0.05, 0.06, 0.11, 0.13 and 0.13 mg/kg and after two to four applications of maneb, < 0.05, < 0.05 and 0.14 mg/kg.

The application conditions were based on the requirement of appropriate control of diseases of okra, but they were not supported by a label or an official declaration of approved use from Côte d'Ivoire.

As no official information on GAP was submitted, the Meeting was unable to estimate a maximum residue level for dithiocarbamates in okra.

5.15 FENBUCONAZOLE (197)

TOXICOLOGY

Fenbuconazole is the ISO-approved common name for 4-(4-chlorophenyl)-2-phenyl-2-(1H-1,2,4-triazol-1-ylmethyl)butyronitrile (IUPAC), with the CAS number 119611-00-6. It is a triazole fungicide intended for agricultural and horticultural use for the control of a variety of fungal infections of crops.

JMPR evaluated fenbuconazole in 1997, when an ADI of 0–0.03 mg/kg bw was established on the basis of a NOAEL of 3 mg/kg bw per day in a chronic toxicity study in rats.

The present Meeting considered the requirement for an ARfD for fenbuconazole, on the basis of data from the previous evaluations and from one new developmental toxicity study in rabbits.

All critical studies complied with GLP.

Toxicological data

Fenbuconazole has low acute oral toxicity (LD_{50} > 2000 mg/kg bw in rats), and clinical signs observed after administration of high doses are generally nonspecific. In short-term studies of toxicity in mice, rats and dogs and in long-term studies of toxicity in mice and rats, fenbuconazole generally induced decreases in body weight gain and feed consumption, liver toxicity and changes in clinical chemistry. Less frequently, kidney, adrenal and thyroid toxicity and haematological effects were seen. The Meeting considered the observed effects in these repeated-dose studies as unlikely to be the result of a single (1 day) exposure to fenbuconazole.

In a previously evaluated two-generation study of reproductive toxicity in rats, the observed adverse effects were similar to those found in the repeated-dose studies. In addition, at 800 ppm (equivalent to 40 mg/kg bw per day), the number of F_0 and F_1 dams that delivered live young was reduced to 10 out of 25 and 4 out of 21, respectively, compared with 21/25 and 22/25 in F_0 and F_1 control dams, respectively, whereas the number of stillborn was increased at the same dose. Some F_0 (n = 4) and F_1 (n = 3) females at this dose level died while delivering their litters. The NOAEL was 80 ppm (equivalent to 4 mg/kg bw per day).

In this multigeneration study, it was reported that a considerable number of high-dose dams did not deliver. The Meeting considered the possible causes for this finding and concluded that it was unlikely to be the result of an acute (single day) exposure.

In a previously evaluated developmental toxicity study in rats, a reduction in body weight gain was observed from gestation day (GD) 6 to GD 8 at 75 mg/kg bw per day. Feed consumption was not measured. Also at this dose, the number of animals with scant faeces was increased, often from GD 7 or 8 onwards. At 150 mg/kg bw per day, an increased incidence of early, late and total resorptions was seen. No effects were observed at 30 mg/kg bw per day.

In a previously evaluated developmental toxicity study in rabbits, a dose-dependent reduction in feed consumption and increased incidences of soft or scant faeces were seen at 30 and 60 mg/kg bw per day. At the high dose, these effects were marked and occurred early after the start of treatment. Feed consumption was 172, 162, 148 and 99 g/dam on GDs 7–8 and 176, 153, 141 and 46 g/dam on GDs 8–9 at 0, 10, 30 and 60 mg/kg bw per day, respectively (these values were calculated by the present Meeting from the tables with individual data). In addition, body weight gain from GD 7 to GD 9 was dose dependently reduced: 1, −13, −43 and −174 g weight gain at 0, 10, 30 and 60 mg/kg bw per day, respectively, reaching statistical significance at 30 and 60 mg/kg bw per day (calculation of the mean body weight changes and statistical analysis performed by the present Meeting). At 60 mg/kg bw per day, only 1 out of 19 does produced a viable litter, whereas 10 does had litters that were totally resorbed and 6 does aborted. At this high dose, an increase in the number of early resorptions was observed (mean number 0.3, 0.2, 0.1 and 4.4 per dam at 0, 10, 30 and 60 mg/kg bw per day, respectively). The NOAEL for maternal toxicity was 10 mg/kg bw per day on the basis of a

decrease in feed consumption and body weight (gain) soon after the commencement of treatment and an increase in soft or scant faeces at 30 mg/kg bw per day. The NOAEL for developmental effects was 30 mg/kg bw per day, on the basis of early resorptions and abortions at 60 mg/kg bw per day.

A second oral developmental toxicity study in rabbits[1], which was not previously evaluated by JMPR, was performed according to OECD Test Guideline 414. Pregnant New Zealand White rabbits (21 per group) were exposed from GD 7 to GD 19 to fenbuconazole technical (lot no. 3-2508R FL-12L-656,748-038W002, purity 97.01%) by gavage at doses of 0, 15 or 45 mg/kg bw per day. All rabbits were observed daily for clinical signs. Body weights were recorded on GDs 0, 7, 9, 11, 14, 17, 20 and 29. Feed consumption was recorded daily from GD 2 to GD 29. Rabbits were killed on GD 29, and gross examination of thoracic and abdominal viscera was performed on all rabbits. The uterus was weighed, and numbers of corpora lutea, implantations, fetuses and early and late resorptions were counted. All live fetuses were weighed and examined for external and visceral alterations. Subsequently, the fetuses were stained with Alizarin Red S and examined for skeletal alterations.

No treatment-related deaths were observed. One low-dose doe died due to an intubation error. One high-dose female that aborted on GD 26 was killed. Scant or no faeces were noted in several does at 45 mg/kg bw per day, but generally only after several days of treatment. Body weight gain in the treatment groups was reduced, not statistically significantly, from GD 7 to GD 9 (does gained 25, −4 and 1 g at 0, 15 and 45 mg/kg bw per day, respectively). Daily feed consumption was not affected during this period (feed consumption was 293, 189 and 297 g at 0, 15 and 45 mg/kg bw per day, respectively). No treatment-related effect on body weight gain of the does over the entire treatment period (GDs 7–19) was noted. Feed consumption was slightly decreased at the high dose from GD 7 to GD 19 (feed consumption was 147, 146 and 136 g/day at 0, 15 and 45 mg/kg bw per day, respectively). No treatment-related effects on gravid uterine weight were noted at any dose level. Necropsy revealed no treatment-related gross lesions in does at any dose level. No treatment-related effects were noted in the number of viable litters, mean numbers of resorptions, live fetuses or dead fetuses or sex ratio per litter at any dose level. A treatment-related decrease (9%) in combined (male and female) fetal body weight was noted in pups at 45 mg/kg bw per day. The difference was not statistically significant when males and females were compared separately. No treatment-related increases were detected in the type or incidence of external, visceral or skeletal variations or malformations at any dose level.

The NOAEL for maternal toxicity was 15 mg/kg bw per day, on the basis of a decrease in feed consumption during the entire treatment period and an increase in scant or no faeces at 45 mg/kg bw per day.

The NOAEL for developmental effects in this study was 15 mg/kg bw per day, based on a reduction in combined male and female fetal body weight.

The overall NOAEL for maternal toxicity in the rabbit was 15 mg/kg bw per day, based on a reduction in body weight (gain) soon after the commencement of treatment at 30 mg/kg bw per day. The overall NOAEL for developmental toxicity in the rabbit was 30 mg/kg bw per day, based on reduced fetal body weight at 45 mg/kg bw per day and early resorptions and abortions at 60 mg/kg bw per day.

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

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[1] Inman-Wood SL, Craig LP, Danberry TL (2000). Fenbuconazole (RH-7592 technical): oral (gavage) developmental toxicity study in rabbits. Unpublished report no. 00R-017 from R&H Spring House Research, Spring House, PA, USA. Submitted to WHO by Dow AgroScience Gmbh, Munich, Germany.

Toxicological evaluation

The Meeting established an ARfD of 0.2 mg/kg bw on the basis of an overall NOAEL of 15 mg/kg bw per day, based on the reductions in body weight, body weight gain and feed consumption observed in developmental toxicity studies in the rabbit and application of a safety factor of 100. The ARfD is supported by the overall NOAEL for developmental toxicity in the rabbit of 30 mg/kg bw per day, based on the increased incidence of early resorptions observed at 60 mg/kg bw per day early after treatment commenced, and a NOAEL of 30 mg/kg bw per day for maternal toxicity in the rat, based on reduced body weight gain at 75 mg/kg bw per day.

A toxicological monograph was not prepared.

Levels relevant to risk assessment

Species	Study	Effect	NOAEL	LOAEL
Rat	Developmental toxicity study[a]	Maternal toxicity Embryo and fetal toxicity	30 mg/kg bw per day 75 g/kg bw per day	75 mg/kg bw per day 150 mg/kg bw per day
Rabbit	Developmental toxicity studies[a,b]	Maternal toxicity Embryo and fetal toxicity	15 mg/kg bw per day 30 mg/kg bw per day	30 mg/kg bw per day 45 mg/kg bw per day

[a] Gavage administration.

[b] Several studies combined.

DIETARY RISK ASSESSMENT

Short-term intake

ARfD for fenbuconazole is 0.2 mg/kg bw. The International Estimated Short-Term Intake (IESTI) for fenbuconazole was calculated for the plant commodities for which STMR and HR levels were estimated by the 2009 JMPR and for which consumption data were available. The results are shown in Annex 4. The IESTI represented a maximum of 10% of the ARfD. The Meeting concluded that the short-term intake of fenbuconazole residues from uses considered by the current Meeting was unlikely to present a public health concern.

5.16 FENPROPATHRIN (185)

TOXICOLOGY

Fenpropathrin is the ISO-approved name for (*RS*)-α-cyano-3-phenoxybenzyl-2,2,3,3-tetramethylcyclopropanecarboxylate (IUPAC), with the CAS number 39515-41-8. Fenpropathrin is a synthetic pyrethroid with insecticidal/acaricidal properties.

Fenpropathrin was evaluated previously by JMPR in 1993, when an ADI of 0–0.03 mg/kg bw was established based on a NOAEL of 3 mg/kg bw per day from a multigeneration reproductive study in rats, a developmental toxicity study in rats and a 1-year toxicity study in dogs and using a 100-fold safety factor. The establishment of an ARfD was not considered by the Meeting in 1993.

Fenpropathrin 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 of fenpropathrin have been submitted: acute and subchronic neurotoxicity studies, a developmental neurotoxicity study and an immunotoxicity study. Published studies primarily evaluating the neurotoxicity of fenpropathrin have also been taken into consideration.

Most 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

Absorption of fenpropathrin following a single oral administration was rapid, and elimination was almost complete (about 57% in urine, about 40% in faeces) within 48 hours. Low concentrations of residues (< 0.6 µg/g tissue) were measured in blood, liver, kidney, fat, muscle and brain within 24 hours after dosing, and concentrations declined rapidly for 8 days, except for those in fat, which were the highest concentrations measured and which also declined, but not as rapidly. Less than 1.5% of the administered dose remained in the body 8 days after treatment. The major biotransformation reactions of fenpropathrin in rats consisted of oxidation at the methyl groups of the acid moiety and at the 2′- and 4′-positions of the alcohol moiety, cleavage of the ester linkage and the conjugation of the resultant carboxylic acids, alcohols and phenols with glucuronic acid, sulfuric acid and glycine.

Most of the urinary metabolites were ester-cleaved products. The predominant urinary metabolites derived from the acid moiety were identified as 2,2,3,3-tetramethylcyclopropane carboxylic acid–glucuronide (TMPA-glucuronide) and TMPA-CH_2OH (*trans*). The major urinary metabolites derived from the alcohol moiety were 3-phenoxybenzoic acid (PB acid) in free form and as glycine conjugate, 4′-OH-PB acid–sulfate and 2′-OH-PB acid–sulfate. The major faecal metabolite was identified as CH_2OH *trans*-fenpropathrin, followed by COOH *trans*-fenpropathrin, 4′-OH-fenpropathrin and 4′-OH-CH_2OH *trans*-fenpropathrin. Depending on the dose administered, 30–50% of the applied radioactivity was excreted in faeces as parent compound. Fenpropathrin and TMPA were the major radiolabelled components in tissues. An aryl-hydroxylated ester (α-cyano-3-(4-hydroxyphenoxy) benzyl ester) was identified in bile.

Toxicological data

Fenpropathrin appears to have both type I and type II properties. It produces repetitive firing of neurons but is associated with type II symptoms. In acute studies with fenpropathrin in mammals, onset of toxic signs is rapid (within a few hours or days), independent of the route of exposure. Recovery of surviving animals is also rapid. Toxic signs are those typical for pyrethroids and include hypersensitivity, fibrillation, tremors, clonic convulsions, salivation, lacrimation, urinary incontinence and hindlimb and/or whole-body ataxia. The acute oral LD_{50} in rats is greater than or equal to 48.5 mg/kg bw, depending on the vehicle. The dermal LD_{50} in a study in rats ranged from 870 mg/kg bw to greater than 5000 mg/kg bw, depending on the vehicle. The acute inhalation LC_{50} in rats was

greater than or equal to 556 mg/m^3. Fenpropathrin is a slight skin irritant and is minimally irritating to the eyes of rabbits. It is not a dermal sensitizer in the Buehler test.

The neurological clinical signs (body tremors, hypersensitivity/hyperreactivity, ataxia and, in dogs only, emesis) and reduced body weight gain are the key and most sensitive toxicological end-points.

In a 28-day toxicity study in mice, the NOAEL was 500 ppm (equal to 63 mg/kg bw per day), based on decreases in body weight gain in males, decreases in feed efficiency in males and clinical signs seen at the LOAEL of 1000 ppm (equal to 123 mg/kg bw per day).

In three 90-day studies of toxicity in rats, the overall NOAEL was 450 ppm (equal to 21.3 mg/kg bw per day).

In a 1-year dietary study of toxicity in dogs, the NOAEL was 100 ppm (equal to 3 mg/kg bw per day), based on reduced body weight gain and clinical signs (emesis, tremors) at 250 ppm (equal to 7.7 mg/kg bw per day). Similar toxic effects were observed at 250 ppm (equal to 7.4 mg/kg bw per day), the lowest dose tested, in a 90-day study of toxicity in dogs.

A 2-year toxicity and carcinogenicity study was performed in mice in which the NOAEL was 600 ppm (equal to 56 mg/kg bw per day), the highest dose tested. No evidence of carcinogenicity was observed. In a second study of carcinogenicity in mice, a dose of 1000 ppm caused the death of 38% of the males and 15% of the females within 13 weeks, indicating a steep toxicity–response curve and permitting the conclusion that the earlier study in which the highest dose tested was 600 ppm (equal to 56 mg/kg bw per day), the maximum achievable dose, was adequate for an assessment of the carcinogenicity of this compound.

Two long-term toxicity and carcinogenicity studies in rats were available. The overall NOAEL was 125 ppm (equal to 5 mg/kg bw per day), based on depression in body weight gain and clinical signs at 600 ppm (equal to 23 mg/kg bw per day). There was no evidence of carcinogenicity.

The Meeting concluded that fenpropathrin was not carcinogenic in mice or rats.

Fenpropathrin was tested for genotoxicity in an adequate range of assays, both in vitro and in vivo. In none of these assays was there any evidence of genotoxic potential.

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

Two multigeneration reproductive studies are available in rats. The overall NOAEL for parental systemic toxicity was 40 ppm (equal to 2.6 mg/kg bw per day), based on depression of body weight gain, increased mortality in females and the occurrence of body tremors and muscle twitches at 120 ppm (equal to 7.8 mg/kg bw per day). No effects on reproductive parameters were observed at doses up to 360 ppm (equal to 23.3 mg/kg bw per day), the highest dose tested. The overall NOAEL for offspring toxicity was 40 ppm (equal to 2.6 mg/kg bw per day), based on body tremors seen in some pups at 120 ppm (equal to 7.8 mg/kg bw per day).

Two studies of developmental toxicity were available. The overall NOAEL for maternal toxicity was 3 mg/kg bw per day, based on reduced feed consumption and body weight gain at the beginning of treatment seen at 6 mg/kg bw per day. The NOAEL for developmental toxicity was 10 mg/kg bw per day, the highest dose tested.

Developmental toxicity studies were conducted with rabbits. The overall NOAEL for maternal toxicity was 4 mg/kg bw per day, based on clinical signs noted at 12 mg/kg bw per day, whereas the overall developmental NOAEL was 36 mg/kg bw per day, the highest dose tested.

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

In an acute neurotoxicity study, the NOAEL was 10 mg/kg bw, based on tremors at 25 mg/kg bw. In a separate study, no histopathology of sciatic and tibial nerves or increase in β-glucuronidase

activity (indicative of Wallerian degeneration in nerves) was observed in rats at doses up to 500 ppm (equivalent to 25 mg/kg bw per day).

In a published study, effects on motor activity were measured for several pyrethroids, including fenpropathrin, following administration of a single gavage dose in corn oil to rats. Threshold doses (calculated dose at which treated rats did not display any decreases in motor activity) were calculated for these pyrethroids. The threshold dose for fenpropathrin was 3.06 mg/kg bw. In an acute neurotoxicity study in rats, the NOAEL was 15 mg/kg bw, based on slight tremors and clonic convulsions (whole-body tremors) in both sexes at the time of peak effect seen at the LOAEL of 30 mg/kg bw.

In a 90-day neurotoxicity study, treatment at 570 ppm caused the death of 1 of 12 females, decreased body weight gain and feed consumption in both sexes, and led to clinical signs and a number of alterations in functional observational batteries. At 190 ppm, walking on tiptoes and hunched body were observed during the open-field observations in females only. The NOAEL was 60 ppm (equal to 5 mg/kg bw per day for females).

The range-finding study for a guideline developmental neurotoxicity study in rats confirmed the presence of fenpropathrin in milk of lactating females as well as in plasma of mothers and pups, demonstrating that the dietary route of exposure was valid for the main developmental neurotoxicity study. The LOAEL for developmental neurotoxicity was 250 ppm (equal to 19 mg/kg bw per day), based on small pups and decreased body weights and body weight gains during the pre-weaning period, decreased habituation, increased mean overall maximum startle response amplitude and average response amplitude in the females, and decreased absolute brain weights in the males. The NOAEL for developmental neurotoxicity was 100 ppm (equal to 8 mg/kg bw per day).

No signs of neurotoxicity and no histopathological findings were observed in the nervous system of hens treated with fenpropathrin at 1000 mg/kg bw per day.

No immunotoxic potential for fenpropathrin was evidenced in a specific study in which rats were administered up to 450 ppm (42 mg/kg bw per day), a dose level causing systemic toxicity.

No adverse effects were reported by 14 workers engaged in fenpropathrin manufacturing (2002–2011), and no health problems or adverse findings were noted at periodic examinations.

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

Toxicological evaluation

The Meeting reaffirmed the ADI of 0–0.03 mg/kg bw on the basis of an overall NOAEL of 100 ppm (equal to 3.1 mg/kg bw per day) in the 90-day and 1-year toxicity studies in dogs, based on the occurrence of tremors seen at 250 ppm (equal to 7.4 mg/kg bw per day), and using a safety factor of 100. This ADI was supported by the NOAEL of 40 ppm (equal to 2.6 mg/kg bw per day) observed in a multigeneration reproductive study in rats, on the basis of the occurrence of body tremors and muscle twitches and mortality of two females seen at 120 ppm (equal to 7.8 mg/kg bw per day). It is further supported by the NOAEL of 3 mg/kg bw per day observed in the developmental toxicity study in rats, on the basis of decreases in body weight gain and feed consumption seen at 10 mg/kg bw per day.

The Meeting established an ARfD of 0.03 mg/kg bw on the basis of the threshold dose of 3.06 mg/kg bw from a published study measuring motor activity at the time of peak effects following a single oral dose in rats and using a safety factor of 100. This ARfD value was supported by the combined NOAEL of 3 mg/kg bw per day seen in the developmental toxicity studies in rats, based on a decrease in body weight gain and feed consumption in dams during the first 2 days of dosing at 6 mg/kg bw per day.

A toxicological monograph was prepared.

Levels relevant to risk assessment

Species	Study	Effect	NOAEL	LOAEL
Mouse	Two-year study of toxicity and carcinogenicity[a]	Toxicity	600 ppm, equal to 56 mg/kg bw per day[b]	—
		Carcinogenicity	600 ppm, equal to 56 mg/kg bw per day[b]	—
Rat	Acute neurotoxicity study[c] (published)	Neurotoxicity	Threshold dose: 3.06 mg/kg bw	Estimated ED_{30}: 7.70 mg/kg bw
	Ninety-day studies of toxicity[a,d]	Toxicity	250 ppm, equivalent to 12.5 mg/kg bw per day	600 ppm, equal to 28.8 mg/kg bw per day
	Ninety-day study of neurotoxicity[a]	Toxicity	60 ppm, equal to 5 mg/kg bw per day	190 ppm, equal to 15 mg/kg bw per day
	Two-year studies of toxicity and carcinogenicity[a,d]	Toxicity	125 ppm, equal to 6.25 mg/kg bw per day	450 ppm, equal to 21.9 mg/kg bw per day
		Carcinogenicity	600 ppm, equal to 22.7 mg/kg bw per day[b]	—
	Multigeneration study of reproductive toxicity[a,d]	Reproductive toxicity	360 ppm, equal to 23.3 mg/kg bw per day[b]	—
		Parental toxicity	40 ppm, equal to 2.6 mg/kg bw per day	120 ppm, equal to 7.8 mg/kg bw per day
		Offspring toxicity	40 ppm, equal to 2.6 mg/kg bw per day	120 ppm, equal to 7.8 mg/kg bw per day
	Developmental toxicity studies[c,d]	Maternal toxicity	3 mg/kg bw per day	10 mg/kg bw per day
		Embryo and fetal toxicity	10 mg/kg bw per day[b]	—
Rabbit	Developmental toxicity studies[c,d]	Maternal toxicity	4 mg/kg bw per day	12 mg/kg bw per day
		Embryo and fetal toxicity	36 mg/kg bw per day[b]	—
Dog	Ninety-day and 1-year studies of toxicity[a,d]	Toxicity	100 ppm, equal to 3.1 mg/kg bw per day	250 ppm, equal to 7.4 mg/kg bw per day

ED_{30}, dose (mg/kg bw) required to induce a 30% decrease in total motor activity compared with the corresponding vehicle-treated control group

[a] Dietary administration.

[b] Highest dose tested.

[c] Gavage administration.

[d] Two or more studies combined.

Estimate of acceptable daily intake for humans

0–0.03 mg/kg bw

Estimate of acute reference dose

0.03 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 fenpropathrin

Absorption, distribution, excretion and metabolism in mammals	
Rate and extent of oral absorption	Rapid, at least 57%
Dermal absorption	Not available
Distribution	Widely distributed
Potential for accumulation	No
Rate and extent of excretion	Rapid and complete
Metabolism in animals	Extensive
Toxicologically significant compounds in animals, plants and the environment	Parent compound
Acute toxicity	
Rat, LD_{50}, oral	≥ 48.5 mg/kg bw (vehicle dependent)
Rat, LD_{50}, dermal	≥ 870 mg/kg bw (vehicle dependent)
Rat, LC_{50}, inhalation	≥ 556 mg/m^3 (nose-only exposure)
Rabbit, dermal irritation	Slightly irritating
Rabbit, ocular irritation	Mildly irritating
Dermal sensitization	Non-sensitizing, Buehler test
Short-term studies of toxicity	
Target/critical effect	Neurotoxic signs
Lowest relevant oral NOAEL	5 mg/kg bw per day
Lowest relevant dermal NOAEL	3000 mg/kg bw per day (rabbits)
Lowest relevant inhalation NOAEC	Not available
Long-term studies of toxicity and carcinogenicity	
Target/critical effect	Neurotoxic signs
Lowest relevant oral NOAEL	3.1 mg/kg bw per day (dog)
Carcinogenicity	Not carcinogenic
Genotoxicity	
	Not genotoxic
Reproductive toxicity	
Target/critical effect	Neurotoxic signs
Lowest relevant parental NOAEL	2.6 mg/kg bw per day
Lowest relevant offspring NOAEL	2.6 mg/kg bw per day
Lowest relevant reproductive NOAEL	23.3 mg/kg bw per day (highest dose tested)
Developmental toxicity	
Target/critical effect	Decreased body weight gain and secondary effects on locomotor activity
Lowest relevant maternal NOAEL	3 mg/kg bw per day
Lowest relevant embryo/fetal NOAEL	10 mg/kg bw per day
Neurotoxicity/delayed neurotoxicity	
Acute and subchronic neurotoxicity	No specific signs of acute or subchronic neurotoxicity
Delayed neurotoxicity NOAEL	1000 mg/kg bw per day
Immunotoxicity	
	42 mg/kg bw per day (highest dose tested)
Medical data	
	No adverse health effects reported in manufacturing plant personnel

Summary

	Value	Study	Safety factor
ADI	0–0.03 mg/kg bw	Ninety-day and 1-year toxicity studies (dog)	100
ARfD	0.03 mg/kg bw	Single-dose neurotoxicity study (rat)	100

5.17 FENVALERATE (119)

TOXICOLOGY

Fenvalerate is the ISO-approved common name for (*RS*)-α-cyano-3-phenoxybenzyl (*RS*)-2-(4-chlorophenyl)-3-methylbutyrate (IUPAC), for which the CAS number is 51630-58-1. It is a broad-spectrum pyrethroid with neurotoxic effects on insect pests.

Fenvalerate is a racemic mixture of four stereoisomers ([2*S*,α*S*], [2*S*,α*R*], [*2R*,α*S*] and [2*R*,α*R*]) found in approximately equal proportions owing to the presence of two chiral centres. One of these four chiral isomers, esfenvalerate, is the [2*S*,α*S*] or A-α isomer and has been developed separately in the knowledge that it was the biologically active component of the fenvalerate racemic mixture. Fenvalerate is classified, according to its structure, as a type II pyrethroid.

Fenvalerate was reviewed by JMPR on four previous occasions. Temporary ADIs of 0–0.06, 0–0.007 and 0–0.02 mg/kg bw were established by the Meeting in 1979, 1981 and 1984, respectively, and an ADI of 0–0.02 mg/kg bw was established by the Meeting in 1986.

Fenvalerate is being reviewed by the present Meeting at the request of CCPR.

As the compound was not supported by a company that would provide toxicological studies for review, access to the toxicological studies for the current evaluation was provided by the USEPA. The evaluation of fenvalerate was based on the previous reviews by JMPR, an IPCS evaluation, the esfenvalerate review by JMPR, studies submitted to the USEPA and published studies from the open literature.

Most 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

Metabolism studies have been conducted in rats, mice and dogs using ^{14}C-labelled esfenvalerate and fenvalerate. Fenvalerate was rapidly absorbed in these mammals, widely distributed to organs and tissues and rapidly metabolized. Excretion of an isomeric mixture of fenvalerate and esfenvalerate was very rapid in rats and mice, with 63–94% of the administered label being excreted within 1 day after oral dosing. Approximately equal quantities of radioactivity were eliminated in the urine and faeces. Tissue residue concentrations were generally very low, with residue levels being higher in mice than in other species. Fenvalerate and its esters concentrate in adipose tissue, adrenal gland, intestinal mucosa, skin and hair. The cyano moiety remains in the body (particularly in skin and hair) longer than other components. A placental transfer study of fenvalerate and esfenvalerate in rats indicated that there was virtually no transfer of radioactivity from maternal blood to the fetus and no evidence of accumulation in the fetus or amniotic fluid. In dogs administered fenvalerate orally, the total recovery of radioactivity in excreta was less than that in mice or rats, but the elimination half-life was similar to those found in the rodents (0.5–0.6 day).

Fenvalerate undergoes several major metabolic reactions, including cleavage of the ester linkage, hydroxylation in the acid and alcohol moieties and conversion of the cyano group to thiocyanate and carbon dioxide. The pattern of hydroxylation was different in rats and dogs, and the glycine conjugate, 3-phenoxybenzylglycine, was the major conjugate of the alcohol moiety in dogs, whereas it was a minor one in rats. The proportions of glucuronides formed at the acid moiety and its hydroxy derivatives were also greater in dogs. There were no major sex differences in the metabolism of fenvalerate.

In a 28-day feeding study in mice, the major metabolites in the liver and kidney of animals fed [^{14}C-chlorophenyl]esfenvalerate and [^{14}C-chlorophenyl]fenvalerate were chlorophenylisovaleric acid (CPIA) and the hydroxylated derivative of CPIA. These disappeared after administration of

untreated diets. In addition, "CPIA-cholesterol ester" was found in mice fed [^{14}C-chlorophenyl]fenvalerate, but not in mice fed [^{14}C-chlorophenyl]esfenvalerate.

Photolytic degradation on plants can produce a decarboxylated fenvalerate not known to occur in mammals.

Toxicological data

Clinical signs, such as choreoathetosis (coarse tremors progressing to sinuous writhing), sedation, salivation, dyspnoea and/or clonic seizures and sometimes body tremors and prostration, were observed in acute studies. These signs, which are typical of a type II pyrethroid, have been observed in various mammalian species tested with either esfenvalerate or fenvalerate and are characteristic of a strong excitatory action on the nervous system.

The oral LD_{50} in rats was greater than or equal to 451 mg/kg bw (vehicle dependent), whereas in mice, it was greater than or equal to 100 mg/kg bw (vehicle dependent). The dermal LD_{50} in rats was 5000 mg/kg bw. The inhalation LC_{50} in rats was greater than 101 mg/m^3 (3-hour exposure). No data are available on skin and eye irritation or skin sensitization. However, data are available on esfenvalerate, which is not irritating to the skin and minimally irritating to the unwashed eyes of rabbits. It was a skin sensitizer in guinea-pigs using the Magnusson & Kligman maximization test, but was not a sensitizer using the Buehler test method.

In a 90-day dietary toxicity study of fenvalerate in rats, the NOAEL was 125 ppm (equivalent to 12.5 mg/kg bw per day), based on increased relative kidney weight at 500 ppm (equivalent to 50 mg/kg bw per day). Although survival was reduced at 2000 ppm (equivalent to 200 mg/kg bw per day), the highest dose tested in this study, no degeneration of the sciatic nerve was observed.

The overall NOAEL in dogs fed fenvalerate for 3 or 6 months was 250 ppm (equivalent to 18.7 mg/kg bw per day), based on hepatic multifocal microgranulomas and histiocytic infiltration of the mesenteric lymph nodes in females at 500 ppm (equivalent to 35.5 mg/kg bw per day).

Three 18-month dietary studies of fenvalerate toxicity and carcinogenicity in mice have been reported. In the first study, the NOAEL was 300 ppm (equivalent to 15 mg/kg bw per day), based on reduced body weight gain, clinical signs of hyperactivity, mortality, clinical chemistry changes and microscopic changes in liver, kidney and mesenteric lymph nodes observed at 1000 ppm (equivalent to 50 mg/kg bw per day). In the second study, the NOAEL was 10 ppm (equivalent to 1.5 mg/kg bw per day), based on an increased incidence of microgranulomatous changes in mesenteric lymph nodes and other visceral and peripheral lymph nodes observed at 50 ppm (equivalent to 7.5 mg/kg bw per day). In the third study, the NOAEL was 30 ppm (equal to 3.48 mg/kg bw per day), based on slightly decreased erythrocyte counts, decreased serum glucose concentrations and increased histiocytic infiltration (liver and lymph nodes) and granulomatous changes in the liver and lymph nodes at 100 ppm (equal to 12.3 mg/kg bw per day). The overall NOAEL for long-term dietary exposure of mice to fenvalerate was 30 ppm (equal to 3.48 mg/kg bw per day), based on histopathology in various organs, but most consistently in lymph nodes, at 50 ppm (equivalent to 7.5 mg/kg bw per day).

There was no evidence for carcinogenicity from any of these studies in mice at fenvalerate concentrations up to 3000 ppm (equivalent to 450 mg/kg bw per day).

In a published oral gavage study of carcinogenicity of fenvalerate in mice, no evidence for carcinogenicity was observed at the highest dose of 80 mg/kg bw per day.

Four chronic toxicity and carcinogenicity studies of fenvalerate have been performed in rats, but two of the studies are inadequate for the assessment of carcinogenic potential.

Groups of Sprague-Dawley rats were administered diets containing fenvalerate at either 0 or 1000 ppm (equivalent to 50 mg/kg bw per day) for 2 years. No group difference in the incidence of any specific tumours was reported.

In a second 2-year study in rats (Wistar/SCL strain), there were observations of body weight gain depressions and giant cell infiltration of lymph nodes and adrenals and reticuloendothelial cell proliferation in the lymph nodes at 500 ppm (equivalent to 25 mg/kg bw per day).

The overall NOAEL for long-term toxicity of fenvalerate in rats was 150 ppm (equivalent to 7.5 mg/kg bw per day), on the basis of body weight gain reduction in males and giant cell infiltration of lymph nodes and adrenals and reticuloendothelial cell proliferation in the lymph nodes at 500 ppm (equivalent to 25 mg/kg bw per day). In males, Leydig cell atrophy, Leydig cell hyperplasia and Leydig cell adenomas were significantly increased in some groups, but there was no clear dose–response relationship. Similar to the Fischer 344 strain rats, Leydig cell adenomas are particularly common and variable in the Wistar/SCL strain (which is not to be confused with the Wistar strain, in which incidences of these tumours are low). Consequently, variation in the incidence of this tumour type cannot be used with any confidence in carcinogen evaluation. There was no evidence of carcinogenicity in rats at doses up to 1500 ppm (equivalent to 75 mg/kg bw per day), the highest dose tested.

The Meeting concluded that fenvalerate was not carcinogenic in mice or rats.

Fenvalerate was tested for genotoxicity in an adequate range of assays, both in vitro and in vivo. No evidence of genotoxicity emerged from the in vitro assays, but inconsistent results were obtained in the male mouse dominant lethal assays and the in vivo cytogenetic assays.

Available data allowed the Meeting to conclude that fenvalerate is unlikely to be a deoxyribonucleic acid (DNA) reactive compound, but no firm conclusion could be reached on its in vivo clastogenicity.

On the basis of the absence of carcinogenicity in mice and rats and the absence of DNA reactivity, the Meeting concluded that fenvalerate is unlikely to pose a carcinogenic risk to humans at expected dietary levels.

In a three-generation reproduction study in rats, the NOAEL for parental toxicity was 25 ppm (equivalent to 1.7 mg/kg bw per day), based on reduced mean body weights seen at 250 ppm (equivalent to 16.7 mg/kg bw per day). The NOAEL for reproductive and offspring toxicity was 250 ppm (equivalent to 16.7 mg/kg bw per day), the highest dose tested.

In a developmental toxicity study in mice, the NOAEL for maternal toxicity was 15 mg/kg bw per day, based on irregular respiration, hypersensitivity, tremors and salivation after administration of the compound (first 30–60 minutes after dosing only) seen at 50 mg/kg bw per day. The NOAEL for developmental toxicity was 50 mg/kg bw per day, the highest dose tested.

In a developmental toxicity study in rabbits, the NOAEL for maternal toxicity was 25 mg/kg bw per day, based on reduced body weight of dams seen at 50 mg/kg bw per day. The NOAEL for developmental toxicity was 50 mg/kg bw per day, the highest dose tested.

The Meeting concluded that fenvalerate is not teratogenic in mice or rabbits.

A study of the neurotoxic potential of esfenvalerate and fenvalerate in corn oil was conducted in rats following a single oral gavage dose. The NOAEL was 5 and 20 mg/kg bw for esfenvalerate and fenvalerate, respectively, based on the toxic signs typical of type II pyrethroids. Signs were observed within 2 hours of dosing at 20 and 90 mg/kg bw for esfenvalerate and fenvalerate, respectively.

No histopathological lesions were observed in rats following a single-dose administration of fenvalerate at 200 mg/kg bw. In a separate study, rats were administered fenvalerate orally at dose levels ranging from 0 to 400 mg/kg bw per day for 7 consecutive days. A significant neurological deficit was demonstrated using an inclined plane test (expressed as the angle at which the animals cannot maintain their hold on an inclining plane). In addition to functional deficits, increases in the activity of the lysosomal enzymes β-glucuronidase and β-galactosidase in the posterior tibular nerve and trigeminal ganglia were observed.

Fenvalerate did not cause delayed neuropathy in hens at 1000 mg/kg bw per day for 5 days.

The acute intraperitoneal toxicity study results indicate that fenvalerate metabolites were less toxic than the parent compound fenvalerate.

The major photodegradation product of fenvalerate, decarboxyfenvalerate, or 2-(3-phenoxyphenyl)-3-(4-chlorophenyl)-4-methylpentanenitrile, was evaluated for its acute toxicity;

results indicated that it was less toxic than the parent compound. In a 90-day toxicity study in rats with decarboxyfenvalerate, the NOAEL was 300 ppm (equivalent to 30 mg/kg bw per day), based on reduced body weight gains in males during the first 7 weeks, a decrease in white blood cell count in females, reduced mean corpuscular volume in both sexes, increases in liver and kidney weights, and hepatocellular necrosis at 1000 ppm (equivalent to 100 mg/kg bw per day). In a developmental toxicity study with decarboxyfenvalerate in rats, the NOAEL for maternal toxicity was 300 mg/kg bw per day, based on decreases in body weights and increases in relative liver weights seen at 3000 mg/kg bw per day. The developmental toxicity NOAEL was 3000 mg/kg bw per day, the highest dose tested.

Several published studies are available that evaluate the effects of fenvalerate in mice and rats on sexual maturation, stereotyped and sexual behaviour, hormonal measurements, sperm measurements and changes in various organ weights and histopathology. These studies were conducted following single or multiple oral administrations of fenvalerate. Generally, reproductive parameters and neurobehavioural parameters were affected at about 20 mg/kg bw per day via oral doses.

Observations in humans indicate that fenvalerate causes the transient facial sensations that appear to be common to pyrethroids, particularly those possessing a cyano group.

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

Toxicological evaluation

The Meeting reaffirmed the ADI of 0–0.02 mg/kg bw on the basis of a parental systemic toxicity NOAEL of 1.7 mg/kg bw per day observed in the three-generation reproduction study in rats, based on reduced mean body weights seen at 16.7 mg/kg bw per day and using a safety factor of 100. This ADI was supported by the NOAEL of 3.5 mg/kg bw per day observed in the 2-year toxicity and carcinogenicity study in mice, based on the slight decrease in erythrocyte counts, increased histiocytes and granulomatous changes in the liver and lymph nodes (mesenteric, visceral and peripheral) at 7.5 mg/kg bw per day.

The Meeting established an ARfD of 0.2 mg/kg bw on the basis of the NOAEL of 20 mg/kg bw observed in the single oral dose neurotoxicity study in rats, based on clinical signs of toxicity (muscular fibrillation, ataxia, salivation and/or hunched posture) seen at 90 mg/kg bw and using a safety factor of 100. This ARfD was supported by the developmental toxicity study in mice in which the NOAEL was 15 mg/kg bw per day, based on irregular respiration, hypersensitivity, tremors and salivation after administration of the compound (first 30–60 minutes after dosing) seen at 50 mg/kg bw per day.

A toxicological monograph was prepared.

Levels relevant to risk assessment

Species	Study	Effect	NOAEL	LOAEL
Mouse	Eighteen-month studies of toxicity and carcinogenicity[a,b]	Toxicity	30 ppm, equal to 3.5 mg/kg bw per day	50 ppm, equivalent to 7.5 mg/kg bw per day
		Carcinogenicity	3000 ppm, equivalent to 450 mg/kg bw per day[c]	—
	Developmental toxicity study[d]	Maternal toxicity	15 mg/kg bw per day	50 mg/kg bw per day
		Embryo and fetal toxicity	50 mg/kg bw per day[c]	—
Rat	Three-year studies of toxicity and carcinogenicity[a,b]	Toxicity	150 ppm, equivalent to 7.5 mg/kg bw per day	500 ppm, equivalent to 25 mg/kg bw per day

Species	Study	Effect	NOAEL	LOAEL
		Carcinogenicity	1500 ppm, equivalent to 75 mg/kg bw per day[c]	—
	Two-generation study of reproductive toxicity[a]	Reproductive toxicity	250 ppm, equivalent to 16.7 mg/kg bw per day[c]	—
		Parental toxicity	25 ppm, equivalent to 1.7 mg/kg bw per day	250 ppm, equivalent to 16.7 mg/kg bw per day
		Offspring toxicity	250 ppm, equivalent to 16.7 mg/kg bw per day[c]	—
	Neurotoxicity study (single dose)[d]	Neurotoxicity	20 mg/kg bw	90 mg/kg bw
Rabbit	Developmental toxicity study[d]	Maternal toxicity	25 mg/kg bw per day	50 mg/kg bw per day
		Embryo and fetal toxicity	50 mg/kg bw per day[c]	—
Dog	Thirteen-week and 6-month studies of toxicity[a,b]	Toxicity	250 ppm, equal to 18.7 mg/kg bw per day	500 ppm, equal to 35.5 mg/kg bw per day

[a] Dietary administration.

[b] Two or more studies combined.

[c] Highest dose tested.

[d] Gavage administration.

Estimate of acceptable daily intake for humans

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 exposures

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

Absorption, distribution, excretion and metabolism in mammals	
Rate and extent of oral absorption	Rapid and complete
Dermal absorption	Not available
Distribution	Widely distributed
Potential for accumulation	None
Rate and extent of excretion	Rapid and complete (half life 0.5–0.6 day)
Metabolism in animals	Extensive
Toxicologically significant compounds in animals, plants and the environment	Parent compound and decarboxylated fenvalerate
Acute toxicity	
Rat, LD_{50}, oral	≥ 451 mg/kg bw (vehicle dependent)
Rat, LD_{50}, dermal	5000 mg/kg bw
Rat, LC_{50}, inhalation	> 101 mg/m^3 (3 h)
Rabbit, dermal irritation	Not available
Rabbit, ocular irritation	Not available
Dermal sensitization	Not available

Short-term studies of toxicity	
Target/critical effect	Nervous system, clinical signs
Lowest relevant oral NOAEL	12.5 mg/kg bw per day
Lowest relevant dermal NOAEL	1000 mg/kg bw per day
Lowest relevant inhalation NOAEC	7 mg/L
Long-term studies of toxicity and carcinogenicity	
Target/critical effect	Multiple target organs
Lowest relevant NOAEL	3.5 mg/kg bw day
Carcinogenicity	Not carcinogenic in mice or rats
Genotoxicity	
	Not DNA reactive, inconsistent results in in vivo cytogenetic assay
Reproductive toxicity	
Target/critical effect	None
Lowest relevant reproductive NOAEL	16.7 mg/kg bw per day (highest dose tested)
Lowest relevant parental NOAEL	1.7 mg/kg bw per day
Lowest relevant offspring NOAEL	16.7 mg/kg bw per day (highest dose tested)
Developmental toxicity	
Target/critical effect	None
Lowest relevant maternal NOAEL	15 mg/kg bw per day
Lowest relevant embryo/fetal NOAEL	50 mg/kg bw per day
Neurotoxicity	
Target/critical effect	Clinical signs typical of type II pyrethroids
Acute neurotoxicity NOAEL	20 mg/kg bw
Subchronic neurotoxicity	No data
Other toxicological studies	
Studies on metabolites	Metabolites/degradation products less toxic than parent
Immunotoxicity	No data
Medical data	
	Transient facial sensations in humans

Summary

	Value	Study	Safety factor
ADI	0–0.02 mg/kg bw	Three-generation reproduction study (rat)	100
ARfD	0.2 mg/kg bw	Single-dose study (rat)	100

RESIDUE AND ANALYTICAL ASPECTS

Fenvalerate is a broad-spectrum pyrethroid insecticide consisting of four isomers (SS, RS, SR and RR) all being present at equal amounts in the technical material (see FAO Specification from 1993). The active substance was evaluated by JMPR several times between 1979 and 1991 for residues and toxicology.

In 2002 esfenvalerate, which is the purified SS-isomer (84%), was evaluated as a new compound by the JMPR for residues as well as for toxicology.

Fenvalerate was scheduled at the Forty-third Session of the CCPR under the periodic review program to be evaluated for toxicology and residues by the 2012 JMPR. However, no data on animal or plant metabolism, the environment, analytical methods or storage stability were submitted to the 2012 JMPR, studies normally required for a periodic re-evaluation of a compound.

The Meeting noted that in 2002 esfenvalerate was evaluated for residues as a new compound. The JMPR Evaluation, presented in a comprehensive form, was primarily based on studies for fenvalerate. It included data on animal metabolism (lactating cows), plant metabolism (apple trees, cabbage, kidney beans, lettuce, soya bean, tomato and wheat), the environment (soil photolysis, aerobic and anaerobic soil metabolism, field dissipation and rotational crops) and livestock feeding

studies (dairy cattle and laying hens). Residue analytical methods and storage stability were reported for esfenvalerate only, however all isomers of fenvalerate were covered within these studies.

The Meeting recognized that basic principles for the evaluation of key studies (animal and plant metabolism, environment, analytical methods and storage stability) have not changed significantly since 2002 and concluded that a re-evaluation of the data would result in an identical recommendation for the definition of fenvalerate residues in plant and animal commodities.

The absence of key studies normally precludes the re-evaluation of an active compound under the periodic review program by JMPR. However, the Meeting noted that its evaluation for esfenvalerate in 2002 still reflects current scientific knowledge and covers fenvalerate also. In view of the closely related chemical composition of fenvalerate and esfenvalerate the Meeting decided, as an exception, to apply its 2002 evaluation of esfenvalerate for decision making to fenvalerate without re-reviewing study data previously reported.

Definition of the residue

The 2012 JMPR considered its evaluation for esfenvalerate in 2002 and confirmed that the recommended definition of the residue for plant and animal commodities is also applicable to fenvalerate.

Definition of the residue (for compliance with MRL and for estimation of dietary intake, plant and animal commodities): *sum of fenvalerate isomers*

The residue is fat-soluble.

Results of supervised residue trials on crops

The Meeting received supervised trial data for applications of fenvalerate on mango and Chinese kale conducted in Thailand. The OECD MRL calculator was used as a tool to assist in the estimation of maximum residue levels from the selected residue data set obtained from the supervised residue trials. As a first step, the Meeting reviewed all relevant factors related to each data set in arriving at a best estimate of the maximum residue level using expert judgement. Then the OECD calculator was employed. If the statistical calculation spreadsheet suggested a different value from that recommended by the Meeting, a brief explanation of the deviation was supplied.

In trials where duplicate field samples from replicated or unreplicated plots were taken at each sampling time and analysed separately, the mean sample was taken as the best estimate of the residue from the plot.

Labels (or translation of labels) were available from Thailand, describing the registered uses of fenvalerate.

Within the periodic review program for fenvalerate only uses for mango and Chinese kale from Thailand were reported to the Meeting and evaluated.

As a consequence the Meeting withdraws its previous recommendations for fenvalerate of 20 mg/kg in alfalfa fodder, 0.1 mg/kg in beans, shells, 1 mg/kg for beans, except broad beans and soya beans, 1 mg/kg for berries and other small fruit, 2 mg/kg for broccoli, 2 mg/kg for Brussels sprouts, 3 mg/kg for cabbage, head, 2 mg/kg for cauliflower, 2 mg/kg for celery, 2 mg/kg (Po) for cereal grains, 2 mg/kg for cherries, 1 mg/kg for Chinese cabbage (type Pak-choi), 2 mg/kg for citrus fruit, 0.2 mg/kg for cotton seed, 0.1 mg/kg for cotton seed oil, crude, 0.1 mg/kg for cotton seed oil, edible, 0.02 mg/kg for cucumber, 0.02 mg/kg for edible offal (mammalian), 10 mg/kg for kale, 5 mg/kg for kiwifruit, 2 mg/kg for lettuce, head, 1 mg/kg (F) for meat (from mammals other than marine mammals), 0.2 mg/kg for melons, except watermelons, 0.1 mg/kg for milks, 5 mg/kg for peach, 0.1 mg/kg for peanut, whole, 0.1 mg/kg for peas, shelled (succulent seeds), 0.5 mg/kg for peppers, sweet (including pimento or pimiento), 2 mg/kg for pome fruit, 0.05 mg/kg for root and tuber vegetables, 0.1 mg/kg for soya bean (dry), 0.5 mg/kg for squash, summer, 0.1 mg/kg for sunflower, seed, 0.1 mg/kg for sweet corn (corn-on-the-cob), 1 mg/kg for tomato, 0.2 mg/kg for tree nuts,

0.5 mg/kg for watermelon, 5 mg/kg (Po) for wheat bran, unprocessed, 0.2 mg/kg (Po) for wheat flour, 2 mg/kg (Po) for wheat wholemeal and 2 mg/kg for winter squash.

The Meeting also withdrawn its previous recommendation given in 2004 for dried chili pepper of 5 mg/kg, which was based on the previously estimated maximum residue level of 0.5 mg/kg for peppers, sweet (including pimento or pimiento) and a default processing factor of 10 for sweet pepper to dried chili pepper derived in 2004.

Mango

GAP for mango in Thailand is foliar spraying at rates of 0.0105 kg ai/hl with a PHI of 7 days. In corresponding field trials conducted in Thailand residues of fenvalerate, sum of isomers in mangos (whole fruit) were (n=4): 0.3, 0.35, 0.43, 0.48 mg/kg.

The Meeting estimated a maximum residue level, an STMR and an HR of 1.5 mg/kg, 0.39 mg/kg and 0.48 mg/kg for fenvalerate in mango, respectively.

Chinese kale

The GAP for Chinese kale in Thailand is foliar applications at rates of 0.021 kg ai/hL with a PHI of 7 days. In corresponding field trials conducted in Thailand residues of fenvalerate, sum of isomers in Chinese kale were (n=6): 0.36, 0.36, 0.7, 0.92, 1.0, 1.8 mg/kg.

The Meeting noted that Chinese kale belongs to the Chinese broccoli commodity (VB 0401) within the Codex Classification of foods and animal feeds.

The Meeting estimated a maximum residue level, an STMR and an HR of 3 mg/kg, 0.81 mg/kg and 1.8 mg/kg for fenvalerate in Chinese broccoli, respectively.

Residues in animal commodities

As mango and Chinese kale are not potential animal feed items, no evaluation of residues in livestock was undertaken.

DIETARY RISK ASSESSMENT

Long-term intake

The evaluation of fenvalerate resulted in recommendations for MRLs and STMR values for mango and broccoli. 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 0–1% of the maximum ADI (0.02 mg/kg bw). The Meeting concluded that the long-term intake of residues of fenvalerate from uses that have been considered by the JMPR is unlikely to present a public health concern.

Short-term intake

The IESTI for fenvalerate calculated on the basis of the recommendations made by the JMPR represented 0–40% of the ARfD (0.2 mg/kg bw) for children and 0–20% for the general population.

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

5.18 FLUDIOXONIL (211)

RESIDUE AND ANALYTICAL ASPECTS

Fludioxonil (4-(2,2-difluoro-1,3-benzodioxol-4-yl)pyrrole-3-carbonitrile) was first evaluated by the 2004 JMPR. The 2004 JMPR recommended 48 maximum residue levels for a variety of commodities and an ADI of 0–0.4 mg/kg bw. ARfD was considered unnecessary. The 2004 JMPR recommended the residue definition for plant commodities (for both compliance with the MRL and estimation of dietary intakes) should be fludioxonil. Fludioxonil is considered fat-soluble.

Fludioxonil was reviewed also by the 2006 and 2010 JMPR which together recommended six additional maximum residue levels and withdrew two previous maximum residue levels. At the Forty-third Session, CCPR included fludioxonil in the Priority List for review by the current Meeting for an additional MRL.

After the 2010 JMPR, a post-harvest use of fludioxonil on mango was approved and the label was available to the current Meeting from South Africa. The current Meeting received information on residue trials conducted in Australia and South Africa to support this use, along with information on methods of analysis for fludioxonil in mango.

Methods of analysis

The Meeting received information on validation of three methods of analysis used in the supervised field trial studies, HPLC/UV method already reviewed by the 2008 JMPR and two new methods, GC/MS method and HPLC/MS/MS method, for determination of fludioxonil in mango. These methods were satisfactorily validated for determination of fludioxonil in mango pulp and peel with mean recoveries within a range of 70–110% and RSD less than 20%.

Stability of residues in stored analytical samples

The 2004, 2006 and 2010 JMPR concluded that fludioxonil is stable when stored frozen for at least the following periods: 24 months in apple and grape; 14 months in grapefruit; and 10 months in lemon pulp and potato. In supervised trials, samples were stored deep-frozen for a maximum of 8 months.

Results of supervised residue trials on crops

The Meeting received information on supervised post-harvest trials of fludioxonil on mango.

The OECD MRL calculator was used as a tool to assist in the estimation of maximum residue levels from the selected residue data set obtained from the supervised residue trials. As a first step, the Meeting reviewed trial conditions and other relevant factors related to each data set to arrive at a best estimate of the maximum residue level using expert judgement. Then, the OECD calculator was employed. If the statistical calculation spreadsheet suggested a different value, a brief explanation of the derivation was supplied.

Mango

A number of trials were conducted in Australia and South Africa. The registered post-harvest use of fludioxonil on mango in South Africa allows hot dip at 52 °C for a minimum of 30 seconds to a maximum of 5 minutes at the maximum rate of 34.5 g ai/hL. As the intended use was post-harvest application, the trials conducted in Australia and those in South Africa using post-harvest application were considered together.

Residues in whole fruit (including stone) from trials conducted in Australia and South Africa using post-harvest application following GAP in South Africa were in rank order (14): 0.29, 0.31, 0.34, 0.36, 0.37, 0.42, 0.49, 0.59, 0.62, 0.66, 0.67, 0.74, 1.1 and 1.2 mg/kg.

Corresponding residues in pulp, in rank order were (n = 14): < 0.01 (6), < 0.02(4), 0.02, 0.04(2), and 0.09 mg/kg.

The Meeting estimated a maximum residue level of 2 mg/kg and an STMR of 0.02 mg/kg.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Daily Intakes (IEDIs) of fludioxonil were calculated for the 13 GEMS/Food cluster diets using STMRs and STMRPs estimated by the 2004, 2006, 2010 and current Meetings (Annex 3). The ADI is 0–0.4 mg/kg bw and the calculated IEDIs were 0–2% of the maximum ADI. The Meeting concluded that the long-term intake of residues of fludioxonil resulting from the uses considered by the 2004, 2006, 2010 and current JMPR is unlikely to present a public health concern.

Short-term intake

The 2004 JMPR concluded that an ARfD for fludioxonil is unnecessary. The Meeting therefore concluded that the short-term intake of fludioxonil residues is unlikely to present a public health concern.

5.19 FLUOPYRAM (243)

RESIDUE AND ANALYTICAL ASPECTS

Fluopyram, a pyridylethylamide broad spectrum fungicide was evaluated for the first time by the 2010 JMPR, where an ADI of 0–0.01 mg/kg bw and an ARfD of 0.5 mg/kg bw were established, residue definitions were proposed and maximum residue levels were recommended for a number of uses where GAP information was available.

Residue definitions recommended by the 2010 JMPR are:

- For compliance with the MRL and for dietary intake estimation for plant commodities: *fluopyram*
- For MRL-compliance for animal commodities: s*um of fluopyram and 2-(trifluoromethyl) benzamide, expressed as fluopyram*
- For dietary intake estimation for animal products: *sum of fluopyram, 2-(trifluoromethyl)benzamide and the combined residues N-{(E)-2-[3-chloro-5-(trifluoromethyl)pyridin-2-yl]ethenyl}-2-trifluoromethyl) benzamide and N-{(Z)-2-[3-chloro-5-(trifluoromethyl)pyridin-2-yl]ethenyl}-2-trifluoromethyl) benzamide, all expressed as fluopyram*

The residue is not fat-soluble.

New GAP information, supporting residue data and additional analytical sample storage stability studies were provided by the manufacturer for evaluation by the Meeting.

Stability of residues in stored analytical samples

The Meeting received updated information on the stability of residues in frozen analytical samples of representative substrates covering those with a high water content (lettuce), a high starch content (wheat grain), a high protein content (dry pea seed), a high oil content (rape seed) and a high acid content (orange).

Residues of fluopyram and its -benzamide, -pyridyl-acetic acid and -pyridyl-carboxylic acid metabolites were all stable in these representative substrates (except orange) stored frozen for up to 36–37 months. In orange, levels of the -pyridyl-acetic acid metabolite decreased from about 80% of the spiked level after 6 months to about 50% after 36 months storage.

Results of supervised residue trials on crops

The Meeting received new supervised trial data for foliar applications of fluopyram (SC formulations) on apples, wine grapes and peppers and agreed to use the data provided to the 2010 JMPR to estimate maximum residue levels for commodities for which new GAP information was available.

The results from these new trials and those previously reported by the 2010 JMPR and either matching critical GAP or where the results can be proportionally adjusted (scaled) to reflect GAP application rates were used to estimate maximum residue levels, STMRs and HRs for a number of commodities. The approach used to scale the results from trials where the application rates range from 0.33 × GAP to 5 × GAP (but otherwise match the critical GAP) is described in the Report of the 2010 JMPR (Section 2.8).

The OECD MRL calculator was used as a tool to assist in the estimation of maximum residue levels from the selected residue data set obtained from the supervised residue trials. As a first step, the Meeting reviewed all relevant factors related to each data set in arriving at a best estimate of the maximum residue level using expert judgement. Then the OECD calculator was employed. If the statistical calculation spreadsheet suggested a different value from that recommended by the Meeting, a brief explanation of the deviation was supplied.

Pome fruit

Results from supervised field trials on apples and pears conducted in Europe and North America were provided to the 2010 JMPR and the results from additional trials on apples in North America were provided to the Meeting.

The critical GAP for pome fruit is in Germany, a maximum of 4 applications of 0.05 kg ai/ha/metre of canopy height, PHI 14 days (equivalent to 0.15 kg ai/ha for 3m canopy trees). In trials on apples (6) and pears (2) from northern Europe, reported by the 2010 JMPR and matching the GAP in Germany, fluopyram residues were: 0.11, 0.11, 0.12, 0.12, 0.15, 0.2, 0.21 and 0.28 mg/kg.

The Meeting estimated a group maximum residue level of 0.5 mg/kg, an STMR of 0.135 mg/kg and an HR of 0.28 mg/kg for fluopyram on pome fruits.

Stone fruit

Results from supervised field trials on cherries conducted in USA and peaches conducted in Europe and USA were provided to the 2010 JMPR.

Cherries

The critical GAP for cherries is in Canada, up to 3 applications of 0.125 kg ai/ha, 14 days apart, PHI 0 days and a maximum seasonal rate of 0.375 kg ai/ha. None of the trials reported by the 2010 JMPR matched this GAP.

GAP for cherries in USA is 0.1 kg ai/ha, PHI 0 days, a 5–7 day spraying interval and a maximum of 0.21 kg ai/ha/season. In trials from USA reported by the 2010 JMPR, where cherries were treated with 2 × 0.25–0.26 kg ai/ha fluopyram, residues at 0 DAT (days after the last treatment) were: 0.07, 0.15, 0.21, 0.28, 0.35, 0.51, 0.51, 0.57, 0.63, 0.64 and 1.2 mg/kg. When proportionally adjusted to the 0.1 kg ai/ha GAP application rate (scaling factors of 0.38–0.4), fluopyram residues in cherries from these trials were: 0.03, 0.06, 0.08, 0.11, 0.14, 0.20, 0.21, 0.22, 0.22, 0.25, 0.26 and 0.47 mg/kg (n=12).

The Meeting agreed to use the proportionally adjusted data matching the GAP of the USA for cherries to estimate a maximum residue level of 0.7 mg/kg, an STMR of 0.205 mg/kg and an HR of 0.47 mg/kg for fluopyram on cherries.

Peaches

The critical GAP for peaches is in Turkey, 0.005 kg ai/hL, PHI 3 days. In trials from Southern Europe reported by the 2010 JMPR, where peaches were treated with 3 × 0.01–0.018 kg ai/hL fluopyram, residues at 3 DAT were: 0.11, 0.15, 0.2, 0.24, 0.26, 0.33, 0.34 and 0.34 mg/kg. When proportionally adjusted to the 0.005 kg ai/hL GAP application rate (scaling factors of 0.28–0.5), fluopyram residues in peaches from these trials were: 0.03, 0.06, 0.10, 0.12, 0.14, 0.16, 0.16 and 0.17 mg/kg (n=9).

The Meeting agreed to use the Southern European trial results, proportionally adjusted to match the GAP in Turkey to estimate a maximum residue level of 0.4 mg/kg, an STMR of 0.13 mg/kg and an HR of 0.17 mg/kg for fluopyram on peach.

Berries and small fruit

Grapes

Results from supervised field trials on wine and table grapes conducted in Europe and on table grapes in USA were provided to the 2010 JMPR and additional trial results on wine grapes from USA were provided to the Meeting.

New GAP information was provided to the Meeting for wine grapes in USA (0.25 kg ai/ha, PHI 7 days with a maximum seasonal rate of 0.5 kg ai/ha) and in North American trials matching this GAP, fluopyram residues in grapes were: 0.1, 0.15, 0.15, 0.19, 0.21, 0.27, 0.32, 0.37, 0.43, 0.47, 0.49, 0.52, 0.57, 0.62, 0.63 and 0.95 mg/kg (n=16).

The Meeting noted that the 2010 JMPR had estimated a maximum residue level of 2 mg/kg, an STMR of 0.58 mg/kg and an HR of 1 mg/kg for fluopyram on grape, based on data from European trials matching the Romanian GAP for table grapes (2 × 0.25 kg ai/ha, PHI 3 days) and that this 2010 recommendation accommodated the new GAP in USA.

Strawberries

Results from supervised field trials on strawberries in USA (foliar applications and drip irrigation treatments) and Europe (foliar applications) to strawberries were provided to the 2010 JMPR.

The critical GAP for strawberries is in Morocco, 2 applications of 0.015 kg ai/hL, PHI 3 days but none of the European trials matched this GAP.

GAP for strawberries in Canada is for a maximum of 2 drip irrigation treatments of up to 0.25 kg ai/ha, PHI 0 days with a maximum seasonal application rate of 0.5 kg ai/ha. In trials from USA, reported by the 2010 JMPR and matching the GAP in Canada, fluopyram residues were: < 0.01, < 0.01, 0.01, 0.02, 0.02, 0.03, 0.03, 0.06, 0.1 and 0.23 mg/kg (n=10).

The Meeting estimated a maximum residue level of 0.4 mg/kg, an STMR of 0.025 mg/kg and an HR of 0.23 mg/kg for fluopyram on strawberries..

Banana

Results from supervised field trials on bagged and unbagged bananas in Mexico, Central and South America were provided to the 2010 JMPR.

The critical GAP for bananas is in Panama, a maximum of 5 foliar applications of 0.1 kg ai/ha, PHI 0 days. In trials on bananas, reported by the 2010 JMPR and matching the GAP in Panama (but involving 6 applications), fluopyram residues in unbagged bananas (whole fruit) were: 0.02, 0.04, 0.04, 0.05, 0.05, 0.06, 0.17, 0.18, 0.18, 0.21, 0.22, 0.25, 0.34 and 0.51 mg/kg (n=14).

The Meeting considered that residue contribution from the first of the six applications, applied at least 30 days before harvest would not significantly influence the final residue.

The Meeting estimated a maximum residue level of 0.8 mg/kg, an STMR of 0.175 mg/kg and an HR of 0.51 mg/kg for fluopyram on banana.

Cucumber

The 2010 JMPR evaluated residue trial data and GAP information on the use of fluopyram as a foliar spray on cucumber in China (3 × 0.075 kg ai/ha, 2-day PHI) and estimated an STMR of 0.11 mg/kg, an HR of 0.19 mg/kg and recommended a maximum residue level of 0.5 mg/kg for fluopyram on cucumbers.

New information was provided to the Meeting on the GAP in Turkey for cucumbers grown under cover (0.006 kg ai/hL, 3 day PHI). None of the trials in Europe, reported by the 2010 JMPR, matched the GAP in Turkey.

Fruiting vegetables, other than Cucurbits

Peppers

The critical GAP for peppers is in Turkey, 0.006 kg ai/hL, 3 day PHI. In the two new trials provided to the Meeting on peppers grown under cover in Turkey and matching the GAP in Turkey, fluopyram residues were 0.23 and 0.24 mg/kg.

In trials reported by the 2010 JMPR, where fluopyram was applied 2 × 0.025–0.03 kg ai/hL to peppers grown under cover, residues 3 DAT were: 0.16, 0.25, 0.29, 0.31, 0.42 and 0.58 mg/kg. When proportionally adjusted to the 0.006 kg ai/hl GAP application rate in Turkey (scaling factors of 0.2–0.3), residues of fluopyram in peppers were: 0.03, 0.05, 0.08, 0.08, 0.09 and 0.13 mg/kg (n=6).

The combined data set of results from the pepper trials matching the GAP in Turkey, including the proportionally scaled results were: 0.03, 0.05, 0.08, 0.08, 0.09, 0.13, 0.23 and 0.24 mg/kg (n=8).

The Meeting estimated a maximum residue level of 0.5 mg/kg, an STMR of 0.085 mg/kg and an HR of 0.24 mg/kg for fluopyram on peppers.

For dried chili peppers, using the data set for peppers and a dehydration factor of 10, the Meeting estimated an STMR of 0.85 mg/kg, an HR of 2.4 mg/kg and recommended a maximum residue level of 5 mg/kg for fluopyram on peppers chili, dried.

Tomato

The critical GAP for tomato is in Morocco, up to 2 applications/season of 0.0125 kg ai/hL, 3 day PHI. None of the trials on tomatoes in Europe, reported by the 2010 JMPR, matched the GAP in Morocco and the Meeting decided to assess the results of the trials on indoor-grown tomatoes against the Moroccan GAP. In these trials, where fluopyram was applied 2 × 0.02 or 0.03 kg ai/hL (2 × 0.3 kg ai/ha), residues 3 DAT were: 0.13, 0.15, 0.15, 0.15, 0.16, 0.19, 0.19, 0.24, 0.28, 0.36, 0.44 and 0.62 mg/kg. When proportionally adjusted to the 0.0125 kg ai/hl GAP application rate (scaling factors of 0.31–0.63), fluopyram residues in tomatoes were: 0.05, 0.06 (3), 0.08, 0.08, 0.1, 0.15, 0.18, 0.19, 0.22 and 0.23 mg/kg (n=12).

Based on the results of the trials on indoor-grown tomatoes, the Meeting estimated a maximum residue level of 0.4 mg/kg, an STMR of 0.09 mg/kg and an HR of 0.23 mg/kg for fluopyram on tomato.

Beans (dry)

The critical GAP for dry beans (except soya beans) is in USA, 0.15 kg ai/ha, at 7-10 day intervals, 14 day PHI with a maximum seasonal rate of 0.3 kg ai/ha. None of the trials reported by the 2010 JMPR matched the USA GAP but in trials in USA on dry beans where fluopyram was applied 2 × 0.24–0.26 kg ai/ha, residues 14 DAT were: < 0.01, < 0.01, < 0.01, 0.01, 0.01, 0.01, 0.03, 0.05 and 0.07 mg/kg. When proportionally adjusted to the 0.15 kg ai/ha GAP application rate (scaling factors of 0.58-0.63), fluopyram residues in beans (dry) from these trials were: < 0.01 (6), 0.02, 0.03 and 0.04 mg/kg (n=9).

The Meeting noted that the GAP in USA for 'dry beans' crop group includes lupins, chick-pea and lentil, which are not covered by the Codex 'beans (dry)' crop group and agreed to extrapolate the data for dry beans to these commodities.

The Meeting estimated a maximum residue level of 0.07 mg/kg and an STMR of 0.01 mg/kg for fluopyram on beans (dry), lupin (dry), chick-pea (dry) and lentil (dry).

Root & tuber vegetables

Results from supervised field trials on carrots, potatoes and sugar beet in North America and on carrots in Europe were provided to the 2010 JMPR.

Carrots

GAP for carrots in Ukraine is for a maximum of 2 foliar applications of 0.15 kg ai/ha, 30 day PHI. In carrot trials in Northern Europe matching the GAP in Ukraine and reported by the 2010 JMPR, residues were: 0.03, 0.04, 0.07, 0.08, 0.1, 0.13, 0.15 and 0.19 mg/kg (n=8).

The Meeting estimated a maximum residue level of 0.4 mg/kg, an STMR of 0.09 mg/kg and an HR of 0.19 mg/kg for fluopyram on carrot.

Potato

The critical GAP for potatoes is in USA, 0.2 kg ai/ha, 7 day PHI with a maximum seasonal rate of 0.4 kg ai/ha. In potato trials in USA matching the GAP in USA and reported by the 2010 JMPR, residues were: < 0.01 (14), 0.01 and 0.02 mg/kg (n=16).

The Meeting estimated a maximum residue level of 0.03 mg/kg, an STMR of 0.01 mg/kg and an HR of 0.02 mg/kg for fluopyram on potatoes. The OECD Calculator recommended a value of 0.02 mg/kg but the Meeting noted the high level of censored data and proposed a higher level.

Sugar beet

The critical GAP for sugar beet in USA is 0.125 kg ai/ha, 7 day PHI with a maximum seasonal rate of 0.25 kg ai/ha. None of the sugar beet trials reported by the 2010 JMPR matched the GAP in USA, but in trials in USA where fluopyram was applied 2 × 0.24–0.26 kg ai/ha, residues 7 DAT in sugar beet roots were: 0.02 (4), 0.03 (3), 0.04 (3) and 0.05 mg/kg. When proportionally adjusted to the 0.125 kg ai/ha GAP application rate (scaling factors of 0.48–0.52), fluopyram residues in sugar beet roots were: < 0.01, < 0.01, 0.01, 0.01, 0.01, 0.01, 0.02, 0.02, 0.02, 0.02 and 0.02 mg/kg (n=11).

The Meeting estimated a maximum residue level of 0.04 mg/kg, an STMR of 0.01 mg/kg and an HR of 0.02 mg/kg for fluopyram on sugar beet roots.

Tree nuts

The critical GAP for tree nuts is in USA, 0.25 kg ai/ha, 14 day PHI with a seasonal maximum rate of 0.5 kg ai/ha.

In almond trials in USA, reported by the 2010 JMPR, matching the GAP for tree nuts in USA, fluopyram residues in almond nutmeat were: < 0.01, < 0.01, < 0.01, 0.01 and 0.02 mg/kg (n=5).

In pecan trials in USA, reported by the 2010 JMPR, matching the GAP for tree nuts in USA, fluopyram residues in pecan nutmeat were: < 0.01, < 0.01, < 0.01, 0.01 and 0.03 mg/kg (n=5).

The Meeting noted that the residue distributions in almonds and pecans were similar and agreed to combine them to support a group maximum residue level. The combined data set is: < 0.01 (6), 0.01, 0.01, 0.02 and 0.03 mg/kg (n=12).

The Meeting estimated a maximum residue level of 0.04 mg/kg, an STMR of 0.01 mg/kg and an HR of 0.03 mg/kg for fluopyram on tree nuts.

Oilseeds

Peanut

The critical GAP for peanuts is in USA, 0.25 kg ai/ha, 7 day PHI with a maximum seasonal rate of 0.5 kg ai/ha..

In peanut trials reported by the 2010 JMPR, matching the GAP in USA, fluopyram residues in peanut (nutmeat) were: < 0.01 (10), 0.01 and 0.02 mg/kg (n=12).

The Meeting estimated a maximum residue level of 0.03 mg/kg and an STMR of 0.01 mg/kg for fluopyram on peanut.

Rape seed

The critical GAP for oilseed rape is in Germany, a single application of 0.125 kg ai/ha over the flowering period (from BBCH 57 to BBCH 69, i.e., up to the end of flowering). In the Northern European supervised trials on oilseed rape reported by the 2010 JMPR, one fluopyram application of 0.125 kg ai/ha was made early flowering (about BBCH 63) and a second treatment was applied between 14 and 39 days later, at BBCH 73 (30% pods at full size).

Fluopyram residues in rape seed from these Northern European trials were: 0.02, 0.04, 0.08, 0.09, 0.1, 0.11, 0.11 and 0.19 mg/kg.

The Meeting agreed that these trials did not match the GAP in Germany and could not be used to estimate a maximum residue level for rape seed.

Animal feeds

Bean forage and fodder

The critical GAP for dry beans (except soya beans) is in USA, 0.15 kg ai/ha, at 7–10 day intervals, 14 day PHI with a maximum seasonal rate of 0.3 kg ai/ha, but as the GAP includes a restriction that livestock should not be grazed on or fed hay or threshings from treated crops, the Meeting did not estimate a median residue for livestock dietary burden estimation.

Sugar beet tops

The critical GAP for sugar beet in USA is 0.125 kg ai/ha, 7 day PHI with a maximum seasonal rate of 0.25 kg ai/ha. None of the sugar beet trials reported by the 2010 JMPR matched the GAP in USA, but in trials in USA where fluopyram was applied 2 × 0.24–0.26 kg ai/ha, residues 7 DAT in sugar beet tops were: 0.35, 0.38, 0.67, 0.69, 0.7, 0.89, 1.8, 3.2, 4.7, 9.4 and 16.5 mg/kg. When proportionally adjusted to the 0.125 kg ai/ha GAP application rate (scaling factors of 0.48-0.52), fluopyram residues in sugar beet tops were: 0.18, 0.19, 0.34, 0.35, 0.37, 0.46, 0.89, 1.6, 2.3, 4.7 and 8.3 mg/kg.

For livestock dietary burden estimation, the Meeting estimated a median residue of 0.46 mg/kg and a highest residue of 8.3 mg/kg for fluopyram on sugar beet tops.

Almond hulls

The critical GAP for tree nuts is in USA; 0.25 kg ai/ha, 14 day PHI with a seasonal maximum rate of 0.5 kg ai/ha. In almond trials in USA, reported by the 2010 JMPR, matching the GAP for tree nuts in USA, fluopyram residues in almond hulls were: 2.4, 3.2, 3.6, 4.3 and 5.4 mg/kg.

For animal dietary burden estimation, the Meeting estimated a median residue of 3.6 mg/kg for fluopyram on almond hulls.

Peanut forage and fodder

The critical GAP for peanuts is in USA; 0.25 kg ai/ha, 7 day PHI with a maximum seasonal rate of 0.5 kg ai/ha but as the GAP includes a restriction that livestock should not be grazed on or fed hay or threshings from treated crops, the Meeting did not estimate a median residue for livestock dietary burden estimation.

Fate of residues during processing

The 2010 JMPR reported that fluopyram was stable under conditions simulating pasteurisation, boiling and sterilisation and also estimated processing factors and STMR-Ps for a range of commodities. Relevant processing factors and STMR-Ps for the commodities considered at this Meeting and used for dietary intake risk assessment or for estimating livestock animal burdens are summarized below.

Summary of relevant processing factors and STMR-P values for fluopyram residues.

Raw agricultural commodity	Processed commodity	Processing factor [a] (mean or median)	RAC STMR (HR) (mg/kg)	STMR-P (HR-P) (mg/kg)
Tomato	Juice	0.36	0.09	0.03
Tomato	Pomace (wet)	0.1	0.09	0.01
Tomato	Preserve	0.21	0.09	0.02
Tomato	Puree	0.73	0.09	0.07

Raw agricultural commodity	Processed commodity	Processing factor [a] (mean or median)	RAC STMR (HR) (mg/kg)	STMR-P (HR-P) (mg/kg)
Tomato	Paste	0.46	0.09	0.04
Potato	Peeled tubers	< 0.64	0.01 (0.02)	< 0.006 (< 0.013)
Potato	Chips (crisps)	< 0.64	0.01	< 0.006
Potato	Flakes	1	0.01	0.01
Potato	Wet peel (process waste)	4.3	0.01	0.04
Sugar beet	Sugar	1.3	0.01	0.01
Sugar beet	Thick juice (Molasses)	0.92	0.01	0.01
Sugar beet	Dried pulp	1.3	0.01	0.01
Apples	Dried fruit	0.64 (median)	0.135	0.09
Apples	Sauce	0.36 (median)	0.135	0.05
Apples	Juice	< 0.09 (median)	0.135	< 0.01
Apples	Pomace (wet)	2.3 (median)	0.135	0.31
Peanut	Meal	0.19	0.01	0.002
Peanut	Butter	0.22	0.01	0.002
Peanut	Oil	0.01	0.01	0.0001
Strawberry	Preserve	0.31	0.025	0.008
Strawberry	Jam	0.65	0.025	0.02

[a] The processing factor is the ratio of the total residue in the processed item divided by the total residue in the RAC.

Residues in animal commodities

Farm animal dietary burden

The Meeting estimated the dietary burden of fluopyram in farm animals on the basis of the diets listed in Annex 6 of the 2009 JMPR Report (OECD Feedstuffs Derived from Field Crops).

	Animal dietary burden, fluopyram, ppm of dry matter diet							
	US-Canada		EU		Australia		Japan	
	Max	Mean	Max	Mean	Max	Mean	Max	Mean
Beef cattle	0.13	0.12	7.69	0.74	2.97	2.93[c]	-	-
Dairy cattle	0.64	0.55	11.2 [a b]	0.87	2.96	2.92[d]	-	-
Poultry – broiler	0.002	0.002	0.16	0.08	0.008	0.008	-	-
Poultry – layer	0.002	0.002	1.97[e g]	0.18[f h]	0.008	0.008	-	-

[a] Highest maximum beef or dairy cattle dietary burden suitable for MRL estimates for mammalian tissues

[b] Highest maximum dairy cattle dietary burden suitable for MRL estimates for mammalian milk

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

[d] Highest mean dairy cattle dietary burden suitable for STMR estimates for milk.

[e] Highest maximum poultry dietary burden suitable for MRL estimates for poultry tissues.

[f] Highest mean poultry dietary burden suitable for STMR estimates for poultry tissues.

[g] Highest maximum poultry dietary burden suitable for MRL estimates for poultry eggs.

[h] Highest mean poultry dietary burden suitable for STMR estimates for poultry eggs.

Farm animal feeding studies

The 2010 JMPR reviewed feeding studies with fluopyram on lactating dairy cows and laying hens and the conclusions from these residue transfer studies were used to estimate residue levels of fluopyram and its metabolites in milk, eggs and livestock tissues, based on the above dietary burdens.

Animal commodity maximum residue levels

Cattle

Maximum and mean residues expected in milk and tissues were obtained by using the residue transfer factors estimated by the 2007 JMPR.

For maximum residue estimation, the high residues of fluopyram and BZM (expressed as fluopyram equivalents) were calculated by interpolating the maximum dietary burden (11.2 ppm) from the 1.5:14.4 ppm feeding levels in the dairy cow feeding study and using the highest tissue concentrations of fluopyram plus BZM (fluopyram equivalents) from individual animals within those feeding groups. The same interpolation was used to calculate the highest tissue concentrations of fluopyram, BZM plus total olefins (fluopyram equivalents) for estimating HRs for dietary intake estimation.

The STMR values for the tissues were calculated by interpolating the STMR dietary burden (2.93 ppm from the same feeding levels and using the mean tissue concentrations of fluopyram, BZM plus total olefins (fluopyram equivalents) from those feeding groups.

For milk MRL estimation, the high residues in the milk were calculated by interpolating the maximum dietary burden for dairy cattle (11.2 ppm) from the 1.5:14.4 ppm feeding levels in the dairy cow feeding study and using the mean milk concentrations of fluopyram and BZM (fluopyram equivalents) from this feeding group.

The STMR value for milk was calculated by interpolating the mean dietary burden for dairy cows (2.92 ppm) from the 1.5:14.4 ppm feeding levels and using the mean milk concentrations of fluopyram, BZM plus total olefins (fluopyram equivalents).

	Feed level for milk (ppm)	Residues in milk (mg/kg)	Feed level for tissues (ppm)	Residues (mg/kg)			
				Muscle	Liver	Kidney	Fat
Maximum residue level beef or dairy cattle ((fluopyram + BZM)							
Feeding study (1)	1.5 14.4	0.02 0.25	1.5 14.4	0.02 < 0.45	0.36 2.88	0.03 < 0.39	< 0.02 0.4
Dietary burden/residue estimate	11.2[b]	0.193	2.43[a]	0.343	2.25	0.301	0.306
High residue beef or dairy cattle (fluopyram + BZM + Total olefins)							
Feeding study (2)			1.5 14.4	0.02 < 0.47	< 0.38 2.94	0.03 < 0.41	< 0.04 0.52
Dietary burden/residue estimate			2.43[a]	0.358	2.305	0.316	0.401
STMR beef or dairy cattle ((fluopyram + BZM + Total olefins)							
Feeding study (2)	1.5 14.4	0.02 < 0.27	1.5 14.4	0.02 < 0.47	0.36 2.92	0.03 < 0.41	< 0.04 0.49
Dietary burden/residue estimate	2.92	0.048	2.93	0.053	0.527	0.061	0.059

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

[b] Mean residues for tissues and for milk

Combined residues of fluopyram and BZM (expressed as fluopyram equivalents) expected in cattle milk and tissues for use in estimating maximum residue levels are: 0.31 mg/kg (fat), 0.34 mg/kg (muscle), 2.25 mg/kg (liver) and 0.3 mg/kg (kidney) and the mean residue for milk is 0.19 mg/kg.

The Meeting estimated maximum residue levels of 0.5 mg/kg for fluopyram in meat (from mammals other than marine mammals), 3 mg/kg for liver of cattle, goats, pigs and sheep, 0.5 mg/kg for kidney of cattle, goats, pigs and sheep and 0.3 mg/kg for milks and agreed to withdraw the previous recommendations for meat (from mammals other than marine mammals), edible offal (mammalian) and milks.

Estimated HRs for dietary intake estimation for fluopyram (and including residues of BZM and total olefins) are 0.4 mg/kg for mammalian fat, 0.36 mg/kg for mammalian muscle, 2.3 mg/kg for liver and 0.32 mg/kg for kidney.

Estimated STMRs for dietary intake estimation for fluopyram (and including residues of BZM and total olefins) are 0.06 mg/kg for mammalian fat, 0.05 mg/kg for mammalian muscle, 0.53 mg/kg for liver of cattle, goats, pigs and sheep, 0.06 mg/kg for kidney of cattle, goats, pigs and sheep and 0.05 mg/kg for milks

Poultry

The dietary burdens for poultry broilers are 0.18 ppm (maximum) and 0.08 ppm (mean) but the Meeting decided to estimate residue levels in poultry tissues using the higher mean/maximum dietary burden in poultry layers (1.97 ppm) as they may also be consumed. Tissue concentrations of fluopyram plus BZM (fluopyram equivalents) for maximum residue level estimation and of fluopyram, BZM plus total olefins (fluopyram equivalents) for dietary intake were obtained by interpolation between the 1.6 ppm and the 4.8 ppm feeding levels in the poultry study reported by the 2010 JMPR.

For eggs, for MRL estimation, residue levels in eggs were also estimated by interpolation between the higher dose levels (1.6 ppm and 4.8 ppm) because of the higher poultry layer dietary burden (1.97 ppm) but for estimating the STMR, based on a mean dietary burden of 0.18 ppm for poultry layers, mean residue levels were estimated by interpolation between the 0.05 ppm and the 0.49 ppm feeding levels.

	Feed level for eggs (ppm)	Residues in eggs (mg/kg)	Feed level for tissues (ppm)	Residues (mg/kg)		
				Muscle	Liver	Skin with Fat
Maximum residue level broiler or laying hen (fluopyram + BZM)						
Feeding study (1)	1.6 4.8	0.22 0.72	1.6 4.8	0.1 0.33	0.43 1.6	0.11 < 0.64
Dietary burden/residue estimate	1.97 [b]	0.193	1.97 [a]	0.127	0.565	0.171
High residue broiler or laying hen (fluopyram + BZM + Total olefins)						
Feeding study (2)			1.6 4.8	0.1 0.39	< 0.45 1.8	< 0.14 < 072
Dietary burden/residue estimate			1.97 [a]	0.134	0.585	0.207
STMR broiler or laying hen (fluopyram + BZM + Total olefins)						
Feeding study (2)	0.05 0.49	0 0.8	0.05 0.49	< 0.01 0.03	0.1 0.16	< 0.01 < 0.06
Dietary burden/residue estimate	0.18	0.008	0.18	0.011	0.02	0.013

[a] Highest residues for tissues and mean residues for eggs

[b] Mean residues for tissues and for eggs

Combined residues of fluopyram and BZM (expressed as fluopyram equivalents) expected in poultry eggs and tissues for use in estimating maximum residue levels are: 0.17 mg/kg (fat), 0.13 mg/kg (muscle), 0.56 mg/kg (liver) and 0.19 mg/kg (eggs).

The Meeting estimated maximum residue levels of 0.2 mg/kg for fluopyram in poultry meat, 0.7 mg/kg for poultry edible offal and 0.3 mg/kg for eggs.

Estimated HRs for dietary intake estimation for fluopyram (and including residues of BZM and total olefins) are 0.2 mg/kg for poultry fat, 0.13 mg/kg for poultry muscle and 0.58 mg/kg for poultry edible offal.

Estimated STMRs for dietary intake estimation for fluopyram (and including residues of BZM and total olefins) are 0.01 mg/kg for poultry fat, 0.01 mg/kg for poultry muscle, 0.02 mg/kg for poultry edible offal and 0.008 mg/kg for eggs.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Daily Intakes (IEDIs) for fluopyram were calculated for the food commodities for which STMRs or HRs were estimated and for which consumption data were available. The results are shown in Annex 3.

The International Estimated Daily Intakes of fluopyram for the 13 GEMS/Food regional diets, based on estimated STMRs were 2–20% of the maximum ADI of 0.01 mg/kg bw (Annex 3). The Meeting concluded that the long-term intake of residues of fluopyram from uses that have been considered by the JMPR is unlikely to present a public health concern.

Short-term intake

The International Estimated Short-term Intakes (IESTIs) for fluopyram were calculated for the food commodities for which STMRs or HRs were estimated and for which consumption data were available (Annex 4).

For fluopyram the IESTI varied from 0–10% of the ARfD (0.5 mg/kg bw) and the Meeting concluded that the short-term intake of residues of fluopyram from uses considered by the Meeting is unlikely to present a public health concern.

5.20 FLUXAPYROXAD (256)

TOXICOLOGY

Fluxapyroxad is the ISO-approved name for 3-(fluoromethyl)-1-methyl-*N*-(3′,4′,5′-trifluoro[1,1′-biphenyl]-2-yl)-1H-pyrazole-4-carboxamide (IUPAC) (CAS No. 907204-31-3). It is a fungicide that belongs to the carboxamide class. Its proposed fungicidal mode of action is inhibition of succinate dehydrogenase, resulting in the inhibition of the citric acid cycle and mitochondrial electron transport pathways.

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

All the critical studies contained certificates of compliance with GLP.

Biochemical aspects

In rats, ^{14}C-labelled fluxapyroxad was rapidly and moderately well absorbed from the gastrointestinal tract following oral dosing. The extent of absorption was approximately 65–80% of the administered dose, independent of dose and sex. Maximum concentrations of radioactivity in plasma were observed within 1 hour of dosing for the low-dose group (5 mg/kg bw), 8 hours for the mid-dose group (50 mg/kg bw) and 24 hours for the high-dose group (500 mg/kg bw). In another study in rats, maximum tissue concentrations occurred within 1 hour post-dosing at the low dose (7.5 mg/kg bw) and 16 hours post-dosing at the high dose (150 mg/kg bw), with higher concentrations of radioactivity found in liver, thyroid and adrenals. Very little fluxapyroxad was present in other tissues at the end of the study (7 days). There were no major sex-related differences in the pattern of excretion. Faecal excretion was the primary route of elimination, and excretion was rapid, with the majority of the administered dose (61–83%) excreted by all routes within 48 hours after dosing.

The main biotransformation mechanisms of fluxapyroxad in rats are hydroxylation at the biphenyl ring, *N*-demethylation at the pyrazole ring, loss of a fluorine atom at the biphenyl ring and conjugation with glucuronic acid or glutathione, yielding about 50 metabolites.

Toxicological data

The LD_{50} in rats treated orally or dermally with fluxapyroxad was greater than 2000 mg/kg bw. The LC_{50} in rats treated by inhalation was greater than 5.1 mg/L of air. Fluxapyroxad was minimally irritating to the skin of rabbits, not irritating to the eyes of rabbits and not sensitizing in guinea-pigs under the conditions of the maximization test.

Following repeated gavage or dietary dosing, the liver was the main target organ in mice, rats and dogs. In general, the main effects in mice and rats were increased liver weight, liver enlargement and centrilobular hepatocellular hypertrophy, as well as alterations in clinical chemistry. In the dog, increased liver weights and alterations in clinical chemistry were accompanied by fibrosis. The thyroid was also a target in mice and rats, with effects including increased thyroid weight, changes in hormone levels (thyroxine and thyroid stimulating hormone) and thyroid follicular cell hypertrophy and hyperplasia. Other treatment-related effects at higher doses consisted of siderosis and impaired iron storage in rats and dogs, as well as teeth whitening and shortened prothrombin time in rats only.

The NOAEL in a 90-day rat study was 100 ppm (equal to 7.3 mg/kg bw per day), based on liver and thyroid effects in females (increased absolute and relative liver weights, increased incidences of centrilobular hepatocellular hypertrophy and hypertrophy/hyperplasia of thyroid follicular cells) at 500 ppm (equal to 35.1 mg/kg bw per day). The NOAEL in a 90-day mouse study was 2000 ppm (equal to 390 mg/kg bw per day), based on decreased body weight and multifocal necrosis in the liver in males at 6000 ppm (equal to 1136 mg/kg bw per day). The NOAEL in a 1-year dog study was 300 ppm (equal to 9 mg/kg bw per day), based on clinical chemistry alterations and fibrosis in the liver in females at 1500 ppm (equal to 43 mg/kg bw per day).

In an 18-month carcinogenicity study in mice, the NOAEL was 750 ppm (equal to 107 mg/kg bw per day), based on decreased body weight gain at 3000 ppm (equal to 468 mg/kg bw per day). There was no evidence of carcinogenicity in mice.

In a 2-year rat study, the NOAEL was 50 ppm (equal to 2.1 mg/kg bw per day), based on reduced body weight gain in the absence of an effect on feed consumption at 250 ppm (equal to 11 mg/kg bw per day). The incidence of combined hepatocellular adenomas and carcinomas in males was increased at the top two doses of 1500 ppm (equal to 68 mg/kg bw per day) and 3000 ppm (equal to 145 mg/kg bw per day), and there was an increased incidence of hepatocellular adenomas in females at the highest dose (3000 ppm, equal to 145 mg/kg bw per day); this incidence also slightly exceeded the historical control range. There was a small increase in the incidence of thyroid follicular cell adenomas and carcinomas in males at the highest dose tested; this incidence was within the historical control range (4–30%), but above the historical control mean (15%). The incidence and severity of follicular cell hyperplasia were increased starting at 1500 ppm (equal to 68 mg/kg bw per day). The Meeting concluded that high doses of fluxapyroxad caused an increased incidence of hepatocellular adenomas and carcinomas in males, hepatocellular adenomas in females, and follicular cell adenomas and carcinomas combined in the thyroid in males.

Special studies were conducted to examine liver effects in the rat. These studies showed that fluxapyroxad increased microsomal protein levels and cytochrome P450 activity, specifically benzyloxyresorufin *O*-dealkylase and pentoxyresorufin *O*-dealkylase, and cell proliferation in the liver of rats. The Meeting concluded that for the liver tumours in rats, there was sufficient evidence to support the proposed mitogenic mode of action associated with induction of CYP2B-type cytochrome P450. Special studies on the mode of action in the thyroid produced equivocal results.

Fluxapyroxad was adequately tested for genotoxicity in vitro and in vivo in a range of assays and was not found to be genotoxic.

The Meeting concluded that fluxapyroxad was unlikely to be genotoxic.

On the basis of the lack of genotoxicity, the absence of carcinogenicity in mice and the presence of liver and thyroid follicular cell tumours in rats only at high doses, the Meeting concluded that fluxapyroxad is unlikely to pose a carcinogenic risk to humans at anticipated dietary residue levels.

No effects on reproduction were noted in a multigeneration reproductive toxicity study in the rat. However, there was a decrease in body weight and increased incidences of hepatocellular hypertrophy and thyroid follicular cell hypertrophy/hyperplasia in the offspring in both generations at 50 mg/kg bw per day and above. The marginal increase in the incidence of very slight hepatocellular hypertrophy at 10 mg/kg bw per day in F_1 offspring was not considered to be toxicologically relevant. At the high dose only, whitening of the incisors due to a decrease in iron-containing pigment in ameloblasts was observed. The NOAEL for parental toxicity was 10 mg/kg bw per day, based on decreased body weight gain and effects on the liver and thyroid at 50 mg/kg bw per day. The NOAEL for offspring toxicity was 10 mg/kg bw per day, based on reduced body weight and body weight gain and liver effects at 50 mg/kg bw per day. The NOAEL for reproductive toxicity was 300 mg/kg bw per day, the highest dose tested.

In a developmental toxicity study in rats, there were no effects on development observed when pregnant rats were administered doses up to 1000 mg/kg bw per day. There was a transient decrease in body weight gain from GD 6 to GD 8 in dams at and above 200 mg/kg bw per day. Increased liver and thyroid weights and increased incidences of thyroid follicular hypertrophy/hyperplasia were observed in maternal animals at 1000 mg/kg bw per day. The NOAEL for maternal toxicity in rats was 25 mg/kg bw per day, and the NOAEL for developmental toxicity was 1000 mg/kg bw per day, the highest dose tested. In rabbits, there was an increase in early resorptions, as well as one abortion, and a decrease in fetal weight at the high dose (60 mg/kg bw per day), which occurred in the presence of a marked reduction in feed consumption and body weight. Fetal weights were also reduced, and there was an increased incidence of paw hyperflexion at the high dose. The NOAEL for maternal and developmental toxicity in rabbits was 25 mg/kg bw per day.

The Meeting concluded that fluxapyroxad was not teratogenic in rats or rabbits.

In an acute neurotoxicity study in rats, the NOAEL was 125 mg/kg bw, based on decreased motor activity and rearing at a dose of 500 mg/kg bw. There was no histological evidence of damage to the central or peripheral nervous system. There was no evidence of neurotoxicity in a 90-day neurotoxicity study in rats.

In a 4-week immunotoxicity study in mice, no adverse effects were observed at any dose up to 6000 ppm (equal to 1323 mg/kg bw per day), the highest dose tested.

Three minor metabolites in rats that are also found in plants and soil were assessed for toxicity. The oral LD_{50} in rats for the metabolite M700F001 was greater than 2000 mg/kg bw. In a 90-day feeding study in rats, the NOAEL for M700F001 was 954 mg/kg bw per day, the highest dose tested. The metabolite was not genotoxic in any of an adequate range of in vitro and in vivo genotoxicity assays. In a developmental toxicity study in rabbits, the maternal and developmental NOAEL was 250 mg/kg bw per day, the highest dose tested.

The oral LD_{50} in rats for the metabolite M700F002 was greater than 2000 mg/kg bw. In a 28-day dietary study of M700F002 in rats, the NOAEL was 1165 mg/kg bw per day, the highest dose tested. In a 90-day feeding study in rats, the NOAEL for M700F002 was 958 mg/kg bw per day, the highest dose tested. This metabolite was not genotoxic in any of an adequate range of in vitro and in vivo genotoxicity assays. In a developmental toxicity study in rabbits, the maternal and developmental NOAEL was 300 mg/kg bw per day, based on increased maternal mortality, abortions and stomach erosions as well as decreased body weight gain at 1000 mg/kg bw per day.

The oral LD_{50} in rats for the metabolite M700F048 was greater than 2000 mg/kg bw. In a 28-day dietary study of M700F048 in rats, the NOAEL was 189 mg/kg bw per day, based on decreased body weight gain at 1478 mg/kg bw per day. This metabolite was not genotoxic in any of an adequate range of in vitro and in vivo genotoxicity assays. In a developmental toxicity study in rabbits, the maternal and developmental NOAEL was 30 mg/kg bw per day, based on increased maternal mortality, abortions, late resorptions and stomach erosions as well as decreased body weight gain at 100 mg/kg bw per day.

The metabolites were not considered to be more toxic than fluxapyroxad.

There was no information available on adverse health effects in manufacturing plant personnel or in operators and workers exposed to fluxapyroxad formulations during their use. There are no reports of poisoning with fluxapyroxad.

The Meeting concluded that the existing database on fluxapyroxad 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 the NOAEL of 2.1 mg/kg bw per day in the 2-year rat combined chronic toxicity/carcinogenicity study for body weight effects in both sexes in the absence of effects on feed consumption. A safety factor of 100 was applied.

The Meeting established an ARfD of 0.3 mg/kg bw on the basis of the NOAEL of 25 mg/kg bw per day in the developmental toxicity study in rabbits for early resorptions and the rat developmental toxicity study based on a transient decrease in body weight gain from GD 6 to GD 8. A safety factor of 100 was applied.

A toxicological monograph was prepared.

Levels relevant to risk assessment

Species	Study	Effect	NOAEL	LOAEL
Mouse	Eighteen-month study of toxicity and carcinogenicity[a]	Toxicity	750 ppm, equal to 107 mg/kg bw per day	3000 ppm, equal to 468 mg/kg bw per day

Species	Study	Effect	NOAEL	LOAEL
		Carcinogenicity	6000 ppm, equal to 1119 mg/kg bw per day[b]	—
Rat	Two-year study of toxicity and carcinogenicity[a]	Toxicity	50 ppm, equal to 2.1 mg/kg bw per day	250 ppm, equal to 11 mg/kg bw per day
		Carcinogenicity	250 ppm, equal to 11 mg/kg bw per day	1500 ppm, equal to 68 mg/kg bw per day
	Two-generation study of reproductive toxicity[a]	Reproductive toxicity	300 mg/kg bw per day[b]	—
		Parental toxicity	10 mg/kg bw per day	50 mg/kg bw per day
		Offspring toxicity	10 mg/kg bw per day	50 mg/kg bw per day
	Developmental toxicity study[c]	Maternal toxicity	25 mg/kg bw per day	200 mg/kg bw per day
		Embryo and fetal toxicity	1000 mg/kg bw per day[b]	—
Rabbit	Developmental toxicity study[c]	Maternal toxicity	25 mg/kg bw per day	60 mg/kg bw per day
		Embryo and fetal toxicity	25 mg/kg bw per day	60 mg/kg bw per day
Dog	One-year study of toxicity[a]	Toxicity	300 ppm, equal to 9 mg/kg bw per day	1500 ppm, equal to 43 mg/kg bw per day

[a] Dietary administration.

[b] Highest dose tested.

[c] Gavage administration.

Estimate of acceptable daily intake for humans

0–0.02 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 fluxapyroxad

Absorption, distribution, excretion and metabolism in mammals	
Rate and extent of oral absorption	Rapid; to a moderate extent
Dermal absorption	Not available
Distribution	Widely distributed; highest concentrations in liver, thyroid and adrenals
Potential for accumulation	No evidence of accumulation
Rate and extent of excretion	Largely complete within 24 h; primarily via faeces (70–85%, bile 30–54%) and to a lesser extent urine (8–17%)
Metabolism in animals	Extensive
Toxicologically significant compounds in animals, plants and the environment	Parent compound, M007F048
Acute toxicity	
Rat, LD_{50}, oral	> 2000 mg/kg bw
Rat, LD_{50}, dermal	> 2000 mg/kg bw

Rat, LC_{50}, inhalation	> 5.1 mg/L
Rabbit, dermal irritation	Minimally irritating
Rabbit, ocular irritation	Not irritating
Dermal sensitization	Not sensitizing (Magnusson & Kligman)
Short-term studies of toxicity	
Target/critical effect	Liver (clinical chemistry changes), thyroid (hypertrophy/hyperplasia)
Lowest relevant oral NOAEL	7.3 mg/kg bw per day (rats)
Lowest relevant dermal NOAEL	1000 mg/kg bw per day (rats)
Lowest relevant inhalation NOAEC	No data
Long-term studies of toxicity and carcinogenicity	
Target/critical effect	Body weight
Lowest relevant NOAEL	2.1 mg/kg bw per day (rats)
Carcinogenicity	Liver and thyroid tumours observed in rats at high doses; unlikely to pose a carcinogenic risk to humans at anticipated dietary intake levels
Genotoxicity	
	Not genotoxic
Reproductive toxicity	
Target/critical effect	No effect on fertility at highest dose tested; decrease in body weight, liver and thyroid effects in pups at parentally toxic dose
Lowest relevant parental NOAEL	10 mg/kg bw per day
Lowest relevant reproductive NOAEL	300 mg/kg bw per day (highest dose tested)
Lowest relevant offspring NOAEL	10 mg/kg bw per day
Developmental toxicity	
Target/critical effect	Decreased fetal weight and paw hyperflexion at maternally toxic dose (rabbits)
Lowest relevant maternal NOAEL	25 mg/kg bw per day (rats and rabbits)
Lowest relevant developmental NOAEL	25 mg/kg bw per day (rabbits)
Neurotoxicity	
Target/critical effect	Decreased motor activity and rearing
Acute neurotoxicity NOAEL	125 mg/kg bw (rats)
Immunotoxicity	
	1323 mg/kg bw per day (highest dose tested; mice)
Other toxicological studies	
	Toxicity studies on metabolites Special studies on liver and thyroid tumour modes of action
Medical data	
	No reports received

Summary

	Value	Study	Safety factor
ADI	0–0.02 mg/kg bw	Two-year toxicity/carcinogenicity study (rat)	100
ARfD	0.3 mg/kg bw	Developmental toxicity studies (rat and rabbit)	100

RESIDUE AND ANALYTICAL ASPECTS

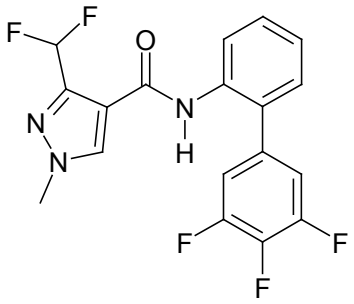
Residue and toxicological aspects of fluxapyroxad were considered for the first time by the present Meeting. The toxicological and residue evaluation was scheduled by the Forty-second Session of the CCPR[1].

[1] ALINORM 10/33/24

Fluxapyroxad is a new active ingredient developed to control a broad spectrum of fungal diseases. It belongs to the carboxamide class of chemicals and its mode of action is inhibition of succinate dehydrogenase in complex II of the mitochondrial respiratory chain, which results in inhibition of spore germination, germ tubes and mycelial growth within the fungus target species.

The manufacturer supplied information on identity, metabolism and environmental fate, methods of residue analysis, freezer storage stability, registered use patterns, supervised residue trials, fate of residues in processing and farm animal feeding studies.

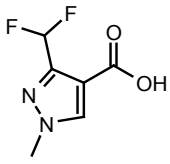
The IUPAC name is 3-(difluoromethyl)-1-methyl-N- (3′,4′,5′-trifluoro [1,1′-biphenyl]-2-yl)-1H-pyrazole-4-carboxamide.



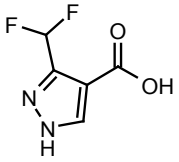
Fluxapyroxad

The 2012 JMPR established an ADI for fluxapyroxad of 0–0.02 mg/kg bw and an ARfD of 0.3 mg/kg bw.

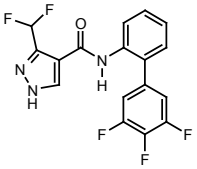
The structures of key metabolites discussed are listed below:



M700F001



M700F002



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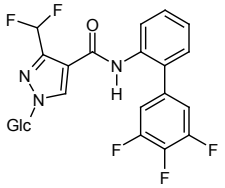

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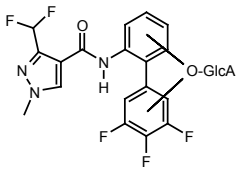

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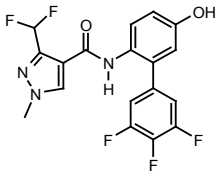

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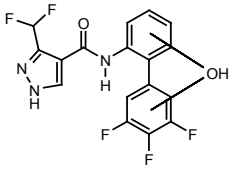

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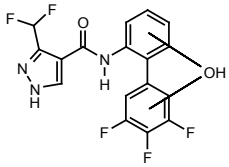


M700F010

Animal metabolism

The Meeting received animal metabolism studies with fluxapyroxad in rats, hens and goats.

Rats

Evaluation of the metabolism studies in rats, which was carried out by the WHO Core Assessment Group, showed that ^{14}C-labelled fluxapyroxad was rapidly and moderately well absorbed from the gastrointestinal tract of rats following oral dosing. The extent of absorption was approximately 65–80% of the administered dose, independent of dose and sex. Very little fluxapyroxad was retained in the tissues. There were no major sex-related differences in the pattern of excretion. Faecal excretion was the primary route of elimination, and excretion was rapid, with the majority excreted by all routes 48 hours after dosing (61–83%). Fluxapyroxad in rats is metabolized mainly by hydroxylation at the

biphenyl moiety (sometimes repeated), loss of a fluorine atom at the biphenyl ring, N-demethylation at the pyrazole moiety, conjugation of the hydroxyl-groups with glucuronic acid or with sulfate and conjugation with glutathione derivatives.

Goats - Fluxapyroxad

Fluxapyroxad labelled in the aniline or pyrazole ring was orally administered by gavage to lactating goats at 11.33–11.75 ppm in the feed or 0.39–0.44 mg/kg bw/day for 8 consecutive days. Milk was sampled twice daily (in the morning before administration of the test substance and in the afternoon). Animals were sacrificed approximately 24 hours after the last dose.

Overall, ≥ 80% of the total administered dose was eliminated in excreta. In milk, 0.09–0.10% of the administered dose was detected. A plateau was reached within 24 hours after administration. Tissues and organs retained < 0.4% of the administered dose. TRRs were 0.007–0.009 mg/kg equiv. in muscle, 0.021–0.025 mg/kg equiv. in fat, 0.036–0.078 mg/kg equiv. in kidney and 0.35–0.56 mg/kg equiv. in liver. The extractability of the radioactive residues in methanol or acetonitrile was ≥ 79% for all tissues other than liver. In liver, extractability was 30–34%. A major proportion of the residual radioactive residues (polar components, probably bound to proteins) was released from extracted liver tissue after incubation with protease.

Fluxapyroxad represented one of the major residues in milk (13–20% of the TRRs, 0.0015–0.0033 mg/kg equiv.), muscle (12%, 0.0009 mg/kg equiv., aniline label only) and fat (34–44% of the TRRs, 0.0084–0.0092 mg/kg equiv.), while accounting for minor proportions in liver and kidney (3–7% of the TRRs, 0.0025–0.020 mg/kg equiv.). The other predominant compound was the desmethyl metabolite M700F008, representing a main proportion in milk (24–25% of the TRRs, 0.0027–0.0043 mg/kg equiv.), muscle (55–83% of the TRRs, 0.0041–0.0078 mg/kg equiv.), fat (26% of the TRRs, 0.0054–0.0064 mg/kg equiv.), liver (13–17% of the TRRs, 0.058–0.071 mg/kg equiv.) and kidney (23–26% of the TRRs, 0.0093–0.017 mg/kg equiv).

Further metabolites at > 10% of the TRRs were detected in milk, kidney and fat. In milk, the metabolite M700F010 was found at levels of 12–15% of the TRRs (≤ 0.0025 mg/kg). The metabolite M700F005 was present in fat at 14% of the TRRs (0.0034 mg/kg equiv.) and in kidney at 19% of the TRRs (0.015 mg/kg equiv.), with pyrazole label only. The metabolite M700F004 was present in kidney at levels of 12–13% of the TRRs (≤ 0.010 mg/kg equiv.).

With both labels, comparable metabolic pathways were observed. Hydrolytic cleavage of fluxapyroxad at the carboxamide bond was not seen. Fluxapyroxad was metabolized *via* two main transformation reactions, N-demethylation of the pyrazole moiety and hydroxylation of the biphenyl moiety. These reactions, occurring also in combination, followed by conjugation with glucuronic acid, led to the main metabolites. Several minor metabolic routes, i.e., hydroxylation at the pyrazole ring, conversion of the pyrazole CHF_2 group into a carboxy group, N-glucuronidation of the desmethyl metabolite and removal of an aromatic fluorine substituent, led to a range of minor components.

Goats – M700F002

Since the metabolite M700F002 was observed in soya bean seed and in confined rotational crop matrices at levels > 10% of the TRRs, livestock metabolism studies were conducted with this compound.

The test item ^{14}C-labelled on the carbon of the pyrazole ring bearing the carboxyl group, was fed to two lactating goats for eight consecutive days at 11.0–12.5 ppm in the feed, 0.38–0.42 mg/kg bw/day. Milk was collected in the morning before administration of the test item and in the afternoon. Animals were sacrificed approximately 4 hours after the final dose. Of the applied dose, 32% was found in urine and 54% in faeces. Milk contained 0.05% of the applied dose. Residues remaining in whole organs accounted for < 0.04% of the administered dose. Residues were 0.006 mg/kg equiv. in fat, 0.012 mg/kg equiv. in muscle, 0.023 mg/kg equiv. in liver and 0.146 mg/kg equiv. in kidney. In total, 98% of the applied dose could be recovered. In goat, the test item M700F002 was the only

radioactive component detected in the matrices analysed, indicating that M700F002 is not significantly transformed in the goat.

Goats – M700F048

Metabolism studies were also conducted on lactating goats with M700F048, a plant metabolite of fluxapyroxad which was not observed in animals. ^{14}C-M700F048, labelled in the aniline moiety was fed to two lactating goats at doses of 12.94 and 12.80 ppm in the feed, 0.39 and 0.40 mg/kg bw/day, for ten consecutive days. Milk was collected in the morning before administration of the test item and in the afternoon. Animals were sacrificed within 20 hours after the last dose. Excreta accounted for 92.4% of the M700F048 administered. The pooled milk sample (Day 4–10) contained 0.045% of the applied dose. Overall, < 0.5% of the total administered dose was found in tissues and organs. The TRRs in organs and tissues amounted to 0.575 mg/kg equiv. for liver, 0.075 mg/kg equiv. for kidney, 0.033 mg/kg equiv. for fat and 0.011 mg/kg equiv. for muscle.

M700F048 was found at ≤ 3% of the TRRs in milk and tissues. In muscle and liver, no M700F048 was detected. One of the main components identified in all matrices was the deglycosylated metabolite M700F008, accounting for 14–54% of the TRRs. Further biotransformation products were the biphenyl-hydroxylated metabolites M700F009 and M700F010. M700F010 was the main metabolite identified in milk (32% of the TRRs) and was also detected in higher portions in kidney (14% of the TRRs).

The main biotransformation reactions were deglycosylation of M700F048 and hydroxylation at the biphenyl moiety. Further biotransformation reactions observed were hydroxylation at the pyrazole ring, replacement of an aromatic fluorine atom, presumably by a hydroxy group and oxidation and hydrolysis of the CHF_2 group (forming a carboxy group) with subsequent protein conjugation.

Hens – Fluxapyroxad

Fluxapyroxad labelled in the aniline ring was orally administered by gavage to 12 laying hens at 11.5 ppm in the feed or 0.76 mg/kg bw (1.59 mg/animal/day) for 12 consecutive days. Eggs were collected twice daily (in the afternoon after administration of the test substance and the morning before subsequent administration). Animals were sacrificed approximately 23 hours after the last dose.

Overall, ≥ 86% of the total administered dose was eliminated in excreta. In eggs, 0.18% of the administered dose was detected. A plateau was reached at Day 9 of the dosing period. Tissues and organs (with the exception of the GI tract) retained < 0.5% of the administered dose. TRRs were 0.010 mg/kg equiv. in leg muscle, 0.059 mg/kg equiv. in fat and 0.210 mg/kg equiv. in liver. The extractability of the radioactive residues was ≥ 79% for all tissues other than liver. In liver, extractability was 68%. A significant proportion of the residual radioactive residue, probably bound to proteins, was released from extracted liver tissue after incubation with protease.

Fluxapyroxad was one of the major residues in egg (14% of the TRRs, 0.009 mg/kg equiv.), leg muscle (18% of the TRRs, 0.0011 mg/kg equiv.), fat (63% of the TRRs, 0.023 mg/kg equiv.) and was observed in minor amounts in liver (1% of the TRRs, 0.002 mg/kg equiv.). The other predominant compound was the desmethyl metabolite M700F008, being a large proportion in egg (50% of the TRRs, 0.033 mg/kg equiv.), leg muscle (together with M700F016 amounting to 26% of the TRRs, 0.0016 mg/kg equiv.), and fat (25% of the TRRs, 0.009 mg/kg equiv.). M700F008 was detected in minor amounts in liver.

The metabolism of fluxapyroxad in laying hens mainly proceeds *via* hydroxylation at the biphenyl moiety, loss of a fluorine atom at the biphenyl ring (presumably by substitution with a hydroxyl–group), conjugation of the hydroxyl groups with glucuronic acid, and demethylation at the pyrazole ring. Additionally, conjugates with glutathione derivatives were identified.

Hens – M700F002

Labelled ^{14}C–M700F002 was fed to 10 laying hens at 13.1 ppm in the feed, 0.84 mg/kg bw/day or 1.66 mg/animal/day for ten consecutive days. Eggs were sampled in the morning before administration of the test substance and in the afternoon. Animals were sacrificed approximately 23 hours after the last dose. In excreta, 82% of the applied dose was found. Eggs contained 0.009% of the applied dose. Residues were 0.0041 mg/kg in liver, 0.0022 mg/kg in breast muscle, 0.0030 mg/kg in leg muscle, 0.0023 mg/kg for abdominal fat and 0.0058 mg/kg for body fat. In total, 84% of the applied dose was recovered in excreta, eggs, blood, tissues, GI tract and cage wash. The unchanged test item M700F002 was the only component identified in the extracts of egg, tissues and excreta and the only component detected in the methanol extracts of liver, leg muscle, body fat and excreta. It was concluded that the test item M700F002 is not considerably metabolized in laying hens.

Hens – M700F048

^{14}C–M700F048, labelled in the aniline moiety was fed to 12 laying hens at 12.9 ppm feed or 0.78 mg/kg bw/day for 11 consecutive days. Eggs were collected in the afternoon after administration of the test item and in the morning before the subsequent administration. Animals were sacrificed 18–22 hours after the last dose.

Overall, excreta contained 91.8% of the M700F048 administered, and excreta and cage wash together amounted to 94.1% of the total administered dose. In eggs, 0.15% of the total radioactivity administered was found. Total radioactive residues in eggs increased until day 8 and thereafter remained unchanged until day 11. At sacrifice, 18–22 hours after the last administration, organ and tissues were pooled from all animals. In total, < 0.5% of the total administered dose could be found in the tissues and organs. The residue levels in edible tissues and organs were 0.187 mg/kg equiv. for liver, 0.0079 mg/kg equiv. for breast muscle, 0.0091 mg/kg equiv. for leg muscle, 0.033 mg/kg equiv. for abdominal fat, and 0.032 mg/kg equiv. for body fat.

The unchanged test item M700F048 was present in only minor amounts in eggs and tissues (< 4% of the TRRs). The main metabolite in eggs and all tissues was the deglycosylated component M700F008, accounting for ≥ 67% of the TRRs (except in liver, where it accounted for 23% of the TRRs).

The results show that M700F048 is metabolized in hens mainly by the splitting-off of the sugar moiety. All metabolites identified in edible matrices (M700F008, M700F047, M700F009 and M700F010) were also found upon administration of M700F048 to rats.

Summary of animal metabolism

The metabolic pathways of fluxapyroxad in rats, goats and poultry were similar. The metabolism of fluxapyroxad mainly proceeds *via* hydroxylation at the biphenyl moiety, loss of a fluorine atom at the biphenyl ring, conjugation of the hydroxyl groups with glucuronic acid and demethylation at the pyrazole ring. Additionally, conjugates with glutathione derivatives were identified in rat and hen metabolism. The metabolism of rats was more complex than the metabolism of goats and hens, with a much larger number of metabolites observed.

Plant metabolism

The metabolism of fluxapyroxad was investigated in soya beans, tomato and wheat.

Aniline or pyrazole labelled fluxapyroxad was applied by foliar methods to tomatoes at a rate of 100 g ai/ha. Three applications took place 17, 10 and 3 days before harvest (55, 62 and 69 days after planting). Ripe tomato fruit were sampled 3 days after the last treatment. Other green parts of the plants (stem, panicles and leaves – referred to as tomato leaves) were also sampled.

Aniline or pyrazole labelled fluxapyroxad was applied by foliar methods to soya beans at a rate of 60 g ai/ha. Three applications were made at BBCH 16/17, 51–59 and 71–75. Samples of soya bean forage were taken after the first application (0 days after treatment; DAT) and immediately before the third application (21 days after the first treatment; 14 days after the second treatment). Soya

bean hay, straw, hulls and seed were harvested at BBCH 89, approximately a month after the third application.

Parent compound was generally the main component of the TRR. In the tomato and foliar wheat studies, parent was the only component observed at > 10% of the TRR. In tomatoes parent accounted for > 94% of the TRR in fruit (0.156 mg/kg equiv.) and > 90% TRR (6.039 mg/kg equiv.) in leaves. In wheat parent accounted for 60–91% of the TRR after foliar treatment and 58–79% TRR for forage, hay, straw and chaff after seed treatment, but only 7–17% TRR in grain after seed treatment. The group of metabolites M700F008, M700F043, M700F041 and M700F006 was found to occur in all wheat matrices after foliar treatment as the second most predominant component of radioactivity, representing 2–7% of the TRRs. After seed treatment, M700F008 was observed in all wheat matrices for both labels as the second most predominant component, representing 2–11% of the TRRs.

Aniline or pyrazole labelled fluxapyroxad was applied by foliar methods to spring wheat at a rate of 125 g ai/ha. Two applications were made at BBCH 30/35 and 69. Wheat forage samples were collected 36 days after the first application at BBCH 59. Wheat hay was sampled at 4 DALA (BBCH 73–75); straw, chaff and grain samples were collected at 34 and 35 DALA for the aniline and pyrazole label, respectively (BBCH 89).

Aniline or pyrazole labelled fluxapyroxad was applied as a seed treatment to spring wheat at a rate of 75 g ai/100 kg seed (equivalent to an application rate of 135g ai/ha). Wheat forage samples were collected at BBCH 59, wheat hay was sampled at BBCH 73–75 while straw, chaff and grain samples were collected at BBCH 89.

In the soya bean studies, parent accounted for 54–98% of the TRR in all matrices except seed, where it accounted for 7–21% of the TRR. The major metabolite in soya bean seed was M700F002 at 33% of the TRR (0.087 mg/kg equiv.) which is specific for the pyrazole label only. The corresponding cleavage product was not observed for the aniline label. An additional metabolite, M700F048 accounted for 9–20% (0.023 mg/kg equiv.) of the TRR in soya bean seed.

Two plant metabolites which were not observed in the animal metabolism studies with fluxapyroxad were M700F002 and M700F048. For M700F048, separate goat and hen metabolism studies have confirmed that M700F048 follows the same route of metabolism as fluxapyroxad. Both fluxapyroxad and M700F048 are degraded to the common metabolite M700F008, followed by hydroxylation of the biphenyl moiety and conjugation steps. Separate goat and hen metabolism studies for M700F002 have shown that M700F002 is not significantly transformed in the goat or the hen.

Confined Rotational Crops

Studies of residues in confined rotational crops have been submitted in which soil was treated at 250g ai/ha, followed by soil aging at 30, 120/149 and 365 days (aniline and pyrazole ^{14}C labels respectively). Representative succeeding crops of spinach (leafy vegetable), radish (root vegetable) and wheat (cereal grain) were planted at the above intervals to determine whether fluxapyroxad residues or degradates appear in follow crops. At all three plant-back intervals significant translocation of radioactivity from soil to plant was observed with radioactive residues in wheat straw up to 2.65 mg/kg and spinach up to 0.18 mg/kg. Lower residues were observed in radish roots (maximum of 0.015 mg/kg) and wheat grain (maximum of 0.043 mg/kg).

The metabolite pattern was similar to that observed for primary crops. No metabolites specific to rotational crops were observed. As observed in foliar treated plants, fluxapyroxad was the main component of the residue in both studies. It was the major residue observed in almost every matrix and every plant back interval. Major metabolites observed include M700F008 and M700F048 and in the pyrazole label only, M700F001 and M700F002. The latter two metabolites were observed in soil metabolism studies with fluxapyroxad.

Environmental Fate in Soil

The Meeting received information on soil photolysis, aerobic and anaerobic soil metabolism, field dissipation and adsorption/ desorption behaviour in different soils. Only those studies relevant to the current evaluation were considered.

Light was found to have little influence on the behaviour and degradation of fluxapyroxad in soils. Fluxapyroxad was found to be stable in aqueous solution at pH 4, 5, 7 and 9 (50 °C) for five days.

Under aerobic laboratory conditions at 20–27 °C fluxapyroxad degrades at a moderate to slow rate with DT_{50} values ranging from 69 to 689 days and DT_{90} values from >120 to >1000 days. There was no apparent correlation between half–lives and soil characteristics of pH and organic carbon. Cleavage of the carboxamide bridge produced M700F001, followed by demethylation to form M700F002. Both metabolites were observed at levels greater than 10% applied radioactivity in some soils and both declined over time. Laboratory aerobic soil degradation studies were conducted on both metabolites. Metabolite M700F001 degraded rapidly with DT_{50} values ranging from 2–9 days while DT_{50} values for M700F002 ranged from 77–197 days.

Field dissipation studies were carried out at six European sites, five sites in the USA and one in Canada. In general the field behaviour of fluxapyroxad was consistent with the model developed from the laboratory studies. Fluxapyroxad dissipated by aerobic soil processes and formed M700F001 and M700F002. These metabolites also dissipated, presumably metabolized to CO_2 and/or incorporated into soil organic fractions as observed in radiolabelled laboratory studies.

Fluxapyroxad dissipated with DT_{50} values of 9.9 to 370 days in the field studies. European field dissipation studies carried out on M700F002 at four sites showed DT_{50} values ranging from 26–39 days.

Generally the DT_{50} and DT_{90} values and residues at the end of study periods indicated that fluxapyroxad has a potential for residue carry over to the following cropping season if application is performed annually.

Methods of analysis

The Meeting received information on analytical methods for the determination of residues of the active substance, fluxapyroxad and the metabolites M700F002, M700F008 and M700F048 in plant matrices and animal matrices.

The methods used are based on HPLC/MS-MS and UPLC/MS-MS for plant matrices and HPLC/MS-MS for animal matrices. All methods involve extraction with either methanol/water (plant matrices) or acetonitrile/water (animal matrices). All methods have been adequately validated with LOQs of 0.01 mg/kg for fluxapyroxad, M700F002, M700F008 and M700F048 in plant matrices and LOQs of 0.01 mg/kg for bovine muscle, liver, kidney and fat or 0.001 mg/kg for milk, milk products and egg in animal matrices.

Radio-validation of the plant matrices method was carried out during the soya bean, tomato and wheat metabolism studies and the animal matrices method during the laying goat and hen metabolism studies. No multi–residue method was submitted for evaluation.

Stability of pesticide residues in stored analytical samples

The Meeting received information on the freezer storage stability of fluxapyroxad and the metabolites M700F002, M700F008 and M700F048 in plant and animal commodities.

Freezer storage stability studies showed that fluxapyroxad, M700F002 and M700F048 were stable for up to 24, 27 and 24 months in a variety of matrices. M700F008 was found to be stable for up to 24 months in wheat straw and dried pea seed. A decrease in stability was observed after 3 months for the other four matrices tested, i.e., wheat whole plant, wheat grain, lemon fruit and soya bean seed. The recoveries observed for storage intervals between 4–24 months did not show any subsequent significant decrease.

Samples from the fluxapyroxad wheat and soya bean metabolism studies were re–analysed after a storage interval of approximately 37 months to investigate the stability of incurred residues of M700F008 in wheat forage (pyrazole label), wheat straw (aniline label), wheat grain (pyrazole label) and soya bean seed (aniline label). Recoveries of M700F008 in these matrices after approximately 37–39 months were shown to be similar to those obtained in the original study.

Fluxapyroxad and the metabolites M700F002, M700F008 and M700F048 were demonstrated to be stable in extracts of animal matrices under refrigerator conditions for 7 days at the time of the validation of Method L01040/02.

In the hen metabolism study for fluxapyroxad a comparison of the extractabilities and metabolite patterns (HPLC chromatograms) showed no relevant changes in the nature of the radioactive residues during sample storage over approximately 16 months.

In the goat metabolism study for fluxapyroxad the stability of the residues in acetonitrile and methanol extracts was demonstrated for the whole period of metabolite investigation. Extracts which were obtained after storage of the matrices for about 18 months (milk, kidney and muscle) or 10–23 months (fat) showed concentrations and metabolite patterns comparable to data generated during earlier workups.

For the study of the metabolism of metabolite M700F002 in goat, the radiochemical stability of the test item over the 8 day dosing period was confirmed. Extractions were performed several times during the course of the study. No differences in the extraction characteristics at approximately 2–5 months after sampling were observed. The stability of radioactivity in extracts stored in a refrigerator was also proven for up to 83 days of storage by comparison of the HPLC chromatograms.

Residue Definition

Animals

In the goat metabolism studies, fluxapyroxad represented one of the major residues in milk, muscle and fat (12–44% of the TRRs), while accounting for minor proportions in liver and kidney (3–7% of the TRRs). The other predominant compound was the desmethyl metabolite M700F008, representing a main proportion in milk, muscle, fat, liver and kidney (13–83% of the TRRs). The dairy cow feeding study showed that levels of M700F008 in milk were generally of the same order as fluxapyroxad. Residues in fat were lower than fluxapyroxad residues, while those in liver and kidney were somewhat higher than fluxapyroxad residues.

In the hen metabolism study, fluxapyroxad represented one of the major residues in egg (14% leg muscle and fat (14–63% of the TRRs) and was observed in minor amounts in liver (1% of the TRRs). The other predominant compound was the desmethyl metabolite M700F008, representing a main proportion in egg, leg muscle and fat (25–50% of the TRRs). M700F008 was detected at minor amounts (4% of the TRRs) in liver (0.009 mg/kg). The laying hen feeding study showed that levels of M700F008 in egg were higher than fluxapyroxad. Residues of M700F008 were observed in liver at the two highest feeding levels (1.8 and 6.0 ppm), but fluxapyroxad residues were not observed. Residues in fat were lower than fluxapyroxad residues (both only observed at 6.0 ppm).

Two plant metabolites which were not observed in the animal metabolism studies with fluxapyroxad were M700F002 and M700F048. For M700F048 separate goat and hen metabolism studies have confirmed that M700F048 follows the same route of metabolism as fluxapyroxad. Both fluxapyroxad and M700F048 are degraded to the common metabolite M700F008 followed by hydroxylation of the biphenyl moiety and conjugation steps.

In residue field trials M700F048 was usually only found in minor proportions compared to parent or was found at low absolute levels. It is therefore not necessary to include M700F048 in the residue definition for animal commodities. Similarly the metabolite M700F002 was not detected in most residues trials provided (maximum observation across all trials was 0.02 mg/kg). In the animal feeding studies M700F002 was not seen above the LOQ in any animal matrix at any dose level. It is therefore not necessary to include M700F002 in the residue definition for animal commodities.

It is considered that a residue definition of parent is appropriate for commodities of animal origin for compliance with MRLs (enforcement). Parent fluxapyroxad and M700F008 are of comparable toxicity and because M700F008 is detected as a predominant compound in a number of animal matrices, a residue definition of parent plus M700F008 (expressed as parent equivalents) is appropriate for commodities of animal origin for risk assessment.

Plants

In the plant metabolism studies parent was generally the main component of the TRR. In the tomato and foliar wheat studies, parent was the only component observed at > 10% of the TRR (58 to > 94% TRR in tomato fruit and leaves and all wheat matrices). After wheat seed treatment parent accounted for 58–79% TRR in forage, hay, straw and chaff but only 7–17% TRR in grain. A group of metabolites that includes M700F008 was found to occur in all wheat matrices after foliar treatment as the second most predominant component of radioactivity, representing 2–7% of the TRRs. After seed treatment, M700F008 was observed in all wheat matrices for both labels as the second most predominant component, representing 2–11% of the TRRs.

In the soya bean studies, parent accounted for 54–98% of the TRR in all matrices except seed, where it accounted for 7–21% of the TRR. The major metabolite in soya bean seed was M700F002 at 33% of the TRR (0.087 mg/kg equiv.) which is specific for the pyrazole label only. An additional metabolite, M700F048 accounted for 9–20% (0.023 mg/kg equiv.) of the TRR in soya bean seed.

No metabolites specific to rotational crops were observed. As observed in foliar treated plants, fluxapyroxad was the main component of the residue. Major metabolites observed include M700F008 and M700F048 and in the pyrazole label only, the soil metabolites M700F001 and M700F002.

Residues trials over a wide variety of crops (pome fruit, stone fruit, fruiting vegetables other than cucurbits, legume vegetables, pulses, root and tuber vegetables, cereal grains, oilseeds and various animal feeds) as well as rotational crop studies were submitted in which the residues of parent fluxapyroxad, M700F002, M700F008, M700F048 were determined. In general detectable residues of M700F002 were very rarely observed and then at very low levels. It is considered unnecessary to include M700F002 in the residue definition for plant commodities.

M700F008 and M700F048 were observed more frequently than M700F002 in plants but parent fluxapyroxad was almost always present when detectable residues were observed in either M700F008 or M700F048 and was, in the vast majority of cases, the significantly dominant residue. However in stone fruit (particularly cherries) and in canola, M700F008 and M700F048 were significant residues while M700F008 was also a significant residue in peppers and soya beans.

It is considered that a residue definition of parent only is appropriate for fluxapyroxad in plant commodities for compliance against MRLs as parent is present in most plant matrices. Fluxapyroxad and the metabolites M700F008 and M700F048 are of comparable toxicity and as the metabolites are present in significant amounts in some plant matrices, it is considered that a residue definition of fluxapyroxad + M700F008 + M700F048 (fluxapyroxad total residues expressed as parent equivalents) is appropriate for risk assessment.

The log K_{ow} of fluxapyroxad (log K_{ow} 3.13, pH 7) suggests that fluxapyroxad might be moderately fat-soluble.

The ratio of fluxapyroxad residues in muscle and fat observed in the livestock metabolism and feeding studies (*e.g.* in the lactating dairy cow feeding study: up to 14× higher in fat based on mean residues) support the conclusion that fluxapyroxad is fat-soluble.

Definition of the residue (for compliance with the MRL for plant and animal commodities): *Fluxapyroxad*

Definition of the residue (for estimation of dietary intake for plant commodities): *Sum of fluxapyroxad and 3-(difluoromethyl)- N-(3',4',5'-trifluoro[1,1'-biphenyl]-2-yl)-1H-pyrazole-4-*

carboxamide (M700F008) and 3–(difluoromethyl)- 1-(ß-D-glucopyranosyl)-N-(3',4',5'-triflurobipheny-2-yl)-1H-pyrzaole-4-carboxamide (M700F048) and expressed as parent equivalents

Definition of the residue (for estimation of dietary intake for animal commodities): *Sum of fluxapyroxad and 3-(difluoromethyl)- N-(3',4',5'-trifluoro[1,1'-biphenyl]-2-yl)-1H-pyrazole-4-carboxamide (M700F008) and expressed as parent equivalents*

The residue is fat-soluble.

Results of supervised residue trials on crops

Supervised trials were available for the use of fluxapyroxad on numerous crops: apples, pears, cherries, peaches, plums, tomatoes, bell and non-bell peppers, sweet corn, peas, beans, soya beans, potatoes, sugar beet, barley, field corn, oats, rice, sorghum, triticale, wheat, canola, sunflowers, cotton and peanuts.

After sampling, if a higher residue level was observed at a longer PHI than the GAP, the higher value has been used in maximum residue level estimation.

In trials where duplicate field samples from replicated or unreplicated plots were taken at each sampling time and analysed separately, the mean was taken as the best estimate of the residue. Where residues have been reported as < LOD (less than the limit of detection) the values have been considered as < LOQ (< 0.01 mg/kg) for the purposes of maximum residue level estimation.

The OECD calculator was used as a tool to assist in the estimation of maximum residue levels from the selected residue data set obtained from the supervised residue trials. As a first step, the Meeting reviewed all relevant factors related to each data set in arriving at a best estimate of the maximum residue using expert judgement. Then the OECD calculator was employed. If the statistical calculation spreadsheet suggested a different value from that recommended by the Meeting, a brief estimation of the deviation was supplied.

For dietary intake assessment the residues are expressed as the sum of fluxapyroxad + M700F008 + M700F048 expressed as fluxapyroxad (referred to as "total"). In most cases the metabolites were tabulated as mg/kg of specific analyte, so the M700F008 and M700F048 amounts were converted to fluxapyroxad by multiplying by 1.038 and 0.72 respectively. The treatment of values at < LOQ is illustrated below. Residues data for most crops show that the metabolites M700F008 and M700F048 are commonly < LOD. Although this is expressed as < LOQ for the purposes of maximum residue level estimation, it is considered appropriate that when one component is above the LOQ and the others are below the LOQ, that the combined residue is assumed to be equal to the main component.

Fluxapyroxad	M700F008	M700F048	Total Residues (mg/kg) (Sum of fluxapyroxad + M700F008 + M700F048)
0.10	< 0.01	< 0.01	0.10
< 0.01	< 0.01	< 0.01	< 0.01
< 0.01	0.03	< 0.01	0.03

Product labels were available from Australia, Brazil, France, Germany, United Kingdom and the United States of America.

Pome Fruits

Residue trials were conducted in apples according to the GAP in the USA for pome fruit (4 applications at 97–100g ai/ha, 0 day PHI). Applications were made using either concentrate or dilute spray volumes.

Residues of fluxapyroxad in apples from supervised trials matching US GAP, in ranked order, were: 0.14, 0.15, 0.21, 0.24, 0.25, 0.26, 0.28, 0.31, 0.35, 0.36 and 0.37 mg/kg.

The ranked order of total residues in apples from supervised trials according to GAP were: 0.14, 0.15, 0.21, 0.24, 0.25, 0.26, 0.31, 0.35, 0.36, 0.36 and 0.37 mg/kg

Residue trials were conducted in pears in the USA and Canada according to GAP in the USA (4 applications at 97–100 g ai/ha, 0 day PHI). Applications were made using either concentrate or dilute spray volumes.

Residues of fluxapyroxad in pears from supervised trials according to US GAP, in ranked order, were: 0.18, 0.20, 0.23, 0.29, 0.34, 0.38, 0.45 and 0.47 mg/kg.

The total residues in pears from supervised trials according to GAP, in ranked order were: 0.18, 0.20, 0.23, 0.30, 0.34, 0.38, 0.46 and 0.47 mg/kg.

The use pattern in the USA is for pome fruit. The Meeting noted that the USA and Canadian datasets matching US GAP for apples and pears resulted in similar residues (Mann-Whitney U-Test). The Meeting decided to combine the data for apples and pears to increase the data set for the purposes of estimating a maximum residue level, STMR, HR and to make a recommendation for pome fruit.

The ranked order of residues of fluxapyroxad in apples and pears from supervised trials according to GAP were: 0.14, 0.15, 0.18, 0.20, 0.21, 0.23, 0.24, 0.25, 0.26, 0.28, 0.29, 0.31, 0.34, 0.35, 0.36, 0.37, 0.38, 0.45 and 0.47 mg/kg.

The ranked order of total residues in apples and pears from supervised trials according to GAP were: 0.14, 0.15, 0.18, 0.20, 0.21, 0.23, 0.24, 0.25, 0.26, 0.30, 0.31, 0.34, 0.35, 0.36, 0.36, 0.37, 0.38, 0.46 and 0.47 mg/kg.

The Meeting estimated maximum residue level, STMR and HR values for fluxapyroxad in pome fruit of 0.9, 0.30 and 0.47 mg/kg respectively.

Stone Fruits

Residue trials were conducted in cherries in the USA and Canada matching the GAP in the USA for stone fruit (3 applications at 121–123 g ai/ha, 0 day PHI). Applications were made using either concentrate or dilute spray volumes.

The ranked order of residues of fluxapyroxad in cherries from supervised trials according to GAP were: 0.26, 0.31, 0.55, 0.56, 0.59, 0.82, 1.10 and 1.87 mg/kg.

The ranked order of total residues in cherries from supervised trials according to US GAP were: 0.37, 0.50, 0.72, 0.73, 0.78, 1.13, 1.38 and 2.32 mg/kg.

Residue trials were conducted in peaches in the USA and Canada matching to the GAP in the USA for stone fruit (3 applications at 121–123g ai/ha, 0 day PHI).

The ranked order of residues of fluxapyroxad in peaches from supervised trials according to GAP were: 0.28, 0.30, 0.32, 0.33, 0.34, 0.43, 0.45, 0.55, 0.57, 0.58, 0.59 and 0.63 mg/kg.

The total residues in peaches from supervised trials according to GAP, in ranked order were: 0.30, 0.31, 0.33, 0.34, 0.35, 0.45, 0.48, 0.58, 0.62, 0.63, 0.66 and 0.66 mg/kg.

Residue trials were conducted in plums in the USA and Canada matching the GAP in the USA for stone fruit (3 applications at 121–123g ai/ha, 0 day PHI).

The ranked order of residues of fluxapyroxad in plums from supervised trials according to GAP were: 0.23, 0.24, 0.27, 0.37, 0.38, 0.49, 0.55, 0.56, 0.64 and 0.95 mg/kg.

The total residues in plums from supervised trials according to GAP, in ranked order were: 0.23, 0.24, 0.27, 0.38, 0.39, 0.49, 0.55, 0.56, 0.64 and 0.95 mg/kg.

The use pattern in the USA is for stone fruit. The Meeting noted that the USA and Canadian datasets matching GAP for cherries, peaches and plums resulted in similar residues. The Meeting decided to combine the data for cherries, peaches and plums to increase the database for the purposes of estimating a maximum residue level and STMR and to make a recommendation for stone fruit.

The ranked order of residues of fluxapyroxad in cherries, peaches and plums from supervised trials according to GAP were: 0.23, 0.24, 0.26, 0.27, 0.28, 0.30, 0.31, 0.32, 0.33, 0.34, 0.37, 0.38, 0.43, 0.45, 0.49, 0.55, 0.55, 0.55, 0.56, 0.56, 0.57, 0.58, 0.59, 0.59, 0.63, 0.64, 0.82, 0.95, 1.10 and 1.87 mg/kg.

The ranked order of total residues in cherries, peaches and plums from supervised trials according to GAP were: 0.23, 0.24, 0.27, 0.30, 0.31, 0.33, 0.34, 0.35, 0.37, 0.38, 0.39, 0.45, 0.48, 0.49, 0.50, 0.55, 0.56, 0.58, 0.62, 0.63, 0.64, 0.66, 0.66, 0.72, 0.73, 0.78, 0.95, 1.13, 1.38 and 2.32 mg/kg.

The Meeting estimated maximum residue level, STMR and HR values for fluxapyroxad in stone fruits of 2, 0.525 and 2.3 mg/kg, respectively.

Fruiting Vegetables, other than Cucurbits

Residue trials were conducted in tomatoes in the USA and Canada matching to the GAP of the USA for fruiting vegetables other than cucurbits (3 applications at 97–101g ai/ha with a 7 day PHI). In addition two trials were carried out in cherry tomatoes in California according to the same USA GAP. Each trial was also carried out with 2 applications of fluxapyroxad to tomatoes. The highest residue observations, regardless of whether 2 or 3 applications of fluxapyroxad were made, will be considered for the purpose of estimating a maximum residue level.

The ranked order of residues of fluxapyroxad in tomatoes from supervised trials according to the GAP were: 0.03, 0.04, 0.0455, 0.05, 0.06, 0.07, 0.07, 0.07, 0.07, 0.08, 0.09, 0.11, 0.13, 0.27 and 0.44 mg/kg.

The total residues in tomatoes from supervised trials according to GAP, in ranked order were: 0.03, 0.04, 0.045, 0.055, 0.06, 0.07, 0.07, 0.07, 0.07, 0.08, 0.09, 0.11, 0.13, 0.27 and 0.44 mg/kg.

Residue trials were conducted in bell peppers in the USA and Canada according to the GAP of the USA for fruiting vegetables other than cucurbits (3 applications at 97–101g ai/ha, 7 day PHI).

The ranked order of residues of fluxapyroxad in bell peppers from supervised trials according to the GAP were: < 0.01, 0.01, 0.01, 0.02, 0.04, 0.09, 0.09 and 0.24 mg/kg.

The total residues in bell peppers from supervised trials according to GAP, in ranked order were: < 0.01, 0.01, 0.03, 0.03, 0.06, 0.15, 0.16 and 0.37 mg/kg.

Residue trials were conducted in chili peppers at two locations in the USA matching the critical GAP of the USA for fruiting vegetables other than cucurbits (3 applications at 97–101g ai/ha, 7 day PHI).

The residues of fluxapyroxad in non-bell chili peppers from supervised trials according to the GAP were: 0.02 and 0.30 mg/kg.

The total residues in non-bell chili peppers from supervised trials according to GAP, in ranked order were: 0.03 and 0.32 mg/kg.

The use pattern in the USA is for Fruiting vegetables (eggplant, ground cherry, pepino, pepper (all varieties), tomatillo and tomato). The Meeting noted that the USA and Canadian datasets matching GAP for tomatoes and peppers resulted in similar residues (Mann-Whitney U-Test). The Meeting decided to combine the data in estimating a maximum residue level and STMR for fruiting vegetables other than cucurbits (except mushrooms and sweet corn).

Residues of fluxapyroxad in tomatoes and peppers from supervised trials according to the GAP were: < 0.01, 0.01, 0.01, 0.02, 0.02, 0.03, 0.04, 0.04, 0.04, 0.05, 0.06, 0.07, 0.07, 0.07, 0.07, 0.08, 0.09, 0.09, 0.09, 0.11, 0.13, 0.24, 0.27, 0.30 and 0.44 mg/kg.

The total residues in tomatoes and peppers from supervised trials according to GAP, in ranked order were: < 0.01, 0.01, 0.03, 0.03, 0.03, 0.03, 0.04, 0.04, 0.05, 0.06, 0.06, 0.07, 0.07, 0.07, 0.07, 0.08, 0.09, 0.11, 0.13, 0.15, 0.16, 0.27, 0.32, 0.37 and 0.44 mg/kg.

The Meeting estimated maximum residue level, STMR and HR values for fluxapyroxad in fruiting vegetables other than cucurbits (except mushrooms and sweet corn) of 0.6, 0.07 and 0.44 mg/kg, respectively.

On the basis of the STMR and HR for fruiting vegetables other than cucurbits and the dehydration factor of 10, an STMR and HR were calculated as 0.70 and 4.4 mg/kg respectively for chili peppers. Based on the estimated maximum residue level for fruiting vegetables other than cucurbits, the Meeting recommended a maximum residue level of 6 mg/kg for chili peppers (dry).

Sweet corn, corn-on-the-cob

Residue trials were conducted in field corn (four trials) and sweet corn (five trials) at various locations in the USA and Canada matching the GAP in the USA (2 applications at 97–100g ai/ha, 7 day for sweet corn). Samples were taken to measure residues in kernels + cobs with husks removed samples.

The ranked order of highest residues of fluxapyroxad (and total residues) in kernels + cobs with husks removed samples from supervised trials collected 5–7 days after the last application was < 0.01 (8) and 0.08 mg/kg.

The Meeting estimated maximum residue level, STMR and HR values for fluxapyroxad in sweet corn (corn-on-the-cob) of 0.15, 0.01 and 0.08 mg/kg respectively.

Legume vegetables

Edible podded peas and beans

Registered use patterns in legumes exist for edible podded legume vegetables and succulent shelled peas and beans.

Residue trials were conducted in peas generally according to the critical GAP in the USA for edible podded legumes (2 applications at 97–101g ai/ha, 7 day PHI).

The ranked order of residues of fluxapyroxad in pea succulent seed with pods from supervised trials according to GAP were: 0.22, 0.23, 0.39, 0.65, 0.66, 0.73 and 0.74 mg/kg.

The ranked order of total residues in pea succulent seed with pods from supervised trials according to GAP were: 0.24, 0.24, 0.40, 0.65, 0.68, 0.73 and 0.74 mg/kg.

The Meeting estimated maximum residue level, STMR and HR values for fluxapyroxad in pea succulent seed with pods of 2, 0.65 and 0.74 mg/kg respectively.

The Meeting decided to extrapolate the maximum residue level and STMR and HR value for pea succulent seed with pods to Beans, except broad bean and soya bean.

Residue trials were conducted in soya beans generally according to the GAP in the USA for edible podded legumes (2 applications at 97–100g ai/ha, 7 day PHI).

The ranked order of residues of fluxapyroxad in soya bean succulent seed with pods from supervised trials according to GAP was 0.10, 0.10, 0.11, 0.11, 0.18, 0.20, 0.21, 0.27, 0.29, 0.29, 0.46, 0.69 and 0.69 mg/kg.

The ranked order of total residues in soya bean succulent seed with pods from supervised trials according to GAP was 0.11, 0.12, 0.12, 0.13, 0.20, 0.21, 0.24, 0.28, 0.31, 0.34, 0.52, 0.71 and 0.74 mg/kg.

The Meeting estimated maximum residue level, STMR and HR values for fluxapyroxad in soya bean (young pods) of 1.5, 0.24 and 0.74 mg/kg, respectively.

Edible peas and beans without pods

Residue trials were conducted in peas at 8 locations in the USA and Canada (9 trials) generally according to the critical GAP in USA for succulent shelled peas and beans (2 applications at 97–101 g ai/ha, 7 day PHI).

Residues of fluxapyroxad in pea succulent seed without pods from supervised trials according to GAP were: < 0.01, 0.03, 0.03, 0.03, 0.03, 0.04 and 0.04 mg/kg.

The total residues in pea succulent seed without pods from supervised trials according to GAP, in ranked order, were: < 0.01, 0.03, 0.03, 0.03, 0.03, 0.04 and 0.04 mg/kg.

The Meeting estimated maximum residue level, STMR and HR values for fluxapyroxad in pea, shelled (succulent seed) of 0.09, 0.03 and 0.04 mg/kg, respectively.

The Meeting decided to extrapolate the maximum residue level and STMR and HR value for pea, shelled (succulent seed) to Beans, shelled.

Residue trials were conducted in soya beans in the USA and Canada matching the GAP in the USA for succulent shelled peas and beans (2 applications at 97–100g ai/ha, 7 day PHI).

The ranked order of residues of fluxapyroxad in soya bean succulent seed without pods from supervised trials according to GAP were: < 0.01 (5), 0.01, 0.01, 0.02, 0.03, 0.04, 0.04, 0.11 and 0.37 mg/kg.

The total residues in soya bean succulent seed without pods from supervised trials according to GAP, in ranked order, were: < 0.01 (5), 0.01, 0.01, 0.03, 0.04, 0.04, 0.04, 0.12 and 0.37 mg/kg.

The Meeting estimated maximum residue level and STMR values for fluxapyroxad in soya beans (immature seeds) of 0.5, 0.01 and 0.37 mg/kg respectively.

Pulses

Soya bean, dry

Residue trials were conducted in soya bean in Brazil, in which four applications were made at 50 g ai/ha at 15 day intervals. Sampling was performed at a 14 day PHI in two trials and 0, 7, 14, 21 and 30 day PHI in two decline trials. The GAP in Brazil is up to 4 applications at 60g ai/ha, 14 day PHI, 10–20 day interval between applications).

The residues of fluxapyroxad (and total residues) in soya bean seeds from supervised trials collected 14 days after the last application were: < 0.01 (4) and 0.03 mg/kg.

Residue trials were conducted in soya bean in the USA and Canada according to the GAP in the USA (2 applications at 97–101g ai/ha, 21 day PHI).

The ranked order of residues of fluxapyroxad in dried soya bean seed from supervised trials collected 20–22 days after the last application were: < 0.01 (10), 0.01, 0.03, 0.04 and 0.10 mg/kg.

The ranked order of total residues in dried soya bean seed from supervised trials collected 20–22 days after the last application were: < 0.01 (10), 0.01, 0.03, 0.04 and 0.11 mg/kg.

Based on the USA and Canadian residues data the Meeting estimated maximum residue level and STMR values for fluxapyroxad in soya bean (dry) of 0.15 and 0.01 mg/kg, respectively.

Dried Shelled Peas and Beans

Residue trials were conducted in peas (dry) in the USA and Canada according to the GAP in the USA (2 applications at 97–101g ai/ha, 21 day PHI).

The ranked order of residues of fluxapyroxad (and total residues) in dried pea seed from supervised trials collected 21–22 days after the last application were: < 0.01, < 0.01, 0.02, 0.02, 0.04, 0.09, 0.11, 0.15 and 0.16 mg/kg.

The Meeting estimated maximum residue level and STMR values for fluxapyroxad in peas (dry) of 0.4 and 0.04 mg/kg respectively.

The Meeting decided to extrapolate the maximum residue level and STMR value for peas (dry) to lentils and chickpeas.

Residue trials were conducted in beans in the USA matching the GAP in the USA (2 applications at 195–200g ai/ha, 21 day PHI).

The ranked order of residues of fluxapyroxad in bean seed from supervised trials approximating GAP were: 0.01, 0.01, 0.02, 0.03, 0.03, 0.04, 0.04, 0.05, 0.05, 0.07 and 0.21 mg/kg.

The ranked order of total residues in bean seed from supervised trials approximating GAP were: 0.01, 0.01, 0.02, 0.03, 0.03, 0.04, 0.05, 0.05, 0.06, 0.07 and 0.25 mg/kg.

The Meeting estimated maximum residue level and STMR values for fluxapyroxad in beans (dry) of 0.3 and 0.04 mg/kg, respectively.

Potatoes

Residue trials were conducted in potatoes in the USA and Canada according to the critical GAP in the USA (3 applications at 97–101g ai/ha, 7 day PHI).

The ranked order of residues of fluxapyroxad (and total residues) in potatoes from supervised trials collected 7 days after the last application were: < 0.01 (17), 0.02 and 0.02 mg/kg.

The Meeting estimated maximum residue level, STMR and HR values for fluxapyroxad in potatoes of 0.03, 0.01 and 0.02 mg/kg respectively.

Sugar beet

Residue trials were conducted in sugar beet in the USA and Canada according to the critical GAP in USA (3 applications at 97–101g ai/ha, 7 day PHI).

The ranked order of residues of fluxapyroxad (and total residues) in sugar beet roots from supervised trials collected 7 days after the last application were: 0.01, 0.01, 0.03, 0.03, 0.03, 0.04, 0.04, 0.04, 0.05, 0.05, 0.06 and 0.06 mg/kg.

The Meeting estimated maximum residue level, STMR and HR values for fluxapyroxad in sugar beet of 0.15, 0.04 and 0.06 mg/kg respectively.

Cotton seed

Residue trials were conducted in cotton in the USA according to the critical GAP in USA (seed treatment application at 20g ai/100 kg seed).

No detectable residues of fluxapyroxad or any metabolite were observed from supervised trials collected 155–193 days after the seed treatment application. In addition, two trials were carried out at 5× the GAP application rate in which no residues were detectable.

The Meeting estimated maximum residue level and STMR values for fluxapyroxad in cotton seed of 0.01* and 0 mg/kg.

Peanuts

Residue trials were conducted in peanuts in the USA according to the critical GAP in USA (3 applications at 97g ai/ha, 7 day PHI).

No residues of fluxapyroxad were observed in peanut nutmeat from supervised trials collected 7 days (3 days in one trial) after application. One decline trial in which residues observations were taken at 0, 4, 7, 14 and 21 days PHI gave fluxapyroxad residues at < 0.01 mg/kg at all sampling intervals. Finite residues of metabolite M700F008 were observed at all sampling times in one trial.

Residues of fluxapyroxad in peanut nutmeat from supervised trials according to GAP were < 0.01 (12) mg/kg.

Total residues in peanut nutmeat from supervised trials according to GAP were: < 0.01 (11) and 0.08 mg/kg.

The Meeting estimated maximum residue level and STMR values for fluxapyroxad in peanut nutmeat of 0.01 and 0.01 mg/kg.

Oilseed - Rape seed and Sunflower seed

Residues observed in rape and sunflowers were higher than those observed in cottonseed and peanuts and were therefore considered separately.

Residue trials were conducted in rape seed (canola) in the USA and Canada matching the GAP in the USA (2 applications at 97–101g ai/ha, 21 day PHI).

The ranked order of residues of fluxapyroxad in rape seed from supervised trials according to GAP were: 0.02, 0.02, 0.04, 0.05, 0.09, 0.09, 0.12, 0.16, 0.19, 0.22 and 0.73 mg/kg.

The total residues in rape seed from supervised trials according to GAP were: 0.02, 0.02, 0.04, 0.05, 0.11, 0.11, 0.15, 0.18, 0.25, 0.27 and 0.83 mg/kg.

Residue trials were conducted in sunflower in the USA and Canada according to the GAP in the USA (2 applications at 97–101g ai/ha, 21 day PHI).

The residues of fluxapyroxad (and total residues) in sunflower seed from supervised trials according to GAP, in ranked order, were: 0.02, 0.02, 0.05, 0.06, 0.09 and 0.11 mg/kg.

The use pattern in the USA is for oilseeds. The Meeting noted that the USA and Canadian datasets, matching GAP for rape seed and sunflower seed, resulted in similar residues (Mann-Whitney U-Test). The Meeting decided to combine the data for rape seed and sunflower seed to increase the dataset for the purposes of estimating a maximum residue level, STMR, HR and to make a recommendation for oilseeds.

The ranked order of residues of fluxapyroxad in rape seed and sunflower seed from supervised trials according to GAP were: 0.02, 0.02, 0.02, 0.02, 0.04, 0.05, 0.05, 0.06, 0.09, 0.09, 0.09, 0.11, 0.12, 0.16, 0.19, 0.22 and 0.73 mg/kg.

The ranked order of total residues in rape seed and sunflower seed from supervised trials according to GAP were: 0.02, 0.02, 0.02, 0.02, 0.04, 0.05, 0.05, 0.06, 0.09, 0.11, 0.11, 0.11, 0.15, 0.18, 0.25, 0.27 and 0.83 mg/kg.

The Meeting estimated maximum residue level and STMR values for fluxapyroxad in oilseeds (except peanuts and cotton) of 1.5 and 0.09 mg/kg, respectively.

Cereals

Barley

Residue trials were conducted in barley in Brazil matching the GAP in Brazil (2 applications at 60 g ai/ha, 30 day PHI, 15–20 day interval between applications).

The residues of fluxapyroxad in barley grain from supervised trials according to the GAP in Brazil were: 0.09, 0.14, 0.15 and 0.28 mg/kg.

The ranked order of total residues of fluxapyroxad in barley grain from supervised trials according to the GAP in Brazil were: 0.09, 0.14, 0.15 and 0.30 mg/kg.

Residue trials were conducted in barley in various European countries (Germany, the Netherlands, France, the UK, Greece, Spain and Italy) in each of two growing seasons, according to the GAP in Europe. (GAP in European countries is 2 applications at 125g ai/ha, 35 day PHI (France) or in the United Kingdom not required if application is at or before GS 69). Trials were also run at a lower rate of application (77–90g ai/ha). Residues data were collected at PHIs ranging from 29–63 days.

The ranked order of residues of fluxapyroxad in barley grain, from supervised trials in Europe collected 35–63 days after the last application, were: 0.02, 0.05, 0.08, 0.09, 0.09, 0.10, 0.10, 0.13, 0.15, 0.17, 0.18, 0.19, 0.23, 0.23, 0.24 and 0.41 mg/kg.

The ranked order of total residues in barley grain, from supervised trials in Europe collected 29–63 days after the last application, were: 0.02, 0.05, 0.08, 0.09, 0.09, 0.10, 0.10, 0.13, 0.16, 0.17, 0.18, 0.19, 0.23, 0.23, 0.24 and 0.45 mg/kg.

Residue trials were conducted in barley in Australia according to the GAP in Australia (2 applications at 62.5g ai/ha).

The residues of fluxapyroxad (and total residues) in barley grain from supervised trials collected at harvest were 0.03 and 0.05 mg/kg.

Residue trials were conducted in barley in the USA and Canada according to the critical GAP in the USA (2 applications at 97–100g ai/ha, 21 day PHI).

The residues of fluxapyroxad in barley grain from supervised trials approximating GAP, in ranked order, were: < 0.01, 0.39, 0.39, 0.41, 0.50, 0.52, 0.52, 0.54, 0.82, 0.87, 1.02 and 1.22 mg/kg.

The total residues in barley grain from supervised trials approximating US GAP were: < 0.01, 0.39, 0.41, 0.44, 0.51, 0.53, 0.54, 0.54, 0.84, 0.87, 1.02 and 1.26 mg/kg.

The data from the USA and Canada were used to estimate a maximum residue level and STMR for barley grain.

The Meeting estimated maximum residue level and STMR values for fluxapyroxad in barley grain of 2 and 0.535 mg/kg respectively.

Oats

Residue trials were conducted in oats in Brazil according to the GAP in Brazil (2 applications at 60 g ai/ha, 30 day PHI, 15–20 day interval between applications).

The residues of fluxapyroxad and (total residues) in oat grain from supervised trials collected 30 days after the last application were < 0.01, < 0.01, 0.05 and 0.28 mg/kg.

The Meeting considered that there were insufficient data reflecting the GAP for fluxapyroxad on oats in Brazil to estimate an appropriate maximum residue level. In addition the GAP in Brazil is less critical than the GAP in the USA (2 applications at 97–100g ai/ha, 21 day PHI).

The Meeting recognized that barley and oats share an identical GAP and normally show comparable residues. It was therefore decided to apply the maximum residue level and STMR recommended for fluxapyroxad on barley to oats (2 and 0.535 mg/kg respectively).

Maize

Residue trials were conducted in maize in Brazil according to the GAP in Brazil (2 applications at 60g ai/ha, 45 day PHI, 15–20 days between applications).

No detectable residues of fluxapyroxad or metabolites in corn grain were observed in samples from supervised trials collected 45 days after the last application.

Residue trials were conducted in maize in the USA and Canada according to the critical GAP in USA (2 applications at 97–100g ai/ha, 21 day PHI).

No residues of fluxapyroxad or the metabolites M700F008 or M700F048 were detected in corn grain (maize) from supervised trials approximating GAP.

The Meeting estimated maximum residue level and STMR values for fluxapyroxad in maize (corn grain) of 0.01* and 0.01 mg/kg respectively.

Rice

Residue trials were provided for rice but none of the submitted labels had a use pattern. As no GAP is available it was not possible to estimate a maximum residue level for the use of fluxapyroxad on rice.

Sorghum

Residue trials were conducted in sorghum in the USA in which two applications were made at 97–104 g ai/ha (6–7 day retreatment interval) with a 20–23 day PHI. It was not possible to establish a maximum residue level based on any label use of fluxapyroxad on sorghum as the submitted residue trial data did not correspond to any label GAP.

Wheat and triticale

Residue trials were conducted in wheat in Brazil, in which three applications were made at 60 g ai/ha at 15 day intervals. Sampling was performed at a 30 day PHI in two trials and 0, 7, 15, 30 and 45 day PHI in two decline trials. The GAP in Brazil is 3 or 4 applications at 60 g ai/ha, 30 day PHI, 15–20 day interval between applications).

The ranked order of residues of fluxapyroxad (and total residues) in wheat grain from supervised trials collected 30 days after the last application were: 0.02, 0.03, 0.04 and 0.08 mg/kg.

Residue trials were conducted in wheat or triticale in various countries in Europe (Germany, the UK, France, Spain and Italy) in each of two growing seasons, matching a GAP in Europe. (GAP in various European countries is 2 applications at 125g ai/ha, 35 day PHI (France) or in the United Kingdom no PHI required if application is at or before GS 69). Residues data were collected at PHIs ranging from 34–60 days.

The ranked order of residues of fluxapyroxad (and total residues) in wheat or triticale (t) grain, from supervised trials in Europe collected 34–60 days after the last application, were: < 0.01 (t), 0.01, 0.01, 0.01, 0.01, 0.02 (t), 0.02 (t), 0.02, 0.02, 0.03 (t), 0.03, 0.03, 0.04, 0.04, 0.05 and 0.06 mg/kg.

Residue trials were conducted in wheat at four locations in Australia in which 2 applications were made at 61–62g ai/ha or 122–124g ai/ha. There is no corresponding GAP.

Residue trials were conducted in wheat in the USA and Canada according to the GAP in the USA (2 applications at 97–100g ai/ha, 21 day PHI). The residues of fluxapyroxad in wheat grain from supervised trials corresponding to GAP, in ranked order, were: 0.03, 0.03, 0.05, 0.05, 0.05, 0.05, 0.06, 0.06, 0.06, 0.07, 0.08, 0.09, 0.10, 0.11, 0.11, 0.12, 0.12, 0.13, 0.19 and 0.21 mg/kg.

The total residues in wheat grain from supervised trials corresponding to GAP, in ranked order were: 0.03, 0.03, 0.05, 0.05, 0.05, 0.06, 0.06, 0.06, 0.07, 0.08, 0.09, 0.09, 0.11, 0.11, 0.12, 0.13, 0.13, 0.15, 0.19 and 0.21 mg/kg.

The data from the USA and Canada were used to estimate a maximum residue level and STMR for wheat grain.

The Meeting estimated maximum residue level and STMR values for fluxapyroxad in wheat grain of 0.3 and 0.085 mg/kg respectively.

The Meeting recognized that wheat, rye and triticale share an identical GAP and normally show comparable residues. The Meeting agreed to apply the maximum residue level and STMR recommended for fluxapyroxad from wheat to rye and triticale.

Animal feeds

The Meeting received supervised trials data for a variety of animal feeds (pea vines and hay, soya bean forage and hay, sugar beet tops, barley forage, straw, hay, whole plant without roots, ears and rest of plant without roots, corn forage and stover, rice straw, sorghum forage and stover, wheat forage, straw, hay, whole plant without roots, ears and rest of plant without roots, cotton gin by–products and peanut hay).

Moisture content percentages for animal feeds have been determined for selected samples (usually control samples). Where available these values have been used to calculate dry weight residues values from residues observations from the same trials, which were then used in calculation of suitable maximum residue levels of the animal feeds. Where these values were not determined, the

values from the FAO Manual on the Submission and Evaluation of Pesticides Residues Data for the feeds, has been used to convert wet weight residues values to dry weight residues values.

Pea vines

Residue trials were conducted in peas in the USA and Canada according to the GAP in USA (2 applications at 97–101g ai/ha, 7 day PHI and a 7 day PHI for pea vines).

The ranked order of total residues in pea vines (wet weight) from supervised trials collected 6–8 days after the last application were: 0.83**,** 1.62**,** 1.76, 2.85**,** 2.90**,** 3.23 and 3.35 mg/kg.

The ranked order of total residues in pea vines (dry weight) from supervised trials collected 6–8 days after the last application were: 4.69, 6.78, 11, 11.6, 12.9, 14.8, 22.9 mg/kg.

The Meeting did not estimate a maximum residue level for pea vines as it is understood the commodity is not normally traded internationally. The Meeting estimated median and highest residues values for fluxapyroxad in pea vines of 12 and 23 mg/kg respectively.

Pea hay

Residue trials were conducted in peas in the USA and Canada according to the GAP in the USA (2 applications at 97–101g ai/ha, 7 day PHI and a 7 day PHI for pea hay).

The residues of fluxapyroxad in pea hay (fresh weight) from supervised trials collected 6–8 days after the last application, ranked order were: 4.53, 6.01, 7.20, 9.18, 9.49, 10.8 and 12.1 mg/kg.

The residues of fluxapyroxad in pea hay (dry weight) from supervised trials collected 6–8 days after the last application, ranked order were: 5.21, 6.87, 10.8, 11.1, 11.3, 16.0 and 17.4 mg/kg.

The total residues in pea hay (fresh weight) from supervised trials collected 6–8 days after the last application, in ranked order were: 4.61, 6.12, 7.22, 9.38, 9.56, 10.8 and 12.2 mg/kg.

The total residues in pea hay (dry weight) from supervised trials collected 6–8 days after the last application, ranked order were: 5.30, 6.99, 11.0, 11.2, 11.3, 16.2 and 17.4 mg/kg.

The Meeting estimated maximum residue level, median and highest residues values for fluxapyroxad in pea hay of 40, 11 and 17 mg/kg respectively.

Soya bean forage

Residue trials were conducted in soya beans in the USA and Canada according to the GAP in the USA (2 applications at 97–101g ai/ha, 7 day PHI and a 7 day PHI for bean forage).

The ranked order of total residues in soya bean forage (fresh weight) from supervised trials collected 6–8 days after the last application were: 0.87, 0.96, 1.18, 1.20, 1.70, 1.98, 2.24, 2.25, 2.31, 2.43, 2.95, 3.31 and 6.56 mg/kg.

The ranked order of total residues in soya bean forage (dry weight) from supervised trials collected 6–8 days after the last application were: 3.88, 4.90, 5.31, 5.39, 6.42, 7.70, 7.71, 7.86, 8.01, 8.78, 11.0, 12.4 and 25.9 mg/kg.

Meeting did not estimate a maximum residue level for soya bean forage as it is understood the commodity is not traded internationally. The Meeting estimated median and highest residues values for fluxapyroxad in soya bean forage of 7.7 and 26 mg/kg.

Soya bean hay

Residue trials were conducted in soya beans at 14 locations in the USA and Canada (15 trials) according to the critical GAP in USA (2 applications at 97–101g ai/ha, 7 day PHI and a 7 day PHI for bean hay).

The ranked order of residues of fluxapyroxad in soya bean hay (fresh weight) from supervised trials collected 6–8 days after the last application were: 0.54, 1.79, 2.33, 3.60, 3.64, 4.39, 4.60, 4.79, 5.20, 5.87, 6.32, 6.44 and 16.25 mg/kg.

The ranked order of residues of fluxapyroxad in soya bean hay (dry weight) from supervised trials collected 6–8 days after the last application were: 1.36, 3.94, 4.57, 5.21, 5.91, 7.27, 7.38, 7.39, 7.63, 8.58, 9.09, 9.77 and 19.6 mg/kg.

The ranked order of total residues in soya bean hay (fresh weight) from supervised trials collected 6–8 days after the last application were: 0.56, 1.87, 2.38, 3.73, 3.79, 4.49, 4.67, 4.83, 5.30, 5.99, 6.51, 6.60 and 16.45 mg/kg.

The ranked order of total residues in soya bean hay (dry weight) from supervised trials collected 6–8 days after the last application were: 1.41, 4.77, 4.15, 5.32, 5.96, 7.43, 7.58, 7.61, 7.79, 8.80, 9.27, 9.92 and 19.9 mg/kg.

The Meeting estimated maximum residue level, median and highest residues values for fluxapyroxad in soya bean fodder of 30, 7.6 and 20 mg/kg respectively.

Sugar beet tops

Residue trials were conducted in sugar beet in the USA and Canada according to the critical GAP in USA (3 applications at 97–101g ai/ha, 7 day PHI for leaves, roots and tops).

The ranked order of total residues in sugar beet tops (fresh weight) from supervised trials collected 7–8 days after the last application were: 0.76, 0.84, 1.18, 1.84, 2.11, 2.17, 2.59, 3.01, 3.43, 3.84, 3.88 mg/kg.

The ranked order of total residues of fluxapyroxad in sugar beet tops (dry weight) from supervised trials collected 7–8 days after the last application were: 3.30, 3.65, 5.13, 8.00, 9.17, 9.43, 11.3, 13.1, 14.9, 16.7 and 16.9 mg/kg.

Meeting did not estimate a maximum residue level for the commodity as it is not traded internationally. The Meeting estimated median and highest residues values for fluxapyroxad in sugar beet tops of 9.4 and 17 mg/kg respectively.

Maize forage and stover

Residue trials were conducted in maize (corn) in the USA and Canada according to the critical GAP in USA (2 applications at 97–100g ai/ha, harvest 21 day PHI, forage 7 days).

The ranked order of total residues of fluxapyroxad in maize forage (fresh weight) from supervised trials collected 6–8 days after the last application were: 0.23, 0.36, 0.42, 0.48, 0.68, 0.69, 0.73, 0.81, 0.88, 0.88, 0.95, 1.07 and 1.38 mg/kg.

The ranked order of total residues of fluxapyroxad in maize forage (dry weight) from supervised trials collected 6–8 days after the last application were: 0.84, 1.42, 1.62, 1.80, 2.10, 2.74, 2.82, 3.02, 3.08, 3.23, 3.45, 3.59 and 3.62 mg/kg.

Meeting did not estimate a maximum residue level for the commodity as it is not traded internationally. The Meeting estimated median and highest residues values for fluxapyroxad in maize forage of 2.8 and 3.6 mg/kg respectively.

The residues of fluxapyroxad in maize stover (fresh weight) from supervised trials collected 20–22 days after the last application, in ranked order, were: 0.23, 0.39, 0.59, 0.60, 0.93, 0.96, 1.43, 1.45, 2.12, 2.13, 2.21, 2.22 and 3.57 mg/kg.

The residues of fluxapyroxad in maize stover (dry weight) from supervised trials collected 20–22 days after the last application, in ranked order, were: 0.80, 0.96, 1.12, 1.70, 2.30, 2.65, 3.57, 4.37, 4.45, 4.64, 5.04, 5.89 and 6.44 mg/kg.

The ranked order of total residues of fluxapyroxad in maize stover (wet weight) from supervised trials collected 20–22 days after the last application were: 0.25, 0.39, 0.62, 0.63, 0.98, 1.01, 1.45, 1.48, 2.17, 2.19, 2.25, 2.25 and 3.64 mg/kg.

The ranked order of total residues of fluxapyroxad in maize stover (dry weight) from supervised trials collected 20–22 days after the last application were: 0.87, 0.96, 1.18, 1.81, 2.42, 2.74, 3.62, 4.50, 4.54, 4.71, 5.15, 6.00 and 6.57 mg/kg.

The Meeting estimated maximum residue level, median and highest residues values for fluxapyroxad in maize fodder of 15, 3.6 and 6.6 mg/kg respectively.

Rice Straw

Residue trials were provided for rice but none of the submitted labels have a use pattern.

Sorghum Forage and Hay

Residue trials were conducted in sorghum at 9 locations in the USA in which two applications were made at 97–104 g ai/ha (6–7 day retreatment interval). Forage data was collected at a 7 day PHI and stover data at a 20 to 23 day PHI.

It is not possible to estimate a maximum residue level for sorghum as the submitted data did not correspond to any label GAP.

Barley and wheat forage, hay and straw

Barley animal feed data (whole plant no roots, straw, ears, rest of plants without roots) were collected in the trials carried out in various European countries (Germany, the Netherlands, France, the UK, Greece, Spain and Italy) in the 2008 and 2009 growing seasons (2 applications at either 77–90 g ai/ha or 121–135 g ai/ha) which approximates the UK GAP (2 applications at 125g ai/ha – used up to and including flowering GS 69 with no restrictions on animal feeding).

The ranked order of total residues in barley rest of plant no roots (forage) samples collected 27–48 days after the second application (fresh weight) at the GAP application rate were: 0.11, 0.13, 0.17, 0.22, 0.24, 0.25, 0.27, 0.50, 0.70, 0.78, 0.97 and 1.33 mg/kg.

The ranked order of total residues in barley rest of plant no roots (forage) dry weight samples after applications at the higher (GAP) rate were: 0.37, 0.43, 0.57, 0.73, 0.80, 0.83, 0.90, 1.67, 2.33, 2.6, 3.23 and 4.43 mg/kg.

Residue trials were conducted in barley at two locations in Australia in which 2 applications were made at 61–62g ai/ha or 122–123g ai/ha. There is a 14 day restriction on grazing or using for stock feed. Forage data was nominally collected at 0, 7 and 14 days after the first application and immediately before the second application. In one trial forage was collected at 14 days after the first application and at -0, 0, 8 and 15 days after the second application.

The ranked order of total residues in barley forage (dry weight) from supervised trials collected at 14/15 days only in each trial was 2.46 (after 1st application) and 3.39 (after 1st application) mg/kg for the trials at the lower rate.

The residues of fluxapyroxad in barley straw (dry weight) from supervised trials collected at harvest were 1.07 and 2.57 mg/kg for the trials at the lower rate.

The total residues in barley straw (dry weight) from supervised trials collected at harvest were 1.13 and 2.67 mg/kg for the trials at the lower rate.

Residue trials were conducted in barley in the USA and Canada matching the critical GAP in the USA (2 applications at 97–100g ai/ha, harvest 21 day PHI, barley hay or green chopped wheat 7 days). Barley hay and straw samples were obtained at six of the trial sites.

Barley hay was obtained for samples collected at a 20–26 day PHI except for one trial (RCN R080746) at which sampling occurred at 20, 21, 25, 27 and 31 day PHIs. As the GAP for hay is a 7

day PHI, these data could be utilized to estimate an appropriate maximum residue level for fluxapyroxad in barley hay.

Barley straw was obtained for samples collected at a 20–26 day PHI except for one trial (RCN R080746) at which sampling occurred at 20, 21, 25, 27 and 31 day PHIs.

The residues of fluxapyroxad in barley straw (fresh weight) from supervised trials collected 20–22 days after the last application, in ranked order were: 0.72, 3.17, 3.45, 3.89, 5.43 and 9.52 mg/kg.

The residues of fluxapyroxad in barley straw (dry weight) from supervised trials collected 20–22 days after the last application, in ranked order were: 1.61, 5.78, 6.73, 7.79, 9.92 and 14.1 mg/kg.

The total residues in barley straw (fresh weight) from supervised trials collected 20–22 days after the last application, in ranked order were: 0.84, 3.48, 3.60, 3.96, 5.49 and 9.82 mg/kg.

The total residues in barley straw (dry weight) from supervised trials collected 20–22 days after the last application, ranked order were: 1.88, 5.88, 7.02, 8.55, 10.0 and 14.6 mg/kg.

Wheat animal feed data (whole plant no roots, straw, ears, rest of plants without roots) were collected in the trials carried out in Europe (Germany, he UK, France, Spain and Italy) in the 2008 and 2009 growing seasons (2 applications at 116–135g ai/ha) which approximated the UK GAP (2 applications at 125 g ai/ha and use up to GS 67). The labels for European GAP have no restrictions on animal feeding.

The ranked order of total residues in wheat rest of plant no roots (forage) samples collected 34–49 days after the second application (wet weight) at the GAP application rate were: 0.22, 0.25, 0.33, 0.39, 0.53, 0.61, 0.64, 0.77, 1.23, 2.56 and 5.05 mg/kg.

The total residues in wheat rest of plant no roots (forage) dry weight samples after applications at the higher (GAP) rate, in ranked order were: 0.88, 1.00, 1.32, 1.56, 2.12, 2.44, 2.56, 3.08, 4.92, 10.2 and 20.2 mg/kg.

The ranked order of residues of fluxapyroxad in wheat straw samples collected 34–60 days PHI (wet weight – highest value taken in each trial when readings at various PHIs) were: 0.32, 0.44, 0.46, 0.49, 0.55, 0.55, 0.64, 1.00, 1.00, 1.02, 1.19, 1.55, 1.80, 2.58, 2.78 and 6.05 mg/kg.

The ranked order of residues of fluxapyroxad in wheat straw samples collected 34–60 days PHI (dry weight – highest value taken in each trial when readings at various PHI) were: 0.36, 0.50, 0.52, 0.56, 0.63, 0.63, 0.73, 1.14, 1.14, 1.16, 1.35, 1.76, 2.05, 2.93, 3.16 and 6.88 mg/kg.

The ranked order of total residues in wheat straw samples collected 34–60 days PHI (fresh weight – highest value taken in each trial when readings at various PHIs) were: 0.35, 0.51, 0.53, 0.56, 0.58, 0.61, 0.68, 1.08, 1.08, 1.12, 1.31, 1.62, 1.96, 2.85, 2.92 and 6.24 mg/kg.

The ranked order of total residues of wheat straw samples collected 34–49 days PHI (dry weight – highest value taken in each trial when readings at various PHIs) were: 0.39, 0.58, 0.59, 0.64, 0.66, 0.69, 0.77, 1.23, 1.23, 1.27, 1.49, 1.8, 2.23, 3.24, 3.32 and 7.09 mg/kg.

Residue trials were conducted in wheat at four locations in Australia in which 2 applications were made at 61–62g ai/ha or 122–124g ai/ha. There is no corresponding GAP.

Residue trials were conducted in wheat at 22 locations in the USA and Canada (25 trials) generally according to the GAP in USA (2 applications at 97–100g ai/ha, harvest 21 day PHI, wheat hay or green chopped wheat 7–days). Observations from trials, in which, sampling took place at 25 and 27 days PHI, were not considered for the purposes of estimating a maximum residue level for straw.

The ranked order of total residues of fluxapyroxad in wheat forage (fresh weight) from supervised trials collected 6–8 days after the last application were: 0.10, 0.19, 0.21, 0.25, 0.32, 0.36, 0.57, 0.60, 0.64, 0.81, 0.85, 0.89, 0.95, 0.99, 1.19, 1.23, 1.40, 3.45, 3.60, 3.71, 4.80 and 9.27 mg/kg.

The ranked order of total residues of fluxapyroxad in wheat forage (dry weight) from supervised trials collected 6–8 days after the last application were: 0.64, 0.99, 1.09, 1.25, 1.84, 2.37, 3.33, 3.37, 3.39, 3.64, 3.73, 3.90, 4.52, 4.76, 5.34, 5.65, 6.26, 9.28, 12.1, 17.9, 19.4 and 40.66 mg/kg.

There is no necessity to estimate a maximum residue level for forage as it is not traded. Although the UK GAP is the critical GAP (application rates higher and no restrictions on animal feeding), on the basis that the residues are substantially higher in the USA trials, the highest and median residues will be taken from the USA trials. The Meeting estimated median and highest residues values for fluxapyroxad in wheat forage of 3.8 and 41 mg/kg.

The ranked order of fluxapyroxad in wheat straw (fresh weight) from supervised trials collected 20–22 days after the last application were: 0.75, 0.78, 0.80, 0.85, 0.97, 0.99, 1.07, 1.08, 1.24, 1.92, 2.29, 2.56, 3.08, 3.40, 4.61, 5.14, 6.39, 6.53, 7.16 and 7.29 mg/kg.

The ranked order of fluxapyroxad in wheat straw (dry weight) from supervised trials collected 20–22 days after the last application were: 1.24, 1.40, 1.46, 1.57, 1.61, 1.66, 1.72, 1.90, 2.07, 3.40, 4.01, 4.12, 4.28, 4.36, 5.26, 5.60, 7.33, 8.35, 8.47 and 10.1 mg/kg.

The ranked order of total residues of fluxapyroxad in wheat straw (wet weight) from supervised trials collected 20–22 days after the last application were: 0.91, 0.97, 1.00, 1.05, 1.09, 1.21, 1.25, 1.29, 1.65, 2.09, 2.79, 2.87, 3.59, 4.13, 4.79, 5.40, 6.41, 7.03, 7.61 and 8.00 mg/kg.

The ranked order of total residues of fluxapyroxad in wheat straw (dry weight) from supervised trials collected 20–22 days after the last application were: 1.25, 1.80, 1.83, 1.86, 1.89, 1.90, 2.31, 2.40, 2.75, 3.70, 4.37, 4.52, 5.16, 5.47, 5.85, 5.89, 7.35, 8.88, 9.29 and 10.8 mg/kg.

The ranked order of residues of fluxapyroxad in wheat hay (wet weight) from supervised trials collected 6–8 days after the last application were: 0.33, 0.37, 0.51, 0.51, 1.38, 1.42, 2.09, 2.12, 2.24, 2.58, 2.64, 2.72, 2.74, 2.86, 2.87, 3.29, 4.80, 5.75, 6.68, 5.97, 7.46 and 9.60 mg/kg.

The ranked order of residues of fluxapyroxad in wheat hay (dry weight) from supervised trials collected 6–8 days after the last application were: 0.65, 0.69, 0.76, 0.90, 2.58, 2.66, 3.00, 3.03, 3.33, 3.53, 3.73, 4.18, 4.61, 4.79, 7.21, 8.48, 8.59, 9.42, 9.83, 13.8, 15.7 and 17.6 mg/kg.

The ranked order of total residues of fluxapyroxad in wheat hay (wet weight) from supervised trials collected 6–8 days after the last application were: 0.35, 0.42, 0.54, 0.56, 1.42, 1.53, 2.19, 2.34, 2.35, 2.74, 2.74, 2.88, 2.97, 2.98, 3.13, 3.41, 4.99, 5.91, 6.17, 7.01, 7.56 and 9.93 mg/kg.

The ranked order of total residues of fluxapyroxad in wheat hay (dry weight) from supervised trials collected 6–8 days after the last application were: 0.68, 0.78, 0.81, 0.99, 2.78, 2.95, 3.12, 3.14, 3.48, 3.75, 3.86, 4.34, 4.84, 4.98, 7.49, 8.59, 9.01, 9.73, 10.1, 15.1, 17.2 and 18.3 mg/kg.

The Meeting used the wheat hay data to estimate maximum residue level, median and highest residues values for fluxapyroxad in wheat straw and fodder (dry) of 30, 4.1 and 18 mg/kg.

In practical conditions it is difficult to distinguish between forage and fodder of various cereal grains. The Meeting decided to use the wheat forage data to establish dietary parameters for barley. The Meeting estimated median and highest residues values for fluxapyroxad in wheat forage of 3.8 and 41 mg/kg and will extrapolate these values to barley forage. Similarly the wheat straw and fodder (dry) maximum residue level, STMR and HR will be extrapolated to barley.

The wheat and barley straw and fodder (dry) maximum residue level, median and highest residues and wheat and barley forage median and highest residues are also recommended for oats, rye and triticale as residues in these crops are not expected to significantly differ.

Cotton gin by–products (gin trash)

Residue trials were conducted in cotton at seven locations in the USA according to the critical GAP in USA (seed treatment application at 20 g ai/100 kg seed). No residues were detected in any sample. In addition two trials were carried out at 5× the GAP application rate in which no residues were detectable.

The Meeting estimated a maximum residue level for fluxapyroxad on cotton gin by-products of 0.01* mg/kg. The median residues are 0 mg/kg.

Peanut Hay

Residue trials were conducted at 12 different sites in the USA, matching the US GAP (3 applications at 97g ai/ha – maximum of 2 consecutive with a 7 day PHI). However the following restraint applies, "DO NOT graze or harvest for forage use".

Although residues data for peanut hay were submitted (sampling at 7, 14 and 21 days in 10 trials and sampling at either 3, 10 and 17 days or 0, 4, 7, 14 and 21 days in the other two trials, these data were not used to estimate a maximum residue level, as there is no GAP on which to base a recommendation.

Rotational Crops

Residues of fluxapyroxad are persistent in soil and may be taken up by following crops. In the USA the total seasonal application rate for crops apart from pome fruit, stone fruit and fruiting vegetables other than cucurbits is 200 g ai/ha. In Europe the total seasonal rate for cereals is 250 g ai/ha. In Australia the total seasonal rate for barley is 125 g ai/ha and in Brazil the total seasonal rate for cereals is up to 240 g ai/ha.

Field rotational crop studies conducted in the USA (one study) and Europe (four studies) have been made available to this Meeting.

Plots received either 2 applications to bare soil at 99–101 g ai/ha (198 g ai/season) or 1 application at 250 g ai/ha. Carrot/radish, potato and sugar beet, cauliflower/broccoli and lettuce, corn and wheat and canola and sunflower, were planted at various plant back intervals from 29–30 to 365 DALA). Another study was conducted in Germany and the UK where applications was made twice to barley (Germany) or wheat (UK) at a single rate equivalent to 125 g ai/ha. After harvest of the cereals, the rotational crops lettuce, radish and carrots were cultivated as secondary crops.

In general, residues of fluxapyroxad were observed more frequently than M700F008, while residues of M700F048 were rarely observed.

If the highest field rate is considered (250 g ai/ha) and a DT_{50} of 370 days (the highest in the field), then a plateau of residues in the soil will be reached after approximately 5 years. If it is considered that 50% of this residue is captured by plants, then the rotational crop studies can be considered to be reflective of practical conditions.

The Meeting considered that residues of fluxapyroxad may occur in succeeding crops but at insignificant levels in most crops, apart for cereal straw. Therefore, the Meeting considered it unnecessary to change or estimate new maximum residue levels to account for any uptake of residues of fluxapyroxad *via* the roots. For cereal straw, for which there is the possibility of an additional uptake of up to 0.6 mg/kg, it is considered that this is not significant in comparison with the residues in cereal straw from direct foliar treatment.

Fate of residues during processing

The Meeting received processing studies for apples, plums, tomatoes, soya bean, potatoes, sugar beet, barley, wheat, corn, sorghum, rice, peanuts, rape seed, sunflower seed and cotton seed. The table summarizes STMR-P and HR-P values calculated on the determined processing factors. In addition the following maximum residue levels were proposed.

Plums, based on the processing factor of 2.81 for dried prunes and the plum HR of 0.95 mg/kg, the Meeting estimated a maximum residue level for fluxapyroxad in prunes of 5 mg/kg.

Soya beans, based on the processing factor of 1.15 for soya bean hulls and the soya bean (dry) maximum residue level estimate of 0.15, the Meeting recommended a maximum residue level for fluxapyroxad in soya bean hulls of 0.3 mg/kg.

Wheat, based on the processing factor of 2.90 for wheat bran and the wheat grain maximum residue level estimate of 0.3 mg/kg the Meeting recommended a maximum residue level for fluxapyroxad in wheat bran of 1 mg/kg.

Barley, based on the processing factor of 1.89 for barley bran and the barley grain maximum residue level estimate of 2 mg/kg, the calculated expected highest residues in barley bran are 3.78 mg/kg. The Meeting recommended a maximum residue level for fluxapyroxad in barley bran of 4 mg/kg.

The processing factors derived from the processing studies and the resulting recommendations for STMR-Ps, HR-Ps, and/or 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 Fluxapyroxad

RAC	Processed Commodity	Processing Factor	RAC Maximum residue level	Processed Commodity Maximum residue level	RAC STMR	Processed Commodity STMR–P	RAC HR	Processed Commodity HR–P
Apple	Juice	0.21	0.9	–	0.26	0.05	0.37	0.08
	Pomace, wet	4.60		–		1.20		1.70
	Apple sauce	0.24		–		0.06		0.09
	Canned apples	0.22		–		0.06		0.08
	Dried apples	0.54		–		0.14		0.20
Plum	Washed plums	0.77	2	–	0.44	0.34	0.95	0.73
	Puree	0.83		–		0.37		0.79
	Jam	0.41		–		0.18		0.39
	Dried Prunes	2.81		5		1.23		2.66
Tomatoes	Canned tomatoes	0.19	0.6	–	0.07	0.013	0.44	0.08
	Paste	0.73		–		0.051		0.32
	Puree	0.37		–		0.026		0.16
	Raw juice	0.18		–		0.013		0.08
	Tomato peel	2.37		–		0.17		1.04
	Pomace, wet	3.40		–		0.24		1.50
Soya bean seed	Flour	0.50	0.15	0.3	0.01	0.005	0.11	0.055
	Hulls	1.15		–		0.012		0.13
	Meal	0.50		–		0.005		0.055
	Miso	0.50		–		0.005		0.055
	Refined oil	0.55		–		0.055		0.061
	Soy milk	0.50		–		0.005		0.055
	Soy sauce	0.50		–		0.005		0.055
	Tofu	0.50		–		0.005		0.055
	Aspirated grain fractions	158				1.58		17.38
Potato	Granules/flakes	0.5	0.03	–	0.01	0.005	0.02	0.01
	Chips	0.5		–		0.005		0.01
	Peel, wet	5.0		–		0.05		0.1
	Peeled potatoes	0.5		–		0.005		0.01
	Boiled potatoes (unpeeled)	0.5		–		0.005		0.01
	Microwave, boiled potatoes (unpeeled)	0.5		–		0.005		0.01
	Baked potato (unpeeled)	0.5		–		0.005		0.01
	Fried potato (unpeeled)	0.5		–		0.005		0.01

RAC	Processed Commodity	Processing Factor	RAC Maximum residue level	Processed Commodity Maximum residue level	RAC STMR	Processed Commodity STMR–P	RAC HR	Processed Commodity HR–P
	Process waste	0.5		–		0.005		0.01
	Dried pulp	7.0		–		0.07		0.14
Sugar beet	Refined sugar	0.17	0.15	–	0.04	0.007	0.06	0.010
	Dried pulp	1.75		–		0.07		0.11
	Molasses	0.80		–		0.032		0.048
	Thick juice	0.75		–		0.03		0.045
	Ensiled pulp	0.37		–		0.015		0.022
Wheat	Bran	2.90	0.3	1	0.085	0.25	0.21	0.61
	Flour	0.16		–		0.014		0.032
	Middlings	0.36		–		0.031		0.076
	Shorts	0.50		–		0.043		0.11
	Germ	1.22		–		0.10		0.26
	Bread (white)	0.12		–		0.010		0.03
	Whole meal	0.96		–		0.082		0.20
	Bread whole meal	0.64		–		0.054		0.13
	Aspirated grain fractions	220		–		18.7		46.2
Barley	Pot barley	0.16	2	–	0.535	0.086	1.26	0.20
	Bran	1.89		4		1.01		2.38
	Flour	0.15		–		0.080		0.19
	Brewing malt	0.01		–		0.0054		0.013
	Spent grain	0.25		–		0.13		0.32
	Beer	0.02		–		0.011		0.025
Maize	Meal	0.7	0.01	–	0.01	0.007	0.01	0.007
	Flour	0.9		–		0.009		0.009
	Grits	0.3		–		0.003		0.003
	Starch	0.1		–		0.001		0.001
Canola seed	Meal	0.42	1.5	–	0.11	0.046	0.83	0.35
	Refined oil	0.23		–		0.025		0.19
Sunflower seed	Meal	0.12	1.5	–	0.055	0.006	0.11	0.013
	Refined oil	0.08		–		0.004		0.008

Processed commodity STMR–Ps and HR–Ps were calculated on the basis of the total residues (fluxapyroxad + M700F008 + M700F048) process factor.

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: apple pomace, tomato pomace, oat grain, sugar beet tops, sugar beet dried pulp, sugar beet ensiled pulp, sugar beet molasses, barley grain, forage, hay and straw, brewer's grain, wheat grain, forage, hay and straw, wheat milled by-products, wheat aspirated grain fractions, maize grain fodder and forage, maize meal, maize milled by-products, potato culls and dried pulp (potato process waste), sunflower meal, barley bran, sugar beet tops, cotton seed, cotton seed meal and hulls, cotton gin by-products, soya bean forage and fodder (hay), soya beans, soya bean meal and hulls, soya bean aspirated grain fractions, bean and pea seed, bean vines and pea vines and hay/ fodder and canola meal.

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

	US–Canada		EU		Australia		Japan	
	max	mean	max	mean	max	mean	max	mean
Beef cattle	4.61	2.25	19.3	5.51	40.7a	11.4c	0.60	0.60
Dairy cattle	18.4	4.17	18.8	5.78	39.2b	9.37d	3.93	1.77

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

[b] Highest maximum dairy cattle dietary burden suitable for HR and maximum residue level estimates for mammalian milk

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

[s] Highest mean dairy cattle dietary burden suitable for STMR estimates for mammalian milk

Potential poultry feed items include: apple pomace, tomato pomace, oat grain, sugar beet tops, sugar beet dried pulp, sugar beet ensiled pulp, sugar beet molasses, barley grain, forage, hay and straw, brewer's grain, wheat grain, forage, hay and straw, wheat milled by-products, maize grain fodder and forage, maize meal, maize milled by-products, potato culls and dried pulp (potato process waste), sunflower meal, barley bran, sugar beet tops, cotton seed, cotton seed meal and hulls, cotton gin by-products, soya bean forage and fodder (hay), soya beans, soya bean meal and hulls, soya bean aspirated grain fractions, bean and pea seed, bean vines and pea vines and hay/ fodder and canola meal.

Summary of poultry dietary burden for fluxapyroxad (ppm of dry matter diet)

	US–Canada		EU		Australia		Japan	
	max	mean	max	mean	max	mean	max	mean
Poultry Broiler	0.53	0.53	0.50	0.50	0.18	0.18	0.079	0.079
Poultry Layer	0.53	0.53	7.14[a]	2.10[b]	0.18	0.18	0.14	0.14

[a] Highest maximum poultry dietary burden suitable for HR and maximum residue level estimates for poultry meat and eggs

[b] Highest mean 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 fluxapyroxad, M700F002 and M700F048 arising in tissues and milk when dairy cows were dosed with fluxapyroxad and metabolite M700F002 for 28 days, at target feeding levels equivalent to 3, 6, 18 and 60 ppm (fluxapyroxad) and 0, 0.1, 0.3 and 1 ppm (M700F002) in the diet. A depuration period of 7 days followed.

Residues of fluxapyroxad and M700F008 were observed in milk at all feeding levels although in the lowest dose group most milk samples showed fluxapyroxad residues below LOQ. Residues of fluxapyroxad and M700F008 in the higher dose groups reached a plateau after five to seven days. Analysis of milk samples from depuration animals showed no fluxapyroxad or M700F008 residues above LOQ were detectable after four days of withdrawal. Generally residue levels of M700F008 in milk were similar to the fluxapyroxad residue levels. The highest total residues (fluxapyroxad + M700F008) in milk at the highest dosing regime were 0.054 mg/kg (mean 0.031 mg/kg). Residues were demonstrated to concentrate into cream. The highest total residues (mean in brackets) in liver, kidney, fat and muscle were 0.45 (0.35), 0.098 (0.067), 0.264 (0.260) and 0.045 (0.036) mg/kg respectively. Analysis of the depuration tissue samples showed no residues of fluxapyroxad or M700F008 above LOQ after two days of withdrawal.

No residues of M700F002 above LOQ (0.001 mg/kg) were detected in any milk or tissue samples from any dose group.

The Meeting also received information on the residue levels arising in tissues and eggs when laying hens were dosed with fluxapyroxad and metabolite M700F002 for 28 days, at target feeding levels equivalent to 0.3, 0.6, 1.8 and 6 ppm (fluxapyroxad) and 0.025, 0.05, 0.15 and 0.5 ppm (M700F002) in the diet. A depuration period of 14 days followed.

Residues of fluxapyroxad were observed in egg at all feeding levels although in the lowest dose group all but one mean egg samples showed fluxapyroxad residues below LOQ and all egg samples showed M700F008 residues below LOQ. In the highest dose group fluxapyroxad and M700F008 residues reached a plateau at five days. No residues of either fluxapyroxad or M700F008 were detected at the highest feeding level in muscle and skin with fat. The highest total residues (mean in brackets) in liver and fat were 0.029 (0.025) and 0.042 (0.040) mg/kg respectively.

No residues of M700F002 above LOQ (0.001 mg/kg) were detected in any egg or tissue samples from any dose group.

Analysis of the depuration egg samples showed that residues of fluxapyroxad and M700F008 were < LOQ after four and eight days of withdrawal respectively and not detectable after eight and ten days of withdrawal respectively. Analysis of the depuration tissue samples showed that residues of fluxapyroxad and M700F008 were < LOQ after three days of withdrawal.

Animal commodity maximum residue levels

Cattle STMR and HR

For highest residue level estimation, the high residues in the cattle tissues were calculated by interpolating the maximum dietary burden for beef cattle (40.7 ppm) between the relevant feeding levels (18.2 and 60.3) in the dairy cow feeding study and using the highest tissue concentrations (fluxapyroxad + M700F008) 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 (39.2 ppm) between the relevant feeding levels (18.2 and 60.3) in the dairy cow feeding study and using the highest mean milk concentrations (fluxapyroxad + M700F008) from those feeding groups.

The STMR values for the tissues were calculated by interpolating the mean dietary burden for beef cattle (11.4 ppm) between the relevant feeding levels (6.1 and 18.2 ppm) from the dairy cow feeding study and using the mean tissue concentrations (fluxapyroxad + M700F008) from those feeding groups. The STMR values for the milk were calculated by interpolating the mean dietary burden for dairy cattle (9.37 ppm) between the relevant feeding levels (6.1 and 18.2 ppm) from the dairy cow feeding study and using the mean milk concentrations (fluxapyroxad + M700F008) from those feeding groups.

Fluxapyroxad 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	18.2 60.3	0.0099 0.031	18.2 60.3	< 0.02 0.045	0.15 0.45	0.032 0.098	0.077 0.264
Dietary burden and estimate of highest residue	39.2	0.020	40.7	0.033	0.31	0.067	0.176
STMR Determination (beef or dairy cattle)							
Feeding Study	6.1 18.2	0.0032 0.0078	6.1 18.2	< 0.02 < 0.02	0.052 0.12	0.021 0.027	0.029 0.070
Dietary burden and estimate of highest residue	9.37	0.004	11.4	< 0.02	0.081	0.024	0.047

The Meeting estimated the following STMR values: milk 0.004 mg/kg; muscle < 0.02 mg/kg; edible offal (based on liver) 0.081 mg/kg and fat 0.047 mg/kg.

The Meeting estimated the following HR values: milk 0.020 mg/kg; muscle 0.033 mg/kg; edible offal (based on liver) 0.31 mg/kg and fat 0.18 mg/kg.

At various dosing levels (day 21) the mean residues observed in cream were up to 9× the mean residues in milk. It is therefore calculated that maximum residues in cream will be 0.18 mg/kg and STMR is 0.036.

It is assumed that cream is 40% fat, therefore the estimated highest residue and STMR for milk fats for dietary purposes are 0.45 and 0.09 mg/kg.

Cattle – maximum residue level

For maximum residue level estimation, the high residues in the cattle tissues were calculated by interpolating the maximum dietary burden (40.7 ppm) between the relevant feeding levels (18.2 and 60.3) in the dairy cow feeding study and using the highest tissue concentrations (fluxapyroxad) from individual animals within those feeding groups. For maximum residue level estimation, the high residues in the milk were calculated by interpolating the maximum dietary burden (39.2 ppm) between the relevant feeding levels (18.2 and 60.3) in the dairy cow feeding study and using the highest mean milk concentrations (fluxapyroxad) from those feeding groups.

Fluxapyroxad 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
Maximum residue level determination (beef or dairy cattle)							
Feeding Study	18.2 60.3	0.0052 0.015	18.2 60.3	< 0.01 0.012	0.032 0.094	< 0.01 0.019	0.059 0.171
Dietary burden and estimate of highest residue	39.2	0.010	40.7	0.011	0.065	0.015	0.119

The Meeting estimated the following highest residues for the purposes of maximum residue level estimation: milk 0.010 mg/kg; muscle 0.011 mg/kg; edible offal (based on liver) 0.065 mg/kg and fat 0.12 mg/kg.

At various dosing levels (day 21) the mean residues observed in cream were up to 10.5× the mean residues in milk. It is therefore calculated that maximum residues in cream will be 0.11 mg/kg.

It is assumed that cream is 40% fat, therefore the estimated highest residue for milk fats is 0.26 mg/kg.

The Meeting estimated the following maximum residue level values: milk 0.02 mg/kg; milk fats 0.5 mg/kg; meat (mammalian except marine) (fat) 0.2 mg/kg and edible offal (mammalian) 0.1 mg/kg.

Poultry STMR and HR

For highest residue level estimation, the high residues in the hen tissues and eggs were calculated by extrapolating the maximum dietary burden (7.1 ppm) with the highest feeding level (6.0 ppm) in the laying hen feeding study and using the highest tissue concentrations (fluxapyroxad + M700F008) from individual animals within that feeding group and using the highest mean egg concentration (fluxapyroxad + M700F008) from that feeding group.

The STMR values for the tissues and eggs were calculated by interpolating the mean dietary burden (2.1 ppm) between the relevant feeding levels (1.8 and 6.0 ppm) from the poultry feeding study and using the mean tissue and egg concentrations (fluxapyroxad + M700F008) from those feeding groups.

Fluxapyroxad Feeding Study	Feed Level (ppm) for egg residues	Residues (mg/kg) in egg	Feed Level (ppm) for tissue residues	Residues (mg/kg)			
				Muscle	Liver	Skin with Fat	Fat
HR Determination (poultry broiler or layer)							
Feeding Study	6.0	0.020	6.0	< 0.02	0.029	< 0.02	0.042
Dietary burden and estimate of highest residue	7.1	0.023	7.1	< 0.024	0.034	< 0.024	0.050
STMR Determination (poultry broiler or layer)							
Feeding Study	1.8 6.0	0.0053 0.014	1.8 6.0	< 0.02 < 0.02	0.021 0.025	< 0.02 < 0.02	< 0.02 0.040
Dietary burden and estimate of highest residue	2.1	0.006	2.1	< 0.02	0.021	< 0.02	0.021

The Meeting estimated the following STMR values: egg 0.006 mg/kg; muscle 0.02 mg/kg; edible offal (based on liver) 0.021 mg/kg and fat 0.021 mg/kg.

The Meeting estimated the following HR values: egg 0.023 mg/kg; muscle 0.024 mg/kg; edible offal (based on liver) 0.034 mg/kg and fat 0.050 mg/kg.

Poultry maximum residue level

For maximum residue level estimation, the high residues in the hen tissues and eggs were calculated by extrapolating the maximum dietary burden (7.1 ppm) with the highest feeding level (6.0 ppm) in the laying hen feeding study and using the highest tissue concentrations (fluxapyroxad) from individual animals within that feeding group and using the highest mean egg concentration (fluxapyroxad) from that feeding group.

Fluxapyroxad Feeding Study	Feed Level (ppm) for egg residues	Residues (mg/kg) in egg	Feed Level (ppm) for tissue residues	Residues (mg/kg)			
				Muscle	Liver	Skin with Fat	Fat
Maximum residue level determination (poultry broiler or layer)							
Feeding Study	6.0	0.0065	6.0	< 0.01	< 0.01	< 0.01	0.028
Dietary burden and estimate of highest residue	7.1	0.0077	7.1	< 0.012	< 0.012	< 0.012	0.033

The Meeting estimated the following highest residue values for the purpose of maximum residue level estimation: egg 0.0077 mg/kg; muscle 0.012 mg/kg; liver 0.012 mg/kg, skin with fat 0.012 mg/kg and fat 0.033 mg/kg.

The Meeting estimated the following maximum residue levels: poultry meat 0.02 mg/kg; poultry fats 0.05 mg/kg, poultry edible offal 0.02 mg/kg and eggs 0.02 mg/kg.

DIETARY RISK ASSESSMENT

Long-term intake

The evaluation of fluxapyroxad has resulted in recommendations for maximum residue levels 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 1–10% of the maximum ADI of 0.02 mg/kg bw (Annex 3).

The Meeting concluded that the long-term intake of residues of fluxapyroxad 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 fluxapyroxad was calculated for the food commodities (and their processing fractions) for which maximum residue levels and HRs were estimated and for which consumption data were available. The results are shown in Annex 4. The IESTI of fluxapyroxad varied from 0–20% of the ARfD (0.3 mg/kg bw).

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

5.21 GLUFOSINATE-AMMONIUM (175)

TOXICOLOGY

Glufosinate-ammonium is the ISO-approved name for ammonium-DL-homoalanin-4-yl(methyl)phosphinate (IUPAC), with CAS number 77182-82-2. Glufosinate-ammonium is used as a non-selective herbicide for total vegetation control and as a desiccant to aid in crop harvesting. Glufosinate-ammonium, a racemic mixture of the D- and L-isomers, is a phosphinic acid analogue of glutamic acid. Its herbicidal action is related to the inhibition of glutamine synthetase, an enzyme that plays an important role in ammonia detoxification, amino acid metabolism, and protein and nucleotide biosynthesis in plants.

Glufosinate-ammonium was previously evaluated by JMPR in 1991 and 1999. In 1999, the Meeting established a group ADI of 0–0.02 mg/kg bw for glufosinate-ammonium, 3-[hydroxy(methyl) phosphinoyl]propionic acid (MPP) and *N*-acetylglufosinate (NAG) (alone or in combination) on the basis of a NOAEL of 2 mg/kg bw per day in a long-term study in rats given technical-grade glufosinate-ammonium.

Glufosinate-ammonium was re-evaluated by the present Meeting as part of the periodic review programme at the request of CCPR. The present Meeting evaluated studies on glufosinate as well as studies on 3-methylphosphinico-propionic acid (= MPP), NAG and 2-methylphosphinico-acetic acid (MPA), three metabolites that are found in plants, soil and livestock. Both the new data and previously submitted studies were considered by the present Meeting.

All critical studies complied with GLP.

Glufosinate-ammonium

Biochemical aspects

After administration of single (2–500 mg/kg bw) or repeated oral doses (2 mg/kg bw), [^{14}C]glufosinate-ammonium was rapidly but incompletely absorbed (approximately 10%). Peak plasma concentrations were reached within 0.5–1 hour. The radiolabel was widely distributed, with highest concentrations in liver and kidneys. Radiolabel concentrations were low in the brain and fetus. The plasma half-life of the initial elimination phase was 4–5 hours. Excretion after single or repeated doses was rapid, with more than 90% excreted within 24 hours after administration of a low dose. Administration of higher doses resulted in slower absorption and excretion. In faeces, mainly glufosinate-ammonium and low concentrations (up to 10% of faecal radioactivity) of NAG were found, indicative of acetylation by microflora in the gut, as this metabolite is not found in urine. In urine, parent compound represented about 50% of the radioactivity, whereas 4-methylphosphinico-butanoic acid (MPB) and MPP each represented 8–22% of the urinary radioactivity. Very low levels of MPA were found in urine. MPP represented 10–20% of residue found in liver. There were no marked sex differences in the kinetics and metabolism of glufosinate-ammonium.

Toxicological data

In 1999, the Meeting considered reports on the relevance of glutamine synthetase activity in the liver, kidney and brain of experimental animals and humans and concluded the following:

- A less than 50% inhibition of glutamine synthetase in rat liver was not associated with increased ammonia concentrations and thus was not considered to be adverse.
- Inhibition of kidney glutamine synthetase in the absence of pathological findings was not considered to be relevant to human risk assessment.
- Any statistically significant inhibition of glutamine synthetase activity in brain by more than 10% was considered a marker of potentially adverse effects on brain biochemistry and behaviour.

The present Meeting confirmed the conclusion of the 1999 JMPR, which is also supported by a recent published study on the essential role of glutamine synthetase in the implantation of mouse embryos.

The acute toxicity of glufosinate-ammonium is low in rats (oral LD_{50} > 1500 mg/kg bw; dermal LD_{50} > 2000 mg/kg bw; inhalation $LC_{50} \geq 1.26$ mg/L). Glufosinate-ammonium is not irritating to the skin or eyes of rabbits and is not a skin sensitizer (Magnusson & Kligman test and Buehler test in guinea-pigs; local lymph node assay in mice).

In acute toxicity studies in mice, clinical signs of neurotoxicity were observed at 231 mg/kg bw (the lowest dose tested) and above. Mortality was observed at doses greater than or equal to 300 mg/kg bw.

In a single-dose toxicity study in dogs, clinical signs of neurotoxicity were observed at 200 mg/kg bw (the lowest dose tested), and mortality was observed at 400 mg/kg bw.

In three 13-week dietary studies in mice, the overall NOAEL was 1280 ppm (equal to 278 mg/kg bw per day), based on clinical signs (ruffled fur, sedation, ventral recumbence or hunched posture, and emaciation) observed at 3500 ppm (equal to 561 mg/kg bw per day).

In a 28-day dietary range-finding and two 13-week dietary studies in rats, the overall NOAEL was 4000 ppm (equal to 263 mg/kg bw per day), based on neurological effects in both sexes and reduced body weight gain and feed consumption, reductions in erythrocyte count and low reticulocyte ratios in males at 7500 ppm (equal to 521 mg/kg bw per day). Glutamine synthetase activity was not measured in these studies.

In a 28-day capsule study in dogs, the NOAEL was 1 mg/kg bw per day, based on reductions in glutamine synthetase activity in the central nervous system (8–53%), a slight 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 first week of treatment at 8 mg/kg bw per day.

In a 90-day dietary study in dogs, the NOAEL was 64 ppm (equal to 2.0 mg/kg bw per day), based on a reduction in body weight gain and feed consumption in females at 256 ppm (equal to 7.8 mg/kg bw per day).

In a 1-year dietary study in dogs, mortality on days 10 and 14 and severe clinical signs, starting on day 9 of treatment, were observed after treatment with 375 ppm (equal to 10.6–16.0 mg/kg bw per day). The two deaths out of 16 animals at the high dose were caused by heart and circulatory failure attributed to marked myocardial necrosis in one dog and to severe necrotizing aspiration pneumonia in the other dog. After lowering the dose to 250 ppm (equal to 8.4 mg/kg bw per day), no adverse effects were observed. The NOAEL was 150 ppm (equal to 4.5 mg/kg bw per day). The study indicates that glufosinate-ammonium has a steep dose–response curve in dogs.

In the absence of glutamine synthetase measurements in the 90-day and 1-year studies in dogs, an overall NOAEL of 1 mg/kg bw per day was established for these studies.

In a 2-year feeding study in mice, the NOAEL was 80 ppm (equal to 10.8 mg/kg bw per day), based on increased mortality and reduced body weight gain in males and changes in clinical chemistry parameters in both sexes at 160 ppm (equal to 23 mg/kg bw per day). No effect on tumour incidence was observed.

In a 130-week feeding study in rats, the NOAEL was 140 ppm (equal to 7.6 mg/kg bw per day), based on effects on haematology, glutathione levels in liver and blood, and a reduction of brain glutamine synthetase activity at 500 ppm (equal to 26.7 mg/kg bw per day). In this study and a 2-year carcinogenicity study in rats, no effect on tumour incidence was found.

The Meeting concluded that glufosinate-ammonium is not carcinogenic in mice or rats.

Glufosinate-ammonium was tested for genotoxicity in an adequate range of studies of genotoxicity in vitro and in vivo. No evidence for genotoxicity was observed in any test.

The Meeting concluded that glufosinate-ammonium 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 glufosinate-ammonium is unlikely to pose a carcinogenic risk to humans.

A range-finding one-generation study and a two-generation study of reproductive toxicity in rats were available. The overall NOAEL for parental toxicity was 500 ppm (equal to 44 mg/kg bw per day), based on reduced feed consumption in males at 2500 ppm (equal to 206 mg/kg bw per day). At 2500 ppm and above, the dams delivered no pups. The overall NOAEL for offspring toxicity was 500 ppm (equal to 44 mg/kg bw per day), the highest dose at which dams produced a litter. The overall NOAEL for reproductive toxicity was 120 ppm (equal to 8.7 mg/kg bw per day), based on reduced litter sizes in all litters at 360 ppm (equal to 18 mg/kg bw per day). The Meeting considered the possibility that the increased pre-implantation loss observed in the range-finding one-generation study of reproductive toxicity at 2500 ppm (equal to 207 mg/kg bw per day) might be caused by an inhibition of glutamine synthetase prior to implantation; a published mechanistic study in mice indicates that glutamine synthetase activity in pre-implantation embryonic cells is essential for the blastocyst to complete implantation. The Meeting concluded that the pre-implantation loss and early deaths in the reproductive toxicity studies might be caused by a single exposure to glufosinate-ammonium.

In three developmental toxicity studies in rats, the overall NOAEL for maternal toxicity was 10 mg/kg bw per day, based on clinical signs and abortions at 50 mg/kg bw per day. The overall NOAEL for developmental toxicity was 10 mg/kg bw per day, based on intrauterine deaths at 50 mg/kg bw per day.

In a developmental toxicity study in rabbits, the NOAEL for maternal toxicity was 6.3 mg/kg bw per day, based on clinical signs, body weight loss and reduced feed consumption, an increased number of abortions and increased kidney weight at 20 mg/kg bw per day. The NOAEL for developmental toxicity was 6.3 mg/kg bw per day, based on an increased number of dead fetuses at 20 mg/kg bw per day.

The Meeting concluded that glufosinate-ammonium is not teratogenic in rats or rabbits.

In an acute gavage study of neurotoxicity in rats, the NOAEL was 100 mg/kg bw, based on clinical signs at 500 mg/kg bw.

In a dietary 38-day neurotoxicity study in rats and a 90-day dietary study investigating brain and liver glutamine synthetase inhibition in rats, the overall NOAEL was 100 ppm (equivalent to 6.2 mg/kg bw per day), based on a greater than 50% reduction in glutamine synthetase activity in the liver in males at 200 ppm (equal to 15 mg/kg bw per day).

In a dietary developmental neurotoxicity study in rats, the NOAEL for maternal toxicity was 1000 ppm (equal to 69 mg/kg bw per day), based on decreased body weight gain and feed consumption at 4500 ppm (equal to 292 mg/kg bw per day). The NOAEL for offspring toxicity was 200 ppm (equal to 14 mg/kg bw per day), based on reduced body weight gain during the pre-weaning period, effects on motor activity at postnatal days 17, 21 and 62, and hippocampal pathology in males at 1000 ppm (equal to 69 mg/kg bw per day).

Medical surveillance of plant production personnel did not find any effects related to the production of glufosinate-ammonium. Several human poisoning cases, sometimes leading to death, due to (suicidal) ingestion of glufosinate-ammonium have been reported in the literature. A variety of neurological symptoms have been described. It is not clear whether the toxicity was due to the active ingredient, to the surfactant contained in relatively high amounts in the formulation or to the combination of both.

Toxicological studies with the metabolites NAG, MPP and MPA, three metabolites that are found in plants, soil and livestock as well as in laboratory animals, were available. The toxicity of NAG, MPP and MPA is described separately below.

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

N-Acetyl-glufosinate (NAG)

Biochemical aspects

After administration of a single oral dose (3 mg/kg bw) of ^{14}C-labelled NAG to rats, it was rapidly but incompletely absorbed (approximately 5–10%). Peak plasma concentrations were reached within 1 hour. The highest residue levels were found in kidneys, followed by liver. Excretion after a single oral dose (3 mg/kg bw) was rapid, with approximately 95% of the absorbed dose excreted within 24 hours after administration. The absorbed NAG was predominantly excreted in urine. In faeces, mainly unchanged NAG was found, but about 10% was deacetylated to glufosinate by the intestinal microflora. In faeces, urine and tissues, minor amounts of MPP and MPA were found.

Toxicological data

The oral acute toxicity of NAG is low in rats and mice (LD_{50} > 2985 mg/kg bw). NAG is not a skin sensitizer (Magnusson & Kligman test in guinea-pigs).

In 4-week and 13-week dietary studies with NAG in mice, the overall NOAEL was 500 ppm (equal to 83 mg/kg bw per day), based on the inhibition of brain glutamine synthetase activity (11–13%) at 2000 ppm (equal to 233 mg/kg bw per day).

In a 4-week dietary range-finding study, two 13-week dietary studies and a 38-day dietary neurotoxicity study in rats, the overall NOAEL was 2000 ppm (equal to 331 mg/kg bw per day), based on statistically significant inhibition (11–12%) of liver glutamine synthetase activity at 10 000 ppm (equal to 658 mg/kg bw per day). Brain glutamine synthetase activity was reduced at 10 000 ppm (equal to 738 mg/kg bw per day). In the neurotoxicity study, no effects on glutamine synthetase and neurotoxicity parameters were observed at doses up to 2000 ppm (equal to 159 mg/kg bw per day), the highest dose tested.

In a 13-week dietary study in dogs, the NOAEL was 500 ppm (equal to 45 mg/kg bw per day), based on a reduction in brain glutamine synthetase activity (≥ 16%) at 2000 ppm (equal to 171 mg/kg bw per day).

In a 2-year dietary carcinogenicity study in rats, there were no toxicological findings and no increase in tumour incidence at the highest dose tested of 8000 ppm (equal to 1188 mg/kg bw per day). Glutamine synthetase activity was not measured.

In a 2-year dietary toxicity study in rats, the NOAEL was 2000 ppm (equal to 91 mg/kg bw per day), based on decreased body weight gain, increased incidence of soft faeces and increased incidences of polyarteritis nodosa in blood vessels and testes and urolithiasis at 20 000 ppm (equal to 998 mg/kg bw per day).

The Meeting concluded that NAG is not carcinogenic in rats.

NAG was tested for genotoxicity in an adequate range of in vitro and in vivo studies. No evidence for genotoxicity was observed in any test.

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

In a range-finding one-generation study and a two-generation study of reproductive toxicity with NAG, the NOAEL for parental, offspring and reproductive toxicity was 10 000 ppm (equal to 622 mg/kg bw per day), the highest dose tested.

In a developmental toxicity study in rats, the NOAEL for maternal and developmental toxicity was 1000 mg/kg bw per day, the only dose tested.

In a developmental toxicity study in rabbits, the NOAEL for maternal toxicity was 64 mg/kg bw per day, based on reduced feed consumption at 160 mg/kg bw per day. The NOAEL for developmental toxicity was 64 mg/kg bw per day, based on an increased incidence of extra thoracic ribs at 160 mg/kg bw per day.

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

In two acute oral (gavage) studies of neurotoxicity in rats, the NOAEL was 1000 mg/kg bw, based on clinical signs (diarrhoea, ruffled fur and sedation) observed at 2000 mg/kg bw. No overt neurotoxicity was observed. Glutamine synthetase activity was not measured.

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

3-Methylphosphinico-propionic acid (MPP)

Biochemical aspects

During the first 24 hours following a single oral dose of ^{14}C-labelled MPP administered to rats, 83% and 4% of the radiolabel were excreted in urine and faeces, respectively.

Toxicological data

The acute oral toxicity of MPP is low in rats (oral LD_{50} = 1900 mg/kg bw). MPP is not a skin sensitizer (Magnusson & Kligman test in guinea-pigs).

In short-term dietary studies in mice (13 weeks, doses up to 8000 ppm, equal to 1288 mg/kg bw per day), rats (4 weeks and 13 weeks, doses up to 6400 ppm, equal to 546 mg/kg bw per day) and dogs (28 days and 90 days, doses up to 1600 ppm, equal to 103 mg/kg bw per day), no toxicity was observed. In the 4-week study in rats, glutamine synthetase activity in liver was not affected at doses up to 5000 ppm (equal to 554 mg/kg bw per day). In the two short-term studies in dogs, glutamine synthetase activity in liver, kidney and brain was not affected at doses up to 1600 ppm (equal to 103 mg/kg bw per day).

No long-term studies with MPP were available.

Glufosinate-ammonium was tested for genotoxicity in a limited range of studies in vitro. No evidence for genotoxicity was observed in any of these tests.

In a developmental toxicity study in rats, the NOAEL for maternal toxicity was 300 mg/kg bw per day, on the basis of one death out of 20 animals, clinical signs of toxicity, and reduced body weight gain and feed consumption observed at 900 mg/kg bw per day. The NOAEL for fetal toxicity was 300 mg/kg bw per day, on the basis of 3 dams out of 20 with total litter loss at 900 mg/kg bw per day.

In a developmental toxicity study in rabbits, the NOAEL for maternal toxicity was 50 mg/kg bw per day, on the basis of one death out of 15 animals, one abortion, clinical signs of toxicity, and reduced body weight gain and feed consumption observed at 100 mg/kg bw per day. The NOAEL for fetal toxicity was 50 mg/kg bw per day, on the basis of one dam with seven conceptuses undergoing resorption at 100 mg/kg bw per day.

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

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

2-Methylphosphinico-acetic acid (MPA)

The acute oral toxicity of MPA in rats was low (LD_{50} > 2000 mg/kg bw). In a 90-day dietary study in rats, the NOAEL was 10 000 ppm (equal to 684 mg/kg bw per day), the highest dose tested. Glutamine synthetase activity was not measured, but in view of the structural similarity between MPA

and MPP, the Meeting considered it unlikely that MPA would inhibit this enzyme. MPA was not genotoxic in three genotoxicity tests in vitro.

Toxicological evaluation

The present Meeting compared the toxicity of NAG, MPP and MPA with that of glufosinate-ammonium and concluded that the toxicity of the metabolites was less than that of the parent compound. The Meeting established an ADI of 0–0.01 mg/kg bw for glufosinate-ammonium, on the basis of an overall 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. This ADI also applies to its metabolites NAG, MPP and MPA. In view of the lower toxicity of NAG, MPP and MPA compared with glufosinate-ammonium, the Meeting noted that the application of the ADI to these metabolites is likely to be conservative. This ADI is considered to be adequately protective for any reproductive and developmental effects.

The Meeting established an ARfD for glufosinate-ammonium of 0.01 mg/kg bw, based on the NOAEL of 1 mg/kg bw per day in the 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 first week of treatment with 8 mg/kg bw per day and application of a safety factor of 100. This ARfD also applies to its metabolites NAG, MPP and MPA. In view of the lower acute toxicity of NAG, MPP and MPA compared with glufosinate-ammonium, the Meeting noted that the application of the ARfD to these metabolites is likely to be conservative. This ARfD is considered to be adequately protective for any reproductive and developmental effects.

A toxicological monograph was prepared.

Levels relevant for risk assessment of glufosinate-ammonium

Species	Study	Effect	NOAEL	LOAEL
Mouse	Two-year study of toxicity and carcinogenicity[a]	Toxicity	80 ppm, equal to 10.8 mg/kg bw per day	160 ppm, equal to 23 mg/kg bw per day
		Carcinogenicity	23 mg/kg bw per day[b]	—
Rat	Short-term studies of toxicity[c,d,e]	Toxicity	100 ppm, equal to 6.21 mg/kg bw per day	200 ppm, equal to 15 mg/kg bw per day
	Two-year study of toxicity and carcinogenicity[a]	Toxicity	140 ppm, equal to 7.6 mg/kg bw per day	500 ppm, equal to 26.7 mg/kg bw per day
		Carcinogenicity	500 ppm, equal to 26.7 mg/kg bw per day[b]	—
	Two-generation study of reproductive toxicity[a]	Parental toxicity	500 ppm, equal to 44 mg/kg bw per day	2500 ppm, equal to 206 mg/kg bw per day
		Offspring toxicity	500 ppm, equal to 44 mg/kg bw per day[b]	—
		Reproductive toxicity	120 ppm, equal to 8.7 mg/kg bw per day	360 ppm, equal to 18 mg/kg bw per day
	Developmental toxicity study[c]	Maternal toxicity	10 mg/kg bw per day	50 mg/kg bw per day
		Embryo and fetal toxicity	10 mg/kg bw per day	50 mg/kg bw per day
	Developmental neurotoxicity study[c]	Maternal toxicity	1000 ppm, equal to 69 mg/kg bw per day	4500 ppm, equal to 292 mg/kg bw per day
		Embryo and fetal toxicity	200 ppm, equal to 14 mg/kg bw per day	1000 ppm, equal to 69 mg/kg bw per day
Rabbit	Developmental toxicity study[c]	Maternal toxicity	6.3 mg/kg bw per day	20 mg/kg bw per day
		Embryo and fetal toxicity	6.3 mg/kg bw per day	20 mg/kg bw per day
Dog	Short-term study of toxicity	Toxicity	1 mg/kg bw per day	8 mg/kg bw per day

[a] Dietary administration.

[b] Highest dose tested.

[c] Gavage administration.

[d] Two or more studies combined.

[e] Based on inhibition of liver glutamine synthetase in a neurotoxicity study.

Levels relevant for risk assessment of NAG

Species	Study	Effect	NOAEL	LOAEL
Mouse	Short-term studies of toxicity[a,b]	Toxicity	500 ppm, equal to 83 mg/kg bw per day	2000 ppm, equal to 233 mg/kg bw per day
	Two-year study of carcinogenicity[a]	Carcinogenicity	8000 ppm, equivalent to 1188 mg/kg bw per day[c]	—
Rat	Short-term studies of toxicity[a,b]	Toxicity	2000 ppm, equal to 331 mg/kg bw per day	10 000 ppm, equal to 658 mg/kg bw per day
	Two-year study of toxicity and carcinogenicity[a]	Toxicity	2000 ppm, equal to 91 mg/kg bw per day	20 000 ppm, equal to 998 mg/kg bw per day
		Carcinogenicity	20 000 ppm, equal to 998 mg/kg bw per day[c]	—
	One-generation study of reproductive toxicity[a]	Parental toxicity	10 000 ppm, equivalent to 622 mg/kg bw per day[c]	—
		Offspring toxicity	10 000 ppm, equivalent to 622 mg/kg bw per day[c]	—
		Reproductive toxicity	10 000 ppm, equivalent to 622 mg/kg bw per day[c]	—
	Developmental toxicity study[d]	Maternal toxicity	1000 mg/kg bw per day[c]	—
		Embryo and fetal toxicity	1000 mg/kg bw per day[c]	—
Rabbit	Developmental toxicity study[d]	Maternal toxicity	64 mg/kg bw per day	160 mg/kg bw per day
		Embryo and fetal toxicity	64 mg/kg bw per day	160 mg/kg bw per day
Dog	Short-term study of toxicity[a]	Toxicity	500 ppm, equal to 45 mg/kg bw per day	2000 ppm, equal to 171 mg/kg bw per day

[a] Dietary administration.

[b] Two or more studies combined.

[c] Highest dose tested.

[d] Gavage administration.

Levels relevant for risk assessment of MPP

Species	Study	Effect	NOAEL	LOAEL
Mouse	Short-term study of toxicity[a]	Toxicity	8000 ppm, equivalent to 1288 mg/kg bw per day[b]	—
Rat	Short-term study of toxicity[a]	Toxicity	6400 ppm, equal to 546 mg/kg bw per day[b]	—
	Developmental toxicity study[c]	Maternal toxicity	300 mg/kg bw per day	900 mg/kg bw per day
		Embryo and fetal toxicity	300 mg/kg bw per day	900 mg/kg bw per day
Rabbit	Developmental toxicity study[c]	Maternal toxicity	50 mg/kg bw per day	100 mg/kg bw per day
		Embryo and fetal toxicity	50 mg/kg bw per day	100 mg/kg bw per day
Dog	Short-term study of toxicity[a]	Toxicity	1600 ppm, equal to 103 mg/kg bw per day[b]	—

[a] Dietary administration.

[b] Highest dose tested.

[c] Gavage administration.

Levels relevant for risk assessment of MPA

Species	Study	Effect	NOAEL	LOAEL
Rat	Short-term study of toxicity[a]	Toxicity	10 000 ppm, equal to 684 mg/kg bw per day[b]	—

[a] Dietary administration.

[b] Highest dose tested.

Estimate of acceptable daily intake for humans

0–0.01 mg/kg bw (ADI for glufosinate-ammonium, also applies to NAG, MPP and MPA)

Estimate of acute reference dose

0.01 mg/kg bw (ARfD for glufosinate-ammonium, also applies to NAG, MPP and MPA)

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

Results from epidemiological, occupational health and other such observational studies of exposures in humans

Critical end-points for setting guidance values for exposure to glufosinate-ammonium and its metabolites NAG and MPP

	Glufosinate-ammonium	NAG	MPP
Absorption, distribution, excretion and metabolism in animals			
Rate and extent of absorption	Rapid, incomplete (~10%)	Rapid, incomplete (5–10%)	Rapid and complete (87%)
Distribution	Extensive; highest concentrations in liver and kidney	Extensive; highest concentrations in liver and kidney	No data
Potential for accumulation	Low	Low	Low
Rate and extent of excretion	> 90% within 24 h, primarily in faeces	> 95% within 24 h, primarily in faeces	87% within 24 h, primarily in urine
Metabolism in animals	Limited	Limited	No data
Toxicologically significant compounds in animals, plants and the environment	Glufosinate-ammonium, NAG, MPP, MPA	NAG, glufosinate-ammonium, MPP, MPA	MPP, MPA
Acute toxicity			
LD_{50}, oral, rat	> 1500 mg/kg bw	> 2985 mg/kg bw	1900 mg/kg bw
LD_{50}, dermal, rat	> 2000 mg/kg bw	No data	No data
LC_{50}, inhalation, rat	≥ 1.26 mg/L air	No data	No data
Rat, dermal irritation	Not an irritant	No data	No data
Rabbit, ocular irritation	Not an irritant	No data	No data
Dermal sensitization	Not a sensitizer (Magnusson & Kligman, Buehler, local lymph node assay)	Not a sensitizer (Magnusson & Kligman)	Not a sensitizer (Magnusson & Kligman)
Short-term studies of toxicity			
Target/critical effect	Brain (inhibition of glutamine synthetase) (dog)	Brain (inhibition of glutamine synthetase) (mouse, rat, dog)	None identified
Lowest relevant oral NOAEL	1 mg/kg bw per day (dog)	500 ppm, equal to 45 mg/kg bw per day (dog)	1600 ppm, equal to 103 mg/kg bw per day, highest dose tested (dog)
Lowest relevant dermal NOAEL	100 mg/kg bw per day (rat)	No data	No data
Long-term studies of toxicity and carcinogenicity			
Target/critical effect	Mortality, body weight gain, clinical chemistry (mouse) Haematology, brain glutamine synthetase (rats)	Body weight gain, clinical signs, polyarteritis nodosa in blood vessels and testes, urolithiasis (rat)	No data

	Glufosinate-ammonium	NAG	MPP
Lowest relevant NOAEL	80 ppm, equal to 10.8 mg/kg bw per day (mouse) 140 ppm, equal to 7.6 mg/kg bw per day (rat)	2000 ppm, equal to 91 mg/kg bw per day (rat)	—
Carcinogenicity	Not carcinogenic (mouse, rat)	Not carcinogenic (rat)	—
Genotoxicity	Not genotoxic	Not genotoxic	Not genotoxic in a limited range of studies
Reproductive toxicity			
Target/critical effect	Reduced litter size (rat)	No reproductive target	No data
Lowest relevant parental NOAEL	500 ppm, equal to 44 mg/kg bw per day (rat)	10 000 ppm, equal to 622 mg/kg bw per day (rat)	—
Lowest relevant reproductive NOAEL	120 ppm, equal to 8.7 mg/kg bw per day (rat)	10 000 ppm, equal to 622 mg/kg bw per day (rat)	—
Lowest relevant offspring NOAEL	500 ppm, equal to 44 mg/kg bw per day (rat)	10 000 ppm, equal to 622 mg/kg bw per day (rat)	—
Developmental toxicity			
Target/critical effect	Intrauterine deaths (rat, rabbit)	Increased incidence of extra thoracic ribs (rabbit)	Intrauterine deaths (rat, rabbit)
Lowest relevant maternal NOAEL	120 ppm, equal to 8.7 mg/kg bw per day (rat)	64 mg/kg bw per day	50 mg/kg bw per day (rabbit)
Lowest relevant developmental NOAEL	10 mg/kg bw per day (rat) 6.3 mg/kg bw per day (rabbit)	64 mg/kg bw per day	50 mg/kg bw per day (rabbit)
Neurotoxicity			
Acute oral neurotoxicity NOAEL	1 mg/kg bw per day (dog); increased motor activity	Not neurotoxic (2000 mg/kg bw)	No data
Short-term neurotoxicity NOAEL	1 mg/kg bw per day (dog); inhibition of brain glutamine synthetase, increased motor activity	500 ppm, equal to 45 mg/kg bw per day (dog); inhibition of brain glutamine synthetase	Not neurotoxic Brain glutamine synthetase was not inhibited in dogs at 1000 ppm, equal to 58 mg/kg bw per day
Developmental neurotoxicity NOAEL	200 ppm, equal to 14 mg/kg bw per day (rat); increased motor activity, hippocampal pathology	No data	No data
Medical data	(Suicidal) poisonings producing several neurological effects and deaths. No adverse effects reported in plant production personnel.	No data	No data

Summary for glufosinate-ammonium

	Value	Study	Safety factor
ADI	0–0.01 mg/kg bw	Short-term studies (dog)	100
ARfD	0.01 mg/kg bw	Short-term studies (dog)	100

RESIDUE AND ANALYTICAL ASPECTS

Glufosinate is a non-selective contact herbicide with uses on many crops, both conventional and glufosinate tolerant. Glufosinate has been evaluated several times by the JMPR with the initial evaluation in 1991 and the latest in 1999. Glufosinate-ammonium was scheduled at the Forty-third Session of the CCPR (2011) for periodic re-evaluation of toxicology and residues by the 2012 JMPR.

Glufosinate is a synthetic version of the natural product, phosphinothricin, and exists as a racemic mixture (i.e., 50:50 D- and L-glufosinate). The D-enantiomer is not herbicidally active. The L-enantiomer of glufosinate acts by inhibition of glutamine synthetase thereby causing accumulation of toxic levels of ammonium ion and indirectly stopping photosynthesis. Two genes for acetyltransferase, *bar* and *pat*, that were isolated from *Streptomyces hygroscopicus* and *Streptomyces viridochromogenes*, respectively, have been used to produce glufosinate-tolerant crops. For the current evaluation data have been submitted covering herbicide use on conventional and crops genetically modified by inclusion of the *pat* and *bar* gene to be glufosinate tolerant. These crops inactivate L-glufosinate by converting it to *N*-acetyl-glufosinate (NAG).

The Meeting received information on the metabolism of glufosinate and NAG (the main metabolite expected to be formed in tolerant plants) in animals, on glufosinate metabolism in conventional crops, and on crops genetically modified to contain the *pat* or *bar* genes and be glufosinate tolerant, methods of residue analysis, freezer storage stability, GAP information, supervised residue trials on conventional and glufosinate tolerant crops, fate of residue during storage and processing, and livestock feeding studies.

Metabolites referred to in the appraisal were addressed by their common names,

NAG	N-acetyl-glufosinate;
MPP	3-methyl-phosphinico-propionic acid;
MPA	2-methyl-phosphinico-acetic acid;
MPB	4-methyl-phosphinico -butanoic acid;
MHB	4-methyl-phosphinico-hydroxy-butanoic acid;
PPO	4-methyl-phosphinico-2-oxo-butanoic acid.

Animal metabolism

Metabolism of glufosinate in cattle and hens involves formation of MPP and the slow transformation to MPA. NAG is metabolized by de-acetylation to form glufosinate with subsequent transformation proceeding as for glufosinate.

In one study a lactating goat was orally treated twice daily for 4 consecutive days with [3,4-^{14}C]- glufosinate at a dose equivalent to 101 ppm in the feed. Approximately 84% of the administered dose was recovered with the majority in the excreta (69% faeces, 3% urine) or gastrointestinal tract (12%). The radioactivity in the tissues ranged from 0.004 in fat to 0.61 mg/kg glufosinate equivalents in kidney. TRR values in milk were 0.003 to 0.022 mg/kg glufosinate equivalents during the dosing period with plateau levels reached after two days of dosing.

Major components of the ^{14}C residues were unchanged glufosinate (kidney 49% TRR, liver 53% TRR, milk 49% TRR) and MPP (kidney 29% TRR, liver 36% TRR and milk 6.3% TRR). The minor metabolites MPA and NAG individually accounted for no more than 5.3% TRR in kidney, liver and milk.

In a separate study a lactating goat was dosed twice a day with NAG at a dose equivalent to 84 ppm in the feed for 3 consecutive days. Most of the administered dose was recovered in the faeces (68%), urine (7.3%) and gastrointestinal tract (19%). Radioactive residues were highest in kidney (0.93 mg/kg NAG equivalents) with lowest levels in fat and muscle (< 0.01 mg eq./kg). ^{14}C levels in milk were 0.023 mg/kg NAG equivalents by the third day of dosing. Major components of the ^{14}C residues were glufosinate (kidney 40% TRR, liver 33% TRR, milk 40% TRR), unchanged NAG

(kidney 32% TRR, liver 19% TRR, milk 9% TRR) and MPP (kidney 20% TRR, liver 21% TRR, milk 14% TRR). MPA was detected as a minor metabolite < 5% TRR.

Laying hens were orally treated twice daily for 14 consecutive days with [3,4-^{14}C]-glufosinate at a dose equivalent to 24.5 ppm in the feed and were sacrificed 15–16 hours after the last dose. The majority (92%) of the dose was eliminated in the excreta with 1.3% of the dose recovered from the GIT. Radioactivity in tissues ranged from 0.11 mg/kg glufosinate equivalents in kidney to 0.003 mg/kg glufosinate equivalents in fat and < 0.004 mg/kg glufosinate equivalents in muscle. The ^{14}C levels in egg whites and yolks reached 0.067 and 0.024 mg/kg glufosinate equivalents respectively by 14 days of dosing.

Unchanged glufosinate was the main residue component (liver 31% TRR, yolk 53% TRR, whites 78% TRR). MPP was a significant component of ^{14}C residues in liver (44% TRR) but a minor component in eggs (< 5%). MPA and NAG were also detected but at levels that represented < 5% TRR in liver and eggs.

The metabolism of NAG was studied in laying hens dosed orally twice daily for 14 consecutive days with [^{14}C]-NAG at a dose equivalent to 27 ppm in the feed and sacrificed 15 hours after the last dose. Most of the administered dose was recovered in the excreta (86%) with an additional portion (1%) found in the gastrointestinal tract at sacrifice. Radioactive residues in egg white reached a plateau by day 9 of dosing with a maximum level of 0.015 mg/kg NAG equivalents while egg yolk reached a plateau by day 12 with a maximum residue of 0.056 mg/kg NAG equivalents. In tissues at sacrifice, ^{14}C residues were highest in liver (0.076 mg/kg NAG equivalents) and much lower in muscle and fat (0.013 and 0.011 mg/kg NAG equivalents respectively).

NAG was a major component of the ^{14}C residues (liver 27% TRR, egg yolk 13% TRR, egg white 5% TRR) together with glufosinate (liver 15% TRR, egg yolk 3% TRR, egg white14% TRR) and MPP (liver 17% TRR, egg yolk 2.2% TRR, egg white 2% TRR). MPA was only detected as a minor metabolite and was present at < 1.1%TRR.

Metabolism in laboratory animals (rat) was summarized and evaluated by the WHO panel of the JMPR in the present meeting.

The metabolism of glufosinate and NAG in ruminants and laying hens is qualitatively the same as observed in rats.

Plant metabolism

Glufosinate-ammonium is used for three different situations:

- Directed sprays for weed control (crop not intentionally treated)
- Use as a crop desiccant to facilitate crop harvest (crop treated)
- Selective use in genetically modified glufosinate-tolerant crops (crop treated)

Plant metabolism studies were conducted with glufosinate-ammonium to investigate these three situations.

Directed sprays to weeds present in conventional crops

For weed control in conventional crops where the crop is not treated, metabolism studies were conducted in apple, grape, lettuce, corn/maize, wheat and potato as well as in artificial systems such as excised roots and leaves and cell cultures of a variety of weed and non-weed species.

The main metabolite observed in excised shots and leaves from conventional plants was MPP with lower amounts of MHB also detected.

When L-glufosinate was applied to conventional tobacco, alfalfa and carrot plants the main metabolites identified were MPP, MPB and MHB.

MPP was the only compound (89% TRR) detected in apples harvested 14 weeks after the soil under the trees was treated at 1.5 kg ai/ha with [2-^{14}C]-glufosinate-ammonium.

There was limited translocation of ^{14}C from soil-applied ^{14}C-glufosinate in a two year trial with grapevines where a single application was made in the first year and two in the second, all at 1.5 kg ai/ha. Levels of ^{14}C in grapes reached a maximum of 0.008 mg eq./kg and were too low to enable identification of components.

In a study where lettuce plants were transplanted in hydroponic solutions to which [3-^{14}C]-glufosinate-ammonium had been added, MPP represented about 90% of the TRR in leaves.

Following pre-crop emergent application of [3,4-^{14}C]-glufosinate-ammonium to potatoes at a rate equivalent to 1.0 kg ai/ha, 90% of the TRR in tubers at harvest was MPP while MPP represented > 80% TRR in leaves, stems and new sprouts.

In studies identifying residues in corn/maize following pre-crop emergent use of [3,4-^{14}C]-glufosinate-ammonium at 1.0 to 1.9 kg ai/ha, only low levels of ^{14}C were found in grain that precluded identification of components. Fodder had higher ^{14}C levels which were mostly MPP (60% TRR) with the remaining attributed to incorporation of ^{14}C into natural components (hemicellulose, lignin, cellulose, proteins and starch).

MPP was also the major component of the solvent extracted residue in wheat when [2-^{14}C]-glufosinate-ammonium is applied to soil at 1.2 kg ai/ha prior to crop emergence (straw 70%; husks 106%; grain 86%).

In summary, following directed application to soil and weeds, glufosinate related residues in conventional plants are almost entirely MPP.

Crop desiccation

The use as a pre-harvest desiccant was investigated in potato, rape and beans following foliar spray application to the crop. When applied to conventional crops for desiccation the residues consist primarily of glufosinate and its metabolite MPP. 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, glufosinate was the major component of the ^{14}C residue in potato leaves and tubers, bean leaves, hulls and seeds and rape leaves, hulls and seeds accounting for more than 80% of TRR in combined surface rinses and solvent extracts. MPP was also detected but generally represented less than 10% of the TRR.

Glufosinate-tolerant crops

The use as a selective herbicide on tolerant plants was investigated following foliar application to glufosinate-tolerant crops such as corn/maize, rape, soya bean, rice, tomato and cotton.

The metabolic fate of [3,4-^{14}C]-glufosinate-ammonium in glufosinate tolerant tomato plants was examined following a single foliar application at 0.8 kg ai/ha at the 7–8 leaf growth stage. Extracts of rinsed leaves (absorbed ^{14}C) contained almost equal amounts of NAG and glufosinate and together accounted for > 90% TRR in the extracts. MPP was present as a minor component (< 10% TRR). Residues in fruit that developed after application were almost completely due to NAG.

The metabolic fate of [3,4-^{14}C]-glufosinate-ammonium in glufosinate-tolerant (*pat* gene) soya bean plants was examined in two studies where plants were sprayed with two applications at about 0.5 kg ai/ha. Soya bean plants were harvested at typical forage stage and at maturity (PHI 84–85 days). In soya forage the major components of the ^{14}C residues were NAG (26–60%) and glufosinate (18–23%) with MPP and MPA present at < 10% TRR. For straw, pods, husks and beans at harvest, NAG (28–63%), glufosinate (11–18%) and MPP (10–22%) were major components of ^{14}C with smaller amounts of MPA also observed (1.3–7.1%).

In a study of [3,4-^{14}C]-glufosinate-ammonium metabolism in glufosinate-tolerant sugar beet plants were sprayed twice, at 5 weeks after sowing and 22 days later, at 0.6 kg ai/ha. At harvest, 146 days after the last application, the major components of ^{14}C identified in leaves and roots were NAG (67–68%) and glufosinate (19–24%) with low levels of MPP (2.7–6%).

The metabolic fate of [^{14}C]-glufosinate-ammonium in tolerant (*pat* gene) corn/maize plants was examined following application at 0.5 kg ai/ha when plants were 40 cm high and 10 days later when 60 cm high. ^{14}C residues in forage at 28 days after treatment were 2.6 mg/kg glufosinate equivalents with major components NAG (52%), glufosinate (13%) and MPP (12%). Maize fodder at harvest contained 0.2 mg eq./kg comprising NAG (54%), MPP (11%) and glufosinate (10%) as the main ^{14}C residue components. In grain at harvest, ^{14}C residues were 0.13 mg/kg glufosinate equivalents comprising MPP (37%), NAG (19%), MPB (9.8%) and MPA (4.4%) with glufosinate present but only at very low levels (< 1.5%). In a comparison of crops made tolerant through incorporation of the *pat* or *bar* genes the same metabolite profile was observed for both modifications.

The metabolic fate of [^{14}C]-glufosinate-ammonium in tolerant rice plants was examined following application at 0.5 kg ai/ha when plants were at the 2–4 leaf stage and then at the 2–4 tiller stage. Plants were managed under two flooding regimes, the first was with flooding 2 days prior to the first treatment and the second regime was flooding one day after the second treatment. There were no significant differences in metabolite profiles between the two management regimes. ^{14}C residues in forage at 18 days after the last treatment were 2.0–2.6 mg/kg glufosinate equivalents with major components NAG (54–64%), glufosinate (8.1%) and MPP (7.8–9%). Straw at harvest (184 days after the last application) contained 9.5–13.1 mg eq./kg comprising NAG (60%), MPP (10–13%) and glufosinate (18%) as the main components. In grain at harvest ^{14}C residues were 1.1–1.4 mg/kg glufosinate equivalents comprising MPP (68–72%), NAG (11%), MPB (9.8%) and glufosinate (5–6%) with MPA also present but only at very low levels (0.6–0.8%).

In an additional study tolerant (*bar* gene) and conventional cotton were treated at the 10 leaf stage with a commercial formulation of glufosinate-ammonium at 0.5 kg ai/ha, and selected individual leaves spotted with a solution of ^{14}C-glufosinate-ammonium. Tolerant cotton showed high levels of metabolism with NAG accounting for 72% TRR at 72 hours after application while in conventional cotton glufosinate accounted for 73% TRR at 72 hours.

The metabolic fate of [^{14}C]-glufosinate-ammonium in tolerant rape plants was examined in several studies. Following application to tolerant rape at the three leaf growth stage at 0.75 kg ai/ha, ^{14}C residues in foliage at 21 days were 4.3 mg/kg glufosinate equivalents with major components NAG (60%), glufosinate (21%) and MPP (6.7%). In seeds at harvest (120 days after application) ^{14}C residues were 0.04–0.11 mg/kg glufosinate equivalents comprising glufosinate (0–14%) and MPP (3-45%) with NAG present but only at very low levels (< 2%). Following two applications at 0.8 kg ai/ha to tolerant (*pat* gene) rape at the 5–6 leaf growth stage and when plants were 50 cm high, residues in forage 154 days after the first application were 0.2 mg eq./kg and with major components NAG (71%) and glufosinate (7.9%). At harvest 102 days after the last application, ^{14}C residues in straw and hulls were 12.7 and 7.1 mg eq./kg respectively with major components NAG (57–77%) and glufosinate (21–31%). Lower levels of ^{14}C were detected in seed (0.5 mg eq./kg) with NAG (32%) the major component and glufosinate (6.2%) and MPP (9.7%) minor components together with trace amounts of MPA and MPB. In a comparison of crops made tolerant through incorporation of the *pat* or *bar* genes, the same metabolite profile was observed in shoots sampled 14 and 28 days after treatment for both modifications.

The pathway of glufosinate-ammonium in tolerant plants genetically modified to contain the *pat* or *bar* genes is rapid deactivation of L-glufosinate through N-acetylation to form NAG. D-glufosinate is not acetylated but rather undergoes slow metabolism to form MPP, MPB and MPA.

The metabolism of glufosinate-ammonium by plants is well understood for the three different situations. The metabolism of glufosinate-ammonium in conventional (glufosinate-susceptible) crops following directed application to weeds or as a pre-harvest desiccation use is in principle identical for the five standard crop groups: fruit crops, cereal/grass crops, leafy crops, root crops and pulses and oilseeds. For these crop groups major residue components consist of parent glufosinate and the metabolite MPP. In case of glufosinate-tolerant crops, NAG, MPP and glufosinate are the major components of the residue.

Environmental fate

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

Glufosinate-ammonium residues are not persistent in soils and residues in soils resulting from approved uses should not contribute significantly to the residues in succeeding crops.

In soil incubation studies under aerobic conditions in the dark at 20 °C, glufosinate disappeared with a half-life of 1–25 days. Glufosinate was not significantly metabolized in sterile soil demonstrating the importance of microbial metabolism in its soil degradation. Under aerobic soil incubation, the first metabolite formed was MPP followed by MPA, which mostly disappeared with half-lives in the range of 13–22 days (n=4) and 18 days (n=1) respectively. After 120 days, 17–81% of the applied dose was mineralised with 20–38% remaining unextracted with the solvents used. Further analysis of the unextracted portion of ^{14}C demonstrated incorporation into humin, fulvic acid and humic acid fractions present in the soil.

In a soil photolysis study with application of ^{14}C-glufosinate-ammonium on the surface of a sterilised sandy loam soil, glufosinate was stable to continuous irradiation for 120 hours suggesting photolysis has negligible effect on degradation when compared to metabolism.

Glufosinate-ammonium was also stable to hydrolysis in aqueous solutions at pH 5, 7 and 9 suggesting hydrolysis plays a negligible role in the degradation of glufosinate when compared to metabolism.

In a confined rotational crop study with wheat, lettuce and radish, a plot of sandy loam soil was treated with [^{14}C]-glufosinate-ammonium at the equivalent of 1.0 kg ai/ha and crops sown 28, 119 and 300/364 days. The proportion of ^{14}C residue attributed to glufosinate-related compounds decreased with increasing plant-back interval (PBI). In wheat straw and grain sown at a PBI of 119 days, MPP represented 22% TRR in straw and 12% in grain while MPA represented 6% TRR in straw and 0.3% in grain. Natural products accounted for the remaining TRR.

In summary, glufosinate 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 glufosinate and its metabolites MPP and NAG in various plant and animal commodities. Most of the analytical methods for the determination of glufosinate-derived residues developed prior to 2006 follow the same general principle. The relevant residues are usually extracted in water. Thereafter, the aqueous extract is concentrated to dryness and reacted with trimethyl orthoacetate in the presence of acetic acid. After silica gel purification the obtained derivatives are measured by GC/FPD or more recently by LC-MS/MS. LOQs are typically 0.01–0.05 mg/kg for glufosinate and MPP.

When reacted with trimethyl orthoacetate in the presence of acetic acid, glufosinate and NAG yield the same derivative. Therefore, glufosinate and NAG are usually determined together as a sum. However, if the two compounds are separated before derivatisation by means of cation exchange clean-up it is possible to determine the residues of glufosinate and NAG separately. In some methods glufosinate, NAG and MPP were measured separately with LOQs typically in the range 0.01 to 0.05 mg/kg.

With the availability of new liquid chromatography-columns specially designed for highly polar character and comparatively low molecular weight compounds such as glufosinate and its metabolites, it is possible to quantify glufosinate, MPP and NAG using LC/MS/MS without prior derivatisation (LOQs 0.01–0.02 mg/kg).

In another method, derivatisation of glufosinate was carried out with a mixture of o-phthalic dialdehyde and mercapto-propionic acid in the presence of sodium borate. The derivative of glufosinate is quantified by LC-MS/MS while the metabolites MPP and NAG are measured by LC-

MS/MS without prior derivatisation as in the previous approach (LOQs 0.01 mg/kg for each analyte for plant and animal matrices).

Multi-residue methods are currently not validated for glufosinate and its metabolites.

Stability of pesticide residues in stored analytical samples

The Meeting received information on the stability of glufosinate-ammonium and its metabolites MPP and NAG in samples of commodities from conventional crops stored frozen. NAG is not expected to be present in commodities from conventional crops.

Glufosinate, NAG and MPP are stable for at least 24 months in peaches when stored frozen. Glufosinate and MPP (NAG not studied) residues are stable for at least 6 months in kiwifruit, 12 months in almond, 20 months in blueberries, 24 months in apple, orange, maize grain and soya bean seeds from conventional crops stored frozen.

Glufosinate, NAG and MPP residues are stable for at least 24 months in tolerant sugar beet roots and tops and for at least 9 months in sugar beet processed fractions, for at least 24 months in soya bean seed and hay and at least 12 months for soya bean processed fractions, at least 23 months for rape seed, at least 24 months in maize forage and grain and at least 12 months in maize processed fractions, at least 26 months for sweet corn forage, at least 30 months for sweet corn ears, and at least 12 months for rice grain.

In animal commodities, glufosinate-ammonium, NAG and MPP were stable for at least 14 months in cow milk, muscle, liver and kidney. Glufosinate, NAG and MPP were stable for at least 15 months in hen eggs, muscle and liver.

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

Definition of the residue

Livestock may be exposed to residues present in feeds prepared from conventional and glufosinate-tolerant crops. Residues in conventional crops are principally glufosinate and MPP while in tolerant crops they are glufosinate and NAG. Metabolism of glufosinate in goats and hens involves formation of MPP and the slow transformation to MPA. NAG is metabolized by de-acetylation to form glufosinate with subsequent metabolism proceeding as for glufosinate. The major components of the residue in livestock are glufosinate, MPP and NAG and should be included in the residue definition for compliance with MRLs and estimation of dietary intake in animal commodities.

In the metabolism studies, residues in muscle and fat were too low to identify the proportions of the individual components required to determine relative partitioning between fat and muscle. In the metabolism study for NAG in lactating goats, radioactive residues in whole milk were 0.005–0.023 mg eq./kg, skim milk 0.007–0.023 mg eq./kg and cream 0.022–0.046 mg eq./kg with the profile of components similar in all three products. The data for milk suggest NAG partitions slightly more into the fat than aqueous portions of milk. In eggs, the concentration of glufosinate was greater in whites when compared to yolks while for NAG the opposite occurred. In the lactating cow feeding study with glufosinate and MPP, higher concentrations of glufosinate and MPP were found in fat compared to muscle. The combined residues of glufosinate (glufosinate +MPP+NAG) are borderline fat-soluble. The Meeting decided that residues of glufosinate are not fat-soluble.

Glufosinate ammonium is used on crops for three different situations:

- Directed sprays for weed control (crop not intentionally treated)
- Use as a crop desiccant to facilitate crop harvest (crop treated)
- Selective use in genetically modified glufosinate-tolerant crops (crop treated)

The main metabolite observed in studies with conventional crops (directed sprays for weed control, pre-emergent or pre-sowing applications) is MPP representing greater than 80% of the ^{14}C residue not attributed to natural products in apples, grapes, potatoes, wheat and corn fodder. However,

the residue levels are generally low, less than 0.1 mg/kg, with only occasional higher residues detected.

Following use as a crop desiccant, glufosinate was the major component of the residue in potato leaves and tubers, bean leaves, hulls and seeds and rape leaves, hulls and seeds accounting for more than 80% of TRR. MPP was also detected but generally represented less than 10% of the TRR.

In the case of foliar applications to glufosinate-tolerant crops, glufosinate, NAG and MPP are the major residue components. NAG accounted for 19–77% TRR in soya, maize, rape, rice and sugar beet foliage (forage, fodder, straw), 68% TRR in sugar beet roots, 11–63% TRR in grain and husks (soya, maize, rice, rapeseed). Glufosinate accounted for 8–31% TRR in soya, maize, rape, rice and sugar beet foliage (forage, fodder, straw), 19–24% TRR in sugar beet roots, < 2–18% TRR in grain and husks (soya, maize, rice, rapeseed). MPP generally represented no more than 12% TRR in foliage but was a significant component of the residue in grains at 3–72% TRR.

In plants, the majority of glufosinate-related residues in conventional and tolerant crops are accounted for in the previous residue definition; the sum of glufosinate, MPP and NAG. Although NAG is not a significant residue in conventional crops, some analytical methods do not distinguish between residues of glufosinate and NAG and so NAG should be included in the residue definition for compliance for conventional and tolerant crops.

The toxicological evaluation of glufosinate-ammonium concluded that the ADI and ARfD apply to glufosinate, NAG, MPP and MPA. MPA is a minor component of the residue and does not contribute significantly to dietary intake. The Meeting decided it was not necessary to include MPA in the residue definition for estimation of dietary intake.

Based on the above the Meeting confirmed the previous residue definition for compliance with MRLs and estimation of dietary intake as follows:

Definition of the residue for compliance with MRL and estimation of dietary intake (for animal and plant commodities): *sum of glufosinate, 3-[hydroxy(methyl)phosphinoyl]propionic acid (MPP) and N-acetyl-glufosinate (NAG), calculated as glufosinate (free acid).*

The residue is not fat-soluble.

Results of supervised residue trials on crops

The Meeting received supervised residue trial data for glufosinate-ammonium on citrus fruit, pome fruit, stone fruit, small fruit and berries including grapes, tropical fruit (inedible and edible peel), bulb onions, glufosinate-tolerant sweet corn, leafy vegetables, legume vegetables, pulses including glufosinate tolerant soy beans, carrots, potatoes, glufosinate tolerant sugar beet, asparagus, glufosinate tolerant maize, glufosinate tolerant rice, tree nuts, glufosinate tolerant cotton, conventional rape, glufosinate tolerant rape, sunflower and coffee as well as for some animal feed commodities.

Residues reported in supervised trials consist of glufosinate and NAG, often reported as the sum, and MPP. In metabolism studies, one of the three components comprises the majority of the combined total when all three are present. It is reasonable to assume when all three components are below the LOQ, the combined total is also below or close to the LOQ. Also when one component is above and the others below the LOQ, the combined residue is assumed to be equal to the residue of the main component. This is illustrated below.

Glufosinate	MPP	NAG	Total residues (glufosinate+MPP+NAG)
< 0.05	< 0.05	< 0.05	< 0.05 or where LOQs differ, the highest LOQ
< 0.05	< 0.05	0.06	0.06
0.05	< 0.05	0.09	0.14
< 0.05	0.06	< 0.05	0.06

The OECD calculator was used as a tool in the estimation of the maximum residue level from the selected residue data set obtained from trials conducted according to GAP. As a first step, the Meeting reviewed all relevant factors related to each data set in arriving at a best estimate of the

maximum residue level using expert judgement. Then, the OECD calculator was employed. If the statistical calculation spreadsheet suggested a different value from that recommended by the JMPR, a brief explanation of the deviation was provided.

Some use patterns for field crops include the possibility of pre-planting or pre-emergent applications together with post-emergent applications. Often the supervised trials for these field crops did not include pre-emergent application. However, as metabolism and rotational crop studies suggest the contribution from pre-emergent applications are negligible in comparison to the contribution from post-emergent applications, the lack of a pre-emergent application should not affect the decision as to whether the trials approximate critical GAP.

As no data were available for almond hulls, broad bean (dry) and peas (dry) the previous recommendations for these commodities are withdrawn.

Citrus (application to weeds)

Field trials involving citrus orchards where glufosinate-ammonium was applied to weeds were conducted in Brazil, Europe and the USA and were available to the Meeting.

The GAP for citrus in Brazil is application directed to weeds at 0.4 kg ai/ha with a PHI of 40 days. In the trials matching this GAP total glufosinate residues (glufosinate + NAG + MPP) in ranked order were (n=2): < 0.04 (2) mg/kg.

In Portugal, glufosinate ammonium is applied to weeds in citrus orchards at up to 1.5 kg ai/ha with a 0 day PHI. None of the trials from Europe matched the GAP of Portugal and an approved use on citrus in the USA was not available.

As the use pattern is application to weeds and not the crop, trials from different regions of the world can be used to support maximum residue level recommendations based on GAP from another region. The Meeting noted that total residues were < 0.05 (21) mg/kg in the trials on citrus (oranges, mandarin, grapefruit and lemons) conducted in the USA that utilized rates higher than permitted in Portugal (3×1.7 kg ai/ha USA versus 1–2 × 0.4–1.5 kg ai/ha in Portugal). Additionally, no residues were detected in trials in Europe that were conducted at rates lower than the maximum Portugal rate (2 sprays the last at 0.75 to 1.0 kg ai/ha). One trial from Brazil conducted at a much lower rate (0.4 kg ai/ha) reported very high residues at 10, 20 and 30 days after application with glufosinate the major component of the residue in fruit suggesting application to the fruit. This trial was not used in maximum residue estimation. The Meeting concluded that residues above LOQ are not expected in citrus fruit following application of glufosinate-ammonium to weeds growing in orchards.

The Meeting estimated a maximum residue level of 0.05 mg/kg for citrus fruit to replace its previous recommendation of 0.1 mg/kg. The Meeting estimated an STMR of 0.05 mg/kg and an HR of 0.05 mg/kg for citrus fruit.

Pome fruits (application to weeds)

Field trials involving apples and pears conducted in Brazil, Europe and the USA were made available to the Meeting.

Apples

The GAP for apples in Brazil is application directed to weeds at 0.4 kg ai/ha with a PHI of 7 days. In the trials matching this GAP the total glufosinate residues were (n=4): < 0.04 (4) mg/kg.

In Germany, glufosinate-ammonium is applied to weeds in apple orchards as two applications at up to 1.5 (spring) + 1 (spring/summer) kg ai/ha with a 14 day PHI. No residues (total glufosinate) were observed in 10 trials from Europe that approximated maximum GAP for Germany (n=10): < 0.05 (8) and < 0.06 (2) mg/kg.

GAP in the USA is application to weeds at a maximum rate of 1.7 kg ai/ha with a maximum annual rate of 5 kg ai/ha/year. The PHI is 14 days. No residues (total glufosinate) were detected (< 0.05 mg/kg) in 10 trials where application rates ranged from 1 × 1.1 kg ai/ha to 3 × 4.5 kg ai/ha.

The Meeting decided that residues of glufosinate are not expected in apples following directed application to orchard weeds.

Pears

Trials on pears with application to weeds were conducted in the USA but use of glufosinate-ammonium in pear orchards is not listed on USA labels. The use pattern in Germany allows glufosinate-ammonium to be applied to weeds in pear orchards as two applications at up to 1.5 (spring) + 1 (spring/summer) kg ai/ha with a 14 day PHI. Trials in the USA were assessed against the GAP of Germany. Total residues in six trials that approximated maximum GAP for Germany (n=6) were: < 0.05 (5) and 0.08 mg/kg.

In 25 of 26 trials on apples and pears that approximated the GAP of Germany or the USA, total residues were < LOQ. The residue value of 0.08 mg/kg in pear was due to MPP, likely taken up from soil. In the apple metabolism study where the soil beneath a tree was treated at 1.5 kg ai/ha, total residues in fruit were 0.1 mg/kg at harvest, fourteen weeks after the soil treatment. Occasional residues due to uptake of the soil degradation product MPP are expected, as are occasional residues of glufosinate due to spray directed to weeds inadvertently contacting fruit. As location of the trials should not be an important factor in the residues, the Meeting decided to combine the results for apples and pears and estimated a maximum residue level of 0.1 mg/kg for glufosinate residues in pome fruit replacing its previous recommendation of 0.05* mg/kg.

The STMR and HR for pome fruit are 0.05 and 0.08 mg/kg respectively.

Stone fruit (application to weeds)

Field trials involving application to weeds under apricot, cherry, peach, plum and nectarine trees were made available from Brazil, Europe and the USA.

In Brazil, weeds under peach and nectarine trees may be treated at 0.4 kg ai/ha with a PHI of 7 days. In the Netherlands weeds in fruit tree orchards may be sprayed at up to 1 kg ai/ha, no PHI required. In Canada weeds in peach and plum orchards may be sprayed at up to 0.75 kg ai/ha, maximum 1 kg ai/ha/year with a PHI of 40 days. In Portugal and Germany (except peach), weeds under stone fruit trees may be sprayed at up to 1.5 kg ai/ha with PHIs of not required for Portugal and 14 days for Germany. Use on stone fruit in the UK as at rates up to 0.75 kg ai/ha with no PHI required.

The location of the trial sites should not be a significant influence on residues in fruit when glufosinate-ammonium is applied to weeds. In a large number of trials from various locations total residues above the LOQ were infrequent. Occasional residues due to uptake of the soil degradation product MPP might be expected as are occasional residues of glufosinate due to spray directed to weeds inadvertently contacting fruit. Total residues in fruit from trials carried out with application rates ranging from 1 × 0.4 to 2 × 1.7 kg ai/ha were (n=42): apricot < 0.02, 0.05; cherry 0.02, < 0.05 (7); peach and nectarine < 0.02 (2), < 0.05 (19), 0.08; plum < 0.01 (5), 0.01 (3), < 0.05 (4), 0.06 and 0.07 mg/kg.

The Meeting estimated a maximum residue level of 0.15 mg/kg for stone fruit to replace its previous recommendation of 0.05* mg/kg. The Meeting estimated an STMR of 0.05 mg/kg and an HR 0.08 mg/kg.

Berries and other small fruit (application to weeds)

Currants

Glufosinate-ammonium is approved for application using spray shields to weeds between currant bushes in the Netherlands (1 kg ai/ha, no PHI required), the UK (soft fruit 0.75 kg ai/ha, no PHI required) and the USA (1.7 kg ai/ha, maximum 3.4 kg ai/ha/year, PHI 14 days). In twelve trials conducted in France, Germany and the UK where glufosinate-ammonium was applied as two sprays at 1 kg ai/ha, as two sprays with one at 1.6 kg ai/ha and the other at 1 kg ai/ha or as three sprays at

0.75 kg ai/ha, total residues in currants at PHIs of 0 to 28 days were (n=11): < 0.01_s (3), 0.01_s, < 0.02, $\underline{0.02}_s$, 0.05, 0.08_s, 0.12, 0.43_s and 0.48 mg/kg. Trials indicated with an "s" utilized a spray shield to reduce crop contamination. The major component of the samples with total residues 0.43 and 0.48 mg/kg were glufosinate and MPP respectively. Residues in currants appear to be from both uptake of MPP from soil and inadvertent contamination when spraying weeds. A trial with a total residue of 2.4 mg/kg was not used as the level was much higher than observed in the other trials with the residue due almost entirely to glufosinate. The magnitude of the residue was considered too high to represent good practice in application of glufosinate.

The Meeting estimated a maximum residue level of 1 mg/kg for currants to replace its previous recommendation of 0.5 mg/kg.

The Meeting estimated an STMR of 0.02 mg/kg and an HR of 0.48 mg/kg for currants.

Grapes

Trials were available from Brazil, Europe and the USA. The use pattern in Argentina is application to weeds at up to 1.6 kg ai/ha, no PHI required while Brazil allows application to weeds at 0.4 kg ai/ha with a PHI of 7 days. In Australia application to weeds is at up to 1 kg ai/ha no PHI required. Germany allows an application to weeds at 1.5 kg ai/ha in spring and one in summer at 1 kg ai/ha with a 14 day PHI. In the USA application to weeds is at up to 1.4 kg ai/ha with a maximum of 5 kg ai/ha/year and a PHI of 14 days. Residue data were available from 30 different trial locations with data presented for berries in accordance with the Codex Classification or for bunches. Where both berries and bunches were analysed only values for berries were considered.

In trials from Brazil matching GAP of that country total residues were: < 0.04 (3) mg/kg.

In trials from Europe approximating the GAP of Germany total residues were (n=14): < 0.01 (3), < 0.02 (3) $\underline{0.02}$ (2), < 0.05 (4), 0.06 and 0.12 mg/kg.

Total residues in grapes from US trials that approximated the GAP of the USA were (n=5): < 0.05 (5) mg/kg.

The Meeting considered the number of trials available from Brazil and the USA too few and utilized the trials from Europe approximating German GAP to estimate a maximum residue level of 0.15 mg/kg for grapes. The Meeting estimated an STMR of 0.02 mg/kg and an HR of 0.12 mg/kg for grapes.

Strawberries

Trials were available from Finland, France and Germany. GAP in strawberry in Australia is application to weeds at 1 kg ai/ha with no PHI required, Germany as a single shielded application to weeds at 0.8 kg ai/ha (pre-flowering of strawberry plants) with a 42 day PHI and UK one to two applications to weeds at up to 0.75 kg ai/ha with no PHI required.

Total residues in three trials approximating German GAP (but not using spray shields) were: < 0.05 (3) mg/kg.

Total residues in 8 trials approximating UK GAP, conducted as one to four sprays at 0.75 kg ai/ha with harvest 4 days after last application, were (n=8): < 0.01_s, < 0.01_s, 0.02_s, $\underline{0.02, 0.02}$, 0.03, 0.06 and 0.15 mg/kg. Trials indicated with an "s" utilized a spray shield to reduce crop contamination. Although the number of applications was greater than recommended, earlier applications should not contribute significantly to residues as the interval between sprays was 21–101 days compared to a typical interval between flowering and harvest of about 28 days.

The Meeting utilized trials approximating UK GAP to estimate a maximum residue level of 0.3 mg/kg for strawberries. The Meeting estimated an STMR of 0.02 mg/kg and an HR of 0.15 mg/kg for strawberries.

Blueberries

In trials conducted in the USA according to US GAP (application to weeds at 1.7 kg ai/ha, maximum 3.4 kg ai/ha/year, PHI 14 days) total residues in blueberries were (n=5): < 0.05 (4) and 0.06 mg/kg. The individual component responsible for the highest residue was glufosinate, possibly reflecting inadvertent exposure to spray during application. An additional trial with residues < 0.05 mg/kg had residues in control samples of 0.07 mg/kg and was therefore not considered. Inadvertent contamination of blueberries with glufosinate may occur when spraying weeds between bushes. The Meeting estimated a maximum residue level of 0.1 mg/kg, an STMR of 0.05 mg/kg and an HR of 0.06 mg/kg for blueberries.

Gooseberries

GAP in Germany is application using spray shields to weeds between bushes at 1×1 kg ai/ha, PHI 14 days, in the UK (soft fruit) application to weeds at 0.75 kg ai/ha with no PHI required and in the USA application to weeds at1.7 kg ai/ha with a maximum of 3.4 kg ai/ha/year and a PHI of 14 days). In three trials from Germany where weeds were sprayed at 2 × 1.5 kg ai/ha and approximating the GAP of the USA total residues were (n=3): < 0.02 (3) mg/kg.

Inadvertent contamination of gooseberries with glufosinate may occur when spraying weeds between bushes. The Meeting estimated an STMR of 0.02 mg/kg, an HR of 0.02 mg/kg and a maximum residue level of 0.1 mg/kg for gooseberries.

Raspberries

Trials were conducted on raspberry bushes in France, Germany and Italy. GAP in Australia is application to weeds at up to 1 kg ai/ha with no PHI required; Canada application to weeds at 1 kg ai/ha with no PHI required; Germany application using spray shields to weeds at 1 kg ai/ha with a PHI of 14 days; in the Netherlands application using spray shields to weeds at 1 kg ai/ha with no PHI required; and in the UK (soft fruit) application to weeds at 0.75 kg ai/ha with no PHI required. Total residues, after application at 3 × 0.75 kg ai/ha approximating the GAP of the UK were: < 0.01, 0.03 and 0.03 mg/kg. A spray shield was used in these trials to minimise crop contamination.

Inadvertent contamination of raspberries with glufosinate may occur when spraying weeds between raspberry plants. The Meeting estimated an STMR of 0.03 mg/kg, an HR of 0.03 mg/kg and a maximum residue level of 0.1 mg/kg for raspberries.

The Meeting agreed to withdraw its previous recommendation for berries and other small fruits (except currants) of 0.1 mg/kg.

Assorted tropical and sub-tropical fruit, edible peel (application to weeds)

Carambola

In Malaysia, weeds under carambola trees may be sprayed at 0.5 kg ai/ha, PHI 14 days. In two trials approximating GAP of Malaysia total residues were: < 0.05 (2) mg/kg.

Olives

Trials on olives were available from Europe and the USA. GAP in Portugal and Spain is application to weeds at up to 1.5 kg ai/ha, no PHI required in Portugal and 21 days in Spain while in Australia application to weeds of up to 1 kg ai/ha is permitted with no PHI required. In four trials from Europe where weeds in orchards were sprayed with two applications, the first at 1.1 and the second at 0.75 kg ai/ha, total residues at a PHI of 0 days were < 0.01 (2), 0.01 and 0.03 mg/kg. In three trials from the USA where weeds were treated at 3 × 1.5 kg ai/ha, total residues were all < 0.05 mg/kg 14 days after the last application.

Following the use of glufosinate-ammonium as a directed spray to control weeds in orchards residues of glufosinate are generally not expected as glufosinate is not readily taken up by roots. Occasional residues of MPP, the main degradation product in soil, are expected as MPP is

translocated through the crop. Inadvertent contamination of fruit by small amounts of glufosinate spray may also occur. The Meeting agreed that recommendations for maximum residue levels for assorted tropical and sub-tropical fruit, edible peel should accommodate the occasional residues that occur by the routes discussed above and that a level of 0.1 mg/kg would be adequate to accommodate such residues.

The Meeting estimated an STMR of 0.05 mg/kg, an HR of 0.05 mg/kg and a maximum residue level of 0.1 mg/kg for assorted tropical and subtropical fruit, edible peel.

Assorted tropical and sub-tropical fruit, inedible peel (application to weeds)

Banana

Glufosinate-ammonium is permitted to be used for weed control in banana plantations in Australia (1 kg ai/ha, PHI 0 days), Brazil (0.4 kg ai/ha, PHI 10 days), Columbia (0.3 kg ai/ha, PHI 0 days), Malaysia (0.5 kg ai/ha, PHI 14 days), Mexico (0.56 kg ai/ha, PHI 0 days), Philippines (2 kg ai/ha, PHI 0 days), Portugal (1.5 kg ai/ha, PHI 0 days) and Taiwan (1 kg ai/ha PHI 0 days).

Residues do not show a decline typical for application to fruit or foliage of bananas but rather following application to weeds and soil residues often only develop in fruit following a significant interval between spraying weeds and harvest of bananas, presumably due to uptake of MPP or D-glufosinate from soil. The Meeting decided to use the highest residue observed at any interval after application to weeds. In addition in many of the trials multiple applications were made at relatively long intervals between sprays (23 to 137 days) with harvest between sprays. The conditions preceding each harvest are sufficiently different to be considered as independent trials. Total residues in trials from Central and South America and the Philippines where weeds were treated at 1 × 0.3 kg ai/ha to 5 × 2 kg ai/ha + 8 × 1.2 kg ai/ha were (highest of pulp or peel if whole fruit not measured) (n=86): 0.02, < 0.04 (2), 0.04, < 0.05 (56), 0.05 (3), < 0.06 (3), 0.06 (8), 0.07 (3), 0.08 (4), 0.09, 0.10, 0.11 (2) and 0.13 mg/kg.

In two trials from Brazil conducted at a much lower rate (0.4 kg ai/ha), residues at 0 days after a single application at 0.4 kg ai/ha were 0.49 and 0.53 mg/kg with residues also observed at 3 and 7 days after application. As the high residue levels and the observation that glufosinate was the major component of the residue in fruit suggest direct application to the banana plants the Meeting could not be sure the residues represent inadvertent contamination. These two trials were not used for maximum residue estimation.

Using the available data, the Meeting estimated an STMR of 0.05 mg/kg, an HR of 0.13 mg/kg and a maximum residue level of 0.2 mg/kg to for bananas to confirm its previous recommendation of 0.2 mg/kg. The Meeting noted that for banana the IESTI accounts for 110% of the ARfD. The residues arise from uptake of glufosinate related residues from the soil. No suitable alternative GAP was identified that would resolve the intake concern.

Kiwifruit

Trials were available from Italy and the USA. GAP in Australia is application to weeds at 1 kg ai/ha with no PHI required and in Japan 1.4 kg ai/ha with a PHI of 21 days. Weeds under “woody crops” in Spain may be treated at 0.45–1.5 kg ai/ha, no PHI required. Total residues in nine trials conducted approximating the GAP of Spain with applications ranging from two sprays at 1.4 and 1.0 kg ai/ha to three sprays at 2.0 kg ai/ha were: < 0.01 (2), < 0.05 (4), 0.07, 0.10 and 0.37 mg/kg.

Using GAP of Spain, the Meeting estimated an STMR of 0.05 mg/kg, an HR of 0.37 mg/kg and a maximum residue level of 0.6 mg/kg to for kiwifruit. The Meeting noted that for kiwifruit the IESTI accounts for 110% of the ARfD. No residue data were identified that complied with an alternative GAP that would resolve the intake concern.

Avocado

In two trials approximating GAP in Australia for application to weeds in avocado orchards (1 kg ai/ha, no PHI required) total residues were: < 0.06 (2) mg/kg.

Guava

In two trials approximating GAP in Malaysia for weed control in guava orchards (0.5 kg ai/ha, PHI 14 days) total residues were: < 0.05 (2) mg/kg.

Mango

In two trials approximating GAP in Australia for weed control in mango orchards (1 kg ai/ha, no PHI required) total residues were: < 0.05 (2) mg/kg.

Papaya

In one trial approximating GAP in Australia for weed control in papaya orchards (1 kg ai/ha, no PHI required) total residues were: < 0.06 mg/kg.

As noted earlier, following the use of glufosinate-ammonium as a directed spray to control weeds in orchards residues of glufosinate are generally not expected as glufosinate is not readily taken up by roots. Occasional residues of MPP, the main degradation product in soil, are expected as MPP is translocated through the crop. Inadvertent contamination of fruit by small amounts of glufosinate spray may also occur. The Meeting agreed that recommendations for maximum residue levels for assorted tropical and sub-tropical fruit, inedible peel should accommodate the occasional residues that occur by the routes discussed above and that a level of 0.1 mg/kg would be adequate to accommodate such residues for fruit other than banana and kiwifruit.

The Meeting estimated an STMR of 0.05 mg/kg, an HR of 0.05 mg/kg and a maximum residue level of 0.1 mg/kg for assorted tropical and subtropical fruit, inedible peel (except banana and kiwifruit).

The Meeting agreed to withdraw its previous recommendation for assorted tropical and sub-tropical fruits-inedible peel (except banana) of 0.05* mg/kg.

Onion, bulb (pre-crop emergence or pre-sowing)

Use on glufosinate-ammonium on onions for control of weeds when applied pre-emergent or pre-sowing of onions is permitted in Canada (GAP 0.75 kg ai/ha, no PHI required). In twenty trials approximating Canada GAP total residues were: < 0.01 (6) and < 0.05 (14) mg/kg. The Meeting estimated an STMR of 0.05 mg/kg, an HR of 0.05 mg/kg and a maximum residue level of 0.05 mg/kg for bulb onions to confirm its previous recommendation of 0.05 mg/kg.

Sweet corn (tolerant)

Residue trials from the USA were received for use on glufosinate tolerant sweet corn however there is no associated GAP in the USA.

Corn salad (pre-crop emergence)

In Germany glufosinate-ammonium is approved for control of weeds in corn salad (lambs lettuce) when applied prior to emergence of the crop. The application rate is 0.6 kg ai/ha with no PHI required. Four trials were available from Germany on corn salad that matched GAP with total residues < 0.05 (4) mg/kg. The Meeting estimated an STMR of 0.05 mg/kg, an HR of 0.05 mg/kg and a maximum residue level of 0.05 mg/kg for corn salad to replace its previous recommendation of 0.05* mg/kg.

Lettuce (application to weeds)

Residue trials were available from Brazil and various countries from Europe following one directed spray to weeds or one spray pre-planting or a combination of the two. GAP was available for Brazil (directed application to weeds at 0.4 kg ai/ha, PHI 7 days, protect plants with plastic cups), Canada (pre-crop emergence, pre-crop sowing application to weeds at 0.75 kg ai/ha, no PHI required), Japan (directed application to weeds at 0.7 kg ai/ha, PHI 60 days) and Portugal (application to weeds pre-sowing/pre-emergence/pre-planting at 0.75 kg ai/ha, no PHI required). The Meeting decided to combine the dataset to recommend a maximum residue level for lettuce (leaf and head).

Total residues in trials approximating GAP of Brazil (0.4 kg ai/ha, PHI 7 days) were: < 0.04 (4) mg/kg.

Total residues from Europe approximating GAP of Portugal and following a single application to weeds at 0.75 kg ai/ha prior to planting the crop were: < 0.05 (7), 0.10 and 0.29 mg/kg.

The Meeting used the data from Europe to estimate an STMR of 0.05 mg/kg, an HR of 0.29 mg/kg and a maximum residue level of 0.4 mg/kg for both leaf lettuce and head lettuce. The Meeting noted that for lettuce the IESTI accounts for 180% of the ARfD. No suitable alternative GAP was identified that would resolve the intake concern.

Legume vegetables

Common bean (pre-crop emergence or application to weeds)

Glufosinate-ammonium is permitted to be used as a spray directed to weeds (Portugal 0.75 kg ai/ha, no PHI required; Germany 1 kg ai/ha, using a screen to protect the crop PHI 14 days; France 0.75 kg ai/ha no PHI required) and also as a spray to control weeds prior to crop emergence (the Netherlands 0.6 kg ai/ha, no PHI required).

Total residues in beans harvested immature (pods and/or immature seeds) from trials that did not use a screen to protect the crop from accidental contamination but otherwise complied with German GAP (1.0 kg ai/ha) were (n=7): < 0.05 (7) mg/kg. If a protective screen were used during application of glufosinate-ammonium, lower total residues would be expected.

The Meeting estimated an STMR of 0.05 mg/kg, an HR of 0.05 mg/kg and a maximum residue level of 0.05* mg/kg for common bean (pods and/or immature seeds) confirming its previous recommendation of 0.05 * mg/kg.

Pulses

Common beans (dry) (pre-harvest desiccation)

Residue data from trials in beans were made available from Brazil for pre-harvest desiccation use. The use pattern in Brazil is 0.4 kg ai/ha with a PHI of 5 days. The UK use is for pre-harvest desiccation at 0.45 kg ai/ha with a 7 day PHI.

In seven trials conducted in Brazil approximating Brazil GAP total residues were < 0.04 (4) and < 0.05 (3) mg/kg.

Common beans (dry) (directed application to weeds)

Directed sprays in the Portugal are permitted at up to 0.75 kg ai/ha with no PHI required and in Germany at up to 1 kg ai/ha using spray shields with a 14 day PHI. In eight trials conducted in Germany, total residues following a directed application at 1 kg ai/ha and after a 14 day PHI were: < 0.05 (8). In eight trials in Europe, total residues following two directed sprays at 0.75 kg ai/ha residues were: < 0.01 (8) at 62 to 122 days after the last application.

Rotational crop metabolism studies gave detectable residues suggesting the STMR should not be zero.

Residues were less than the limit of quantification following both pre-harvest desiccation and directed sprays to weeds. Utilising the dataset from Brazil, the Meeting estimated an STMR of 0.04 mg/kg and a maximum residue level of 0.05 mg/kg for common beans, dry to replace its previous recommendation of 2 mg/kg.

Soya beans, tolerant

The Meeting received field trials performed in the USA involving glufosinate tolerant soya beans. GAP for USA is for (1) one application pre-planting or pre-emergence at 0.59–0.74 kg ai/ha with additional applications from post-emergence to the early bloom growth stage at 0.45–0.59 kg ai/ha with a maximum seasonal rate of 1.3 kg ai/ha/year or (2) post-emergence only with applications from post-emergence to the early bloom growth stage at 0.41–0.50 kg ai/ha with a maximum seasonal rate of 0.91 kg ai/ha/year. The PHI is 70 days. Post-emergent application leads to higher residues. In trials approximating critical GAP in the USA total residues in soya bean seeds were (n=24): 0.22, 0.32, 0.39, 0.43, 0.51, 0.51, 0.56, 0.68, 0.70, 0.71, 0.78, 0.81, 0.84, 0.89, 0.96, 1.0, 1.1, 1.2, 1.2, 1.3, 1.3, 1.6, 1.7 and 1.9 mg/kg.

The Meeting estimated an STMR of 0.825 mg/kg and a maximum residue level of 3 mg/kg for soya bean, dry to replace its previous recommendation of 2 mg/kg.

Carrots (pre-crop emergence)

In Canada glufosinate-ammonium is approved for pre-emergent weed control in carrot crops (GAP: 0.41–0.75 kg ai/ha, PHI not required). The Netherlands permits the pre-crop emergence use of glufosinate-ammonium for weed control at a rate of 0.6 kg ai/ha and France allows bare soil cultivation at 0.75 kg ai/ha. In seventeen trials conducted in Europe with pre-crop emergence application at 0.6–0.75 kg ai/ha residues were: < 0.05 (17) mg/kg. Confined rotation crop studies suggest the residue is not zero.

The Meeting estimated an STMR of 0.05 mg/kg, an HR of 0.05 mg/kg and a maximum residue level of 0.05* mg/kg for carrots to confirm its previous recommendation of 0.05* mg/kg.

Potato (pre-harvest desiccation)

Glufosinate-ammonium is approved for pre-crop emergence or pre-harvest desiccation of potato crops in various countries. Use of glufosinate-ammonium prior to crop emergence does not lead to significant residues compared to use for pre-harvest desiccation. The Meeting agreed to use trials involving pre-harvest desiccation, with or without an application prior to crop emergence, to estimate a maximum residue level. Pre-harvest desiccation use-patterns approved in various countries include Brazil (GAP 0.4 kg ai/ha, PHI 10 days), France (GAP 2 × 0.38 kg ai/ha, PHI 14 days), Germany (GAP: 0.5 kg ai/ha at BBCH 90, PHI 14 days), Mexico (GAP 0.6 kg ai/ha), the Netherlands (GAP: 0.45 kg ai/ha or 0.38 kg ai/ha if crop is flailed), Portugal (GAP: 0.45 kg ai/ha, PHI 14 days), the UK (GAP:0.45 kg ai/ha, PHI 7 days) and the USA (GAP:0.42 kg ai/ha, PHI 9 days).

In trials conducted according to the GAP of Brazil total residues were: < 0.04 (4), < 0.05 (3) mg/kg.

In residue trials involving pre-harvest desiccation and approximating GAP of France total residues were: < 0.01, < 0.05 (6), 0.07, 0.08, 0.09, 0.11, 0.15, 0.16 (2) and 0.22 mg/kg.

In residue trials involving pre-harvest desiccation and approximating GAP of Germany total residues were: < 0.01 (3), 0.01, < 0.05, 0.06, 0.12, 0.21, 0.27 and 0.34 mg/kg.

In residue trials involving pre-harvest desiccation and approximating GAP of USA total residues were: < 0.05 (4), 0.06 (2), 0.1 (2), 0.11, 0.12 (2), 0.14, 0.16, 0.18, 0.24, 0.26, 0.28, 0.32, 0.38 and 0.62 mg/kg.

Using the residue data from the USA, the Meeting estimated an STMR of 0.12 mg/kg, an HR of 0.62 mg/kg and a maximum residue level of 0.8 mg/kg. The Meeting noted that for potatoes the IESTI accounts for 320% of the ARfD.

An alternative GAP was available from Brazil for pre-harvest desiccation at an application rate of 0.4 kg ai/ha with a PHI of 10 days. Total residues were < 0.04 (4), < 0.05 (3) mg/kg. The Meeting estimated a maximum residue level of 0.1 mg/kg for potatoes and noted in estimating STMR and HR values of 0.05 and 0.05 mg/kg respectively that occasional finite residues are expected.

Sugar beet, tolerant

In the USA glufosinate-ammonium is approved for use on glufosinate tolerant sugar beet. GAP for USA is for either (i) a pre-planting or pre-emergence application at 0.59–0.74 kg ai/ha or (ii) post-emergence application from post-emergence from the cotyledon stage up to the 10-leaf stage (BBCH 19) at 0.29–0.61 kg ai/ha with a maximum seasonal rate of 1.2 kg ai/ha/year and a PHI of 60 days. Post-emergent application leads to higher residues. In trials approximating critical GAP in the USA total residues in sugar beet roots were (n=13): 0.06, 0.11, 0.14, 0.20, 0.27, 0.27, 0.28, 0.31, 0.39, 0.42, 0.54, 0.62 and 0.67 mg/kg.

The Meeting estimated an STMR of 0.28 mg/kg and a maximum residue level of 1.5 mg/kg for sugar beet to replace its previous recommendation of 0.05 (*) mg/kg.

Asparagus (pre-crop emergence)

Trials were available following application pre-crop emergence for weed control in asparagus. In Canada pre-crop emergence application is permitted with an application rate of 0.4–0.75 kg ai/ha with a PHI not required while the Netherlands permits pre-emergence application to crops at 0.6 kg ai/ha with application no later than 3 days before crop emergence (PHI 3 days). GAP in Germany is application at prior to crop emergence at 0.6 kg ai/ha with no PHI required.

The trials were assessed against the GAP of Canada providing total residues of 0.01, < 0.05 (6), 0.16 and 0.27 mg/kg.

The Meeting estimated an STMR of 0.05 mg/kg, an HR of 0.27 mg/kg and a maximum residue level of 0.4 mg/kg for asparagus to replace its previous recommendation of 0.05* mg/kg.

Maize, tolerant

The Meeting received field trials performed in the USA involving glufosinate tolerant maize. GAP for USA is for (i) pre-planting or pre-emergence application at 0.59–0.74 kg ai/ha with a maximum seasonal rate of 0.74 kg ai/ha or (ii) post-emergence application from post-emergence until corn is 61 cm tall or in the V-7 growth stage (i.e., 7 developed collars) at 0.41–0.5 kg ai/ha with a maximum seasonal rate of 0.91 kg ai/ha/year and a PHI of 70 days. Post-emergent application leads to higher residues. In trials approximating critical GAP in the USA total residues in maize grain were (n=32): < 0.05 (27), 0.05, 0.06 and 0.07 (3) mg/kg.

The Meeting estimated an STMR of 0.05 mg/kg and a maximum residue level of 0.1 mg/kg for maize confirming its previous recommendation of 0.1 mg/kg.

Rice, tolerant

The Meeting received field trials performed in the USA involving glufosinate tolerant rice. GAP for USA is for (i) pre-planting or pre-emergence application at 0.59–0.74 kg ai/ha with a maximum seasonal rate of 0.74 kg ai/ha or (ii) applications post-emergence from the 1-leaf stage through the mid-tillering stage of crop development at 0.41–0.5 kg ai/ha with a maximum seasonal rate of 0.91 kg ai/ha/year and a PHI of 70 days. Post-emergent application leads to higher residues. The Meeting considered the growth stage at last application to be an important factor in considering whether or not trials were conducted according to critical GAP. In trials approximating critical GAP in the USA total residues in rice grain (with husk) were (n=20): < 0.05 (5), 0.05, 0.07, 0.07, 0.08, 0.08, 0.10, 0.10, 0.14, 0.15, 0.17, 0.20, 0.35, 0.47, 0.51 and 0.73 mg/kg.

The Meeting estimated an STMR of 0.09 mg/kg and a maximum residue level of 0.9 mg/kg for rice.

Tree nuts (application to weeds)

Application to tree nuts is for weed control in the orchard including under the tree canopy. The use pattern in the USA is application to weeds at 0.84–1.68 kg ai/ha with a maximum seasonal rate of 5.0 kg ai/ha and a PHI of 14 days. Application to tree nuts in Australia is at 0.2–1.0 kg ai/ha and in the UK at 0.45–0.75 kg ai/ha, both with a PHI not required. In trials approximating GAP, total residues in tree nuts were:

Almonds: < 0.05, < 0.05, < 0.05, 0.07 mg/kg (GAP of USA)

Hazelnut: < 0.05, < 0.05, < 0.05 mg/kg (two times GAP of UK)

Macadamia: < 0.06, < 0.12 mg/kg (GAP of Australia)

Pecan: < 0.05, < 0.05, < 0.05 mg/kg (GAP of USA)

Walnut: < 0.05, < 0.05, < 0.05, < 0.05, < 0.05 mg/kg (GAP of USA).

Residues for the sum of glufosinate and NAG were: Almonds: < 0.05 (4) mg/kg (GAP of USA), Hazelnut: < 0.05 (3) mg/kg (two times GAP of the UK), Macadamia: < 0.05, < 0.09 mg/kg (GAP of Australia), Pecan: < 0.05 (3) mg/kg (GAP of USA) and Walnut: < 0.05 (5) mg/kg (GAP of the USA).

The Meeting considered the four almond, three pecan, five walnut, two macadamia and three hazelnut trials as a group. The Meeting estimated an STMR of 0.05 mg/kg and a maximum residue level of 0.1 mg/kg for tree nuts confirming its previous recommendation.

Cotton seed, tolerant

The Meeting received field trials performed in the USA involving glufosinate tolerant cotton. GAP for USA is for (i) pre-planting or pre-emergence application at 0.59 kg ai/ha and post-emergence use from emergence up to the early bloom stage at 0.45–0.59 kg ai/ha with a maximum seasonal rate of 1.8 kg ai/ha/year or (ii) pre-planting or pre-emergence application at 0.561–0.88 kg ai/ha and post-emergence use from emergence up to the early bloom stage at 0.45–0.59 kg ai/ha with a maximum seasonal rate of 1.5 kg ai/ha/year or (iii) post-emergence use from emergence up to the early bloom stage at 0.29–0.58 kg ai/ha with a maximum seasonal rate of 1.2 kg ai/ha/year. The PHI is 70 days. Post-emergent application leads to higher residues. In trials approximating critical GAP in the USA total residues in cotton seed were (n=14): 0.15, 0.24, 0.30, 0.30, 0.34, 0.57, 0.63, 0.78, 1.1, 1.1, 1.3, 1.7, 2.3 and 3.2 mg/kg.

The Meeting estimated an STMR of 0.705 mg/kg and a maximum residue level of 5 mg/kg for cotton seed.

Rape seed, conventional (pre-harvest desiccation) and tolerant

Glufosinate-ammonium is approved for pre-harvest desiccation of conventional rape in Germany (GAP: 0.5 kg ai/ha, PHI 14 days) and the UK (GAP: 0.45 kg ai/ha, PHI 7 days). Total residues in rape seeds from trials conducted in Germany approximating German GAP were (n=12): < 0.05, 0.15, 0.19, < 0.2, < 0.2, < 0.2, 0.25, 0.25, 0.26, 0.63 and 0.76 mg/kg.

The Meeting received field trials performed in the USA involving glufosinate tolerant rape. GAP for USA is for (i) pre-planting or pre-emergence application at 0.59–0.74 kg ai/ha with a maximum seasonal rate of 0.74 kg ai/ha or (ii) application post-emergence from the cotyledon stage up to the early bolting stage of crop development at 0.47–0.5 kg ai/ha with a maximum seasonal rate of 0.99 kg ai/ha/year and a PHI of 65 days. Post-emergent application leads to higher residues. In trials approximating GAP in the USA total residues in rape seeds were (n=5): < 0.05, 0.06, 0.19, 0.22 and 7.9 mg/kg.

The Meeting considered five trials inadequate to estimate a maximum residue level for rape when glufosinate-ammonium is used on tolerant crops and decided to use the trials for pre-harvest desiccation of conventional crops to estimate an STMR of 0.225 mg/kg and a maximum residue level of 1.5 mg/kg for rape seed replacing its previous recommendation of 5 mg/kg.

Sunflower seed (pre-harvest desiccation)

Glufosinate–ammonium is approved for pre-harvest desiccation of sunflowers in Germany (GAP: 0.5 kg ai/ha, PHI 14 days). Total residues in trials from Germany approximating German GAP were: 0.43, 0.79, 1.2 and 2.3 mg/kg (all at 0.6 kg ai/ha). Additional trials from Hungary had total residues: 0.05, 0.25, 0.38, 0.27 and 0.46 mg/kg (all at rates 0.34–0.36 kg ai/ha)

The Meeting noted that the number of trials available from Germany is inadequate for the purpose of estimating a maximum residue level and the trials from Hungary do not match a relevant GAP. However, as the application of glufosinate-ammonium is for desiccation, the Meeting considered it valid to scale the residues in both sets of trials to the German GAP application rate. Total residues (scaled to an application rate of 0.5 kg ai/ha) in sunflower were (n=9): 0.07, 0.36, 0.36, 0.40, 0.53, 0.66, 0.68, 1.0 and 1.9 mg/kg.

The Meeting estimated an STMR of 0.53 mg/kg and a maximum residue level of 3 mg/kg for sunflower seed replacing its previous recommendation of 5 mg/kg.

Coffee beans (application to weeds)

In two trials from Brazil residues in coffee beans were < 0.04 (2). The Meeting considered two trials inadequate to estimate a maximum residue level. However, the Meeting considered there is sufficient other evidence, including from other fruiting trees and shrubs, to conclude the use pattern should not lead to residues above the LOQ although occasional residues of MPP through uptake from soil may occur and decided to estimate an STMR of 0.04 mg/kg and a maximum residue level of 0.1 mg/kg for coffee beans.

Animal feeds

Sweet corn forage, tolerant

The current Meeting received trials on glufosinate tolerant sweet corn forage and stover performed in USA. No GAP for the USA was available.

Bean forage and fodder (Common bean) (pre-crop emergence or application to weeds in crop)

Residue levels occurring in shoots and green material of conventional beans were evaluated. Glufosinate-ammonium is permitted to be used as a spray directed to weeds growing in bean crops (Portugal 0.75 kg ai/ha, no grazing restriction; Germany 1 kg ai/ha, using a screen to protect the crop, no grazing restriction; France 0.75 kg ai/ha no grazing restriction) and also as a spray to control weeds prior to crop emergence (the Netherlands 0.6 kg ai/ha, no grazing restriction).

In considering the available trials it was agreed that shoots at 14 or more days after application at beginning of flowering would be representative of forage. Total residues approximating GAP of France and Portugal (0.75 kg ai/ha) were (n=8): < 0.05, < 0.05, < 0.05, < 0.05, < 0.05, 0.06, 0.08 and 0.19 mg/kg. The Meeting estimated a median and a highest residue level of 0.05 mg/kg and 0.19 mg/kg respectively for bean forage (both on an as received basis).

Residue levels occurring in straw of conventional beans following directed application use were also available to the Meeting. In eight trials conducted in Germany, total residues following a directed application at 1 kg ai/ha with harvest 39 to 65 days after application were: < 0.05 (4), < 0.1, 0.15, 0.22 and 0.63 mg/kg (on an as received basis). The Meeting estimated a median residue of 0.075 mg/kg, a highest residue of 0.63 mg/kg (both on an as received basis) and a maximum residue level of 1 mg/kg for bean fodder (on a dry weight basis).

Miscellaneous fodder and forage crops

Sugar beet tops, tolerant

The Meeting received trials on glufosinate tolerant sugar beet) performed in the USA.

GAP for USA is for either (i) a pre-planting or pre-emergence application at 0.59–0.74 kg ai/ha or (ii) post-emergence application from post-emergence from the cotyledon stage up to the 10-leaf stage (BBCH 19) at 0.29–0.61 kg ai/ha with a maximum seasonal rate of 1.2 kg ai/ha/year and a PHI of 60 days. There is a restriction on the use of treated glufosinate tolerant sugar beet tops for livestock feed: Do not graze the treated crop or cut for hay. The Meeting did not receive GAP relevant to the use of sugar beet tops for livestock feed.

Straw, forage and fodder of cereal grains and grasses

Maize forage and stover, tolerant

For the current evaluation the Meeting received field trials involving glufosinate tolerant maize performed in USA. GAP for USA is for (i) pre-planting or pre-emergence application at 0.59–0.74 kg ai/ha with a maximum seasonal rate of 0.74 kg ai/ha or (ii) post-emergence application from post-emergence until corn is 61 cm tall or in the V-7 growth stage, (i.e., 7 developed collars) at 0.41–0.5 kg ai/ha with a maximum seasonal rate of 0.91 kg ai/ha/year and a PHI of 60 days for forage and 70 days for fodder. Post-emergent application leads to higher residues.

Total residues in maize forage from trials approximating USA critical GAP were (n=13): < 0.05, 0.06, 0.33, 0.50, 0.53, 0.54, 0.78, 0.82, 0.89, 1.1, 1.2, 1.5 and 1.6 mg/kg (fresh weight basis). The Meeting estimated median and highest residues of 0.78 and 1.6 mg/kg respectively.

Total residues in maize silage from trials approximating critical GAP in the USA were: < 0.05, 0.11, 0.12, 0.15, 0.32, 0.34, 0.36, 0.40, 0.43, 0.90, 1.2, 1.2, 1.6, 1.7 and 2.1 mg/kg (fresh weight basis). The Meeting estimated median and highest residues of 0.40 and 2.1 mg/kg respectively, both on a fresh weight basis.

Total residues in maize fodder/stover (fresh weight basis) from trials approximating USA GAP were (n=31): < 0.05, 0.09, 0.12, 0.13, 0.16, 0.17, 0.18, 0.24, 0.33, 0.41, 0.50, 0.53, 0.64, 0.68, 0.69, 0.72, 0.78, 1.3, 1.4, 1.4, 1.4, 1.4, 1.5, 1.7, 1.8, 1.9, 1.9, 2.8, 2.9 and 5.3 mg/kg. The Meeting estimated median and highest residues of 0.72 and 5.3 mg/kg respectively, both on a fresh weight basis and a maximum residue level of 8 mg/kg for maize fodder.

Rice, tolerant

The Meeting received field trials performed in the USA involving glufosinate tolerant rice. GAP for USA is for (i) pre-planting or pre-emergence application at 0.59–0.74 kg ai/ha with a maximum seasonal rate of 0.74 kg ai/ha or (ii) application post-emergence from the 1-leaf stage through the mid-tillering stage of crop development at 0.41–0.5 kg ai/ha with a maximum seasonal rate of 0.91 kg ai/ha/year and a PHI of 70 days. Post-emergent application leads to higher residues.

In the trials matching the critical GAP, glufosinate total residues in rice straw on an as received basis were (n=21): 0.05 (2), 0.06, 0.11, 0.12 (2), 0.14, 0.16, 0.24, 0.25, 0.26, 0.29, 0.30, 0.34, 0.35, 0.37, 0.54, 0.62, 0.63, 0.93 and 1.3 mg/kg.

The Meeting estimated median and highest residues of 0.26 and 1.3 mg/kg respectively together with a maximum residue level of 2 mg/kg for rice straw.

Cotton (tolerant) gin trash, tolerant

The Meeting received field trials performed in the USA involving glufosinate tolerant cotton. GAP in the USA is (i) pre-planting or pre-emergence application at 0.59 kg ai/ha and post-emergence use from emergence up to the early bloom stage at 0.45–0.59 kg ai/ha with a maximum seasonal rate of 1.8 kg ai/ha/year or (ii) pre-planting or pre-emergence application at 0.561–0.88 kg ai/ha and post-emergence use from emergence up to the early bloom stage at 0.45–0.59 kg ai/ha with a maximum seasonal rate of 1.5 kg ai/ha/year or (iii) post-emergence use from emergence up to the early bloom stage at 0.29–0.58 kg ai/ha with a maximum seasonal rate of 1.2 kg ai/ha/year. Post-emergent application leads to higher residues. In trials approximating critical GAP in the USA total residues in cotton gin trash were (n=7): 0.62, 0.65, 1.1, 1.5, 3.4, 4.0 and 7.4 mg/kg (on an as received basis).

The Meeting estimated a median residue of 1.5 mg/kg for cotton gin trash.

Rotational crop residues

Soil residues of glufosinate, MPP and NAG are not persistent and the maximum single spray application rate for weeds in non-permanent crops of 1 kg ai/ha can be used (after adjusting for likely interception of spray by crops and weeds) as a basis for estimating likely residues in soil that might transfer to rotational (follow) crops. If it is assumed weeds and crop present at the time of application intercept 50% of the spray, the amount reaching the soil would be equivalent to an application rate to bare soil of 0.5 kg ai/ha. Trials on residues in follow crops were made available to the Meeting. At plant-back intervals of 69 to 174 days after application at 0.6 to 0.9 kg ai/ha to cotton, residues in follow crops (mustard greens, turnips) were < LOQ except for some wheat forage, straw and hay samples for which total residues ranged from < 0.05 to 0.14 mg/kg. Residues were also < 0.05 mg/kg in wheat commodities grown following a potato crop treated at 0.45 kg ai/ha and at plant back intervals of 30 days.

In the confined rotation crop study where crops were rotated into soil previously treated with ^{14}C-glufosinate-ammonium at the equivalent of 1 kg ai/ha, total residues (sum of glufosinate, MPP and NAG) were < 0.05 mg/kg in radish tops and lettuce at a plant back interval of 28 days and 0.15, 0.38 and 0.12 mg/kg in wheat forage, straw and grain respectively. At longer plant back intervals residues were all < 0.05 mg/kg.

The Meeting considered residues in rotational crops above the LOQ would be unlikely.

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 glufosinate during the processing of oranges, plums, grapes, olives, potatoes, sugar beet, soy bean, oilseed rape/canola, cotton seed, sunflower seed, maize and rice. A study of the nature of the residue of glufosinate, NAG and MPP under simulated processing conditions (pasteurization, baking/brewing/boiling, sterilization) showed glufosinate, MPP and NAG are stable.

Summary of selected processing factors for glufosinate

Raw commodity	Processed commodity	Individual PF	Best estimate PF	$STMR_{RAC}$ (mg/kg)	$STMR_{RAC}$ × PF (mg/kg)
Orange	Juice	0.71	0.71	0.05	0.036
	Dried peel / pulp	2.21	2.21		0.11
	Molasses	2.65	2.65		0.13
	Oil	< 0.13	< 0.13		< 0.0065
Plum	Dried fruit	1.79	1.79	0.05	0.090
Olive	Oil	< 0.65	< 0.65	0.05	< 0.0325
Potato	Chips	2.2	2.2	0.05	0.11
	Flakes	1.78 2.77 2.91 3.43 3.06	2.91		0.146
	Crisps	1.61 1.61 1.70 2.12	1.655		0.083
	French fries	0.89 1.18 1.30 1.48	1.24		0.062
	Boiled potatoes	0.47 0.60 0.79 0.99	0.695		0.035
	Fried potatoes	0.95 1.48 1.78 2.01	1.63		0.082
	Baked potatoes	1.05 1.26 1.29 1.54	1.275		0.064
Sugar beet	Dried pulp	0.59	0.59	0.28	0.168
	Molasses	3.70 4.94 6.32 6.82	5.63		1.568
	Raw or refined sugar	< 0.08 < 0.10 < 0.29 < 0.91	< 0.195		0.056
Soya bean	Aspirated grain fraction	2.73 8.89	5.81	0.825	4.78
	Hulls	3.15, 11.4	7.275		6.02
	Meal	1.22	1.22		0.99
	Oil	< 0.04 < 0.74	< 0.74		< 0.61
Rape/canola	Meal	1.74, 1.94, 2.44, 2.55	2.19	0.225	0.495
	Oil	< 0.13 < 0.22 < 0.48 < 0.94 < 0.94	< 0.48		< 0.108
Cottonseed	Hulls	1.16	1.16	0.705	0.818

Raw commodity	Processed commodity	Individual PF	Best estimate PF	$STMR_{RAC}$ (mg/kg)	$STMR_{RAC}$ × PF (mg/kg)
	Meal	1.25	1.25		0.881
	Oil	< 0.02	< 0.02		< 0.014
Sunflower seed	Oil	< 0.03 < 0.07 < 0.08	< 0.07	0.53	< 0.037
Maize	Aspirated grain fraction	8.85 12.06	10.455	0.05	0.52275
Rice	Hull	1.85 2.29	2.07	0.09	0.1863
	Bran	0.74 0.87	0.805		0.0724
	Polished grain	0.60 0.94	0.77		0.0693

Residues are not expected in oils obtained from treated crops and did not concentrate in bran.

Residues in sugar beet molasses were much higher than in sugar beets. The Meeting estimated a maximum residue level of 8 mg/kg based on the recommended maximum residue level for sugar beet (1.5 mg/kg) and a processing factor of 5.63.

Residues in prunes were also higher than in fresh plums and the Meeting estimated a maximum residue level of 0.3 mg/kg for dried prunes based on the recommended maximum residue level for stone fruit (0.15 mg/kg) and a processing factor of 1.79.

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 glufosinate and MPP at total dietary levels of 4, 12 and 40 ppm for the sum of glufosinate and MPP expressed as glufosinate free acid for 28 consecutive days. The ratio of glufosinate to MPP in the feed was 3:1. Apart from milk of a single dosed cow on days 0, 1 (0.03 mg/kg) and 9 (0.02 mg/kg) and a control milk sample (0.03 mg/kg), no residues were detected in milk (LOQ of 0.02 mg/kg) samples analysed at all dose levels and time intervals. The highest total residues (mean in brackets) in liver, kidney, fat and muscle from the highest dose animals were 10.7 (9.0), 7.5 (5.4), 0.16 (0.10) and < 0.05 (< 0.05) mg/kg respectively.

In an additional study dairy cows were fed glufosinate and NAG at total dietary levels of 9.1, 27.3 and 91 ppm for the sum of glufosinate and NAG expressed as glufosinate free acid for 28 consecutive days. The ratio of glufosinate to NAG in the dose was 1:5.5. Milk residues for the highest dose group were 0.07 mg/kg. Milk from one animal had much higher residues on two consecutive days that coincided with a dramatic reduction in feed consumption. These results were excluded from the analysis. The highest total residues (mean in brackets) in liver, kidney, fat and muscle from the highest dose animals were 0.13 (0.11), 0.29 (0.27), < 0.05 (< 0.05) and < 0.05 (< 0.05) mg/kg respectively.

The Meeting also received information on the residue levels arising in tissues and eggs, when laying hens were fed a diet containing glufosinate and MPP at total dietary levels of 4.5, 13.5 and 45 ppm glufosinate and MPP (both as glufosinate free acid) for 28 consecutive days. The ratio of glufosinate to MPP in the feed was 3.5:1. Residues in eggs for the highest feed group reached a maximum of 0.07 mg/kg at between day 7 and 13 of exposure. The mean total residues in liver, fat and muscle from the highest dose animals were < 0.10, 8.0, < 0.05 and < 0.05 mg/kg respectively.

In an additional study laying hens were dosed with glufosinate and NAG at levels equivalent to 0.44, 1.3 and 4.4 ppm in the feed for the sum of glufosinate and NAG expressed as glufosinate free acid for 28 consecutive days. The ratio of glufosinate to NAG in the dose was 1:5.3. Egg residues were < 0.05 mg/kg for all dose groups. Similarly, residues in liver, kidney, fat and muscle were all < LOQ (< 0.05 mg/kg for muscle, kidney, skin and fat and < 0.1 mg/kg for liver).

Animal commodity maximum residue levels

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

Potential cattle feed items include: soya bean hulls, cotton gin by-products, sugar beet molasses, cottonseed meal, maize forage/silage, soya bean meal, soya bean seed, potato culls, maize aspirated grain fractions, rice straw.

Potential poultry feed items include: soya bean hulls, cotton seed meal, maize forage/silage, soya bean meal, soya bean seed, potato culls, rice grain, rice bran/pollard, bean seed, maize grain.

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	2.4	1.8	4.7[a]	2.4[c]	4.3	1.8	1.3	0.9
Dairy cattle	2.7	1.4	4.0	2.3[d]	4.4[b]	1.8	2.5	1.5
Poultry Broiler	0.5	0.5	1.2	1.2[f]	0.7	0.7	0.4	0.4
Poultry Layer	0.5	0.5	1.4[e]	0.9[g]	0.7	0.7	0.4	0.4

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

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

Two lactating dairy cow feeding studies were available to the Meeting. The first addressed feed consisting of ingredients selected from conventional crops and therefore with residues dominated by glufosinate (crop desiccation uses) and MPP (weed control uses). Estimates of highest and median residues made using the first feeding study are relevant if glufosinate is the major component of the total glufosinate residue in the feed. A review of metabolism and residue studies available for feed items that contribute most to the dietary burden for dairy and beef cattle showed that glufosinate is the major component of the total residues in livestock feed. Therefore the first feeding study is used to estimate residues in meat, edible offal and milk.

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

Glufosinate + MPP feeding study	Feed level	Residues	Feed level	Residues (mg/kg) in			
	(ppm) for milk residues	(mg/kg) in milk	(ppm) for tissue residues	Muscle	Liver	Kidney	Fat
Maximum residue level beef or dairy cattle							
Feeding study [a]	4.0 12	< 0.02 0.02	4.0 12	< 0.05 < 0.05	1.63 4.2	0.41 2.0	0.06 0.08
Dietary burden and high residue	4.4	< 0.02	4.7	< 0.05	1.85	0.55	0.062
STMR beef or dairy cattle							
Feeding study [b]	4.0	< 0.02	4.0	< 0.05	1.18	0.38	0.05
Dietary burden and residue estimate	2.3	< 0.012	2.4	< 0.03	0.708	0.228	0.03

[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 STMR values: milk 0.012 mg/kg; muscle 0.03 mg/kg; edible offal 0.708 mg/kg for liver and 0.228 mg/kg for kidney and fat 0.03 mg/kg. The following HR values are also estimated: milk 0.02 mg/kg; muscle 0.05 mg/kg; edible offal 1.85 mg/kg for liver and 0.55 mg/kg for kidney and fat 0.062 mg/kg.

The Meeting estimated the following maximum residue levels: milk 0.02 mg/kg; meat (mammalian except marine mammals) 0.1 mg/kg and edible offal 3 mg/kg to replace its previous recommendations of: milk 0.02* mg/kg; meat (mammalian except marine mammals) 0.05* mg/kg and edible offal 0.1* mg/kg. The Meeting noted that for cattle liver the IESTI accounts for 140–170% of the ARfD.

The corresponding calculations for poultry are provided below.

	Feed level	Residues	Feed level	Residues (mg/kg) in			
	(ppm) for egg residues	(mg/kg) in egg	(ppm) for tissue residues	Muscle	Liver	Skin	Fat
Maximum residue level broiler or laying hen							
Feeding study [a]	4.5	< 0.05	4.5	< 0.05	< 0.1	< 0.05	< 0.05
Dietary burden and residue estimate	1.4	< 0.016	1.4	< 0.016	< 0.031	< 0.016	< 0.016
STMR broiler or laying hen							
Feeding study [b]	4.5	< 0.05	4.5	< 0.05	< 0.1	< 0.05	< 0.05
Dietary burden and residue estimate	0.9	< 0.01	1.2	< 0.013	< 0.027	< 0.013	< 0.013

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

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

For poultry no residues are expected. The Meeting estimated the following maximum residue levels for poultry commodities: poultry meat 0.05* mg/kg; poultry edible offal 0.1* mg/kg and eggs 0.05* mg/kg.

The mean dietary burden of poultry is 0.9 ppm for layers and 1.4 ppm for broilers. The Meeting estimated the following STMR values: poultry meat 0 mg/kg; poultry fat 0 mg/kg; poultry edible offal (based on liver) 0 mg/kg and eggs 0 mg/kg.

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.

The evaluation of glufosinate resulted in recommendations for maximum residue levels and STMR values for raw and processed commodities. Where data on consumption were available for the listed food commodities, dietary intakes were calculated for the 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 6–10% of the maximum ADI (0.01 mg/kg bw). The Meeting concluded that the long-term intake of residues of glufosinate 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.

For bananas, kiwifruit, lettuce, soya bean (dry) and cattle liver, the IESTI represented 110, 110, 180, 120 and 170% respectively of the ARfD of 0.01 mg/kg bw. Since MPP represents the

majority of the residue in bananas, kiwifruit, lettuce and cattle liver, and because MPP is of lower toxicity than glufosinate, these exceedances are unlikely to present a public health concern. Although the IESTI for soya beans represented 120% of the ARfD, MPP represents about 15% of the residues. The Meeting concluded that the short-term intake of residues of glufosinate resulting from uses that have been considered by the JMPR is unlikely to present a public health concern.

5.22 IMIDACLOPRID (206)

RESIDUE AND ANALYTICAL ASPECTS

Imidacloprid was first evaluated by the JMPR in 2001 for toxicology. The Meeting derived an ADI of 0–0.06 mg/kg bw and an ARfD of 0.4 mg/kg bw. The compound was evaluated for residues in 2002, 2006 and 2008. In 2002, the Meeting agreed that the residue definition for compliance with the MRL and for estimation of dietary intake for plant and animal commodities should be the sum of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, expressed as imidacloprid.

Imidacloprid was scheduled by the Forty-third Session of the CCPR for residue evaluation of additional crops. The 2012 JMPR received information on GAP and residue data for artichoke, avocado, banana, beans (dry), celery, guava, litchi and papaya.

Methods of analysis

The Meeting received information on analytical methods used for the determination of imidacloprid residues in samples derived from supervised trials on avocado, artichoke, banana, bean (dry), celery, guava, litchi and papaya. Samples were fortified with an equimolar combination of imidacloprid and its metabolites desnitro-imidacloprid, olefin-imidacloprid, hydroxyl-imidacloprid and 6-chloro-nicotinic acid following conversion to 6-chloronicotinic acid-trimethylsilylester with 6-N-methyl-trimethylsilyl-trifluoroacetamide (MSTFA) and analysed by GC-MS. The LOQ was 0.05 mg/kg (expressed in parent equivalents) for the crops mentioned above, except for dry beans.

The Meeting noted that the mean recoveries for dry beans were at the fortification levels of 0.1 mg/kg 59.9% (RSD 27.8%, n=9), of 0.2 mg/kg 57% (n=2), of 0.5 mg/kg 72% (RSD 22.4%, n=6), of 1 mg/kg 107% (RSD 11%, n=5) and of 5 mg/kg 95.6% (RSD 2.3%, n=3).

The freezer storage stability studies carried out with artichoke and beans, dry showed that the residues were stable for the longest period for which the samples were stored at or below -18 °C. The studies reported by the 2002, 2006 and 2008 JMPR cover the other sample materials evaluated by the present Meeting.

Results of supervised residue trials on crops

The OECD calculator was used as a tool in the estimation of the maximum residue level from the selected residue data set obtained from trials conducted according to GAP. As a first step, the Meeting reviewed all relevant factors related to each data set in arriving at a best estimate of the maximum residue level using expert judgment. Then, the OECD calculator was employed. If the statistical calculation spreadsheet suggested a different value from that recommended by the JMPR, a brief explanation of the deviation was provided.

Avocado

The registered GAP on avocado in the USA is soil application at a maximum rate of 0.56 kg ai/ha with a PHI of 6 days, and/or a maximum of five foliar applications at a maximal rate of 0.56 kg ai/ha with an interval of 10 days and a PHI of 7 days. Five field trials[1] were conducted with soil application at 98–104 % GAP rate, but a PHI of 50–69 days indicated that no trials matched the registered GAP in the USA.

The Meeting decided that the data were inadequate for the purpose of estimating a maximum residue level for avocado.

[1] These residue trials data on avocado were submitted already to the JMPR in 2008.

Banana

The 2002 JMPR evaluated trials from Africa and Central America with application of 0.25 g ai/plant to the base of the pseudo-trunk or with a single basal drench application of 0.21–0.29 g ai/plant and estimated a maximum residue level of 0.05 mg/kg.

The GAP in the USA is soil application at a maximum rate of 0.56 kg ai/ha with a 0 day PHI and/or a maximum of five foliar applications at a maximum rate of 0.56 kg ai/ha with an interval of 14 days and a 0 day PHI. Five field trials[1] were conducted with foliar application and matched the registered GAP in the USA, four of them with unbagged and one with bagged bananas. Residues in the whole fruit were 0.40, 0.48, 0.52 and 0.60 mg/kg for unbagged bananas and 0.12 mg/kg for bagged bananas.

The Meeting decided that four trials on unbagged and one on bagged bananas were not sufficient to estimate a maximum residue level for such a major crop and that the previous recommendation of 0.05 mg/kg should be maintained.

Litchi

Three trials were conducted on litchi in the USA in 2004 with foliar treatment according to GAP (GAP 5 × 0.11 kg ai/ha, PHI 7 days) resulting in residues of 0.16, 0.21 and 0.26 mg/kg. The data were submitted as separate trials but several of the parameters were identical, i.e., location, variety, treatment time and personnel

The Meeting considered the three trials as not independent and concluded that there were insufficient data to estimate a maximum residue level for imidacloprid in litchi.

Papaya

The GAP in the USA is maximal five foliar applications of 0.11 kg ai/ha at a maximal rate of 0.56 kg ai/ha and a PHI of 7 days. Four trials were conducted on papaya in the USA in 2005 with foliar treatment by 5 × 0.11–0.12 kg ai/ha. Residues were 0.13, 0.35, 0.36 and 0.44 mg/kg in samples taken one day after application.

As no trials according to GAP were submitted, the Meeting could not estimate a maximum residue level for imidacloprid in papaya.

Guava

The GAP in the USA is maximum five foliar applications of 0.11 kg ai/ha at a maximum rate of 0.56 kg ai/ha and a PHI of 7 days. Four trials were conducted on guava in the USA in 2000 with foliar treatment by 5 × 0.11 kg ai/ha, samples were taken at a PHI of 14–15 days only. The data were submitted as separate trials but several of the parameters were the same (place, treatment date, personnel). Residues were 0.12, 0.26, 0.28 and 0.38 mg/kg in samples taken 14–15 days after application.

As no trials according to GAP were submitted, the Meeting could not estimate a maximum residue level for imidacloprid in guava.

Artichoke

Three US trials treated in 1997 with foliar application at 2 × 0.28 kg ai/ha and a PHI of 7 days did not match the GAP (0.056–0.14 kg ai/ha, maximum 0.56 kg ai/ha per season, PHI 7 days). Furthermore, the data were submitted as separate trials but several of the parameters were identical, i.e., location, variety, treatment time and personnel.

[1] These residue trials data on banana were submitted already to the JMPR in 2008.

The Meeting concluded that there were insufficient data to estimate a maximum residue level for imidacloprid in artichoke.

Celery

The US labels for imidacloprid in celery allow soil application with 0.18–0.42 kg ai/ha and a 45 day PHI. Twelve trials[1] with different treatment scenarios were conducted in the USA: In six field trials, plant drench application with 0.54–0.59 kg ai/ha was used, 43–46 days prior to harvest. The remaining six other trials were bridging studies to compare the residues arising from various types of soil applications.

In the trials treated with 0.54–0.59 kg ai/ha, the application rate exceeded the maximum GAP rate of 0.42 kg ai/ha for more than 30 % and the residues were 0.13, 0.13, 0.42, 0.57, 1.0 and 4.3 mg/kg. Applying the principle of proportionality (scaling factors of 0.71–0.778), imidacloprid residues in celery were: 0.096, 0.1, 0.3, 0.43, 0.75 and 3.2 mg/kg (n=6).

Tthe Meeting estimated a maximum residue level of 6 mg/kg, an STMR of 0.365 mg/kg and an HR of 3.2 mg/kg for imidacloprid in celery.

Beans, dry

The registered GAP in the USA on dried shelled bean (except soya bean) and dried shelled peas is soil application at a maximum rate of 0.42 kg ai/ha with a PHI of 21 days, and/or maximum of three foliar applications of 0.048 kg ai/ha at a maximal rate of 0.147 kg ai/ha with an interval of 7 days and a PHI of 7 days.

Eleven field trials were conducted with the following use pattern: a combination of one seed treatment with 0.25 kg ai/100 kg seed before sowing, one soil application matching the registered soil application GAP and three foliar applications matching the registered foliar application GAP. The residues were < 0.5 (6), 0.59, 0.69, 0.71, 0.79 and 0.99 mg/kg in dry beans. Using the OECD MRL calculator, a maximum residue level of 1.5 mg/kg is calculated. The Meeting was aware of the high uncertainty of this value because 55% of the data population were censored data.

The Meeting noted that the GAP in the USA is the same for dried shelled pea and bean, except soya bean. For peas, dry the 2008 JMPR estimated a maximum residue level of 2 mg/kg and an STMR of 0.62 mg/kg.

The Meeting agreed to extrapolate from beans, dry and peas, dry to pulses and estimated a maximum residue level of 2 mg/kg and an STMR of 0.62 mg/kg for pulses, except soya beans. The previous recommendation for peas, dry of 2 mg/kg should be withdrawn.

Residues in animal commodities

The 2012 JMPR evaluated residues of imidacloprid in beans, dry, which is listed in the OECD feeding table. The Meeting noted that the estimation did not result in a significant change of the dietary burdens of farm animals. The previous MRL recommendations for animal commodities were maintained.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Daily Intake (IEDI) of imidacloprid were calculated for the 13 GEMS/Food cluster diets using STMRs and STMR-Ps estimated by the JMPR in 2002, 2006, 2008 and 2012. The results are shown in Annex 3.

[1] These residue trials data on celery were already submitted to the 2002 JMPR.

The ADI is 0–0.06 mg/kg bw and the calculated IEDI were 2–5 % of the maximum ADI. The Meeting concluded that the long-term intake of residues of imidacloprid from the uses considered by the JMPR is unlikely to present a public health concern.

Short-term intake

The International Estimated Short Term Intakes (IESTIs) of imidacloprid was calculated for the food commodities for which maximum residue levels, STMRs and HRs were estimated by the current Meeting and for which consumption data was available. The results are shown in Annex 4.

The IESTIs represented 0–30 % of the ARfD (0.4 mg/kg bw). The Meeting concluded that the short-term intake of residues of imidacloprid from uses considered by the current Meeting was unlikely to present a public health concern.

5.23 MCPA (257)

TOXICOLOGY

MCPA is the ISO-approved common name for 4-chloro-*o*-tolyloxyacetic acid (IUPAC) (CAS No. 94-76-6). MCPA is a selective, systemic, hormone-type herbicide belonging to the phenoxyacetic acid family. It is used to control annual and perennial weeds in cereals, grassland and turf. MCPA has not previously been evaluated by JMPR and was reviewed by the present Meeting at the request of CCPR.

Studies on the 2-ethylhexyl ester (2-EHE) (CAS No. 29450-45-1) and dimethylamine (DMA) (CAS No. 2039-46-5) salt of MCPA were also evaluated. For comparative purposes, and because both preparations convert to MCPA ion prior to gastrointestinal absorption, doses of MCPA 2-EHE and MCPA DMA are expressed as MCPA acid equivalents.

All critical studies contained certificates of compliance with principles of GLP or good clinical practice and the Declaration of Helsinki, as appropriate.

Biochemical aspects

In studies conducted in rats, dogs and humans using either radiolabelled or unlabelled MCPA, MCPA 2-EHE or MCPA DMA, the time to reach the maximum plasma concentration of radioactivity or of MCPA ion ranged from 1 to 8 hours, depending on the dose. In rats, gastrointestinal absorption was at least 95% of the administered dose, with in vitro data suggesting both a saturable carrier-mediated process and a non-saturable process involving simple diffusion. Following oral dosing of rats, there was no evidence of accumulation of radioactivity in any tissues, with the concentrations in the majority of tissues lower than those in blood. In a study conducted in pregnant rats, the concentration of radioactivity in fetal plasma and amniotic fluid was approximately 3- to 9-fold lower than that in maternal plasma.

MCPA, like other organic acids, is excreted via the kidneys by an active mechanism, with this process saturated at sufficiently high doses in rats, dogs and humans; the threshold of renal saturation is lower in dogs than in rats and humans. In rats, excretion of radioactivity was predominantly via the urine (approximately 90% of the administered dose), with relatively low levels detected in faeces (approximately 5% of the administered dose), although increasing the dose from 5 to 100 mg/kg bw increased the level of radioactivity in the faeces of females (approximately 20% of the administered dose). A different pattern of excretion was evident in dogs, with a greater proportion of radioactivity detected in faeces (17% of the administered dose at 5 mg/kg bw and 49% at 100 mg/kg bw). The plasma elimination half-life was longer in dogs (approximately 45 hours) than in rats and humans (approximately 6–10 hours), with this slower elimination resulting in higher systemic exposure at comparable doses. As a consequence of its longer residence time, MCPA ion undergoes more extensive metabolism in dogs. MCPA ion was the predominant compound detected in rat and dog excreta, followed by 4-chloro-2-hydroxymethyl phenoxyacetic acid (HMCPA) and glycine-conjugated MCPA. The proportions of MCPA and HMCPA in rat urine ranged from about 51% to 80% and from about 6% to 16% of the administered dose, respectively. In rat faeces, MCPA and HMCPA accounted for approximately 1–2% and 1–7% of the administered dose, respectively. In dogs, MCPA (up to approximately 30% of the administered dose) and HMCPA (up to approximately 15% of the administered dose) were detected in urine, in addition to a glycine and taurine conjugate (up to 38% and 11% of the administered dose, respectively). In dog faeces, MCPA and the glycine and taurine conjugates were identified (up to 28%, 4% and 19% of the administered dose, respectively).

MCPA induced a variety of drug metabolizing enzymes in rats at relatively high oral doses (100–300 mg/kg bw) and increased fatty acid β-oxidation and the number of hepatic peroxisomes. MCPA's peroxisome proliferating potential was not overtly expressed at lower doses in rodents, with a decrease in serum triglycerides the most consistent finding.

Toxicological data

Acute toxicity studies were conducted with MCPA, MCPA 2-EHE and MCPA DMA. The oral LD_{50} in rats was 500–1200 mg/kg bw, depending on the vehicle. Clinical signs generally occurred within hours of dosing and included piloerection, apathy, hunched posture, abnormal gait, decreased respiration, ptosis, pallor and occasionally ataxia, twitching and tonic convulsions; survivors recovered within about 2 days. The dermal LD_{50} in rats and rabbits was greater than 2000 mg/kg bw, whereas the LC_{50} in rats was greater than 4.5 mg/L. Nil to slight skin irritation and slight to severe eye irritation occurred in rabbits, depending on the formulation. No skin sensitization occurred in guinea-pigs (maximization, open epicutaneous and Buehler tests).

The target organs for MCPA ion are the kidney, liver and blood. In laboratory animals, toxicity following repeated dosing typically manifested as perturbations in clinical pathology parameters (increased serum creatinine, urea, liver enzymes and clotting time and reduced red cell parameters and serum protein) and, in some species, increased kidney and liver weights in conjunction with histopathological changes in these organs. Reduced body weight gain and feed consumption, clinical signs and deaths also occurred.

Short-term studies of toxicity of less than 12 months' duration using MCPA, MCPA 2-EHE or MCPA DMA were performed in rats and dogs. In a 3-month study in rats, the NOAEL was 150 ppm (equal to 12 mg/kg bw per day) for increased serum creatinine and kidney weight at 450 ppm (equal to 35 mg/kg bw per day). In dogs, the overall NOAEL from five studies of 13 or 52 weeks' duration was 6 ppm (equal to 0.2 mg/kg bw per day) for increased serum creatinine and urea and increased pigmentation in the proximal tubules at 30 ppm (equal to 1 mg/kg bw per day).

Long-term studies of the toxicity and carcinogenicity of MCPA were conducted in mice and rats, with no indication of any treatment-related neoplastic lesions up to dietary concentrations of 500 and 320 ppm, respectively (equal to 100 and 20 mg/kg bw per day, respectively). The chronic NOAEL in mice was 100 ppm (equal to 16 mg/kg bw per day) for increased kidney weight and an increased incidence of intratubular calcification, hyaline casts and tubular epithelial hyperplasia at 500 ppm (equal to 83 mg/kg bw per day). The chronic NOAEL in rats was 80 ppm (equal to 5 mg/kg bw per day), based on increased kidney weight and slight increases in the severity of chronic progressive nephropathy in males and haemosiderin deposition in the spleen of both sexes at 12 but not 24 months at 320 ppm (equal to 19 mg/kg bw per day), findings considered to be of questionable relevance.

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

The genotoxicity of MCPA, MCPA 2-EHE and MCPA DMA has been extensively tested in vitro and in vivo, and all were found to have no genotoxic potential. The Meeting concluded that the MCPA ion is unlikely to be genotoxic to humans.

In the absence of genotoxicity potential and a carcinogenic response in mice and rats, the Meeting concluded that MCPA ion is unlikely to pose a carcinogenic risk to humans.

In multigeneration studies in rats on MCPA or MCPA 2-EHE, there was no evidence of reproductive toxicity up to the highest tested dietary concentrations of 1600 and 450 ppm (equal to 150 and 40 mg/kg bw per day, respectively) over one or two generations, respectively. In the two-generation study on MCPA, the NOAEL for parental and offspring toxicity was 150 ppm (equal to 12 mg/kg bw per day) for reduced body weight gain at 450 ppm (equal to 40 mg/kg bw per day). The LOAEL for parental toxicity in this study is consistent with those in four subchronic rat studies. In one-generation studies on MCPA or MCPA 2-EHE, reduced parental body weight gain occurred at the lowest tested dietary concentrations of 450 and 700 ppm (equal to 40 and 65 mg/kg bw per day, respectively), whereas the NOAEL for offspring toxicity was 750 or 700 ppm (equal to 115 and 100 mg/kg bw per day, respectively) for reduced body weight gain at 1000 or 1600 ppm (equal to 160 and 230 mg/kg bw per day, respectively).

In rat developmental toxicity studies conducted on MCPA, MCPA 2-EHE and MCPA DMA, the overall NOAEL for maternal toxicity and fetal and embryo toxicity was 60 mg/kg bw per day for reduced maternal body weight gain and feed consumption, reduced fetal body weight and an increase

in fetal anomalies (mainly delayed ossification), post-implantation losses and early resorptions at 120 mg/kg bw per day. The reduction in maternal body weight gain and feed consumption was evident 1 or 2 days after the commencement of dosing and persisted throughout gestation. The Meeting noted that the developmental findings occurred only at maternally toxic doses.

In a rabbit developmental toxicity study on MCPA, no developmental effects occurred up to the highest tested dose of 60 mg/kg bw per day. The NOAEL for maternal toxicity was 15 mg/kg bw per day, based on clinical signs (piloerection, no defecation and blood in the bedding) and deaths at 30 mg/kg bw per day. The NOAEL for embryo and fetal toxicity was 60 mg/kg bw per day, the highest dose tested.

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

Acute and subchronic neurotoxicity studies were conducted on MCPA, MCPA 2-EHE and MCPA DMA in rats. In the acute studies, clinical signs of toxicity observed 24 hours after dosing and transiently impaired motor activity were attributable to acute systemic toxicity rather than to a direct neurotoxic effect. No pathology of the brain or nervous tissue was observed in these or other toxicity studies. The acute NOAEL for MCPA was 150 mg/kg bw, whereas clinical signs (mainly ataxia) were observed at the lowest tested doses of MCPA 2-EHE and MCPA DMA (160 and 143 mg/kg bw, respectively). The overall NOAEL in the three subchronic studies was 4 mg/kg bw per day, with increased serum creatinine the most consistent effect seen at the next higher dose of 30–40 mg/kg bw per day.

4-Chloro-2-carboxyphenoxyacetic acid (CCPA) is a metabolite of MCPA specific to plants. The oral LD_{50} in rats was greater than 2000 mg/kg bw. CCPA was not mutagenic. In a 4-week dietary study, CCPA was approximately 5-fold less toxic than MCPA. The NOAEL for CCPA was 176 mg/kg bw per day, based on reduced serum albumin, increased serum magnesium, increased urine specific gravity and increased renal calcification at approximately 1100 mg/kg bw per day. The LOAEL for MCPA was approximately 170 mg/kg bw per day. The Meeting concluded that CCPA was less toxic than MCPA ion.

Poisoning case reports described clinical observations in humans following deliberate ingestion of relatively large doses of MCPA formulations. Clinical signs consistent with those observed in laboratory animals and renal toxicity were reported.

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

Toxicological evaluation

The Meeting concluded that the dog was an unsuitable surrogate for humans because of its relatively low renal capacity to excrete MCPA ion, leading to higher toxicity than in other species. Therefore, the Meeting established an ADI of 0–0.1 mg/kg bw per day for MCPA ion, based on the overall NOAEL of 12 mg/kg bw per day from four subchronic studies in rats for changes in clinical chemistry parameters indicative of effects on the kidneys at 35 mg/kg bw per day and using a 100-fold safety factor. This overall NOAEL is supported by the NOAEL of 12 mg/kg bw per day for parental and offspring toxicity from the two-generation reproductive toxicity study in rats and the NOAEL of 15 mg/kg bw per day for maternal toxicity in the developmental toxicity study in rabbits. The Meeting considered that this ADI would adequately cover the kidney and spleen effects observed in the 2-year rat study at 19 mg/kg bw per day. The ADI is established for the sum of MCPA and its salts and esters, expressed as MCPA acid equivalents.

The Meeting established an ARfD of 0.6 mg/kg bw for MCPA ion, based on the overall NOAEL for maternal and developmental toxicity of 60 mg/kg bw and using a 100-fold safety factor. At 120 mg/kg bw, maternal body weight gain and feed consumption were reduced within 1 or 2 days after commencement of dosing in three rat developmental toxicity studies, in addition to an increase in early resorptions in two of these studies. The Meeting considered that the maternal toxicity observed in the rabbit developmental toxicity study was an unsuitable basis for the ARfD because it

was not an acute effect. The ARfD is established for the sum of MCPA and its salts and esters, expressed as MCPA acid equivalents.

A toxicological monograph was prepared.

Levels relevant to risk assessment based on studies conducted on MCPA, MCPA 2-EHE and MCPA DMA

Species	Study	Effect	NOAEL	LOAEL
Mouse	Two-year study of toxicity and carcinogenicity[a]	Toxicity	100 ppm, equal to 16 mg/kg bw per day	500 ppm, equal to 83 mg/kg bw per day
		Carcinogenicity	500 ppm, equal to 83 mg/kg bw per day[b]	—
Rat	Thirteen-week studies of toxicity[a,c]	Toxicity	150 ppm, equal to 12 mg/kg bw per day	450 ppm, equal to 35 mg/kg bw per day
	Two-generation study of reproductive toxicity[a]	Reproductive toxicity	450 ppm, equal to 40 mg/kg bw per day[b]	—
		Parental toxicity	150 ppm, equal to 12 mg/kg bw per day	450 ppm, equal to 40 mg/kg bw per day
		Offspring toxicity	150 ppm, equal to 12 mg/kg bw per day	450 ppm, equal to 40 mg/kg bw per day
	Developmental toxicity studies[c,d]	Maternal toxicity	60 mg/kg bw per day	120 mg/kg bw per day
		Embryo and fetal toxicity	60 mg/kg bw per day	120 mg/kg bw per day
Rabbit	Developmental toxicity study[d]	Maternal toxicity	15 mg/kg bw per day	30 mg/kg bw per day
		Embryo and fetal toxicity	60 mg/kg bw per day[b]	—

[a] Dietary administration.

[b] Highest dose tested.

[c] Two or more studies combined.

[d] Gavage administration.

Estimate of acceptable daily intake for humans

0–0.1 mg/kg bw

Estimate of acute reference dose

0.6 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 MCPA ion

Absorption, distribution, excretion and metabolism in mammals	
Rate and extent of oral absorption	Rapid and almost complete
Distribution	Widespread tissue distribution
Potential for accumulation	No potential for accumulation
Rate and extent of excretion	Rapid except in dogs
Metabolism in animals	Limited; more extensive in dogs

Toxicologically significant compounds in animals, plants and the environment	MCPA, CCPA (plant metabolite)
Acute toxicity	
Rat, LD_{50}, oral	> 500 mg/kg bw
Rat, LD_{50}, dermal	> 2000 mg/kg bw
Rat, LC_{50}, inhalation	> 4.5 mg/L (4 h, whole-body)
Rabbit, dermal irritation	Non-irritating to slightly irritating
Rabbit, ocular irritation	Slightly to severely irritating
Dermal sensitization	Non-sensitizing (guinea-pigs)
Short-term studies of toxicity	
Target/critical effect	Kidney, liver and blood
Lowest relevant oral NOAEL	12 mg/kg bw per day (rat)
Lowest relevant dermal NOAEL	160 mg/kg bw per day (rat)
Lowest relevant inhalation NOAEC	No data
Long-term studies of toxicity and carcinogenicity	
Target/critical effect	Kidney, liver and blood
Lowest relevant NOAEL	16 mg/kg bw per day (mouse)
Carcinogenicity	Not carcinogenic
Genotoxicity	
	Not genotoxic
Reproductive toxicity	
Target/critical effect	No evidence of reproductive toxicity (rat)
Lowest relevant parental NOAEL	12 mg/kg bw per day
Lowest relevant offspring NOAEL	12 mg/kg bw per day
Lowest relevant reproductive NOAEL	40 mg/kg bw per day (highest dose tested)
Developmental toxicity	
Target/critical effect	Effects on fetuses at maternally toxic doses (rat)
Lowest relevant maternal NOAEL	15 mg/kg bw per day (rabbits)
Lowest relevant embryo/fetal NOAEL	60 mg/kg bw per day (rat)
Neurotoxicity	
Acute and subchronic neurotoxicity	Not neurotoxic
Medical data	
	Effects following human poisonings consistent with laboratory animal findings

Summary

	Value	Studies	Safety factor
ADI	0–0.1 mg/kg bw	Short-term repeated-dose studies (rat), two-generation reproductive toxicity study (rat) and developmental toxicity study (rabbit)	100
ARfD	0.6 mg/kg bw	Developmental toxicity studies (rat)	100

RESIDUE AND ANALYTICAL ASPECTS

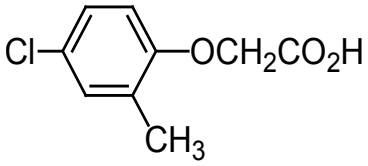
Residue and analytical aspects of MCPA were considered for the first by the present Meeting. It was scheduled for evaluation by the 2012 JMPR by the Forty-third Session of the CCPR.

MCPA is a herbicide in the phenoxyacetic acid class and works by concentrating in the actively growing regions of a plant (meristematic tissue), where it interferes with protein synthesis, cell division and the growth of the plant. It is used for the selective control of broadleaf weeds. MCPA is an acid, but it is usually formulated and applied as a salt, an amine salt or an ester.

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.

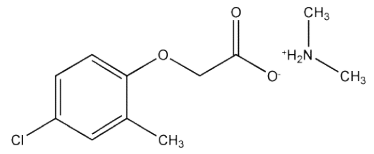
The 2012 JMPR established an ADI for MCPA of 0–0.1 mg/kg bw/day and an ARfD of 0.6 mg/kg bw.

MCPA is 4-chloro-o-tolyloxyaceic acid.

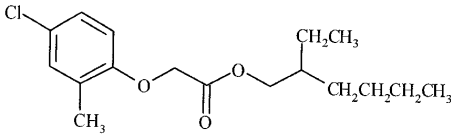


The following compounds are used for the metabolites discussed below:

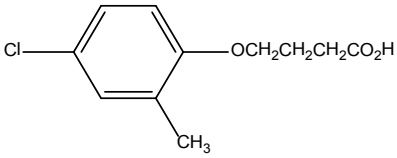
MCPA DMA
(4-chloro-2-methylphenoxyacetic acid) dimethylamine salt



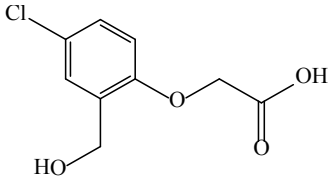
MCPA 2-EHE
2-ethylhexyl (4-chloro-2-methylphenoxy)acetate



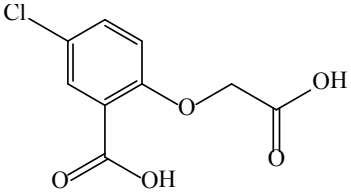
MCPB
4-(4-chloro-2-methylphenoxy) butanoic acid



HMCPA or CHTA
2-hydroxy-4-chlorophenoxyacetic acid



CCPA
2-carboxy-4-chlorophenoxyacetic acid



Animal metabolism

Information was available on metabolism of MCPA in rats, lactating goats and laying hens.

In rats, following oral dose of uniformly ring-labelled [^{14}C]-MCPA, approximately 90% of the administered dose was excreted in urine, with low levels detected in faeces (~5% of the administered dose). MCPA ion was the major compound detected in rat excreta followed by HMCPA and glycine-conjugated MCPA. The proportions of MCPA and HMCPA in rat urine ranged from 51–80% and 6–16% of the administered dose, respectively. In rat faeces, MCPA and HMCPA accounted for approximately 1–2% and 1–7% of the administered dose, respectively. Following oral dosing of rats, there was no evidence of accumulation of radioactivity in any tissues, with the concentration in the majority of tissues lower than in blood.

In a lactating goat study, uniformly ring-labelled [^{14}C]-MCPA was fed to goats for 3 consecutive days at 694 and 832 ppm in feed. Following oral administration, the goats excreted the majority of the dose (99.3%) within 24 hours of dosing, primarily in the urine as unmetabolized MCPA. The primary [^{14}C] component excreted in faeces was also MCPA. Milk and tissues each contained < 0.1% of the total radioactive residues. The small amount of MCPA that is not excreted is

metabolized to the glycine conjugate of MCPA in milk and to an unknown metabolite mainly in liver, kidney, and bile, later identified as composed of three compounds of similar polarity, characterized as triglyceride-like compounds with a dechlorinated MCPA-like structure incorporated by ester or ether linkage.

Unchanged parent MCPA was a significant residue in goat fat (30.2% TRR, 0.042 mg/kg), in milk (28.5% TRR, 0.046 mg/kg), in muscle (22.3% TRR, 0.022 mg/kg) and only a small proportion of the residue in goat kidney (6.7% TRR, 0.060 mg/kg) and liver (4.9% TRR, 0.024 mg/kg).

The conjugate MCPA-glycine was a major residue in milk at 53.9% TRR (0.086 mg eq./kg) but wasn't found in fat, muscle, kidney and liver. Triglyceride-like compounds with a dechlorinated MCPA-like structure were identified as a major residue in fat (30.3% TRR, 0.042 mg eq./kg), kidney (57.4% TRR, 0.509 mg eq./kg) and liver (50.5% TRR, 0.242 mg eq./kg) and as a minor residue in muscle (0.2% TRR, < 0.001 mg eq./kg).

Fifteen laying hens had uniformly ring-labelled [^{14}C]-MCPA administered via feed at 100 ppm for 7 consecutive days, 99.5% of the radioactivity was recovered, primarily as MCPA and acid labile MCPA conjugates in the excreta. The tissues and eggs combined accounted for only 0.04% of the dose administered over 7 days. MCPA was the major component identified in egg white (90.3% TRR, 0.029 mg/kg), egg yolk (57.4% TRR, 0.127 mg/kg), fat (12.0% TRR, 0.004 mg/kg), thigh muscle (35.5% TRR, 0.006 mg/kg) and liver (78.2% TRR, 0.0663 mg/kg). The parent compound was a major component in animal muscle, fat, milk and egg. The metabolism of MCPA in rats, lactating goats and laying hens is qualitatively similar.

Plant metabolism

The Meeting received plant metabolism studies with MCPA on wheat and MCPB on peas.

Metabolism studies of MCPA in two different crops (wheat and peas) demonstrated that metabolism of MCPA was similar, and that the compound undergoes oxidation of the phenyl methyl, and the resulting hydroxymethyl compound forms conjugates, including a glucose conjugate. Further metabolism to the carboxyl compound (CCPA) is also seen.

A wheat metabolism study was conducted with [^{14}C]-MCPA 2-EHE and [^{14}C]-MCPA DMA, labelled with ^{14}C in the ring position. The residue in forage and straw of wheat treated with either form of MCPA was qualitatively similar. A higher proportion of parent MCPA was found in the forage (54.4% TRR, 28.3 mg/kg) and straw (26.6% TRR, 35.9 mg/kg) of wheat for [^{14}C]-MCPA DMA salt. A lower proportion of parent MCPA was found in forage (10.0% TRR, 3.30 mg/kg) and straw (13.7% TRR, 11.3 mg/kg) of wheat for [^{14}C]-MCPA 2-EHE. The residue profiles in grain were similar for either form of MCPA. The main residue in grain was CCPA with a concentration of 25.3% TRR (0.103 mg/kg) for [^{14}C]-MCPA 2-EHE, and 16.5% TRR (0.091 mg/kg) for [^{14}C]-MCPA DMA. Analysis of the hydrolysates of the unextracted residue in forage and straw demonstrated the presence of conjugated forms of MCPA, HMCPA and CCPA. Unextractable residue in grain was subjected to chemical and enzymatic hydrolysis. Analysis of the hydrolysates of bound residue from grain demonstrated the presence of HMCPA and CCPA conjugates. A majority of the resident residue in grain was incorporated into cellular endogenous compounds, primarily glucose, which could be further incorporated into starch or cellulose.

MCPB breaks down into MCPA by the process of β-oxidation. MCPB metabolism study in peas could provide relevant information about the residue pattern of MCPA metabolized in plant. The metabolism of MCPB in peas was investigated using [^{14}C]-MCPB uniformly labelled in the ring position, applied at the rate of 2.26 kg ai/ha. Although the majority of the residues were found in the mature and immature vine, adequate total radioactivity was found in mature pods (0.025 mg eq./kg), seeds (0.024 mg eq./kg) and foliage (4.97 mg eq./kg) to permit extraction and identification of major metabolites. A combination of acetone and acetone/water extracted the majority of the radiolabelled residue from mature vine (92% TRR, 4.57 mg eq./kg) and pod (86% TRR, 0.022 mg eq./kg). Solvents extracted only 38% TRR (0.0092 mg eq./kg) from mature seed. Another 40% TRR (0.0095 mg/kg) was recovered by sequential base and acid hydrolysis. Some of the radiolabelled residue was

identified in mature forage, pod and seed. Mature vine contained mainly the parent, 72% MCPB (3.59 mg/kg), 5.8% MCPA (0.29 mg/kg), and 13% polar unknowns (0.63 mg/kg). Mature pod contained 40% MCPB (0.01 mg/kg), 0.8% MCPA (0.0002 mg/kg) and 48% polar unknowns (0.012 mg/kg). Mature seed contained 1.2% MCPB (0.0003 mg/kg), 11.3% MCPA/MCPA ester (0.0027 mg/kg), 12.5% glucose conjugate of HMCPA (0.003 mg/kg) and about 27% polar unknowns (0.0065 mg/kg). About 29% TRR was unaccounted, including 15% TRR in the residual solid. Based on the study, MCPA and MCPB are the major residues in mature pea vines and pods after treatment of with [^{14}C]-MCPB. The minor residues of MCPB and MCPA were found in grain about 1.2%-4.2% TRR (0.0003-0.001 mg/kg).

Environmental fate in soil

The Meeting received information on the environmental fate of MCPA in soil, including studies on aerobic soil metabolism, soil photolysis and crop rotational studies.

Aerobic soil metabolism

The primary hydrolysis rate of ring-labelled [^{14}C]-MCPA 2-EHE was studied in two US soils, a clay loam and a sandy loam. MCPA 2-EHE hydrolysed quickly to MCPA in both soils. Half-life values ranged between 4.5 and 16.6 hours. A further study on aerobic metabolism and degradation of [^{14}C]-MCPA 2-EHE was conducted in a sandy loam soil for 209 days. The calculated half-life was 24 days. A total of 65.6% of applied radioactivity was evolved as volatile radioactivity identified as $^{14}CO_2$ over the 209-day incubation period.

Soil Photolysis

[^{14}C]-MCPA degraded moderately under sunlight. PCOC which is the major degradate did not exceed 5.1% of applied radioactivity. Calculated first order half-lives were 4,718 hours for artificially irradiated soil and 220 hours for naturally irradiated soil.

Confined rotational crop

In a confined rotational crop study in the USA, soil was treated directly with [^{14}C]-MCPA in phenol ring. Crops of lettuce, turnips, and barley were sown into the treated soil at intervals of 30, 120 and 365 days after treatment and were grown to maturity and harvested except for lettuce, which was harvested at intermediate intervals whenever sufficient leaf material could be obtained. [^{14}C]-residues in the top 0–15 cm of soil were 0.276 mg eq./kg on the day of application and declined to 0.045 mg eq./kg by the final barley grain and straw harvest at 582 days after treatment. The decline in soil [^{14}C] residues appeared biphasic with a rapid initial phase (0 to 120 days) having a half-life of 63 days, and a slow secondary phase (120 to 582 days) with a half-life of 511 days. Following application of [^{14}C]-MCPA at 0.84 kg ai/ha, radioactive residues were generally highest in lettuce (0.044 mg eq./kg) at the first harvest from the 120-day plant back interval and lowest in barley grain, turnip roots and tops (< 0.013 mg eq./kg, LOD) at all plant back intervals. For lettuce at the 30-day and 120 day plant-back intervals, residues were greatest at initial sampling (0.029 or 0.044 mg eq./kg), declining to < 0.013 mg eq./kg by the final harvest. For turnip tops and roots and barley grain, residues were non-detectable at all plant-back intervals. Residues in barley forage were detectable at the 30 day plant-back interval (0.017 mg eq./kg), while in barley straw, they were detectable at the 30-day and 120 day plant-back intervals (0.021 and 0.029 mg eq./kg). Residues were all at non-detectable levels at the 365 day plant-back interval. Total MCPA-equivalent residues obtained from rotational crops were below the LOQ at all plant-back intervals. The results of this study indicated that potential for uptake of MCPA 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 MCPA in raw agricultural commodities, feed commodities and animal commodities.

The crop and animal methods typically use an initial extraction and hydrolysis step, either with acid, base or enzymatic treatment to hydrolyse any esters. After solvent partition and SPE or GPC clean-up, the MCPA, HMCPA and CCPA are methylated ready for GC-MSD analysis or further clean-up before the GC-MSD analysis. After solvent partition and SPE clean-up, reaction with acidic methanol yields the methyl ester and methyl ether derivatives which are analysed by GC/MSD or hydrolysed to MCPA free acid and HMCPA mono-methyl ether for analysis by LC/MS. MCPA residues can be measured in most matrices to an LOQ of 0.01 to 0.05 mg/kg. All methods are considered sufficiently validated for the determination of MCPA, CCPA and HMCPA including conjugates, esters and salts thereof.

The multi-residue method included in the Pesticide Analytical Manual was suitable for enforcement of MCPA residues in a variety of commodities.

Stability of residues in stored analytical samples

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

Storage stability studies conducted on cereal and grass commodities demonstrated that MCPA DMA, HMCPA, CCPA and MCPA 2-EHE are stable for up to 12 months in wheat forage, straw and grain, and grass forage and hay samples. MCPA DMA, HMCPA and MCPA 2-EHE are stable up to 17.5 months in wheat flour samples except CCPA stable up to about 14 months. Storage stability studies on cereal green plants, grain and straw showed that MCPA and HMCPA are stable in samples for up to 18 months.

In animal commodities the storage stability studies on MCPA, conducted concurrently with a cattle feeding study, confirmed that residues of MCPA are stable when stored frozen up to at least 4 months in liver and milk, 5 months in kidney and fat, and 3 months in muscle samples. Samples from the metabolism study showed that MCPA and MCPA-glycine (milk only) were stable in frozen storage up to about 46 weeks.

Definition of the residue

The composition of the residue in the metabolism studies, the available residue data in the supervised trials, the toxicological significance of metabolites, the capabilities of enforcement analytical methods and the national residue definitions already operating all influence the decision on residue definition.

A metabolism study showed unchanged parent MCPA comprised the main residue in animal tissues. The major component of residue in milk was MCPA-glycine and wasn't found in any other animal tissues. The Meeting decided that for animal commodities, parent MCPA is the appropriate residue of concern for MRL enforcement, and parent MCPA and its conjugates is the appropriate residue of concern for dietary risk assessment.

The metabolism of MCPA was investigated in wheat and peas. Unchanged parent compound formed the major part of the residue in these studies except wheat grain. CCPA was the major part of residue in wheat grain, but is 5 times less toxic than parent. A certain percentage of the parent residue was present in conjugated form, as uncleaved MCPA 2-EHE (in forage only) or was only released after hydrolysis (forage 15–60%, straw 40–73%, grain 76–85%). Since unconjugated parent MCPA was found in all plant commodities investigated, the Meeting concluded the parent substance is a suitable marker for enforcement purposes in plant commodities and could easily be implemented in multi-residue methods. For dietary intake assessment MCPA-conjugates and esters are easily cleaved and bioavailable. Therefore the Meeting decided to also include conjugates and esters into the residue definition for intake assessment for plant commodities.

The maximum octanol-water partition coefficient of MCPA (log K_{OW} = -0.81–0.71 at pH 7) implied that MCPA may be not fat-soluble. In the goat metabolism study, TRRs in fat and muscle were at similar levels. Based on the above information, the Meeting agreed that MCPA is not fat-soluble.

Definition of the residue (for compliance with the MRL for plant and animal commodities)*: MCPA*.

Definition of the residue (for estimation of dietary intake for plant commodities): *Sum of MCPA, its conjugates and esters, expressed as MCPA*.

Definition of the residue (for estimation of dietary intake animal commodities): *Sum of MCPA and its conjugates, expressed as MCPA*.

The residue is considered as not fat-soluble.

Results of supervised residue trials on crops

The Meeting received supervised trials data for MCPA using 2-EHE, DMA salt, sodium salt and potassium salt formulations for barley, wheat, corn, peas (legume vegetable and pulses), flax and grasses. Although the residue definition for compliance with MRLs is MCPA only, the analytical methods used in the supervised trials include hydrolysis steps that release the conjugates and the esters.

The OECD calculator was used as a tool in the estimation of the maximum residue level from the selected residue data set obtained from the supervised trials. As a first step, the Meeting reviewed all relevant factors related to each data set in arriving at a best estimate of the maximum residue level using expert judgement. Then the OECD calculator was employed. If the statistical calculation spreadsheet suggested a different value from that recommended by the Meeting, a brief explanation of the deviation was supplied.

Peas (legume vegetables)

The GAP of the USA for the DMA salt and MCPA Sodium salt, SL formulation, is one spray application at 0.13–0.42 kg ae/ha at 3 node stage up to before flowering. Three trials were carried out in USA in 1996. Residues in green peas without pods were: < 0.01 (3) mg/kg. Three trials were carried out in the USA in 1996 and 2005 in which residues in green peas with pods were: < 0.03 (3) mg/kg.

The Meeting considered the residue data for peas with pods and residue data for peas without pods were insufficient upon which to base a recommendation.

Peas, dry

The GAP for dry peas in the USA (DMA salt and MCPA Sodium salt, SL formulation) is one spray application at 0.13–0.42 kg ae/ha at the 3 node stage up to before flowering.

In eight trials on peas from Canada matching the US GAP residues in dry peas were: < 0.01(8) mg/kg.

The Meeting estimated a maximum residue level and STMR value for MCPA in dry peas of 0.01* and 0 mg/kg, respectively.

Barley and wheat

The GAP for the UK is for one spray application at 1.7 kg ae/ha at BBCH 30(DMA salt SL formulation). Four barley trials were conducted in France and the UK matching the GAP of the UK. In the trials residues in barley grain were < 0.05 (4) mg/kg.

The GAP in Spain (DMA salt SL formulation), is for one spray application at 1.2 kg ae/ha at BBCH 30. Four barley trials were conducted in France and Spain in line with Spanish GAP. The residues in barley were: < 0.05 (3) and 0.12 mg/kg.

The GAP for the UK is for one spray application at 1.7 kg ae/ha at BBCH 31 (DMA salt SL formulation). Five wheat trials were conducted in France and the UK in line with the UK GAP. The residues in wheat were: < 0.05 (4) and 0.16 mg/kg.

The GAP in Spain consists of one spray application at 1.2 kg ae/ha at BBCH 31 (Sodium or potassium salt SL formulation). Four wheat trials were conducted in France and Spain in line with Spanish GAP. Residues found in wheat grain were: < 0.05 (4) mg/kg.

The Meeting noted that MCPA applied to barley and wheat before flowering results in comparable residues and agreed to combine all data from France and the UK against the UK GAP to support a maximum residue level for grain of barley, oats, rye, triticale and wheat. The residues found, median underlined, were: < 0.<u>05</u>(11) and 0.16 mg/kg.

The Meeting estimated a maximum residue level and an STMR in the cereals grains barley, oats, rye, triticale and wheat of 0.2 and 0.05 mg/kg, respectively.

Maize

The GAP of Canada consists of one spray application at 0.55 kg ae/ha (DMA salt SL formulation); one spray application at 0.6 kg ae/ha, at 15 cm height stage (MCPA sodium salt SL formulation). All eight trials in Canada were treated at 1.5× the maximum rate and resulted in non-detectable residues in maize grain: < 0.01(8) mg/kg.

The Meeting estimated a maximum residue level and an STMR for MCPA in maize grain of 0.01* and 0 mg/kg, respectively.

Flax seeds

The GAP of Canada consists of one spray application at 0.41–0.875 kg ae/ha, before bud stage (MCPA 2-EHE EC formulation, DMA salt SL formulation, and MCPA sodium salt SL formulation). In six trials on flax against the Canadian GAP residues in linseeds were: < 0.01(6) mg/kg for MCPA.

The Meeting estimated a maximum residue level and an STMR value for MCPA in flax seeds of 0.01* and 0 mg/kg, respectively.

Animal feedstuffs

Pea forage

The GAP of the USA (DMA salt and MCPA sodium salt, SL formulation), consists of one spray application at 0.13–0.42 kg ae/ha at the 3 node stage up to before flowering. Two trials on pea were carried out in Canada against the US GAP. The ranked order of residues on pea forage was: < 0.25 and 0.42 mg/kg.

The Meeting considered the residue data for peas forage to be insufficient upon which to base recommendations.

Pea hay

The GAP of the USA (DMA salt and MCPA Sodium salt, SL formulation), consists of one spray application at 0.13–0.42 kg ae/ha at 3 node stage up to before flowering. Two trials on pea were carried out in Canada against the US GAP. The residues in pea hay were: 0.74 and 1.97 mg/kg (fresh weight).

The Meeting considered the residue data for pea hay to be insufficient upon which to base a maximum residue level recommendation.

Barley, oats, rye, triticale and wheat forage

The GAP of the UK (DMA salt SL formulation), is one spray application at 1.7 kg ae/ha at BBCH 30. Two trials on barley and wheat each were carried out in France and the UK matching UK GAP. The ranked order of concentrations on barley forage (fresh weight) was: 4.2, 4.3, 7.5 and 23 mg/kg.

The GAP of Spain (DMA salt SL formulation), consists of one spray application at 1.2 kg ae/ha; (MCPA sodium or potassium salt SL formulation), one spray application at 1.2 kg ae/ha, at

BBCH 30 stage. Four trials on barley and wheat were carried out in Spain against Spanish GAP. The residues found on barley forage were: 0.6, 1.1, 1.4 and 5.1 mg/kg.

The GAP of Canada (MCPA 2-EHE EC formulation), is one spray application at 0.35–0.88 kg ae/ha; or one spray application at 0.63–0.88 kg ae/ha (DMA salt SL formulation); or one spray application at 0.45–0.83 kg ae/ha (MCPA sodium salt SL formulation), at 15 cm height stage. The GAP of the USA (MCPA 2-EHE EC formulation and DMA salt SL formulation) consists of one spray application at 0.88 kg ae/ha at early boot stage.

In 25 trials on wheat forage from Canada (15 trials) and the USA (10 trials) at about double the maximum rate of the Canadian or US GAP, residues were: 3.08, 3.18, 3.46, 4.13, 5.38, 5.48, 5.55, 5.82, 6.37, 7.14, 7.15, 7.36, 7.73, 7.94, 8.30, 8.74, 9.02, 9.12, 9.75, 9.79, 11.0, 12.6, 12.8, 13.6 and 21.2 mg/kg

The residues were scaled to the application rates authorised by Canada and the USA were calculated by dividing by 2 (1.85 kg ae/ha / 0.88 kg ae/ha) and were (n = 25): 1.56, 1.57, 1.70, 2.09, 2.45, 2.66, 2.76, 2.89, 3.01, 3.38, 3.81, 3.87, 3.93, 4.09(2), 4.43, 4.51, 4.69, 4.72, 4.91, 5.19, 6.03, 6.59, 7.00 and 9.52 mg/kg.

The Meeting considered the residue data for barley and wheat forage from European trials matching the UK GAP to be insufficient, and agreed to base the estimations on the Canadian dataset and to extrapolate the estimated values to oats, rye and triticale.

The Meeting estimated an STMR and a highest residue values for MCPA in barley, oats, rye, triticale and wheat forage of 3.93 and 9.52 mg/kg.

Maize forage

The GAP of Canada consists of one spray application at 0.55 kg ae/ha (DMA salt SL formulation), or one spray application at 0.6 kg ae/ha at 15 cm height stage (MCPA sodium salt SL formulation). No trials in Canada complied with the Canadian GAP.

The Meeting considered the residue data for maize forage to be insufficient upon which to base an estimate.

Grass forage

The GAP of the USA, consists of either one spray application at 1.6–2.1 kg ae/ha at early bud to full bloom stage (MCPA 2-EHE EC formulation) or, one spray application at 1.7 kg ae/ha when grasses begin to tiller or before heads come to boot stage (MCPA DMA salt, SL formulation). All eight trials on grasses were carried out in the US matched GAP. The residues on grass forage, median underlined, in ranked order were: 16.4, 21.0, 31.0, 40.5, 53.5, 70.2, 94.3 and 108 mg/kg.

The GAP in Spain consists of one spray application at 1.2–1.6 kg ae/ha targeting weeds in active growth stage (DMA salt SL formulation). Four trials on grasses were carried out in France and Spain matching Spanish GAP. The residues in forage were: 3.70, 6.60, 11.0 and 19.0 mg/kg.

The Meeting noted that the US trials resulted in higher residues in grass forage and decided to use the US data to estimate a STMR and a highest residue values for MCPA in grass forage of 47 and 108 mg/kg, respectively.

Grass hay

The GAP of the USA consists of one spray application at 1.6–2.1 kg ae/ha at early bud to full bloom stage (MCPA 2-EHE EC formulation), or one spray application at 1.7 kg ae/ha when grasses begin to tiller or before heads come to boot stage (MCPA DMA salt, SL formulation). Eight trials on grasses were carried out in US matching GAP. The residues on grass hay, median underlined, in ranked order were: 37.4, 40.3, 42.5, 68.0, 80.7, 94.8, 196 and 217 mg/kg (air dry).

Based on an average dry-mass of 88% residues in grass hay (dry weight) were: 42.5, 45.8, 48.3, 77.3, 91.7, 107.7, 222.7 and 246.6 mg/kg.

The Meeting estimated a maximum residue level, an STMR and a highest residue for MCPA in grass hay of 500 mg/kg (DM based), 74.35 mg/kg and 217 mg/kg (air dry), respectively.

Straw and fodder of cereal grain (dry)

Barley, oat, rye, triticale and wheat hay

The GAP of Canada for barley consists of one spray application at 0.35–0.88 kg ae/ha (MCPA 2-EHE EC formulation), or one spray application at 0.63–0.88 kg ae/ha (DMA salt SL formulation), or one spray application at 0.45–0.83 kg ae/ha, at early flag leaf stage (MCPA Sodium salt SL formulation). In two trials in Canada matching the GAP the residues on barley hay were: 5.18 and 6.61 mg/kg.

The GAP in Canada on wheat consists of one spray application at 0.35–0.88 kg ae/ha (MCPA 2-EHE EC formulation); or, one spray application at 0.63–0.88 kg ae/ha (DMA salt SL formulation); or, one spray application at 0.45–0.83 kg ae/ha, at 15 cm height stage (MCPA sodium salt SL formulation). The US GAP on wheat consists of, one spray application at 0.88 kg ae/ha at early boot stage (MCPA 2-EHE EC formulation and DMA salt SL formulation). In 25 wheat trials from Canada (15 trials) and US (10 trials) treated at about 2× the maximum GAP rate of Canadian and the US residues were: 4.25, 6.68, 7.34, 8.09, 10.9, 11.3(2), 13.5, 14.6, 15.7(2), 16.7, 19.8, 20.9, 21.6, 23.3, 26.5, 30.6, 30.7, 30.9, 32.7, 35.5, 49.3, 50.5 and 66.0 mg/kg (air dry).

The residues scaled to the application rates authorised by Canada and the USA were calculated by dividing by 2 (1.85 kg ae/ha / 0.88 kg ae/ha) and were (n = 25): 2.15, 3.03, 3.91, 4.07, 5.00, 5.39, 5.56, 7.12, 7.20, 7.30, 7.85, 8.35, 10.5, 10.8, 11.2(2), 12.5, 14.4, 14.7, 15.8, 16.1, 16.5, 24.3, 26.3 and 28.9 mg/kg.

Barley, oat, rye, triticale and wheat straw

The GAP of the UK is one spray application at 1.7 kg ae/ha at BBCH 30 stage (DMA salt SL formulation). In 12 trials on barley and wheat carried out in Austria, France and the UK matching UK GAP. The residues on barley straw were: < 0.05(3), 0.07, 0.22, 0.28 and 1.04 mg/kg. The residues on wheat straw were: < 0.05(2), 0.05, 0.09 and 0.22 mg/kg.

The GAP of Spain consists of one spray application at 1.2 kg ae/ha (DMA salt SL formulation), or one spray application at 1.2 kg ae/ha, at BBCH 30 stage (MCPA sodium or potassium salt SL formulation). Nine trials on barley were carried out in France and Spain matching Spanish GAP. The residues on barley straw were: < 0.05(4) and 0.24 mg/kg. The residues on wheat straw were: < 0.05(4) mg/kg.

The GAP of Canada on barley consists of one spray application at 0.35–0.88 kg ae/ha (MCPA 2-EHE EC formulation); or, one spray application at 0.63–0.88 kg ae/ha (DMA salt SL formulation); or one spray application at 0.45–0.83 kg ae/ha (MCPA sodium salt SL formulation), at early flag leaf stage In 36 trials matching Canadian GAP the residues on barley straw, median underlined, were: < 0.25(34), 0.25 and 0.29 mg/kg.

The GAP of Canada on wheat consists of one spray application at 0.35–0.88 kg ae/ha (MCPA 2-EHE EC formulation); or one spray application at 0.63–0.88 kg ae/ha (DMA salt SL formulation); or one spray application at 0.45–0.83 kg ae/ha (MCPA sodium salt SL formulation), at 15 cm height growth stage. The GAP of the USA consists of, one spray application at 0.88 kg ae/ha at early boot stage (MCPA 2-EHE EC formulation and DMA salt SL formulations). In wheat trials from Canada (15) and US (10) treatment rates were 2× the maximum rate of Canadian and US GAP. Residues found, in ranked order were: < 0.25(6), 0.31, 0.34, 0.37, 0.42, 0.65, 0.82, 1.16, 1.30, 1.62, 1.72, 1.73, 2.51, 2.99, 3.65, 3.98, 4.93, 5.54, 7.19 and 11.3 mg/kg.

Based on an average dry-mass of 88% residues in wheat hay (dry weight) were: 2.44, 3.44, 4.44, 4.63, 5.68, 6.13, 6.32, 8.09, 8.18, 8.30, 8.92, 9.49, 11.9, 12.3, 12.7(2), 14.2, 16.4, 16.7, 18.0, 18.3, 18.8, 27.6, 29.9 and 32.8 mg/kg.

The Meeting noted that higher residues data came from the scaled datasets at 2× US and Canadian GAPs on wheat hay. Based on wheat hay, the Meeting agreed to estimate a maximum

residue level, a highest residue and an STMR for MCPA on wheat hay of 50 (DW), 28.9 and 10.5 mg/kg, and extrapolate them to straw of barley, oat, rye and triticale.

Maize fodder, dry

The GAP of Canada consists of, one spray application at 0.55 kg ae/ha (MCPA DMA salt SL formulation); or one spray application at 0.60 kg ae/ha (MCPA sodium salt SL formulation), at the 15 cm height stage. Eight trials were carried out in Canada at 1.5× the maximum rate and resulted in residues in maize stover of < 0.25(8) mg/kg.

Based on an average dry-mass of 83%, residues in maize fodder (dry weight) were: < 0.30(8) mg/kg.

The Meeting estimated an STMR and a highest residue for MCPA in maize stover of 0 mg/kg (fresh weight) and recommended a maximum residue level of 0.3 mg/kg for maize fodder, dry.

Fate of residues during processing

The Meeting received information on the fate of MCPA residues during the food processing of wheat grain.

Calculated processing factors are summarized in the following table. Factors are indicated with a "<" (less than) sign when the residue in the processed commodity is below the LOQ of the analytical method. The calculation is then made on the LOQ of the analytical method and the residue concentration of the RAC (raw agricultural commodity).

Processed Fractions	MCPA DMA salt	MCPA 2-EHE	Average process factor	Wheat grain STMR (mg/kg)	STMR-P (mg/kg)
Germ	0.67	0.29	0.48		0.024
Bran	0.67	0.29	0.48	0.05	0.024
Flour	0.67	0.29	0.48		0.024

Residues in animal commodities

Farm animal feeding

The Meeting received lactating dairy cow feeding studies, which provided information on likely residues resulting in animal tissues and milk from residues in the animal diet. Animals were orally administered the equivalent to 50(1×), 150(3×), and 500(10×) ppm in feed on a dry weight basis.

Residues of MCPA in whole milk in the 50, 150 and 500 ppm groups were < 0.01 mg/kg, < 0.01 mg/kg and 0.015–0.023 mg/kg (average values) respectively. In muscle, for the same groups, residues were < 0.05 mg/kg, < 0.05 mg/kg, and < 0.05–0.08 mg/kg respectively. Residues of MCPA in fat were < 0.05 mg/kg, < 0.05–0.17 mg/kg and < 0.05–0.13 mg/kg respectively. Residues of MCPA in liver were < 0.05 mg/kg, < 0.05–0.09 mg/kg and 0.16–0.28 mg/kg respectively. Residues in kidney were 0.28–0.41 mg/kg, 0.60–1.23 mg/kg and 1.66–2.44 mg/kg respectively.

In a hen metabolism study [^{14}C]-MCPA was fed at 100 ppm in the diet for 7 consecutive days. Residue levels in edible tissues and eggs were 0.004 mg/kg in fat, 0.006 mg/kg in muscle, 0.0663 mg/kg in liver, and 0.156 mg/kg in eggs.

Estimated maximum and mean dietary burdens of farm animals

Dietary burden calculations for beef cattle, dairy cattle, broilers and layer 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, MCPA, ppm of dry matter diet							
	US-Canada		EU		Australia		Japan	
	max	mean	max	mean	max	mean	max	mean
Beef cattle	37.0	12.7	216	94.0	432 [a]	188 [b]	107.9	39.0
Dairy cattle	194.4	84.6	259.2	112.8	432 [c]	188 [d]	191.2	69.5
Poultry-broiler	0.043	0.043	0.04	0.043	0.009	0.009	0.006	0.006
Poultry-layer	0.043	0.043	43.3 [e]	18.9 [f]	0.009	0.009	-	-

[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.

Both the highest maximum dietary burden (432 ppm) and the mean dietary burden for cattle (188 ppm) is greater than the actual 3× dose in the feeding study (150 ppm) and lower than the actual 10× dose in the feeding study (500 ppm). The MRL and STMR values were estimated by interpolation of data between dose levels.

Tabulated below are the calculations of maximum residue levels and STMRs for milk and animal tissues.

	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]	500/150	0.043/< 0.01	500/150	0.08/0.08	0.28/0.09	2.44/1.20	0.17/0.13
Dietary burden and residue estimate	432	0.035	432	0.08	0.25	2.20	0.16
STMR beef or dairy cattle							
Feeding study[b]	500/150	0.043/< 0.01	500/150	0.08/< 0.08	0.28/0.09	2.44/1.20	0.17/0.13
Dietary burden and residue estimate	188	0.013	188	0.08	0.10	1.33	0.13

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

[b] Mean residues for tissue and milk

The Meeting estimated maximum residue levels of 0.1 mg/kg for meat from mammals other than marine mammals, 0.2 mg/kg for mammalian fat, 3 mg/kg for mammalian edible offal, and 0.04 mg/kg for milks. The Meeting estimated STMRs of 0.08 mg/kg for meat from mammals other than marine mammals, 0.13 mg/kg for mammalian fat, 1.33 mg/kg for mammalian edible offal, 0.013 mg/kg for milks. The Meeting estimated HRs of 0.08 mg/kg for meat from mammals other than marine mammals, 0.16 mg/kg for mammalian fat and2.20 mg/kg for mammalian edible offal.

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	0.156	100	0.006	0.0663	0.004

	Feed level (ppm) for egg residues	Residues (mg/kg) in egg	Feed level (ppm) for tissue residues	Residues (mg/kg) in		
				Muscle	Liver	Fat
Dietary burden and residue estimate	43.3	0.068	43.3	0.003	0.029	0.002
STMR broiler or layer poultry						
Feeding study[b]	100	0.156	100	0.006	0.0663	0.004
Dietary burden and residue estimate	18.9	0.029	18.9	0.001	0.0125	0.0008

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

[b] Mean residues for tissue and egg

The Meeting noted that the LOQ of analytical method is 0.05 mg/kg, and agreed to estimate maximum residue levels of 0.05* mg/kg for poultry meat (fat), poultry edible offal and for eggs. The Meeting estimated STMRs of 0.05 mg/kg for poultry meat, poultry fat, edible offal and for eggs. The Meeting estimated HRs of 0.05 mg/kg for poultry meat, poultry fat, edible offal and for eggs.

DIETARY RISK ASSESSMENT

Long term intake

The evaluation of MCPA resulted in recommendations for MRLs and STMR values for raw and processed commodities. Data on consumption were available for 19 food commodities and were used to calculate dietary intake. The results are shown in Annex 3.

The International Estimated Daily Intakes (IEDIs) of MCPA, based on the STMRs estimated, were 0–1% of the maximum ADI of 0.1 mg/kg bw for the thirteen GEMS/Food cluster diets. The Meeting concluded that the long-term intake of residues of MCPA resulting from its uses that have been considered by JMPR is unlikely present a public health concern.

Short-term intake

The IESTI of MCPA calculated on the basis of the recommendations made by the JMPR ranged from 0–5% of the ARfD (0.6 mg/kg bw). The results are shown in Annex 4.

The Meeting therefore concluded that the short-term intake of MCPA residues, when used in ways that have been considered by the JMPR, is unlikely present a public health concern.

5.24 METHOXYFENOZIDE (209)

RESIDUE AND ANALYTICAL ASPECTS

Methoxyfenozide was evaluated for residues and toxicology by the 2003 JMPR. The 2003 Meeting established an ADI of 0–0.1 mg/kg bw and an ARfD of 0.9 mg/kg bw, and made a number of maximum residue level recommendations. The 2009 JMPR also recommended a number of maximum residue levels. The residue was defined as methoxyfenozide for compliance with MRLs and for dietary intake estimation in both plant and animal commodities. The residue is fat-soluble, but is not classified as fat-soluble with respect to its distribution in milk.

The current Meeting evaluated residue trial data for various crops including field accumulation data in rotational crops, analytical methods, and storage stability tests.

Methods of analysis

Analytical methods used in field trials, based on LC-MS/MS detection, were fully validated for representative samples of high and low-moisture content crops. Recoveries of methoxyfenozide ranged between 69% and 113% at fortification levels of 0.02–1.0 mg/kg.

The LOQ of 0.02 mg/kg was also confirmed by independent validation.

Stability of residues in stored analytical samples

The tests for stability of residues under frozen conditions were performed in guava, litchi, papaya, spring onion, cucumber, pea (pods and vines) and globe artichoke. They indicated that the residues were stable during the frozen storage intervals prevailed in the field trials. Residues in non-tested commodities were also considered stable. The results conform to previous JMPR reviews indicating that methoxyfenozide residues are stable for 1–2 years in various matrices under frozen conditions.

Results of supervised residue trials on crops

The Meeting received information on supervised field trials in citrus fruits, guava, litchi, papaya, spring onion, melons, cucumber, summer squash, spinach, common bean, pea (pods), pea (dry), globe artichoke, alfalfa and clover.

As a representative residue value for each field trial, the mean of replicate samples was used for estimation of a maximum residue level.

The OECD MRL calculator was used as a tool in estimation of the maximum residue level. Where different estimates were made, the reasons are indicated under corresponding recommendations.

Citrus fruits

The 2009 JMPR estimated a maximum residue level of 0.7 mg/kg on citrus based on the European GAP. The present Meeting received new residue information on US citrus trials matching the GAP of the USA.

The maximum US GAP for citrus fruits is a rate of 0.28 kg ai/ha, four applications at 14–17 days intervals with a 1 day PHI.

Residues from nine trials on oranges, in ranked order, were: 0.16, 0.21, 0.25, 0.26, 0.28, 0.32, 0.32, 0.55, and 1.7 mg/kg.

For grapefruits, residues for six trials, in ranked order, were: 0.12, 0.15, 0.22, 0.26, 0.27, and 0.28 mg/kg.

For lemon, residues from five trials were: 0.21, 0.33, 0.35, 0.39 and 0.79 mg/kg.

As the residue distributions in oranges, grapefruits and lemon were not significantly different, the datasets could be combined (n=20): 0.12, 0.15, 0.16, 0.21, 0.21, 0.22, 0.25, 0.26 (2), 0.27, 0.28, 0.28, 0.32, 0.32, 0.33, 0.35, 0.39, 0.55, 0.79 and 1.7 mg/kg. The Meeting decided to estimate a group MRL for citrus fruits. Based on the residues the Meeting estimated a maximum residue level of 2 mg/kg, an STMR of 0.28 mg/kg and an HR of 1.7 mg/kg for citrus fruits. The Meeting agreed to withdraw its previous maximum residue level of 0.7 mg/kg for citrus fruits.

Assorted tropical and sub-tropical fruits-edible peel

Guava

The GAP in the USA consists of six applications at a rate of 0.18–0.28 kg ai/ha with 6 day intervals, total seasonal rate of 1.12 kg ai/ha, and a 3 day PHI. Three trials were conducted in the USA matching maximum US GAP, in which methoxyfenozide was applied four times at a rate of 0.28–0.29 kg ai/ha, at 7–8 day intervals and 3–4 day PHI.

The Meeting decided the trials were not independent as they were conducted at the same site, same variety and with only few days' difference in treatment dates. As a result the Meeting considered them insufficient to estimate a maximum residue level.

Assorted tropical and sub-tropical - fruits-inedible peel

Litchi

The GAP in the USA consists of five applications at rate of 0.18–0.28 kg ai/ha, 10 day intervals, and a 14 day PHI. Three trials were conducted in the USA matching maximum US GAP (0.25–0.33 kg ai/ha with six applications, at 9–16 interval days, 13 day PHI).

However, as the trials were conducted with the same variety at neighbouring locations with application dates 0–7 days apart the Meeting judged the trials not to be independent. As a result the Meeting considered them insufficient to estimate a maximum residue level.

Mango and Pomegranate

The 2009 JMPR recommended maximum residue levels of 1 mg/kg for papaya and 0.7 mg/kg for avocado. The present Meeting received a request of extrapolating existing information for papaya and avocado to mango and pomegranate.

According to US GAP, the four crops have different PHIs (2 days for avocado, 3 days for papaya and mango and 7 days for pomegranate). As the GAPs are different, the Meeting could not consider the extrapolation of residue data from papaya and avocado to mango and pomegranate.

Spring onion

The GAP in the USA is for six applications at 0.21 kg ai/ha, total seasonal rate of 1.12 kg ai/ha and a 1 day PHI. Five trials were conducted in the USA with application rates of 4 × 0.28 kg ai/ha, which is 1.33 times higher than maximum US GAP rate. The residues, in ranked order, were: 0.060, 0.50, 0.60, 1.6, and 3.5 mg/kg.

The lack of two applications early in the growing season was considered non-influential on the final residue levels. The Meeting applied the proportionality principle and used the scaling factor of 0.8. The resultant scaled residue values were: 0.048, 0.40, 0.48, 1.3, and 2.8 mg/kg.

The Meeting estimated a maximum residue level of 6 mg/kg, an STMR of 0.48 mg/kg and an HR of 2.8 mg/kg for spring onion.

Fruiting vegetables, Cucurbits

Melons, except watermelon

Seven field trials conducted in the USA in 1999 on cantaloupe were re-submitted. The use of proportionality approach was considered by this Meeting for estimating a maximum residue level.

The 2009 Meeting did not estimate a maximum residue level, as the trials did not match US GAP. The treatment rate in the trials was 1.55 times the maximum US GAP (4 × 0.18 kg ai/ha at 7 day, PHI of 3 days) and resulted in which were: 0.071, 0.11, 0.13, 0.13, 0.15, 0.19, and 0.21 mg/kg.

The Meeting noted that other residue information on melons was not available. The Meeting agreed to use a proportionality approach with a scaling factor of 0.7 (rounded value for 0.60–0.67). The adjusted residue values were: 0.050, 0.077, 0.091, 0.091, 0.11, 0.13, and 0.15 mg/kg at maximum US GAP.

Cucumber

Eight trials conducted in cucumber in the USA in 1999 were re-submitted. The application of proportionality for estimating a maximum residue level was considered by this Meeting.

The 2009 Meeting did not estimate a maximum residue level as the trials did not match US GAP. The residue concentrations in cucumber were: 0.011, 0.019, 0.026, 0.033, 0.033, 0.048, 0.051, and 0.052 mg/kg, at dosage rate of 1.55 times maximum US GAP (4 × 0.18 kg ai/ha at 7 day, PHI of 3 days).

The Meeting noted that other residue information on cucumber was not available. In addition, it was considered that the proportionality approach could be applied. The Meeting decided to use the proportionality approach and estimate a scaling factor.

Using a scaling factor of 0.7 (rounded value for 0.60–0.67), the adjusted residue values were: < 0.01, 0.013, 0.018, 0.023, 0.023, 0.034, 0.036, and 0.036 mg/kg at maximum US GAP.

Squash, summer

Six trials conducted in the USA in 1999 were re-submitted. The application of proportionality in estimating a maximum residue level was considered by this Meeting.

The 2009 Meeting did not estimate a maximum residue level as the trials did not match US GAP. The residue concentrations were: < 0.02, 0.02, 0.034, 0.089, 0.10, and 0.16 mg/kg, at 1.55 times the maximum US GAP rate (4 × 0.18 kg ai/ha at 7 day, PHI of 3 days).

Other residue information on cucumber was not available. The Meeting agreed to apply a proportionality approach and estimate a scaling factor.

Using the scaling factor of 0.7 (rounded from 0.64–0.67), adjusted residue values were: < 0.02, < 0.02, 0.024, 0.062, 0.070, and 0.11 mg/kg at maximum US GAP.

Taking into account that GAPs for melons, cucumber, and summer squash are the same, the Meeting decided to estimate a group maximum residue level of 0.3 mg/kg for fruiting vegetables, cucurbits, except watermelon based on residues in melons. For dietary intake purposes of cucurbits except watermelon, the Meeting estimated an STMR 0.091 mg/kg and an HR of 0.15 mg/kg.

Leafy vegetables

Spinach

The current Meeting received residue information for three new trials. As the GAP was not changed, the Meeting also considered the residue data evaluated by the 2003 JMPR and combined the data, thus residues are in rank order: *5.5,10, 10*, 11, 12, 14, 18, 23, and 43 mg/kg (*new data in italic*).

The Meeting maintained its previous estimates for the maximum residue level of 50 mg/kg, the HR of 43 mg/kg, and estimated an STMR of 12 mg/kg.

Legume vegetables

Common bean (pods and/or immature seeds)

The Meeting received two new trials which were assessed with six trials previously evaluated by the 2009 JMPR. All trials were conducted at maximum US GAP (4 × 0.28 kg ai/ha at 7 days, with a PHI of 7 days). Residues were: < 0.05 (4), *0.075, 0.10*, 0.57, and 0.81 mg/kg (*new data in italic*). The new trials did not affect the estimates made by 2009 JMPR.

Peas (pods and succulent=immature seeds)

Three trials were conducted in the USA according to maximum US GAP (4 × 0.28 kg ai/ha at 7 days, with a PHI of 7 days). The residues in peas with pods were: 0.11, 0.13, and 0.42 mg/kg.

The Meeting considered the similarity of common bean and pea crops, and noted that three residue data measured in peas were in the range of those in common beans. The combined data base of residues in common bean and peas (pods) supports the estimation of maximum residue level of 2 mg/kg, an STMR of 0.10, an HR of 0.81 mg/kg for peas *(pods and succulent=immature seeds).*

Thus, the Meeting agreed to recommend a maximum residue level of 2 mg/kg, an STMR of 0.10 mg/kg and an HR of 0.81 mg/kg for peas *(pods and succulent=immature seeds).*

Peas (dry)

Six trials were conducted in the USA. Four trials matched maximum US GAP (4 × 0.28 kg ai/ha at 7 day intervals, a PHI of 7 days.

Residue concentrations from the four trials were: 0.068, 0.097, 0.17, and 0.17 mg/kg.

The 2009 Meeting evaluated data in cowpea, in which residues were: 0.13, 0.17, 0.56, 0.67, and 3.4 mg/kg.

As the GAPs for pea (dry) and cowpea are the same, the Meeting decided to estimate a group maximum residue level. The combined residues were: 0.068, 0.097, 0.13, 0.17 (n=3), 0.56, 0.67, and 3.4 mg/kg. The Meeting estimated a maximum residue level of 5 mg/kg and an STMR of 0.17 mg/kg for peas (dry), based on the combined dataset. The Meeting withdrew its previous recommendation for a maximum residue level of 5 mg/kg for cowpea (dry).

Artichoke, globe

Three trials conducted in the USA matched maximum US GAP (4 × 0.28 kg ai/ha at PHI of 4 days and total seasonal rate of 1.12 kg ai/ha). The residues were: 0.97, 1.1, and 1.2 mg/kg.

The trials were not independent as they were conducted at the same site using the same variety with the same dates of application.

The Meeting did not consider the data sufficient to estimate a maximum residue level for globe artichoke.

Legume animal feeds

Alfalfa (forage and fodder)

Nine trials for alfalfa forage and fodder each were conducted in the USA (US GAP: at a rate of 0.13 kg ai/ha, one application per cutting, and 0 day PHI for forage, 7 day PHI for fodder).

The treatment regime in the forage trials differed from the US GAP (4 × 0.14 kg ai/ha per cutting and a 0 day PHI). For the fodder trials the PHI also differed from the US GAP (4 × 0.14 kg ai/ha per cutting and 3 day PHI).

As the alfalfa trials did not match US GAP the Meeting did not estimate a maximum residue level for alfalfa fodder.

Clover (forage and hay)

Nine trials for clover forage and hay each were conducted in the USA (US GAP: a dosage rate of 0.13 kg ai/ha, one application per cutting, and 0 day PHI for forage, 7 day PHI for hay).

The treatment regime in the forage trials differed from the US GAP (4 × 0.14 kg ai/ha per cutting and a 0 day PHI). For the hay trials the PHI also differed from the US GAP (4 × 0.14 kg ai/ha per cutting and 3 day PHI).

As the clover trials did not match US GAP the Meeting did not estimate a maximum residue level for clover hay.

Bean forage

The residues were measured in bean foliage derived from supervised trials conducted according to maximum US GAP for the common bean commodity described previously.

Residues from eight trials conducted according to maximum US GAP were: 3.3, 3.6, 4.1, 4.6, 5.1, 5.8, 15, and 26 mg/kg. The Meeting estimated a median residue of 4.9 mg/kg and the highest residue of 26 mg/kg.

Pea vines

The residues in pea foliage were derived from the supervised trials for pea (pods), which were conducted according to maximum US GAP as described previously under the common bean commodity: 3.5, 6.1, and 8.6 mg/kg.

The Meeting decided to combine the data for bean forage, beans and peas for mutual support. The resulting residues were: 3.3, 3.5, 3.6, 4.1, 4.6, 5.1, 5.8, 6.1, 8.6, 15, and 26 mg/kg.

The Meeting estimated a median residue of 5.1 mg/kg and the highest residue of 26 mg/kg for bean forage and pea vines and withdrew its previous recommendations for bean forage.

Fate of residues during processing

The 2009 JMPR estimated processing factors for orange products. Taking into account the STMR for citrus fruits estimated by the present Meeting, new STMR-Ps for citrus products were calculated. The STMR-P values are summarized below.

Raw agricultural commodity (RAC)	Processed commodity	Processing factor	RAC-STMR (mg/kg)	STMR-P (mg/kg)
Citrus	Citrus juice	0.22	0.28	0.062
	Marmalade	0.77	0.28	0.22
	Citrus oil	42.5	0.28	12
	Citrus dry pulp	1.1	0.28	0.31

Residues in animal commodities

Estimated dietary burdens of farm animals

The Meeting estimated the dietary burden of methoxyfenozide residues by applying the OECD feed table for maximum proportion of agricultural commodities in animal feed (FAO Manual 2nd ed. 2009, Appendix IX).

Dietary burden calculations for beef cattle, dairy cattle are provided in Annex 6. A mean and maximum dietary burden for livestock, based on methoxyfenozide use, is shown below.

	Livestock dietary burden, methoxyfenozide, ppm of dry matter diet							
	US-Canada		EU		Australia		Japan	
	max	mean	max	mean	max	mean	max	mean
Beef cattle	16.97	9.01	110.8	48.19	110.8	48.25	0.0222	0.0222
Dairy cattle	66.10	29.57	96.57	38.40	110.8[a]	48.25[b]	56.30	27.54
Poultry, broilers	0.0923	0.0923	0.321	0.171	0.0668	0.0668	0.0159	0.0159
Poultry, layers	0.0923	0.0923	24.03[c]	8.058[d]	0.0668	0.0668	0.0182	0.0182

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

[b] Highest mean beef or dairy cattle dietary burden suitable for STMR estimates for mammalian meat, edible offal and milk

[c] Highest maximum broiler or layer poultry dietary burden suitable for maximum residue level estimates for poultry meat, edible offal and eggs

[d] Highest mean broiler or layer poultry dietary burden suitable for STMR estimates for poultry meat, edible offal and eggs

Farm animal feeding studies

The present Meeting used the feeding studies utilized by the 2003 and 2009 JMPR. In the studies, cows at each level were dosed orally at feeding levels of 16, 54 or 180 ppm for 28 consecutive days. The methoxyfenozide residues detected in various tissues are summarized below.

Tissue	Feeding level in cows					
	16 ppm		54 ppm		180 ppm	
	Maximum Res [a], mg/kg	Average Res, mg/kg	Maximum Res, mg/kg	Average Res, mg/kg	Maximum Res, mg/kg	Average Res, mg/kg
Milk	< 0.01	< 0.01	< 0.01	< 0.01	0.1	0.028
Muscle	< 0.003	< 0.003	< 0.003	< 0.003	0.01	0.0073
Fat	0.011	< 0.01	0.082	0.041	0.44	0.28
Liver	< 0.01	< 0.01	0.03	0.028	0.15	0.13
Kidney	< 0.01	< 0.01	< 0.01	< 0.01	0.034	0.026

[a] Methoxyfenozide

Estimated residues in animal commodities

The residues in animal commodities were estimated based on the calculated animal dietary burden and by interpolating with feeding study residues. 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]	54 180	< 0.01 0.028	54 180	< 0.003 0.01	0.03 0.15	< 0.01 0.034	0.082 0.44
Dietary burden and residue estimate	110.8	0.018	110.8	0.0062	0.096	0.021	0.24
STMR beef or dairy cattle							
Feeding study [b]	16 54	< 0.01 < 0.01	16 54	< 0.003 < 0.003	< 0.01 0.028	< 0.01 < 0.01	< 0.01 0.041
Dietary burden and residue estimate	48.3	< 0.01	48.3	< 0.003	0.025	< 0.01	0.036

[a] Highest residues for tissues and mean residue for milk

[b] Mean residues for tissues and milk

For meat from mammals other than marine mammals, the Meeting estimated a maximum residue level of 0.3 mg/kg, an STMR of 0.036 mg/kg and an HR of 0.24 mg/kg, based on fat, and an STMR of < 0.003 mg/kg and an HR of 0.0062 mg/kg, based on muscle. For edible offal from mammals, the Meeting estimated a maximum residue level of 0.2 mg/kg, an STMR of 0.025 mg/kg

and an HR of 0.096 mg/kg, based on residues in liver. In addition, the Meeting withdrew its previous estimates for those commodities. The maximum residue levels for milk, as recommended by the 2009 JMPR, remained the same.

Estimated STMRs or HRs for the poultry commodities based on present animal burden calculation did not affect previous JMPR recommendations.

DIETARY RISK ASSESSMENT

Long –term intake

The ADI for methoxyfenozide is 0–0.1 mg/kg bw. The International Estimated Daily Intakes (IEDI) for methoxyfenozide 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 IEDI ranged 0–5% of the maximum ADI. The Meeting concluded that the long-term intake of residues of methoxyfenozide from uses considered by the JMPR is unlikely to present a public health concern.

Short-term intake

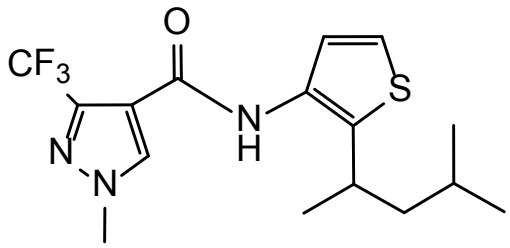
The ARfD for methoxyfenozide is 0.9 mg/kg bw. The International Estimated Short-Term Intake (IESTI) for methoxyfenozide was calculated for the food commodities for which STMRs or HRs were estimated by the present Meeting and for which consumption data were available. The results are shown in Annex 4. The IESTI varied from 0–10% of the ARfD.

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

5.25 PENTHIOPYRAD (253)

RESIDUE AND ANALYTICAL ASPECTS

Penthiopyrad (ISO common name) is a carboxamide fungicide used to control a broad spectrum of diseases on large varieties 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.

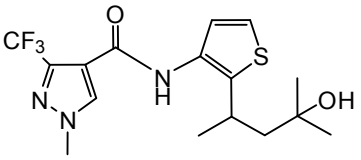


The IUPAC name of penthiopyrad is (RS)-N-[2-(1,3-dimethylbutyl)-3-thienyl]-1-methyl-3-(trifluoromethyl) pyrazole-4-carboxamide and the CA name is N-[2-(1,3-dimethylbutyl)-3-thienyl]-1-methyl-3-(trifluoromethyl)-1H-pyrazole-4-carboxamide (9CI).

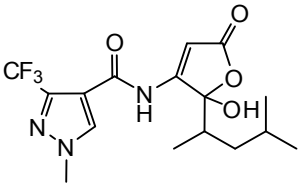
Penthiopyrad labelled either in the pyrazole- (P-label) or thienyl-moiety (T-label) was used in the metabolism and environmental fate studies.

The following abbreviations are used for the metabolites discussed below:

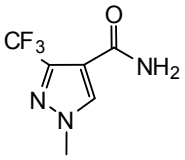
753-A-OH



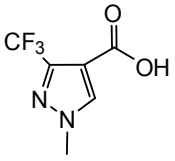
753-F-DO



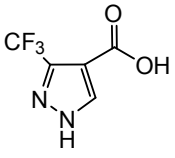
PAM



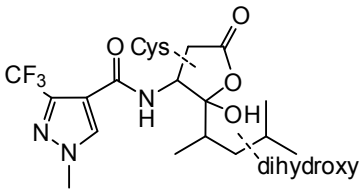
PCA



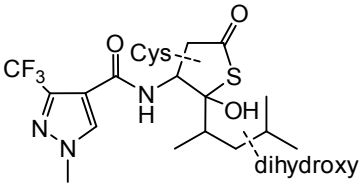
DM-PCA



dihydroxy-cys-F-DO



dihydroxy-cys-T-DO



Animal metabolism

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

Rats

In the 2011 JMPR Report on penthiopyrad the following conclusions were drawn by the WHO Experts regarding the metabolism of the active substance in rats:

"The absorption, distribution, metabolism and excretion of penthiopyrad were investigated in rats. ^{14}C labelled penthiopyrad was rapidly and extensively absorbed from the gastrointestinal tract of rats following oral dosing. The extent of absorption was approximately 80–90% of the administered dose, independent of dose and sex.

Very little penthiopyrad was retained in the tissues.

Faecal excretion was the primary route of elimination, and excretion was rapid, with the majority excreted by all routes 24 hours after dosing (74.8–85.0%).

Extensive metabolism occurred at numerous positions within the molecule, including thienyl ring oxidation and conjugation with glutathione, thienyl ring opening, N-demethylation and alkyl side-chain hydroxylation, followed by oxidation to carboxylic acids and glucuronidation. The most abundant metabolite in both urine and faeces was formed as the result of N-demethylation and oxidation of the methyl moiety of the alkyl side-chain. The most abundant metabolites found in bile were formed as a result of thienyl ring oxidation to 753-F-DO, followed by its conjugation with glutathione and the catabolism of this product. Other significant metabolites in bile were glucuronic acid conjugates of the intermediate demethylated and hydroxylated metabolites. Four metabolites containing the pyrazole moiety following cleavage from the thienyl moiety were excreted in both urine and faeces. The two acids, 1-methyl-3-trifluoromethyl-1H-pyrazole-4-carboxylic acid (PCA) and 3-trifluoromethyl-1H-pyrazole-4-carboxylic acid (DM-PCA) are likely formed by amide hydrolysis from 1-methyl-3-trifluoromethyl-1H-pyrazole-4-carboxamide (PAM) and DM-PAM. PAM and subsequent metabolites account for less than 1% of the administered dose. The thienyl ring appears to be completely degraded."

Goats

Two studies on metabolism in goats were available. In the first study on lactating goats radiolabelled penthiopyrad was administered at a rate equivalent to 20 ppm in the feed, less than 1% of the total dose was recovered from milk or tissues of the animals. Most of the radioactivity was excreted via faeces and urine.

In muscle and fat TRR levels were 0.011–0.038 mg eq./kg and 0.015–0.028 mg eq./kg, respectively. For muscle only PAM and PCA were identified present at 51% and 7% of the TRR. In fat unchanged penthiopyrad (32% TRR, 0.009 mg eq./kg) and PAM (12% TRR, 0.003 mg eq./kg) were the only structures identified.

For kidney (TRR: 0.11–0.33 mg eq./kg) PAM was the major component for the P-label accounting for 19% of the TRR (0.062 mg eq./kg). Unchanged penthiopyrad was detected in traces only (3% TRR, 0.011 mg eq./kg). For the T-label only 753-A-OH was identified, being present at 6% of the TRR (0.007 mg eq./kg). The remaining radioactivity for both labels could not be attributed to specific reference compounds.

In liver TRR levels were 1.9 mg eq./kg for P- and 0.99 mg eq./kg for the T-label. Of the TRR 2% (0.037 mg eq./kg, T-label only) could be attributed to penthiopyrad. The radioactivity recovered was distributed between numerous analytical peaks accounting less than 10% of the TRR each. Identified metabolites were PAM (3% TRR, 0.053 mg eq./kg), PCA (9% TRR, 0.17 mg eq./kg), 753-F-DO (1% TRR, 0.02 mg eq./kg) and 753-A-OH (0.5% TRR, 0.005 mg eq./kg).

In the second study on lactating goats the animals were administered radiolabelled penthiopyrad at rates equivalent to 10 ppm in the feed. TRR levels found were 0.66–0.74 mg eq./kg in liver, followed by kidney (0.15–0.17 mg eq./kg). In muscle, fat and milk the TRR was between 0.013 to 0.072 mg eq./kg.

In muscle PAM was identified as major metabolite being present at levels of 46% of the TRR (0.012 mg eq./kg). In addition traces of DM-PAM were detected (12% TRR, 0.003 mg eq./kg). In fat only DM-PAM, PAM and penthiopyrad were detected at traces up to 0.005 mg eq./kg.

In milk PAM was the major residue at 30% of the TRR (0.013 mg eq./kg) for the P-label, followed by cys-T-DO-isomer with 16% of the TRR (0.007 mg eq./kg). For the T-label the degradation was more extensive, showing unattributed analytical peaks at levels of 8% of the TRR or less (0.008 mg eq./kg or less) each.

In liver solvent extraction with ACN/water released approx. 40% of the TRR, characterised as numerous unassigned analytical peaks present at < 10% of the TRR each. Only hydroxy-penthiopyrad was found in the T-label sample at or above 10% of the TRR (10% TRR, 0.069 mg eq./kg). Following protease, acid and base hydrolysis 97–99% of the TRR could be released. Identification of the residue again gave mainly unassigned chromatographic peaks quantified at rates of < 4% of the TRR each. Only PCA and PAM were identified at levels of 13% (0.10 mg eq./kg) and 8% (0.063 mg eq./kg) of the TRR, respectively.

For kidney solvent extraction with ACN/water gave numerous single metabolites each below 10% of the TRR (0.017 mg eq./kg and less). For the T-label only PAM and the dihydroxy-cys-F-DO isomer were present at amounts of 10% (0.016 mg eq./kg) and 11% (0.017 mg eq./kg) of the TRR, respectively. After protease, acid and base hydrolysis 97–103% of the TRR were released. A large number of substances at individual levels all below 4% of the TRR (0.006 mg eq./kg or less) were found. Additional major metabolites at levels > 10% of the TRR could not be identified.

Laying hens

For laying hens radiolabelled penthiopyrad equivalent to 10 ppm in the diet was administered for 14 consecutive days. For both the P- and the T-label TRR levels in egg yolk (0.28–0.37 mg eq./kg) were higher than in the egg white (0.05–0.06 mg eq./kg). In tissues TRR levels were 0.021–0.049 mg eq./kg in fat, 0.038–0.052 mg eq./kg in muscle, 0.053–0.059 mg eq./kg in skin and 0.6–0.68 mg eq./kg in liver.

In egg white PAM was the major residue present following administration of the P-label, being present up to 50% of the TRR. Unchanged penthiopyrad was identified in all samples, but near the LOQ (0.001 mg/kg). In addition minor levels of 753-A-OH (5–7% TRR) were found.

For egg yolk PAM was the major residue (24–28% of the TRR) following solvent extraction. Hydrolysis released additional 10% of the TRR as PAM. Penthiopyrad was found at levels of 2–15% of the TRR following hydrolysis. Additional minor metabolites all being present at levels of < 10% of the TRR each could be attributed to known reference substances.

For hens' liver also numerous metabolites were present at individual levels of 13% of the TRR and less (0.079 mg eq./kg and less). The only substances identified were PCA with 1.4% TRR

(0.009 mg eq./kg) and PAM with 8% TRR (0.05 mg eq./kg). Following hydrolysis, releasing the major part of the radioactivity, PCA and PAM gave additional amounts of 2% TRR (0.012 mg eq./kg) and 7% TRR (0.043 mg eq./kg), respectively.

In a second study laying hens were administered radiolabelled penthiopyrad equivalent to 10 ppm in the diet. TRR levels found were 0.062–0.094 mg eq./kg in whole eggs, 0.014–0.022 mg eq./kg in muscle, 0.014–0.02 mg eq./kg in fat and 0.24–0.35 mg eq./kg in liver. Further investigation on the nature of residues was performed for eggs and liver only.

For eggs a broad pattern of metabolites all being present below 0.01 mg eq./kg (less than 16% of the TRR) was found. PAM was identified as major residue (0.007 mg eq./kg, 11% TRR) followed by DM-PAM (0.004 mg eq./kg, 7% TRR). Hydrolysis released some additional radioactivity too low for further identification. Only two major chromatographic peaks attributed to PAM were detected, adding 0.01 mg eq./kg for the P-label and 0.008 mg eq./kg for the T-label.

In liver numerous metabolites were found mainly being present at individual levels of < 10% of the TRR for both labels. PAM was the major residue in hens' liver for the P-label with a total amount of 0.046 mg eq./kg parent equivalents (19% of the TRR). For the T-label dihydroxy-cys-T-DO was identified following digestion at a total of 0.042 mg eq./kg parent equivalents (12% of the TRR).

No unchanged penthiopyrad could be identified in hens liver or eggs.

In summary penthiopyrad is effectively degraded in goats and hens into a large number of minor metabolites following hydrolysis, oxidation, N-demethylation and conjugation. Major metabolites were mainly PAM, formed by cleavage of the molecule, or the hydroxylation product 753-A-OH. Unchanged parent substance was found in several samples; however, individual levels were normally below 10% of the TRR. The metabolites dihydroxy-cys-F-DO in goats' kidney (11%TRR, 0.017 mg eq./kg) and dihydroxy-cys-T-DO in hens liver (12%TRR, 0.042 mg eq./kg) wer not identified in rats. All other major metabolites identified were also found in rats.

Plant metabolism

The Meeting received plant metabolism studies for penthiopyrad following foliar application to grapes, cabbage, tomatoes, wheat and rape using a mixture of both radiolabelled active substances.

Grapes

Two plots of grapes were treated with a 1:1 mixture of P- and T-radiolabelled penthiopyrad at rates equivalent to 0.4 kg ai/ha each. Samples of grapes and leaves were collected after either 30 of 60 days. Total radioactive residues in grapes were 0.20–0.24 mg eq./kg after 30 days and 0.083–0.21 mg eq./kg after 60 days. In leaves TRR levels of 5.1 mg eq./kg were found 30 day after treatment (DAT) and of 3.3 mg eq./kg 60 DAT.

Rinsing of grapes released 24% and 12% of the TRR from 30 DAT and 60 DAT samples, respectively. In the rinse unchanged parent penthiopyrad was the major residue (11% TRR for 30 DAT and 2.4% TRR for 60 DAT). In the rinsed fruits penthiopyrad amounts of 9% TRR for 30 DAT and 2.4% TRR for 60 DAT were found. Besides PAM in grapes after 60 DAT (13% TRR) no further metabolites present at relative amounts > 10 of the TRR were identified. Additional attempts for identification using acid hydrolysis released minor amounts of 753-A-OH.

Cabbage

Cabbage plants were treated with a SC formulation using application rates equivalent to either 0.2 or 1 kg ai/ha. After 21 days samples of outer leaves, inner heads and roots were samples and analysed for residues. Total radioactive residues were 1.4 mg eq./kg and 7.9 mg eq./kg for outer leaves, 0.045 mg eq./kg and 0.16 mg eq./kg for inner heads and 0.48 mg eq./kg and 2.6 mg eq./kg for roots, following the lower or higher application rate, respectively.

Rinsing of the outer leaves recovered 44% of the TRR for both application rates. Rinsing the inner leaves additionally recovered 8–11% of the TRR. In the rinses and extracts of leaves penthiopyrad was identified as the major residue, represent at 20–34% of the TRR. Metabolites DM-753, 753-F-DO, 753-A-OH, PCA and PAM were identified, however only PAM was present at amounts higher than 10% of the TRR (10–11% TRR).

Tomatoes

Field grown tomatoes were treated with a 1:1 mixture of P- or T-radiolabelled penthiopyrad at rates equivalent to either 0.3 kg ai/ha or 1.5 kg ai/ha. Total radioactive residues for the low and high rate plots found in fruits after 14 days were 0.014 mg eq./kg and 0.46 mg eq./kg and after 21 days 0.022 mg eq./kg and 0.28 mg eq./kg, respectively. In leaves (21 DAT) TRR levels of 0.65 mg eq./kg for the low rate and 4.8 mg eq./kg for the high rate samples were found.

Rinsing of fruits treated with the higher application rate recovered 76% of the TRR after 14 days and 68% of the TRR after 21 days. In the 14 DAT samples 45% of the TRR (combined rinse and extract) were identified as penthiopyrad, decreasing to 23–38% TRR after 21 days of the TRR. Other metabolites identified were PAM (4–6% TRR), PCA (4–8% TRR), 753-A-OH (1% TRR) and 753-F-DO (3–4% TRR).

In leaves treated with low or high rates penthiopyrad was the major residue with levels ranging from 37% to 55% (0.24 and 2.7 mg eq./kg), respectively. Identified metabolites were PCA (8% TRR or 0.053 mg eq./kg; 3% TRR or 0.14 mg eq./kg), PAM (4% TRR or 0.027 mg eq./kg; 5% TRR or 0.24 mg eq./kg) and 753-F-DO (2% TRR or 0.014 mg eq./kg; 5% TRR or 0.22 mg/kg).

Wheat

Wheat plants were treated with a 1:1 mixture of P- and T-radiolabelled penthiopyrad in the field at application rates equivalent to 2× 0.25 kg ai/ha or 2× 0.75 kg ai/ha. The applications were conducted at stem elongation and the end of flowering (BBCH 59). Samples of forage (7 days after 1st application), hay (5 days after 2nd application), wheat and straw (32 days after 2nd application) were collected. TRR levels found were 6.5 mg eq./kg and 22 mg eq./kg for forage, 4.0 mg eq./kg and 17 mg eq./kg for hay, 9.4 mg eq./kg and 42 mg eq./kg for straw and 0.34 mg eq./kg and 0.87 mg eq./kg for grain following low or high rate treatment, respectively. Only low rate samples were further analysed.

In forage and hay unchanged penthiopyrad was the major residue being present at 75% and 44% of the TRR. Other metabolites identified (PAM, PCA, F-DO and 753-T-DO) each amounted less than 5% of the TRR in forage and hay. In straw penthiopyrad also contributed most to the TRR (19%). Identified metabolites were identical to forage and hay; however PCA and PAM were found at slightly higher levels of 9% and 6% of the TRR, respectively.

In grain penthiopyrad was found at 8% of the TRR, representing the major residue. Both PAM and PCA were present at 4% of the TRR. No further metabolites were identified in grain.

Rape seed

Rape seed (canola) was treated with a 1:1 mixture of P- or T-radiolabelled penthiopyrad in the field two times with 0.4 kg ai/ha at stem elongation and the end of flowering. Forage was collected 14 days after the first application, mature seeds 34 days after the second application. TRR levels in forage and seeds were 12 mg eq./kg and 0.14 mg eq./kg, respectively.

In forage the major residue was 753-A-OH malonyl glucoside (25% TRR, 3.0 mg eq./kg). Unchanged penthiopyrad was found at 11% of the TRR (1.4 mg eq./kg). Other metabolites were all below 10% of the TRR remained mainly unidentified except PAM (1 % TRR, 0.16 mg eq./kg), PCA (0.5% TRR, 0.062 mg eq./kg) and DM-A-OH malonyl glucoside (9%TRR, 1.1 mg eq./kg).

In seeds penthiopyrad and PCA were identified at the LOQ of 0.001 mg/kg (0.7% TRR) in the organic phase following extraction. Approximately 27% of the TRR (0.038 mg eq./kg) was indistinguishable from natural lipids. In the aqueous phase DM-PAM and PAM were attributed to 2

chromatographic peaks at levels of 5% TRR (0.007 mg eq./kg) and 8% TRR (0.011 mg eq./kg), respectively. Additional PCA was found with 2% TRR (0.003 mg/kg). No further metabolites were identified in the aqueous phase.

Summary

In summary the plant metabolism of penthiopyrad is extensive. Following hydroxylation of the dimethyl-butyl-side chain, 753-A-OH is formed as the first stable intermediate. Subsequently conjugation with glucose or glucose malonyl occurs. In case of a hydroxylation at the thienyl moiety, the metabolite 753-F-DO is formed after substitution of the sulphur by oxygen. This structure is then cleaved, leaving the pyrazole moiety to form PAM, PCA and DM-PCA. All major metabolites identified were also found in rats.

Environmental fate in soil

The Meeting received information on the fate of penthiopyrad after aerobic degradation in soil and after photolysis on the soil surface. In addition, the Meeting received information on the uptake of penthiopyrad soil residues by rotational crops. Experiments were carried out using penthiopyrad ^{14}C labelled in the pyrazole or thienyl moiety.

In aerobic soil metabolism studies the metabolic pattern was more or less comparable to the plant metabolism. In nearly all samples PAM, PCA, 753-A-OH and 753-F-DO were found at levels of 2–10% of the applied radioactivity (AR). DM-PCA was identified as major residue in most samples, although mainly being present at levels below 10% of the AR after 140–269 days (in two samples up to 17% and 28% of the AR). Depending on the soil type remaining levels of penthiopyrad ranged from 11% to 78% of the AR (161–300 d). Estimated half-life times (1st order kinetics) were between 65 to 356 days for penthiopyrad.

Soil photolysis of penthiopyrad resulted in less than 50% remaining after three days. After 15 days only 4% of the initial concentration of the parent was recovered from the soil. According to the underlying study the irradiation of 15 days corresponds to 29 midsummer days at latitude 50°N. Main degradation products were PAM and PCA with 27% and 23% of the initial activity, respectively.

Residues in rotational crops

In a confined rotational crop study, a 1:1 mixture of P- and T-radiolabelled penthiopyrad was applied to bare soil at a rate equivalent to 0.8 kg ai/ha. Rotational crops (spinach, lettuce, radish and wheat) were sown or planted 30, 120 and 360 days later. Radioactive residues above the LOQ of 0.001 mg eq./kg were found in all samples, ranging from 0.011–0.73 mg eq./kg after the first, 0.005–0.16 mg eq./kg for the second and 0.003–0.086 mg eq./kg after the third rotation.

Identification of radioactivity was performed for samples with TRR levels above 0.01 mg/kg parent equivalents. Although extraction released 50–100% of the TRRs, rates of identification were low, showing 753-A-OH as highest residue present in spinach leaves (0.039 mg eq./kg). Parent penthiopyrad was identified in chaff samples from 30 days crops rotation. In addition PCA and DM-PAM were identified in spinach leaves and chaff (0.012–0.014 mg eq./kg). In other samples the radioactivity was present in polar fractions consisting of at least 14 individual components not further identified.

Field rotation studies reflecting authorised application rates are available from Europe and the USA. In Europe either cucumbers (Southern Europe) or barley (Northern Europe) were treated with two sprayings of 0.4 kg ai/ha each. Lettuce, spinach, radish, wheat and barley were planted as rotational crops. In all samples no residues above the LOQ were found for penthiopyrad except one detect at 0.017 mg/kg in radish roots. PCA and DM-PCA were frequently present in lettuce, radish and wheat, ranging up to 0.16 mg/kg for DM-PCA in wheat forage. PAM, 753-A-OH and 753-F-DO were not found above the LOQs of 0.01–0.05 mg/kg.

In USA trials field crops were treated with application rates of four sprayings with 0.25 kg ai/ha each. Radish, lettuce and wheat were planted as rotational crops and grown to maturity.

In none of the samples residues above the LOQ were found for penthiopyrad, 753-A-OH, 753-F-DO and PCA. Several minor results of up to 0.064 mg/kg were found for PAM, while DM-PCA was present in most samples ranging up to 0.12 mg/kg (radish tops).

In soil the degradation pathway is similar to plants, although no conjugates were observed. The translocation of residues into rotational crops was limited mainly to PCA and DM-PCA, latter being found in concentrations up to 0.09 mg/kg in food commodities, but without a tendency for accumulation. Based on the current use pattern from the USA, the submitted field rotation studies provide a realistic estimate for potential residues arising. For penthiopyrad, PAM, 753-A-OH and 753-F-DO no significant uptake via the roots occurred.

Methods of analysis

The Meeting received a number of analytical methods have for the analysis of penthiopyrad, PAM, PCA, 753-A-OH, 753-F-DO and DM-PCA in plant and animal matrices. The basic principle employs extraction by homogenisation with acetone/water or acetonitrile/water. After partitioning against an organic solvent (normally ethyl acetate) the extracts were cleaned with GPC or directly used for analysis. Residues are determined by liquid chromatography (LC) in combination with tandem mass spectroscopy (MS/MS). Validated LOQs for all analytes were 0.01 mg/kg for plant and animal matrices.

For the application of multi-residue methods the DFG S-19 was tested with satisfactory recoveries for parent penthiopyrad. The metabolites PAM, PCA and DM-PCA did not give acceptable recoveries using the DFG S-19 method.

Stability of residues in stored analytical samples

The Meeting received information on the storage stability of penthiopyrad, PAM, PCA, 753-A-OH, 753-F-DO and DM-PCA in plant and animal matrices. The results confirmed the stability of residues for all analytes for at least 18 months in plant matrices.

In animal matrices the percentage of recoveries were measured after a period of one month. Within this timeframe, which covers the storage period of animal metabolism and feeding studies submitted, no significant degradation of the analytes was observed. For bovine milk the storage stability of penthiopyrad, 753-A-OH, PAM and PCA was tested for up to 6 months without significant degradation.

Definition of the residue

Livestock animal metabolism studies were conducted on laying hens (10 ppm) and lactating goats (10 and 20 ppm). In lactating goats penthiopyrad was seldom present, normally near the LOQ amounting 2–3% of the TRR in liver and kidney. In fat 32% of the TRR were present as penthiopyrad, however absolute levels were low (0.009 mg eq./kg). The major residue in goats was PAM, being present at 10% TRR in milk, 3% TRR in liver, 19 % TRR in kidney, 8% TRR in muscle and 12% TRR in fat. Except for dihydroxy-cys-F-DO in goats kidney (11%TRR, 0.017 mg eq./kg) other metabolites were only identified at minor levels less than 10% TRR or less than 0.01 mg eq./kg in tissues and milk, even following acidic, basic or enzymic hydrolysis.

For laying hens parent penthiopyrad was only detected in eggs (up to 0.038 mg eq./kg or 15% TRR in egg yolk). The major residue identified was PAM with levels of 50% TRR in egg white, 24% TRR in egg yolk and 15% TRR in liver (sum of extracts). Except for dihydroxy-cys-T-DO found in one hen's liver sample (0.042 mg eq./kg, 12% TRR) all other metabolites were present at less than 10% of the TRR or less than 0.01 mg eq./kg in tissue and eggs even following acidic, basic or enzymic hydrolysis..

The Meeting concluded that penthiopyrad and PAM were the major residues found in all animal matrices. While parent penthiopyrad was more associated with fatty compartments, PAM was the dominant residue found in tissues, milk and eggs. Analytical methods are capable of measuring both analytes.

Concerning the toxicological relevance of penthiopyrad and its metabolites, PAM was identified to be of higher acute toxicity compared to the parent substance. However PAM was also identified in rats and is covered by the toxicological endpoints of the parent penthiopyrad. The major metabolites dihydroxy-cys-F-DO in goats' kidney and dihydroxy-cys-T-DO in hens' liver were not found in the rat. Dihydroxy degradates would be derived from the monohydroxy-F and –T-DO metabolites, which are found in rats and have very little toxicity concern. Any further metabolism would result in non-toxic products and they would be readily excreted in the body. Other metabolites (PCA, 753-F-DO, 753-A-OH and DM-PCA) are also of lower acute toxicity than penthiopyrad.

For MRL compliance and for dietary intake assessment the Meeting recommended use of the sum of penthiopyrad and PAM, expressed as penthiopyrad, in animal matrices. Although the parent substance was found at higher levels in fat than in muscle, the overall residue including PAM was evenly distributed, suggesting that the residue is not fat-soluble.

The fate of penthiopyrad in plants was investigated following foliar application to grapes, cabbage, tomatoes, wheat and rape. The parent substance was the major residue, being present at levels of 21% TRR in grapes, 20–34% TRR in cabbage, 45–46% TRR in tomatoes, 19% TRR in wheat grain and 11% TRR in rapeseeds. The only other major metabolite found was PAM (14% TRR in grapes, 11% TRR in cabbage, 6% TRR in tomato, 6% TRR in wheat grain and 1% TRR in rapeseeds). Further minor metabolites identified (PCA, 753-F-DO, 753-A-OH, DM-PCA) were normally below 10% of the TRR and often below the limit for identification.

Data from supervised field trials confirmed the results of the plant metabolism studies. Parent penthiopyrad was the highest residue of all analytes, followed by PAM and PCA. 753-F-DO and 753-A-OH were normally not present above the LOQ (0.01 mg/kg). DM-PCA was found in soil and may be taken up by following crops, resulting in detectable residues above the LOQ up to 0.09 mg/kg in food items under field conditions. However, DM-PCA is of lower acute toxicity than the parent substance and its residues make an insignificant contribution to the overall exposure compared to penthiopyrad and PAM.

Based on the overall data in plants the Meeting concluded that parent penthiopyrad is a suitable marker substance for compliance of MRLs for plant commodities. Penthiopyrad can be analysed using established analytical methods.

For dietary intake purposes PAM is covered by the toxiological reference values for penthiopyrad. Other metabolites (PCA, 753-F-DO, 753-A-OH and DM-PCA) were of lower acute toxicity compared to parent penthiopyrad and contributing insignificantly to the overall exposure compared to concentrations found for penthiopyrad and PAM.

The Meeting recommends that for MRL compliance the residue definition for plant commodities should be penthiopyrad. For dietary intake purposes the residue is defined as sum of penthiopyrad and PAM, expressed as penthiopyrad.

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.

Results of supervised residue trials on crops

The Meeting received supervised trial data for applications of penthiopyrad on a range of crops (fruits, vegetables, oilseed and cereal grains), conducted in Europe and North America. The OECD MRL calculator was used as a tool to assist in the estimation of maximum residue levels from the selected residue data set obtained from the supervised residue trials. As a first step, the Meeting reviewed all relevant factors related to each data set in arriving at a best estimate of the maximum residue level using expert judgement. Then the OECD calculator was employed. If the statistical

calculation spreadsheet suggested a different value from that recommended by the Meeting, a brief explanation of the deviation was supplied.

In trials where duplicate field samples from replicated or unreplicated plots were taken at each sampling time and analysed separately, the mean sample was taken as the best estimate of the residue from the plot.

Labels (or translation of labels) were available from Japan and the USA, describing the registered uses of penthiopyrad.

Supervised field trial data for penthiopyrad conducted in Europe were submitted for various crops. However authorisations in European Member states are still pending, not allowing an assessment of these field trials.

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. Therefore 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)

Pome fruits

Penthiopyrad is registered in Canada and the USA for the use on pome fruit at rates of 3–4 × 0.3 kg ai/ha with a PHI of 28 day. Supervised field trials conducted in the USA on apples and pears according to these GAPs were submitted.

Residues of parent penthiopyrad in apple were (n=17): < 0.01, 0.076, 0.099, 0.12(4), 0.13, 0.14, 0.14, 0.15, 0.16, 0.21, 0.22 and 0.23(3) mg/kg.

The total residues in apples were (n=17): < 0.01, 0.10, 0.12, 0.13, 0.13, 0.14, 0.14, 0.15, 0.15, 0.16, 0.17, 0.17, 0.22, 0.24, 0.24, 0.25 and 0.26 mg/kg.

Residues of parent penthiopyrad in pears were (n=10): < 0.01, 0.035, 0.064, 0.097, 0.12, 0.17, 0.18, 0.19, 0.22 and 0.25 mg/kg.

The total residues in pears were (n=10): < 0.01, 0.05, 0.09, 0.12, 0.13, 0.19, 0.20, 0.22, 0.24 and 0.27 mg/kg.

The Meeting noted that corresponding GAP is for all pome fruits and decided to make recommendations for the whole group. Residues in apples and pears treated according to the US GAP for pome fruits were not significantly different and may be combined.

Residues of parent penthiopyrad in pome fruits were (n=27): < 0.01, < 0.01, 0.035, 0.064, 0.076, 0.097, 0.099, 0.12(5), 0.13, 0.14, 0.14, 0.15, 0.16, 0.17, 0.18, 0.19, 0.21, 0.22, 0.22, 0.23(3) and 0.25 mg/kg.

The total residues in pome fruits were (n=27): < 0.01, < 0.01, 0.05, 0.09, 0.10, 0.12, 0.12, 0.13(3), 0.14, 0.14, 0.15, 0.15, 0.16, 0.17, 0.17, 0.19, 0.20, 0.22, 0.22, 0.24(3), 0.25, 0.26 and 0.27 mg/kg.

Based on the combined dataset for apples and pears the Meeting estimated a maximum residue level, an STMR and an HR of 0.4 mg/kg, 0.15 mg/kg and 0.27 mg/kg for penthiopyrad in pome fruits, respectively.

Stone fruits

Residue data were provided to the Meeting from trials in USA on cherries, peaches and plums. GAP for stone fruits is for a maximum of four foliar applications of up to 0.3 kg ai/ha in Canada and for a maximum of three foliar applications of up to 0.35 kg ai/ha in the USA with a PHI of 0 days, respectively.

Residues of parent penthiopyrad in cherries (whole fruits) were (n=9): 0.38, 0.44, 0.9, 0.96, 1.1, 1.1, 1.3, 1.6 and 1.7 mg/kg.

The total residues in cherries (pitted fruits) were (n=9): 0.71, 0.8, 1.0, 1.0, 1.3, 1.3, 1.4, 1.8 and 1.9 mg/kg.

Residues of parent penthiopyrad in peaches (whole fruits) were (n=13): 0.18, 0.2, 0.28, 0.35, 0.44, 0.47, 0.56, 0.58, 0.61, 0.61, 0.69, 0.7 and 1.4 mg/kg.

The total residues in peaches (pitted fruits) were (n=13): 0.2, 0.31, 0.32, 0.4, 0.54, 0.60, 0.63, 0.67, 0.67, 0.71, 0.73, 0.76 and 1.6 mg/kg.

Residues of parent penthiopyrad in plums (whole fruits) were (n=12): 0.047, 0.076, 0.08, 0.089, 0.1, 0.11, 0.12, 0.13, 0.15, 0.29, 0.51 and 0.77 mg/kg.

The total residues in plums (pitted fruits) were (n=12): 0.068, 0.072, 0.099, 0.10, 0.12, 0.12, 0.13, 0.14, 0.14, 0.24, 0.33 and 0.83 mg/kg.

The Meeting noted that the corresponding GAP is for all stone fruits and decided to make recommendations on the whole group. However the Meeting recognized that datasets for individual commodities within the group were significantly different and could not be combined. Therefore recommendations on stone fruits will be based on cherries, representing the commodity resulting in highest residues within the group.

Based on cherries the Meeting estimated a maximum residue level, an STMR and an HR of 4 mg/kg, 1.3 mg/kg and 1.9 mg/kg for stone fruits, respectively.

Strawberries

Penthiopyrad is registered in Canada and the USA for the use on strawberries at rates of 3× 0.36 kg ai/ha with a PHI of 0 day. Supervised field trials conducted in the USA on strawberries according to these GAPs were submitted.

Residues of parent penthiopyrad in strawberry fruits were (n=9): 0.37, 0.41, 0.46, 0.62, 0.77, 0.87, 1.0, 1.4 and 1.8 mg/kg.

The total residues in strawberry fruits were (n=9): 0.39, 0.43, 0.47, 0.64, 0.80, 0.89, 1.1, 1.4 and 1.8 mg/kg.

The Meeting estimated a maximum residue level, an STMR and an HR of 3 mg/kg, 0.8 mg/kg, and 1.8 mg/kg for penthiopyrad in strawberries, respectively.

Bulb vegetables

Residue data were provided to the Meeting from trials in Canada and the USA on bulb and green onions. GAP for bulb vegetables is for a maximum of three foliar applications of up to 0.36 kg ai/ha with a PHI of 3 days.

Residues of parent penthiopyrad in bulb onions were (n=11): 0.01, 0.014, 0.043, 0.05, 0.054, 0.064, 0.065, 0.13, 0.14, 0.36 and 0.45 mg/kg.

The total residues in bulb onions were (n=11): 0.029, 0.033, 0.062, 0.068, 0.072, 0.082, 0.085, 0.14, 0.15, 0.37 and 0.72 mg/kg.

The Meeting estimated a maximum residue level, an STMR and an HR of 0.7 mg/kg, 0.074 mg/kg and 0.72 mg/kg for penthiopyrad in onions, bulb, respectively.

Residues of parent penthiopyrad in onions, green were (n=6): 0.21, 0.23, 0.55, 0.93, 1.4 and 1.8 mg/kg.

The total residues in onions, green were (n=6): 0.35, 0.66, 0.68, 1.1, 1.4 and 2.0 mg/kg.

The Meeting estimated a maximum residue level, an STMR and an HR of 4 mg/kg, 0.89 mg/kg and 2.0 mg/kg for penthiopyrad in onions, Welsh and spring onions.

Flowerhead brassica

Residue data were provided to the Meeting from trials in Canada and the USA on broccoli and cauliflower. GAP for flowerhead brassica is for a maximum of three foliar applications of up to 0.45 kg ai/ha and a PHI of 0 days.

Residues of parent penthiopyrad in broccoli were (n=7): 0.65, 0.87, 1.4, 1.4, 1.9, 1.9 and 2.4 mg/kg.

The total residues in broccoli were (n=7): 0.67, 0.89, 1.4, 1.4, 1.9, 1.9 and 2.4 mg/kg.

Residues of parent penthiopyrad in cauliflower were (n=3): 0.11, 0.5 and 0.5 mg/kg.

The total residues in cauliflower were (n=3): 0.13, 0.51 and 0.52 mg/kg.

The Meeting noted that the corresponding GAP is for all flowerhead brassica and decided to make recommendations on the whole group. However the Meeting recognized that datasets for individual commodities within the group were significantly different and could not be combined. Therefore recommendations on flowerhead brassica will be based on broccoli, representing the commodity resulting in highest residues within the group.

Based on broccoli the Meeting estimated a maximum residue level, an STMR and an HR of 5 mg/kg, 1.4 mg/kg and 2.4 mg/kg for penthiopyrad in flowerhead brassicas, respectively.

Cabbages, Head

Residue data were provided to the Meeting from trials in Canada and the USA on head cabbage. GAP for head cabbages is for a maximum of three foliar applications of up to 0.45 kg ai/ha and a PHI of 0 days.

Residues of parent penthiopyrad in head cabbage were (n=10): 0.024, 0.089, 0.19, 0.22, 0.29, 0.48, 1.0, 1.3, 1.5 and 2.3 mg/kg.

The total residues in head cabbage were (n=10): 0.043, 0.11, 0.21, 0.24, 0.31, 0.49, 1.0, 1.3, 1.5 and 2.4 mg/kg.

The Meeting estimated a maximum residue level, an STMR and an HR of 4 mg/kg, 0.4 mg/kg and 2.4 mg/kg for penthiopyrad in head cabbages, respectively.

Fruiting vegetables, Cucurbits

Residue data were provided to the Meeting from trials in Canada and the USA on summer squash, cucumber, melon and winter squash. GAP in the field for cucurbits (cucumbers, melons, watermelons, squashes) is for a maximum of four foliar applications of up to 0.3 kg ai/ha and a PHI of 1 days.

Residues of parent penthiopyrad in summer squash were (n=4): 0.01, 0.13, 0.18 and 0.19 mg/kg.

Residues of parent penthiopyrad in cucumber were (n=10): 0.012, 0.015, 0.029, 0.034, 0.043, 0.047, 0.065, 0.086, 0.11 and 0.13 mg/kg.

Residues of parent penthiopyrad in melon (whole fruit) were (n=8): 0.098, 0.17, 0.17, 0.18, 0.22, 0.26, 0.26 and 0.27 mg/kg.

Residues of parent penthiopyrad in winter squash were (n=5): 0.067, 0.1, 0.12, 0.18 and 0.21 mg/kg.

The Meeting noted that Canadian and US GAP are for all members of the cucurbits group and decided to make recommendations for the whole group. Residues of penthiopyrad in summer squash, cucumber, melon, and winter squash (whole fruits) treated according to the US GAP for cucurbits were not significantly different and may be combined.

The combined residues for penthiopyrad in cucurbits (whole fruits) were (n=27): 0.01, 0.012, 0.015, 0.029, 0.034, 0.043, 0.047, 0.065, 0.067, 0.086, 0.098, 0.1, 0.11, 0.12, 0.13, 0.13, 0.17, 0.17, 0.18(3), 0.19, 0.21, 0.22, 0.26, 0.26 and 0.27 mg/kg.

Based on the combined dataset the Meeting estimated a maximum residue level of 0.5 mg/kg for penthiopyrad in fruiting vegetables, cucurbits.

The total residues in summer squash were (n=4): 0.029, 0.14, 0.2 and 0.21 mg/kg.

The total residues in cucumber were (n=10): 0.031, 0.033, 0.048, 0.052, 0.061, 0.066, 0.084, 0.10, 0.13 and 0.15 mg/kg.

The total residues in melon (whole fruit) were (n=8): 0.12, 0.18, 0.19, 0.19, 0.24, 0.28, 0.29 and 0.3 mg/kg.

The total residues in melon (pulp) were (n=8): < 0.01(8) mg/kg.

The total residues in winter squash were (n=5): 0.086, 0.12, 0.14, 0.21 and 0.22 mg/kg.

For dietary intake purposes the Meeting noted that residues in cucurbits, whole fruits and in the pulp (based on melons) differ significantly.

Therefore the Meeting decided to extrapolate all data on whole fruits to cucurbits with edible peel, also accommodating large varieties within the group like pumpkins with edible peel. The combined total residues in cucurbits (whole fruits) were (n=27): 0.02, 0.025, 0.031, 0.039, 0.044, 0.053, 0.057, 0.075, 0.077, 0.096, 0.11, 0.12, 0.12, 0.13, 0.14, 0.15, 0.18, 0.19(3), 0.2, 0.21, 0.22, 0.24, 0.28, 0.29 and 0.3 mg/kg.

For dietary intake purposes of cucurbits with edible peel, the Meeting estimated an STMR and an HR of 0.13 mg/kg and 0.3 mg/kg, based on the combined dataset for the total residue in all cucurbits (whole fruits).

The Meeting also decided to extrapolate data on melon pulp to the edible portion of all cucurbits with inedible peel, to reflect to the much lower residue situation in these commodities.

For dietary intake purposes of cucurbits with inedible peel, the Meeting estimated an STMR and an HR of 0.01 mg/kg and 0.01 mg/kg, based on the total residue in melon pulp.

Fruiting vegetables, other than cucurbits (except sweet corn and mushroom)

Residue data were provided to the Meeting from trials in Canada and the USA on peppers (sweet and chili) and tomatoes. GAP for fruiting vegetables is for a maximum of three foliar applications of up to 0.36 kg ai/ha and a PHI of 0 days.

Residues of parent penthiopyrad in sweet peppers were (n=11): 0.15, 0.15, 0.17, 0.17, 0.18, 0.19, 0.19, 0.21, 0.22, 0.68 and 0.77 mg/kg.

The total residues in sweet peppers were (n=11): 0.16, 0.16, 0.18, 0.19, 0.2(3), 0.22, 0.23, 0.70 and 0.79 mg/kg.

Residues of parent penthiopyrad in chili peppers were (n=9): 0.17, 0.2, 0.33, 0.36, 0.41, 0.57, 0.71, 0.88 and 1.6 mg/kg.

The total residues in chili peppers were (n=9): 0.19, 0.23, 0.35, 0.38, 0.43, 0.59, 0.73, 0.92 and 1.6 mg/kg.

Residues of parent penthiopyrad in tomatoes were (n=20): 0.085, 0.15, 0.16, 0.17, 0.17, 0.18, 0.22, 0.24, 0.25, 0.27, 0.28, 0.36(3), 0.4, 0.41, 0.42, 0.7, 1.3 and 1.4 mg/kg.

The total residues in tomatoes were (n=20): 0.10, 0.17, 0.17, 0.18, 0.18, 0.2, 0.24, 0.26, 0.27, 0.29, 0.30, 0.37, 0.38, 0.38, 0.42, 0.42, 0.43, 0.72, 1.3, 1.4 mg/kg.

The Meeting noted that the corresponding GAP is for all fruiting vegetables other than cucurbits, except sweet corn and mushroom and decided to make recommendations for the whole group. Based on the Kruskal-Wallis test the dataset for sweet peppers, chili peppers and tomatoes were not significantly different and may be combined.

Residues of parent penthiopyrad in fruiting vegetables, other than cucurbits except sweet corn and mushroom were (n=40): 0.085, 0.15(3), 0.16, 0.17(5), 0.18, 0.19(3), 0.2, 0.21, 0.22, 0.22, 0.24, 0.25, 0.27, 0.28, 0.33, 0.36(4), 0.4, 0.41, 0.41, 0.42, 0.57, 0.68, 0.7, 0.71, 0.77, 0.88, 1.3, 1.4 and 1.6 mg/kg.

The total residues in fruiting vegetables, other than cucurbits except sweet corn and fungi were (n=40): 0.095, 0.16(3), 0.17, 0.18(5), 0.2(4), 0.22, 0.23(3), 0.25, 0.26, 0.28, 0.29, 0.34, 0.37, 0.37, 0.38, 0.38, 0.41, 0.42, 0.43, 0.44, 0.58, 0.69, 0.71, 0.73, 0.78, 0.92, 1.3, 1.4 and 1.6 mg/kg.

Based on the combined dataset for sweet pepper, chili pepper and tomatoes the Meeting estimated a maximum residue level, an STMR and an HR of 2 mg/kg, 0.27 mg/kg and 1.6 mg/kg for penthiopyrad in fruiting vegetables, other than cucurbits except sweet corn and mushroom, respectively.

The Meeting noted that residues in chili pepper and in other commodities within the group of fruiting vegetables, except sweet corn and mushroom do not differ significantly. Since the group maximum residue level of 2 mg/kg is expected to provide a reliable estimate for chili peppers also, the default dehydration factor of 7 for chili pepper instead of the default factor of 10 for peppers was used to estimate a maximum residue level of 14 mg/kg for dried chili peppers.

Sweet corn (corn-on-the-cob)

For sweet corn GAP is for a maximum of two foliar applications of up to 0.36 kg ai/ha and a PHI of 30 days.

Residues of parent penthiopyrad in sweet corn (corn-on-the-cob) were (n=11): < 0.01(11) mg/kg.

The total residues in sweet corn (corn on the cob) were (n=11): < 0.01(11) mg/kg.

The Meeting estimated a maximum residue level, an STMR and an HR of 0.01 mg/kg, 0.01 mg/kg and 0.02 mg/kg for penthiopyrad in sweet corn (corn on the cob), respectively. The Meeting noted the in maize treated identically as sweet corn following processing finite residues in processed products occur, also precluding a zero-residue situation for sweet corn.

Brassica leafy vegetables

Residue data were provided to the Meeting from trials in Canada and the USA on mustard greens and turnip leaves. GAP from the US for brassica, leafy vegetables is for a maximum of three foliar applications of up to 0.45 kg ai/ha and a PHI of 0 days.

Residues of parent penthiopyrad in mustard greens were (n=9): 7.6, 8.3, 8.7, 8.75, 11, 16, 17, 23 and 30 mg/kg.

The total residues in mustard greens were (n=9): 7.7, 8.4, 8.9, 9.0, 11, 16, 17, 23 and 30 mg/kg.

The Meeting estimated a maximum residue level, an STMR and an HR of 50 mg/kg, 11 mg/kg and 30 mg/kg for penthiopyrad in mustard greens, respectively.

The Meeting noted that for mustard greens the IESTI exceeds the ARfD by 150%. No alternative GAP for mustard greens is available.

Residues of parent penthiopyrad in turnip greens were (n=6): 4, 4.8, 6.1, 13, 20 and 23 mg/kg.

The total residues in turnip greens were (n=6): 4.1, 4.9, 6.4, 13, 20 and 23 mg/kg.

The Meeting estimated a maximum residue level, an STMR and an HR of 50 mg/kg, 9.4 mg/kg and 23 mg/kg for penthiopyrad in turnip greens, respectively.

Leafy vegetables, except brassica leafy vegetables

Residue data were provided to the Meeting from trials in Canada and the USA on lettuce and spinach. GAP for leafy vegetables is for a maximum of three foliar applications of up to 0.36 kg ai/ha and a PHI of 3 days.

Residues of parent penthiopyrad in head lettuce were (n=12): < 0.01, 0.37(3), 0.41, 0.49, 0.6, 1.6, 2.0, 2.3, 2.8 and 3.5 mg/kg.

The total residues in head lettuce were (n=12): < 0.01, 0.38, 0.38, 0.41, 0.42, 0.52, 0.68, 1.7, 2.2, 2.3, 2.8 and 3.5 mg/kg.

Residues of parent penthiopyrad in leaf lettuce were (n=12): 1.1, 1.2, 1.2, 1.8, 1.8, 2.0, 3.5, 4.1, 4.4, 5.3, 7.4 and 11 mg/kg.

The total residues in leaf lettuce were (n=12): 1.2, 1.2, 1.4, 2.0, 2.2, 2.3, 3.5, 4.2, 4.6, 5.4, 7.5 and 11 mg/kg.

Residues of parent penthiopyrad in spinach were (n=10): 0.81, 1.2 1.5, 2, 2.7, 2.8, 2.8, 8.1, 11 and 15 mg/kg.

The total residues in spinach were (n=10): 0.95, 1.4, 1.8, 2.9, 3.1, 3.2, 3.9, 8.3, 12 and 15 mg/kg.

The Meeting notes that the corresponding GAP is for all leafy vegetables, except brassica leafy vegetables, and decided to make recommendations on the whole group. However the Meeting recognized that datasets for individual commodities within the group were significantly different and could not be combined. Therefore recommendations on leafy vegetables, except brassica leafy vegetables, will be based on spinach, representing the commodity resulting in highest residues within the group.

Based on the critical use on spinach the Meeting estimated a maximum residue level, an STMR and an HR of 30 mg/kg, 3.15 mg/kg and 15 mg/kg for penthiopyrad in leafy vegetables, except brassica leafy vegetables, respectively.

Celery

Residue data were provided to the Meeting from trials in Canada and the USA on celery. GAP for celery is for a maximum of three foliar applications of up to 0.36 kg ai/ha and a PHI of 3 days.

Residues of parent penthiopyrad in celery were (n=11): 1.7, 2, 2.1, 2.5, 2.8, 3, 3.1, 5.3, 5.3, 5.8 and 8.7 mg/kg.

The total residues in celery were (n=11): 1.7, 2.0, 2.3, 2.6, 2.9, 3.1, 3.2, 5.4, 5.6, 6.1 and 8.8 mg/kg.

The Meeting estimated a maximum residue level, an STMR and an HR of 15 mg/kg, 3.1 mg/kg and 8.8 mg/kg for penthiopyrad in celery, respectively.

Legume vegetables, immature with pods

Residue data were provided to the Meeting from trials in Canada and the USA on succulent beans and peas. GAP for legume vegetables is for a maximum of three foliar applications of up to 0.45 kg ai/ha and a PHI of 0 days.

Residues of parent penthiopyrad in green beans with pods were (n=8): 0.13, 0.16, 0.36, 0.47, 0.77, 0.9, 0.99 and 1.5 mg/kg.

The total residues in green beans with pods were (n=8): 0.14, 0.17, 0.38, 0.49, 0.79, 0.92, 1.1 and 1.5 mg/kg.

Residues of parent penthiopyrad in green peas with pods were (n=4): 0.88, 1.0, 1.3 and 1.5 mg/kg.

The total residues in peas with pods were (n=4): 0.90, 1.1, 1.3 and 1.6 mg/kg.

The Meeting decided that residues in green beans with pods and in green peas with pods are similar and can be combined for mutual support. Residues of parent penthiopyrad in green beans with pods and peas with pods were (n=12): 0.13, 0.16, 0.36, 0.47, 0.77, 0.88, 0.9, 0.99, 1.0, 1.3, 1.5 and 1.5 mg/kg.

The total residues in green beans with pods and peas with pods were (n=12): 0.14, 0.178, 0.37, 0.49, 0.78, 0.89, 0.91, 1.1, 1.1, 1.3, 1.5 and 1.6 mg/kg.

Based on the combined dataset of the Meeting estimated a maximum residue level, an STMR and an HR of 3 mg/kg, 0.9 mg/kg and 1.6 mg/kg for penthiopyrad in beans, except broad bean and soya bean (green pods and immature seeds) and in peas (pods and succulent), respectively.

Legume vegetables, shelled

Residue data were provided to the Meeting from trials in Canada and the USA on shelled succulent beans and peas. GAP for legume vegetables is for a maximum of three foliar applications of up to 0.45 kg ai/ha and a PHI of 0 days.

Residues of parent penthiopyrad in shelled beans were (n=7): 0.011, 0.024, 0.025, 0.035, 0.052 and 0.056, 0.13 mg/kg.

The total residues in shelled beans were (n=7): 0.029, 0.043, 0.043, 0.054, 0.071, 0.075 and 0.16 mg/kg.

Residues of parent penthiopyrad in shelled peas were (n=7): 0.04, 0.05, 0.067, 0.069, 0.077, 0.09 and 0.14 mg/kg.

The total residues in shelled peas were (n=7): 0.059, 0.068, 0.085, 0.088, 0.095, 0.11 and 0.16 mg/kg.

The Meeting decided that residues in shelled beans and in shelled peas without pods are similar and can be combined for mutual support. Residues of parent penthiopyrad in shelled beans and peas without pods were (n=14): 0.011, 0.024, 0.025, 0.035, 0.04, 0.05, 0.052, 0.056, 0.067, 0.069, 0.077, 0.09, 0.13 and 0.14 mg/kg.

The total residues in shelled beans and peas without pods were (n=14): 0.021, 0.034, 0.035, 0.045, 0.05, 0.06, 0.062, 0.075, 0.077, 0.079, 0.087, 0.1, 0.15 and 0.16 mg/kg.

Based on the combined dataset the Meeting estimated a maximum residue level, an STMR and an HR of 0.3 mg/kg, 0.0685 mg/kg and 0.16 mg/kg for penthiopyrad in beans, shelled and in peas, shelled, respectively.

Pulses, except soya beans

Residue data were provided to the Meeting from trials in Canada and the USA on beans and peas as pulses. GAP for pulses except soya beans is for a maximum of three foliar applications of up to 0.35 kg ai/ha and a PHI of 21 days.

Residues of parent penthiopyrad in beans were (n=14): < 0.01(10), 0.011, 0.026, 0.033 and 0.2 mg/kg.

The total residues in beans were (n=14): < 0.01(10), 0.029, 0.030, 0.045 and 0.29 mg/kg.

Residues of parent penthiopyrad in peas were (n=14): < 0.01(7), 0.011, 0.012, 0.014, 0.014, 0.032, 0.034 and 0.088 mg/kg.

The total residues in peas were (n=14): < 0.01(7), 0.030, 0.031, 0.033, 0.033, 0.051, 0.052 and 0.12 mg/kg.

The Meeting noted that corresponding GAP is for all pulses, except soya beans and decided to make recommendations for the whole group. The Meeting also noted that beans and peas treated according to the same GAP result in comparable residues and could be combined.

Combined residues of parent penthiopyrad in beans and peas were (n=28): < 0.01(17), 0.011, 0.011, 0.012, 0.014, 0.014, 0,026, 0.032, 0.033, 0.034, 0.088 and 0.2 mg/kg.

The total residues in beans and peas were (n=28): < 0.01(17), 0.029, 0.030, 0.030, 0.031, 0.033, 0.033, 0.045, 0.051, 0.052, 0.12 and 0.29 mg/kg.

Based on the combined dataset of the Meeting estimated a maximum residue level and an STMR of 0.3 mg/kg and 0.01 mg/kg for penthiopyrad in pulses, except soya beans, respectively.

Soya beans

Residue data were provided to the Meeting from trials in Canada and the USA on soya beans. GAP for soya beans is for a maximum of three foliar applications of up to 0.45 kg ai/ha and a PHI of 14 days.

Residues of parent penthiopyrad in soya beans were (n=21): < 0.01(9), 0.012, 0.013, 0.014, 0.022, 0.022, 0.024, 0.025, 0.049, 0.056, 0.068, 0.1 and 0.21 mg/kg.

The total residues in soya beans were (n=21): < 0.01(9), 0.030, 0.031, 0.033, 0.041, 0.042, 0.043, 0.043, 0.069, 0.074, 0.087, 0.12 and 0.23 mg/kg.

The Meeting estimated a maximum residue level and an STMR of 0.3 mg/kg and 0.032 mg/kg for penthiopyrad in soya beans, respectively.

Carrots

Residue data were provided to the Meeting from trials in Canada and the USA on carrots. GAP for carrots in the USA is for a maximum of two foliar applications of up to 0.39 kg ai/ha and a PHI of 0 days.

Residues of parent penthiopyrad in carrots were (n=9): 0.021, 0.025, 0.047, 0.051, 0.071, 0.085, 0.12, 0.1 and, 0.4 mg/kg.

The total residues in carrots were (n=9): 0.039, 0.044, 0.066, 0.070, 0.09, 0.10, 0.14, 0.18 and 0.41 mg/kg.

The Meeting estimated a maximum residue level, an STMR and an HR of 0.6 mg/kg, 0.09 mg/kg and 0.41 mg/kg for penthiopyrad in carrots, respectively.

Potatoes

Residue data were provided to the Meeting from trials in Canada and the USA on potatoes.

GAP for potatoes in the USA is for a maximum of three foliar applications of up to 0.31 kg ai/ha and a PHI of 7 days.

Residues of parent penthiopyrad in potato tubers were (n=22): < 0.01(15), 0.011, 0.011, 0.014, 0.015, 0.017, 0.025 and 0.033 mg/kg.

The total residues in potato tubers were (n=22): < 0.01(15), 0.029, 0.030, 0.033, 0.03, 0.036, 0.044 and 0.051 mg/kg.

The OECD Calculator suggests a maximum residue level of 0.04 mg/kg for penthiopyrad in potatoes; however, a high uncertainty due to the limited number of results above the LOQ was

indicated. The Meeting decided to estimate a maximum residue level at the next higher MRL-step of 0.05 mg/kg.

The Meeting estimated a maximum residue level, an STMR and an HR of 0.05 mg/kg, 0.01 mg/kg and 0.051 mg/kg for penthiopyrad in potatoes, respectively.

Radish

Residue data were provided to the Meeting from trials in Canada and the USA on radishes.

GAP for radish in the USA is for a maximum of three foliar applications of up to 0.45 kg ai/ha and a PHI of 0 days.

Residues of parent penthiopyrad in radish roots were (n=6): < 0.01, 0.14, 0.22, 0.33, 0.92 and 1.2 mg/kg.

The total residues in radish roots were (n=6): < 0.01, 0.15, 0.24, 0.35, 0.93 and 1.2 mg/kg.

The Meeting estimated a maximum residue level, an STMR and an HR of 3 mg/kg, 0.305 mg/kg and 1.2 mg/kg for penthiopyrad in radish roots, respectively.

Sugar beet

Residue data were provided to the Meeting from trials in Canada and the USA on sugar beets.

GAP for sugar beets in the USA is for a maximum of three foliar applications of up to 0.45 kg ai/ha and a PHI of 7 days.

Residues of parent penthiopyrad in sugar beet roots were (n=12): 0.015, 0.017, 0.019, 0.033, 0.042, 0.085, 0.090, 0.13, 0.18, 0.19, 0.2 and 0.27 mg/kg.

The total residues in sugar beet roots were (n=12): 0.033, 0.035, 0.037, 0.051, 0.060, 0.1, 0.11, 0.15, 0.20, 0.20, 0.21 and 0.29 mg/kg.

The Meeting estimated a maximum residue level and an STMR of 0.5 mg/kg and 0.105 mg/kg for penthiopyrad in sugar beets, respectively.

Barley and oats

Residue data were provided to the Meeting from trials in Canada and the USA on barley grain. GAP for barley and oats in the USA is for a maximum of two foliar applications before flowering (BBCH 59) of up to 0.36 kg ai/ha without a specified PHI for the grain (covered by growth stage).

Residues of parent penthiopyrad in barley grain were (n=13): < 0.01(7), 0.01, 0.011, 0.02, 0.024, 0.03 and 0.11 mg/kg.

The total residues in barley grain were (n=13): < 0.01(7), 0.029, 0.029, 0.038, 0.042, 0.048 and 0.14 mg/kg.

The Meeting recognized that barley and oats share an identical GAP and normally show comparable residues. It was therefore decided to extrapolate residue data from barley to oats.

The Meeting estimated a maximum residue level and an STMR of 0.15 mg/kg and 0.01 mg/kg for penthiopyrad in barley and oats, respectively.

Rye, triticale and wheat

Residue data were provided to the Meeting from trials in Canada and the USA on wheat grain. GAP for rye, triticale and wheat in the USA is for a maximum of two foliar applications before flowering (BBCH 59) of up to 0.36 kg ai/ha without a specified PHI for the grain (covered by growth stage).

Residues of parent penthiopyrad in wheat grain were (n=29): < 0.01(24), 0.011, 0.012, 0.017, 0.019 and 0.034 mg/kg.

The total residues in wheat grain were (n=29): < 0.01(24), 0.030, 0.033, 0.036, 0.037 and 0.053, mg/kg.

The Meeting recognized that wheat, triticale and rye share an identical GAP and normally show comparable residues. It was therefore decided to extrapolate residue data from wheat to rye and triticale.

The Meeting estimated a maximum residue level and an STMR of 0.04 mg/kg and 0.01 mg/kg for penthiopyrad in rye, triticale and wheat, respectively.

Maize

Residue data were provided to the Meeting from trials in Canada and the USA on maize. GAP for maize in the USA is for a maximum of two foliar applications of up to 0.36 kg ai/ha and a PHI of 30 days.

Residues of parent penthiopyrad in maize grain were (n=14): < 0.01(14) mg/kg.

The total residues in maize grain were (n=14): < 0.01(14) mg/kg.

The Meeting estimated a maximum residue level and an STMR of 0.01 mg/kg and 0.01 mg/kg for penthiopyrad in maize, respectively. The Meeting noted the in maize processing finite residues in processed products occur, precluding a zero-residue situation for maize grain.

Millet and sorghum

Residue data were provided to the Meeting from trials in Canada and the USA on sorghum. GAP for sorghum and millet in the USA is for a maximum of two foliar applications of up to 0.36 kg ai/ha and a PHI of 30 days.

Residues of parent penthiopyrad in sorghum grain were (n=9): 0.06, 0.093, 0.12, 0.16, 0.18, 0.28, 0.3, 0.39 and 0.43 mg/kg.

The total residues in sorghum grain were (n=9): 0.084, 0.13, 0.14, 0.2, 0.22, 0.34, 0.4, 0.45 and 0.69 mg/kg.

The Meeting recognized that sorghum and millet share an identical GAP and normally show comparable residues. It was therefore decided to extrapolate residue data from sorghum to millet.

The Meeting estimated a maximum residue level and an STMR of 0.8 mg/kg and 0.22 mg/kg for penthiopyrad in millet and sorghum grain, respectively.

Tree nuts

Residue data were provided to the Meeting from trials in Canada and the USA on almonds and pecans. GAP for tree nuts in the USA is for a maximum of four foliar applications of up to 0.3 kg ai/ha and a PHI of 14 days.

Residues of parent penthiopyrad in almond nutmeat were (n=6): < 0.01(4), 0.01 and 0.037 mg/kg.

The total residues in almond nutmeat were (n=6): < 0.01(4), 0.029 and 0.056 mg/kg.

Residues of parent penthiopyrad in pecan nutmeat were (n=6): < 0.01(6) mg/kg.

The total residues in pecan nutmeat were (n=6): < 0.01(6) mg/kg.

The Meeting noted that corresponding GAP is for all tree nuts and decided to make recommendations for the whole group. The Meeting concluded that the dataset for almonds and pecan treated according to US GAP for tree nuts are not significantly different and can be combined.

Residues of parent penthiopyrad in almond and pecan nutmeat were (n=6): < 0.01(10), 0.01 and 0.037 mg/kg.

The total residues in almond and pecan nutmeat were (n=6): < 0.01(10), 0.02 and 0.047 mg/kg.

Based on the combined dataset of the Meeting estimated a maximum residue level, an STMR and an HR of 0.05 mg/kg, 0.01 mg/kg and 0.047 mg/kg for penthiopyrad in tree nuts, respectively.

Cotton

Residue data were provided to the Meeting from trials in the USA on cotton. GAP for cotton in the USA is one in-furrow spray and a maximum of two foliar applications of up to 0.35 kg ai/ha each and a PHI of 21 days.

Residues of parent penthiopyrad in cotton seeds were (n=13): < 0.01, < 0.01, 0.011, 0.036, 0.04, 0.091, 0.093, 0.11, 0.13, 0.13, 0.14, 0.23 and 0.25 mg/kg.

The total residues in cotton seeds were (n=13): 0.035, 0.036, 0.043, 0.060, 0.083, 0.12, 0.17, 0.17, 0.22, 0.22, 0.37, 0.39 and 0.39 mg/kg.

The Meeting estimated a maximum residue level and an STMR of 0.5 mg/kg and 0.17 mg/kg for penthiopyrad in cotton seeds, respectively.

Rape seed

Residue data were provided to the Meeting from trials in Canada and the USA on oilseed rape. GAP for rape in the USA is for a maximum of three foliar applications of up to 0.3 kg ai/ha and a PHI of 21 days.

Residues of parent penthiopyrad in rape seeds were (n=21): < 0.01(7), 0.011, 0.017, 0.024, 0.025, 0.028, 0.033, 0.052, 0.054, 0.065, 0.08, 0.081, 0.085, 0.13 and 0.42 mg/kg.

The total residues in rape seeds were (n=21): < 0.01(5), 0.03, 0.046, 0.048, 0.071, 0.073, 0.074, 0.083, 0.084, 0.087, 0.094, 0.099, 0.12, 0.13, 0.15, 0.15 and 0.44 mg/kg.

The Meeting estimated a maximum residue level and an STMR of 0.5 mg/kg and 0.084 mg/kg for penthiopyrad in rape seeds, respectively.

Peanuts

Residue data were provided to the Meeting from trials in the USA on peanuts. GAP for peanuts in the USA is for a maximum of three foliar applications of up to 0.36 kg ai/ha and a PHI of 14 days.

Residues of parent penthiopyrad in peanut nutmeat were (n=13): < 0.01(12) and 0.034 mg/kg.

The total residues in peanut nutmeat were (n=13): < 0.01(12) and 0.055 mg/kg.

The OECD Calculator suggests a maximum residue level of 0.04 mg/kg for penthiopyrad in peanuts; however, a high uncertainty due to the limited number of results above the LOQ was indicated. The Meeting decided to estimate a maximum residue level at the next higher MRL-step of 0.05 mg/kg.

The Meeting estimated a maximum residue level and an STMR of 0.05 mg/kg and 0.01 mg/kg for penthiopyrad in peanuts, respectively.

Sunflowers

Residue data were provided to the Meeting from trials in Canada and the USA on sunflowers. GAP for sunflowers in the USA is for a maximum of three foliar applications of up to 0.45 kg ai/ha and a PHI of 14 days.

Residues of parent penthiopyrad in sunflower seeds were (n=9): < 0.01, 0.078, 0.079, 0.079, 0.1, 0.28, 0.34, 0.44 and 0.81 mg/kg.

The total residues in sunflower seeds were (n=9): < 0.01, 0.097, 0.097, 0.098, 0.12, 0.32, 0.51, 0.57 and 0.94 mg/kg.

The Meeting estimated a maximum residue level and an STMR of 1.5 mg/kg and 0.12 mg/kg for penthiopyrad in sunflower seeds, respectively.

Animal feeds

Alfalfa, forage and hay

Residue data were provided to the Meeting from trials in Canada and the USA on alfalfa. GAP for alfalfa in the USA is for a maximum of two foliar applications of up to 0.36 kg ai/ha and a PHI of 14 days.

The total residues in alfalfa forage were (n=15): 0.1, 0.21, 0.45, 0.47, 0.59, 0.62, 0.7, 0.73, 0.95, 1.0, 1.4, 1.8, 2.0, 2.1 and 4.6 mg/kg.

Residues of parent penthiopyrad in alfalfa hay were (n=15): 0.11, 0.28, 0.58, 0.77, 0.97, 1.6, 1.6, 1.8, 1.8, 1.9, 3.2, 3.6, 4.7, 4.9 and 14 mg/kg.

The total residues in alfalfa hay were (n=15): 0.6, 1.2, 1.9, 2.3, 2.5(3), 2.9, 3.3, 3.4, 4.5, 4.9, 5.9, 6.4 and 16 mg/kg.

The Meeting estimated STMR values of 0.73 mg/kg and 2.9 mg/kg and highest residue values of 4.6 mg/kg and 16 mg/kg for alfalfa forage and hay (fresh weight basis), respectively.

The Meeting also estimated a maximum residue level of 20 mg/kg for penthiopyrad in alfalfa fodder (DM basis, 89% dry-matter content).

Pea vines and hay

Residue data were provided to the Meeting from trials in Canada and the USA on pea vines. GAP for peas in the USA are for a maximum of three foliar applications of up to 0.3 kg ai/ha and a PHI of 0 days for vines and hay.

The total residues in pea vines were (n=7): 4.5, 5.3, 6.1, 6.2, 6.3, 12 and 23 mg/kg.

Residues of parent penthiopyrad in pea hay were (n=7): 3.7, 8.7, 9.4, 11, 14, 15 and 30 mg/kg.

The total residues in pea hay were (n=7): 3.9, 8.9, 11, 12, 14, 15 and 31 mg/kg.

The Meeting estimated STMR values of 6.2 mg/kg and 12 mg/kg and highest residue values of 23 mg/kg and 31 mg/kg for pea vines and hay (fresh weight basis), respectively.

The Meeting also estimated a maximum residue level of 60 mg/kg for penthiopyrad in pea hay (DM basis, 88% dry-matter content).

Soya bean, forage and hay

Residue data were provided to the Meeting from trials in Canada and the USA on soya beans. GAP for soya beans in the USA is for a maximum of three foliar applications of up to 0.45 kg ai/ha and a PHI of 0 days for forage and hay.

The total residues in soya forage were (n=16): 4.1, 4.9, 6.4, 11, 14, 14, 15, 16(3), 19, 20, 21, 23, 24 and 24 mg/kg.

Residues of parent penthiopyrad in soya hay were (n=16): 11, 22, 33, 45, 47, 48, 49, 50, 53, 54, 55, 59, 73, 99, 100 and 123 mg/kg.

The total residues in soya hay were (n=16): 11, 22, 33, 45, 48, 49, 50, 51, 54, 55, 55, 61, 73, 100, 102 and 125 mg/kg.

The Meeting estimated STMR values of 16 mg/kg and 52.5 mg/kg and highest residue values of 24 mg/kg and 125 mg/kg for soya forage and fodder (fresh weight basis), respectively.

The Meeting also estimated a maximum residue level of 200 mg/kg for penthiopyrad in soya bean fodder (DM basis, 85% dry-matter content).

Barley, oats, rye, triticale and wheat—straw, fodder and forage of cereals

GAPs for barley, oats, rye, triticale and wheat in the USA are for a maximum of two foliar applications before flowering (BBCH 59) of up to 0.36 kg ai/ha and a 0 day PHI for the forage/hay and an unspecified PHI for the straw (covered by growth stage).

The Meeting concluded that straw, fodder and forage of barley, oats, rye, triticale and wheat are indistinguishable and result in comparable residues following treatment according to the identical US GAPs for these crops. Therefore all estimations on forage, fodder and straw will be based on the combined residue dataset for these crops and applied to each of them.

The total residues in forage based on wheat trials were (n=26): 5.5, 5.8, 6.2, 7.3, 8.3, 8.7, 8.8, 8.9, 9.2, 9.5, 9.8, 10(3), 11, 12, 12, 13(4), 14, 14, 15, 16 and 17 mg/kg (fresh weight basis).

Residues of parent penthiopyrad in hay based on barley and wheat trials were (n=39): 2.6, 3.9, 4.4, 4.5, 4.7, 6.4, 7.0, 7.4, 7.7, 8.2, 8.9, 11, 12, 12, 13, 14, 17, 17, 19, 19, 22, 23, 23, 25, 25, 27, 28(3), 29(3), 30, 34, 35, 38, 40, 44 and 53 mg/kg.

Residues of parent penthiopyrad in straw based on barley and wheat trials were (n=13): < 0.05, < 0.05, 0.051, 0.053, 0.054, 0.058, 0.06, 0.084, 0.088, 0.095, 0.096, 0.11(5), 0.12, 0.12, 0.14, 0.14, 0.15, 0.18, 0.19(3), 0.2, 0.22, 0.22, 0.23, 0.24, 0.24, 0.3, 0.34, 0.36, 0.37, 0.37, 0.4, 0.42 and 0.7 mg/kg.

The total residues in hay based on barley and wheat trials were (n=39): 2.9, 4.2, 4.9, 5.1, 5.7, 7.1, 7.9, 8.1, 9.3, 9.7, 9.8, 13(4), 16, 17, 20, 20, 21, 23, 24, 24, 26, 27, 28, 29(3), 30(3), 31, 36, 36, 39, 42, 47 and 54 mg/kg

The total residues in straw based on barley and wheat trials were (n=39): < 0.1, < 0.1, 0.14, 0.15(3), 0.18, 0.18, 0.19, 0.20(4), 0.21, 0.21, 0.23, 0.23, 0.26, 0.27, 0.27, 0.32, 0.32, 0.34, 0.34, 0.35, 0.40, 0.41, 0.42, 0.42, 0.43, 0.50, 0.54, 0.57, 0.61, 0.61, 0.66, 0.69, 0.81 and 0.97 mg/kg.

The Meeting concluded that residues in hay are significantly higher as in straw and should be used as basis for recommendations on straw, fodder and forage of barley, oats, rye, triticale and wheat.

The Meeting estimated an STMR value of 10 mg/kg and a highest residue value of 17 mg/kg for barley, oats, rye, triticale and wheat forage (fresh weight basis).

The Meeting also estimated a maximum residue level, an STMR value and a highest residue of 80 mg/kg (DM based, 88% dry-matter content), 21 mg/kg (fresh weight basis) and 54 mg/kg (fresh weight basis) for penthiopyrad in barley, oats, rye, triticale and wheat straw and fodder.

Maize, millet and sorghum—forage and fodder

GAP for maize, sorghum and millet in the USA is for a maximum of two foliar applications of up to 0.36 kg ai/ha and a PHI of 0 days for forage and hay and of 30 days for stover.

The total residues in maize forage were (n=13): 3.0, 3.4, 3.4, 3.6, 3.7, 4.3, 4.4, 4.7, 4.9, 5.1, 5.2, 5.3 and 7.3 mg/kg.

The total residues in sorghum forage were (n=9): 3.6, 3.9, 6.2, 6.7, 6.7, 7.0, 7.5, 7.9 and 14 mg/kg.

Residues of parent penthiopyrad in sorghum stover were (n=9): 0.14, 0.19, 0.23, 0.32, 0.44, 0.62, 0.66, 2.5 and 5.5 mg/kg.

The total residues in sorghum stover were (n=9): 0.23, 0.42, 0.47, 0.52, 0.55, 0.75, 0.82, 2.7 and 5.9 mg/kg.

Supervised field trial data on maize stover from the USA was not conducted according to the submitted GAPs.

The Meeting concluded that forage and fodder of maize, millet and sorghum treated according to identical US GAPs result in comparable residues and may be combined for mutual support. Therefore all estimations on forage and fodder will be based on the combined residue dataset for these crops and applied to each of them.

For forage of maize and stover combined total residues were (n=22): 3.0, 3.4, 3.4, 3.6, 3.6, 3.7, 3.9, 4.3, 4.4, 4.7, 4.9, 5.1, 5.2, 5.3, 6.2, 6.7, 6.7, 7.0, 7.3, 7.5, 7.9 and 14 mg/kg.

The Meeting estimated an STMR value of 5 mg/kg and a highest residue value of 14 mg/kg for maize, millet and sorghum forage (fresh weight basis).

The Meeting also estimated a maximum residue level, an STMR value and a highest residue of 10 mg/kg (DM basis, 88% dry-matter content), 0.52 mg/kg (fresh weight basis) and 5.9 mg/kg (fresh weight basis) for penthiopyrad in maize, millet and sorghum fodder.

Sugar beet leaves

GAP for sugar beets in the USA is for a maximum of three foliar applications of up to 0.45 kg ai/ha and a PHI of 0 days for the forage. In Canada GAP for sugar beets is for a maximum of three foliar applications of up to 0.3 kg ai/ha and a PHI of 7 days for the forage.

All supervised field trials on sugar beet leaves involve two treatments of 0.45 kg ai/ha and a PHI of 6–8 days. Since neither the Canadian nor the US GAP matched these field trials, the Meeting concluded that for sugar beets leaves no STMR value or highest residue can be estimated.

Oilseed rape forage

GAP for oilseed rape in the USA is for a maximum of three foliar applications of up to 0.3 kg ai/ha and a PHI of 21 days.

Supervised field trial data submitted from Europe involve single treatment at 0.3 kg ai/ha. The Meeting noted that the data submitted involving single application probably underestimates the true residue situation according to US GAP and concluded that for rape forage no STMR value or highest residue could be estimated.

Peanut hay

GAP for peanuts in the USA is for a maximum of three foliar applications of up to 0.36 kg ai/ha (maximum annual rate in 1.1 kg ai/ha) and a PHI of 14 days.

Residues of parent penthiopyrad in peanut hay were (n=13): 1.5, 1.8, 1.8, 1.9, 2.9, 4.5, 5.4, 6.8, 6.9, 7.1, 8.6, 8.8 and 17 mg/kg.

The total residues in peanut hay were (n=13): 1.6, 2.0, 2.1, 2.1, 3.6, 4.9, 5.9, 7.3, 7.9, 8.7, 9.2, 9.4 and 18 mg/kg.

The Meeting estimated a maximum residue level, an STMR and an highest residue of 30 mg/kg (DM basis, 85% dry-matter content), 5.9 mg/kg (fresh weight basis) and 18 mg/kg (fresh weight basis) for penthiopyrad in peanut hay(fresh weight basis), respectively.

Almond hulls

GAP for tree nuts in the USA is for a maximum of four foliar applications of up to 0.3 kg ai/ha and a PHI of 14 days.

Residues of parent penthiopyrad in almond hulls were (n=6): 0.8, 1.1, 1.4, 2.1, 2.4 and 2.7 mg/kg.

The total residues in almond hulls were (n=6): 0.91, 1.6, 1.9, 2.9, 3.0 and 3.1 mg/kg.

The Meeting estimated a maximum residue level and an STMR of 6 mg/kg (DM basis, 90% dry-matter content) and 2.4 mg/kg (fresh weight basis) for penthiopyrad in almond hulls, respectively.

Cotton gin trash

GAP for cotton in the USA is for a maximum of three foliar applications of up to 0.35 kg ai/ha and a PHI of 21 days.

The total residues in cotton gin trash were (n=4): 3.0, 4.2, 4.9 and 7.8 mg/kg.

The Meeting estimated an STMR of 4.55 mg/kg (fresh weight basis) for penthiopyrad in cotton gin trash.

Fate of residues during processing

The Meeting received information on the hydrolysis of radiolabelled penthiopyrad as well as processing studies using unlabelled material on grown residues in apples, plums, tomatoes, soya beans, potatoes, sugar beet, barley, maize, wheat, oilseed rape and peanuts.

In a hydrolysis study using radiolabelled penthiopyrad (1:1 mixture) 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 of the parent substance was observed.

In the following table all processing factor relevant for the estimation of the dietary intake or recommendation of maximum residue levels for processed commodities are summarized. Processing factors for additional processed products are reported in the corresponding evaluation for penthiopyrad; however no conclusion could be drawn based on this information. If analytes were present below the LOQ in the RAC for specific commodities, no processing factors were derived.

Commodity	Processing factor		Processing factor (median or best estimate)		HR / STMR (mg/kg)		MRL, HR-P / STMR-P (mg/kg)
Apple juice	Total:	< 0.13, < 0.14, 0.14	Total:	0.14	STMR:	0.15	STMR-P: 0.021
Apple pomace (wet)	Total:	4.4, 4.6, 6	Total:	4.6	STMR:	0.15	STMR-P: 0.69
Apple pomace (dry)	Total:	5.9, 8.8, 11	Total:	8.8	STMR:	0.15	STMR-P: 1.3
Prunes	Total:	1.3, 1.4	Total:	1.4	STMR: HR:	1.3 1.9	STMR-P: 1.8 HR-P: 2.7
Tomato juice	Total:	0.26, 0.34, 0.5	Total:	0.34	STMR:	0.27	STMR-P: 0.092
Tomato puree	Total:	1.5, 2.0, 2.0	Total:	2.0	STMR:	0.27	STMR-P: 0.54
Tomato paste	Total:	0.1, 3.4, 3.5	Total:	3.4	STMR:	0.27	STMR-P: 0.92
Tomato pomace (wet)	Total:	4.3, 5.0, 5.5	Total:	5.0	STMR:	0.27	STMR-P: 1.4
Tomato pomace (dry)	Total:	24, 39, 41	Total:	39	STMR:	0.27	STMR-P: 11
Soya beans, meal	Total:	0.23, <1.4	Total:	0.23	STMR:	0.032	STMR-P: 0.007
Soya beans, hulls	Total:	0.44, 4.7	Total:	2.5	STMR:	0.032	STMR-P: 0.08
Soya beans, refined oil	Total:	0.1, 1.8	Total:	1	STMR:	0.032	STMR-P: 0.032
Peeled potatoes (steam peeled and abrasion peeled)	Total:	< 0.21, < 0.45	Total:	< 0.33	STMR: HR:	0.01 0.05	STMR-P: 0.003 HR-P: 0.017
Sugar beet, refined sugar	Total:	0.27, 0.35	Total:	0.31	STMR:	0.105	STMR-P: 0.033
Sugar beet, molasses	Total:	0.20, 0.51	Total:	0.36	STMR:	0.105	STMR-P: 0.038
Sugar beet, dried pulp	Total:	4.9, 5.6	Total:	5.3	STMR:	0.105	STMR-P: 0.56
Barley beer	Total:	< 0.11, < 0.36	Total:	< 0.24	STMR:	0.01	STMR-P: 0.002
Pot barley	Total:	0.67, 0.68	Total:	0.68	STMR:	0.01	STMR-P: 0.007
Maize flour	Penthiopyrad:	2.1	Penthiopyrad:	2.1	MRL:	0.01	MRL: 0.03

Commodity	Processing factor		Processing factor (median or best estimate)		HR / STMR (mg/kg)		MRL, HR-P / STMR-P (mg/kg)
	Total:	1.4	Total:	1.4	STMR:	0.01	STMR-P: 0.014
Maize oil (wet milled)	Penthiopyrad:	5.6	Penthiopyrad:	5.6	MRL:	0.01	MRL: 0.05
	Total:	2.7	Total:	2.7	STMR:	0.01	STMR-P: 0.027
Wheat bran	Penthiopyrad:	1.8	Penthiopyrad:	1.8	MRL:	0.04	MRL: 0.1
	Total:	1.8	Total:	1.8	STMR:	0.01	STMR-P: 0.018
Wheat flour	Total:	0.39	Total:	0.39	STMR:	0.01	STMR-P: 0.004
Wheat germ	Penthiopyrad:	2.1	Penthiopyrad:	2.1	MRL:	0.04	MRL: 0.1
	Total:	1.9	Total:	1.9	STMR:	0.01	STMR-P: 0.019
Oilseed rape crude oil (mechanically extracted)	Penthiopyrad:	0.78, 1.9, 2.5	Penthiopyrad:	1.9	MRL:	0.5	MRL: 1
Oilseed rape refined oil	Penthiopyrad:	0.48, 1.6, 2.5	Penthiopyrad:	1.6	MRL:	0.5	MRL: 1
	Total:	0.39, 1.3, 2.1	Total:	1.3	STMR:	0.084	STMR-P: 0.11
Peanuts, meal	Total:	0.84, 2.5	Total:	1.7	STMR:	0.01	STMR-P: 0.017
Peanut refined oil	Penthiopyrad:	1.4, 18	Penthiopyrad:	9.7	MRL:	0.05	MRL-P: 0.5
	Total:	1.2, 6.7	Total:	4	STMR:	0.01	STMR-P: 0.04

Processing factors, STMR-P, HR-P and, if necessary, maximum residue levels for processed commodities are presented in the table above. Under consideration of penthiopyrad being the major residue in all supervised field trials, the processing factors for the parent substance were selected for the estimations.

For the processing for plums into prunes a processing factor of 1.4 was derived for penthiopyrad. In view of the highest residue of 0.77 mg/kg found in plums, the Meeting concluded that residues in prunes will be covered by the estimated maximum residue level for the stone fruit group.

For maize processed into maize flour and maize oil the Meeting estimated maximum residue levels of 0.05 mg/kg and 0.15 mg/kg, respectively.

For wheat processed into wheat bran and wheat germ the Meeting estimated maximum residue levels of 0.1 mg/kg, respectively.

For rape seed processed into crude and refined oil the Meeting estimated maximum residue levels of 1 mg/kg, respectively.

Peanuts processed into refined peanut oil show an accumulation of residues exceeding the recommended maximum residue for peanuts of 0.05 mg/kg. Under consideration of the derived processing factor of 9.7 the Meeting recommended a maximum residue level of 0.5 mg/kg for penthiopyrad in peanut oil, edible.

Residues in animal commodities

Livestock dietary burden

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

Three groups of lactating cows were dosed daily at levels of 8.4, 21.4 and 74.6 ppm dry weight feed (0.15, 0.48 and 1.65 mg/kg bw) for 28 consecutive days. Milk was collected throughout the study and tissues were collected on day 29 within 24 hrs after the last dose.

In milk no residues above the LOQ of 0.01 mg/kg were found for the two lower dose groups. Only the 74.6 ppm dose group contained single positive detects of PAM between 0.01 and 0.02 mg/kg. Separation of milk obtained from high dosed animals into cream and skim milk revealed

a slight concentration of parent penthiopyrad in cream (positive detect at 0.01 mg/kg). However, the results were not sufficient to estimate a ratio (< 0.01 to 0.01 mg/kg).

In tissues penthiopyrad was only found for the highest dose group, resulting in residues above the LOQ in liver (0.02–0.03 mg/kg) and fat (0.01–0.02 mg/kg). PAM was present in all dose groups except the lowest, giving residues of 0.01–0.02 mg/kg in liver, < 0.01 mg/kg in muscle, 0.01 mg/kg in kidney and 0.01 mg/kg in fat for the 51.4 ppm dose group and 0.03–0.06 mg/kg in liver, 0.01–0.02 mg/kg in muscle, 0.02–0.03 mg/kg in kidney and 0.01–0.02 mg/kg in fat for the 74.6 ppm dose group.

For laying hens three groups of animals were dosed with rates of 5.85, 17.54 and 58.46 ppm in the dry weight feed (0.4, 1.2 and 1.2 mg/kg bw) for 28 consecutive days. Eggs were collected throughout the study and tissues were collected on day 29 within 6 hrs after the last dose.

In eggs residues were very low showing detectable residues only for the highest dose group. PAM was quantified in all samples from Day 3 until Day 27 at levels ranging from 0.011 to 0.028 mg/kg. Penthiopyrad was measurable in only 7 of the 48 samples with concentration ranging from 0.011 to 0.016 mg/kg.

In tissues again only the highest dose group gave detectable residues above the LOQ. Penthiopyrad was found at levels of < 0.01–0.021 mg/kg in liver, < 0.01 mg/kg in muscle, < 0.01–0.018 mg/kg in skin and 0.016–0.036 mg/kg in fat. PAM was present above the LOQ in liver (0.017–0.019 mg/kg) and in a single sample of muscle (0.01 mg/kg). In other tissues no residues above the LOQ were found.

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 calculations were made according to the livestock diets from US-Canada, EU, Australia and Japan in the OECD Table (Annex 6 of the 2006 JMPR Report).

	Livestock dietary burden, ACTIVE-SUBSTANCE, ppm of dry matter diet							
	US-Canada		EU		Australia		Japan	
	max.	mean	max.	mean	max.	mean	max.	mean
Beef cattle	12	4.5	56	23	130 [a]	57 [b]	1.9	0.5
Dairy cattle	55	26	43	20	100 [c]	49 [d]	24	7.9
Poultry—broiler	0.2	0.2	0.2	0.2	0.2	0.2	0.8	0.3
Poultry—layer	0.2	0.2	22 [e]	10 [f]	0.2	0.2	0.1	0.1

[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

Animal commodities, MRL estimation

	Feed level (ppm) for eggs and tissues	Total residues (mg/kg)			
		Eggs	Muscle	Liver	Fat
Maximum residue level poultry					
Feeding study	18 58	< 0.02 0.044	< 0.02 0.029	< 0.02 0.045	< 0.02 0.046
Dietary burden and residue estimate	22	0.023	0.021	0.023	0.023
STMR poultry					
Feeding study	5.9	< 0.02	< 0.02	< 0.02	< 0.02

	18	< 0.02	< 0.02	< 0.02	< 0.02
Dietary burden and residue estimate	10	0.02	0.02	0.02	0.02

For beef and dairy cattle the maximum dietary burden (130 ppm) exceeds the highest dose level of 74.6 ppm in the corresponding lactating cow feeding study. The Meeting concluded that based on the available information no recommendation for residues of penthiopyrad in mammalian tissues and milk can be made.

For poultry the maximum calculated dietary burden resulted in HR values for the sum of penthiopyrad and PAM, expressed as penthiopyrad of 0.023 mg/kg in eggs, 0.021 mg/kg in muscle, 0.023 mg/kg in liver and 0.023 mg/kg in fat.

Correlating to this estimation the Meeting recommended maximum residue levels of 0.03 mg/kg for poultry meat, fat and eggs. The Meeting also decided to extrapolate the data on poultry liver to poultry, edible offal of and also recommended a maximum residue level of 0.03 mg/kg for this commodity.

For dietary intake purposes no residues above the LOQ of 0.02 mg/kg were found in samples collected from animals dosed above and below the calculated mean dietary burden. The Meeting estimated STMR values for poultry meat, fat and edible offal of as well as for eggs of 0.02 mg/kg.

DIETARY 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 evaluation of penthiopyrad resulted in recommendations for MRLs and STMR values for raw and processed commodities. Where data on consumption were available for the listed food commodities, dietary intakes were calculated for the 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.

For mustard greens, the IESTI represented 150% of the ARfD of 1 mg/kg bw. On the basis of the information provided to the JMPR it was not possible to conclude that the estimate of the short-term intake of penthiopyrad, from the consumption of mustard greens, was less than the ARfD. The Meeting noted that an alternative GAP for mustard greens was not available.

For other commodities the IESTI for penthiopyrad calculated on the basis of the recommendations made by the JMPR represented 0–90% of the ARfD (1 mg/kg bw) for children and 0–90% for the general population.

The Meeting concluded that the short-term intake of residues of penthiopyrad resulting from uses that have been considered by the JMPR (other than mustard greens) is unlikely to present a public health concern.

5.26 PHORATE (112)

RESIDUE AND ANALYTICAL ASPECTS

Phorate is a systemic organophosphate contact insecticide and acaracide that inhibits acetylcholinesterase activity. Residue and analytical aspects of phorate were evaluated by the JMPR in 1977, 1984, 1990, 1991, 1992 and 2005. The evaluation of 2005 was a periodic review. The toxicological review was conducted in 2004, which established an ADI of 0–0.0007 mg/kg bw and an ARfD of 0.003 mg/kg bw. The residue definition for phorate, both for enforcement and for risk assessment for animal and plant commodities, is: Sum of the parent, its oxygen analogue, and their sulfoxides and sulfones, expressed as phorate. The total residue is not fat-soluble.

During the 2005 periodic review of phorate, the JMPR noted that the acute dietary intake of potato by children aged up to 6 years amounted to 120% of the ARfD. This value represents the IESTI for potato, microwaved with peel. The CCPR decided therefore in 2006 not to advance the maximum residue level in the Codex step system. The CCPR in 2007 was informed that the manufacturers would provide additional data for processed potato in 2008 for evaluation by the 2009 JMPR.

The 2009 JMPR reviewed a new processing study in potatoes to facilitate a refinement of the risk assessment. The Meeting decided however that the experiment in which frozen potatoes with peel were microwaved did not reflect common practice. The Meeting also could not confirm that the extensive weight loss noted in the study did not result in an unusual loss of phorate residues. The Meeting therefore decided to not use the results of the new processing study, and confirmed its previous recommendations.

Following the registration of phorate in Mexico, information on a new Mexican (alternative) GAP was provided by the manufacturer to enable the assessment of existing and proposed MRLs on potatoes.

Methods of analysis

The Meeting received description and validation data for an analytical method used in the study report.

The method was validated for the determination of phorate and its related metabolites (phorate sulfoxides, phorate oxon, phorate sulfone and phorate oxon sulfoxides) after oxidation to a common fully oxidized moiety, phorate oxon sulfone, in potatoes. Phorate-related residues were determined by gas chromatography with flame photometric detection (GC-FPD) with a LOQ of 0.048 mg/kg.

Stability of pesticide residues in stored analytical samples

The Meeting received no new data on the stability of residues in potatoes. The stability of phorate residues in potatoes was confirmed for 706 days in study data submitted to the 2005 Meeting of the JMPR.

Results of supervised residue trials on crops

The Meeting received supervised trials data for phorate-related residues on potatoes.

Potatoes

Field trials involving phorate treatment on potatoes were conducted in Mexico in 2011. A phorate granular formulation was applied in-furrow at planting, at a rate of 2.55 kg ai/ha.

The GAP in Mexico for phorate on potatoes is for a single in-furrow application at planting at 1.95–2.55 kg ai/ha at PHI 90 days. All field trials conducted in Mexico matched the critical GAP. Total phorate-related residues in potato were: < 0.048, < 0.048, < 0.048, < 0.048, < 0.048, < 0.048, 0.048, 0.17 mg/kg (n=8).

The Meeting estimated a maximum residue limit of 0.3 mg/kg. The Meeting estimated an STMR value of 0.048 mg/kg and an HR value of 0.17 mg/kg. The Meeting agreed to withdraw the previous recommendation of 0.5 mg/kg and to replace it by the recommendation of 0.3 mg/kg based on alternative GAP from Mexico.

Fate of residues during processing

The Meeting did not receive new information on the fate of phorate-related residues during processing of potatoes.

The 2005 JMPR estimated processing factors (median or best estimate) for potato as indicated below.The 2009 JMPR reviewed a new study of processing but decided not to use the results. Using the HR and the STMR for potato (0.17 mg/kg and 0.048 mg/kg respectively), the Meeting estimated HR-Ps and STMR-Ps for their processed commodities as listed below.

Commodity	Processing factors	STMR-P mg/kg	HR-P mg/kg
Potato chips	< 0.07	0.0034	
Potato granules	2.4	0.12	
Peeled potatoes	0.265	0.013	0.045
Potatoes boiled with peel	0.13	0.006	0.022
Potatoes boiled without peel	0.11	0.005	0.019
Potatoes baked with peel	0.28	0.013	0.048
Potatoes baked without peel	0.27	0.013	0.046
French fries	0.38	0.018	
Raw potato peels	0.68	0.033	
Potatoes microwaved with peel	0.36	0.017	0.061

Livestock dietary burden

The Meeting noted that the potato median and highest residues and potato processed commodity median residues did not result in a significant change in livestock dietary burden, therefore having no impact on the previous recommendations for animal commodities.

RECOMMENDATIONS

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

Definition of the residue for compliance with the MRL and for dietary risk assessment for plant and animal commodities: *sum of the parent, its oxygen analogue, and their sulfoxides and sulfones, expressed as phorate.*

The Meeting considers the residue not fat-soluble.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Daily Intakes (IEDI) of phorate, based on the STMRs estimated for commodities, for the five GEMS/Food regional diets, were in the range of 10 to 40% of the maximum ADI (0.0007 mg/kg bw), see Annex 3. Since raw potatoes with peel are not consumed in significant amounts, the highest STMR for potato processed commodities (i.e., 0.018 mg/kg for French fries) was used in the IEDI calculations. The Meeting concluded that the long-term intake of residues of phorate resulting from the uses that have been considered by JMPR are unlikely to present a public health concern.

Short-term intake

The International Estimated Short Term Intake (IESTI) for phorate was calculated for food commodities for which maximum residue levels were estimated and for which consumption data was available. The results are shown in Annex 4.

The IESTI for potatoes using alternative GAP from Mexico represented 0–100% of the ARfD (0.003 mg/kg bw) for children. Since raw potatoes with peel are not consumed in significant amounts, the highest HR for potato processed commodities (i.e., 0.061 mg/kg for microwaved potatoes with peel) was used for the aggregate total large portion values. When the total for raw and processed potatoes is refined using data from other countries, potato microwaved with peel represents 0–60% of the ARfD and potato dried (granules/flakes) represents 0–70% of the ARfD for children. The Meeting concluded that the short-term intake of residues of phorate resulting from the uses that have been considered by the JMPR are unlikely to present a public health concern.

5.27 PICOXYSTROBIN (258)

TOXICOLOGY

Picoxystrobin is the ISO-approved name for methyl (*E*)-3-methoxy-2-[2-(6-trifluoromethyl-2-pyridyloxymethyl)phenyl]acrylate (IUPAC) (CAS No. 117428-22-5). Picoxystrobin is a broad-spectrum, systemic cereal fungicide from the strobilurin group. Picoxystrobin's mode of fungicidal activity is to block mitochondrial electron transport at the Q_o site of complex III, reducing ATP production and inhibiting cellular respiration.

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

All critical studies contained statements of compliance with GLP and met the minimum requirements of the applicable OECD or national test guidelines.

Biochemical aspects

Radiolabelled picoxystrobin administered by oral gavage is rapidly absorbed, with peak plasma ^{14}C levels seen at approximately 2 or 12 hours in rats administered 10 or 100 mg/kg bw, respectively. Picoxystrobin is well absorbed, with approximately 70% of the radioactivity from an oral dose of 100 mg/kg bw detected in bile and urine. Distribution is extensive, with peak radioactivity levels being detected in liver, pancreas, kidney and blood plasma. Excretion is predominantly via the bile and thence into faeces and is essentially complete within 120 hours for a dose of 100 mg/kg bw. Excretion in urine was greater in females (approximately 30%) than in males (approximately 20%). Picoxystrobin is extensively metabolized, with over 30 identified metabolites. Significant biotransformation reactions include ester hydrolysis, oxidation, *O*-demethylation and glucuronide conjugation.

Toxicological data

In the rat, picoxystrobin is of low acute oral and dermal toxicity (LD_{50}s > 2000 mg/kg bw), but is of high acute toxicity by inhalation (LC_{50} = 0.11 mg/L). In the rabbit, picoxystrobin is slightly irritating to the skin and moderately irritating to the eye, and it was not a skin sensitizer in a maximization test in guinea-pigs.

A consistent finding in animals exposed to picoxystrobin is reduced body weight gain, frequently associated with reduced feed consumption. Given the mode of pesticidal action on ATP production, the body weight effects might not be entirely secondary to the reduced feed consumption. Another common finding is increased liver weights.

In a 90-day dietary toxicity study in mice, the NOAEL was 800 ppm (equal to 137 mg/kg bw per day), based on increased relative liver weight (> 10%) and reduced body weight gains at 1600 ppm (equal to 291 mg/kg bw per day).

In a 90-day dietary toxicity study in rats, body weight gain was reduced from the first observation period (week 1), and terminal body weights were approximately 10% lower in the 1250 ppm (equal to 105 mg/kg bw per day) groups than in controls. Liver weight corrected for body weight was increased by more than 10% at 1250 ppm and by 5–8% at 500 ppm, but there were no associated pathological findings. The NOAEL was 500 ppm (equal to 42 mg/kg bw per day), based on the reductions in body weight gain and increased liver weights (> 10%) at 1250 ppm.

In a 90-day dietary toxicity study in dogs, reductions in body weights and feed consumption were seen from the first observation period (week 1) at 500 ppm (equal to 17 mg/kg bw per day), with a NOAEL of 250 ppm (equal to 8.5 mg/kg bw per day). In a 1-year dietary toxicity study in dogs, reddened gums, fluid faeces and thin appearance were seen, together with reductions in body weight and feed consumption, at 500 ppm (equal to 16 mg/kg bw per day). The NOAEL was 150 ppm (equal to 4.6 mg/kg bw per day). The Meeting concluded that an overall NOAEL for the dog studies was 8.5 mg/kg bw per day.

The chronic toxicity and carcinogenicity of picoxystrobin have been investigated in two studies in mice at dose levels up to 800 ppm or 4800 ppm and in two studies in rats at dose levels up to 750 ppm or 3500 ppm. In the first mouse carcinogenicity study, slight, but not adverse, reductions in body weight (approximately 5%) and increases in liver weights (approximately 10%) were seen at 800 ppm (equal to 109 mg/kg bw per day), the highest dose tested. In the second mouse carcinogenicity study, survival was significantly increased in males receiving 2400 or 4800 ppm. Pathological changes seen in the liver in the 4800 ppm groups were macroscopic nodules, microscopic foci of alteration and a significant increase in total hepatocellular tumours in males and centrilobular hepatocyte hypertrophy in females. The tumours were seen predominantly in males surviving to the end of the study, and additional statistical analyses indicated that the increases were related to the increased survival in these mice. The NOAEL for toxicity in mice was 600 ppm (equal to 71 mg/kg bw per day), based on increased liver weights (> 10%) in both sexes at 2400 ppm (equal to 293 mg/kg bw per day). The NOAEL for carcinogenicity was 4800 ppm (equal to 585 mg/kg bw per day), the highest dose tested, as the increase in liver tumours in males at 2400 and 4800 ppm is considered to be secondary to increased survival in these groups and therefore not relevant to the risk assessment of picoxystrobin.

In the first rat chronic toxicity and carcinogenicity study, Alpk (Wistar-derived) male rats receiving 750 ppm had increased survival and increased incidences of large granular lymphocyte leukaemia. The incidence of leukaemia was outside the test facility's historical control range and was still statistically significant when corrected for the increased survival. The leukaemia incidence was of marginal statistical significance, it is a spontaneous finding in this strain of rat, there were no associated pathological changes in other organs (e.g. the spleen) and the finding was not duplicated in a second study that employed higher dose levels; therefore, the Meeting concluded that these leukaemias were incidental findings. In the first study, the NOAEL for toxicity was 200 ppm (equal to 12 mg/kg bw per day), based on reduced body weight gain and kidney weights. In the second rat chronic toxicity and carcinogenicity study, in Crl:CD(SD) rats (Sprague-Dawley derived), survival was increased in the picoxystrobin groups, with over twice as many rats from the 3500 ppm groups surviving to the end of the study. Reductions in body weight gain, feed consumption and feed conversion efficiency were seen during the first year of the study in the 3500 ppm groups. Liver weight relative to body weight was increased by more than 10% at both interim and terminal kills in the 3500 ppm groups. Testes weights were increased in top-dose rats at the interim kill. Statistically significant increases in the incidences of interstitial cell hyperplasia and benign adenoma in the testes were observed in male rats at 3500 ppm. Although the majority of adenomas and hyperplasia occurred in terminal or near-terminal animals, the results were still statistically significant when corrected for the increased survival, and the Meeting considered it likely that the increases in testicular interstitial cell adenoma and hyperplasia in the 3500 ppm males were related to exposure to the test substance. The NOAEL for toxicity in rats was 1000 ppm (equal to 45 mg/kg bw per day), based on testicular interstitial cell hyperplasia and benign adenoma, reduced body weights and increased relative liver weights at 3500 ppm (equal to 162 mg/kg bw per day).

The Meeting concluded that picoxystrobin is not carcinogenic to mice or rats.

Picoxystrobin has been tested in an adequate range of genotoxicity studies. No evidence of genotoxicity was seen, other than a weak response in a mouse lymphoma mammalian cell gene mutation assay with metabolic activation.

The Meeting concluded that picoxystrobin is unlikely to be genotoxic.

Based on the lack of genotoxicity and the absence of carcinogenicity in rats and mice, the Meeting concluded that picoxystrobin is unlikely to pose a carcinogenic risk to humans.

Two multigeneration reproductive toxicity studies in rats have been performed with picoxystrobin at dose levels up to 750 ppm or 2500 ppm. In the first study, the NOAEL for reproduction was 750 ppm (equal to 78 mg/kg bw per day), the highest dose tested. The NOAEL for parental toxicity and offspring toxicity was 200 ppm (equal to 21 mg/kg bw per day), based on reductions in body weight gain at 750 ppm. In the second study, the NOAEL for reproduction was 2500 ppm (equal to 130 mg/kg bw per day), the highest dose tested. The NOAEL for parental and

offspring toxicity was 1000 ppm (equal to 52 mg/kg bw per day), based on body weight deficits and thymic atrophy at 2500 ppm in parental animals and pups.

The developmental toxicity of picoxystrobin has been assessed in rats and rabbits. In rats, misaligned fifth sternebrae were present in 1.5% of fetuses in the 100 mg/kg bw per day group, above the cited historical control range of 0–1.4%. The NOAEL for developmental toxicity was 30 mg/kg bw per day, based on an increased incidence of misaligned fifth sternebrae at 100 mg/kg bw per day. The NOAEL for maternal toxicity was 30 mg/kg bw per day, based on body weight deficits and reduced feed consumption during the dosing period at 100 mg/kg bw per day.

In rabbits, the mean number of fetuses per litter was reduced at 100 mg/kg bw per day, but this appeared to be related to increased pre-implantation losses, which occur before the start of administration of picoxystrobin. Increased incidences of skeletal anomalies were seen in the 100 mg/kg bw per day group. The NOAEL for developmental toxicity was 25 mg/kg bw per day, based on an increase in skeletal anomalies at 100 mg/kg bw per day. The NOAEL for maternal toxicity was 25 mg/kg bw per day, based on body weight deficits and reduced feed consumption during the dosing period at 100 mg/kg bw per day.

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

In an acute neurotoxicity study in rats, there was no evidence of neuropathy at 2000 mg/kg bw, the highest dose tested. The NOAEL for toxicity was less than 200 mg/kg bw, based on dose-related, transient decreases in motor activity and in body weight at all dose levels. A benchmark dose evaluation indicated that a derived NOAEL in the acute neurotoxicity study was likely to be much lower than 200 mg/kg bw. There was no evidence of neurotoxicity in a 90-day neurotoxicity study in rats at dose levels up to 3500 ppm (equal to 207 mg/kg bw per day), the highest dose tested.

In a 28-day dietary immunotoxicity study in rats and mice, no effects on immunoglobulin M response to sheep red blood cells were observed at the highest doses tested, 4800 ppm (equal to 727 mg/kg bw per day) in mice or 3500 ppm (equal to 229 mg/kg bw per day) in rats.

The plant metabolite IN-H8612 (1,3-dihydro-3-oxoisobenzofuran-1-carboxylic acid) was of low acute oral toxicity to rats (LD_{50} > 2000 mg/kg bw). In a 28-day toxicity study in rats, the NOAEL was 1600 ppm (equal to 182 mg/kg bw per day), the highest dose tested. IN-H8612 was negative in an Ames test for bacterial gene mutation and produced equivocal results at high concentrations in a chromosomal aberration assay in human lymphocytes. On the basis of the limited in vivo data available, the toxicological potency of IN-H8612 is similar to or lower than that of picoxystrobin, but additional data are required to resolve its potential to induce chromosomal aberrations in vivo. The Meeting was unable to conclude on the genotoxic potential of IN-H8612. The international estimated daily intake (IEDI) was above 0.15 µg/person per day, the threshold of toxicological concern (TTC) for a compound with evidence of genotoxicity. The Meeting was unable to conclude on the toxicological relevance of estimated intakes of IN-H8612.

The soil metabolite IN-QDY63 (2-[2-(6-trifluoromethyl-2-pyridyloxymethyl)] benzoic acid) was of moderate acute oral toxicity to rats (LD_{50} = 387 mg/kg bw). IN-QDY63 was negative in an Ames test for bacterial gene mutation. In a 90-day dietary toxicity study in rats, the NOAEL was 180 ppm (equal to 14 mg/kg bw per day), based on increased kidney weights and renal tubule pathological changes at 600 ppm (equal to 48 mg/kg bw per day). The limited data available indicate that the toxicity of IN-QDY63 is quantitatively similar to or greater than that of picoxystrobin. The estimated IEDI for IN-QDY63 was 9.7 µg/person per day, below the applicable TTC of 90 µg/person per day. The Meeting concluded that IN-QDY63 was not of toxicological concern at the estimated dietary intake levels.

Three other plant metabolites of picoxystrobin were considered:

- Phthalic acid is a widely used industrial chemical. It is not genotoxic and is not a developmental toxicant in rats (NOAEL = 1763 mg/kg bw per day). Phthalic anhydride, which hydrolyses to phthalic acid, is not carcinogenic in mice or rats, with NOAELs above

748 mg/kg bw per day. The Meeting concluded that phthalic acid is not a toxicologically relevant metabolite of picoxystrobin.

- 2-(2-Formylphenyl)-2-oxoacetic acid is not supported by any toxicological studies, but a structural alert for genotoxicity was identified. The IEDI was above 0.15 µg/person per day, the TTC for a compound with a structural alert for genotoxicity. The Meeting was unable to conclude on the toxicological relevance of estimated intakes of 2-(2-formylphenyl)-2-oxoacetic acid.
- 2-(2-Hydroxymethylphenyl)-2-oxoacetic acid (PAG3) is not supported by any toxicological studies, and no structural alerts for genotoxicity were identified. The estimated IEDI for PAG3 was 16.4 µg/person per day, below the applicable TTC of 90 µg/person per day. The Meeting concluded that PAG3 was not of toxicological concern at the estimated dietary intake levels.

Medical surveillance of production plant workers has not identified any cases of occupational illness related to picoxystrobin. There are no reports of poisoning cases with picoxystrobin.

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

Toxicological evaluation

The Meeting established an ADI of 0–0.09 mg/kg bw on the basis of the overall NOAEL of 8.5 mg/kg bw per day in the 90-day and 1-year dog studies, based on body weight loss, reduced feed consumption and clinical signs at 16 mg/kg bw per day. A safety factor of 100 was applied.

The Meeting established an ARfD of 0.09 mg/kg bw on the basis of the overall NOAEL of 8.5 mg/kg bw per day in the 90-day and 1-year dog studies, based on body weight loss and reduced feed consumption at the beginning of the study at 16 mg/kg bw per day. A safety factor of 100 was applied. This value is supported by a benchmark dose analysis of the motor activity changes seen at the lowest dose in the acute neurotoxicity study. The Meeting noted that this ARfD is possibly conservative and that it might be possible to refine it.

Picoxystrobin's mode of fungicidal activity is to block mitochondrial electron transport, reducing ATP production and inhibiting cellular respiration; this could result in impaired body weight gains. In the absence of any information on the mode of toxicological action for reductions in body weight and body weight gain, these effects were considered as adverse and relevant for the setting of guidance values.

A toxicological monograph was prepared.

Levels relevant to risk assessment

Species	Study	Effect	NOAEL	LOAEL
Mouse	Eighteen-month studies of toxicity and carcinogenicity[a,b]	Toxicity	600 ppm, equal to 71 mg/kg bw per day	2400 ppm, equal to 293 mg/kg bw per day
		Carcinogenicity	4800 ppm, equal to 585 mg/kg bw per day[c]	—
Rat	Acute neurotoxicity study[d]	Toxicity	—	200 mg/kg bw per day[e]
	Ninety-day study of toxicity[a]	Toxicity	500 ppm, equal to 42 mg/kg bw per day	1250 ppm, equal to 105 mg/kg bw per day
	Two-year studies of toxicity and carcinogenicity[a,b]	Toxicity	1000 ppm, equal to 45 mg/kg bw per day	3500 ppm, equal to 162 mg/kg bw per day
		Carcinogenicity	3500 ppm, equal to 162 mg/kg bw per day[c]	—
	Multigeneration study of reproductive toxicity[a,b]	Reproductive toxicity	2500 ppm, equal to 130 mg/kg bw per day[c]	—

Species	Study	Effect	NOAEL	LOAEL
		Parental toxicity	1000 ppm, equal to 52 mg/kg bw per day	2500 ppm, equal to 130 mg/kg bw per day
		Offspring toxicity	1000 ppm, equal to 52 mg/kg bw per day	2500 ppm, equal to 130 mg/kg bw per day
	Developmental toxicity study[d]	Maternal toxicity	30 mg/kg bw per day	100 mg/kg bw per day
		Embryo and fetal toxicity	30 mg/kg bw per day	100 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	Ninety-day and 1-year studies of toxicity[a,b]	Toxicity	250 ppm, equal to 8.5 mg/kg bw per day	500 ppm, equal to 16 mg/kg bw per day

[a] Dietary administration.

[b] Two or more studies combined.

[c] Highest dose tested.

[d] Gavage administration.

[e] Lowest dose tested.

Estimate of acceptable daily intake for humans

0–0.09 mg/kg bw

Estimate of acute reference dose

0.09 mg/kg bw

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

Additional data on the genotoxicity of the plant metabolites IN-H8612 and 2-(2-formylphenyl)-2-oxoacetic acid

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

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

Absorption, distribution, excretion and metabolism in mammals	
Rate and extent of oral absorption	75% in 48 h, based on urinary and biliary excretion
Distribution	Extensive; highest levels in liver and kidneys
Potential for accumulation	No evidence for accumulation
Rate and extent of excretion	> 95% within 5 days (low dose); mainly bile and faeces
Metabolism in animals	Extensive, with over 30 identified metabolites
Toxicologically significant compounds in animals, plants and the environment	Picoxystrobin, IN-H8612 and 2-(2-formylphenyl)-2-oxoacetic acid (plant metabolites) and IN-QDY63 (soil metabolite)
Acute toxicity	
Rat, LD_{50}, oral	> 5000 mg/kg bw
Rat, LD_{50}, dermal	> 2000 mg/kg bw
Rat, LC_{50}, inhalation	0.11 mg/L (4 h, nose-only)
Rabbit, dermal irritation	Slightly irritating
Rabbit, ocular irritation	Moderately irritating
Dermal sensitization	Not a sensitizer (Magnusson & Kligman test in guinea-pigs)
Short-term studies of toxicity	
Target/critical effect	Reduced body weight and feed consumption; clinical signs (dog)
Lowest relevant oral NOAEL	8.5 mg/kg bw per day (90-day and 1-year dog combined)
Lowest relevant dermal NOAEL	1000 mg/kg bw per day (28-day rat)

Lowest relevant inhalation NOAEC	0.025 mg/L (28-day rat)
Long-term studies of toxicity and carcinogenicity	
Target/critical effect	Reduced body weight and feed consumption; liver (mouse); testes, interstitial cell hyperplasia and adenoma (rat)
Lowest relevant NOAEL	45 mg/kg bw per day (2-year rat)
Carcinogenicity	Not carcinogenic
Genotoxicity	
	Unlikely to be genotoxic
Reproductive toxicity	
Target/critical effect	Reduced body weight gain in parents and pups
Lowest relevant reproductive NOAEL	130 mg/kg bw per day (highest dose tested)
Lowest relevant parental NOAEL	70 mg/kg bw per day
Lowest relevant offspring NOAEL	70 mg/kg bw per day
Developmental toxicity	
Target/critical effect	Reduced maternal and fetal body weight; skeletal anomalies
Lowest relevant maternal NOAEL	25 mg/kg bw per day (rabbit)
Lowest relevant embryo/fetal NOAEL	25 mg/kg bw per day (rabbit)
Neurotoxicity	
Acute neurotoxicity	Reduced motor activity, reduced body weight: LOAEL 200 mg/kg bw (rat)
Subchronic (90-day) neurotoxicity	Not neurotoxic: NOAEL 207 mg/kg bw per day (highest dose tested) (rat)
Immunotoxicity	
Twenty-eight-day study	Not immunotoxic in mice or rats: NOAEL 229 mg/kg bw per day (highest dose tested) (rats)
Other toxicological studies	
Metabolite IN-H8612	Oral LD_{50} > 2000 mg/kg bw (rat) 28-day toxicity study in rats: NOAEL 182 mg/kg bw per day Not mutagenic in bacteria; equivocal results for chromosomal aberrations in vitro
Metabolite IN-QDY63	Oral LD_{50} 387 mg/kg bw (rat) 90-day toxicity study in rats: NOAEL 14 mg/kg bw per day Not mutagenic in bacteria
Medical data	
	No reports of poisonings or adverse effects in production plant workers

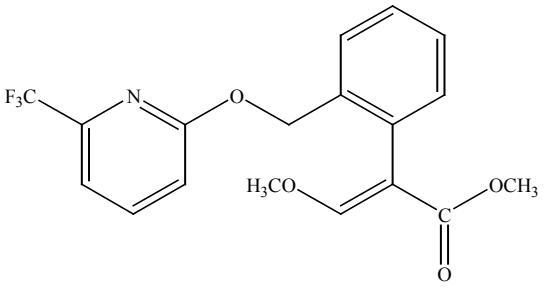
Summary

	Value	Study	Safety factor
ADI	0–0.09 mg/kg bw	90-day and 1-year studies (dog)	100
ARfD	0.09 mg/kg bw	90-day and 1-year studies (dog)	100

RESIDUE AND ANALYTICAL ASPECTS

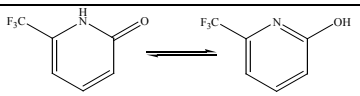
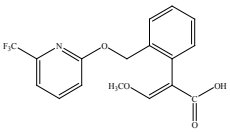
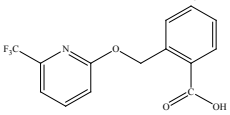
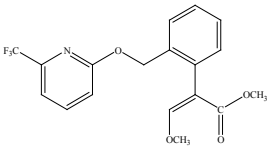
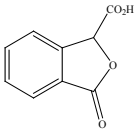
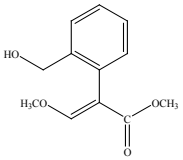
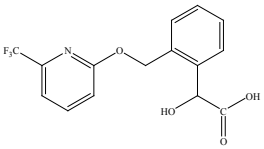
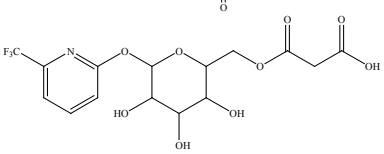
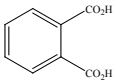
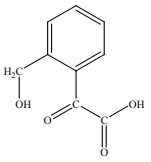
Picoxystrobin (ISO common name) is a strobilurin type fungicide for use by foliar application in a range of broadacre crops including cereals, sweet corn, soya bean, rape and pulses. At the Forty-third Session of the CCPR, picoxystrobin was scheduled for evaluation as a new compound by the 2012 JMPR. Data was provided on the metabolism of picoxystrobin in food producing animals and plants, methods of analysis, stability of residues in stored analytical samples, GAP information, supervised residue trials, processing and animal feeding studies.

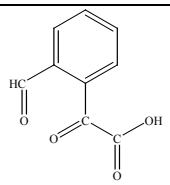
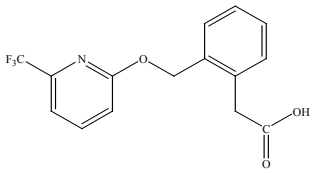
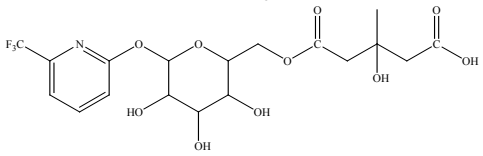
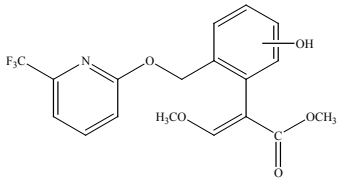
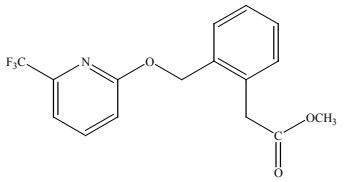
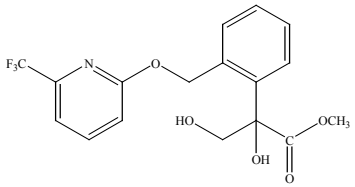
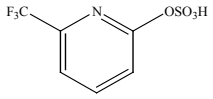
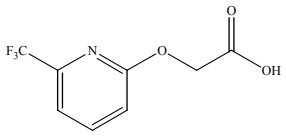
The IUPAC name for picoxystrobin is methyl (*E*)-3-methoxy-2-[2-(6-trifluoromethyl-2-pyridyloxymethyl)phenyl]acrylate



The 2012 JMPR established an ADI of 0–0.09 mg/kg bw for picoxystrobin and an ARfD of 0.09 mg/kg bw.

The following abbreviations are used for the metabolites discussed below:

Code	Chemical name	Structure
IN-QDK50	6-(Trifluoromethyl)-1*H*-pyridin-2-one	
IN-QDY62	(*E*)-3-Methoxy-2-[2-(6-trifluoromethyl-2-pyridyloxymethyl)-phenyl]acrylic acid	
IN-QDY63	2-[2-(6-Trifluoromethyl-2-pyridyloxymethyl)] benzoic acid	
IN-QCD12	Methyl (*Z*)-3-methoxy-2-[2-(6-trifluoromethyl-2-pyridyloxymethyl)-phenyl]acrylate	
IN-H8612	1,3-Dihydro-3-oxoisobenzofuran-1-carboxylic acid	
IN-QDY60	Methyl (*E*)-3-methoxy-2-(2-hydroxymethylphenyl)acrylate	
IN-QGS46	2-Hydroxy-2-[2-(6-trifluoromethyl-2-pyridyloxymethyl)phenyl] acetic acid	
IN-QGU72	2-Malonylglucosyl-6-trifluoromethylpyridine	
IN-K2122	Phthalic acid	
PAG3	2-(2-Hydroxymethylphenyl)-2-oxoacetic acid	

Code	Chemical name	Structure
-	2-(2-Formylphenyl)-2-oxoacetic acid	
IN-QFA35	2-[2-(6-Trifluoromethyl-2-pyridyloxymethyl)phenyl] acetic acid	
IN-QGU73	Mixture of isomers, where n=3, 4 or 6 2-{n-(3-Hydroxy-3-methylglutaryl)glucosyl}-6-trifluoromethylpyridine	
R290447	Methyl (*E*)-3-methoxy-2-[n-hydroxy-2-(6-trifluoromethyl-2-pyridyloxymethyl)-phenyl]acrylate	
IN-QCD09	Methyl 2-[2-(6-trifluoromethyl-2-pyridyloxymethyl)-phenyl]acetate	
R290461	Methyl 2,3-dihydroxy-2-[2-(6-trifluoromethyl-2-pyridyloxymethyl)-phenyl]propionate	
PYST2	6-Trifluoromethyl-2-pyridylsulfuric acid	
R409665, metabolite 30	2-(6-Trifluoromethyl-2-pyridyloxy)acetic acid	

Animal metabolism

The Meeting received information on the metabolism of radio-labelled picoxystrobin (separately ^{14}C-labelled at the pyridinyl and phenacrylate rings) in rats, lactating goats and laying hens.

The metabolism of picoxystrobin in rats was evaluated by the WHO panel of the JMPR at the present Meeting. It was concluded that picoxystrobin is extensively metabolized with over 30 identified metabolites. Significant biotransformation reactions include ester hydrolysis, oxidation, O-demethylation and glucuronide conjugation.

Picoxystrobin was administered to lactating goats by capsule twice daily immediately after milking for 7 days at 10 and 13.5 ppm in feed for the pyridinyl and phenacrylate labels respectively (0.244 and 0.296 mg/kg bw/day).

The majority of the dose was excreted in urine (46–49%), and faeces (27–36%).

Residues in milk reached a plateau by day 4 (maximum TRR of 0.010–0.012 mg parent equivalents/kg (mg eq./kg)). A total of 0.06–0.20 % of the administered dose was recovered in milk.

Total residues in muscle were 0.006–0.010 mg eq./kg. In fat, total residues were 0.021–0.034 mg eq./kg. In liver, total residues were 0.12–0.34 mg eq./kg, and kidney residues were 0.057–0.15 mg eq./kg. A total of 0.11–0.20% of the administered dose was recovered in liver, with 0.01–0.02% recovered in kidney.

Residues in milk and muscle were not characterised due to the low total residues.

Parent was present in fat, liver and kidney. In fat, parent was the only significant residue, at 55–81% of TRR and 0.012–0.024 mg eq./kg. Other compounds (unidentified) ranged from 0.002–0.004 mg eq./kg (5.2–20% TRR) in fat.

In liver, parent was only present at 0.003 mg eq./kg (1.0–2.7% TRR). A number of components were found; only IN-QDY62 and IN-QFA35, at 0.017 and 0.013 mg eq./kg respectively, exceeded 0.01 mg eq./kg, and no component exceeded 10% TRR.

Parent was found in kidney at 0.002–0.004 mg eq./kg (2.5–3.8% TRR). The only significant component was IN-QFA35, at 14–15% TRR (0.008–0.020 mg eq./kg).

IN-QDY62, a rat metabolite, was found in the faeces, urine and bile. IN-QFA35, another rat metabolite, was found in bile.

Hens were dosed for 10 days, at a mean dose of 11.3 and 10.9 ppm in feed for the pyridinyl and phenacrylate labels respectively (0.947 and 0.883 mg/kg bw/day).

The majority (65–94%) of the administered dose was excreted.

Residues in egg yolks and whites reached a plateau at 8–10 days, at 0.19–0.21 mg eq./kg for yolks and 0.006–0.015 mg eq./kg for whites. Total residues in muscle, fat and liver were 0.019–0.023, 0.027–0.070 and 0.16–0.31 mg eq./kg respectively. In yolks, 0.08–0.10% of the administered dose was recovered, compared with 0.01–0.02% in white, 0.04–0.05% in muscle, 0.01–0.02% in fat, and 0.07–0.14% in liver.

Only day 10 yolks were extracted and characterised. Parent was found in yolk (0.003–0.005 mg eq./kg, or 1.3–2.2% of TRR), along with three metabolites IN-QDK50, IN-QFA35 and IN-QCD09, none of which exceeded 0.01 mg eq./kg or 10% of the TRR.

All three of these metabolites, IN-QDK50 (urine), IN-QFA35 (bile), and IN-QCD09 (bile), are metabolites found in rats.

The metabolism of picoxystrobin was similar in lactating goats and laying hens. Important metabolic pathways were:

- Oxidative cleavage of the molecule at the ether bridge to yield IN-QDK50 and IN-QDY60. Only IN-QDK50 was found in hens, while both metabolites were found in goats.
- Hydrolysis of the methyl ester to IN-QDY62.
- Loss of the methoxy methyl group, with subsequent hydroxylation of the carbon side chain, hydrolysis of the methyl ester, and further cleavage of the side chain yielding IN-QDY63 as a terminal metabolite.
- Cleavage of the acrylate side chain at the 2 position to yield phenyl acetate metabolites, with or without subsequent hydrolysis of the methyl ester, and/or hydroxylation at the 2 position, yielding IN–QGS46 and IN-QFA35.
- Hydroxylation of the phenyl ring (R290447).

Plant metabolism

Metabolism of ^{14}C-pyridinyl- and ^{14}C-phenacrylate-picoxystrobin was investigated in wheat, rape seed and soya bean.

Wheat (field grown) was treated twice by foliar application at Zadok's stages 32 and 65–69 at 405–437 g ai/ha, giving a total seasonal rate of 842 and 817 g ai/ha for the pyridinyl and phenacrylate labels respectively. Forage was harvested 14 days after the second application, with straw and grain being collected at normal harvest.

Parent was identified in grain (3.5–7.6% of TRR, 0.006–0.011 mg eq./kg). The only other components identified in grain were phthalic acid, IN-H8612 and PAG3 at 7.4%, 15%, and 7.9% (0.023, 0.046, and 0.024 mg eq./kg) respectively. Parent was the largest residue in forage (50–56% of TRR, 2.0–3.3 mg eq./kg) and straw (20–21% and 2.0–2.4 mg eq./kg). No other residue components exceeded 10% TRR in forage or straw, although a number of metabolites exceeded 0.01 mg eq./kg.

Phthalic acid, IN-H8612, and PAG3 were not found in rats.

Rape (greenhouse grown) was treated with two late season foliar applications at BBCH growth stages 80 and 85 with either the pyridinyl or the phenacrylate label at individual rates of 403–483 g ai/ha. Forage was sampled 7 days after the first application and 14 days after the second application, with remaining plant material and seed collected at normal harvest 21 days after the second application.

In all cases, parent was the most significant residue, at 80–96% of the TRR (5.6–9.9 mg eq./kg) in forage, 70–72% of TRR (8.3–9.4 mg eq./kg) in foliage at harvest, and 89–94% of TRR (1.5–2.3 mg eq./kg) in seed. All metabolites were < 10% of the TRR. The only other component identified in seed was Z-isomer (IN-QC12), at 0.6% TRR (0.02 mg eq./kg). In forage and dry plant material at harvest, Z-isomer, IN-QDY62, IN-QDY63, IN-QDK50 and its glucose conjugate were identified (maximum 7.4% TRR or 0.96 mg eq./kg). The small extent of metabolism of picoxystrobin in rape compared with wheat and soya bean is likely the result of the late application and the fact that the experiment was conducted in a greenhouse rather than in the field.

IN-QDY62 (faeces, urine and bile), IN-QDY63 (bile) and IN-QDK50 (urine) are all rat metabolites.

Soya beans (field grown) was treated with ^{14}C-pyridinyl or ^{14}C-phenacrylate-labelled picoxystrobin. Two foliar applications were made at BBCH 69 and 73–75 to give target seasonal rates of 200 g ai/ha. Foliage (hay) samples were collected 14 days after the second application, with dry stalks and seed collected at normal harvest.

Parent was found in seed (1.5–5.9% TRR, or 0.002–0.004 mg eq./kg). In forage, parent was significant at 7.4–10% TRR (0.13–0.18 mg eq./kg). In seed, only phthalic acid (INK2122) and 2-(2-formylphenyl)-2-oxoacetic acid (R730529) were found at levels above 10% TRR and 0.01 mg eq./kg (21% TRR/0.030 mg eq./kg and 26% TRR/0.036 mg eq./kg respectively). Other significant residues in forage included the glucose conjugate of IN-QGS46 (8.4–14%, or 0.14–0.26 mg eq./kg, mixed glucose conjugates of R290461 (total 26–31%/0.44–0.55 mg eq./kg and malonyl glucose conjugate of R290461 (10%/0.18 mg eq./kg).

Phthalic acid and 2-(2-formylphenyl)-2-oxoacetic acid are not rat metabolites. IN-QGS46 (bile and urine) and R290461 (urine) are rat metabolites.

The major metabolic pathways for picoxystrobin in plants were:

- Oxidative cleavage of the molecule at the ether bridge to yield IN-QDK50 and IN-QDY60. IN-QDK50 was subsequently conjugated with glucose and malonic or glutaric acid, while the phenacrylate cleavage product was subject to further oxidation and cleavage giving phthalic acid or IN-H8612;
- Loss of the methoxy methyl group followed by reduction of the enol, further hydroxylation of the side chain, and conjugation of the hydroxyl groups with glucose and malonic acid (R290461 and conjugates); and
- Hydrolysis of the ester, followed by oxidation and cleavage of the acrylate moiety ultimately yielding the benzoic acid metabolite IN-QDY63 or a phenyl-acetic acid metabolite (IN-QFA35), with or without glucose conjugation of the hydroxyl or carboxylic acid functionalities.

Hydroxylation of the phenyl ring was also observed in wheat, while small amounts of the *Z*-isomer of picoxystrobin (IN-QCD12) were found in rape and wheat.

Environmental fate

The Meeting received information on the aerobic degradation of picoxystrobin in soil, photolysis on the soil surface, field dissipation in soil, hydrolysis, aqueous photolysis, and metabolism in rotational cropping (both field and confined).

Aerobic metabolism of picoxystrobin in the dark was studied in various soil types at 20 °C. The DT_{50} values were 16–38 days, with DT_{90} values of 76–337 days. The major degradation pathways were ester hydrolysis, cleavage of the ether bridge to give IN-QDK50 (subsequently methylated), and mineralisation to carbon dioxide.

Picoxystrobin applied to thin layers of soil and irradiated for a period equivalent to 30 summer days at 50 ° latitude degraded rapidly with a DT_{50} of 7 days. The major degradation pathways were cleavage of the ether bridge and methyl acrylate moiety, yielding IN-QDK50 and phthalic acid, and finally mineralisation to carbon dioxide.

Microbial and photolytic degradation are both significant for picoxystrobin in/on soil.

Field dissipation studies for picoxystrobin were conducted in France, Germany, the UK, Canada and the USA. Degradation was relatively rapid (DT_{50} = 1.3–35 days, DT_{90} = 42–437 days). Metabolite levels were low, often below the limit of quantification, and less than parent. There was no evidence of accumulation of parent or metabolites.

Residues on succeeding crops

Rotational crop metabolism studies were conducted for ^{14}C-pyridinyl- and ^{14}C-phenacrylate-labelled picoxystrobin.

In one field rotation study, spring wheat, lettuce and carrot were sown 304–308 days after final application of radiolabelled compound at seasonal rates of 820–888 g ai/ha. The second field study involved winter wheat sown 107 days after the second of two foliar applications of labelled compound at a seasonal rate of 817–842 g ai/ha.

Picoxystrobin breaks down relatively rapidly in soil, and does not accumulate to a significant extent in following crops. Total residues did not exceed 0.01 mg eq./kg in wheat grain, lettuce and carrot roots from the field rotational studies. In wheat forage and straw and carrot leaves in the field studies, the most significant component was IN-QDK50 and conjugates, with a maximum total of 0.058 mg eq./kg (35–63% TRR), with free IN-QDK50 comprising only 0.002–0.006 mg eq./kg, or 2.0–6.9% TRR. No other components exceeded 0.01 mg eq./kg, or 10% TRR in any of the field rotational crop matrices. IN-QDK50 is a rat metabolite, found in urine.

Residues of picoxystrobin or its metabolites in following crops are therefore unlikely to be significant.

Methods of analysis

The Meeting received details of analytical methods for picoxystrobin residues in plant and animal matrices.

Analysis of picoxystrobin and the metabolites IN-QDK50, IN-QDY62 and IN-QDY63 in plant matrices involved extraction with acetonitrile/water, solid phase extraction clean-up, and GC/MS or LC/MS/MS analysis. LOQs are 0.01 mg/kg.

Methods were developed for analysis of parent in animal matrices. Samples were extracted with acetonitrile and in some cases cleaned up by solid phase extraction clean-up, with analysis by GC/MS or LC/MS/MS. LOQs are 0.01 mg/kg.

The suitability of the US FDA Pesticide Analytical Manual, Volume I (PAM I 3rd edition) protocols was assessed, with the GC method being found suitable for analysis of parent only in fatty and non-fatty plant matrices (apple and soya bean).

Suitable single residue analytical methods therefore exist for parent and the metabolites IN-QDK50, IN-QDY62 and IN-QDY63 in plant matrices, and for parent in animal matrices. A multi-residue method has been validated for the determination of parent only in plant matrices.

Stability of residues in stored analytical samples

Storage stability of picoxystrobin and the metabolites IN-QDK50, IN-QDY62 and IN-QDY63 in a range of plant commodities including high (apples, apple juice and lettuce), medium (wheat forage and apple pomace) and low (wheat straw and soya bean meal) water content, high acid (grapes), high protein (dry pea), high starch (potato), and high oil (soya bean seed and refined oil) content was assessed for samples stored frozen for 24 months. With the exception of the metabolites IN-QDY62 and IN-QDY63 in soya bean oil, which were stable for 18 and 6 months respectively, all analyte/sample combinations were stable for 24 months frozen storage.

The stability of residues of picoxystrobin in animal commodity samples over the period of storage in the feeding studies was acceptable.

Definition of the residue

Total residues in milk and muscle were very low (≤ 0.012 mg eq./kg). In goat fat, parent was the only identified component, at 55–81% of the TRR and 0.012–0.024 mg/kg. In liver and kidney, parent was present at low levels (1.0–3.8% TRR; 0.002–0.004 mg eq./kg). The only components in liver > 0.01 mg eq./kg were IN-QDY62 and IN-QFA35 at 0.017 and 0.035 mg/kg respectively. No components exceeded 10% of the TRR in liver. In kidney, only IN-QFA35 (14–15% TRR, or 0.008–0.020 mg/kg) was significant. In egg yolks, no components were found at > 10% of TRR or 0.01 mg eq./kg. Both IN-QFA35 and IN-QDY62 are also metabolites found in rats.

As parent was the only identified residue in fat, and was found in all analysed animal tissues, it is a suitable marker compound for analysis. A residue definition of parent compound only is proposed for picoxystrobin in animal commodities for both compliance and risk assessment purposes.

The octanol-water partition coefficient ($\log_{10}K_{OW}$) for picoxystrobin is 3.7. In the cattle feeding study at the highest feeding level, mean residues of picoxystrobin were < 0.01 mg/kg in muscle, compared with 0.028 mg/kg in subcutaneous fat. Residues were undetectable in skim milk, with a mean level of 0.026 mg/kg in cream. The Meeting concluded that picoxystrobin residues are fat-soluble.

In oilseed rape, the major component was parent at 89–94% of the TRR (1.5–2.3 mg eq./kg) in seed, and 70–96% of the TRR (5.6–9.9 mg eq./kg) in foliage. In wheat, parent was the only significant component in forage and straw (20–55% TRR, 2.0–3.3 mg eq./kg), and was found in grain (3.5–7.6% TRR, 0.006–0.011 mg eq./kg). In soya bean, parent was found at low levels in seed (1.5–5.9% TRR, 0.002–0.004 mg eq./kg). Parent was present at 0.13–0.18 mg eq./kg (7.4–10% TRR) in soya bean forage.

Other identified components in wheat grain were phthalic acid (IN-K2122) at 7.4% TRR, 0.023 mg eq./kg, PAG3 (7.9% of TRR, 0.024 mg eq./kg), and IN-H8612 (15% TRR, 0.046 mg eq./kg). In soya bean, only phthalic acid (21% TRR, 0.030 mg eq./kg) and 2-(2-formylphenyl)-2-oxoacetic acid (26% TRR, 0.036 mg eq./kg) were significant for seed. In soya bean forage, residue profiles were qualitatively similar to those for seed. IN-QGS46-glucoside was present at 0.26 mg eq./kg (14% TRR), with R290461-glucosides at 31% (0.55 mg eq./kg), and R290461 malonyl glucoside at 10% TRR (0.18 mg eq./kg).

Total residues did not exceed 0.01 mg eq./kg in wheat grain, lettuce and carrots from the field rotation studies. In wheat forage and straw and carrot leaves, the only significant (> 0.01 mg eq./kg, > 10% TRR) residue was IN-QDK50 and conjugates, which reached a total of 0.058 mg eq./kg (35–63% of TRR), with free IN-QDK50 comprising only 0.002–0.006 mg eq./kg, or 2.0–6.9% TRR. Picoxystrobin breaks down relatively rapidly in soil, and does not accumulate significantly in following crops. Residues of picoxystrobin or its metabolites in following crops are therefore unlikely

to be significant, and inclusion of metabolites in the residue definition for rotational crops is not necessary, especially as IN-QDK50 is a metabolite found in rats.

The Meeting concluded that phthalic acid is not a toxicologically relevant metabolite, while PAG3 and IN-QDY63 were not of toxicological concern at the estimated dietary intake levels.

The International Estimate Daily Intake (IEDI) of IN-H8612 was 0.15 µg/person/day, above the Threshold of Toxicological Concern (TTC) for a compound with evidence of genotoxicity. The Meeting was unable to conclude on the toxicological relevance of the estimated intakes of IN-H8612.

2-(2-Formylphenyl)-2-oxoacetic acid is not supported by any toxicological studies but a structural alert for genotoxicity was identified. The IEDI was above 0.15 µg/person/day, the TTC for a compound with a structural alert for genotoxicity. The Meeting was unable to conclude on the toxicological relevance of the estimated intakes of 2-(2-formylphenyl)-2-oxoacetic acid.

Conjugated compounds (such as those of IN-QDK50, IN-QGS46 or R290461) are not suitable for inclusion in the residue definition, as their analysis requires specialised analytical methods incorporating enzymatic digestion or hydrolysis steps. IN-QDK50 is a metabolite in the rat.

Given that parent is the major component of the residue in many plant matrices (rape seed and forage, and wheat forage and straw), and was found in all other plant matrices tested, it is the most suitable marker compound for analysis of picoxystrobin residues. A residue definition of parent compound is proposed for plant matrices for the purposes of compliance.

Because the Meeting was unable to conclude on the toxicological relevance of the metabolites IN-H8612 and 2-(2-formylphenyl)-2-oxoacetic acid, the Meeting could not reach a conclusion on a residue definition for dietary risk assessment.

Residue definition for picoxystrobin in plant and animal commodities (for compliance with maximum residue levels): *picoxystrobin.*

Residue definition for picoxystrobin in plant and animal commodities (for dietary risk assessment): *a conclusion could not be reached*.

Picoxystrobin residue is fat-soluble.

Residues of supervised residue trials on crops

The Meeting received supervised trial data for application of picoxystrobin on sweet corn, peas (dry), beans (dry), soya bean (dry), wheat, barley and rape seed conducted in the USA and Canada. The OECD MRL calculator was used as a tool to assist in the estimation of maximum residue levels from the selected residue data set obtained from the supervised residue trials. As a first step, the Meeting reviewed all relevant factors related to each data set in arriving at a best estimate of the maximum residue level using expert judgement. Then the OECD MRL calculator was employed. If the statistical calculation spreadsheet suggested a different value from that estimated by the Meeting, a brief explanation of the deviation was supplied.

In all trials, duplicate field samples were collected at each sampling interval and separately analysed. The mean result of the duplicate analyses was taken as the best estimate of the residue.

Labels were available from Canada, describing the registered uses of picoxystrobin.

Sweet corn

Picoxystrobin is registered in Canada for use in sweet corn at a GAP of 4 × 0.22 kg ai/ha and a 7 day PHI. The Canadian use pattern constitutes the critical GAP for sweet corn.

Eleven trials were conducted in sweet corn at GAP in the USA and Canada. Residues in sweet corn cobs at the 7 day PHI were < 0.01 (11) mg/kg.

The meeting estimated a maximum residue level of 0.01* mg/kg for picoxystrobin in sweet corn (corn-on-the-cob), together with a median residue and a highest residue both at 0.01 mg/kg.

Pulses

Picoxystrobin is registered in pulses except soya bean (chickpea, lentil, guar bean, lablab bean, broad bean (dry), pigeon, pea, lupin, field bean, kidney bean, lima bean, navy bean, pinto bean, tepary bean, adzuki bean, black-eyed pea, catjang, cowpea, cowpea, crowder pea, moth bean, mung bean, rice bean, southern pea, urd bean, and field pea) in Canada, at a maximum rate of 2 × 0.22 kg ai/ha with a 14 day PHI for harvest for human consumption.

Eleven trials were conducted in peas (dry) and eleven in beans (dry) in the USA and Canada and were evaluated against the Canadian GAP.

Residues in pea seed at the Canadian GAP were: < 0.01 (4), 0.010, 0.012, 0.013, 0.016 (2), 0.025 and 0.033 mg/kg. Residues in bean seed at the 14 day PHI were: < 0.01 (6), 0.011 (2), 0.016 and 0.038 (2) mg/kg.

Given the similarity of the data sets (confirmed by the Mann-Whitney U test), and the identical GAPs, the Meeting decided to combine the data sets for peas (dry) and beans (dry) for the purposes of determining a group maximum residue level. Residues were: < 0.01 (10), 0.010, 0.011 (2), 0.012, 0.013, 0.016 (3), 0.025, 0.033, and 0.038 (2) mg/kg.

The Meeting estimated a maximum residue level of 0.06 mg/kg for pulses (except soya bean), along with a median residue of 0.0105 mg/kg.

Picoxystrobin is registered in soya bean in Canada at a GAP of 3 × 0.22 kg ai/ha and a 14 day PHI. The Canadian use pattern represents the critical GAP for picoxystrobin in soya bean.

Twenty trials were conducted in soya bean in the USA and Canada and were assessed against the Canadian GAP. Residues in soya bean (dry) at the 14 day PHI were: < 0.01 (13), 0.010, 0.011, 0.012, 0.019, 0.031, 0.035, and 0.039 mg/kg.

The Meeting estimated a maximum residue level of 0.06 mg/kg for soya bean (dry), with a median residue of 0.01 mg/kg.

Cereal grains

In Canada, picoxystrobin is registered in cereal grains: wheat, barley, oats, rye, and triticale at a GAP of 3 × 0.22 kg ai/ha, with a PHI of 45 days.

Twenty-three trials were conducted in wheat in the USA and Canada and were assessed against the GAP of Canada. Residues in wheat grain from trials matching Canadian GAP were: < 0.01 (15), 0.010 (2), 0.013, 0.014, 0.019, 0.022, 0.025, and 0.028 mg/kg.

Seventeen trials were conducted in the USA and Canada in barley and were assessed against the Canadian GAP. Residues in barley grain from trials matching the Canadian GAP were: < 0.01 (4), 0.011, 0.014, 0.016 (2), 0.017, 0.022, 0.028 (2), 0.029, 0.047, 0.087, 0.12, and 0.22 mg/kg.

The Meeting decided that the residue data sets for wheat and barley were not sufficiently similar to combine for the purposes of establishing a group maximum residue level for cereal grains.

The Meeting estimated a maximum residue level of 0.04 mg/kg for picoxystrobin in wheat, with a median residue of 0.01 mg/kg.

Given the GAPs in Canada are the same for wheat, rye and triticale and the similarity of the crops, the Meeting decided to extrapolate from the wheat residue data to estimate maximum residue levels of 0.04 mg/kg for picoxystrobin in rye and triticale, with median residues of 0.01 mg/kg.

The Meeting estimated a maximum residue level of 0.3 mg/kg for picoxystrobin in barley, with a median residue of 0.017 mg/kg.

Given the GAPs are the same for barley and oats and the similarity of the crops, the Meeting decided to extrapolate from the barley residue data to estimate a maximum residue level of 0.3 mg/kg for picoxystrobin in oats, with a median residue of 0.017 mg/kg.

Picoxystrobin is registered in Canada for use in maize (field, seed and popcorn), with a GAP of 3 × 0.22 kg ai/ha, and a 7 day PHI.

Fifteen trials were conducted in maize at GAP in the USA and Canada. Residues in maize grain matching the Canadian GAP were: < 0.01 (13), 0.011, and 0.012 mg/kg.

The Meeting estimated a maximum residue level of 0.02 mg/kg for picoxystrobin in maize, together with a median residue of 0.01 mg/kg. The OECD MRL calculator yielded a value of 0.015 mg/kg. A higher limit than that generated by the calculator was chosen, noting the high level of censoring in the data set.

Rape seed

Seventeen trials were conducted in oilseed rape in the USA and Canada but were not according to a registered GAP. As a result the Meeting was unable to make a maximum residue level recommendation.

Animal feeds

Sweet corn forage

The GAP for sweet corn in Canada is 4 × 0.22 kg ai/ha, with a 0 day grazing interval. Residue data for sweet corn forage was collected for the USA and Canadian sweet corn trials. However, most samples were collected 7 days after treatment, which is not consistent with Canadian GAP.

Residues in sweet corn forage at 0 days after treatment (DAT) were 8.4 and 17 mg/kg.

The Meeting concluded that there were insufficient data points to estimate a highest residue and a median residue value for sweet corn forage.

Soya bean forage and hay

The Canadian GAP for soya bean (when forage is to be grazed or hay is to be harvested) is 1 × 0.22 kg ai/ha with a 14 day PHI.

Residue data for soya bean forage and hay were collected for the USA and Canadian soya bean residue trials.

At a 14 day PHI, residues of picoxystrobin in soya bean forage were: < 0.01, 0.25, 0.46, 0.57 (2), 0.80, 0.84, 0.88, 0.93, 1.4, 1.6 (3), 1.9, 2.0 (2), 2.1, 2.9, and 3.5 mg/kg (dry weight basis).

Residues of picoxystrobin in soya bean hay on a dry weight basis at the same interval were: < 0.01, 0.14, 0.39, 0.50, 0.51, 0.52, 0.59, 0.73, 0.81, 1.2, 1.6 (2), 1.7 (2), 1.8, 2.0, 2.1, 2.3 and 2.7 mg/kg.

The Meeting estimated a maximum residue level of 5 mg/kg for picoxystrobin in soya bean fodder, together with a median residue and a highest residue of 1.2 and 2.7 mg/kg respectively. The Meeting estimated a median residue and a highest residue of 1.4 and 3.5 mg/kg respectively for soya bean forage (dry weight).

Pea vines and hay

The GAP for picoxystrobin in pulses (except soya bean) in Canada is 2 × 0.22 kg ai/ha, with a 0 day PHI for vines (forage) and hay.

Data for pea vines and pea hay were collected for selected sites in the USA and Canadian pulse residue trials.

At a 0 day PHI, residues of picoxystrobin in pea vines were: 9.5, 14, 19, 22, 35 and 55 mg/kg (dry weight basis).

Residues of picoxystrobin in pea hay on a dry weight basis at the same interval were: 4.1, 7.1, 11, 14, 18, and 64 mg/kg.

The Meeting estimated a maximum residue level of 100 mg/kg for picoxystrobin in pea hay or pea fodder (dry), noting the value of 150 mg/kg estimated by the OECD MRL calculator. However, the Meeting agreed that 100 mg/kg represented a more realistic estimate of the maximum residue expected in pea fodder treated in accordance with GAP.

The highest residue and median residue values for pea hay are 64 and 12.5 mg/kg respectively (dry weight basis). The Meeting estimated a highest residue and a median residue value for pea vines of 55 and 20.5 mg/kg respectively (dry weight basis).

Wheat, barley, oat, rye and triticale forage, hay and straw

The Canadian GAP for wheat, barley, oat, rye and triticale forage is 1 × 0.22 kg ai/ha, with a 7 day grazing interval. The Canadian GAP for wheat, barley, oat, rye and triticale hay is 3 × 0.22 kg ai/ha, with a 14 day PHI. The Canadian GAP for wheat, barley, rye, oat and triticale straw is 3 × 0.22 kg ai/ha, with a 45 day PHI.

Residue data for wheat forage, hay and straw, and barley hay and straw were generated in the USA and Canada in accordance with the Canadian GAP.

Residues of picoxystrobin in wheat forage at a 7 day PHI were: 1.1, 1.3, 1.6, 1.7, 1.9, 2.2, 2.3, 3.6 (2), 3.7, 3.8, 3.9, 4.5, 4.6, 4.8, 6.3, 6.4, 7.0, 7.4, 8.9, 9.7, 11 (2), 12, and 31 mg/kg (dry weight basis).

Residues of picoxystrobin in wheat hay at a 14 day PHI were: 0.18, 0.19, 0.24, 0.41, 0.48, 0.51, 0.61, 0.68, 0.72, 0.78, 0.81, 0.90, 1.0, 1.1 (2), 1.4, 1.5, 1.7, 1.8, 2.4, 2.5, 2.8, 3.4, 3.6, and 4.0 mg/kg (dry weight basis).

Residues of picoxystrobin wheat straw at a 45 day PHI were: < 0.01, 0.016, 0.022 (2), 0.029, 0.033, 0.043, 0.079, 0.10 (2), 0.11, 0.15, 0.28, 0.29, 0.32, 0.36, 0.49, 0.50, 0.52, 0.62, 0.86, 1.2 (2), and 1.7 mg/kg (dry weight basis).

Residues of picoxystrobin in barley hay at a 14 day PHI were: 0.20, 0.32, 0.34, 0.38, 0.39, 0.46, 0.55, 0.66, 0.77, 0.78, 0.86, 1.3, 1.4, 1.7 (2), 2.3, 2.4, 3.5, and 5.5 mg/kg (dry weight basis).

Residues of picoxystrobin in barley straw at a 45 day PHI were: 0.049, 0.050, 0.066, 0.069, 0.082, 0.087, 0.13, 0.22, 0.23, 0.24, 0.28, 0.35, 0.40, 0.41, 0.80, and 1.2 mg/kg (dry weight basis).

A median residue value and a highest residue value of 4.5, and 31 mg/kg respectively were estimated for wheat forage for use in livestock dietary burden calculations. The Meeting agreed that these values could be extrapolated to barley, oat, rye and triticale forage for the purposes of the livestock dietary burden calculations.

Hay and straw of different cereal grains are generally indistinguishable in trade.

The Meeting determined that the residue data sets for wheat and barley hay and for wheat and barley straw were similar (Mann-Whitney U-test).

The Meeting agreed to combine the data sets for wheat and barley hay for the purposes of estimating maximum residue levels for cereal fodders. The combined data set for wheat and barley hay were: 0.18, 0.19, 0.20, 0.24, 0.32, 0.34, 0.38, 0.39, 0.41, 0.46, 0.48, 0.51, 0.55, 0.61, 0.66, 0.68, 0.72, 0.77, 0.78 (2), 0.81, 0.86, 0.90, 1.0, 1.1 (2), 1.3, 1.4 (2), 1.5, 1.7 (3), 1.8, 2.3, 2.4 (2), 2.5, 2.8, 3.4, 3.5, 3.6, 4.0, and 5.5 mg/kg.

The Meeting agreed to combine the data sets for wheat and barley straw for the purposes of estimating median and highest residue values for cereal straws. The combined data set for wheat and barley straw were: < 0.01, 0.016, 0.022 (2), 0.029, 0.033, 0.043, 0.049, 0.050, 0.066, 0.069, 0.079, 0.082, 0.087, 0.10 (2), 0.11, 0.13, 0.15, 0.22, 0.23, 0.24, 0.28 (2), 0.29, 0.32, 0.35, 0.36, 0.40, 0.41, 0.49, 0.50, 0.52, 0.62, 0.80, 0.86, 1.2 (3), and 1.7 mg/kg.

Using the combined wheat and barley hay data set, the Meeting estimated maximum residue levels of 7 mg/kg for barley straw and fodder, dry and for wheat straw and fodder, dry, with median

and highest residue values of 0.88 and 5.5 mg/kg (dry weight basis) respectively, for wheat and barley hay.

The Meeting agreed that the combined data set for barley and wheat hay could be extrapolated to the other cereal crops with the same GAP in Canada and estimated maximum residue levels of 7 mg/kg for oat straw and fodder, dry, for rye straw and fodder, dry, and for triticale straw and fodder, dry.

The Meeting estimated median and highest residue values of 0.88 mg/kg and 5.5 mg/kg (dry weight basis) respectively for oat hay, rye hay and triticale hay, using the barley and wheat hay data set.

Using the combined wheat and barley straw data set, the Meeting estimated median and highest residue values of 0.225 and 1.7 mg/kg (dry weight basis) respectively, for wheat and barley straw.

The Meeting estimated median and highest residue values of 0.225 and 1.7 mg/kg (dry weight basis) for oat straw, rye straw and triticale straw, using the barley and wheat straw data set.

Maize forage and stover

The GAP for picoxystrobin in maize in Canada is 3 × 0.22 kg ai/ha, with a 0 day PHI for grazing of forage, and a 7 day PHI for grain and stover.

Residue data for maize forage and maize stover were collected for the USA and Canadian trials.

Residues in maize forage in accordance with the Canadian GAP were: 3.5, 4.6, 5.0, 5.7, 6.2, 6.3, 6.7, 7.1, 8.0, 8.5, 9.7, 11, 12, 13, and 14 mg/kg (dry weight basis).

Residues in maize stover in accordance with the Canadian GAP were: 0.023, 0.94, 1.0, 2.1, 2.2, 3.2, 3.5, 3.8, 5.7, 6.0, 6.6, 7.4, 8.2, 8.5 and 8.6 mg/kg (dry weight basis).

A median and a highest residue value of 7.1, and 14 mg/kg (dry weight) respectively were estimated for maize forage for use in livestock dietary burden calculations.

The Meeting determined a maximum residue level of 20 mg/kg for picoxystrobin in maize fodder, together with a median and a highest residue of 3.8 and 8.6 mg/kg (dry weight) respectively.

Processing studies

Processing studies were conducted in wheat, barley, soya bean, and maize. Processing factors are tabulated below.

Raw agricultural commodity (RAC)	Processed commodity	Processing factors	Best estimate processing factor	RAC median residue (mg/kg)	RAC MRL (mg/kg)	Processed commodity median residue (mg/kg)	PF × RAC MRL, where required
Barley	Beer	< 0.05, < 0.25 (2), < 0.5	0.26			< 0.01	–
	Spent grain	0.5, 0.81	0.66			0.011	–
Wheat	Bran	1.9, 2.1, 3.0, 3.8	2.7	0.01	0.04	0.027	0.108
	Germ	2.6, 3.8	3.2			0.032	0.128
	Wholemeal flour	1.1, 1.3	1.2			0.012	–
	Flour	0.21, 0.26	0.24			< 0.01	–
	Type 550 (white) flour	0.83, 1.1	0.97			< 0.01	–
	Patent flour	1.1, 1.2	1.2			0.012	–
	Wholemeal bread	0.45, 1.0	0.73			< 0.01	–
	Type 550 (white) bread	0.64, 0.67	0.66			< 0.01	–

Raw agricultural commodity (RAC)	Processed commodity	Processing factors	Best estimate processing factor	RAC median residue (mg/kg)	RAC MRL (mg/kg)	Processed commodity median residue (mg/kg)	PF × RAC MRL, where required
	Screenings	1.7, 5.1	3.4			0.034	–
Soya bean	Refined oil (solvent extracted)	0.93, 1.0, 1.6, 2.2	1.4	0.01	0.06	0.014	0.084
	Refined oil (mechanically extracted)	3.4, 3.4	3.4			0.034	0.204
	Meal (solvent extracted)	0.03, 0.06, < 0.09, 1.1	0.32			< 0.01	–
	Meal (mechanically extracted)	0.36, 0.60	0.48			< 0.01	–
	Aspirated grain fractions	190, 320	260			2.6	–
	Hulls	2.2, 4.4, 5.1, 5.6	4.3			0.043	–
Maize	Starch	0.025, < 0.068	0.047	0.01	0.02	< 0.01	–
	Grits	0.34, 0.51	0.43			< 0.01	–
	Flour	1.0, 1.2	1.1			0.011	–
	Refined oil (wet milled)	6.4, 7.3	6.9			0.069	0.138
	Refined oil (dry milled)	3.4, 5.4	4.4			0.044	0.088
	Meal	0.77, 0.79	0.78			< 0.01	–
	Aspirated grain fractions	13, 17	15			0.15	

Picoxystrobin concentrated significantly in wheat bran, wheat germ, soya bean refined oil, and maize refined oil.

The Meeting therefore estimated maximum residue levels of 0.15, 0.15, 0.2, and 0.15 mg/kg for wheat bran, processed, wheat germ, soya bean oil, refined, and maize oil, edible, respectively, based on the best estimate processing factors and the raw agricultural commodity maximum residue levels.

Residues in animal commodities

Farm animal dietary burden

The Meeting estimated the dietary burden of picoxystrobin in farm animals on the basis of the diets listed in Appendix IX of the FAO Manual 2009. Calculation from highest residue, median residue (some bulk commodities), and median processed commodity residue values provides levels in feed suitable for estimating maximum residue levels. The percentage dry matter is taken as 100% when the highest residue levels and median residue levels are already expressed on a dry weight basis.

	US/Canada, maximum	EU, maximum	Australia, maximum	Japan, maximum
Beef cattle	2.29	31.6	64[a]	0.029
Dairy cattle	18.2	32.7	54.1[b]	7.87
Poultry (broiler)	0.028	0.026	0.02	0.004
Poultry (layer)	0.028	9.52[c,d]	0.02	0.02

[a] Maximum calculated dietary burden for beef cattle, used for calculation of mammalian tissue maximum residue levels.

[b] Maximum calculated dietary burden for dairy cattle, used for calculation of the milk maximum residue level.

[c] Maximum calculated dietary burden for laying hens, used for calculation of egg maximum residue level.

[d] Maximum calculated dietary burden for broiler hens, used for calculation of poultry tissue maximum residue levels.

The detailed dietary burden calculations are provided in Annex 6.

Animal feeding studies

Lactating cattle were dosed orally twice daily with picoxystrobin for 29 days at 39.7, 119.5, and 402.8 ppm in feed or 1.35, 4.12 and 12.9 mg/kg bw/day.

Picoxystrobin was not detected in whole milk from the low and mid-dose groups. Low levels (maximum 0.014 mg/kg), were found in some high-dose group samples. Milk residues reached a maximum around day 14. No residues were detected in skim milk, with levels in cream of 0.016–0.048 mg/kg for the high-dose group.

Picoxystrobin was not detected in muscle and kidney for the low or mid-dose groups, was found at < 0.01 mg/kg in muscle and 0.010 mg/kg in kidney for the high-dose group. Residues were detected in liver and fat at all doses. A roughly linear relationship between dose and residue was observed for liver and fat. The maximum residue at the high dose level was 0.10 mg/kg and 0.077 mg/kg for liver and fat (omental) respectively.

Depuration data indicated rapid clearance of residues from milk and tissues. No residues were detected in milk, muscle, perirenal fat or kidney from the depuration animals. Liver residues were undetectable by 8 days after the final dose, and were below the limit of quantification in fat (subcutaneous) by 3 and 15 days.

Laying hens were dosed orally daily with picoxystrobin for 36 days at 15.1, 45.4, 153 (main high-dose group) and 152 (depuration group) ppm in feed, or 0.97, 2.84, 9.49 and 9.53 mg/kg bw/day respectively. No residues were detected in eggs from the low and mid-dose group. In the high-dose group, residues in eggs reached a maximum of 0.014 mg/kg.

In fat, picoxystrobin was below the limit of quantification in the low dose group, while in the mid-dose group residues up to 0.010 mg/kg were found. Fat residues for the high-dose group reached a maximum of 0.016 mg/kg. In muscle, no residues were detected for the low or mid-dose groups, and were below the limit of quantification in the high-dose group. In liver, residues were undetectable in the low and mid-dose groups, and were below the limit of quantification in the high-dose group.

Picoxystrobin cleared rapidly from hen eggs and tissues, with no residues being detected in any samples after depuration day 2.

Animal commodity maximum residue levels

Mammals

The maximum dietary burdens for beef and dairy cattle are 64 and 54 ppm dry weight in feed respectively. Highest residue values calculated by interpolation or using transfer factors for picoxystrobin in mammalian animal matrices are tabulated below.

	Feed level	Residues	Feed level	Residues (mg/kg)			
	(ppm) for milk residues	(mg/kg) in milk	(ppm) for tissue residues	Muscle	Liver	Kidney	Fat
Highest residue determination (beef or dairy cattle)							
Feeding study	120	< 0.01	120	< 0.01	0.017	< 0.01	0.026
	40	< 0.01	40	< 0.01	< 0.01	< 0.01	< 0.01
Dietary burden and estimate of highest residue	54	0	64	0	0.012	0	0.015

Residues of picoxystrobin were not detected in milk from cattle at the two feeding levels bracketing the calculated maximum dietary burden for dairy animals. The Meeting therefore estimated a maximum residue level of 0.01* mg/kg for picoxystrobin in milk.

Residues of picoxystrobin were not detected in muscle or kidney from cattle at the two feeding levels bracketing the calculated maximum dietary burden for beef cattle. Residues were found at low levels above the LOQ in fat and liver of cattle at the next highest feeding level above the maximum dietary burden for beef cattle, and were below the LOQ for the next lowest feeding level.

The Meeting therefore estimated maximum residue levels of 0.02 mg/kg for edible offal (mammalian), meat (from mammals other than marine mammals) (fat), and mammalian fats (except milk fats).

Poultry

The maximum dietary burdens for broiler chickens and laying hens was 9.5 ppm dry weight in feed. Highest residue values calculated by interpolation or using transfer factors for picoxystrobin in poultry animal matrices are tabulated below.

	Feed level	Residues	Feed level	Residues (mg/kg)		
	(ppm) for egg residues	(mg/kg) in egg	(ppm) for tissue residues	Muscle	Liver	Fat
Highest residue determination (broiler or laying hens)						
Feeding study	15	< 0.01	15	< 0.01	< 0.01	< 0.01
Dietary burden and estimate of highest residue	9.5	0	9.5	0	0	< 0.01

Residues of picoxystrobin were not detected in the eggs, muscle or liver of hens fed at the next highest feeding level (15 ppm) above the maximum poultry dietary burden (9.5 ppm). Residues were detectable, but below the LOQ, in the fat of birds fed at 15 ppm.

The Meeting therefore estimated maximum residue levels of 0.01* mg/kg for picoxystrobin in eggs, poultry meat, and poultry, edible offal of. The Meeting estimated a maximum residue level of 0.01 mg/kg for picoxystrobin in poultry fats.

DIETARY RISK ASSESSMENT

Because the Meeting was unable to conclude on the toxicological relevance of the metabolites IN-H8612 and 2-(2-formylphenyl)-2-oxoacetic acid, the Meeting could not reach a conclusion on a residue definition for dietary risk assessment.

As a result, long- and short-term dietary intake assessments could not be conducted.

5.28 SEDAXANE (259)

TOXICOLOGY

Sedaxane is the common name that has been provisionally approved by the ISO for mixtures of two *cis* isomers, 2′-[(1*RS*,2*RS*)-1,1′-bicycloprop-2-yl]-3-(difluoromethyl)-1-methylpyrazole-4-carboxanilide, and two *trans* isomers, 2′-[(1*RS*,2*SR*)-1,1′-bicycloprop-2-yl]-3-(difluoromethyl)-1-methylpyrazole-4-carboxanilide (IUPAC), for which the CAS number is 874967-67-6. Sedaxane contains approximately 81–85% of the *trans* isomers and approximately 10–15% of the *cis* isomers.

Sedaxane is a broad-spectrum fungicide belonging to the chemical class of pyrazole-carboxamides. The pesticidal mode of action of this group of fungicides is inhibition of succinate dehydrogenase, which is a functional part of the mitochondrial electron transport chain and oxidative phosphorylation involved in the tricarboxylic acid cycle.

Sedaxane is being reviewed for the first time by JMPR at the request of CCPR. All critical studies complied with GLP.

Biochemical aspects

In rats given [^{14}C]sedaxane labelled in either the phenyl or pyrazole ring as a single oral dose of 1 or 80 mg/kg bw, the radiolabelled material was rapidly and extensively absorbed, based on recoveries in excreta from bile duct–cannulated rats. The times to reach C_{max} were approximately 1 hour and 5–6 hours following the low and high doses, respectively. The mean C_{max} and AUC values for the *trans* isomers were higher than those for the *cis* isomers and their mixture in rats. Approximately 90% of the administered dose was absorbed at both the low and high doses. Radiolabelled material was widely distributed throughout the body within 5 hours. The half-lives of elimination of total radioactivity from different tissues varied from 0.1–0.2 days in brain to 2.0–3.2 days in thyroid. Elimination half-lives from blood ranged from 30 to 40 hours and were generally similar in males and females at both dose levels. Less than 0.8% of the administered dose remained in the body at 96 hours after dosing.

The sedaxane administered to rats was rapidly excreted, predominantly in the faeces (75–88%) and in urine (12–20%). Sedaxane was extensively metabolized in rats by demethylation, hydroxylation, oxidation and conjugation, resulting in many hydroxylated metabolites and metabolites formed by cleavage of the terminal cyclopropyl moiety. The major metabolites have been identified as the *trans*-*para*-phenol sedaxane and the desmethyl *trans*-*para*-phenol sedaxane, which, together with the equivalent *cis*-*para*-phenol isomers of sedaxane, account for approximately half of the administered dose. There appear to be no major sex- or dose-related differences in the qualitative metabolite profile of sedaxane. There is little evidence of any cleavage between the phenyl and pyrazole moieties of the sedaxane molecule. A small amount (< 1%) of a pyrazole amide metabolite of sedaxane also found in plants can be found in bile samples. The phenolic and hydroxy metabolites of sedaxane and desmethyl sedaxane are subject to glucuronic acid, sulfate and glutathione conjugation.

Toxicological data

The oral LD_{50} was 5000 mg/kg bw in rats. Significant clinical signs of toxicity (ruffled fur, hunched posture, sedation, poor coordination, ventral recumbency, deep respiration, rales, salivation and bradypnoea) were observed at lower doses (1750 and 550 mg/kg bw) for a few hours following treatment. The dermal LD_{50} in rats was greater than 2000 mg/kg bw. The 4-hour acute inhalation LC_{50} in rats was greater than 5.2 mg/L. Sedaxane was not irritating to rabbit skin and minimally irritating to rabbit eyes. Sedaxane was not a skin sensitizer in the mouse local lymph node assay.

The short-term oral toxicity of sedaxane was evaluated in mice, rats and dogs, in which the main effects were on body weight gain and liver. In a 28-day study of toxicity in mice, no toxicity was observed at doses up to 7000 ppm (equal to 1268 mg/kg bw per day). In a 90-day dietary toxicity

study in mice, the NOAEL was 3500 ppm (equal to 566 mg/kg bw per day), based on a decrease in body weight gain throughout the study in males at 7000 ppm (equal to 1167 mg/kg bw per day).

Two 90-day toxicity studies were conducted in rats, each demonstrating the liver as the target for sedaxane. In the first study, the NOAEL was 1000 ppm (equal to 72.9 mg/kg bw per day), based on lower body weights, centrilobular hepatocyte hypertrophy and pigmentation, and blood chemistry indicating liver dysfunction in males and females at 4000 ppm (equal to 299.6 mg/kg bw per day). In the second study, the NOAEL was 300 ppm (equal to 28 mg/kg bw per day), based on reduced body weight and body weight gain and significant decreases in forelimb grip strength at 2000 ppm (equal to 186 mg/kg bw per day); liver toxicity was observed at 4000 ppm (equal to 325.1 mg/kg bw per day). The overall NOAEL from these studies was 1000 ppm (equal to 72.9 mg/kg bw per day).

The toxicity of sedaxane administered in capsules was tested in dogs in 90-day and 1-year toxicity studies. The overall NOAEL was 50 mg/kg bw per day, based on reduced body weight gain in females at 150 mg/kg bw per day.

The NOAEL in an 18-month dietary study in mice was 1250 ppm (equal to 157 mg/kg bw per day), based on a decrease in body weight and body weight gain in both sexes at 7000 ppm (equal to 900 mg/kg bw per day). A slightly increased incidence of hepatocellular adenomas and carcinomas combined was observed in male mice at the high dose in comparison with the control group incidence. The NOAEL for equivocal carcinogenicity in mice was 1250 ppm (equal to 157 mg/kg bw per day).

The NOAEL in a 104-week dietary study in rats was 200 ppm (equal to 11 mg/kg bw per day), based on increases in liver weight and histopathological changes (centrilobular hypertrophy) in the liver in males, histopathological changes in the thyroid in males and females, and reduced body weight gain in females at 1200 ppm (equal to 67 mg/kg bw per day). Hepatocellular eosinophilic foci were also increased at 200 ppm in females at 52 weeks, but did not persist at 2 years. Uterine adenocarcinomas were increased at 3600 ppm (equal to 218 mg/kg bw per day). The NOAEL for carcinogenicity was 1200 ppm (equal to 86 mg/kg bw per day), based on uterine tumours in female rats.

Sedaxane was tested for genotoxicity in vitro and in vivo in an adequate range of assays. In none of these assays was there any evidence of genotoxic potential.

The Meeting concluded that sedaxane is unlikely to be genotoxic.

On the basis of the absence of genotoxicity and the fact that equivocal increased incidences of hepatocellular adenomas and carcinomas combined in male mice and uterine endometrial adenocarcinomas in rats occurred only at the highest doses tested, the Meeting concluded that sedaxane is unlikely to pose a carcinogenic risk to humans at dietary exposure levels.

In a multigeneration reproductive toxicity study in rats, the NOAEL for parental toxicity was 500 ppm (equal to 41 mg/kg bw per day), based on significantly reduced body weight gain at 1500 ppm (equal to 120 mg/kg bw per day) in parental generation males. Decreased ovarian follicle counts were observed at 1500 ppm (low and middle doses not examined). Slightly decreased ovary weights were observed at 1500 ppm. The NOAEL for reproductive toxicity was 1500 ppm (equal to 120 mg/kg bw per day). The NOAEL for offspring toxicity was 500 ppm (equal to 43 mg/kg bw per day), based on significantly lower body weights of F_1 generation males during pre-mating at 1500 ppm (equal to 134 mg/kg bw per day).

In a developmental toxicity study in rats, the NOAEL for maternal toxicity was 25 mg/kg bw per day, based on reductions in body weight gain and feed consumption at 100 mg/kg bw per day. The NOAEL for developmental toxicity was 200 mg/kg bw per day, the highest dose tested.

In a developmental toxicity study in rabbits, the NOAEL for maternal toxicity was 100 mg/kg bw per day, based on reductions in body weight gain and feed consumption at 200 mg/kg bw per day. The NOAEL for developmental toxicity was 100 mg/kg bw per day, based on slight reductions in fetal body weights at 200 mg/kg bw per day.

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

The NOAEL in a single-dose neurotoxicity study in rats was 30 mg/kg bw, based on severe loss of general condition, decreased body weight and decreased feed consumption at 250 mg/kg bw.

The NOAEL for systemic toxicity in a 13-week neurotoxicity study was 1000 ppm (equal to 66 mg/kg bw per day), based on decreased body weight, body weight gain, feed consumption and feed efficiency, as well as reduced locomotor activity, at 4000 ppm (equal to 260 mg/kg bw per day).

The Meeting concluded that sedaxane is not neurotoxic.

In an immunotoxicity study in mice, sedaxane was not immunotoxic at doses up to 5500 ppm (equal to 1080 mg/kg bw per day).

A 28-day comparative study of the toxicities of *trans* and *cis* isomers and their mixture in rats demonstrated that their toxicological profiles were qualitatively similar.

The toxicity of a sedaxane plant metabolite (3-(difluoromethyl)-1H-pyrazole-4-carboxylic acid) has been investigated. The LD_{50} value in rats was greater than 2000 mg/kg bw, and the NOAEL in a 28-day oral (gavage) toxicity study in rats was 12 000 ppm (equal to 1018 mg/kg bw per day), the highest dose tested. There was no evidence for genotoxicity in in vitro assays.

No information on medical surveillance or poisoning incidents was available.

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

Toxicological evaluation

The Meeting established an ADI of 0–0.1 mg/kg bw on the basis of a NOAEL of 200 ppm (equal to 11 mg/kg bw per day) in a 2-year study of toxicity and carcinogenicity in rats, based on reduced body weight gain in females and histopathological changes in the liver in males and in the thyroid in males and females at 1200 ppm (equal to 67 mg/kg bw per day). A safety factor of 100 was applied. The ADI provides a margin of exposure of at least 860 relative to the NOAEL for uterine tumours in rats and at least 1570 for equivocal liver tumour response in mice. Thus, the Meeting considered that sedaxane is not likely to pose a carcinogenic risk to humans at dietary levels of exposure.

An ARfD of 0.3 mg/kg bw was established on the basis of a NOAEL of 30 mg/kg bw in a single-dose neurotoxicity study in rats, based on severe loss of general condition, decreased body weight and decreased feed consumption. A safety factor of 100 was applied.

A toxicological monograph was prepared.

Levels relevant to risk assessment

Species	Study	Effect	NOAEL	LOAEL
Mouse	Eighteen-month study of toxicity and carcinogenicity[a]	Toxicity	1250 ppm, equal to 157 mg/kg bw per day	7000 ppm, equal to 900 mg/kg bw per day
		Carcinogenicity (equivocal)	1250 ppm, equal to 157 mg/kg bw per day	7000 ppm, equal to 900 mg/kg bw per day
Rat	Single-dose test of neurotoxicity[b]	Toxicity	30 mg/kg bw	250 mg/kg bw
	Ninety-day studies of toxicity[a,c]	Toxicity	1000 ppm, equal to 73 mg/kg bw per day	2000 ppm, equal to 186 mg/kg bw per day
	Twenty-four-month study of toxicity and carcinogenicity[a]	Toxicity	200 ppm, equal to 11 mg/kg bw per day	1200 ppm, equal to 67 mg/kg bw per day
		Carcinogenicity	1200 ppm, equal to 86 mg/kg bw per day	3600 ppm, equal to 218 mg/kg bw per day
	Two-generation study of	Reproductive	1500 ppm, equal to	—

Species	Study	Effect	NOAEL	LOAEL
	reproductive toxicity[a]	toxicity	120 mg/kg bw per day[d]	
		Parental toxicity	500 ppm, equal to 41 mg/kg bw per day	1500 ppm, equal to 120 mg/kg bw per day
		Offspring toxicity	500 ppm, equal to 43 mg/kg bw per day	1500 ppm, equal to 134 mg/kg bw per day
	Developmental toxicity study[b]	Maternal toxicity	25 mg/kg bw per day	100 mg/kg bw per day
		Developmental toxicity	200 mg/kg bw per day[d]	—
Rabbit	Developmental toxicity study[b]	Maternal toxicity	100 mg/kg bw per day	200 mg/kg bw per day
		Developmental toxicity	100 mg/kg bw per day	200 mg/kg bw per day
Dog	Ninety-day and 12-month studies of toxicity[b,c]	Toxicity	50 mg/kg bw per day	150 mg/kg bw per day

[a] Dietary administration.

[b] Gavage administration.

[c] Two or more studies combined.

[d] Highest dose tested.

Estimate of acceptable daily intake for humans

0–0.1 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 sedaxane

Absorption, distribution, excretion and metabolism in mammals	
Rate and extent of oral absorption	Rapid , > 87%
Dermal absorption	No data
Distribution	Widely distributed
Potential for accumulation	None
Rate and extent of excretion	Rapid, > 99.5% within 2 days
Metabolism in animals	Main four metabolites by demethylation, hydroxylation, oxidation and conjugation
Toxicologically significant compounds in animals, plants and the environment	Parent compound and all of the individual isomers
Acute toxicity	
Rat, LD_{50}, oral	5000 mg/kg bw
Rat, LD_{50}, dermal	> 2000 mg/kg bw per day
Rat, LC_{50}, inhalation	> 5.244 mg/L
Rabbit, dermal irritation	Not irritating
Rabbit, ocular irritation	Mildly irritating
Dermal sensitization	Not sensitizing (local lymph node assay)
Short-term studies of toxicity	
Target/critical effect	Liver and reduced body weight gain
Lowest relevant oral NOAEL	50 mg/kg bw per day
Lowest relevant dermal NOAEL	1000 mg/kg bw per day

Lowest relevant inhalation NOAEC	No data
Long-term studies of toxicity and carcinogenicity	
Target/critical effect	Liver, thyroid and reduced body weight gain
Lowest relevant NOAEL	11 mg/kg bw per day
Carcinogenicity	Equivocal hepatic tumours in mice and uterine tumours in rats; unlikely to pose a carcinogenic risk at dietary exposure levels
Genotoxicity	
	Not genotoxic
Reproductive toxicity	
Target/critical effect	No reproductive toxicity
Lowest relevant reproductive NOAEL	120 mg/kg bw per day (highest dose tested)
Lowest relevant parental NOAEL	41 mg/kg bw per day
Lowest relevant offspring NOAEL	43 mg/kg bw per day
Developmental toxicity	
Target/critical effect	No developmental toxicity
Lowest relevant maternal NOAEL	25 mg/kg bw per day
Lowest relevant developmental NOAEL	100 mg/kg bw per day
Neurotoxicity	
Acute neurotoxicity	Not neurotoxic; 250 mg/kg bw (highest dose tested) NOAEL for toxicity: 30 mg/kg bw
Subchronic neurotoxicity	Not neurotoxic; 260 mg/kg bw per day (highest dose tested)
Other toxicological studies	
Comparative toxicity	Toxicological profile similar for trans and cis isomers and their mixture in rats
Immunotoxicity	Not immunotoxic; 1080 mg/kg bw per day (highest dose tested)
Medical data	
	No reports of toxicity in workers exposed during manufacture or use

Summary

	Value	Study	Safety factor
ADI	0–0.1 mg/kg bw	Two-year study (rats)	100
ARfD	0.3 mg/kg bw	Single-dose study (rats)	100

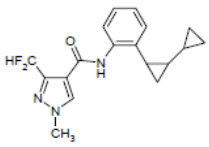
RESIDUE AND ANALYTICAL ASPECTS

Sedaxane is a novel seed treatment fungicide. It is a succinate dehydrogenase inhibitor and affords broad spectrum control of pathogens such as Ascomycete and Oomycete species in crops. It has been registered in France, Canada, and the USA. At the Forty-third Session of the CCPR, it was scheduled for evaluation as a new compound by the 2012 JMPR.

The Meeting received information from the manufacturer on identity, metabolism, storage stability, residue analysis, use pattern, fate of residues during processing, livestock feeding studies, and residues resulting from supervised trials on cereal grains (wheat, oats, and barley), soya bean, and rape.

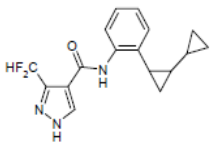
The IUPAC name for sedaxane recognizes a mixture of two *cis*-isomers 2'-[(RS,2RS)-1,1'-bicycloprop-2-yl]-3-(difluoromethyl)-1-methylpyrazole-4-carboxanilide and two *trans*-isomers 2'-[(RS,2SR)-1,1'-bicycloprop-2-yl]-3-(difluoromethyl)-1-methylpyrazole-4-carboxanilide. The CA name is *N*-[2-[1,1′-bicyclopropyl]-2-ylphenyl]-3-(difluoromethyl)-1-methyl-1*H*-pyrazole-4-carboxamide.

Sedaxane labelled in the pyrazole and phenyl rings was used in the metabolism and environmental fate studies. The chemical structures of sedaxane and its metabolites/degradates are shown below. Sedaxane is a mixture of *trans* and *cis* isomers, in an approximate 6:1 ratio.



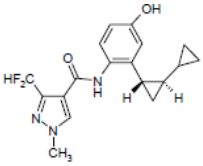
SYN524464

Sedaxane



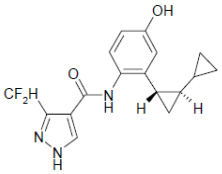
CSCD667584

N-desmethyl sedaxane



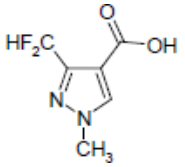
CSCD658906

Trans-para phenol sedaxane



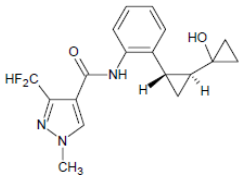
CSCD659087

N-desmethyl trans para phenol sedaxane



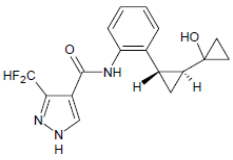
CSAA798670

Pyrazole acid



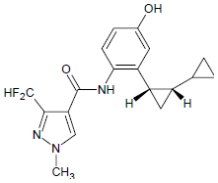
CSCD659089

Cyclopropyl alcohol sedaxane



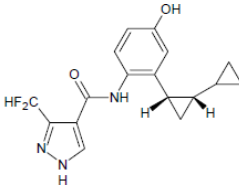
CSCD659088

Desmethyl cyclopropyl alcohol sedaxane



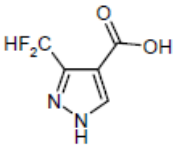
CSCD659090

Cis para phenol sedaxane



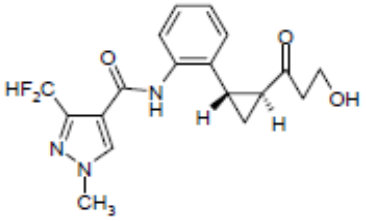
CSCD668404

Cis desmethyl para phenol sedaxane



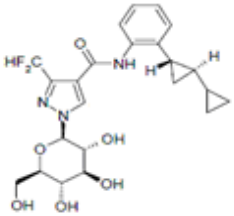
CSCD465008

N-desmethyl pyrazole acid



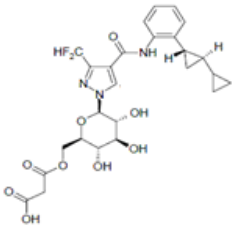
CSCD668403

β-hydroxy carbonyl sedaxane



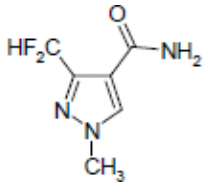
CSCD667555

N-glucoside (trans) sedaxane



CSCD667556

N-malonyl-glucoside of sedaxane



CSCC210616

pyrazole amide

Animal metabolism

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

Sedaxane metabolism in rats was reviewed by the WHO panel of the JMPR in 2012. The sedaxane administered to rats was rapidly excreted, predominantly in the faeces (75–88%) and in urine (12–20%). Sedaxane was extensively metabolized in rats by demethylation, hydroxylation, oxidation and conjugation, resulting in many hydroxylated metabolites and metabolites formed by cleavage of the terminal cyclopropyl moiety. The major metabolites have been identified as the trans para phenol sedaxane and the desmethyl trans para phenol sedaxane, which together with the equivalent cis para phenol isomers of sedaxane account for approximately half of the administered dose. There appear to be no major sex or dose related differences in the qualitative metabolite profile

of sedaxane and the position of radiolabelling. There is little evidence of any cleavage between the phenyl and pyrazole moieties of the sedaxane molecule. A small amount (< 1%) of a pyrazole amide metabolite of sedaxane also found in plants can be found in bile samples. The phenolic and hydroxy metabolites of sedaxane and desmethyl sedaxane are subject to glucuronic acid, sulphate and glutathione conjugation.

Two studies were conducted to investigate the nature of residues in milk and tissues from lactating goats, involving dosing of [phenyl-U-^{14}C]sedaxane and [pyrazole-5-^{14}C]sedaxane. Two goats were treated (one per radiolabel) at a dose rate equivalent to a dietary concentration of 20 ppm (in dry matter) daily for 7 consecutive days. Of the total administered radioactivity (TAR), 49–62% and 18–26% was eliminated in the faeces and urine, respectively. Total recovered radioactivity was 85% of the TAR.

The highest total radioactive residues (TRRs) were found in liver (0.47–0.61 mg eq./kg) and kidney (0.080–0.19 mg eq./kg) and the lowest in fat (0.011–0.015 mg eq./kg) and muscle (0.004–0.006 mg eq./kg). Results for milk indicated that a plateau was reached after approximately 2 days, at 0.033 and 0.045 mg eq./kg in the pyrazole and phenyl experiments, respectively.

In the milk, kidney, and muscle samples, sedaxane was not detected. Low TRR levels in muscle (0.004–0.006 mg eq./kg) precluded metabolite identification. In the liver, sedaxane was found at low levels: 0.009 mg/kg [2.0 % TRR] and 0.034 mg/kg [5.5% TRR] in the pyrazole and phenyl experiments, respectively. In the fat, sedaxane was the predominant residue at 28–44% TRR, but at low concentrations of 0.004–0.005 mg/kg.

Metabolites were present mainly as conjugates except in fat and milk. The principle metabolites identified were the *trans* para phenols CSCD658906 and CSCD659087 and the *cis* para phenol isomer CSCD668404. CSCD658906 was the major component in liver (13–19% TRR, 0.063–0.12 mg eq./kg) and kidney (14–22% TRR, 0.011–0.042 mg eq./kg). CSCD659087 and CSCD668404 were found in milk (9–10% TRR, 0.003–0.004 mg eq./kg), and kidney (11–13% TRR, 0.008–0.024 mg eq./kg).

Two studies were conducted to investigate the nature of residues in eggs and tissues from laying hens, involving dosing of [phenyl-U-^{14}C]sedaxane and [pyrazole-5-^{14}C]sedaxane. The test substances were administered at a dose rate equivalent to a dietary concentration of 20 ppm (in dry matter) daily for 14 consecutive days. Of the total administered radioactivity (TAR), 89–94% was eliminated in the excreta. Total recovered radioactivity was 94–98% of the TAR.

Total radioactivity results for egg indicated that a plateau was reached after approximately 9 days. TRRs in the egg white and yolk samples were 0.007–0.009 and 0.070–0.078 mg eq./kg, respectively, in the phenyl and pyrazole studies.

The TRR in tissues after sacrifice (12 hours after the last dose) were 0.19–0.26 mg eq./kg, 0.005 mg eq./kg, 0.12–0.24 mg eq./kg, and 0.008–0.016 mg eq./kg in liver, muscle, skin and attached fat, and abdominal fat, respectively.

Sedaxane was found at low levels (< 0.01 mg/kg) in all hen matrices except liver, where no sedaxane residues were detected. Sedaxane was the predominant residue in hen abdominal fat (46–53% TRR, 0.004–0.007 mg/kg).

Metabolites were present mainly as conjugates in liver and egg yolk. CSCD658906 was the principle metabolite identified in liver (14–16% TRR, 0.031–0.036 mg eq./kg) and egg yolk (13–16% TRR, 0.009 –0.013 mg eq./kg).

Animal metabolism summary

Metabolism studies in the laying hen and lactating goat demonstrated similar metabolic pathways. Specifically, oxidation reactions at the phenyl and cyclopropyl rings were noted, as well as demethylation, either prior to or after oxidation. No major differences were noted in the metabolic profiles resulting from the two radiolabelled experiments. There was no indication of significant cleavage between the phenyl and pyrazole moieties. The primary mechanisms for the proposed

biotransformation pathway of sedaxane in animals were: N-demethylation to form CSCD667584; hydroxylation of sedaxane to give the para phenols CSCD658906 and CSCD659090, and the cyclopropyl alcohol CSCD659089; hydroxylation of desmethyl sedaxane to give the para phenols CSCD659087 and CSCD668404, and the desmethyl cyclopropyl alcohol CSCD659088. Metabolites were present mainly as conjugates.

The distribution of sedaxane residues in tissues was consistent, with lowest residues in muscle, and highest in liver. Parent sedaxane was the predominant residue in fat tissues at up to 53% TRR in hen fat, although the absolute level was low (0.004 mg/kg). No sedaxane was found in goat muscle samples; trace levels were reported in hen muscle samples (0.001 mg/kg). Overall, the metabolism found in livestock was qualitatively similar to that observed in the rat.

Plant metabolism

Information was available on the metabolism of sedaxane from seed treatment uses in wheat, Swiss chard, and soya bean. Separate studies were reported using phenyl and pyrazole labelled sedaxane for all three crops. In addition, an uptake study in oilseed rape was conducted.

The oilseed rape uptake study demonstrated no residue uptake into oilseed rape seed when a sedaxane seed treatment application rate of 7.5 g ai/100 kg seed is used to grow oilseed rape plants to maturity.

Formulated [phenyl-U-^{14}C]sedaxane or [pyrazole-5-^{14}C]sedaxane was applied directly to spring wheat seeds at a concentration of 40 g ai/100 kg seeds. Seeds were sown into containers filled with sandy loam soil on the same day as treatment. The wheat was grown under greenhouse conditions and harvested at the following intervals: forage, 27 days after planting (DAP), BBCH 22; hay, 56 DAP, BBCH 41–57; and grain and straw, 111 DAP, BBCH 89.

The total radioactive residues in wheat grain RAC samples from both radiolabels were < 0.01 mg eq./kg and were not further analysed. The TRR of the remaining wheat commodities ranged from 0.45 mg eq./kg for wheat forage (phenyl label) to 1.1 mg eq./kg for wheat straw (phenyl label). The residue profiles for wheat forage, hay, and straw were all similar.

The highest residue level of sedaxane was in wheat forage (16% TRR, 0.16 mg/kg). Parent sedaxane was found in all commodities at 11 to 18% TRR (0.066 to 0.16 mg/kg). The N-demethylated compound, CSCD667584, was also found in all commodities at 2.9–5.1% TRR (0.019–0.036 mg eq./kg). The *trans* para phenol metabolite CSCD658906, in both free and conjugated forms, was a major residue in all commodities with residues between 9.5–17% (0.069–0.18 mg eq./kg). Other significant metabolites in forage, hay and straw were the cyclopropyl alcohol CSCD659089 (4.3–12% TRR, 0.042–0.068 mg eq./kg), the β-hydroxyl carbonyl compound CSCD668403 (4.9–11% TRR, 0.036–0.083 mg eq./kg), and the N-desmethyl *trans* para phenol metabolite CSCD659087 (5.0–7.2% TRR, 0.032–0.062 mg eq./kg). Trace levels [< 1% TRR & < 0.01 mg/kg] of the N-desmethyl pyrazole acid CSCD465008, the pyrazole acid CSAA798670 and the pyrazole amide CSCC210616 were also observed.

Formulated [phenyl-U-^{14}C]sedaxane or [pyrazole-5-^{14}C]sedaxane was applied directly to soya bean seeds at a nominal concentration of 110 g ai/100 kg seeds. Seeds were sown into containers filled with sandy loam soil on the same day as treatment. The soya bean plants were grown under greenhouse conditions and harvested at the following intervals: forage, 28 DAP, BBCH 16; hay, 35–42 DAP, BBCH 61; and seed, 96–103 DAP, BBCH 89.

The highest residue levels of sedaxane were in soya bean hay (23% TRR, 0.082 mg/kg) and soya bean forage (17% TRR, 0.020 mg/kg). The parent compound was not detected in the soya bean seeds; the only metabolite identified in this matrix was CSCD465008, free and conjugated, at a level of 0.017 mg eq./kg. The N-glucoside metabolite (CSCD667555) and N-malonyl glucoside metabolite (CSCD667556) were major metabolites in forage and hay (13–28% TRR, 0.018–0.098 mg eq./kg), resulting from N-demethylation of sedaxane and subsequent conjugation with glucose and then malonic acid. CSCC210616 and CSCD465008, resulting from the cleavage of the amide bridge, were

also observed in pyrazole label forage and hay samples, at levels ranging from 1.0–4.2% TRR (0.004–0.014 mg eq./kg).

The metabolism of [phenyl-U-^{14}C]sedaxane and [pyrazole-5-^{14}C]sedaxane was investigated in Swiss chard after treatment of seeds with a suspension concentrate containing either [phenyl-U-^{14}C]sedaxane or [pyrazole-5-^{14}C]sedaxane. Swiss chard seeds were treated at a nominal application rate of 40 g ai/100 kg seeds and sown into containers of soil on the same day as treatment. Swiss chard plants were grown under greenhouse conditions and harvested 49 days after the seeds were planted at the growth stage BBCH 14–15 (4 to 5 fully open leaves).

The predominant residue identified in Swiss chard was sedaxane: 29% TRR and 0.016 mg/kg in the pyrazole-label experiment, and 52% TRR and 0.024 mg/kg in the phenyl-label experiment.

In the phenyl-label study, N-desmethyl sedaxane, CSCD667584, was present at 4.5% TRR (0.002 mg eq./kg) and two components were tentatively identified as glycoside conjugates: CSCD658906/CSCD659089 at 1.1% TRR (< 0.001 mg eq./kg) and CSCD668403 at 1.5% TRR (< 0.001 mg eq./kg).

In the pyrazole label study, CSCC210616 (pyrazole amide; free and conjugated) was present at 12.9% TRR (0.0072 mg eq./kg), CSCD465008 (N-desmethyl pyrazole acid; free and conjugated) was present at 12% TRR (0.0064 mg eq./kg), the N-desmethyl parent CSCD667584 was present at 2.3% TRR (0.0013 mg eq./kg) and CSAA798670 (pyrazole acid; free and conjugated) was present at 0.8% TRR (< 0.001 mg eq./kg). Two glycoside conjugated components tentatively identified as CSCD658906/CSCD659089, and CSCD668403 were present at 0.9% TRR and < 0.001 mg eq./kg each.

Plant metabolism summary

Metabolism of sedaxane was similar in wheat, Swiss chard, and soya bean, although different major metabolites were found among the plants studied. Residues in wheat grain were too low for analysis. In soya bean seed, the only identified compound was CSCD465008, free and conjugated. In Swiss chard, parent sedaxane was the predominant residue.

The two most abundant compounds in wheat feedstuffs were parent sedaxane and CSCD658906; in soya feedstuffs were sedaxane and conjugates of CSCD667584; and in Swiss chard were sedaxane and the pyrazole metabolites. Although cleavage of the amide bond was relatively more important in Swiss chard in comparison to wheat or soya, the absolute levels were low (≤ 0.01 mg eq./kg).

Metabolism of sedaxane in plants occurs via the following reactions: oxidative metabolism of the phenyl and cyclopropane rings, N-demethylation of the pyrazole ring, and cleavage between the pyrazole and phenyl rings. There was variation in the significance of the different pathways and the nature of the observed conjugations between crops.

Environmental fate in soil

The Meeting reviewed aerobic soil degradation, soil photolysis, and succeeding crop studies.

Aerobic Soil Degradation

The rate of degradation of radiolabelled sedaxane was investigated under aerobic conditions at in three soils in the dark for up to 367 days. The levels of sedaxane declined steadily, reaching ≤ 50% of total applied radioactivity (TAR) in all soils by 1 year in soil treated directly and generally by 100 days in soils where sedaxane-treated seeds had been sown. Two major metabolites, identified as CSAA798670 and CSCD465008, were observed in all soils. CSCD465008 reached a maximum value of 32% of TAR in North Dakota sandy clay loam after 237 days following seed treatment application of sedaxane. CSAA798670 reached a maximum value of 14% of TAR in California sand after 365 days following direct soil application of sedaxane.

Soil Photolysis

The photolysis of [^{14}C]-sedaxane (both labels) on moist and dry soils was investigated under aerobic conditions, with continuous irradiation by artificial sunlight. No photodegradation products were detected at more than4.3% of the applied radioactivity at any analysis time in moist or dry soils. These studies suggest that photolysis is not a significant pathway for degradation of sedaxane.

Rotational crops

Confined rotational crop studies demonstrated that sedaxane pyrazole metabolites may be taken up by plant roots of succeeding crops. Therefore, a field rotational crop study was conducted to assess the potential for accumulation in successive crops at typical plant back intervals. This study was conducted at application rates matching GAP, and showed that no residues of sedaxane or its metabolites are likely in succeeding crops resulting from the use of sedaxane as a seed treatment.

Methods of analysis

Acceptable analytical methods were developed and validated for determination of sedaxane and its metabolites in plant and animal matrices.

The methods for enforcement and data generation involve homogenization and extraction with a mixture of acetonitrile and water (80:20, v/v), clean-up with solid phase extraction, centrifugation and dilution; then determination of analytes using LC-MS/MS. Additional clean up procedures, often including hydrolysis reactions, were made as necessary to improve analytical results for the metabolites. The reported LOQ for the sedaxane isomers was 0.005 mg/kg, while the LOQ for all metabolites was 0.01 mg/kg in all matrices (plant and animal).

The FDA Multi-Residue Method Test guidelines in the Pesticide Analytical Manual (PAM) (Third Edition, January 1994) is not applicable for the analysis of sedaxane, due to low recoveries.

Stability of residues in stored analytical samples

The stability of sedaxane residues during frozen storage (approximately -18 ºC) was investigated in plant matrices and processed commodities. The plant matrices tested were: wheat grain and straw, spinach, potato, orange, lentils, and soya beans. The processed commodities were derived from wheat (flour, germ, and bran), soya bean (meal, hulls, and oil), and orange (dried pulp, juice, and oil).

Compounds tested on plants were: both isomers of sedaxane, CSAA798670, CSCD667584, CSCD658906, CSCD659089, CSCD668403, CSCD667555, CSCC210616, and CSCD465008. For the processed commodities, the testing was limited to both isomers of sedaxane and CSCD456008. Each compound was added to matrices at 0.2 mg/kg.

No stability problems were found in any of the studies. Sedaxane and all isomers are stable for at least 24 months in frozen plant matrices, except for CSAA798670, which was only studied for 12 months. Similarly, stability for 12 months was demonstrated for sedaxane and CSCD456008 in processed commodities.

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

No separate storage stability studies were submitted for animal commodities. However, all samples were analysed within 30 days of collection in the bovine feeding study, and no significant changes were noted in the radio-profiles of the principle extracts from milk, liver, kidney, muscle and fat samples at the end of the analytical phase of the animal metabolism studies.

Definition of the residue

Results of the goat and hen metabolism studies were similar, indicating that residue levels are highest in liver and kidney, lower in milk, egg, and fat, and nearly undetectable in muscle. Parent sedaxane was found in fat, liver, egg, and hen muscle at levels ≤ 0.034 mg/kg. Sedaxane was the predominant residue in fat tissues at up to 53% TRR in hen fat, although the absolute level was low (0.004 mg/kg).

No sedaxane was found in goat muscle samples; trace levels were reported in hen muscle samples (0.001 mg/kg).

The predominant metabolites in kidney and liver are CSCD658906 and CSCD659087. Hence the bovine feeding study analysed for these compounds and for parent sedaxane. Although metabolite CSCD658906 was the only residue detected in the bovine feeding study, it was only found in liver and kidney samples from animals dosed at the most exaggerated rate (~24× the maximum dietary burden), and was present at ≤ 0.027 mg eq./kg. Because CSCD658906 is found in liver and kidney as glucose conjugates, inclusion in the residue definition would require an analytical method using hydrolysis procedures. Based on practical considerations regarding the analytical enforcement method together with the expectation of residue levels below the LOQ, it is not appropriate to include metabolite CSCD658906 in the residue definition for enforcement. Noting the low levels of sedaxane residues expected in animal tissues following sedaxane seed treatment uses, the Meeting concluded that the residue definition for animal commodities for purposes of enforcement and dietary intake is sedaxane.

The plant metabolism studies demonstrated that no sedaxane residues are found in grains or seeds. Low level residues may occur in the forage, hay and straw of plants grown from treated seeds. Predominant residues consist of parent sedaxane and CSCD658906 in wheat feedstuffs; sedaxane and conjugates of CSCD667584 in soya feedstuffs; and sedaxane and the pyrazole metabolites in Swiss chard.

The Meeting agreed that parent sedaxane is the best marker compound for plants as it was the only compound found at significant levels (> 10% TRR and 0.01 mg/kg) in all three plant metabolism studies, and is appropriate for both MRL enforcement and dietary intake assessments.

Sedaxane has a log K_{ow} of 3.3. In the goat and hen metabolism studies, sedaxane was the predominant residue found in fat, and was present only in trace amounts in muscle. The Meeting considered sedaxane to be a fat-soluble compound.

The Meeting recommended the following residue definition for sedaxane, when used as a seed-treatment.

For plants and animals: Definition of the residue (for compliance with the MRL and for estimation of dietary intake): *sedaxane*.

The residue is fat-soluble.

Results of supervised residue trials on crops

The Meeting received supervised field trials data for sedaxane uses on rape, cereal grains (barley, oats, and wheat), and soya bean.

The OECD MRL calculator was used as a tool in the estimation of the maximum residue level from the selected residue data set obtained from trials conducted according to proposed GAP. As a first step, the Meeting reviewed all relevant factors related to each data set in arriving at a best estimate of the maximum residue level using expert judgement. Then, the OECD calculator was employed. If the statistical calculation spreadsheet suggested a different value from that recommended by the JMPR, a brief explanation of the deviation was provided.

Soya bean (immature seeds)

The GAP for soya bean is from Canada and the USA, and specifies seed treatment use of sedaxane at a rate of 5 g ai/100 kg seed. Trials from the USA were conducted at a rate of 40 g ai/100 kg seed. As no residues were detected, the Meeting agreed to make use of these exaggerated rate trials.

A total of 20 trials were available from the USA. Sedaxane residue concentrations in soya bean seed from the USA were: < 0.01 (20) mg/kg.

Based on the results of the soya bean metabolism study, which showed that parent sedaxane residues are not found in soya bean seed, together with the results of the 20 field trials from the USA, the Meeting agreed that no sedaxane residues are expected in soya bean seed.

The Meeting estimated a maximum residue level of 0.01* mg/kg for sedaxane on soya bean (immature seeds), and an STMR of 0 mg/kg.

Cereal grains

Supervised trials data were available for barley, oats, and wheat.

Barley

The critical GAP for barley is from France and lists seed treatment use of sedaxane at a rate of 10 g ai/100 kg seed.

A total of 28 trials on barley grain were available from Australia (4), Canada (12), and USA (12). However, only the four trials from Australia match the GAP of France.

Sedaxane residue concentrations in barley grain from Australia were: < 0.010 (4) mg/kg.

Based on the results of the wheat metabolism study, which showed no transfer of radioactivity to the grain, together with the four field trials from Australia, the Meeting agreed that no sedaxane residues are expected in barley grain.

The Meeting estimated a maximum residue level for sedaxane in barley grain of 0.01* mg/kg, and an STMR of 0 mg/kg.

Oats

The critical GAP for oats is from France and specifies seed treatment use of sedaxane at a rate of 10 g ai/100 kg seed.

A total of four trials on oat grain were available from Australia matching the GAP of France.

Sedaxane residue concentrations in oat grain from Australia were: < 0.010 (4) mg/kg.

Based on the results of the wheat metabolism study, which showed no transfer of radioactivity to the grain, together with the results of the field trials from Australia, the Meeting agreed that no sedaxane residues are expected in oat grain.

The Meeting estimated a maximum residue level for sedaxane in oat grain of 0.01* mg/kg, an STMR of 0 mg/kg, and an HR of 0 mg/kg.

Wheat

The critical GAP for wheat is from France and specifies seed treatment use of sedaxane at a rate of 10 g ai/100 kg seed. GAP rates in Canada and the USA were 5 g ai/100 kg seed. Single and double rate trials were conducted in Australia.

A total of 31 trials on wheat grain matching GAP were available from Australia (8), North Europe (13), and South Europe (10).

Sedaxane residue concentrations in wheat grain from Australia were: < 0.010 (8) mg/kg.

Sedaxane residue concentrations in wheat grain from North Europe were: < 0.010 (13) mg/kg.

Sedaxane residue concentrations in wheat grain from South Europe were: < 0.010 (10) mg/kg.

Based on the results of the wheat metabolism study, which showed no transfer of radioactivity to the grain, together with the results of the field trials from Australia and Europe, the Meeting agreed that no sedaxane residues are expected in wheat grain.

The Meeting estimated a maximum residue level for sedaxane in wheat grain of 0.01* mg/kg, and an STMR of 0 mg/kg.

The Meeting decided to extrapolate the maximum residue level, median residue and highest residue for wheat to rye and triticale, noting that these crops have an identical GAP.

Rape seed

The GAP for rape seed from Canada and the USA lists seed treatment use of sedaxane at a rate of 5 g ai/100 kg seed.

A total of 16 trials on rape seed matching Canadian GAP were available from Canada.

Sedaxane residue concentrations in rape seed from Canada were: < 0.01 (16) mg/kg.

Based on the results of the rape seed metabolism study, which showed no transfer of radioactivity to the seed, together with the results of the rape field trials, the Meeting agreed that no sedaxane residues are expected in rape seed.

The Meeting estimated a maximum residue level for sedaxane in rape seed of 0.01* mg/kg, and an STMR of 0 mg/kg.

Animal feedstuffs

Soya bean forage and hay (fodder)

The GAP for soya bean is from Canada and the USA specifies seed treatment use of sedaxane at a rate of 5 g ai/100 kg seed. Trials from the USA were conducted at a rate of 40 g ai/100 kg seed (8 × USA GAP rate). As residues were detected in soya bean forage and hay samples, the Meeting determined that no maximum residue estimates could be made for these commodities on the basis of the exaggerated rate trials.

Forages (Barley, Oats, and Wheat)

The critical GAP for forages is from France and lists seed treatment use of sedaxane at a rate of 10 g ai/100 kg seed. Because there is no label feeding/grazing restriction for forages in France, the Meeting selected the highest residue concentration from each trial conducted that matched GAP.

Australian trials for barely and oat forage were submitted but not used for residue estimates since an Australian GAP for sedaxane is not available.

Barley straw and fodder

The critical GAP for barley is from France and lists seed treatment use of sedaxane at a rate of 10 g ai/100 kg seed.

Barley straw

A total of four trials on barley straw matching France GAP were available from Australia. Sedaxane residue concentrations in barley straw from Australia were: < 0.010 (4) mg/kg.

Barley hay

No barley hay trials matching the GAP of France were available. The Canadian and USA GAP lists seed treatment use of sedaxane at a rate of 5 g ai/100 kg seed.

A total of 24 trials on barley hay matching the GAP of the USA were available from Canada (12) and USA (12).

Sedaxane residue concentrations in barley hay from Canada and the USA were (n=24): < 0.010 (19), 0.011 (2), 0.025 (3) mg/kg.

Oat straw

The critical GAP for oat is from France and lists seed treatment use of sedaxane at a rate of 10 g ai/100 kg seed. A total of 4 trials on oat straw matching France GAP were available from Australia.

Sedaxane residue concentrations in oat straw from Australia were: < 0.010 (4) mg/kg.

Wheat straw, fodder, and forage

The critical GAP for wheat is from France and lists seed treatment use of sedaxane at a rate of 10 g ai/100 kg seed. Supervised trials data were available for wheat straw, hay, and forage.

Wheat forage

A total of 23 trials on wheat forage matching France GAP were available from North Europe (13), and South Europe (10).

Sedaxane residue concentrations in wheat forage from North Europe were: < 0.010 (9), 0.013 (2), 0.016, and 0.017 mg/kg.

Sedaxane residue concentrations in wheat forage from South Europe were: < 0.010 (6), 0.011, 0.013, and 0.023 (2) mg/kg.

As the results from North and South Europe are similar, the Meeting decided to combine these datasets (n=23): < 0.010 (15), 0.011, 0.013 (3), 0.016, 0.017, and 0.023 (2) mg/kg.

Based on the trials conducted in Europe, the Meeting estimated an STMR of 0.01 mg/kg and a HR of 0.023 mg/kg for wheat forage. The Meeting agreed to extrapolate the residue estimates from wheat forage to the other forages (barley, oats, rye, and triticale).

Wheat straw

A total of 23 trials on wheat straw matching GAP from France were available from North Europe (13) and South Europe (10).

Sedaxane residue concentrations in wheat grain from Europe were: < 0.010 (21), 0.011, and 0.012 mg/kg.

Wheat hay

No wheat hay trials matching the French GAP were available. The Canadian and USA GAP lists seed treatment use of sedaxane at a rate of 5 g ai/100 kg seed.

A total of 36 trials on wheat hay matching Canadian and US GAP were available from Canada (16) and USA (20).

Rank-order sedaxane residues in wheat hay from Canada and USA were (n=36): < 0.01 (27), 0.013, 0.014 (2), 0.025 (3), 0.035, 0.045, 0.075 mg/kg.

Summary of straw and fodder from barley, oats, rye, triticale, and wheat

Straw and fodder from barley, oats, rye, triticale, and wheat, may not always be readily distinguishable from each other in trade. Thus, it is preferable for these commodities to have the same MRLs. For sedaxane, residues in wheat hay were found to have the highest residue levels among the straw and fodder feedstuffs from small grains. The Meeting agreed to use the wheat hay data from Canada and the USA as a basis for estimating the maximum residue levels of these livestock feedstuffs.

On a dry-weight basis (DM = 88%), sedaxane residues in wheat hay were (n=36): < 0.011 (27), 0.015, 0.016 (2), 0.028 (3), 0.040, 0.051 and 0.085 mg/kg.

The Meeting estimated a maximum residue level of 0.10 mg/kg for sedaxane on barley, oats, rye, triticale, and wheat straw and fodder, dry. The Meeting estimated median and highest residue values of 0.01 and 0.075 mg/kg (as received), respectively, for sedaxane residues in straw and fodder of barley, oats, rye, triticale, and wheat, for the purposes of calculating livestock dietary burdens.

Fate of residues during food processing

High temperature hydrolysis

A high-temperature aqueous hydrolysis study was conducted to determine the nature of any sedaxane-derived residues in processed crop commodities or by-products under conditions typical of industrial or household processing.

In experiments conducted at 90, 100, and 120 ºC over a range of pHs, no significant degradation of sedaxane was found. Thus, sedaxane is hydrolytically stable under conditions representative of pasteurization, baking/brewing/boiling, and sterilization.

Processing

The Meeting received information on the processing of barley, oilseed rape, soya bean, and wheat. Neither sedaxane nor any metabolites were detected above the LOQ in any RAC or processed commodity sample. Thus, no processing factors for sedaxane could be determined.

Residues in animal commodities

The Meeting received a lactating dairy cow feeding study, which provided information on potential residues resulting in ruminant tissues and milk from sedaxane residues in the animal diet.

Lactating Holstein dairy cows were dosed for 28–30 days once daily via gelatin capsule with sedaxane. The sedaxane dosing rates were 0.11, 0.54, and 2.2 ppm in the dry-weight diet.

No sedaxane transferred into any tissue or milk at any dose level.

Due to low dietary burdens to poultry and low residue transfer noted in the poultry metabolism study, no poultry feeding study was conducted.

Livestock dietary burden

The Meeting estimated the dietary burden of sedaxane in livestock on the basis of the diets listed in OECD Feed Table 2009 (available from the FAO website: http://www.fao.org/agriculture/crops/core-themes/theme/pests/pm/jmpr/jmpr-docs/en/). Calculation from highest residue, STMR (some bulk commodities) and STMR-P values provides the levels in feed suitable for estimating maximum residue levels, while calculation from STMR and STMR-P values for feed is suitable for estimating STMR values for animal commodities.

Estimated maximum and mean dietary burdens of livestock

Dietary burden calculations for beef cattle, dairy cattle, broilers and laying poultry are provided in Annex 6. The calculations were made according to the livestock diets from US-Canada, EU, Australia and Japan in the OECD Feed Table 2009.

		Livestock dietary burden, sedaxane, ppm of dry matter diet			
		US-Canada	EU	Australia	Japan
Max	beef cattle	0.013	0.028	**0.092** [a]	0.002
	dairy cattle	0.028	0.028	**0.081** [c]	0.001
	poultry - broiler	0.002	0.002	0.002	0.000
	poultry - layer	0.002	**0.011** [e]	0.002	0.000
Mean	beef cattle	0.002	0.011	**0.040** [b]	0.000
	dairy cattle	0.011	0.011	**0.034** [d]	0.000

	Livestock dietary burden, sedaxane, ppm of dry matter diet			
	US-Canada	EU	Australia	Japan
poultry - broiler	0.000	0.000	0.000	0.000
poultry - layer	0.000	**0.004** [f]	0.000	0.000

[a] Highest maximum beef or dairy cattle dietary burden suitable for MRL estimates for mammalian tissues.

[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 milk.

[d] Highest mean dairy cattle dietary burden suitable for STMR estimates for milk.

[e] Highest maximum poultry dietary burden suitable for MRL estimates for poultry meat and eggs.

[f] Highest mean poultry dietary burden suitable for STMR estimates for poultry meat and eggs.

Animal commodities, maximum residue level estimation

Cattle

The sedaxane maximum dietary burden for beef and dairy cattle is 0.09 and 0.08 ppm, respectively. Sedaxane residues in all tissues in the bovine feeding study were below the LOQ of 0.01 mg/kg at all three dosing levels (highest of 2.2 ppm). No detectable residues of sedaxane are expected in any ruminant tissue from seed-treatment uses of sedaxane.

The Meeting estimated a maximum residue level of 0.01* mg/kg for sedaxane in/on: edible offal (mammalian); mammalian fats (except milk fats); meat (from mammals other than marine mammals); milks; and milk fats.

Based on no detectable levels of sedaxane being found in any tissue in the bovine feeding study, and the results of the goat metabolism studies demonstrating sedaxane levels are < 0.01 mg/kg in all tissues at exaggerated dose rates, the Meeting estimated STMR and HR values of 0 for mammalian commodities.

Poultry

The sedaxane maximum dietary burden for layer and broiler poultry is 0.01 and 0 ppm, respectively. No detectable residues of sedaxane are expected in any poultry tissue from seed-treatment uses of sedaxane.

The Meeting estimated a maximum residue level of 0.01* mg/kg for sedaxane in/on: poultry fats; poultry meat; poultry, edible offal of; and eggs.

Based on the results of the hen metabolism studies demonstrating sedaxane levels are < 0.01 mg/kg in all tissues at exaggerated dose rates, the Meeting estimated STMR and HR values of 0 for poultry commodities.

DIETARY RISK ASSESSMENT

Long-term intake

The ADI for sedaxane is 0–0.11 mg/kg bw. No long-term intake dietary risk assessment is needed for sedaxane because no uses result in residues in human foods. The Meeting concluded that the long-term intake of residues of sedaxane, from uses that have been considered by the JMPR, is unlikely to present a public health concern.

Short-term intake

The ARfD for sedaxane is 0.3 mg/kg bw. No short-term intake dietary risk assessment is needed for sedaxane because no sedaxane uses result in residues in human foods. The Meeting concluded that the short-term intake of residues of sedaxane, from uses that have been considered by the JMPR, is unlikely to present a public health concern.

5.29 SPINETORAM (233)

RESIDUE AND ANALYTICAL ASPECTS

Spinetoram belongs to the class of spinosyn insecticides obtained from chemical modification of the fermentation product of *Saccharopolyspora spinosa.* It consists of two closely related active ingredients (XDE-175-J and XDE-175-L) present approximately in a three to one ratio.

It was first evaluated by the 2008 JMPR which established an ADI of 0–0.05 mg/kg bw and decided that an ARfD is unnecessary. The 2008 Meeting estimated 11 maximum residue levels on a basis of the following residue definition.

Definition of the residue (for compliance with the MRL): *Spinetoram*.

Definition of the residue (for estimation of dietary intake): *Spinetoram and N-demethyl and N-formyl metabolites of the major spinetoram component*.

The residue is fat-soluble.

Note: Spinetoram consists of two related components.

At the Forty-third Session, the CCPR included spinetoram in the Priority List for additional MRLs. The current Meeting received information on supervised trials on additional crops in support of additional maximum residue levels.

Methods of analysis

The analytical methods used in the supervised trials provided to the current Meeting were already reviewed by the 2008 JMPR to be satisfactorily validated. These methods had been developed for the determination of residues of XDE-175-J and XDE-175-L and their metabolites N-demethyl-175-J and -L, N-formyl-175-J and -L in plant matrices using HPLC with positive-ion electron-spray (ESI) tandem mass spectrometry (LC-MS/MS).

Procedural recoveries in the analysis of commodities for which supervised trial data were submitted to the current Meeting were available. The mean recovery ranged from 73% to 111% except that the mean recovery of N-formyl-J in blueberry which was 64%. The relative standard deviations were all < 20%, where it could be calculated.

Stability of pesticide residues in stored analytical samples

The 2008 JMPR concluded that at -20 ºC, spinetoram and its N-demethyl and N-formyl metabolites were stable for about 12 months (372 days) in orange, sugar beet, soya bean and wheat. The storage periods of samples in the supervised trial studies were mostly within 372 days or only slightly longer.

Results of supervised residue trials on crops

The Meeting received information on supervised field trials of spinetoram on citrus fruits, stone fruits, berries and other small fruits, bulb vegetables, Brassica vegetables, common beans, spinach and celery.

For all analytes and matrices, the LOQ was 0.01 mg/kg. The LOD was reported to be 0.003 mg/kg for trials conducted in the USA and 0.005 mg/kg for trials conducted in Australia.

The OECD MRL calculator was used as a tool to assist in the estimation of maximum residue levels from the selected residue data set obtained from the supervised residue trials. As a first step, the Meeting reviewed trial conditions and other relevant factors related to each data set to arrive at a best estimate of the maximum residue level using expert judgement. Then, the OECD calculator was employed. If the statistical calculation spreadsheet suggested a different value, a brief explanation of the derivation was supplied.

Citrus fruits

There is an existing CXL of 0.07 mg/kg for oranges (sweet, sour) estimated by the 2008 JMPR on the basis of supervised trials in the USA conducted according to US GAP (3 applications of a maximum rate of 103 g ai/ha for a total seasonal rate of 210 g ai/ha and a PHI of 1 day). Additional trials conducted on oranges and tangerines in Brazil were submitted in support of a group MRL on citrus fruits.

Orange

Twelve supervised trials on oranges were conducted in the USA between 2004 and 2007 following the US GAP for citrus fruits (maximum rate of 103 g ai/ha, three applications, maximum seasonal rate of 210 g ai/ha, PHI one day). They were reviewed by the 2008 JMPR and regarded as six valid trials. While there were six valid trial results, the 2008 Meeting concluded that since each of the trials was conducted using low (approximately 700 L/ha) and high (approximately 3300 L/ha) spray volume and resulting in similar residue situation, two data sets from the two different spray volume applications were considered mutually supportive.

Residues of spinetoram in oranges from trials in the USA conducted following US GAP for citrus fruits were re-evaluated by the current Meeting. In rank order they were: < 0.01, 0.011, 0.018, 0.021, 0.027 and 0.029 mg/kg.

Corresponding total residues of spinetoram and the two metabolites for estimation of STMR in ranked order were: 0.022, 0.038, 0.039, 0.046, 0.061 and 0.062 mg/kg.

Four supervised trials on oranges were carried out in Brazil in 2004 with three applications at the spray concentration of 2.3–14 g ai/hL, corresponding to the application rate of 70 g ai/ha or 140 g ai/ha for a total seasonal rate of 210 g ai/ha. The registered use in Brazil for citrus fruits allows the maximum of three applications of 20–40 hL/ha at 1.25–2.5 g ai/hL with a PHI of 1 day.

Residues of spinetoram in oranges from one trial in Brazil conducted following GAP in Brazil were < 0.01 mg/kg and corresponding total residues were < 0.02 mg/kg.

Tangerine

A total of eight supervised trials on tangerines were carried out in Brazil in 2006 with 3 applications at the spray concentration of 3.5–7 g ai/hL, corresponding to the application rate of 70 g ai/ha for a total of 210 g ai/ha per season.

No trials conducted in Brazil matched the GAP of Brazil.

As for the trials conducted on oranges in Brazil, only one trial matched the GAP in Brazil. The Meeting decided to maintain the previous recommendation of 0.07 mg/kg for oranges, sweet, sour.

Stone Fruits

The 2008 JMPR reviewed information on the supervised field trial data on apricot, cherries, nectarine and peach conducted in Australia and New Zealand and decided that since no approved GAP was available, no maximum residue level could be recommended for spinetoram in stone fruits. The GAPs in Australia and New Zealand have since been approved.

In addition, supervised trials on stone fruits were also available from Chile, Argentina, Japan and Europe.

A total of 23 supervised trials were conducted in Australia during the 2005–2006 season (four on apricot, eight on cherry, four on nectarine and seven on peaches). Each plot was treated with 4 or 7 applications at a spray concentration of 5 g or 7.5 g ai/hL. The registered use of spinetoram in Australia for stone fruits allows a maximum of four applications at a spray concentration of 2.5–5 g ai/hL with a PHI of 3 days. However, in all of the trials conducted, samples were not taken 3 days

after the last application (taken 0 day, 7 days and later after the last application). Therefore, the results of these trials could not be used for estimating maximum residue levels.

A total of 28 supervised trials were conducted in New Zealand during the 2005-2006 season (eight on apricot, 12 on cherry and eight on peach). Four applications were made to each plot at rates of 2.5 g ai/hL, 3.7 g ai/hL, 5 g ai/hL or 7.6 g ai/ha.

Apricot

Residues of spinetoram in apricot from trials in New Zealand conducted in accordance with GAP in Australia in ranked order were: 0.078 and 0.11 mg/kg.

Corresponding total residues of spinetoram and the two metabolites in ranked order were: 0.11 and 0.14 mg/kg.

One trial was conducted in Chile in which two applications were made to apricot trees at the spray concentration of 3.6 g ai/hL corresponding to the application rate of 75–79 g ai/ha. There was no GAP available for apricot in Chile or Argentina.

Cherries

Residues of spinetoram in cherries from trials in New Zealand conducted in accordance with GAP in Australia in ranked order were: 0.036, 0.055 and 0.067 mg/kg.

Corresponding total residues of spinetoram and the two metabolites in rank order were: 0.062, 0.078 and 0.10 mg/kg.

One trial was conducted in Chile during 2007. In this trial, cherry trees were treated with two applications at the spray concentration of 3.6 g ai/hL corresponding to the rate of 78 g ai/ha. There is no GAP in Chile or in Argentina for cherries.

Nectarine

Two supervised trials were conducted in Argentina during 2008, and one trial in Chile in 2007. The trials in Argentina used 3 applications at a spray concentration of 4 g ai/hL resulting in a rate of 71–75 g ai/ha and a PHI of 1 day. The registered use in Argentina for nectarine allows a maximum of 3 applications at a spray concentration of 3.75–5 g ai/hL with the minimum application rate of 60 g ai/ha and a PHI of 1 day.

The trial in Chile used two applications at a spray concentration of 4 g ai/hL corresponding to a rate of 72 g ai/ha. There is no current GAP for nectarine in Chile. However, the trial was conducted at the same rate as the trials in Argentina with 2 applications instead of three applications. As the decline studies on stone fruits indicate that the contribution of earlier applications (interval of 14 days between applications) to the residues of spinetoram in harvested fruits was insignificant (on average no more than 20%), the Meeting decided to use the residue result from this trial.

Residues of spinetoram in nectarine from trials in Argentina and Chile conducted in accordance with GAP in Argentina in rank order were: 0.012, 0.013 and 0.072 mg/kg.

Corresponding total residues of spinetoram and the two metabolites in ranked order were: 0.022, 0.023 and 0.082 mg/kg.

Peach

Four trials were conducted in Argentina and two in Japan. Trials were also conducted on peaches in Spain (4), France (6), but no registration has yet been granted in Europe.

Residues of spinetoram in peach from trials in New Zealand conducted in accordance with GAP in Australia in ranked order were: 0.026 and 0.084 mg/kg.

Corresponding total residues of spinetoram and the two metabolites in ranked order were: 0.041 and 0.12 mg/kg.

In four supervised trials conducted in Argentina during 2007 and 2008, 3 applications were made at a spray concentration of 3.75 g ai/ hL resulting in the rate of 75 g ai/ha. The registered use in Argentina for peach is identical to that for nectarine, i.e., a maximum of 3 applications at a spray concentration of 3.75–5 g ai/ha with the minimum application rate of 60 g ai/ha and a PHI of 1 day.

The trial in Chile used 3 applications at the spray concentration of 6 g ai/hL resulting in a rate of 108 g ai/ha. There is no current GAP for peach in Chile but this trial was matching GAP in Argentina.

Residues of spinetoram in peach from trials in Argentina and Chile conducted in accordance with GAP in Argentina in ranked order were: 0.021, 0.039, 0.050, 0.068 and 0.14 mg/kg.

Corresponding total residues of spinetoram and the two metabolites in ranked order were: 0.031, 0.049, 0.060, 0.078 and 0.17 mg/kg.

Two supervised trials were conducted in Japan during 2006 with 2 applications at the spray concentration of 5 g ai/ha. The registered use in Japan for peach allows two applications at 2.5–5 g ai/hL and 20–70 hL/ha and a PHI of 1 day.

Residues of spinetoram in peach from trials in Japan conducted in accordance with GAP in Japan in ranked order were: 0.20 and 0.27 mg/kg.

Corresponding total residues of spinetoram and the two metabolites in ranked order were: 0.27 and 0.35 mg/kg.

A total of ten supervised trials were conducted in Southern Europe on different varieties of peaches during 2006 and 2007 with 3 or 4 applications at the spray concentration of 8–11 g ai/hL corresponding to 97–102 g ai/ha. Spinetoram is yet to be registered in Europe.

Plum

Eleven supervised trials were carried out in France (6), Germany (4) and Italy (1) during 2007 and 2008. Each treated plot received 3 or 4 applications at the spray concentrations of 10–13 g ai/hL resulting in rates of 98–109 g ai/ha. Spinetoram is yet to be registered in Europe.

One trial was conducted in Chile. Two applications at spray concentration of 4 g ai/hL corresponding to 72 g ai/ha were made. There is no GAP in Chile or in Argentina for plum.

Summary for stone fruits

Data sets for individual stone fruits from trials matching GAP were not sufficient for estimating individual maximum residue levels for them as shown below.

Commodity	Trials conducted in	Residues, mg/kg
Trials matching GAP of Australia		
Apricot	New Zealand	0.078, 0.11
Cherries	New Zealand	0.036, 0.055, 0.067
Peach	New Zealand	0.026, 0.084
Trials matching GAP of Argentina		
Nectarine	Argentina/Chile	0.012, 0.013, 0.072
Peach	Argentina/Chile	0.021, 0.039, 0.050, 0.068, 0.14
Trials matching GAP of Japan		
Peach	Japan	0.20, 0.27

Among these data sets from four different countries, residues in the Japanese trials on peach were significantly higher than those from the trials conducted in other countries. However, the data from Japanese trials were considered insufficient to estimate a maximum level.

While GAP in Australia was for stone fruits, the number of trials on each crop matching Australian GAP was not sufficient to estimate a maximum residue level for individual commodities or for the stone fruit group.

The Meeting decided to use the results of trials conducted on nectarine and peach in Argentina and Chile matching GAP of Argentina to estimate maximum residue levels for nectarine and peach.

Combined residues, in rank order, were (n=8): 0.012, 0.013, 0.021, 0.039, 0.050, 0.068, 0.072 and 0.14 mg/kg.

Corresponding total residues of spinetoram and the two metabolites in ranked order were: 0.022, 0.023, 0.031, 0.049, 0.060, 0.078, 0.082 and 0.17 mg/kg.

The Meeting estimated a maximum level of 0.3 mg/kg and an STMR of 0.055 mg/kg for both nectarine and peach.

Berries and other small fruits

Raspberries

Six supervised trials were conducted in the USA during 2010. Each treated plot received 4 applications at 25–105 g ai/ha of a 250 WG formulation of spinetoram. The total treatment for the season was 324–330 g ai/ha. The registered use in the USA for caneberries including raspberry allows up to 6 applications at 53–105 g ai/ha for a seasonal maximum of 342 g ai/ha and PHI of 1 day. Although the number of applications in the trials was four while the GAP allows up to six applications, the decline data show that contribution of the two earlier applications to the residues in harvested fruits was negligible.

Residues of spinetoram in raspberry from trials in the USA conducted in accordance with US GAP, in ranked order, were: 0.034, 0.17, 0.18, 0.26, 0.32 and 0.42 mg/kg.

Corresponding total residues of spinetoram and the two metabolites in ranked order were: 0.057, 0.21, 0.32, 0.51, 0.55 and 0.78 mg/kg.

The Meeting estimated a maximum residue level of 0.8 mg/kg and STMR of 0.42 mg/kg for raspberries, red, black.

Blueberries

Six supervised trials were conducted on blueberries during 2010 in the USA. Each treated plot received 4 applications at 25–104 g ai/ha of a 250 WG formulation of spinetoram. The total treatment for the season was 327–330 g ai/ha. The registered use in the USA for blueberry allows up to 6 applications at 53–105 g ai/ha for a seasonal maximum of 342 g ai/ha and PHI of 3 days. Although the number of applications in the trials was four while the GAP allows up to six applications, the decline data show that contribution of the two extra earlier applications to the residues in harvested fruits was insignificant.

Residues of spinetoram in blueberry from trials in the USA conducted in accordance with US GAP, in ranked order, were: 0.049, 0.050, 0.053, 0.056, 0.069 and 0.080 mg/kg.

Corresponding total residues of spinetoram and the two metabolites in ranked order were: 0.10, 0.11, 0.11, 0.13, 0.16, and 0.19 mg/kg.

The Meeting estimated a maximum residue level of 0.2 mg/kg and STMR of 0.12 mg/kg for blueberries.

Grapes

Eight supervised trials, four in France and four in Italy, were conducted during 2007 and 2008. The trials in Italy used 3 applications at 6–7 g ai/hL while those in France 4 applications from 4.5 to 5 g ai/hL. While registration of spinetoram is yet to be granted in these countries, the registered use in Turkey for grapes allows spray concentration of 4–6 g ai/hL with a PHI of 7 days. There was no description of maximum number of applications on the label.

One trial was conducted in Chile during 2008, in which 2 applications of 250 WG spinetoram were made at 60 g ai/ha. There is no GAP for grapes in Chile.

Residues of spinetoram in grapes from trials in France and Italy conducted in accordance with the GAP in Turkey, in ranked order, were: < 0.01, 0.018, 0.029, 0.039, 0.081, 0.096, 0.097 and 0.17 mg/kg.

Corresponding total residues of spinetoram and the two metabolites in ranked order were: < 0.02, 0.028, 0.039, 0.049, 0.098, 0.11, 0.14 and 0.23 mg/kg.

The Meeting estimated a maximum residue level of 0.3 mg/kg and STMR of 0.074 mg/kg for grapes.

Bulb vegetables

Onion, bulb

Eight trials were conducted on bulb onions during 2007 in Brazil. Onion plants were treated 4 times with spinetoram at the rate of 62.5 g ai/ha for a seasonal total of 250 g ai/ha. The trials were carried out according to the US GAP as the proposed label for Brazil had not yet been approved. The US GAP for bulb vegetables allows up to five applications at 44–88 g ai/ha for a maximum seasonal rate of 263 g ai/ha with a PHI of 1 day. As there was no residue expected to be found in onion bulb and there was no significant translocation of spinetoram occurring in plant, the Meeting agreed to evaluate the residue data of onion bulb from trials in Brazil against US GAP.

Residues of spinetoram in onion bulb from trials in Brazil conducted in accordance with US GAP in ranked order were: < 0.01 (8) mg/kg.

Corresponding total residues of spinetoram and the two metabolites in ranked order were: < 0.02 (8) mg/kg. However, as residues of the four components were below the limit of detection except that the major component of spinetoram (XDE-175-J) was found < 0.01 mg/kg on 1 day after the last application in two trials only, the Meeting concluded that in the case of onion, bulb, it was more appropriate to use < 0.01 mg/kg rather than < 0.02 mg/kg for total residue concentrations.

The Meeting therefore estimated a maximum residue level of 0.01* mg/kg and STMR of 0.01 mg/kg for onion, bulb.

Welsh onions and spring onion

Two supervised trials on Welsh onions were conducted in Japan during 2006. Each treated plot received 2 applications of spinetoram of 20 hL/ha at the spray concentration of 4.8 g ai/hL resulting in the application rate of 96 g ai/ha. The registered use in Japan for Welsh onion allows 2 applications of 10–30 hL/ha at the spray concentration of 4.8 g ai/hL with a PHI of 1 day.

Residues of spinetoram in Welsh onion from trials in Japan complying with GAP in Japan, in ranked order were: 0.10 and 0.13 mg/kg.

Corresponding total residues of spinetoram and the two metabolites in ranked order were: 0.12 and 0.20 mg/kg.

Six field trials were conducted in the USA on green onion during 2010 and 2011. Each treated plot received three applications of spinetoram at the rate of 87–92 g ai/ha (total seasonal rate of 262–268 g ai/ha). The registered use in the USA for bulb vegetables allows up to 5 applications at 44–87 g ai/ha with the maximum seasonal rate of 262 g ai/ha with a PHI of 1 day.

Residues of spinetoram in green onion from trials in the USA conducted in accordance with US GAP, in ranked order were: 0.029, 0.042, 0.066, 0.094, 0.10 and 0.43 mg/kg.

Corresponding total residues of spinetoram and the two metabolites in ranked order were: 0.13, 0.18, 0.22, 0.40, 0.42 and 0.86 mg/kg.

Based on the results of trials conducted in the USA, the Meeting estimated a maximum residue level of 0.8 mg/kg and STMR of 0.33 mg/kg for spring onion and Welsh onion.

Brassica vegetables

Numerous trials on Brassica vegetables were conducted during 2009 in Australia (10 on broccoli, 10 on cabbage, and one each on cauliflower and Brussels sprouts). One trial each for broccoli, cauliflower, cabbage, and Brussels sprouts were conducted in New Zealand. In one set of trials, spinetoram was applied once at a target rate of 35 g ai/ha, followed by three applications at 7 day intervals at a target rate of 88 g ai/ha, for a seasonal total of about 300 g ai/ha. The other set of trials used 4 applications at target rates of 18, 24, and 36 g ai/ha. The GAP in Australia allows 4 applications of spinetoram at the rate of 24–48 g ai/ha and a PHI of 3 days.

In the trials conducted in Australia and New Zealand, concentrations of spinetoram and total concentrations of spinetoram and the two metabolites were reported. As for the latter, the calculation method was clearly different from that of JMPR as the value of 0.01 mg/kg was reported.

Broccoli

In three trials the actual application rates were up to on average 77% of the maximum GAP rate. In other trials the application rates of last three applications were on average 1.9 times the maximum GAP rate. As the number of trials conducted with the application rate within ± 25% of the maximum GAP rate was three, the Meeting decided to use proportionality approach for estimating residues at the maximum GAP rate; i.e., multiplying the highest residue at PHI in each trial by a relevant scaling factor.

Scaled residues of spinetoram in broccoli from trials in Australia and New Zealand, in ranked order were (n=7)(residues found in the trials and scaling factor in parentheses): 0.022 (0.04 × 48/86), 0.026 (0.02 × 48/37) , 0.031 (0.06 × 48/92), 0.045 (0.09 × 48/91), 0.052 (0.10 × 48/92), 0.16 (0.08 × 48/24) and 0.17 (0.09 × 48/26) mg/kg.

Corresponding total residues of spinetoram and the two metabolites in ranked order were: 0.033 (0.06 × 48/86), 0.052 (0.10 × 48/92), 0.058 (0.03 × 48/25), 0.063 (0.12 × 48/91), 0.073 (0.14 × 48/92), 0.16 (0.08 × 48/24) and 0.18 (0.10 × 48/26) mg/kg.

Cauliflower

Residues of spinetoram in cauliflower from trials in Australia and New Zealand conducted in accordance with GAP in Australia in ranked order were: 0.01 and 0.10 mg/kg.

Corresponding total residues of spinetoram and the two metabolites in ranked order were: 0.01 and 0.11 mg/kg.

Cabbages, Head

In three trials the application rates were on average 81% of the maximum GAP rate. In other trials the application rates of last three applications were on average 1.9 times the maximum GAP rate. As the number of trials conducted with the application rate within ± 25% of the maximum GAP rate was three, the Meeting decided to use proportionality approach for estimating residues at the maximum GAP rate; i.e., multiplying the highest residue at PHI in each trial by a relevant scaling factor.

Scaled residues of spinetoram in broccoli from trials in Australia and New Zealand in ranked order were (n=7)(residues found in the trials and scaling factor in parentheses): < 0.013 (< 0.01 × 48/37), 0.011 (0.02 × 48/90), 0.011 (0.01 × 48/43), 0.016 (0.03 × 48/88), 0.026 (0.02 × 48/37), 0.034 (0.06 × 48/84) and 0.063 (0.12 × 48/92) mg/kg.

Corresponding total residues of spinetoram and the two metabolites in ranked order were: 0.011 (0.02 × 48/90), 0.022 (0.04 × 48/88), 0.026 (0.02 × 48/37), 0.033 (0.03 × 48/43), 0.051 (0.09 × 48/84), 0.052 (0.04 × 48/37) and 0.10 (0.20 × 48/92) mg/kg.

Two supervised trials on cabbage were conducted in Japan during 2006. Each treated plot received 2 applications of 20 hL/ha at the spray concentration of 4.8 g ai/hL resulting in the rate of 96 g ai/ha.

Residues of spinetoram in cabbage from trials in Japan conducted in accordance with GAP in Japan in ranked order were: 0.03 and 0.14 mg/kg.

Corresponding total residues of spinetoram and the two metabolites in ranked order were: 0.05 and 0.15 mg/kg.

Brussels sprouts

Residues of spinetoram in Brussels sprout from trials in Australia and New Zealand conducted in accordance with GAP in Australia in ranked order were: 0.02 (2) mg/kg.

Corresponding total residues of spinetoram and the two metabolites in ranked order were: 0.02 and 0.03 mg/kg.

Summary for Brassica vegetables

Data sets for individual brassica vegetable commodities from trials matching GAP were not sufficient for estimating individual maximum residue levels for them.

Residues in these commodities from trials conducted in Australia and New Zealand matching GAP of Australia, and scaled residues are as follows for these commodities.

Commodity	Trials conducted in	Residues, mg/kg
Broccoli	Australia, New Zealand (scaled)	0.022, 0.026, 0.031, 0.045, 0.052, 0.16, 0.17
Cauliflower	Australia, New Zealand	0.01, 0.10
Cabbage	Australia, New Zealand (scaled)	< 0.013, 0.011, 0.011, 0.016, 0.026, 0.034, 0.063
Brussels sprout	Australia, New Zealand	0.02, 0.02

As the residue concentrations in broccoli, cauliflower, cabbage and Brussels sprout from trials in Australia and New Zealand were not significantly different, and the GAP in Australia is for Brassica vegetables, the Meeting considered estimating a maximum residue level for Brassica vegetables.

The residues in broccoli, cauliflower, cabbage and Brussels sprout from trials in Australia and New Zealand were considered together.

The combined residues of spinetoram in broccoli, cauliflower, cabbage and Brussels sprout from trials in Australia and New Zealand in ranked order were (n=18): < 0.01, 0.01, 0.01, 0.01, 0.02, 0.02, 0.02, 0.022, 0.03, 0.03, 0.03, 0.03, 0.04, 0.05, 0.06, 0.10, 0.16 and 0.17 mg/kg.

Corresponding total residues of spinetoram and the two metabolites in ranked order were (n=18): 0.01, 0.01, 0.02, 0.02, 0.03, 0.03, 0.03, 0.03, 0.05, 0.05, 0.05, 0.06, 0.06, 0.07, 0.10, 0.11, 0.16 and 0.18 mg/kg.

The Meeting estimated a maximum residue level of 0.3 mg/kg and STMR of 0.05 mg/kg for Brassica vegetables.

For the purpose of calculating animal dietary burden on a basis of spinetoram residues in cabbage leaves, the Meeting estimated a highest residue of 0.063 mg/kg and median residue of 0.016 mg/kg.

Spinach

Six supervised field trials were conducted during 2010 in the USA. Each treated plot received four applications of spinetoram at the target rate of 35 g ai/ha for the first application and 87 g ai/ha for the second through fourth applications. The registered use in the USA for leafy vegetables allows up to 6

applications at the rate of 43–87 g ai/ha with the maximum seasonal rate of 300 g ai/ha and a PHI of 1 day.

Residues of spinetoram in spinach from trials in the USA conducted in accordance with US GAP, in ranked order were: 0.28, 0.36, 0.75, 0.80, 3.6 and 3.7 mg/kg.

Corresponding total residues of spinetoram and the two metabolites in ranked order were: 0.52, 0.82, 1.5, 1.7, 6.6 and 7.3 mg/kg.

The Meeting estimated a maximum residue level of 8 mg/kg and STMR of 1.6 mg/kg for spinach.

Common beans

Eight greenhouse trials were conducted in Brazil during 2006. For each of the sites, four applications of a 250 WG formulation of spinetoram were made to French beans at the rate of 50 g ai/ha for a seasonal total of 200 g ai/ha.

The GAP has not yet been approved in Brazil. The closest GAP that matched these trials is the GAP in USA (total seasonal rate of 245 g ai/ha and a PHI of 3 days). Since the label in the USA does not preclude greenhouse use, the Meeting decided to evaluate the results of greenhouse trials conducted in Brazil against the US GAP.

Residues of spinetoram in French beans from trials in Brazil matching US GAP, in ranked order were: < 0.01 (2), 0.014, 0.014, 0.016, 0.017 and 0.030 mg/kg.

Corresponding total residues of spinetoram and the two metabolites in ranked order were: < 0.02 (2), 0.024, 0.024, 0.026, 0.027 and 0.040 mg/kg.

The Meeting estimated a maximum residue level of 0.05 mg/kg and STMR of 0.024 mg/kg for common bean (pods and/or immature seeds). The Meeting agreed to extend the maximum residue level and STMR to beans, except broad bean and soya bean (green pods and immature seeds).

Celery

Eight supervised field trials on celery were conducted in the USA. Each treated plot received four applications of spinetoram at the target rate of 35 g ai/ha for the first application and 87 g ai/ha for the second through fourth applications. The registered use in the USA for celery allows up to six applications at the rate of 44–88 g ai/ha with the maximum total seasonal application of 300 g ai/ha and a PHI of 1 day. In trials the number of application was four, different from six specified as the maximum in GAP. The decline data indicate that only the last application contributes significantly to residues in harvested celery.

Residues of spinetoram in celery from trials in the USA conducted in accordance with US GAP in ranked order were: 0.024, 0.086, 0.10, 0.16, 0.18, 0.19, 2.6 and 3.0 mg/kg.

Corresponding total residues of spinetoram and the two metabolites in ranked order were: 0.097, 0.17, 0.22, 0.29, 0.31, 0.73, 5.0 and 5.3 mg/kg.

The Meeting estimated a maximum residue level of 6 mg/kg and STMR of 0.30 mg/kg for celery.

Residues in animal commodities

Farm animal dietary burden

The commodities for which maximum residues were estimated by the current Meeting include cabbage which can be used as feed. Since the contribution of cabbage in feed of cattle or other mammals is insignificant, the Meeting did not re-calculate dietary burden for cattle.

Calculated dietary burdens for layer are shown below.

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

	US-Canada		EU		Australia		Japan	
	max	mean	max	Mean	max	mean	Max	mean
Layers	0	0	0.043 [a]	0.029 [b]	0	0	0	0

[a] Suitable for estimating maximum residue levels for meat, fat and edible offal of poultry and eggs.

[b] Suitable for estimating STMRs for meat, fat and edible offal of poultry and eggs.

Residues in poultry tissues and eggs

No information was available on a poultry feeding study.

The maximum burden for layers was calculated to be 0.043 ppm and mean burden was 0.029 ppm. The dose level used in the metabolism study on laying hens was 10 ppm in the diet. The concentration of spinetoram found was the highest in abdominal fat at 1.37 mg/kg, followed by 0.78 mg/kg in skin with fat, 0.11 mg/kg in eggs, 0.11 mg/kg in liver and 0.048 mg/kg in muscle. The metabolites included in the residue definition were not identified or found at lower concentrations than the parent.

At 0.043 ppm dietary burden, the concentration of spinetoram was calculated to be 0.005 mg/kg in abdominal fat and significantly lower in muscle, liver and eggs. The Meeting estimated a maximum residue level of 0.01* mg/kg for poultry meat, poultry fats, edible offal of poultry, and eggs; and an STMR of 0.01 mg/kg for poultry fats, poultry meat, edible offal of poultry and eggs.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Daily Intakes (IEDIs) of spinetoram were calculated for the 13 GEMS/Food cluster diets using STMRs estimated by the Meeting in 2009 and 2012 (Annex 3). The ADI is 0–0.05 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 spinetoram resulting from the uses considered by the 2009 and current JMPR is unlikely to present a public health concern.

Short-term intake

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

5.30 THIAMETHOXAM (245) AND CLOTHIANIDIN (238)

RESIDUE AND ANALYTICAL ASPECTS

Thiamethoxam and clothianidin were evaluated for toxicology and residues as a new compound in 2010, resulting in a number of MRL recommendations. Additional residue data for both compounds were evaluated in 2011. 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 CGA322704 (clothianidin), considered separately. The residue definition for clothianidin in plant commodities for enforcement and dietary risk assessment is clothianidin.

At the 2010 JMPR Meeting, a Codex MRL of 0.01* mg/kg for thiamethoxam and 0.01* mg/kg for clothianidin were recommended based on thiamethoxam use on papaya. Subsequent to the 2010 JMPR meeting a more critical GAP for the use of thiamethoxam on papaya was supported by the Brazilian authorities. Residue trials were conducted in 2006 to support the use on papaya and summaries of the trials have been provided to support a revised Codex MRL for thiamethoxam and clothianidin on papaya.

Methods of Analysis

The methods reported to the Meeting and used in the supervised residue trials, determined parent thiamethoxam and the metabolite CGA 322704 (clothianidin). Samples were extracted with methanol:water. The final residue could then be determined by HPLC-MS-MS. The Meeting considers validation sufficient for papaya with an LOQ of 0.01 mg/kg for parent and 0.01 mg/kg for its metabolite.

Stability of pesticide residues in stored analytical samples

The 2010 JMPR received data that showed thiamethoxam and clothianidin were stable for 1–2 years when stored frozen at -10 °C or lower for a large range of commodities.

Results of supervised residue trials on crops

The Meeting received supervised field trials data for thiamethoxam use on papaya in Brazil.

Critical GAP for papaya in Brazil is for 1 soil drench application at 0.2 kg ai/ha followed by 2 foliar spray applications (interval 16 days) at 0.050 kg ai/ha with a PHI of 14 days. Trials from Brazil (one drench at 0.20 kg ai/ha, one foliar spray at 0.050 kg ai/ha, one drench at 0.20 kg ai/ha plus three foliar sprays at 0.050 kg ai/ha and PHI up to 7 days) did not match this GAP. As both the number of applications and the PHI did not match the critical GAP, it was not possible to apply the proportionality approach.

Trials in/on papaya submitted for the 2010 JMPR supported only drench applications and were used to set the current MRL of 0.01* mg/kg for thiamethoxam and clothianidin.

The Meeting agreed that the Brazilian datasets for papaya matching Brazilian GAP could not be used to support a higher papaya maximum residue level recommendation. The Meeting confirmed the previous maximum residue level recommendation of 0.01* mg/kg thiamethoxam on papaya and 0.01* mg/kg clothianidin on papaya.

5.31 TRIFLOXYSTROBIN (213)

RESIDUE AND ANALYTICAL ASPECTS

Trifloxystrobin was first evaluated for toxicology and residues by the JMPR in 2004. The Meeting derived an ADI of 0.04 mg/kg bw per day and decided that an ARfD is unnecessary. Maximum residue levels, STMRs and STMR-Ps for 73 commodities or commodity groups were estimated.

In 2004 the Meeting agreed that the residue definition for enforcement purposes for plant commodities should be trifloxystrobin *per se*. For enforcement of animal commodities and for consideration of dietary intake of plant or animal commodities the residue definition should be parent compound and *(E,E)*-methoxyimino-{2-[1-(3-trifluoromethyl-phenyl) ethylideneaminooxymethyl]-phenyl}acetic acid) (expressed as trifloxystrobin equivalents). The metabolite is also known as CGA 321113.

The compound was listed by the Forty-third Session of the CCPR for the review of additional MRLs. The 2012 JMPR received residue data for strawberries, papaya, olives, tomato, lettuce, radish and asparagus.

Methods of analysis

The Meeting received information on analytical methods used for the determination of trifloxystrobin residues and its acid metabolite CGA 321113 in samples derived from supervised trials on asparagus, lettuce, olives, papaya, radish, strawberry and tomatoes. The residues were determined by LC-MS/MS or GC-MS/MS with LOQs of 0.01–0.02 mg/kg.

The freezer storage stability studies carried out with asparagus and papaya showed that the trifloxystrobin residues and the metabolite CGA 321113 were stable for the longest period for which the samples were stored at or below -15 °C. The studies reported by the 2004 JMPR cover the other sample materials evaluated by the present Meeting.

Results of supervised residue trials on crops

The OECD calculator was used as a tool in the estimation of the maximum residue level from the selected residue data set obtained from trials conducted according to GAP. As a first step, the Meeting reviewed all relevant factors related to each data set in arriving at a best estimate of the maximum residue level using expert judgment. Then, the OECD calculator was employed. If the statistical calculation spreadsheet suggested a different value from that recommended by the JMPR, a brief explanation of the deviation was provided.

Strawberry

Based on the Swiss GAP (3 × 0.25 kg ai/ha, PHI 14 days) and five European supervised trials, the 2004 JMPR estimated a maximum residue level of 0.2 mg/kg and an STMR of 0.1 mg/kg.

The 2012 Meeting received additional residue data from the USA and Australia. The Australian trials were carried out with 3 × 0.2 kg ai/ha and did not match the GAP (3 × 0.15 kg ai/ha, PHI 1 day). The registered GAP in the USA is 6 × 0.11 kg ai/ha and a 0-day PHI. In eight trials matching GAP conditions, the residue levels of trifloxystrobin *per se* were (n=8): 0.10, 0.19, 0.20, 0.28, 0.30, 0.44, 0.47 and 0.50 mg/kg. The residue concentrations of the sum of trifloxystrobin and CGA 321113 were: 0.23, 0.23, 0.27, 0.31, 0.36, 0.47, 0.51 and 0.56 mg/kg.

The Meeting estimated a maximum residue level of 1 mg/kg and an STMR of 0.335 mg/kg for trifloxystrobin in strawberries to replace the former recommendation.

Olives

The Spanish GAP is 2×0.005 kg ai/hL and a PHI of 14 days. The first application is recommended in spring, the second in autumn. Eight trials conducted in Southern Europe with one treatment of 0.005 kg ai/hL in autumn and a PHI of 14 days showed residues of trifloxystrobin *per se* of 0.04, 0.05, 0.07, 0.07, 0.10, 0.11, 0.12 and 0.13 mg/kg. In four Southern European trials with two applications (one in spring and one in autumn with 0.006 kg ai/hL, spraying interval of 71–99 days between the two treatments), the residue levels of trifloxystrobin *per se* were 0.02, 0.04, 0.10 and 0.13 mg/kg. The Meeting noticed that the first spray treatment did not influence the residue concentration and decided to combine the two datasets. The trifloxystrobin residues (n=12) were: 0.02, 0.04, 0.04, 0.05, 0.07, 0.07, 0.10, 0.10, 0.11, 0.12, 0.13 and 0.13 mg/kg.

Because the residues of CGA 321113 were below the LOQ, for estimation of STMR (sum of parent and CGA 321113), the trifloxystrobin data were used.

The Meeting estimated a maximum residue level of 0.3 mg/kg and an STMR of 0.085 mg/kg for trifloxystrobin in olives.

Papaya

The GAP in the USA is maximal four foliar applications of 0.14 kg ai/ha at a maximal seasonal rate of 0.56 kg ai/ha and a PHI of 0 days. Four trials were conducted on papaya in the USA in 2003 with foliar treatment by 4 × 0.14–0.15 kg ai/ha, PHI 0 days. The trifloxystrobin residues were 0.07, 0.15, 0.22 and 0.27 mg/kg. The residue concentrations of the sum of trifloxystrobin and CGA 321113 were: 0.07, 0.15, 0.25 and 0.31 mg/kg.

The Meeting estimated a maximum residue level of 0.6 mg/kg and an STMR of 0.2 mg/kg for trifloxystrobin in papaya.

Brussels sprouts

The 2004 JMPR estimated a maximum residue level of 0.5 mg/kg and a STMR of 0.17 mg/kg for residues of trifloxystrobin in flowerhead brassica, Brussels sprouts and head cabbage but in the CCPR reports, a CXL of 0.1 mg/kg was listed for Brussels sprouts. The company requested a clarification. No new data were submitted.

The current Meeting noted that the value of 0.1 mg/kg as CXL for Brussels sprouts is an administrative error in the Codex System. The MRL recommendation made by the 2004 JMPR was 0.5 mg/kg.

Tomatoes

Based on the US GAP (4 × 0.14 kg ai/ha, PHI 3 days) and 18 supervised trials, the 2004 JMPR estimated a maximum residue level of 0.7 mg/kg and an STMR of 0.08 mg/kg.

The 2012 JMPR received six further US outdoor trials according to US GAP. The residue concentrations of the sum of trifloxystrobin and CGA 321113 were: 0.03, 0.04, 0.06, 0.06, 0.09 and 0.11 mg/kg.

The Meeting agreed that a new recommendation for trifloxystrobin on tomatoes based on the data submitted to the 2012 JMPR was not necessary. Therefore, the previous recommendations for a maximum residue level and STMR were maintained.

Egg plant

The US GAP of trifloxystrobin on eggplant is 5 × 0.07–0.14 kg ai/ha at a maximum of 0.56 kg ai/ha per season and a 3 day PHI, the same GAP is registered for tomatoes.

The Meeting agreed to extrapolate from tomato to eggplant and recommended a maximum residue level of 0.7 mg/kg and an STMR of 0.08 mg/kg for trifloxystrobin in egg plant.

Lettuce, head

The GAP for greenhouse grown lettuce is in the Netherlands 3 × 0.2 kg ai/ha and a PHI of 7 days. Eight indoor European trials (France (2), Germany (2), Italy (2), Portugal (1), the Netherlands (1)) treated with 3 × 0.25 kg ai/ha were received.

In eight trials on head lettuce matching the GAP conditions of the Netherlands (application rate +25 %), the residue levels of trifloxystrobin *per se* were: 2.4, 2.5, 2.7, 5.4, 5.6, 5.7, 6.6 and 7.2 mg/kg. The residue concentrations of the sum of trifloxystrobin and CGA 321113 were: 2.4, 2.7, 2.7, 5.4, 5.7, 5.8, 6.7 and 7.2 mg/kg.

The Meeting estimated a maximum residue level of 15 mg/kg and an STMR of 5.55 mg/kg for trifloxystrobin in lettuce, head.

Radish leaves (including Radish tops)

The registered GAP on radish in the USA is 4 × 0.07–0.14 kg ai/ha at a maximal rate of 0.28 kg ai/ha per year and a PHI of 7 days. Six field trials were conducted with 2 × 0.14–0.15 kg ai/ha and a PHI of 6–8 days.

In radish tops, the residue levels of trifloxystrobin *per se* were: 0.07, 0.22, 0.26, 2.3, 5.3 and 6.8 mg/kg. The residue concentrations of the sum of trifloxystrobin and CGA 321113 were: 0.13, 0.32, 0.37, 2.4, 5.4 and 7.2 mg/kg.

The Meeting estimated a maximum residue level of 15 mg/kg and an STMR of 1.4 mg/kg for trifloxystrobin in radish leaves.

Radish

The registered GAP on radish in the USA is 4 × 0.07–0.14 kg ai/ha at a maximal rate of 0.28 kg ai/ha per year and a PHI of 7 days. Six field trials were conducted with 2 × 0.14–0.15 kg ai/ha and a PHI of 6–8 days.

In radish roots, the residue levels of trifloxystrobin *per se* were: < 0.02 (3), 0.03, 0.04 and 0.05 mg/kg. The residue concentrations of the sum of trifloxystrobin and CGA 321113 were: < 0.02, 0.06, 0.06 and 0.07 (3) mg/kg.

The Meeting estimated a maximum residue level of 0.08 mg/kg and an STMR of 0.065 mg/kg for trifloxystrobin in radish.

Asparagus

The GAP in the USA is 3 × 0.11–0.14 kg ai/ha at a maximal seasonal rate of 0.42 kg ai/ha and a PHI of 180 days (California 90 days). Seven trials were conducted on asparagus in the USA in 2002 with foliar treatment by 3 × 0.14–0.15 kg ai/ha and PHIs of 92–188 days. In the sprouts, neither residues of trifloxystrobin (< 0.05 mg/kg) nor the metabolite CGA 321113 (< 0.02 mg/kg) were detected.

The Meeting estimated a maximum residue level of 0.05* mg/kg and an STMR of 0 for trifloxystrobin in asparagus.

Fate of residues during processing

The effect of processing on the level of residues of trifloxystrobin and the metabolite CGA 321113 has been studied for strawberries and olives. The processing factors (PF) were calculated from the total residue levels (sum of trifloxystrobin and CGA 321113). The best estimates of the processing factors are shown below. Processes included in the table are those that lead to STMR-P values useful for dietary intake estimations.

Raw agricultural commodity (RAC)	Processed commodity	Best estimate processing factor (PF)	RAC STMR	STMR-P
Strawberry	Strawberry jam Strawberry preserves	0.58 0.29	0.335	0.194 0.097

Raw agricultural commodity (RAC)	Processed commodity	Best estimate processing factor (PF)	RAC STMR	STMR-P
Olives	Olive oil, crude Olive oil, refined	3 4.15	0.085	0.255 0.353

The Meeting estimated the following STMR-P values: 0.194 mg/kg for strawberry jam, 0.097 mg/kg for strawberry, canned, 0.255 mg/kg for olive oil, crude and 0.353 for olive oil, refined.

A maximum residue level for the processed commodity will only be recommended if the resulting residue value is higher than the maximum residue level proposed for the corresponding RAC. Because of the fact that the PF is >1 for olive oils and the oils are commodities in trade, maximum residue levels were proposed for olive oil, crude and olive oil, refined.

The Meeting estimated a maximum residue level for olive oil, crude of 0.9 mg/kg and for olive oil, refined of 1.2 mg/kg.

Residues in animal commodities

As the commodities evaluated by the 2012 JMPR are not included in the OECD farm animal feeding table, there is no need to re-calculate the farm animal dietary burden.

The Meeting concluded that a re-evaluation of the maximum residue levels for animal commodities was not necessary.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Daily Intakes (IEDIs) of trifloxystrobin were calculated for the 13 GEMS/Food cluster diets using STMRs and STMR-Ps estimated by the JMPR in 2004 and 2012. The results are shown in Annex 3.

The ADI is 0–0.04 mg/kg bw and the calculated IEDIs were 1–5 % of the maximum ADI. The Meeting concluded that the long-term intake of residues of trifloxystrobin from the uses considered by the JMPR is unlikely to present a public health concern.

Short-term intake

The 2004 JMPR decided that it was unnecessary to establish an ARfD. The present Meeting therefore concluded that the short-term intake of trifloxystrobin residues is unlikely to present a public health concern.

6. FUTURE WORK

The items listed below are tentatively scheduled to be considered by the Meeting in 2014 and 2015. The compounds listed include those recommended as priorities by the CCPR at its Forty-fourth and earlier sessions and compounds scheduled for re-evaluation within the CCPR periodic review programme.

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

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

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

2014 JMPR

TOXICOLOGICAL EVALUATIONS	RESIDUE EVALUATIONS
NEW COMPOUNDS	**NEW COMPOUNDS**
Aminocyclopyrachlor [DuPont] USA	Aminocyclopyrachlor Meat, milk and edible offal
Dichlobenil [Chemtura] USA	Dichlobenil Cranberry, blackberry, blueberry, raspberry, grapes, cherry, pome fruit, hazelnut, and rhubarb
Fenamidone [Bayer CropScience] Germany priority 1	Fenamidone Broccoli, Brussels sprouts, Carrots, Chinese cabbage, Cauliflower, Courgettes (Summer squash), Cucumber, Eggplant, Gherkin, Grapes (Table and wine), Head cabbage, Kale, Leek, Lettuce (Head and leafy), Melon, Onion, Pepper (Bell and sweet), Potato, Pumpkin (Winter squash), Spinach, Strawberries, Sunflower seeds, Tomato, Watermelon
Fluazifop-p-butyl [Syngenta] - Switzerland	Fluazifop-p-butyl Oil seed rape, Soya bean, dry beans, cotton, Potato, Sweet potato, Sugar beets, Citrus fruits, Pome fruit, Stone fruit, Grapes, Tree nuts, Onion, Cabbage, Carrots, Vegetables, Bananas, Coffee bean, (Palm oil)
Fluensulfone Exponent	Fluensulfone
Flufenoxuron [BASF] Brazil priority 1	Flufenoxuron Soya bean, pome fruit (apple, pear), orange, melon, tomato, grape
Imazamox [BASF] Argentina	Imazamox Legume group: peas and beans (fresh), beans and beans (pulses), lentils, soybean, peanuts, cereal group (rice, wheat, maize), Oilseed group (sunflower, oilseed rape), Alfalfa
Mesotrione [Syngenta] USA	Mesotrione Asparagus, berries, Corn (grain, pop, sweet), Cranberry, Millet, Lingonberry, Oat (grain), Rhubarb, Sorghum (grain), Soybean, Sugarcane, Okra
Metrafenone [BASF] USA	Metrafenone
Norfluazuron [Syngenta] USA	Norfluazuron almond, apple, apricot, asparagus, avocado, blackberry,

	blueberry, cranberry, cherry (sweet and tart), citrus fruits group, cottonseed, grape, hazelnut, hops, nectarine, peach, peanut, pear, pecan, plums and prunes, raspberry, soybean, and walnut.
pymetrozine [Syngenta] USA	Pymetrozine Hops; vegetables (tuberous and corm); asparagus; vegetable (leafy, except *Brassica*); *Brassica* (head and Stem); *Brassica* (leafy greens); fruiting vegetables; cucurbit vegetables; cottonseed; pecans
PERIODIC RE-EVALUATIONS	**PERIODIC RE-EVALUATIONS**
metalaxyl (138) [Quimicas del Vallés SCC GMBH]	metalaxyl (138) Review in 2004 for residues was for evaluation of metalaxyl-M, Support from Quimicas del Vallés - SCC GmbH , USA - Supervised trials by Thailand
triforine (116) [Sumitomo Corp]	triforine (116) Apple, Blueberries, Brussels sprouts, Cereal grains, Cherries, Common bean, Currants(Black,Rd, White), Fruiting vegetables, Cucurbits, Gooseberry, Peach, Plums(including prunes), Strawberry, Tomato
myclobutanil (181) [Dow AgroSciences]	myclobutanil (181) pome fruits, stone fruits, black currant, grapes, strawberry, banana, hops, tomato Pesticide Initiative Project – beans with pods
penconazole (182) [Syngenta]	penconazole (182) Brassica Vegetables (Broccoli, Brussels sprouts, Cauliflower, Chinese cabbage), Pome Fruit, Fruiting Vegetables (Tomato, Pepper, Aubergine), Root and Tuber Vegetables (Carrot, Parsnip, Turnip), Cucurbit vegetables (Cucumber, Melon, Watermelon, Pumpkin, Zuchini), Berries (Blackberry, Blueberry, Blackcurrant, Gooseberry, Raspberry, Cranberry), Stone Fruit (Apricot, Cherry, Peach, Plum), Legume Vegetables (peas, beans), Nuts (Almond, Pecan, Cashew, Jujube, Pistachio, Hazelnut, Pine nut, Macadamia, Chestnut), Soya, Strawberry, Loganberry, Sugarbeet, Tobacco, Potato, Clementine, grapefruit, Nectarine, Cumquat, Mango, Gherkin, Loquat, Asparagus, Leek, Banana, Lambs Lettuce, Rocket, Chicory, Canola, Parsley, Mint, Papaya, Alfalfa, Barley, Rice, Wheat, Sweet Corn, Hops, Lentil, Persimmon, Avocado, Artichoke, Grapes, Onion, Fennel
EVALUATIONS	**EVALUATIONS**
	2,4-D (020) [Dow AgroSciences] - New GAP for soya bean
	Bifenthrin (178) [FMC] - Barley, barley (straw fodder), strawberry (alternative GAP)

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

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

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 2012 MEETING

Pesticide (Codex reference number)	CCN	Commodity	**Recommended MRL mg/kg** New	Previous	**STMR or STMR-P mg/kg**	**HR or HR-P mg/kg**
Acetamiprid (246)	VL 0053	Leafy vegetables (except spinach)	3 [a]	3	0.64	1.9
ADI: 0–0.07 mg/kg bw ARfD: 0.1 mg/kg bw						
Definition of the residue (for compliance with the MRL for plant commodities and for estimation of dietary intake for plant and animal commodities): *acetamiprid*. Definition of the residue (for compliance with the MRL for animal commodities and for estimation of dietary intake for plant and animal commodities): *sum of acetamiprid and its desmethyl (IM-2-1) metabolite, expressed as acetamiprid*. *The residue is not fat-soluble.* [a] On the basis of information provided to the JMPR it was not possible to conclude from the estimate of short-term intake for acetamiprid that for children the consumption of lettuce, leaf; Chinese cabbage, type pak-choi; Chinese cabbage, type pe-tsai; spinach and endive was less than the ARfD.						
Ametoctradin (253)	VB 0040	Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead brassicas	9		nn	7.5 (ldb)
ADI: Unnecessary	VS 0624	Celery	20		nn	nn
ARfD: Unnecessary	VC 0424	Cucumber	0.4		nn	nn
	DF 0269	Dried grapes (=currants, raisins and sultanas)	20		4.1	
	PE 0112	Eggs	0.03*		nn	nn
	VC 0045	Fruiting vegetables, Cucurbits, except cucumber	3		nn	nn
	VO 0050	Fruiting vegetables, other than cucurbits, except sweet corn and except mushroom	1.5		0.16 (ldb)	nn
	VA 0381	Garlic	1.5		nn	nn
	FB 0269	Grapes	6		0.605 (ldb)	nn
	DH 1100	Hops, dry	30		nn	nn
	VL 0053	Leafy vegetables	50		nn	35 (ldb)
	VA 0385	Onion, Bulb	1.5		nn	nn
	HS 0444	Peppers Chili, dried	15		nn	nn
	VR 0589	Potato	0.05		nn	0.01 (ldb)
	PF 0111	Poultry fats	0.03*		nn	nn
	PM 0110	Poultry meat	0.03*		nn	nn
	PO 0111	Poultry, Edible offal of	0.03*		nn	nn
	VA 0388	Shallot	1.5		nn	nn
	VA 0389	Spring Onion	20		nn	nn
Definition of the residue for compliance with the MRL for plant commodities: *ametoctradin.* Definition of the residue for compliance with the MRL for animal commodities: *sum of ametoctradin, M650F01 and M650F06, expressed as Ametoctradin.* *The residue is not fat-soluble* nn: not needed ldb: STMR needed for livestock dietary burden calculation						

Pesticide (Codex reference number)	CCN	Commodity	**Recommended MRL mg/kg** New	Previous	**STMR or STMR-P mg/kg**	**HR or HR-P mg/kg**
Azoxystrobin (229)	FT 0289	Carambola	0.1		0.023	
ADI: 0–0.2 mg/kg bw	DV 0604	Ginseng, dried including red ginseng	0.3		0.069	
ARfD: Unnecessary	DM 0604	Ginseng, extracts	0.5		0.12	
		Ginseng processed products(dried, red, ethanol and water extracts)	W	0.5		
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.						
Bentazone (172)						
ADI: 0–0.09 mg/kg bw						
ARfD: Unnecessary						
Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant commodities: *Sum of bentazone, 6-hydroxybentazone and 8-hydroxybentazone expressed as bentazone.*						
Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for animal commodities: *Bentazone.*						
Buprofezin (173)	FI 0327	Banana	0.3		0.01	0.01
ADI: 0–0.009 mg/kg bw	DT	Tea, Green	30		9.0	
ARfD: 0.5 mg/kg bw						
For compliance with the MRL and for estimation of dietary intake for plant and animal commodities: *buprofezin*.						
The residue not fat soluble.						
Carbofuran (096)	FI 0327	Banana	0.01*	0.02*	0.01	0.01
ADI: 0–0.001 mg/kg bw						
ARfD: 0.001 mg/kg bw						
Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities: carbofuran and 3-hydroxy carbofuran expressed as carbofuran.						
The residue is not fat-soluble.						
Chlorfenapyr (254)						
ADI: 0–0.03 mg/kg bw						
ARfD: 0.03 mg/kg bw						
Definition of the residue (for compliance with the MRL) for plant and animal commodities: chlorfenapyr						
Definition of the residue (for estimation of dietary intake) for plant and animal commodities: *a conclusion could not be reached.*						
The residue is fat soluble.						
Chlorothalonil (081)	FI 0327	Bananas	15	0.01* [a]	Chlorothalonil: 0.033 [b]	Chlorothalonil: 0.71 [b]
ADI: 0–0.02 mg/kg bw	VL 0464	Chard	50		Chlorothalonil: 16	Chlorothalonil: 19
ARfD: 0.6 mg/kg bw						

Pesticide (Codex reference number)	CCN	Commodity	**Recommended MRL mg/kg**		**STMR or STMR-P mg/kg**	**HR or HR-P mg/kg**
			New	**Previous**		
*Definition of the residue f*or compliance with MRL for plant commodities: chlorothalonil. Definition of the residue for estimation of dietary intake for plant commodities: *chlorothalonil - SDS-3701 (2,5,6-trichloro-4-hydroxyisophthalonitrile) all considered separately.* Definition of the residue for compliance with MRL and for estimation of dietary intake for animal commodities: *SDS-3701 (2,5,6-trichloro-4-hydroxyisophthalonitrile).* *The residue is not fat-soluble.* [a] Based on bagged bananas [b] For banana pulp						
Chlorpyrifos-methyl (090) ADI: 0–0.01 mg/kg bw ARfD: 0.1 mg/kg bw For compliance with the MRL and for estimation of dietary intake) for plant and animal commodities: *chlorpyrifos-methyl.* *The residue is fat-soluble.*	GC 0645	Maize	W	3 Po		
Cycloxydim (179) ADI:0–0.07 mg/kg bw ARfD: 2 mg/kg bw for Women of childbearing Age. Not necessary for the general population.	VD 0071	Beans, dry	30	2	4.4	
	VP 0061	Beans except broad bean & soya bean (green pods & immature seeds)	15		0.35	11
	VR 0574	Beetroot	0.2		0.09	0.10
	VB 0040	Brassica (Cole or Cabbage) Vegetables, Head Cabbage, Flowerhead Brassicas	9	2	1.95	6
	VR 0577	Carrot	5	0.5	0.44	3
	VR 0578	Celeriac	1		0.13	0.64
	MO 0105	Edible offal (Mammalian)	0.5		0.098	0.403
	PE 0112	Eggs	0.15		0.018	0.092
	FB 0269	Grapes	0.3	0.5	0.11	0.18
	VL 4355	Kale, curly	3		0.65	1.1
	VA 0384	Leek	4		0.36	2.3
	VL 0482	Lettuce, Head	1.5	0.2	0.335	1
	VL 0483	Lettuce, Leaf	1.5	0.2	0.335	1
	SO 0693	Linseed	7		1.9	
	MF 0100	Mammalian fats (except milk fats)	0.1		0.021	0.066
	GC 0645	Maize	0.2		0.09	
	AS 0645	Maize fodder (dry)	3		0.247	1.1
	MM 0095	Meat (from mammals other than marine mammals)	0.06		0.021	0.047
	ML 0106	Milks	0.02		0.005	
	VA 0385	Onion, Bulb	3		0.31	1.43
	VP 0063	Peas (pods and succulent=immature seeds)	W	1		
	VP 0072	Peas (dry)	30		5.6	
	VP 0064	Peas, Shelled (succulent seeds)	15	2	2.7	
	VO 0051	Peppers	9		1.55	5.3
	HS 0444	Peppers Chilli, dried	90		15.5	53
	FP 0009	Pome fruits	0.09*		0.09	0.09
	VR 0589	Potato	3	2	0.735	1.6
	PM 0110	Poultry meat	0.03*		0	0.03
	PF 0111	Poultry fats	0.03*		0	0.03
	PO 0111	Poultry, Edible offal of	0.02		0.005	0.014
	SO 0495	Rape seed	7	2	1.9	
	GC 0649	Rice	0.09*		0.09	
	AS 0649	Rice straw or fodder Dry	0.09		0.09	0.09

Pesticide (Codex reference number)	CCN	Commodity	**Recommended MRL mg/kg**		**STMR or STMR-P mg/kg**	**HR or HR-P mg/kg**
			New	**Previous**		
	VD 4521	Soya bean (dry)	80	2	13	
	FS 0012	Stone fruits	0.09*		0.09	0.09
	FB 0275	Strawberry	3	0.5	0.53	1.4
	VR 0596	Sugar beet	0.2	0.2	0.09	0.10
	SO 0702	Sunflower seed	6		0.375	
	VR 0497	Swede	0.2		0.09	0.10
	VO 0448	Tomato	1.5		0.445	0.89
Definition of the residue for compliance with maximum residue levels and estimation of dietary intake in plant and animal commodities: *Cycloxydim, metabolites and degradation products which can be oxidized to 3-(3-thianyl) glutaric acid S-dioxide and 3-hydroxy-3-(3-thianyl) glutaric acid S-dioxide, expressed as cycloxydim.* *The residue is not fat soluble.*						
Cyfluthrin/beta-cyfluthrin (157)	VB 0041	Cabbages, Head	0.08	4	0.01	0.05
ADI: 0–0.04 mg/kg bw	MO 0105	Edible offal (mammalian)	0.02		0.005	0.01
ARfD: 0.04 mg/kg bw	MO 0098	Kidney of cattle, goats, pigs and sheep	W	0.05		
	MO 0099	Liver of cattle, goats, pigs and sheep	W	0.05		
	MM 0095	Meat (from mammals other than marine mammals)	0.2 fat	1.0	0.07 (fat) 0.01 (muscle)	0.16 (fat) 0.01 (muscle)
	ML 0106	Milks	0.01	0.04	0.004	
	VD 0541	Soya bean (dry)	0.03		0.01	
	AL 0541	Soya bean fodder	4		1.15 (fw)	2.2 (fw)
Definition of the residue for compliance with the MRL and for estimation of dietary intake for plant and animal commodities: *cyfluthrin (sum of isomers).* *The residue is fat-soluble.*						
Cyromazine (169)	VD 0524	Chick-pea (dry)	3		1.0	
ADI: 0–0.06 mg/kg bw	VD 0533	Lentil (dry)	3		1.0	
ARfD: 0.1 mg/kg bw	VD 0545	Lupin (dry)	3		1.0	
Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities: c*yromazine*						
Dichlorvos (025)	GC 0080	Cereal grains	W	5		
ADI: 0–0.004 mg/kg bw	MO 0105	Edible offal (mammalian)	0.01 *		0	
ARfD: 0.1 mg/kg bw	PE 0112	Eggs	0.01 *		0	
	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	
	PF 0111	Poultry fat	0.01 *		0	
	PM 0110	Poultry meat	0.01 *		0	
	PO 0111	Poultry, Edible offal of	0.01 *		0	
	GC 0649	Rice	7		2.8	5.2
	CM 1206	Rice bran, Unprocessed	15 PoP		2.94	5.46
	CM 0649	Rice, Husked	1.5 PoP		0.45	0.83
	CM 1205	Rice, Polished	0.15 PoP		0.014	0.03
	GC 0654	Wheat	7 Po		2.2	4.1
	CM 0654	Wheat bran, Unprocessed	15 PoP	10	4.33	
	CF 1211	Wheat flour	0.7PoP	1	0.22	

Pesticide (Codex reference number)	CCN	Commodity	**Recommended MRL mg/kg**		**STMR or STMR-P mg/kg**	**HR or HR-P mg/kg**
			New	**Previous**		
	CF 1210	Wheat germ	W	10		
	CF 1212	Wheat wholemeal	3 PoP	2	0.88	
Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities: *dichlorvos.* *The residue is not fat soluble.*						
Dicofol (026)	VD 0071	Beans (dry)	W	0.1		
ADI: 0–0.002 mg/kg bw	MM 0812	Cattle meat	W	3(fat)		
ARfD: 0. 2 mg/kg bw	MO 0812	Cattle, Edible offal of	W	1		
	FS 0013	Cherries	W	5		
	FC 0001	Citrus fruits	W	5		
	VP 0526	Common bean (pods and/or immature seeds)	W	2		
	SO 0691	Cotton seed	W	0.1		
	OC 0691	Cotton seed oil, Crude	W	0.5		
	OR 0691	Cotton seed oil, Edible	W	0.5		
	VC 0424	Cucumber	W	0.5		
	PE 0112	Eggs	W	0.05		
	FB 0269	Grapes	W	5		
	DH 1100	Hops, Dry	W	50		
	VC 0046	Melons, except watermelon	W	0.2		
	ML 0106	Milks	W	0.1		
	FS 0247	Peach	W	5		
	TN 0672	Pecan	W	0.01*		
	VO 0051	Peppers	W	1		
	HS 0444	Peppers Chili, dried	W	10		
	FS 0014	Plums (including prunes)	W	1		
	PM 0110	Poultry meat	W	0.1(fat)		
	PO 0111	Poultry, Edible offal of	W	0.05*		
	DF 0014	Prunes	W	3		
	VC 0431	Squash, summer	W	1		
	DT 1114	Tea, Green, Black (black, fermented and dried)	40[a]	50	11.2	15.6
	TN 0678	Walnuts	W	0.01*		
Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant commodities: *Dicofol (sum of o,p' and p,p' isomers)* *Residue is fat-soluble.* [a] DDT may be present in tea as a result of its presence as a contaminant in the technical grade dicofol.						
Dinotefuran (255)	VB 0040	Brassica (Cole or Cabbage) Vegetables, Head Cabbage, Flowerhead Brassicas	2		0.40	1.1
ADI: 0–0.2 mg/kg bw	VS 0624	Celery	0.6		0.435	0.67
ARfD: 1 mg/kg bw	SO 0691	Cotton seed	0.2		0.15	
	FB 0265	Cranberry	0.15		0.065	0.1
	DF 0269	Dried grapes (= currants, Raisins and Sultanas)	3		0.81	2.479
	MO 0105	Edible offal (Mammalian),	0.1		0.03	0.076
	PE 0112	Eggs	0.02*		0	0
	VC 0045	Fruiting vegetables, Cucurbits	0.5		0.25	0.33
	VO 0050	Fruiting vegetables other than Cucurbits (except sweet corn and mushrooms)	0.5		0.15	0.55
	FB 0269	Grapes	0.9		0.22	0.67

Pesticide (Codex reference number)	CCN	Commodity	**Recommended MRL mg/kg**		**STMR or STMR-P mg/kg**	**HR or HR-P mg/kg**
			New	**Previous**		
	VL 0053	Leafy vegetables	6		1.2	4.4
	MM 0095	Meat (from mammals other than marine mammals	0.1		0.03	0.062
	ML 0106	Milks	0.1		0.039	
	FS 0245	Nectarine	0.8		0.28	0.57
	VA 0385	Onion, Bulb	0.1		0.04	0.09
	FS 0247	Peach	0.8		0.28	0.57
	HS 0444	Peppers, Chili, dried	5		1.75	5.0
	PO 0111	Poultry, Edible offal of	0.02*		0	0
	PM 0110	Poultry meat	0.02*		0	0
	GC 0649	Rice	8		3.3	
	GC 1205	Rice, Polished	0.3		0.132	
	AS 0649	Rice straw and fodder, Dry	6		1.6	4.3
	VA 0389	Spring Onion	4		0.91	2.3
	VL 0473	Watercress	7		2.9	3.8
	OR 0691	Cotton seed oil			0.0105	
	JF 0269	Grape juice			0.264	
	CM 1206	Rice bran, Unprocessed			0.264	
	CM 1207	Rice hulls			2.112	
	VW 0448	Tomato paste			0.46	
		Tomato puree			0.16	
Definition of the residue (for compliance with the MRL) for plant commodities: dinotefuran Definition of the residue (for estimation of dietary intake) for plant commodities: *Sum of dinotefuran, 1-methyl-3-(tetrahydro-3furylmethyl) urea (UF) and 1-methyl-3-(tetrahydro-3furylmethyl)guanidium dihydrogen (DN) expressed as dinotefuran*. Definition of the residue (for compliance with the MRL and estimation of dietary intake) for animal commodities: *Sum of dinotefuran, 1-methyl-3-(tetrahydro-3furylmethyl) urea (UF) expressed as dinotefuran.* *The residue is not fat soluble.*						
Fenbuconazole (197) ADI: 0–0.03 mg/kg bw ARfD: 0.2 mg/kg bw Definition of the residue for compliance with the MRL and for estimation of dietary intake for plant and animal commodities: *fenbuconazole*. *The residue is fat-soluble.*						
Fenpropathrin (185) ADI: 0–0.03 mg/kg bw ARfD: 0.03 mg/kg bw For compliance with the MRLs and for estimation of the dietary intake: *fenpropathrin.* *The residue is fat-soluble.*						
Fenvalerate (119) ADI: 0–0.02 mg/kg bw ARfD: 0.2 mg/kg bw	AL 1020	Alfalfa fodder	W	20		
	VP 0062	Beans, Shelled	W	0.1		
	VP 0061	Beans, except broad beans and soya beans	W	1		
	FB 0018	Berries and other small fruits	W	1		
	VB 0400	Broccoli	W	2		
	VB 0401	Broccoli, Chinese	3		0.81	1.8
	VB 0402	Brussels sprouts	W	2		
	VB 0041	Cabbages, Head	W	3		
	VB 0404	Cauliflower	W	2		
	VX 0624	Celery	W	2		
	GC 0080	Cereal grains	W	2 (Po)		

Pesticide (Codex reference number)	CCN	Commodity	**Recommended MRL mg/kg** New	Previous	**STMR or STMR-P mg/kg**	**HR or HR-P mg/kg**
	FS 0013	Cherries	W	2		
	VL 0466	Chinese cabbage (type pack-choi)	W	1		
	FC 0001	Citrus fruits	W	2		
	SO 0691	Cotton seed	W	0.2		
	OC 0691	Cotton seed oil, Crude	W	0.1		
	OR 0691	Cotton seed oil, Edible	W	0.1		
	VC 0424	Cucumber	W	0.02		
	MO 0105	Edible offal (mammalian)	W	0.02		
	VL 0480	Kale (including among others: Collards, Curly kale, Scotch kale, thousand-headed kale; not including Marrow-stem kale)	W	10		
	FI 0341	Kiwifruit	W	5		
	VL 0482	Lettuce, Head	W	2		
	FI 0345	Mango	1.5	-	0.39	0.48
	MM 0095	Meat (from mammals other than marine mammals)	W	1 (fat)		
	VC 0046	Melons, except watermelons	W	0.2		
	ML 0106	Milks	W	0.1F		
	FS 0247	Peach	W	5		
	SO 0703	Peanut, whole	W	0.1		
	VP 0064	Peas, Shelled (succulent seeds)	W	0.1		
	VO 0445	Peppers, Sweet (including pimento or pimiento)	W	0.5		
	FP 0009	Pome fruits	W	2		
	VR 0075	Root and tuber vegetables	W	0.05		
	VD 0541	Soya bean (dry)	W	0.1		
	VC 0431	Squash, summer	W	0.5		
	SO 0702	Sunflower seed	W	0.1		
	VO 0447	Sweet corn (corn-on-the-cob)	W	0.1		
	VO 0448	Tomato	W	1		
	TN 0085	Tree nuts	W	0.2		
	VC 0432	Watermelon	W	0.5		
	CM 0654	Wheat bran, Unprocessed	W	5 (Po)		
	CF 1211	Wheat flour	W	0.2 (Po)		
	CF 1212	Wheat wholemeal	W	2 (Po)		
	VC 0433	Winter squash	W	2		
Definition of the residue (for compliance with MRL and for estimation of dietary intake) for plant and animal commodities*: sum of fenvalerate isomers.* *The residue is fat-soluble.*						
Fludioxonil (211) ADI: 0–0.4 mg/kg bw ARfD: Unnecessary	FI 0345	Mango	2		0.02	
Definition of residue for compliance with the MRLs and estimation of dietary intake in plant commodities: *fludioxonil* Definition of residue for compliance with the MRLs and estimation of dietary intake: *sum of fludioxonil and its benzopyrrole metabolites, determined as 2,2-difluorobeno[1,1]dioxole-4-carboxylic acid and expressed as fludioxonil.* *The residue is fat-soluble.*						
Fluopyram (243) ADI: 0–0.01 mg/kg bw ARfD: 0.5 mg/kg bw	FI 0327	Banana	0.8		0.175	0.51
	VD 0071	Beans (dry)	0.07		0.01	
	VR 0577	Carrot	0.4		0.09	0.19

Pesticide (Codex reference number)	CCN	Commodity	**Recommended MRL mg/kg**		**STMR or STMR-P mg/kg**	**HR or HR-P mg/kg**
			New	**Previous**		
	FS 0013	Cherries	0.7		0.205	0.47
	VD 0524	Chick-pea (dry)	0.07		0.01	
	MO 0105	Edible offal (mammalian)	W	0.7		
	PE 0112	Eggs	0.3		0.008	
	MO 0098	Kidney of cattle, goats, pigs and sheep	0.5		0.06	0.32
	VD 0533	Lentil (dry)	0.07		0.01	
	MO 0099	Liver of cattle, goats, pigs and sheep	3		0.53	2.3
	VD 0545	Lupin (dry)	0.07		0.01	
	MM 0095	Meat (from mammals other than marine mammals)	0.5	0.1	0.05 (muscle) 0.06 (fat)	0.36 (muscle) 0.4 (fat)
	ML 0106	Milks	0.3	0.07	0.05	
	FS 0247	Peach	0.4		0.13	0.17
	SO 0697	Peanut	0.03		0.01	
	VO 0051	Peppers	0.5		0.085	0.24
	HS 0444	Peppers Chili, dried	5		0.85	2.4
	FP 0009	Pome fruits	0.5		0.135	0.28
	VR 0589	Potato	0.03		0.01	0.02
	PM 0110	Poultry meat	0.2		0.01 (muscle) 0.01 (fat)	0.13 (muscle) 0.2 (fat)
	PO 0105	Poultry, Edible offal of	0.7		0.02	0.58
	FB 0275	Strawberry	0.4		0.025	0.23
	VR 0596	Sugar beet	0.04		0.01	0.02
	VO 0448	Tomato	0.4		0.09	0.23
	TN 0085	Tree nuts	0.04		0.01	0.03
	DF 0226	Apples, dried			0.09	
	JF 0226	Apple juice			0.01	
		Apple sauce			0.05	
		Peanut butter			0.002	
	OR 0697	Peanut oil, Edible			0.0001	
		Potato (peeled)			0.006	0.013
		Potato chips (crisps)			0.006	
		Potato flakes			0.01	
		Strawberry jam			0.02	
		Strawberry preserve			0.008	
		Sugar beet (sugar)			0.01	
	JF 0448	Tomato juice			0.03	
	VW 0448	Tomato paste			0.04	
		Tomato preserve			0.02	
		Tomato puree			0.07	
Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant commodities: *fluopyram.* Definition of the residue (for compliance with the MRL) for animal commodities: *Sum of fluopyram and 2-(trifluoromethyl) benzamide, expressed as fluopyram.* Definition of the residue (for estimation of dietary intake) for animal commodities: *Sum of fluopyram, 2-(trifluoromethyl)benzamide and the combined residues N-{(E)-2-[3-chloro-5-(trifluoromethyl)pyridin-2-yl]ethenyl}-2-trifluoromethyl) benzamide and N-{(Z)-2-[3-chloro-5-(trifluoromethyl)pyridin-2-yl]ethenyl}-2-trifluoromethyl) benzamide, all expressed as fluopyram.* *The residue is not fat soluble.*						
Fluxapyroxad (256)						
ADI: 0-0.02 mg/kg bw	GC 0640	Barley	2		0.535	
ARfD: 0.3 mg/kg bw		Barley bran	4		1.0	
	AS 0640	Barley straw and fodder, Dry	30		4.1 dw	18
	VD 0071	Beans (dry)	0.3		0.04	

Pesticide (Codex reference number)	CCN	Commodity	**Recommended MRL mg/kg** New	Previous	**STMR or STMR-P mg/kg**	**HR or HR-P mg/kg**
	VP 0061	Beans, except broad bean and soya bean	2		0.65	0.74
	VP 0062	Beans, shelled	0.09		0.03	0.04
	VD 0524	Chick-pea (dry)	0.4		0.04	
	SO 0691	Cotton seed	0.01*		0	
	MO 0105	Edible offal (mammalian)	0.1		0.081	0.31
	PE 0112	Eggs	0.02		0.006	0.023
	VO 0050	Fruiting vegetables other than cucurbits (except sweet corn and mushrooms)	0.6		0.07	0.44
	VD 0533	Lentil (dry)	0.4		0.04	
	GC 0645	Maize	0.01*		0.01	
	AS 0645	Maize fodder (dry)	15		3.62 dw	6.57
	MM 0095	Meat (from mammals other than marine mammals) (fat)	0.2 (fat)		< 0.02 (muscle) 0.047 (fat)	0.033 (muscle) 0.18 (fat)
	ML 0106	Milks	0.02		0.004	0.020
	FM 0183	Milk fats	0.5		0.09	0.45
	GC 0647	Oats	2		0.535	
	AS 0647	Oat straw and fodder, Dry	30		4.1dw	18.3
	SO 0088	Oilseed (except peanut and cotton)	1.5		0.09	
	AL 0072	Pea hay or Pea fodder (dry) (dry weight)	40		11	17
	VP 0063	Peas (pods and succulent = immature seeds)	2		0.65	0.74
	VP 0064	Peas, Shelled (succulent seeds)	0.09		0.03	0.04
	SO 0697	Peanut	0.01		0.01	
	VD 0072	Peas (dry)	0.4		0.04	
	HS 0444	Peppers Chili, dried	6		0.70	4.4
	FP 0009	Pome fruits	0.9		0.30	0.47
	VR 0589	Potato	0.03		0.01	0.02
	PM 0110	Poultry meat	0.02		0.02 (meat)	0.024 (meat)
	PM 0111	Poultry fats	0.05		0.021 (fat)	0.050 (fat
	PO 0111	Poultry, Edible offal of	0.02		0.021	0.034
	DF 0014	Prunes	5		1.2	2.7
	GC 0650	Rye	0.3		0.085	
	AS 0650	Rye straw and fodder, Dry	30		4.1 dw	18
	VD 0541	Soya bean (dry)	0.15		0.01	
	AB 0541	Soya bean hulls	0.3		0.012	0.15
	VP 0541	Soya bean (immature seeds)	0.5		0.01	0.37
	AL 0541	Soya bean fodder (dry weight)	30		7.58	19.9
	VP 0546	Soya bean (young pod)	1.5		0.24	0.74
	FS 0012	Stone fruits	2		0.525	2.3
	VR 0596	Sugar beet	0.15		0.04	0.06
	VO 0447	Sweet corn (corn-on-the-cob)	0.15		0.01	0.08
	GC 0653	Triticale	0.3		0.085	
	AS 0653	Triticale straw and fodder, Dry	30		4.1dw	18
	GC 0654	Wheat	0.3		0.085	
	CM 0654	Wheat bran	1		0.25	0.61
	AS 0654	Wheat straw and fodder, Dry	30		4.1dw	18
	CF 1210	Wheat germ			0.10	0.26

Definition of the residue (for compliance with the MRL for plant and animal commodities and for estimation of dietary intake for plant commodities): *Fluxapyroxad.*
Definition of the residue (for estimation of dietary intake for plant commodities): *Sum of fluxapyroxad and 3-(difluoromethyl)- N-(3',4',5'-trifluoro[1,1'-biphenyl]-2-yl)-1H-pyrazole-4-carboxamide (M700F008) and 3-(difluoromethyl)-1-(ß-D-glucopyranosyl)-N-(3',4',5'-triflurobipheny-2-yl)-1H-pyrzaole-4-carboxamide (M700F048) and expressed as parent equivalents.*

Pesticide (Codex reference number)	CCN	Commodity	**Recommended MRL mg/kg**		**STMR or STMR-P mg/kg**	**HR or HR-P mg/kg**
			New	**Previous**		
Definition of the residue (for estimation of dietary intake for animal commodities): *Sum of fluxapyroxad and 3-(difluoromethyl)- N-(3',4',5'-trifluoro[1,1'-biphenyl]-2-yl)-1H-pyrazole-4-carboxamide (M700F008) expressed as parent equivalents.* *The residue is fat soluble*						
Glufosinate ammonium (175)	AM 0660	Almond hulls	W	0.5		
ADI: 0–0.01 mg/kg bw	VS 0621	Asparagus	0.4	0.05 *	0.05	0.27
ARfD: 0.01 mg/kg bw	FI 0030	Assorted tropical and sub-tropical fruits - inedible peel (except banana)	W	0.05 *		
	FI 0030	Assorted tropical and sub-tropical fruits - inedible peel (except banana and kiwifruit)	0.1		0.05	0.05
	FT0026	Assorted tropical and sub-tropical fruits - edible peel	0.1		0.05	0.05
	FI 0327	Banana	0.2	0.2	0.05	0.13
	AL 0061	Bean fodder	1		0.075 fw	0.63 fw
	FB 0018	Berries and other small fruits (except currants)	W	0.1	0.03	
	FB 0020	Blueberries	0.1		0.05	0.06
	VD 0523	Broad bean (dry)	W	2		
	VR 0577	Carrot	0.05	0.05 *	0.05	0.05
	FC 0001	Citrus fruits	0.05	0.1	0.05	0.05
	VD 0526	Common bean (dry)	0.05	2	0.04	
	SB 0716	Coffee beans	0.1		0.04	
	VP 0526	Common bean (pods and/or immature seeds)	0.05 *	0.05 *	0.05	0.05
	VL 0470	Corn salad	0.05	0.05 *	0.05	0.05
	SO 0691	Cotton seed	5		0.705	
	FB 0021	Currants, Black, Red, White	1	0.5	0.02	0.48
	MO 0105	Edible offal (mammalian)	3	0.1 *	0.228 K 0.55 L	0.708 K 1.85 L
	PE 0112	Eggs	0.05 *	0.05 *	0	0.02
	FB 0268	Gooseberry	0.1		0.02	0.02
	FB 0269	Grapes	0.15		0.02	0.12
	FI 0341	Kiwifruit	0.6		0.05	0.37
	VL 0482	Lettuce, Head	0.4		0.05	0.29
	VL 0483	Lettuce, Leaf	0.4		0.05	0.29
	GC 0645	Maize	0.1	0.1	0.05	
	AS 0645	Maize fodder (dry)	8	10	0.78 fw	5.3fw
	AF 0645	Maize forage	W	5	0.66 fw	1.6 fw
	MM 0095	Meat (from mammals other than marine mammals)	0.05	0.05 *	0.026 M 0.028 F	0.05 M 0.062 F
	ML 0106	Milks	0.02 *	0.02 *	0.01	0.020
	VA 0385	Onion, Bulb	0.05	0.05	0.05	0.05
	VD 0072	Peas (dry)	W	3		
	FP 0009	Pome fruits	0.1	0.05 *	0.05	0.08
	VR 0589	Potato	0.1	0.5	0.05	0.05
	PM 0110	Poultry meat	0.05 *	0.05 *	0	0.02
	PO 0111	Poultry, Edible offal of	0.1 *	0.1 *	0	0.04
	DF 0014	Prunes	0.3		0.09	
	SO 0495	Rape seed	1.5	5	0.225	
	OC 0495	Rape seed oil, Crude	0.05 *	0.05 *		
	FB 0272	Raspberries, Red, Black	0.1		0.03	0.03
	GC 0349	Rice	0.9		0.09	
	AS 0649	Rice straw and fodder, dry	2		0.26 fw	1.3 fw
	VD 0541	Soya bean (dry)	3	2	0.825	

Pesticide (Codex reference number)	CCN	Commodity	**Recommended MRL mg/kg**		**STMR or STMR-P mg/kg**	**HR or HR-P mg/kg**
			New	**Previous**		
	FS 0012	Stone fruits	0.15	0.05 *	0.05	0.08
	FB 0275	Strawberry	0.3		0.02	0.15
	VR 0596	Sugar beet	1.5	0.05 *	0.28	
	DM 0596	Sugar beet molasses	8		1.24	
	SO 0702	Sunflower seed	3	5	0.47	
	OC 0702	Sunflower seed oil, crude	0.05 *	0.05 *		
	TN 0085	Tree nuts	0.1	0.1	0.05	0.05
Definition of the residue for compliance with MRL and estimation of dietary intake (for animal and plant commodities*): sum of glufosinate, 3-[hydroxy(methyl)phosphinoyl]propionic acid (MPP) and N-acetyl-glufosinate (NAG), calculated as glufosinate (free acid).* *The residue is not fat soluble.* fw - fresh weight basis K - Kidney L - Liver						
Imidacloprid (206) ADI: 0–0.06 mg/kg bw ARfD: 0.4 mg/kg bw	VS 0624	Celery	6		0.365	
	VD 0072	Peas (dry)	W	2		
	VD 0070	Pulses (except soya beans)	2		0.62	
Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities*: Sum of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, expressed as imidacloprid.*						
Indoxacarb (216) ADI: 0–0.01 mg/kg bw ARfD: 0.1 mg/kg bw	VL 0483	Lettuce, Leaf	3	15	0.52	1.6
Definition of the residue for compliance with the MRL (for animal and plant 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.*						
MCPA (257) ADI: 0–0.1 mg/kg bw ARfD: 0.6 mg/kg bw	GC 0640	Barley	0.2		0.05	
	AS 0640	Barley straw and fodder, Dry	50		10.5	28.9
	PE 0112	Eggs	0.05*		0.05	0.05
	SO 0693	Flax-seed	0.01*		0	
	AS 0162	Hay or fodder (dry) of grasses	500		74.35	217
	MO 0105	Edible offal (mammalian)	3		1.33	2.20
	GC 0645	Maize	0.01*		0	
	AS 0645	Maize straw and fodder, Dry	0.3		0.25	0.25
	MF 0100	Mammalian fats	0.2		0.13	0.16
	MM 0095	Meat from mammals other than marine mammals	0.1		0.08	0.08
	ML 0106	Milks	0.04		0.013	0.035
	GC 0647	Oat	0.2		0.05	
	AF 0647	Oat straw and fodder, Dry	50		10.5	28.9
	VD 0072	Peas, dry	0.01*		0	
	PF 0111	Poultry meat	0.05*		0.05	0.05
	PF 0110	Poultry fats	0.05*		0.05	0.05
	PO 0111	Poultry, Edible offal of	0.05*		0.05	0.05
	GC 0650	Rye	0.2		0.05	
	AF 0650	Rye straw and fodder, Dry	50		10.5	28.9
	GC 0653	Triticale	0.2		0.05	
	AS 0653	Triticale straw and fodder, Dry	50		10.5	28.9

Pesticide (Codex reference number)	CCN	Commodity	**Recommended MRL mg/kg** New	Previous	**STMR or STMR-P mg/kg**	**HR or HR-P mg/kg**
	GC 0654	Wheat	0.2		0.05	
	AF 0654	Wheat straw and fodder, Dry	50		10.5	28.9
	CM 0654	Wheat bran			0.024	
	CF 1211	Wheat flour			0.024	
	CF 1210	Wheat germ			0.024	
Definition of the residue for compliance with the MRL for plant and animal commodities: *MCPA* Definition of the residue for estimation of dietary intake for plant commodities: *Sum of MCPA, its conjugates, esters and salts, all expressed as MCPA.* Definition of the residue for the estimation of dietary intake for animal commodities: *Sum of MCPA and its conjugates, expressed as MCPA.* *The residue is not fat-soluble*						
Methoxyfenozide (209) ADI: 0–0.1 mg/kg bw ARfD: 0.9 mg/kg bw	FC 0001	Citrus fruits	2	0.7	0.28	1.7
	JF 0001	Citrus juice			0.062	
	OR 0001	Citrus oil, Edible			12	
	AB 0001	Citrus pulp, Dry			0.31	
	VP 0526	Common bean (pods and/or immature seeds)		2	0.065	0.99
	MO 0105	Edible offal (mammalian)	0.2	0.1	0.025	0.096
	VC 0045	Fruiting vegetable, cucurbits, except watermelon	0.3		0.091	0.15
	MF 0100	Mammalian fats (except milk fats)	0.3	0.2	0.036	0.24
	MM 0095	Meat (from mammals other than marine mammals)	0.3 (fat)	0.2 (fat)	0.036 (fat) < 0.003 (muscle)	0.24 (fat) 0.0062 (muscle)
	VD 0072	Peas (dry)	5		0.17	
	VP 0063	Peas (pods and succulent=immature seeds)	2		0.1	0.81
	VA 0389	Spring Onion	6		0.48	2.8
Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities: *methoxyfenozide* *The residue is fat-soluble, but is not classified as fat-soluble with respect to its distribution in milk.*						
Penthiopyrad (253) ADI: 0–0.1 mg/kg bw ARfD: 1 mg/kg bw	AL 1020	Alfalfa, fodder	20 (DM)		2.9 (fw)	16 (fw)
	AM 0660	Almond hulls	6 (DM)		2.4 (fw)	3.1 (fw)
	GC 0640	Barley	0.15		0.02	
	AS 0640	Barley, straw and fodder	80 (DM)		21 (fw)	54 (fw)
	VP 0061	Beans, except broad bean and soya bean (green pods and immature seeds)	3		0.9	1.6
	VP 0062	Beans, Shelled	0.3		0.0685	0.16
	VB 0041	Cabbages, Head	4		0.4	2.4
	VR 0577	Carrots	0.6		0.09	0.41
	VX 0624	Celery	15		3.1	8.8
		Cotton gin trash	20 (DM)		4.55	
	SO 0691	Cotton seed	0.5		0.17	
	HS 0444	Peppers Chili, dried	14		See fruiting vegetables, other cucurbits, except sweet corn and mushroom	See fruiting vegetables, other cucurbits, except sweet corn and mushroom
	PE 0112	Eggs	0.03		0.02	0.023

Pesticide (Codex reference number)	CCN	Commodity	**Recommended MRL mg/kg** New	Previous	**STMR or STMR-P mg/kg**	**HR or HR-P mg/kg**
	VB 0042	Flowerhead brassicas (includes Broccoli: Broccoli, Chinese and Cauliflower)	5		1.4	2.4
	VC 0045	Fruiting vegetables, Cucurbits	0.5		Edible peel: 0.13 in-edible peel: 0.01	Edible peel: 0.3 in-edible peel: 0.01
	VO 0050	Fruiting vegetables, other than cucurbits, except sweet corn and mushroom	2		0.27	1.6
	VL 0053	Leafy vegetables, except brassica leafy vegetables	30		3.15	15
	GC 0645	Maize	0.01		0.01	
	AS 0645	Maize fodder (dry)	10 (DM)		0.52 (fw)	5.9 (fw)
	CF 1255	Maize flour	0.05		0.014	
	OC 0645	Maize oil, Crude	0.15		0.027	
	GC 0646	Millet (Including Barnyard Millet, Bulrush Millet, Common Millet, Finger Millet, Foxtail Millet, Little Millet)	0.8		0.22	
	AS 0646	Millet fodder, dry	10 (DM)		0.52 (fw)	5.9 (fw)
	VL 0485	Mustard greens	50 [a]		11	30
	GC 0647	Oats	0.15		0.02	
	AS 0647	Oats, straw and fodder, Dry	80 (DM)		21 (fw)	54 (fw)
	VA 0385	Onion, Bulb	0.7		0.074	0.72
	VA 0387	Onion, Welsh	4		0.89	2.0
	AL 0072	Pea hay or pea fodder (dry)	60 (DM)		12 (fw)	31 (fw)
	SO 0697	Peanut	0.05		0.01	
	OR 0697	Peanut oil, Edible	0.5		0.04	
	AL 0697	Peanut fodder	30 (DM)		5.9 (fw)	18 (fw)
	VP 0063	Peas (pods and succulent=immature seeds)	3		0.9	1.6
	VP 0064	Peas, Shelled (succulent seeds)	0.3		0.0685	0.16
	FP 0009	Pome fruits	0.4		0.15	0.27
	VR 0589	Potato	0.05		0.01	0.051
	PO 0111	Poultry, Edible offal of	0.03		0.02	0.023
	PF 0111	Poultry Fats	0.03		0.02	0.023
	PM 0110	Poultry meat	0.03		0.02	0.021
	VD 0070	Pulses, except soya beans	0.3		0.01	
	VR 0494	Radish	3		0.305	1.2
	SO 0495	Rape seed	0.5		0.084	
	OC 0495	Rape seed oil, Crude	1			
	OR 0495	Rape seed oil, Edible	1		0.11	
	GC 0650	Rye	0.04		0.01	
	AS 0650	Rye, straw and fodder, Dry	80 (DM)		21 (fw)	54 (fw)
	GC 0651	Sorghum	0.8		0.22	
	AS 0651	Sorghum, straw and fodder, Dry	10 (DM)		0.52 (fw)	5.9 (fw)
	VD 0054	Soya bean, dry	0.3		0.032	
	AL 0541	Soya bean fodder	200 (DM)		52.5 (fw)	125 (fw)
	VA 0389	Spring Onion	4		0.89	2.0
	FS 0012	Stone fruits	4		1.3	1.9
	FB 0275	Strawberry	3		0.8	1.8
	VR 0596	Sugar beet	0.5		0.105	
	SO 0702	Sunflower seed	1.5		0.12	
	VO 0447	Sweet corn (on the cob)	0.02		0.01	0.01
	TN 0085	Tree nuts	0.05		0.01	0.047
	GC 0653	Triticale	0.04		0.01	
	AS 0653	Triticale, straw and fodder, Dry	80 (DM)		21 (fw)	54 (fw)

Pesticide (Codex reference number)	CCN	Commodity	**Recommended MRL mg/kg** New	Previous	**STMR or STMR-P mg/kg**	**HR or HR-P mg/kg**
	VL 0506	Turnip greens	50		9.4	23
	GC 0654	Wheat	0.04		0.01	
	CF 0654	Wheat, bran	0.1		0.018	
	CF 1210	Wheat, germ	0.1		0.019	
	AS 0654	Wheat, straw and fodder, Dry	80 (DM)		21 (fw)	54 (fw)
	JF 0226	Apple juice			0.021	
	-	Barley, beer			0.002	
		Peeled potato			0.003	0.017
	DF 0014	Prunes			1.8	2.7
	OR 0541	Soya bean, refined oil			0.032	
		Sugar beet, refined sugar			0.033	
	JF 0048	Tomato, juice			0.092	
	VW 0448	Tomato, paste			0.92	
	-	Tomato, puree			0.54	
	CF 1211	Wheat, flour			0.004	
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.* [a] On the basis of information provided to the JMPR it was not possible to conclude from the estimate of short-term intake for Penthiopyrad that the consumption of mustard greens was less than the ARfD. fw - fresh weight basis						
Phorate (112) ADI: 0-0.0007 mg/kg bw ARfD: 0.003 mg/kg bw	VR 0589	Potato	0.3	0.5	0.048	0.17
		Potato crisps			0.0034	
		Potato granules			0.12	
		Peeled potatoes			0.013	0.045
		Potatoes boiled with peel			0.006	0.022
		Potatoes boiled without peel			0.005	0.019
		Potatoes baked with peel			0.013	0.048
		Potatoes baked without peel			0.013	0.046
		French fries			0.018	
		Potatoes microwaved with peel			0.017	0.061
Definition of the residue for compliance with the MRL and for dietary risk assessment for plant and animal commodities: *sum of the parent, its oxygen analogue, and their sulfoxides and sulfones, expressed as phorate.* *The residue is not fat soluble.*						
Picoxystrobin (258) ADI: 0–0.09 mg/kg bw ARfD: 0.09 mg/kg bw Definition of the residue for compliance with the maximum residue levels for animal and plant commodities: *picoxystrobin*. Definition of the residue (for estimation of dietary intake) for plant and animal commodities: *a conclusion could not be reached* *The residue is fat soluble*						
Pyraclostrobin (210) ADI: 0–0.03 mg/kg bw ARfD: 0.05 mg/kg bw	OR 0001	Citrus oil, edible	10		3.03	8.17
	OR 0004	Orange oil, edible	W	10		

Pesticide (Codex reference number)	CCN	Commodity	**Recommended MRL mg/kg** New	Previous	**STMR or STMR-P mg/kg**	**HR or HR-P mg/kg**
Definition of the residue (for compliance with MRL and for estimation of dietary intake) for plant and animal commodities: *pyraclostrobin*. *The residue is fat-soluble.*						
Saflufenacil (251)	VD 0071	Beans (dry)	W	0.3		
ADI: 0–0.05 mg/kg bw	VD 0072	Peas (dry)	W	0.05		
ARfD: Unnecessary	VD 0070	Pulses	0.3		0.01	
	VD 0541	Soya bean (dry)	W	0.07		
Definition of the residue (for compliance with MRL and for estimation of dietary intake) for plant and animal commodities: *saflufenacil.* *The residue is not fat-soluble.*						
Sedaxane (259)	GC 0640	Barley	0.01*		0	
ADI: 0–0.1 mg/kg bw	AS 0640	Barley straw and fodder, Dry	0.1		0.01	0.075
ARfD: 0.3 mg/kg bw	MO 0105	Edible offal (Mammalian)	0.01*		0	
	MF 0100	Mammalian fats (except milk fat)	0.01*		0	
	MM 0095	Meat (from mammals other than marine mammals)	0.01* (fat)		0	
	ML 0106	Milks	0.01*		0	
	FM 0183	Milk fats	0.01*		0	
	GC 0647	Oat	0.01*		0	
	AS 0647	Oat straw and fodder, Dry	0.1		0.01	0.075
	PF 0111	Poultry fats	0.01*		0	
	PM 0110	Poultry meat	0.01*		0	
	PO 0111	Poultry, Edible offal of	0.01*		0	
	PE 0112	Eggs	0.01*		0	
	SO 0495	Rape seed	0.01*		0	
	GC 0650	Rye	0.01*		0	
	AS 0650	Rye straw and fodder, Dry	0.1		0.01	0.075
	GC 0653	Triticale	0.01*		0	
	AS 0653	Triticale straw and fodder, Dry	0.1		0.01	0.075
	GC 0654	Wheat	0.01*		0	
	AS 0654	Wheat straw and fodder, Dry	0.1		0.01	0.075
Definition of the residue for compliance with the MRL for plants and animals*: sedaxane.* *The residue is fat soluble.*						
Spinetoram (233)	VP 0061	Beans, except broad bean and soya bean (green pods and immature seeds)	0.05		0.024	
ADI: 0–0.05 mg/kg bw	FB 0020	Blueberries	0.2		0.12	
ARfD: Unnecessary	VB 0040	Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead brassicas	0.3		0.05	
	VS 0624	Celery	6		0.30	
	PE 0112	Eggs	0.01 *		0.01	
	FB 0269	Grapes	0.3		0.074	
	FS 0245	Nectarine	0.3		0.055	
	VA 00385	Onion, Bulb	0.01 *		0.01	
	VA 0387	Onion, Welsh	0.8		0.33	
	FS 0247	Peach	0.3		0.055	

Pesticide (Codex reference number)	CCN	Commodity	**Recommended MRL mg/kg** New	Previous	**STMR or STMR-P mg/kg**	**HR or HR-P mg/kg**
	PF 0111	Poultry fats	0.01 *		0.01	
	PM 0110	Poultry meat	0.01 *		0.01 (fat) 0.01 (muscle)	
	PO 0111	Poultry, Edible offal of	0.01 *		0.01	
	FB 0272	Raspberries, Red, Black	0.8		0.42	
	VL 0502	Spinach	8		1.6	
	VA 0389	Spring onion	0.8		0.33	
Definition of the residue for compliance with MRLs: Spinetoram. Definition of the residue for estimation of dietary intake: *Spinetoram and N-demethyl and N-formyl metabolites of the major spinetoram component.* *The residue is fat soluble.*						
Spirotetramat (234) ADI: 0–0.05 mg/kg bw ARfD: 1.0 mg/kg bw	ML 0106	Milks	0.005	0.01	0.005	0.005
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-methoxy-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*.						
Trifloxystrobin (213) ADI: 0-0.04 mg/kg bw ARfD: Unnecessary	VS 0621	Asparagus	0.05 *		0	
	VO 0440	Eggplant	0.7		0.08	
	VL 0482	Lettuce, head	15		5.55	
	FT 0305	Olives	0.3		0.085	
	OC 0305	Olive oil, crude	0.9		0.255	
	OR 0305	Olive oil, refined	1.2		0.353	
	FI 0350	Papaya	0.6		0.2	
	VL 0494	Radish leaves	15		1.4	
	VR 0494	Radish	0.08		0.065	
	FB 0275	Strawberry	1	0.2	0.335	
		Strawberry, canned			0.097	
		Strawberry jam			0.194	
Definition of the residue for compliance with MRLs for plant commodities: *trifloxystrobin;* Definition of the residue for estimation of dietary intake of plant commodities: *sum of trifloxystrobin and [(E,E)-methoxyimino-{2-[1-(3- trifluoromethylphenyl)ethylideneaminooxymethyl]phenyl}acetic acid] (CGA 321113), expressed as trifloxystrobin.* Definition of the residue for compliance with MRLs and estimation of dietary intake in animal commodities: *sum of trifloxystrobin and [(E,E)-methoxyimino-{2-[1-(3-trifluoromethylphenyl)ethylideneamino-oxymethyl]phenyl}acetic acid] (CGA 321113), expressed as trifloxystrobin.* *The residue is fat-soluble.*						

ANNEX 2: INDEX OF REPORTS AND EVALUATIONS OF PESTICIDES BY THE JMPR

Numbers in parentheses after the names of pesticides are Codex classification numbers. The abbreviations used are:

T, evaluation of toxicology

R, evaluation of residue and analytical aspects

E, evaluation of effects on the environment

Abamectin (177)	1992 (T,R), 1994 (T,R), 1995 (T), 1997 (T,R), 2000 (R)
Acephate (095)	1976 (T, R), 1979 (R), 1981 (R), 1982 (T), 1984 (T,R), 1987 (T), 1988 (T), 1990 (T,R), 1991 (corr. to 1990 R evaluation), 1994 (R), 1996 (R), 2002 (T), 2003 (R), 2004 (corr. to 2003 report), 2005 (T), 2006 (R), 2011 (R)
Acetamiprid (246)	2011 (T, R), 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 (246)	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)

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)
Beta-cyfluthrin (228)	2007 (R)
BHC (technical-grade)	1965 (T), 1968 (T,R), 1973 (T,R) (see also Lindane)
Bifenazate (219)	2006 (T, R), 2008 (R), 2010(R)
Bifenthrin (178)	1992 (T,R), 1995 (R), 1996 (R), 1997 (R), 2009 (T), 2010 (R)
Binapacryl (003)	1969 (T,R), 1974 (R), 1982 (T), 1984 (R), 1985 (T,R)
Bioresmethrin (093)	1975 (R), 1976 (T,R), 1991 (T,R)
Biphenyl	See Diphenyl
Bitertanol (144)	1983 (T), 1984 (R), 1986 (R), 1987 (T), 1988 (R), 1989 (R), 1991 (R), 1998 (T), 1999 (R), 2002 (R)
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)
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)
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)
Carbofuran (096)	1976 (T,R), 1979 (T,R), 1980 (T), 1982 (T), 1991 (R), 1993 (R), 1996 (T), 1997 (R), 1999 (corr. to 1997 report), 2002 (T, R), 2003 (R) (See also carbosulfan), 2004 (R), 2008 (T), 2009 (R), 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), 2010 (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)
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)
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)
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)
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), 2012 (R)
Cyhalothrin (146)	1984 (T,R), 1986 (R), 1988 (R), 2007 (T), 2008 (R)
Cyhexatin (067)	1970 (T,R), 1973 (T,R), 1974 (R), 1975 (R), 1977 (T), 1978 (T,R), 1980 (T), 1981 (T), 1982 (R), 1983 (R), 1985 (R), 1988 (T), 1989 (T), 1991 (T,R), 1992 (R), 1994 (T), 2005 (T,R)
Cypermethrin (118)	1979 (T,R), 1981 (T,R), 1982 (R), 1983 (R), 1984 (R), 1985 (R), 1986 (R), 1987 (corr. to 1986 evaluation), 1988 (R), 1990 (R), 2006 (T), 2008 (R), 2009 (R), 2011 (R)
Cyproconazole (239)	2010 (T, R)
Cyprodinil (207)	2003 (T,R), 2004 (corr. to 2003 report)
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)
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)
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)
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)
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)
Endosulfan (032)	1965 (T), 1967 (T,R), 1968 (T,R), 1971 (R), 1974 (R), 1975 (R), 1982 (T), 1985 (T,R), 1989 (T,R), 1993 (R), 1998 (T), 2006 (R), 2010 (R)
Endrin (033)	1965 (T), 1970 (T,R), 1974 (R), 1975 (R), 1990 (R), 1992 (R)
Esfenvalerate (204)	2002 (T, R)
Ethephon (106)	1977 (T,R), 1978 (T,R), 1983 (R), 1985 (R), 1993 (T), 1994 (R), 1995 (T), 1997 (T), 2002 (T)
Ethiofencarb (107)	1977 (T,R), 1978 (R), 1981 (R), 1982 (T,R), 1983 (R)
Ethion (034)	1968 (T,R), 1969 (R), 1970 (R), 1972 (T,R), 1975 (R), 1982 (T), 1983 (R), 1985 (T), 1986 (T), 1989 (T), 1990 (T), 1994 (R)
Ethoprophos (149)	1983 (T), 1984 (R), 1987 (T), 1999 (T), 2004 (R)

Ethoxyquin (035)	1969 (T,R), 1998 (T), 1999 (R). 2005 (T), 2008 (R)
Ethylene dibromide	See 1,2-Dibromoethane
Ethylene dichloride	See 1,2-Dichloroethane
Ethylene oxide	1965 (T,R), 1968 (T,R), 1971 (R)
Ethylenethiourea (ETU) (108)	1974 (R), 1977 (T,R), 1986 (T,R), 1987 (R), 1988 (T,R), 1990 (R), 1993 (T,R)
Etofenprox (184)	1993 (T, R), 2011 (T, R)
Etoxazole (241)	2010 (T, R), 2011 (R)
Etrimfos (123)	1980 (T,R), 1982 (T,R[1]), 1986 (T,R), 1987 (R), 1988 (R), 1989 (R), 1990 (R)
Famoxadone (208)	2003 (T,R)
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)
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)
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)
Flumethrin (195)	1996 (T, R)
Fluopicolide (235)	2009 (T, R)
Fluopyram (243)	2010 (T, R), 2012 (R)
Flusilazole (165)	1989 (T, R), 1990 (R), 1991 (R), 1993 (R), 1995 (T), 2007 (T, R)
Flutolanil (205)	2002 (T, 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)
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)
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)
Imidacloprid (206)	2001 (T), 2002 (R), 2006 (R), 2008 (R), 2012 (R)
Indoxacarb (216)	2005 (T,R), 2007 (R), 2009 (R), 2012 (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)
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)
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)
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)
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)
Oxydemeton-methyl (166)	1965 (T, as demeton-*S*-methyl sulfoxide), 1967 (T), 1968 (R), 1973 (T,R), 1982 (T), 1984 (T,R), 1989 (T,R), 1992 (R), 1998 (R), 1999 (corr. to 1992 report), 2002 (T), 2004 (R)
Oxythioquinox	See Chinomethionat

Paclobutrazol (161)	1988 (T,R), 1989 (R)
Paraquat (057)	1970 (T,R), 1972 (T,R), 1976 (T,R), 1978 (R), 1981 (R), 1982 (T), 1985 (T), 1986 (T), 2003 (T), 2004 (R), 2009 (R)
Parathion (058)	1965 (T), 1967 (T,R), 1969 (R), 1970 (R), 1984 (R), 1991 (R), 1995 (T,R), 1997 (R), 2000 (R)
Parathion-methyl (059)	1965 (T), 1968 (T,R), 1972 (R), 1975 (T,R), 1978 (T,R), 1979 (T), 1980 (T), 1982 (T), 1984 (T,R), 1991 (R), 1992 (R), 1994 (R), 1995 (T), 2000 (R), 2003 (R)
Penconazole (182)	1992 (T,R), 1995 (R)
Penthiopyrad (253)	2011 (T), 2012 (R)
Permethrin (120)	1979 (T,R), 1980 (R), 1981 (T,R), 1982 (R), 1983 (R), 1984 (R), 1985 (R), 1986 (T,R), 1987 (T), 1988 (R), 1989 (R), 1991 (R), 1992 (corr. to 1991 report), 1999 (T)
2-Phenylphenol (056)	1969 (T,R), 1975 (R), 1983 (T), 1985 (T,R), 1989 (T), 1990 (T,R), 1999 (T,R), 2002 (R)
Phenothrin (127)	1979 (R), 1980 (T,R), 1982 (T), 1984 (T), 1987 (R), 1988 (T,R)
Phenthoate (128)	1980 (T,R), 1981 (R), 1984 (T)
Phorate (112)	1977 (T,R), 1982 (T), 1983 (T), 1984 (R), 1985 (T), 1990 (R), 1991 (R), 1992 (R), 1993 (T), 1994 (T), 1996 (T), 2004 (T), 2005 (R), 2012 (R)
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)
Piperonyl butoxide (062)	1965 (T,R), 1966 (T,R), 1967 (R), 1969 (R), 1972(T,R), 1992 (T,R), 1995 (T), 2001 (R), 2002 (R)
Pirimicarb (101)	1976 (T,R), 1978 (T,R), 1979 (R), 1981 (T,R), 1982 (T), 1985 (R), 2004 (T), 2006 (R)
Pirimiphos-methyl (086)	1974 (T,R), 1976 (T,R), 1977 (R), 1979 (R), 1983 (R), 1985 (R), 1992 (T), 1994 (R), 2003 (R), 2004 (R, corr. to 2003 report), 2006 (T)

Prochloraz (142)	1983 (T,R), 1985 (R), 1987 (R), 1988 (R), 1989 (R), 1990 (R), 1991 (corr. to 1990 report, Annex I, and R evaluation), 1992 (R), 2001 (T), 2004 (R), 2009 (R)
Procymidone(136)	1981 (R), 1982 (T), 1989 (T,R), 1990 (R), 1991 (corr. to 1990 Annex I), 1993 (R), 1998 (R), 2007 (T)
Profenofos (171)	1990 (T,R), 1992 (R), 1994 (R), 1995 (R), 2007 (T), 2008 (R), 2011 (R)
Propamocarb (148)	1984 (T,R), 1986 (T,R), 1987 (R), 2005 (T), 2006 (R)
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)
Propineb	1977 (T,R), 1980 (T), 1983 (T), 1984 (R), 1985 (T,R), 1993 (T,R), 2004 (R)
Propoxur (075)	1973 (T,R), 1977 (R), 1981 (R), 1983 (R), 1989 (T), 1991 (R), 1996 (R)
Propylene oxide (250)	2011 (T, R)
Propylenethiourea (PTU, 150)	1993 (T,R), 1994 (R), 1999 (T)
Prothioconazole (232)	2008 (T, R), 2009 (R)
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)
Pyriproxyfen (200)	1999 (R,T), 2000 (R), 2001 (T)
Quinoxyfen (223)	2006 (T,R)
Quintozene (064)	1969 (T,R) 1973 (T,R), 1974 (R), 1975 (T,R), 1976 (Annex I, corr. to 1975 R evaluation), 1977 (T,R), 1995 (T,R), 1998 (R)
Saflufenacil (251)	2011 (T,R), 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)
Spirotetramat (234)	2008 (T,R), 2011 (R), 2012 (R)
Sulfoxaflor (252)	2011 (T,R)
Sulfuryl fluoride (218)	2005 (T,R)
2,4,5-T (121)	1970 (T,R), 1979 (T,R), 1981 (T)

Tebuconazole (189)	1994 (T,R), 1996 (corr. to Annex II of 1995 report), 1997 (R), 2008 (R), 2010 (T), 2011 (R)
Tebufenozide (196)	1996 (T,R), 1997 (R), 1999 (R), 2001 (T,R), 2003(T)
Tecnazine (115)	1974 (T,R), 1978 (T,R), 1981 (R), 1983 (T), 1987 (R), 1989 (R), 1994 (T,R)
Teflubenzuron (190)	1994 (T), 1996 (R)
Temephos	2006 (T)
Terbufos (167)	1989 (T,R), 1990 (T,R), 2003 (T), 2005 (R)
Thiabendazole (065)	1970 (T,R), 1971 (R), 1972 (R), 1975 (R), 1977 (T,R), 1979 (R), 1981 (R), 1997 (R), 2000 (R), 2006 (T, R)
Thiacloprid (223)	2006 (T, R)
Thiamethoxam (245)	2010 (T, R), 2011 (R), 2012 (R)
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)
Tolylfluanid (162)	1988 (T,R), 1990 (R), 1991 (corr. to 1990 report), 2002 (T,R), 2003 (R)
Toxaphene	See Camphechlor
Triadimefon (133)	1979 (R), 1981 (T,R), 1983 (T,R), 1984 (R), 1985 (T,R), 1986 (R), 1987 (R and corr. to 1986 R evaluation), 1988 (R), 1989 (R), 1992 (R), 1995 (R), 2004 (T), 2007 (R)
Triadimenol (168)	1989 (T, R), 1992 (R), 1995 (R), 2004 (T), 2007 (R)
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)
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)
Triforine (116)	1977 (T), 1978 (T, R), 1997 (T)
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

AMETOCTRADIN (253) Margins of exposure Highest dose tested = 0–1000.00 mg/kg bw

Codex Code	Commodity	median residues 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
FT 0026	Assorted tropical and subtropical fruits - edible peel	13	9.6	124.8	9.7	126.1	36.8	477.8	5.8	75.4	3.1	39.7	1.6	20.8
FI 0030	Assorted tropical and subtropical fruits - inedible peel	13	338.9	4405.7	37.6	488.8	22.8	295.8	8.0	104.0	50.8	659.8	44.9	583.7
FB 0018	Berries and other small fruits	13	3.8	49.4	145.8	1895.4	29.1	378.3	41.0	533.0	118.3	1537.9	53.0	689.0
VB 0040	Brassica vegetables	13	1.7	22.1	25.7	334.1	9.1	118.3	27.8	361.4	36.9	479.7	26.4	343.2
VA 0035	Bulb vegetables	13	8.5	110.5	60.3	783.9	37.7	490.1	37.2	483.6	31.8	413.4	16.7	217.1
GC 0080	Cereal grains	13	356.9	4639.7	713.9	9280.7	763.0	9919.0	504.5	6558.5	365.2	4747.6	328.7	4273.1
FC 0001	Citrus fruit (incl lemon juice, incl mandarin juice, incl orange juice, incl grapefruit juice, incl NES juice)	13	15.7	204.1	100.5	1306.5	63.2	821.6	27.8	361.4	52.6	683.8	56.9	739.7
SB 0715	Cocoa beans (incl mass)	13	0.8	10.4	3.4	44.2	0.8	10.4	0.8	10.4	5.6	72.8	5.2	67.6
DH 0170	Dried herbs (excl dry hops)	13	0.2	3.0	0.3	3.6	0.2	3.1	0.4	5.2	0.3	3.9	0.0	0.1
MO 0105	Edible offal (mammalian)	0.031	3.9	0.1	14.4	0.4	5.2	0.2	11.8	0.4	11.7	0.4	7.6	0.2
PE 0112	Eggs	0.031	2.5	0.1	29.7	0.9	25.1	0.8	24.5	0.8	37.8	1.2	27.4	0.8
VO 0050	Fruiting vegetables other than cucurbits	13	33.5	435.5	236.9	3079.7	148.9	1935.7	70.2	912.6	50.4	655.2	53.9	700.7
VC 0045	Fruiting vegetables, cucurbits	13	26.6	345.8	107.5	1397.5	95.9	1246.7	82.2	1068.6	25.4	330.2	23.2	301.6
HH 0720	Herbs	13	2.3	29.9	2.8	36.4	2.4	31.2	4.0	52.0	3.0	39.0	0.1	1.3
VL 0053	Leafy vegetables	13	5.8	75.4	45.4	590.2	10.9	141.7	26.7	347.1	17.1	222.3	38.9	505.7
VP 0060	Legume vegetables	13	6.1	79.3	23.0	299.0	18.0	234.0	12.8	166.4	26.9	349.7	5.3	68.9
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	0.031	27.7	0.9	116.5	3.6	38.5	1.2	55.1	1.7	90.2	2.8	131.3	4.1
ML 0106	Milks (excl processed products)	0.031	68.8	2.1	190.6	5.9	79.4	2.5	302.6	9.4	179.6	5.6	237.9	7.4
SO 0088	Oilseed	13	22.3	289.9	65.2	847.6	35.4	460.2	52.0	676.0	62.1	807.3	39.4	512.2
FP 0009	Pome fruit (incl apple juice)	13	0.5	6.5	84.1	1093.3	21.9	284.7	45.2	587.6	61.7	802.1	46.2	600.6
PM 0110	Poultry meat	0.031	7.1	0.2	58.5	1.8	31.9	1.0	24.0	0.7	61.0	1.9	27.3	0.8
PO 0111	Poultry, edible offal of	0.031	0.4	0.0	0.4	0.0	1.7	0.1	0.1	0.0	0.6	0.0	0.2	0.0
PF 0111	Poultry, fats	0.031	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	13	54.5	708.5	62.9	817.7	51.4	668.2	36.8	478.4	49.4	642.2	47.9	622.7

AMETOCTRADIN (253) Margins of exposure Highest dose tested = 0–1000.00 mg/kg bw

Codex Code	Commodity	median residues 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
VR 0075	Root and tuber vegetables	13	528.2	6866.6	352.8	4586.4	78.5	1020.0	270.3	3513.9	324.1	4213.3	261.3	3396.9
HS 0093	Spices	13	2.8	36.4	1.0	13.0	2.5	32.5	0.8	10.4	1.6	20.8	1.1	14.3
VS 0078	Stalk and stem vegetables	13	0.0	0.0	12.2	158.6	2.7	35.1	4.4	57.2	5.3	68.9	0.2	2.6
FS 0012	Stone fruit (incl dried plums, incl dried apricots)	13	0.7	9.1	44.7	581.1	14.1	183.3	26.9	349.7	27.7	360.1	10.0	130.0
GS 0659	Sugar cane	13	30.9	401.7	43.1	560.3	51.3	666.9	0.1	1.3	5.5	71.5	0.0	0.0
DT 0171	Teas (tea and herb teas)	13	0.3	3.9	2.4	31.2	2.8	36.4	2.1	27.3	2.0	26.0	0.8	10.4
TN 0085	Tree nuts	13	4.2	54.6	21.5	279.5	3.9	50.7	3.0	39.0	5.5	71.5	10.2	132.6
	Total intake (µg/person)=			18916.2		28647.9		19547.3		16793.6		17330.8		13948.3
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	IESTI (mg/kg bw)			0.315		0.477		0.326		0.280		0.289		0.232
	Margin of exposure			3172		2094		3069		3573		3462		4302

AMETOCTRADIN (253) International Estimated Daily Intake (IEDI) Highest dose tested = 0–1000.00 mg/kg bw

Codex Code	Commodity	median residues mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G diet	intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake	M diet	intake
FT 0026	Assorted tropical and subtropical fruits - edible peel	13	2.8	35.8	0.6	7.8	0.2	2.6	3.9	50.7	17.3	224.9	6.7	87.1	2.3	29.3
FI 0030	Assorted tropical and subtropical fruits - inedible peel	13	48.5	629.9	156.2	2030.6	128.5	1670.5	90.2	1172.6	168.1	2185.3	125.0	1625.0	63.5	824.9
FB 0018	Berries and other small fruits	13	2.8	36.4	6.6	85.8	11.8	153.4	0.3	3.9	8.6	111.8	17.1	222.3	69.4	902.2
VB 0040	Brassica vegetables	13	26.4	343.2	9.3	120.9	7.8	101.4	1.5	19.5	3.3	42.9	40.8	530.4	26.0	338.0
VA 0035	Bulb vegetables	13	31.6	410.8	29.6	384.8	9.7	126.1	19.6	254.8	25.7	334.1	47.2	613.6	33.1	430.3
GC 0080	Cereal grains	13	617.0	8021.0	487.1	6332.3	389.4	5062.2	385.7	5014.1	440.2	5722.6	567.7	7380.1	409.9	5328.7
FC 0001	Citrus fruit (incl lemon juice, incl mandarin juice, incl orange juice, incl grapefruit juice, incl NES juice)	13	17.3	224.9	156.8	2038.4	14.9	193.7	42.5	552.5	222.8	2896.4	40.4	525.2	132.3	1719.9
SB 0715	Cocoa beans (incl mass)	13	0.8	10.4	1.9	24.7	0.8	10.4	0.8	10.4	2.1	27.3	1.2	15.6	5.4	70.2
DH 0170	Dried herbs (excl dry hops)	13	0.7	9.1	0.1	0.8	0.2	3.0	0.3	4.3	0.2	2.6	0.1	1.6	0.1	0.7
MO 0105	Edible offal (mammalian)	0.031	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	0.2

Annex 3

AMETOCTRADIN (253) International Estimated Daily Intake (IEDI) Highest dose tested = 0–1000.00 mg/kg bw

Codex Code	Commodity	median residues mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G diet	intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake	M diet	intake
PE 0112	Eggs	0.031	22.1	0.7	71.5	2.2	16.6	0.5	5.1	0.2	17.6	0.5	35.2	1.1	57.4	1.8
VO 0050	Fruiting vegetables other than cucurbits	13	57.2	743.6	60.1	781.3	35.5	461.5	51.1	664.3	42.2	548.6	31.5	409.5	134.8	1752.4
VC 0045	Fruiting vegetables, cucurbits	13	69.7	906.1	25.9	336.7	14.9	193.7	18.0	234.0	18.7	243.1	39.1	508.3	44.2	574.6
HH 0720	Herbs	13	7.0	91.0	0.6	7.8	2.3	29.9	3.3	42.9	2.0	26.0	1.2	15.6	0.5	6.5
VL 0053	Leafy vegetables	13	40.8	530.4	12.0	156.0	12.5	162.5	9.5	123.5	5.4	70.2	50.0	650.0	39.1	508.3
VP 0060	Legume vegetables	13	19.6	254.8	6.2	80.6	6.9	89.7	6.0	78.0	1.7	22.1	29.5	383.5	26.3	341.9
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	0.031	54.8	1.7	89.4	2.8	30.6	0.9	28.6	0.9	82.1	2.5	61.1	1.9	158.3	4.9
ML 0106	Milks (excl processed products)	0.031	66.0	2.0	121.1	3.8	81.6	2.5	102.4	3.2	207.7	6.4	57.0	1.8	287.9	8.9
SO 0088	Oilseed	13	26.2	340.6	19.8	257.4	24.9	323.7	39.9	518.7	7.4	96.2	62.7	815.1	29.9	388.7
FP 0009	Pome fruit (incl apple juice)	13	20.9	271.7	12.3	159.9	3.4	44.2	0.1	1.3	11.7	152.1	24.9	323.7	45.4	590.2
PM 0110	Poultry meat	0.031	17.6	0.5	131.3	4.1	25.1	0.8	4.7	0.1	145.9	4.5	27.7	0.9	115.1	3.6
PO 0111	Poultry, edible offal of	0.031	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
PF 0111	Poultry, fats	0.031	0.1	0.0	8.2	0.3	0.0	0.0	0.1	0.0	0.0	0.0	0.1	0.0	4.2	0.1
VD 0070	Pulses	13	41.9	544.7	91.8	1193.4	35.9	466.7	45.2	587.6	160.0	2080.0	59.5	773.5	140.1	1821.3
VR 0075	Root and tuber vegetables	13	139.1	1808.3	109.8	1427.4	409.6	5325.3	444.6	5780.3	145.3	1888.9	127.0	1651.3	225.6	2932.8
HS 0093	Spices	13	2.9	37.7	1.8	23.4	1.3	16.9	2.6	33.8	0.5	6.5	2.0	26.0	1.3	16.9
VS 0078	Stalk and stem vegetables	13	3.8	49.4	0.7	9.1	0.2	2.6	0.0	0.0	2.0	26.0	0.5	6.5	7.3	94.9
FS 0012	Stone fruit (incl dried plums, incl dried apricots)	13	7.0	91.0	4.9	63.7	1.4	18.2	0.1	1.3	5.5	71.5	5.5	71.5	19.4	252.2
GS 0659	Sugar cane	13	26.2	340.6	1.5	19.5	33.8	439.4	5.5	71.5	18.6	241.8	3.0	39.0	20.2	262.6
DT 0171	Teas (tea and herb teas)	13	1.3	16.9	0.2	2.6	0.9	11.7	0.6	7.8	0.1	1.3	1.5	19.5	1.0	13.0
TN 0085	Tree nuts	13	16.3	211.9	15.7	204.1	9.7	126.1	1.9	24.7	19.1	248.3	29.0	377.0	5.6	72.8
	Total intake (µg/person)=			15965.3		15763.0		15040.4		15257.0		17285.0		17076.8		19293.2
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	IESTI (mg/kg bw)			0.290		0.263		0.251		0.254		0.288		0.310		0.322
	Margin of exposure			3445		3806		3989		3933		3471		3221		3110

AZOXYSTROBIN (229) International Estimated Daily Intake (IEDI) ADI = 0–0.20 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
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)	0.08	40.6	3.2	0.0	0.0	93.9	7.5	0.0	0.0	0.0	0.0	3.8	0.3
-	Barley beer	0.002	18.3	0.0	84.1	0.2	4.1	0.0	66.0	0.1	243.1	0.5	161.3	0.3
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	-
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
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
FC 0001	Citrus fruit (excl lemon juice, excl mandarin juice, excl orange juice, incl grapefruit juice, incl NES juice)	4.9	15.7	76.9	91.3	447.4	53.0	259.9	24.4	119.6	21.4	104.8	13.2	64.7
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, 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
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
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)	0.01	3.9	0.0	14.4	0.1	5.2	0.1	11.8	0.1	11.7	0.1	7.6	0.1

Annex 3

AZOXYSTROBIN (229) International Estimated Daily Intake (IEDI) ADI = 0–0.20 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
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
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)	0.01	0.8	0.0	10.0	0.1	0.9	0.0	6.6	0.1	11.8	0.1	3.7	0.0
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	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
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
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)	0.08	1.4	0.1	0.6	0.0	0.2	0.0	4.2	0.3	5.7	0.5	8.9	0.7
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
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

AZOXYSTROBIN (229) International Estimated Daily Intake (IEDI) ADI = 0–0.20 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 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
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
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
VR 0075	Root and tuber vegetables	0.23	528.2	121.5	352.8	81.1	78.5	18.0	270.3	62.2	324.1	74.5	261.3	60.1
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
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
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
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
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 (excl bulgur wholemeal, excl flour)	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
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

Annex 3

AZOXYSTROBIN (229) International Estimated Daily Intake (IEDI) ADI = 0–0.20 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
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
	Total intake (µg/person)=			369.6		1031.5		586.2		546.3		525.4		260.1
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			12000		12000		12000		12000		12000		12000
	%ADI=			3.1%		8.6%		4.9%		4.6%		4.4%		2.2%
	Rounded %ADI=			3%		9%		5%		5%		4%		2%

AZOXYSTROBIN (229) International Estimated Daily Intake (IEDI) ADI = 0–0.20 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G diet	intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake	M 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)	0.08	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	0.002	21.9	0.0	102.7	0.2	29.5	0.1	12.6	0.0	100.9	0.2	82.2	0.2	218.8	0.4
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	-

AZOXYSTROBIN (229) International Estimated Daily Intake (IEDI) ADI = 0–0.20 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G diet	intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake	M diet	intake
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
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
FC 0001	Citrus fruit (excl lemon juice, excl mandarin juice, excl orange juice, incl grapefruit juice, incl NES juice)	4.9	15.1	73.8	153.9	754.1	5.8	28.3	41.7	204.4	218.9	1072.7	24.5	120.1	23.3	114.2
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, 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
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
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)	0.01	4.8	0.0	10.7	0.1	4.0	0.0	4.0	0.0	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
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

Annex 3

AZOXYSTROBIN (229) International Estimated Daily Intake (IEDI) ADI = 0–0.20 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day G diet	Intake = daily intake: µg/person intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake	M diet	intake
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)	0.01	2.2	0.0	18.6	0.2	0.5	0.0	0.8	0.0	5.7	0.1	4.5	0.0	18.2	0.2
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	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
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
GC 0647	Oats (incl rolled)	0.08	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	0.6
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
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
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
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
VR 0075	Root and tuber vegetables	0.23	139.1	32.0	109.8	25.3	409.6	94.2	444.6	102.3	145.3	33.4	127.0	29.2	225.6	51.9
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
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

AZOXYSTROBIN (229) International Estimated Daily Intake (IEDI) ADI = 0–0.20 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)	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
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
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
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 (excl 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
	Total intake (µg/person)=			544.5		926.1		275.0		526.3		1346.7		431.6		426.1
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			11000		12000		12000		12000		12000		11000		12000
	%ADI=			4.9%		7.7%		2.3%		4.4%		11.2%		3.9%		3.6%
	Rounded %ADI=			5%		8%		2%		4%		10%		4%		4%

Annex 3

BUPROFEZIN (173) International Estimated Daily Intake (IEDI) ADI = 0–0.009 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
FC 0001	Citrus fruit (excl lemon juice, excl mandarin juice, excl orange juice, excl grapefruit juice, excl NES juice)	0.04	15.7	0.6	86.5	3.5	52.6	2.1	24.2	1.0	16.2	0.6	12.0	0.5
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
FP 0226	Apple (excl juice)	0.28	0.3	0.1	56.3	15.8	18.4	5.1	38.3	10.7	40.6	11.4	28.3	7.9
JF 0226	Apple juice	0.16	0.0	0.0	2.8	0.4	0.1	0.0	1.1	0.2	6.8	1.1	7.4	1.2
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
FS 0013	Cherries	0.73	0.0	0.0	6.8	5.0	0.9	0.7	6.2	4.5	3.6	2.6	0.4	0.3
-	Citrus juice NES	0.13	0.0	0.0	1.7	0.2	0.1	0.0	0.0	0.0	1.1	0.1	0.3	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
VC 0045	Fruiting vegetables, cucurbits	0.195	26.6	5.2	107.5	21.0	95.9	18.7	82.2	16.0	25.4	5.0	23.2	4.5
FB 0269	Grape (excl dried, excl juice, excl wine)	0.17	1.9	0.3	9.2	1.6	23.8	4.0	9.8	1.7	0.0	0.0	0.0	0.0
JF 0269	Grape juice	0.098	0.0	0.0	0.1	0.0	0.1	0.0	0.1	0.0	1.4	0.1	1.0	0.1
DF 0269	Grape, dried (= currants, raisins and sultanas)	0.37	0.0	0.0	2.9	1.1	0.4	0.1	0.4	0.1	2.3	0.9	1.7	0.6
JF 0203	Grapefruit juice	0.13	0.0	0.0	0.2	0.0	0.1	0.0	0.1	0.0	1.1	0.1	0.2	0.0
-d	Lemon juice	0.13	0.0	0.0	0.9	0.1	0.1	0.0	0.0	0.0	0.2	0.0	0.4	0.1
-	Mandarin + mandarin-like hybrid juice	0.13	0.0	0.0	1.4	0.2	0.9	0.1	0.4	0.1	0.7	0.1	0.9	0.1
FI 0345	Mango (incl juice, incl pulp)	0.01	6.3	0.1	1.0	0.0	4.6	0.0	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	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
FS 0245	Nectarine	1.355	0.0	0.0	0.5	0.7	3.3	4.5	1.8	2.4	2.8	3.8	1.6	2.2
FT 0305	Olive (table olives, only)	1.125	0.0	0.0	4.8	5.4	0.8	0.9	0.4	0.5	1.0	1.1	0.8	0.9
OR 0305	Olive oil, refined	3.49	0.0	0.0	14.3	49.9	3.9	13.6	0.0	0.0	1.5	5.2	0.8	2.8
JF 0004	Orange juice	0.13	0.0	0.0	2.1	0.3	4.4	0.6	1.4	0.2	16.2	2.1	22.6	2.9
FS 0247	Peach	1.355	0.2	0.3	24.8	33.6	3.3	4.5	1.8	2.4	5.4	7.3	1.6	2.2
FP 0230	Pear	1.09	0.1	0.1	22.3	24.3	2.8	3.1	4.8	5.2	10.7	11.7	6.8	7.4
VO 0051	Peppers	0.33	1.4	0.5	29.9	9.9	13.0	4.3	6.3	2.1	6.2	2.0	4.0	1.3
FS 0014	Plum (excl dried)	0.155	0.1	0.0	5.3	0.8	2.5	0.4	7.0	1.1	5.5	0.8	0.9	0.1
DF 0014	Plum, dried (prunes)	0.465	0.0	0.0	0.2	0.1	0.0	0.0	0.1	0.0	0.5	0.2	0.6	0.3
FB 0275	Strawberry	0.44	0.0	0.0	5.0	2.2	2.0	0.9	1.7	0.7	5.2	2.3	4.1	1.8
DT 1114	Tea, green, black (black, fermented and dried)	9	0.3	2.7	2.4	21.6	2.8	25.2	2.1	18.9	2.0	18.0	0.8	7.2

BUPROFEZIN (173) International Estimated Daily Intake (IEDI) ADI = 0–0.009 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
VO 0448	Tomato (excl juice, excl paste, incl canned)	0.24	3.3	0.8	179.2	43.0	103.5	24.8	54.1	13.0	7.8	1.9	3.9	0.9
JF 0448	Tomato juice	0.053	5.2	0.3	0.5	0.0	0.4	0.0	2.1	0.1	6.9	0.4	15.2	0.8
-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
-	Wine	0.15	1.3	0.2	76.8	11.5	1.1	0.2	15.4	2.3	68.8	10.3	25.6	3.8
	Total intake (µg/person)=			11.6		252.7		114.9		83.6		90.4		51.4
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			540		540		540		540		540		540
	%ADI=			2.1%		46.8%		21.3%		15.5%		16.7%		9.5%
	Rounded %ADI=			2%		50%		20%		20%		20%		10%

BUPROFEZIN (173) International Estimated Daily Intake (IEDI) ADI = 0–0.009 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G diet	intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake	M diet	intake
FC 0001	Citrus fruit (excl lemon juice, excl mandarin juice, excl orange juice, excl grapefruit juice, excl NES juice)	0.04	15.1	0.6	153.9	6.2	3.4	0.1	41.7	1.7	218.9	8.8	23.1	0.9	18.0	0.7
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
FP 0226	Apple (excl juice)	0.28	14.3	4.0	9.4	2.6	2.1	0.6	0.0	0.0	8.8	2.5	16.6	4.6	27.8	7.8
JF 0226	Apple juice	0.16	0.1	0.0	0.5	0.1	0.1	0.0	0.0	0.0	0.7	0.1	0.9	0.1	5.7	0.9
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
FS 0013	Cherries	0.73	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	1.8
-	Citrus juice NES	0.13	0.0	0.0	0.0	0.0	0.5	0.1	0.0	0.0	0.0	0.0	0.3	0.0	0.1	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
VC 0045	Fruiting vegetables, cucurbits	0.195	69.7	13.6	25.9	5.1	14.9	2.9	18.0	3.5	18.7	3.6	39.1	7.6	44.2	8.6
FB 0269	Grape (excl dried, excl juice, excl wine)	0.17	1.2	0.2	2.6	0.4	0.0	0.0	0.2	0.0	0.0	0.0	3.7	0.6	0.0	0.0
JF 0269	Grape juice	0.098	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)	0.37	0.0	0.0	0.2	0.1	0.2	0.1	0.0	0.0	0.3	0.1	0.4	0.1	2.6	1.0
JF 0203	Grapefruit juice	0.13	0.0	0.0	0.0	0.0	0.5	0.1	0.0	0.0	0.0	0.0	0.3	0.0	2.4	0.3
-d	Lemon juice	0.13	0.3	0.0	0.0	0.0	1.0	0.1	0.3	0.0	0.0	0.0	0.5	0.1	2.6	0.3
-	Mandarin + mandarin-like hybrid juice	0.13	0.5	0.1	0.5	0.1	0.1	0.0	0.0	0.0	0.7	0.1	1.4	0.2	0.0	0.0
FI 0345	Mango (incl juice, incl pulp)	0.01	12.7	0.1	26.2	0.3	6.1	0.1	12.7	0.1	9.2	0.1	8.0	0.1	1.9	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
FS 0245	Nectarine	1.355	1.7	2.3	1.7	2.3	0.0	0.0	0.0	0.0	1.0	1.4	1.7	2.3	1.4	1.9

Annex 3

BUPROFEZIN (173) International Estimated Daily Intake (IEDI) ADI = 0–0.009 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G diet	intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake	M diet	intake
FT 0305	Olive (table olives, only)	1.125	0.0	0.0	0.1	0.1	0.0	0.0	0.0	0.0	0.6	0.7	0.0	0.0	1.0	1.1
OR 0305	Olive oil, refined	3.49	0.0	0.0	0.1	0.3	0.0	0.0	0.0	0.0	0.3	1.0	0.3	1.0	1.6	5.6
JF 0004	Orange juice	0.13	0.2	0.0	1.0	0.1	3.5	0.5	0.0	0.0	1.3	0.2	6.4	0.8	56.8	7.4
FS 0247	Peach	1.355	1.7	2.3	1.7	2.3	1.1	1.5	0.1	0.1	1.0	1.4	1.7	2.3	10.2	13.8
FP 0230	Pear	1.09	6.4	7.0	1.9	2.1	1.2	1.3	0.0	0.0	1.8	2.0	6.9	7.5	7.8	8.5
VO 0051	Peppers	0.33	8.7	2.9	22.4	7.4	8.4	2.8	9.4	3.1	3.3	1.1	5.3	1.7	8.9	2.9
FS 0014	Plum (excl dried)	0.155	3.0	0.5	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)	0.465	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
FB 0275	Strawberry	0.44	0.0	0.0	1.8	0.8	0.1	0.0	0.0	0.0	0.3	0.1	6.2	2.7	5.9	2.6
DT 1114	Tea, green, black (black, fermented and dried)	9	1.3	11.7	0.2	1.8	0.9	8.1	0.6	5.4	0.1	0.9	1.5	13.5	1.0	9.0
VO 0448	Tomato (excl juice, excl paste, incl canned)	0.24	23.1	5.5	22.3	5.4	12.5	3.0	5.6	1.3	33.2	8.0	1.3	0.3	41.7	10.0
JF 0448	Tomato juice	0.053	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	2.4
-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
-	Wine	0.15	1.0	0.2	0.9	0.1	6.8	1.0	0.1	0.0	3.4	0.5	3.6	0.5	31.0	4.7
	Total intake (µg/person)=			51.3		38.6		22.6		15.9		33.4		48.7		92.7
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			495		540		540		540		540		495		540
	%ADI=			10.4%		7.1%		4.2%		3.0%		6.2%		9.8%		17.2%
	Rounded %ADI=			10%		7%		4%		3%		6%		10%		20%

CHLOROTHALONIL (081) International Estimated Daily Intake (IEDI) ADI = 0–0.02 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
FI 0327	Banana	0.033	38.8	1.3	17.4	0.6	16.0	0.5	6.6	0.2	21.5	0.7	33.8	1.1
VB 0400	Broccoli	5	0.0	0.0	0.7	3.5	1.2	6.0	0.1	0.5	4.2	21.0	4.0	20.0
VB 0402	Brussels sprouts	1.5	0.0	0.0	0.1	0.2	2.8	4.2	5.5	8.3	1.5	2.3	1.9	2.9
VB 0404	Cauliflower	5	0.1	0.5	5.2	26.0	1.2	6.0	0.1	0.5	1.7	8.5	0.1	0.5
VS 0624	Celery	2.65	0.0	0.0	0.9	2.4	0.0	0.0	2.0	5.3	1.5	4.0	0.0	0.0
VL 0464	Chard	16	2.3	36.8	2.2	35.2	0.1	1.6	2.0	32.0	0.2	3.2	0.0	0.0
VC 0424	Cucumber	0.41	0.3	0.1	12.7	5.2	5.9	2.4	11.5	4.7	6.1	2.5	7.1	2.9
FB 0021	Currants, red, black, white	20	0.0	0.0	0.0	0.0	0.0	0.0	2.2	44.0	3.1	62.0	2.0	40.0
VC 0425	Gherkin	0.41	0.3	0.1	12.7	5.2	5.9	2.4	11.5	4.7	6.1	2.5	7.1	2.9
FB 0268	Gooseberries	20	0.0	0.0	12.0	240.0	0.0	0.0	0.6	12.0	1.1	22.0	0.2	4.0
FB 0269	Grape (excl dried, excl juice, excl wine)	0.955	1.9	1.8	9.2	8.8	23.8	22.7	9.8	9.4	0.0	0.0	0.0	0.0
JF 0269	Grape juice	0.134	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)	0.248	0.0	0.0	2.9	0.7	0.4	0.1	0.4	0.1	2.3	0.6	1.7	0.4
VA 0384	Leek	17.5	0.3	5.3	5.3	92.8	0.0	0.0	0.2	3.5	4.6	80.5	1.5	26.3

CHLOROTHALONIL (081) International Estimated Daily Intake (IEDI) ADI = 0–0.02 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
VC 0046	Melons, except watermelon	0.04	3.6	0.1	26.7	1.1	22.6	0.9	11.5	0.5	5.6	0.2	2.0	0.1
VA 0387	Onion, Welsh	0.835	0.3	0.3	1.0	0.8	1.4	1.2	0.3	0.3	0.3	0.3	0.6	0.5
FI 0350	Papaya	2.3	5.1	11.7	0.1	0.2	0.0	0.0	0.0	0.0	0.1	0.2	0.0	0.0
SO 0697	Peanut, shelled (incl oil)	0.01	5.4	0.1	3.1	0.0	2.1	0.0	0.7	0.0	4.0	0.0	1.4	0.0
VD 0070	Pulses	0.19	54.5	10.4	62.9	12.0	51.4	9.8	36.8	7.0	49.4	9.4	47.9	9.1
VR0075	Root and tuber vegetables	0.3	528.2	158.5	352.8	105.8	78.5	23.5	270.3	81.1	324.1	97.2	261.3	78.4
VA 0389	Spring onion	0.835	0.3	0.3	1.0	0.8	1.4	1.2	0.3	0.3	0.3	0.3	0.6	0.5
VC 0431	Squash, summer (= courgette, zuchini)	0.41	0.0	0.0	8.3	3.4	11.4	4.7	7.3	3.0	3.2	1.3	0.3	0.1
FB 0275	Strawberry	2.05	0.0	0.0	5.0	10.3	2.0	4.1	1.7	3.5	5.2	10.7	4.1	8.4
-	Wine	0.0096	1.3	0.0	76.8	0.7	1.1	0.0	15.4	0.1	68.8	0.7	25.6	0.2
	Total intake (µg/person)=			227.1		555.7		91.4		220.8		330.2		198.4
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			1200		1200		1200		1200		1200		1200
	%ADI=			18.9%		46.3%		7.6%		18.4%		27.5%		16.5%
	Rounded %ADI=			20%		50%		8%		20%		30%		20%

CHLOROTHALONIL (081) International Estimated Daily Intake (IEDI) ADI = 0–0.02 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G diet	intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake	M diet	intake
FI 0327	Banana	0.033	21.4	0.7	36.6	1.2	11.4	0.4	9.2	0.3	70.2	2.3	40.5	1.3	32.6	1.1
VB 0400	Broccoli	5	3.2	16.0	7.8	39.0	0.0	0.0	0.0	0.0	0.3	1.5	0.4	2.0	6.6	33.0
VB 0402	Brussels sprouts	1.5	3.4	5.1	0.4	0.6	0.0	0.0	0.0	0.0	0.5	0.8	7.9	11.9	0.3	0.5
VB 0404	Cauliflower	5	3.2	16.0	0.1	0.5	0.3	1.5	0.1	0.5	0.6	3.0	0.4	2.0	1.4	7.0
VS 0624	Celery	2.65	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	11.1
VL 0464	Chard	16	7.0	112.0	0.3	4.8	2.3	36.8	3.3	52.8	1.0	16.0	7.4	118.4	0.1	1.6
VC 0424	Cucumber	0.41	7.9	3.2	0.6	0.2	0.2	0.1	0.0	0.0	0.4	0.2	5.5	2.3	5.3	2.2
FB 0021	Currants, red, black, white	20	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
VC 0425	Gherkin	0.41	7.9	3.2	0.6	0.2	0.2	0.1	0.0	0.0	0.4	0.2	5.5	2.3	5.3	2.2
FB 0268	Gooseberries	20	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	20.0	0.0	0.0	0.0	0.0
FB 0269	Grape (excl dried, excl juice, excl wine)	0.955	1.2	1.1	2.6	2.5	0.0	0.0	0.2	0.2	0.0	0.0	3.7	3.5	0.0	0.0
JF 0269	Grape juice	0.134	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
DF 0269	Grape, dried (= currants, raisins and sultanas)	0.248	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

Annex 3

CHLOROTHALONIL (081) International Estimated Daily Intake (IEDI) ADI = 0–0.02 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day Intake = daily intake: µg/person													
			G diet	intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake	M diet	intake
VA 0384	Leek	17.5	0.8	14.0	0.2	3.5	0.0	0.0	0.0	0.0	0.0	0.0	0.3	5.3	0.1	1.8
VC 0046	Melons, except watermelon	0.04	7.5	0.3	6.1	0.2	0.7	0.0	1.4	0.1	2.5	0.1	6.9	0.3	12.4	0.5
VA 0387	Onion, Welsh	0.835	0.1	0.1	4.8	4.0	0.1	0.1	1.0	0.8	1.0	0.8	2.7	2.3	0.6	0.5
FI 0350	Papaya	2.3	1.3	3.0	11.5	26.5	1.6	3.7	13.7	31.5	14.5	33.4	1.0	2.3	0.6	1.4
SO 0697	Peanut, shelled (incl oil)	0.01	7.6	0.1	2.1	0.0	4.7	0.0	21.8	0.2	0.9	0.0	0.7	0.0	6.9	0.1
VD 0070	Pulses	0.19	41.9	8.0	91.8	17.4	35.9	6.8	45.2	8.6	160.0	30.4	59.5	11.3	140.1	26.6
VR0075	Root and tuber vegetables	0.3	139.1	41.7	109.8	32.9	409.6	122.9	444.6	133.4	145.3	43.6	127.0	38.1	225.6	67.7
VA 0389	Spring onion	0.835	0.1	0.1	4.8	4.0	0.1	0.1	1.0	0.8	1.0	0.8	2.7	2.3	0.6	0.5
VC 0431	Squash, summer (= courgette, zuchini)	0.41	2.4	1.0	1.5	0.6	0.0	0.0	0.0	0.0	3.8	1.6	2.2	0.9	2.5	1.0
FB 0275	Strawberry	2.05	0.0	0.0	1.8	3.7	0.1	0.2	0.0	0.0	0.3	0.6	6.2	12.7	5.9	12.1
-	Wine	0.0096	1.0	0.0	0.9	0.0	6.8	0.1	0.1	0.0	3.4	0.0	3.6	0.0	31.0	0.3
	Total intake (µg/person)=		257	225.6		142.9		172.9		229.2		158.0		219.2		172.1
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			1100		1200		1200		1200		1200		1100		1200
	%ADI=			20.5%		11.9%		14.4%		19.1%		13.2%		19.9%		14.3%
	Rounded %ADI=			20%		10%		10%		20%		10%		20%		10%

CHLOPRYRIFOS METHYL (090) 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 diet	intake	B diet	intake	C diet	intake	D diet	intake	E diet	intake	F 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)	2.1	40.6	85.3	0.0	0.0	93.9	197.2	0.0	0.0	0.0	0.0	3.8	8.1
-	Barley beer	0.002	18.3	0.0	84.1	0.2	4.1	0.0	66.0	0.1	243.1	0.5	161.3	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

CHLOPRYRIFOS METHYL (090) 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
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
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
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
GC 0654	Wheat (incl bulgur wholemeal, excl flour)	2.1	6.0	12.6	11.1	23.3	0.8	1.6	0.2	0.4	0.2	0.5	0.0	0.0
CM 0654	Wheat bran, unprocessed	5.14	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CF 1211	Wheat flour (incl macaroni, bread, pastry, starch, gluten)	0.525	63.4	33.3	296.3	155.6	327.5	171.9	300.0	157.5	181.6	95.3	166.2	87.3
CF 1210	Wheat germ	3.99	0.0	0.0	1.3	5.2	0.0	0.0	1.3	5.2	0.9	3.6	1.2	4.8
CF 1212	Wheat wholemeal	2.1	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CP 1211	White bread	0.105	0.0	0.0	0.1	0.0	0.0	0.0	0.1	0.0	0.1	0.0	1.0	0.1
CP 1212	Wholemeal bread	1.06	0.0	0.0	0.1	0.1	0.0	0.0	0.1	0.1	0.1	0.1	1.0	1.1
-	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)=			132.1		206.2		382.3		171.5		106.9		107.2
Bodyweight per region (kg bw) =				60		60		60		60		60		60
	ADI (µg/person)=			600		600		600		600		600		600
	%ADI=			22.0%		34.4%		63.7%		28.6%		17.8%		17.9%
	Rounded %ADI=			20%		30%		60%		30%		20%		20%

CHLOPRYRIFOS METHYL (090) 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

Annex 3

CHLOPRYRIFOS METHYL (090) 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
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)	2.1	1.5	3.2	0.0	-0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.4	0.8	0.0	0.1
-	Barley beer	0.002	21.9	0.0	102.7	0.2	29.5	0.1	12.6	0.0	100.9	0.2	82.2	0.2	218.8	0.4
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
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	Eggplant (= 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
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
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 0654	Wheat (incl bulgur wholemeal, excl flour)	2.1	0.0	0.0	0.9	1.8	0.0	0.0	0.0	0.1	0.1	0.2	0.0	0.0	0.1	0.1
CM 0654	Wheat bran, unprocessed	5.14	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CF 1211	Wheat flour (incl macaroni, bread, pastry, starch, gluten)	0.525	133.0	69.8	60.1	31.6	52.4	27.5	32.2	16.9	87.7	46.0	79.6	41.8	180.1	94.6

CHLOPRYRIFOS METHYL (090) 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
CF 1210	Wheat germ	3.99	0.1	0.4	48.1	191.9	1.8	7.2	0.0	0.0	0.0	0.0	0.0	0.0	0.6	2.4
CF 1212	Wheat wholemeal	2.1	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CP 1211	White bread	0.105	0.0	0.0	2.2	0.2	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
CP 1212	Wholemeal bread	1.06	0.0	0.0	2.2	2.3	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)=			78.6		234.3		37.0		19.0		52.5		46.3		106.4
Bodyweight per region (kg bw) =				55		60		60		60		60		55		60
	ADI (µg/person)=			550		600		600		600		600		550		600
	%ADI=			14.3%		39.0%		6.2%		3.2%		8.8%		8.4%		17.7%
	Rounded %ADI=			10%		40%		6%		3%		9%		8%		20%

Annex 3

CYCLOXIDIM (179) International Estimated Daily Intake (IEDI) ADI = 0–0.07 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day A diet	A intake	B diet	B intake	C diet	C intake	D diet	D intake	E diet	E intake	F diet	F intake
			Intake = daily intake: µg/person											
VD 0071	Beans (dry)	3	15.8	47.4	6.1	18.3	1.7	5.1	6.3	18.9	1.8	5.4	5.0	15.0
VP 0061	Beans except broad bean & soya bean (green pods & immature seeds)	0.35	1.0	0.4	17.4	6.1	7.5	2.6	0.9	0.3	16.4	5.7	0.1	0.0
VR 0574	Beetroot	0.09	0.0	0.0	40.7	3.7	0.0	0.0	0.1	0.0	6.0	0.5	0.1	0.0
VB 0040	Brassica vegetables	1.5	1.7	2.6	25.7	38.6	9.1	13.7	27.8	41.7	36.9	55.4	26.4	39.6
VR 0577	Carrot	0.44	0.6	0.3	15.1	6.6	8.1	3.6	13.9	6.1	27.1	11.9	28.4	12.5
VR 0578	Celeriac	0.13	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
MO 0105	Edible offal (mammalian)	0.084	3.9	0.3	14.4	1.2	5.2	0.4	11.8	1.0	11.7	1.0	7.6	0.6
PE 0112	Eggs	0.026	2.5	0.1	29.7	0.8	25.1	0.7	24.5	0.6	37.8	1.0	27.4	0.7
FB 0269	Grape (incl dried, incl juice, incl wine)	0.11	3.7	0.4	28.5	14.1	27.1	3.0	33.1	3.6	107.5	11.8	44.0	4.8
VL 0480	Kale	0.65	0.0	0.0	0.0	0.0	0.0	0.0	5.5	3.6	0.6	0.4	1.9	1.2
VA 0384	Leek	0.36	0.3	0.1	5.3	1.9	0.0	0.0	0.2	0.1	4.6	1.7	1.5	0.5
SO 0693	Linseed (incl oil)	1.9	2.6	4.9	14.2	27.0	5.7	10.8	19.2	36.5	0.0	0.0	1.3	2.5
VL 0482	Lettuce, head	0.335	0.1	0.0	6.2	2.1	0.7	0.2	0.1	0.0	0.1	0.0	0.0	0.0
VL 0483	Lettuce, leaf	0.335	0.0	0.0	9.2	3.1	1.0	0.3	0.1	0.0	5.4	1.8	18.0	6.0
GC 0645	Maize (incl flour, incl oil, incl beer)	0.09	82.7	7.4	148.4	13.4	135.9	12.2	31.8	2.9	33.3	3.0	7.5	0.7
MF 0100	Mammalian fats (except milk fats)	0.01	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	0.002	5.5	0.0	23.3	0.0	7.7	0.0	11.0	0.0	18.0	0.0	26.3	0.1
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0.008	###	0.2	93.2	0.7	30.8	0.2	44.1	0.4	72.2	0.6	105.0	0.8
ML 0106	Milks (excl processed products)	0.004	###	0.3	####	0.8	79.4	0.3	302.6	1.2	####	0.7	237.9	1.0
-	Onion, dry	0.34	4.3	1.5	45.6	15.5	27.4	9.3	30.2	10.3	22.1	7.5	12.2	4.1
VD 0072	Peas (dry) (= field pea + cowpea)	3.2	6.8	21.8	1.3	4.2	1.0	3.2	2.3	7.4	4.6	14.7	3.4	10.9
VP 0064	Peas, shelled (immature seeds only)	2.7	0.0	0.0	0.9	2.4	6.0	16.2	0.6	1.6	9.7	26.2	3.2	8.6
VO 0051	Peppers	1.55	1.4	2.2	29.9	46.3	13.0	20.2	6.3	9.8	6.2	9.6	4.0	6.2
FP 0009	Pome fruit (incl apple juice)	0.09	0.5	0.0	84.1	7.6	21.9	2.0	45.2	4.1	61.7	5.6	46.2	4.2
VR 0589	Potato (incl flour, frozen, starch, tapioca)	0.735	###	14.0	####	118.2	61.2	45.0	243.6	179.0	####	169.1	204.7	150.5
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	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

CYCLOXIDIM (179) International Estimated Daily Intake (IEDI) ADI = 0–0.07 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day Intake = daily intake: µg/person A diet	A intake	B diet	B intake	C diet	C intake	D diet	D intake	E diet	E intake	F diet	F intake
	muscle													
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	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)	1.9	0.1	0.2	0.0	0.0	0.0	0.0	0.1	0.2	0.1	0.2	0.1	0.2
OR 0495	Rape seed oil, edible	0.095	0.3	0.0	0.7	0.1	1.0	0.1	0.7	0.1	13.7	1.3	10.0	1.0
GC 0649	Rice (incl husked, incl polished)	0.09	91.0	8.2	31.6	2.8	94.6	8.5	33.2	3.0	12.7	1.1	12.7	1.1
VD 0541	Soya bean (dry, incl oil)	13	9.9	128.7	36.4	473.2	34.3	445.9	22.4	291.2	35.3	458.9	39.2	509.6
FS 0012	Stone fruit (incl dried plums, incl dried apricots)	0.09	0.7	0.1	44.7	4.0	14.1	1.3	26.9	2.4	27.7	2.5	10.0	0.9
FB 0275	Strawberry	0.53	0.0	0.0	5.0	2.7	2.0	1.1	1.7	0.9	5.2	2.8	4.1	2.2
VR 0596	Sugar beet	0.09	0.0	0.0	40.7	3.7	0.0	0.0	0.1	0.0	6.0	0.5	0.1	0.0
SO 0702	Sunflower seed (incl oil)	0.375	0.7	0.3	44.5	16.7	20.5	7.7	29.6	11.1	21.2	8.0	5.4	2.0
VR 0497	Swede	0.09	0.0	0.0	0.0	0.0	0.0	0.0	2.0	0.2	0.8	0.1	14.0	1.3
VO 0448	Tomato (excl juice, incl paste, excl canned)	0.445	5.2	2.3	183.9	81.8	116.9	52.0	57.6	25.6	16.9	7.5	17.9	8.0
JF 0448	Tomato juice	0.49	5.2	2.5	0.5	0.2	0.4	0.2	2.1	1.0	6.9	3.4	15.2	7.4
-d	Tomato, canned	0.254	0.1	0.0	0.4	0.1	0.5	0.1	0.4	0.1	4.9	1.2	3.2	0.8
	Total intake (µg/person)=			246.2		917.9		665.9		664.9		821.2		805.1
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			4200		4200		4200		4200		4200		4200
	%ADI=			5.9%	21.9%			15.9%		19.6%		19.6%		19.2%
	Rounded %ADI=			6%		20%		20%		20%		20%		20%

CYCLOXIDIM (179) International Estimated Daily Intake (IEDI) ADI = 0–0.07 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
VD 0071	Beans (dry)	3	3.4	10.2	25.5	76.5	7.8	23.4	2.1	6.3	44.7	134.1	5.5	16.5	7.3	21.9
VP 0061	Beans except broad bean & soya bean (green pods & immature seeds)	0.35	2.6	0.9	2.6	0.9	1.0	0.4	0.5	0.2	0.6	0.2	2.8	1.0	9.8	3.4
VR 0574	Beetroot	0.09	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	1.3
VB 0040	Brassica vegetables	1.5	26.4	39.6	9.3	14.0	7.8	11.7	1.5	2.3	3.3	5.0	40.8	61.2	26.0	39.0
VR 0577	Carrot	0.44	5.4	2.4	7.9	3.5	2.5	1.1	3.5	1.5	4.1	1.8	8.6	3.8	19.4	8.5
VR 0578	Celeriac	0.13	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
MO 0105	Edible offal (mammalian)	0.084	4.8	0.4	10.7	0.9	4.0	0.3	4.0	0.3	6.5	0.5	6.6	0.6	5.6	0.5
PE 0112	Eggs	0.026	22.1	0.6	71.5	1.9	16.6	0.4	5.1	0.1	17.6	0.5	35.2	0.9	57.4	1.5
FB 0269	Grape (incl dried,	0.11	2.6	0.3	4.8	0.5	11.7	1.3	0.3	0.0	6.8	0.7	10.9	1.2	58.8	6.5

Annex 3

CYCLOXIDIM (179) International Estimated Daily Intake (IEDI) ADI = 0–0.07 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
	incl juice, incl wine)															
VL 0480	Kale	0.65	0.0	0.0	0.4	0.3	0.0	0.0	0.0	0.0	0.4	0.3	0.0	0.0	0.3	0.2
VA 0384	Leek	0.36	0.8	0.3	0.2	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.3	0.1	0.1	0.0
SO 0693	Linseed (incl oil)	1.9	3.9	7.4	1.9	3.6	3.0	5.7	4.0	7.6	0.0	0.0	43.3	82.3	0.9	1.7
VL 0482	Lettuce, head	0.335	1.2	0.4	3.5	1.2	0.1	0.0	0.3	0.1	1.0	0.3	1.2	0.4	7.9	2.6
VL 0483	Lettuce, leaf	0.335	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	0.8
GC 0645	Maize (incl flour, incl oil, incl beer)	0.09	35.2	3.2	298.6	26.9	248.1	22.3	57.4	5.2	63.1	5.7	58.6	5.3	85.5	7.7
MF 0100	Mammalian fats (except milk fats)	0.01	2.2	0.0	18.6	0.2	0.5	0.0	0.8	0.0	5.7	0.1	4.5	0.0	18.2	0.2
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.002	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	0.1
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0.008	43.8	0.4	71.5	0.6	24.5	0.2	22.9	0.2	65.7	0.5	48.9	0.4	####	1.0
ML 0106	Milks (excl processed products)	0.004	66.0	0.3	121.1	0.5	81.6	0.3	###	0.4	####	0.8	57.0	0.2	####	1.2
-	Onion, dry	0.34	16.8	5.7	8.6	2.9	6.9	2.3	12.1	4.1	18.6	6.3	23.8	8.1	28.4	9.7
VD 0072	Peas (dry) (= field pea + cowpea)	3.2	1.8	5.8	2.2	7.0	3.2	10.2	26.7	85.4	1.5	4.8	1.8	5.8	1.8	5.8
VP 0064	Peas, shelled (immature seeds only)	2.7	3.9	10.5	1.6	4.3	0.0	0.0	0.0	0.0	0.4	1.1	1.0	2.7	0.8	2.2
VO 0051	Peppers	1.55	8.7	13.5	22.4	34.7	8.4	13.0	9.4	14.6	3.3	5.1	5.3	8.2	8.9	13.8
FP 0009	Pome fruit (incl apple juice)	0.09	20.9	1.9	12.3	1.1	3.4	0.3	0.1	0.0	11.7	1.1	24.9	2.2	45.4	4.1
VR 0589	Potato (incl flour, frozen, starch, tapioca)	0.735	52.7	38.7	57.1	42.0	50.1	36.8	4.3	3.2	54.7	40.2	41.0	30.1	####	123.5
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	####	0.0	24.9	0.0	####	0.0
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	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)	1.9	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
OR 0495	Rape seed oil, edible	0.095	3.8	0.4	2.3	0.2	0.1	0.0	0.4	0.0	0.0	0.0	6.0	0.6	3.8	0.4
GC 0649	Rice (incl husked, incl polished)	0.09	376.9	33.9	64.3	5.8	38.0	3.4	74.3	6.7	1238.4	21.5	381.3	34.3	34.6	3.1

CYCLOXIDIM (179) International Estimated Daily Intake (IEDI) ADI = 0–0.07 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
VD 0541	Soya bean (dry, incl oil)	13	25.9	336.7	59.4	772.2	11.2	145.6	11.0	143.0	109.3	1420.9	51.5	669.5	123.2	1601.6
FS 0012	Stone fruit (incl dried plums, incl dried apricots)	0.09	7.0	0.6	4.9	0.4	1.4	0.1	0.1	0.0	5.5	0.5	5.5	0.5	19.4	1.7
FB 0275	Strawberry	0.53	0.0	0.0	1.8	1.0	0.1	0.1	0.0	0.0	0.3	0.2	6.2	3.3	5.9	3.1
VR 0596	Sugar beet	0.09	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	1.3
SO 0702	Sunflower seed (incl oil)	0.375	2.7	1.0	8.8	3.3	13.5	5.1	0.2	0.1	3.6	1.4	0.6	0.2	10.4	3.9
VR 0497	Swede	0.09	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.1	0.0	0.0	1.1	0.1
VO 0448	Tomato (excl juice, incl paste, excl canned)	0.445	23.3	10.3	12.6	5.6	14.6	6.5	7.2	3.2	35.2	15.7	5.9	2.6	45.0	20.0
JF 0448	Tomato juice	0.49	0.0	0.0	0.8	0.4	0.1	0.0	7.2	3.5	0.0	0.0	2.4	1.2	45.2	22.1
-d	Tomato, canned	0.254	0.2	0.1	14.5	3.7	0.2	0.1	0.0	0.0	0.3	0.1	0.8	0.2	1.2	0.3
			525.4		1016.1		290.9		288.1		1669.4		943.4		1914.8	
			55		60		60		60		60		55		60	
			3850		4200		4200		4200		4200		3850		4200	
			13.6		24.2%		6.9%		6.9%		39.7%		24.5%		45.6%	
			10%		20%		7%		7%		40%		20%		50%	

Annex 3

	CYFLUTHRIN (157)	International Estimated Daily Intake (IEDI)							ADI = 0–0.04 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
FP 0226	Apple (excl juice)	0.02	0.3	0.0	56.3	1.1	18.4	0.4	38.3	0.8	40.6	0.8	28.3	0.6
JF 0226	Apple juice	0.0012	0.0	0.0	2.8	0.0	0.1	0.0	1.1	0.0	6.8	0.0	7.4	0.0
VB 0400	Broccoli	0.2	0.0	0.0	0.7	0.1	1.2	0.2	0.1	0.0	4.2	0.8	4.0	0.8
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 0404	Cauliflower	0.24	0.1	0.0	5.2	1.2	1.2	0.3	0.1	0.0	1.7	0.4	0.1	0.0
FC 0001	Citrus fruit (incl lemon juice, incl mandarin juice, excl orange juice, incl grapefruit juice, incl NES juice)	0.06	15.7	0.9	96.7	5.8	55.3	3.3	25.3	1.5	23.4	1.4	16.2	1.0
OR 0691	Cotton seed oil, edible	0.14	0.9	0.1	4.9	0.7	1.7	0.2	6.6	0.9	0.0	0.0	0.3	0.0
MO 0105	Edible offal (mammalian)	0.005	3.9	0.0	14.4	0.1	5.2	0.0	11.8	0.1	11.7	0.1	7.6	0.0
VO 0440	Eggplant (= aubergine)	0.05	1.7	0.1	17.5	0.9	12.3	0.6	1.7	0.1	0.8	0.0	0.4	0.0
FC 0204	Lemon (incl juice)	0.06	0.0	0.0	13.7	0.8	4.0	0.2	2.5	0.2	0.3	0.0	0.9	0.1
FC 0003	Mandarin + mandarin-like hybrid (incl juice)	0.06	0.6	0.0	19.1	1.1	12.3	0.7	5.5	0.3	9.9	0.6	11.7	0.7
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.07	5.5	0.4	23.3	1.6	7.7	0.5	11.0	0.8	18.0	1.3	26.3	1.8
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
ML 0106	Milks (excl processed products)	0.004	68.8	0.3	190.6	0.8	79.4	0.3	302.6	1.2	179.6	0.7	237.9	1.0
JF 0004	Orange juice	0.003	0.0	0.0	2.1	0.0	4.4	0.0	1.4	0.0	16.2	0.0	22.6	0.1
FC 0004	Orange, sweet, sour + orange-like hybrid (excl juice)	0.06	4.2	0.3	54.1	3.2	30.1	1.8	11.9	0.7	0.2	0.0	0.5	0.0
FP 0230	Pear	0.02	0.1	0.0	22.3	0.4	2.8	0.1	4.8	0.1	10.7	0.2	6.8	0.1
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
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
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
FC 0005	Shaddock or pomelo + shaddock-like hybrid (incl juice)	0.06	0.5	0.0	5.3	0.3	0.9	0.1	0.5	0.0	9.1	0.5	1.4	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
VO 0448	Tomato (excl juice, excl paste, incl canned)	0.07	3.3	0.2	179.2	12.5	103.5	7.2	54.1	3.8	7.8	0.5	3.9	0.3
JF 0448	Tomato juice	0.02	5.2	0.1	0.5	0.0	0.4	0.0	2.1	0.0	6.9	0.1	15.2	0.3
-d	Tomato paste	0.126	0.5	0.1	1.3	0.2	3.5	0.4	1.0	0.1	3.8	0.5	4.5	0.6
	Total intake (µg/person)=			3.2		36.0		18.7		14.4		13.8		12.7
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			2400		2400		2400		2400		2400		2400
	%ADI=			0.1%		1.5%		0.8%		0.6%		0.6%		0.5%
	Rounded %ADI=			0%		1%		1%		1%		1%		1%

CYFLUTHRIN (157) International Estimated Daily Intake (IEDI) ADI = 0–0.04 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G diet	intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake	M diet	intake
FP 0226	Apple (excl juice)	0.02	14.3	0.3	9.4	0.2	2.1	0.0	0.0	0.0	8.8	0.2	16.6	0.3	27.8	0.6
JF 0226	Apple juice	0.0012	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
VB 0400	Broccoli	0.2	3.2	0.6	7.8	1.6	0.0	0.0	0.0	0.0	0.3	0.1	0.4	0.1	6.6	1.3
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 0404	Cauliflower	0.24	3.2	0.8	0.1	0.0	0.3	0.1	0.1	0.0	0.6	0.1	0.4	0.1	1.4	0.3
FC 0001	Citrus fruit (incl lemon juice, incl mandarin juice, excl orange juice, incl grapefruit juice, incl NES juice)	0.06	16.9	1.0	155.0	9.3	8.6	0.5	42.5	2.6	220.5	13.2	28.9	1.7	30.1	1.8
OR 0691	Cotton seed oil, edible	0.14	1.0	0.1	0.7	0.1	1.0	0.1	1.4	0.2	1.5	0.2	5.5	0.8	1.2	0.2
MO 0105	Edible offal (mammalian)	0.005	4.8	0.0	10.7	0.1	4.0	0.0	4.0	0.0	6.5	0.0	6.6	0.0	5.6	0.0
VO 0440	Eggplant (= aubergine)	0.05	20.1	1.0	0.1	0.0	0.6	0.0	6.3	0.3	0.5	0.0	6.3	0.3	0.7	0.0
FC 0204	Lemon (incl juice)	0.06	0.8	0.0	21.1	1.3	0.0	0.0	0.0	0.0	6.3	0.4	1.5	0.1	0.4	0.0
FC 0003	Mandarin + mandarin-like hybrid (incl juice)	0.06	7.0	0.4	6.5	0.4	0.8	0.0	0.2	0.0	9.3	0.6	19.1	1.1	6.5	0.4
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.07	11.0	0.8	17.9	1.3	6.1	0.4	5.7	0.4	16.4	1.1	12.2	0.9	31.7	2.2
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
ML 0106	Milks (excl processed products)	0.004	66.0	0.3	121.1	0.5	81.6	0.3	102.4	0.4	207.7	0.8	57.0	0.2	287.9	1.2
JF 0004	Orange juice	0.003	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	0.2
FC 0004	Orange, sweet, sour + orange-like hybrid (excl juice)	0.06	7.0	0.4	117.1	7.0	2.0	0.1	2.4	0.1	200.7	12.0	0.5	0.0	0.2	0.0
FP 0230	Pear	0.02	6.4	0.1	1.9	0.0	1.2	0.0	0.0	0.0	1.8	0.0	6.9	0.1	7.8	0.2
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
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
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
FC 0005	Shaddock or pomelo + shaddock-like hybrid (incl juice)	0.06	0.4	0.0	8.6	0.5	1.3	0.1	0.8	0.0	4.2	0.3	4.8	0.3	13.1	0.8
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
VO 0448	Tomato (excl juice, excl paste, incl canned)	0.07	23.1	1.6	22.3	1.6	12.5	0.9	5.6	0.4	33.2	2.3	1.3	0.1	41.7	2.9
JF 0448	Tomato juice	0.02	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	0.9
-d	Tomato paste	0.126	0.1	0.0	2.1	0.3	0.6	0.1	0.4	0.1	0.6	0.1	1.4	0.2	1.2	0.2
	Total intake (µg/person)=			9.9		27.6		4.3		5.7		34.0		9.2		18.5
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			2200		2400		2400		2400		2400		2200		2400
	%ADI=			0.5%		1.1%		0.2%		0.2%		1.4%		0.4%		0.8%
	Rounded %ADI=			0%		1%		0%		0%		1%		0%		1%

CYROMAZINE (169) International Estimated Daily Intake (IEDI) ADI = 0–0.06 mg/kg bw

	STMR or STMR-P	Diets: g/person/day / Intake = daily intake: µg/person					
		A	B	C	D	E	F

Annex 3

Codex Code	Commodity	mg/kg	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
VS 0620	Artichoke globe	1	0.0	0.0	10.0	10.0	2.1	2.1	0.1	0.1	0.8	0.8	0.1	0.1
VD 0071	Beans (dry)	1	15.8	15.8	6.1	6.1	1.7	1.7	6.3	6.3	1.8	1.8	5.0	5.0
VB 0400	Broccoli	0.15	0.0	0.0	0.7	0.1	1.2	0.2	0.1	0.0	4.2	0.6	4.0	0.6
VB 0041	Cabbage, head	0.26	1.2	0.3	14.4	3.7	2.7	0.7	16.4	4.3	15.4	4.0	18.5	4.8
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 0524	Chick-pea (dry)	1	3.3	3.3	5.8	5.8	3.2	3.2	3.1	3.1	0.2	0.2	0.1	0.1
VC 0424	Cucumber	0.48	0.3	0.1	12.7	6.1	5.9	2.8	11.5	5.5	6.1	2.9	7.1	3.4
MO 0105	Edible offal (mammalian)	0.01	3.9	0.0	14.4	0.1	5.2	0.1	11.8	0.1	11.7	0.1	7.6	0.1
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)	0.16	18.8	3.0	233.4	37.3	148.6	23.8	68.8	11.0	38.6	6.2	45.3	7.2
VD 0533	Lentil (dry)	1	0.9	0.9	5.4	5.4	3.1	3.1	1.3	1.3	0.7	0.7	0.1	0.1
VL 0482	Lettuce, head	0.34	0.1	0.0	6.2	2.1	0.7	0.2	0.1	0.0	0.1	0.0	0.0	0.0
VL 0483	Lettuce, leaf	0.34	0.0	0.0	9.2	3.1	1.0	0.3	0.1	0.0	5.4	1.8	18.0	6.1
VP 0534	Lima bean (green pods and/or immature seeds)	0.23	0.0	0.0	0.0	0.0	0.0	0.0	0.9	0.2	0.0	0.0	0.1	0.0
VD 0545	Lupin (dry)	1	0.0	0.0	0.0	0.0	0.1	0.1	0.1	0.1	0.0	0.0	0.0	0.0
FI 0345	Mango (incl juice, incl pulp)	0.125	6.3	0.8	1.0	0.1	4.6	0.6	0.2	0.0	0.7	0.1	0.3	0.0
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
VC 0046	Melons, except watermelon	0.04	3.6	0.1	26.7	1.1	22.6	0.9	11.5	0.5	5.6	0.2	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
VO 0450	Mushrooms	2.2	0.0	0.0	1.5	3.3	0.1	0.2	0.2	0.4	5.3	11.7	1.4	3.1
VL 0485	Mustard greens	2.7	0.3	0.8	0.3	0.8	0.0	0.0	5.5	14.9	0.0	0.0	1.9	5.1
VA 0385	Onion, bulb (= dry + green onion)	0.05	5.5	0.3	49.5	2.5	33.0	1.7	31.3	1.6	23.2	1.2	14.6	0.7
PM 0110	Poultry meat	0.05	7.1	0.4	58.5	2.9	31.9	1.6	24.0	1.2	61.0	3.1	27.3	1.4
PO 0111	Poultry, edible offal of	0.065	0.4	0.0	0.4	0.0	1.7	0.1	0.1	0.0	0.6	0.0	0.2	0.0
VL 0502	Spinach	2	0.0	0.0	5.0	10.0	1.1	2.2	0.1	0.2	2.6	5.2	0.1	0.2
VA 0389	Spring onion	0.345	0.3	0.1	1.0	0.3	1.4	0.5	0.3	0.1	0.3	0.1	0.6	0.2
VC 0431	Squash, summer (= courgette, zuchini)	0.16	0.0	0.0	8.3	1.3	11.4	1.8	7.3	1.2	3.2	0.5	0.3	0.0
VO 0448	Tomato (excl juice, excl paste, excl canned)	0.11	1.3	0.1	178.4	19.6	102.8	11.3	53.4	5.9	1.6	0.2	0.0	0.0
JF 0448	Tomato juice	0.12	5.2	0.6	0.5	0.1	0.4	0.0	2.1	0.3	6.9	0.8	15.2	1.8
-d	Tomato paste	0.34	0.5	0.2	1.3	0.4	3.5	1.2	1.0	0.3	3.8	1.3	4.5	1.5
-d	Tomato, canned	0.09	0.1	0.0	0.4	0.0	0.5	0.0	0.4	0.0	4.9	0.4	3.2	0.3
	Total intake (µg/person)=			27.8		127.2		63.0		63.5		49.3		46.5
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			3600		3600		3600		3600		3600		3600
	%ADI=			0.8%		3.5%		1.7%		1.8%		1.4%		1.3%
	Rounded %ADI=			1%		4%		2%		2%		1%		1%

CYROMAZINE (169) International Estimated Daily Intake (IEDI) ADI = 0–0.06 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G diet	intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake	M diet	intake
VS 0620	Artichoke globe	1	0.1	0.1	0.1	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	1.0
VD 0071	Beans (dry)	1	3.4	3.4	25.5	25.5	7.8	7.8	2.1	2.1	44.7	44.7	5.5	5.5	7.3	7.3
VB 0400	Broccoli	0.15	3.2	0.5	7.8	1.2	0.0	0.0	0.0	0.0	0.3	0.0	0.4	0.1	6.6	1.0
VB 0041	Cabbage, head	0.26	10.0	2.6	1.0	0.3	7.2	1.9	1.0	0.3	1.4	0.4	23.9	6.2	17.0	4.4
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 0524	Chick-pea (dry)	1	5.0	5.0	0.5	0.5	0.6	0.6	0.2	0.2	0.2	0.2	0.0	0.0	0.6	0.6
VC 0424	Cucumber	0.48	7.9	3.8	0.6	0.3	0.2	0.1	0.0	0.0	0.4	0.2	5.5	2.6	5.3	2.5
MO 0105	Edible offal (mammalian)	0.01	4.8	0.0	10.7	0.1	4.0	0.0	4.0	0.0	6.5	0.1	6.6	0.1	5.6	0.1
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)	0.16	56.4	9.0	55.2	8.8	31.0	5.0	47.8	7.6	40.5	6.5	25.4	4.1	112.8	18.0
VD 0533	Lentil (dry)	1	1.1	1.1	1.1	1.1	0.1	0.1	0.2	0.2	1.0	1.0	0.0	0.0	1.6	1.6
VL 0482	Lettuce, head	0.34	1.2	0.4	3.5	1.2	0.1	0.0	0.3	0.1	1.0	0.3	1.2	0.4	7.9	2.7
VL 0483	Lettuce, leaf	0.34	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	0.9
VP 0534	Lima bean (green pods and/or immature seeds)	0.23	2.5	0.6	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.2
VD 0545	Lupin (dry)	1	0.0	0.0	0.7	0.7	0.3	0.3	0.0	0.0	0.1	0.1	0.0	0.0	0.0	0.0
FI 0345	Mango (incl juice, incl pulp)	0.125	12.7	1.6	26.2	3.3	6.1	0.8	12.7	1.6	9.2	1.2	8.0	1.0	1.9	0.2
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
VC 0046	Melons, except watermelon	0.04	7.5	0.3	6.1	0.2	0.7	0.0	1.4	0.1	2.5	0.1	6.9	0.3	12.4	0.5
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
VO 0450	Mushrooms	2.2	0.4	0.9	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.5	1.1	3.9	8.6
VL 0485	Mustard greens	2.7	3.4	9.2	0.4	1.1	2.4	6.5	0.3	0.8	0.5	1.4	7.9	21.3	0.3	0.8
VA 0385	Onion, bulb (= dry + green onion)	0.05	17.4	0.9	27.9	1.4	7.3	0.4	16.0	0.8	22.8	1.1	34.5	1.7	30.1	1.5
PM 0110	Poultry meat	0.05	17.6	0.9	131.3	6.6	25.1	1.3	4.7	0.2	145.9	7.3	27.7	1.4	115.1	5.8
PO 0111	Poultry, edible offal of	0.065	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
VL 0502	Spinach	2	9.4	18.8	0.4	0.8	0.0	0.0	0.0	0.0	0.2	0.4	4.3	8.6	2.0	4.0
VA 0389	Spring onion	0.345	0.1	0.0	4.8	1.7	0.1	0.0	1.0	0.3	1.0	0.3	2.7	0.9	0.6	0.2
VC 0431	Squash, summer (= courgette, zuchini)	0.16	2.4	0.4	1.5	0.2	0.0	0.0	0.0	0.0	3.8	0.6	2.2	0.4	2.5	0.4
VO 0448	Tomato (excl juice, excl paste, excl canned)	0.11	22.8	2.5	4.1	0.5	12.3	1.4	1.8	0.2	32.8	3.6	0.4	0.0	27.3	3.0
JF 0448	Tomato juice	0.12	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	5.4
-d	Tomato paste	0.34	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
-d	Tomato, canned	0.09	0.2	0.0	14.5	1.3	0.2	0.0	0.0	0.0	0.3	0.0	0.8	0.1	1.2	0.1
	Total intake (µg/person)=			64.5		64.3		28.3		16.7		73.4		60.0		80.7
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			3300		3600		3600		3600		3600		3300		3600
	%ADI=			2.0%		1.8%		0.8%		0.5%		2.0%		1.8%		2.2%
	Rounded %ADI=			2%		2%		1%		0%		2%		2%		2%

Annex 3

DICHLORVOS (25) International Estimated Daily Intake (IEDI) ADI = 0–0.004 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
GC 0649	Rice (excl husked, excl polished)	2.8	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 1206	Rice bran, unprocessed	2.94	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CM 0649	Rice, husked (incl milled)	0.448	35.6	15.9	0.2	0.1	2.6	1.2	6.9	3.1	3.3	1.5	0.4	0.2
CM 1205	Rice, polished (incl flour)	0.014	29.8	0.4	20.9	0.3	60.8	0.9	16.1	0.2	5.6	0.1	8.1	0.1
GC 0654	Wheat (excl bulgur wholemeal, excl flour)	2.2	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.2	0.0	0.0
CM 0654	Wheat bran, unprocessed	3.81	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CF 1211	Wheat flour (incl macaroni, bread, pastry, starch, gluten)	0.22	63.4	13.9	296.3	65.2	327.5	72.1	300.0	66.0	181.6	40.0	166.2	36.6
CF 1212	Wheat wholemeal	0.88	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CP 1212	Wholemeal bread	0.12	0.0	0.0	0.1	0.0	0.0	0.0	0.1	0.0	0.1	0.0	1.0	0.1
	Total intake (µg/person)=			30.4		65.6		74.1		69.6		41.8		37.1
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			240		240		240		240		240		240
	%ADI=			12.7%		27.3%		30.9%		29.0%		17.4%		15.4%
	Rounded %ADI=			10%		30%		30%		30%		20%		20%

DICHLORVOS (25) International Estimated Daily Intake (IEDI) ADI = 0–0.004 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G diet	intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake	M diet	intake
GC 0649	Rice (excl husked, excl polished)	2.8	0.0	0.1	0.0	-0.1	0.0	-0.1	0.1	0.3	0.0	-0.1	0.1	0.1	0.0	0.0
CM 1206	Rice bran, unprocessed	2.94	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CM 0649	Rice, husked (incl milled)	0.448	1.1	0.5	0.8	0.4	1.8	0.8	22.7	10.2	70.8	31.7	7.0	3.1	0.3	0.1
CM 1205	Rice, polished (incl flour)	0.014	250.3	3.5	42.2	0.6	23.8	0.3	29.8	0.4	97.6	1.4	248.1	3.5	22.8	0.3
GC 0654	Wheat (excl bulgur wholemeal, excl flour)	2.2	0.0	0.0	0.9	1.9	0.0	0.0	0.0	0.1	0.1	0.2	0.0	0.0	0.1	0.2
CM 0654	Wheat bran, unprocessed	3.81	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CF 1211	Wheat flour (incl macaroni, bread, pastry, starch, gluten)	0.22	133.0	29.3	60.1	13.2	52.4	11.5	32.2	7.1	87.7	19.3	79.6	17.5	180.1	39.6
CF 1212	Wheat wholemeal	0.88	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CP 1212	Wholemeal bread	0.12	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
	Total intake (µg/person)=			33.3		16.2		12.6		18.0		52.5		24.3		40.3
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			220		240		240		240		240		220		240
	%ADI=			15.1%		6.8%		5.2%		7.5%		21.9%		11.0%		16.8%
	Rounded %ADI=			20%		7%		5%		8%		20%		10%		20%

DICOFOL (26) International Estimated Daily Intake (IEDI) ADI = 0–0.002 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
DT 1114	Tea, green, black (black, fermented and dried)	11.2	0.3	3.4	2.4	26.9	2.8	31.4	2.1	23.5	2.0	22.4	0.8	9.0
	Total intake (µg/person)=			3.4		26.9		31.4		23.5		22.4		9.0
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			120		120		120		120		120		120
	%ADI=			2.8%		22.4%		26.1%		19.6%		18.7%		7.5%
	Rounded %ADI=			3%		20%		30%		20%		20%		7%

DICOFOL (26) International Estimated Daily Intake (IEDI) ADI = 0–0.002 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G diet	intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake	M diet	intake
DT 1114	Tea, green, black (black, fermented and dried)	11.2	1.3	14.6	0.2	2.2	0.9	10.1	0.6	6.7	0.1	1.1	1.5	16.8	1.0	11.2
	Total intake (µg/person)=			14.6		2.2		10.1		6.7		1.1		16.8		11.2
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			110		120		120		120		120		110		120
	%ADI=			13.2%		1.9%		8.4%		5.6%		0.9%		15.3%		9.3%
	Rounded %ADI=			10%		2%		8%		6%		1%		20%		9%

DINOTEFURAN (255) International Estimated Daily Intake (IEDI) ADI = 0–0.20 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
VL 0054	Brassica leafy vegetables	1.2	1.0	1.2	5.5	6.6	2.8	3.4	22.1	26.5	0.7	0.8	7.7	9.2
VB 0040	Brassica vegetables	0.4	1.7	0.7	25.7	10.3	9.1	3.6	27.8	11.1	36.9	14.8	26.4	10.6
VS 0624	Celery	0.435	0.0	0.0	0.9	0.4	0.0	0.0	2.0	0.9	1.5	0.7	0.0	0.0
VL 0469	Chicory leaves (green and red)	1.2	0.1	0.1	1.2	1.4	0.1	0.1	0.1	0.1	1.6	1.9	0.0	0.0
VL 0510	Cos lettuce	1.2	0.1	0.1	6.2	7.4	0.7	0.8	0.1	0.1	0.1	0.1	0.0	0.0
SO 0691	Cotton seed (for oil processing only)	0.15	5.6	0.8	30.6	4.6	10.6	1.6	41.3	6.2	0.0	0.0	1.9	0.3
OR 0691	Cotton seed oil, edible	0.0105	0.9	0.0	4.9	0.1	1.7	0.0	6.6	0.1	0.0	0.0	0.3	0.0
FB 0265	Cranberries	0.065	0.1	0.0	0.0	0.0	0.0	0.0	0.3	0.0	0.0	0.0	0.6	0.0
MO 0105	Edible offal (mammalian)	0.03	3.9	0.1	14.4	0.4	5.2	0.2	11.8	0.4	11.7	0.4	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
VL 0476	Endive	1.2	0.0	0.0	0.9	1.1	0.0	0.0	0.1	0.1	1.6	1.9	0.0	0.0
VC 0045	Fruiting vegetables, cucurbits	0.25	26.6	6.7	107.5	26.9	95.9	24.0	82.2	20.6	25.4	6.4	23.2	5.8
VO 0050	Fruiting vegetables other than cucurbits (excl sweet corn, excl mushrooms)	0.15	18.8	2.8	233.4	35.0	148.6	22.3	68.8	10.3	38.6	5.8	45.3	6.8

FB 0269	Grape (excl dried, excl juice, incl wine)	0.22	3.7	0.8	116.8	25.7	25.4	5.6	31.4	6.9	96.3	21.2	35.8	7.9
DF 0269	Grape, dried (= currants, raisins and sultanas)	0.81	0.0	0.0	2.9	2.3	0.4	0.3	0.4	0.3	2.3	1.9	1.7	1.4
JF 0269	Grape juice	0.264	0.0	0.0	0.1	0.0	0.1	0.0	0.1	0.0	1.4	0.4	1.0	0.3
VL 0482	Lettuce, head	1.2	0.1	0.1	6.2	7.4	0.7	0.8	0.1	0.1	0.1	0.1	0.0	0.0
VL 0483	Lettuce, leaf	1.2	0.0	0.0	9.2	11.0	1.0	1.2	0.1	0.1	5.4	6.5	18.0	21.6
MM 0095	Meat from mammals other than marine mammals	0.03	27.7	0.8	116.5	3.5	38.5	1.2	55.1	1.7	90.2	2.7	131.3	3.9
ML 0106	Milks (excl processed products)	0.039	68.8	2.7	190.6	7.4	79.4	3.1	302.6	11.8	179.6	7.0	237.9	9.3
FS 0245	Nectarine	0.28	0.0	0.0	0.5	0.1	3.3	0.9	1.8	0.5	2.8	0.8	1.6	0.4
-	Onion, dry	0.04	4.3	0.2	45.6	1.8	27.4	1.1	30.2	1.2	22.1	0.9	12.2	0.5
FS 0247	Peach	0.28	0.2	0.1	24.8	6.9	3.3	0.9	1.8	0.5	5.4	1.5	1.6	0.4
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
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
VL 0492	Purslane	1.2	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CM 1206	Rice bran, unprocessed	2.112	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
GC 0649	Rice (incl husked, excl polished)	3.3	46.3	152.8	0.3	0.8	3.4	11.2	9.1	29.9	4.3	14.2	0.6	1.8
CM 1205	Rice, polished (incl flour)	0.132	29.8	3.9	20.9	2.8	60.8	8.0	16.1	2.1	5.6	0.7	8.1	1.1
VL 0502	Spinach	1.2	0.0	0.0	5.0	6.0	1.1	1.3	0.1	0.1	2.6	3.1	0.1	0.1
VA 0389	Spring onion	0.91	0.3	0.3	1.0	0.9	1.4	1.3	0.3	0.3	0.3	0.3	0.6	0.5
VL 0473	Watercress	2.9	2.3	6.7	0.0	0.0	3.3	9.6	2.0	5.8	0.1	0.3	0.0	0.0
	Total intake (µg/person)=			180.8		170.9		102.4		137.6		94.1		82.2
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			12000		12000		12000		12000		12000		12000
	%ADI=			1.5%		1.4%		0.9%		1.1%		0.8%		0.7%
	Rounded %ADI=			2%		1%		1%		1%		1%		1%

DINOTEFURAN (255) International Estimated Daily Intake (IEDI) ADI = 0–0.20 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G diet	intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake	M diet	intake
VL 0054	Brassica leafy vegetables	1.2	10.3	12.4	4.0	4.8	7.3	8.8	1.0	1.2	2.0	2.4	23.8	28.6	1.7	2.0
VB 0040	Brassica vegetables	0.4	26.4	10.6	9.3	3.7	7.8	3.1	1.5	0.6	3.3	1.3	40.8	16.3	26.0	10.4
VS 0624	Celery	0.435	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
VL 0469	Chicory leaves (green and red)	1.2	2.4	2.9	0.0	0.0	0.2	0.2	0.6	0.7	0.0	0.0	2.4	2.9	0.1	0.1
VL 0510	Cos lettuce	1.2	1.2	1.4	3.5	4.2	0.1	0.1	0.3	0.4	1.0	1.2	1.2	1.4	7.9	9.4
SO 0691	Cotton seed (for oil processing only)	0.15	6.3	0.9	4.4	0.7	6.3	0.9	8.8	1.3	9.4	1.4	34.4	5.2	7.5	1.1
OR 0691	Cotton seed oil, edible	0.0105	1.0	0.0	0.7	0.0	1.0	0.0	1.4	0.0	1.5	0.0	5.5	0.1	1.2	0.0
FB 0265	Cranberries	0.065	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
MO 0105	Edible offal (mammalian)	0.03	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	0.2
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
VL 0476	Endive	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	0.2	0.2

DINOTEFURAN (255) International Estimated Daily Intake (IEDI) ADI = 0–0.20 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G diet	intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake	M diet	intake
VC 0045	Fruiting vegetables, cucurbits	0.25	69.7	17.4	25.9	6.5	14.9	3.7	18.0	4.5	18.7	4.7	39.1	9.8	44.2	11.1
VO 0050	Fruiting vegetables other than cucurbits (excl sweet corn, excl mushrooms)	0.15	56.4	8.5	55.2	8.3	31.0	4.7	47.8	7.2	40.5	6.1	25.4	3.8	112.8	16.9
FB 0269	Grape (excl dried, excl juice, incl wine)	0.22	2.6	0.6	3.9	0.8	9.5	2.1	0.3	0.1	4.8	1.0	8.7	1.9	43.4	9.5
DF 0269	Grape, dried (= currants, raisins and sultanas)	0.81	0.0	0.0	0.2	0.2	0.2	0.2	0.0	0.0	0.3	0.2	0.4	0.3	2.6	2.1
JF 0269	Grape juice	0.264	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
VL 0482	Lettuce, head	1.2	1.2	1.4	3.5	4.2	0.1	0.1	0.3	0.4	1.0	1.2	1.2	1.4	7.9	9.4
VL 0483	Lettuce, leaf	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
MM 0095	Meat from mammals other than marine mammals	0.03	54.8	1.6	89.4	2.7	30.6	0.9	28.6	0.9	82.1	2.5	61.1	1.8	158.3	4.7
ML 0106	Milks (excl processed products)	0.039	66.0	2.6	121.1	4.7	81.6	3.2	102.4	4.0	207.7	8.1	57.0	2.2	287.9	11.2
FS 0245	Nectarine	0.28	1.7	0.5	1.7	0.5	0.0	0.0	0.0	0.0	1.0	0.3	1.7	0.5	1.4	0.4
-	Onion, dry	0.04	16.8	0.7	8.6	0.3	6.9	0.3	12.1	0.5	18.6	0.7	23.8	1.0	28.4	1.1
FS 0247	Peach	0.28	1.7	0.5	1.7	0.5	1.1	0.3	0.1	0.0	1.0	0.3	1.7	0.5	10.2	2.9
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
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
VL 0492	Purslane	1.2	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CM 1206	Rice bran, unprocessed	2.112	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
GC 0649	Rice (incl husked, excl polished)	3.3	1.4	4.8	1.0	3.3	2.3	7.6	29.6	97.7	92.0	303.6	9.2	30.2	0.4	1.3
CM 1205	Rice, polished (incl flour)	0.132	250.3	33.0	42.2	5.6	23.8	3.1	29.8	3.9	97.6	12.9	248.1	32.7	22.8	3.0
VL 0502	Spinach	1.2	9.4	11.3	0.4	0.5	0.0	0.0	0.0	0.0	0.2	0.2	4.3	5.2	2.0	2.4
VA 0389	Spring onion	0.91	0.1	0.1	4.8	4.4	0.1	0.1	1.0	0.9	1.0	0.9	2.7	2.5	0.6	0.5
VL 0473	Watercress	2.9	7.0	20.3	0.3	0.9	2.3	6.7	3.3	9.6	0.3	0.9	7.4	21.5	0.0	0.0
	Total intake (µg/person)=			131.6		57.1		46.5		133.9		350.7		170.0		106.1
	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%		0.4%		1.1%		2.9%		1.5%		0.9%
	Rounded %ADI=			1%		0%		0%		1%		3%		2%		1%

FENVALERATE (119) International Estimated Daily Intake (IEDI) ADI = 0–0.02 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
VB 0401	Broccoli, Chinese	0.81	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
FI 0345	Mango (incl juice, incl pulp)	0.39	6.3	2.5	1.0	0.4	4.6	1.8	0.2	0.1	0.7	0.3	0.3	0.1
	Total intake (µg/person)=			2.5		0.4		1.8		0.1		0.3		0.1
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			1200		1200		1200		1200		1200		1200
	%ADI=			0.2%		0.0%		0.1%		0.0%		0.0%		0.0%

Rounded %ADI=			0%		0%		0%		0%		0%		0%		0%	

FENVALERATE (119) International Estimated Daily Intake (IEDI) ADI = 0–0.02 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
VB 0401	Broccoli, Chinese	0.81	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
FI 0345	Mango (incl juice, incl pulp)	0.39	12.7	5.0	26.2	10.2	6.1	2.4	12.7	5.0	9.2	3.6	8.0	3.1	1.9	0.7
	Total intake (µg/person)=			5.0		10.2		2.4		5.0		3.6		3.1		0.7
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			1100		1200		1200		1200		1200		1100		1200
	%ADI=			0.5%		0.9%		0.2%		0.4%		0.3%		0.3%		0.1%
	Rounded %ADI=			0%		1%		0%		0%		0%		0%		0%

FLUDIOXONIL (211) International Estimated Daily Intake (IEDI) ADI = 0–0.40 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day Intake = daily intake: µg/person A diet	A intake	B diet	B intake	C diet	C intake	D diet	D intake	E diet	E intake	F diet	F intake
FC 0001	Citrus fruit (incl lemon juice, incl mandarin juice, incl orange juice, incl grapefruit juice, incl NES juice)	0.41	15.7	6.4	100.5	41.2	63.2	25.9	27.8	11.4	52.6	21.6	56.9	23.3
TN 0675	Pistachio nut	0.05	0.0	0.0	0.7	0.0	0.5	0.0	0.9	0.0	0.3	0.0	0.0	0.0
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
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
FS 0012	Stone fruit (excl dried plums, incl dried apricots)	0.8	0.7	0.6	44.1	35.3	14.1	11.3	26.6	21.3	26.3	21.0	8.3	6.6
DF 0014	Plum, dried (prunes)	0.96	0.0	0.0	0.2	0.2	0.0	0.0	0.1	0.1	0.5	0.5	0.6	0.6
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
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 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
FB 0269	Grape (excl dried, excl juice, excl wine)	0.28	1.9	0.5	9.2	2.6	23.8	6.7	9.8	2.7	0.0	0.0	0.0	0.0
DF 0269	Grape, dried (= currants, raisins and sultanas)	0.31	0.0	0.0	2.9	0.9	0.4	0.1	0.4	0.1	2.3	0.7	1.7	0.5
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
-	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
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
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
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
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
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
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
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

FLUDIOXONIL (211)		International Estimated Daily Intake (IEDI)							ADI = 0–0.40 mg/kg bw					
		STMR or STMR-P	Diets: g/person/day			Intake = daily intake: µg/person								
Codex Code	Commodity	mg/kg	A diet	intake	B diet	intake	C diet	intake	D diet	intake	E diet	intake	F diet	intake
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
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
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 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
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
VC 0431	Squash, summer (= courgette, zucchini)	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
VO 0445	Peppers, sweet (incl. pimiento)	0.18	0.7	0.1	14.9	2.7	8.8	1.6	3.2	0.6	3.1	0.6	2.0	0.4
VO 0440	Eggplant (= 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
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
VO 0448	Tomato (excl juice, excl paste, incl canned)	0.12	3.3	0.4	179.2	21.5	103.5	12.4	54.1	6.5	7.8	0.9	3.9	0.5
JF 0448	Tomato juice	0.026	5.2	0.1	0.5	0.0	0.4	0.0	2.1	0.1	6.9	0.2	15.2	0.4
-d	Tomato paste	0.17	0.5	0.1	1.3	0.2	3.5	0.6	1.0	0.2	3.8	0.6	4.5	0.8
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
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
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
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 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
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
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
VP 0064	Peas, shelled (immature seeds only)	0.02	0.0	0.0	0.9	0.0	6.0	0.1	0.6	0.0	9.7	0.2	3.2	0.1
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 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
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 0691	Cotton seed (for oil processing only)	0.05	5.6	0.3	30.6	1.5	10.6	0.5	41.3	2.1	0.0	0.0	1.9	0.1
DH 0170	Dried herbs (excl dry hops)	22	0.2	5.1	0.3	6.2	0.2	5.3	0.4	8.8	0.3	6.6	0.0	0.2
GC 0080	Cereal grains	0.02	356.9	7.1	713.9	14.3	763.0	15.3	504.5	10.1	365.2	7.3	328.7	6.6
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
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
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)=			459.9		352.0		159.1		181.7		209.2		148.6
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			24000		24000		24000		24000		24000		24000
	%ADI=			1.9%		1.5%		0.7%		0.8%		0.9%		0.6%
	Rounded %ADI=			2%		1%		1%		1%		1%		1%

Annex 3

FLUDIOXONIL (211) International Estimated Daily Intake (IEDI) ADI = 0–0.40 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day G diet	Intake = daily intake: µg/person intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake	M diet	intake
FC 0001	Citrus fruit (incl lemon juice, incl mandarin juice, incl orange juice, incl grapefruit juice, incl NES juice)	0.41	17.3	7.1	156.8	64.3	14.9	6.1	42.5	17.4	222.8	91.3	40.4	16.6	132.3	54.2
TN 0675	Pistachio nut	0.05	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	0.0
FP 0009	Pome fruit (excl apple juice)	2.1	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
JF 0226	Apple juice	0.17	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
FS 0012	Stone fruit (excl dried plums, incl dried apricots)	0.8	6.7	5.4	4.3	3.5	1.4	1.1	0.1	0.1	4.9	3.9	4.9	3.9	17.7	14.1
DF 0014	Plum, dried (prunes)	0.96	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	0.6
FB 0020	Blueberries	0.6	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 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 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
FB 0269	Grape (excl dried, excl juice, excl wine)	0.28	1.2	0.3	2.6	0.7	0.0	0.0	0.2	0.0	0.0	0.0	3.7	1.0	0.0	0.0
DF 0269	Grape, dried (= currants, raisins and sultanas)	0.31	0.0	0.0	0.2	0.1	0.2	0.1	0.0	0.0	0.3	0.1	0.4	0.1	2.6	0.8
JF 0269	Grape juice	0.26	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
-	Wine	0.01	1.0	0.0	0.9	0.0	6.8	0.1	0.1	0.0	3.4	0.0	3.6	0.0	31.0	0.3
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
FB 0275	Strawberry	0.27	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
FI 0341	Kiwi fruit	7.2	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
FI 0345	Mango (incl juice, incl pulp)	0.02	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
VR 0508	Sweet potato	3.5	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
VR 0577	Carrot	0.2	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
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
VR 0600	Yams	3.5	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
VA 0385	Onion, bulb (= dry + green onion)	0.04	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
VA 0389	Spring onion	0.59	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
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
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
VC 0431	Squash, summer (= courgette, zucchini)	0.06	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
VO 0445	Peppers, sweet (incl. pimiento)	0.18	0.0	0.0	9.4	1.7	4.2	0.8	4.7	0.8	1.7	0.3	2.6	0.5	4.4	0.8
VO 0440	Eggplant (= 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
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
VO 0448	Tomato (excl juice, excl paste, incl canned)	0.12	23.1	2.8	22.3	2.7	12.5	1.5	5.6	0.7	33.2	4.0	1.3	0.2	41.7	5.0
JF 0448	Tomato juice	0.026	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	1.2
-d	Tomato paste	0.17	0.1	0.0	2.1	0.4	0.6	0.1	0.4	0.1	0.6	0.1	1.4	0.2	1.2	0.2
VB 0041	Cabbage, head	0.24	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
VB 0400	Broccoli	0.23	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
VL 0473	Watercress	1.2	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
VL 0482	Lettuce, head	2.7	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
VL 0485	Mustard greens	1.2	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

FLUDIOXONIL (211) International Estimated Daily Intake (IEDI) ADI = 0–0.40 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day Intake = daily intake: µg/person G diet	intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake	M diet	intake
VP 0061	Beans except broad bean & soya bean (green pods & immature seeds)	0.04	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
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
VP 0063	Peas (green pods and/or immature seeds)	0.04	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
VP 0064	Peas, shelled (immature seeds only)	0.02	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
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 0072	Peas (dry) (= field pea + cowpea)	0.02	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
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 0691	Cotton seed (for oil processing only)	0.05	6.3	0.3	4.4	0.2	6.3	0.3	8.8	0.4	9.4	0.5	34.4	1.7	7.5	0.4
DH 0170	Dried herbs (excl dry hops)	22	0.7	15.4	0.1	1.3	0.2	5.1	0.3	7.3	0.2	4.4	0.1	2.6	0.1	1.1
GC 0080	Cereal grains	0.02	617.0	12.3	487.1	9.7	389.4	7.8	385.7	7.7	440.2	8.8	567.7	11.4	409.9	8.2
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
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
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)=			277.4		173.5		422.7		507.7		186.6		226.8		235.6
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			22000		24000		24000		24000		24000		22000		24000
	%ADI=			1.3%		0.7%		1.8%		2.1%		0.8%		1.0%		1.0%
	Rounded %ADI=			1%		1%		2%		2%		1%		1%		1%

FLUOPYRAM (243) 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 diet	intake	B diet	intake	C diet	intake	D diet	intake	E diet	intake	F 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	0.09	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
FI 0327	Banana	0.175	38.8	6.8	17.4	3.0	16.0	2.8	6.6	1.2	21.5	3.8	33.8	5.9
VD 0071	Beans (dry)	0.01	15.8	0.2	6.1	0.1	1.7	0.0	6.3	0.1	1.8	0.0	5.0	0.1
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
MO 1280	Cattle kidney	0.06	0.4	0.0	4.4	0.3	0.0	0.0	0.9	0.1	0.0	0.0	0.6	0.0
MO 1281	Cattle liver	0.53	0.4	0.2	4.4	2.3	1.7	0.9	0.9	0.5	1.0	0.5	0.6	0.3
FS 0013	Cherries	0.205	0.0	0.0	6.8	1.4	0.9	0.2	6.2	1.3	3.6	0.7	0.4	0.1

Annex 3

	FLUOPYRAM (243)	International Estimated Daily Intake (IEDI)								ADI = 0–0.01 mg/kg bw			
		STMR or	Diets: g/person/day				Intake = daily intake: µg/person						
Codex Code	Commodity	STMR-P mg/kg	A diet	intake	B diet	intake	C diet	intake	D diet	intake	E diet	intake	F diet	intake
VD 0524	Chick-pea (dry)	0.01	3.3	0.0	5.8	0.1	3.2	0.0	3.1	0.0	0.2	0.0	0.1	0.0
VC 0424	Cucumber	0.11	0.3	0.0	12.7	1.4	5.9	0.6	11.5	1.3	6.1	0.7	7.1	0.8
PE 0112	Eggs	0.008	2.5	0.0	29.7	0.2	25.1	0.2	24.5	0.2	37.8	0.3	27.4	0.2
FB 0269	Grape (excl dried, excl juice, excl wine)	0.58	1.9	1.1	9.2	5.4	23.8	13.8	9.8	5.7	0.0	0.0	0.0	0.0
JF 0269	Grape juice	0.012	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)	1.68	0.0	0.0	2.9	4.9	0.4	0.7	0.4	0.7	2.3	3.9	1.7	2.9
VD 0533	Lentil (dry)	0.01	0.9	0.0	5.4	0.1	3.1	0.0	1.3	0.0	0.7	0.0	0.1	0.0
VD 0545	Lupin (dry)	0.01	0.0	0.0	0.0	0.0	0.1	0.0	0.1	0.0	0.0	0.0	0.0	0.0
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.06	5.5	0.3	23.3	1.4	7.7	0.5	11.0	0.7	18.0	1.1	26.3	1.6
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0.05	22.2	1.1	93.2	4.7	30.8	1.5	44.1	2.2	72.2	3.6	105.0	5.3
ML 0106	Milks (excl processed products)	0.05	68.8	3.4	190.6	9.5	79.4	4.0	302.6	15.1	179.6	9.0	237.9	11.9
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
OR 0697	Peanut oil, edible	0.0001	1.7	0.0	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
VO 0051	Peppers	0.085	1.4	0.1	29.9	2.5	13.0	1.1	6.3	0.5	6.2	0.5	4.0	0.3
FP 0009	Pome fruit (excl apple juice)	0.135	0.5	0.1	79.9	10.8	21.8	2.9	43.6	5.9	51.5	7.0	35.1	4.7
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: 10% as fat	0.01	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	0.01	6.4	0.1	52.7	0.5	28.7	0.3	21.6	0.2	54.9	0.5	24.6	0.2
PO 0113	Poultry skin	0.02	0.1	0.0	0.0	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0
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
MO 1288	Sheep kidney	0.06	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
MO 1289	Sheep liver	0.53	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
FB 0275	Strawberry	0.025	0.0	0.0	5.0	0.1	2.0	0.1	1.7	0.0	5.2	0.1	4.1	0.1
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
VO 0448	Tomato (excl juice, excl paste, excl canned)	0.09	1.3	0.1	178.4	16.1	102.8	9.3	53.4	4.8	1.6	0.1	0.0	0.0
JF 0448	Tomato juice	0.03	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	0.04	0.5	0.0	1.3	0.1	3.5	0.1	1.0	0.0	3.8	0.2	4.5	0.2
-d	Tomato, canned	0.02	0.1	0.0	0.4	0.0	0.5	0.0	0.4	0.0	4.9	0.1	3.2	0.1
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
-	Wine	0.1	1.3	0.1	76.8	7.7	1.1	0.1	15.4	1.5	68.8	6.9	25.6	2.6
	Total intake (µg/person)=			14.3		79.4		41.1		46.0		44.9		42.7
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			600		600		600		600		600		600
	%ADI=			2.4%		13.2%		6.8%		7.7%		7.5%		7.1%
	Rounded %ADI=			2%		10%		7%		8%		7%		7%

FLUOPYRAM (243) 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
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	0.09	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
FI 0327	Banana	0.175	21.4	3.7	36.6	6.4	11.4	2.0	9.2	1.6	70.2	12.3	40.5	7.1	32.6	5.7
VD 0071	Beans (dry)	0.01	3.4	0.0	25.5	0.3	7.8	0.1	2.1	0.0	44.7	0.4	5.5	0.1	7.3	0.1
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
MO 1280	Cattle kidney	0.06	0.0	0.0	0.9	0.1	0.4	0.0	0.2	0.0	0.7	0.0	0.0	0.0	0.0	0.0
MO 1281	Cattle liver	0.53	0.0	0.0	0.9	0.5	0.4	0.2	0.2	0.1	0.7	0.4	0.0	0.0	0.4	0.2
FS 0013	Cherries	0.205	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
VD 0524	Chick-pea (dry)	0.01	5.0	0.1	0.5	0.0	0.6	0.0	0.2	0.0	0.2	0.0	0.0	0.0	0.6	0.0
VC 0424	Cucumber	0.11	7.9	0.9	0.6	0.1	0.2	0.0	0.0	0.0	0.4	0.0	5.5	0.6	5.3	0.6
PE 0112	Eggs	0.008	22.1	0.2	71.5	0.6	16.6	0.1	5.1	0.0	17.6	0.1	35.2	0.3	57.4	0.5
FB 0269	Grape (excl dried, excl juice, excl wine)	0.58	1.2	0.7	2.6	1.5	0.0	0.0	0.2	0.1	0.0	0.0	3.7	2.1	0.0	0.0
JF 0269	Grape juice	0.012	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)	1.68	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
VD 0533	Lentil (dry)	0.01	1.1	0.0	1.1	0.0	0.1	0.0	0.2	0.0	1.0	0.0	0.0	0.0	1.6	0.0
VD 0545	Lupin (dry)	0.01	0.0	0.0	0.7	0.0	0.3	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.0
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.06	11.0	0.7	17.9	1.1	6.1	0.4	5.7	0.3	16.4	1.0	12.2	0.7	31.7	1.9
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0.05	43.8	2.2	71.5	3.6	24.5	1.2	22.9	1.1	65.7	3.3	48.9	2.4	126.6	6.3
ML 0106	Milks (excl processed products)	0.05	66.0	3.3	121.1	6.1	81.6	4.1	102.4	5.1	207.7	10.4	57.0	2.9	287.9	14.4
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
OR 0697	Peanut oil, edible	0.0001	3.0	0.0	0.3	0.0	1.5	0.0	7.9	0.0	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
VO 0051	Peppers	0.085	8.7	0.7	22.4	1.9	8.4	0.7	9.4	0.8	3.3	0.3	5.3	0.5	8.9	0.8
FP 0009	Pome fruit (excl apple juice)	0.135	20.8	2.8	11.6	1.6	3.3	0.4	0.1	0.0	10.7	1.4	23.6	3.2	36.9	5.0
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: 10% as fat	0.01	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	0.01	15.8	0.2	118.2	1.2	22.6	0.2	4.2	0.0	131.3	1.3	24.9	0.2	103.6	1.0
PO 0113	Poultry skin	0.02	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0	1.9	0.0
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
MO 1288	Sheep kidney	0.06	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-

Annex 3

FLUOPYRAM (243) 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
MO 1289	Sheep liver	0.53	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
FB 0275	Strawberry	0.025	0.0	0.0	1.8	0.0	0.1	0.0	0.0	0.0	0.3	0.0	6.2	0.2	5.9	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
VO 0448	Tomato (excl juice, excl paste, excl canned)	0.09	22.8	2.1	4.1	0.4	12.3	1.1	1.8	0.2	32.8	3.0	0.4	0.0	27.3	2.5
JF 0448	Tomato juice	0.03	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	0.04	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	0.0
-d	Tomato, canned	0.02	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
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
-	Wine	0.1	1.0	0.1	0.9	0.1	6.8	0.7	0.1	0.0	3.4	0.3	3.6	0.4	31.0	3.1
	Total intake (µg/person)=			19.0		27.8		12.7		10.2		36.3		23.3		53.7
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			550		600		600		600		600		550		600
	%ADI=			3.5%		4.6%		2.1%		1.7%		6.0%		4.2%		9.0%
	Rounded %ADI=			3%		5%		2%		2%		6%		4%		9%

FLUXAPYROXAD (256) International Estimated Daily Intake (IEDI) ADI = 0–0.02 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
GC 0640	Barley (incl pot, incl pearled, incl flour & grits, incl beer)	0.535	40.6	21.7	16.8	9.0	93.9	50.2	13.2	7.1	48.6	26.0	36.1	19.3
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)	0.65	1.0	0.7	17.4	11.3	7.5	4.9	0.9	0.6	16.4	10.7	0.1	0.1
VP 0062	Beans, shelled (immature seeds)	0.03	0.5	0.0	12.7	0.4	4.1	0.1	0.9	0.0	13.1	0.4	0.1	0.0
VD 0524	Chick-pea (dry)	0.04	3.3	0.1	5.8	0.2	3.2	0.1	3.1	0.1	0.2	0.0	0.1	0.0
SO 0691	Cotton seed (for oil processing only)	0	5.6	0.0	30.6	0.0	10.6	0.0	41.3	0.0	0.0	0.0	1.9	0.0
MO 0105	Edible offal (mammalian)	0.081	3.9	0.3	14.4	1.2	5.2	0.4	11.8	1.0	11.7	0.9	7.6	0.6
PE 0112	Eggs	0.006	2.5	0.0	29.7	0.2	25.1	0.2	24.5	0.1	37.8	0.2	27.4	0.2
VO 0050	Fruiting vegetables other than cucurbits (excl sweet corn, excl mushrooms)	0.07	18.8	1.3	233.4	16.3	148.6	10.4	68.8	4.8	38.6	2.7	45.3	3.2

FLUXAPYROXAD (256) International Estimated Daily Intake (IEDI) ADI = 0–0.02 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
VD 0533	Lentil (dry)	0.04	0.9	0.0	5.4	0.2	3.1	0.1	1.3	0.1	0.7	0.0	0.1	0.0
GC 0645	Maize (incl flour, incl oil, incl beer)	0.01	82.7	0.8	148.4	1.5	135.9	1.4	31.8	0.3	33.3	0.3	7.5	0.1
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.047	5.5	0.3	23.3	1.1	7.7	0.4	11.0	0.5	18.0	0.8	26.3	1.2
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0.02	22.2	0.4	93.2	1.9	30.8	0.6	44.1	0.9	72.2	1.4	105.0	2.1
ML 0106	Milks (excl processed products)	0.004	68.8	0.3	190.6	0.8	79.4	0.3	302.6	1.2	179.6	0.7	237.9	1.0
GC 0647	Oats (incl rolled)	0.535	1.4	0.7	0.6	0.3	0.2	0.1	4.2	2.2	5.7	3.0	8.9	4.8
SO 0089	Oilseed (except peanut)	0.09	16.9	1.5	62.1	5.6	33.3	3.0	51.3	4.6	58.1	5.2	38.0	3.4
SO 0697	Peanut, shelled (incl oil)	0.01	5.4	0.1	3.1	0.0	2.1	0.0	0.7	0.0	4.0	0.0	1.4	0.0
VD 0072	Peas (dry) (= field pea + cowpea)	0.04	6.8	0.3	1.3	0.1	1.0	0.0	2.3	0.1	4.6	0.2	3.4	0.1
VP 0063	Peas (green pods and/or immature seeds)	0.65	0.1	0.1	2.9	1.9	6.0	3.9	0.6	0.4	9.7	6.3	5.2	3.4
VP 0064	Peas, shelled (immature seeds only)	0.03	0.0	0.0	0.9	0.0	6.0	0.2	0.6	0.0	9.7	0.3	3.2	0.1
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
FP 0009	Pome fruit (excl apple juice)	0.3	0.5	0.2	79.9	24.0	21.8	6.5	43.6	13.1	51.5	15.5	35.1	10.5
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: 10% as fat	0.021	0.7	0.0	5.9	0.1	3.2	0.1	2.4	0.1	6.1	0.1	2.7	0.1
PM 0110	Poultry meat: 90% as muscle	0.02	6.4	0.1	52.7	1.1	28.7	0.6	21.6	0.4	54.9	1.1	24.6	0.5
PO 0111	Poultry, edible offal of	0.021	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 0650	Rye (incl flour)	0.085	0.1	0.0	3.7	0.3	0.3	0.0	24.3	2.1	25.8	2.2	45.8	3.9
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
VP 0541	Soya bean (immature seeds only)	0.01	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 (excl dried plums, incl dried apricots)	0.525	0.7	0.4	44.1	23.2	14.1	7.4	26.6	14.0	26.3	13.8	8.3	4.3
VR 0596	Sugar beet	0.04	0.0	0.0	40.7	1.6	0.0	0.0	0.1	0.0	6.0	0.2	0.1	0.0
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
GC 0653	Triticale (incl flour)	0.085	0.0	0.0	115.8	9.8	0.0	0.0	0.0	0.0	0.3	0.0	0.0	0.0
GC 0654	Wheat (incl bulgur wholemeal, excl flour)	0.085	6.0	0.5	11.1	0.9	0.8	0.1	0.2	0.0	0.2	0.0	0.0	0.0
CM 0654	Wheat bran, unprocessed	0.25	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CF 1211	Wheat flour (incl macaroni, bread, pastry, starch, gluten)	0.014	63.4	0.9	296.3	4.1	327.5	4.6	300.0	4.2	181.6	2.5	166.2	2.3
CF 1210	Wheat germ	0.1	0.0	0.0	1.3	0.1	0.0	0.0	1.3	0.1	0.9	0.1	1.2	0.1
CF 1212	Wheat wholemeal	0.082	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CP 1211	White bread	0.01	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	0.054	0.0	0.0	0.1	0.0	0.0	0.0	0.1	0.0	0.1	0.0	1.0	0.1
	Total intake (µg/person)=			31.9		119.9		96.7		61.2		98.7		65.1
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			1200		1200		1200		1200		1200		1200
	%ADI=			2.7%		10.0%		8.1%		5.1%		8.2%		5.4%
	Rounded %ADI=			3%		10%		8%		5%		8%		5%

Annex 3

FLUXAPYROXAD (256) International Estimated Daily Intake (IEDI) ADI = 0–0.02 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day G diet	Intake = daily intake: µg/person intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake	M 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
GC 0640	Barley (incl pot, incl pearled, incl flour & grits, incl beer)	0.535	5.9	3.2	20.5	11.0	5.9	3.2	2.5	1.3	20.2	10.8	16.8	9.0	43.8	23.4
VD 0071	Beans (dry)	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 0061	Beans except broad bean & soya bean (green pods & immature seeds)	0.65	2.6	1.7	2.6	1.7	1.0	0.7	0.5	0.3	0.6	0.4	2.8	1.8	9.8	6.4
VP 0062	Beans, shelled (immature seeds)	0.03	2.6	0.1	1.9	0.1	1.0	0.0	0.5	0.0	0.3	0.0	1.8	0.1	9.0	0.3
VD 0524	Chick-pea (dry)	0.04	5.0	0.2	0.5	0.0	0.6	0.0	0.2	0.0	0.2	0.0	0.0	0.0	0.6	0.0
SO 0691	Cotton seed (for oil processing only)	0	6.3	0.0	4.4	0.0	6.3	0.0	8.8	0.0	9.4	0.0	34.4	0.0	7.5	0.0
MO 0105	Edible offal (mammalian)	0.081	4.8	0.4	10.7	0.9	4.0	0.3	4.0	0.3	6.5	0.5	6.6	0.5	5.6	0.5
PE 0112	Eggs	0.006	22.1	0.1	71.5	0.4	16.6	0.1	5.1	0.0	17.6	0.1	35.2	0.2	57.4	0.3
VO 0050	Fruiting vegetables other than cucurbits (excl sweet corn, excl mushrooms)	0.07	56.4	3.9	55.2	3.9	31.0	2.2	47.8	3.3	40.5	2.8	25.4	1.8	112.8	7.9
VD 0533	Lentil (dry)	0.04	1.1	0.0	1.1	0.0	0.1	0.0	0.2	0.0	1.0	0.0	0.0	0.0	1.6	0.1
GC 0645	Maize (incl flour, incl oil, incl beer)	0.01	35.2	0.4	298.6	3.0	248.1	2.5	57.4	0.6	63.1	0.6	58.6	0.6	85.5	0.9
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.047	11.0	0.5	17.9	0.8	6.1	0.3	5.7	0.3	16.4	0.8	12.2	0.6	31.7	1.5
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0.02	43.8	0.9	71.5	1.4	24.5	0.5	22.9	0.5	65.7	1.3	48.9	1.0	126.6	2.5
ML 0106	Milks (excl processed products)	0.004	66.0	0.3	121.1	0.5	81.6	0.3	102.4	0.4	207.7	0.8	57.0	0.2	287.9	1.2
GC 0647	Oats (incl rolled)	0.535	0.2	0.1	2.0	1.1	0.8	0.4	0.0	0.0	3.5	1.9	0.7	0.4	7.6	4.1
SO 0089	Oilseed (except peanut)	0.09	18.6	1.7	17.7	1.6	20.2	1.8	18.1	1.6	6.5	0.6	62.0	5.6	23.0	2.1
SO 0697	Peanut, shelled (incl oil)	0.01	7.6	0.1	2.1	0.0	4.7	0.0	21.8	0.2	0.9	0.0	0.7	0.0	6.9	0.1
VD 0072	Peas (dry) (= field pea + cowpea)	0.04	1.8	0.1	2.2	0.1	3.2	0.1	26.7	1.1	1.5	0.1	1.8	0.1	1.8	0.1
VP 0063	Peas (green pods and/or immature seeds)	0.65	3.9	2.5	1.6	1.0	0.4	0.3	0.0	0.0	0.9	0.6	1.0	0.7	8.6	5.6
VP 0064	Peas, shelled (immature seeds only)	0.03	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
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)	0.3	20.8	6.2	11.6	3.5	3.3	1.0	0.1	0.0	10.7	3.2	23.6	7.1	36.9	11.1
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: 10% as fat	0.021	1.8	0.0	13.1	0.3	2.5	0.1	0.5	0.0	14.6	0.3	2.8	0.1	11.5	0.2
PM 0110	Poultry meat: 90% as muscle	0.02	15.8	0.3	118.2	2.4	22.6	0.5	4.2	0.1	131.3	2.6	24.9	0.5	103.6	2.1
PO 0111	Poultry, edible offal of	0.021	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 0650	Rye (incl flour)	0.085	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	0.1
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
VP 0541	Soya bean (immature seeds only)	0.01	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 (excl dried plums, incl dried apricots)	0.525	6.7	3.5	4.3	2.3	1.4	0.7	0.1	0.1	4.9	2.6	4.9	2.6	17.7	9.3
VR 0596	Sugar beet	0.04	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	0.6
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

FLUXAPYROXAD (256) International Estimated Daily Intake (IEDI) ADI = 0–0.02 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G diet	intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake	M diet	intake
GC 0653	Triticale (incl flour)	0.085	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, excl flour)	0.085	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	0.25	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CF 1211	Wheat flour (incl macaroni, bread, pastry, starch, gluten)	0.014	133.0	1.9	60.1	0.8	52.4	0.7	32.2	0.5	87.7	1.2	79.6	1.1	180.1	2.5
CF 1210	Wheat germ	0.1	0.1	0.0	48.1	4.8	1.8	0.2	0.0	0.0	0.0	0.0	0.0	0.0	0.6	0.1
CF 1212	Wheat wholemeal	0.082	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CP 1211	White bread	0.01	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	0.054	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
	Total intake (µg/person)=			29.5		44.3		16.9		11.0		35.1		35.6		87.0
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			1100		1200		1200		1200		1200		1100		1200
	%ADI=			2.7%		3.7%		1.4%		0.9%		2.9%		3.2%		7.3%
	Rounded %ADI=			3%		4%		1%		1%		3%		3%		7%

Annex 3

GLUFOSINATE-AMMONIUM (175) 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 diet	intake	B diet	intake	C diet	intake	D diet	intake	E diet	intake	F diet	intake
VS 0621	Asparagus	0.05	0.0	0.0	1.1	0.1	0.6	0.0	0.2	0.0	1.2	0.1	0.1	0.0
FT 0026	Assorted tropical and subtropical fruits - edible peel	0.05	9.6	0.5	9.7	0.5	36.8	1.8	5.8	0.3	3.1	0.2	1.6	0.1
FI 0030	Assorted tropical and subtropical fruits - inedible peel	0.05	338.9	16.9	37.6	1.9	22.8	1.1	8.0	0.4	50.8	2.5	44.9	2.2
FB 0020	Blueberries	0.05	0.0	0.0	0.0	0.0	0.0	0.0	0.2	0.0	0.3	0.0	0.8	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
FC 0001	Citrus fruit (incl lemon juice, incl mandarin juice, incl orange juice, incl grapefruit juice, incl NES juice)	0.05	15.7	0.8	100.5	5.0	63.2	3.2	27.8	1.4	52.6	2.6	56.9	2.8
SB 0716	Coffee beans (incl green, incl extracts, incl roasted)	0.04	3.1	0.1	12.6	0.5	2.9	0.1	1.4	0.1	10.1	0.4	18.0	0.7
VP 0526	Common bean (green pods and/or immature seeds)	0.05	0.5	0.0	4.7	0.2	4.1	0.2	0.0	0.0	13.1	0.7	0.0	0.0
VL 0470	Corn salad	0.05	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
SO 0691	Cotton seed (for oil processing only)	0.625	5.6	3.5	30.6	19.1	10.6	6.6	41.3	25.8	0.0	0.0	1.9	1.2
OR 0691	Cotton seed oil, edible	0.012	0.9	0.0	4.9	0.1	1.7	0.0	6.6	0.1	0.0	0.0	0.3	0.0
FB 0021	Currants, red, black, white	0.02	0.0	0.0	0.0	0.0	0.0	0.0	2.2	0.0	3.1	0.1	2.0	0.0
MO 0105	Edible offal (mammalian)	0.708	3.9	2.8	14.4	10.2	5.2	3.7	11.8	8.4	11.7	8.3	7.6	5.4
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 0268	Gooseberries	0.02	0.0	0.0	12.0	0.2	0.0	0.0	0.6	0.0	1.1	0.0	0.2	0.0
FB 0269	Grape (incl dried, incl juice, incl wine)	0.015	3.7	0.1	128.5	1.9	27.1	0.4	33.1	0.5	107.5	1.6	44.0	0.7
VL 0482	Lettuce, head	0.05	0.1	0.0	6.2	0.3	0.7	0.0	0.1	0.0	0.1	0.0	0.0	0.0
VL 0483	Lettuce, leaf	0.05	0.0	0.0	9.2	0.5	1.0	0.1	0.1	0.0	5.4	0.3	18.0	0.9
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
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	0.03	22.2	0.7	93.2	2.8	30.8	0.9	44.1	1.3	72.2	2.2	105.0	3.2
ML 0106	Milks (excl processed products)	0.012	68.8	0.8	190.6	2.3	79.4	1.0	302.6	3.6	179.6	2.2	237.9	2.9
VA 0385	Onion, bulb (= dry + green onion)	0.05	5.5	0.3	49.5	2.5	33.0	1.7	31.3	1.6	23.2	1.2	14.6	0.7
DF 0014	Plum, dried (prunes)	0.09	0.0	0.0	0.2	0.0	0.0	0.0	0.1	0.0	0.5	0.0	0.6	0.1
FP 0009	Pome fruit (incl apple juice)	0.05	0.5	0.0	84.1	4.2	21.9	1.1	45.2	2.3	61.7	3.1	46.2	2.3
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	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 (excl oil)	0.17	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	0.082	0.3	0.0	0.7	0.1	1.0	0.1	0.7	0.1	13.7	1.1	10.0	0.8
FB 0272	Raspberries, red, black	0.01	0.0	0.0	0.0	0.0	0.0	0.0	1.8	0.0	0.9	0.0	0.2	0.0
GC 0649	Rice (incl husked, excl polished)	0.08	46.3	3.7	0.3	0.0	3.4	0.3	9.1	0.7	4.3	0.3	0.6	0.0

GLUFOSINATE-AMMONIUM (175) 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 diet	intake	B diet	intake	C diet	intake	D diet	intake	E diet	intake	F diet	intake
CM 1205	Rice, polished (incl flour)	0.0616	29.8	1.8	20.9	1.3	60.8	3.7	16.1	1.0	5.6	0.3	8.1	0.5
FS 0012	Stone fruit (excl dried plums, incl dried apricots)	0.05	0.7	0.0	44.1	2.2	14.1	0.7	26.6	1.3	26.3	1.3	8.3	0.4
VR 0596	Sugar beet	0.22	0.0	0.0	40.7	9.0	0.0	0.0	0.1	0.0	6.0	1.3	0.1	0.0
SO 0702	Sunflower seed (excl oil)	0.47	0.0	0.0	13.1	6.1	0.0	0.0	0.1	0.0	0.1	0.0	0.1	0.1
OR 0702	Sunflower seed oil, edible	0.033	0.3	0.0	13.1	0.4	8.6	0.3	12.3	0.4	8.8	0.3	2.2	0.1
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
	Total intake (µg/person)=			37.6		89.4		37.7		64.3		45.5		38.5
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			600		600		600		600		600		600
	%ADI=			6.3%		14.9%		6.3%		10.7%		7.6%		6.4%
	Rounded %ADI=			6%		10%		6%		10%		8%		6%

GLUFOSINATE-AMMONIUM (175) 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 diet	intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake	M diet	intake
VS 0621	Asparagus	0.05	3.7	0.2	0.3	0.0	0.2	0.0	0.0	0.0	0.0	0.0	0.5	0.0	1.1	0.1
FT 0026	Assorted tropical and subtropical fruits - edible peel	0.05	2.8	0.1	0.6	0.0	0.2	0.0	3.9	0.2	17.3	0.9	6.7	0.3	2.3	0.1
FI 0030	Assorted tropical and subtropical fruits - inedible peel	0.05	48.5	2.4	156.2	7.8	128.5	6.4	90.2	4.5	168.1	8.4	125.0	6.3	63.5	3.2
FB 0020	Blueberries	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	1.3	0.1
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
FC 0001	Citrus fruit (incl lemon juice, incl mandarin juice, incl orange juice, incl grapefruit juice, incl NES juice)	0.05	17.3	0.9	156.8	7.8	14.9	0.7	42.5	2.1	222.8	11.1	40.4	2.0	132.3	6.6
SB 0716	Coffee beans (incl green, incl extracts, incl roasted)	0.04	0.2	0.0	7.0	0.3	0.5	0.0	0.2	0.0	5.3	0.2	5.7	0.2	12.4	0.5
VP 0526	Common bean (green pods and/or immature seeds)	0.05	0.0	0.0	1.9	0.1	0.0	0.0	0.0	0.0	0.3	0.0	1.8	0.1	8.0	0.4
VL 0470	Corn salad	0.05	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
SO 0691	Cotton seed (for oil processing only)	0.625	6.3	3.9	4.4	2.7	6.3	3.9	8.8	5.5	9.4	5.9	34.4	21.5	7.5	4.7
OR 0691	Cotton seed oil, edible	0.012	1.0	0.0	0.7	0.0	1.0	0.0	1.4	0.0	1.5	0.0	5.5	0.1	1.2	0.0
FB 0021	Currants, red, black, white	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	0.0	0.0
MO 0105	Edible offal (mammalian)	0.708	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
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 0268	Gooseberries	0.02	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0	0.0	0.0
FB 0269	Grape (incl dried, incl juice, incl wine)	0.015	2.6	0.0	4.8	0.1	11.7	0.2	0.3	0.0	6.8	0.1	10.9	0.2	58.8	0.9

Annex 3

GLUFOSINATE-AMMONIUM (175) 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 diet	intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake	M diet	intake
VL 0482	Lettuce, head	0.05	1.2	0.1	3.5	0.2	0.1	0.0	0.3	0.0	1.0	0.1	1.2	0.1	7.9	0.4
VL 0483	Lettuce, leaf	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	2.5	0.1
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
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	0.03	43.8	1.3	71.5	2.1	24.5	0.7	22.9	0.7	65.7	2.0	48.9	1.5	126.6	3.8
ML 0106	Milks (excl processed products)	0.012	66.0	0.8	121.1	1.5	81.6	1.0	102.4	1.2	207.7	2.5	57.0	0.7	287.9	3.5
VA 0385	Onion, bulb (= dry + green onion)	0.05	17.4	0.9	27.9	1.4	7.3	0.4	16.0	0.8	22.8	1.1	34.5	1.7	30.1	1.5
DF 0014	Plum, dried (prunes)	0.09	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 (incl apple juice)	0.05	20.9	1.0	12.3	0.6	3.4	0.2	0.1	0.0	11.7	0.6	24.9	1.2	45.4	2.3
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	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 (excl oil)	0.17	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	0.082	3.8	0.3	2.3	0.2	0.1	0.0	0.4	0.0	0.0	0.0	6.0	0.5	3.8	0.3
FB 0272	Raspberries, red, black	0.01	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.2	0.0	0.0	0.0	0.5	0.0
GC 0649	Rice (incl husked, excl polished)	0.08	1.4	0.1	1.0	0.1	2.3	0.2	29.6	2.4	92.0	7.4	9.2	0.7	0.4	0.0
CM 1205	Rice, polished (incl flour)	0.0616	250.3	15.4	42.2	2.6	23.8	1.5	29.8	1.8	97.6	6.0	248.1	15.3	22.8	1.4
FS 0012	Stone fruit (excl dried plums, incl dried apricots)	0.05	6.7	0.3	4.3	0.2	1.4	0.1	0.1	0.0	4.9	0.2	4.9	0.2	17.7	0.9
VR 0596	Sugar beet	0.22	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	3.1
SO 0702	Sunflower seed (excl oil)	0.47	0.1	0.0	0.2	0.1	0.1	0.0	0.0	0.0	0.0	0.0	0.1	0.1	1.8	0.8
OR 0702	Sunflower seed oil, edible	0.033	1.1	0.0	3.6	0.1	5.6	0.2	0.1	0.0	1.5	0.0	0.2	0.0	3.6	0.1
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
	Total intake (µg/person)=			37.1		55.1		34.0		25.7		58.8		64.6		53.7
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			550		600		600		600		600		550		600
	%ADI=			6.7%		9.2%		5.7%		4.3%		9.8%		11.7%		8.9%
	Rounded %ADI=			7%		9%		6%		4%		10%		10%		9%

IMIDACLOPRID (206) International Estimated Daily Intake (IEDI) ADI = 0–0.06 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day A diet	intake	B diet	intake	C diet	intake	D diet	intake	E diet	intake	F diet	intake
			Intake = daily intake: µg/person											
FP 0226	Apple (excl juice)	0.07	0.3	0.0	56.3	3.9	18.4	1.3	38.3	2.7	40.6	2.8	28.3	2.0
JF 0226	Apple juice	0.046	0.0	0.0	2.8	0.1	0.1	0.0	1.1	0.1	6.8	0.3	7.4	0.3
DF 0226	Apple, dried	0.061	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
FS 0240	Apricot (incl dried)	0.12	0.3	0.0	6.2	0.7	3.9	0.5	3.2	0.4	2.0	0.2	0.8	0.1
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
VP 0061	Beans except broad bean & soya bean (green pods & immature seeds)	0.4	1.0	0.4	17.4	7.0	7.5	3.0	0.9	0.4	16.4	6.6	0.1	0.0
FB 0264	Blackberries	0.89	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	0.89	0.0	0.0	0.0	0.0	0.0	0.0	0.2	0.2	0.3	0.3	0.8	0.7
FB 4079	Boysenberry	0.89	0.0	0.0	0.0	0.0	0.0	0.0	0.3	0.3	0.0	0.0	0.3	0.3
VB 0400	Broccoli	0.08	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 0402	Brussels sprouts	0.08	0.0	0.0	0.1	0.0	2.8	0.2	5.5	0.4	1.5	0.1	1.9	0.2
VB 0041	Cabbage, head	0.08	1.2	0.1	14.4	1.2	2.7	0.2	16.4	1.3	15.4	1.2	18.5	1.5
VB 0404	Cauliflower	0.08	0.1	0.0	5.2	0.4	1.2	0.1	0.1	0.0	1.7	0.1	0.1	0.0
VS 0624	Celery	0.365	0.0	0.0	0.9	0.3	0.0	0.0	2.0	0.7	1.5	0.5	0.0	0.0
GC 0080	Cereal grains	0.05	356.9	17.8	713.9	35.7	763.0	38.2	504.5	25.2	365.2	18.3	328.7	16.4
FS 0244	Cherries, sweet	0.14	0.0	0.0	5.4	0.8	0.9	0.1	3.5	0.5	2.1	0.3	0.4	0.1
FC 0001	Citrus fruit (excl lemon juice, excl mandarin juice, excl orange juice, excl grapefruit juice, excl NES juice)	0.05	15.7	0.8	86.5	4.3	52.6	2.6	24.2	1.2	16.2	0.8	12.0	0.6
-	Citrus juice NES	0.014	0.0	0.0	1.7	0.0	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)	0.35	3.1	1.1	12.6	4.4	2.9	1.0	1.4	0.5	10.1	3.5	18.0	6.3
FB 0265	Cranberries	0.05	0.1	0.0	0.0	0.0	0.0	0.0	0.3	0.0	0.0	0.0	0.6	0.0
VC 0424	Cucumber	0.31	0.3	0.1	12.7	3.9	5.9	1.8	11.5	3.6	6.1	1.9	7.1	2.2
FB 0021	Currants, red, black, white	0.89	0.0	0.0	0.0	0.0	0.0	0.0	2.2	2.0	3.1	2.8	2.0	1.8
FB 0266	Dewberries, incl boysen- & loganberry	0.89	0.0	0.0	0.0	0.0	0.0	0.0	0.3	0.3	0.0	0.0	0.3	0.3
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
VO 0440	Egg plant (= aubergine)	0.05	1.7	0.1	17.5	0.9	12.3	0.6	1.7	0.1	0.8	0.0	0.4	0.0
PE 0112	Eggs	0.003	2.5	0.0	29.7	0.1	25.1	0.1	24.5	0.1	37.8	0.1	27.4	0.1
FB 0267	Elderberries	0.89	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
FB 0268	Gooseberries	0.89	0.0	0.0	12.0	10.7	0.0	0.0	0.6	0.5	1.1	1.0	0.2	0.2
FB 0269	Grape (incl dried, excl juice, incl wine)	0.11	3.7	0.4	128.4	14.1	27.0	3.0	33.0	3.6	105.5	11.6	42.6	4.7
JF 0269	Grape juice	0.08	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	0.014	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	0.7	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.3	0.2	0.1	0.1
VA 0384	Leek	0.05	0.3	0.0	5.3	0.3	0.0	0.0	0.2	0.0	4.6	0.2	1.5	0.1
-d	Lemon juice	0.014	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	0.9	0.1	0.0	6.2	5.5	0.7	0.6	0.1	0.0	0.1	0.0	0.0	0.0
-	Mandarin + mandarin-like hybrid juice	0.014	0.0	0.0	1.4	0.0	0.9	0.0	0.4	0.0	0.7	0.0	0.9	0.0
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:	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

Annex 3

	IMIDACLOPRID (206)	International Estimated Daily Intake (IEDI)							ADI = 0–0.06 mg/kg bw					
		STMR or STMR-P	Diets: g/person/day		Intake = daily intake: µg/person									
Codex Code	Commodity	mg/kg	A diet	intake	B diet	intake	C diet	intake	D diet	intake	E diet	intake	F diet	intake
	20% as fat													
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0.012	22.2	0.3	93.2	1.1	30.8	0.4	44.1	0.5	72.2	0.9	105.0	1.3
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
FS 0245	Nectarine	0.12	0.0	0.0	0.5	0.1	3.3	0.4	1.8	0.2	2.8	0.3	1.6	0.2
VA 0385	Onion, bulb (= dry + green onion)	0.05	5.5	0.3	49.5	2.5	33.0	1.7	31.3	1.6	23.2	1.2	14.6	0.7
JF 0004	Orange juice	0.014	0.0	0.0	2.1	0.0	4.4	0.1	1.4	0.0	16.2	0.2	22.6	0.3
FS 0247	Peach	0.12	0.2	0.0	24.8	3.0	3.3	0.4	1.8	0.2	5.4	0.6	1.6	0.2
SO 0697	Peanut, shelled (incl oil)	0.12	5.4	0.6	3.1	0.4	2.1	0.3	0.7	0.1	4.0	0.5	1.4	0.2
FP 0230	Pear	0.38	0.1	0.0	22.3	8.5	2.8	1.1	4.8	1.8	10.7	4.1	6.8	2.6
VP 0063	Peas (green pods and/or immature seeds)	0.6	0.1	0.1	2.9	1.7	6.0	3.6	0.6	0.4	9.7	5.8	5.2	3.1
VP 0064	Peas, shelled (immature seeds only)	0.58	0.0	0.0	0.9	0.5	6.0	3.5	0.6	0.3	9.7	5.6	3.2	1.9
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)	0.05	0.1	0.0	5.9	0.3	2.5	0.1	7.3	0.4	6.9	0.3	2.6	0.1
PM 0110	Poultry meat: 10% as fat	0.0004	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	0.007	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)	0.62	44.6	27.7	26.5	16.4	17.1	10.6	14.4	8.9	14.1	8.7	8.7	5.4
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
FB 0272	Raspberries, red, black	0.89	0.0	0.0	0.0	0.0	0.0	0.0	1.8	1.6	0.9	0.8	0.2	0.2
VR 0075	Root and tuber vegetables	0.05	528.2	26.4	352.8	17.6	78.5	3.9	270.3	13.5	324.1	16.2	261.3	13.1
FB 0273	Rose hips	0.89	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
VC 0431	Squash, summer (= courgette, zuchini)	0.31	0.0	0.0	8.3	2.6	11.4	3.5	7.3	2.3	3.2	1.0	0.3	0.1
FB 0275	Strawberry	0.17	0.0	0.0	5.0	0.9	2.0	0.3	1.7	0.3	5.2	0.9	4.1	0.7
SO 0702	Sunflower seed (incl oil)	0.05	0.7	0.0	44.5	2.2	20.5	1.0	29.6	1.5	21.2	1.1	5.4	0.3
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, incl canned)	0.08	3.3	0.3	179.2	14.3	103.5	8.3	54.1	4.3	7.8	0.6	3.9	0.3
JF 0448	Tomato juice	0.11	5.2	0.6	0.5	0.1	0.4	0.0	2.1	0.2	6.9	0.8	15.2	1.7
-d	Tomato paste	0.458	0.5	0.2	1.3	0.6	3.5	1.6	1.0	0.5	3.8	1.7	4.5	2.1
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
VC 0432	Watermelon	0.05	6.1	0.3	43.1	2.2	47.1	2.4	25.8	1.3	4.4	0.2	6.0	0.3
	Total intake (µg/person)=			79.4		177.0		100.6		86.8		109.5		76.3
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			3600		3600		3600		3600		3600		3600
	%ADI=			2.2%		4.9%		2.8%		2.4%		3.0%		2.1%
	Rounded %ADI=			2%		5%		3%		2%		3%		2%

IMIDACLOPRID (206) International Estimated Daily Intake (IEDI) ADI = 0–0.06 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day Intake = daily intake: µg/person													
			G diet	intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake	M diet	intake
FP 0226	Apple (excl juice)	0.07	14.3	1.0	9.4	0.7	2.1	0.1	0.0	0.0	8.8	0.6	16.6	1.2	27.8	1.9
JF 0226	Apple juice	0.046	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
DF 0226	Apple, dried	0.061	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
FS 0240	Apricot (incl dried)	0.12	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 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
VP 0061	Beans except broad bean & soya bean (green pods & immature seeds)	0.4	2.6	1.0	2.6	1.0	1.0	0.4	0.5	0.2	0.6	0.2	2.8	1.1	9.8	3.9
FB 0264	Blackberries	0.89	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	0.89	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	1.2
FB 4079	Boysenberry	0.89	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
VB 0400	Broccoli	0.08	3.2	0.3	7.8	0.6	0.0	0.0	0.0	0.0	0.3	0.0	0.4	0.0	6.6	0.5
VB 0402	Brussels sprouts	0.08	3.4	0.3	0.4	0.0	0.0	0.0	0.0	0.0	0.5	0.0	7.9	0.6	0.3	0.0
VB 0041	Cabbage, head	0.08	10.0	0.8	1.0	0.1	7.2	0.6	1.0	0.1	1.4	0.1	23.9	1.9	17.0	1.4
VB 0404	Cauliflower	0.08	3.2	0.3	0.1	0.0	0.3	0.0	0.1	0.0	0.6	0.0	0.4	0.0	1.4	0.1
VS 0624	Celery	0.365	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	1.5
GC 0080	Cereal grains	0.05	617.0	30.9	487.1	24.4	389.4	19.5	385.7	19.3	440.2	22.0	567.7	28.4	409.9	20.5
FS 0244	Cherries, sweet	0.14	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.3	0.0	1.3	0.2
FC 0001	Citrus fruit (excl lemon juice, excl mandarin juice, excl orange juice, excl grapefruit juice, excl NES juice)	0.05	15.1	0.8	153.9	7.7	3.4	0.2	41.7	2.1	218.9	10.9	23.1	1.2	18.0	0.9
-	Citrus juice NES	0.014	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)	0.35	0.2	0.1	7.0	2.5	0.5	0.2	0.2	0.1	5.3	1.9	5.7	2.0	12.4	4.3
FB 0265	Cranberries	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	2.5	0.1
VC 0424	Cucumber	0.31	7.9	2.4	0.6	0.2	0.2	0.1	0.0	0.0	0.4	0.1	5.5	1.7	5.3	1.6
FB 0021	Currants, red, black, white	0.89	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	0.89	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)	0.06	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
VO 0440	Egg plant (= aubergine)	0.05	20.1	1.0	0.1	0.0	0.6	0.0	6.3	0.3	0.5	0.0	6.3	0.3	0.7	0.0
PE 0112	Eggs	0.003	22.1	0.1	71.5	0.2	16.6	0.0	5.1	0.0	17.6	0.1	35.2	0.1	57.4	0.2
FB 0267	Elderberries	0.89	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
FB 0268	Gooseberries	0.89	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.9	0.0	0.0	0.0	0.0
FB 0269	Grape (incl dried, excl juice, incl wine)	0.11	2.6	0.3	4.7	0.5	10.3	1.1	0.3	0.0	6.0	0.7	10.3	1.1	53.8	5.9
JF 0269	Grape juice	0.08	0.0	0.0	0.1	0.0	1.0	0.1	0.0	0.0	0.6	0.0	0.4	0.0	3.6	0.3
JF 0203	Grapefruit juice	0.014	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
DH 1100	Hops, dry	0.7	0.0	0.0	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.6	0.4
VA 0384	Leek	0.05	0.8	0.0	0.2	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.3	0.0	0.1	0.0
-d	Lemon juice	0.014	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
VL 0482	Lettuce, head	0.9	1.2	1.1	3.5	3.2	0.1	0.1	0.3	0.3	1.0	0.9	1.2	1.1	7.9	7.1

Annex 3

IMIDACLOPRID (206) International Estimated Daily Intake (IEDI) ADI = 0–0.06 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day Intake = daily intake: µg/person G diet	intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake	M diet	intake
-	Mandarin + mandarin-like hybrid juice	0.014	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
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	0.007	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	0.012	43.8	0.5	71.5	0.9	24.5	0.3	22.9	0.3	65.7	0.8	48.9	0.6	126.6	1.5
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
FS 0245	Nectarine	0.12	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
VA 0385	Onion, bulb (= dry + green onion)	0.05	17.4	0.9	27.9	1.4	7.3	0.4	16.0	0.8	22.8	1.1	34.5	1.7	30.1	1.5
JF 0004	Orange juice	0.014	0.2	0.0	1.0	0.0	3.5	0.0	0.0	0.0	1.3	0.0	6.4	0.1	56.8	0.8
FS 0247	Peach	0.12	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	1.2
SO 0697	Peanut, shelled (incl oil)	0.12	7.6	0.9	2.1	0.3	4.7	0.6	21.8	2.6	0.9	0.1	0.7	0.1	6.9	0.8
FP 0230	Pear	0.38	6.4	2.4	1.9	0.7	1.2	0.5	0.0	0.0	1.8	0.7	6.9	2.6	7.8	3.0
VP 0063	Peas (green pods and/or immature seeds)	0.6	3.9	2.3	1.6	1.0	0.4	0.2	0.0	0.0	0.9	0.5	1.0	0.6	8.6	5.2
VP 0064	Peas, shelled (immature seeds only)	0.58	3.9	2.3	1.6	0.9	0.0	0.0	0.0	0.0	0.4	0.2	1.0	0.6	0.8	0.5
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)	0.05	3.3	0.2	1.4	0.1	0.1	0.0	0.0	0.0	0.6	0.0	1.5	0.1	2.2	0.1
PM 0110	Poultry meat: 10% as fat	0.0004	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	0.007	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)	0.62	16.0	9.9	32.4	20.1	24.7	15.3	34.2	21.2	50.7	31.4	8.0	5.0	16.9	10.5
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
FB 0272	Raspberries, red, black	0.89	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	0.4
VR 0075	Root and tuber vegetables	0.05	139.1	7.0	109.8	5.5	409.6	20.5	444.6	22.2	145.3	7.3	127.0	6.4	225.6	11.3
FB 0273	Rose hips	0.89	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
VC 0431	Squash, summer (= courgette, zuchini)	0.31	2.4	0.7	1.5	0.5	0.0	0.0	0.0	0.0	3.8	1.2	2.2	0.7	2.5	0.8
FB 0275	Strawberry	0.17	0.0	0.0	1.8	0.3	0.1	0.0	0.0	0.0	0.3	0.1	6.2	1.1	5.9	1.0
SO 0702	Sunflower seed (incl oil)	0.05	2.7	0.1	8.8	0.4	13.5	0.7	0.2	0.0	3.6	0.2	0.6	0.0	10.4	0.5
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, incl canned)	0.08	23.1	1.8	22.3	1.8	12.5	1.0	5.6	0.4	33.2	2.7	1.3	0.1	41.7	3.3
JF 0448	Tomato juice	0.11	0.0	0.0	0.8	0.1	0.1	0.0	7.2	0.8	0.0	0.0	2.4	0.3	45.2	5.0
-d	Tomato paste	0.458	0.1	0.0	2.1	1.0	0.6	0.3	0.4	0.2	0.6	0.3	1.4	0.6	1.2	0.5
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
VC 0432	Watermelon	0.05	39.3	2.0	14.0	0.7	2.5	0.1	13.6	0.7	8.4	0.4	14.5	0.7	13.6	0.7
	Total intake (µg/person)=			75.4		83.9		64.7		74.3		89.4		66.2		105.5
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			3300		3600		3600		3600		3600		3300		3600
	%ADI=			2.3%		2.3%		1.8%		2.1%		2.5%		2.0%		2.9%
	Rounded %ADI=			2%		2%		2%		2%		2%		2%		3%

MCPA (257) International Estimated Daily Intake (IEDI) ADI = 0–0.10 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
VD 0072	Peas (dry) (= field pea + cowpea)	0	6.8	0.0	1.3	0.0	1.0	0.0	2.3	0.0	4.6	0.0	3.4	0.0
SO 0693	Linseed (incl oil)	0.03	2.6	0.1	14.2	0.4	5.7	0.2	19.2	0.6	0.0	0.0	1.3	0.0
GC 0640	Barley (incl pot, incl pearled, incl flour & grits, incl beer)	0.05	40.6	2.0	16.8	0.8	93.9	4.7	13.2	0.7	48.6	2.4	36.1	1.8
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
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
GC 0650	Rye (incl flour)	0.05	0.1	0.0	3.7	0.2	0.3	0.0	24.3	1.2	25.8	1.3	45.8	2.3
GC 0653	Triticale (incl flour)	0.05	0.0	0.0	115.8	5.8	0.0	0.0	0.0	0.0	0.3	0.0	0.0	0.0
GC 0654	Wheat (incl bulgur wholemeal, excl flour)	0.05	6.0	0.3	11.1	0.6	0.8	0.0	0.2	0.0	0.2	0.0	0.0	0.0
CF 1210	Wheat germ	0.024	0.0	0.0	1.3	0.0	0.0	0.0	1.3	0.0	0.9	0.0	1.2	0.0
CF 1211	Wheat flour (incl macaroni, bread, pastry, starch, gluten)	0.024	63.4	1.5	296.3	7.1	327.5	7.9	300.0	7.2	181.6	4.4	166.2	4.0
CM 0654	Wheat bran, unprocessed	0.024	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.13	5.5	0.7	23.3	3.0	7.7	1.0	11.0	1.4	18.0	2.3	26.3	3.4
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0.08	22.2	1.8	93.2	7.5	30.8	2.5	44.1	3.5	72.2	5.8	105.0	8.4
MF 0100	Mammalian fats (except milk fats)	0.13	0.8	0.1	10.0	1.3	0.9	0.1	6.6	0.9	11.8	1.5	3.7	0.5
MO 0105	Edible offal (mammalian)	1.33	3.9	5.2	14.4	19.2	5.2	6.9	11.8	15.7	11.7	15.6	7.6	10.1
PM 0110	Poultry meat: 10% as fat	0.05	0.7	0.0	5.9	0.3	3.2	0.2	2.4	0.1	6.1	0.3	2.7	0.1
PM 0110	Poultry meat: 90% as muscle	0.05	6.4	0.3	52.7	2.6	28.7	1.4	21.6	1.1	54.9	2.7	24.6	1.2
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
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
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
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
	Total intake (µg/person)=			13.2		52.8		27.3		37.8		40.9		36.8
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			6000		6000		6000		6000		6000		6000
	%ADI=			0.2%		0.9%		0.5%		0.6%		0.7%		0.6%
	Rounded %ADI=			0%		1%		0%		1%		1%		1%

Annex 3

MCPA (257) International Estimated Daily Intake (IEDI) ADI = 0–0.10 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G diet	intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake	M diet	intake
VD 0072	Peas (dry) (= field pea + cowpea)	0	1.8	0.0	2.2	0.0	3.2	0.0	26.7	0.0	1.5	0.0	1.8	0.0	1.8	0.0
SO 0693	Linseed (incl oil)	0.03	3.9	0.1	1.9	0.1	3.0	0.1	4.0	0.1	0.0	0.0	43.3	1.3	0.9	0.0
GC 0640	Barley (incl pot, incl pearled, incl flour & grits, incl beer)	0.05	5.9	0.3	20.5	1.0	5.9	0.3	2.5	0.1	20.2	1.0	16.8	0.8	43.8	2.2
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
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
GC 0650	Rye (incl flour)	0.05	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 0653	Triticale (incl flour)	0.05	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, excl flour)	0.05	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
CF 1210	Wheat germ	0.024	0.1	0.0	48.1	1.2	1.8	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.6	0.0
CF 1211	Wheat flour (incl macaroni, bread, pastry, starch, gluten)	0.024	133.0	3.2	60.1	1.4	52.4	1.3	32.2	0.8	87.7	2.1	79.6	1.9	180.1	4.3
CM 0654	Wheat bran, unprocessed	0.024	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.13	11.0	1.4	17.9	2.3	6.1	0.8	5.7	0.7	16.4	2.1	12.2	1.6	31.7	4.1
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0.08	43.8	3.5	71.5	5.7	24.5	2.0	22.9	1.8	65.7	5.3	48.9	3.9	126.6	10.1
MF 0100	Mammalian fats (except milk fats)	0.13	2.2	0.3	18.6	2.4	0.5	0.1	0.8	0.1	5.7	0.7	4.5	0.6	18.2	2.4
MO 0105	Edible offal (mammalian)	1.33	4.8	6.4	10.7	14.2	4.0	5.3	4.0	5.3	6.5	8.6	6.6	8.8	5.6	7.4
PM 0110	Poultry meat: 10% as fat	0.05	1.8	0.1	13.1	0.7	2.5	0.1	0.5	0.0	14.6	0.7	2.8	0.1	11.5	0.6
PM 0110	Poultry meat: 90% as muscle	0.05	15.8	0.8	118.2	5.9	22.6	1.1	4.2	0.2	131.3	6.6	24.9	1.2	103.6	5.2
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
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
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
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
	Total intake (µg/person)=			18.2		40.7		13.1		10.8		31.0		22.9		43.6
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			5500		6000		6000		6000		6000		5500		6000
	%ADI=			0.3%		0.7%		0.2%		0.2%		0.5%		0.4%		0.7%
	Rounded %ADI=			0%		1%		0%		0%		1%		0%		1%

METHOXYFENOZIDE (209) International Estimated Daily Intake (IEDI) ADI = 0–0.10 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
FC 0001	Citrus fruit (excl lemon juice, excl mandarin juice, excl orange juice, excl grapefruit juice, excl NES juice)	0.28	15.7	4.4	86.5	24.2	52.6	14.7	24.2	6.8	16.2	4.5	12.0	3.4
-d	Lemon juice	0.062	0.0	0.0	0.9	0.1	0.1	0.0	0.0	0.0	0.2	0.0	0.4	0.0
-	Citrus juice NES	0.062	0.0	0.0	1.7	0.1	0.1	0.0	0.0	0.0	1.1	0.1	0.3	0.0
JF 0004	Orange juice	0.062	0.0	0.0	2.1	0.1	4.4	0.3	1.4	0.1	16.2	1.0	22.6	1.4
JF 0203	Grapefruit juice	0.062	0.0	0.0	0.2	0.0	0.1	0.0	0.1	0.0	1.1	0.1	0.2	0.0
TN 0085	Tree nuts	0.021	4.2	0.1	21.5	0.5	3.9	0.1	3.0	0.1	5.5	0.1	10.2	0.2
FP 0009	Pome fruit (excl apple juice)	0.43	0.5	0.2	79.9	34.4	21.8	9.4	43.6	18.7	51.5	22.1	35.1	15.1
JF 0226	Apple juice	0.13	0.0	0.0	2.8	0.4	0.1	0.0	1.1	0.1	6.8	0.9	7.4	1.0
FS 0012	Stone fruit (excl dried plums, incl dried apricots)	0.34	0.7	0.2	44.1	15.0	14.1	4.8	26.6	9.0	26.3	8.9	8.3	2.8
DF 0014	Plum, dried (prunes)	0.44	0.0	0.0	0.2	0.1	0.0	0.0	0.1	0.0	0.5	0.2	0.6	0.3
FB 0020	Blueberries	1.25	0.0	0.0	0.0	0.0	0.0	0.0	0.2	0.3	0.3	0.4	0.8	1.0
FB 0265	Cranberries	0.1	0.1	0.0	0.0	0.0	0.0	0.0	0.3	0.0	0.0	0.0	0.6	0.1
FB 0269	Grape (excl dried, excl juice, excl wine)	0.33	1.9	0.6	9.2	3.0	23.8	7.9	9.8	3.2	0.0	0.0	0.0	0.0
DF 0269	Grape, dried (= currants, raisins and sultanas)	0.73	0.0	0.0	2.9	2.1	0.4	0.3	0.4	0.3	2.3	1.7	1.7	1.2
JF 0269	Grape juice	0.1	0.0	0.0	0.1	0.0	0.1	0.0	0.1	0.0	1.4	0.1	1.0	0.1
-	Wine	0.13	1.3	0.2	76.8	10.0	1.1	0.1	15.4	2.0	68.8	8.9	25.6	3.3
FB 0275	Strawberry	0.24	0.0	0.0	5.0	1.2	2.0	0.5	1.7	0.4	5.2	1.2	4.1	1.0
FI 0326	Avocado	0.13	3.7	0.5	1.0	0.1	0.2	0.0	0.0	0.0	0.9	0.1	0.8	0.1
FI 0350	Papaya	0.31	5.1	1.6	0.1	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0
VR 0494	Radish	0.08	0.0	0.0	1.3	0.1	0.6	0.0	2.0	0.2	1.2	0.1	0.0	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 0577	Carrot	0.13	0.6	0.1	15.1	2.0	8.1	1.1	13.9	1.8	27.1	3.5	28.4	3.7
VR 0596	Sugar beet	0.11	0.0	0.0	40.7	4.5	0.0	0.0	0.1	0.0	6.0	0.7	0.1	0.0
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 0045	Fruiting vegetables, cucurbits (excl watermelon)	0.091	20.5	1.9	64.4	5.9	48.8	4.4	56.4	5.1	21.0	1.9	17.2	1.6
VC 0424	Cucumber	0.021	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	0.16	1.4	0.2	29.9	4.8	13.0	2.1	6.3	1.0	6.2	1.0	4.0	0.6
VO 0447	Sweet corn (corn-on-the-cob, only)	0	7.3	0.0	1.0	0.0	0.1	0.0	0.5	0.0	3.3	0.0	3.6	0.0
VO 0448	Tomato (excl juice, excl paste, incl canned)	0.06	3.3	0.2	179.2	10.8	103.5	6.2	54.1	3.2	7.8	0.5	3.9	0.2
JF 0448	Tomato juice	0.06	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 paste	0.44	0.5	0.2	1.3	0.6	3.5	1.5	1.0	0.4	3.8	1.7	4.5	2.0
VB 0041	Cabbage, head	0.93	1.2	1.1	14.4	13.4	2.7	2.5	16.4	15.3	15.4	14.3	18.5	17.2
VB 0400	Broccoli	0.94	0.0	0.0	0.7	0.7	1.2	1.1	0.1	0.1	4.2	3.9	4.0	3.8
VL 0482	Lettuce, head	6.1	0.1	0.3	6.2	37.5	0.7	4.0	0.1	0.3	0.1	0.3	0.0	0.0
VL 0483	Lettuce, leaf	12	0.0	0.0	9.2	110.4	1.0	12.0	0.1	1.2	5.4	64.8	18.0	216.0
VL 0485	Mustard greens	16	0.3	4.8	0.3	4.8	0.0	0.0	5.5	88.0	0.0	0.0	1.9	30.4

Annex 3

METHOXYFENOZIDE (209) International Estimated Daily Intake (IEDI) ADI = 0–0.10 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
VP 0062	Beans, shelled (immature seeds)	0.051	0.5	0.0	12.7	0.6	4.1	0.2	0.9	0.0	13.1	0.7	0.1	0.0
VP 0526	Common bean (green pods and/or immature seeds)	0.065	0.5	0.0	4.7	0.3	4.1	0.3	0.0	0.0	13.1	0.9	0.0	0.0
VP 0063	Peas (green pods and/or immature seeds)	0.1	0.1	0.0	2.9	0.3	6.0	0.6	0.6	0.1	9.7	1.0	5.2	0.5
VP 0064	Peas, shelled (immature seeds only)	0.051	0.0	0.0	0.9	0.0	6.0	0.3	0.6	0.0	9.7	0.5	3.2	0.2
VS 0620	Artichoke globe	1.1	0.0	0.0	10.0	11.0	2.1	2.3	0.1	0.1	0.8	0.9	0.1	0.1
VS 0624	Celery	3.4	0.0	0.0	0.9	3.1	0.0	0.0	2.0	6.8	1.5	5.1	0.0	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
VD 0072	Peas (dry) (= field pea + cowpea)	0.17	6.8	1.2	1.3	0.2	1.0	0.2	2.3	0.4	4.6	0.8	3.4	0.6
OR 0691	Cotton seed oil, edible	0.12	0.9	0.1	4.9	0.6	1.7	0.2	6.6	0.8	0.0	0.0	0.3	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
OR 0697	Peanut oil, edible	0.029	1.7	0.0	0.8	0.0	0.5	0.0	0.1	0.0	1.4	0.0	0.4	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
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.036	5.5	0.2	23.3	0.8	7.7	0.3	11.0	0.4	18.0	0.6	26.3	0.9
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0.003	22.2	0.1	93.2	0.3	30.8	0.1	44.1	0.1	72.2	0.2	105.0	0.3
MF 0100	Mammalian fats (except milk fats)	0.036	0.8	0.0	10.0	0.4	0.9	0.0	6.6	0.2	11.8	0.4	3.7	0.1
MO 0105	Edible offal (mammalian)	0.025	3.9	0.1	14.4	0.4	5.2	0.1	11.8	0.3	11.7	0.3	7.6	0.2
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
ML 0106	Milks (excl processed products)	0.03	68.8	2.1	190.6	5.7	79.4	2.4	302.6	9.1	179.6	5.4	237.9	7.1
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
	Total intake (µg/person)=			24.0		314.7		84.2		177.9		161.6		318.4
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			6000		6000		6000		6000		6000		6000
	%ADI=			0.4%		5.2%		1.4%		3.0%		2.7%		5.3%
	Rounded %ADI=			0%		5%		1%		3%		3%		5%

METHOXYFENOZIDE (209) International Estimated Daily Intake (IEDI) ADI = 0–0.10 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
FC 0001	Citrus fruit (excl lemon juice, excl mandarin juice, excl orange juice, excl grapefruit juice, excl NES juice)	0.28	15.1	4.2	153.9	43.1	3.4	1.0	41.7	11.7	218.9	61.3	23.1	6.5	18.0	5.0
-d	Lemon juice	0.062	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
-	Citrus juice NES	0.062	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	0.062	0.2	0.0	1.0	0.1	3.5	0.2	0.0	0.0	1.3	0.1	6.4	0.4	56.8	3.5
JF 0203	Grapefruit juice	0.062	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

METHOXYFENOZIDE (209) International Estimated Daily Intake (IEDI) ADI = 0–0.10 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day Intake = daily intake: µg/person G diet	intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake	M diet	intake
TN 0085	Tree nuts	0.021	16.3	0.3	15.7	0.3	9.7	0.2	1.9	0.0	19.1	0.4	29.0	0.6	5.6	0.1
FP 0009	Pome fruit (excl apple juice)	0.43	20.8	8.9	11.6	5.0	3.3	1.4	0.1	0.0	10.7	4.6	23.6	10.1	36.9	15.8
JF 0226	Apple juice	0.13	0.1	0.0	0.5	0.1	0.1	0.0	0.0	0.0	0.7	0.1	0.9	0.1	5.7	0.7
FS 0012	Stone fruit (excl dried plums, incl dried apricots)	0.34	6.7	2.3	4.3	1.5	1.4	0.5	0.1	0.0	4.9	1.7	4.9	1.7	17.7	6.0
DF 0014	Plum, dried (prunes)	0.44	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
FB 0020	Blueberries	1.25	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	1.6
FB 0265	Cranberries	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	2.5	0.3
FB 0269	Grape (excl dried, excl juice, excl wine)	0.33	1.2	0.4	2.6	0.9	0.0	0.0	0.2	0.1	0.0	0.0	3.7	1.2	0.0	0.0
DF 0269	Grape, dried (= currants, raisins and sultanas)	0.73	0.0	0.0	0.2	0.1	0.2	0.1	0.0	0.0	0.3	0.2	0.4	0.3	2.6	1.9
JF 0269	Grape juice	0.1	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
-	Wine	0.13	1.0	0.1	0.9	0.1	6.8	0.9	0.1	0.0	3.4	0.4	3.6	0.5	31.0	4.0
FB 0275	Strawberry	0.24	0.0	0.0	1.8	0.4	0.1	0.0	0.0	0.0	0.3	0.1	6.2	1.5	5.9	1.4
FI 0326	Avocado	0.13	0.2	0.0	13.9	1.8	1.0	0.1	1.7	0.2	3.4	0.4	0.5	0.1	2.1	0.3
FI 0350	Papaya	0.31	1.3	0.4	11.5	3.6	1.6	0.5	13.7	4.2	14.5	4.5	1.0	0.3	0.6	0.2
VR 0494	Radish	0.08	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
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 0577	Carrot	0.13	5.4	0.7	7.9	1.0	2.5	0.3	3.5	0.5	4.1	0.5	8.6	1.1	19.4	2.5
VR 0596	Sugar beet	0.11	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	1.6
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 0045	Fruiting vegetables, cucurbits (excl watermelon)	0.091	30.4	2.8	11.9	1.1	12.4	1.1	4.4	0.4	10.3	0.9	24.6	2.2	30.6	2.8
VC 0424	Cucumber	0.021	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	0.16	8.7	1.4	22.4	3.6	8.4	1.3	9.4	1.5	3.3	0.5	5.3	0.8	8.9	1.4
VO 0447	Sweet corn (corn-on-the-cob, only)	0	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	0.0
VO 0448	Tomato (excl juice, excl paste, incl canned)	0.06	23.1	1.4	22.3	1.3	12.5	0.7	5.6	0.3	33.2	2.0	1.3	0.1	41.7	2.5
JF 0448	Tomato juice	0.06	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 paste	0.44	0.1	0.0	2.1	0.9	0.6	0.3	0.4	0.2	0.6	0.3	1.4	0.6	1.2	0.5
VB 0041	Cabbage, head	0.93	10.0	9.3	1.0	0.9	7.2	6.7	1.0	0.9	1.4	1.3	23.9	22.2	17.0	15.8
VB 0400	Broccoli	0.94	3.2	3.0	7.8	7.3	0.0	0.0	0.0	0.0	0.3	0.3	0.4	0.4	6.6	6.2
VL 0482	Lettuce, head	6.1	1.2	7.3	3.5	21.4	0.1	0.6	0.3	1.8	1.0	6.1	1.2	7.3	7.9	47.9
VL 0483	Lettuce, leaf	12	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	30.0
VL 0485	Mustard greens	16	3.4	54.4	0.4	6.4	2.4	38.4	0.3	4.8	0.5	8.0	7.9	126.4	0.3	4.8
VP 0062	Beans, shelled (immature seeds)	0.051	2.6	0.1	1.9	0.1	1.0	0.1	0.5	0.0	0.3	0.0	1.8	0.1	9.0	0.5
VP 0526	Common bean (green pods and/or immature seeds)	0.065	0.0	0.0	1.9	0.1	0.0	0.0	0.0	0.0	0.3	0.0	1.8	0.1	8.0	0.5

Annex 3

METHOXYFENOZIDE (209) International Estimated Daily Intake (IEDI) ADI = 0–0.10 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day Intake = daily intake: µg/person G diet	intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake	M diet	intake
VP 0063	Peas (green pods and/or immature seeds)	0.1	3.9	0.4	1.6	0.2	0.4	0.0	0.0	0.0	0.9	0.1	1.0	0.1	8.6	0.9
VP 0064	Peas, shelled (immature seeds only)	0.051	3.9	0.2	1.6	0.1	0.0	0.0	0.0	0.0	0.4	0.0	1.0	0.1	0.8	0.0
VS 0620	Artichoke globe	1.1	0.1	0.1	0.1	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	1.1
VS 0624	Celery	3.4	0.0	0.0	0.3	1.0	0.0	0.0	0.0	0.0	1.0	3.4	0.0	0.0	4.2	14.3
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
VD 0072	Peas (dry) (= field pea + cowpea)	0.17	1.8	0.3	2.2	0.4	3.2	0.5	26.7	4.5	1.5	0.3	1.8	0.3	1.8	0.3
OR 0691	Cotton seed oil, edible	0.12	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	0.1
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
OR 0697	Peanut oil, edible	0.029	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
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
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.036	11.0	0.4	17.9	0.6	6.1	0.2	5.7	0.2	16.4	0.6	12.2	0.4	31.7	1.1
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0.003	43.8	0.1	71.5	0.2	24.5	0.1	22.9	0.1	65.7	0.2	48.9	0.1	126.6	0.4
MF 0100	Mammalian fats (except milk fats)	0.036	2.2	0.1	18.6	0.7	0.5	0.0	0.8	0.0	5.7	0.2	4.5	0.2	18.2	0.7
MO 0105	Edible offal (mammalian)	0.025	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
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
ML 0106	Milks (excl processed products)	0.03	66.0	2.0	121.1	3.6	81.6	2.4	102.4	3.1	207.7	6.2	57.0	1.7	287.9	8.6
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
	Total intake (µg/person)=			102.8		118.3		64.0		37.6		109.6		191.9		192.0
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			5500		6000		6000		6000		6000		5500		6000
	%ADI=			1.9%		2.0%		1.1%		0.6%		1.8%		3.5%		3.2%
	Rounded %ADI=			2%		2%		1%		1%		2%		3%		3%

PENTHIOPYRAD (253) International Estimated Daily Intake (IEDI) ADI = 0–0.10 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
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, incl pearled, incl flour & grits, excl beer)	0.01	40.6	0.4	0.0	0.0	93.9	0.9	0.0	0.0	0.0	0.0	3.8	0.0
-	Barley beer	0.002	18.3	0.0	84.1	0.2	4.1	0.0	66.0	0.1	243.1	0.5	161.3	0.3
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

PENTHIOPYRAD (253) International Estimated Daily Intake (IEDI) ADI = 0–0.10 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day A diet	intake	B diet	intake	C diet	intake	D diet	intake	E diet	intake	F diet	intake
			Intake = daily intake: µg/person											
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
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
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
VO 0050	Fruiting vegetables other than cucurbits (excl sweet corn, excl mushrooms)	0.27	18.8	5.1	233.4	63.0	148.6	40.1	68.8	18.6	38.6	10.4	45.3	12.2
VC 0045	Fruiting vegetables, cucurbits (excl melons, excl watermelons)	0.13	16.9	2.2	37.7	4.9	26.2	3.4	44.9	5.8	15.4	2.0	15.2	2.0
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
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
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)	0.01	1.4	0.0	0.6	0.0	0.2	0.0	4.2	0.0	5.7	0.1	8.9	0.1
VA 0385	Onion, bulb (= dry + green onion)	0.074	5.5	0.4	49.5	3.7	33.0	2.4	31.3	2.3	23.2	1.7	14.6	1.1
VA 0387	Onion, Welsh	0.89	0.3	0.3	1.0	0.9	1.4	1.2	0.3	0.3	0.3	0.3	0.6	0.5
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)	0.01	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
DF 0014	Plum, dried (prunes)	1.8	0.0	0.0	0.2	0.4	0.0	0.0	0.1	0.2	0.5	0.9	0.6	1.1
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
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
VR 0590	Radish, black	0.305	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
VR 0591	Radish, Japanese	0.305	2.3	0.7	0.0	0.0	0.0	0.0	2.0	0.6	0.0	0.0	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)	0.01	36.9	0.4	0.0	0.0	10.2	0.1	0.0	0.0	0.0	0.0	0.0	0.0
VD 0541	Soya bean (dry, excl oil)	0.031	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	0.031	1.6	0.0	6.5	0.2	6.0	0.2	4.0	0.1	6.3	0.2	7.0	0.2

Annex 3

PENTHIOPYRAD (253) International Estimated Daily Intake (IEDI) ADI = 0–0.10 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
VA 0389	Spring onion	0.89	0.3	0.3	1.0	0.9	1.4	1.2	0.3	0.3	0.3	0.3	0.6	0.5
FS 0012	Stone fruit (excl dried plums, incl dried apricots)	1.9	0.7	1.3	44.1	83.8	14.1	26.8	26.6	50.6	26.3	49.9	8.3	15.7
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	0.105	0.0	0.0	40.7	4.3	0.0	0.0	0.1	0.0	6.0	0.6	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
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
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)=			39.3		370.2		136.6		197.0		189.9		189.9
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			6000		6000		6000		6000		6000		6000
	%ADI=			0.7%		6.2%		2.3%		3.3%		3.2%		3.2%
	Rounded %ADI=			1%		6%		2%		3%		3%		3%

PENTHIOPYRAD (253) International Estimated Daily Intake (IEDI) ADI = 0–0.10 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G diet	intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake	M 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, incl pearled, incl flour & grits, excl beer)	0.01	1.5	0.0	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	0.002	21.9	0.0	102.7	0.2	29.5	0.1	12.6	0.0	100.9	0.2	82.2	0.2	218.8	0.4
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
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
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
VO 0050	Fruiting vegetables other than cucurbits (excl sweet corn, excl mushrooms)	0.27	56.4	15.2	55.2	14.9	31.0	8.4	47.8	12.9	40.5	10.9	25.4	6.9	112.8	30.5
VC 0045	Fruiting vegetables, cucurbits (excl melons,	0.13	22.9	3.0	5.8	0.8	11.7	1.5	3.0	0.4	7.8	1.0	17.7	2.3	18.2	2.4

PENTHIOPYRAD (253) International Estimated Daily Intake (IEDI) ADI = 0–0.10 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day G diet	Intake = daily intake: µg/person intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake	M diet	intake
	excl watermelons)															
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
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
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)	0.01	0.2	0.0	2.0	0.0	0.8	0.0	0.0	0.0	3.5	0.0	0.7	0.0	7.6	0.1
VA 0385	Onion, bulb (= dry + green onion)	0.074	17.4	1.3	27.9	2.1	7.3	0.5	16.0	1.2	22.8	1.7	34.5	2.6	30.1	2.2
VA 0387	Onion, Welsh	0.89	0.1	0.1	4.8	4.3	0.1	0.1	1.0	0.9	1.0	0.9	2.7	2.4	0.6	0.5
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
DF 0014	Plum, dried (prunes)	1.8	0.1	0.2	0.2	0.4	0.0	0.0	0.0	0.0	0.2	0.4	0.2	0.4	0.6	1.1
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
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
VR 0590	Radish, black	0.305	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
VR 0591	Radish, Japanese	0.305	7.0	2.1	0.3	0.1	2.3	0.7	3.3	1.0	1.0	0.3	7.4	2.3	0.0	0.0
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)	0.01	9.8	0.1	19.9	0.2	18.6	0.2	112.3	1.1	0.1	0.0	3.3	0.0	3.0	0.0
VD 0541	Soya bean (dry, excl oil)	0.031	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	0.031	4.3	0.1	10.6	0.3	2.0	0.1	1.4	0.0	19.5	0.6	9.2	0.3	22.0	0.7
VA 0389	Spring onion	0.89	0.1	0.1	4.8	4.3	0.1	0.1	1.0	0.9	1.0	0.9	2.7	2.4	0.6	0.5
FS 0012	Stone fruit (excl dried plums, incl dried apricots)	1.9	6.7	12.7	4.3	8.2	1.4	2.7	0.1	0.2	4.9	9.3	4.9	9.3	17.7	33.6
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	0.105	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	1.5
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
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

Annex 3

PENTHIOPYRAD (253) International Estimated Daily Intake (IEDI) ADI = 0–0.10 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
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)=			204.5		97.8		73.3		76.0		59.9		232.5		269.7
	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%		1.6%		1.2%		1.3%		1.0%		4.2%		4.5%
	Rounded %ADI=			4%		2%		1%		1%		1%		4%		4%

PHORATE (112) International Estimated Daily Intake (IEDI) ADI = 0–0.0007 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
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
SB 0716	Coffee beans (incl green, incl extracts, incl roasted)	0.05	3.1	0.2	12.6	0.6	2.9	0.1	1.4	0.1	10.1	0.5	18.0	0.9
VP 0526	Common bean (green pods and/or immature seeds)	0.05	0.5	0.0	4.7	0.2	4.1	0.2	0.0	0.0	13.1	0.7	0.0	0.0
SO 0691	Cotton seed (for oil processing only)	0	5.6	0.0	30.6	0.0	10.6	0.0	41.3	0.0	0.0	0.0	1.9	0.0
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
CF 1255	Maize flour	0.046	68.9	3.2	15.4	0.7	51.3	2.4	16.6	0.8	14.7	0.7	2.0	0.1
GC 0645	Maize (excl flour, excl oil, incl beer)	0.02	0.0	0.0	1.4	0.0	51.4	1.0	11.9	0.2	0.2	0.0	0.2	0.0
OR 0645	Maize oil, edible	0.0162	0.1	0.0	4.0	0.1	2.3	0.0	0.5	0.0	0.9	0.0	0.2	0.0
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.02	5.5	0.1	23.3	0.5	7.7	0.2	11.0	0.2	18.0	0.4	26.3	0.5
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0.02	22.2	0.4	93.2	1.9	30.8	0.6	44.1	0.9	72.2	1.4	105.0	2.1
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
VR 0589	Potato (incl flour, frozen, starch, tapioca)	0.018	19.1	0.3	160.8	2.9	61.2	1.1	243.6	4.4	230.1	4.1	204.7	3.7
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
GC 0651	Sorghum (incl flour, incl beer)	0.05	36.9	1.8	0.0	0.0	10.2	0.5	0.0	0.0	0.0	0.0	0.0	0.0
VD 0541	Soya bean (dry, incl oil)	0	9.9	0.0	36.4	0.0	34.3	0.0	22.4	0.0	35.3	0.0	39.2	0.0
VR 0596	Sugar beet	0.05	0.0	0.0	40.7	2.0	0.0	0.0	0.1	0.0	6.0	0.3	0.1	0.0
	Total intake (µg/person)=			7.3		10.5		6.7		8.6		9.3		8.9

PHORATE (112) International Estimated Daily Intake (IEDI) ADI = 0–0.0007 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
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			42		42		42		42		42		42
	%ADI=			17.4%		24.9%		16.1%		20.6%		22.2%		21.2%
	Rounded %ADI=			20%		20%		20%		20%		20%		20%

PHORATE (112) International Estimated Daily Intake (IEDI) ADI = 0–0.0007 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day Intake = daily intake: µg/person G diet	intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake	M diet	intake
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
SB 0716	Coffee beans (incl green, incl extracts, incl roasted)	0.05	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	0.6
VP 0526	Common bean (green pods and/or immature seeds)	0.05	0.0	0.0	1.9	0.1	0.0	0.0	0.0	0.0	0.3	0.0	1.8	0.1	8.0	0.4
SO 0691	Cotton seed (for oil processing only)	0	6.3	0.0	4.4	0.0	6.3	0.0	8.8	0.0	9.4	0.0	34.4	0.0	7.5	0.0
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
CF 1255	Maize flour	0.046	28.8	1.3	248.8	11.4	206.7	9.5	47.8	2.2	46.2	2.1	10.5	0.5	21.5	1.0
GC 0645	Maize (excl flour, excl oil, incl beer)	0.02	0.6	0.0	0.0	0.0	0.1	0.0	0.0	0.0	7.7	0.2	0.0	0.0	19.4	0.4
OR 0645	Maize oil, edible	0.0162	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
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.02	11.0	0.2	17.9	0.4	6.1	0.1	5.7	0.1	16.4	0.3	12.2	0.2	31.7	0.6
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0.02	43.8	0.9	71.5	1.4	24.5	0.5	22.9	0.5	65.7	1.3	48.9	1.0	126.6	2.5
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
VR 0589	Potato (incl flour, frozen, starch, tapioca)	0.018	52.7	0.9	57.1	1.0	50.1	0.9	4.3	0.1	54.7	1.0	41.0	0.7	168.0	3.0
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
GC 0651	Sorghum (incl flour, incl beer)	0.05	9.8	0.5	19.9	1.0	18.6	0.9	112.3	5.6	0.1	0.0	3.3	0.2	3.0	0.2
VD 0541	Soya bean (dry, incl oil)	0	25.9	0.0	59.4	0.0	11.2	0.0	11.0	0.0	109.3	0.0	51.5	0.0	123.2	0.0
VR 0596	Sugar beet	0.05	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	0.7
	Total intake (µg/person)=			4.5		17.8		12.9		9.2		8.6		3.7		11.4
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			38.5		42		42		42		42		38.5		42
	%ADI=			11.6%		42.4%		30.7%		21.8%		20.5%		9.6%		27.1%
	Rounded %ADI=			10%		40%		30%		20%		20%		10%		30%

Annex 3

	SPINETORAM (233)	International Estimated Daily Intake (IEDI)								ADI = 0–0.05 mg/kg bw			
		STMR or STMR-P	Diets: g/person/day		Intake = daily intake: µg/person								
			A		B		C		D		E		F	
Codex Code	Commodity	mg/kg	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
JF 0226	Apple juice	0.011	0.0	0.0	2.8	0.0	0.1	0.0	1.1	0.0	6.8	0.1	7.4	0.1
VP 0061	Beans except broad bean & soya bean (green pods & immature seeds)	0.024	1.0	0.0	17.4	0.4	7.5	0.2	0.9	0.0	16.4	0.4	0.1	0.0
FB 0020	Blueberries	0.012	0.0	0.0	0.0	0.0	0.0	0.0	0.2	0.0	0.3	0.0	0.8	0.0
VB 0040	Brassica vegetables	0.05	1.7	0.1	25.7	1.3	9.1	0.5	27.8	1.4	36.9	1.8	26.4	1.3
VS 0624	Celery	0.3	0.0	0.0	0.9	0.3	0.0	0.0	2.0	0.6	1.5	0.5	0.0	0.0
MO 0105	Edible offal (mammalian)	0.0069	3.9	0.0	14.4	0.1	5.2	0.0	11.8	0.1	11.7	0.1	7.6	0.1
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
FB 0269	Grape (incl dried, incl juice, incl wine)	0.074	3.7	0.3	128.5	9.5	27.1	2.0	33.1	2.4	107.5	8.0	44.0	3.3
VL 0482	Lettuce, head	0.0895	0.1	0.0	6.2	0.6	0.7	0.1	0.1	0.0	0.1	0.0	0.0	0.0
VL 0483	Lettuce, leaf	0.0895	0.0	0.0	9.2	0.8	1.0	0.1	0.1	0.0	5.4	0.5	18.0	1.6
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
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.049	5.5	0.3	23.3	1.1	7.7	0.4	11.0	0.5	18.0	0.9	26.3	1.3
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0.0069	22.2	0.2	93.2	0.6	30.8	0.2	44.1	0.3	72.2	0.5	105.0	0.7
ML 0106	Milks (excl processed products)	0.0098	68.8	0.7	190.6	1.9	79.4	0.8	302.6	3.0	179.6	1.8	237.9	2.3
FS 0245	Nectarine	0.055	0.0	0.0	0.5	0.0	3.3	0.2	1.8	0.1	2.8	0.2	1.6	0.1
VA 0385	Onion, bulb (= dry + green onion)	0.01	5.5	0.1	49.5	0.5	33.0	0.3	31.3	0.3	23.2	0.2	14.6	0.1
VA 0387	Onion, Welsh	0.33	0.3	0.1	1.0	0.3	1.4	0.5	0.3	0.1	0.3	0.1	0.6	0.2
JF 0004	Orange juice	0.003	0.0	0.0	2.1	0.0	4.4	0.0	1.4	0.0	16.2	0.0	22.6	0.1
FC 0004	Orange, sweet, sour + orange-like hybrid (excl juice)	0.045	4.2	0.2	54.1	2.4	30.1	1.4	11.9	0.5	0.2	0.0	0.5	0.0
FS 0247	Peach	0.055	0.2	0.0	24.8	1.4	3.3	0.2	1.8	0.1	5.4	0.3	1.6	0.1
FP 0009	Pome fruit (excl apple juice)	0.025	0.5	0.0	79.9	2.0	21.8	0.5	43.6	1.1	51.5	1.3	35.1	0.9
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
FB 0272	Raspberries, red, black	0.42	0.0	0.0	0.0	0.0	0.0	0.0	1.8	0.8	0.9	0.4	0.2	0.1
VL 0502	Spinach	1.6	0.0	0.0	5.0	8.0	1.1	1.8	0.1	0.2	2.6	4.2	0.1	0.2
VA 0389	Spring onion	0.33	0.3	0.1	1.0	0.3	1.4	0.5	0.3	0.1	0.3	0.1	0.6	0.2
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
TN 0085	Tree nuts	0.02	4.2	0.1	21.5	0.4	3.9	0.1	3.0	0.1	5.5	0.1	10.2	0.2
	Total intake (µg/person)=			2.2		34.2		10.2		12.5		23.0		13.5
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			3000		3000		3000		3000		3000		3000
	%ADI=			0.1%		1.1%		0.3%		0.4%		0.8%		0.5%
	Rounded %ADI=			0%		1%		0%		0%		1%		0%

SPINETORAM (233) International Estimated Daily Intake (IEDI) ADI = 0–0.05 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G diet	intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake	M diet	intake
JF 0226	Apple juice	0.011	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
VP 0061	Beans except broad bean & soya bean (green pods & immature seeds)	0.024	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	0.2
FB 0020	Blueberries	0.012	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	0.0
VB 0040	Brassica vegetables	0.05	26.4	1.3	9.3	0.5	7.8	0.4	1.5	0.1	3.3	0.2	40.8	2.0	26.0	1.3
VS 0624	Celery	0.3	0.0	0.0	0.3	0.1	0.0	0.0	0.0	0.0	1.0	0.3	0.0	0.0	4.2	1.3
MO 0105	Edible offal (mammalian)	0.0069	4.8	0.0	10.7	0.1	4.0	0.0	4.0	0.0	6.5	0.0	6.6	0.0	5.6	0.0
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
FB 0269	Grape (incl dried, incl juice, incl wine)	0.074	2.6	0.2	4.8	0.4	11.7	0.9	0.3	0.0	6.8	0.5	10.9	0.8	58.8	4.4
VL 0482	Lettuce, head	0.0895	1.2	0.1	3.5	0.3	0.1	0.0	0.3	0.0	1.0	0.1	1.2	0.1	7.9	0.7
VL 0483	Lettuce, leaf	0.0895	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
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	0.049	11.0	0.5	17.9	0.9	6.1	0.3	5.7	0.3	16.4	0.8	12.2	0.6	31.7	1.6
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0.0069	43.8	0.3	71.5	0.5	24.5	0.2	22.9	0.2	65.7	0.5	48.9	0.3	126.6	0.9
ML 0106	Milks (excl processed products)	0.0098	66.0	0.6	121.1	1.2	81.6	0.8	102.4	1.0	207.7	2.0	57.0	0.6	287.9	2.8
FS 0245	Nectarine	0.055	1.7	0.1	1.7	0.1	0.0	0.0	0.0	0.0	1.0	0.1	1.7	0.1	1.4	0.1
VA 0385	Onion, bulb (= dry + green onion)	0.01	17.4	0.2	27.9	0.3	7.3	0.1	16.0	0.2	22.8	0.2	34.5	0.3	30.1	0.3
VA 0387	Onion, Welsh	0.33	0.1	0.0	4.8	1.6	0.1	0.0	1.0	0.3	1.0	0.3	2.7	0.9	0.6	0.2
JF 0004	Orange juice	0.003	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	0.2
FC 0004	Orange, sweet, sour + orange-like hybrid (excl juice)	0.045	7.0	0.3	117.1	5.3	2.0	0.1	2.4	0.1	200.7	9.0	0.5	0.0	0.2	0.0
FS 0247	Peach	0.055	1.7	0.1	1.7	0.1	1.1	0.1	0.1	0.0	1.0	0.1	1.7	0.1	10.2	0.6
FP 0009	Pome fruit (excl apple juice)	0.025	20.8	0.5	11.6	0.3	3.3	0.1	0.1	0.0	10.7	0.3	23.6	0.6	36.9	0.9
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
FB 0272	Raspberries, red, black	0.42	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.2	0.1	0.0	0.0	0.5	0.2
VL 0502	Spinach	1.6	9.4	15.0	0.4	0.6	0.0	0.0	0.0	0.0	0.2	0.3	4.3	6.9	2.0	3.2
VA 0389	Spring onion	0.33	0.1	0.0	4.8	1.6	0.1	0.0	1.0	0.3	1.0	0.3	2.7	0.9	0.6	0.2
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
TN 0085	Tree nuts	0.02	16.3	0.3	15.7	0.3	9.7	0.2	1.9	0.0	19.1	0.4	29.0	0.6	5.6	0.1
	Total intake (µg/person)=			20.3		17.1		3.6		2.7		17.4		15.8		22.3
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			2750		3000		3000		3000		3000		2750		3000
	%ADI=			0.7%		0.6%		0.1%		0.1%		0.6%		0.6%		0.7%
	Rounded %ADI=			1%		1%		0%		0%		1%		1%		1%

Annex 3

TRIFLOXYSTROBIN (213) International Estimated Daily Intake (IEDI) ADI = 0–0.04 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day A diet	intake	B diet	intake	C diet	intake	D diet	intake	E diet	intake	F diet	intake
			Intake = daily intake: µg/person											
JF 0226	Apple juice	0.018	0.0	0.0	2.8	0.1	0.1	0.0	1.1	0.0	6.8	0.1	7.4	0.1
DF 0226	Apple, dried	0.043	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
VS 0621	Asparagus	0	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	0.02	38.8	0.8	17.4	0.3	16.0	0.3	6.6	0.1	21.5	0.4	33.8	0.7
GC 0640	Barley (incl pot, incl pearled, incl flour & grits, incl beer)	0.04	40.6	1.6	16.8	0.7	93.9	3.8	13.2	0.5	48.6	1.9	36.1	1.4
VB 0402	Brussels sprouts	0.17	0.0	0.0	0.1	0.0	2.8	0.5	5.5	0.9	1.5	0.3	1.9	0.3
VB 0041	Cabbage, head	0.17	1.2	0.2	14.4	2.4	2.7	0.5	16.4	2.8	15.4	2.6	18.5	3.1
VR 0577	Carrot	0.035	0.6	0.0	15.1	0.5	8.1	0.3	13.9	0.5	27.1	0.9	28.4	1.0
VS 0624	Celery	0.18	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 (excl lemon juice, excl mandarin juice, excl orange juice, excl grapefruit juice, excl NES juice)	0.095	15.7	1.5	86.5	8.2	52.6	5.0	24.2	2.3	16.2	1.5	12.0	1.1
-	Citrus juice NES	0.018	0.0	0.0	1.7	0.0	0.1	0.0	0.0	0.0	1.1	0.0	0.3	0.0
MO 0097	Edible offal of cattle, pigs & sheep	0.008	3.2	0.0	13.3	0.1	3.5	0.0	11.0	0.1	11.7	0.1	7.5	0.1
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	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	0.17	0.2	0.0	11.1	1.9	3.6	0.6	0.4	0.1	7.7	1.3	4.1	0.7
VC 0045	Fruiting vegetables, cucurbits	0.095	26.6	2.5	107.5	10.2	95.9	9.1	82.2	7.8	25.4	2.4	23.2	2.2
FB 0269	Grape (excl dried, excl juice, excl wine)	0.15	1.9	0.3	9.2	1.4	23.8	3.6	9.8	1.5	0.0	0.0	0.0	0.0
JF 0269	Grape juice	0.036	0.0	0.0	0.1	0.0	0.1	0.0	0.1	0.0	1.4	0.1	1.0	0.0
DF 0269	Grape, dried (= currants, raisins and sultanas)	0.345	0.0	0.0	2.9	1.0	0.4	0.1	0.4	0.1	2.3	0.8	1.7	0.6
JF 0203	Grapefruit juice	0.018	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	9.95	0.1	1.0	0.1	1.0	0.1	1.0	0.1	1.0	0.3	3.0	0.1	1.0
VA 0384	Leek	0.31	0.3	0.1	5.3	1.6	0.0	0.0	0.2	0.1	4.6	1.4	1.5	0.5
-d	Lemon juice	0.018	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	5.55	0.1	0.3	6.2	34.1	0.7	3.6	0.1	0.3	0.1	0.3	0.0	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
-	Mandarin + mandarin-like hybrid juice	0.018	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: 20% as fat	0.006	5.5	0.0	23.3	0.1	7.7	0.0	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
FT 0305	Olive (table olives, only)	0.085	0.0	0.0	4.8	0.4	0.8	0.1	0.4	0.0	1.0	0.1	0.8	0.1
OR 0305	Olive oil, refined	0.353	0.0	0.0	14.3	5.0	3.9	1.4	0.0	0.0	1.5	0.5	0.8	0.3
JF 0004	Orange juice	0.018	0.0	0.0	2.1	0.0	4.4	0.1	1.4	0.0	16.2	0.3	22.6	0.4
FI 0350	Papaya	0.2	5.1	1.0	0.1	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	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
-	Pear, dried	0.043	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-

TRIFLOXYSTROBIN (213) International Estimated Daily Intake (IEDI) ADI = 0–0.04 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 0445	Peppers, sweet (incl. pim(i)ento)	0.1	0.7	0.1	14.9	1.5	8.8	0.9	3.2	0.3	3.1	0.3	2.0	0.2
DF 0014	Plum, dried (prunes)	0.57	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)	0.11	0.5	0.1	79.9	8.8	21.8	2.4	43.6	4.8	51.5	5.7	35.1	3.9
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
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 0590	Radish, black	0.065	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
VR 0591	Radish, Japanese	0.065	2.3	0.1	0.0	0.0	0.0	0.0	2.0	0.1	0.0	0.0	0.0	0.0
GC 0649	Rice (incl husked, excl polished)	0.16	46.3	7.4	0.3	0.0	3.4	0.5	9.1	1.4	4.3	0.7	0.6	0.1
CM 1206	Rice bran, unprocessed	0.25	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CM 1205	Rice, polished (incl flour)	0.029	29.8	0.9	20.9	0.6	60.8	1.8	16.1	0.5	5.6	0.2	8.1	0.2
FS 0012	Stone fruit (excl dried plums, incl dried apricots)	0.38	0.7	0.3	44.1	16.8	14.1	5.4	26.6	10.1	26.3	10.0	8.3	3.1
FB 0275	Strawberry	0.335	0.0	0.0	5.0	1.7	2.0	0.7	1.7	0.6	5.2	1.7	4.1	1.4
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
VO 0448	Tomato (incl juice, excl paste, incl canned)	0.08	9.8	0.8	179.8	14.4	104.0	8.3	56.7	4.5	16.4	1.3	22.9	1.8
-d	Tomato paste	0.13	0.5	0.1	1.3	0.2	3.5	0.5	1.0	0.1	3.8	0.5	4.5	0.6
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 (excl bulgur wholemeal, excl flour)	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
CM 0654	Wheat bran, unprocessed	0.062	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CF 1211	Wheat flour (incl macaroni, bread, pastry, starch, gluten)	0.008	63.4	0.5	296.3	2.4	327.5	2.6	300.0	2.4	181.6	1.5	166.2	1.3
CF 1210	Wheat germ	0.013	0.0	0.0	1.3	0.0	0.0	0.0	1.3	0.0	0.9	0.0	1.2	0.0
CF 1212	Wheat wholemeal	0.01	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
-	Wine	0.023	1.3	0.0	76.8	1.8	1.1	0.0	15.4	0.4	68.8	1.6	25.6	0.6
	Total intake (µg/person)=			21.8		126.1		57.9		49.6		47.7		31.7
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			2400		2400		2400		2400		2400		2400
	%ADI=			0.9%		5.3%		2.4%		2.1%		2.0%		1.3%
	Rounded %ADI=			1%		5%		2%		2%		2%		1%

TRIFLOXYSTROBIN (213) International Estimated Daily Intake (IEDI) ADI = 0–0.04 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	0.018	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	0.043	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
VS 0621	Asparagus	0	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	0.02	21.4	0.4	36.6	0.7	11.4	0.2	9.2	0.2	70.2	1.4	40.5	0.8	32.6	0.7

Annex 3

TRIFLOXYSTROBIN (213) International Estimated Daily Intake (IEDI) ADI = 0–0.04 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day G diet	Intake = daily intake: µg/person intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake	M diet	intake
GC 0640	Barley (incl pot, incl pearled, incl flour & grits, incl beer)	0.04	5.9	0.2	20.5	0.8	5.9	0.2	2.5	0.1	20.2	0.8	16.8	0.7	43.8	1.8
VB 0402	Brussels sprouts	0.17	3.4	0.6	0.4	0.1	0.0	0.0	0.0	0.0	0.5	0.1	7.9	1.3	0.3	0.1
VB 0041	Cabbage, head	0.17	10.0	1.7	1.0	0.2	7.2	1.2	1.0	0.2	1.4	0.2	23.9	4.1	17.0	2.9
VR 0577	Carrot	0.035	5.4	0.2	7.9	0.3	2.5	0.1	3.5	0.1	4.1	0.1	8.6	0.3	19.4	0.7
VS 0624	Celery	0.18	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 (excl lemon juice, excl mandarin juice, excl orange juice, excl grapefruit juice, excl NES juice)	0.095	15.1	1.4	153.9	14.6	3.4	0.3	41.7	4.0	218.9	20.8	23.1	2.2	18.0	1.7
-	Citrus juice NES	0.018	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
MO 0097	Edible offal of cattle, pigs & sheep	0.008	4.0	0.0	10.4	0.1	3.5	0.0	2.7	0.0	6.4	0.1	6.2	0.0	5.4	0.0
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	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	0.17	9.6	1.6	7.9	1.3	0.6	0.1	0.2	0.0	0.9	0.2	1.1	0.2	8.0	1.4
VC 0045	Fruiting vegetables, cucurbits	0.095	69.7	6.6	25.9	2.5	14.9	1.4	18.0	1.7	18.7	1.8	39.1	3.7	44.2	4.2
FB 0269	Grape (excl dried, excl juice, excl wine)	0.15	1.2	0.2	2.6	0.4	0.0	0.0	0.2	0.0	0.0	0.0	3.7	0.6	0.0	0.0
JF 0269	Grape juice	0.036	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
DF 0269	Grape, dried (= currants, raisins and sultanas)	0.345	0.0	0.0	0.2	0.1	0.2	0.1	0.0	0.0	0.3	0.1	0.4	0.1	2.6	0.9
JF 0203	Grapefruit juice	0.018	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
DH 1100	Hops, dry	9.95	0.0	0.0	0.1	1.0	0.1	1.0	0.1	1.0	0.1	1.0	0.1	1.0	0.6	6.0
VA 0384	Leek	0.31	0.8	0.2	0.2	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.3	0.1	0.1	0.0
-d	Lemon juice	0.018	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
VL 0482	Lettuce, head	5.55	1.2	6.7	3.5	19.4	0.1	0.6	0.3	1.7	1.0	5.6	1.2	6.7	7.9	43.6
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
-	Mandarin + mandarin-like hybrid juice	0.018	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 mammals: 20% as fat	0.006	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	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
FT 0305	Olive (table olives, only)	0.085	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.6	0.1	0.0	0.0	1.0	0.1
OR 0305	Olive oil, refined	0.353	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.3	0.1	0.3	0.1	1.6	0.6
JF 0004	Orange juice	0.018	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	1.0
FI 0350	Papaya	0.2	1.3	0.3	11.5	2.3	1.6	0.3	13.7	2.7	14.5	2.9	1.0	0.2	0.6	0.1
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
-	Pear, dried	0.043	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
VO 0445	Peppers, sweet (incl. pim(i)ento)	0.1	0.0	0.0	9.4	0.9	4.2	0.4	4.7	0.5	1.7	0.2	2.6	0.3	4.4	0.4
DF 0014	Plum, dried (prunes)	0.57	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)	0.11	20.8	2.3	11.6	1.3	3.3	0.4	0.1	0.0	10.7	1.2	23.6	2.6	36.9	4.1
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
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

TRIFLOXYSTROBIN (213) International Estimated Daily Intake (IEDI) ADI = 0–0.04 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day Intake = daily intake: µg/person G diet	intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake	M 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
VR 0590	Radish, black	0.065	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
VR 0591	Radish, Japanese	0.065	7.0	0.5	0.3	0.0	2.3	0.1	3.3	0.2	1.0	0.1	7.4	0.5	0.0	0.0
GC 0649	Rice (incl husked, excl polished)	0.16	1.4	0.2	1.0	0.2	2.3	0.4	29.6	4.7	92.0	14.7	9.2	1.5	0.4	0.1
CM 1206	Rice bran, unprocessed	0.25	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CM 1205	Rice, polished (incl flour)	0.029	250.3	7.3	42.2	1.2	23.8	0.7	29.8	0.9	97.6	2.8	248.1	7.2	22.8	0.7
FS 0012	Stone fruit (excl dried plums, incl dried apricots)	0.38	6.7	2.5	4.3	1.6	1.4	0.5	0.1	0.0	4.9	1.9	4.9	1.9	17.7	6.7
FB 0275	Strawberry	0.335	0.0	0.0	1.8	0.6	0.1	0.0	0.0	0.0	0.3	0.1	6.2	2.1	5.9	2.0
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
VO 0448	Tomato (incl juice, excl paste, incl canned)	0.08	23.1	1.8	23.3	1.9	12.6	1.0	14.6	1.2	33.2	2.7	4.3	0.3	98.2	7.9
-d	Tomato paste	0.13	0.1	0.0	2.1	0.3	0.6	0.1	0.4	0.1	0.6	0.1	1.4	0.2	1.2	0.2
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 (excl 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	0.062	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CF 1211	Wheat flour (incl macaroni, bread, pastry, starch, gluten)	0.008	133.0	1.1	60.1	0.5	52.4	0.4	32.2	0.3	87.7	0.7	79.6	0.6	180.1	1.4
CF 1210	Wheat germ	0.013	0.1	0.0	48.1	0.6	1.8	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.6	0.0
CF 1212	Wheat wholemeal	0.01	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
-	Wine	0.023	1.0	0.0	0.9	0.0	6.8	0.2	0.1	0.0	3.4	0.1	3.6	0.1	31.0	0.7
	Total intake (µg/person)=			39.4		60.4		16.0		21.3		62.5		42.1		96.7
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			2200		2400		2400		2400		2400		2200		2400
	%ADI=			1.8%		2.5%		0.7%		0.9%		2.6%		1.9%		4.0%
	Rounded %ADI=			2%		3%		1%		1%		3%		2%		4%

ANNEX 4: INTERNATIONAL ESTIMATES OF SHORT-TERM DIETARY INTAKES OF PESTICIDE RESIDUES

ACETAMIPRID (246) International estimate of short term intake (IESTI) Acute RfD= 0.100 mg/kg bw (100 µg/kg bw)

Maximum %ARfD: 120% all-mixed 120% children 70% gen pop

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Mixed population groups Coun try	Population group	n	Large portion, g/person	Unit weight, ed portion, g	Varia-bility factor	Case	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
-	Amaranth (Bledo)	raw		1.9	1.000	CN	Gen pop, > 1 yrs	714	581.7	85.8	3	2a	30%	NC	30%
VL 0464	Chard (silver beet)	Total		1.9	1.000	NL	Child, 2-6 yrs	2	136.2	175.0	3	2b	40%	40%	20%
-	Chicory leaves (sugar loaf)	raw		1.9	1.000	DE	Child, 2-4 yrs	16	82.4	280.5	3	2b	30%	30%	9%
-	Chinese cabbage, type pak-choi	raw		1.9	1.000	CN	Child, 1-6 yrs	1966	327.1	1548.4	3	2b	120%	120%	60%
VL 0467	Chinese cabbage, type pe-tsai	Total		1.9	1.000	CN	Child, 1-6 yrs	2788	336.2	1500.0	3	2b	120%	120%	70%
-	Corn salad (lambs lettuce)	raw		1.9	1.000	DE	Child, 2-4 yrs	13	41.2	7.8	NR	1	5%	5%	2%
-	Cos lettuce	raw		1.9	1.000	NL	Child, 2-6 yrs	91	140.1	289.9	3	2b	40%	40%	10%
-	Cress, garden	raw		1.9	1.000	CN	Gen pop, > 1 yrs	1443	352.5	15.0	NR	1	10%	0%	10%
-	Dandelion leaves	raw		1.9	1.000	NL	gen pop, > 1 yrs	E	49.9	35.0	3	2a	3%	-	3%
VL 0476	Endive	Total		1.9	1.000	NL	toddler, 8-20 m	54	201.9	375.0	3	2b	110%	110%	30%
VL 0269	Grape leaves	Total		1.9	1.000	NL	Gen pop, > 1 yrs	1	54.6	1.4	NR	1	2%	1%	2%
-	Indian mustard (Amsoi)	raw		1.9	1.000	NL	Gen pop, > 1 yrs	E	49.9	250.0	3	2b	4%	NC	4%
-	Japanese greens: Chrysanthemum leaves	raw		1.9	1.000	CN	Gen pop, > 1 yrs	993	332.7	< 25	NR	1	10%	-	10%
VL 0479	Japanese greens: Mizuna	Total		1.9	1.000	JP	Gen pop, > 1 yrs	1787	137.7	< 25	NR	1	5%	4%	5%
VL 0480	Kale (borecole, collards)	Total		1.9	1.000	NL	toddler, 8-20 m	33	100.6	672.0	3	2b	60%	60%	50%
-	Kangkung (water spinach)	raw		1.9	1.000	CN	Child, 1-6 yrs	183	270.7	85.8	3	2a	50%	50%	30%
VL 0481	Komatsuna	Total		1.9	1.000	JP	Child, 1-6 yrs	73	71.4	< 25	NR	1	8%	8%	5%
VL 0483	Lettuce, leaf	Total		1.9	1.000	CN	Child, 1-6 yrs	243	387.3	305.4	3	2a	120%	120%	40%
-	Mustard greens	raw		1.9	1.000	CN	Child, 1-6 yrs	635	299.3	244.8	3	2a	90%	90%	40%
VL 0492	Purslane	Total		1.9	1.000	NL	Gen pop, > 1 yrs	8	452.0	< 25	NR	1	10%	-	10%
-	Rape greens	cooked/boiled		1.9	1.000	JP	Gen pop, > 1 yrs	533	147.9	34.0	3	2a	7%	10%	7%
VL 0496	Rucola (arrugula, rocket)	Total		1.9	1.000	AU	Gen pop, > 2 yrs	10	157.3	212.8	3	2b	10%	-	10%
VL 0502	Spinach	Total		2.5	1.000	ZA	Child, 1-5 yrs	-	237.5	197.8	3	2a	110%	110%	30%
-	Taro leaves	raw		1.9	1.000	NL	Gen pop, > 1 yrs	E	77.8	85.8	3	2b	7%	NC	7%
VL 0506	Turnip greens (Namenia)	Total		1.9	1.000	NL	toddler, 8-20 m	110	322.0	< 25	NR	1	60%	60%	20%
-	Watercress	raw		1.9	1.000	BR	gen pop, >10 yrs	97	90.9	254.6	3	2b	8%	2%	8%

Annex 4

BUPROFEZIN (173) International estimate of short term intake (IESTI) Acute RfD= 0.500 mg/kg bw (500 µg/kg bw)

Maximum %ARfD: 7% all-mixed 7% children 6% gen pop

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Mixed population groups 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
-	Banana	raw without peel		0.01	1.000	CN	Child, 1-6 yrs	286	455.8	767.3	3	2b	0%	0%	0%
DT 1114	Tea, green, black (black, fermented and dried)	Total	9		1.000	FR	Child, 3-6 yrs	5.9 %	75.9	< 25	NR	3	7%	7%	6%

CHLOROTHALONIL (81) International estimate of short term intake (IESTI) Acute RfD= 0.600 mg/kg bw (600 µg/kg bw)

Maximum %ARfD: 70% all-mixed 70% children 30% gen pop

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Mixed population groups 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
-	Banana	raw without peel		1	1.000	CN	Child, 1-6 yrs	286	455.8	767.3	3	2b	10%	10%	7%
VL 0464	Chard (silver beet)	Total		19.4	1.000	NL	Child, 2-6 yrs	2	136.2	175.0	3	2b	70%	70%	30%

CYCLOXYDIM (179) International estimate of short term intake (IESTI) Acute RfD= 2 mg/kg bw (for women of childbearing age)

Max %ARfD: 4% Women of childbearing age 14-50 ys Max %ARfD: 10% General population (> 1 yrs)

Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	Country	Large portion, g/person	Unit weight, edible portion, g	Case	% acute RfD rounded	Country	Large portion, g/person	Unit weight, edible portion, g	Case	% acute RfD rounded
FP 0226	Apple	raw with peel (incl consumption without peel)		0.09	DE	517.3	167.1	2a	0%	CN	693.1	255.0	2a	0%
FP 0230	Pear	raw with peel (incl consumption without peel)		0.09	DE	303.4	192.0	2a	0%	CN	685.0	255.0	2a	0%
FP 0231	Quince	Total		0.09	DE	1.1	301.2	2b	0%	NL	2.0	301.2	2b	0%
FS 0013	Cherries	raw		0.09	DE	740.5	7.2	1	0%	AU	712.8	5.1	1	0%

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CYCLOXYDIM (179) International estimate of short term intake (IESTI) Acute RfD= 2 mg/kg bw (for women of childbearing age)

Max %ARfD: 4% Max %ARfD: 10%

Women of childbearing age 14-50 ys General population (> 1 yrs)

Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	Country	Large portion, g/person	Unit weight, edible portion, g	Case	% acute RfD rounded	Country	Large portion, g/person	Unit weight, edible portion, g	Case	% acute RfD rounded
FS 0014	Plum	raw with peel (incl consumption without peel)		0.09	DE	705.0	48.4	2a	0%	AU	609.9	84.0	2a	0%
-	Japanese apricot	Total		0.09	-	-	-	-	-	JP	30.6	< 25	1	0%
FS 0240	Apricot	raw with peel (incl consumption without peel)		0.09	DE	418.6	45.5	2a	0%	AU	1056.9	54.5	2a	0%
FS 0245	Nectarine	raw with peel (incl consumption without peel)		0.09	DE	315.0	97.1	2a	0%	AU	617.9	121.0	2a	0%
FS 0247	Peach	raw with peel (incl consumption without peel)		0.09	DE	315.0	127.6	2a	0%	AU	704.0	146.9	2a	0%
FB 0269	Grape	raw with skin		0.18	DE	381.2	636.6	2b	0%	CN	570.3	636.6	2b	0%
FB 0275	Strawberry	Raw with skin		1.4	DE	500.0	18.0	1	1%	NL	442.2	18.0	1	0%
-	Strawberry	canned/preserved		1.26	-	-	-	-	-	NL	107.5	7.0	1	0%
VR 0577	Carrot	raw with skin		3	DE	145.8	50.3	2a	1%	CN	354.8	300.0	2a	3%
-	Carrot	cooked/boiled (with skin)		2.31	-	-	-	-	-	NL	406.8	270.0	2a	2%
-	Carrot	canned/preserved		1.08	-	-	-	-	-	NL	536.8	4.7	1	0%
-	Carrot	juice (pasteurised)	0.22		-	-	-	-	-	AU	772.6	NR	3	0%
VR 0578	Celeriac	Total		0.69	DE	33.4	476.2	2b	0%	NL	295.4	508.2	2b	0%
-	Celeriac	raw without skin		0.69	-	-	-	-	-	NL	137.1	508.2	2b	0%
VR 0589	Potato	Total		1.6	DE	343.8	71.6	2a	1%	NL	692.2	134.1	2a	1%
-	Potato	boiled\microwaved (without peel)		2.4	-	-	-	-	-	AU	649.1	123.0	2a	2%
-	Potato	fried (without peel)		2.08	-	-	-	-	-	BR	420.0	140.0	2a	1%
VR 0574	Beetroot	total		0.1	DE	1421	29.3	2b	0%	NL	429.7	215.0	2b	0%
VA 0384	Leek	Total		2.3	DE	45.9	90.8	2b	0%	NL	365.8	175.5	2a	1%
VA 0385	Onion, bulb	raw without skin		0.429	-	-	-	-	-	JP	153.0	244.4	2b	0%
VO 0444	Peppers, chili	raw with skin		5.3	-	-	-	-	-	CN	295.7	43.2	2a	2%
-	Peppers, chili	dried (incl powder)		53	-	-	-	-	-	CN	32.2	0.0	1	10%

CYCLOXYDIM (179)

International estimate of short term intake (IESTI)
Max %ARfD: 4%
Women of childbearing age 14-50 ys

Acute RfD= 2 mg/kg bw (for women of childbearing age)
Max %ARfD: 10%
General population (> 1 yrs)

Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	Country	Large portion, g/person	Unit weight, edible portion, g	Case	% acute RfD rounded	Country	Large portion, g/person	Unit weight, edible portion, g	Case	% acute RfD rounded
VO 0445	Peppers, sweet (incl. pim(i)ento) (bell pepper, paprika)	raw with skin		5.3	DE	191.7	119.3	2a	2%	CN	280.6	170.0	2a	3%
VO 0448	Tomato	raw with peel		0.89	DE	200.0	98.5	2a	0%	CN	376.8	174.6	2a	1%
-	Tomato	canned/preserved (without peel)		0.51	-	-	-	-	-	AU	479.0	128.7	2a	0%
JF 0448	Tomato	juice (pasteurised)	0.49		-	-	-	-	-	DE	1000.3	NR	3	0%
-	Tomato	sauce/puree (single strength)	1.65		-	-	-	-	-	NL	540.3	NR	3	1%
VB 0041	Cabbage, head	Total		6	DE	329.7	1226.2	2b	4%	NL	439.5	895.2	2b	6%
-	Cabbage, head	cooked/boiled		3.36	-	-	-	-	-	NL	344.7	833.0	2b	3%
VB 0402	Brussels sprouts	Total		6	DE	309.1	9.5	1	1%	NL	375.7	8.3	1	2%
VB 0400	Broccoli	Total		6	DE	285.5	211.7	2a	3%	NL	465.9	304.0	2a	5%
VB 0401	Broccoli, Chinese (Kailan)	raw		6	-	-	-	-	-	CN	385.1	311.0	2a	6%
VB 0404	Cauliflower	Total		6	DE	169.8	554.0	2b	2%	NL	584.3	797.0	2b	8%
VB 0405	Kohlrabi	Total		6	DE	169.7	175.2	2b	2%	DE	169.7	175.2	2b	2%
VL 0480	Kale (borecole, collards)	Total		1.1	DE	366.4	672.0	2b	1%	DE	669.8	672.0	2b	1%
VL 0482	Lettuce, head	raw		1	DE	73.7	534.7	2b	0%	NL	159.8	338.9	2b	0%
VL 0483	Lettuce, leaf	raw		1	DE	73.7	305.4	2b	0%	NL	159.8	117.8	2a	0%
VP 0061	Beans except broad bean & soya bean (green pods & immature seeds) (Phaseolus spp)	Total		11	DE	213.7	19.4	1	2%	FR	388.2	19.4	1	4%
VP 0064	Peas, shelled (immature seeds) (Pisum spp, Vigna spp)	Total	2.7		DE	102.6	< 25	3	0%	FR	435.0	< 25	3	1%
VD 0071	Beans (dry) (Phaseolus spp)	cooked/boiled	3		-	-	-	-	-	CN	1313.2	0.5	3	1%
-	Peas (dry) (Pisum spp, Vigna spp)	cooked/boiled	3.2		-	-	-	-	-	CN	1673.8	< 25	3	2%

Annex 4

CYCLOXYDIM (179) International estimate of short term intake (IESTI) Acute RfD= 2 mg/kg bw (for women of childbearing age)

Max %ARfD: 4% Max %ARfD: 10%

Women of childbearing age 14-50 ys General population (> 1 yrs)

Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	Country	Large portion, g/person	Unit weight, edible portion, g	Case	% acute RfD rounded	Country	Large portion, g/person	Unit weight, edible portion, g	Case	% acute RfD rounded
VD 0541	Soya bean (dry) (Glycine spp)	Total	13		DE	30.8	< 25	3	0%	CN	446.8	< 25	3	5%
SO 0495	Rape seed	Total	1.9		DE	18.5	< 25	3	0%	NL	55.9	< 25	3	0%
OR 0495	Rape seed	Oil (refined)	0.095		DE	35.0	NR	3	0%	AU	40.7	NR	3	0%
SO 0702	Sunflower seed	Total	0.375		DE	68.6	< 25	3	0%	CN	235.5	< 25	3	0%
SO 0693	Linseed	total	1.9		DE	19.5	< 25	3	0%	FI	58.5	< 25	3	0%
GC 0645	Maize (corn)	Total	0.09		DE	100.6	< 25	3	0%	CN	890.8	< 25	3	0%
CM 1205	Rice	polished rice (cooked)	0.09		-	-	-	-	-	CN	2047.3	< 25	3	0%
MM 0095	Meat from mammals other than marine mammals: 20% as fat	Total		9E-04	-	-	-	-	-	AU	111.7	NR	1	0%
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	Total		0.035	-	-	-	-	-	AU	447.0	NR	1	0%
MM 0812	Cattle meat: 20% as fat	Total		9E-04	DE	44.5	NR	1	0%	FR	104.4	NR	1	0%
MM 0812	Cattle meat: 80% as muscle	Total		0.035	DE	177.9	NR	1	0%	FR	417.6	NR	1	0%
MM 0813	Deer meat: 20% as fat	Total		9E-04	DE	104.2	NR	1	0%	AU	88.2	NR	1	0%
MM 0813	Deer meat: 80% as muscle	Total		0.035	DE	416.9	NR	1	0%	AU	352.7	NR	1	0%
MF 0812	Cattle fat	Total		0.01	DE	20.4	NR	1	0%	AU	92.1	NR	1	0%
MF 0818	Pig fat	Total		0.061	DE	51.6	NR	1	0%	FR	108.0	NR	1	0%
MO 0105	Edible offal (mammalian)	Total		0.038	-	-	-	-	-	US	787.8	NR	1	0%
PM 0110	Poultry meat: 10% as fat	Total		0.003	DE	45.7	NR	1	0%	DE	59.4	NR	1	0%
PM 0110	Poultry meat: 90% as muscle	Total		0.027	DE	410.9	NR	1	0%	DE	534.2	NR	1	0%
PF 0111	Poultry, fats	Total		0.03	DE	15.0	NR	1	0%	US	42.9	NR	1	0%

CYCLOXYDIM (179) International estimate of short term intake (IESTI) Acute RfD= 2 mg/kg bw (for women of childbearing age)

Max %ARfD: 4% Max %ARfD: 10%

Women of childbearing age 14-50 ys General population (> 1 yrs)

Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	Country	Large portion, g/person	Unit weight, edible portion, g	Case	% acute RfD rounded	Country	Large portion, g/person	Unit weight, edible portion, g	Case	% acute RfD rounded
PO 0111	Poultry, edible offal of (includes kidney, liver and skin)	Total		0.018	DE	231.3	NR	1	0%	DE	341.3	NR	1	0%
ML 0812	Cattle milk	Total	0.004		-	-	-	-	-	AU	3235.2	NR	3	0%
PE 0112	Eggs	Total		0.092	-	-	-	-	-	TH	194.9	NR	1	0%
PE 0840	Chicken eggs	Total		0.092	DE	136.6	NR	1	0%	FR	382.8	NR	1	0%

CYFLUTHRIN (157) International estimate of short term intake (IESTI) Acute RfD = 0.040 mg/kg bw (40 µg/kg bw)

Maximum %ARfD: 6% all-mixed 6% children 3% gen pop

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Mixed population groups 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
–	Cabbage, head	raw		0.05	1.000	CN	Child, 1–6 yrs	287	255.5	1402.5	3	2b	6%	6%	3%
MM 0812	Cattle meat	Total	NA	NA	1.000	FR	Child, 3–6 yrs	98.8%	254.6	NR	NR	1	1%	1%	1%
MM 0812	Cattle meat: 20% as fat	Total		0.16	1.000	FR	Child, 3–6 yrs	98.8%	50.9	NR	NR	1	1%	1%	1%
MM 0812	Cattle meat: 80% as muscle	Total		0.01	1.000	FR	Child, 3–6 yrs	98.8%	203.7	NR	NR	1	0%	0%	0%
MO 0105	Edible offal (mammalian)	Total		0.01	1.000	US	Child, 1–6 yrs	–	186.6	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	1%	1%	1%
MM 0095	Meat from mammals other than marine mammals: 20% as fat	Total		0.16	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		0.01	1.000	AU	Child, 2–6 yrs	2269	203.5	NR	NR	1	0%	0%	0%
ML 0106	Milks	Total	0.004		1.000	AU	Child, 2–6 yrs	2923	1933.6	NR	NR	3	1%	1%	0%
–	Soya bean (dry) (Glycine spp)	soybean milk	0.01		1.000	AU	Child, 2–6 yrs	102	1131.2	NR	NR	3	1%	1%	0%

CYROMAZINE (166) International estimate of short term intake (IESTI) Acute RfD= 0.100 mg/kg bw (100 µg/kg bw)

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													Maximum %ARfD:		20% all-mixed	20% children	10% gen pop
Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Mixed population groups 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
-	Chick-pea (dry) (Cicer spp)	canned/preserved	1		0.400	NL	Child, 2-6 yrs	6	144.7	< 25	NR	3	3%	3%	3%
VD 0533	Lentil (dry) (Lens spp)	Total	1		1.000	FR	Child, 3-6 yrs	19.4%	290.8	0.1	NR	3	20%	20%	10%

DICHLORVOS (0.25) International estimate of short term intake (IESTI) Acute RfD= 0.100 mg/kg bw (100 µg/kg bw)

													Maximum %ARfD:		110% all-mixed	110% children	20% women	70% gen pop
Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Mixed population groups 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	% acute RfD rounded
GC 0649	Rice	Total		5.2	1.000	US	Child, 1-6 yrs	-	99.8	< 25	NR	1	30%	30%	6%	20%
-	Rice	rice wine	2.8		1.000	AU	Child, 2-6 yrs	25	772.5	NR	NR	3	110%	110%	-	70%
GC 0654	Wheat	Total	2.2	4.1	1.000	FR	Child, 3-6 yrs	100.0%	384.3	< 25	NR	1	80%	80%	20%	60%
-	Wheat	Pasta/noodles (dry)	0.132		1.000	CN	Child, 1-6 yrs	2023	225.9	NR	NR	3	2%	2%	-	1%
CP 1211	Wheat	White bread	0.073		1.000	CN	Child, 1-6 yrs	1756	322.7	NR	NR	3	1%	1%	-	1%
CP 1212	Wheat	Wholemeal bread	0.123		1.000	ZA	gen pop, > 10 yrs	-	395.5	NR	NR	3	1%	1%	-	1%
CF 1211	Wheat	flour (cereals)	0.22		1.000	CN	Child, 1-6 yrs	3556	415.9	NR	NR	3	6%	6%	-	3%

Annex 4

DICOFOL (26) International estimate of short term intake (IESTI) Acute RfD= 0.200 mg/kg bw (200 µg/kg bw)

Maximum %ARfD: 20% all-mixed; 20% children; 2% women; 20% gen pop

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Mixed population groups: 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	% acute RfD rounded
DT 1114	Tea, green, black (black, fermented and dried)	Total	11.2		1.000	FR	Child, 3-6 yrs	5.9%	75.9	< 25	NR	3	20%	20%	2%	20%
-	Tea, green, black (black, fermented and dried)	infusion (brew/beverage)	0.18		0.010	BR	Gen pop, > 10 yrs	3534	2640.0	NR	NR	3	0%	0%	-	0%

DINOTEFURAN (255) International estimate of short term intake (IESTI) Acute RfD= 1.000 mg/kg bw (1000 µg/kg bw)

Maximum %ARfD: 30% all-mixed; 30% children; 20% gen pop

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Mixed population groups: 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
-	Amaranth (Bledo)	raw		4.4	1.000	CN	Gen pop, > 1 yrs	714	581.7	85.8	3	2a	6%	NC	6%
-	Balsam pear (Bitter cucumber, Bitter gourd, Bitter melon)	raw without peel		0.33	1.000	CN	Gen pop, > 1 yrs	1387	400.2	607.5	3	2b	1%	1%	1%
-	Bottle gourd (Cucuzzi)	raw with skin		0.33	1.000	CN	Gen pop, > 1 yrs	519	453.0	325.0	3	2a	1%	NC	1%
VB 0400	Broccoli	Total		1.1	1.000	NL	toddler, 8-20 m	128	171.0	304.0	3	2b	6%	6%	2%
-	Broccoli, Chinese (Kailan)	raw		1.1	1.000	CN	Child, 1-6 yrs	334	222.5	311.0	3	2b	5%	5%	2%
VB 0402	Brussels sprouts	Total		1.1	1.000	NL	toddler, 8-20 m	11	103.8	8.3	NR	1	1%	1%	1%
-	Cabbage, head	raw		1.1	1.000	CN	Child, 1-6 yrs	287	255.5	1402.5	3	2b	5%	5%	2%
MM 0812	Cattle meat	Total	NA	NA	1.000	FR	Child, 3-6 yrs	98.8%	254.6	NR	NR	1	0%	0%	0%
MM 0812	Cattle meat: 20% as fat	Total		0.062	1.000	FR	Child, 3-6 yrs	98.8%	50.9	NR	NR	1	0%	0%	0%
MM 0812	Cattle meat: 80% as muscle	Total		0.062	1.000	FR	Child, 3-6 yrs	98.8%	203.7	NR	NR	1	0%	0%	0%
ML 0812	Cattle milk	Total	0.039		1.000	NL	toddler, 8-20 m	1882	1060.7	NR	NR	3	0%	0%	0%

Annex 4

DINOTEFURAN (255) International estimate of short term intake (IESTI) Acute RfD= 1.000 mg/kg bw (1000 µg/kg bw)

Maximum %ARfD: 30% all-mixed 30% children 20% gen pop

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Mixed population groups 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
VB 0404	Cauliflower	Total		1.1	1.000	NL	toddler, 8-20 m	173	148.1	797.0	3	2b	5%	5%	3%
-	Celery	raw		0.67	1.000	CN	Child, 1-6 yrs	454	180.3	861.1	3	2b	2%	2%	1%
VL 0464	Chard (silver beet)	Total		4.4	1.000	NL	Child, 2-6 yrs	2	136.2	175.0	3	2b	10%	10%	4%
-	Chayote (Christophine)	raw with skin		0.33	1.000	CN	Child, 1-6 yrs	124	284.7	197.4	3	2a	1%	1%	1%
-	Chervil	raw		4.4	1.000	NL	Child, 2-6 yrs	E	3.5	< 25	NR	1	0%	0%	0%
PE 0840	Chicken eggs	Total		0	1.000	CN	Child, 1-6 yrs	3025	194.7	NR	NR	1	0%	0%	0%
-	Chicory leaves (sugar loaf)	raw		4.4	1.000	DE	Child, 2-4 yrs	16	82.4	280.5	3	2b	7%	7%	2%
-	Chinese cabbage flowering stalk	pickled/salted		4.4	1.000	CN	Gen pop, > 1 yrs	183	175.2	NR	NR	3	-	-	-
-	Chinese cabbage, type pak-choi	raw		4.4	1.000	CN	Child, 1-6 yrs	1966	327.1	1548.4	3	2b	30%	30%	10%
VL 0467	Chinese cabbage, type pe-tsai	Total		4.4	1.000	CN	Child, 1-6 yrs	2788	336.2	1500.0	3	2b	30%	30%	20%
-	Corn salad (lambs lettuce)	raw		4.4	1.000	DE	Child, 2-4 yrs	13	41.2	7.8	NR	1	1%	1%	1%
-	Cos lettuce	raw		4.4	1.000	NL	Child, 2-6 yrs	91	140.1	289.9	3	2b	10%	10%	3%
SO 0691	Cotton seed	Total	0.15		1.000	US	Gen pop, all ages	-	3.3	< 25	NR	3	0%	0%	0%
-	Cress, garden	raw		4.4	1.000	CN	Gen pop, > 1 yrs	1443	352.5	15.0	NR	1	3%	0%	3%
-	Cucumber	raw with skin		0.33	1.000	CN	Child, 1-6 yrs	340	212.1	458.1	3	2b	1%	1%	1%
-	Dandelion leaves	raw		4.4	1.000	NL	gen pop, > 1 yrs	E	49.9	35.0	3	2a	1%	-	1%
PM 0841	Duck meat	Total	NA	NA	1.000	CN	Child, 1-6 yrs	175	347.0	NR	NR	1	0%	0%	0%
PM 0841	Duck meat: 10% as fat	Total		0	1.000	CN	Child, 1-6 yrs	175	34.7	NR	NR	1	0%	0%	0%
PM 0841	Duck meat: 90% as musccle	Total		0	1.000	CN	Child, 1-6 yrs	175	312.3	NR	NR	1	0%	0%	0%
PO 0841	Duck, edible offal of (includes kidney and liver)	Total		0	1.000	CN	Gen pop, > 1 yrs	421	345.6	NR	NR	1	0%	-	0%
MO 0105	Edible offal (mammalian)	Total		0.076	1.000	US	Child, 1-6 yrs	-	186.6	NR	NR	1	0%	0%	0%
-	Egg plant (aubergine)	raw with skin		0.55	1.000	CN	Child, 1-6 yrs	969	253.4	443.9	3	2b	3%	3%	1%
VL 0476	Endive	Total		4.4	1.000	NL	toddler, 8-20 m	54	201.9	375.0	3	2b	30%	30%	8%
-	Gherkin	raw with skin		0.33	1.000	JP	Child, 1-6 yrs	484	91.8	54.5	3	2a	0%	0%	0%

DINOTEFURAN (255) International estimate of short term intake (IESTI) Acute RfD= 1.000 mg/kg bw (1000 µg/kg bw)

Maximum %ARfD: 30% all-mixed 30% children 20% gen pop

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Mixed population groups 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
-	Gilo (scarlet egg plant)	cooked/boiled (with skin)		0.55	1.000	BR	Gen pop, > 10 yrs	280	360.5	28.5	3	2a	0%	-	0%
-	Goji berry	Dried		0.55	3.000	AU	Child, 2-6 yrs	1	28.4	< 25	NR	1	0%	0%	-
-	Grape	raw with skin		0.67	1.000	CN	Child, 1-6 yrs	232	366.7	636.6	3	2b	5%	5%	2%
VL 0269	Grape leaves	Total		4.4	1.000	NL	Gen pop, > 1 yrs	1	54.6	1.4	NR	1	0%	0%	0%
-	Indian mustard (Amsoi)	raw		4.4	1.000	NL	Gen pop, > 1 yrs	E	49.9	250.0	3	2b	1%	NC	1%
-	Japanese greens: Chrysanthemum leaves (Chrysanthemum spp)	raw		4.4	1.000	CN	Gen pop, > 1 yrs	993	332.7	< 25	NR	1	3%	-	3%
VL 0479	Japanese greens: Mizuna (Brassica rapa nipposinica)	Total		4.4	1.000	JP	Gen pop, > 1 yrs	1787	137.7	< 25	NR	1	1%	1%	1%
VL 0480	Kale (borecole, collards)	Total		4.4	1.000	NL	toddler, 8-20 m	33	100.6	672.0	3	2b	10%	10%	10%
-	Kangkung (water spinach)	raw		4.4	1.000	CN	Child, 1-6 yrs	183	270.7	85.8	3	2a	10%	10%	6%
VB 0405	Kohlrabi	Total		1.1	1.000	DE	Child, 2-4 yrs	34	161.8	175.2	3	2b	3%	3%	1%
VL 0481	Komatsuna	Total		4.4	1.000	JP	Child, 1-6 yrs	73	71.4	< 25	NR	1	2%	2%	1%
-	Lettuce, head	raw		4.4	1.000	NL	Child, 2-6 yrs	91	140.1	338.9	3	2b	10%	10%	3%
VL 0483	Lettuce, leaf	Total		4.4	1.000	CN	Child, 1-6 yrs	243	387.3	305.4	3	2a	30%	30%	9%
-	Loofah, Smooth	raw without peel		0.33	1.000	CN	Child, 1-6 yrs	196	296.6	133.0	3	2a	1%	1%	0%
VC 0046	Melons, except watermelon	Total		0.33	1.000	FR	Child, 3-6 yrs	16.4%	358.1	420.0	3	2b	2%	2%	1%
-	Mustard greens	raw		4.4	1.000	CN	Child, 1-6 yrs	635	299.3	244.8	3	2a	20%	20%	9%
-	Nectarine	raw with peel (incl consumption without peel)		0.57	1.000	NL	toddler, 8-20 m	6	183.6	131.0	3	2a	2%	2%	1%
-	Okra (Lady's finger)	cooked/boiled (with skin)		0.55	1.000	JP	Child, 1-6 yrs	58	84.3	8.5	NR	1	0%	0%	0%
-	Onion, bulb	raw without skin		0.09	1.000	JP	Child, 1-6 yrs	748	102.0	244.4	3	2b	0%	0%	0%
-	Peach	raw with peel (incl consumption without peel)		0.57	1.000	JP	Child, 1-6 yrs	76	306.0	255.0	3	2a	3%	3%	1%
VO 0443	Pepino (Melon pear, Tree	Total		0.55	1.000	AU	Gen pop, > 2	3	73.9	122.9	3	2b	0%	-	0%

Annex 4

DINOTEFURAN (255) International estimate of short term intake (IESTI) Acute RfD= 1.000 mg/kg bw (1000 µg/kg bw)

Maximum %ARfD: 30% all-mixed 30% children 20% gen pop

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Mixed population groups 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
	melon)						yrs								
-	Peppers, chili	raw with skin		0.55	1.000	CN	Gen pop, > 1 yrs	1743	295.7	43.2	3	2a	0%	NC	0%
-	Peppers, sweet (incl. pim(i)ento) (bell pepper, paprika)	raw with skin		0.55	1.000	CN	Child, 1-6 yrs	1002	169.8	170.0	3	2b	2%	2%	1%
-	Pumpkins	raw without peel		0.33	1.000	CN	Child, 1-6 yrs	561	322.7	1851.8	3	2b	2%	2%	1%
VL 0492	Purslane	Total		4.4	1.000	NL	Gen pop, > 1 yrs	8	452.0	< 25	NR	1	3%	-	3%
-	Rape greens	cooked/boiled		4.4	1.000	JP	Gen pop, > 1 yrs	533	147.9	34.0	3	2a	2%	2%	2%
GC 0649	Rice	Total	3.3		1.000	US	Child, 1-6 yrs	-	99.8	< 25	NR	3	2%	2%	2%
VL 0496	Rucola (arrugula, rocket salad, roquette)	Total		4.4	1.000	AU	Gen pop, > 2 yrs	10	157.3	212.8	3	2b	3%	-	3%
-	Snake gourd	raw without peel		0.33	1.000	TH	Child, 3-6 yrs	759	129.6	133.0	3	2b	1%	1%	0%
-	Sowthistle	raw		4.4	1.000	CN	Gen pop, > 1 yrs	1187	592.5	-	-	-	-	-	-
VL 0502	Spinach	Total		4.4	1.000	ZA	Child, 1-5 yrs	-	237.5	197.8	3	2a	20%	20%	5%
-	Spring onion	cooked/boiled		2.3	1.000	NL	Child, 2-6 yrs	E	20.3	30.0	3	2b	1%	1%	0%
VC 0431	Squash, summer (courgette, marrow, zucchetti, zucchini)	Total		0.33	1.000	NL	toddler, 8-20 m	11	82.1	328.3	3	2b	1%	1%	1%
-	Taro leaves	raw		4.4	1.000	NL	Gen pop, > 1 yrs	E	77.8	85.8	3	2b	2%	NC	2%
-	Tomato	dried		0.55	5.000	AU	Gen pop, > 2 yrs	61	861.1	8.0	NR	1	4%	0%	4%
VL 0506	Turnip greens (Namenia, Tendergreen)	Total		4.4	1.000	NL	toddler, 8-20 m	110	322.0	< 25	NR	1	10%	10%	5%
FB 0019	Vaccinium berries (incl. Bearberry) (excl blueberries)	Total		0.1	1.000	AU	Child, 2-16 yrs	103	279.7	1.8	NR	1	0%	0%	0%
-	Watercress	raw		3.8	1.000	BR	gen pop, > 10 yrs	97	90.9	254.6	3	2b	2%	0%	2%
VC 0432	Watermelon	Total		0.33	1.000	AU	Gen pop, > 2 yrs	267	2542.2	2095.6	3	2a	3%	3%	3%

Annex 4

FENBUCONAZOLE (197) International estimate of short term intake (IESTI) Acute RfD= 0.200 mg/kg bw (200 µg/kg bw)

Maximum %ARfD: 10% all-mixed 10% children 4% gen pop

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Mixed population groups 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
-	Almonds	raw incl roasted		0	1.000	DE	Women, 14-50 yrs	24	100.0	1.2	NR	1	0%	0%	0%
FP 0226	Apple	Total		0.28	1.000	NL	toddler, 8-20 m	1314	443.7	148.3	3	2a	10%	10%	3%
JF 0226	Apple	juice (pasteurised)	0.01		1.000	DE	Child, 2-4 yrs	1605	724.2	NR	NR	3	0%	0%	0%
	Blueberries	Total		0.2	1.000	NL	Child, 2-6 yrs	3	73.8	<25	NR	1	0%	0%	0%
FB 0020	Blueberries	raw with skin		0.2	1.000	DE	Gen pop, 14-80 yrs	70	388.0	1.8	NR	1	1%	0%	1%
TN 0662	Brazil nut	Total		0	1.000	FR	Gen pop, > 3 yrs	0.0%	57.6	4.0	NR	1	0%	0%	0%
-	Cashew nut	raw incl roasted		0	1.000	TH	child, 3-6 yrs	374	98.8	2.5	NR	1	0%	0%	0%
MM 0812	Cattle meat: 20% as fat	Total		0.002	1.000	FR	Child, 3-6 yrs	98.8%	50.9	NR	NR	1	0%	0%	0%
MM 0812	Cattle meat: 80% as muscle	Total		0.008	1.000	FR	Child, 3-6 yrs	98.8%	203.7	NR	NR	1	0%	0%	0%
ML 0812	Cattle milk	Total	0		1.000	NL	toddler, 8-20 m	1882	1060.7	NR	NR	3	0%	0%	0%
TN 0664	Chestnuts	Total		0	1.000	FR	child, 3-6 yrs	4.1%	170.4	17.4	NR	1	0%	0%	0%
PE 0840	Chicken eggs	Total		0	1.000	CN	Child, 1-6 yrs	3025	194.7	NR	NR	1	0%	0%	0%
-	Coconut (young coconut)	raw incl copra (incl coconut juice)		0	1.000	TH	child, 3-6 yrs	826	423.4	383.0	3	2a	0%	0%	0%
PM 0841	Duck meat: 10% as fat	Total		0	1.000	CN	Child, 1-6 yrs	175	34.7	NR	NR	1	0%	0%	0%
PM 0841	Duck meat: 90% as musccle	Total		0	1.000	CN	Child, 1-6 yrs	175	312.3	NR	NR	1	0%	0%	0%
PO 0841	Duck, edible offal of (includes kidney and liver)	Total		0	1.000	CN	Gen pop, > 1 yrs	421	345.6	NR	NR	1	0%	-	0%
MO 0105	Edible offal (mammalian)	Total		0.09	1.000	US	Child, 1-6 yrs	-	186.6	NR	NR	1	1%	1%	1%
PE 0112	Eggs	Total		0	1.000	TH	Child, 3-6 yrs	2171	109.1	NR	NR	1	0%	0%	0%
TN 0666	Hazelnut	Total		0	1.000	FR	Child, 3-6 yrs	43.4%	27.2	1.2	NR	1	0%	0%	0%
TN 0669	Macadamia nut	Total		0	1.000	US	Gen pop, all ages	-	106.6	3.2	NR	1	0%	0%	0%
MM 0095	Meat from mammals other than marine mammals: 20% as fat	Total		0.002	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		0.008	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%
-	Peanut, shelled (groundnut)	raw incl roasted		0.05	1.000	CN	Child, 1-6 yrs	290	163.1	<25	NR	1	0%	0%	0%
OR 0697	Peanut, shelled (groundnut)	Oil (refined)	0.04		1.000	FR	Child, 3-6 yrs	16.7%	19.8	NR	NR	3	0%	0%	0%
FP 0230	Pear	raw with peel (incl		0.28	1.000	CN	Child, 1-6 yrs	413	418.3	255.0	3	2a	8%	8%	3%

Annex 4

FENBUCONAZOLE (197) International estimate of short term intake (IESTI) Acute RfD= 0.200 mg/kg bw (200 µg/kg bw)

Maximum %ARfD: 10% all-mixed 10% children 4% gen pop

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Mixed population groups 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)													
TN 0672	Pecan	Total		0	1.000	AU	Child, 2-16 yrs	52	80.9	5.0	NR	1	0%	0%	0%
-	Peppers, chili	raw with skin		0.21	1.000	CN	Gen pop, > 1 yrs	1743	295.7	43.2	3	2a	1%	NC	1%
-	Peppers, chili	dried (incl powder)		2	7.000	CN	Gen Pop, > 1 yrs	1583	32.2	0.0	NR	1	4%	1%	4%
-	Peppers, sweet (incl. pim(i)ento) (bell pepper, paprika)	raw with skin		0.21	1.000	CN	Child, 1-6 yrs	1002	169.8	170.0	3	2b	3%	3%	1%
TN 0673	Pine nut	Total		0	1.000	BR	Gen pop, > 10 yrs	47	200.0	0.2	NR	1	0%	0%	0%
TN 0675	Pistachio nut	Total		0	1.000	FR	child, 3-6 yrs	2.6%	44.9	0.9	NR	1	0%	0%	0%
FS 0014	Plum	raw with peel (incl consumption without peel)		0.17	1.000	TH	Child, 3-6 yrs	11	376.9	93.0	3	2a	3%	3%	1%
DF 0014	Plum	dried (prunes)		0.17	3.090	AU	Child, 2-6 yrs	13	447.6	10.4	NR	1	6%	6%	2%
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%
FP 0231	Quince	Total		0.28	1.000	DE	child, 2-4 yrs	16	26.3	301.2	3	2b	1%	1%	0%
FB 0019	Vaccinium berries (incl. Bearberry) (excl blueberries)	Total		0.45	1.000	AU	Child, 2-16 yrs	103	279.7	1.8	NR	1	2%	2%	1%
-	Walnut	raw incl roasted		0	1.000	DE	Child, 2-4 yrs	75	49.4	7.0	NR	1	0%	0%	0%

FENVALERATE (119) International estimate of short term intake (IESTI) Acute RfD= 0.200 mg/kg bw (200 µg/kg bw)

Maximum %ARfD:													40% all-mixed	40% children	3% women	20% gen pop
Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Mixed population groups 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	% acute RfD rounded
VB 0401	Broccoli, Chinese (Kailan)	Total		1.80	1.000	AU	gen pop, > 2 yrs	13	302.9	311.0	3	2b	10%	-	-	10%
-	Broccoli, Chinese (Kailan)	raw		1.8	1.000	CN	Child, 1-6 yrs	334	222.5	311.0	3	2b	40%	40%	-	20%
FI 0345	Mango	Total		0.48	1.000	NL	toddler, 8-20 m	11	160.4	288.8	3	2b	10%	10%	-	4%
-	Mango	raw without peel		0.48	1.000	NL	toddler, 8-20 m	11	160.4	288.8	3	2b	10%	10%	3%	4%
-	Mango	canned/preserved	0.39		1.000	NL	Child, 2-6 yrs	E	85.0	NR	NR	3	1%	1%	-	0%
-	Mango	dried	0.39		3.000	AU	Child, 2-6 yrs	4	35.2	NR	NR	3	1%	1%	-	1%
-	Mango	juice (pasteurised)	0.39		1.000	BR	Gen pop, > 10 yrs	864	720.0	NR	NR	3	2%	0%	0%	2%
-	Mango	sauce/puree	0.39		1.000	NL	Child, 2-6 yrs	E	20.4	NR	NR	3	0%	0%	-	0%
-	Mango	canned babyfood	0.39		1.000	NL	toddler, 8-20 m	15	29.8	NR	NR	3	1%	1%	-	NC
-	Mango	sec processing / composite foods	0.39		1.000	NL	Child, 2-6 yrs	274	5.1	NR	NR	3	0%	0%	-	0%

Annex 4

FLUOPYRAM (243) International estimate of short term intake (IESTI) Acute RfD= 0.500 mg/kg bw (500 µg/kg bw)

Maximum %ARfD: 10% all-mixed 10% children 3% women 6% gen pop

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Mixed population groups 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	% acute RfD rounded
-	Almonds	raw incl roasted		0.03	1.000	DE	Women, 14-50 yrs	24	100.0	1.2	NR	1	0%	0%	0%	0%
-	Apple	raw with peel (incl consumption without peel)		0.28	1.000	CN	Child, 1-6 yrs	1314	403.4	255.0	3	2a	3%	3%	1%	1%
JF 0226	Apple	juice (pasteurised)	0.01		1.000	DE	Child, 2-4 yrs	1605	724.2	NR	NR	3	0%	0%	0%	0%
-	Apple	sauce/puree	0.05		1.000	NL	toddler, 8-20 m	221	106.6	NR	NR	3	0%	0%	-	0%
-	Banana	raw without peel		0.51	1.000	CN	Child, 1-6 yrs	286	455.8	767.3	3	2b	9%	9%	0%	5%
-	Beans (dry) (Phaseolus spp)	cooked/boiled	0.01		0.400	CN	Gen pop, > 1 yrs	722	1313.2	0.5	NR	3	0%	0%	-	0%
TN 0662	Brazil nut	Total		0.03	1.000	FR	Gen pop, > 3 yrs	0.0%	57.6	4.0	NR	1	0%	0%	-	0%
-	Carrot	raw with skin		0.19	1.000	CN	Child, 1-6 yrs	400	234.7	300.0	3	2b	2%	2%	0%	1%
-	Cashew nut	raw incl roasted		0.03	1.000	TH	child, 3-6 yrs	374	98.8	2.5	NR	1	0%	0%	0%	0%
MM 0812	Cattle meat	Total	NA	NA	1.000	FR	Child, 3-6 yrs	98.8%	254.6	NR	NR	1	1%	1%	0%	1%
MM 0812	Cattle meat: 20% as fat	Total		0.4	1.000	FR	Child, 3-6 yrs	98.8%	50.9	NR	NR	1	0%	0%	0%	0%
MM 0812	Cattle meat: 80% as muscle	Total		0.36	1.000	FR	Child, 3-6 yrs	98.8%	203.7	NR	NR	1	1%	1%	0%	1%
ML 0812	Cattle milk	Total	0.05		1.000	NL	toddler, 8-20 m	1882	1060.7	NR	NR	3	1%	1%	-	0%
MO 1280	Cattle, kidney	Total		0.32	1.000	FR	gen pop, > 3 yrs	0.2%	192.0	NR	NR	1	0%	-	-	0%
MO 1281	Cattle, liver	Total		2.3	1.000	US	Child, 1-6 yrs	-	136.1	NR	NR	1	4%	4%	2%	3%
-	Cherries	raw		0.47	1.000	DE	Child, 2-4 yrs	24	187.5	7.2	NR	1	1%	1%	1%	1%
TN 0664	Chestnuts	Total		0.03	1.000	FR	child, 3-6 yrs	4.1%	170.4	17.4	NR	1	0%	0%	-	0%
-	Chick-pea (dry) (Cicer spp)	canned/preserved	0.01		0.400	NL	Child, 2-6 yrs	6	144.7	< 25	NR	3	0%	0%	-	0%
-	Coconut (young coconut)	raw incl copra (incl coconut juice)		0.03	1.000	TH	child, 3-6 yrs	826	423.4	383.0	3	2a	0%	0%	-	0%
-	Cucumber	raw with skin		0.19	1.000	CN	Child, 1-6 yrs	340	212.1	458.1	3	2b	1%	1%	0%	1%
PM 0841	Duck meat	Total	NA	NA	1.000	CN	Child, 1-6 yrs	175	347.0	NR	NR	1	1%	1%	-	0%
PM 0841	Duck meat: 10% as fat	Total		0.2	1.000	CN	Child, 1-6 yrs	175	34.7	NR	NR	1	0%	0%	-	0%
PM 0841	Duck meat: 90% as musccle	Total		0.13	1.000	CN	Child, 1-6 yrs	175	312.3	NR	NR	1	1%	1%	-	0%
PO 0841	Duck, edible offal of (includes kidney and liver)	Total		0.58	1.000	CN	Gen pop, > 1 yrs	421	345.6	NR	NR	1	1%	-	-	1%
-	Grape	raw with skin		1	1.000	CN	Child, 1-6 yrs	232	366.7	636.6	3	2b	10%	10%	3%	6%
-	Grape	canned/preserved		1	1.000	NL	Child, 2-6 yrs	E	58.3	< 25	NR	1	1%	1%	-	0%
DF 0269	Grape	dried (currants, raisins, sultanas)		2.9	1.000	AU	Child, 2-6 yrs	918	83.5	1.0	NR	1	3%	3%	-	1%
JF 0269	Grape	juice (pasteurised)	0.012		1.000	NL	Child, 2-6 yrs	8	803.2	NR	NR	3	0%	0%	0%	0%
-	Grape	red wine	0.1		1.000	FR	Gen pop, > 3 yrs	95.8%	1006.5	NR	NR	3	0%	0%	0%	0%
-	Grape	white wine	0.1		1.000	FR	Gen pop, > 3 yrs	95.8%	1006.5	NR	NR	3	0%	0%	0%	0%

FLUOPYRAM (243) International estimate of short term intake (IESTI) Acute RfD= 0.500 mg/kg bw (500 µg/kg bw)

Maximum %ARfD: 10% all-mixed 10% children 3% women 6% gen pop

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Mixed population groups 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	% acute RfD rounded
TN 0666	Hazelnut	Total		0.03	1.000	FR	Child, 3-6 yrs	43.4%	27.2	1.2	NR	1	0%	0%	-	0%
VD 0533	Lentil (dry) (Lens spp)	Total	0.01		1.000	FR	Child, 3-6 yrs	19.4%	290.8	0.1	NR	3	0%	0%	0%	0%
-	Loquat (Japanese medlar)	raw without peel		0.28	1.000	JP	Gen pop, > 1 yrs	113	326.4	49.0	3	2a	0%	-	-	0%
TN 0669	Macadamia nut	Total		0.03	1.000	US	Gen pop, all ages	-	106.6	3.2	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	1%	1%	-	1%
MM 0095	Meat from mammals other than marine mammals: 20% as fat	Total		0.4	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		0.36	1.000	AU	Child, 2-6 yrs	2269	203.5	NR	NR	1	1%	1%	-	0%
-	Peach	raw with peel (incl consumption without peel)		0.17	1.000	JP	Child, 1-6 yrs	76	306.0	255.0	3	2a	2%	2%	0%	1%
-	Peanut, shelled (groundnut)	raw incl roasted	0.01		1.000	CN	Child, 1-6 yrs	290	163.1	< 25	NR	3	0%	0%	-	0%
OR 0697	Peanut, shelled (groundnut)	Oil (refined)	0.0001		1.000	FR	Child, 3-6 yrs	16.7%	19.8	NR	NR	3	0%	0%	0%	0%
-	Peanut, shelled (groundnut)	butter/paste (nuts/oilseeds)	0.002		1.000	NL	Child, 2-6 yrs	469	66.6	NR	NR	3	0%	0%	-	0%
-	Pear	raw with peel (incl consumption without peel)		0.28	1.000	CN	Child, 1-6 yrs	413	418.3	255.0	3	2a	3%	3%	1%	1%
-	Pear	cooked/boiled (without peel)		0.28	1.000	NL	Gen pop, > 1 yrs	E	207.7	164.0	3	2a	0%	NC	-	0%
-	Pear	canned/preserved		0.28	1.000	NL	Child, 2-6 yrs	E	138.5	48.0	3	2a	1%	1%	-	0%
-	Pear	dried	0.09		1.000	NL	Child, 2-6 yrs	E	17.4	16.0	NR	1	-	-	-	-
-	Pear	juice (pasteurised)	0.01		1.000	NL	Child, 2-6 yrs	129	599.5	NR	NR	3	0%	0%	-	0%
-	Pear	sauce/puree	0.05		1.000	NL	Child, 2-6 yrs	E	20.4	NR	NR	3	0%	0%	-	0%
TN 0672	Pecan	Total		0.03	1.000	AU	Child, 2-16 yrs	52	80.9	5.0	NR	1	0%	0%	-	0%
-	Peppers, chili	raw with skin		0.24	1.000	CN	Gen pop, > 1 yrs	1743	295.7	43.2	3	2a	0%	NC	-	0%
-	Peppers, chili	dried (incl powder)		2.4	1.000	CN	Gen Pop, > 1 yrs	1583	32.2	0.0	NR	1	0%	0%	-	0%
-	Peppers, sweet (incl. pim(i)ento) (bell pepper, paprika)	raw with skin		0.24	1.000	CN	Child, 1-6 yrs	1002	169.8	170.0	3	2b	2%	2%	0%	1%
MO 1284	Pig kidney	Total		0.32	1.000	CN	Gen pop, > 1 yrs	205	224.8	NR	NR	1	0%	0%	0%	0%
MO 1285	Pig liver	Total		2.3	1.000	BR	Gen pop, > 10 yrs	20	505.0	-	-	-	-	-	0%	-
TN 0673	Pine nut	Total		0.03	1.000	BR	Gen pop, > 10 yrs	47	200.0	0.2	NR	1	0%	0%	-	0%
TN 0675	Pistachio nut	Total		0.03	1.000	FR	child, 3-6 yrs	2.6%	44.9	0.9	NR	1	0%	0%	-	0%

Annex 4

FLUOPYRAM (243) International estimate of short term intake (IESTI) Acute RfD= 0.500 mg/kg bw (500 µg/kg bw)

Maximum %ARfD: 10% all-mixed 10% children 3% women 6% gen pop

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Mixed population groups 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	% acute RfD rounded
-	Potato	boiled\microwaved (without peel)		0.02	1.000	AU	Child, 2-6 yrs	1487	300.5	123.0	3	2a	0%	0%	-	0%
-	Potato	baked (with peel)		0.02	1.000	BR	Gen pop, > 10 yrs	4471	420.0	140.0	3	2a	0%	NC	-	0%
-	Potato	canned/preserved		0.02	1.000	NL	Child, 2-6 yrs	E	83.3	17.0	NR	1	0%	0%	-	0%
-	Potato	dried (granule/flake)	0.01		1.000	NL	Child, 2-6 yrs	47	33.7	NR	NR	3	0%	0%	-	0%
-	Potato	crisps	0.006		1.000	NL	Child, 2-6 yrs	423	40.1	NR	NR	3	0%	0%	-	0%
-	Potato	fried (without peel)		0.02	1.000	NL	toddler, 8-20 m	49	148.5	134.0	3	2a	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%	0%
PM 0110	Poultry meat: 10% as fat	Total		0.2	1.000	AU	Child, 2-6 yrs	1563	27.5	NR	NR	1	0%	0%	0%	0%
PM 0110	Poultry meat: 90% as muscle	Total		0.13	1.000	AU	Child, 2-6 yrs	1563	247.1	NR	NR	1	0%	0%	0%	0%
PO 0111	Poultry, edible offal of (includes kidney, liver and skin)	Total		0.58	1.000	FR	Child, 3-6 yrs	7.3%	99.5	NR	NR	1	1%	1%	0%	1%
FP 0231	Quince	Total		0.28	1.000	DE	child, 2-4 yrs	16	26.3	301.2	3	2b	0%	0%	0%	0%
MO 1288	Sheep kidney	Total		0.32	1.000	AU	Gen pop, > 2 yrs	112	87.6	NR	NR	1	0%	NC	-	0%
MO 1289	Sheep liver	Total		2.3	1.000	AU	Child, 2-16 yrs	2	169.8	NR	NR	1	2%	NC	2%	1%
-	Strawberry	Raw with skin		0.23	1.000	NL	toddler, 8-20 m	52	166.7	18.0	NR	1	1%	1%	0%	0%
-	Strawberry	Dried		0.23	3.000	NL	Gen pop, > 1 yrs	E	25.0	< 25	NR	1	0%	0%	-	0%
-	Strawberry	jam	0.02		1.000	NL	Child, 2-6 yrs	E	55.7	NR	NR	3	0%	0%	-	0%
-	Sugar beet	sugar	0.01		1.000	FR	Child, 3-6 yrs	100.0%	274.7	NR	NR	3	0%	0%	-	0%
-	Tomato	raw with peel		0.23	1.000	CN	Child, 1-6 yrs	1117	263.8	180.0	3	2a	2%	2%	0%	1%
-	Tomato	cooked/boiled (with peel)		0.23	1.000	NL	toddler, 8-20 m	31	81.8	86.0	3	2b	1%	1%	-	0%
-	Tomato	dried		0.23	5.000	AU	Gen pop, > 2 yrs	61	861.1	8.0	NR	1	3%	0%	-	3%
JF 0448	Tomato	juice (pasteurised)	0.03		1.000	DE	Gen pop, 14-80 yrs	119	1000.3	NR	NR	3	0%	0%	-	0%
-	Tomato	sauce/puree (single strength)	0.07		1.000	NL	Child, 2-6 yrs	168	175.5	NR	NR	3	0%	0%	-	0%
-	Tomato	paste (=concentrated sauce/puree)	0.04		1.000	CN	Gen pop, > 1 yrs	328	622.5	NR	NR	3	0%	0%	-	0%
-	Walnut	raw incl roasted		0.03	1.000	DE	Child, 2-4 yrs	75	49.4	7.0	NR	1	0%	0%	0%	0%

FLUXAPYROXAD (256) International estimate of short term intake (IESTI) Acute RfD= 0.300 mg/kg bw (300 µg/kg bw)

						Maximum %ARfD:							20% all-mixed	20% children	8% women	9% gen pop
Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Mixed population groups 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	% acute RfD rounded
FP 0226	Apple	Total		0.37	1.000	NL	toddler, 8-20 m	1314	443.7	148.3	3	2a	9%	9%	-	3%
GC 0640	Barley	Total	0.535		1.000	NL	Gen pop, > 1 yrs	1873	437.6	< 25	NR	3	1%	0%	1%	1%
-	Beans (dry) (Phaseolus spp)	cooked/boiled	0.04		0.400	CN	Gen pop, > 1 yrs	722	1313.2	0.5	NR	3	0%	0%	-	0%
VP 0061	Beans except broad bean & soya bean (green pods & immature seeds) (Phaseolus spp)	Total		0.74	1.000	NL	toddler, 8-20 m	218	140.5	19.4	NR	1	3%	3%	1%	2%
VP 0062	Beans, shelled (immature seeds)	Total		0.04	1.000	FR	Child, 3-6 yrs	63.3 %	219.6	5.8	NR	1	0%	0%	0%	0%
-	Borage seeds	raw	0.09		1.000	DE	Gen pop, 14-80 yrs	2	42.0	< 25	NR	3	0%	NC	-	0%
MM 0812	Cattle meat	Total	NA	NA	1.000	FR	Child, 3-6 yrs	98.8 %	254.6	NR	NR	1	0%	0%	0%	0%
MM 0812	Cattle meat: 20% as fat	Total	0.047	0.176	1.000	FR	Child, 3-6 yrs	98.8 %	50.9	NR	NR	1	0%	0%	0%	0%
MM 0812	Cattle meat: 80% as muscle	Total	0.02	0.033	1.000	FR	Child, 3-6 yrs	98.8 %	203.7	NR	NR	1	0%	0%	0%	0%
ML 0812	Cattle milk	Total	0.004	0.02	1.000	NL	toddler, 8-20 m	1882	1060.7	NR	NR	3	0%	0%	-	0%
FM 0812	Cattle milk fat	Total	0.09	0.45	1.000	BR	Gen pop, > 10 yrs	441	150.0	NR	NR	3	0%	0%	-	0%
-	Cherries	raw		2.32	1.000	DE	Child, 2-4 yrs	24	187.5	7.2	NR	1	9%	9%	8%	8%
PE 0840	Chicken eggs	Total	0.006	0.023	1.000	CN	Child, 1-6 yrs	3025	194.7	NR	NR	1	0%	0%	0%	0%
-	Chick-pea (dry) (Cicer spp)	canned/preserved	0.04		0.400	NL	Child, 2-6 yrs	6	144.7	< 25	NR	3	0%	0%	-	0%
OR 0691	Cotton seed	Oil (refined)	0		1.000	US	gen pop, all ages	-	9.1	NR	NR	3	0%	-	-	0%
PO 0841	Duck, edible offal of (includes kidney and liver)	Total	0.021	0.034	1.000	CN	Gen pop, > 1 yrs	421	345.6	NR	NR	1	0%	-	-	0%
MO 0105	Edible offal (mammalian)	Total	0.081	0.31	1.000	US	Child, 1-6 yrs	-	186.6	NR	NR	1	1%	1%	-	1%

Annex 4

FLUXAPYROXAD (256) International estimate of short term intake (IESTI) Acute RfD= 0.300 mg/kg bw (300 µg/kg bw)

Maximum %ARfD: 20% all-mixed 20% children 8% women 9% gen pop

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Mixed population groups 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	% acute RfD rounded
-	Grape seed	Oil (refined)	0.09		1.000	NL	Child, 2-6 yrs	E	3.8	NR	NR	3	0%	0%	-	0%
VD 0533	Lentil (dry) (Lens spp)	Total	0.04		1.000	FR	Child, 3-6 yrs	19.4 %	290.8	0.1	NR	3	0%	0%	0%	0%
-	Linseed (Flax-seed)	raw	0.09		1.000	DE	Gen pop, 14-80 yrs	116	58.5	< 25	NR	3	0%	0%	-	0%
GC 0645	Maize (corn)	Total	0.01		1.000	CN	Child, 1-6 yrs	166	524.7	< 25	NR	3	0%	0%	0%	0%
SO 0090	Mustard seed	Total	0.09		1.000	AU	Gen pop, > 2 yrs	2049	21.4	< 25	NR	3	0%	0%	0%	0%
GC 0647	Oats	Total	0.535		1.000	CN	Gen pop, > 1 yrs	1740	330.6	< 25	NR	3	1%	1%	0%	1%
-	Peach	raw with peel (incl consumption without peel)		0.66	1.000	JP	Child, 1-6 yrs	76	306.0	255.0	3	2a	10%	10%	2%	3%
-	Peanut, shelled (groundnut)	raw incl roasted	0.01		1.000	CN	Child, 1-6 yrs	290	163.1	< 25	NR	3	0%	0%	-	0%
-	Pear	raw with peel (incl consumption without peel)		0.47	1.000	CN	Child, 1-6 yrs	413	418.3	255.0	3	2a	9%	9%	2%	4%
-	Peas (dry) (Pisum spp, Vigna spp)	cooked/boiled	0.04		0.400	CN	Gen pop, > 1 yrs	268	1673.8	< 25	NR	3	0%	0%	-	0%
-	Peas (green pods & immature seeds) (Pisum spp, Vigna spp)	cooked/boiled		0.74	1.000	CN	Child, 1-6 yrs	1056	290.2	6.2	NR	1	4%	4%	-	2%
VP 0064	Peas, shelled (immature seeds) (Pisum spp, Vigna spp)	Total		0.04	1.000	UK	Child, 1.5-4.5 yrs	57	174.0	< 25	NR	1	0%	0%	0%	0%
-	Peppers, chili	dried (incl powder)		4.4	7.000	CN	Gen Pop, > 1 yrs	1583	32.2	0.0	NR	1	6%	1%	-	6%
-	Peppers, sweet (incl. pim(i)ento) (bell pepper, paprika)	raw with skin		0.37	1.000	CN	Child, 1-6 yrs	1002	169.8	170.0	3	2b	4%	4%	1%	1%
MF 0818	Pig fat	Total	0.047	0.176	1.000	FR	Child, 3-6 yrs	30.2 %	64.8	NR	NR	1	0%	0%	0%	0%
DF 0014	Plum	dried (prunes)		2.7	1.000	AU	Child, 2-6 yrs	13	447.6	10.4	NR	1	20%	20%	-	7%
SO 0698	Poppy seed	Total	0.09		1.000	DE	Women, 14-50 yrs	50	67.5	< 25	NR	3	0%	0%	0%	0%
VR 0589	Potato	Total		0.02	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%	0%	0%

FLUXAPYROXAD (256) International estimate of short term intake (IESTI) Acute RfD= 0.300 mg/kg bw (300 µg/kg bw)

Maximum %ARfD: 20% all-mixed 20% children 8% women 9% gen pop

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Mixed population groups 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	% acute RfD rounded
PM 0110	Poultry meat: 10% as fat	Total	0.021	0.05	1.000	AU	Child, 2-6 yrs	1563	27.5	NR	NR	1	0%	0%	0%	0%
PM 0110	Poultry meat: 90% as muscle	Total	0.02	0.024	1.000	AU	Child, 2-6 yrs	1563	247.1	NR	NR	1	0%	0%	0%	0%
PF 0111	Poultry, fats	Total	0.021	0.05	1.000	US	gen pop, all ages	-	42.9	NR	NR	1	0%	0%	0%	0%
SO 0495	Rape seed	Total	0.11		1.000	NL	toddler, 8-20 m	1882	21.3	< 25	NR	3	0%	0%	0%	0%
CF 1251	Rye	Wholemeal	0.085		1.000	DE	Child, 2-4 yrs	242	95.2	NR	NR	3	0%	0%	-	0%
OR 0699	Safflower seed	Oil (refined)	0.09		1.000	JP	Child, 1-6 yrs	6	20.4	NR	NR	3	0%	0%	0%	0%
-	Seeds of cucurbitacea (pumpkin, watermelon)	raw (incl roasted)	0.09		1.000	CN	Gen pop, > 1 yrs	128	158.1	< 25	NR	3	0%	0%	-	0%
-	Sesame seed	butter/paste (nuts/oilseeds)	0.09		1.000	CN	Gen pop, > 1 yrs	174	151.2	NR	NR	3	0%	-	-	0%
-	Soya bean (dry) (Glycine spp)	soybean milk	0.01		1.000	AU	Child, 2-6 yrs	102	1131.2	NR	NR	3	0%	0%	-	0%
VP 0541	Soya bean (immature seeds) (Glycine spp)	Total		0.37	1.000	AU	gen pop, > 2 yrs	661	114.3	< 25	NR	1	0%	-	-	0%
-	Soya bean (immature seeds) (Glycine spp)	cooked/boiled		0.37	1.000	CN	Child, 1-6 yrs	195	260.3	< 25	NR	1	2%	2%	-	1%
-	Sugar beet	sugar	0.04		1.000	FR	Child, 3-6 yrs	100.0%	274.7	NR	NR	3	0%	0%	-	0%
SO 0702	Sunflower seed	Total	0.055		1.000	CN	Gen pop, > 1 yrs	781	235.5	< 25	NR	3	0%	0%	0%	0%
-	Sweet corn (corn-on-the-cob)	cooked/boiled		0.08	1.000	TH	Child, 3-6 yrs	1383	197.0	191.1	3	2a	1%	1%	-	0%
-	Tomato	dried		0.44	5.000	AU	Gen pop, > 2 yrs	61	861.1	8.0	NR	1	9%	0%	-	9%
GC 0653	Triticale	Total	0.085		1.000	DE	Gen pop, 14-80 yrs	27100	394.7	< 25	NR	3	0%	0%	0%	0%
CF 1211	Wheat	flour (cereals)	0.085		1.000	CN	Child, 1-6 yrs	3556	415.9	NR	NR	3	1%	1%	-	0%

Annex 4

GLUFOSINATE-AMMONIUM (175) International estimate of short term intake (IESTI) Acute RfD= 0.010 mg/kg bw (10 µg/kg bw)

Maximum %ARfD: 180% all-mixed 180% children 130% gen pop

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Mixed population groups 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
-	Açai berry	raw		0.05	1.000	BR	Gen pop, > 10 yrs	832	808.0	< 25	NR	1	6%	-	6%
-	Almonds	raw incl roasted		0.05	1.000	DE	Women, 14-50 yrs	24	100.0	1.2	NR	1	1%	0%	1%
FP 0226	Apple	Total		0.08	1.000	NL	toddler, 8-20 m	1314	443.7	148.3	3	2a	60%	60%	20%
-	Apricot	raw with peel (incl consumption without peel)		0.08	1.000	AU	Gen pop, > 2 yrs	77	1056.9	54.5	3	2a	10%	10%	10%
VS 0621	Asparagus	Total		0.27	1.000	US	Child, 1-6 yrs	-	142.6	42.4	3	2a	40%	40%	20%
FI 0326	Avocado	Total		0.05	1.000	AU	Child, 2-6 yrs	182	229.9	171.4	3	2a	20%	20%	6%
-	Babaco	Total		0.05	1.000	-	-	-	-	1107.4	3	-	-	-	-
-	Banana	raw without peel		0.13	1.000	CN	Child, 1-6 yrs	286	455.8	767.3	3	2b	110%	110%	60%
FT 0287	Barbados cherry (acerola)	Total		0.05	1.000	-	-	-	-	-	-	-	-	-	-
-	Beans (dry) (Phaseolus spp)	cooked/boiled	0.04		0.400	CN	Gen pop, > 1 yrs	722	1313.2	0.5	NR	3	4%	3%	4%
VP 0061	Beans except broad bean & soya bean (green pods & immature seeds) (Phaseolus spp)	Total		0.05	1.000	NL	toddler, 8-20 m	218	140.5	19.4	NR	1	7%	7%	4%
-	Blueberries	sauce/puree		0.06	1.000	NL	Child, 2-6 yrs	E	109.7	NR	NR	3	-	-	-
TN 0662	Brazil nut	Total		0.05	1.000	FR	Gen pop, > 3 yrs	0.0%	57.6	4.0	NR	1	1%	0%	1%
FI 0329	Breadfruit	Total		0.05	1.000	NL	Gen pop, > 1 yrs	0	NC	-	-	-	NC	NC	NC
-	Carambola (= star fruit)	raw with peel		0.05	1.000	TH	Child, 3-6 yrs	160	245.0	155.0	3	2a	20%	20%	7%
-	Carob (Locust Tree, St John's Bread)	flour		0.05	1.000	NL	Child, 2-6 yrs	E	33.6	NR	NR	3	-	-	-
-	Carrot	raw with skin		0.05	1.000	CN	Child, 1-6 yrs	400	234.7	300.0	3	2b	20%	20%	9%
-	Cashew apple	raw		0.05	1.000	BR	Gen pop, > 10 yrs	179	1088.8	72.6	3	2a	10%	-	10%
-	Cashew nut	raw incl roasted		0.05	1.000	TH	child, 3-6 yrs	374	98.8	2.5	NR	1	3%	3%	2%
MO 1280	Cattle, kidney	Total		0.55	1.000	FR	gen pop, > 3 yrs	0.2%	192.0	NR	NR	1	20%	-	20%
MO 1281	Cattle, liver	Total		1.85	1.000	US	Child, 1-6 yrs	-	136.1	NR	NR	1	170%	170%	130%
-	Cherimoya	raw without peel		0.05	1.000	DE	Gen pop, 14-80 yrs	2	250.0	-	-	-	-	-	-
-	Cherries	raw		0.08	1.000	DE	Child, 2-4 yrs	24	187.5	7.2	NR	1	9%	9%	9%
TN 0664	Chestnuts	Total		0.05	1.000	FR	child, 3-6 yrs	4.1%	170.4	17.4	NR	1	5%	5%	4%
SB 0715	Cocoa beans	Total	0.04		1.000	FR	Child, 3-6 yrs	98.8%	56.4	-	-	-	-	-	-
VL 0470	Corn salad (lambs lettuce)	Total		0.05	1.000	NL	Child, 2-6 yrs	7	44.3	7.8	NR	1	1%	1%	1%
OR 0691	Cotton seed	Oil (refined)	0.014		1.000	US	gen pop, all ages	-	9.1	NR	NR	3	0%	-	0%
-	Crab-apple	raw with peel		0.08	1.000	CN	Gen pop, > 1 yrs	204	488.3	-	-	-	-	-	-

Annex 4

GLUFOSINATE-AMMONIUM (175) International estimate of short term intake (IESTI) Acute RfD= 0.010 mg/kg bw (10 µg/kg bw)

													Maximum %ARfD:	180% all-mixed	180% children	130% gen pop
Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Mixed population groups 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
-	Cupuaçu	juice (pasteurised)		0.05	1.000	BR	Gen pop, > 10 yrs	407	771.0	NR	NR	3	-	-	-
-	Currants, red, black, white	juice (pasteurised)		0.48	1.000	NL	Child, 2-6 yrs	E	525.8	NR	NR	3	-	-	-
FI 0332	Custard apple	Total		0.05	1.000	-	-	-	-	360.0	3	-	-	-	-
DF 0295	Date	dried (incl candied)		0.05	2.000	AU	Child, 2-6 yrs	23	64.2	5.4	NR	1	3%	3%	2%
-	Durian	raw without peel		0.05	1.000	TH	Child, 3-6 yrs	1185	288.8	930.0	3	2b	30%	30%	10%
PE 0112	Eggs	Total		0	1.000	TH	Child, 3-6 yrs	2171	109.1	NR	NR	1	0%	0%	0%
FI 0335	Feijoa (Pineapple guava)	Total		0.05	1.000	AU	gen pop, > 2 yrs	4	126.6	-	-	-	-	-	-
FT 0297	Fig	Total		0.05	1.000	FR	Child, 3-6 yrs	0.6%	164.3	81.0	3	2a	9%	9%	6%
-	Gooseberries	raw with skin		0.02	1.000	DE	Women, 14-50 yrs	10	338.1	< 25	NR	1	1%	0%	1%
-	Grape	raw with skin		0.12	1.000	CN	Child, 1-6 yrs	232	366.7	636.6	3	2b	80%	80%	40%
-	Guava	raw without peel		0.05	1.000	BR	Gen pop, > 10 yrs	398	850.0	170.0	3	2a	9%	20%	9%
TN 0666	Hazelnut	Total		0.05	1.000	FR	Child, 3-6 yrs	43.4%	27.2	1.2	NR	1	1%	1%	0%
-	Jaboticaba	raw with peel		0.05	1.000	CN	Gen pop, > 1 yrs	236	268.1	-	-	-	-	-	-
-	Jackfruit	raw without peel		0.05	1.000	TH	Child, 3-6 yrs	1013	215.1	802.8	3	2b	20%	20%	10%
FI 0339	Jambolan	Total		0.05	1.000	NL	Gen pop, > 1 yrs	0	NC	-	-	-	NC	NC	NC
-	Japanese apricot (ume)	Total		0.08	1.000	JP	Child, 1-6 yrs	25	25.5	< 25	NR	1	1%	1%	0%
-	Java apple	raw without peel		0.05	1.000	TH	Child, 3-6 yrs	1352	249.5	94.9	3	2a	10%	10%	6%
FT 0302	Jujube, Chinese	Total		0.05	1.000	CN	Gen pop, > 1 yrs	1328	286.2	-	-	-	-	-	-
-	Jujube, Indian	raw		0.05	1.000	TH	Child, 3-6 yrs	893	230.0	126.2	3	2a	10%	10%	6%
-	Kiwi fruit	raw without peel		0.37	1.000	NL	toddler, 8-20 m	260	136.6	83.0	3	2a	110%	110%	50%
FT 0303	Kumquats	Total		0.05	1.000	AU	Gen pop, > 2 yrs	2	18.0	12.0	NR	1	0%	-	0%
-	Lansat/longkong	raw without peel		0.05	1.000	TH	Child, 3-6 yrs	1599	222.1	13.4	NR	1	6%	6%	3%
FC 0204	Lemon	Total		0.05	1.000	FR	child, 3-6 yrs	16.1%	58.2	64.0	3	2b	5%	5%	3%
VL 0482	Lettuce, head	Total		0.29	1.000	NL	Child, 2-6 yrs	91	140.0	338.9	3	2b	70%	70%	30%
VL 0483	Lettuce, leaf	Total		0.29	1.000	CN	Child, 1-6 yrs	243	387.3	305.4	3	2a	180%	180%	60%
FC 0205	Lime	Total		0.05	1.000	AU	Gen pop, > 2 yrs	579	259.2	49.0	3	2a	3%	2%	3%
-	Litchi	raw without peel		0.05	1.000	TH	Child, 3-6 yrs	762	147.1	16.4	3	1	4%	4%	2%
-	Longan	raw without peel		0.05	1.000	TH	Child, 3-6 yrs	1537	232.2	6.3	NR	1	7%	7%	4%
-	Loquat (Japanese medlar)	raw without peel		0.08	1.000	JP	Gen pop, > 1 yrs	113	326.4	49.0	3	2a	6%	-	6%
TN 0669	Macadamia nut	Total		0.05	1.000	US	Gen pop, all ages	-	106.6	3.2	NR	1	1%	0%	1%
GC 0645	Maize (corn)	Total	0.05		1.000	CN	Child, 1-6 yrs	166	524.7	< 25	NR	3	20%	20%	8%
-	Mandarin + mandarin-like hybrid	raw, without peel		0.05	1.000	CN	Child, 1-6 yrs	151	586.7	124.3	3	2a	30%	30%	10%
-	Mango	raw without peel		0.05	1.000	NL	toddler, 8-20 m	11	160.4	288.8	3	2b	20%	20%	8%
-	Mangostan	raw without peel		0.05	1.000	TH	Child, 3-6 yrs	1581	173.2	28.2	3	2a	7%	7%	3%
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	7%	7%	4%

Annex 4

GLUFOSINATE-AMMONIUM (175) International estimate of short term intake (IESTI) Acute RfD= 0.010 mg/kg bw (10 µg/kg bw)

Maximum %ARfD: 180% all-mixed 180% children 130% gen pop

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Mixed population groups 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
MM 0095	Meat from mammals other than marine mammals: 20% as fat	Total		0.062	1.000	AU	Child, 2-6 yrs	2269	50.9	NR	NR	1	2%	2%	1%
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	Total		0.05	1.000	AU	Child, 2-6 yrs	2269	203.5	NR	NR	1	5%	5%	3%
FP 0229	Medlar	Total		0.08	1.000	NL	Gen pop, > 1 yrs	0	NC	-	-	-	NC	NC	NC
ML 0106	Milks	Total		0.02	1.000	AU	Child, 2-6 yrs	2923	1933.6	NR	NR	3	-	-	-
-	Nectarine	raw with peel (incl consumption without peel)		0.08	1.000	NL	toddler, 8-20 m	6	183.6	131.0	3	2a	30%	30%	10%
FT 0305	Olive	Total		0.05	1.000	AU	Child, 2-6 yrs	77	66.4	4.4	NR	1	2%	2%	1%
-	Onion, bulb	raw without skin		0.05	1.000	JP	Child, 1-6 yrs	748	102.0	244.4	3	2b	9%	9%	4%
FC 0004	Orange, sweet, sour + orange-like hybrid	Total		0.05	1.000	AU	Child, 2-6 yrs	1735	800.8	155.8	3	2a	30%	30%	20%
-	Papaya	raw without peel		0.05	1.000	CN	Gen pop, > 1 yrs	350	733.9	526.4	3	2a	20%	9%	20%
-	Passion fruit	juice (pasteurised)		0.05	1.000	BR	Gen pop, > 10 yrs	2624	720.0	NR	NR	3	-	-	-
-	Peach	raw with peel (incl consumption without peel)		0.08	1.000	JP	Child, 1-6 yrs	76	306.0	255.0	3	2a	40%	40%	10%
-	Pear	raw with peel (incl consumption without peel)		0.08	1.000	CN	Child, 1-6 yrs	413	418.3	255.0	3	2a	50%	50%	20%
VP 0063	Peas (green pods & immature seeds) (Pisum spp, Vigna spp)	Total		0.05	1.000	US	child, 1-6 yrs	-	105.0	6.2	NR	1	3%	3%	2%
TN 0672	Pecan	Total		0.05	1.000	AU	Child, 2-16 yrs	52	80.9	5.0	NR	1	1%	1%	0%
FI 0352	Persimmon, American	Total		0.05	1.000	AU	gen pop, > 2 yrs	4	738.9	77.3	3	2a	7%	-	7%
-	Persimmon, Japanese	raw with peel (incl consumption without peel)		0.05	1.000	TH	Child, 3-6 yrs	20	264.9	227.5	3	2a	20%	20%	10%
TN 0673	Pine nut	Total		0.05	1.000	BR	Gen pop, > 10 yrs	47	200.0	0.2	NR	1	2%	0%	2%
-	Pineapple	raw without peel		0.05	1.000	JP	Child, 1-6 yrs	67	499.8	1116.0	3	2b	40%	40%	10%
TN 0675	Pistachio nut	Total		0.05	1.000	FR	child, 3-6 yrs	2.6%	44.9	0.9	NR	1	1%	1%	1%
-	Pitahaya	raw without peel		0.05	1.000	TH	Child, 3-6 yrs	307	202.5	279.7	3	2b	20%	20%	8%
FI 0354	Plantain	Total		0.05	1.000	AU	Gen pop, > 2 yrs	1	135.9	-	-	-	-	-	-
DF 0014	Plum	dried (prunes)		0.3	1.000	AU	Child, 2-6 yrs	13	447.6	10.4	NR	1	70%	70%	20%
-	Pomegranate	raw without peel		0.05	1.000	CN	Gen pop, > 1 yrs	222	570.3	239.4	3	2a	10%	10%	10%
VR 0589	Potato	Total	0.05	0.05	1.000	ZA	Child, 1-5 yrs	-	299.6	216.0	3	2a	30%	30%	7%

Annex 4

GLUFOSINATE-AMMONIUM (175) International estimate of short term intake (IESTI) Acute RfD= 0.010 mg/kg bw (10 µg/kg bw)

Maximum %ARfD: 180% all-mixed 180% children 130% gen pop

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Mixed population groups 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	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	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%
-	Prickly pear (Indian fig)	raw without peel		0.05	1.000	NL	Child, 2-6 yrs	E	58.7	87.8	3	2b	5%	5%	3%
FP 0231	Quince	Total		0.08	1.000	DE	child, 2-4 yrs	16	26.3	301.2	3	2b	4%	4%	0%
-	Rambutan	raw without peel		0.05	1.000	TH	Child, 3-6 yrs	1980	250.5	14.7	3	1	7%	7%	-
OR 0495	Rape seed	Oil (refined)	0.108		1.000	AU	Gen pop, > 2 yrs	2407	40.7	NR	NR	3	1%	1%	1%
FB 0272	Raspberries, red, black	Total		0.03	1.000	FR	Child, 3-6 yrs	6.2%	157.5	4.3	NR	1	3%	3%	1%
GC 0649	Rice	Total	0.08		1.000	US	Child, 1-6 yrs	-	99.8	< 25	NR	3	5%	5%	4%
-	Rose apple	raw with peel		0.05	1.000	TH	Child, 3-6 yrs	1352	249.5	94.9	3	2a	10%	10%	6%
-	Sapodilla	raw without peel		0.05	1.000	TH	Child, 3-6 yrs	684	225.7	48.6	3	2a	9%	9%	5%
FI 0360	Sapote, black	Total		0.05	1.000	-	-	-	-	396.0	3	-	-	-	-
-	Sentul	raw without peel		0.05	1.000	TH	Child, 3-6 yrs	367	85.5	378.0	3	2b	8%	8%	5%
-	Shaddock or pomelo + shaddock-like hybrid	raw, without peel		0.05	1.000	DE	Child, 2-4 yrs	12	358.6	178.5	3	2a	20%	20%	10%
-	Soursop (Guanabana)	juice (pasteurised)		0.05	1.000	NL	Child, 2-6 yrs	E	5.0	NR	NR	3	-	-	-
VD 0541	Soya bean (dry) (Glycine spp)	Total	0.825		1.000	CN	Child, 1-6 yrs	179	239.0	< 25	NR	3	120%	120%	70%
FI 0367	Star apple	Total		0.05	1.000	NL	Gen pop, > 1 yrs	0	NC	-	-	-	NC	NC	NC
FB 0275	Strawberry	Total		0.15	1.000	FR	Child, 3-6 yrs	32.3%	339.4	13.4	NR	1	30%	30%	10%
-	Sugar beet	sugar	0.056		1.000	FR	Child, 3-6 yrs	100.0%	274.7	NR	NR	3	8%	8%	5%
SO 0702	Sunflower seed	Total	0.53		1.000	CN	Gen pop, > 1 yrs	781	235.5	< 25	NR	3	20%	20%	20%
-	Tamarind (sweet)	raw without peel		0.05	1.000	TH	Child, 3-6 yrs	822	126.5	10.6	NR	1	4%	4%	2%
FT 0312	Tree tomato	Total		0.05	1.000	AU	Gen pop, > 2 yrs	1	28.5	70.5	3	2b	1%	-	1%
-	Walnut	raw incl roasted		0.05	1.000	DE	Child, 2-4 yrs	75	49.4	7.0	NR	1	2%	2%	1%

Annex 4

IMIDACLOPRID (206) International estimate of short term intake (IESTI) Acute RfD= 0.4 mg/kg bw (400 µg/kg bw)

Maximum %ARfD: 30% all-mixed 30% children 10% gen pop

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Mixed population groups: 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
-	Beans (dry) (Phaseolus spp)	cooked/boiled	0.62		0.400	CN	Gen pop, > 1 yrs	722	1313.2	0.5	NR	3	2%	1%	2%
-	Broad bean (dry) (Vicia spp)	cooked/boiled	0.62		0.400	CN	Gen pop, > 1 yrs	737	1190.2	< 25	NR	3	1%	0%	1%
-	Celery	raw		3.2	1.000	CN	Child, 1-6 yrs	454	180.3	861.1	3	2b	30%	30%	10%
-	Chick-pea (dry) (Cicer spp)	canned/preserved	0.62		0.400	NL	Child, 2-6 yrs	6	144.7	< 25	NR	3	0%	0%	0%
-	Hyacinth bean (dry) (Lablab spp)	cooked/boiled	0.62		0.400	CN	Gen pop, > 1 yrs	1219	972.4	< 25	NR	3	1%	-	1%
VD 0533	Lentil (dry) (Lens spp)	Total	0.62		1.000	FR	Child, 3-6 yrs	19.4%	290.8	0.1	NR	3	2%	2%	2%
-	Lupin (dry) (Lupinus spp)	raw	0.62		1.000	NL	Gen pop, > 1 yrs	0	NC	< 25	NR	3	NC	NC	NC
-	Peas (dry) (Pisum spp, Vigna spp)	cooked/boiled	0.62		0.400	CN	Gen pop, > 1 yrs	268	1673.8	< 25	NR	3	2%	0%	2%
VD 0537	Pigeon pea (dry) (Cajanus spp)	Total	0.62		1.000	AU	Gen pop, > 2 yrs	129	95.8	< 25	NR	3	0%	-	0%

INDOXACARB (216) International estimate of short term intake (IESTI) Acute RfD= 0.100 mg/kg bw (100 µg/kg bw)

Maximum %ARfD: 100% all-mixed 100% children 5% women 30% gen pop

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Mixed population groups: 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	% acute RfD rounded
VL 0483	Lettuce, leaf	Total		1.6	1.000	CN	Child, 1-6 yrs	243	387.3	305.4	3	2a	100%	100%	-	30%
-	Lettuce, leaf	raw		1.6	1.000	NL	Child, 2-6 yrs	91	140.1	117.8	3	2a	30%	30%	5%	10%

Annex 4

MCPA (257) International estimate of short term intake (IESTI) Acute RfD= 0.600 mg/kg bw (600 µg/kg bw)

Maximum %ARfD: 5% all-mixed 5% children 4% gen pop

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Mixed population groups 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
-	Barley	beer	0.05		0.190	BR	Gen pop, > 10 yrs	1636	3600.0	NR	NR	3	0%	0%	0%
MM 0812	Cattle meat	Total	NA	NA	1.000	FR	Child, 3-6 yrs	98.8%	254.6	NR	NR	1	0%	0%	0%
MM 0812	Cattle meat: 20% as fat	Total		0.08	1.000	FR	Child, 3-6 yrs	98.8%	50.9	NR	NR	1	0%	0%	0%
MM 0812	Cattle meat: 80% as muscle	Total		0.08	1.000	FR	Child, 3-6 yrs	98.8%	203.7	NR	NR	1	0%	0%	0%
ML 0812	Cattle milk	Total	0.035		1.000	NL	toddler, 8-20 m	1882	1060.7	NR	NR	3	1%	1%	0%
PE 0840	Chicken eggs	Total		0.05	1.000	CN	Child, 1-6 yrs	3025	194.7	NR	NR	1	0%	0%	0%
PM 0841	Duck meat	Total	NA	NA	1.000	CN	Child, 1-6 yrs	175	347.0	NR	NR	1	0%	0%	0%
PM 0841	Duck meat: 10% as fat	Total		0.05	1.000	CN	Child, 1-6 yrs	175	34.7	NR	NR	1	0%	0%	0%
PM 0841	Duck meat: 90% as musccle	Total		0.05	1.000	CN	Child, 1-6 yrs	175	312.3	NR	NR	1	0%	0%	0%
PO 0841	Duck, edible offal of (includes kidney and liver)	Total		0.05	1.000	CN	Gen pop, > 1 yrs	421	345.6	NR	NR	1	0%	-	0%
MO 0105	Edible offal (mammalian)	Total		2.2	1.000	US	Child, 1-6 yrs	-	186.6	NR	NR	1	5%	5%	4%
-	Linseed (Flax-seed)	raw	0		1.000	DE	Gen pop, 14-80 yrs	116	58.5	< 25	NR	3	0%	0%	0%
GC 0645	Maize (corn)	Total	0		1.000	CN	Child, 1-6 yrs	166	524.7	< 25	NR	3	0%	0%	0%
MF 0100	Mammalian fats (except milk fats)	Total		0.16	1.000	FR	Child, 3-6 yrs	39.9%	30.2	NR	NR	1	0%	0%	0%
GC 0647	Oats	Total	0.05		1.000	CN	Gen pop, > 1 yrs	1740	330.6	< 25	NR	3	0%	0%	0%
-	Peas (dry) (Pisum spp, Vigna spp)	cooked/boiled	0		0.400	CN	Gen pop, > 1 yrs	268	1673.8	< 25	NR	3	0%	0%	0%
PF 0111	Poultry, fats	Total		0.05	1.000	US	gen pop, all ages	-	42.9	NR	NR	1	0%	0%	0%
CF 1251	Rye	Wholemeal	0.05		1.000	DE	Child, 2-4 yrs	242	95.2	NR	NR	3	0%	0%	0%
GC 0653	Triticale	Total	0.05		1.000	DE	Gen pop, 14-80 yrs	27100	394.7	< 25	NR	3	0%	0%	0%
CF 1211	Wheat	flour (cereals)	0.024		1.000	CN	Child, 1-6 yrs	3556	415.9	NR	NR	3	0%	0%	0%

Annex 4

METHOXYFENOZIDE (209) International estimate of short term intake (IESTI) Maximum %ARfD: 10% all-mixed 10% children 6% gen pop

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Mixed population groups 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
-	Balsam pear (Bitter cucumber, Bitter gourd, Bitter melon)	raw without peel		0.15	1.000	CN	Gen pop, > 1 yrs	1387	400.2	607.5	3	2b	0%	0%	0%
VP 0061	Beans except broad bean & soya bean (green pods & immature seeds) (Phaseolus spp)	Total		0.99	1.000	NL	toddler, 8-20 m	218	140.5	19.4	NR	1	2%	2%	1%
-	Bottle gourd (Cucuzzi)	raw with skin		0.15	1.000	CN	Gen pop, > 1 yrs	519	453.0	325.0	3	2a	0%	NC	0%
MM 0812	Cattle meat	Total	NA	NA	1.000	FR	Child, 3-6 yrs	98.8%	254.6	NR	NR	1	0%	0%	0%
MM 0812	Cattle meat: 20% as fat	Total		0.24	1.000	FR	Child, 3-6 yrs	98.8%	50.9	NR	NR	1	0%	0%	0%
MM 0812	Cattle meat: 80% as muscle	Total		0.0062	1.000	FR	Child, 3-6 yrs	98.8%	203.7	NR	NR	1	0%	0%	0%
-	Cucumber	raw with skin		0.15	1.000	CN	Child, 1-6 yrs	340	212.1	458.1	3	2b	1%	1%	0%
MO 0105	Edible offal (mammalian)	Total	0.025	0.096	1.000	US	Child, 1-6 yrs	-	186.6	NR	NR	1	0%	0%	0%
-	Gherkin	raw with skin		0.15	1.000	JP	Child, 1-6 yrs	484	91.8	54.5	3	2a	0%	0%	0%
FC 0204	Lemon	Total		1.7	1.000	FR	child, 3-6 yrs	16.1%	58.2	64.0	3	2b	2%	2%	1%
FC 0205	Lime	Total		1.7	1.000	AU	Gen pop, > 2 yrs	579	259.2	49.0	3	2a	1%	1%	1%
-	Loofah, Smooth	raw without peel		0.15	1.000	CN	Child, 1-6 yrs	196	296.6	133.0	3	2a	1%	1%	0%
-	Mandarin + mandarin-like hybrid	raw, without peel		1.7	1.000	CN	Child, 1-6 yrs	151	586.7	124.3	3	2a	10%	10%	4%
VC 0046	Melons, except watermelon	Total		0.15	1.000	FR	Child, 3-6 yrs	16.4%	358.1	420.0	3	2b	1%	1%	0%
FC 0004	Orange, sweet, sour + orange-like hybrid	Total		1.7	1.000	AU	Child, 2-6 yrs	1735	800.8	155.8	3	2a	10%	10%	6%
-	Peas (dry) (Pisum spp, Vigna spp)	cooked/boiled	0.17		0.400	CN	Gen pop, > 1 yrs	268	1673.8	< 25	NR	3	0%	0%	0%
VP 0063	Peas (green pods & immature seeds) (Pisum spp, Vigna spp)	Total	0.1		1.000	US	child, 1-6 yrs	-	105.0	6.2	NR	1	-	-	-
-	Peas (green pods & immature seeds) (Pisum spp, Vigna spp)	cooked/boiled		0.81	1.000	CN	Child, 1-6 yrs	1056	290.2	6.2	NR	1	2%	2%	1%
MF 0818	Pig fat	Total		0.24	1.000	FR	Child, 3-6 yrs	30.2%	64.8	NR	NR	1	0%	0%	0%
-	Pumpkins	raw without peel		0.15	1.000	CN	Child, 1-6 yrs	561	322.7	1851.8	3	2b	1%	1%	1%
-	Shaddock or pomelo + shaddock-like hybrid	raw, without peel		1.7	1.000	DE	Child, 2-4 yrs	12	358.6	178.5	3	2a	8%	8%	5%
-	Snake gourd	raw without peel		0.15	1.000	TH	Child, 3-6 yrs	759	129.6	133.0	3	2b	0%	0%	0%
-	Spring onion	cooked/boiled		2.8	1.000	NL	Child, 2-6 yrs	E	20.3	30.0	3	2b	1%	1%	0%
VC 0431	Squash, summer (courgette, marrow, zucchetti, zucchini)	Total		0.15	1.000	NL	toddler, 8-20 m	11	82.1	328.3	3	2b	0%	0%	0%

PENTHIOPYRAD (253) International estimate of short term intake (IESTI

Acute RfD= 0.001 mg/kg bw (1000 µg/kg bw)

Maximum %ARfD: 150% all-mixed 150% children 60% gen pop

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Mixed population groups 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
-	Almonds	raw incl roasted		0.047	1.000	DE	Women. 14-50 yrs	24	100.0	1.2	NR	1	0%	0%	0%
-	Amaranth (Bledo)	raw		15	1.000	CN	Gen pop. > 1 yrs	714	581.7	85.8	3	2a	20%	NC	20%
-	Apple	raw with peel (incl consumption without peel)		0.27	1.000	CN	Child. 1-6 yrs	1314	403.4	255.0	3	2a	2%	2%	1%
JF 0226	Apple	juice (pasteurised)	0.021		1.000	DE	Child. 2-4 yrs	1605	724.2	NR	NR	3	0%	0%	0%
-	Apricot	raw with peel (incl consumption without peel)		1.9	1.000	AU	Gen pop. > 2 yrs	77	1056.9	54.5	3	2a	3%	3%	3%
-	Balsam pear (Bitter cucumber, Bitter gourd, Bitter melon)	raw without peel		0.01	1.000	CN	Gen pop. > 1 yrs	1387	400.2	607.5	3	2b	0%	0%	0%
-	Barley	beer	0.002		0.190	BR	Gen pop. > 10 yrs	1636	3600.0	NR	NR	3	0%	0%	0%
-	Beans (dry) (Phaseolus spp)	cooked/boiled	0.01		0.400	CN	Gen pop. > 1 yrs	722	1313.2	0.5	NR	3	0%	0%	0%
VP 0061	Beans except broad bean & soya bean (green pods & immature seeds) (Phaseolus spp)	Total		1.6	1.000	NL	toddler. 8-20 m	218	140.5	19.4	NR	1	2%	2%	1%
VP 0062	Beans, shelled (immature seeds)	Total		0.16	1.000	FR	Child, 3-6 yrs	63.3%	219.6	5.8	NR	1	0%	0%	0%
-	Bottle gourd (Cucuzzi)	raw with skin		0.3	1.000	CN	Gen pop, > 1 yrs	519	453.0	325.0	3	2a	1%	NC	1%
TN 0662	Brazil nut	Total		0.047	1.000	FR	Gen pop, > 3 yrs	0.0%	57.6	4.0	NR	1	0%	0%	0%
-	Broad bean (dry) (Vicia spp)	cooked/boiled	0.01		0.400	CN	Gen pop, > 1 yrs	737	1190.2	< 25	NR	3	0%	0%	0%
VB 0400	Broccoli	Total		2.4	1.000	NL	toddler, 8-20 m	128	171.0	304.0	3	2b	10%	10%	4%
-	Broccoli, Chinese (Kailan)	raw		2.4	1.000	CN	Child, 1-6 yrs	334	222.5	311.0	3	2b	10%	10%	5%
-	Cabbage, head	raw		2.4	1.000	CN	Child. 1-6 yrs	287	255.5	1402.5	3	2b	10%	10%	5%
-	Carrot	raw with skin		0.41	1.000	CN	Child, 1-6 yrs	400	234.7	300.0	3	2b	2%	2%	1%
-	Cashew nut	raw incl roasted		0.047	1.000	TH	child, 3-6 yrs	374	98.8	2.5	NR	1	0%	0%	0%
VB 0404	Cauliflower	Total		2.4	1.000	NL	toddler, 8-20 m	173	148.1	797.0	3	2b	10%	10%	6%
-	Celery	raw		8.8	1.000	CN	Child, 1-6 yrs	454	180.3	861.1	3	2b	30%	30%	20%
VL 0464	Chard (silver beet)	Total		15	1.000	NL	Child, 2-6 yrs	2	136.2	175.0	3	2b	30%	30%	20%
-	Chayote (Christophine)	raw with skin		0.3	1.000	CN	Child, 1-6 yrs	124	284.7	197.4	3	2a	1%	1%	1%
-	Cherries	raw		1.9	1.000	DE	Child, 2-4 yrs	24	187.5	7.2	NR	1	2%	2%	2%
-	Chervil	raw		15	1.000	NL	Child, 2-6 yrs	E	3.5	< 25	NR	1	0%	0%	0%
TN 0664	Chestnuts	Total		0.047	1.000	FR	child, 3-6 yrs	4.1%	170.4	17.4	NR	1	0%	0%	0%
-	Chick-pea (dry) (Cicer spp)	canned/preserved	0.01		0.400	NL	Child, 2-6 yrs	6	144.7	< 25	NR	3	0%	0%	0%
PE 0840	Chicken eggs	Total		0.023	1.000	CN	Child, 1-6 yrs	3025	194.7	NR	NR	1	0%	0%	0%
-	Chicory leaves (sugar loaf)	raw		15	1.000	DE	Child, 2-4 yrs	16	82.4	280.5	3	2b	20%	20%	7%
-	Coconut (young coconut)	raw incl copra (incl coconut juice)		0.047	1.000	TH	child, 3-6 yrs	826	423.4	383.0	3	2a	0%	0%	0%
-	Corn salad (lambs lettuce)	raw		15	1.000	DE	Child. 2-4 yrs	13	41.2	7.8	NR	1	4%	4%	2%

Annex 4

PENTHIOPYRAD (253) International estimate of short term intake (IESTI

Acute RfD= 0.001 mg/kg bw (1000 µg/kg bw)

Maximum %ARfD: 150% all-mixed 150% children 60% gen pop

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Mixed population groups 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
-	Cos lettuce	raw		15	1.000	NL	Child, 2-6 yrs	91	140.1	289.9	3	2b	30%	30%	10%
OR 0691	Cotton seed	Oil (refined)	0.17		1.000	US	gen pop, all ages	-	9.1	NR	NR	3	0%	-	0%
-	Crab-apple	raw with peel		0.27	1.000	CN	Gen pop, > 1 yrs	204	488.3	-	-	-	-	-	-
-	Cress, garden	raw		15	1.000	CN	Gen pop, > 1 yrs	1443	352.5	15.0	NR	1	10%	0%	10%
-	Cucumber	raw with skin		0.3	1.000	CN	Child, 1-6 yrs	340	212.1	458.1	3	2b	1%	1%	1%
-	Dandelion leaves	raw		15	1.000	NL	gen pop, > 1 yrs	E	49.9	35.0	3	2a	3%	-	3%
PM 0841	Duck meat	Total	NA	NA	1.000	CN	Child, 1-6 yrs	175	347.0	NR	NR	1	0%	0%	0%
PM 0841	Duck meat: 10% as fat	Total		0.023	1.000	CN	Child, 1-6 yrs	175	34.7	NR	NR	1	0%	0%	0%
PM 0841	Duck meat: 90% as musccle	Total		0.021	1.000	CN	Child, 1-6 yrs	175	312.3	NR	NR	1	0%	0%	0%
PO 0841	Duck, edible offal of (includes kidney and liver)	Total		0.023	1.000	CN	Gen pop. > 1 yrs	421	345.6	NR	NR	1	0%	-	0%
-	Egg plant (aubergine)	raw with skin		1.6	1.000	CN	Child, 1-6 yrs	969	253.4	443.9	3	2b	8%	8%	4%
VL 0476	Endive	Total		15	1.000	NL	toddler, 8-20 m	54	201.9	375.0	3	2b	90%	90%	30%
-	Gherkin	raw with skin		0.3	1.000	JP	Child, 1-6 yrs	484	91.8	54.5	3	2a	0%	0%	0%
-	Gilo (scarlet egg plant)	cooked/boiled (with skin)		1.6	1.000	BR	Gen pop, > 10 yrs	280	360.5	28.5	3	2a	1%	-	1%
VL 0269	Grape leaves	Total		15	1.000	NL	Gen pop, > 1 yrs	1	54.6	1.4	NR	1	1%	0%	1%
TN 0666	Hazelnut	Total		0.047	1.000	FR	Child, 3-6 yrs	43.4%	27.2	1.2	NR	1	0%	0%	0%
-	Hyacinth bean (dry) (Lablab spp)	cooked/boiled	0.01		0.400	CN	Gen pop, > 1 yrs	1219	972.4	< 25	NR	3	0%	-	0%
-	Indian mustard (Amsoi)	raw		30.2	1.000	NL	Gen pop, > 1 yrs	E	49.9	250.0	3	2b	7%	NC	7%
-	Japanese apricot (ume)	Total		1.9	1.000	JP	Child, 1-6 yrs	25	25.5	< 25	NR	1	0%	0%	0%
-	Japanese greens: Chrysanthemum leaves (Chrysanthemum spp)	raw		15	1.000	CN	Gen pop, > 1 yrs	993	332.7	< 25	NR	1	9%	-	9%
-	Kangkung (water spinach)	raw		23	1.000	CN	Child, 1-6 yrs	183	270.7	85.8	3	2a	60%	60%	30%
VL 0481	Komatsuna	Total		30.2	1.000	JP	Child, 1-6 yrs	73	71.4	< 25	NR	1	10%	10%	8%
VD 0533	Lentil (dry) (Lens spp)	Total	0.01		1.000	FR	Child, 3-6 yrs	19.4%	290.8	0.1	NR	3	0%	0%	0%
-	Lettuce, head	raw		15	1.000	NL	Child. 2-6 yrs	91	140.1	338.9	3	2b	30%	30%	10%
VL 0483	Lettuce, leaf	Total		15	1.000	CN	Child, 1-6 yrs	243	387.3	305.4	3	2a	90%	90%	30%
-	Loofah, Smooth	raw without peel		0.01	1.000	CN	Child, 1-6 yrs	196	296.6	133.0	3	2a	0%	0%	0%
-	Loquat (Japanese medlar)	raw without peel		0.27	1.000	JP	Gen pop, > 1 yrs	113	326.4	49.0	3	2a	0%	-	0%
-	Lupin (dry) (Lupinus spp)	raw	0.01		1.000	NL	Gen pop, > 1 yrs	0	NC	< 25	NR	3	NC	NC	NC
TN 0669	Macadamia nut	Total		0.047	1.000	US	Gen pop, all ages	-	106.6	3.2	NR	1	0%	0%	0%
GC 0645	Maize (corn)	Total	0.01		1.000	CN	Child. 1-6 yrs	166	524.7	< 25	NR	3	0%	0%	0%
OR 0645	Maize (corn)	Oil (refined)	0.027		1.000	AU	Child, 2-6 yrs	4	28.3	NR	NR	3	0%	0%	0%
CF 1255	Maize (corn)	Flour (cereals)	0.014		1.000	CN	Child, 1-6 yrs	213	361.2	NR	NR	3	0%	0%	0%
FP 0229	Medlar	Total		0.27	1.000	NL	Gen pop, > 1 yrs	0	NC	-	-	-	NC	NC	NC
VC 0046	Melons, except watermelon	Total		0.01	1.000	FR	Child, 3-6 yrs	16.4%	358.1	420.0	3	2b	0%	0%	0%
GC 0646	Millet	Total	0.22		1.000	CN	Child, 1-6 yrs	826	219.5	< 25	NR	3	0%	0%	0%

PENTHIOPYRAD (253) International estimate of short term intake (IESTI Acute RfD= 0.001 mg/kg bw (1000 µg/kg bw)

Maximum %ARfD: 150% all-mixed 150% children 60% gen pop

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Mixed population groups 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
-	Mustard greens	raw		30	1.000	CN	Child. 1-6 yrs	635	299.3	244.8	3	2a	150%	150%	60%
-	Nectarine	raw with peel (incl consumption without peel)		1.9	1.000	NL	toddler. 8-20 m	6	183.6	131.0	3	2a	8%	8%	2%
GC 0647	Oats	Total	0.01		1.000	CN	Gen pop. > 1 yrs	1740	330.6	< 25	NR	3	0%	0%	0%
-	Okra (Lady's finger)	cooked/boiled (with skin)		1.6	1.000	JP	Child. 1-6 yrs	58	84.3	8.5	NR	1	1%	1%	1%
-	Onion, bulb	raw without skin		0.72	1.000	JP	Child. 1-6 yrs	748	102.0	244.4	3	2b	1%	1%	1%
-	Onion, Welsh (Japanese bunching onion, multiplying onion)	raw		2	1.000	JP	Child. 1-6 yrs	305	35.7	97.0	3	2b	1%	1%	1%
-	Peach	raw with peel (incl consumption without peel)		1.9	1.000	JP	Child. 1-6 yrs	76	306.0	255.0	3	2a	10%	10%	3%
-	Peanut, shelled (groundnut)	raw incl roasted	0.01		1.000	CN	Child. 1-6 yrs	290	163.1	< 25	NR	3	0%	0%	0%
OR 0697	Peanut, shelled (groundnut)	Oil (refined)	0.04		1.000	FR	Child. 3-6 yrs	16.7%	19.8	NR	NR	3	0%	0%	0%
-	Pear	raw with peel (incl consumption without peel)		0.27	1.000	CN	Child. 1-6 yrs	413	418.3	255.0	3	2a	2%	2%	1%
-	Peas (dry) (Pisum spp. Vigna spp)	cooked/boiled	0.01		0.400	CN	Gen pop. > 1 yrs	268	1673.8	< 25	NR	3	0%	0%	0%
VP 0063	Peas (green pods & immature seeds) (Pisum spp, Vigna spp)	Total		1.6	1.000	US	child. 1-6 yrs	-	105.0	6.2	NR	1	1%	1%	1%
VP 0064	Peas, shelled (immature seeds) (Pisum spp, Vigna spp)	Total		0.16	1.000	UK	Child. 1.5-4.5 yrs	57	174.0	< 25	NR	1	0%	0%	0%
TN 0672	Pecan	Total		0.047	1.000	AU	Child. 2-16 yrs	52	80.9	5.0	NR	1	0%	0%	0%
VO 0443	Pepino (Melon pear, Tree melon)	Total		1.6	1.000	AU	Gen pop. > 2 yrs	3	73.9	122.9	3	2b	1%	-	1%
-	Peppers, chili	raw with skin		1.6	1.000	CN	Gen pop. > 1 yrs	1743	295.7	43.2	3	2a	1%	NC	1%
-	Peppers, sweet (incl. pim(i)ento) (bell pepper, paprika)	raw with skin		1.6	1.000	CN	Child. 1-6 yrs	1002	169.8	170.0	3	2b	5%	5%	2%
VD 0537	Pigeon pea (dry) (Cajanus spp)	Total	0.01		1.000	AU	Gen pop. > 2 yrs	129	95.8	< 25	NR	3	0%	-	0%
TN 0673	Pine nut	Total		0.047	1.000	BR	Gen pop. > 10 yrs	47	200.0	0.2	NR	1	0%	0%	0%
TN 0675	Pistachio nut	Total		0.047	1.000	FR	child. 3-6 yrs	2.6%	44.9	0.9	NR	1	0%	0%	0%
-	Plum	raw with peel (incl consumption without peel)		1.9	1.000	TH	Child. 3-6 yrs	11	376.9	93.0	3	2a	6%	6%	2%
DF 0014	Plum	dried (prunes)		2.8	1.000	AU	Child. 2-6 yrs	13	447.6	10.4	NR	1	7%	7%	2%
VR 0589	Potato	Total		0.051	1.000	ZA	Child. 1-5 yrs	-	299.6	216.0	3	2a	0%	0%	0%
PF 0111	Poultry, fats	Total		0.023	1.000	US	gen pop. all ages	-	42.9	NR	NR	1	0%	0%	0%
-	Pumpkins	raw without peel		0.01	1.000	CN	Child. 1-6 yrs	561	322.7	1851.8	3	2b	0%	0%	0%
-	Pumpkins	cooked/boiled with peel		0.3	1.000	JP	Child. 1-6 yrs	142	86.7	900.0	3	2b	0%	0%	0%
VL 0492	Purslane	Total		15	1.000	NL	Gen pop. > 1 yrs	8	452.0	< 25	NR	1	10%	-	10%
FP 0231	Quince	Total		0.27	1.000	DE	child. 2-4 yrs	16	26.3	301.2	3	2b	0%	0%	0%
-	Radish	raw with skin		1.20	1.000	NL	Child. 2-6 yrs	E	64.4	172.0	3	2b	1%	1%	1%
-	Radish, black	raw without skin		1.2	1.000	NL	Child. 2-6 yrs	E	64.4	180.3	3	2b	1%	1%	1%
-	Radish, Japanese (Chinese radish.	raw without skin		1.2	1.000	CN	Child. 1-6 yrs	1187	293.4	1000.0	3	2b	7%	7%	3%

Annex 4

PENTHIOPYRAD (253) International estimate of short term intake (IESTI

Acute RfD= 0.001 mg/kg bw (1000 µg/kg bw)

Maximum %ARfD:													150% all-mixed	150% children	60% gen pop
Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Mixed population groups 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
	Daikon)														
OR 0495	Rape seed	Oil (refined)	0.11		1.000	AU	Gen pop. > 2 yrs	2407	40.7	NR	NR	3	0%	0%	0%
VL 0496	Rucola (arugula, rocket salad, roquette)	Total		15	1.000	AU	Gen pop. > 2 yrs	10	157.3	212.8	3	2b	10%	-	10%
CF 1251	Rye	Wholemeal	0.01		1.000	DE	Child. 2-4 yrs	242	95.2	NR	NR	3	0%	0%	0%
-	Snake gourd	raw without peel		0.01	1.000	TH	Child. 3-6 yrs	759	129.6	133.0	3	2b	0%	0%	0%
-	Sorghum (Chicken corn, Dari seed, Durra, Feterita)	cooked/boiled	0.22		0.400	CN	Gen pop. > 1 yrs	356	1348.7	< 25	NR	3	0%	0%	0%
-	Sowthistle	raw		15	1.000	CN	Gen pop. > 1 yrs	1187	592.5	-	-	-	-	-	-
OR 0541	Soya bean (dry) (Glycine spp)	Oil (refined)	0.032		1.000	US	Child. 1-6 yrs	-	35.4	NR	NR	3	0%	0%	0%
-	Soya bean (dry) (Glycine spp)	soybean milk	0.032		1.000	AU	Child. 2-6 yrs	102	1131.2	NR	NR	3	0%	0%	0%
VL 0502	Spinach	Total		15	1.000	ZA	Child. 1-5 yrs	-	237.5	197.8	3	2a	70%	70%	20%
-	Spring onion	cooked/boiled		2	1.000	NL	Child. 2-6 yrs	E	20.3	30.0	3	2b	1%	1%	0%
VC 0431	Squash, summer (courgette, marrow, zucchetti, zucchini)	Total		0.3	1.000	NL	toddler. 8-20 m	11	82.1	328.3	3	2b	1%	1%	0%
FB 0275	Strawberry	Total		1.81	1.000	FR	Child. 3-6 yrs	32.3%	339.4	13.4	NR	1	3%	3%	2%
-	Sugar beet	sugar	0.033		1.000	FR	Child. 3-6 yrs	100.0%	274.7	NR	NR	3	0%	0%	0%
SO 0702	Sunflower seed	Total	0.12		1.000	CN	Gen pop. > 1 yrs	781	235.5	< 25	NR	3	0%	0%	0%
-	Sweet corn (corn-on-the-cob)	cooked/boiled		0.01	1.000	TH	Child. 3-6 yrs	1383	197.0	191.1	3	2a	0%	0%	0%
-	Taro leaves	raw		15	1.000	NL	Gen pop. > 1 yrs	E	77.8	85.8	3	2b	5%	NC	5%
-	Tomato	raw with peel		1.6	1.000	CN	Child. 1-6 yrs	1117	263.8	180.0	3	2a	6%	6%	2%
-	Tomato	dried		1.60	5.000	AU	Gen pop. > 2 yrs	61	861.1	8.0	NR	1	10%	0%	10%
GC 0653	Triticale	Total	0.01		1.000	DE	Gen pop. 14-80 yrs	27100	394.7	< 25	NR	3	0%	0%	0%
VL 0506	Turnip greens (Namenia. Tendergreen)	Total		23	1.000	NL	toddler. 8-20 m	110	322.0	< 25	NR	1	70%	70%	30%
-	Walnut	raw incl roasted		0.47	1.000	DE	Child. 2-4 yrs	75	49.4	7.0	NR	1	0%	0%	0%
-	Watercress	raw		15	1.000	BR	gen pop. > 10 yrs	97	90.9	254.6	3	2b	6%	1%	6%
VC 0432	Watermelon	Total		0.01	1.000	AU	Gen pop. > 2 yrs	267	2542.2	2095.6	3	2a	0%	0%	0%
CF 0654	Wheat	Bran (processed)	0.018		1.000	US	Child. 1-6 yrs	-	29.7	NR	NR	3	0%	0%	0%
CF 1210	Wheat	Germs	0.019		1.000	FR	Gen Pop. > 3 yrs	4.4%	803.1	NR	NR	3	0%	0%	0%
CF 1211	Wheat	flour (cereals)	0.004		1.000	CN	Child, 1-6 yrs	3556	415,9	NR	NR	3	0%	0%	0%

Annex 4

PHORATE (112) International estimate of short term intake (IESTI) Acute RfD= 0.003 mg/kg bw (3 µg/kg bw)

Maximum %ARfD: 100% all-mixed; 100% children; 10% women; 50% gen pop

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	diet corr fact	Mixed population groups: 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	% acute RfD rounded
VR 0589	Potato	Total		0.061	1.000	ZA	Child, 1-5 yrs	-	299.6	216.0	3	2a	100%	100%	10%	30%
-	Potato	raw without peel		0.045	1.000	NL	Gen pop, > 1 yrs	0	NC	134.1	3	2a	NC	NC	-	NC
-	Potato	boiled\microwaved (with peel)		0.061	1.000	AU	Child, 2-6 yrs	1487	300.5	123.0	3	2a	60%	60%	-	30%
-	Potato	baked (with peel)		0.048	1.000	BR	Gen pop, > 10 yrs	4471	420.0	140.0	3	2a	20%	NC	-	20%
-	Potato	dried (granule/flake)	0.12		9.500	NL	Child, 2-6 yrs	47	33.7	NR	NR	3	70%	70%	-	50%
-	Potato	deep-fried (chips/french fries without peel)	0.018		1.000	NL	toddler, 8-20 m	76	120.8	NR	NR	3	7%	7%	-	5%
-	Potato	crisps	0.0034		1.000	NL	Child, 2-6 yrs	423	40.1	NR	NR	3	0%	0%	-	0%

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

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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.
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5. Evaluation of the hazards to consumers resulting from the use of fumigants in the protection of food. FAO Meeting Report, No. PL/1965/10/2; WHO/Food Add./28.65, 1965.
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ANNEX 6: LIVESTOCK DIETARY BURDEN

AMETOCTRADIN

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	35	HR	15	233.33		20				46.67		
Rape forage	AM/AV	35	HR	30	116.67			100				116.7	
Potato culls	VR	0.035	HR	20	0.18	30	30			0.053	0.053		
Total						30	50	100		0.053	46.72	116.7	

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	35	HR	15	233.33		20	40			46.67	93.33	
Rape forage	AM/AV	35	HR	30	116.67	10				11.67			
Grape pomace, wet	AB	2.1	STMR	15	14.00			20				2.8	
Potato culls	VR	0.035	HR	20	0.18	10	30	10		0.02	0.053	0.018	
Total						20	50	70		11.68	46.72	96.15	

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	0.035	HR	20	0.18		10				0.018		
Total							10				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
Kale leaves	AM/AV	35	HR	15	233.33		5				11.67		
Rape forage	AM/AV	35	HR	30	116.67		5				5.833		
Potato culls	VR	0.035	HR	20	0.18		10				0.018		
Total							20				17.52		

AMETOCTRADIN

BEEF CATTLE **MEAN**

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Kale leaves	AM/A	13	STMR/STMR-	15	86.67		20				17.33		

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
	V		P										
Rape forage	AM/AV	13	STMR/STMR-P	30	43.33			100				43.33	
Potato culls	VR	0.01	STMR/STMR-P	20	0.05	30	30			0.015	0.015		
Total						30	50	100		0.015	17.35	43.33	

DAIRY CATTLE **MEAN**

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Kale leaves	AM/AV	13	STMR/STMR-P	15	86.67		20	40			17.33	34.67	
Rape forage	AM/AV	13	STMR/STMR-P	30	43.33	10				4.33			
Grape pomace, wet	AB	2.1	STMR/STMR-P	15	14.00	0		20		0.00		2.8	
Potato culls	VR	0.01	STMR/STMR-P	20	0.05	10	30	10		0.01	0.015	0.005	
Total						20	50	70		4.34	17.35	37.47	

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	0.01	STMR/STMR-P	20	0.05		10				0.005		
Total							10				0.005		

POULTRY LAYER **MEAN**

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Kale leaves	AM/AV	13	STMR/STMR-P	15	86.67		5				4.333		
Rape forage	AM/AV	13	STMR/STMR-P	30	43.33		5				2.167		
Potato culls	VR	0.01	STMR/STMR-P	20	0.05		10				0.005		
Total							20				6.505		

CHLORFENAPYR

BEEF CATTLE **MAX**

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Tomato pomace,wet	AB	4.1	STMR	20	20.50			10				2.05	
Citrus dried pulp	AB	0.704	STMR	91	0.77	10	5	20		0.07736	0.039	0.155	
Potato culls	VR	0.01	HR	20	0.05	30	30	10		0.015	0.015	0.005	
Total						40	35	40		0.09236	0.054	2.21	

DAIRY CATTLE **MAX**

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Tomato pomace,wet	AB	4.1	STMR	20	20.50			10				2.05	
Citrus dried pulp	AB	0.704	STMR	91	0.77	10	20	20		0.07736	0.155	0.155	
Potato culls	VR	0.01	HR	20	0.05	10	30	10		0.005	0.015	0.005	
Total						20	50	40		0.08236	0.17	2.21	

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	0.01	HR	20	0.05		10				0.005		
Total							10				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	0.01	HR	20	0.05		10				0.005		
Total							10				0.005		

CHLORFENAPYR

BEEF CATTLE **MEAN**

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Tomato pomace,wet	AB	4.1	STMR/STMR-P	20	20.50			10				2.05	
Citrus dried pulp	AB	0.704	STMR/STMR-P	91	0.77	10	5	20		0.077363	0.039	0.155	
Potato culls	VR	0.01	STMR/STMR-P	20	0.05	30	30	10		0.015	0.015	0.005	
Total						40	35	40		0.092363	0.054	2.21	

DAIRY CATTLE **MEAN**

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Tomato pomace,wet	AB	4.1	STMR/STMR-P	20	20.50		0	10			0	2.05	
Citrus dried pulp	AB	0.704	STMR/STMR-P	91	0.77	10	20	20		0.077363	0.155	0.155	
Potato culls	VR	0.01	STMR/STMR-P	20	0.05	10	30	10		0.005	0.015	0.005	
Total						20	50	40		0.082363	0.17	2.21	

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	0.01	STMR/STMR-P	20	0.05		10				0.005		
Total							10				0.005		

POULTRY LAYER **MEAN**

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Potato culls	VR	0.01	STMR/STMR-P	20	0.05		10				0.005		
Total							10				0.005		

CYCLOXYDIM

BEEF CATTLE **MAX**

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Cabbage heads, leaves	AM/AV	6	HR	15	40		20				8		
Pea vines	AL	9	HR	25	36		20	60			7.2	21.6	
Carrot culls	VR	3	HR	12	25		15	5			3.75	1.25	
Soya bean seed	VD	13	STMR	89	14.61	5	10	20	15	0.7	1.46	2.9	2.19
Potato culls	VR	1.6	HR	20	8	30	15	5		2.4	1.2	0.4	
Pea seed	VD	5.6	STMR	90	6.22		10	10			0.62	0.4	
Canola meal	SM	2.85	STMR	88	3.239	5				0.16			
Corn, field stover	AF/AS	1.1	HR	83	1.33	15	10			0.2	0.13		
Corn, field grain	GC	0.09	STMR	88	0.102	45			75	0			0.08
Rice straw	AF/AS	0.09	HR	90	0.1				10				0.01
Total						100	100	100	100	3.54	22.4	26.8	2.28

DAIRY CATTLE **MAX**

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Cabbage heads, leaves	AM/AV	6	HR	15	40		20				8		
Pea vines	AL	9	HR	25	36	10	20	40		3.6	7.2	14.4	
Carrot culls	VR	3	HR	12	25	10	15	5		2.5	3.75	1.25	
Soya bean seed	VD	13	STMR	89	14.61	10	10	20	10	1.46	1.46	2.92	1.46
Potato culls	VR	1.6	HR	20	8		15				1.2		
Bean vines	AL	5.6	HR	35	6.22			30				1.71	
Pea seed	VD	2	STMR	90	5.714		10				0.62		
Canola meal	SM	2.85	STMR	88	3.239	10	10	5		0.32	0.32	0.16	
Corn, field stover	AF/AS	1.1	HR	83	1.33	15				0.2			
Corn, field grain	GC	0.09	STMR	88	0.102	45			80	0.05			0.08
Rice straw	AF/AS	0.09	HR	90	0.1				10				0.01
Total						100	100	100	100	8.13	22.6	20.4	1.55

POULTRY BROILER **MAX**

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Carrot culls	VR	3	HR	12	25		10				2.5		
Soya bean seed	VD	13	STMR	89	14.61	20	20	15		2.92	2.9	2.19	
Bean seed	VD	4.4	STMR	88	5			55				2.75	
Canola meal	SM	2.85	STMR	88	3.239	15	18	5		0.49	0.58	0.16	
Corn, field grain	GC	0.09	STMR	88	0.102	65	52		70	0.07	0.05		0.07
Total						100	100	75	70	3.47	6.06	5.1	0.07

POULTRY LAYER **MAX**

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Cabbage heads, leaves	AM/AV	6	HR	15	40		5				2		
Pea vines	AL	9	HR	25	36		10				3.6		
Carrot culls	VR	3	HR	12	25		10				2.5		
Soya bean seed	VD	13	STMR	89	14.61	20	15	15		2.92	2.19	2.19	
Bean seed	VD	4.4	STMR	88	5			55				2.75	
Canola meal	SM	2.85	STMR	88	3.239	15	10	5		0.49	0.32	0.16	
Corn, field stover	AF/AS	1.1	HR	83	1.325		10				0.13		
Corn, field grain	GC	0.09	STMR	88	0.102	65	40		80	0.07	0.04		0.08
Total						100	100	75	80	3.47	10.8	5.1	0.08

CYCLOXYDIM

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 seed	VD	13	STMR/STMR-P	89	14.61	5	10	20	15	0.73	1.461	2.92	2.191
Cabbage heads, leaves	AM/AV	1.95	STMR/STMR-P	15	13		20				2.6		
Pea vines	AL	1.8	STMR/STMR-P	25	7.2		20	60			1.44	4.32	

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
Potato culls	VR	5.6	STMR/ STMR-P	20	6.22	30	30	10			0.622	1.24	
Pea seed	VD	0.74	STMR/ STMR-P	90	3.675		10	10		1.103	1.103		
Canola meal	SM	2.85	STMR/ STMR-P	88	3.239	5				0.162			
Corn, field stover	AF/ AS	0.25	STMR/ STMR-P	83	0.298	15	10			0.045	0.03		
Corn, field grain	GC	0.09	STMR/ STMR-P	88	0.102	45			75	0.046			0.077
Rice straw	AF/ AS	0.09	STMR/ STMR-P	90	0.1				10				0.01
Total						100	100	100	100	2.085	7.255	8.49	2.278

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 seed	VD	13	STMR/ STMR-P	89	14.61	10	10	20	10	1.461	1.461	2.92	1.461
Cabbage heads, leaves	AM/AV	1.95	STMR/ STMR-P	15	13	0	20			0	2.6		
Pea vines	AL	1.8	STMR/ STMR-P	25	7.2	10	20	40		0.72	1.44	2.88	
Potato culls	VR	5.6	STMR/ STMR-P	20	6.22	10	30	10		0	0.622		
Pea seed	VD	0.74	STMR/ STMR-P	90	3.675	0	10			0.368	1.103	0.37	
Canola meal	SM	2.85	STMR/ STMR-P	88	3.239	10	10	15		0.324	0.324	0.49	
Bean vines	AL	0.25	STMR/ STMR-P	35	0.298	0		15		0		0.33	
Corn, field stover	AF/AS	0.09	STMR/ STMR-P	83	0.102	15				0.045			
Corn, field grain	GC	0.09	STMR/ STMR-P	88	0.1	45			80	0.046			0.082
Rice straw	AF/AS	13	STMR/STMR-P	90	14.61	0			10	0			0.01
Total						100	100	100	100	2.963	7.549	6.98	1.552

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 seed	VD	13	STMR/STMR-P	89	14.61	20	20	15		2.921	2.921	2.19	
Potato culls	VR	4.4	STMR/STMR-P	20	5		10					2.75	
Bean seed	VD	0.74	STMR/STMR-P	88	3.675			55			0.368		
Canola meal	SM	2.85	STMR/STMR-P	88	3.239	15	18	5		0.486	0.583	0.16	
Corn, field grain	GC	0.09	STMR/STMR-P	88	0.102	65	52		70	0.066	0.053		0.07
Total						100	100	75	70	3.474	3.925	5.1	0.07

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 seed	VD	13	STMR/STMR-P	89	14.61	20	15	15		2.921	2.191	2.19	
Cabbage heads, leaves	AM/AV	1.95	STMR/STMR-P	15	13		5				0.65		
Pea vines	AL	1.8	STMR/STMR-P	25	7.2		10				0.72		
Potato culls	VR	4.4	STMR/STMR-P	20	5		10					2.75	
Bean seed	VD	0.74	STMR/STMR-P	88	3.675			55			0.368		
Canola meal	SM	2.85	STMR/STMR-P	88	3.239	15	10	5		0.486	0.324	0.16	
Corn, field stover	AF/AS	0.25	STMR/STMR-P	83	0.298		10				0.01		
Corn, field grain	GC	0.09	STMR/STMR-P	88	0.102	65	40		80	0.066	0.041		0.08
Total						100	100	75	80	3.474	4.323	5.1	0.08

CYFLUTHRIN

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 asp gr fn	SM	22	STMR	85	25.8824	5				1.2941			
Soya bean hay	AL	2.2	HR	85	2.5882			80				2.0706	
Soya bean forage	AL	1	HR	56	1.7857			20				0.3571	
Rape forage	AM/AV	0.34	HR	30	1.1333		10				0.1133		
Citrus dried pulp	AB	0.29	STMR	91	0.3187	10	5			0.0319	0.0159		
Cotton hulls	SM	0.19	STMR	90	0.2111	5				0.0106			
Apple pomace, wet	AB	0.082	STMR	90	0.0911		15				0.0137		
Potato culls	VR	0.01	HR	20	0.0500	30	30			0.0150	0.0150		
Soya bean seed	VD	0.01	STMR	89	0.0112	5	10		15	0.0006	0.0011		0.0017
Total						55	70	100	15	1.3521	0.1591	2.4277	0.0017

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	2.2	HR	85	2.5882	20		40		0.5176		1.0353	
Rape forage	AM/AV	0.34	HR	30	1.1333	10	10	40		0.1133	0.1133	0.4533	
Citrus dried pulp	AB	0.29	STMR	91	0.3187	10	20	20		0.0319	0.0637	0.0637	
Cotton un-delinted seed	SO	0.1	STMR	88	0.1136	10	10			0.0114	0.0114		
Canola meal	SM	0.05	STMR	88	0.0568	10	10			0.0057	0.0057		
Potato culls	VR	0.01	HR	20	0.0500	10	30			0.0050	0.0150		
Soya bean seed	VD	0.01	STMR	89	0.0112	10	10		10	0.0011	0.0011		0.0011
Total						80	90	100	10	0.6860	0.2102	1.5524	0.0011

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
Canola meal	SM	0.05	STMR	88	0.0568	15	18	5		0.0085	0.0102	0.0028	
Potato culls	VR	0.01	HR	20	0.0500		10				0.0050		

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
Soya bean seed	VD	0.01	STMR	89	0.0112	20	20	15		0.0022	0.0022	0.0017	
Cotton meal	SM	0.008	STMR	89	0.0090	5		5		0.0004		0.0004	
Total						40	48	25		0.0112	0.0175	0.0050	

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	2.2	HR	85	2.5882		10				0.2588		
Rape forage	AM/AV	0.34	HR	30	1.1333		10				0.1133		
Canola meal	SM	0.05	STMR	88	0.0568	15	10	5		0.0085	0.0057	0.0028	
Potato culls	VR	0.01	HR	20	0.0500		10				0.0050		
Soya bean seed	VD	0.01	STMR	89	0.0112	20	15	15		0.0022	0.0017	0.0017	
Cotton meal	SM	0.008	STMR	89	0.0090	5		5		0.0004		0.0004	
Total						40	55	25		0.0112	0.3845	0.0050	

CYFLUTHRIN

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 asp gr fn	SM	22	STMR/-P	85	25.8824	5				1.2941			
Soya bean hay	AL	1.15	STMR/-P	85	1.3529			80				1.0824	
Soya bean forage	AL	0.4	STMR/-P	56	0.7143			20				0.1429	
Rape forage	AM/AV	0.205	STMR/-P	30	0.6833		10				0.0683		
Citrus dried pulp	AB	0.29	STMR/-P	91	0.3187	10	5			0.0319	0.0159		
Cotton hulls	SM	0.19	STMR/-P	90	0.2111	5				0.0106			
Apple pomace, wet	AB	0.082	STMR/-P	90	0.0911		15				0.0137		
Potato culls	VR	0.01	STMR/-P	20	0.0500	30	30			0.0150	0.0150		
Soya bean seed	VD	0.01	STMR/-P	89	0.0112	5	10		15	0.0006	0.0011		0.0017
Total						55	70	100	15	1.3521	0.1141	1.2252	0.0017

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	1.15	STMR/-P	85	1.3529	20	0	40		0.2706	0.0000	0.5412	
Rape forage	AM/AV	0.205	STMR/-P	30	0.6833	10	10	40		0.0683	0.0683	0.2733	
Citrus dried pulp	AB	0.29	STMR/-P	91	0.3187	10	20	20		0.0319	0.0637	0.0637	
Cotton undelinted seed	SO	0.1	STMR/-P	88	0.1136	10	10			0.0114	0.0114		
Canola meal	SM	0.05	STMR/-P	88	0.0568	10	10			0.0057	0.0057		
Potato culls	VR	0.01	STMR/-P	20	0.0500	10	30			0.0050	0.0150		
Soya bean seed	VD	0.01	STMR/-P	89	0.0112	10	10		10	0.0011	0.0011		0.0011
Total						80	90	100	10	0.3940	0.1652	0.8782	0.0011

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
Canola meal	SM	0.05	STMR/-P	88	0.0568	15	18	5		0.0085	0.0102	0.0028	
Potato culls	VR	0.01	STMR/-P	20	0.0500		10				0.0050		
Soya bean seed	VD	0.01	STMR/-P	89	0.0112	20	20	15		0.0022	0.0022	0.0017	
Cotton meal	SM	0.008	STMR/-P	89	0.0090	5		5		0.0004		0.0004	
Total						40	48	25		0.0112	0.0175	0.0050	

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	1.15	STMR/-P	85	1.3529		10				0.1353		
Rape forage	AM/AV	0.205	STMR/-P	30	0.6833		10				0.0683		
Canola meal	SM	0.05	STMR/-P	88	0.0568	15	10	5		0.0085	0.0057	0.0028	
Potato culls	VR	0.01	STMR/-P	20	0.0500		10				0.0050		
Soya bean seed	VD	0.01	STMR/-P	89	0.0112	20	15	15		0.0022	0.0017	0.0017	
Cotton meal	SM	0.008	STMR/-P	89	0.0090	5		5		0.0004		0.0004	
Total						40	55	25		0.0112	0.2160	0.0050	

DICHLORVOS

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 hulls	CM/CF	15.3	STMR-P	90	17.00			5				0.85	
Wheat milled bypdts	CM/CF	3.87	STMR-P	88	4.40	40	30	35	55	1.76	1.32	1.54	2.42
Rice grain	GC	2.8	STMR-P	88	3.18	20		40		0.64		1.27	
Wheat grain	GC	2.2	STMR-P	89	2.47		40	20	25		0.99	0.49	0.62
Total						60	70	100	80	2.40	2.31	4.16	3.04

DAIRY CATTLE **MAX**

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Rice hulls	CM/CF	15.3	STMR-P	90	17.00			10				1.7	
Wheat milled bypdts	CM/CF	3.87	STMR-P	88	4.40	30	30	30	45	1.32	1.32	1.32	1.98
Rice grain	GC	2.8	STMR-P	88	3.18	20		20		0.63		0.64	
Wheat grain	GC	2.2	STMR-P	89	2.47		40				0.99		
Total						50	70	60	45	1.96	2.31	3.66	1.98

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	3.87	STMR-P	88	4.40	50	20	20	30	2.199	0.88	0.88	1.32
Rice grain	GC	2.8	STMR-P	88	3.18	20		50		0.636		1.591	
Wheat grain	GC	2.2	STMR-P	89	2.47	30	70	5		0.742	1.73	0.124	
Total						100	90	75	30	3.58	2.61	2.59	1.32

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	3.87	STMR	88	4.40	50	20	20	5	2.198864	0.88	0.88	0.22
Rice grain	GC	2.8	STMR	88	3.18	20		50		0.636364		1.591	
Wheat grain	GC	2.2	STMR	89	2.47	30	70	20		0.741573	1.73	0.494	
Total						100	90	90	5	3.58	2.61	2.96	0.22

DICHLORVOS

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	15.3	STMR-P	90	17.00			5				0.85	
Wheat milled bypdts	CM/CF	3.87	STMR-P	88	4.40	40	30	35	55	1.75	1.32	1.54	2.42
Rice grain	GC	2.8	STMR-P	88	3.18	20		40		0.64		1.27	
Wheat grain	GC	2.2	STMR-P	89	2.47		40	20	25		0.99	0.494	0.618
Total						60	70	100	80	2.40	2.31	4.16	3.04

DAIRY CATTLE **MEAN**

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Rice hulls	CM/CF	15.3	STMR-P	90	17.00		0	10			0	1.7	
Wheat milled bypdts	CM/CF	3.87	STMR-P	88	4.40	30	30	30	45	1.32	1.32	1.32	1.98
Rice grain	GC	2.8	STMR-P	88	3.18	20		20		0.64		0.64	
Wheat grain	GC	2.2	STMR-P	89	2.47	0	40			0	0.989		
Total						50	70	60	45	1.96	2.31	3.66	1.98

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	3.87	STMR-P	88	4.40	50	20	20	30	2.199	0.88	0.88	1.32
Rice grain	GC	2.8	STMR-P	88	3.18	20		50		0.636		1.591	
Wheat grain	GC	2.2	STMR-P	89	2.47	30	70	5		0.742	1.73	0.12	

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
Total						100	90	75	30	3.5768	2.61	2.594	1.319

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	3.87	STMR-P	88	4.40	50	20	20	5	2.198864	0.88	0.88	0.22
Rice grain	GC	2.8	STMR	88	3.18	20		50		0.636364		1.591	
Wheat grain	GC	2.2	STMR	89	2.47	30	70	20		0.74	1.73	0.49	
Total						100	90	90	5	3.58	2.61	2.96	0.22

DINOTEFURAN

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	4.4	HR	15	29.33		20				5.867		
Rice hulls	CM/CF	15.18	STMR	90	16.87			5				0.843	
Turnip tops (leaves)	AM/AV	4.4	HR	30	14.67		20	80			2.933	11.73	
Cotton gin byproducts	AM/AV	7.1	HR	90	7.89	5				0.394			
Rice straw	AF/AS	4.3	HR	90	4.78		10	15	55		0.478	0.717	2.628
Rice grain	GC	3.3	STMR	88	3.75	20				0.75			
Rice bran/pollard	CM/CF	2.112	STMR	90	2.35	15			20	0.352			0.469
Cotton hulls	SM	0.0765	STMR	90	0.09	10				0.0085			
Total						50	50	100	75	1.51	9.278	13.29	3.097

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	4.4	HR	15	29.33		20	40			5.867	11.73	
Rice hulls	CM/CF	15.18	STMR	90	16.87			10				1.687	
Turnip tops (leaves)	AM/AV	4.4	HR	30	14.67	30				4.4			
Rice straw	AF/AS	4.3	HR	90	4.78		5	20	25		0.239	0.956	1.194
Rice grain	GC	3.3	STMR	88	3.75	20		20		0.75		0.75	
Rice bran/pollard	CM/CF	2.112	STMR	90	2.35	15	20	10	10	0.352	0.469	0.235	0.235
Cotton undelinted seed	SO	0.15	STMR	88	0.17	10	10			0.017045	0.017		
Cotton meal	SM	0.0555	STMR	89	0.06	10	5			0.006236	0.003		
Total						85	60	100	35	5.525281	6.595	15.36	1.429

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 grain	GC	3.3	STMR	88	3.75	20		50		0.75		1.875	
Rice bran/pollard	CM/CF	2.112	STMR	90	2.35	10	10	20	5	0.234667	0.235	0.469	0.117
Cotton meal	SM	0.0555	STMR	89	0.06	20	5	10		0.012472	0.003	0.006	
Total						50	15	80	5	0.997139	0.238	2.351	0.117

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	4.4	HR	15	29.33		5				1.467		
Rice grain	GC	3.3	STMR	88	3.75	20		50		0.75		1.875	
Rice bran/pollard	CM/CF	2.112	STMR	90	2.35	10	5	20	20	0.234667	0.117	0.469	0.469
Cotton meal	SM	0.0555	STMR	89	0.06	20	5	10		0.012472	0.003	0.006	
Total						50	15	80	20	0.997139	1.587	2.351	0.469

DINOTEFURAN

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	15.18	STMR/STMR-P	90	16.87			5				0.843	
Kale leaves	AM/AV	1.2	STMR/STMR-P	15	8.00		20				1.6		
Cotton gin byproducts	AM/AV	3.8	STMR/STMR-P	90	4.22	5				0.21			
Turnip tops (leaves)	AM/AV	1.2	STMR/STMR-P	30	4.00		20	80			0.8	3.2	
Rice grain	GC	3.3	STMR/STMR-P	88	3.75	20		15		0.75		0.563	
Rice bran/pollard	CM/CF	2.112	STMR/STMR-P	90	2.35	15			20	0.352			0.469
Rice straw	AF/AS	1.6	STMR/STMR-P	90	1.78		10		55		0.178		0.978
Cotton hulls	SM	0.0765	STMR/STMR-P	90	0.09	10				0.0085			
Total						50	50	100	75	1.3216	2.578	4.606	1.447

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	15.18	STMR/STMR-P	90	16.87		0	10			0	1.687	
Kale leaves	AM/AV	1.2	STMR/STMR-P	15	8.00	0	20	40		0	1.6	3.2	

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
Turnip tops (leaves)	AM/AV	1.2	STMR/STMR-P	30	4.00	30				1.2			
Rice grain	GC	3.3	STMR/STMR-P	88	3.75	20		20		0.75		0.75	
Rice bran/pollard	CM/CF	2.112	STMR/STMR-P	90	2.35	15	20	30	10	0.352	0.469	0.704	0.235
Rice straw	AF/AS	1.6	STMR/STMR-P	90	1.78	0	5		25	0	0.089		0.444
Cotton undelinted seed	SO	0.15	STMR/STMR-P	88	0.17	10	10			0.017045	0.017		
Cotton meal	SM	0.0555	STMR/STMR-P	89	0.06	10	5			0.006236	0.003		
Total						85	60	100	35	2.325281	2.178	6.341	0.679

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 grain	GC	3.3	STMR/STMR-P	88	3.75	20		50		0.75		1.875	
Rice bran/pollard	CM/CF	2.112	STMR/STMR-P	90	2.35	10	10	20	5	0.234667	0.235	0.469	0.117
Cotton meal	SM	0.0555	STMR/STMR-P	89	0.06	20	5	10		0.012472	0.003	0.006	
Total						50	15	80	5	0.997139	0.238	2.351	0.117

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	1.2	STMR/STMR-P	15	8.00		5				0.4		
Rice grain	GC	3.3	STMR/STMR-P	88	3.75	20		50		0.75		1.875	
Rice bran/pollard	CM/CF	2.112	STMR/STMR-P	90	2.35	10	5	20	20	0.234667	0.117	0.469	0.469
Cotton meal	SM	0.0555	STMR/STMR-P	89	0.06	20	5	10		0.012472	0.003	0.006	
Total						50	15	80	20	0.997139	0.52	2.351	0.469

FLUOPYRAM

BEEF CATTLE **MAX**

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Beet, sugar tops	AM/AV	8.3	HR	23	36.09		20				7.2174		
Grape pomace, wet	AB	1.86	STMR	15	12.40			20				2.4800	
Almond hulls	AM/AV	3.6	STMR	90	4.00			10				0.4000	

Carrot culls	VR	0.19	HR	12	1.58		15	5			0.2375	0.0792	
Apple pomace, wet	AB	0.31	STMR	40	0.78		20				0.1550		
Potato process waste	AB	0.04	STMR	12	0.33	30	20			0.1000	0.0667		
Potato culls	VR	0.02	HR	20	0.10	30	15	5		0.0300	0.0150	0.0050	
Beet, sugar molasses	DM	0.01	STMR	75	0.01	10	10			0.0013	0.0013		
Bean seed	VD	0.01	STMR	88	0.01			50				0.0057	
Peanut meal	SM	0.002	STMR	85	0.00			10				0.0002	
Total						70	100	100		0.1313	7.6929	2.9701	

DAIRY CATTLE **MAX**

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Beet, sugar tops	AM/AV	8.3	HR	23	36.09		30				10.826		
Grape pomace, wet	AB	1.86	STMR	15	12.40			20				2.4800	
Almond hulls	AM/AV	3.6	STMR	90	4.00	10		10		0.4000		0.4000	
Carrot culls	VR	0.19	HR	12	1.58	10	15	5		0.1583	0.2375	0.0792	
Apple pomace, wet	AB	0.31	STMR	40	0.78	10	10			0.0775	0.0775		
Potato process waste	AB	0.04	STMR	12	0.33		20				0.0667		
Potato culls	VR	0.02	HR	20	0.10		15				0.0150		
Beet, sugar molasses	DM	0.01	STMR	75	0.01	10	10			0.0013	0.0013		
Bean seed	VD	0.01	STMR	88	0.01			15				0.0017	
Lupin seed	VD	0.01	STMR	88	0.01			5				0.0006	
Peanut meal	SM	0.002	STMR	85	0.00	10		15		0.0002		0.0004	
Total						50	100	70		0.6374	11.224	2.9618	

POULTRY BROILER **MAX**

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Carrot culls	VR	0.19	HR	12	1.58		10				0.1583		
Bean seed	VD	0.01	STMR	88	0.01		20	70			0.0023	0.0080	
Lupin seed	VD	0.01	STMR	88	0.01	10				0.0011			
Peanut meal	SM	0.002	STMR	85	0.00	25	10	10		0.0006	0.0002	0.0002	
Total						35	40	80		0.0017	0.1608	0.0082	

POULTRY LAYER **MAX**

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Beet, sugar tops	AM/AV	8.3	HR	23	36.09		5				1.8043		

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	0.19	HR	12	1.58		10				0.1583		
Bean seed	VD	0.01	STMR	88	0.01		20	70			0.0023	0.0080	
Lupin seed	VD	0.01	STMR	88	0.01	10				0.0011			
Peanut meal	SM	0.002	STMR	85	0.00	25	10	10		0.0006	0.0002	0.0002	
Total						35	45	80		0.0017	1.9652	0.0082	

FLUOPYRAM

BEEF CATTLE **MEAN**

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Grape pomace, wet	AB	1.86	STMR/-P	15	12.40			20				2.48	
Almond hulls	AM/AV	3.6	STMR/-P	90	4.00			10				0.4	
Beet, sugar tops	AM/AV	0.46	STMR/-P	23	2.00		20				0.4		
Apple pomace, wet	AB	0.31	STMR/-P	40	0.78		20				0.155		
Carrot culls	VR	0.09	STMR/-P	12	0.75		15	5			0.113	0.038	
Potato process waste	AB	0.04	STMR/-P	12	0.33	30	20			0.1	0.067		
Potato culls	VR	0.01	STMR/-P	20	0.05	30	15	5		0.015	0.008	0.003	
Beet, sugar molasses	DM	0.01	STMR/-P	75	0.01	10	10			0.001333	0.001		
Bean seed	VD	0.01	STMR/-P	88	0.01			50				0.006	
Peanut meal	SM	0.002	STMR/-P	85	0.00			10				2E-04	
Total						70	100	100		0.116333	0.743	2.926	

DAIRY CATTLE **MEAN**

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Grape pomace, wet	AB	1.86	STMR/-P	15	12.40		0	20			0	2.48	
Almond hulls	AM/AV	3.6	STMR/-P	90	4.00	10		10		0.4		0.4	
Beet, sugar tops	AM/AV	0.46	STMR/-P	23	2.00	0	30			0	0.6		
Apple pomace, wet	AB	0.31	STMR/-P	40	0.78	10	10			0.0775	0.078		
Carrot culls	VR	0.09	STMR/-P	12	0.75	10	15	5		0.075	0.113	0.038	
Potato process waste	AB	0.04	STMR/-P	12	0.33	0	20			0	0.067		
Potato culls	VR	0.01	STMR/-P	20	0.05	0	15			0	0.008		

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 molasses	DM	0.01	STMR/-P	75	0.01	10	10			0.001333	0.001		
Bean seed	VD	0.01	STMR/-P	88	0.01	0		15		0		0.002	
Lupin seed	VD	0.01	STMR/-P	88	0.01	0		5		0		6E-04	
Peanut meal	SM	0.002	STMR/-P	85	0.00	10		15		0.000235		4E-04	
Total						50	100	70		0.554069	0.866	2.92	

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/-P	12	0.75		10				0.075		
Bean seed	VD	0.01	STMR/-P	88	0.01		20	70			0.002	0.008	
Lupin seed	VD	0.01	STMR/-P	88	0.01	10				0.001136			
Peanut meal	SM	0.002	STMR/-P	85	0.00	25	10	10		0.000588	2E-04	2E-04	
Total						35	40	80		0.001725	0.078	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
Beet, sugar tops	AM/AV	0.46	STMR/-P	23	2.00		5				0.1		
Carrot culls	VR	0.09	STMR/-P	12	0.75		10				0.075		
Bean seed	VD	0.01	STMR/-P	88	0.01		20	70			0.002	0.008	
Lupin seed	VD	0.01	STMR/-P	88	0.01	10				0.001136			
Peanut meal	SM	0.002	STMR/-P	85	0.00	25	10	10		0.000588	2E-04	2E-04	
Total						35	45	80		0.001725	0.178	0.008	

FLUXAPYROXAD

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	40.66	HR	100	40.66		30	50			12.2	20.33	
Oat forage	AF/AS	40.66	HR	100	40.66			50				20.33	

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	22.9	HR	100	22.90		20				4.58		
Wheat asp gr fn	CM/CF	18.7	STMR	85	22.00	5				1.1			
Oat hay	AF/AS	18.3	HR	90	20.33	15				3.05			
Pea hay	AL	17.4	HR	100	17.40		5				0.87		
Corn, field forage/silage	AF/AS	3.62	HR	100	3.62		45				1.629		
Soya bean asp gr fn	SM	1.58	STMR	85	1.86	5				0.092941			
Barley bran fractions	CM/CF	1.01	STMR	90	1.12				10				0.112
Barley grain	GC	0.535	STMR	88	0.61	50			70	0.303977			0.426
Wheat milled bypdts	CM/CF	0.25	STMR	88	0.28	25			20	0.071023			0.057
Total						100	100	100	100	4.617941	19.28	40.66	0.595

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	40.66	HR	100	40.66		30	50			12.2	20.33	
Oat forage	AF/AS	40.66	HR	100	40.66	30		40	5	12.198		16.26	2.033
Soya bean forage	AL	25.9	HR	100	25.90	20		10		5.18		2.59	
Pea hay	AL	17.4	HR	100	17.40		30				5.22		
Corn, field forage/silage	AF/AS	3.62	HR	100	3.62	15	30		45	0.543	1.086		1.629
Apple pomace, wet	AB	1.2	STMR	40	3.00	10	10			0.3	0.3		
Barley grain	GC	0.535	STMR	88	0.61	25			40	0.151989			0.243
Wheat milled bypdts	CM/CF	0.25	STMR	88	0.28				10				0.028
Total						100	100	100	100	18.37299	18.8	39.18	3.934

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	0.535	STMR	88	0.61	75	70	15	10	0.455966	0.426	0.091	0.061
Wheat milled bypdts	CM/CF	0.25	STMR	88	0.28	25	20	20	5	0.071023	0.057	0.057	0.014
Brewer's grain dried	SM	0.13	STMR	92	0.14		10				0.014		
Canola meal	SM	0.046	STMR	88	0.05			5				0.003	
Rape meal	SM	0.046	STMR	88	0.05				5				0.003
Bean seed	VD	0.04	STMR	88	0.05			60				0.027	
Soya bean meal	SM	0.005	STMR	92	0.01				30				0.002
Total						100	100	100	50	0.526989	0.497	0.178	0.079

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	40.66	HR	100	40.66		10				4.066		
Soya bean forage	AL	25.9	HR	100	25.90		10				2.59		
Barley bran fractions	CM/CF	1.01	STMR	90	1.12				5				0.056
Barley grain	GC	0.535	STMR	88	0.61	75	80	15		0.455966	0.486	0.091	
Wheat milled bypdts	CM/CF	0.25	STMR	88	0.28	25		20	25	0.071023		0.057	0.071
Canola meal	SM	0.046	STMR	88	0.05			5				0.003	
Rape meal	SM	0.046	STMR	88	0.05				15				0.008
Bean seed	VD	0.04	STMR	88	0.05			60				0.027	
Corn, field grain	GC	0.01	STMR	88	0.01				55				0.006
Total						100	100	100	100	0.526989	7.142	0.178	0.141

FLUXAPYROXAD

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 asp gr fn	CM/CF	18.7	STMR/STMR-P	85	22.00	5				1.1			
Pea vines	AL	11.6	STMR/STMR-P	100	11.60		20	60			2.32	6.96	
Pea hay	AL	11.2	STMR/STMR-P	100	11.20		5	40			0.56	4.48	
Oat hay	AF/AS	4.1	STMR/STMR-P	90	4.56	15	20			0.683333	0.911		
Corn, pop stover	AF/AS	3.62	STMR/STMR-P	85	4.26		5				0.213		
Barley straw	AF/AS	4.1	STMR/STMR-P	100	4.10		5				0.205		
Apple pomace, wet	AB	1.2	STMR/STMR-P	40	3.00		20				0.6		
Corn, field forage/silage	AF/AS	2.82	STMR/STMR-P	100	2.82		25				0.705		
Soya bean asp gr fn	SM	1.58	STMR/STMR-P	85	1.86	5				0.092941			
Barley bran fractions	CM/CF	1.01	STMR/STMR-P	90	1.12				10				0.112
Barley grain	GC	0.535	STMR/STMR-P	88	0.61	50			70	0.303977			0.426
Wheat milled bypdts	CM/CF	0.25	STMR/STMR-P	88	0.28	25			20	0.071023			0.057
Total						100	100	100	100	2.251275	5.514	11.44	0.595

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	11.6	STMR/STMR-P	100	11.60	10	20	40		1.16	2.32	4.64	
Pea hay	AL	11.2	STMR/STMR-P	100	11.20	0	10	30		0	1.12	3.36	
Soya bean	AL	7.71	STMR/STMR-	100	7.71	10				0.771			

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
forage			P										
Oat hay	AF/AS	4.1	STMR/STMR-P	90	4.56	30	20	30	5	1.366667	0.911	1.367	0.228
Apple pomace, wet	AB	1.2	STMR/STMR-P	40	3.00	10	10			0.3	0.3		
Corn, field forage/silage	AF/AS	2.82	STMR/STMR-P	100	2.82	15	40		45	0.423	1.128		1.269
Barley grain	GC	0.535	STMR/STMR-P	88	0.61	25			40	0.151989			0.243
Wheat milled bypdts	CM/CF	0.25	STMR/STMR-P	88	0.28	0			10	0			0.028
Total						100	100	100	100	4.172655	5.779	9.367	1.768

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	0.535	STMR/STMR-P	88	0.61	75	70	15	10	0.455966	0.426	0.091	0.061
Wheat milled bypdts	CM/CF	0.25	STMR/STMR-P	88	0.28	25	20	20	5	0.071023	0.057	0.057	0.014
Brewer's grain dried	SM	0.13	STMR/STMR-P	92	0.14		10				0.014		
Canola meal	SM	0.046	STMR/STMR-P	88	0.05			5				0.003	
Rape meal	SM	0.046	STMR/STMR-P	88	0.05				5				0.003
Bean seed	VD	0.04	STMR/STMR-P	88	0.05			60				0.027	
Soya bean meal	SM	0.005	STMR/STMR-P	92	0.01				30				0.002
Total						100	100	100	50	0.526989	0.497	0.178	0.079

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	11.6	STMR/STMR-P	100	11.60		10				1.16		
Oat hay	AF/AS	4.1	STMR/STMR-P	90	4.56		10				0.456		
Barley bran fractions	CM/CF	1.01	STMR/STMR-P	90	1.12				5				0.056
Barley grain	GC	0.535	STMR/STMR-P	88	0.61	75	80	15		0.455966	0.486	0.091	
Wheat milled bypdts	CM/CF	0.25	STMR/STMR-P	88	0.28	25		20	25	0.071023		0.057	0.071
Canola meal	SM	0.046	STMR/STMR-P	88	0.05			5				0.003	
Rape meal	SM	0.046	STMR/STMR-	88	0.05				15				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
			P										
Bean seed	VD	0.04	STMR/STMR-P	88	0.05			60				0.027	
Corn, field grain	GC	0.01	STMR/STMR-P	88	0.01				55				0.006
Total						100	100	100	100	0.526989	2.102	0.178	0.141

GLUFOSINATE

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 hulls	SM	6.02	STMR	90	6.69	15	10			1.003333	0.669		
Corn, field stover	AF/AS	5.3	HR	83	6.39	15	25	40		0.957831	1.596	2.554	
Corn, field forage/silage	AF/AS	1.6	HR	40	4.00		55	40			2.2	1.6	
Beet, sugar molasses	DM	1.57	STMR	75	2.09	10	10			0.209333	0.209		
Rice straw	AF/AS	1.3	HR	90	1.44				55				0.794
Soya bean meal	SM	0.99	STMR	92	1.08				45				0.484
Cotton meal	SM	0.846	STMR	89	0.95			20				0.19	
Soya bean seed	VD	0.825	STMR	89	0.93	5				0.046348			
Corn, field asp gr fn	CM/CF	0.525	STMR	85	0.62	5				0.030882			
Potato culls	VR	0.05	HR	20	0.25	30				0.075			
Beet, sugar dried pulp	AB	0.168	STMR	88	0.19	15				0.028636			
Rice grain	GC	0.09	STMR	88	0.10	5				0.005114			
Total						100	100	100	100	2.36	4.67	4.34	1.28

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 hulls	SM	6.02	STMR	90	6.69		10				0.669		
Corn, field stover	AF/AS	5.3	HR	83	6.39	15	20	40		0.957831	1.277	2.554	
Corn, field forage/silage	AF/AS	1.6	HR	40	4.00	30	40	40	50	1.2	1.6	1.6	2
Beet, sugar molasses	DM	1.57	STMR	75	2.09	10	10			0.209333	0.209		
Soya bean meal	SM	0.99	STMR	92	1.08	10	15	15	50	0.107609	0.161	0.161	0.538
Soya bean seed	VD	0.825	STMR	89	0.93	10	5	5		0.092697	0.046	0.046	
Cotton	SO	0.705	STMR	88	0.80	10				0.080114			

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
undelinted seed													
Carrot culls	VR	0.05	HR	12	0.42	10				0.041667			
Beet, sugar dried pulp	AB	0.168	STMR	88	0.19	5				0.009545			
Total						100	100	100	100	2.7	4.0	4.4	2.5

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
Soya bean hulls	SM	6.02	STMR	90	6.69		10	5			0.669	0.334	
Soya bean meal	SM	0.99	STMR	92	1.08	25	30	20	35	0.269022	0.323	0.215	0.377
Soya bean seed	VD	0.825	STMR	89	0.93	20	20	15		0.185393	0.185	0.139	
Carrot culls	VR	0.05	HR	12	0.42		10				0.042		
Rice grain	GC	0.09	STMR	88	0.10	20		50		0.020455		0.051	
Rice bran/pollard	CM/CF	0.064	STMR	90	0.07	10	10	10	5	0.007111	0.007	0.007	0.004
Corn, field grain	GC	0.05	STMR	88	0.06	25	20		60	0.014205	0.011		0.034
Total						100	100	100	100	0.50	1.24	0.7	0.41

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 hulls	SM	6.02	STMR	90	6.69		5	5			0.334	0.334	
Corn, field stover	AF/AS	5.3	HR	83	6.39		10				0.639		
Soya bean meal	SM	0.99	STMR	92	1.08	25	20	20	30	0.269022	0.215	0.215	0.323
Soya bean seed	VD	0.825	STMR	89	0.93	20	15	15		0.185393	0.139	0.139	
Carrot culls	VR	0.05	HR	12	0.42		10				0.042		
Rice grain	GC	0.09	STMR	88	0.10	20		50		0.020455		0.051	
Rice bran/pollard	CM/CF	0.064	STMR	90	0.07	10	5	10	20	0.007111	0.004	0.007	0.014
Corn, field grain	GC	0.05	STMR	88	0.06	25	35		50	0.014205	0.02		0.028
Total						100	100	100	100	0.496185	1.392	0.747	0.365

GLUFOSINATE

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 hulls	SM	6.02	STMR/STMR-P	90	6.69	15	10			1.003333	0.669		
Beet, sugar molasses	DM	1.57	STMR/STMR-P	75	2.09	10	10			0.209333	0.209		
Corn, field forage/silage	AF/AS	0.78	STMR/STMR-P	40	1.95	15	80	80		0.2925	1.56	1.56	
Cotton gin byproducts	AM/AV	1.5	STMR/STMR-P	90	1.67	5				0.083333			
Soya bean	SM	0.99	STMR/STMR-	92	1.08				65				0.699

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
meal			P										
Cotton meal	SM	0.846	STMR/STMR-P	89	0.95			20				0.19	
Soya bean seed	VD	0.825	STMR/STMR-P	89	0.93	5			15	0.046348			0.139
Corn, field asp gr fn	CM/CF	0.525	STMR/STMR-P	85	0.62	5				0.030882			
Rice straw	AF/AS	0.26	STMR/STMR-P	90	0.29				20				0.058
Potato culls	VR	0.05	STMR/STMR-P	20	0.25	30				0.075			
Beet, sugar dried pulp	AB	0.168	STMR/STMR-P	88	0.19	15				0.028636			
Total						100	100	100	100	1.77	2.44	1.75	0.90

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 hulls	SM	6.02	STMR/STMR-P	90	6.69		10	0			0.669	0	
Beet, sugar molasses	DM	1.57	STMR/STMR-P	75	2.09	10	10			0.209333	0.209		
Corn, field forage/silage	AF/AS	0.78	STMR/STMR-P	40	1.95	45	60	80	50	0.8775	1.17	1.56	0.975
Soya bean meal	SM	0.99	STMR/STMR-P	92	1.08	10	15	15	50	0.107609	0.161	0.161	0.538
Soya bean seed	VD	0.825	STMR/STMR-P	89	0.93	10	5	5		0.092697	0.046	0.046	
Cotton undelinted seed	SO	0.705	STMR/STMR-P	88	0.80	10				0.080114			
Carrot culls	VR	0.05	STMR/STMR-P	12	0.42	10				0.041667			
Beet, sugar dried pulp	AB	0.168	STMR/STMR-P	88	0.19	5				0.009545			
Total						100	100	100	100	1.4	2.3	1.8	1.5

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 hulls	SM	6.02	STMR/STMR-P	90	6.69		10	5			0.669	0.334	
Soya bean meal	SM	0.99	STMR/STMR-P	92	1.08	25	30	20	35	0.269022	0.323	0.215	0.377
Soya bean seed	VD	0.825	STMR/STMR-P	89	0.93	20	20	15		0.185393	0.185	0.139	
Carrot culls	VR	0.05	STMR/STMR-P	12	0.42		10				0.042		
Rice grain	GC	0.09	STMR/STMR-	88	0.10	20		50		0.020455		0.051	

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
			P										
Rice bran/pollard	CM/CF	0.064	STMR/STMR-P	90	0.07	10	10	10	5	0.007111	0.007	0.007	0.004
Corn, field grain	GC	0.05	STMR/STMR-P	88	0.06	25	20		60	0.014205	0.011		0.034
Total						100	100	100	100	0.496185	1.237	0.747	0.414

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 hulls	SM	6.02	STMR/STMR-P	90	6.69		5	5			0.334	0.334	
Corn, field forage/silage	AF/AS	0.78	STMR/STMR-P	40	1.95		10				0.195		
Soya bean meal	SM	0.99	STMR/STMR-P	92	1.08	25	20	20	30	0.269022	0.215	0.215	0.323
Soya bean seed	VD	0.825	STMR/STMR-P	89	0.93	20	15	15		0.185393	0.139	0.139	
Carrot culls	VR	0.05	STMR/STMR-P	12	0.42		10				0.042		
Rice grain	GC	0.09	STMR/STMR-P	88	0.10	20		50		0.020455		0.051	
Rice bran/pollard	CM/CF	0.064	STMR/STMR-P	90	0.07	10	5	10	20	0.007111	0.004	0.007	0.014
Corn, field grain	GC	0.05	STMR/STMR-P	88	0.06	25	35		50	0.014205	0.02		0.028
Total						100	100	100	100	0.496185	0.949	0.747	0.365

MCPA

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	108	HR	25	432.00		50	100	5		216	432	21.6
Grass hay	AF/AS	217	HR	88	246.59	15			35	36.98864			86.31
Barley grain	GC	0.05	STMR	88	0.06	50	50		60	0.028409	0.028		0.034
Total						65	100	100	100	37.01705	216	432	107.9

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	108	HR	25	432.00	45	60	100	10	194.4	259.2	432	43.2
Grass hay	AF/AS	217	HR	88	246.59				60				148

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 grain	GC	0.05	STMR	88	0.06	45	40		30	0.025568	0.023		0.017
Total						90	100	100	100	194.4256	259.2	432	191.2

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
Barley grain	GC	0.05	STMR	88	0.06	75	70	15	10	0.042614	0.04	0.009	0.006
Total						75	70	15	10	0.042614	0.04	0.009	0.006

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	108	HR	25	432.00		10				43.2		
Barley grain	GC	0.05	STMR	88	0.06	75	90	15		0.042614	0.051	0.009	
Total						75	100	15		0.042614	43.25	0.009	

MCPA

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	47	STMR/STMR-P	25	188.00		50	100	5		94	188	9.4
Grass hay	AF/AS	74.35	STMR/STMR-P	88	84.49	15			35	12.6733			29.57
Barley grain	GC	0.05	STMR/STMR-P	88	0.06	50	50		60	0.028409	0.028		0.034
Total						65	100	100	100	12.7017	94.03	188	39.01

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	47	STMR/STMR-P	25	188.00	45	60	100	10	84.6	112.8	188	18.8
Grass hay	AF/AS	74.35	STMR/STMR-P	88	84.49	0			60	0			50.69
Barley grain	GC	0.05	STMR/STMR-P	88	0.06	45	40		30	0.025568	0.023		0.017
Total						90	100	100	100	84.62557	112.8	188	69.51

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	0.05	STMR/STMR-P	88	0.06	75	70	15	10	0.042614	0.04	0.009	0.006
Total						75	70	15	10	0.042614	0.04	0.009	0.006

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	47	STMR/STMR-P	25	188.00		10				18.8		
Barley grain	GC	0.05	STMR/STMR-P	88	0.06	75	90	15		0.042614	0.051	0.009	
Total						75	100	15		0.042614	18.85	0.009	

METHOXYFENOZIDE

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	45	HR	40	112.50	15	80	80		16.88	90	90	
Pea vines	AL	26	HR	25	104.00		20	20			20.8	20.8	
Citrus dried pulp	AB	0.31	STMR	91	0.34	10				0.034			
Cotton meal	SM	0.18	STMR	89	0.20	5				0.010			
Beet, sugar molasses	DM	0.126	STMR	75	0.17	10				0.017			
Beet, sugar dried pulp	AB	0.09	STMR	88	0.10	5			5	0.005			0.005
Cotton hulls	SM	0.055	STMR	90	0.06	5				0.003			
Potato culls	VR	0.012	HR	20	0.06	30				0.018			
Corn, field grain	GC	0.02	STMR	88	0.02	20			75	0.005			0.017
Total						100	100	100	80	16.97	110.8	110.8	0.022

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	45	HR	40	112.5	45	60	80	50	50.63	67.5	90	56.25
Pea vines	AL	26	HR	25	104.0	10	20	20		10.4	20.8	20.8	
Peanut hay	AL	51	HR	85	60.0	5				3			
Cabbage heads, leaves	AM/AV	6.2	HR	15	41.33		20				8.2667		

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
Almond hulls	AM/AV	13	STMR	90	14.44	10				1.444			
Apple pomace, wet	AB	1.3	STMR	40	3.25	10				0.325			
Carrot culls	VR	0.31	HR	12	2.58	10				0.258			
Cotton undelinted seed	SO	0.39	STMR	88	0.44	10				0.044			
Beet, sugar dried pulp	AB	0.09	STMR	88	0.10				40				0.041
Corn, field grain	GC	0.02	STMR	88	0.02				10				0.002
Total						100	100	100	100	66.10	96.57	110.8	56.30

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	0.31	HR	12	2.58		10				0.258		
Cotton meal	SM	0.18	STMR	89	0.20	20	5	10		0.040	0.010	0.020	
Cowpea seed	VD	0.17	STMR	88	0.19	10	5	5		0.019	0.010	0.010	
Pea seed	VD	0.17	STMR	90	0.19	10	15			0.0189	0.028		
Bean seed	VD	0.05	STMR	88	0.06			65				0.0369	
Corn, field grain	GC	0.02	STMR	88	0.02	60	65		70	0.0134	0.015		0.016
Total						100	100	80	70	0.0923	0.3212	0.0668	0.0159

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	45	HR	40	112.50		10				11.25		
Pea vines	AL	26	HR	25	104.00		10				10.4		
Cabbage heads, leaves	AM/AV	6.2	HR	15	41.33		5				2.067		
Carrot culls	VR	0.31	HR	12	2.58		10				0.2587		
Cotton meal	SM	0.18	STMR	89	0.20	20	5	10		0.040	0.0107	0.020	
Cowpea seed	VD	0.17	STMR	88	0.19	10	10	5		0.019	0.0197	0.010	
Pea seed	VD	0.17	STMR	90	0.19	10	10			0.0189	0.019		
Bean seed	VD	0.05	STMR	88	0.06			65				0.037	
Corn, field grain	GC	0.02	STMR	88	0.02	60	40		80	0.014	0.009		0.018
Total						100	100	80	80	0.09229	24.03	0.0668	0.018

METHOXYFENOZIDE

BEEF CATTLE **MEAN**

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-	EU	AU	JP	US-	EU	AU	JP

						CAN				CAN			
Corn, field stover	AF/AS	46	STMR/ STMR-P	83	55.42	15	25	40		8.313	13.86	22.17	
Corn, field forage/silage	AF/AS	22	STMR/ STMR-P	40	55.00		55	40			30.25	22	
Pea vines	AL	5.1	STMR/ STMR-P	25	20.40		20	20			4.08	4.08	
Cotton gin byproducts	AM/AV	11	STMR/ STMR-P	90	12.22	5				0.611			
Citrus dried pulp	AB	0.31	STMR/ STMR-P	91	0.34	10				0.034			
Cotton meal	SM	0.18	STMR/ STMR-P	89	0.20	5				0.010			
Beet, sugar molasses	DM	0.126	STMR/ STMR-P	75	0.17	10				0.017			
Beet, sugar dried pulp	AB	0.09	STMR/STMR-P	88	0.10	5			5	0.005			0.0051
Cotton hulls	SM	0.055	STMR/ STMR-P	90	0.06	5				0.003			
Potato culls	VR	0.01	STMR/ STMR-P	20	0.05	30				0.015			
Corn, field grain	GC	0.02	STMR/ STMR-P	88	0.02	15			75	0.003			0.017
Total						100	100	100	80	9.01	48.19	48.25	0.022

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 stover	AF/AS	46	STMR /STMR-P	83	55.42	15	20	40		8.313	11.08	22.17	
Corn, field forage/silage	AF/AS	22	STMR /STMR-P	40	55.00	30	40	40	50	16.5	22	22	27.5
Pea vines	AL	5.1	STMR /STMR-P	25	20.40	10	20	20		2.04	4.08	4.08	
Peanut hay	AL	13.5	STMR /STMR-P	85	15.88	5				0.794			
Almond hulls	AM/AV	13	STMR /STMR-P	90	14.44	10				1.444			
Cabbage heads, leaves	AM/AV	0.93	STMR /STMR-P	15	6.20	0	20			0	1.24		
Apple pomace, wet	AB	1.3	STMR /STMR-P	40	3.25	10				0.325			
Carrot culls	VR	0.13	STMR /STMR-P	12	1.08	10				0.108			
Cotton undelinted seed	SO	0.39	STMR /STMR-P	88	0.44	10				0.044			
Beet, sugar dried pulp	AB	0.09	STMR /STMR-P	88	0.10	0			40	0			0.041
Corn, field grain	GC	0.02	STMR /STMR-P	88	0.02	0			10	0			0.002
Total						100	100	100	100	29.57	38.40	48.25	27.54

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	0.13	STMR/ STMR-P	12	1.08		10				0.108		
Cotton meal	SM	0.18	STMR/ STMR-P	89	0.20	20	5	10		0.040	0.010	0.020	
Cowpea seed	VD	0.17	STMR/ STMR-P	88	0.19	10	5	5		0.019	0.010	0.010	
Pea seed	VD	0.17	STMR/ STMR-P	90	0.19	10	15			0.0189	0.028		
Bean seed	VD	0.05	STMR/ STMR-P	88	0.06			65				0.037	
Corn, field grain	GC	0.02	STMR/ STMR-P	88	0.02	60	65		70	0.014	0.015		0.0159
Total						100	100	80	70	0.09229	0.1712	0.0668	0.0159

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 stover	AF/AS	46	STMR/ STMR-P	83	55.42		10				5.542		
Pea vines	AL	5.1	STMR/ STMR-P	25	20.40		10				2.04		
Cabbage heads, leaves	AM/AV	0.93	STMR/ STMR-P	15	6.20		5				0.31		
Carrot culls	VR	0.13	STMR/ STMR-P	12	1.08		10				0.108		
Cotton meal	SM	0.18	STMR/ STMR-P	89	0.20	20	5	10		0.040	0.010	0.020	
Cowpea seed	VD	0.17	STMR/ STMR-P	88	0.19	10	10	5		0.019	0.019	0.010	
Pea seed	VD	0.17	STMR/STMR-P	90	0.19	10	10			0.019	0.019		
Bean seed	VD	0.05	STMR/ STMR-P	88	0.06			65				0.037	
Corn, field grain	GC	0.02	STMR STMR-P	88	0.02	60	40		80	0.014	0.009		0.018
Total						100	100	80	80	0.092	8.058	0.067	0.018

PENTHIOPYRAD

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 hay	AL	125	HR	85	147.06			80				117.65	
Pea vines	AL	23	HR	25	92.00		20				18.40		
Wheat forage	AF/AS	17	HR	25	68.00		20	20			13.60	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		
Pea hay	AL	31	HR	88	35.23		5				1.76		
Corn, field forage/silage	AF/AS	14	HR	40	35.00		45				15.75		
Alfalfa hay	AL	16	HR	89	17.98	15			10	2.70			1.80
Beet, sugar dried pulp	AB	0.56	STMR	88	0.64	15			5	0.10			0.03
Sorghum, grain	GC	0.22	STMR	86	0.26	40			35	0.10			0.09
Millet grain	GC	0.22	STMR	88	0.25	10				0.03			
Soya bean hulls	SM	0.08	STMR	90	0.09	5				0.00			

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 seed	VD	0.032	STMR	89	0.04				15				0.01
Barley grain	GC	0.02	STMR	88	0.02				35				0.01
Total						100	100	100	100	12.13	55.58	131.25	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		40		29.41		58.82	
Wheat forage	AF/AS	17	HR	25	68.00	20	20	60		13.60	13.60	40.80	
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			40	4.00			16.00
Pea hay	AL	31	HR	88	35.23		30				10.57		
Corn, field forage/silage	AF/AS	14	HR	40	35.00	5	30		10	1.75	10.50		3.50
Alfalfa hay	AL	16	HR	89	17.98		10		25		1.80		4.49
Almond hulls	AM/AV	2.4	STMR	90	2.67	10				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			25	0.03			0.16
Sorghum, grain	GC	0.22	STMR	86	0.26	10				0.03			
Total						100	100	100	100	55.26	42.53	99.62	24.15

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	4.6	HR	35	13.14				5				0.66
Sorghum, grain	GC	0.22	STMR	86	0.26	75	70	70	65	0.19	0.18	0.18	0.17
Soya bean hulls	SM	0.08	STMR	90	0.09		10	5			0.01	0.00	
Peanut meal	SM	0.034	STMR	85	0.04	25		5		0.01		0.00	
Soya bean seed	VD	0.032	STMR	89	0.04		20	15			0.01	0.01	
Bean seed	VD	0.02	STMR	88	0.02			5				0.00	
Soya bean meal	SM	0.007	STMR	92	0.01				30				0.00
Total						100	100	100	100	0.20	0.20	0.19	0.83

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	GC	0.22	STMR	86	0.26	75	70	70	55	0.19	0.18	0.18	0.14
Soya bean hulls	SM	0.08	STMR	90	0.09		5	5			0.00	0.00	
Peanut meal	SM	0.034	STMR	85	0.04	25		5		0.01		0.00	

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 seed	VD	0.032	STMR	89	0.04			15				0.01	
Bean seed	VD	0.02	STMR	88	0.02			5				0.00	
Soya bean meal	SM	0.007	STMR	92	0.01				30				0.00
Total						100	100	100	85	0.20	22.49	0.19	0.14

PENTHIOPYRAD

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 hay	AL	52.5	STMR	85	61.76			80				49.41	
Wheat forage	AF/AS	10	STMR	25	40.00		20	20			8.00	8.00	
Barley forage	AF/AS	10	STMR	30	33.33		10				3.33		
Pea vines	AL	6.2	STMR	25	24.80		20				4.96		
Barley hay	AF/AS	21	STMR	88	23.86	15				3.58			
Pea hay	AL	12	STMR	88	13.64		5				0.68		
Corn, field forage/silage	AF/AS	5	STMR	40	12.50		45				5.63		
Cotton gin by-products	AM/AV	4.55	STMR	90	5.06	5				0.25			
Alfalfa hay	AL	2.9	STMR	89	3.26	15			10	0.49			0.33
Beet, sugar dried pulp	AB	0.56	STMR	88	0.64	15			5	0.10			0.03
Sorghum, grain	GC	0.22	STMR	86	0.26	40			35	0.10			0.09
Millet grain	GC	0.22	STMR	88	0.25	10				0.03			
Soya bean seed	VD	0.032	STMR	89	0.04				15				0.01
Barley grain	GC	0.02	STMR	88	0.02				35				0.01
Total						100	100	100	100	4.54	22.60	57.41	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	85	61.76	20	0	40		12.35	0.00	24.71	
Wheat forage	AF/AS	10	STMR	25	40.00	20	20	60		8.00	8.00	24.00	
Barley forage	AF/AS	10	STMR	30	33.33	0	10			0.00	3.33		
Oat forage	AF/AS	10	STMR	30	33.33	10				3.33			
Sorghum, grain forage	AF/AS	5	STMR	35	14.29	10			40	1.43			5.71
Pea hay	AL	12	STMR	88	13.64	0	30			0.00	4.09		
Corn, field forage/silage	AF/AS	5	STMR	40	12.50	5	30		10	0.63	3.75		1.25
Alfalfa hay	AL	2.9	STMR	89	3.26	0	10		25	0.00	0.33		0.81
Almond hulls	AM/AV	2.4	STMR	90	2.67	10				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			25	0.03			0.16
Sorghum, grain	GC	0.22	STMR	86	0.26	10				0.03			
Total						100	100	100	100	26.24	19.50	48.71	7.94

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	0.73	STMR	35	2.09				5				0.10
Sorghum, grain	GC	0.22	STMR	86	0.26	75	70	70	65	0.19	0.18	0.18	0.17
Soya bean hulls	SM	0.08	STMR	90	0.09		10	5			0.01	0.00	
Peanut meal	SM	0.034	STMR	85	0.04	25		5		0.01		0.00	
Soya bean seed	VD	0.032	STMR	89	0.04		20	15			0.01	0.01	
Bean seed	VD	0.02	STMR	88	0.02			5				0.00	
Soya bean meal	SM	0.007	STMR	92	0.01				30				0.00
Total						100	100	100	100	0.20	0.20	0.19	0.27

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	85	61.76		10				6.18		
Wheat forage	AF/AS	10	STMR	25	40.00		10				4.00		
Cabbage heads, leaves	AM/AV	0.4	STMR	15	2.67		5				0.13		
Sorghum, grain	GC	0.22	STMR	86	0.26	75	70	70	55	0.19	0.18	0.18	0.14
Soya bean hulls	SM	0.08	STMR	90	0.09		5	5			0.00	0.00	
Peanut meal	SM	0.034	STMR	85	0.04	25		5		0.01		0.00	
Soya bean seed	VD	0.032	STMR	89	0.04			15				0.01	
Bean seed	VD	0.02	STMR	88	0.02			5				0.00	
Soya bean meal	SM	0.007	STMR	92	0.01				30				0.00
Total						100	100	100	85	0.20	10.49	0.19	0.14

PICOXYSTROBIN

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	64	HR	100	64.00		25	100			16	64	
Barley forage	AF/AS	31	HR	100	31.00		30				9.3		
Corn, field forage/silage	AF/AS	14	HR	100	14.00	15	45			2.1	6.3		
Soya bean asp gr fn	SM	2.6	STMR	85	3.06	5				0.1529			
Corn, field asp gr fn	CM/CF	0.15	STMR	85	0.18	5				0.0088			
Soya bean hulls	SM	0.043	STMR	90	0.05	10				0.0048			
Wheat milled bypdts	CM/CF	0.032	STMR	88	0.04	35			55	0.0127			0.02
Barley grain	GC	0.017	STMR	88	0.02	30			45	0.0058			0.009
Total						100	100	100	100	2.2851	31.6	64	0.029

DAIRY CATTLE **MAX**

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-	EU	AU	JP	US-CAN	EU	AU	JP

						CAN							
Pea hay	AL	64	HR	100	64.00	10	30	70		6.4	19.2	44.8	
Barley forage	AF/AS	31	HR	100	31.00		30	30			9.3	9.3	
Oat forage	AF/AS	31	HR	100	31.00	30			5	9.3			1.55
Corn, field forage/silage	AF/AS	14	HR	100	14.00	15	30		45	2.1	4.2		6.3
Soya bean forage	AL	3.5	HR	100	3.50	10				0.35			
Soya bean hulls	SM	0.043	STMR	90	0.05		10				0.005		
Wheat milled bypdts	CM/CF	0.032	STMR	88	0.04	30			45	0.010909			0.016
Barley grain	GC	0.017	STMR	88	0.02	5			5	0.000966			1E-03
Total						100	100	100	100	18.16188	32.7	54.1	7.867

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
Soya bean hulls	SM	0.043	STMR	90	0.05		10	5			0.005	0.002	
Wheat milled bypdts	CM/CF	0.032	STMR	88	0.04	50	20	20	5	0.018182	0.007	0.007	0.002
Barley grain	GC	0.017	STMR	88	0.02	50	70	15	10	0.009659	0.014	0.003	0.002
Bean seed	VD	0.0105	STMR	88	0.01			60				0.007	
Total						100	100	100	15	0.027841	0.026	0.02	0.004

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	64	HR	100	64.00		10				6.4		
Oat forage	AF/AS	31	HR	100	31.00		10				3.1		
Soya bean hulls	SM	0.043	STMR	90	0.05		5	5			0.002	0.002	
Wheat milled bypdts	CM/CF	0.032	STMR	88	0.04	50	20	20	30	0.018182	0.007	0.007	0.011
Barley grain	GC	0.017	STMR	88	0.02	50	55	15		0.009659	0.011	0.003	
Bean seed	VD	0.0105	STMR	88	0.01			60				0.007	
Corn, field grain	GC	0.01	STMR	88	0.01				70				0.008
Total						100	100	100	100	0.027841	9.52	0.02	0.019

PICOXYSTROBIN

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	20.5	STMR/STMR-P	100	20.50		20	60			4.1	12.3	
Pea hay	AL	12.5	STMR/STMR-P	100	12.50		5	40			0.625	5	
Corn, field forage/silage	AF/AS	7.1	STMR/STMR-P	100	7.10	15	75			1.065	5.325		
Soya bean asp gr fn	SM	2.6	STMR/STMR-P	85	3.06	5				0.152941			
Corn, field asp gr fn	CM/CF	0.15	STMR/STMR-P	85	0.18	5				0.008824			

Soya bean hulls	SM	0.043	STMR/STMR-P	90	0.05	10				0.004778			
Wheat milled bypdts	CM/CF	0.032	STMR/STMR-P	88	0.04	35			55	0.012727			0.02
Barley grain	GC	0.017	STMR/STMR-P	88	0.02	30			45	0.005795			0.0087
Total						100	100	100	100	1.250065	10.05	17.3	0.0287

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	20.50	STMR/STMR-P	100.00	20.50	10.00	20.00	40.00		2.05	4.10	8.20	
Pea hay	AL	12.50	STMR/STMR-P	100.00	12.50	0.00	10.00	30.00		0.00	1.25	3.75	
Corn, field forage/silage	AF/AS	7.10	STMR/STMR-P	100.00	7.10	45.00	60.00	30.00	50.00	3.20	4.26	2.13	3.55
Soya bean forage	AL	1.40	STMR/STMR-P	100.00	1.40	10.00				0.14			
Soya bean hulls	SM	0.04	STMR/STMR-P	90.00	0.05	0.00	10.00			0.00	0.00		
Wheat milled bypdts	CM/CF	0.03	STMR/STMR-P	88.00	0.04	30.00			45.00	0.01			0.02
Barley grain	GC	0.02	STMR/STMR-P	88.00	0.02	5.00			5.00	0.00			0.00
Total						100.00	100.00	100.00	100.00	5.40	9.61	14.08	3.57

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 hulls	SM	0.04	STMR/STMR-P	90.00	0.05		10.00	5.00			0.00	0.00	
Wheat milled bypdts	CM/CF	0.03	STMR/STMR-P	88.00	0.04	50.00	20.00	20.00	5.00	0.02	0.01	0.01	0.00
Barley grain	GC	0.02	STMR/STMR-P	88.00	0.02	50.00	70.00	15.00	10.00	0.01	0.01	0.00	0.00
Bean seed	VD	0.01	STMR/STMR-P	88.00	0.01			60.00				0.01	
Total						100.00	100.00	100.00	15.00	0.03	0.03	0.02	0.00

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	20.50	STMR/STMR-P	100.00	20.50		10.00				2.05		
Corn, field forage/silage	AF/AS	7.10	STMR/STMR-P	100.00	7.10		10.00				0.71		
Soya bean hulls	SM	0.04	STMR/STMR-P	90.00	0.05		5.00	5.00			0.00	0.00	

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	0.03	STMR/STMR-P	88.00	0.04	50.00	20.00	20.00	30.00	0.02	0.01	0.01	0.01
Barley grain	GC	0.02	STMR/STMR-P	88.00	0.02	50.00	55.00	15.00		0.01	0.01	0.00	
Bean seed	VD	0.01	STMR/STMR-P	88.00	0.01			60.00				0.01	
Corn, field grain	GC	0.01	STMR/STMR-P	88.00	0.01				70.00				0.01
Total						100.00	100.00	100.00	100.00	0.03	2.78	0.02	0.02

SEDAXANE

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	0.023	HR	25	0.09		20	100			0.018	0.092	
Barley hay	AF/AS	0.075	HR	88	0.09	15				0.013			
Barley straw	AF/AS	0.075	HR	89	0.08		10				0.008		
Soya bean seed	VD	0.01	STMR	89	0.01	5	10		15	0.001	0.001		0.002
Total						20	40	100	15	0.013	0.028	0.092	0.002

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	0.023	HR	25	0.09	20	20	60		0.018	0.018	0.055	
Barley straw	AF/AS	0.075	HR	89	0.08		10				0.008		
Oat hay	AF/AS	0.075	HR	90	0.08	10		30		0.008		0.025	
Soya bean seed	VD	0.01	STMR	89	0.01	10	10	10	10	0.001	0.001	0.001	0.001
Total						40	40	100	10	0.028	0.028	0.081	0.001

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
Soya bean seed	VD	0.01	STMR	89	0.01	20	20	15		0.002	0.002	0.002	
Total						20	20	15		0.002	0.002	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
Wheat forage	AF/AS	0.023	HR	25	0.09		10				0.009		
Soya bean seed	VD	0.01	STMR	89	0.01	20	15	15		0.002	0.002	0.002	

Total						20	25	15		0.002	0.011	0.002	

SEDAXANE

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	0.01	STMR/STMR-P	25	0.04		20	100			0.008	0.04	
Barley forage	AF/AS	0.01	STMR/STMR-P	30	0.03		10				0.003		
Barley hay	AF/AS	0.01	STMR/STMR-P	88	0.01	15				0.002			
Total						15	30	100		0.002	0.011	0.04	

DAIRY CATTLE **MEAN**

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Wheat forage	AF/AS	0.01	STMR/STMR-P	25	0.04	20	20	60		0.008	0.008	0.024	
Barley forage	AF/AS	0.01	STMR/STMR-P	30	0.03	0	10			0.000	0.003		
Oat forage	AF/AS	0.01	STMR/STMR-P	30	0.03	10		30		0.003		0.01	
Total						30	30	90		0.011	0.011	0.034	

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
No feed items applicable!													

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	0.01	STMR/STMR-P	25	0.04		10				0.004		
Total							10				0.004		

SPINETORAM

POULTRY LAYER **MAX**

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Beet, sugar tops	AM/AV	0.2	HR	23	0.87		5				0.043		
Total							5				0.043		

POULTRY LAYER **MEAN**

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Beet, sugar tops	AM/AV	0.135	STMR/STMR-P	23	0.59		5				0.029		
Total							5				0.029		

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The annual Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues was held in Rome, Italy, from 11 to 20 September 2012. The FAO Panel of Experts had met in preparatory sessions from 6 to 10 September. The Meeting was held in pursuance of recommendations made by previous Meetings and accepted by the governing bodies of FAO and WHO that studies should be undertaken jointly by experts to evaluate possible hazards to humans arising from the occurrence of pesticide residues in foods. During the meeting the FAO Panel of Experts was responsible for reviewing pesticide use patterns (use of good agricultural practices), data on the chemistry and composition of the pesticides and methods of analysis for pesticide residues and for estimating the maximum residue levels that might occur as a result of the use of the pesticides according to good agricultural use practices. The WHO Core Assessment Group was responsible for reviewing toxicological and related data and for estimating, where possible and appropriate, acceptable daily intakes (ADIs) and acute reference doses (ARfDs) of the pesticides for humans. This report contains information on ADIs, ARfDs, maximum residue levels, and general principles for the evaluation of pesticides. The recommendations of the Joint Meeting, including further research and information, are proposed for use by Member governments of the respective agencies and other interested parties.

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